L-Università ta' Malta

A ‘Prosthesis Life-Cycle Ontology’-Based Service System Framework to Cater for Amputees’ Evolving Needs

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Abstract

Lower-limb prostheses remain essential to restoring mobility and independence for amputees, yet their design and aftercare continue to be fragmented, reactive, and inefficient. Current practices are characterised by siloed stakeholder input, tacit rather than structured knowledge, and limited methods for adapting to the evolving needs of both amputees and prosthesis sub-systems. This thesis addresses these systemic inefficiencies by developing the Adaptive Prosthesis Life-Cycle Service System Framework (adProLiSS), an ontology-based, consequence-aware framework that reconceptualises prosthesis management as an integrated product–service system (PSS).

The research aim was to improve amputees' overall prosthesis experience, measured in terms of time efficiency, cost efficiency, functionality, user comfort, emotional well-being, and aftercare quality, through the design, implementation, and evaluation of a prosthesis life-cycle framework that supports adaptive, knowledge-based decision-making. To test this aim, seven research questions (RQ1–RQ7) were formulated, spanning the identification of life-cycle activities, stakeholder roles, tools and methods, critical constraints, specifications of a prosthesis PSS, and its applicability and evaluability across prosthesis types.

Conceptually, the thesis advances the state of the art by introducing the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF), a domain-specific ontology that formalises heterogeneous consequence knowledge, including intended and unintended, interacting and non-interacting outcomes, across physical, functional, emotional, systemic, and semantic domains. Methodologically, the work contributes a closed-loop life-cycle methodology, digital tool support through the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST), and a scenario-based evaluation strategy combining physical demonstrators, digital platforms, and stakeholder engagement. Practically, these contributions were validated through prototype demonstrations addressing ulcer detection, weight distribution monitoring, fall risk, maintenance alerts, and daily logging.

Evaluation findings indicate that adProLiSS delivers measurable improvements across the six evaluation criteria, enhances stakeholder collaboration, and enables decision traceability in ways not achieved by conventional approaches. The framework was shown to reframe amputees from passive recipients to active contributors of consequence knowledge, support clinicians in preventive and evidence-based aftercare, and allow engineers to anticipate design consequences before physical prototyping. The findings carry implications for service providers and policymakers, particularly in highlighting how consequence awareness and interoperability standards such as HL7/FHIR could guide future procurement practices and rehabilitation service models.

The research is not without limitations. The scope was bounded to lower-limb prostheses, early-stage digital and physical prototypes, and a geographically localised but scientifically justified stakeholder sample. Nonetheless, the framework establishes a demonstrable foundation that can be extended to upper-limb prostheses, scaled through multi-centre evaluations, and advanced via ontology governance methods and higher-TRL digital systems. Future work also envisions adProLiSS as an educational simulator and as a bi-directional communication platform for real-time patient–clinician interaction.

In conclusion, this thesis contributes to engineering design knowledge by embedding consequence awareness and ontology-driven reasoning into the prosthesis life-cycle, demonstrating how structured knowledge representation and adaptive service-system integration can improve both design and aftercare. The adProLiSS framework thus stands as a novel paradigm for prosthesis life-cycle management, bridging conceptual, methodological, and practical advances, and as a commitment to enhancing the lived experiences of amputees through more collaborative, knowledge-based, and adaptive healthcare systems.

Acknowledgements

I would like to express my deepest gratitude to my supervisor, Prof. Ing. Jonathan C. Borg, for his invaluable guidance, mentorship, and unwavering support throughout this journey. His dedication, time, and encouragement have been instrumental in shaping not only this thesis but also my academic and personal growth, imparting lessons that extend well beyond research.

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My sincere appreciation goes to my colleagues and fellow researchers at the Engineering Research and Innovation Laboratories (E.R.I.L). Their encouragement, collaboration, and friendship created a welcoming and stimulating environment, where ideas could be shared openly and challenges faced collectively. The sense of teamwork and camaraderie within this group has been a constant source of motivation.

I owe my deepest thanks to my parents for their endless support and sacrifices throughout life's many challenges. Their belief in me has been a foundation on which I could always rely. I am equally grateful to my wider family and friends for their constant encouragement, patience, and understanding during the many demanding phases of this research.

Finally, I am grateful for the opportunity this research has given me, not only to further my education, but also to grow beyond my comfort zone. The challenges encountered along the way have been as valuable as the outcomes achieved, leaving me with lasting experiences and life lessons that will continue to guide me in the future.

Dedication

To my parents, thank you for your unwavering love and support

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Abbreviations

ADCATER – Adaptive and Context-Aware e-Tutoring based on Human Learners' Emotions (EU FP7 project)

adProLiSS – Adaptive Prosthesis Life-Cycle Service System

AI – Artificial Intelligence

AKP – Above Knee Prosthesis

AMP – Amputee Mobility Predictor

AMPUTEES – Facebook Group

API – Application Programming Interface

BA – Business Adaptation Pillar

BCP – Business Customisation Pillar

BSP – Business Service Pillar

CAD – Computer-Aided Design

CD-CST – Consequence-Driven Co-Design Support Tool

CERU – Concurrent Engineering Research Unit

COMPASS – Core Outcome Measures for Prosthetics and Orthotics (ISPO project for consensus outcome measures)

CT – Computed Tomography

DA – Design Adaptation Pillar

DCP – Design Customisation Pillar

DF – Delay Frequency

DOCYKE – Servo Motor

DRM – Design Research Methodology

DSP – Design Service Pillar

FFF – Fused Filament Fabrication

FHIR – Fast Healthcare Interoperability Resources

FPD – Functional Product Development

FSR – Force-Sensitive Resistor

GDPR – General Data Protection Regulation

GPIO – General Purpose Input/Output

GPS – Global Positioning System

IEEE – Institute of Electrical and Electronics Engineers

IMU – Inertial Measurement Unit

IMUZ – Inertial Measurement Unit-axis

IPD – Integrated Product Development

ISO – International Organization for Standardization

ISPO – International Society for Prosthetics and Orthotics

IT – Information Technology

LEAP – Lower Extremity Amputation Protocol

MA – Manufacturing Adaptation Pillar

MCP – Manufacturing Customisation Pillar

ML – Machine Learning

MPA – Modular Product Architecture

MSP – Manufacturing Service Pillar

NZF – nominal Z-axis Fast Speed Threshold

OWL – Web Ontology Language

PDE – Prosthesis Development Element

PDM – Product Data Management

PDPDDM – Prosthetic Device Product Development Descriptive Model

PECK – Prosthesis Experiential Consequence Knowledge

PEQ – Prosthesis Evaluation Questionnaire

PI-COS – Population, Intervention, Comparator, Outcomes, Study design (framework for structuring clinical questions and outcome measures)

PLA – Polylactic Acid

PLCCKMF – Prosthesis Life-Cycle Consequence Knowledge Modelling Frame

PLM – Product Life-Cycle Management

PLUS-M – Prosthetic Limb Users Survey of Mobility

PPMS – Patient–Prosthesis Management System

PREMIER – Product Service System for a Smart and Modular, Emotionally Pleasing Above Knee Prosthesis

PRUSA – Brand of 3D Printers

PSS – Product–Service System

RDF – Resource Description Framework

RQ – Research Question

SNOMED – Systematized Nomenclature of Medicine

SPARQL – SPARQL Protocol and RDF Query Language

SWRL – Semantic Web Rule Language

TRL – Technology Readiness Level

TUG – Timed Up and Go

USD – United States Dollar

WHO – World Health Organization

Part A

Establishing the Research Context

1

1 Introduction

Limb loss & impacts

The loss of a limb has profound physical, psychological, and social challenges. Amputees frequently face challenges in mobility, independence, self-image, mental health, social integration and quality of life (Horgan and MacLachlan, 2004; Roșca *et al.*, 2021). In many cases, amputation represents not just a biomedical intervention but a life-altering event, in which individuals must reconstruct their bodily identity, adapt to new functional constraints, and negotiate emotional dissonance (Jo *et al.*, 2021).

Amputee challenges beyond function

These multifaceted challenges are not limited to physical function but also extend to psychosocial, financial, and emotional dimensions. Figure 1.1 illustrates a conceptual representation of the challenges most frequently reported by amputees, encompassing issues such as loss of independence, identity reconstruction, and high prosthesis costs. Such challenges motivate the need for prosthesis design and aftercare frameworks that address not only biomechanical performance but also user experience and long-term well-being.

Figure 1.1: Challenges commonly experienced by amputees
Source: https://www.thestar.com/news/canada/2016/01/30/canadian-doctors-help-turn-around-injured-ukrainian-boys-life.html

Prosthesis advances & systemic limits

Advances in rehabilitation medicine and biomedical engineering have enabled the development of prosthetic devices that extend well beyond mere functional replacements, serving instead as integral artefacts (Roozenburg and Eekels, 1995; Blessing and Chakrabarti, 2009), defined here as engineered objects or systems intentionally designed to fulfil specified functions, that support physical performance, emotional well-being, and long-term rehabilitation outcomes (Huang *et al.*, 2024; Varaganti and Seo, 2024). However, despite progress in material technologies, socket design, embedded sensing, and control systems, the development and aftercare of prosthetic devices continue to encounter systemic limitations (Bates, Fergason and Pierrie, 2020; Kooiman *et al.*, 2023). These limitations manifest not only in terms of time and cost inefficiencies but also in the inability to consistently adapt prostheses to the evolving physical and emotional needs of amputees (Pezzin, Dillingham and Mackenzie, 2000).

Rise of prosthetic demand

The demand for prosthetic devices is rising globally, driven by the increasing prevalence of diabetes, vascular diseases, trauma, and age-related conditions (Ziegler-Graham et al., 2008; Ephraim et al., 2016). This growing demand is coupled with heightened expectations: amputees and healthcare providers seek prostheses that are affordable, comfortable, functional, aesthetically acceptable, and supported by responsive aftercare services.

Fragmented practice & tacit decisions

Despite technological progress, current prosthesis development and aftercare remain constrained by fragmented practices that limit knowledge sharing and adaptability. These challenges motivate the need for approaches that integrate perspectives across stakeholders and life-cycle phases.(Schaffalitzky *et al.*, 2012; Wyss *et al.*, 2015; Rekant *et al.*, 2020; Patiniott *et al.*, 2022, 2023). Decision-making is still largely reliant on tacit experience, trial-and-error adjustments, and locally available expertise, which restricts the traceability of design choices and hampers the systematic reuse of accumulated knowledge (Tichem, 1997; Duffy and O'Donnell, 1998; Sanders and Fatone, 2011).

Constraints of conventional prosthesis approaches

Conventional approaches to prosthesis design are further constrained by the complexity of the life-cycle itself. A prosthesis passes through successive phases of conception, design, fitting, rehabilitation, maintenance, and replacement. Each phase introduces intended and unintended consequences that propagate across technical, clinical, and user-centred domains. While the prosthesis does not 'evolve', choices made in earlier phases (such as socket geometry, alignment) propagate downstream, affecting comfort, durability, maintenance, rehabilitation time, and user acceptance (Andreasen and Mortensen, 1997; Borg, 1999).

Knowledge gaps hinder efficiency

Similarly, inadequate communication of clinical findings to engineers can lead to design iterations that extend development timelines and increase costs. The heterogeneous knowledge required, ranging from biomechanical data and clinical assessments to user experiences and emotional feedback, often exceeds the capacity of individual stakeholders to process effectively, leading to inefficiencies, overlooked risks, and avoidable prosthesis downtime (Jones *et al.*, 2021; Xu and Qin, 2023; Anderson, Fatone and Christiansen, 2024).

Prosthesis as product-service system

These systemic limitations resonate with insights from Product–Service Systems (PSS) research, which emphasises that products and services must be treated as inseparable entities across their life-cycle. In this thesis, the prosthesis is therefore framed as a product–service offering, where value is realised not only at the point of fitting but throughout rehabilitation, maintenance, and long-term aftercare.

Limitations of linear models

Furthermore, these challenges highlight the limitations of linear, reductionist models of prosthesis development and motivate the need for more integrated, knowledge-driven approaches that can model the propagation of design decisions, address stakeholder complexity and consequence propagation. PSS research within engineering design has long emphasised that artefacts and services are inseparable, and that sustained value is realised across the product's life-cycle rather than at the point of delivery (Mont, 2002; Baines *et al.*, 2007). More recent work on PSS business models and tactics also underscores how firms orchestrate value through combinations of product and service offerings (Reim, Parida and Örtqvist, 2015).

Success beyond fitting moment

By extension, prostheses cannot be evaluated solely at the moment of fitting; their success must also be judged in terms of adaptability, comfort, emotional resonance, and the quality of ongoing support. An ontology-based PSS framework offers a means of structuring and formalising this multifaceted knowledge, enabling systematic capture, reasoning, and exchange across stakeholders and sub-systems.

adProLiSS framework introduced

This thesis addresses the above challenges by proposing an Adaptive Prosthesis Life-Cycle Service System Framework (adProLiSS). The framework integrates consequence knowledge, stakeholder communication, and adaptive decision-making to improve prosthesis design and aftercare. By embedding structured ontologies and consequence reasoning into both physical prototypes and digital support tools, adProLiSS seeks to enhance efficiency in time and cost, optimise prosthesis functionality and comfort, and strengthen the emotional and experiential aspects of amputee aftercare. Ultimately, this research argues for a paradigm shift in prosthesis development: from fragmented, trial-and-error practices to a consequence-aware, knowledge-driven, and stakeholder-centred system that is capable of catering for the evolving needs of amputees across the entire prosthesis life-cycle.

1.1 Problem Background and Research Motivation

Causes & types of amputations

Limb amputation arises from multiple causes, including trauma, vascular disease, diabetes, cancer, and congenital limb deficiencies. Among these, peripheral arterial disease and diabetes mellitus are the leading causes of lower limb amputations worldwide, with trauma contributing significantly in younger populations (Horgan and MacLachlan, 2004; Ziegler-Graham *et al.*, 2008; Eidmann *et al.*, 2023; Yuan *et al.*, 2023). The clinical manifestation of amputation varies across different anatomical levels, which in turn dictates rehabilitation complexity and prosthesis requirements. Figure 1.2 illustrates the principal categories of lower limb amputations, ranging from partial foot to hip disarticulation, each presenting distinct biomechanical and psychosocial challenges.

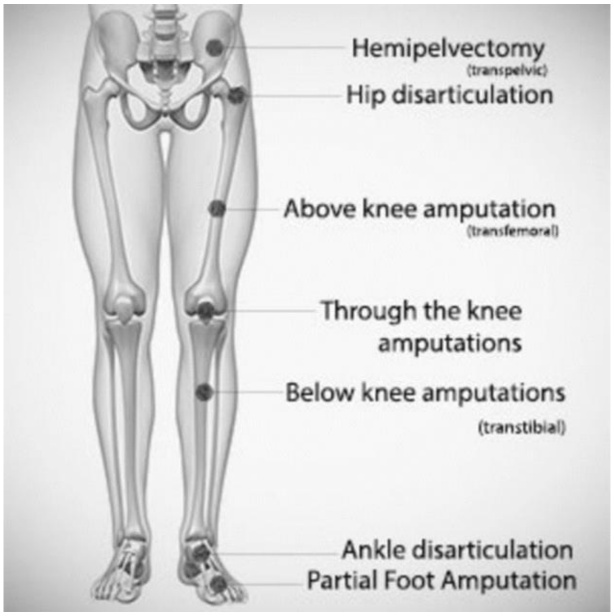


Figure 1.2: Lower limb amputation levels
Source: (Mishra, 2014)

Rising global prevalence

The global prevalence of limb loss is projected to rise steadily due to demographic and epidemiological transitions. Increasing rates of diabetes, obesity, and age-related vascular conditions are contributing to a surge in amputations, with estimates suggesting that the number of people living with limb loss will more than double by 2050 (Dillingham, Pezzin and MacKenzie, 2002; Ziegler-Graham *et al.*, 2008; Rivera *et al.*, 2024; Beckley, Ton and Wong, 2025). This translates directly into a heightened demand for prosthetic devices and associated rehabilitation services.

Figure 1.3 depicts the projected rise in prosthesis need over time, reflecting both the clinical and societal urgency of advancing prosthesis development and provision.

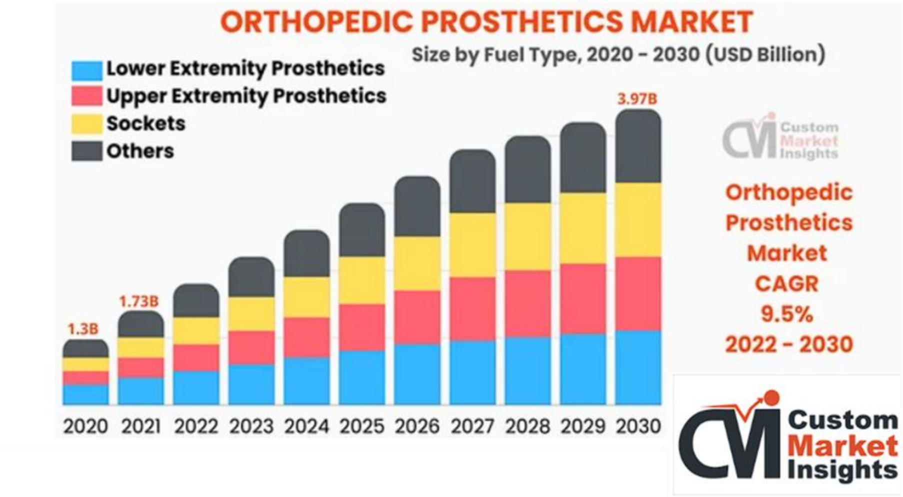


Figure 1.3: Projected rise in global prosthesis demand over time, reflecting demographic and epidemiological trends
Source: Custom Market Insights

Access & service inequities

Despite advances in prosthetic materials, socket technology, embedded sensing, and control systems (Bates, Fergason and Pierrie, 2020; Kooiman *et al.*, 2023), access to effective and sustainable prosthesis solutions remains inconsistent. Many amputees face extended waiting periods for fitting, repeated refitting due to residual limb volume changes, and limited aftercare resources (Sanders and Fatone, 2011; Miller *et al.*, 2020, 2023). In resource-constrained contexts, financial burdens exacerbate inequities, with high prosthesis costs and inconsistent service delivery contributing to suboptimal outcomes (Pezzin, Dillingham and Mackenzie, 2000; Donnelley *et al.*, 2021; Raval *et al.*, 2024). These constraints emphasise the need for more adaptive and integrated approaches that extend beyond the device alone to include the wider service system.

Evolving amputee needs

A further challenge lies in the evolving nature of amputee needs throughout the amputee's lifetime. Immediately post-amputation, priorities often centre on wound healing, pain management, and psychological adaptation. In the medium term, functional restoration, mobility training, and socket comfort dominate. Over time, however, needs broaden to include durability, aesthetics, emotional acceptance, social participation, and independence (Schaffalitzky *et al.*, 2012; Roșca *et al.*, 2021).

Temporal pattern priorities

Figure 1.4 illustrates this temporal pattern at both macro and micro scales, showing how amputee priorities evolve from early recovery and functional restoration toward long-term goals of quality-of-life, emotional well-being, and social participation. At the micro scale, two examples are highlighted: first, an instance where the amputee's needs shift, requiring a different prosthesis for a specific activity; and second, a situation where needs change abruptly due to a prosthesis-related fault.

Figure 1.4: Evolving amputee needs across their lifetime

Need for integrated frameworks

Collectively, these challenges illustrate a dual motivation. First, there is a pressing clinical and societal need to provide prosthetic solutions that are accessible, affordable, and adaptive to rising demand. Second, the evolving and multifaceted nature of amputee needs highlights the inadequacy of linear and fragmented prosthesis development approaches. Addressing these issues requires a more integrated framework that can simultaneously account for technical performance, stakeholder interaction, and psychosocial well-being across the prosthesis life-cycle. This motivation drives the research focus of this thesis.

1.2 Existing Situation and Problem Landscape

Stakeholder fragmentation & inefficiencies

The development and aftercare of prosthetic devices involve a broad spectrum of stakeholders, including amputees, prosthetists, physiotherapists, engineers, designers, and manufacturers. However, interactions between these groups are typically episodic and siloed, with limited communication across disciplinary boundaries. Decision-making is often reliant on tacit knowledge and trial-and-error adjustments, restricting traceability and the systematic reuse of experience. As a result, inefficiencies in time and cost persist, and prostheses are not consistently adapted to the evolving needs of amputees which change over time with the use of the device and are influenced by factors such as mobility level, age, and lifestyle (Manz *et al.*, 2022). (Chadwell *et al.*, 2020; Healy *et al.*, 2020; Anderson *et al.*, 2022; Patiniott and Borg, 2025). Each contributes unique expertise, tools, and perspectives, but their interactions are often fragmented across the prosthesis life-cycle. While advances in socket design, embedded sensors, additive manufacturing, and digital rehabilitation platforms have expanded technical capabilities (Bates, Fergason and Pierrie, 2020; Kooiman *et al.*, 2023), the underlying processes remain largely dependent on episodic consultations and siloed practices (Bates, Fergason and Pierrie, 2020). As a result, the integration of clinical, technical, and experiential knowledge is frequently inconsistent, limiting opportunities for systematic improvement.

Tacit knowledge limits traceability & outcomes

Decision-making within current prosthesis pathways is heavily reliant on tacit practitioner knowledge, incremental adjustments, and trial-and-error fitting strategies (Blessing and Chakrabarti, 2009; Sanders and Fatone, 2011; Patiniott and Borg, 2025). This approach restricts the traceability of design choices, constrains the reuse of knowledge across cases, and reduces the ability to anticipate the long-term consequences of early design or fitting decisions (Chadwell *et al.*, 2020; Patiniott and Borg, 2025). For amputees, these shortcomings often manifest as extended rehabilitation timelines, repeated socket refittings, increased prosthesis downtime, and heightened financial and emotional burdens (Pezzin, Dillingham and Mackenzie, 2000; Raval *et al.*, 2024).

Disciplinary communication barriers

Communication between prosthesis stakeholders (such as prosthetists and physiotherapists) is further challenged by disciplinary boundaries (Anderson *et al.*, 2022; Jones *et al.*, 2022). Engineers and clinicians frequently operate with different terminologies, priorities, and decision criteria. Feedback from amputees may not always be captured in a structured or reusable manner, and clinical findings are not consistently translated into design knowledge for engineers or manufacturers (Jones *et al.*, 2021; Xu and Qin, 2023). This leads to missed opportunities for collaboration, duplication of effort, and delays in delivering effective prosthesis solutions.

Limits of conventional design approaches

Conventional engineering design approaches, while well-established, are not optimally configured to handle the heterogeneity of prosthesis knowledge (Pannunzio, Kleinsmann and Snelders, 2019; Bodell *et al.*, 2025). Biomedical research typically concentrates on isolated aspects such as socket fit, gait analysis, or user comfort, while service models for prosthesis provision remain fragmented and unevenly distributed across healthcare systems (Schaffalitzky *et al.*, 2012; Anderson, Fatone and Christiansen, 2024). As a result, there is no unifying structure that coherently connects design, clinical practice, and service delivery to support amputees' evolving needs.

Need for integrated, consequence-aware frameworks

This situation highlights the pressing need for approaches that can integrate technical, clinical, and experiential knowledge across stakeholders and life-cycle phases. Addressing this problem requires not only new prosthetic technologies but also new frameworks for structuring information, supporting consequence-aware decision-making, and enabling stakeholder collaboration. Figure 1.5 contrasts the current fragmented practices with the envisioned integrated, stakeholder-centred, consequence-aware framework that underpins this thesis. These considerations provide the foundation for the research problem articulated in Section 1.3.

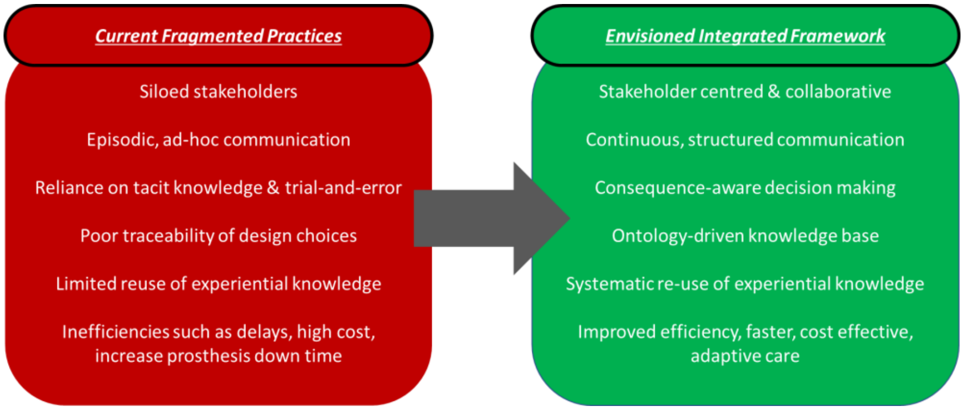


Figure 1.5: Conceptual contrast between current, fragmented prosthesis-lifecycle practices and the intended integrated, stakeholder-centred, consequence-aware framework

1.3 The Research Problem

Absence of integrated, consequence-aware framework

Taken together, these issues highlight the absence of a formalised, consequence-aware framework capable of integrating heterogeneous knowledge across stakeholders and life-cycle phases. This gap defines the research problem addressed in this thesis. Clinical and technical progress has not been matched by equivalent advances in the way knowledge is structured, shared, and reused across the prosthesis life-cycle. This gap defines the research problem addressed in this thesis. Current practices rely heavily on fragmented interactions between stakeholders, where decision-making is often informed by tacit experience, trial-and-error adjustments, and episodic communication (Sanders and Fatone, 2011; Anderson *et al.*, 2022). This fragmentation results in inefficiencies, extended rehabilitation timelines, high costs, and prosthesis downtime, while limiting opportunities for systematic improvement.

Limits of engineering & biomedical approaches

Building on this challenge, the heterogeneity of prosthesis knowledge extends beyond technical biomechanical modelling and clinical data to include patient-reported outcomes, experiential feedback, and emotional or psychosocial considerations that influence long-term prosthesis use (Pannunzio, Kleinsmann and Snelders, 2019; Bodell *et al.*, 2025). However, these dimensions are rarely integrated within existing engineering or healthcare frameworks. Biomedical studies frequently isolate single variables such as gait or socket fit, while broader service-level concerns related to affordability, comfort, functionality, and aftercare quality remain insufficiently addressed (Schaffalitzky *et al.*, 2012) (Raval *et al.*, 2024). This fragmentation highlights the need for approaches that can account for the prosthesis as part of an evolving, service-embedded system rather than a standalone artefact.

Lack of formalised consequence reasoning

A further limitation is the absence of formalised approaches to consequence reasoning. Decisions taken in early design or fitting phases propagate across the prosthesis life-cycle, influencing comfort, durability, maintenance requirements, and user satisfaction (Borg, 1999; Patiniott and Borg, 2025). Yet current systems do not provide a structured means of anticipating or managing these intended and unintended consequences. Knowledge that could direct better outcomes is often locked in individual expertise, case-specific experiences, or unstructured feedback, and therefore not reused effectively across contexts.

Need for unifying, adaptive framework

Taken together, these challenges point to a significant research gap. Existing approaches cannot adequately support integrated, transparent, and adaptive decision-making across the prosthesis life-cycle. There is a need for a unifying framework that connects stakeholders, structures heterogeneous knowledge, and embeds consequence awareness into design and aftercare processes.

Fragmented, tacit, & inefficient practices

Problem Statement: Current prosthesis development and aftercare practices are fragmented, reliant on tacit knowledge, and unable to systematically integrate the diverse technical, clinical, and experiential inputs required to meet the evolving needs of amputees. This lack of a formalised, consequence-aware, and knowledge-driven framework results in inefficiencies, increased costs, limited adaptability, and reduced long-term quality of prosthesis outcomes.

1.4 Research Aim and Objectives

Need for integrated, consequence-aware approach

The limitations identified in current prosthesis development and aftercare practices point to the need for an integrated, knowledge-driven, and consequence-aware approach capable of addressing the diverse and evolving requirements of amputees. Conventional methods, while effective in isolated domains, do not sufficiently account for the heterogeneity of stakeholder inputs, the propagation of design and service decisions across the prosthesis life-cycle, or the need for systematic reuse of experiential knowledge. This thesis therefore aims:

Research Aim

Ontology-based, consequence-aware service framework

To develop, implement, and evaluate an ontology-based, consequence-aware prosthesis life-cycle service system framework that integrates heterogeneous technical, clinical, and experiential knowledge in order to improve stakeholder collaboration, decision-making, and aftercare outcomes for amputees.

Research Objectives

RO1–RO5: Analyse, develop, implement, evaluate, & communicate

In order to achieve this aim, the thesis pursues the following objectives:

RO1 – To analyse the prosthesis life-cycle and stakeholder landscape, identifying technical, clinical, and psychosocial challenges that current approaches fail to address;

RO2 – To develop an ontology-based, consequence-aware prosthesis life-cycle service system framework that structures heterogeneous knowledge and supports stakeholder collaboration and decision-making;

RO3 – To implement the framework through digital and physical demonstrators, including ontology models, a patient–prosthesis management system, and prototype smart prosthesis integration;

RO4 – To evaluate the framework and demonstrators with multiple stakeholders (amputees, prosthetists, physiotherapists, engineers, and designers), assessing their impact on time efficiency, cost optimisation, functionality, comfort, emotional well-being, and aftercare quality;

RO5 – To contribute to the advancement of engineering design knowledge by demonstrating how ontology-based, consequence-aware approaches can enhance complex healthcare product–service systems.

Objectives aligned with thesis structure

These objectives establish a clear pathway from the identification of the research problem to the development and evaluation of a novel framework. They also align with the structure of the thesis: Chapters 2 and 3 address RO1; Chapters 4 to 7 address RO2; Chapter 8 addresses RO3; Chapter 9 addresses RO4; and the concluding chapter synthesises contributions in line with RO5.

Research questions deferred to Chapter 3

While the research aims and objectives are introduced here to provide a high-level direction for the thesis, the detailed research questions are intentionally deferred to Chapter 3. This is because the questions are derived directly from the literature review in Chapter 2 and the identification of the research gap. Placing them after the gap analysis ensures a clear and logical progression from background, to problem landscape, to the formulation of guiding questions.

1.5 Research Hypothesis

Building on the challenges outlined in Sections 1.1–1.3 and the research aim in Section 1.4, this thesis advances the following hypothesis:

Hypothesis introduced

The amputee's overall 'prosthesis experience' can be improved in terms of time efficiency, cost efficiency, functionality, comfort, emotional well-being, and aftercare quality if a 'Prosthesis Life-Cycle Ontology' -based Service System Framework is adopted across life-cycle phases, catering for the evolving needs of both amputees and prosthesis sub-systems.

Two core propositions

This hypothesis reflects two critical propositions. First, that conventional prosthesis development approaches, which rely heavily on fragmented stakeholder interactions and tacit decision-making, limit opportunities for consistent improvement in user outcomes. Second, that a structured, ontology-based framework offers the capacity to integrate diverse technical, clinical, and experiential knowledge in a way that is both transparent and reusable across contexts.

Figure 1.6 links problem, framework, improvements

The relationship between current fragmented practices, the proposed ontology-based framework, and the hypothesised improvements is summarised in Figure 1.6.

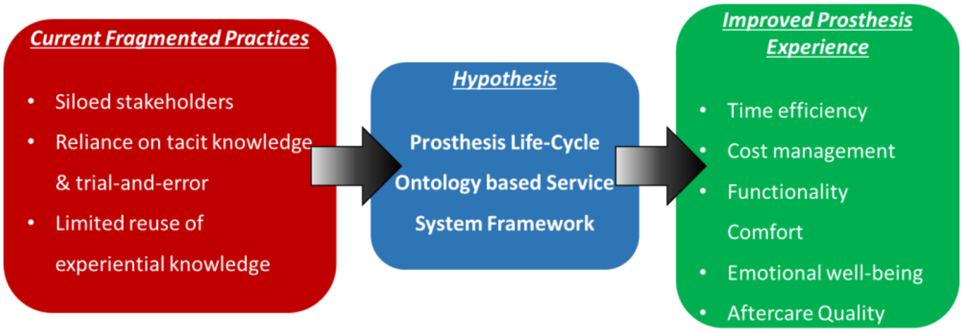


Figure 1.6: Conceptual schematic of the research hypothesis, contrasting fragmented practices with the proposed Prosthesis Life-Cycle Ontology- based Service System framework and its expected outcomes

Evaluation criteria defined (time, cost, functionality, comfort, emotion, aftercare)

The hypothesis provides a testable basis for the research. Its evaluation is operationalised through the framework's implementation and demonstration, where specific scenarios are used to assess improvements across six criteria: time, cost, functionality, comfort, emotional well-being, and aftercare quality. These criteria, drawn from both literature and stakeholder feedback, serve as the core evaluation criteria against which the proposed framework is assessed in Chapter 9.

Justification of six criteria (literature & stakeholder input)

They were selected because they reflect the most critical aspects of the prosthesis experience identified in the state-of-the-art (Chapter 2) and in stakeholder interviews (Chapter 3). Time and cost efficiency address systemic inefficiencies frequently reported in prosthesis provision and rehabilitation services (Healy *et al.*, 2020). Functionality and user comfort capture long-standing design challenges in socket fit, alignment, and material performance. Emotional well-being accounts for the affective consequences of prosthesis use, such as confidence, trust, and satisfaction (Desmet, 2015; Farrugia, 2017), while aftercare quality reflects the long-term support and adaptation needs emphasised in rehabilitation practice (Manz *et* *al.*, 2022). Together, these six criteria provide a balanced framework for evaluating whether adProLiSS achieves its aim of enhancing the amputee's overall prosthesis experience.

1.6 Research Methodology and Approach

Alternative research methodologies considered

This research is situated within the discipline of design research, where the dual goals are to generate knowledge about the design process and to develop methods or frameworks that support improved design practice. A number of methodological traditions could potentially have been adopted. For instance, **Case Study Research** (Yin, 2018) offers rich contextual understanding but is limited in its prescriptive capacity, making it unsuitable as the primary methodology for developing a novel framework. **Action Research** (Reason and Bradbury, 2008) emphasises collaborative cycles of intervention and reflection, but while participatory in nature, it does not provide structured mechanisms for formalising heterogeneous knowledge into reusable models. **Grounded Theory** (Charmaz, 2014) is well suited to inductively building conceptual categories from data, yet it is not inherently prescriptive and lacks alignment with the engineering design focus of this thesis. Similarly, **Mixed Methods Research** (Creswell and Plano Clark, 2018) can yield comprehensive evaluation evidence but functions primarily as a strategy for data collection and analysis, rather than a guiding methodology for framework development.

Design research methodology selected as moist suitable (Duffy et al.)

Given the need to both understand and structure the problem landscape and to develop a prescriptive framework supported by formal models and demonstrators, a design research methodology was deemed most appropriate. This thesis therefore primarily adopts the research methodology of (Duffy *et al.*, 1993; Duffy and O'Donnell, 1998). This approach emphasises concurrency in research activities, allowing literature review, stakeholder analysis, and problem development to be performed iteratively and in parallel. It also explicitly supports the development of knowledge-based and computer-supported design tools, which directly aligns with the ontology-based and consequence-aware focus of this research.

Duffy et al. introduced concurrency & collaboration in design research

The methodological foundation adopted in this thesis traces back to the work of (Duffy *et al.*, 1993), which introduced principles of design coordination, collaboration, and concurrency in design research. This early contribution provided the basis for understanding how multiple perspectives and activities could be integrated within a design process. The subsequent refinement by (Duffy and O'Donnell, 1998) formalised these principles into a more structured Design Research Methodology, emphasising knowledge modelling, computational support, and iterative cycles of descriptive and prescriptive research. Together, these works provide both the conceptual and methodological grounding for the adapted approach employed in this thesis (Figure 1.7).

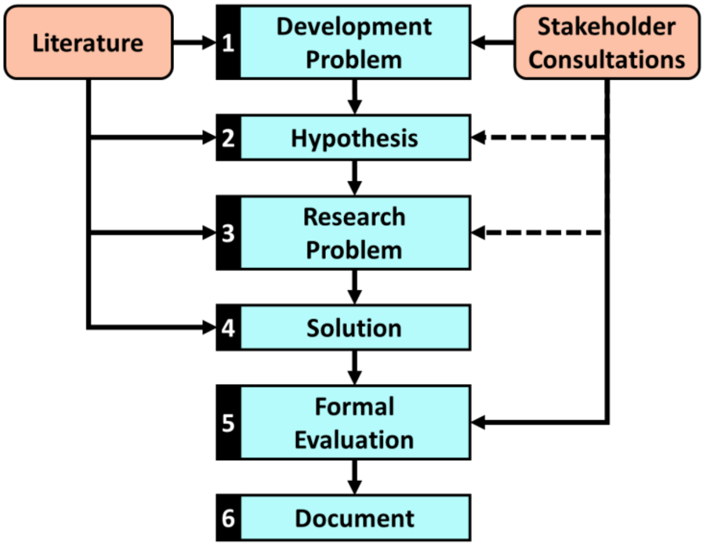


Figure 1.7: Adapted version of Duffy's methodology used in this research

Blessing & Chakrabarti's DRM provides complementary structure

Complementing this, the Design Research Methodology (DRM) of (Blessing and Chakrabarti, 2009) guides the structuring of the research into descriptive and prescriptive studies, thereby strengthening the empirical grounding and traceability of the process. DRM's distinction between Descriptive Study I (understanding the current situation), Prescriptive Study (designing support), and Descriptive Study II (evaluating the support) provided a valuable reference structure that guided the sequencing of activities in this thesis. However, DRM alone was considered less suited as the primary methodology because it places less emphasis on the modelling of knowledge and the development of computationally supported frameworks.

Adopted methodology combines Duffy et al. & DRM

Accordingly, the methodological stance adopted in this thesis can be described as an adaptation of Duffy et al.'s methodology, reinforced by concepts from DRM. This adaptation allowed the research to proceed through the following steps:

Sequential stages: problem definition, hypothesis, research problem, solution, development, implementation & evaluation

1 **Development Problem Definition -** The first stage involved defining the development problem by examining the prosthesis life-cycle, stakeholder interactions, and systemic limitations of current practices. This was achieved through a detailed literature review and stakeholder analyses, which together identified inefficiencies in communication, knowledge reuse, and consequence management. The outcomes of this stage are reported in Chapters 2 and 3;

2 **Hypothesis Formulation -** Building on the development problem, a hypothesis was articulated: that amputees' overall prosthesis experience, measured in terms of time, cost, functionality, comfort, emotional well-being, and aftercare quality, could be significantly improved by guiding prosthesis development and aftercare through a Prosthesis Life-Cycle Ontology-based Service System Framework. This hypothesis, set out in Section 1.5, provided the central claim to be tested throughout the research;

3 **Research Problem Formulation** – The broad development problem and hypothesis were then translated into a formal research problem, including the specification of research questions and the boundaries of the study. This ensured the research was appropriately scoped and methodologically tractable. The formulation of research questions is detailed in Chapter 3;

4 **Solution Development** – The prescriptive phase of the research focused on developing a solution to the identified problem in the form of the "Adaptive Prosthesis Life-Cycle Service System Framework" (adProLiSS). This involved designing an ontology-based, consequence-aware service system framework, supported by a prescriptive methodology and formal knowledge models. These developments are presented in Chapters 4 to 7;

5 **Solution Implementation and Formal Evaluation –** To test the hypothesis in practice, the proposed framework was implemented through physical and digital scenario-based demonstrations, including a Patient–Prosthesis Management System, consequence-driven simulation tools, and an integrated smart prosthesis prototype. These implementations (Chapter 8) provided the means for formal evaluation with amputees, clinicians, engineers, and designers. Evaluation was conducted through scenario-based demonstrations, stakeholder feedback, and mixed methods analysis, as reported in Chapter 9.

Adaptation extends Duffy's methodology with explicit implementation step

This adapted sequence maintains fidelity to the five stages defined by (Duffy *et al.*, 1993; Duffy and O'Donnell, 1998) while extending them with an explicit implementation step. The addition of this step was necessary to move beyond conceptual modelling and ensure that the framework could be tested in practical contexts before formal evaluation.

Figure 1.8 shows rationale for selecting methodology

To clarify the rationale for the chosen research methodology, Figure 1.8 illustrates how alternative approaches were considered, and why Duffy et al. was selected as the primary foundation, supported by DRM.

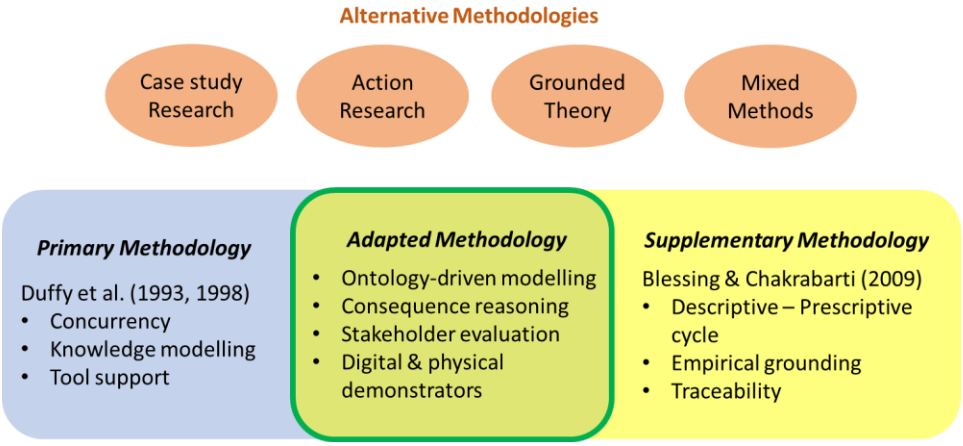


Figure 1.8: Methodological positioning of this thesis, contrasting alternative approaches with the adopted methodology based on Duffy et al. (1993; 1998), supported by DRM (Blessing & Chakrabarti, 2009), and adapted for this research.

1.7 Thesis Scope and Structure

Scope limited to lower-limb prosthesis, mid-TRL demonstrations, & scenario-based evaluation

This thesis focuses on the design, development, and evaluation of a Prosthesis Life-Cycle Ontology-based Service System Framework. This research is situated at the intersection of engineering design, healthcare service systems, and ontology-based modelling. The scope is deliberately constrained in the following ways:

Defines boundaries: domain, contribution, implementation level, & evaluation strategy

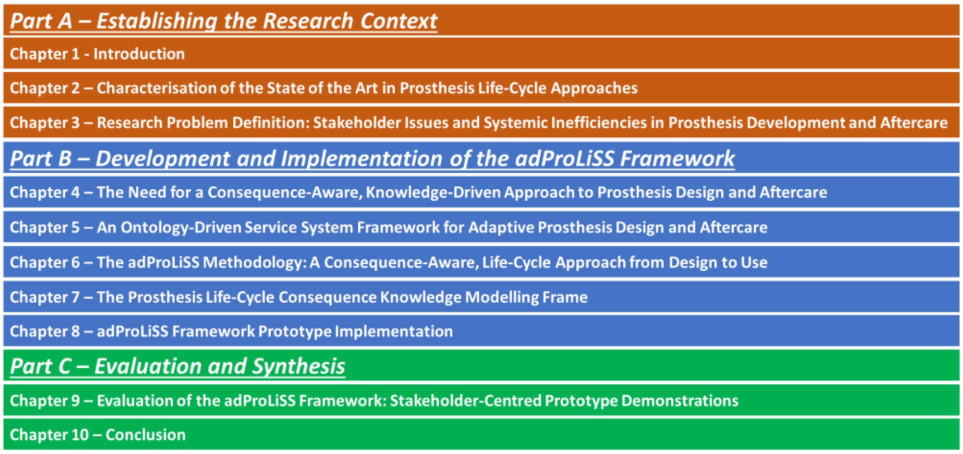
- **Domain focus:** The research concentrates on lower-limb prostheses and their life-cycle (design, fitting, rehabilitation, maintenance, and replacement). While many of the principles are generalisable, upper-limb prostheses and exoskeletons are beyond the immediate scope;

- **Contribution focus:** The emphasis is on knowledge integration, consequence reasoning, and stakeholder-centred design support, rather than on the invention of new mechanical actuation systems or clinical protocols;

- **Implementation level:** The research delivers mid-TRL demonstrators, including ontology models, a Patient–Prosthesis Management System (PPMS), consequence-driven simulation tools, and a smart prosthesis prototype. Full-scale clinical trials and long-term epidemiological studies are excluded but identified as directions for future work;

- **Evaluation strategy:** Evaluation is conducted through scenario-based demonstrations and stakeholder-informed assessments, focusing on the six criteria of time, cost, functionality, comfort, emotional well-being, and aftercare quality. The approach emphasises feasibility and depth within available resources rather than exhaustive statistical generalisation.

A high-level view of the thesis structure is presented in Figure 1.9, followed by a detailed description of each chapter.



Part A – Establishing the Research Context

Chapter 1 - Introduction

Chapter 2 – Characterisation of the State of the Art in Prosthesis Life-Cycle Approaches

Chapter 3 – Research Problem Definition: Stakeholder Issues and Systemic Inefficiencies in Prosthesis Development and Aftercare

Part B – Development and Implementation of the adProLiSS Framework

Chapter 4 – The Need for a Consequence-Aware, Knowledge-Driven Approach to Prosthesis Design and Aftercare

Chapter 5 – An Ontology-Driven Service System Framework for Adaptive Prosthesis Design and Aftercare

Chapter 6 – The adProLiSS Methodology: A Consequence-Aware, Life-Cycle Approach from Design to Use

Chapter 7 – The Prosthesis Life-Cycle Consequence Knowledge Modelling Frame

Chapter 8 – adProLiSS Framework Prototype Implementation

Part C – Evaluation and Synthesis

Chapter 9 – Evaluation of the adProLiSS Framework: Stakeholder-Centred Prototype Demonstrations

Chapter 10 – Conclusion

Figure 1.9: Thesis structure

Establishes context (state of the art, stakeholder issues, research questions)

Part A sets the foundation of the research. Chapter 2 characterises the state of the art in prosthesis life-cycle approaches, reviewing prosthesis design and aftercare practices, related Product–Service System (PSS) research, consequence management theories, and ontology-based approaches. This establishes the theoretical and practical background required to define the research gap. Building on this, Chapter 3 synthesises insights from literature and stakeholder studies, identifying systemic inefficiencies in current prosthesis development and aftercare practices. These findings lead directly to the formulation of the research questions that guide the remainder of the thesis.

Framework design, methodology, ontology model, & demonstrations

Part B focuses on the conceptualisation, design, and implementation of the proposed solution. Chapter 4 sets out the design rationale, highlighting the limitations of conventional approaches, the role of consequence propagation, and the need for structured, ontology-based knowledge systems. Chapter 5 introduces the conceptual adProLiSS framework, outlining its frames, pillars, and stakeholder roles. Chapter 6 then develops the prescriptive methodology that grounds the framework, detailing processes, knowledge flows, and decision-making pathways. Chapter 7 presents the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, which formalises consequence reasoning through taxonomies, rules, and ontology-based structures across the prosthesis life-cycle. Finally, Chapter 8 describes the realisation of the framework in both physical and digital demonstrators, including the Patient–

Prosthesis Management System (PPMS), consequence-driven simulators, and the integrated smart prosthesis prototype.

Evaluation, results, & conclusions

Part C evaluates and synthesises the research outcomes. Chapter 9 reports on the evaluation strategy, methods, and findings from scenario-based demonstrations involving amputees, prosthetists, physiotherapists, and engineers. The results are analysed against six key evaluation criteria: time, cost, functionality, comfort, emotional well-being, and aftercare quality. Chapter 10 concludes the thesis by synthesising the overall contributions, reflecting on limitations, and outlining avenues for future research and application.

Thesis trajectory: problem, framework, implementation, evaluation

Together, these chapters establish a coherent trajectory: from problem identification, to framework design and methodological development, through to implementation and evaluation. This structure ensures that the thesis addresses both the theoretical and practical dimensions of ontology-based, consequence-aware prosthesis service system design.

2

2 Characterisation of the State of the Art in Prosthesis Life-Cycle Approaches

Introduces focus: PPS, prosthesis aftercare, & ontology-based knowledge systems

The preceding chapter introduced the motivation for this research, outlining the challenges of prosthesis design and aftercare, the complexity of multi-stakeholder interactions, and the overarching research questions that guide this thesis. Building on that foundation, this chapter characterises the state of the art across three interrelated domains: Product–Service Systems (PSS) in engineering design, which provide principles for integrating products and services across a life-cycle perspective; prosthesis and amputee aftercare systems, which highlight the clinical, technical, and organisational challenges that motivate the need for more adaptive and consequence-aware approaches; and knowledge representation approaches, particularly ontology-based systems, which offer methods for structuring and reusing complex, heterogeneous knowledge across stakeholders and life-cycle phases.

Synthesises perspectives to expose convergences, divergences, and gaps

By synthesising these perspectives, the chapter establishes the intellectual scaffolding of the thesis, identifying where existing approaches converge, where they diverge, and where critical gaps remain. The analysis sets the stage for the development of the research framework by clarifying the theoretical and methodological foundations against which the proposed contribution will be positioned.

Chapter structure: scope, source mapping, domain analysis, synthesis of gaps

This chapter is organised into four sections. Section 2.1 outlines the scope and criteria guiding the characterisation. Section 2.2 presents the source classification and thematic mapping. Section 2.3 provides a deeper analysis of each domain, highlighting current advances and limitations. Finally, Section 2.4 synthesises the findings to highlight high-level theoretical gaps, which, together with the stakeholder perspectives examined in Chapter 3, form the basis for defining the research gaps for this thesis.

2.1 Scope and Criteria for Characterisation

Defines focus: PSS, prosthesis aftercare, & knowledge representation

The purpose of this characterisation is to establish the theoretical and practical foundations relevant to prosthesis life-cycle systems, with particular attention to three domains: Product-Service Systems (PSS) in engineering design, prosthesis and amputee aftercare systems, and knowledge representation approaches. Together, these domains define the intellectual landscape within which this doctoral research is situated.

To ensure methodological transparency and reproducibility, the characterisation follows a systematic, SLR-informed approach to literature identification, screening, and thematic synthesis, aligned with the principles of the PRISMA reporting framework, while remaining tailored to the interdisciplinary nature of engineering design and healthcare research.

Outlines scope: databases, peer-reviewed sources, standards

Sources were identified through academic databases including Scopus, Web of Science, IEEE Xplore, PubMed, and Google Scholar, supplemented by targeted searches in SpringerLink and Elsevier ScienceDirect. The review prioritised peer-reviewed journal articles, conference proceedings, and authoritative monographs, with inclusion of selected standards and policy reports where these directly shaped prosthesis development or aftercare practice.

Sets timeframe: 2000-2025, with

The timeframe was set broadly between 2000 and 2025, a period that reflects both the emergence of PSS as a significant paradigm in engineering design and the seminal earlier works

increased adoption of data-driven, digital, and ontology-based approaches in healthcare. Earlier seminal works (e.g. on product life-cycle theory, design methods, and rehabilitation systems) were included where necessary to provide historical grounding.

Inclusion criteria: design frameworks, prosthesis aftercare, knowledge structuring

Inclusion criteria focused on works that:

i. explicitly address design frameworks or service-oriented models in engineering;
ii. present clinical, technical, or socio-organisational aspects of prosthesis aftercare;
iii. apply formal knowledge structuring approaches (taxonomies, knowledge graphs, expert systems, ontologies) in engineering or healthcare contexts.

Exclusion criteria: surgical-only, technical-only, or opinion-based studies

Exclusion criteria were applied to:

i. purely clinical studies of surgical procedures or rehabilitation outcomes without implications for systemic prosthesis management;
ii. purely technical publications on sensor hardware or component optimisation without relevance to life-cycle integration;
iii. opinion articles lacking methodological grounding.

Concludes: structured mapping to identify domain intersections & gaps

By applying these criteria, the characterisation moves beyond a descriptive survey to construct a structured map of the state of the art, identifying how the three selected domains have evolved, where they intersect, and where significant gaps remain. The following sections (2.2–2.4) organise these sources into thematic clusters, progressively deepening the analysis to highlight the research gap that motivates framework of this thesis.

2.2 Source Classification and Thematic Mapping

Explains rational for classifying & mapping sources

The domains relevant to this thesis span engineering design, healthcare, and knowledge representation. To ensure clarity and coherence, the sources were classified and mapped according to their disciplinary focus and thematic contribution. This approach allows for a structured analysis of how different bodies of literature contribute to the prosthesis life-cycle problem and where integration between domains remains underdeveloped.

Outlines classification criteria: domain relevance & analytical depth

The classification was guided by two criteria:

- Domain relevance – whether the source addresses engineering design approaches (including Product–Service Systems), prosthesis and amputee aftercare systems, or knowledge structuring methods;
- Analytical depth – whether the source provides theoretical principles, applied case studies, or methodological tools that contribute to understanding the prosthesis life-cycle.

Introduces three thematic domains for clustering literature

Based on these criteria, the literature was clustered into three thematic domains (Figure 2.1):

- **2.2.1 Engineering Design and Product–Service Systems (PSS):** covering design methodologies, service-oriented frameworks, and integration of products and services across life-cycle phases;
- **2.2.2 Prosthesis and Aftercare Approaches:** encompassing clinical practices, rehabilitation models, service delivery systems, and limitations in current prosthesis management;
- **2.2.3 Knowledge Representation Approaches:** reviewing methods used to structure and apply complex knowledge, including taxonomies, relational databases, knowledge graphs, expert systems, machine learning models, and ontologies. This subsection highlights the relative strengths and weaknesses of these approaches.

Notes purpose: ensures integrated analysis across domains

This thematic mapping ensures that the subsequent in-depth analysis (Section 2.3) addresses not only each domain in isolation but also their intersections.

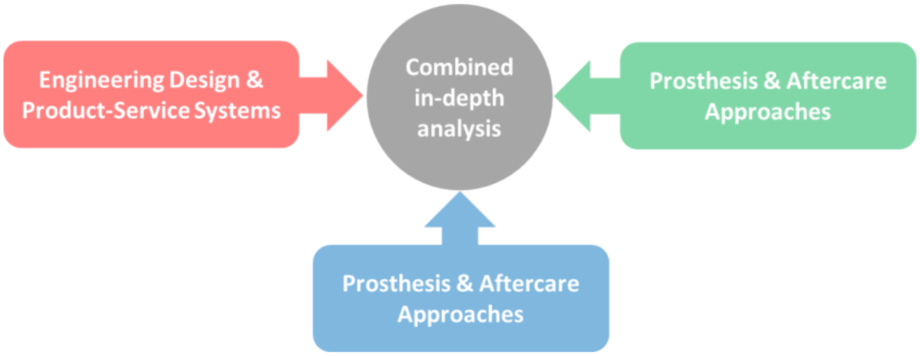


Figure 2.1: Source classification into three thematic domains relevant to engineering the prosthesis life-cycle

2.2.1 Product-Service Systems in Engineering Design

PSS framed as engineering design paradigm; relevance to prosthesis life-cycle

In this thesis, Product–Service Systems (PSS) are examined primarily as an engineering design paradigm, rather than as a business or management construct. The focus lies on how PSS research in engineering has addressed artefact–service integration, adaptation of design processes, life-cycle costing, and digital enablement, providing transferable insights for the prosthesis life-cycle. At its core, PSS emphasises that value is realised during use rather than at the point of sale, and that sustained outcomes depend on the integration of artefacts, defined here as engineered objects or systems intentionally designed to fulfil specified functions (Roozenburg and Eekels, 1995; Blessing and Chakrabarti, 2009), with supporting processes such as training, maintenance, and adaptation. This systemic perspective resonates strongly with the prosthesis life-cycle, where a device's success cannot be judged solely at delivery but must also account for rehabilitation, comfort, and ongoing support.

Tukker's topology; ownership & responsibility shifts; industry parallels

Tukker's typology of eight archetypes (Tukker, 2004), often grouped into product-oriented, use-oriented, and result-oriented systems, highlights the shifting balance of ownership and responsibility between provider and user. Product-oriented systems emphasise the sale of the artefact, with services such as manuals, spare parts, or scheduled maintenance added around it. Use-oriented systems shift ownership to the provider, who leases or shares the product and remains responsible for availability. Result-oriented systems go further by contracting on outcomes, such as guaranteed performance, availability, or functional results (Tukker, 2004). These models capture the degree to which ownership, responsibility, and risk shift from the user to the provider. (Mont, 2002; Baines *et al.*, 2007) expanded this framing by demonstrating that PSS is not simply a contractual model but a design paradigm that demands explicit attention to serviceability, maintainability, and reliability within the engineered system. These distinctions have been widely applied across industrial sectors, with (Baines *et al.*, 2007) illustrating the contrast between traditional product delivery and service-integrated delivery in the context of office photocopiers (Figure 2.2).

Healthcare PSS logic; parallels with prosthesis delivery

In healthcare, similar logics are reflected in managed equipment services and performance-based contracts, where providers guarantee availability or clinical outcomes (Ng, Maull and Yip, 2009). These approaches suggest a parallel for prosthesis delivery: a result-oriented stance could shift attention away from one-off delivery towards sustained performance indicators such as mobility outcomes, downtime reduction, and patient comfort.

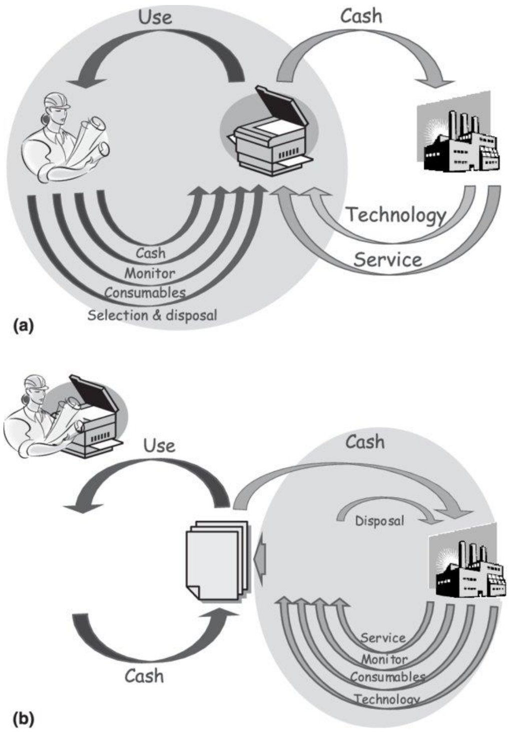


Figure 2.2: Traditional product delivery (a) versus service-integrated delivery (b) in a photocopying context adapted from (Baines et al., 2007)

To further clarify these categories, Table 2.1 summarises the three principal PSS types, their defining characteristics, typical industrial examples, and their potential parallels in prosthesis contexts.

Table 2.1: Summary of PSS typologies and their parallels for prosthesis context

PSS Type	Definition	Typical Example	Prosthesis Analogy
Product - oriented	Artefact sold; provider offers add-on services (manuals, spares, scheduled maintenance)	Car with warranty and spare parts	Prosthesis delivered with manual consumables (liners), and occasional clinic visits
Use - oriented	Ownership retained by provider, user access through lease, hire, or pay-per-use	Car leasing scheme	Prosthesis leased via hospital, maintained and upgraded under service contract
Result - oriented	Contract tied to outcomes such as performance, availability, or functionality	“Power by the hour” in aerospace	Prosthesis service agreement linked to user mobility outcomes, downtime reduction, comfort

Adaptation of design process: blueprinting, modularity, co-creation; prosthesis implications

Alongside typologies, significant research has focused on adapting engineering design processes to account for the duality of product and service. (Mont, 2002; Aurich, Fuchs and Wagenknecht, 2006; Sakao and Shimomura, 2007) proposed methods in which service blueprinting, journey mapping, and co-creation methods are integrated into classical design activities. Such methods are used to identify service touchpoints, potential bottlenecks, and dependencies that extend beyond the artefact itself. In prosthesis contexts, where fitting, alignment, and rehabilitation involve multiple iterative adjustments, service blueprinting could expose critical interactions that are often left implicit, such as the interdependence between socket alignment decisions and downstream maintenance demands. Modularity and platform strategies further extend this approach, allowing for both product flexibility and service adaptability (Maussang, Zwolinski and Brissaud, 2009; Vasantha *et al.*, 2012). For prostheses, modular sockets and actuators designed in parallel with modular training or maintenance packages could reduce variation and improve scalability without sacrificing personalisation.

Life-cycle cost analysis; early design decisions impact cost;

Life-cycle cost analysis has long been recognised as a critical dimension of design decision-making. (Asiedu and Gu, 1998) provided one of the earliest comprehensive reviews, demonstrating that up to 70–80% of life-cycle costs are determined by relevance to prosthesis

decisions taken in the design phase. Since then, the literature has developed to account for service-oriented and outcome-based models. (Kambanou and Lindahl, 2016) reviewed applications of life-cycle costing in Product–Service Systems, highlighting how cost responsibility shifts from users to providers when assets remain under provider ownership. More recently, (Kambanou, 2020a) examined how life-cycle costing is actually practised in organisations, showing that while it is conceptually well established, its application varies widely depending on methodological choices, data availability, and organisational priorities. A further body of research has focused on uncertainty in financial parameters, with (Sun and Carmichael, 2018) reviewing methods for handling escalation rates, discount factors, and stochastic variation in long-term cost models. These insights collectively reinforce the importance of considering not only direct manufacturing costs but also the service, adjustment, and aftercare expenses that accumulate across the prosthesis life-cycle. Outcome-based contracting examples from aerospace, such as Rolls-Royce's "power by the hour," illustrate how reallocation of risk and incentives drives design for reliability and maintainability (Ng, Maull and Yip, 2009). Translating these ideas to prosthesis contexts implies that downtime, repair frequency, and maintenance effort should be anticipated and minimised through design choices, rather than managed reactively in aftercare.

Digitalisation & servitisation; digital twins, predictive analytics; prosthesis applications

Digitalisation has accelerated the integration of products and services, with embedded sensing, connectivity, and predictive analytics recognised as enablers of adaptive PSS (Meier, Roy and Seliger, 2010; Alcayaga, Wiener and Hansen, 2019). More recent work (Langley, 2022; Minaya, Avella and Trespalacios, 2024; Soellner *et al.*, 2024) deepens this trajectory by examining how data-driven PSS models evolve under digital servitisation pressures. These technologies enable prognostics and health management, configuration control, and digital twins that simulate interventions before they are physically enacted (Tao, Zhang, *et al.*, 2019). In prosthesis design, such capabilities are no longer speculative: accelerometers, force sensors, and pressure mapping tools are already used to monitor gait, loading, and skin health. Within a PSS logic, these data streams could become part of the designed system, linking device configuration to clinical outcomes and enabling evidence-based adjustment cycles.

Organisational transformation; aligning actors for outcome-based care

The literature also emphasises organisational transformation, often framed as "servitisation" (Baines and Lightfoot, 2014; Minaya, Avella and Trespalacios, 2024). PSS adoption requires not only technical changes but also new organisational capabilities such as service engineering competence, data governance, and cross-functional integration. Studies note the difficulty of aligning incentives across product and service functions and the need for governance methods that support outcome delivery across ecosystems of providers, users, and regulators. Prosthesis delivery involves similar complexity: hospitals, clinics, insurers, suppliers, and technicians each influence (Highsmith, Andrews, *et al.*, 2016a; Highsmith, Kahle, *et al.*, 2016; Mihailović, Stošić and Milutinović, 2025). Lessons from servitisation research highlight the necessity of aligning these actors to deliver integrated, outcome-focused prosthesis care, rather than treating device design and aftercare as separate domains.

Decision traceability & consequence-aware design; importance in prosthesis

Finally, decision traceability and attention to downstream effects are recurring themes in PSS engineering. (Erkoyuncu *et al.*, 2009) stressed the importance of capturing rationale and assumptions to manage uncertainty in long-term service contracts. More recent studies by (Isaksson, Larsson and Rönnbäck, 2009) argued for consequence-aware decision support, where downstream effects of design choices are explicitly modelled and fed back into iterative design cycles. In prosthesis design, this need is pronounced: local adjustments to socket fit or actuator tuning can cascade into unintended consequences for patient comfort, rehabilitation progress, or maintenance frequency (Klute *et al.*, 2011; Gholizadeh *et al.*, 2014). Explicit capture and reuse of such decision consequences is critical if improvements are to extend beyond individual cases and inform future design. At present this remains fragmented, with no formalised approach to integrating such knowledge.

Evidence of PSS in healthcare; managed equipment services; telemedicine examples

While much of this literature is rooted in manufacturing, evidence is emerging that PSS concepts can be successfully translated into healthcare contexts. (Ng, Maull and Yip, 2009) describe outcome-based contracting models in which medical equipment providers guarantee clinical performance rather than simply delivering devices. Managed equipment services in hospitals operate on similar principles, with suppliers retaining ownership of diagnostic or therapeutic equipment and assuming responsibility for uptime, maintenance, and upgrades (Matschewsky, Kambanou and Sakao, 2018; Matschewsky, Lindahl and Sakao, 2020). (Ceschin, 2014) further demonstrates how PSS frameworks can extend to community health services and telemedicine, highlighting the integration of product design with service delivery to improve continuity of care. These cases show that PSS is not confined to industrial settings; rather, it can support the reorganisation of healthcare delivery around outcomes and life-cycle responsibilities. This precedent strengthens the rationale for applying PSS thinking to prosthesis delivery and aftercare, where outcomes depend equally on technical artefacts and the service processes that sustain them.

Healthcare PSS characterised; complexity, regulatory constraints; need for tailored approaches

Beyond these examples, (Yip, Phaal and Probert, 2015) offer a more systematic attempt to characterise PSS in the healthcare industry through an empirical study of eleven case studies covering 25 product–service offerings. Their work identifies four dimensions, customer value level, type and degree of connectivity, connectivity number, and PSS configuration type, that together provide a framework for describing how healthcare PSS are structured in early development. Importantly, their study highlights that healthcare PSS design is conditioned by factors such as regulatory constraints, stakeholder conflicts, and service–product interdependencies, which complicate the transfer of generic PSS models into clinical settings. This characterisation demonstrates that PSS principles can be translated into healthcare contexts, but also that healthcare requires tailored approaches to manage complexity, multiple stakeholders, and patient outcomes. For prosthesis aftercare, this reinforces the need to move beyond industrial analogies to frameworks that explicitly accommodate clinical pathways, patient-centred measures, and long-term consequence management.

Synthesis of six recurring PSS themes; relevance to prosthesis care

The diverse PSS literature can be synthesised into six recurring themes, each of which carries implications for prosthesis design and aftercare. Table 2.2 summarises these themes, key references, and their specific relevance to the prosthesis life-cycle.

Taken together, the PSS literature provides a comprehensive foundation for conceptualising prostheses not as static artefacts but as systems embedded in service and stakeholder networks. Its emphasis on outcome orientation, integrated design processes, life-cycle cost awareness, digital enablement, organisational capability, and decision traceability parallels the core challenges of prosthesis delivery. For these reasons, PSS constitutes the first thematic pillar in this thesis' characterisation of the state of the art, setting the stage for the subsequent consideration of prosthesis aftercare systems (Section 2.2.2) and knowledge representation approaches (Section 2.2.3).

Table 2.2: Key themes in PSS literature and their relevance to prosthesis contexts

Theme	Key Reference	Prosthesis Relevance
Typologies & risk transfer	(Mont, 2002; Tukker, 2004; Baines and Lightfoot, 2014)	Aligns delivery with outcomes (mobility, downtime) rather than one-off fitting
Integrated design methods	(Mont, 2002; Aurich, Fuchs and Wagenknecht, 2006; Sakao and Shimomura, 2007)	Service blueprinting for fitting/rehab; modular sockets with modular service packages
Life-cycle costing	(Asiedu and Gu, 1998; Sun and Carmichael, 2018; Kambanou, 2020a, 2020b)	Anticipate downtime and aftercare costs in design; reduce long-term total cost of ownership.
Digitalisation & cyber-physical	(Meier, Roy and Seliger, 2010; Alcayaga, Wiener and Hansen, 2019)Sensors for gait/skin health; predictive analytics; digital twin for what-if adjustments	Sensors for gait/skin health; predictive analytics; digital twin for what-if adjustments
Servitisation & organisational change	(Ng, Maull and Yip, 2009; Baines and Lightfoot, 2014)	Align hospitals, clinics, insurers, suppliers for integrated outcome-focused prosthesis service
Decision traceability & attention to downstream effects	(Erkoyuncu *et al.*, 2009; Isaksson, Larsson and Rönnbäck, 2009)	Capture rationale for socket/actuator adjustments; reuse knowledge to improve future prosthesis designs

2.2.2 Characterising Prosthesis and Aftercare Approaches

Aftercare as critical determinant; natural candidate for PSS framing

Aftercare is widely recognised as a critical determinant of prosthesis success, encompassing clinical, technical, organisational, and experiential dimensions that extend well beyond the point of device delivery (Highsmith, Kahle, *et al.*, 2016; WHO, 2017). The challenge is not only to design effective prosthetic technologies but to sustain their performance and relevance across a patient prosthesis life-cycle through adaptive service delivery, outcome monitoring, and continuous stakeholder engagement. This makes prosthesis aftercare a natural candidate for Product–Service System (PSS) perspectives, which explicitly consider the integration of artefacts, service processes, and user experience.

Healthcare PSS examples; emotion-centred care; co-design in regulated contexts

Although much of the PSS literature has historically focused on manufacturing, several studies demonstrate that healthcare contexts can benefit from product–service integration. (Stacey and Tether, 2014), for example, applied an emotion-centred PSS approach to the design of a cancer care facility, showing that care environments must be designed not only for functional efficiency but also for emotional well-being. Their work emphasises the importance of considering patient experience and emotional outcomes as integral to service delivery, a principle that resonates strongly with prosthesis aftercare where comfort, stigma, and user satisfaction directly shape device acceptance. Similarly, (Mittermeyer, Njuguna and Alcock, 2011) examined a drug–device combination as a healthcare PSS case, demonstrating how product and service elements must be co-designed in regulated medical contexts.

Strategic/business model perspectives; customisation in prosthesis; fragmented healthcare PSS

At a more strategic level, (Pourabdollahian and Copani, 2015) argued that PSS-oriented business models are required to support customisation in healthcare. Their findings are particularly relevant to prostheses, which rely on standardised sub-systems but require individualised fitting and adaptive service support to meet each users' physical and emotional needs. (Xing, Rapaccini and Visintin, 2017) reinforced this point by characterising PSS in healthcare as an under-explored field, noting that while the potential is high, systematic methodologies and frameworks remain limited. (Yip, Phaal and Probert, 2015) attempted address this gap through an empirical study of healthcare PSS, identifying four dimensions; customer value level (the extent to which value is derived from outcomes rather than products), connectivity type (the nature of information and service linkages between stakeholders), connectivity number (the number of actors involved in value co-creation), and PSS configuration type (the balance between product and service dominant offerings), that characterise early development. These studies collectively demonstrate that healthcare PSS is possible but still fragmented, with no unified framework to capture clinical, organisational, technical, and experiential factors.

Table 2.3: lessons from healthcare PSS applied to prosthesis aftercare

Table 2.3 summarises the key lessons drawn from PSS applications in healthcare and highlights their implications for prosthesis aftercare. This mapping illustrates how principles developed in broader healthcare contexts, such as emotion-centred care, business model innovation, and stakeholder co-design, can guide the design of more integrated and adaptive prosthesis service systems.

Table 2.3: Healthcare PSS Lessons and Implications for Prosthesis Aftercare

Healthcare PSS Lesson	Illustrative Source	Implications for Prosthesis Aftercare
Emotion-centred PSS emphasises experiential dimensions	(Stacey and Tether, 2014)	Prosthesis aftercare must address stigma, comfort, and emotional well-being, not just function
PSS in healthcare is under-explored and fragmented	(Xing, Rapaccini and Visintin, 2017)	Prosthesis aftercare lacks systemic PSS frameworks and requires new integration models
Business model orientation towards customisation	(Pourabdollahian and Copani, 2015)	Prostheses need adaptive service models that can flex around standardised sub-systems but provide individualised fitting/support
Early characterisation frameworks in healthcare PSS	(Yip, Phaal and Probert, 2015)	Prosthesis aftercare requires early structuring of complexity (stakeholders, regulations, pathways) to avoid fragmentation
Co-design in health research strengthens adoption and outcomes	(Slattery, Saeri and Bragge, 2020)	Multi-stakeholder participation in aftercare planning is essential for effective, consequence-aware systems

Prosthesis aftercare mirrors healthcare complexity; current

This broader healthcare perspective is directly relevant to prosthesis aftercare, which embodies many of the same complexities: multiple stakeholders, regulated approaches piecemeal

contexts, strong personalisation requirements in fitting and service, and strong emotional dimensions. Yet in prosthetics, most approaches remain piecemeal and technologically oriented, with limited systemic integration.

Clinical rehabilitation pathways: peri-operative care protocols; fragmentation persists

Clinically, aftercare is structured around rehabilitation pathways, multidisciplinary care plans that guide patients from surgery through fitting, gait training, and long-term monitoring. These include peri-operative care, which refers to management before, during and immediately after surgery (Noblet *et al.*, 2019), and is critical for preparing residual limbs and enabling smoother transitions into prosthesis fitting. Protocols such as the Lower Extremity Amputation Protocol (LEAP) (O'Banion *et al.*, 2022) and more recent peri-operative frameworks demonstrate that structured, co-ordinated care can shorten hospital stays and improve functional outcomes (Pezzin, Dillingham and Mackenzie, 2000; Patel *et al.*, 2022). Despite its recognised importance, peri-operative care is often fragmented in practice: responsibilities are split between surgical teams, rehabilitation centres, prosthetists, and community providers, leading to variable follow-up and inconsistent documentation. The WHO standards explicitly identify governance and financing as major obstacles to continuity, highlighting that systemic organisation is as critical as clinical expertise (WHO, 2017).

Technical aftercare focus: socket fit, suspension, skin health issues

Technical approaches within aftercare primarily address socket fit, suspension, alignment, and component adjustment. Socket fit is consistently identified as the single most important factor influencing comfort, satisfaction, and mobility (Turner and McGregor, 2020). Vacuum-assisted suspension systems, for example, reduce pistoning, vertical movement of the residual limb within the socket during walking, and improve coupling between limb and socket, yet evidence shows user preference and long-term outcomes are inconsistent, highlighting the trade-offs between mechanical optimisation and lived experience (Klute *et al.*, 2011). Persistent residual-limb skin issues continue to affect a large proportion of prosthesis users, with systematic reviews highlighting dermatological complications that limit device use and rehabilitation progress (Meulenbelt *et al.*, 2006). These findings reveal that purely technical approaches, while essential, are insufficient: each adjustment introduces new consequences for user experience, skin health, and long-term adherence.

Digital monitoring protentional; barriers to integration with protocol

Digital monitoring has recently emerged as an adjunct to these technical approaches. Wearable sensors and activity monitors now enable the collection of real-world data on gait, loading, usage time, and asymmetry (Chadwell *et al.*, 2020). Such technologies have the potential to transform aftercare from episodic and reactive to continuous and proactive, allowing early identification of problems such as unsafe gait patterns or reduced wear time. Yet integration remains limited: few systems link these data streams to formal clinical protocols or design updates, and barriers persist around data validity, patient burden, and workflow alignment.

Outcome measurement tools; inconsistent application; ISPO COMPASS efforts

A further dimension of aftercare involves outcome measurement, what should be measured, how, and how consistently across contexts. Tools such as the Timed Up and Go (TUG), Six-Minute Walk Test (6MWT), Amputee Mobility Predictor (AMP), Prosthesis Evaluation Questionnaire (PEQ), and Prosthetic Limb Users Survey of Mobility (PLUS-M) offer partial coverage across domains of function, activity, and satisfaction (Gailey *et al.*, 2002; Hafner *et al.*, 2007, 2023). However, their inconsistent application across clinics complicates comparison and learning. Consensus efforts such as the ISPO COMPASS project seek to establish core outcome sets, yet systematic reviews highlight that no single standard has achieved widespread adoption (Clarke, Ridgewell and Dillon, 2024). This variability weakens feedback loops into design and obstructs the accumulation of generalisable knowledge about downstream effects of prosthesis use.

Service deliver models: inequities in high vs low income contexts; organisational challenges

Service delivery models, financing, and workforce capacity strongly shape aftercare outcomes. In high-income contexts, networks typically include prosthetists, physiotherapists, physicians, insurers, and suppliers, but incentives are often misaligned and information systems fragmented (Highsmith, Andrews, *et al.*, 2016b; Highsmith, Kahle, *et al.*, 2016). In lower-income and middle-income countries, literature reviews of prosthetic and orthotic services point to persistent evidence gaps, workforce shortages, insufficient training infrastructure, and weak financing methods (Harkins, McGarry and Buis, 2013). Comparative studies between low- and high-income settings (Wyss *et al.*, 2015) further highlight systemic constraints in service delivery. Even when technical or classification standards exist (such as ISO 13405 for component taxonomy), they focus on artefact description and do not guarantee care continuity or integrated service workflows. These systemic constraints emphasise that prosthesis delivery is not merely a technical challenge but an organisational one requiring governance, policy support, and sustainable business models.

Table 2.4: synthesis of aftercare approaches & limitations

The diverse approaches to prosthesis aftercare, spanning clinical, technical, evaluative, and organisational dimensions, can be synthesised as shown in Table 2.4. This table consolidates the focus, literature evidence, and limitations of each approach, providing a structured overview that highlights both their individual contributions and their systemic shortcomings.

Table 2.4: Dimensions of Prosthesis Aftercare Approaches

Approach	Focus	Examples in Literature	Limitations Identified
Clinical / Rehabilitative	Peri-operative management, residual-limb care, rehabilitation pathways	(Pezzin, Dillingham and Mackenzie, 2000; Patel *et al.*, 2022)	Fragmentation between providers, variable follow-up, inconsistent documentation
Technical / Technological	Socket fit, suspension, skin health, digital monitoring	(Peery, Ledoux and Klute, 2005; Meulenbelt *et al.*, 2006; Chadwell *et al.*, 2020)	Persistent skin issues, inconsistent user outcomes, limited integration of digital data
Measurement / Evaluative	Mobility, function, quality of life, satisfaction	(Gailey *et al.*, 2002; Hafner *et al.*, 2007, 2023; Clarke, Ridgewell and Dillon, 2024)	Lack of standardised outcome sets, heterogeneous application, weak feedback into design
Service / Organisational	Workforce, financing, governance, equity	(Harkins, McGarry and Buis, 2013; Wyss *et al.*, 2015; WHO, 2017)	Workforce shortages, fragile financing, inequitable access, disjointed governance

Recurring limitations: episodic care, fragmented service, poor integration of knowledge

Across these approaches, several limitations recur. Aftercare is often episodic and reactive, initiated by scheduled appointments or user-reported problems rather than continuous consequence-aware monitoring. Outcome measurement is heterogeneous, hindering benchmarking and knowledge accumulation. Technical innovations remain partial, addressing mechanical issues without fully resolving skin health or comfort challenges. Digital monitoring is under-integrated, producing data but not systematically feeding it into design or service adjustments. Service delivery is fragmented and inequitable, shaped by workforce and policy constraints rather than holistic life-cycle planning.

Gap persists between technical fixes & systematic integration, motivation for 2.2.3

These limitations, summarised in Table 2.4, reveal why prosthesis aftercare struggles to evolve into a cohesive life-cycle system. When viewed alongside the healthcare PSS lessons in Table 2.3, they point to the persistent gap between technical problem-solving and systemic integration. Addressing this gap requires not only improved service models but also methods to structure and manage knowledge across diverse stakeholders and life-cycle phases. Section 2.2.3 therefore reviews knowledge representation approaches in engineering design and considers their relevance to prosthesis aftercare.

2.2.3 Knowledge Representation Approaches

Knowledge representation central in engineering; relevance to prosthesis life-cycle

Knowledge representation has long been recognised as a cornerstone of engineering design, where complex artefacts, processes, and systems must be described in ways that enable analysis, communication, and decision support. Unlike raw data, knowledge representation structures information in a manner that makes it usable for reasoning, integration, and reuse. In engineering contexts, methods range from simple taxonomies to advanced formal ontologies, each offering different levels of expressivity, interoperability, and support for design activities. This section reviews the main approaches to knowledge representation used in engineering design and systems engineering, highlighting their strengths and limitations. Their relevance to prosthesis life-cycle management is illustrated throughout, as this domain embodies many of the same complexities, heterogeneous data, multiple stakeholders, evolving requirements, and high stakes in terms of user outcomes.

Taxonomies: structured but limited; examples in prosthetics

Taxonomies provide hierarchical classification of artefacts, functions, or processes. They are widely used in engineering design for part classification, assembly hierarchies, and functional decomposition (Andreasen and Hein, 1987; Blessing and Chakrabarti, 2009; Chandrasegaran *et al.*, 2013). Taxonomies simplify retrieval and standardisation, enabling activities such as design reuse and component substitution. However, they offer limited expressivity: relationships are constrained to parent–child hierarchies, and dynamic interactions between components or stakeholders cannot be represented. In prosthetics, classification schemes exist such as ISO 13405 for lower-limb prosthesis components, or diagnostic coding for rehabilitation. While these taxonomies ensure consistency, they do not capture interdependencies such as how socket alignment influences gait training, or how service delays impact comfort.

Relational databases: efficient but siloed; poor adaptability in prosthesis aftercare

Relational databases form the backbone of many engineering information systems, including Computer-Aided Design (CAD), Product Data Management (PDM), and Product Life-Cycle Management (PLM) systems (Baxter *et al.*, 2008; Xu, Xu and Li, 2018). Their strength lies in efficient storage, fast retrieval, and schema-based organisation of data. However, their rigidity limits interoperability across contexts, and they are often siloed within specific organisations. In prosthesis aftercare, similar issues are observed: clinical records and prosthesis workshop logs are frequently stored in isolated databases, making it difficult to integrate user outcomes with device specifications or rehabilitation activities. The database approach ensures traceability of events but is poorly suited for adaptive reasoning across the life-cycle.

Expert systems: early AI; rule-based, consistent but brittle

Expert systems emerged as one of the earliest applications of artificial intelligence in engineering, supporting configuration design, diagnostics, and fault detection (Feigenbaum, 1984). They encode expert knowledge into rule sets, providing structured decision support. In engineering, expert systems helped capture tacit expertise and guide less experienced practitioners. Subsequent reviews confirm both their breadth of application and their persistent limitations: (Liao, 2005) identified brittleness, maintenance difficulty, and poor scalability as recurring challenges, while more recent assessments highlight that such systems often fail to adapt when domains evolve and knowledge bases require frequent updating (Tan *et al.*, 2016; Salem *et al.*, 2021). In prosthesis aftercare, a comparable application might be encoding clinical guidelines for socket fitting or rehabilitation scheduling into decision rules. While this could ensure consistency, it would struggle to accommodate the diversity of patient needs and the evolving evidence regarding downstream effects.

Knowledge graphs: flexible links; descriptive not predictive

Knowledge graphs extend taxonomies by representing entities and their relationships in flexible, graph-based structures. They are increasingly used in engineering to link product data with service information, supply chain partners, and operational contexts (Heath and Bizer, 2011; Buchgeher *et al.*, 2021; Wan *et al.*, 2024). Unlike rigid databases, knowledge graphs can integrate heterogeneous data sources and support queries across domains. However, without a formal logic layer, they provide limited reasoning capability: they can show connections but not infer consequences. In prosthesis contexts, a knowledge graph could represent relationships between users, devices, clinicians, and outcomes. This would enable queries such as identifying which socket designs correlate with higher satisfaction scores. Still, without formal rules, such connections remain descriptive rather than predictive or normative.

Healthcare applications show potential; need formal structure’s

Similar approaches have been explored in healthcare education, where ontologies and procedural reasoning have been used to personalise patient learning pathways (Michalowski *et al.*, 2021). This illustrates how graph-like and rule-based representations can enhance service delivery, but also highlights their dependence on more formal structures when applied to complex, adaptive systems such as prosthesis aftercare.

Machine learning: predictive power; lacks explainability & traceability

Machine learning (ML) has gained prominence in engineering design for optimisation, predictive maintenance, and generative design (Jordan and Mitchell, 2015). ML excels at identifying patterns in large datasets, handling complexity that exceeds human cognitive capacity. Yet its weakness lies in explainability and traceability: while models may predict failures or recommend designs, their reasoning is opaque. This "black box" nature is problematic in safety-critical or regulated fields, where decision justification is mandatory (Burkart and Huber, 2021). In prosthesis research, ML has been applied to gait analysis, socket fit optimisation, and ulcer risk prediction (Chadwell *et al.*, 2020). Such applications show strong predictive power but limited capacity to explain why a given recommendation is made. For consequence-aware frameworks, where traceability and justification are critical, reliance on ML alone is insufficient.

Ontologies: formal, semantic, and inferential; strongest for consequence-aware prosthesis frameworks.

Ontologies represent a more formalised approach to knowledge representation, defined as explicit, formal specifications of shared conceptualisations (Gruber, 1993; Studer, Benjamins and Fensel, 1998a). In engineering, ontologies have been developed to capture product–service logic, functional–behavioural–structural models, and design rationale (Kitamura and Mizoguchi, 2003; Cocco *et al.*, 2024). They extend taxonomies by enabling the representation of relationships, axioms, and constraints, and can be linked with reasoning engines for inference. Ontologies promote interoperability and reuse by creating a shared vocabulary across stakeholders and domains (Chatterjee *et al.*, 2021). Recent advances in ontology research further strengthen this position. (Mizoguchi and Borgo, 2025a) emphasise that ontologies are not merely classificatory tools but formal systems of representation that capture the semantics of entities and their interactions. This distinction is essential in engineering contexts, where consequence-aware decision-making depends on precise representation of both artefacts and their interdependencies. In prosthesis contexts, ontologies can capture the relationships between device components, clinical outcomes, service processes, and user experiences, while also enabling reasoning about consequences of design or service choices. Their development requires substantial effort and expertise, but they provide the most comprehensive foundation for integrating engineering knowledge with clinical and experiential dimensions.

Figure 2.3: comparison of approaches by

The relative positioning of these approaches in terms of formal expressivity and reasoning capability is illustrated in Figure 2.3. This spectrum highlights why expressivity and reasoning capability

taxonomies and databases, while useful for structure, lack adaptability; why machine learning, though powerful, struggles with explainability; and why ontologies occupy a distinctive position by balancing semantic richness with inferential rigour.

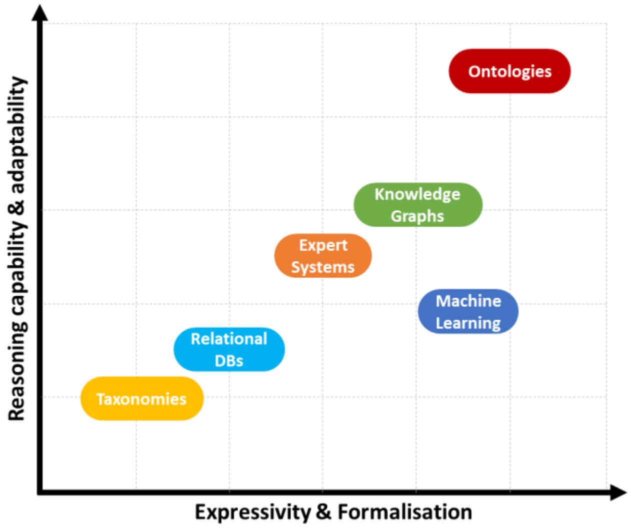


Figure 2.3: Visualisation of approaches in terms of formal expressivity and reasoning capability

To consolidate the discussion, Table 2.5 compares the main knowledge representation approaches reviewed in this section, highlighting their strengths, limitations, and relevance to prosthesis aftercare.

Table 2.5: Strengths, limits, & prosthesis relevance

Table 2.5: Comparison of Knowledge Representation Approaches

Approach	Use in Engineering Design	Limitations	Illustration in Prosthesis Aftercare
Taxonomies	Classification of parts and product info (Chandrasegaran *et al.*, 2013)	Rigid, static, poor for dynamics	ISO 13405 classification, rehab coding
Relational Databases	PLM/PDM for product data (Xu, Xu and Li, 2018)	Schema rigidity, siloed, poor interoperability	Fragmented prosthesis / EHR records
Expert Systems	Knowledge-based engineering decision support (Tan *et al.*, 2016; Salem *et al.*, 2021)	Brittle, high maintenance	Encoding aftercare guidelines, limited adaptability
Knowledge Graphs	Semantic integration in manufacturing (Buchgeher *et al.*, 2021; Wan *et al.*, 2024)	Weak reasoning unless formalised	Linking stakeholders, devices, outcomes; ontology-enhanced reasoning used in personalised healthcare learning (Michalowski *et al.*, 2021)
Machine Learning	Optimisation, predictive maintenance (Burkart and Huber, 2021)	Black box, low explainability	Predict gait anomalies, ulcer risk
Ontologies	PSS ontologies, engineering rationale capture	Development effort, expertise required	Captures device, clinical, service, and outcome-related knowledge; formal representational rigour emphasised in ontology theory (Mizoguchi and Borgo, 2025a)

As Table 2.5 makes clear, each approach contributes specific strengths, but most fall short when applied to dynamic and heterogeneous systems such as prosthesis life-cycles. In particular, approaches such as taxonomies and databases provide structure without adaptability, while machine learning offers predictive power without traceability. Ontologies, while demanding in their development, stand out as uniquely positioned to balance formal rigour, interoperability, and attention to downstream effects.

Most methods limited: ontologies balance rigour & adaptability

While Table 2.5 structures the strengths and limitations of each approach, their relative scope within the prosthesis life-cycle can be further clarified through Figure 2.4, which positions each representation method against specific phases of design, realisation, and use. Within these phases, activities such as fitting (in the realisation phase) and aftercare (in the use phase) illustrate where different methods are typically used.

Figure 2.4: mapping methods to life-cycle phases

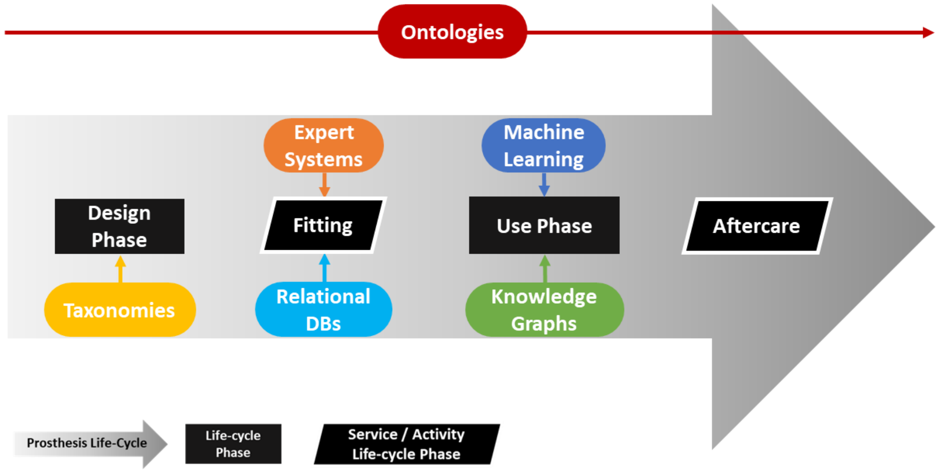


Figure 2.4: Position of knowledge representation methods in prosthesis life-cycle

Ontologies unify artefact, service, & outcome knowledge

As shown in Figure 2.4, approaches such as taxonomies, relational databases, and expert systems tend to provide value within isolated activities or phases, whereas machine learning offers predictive support without interpretability. Ontologies, in contrast, have been recognised for their potential to act as unifying frameworks by enabling formal representation, interoperability, and reasoning across domains (Kitamura and Mizoguchi, 2003; Cocco *et al.*, 2024) . While existing applications typically address specific aspects, such as artefact structure, service processes, or clinical pathways, their formal rigour positions them as uniquely suited to span the prosthesis life-cycle and integrate artefact, service, and outcome-related knowledge across stakeholders.

2.3 In-Depth Literature Analysis

Shared integration concern, but partial solutions

The three thematic domains reviewed above, Product–Service Systems (PSS) in engineering design, prosthesis and aftercare approaches, and knowledge representation methods, share a common concern with integration across boundaries. Yet each originates from a distinct disciplinary foundation, which explains both their complementary insights and their persistent blind spots. Synthesising them highlights how existing research offers only partial solutions to the prosthesis life-cycle problem, while also exposing unresolved tensions that provide the basis for this thesis.

PSS: outcomes, cost, servitisation; prosthesis use underexplored

PSS literature emphasises the inseparability of products and services, advancing typologies, cost models, and servitisation frameworks that foreground outcomes rather than artefacts. This body of work provides clear principles for shifting responsibility, aligning incentives, and embedding service thinking within design processes. Its application to prosthesis contexts promises to move delivery away from episodic delivery and towards long-term mobility outcomes, downtime reduction, and adaptive service packages. However, while industrial and healthcare case studies demonstrate feasibility, translation into prosthesis aftercare remains fragmentary. Most studies stop short of engaging with the lived complexity of prosthesis use, the iterative adjustments, emotional dimensions, and multi-stakeholder negotiations, or of embedding PSS logic directly within rehabilitation and clinical care.

Aftercare: clinical & organisational focus; lacks design formalisation

By contrast, prosthesis and aftercare literature is grounded in clinical, organisational, and human-centred concerns. Research highlights the centrality of rehabilitation pathways, user satisfaction, residual limb health, and organisational co-ordination, all of which critically influence device success. Systematic reviews confirm the absence of harmonised outcome measures and the variability of service quality across settings, from high-income hospitals to resource-constrained clinics. Attempts to systematise practice through WHO standards or consensus frameworks (e.g. COMPASS, PI-COS) remain under-adopted, resulting in fragmented evidence and weak feedback loops into design. This literature captures the real-world service dimension missing from engineering-oriented PSS research, but it rarely articulates its findings in terms of designable structures, transfer methods, or formalised models.

Knowledge methods compared; ontologies uniquely unify

Knowledge representation approaches offer precisely those structuring capacities. Taxonomies and databases provide stable classification and traceability, yet lack adaptability. Expert systems encode rules but struggle with diversity and change. Knowledge graphs afford integration but limited reasoning. Machine learning enables prediction but not explanation. Ontologies emerge from this comparison as the only approach capable of combining semantic rigour with reasoning support, thus offering the potential to unify artefact, service, and outcome-related knowledge. Nevertheless, their application in prosthesis contexts remains nascent. Existing ontologies in engineering and healthcare have typically been developed for isolated purposes, such as capturing functional structures, modelling clinical pathways, or supporting education, without spanning the full device–service–stakeholder network that defines prosthesis life-cycles.

Venn: overlaps exist, but central integration gap

The overlaps and persistent gaps between these three domains can be usefully illustrated through a Venn representation. Each contributes distinct strengths: PSS highlights outcome orientation and risk transfer, aftercare research foregrounds clinical pathways and service standards, and knowledge representation offers structuring methods ranging from taxonomies to ontologies. Yet when combined, they reveal areas of partial overlap and a central absence of integration across the prosthesis life-cycle. The overlaps and persistent gaps between these domains are summarised in Figure 2.5.

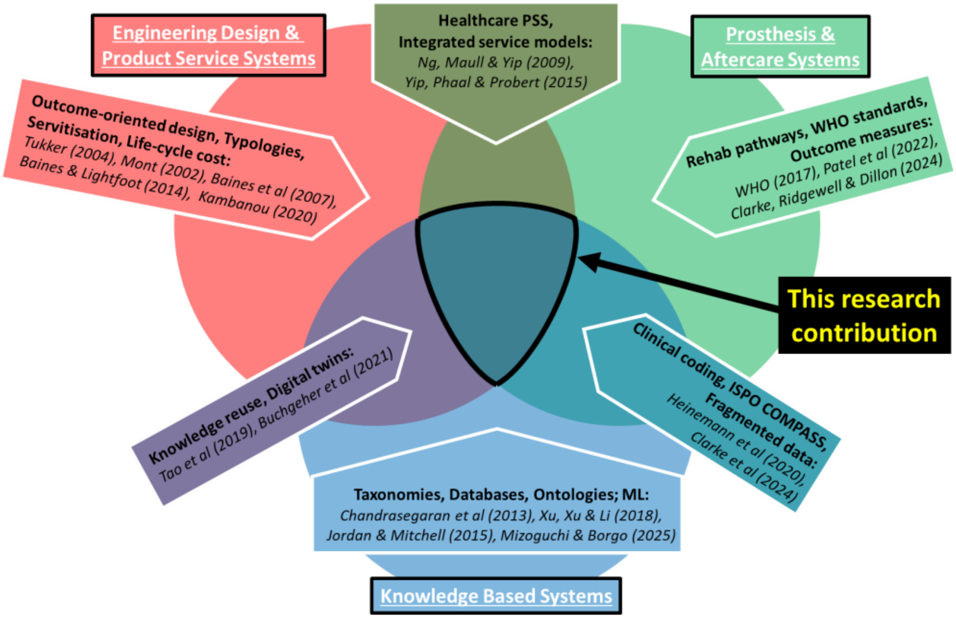


Figure 2.5: Overlap of thematic domains showing complementary insights and the central research gap: the absence of an integrated prosthesis life-cycle framework

Convergence gap: need for unified prosthesis framework

As shown in Figure 2.5, PSS and healthcare research intersect where service models are embedded into care delivery, but these remain conceptually rather than operationally aligned. Knowledge representation overlaps with PSS through digital twin applications and with aftercare through clinical coding systems, but both intersections remain fragmented. The central space, currently unaddressed in the literature, corresponds to the as-yet unaddressed need for an integrated prosthesis life-cycle framework that is capable of unifying artefact, service, and outcome-related knowledge across stakeholders. This research gap frames the motivation for the framework developed in subsequent chapters.

PSS integration perspective

Taken together, these three domains display a complementary but incomplete perspective: PSS provides the logic of integration, aftercare research reveals the clinical and organisational realities, and knowledge representation approaches offer the structuring methods through which such integration might be achieved. Yet no existing work demonstrates how these strands might be brought together into a single framework capable of capturing heterogeneous knowledge, supporting adaptive reasoning, and sustaining stakeholder co-ordination across the entire prosthesis life-cycle. This convergence challenge defines the central theoretical gap. In the next chapter, stakeholder perspectives are examined to further contextualise and validate this gap, before a framework is proposed in later chapters to address it.

2.4 Chapter Summary

Three domains: insights persistent, integration missing

This review has characterised three interrelated domains: Product–Service Systems, prosthesis and aftercare approaches, and knowledge representation methods. Each provides critical insights but also displays limitations when considered in isolation. PSS contributes principles of integration and outcome orientation, but its application to prosthesis contexts remains fragmented. Aftercare literature highlights the realities of clinical pathways, service variability, and organisational challenges, yet lacks systematic translation into designable models. Knowledge representation methods provide structuring tools but often fall short of unifying heterogeneous knowledge across artefacts, services, and outcomes. Taken together, these gaps reveal the absence of a cohesive framework that can bridge technical, clinical, and organisational perspectives across the prosthesis life-cycle.

Next: stakeholder perspectives to ground gaps

Chapter 3 complements this theoretical characterisation with stakeholder perspectives, ensuring that the identified gaps are grounded in the lived experiences and practical challenges of those directly involved in prosthesis delivery and use.

3

3 Stakeholder Issues and Systemic Inefficiencies in Prosthesis Development and Aftercare

Persistent prosthesis challenges despite progress

The development, management, and utilisation of prosthetic devices present a complex interplay of technical, emotional, and financial challenges that impact amputees and stakeholders across the prosthesis life-cycle (Turner, Belsi and McGregor, 2021; Alessa *et al.*, 2022). While advancements in prosthetic technology have improved functionality and user experience (Thibaut *et al.*, 2022; Lathouwers *et al.*, 2023), the field continues to grapple with unresolved issues such as delayed access, misalignment, lack of customisation options, and the high cost of advanced devices (Miller *et al.*, 2020; Varsavas *et al.*, 2022). These challenges are compounded by the evolving needs of amputees, for example, physical changes such as stump ulcers, wear-related prosthetic failures, or changes in mobility, which call for timely and effective interventions. Existing prosthesis development approaches often prioritise isolated aspects of prosthesis development (such as component design or socket fit), overlooking the broader interactions between stakeholders (amputees, prosthetists and manufacturers), devices (such as sockets, knee and ankle-foot sub-systems), and processes (such as diagnostic fitting, follow-up consultations, and maintenance). This fragmentation hinders prosthetists' ability to make informed decisions during design and reduces capacity to anticipate and respond to amputees' evolving needs. Consequently, there is a strong need to define the research problem clearly, by identifying gaps in current practice (synthesised in Section 3.5). The rationale for the proposed framework is developed in Chapter 4.

Evolving amputee needs require timely responses

Fragmented practices limit informed decision-making

Need to define research problem & framework rationale

3.1 Research Questions and Boundaries

Need to address dynamic prosthesis requirements

The scientific gaps in Chapter 2 highlights the need for enhancing the overall prosthesis development service by systematically addressing the dynamic requirements during the design and use phases of the prosthesis to cater for amputee evolving needs.

Research questions derived from hypothesis

From the hypothesis (Chapter 1 section 1.3), a series of Research Questions (RQs) were formulated. The research carried out will address the hypothesis effectively and comprehensively. The RQs are as follows:

Seven research questions guiding the study

- RQ1 - What are the activities that are involved in developing a prosthetic device?
- RQ2 - Who is involved in the different prosthesis life-cycle phases, and what tools, methods and /or systems are used?
- RQ3 - Which activities and/or systems in the prosthesis life-cycle phases drive high cost, poor quality, long development cycles, or difficulty adapting to amputees’ evolving needs?
- RQ4 - What specifications should a Product Service System (PSS) approach have to result in improved time efficiency, cost efficiency, functionality, user comfort, emotional well-being and aftercare?
- RQ5 - What elements should such a PSS approach framework involve?
- RQ6 - Is the proposed PSS framework applicable to all ranges of prosthesis?
- RQ7- How can the proposed ontology-based service system framework be evaluated to assess its effectiveness, applicability and scalability?

To ensure the research remains focused, feasible, and aligned with the objectives of this PhD research, a set of well-defined boundaries has been established:

Boundary on lower-limb prosthesis

1. *Boundary of Prosthetic Devices* - The research is centred on lower-limb prosthetic devices, which represent a significant and complex domain of both prosthesis development and use. This boundary aligns with the need to

address functionality, user comfort, and adaptability in devices where dynamic performance is critical. Upper-limb prosthetics and other assistive technologies are excluded to allow for a concentrated investigation of the targeted domain.

Stakeholder scope & engagement defined

2. *Stakeholder Engagement* - The research initially focused on primary stakeholders directly engaged during data collection, namely prosthetists, amputees and their family members, as they play pivotal roles throughout the prosthesis life-cycle. As the research progressed, two additional groups were recognised as essential: physiotherapists, whose role in rehabilitation and aftercare was highlighted through consultation with senior clinical experts and literature evidence; engineers, whose perspectives became integral during the iterative refinement of the research solution and framework design. Although these groups were not directly interviewed in the early stages, their contributions are incorporated in Chapter 4 to ensure the framework reflects the full interdisciplinary nature of prosthesis development and aftercare services.

   Prosthesis manufacturers are also fundamental stakeholders; however, direct engagement with them was not possible within the scope of this research. Instead, manufacturer-related challenges (such as sub-system availability and delivery times) were captured through literature analysis and through reports by prosthetists and amputees, who experience the downstream effects of manufacturing constraints. Secondary stakeholders, such as funding agencies or government bodies, are excluded.

Priority on design & use

3. *Prosthesis Life-Cycle Phases* – This PhD research prioritises the design and use phases of the prosthesis life-cycle as these phases are most critical for addressing amputees' evolving needs in terms of functionality, cost, comfort, time, emotions and aftercare. While manufacturing processes for sub-systems (e.g. knees, ankles) are not deeply examined due to the absence of

direct manufacturer engagement, their influence is incorporated through evidence from the literature and stakeholder feedback.

Ontology scope limited to essential elements

4. *Ontological Development* - The development of the 'Prosthesis Life-Cycle Ontology' is confined to elements identified through literature analysis and stakeholder engagement as essential for representing requirements, supporting decision-making, and enabling system adaptability across the prosthesis life-cycle.

Evaluation through case studies

5. *Case Studies and Evaluation* - The evaluation of the framework is conducted through representative case studies focusing on lower-limb prosthetic devices. These case studies are selected to demonstrate the applicability of the framework in realistic and diverse scenarios in relation to the hypothesis and research questions.

Geographical scope in established healthcare systems

6. *Geographical Context* - The research primarily addresses prosthesis development practices in regions with established healthcare systems that provide prosthetic devices. While the framework aims for generalisability, it acknowledges that some insights may not apply universally due to economic, cultural, or systemic variations in other regions.

Boundaries ensure research focus & feasibility

By adhering to these research boundaries, this research ensures a rigorous and focused approach to addressing the research hypothesis and questions within a PhD time frame.

3.2 Prosthetic Device Product Development Descriptive Model

Focus on AKP system to study challenges

To understand the challenges encountered by current prosthesis stakeholders, this PhD research focuses on an above-knee lower-limb prosthesis system, as outlined in the research boundary. These challenges concern the ability to provide amputees with a prosthesis that aligns with their functional, comfort, and lifestyle needs, while also ensuring that appropriate aftercare services are available to manage adjustments, maintenance, and long-term use. The lower-limb prosthesis (Figure 3.1) consists of several sub-systems, some of which are custom made to fit an individual amputee, while other systems are standard sub-systems.

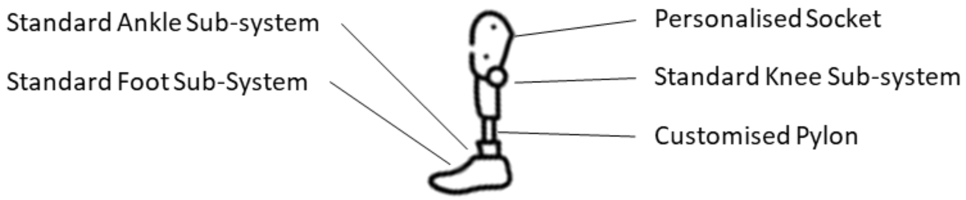


Figure 3.1: Prosthesis consisting of personalised, customised and standard systems

PDPDDM model depicts process & flow

Through insights from systematic reviews on prosthetic adaptation and therapeutic benefits of lower-limb prostheses (Olaya-Mira *et al.*, 2025), *the Prosthetic Device Product Development Descriptive Model* (PDPDDM) was developed. This model (Figure 3.2) depicts the processes by which an amputee receives their prosthesis. Information flows, such as information regarding amputee requirements, are indicated by pink arrows, while material flow (such as prosthesis sub-systems) is indicated by blue arrows. This model aided in understanding the various current processes and steps involved, as well as the key stakeholders and their role.

Design Phase: consultation & prosthesis design

Consultation with the prosthetist (Step 2) can occur as early as 6-8 weeks after the amputation, once surgical wounds have healed and swelling is reduced (O'Keeffe and Rout, 2019). In cases with slower healing, this may extend to 2-6 months until the residual limb stabilises (*Prosthetic FAQs for the New Amputee – Amputee Coalition*, 2021). Here the prosthetist and the amputee discuss the requirements, informed by recent findings on what matters most for amputees' prosthetic use and adaptation (Olaya-Mira *et al.*, 2025) and the options available to the amputee, establishing the Prosthesis *Design Requirements*. The prosthetist designs the prosthesis (Step 3) from the standard Above Knee Prosthesis (AKP) system parts that are available to come up with the *Design Solution* that best suit the amputee's needs. Collectively, Steps 2 and 3 form the Prosthesis '*Design Phase'*. The prosthetist then orders (Step 4) the required standard AKP sub-systems (e.g. knee and ankle). Having received the order (Step 5b1) for the standard AKP sub-systems, the manufacturer will source the required components either from existing stock, or if unavailable, proceed with manufacture (Step 5b2). The sub-systems are then assembled (Step 5b3) and dispatched (Step 5b4).

Realisation Phase: ordering, casting, assembly, fitting

Around the time of ordering the standard AKP sub-system parts, the prosthetist will also take the biometric measurements of the amputee's residual limb (referred to as the stump) and make a cast, from which the socket (the interface that attaches the prosthesis to the stump) can be produced (Step 5a in Figure 3.2). Once the standard AKP sub-system parts arrive, a process that can typically take between a few weeks to a few months (Miller *et al.*, 2020; Brauckmann *et al.*, 2024; Olaya-Mira *et al.*, 2025), the prosthetist will then assemble the standard AKP sub-system parts with the socket to form the whole prosthesis (Step 7). Following the assembly of the prosthesis, the amputee is called in for a Diagnostic Fitting (Step 8). This will be the first meeting where the amputee will wear and test the prosthesis. Here the amputee and the prosthetist will determine if the socket fit is good, and if the functionality and stability of the prosthesis meet the amputee's requirements. At this stage, minor adjustments can be made to either the socket, to adjust socket fit, or to the prosthesis, to adjust overall alignment. Collectively Steps 5a, 7 and 8 form the Prosthesis *'Realisation Phase'*. Once both the amputee and prosthetist are satisfied with the prosthesis, the amputee can use the prosthesis.

Follow-up visit determines adjustments

A '*Follow Up Visit'* (Step 9) is typically scheduled two to four weeks after the amputee has been using the prosthesis, as part of their rehabilitation process (*Prosthetics Process | Hanger Clinic*, 2024). During this visit, an evaluation process is carried out to see if any amendments to the prosthesis or the socket are required. Here (Step 10), the prosthetist and amputee must determine: a) Does the prosthesis need adjustment? If yes, then it requires adjustments and another diagnostic fitting; b) Does the prosthesis fit the amputee's needs? If no, then the prosthesis must be redesigned and the previous one disposed of; c) Does the prosthesis fit the amputee's needs, and can it be used? If yes, then the amputee can continue using the prosthesis.

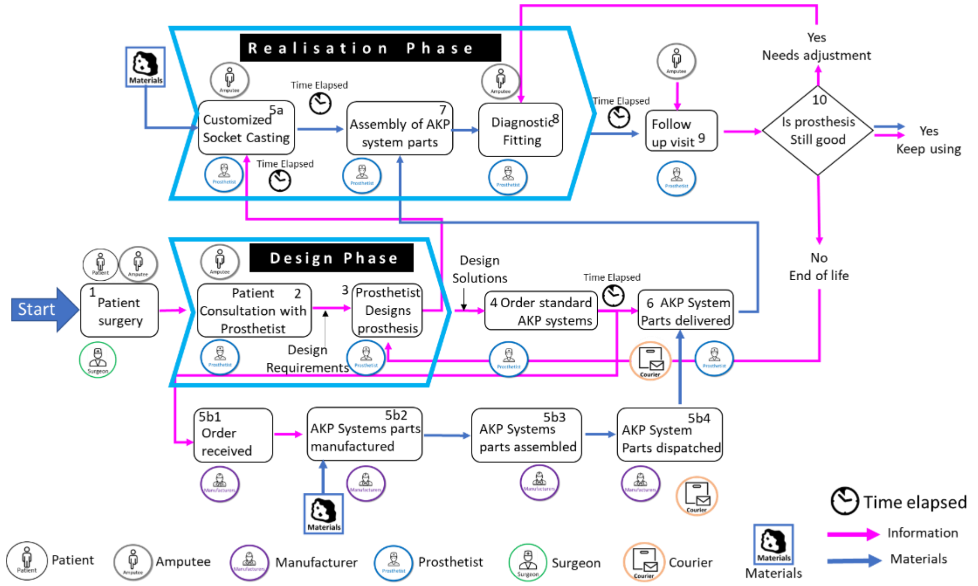


Figure 3.2: Prosthetic Device Product Development Descriptive Model

Average prosthesis lifespan approximately 5 years

During its life-cycle, the prosthesis is utilised by the amputee for a period that typically ranges from several months to several years, with an average lifespan of approximately five years (Wanamaker, Andridge and Chaudhari, 2017; *What to consider when it's time for a new prosthetic knee*, 2024). The variability in prosthesis lifespan arises from factors such as wear and tear, physical damage, significant discomfort experienced by the amputee, or the need for replacement due to physical changes, such as growth.

Follow-ups attempts to address issues

Throughout this life-cycle, as depicted in Figure 3.3, the amputee undergoes routine follow-up consultations to assess the continued suitability of the prosthesis. These evaluations aim to ensure the device aligns with the amputee's needs. In cases where issues arise, such as mechanical failures, discomfort, or misalignment, additional follow-up appointments are scheduled to facilitate necessary adjustments. Minor modifications typically enable the amputee to resume using the prosthesis without disruption. However, major alterations may require the amputee to engage in physiotherapy to adapt to the changes and regain proficiency in using the modified prosthesis.

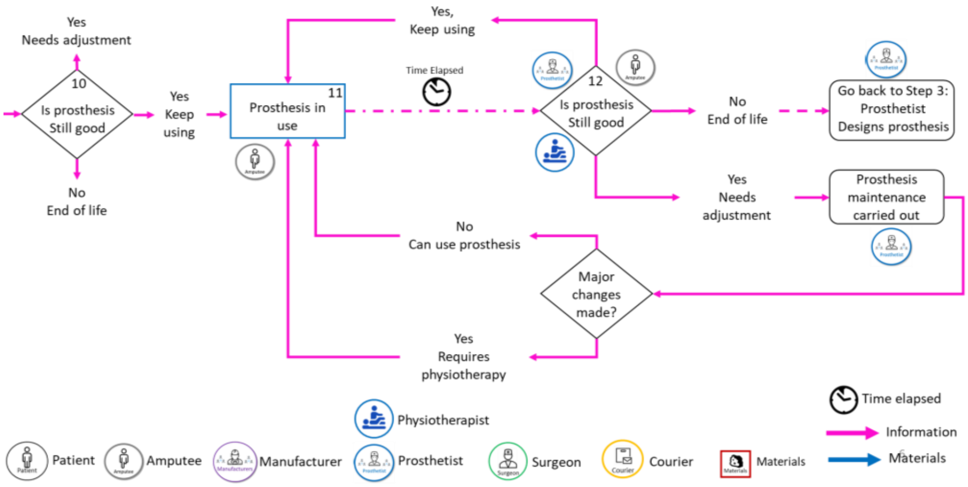


Figure 3.3: Process and stakeholders involved in maintaining a prosthesis

Figures show multi-stakeholder roles across life-cycles

The processes depicted in Figures 3.2 and 3.3 highlight the involvement of multiple interconnected procedures and different stakeholders throughout the prosthesis life-cycle. Key stakeholders identified include the amputee, the prosthetist, and the prosthesis manufacturer, each of whom plays a critical role in ensuring the functionality, suitability, and longevity of the prosthetic device. Figure 3.2 outlines the sequence of activities following amputation surgery, culminating in the acquisition of a new prosthesis, while Figure 3.3 provides a graphical representation of the stages and considerations associated with the prosthesis's ownership and usage throughout its operational lifespan.

3.3 Stakeholder Interviews

Stakeholder insight gathered through informal (online) & formal (in-person) analysis

This section presents the findings from interviews and surveys conducted with key stakeholders. An informal stakeholder analysis was performed using social media platforms, followed by online interviews and discussions to gather preliminary insights, while a formal stakeholder analysis was conducted through in-person interviews and discussions to obtain a more structured and comprehensive understanding of stakeholder perspectives.

3.3.1 Informal Stakeholder Interviews

Informal interviews via social media enabled access to diverse amputee experiences

To expand the scope and inclusivity of this research, international social media groups dedicated to individuals with limb amputations (such as a Facebook group 'AMPUTEES' consisting of around 9.8k members) were utilised as platforms for informal interviews and discussions. In this context, "informal interviews" refer to conversational, unstructured interactions that allowed participants to share experiences and perspectives in their own terms, rather than following a predefined set of questions. This approach was selected as it enabled access to a diverse, international group of amputees that would otherwise have been inaccessible within the time and resource constraints of this PhD. While not intended to provide statistically representative data, these interactions yielded valuable experiential knowledge that complements the formal interviews described in Section 3.3.2.

Amputees shared evolving needs influencing prosthesis design and aftercare

Through these engagements, amputees were able to articulate the challenges they face, share personal insights, and propose potential solutions within a supportive online community where advice and assistance are routinely exchanged. The issues identified are particularly relevant to this research because they illustrate how evolving amputee needs influence prosthesis design, fitting, and aftercare, and thus highlight the types of experiential knowledge that must be systematically captured in order to support adaptive, service-oriented frameworks.

The key issues identified from these discussions include:

Residual limb size fluctuates daily, affecting socket fit.

- *Fluctuations in residual limb size:* The residual limb undergoes minor yet significant size variations throughout the day, directly impacting the fit and comfort of the prosthetic socket and the alignment of the prosthesis. For instance, residual limb swelling is more pronounced upon waking due to fluid retention, necessitating the use of a thinner inner liner, such as a single-ply sock. As the day progresses and activity levels increase, swelling typically subsides, resulting in a looser socket fit. This necessitates frequent adjustments in liner thickness throughout the day until the residual limb size stabilises. Such fluctuations create ongoing demands for adaptation in prosthesis use and aftercare, reinforcing the importance of systems that can anticipate and respond to dynamic physical changes.

Sensory variation impacts comfort and usability

- *Variations in sensation levels:* The type of amputation surgery and the extent of associated nerve damage significantly influence sensory perception in the residual limb. While some amputees retain varying degrees of sensation around the residual limb, others may experience complete sensory loss. These differences affect the interaction between the residual limb and the prosthetic socket, with implications for comfort, fit, and overall usability. In practice, such variation requires prosthesis design and aftercare strategies that are tailored to an individual's sensory profile, underscoring the need for frameworks that capture and formalise these distinctions.

Phantom limb pain complicates fit and emotional well-being

- *Phantom limb pain and sensory misperceptions:* Many amputees report experiencing phantom limb pain, characterised by pain, itching, or other sensations perceived in the absent limb. The intensity and localisation of these sensations vary widely among individuals. In some cases, phantom sensations render specific areas of the residual limb highly sensitive, complicating the achievement of a comfortable and stable socket fit. These issues affect both the functional performance of the prosthesis and the amputee's emotional well-being, dimensions which this research explicitly evaluates.

Support networks and suitable technology are critical for resilience

Addressing these challenges requires a comprehensive approach that includes physical rehabilitation, psychological support, access to appropriate prosthetic technology, and effective social support networks. Recent work by (Ghailani *et al.*, 2025) emphasizes that psychological and social support significantly enhance resilience among amputees, while (Rodrigues, Carvalho and Pinto, 2025) highlights that caregivers and prosthesis users both cite support networks and access to suitable technology as key unmet needs. These informal interview findings therefore provide early evidence of the value of capturing lived experiences systematically and integrating them into structured decision-making processes, an aspect developed further in later chapters of this thesis.

Informal insights complement formal data, ensuring lived experience is included

While exploratory in nature, these informal interviews were deliberately employed as a complementary method to formal data collection, ensuring that lived experiences and everyday challenges of amputees were not overlooked in defining the research problem.

3.3.2 Formal Stakeholder Interviews

Structured questionnaires ensured systematic, rigorous data collection

To gain deeper insights into the challenges experienced by amputees and prosthetists, tailored questionnaires were designed for both prosthetist and amputee stakeholders. In contrast to the informal interviews described in Section 3.3.1, which were exploratory and unstructured in nature, the formal interviews employed here were systematically designed using tailored questionnaires. These instruments were structured to elicit comparable responses across participants, thereby allowing for the systematic identification of common challenges, user needs, and stakeholder perspectives. Whereas informal interviews provided breadth and diversity of lived experience, the formal interviews were intended to provide depth and consistency, enabling triangulation of findings and ensuring greater methodological rigour. The questionnaires are provided in Appendices 1. Key concerns raised by amputees and prosthetists included:

Socket comfort repeatedly compromised by residual limb fluctuations

- *Achieving socket comfort:* Amputees underscored the importance of socket comfort, which is frequently compromised due to fluctuations in the size and shape of the residual limb. This issue often necessitates regular socket adjustments, a process further complicated for individuals prone to sores or abrasions.

Heavy prostheses cause discomfort and inefficient movement

- *Prosthesis weight and associated discomfort:* Many amputees reported that the weight of their prosthetic device contributes to discomfort, requiring excessive effort and exaggerated movements to achieve proper positioning.

Alignment process is complex, time-consuming, and fatiguing

- *Time-intensive alignment process:* The process of aligning the socket and prosthesis was highlighted as a significant challenge due to its complexity and the time required. This process, which heavily depends on the expertise of prosthetists and technical teams, often results in prolonged sessions that contribute to patient fatigue.

Trust-building period crucial for prosthesis acceptance and safe use

- *Trust and adaptation:* Amputees emphasised the importance of an adjustment period to develop familiarity and trust with their prosthetic device. This trust is crucial for ensuring confidence in using the prosthesis. A lack of trust can lead to apprehension, increasing the likelihood of falls and the potential rejection of the device.

Emotional well-being affects acceptance, mobility, and social confidence

- *Emotional well-being:* Amputees consistently reported that their emotional and psychosocial needs were insufficiently addressed within current prosthesis delivery and aftercare practices. Reduced mobility was cited as a factor limiting social participation and independence, often leading to feelings of isolation and frustration. In addition, concerns about appearance and changes in body image were found to negatively influence self-esteem and confidence in social interactions. These findings underscore the importance of addressing emotional well-being as a central dimension of prosthesis acceptance and long-term use, aligning with recent evidence that links psychosocial adjustment directly to rehabilitation outcomes (Nugent *et al.*, 2025; Rodrigues, Carvalho and Pinto, 2025).

Communication gaps hinder understanding, collaboration, and continuity of care.

- *Communication challenges:* Both amputees and prosthetists identified gaps in communication gaps as a significant concern. Prosthetists reported difficulty in ensuring that amputees understood their rehabilitation plans and in liaising effectively with other healthcare professionals, such as physiotherapists. Amputees, on the other hand, described challenges in articulating their needs and concerns to healthcare providers, often leaving issues unaddressed. Similarly, healthcare professionals highlighted difficulties in obtaining comprehensive patient histories, which impeded the delivery of optimal care.

3.4 Detailed Stakeholder Issues

Stakeholder challenges highlight systemic inefficiencies in prosthesis life-cycle

The successful development, delivery, and utilisation of prosthetic devices rely on the collaborative efforts of multiple stakeholders (such as amputees and prosthetist), each of whom encounters distinct challenges throughout the prosthesis life-cycle. From amputees dealing with emotional acceptance and evolving physical needs, to prosthetists managing labour-intensive processes and limited budgets, balancing high end prosthesis with cost constraints, the issues are diverse and interconnected. These challenges are compounded by the lack of adaptive methods to address emergent problems, such as prosthetic wear or evolving user requirements. Therefore, this section provides a detailed examination of these stakeholder-specific issues, highlighting systemic inefficiencies, defined here as recurring process-level shortcomings such as fragmented communication, lack of knowledge integration, duplicated or poorly co-ordinated tasks, and delays in decision-making, that collectively hinder optimal outcomes in prosthesis delivery and aftercare.

Clinician evidence confirms socket fit, service disparity, and resource limits as key barriers.

(Turner, Belsi and McGregor, 2021) provide clinician-perspective evidence showing that issues like ill-fitting sockets, service disparity (wait times, resource constraints), and limitations in practice are significant barriers to effective prosthetic rehabilitation.

3.4.1 Amputee Related Issues

Amputee stakeholder issues

This section examines the key challenges faced by amputees, focusing on three primary areas: the high cost of prosthetic devices, prolonged delivery periods, and the emotional impact associated with limb loss and prosthetic use.

3.4.1.1 High Prosthesis Cost

High variability in prosthesis costs linked to functionality and amputee factors

The first issue encountered by amputees is the cost of the prosthetic device, where low-end a lower limb prosthesis can cost anywhere in the range of 5,000USD to 50,000USD upwards and an upper limb prosthesis can cost between 3,000 USD to 30,000 USD upwards (*Prosthetics Costs: The High Price of Prosthetic Limbs*, 2025). The difference in price directly affects the Degrees of Freedom (DoF), functionality and mobility offered by the prosthetic device can. A low end, low priced prosthetic device would offer the amputee limited functionality, DoF and mobility, while a high end, high-cost device would offer significantly more functionality, DoF and mobility. The variation in cost of these devices comes from the quality of the materials, how technologically advanced they are, the number of moving parts, the amount of maintenance needed, and wear and tear (*Prosthetics Costs: The High Price of Prosthetic Limbs*, 2025). The type of prosthesis needed also varies according to the amputee's condition and biological factors such as age, height, weight, muscle strength and their desired level of mobility. Each of these factors contribute to the cost of the prosthetic device. Some examples, taken from (*Prosthetics Costs: The High Price of Prosthetic Limbs*, 2025), for the cost of these devices are as follows:

- 5,000 USD - 7,000 USD for a lower limb prosthetic that allows the amputee to walk on flat ground;
- 10,000 USD for a lower limb prosthetic that allows the amputee to walk on stairs and bumpy ground;
- Up to 15,000 USD for a device that allows the amputee to walk and run as well as a non-amputee;
- 15,000 USD to 20,000 USD for a device with special hydraulic or mechanical systems that allow for movement control;
- 20,000 USD for a computer assisted prosthetic leg;
- 50,000 USD - 70,000 USD upwards for and Otto-Bock C-Leg computerised prosthetic leg.

Figure 3.4 depicts a graphical example of the cost of the prosthetic leg in relation to DoF and functionality.

Figure 3.4: Graph shows examples of prosthesis on a plot of DoF and functionality against cost

Lifetime replacements, maintenance, and access disparities in developing countries

A prosthetic device typically requires replacement several times over an amputee's lifetime and undergoes multiple adjustments and maintenance during its functional lifespan. These factors substantially increase the overall cost (*Cost of a Prosthetic Leg - 2023 Healthcare Costs*, 2024). Consequently, only 5% of the 40 million amputees in developing countries have access to prosthetic devices(*3D printing prosthetics: Meet the real revolution*, 2024). Furthermore, higher-cost prostheses often entail increased maintenance and warranty expenses. For example, a C-Leg, priced at €18,616, requires an annual warranty extension costing €1,440. In contrast, a mechanical prosthesis priced at €3,000 without warranty incurs an average annual maintenance cost of €600 (Amsan, Nasution and Ramlee, 2019). Another significant contributor to the cost of prosthetic devices is the incorporation of *smart features* (Da Silva Júnior, De Oliveira and Bonvent, 2015). These features range from motorised control systems enabling knee flexion and extension on command, to sensors embedded in the foot sole that provide tactile feedback. While such functionalities enhance user experience and expand prosthesis capabilities, they considerably elevate costs. For instance, the Otto Bock C-Leg, mentioned above, exemplifies the high cost associated with advanced features. Consequently, lower-end prostheses are often designed without smart technologies to remain affordable

Advanced smart features drive up cost

3D-printed alternatives offer affordability but limited durability

(Da Silva Júnior, De Oliveira and Bonvent, 2015). Efforts to address these cost barriers have prompted research into alternative, cost-effective solutions, such as 3D printing. 3D-printed prostheses are gaining popularity due to their ability to offer customised designs at a lower cost of under 3,500 Euro (Jagyasi, 2020). However, this approach comes with limitations. The prosthetic devices produced are generally more simplistic, with reduced degrees of freedom and mobility. Moreover, the limited range of materials suitable for 3D printing results in devices that are less durable compared to traditionally manufactured prostheses.

3.4.1.2 Delivery Period

Lengthy fitting process (days–39 weeks) due to complexity and multi-stakeholder co-ordination

Another significant challenge faced by amputees is the time required between the initial measurement and the final fitting of a prosthesis. This process can range from a few days to approximately 39 weeks (Wanamaker, Andridge and Chaudhari, 2017, 2020). The lengthy timeline is attributed to the complexity of the procedure, which involves multiple stages and the co-ordination of various stakeholders at different phases. The nature of this process is illustrated in Figure 3.2.

3.4.1.3 Emotional Impact

Emotional acceptance affects identity, body image, & mental health

Emotional acceptance of a prosthesis represents a critical challenge for many amputees. The loss of a lower limb profoundly affects an individual's psychological well-being, as it is often perceived as a loss of identity. Without acceptance of the prosthesis, amputees may experience social discomfort and heightened body image anxiety, potentially leading to activity restrictions and depression. Therefore, it is essential for the prosthesis to evoke positive emotions, facilitating acceptance and integration into the amputee's life (Horgan and MacLachlan, 2004; Roșca *et al.*, 2021; Calabrese *et al.*, 2023; Kumar *et al.*, 2023).

Emotionally appealing prosthesis often limited to high-cost devices

This challenge is further exacerbated by the fact that emotionally appealing prostheses are typically limited to higher-cost devices. Figure 3.5 illustrates this issue, presenting a graph that compares various prosthetic devices based on their cost and the extent to which they are perceived as emotionally pleasing.

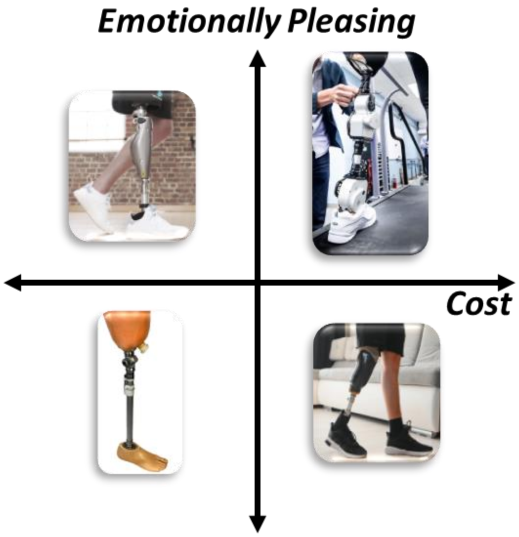


Figure 3.5: Examples of prosthesis on a plot of DoF and functionality against cost

3.4.1.4 Prosthesis Misalignment

Misalignment reduces comfort, stability, and user confidence

Misalignment is a critical issue that, if unresolved, can lead to significant discomfort for the amputee and a reduction in overall stability. This instability can cause amputees to feel unsafe while using their prosthesis, leading to hesitation in its use and extended periods of non-usage. Consequently, ensuring proper alignment of the prosthesis is essential to enhance comfort, safety, and user confidence.

3.4.1.5 Amputee Problem Conclusion

Summary of amputee challenges

The key problems encountered by amputees can be summarised by the following:

i. The cost of the prosthesis is too high, forcing patients to go for a less expensive, low-end devices;
ii. Smart features are adding to the device functionality at the cost of increasing device price;
iii. Prosthetic devices do not cater for the emotional needs of the amputee;
iv. Long delivery period;
v. Misalignment is a core problem that causes instability.

3.4.2 Prosthetist Related Issues

Overview of prosthetist challenges: limited customisation, labour-intensive socket fabrication, delays in AKP parts, funding constraints

This section addresses the challenges encountered by prosthetists, focusing on three primary issues: the limited customisation options for Above-Knee Prosthesis (AKP) system components, the lengthy and labour-intensive process of socket casting and manufacturing, and the extended wait times for the delivery of AKP system components.

3.4.2.1 Insufficient Variety of AKP Standard Parts Hindering Individual Adaptation

Socket customisation focuses on anatomy and limited aesthetics; AKP mechanical parts offer minimal adjustability

In terms of lower limb prosthetics, there is a significant emphasis on the *socket* and its customisation. This is due to the unique anatomical characteristics of each amputation, necessitating that each socket be meticulously designed to fit the individual patient. This process is referred to as anatomical customisation (*Customized Comfortable Sockets*, 2025). In addition to functional customisation, some level of aesthetic customisation may also be available, allowing patients to select the appearance of their socket. The prosthetist's role is then to prescribe the most appropriate prosthesis for the amputee, typically by selecting standard sub-system parts from an established manufacturer. However, there is generally limited customisation of the mechanical components of Above-Knee Prosthesis (AKP), with few adjustments made to these parts (Colombo *et al.*, 2010; Buzzi *et al.*, 2012; Varsavas *et al.*, 2022; Salgado Manrique and Cifuentes-De la Portilla, 2025).

3.4.2.2 Socket Casting and Manufacturing

Socket fabrication is complex and time-consuming, requiring negative mould, positive mould, thermoplastic forming, and vacuum shaping

The process of fabricating the prosthetic socket is both complex and time-consuming, relying heavily on the expertise of the prosthetist. The first step in this process involves creating a cast of the residual limb, known as the negative mould. This cast is then used to generate a life-sized, anatomically accurate model of the stump, referred to as the positive mould. A thermoplastic sheet is subsequently heated until it forms a bubble, which is then placed over the positive mould. Vacuum equipment is used to create negative pressure within the bubble, causing the thermoplastic to shrink and conform tightly to the positive mould. After the material cools, the final shape of the socket is formed (Blij, 2024). Figure 3.6 illustrates the critical stages of this process, including the use of the thermoplastic sheet, the vacuum application, and the shrink-wrapping procedure that shapes the socket.

Figure 3.6: Images show part of the process required in making a patient's socket

3.4.2.3 Delivery Period for the AKP Standard Sub-System Parts

Delays in AKP part delivery due to manufacturing and assembly timelines, ranging from weeks to months.

After placing an order for the AKP standard sub-system components, prosthetists must endure a significant waiting period before the delivery of the parts. This delay is primarily due to the extended time required for processing the order, manufacturing the AKP components, assembling the parts, and finally dispatching the system. The steps involved in this process are outlined in Figure 3.2 (Steps 5b1-5b4). Depending on the location of the order, this process can take anywhere from 4 weeks to several months (*What to Expect: The Months After Amputation Surgery*, no date).

3.4.2.4 Funding Issues

Funding limitations force prosthetists to choose affordable but less optimal prosthesis options.

Funding schemes for prosthetics vary significantly across countries, and in some cases, available funding is limited. When funding is constrained, prosthetists are required to work within a finite budget to provide prostheses to amputees. As a result, prosthetists are often compelled to select more affordable, yet less optimal, options for the amputee, which may not offer the same level of functionality or benefit as higher-cost alternatives.

3.4.2.5 Prosthetists Problems Conclusions

Key issues: i) limited AKP customisation, ii) labour-intensive socket casting, iii) long AKP delivery times, iv) funding constraints

The key issues faced by manufacturers can be summarised as follows:

i. Lack of customisation for AKP system parts;
ii. Socket casting and manufacturing is a long, labour-intensive process;
iii. Long waiting time for AKP system parts to arrive;
iv. Funding issues.

3.4.3 Manufacturer Related Issues

Manufacturer challenges included indirectly via literature and stakeholder reports

This section discloses the challenges and issues faced by manufacturers, who are responsible for the design and assembly of Above-Knee Prostheses (AKPs). While direct engagement with manufacturers was not feasible within the scope of this research, stated in boundary conditions 2 and 3, their perspectives were captured indirectly through two complementary sources: i) insights reported in the literature, which highlight systemic issues related to cost, standardisation, and production cycles; and ii) accounts from prosthetists and amputees, who experience the downstream effects of manufacturing constraints, such as delays in component availability, limited part variety, and the high cost of advanced sub-systems, across the prosthesis life-cycle. By triangulating these sources, the research is able to incorporate manufacturer-related issues into the broader analysis of stakeholder challenges, even without direct manufacturer interviews.

3.4.3.1 Limited Multi-X Design Approaches

Historic functionality focus, neglected aesthetics and emotional acceptance

Historically, prosthetic device manufacturers have prioritised functionality, often at the expense of broader design dimensions such as aesthetics, cultural and emotional acceptance (Gaver, 2009; Sansoni *et al.*, 2015; Triberti *et al.*, 2017; Hartson and Pyla, 2019; Lee *et al.*, 2024; Ramstrand *et al.*, 2024). These studies also show that long-term prosthesis acceptance depends not only on functional performance but also on the device's ability to elicit positive emotional responses and support the user's self-image. (Hartson and Pyla, 2019) conceptualise this across three levels: i) *Visceral* *processing*, concerned with immediate appeal and attractiveness; ii) *Behavioural processing*, related to usability, comfort, and day-to-day performance; and iii) *Reflective processing*, tied to identity, satisfaction, and personal meaning.

Emotional design limited to high-end devices; "Uncanny Valley" illustrated in Figure 3.7

Designing for these multi-dimensional needs requires significant investment and resources, which manufacturers typically apply only to high-end prosthetic devices. Lower-cost devices, representing the majority of those available to amputees, tend to neglect emotional design, resulting in reduced acceptance and satisfaction. For example, (Sansoni *et al.*, 2015) demonstrated that prostheses with low human resemblance elicited minimal positive emotions, while devices with medium resemblance were more widely accepted. In contrast, prostheses with highly human-like features triggered negative reactions, reflecting the "Uncanny Valley" phenomenon illustrated in Figure 3.7.

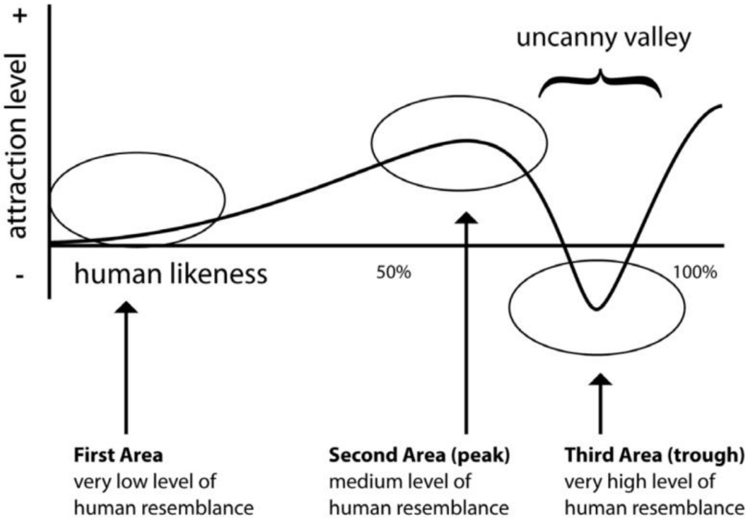


Figure 3.7: Human likeness against attraction level (Sansoni et al., 2015)

Narrow functionality-first model causes downstream challenges for prosthetists, amputees, and health system

From a systemic perspective, this disparity reflects not only technological or cost limitations, but also a lack of structured interaction between manufacturers, amputees, and service providers. Without methods to integrate user experience, cultural considerations, and emotional factors into the design process, manufacturers continue to operate with a narrow functionality-first model. This creates downstream challenges for prosthetists (who must manage dissatisfaction or rejection of devices), for amputees (who may struggle with identity, body image, or stigma), and for healthcare systems (where abandonment of devices leads to wasted resources). Addressing this issue therefore requires not just better product design, but a service-oriented framework that links manufacturers into wider stakeholder knowledge flows

3.4.3.2 Challenges in Developing Low-Cost, High Quality AKPs

Technological advances improved quality and safety (e.g. microprocessor knees)

The primary objective of providing an amputee with a prosthetic device is to enhance their mobility and, consequently, their quality of life. Over recent decades, the quality of prosthetics has significantly improved, largely driven by technological advancements that must be rigorously applied and tested to ensure reliability and performance (Amsan, Nasution and Ramlee, 2019; Donnelley *et al.*, 2021). These innovations have enabled the development of high-quality prosthetic legs, including microprocessor-controlled knees such as the C-Leg, which adapt dynamically to the user’s gait and thereby reduce the risk of falls (Amsan, Nasution and Ramlee, 2019; *Ottobock | Microprocessor Knees: Trust, Move, Live.*, 2024). Such devices represent a major improvement in user safety and comfort, offering greater mobility and independence.

High costs restrict accessibility; lower-cost devices less adaptive, needing frequent adjustments.

However, these advanced prostheses remain prohibitively expensive for many amputees, limiting accessibility and creating inequities in delivery. As a result, less technologically sophisticated prosthetic legs are more widely produced at a lower cost. While more affordable, these devices typically require more frequent attention and adjustment to minimise risks such as misalignment or falls, as they are less adaptive to the user’s gait (Amsan, Nasution and Ramlee, 2019). The cost–quality trade-off therefore produces systemic tensions: prosthetists and healthcare providers must balance limited budgets with the need to supply devices that are safe, reliable, and acceptable to amputees, while amputees themselves often face constrained choices that do not fully meet their evolving functional or lifestyle needs.

Cost–quality tensions reflect systemic constraints beyond technology alone

From a systemic perspective, this challenge is not simply a technological limitation, but a reflection of broader service and market constraints. Manufacturers must operate within economic pressures that restrict their ability to deliver high-quality devices at scale, while healthcare systems and prosthetists absorb the downstream consequences in the form of higher maintenance demands, repeated adjustments, and lower user satisfaction. Amputees, in turn, experience increased prosthesis downtime, reduced confidence in device reliability, and potential disengagement from rehabilitation programmes. This highlights the importance of framing cost–quality tensions not solely as an issue of device engineering, but as a multi-stakeholder service problem that requires more effective integration of economic, clinical, and experiential knowledge across the prosthesis life-cycle.

3.4.3.3 Cultural and Social Barriers to Prosthetic Acceptance

Cultural stigma reduces acceptance of prostheses in some societies

In certain societies and cultural contexts, the use of prosthetic devices is still associated with stigma, which can hinder their acceptance and reduce their long-term use (Arabian *et al.*, 2016). The reasons for this lack of acceptance vary and include social background, cultural upbringing, limited awareness regarding the role of prostheses, or negative emotional responses to the device's appearance. (Arabian *et al.*, 2016) highlight that some participants rejected prosthetic devices for cultural or social reasons, while others cited aesthetic dissatisfaction. More recently, (von Grop and Adams, 2024) emphasised that emotional and social factors remain decisive in shaping amputees' willingness to use prosthetic devices.

Lack of engagement limits cultural adaptation and public awareness

From the perspective of manufacturers, cultural and social rejection presents a barrier to market uptake and widespread distribution of devices. However, when examined systemically, this issue extends beyond manufacturing into the broader service framework of prosthesis delivery. A lack of structured engagement between manufacturers, healthcare providers, and amputees' limits opportunities to address culturally specific expectations and to incorporate user feedback into device design. Furthermore, the absence of widespread public awareness campaigns or educational initiatives perpetuates stigma and restricts acceptance at a societal level.

The result is a multi-layered challenge: amputees in stigmatising contexts may be reluctant to use prostheses, manufacturers struggle to adapt products for diverse cultural settings, and healthcare providers face difficulties encouraging device uptake and long-term rehabilitation. This lack of cultural alignment and structured stakeholder engagement perpetuates limited acceptance and reduces the long-term impact of prosthetic delivery.

3.4.3.4 Lack of Interaction with Amputees

Lack of engagement limits cultural adaptation and public awareness

A recurring issue highlighted in both the literature and stakeholder accounts is the limited interaction between manufacturers and amputees. Unlike prosthetists and physiotherapists, who work directly with patients during fitting, rehabilitation, and aftercare, manufacturers typically operate at a distance from end users. This separation means that manufacturers rely on indirect feedback, such as sales trends, clinician reports, or warranty claims, rather than direct engagement with amputees' lived experiences and evolving needs.

Manufacturers rarely interact directly with amputees; feedback channels absent

From a systemic perspective, the problem is not merely that manufacturers "do not" interact with amputees, but that there are no structured feedback methods within the current service model to facilitate such exchanges. As a result, valuable knowledge about socket comfort, emotional acceptance, cultural considerations, and day-to-day device performance remains localised within the clinic or the amputee community, rarely flowing back into manufacturing and design processes.

Systemic inefficiency perpetuates generalised designs and amputee dissatisfaction

This lack of feedback integration perpetuates a cycle: manufacturers continue designing for a generalised population of amputees, prosthetists and healthcare providers shoulder the burden of adapting ill-suited devices, and amputees experience dissatisfaction or abandonment of their prostheses. The absence of feedback channels between clinical practice, end-user experience, and device production therefore represents a systemic inefficiency that undermines the effectiveness of prosthesis delivery across its life-cycle.

3.4.3.5 Manufacturer Problem Conclusion

Key issues:

In summary, manufacturers face a set of interconnected challenges that are shaped not only by technological and market constraints, but also by the absence of integrated feedback methods across the prosthesis service system. As evidenced in Sections 3.4.3.1–3.4.3.4, these challenges can be summarised as follows:

i) functionality focus over multi-dimensional design

i. A prevailing emphasis on functionality, with limited incorporation of multi-dimensional design considerations such as aesthetics, cultural acceptance, and emotional appeal (Gaver, 2009; Sansoni *et al.*, 2015; Triberti *et al.*, 2017; Hartson and Pyla, 2019; Lee *et al.*, 2024; Ramstrand *et al.*, 2024);

ii) cost, quality trade-offs

ii. Persistent cost–quality trade-offs, whereby advanced technologies (e.g. microprocessor knees) improve safety and comfort but remain inaccessible to many amputees due to high cost, while lower-cost devices demand frequent adjustment and compromise on long-term usability (Amsan, Nasution and Ramlee, 2019; Donnelley *et al.*, 2021; *Ottobock | Microprocessor Knees: Trust, Move, Live.*, 2024)

iii) cultural and social stigma

iii. Cultural and social stigma that reduce acceptance of prosthesis in some countries, with aesthetic and emotional factors further shaping uptake (Arabian *et al.*, 2016; von Grop and Adams, 2024);

iv) lack of feedback integration

iv. Limited opportunities for direct interaction with amputees, stemming from the absence of structured feedback channels in current service models. This results in design processes that rely on generalised assumptions rather than individual needs (Turner, Belsi and McGregor, 2021).

These issues highlight not merely technological limitations but systemic gaps in communication, feedback, cultural factors and integration across the prosthesis life-cycle, reinforcing the need for an ontology-based, service-oriented framework that connects manufacturers more effectively with other stakeholders.

3.5 Integration of Literature and Stakeholder Findings

Integration of literature (Ch.2) and stakeholder challenges (Ch.3) to frame research problem

Chapter 2 characterised three bodies of literature, Product–Service Systems (PSS), prosthesis and aftercare approaches, and knowledge representation methods, while Chapter 3 examined the lived challenges of stakeholders including amputees, prosthetists, and (indirectly) manufacturers. This section integrates these perspectives to highlight convergences, divergences, and systemic gaps that define the research problem.

Convergences: socket fit, alignment, residual limb management as core technical issues

Convergences: emotional acceptance and psychosocial factors validated by both literature and stakeholders

Both literature and stakeholder accounts emphasise the multifaceted nature of prosthesis success. Socket fit, alignment, and residual limb management emerge as core technical challenges, validated by both clinical studies (Klute *et al.*, 2011; Turner and McGregor, 2020) and stakeholder testimony. Likewise, the importance of emotional acceptance is consistently reinforced, with literature on emotional design (Sansoni, Wodehouse and Buis, 2014, 2015; Sansoni *et al.*, 2015; Triberti *et al.*, 2017) aligning closely with amputees' reports of stigma, self-image, and trust in the prosthesis. PSS literature further resonates with stakeholder calls for improved continuity of care, as both stress outcome orientation, decision traceability, and service integration across life-cycle phases.

Divergences: literature shows systemic potential, stakeholders report fragmented, episodic realities.

Divergences illustrate gap between theory and practice; need

A major divergence arises in the degree of systemic integration. The literature demonstrates the potential of PSS frameworks, knowledge-based approaches, and digital monitoring to structure adaptive service models. In contrast, stakeholders described fragmented, episodic processes: amputees endure delays, misalignments, and unmet psychosocial needs; prosthetists face labour-intensive manual processes, limited component variety, and constrained funding; manufacturers rarely interact directly with end-users. These divergences highlight the difficulty of translating theoretical advances into practical improvements in day-to-day prosthesis services. Importantly, they should not be seen as contradictions, but rather as evidence of the for bridging approaches

persistent gap between theory and practice, underscoring the need for approaches that bridge research insights with the lived realities of amputees and practitioners.

Table 3.1 makes convergence, divergence, and gaps explicit

To make the points of convergence, divergence, and systemic gaps explicit, Table 3.1 summarises how insights from the literature (Chapter 2) align with, and in some cases diverge from, the issues raised by stakeholders, highlighting the research gaps that this thesis addresses.

Table 3.1: Integration of Literature and Stakeholder Findings

Theme	Insights from Literature	Insights from Stakeholders	Identified Gap
Knowledge and Processes	PSS research stresses artefact–service integration, knowledge reuse, and outcome-oriented design (Baines *et al.*, 2007; Tukker, 2015)	Amputees and prosthetists report fragmented communication, repeated errors, and lack of traceability in decision-making.	Absence of systematic knowledge capture and reuse across the prosthesis life-cycle.
Customisation	Research highlights potential for digital design and additive manufacturing to enhance personalisation (Colombo *et al.*, 2010; Buzzi *et al.*, 2012)	Stakeholders note socket-level tailoring but limited options in standard sub-systems (e.g. knees, ankles).	Limited ability to customise beyond the socket due to standardisation and funding restrictions.
Emotional and Psychosocial Needs	Emotional design frameworks (Triberti *et al.*, 2017; Hartson and Pyla, 2019) emphasise aesthetics, acceptance, and self-image.	Amputees describe stigma, loss of identity, and dissatisfaction with appearance or trust in devices.	Emotional and psychosocial dimensions remain marginalised in prosthesis design and aftercare.
Cost and Accessibility	Literature shows high-end devices (e.g. microprocessor knees) improve outcomes but remain costly and inaccessible to most users (Donnelley *et al.*, 2021)	Stakeholders emphasise affordability barriers, frequent adjustments, and inequities in access.	Persistent cost trade-offs between affordability and quality, with inequitable delivery
System Integration	PSS and knowledge-based systems propose integrated service models (Aurich, Fuchs and Wagenknecht, 2006; Meier, Roy and Seliger, 2010)	Stakeholders experience fragmented, episodic care with little coordination between manufacturers, clinicians, and users.	Lack of integrated service frameworks linking all stakeholders in the prosthesis life-cycle.

Table 3.5 shows alignment but persistent gaps

As shown in Table 3.5, while literature and stakeholder perspectives frequently reinforce one another, they also expose persistent gaps, particularly in knowledge reuse, customisation, emotional support, cost–quality trade-offs, and systemic integration.

Taken together, the literature and stakeholder evidence expose several recurring gaps:

Gap 1: Fragmented knowledge flows; lack of reuse

1. **Fragmented Knowledge Flows** – Consequences of design or aftercare decisions are rarely captured or reused, leading to repeated errors and missed opportunities for systemic learning;

Gap 2: Customisation limited beyond socket.

2. **Limited Customisation Beyond the Socket** – While socket casting is anatomically customised, broader prosthesis sub-systems remain constrained by manufacturer standardisation and funding limitations;

Gap 3: Emotional and experiential factors neglected

3. **Neglect of Emotional and Experiential Dimensions** – Despite literature emphasising emotional design and psychosocial support, these dimensions remain marginalised in practice, contributing to rejection and abandonment.

Gap 4: Cost–quality trade-offs create inequities.

4. **Inequitable Access and Cost Trade-offs** – Stakeholders highlighted cost as a barrier, while literature confirms that high-end adaptive devices remain inaccessible for most, perpetuating systemic inequities;

Gap 5: Missing consequence-aware, service-oriented frameworks

5. **Absence of Consequence-Aware, Service-Oriented Frameworks** – While PSS and ontology-based methods suggest how technical, clinical, and experiential knowledge can be integrated, current practice lacks the structures needed to unify these insights into a cohesive prosthesis life-cycle system

Consolidation sets foundation for design rationale (Ch.4

By consolidating findings from literature and stakeholder perspectives, this section has established the recurring problems and systemic inefficiencies that underpin the research problem. These insights provide the foundation for the design rationale developed in Chapter 4.

3.6 Chapter Conclusion

Chapter defines research problem: fragmented, inequitable, and psychosocial gaps

This chapter has defined the research problem by consolidating insights from both the literature (Chapter 2) and stakeholder evidence. Through the mapping of the prosthesis development model and the examination of amputee, prosthetist, and manufacturer perspectives, the chapter has shown that prosthesis delivery is characterised by fragmented communication, labour-intensive processes, limited opportunities for customisation, inequitable access to advanced devices, and insufficient attention to emotional and psychosocial dimensions.

Section 3.5 shows divergence between theory and practice

The integration of findings in Section 3.5 further demonstrated that while literature frequently advocates integrated and outcome-oriented approaches, stakeholder accounts reveal a reality of episodic, device-focused, and poorly co-ordinated practices. These systemic inefficiencies, compounded by cost–quality trade-offs and the absence of structured feedback methods, highlight the persistence of gaps between theory and practice.

Findings justify need for ontology-based framework (Ch.4)

Collectively, these findings establish the foundation for this thesis: the need for a new approach capable of aligning technical, clinical, organisational, and experiential knowledge across the prosthesis life-cycle. Chapter 4 therefore develops the design rationale for such an approach, framing the scientific, methodological, and practical motivations for the ontology-based service system framework proposed in this research.

Part B

Development and Implementation of the adProLiSS Framework

4

4 The Need for a Consequence-Aware, Knowledge-Driven Approach to Prosthesis Design and Aftercare

Prosthesis design is complex and multi-stakeholder

Conventional approaches rely on tacit knowledge, causing fragmentation and poor traceability

Knowledge volume exceeds stakeholder capacity, highlighting the need for structured, consequence-aware methods.

The design, development and aftercare of prosthetic devices is a complex, multi-stakeholder process that involves engineering, clinical, emotional and user-centred considerations (Pezzin, Dillingham and Mackenzie, 2000; Sinha, Van Den Heuvel and Arokiasamy, 2011; Raschke, 2022). Conventional prosthesis design approaches often follow linear, trial-and-error practices where critical decisions rely heavily on individual expertise and tacit knowledge, rather than systematically capturing and re-using experiential insights generated across the prosthesis life-cycle. This leads to fragmented communication between stakeholders, limited traceability of design choices, and an inability to anticipate or manage the full spectrum of intended and unintended consequences. In addition, the vast, heterogeneous body of knowledge involved (ranging from clinical rehabilitation data to engineering parameters and subjective user feedback) far exceeds the capacity of any single stakeholder to process effectively. These challenges highlight the need for a *structured, consequence-aware and knowledge-driven approach* that integrates design intent, real-world data, and multi-disciplinary expertise into a cohesive, adaptive service system.

Stakeholders contribute diverse expertise across the life-cycle.

The prosthesis life-cycle involves a wide spectrum of stakeholders (such as amputees and their families, prosthetists, physiotherapists, rehabilitation specialists, engineers, and manufacturers) each contributing unique forms of expertise, requirements and priorities (Brandt, 2021; Ju *et al.*, 2021; Manz *et al.*, 2022). These stakeholders interact at multiple stages of the prosthesis life-cycle, from initial consultation and device design, to aftercare and service adaptation.

Conventional methods lack frameworks to harmonise inputs, isolating knowledge into silos.

Aftercare feedback is rarely formalised or reused, leading to inefficiencies

However, conventional development approaches lack a structured framework to harmonise these diverse inputs (Sinha, Van Den Heuvel and Arokiasamy, 2011; Manz *et al.*, 2022; Kulkarni *et al.*, 2023; Ortiz-Escobar *et al.*, 2023; Rofizah Johari *et al.*, 2025). Patient-Prosthesis related knowledge is often isolated in separate silos; clinical expertise, mechanical design data, or patient-reported experiences, which hinders cross-disciplinary communication and leads to sub-optimal outcomes. Furthermore, feedback collected during the aftercare phase is rarely formalised, structured or systematically re-used to inform future prosthesis design, resulting in repeated inefficiencies and missed opportunities for learning.

Stakeholder needs are dynamic, influenced by time, mobility, age, and lifestyle

No single stakeholder can process all knowledge, highlighting cognitive limits

Formal knowledge bases can capture, structure, and generalise consequence knowledge across cases

The complexity of this challenge is further amplified by the sheer volume, diversity and dynamics of knowledge involved. Stakeholders (such as the prosthetist) attempt to consider evolving patient needs, environmental conditions, and long-term wear effects. These needs are not static but change over time with the use of the device, influenced by factors such as mobility level, age, and lifestyle (Manz *et al.*, 2022). No single stakeholder can realistically process all relevant insights, particularly when designing for diverse patient profiles or across multiple prosthesis cases worldwide. This *human cognitive limitation* highlights the need for a formalised knowledge base capable of capturing, structuring and interpreting consequence knowledge in a reusable, scalable and computationally tractable way. Such an infrastructure ensures that insights (such as technical, clinical and experiential factors) from one prosthesis case can be generalised and reused across multiple patient profiles and contexts, something that would be infeasible to achieve through manual processes alone. This would significantly reduce inefficiencies, increased costs, and a diminished user experience.

Current approaches remain linear and product-focused, lacking adaptability for service and aftercare

Current prosthesis development approaches remain linear, product-centric and fail to account for the service and aftercare dimensions that shape long-term success (Maussang, Zwolinski and Brissaud, 2009; Matschewsky, Kambanou and Sakao, 2018). These provide structured workflows but remain predominantly product-focused, lacking the semantic and adaptive capabilities needed to manage dynamic prosthesis aftercare and multi-stakeholder knowledge flows.

A knowledge-rich, consequence-aware approach is required to link engineering, clinical, and experiential knowledge

This gap calls for a knowledge-rich, consequence aware approach that bridges technical engineering decisions with clinical workflows and patient experience, while systematically learning from past cases to inform future prosthesis configurations.

Calls for a paradigm shift to dynamic, ontology-based, consequence-aware service systems

Therefore, there is a need for a paradigm shift from static, event-driven interventions toward a dynamic, knowledge-driven service system capable of supporting adaptive prosthesis development, collaborative co-design, and long-term aftercare. The following sections examine how this shift can be realised through an ontology-based approach to consequence-aware prosthesis life-cycle management.

4.1 The Complexity of Prosthesis Design and Aftercare

Design decisions in prostheses have delayed and undocumented long-term consequences

Designing prostheses is a socio-technical challenge involving various stakeholders (such as prosthetists, clinicians and amputees). It spans complex knowledge domains including biomechanics, materials engineering, user psychology, and healthcare services. Decisions made at the design phase, such as socket stiffness, knee type, or sensor integration, may have significant long-term effects that only manifest during real-world use (e.g. ulceration, gait instability, emotional dissatisfaction). These delayed, emergent, or unintended consequences are rarely documented systematically, and even less frequently used to inform future cases.

Aftercare lacks structured feedback loops and formal knowledge reuse

Furthermore, prosthesis aftercare is characterised by inconsistent feedback loops. Clinicians and prosthetists often rely on anecdotal reports or delayed consultations to detect issues, rather than leveraging real-time sensor data or shared historical knowledge. The absence of a formal knowledge base limits learning from past cases and hampers the personalisation and sustainability of prosthesis services.

4.2 Limitations of Current Prostheses Design Approaches

Linear, component-driven approaches overlook long-term service, consequence tracking, and interoperability

Current prosthesis design and development approaches are linear and component-driven. They focus on fitting the immediate physical parameters of the amputee but neglect broader, longer-term considerations such as service evolution, consequence propagation, and semantic interoperability. Feedback loops, when present, are informal and depend on stakeholder memory or subjective reporting. Consequences, such as discomfort, component failure, or psychological rejection, are often not traced back to their root design decisions.

Figure 4.1 illustrates isolated stakeholder roles and lost experiential knowledge

An example of this type of limitation is shown in Figure 4.1. In this scenario, each of the four stakeholders (physiotherapist, prosthetist, engineer and amputee) function in isolation, without means to capture or communicate their experiential knowledge. Consequently, critical insights into current issues are not effectively transferred to the design phase.

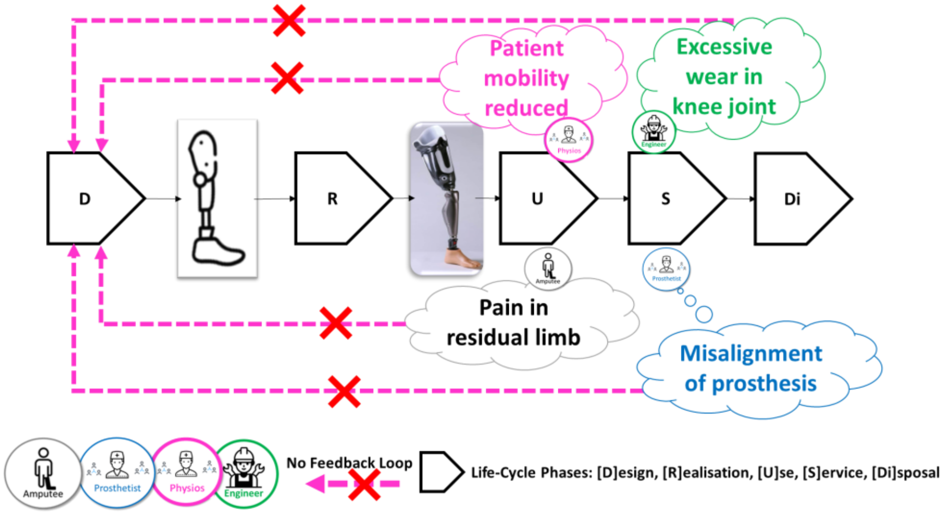


Figure 4.1: Conventional prosthesis design approach with missing feedback

Fragmentation stems from structural and cognitive limits in managing prosthesis knowledge

While these fragmented approaches have led to inconsistent outcomes and limited aftercare learning, their shortcomings are not simply a result of poor practice, they reflect deeper structural and cognitive constraints in the way prosthesis knowledge is managed. The next section explores these limitations and their implications for engineering system design.

4.3 Human Processing Limitations and the Case for Formalised Knowledge

Growing diversity of prostheses and user cases increases decision-making complexity

As the diversity of prosthesis types, modular components, and amputee use-cases expands, so too does the complexity of informed decision-making across the prosthesis life-cycle. Stakeholders, including prosthetists, physiotherapists, and engineers, must interpret heterogeneous data streams, ranging from clinical metrics to subjective amputee feedback, while simultaneously considering evolving user needs. No single stakeholder, however experienced, can retain or process the breadth of knowledge required to design, monitor, and adapt prostheses effectively across contexts, this is further amplified by the fact that amputee needs evolve with time. This cognitive overload often results in fragmented knowledge, loss of tacit expertise, and missed opportunities for consequence-based learning.

Stakeholder cognitive overload leads to fragmented knowledge and missed learning

Introduces Borg's input–storage–output model (Figure 4.2) applied to prosthesis decisions

To understand these challenges, it is necessary to consider how humans process, store, and utilise information. (Borg, 1999) categorises information processing into three interrelated components: Input, Storage, and Output. Figure 4.2, adapted from (Bolock, Abdelrahman and Abdennadher, 2020), illustrates this cognitive information processing model in the context of prosthesis decision-making.

Input phase: sensory cues and amputee communication enter short-lived sensory memory

Input processing begins when sensory stimuli, such as visual cues from the prosthesis or verbal communication from the amputee, enter sensory memory. In the illustrated scenario, the prosthetist perceives both the amputee's verbal account and the observable consequences of water ingress in the prosthesis. Sensory memory retains this raw input briefly before rapid decay occurs, leaving only partial traces.

Working memory compares inputs with long-term memory; cognitive filtering causes data loss

This partial information is then transferred to working memory (short-term memory), where it is actively compared with representations stored in long-term memory. Although humans can receive and register diverse forms of input, they face intrinsic difficulties in organising, prioritising, and drawing inferences from the full scope of available information (Cowan, 2010; Sweller, Ayres and Kalyuga, 2011). As a result, potentially relevant data may be disregarded as irrelevant or overlooked due to cognitive filtering.

Working memory limited to 4–7 items; encoding into long-term memory constrained by cognitive load

Information storage is further constrained by the limited capacity of working memory, broadly accepted to handle only a small number of discrete items at once, typically around four to seven, depending on context (Cowan, 2010; Ma, Husain and Bays, 2014). Information deemed significant may be rehearsed, elaborated, and subsequently encoded into long-term memory for future retrieval. However, transfer between sensory, short-term, and long-term memory is strongly influenced by cognitive operations such as attention, rehearsal, and elaboration, and is susceptible to cognitive load effects (Sweller, Ayres and Kalyuga, 2011).

Output phase: retrieved information informs reasoning and prosthetist decision-making

Finally, in the **output phase**, stored information is retrieved and applied to reasoning tasks. In the prosthetist's case, this involves inferring the likely consequences of water exposure for both prosthesis functionality and amputee comfort, and making subsequent decisions on repair, adjustment, or adaptation.

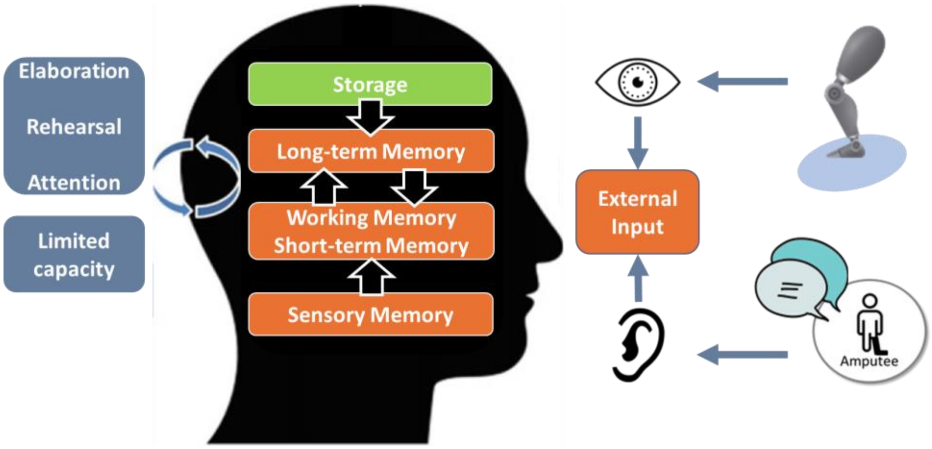


Figure 4.2: Cognitive Information Processing Model, adapted from (Bolock, Abdelrahman and Abdennadher, 2020)

Human cognitive limits justify need for formalised, ontology-based knowledge base for reuse and decision support

These human processing limitations underline the need for a *formalised, semantically structured, and dynamically maintained knowledge base*. Such a system externalises stakeholder expertise, contextual observations, and consequence logic in a machine-readable format, enabling intelligent decision support, improving traceability, and ensuring knowledge reuse across global prosthesis design and aftercare contexts.

4.4 Towards an Ontology-Based, Consequence-Aware Design Approach

Stakeholder limits show need for formal, consequence-aware knowledge base

The limitations outlined in sections 4.1 – 4.3 demonstrate that individual stakeholders cannot reliably capture, organise, and reuse the diverse streams of knowledge generated across the prosthesis life-cycle. This reinforces the need for a formalised and externally maintained knowledge base capable of transcending human memory and processing limits. To be effective, such a system must not only store knowledge but also enable reasoning about the intended and unintended consequences of design and service decisions. An ontology-based, consequence-aware, knowledge-driven design approach provides this foundation: it structures knowledge into a shared semantic vocabulary, enables inference through rule-based reasoning, and incorporates processes for simulation and feedback that support continuous learning. This ensures that decisions are traceable, consequences are anticipated, and learning is cumulative. The following subsections outline the essential building blocks of this paradigm, which collectively establish the basis for the framework introduced in the next chapter.

Structured ontologies provide shared vocabulary linking technical, clinical, and emotional consequences

Structured Ontologies - Formal representation of prosthesis components, user profiles, service actions, and contextual parameters in a consistent and extensible vocabulary is a prerequisite for consequence-aware reasoning. Ontologies provide such representations, enabling heterogeneous knowledge to be structured in a way that supports both semantic consistency and automated inference. For example, a misaligned socket can be formally linked in the ontology to gait asymmetry as a functional consequence and to user frustration as an emotional consequence. In this thesis, emotions are understood as multifaceted phenomena resulting from cognitive appraisal processes, whereby individuals evaluate the relevance and significance of stimuli in relation to their personal concerns (Desmet, 2003, 2004; Scherer, 2005). This interpretation is consistent with prior doctoral work in consequence knowledge and design, which formalised emotions as outcomes of human–system interactions across life phases (Farrugia, 2017).

Ontologies enable multiple stakeholder views and ensure semantic interoperability.

This allows different stakeholders to view the same event through their own lens: the prosthetist monitors alignment data, the physiotherapist examines gait stability, and the amputee receives feedback on comfort. Ontologies have already been shown to support interoperability and reasoning across health and engineering domains (Chatterjee *et al.*, 2021; Cocco *et al.*, 2024). By providing a shared semantic layer, they ensure that clinical, technical, and experiential perspectives are not only consistent but also computable, traceable, and reusable across the prosthesis life-cycle.

Semantic rules allow inference of intended and unintended consequences

Semantic Rules and Inference - Explicit rules connecting heterogeneous inputs, such as sensor data, clinical metrics, and amputee feedback, to potential consequences. These rules allow automated reasoning, enabling both intended and unintended outcomes to be systematically inferred (Bikakis and Antoniou, 2010; Spoladore and Pessot, 2021; Spoladore, Tosi and Lorenzini, 2024). Such rule-based reasoning enhances transparency and supports decision traceability.

Digital twins simulate prosthesis behaviour and user interaction before implementation

Digital Twins and Simulation - Real-time digital representations of prosthesis states and user interactions provide a powerful means to visualise, test, and explore design or service decisions before they are implemented. Recent work in healthcare and rehabilitation demonstrates how digital twins can predict device behaviour, simulate rehabilitation outcomes, and support adaptive interventions (Bruynseels, de Sio and van den Hoven, 2018; Tao, Qi, *et al.*, 2019; Fuller *et al.*, 2020). Such models enhance predictive capacity and provide a safe environment for consequence exploration.

Feedback loops capture real-world experience into reusable consequence knowledge (PECK)

Consequence Feedback Loops - Processes that continuously feed outcomes from real-world use back into the knowledge base transform lived experience into actionable insights. The concept of experiential knowledge capture is central to organisational learning (Nonaka and Takeuchi, 1995; Argote and Miron-Spektor, 2014) and has been adapted to engineering design through knowledge-based and

PSS approaches (Maussang, Zwolinski and Brissaud, 2009; Matschewsky, Lindahl and Sakao, 2020). In the prosthesis context, such loops formalise what may otherwise remain tacit, supporting the emergence of *p**rosthesis experiential consequence knowledge*** (PECK) as an evolving repository of collective stakeholder learning.

Together, these elements form adaptive, systematic foundation for consequence-aware design.

Together, these elements form the foundation of a consequence-aware design paradigm that is both systematic and adaptive. They allow fragmented experiential insights to be externalised, structured, and reused, ensuring that prosthesis development and aftercare are informed by cumulative knowledge rather than isolated episodes of tacit expertise.

4.5 Typology of Consequences in Prosthesis Design and Aftercare

Introduces inevitability of consequences in prosthesis life-cycle decisions

Outlines structured typology: dimensional, directional, and interactional categories

Design and service decisions within the prosthesis life-cycle inevitably give rise to consequences that extend beyond the immediate action or stakeholder. These consequences may manifest at different levels, affect diverse stakeholders, and propagate across multiple life-cycle phases. To systematically capture and reason about them, a structured typology is introduced. This typology supports ontology modelling, knowledge capture, and adaptive response logic, ensuring that both intended and unintended outcomes can be formally represented and managed.

Defines dimensional consequence types with examples: physical, functional, emotional, systemic, semantic

These consequence types can be categorised as follows: a) dimensional types (physical, functional, emotional, systemic, semantic); b) directional orientation (intended or unintended); c) interactional behaviour (interacting or non-interacting).

a) Dimensional Types of Consequences

Physical consequences

Physical Consequences - These relate to the mechanical or physiological interaction between the prosthesis and the user.

Example: a poorly aligned socket may generate localised pressure points, leading to skin ulcers; excessive joint noise may cause discomfort during walking.

Functional consequences

Functional Consequences - These affect the amputee's capacity to perform daily activities, mobility tasks, or rehabilitation exercises.

Example: gait asymmetry may increase energy expenditure, leading to premature fatigue; inappropriate stiffness in a knee sub-system may reduce balance and stability.

Emotional consequences

Emotional Consequences - These are psychological or affective responses to prosthesis use.

Example: visible wear or aesthetic mismatch may generate embarrassment or stigma; repeated device failure can lead to frustration, diminished trust in the clinical team, or withdrawal from social activities.

Systemic consequences

Systemic Consequences - These concern the wider healthcare and service system supporting the prosthesis.

Example: frequent component breakages increase aftercare costs, extend prosthesis downtime, and burden clinical resources with repeated appointments.

Semantic consequences

Semantic Consequences - These reflect the cultural, social, or identity-related meaning attached to the prosthesis.

Example: a cosmetically natural-looking prosthesis may improve self-image and social acceptance; conversely, a visibly bulky design may reinforce feelings of stigmatisation and reduced social acceptance.

b) Direction of Consequences

Intended consequences

Intended, arising from deliberate design or service actions.

Example: integrating an adjustable ankle joint to improve mobility across uneven terrain.

Unintended consequences

Unintended, emerging as side effects not anticipated by the original decision.

Example: using lightweight materials improves comfort but unintentionally reduces durability, leading to more frequent component failures.

c) Interactions Between Consequences

Consequences may occur in isolation (*non-interacting*) or interact (*interacting*) with one another in complex ways.

Non-interacting consequences

Non-interacting consequences - outcomes that remain independent of each other. *Example*: a cosmetic cover peeling does not influence the prosthesis' mechanical function.

Interacting consequences

Interacting consequences - outcomes that propagate or reinforce one another. *Example*: a misaligned socket (physical consequence) causes pain, which leads to reduced prosthesis use (functional consequence) and frustration (emotional consequence).

Table 4.1 synthesises categories into faceted taxonomy for ontology modelling

To consolidate these categories into a systematic and reusable structure, the identified consequence types are synthesised in Table 4.1. The table presents a faceted taxonomy of prosthesis consequences, organised along the three classification axes of dimensional type, directional orientation, and interactional behaviour. Each category is accompanied by illustrative examples that demonstrate how consequences manifest in practice and how they may be traced back to underlying design or service decisions. This structured representation moves beyond anecdotal description by providing a consistent classification scheme that supports ontology modelling and consequence reasoning. In doing so, the table offers a foundation for linking causes, detection methods, and corrective actions in later chapters, and for enabling consequence knowledge to be captured, formalised, and systematically reused across the prosthesis life-cycle.

Table 4.1: Taxonomy of Prosthesis Consequences

	Category	**Definition**	**Example**
Dimensional	Physical	Mechanical / physiological effects at the limb-prosthesis interface.	Socket misfit results in skin ulcer; excessive joint noise results in discomfort.
	Functional	Effects on task performance, mobility, energy use, balance.	Gait asymmetry results in higher energy expenditure; stiff knee results in reduced stability.
	Emotional	Affective / psychological response to device and experience.	Repeated failures result in frustration; aesthetic mismatch results in embarrassment.
	Systemic	Impacts on service operations, cost, downtime, appointments.	Frequent repairs lead to increased aftercare cost and clinical load.
	Semantic	Social / identity meaning, symbolism, and perceived aesthetics.	Natural looking cover results in improved social acceptance; bulky design results in stigmatisation.
Directional	Intended	Planned / desired outcomes from a design or service decision.	Adjustable ankle improves uneven terrain mobility.
	Unintended	Unplanned side-effects or emergent outcomes.	Lightweight material reduces durability resulting in more failures.
Interaction	Interacting	Consequences that propagate, reinforce, or couple with other consequences.	Misalignment (physical) results in pain, which leads to reduced use (functional), which leads to frustration (emotional).
	Non-interacting	Consequences that are largely independent from one another.	Cosmetic scuff without functional impact.

Taxonomies as systematic classification schemes; highlights clarity, consistency, and extensibility

The structured representation of these categories can be described as a taxonomy of consequences, a systematic classification scheme that organises entities based on shared characteristics (Bailey, 1994; Nickerson, Varshney and Muntermann, 2013). Recent research emphasises its importance: taxonomies succinctly capture domain knowledge, support peer understanding, and can be evaluated on quality attributes like clarity, consistency, and extensibility, key considerations for engineering-driven, consequence-aware system design (Unterkalmsteiner and Abdeen, 2023).

In the scope of this research, the identified categories are integrated into a *faceted taxonomy* (Bailey, 1994; Nickerson, Varshney and Muntermann, 2013; Unterkalmsteiner and Abdeen, 2023) to enable systematic classification of prosthesis related consequences.

Applies faceted taxonomy framework to prosthesis

Figure 4.3 illustrates a faceted taxonomy of prosthesis consequences as a three-dimensional classification space. The three axes correspond to dimensional types (e.g. physical, functional), directional types (intended or unintended), and consequences with 3D classification

interactional types (interacting or non-interacting). Any consequence can be positioned within this space by its coordinates, enabling structured categorisation and cross-dimensional reasoning.

Example: pressure sore classified as physical, unintended, and interacting consequence

For example, Figure 4.3 depicts the case of a pressure sore arising at the stump–socket interface. This is classified as a *physical consequence*, since it emerges from direct biomechanical interaction between the residual limb, the prosthetic socket, and associated loading conditions. It is also *unintended*, as the sore is not a deliberate outcome of any design or service decision, but rather an adverse side effect of insufficient fit or material response. Finally, it is *interacting* in nature: perspiration and moisture accumulation within the socket altered frictional conditions, leading to movement of the residual limb relative to the socket wall, known as pistoning. This micro-movement generated repeated shear and compressive stresses on the skin, which over time produced tissue breakdown. The physical outcome (pressure sore) thus interacts with environmental and biomechanical factors, amplifying the original misfit and creating a cascade of negative effects.

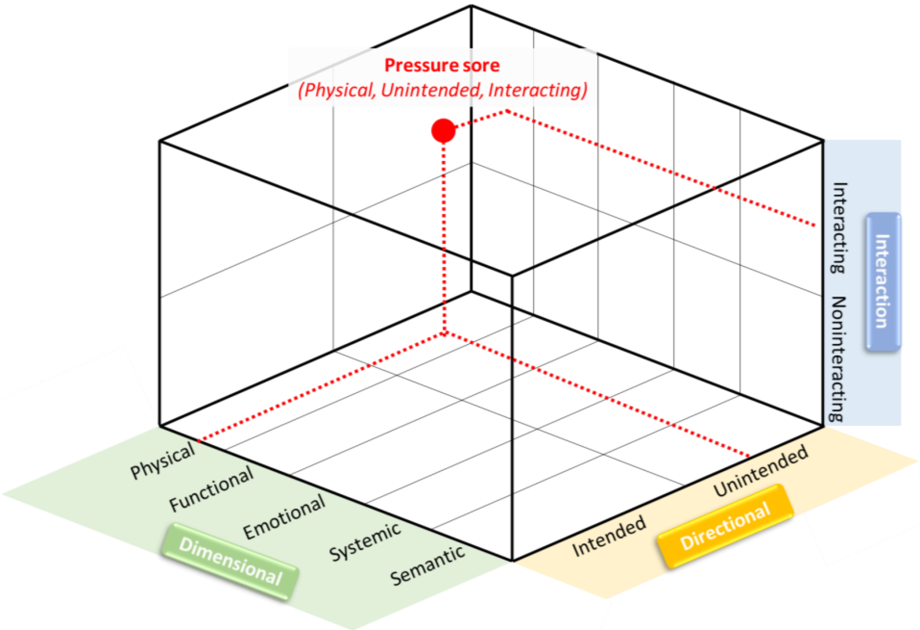


Figure 4.3: Faceted taxonomy of prosthesis consequences, represented as a three-dimensional classification space

Ontology formalisation links consequences with causes, detection, and corrective actions

Such formalisation allows consequences to be explicitly modelled as ontology entities, thereby linking their causes, detection mechanisms, and corrective strategies. For example, a "pressure sore" consequence can be linked to "socket misfit" as a cause, "temperature sensor threshold" as a detection method, and "socket recasting" as a corrective action. By formalising both dimensional types and relational properties (intended/unintended, interacting/non-interacting), this taxonomy provides the foundation for consequence-aware reasoning across the prosthesis life-cycle.

4.6 The Scientific Need for an Ontology-Driven Framework

Ontologies defined as formal, computable representations enabling interoperability, reasoning, and reuse, contrasted with databases and checklists

From a scientific perspective, ontologies provide formal, computable representations of domain knowledge that enable interoperability, traceability, and automated reasoning across heterogeneous systems. Unlike conventional information management approaches such as relational databases or checklists, ontologies allow knowledge to be structured semantically, supporting inference, consistency checking, and knowledge reuse across contexts. This makes them particularly suitable for multi-stakeholder environments such as prosthesis design and aftercare, where decisions span technical, clinical, and experiential dimensions.

Ontology as reasoning backbone, links goals, data, and rules; captures concepts and relationships for consequence-aware reasoning

In this context, an ontology must extend beyond a simple taxonomic catalogue of terms. It functions as the backbone of a reasoning environment, connecting high-level stakeholder goals with low-level sensor data and contextual parameters through formally defined semantic rules. By encoding both conceptual knowledge (e.g. prosthesis components, service processes, user states) and relational properties (e.g. cause–effect, precondition–consequence), the ontology enables consequence-aware reasoning that is not achievable through informal or isolated knowledge repositories. Such formalisation enables the system to adapt as amputee needs evolve over time, ensuring that changing physiological, functional, and emotional requirements are systematically integrated into design and aftercare reasoning.

Capabilities enabled: context-aware adaptation, stakeholder-specific outputs, and historical reasoning

The scientific relevance of an ontology-driven approach becomes evident when examining the types of capabilities it enables. First, context-aware adaptation is achieved through rules that tailor responses to environmental or usage conditions (e.g. different thresholds for urban versus rural ambulation contexts). Second, stakeholder-specific visualisation and alerts can be generated by linking data streams to roles and responsibilities: a prosthetist may receive alignment and load distribution metrics, whereas an amputee may instead view comfort scores and mobility feedback. Third, historical reasoning is supported through the ability to trace recurring patterns of failure, adaptation, or service interventions across multiple patients and devices. These capabilities collectively demonstrate how ontologies transform fragmented data into an integrated, actionable knowledge base.

Aligns ontology-driven systems with engineering principles: modularity, scalability, explainability, provenance, interoperability

Furthermore, ontology-driven systems align with established principles of engineering system design, including modularity (the ontology can be expanded with new classes without disrupting the core model), scalability (reasoning scales as more devices, patients, and contexts are incorporated), explainability (decision paths can be reconstructed via semantic reasoning), provenance (data and knowledge sources are traceable), and semantic interoperability (knowledge can be exchanged across systems and stakeholders). These scientific attributes are essential for building trustworthy and adaptive healthcare-engineering solutions.

Evidence from other domains (UiA eHealth Ontology, ADCATER) shows feasibility and transferability.

The adoption of ontologies in comparable application areas demonstrates their suitability for the prosthesis life-cycle. For example, the UiA eHealth Ontology demonstrates how semantic formalisation enhances interoperability and reasoning across healthcare data streams (Chatterjee *et al.*, 2021). Similarly, the ADCATER ontology illustrates how engineering knowledge can be modelled in OWL to support adaptive design processes and sensor-derived inference (Cocco *et al.*, 2024). These examples validate the scientific need for ontology-based frameworks in contexts characterised by complexity, risk, and the necessity for personalised adaptation.

Concludes that scientific requirements justify ontology-driven prosthesis life-cycle framework

These scientific requirements establish the foundation for an ontology-driven approach to prosthesis life-cycle management, which is operationalised in the service system framework introduced in the following chapter.

4.7 Chapter Summary

Chapter rationale: socio-technical complexity + fragmentation; cognitive limits hinder knowledge reuse

This chapter established the scientific and practical rationale for a consequence-aware, knowledge-driven approach to prosthesis design and aftercare. Firstly, the characterised socio-technical complexity of the prosthesis life-cycle and the fragmentation that arises when design and service decisions rely primarily on tacit expertise and ad-hoc feedback (Sections 4.0–4.2). Then, the examination of human cognitive processing limits, including constraints on attention, working memory, and inference, which explain why stakeholders cannot reliably capture, organise, and reuse the heterogeneous knowledge produced across contexts (Section 4.3).

Principles of consequence-aware design: ontologies, semantic rules, digital twins, feedback loops (PECK)

Building on this analysis, the principles of a consequence-aware design paradigm (Section 4.4) were articulated: structured ontologies to provide a shared semantic layer; semantic rules to operationalise consequence reasoning; digital twins for simulation and anticipatory testing; and feedback loops that transform lived experience into Prosthesis Experiential Consequence Knowledge (PECK). This was followed by a faceted taxonomy of consequences (Section 4.5), distinguishing dimensional, directional, and interactional categories to support systematic capture and traceable reuse.

Ontology-driven framework justified: integrates data, enables adaptation, meets engineering principles

Finally, an argument was made for the scientific need for an ontology-driven framework (Section 4.6). Ontologies move beyond taxonomic catalogues to serve as the backbone of a reasoning environment that integrates clinical, engineering, and experiential data; enables context-aware adaptation and historical analysis; and satisfies core engineering principles, including modularity, explainability, provenance, and semantic interoperability.

Sets conceptual foundation; next chapters detail framework architecture and operationalisation.

Collectively, these elements provide the conceptual foundation for a life-cycle service-system approach in which consequence knowledge is externalised, computable, and reusable. Chapters 5 - 7 operationalises these principles in a concrete architecture, detailing how the proposed framework structures knowledge, executes consequence reasoning, and integrates with design, monitoring, and aftercare services.

5

5 An Ontology-Driven Service System Framework for Adaptive Prosthesis Design and Aftercare

Chapter 5 introduces adProLiSS framework as structured ontology-driven solution

Chapter 5 introduces the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) as the central framework of this thesis, translating the problem landscape defined in earlier chapters into a structured, ontology-driven solution for adaptive prosthesis design and aftercare.

Problem recap: fragmented knowledge, tacit reliance, lack of consequence reasoning

Chapters 3 and 4 defined the research problem space by exposing the limitations of current prosthesis design and aftercare practices. These include the fragmented exchange of stakeholder knowledge, reliance on tacit expertise, and the absence of systematic consequence reasoning across the prosthesis life-cycle. Together, these deficiencies hinder the delivery of prosthetic solutions that are adaptive, cost-effective, and genuinely patient-centred, while posing challenges for amputees, prosthetists, engineers, and healthcare providers alike.

adProLiSS proposed to address deficiencies with ontology, consequence-based methods, and PSS principles.

Building directly on this problem definition, this chapter presents the *Adaptive Prosthesis Life-Cycle Service System (adProLiSS)* as the proposed framework to address these deficiencies. The adProLiSS framework combines an ontology-driven knowledge structure, a consequence-based design methodology, and modular product–service system principles to enable smarter, more responsive, and evidence-informed prosthesis development and aftercare.

Framework positioned as stakeholder-centred PSS enabling consequence

The design, development, and ongoing care of prosthetic devices requires coordination between diverse stakeholders, complex decision-making throughout life-cycle phases, and the capacity to adapt to evolving user needs (Biddiss and Chau, reasoning and integrated decision-making

2007; Peerdeman *et al.*, 2011; Highsmith, Andrews, *et al.*, 2016a). To meet these challenges, adProLiSS is structured as an ontology-driven, stakeholder-centred Product-Service System (PSS) that enables consequence-aware reasoning and system-wide communication. It explicitly maps the dynamic interactions across prosthesis stakeholders, technical sub-systems, and contextual life-cycle data, thereby aligning design and aftercare decisions with amputees' evolving physical, functional, and emotional requirements.

adProLiSS supports full life-cycle: modular design, co-design, adaptive aftercare with semantic knowledge flows

At its core, adProLiSS is designed to support the full prosthesis life-cycle, spanning modular component development, multi-stakeholder co-design, and adaptive aftercare. This integrated approach seeks to ensure that both design intent and aftercare services are informed by semantic knowledge flows, enhancing traceability, adaptability, and overall quality across the product-service system framework.

The framework is presented across Chapters 5 – 7:

Chapter 5: adProLiSS

- **Chapter 5** introduces adProLiSS as a high-level system-of-systems model, detailing its structural layers and the relationships between stakeholders, prosthesis sub-systems, and the service environment;

Chapter 6: adProLiSS Methodology

- **Chapter 6** explains how the framework is operationalised across design and use phases, highlighting its adaptive behaviour and data-driven flows throughout the prosthesis life-cycle;

Chapter 7: Prosthesis Life-cycle Consequence Knowledge Modelling Frame

- **Chapter 7** elaborates the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, which functions as the system's semantic core, enabling knowledge structuring, consequence simulation, and interdisciplinary data integration.

Defines integrated service system approach; feasibility to be shown in Chapter 8

Together, these chapters define an integrated approach: a scientifically grounded and theoretically complete service system framework designed for practical implementation. The adProLiSS framework promotes more collaborative, transparent, and responsive prosthesis design and aftercare, whose operational feasibility will be demonstrated in Chapter 8 through prototype implementations and stakeholder-centred scenarios.

Establishes adProLiSS as thesis's core contribution: ontology-driven framework for adaptive prosthesis design and aftercare

In doing so, Chapter 5 establishes adProLiSS not merely as a conceptual model, but as the thesis's core contribution: an ontology-driven service system framework that systematically addresses the complexities of prosthesis design and aftercare, and provides the foundation for the operationalisation and demonstrator studies that follow.

5.1 The Adaptive Prosthesis Life-Cycle Service System Framework

adProLiSS framework structure and roles

The **Adaptive Prosthesis Life-Cycle Service System (adProLiSS)** framework is designed to address the fragmented, siloed, and often reactive nature of traditional prosthesis design, development processes, and aftercare services. At its core, adProLiSS is a service-oriented, stakeholder-inclusive, and ontology-driven framework that supports the co-design, prosthesis development, and adaptive management of prosthetic devices throughout their life-cycle. This section presents the structural composition of the framework, its architectural layers, and the roles of key stakeholders and artefacts involved.

5.1.1 Framework Motivation and Structural Principles

Prosthesis systems are multidisciplinary and socio-technical

Prosthesis systems are inherently multidisciplinary and socio-technical: they involve a wide range of stakeholders (amputees and family members, clinicians, prosthetists, physiotherapists, designers, technicians), technical sub-systems (mechanical, electronic, software), and emotional and physical user requirements that evolve over time (Biddiss and Chau, 2007; Peerdeman *et al.*, 2011). This is an issue that current approaches (Figure 5.1) to prosthesis design and service delivery often fail to coordinate these factors holistically (Eckert, Maier and McMahon, 2005; Walsh, Dong and Tumer, 2019).

Current approaches rely on tacit prosthetist knowledge and trial-and-error

During the initial consultation of current approaches (Figure 5.1), the prosthetist and the amputee jointly discuss the amputee's functional requirements. Based on this discussion, the prosthetist designs the prosthesis by drawing exclusively on their own professional knowledge, experience and judgement accumulated throughout their career. Once the prosthesis is fabricated and delivered, the amputee begins using it in daily life. Inevitably, various adjustments and refinements are required to maintain comfort, fit and mobility. These adjustments rely heavily on subjective feedback from the amputee and the prosthetist's ability to interpret this feedback and translate it into technical modifications. This remains largely a trial-and-error process. Outcomes depend strongly on the individual prosthetist's skill and tacit knowledge rather than on systematic, evidence-based, or data-driven methods. This lack of explicit, shareable consequence knowledge can result in repeated inefficiencies, inconsistent outcomes, and limited traceability of design decisions across the prosthesis life-cycle.

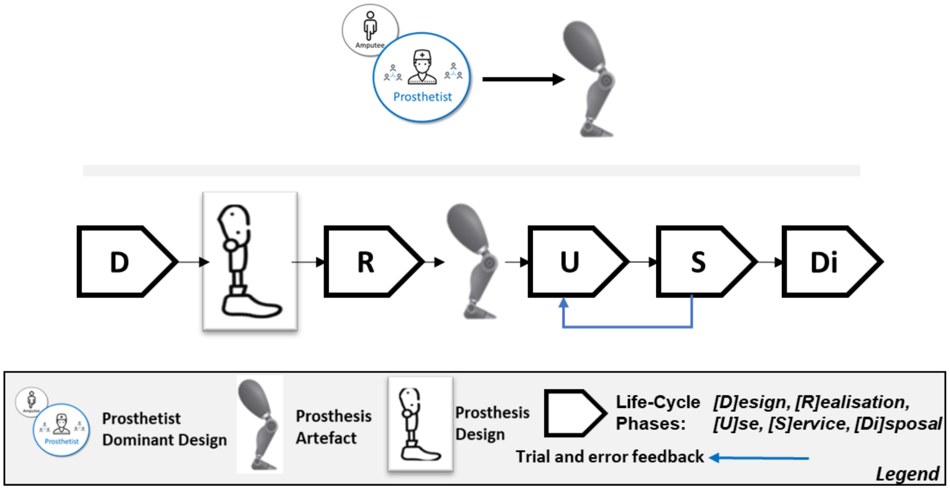


Figure 5.1: Conventional Prosthesis Design and Development Approach

adProLiSS reframes prostheses as adaptive, user-inclusive PSS

The adProLiSS framework responds to this gap by framing the prosthesis system as a **Product-Service System (PSS)** that is not only designed *for* users but also designed *with* users, and capable of adapting to user needs across time and context (Figure 5.2).

Co-design integrates expertise from multiple stakeholders with feedback loops

Within the adProLiSS framework, the initial consultation evolves into a multi-stakeholder co-design process that utilises the specialised expertise of each stakeholder. Here the prosthetist and the amputee are joined by physiotherapists, engineers and technical personnel who contribute knowledge and insights gained through their respective professional practice. This collaborative design process is further strengthened by integrated feedback loops that span multiple phases of the prosthesis life-cycle. These loops would ensure that stakeholders have access to richer consequence knowledge, enabling design decisions, based on systematic, evidence-based, and data-driven methods rather than relying solely on individual tacit expertise, as outlined in Chapter 4 sections 4.2 – 4.4.

Shift enables consequence-aware, traceable, and adaptive prosthesis design

This proposed shift enables prostheses to be designed with greater precision, aligning with amputees' evolving functional and emotional needs while also accounting for downstream service and aftercare requirements. By embedding consequence-aware co-design, the framework enhances traceability, consistency, and overall quality across the entire product–service system.

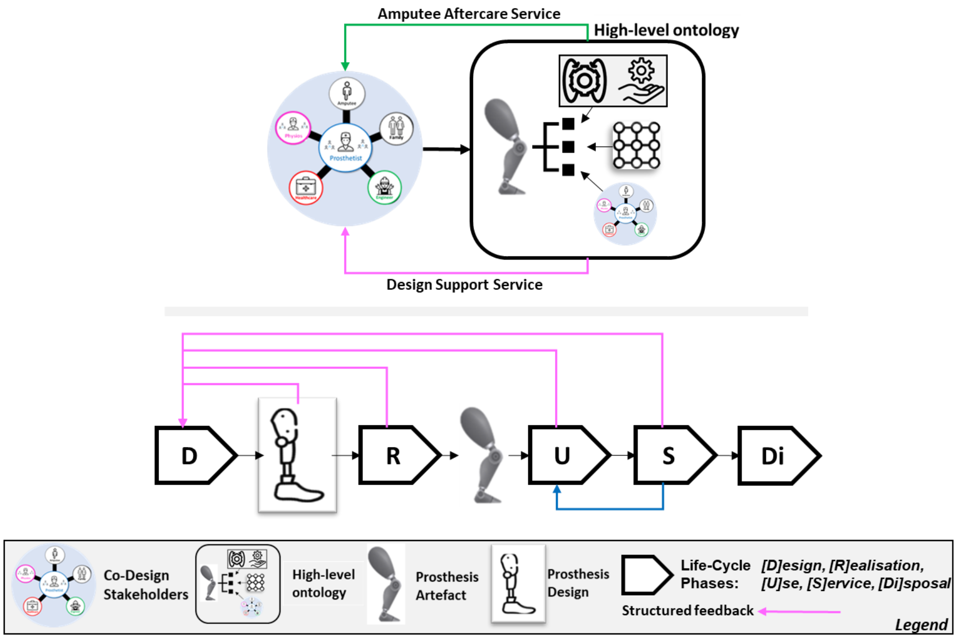


Figure 5.2: High-level view of the adProLiSS Approach

adProLiSS incorporates guiding structural principles addressing complexity, conventional limits, and cognitive constraints

To address the limitations outlined in Chapter 4 sections 4.1 - 4.3, namely the complexity of prosthesis design and aftercare, the limitations of conventional prosthesis approaches, and the constraints of human processing capacity, adProLiSS incorporates a set of guiding structural principles that underpin its entire architecture. These principles ensure systematic knowledge integration, cross-disciplinary coordination, and continuous improvement across all phases of the prosthesis life-cycle, thus aiming to develop a more adaptive, evidence-informed product-service system.

The framework is structured to promote both design and aftercare:

Design principles: communication, semantic consistency, service integration, adaptability.

Design:

- Stakeholder communication, high-quality decision making, co-design and decision traceability;
- Semantic consistency across systems and disciplines, ensuring that all stakeholders and technologies share a common understanding of terms, states and consequences throughout the prosthesis life-cycle;
- Integration of service considerations (rehabilitation workflows, maintenance requirements) into early design stages;
- Anticipation of long-term adaptability and modularity, enabling the prosthesis to evolve with user needs.

Aftercare principles: continuous feedback, early issue detection, sustainability, user alignment

Aftercare:

- Continuous real-time and longitudinal feedback loops incorporating sensor readings, stakeholder insights, and knowledge-driven inferences;
- Early detection and resolution of critical issues (e.g. fall risk, misalignment, poor comfort);
- Support for sustainability through systematic monitoring of component wear, reuse potential, and end-of-life strategies;
- Alignment of clinical interventions with both biomechanical performance and user-reported emotional/functional well-being.

These needs motivate the structural principles detailed in Section 5.1.2

Taken together, these needs motivate the structural principles detailed in section 5.1.2, where IPD and PSS are fused to support consequence-aware, ontology-driven decision-making across design and aftercare.

5.1.2 The adProLiSS Framework Structure

Customised prosthesis must balance physical/emotional needs with efficient manufacture and aftercare.

The design and development of a customised lower-limb prosthesis involves creating a device that not only satisfies the amputee's physical and emotional requirements but is also efficient to manufacture, maintain and adapt. An effective prosthesis development service model should address the technical design specifications of customised prosthetic devices, their manufacturing process, and the delivery of long-term aftercare, whether provided through a public healthcare system, a private clinical provider, or a hybrid service model, to effectively cater to the evolving needs of amputees (Olaya-Mira *et al.*, 2025).

adProLiSS adopts IPD principles to integrate product, production, and business dimensions (Figure 5.3

The novel framework presented in this chapter addresses these design, manufacturing and business aspect challenges of lower-limb prosthesis development concurrently (Borg, Yan and Juster, 2000). At its foundation, the adProLiSS framework is grounded in principles of *Integrated Product Development* (IPD) (Andreasen and Hein, 2000), an approach that promotes the concurrent and systematic development of product, production and market elements to align engineering outcomes with user needs and service objectives, across the product life-cycle. Figure 5.3 illustrates an adapted version of the IPD model, specifically tailored to prosthesis service systems, in which engineering parameters are connected with medical, social and emotional factors that directly influence long-term prosthesis performance and patient well-being.

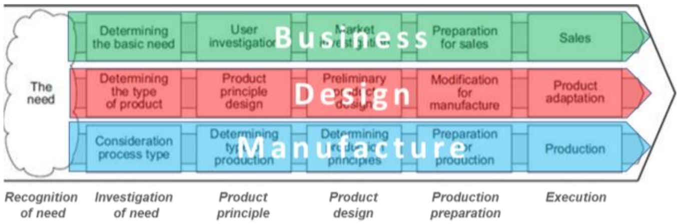


Figure 5.3: Adapted Integrated Product Development Model

IPD pillars: Product, Production, and Business, developed concurrently to manage complexity

The IPD model provides a robust conceptual structure for managing inherent complexity of designing and developing products with multi-faceted, interdependent requirements. It is built around three core pillars: the Product Pillar, which addresses technical functionality and user-specific demands; the Production Pillar, which ensures manufacturability, reliability, and cost-effectiveness; and the Business Pillar, which reflects customer expectations, service delivery strategies, and competitiveness. A key distinction is that the IPD model enables these pillars to be addressed concurrently rather than treating them in isolation, supporting iterative refinement and alignment across diverse stakeholders throughout the design and development process.

Other approaches (Stage-Gate, Mass Customisation, Design Thinking) compared, less suited to prosthesis

In selecting IPD as the foundation for adProLiSS, it is necessary to critically assess its applicability relative to other established approaches. At the level of product development, Stage-Gate models (Cooper, 1990) provide structured, sequential checkpoints that aid in risk management but suffer from rigidity and lack support for the dynamic feedback loops essential in adaptive, user-centred systems like prosthesis. Similarly, Mass Customisation frameworks (Pine, 1993) address variety in output but are traditionally optimised for modular, high-volume contexts such as automotive or consumer electronics, and therefore *do not* capture the personalised clinical and emotional complexity of prosthesis services. At the level of design methodology, Design Thinking (Brown, 2008) brings valuable emphasis on empathy and ideation, yet lacks the integrated product–production–service coordination required for complex, long-life healthcare technologies. IPD operationalises design intent within an integrated development model that concurrently addresses product, production, and business/service pillars. PSS then extends this model with a formal service dimension, ensuring that aftercare and adaptation are engineered from the outset rather than appended post-deployment.

IPD provides integration, but lacks service dimension; PSS extends it with service-centred design.

However, while IPD offers the structural foundation for integrated product and production development, it does not, in its classical form, explicitly address the service dimension that is critical for complex, long-life healthcare technologies such as lower-limb prostheses. To address this limitation, the adProLiSS framework extends the IPD model by incorporating principles of Product-Service Systems (PSS), an approach that integrates physical products and associated services into a unified, value-driven system (Tukker, 2004; Baines *et al.*, 2007). In contrast to traditional product-centric development, PSS frameworks treat products and services as interdependent elements that co-evolve to deliver sustained user-centred value, which is essential in contexts where continuous adaptation, aftercare and human factors are central.

PSS classifications, product, use, and result-oriented, converge in prosthesis services

Various PSS classifications exist, ranging from product-oriented systems, where services augment product use (e.g. training, maintenance), to use-oriented and result-oriented systems, in which the service itself becomes the core value proposition (Tukker, 2004). In prosthesis development, these distinctions often overlap: while the physical prosthetic device remains the core artefact, its value is inseparable from the services that support its fitting, co-design (Sanders and Stappers, 2008; Steen, Manschot and De Koning, 2011a; Bjögvinsson, Ehn and Hillgren, 2012; Steen, 2013; Boukhris, Fritzsche and Möslein, 2017), monitoring, and iterative adaptation. This convergence necessitates a service-dominant logic (Vargo and Lusch, 2008), in which the prosthesis is conceptualised not as a static product but as part of an evolving, socio-technical aftercare service ecosystem.

PSS tools exist, but adProLiSS adapts them for low-volume, high-customisation healthcare

PSS design approaches such as Functional Product Development (FPD) and Service Engineering (Aurich, Fuchs and Wagenknecht, 2006) provide valuable tools for service integration, but are typically optimised for high-volume industrial applications. By contrast, adProLiSS is explicitly configured for low-volume, high-customisation contexts where amputee needs evolve through the device life-cycle and require data-driven, adaptive support. Here, PSS principles are not simply appended to the product development process but is embedded as a co-equal development stream alongside product and production, fully aligned with IPD principles. This synergy ensures that aftercare service considerations (e.g. rehabilitation workflows, emotional well-being, sensor-driven alerts) are embedded from the earliest stages of design, not retrofitted post-deployment.

IPD–PSS integration supports life-cycle thinking, stakeholder feedback, and adaptive decision-making

This research proposes that by combining IPD with a PSS perspective, adProLiSS will support life-cycle thinking that extends beyond manufacturing to include system use, stakeholder feedback, and adaptive decision-making. Within this framework, the internal relationships among IPD's product, production, and business pillars are systematically aligned with the interdependencies between PSS product and service-oriented elements. This is particularly important for prosthesis systems, where device performance, user satisfaction, and clinical outcomes are shaped by usage context and aftercare support services that emerge post prosthesis delivery.

adProLiSS enables real-time information flow, adaptive services, and consequence-aware reasoning.

These relationships are structurally coordinated within adProLiSS through an integrative architecture that enables real-time information flow, adaptive service reconfiguration, and consequence-aware decision-making, capabilities that traditional IPD or PSS models in isolation do not inherently provide. For instance, socket-pressure anomalies (product) can trigger a redesign decision (production constraints, availability of components) and a service pathway (business/aftercare scheduling), coordinated via shared ontological states and rules. The ontological reasoning that underpins this architecture is elaborated further in Chapter 7.

Integration of IPD and PSS results in a user-responsive, consequence-aware framework for prostheses.

In this way, the integration of IPD and PSS within adProLiSS proposes a systems-oriented, user-responsive, and consequence-aware framework suitable for the engineering challenges of lower-limb prosthesis design and development. This aims to address not only the complexities of custom design and manufacturability but also the service delivery and emotional resilience required for lifelong prosthetic care.

Stakeholders (amputees, prosthetists, physiotherapists, engineers) are active agents shaping design and aftercare

A core component of the adProLiSS framework is its explicit modelling of stakeholder roles and interactions across different prosthesis life-cycle phases. Stakeholders are not treated as passive recipients of system outputs, but as active agents whose decisions, expertise and feedback directly shape both the physical configuration and aftercare service dynamics of the prosthesis system.

Stakeholder roles formalised in ontology, supporting decision traceability and knowledge propagation.

These stakeholders include:

- **Amputees**, and by extension their family members, whose evolving mobility goals, physiological conditions, usage contexts, and emotional feedback are the central axis around which personalisation and adaptation are structured;
- **Prosthetists**, who provide expert clinical intervention, socket design, alignment, and functional evaluation, and who act as primary prosthesis designers with authority to finalise configurations;
- **Physiotherapists** who play a key role in post-fitting care, rehabilitation, mobility training, and gait optimisation, with their observations feeding back into the system to inform adaptation and performance optimisation;
- **Engineering and technical team**, including prosthesis engineers, technicians, and digital system developers, are responsible for the development, calibration, and maintenance of both hardware and software subsystems.

The contributions of these four stakeholder groups, span the design of modular components, sensor integration, digital twin implementation, and system-level logic that enables adaptive, consequence-aware behaviour. Within the adProLiSS ontology, these stakeholder roles are formally defined and mapped to service tasks, decision-making points, and knowledge flows. This formalisation supports multi-directional communication, decision traceability, and knowledge propagation throughout the prosthesis life-cycle, ensuring that all interventions and outcomes are context-sensitive, explainable, and aligned with stakeholder responsibilities.

Three frames and pillars define adProLiSS structure (Figure 5.4).

As shown in Figure 5.4, adProLiSS is structured around three interlinked frames, each supported by three core pillars: the *Business Service Pillar*, identifies service objectives, stakeholder roles, cost constraints and user priorities; the *Product-Configuration Design Pillar*, which focuses on functional, aesthetic, and structural specifications; and the *Manufacturing and Assembly Pillar*, which handles the technical realisation, including component fabrication, quality control, and assembly.

These frames are:

Frame 1: Standard Systems Development – scalable design of configurable prosthesis components.

1. **Standard Systems Development Frame**: Focuses on the industrial design and scalable manufacture of prosthesis components such as pylons, ankles, or knee sub-systems, which serve as configurable building blocks for customised assemblies.

Frame 2: Custom Prosthesis Development – patient-specific co-design of devices and services.

2. **Custom Prosthesis Development Frame**: Supports the co-design of patient-specific prosthetic systems and aftercare services. The initial service configuration integrates anatomical data, stakeholder inputs, and standard components into a unified prosthesis design tailored to individual user needs.

Frame 3: Prosthesis Adaptation – post-delivery monitoring and adaptive aftercare

3. **Prosthesis Adaptation Frame**: Provides continuous support post-delivery through real-time monitoring, knowledge-based reasoning, and service adaptation based on contextual and real-world usage data.

adProLiSS Framework

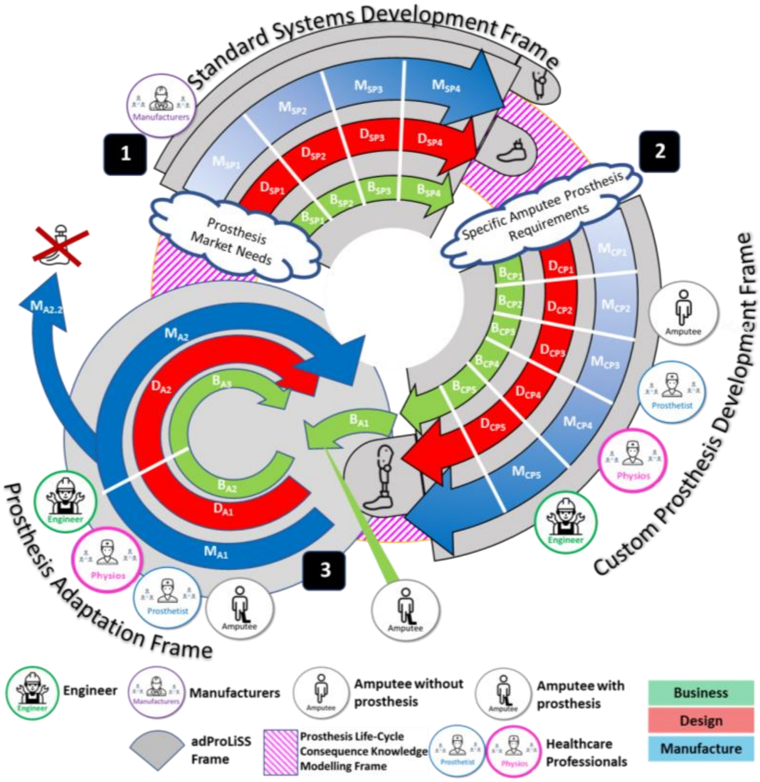


Figure 5.4: The adProLiSS Framework

Prosthesis Life-Cycle Consequence Knowledge Modelling Frame connects all three frames via knowledge flows

A key component of the adProLiSS framework is the **Prosthesis Life-Cycle Consequence Knowledge Modelling Frame**, which functions as a dynamic, bi-directional feedback system connecting the three frames within the system architecture. This modelling frame enables **continuous accumulation, formalisation, and contextualisation** of consequence-driven knowledge across the prosthesis life-cycle, enabling stakeholders to access timely, actionable information to guide their design, clinical, and operational decisions. Rather than operating as a linear pipeline, this architecture embeds a structured knowledge flow that supports **multi-disciplinary, user-centred co-design**, enhances **adaptability** (e.g. variations in age, terrain, or physical condition), and enables both **real-time and longitudinal integration** of sensor-derived data from prosthetic systems with structured knowledge derived from stakeholder interactions, clinical observations and co-design activities. Central to this capability is the use of an **explicit ontology** (Borst, Akkermans and Top, 1997; Nico, 1997; McMahon and Van Leeuwen, 2009), which formally defines the complex network of relationships among prosthesis components, life-cycle phases, evolving user needs, and stakeholder roles. This shared semantic structure, establishing a common vocabulary and a formalised conceptual model, that ensures **traceability of design and service decisions, semantic consistency** across clinical, technical, and experiential domains, and **knowledge interoperability** among diverse stakeholders, including amputees, family members, prosthetists, technicians, physiotherapists, and system designers. By dynamically mapping context-specific knowledge to stakeholder roles and service objectives, the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame supports **informed, collaborative, and adaptive decision-making**, ultimately ensuring that prosthetic systems evolve responsively in line with the changing physical, emotional, and functional needs of amputees. This specific ontological reasoning logic is detailed in Chapter 7.

Ontology ensures semantic consistency, traceability, and stakeholder knowledge interoperability (detailed in Ch.7).

Modular layered architecture enables adProLiSS to deliver dynamic, knowledge-rich, adaptive prosthesis services

This modular, layered architecture enables adProLiSS to function as a knowledge-rich, traceable, and adaptable service system, capable of responding dynamically to individual and evolving prosthesis requirements throughout the full life-cycle. The following sections (5.1.3 – 5.1.5) examine each of the three frames in detail, explaining their structure, roles, and integration within the overall framework.

5.1.3 The Standard Systems Development Frame

Frame 1: Standard Systems Development – design of modular prosthesis sub-systems (Figure 5.5)

The Standard Systems Development Frame (Frame 1) represents the activities undertaken by established prosthesis manufacturers to design, develop and deliver standardised prosthetic sub-systems, such as ankles, pylons, or knees, that can be later configured into custom-built prosthesis (see Figure 5.5). The Standard Systems Development Frame is made up of an accumulation of frames, with each frame dedicated to a specific sub-system type. Every frame is structured around the three interlinked pillars, consistent with the IPD logic. These are: The Business Service Pillar; the Product Design Pillar; and the Standard Systems Manufacturing Pillar.

Each pillar is further subdivided into four discrete stages, as outlined in Table 5.1, to ensure that business objectives, technical design requirements, and production constraints are addressed concurrently and systematically.

Table 5.1: Standard Systems Development Frame Sub-sections

Business Service		Product Design		Standard Systems Manufacture	
BSP 1	Determining the basic prosthetic needs	**DSP 1**	Determining the type of product	**MSP 1**	Consideration of process type
BSP 2	Market Investigation	**DSP 2**	Preliminary product design	**MSP 2**	Determining production principles
BSP 3	Preparation for sales	**DSP 3**	Modification for manufacture	**MSP 3**	Preparation for production
BSP 4	Sales	**DSP 4**	Product adaptation	**MSP 4**	Production

Business Service Pillar: market alignment, user needs, logistics, and sales (BSP1–BSP4)

The **Business Service Pillar** ensures that the manufacturer’s product offering aligns with market demand and stakeholder priorities. Activities under this pillar include:

- **BSP 1:** Identifying baseline prosthetic needs across target user groups.
- **BSP 2:** Conducting structured market investigations to assess trends, competitive solutions, and cost constraints.
- **BSP 3:** Preparing logistical and marketing pathways to support sales and distribution within the intended healthcare or service network.

- **BSP 4:** Executing sales, supported by stakeholder education and service agreements where required.

Product Design Pillar: technical scope, validated design, manufacturability, and adaptability (DSP1–DSP4).

The **Product Design Pillar** focuses on the systematic translation of identified needs into robust, sub-systems that can be integrated into custom prosthetic configurations. Activities include:

- **DSP 1:** Defining the technical and functional scope of each sub-system (e.g. load-bearing capacity, range of motion).
- **DSP 2:** Developing a validated preliminary design, including CAD models, material selection, and basic interface requirements.
- **DSP 3:** Modifying the design for manufacturability, ensuring compatibility with available production technologies and supply chain constraints.
- **DSP 4:** Embedding product features that enable future adaptation, such as interchangeable parts or adjustable mechanisms.

Manufacturing Pillar: process evaluation, production principles, scaling, and execution (MSP1–MSP4).

The **Standard Systems Manufacturing Pillar** governs the transition from design to physical production, ensuring that the modular sub-systems are manufactured efficiently and consistently. Key stages include:

- **MSP 1:** Evaluating suitable process types (e.g. additive manufacturing, precision machining, assembly line automation).
- **MSP 2:** Determining production principles, such as batch size, quality control protocols, and regulatory compliance.
- **MSP 3:** Preparing for scaled production by setting up production lines, sourcing materials, and training operators.
- **MSP 4:** Executing production, including prototyping, pilot runs, and full-scale manufacturing.

Standard Systems Development Frame

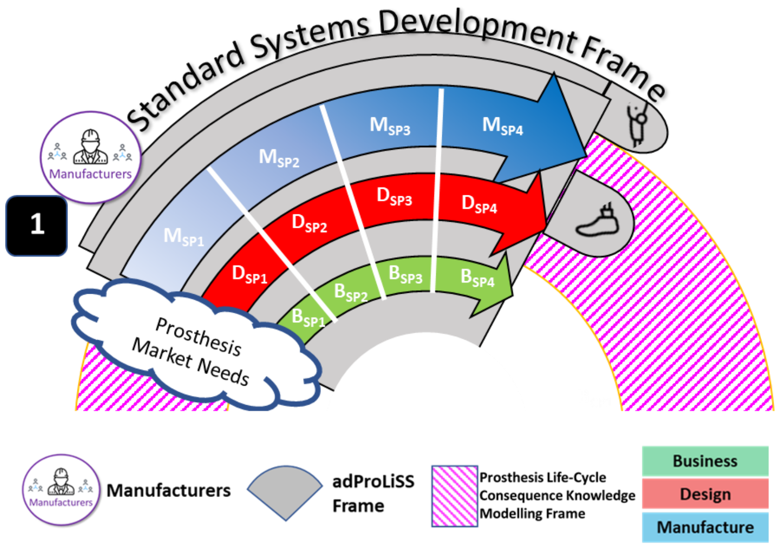


Figure 5.5: The Standard Systems Development Frame

Current sector outputs: static standard modules vs adProLiSS dynamic, ontology-driven integration.

Within the current commercial prosthesis sector, the outputs of the *Standard Systems Development Frame* typically consist of static, standardised sub-systems produced by established manufacturers using conventional design and production methods. These standard modules, such as ankles, pylons, or knee units, are not inherently knowledge-rich or semantically integrated, but instead serve as modular building blocks that can be configured by clinical stakeholders downstream. Within the adProLiSS framework, these static components are subsequently embedded into a broader, ontology-driven service system through *the Custom Prosthesis Development Frame* and *Prosthesis Adaptation Frame*. In this way, adProLiSS does not alter the manufacturer's existing development model directly, but provides a pathway by which these standard systems are dynamically selected, combined, and enhanced through co-design with clinical stakeholders and amputees to deliver fully personalised and adaptive user-specific prosthetic systems and its associated service configuration.

5.1.4 The Custom Prosthesis Development Frame

Frame 2: Custom Prosthesis Development, tailored to amputee needs (Figure 5.6)

The *Custom Prosthesis Development Frame* (Frame 2) (Figure 5.6) addresses the critical phase in which a prosthesis is tailored to the unique requirements of the individual amputee. Rooted in co-design principles (Steen, Manschot and De Koning, 2011a; Boukhris, Fritzsche and Möslein, 2017; Robert, Donetto and Williams, 2021), this frame establishes a structured collaborative process in which the prosthetist, the amputee and family members, physiotherapists, and engineering and technical personnel work together to define needs, configure system components, and plan the service aspects that ensure the device's fit, function, and adaptability.

Co-design as consequence-aware decision process with long-term impacts

Co-design at this stage is an active, consequence-aware decision process (Wilkinson and De Angeli, 2014; Melles, Albayrak and Goossens, 2021; Leason *et al.*, 2022). Stakeholders collectively negotiate technical, clinical, and experiential requirements, selecting from available standard sub-systems developed in Frame 1. This is a scientifically necessary step, because decisions made at this point directly propagate consequences (Borg, Yan and Juster, 2000; Abrams, 2002; Borg and Farrugia, 2014; Couturier *et al.*, 2014; Walsh, Dong and Tumer, 2019) throughout the entire prosthesis life-cycle that affect both the amputee and the prosthesis. For example, selecting a particular knee module affects gait performance, maintenance cycles, user comfort, and future adaptability.

Key decision-makers: prosthetist, amputee/family, physiotherapists, engineers

Within this frame, these stakeholders, the prosthetist, amputee (and family), physiotherapists and engineering and technical personnel, act as the *key prosthesis decision-makers*. The prosthetist plays a dual role as both a clinical expert and the lead design authority, guiding the integration of anthropometric data, functional goals, system constraints, and is thus considered the primary designer. The amputee and family contribute context-specific needs, lifestyle factors, and emotional feedback that shape configuration choices. The engineers and technical personnel support technical feasibility and modular compatibility. The physiotherapists support the ongoing rehabilitation and mobility training for gait optimisation.

Three IPD–PSS pillars structure co-design process

The practical activities that realise this co-design are structured into three interlinked pillars, consistent with the IPD–PSS logic of adProLiSS:

Healthcare Service Business Pillar: needs assessment, preparation, assembly,

The **Healthcare Service Business Pillar** addresses the organisational and operational dimension of providing a customised prosthesis solution within a broader product-service system. In a PSS framework, the business aspect ensures that the delivery of evaluation (BCP1–BCP5).

the physical product is fully integrated with associated services, including fitting, user support, and aftercare (Tukker, 2004; Baines *et al.*, 2007). This pillar focuses on systematically assessing individual amputee needs, coordinating preparation and assembly activities, and verifying that the delivered prosthesis aligns with both clinical standards and user expectations. The service business logic applies whether the provider is a public healthcare institution, a private clinic, or a hybrid service entity. Activities include:

- **BCP 1:** Assess the amputee's basic needs and context of use.
- **BCP 2:** Prepare the required product resources.
- **BCP 3:** Coordination and delivery of the prosthesis service.
- **BCP 4:** Finalise service readiness and deployment.
- **BCP 5:** Service-level evaluation of prosthesis performance and fit.

Configuration Design Pillar: part selection, evaluation, configuration, validation (DCP1–DCP5).

The **Configuration Design Pillar** addresses the systematic selection, evaluation, and arrangement of standard sub-systems to meet the amputee's individual physical and functional needs. In engineering design science, configuration design involves constructing a unique system by combining pre-defined modules and components according to defined constraints and performance goals (Andreasen and Hein, 2000; Pahl *et al.*, 2007). In this frame, a structured investigation of available standard parts is conducted, candidate sub-systems are evaluated against clinical and experiential requirements (Darr, Klein and McGuinness, 1998), and the final configuration is validated collaboratively before procurement. These activities include:

- **DCP 1:** Investigate available standard parts from Frame 1.
- **DCP 2:** Evaluate candidate parts against patient-specific requirements.
- **DCP 3:** Design the full configuration, combining standard modules and custom socket specifications.
- **DCP 4:** Review and validate the configuration design with all stakeholders.
- **DCP 5:** Re-assess standard part performance and compatibility.

Custom Parts & Assembly Pillar: anatomical measurement,

In the **Custom Parts and Standard Systems Assembly Pillar**, the prosthetist implements the customisation plan through precise anatomical measurement and socket fabrication, integration, trial (MCP1–MCP5).

fabrication. This ensures that the final device integrates standard sub-systems with a patient-specific socket, achieving both fit and functional alignment. Here, the focus is on the engineering integration of patient-specific components with pre-manufactured standard sub-systems to produce a fully functional lower-limb prosthesis. This step is technically critical because it transforms generic modular elements into a device customised for an individual's anatomy, gait pattern, and usage context (Wilkinson and De Angeli, 2014). The prosthetist performs precise anatomical measurements and fabricates a custom socket, which is then assembled with the selected standard modules. Final trial fitting and evaluation ensure that the physical configuration meets biomechanical, functional, and user-comfort requirements before delivery. All measurements, adjustments, and test outcomes are documented to support traceability and future adaptation. These activities include:

- **MCP 1:** Take detailed dimensions of the residual limb to produce an accurate cast.
- **MCP 2:** Select materials for socket fabrication based on biomechanical and comfort criteria.
- **MCP 3:** Perform the socket casting and shaping process.
- **MCP 4:** Assemble the socket with the selected standard sub-systems.
- **MCP 5:** Conduct a full prosthesis trial and evaluation, adjusting as necessary.

Table 5.2: The Custom Prosthesis Development Frame Sub-Sections

Healthcare Service Business		Configuration Design		Custom & Standard Systems Assembly	
BCP 1	Amputee Basic Need	DCP 1	Investigation of standard parts	MCP 1	Dimensions taken for cast
BCP 2	Product Preparation	DCP 2	Evaluation of standard parts	MCP 2	Selection of materials for cast
BCP 3	Coordination and delivery of prosthesis service	DCP 3	Configuration design of standard parts	MCP 3	Socket casting
BCP 4	Finalise service readiness and deployment	DCP 4	Evaluation of configuration design	MCP 4	Socket and standard parts assembly
BCP 5	Prosthesis service Evaluation	DCP 5	Standard parts evaluation	MCP 5	Full prosthesis evaluation

Custom Prosthesis Development Frame

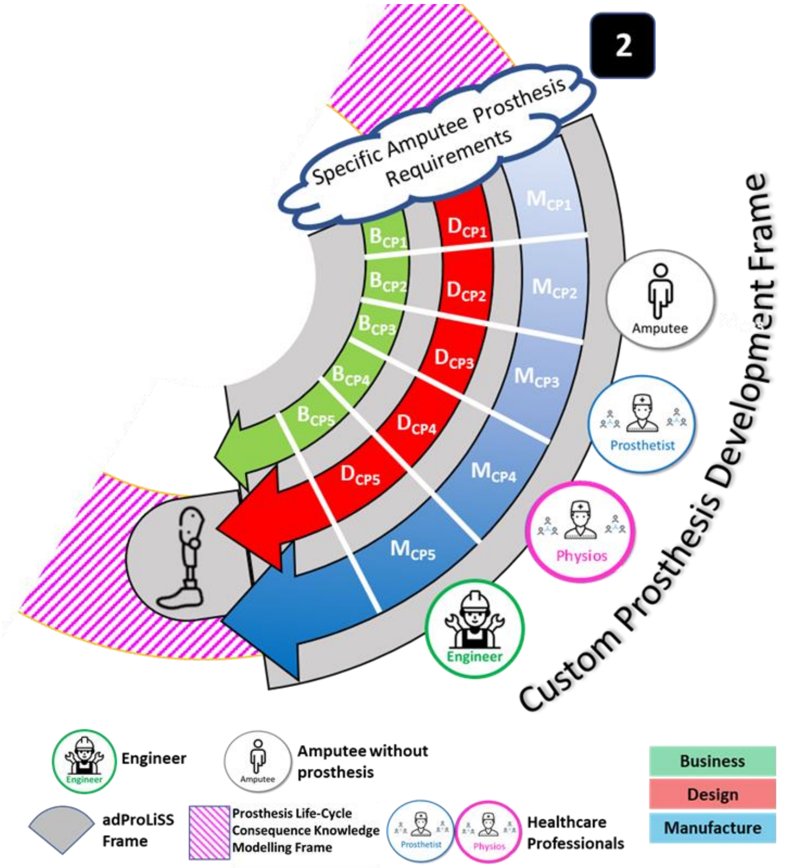


Figure 5.6: The Custom Prosthesis Development Frame

Ontology captures decisions for traceability and consequence-aware adaptation

Within adProLiSS, this frame ensures that configuration decisions and socket fabrication are captured and formalised within the system's ontology and knowledge base. This allows the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (Chapter 7) to track configuration decisions, infer future adaptation needs, and support traceability. This explicit co-design approach guarantees that all relevant design and service consequences are anticipated and managed systematically.

5.1.5 The Prosthesis Adaptation Frame

Frame 3: Prosthesis Adaptation: continuous monitoring & adaptation.

The Prosthesis Adaptation Frame (Frame 3) addresses the essential life-cycle phase in which the lower-limb prosthesis and its user are continuously monitored, and where the prosthesis is maintained and adapted to meet changing physical and emotional conditions, usage contexts, and patient goals. In contrast to conventional static device delivery models, this frame supports a dynamic, knowledge-driven service process in which real-time and longitudinal data streams, combined with stakeholder input, enable evidence-based decision-making for service interventions, component replacement, and sustainability management.

Closed-loop system: sensors & feedback result in actionable knowledge

Scientifically, this frame operationalises a closed-loop adaptive feedback system that integrates sensor-derived data (e.g. socket pressure, temperature, humidity), patient-reported feedback, and clinical observations. This information is transformed into actionable knowledge to inform stakeholders, including prosthetists, physiotherapists, and technical staff, who assess the need for service adjustments, reconfiguration, maintenance or component replacement. This adaptation process ensures that the prosthesis continues to deliver biomechanical performance, comfort, and safety throughout its operational life (Walsh, Dong and Tumer, 2019).

Organised around 3 pillars: Service Business, Configuration Design, Assembly (Figure 5.7, Table 5.3).

To structure this adaptive process, the Prosthesis Adaptation Frame is organised around three interlinked pillars, each addressing a distinct aspect of post-delivery service: Healthcare Service Business, Configuration Design, and Custom Parts & Standard Systems Assembly. Figure 5.7 presents the overall process, while Table 5.3 outlines the specific sub-stages.

Healthcare Service Business Pillar: monitoring, interventions, end-of-life (BA1–BA3)

The **Healthcare Service Business Pillar** provides the organisational structure for delivering continuous monitoring, adaptive service provision, and end-of-life management. In a PSS framework, the business aspect ensures that the delivery of the physical product is fully integrated with supporting services such as health tracking, performance monitoring, and planned sustainability interventions (Tukker, 2004). By embedding continuous monitoring and end-of-life planning within the service business model, this pillar guarantees that the prosthesis is treated not as a static artefact but as an evolving product-service bundle, supporting life-cycle continuity, patient well-being, and responsible resource management.

These activities include:

- **BA 1:** Implement continuous monitoring of amputee health and prosthesis performance, combining real-time data streams and patient feedback.
- **BA 2:** Provide targeted service interventions to adapt the prosthesis or address emerging clinical issues, based on monitoring insights.
- **BA 3:** Manage the end-of-life phase by planning responsible disassembly, part reuse, and disposal of worn-out components in line with sustainability goals.

Configuration Design Pillar: diagnose via data/feedback, plan redesigns (DA1–DA2).

The **Configuration Design Pillar** focuses on transforming monitoring data and stakeholder input into validated diagnostic insights and reconfiguration decisions. In line with engineering design adaptation principles (Darr, Klein and McGuinness, 1998), this pillar ensures that redesigns are evidence-based and tailored to the patient's evolving biomechanical, functional and emotional needs. Critically, it operationalises the closed-loop knowledge cycle by converting empirical feedback into traceable design adjustments, ensuring that all adaptations remain consequence-aware, explainable, and systematically recorded.

- **DA 1:** Analyse collected sensor data, stakeholder feedback, and clinical reports to diagnose performance deviations or patient discomfort.
- **DA 2:** Develop and validate reconfiguration or redesign plans for custom and standard parts, including decisions on adaptation, reuse, or disposal.

Custom Parts & Assembly Pillar: service, repurpose, disassemble, recycle (MA1–MA2)

The **Custom Parts & Standard Systems Assembly Pillar** executes the physical interventions required to implement the planned adaptation. This includes servicing, repurposing viable components, disassembling redundant sub-systems, and recycling worn-out materials. By translating diagnostic and design decisions into precise physical adaptations, this pillar closes the feedback loop, ensuring that the prosthesis remains technically aligned with the patient's requirements while promoting material circularity and sustainable resource use.

These activities include:

- **MA 1.1:** Perform servicing, maintenance, and physical adaptation of the prosthesis in line with updated configuration specifications.
- **MA 1.2:** Identify standard system components that remain functional but no longer match the current amputee's needs, and prepare them for repurposing for other users.
- **MA 2.1:** Disassemble worn or incompatible prosthesis components as part of end-of-life management.
- **MA 2.2:** Dispose of or recycle worn-out parts according to material recovery and sustainability guidelines.

Table 5.3: The Prosthesis Adaptation Frame Sub-section

Healthcare Service Business		Configuration Design		Custom & Standard Systems Assembly	
BA 1	Prosthesis and Patient Health Management	DA 1	Diagnosis and analysis of data	MA 1.1	Prosthesis servicing, Maintenance and Adaptation
BA 2	Prosthesis and Patient Adaptation	DA 2	Redesigning, adaptation and disposal design	MA 1.2	Repurposing standard system parts in good condition that no longer fit amputee needs
BA 3	Prosthesis End-of-Life Management			MA 2.1	Prosthesis Disassembly
				MA 2.2	Disposal of worn-out parts

Prosthesis Adaptation Frame

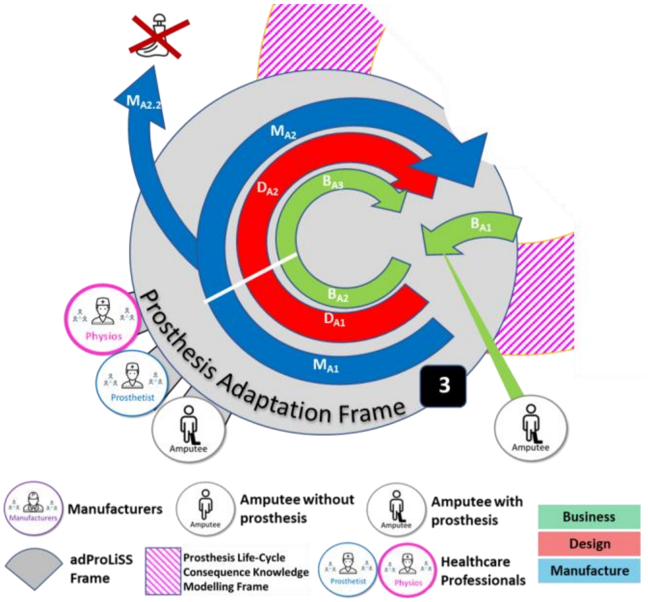


Figure 5.7: The Prosthesis Adaptation Frame

Frame 3 ensures responsiveness, sustainability, and consequence-aware traceability.

Through this integrated structure, the Prosthesis Adaptation Frame ensures that each amputee's prosthesis remains responsive to physical, functional and emotional changes, while supporting sustainable resource management and knowledge traceability. Adaptation activities and outcomes are recorded in the system's knowledge base, enabling consequence-aware reasoning and future design improvements as described in Chapter 7.

5.1.6 Traceable Mapping of Frames, Pillars, Stakeholders, Knowledge Artefacts, and Decisions

adProLiSS as system-of-systems: frames + pillars consolidated in Table 5.4

While Sections 5.1.3 – 5.1.5 described each frame in detail, the system-of-systems nature of adProLiSS becomes most evident when their relationships are considered together. Table 5.4 consolidates the three frames and their supporting pillars, mapping them against the primary stakeholders involved, the knowledge artefacts they interact with, and the decisions typically made. This synthesis highlights the structured traceability of the framework and provides a foundation for its formal ontological representation in Chapter 7.

Manufacturer' expanded to detailed roles (managers, engineers, technicians, QA).

For clarity, in the Standard Systems Development Frame the umbrella term 'Manufacturer' is used in figures and diagrams. Table 5.4 expands this to include the internal stakeholder roles typically encompassed within manufacturing organisations (e.g. business managers, design engineers, technicians, and quality assurance staff), in order to map their contributions to data and decision points more explicitly.

Mapping links stages: stakeholders, knowledge flows, consequence-aware decisions

This mapping demonstrates how adProLiSS ensures that every stage of prosthesis design, development processes, and aftercare services is explicitly linked to responsible stakeholders, associated knowledge flows, and consequence-aware decision points. By making these relationships explicit, adProLiSS supports transparent, interdisciplinary collaboration and prepares the ground for semantic consistency and automated reasoning in its ontology-driven implementation.

Table 5.4: Mapping of frames, pillars, stakeholders, knowledge artefacts, and decisions in adProLiSS

	Pillar	Primary Stakeholders	Knowledge Artefacts	Typical Decisions
Standard Systems Development	Business Service	Manufacturers, business managers	Market analysis, baseline prosthetic needs, cost constraints	Portfolio selection, pricing, service agreements
	Product – Configuration Design	Engineers, designers, technicians	CAD models, material specifications, load-bearing requirements, interface standards	Module design, component validation, manufacturability adjustments
	Manufacturing and Assembly	Production engineers, quality assurance staff	Process plans, batch records, regulatory compliance documents	Process selection, production planning, quality certification
Custom Prosthesis Development	Business Service	Prosthetists, healthcare providers, amputees and families	Patient profiles, lifestyle context, clinical requirements	Service planning, resource preparation, evaluation protocols
	Product – Configuration Design	Prosthetists, engineers, physiotherapists, amputees	Anthropometric data, gait analysis, part catalogues, compatibility matrices	Sub-system selection, configuration validation, socket design
	Manufacturing and Assembly	Prosthetist, technicians	Residual limb casts, socket materials, assembly records	Socket fabrication, prosthesis assembly, trial fitting adjustments
Prosthesis Adaptation Frame	Business Service	Prosthetists, clinicians, service providers	Real-time monitoring data, usage logs, aftercare schedules	Intervention planning, aftercare scheduling, end-of-life management
	Product – Configuration Design	Prosthetists, physiotherapist, engineers	Sensor data (pressure, temperature, gait, voltage, force), clinical reports, patient feedback	Diagnostic interpretation, reconfiguration planning, reuse/disposal decisions
	Manufacturing and Assembly	Technicians, engineers	Servicing records, disassembly notes, recycling guidelines	Maintenance actions, component replacement, repurposing/disposal

5.2 Chapter Summary

This chapter introduced the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) as the thesis's central contribution: an ontology-driven, consequence-aware Product–Service System that integrates design, development processes, and aftercare services for lower-limb prostheses. The chapter motivated the framework by analysing limitations of conventional practice, tacit, trial-and-error decision pathways; poor traceability; and reactive aftercare, and by arguing for the fusion of Integrated Product Development (IPD) with Product–Service Systems (PSS) to support life-cycle coordination. The adProLiSS architecture was detailed through three frames (Standard Systems Development, Custom Prosthesis Development, and Prosthesis Adaptation) and three pillars (Business Service, Product-Configuration Design, and Manufacturing & Assembly), with explicit modelling of stakeholder roles and knowledge flows. A central Prosthesis Life-Cycle Consequence Knowledge Modelling Frame was introduced to semantically structure interactions, propagate consequences, and enable evidence-informed adaptation using real-time and longitudinal data. Collectively, these elements establish a coherent, knowledge-rich service system that improves decision quality, traceability, and responsiveness to evolving amputee needs. The subsequent chapters operationalise the framework (Chapter 6) and formalise its ontological reasoning (Chapter 7), before demonstrating feasibility via prototype implementations and stakeholder-centred scenarios (Chapter 8).

6

6 The adProLiSS Methodology: A Consequence-Aware, Life-Cycle Approach from Design to Use

Methodology implements framework into life-cycle steps

Chapter 4 established the rationale for the consequence-aware, ontology-driven approach to prosthesis design and aftercare, while Chapter 5 translated this rationale into the conceptual architecture of the adProLiSS Framework. Building on these foundations, this chapter advances from framework to methodology, detailing how its principles are systematically enacted in practice. This chapter introduces the *adProLiSS Methodology: a consequence-aware, life-cycle approach from design to use*. Building on the conceptual architecture defined in Chapter 5, the methodology translates the framework into a structured sequence of operational steps that connect design intent with real-world prosthesis use. At its core, the methodology integrates consequence-awareness into each stage of the prosthesis life-cycle, ensuring that design, adaptation, and aftercare decisions are informed by explicit reasoning about both intended and unintended outcomes. By formalising this closed-loop, consequence-driven process, the methodology provides a practical means to bridge engineering design, clinical practice, and stakeholder experience within a single, adaptive service system.

This section now transitions from theory to practice, detailing how the framework is applied through explicit processes, tools, and decision flows that connect design intent with real-world prosthesis use.

6.1 Applying the adProLiSS Methodology

Methodology applies adProLiSS framework through structured steps.

Having defined the conceptual architecture of adProLiSS in Chapter 5, this section explains *how* the framework is systematically applied through an explicit, structured sequence of steps. The **adProLiSS Methodology** provides the practical application logic by which the three frames, the Custom Prosthesis Development Frame, the Prosthesis Adaptation Frame, and the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, interact to deliver an adaptive, consequence-driven prosthesis service system.

Framework vs methodology distinction; methodology = practical enactment with 16 stages.

At this point, it is useful to distinguish between a framework and a methodology. A *framework* provides the conceptual scaffolding that defines relationships between components and guides decision-making (Blessing and Chakrabarti, 2009; Wieringa, 2014). In contrast, a *methodology* translates this scaffolding into a structured sequence of processes, decisions, and supporting artefacts that can be systematically applied in practice (Gregor and Hevner, 2013; Venable, Pries-Heje and Baskerville, 2016). Accordingly, while Chapter 5 introduced the adProLiSS Framework as a high-level architecture, the present chapter elaborates the adProLiSS Methodology as its practical enactment, structured around sixteen sequential but interlinked stages.

Closed-loop cycle integrates stakeholders, performance data, and consequence knowledge.

Unlike traditional prosthesis development, which is typically linear and reactive, the adProLiSS Methodology establishes a **closed-loop design and feedback cycle**. This cycle systematically integrates **stakeholder requirements**, real-time prosthesis performance data, structured experiential consequence knowledge, and decision traceability into a single, coherent operational flow. This ensures that new designs continually benefit from accumulated knowledge and are adapted in response to real-world use.

Sixteen interlinked stages capture, formalise, and reuse knowledge.

The approach is built on sixteen sequential but interlinked stages (Figure 6.1). Together, these stages ensure that knowledge generated during design, realisation and in the use phase, is systematically captured, formalised and re-used.

Methodology functions: capture requirements, configure modules, tailor to cases, realise digital + physical, feedback into knowledge frame.

The methodology provides a means to:

- Systematically capture *stakeholder intentions, preferences, and context-specific circumstances and constraints*.
- Select and configure prosthesis and aftercare elements from a *curated library* of standard and customisable modules.
- Tailor general models to *specific amputee cases* using up-to-date anatomical, biomechanical, and lifestyle requirements.
- Realise the physical prosthesis in parallel with its *digital twin* (Batty, 2018), embedding sensors and real-time monitoring capacity.
- Feed back actual prosthesis performance data, amputee-prosthesis related health data and knowledge gained through stakeholder-prosthesis meetings (Eckert, Maier and McMahon, 2005; Huet *et al.*, 2007) into the **Prosthesis Life-Cycle Consequence Knowledge Modelling Frame,** ensuring that *future configurations* benefit from accumulated experience

Knowledge modelling frame accumulates multi-case, multi-stakeholder experiential knowledge.

The *Prosthesis Life-Cycle Consequence Knowledge Modelling Frame* is not limited to a single prosthesis or user. It continuously accumulates knowledge from multiple prostheses, different amputees, and diverse stakeholder contexts, forming a collective, reusable pool of structured experiential knowledge. This shared knowledge base allows stakeholders, for example, a prosthetist designing a device for an amputee in Malta, to draw on lessons learned from other devices and patients, even in different locations or earlier life-cycle phases.

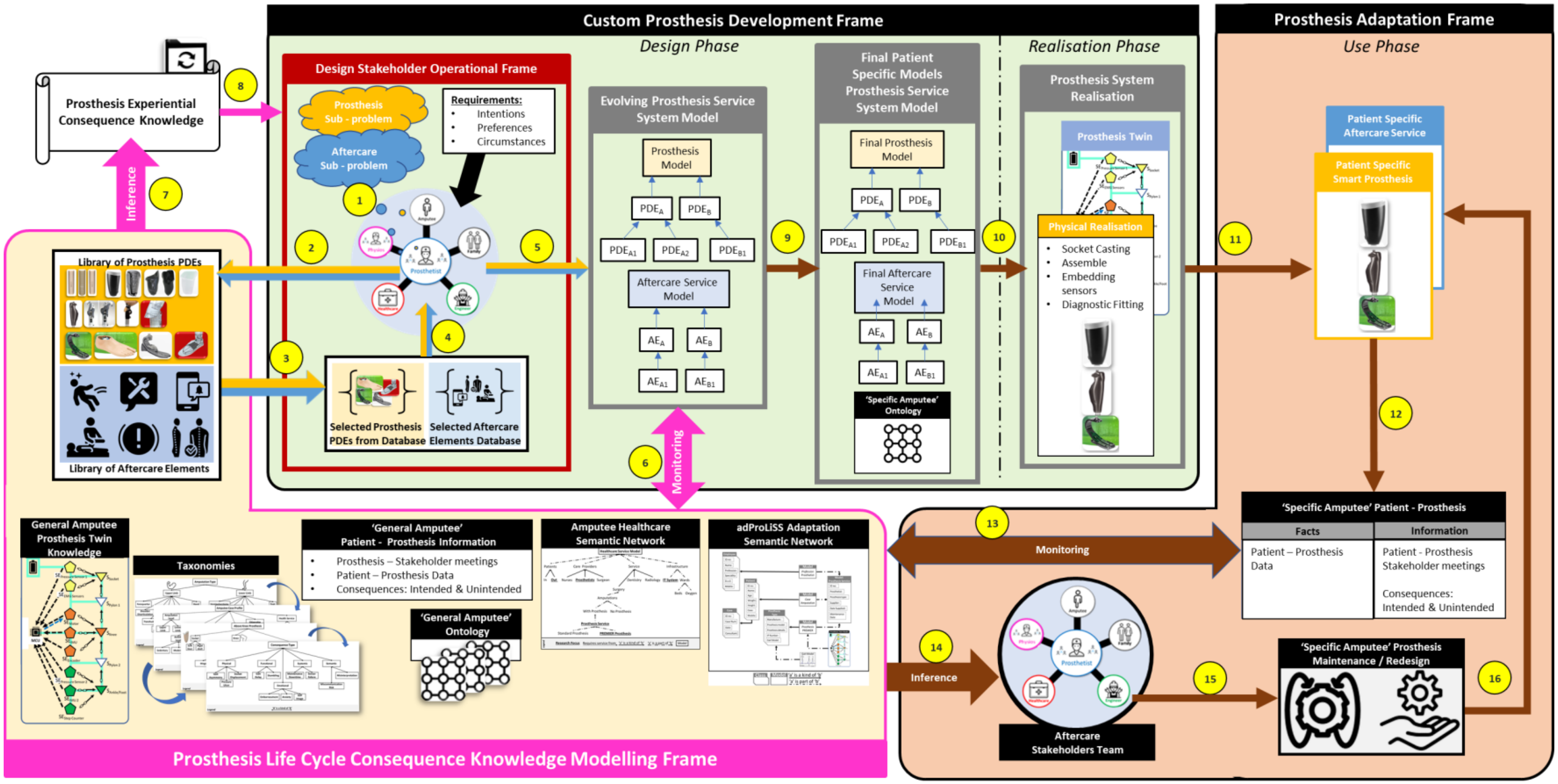


Figure 6.1: The adProLiSS Methodology

CD-CST as methodological construct embedding consequence reasoning in decisions.

The adProLiSS methodology is supported by the adProLiSS Consequence-Driven Co-Design Support Tool (CD-CST). At this stage, the CD-CST should not be understood as a technical tool but a methodological construct that formalises how consequence reasoning is embedded within stakeholder decision-making. It provides a structured model for key stakeholders to collaboratively and iteratively explore design alternatives in real-time, map intended / unintended and interaction / non-interacting consequences, and proactively identifying potential risks before physical implementation. By doing so, the CD-CST applies the ontology-driven reasoning layer within the methodology, ensuring that design and aftercare decisions are systematically evidence-based, collaborative, and traceable. For reasons of terminological consistency across this thesis, the construct is referred to as the CD-CST, even though its technological instantiation as a functional digital tool is only addressed in Chapter 8.

Loop closed: adProLiSS adapts continuously

Together, these components close the loop between design intent and use-phase reality, positioning adProLiSS as a fully integrated **Product-Service System** that continuously adapts to evolving functional and emotions needs of the amputee. The following sections detail this application frame by frame, beginning with the **Custom Prosthesis Development Frame**, which demonstrates how stakeholder requirements are translated into an engineered, patient-specific solution.

6.2 Applying the Custom Prosthesis Development Frame

Custom Prosthesis Development Frame, methodological anchor, translates intentions into engineered patient-specific solution.

The **Custom Prosthesis Development Frame** is the methodological anchor of the adProLiSS Methodology, the point at which stakeholder intentions are translated into an engineered, patient-specific solutions. In this frame, standard prosthetic modules (developed in the Standard Systems Development Frame, Chapter 5 section 5.1.3) are combined with custom aftercare pathways (developed within adProLiSS) and tailored to the individual amputee through collaborative co-design. The result is a fully personalised system that reflects the unique physiological, functional, and emotional needs of the individual amputee.

Stage 1: Design Stakeholder Operational Frame with dual sub-problems (prosthesis & aftercare) defined in co-design

The first stage of this frame is conducted within the **Design Stakeholder Operational Frame (step 1)**. Here, key decision stakeholders, the prosthetist (clinical authority and lead designer), the amputee and family (providing context-specific requirements and feedback), physiotherapists (rehabilitation specialists), and engineering and technical personnel, collectively define the *dual sub-problem* that drives the design process:

- The **prosthesis sub-problem** addresses anatomical fit, biomechanical function, and technical constraints.
- The **aftercare sub-problem** covers prosthesis maintenance, future reconfiguration, adaptation needs, amputee rehabilitation support, and aftercare support services.

Requirements formalised in meetings and mapped into knowledge frame.

These requirements are first formalised through structured stakeholder meetings and co-design sessions. They are then mapped into the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, which serves as a shared semantic structure aligning technical, clinical, and experiential stakeholder perspectives.

Steps 2–8: selection and evaluation of elements from PDE & aftercare libraries.

The key decision makers then examine the Library of Prosthetic Development Elements (PDEs) and the Library of Aftercare Elements (step 2). The aftercare elements represent configurable monitoring, support, and service components that enable ongoing prosthesis supervision, early detection of use-phase issues, and adaptive clinical intervention during daily use (for example, socket-embedded pressure, temperature, or humidity sensors to identify conditions leading to ulcer formation; plantar pressure sensors in the prosthetic foot to detect weight-distribution imbalances; or data-driven rehabilitation feedback and maintenance alert services). From these libraries, they select an initial set of candidate prosthesis and aftercare elements (step 3) that could satisfy the mapped sub-problems. This is followed by careful evaluation and combination of these elements (steps 4 - 8) to develop feasible configuration alternatives.

CD-CST, simulation, environment for reasoning

During this process, the adProLiSS Consequence-Driven Co-Design Support Tool (CD-CST) plays a critical role as a digital simulation environment that enables intentional/ unintended, interacting/non-interacting consequences.

consequence reasoning in real-time, before physical implementation. It allows stakeholders to visualise and compare intentional consequences (e.g. intended functional outcomes) alongside unintended consequences (e.g. emergent side-effects that may hinder or reshape the design goal). The CD-CST also supports reasoning about whether consequences interact, for example how an adjustment to reduce socket pressure might inadvertently affect gait stability, or remain non-interacting, such as improvements in liner material that do not influence electronic sensor performance.

CD-CST uses prosthesis experiential consequence knowledge

The CD-CST draws on the wealth of Prosthesis Experiential Consequence Knowledge that also includes lessons inferred from other prosthesis cases and other stakeholder contexts, ensuring that the design team benefits from shared collective knowledge pool, not only what is already known for this specific amputee. This includes:

- Historical consequence knowledge captured from prosthesis configurations and aftercare outcomes of previous amputees.
- Live digital twin simulations that predict and visualise how the impact of design choices influence multiple, possibly interacting outcomes such as gait dynamics, load distribution, durability, and user comfort.
- Stakeholder-driven scenario testing to explore trade-offs between competing goals (e.g. weight vs. durability, cost vs. adaptability).

Modelling of intentional, unintended, interreacting & non-interacting consequences

By modelling intentional, unintended, interacting, and non-interacting consequences explicitly (as explained in Chapter 4), the CD-CST enables stakeholders to evaluate *what-if* scenarios iteratively and digitally before physical realisation. This directly addresses a critical weakness of conventional prosthesis design, which relies on *trial-and-error* adjustments after delivery and often missing consequence chains (Roozenburg and Eekels, 1995; Walsh, Dong and Tumer, 2019; Patiniott and Borg, 2025).

Definition of design choice

Within the adProLiSS Methodology, a *design choice* refers to a discrete decision taken by the key stakeholders (prosthetist, amputee, physiotherapist and engineer) regarding the selection, configuration, or adaptation of a prosthesis or aftercare element. Such choices may involve trade-offs between competing criteria (e.g. comfort vs. weight, durability vs. cost) and generate multiple types of consequences, both intended and unintended, interacting and non-interacting.

Example: Interacting vs non-interacting design consequences

Take as an example a core design decision taken by the prosthetist in selecting a high-damping knee sub-system to improve swing-phase comfort. This produces an *intentional consequence* (reduced impact shock, improved comfort and improved mobility). However, this choice also generates an *unintended consequence* (increased cost and increased weight). The added weight and the intended comfort benefit *interact*, since the weight change may partially offset gait improvements. Meanwhile, a separate decision, for instance, selecting an advanced ventilated liner, produces a *non-interacting consequence* (better skin comfort) that does not affect the knee's damping or weight. However, this improved liner comfort also supports improved mobility by reducing skin irritation and discomfort. In this way, two non-interacting design decisions produce parallel consequence chains that converge on the same higher-level outcome (improved mobility). By making these causal and converging relationships explicit, the CD-CST helps stakeholders to reason about how multiple design choices create linked, interacting, or independent consequences before physical implementation.

Figure 6.2 illustrates linked intentional / unintended/ interacting consequences

This relationship is shown in Figure 6.2, which shows how intentional, unintended, interacting and non-interacting consequences emerge from a single design decision within the CD-CST.

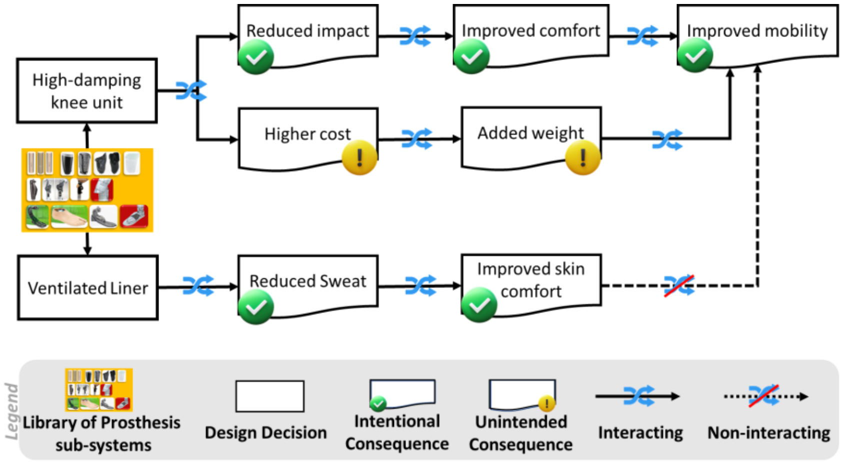


Figure 6.2: Illustrative example of intentional, unintended, interacting and non-interacting consequences as modelled within the CD-CST

Design logic draws on Human-Centred Design & Modular Product Architecture principles

This modular design logic draws on principles of Human-Centred Design (Norman, 2002; Giacomin, 2014; Wilkinson and De Angeli, 2014; Melles, Albayrak and Goossens, 2021; Leason *et al.*, 2022) and Modular Product Architecture (MPA)(Ulrich and Eppinger, 2016), allowing parametric selection of liners, sockets, knees, feet, and smart add-ons that adapt to individual biomechanical and functional requirements.

Figure 6.3: CD-CST as conceptual model integrating ontology & digital twin.

Figure 6.3 illustrates a conceptual model of the *Consequence-Driven Co-Design Support Model* (CD-CST). As a methodological model, the CD-CST provides a structured way for decision-makers to conceptualise the selection of prosthesis sub-systems, adjust design parameters, and simulate consequence scenarios in real-time. These interactions are framed by the adProLiSS ontology and digital twin representations, ensuring that consequence reasoning is explicitly integrated into design decision-making. The technological realisation of this model as a functional prototype is discussed in Chapter 8.

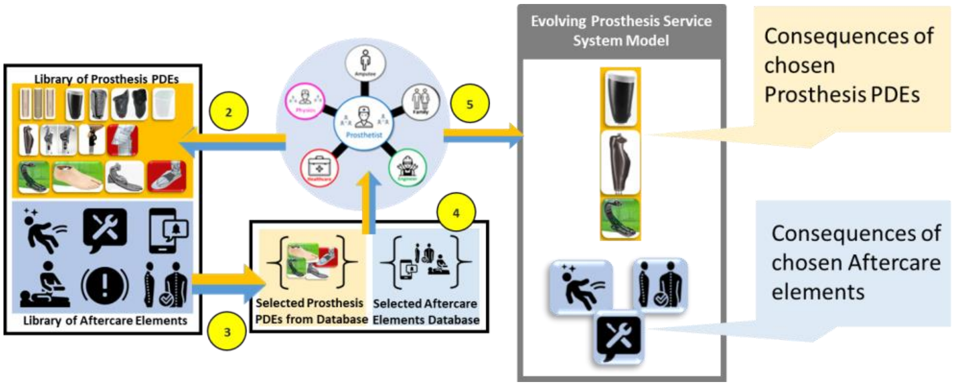


Figure 6.3: The adProLiSS Consequence-Driven Co-Design Support Tool (CD-CST)

Step 9: stakeholders negotiate and commit to final prosthesis/ aftercare solution

Once alternative solutions have been tested and the trade-offs have been evaluated in the CD-CST, stakeholders negotiate and collectively commit to a final prosthesis and aftercare solution (step 9). This reflects a structured configuration design approach (Darr, Klein and McGuinness, 1998) in which standard sub-systems from the PDE Library are selected and combined with the custom-fabricated socket and patient-specific specifications. Each decision point, its rationale, and the expected consequences (including potential unintended effects) are recorded within the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame for traceability and future learning by both the same team and others designing prostheses elsewhere.

Step 10: realisation phase in parallel with digital twin build, includes socket fabrication + sensors.

With the configuration validated, the realisation phase (step 10) proceeds in parallel with digital twin development. Anatomical measurements are used to fabricate the custom socket. Selected standard sub-systems (e.g. ankle or knee) are procured and integrated. Embedded sensors are installed to enable real-time monitoring of critical parameters, including socket pressure, temperature, and gait alignment.

Digital twin enables early detection, iterative refinement, and remains linked to CD-CST.

The digital twin mirrors the physical build, simulating expected performance under a range of use scenarios. This enables early detection of misalignments or risks, real-time simulation of operational conditions, and iterative refinement of both the physical prosthesis and its digital representation. The twin remains linked to the CD-CST, which remains accessible for further adjustments if testing reveals mismatches or unexpected issues.

Custom Prosthesis Development Frame improves design via 1) iterative co-design, 2) integration of data & simulation, 3) shared decision environment, 4) improved outcomes.

Through this integrated application, the Custom Prosthesis Development Frame is intended to show how the adProLiSS Methodology can advance conventional prosthesis design by:

1. Replacing linear, reactive decision chains with an iterative, consequence-driven, co-design loop grounded in ontology-based knowledge;
2. Integrating real-time sensor data, digital twin simulation, stakeholder knowledge, and consequence mapping to minimise unintended failures;
3. Formalising a shared decision environment for collaborative decision-making among key decision makers, providing structured, evidence-based influence over the final configuration;
4. Improving patient outcomes by enabling better design choices upfront, reducing costly physical rework, shortening iteration cycles, and lowering material waste.

Frame provides theoretically replicable foundation for adaptive, consequence-driven prosthetic systems

Together, these advances establish the *Custom Prosthesis Development Frame* as a theoretically replicable and scientifically grounded foundation for engineering next-generation customisable prosthetic systems. While its full implementation and validation in clinical and industrial settings remain future work, its structured operational logic and consequence-driven co-design loop demonstrate how adaptive, knowledge-rich development can better align prosthetic systems with real-world user variation and evolving amputee needs.

6.3 Applying the Prosthesis Adaptation Frame

Use Phase of adProLiSS, prosthesis deployed, monitored, adapted.

The **Prosthesis Adaptation Frame** represents the *Use Phase* of the adProLiSS Methodology, the phase at which the engineered, patient-specific prosthesis is deployed, used, monitored, and iteratively adapted to the amputee’s evolving needs and circumstances.

Contrasts with Custom Frame: development vs continuous adaptive loop for

Whereas the *Custom Prosthesis Development Frame* is intended to address *design and realisation*, the *Prosthesis Adaptation Frame* structures the *continuous adaptive* long-term alignment.

loop that ensures the prosthesis remains functionally, clinically, and emotionally aligned with the user throughout its life-cycle.

Step 11: delivery & fitting results in sensors generating real-time performance and health data.

Once the physical prosthesis is delivered and fitted (step 11), embedded sensors within the device begin to generate continuous real-time prosthesis performance and patient health data, for example, socket interface pressure, temperature and humidity levels, gait dynamics, and load distribution patterns.

Amputee provides subjective feedback on function, comfort, emotional state, rehab progress.

Throughout the use phase, the amputee can provide subjective feedback on prosthesis functionality, comfort, usability concerns, emotional responses and rehabilitation progress, clarifying whether the prosthesis continues to meet their evolving requirements.

Step 12: stakeholder–prosthesis meetings combine objective data (temperature, pressure) with subjective feedback to inform adaptation.

During stakeholder–prosthesis meetings (step 12), stakeholders (for example, the prosthetist) combine objective sensor data (such as increased socket temperature, moisture or pressure) with the amputee’s subjective feedback (such as reports of socket discomfort) to make more informed decisions about adaptations, ensuring that the prosthesis and its services remain aligned with evolving user needs. Together, these complementary streams provide a holistic picture of the patient-prosthesis interaction under real-world conditions.

Step 13: knowledge modelling frame applies ontology-based reasoning to map data and consequences to design intent.

The real-time sensor data and stakeholder experiential feedback are monitored through the *Prosthesis Life-Cycle Consequence Knowledge Modelling Frame* (step 13). This frame applies ontology-based semantic reasoning to map incoming data sensor data, stakeholder experiential feedback and consequences to previously recorded consequence knowledge and original design intent.

Potential issues flagged (e.g., socket pressure, gait deviations), visualised in PPMS (conceptual at this stage).

Patterns indicating potential issues, such as elevated socket pressure that may cause ulceration, or gait deviations suggesting misalignment, are flagged automatically within the knowledge frame and visualised through the *Patient-Prosthesis Management System* (PPMS). For reasons of consistency across this thesis, the concept is referred to as the PPMS, even though at this stage it represents a methodological model; its technical instantiation is discussed later in Chapter 8.

Figure 6.4 PPMS model: records patient & next-of-kin details, embeds monitoring within care context.

The conceptual model of the PPMS (Figure 6.4) illustrates how patient and prosthesis-related information is organised into distinct but interconnected sections. Patient details, such as name, ID, and contact information, are recorded alongside corresponding details for the next of kin, ensuring that clinical monitoring is embedded within a wider care context. The model also incorporates a dedicated alarms area, which symbolically flags safety-critical events requiring urgent attention, and modular data streams that capture input from socket, knee, and foot sensors. These quantitative measures are visually linked to the three principal prosthesis components, each of which is accompanied by a traffic-light indicator to provide an immediate overview of component status. Complementing the sensor data, a patient observations section allows individuals to log their own experiences and feedback, thereby ensuring that qualitative insights are integrated into aftercare. Taken together, the model conveys the dual character of the PPMS as both a data-driven and human-centred system, combining structured monitoring with opportunities for patient participation in the management of their prosthesis.

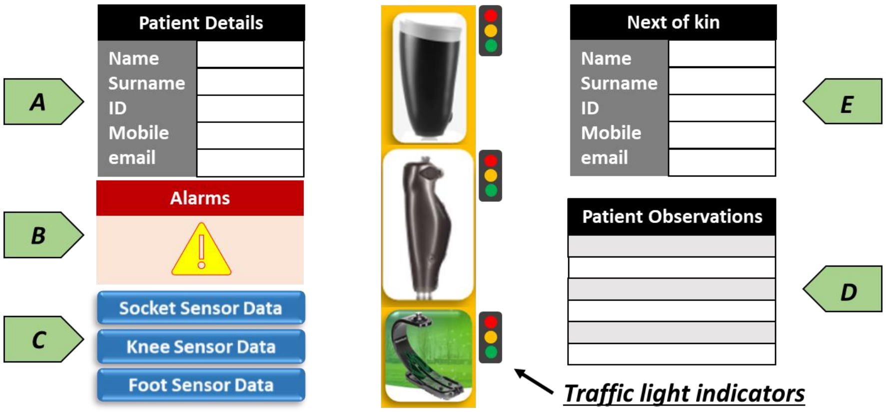


Figure 6.4: Conceptual view of the Patient-Prosthesis Management System (PPMS)

PPMS is a role-based dashboard aggregating data, feedback, and reasoning for stakeholder-specific views

The PPMS represents a secure, role-based dashboard architecture that aggregates real-time sensor data, usage history, experiential feedback, and consequence reasoning into stakeholder-specific views. The actual implementation platform may vary; what is central here is the model's ability to structure consequence-driven monitoring and collaborative adaptation. In this model, information is presented in role-specific formats: amputees, prosthetists, physiotherapists, and engineers access tailored insights relevant to their responsibilities, enabling data-driven adjustments, monitoring, and coordinated service delivery. By acting as the primary interface for the prosthesis digital twin, the PPMS supports consequence-driven monitoring, collaborative decision-making, and adaptive service delivery, without presupposing any particular technical implementation. This interface would include live sensor streams, usage consequences, and adaptation recommendations in a format suited to each stakeholder's role.

Transforms raw data & experiential feedback into reusable consequence knowledge

In this way, adProLiSS transforms raw data and stakeholder experiential feedback, into actionable knowledge that can be interpreted, verified, and acted upon. Importantly, each new consequence recorded though this process not only informs the future adjustments for the same user but becomes part of the share knowledge base that benefits other prosthesis cases, broadening the pool of reusable experience.

Steps 14–15: aftercare team reviews inference output, co-decides on adjustments or redesign.

In steps 14–15, the *Aftercare Stakeholders Team*, including the prosthetist, physiotherapist, engineering and technical personnel, and the amputee, reviews the inference output to co-decide on necessary adjustments, maintenance, and re-design should it be needed. Examples include socket re-alignment, component substitution, or revising rehabilitation routines.

Step 16: CD-CST supports testing interventions before physical implementation

This collaborative decision-making is supported by the *CD-CST*, which remains accessible for consequence simulation. By testing possible interventions, stakeholders can compare alternative actions and minimise the risk of unintended negative impacts. Approved adaptations are then physically implemented (step 16), ensuring that the prosthesis and its associated services evolve responsively.

Tables 6.1a summarises the sixteen stages described above, linking each to its methodological frame, purpose, inputs, outputs, and associated knowledge entries

Table 6.1: Summary of the 16 Stages of the adProLiSS Methodology

Step	Frame	Purpose	Key Inputs	Key Outputs	Knowledge Entries
1	Design Stakeholder Operational Frame	Elicit requirements and define dual sub-problem (prosthesis & aftercare)	Amputee needs, clinical data, stakeholder input	Structured requirement set	Initial consequence entries
2	Custom Prosthesis Development Frame	Query PDE and Aftercare Libraries for user solution	PDE Library, Aftercare Library	User elements	Trace links to requirements
3	Custom Prosthesis Development Frame	Select preliminary prosthesis and aftercare elements	User set, constraints	Initial shortlist	Requirement – element mapping
4	Custom Prosthesis Development Frame	Evaluate and combine shortlisted elements	Shortlist, design rules	Feasible configurations	Emerging consequence annotations
5	Custom Prosthesis Development Frame and CD-CST	Simulate configurations; explore alternatives	Configuration sets, ontology	Comparative scenarios	Consequence maps (intended / unintended; interacting / non-interacting)
6	Custom Prosthesis Development Frame and CD-CST	Analyse interacting / non-interacting, intended /unintended consequences	Simulation outputs	Trade-off insights	Linked consequence chains
7	Custom Prosthesis Development Frame and CD-CST	Run stakeholder-driven what-if scenario testing	Stakeholder goals, scenario data	Tested alternatives	Scenario consequence records
8	Custom Prosthesis Development Frame	Refine feasible alternatives	Simulation results, trade-off insight	Configuration options	Refined rationale entries
9	Custom Prosthesis Development Frame	Negotiate and commit to final design solution	Evaluated options, stakeholder preferences	Agreed prosthesis and aftercare configuration	Decision rationale and consequence log
10	Custom Prosthesis Development Frame	Realise prosthesis and digital twin parallel	Anatomical measures, selected sub-systems, fabrication data	Physical prosthesis and digital twin model	Initial twin validation outcomes
11	Prosthesis Adaptation Frame	Deliver and fit prosthesis to amputee	Fabricate prosthesis, fitting procedures	Deployed device	Fit records, baseline performance data
12	Prosthesis Adaptation Frame	Collect amputee feedback and stakeholder review	User feedback, clinical observation	Qualitative feedback dataset	Subjective consequence entries
13	Prosthesis Adaptation Frame and Consequence Knowledge Frame	Integrate sensor data with experiential knowledge	Real-time sensor streams, feedback	Inference and consequence mapping	Updated knowledge base
14	Prosthesis Adaptation Frame	Stakeholder meeting to review consequence inference	PPMS dashboard, inference outputs	Identified adaptations	Proposed adaptation entries
15	Prosthesis Adaptation Frame and CD-CST	Test alternative interventions digitally	Proposed adaptations, CD-CST simulations	Ranked options	Simulated consequence chains
16	Prosthesis Adaptation Frame	Implement adaptations and continue prosthesis use	Agreed intervention, physical device	Adjusted prosthesis and updated aftercare plan	Finalised adaptation long

Sixteen stages: CDP Frame (1–10): co-design & digital twin; PA Frame (11–16): adaptive use-phase; all feed into knowledge modelling

As shown in Table 6.1, the sixteen stages collectively demonstrate how the adProLiSS Methodology closes the loop between design and use. The Custom Prosthesis Development Frame (steps 1–10) establishes a structured co-design process that captures stakeholder requirements, explores alternatives through consequence reasoning, and realises the prosthesis alongside its digital twin. The Prosthesis Adaptation Frame (steps 11–16) then extends this process into the use phase, combining live sensor data, experiential feedback, and ontology-driven inference to support adaptive decision-making. Together, these stages ensure that every design choice, adaptation, and aftercare action contribute systematically to the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, reinforcing the methodology's consequence-aware, knowledge-driven character.

PPMS is a role-based digital twin dashboard integrating sensors, reasoning, and stakeholder views; Figure 6.5 shows SysML structural model.

In methodological terms, the PPMS can be conceived as a role-based, cloud-enabled dashboard architecture capable of integrating live data streams from embedded prosthesis sensors with consequence reasoning and stakeholder-specific views. While different technical platforms could instantiate this model, its scientific contribution lies in demonstrating how digital twin principles can be applied to prosthesis care. To clarify how sensor sub-systems, data processing, and stakeholder interaction integrate structurally, Figure 6.5 presents a SysML-style (*An OMG Systems Modelling Language*, 2017) Prosthesis Digital Twin Structural and Information Model. This model represents the methodological logic of how real-time sensor data, embedded control rules, and human–machine interfaces form an interconnected cyber–physical layer that supports consequence-based reasoning, live feedback, and adaptive control within the adProLiSS framework.

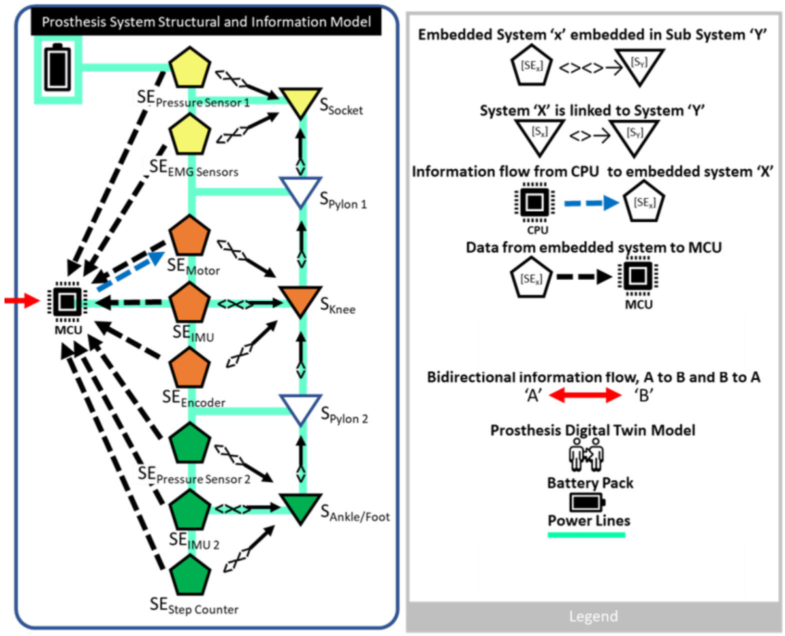


Figure 6.5: SysML-style Prosthesis Digital Twin Structural and Information Model

Adaptation Frame extends to sustainability: repurposing usable modules, recycling worn parts; decisions documented in knowledge frame

Beyond day-to-day monitoring and adjustments enabled by the PPMS, when components reach the end of their usable life, the *Prosthesis Adaptation Frame* extends its scope to sustainability. Standard sub-systems that remain functional but no longer fit the current amputee's needs are documented and repurposed within the adProLiSS library for future configurations. Worn-out components are disassembled and responsibly recycled.

Sustainability decisions produce intended + unintended outcomes; trade-offs (reuse vs. new tech) are systematically recorded

Sustainability decisions are also captured within the Consequence Knowledge Frame, since choices about re-use, substitution, or recycling generate both intended and unintended outcomes that affect future prosthesis design. For example, reusing a knee joint module may lower costs and environmental impact but could also constrain adaptation if newer, lighter alternatives are available. By systematically recording these trade-offs, the Adaptation Frame ensures that sustainability becomes an explicit, knowledge-driven dimension of the prosthesis life-cycle.

All consequences (intended, unintended, interacting, non-interacting) added to Consequence Knowledge Frame

All detected consequences, both intended, unintended, interacting and non-interacting are systematically added to the *Prosthesis Life-Cycle Consequence Knowledge Modelling Frame*. This ensures that each use-phase outcome enriches for cumulative learning

the shared experiential knowledge base that supports future stakeholder decision-making.

Addresses limits of traditional aftercare (fragmented, reactive); embeds real-time monitoring, reasoning, and knowledge reuse.

The *Prosthesis Adaptation Frame* directly addresses the limitations of traditional prosthesis aftercare [see Chapter 4], which is fragmented*,* reactive*,* and insufficiently grounded in real-world, in-use context (Walsh, Dong and Tumer, 2019). By embedding real-time monitoring, structured consequence inference, and a knowledge re-use mechanism, adProLiSS proposes a scientifically grounded, consequence-driven approach for continuous prosthesis adaptation.

Shift from reactive to proactive: stakeholders anticipate/manage evolving needs within closed-loop system.

Rather than reacting only when problems arise, this approach aims to enable stakeholders to *anticipate* and *proactively manage* evolving physical, functional, and emotional requirements within a closed-loop service system.

Four advances:

When applied as intended, the *Prosthesis Adaptation Frame* has the potential to advance prosthesis aftercare in four key ways by:

Real-time data & feedback integration;

1. Integrating real-time patient-prosthesis data and key stakeholder (amputee, prosthetist, physiotherapist and engineer) experiential feedback with ontology-based consequence reasoning;

Collaborative learning

2. Formalising collaborative learning among key stakeholders (amputee, prosthetist, physiotherapist and engineer) the frame enables the integration of subjective experience with objective sensor data;

Adaptive interventions

3. Linking live monitoring to adaptive service interventions that may minimise complications and extend device life;

Reusable consequence knowledge.

4. Ensuring that each use-phase cycle contributes systematically to a growing body of reusable consequence knowledge, supporting future prosthesis design and service improvements.

Frames adProLiSS as testable, adaptive system architecture with future real-world impact.

Together, this frames adProLiSS not merely as a design method, but as a testable, adaptive system architecture for next-generation prosthesis care, with its practical impact contingent on future real-world implementation and validation.

Shared knowledge across prostheses builds collective intelligence benefiting wider amputee/ stakeholder community.

Because this consequence knowledge is shared across prostheses and contexts, each adaptation cycle contributes not only to the individual patient's future care but to a collective pool that supports better decisions for other amputees and stakeholders worldwide.

Adaptation Frame: practical mechanism & methodological artefact; shows consequence-based reasoning in healthcare CPS, extensible across contexts

In this way, the Adaptation Frame functions not only as a practical mechanism for continuous prosthesis adjustment, but also as a methodological artefact that demonstrates how consequence-based reasoning can be embedded within healthcare cyber–physical systems. Its value lies in structuring processes that are replicable, knowledge-driven, and extensible across contexts, independent of any single technological instantiation.

6.4 Chapter Conclusion

Methodology: 16-stage, closed-loop process linking design intent to real-world use

This chapter has presented the adProLiSS Methodology: a consequence-aware, life-cycle approach from design to use. Grounded in the rationale of Chapter 4 and the conceptual architecture of Chapter 5, the methodology structures adProLiSS into sixteen interlinked stages that connect stakeholder intent with real-world prosthesis use. It integrates requirement capture, ontology-driven consequence knowledge, digital-twin representations, and role-based decision support into a closed-loop process spanning design, realisation, and adaptation.

Custom Frame with co-design loop; Adaptation Frame has continuous alignment; CD-CST & PPMS introduced as models

Through the *Custom Prosthesis Development Frame*, the methodology replaces linear, reactive practices with a consequence-driven co-design loop, enabling transparent trade-offs and traceable rationale. Through the *Prosthesis Adaptation Frame*, it formalises continuous alignment between user and device by combining live sensing, stakeholder feedback, and semantic inference within a shared knowledge structure. The *Consequence-Driven Co-Design Support Tool* (CD-CST) and the *Patient–Prosthesis Management System* (PPMS) are introduced here as methodological models that embed consequence reasoning and role-based decision support; their technological realisation is treated separately.

Methodology: replicable foundation; bridges design intent with use-phase reality.

While large-scale clinical and industrial deployments are future work, the methodology establishes a scientifically grounded, replicable foundation for consequence-aware prosthesis design and aftercare. By systematically bridging design intent with use-phase reality, it provides the application logic necessary to realise the ambitions of the adProLiSS Framework and prepares the ground for empirical assessment.

The next chapter details prototype implementations and demonstrator scenarios that instantiate these models, followed by the evaluation (Chapter 9), where methodological effectiveness, usability, and impact are assessed with stakeholders.

7

7 The Prosthesis Life-Cycle Consequence Knowledge Modelling Frame

The Prosthesis Life-Cycle Consequence Knowledge Modelling Frame represents the foundational knowledge backbone of the entire adProLiSS Methodology. While Chapter 6 sections 6.2 to 6.3 describe how the *Custom Prosthesis Development Frame* and the *Prosthesis Adaptation Frame* operate in practice, this section details how and why the Consequence Knowledge Modelling Frame makes this continuous, consequence- driven learning possible.

Formalises PLCCKMF as semantic backbone

This chapter presents the formalisation and implementation of the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, which serves as the semantic backbone of the adProLiSS framework. Section 7.1 introduces the role of consequence knowledge in smart prosthesis design and how it underpins decision support across stakeholder groups. Section 7.2 establishes the knowledge modelling foundations of this frame, including the ontology structure, formalisation level, and computability rationale. Section 7.3 presents a structured set of semantic rules, expressed in SWRL and OWL, that encode domain-specific consequence logic. These examples demonstrate how raw sensor events, stakeholder interactions, and patient states are semantically transformed into traceable, machine-executable consequences. Section 7.4 expands on the system's reasoning capabilities and the symbolic AI mechanisms that operationalise stakeholder coordination in real time. Section 7.5 concludes the chapter by highlighting the importance of semantic knowledge reuse, consequence feedback loops, and ontology-driven simulation for future adaptive prosthesis design and aftercare cycles.

Symbolic AI: SWRL rules, reasoning & reuse

7.1 Purpose and Scientific Rationale

The life-cycle performance of a lower-limb prosthesis does not depend solely on its initial design and fabrication; it depends on how design choices, real-world use, stakeholder interventions, and unintended consequences are systematically captured, understood, to make better future design decisions. Conventional design approaches often fail to capture this evolving complexity, leading to repeated mistakes, missed learning opportunities, and a lack of transparency and traceability (Eckert, Maier and McMahon, 2005; Walsh, Dong and Tumer, 2019).

The *Prosthesis Life-Cycle Consequence Knowledge Modelling Frame* directly addresses this gap. It provides a **formal, ontology-driven structure** for collecting, structuring, and reasoning over experiential consequence knowledge generated throughout the prosthesis life-cycle. *How* this is achieved is by combining:

Semantic modelling showing interacting relationships

- **Semantic Modelling**, which formally defines the relationships between prosthesis components, stakeholder roles, design decisions, and real-world consequences. For example, the ontology may assert that a high-stiffness knee unit installed for an above-knee amputee increases the likelihood of gait instability, necessitation physiotherapy. These relationships are encoded using domain classes such as *KneeUnit, AmputeeType, GaitPattern, Stakeholder,* and object properties like *hasComponent, affectsStability,* and *requiresInterventionBy*.

  This can be formalised in SWRL as:

  (7.1) Prosthesis(?p) ^ hasComponent(?p, Knee_StiffHigh) ^ assignedTo(?p, ?a) ^ Amputee(?a) ^ hasAmputationType(?a, "above-knee") → increasesRisk(?p, GaitInstability)

  These semantic assertions and rule-based inferences ensure that the relationships between design configurations, biomechanical outcomes, and service actions are not only formally structured but also computationally traceable.

Consequence logic, linking intended & unintended effects

- **Consequence Inference Logic**, which computationally links both intended and unintended effects back to design intent using formal rules. For instance, a socket modification aimed at redistributing pressure might inadvertently cause excessive distal loading, leading to ulcer risk.

  This is formalised using SWRL as:

  (7.2) PressureEvent(?x) ^ hasValue(?x, ?v) ^ swrlb:greaterThan(?v, 175) ^ hasLocation(?x, "DistalRegion") → triggers(?x, UlcerRisk)

  This rule enables the ontology to infer that if pressure exceeds 175 units at the distal site, the condition should be flagged as a risk for ulceration. Through such logic, the system captures unintended consequences and links them to the originating design or adaptation.

Definition of knowledge structures

- **Reusable Knowledge Structures**, which ensure that each new data point, whether from sensor-derived, clinical observation, or stakeholder generated feedback, is semantically integrated into a growing body of consequence knowledge. This consequence knowledge is not only linked to a particular amputee case, but rather to a collective knowledge base spanning multiple amputee cases. For example, multiple recorded cases where gait asymmetry following postural regression correlated with socket misalignment can be generalised into an inference rule:

  (7.3) GaitAsymmetry(?g) ^ follows(?g, PosturalRegression) → indicates(?g, SocketMisalignment)

  These structures allow knowledge to be retained and reused across cases, enabling future prosthesis configurations to benefit from previously observed patterns and outcomes. As such, individual learning events become collective design assets.

This knowledge backbone forms the core of adProLiSS's adaptive capability. By making design consequences visible and computable, it enables the closed-loop system described in Chapter 6 sections 6.2 – 6.3.

7.2 Ontology Structure and Core Networks

PLCCKMF, purpose-built multi-layer domain ontology

At the heart of the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF) is a multi-layered, dynamic, domain-specific ontology that organises all relevant entities, relationships, states, and consequences that emerge throughout the prosthesis life-cycle. Unlike general medical coding schemes such as SNOMED CT (Donnelly, 2006), which provide broad clinical terminologies, the adProLiSS ontology is purpose-built to map the *specific functional, emotional, and consequence-related relationships* unique to smart prosthesis design and adaptive aftercare.

Figure 7.1 shows the position of the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame within the broader adProLiSS Methodology.

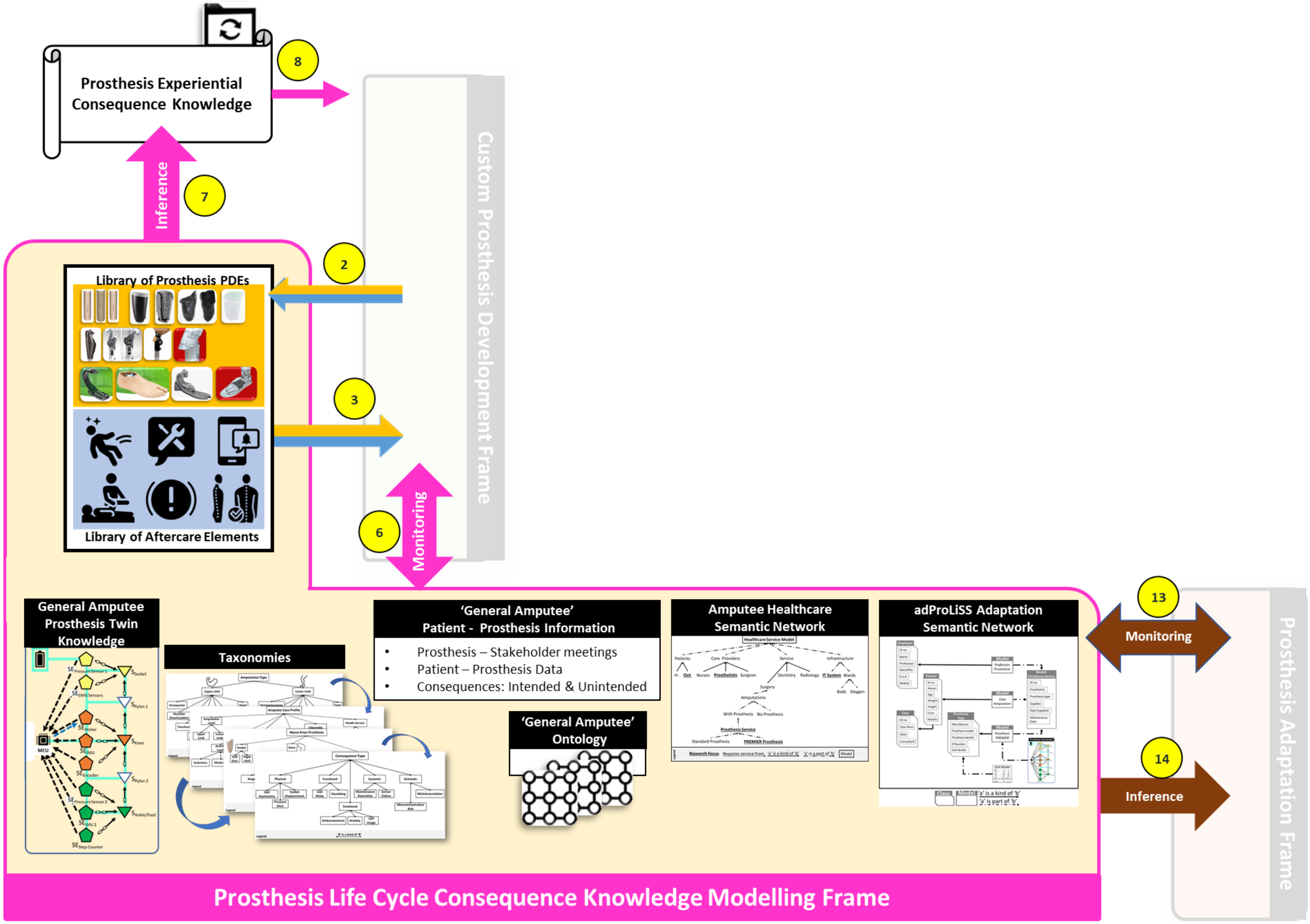


Figure 7.1: The Prosthesis Life-Cycle Consequence Knowledge Modelling Frame within the adProLiSS Methodology

7.2.1 Knowledge Codification and the Need for Compatibility

Tacit vs codified knowledge

In high-stakes, multi-stakeholder domains such as prosthesis design and aftercare, knowledge exists along a spectrum of formality and computability. Drawing from (Studer, Benjamins and Fensel, 1998b; Keet, 2018; Mizoguchi and Borgo, 2025b) knowledge may be unrecognised, tacit, recognised, or codified, ranging from intuitive practitioner know-how to structured rules and digital models. While tacit and unrecognised knowledge (e.g. expert intuition, user emotions) remain valuable, they are inherently non-computable and difficult to systematise or reuse.

Ontology for computable reasoning

To support real-time, explainable reasoning in the adProLiSS framework, stakeholder knowledge must therefore be formalised, codified, and made machine-processable. This codification is implemented through an OWL ontology and SWRL rule base, enabling the semantic linking of sensor data, stakeholder actions, and prosthesis design consequences. The ontology transforms recognised domain knowledge (e.g. ulcer risks, prosthetist actions) into a computable knowledge base that supports digital twin updates, service planning, and consequence learning. This aligns with engineering principles of design knowledge reuse, traceability, and system-level decision integration (Hitzler et al., 2010; Keet, 2018).

7.2.2 Degree of Ontology Formalisation

Ontology Formalisation spectrum

The adProLiSS ontology exhibits a formalisation level that *spans from semi-formal to rigorously formal* (Figure 7.2), in line with updated ontology engineering classifications (Hitzler, Krotzsch and Rudolph, 2009; Blomqvist, Hammar and Presutti, 2016; Keet, 2018). As such, ontologies can be categorised along a spectrum ranging from *informal* (natural language), to *semi-informal* (structured glossaries), *semi-formal* (structured conceptual models with constraints), and *rigorously formal* (logically defined using description logics, axioms, or formal rules).

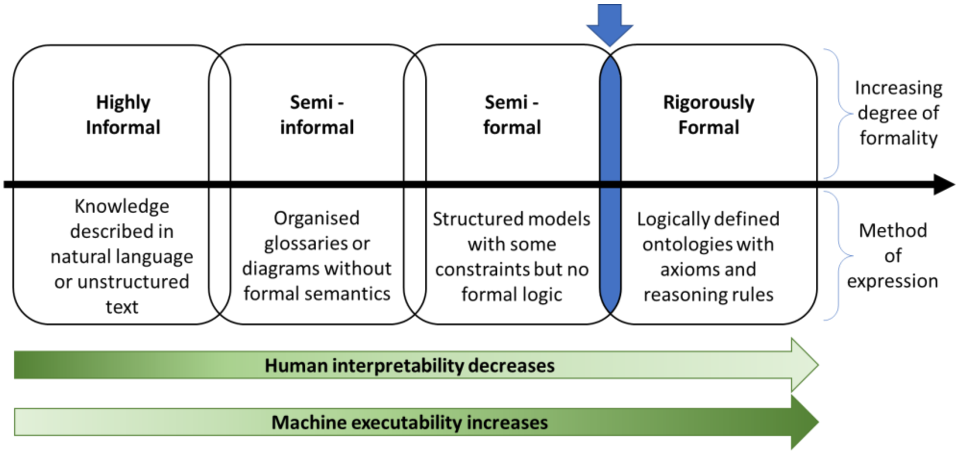


Figure 7.2: adProLiSS position within the Ontology Formalisation Spectrum

Above semi-formal, not full formal

The semantic structures implemented in adProLiSS, such as OWL-based class hierarchies, object/data properties, and SWRL rules, exceed the threshold of semi-formal ontologies by enabling automated reasoning and rule-based inference within tools like Protégé. However, because the ontology deliberately prioritises real-world usability and stakeholder transparency over full logical closure (e.g. not all axioms are defined using first-order predicate logic), it remains short of the fully formal end of the spectrum.

Balanced formality for usability

This level of formality was deliberately selected to support machine-readability, rule-based inference, semantic traceability, and knowledge reuse while still maintaining accessibility for non-technical stakeholders during co-design workshops. The integration of Manchester OWL Syntax fragments, structured SWRL rules, and machine-executable consequence chains further reinforces the ontology’s formal grounding.

Codification ensures reasoning & reuse

This aligns with knowledge engineering principles that recommend the codification of domain expertise into computable ontologies to ensure traceability, reasoning, and knowledge reuse (Keet, 2018; Belani, Solic and Perkovic, 2022; Cocco *et al.*, 2024; Mizoguchi and Borgo, 2025b). In the context of prosthesis life-cycle design and adaptive aftercare, this computable codification supports dynamic consequence reasoning, cross-stakeholder alignment, and case-based experiential learning across the prosthetic ecosystem.

Healthcare ontologies as parallels

Such formalisation is particularly necessary in healthcare-mechatronic systems like smart prosthetics, where complexity, risk, and personalisation intersect. Modern systems such as the ADCATER ontology (Cocco *et al.*, 2024) and the UiA eHealth ontology (Chatterjee *et al.*, 2021) exemplify practical, OWL-based formalisation combined with reasoning and sensor-derived inference, similar to the approach taken in adProLiSS

Multi-layered ontology structure

The *Prosthesis Life-Cycle Consequence Knowledge Modelling Frame* is formalised through a modular, domain-specific ontology that adheres to established and contemporary practices in ontology engineering (Borst, Akkermans and Top, 1997; McGuinness and van Harmelen, 2004a; Schlieder *et al.*, 2020; Hogan *et al.*, 2021). Rather than developing multiple independent ontologies, the system adopts a *multi-layered architecture* that distinguishes between generalised, reusable domain knowledge and individualised, patient-specific knowledge. These layers, hereafter referred to as the *General Amputee Prosthesis Ontology Layer* and the *Specific Amputee Prosthesis Ontology* Layer, are semantically integrated within a single OWL-based ontology to ensure interoperability, scalability, and inferential consistency across the prosthesis life-cycle.

Synchronising general & specific knowledge

This layered approach enables the system to separate and synchronise declarative engineering, clinical, and experiential knowledge (upper layer) with real-time, context-specific procedural knowledge (lower layer) to support dynamic consequence-based reasoning. In this modular structure, the General Ontology Layer functions as the upper layer, representing abstract, reusable domain knowledge, while the Specific Ontology Layer serves as the lower layer, instantiating real-time, context-aware information for individual amputee cases.

The ontology is structured into two core layers:

General Amputee layer, reusable

a) **The General Amputee Prosthesis Ontology Layer:** This upper layer defines the core declarative knowledge that spans all amputee cases, formalising the domain knowledge layer

entities, relationships, constraints, and patterns that characterise prosthesis design and aftercare. It includes standardised representations of prosthesis sub-systems (e.g. sockets, liners, knees, feet), engineering parameters (e.g. material stiffness, damping coefficients), clinical fitting parameters (e.g. residual limb length, residual limb volume), and typical stakeholder roles (e.g. prosthetist, physiotherapist, amputee, engineer). It also encodes canonical consequence types and patterns (e.g. high-pressure ulceration, gait asymmetry, mechanical wear). It is designed to be reusable and extensible, covering all prosthesis types across all amputee case. Stored in OWL, this layer ensures semantic consistency and computational interoperability across all use cases, connecting technical engineering knowledge with clinical knowledge and user-centred feedback.

As an example of declarative knowledge expressed in formal notation, the ontology may assert that a prosthesis *p* includes a socket with high stiffness and is assigned to a specific amputee, as follows:

(7.4) Prosthesis(?p) ^ hasComponent(?p, Socket) ^ hasMaterialStiffness(Socket, "high") ^ assignedTo(?p, Amputee_Jane)

This semantic rule expresses class–property–value relationships without defining any procedural logic. It forms part of the static, reusable knowledge that underpins consequence reasoning and system-wide consistency.

Patient specific, real-time knowledge

b) **The Specific Amputee Prosthesis Ontology Layer:** This lower layer instantiates the general classes for a particular patient, capturing their real-world context and dynamic use-phase events. It links real anthropometric data, prosthesis configuration, real-time sensor inputs (e.g. pressure, acceleration, temperature), observed consequences, subjective stakeholder reports, and context-specific service plans. Procedural knowledge is represented through semantic rules and if-then logic (e.g. using SWRL), enabling automated reasoning about how real-time conditions map to inferred risks and recommended interventions. This layer is tightly integrated with the prosthesis digital twin, which mirrors the amputee's current prosthesis state. This enables the detection of patterns, automatic consequence reasoning and live feedback. For example, repeated high-pressure readings at the distal socket region may trigger a rule that infers ulcer risk and prompts a service plan update.

7.2.3 Structured Taxonomies for Prosthesis and Amputee Knowledge

Structured taxonomies enable reuse

A central requirement of the PLCCKMF is the ability to represent complex, heterogeneous knowledge in a form that is both reusable and scalable across prosthesis types and amputee cases. To achieve this, the ontology incorporates structured taxonomies that formalise domain knowledge into hierarchical classes and subclasses. These taxonomies provide the semantic scaffolding upon which inference rules can operate, ensuring that knowledge about prosthesis components, amputee profiles, and consequence types can be generalised, specialised, and reused across different contexts. By explicitly organising entities into structured categories, the PLCCKMF reduces knowledge duplication, supports inheritance of properties and consequences, and enables consistent reasoning across multiple levels of abstraction. Importantly, such taxonomies also demonstrate how the framework can extend beyond individual use cases, scaling to capture diverse prosthesis configurations, patient conditions, and multi-stakeholder interactions.

Defined taxonomy categories

The taxonomies are as follows: a) Amputation Types; b) Amputee Case Profiles; c) Anthropometric Ratios and Prosthesis Aesthetics; d) Prosthesis Component types; e) Prosthesis Consequence Types; f) Taxonomic Integration for Consequence Reasoning.

a) Amputation Types

Amputation type: Clinical context for reasoning

A foundational taxonomy underpinning the PLCCKMF is the classification of amputation types, which provides the clinical context within which prosthesis design and consequence reasoning must operate. Figure 7.3 and Table 7.1-7.2 present this taxonomy, which distinguishes between upper limb and lower limb amputations, and further refines these into specific levels of limb loss. Upper limb amputations include Forequarter, Shoulder Disarticulation, Transhumeral, Elbow Disarticulation, Forearm (Transradial), Wrist Disarticulation, Hand, and Finger. Lower limb amputations include Hemipelvectomy, Hip Disarticulation, Above-Knee (Transfemoral), Knee Disarticulation, Below-Knee (Transtibial), Ankle Disarticulation, Foot, and Toe. Each level of amputation carries distinct biomechanical, clinical, and psychosocial implications, shaping both the prosthetic components required and the types of consequences likely to arise during rehabilitation and long-term use. By embedding this taxonomy into the ontology, the PLCCKMF ensures that all subsequent reasoning about prosthesis components, user profiles, and consequence propagation is grounded in clinically validated categories of limb loss. This provides the semantic foundation for tailoring prosthesis design to specific amputation contexts while maintaining scalability across the full spectrum of cases.

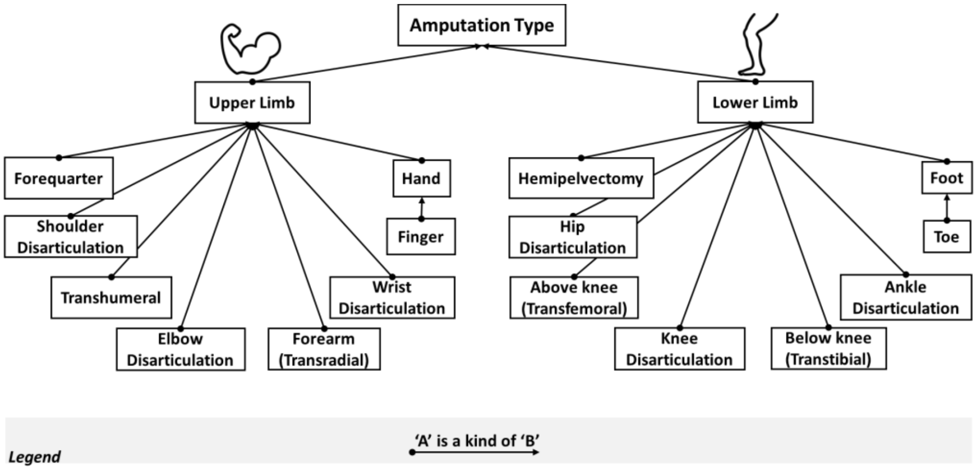


Figure 7.3: Amputation Types

Table 7.1: Upper Limb Amputations

Sub-class	Notes
Forequarter	Amputation through clavicle and scapula
Shoulder disarticulation	Through shoulder joint
Transhumeral	Above elbow
Elbow disarticulation	Through elbow joint
Forearm (transradial)	Below elbow
Wrist disarticulation	Through wrist joint
Hand	Whole hand removal
Finger	Partial hand; one or more digits

Table 7.2: Lower Limb Amputations

Sub-class	Notes
Hemipelvectomy	Entire limb and part of pelvis
Hip disarticulation	Through hip joint
Above-knee (transfemoral)	Between hip and knee
Below-knee (transtibial)	Between knee and ankle
Ankle disarticulation	Through ankle joint
Foot	Whole foot
Toe	Partial foot; one or more toes

b) Amputee Case Profile

Taxonomy of amputee profiles

While the General Ontology Layer provides reusable declarative knowledge, the Specific Amputee Prosthesis Ontology Layer requires context-sensitive instantiations that reflect individual patient cases. To ensure that such variability is captured systematically, the PLCCKMF incorporates a taxonomy of amputee case profiles (Figure 7.4; Table 7.3). This taxonomy defines four essential dimensions of patient characterisation: Amputation Level, Activity Level, Age Group, and Comorbidities.

Dimensions: level, activity, age, comorbidities

Each dimension allows case data to be generalised into reusable classes while remaining sufficiently granular for individual instantiation. For instance, Amputation Level distinguishes between Transtibial, Transfemoral, and Hip Disarticulation, each with specific biomechanical implications. Activity Level (e.g. sedentary, moderate, high activity) influences prosthesis durability requirements and consequence likelihoods. Age Group highlights physiological variability across paediatric, adult, and geriatric populations, while Comorbidities (e.g. diabetes, cardiovascular, neuromuscular conditions) directly affect clinical risks such as ulceration. Citizenship and Health Service affect the different types of healthcare services and how the funding scheme can affect the type of treatment a patient can receive.

Supports scalable, personalised reasoning

By formally encoding these categories, the ontology can apply consequence reasoning across both general and individualised contexts. For example, a rule linking diabetes to ulceration risk can be applied across all diabetic amputees, while refinements based on Activity Level and Age Group enable tailored adaptation. This taxonomy thus provides the scaffolding for scalable, personalised consequence inference across heterogeneous patient populations.

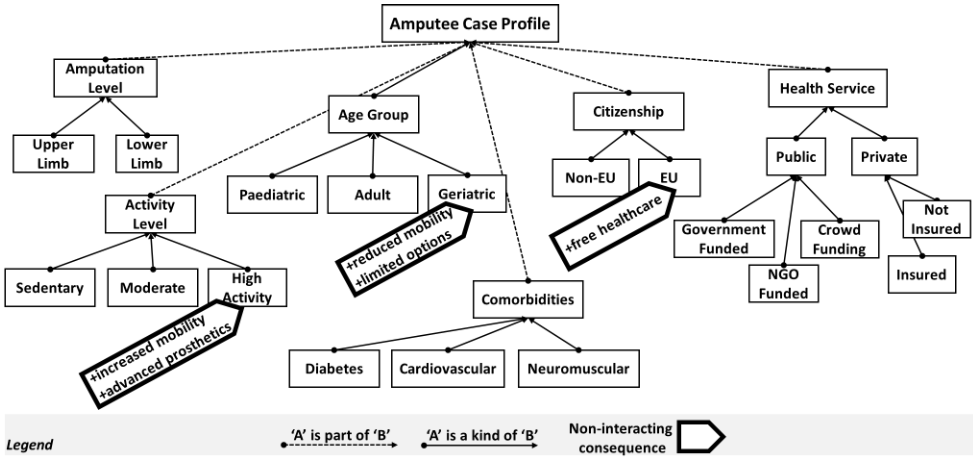


Figure 7.4: Amputee Case Profiles

Table 7.3: Summary of Amputee Case Profiles

Category	Sub-class	Example
Amputation Level	Lower limb	Below-knee, single side
	Upper Limb	Above-elbow, single side
Activity Level	Sedentary	Limited mobility
	Moderate	Active lifestyle, community ambulation
	High activity	Sports or physically demanding routines
Age Group	Paediatric	Child or adolescent
	Adult	Typical working-age individual
	Geriatric	Older adult, higher frailty risk
Comorbidities	Diabetes	Increased ulceration risk
	Cardiovascular	Circulatory and endurance implications
	Neuromuscular	Balance, coordination, or nerve-related issues
Citizenship	EU	Citizen of the European Union
	Non-EU	Citizen outside of the European Union
Health Service	Public	Government funded
		NGO funded
		Crowd funding
	Private	Insured
		Not insured

c) Anthropometric Ratios and Prosthesis Aesthetics

Anthropometric study on limbs ratios

In addition to functional and clinical profiles, aesthetic considerations also influence amputee acceptance and emotional well-being. A comparative study of male versus female lower-limb ratios was conducted to better understand how deviations in limb proportions affect the perceived naturalness of prosthesis appearance (see Appendix

2 for internal report). The analysis revealed clear distinctions: male limbs typically display more angular quadriceps and bulkier calf muscles, while female limbs exhibit smoother, curvaceous transitions between thigh and calf. Female anatomy also tends to present a greater femoral deflection angle, creating wider hip-to-knee alignment. These findings are supported by literature on leg-to-body ratios (Swami, Einon and Furnham, 2006), which shows that variations in limb proportions directly influence perceptions of naturalness and attractiveness.

Design trade-offs: aesthetics vs function

From a prosthesis design perspective, these results highlight the importance of embedding anatomical cues into prosthesis covers. Designs that ignore such ratios risk appearing disproportionate or "medicalised," which can negatively impact amputee confidence and emotional well-being. Conversely, covers that reflect natural anthropometric variation may foster greater acceptance and identity alignment. At the same time, the study also noted the need for balance: excessive calf bulk, while anatomically accurate, can impede clothing fit, emphasising the trade-offs between aesthetic fidelity and functional practicality.

Aesthetics formalised as consequence knowledge

Within the PLCCKMF, these insights extend the emotional consequence domain by formalising aesthetics as a consequence type that directly shapes amputees' lived experiences. By embedding aesthetic concerns within the ontology, adProLiSS ensures that appearance-related dissatisfaction is not treated as anecdotal feedback but as structured consequence knowledge that can inform design and aftercare decisions.

d) Prosthesis Component Types

Taxonomy of prosthesis components

To demonstrate how the General Amputee Prosthesis Ontology Layer formalises prosthesis sub-systems, a taxonomy of prosthesis components is introduced (Figure 7.5; Table 7.4). In this example, the taxonomy is tailored to the case of an above-knee prosthesis. At the highest level, the prosthesis is decomposed into three principal sub-systems: Socket, Knee and Foot/Ankle. Each of these classes is further specialised into sub-classes that reflect clinically and technically relevant distinctions. For instance, the Socket class includes Soft Liner, Rigid Shell, or Elevated Vacuum variants, each with distinct biomechanical, fitting and service implications. Similarly, the Knee class is divided into Passive and Active categories. Passive knees including Hinge and Polycentric mechanisms, while active knees, as a non-interacting consequence, require both power and a microprocessor-controlled system. Examples include the C-Leg, the Pneumatic knee or the PREMIER motorised knee, each having their own functional performance characteristics and potential consequence patterns. A further non-interacting consequence of using the PREMIER motorised knee is that it requires user specific gait calibration. The Foot/Ankle class branches into types such as Cushion Heel, Energy-storing and Multi-axial designs, which are associated with specific gait performance characteristics and rehabilitation outcomes.

Hierarchical rules & scalability

This hierarchical structuring ensures that knowledge about prosthesis elements can be encoded at multiple levels of abstraction, supporting both generalisation and specialisation. A reasoning rule may, for example, be associated at the class level (e.g. “all sockets affect gait stability”), while a more specific rule may apply to a particular sub-class (e.g. “PREMIER motorised knees require user-specific gait calibration”). Inheritance mechanisms within OWL guarantee that consequence knowledge is consistently propagated across sub-classes, reducing redundancy while enabling scalability across diverse prosthesis configurations. The taxonomy also highlights how emerging technologies, such as user-specific calibration protocols, can be incorporated alongside established component classes, ensuring that the PLCCKMF remains extensible as prosthetic technologies evolve.

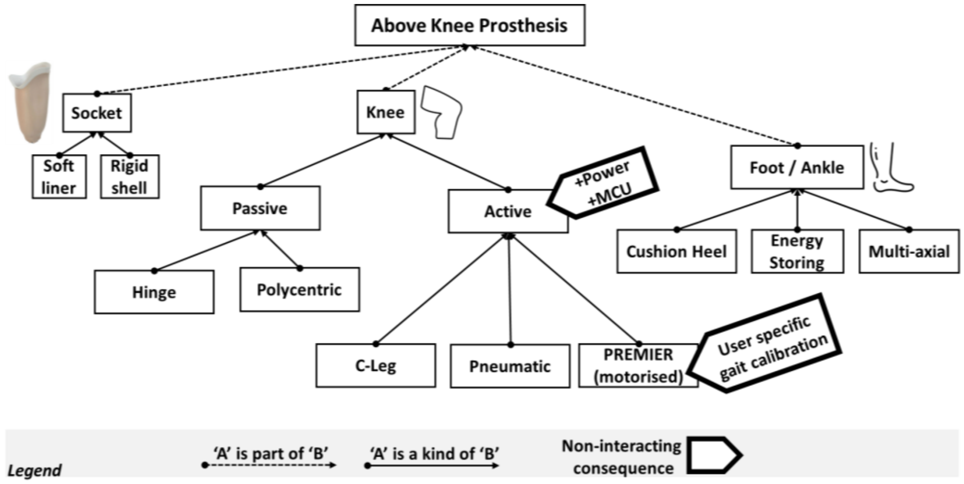


Figure 7.5: Taxonomy of Prosthesis Component Types

Table 7.4: Summary of Prosthesis Component Taxonomy

Class	Sub-class	Examples
Socket	Soft liner	Provides cushioning and pressure distribution
	Rigid shell	Structural stability, weight bearing
Knee (passive)	Hinge	Single-axis movement
	Polycentric	Multi-bar linkage, improved stance stability
Knee (active)	Microprocessor knee	e.g. C-Leg, adaptive stance/swing control
	Pneumatic	Air-based damping for smoother gait
	Motorised	PREMIER prototype, power assistance with MCU integration; user specific calibration to enhance gait tuning and personalisation
Foot / Ankle	Cushion Heel	Basic shock absorption
	Energy storing	Dynamic response, energy return
	Multi-axial	Increased ground adaptation and stability

e) Prosthesis Consequence Types

Taxonomy of consequence types

A core requirement of the PLCCKMF is the ability to represent and reason about the diverse consequences that emerge across the prosthesis life-cycle. To systematise this, a taxonomy of consequence types has been defined (Figure 7.6; Table 7.5). This taxonomy distinguishes five principal categories: Physical, Functional, Emotional, Systemic, and Semantic consequences.

Examples of consequence categories

Physical consequences include biomechanical and physiological outcomes, such as Pressure Ulcers, Gait Asymmetry, and Socket Displacement. Functional consequences refer to mobility or performance effects, including Gait Delay or Stumbling. Emotional consequences refer to inferred affective responses that may arise through cognitive appraisal of prosthesis-related experiences (Scherer, Schorr and Johnstone, 2001; Calvo and D'Mello, 2010; Scherer and Moors, 2019), such as Anxiety, Embarrassment, often mediated by underlining concerns related to self-image, confidence, or social perception. Systemic consequences relate to device- or service-level reliability, for instance Sensor Failure or Maintenance Downtime. Finally, Semantic consequences describe misalignments in knowledge transfer, such as Miscommunication of Risk or Feedback Misinterpretation.

Supports rule-based reasoning & traceability

By encoding consequence types at both general and specific levels, this taxonomy provides a structured foundation for the SWRL rules and inference logic developed in Section 7.3. For instance, a distal socket pressure reading may trigger inference of a Physical consequence (Ulcer Risk), while a fall event may, through cognitive appraisal by the amputee, give rise to inferred an inferred Emotional consequence (Anxiety) (Scherer, Schorr and Johnstone, 2001; Calvo and D'Mello, 2010). Structuring consequences in this way enhances traceability, reuse, and cross-stakeholder communication, ensuring that consequence knowledge remains coherent across cases and contexts.

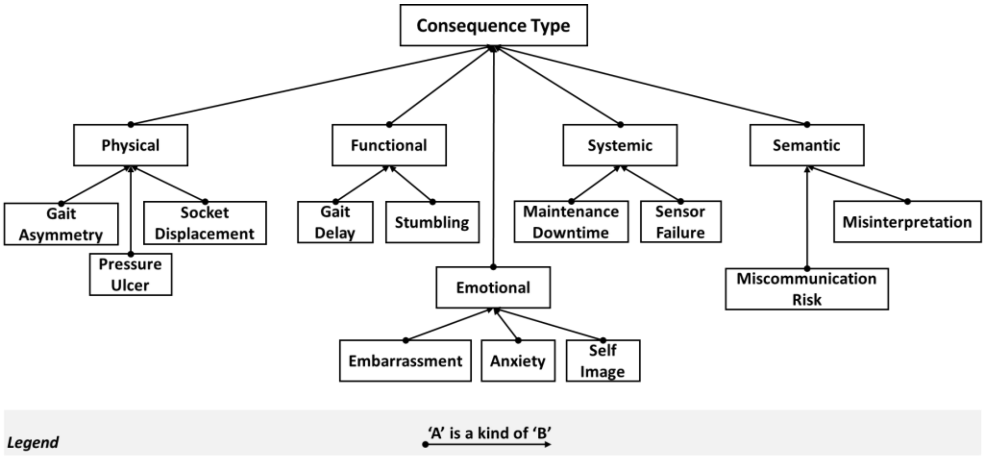


Figure 7.6: Prosthesis Consequence Types

Table 7.5: Summary of Prosthesis Consequences

Consequence Category	Sub-type	Example
Physical	Pressure ulcer, Gait asymmetry, Socket displacement	Relates to biomechanical or physiological outcomes
Functional	Gait delay, Stumbling	Affects user performance and mobility
Emotional	Embarrassment, Anxiety,	Affective response that may arise through cognitive appraisal of prosthesis-related experiences
Cognitive Appraisal (Emotional Antecedents)	Self-image concern, Confidence concern	Appraisal factors that may mediate or give rise to emotional consequences
Systemic	Maintenance downtime, Sensor failure	Reflects service reliability and infrastructure
Semantic	Miscommunication of risk, Feedback misinterpretation	Concerns knowledge transfer and understanding

f) Taxonomic Integration for Consequence Reasoning

Layered taxonomy integration

The scalability and adaptability of the PLCCKMF derive from the integration of its core taxonomies. Figure 7.7 illustrates the layered interaction between Amputation Types, Amputee Case Profiles, Prosthesis Components, and Consequence Types. At the upper layer, the taxonomy of amputation types provides the clinical starting point, establishing the anatomical level of limb loss. This classification then links to amputee case profiles, which refine the context through dimensions such as activity level, age group, comorbidities, and access to healthcare services. These user-specific contexts determine the selection and configuration of prosthesis components at the middle layer, encompassing sockets, knees, and ankle/foot systems, including both established mechanisms and emerging technologies such as motorised knees with user-specific calibration. At the lower layer, consequence types capture the outcomes that emerge from the interaction of patient context and device configuration, spanning physical, functional, emotional, systemic, and semantic domains.

Case-based consequence reasoning

This layered integration ensures that consequence reasoning is grounded in clinical reality, tailored to individual cases, and extendable across diverse prosthesis configurations. For example, a transfemoral amputee with high activity demands, diabetes, and restricted healthcare access may be semantically linked to a motorised knee configuration. The ontology can then infer potential consequence patterns such as Ulcer Risk (physical), Increased Maintenance Load (systemic), or Anxiety following

Stumble Events (emotional). Such reasoning is enabled by the taxonomic layering, which connects anatomical classification, user profiles, component choices, and consequence outcomes into a unified semantic framework.

Bridging to rule formalisation

By embedding these integrated taxonomies into the General and Specific Ontology Layers, the PLCCKMF creates a robust semantic foundation for adaptive prosthesis design and aftercare. This integration also serves as the conceptual bridge into Section 7.3, where the taxonomy-driven structures are formalised into executable semantic rules.

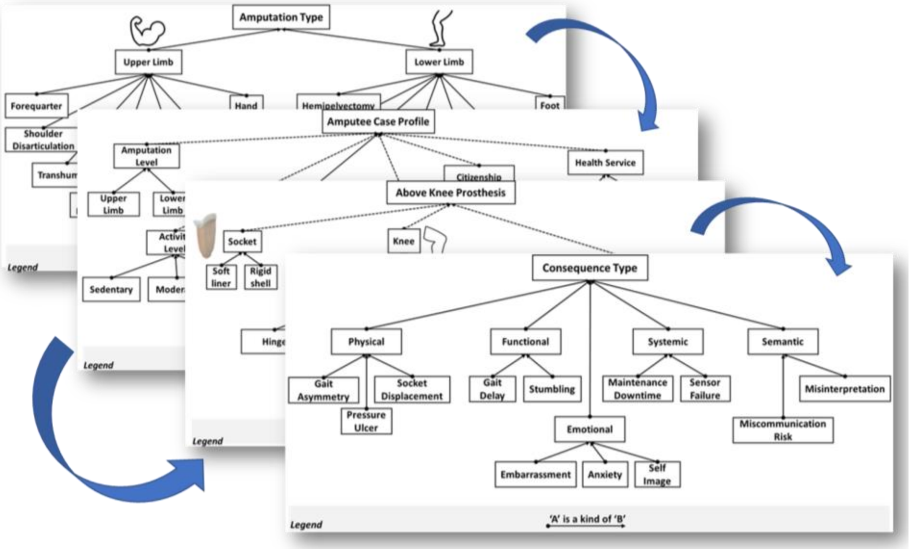


Figure 7.7: Layered Interaction

7.2.4 Semantic Networks of Amputee-Prosthesis Adaptation

From taxonomy to dynamic interactions

While the structured taxonomies in Section 7.2.3 establish the re-usable categories of prosthesis components, amputee profiles, and consequence types, they do not by themselves capture how these entities interact dynamically during real-world use. To represent such interdependencies, the PLCCKMF incorporates semantic networks that extend beyond hierarchical classification to encode causal, functional, and conditional relationships. These networks model how clinical, technical, and experiential elements connect across the prosthesis life-cycle, enabling the ontology to reason not only about what exists but also about how states evolve, why consequences propagate, and where stakeholder interventions are required.

Semantic networks as directed graphs

The adProLiSS framework extends beyond static ontological hierarchies by incorporating dynamic semantic networks to model interrelated entities, conditions, and actions across the prosthesis life-cycle. A semantic network, in this context, is a directed graph where nodes represent concepts (e.g., events, states, stakeholders) and edges denote semantically meaningful relationships (e.g., causes, triggersAction, updatesPlan). These relationships are machine-interpretable and support context-specific reasoning that evolves in parallel with real-world events.

Supporting the core ontology are two key semantic networks (Lambrix and Tan, 2006; Schlieder *et al.*, 2020; Hogan *et al.*, 2021). These are he Amputee Healthcare Semantic Network (Figure 7.8) and the adProLiSS Adaptation Semantic Network (Figure 7.9). These models visualise complex, dynamically evolving interdependencies, such as clinical events, biomedical signals, stakeholder responsibilities, and experiential feedback, that shape the use-phase of smart prostheses. Unlike static OWL class hierarchies, these semantic networks incorporate causal, functional, and conditional relationships that enable real-time consequence inference, service adaptation, and stakeholder co-decision-making.

Amputee Healthcare Semantic network

The **Amputee Healthcare Semantic Network** formalises how amputee-specific services, medical staff, IT systems, rehabilitation workflows, and prosthesis delivery intersect within a healthcare system. It highlights how upstream events, such as surgical amputations or IT-triggered alerts, cascade into downstream prosthesis delivery, configuration, or service initiation and subsequent aftercare decisions. This network also helps stakeholders, such as prosthetists, nurses, and engineers, visualise where they fit in the service flow and what knowledge is required at each step.

adProLiSS Adaptation Semantic Network

The **adProLiSS Adaptation Semantic Network**, by contrast, focuses on the sensor-augmented use-phase. It models how smart prosthesis components, such as pressure sensors or IMUs, generate real-time data that can be semantically classified, interpreted through formal logic, and acted upon. These semantic representations feed back into the Patient–Prosthesis Management System (PPMS), triggering appropriate support actions, updates to the digital twin, or alerts for stakeholders.

For instance, the following semantic chain illustrates how a sensor-based PressureEvent at the distal socket region may trigger a corrective cascade:

(7.5) PressureEvent(?x) ^ hasValue(?x, ?v) ^ swrlb:greaterThan(?v, 175) ^ hasLocation(?x, "DistalRegion") → UlcerRisk(?r) ^ causedBy(?r, ?x) ^ triggersAction(?r, SocketRedesign) ^ updatesPlan(SocketRedesign, ServicePlan)

This rule explicitly encodes the transition from raw sensor input to consequence identification, corrective action, and service-level adaptation. The semantic network supporting this rule would show nodes like *PressureEvent*, *UlcerRisk*, *SocketRedesign*, and *ServicePlan* connected by edges such as *causedBy*, *triggersAction*, and *updatesPlan*. Such graph-based structures enable real-time inference while maintaining transparency and traceability for stakeholders.

Semantic flows enable co-design

By formalising these semantic interaction flows in semantic networks, the adProLiSS methodology ensures not only that knowledge is structured but that it is computable and actionable. The networks are grounded in OWL and RDF-style triple statements, supporting SPARQL querying and symbolic rule reasoning. This allows stakeholders to interact with the prosthesis system not as passive observers but as active co-decision-makers.

Relational links for proactive adaptation

Furthermore, the inclusion of formally defined relational links enhances the system's capability for proactive adaptation, enabling it to infer and respond to cause-effect chains, stakeholder roles, and service-level implications in real-time. This approach is essential for the safe and personalised deployment of smart healthcare-mechatronic systems, where complexity, risk, and patient-specific needs must be balanced dynamically.

Parallels with modern healthcare ontologies

Modern systems such as the ADCATER ontology (Cocco *et al.*, 2024) and the UiA eHealth ontology (Chatterjee *et al.*, 2021) exemplify similar OWL-based formalisation combined with sensor integration and reasoning, supporting adaptive care workflows. These systems validate the direction taken by adProLiSS in extending static ontologies with dynamically linked semantic networks.

Together, these networks strengthen stakeholder understanding, improve design traceability, and ensure that consequence reasoning remains explainable and responsive across the prosthesis life-cycle.

In practice, this means that context-specific relationships are not static but evolve dynamically in parallel with real-world use-phase events. This ensures that the adProLiSS Methodology can reason not only about *what* physical and service elements exist, but also *how* they interact, *why* they propagate consequences, and *how* stakeholders can respond proactively.

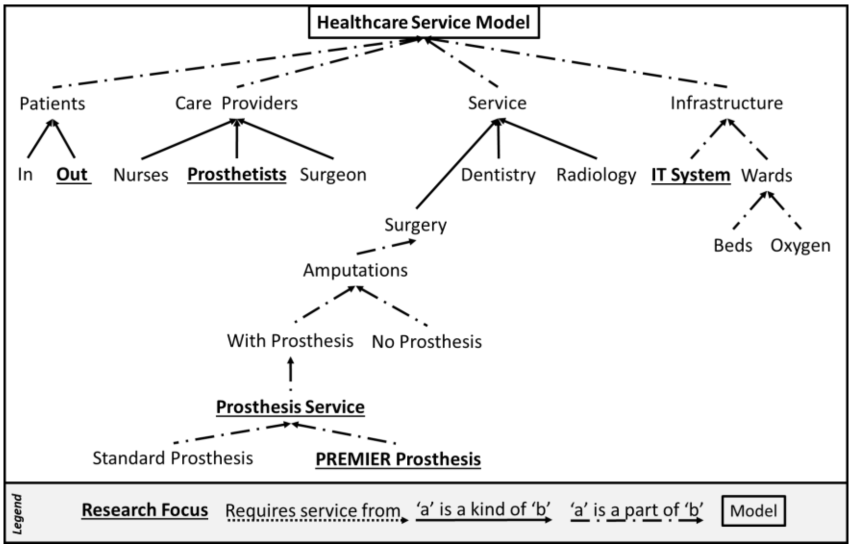


Figure 7.8: Amputee Healthcare Semantic Network

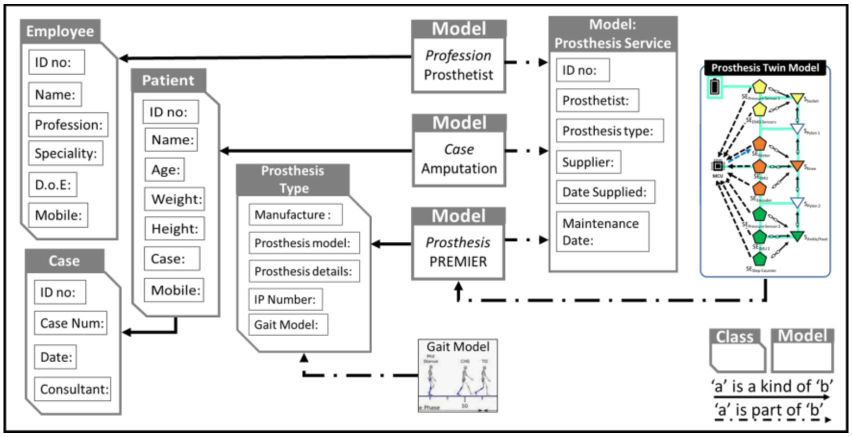


Figure 7.9: adProLiSS Adaptation Semantic Network

General vs specific twin knowledge

Prosthesis Twin Knowledge: Parallel to the semantic networks, the adProLiSS framework connects its ontology to digital twin representations that distinguish between **General Amputee Prosthesis Twin Knowledge** (standard expected behaviours, tolerances, and baseline configurations) and **Specific Amputee Prosthesis Twin Knowledge** (the real-time, individualised state for each user).

Dynamic, data-driven prosthesis twin

The digital twin (Batty, 2018) **serves as a continuously updated computational replica of the physical prosthesis.** Embedded IoT-enabled subsystems, including pressure, gait, and residual limb sensors, feed live data into the twin, which is semantically mapped within the ontology and linked to the adaptation semantic network. Stakeholders (amputees, prosthetists, physiotherapists and engineers) interact with this digital twin through the **Patient–Prosthesis Management System (PPMS)**, where role-based access allows them to visualise live states, test *what-if* adaptation scenarios, and examine predictive consequences for system health and user comfort. Unlike static monitoring, this computational twin evolves dynamically with each data input, ensuring that design intent and use-phase reality stay synchronised and computable. This pairing **enables comparative reasoning** between expected design performance and actual use-phase outcomes, forming the backbone of the consequence knowledge loop.

Ontology links to prothesis library

Finally, the ontology interfaces with the *Library of Prosthesis and Aftercare Elements*, semantically describing each standard part (e.g. knee unit, ankle mechanism) and service process (e.g. socket re-casting, ulcer inspection) in a machine-readable way. This ensures that every physical and service element can be formally related to consequences and stakeholder actions across cases.

Together, these knowledge layers allow adProLiSS to represent not only *what* prosthesis parts exist and *who* uses them but *how* they interact with patient physiology, context, and service workflows, and *why* specific decisions propagate consequences. The next section illustrates how this integrated structure is activated through concrete semantic rules and inference logic that link sensor data, stakeholder input, and design actions into an adaptive, closed-loop decision system.

In summary, the semantic networks transform the PLCCKMF from a static classification of prosthesis and amputee knowledge into a dynamic representation of how these elements interact across the life-cycle. By explicitly encoding causal chains and feedback loops, the networks bridge the gap between structural knowledge (captured in taxonomies) and adaptive reasoning (formalised through inference rules in Section 7.3). This ensures that consequence knowledge is not only categorised and stored, but also continuously updated, contextualised, and actionable within real-world design and aftercare scenarios.

7.3 Example of Semantic Rules and Inference

SWRL rules enable consequence chains

The inferential power of the adProLiSS ontology is unlocked through a suite of explicitly defined semantic rules. These rules, formalised in SWRL (Horrocks *et al.*, 2004) and structured through the underlying OWL ontology, serve to transform raw inputs (e.g. sensor readings, stakeholder feedback, contextual data) into traceable, machine-executable consequence chains. These chains automate stakeholder coordination and drive adaptive prosthesis response mechanisms in real-time. Ontology engineering methodologies evaluated by (Spoladore and Pessot, 2021) emphasise rigorous development cycles, stakeholder collaboration, and modular reuse, principles that underpin the design of the adProLiSS ontology and semantic rule workflows.”

To assist the reader, the following definitions clarify key ontology terms used throughout this section (McGuinness and van Harmelen, 2004a, 2004b):

- *Class*: A defined group or category of entities (e.g. UlcerRisk, ServicePlan).
- *ObjectProperty*: A relationship between two classes (e.g. causedBy, updatesServicePlan).
- *DatatypeProperty*: A relationship between a class and a data value (e.g. hasValue).
- *Individual*: A specific named instance of a class (e.g. Prosthetist, PatientA_KneeV2).

The following examples illustrate how semantic rule chains are structured, interpreted, and computationally executed. Each includes:

- Description
- A SWRL Rule
- A Manchester OWL Syntax Fragment
- An Interpretative Commentary

Example 1: IMU Z-Axis Acceleration Trigger

This simple rule models a sensor-based decision logic.

$$\text{If } (|IMUZ| > NZF) \wedge \neg (DelayAmputee = DF) \wedge (Speed = N) \rightarrow (DelayAmputee = DF) \tag{7.6}$$

Interpretation: If inertial acceleration in Z-axis exceeds the normal threshold for the amputee and the delay is not yet set to fast, and speed is normal, then the system should switch to fast delay mode.

Example 2: Distal Socket Pressure Escalation Chain

This formalisation states that a *PressureEvent* located in the distal region with high value can trigger an *UlcerRisk*. These elements represent engineering–clinical linkage, enabling semantic pattern recognition across use cases.

(7.7) PressureEvent(?x) ^ hasValue(?x, ?v) ^ swrlb:greaterThan(?v, 175) ^ hasLocation(?x, "DistalRegion") → triggers(?x, UlcerRisk)

Interpretation: if distal socket pressure exceeds 175 units, an ulcer risk event should be triggered.

The following Manchester OWL syntax fragment (Horridge and Patel-Schneider, 2012) defines the class restrictions and relationships.

```
Class: PressureEvent
  SubClassOf:
    hasLocation some DistalRegion,
    hasValue some xsd:float
Class: UlcerRisk
  SubClassOf:
    triggeredBy some PressureEvent
```

Manchester OWL Syntax Fragments for (7.7)

See Table 7.6 for a summary of ontology elements used in this rule

Example 3: Prosthetist-Initiated Gait Adjustment

Rules links clinical context to aftercare

This semantic rule captures a situation where a clinical scenario involving a prosthetist results in the recommendation of a gait retraining intervention. The inferred outcome is the automatic update of the patient's physiotherapy plan within the service system. This rule bridges stakeholder-specific contextual knowledge with adaptive aftercare, ensuring that the prosthesis life-cycle responds to both technical and human-centred factors.

(7.8) StakeholderScenario(?s) ^ involvesStakeholder(?s, Prosthetist) ^ triggers(?s, GaitRetraining) → updatesServicePlan(?s,PhysiotherapyPlan)

Interpretation: If a scenario involves a prosthetist and it triggers a gait retraining intervention, then the associated physiotherapy plan in the amputee's service record should be updated accordingly.

```
Class: StakeholderScenario
  SubClassOf:
    involvesStakeholder some Prosthetist,
    triggers some GaitRetraining
Class: PhysiotherapyPlan
  SubClassOf:
    updatedBy some StakeholderScenario
```

Manchester OWL Syntax Fragments for (7.8)

See Table 7.6 for a summary of ontology elements used in this rule.

Rule models pressure-triggered adaptation

Example 4: High Socket Pressure Cascade

This extended semantic rule models how a single physical anomaly, such as excessive pressure within the prosthetic socket, triggers a cascade of clinical and technical adaptations. The rule formalises a real-time consequence-driven reasoning chain that spans sensor events, stakeholder involvement, prosthetic redesign, and patient rehabilitation, core to the adaptive logic of the adProLiSS system.

(7.9) HighPressure(?p) ^ causes(?p, UlcerRisk) ^ triggersReview(?r) ^ updatesConfig(?c) ^ adjustsGait(?g)

Interpretation: In this rule, an instance of *HighPressure*, such as excessive distal socket loading detected by embedded pressure sensors, is inferred to cause an *UlcerRisk*. This consequence is formally linked to a *ReviewAction* initiated via the PPMS, which prompts a clinical or prosthetic review by a relevant stakeholder (e.g. prosthetist or physiotherapist). The outcome of this review leads to an *updatesConfig* action, which may involve modifying the socket geometry, liner material, or alignment parameters. This configuration change, in turn, necessitates a *GaitAdjustment* intervention to realign the user's biomechanics with the updated prosthetic parameters.

```
Class: HighPressure
  SubClassOf: causes some UlcerRisk
Class: UlcerRisk
  SubClassOf: triggersReview some ReviewAction
Class: ReviewAction
  SubClassOf: updatesConfig some ConfigurationUpdate
Class: ConfigurationUpdate
  SubClassOf: adjustsGait some GaitAdjustment
```

Manchester OWL Syntax Fragments for (7.9)

See Table 7.6 for a summary of ontology elements used in this rule.

Each of these elements, *HighPressure*, *UlcerRisk*, *ReviewAction*, *ConfigurationUpdate*, and *GaitAdjustment*, is represented as a class or instance within the ontology and linked through semantically defined properties such as causes, *triggersReview*, *updatesConfig*, and *adjustsGait*. This enables the rule to be processed by the inference engine in real time, ensuring that consequences are not only detected but are proactively addressed through a coordinated, traceable adaptation process across the system.

Table 7.6: Consolidated Ontology Elements Used in Section 7.3 for 7.6 to 7.9

Example	Ontology Element	Type	Description
7.7	PressureEvent	Class	Event capturing abnormal socket pressure
	UlcerRisk	Class	Inferred clinical condition from pressure anomalies
	hasLocation	ObjectProperty	Associates pressure with prosthetic socket region
	hasValue	DataProperty	Numeric measurement of pressure intensity
	triggeredBy	ObjectProperty	Indicates causal relationship between event and risk
	DistalRegion	Class	Distal location of pressure event
7.8	StakeholderScenario	Class	A contextual situation involving one or more stakeholders
	involvesStakeholder	ObjectProperty	Links a scenario to a participating stakeholder
	Prosthetist	Individual	A stakeholder with expertise in prosthetic care
	GaitRetraining	Class	Intervention to modify walking biomechanics
	triggers	ObjectProperty	Denotes causality between scenario and intervention
	PhysiotherapyPlan	Class	Service sub-plan focusing on rehabilitation
	updatesServicePlan	ObjectProperty	Links events to changes in patient’s service plan
7.9	HighPressure	Class	Abnormal pressure condition in socket
	causes	ObjectProperty	Indicates that an event results in a specific risk
	triggersReview	ObjectProperty	Links clinical risks to review actions
	ReviewAction	Class	Stakeholder-triggered reassessment via PPMS
	updatesConfig	ObjectProperty	Connects review outcomes to prosthesis reconfiguration
	ConfigurationUpdate	Class	Change to alignment, socket, or liner
	adjustGait	ObjectProperty	Associates configuration change with gait training
	GaitAdjustment	Class	Gait intervention to restore balance after socket changes

This cascading logic transforms raw sensor events into structured consequence knowledge and enables the adProLiSS framework to embed experiential learning into each prosthesis configuration cycle. Unlike traditional approaches that rely on periodic assessments, this semantic chain supports real-time, stakeholder-specific interventions driven by live system state.

These examples collectively demonstrate how consequence reasoning is formalised, executed, and operationalised within the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, creating a reusable consequence knowledge base across prosthesis cases.

Symbolic AI powers consequence reasoning

AI-Driven Inference: In adProLiSS, this rule-based consequence inference capability constitutes a concrete implementation of ***knowledge-based artificial intelligence*** (Russell and Norvig, 1995, 2021), often termed ***symbolic AI.*** Formally defined ontology classes, semantic networks, and explicit rule sets interact computationally to generate new knowledge automatically. Unlike purely statistical models, this symbolic reasoning approach ensures condition-action chains in real time: when incoming sensor data or stakeholder input satisfies a rule, the inference engine dynamically propagates the resulting consequences, updates prosthesis state parameters within the digital twin, and surfaces targeted recommendations through the PPMS. This means stakeholders interact not only with static datasets but with an ***active AI reasoning process*** that continuously connects real-world events to the Prosthesis Experiential Consequence Knowledge base in an explainable, traceable manner.

In future iterations, this symbolic approach could be augmented through unsupervised machine learning techniques (Nasteski, 2017; Sarker, 2022), enabling the system to discover latent patterns in large-scale, real-time data streams and autonomously refine its inference logic without explicit supervision. Such expansions must account for GDPR-compliant data management (Li, Yu and He, 2019) and address Big Data processing challenges (Fan, Han and Liu, 2014; Oussous *et al.*, 2018; Pastorino *et al.*, 2019), ensuring AI-driven reasoning remains secure, explainable, and ethically robust.

Rule chains automate co-ordinated responses

This layered rule chain illustrates how the adProLiSS framework operationalises symbolic AI to automate multi-stakeholder coordination in response to emergent clinical risks. Rather than requiring manual interpretation of isolated sensor values, the system semantically links events, risks, stakeholder roles, and service plans into a computable structure. This not only enables real-time, explainable consequence reasoning, but also ensures that corrective actions, such as socket inspections or therapy adjustments, are both contextually relevant and procedurally aligned. By embedding these rule chains within the ontology, the system facilitates scalable knowledge reuse across cases, enabling future prosthesis configurations to benefit from previously formalised experiential knowledge.

In OWL (McGuinness and van Harmelen, 2004a, 2004b) terms, *Classes* (e.g. PressureEvent, RiskEvent, Stakeholder), *Properties* (e.g. causes, triggersReview, handledBy), and *Instances* (e.g. PatientA_KneeV2) all link in machine-readable form.

A more complex semantic rule chain demonstrates how multiple ontology classes and properties interact to support dynamic consequence reasoning and stakeholder coordination.

Example 5: Context-Aware Ulcer Risk Escalation chain (7.10-7.12).

This composite rule sequence demonstrates a consequence-aware reasoning cascade that includes sensor-derived risk inference, stakeholder-specific monitoring, and automated service plan updates. These examples show how the ontology facilitates real-time adaptation across physical and procedural domains.

(7.10) SocketPressureEvent(?e) ^ hasValue(?e, ?v) ^ swrlb:greaterThan(?v, 175) ^ hasLocation(?e, "DistalRegion") → UlcerRisk(?r) ^ causedBy(?r, ?e)

Interpretation: If a socket pressure event is detected at the distal end and its value exceeds 175 units, it is inferred to be an *UlcerRisk* with a traceable causal link to the originating event.

```
Class: SocketPressureEvent
  SubClassOf:
    hasValue some xsd:float,
    hasLocation some DistalRegion
Class: UlcerRisk
  SubClassOf:
    causedBy some SocketPressureEvent
```

Manchester OWL Syntax Fragments for (7.10)

The second rule adds stakeholder awareness:

(7.11) UlcerRisk(?r) ^ monitoredBy(?r, ?p) ^ Stakeholder(?p) ^ hasRole(?p, "prosthetist") → triggersNotification(?r, ?p)

Interpretation: If an *UlcerRisk* is monitored by a stakeholder whose role is prosthetist, a notification is triggered for that stakeholder

```
Class: UlcerRisk
 SubClassOf:
  monitoredBy some Stakeholder
Class: Stakeholder
 SubClassOf:
  hasRole value "prosthetist"
ObjectProperty: triggersNotification
 Domain: UlcerRisk
 Range: Stakeholder
```

Manchester OWL Syntax Fragments for (7.11)

The final rule operationalises care planning:

(7.12) triggersNotification(?r, ?p) ^ belongsTo(?p, ?patient) ^ ServicePlan(?s) ^ forPatient(?s, ?patient) → updatePlan(?s, "ScheduleSocketInspection")

Interpretation: If a prosthetist receives a triggered notification, and they are associated with a specific patient, the system updates that patient's *ServicePlan* to schedule a socket inspection.

```
Class: ServicePlan
 SubClassOf:
  forPatient some Patient
ObjectProperty: updatePlan
 Domain: ServicePlan
 Range: xsd:string
```

Manchester OWL Syntax Fragments for (7.12)

Example of full pressure-ulcer rule chain

Full Interpretation of semantic rule chain: When excessive distal socket pressure is detected, the system infers a potential ulcer risk, determines whether a prosthetist is responsible for monitoring that condition, notifies them accordingly, and proactively updates the patient's aftercare plan. Each step in this reasoning chain is machine-executable, traceable, and grounded in formally defined ontology classes (*SocketPressureEvent*, *UlcerRisk*, *Stakeholder*, *ServicePlan*) and properties (*causedBy*, *monitoredBy*, *triggersNotification*, *updatePlan*). This example illustrates how adProLiSS supports context-aware, consequence-driven adaptation, moving beyond passive monitoring to active, semantically informed decision-making.

See Table 7.7 for a summary of ontology elements used in this rule.

Example 6: Emotional Stress Detection from Fall Event (7.13)

Fall events infer emotional consequences

In adaptive prosthesis aftercare, physical incidents such as falls often lead to emotional consequences that may not be immediately visible through physiological sensors. These psychological effects, such as anxiety, loss of confidence, or social withdrawal, are critical to long-term rehabilitation outcomes. To address this, the ontology supports the inference of mental health states from physical events and triggers appropriate support interventions. This example illustrates how a fall event can be semantically linked to an anxiety state and automatically prompt an emotional support plan tailored to the patient's recovery trajectory.

(7.13) FallEvent(?f) ^ causes(?f, Anxiety) ^ affects(?f, Patient) → triggersSupportPlan(?f, EmotionalSupportPlan)

Interpretation: A fall event (*FallEvent*) may induce an emotional condition such as anxiety (*Anxiety*) in the patient. This inference prompts the activation (*triggersSupportPlan*) of an emotional support plan (*EmotionalSupportPlan*).

```
Class: FallEvent
  SubClassOf: causes some Anxiety,
              affects some Patient

Class: Anxiety
  SubClassOf: MentalHealthState

Class: EmotionalSupportPlan
  SubClassOf: triggeredBy some FallEvent
```

Manchester OWL Syntax Fragments for (7.13)

Example 7: Prosthesis Aesthetic Discontent

Aesthetic dissatisfaction linked to care

Beyond mechanical performance, aesthetic satisfaction plays a significant role in prosthesis acceptance and psychological well-being. Some amputees may experience frustration, embarrassment, or diminished self-image due to mismatched prosthesis appearance. This example formalises how such concerns are captured and linked to corrective actions. By modelling aesthetic dissatisfaction within the ontology, adProLiSS ensures that emotional and psychosocial drivers influence clinical review workflows.

(7.14) AppearanceConcern(?a) ^ causedBy(?a, CosmeticMismatch) ^ affects(?a, Patient) → triggersReview(?a)

Interpretation: If a patient expresses concern about prosthesis aesthetics (*AppearanceConcern*) and this concern is caused by a cosmetic mismatch (*CosmeticMismatch*) that affects the patient (affects), the system should initiate a follow-up review (*triggersReview*).

```
Class: AppearanceConcern
  SubClassOf: causedBy some CosmeticMismatch,
        affects some Patient
Class: CosmeticMismatch
  SubClassOf: VisualDiscrepancy
```

Manchester OWL Syntax Fragments for (7.14)

Example 8: Physiotherapist Coordination with Prosthetist

Physio-to-prosthetist feedback

Effective prosthesis management often requires coordinated action between different stakeholders. This example models a communication pathway where a physiotherapist, upon detecting a gait-related issue, triggers a feedback mechanism directed at the prosthetist. The rule ensures that insights from rehabilitation sessions are formally integrated into the prosthesis design and aftercare cycle, closing the loop between use-phase observations and design refinements.

(7.15) FeedbackEvent(?e) ^ issuedBy(?e, Physiotherapist) ^ about(?e, GaitIssue) → notifies(?e, Prosthetist)

Interpretation: A feedback event (*FeedbackEvent*) issued by a physiotherapist (*issuedBy*) and concerning a gait-related issue (*about*) automatically triggers a notification (*notifies*) to the relevant prosthetist. This enables inter-stakeholder communication and ensures that gait-related problems encountered during rehabilitation inform subsequent prosthesis decisions.

```
Class: FeedbackEvent
  SubClassOf: issuedBy some Physiotherapist,
        about some GaitIssue,
        notifies some Prosthetist
```

Manchester OWL Syntax Fragments for (7.15)

Example 9: Sensor Failure Detection and Escalation Protocol (7.16)

Sensor failure triggers fallback protocol

In smart prosthesis systems, robust sensor performance is critical to ensuring safe and adaptive functionality. This example models a semantic chain that detects when a key sensor, such as one monitoring socket pressure, goes offline. The rule activates a predefined fallback protocol to ensure that clinical oversight is maintained despite sensor malfunction. By embedding resilience into the ontology, the system can continue to provide dependable care even under degraded operational conditions.

(7.16) Sensor(?s) ^ hasStatus(?s, "offline") ^ monitors(?s, SocketPressure) → triggersProtocol(?s, FallbackInspection)

Interpretation: If a sensor (*Sensor*) monitoring socket pressure (*monitors*) is marked with the status "offline" (*hasStatus*), the system automatically triggers a predefined inspection protocol (*triggersProtocol*). This rule introduces fault-tolerant logic into the framework by enabling the prosthesis system to respond proactively to hardware failure scenarios.

```
Class: Sensor
  SubClassOf: hasStatus value "offline",
        monitors some SocketPressure,
        triggersProtocol some FallbackInspection
```

Manchester OWL Syntax Fragments for (7.16)

Example 10: Engineer-Initiated Design Modification Following Persistent Fault Reports (7.17)

Fault reports escalate to design review

This semantic consequence chain models how repeated fault reports from other stakeholders (e.g. prosthetists or patients) can lead to the inference that a design-level issue may exist. In such cases, an engineer is formally assigned to initiate a design modification procedure. This rule supports formal traceability and role-specific responsibility allocation in response to long-term system-level patterns.

(7.17) FaultReport(?f) ^ hasFrequency(?f, "high") ^ refersTo(?f, ProsthesisComponent)
→ triggersAction(?f, DesignModification) ^ assignedTo(?f, Engineer)

Interpretation: If a fault report (*FaultReport*) occurs frequently (*hasFrequency* = "high") and refers to a prosthesis component (*refersTo*), the system infers that a design modification (*DesignModification*) is required and assigns this action to a stakeholder with the role of engineer (*assignedTo*).

This rule formalises how long-term trends in fault data can semantically escalate to system-level engineering intervention, ensuring that design iterations are traceable, stakeholder-specific, and data-driven.

```
Class: Sensor
Class: FaultReport
  SubClassOf: hasFrequency value "high",
            refersTo some ProsthesisComponent,
            triggersAction some DesignModification,
            assignedTo some Engineer
Class: ProsthesisComponent
Class: DesignModification
Class: Engineer
```

Manchester OWL Syntax Fragments for (7.17)

See Table 7.9 for a summary of ontology elements used in this rule.

These examples demonstrate how the adProLiSS ontology dynamically coordinates physical, clinical, and procedural domains through formally defined consequence chains. Each rule represents a computable transformation of situational awareness into actionable system behaviour.

Table 7.7: Consolidated Ontology Elements Used in Section 7.3 for 7.10 to 7.12

Example	Ontology Element	Type	Description
7.10	SocketPressureEvent	Class	An event representing abnormal pressure within the prosthetic socket
	hasValue	DataProperty	The numeric intensity of the pressure event
	hasLocation	ObjectProperty	Spatial region where the pressure anomaly is detected
	UlcerRisk	Class	Inferred clinical condition triggered by excessive socket pressure
	causedBy	ObjectProperty	Captures causal linkage from event to inferred clinical risk
	DistalRegion	Class	Distal location of pressure event
7.11	monitoredBy	ObjectProperty	Indicates which stakeholder is monitoring the condition or risk
	Stakeholder	Class	A general stakeholder class (e.g. prosthetist, physiotherapist)
	hasRole	DataProperty	Textual role description of the stakeholder (e.g. “prosthetist”)
	triggersNotification	ObjectProperty	Links a condition to an alert or notification
7.12	belongsTo	ObjectProperty	Associates a stakeholder with a patient
	ServicePlan	Class	Dynamic plan containing aftercare and rehabilitation instructions
	forPatient	ObjectProperty	Links a service plan to a specific patient
	updatePlan	ObjectProperty	Indicates that a service plan has been modified with a new instruction

Table 7.8: Consolidated Ontology Elements Used in Section 7.3 for 7.13 to 7.15

Example	Ontology Element	Type	Description
7.13	FallEvent	Class	Real-world fall incident
	Anxiety	Class	Psychological state triggered by fall
	Patient	Class	Recipient of care in system
	triggersSupportPlan	ObjectProperty	Links condition to support plan
	EmotionalSupportPlan	Class	Mental health follow-up pathway
7.14	AppearanceConcern	Class	Aesthetic concern voiced by patient
	CosmeticMismatch	Class	Visual misalignment with patient preference
	triggersReview	ObjectProprty	Initiates follow-up review process
7.15	FeedbackEvent	Class	Structured input from clinical staff
	issuedBy	ObjectProperty	Sender of feedback event
	about	ObjectProperty	Topic of concern (e.g. gait)
	GaitIssue	Class	Observed abnormality in walking pattern
	notifies	ObjectProperty	Sends event to another stakeholder
	Prosthetist	Individual	Prosthetic care expert

Table 7.9: Consolidated Ontology Elements Used in Section 7.3 for 7.16 to 7.17

Example	Ontology Element	Type	Description
7.16	Sensor	Class	Monitoring hardware component
	hasStatus	DataProperty	Status indicator (e.g. "offline")
	monitors	ObjectProperty	Maps sensor to parameter (e.g. SocketPressure)
	SocketPressure	Class	The parameter being monitored
	TriggersProtocol	ObjectProperty	Links failure to recovery action
	FallbackInspection	Class	Manual check-up procedure
7.17	FaultReport	Class	Record of recurring system issues
	hasFrequency	DatatypeProperty	Indicates number of times an issue has occurred
	refersTo	ObjectProperty	Points to the affected component
	triggersAction	ObjectProperty	Starts a corrective process
	DesignModification	Class	Engineering task initiated in response to faults
	assignedTo	ObjectProperty	Links fault to assigned stakeholder (e.g. engineer)
	Engineer	Class	Stakeholder responsible for prosthesis design improvements
	ProsthesisComponent	Class	Physical element in the prosthesis system

Such cascading logic can be implemented and tested directly in Protégé (Musen, 2015) using the SWRLTab, or exported as OWL-compatible rules. This offers a concrete, shareable tool for stakeholder workshops and future system deployment, supporting real-time decision learning and continuous improvement.

Experiential knowledge reused via CD-CST

These rules produce the Prosthesis Experiential Consequence Knowledge, which is the main operational output of this frame, systematically archived, shared, and reused across prosthesis cases so that each new design or adaptation decision directly benefits from prior real-world lessons. This, being fed back to the stakeholders through the Consequence-Driven Co-Design Support Tool (CD-CST) in the Design Stakeholder Operational Frame, ensuring lessons learned from one prosthesis directly shape the next.

7.4 Ontology-Driven Reasoning Flow

OWL and Protégé support interoperable ontology development

In practice, the adProLiSS ontology will be deployed in a standardised knowledge representation format such as OWL for computational interoperability. Tools such as Protégé are intended to develop, visualise, and maintain the ontology, ensuring that classes, properties, instances, and constraints can be queried dynamically.

Key ontology elements: classes, properties, instances & rules

Key reasoning elements include:

- **Class Definitions:** E.g. *Socket*, *KneeUnit*, *ResidualLimb*, *PatientCondition*, *ProsthesisTwin, Stakeholder*, with subclasses of *Prosthetist, Physiotherapist, Engineer, Amputee.*
- **Properties:** Linking entities via relationships such as *hasComponent*, *causesConsequence*, *triggersReview, handledByStakeholder, monitoredBySensor, hasRole*.
- **Instances:** Individual prosthesis configurations, patient-specific measurements, and real-time events such as a unique *Socket_AS* for Amputee_AndrewSmith, their *Specific Prosthesis Twin*, or a *Physiotherapist_X* role instance.
- **Rules & Queries:** Implemented in SWRL or SPARQL to run automated checks, detect threshold states, and infer adaptation recommendations automatically.

Live PPMS loop enriches general ontology with real-world data

The ontology's reasoning layer underpins the live feedback loop in the **Patient–Prosthesis Management System (PPMS),** ensuring that new data streams continuously update the knowledge base. Each *specific amputee's data* enriches the *General Amputee Prosthesis Ontology*, turning real-time monitoring and stakeholder insights into a growing, reusable body of consequence knowledge, creating an explicit link between real-world consequences and future design improvements. It ensures knowledge does not remain static but grows with each new prosthesis and stakeholder decision cycle, across individual cases and collective global use. Real-time alerts and recommendations are generated for stakeholders according to their roles and access rights.

7.5 Scientific Significance and Future Integration

PLCCKMF formalises consequence knowledge as a shareable design asset

The Prosthesis Life-Cycle Consequence Knowledge Modelling Frame represents a step forward in closing the loop between engineering design, stakeholder decision-making, and actual use-phase consequences. Its unique value lies in formalising

Prosthesis Experiential Consequence Knowledge as a traceable, shareable asset, bridging conventional silos between design, realisation, and aftercare services. Its layered structure, integrating general and specific amputee ontologies, semantic networks, digital twin data, and stakeholder feedback, forms a robust foundation for an adaptive, consequence-aware prosthesis service system.

Next steps: practical ontology deployment and validation

While the adProLiSS framework remains at the conceptual stage, its scientific contribution lies in its testable proposition that prosthesis experiential *consequence knowledge* can be formalised, reused across cases, and embedded into iterative stakeholder co-decision-making and aftercare services.

The next steps will focus on:

- Implementing the ontology in practice using established tools such as Protégé and OWL.
- Aligning core structures with medical semantic standards like SNOMED CT to enable cross-domain interoperability.
- Piloting the integrated knowledge model and PPMS in live stakeholder workshops.
- Evaluating how real-time consequence reasoning improves stakeholder learning, design and traceability.

Together, these steps will ensure that the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame anchors adProLiSS as more than a static design tool: it provides a *scalable, testable architecture* for a new generation of adaptive, human-centred prosthesis life-cycle service systems.

7.6 Chapter Conclusion

Chapter conclusion: adProLiSS concept, rationale and architecture

This chapter has presented the *Adaptive Prosthesis Life-Cycle Service System (adProLiSS)* as a scientifically grounded framework for designing, configuring, adapting, and managing smart lower-limb prostheses and their associated aftercare services. It established the conceptual architecture and design rationale for integrating a consequence-driven methodology with stakeholder-centred co-design, modular product configuration, and continuous service adaptation supported by real-time data-driven feedback loops.

Operationalising summary: closed-loop frames, tools, and reusable knowledge

Next, it described how adProLiSS is operationalised in practice, from initial stakeholder engagement and modular system configuration to digital twin integration, adaptive aftercare, and sustainable reuse strategies. Through its three interlinked frames, the Custom Prosthesis Development Frame, the Prosthesis Adaptation Frame, and the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, adProLiSS delivers a closed-loop, ontology-supported Product–Service System. Its unique contribution lies in formalising and reusing Prosthesis Experiential Consequence Knowledge to inform each new configuration and aftercare cycle. The chapter also explained how the domain-specific ontology, semantic networks, and rule-based AI inference create an explicit link between real-world data and future design decisions. Practical tools such as the Patient–Prosthesis Management System (PPMS), the Digital Twin, and the Consequence-Driven Co-Design Support Tool (CD-CST) translate abstract consequence reasoning into actionable support for real-world stakeholders.

Together, adProLiSS aims to bridge the gap between theoretical design intent and evolving user experience by embedding formalised consequence knowledge into every stage of the prosthesis life-cycle.

The next step is to build on this foundation by demonstrating the practical implementation of the adProLiSS methodology through selected prototype case studies. These prototypes will test how core elements, such as consequence-driven design, digital twin monitoring, and stakeholder feedback loops, can be deployed to support more adaptive, user-centred prosthesis development and aftercare. This, in turn, sets the stage for the evaluation phase, where the effectiveness of adProLiSS will be assessed in collaboration with real stakeholders.

8

8 adProLiSS Framework Prototype Implementation

Chapter focus: prototype realisation

This chapter presents the implementation of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) framework, focusing on how its conceptual design was realised into a functional prototype. Whereas Chapters 5 to 7 established the framework architecture, operational logic, and knowledge modelling foundations. This chapter presents how the adProLiSS framework was realised as a functional prototype, with sufficient fidelity to validate feasibility and enable stakeholder-centred demonstrations reported in Chapter 9.

Extending PREMIER into adProLiSS

The implementation of the physical prototype was closely aligned with the ongoing PREMIER project, which developed a smart prosthesis platform incorporating embedded sensing and actuation. PREMIER provided a foundational hardware baseline, including the integration of actuation, embedded sensors and computing. Building on this, the present research extended the implementation into the adProLiSS framework by embedding consequence-aware reasoning, stakeholder-facing platforms (PPMS and CD-CST), and structured demonstration scenarios. This ensured that the physical developments achieved under PREMIER were contextualised within a broader life-cycle service system capable of addressing evolving amputee needs.

Physical-digital integration for demonstration

The implementation covers three complementary domains. First, the physical prototype integrates sensors, actuation, modular structures, and aesthetic prosthesis covers designed to address both functional performance and amputee emotional needs. Second, the digital platforms include the Patient–Prosthesis

Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST), supported by an embedded computing pipeline based on a Raspberry Pi running Python. These platforms provide real-time data capture, consequence reasoning, and stakeholder interaction capabilities. Third, the system integration layer connects the physical and digital implementations under the adProLiSS framework, linking the knowledge layer, operational layer, and application layer into a coherent whole.

Use-case scenarios for demonstration

In order to demonstrate the implemented capabilities, a series of use-case scenarios were developed. These cover evolving health issues (e.g. socket ulcer detection), evolving daily use situations (e.g. fall detection and emergency response), evolving system behaviour (e.g. weight distribution monitoring and maintenance alerts), and amputee-centred inputs (e.g. daily feedback logging). These scenarios served both as implementation showcases and as the basis for the evaluations presented in the following chapter.

Chapter structure overview

The remainder of this chapter is organised as follows. Section 8.1 presents the physical implementation of the prosthesis prototype. Section 8.2 details the digital implementation platforms, including the embedded computing pipeline, PPMS, and CD-CST. Section 8.3 explains the integration of framework layers, supported by a layered system view. Section 8.4 describes the demonstration scenarios implemented. Section 8.5 discusses challenges and limitations encountered during implementation. Section 8.6 concludes the chapter with a summary of the outcomes and their relevance to subsequent evaluation.

8.1 Physical Implementation of the Prosthesis System Prototype

Modular sensor-integrated prosthesis prototype

The physical implementation of the prosthesis system prototype focused on developing a modular, sensor-integrated, and aesthetically refined prototype capable of supporting the objectives of the adProLiSS framework. Based on the research approach developed in Chapters 5 – 7, the prototype integrates multiple sensor types, actuation mechanisms, and structural adaptations to capture amputee–prosthesis interactions in real-time.

Particular attention was given to modularity, enabling flexible integration of components such as inertial measurement units (IMUs), force-sensitive resistors (FSRs), and stress sensors, as well as the ease of reconfiguration for testing different arrangements. Alongside the functional aspects, the prosthesis system prototype also incorporated 3D-printed prosthesis covers based on an anatomical study, addressing not only mechanical protection but also the aesthetic and emotional needs of amputees. The following subsections detail the implementation of the embedded sensor architecture, actuation sub-systems, modular structural casing, and aesthetic covers.

8.1.1 Embedded Sensor Architecture

Multi-sensor architecture overview

The embedded sensor architecture was developed to capture real-time physiological, mechanical and environmental data from the prosthesis, thereby enabling continuous monitoring of amputee health, gait dynamics, structural integrity and safety. A multi-sensor approach was adopted to provide complementary streams of information: inertial measurement units (IMUs) for motion tracking, force-sensitive resistors (FSRs) for load distribution, temperature, humidity and pressure sensors for residual limb interface conditions, stress/strain sensors for monitoring mechanical loads in the pylon, and a global positioning system (GPS) module for location tracking in the event of a fall. The placement of each sensor type was carefully selected to maximise data relevance, with sensors distributed across the socket, shank, and pylon according to their intended function. Calibration procedures and appropriate sampling rates were applied to ensure that the acquired data was accurate, consistent, and suitable for integration into the broader adProLiSS framework. The sensors are detailed as follows:

a) Inertial Measurement Units (IMUs)

IMUs track gait dynamics

IMUs (Figure 8.1a) were integrated to monitor gait kinematics by measuring acceleration, angular velocity, and orientation of the prosthesis. This information is critical for detecting asymmetries in gait, monitoring mobility, and identifying abnormal events such as falls. Placement of the IMUs along the shank enabled alignment with the primary movement axis, ensuring reliable capture of lower-limb dynamics while minimising motion artefacts. Prior to data collection, the IMUs were calibrated by resetting the gyroscope bias and ensuring stable zero-offset values. Sampling rates in the range of 50–200 Hz were adopted to capture dynamic gait patterns without excessive data redundancy.

b) Force-Sensitive Resistors (FSRs)

FSRs monitor load & pressure

FSRs (Figure 8.1b) were used to measure load distribution and ground reaction forces, providing insight into weight-bearing asymmetries and socket interface pressures. They were positioned in the prosthesis socket and at load-bearing points on the sole of the foot to monitor limb–prosthesis interactions during walking. These data support the early detection of uneven loading, which may contribute to discomfort or ulcer formation. Calibration was performed by applying known weights to generate force–resistance curves, ensuring that sensor outputs corresponded to physiologically meaningful load ranges. Typical sampling rates ranged from 10–100 Hz, appropriate for capturing changes during stance and swing phases of gait.

c) Temperature and Humidity Sensors

Socket microclimate monitoring

Temperature and humidity sensors (Figure 8.1c) were integrated at the residual limb–socket interface to monitor microclimatic conditions associated with skin health. Elevated humidity and temperature are known contributors to skin irritation and ulceration, making these parameters critical for preventative monitoring. To strengthen the clinical relevance of these measurements, each temperature–humidity sensor was paired with a nearby force-sensitive resistor (FSR). This configuration enabled simultaneous monitoring of interface pressure, which is a key factor in ulcer development due to its link with pistoning, the relative movement of the residual limb within the socket, and the associated frictional stresses. Placement within the socket ensured direct exposure to the residual limb microclimate while remaining unobtrusive to the user. As environmental changes occur gradually, sampling frequencies of 1–2 Hz were sufficient for temperature and humidity, while the paired FSRs were sampled at higher rates (10–50 Hz) to capture pressure fluctuations during gait. Calibration was performed against reference environmental sensors for microclimatic variables and known loads for the FSRs, ensuring accurate and meaningful data integration.

d) Stress and Strain Sensors

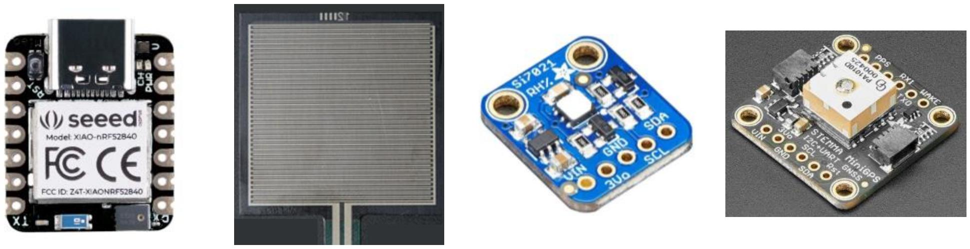
Structural load detection

Stress and strain sensors were incorporated into the pylon and load-bearing components of the prosthesis to measure bending moments and structural stresses. These data enable early detection of abnormal loading conditions, excessive strain, or potential component fatigue. Placement along the pylon was chosen to capture axial and bending forces while avoiding interference with user mobility. Calibration was performed by applying known loads and generating load–strain calibration curves, which allowed the measured signals to be converted into engineering units. Moderate sampling rates (10–50 Hz) were sufficient, as structural load variations occur at a slower frequency than gait kinematics.

e) Global Positioning System (GPS) Module

GPS for fall localisation

A GPS module (Figure 8.1d) was integrated into the prosthesis to provide real-time localisation, primarily for safety-critical applications such as fall detection and emergency response. When paired with inertial measurements indicating an impact or abrupt cessation of gait, the GPS module enables the system to determine the user's geographic location and communicate this information to designated caregivers or family members. This functionality ensures that assistance can be rapidly deployed in the event of a fall, addressing one of the most pressing safety concerns for amputees. The GPS module was positioned within the prosthesis housing in a location that ensured adequate signal reception while maintaining a compact and unobtrusive design. As GPS data is not required at high frequency, a sampling rate of approximately 100 Hz was sufficient for tracking purposes, thereby reducing energy consumption without compromising accuracy.



a) b) c) d)

Figure 8.1: a) XIAO nRF52840 Sense BLE IMU; b) FSR; c) Temperature and Humidity Sensor; d) GPS Module

Integrated sensor system supports PPMS & CD-CST

Together, the embedded sensors formed an integrated monitoring system capable of capturing multi-dimensional data on prosthesis use, amputee–prosthesis interactions and user safety. In addition to the individual contributions of IMUs, FSRs, temperature/humidity, stress/strain sensors, and GPS modules, certain configurations were deliberately combined to enhance clinical relevance. For example, temperature and humidity sensors were paired with co-located FSRs to simultaneously monitor microclimate and interface pressure, thereby providing insight into pistoning effects and the frictional stresses that contribute to ulcer formation. The GPS module extended this monitoring capability beyond the prosthesis itself by enabling real-time localisation, particularly for fall detection and emergency response scenarios. Collectively, this architecture ensured that the captured signals reflected both the physiological and mechanical factors that influence amputee comfort, safety, and device performance. The data generated at this layer served as the foundation for the embedded computing pipeline described in Section 8.2, enabling integration with the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST).

8.1.2 Actuation and Sub-systems

Servo-based knee actuation prototype

The actuation sub-system was implemented to provide controlled knee motion within the prosthesis prototype, enabling functional demonstrations of joint behaviour and facilitating integration with the broader adProLiSS architecture. A servo motor was selected for this purpose due to its compact form factor, ease of control, and sufficient torque for laboratory-based testing. The motor was mounted within the knee joint housing and interfaced with the prosthesis structure to simulate flexion and extension under programmed control. For testing efficiency, the actuator was predominantly powered via a mains supply, which ensured stable operation during extended development sessions. An external battery pack, adapted from an electric drill, was also procured to explore portable operation, though this was not used extensively within the current implementation. The following subsections detail the actuator selection, integration within the prosthesis structure, and supporting mechanical sub-systems that housed and protected the assembly.

a) Actuator Selection and Integration

DOCYKE servo for knee motion

The DOCYKE servo motor was selected to provide controlled knee joint motion, offering a practical balance between simplicity, controllability, and physical integration within the prosthesis prototype. The choice of a servo was guided by its compact dimensions (143mm x 66mm x 58mm), low weight (550g), integrated position feedback, and ability to deliver sufficient torque (35Nm) for demonstrating knee flexion and extension under laboratory conditions. The servo was mounted within a custom-designed knee joint housing, which provided structural stability while allowing the motor shaft to directly interface with the joint axis. This integration enabled programmed angular displacements to be executed reliably during testing and demonstration scenarios.

Figure 8.2: DOCYKE Servo Motor

b) Power Supply

Mains-powered with battery option

For efficiency and continuity during iterative testing, the actuator was primarily powered through a mains supply. This ensured stable performance over extended development sessions without interruptions due to recharging. To investigate options for portable use, an external battery pack adapted from an electric drill was also procured. Although this power source was not extensively deployed during the present implementation, it provided a proof-of-concept for potential untethered operation in future iterations.

c) Mechanical Sub-systems

Modular knee assembly integration

The DOCYKE servo motor was embedded within a modular knee joint assembly (Figure 8.3) designed to accommodate both mechanical and electronic components. The assembly incorporated custom brackets and casings that secured the servo while allowing straightforward replacement or adjustment if required. The modular construction also facilitated integration with the sensor systems described in Section 8.1.1, enabling a coherent link between actuation, data acquisition, and structural elements of the prosthesis prototype. This design approach prioritised accessibility, adaptability, and the ability to reconfigure sub-systems for experimental testing within the adProLiSS framework.

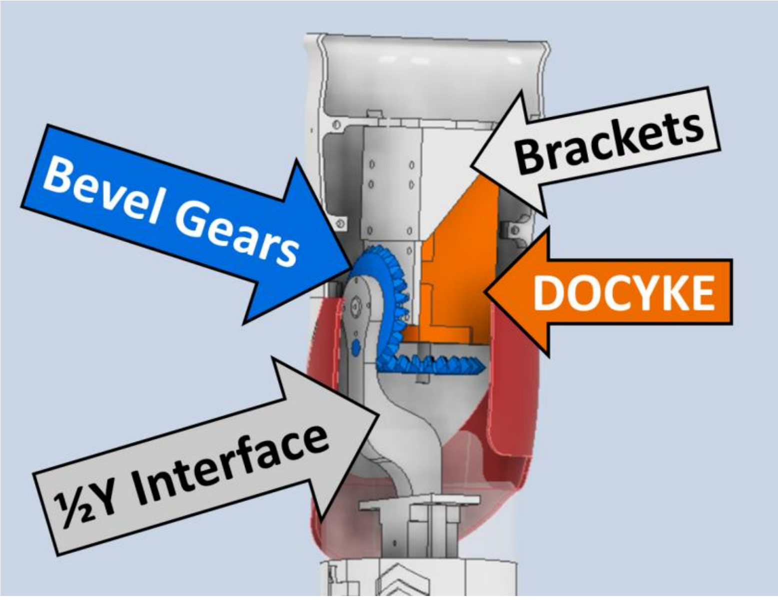


Figure 8.3: Internal view of knee joint

8.1.3 Prosthesis Structural Modularity

Modular structure enables flexible testing

The structural design of the prosthesis prototype incorporated modular case attachments to support the flexible integration of sensors and ancillary components. This modularity was a critical aspect of the implementation, as it allowed different hardware configurations to be tested without requiring a full redesign of the prosthesis structure. For example, discrete sensor housings were designed to be independently mounted or removed, enabling reconfiguration of the prototype to focus on specific measurement objectives such as interface pressure, gait dynamics, or structural stress.

By embedding modularity at the structural level, the prototype was able to serve as a flexible test platform rather than a fixed configuration. This adaptability proved particularly valuable for the demonstration scenarios described in Section 8.4, where different arrangements of sensors and supporting components were required to showcase evolving health, safety, and performance monitoring functions within the adProLiSS framework.

8.1.4 Aesthetic Implementation of Prosthesis Covers

Rationale: aesthetics & acceptance

As discussed in Chapter 3, stakeholder feedback and prior research highlighted the importance of aesthetic considerations in prosthesis acceptance, particularly regarding anatomical proportions and the emotional responses associated with human resemblance. These findings established the design rationale for developing prosthesis covers that balanced anatomical fidelity with practicality, while avoiding the negative emotional effects described in the literature. Building on this rationale, the implementation focused on translating these requirements into a functional, manufacturable cover using 3D CAD design and additive manufacturing techniques.

Four design objectives of cover

The design objectives for the prosthesis cover were fourfold: a) to approximate the anatomical proportions of the lower limb without pursuing hyper-realistic detailing; b) to provide sufficient internal capacity to accommodate sensors, actuators, and structural components without introducing unnecessary bulk; c) to incorporate modular construction that would enable customisation and straightforward replacement of sections; and d) to ensure ease of assembly and disassembly to support maintenance and iterative testing. These objectives guided the development of successive CAD design iterations, the selection of fabrication methods, and the final validation of the cover.

Iterative CAD design process

To achieve these objectives, a series of prosthesis cover designs were modelled in Autodesk Inventor and refined through successive iterations. Each version incorporated lessons learned from its predecessor, with adjustments made to improve manufacturability, structural integrity, and visual appeal. The third version was selected for implementation, as it provided the most effective balance between anatomical fidelity, robustness, and user-centred requirements.

PLA modular covers via 3D printing

The final covers were manufactured using polylactic acid (PLA) with a PRUSA Mini fused filament fabrication (FFF) printer. The modular design divided the cover into thigh and shank sections, allowing components to be interchanged or replaced as required. This adaptability facilitated customisation to the individual amputee's needs and provided a practical means of replacing damaged sections without reprinting the entire cover. Figures 8.4–8.6 illustrate the CAD models of the thigh and shank covers, as well as the assembled configuration.

The novelty of this cover design was formally recognised through a Design Registration (No 1672).

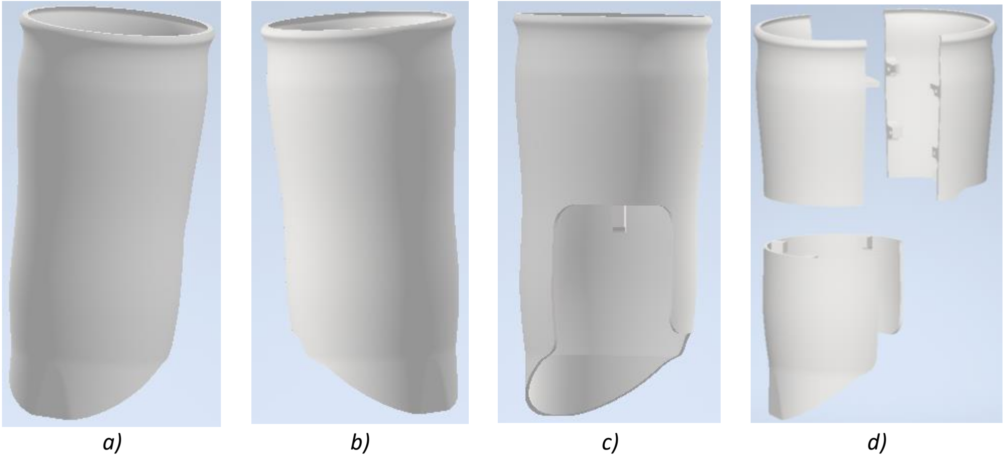
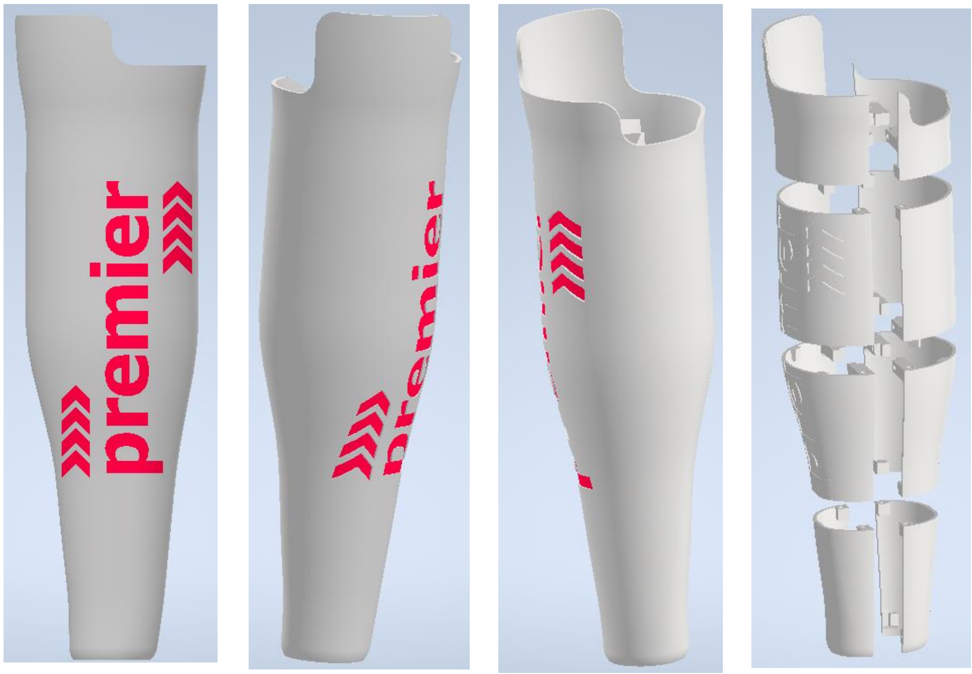

a) *b)* *c)* *d)*

Figure 8.4: Thigh Cover – a) Front Left Perspective; Front Right Perspective; c) Back Left Perspective; d) Exploded View



a) *b)* *c)* *d)*

Figure 8.5: Shank Cover – a) Left Side View; b) Front Left Perspective; c) Back Left Perspective; d) Exploded View

a) *b)*

Figure 8.6: Thigh/Shank Covers a) Original Design; b) Red Highlights

8.2 Digital Implementation Platforms

Digital layer links sensors to decisions

The digital implementation of the adProLiSS framework was designed to complement the physical prosthesis prototype by enabling data acquisition, processing, visualisation, and stakeholder interaction. This digital layer serves as the bridge between raw sensor inputs and consequence-aware decision-making, ensuring that information generated by the prosthesis can be interpreted and acted upon within the broader service system. Three interconnected platforms were developed. First, an embedded computing and data pipeline based on a Raspberry Pi provided the computational hub for sensor data collection, motor control, and cloud-based data transfer. Second, the Patient–Prosthesis Management System (PPMS) offered a role-based interface for stakeholders to access real-time dashboards, alerts, and diagnostic information. Finally, the Consequence-Driven Co-Design Support Tool (CD-CST) enabled stakeholders to configure prosthesis and aftercare options, receiving consequence-aware feedback derived from the underlying knowledge base. Together, these platforms operationalised the digital layer of adProLiSS, supporting both the demonstration scenarios in Section 8.4 and the stakeholder evaluations described in Chapter 9.

8.2.1 Embedded Computing Architecture and Data Flow

Raspberry Pi as processing hub

The embedded computing architecture formed the central digital hub linking sensors, actuation, and the higher-level digital platforms (PPMS, CD-CST). A Raspberry Pi 4 was selected as the processing unit due to its low cost, compact form, and high performance relative to other development boards. Its configurable GPIO pins, integrated Wi-Fi and Bluetooth connectivity, and strong Python support made it particularly suited for rapid prototyping. In addition, the wide availability of Python libraries for sensor communication facilitated efficient integration of heterogeneous devices without requiring customised hardware driver coding at low level.

Multi-sensor acquisition & data flow

The Raspberry Pi enabled simultaneous acquisition and management of multiple sensor streams. Several devices, including the force-sensitive resistors (FSRs) and temperature–humidity sensors, were hardwired to GPIO ports, where their voltage outputs could be directly sampled. The inertial measurement units (IMU), in contrast, were interfaced wirelessly via Bluetooth, demonstrating the board's flexibility in handling both wired and wireless communication protocols. Stress/strain sensors were similarly routed through GPIO channels, completing the multi-sensor configuration described in Section 8.1.1. Leveraging available Python libraries, custom scripts were developed to acquire raw sensor data, apply pre-processing and formatting, and upload the results to cloud storage. Processed data was then streamed into Google Sheets, from which it could be accessed by the Patient–Prosthesis Management System (PPMS) for real-time monitoring.

Actuation synchronised with sensors

Beyond sensor acquisition, the Raspberry Pi was also employed to support actuation. Pre-recorded gait patterns, consisting of knee and hip angle trajectories, were stored on the device and used to drive the servo motor embedded within the prosthesis knee joint (Section 8.1.2). This integration enabled synchronisation between sensor inputs and actuator control, demonstrating the feasibility of a closed-loop prosthesis management system.

PushBullet alerting system for stakeholders

In addition to sensor acquisition and actuator control, the Raspberry Pi was configured to support real-time communication with stakeholders through an event-based alerting system. A Python script was developed to interface with the PushBullet platform, enabling customised notifications to be sent directly to stakeholders' mobile devices when specific conditions were met. For example, threshold violations detected by the FSRs or abnormal gait readings from the IMU could trigger automated alerts. This functionality required stakeholders to install the PushBullet application on their phones, after which messages could be delivered instantaneously. By transforming sensor events into actionable, real-time feedback, the alerting system exemplified the consequence-aware philosophy underpinning the adProLiSS framework.

Modularity supports iterative evolution

A further advantage of adopting the Raspberry Pi platform was its modularity as a development board. Additional sensors or peripheral components could be readily incorporated into the system with minimal reconfiguration, supporting the iterative and exploratory nature of the prototype's implementation. This adaptability ensured that the digital platform could evolve alongside the broader adProLiSS framework, maintaining consistency with its long-term objectives and adapting to meet amputee evolving needs.

Architecture overview Figure 8.7

The overall architecture is illustrated in Figure 8.7, which depicts the integration of wired and wireless communication channels within the embedded computing environment. Temperature–humidity sensors, force-sensitive resistors (FSRs), and the GPS module were hardwired to the Raspberry Pi through its GPIO interfaces, while the inertial measurement unit (IMU) communicated via Bluetooth. The Raspberry Pi also provided a direct wired connection to the servo motor for actuation control. Processed data outputs were transmitted wirelessly to cloud storage (Google Sheets), enabling subsequent access by the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST). In parallel, event-based alerts were delivered to stakeholders' mobile devices, while visual dashboards could be accessed on computers and tablets. This architecture demonstrates how the embedded computing hub operationalised multi-modal data integration, actuation control, and real-time stakeholder communication within the adProLiSS framework.

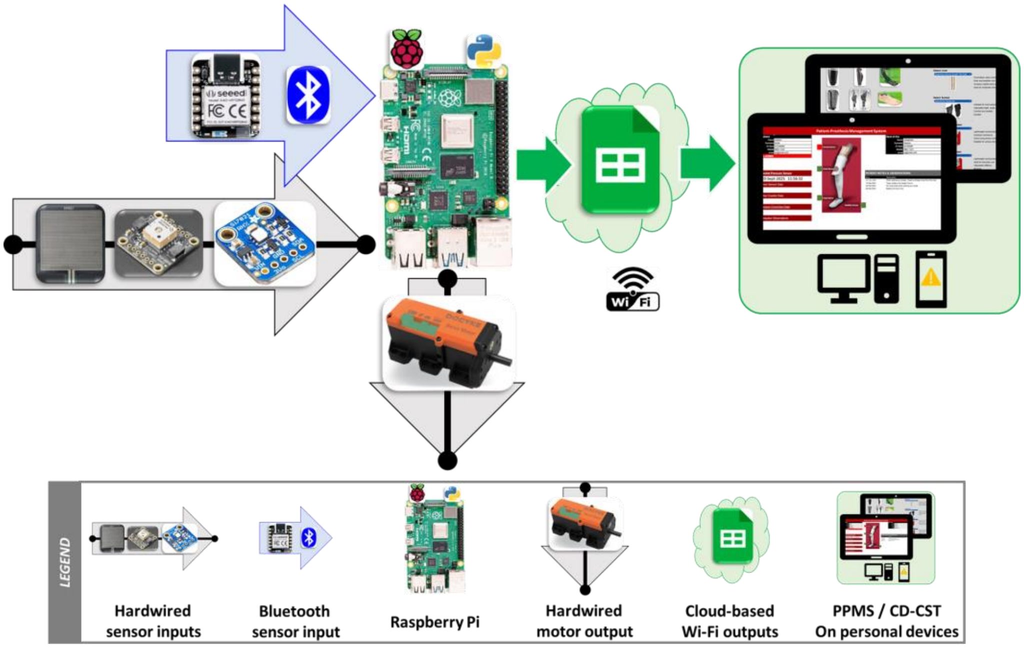


Figure 8.7: Embedded computing architecture linking sensors, Raspberry Pi, actuation, cloud storage, and stakeholder interfaces.

8.2.2 Patient-Prosthesis management System

PPMS: role-based stakeholder interface

The *Patient–Prosthesis Management System* (PPMS) was implemented as the primary digital interface for stakeholders to access and interpret data generated by the prosthesis prototype. Its purpose was to translate raw sensor outputs into structured, meaningful information that could support monitoring, diagnosis, and decision-making of both patient-prosthesis related health and prosthesis functionality across different phases of the prosthesis life-cycle. The system was developed using Google Sheets, supported by Google Apps Script automation, to provide a low-cost, cloud-based, and accessible solution that enabled real-time integration of sensor data with role-based stakeholder views.

Data Acquisition and Storage

Secure upload to Google Sheets

Sensor data collected through the Raspberry Pi (Section 8.2.1) was uploaded to a dedicated Google worksheet via the gspread Python library and the Google Sheets API. API access was secured through a service account credential file, which provided a unique permission key ensuring that only authorised scripts could write to the target worksheet. This configuration prevented uncontrolled data uploads and maintained patient-specific segregation of information.

Within the data acquisition worksheet, separate sub-sheets were created to organise different data streams:

- Patient records: static information such as name, contact details, date of birth, and next-of-kin.
- Emergency stop log: including a timestamp, the event (e.g. emergency stop triggered), and system response notification (e.g. “movement halted”);
- Socket interface data: timestamped values from FSRs, temperature, and humidity sensors;
- Foot FSR data: timestamped pressure readings from individual sensors located under the footplate, with associated event notifications;
- GPS location data: timestamped co-ordinates with contextual alerts (e.g. fall detection events).

- Motion data: including knee cycles, fall count, gait speed, and other movement parameters such as acceleration and velocity.

Each sheet was designed so that the most recent entry appeared at the top row, with earlier entries pushed downward. This ensured that time-critical information remained immediately visible while preserving a full chronological log for historical analysis.

Scalable case-specific worksheets

This structure is inherently scalable, as a dedicated worksheet can be created for each amputee case. Stakeholders with appropriate permissions, such as prosthetists, physiotherapists, and engineers, can therefore access and manage patient-specific datasets while maintaining segregation and traceability of records.

Data Processing and Dashboard Creation

Traffic-light indicators & formatting

A separate Google Sheet, functioning as the PPMS interface, was created to provide stakeholders with a graphically structured dashboard rather than direct exposure to raw data streams. Permissions were configured to allow this sheet to automatically import data from the acquisition worksheet and populate dedicated cells for each monitored variable. Threshold values underpinning the visual indicators were defined using domain knowledge drawn from clinical practice and prosthetics literature, and were configured to be patient-specific rather than fixed constants. For example, weight-distribution thresholds were derived relative to the individual amputee's body weight and expected asymmetry, recognising that unilateral lower-limb amputees typically exhibit a measurable load imbalance between the prosthetic and sound limb. Deviations beyond this personalised baseline were therefore flagged as abnormal, rather than deviations from an able-bodied reference.

Traffic-light UI supports rapid screening and attention prioritisation for experts by reducing extraneous cognitive load

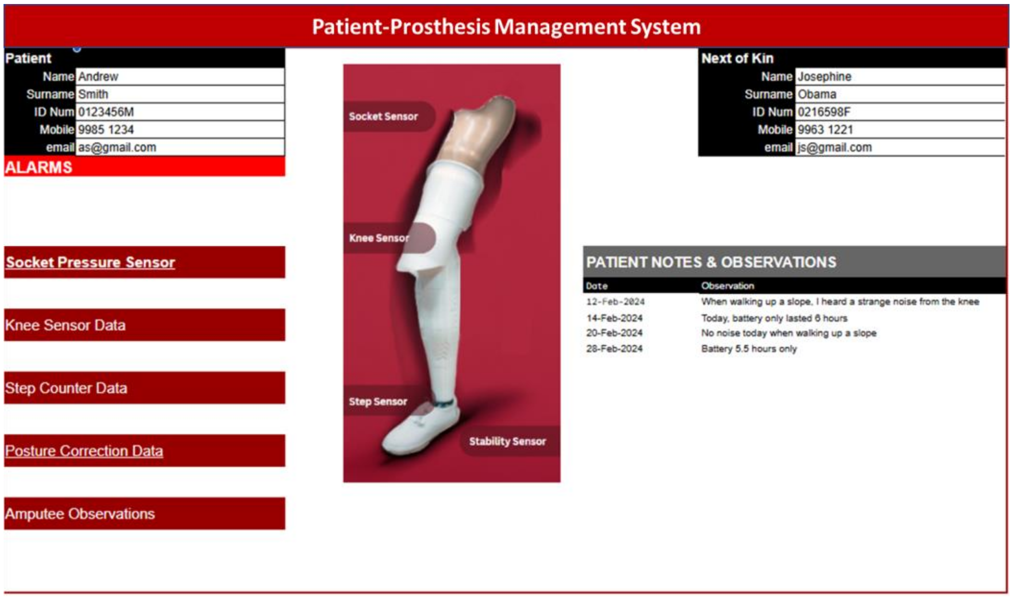
Visual indicators such as colour-coded "traffic lights" and conditional formatting rules were implemented to support rapid screening and anomaly detection, with red flags indicating variables (e.g. excessive socket pressure) requiring further investigation and green indicators signalling normal operation. Although many system users are domain specialists (e.g. prosthetists, physiotherapists, and engineers), this abstraction layer was intentionally introduced to reduce cognitive load during routine monitoring, enabling stakeholders to prioritise attention efficiently and avoid unnecessary interpretation of raw data when no intervention is required. This design choice aligns with Cognitive Load Theory, which emphasises the importance of minimising extraneous cognitive effort in information-dense tasks while preserving access to detailed data when deeper analysis is needed (Sweller, Ayres and Kalyuga, 2011). Raw sensor values remain accessible within the PPMS for expert inspection when flagged conditions arise.

Functional user-friendly PPMS dashboard

The PPMS (Figure 8.8) was designed to be both functional and user-friendly, combining high-level monitoring with interactive access to detailed datasets. Stakeholders could view patient demographics, emergency alerts, and next-of-kin details, alongside modular links to specific prosthesis sub-systems (socket, knee, foot, and posture correction). An integrated prosthesis diagram highlighted the location of sensors, reinforcing spatial understanding of data sources. Timestamped notes and observations provided a structured channel for qualitative feedback. The alarm panel included automated event notifications, such as fall detection, with embedded GPS links enabling rapid localisation of the amputee. This combination of graphical layout, interactive navigation, and contextual information ensured that the PPMS acted as a comprehensive management interface rather than a static data repository.

Stakeholder Interaction and Notes

In addition to numerical and graphical data, the PPMS included a dedicated section for amputee notes and observations. This allowed prosthetists, physiotherapists, or technicians to view record qualitative feedback alongside quantitative sensor data, supporting richer communication and traceability of care decisions. The integration of both objective measurements and subjective annotations reflected the principle of consequence-aware knowledge capture embedded in the adProLiSS framework.



Patient

Name	Andrew
Surname	Smith
ID Num	0123456M
Mobile	9985 1234
email	as@gmail.com

Next of Kin

Name	Josephine
Surname	Obama
ID Num	0216598F
Mobile	9963 1221
email	js@gmail.com

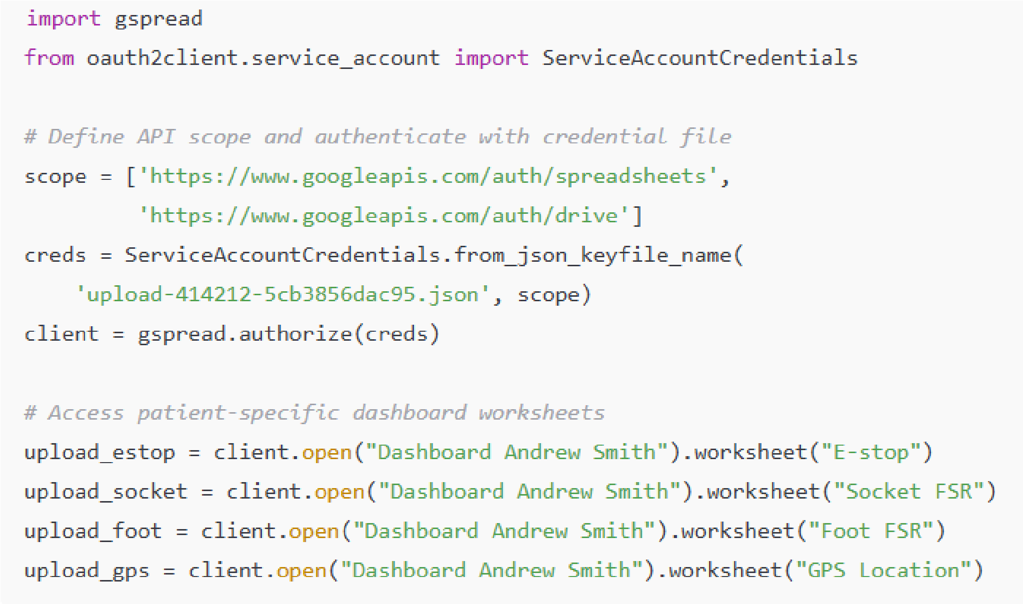
PATIENT NOTES & OBSERVATIONS

Date	Observation
12-Feb-2024	When walking up a slope, I heard a strange noise from the knee
14-Feb-2024	Today, battery only lasted 6 hours
20-Feb-2024	No noise today when walking up a slope
28-Feb-2024	Battery 5.5 hours only

Figure 8.8: The Patient-Prosthesis Management System

Illustrative Code Snippet

The following excerpt (Figure 8.9) shows part of the Python script used to establish API credentials and upload sensor data to the appropriate worksheet tabs. This demonstrates the interface between the embedded computing platform and the cloud-based PPMS:



```python
import gspread
from oauth2client.service_account import ServiceAccountCredentials

# Define API scope and authenticate with credential file
scope = ['https://www.googleapis.com/auth/spreadsheets',
         'https://www.googleapis.com/auth/drive']
creds = ServiceAccountCredentials.from_json_keyfile_name(
    'upload-414212-5cb3856dac95.json', scope)
client = gspread.authorize(creds)

# Access patient-specific dashboard worksheets
upload_estop = client.open("Dashboard Andrew Smith").worksheet("E-stop")
upload_socket = client.open("Dashboard Andrew Smith").worksheet("Socket FSR")
upload_foot = client.open("Dashboard Andrew Smith").worksheet("Foot FSR")
upload_gps = client.open("Dashboard Andrew Smith").worksheet("GPS Location")
```

Figure 8.9: Code snippet of Python script used to establish credentials and upload sensor data

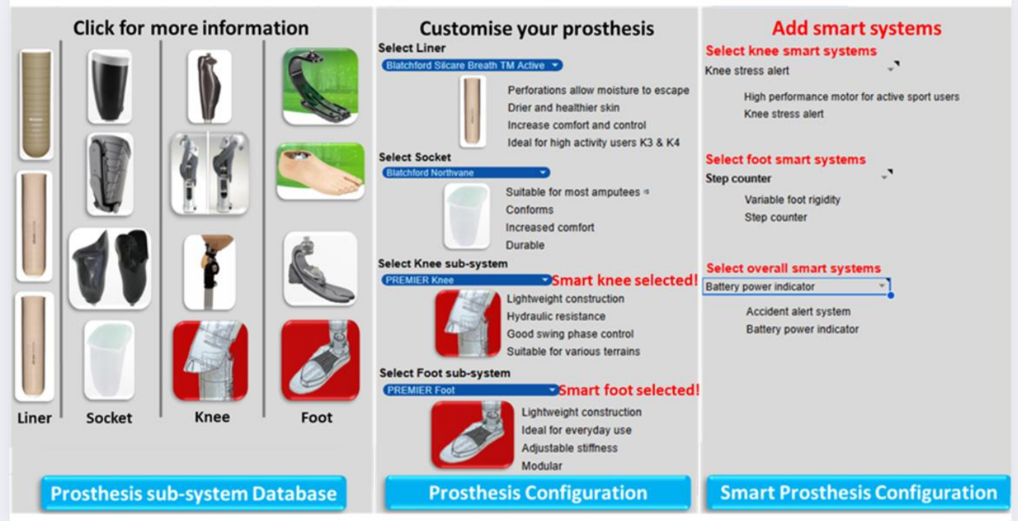
This structure ensured that each dataset was uploaded directly to the correct worksheet, preserving separation of data streams while enabling aggregation at the PPMS level.

Thus, the PPMS operationalised the digital management layer of adProLiSS by transforming raw sensor data into structured, accessible, and actionable information. By combining cloud-based automation, graphical dashboards, and integrated stakeholder notes, the system provided a holistic overview of prosthesis performance and user well-being. It also served as the primary point of access for clinicians, amputees, and technicians, bridging the embedded computing platform (Section 8.2.1) with the decision-support functionality of the CD-CST (Section 8.2.3).

8.2.3 Consequence-Driven Co-Design Support Tool

CD-CST enables collaborative, consequence-aware design

The Consequence-Driven Co-Design Support Tool (CD-CST) (Figure 8.10) was developed to provide stakeholders, the key decision makers who are the amputees, prosthetists, physiotherapists, and engineers, with a collaborative environment for designing prosthesis and aligning them with appropriate aftercare services. Its role within adProLiSS is to operationalise the knowledge structures and consequence reasoning outlined in Chapters 5–7, offering stakeholders a decision-support interface that visualises available options, simulates compatibility, and highlights potential mismatches or risks. The CD-CST was implemented using Google Sheets and its integrated script editor, connected through an API, to ensure accessibility during case study demonstrations and to facilitate future scalability. This platform choice also allowed for seamless interoperability with the PPMS (Section 8.2.2) and provided a pathway for eventual deployment as a standalone application through conversion to a mobile app.



Customise your prosthesis

Select Liner
Blatchford Silcare Breath TM Active
Perforations allow moisture to escape
Drier and healthier skin
Increase comfort and control
Ideal for high activity users K3 & K4

Select Socket
Blatchford Northvane
Suitable for most amputees
Conforms
Increased comfort
Durable

Select Knee sub-system
PREMIER Knee
Smart knee selected!
Lightweight construction
Hydraulic resistance
Good swing phase control
Suitable for various terrains

Select Foot sub-system
PREMIER Foot
Smart foot selected!
Lightweight construction
Ideal for everyday use
Adjustable stiffness
Modular

Add smart systems

Select knee smart systems
Knee stress alert
High performance motor for active sport users
Knee stress alert

Select foot smart systems
Step counter
Variable foot rigidity
Step counter

Select overall smart systems
Battery power indicator
Accident alert system
Battery power indicator

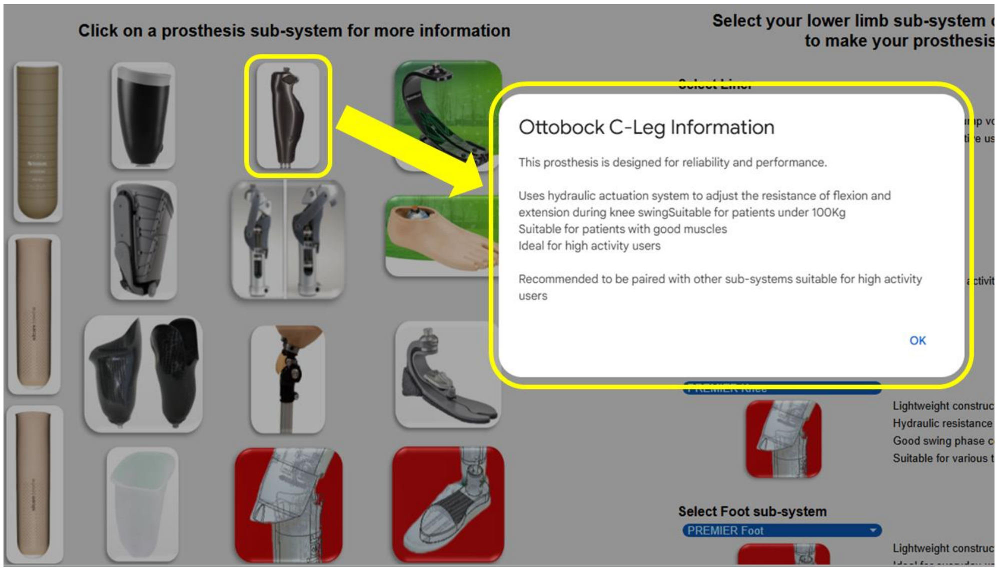
Figure 8.10: The Consequence-Driven Co-Design Support Tool

The CD-CST interface was structured around three main sections.

1. **Prosthesis Sub-system Library**

Sub-system library improves stakeholder awareness

The first section comprises a (currently non-exhaustive) library of prosthesis sub-systems, including liners, sockets, knees, and foot/ankle components. Each item in the library is represented visually through an icon, which when selected triggers a pop-up window (Figure 8.11) containing descriptive information and performance statistics (e.g. weight-bearing capacity, suitability for specific mobility classifications, durability). All information was manually curated and input into the tool to ensure relevance and accuracy. This library addressed a key gap identified through stakeholder interviews: amputees often reported limited awareness of available prosthesis sub-systems and their functional characteristics, leaving them dependent on prosthetist recommendations with minimal prior knowledge. By providing a structured, visual, and accessible database, the CD-CST enabled stakeholders to better understand available options, thereby enhancing their ability to participate meaningfully in shared decision-making.



Ottobock C-Leg Information

This prosthesis is designed for reliability and performance.

Uses hydraulic actuation system to adjust the resistance of flexion and extension during knee swingSuitable for patients under 100Kg
Suitable for patients with good muscles
Ideal for high activity users

Recommended to be paired with other sub-systems suitable for high activity users

Figure 8.11: Sub-system pop-up window

2. **Prosthesis Configuration Module**

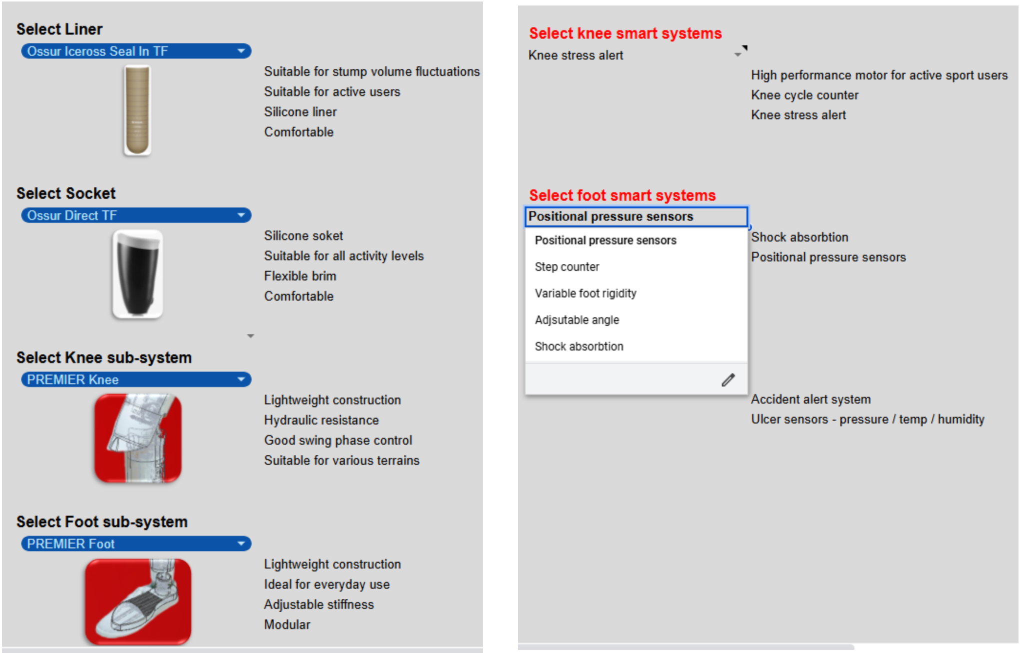
Sub-system selection with consequence checks

The second section supported the customisation of a complete prosthesis by allowing stakeholders to collectively select one sub-system for each category (liner, socket, knee, and foot/ankle) (Figure 8.12a). Once a sub-system was chosen, its icon appeared in the configuration panel accompanied by automated annotations describing performance attributes and suggested pairing recommendations. The CD-CST incorporated a basic simulation of consequence-aware reasoning: once all four selections had been made, the system evaluated their compatibility and generated alerts if inconsistencies or inappropriate matches were detected. For example, if a K-level 1 amputee (low mobility) was matched with a sports blade designed for K-level 4 (high activity) users, the tool flagged the configuration as unsuitable. While full AI-driven reasoning was not yet integrated, these simulated scenarios demonstrated how the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF) could be operationalised within a digital tool to support adaptive, consequence-aware decision-making.

3. **Smart System and Aftercare Integration**

Smart systems link design to aftercare

The third section allowed stakeholders to enrich the prosthesis configuration by adding “smart systems” from a drop-down menu (Figure 8.12b). These smart systems represented the sensor-based technologies that enable personalised aftercare services, such as socket temperature–humidity monitoring, pressure distribution tracking, knee cycle counting, or accident alert systems. Their inclusion enabled the configured prosthesis to be directly linked with aftercare requirements for that specific amputee. For example, by associating a knee cycle counter with predictive maintenance schedules or a temperature–humidity sensor with ulcer prevention monitoring. While the interface primarily displayed prosthesis sub-systems, the selection of smart systems effectively represented the integration of aftercare elements, thereby ensuring consistency with the PLCCKMF framework. This approach demonstrates how the prosthesis and its associated services can be co-designed in a unified environment.



Select Liner
Ossur Iceross Seal In TF
Suitable for stump volume fluctuations
Suitable for active users
Silicone liner
Comfortable

Select Socket
Ossur Direct TF
Silicone soket
Suitable for all activity levels
Flexible brim
Comfortable

Select Knee sub-system
PREMIER Knee
Lightweight construction
Hydraulic resistance
Good swing phase control
Suitable for various terrains

Select Foot sub-system
PREMIER Foot
Lightweight construction
Ideal for everyday use
Adjustable stiffness
Modular

Select knee smart systems
Knee stress alert
High performance motor for active sport users
Knee cycle counter
Knee stress alert

Select foot smart systems
Positional pressure sensors
Shock absorbtion
Positional pressure sensors
Accident alert system
Ulcer sensors - pressure / temp / humidity

a) *b)*

Figure 8.12: Sub-system selection and configuration; b) Smart systems and aftercare selection

Scalability and Interoperability

CD-CST scalable & interoperable with PPMS

The CD-CST was designed to be scalable across multiple amputee cases. A patient selection page allowed authorised stakeholders (prosthetists, physiotherapists, engineers) to view digital representations of patient-specific prostheses, aligned with data drawn from the PPMS. This ensured interoperability between the monitoring and management functions of the PPMS and the configuration and decision-support functions of the CD-CST. By leveraging the cloud-based Google Sheets platform, the CD-CST could be easily deployed in distributed settings without requiring specialised software, making it highly suitable for collaborative use in clinical and engineering contexts.

Prototype consequence-aware co-design tool

In summary, the CD-CST implemented a prototype of consequence-aware co-design, enabling stakeholders to select prosthesis sub-systems, receive feedback on compatibility, and integrate smart systems linked to aftercare. Although AI reasoning was not yet fully embedded, simulated consequence checks provided a proof-of-concept for how ontology-driven inference could be operationalised in practice. By addressing amputees' lack of familiarity with prosthesis sub-systems, the CD-CST not only enhanced stakeholder communication but also provided a foundation for more transparent and inclusive decision-making.

8.3 Integration of Framework Layers

adProLiSS structured in four layers

The implementation of adProLiSS was not confined to isolated physical prototypes or digital platforms, but was structured to reflect the layered architecture introduced in earlier chapters. The framework is composed of four interdependent layers, Knowledge, Physical, Operational, and Application, each fulfilling a distinct role while contributing to the overall system's capability for consequence-aware prosthesis design and aftercare. The purpose of this section is to demonstrate how these layers were integrated within the implemented system, thereby translating the theoretical constructs of Chapters 5–7.

Roles of knowledge, physical, operational & application layers

In this configuration, **the Knowledge Layer** provided the formalised ontology and consequence reasoning logic developed in the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF) in Chapter 7. **The Physical Layer** comprised the prosthesis prototype, embedded sensors, and actuation mechanisms described in Section 8.1, serving as the source of real-world data. **The Operational Layer** reflected the process-oriented adProLiSS framework (Chapters 5-6) that co-ordinated information exchange, modularity, and system logic. Finally, **the Application Layer** encompassed the stakeholder-facing platforms, the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST), through which data, knowledge, and inferences were communicated to users.

Figure shows integrated layered system

Figure 8.13 illustrates the layered view of adProLiSS, portraying how each one of these layers presents a different view of what is involved, to collectively form an integrated, consequence-aware service system. Here, the Knowledge, Physical, Operational, and Application layers are presented as conceptual abstraction layers rather than a strict hierarchy. Each layer provides a distinct perspective on the smart prosthesis service system, focusing respectively on knowledge representation, physical embodiment, process coordination, and stakeholder interaction. In particular, the Physical and Operational layers are intentionally shown as separate but co-existing and interdependent views: the Physical layer captures the embodied prosthesis and sensing infrastructure, while the Operational layer represents the process logic and coordination mechanisms that act upon and are informed by physical system behaviour. The visual separation therefore serves an explanatory purpose, rather than implying precedence or control between layers. The sub-sections that follow detail how these layers were implemented and interconnected within the prototype system.

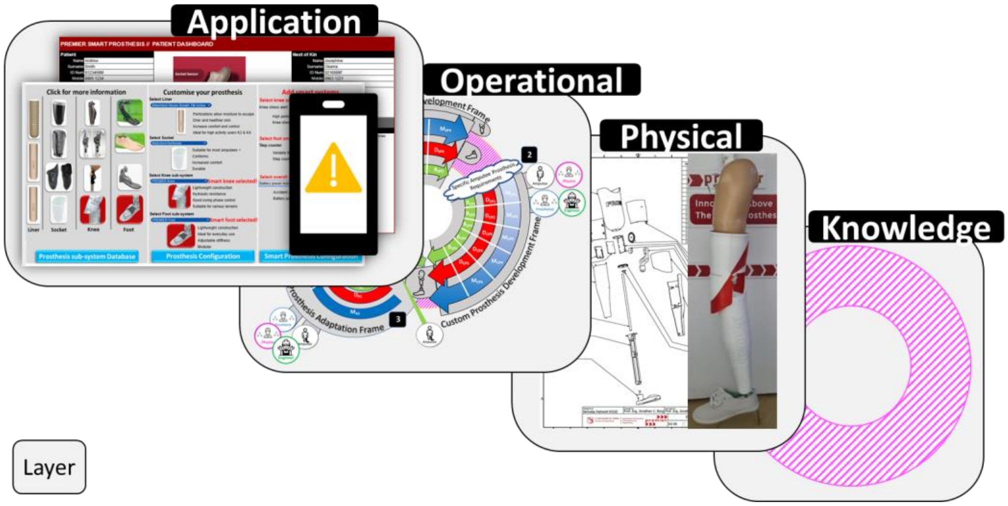


Figure 8.13: adProLiSS Framework Layered View

8.3.1 Knowledge Layer Integration

Knowledge layer as PLCCKMF foundation

The Knowledge Layer of adProLiSS was based on the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF) described in Chapter 7, and forms the bottom, foundational layer of the architecture. It encodes prosthesis sub-systems, amputee profiles, and consequence rules, and guides the layers above while interpreting evidence coming up from the Physical Layer. In practice, this foundation specified what should be measured (e.g. socket pressure, temperature, humidity for ulcer risk) and how measurements should be interpreted, providing the rule base that the Operational and Application layers use to drive workflows, compatibility checks, alerts, and stakeholder feedback.

Integration with Physical layer via sensors

Integration with the Physical Layer occurred through the specification of what data should be captured and how it should be interpreted. For example, the ontology represented the relationship between socket interface conditions (pressure, temperature, humidity) and the risk of ulcer formation. This drove the inclusion of co-located FSRs, temperature, and humidity sensors in the prosthesis (Section 8.1.1). The PLCCKMF therefore provided the rationale for sensor placement and parameter monitoring, ensuring that the physical prototype addressed clinically meaningful risks rather than capturing arbitrary signals.

Integration with Operational Layer via rules

Integration with the Operational Layer was achieved through the embedding of consequence rules into system workflows. For instance, the PLCCKMF encoded knowledge of amputee mobility classifications (K-levels) and the compatibility of different prosthesis sub-systems. This allowed the operational logic of the CD-CST to evaluate stakeholder design choices and flag unsuitable configurations. Without this knowledge base, the operational processes of adProLiSS would have relied on tacit expertise alone. With it, the framework became capable of systematic, traceable decision support.

Integration with Application Layer via PPMS & CD-CST

Integration with the Application Layer was most visible in the PPMS and CD-CST interfaces. In the PPMS, knowledge-driven rules structured the data into meaningful categories (socket, knee, foot, motion) and triggered alerts when thresholds were exceeded (e.g. high pressure combined with elevated temperature and humidity). In the CD-CST, the ontology provided the basis for consequence simulation: a low-mobility amputee being matched with a high-performance sports blade was flagged as an incompatible selection. Although the reasoning engine was simulated in the prototype, these examples demonstrated the potential for the PLCCKMF to directly influence stakeholder-facing decision-making.

Layered data-reasoning flow example

The layered flow of data and reasoning across the system. The Physical Layer supplies sensor data, the Knowledge Layer interprets it through ontology rules, the Operational Layer embeds this interpretation into workflows, and the Application Layer communicates results through dashboards, alerts, and configuration interfaces. A corresponding SWRL rule example is shown below, demonstrating how socket conditions were modelled to trigger an ulcer risk alert:

(8.1) FSR(?s), TemperatureSensor(?t), HumiditySensor(?h), recordsHighPressure(?s, ?p), recordsHighTemperature(?t, ?temp), recordsHighHumidity(?h, ?hum), greaterThan(?p, 80), greaterThan(?temp, 37), greaterThan(?hum, 70) → triggersAlert(UlcerRisk)

This rule highlights how multi-sensor data was mapped to a clinically relevant consequence, enabling event-based alerts to be generated within the PPMS. Similar representations supported the evaluation of sub-system compatibility within the CD-CST.

In summary, the Knowledge Layer acted as the foundation upon which the other three layers were integrated. It defined what the Physical Layer measured, guided the processes of the Operational Layer, and provided the logic that structured and triggered outputs in the Application Layer. By embedding consequence knowledge directly into system implementation, the PLCCKMF ensured that adProLiSS functioned as a knowledge-driven, consequence-aware service system.

8.3.2 Physical Layer Integration

Physical layer as prototype & sub-systems

The Physical Layer constituted the prosthesis prototype and its embedded sub-systems, translating the abstract specifications of the Knowledge Layer into measurable, real-world phenomena. This layer included the socket, knee, and foot sub-systems, together with embedded sensors, actuation mechanisms, and the 3D-printed aesthetic covers described in Section 8.1. Its role within the layered architecture was twofold: i) to provide the data streams that fed upwards into the Operational and Application Layers, and ii) to embody the design constraints and requirements formalised in the Knowledge Layer.

Knowledge Layer guides sensor inclusion

Integration with the Knowledge Layer was achieved through the mapping of prosthesis consequences into sensor specifications. For example, the ontology modelled the relationship between elevated socket pressure, temperature, and humidity and the onset of ulceration. This consequence rule determined the inclusion of co-located FSRs and environmental sensors in the socket design. Similarly, the knowledge representation of fall events and gait irregularities justified the integration of inertial measurement units (IMUs) and GPS modules into the prosthesis. In this way, the Physical Layer was not simply a hardware assembly but a deliberate implementation of ontology-driven monitoring requirements.

Operational Layer processes structured data

Integration with the Operational Layer was facilitated by the organisation of sensor outputs into modular data streams that could be orchestrated by the adProLiSS processes. The Raspberry Pi platform served as the bridge, collecting physical measurements and preparing them for processing within the operational workflows. For instance, raw accelerometer data from the IMU was converted into step counts and fall detection events, which the Operational Layer then used to update patient records and trigger notifications. The Physical Layer therefore provided the evidentiary basis for consequence reasoning and workflow execution.

Application Layer translates data for stakeholders

Finally, **integration with the Application Layer** occurred through the communication of physical measurements in a format meaningful to stakeholders. Socket pressure, gait cycles, or knee actuation states were not presented as raw voltages but as structured indicators (e.g. “high pressure,” “fall event,” “maintenance required”) within the PPMS and CD-CST interfaces. In this way, the Physical Layer’s outputs were contextualised and made actionable for amputees, prosthetists, physiotherapists, and engineers.

Physical Layer grounds framework in reality

In summary, the Physical Layer represented the embodied dimension of adProLiSS, in which theoretical consequence rules from the Knowledge Layer were made measurable, operational processes were supplied with structured data streams, and stakeholder platforms were grounded in real-world evidence. This ensured that adProLiSS was not only a conceptual framework but a tangible system capable of monitoring, interpreting, and supporting the evolving needs of amputees.

8.3.3 Operational Layer Integration

Operational layer as process logic hub

The Operational Layer embodied the process-oriented logic of the adProLiSS framework introduced in Chapters 5 and 6. It acted as the intermediary between raw data supplied by the Physical Layer and the stakeholder-facing platforms in the Application Layer. Its primary role was to co-ordinate the capture, processing, and interpretation of data streams in alignment with the consequence rules specified in the Knowledge Layer, thereby ensuring that the system functioned as a coherent, consequence-aware whole.

Knowledge layer rules embedded in workflows

Integration with the Knowledge Layer was achieved by embedding ontology-based rules and classifications into operational workflows. For example, the PLCCKMF defined how socket interface conditions exceeding specified thresholds translated into an elevated ulcer risk. Within the operational processes, these rules became decision points: measurements of pressure, temperature, and humidity from the Physical Layer were cross-referenced against these thresholds, and if the conditions were met, the workflow escalated the case by triggering alerts and logging the event. In this way, operational logic instantiated consequence reasoning in practice.

Physical data structed into indicators

Integration with the Physical Layer occurred through the structuring of heterogeneous sensor outputs into modular, process-ready streams. Rather than treating raw signals as independent inputs, the Operational Layer consolidated them into semantically meaningful indicators, such as “fall event,” “maintenance due,” or “abnormal gait pattern.” This organisation ensured that upstream processes operated on clinically and functionally relevant states rather than on uninterpreted data.

Application layer receives operational outputs

Integration with the Application Layer was central to the visibility and usability of adProLiSS. Outputs of operational workflows were communicated to stakeholders via the PPMS and CD-CST. For instance, a detected fall event would automatically update the patient's PPMS dashboard, trigger a PushBullet notification to family members, and simultaneously log the event into the system record for longitudinal tracking. Similarly, in the CD-CST, operational workflows used compatibility rules from the Knowledge Layer to flag unsuitable prosthesis configurations in real-time. These examples demonstrated how operational processes acted as the bridge between evidence captured at the physical level and decision-making at the stakeholder interface.

Operational layer co-ordinates system wide flow

In summary, the Operational Layer functioned as the coordination hub of adProLiSS, transforming raw sensor data into consequence-aware knowledge, embedding ontology rules into executable workflows, and transmitting structured outputs to stakeholder applications. It ensured that the system operated seamlessly across layers, enabling adProLiSS to support adaptive, knowledge-driven prosthesis design and aftercare.

8.3.4 Application Layer Integration

Application layer as stakeholder interface

The Application Layer represented the topmost level of the adProLiSS architecture, where knowledge, data, and workflows were made accessible and actionable for stakeholders. Its purpose was to translate the consequence-aware logic of the lower layers into clear, interactive interfaces that could be used by amputees, prosthetists, physiotherapists, and engineers in real-world decision-making and aftercare. In the implementation, this was achieved through two platforms: the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST).

Operational outputs made actionable

Integration with the Operational Layer occurred through the direct communication of workflow outputs to the PPMS and CD-CST. For example, when the Operational Layer processed socket data and identified a potential ulcer risk, the PPMS automatically updated the patient dashboard with a red alert status and logged the timestamped event. Similarly, in the CD-CST, operational workflows provided real-time compatibility checks between selected prosthesis sub-systems, ensuring that unsuitable configurations were flagged during stakeholder consultations. These integrations ensured that operational reasoning results were immediately visible and actionable.

Physical data presented meaningfully

Integration with the Physical Layer was achieved through the presentation of raw sensor measurements in clinically and functionally meaningful formats. Instead of voltages or binary values, the PPMS displayed socket conditions as "normal" or "critical," gait dynamics as cycle counts or fall events, and GPS data as location links. In this way, the Application Layer functioned as the translation interface that rendered complex technical data intelligible for non-engineering stakeholders while retaining sufficient detail for clinical interpretation.

Knowledge rules structure interface logic

Integration with the Knowledge Layer was visible in the way consequence rules shaped the structure and content of the interfaces. In the PPMS, the organisation of dashboard elements into socket, knee, and foot categories reflected the ontology's taxonomies of prosthesis sub-systems. Threshold-based alerts, such as excessive socket pressure combined with high humidity, were not arbitrary warnings but direct instantiations of knowledge-layer consequence rules. In the CD-CST, the ontology underpinned the compatibility checks and simulated consequence reasoning, allowing stakeholders to explore the implications of design decisions before they were physically realised.

PPMS & CD-CST enable stakeholder engagement

Together, the PPMS and CD-CST demonstrated how the Application Layer enables multi-stakeholder engagement with adProLiSS. The PPMS facilitated ongoing monitoring and communication across aftercare teams, while the CD-CST supported collaborative, consequence-aware design of prosthesis configurations. By providing accessible, knowledge-driven interfaces, the Application Layer ensured that the outputs of adProLiSS were not confined to technical subsystems but were translated into actionable insights that directly informed amputee care and prosthesis design.

8.4 Demonstration Scenarios Implemented

Demo scenarios validate integration & evaluation

The final stage of the implementation involved developing and executing a series of demonstration scenarios designed to showcase the capabilities of the adProLiSS framework in practice. These demonstrations served two purposes. First, they provided a means of validating the technical integration of the Physical, Knowledge, Operational, and Application Layers described in Sections 8.1–8.3. Second, they created the foundation for the stakeholder-centred evaluations discussed in Chapter 9, where both the functionality of the scenarios and the usability of the supporting digital platforms were assessed.

Six scenarios reflect evolving amputee needs

The scenarios were designed to reflect evolving amputee needs and the capacity of adProLiSS to provide consequence-aware responses in real-time. Six scenarios were implemented, each corresponding to a distinct aspect of prosthesis use and aftercare:

1. Evolving Health Issues: Socket Ulcer Detection – monitoring residual limb conditions (temperature, humidity and pressure) to anticipate skin breakdown;
2. Evolving Weight Distribution Monitoring – analysing gait dynamics and load balance;
3. Evolving Daily Use Situations: Fall Assist and Emergency Response – detecting impact events and triggering location-based alerts;
4. Evolving Maintenance and Service Alerts – identifying when prosthesis sub-systems require servicing;
5. Handling Amputee Evolving Daily Needs– enabling patients to record daily observations and experiences;
6. Monitoring of Prosthesis Sub-System Evolving Operational Parameters – tracking unusual stresses or abnormal power consumption.

Two digital platforms shown

In addition to these six use cases, two implementation platforms were also demonstrated. Their technical implementation was already described in detail earlier in this chapter; here, they are referenced only in the context of how they supported demonstration scenarios. These are:

7. The Patient–Prosthesis Management System (PPMS) (Section 8.2.2), which provided the secure, role-based interface for monitoring and visualisation;
8. The Consequence-Driven Co-Design Support Tool (CD-CST) (Section 8.2.3), which enabled stakeholders to collaboratively configure prosthesis sub-systems and aftercare options.

Eight demos link theory

Together, these eight demonstrations illustrated how adProLiSS translates theoretical constructs into operational practice, bridging ontology-driven knowledge modelling with physical prototyping and stakeholder-facing applications. The subsections that follow describe each demonstration in turn.

8.4.1 Scenario 1: Evolving Health Issues – Socket Ulcer Detection

Ulcer risk detected via multi-stakeholder thresholds

One of the most critical health risks for amputees is the development of skin ulcers at the socket–residual limb interface. The first demonstration scenario focused on how adProLiSS could anticipate this risk through multi-sensor monitoring, ontology-driven reasoning, and real-time stakeholder notification. To validate this functionality, the ulcer risk condition was simulated under controlled conditions. The temperature and humidity sensor was exposed to a warm, moist surface, representing the elevated microclimate associated with perspiration at the residual limb–socket interface. Simultaneously, localised pressure was applied to the adjacent force-sensitive resistor (FSR), replicating mechanical loading at the same site. The co-occurrence of elevated temperature, increased humidity, and pressure satisfied the predefined thresholds encoded in the PLCCKMF and triggered the *UlcerRiskCondition*, which was then logged in the PPMS and communicated via the stakeholder alert system.

Socket sensors capture ulcer-related conditions

At the Physical Layer, a combination of force-sensitive resistors (FSRs), temperature, and humidity sensors was embedded in the socket to capture the conditions most closely associated with ulcer formation. To enhance clinical relevance, the FSRs were co-located with the environmental sensors, allowing pressure variations to be correlated with temperature and humidity changes. This configuration provided insight into phenomena such as pistoning and friction between the residual limb and socket liner, which contribute to skin breakdown.

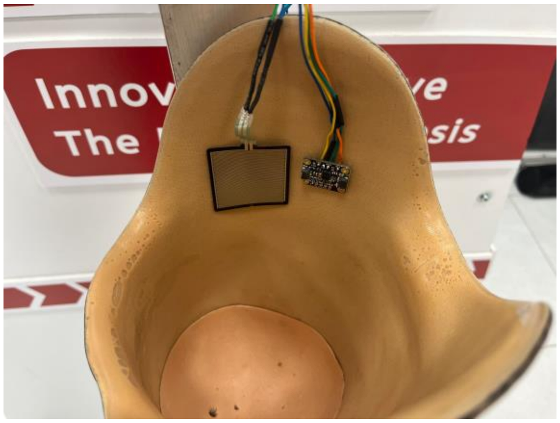


Figure 8.14: Placement of FSR, temperature and humidity sensors within the socket

Knowledge layer encodes ulcer risk

The Knowledge Layer supplied the consequence logic that defined ulcer risk conditions. Within the PLCCKMF, elevated pressure combined with high temperature and humidity was represented as a precursor to ulceration. This knowledge was encoded as formalised SWRL rules, allowing the raw measurements from the Physical Layer to be meaningfully interpreted.

(8.2) FSR(?fsr) ^ TemperatureSensor(?ts) ^ HumiditySensor(?hs) ^ monitorsInterface(?fsr, ?iface) ^ monitorsInterface(?ts, ?iface) ^ monitorsInterface(?hs, ?iface) ^ hasPressure(?fsr, ?P) ^ hasTemp(?ts, ?T) ^ hasHumidity(?hs, ?H) ^ swrlb:greaterThan(?P, 80) ^ swrlb:greaterThan(?T, 37.0) ^ swrlb:greaterThan(?H, 70.0) → UlcerRiskCondition(?iface)

Interpretation: When co-located FSR, temperature, and humidity sensors on the same socket interface all exceed clinically defined thresholds, the system infers that the interface is in an *UlcerRiskCondition*, which is subsequently escalated to the PPMS as an event requiring clinical attention.

Operational layer triggers ulcer risk

At the Operational Layer, incoming data streams from the Raspberry Pi were continuously monitored against these knowledge-based thresholds defined in the PLCCKMF. When these readings exceeded the defined limits, the workflow automatically generated an *ulcer risk event*, tagged it with a timestamp, and relayed the information to the stakeholder-facing applications. This event handling process ensured both traceability and real-time responsiveness. Figure 8.15 shows an excerpt of the python script, highlighting that excessive pressure was detected in the socket.

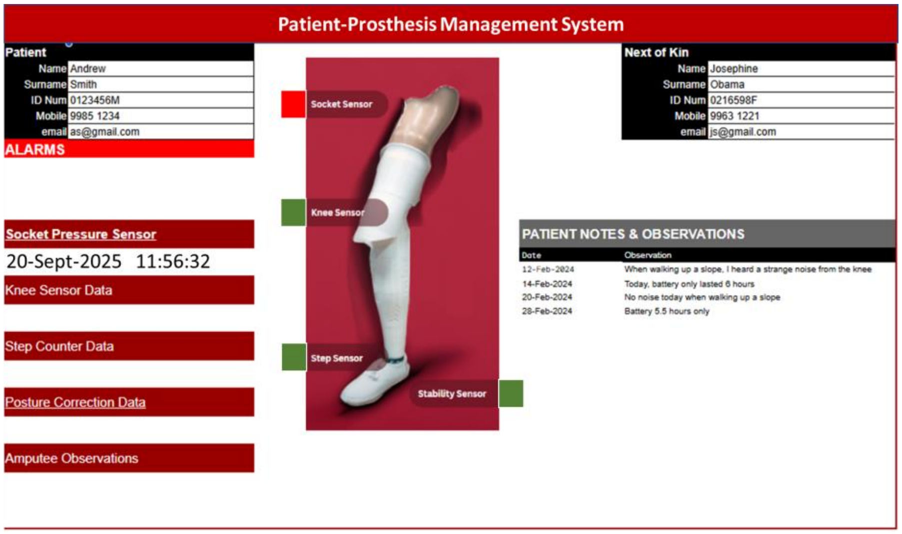
```
if input_SOCKET == 1 and prev_input_socket == 0:
    print("**SOCKET FSR** Warning! Excessive SOCKET pressure detected in Fast Mode")

    # Google Sheet logging
    task = {
        "worksheet": uploadsocket,
        "data": [time_stamp, "Socket", "Fast Mode: High pressure; ulcer 80%"],
        "index": socket_counter
    }
    upload_queue.put(task)

    # PushBullet notification
    push_task1 = {
        "device": dev,
        "title": f"PREMIER PSS\n{time_stamp}",
        "message": (
            "Andrew. Your smart prosthesis is detecting excessive SOCKET "
            "pressure in Fast Mode. No need to worry, we suggest following up "
            "with the invitation you will be receiving from your prosthetist."
        )
    }
```

Figure 8.15: Excerpt of Python code used to log ulcer risk events in the PPMS and notify the amputee via PushBullet.

Application layer issues ulcer alerts

Finally, at the Application Layer, the event was communicated through the PPMS and via PushBullet notifications. In the PPMS, the patient's dashboard displayed a change from a green to red status in the socket health indicator, together with a timestamped entry in the event log. Simultaneously, a custom PushBullet alert was sent to the amputee's registered mobile device, notifying them of the issue and prompting them to contact their prosthetist for assessment.

This scenario demonstrated how adProLiSS enables preventative healthcare by linking sensor-enabled monitoring with ontology-based reasoning and direct communication to stakeholders. Rather than relying solely on amputees to recognise discomfort, the system provided an objective, consequence-aware alerting mechanism that supports early intervention and reduces the risk of serious complications.



Patient
Name Andrew
Surname Smith
ID Num 0123456M
Mobile 9985 1234
email as@gmail.com

20-Sept-2025 11:56:32

Next of Kin
Name Josephine
Surname Obama
ID Num 0216598F
Mobile 9963 1221
email js@gmail.com

PATIENT NOTES & OBSERVATIONS

Date	Observation
12-Feb-2024	When walking up a slope, I heard a strange noise from the knee
14-Feb-2024	Today, battery only lasted 6 hours
20-Feb-2024	No noise today when walking up a slope
28-Feb-2024	Battery 5.5 hours only

Figure 8.16: Figure 8.16: PPMS with socket health indicator and timestamp

8.4.2 Scenario 2: Evolving Weight Distribution Monitoring

Detection of uneven weight distribution

The second demonstration scenario addressed the issue of uneven weight distribution, a common gait characteristic among lower-limb amputees. Whereas able-bodied individuals typically maintain a relatively balanced load across both limbs during standing, amputees often compensate by bearing a disproportionate share of their body weight on the intact limb. Prolonged asymmetry in load transfer can lead to musculoskeletal strain, postural instability, and long-term complications such as joint degeneration. The aim of this scenario was therefore to demonstrate how adProLiSS could identify and flag unbalanced load conditions in real-time.

FSRs in prosthetic foot simulate load balance

At the Physical Layer, two force-sensitive resistors (FSRs) were embedded in the sole of the prosthetic foot, one positioned near the heel and the other under the first metatarsal region (Figure 8.17). This arrangement enabled the system to capture both rearfoot and forefoot loading, providing a simplified but clinically relevant proxy for weight distribution across the prosthesis. To simulate uneven loading under controlled conditions, a horizontal aluminium bar was mounted below the prosthesis and manipulated vertically to apply calibrated pressure onto the foot sole. By selectively varying the force applied to the heel versus the metatarsal FSR, scenarios of balanced and unbalanced weight distribution could be replicated.

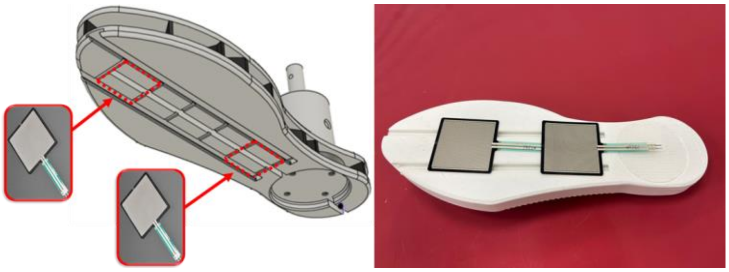


Figure 8.17: Position of FSRs on the sole of the prosthetic foot

Knowledge layer defines weight imbalance

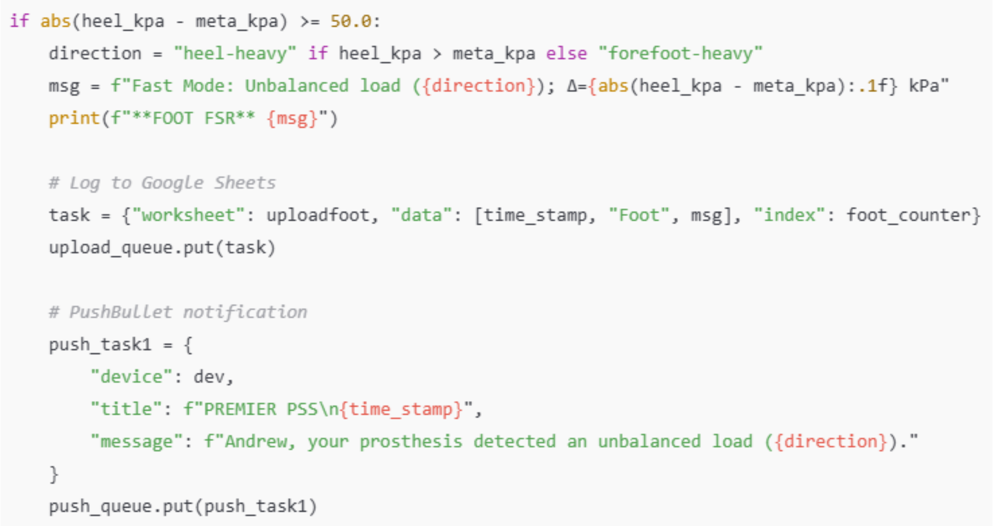
The Knowledge Layer formalised the condition of weight imbalance as a consequence state. Within the PLCCKMF, thresholds were defined such that an excessive differential between heel and forefoot loading, or between left and right limb loading in extended use, was classified as a *WeightDistributionCondition*. A representative SWRL rule is given in (8.3):

(8.3) FSR(?fsr1) ^ FSR(?fsr2) ^ monitorsSoleRegion(?fsr1, Heel) ^ monitorsSoleRegion(?fsr2, Metatarsal) ^ hasPressure(?fsr1, ?P1) ^ hasPressure(?fsr2, ?P2) ^ swrlb:subtract(?Diff, ?P1, ?P2) ^ swrlb:greaterThan(?Diff, 50) → WeightDistributionCondition(?iface)

Interpretation: When the difference in load between heel and forefoot sensors exceeds the defined threshold, the socket–prosthesis interface is inferred to be in a *WeightDistributionCondition*.

Operational layer logs & alerts imbalance events

At the Operational Layer, the Raspberry Pi continuously sampled FSR outputs, compared them against these thresholds, and generated a timestamped imbalance event when the defined conditions were met. The event was automatically packaged and queued for upload to the PPMS database, while simultaneously generating a PushBullet alert.

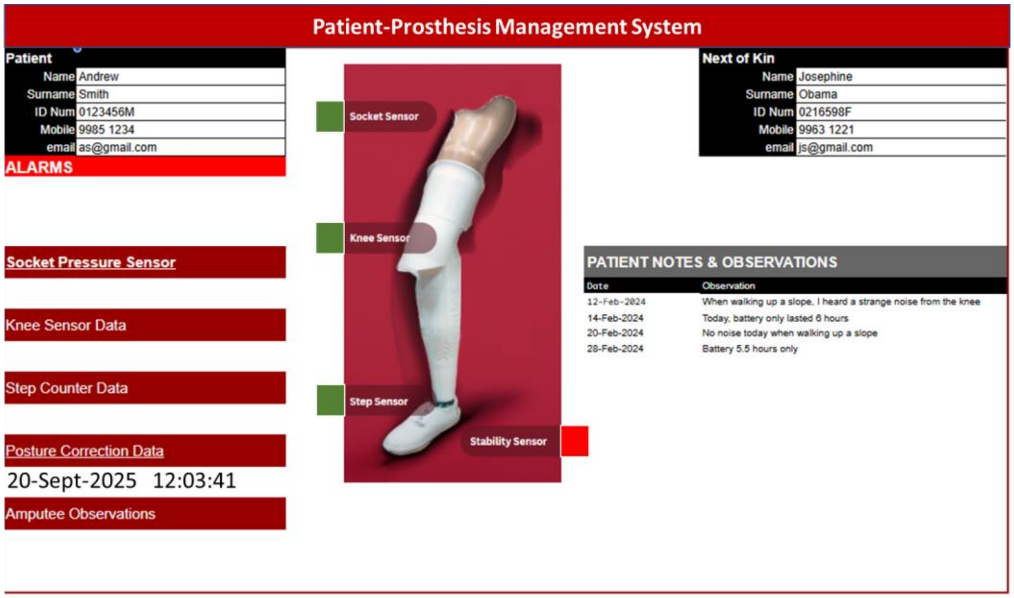


```
if abs(heel_kpa - meta_kpa) >= 50.0:
    direction = "heel-heavy" if heel_kpa > meta_kpa else "forefoot-heavy"
    msg = f"Fast Mode: Unbalanced load ({direction}); Δ={abs(heel_kpa - meta_kpa):.1f} kPa"
    print(f"**FOOT FSR** {msg}")

    # Log to Google Sheets
    task = {"worksheet": uploadfoot, "data": [time_stamp, "Foot", msg], "index": foot_counter}
    upload_queue.put(task)

    # PushBullet notification
    push_task1 = {
        "device": dev,
        "title": f"PREMIER PSS\n{time_stamp}",
        "message": f"Andrew, your prosthesis detected an unbalanced load ({direction})."
    }
    push_queue.put(push_task1)
```

Figure 8.18: Python excerpt computing heel–forefoot imbalance with smoothing and hysteresis, logging the event to the PPMS and notifying the amputee via PushBullet.

Application layer displays imbalance alerts

At the Application Layer, the PPMS visualised the distribution imbalance through its foot pressure dashboard. A green-to-red status change highlighted that the prosthesis was operating outside its expected balance range, while the event log displayed the timestamp and sensor values. This shown in Figure 8.19. Simultaneously, the amputee received a PushBullet notification advising them of the imbalance and recommending consultation with their prosthetist.



Patient-Prosthesis Management System

Patient	
Name	Andrew
Surname	Smith
ID Num	0123456M
Mobile	9985 1234
email	as@gmail.com

Next of Kin	
Name	Josephine
Surname	Obama
ID Num	0216598F
Mobile	9963 1221
email	js@gmail.com

PATIENT NOTES & OBSERVATIONS

Date	Observation
12-Feb-2024	When walking up a slope, I heard a strange noise from the knee
14-Feb-2024	Today, battery only lasted 6 hours
20-Feb-2024	No noise today when walking up a slope
28-Feb-2024	Battery 5.5 hours only

20-Sept-2025 12:03:41

Figure 8.19: PPMS showing active WeightDistributionCondition

This scenario demonstrated the capacity of adProLiSS to extend monitoring beyond socket health and into the domain of functional gait analysis. By integrating physical sensor inputs with ontology-based consequence reasoning, the framework provided objective evidence of abnormal loading, supporting clinicians in adjusting socket alignment, foot components, or rehabilitation strategies to restore balanced weight distribution.

8.4.3 Scenario 3: Evolving Daily Use Situations – Falls Assist and Emergency Response

Fall detection & rapid response

Falls represent one of the most severe risks for lower-limb amputees, with potentially life-threatening consequences including fractures, head trauma, and prolonged hospitalisation. The third demonstration scenario therefore focused on the ability of adProLiSS to detect impact events and provide rapid, automated responses that could assist the amputee and notify their support network.

FSR & GPS simulate and log falls

At the Physical Layer, two complementary sensors were employed: a force-sensitive resistor (FSR) mounted externally on the thigh cover to capture sudden impact forces, and a GPS module embedded within the shank to provide real-time location data. This is shown in Figure 8.20. Since it was not feasible to allow the prosthesis to undergo uncontrolled falls, the fall condition was instead simulated under controlled conditions by striking the thigh-mounted FSR to replicate the force profile of an impact. The FSR signal provided both event detection and an estimate of the impact magnitude, while the GPS module ensured that the prosthesis location at the time of the event was recorded.

Figure 8.20: Location of GPS module and FSR

Knowledge layer encodes fall detection rule

The Knowledge Layer formalised the inference of a fall event by combining an impact threshold with a location capture rule. Within the PLCCKMF, the FSR signal exceeding the specified impact limit triggered a *FallEvent*, which was automatically paired with a timestamped GPS reading. A representative SWRL rule is given in (8.4):

(8.4) FSR(?fsr) ^ GPSModule(?gps) ^ mountedOn(?fsr, ?prosthesis) ^ mountedOn(?gps, ?prosthesis) ^ hasImpactForce(?fsr, ?F) ^ hasLocation(?gps, ?Loc) ^ swrlb:greaterThan(?F, 200) → FallEvent(?prosthesis)

Interpretation: If the impact force registered on the prosthesis exceeds the defined threshold, the system infers a *FallEvent* and associates it with the prosthesis location.

Operational layer generates fall event & alerts

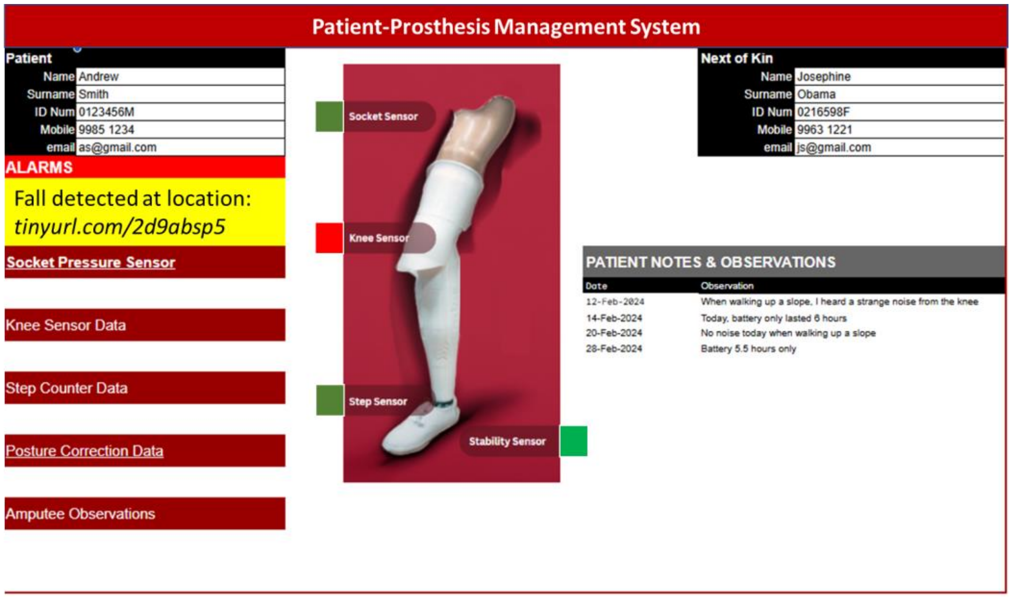
At the Operational Layer, the Raspberry Pi continuously monitored the FSR output and, upon detection of a threshold breach, generated a timestamped fall event. The event was enriched with the corresponding GPS coordinates and the computed impact force, and then queued for upload to the PPMS. In parallel, the system triggered an event handler that created a PushBullet message targeted at the amputee’s designated emergency contact.

```
# Threshold (example units: N); replace with your calibrated limit
FALL_IMPACT_THRESHOLD = 200.0

# Assume: impact_N (from thigh-cover FSR), gps_lat, gps_lon, time_stamp available here

if impact_N >= FALL_IMPACT_THRESHOLD:
    msg_ppms = (f"Fall event: impact={impact_N:.0f} N; "
                f"location=({gps_lat:.5f}, {gps_lon:.5f})")
    print(f"**FALL DETECTED** {msg_ppms}")

    # Log to Google Sheets (e.g., worksheet 'Fall Events')
    task = {
        "worksheet": upload_fall,                   # gspread Worksheet for fall logs
        "data": [time_stamp, "Fall", impact_N, gps_lat, gps_lon, "High priority"],
        "index": fall_counter
    }
    upload_queue.put(task)

    # PushBullet alert to next of kin
    push_task = {
        "device": NOK_device,                       # next-of-kin device handle
        "title": f"PREMIER PSS\n{time_stamp}",
        "message": ("Fall detected. "
                    f"Impact={impact_N:.0f} N. "
                    f"Location: {gps_lat:.5f}, {gps_lon:.5f}.")
    }
    push_queue.put(push_task)
```

Figure 8.21: Python excerpt logging a fall event (impact force & GPS position) to the PPMS and notifying next of kin via PushBullet.

Application layer issues fall alerts with GS

At the Application Layer, the PPMS displayed the fall event in the patient's event log, including the timestamp, impact magnitude, and location. A red alert indicator was triggered on the dashboard, signalling a high-priority event. Simultaneously, a PushBullet notification was dispatched to the amputee's next-of-kin, containing both the impact alert and GPS coordinates, thereby providing immediate situational awareness.


Patient-Prosthesis Management System

Patient
Name: Andrew
Surname: Smith
ID Num: 0123456M
Mobile: 9985 1234
email: as@gmail.com

ALARMS

Fall detected at location:
tinyurl.com/2d9absp5

Next of Kin
Name: Josephine
Surname: Obama
ID Num: 0216598F
Mobile: 9963 1221
email: js@gmail.com

PATIENT NOTES & OBSERVATIONS

Date	Observation
12-Feb-2024	When walking up a slope, I heard a strange noise from the knee
14-Feb-2024	Today, battery only lasted 6 hours
20-Feb-2024	No noise today when walking up a slope
28-Feb-2024	Battery 5.5 hours only

Figure 8.22: PPMS highlighting fall impact

This scenario demonstrated the ability of adProLiSS to provide emergency support functions beyond routine monitoring. By combining sensor input, ontology-based reasoning, and real-time communication, the framework showed how prosthetic systems can evolve into proactive safety devices, mitigating the risks of falls and ensuring timely response by caregivers or family members.

8.4.4 Scenario 4: Evolving maintenance and Service Alerts

Proactive maintenance alerts

A key factor influencing prosthesis reliability and safety is the timely scheduling of maintenance interventions. In conventional practice, servicing is often reactive, initiated only after component failure or patient-reported issues, leading to periods of downtime and reduced patient confidence. The fourth demonstration scenario therefore focused on how adProLiSS can support proactive maintenance by monitoring device usage parameters and triggering service alerts when pre-defined limits are reached.

Knee cycles & time log prosthesis use

At the Physical Layer, the prosthetic knee joint was instrumented to record angular displacement over time, enabling automatic counting of knee cycles during use. Each cycle was defined as a transition from the neutral extended position (175°), through flexion to approximately 95°, and back to the neutral state. The choice of 175° as the upper limit was deliberate: it preserved a slight flexion that enhanced perceived stability for amputees while simultaneously reducing the risk of hyperextension failure beyond 180°. Complementing cycle counting, the system also logged elapsed time since activation, thereby providing a secondary metric of prosthesis usage.

Knowledge layer sets maintenance thresholds

The Knowledge Layer formalised usage-based maintenance thresholds within the PLCCKMF. For demonstration purposes, the system was configured to assert a *MaintenanceRequiredCondition* when the cumulative knee cycles exceeded 100. While this value was intentionally low for testing, the ontology provides the capacity to adapt thresholds to manufacturer guidelines, prosthesis type, or patient-specific requirements. A representative SWRL rule is given in (8.5):

(8.5) KneeJoint(?knee) ^ hasCycleCount(?knee, ?C) ^ swrlb:greaterThan(?C, 100)
→ MaintenanceRequiredCondition(?knee)

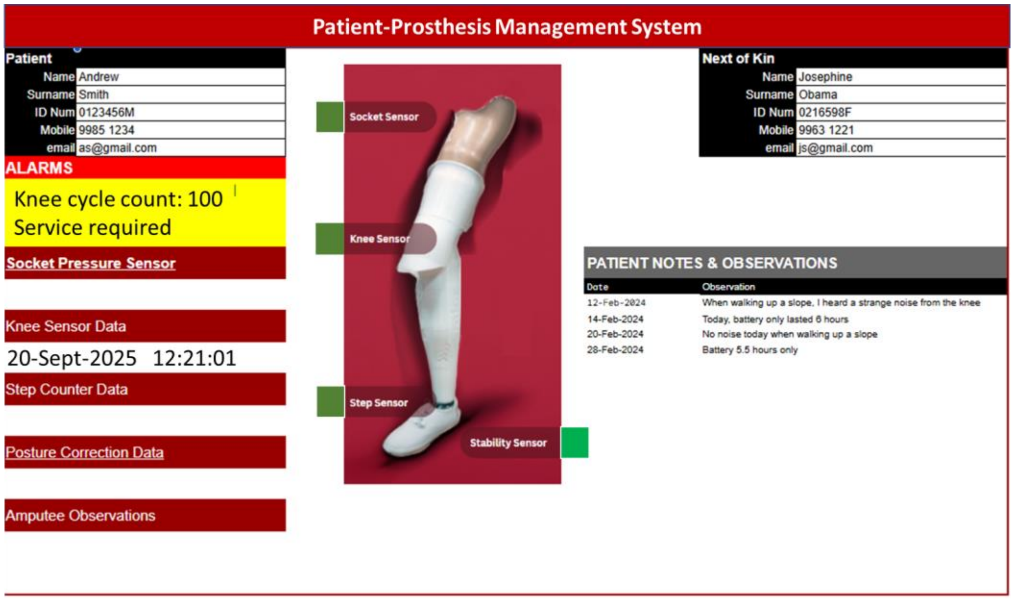
Interpretation: when the recorded cycle count for the prosthetic knee exceeds the threshold of 100, the system infers a *MaintenanceRequiredCondition*.

Operational layer cycles threshold event

At the Operational Layer, the Raspberry Pi monitored the angular position of the knee joint, incremented the cycle counter accordingly, and continuously compared the accumulated value against the threshold. Upon reaching 100 cycles, the system generated a timestamped event and passed it to the event handling workflow for both logging and communication.

Application layer: maintenance alert & log

At the Application Layer, the event was uploaded to the PPMS (Figure 8.23), where it appeared in the maintenance dashboard with the associated timestamp, cycle count, and status indicator. The prosthesis status changed from green to amber, signalling that servicing was due. In parallel, the amputee received a PushBullet notification on their mobile device, reminding them that a maintenance check was required.



Patient-Prosthesis Management System

Patient

Name	Andrew
Surname	Smith
ID Num	0123456M
Mobile	9985 1234
email	as@gmail.com

Next of Kin

Name	Josephine
Surname	Obama
ID Num	0216598F
Mobile	9963 1221
email	js@gmail.com

ALARMS

Knee cycle count: 100
Service required

20-Sept-2025 12:21:01

PATIENT NOTES & OBSERVATIONS

Date	Observation
12-Feb-2024	When walking up a slope, I heard a strange noise from the knee
14-Feb-2024	Today, battery only lasted 6 hours
20-Feb-2024	No noise today when walking up a slope
28-Feb-2024	Battery 5.5 hours only

Figure 8.23: PPMS highlighting knee cycle threshold has been reached and a service is required

This scenario demonstrated the potential of adProLiSS to transition prosthesis servicing from reactive to proactive modes. By embedding usage-based monitoring and automated thresholding, the system ensures that maintenance needs are identified before failure occurs, reducing unplanned downtime, enhancing safety, and increasing the overall dependability of the prosthesis.

8.4.5 Scenario 5: Handling Amputee Evolving Needs

Capturing amputee feedback

Beyond clinical and mechanical monitoring, amputees' experiences are also shaped by subjective perceptions and day-to-day concerns, which are often overlooked in conventional prosthesis management. These can include discomfort due to mechanical resistance, increased exertion during walking, or dissatisfaction with the aesthetic appearance of the device. The fifth demonstration scenario addressed this dimension by providing amputees with a structured means of communicating evolving needs directly into the adProLiSS framework.

At the Physical Layer, no additional hardware was required. Instead, emphasis was placed on enabling the amputee to report personal experiences, thereby integrating experiential knowledge into the broader system.

Knowledge layer formalises feedback as consequence

The Knowledge Layer formalised this input as part of the PLCCKMF under the category of user feedback consequences. This enabled subjective reports to be treated as actionable knowledge, comparable to sensor-derived events. For example, an amputee's report of "excessive resistance in the knee during swing phase" could be linked to potential issues in the knee sub-system, while feedback about aesthetic dissatisfaction could be logged under psychosocial consequence types.

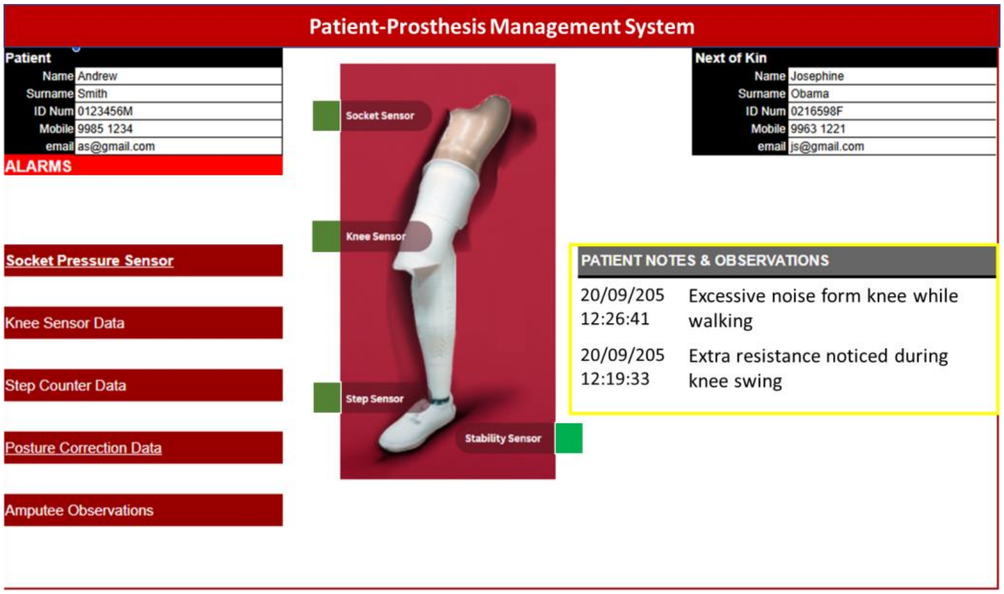
Operational layer logs feedback via portal

At the Operational Layer, a patient-facing portal was developed using Google Sheets, providing a simple, accessible interface for logging feedback. Amputees were instructed to enter the date, time, and a description of the issue, which was automatically uploaded to the central PPMS database. Each entry was timestamped, indexed, and categorised, enabling subsequent retrieval by clinicians and engineers. This workflow ensured that qualitative feedback was managed with the same rigour as quantitative sensor data.

Application layer displays notes for stakeholders

At the Application Layer, the PPMS incorporated a dedicated section for Patient Notes and Observations, where entries from the portal were displayed. Stakeholders such as prosthetists, physiotherapists, and engineers could view this feedback during consultations, cross-reference it with sensor data, and decide on appropriate interventions. For example, repeated reports of excessive walking effort could be examined alongside gait dynamics data, while aesthetic concerns could guide the selection of alternative prosthesis covers.

This scenario demonstrated the value of integrating amputee-reported experience into the adProLiSS framework. By formalising subjective input as part of the knowledge base and linking it to stakeholder workflows, the system ensured that patient voices were not only heard but systematically incorporated into decision-making. In doing so, adProLiSS moved towards a more holistic and adaptive service model, addressing both the functional and psychosocial aspects of prosthesis acceptance.



Patient

Name	Andrew
Surname	Smith
ID Num	0123456M
Mobile	9985 1234
email	as@gmail.com

Next of Kin

Name	Josephine
Surname	Obama
ID Num	0216598F
Mobile	9963 1221
email	js@gmail.com

PATIENT NOTES & OBSERVATIONS

20/09/205 12:26:41	Excessive noise form knee while walking
20/09/205 12:19:33	Extra resistance noticed during knee swing

Figure 8.24: Amputee experiences displayed on the PPMS

8.4.6 Scenario 6: Monitoring Prosthesis Sub-System Operational Parameters

Monitors internal sub-systems

In addition to health and use-related monitoring, reliable prosthesis performance depends on continuous surveillance of the operational status of its sub-systems, including load-bearing structures, actuation reliability, and power supply levels. The sixth demonstration scenario was therefore designed to illustrate how adProLiSS could extend monitoring to the internal mechanical and electrical elements of the prosthesis, thereby enabling early detection of abnormal operating conditions.

FSR & servo feedback detect overload / faults

At the Physical Layer, two monitoring mechanisms were implemented. First, a force-sensitive resistor (FSR) was inserted between two sections of the pylon, allowing the system to estimate applied loads. Functionally analogous to the foot-sole FSRs, this sensor provided a means of identifying instances when the prosthesis was subjected to weight levels exceeding its design limits. In such cases, the duration of overload was measured and timestamped, ensuring that both magnitude and exposure time were captured. Second, a feedback signal was obtained from the servo motor encoder, which provided the achieved angular position of the knee joint. This value was compared with the programmed command angle generated by the Python control script, thereby enabling detection of deviations between desired and actual motion. Such deviations could indicate excessive resistance, mechanical wear, or electrical malfunction.

Knowledge layer formalises overload & deviation rules

The Knowledge Layer formalised these conditions within the PLCCKMF as *OverloadCondition* and *ActuationDeviationCondition*. For example, excessive pylon load sustained over a given duration was linked to structural fatigue consequences, while discrepancies between commanded and actual motor positions were interpreted as actuation faults. Although the ontology also anticipates further sub-system conditions, such as battery depletion, motor overheating, and abnormal current draw, these could not be fully implemented in the prototype. Instead, they were simulated during evaluation sessions, allowing stakeholders to assess how such alerts would be represented and managed within the framework.

Operational layer logs thresholds & simulation data

At the Operational Layer, the Raspberry Pi processed the load and encoder feedback in real-time. Events exceeding thresholds were timestamped and logged in the PPMS database. Simulated data streams for battery voltage, motor temperature, and current draw were also introduced during evaluations, ensuring that the operational workflow for these conditions was validated even in the absence of hardware measurements.

Application layer displays alerts in PPMS

At the Application Layer, the PPMS displayed overload or actuation deviation events within the prosthesis status dashboard. Each entry included a timestamp, sensor value, and duration of exceedance, while simulated data appeared in the same format to illustrate the intended operation. PushBullet alerts were configured to notify the amputee or prosthetist when sustained overloads or significant motor deviations occurred.

This shows pathway to predictive maintenance

This scenario demonstrated the potential of adProLiSS to provide comprehensive sub-system diagnostics, bridging mechanical, actuation, and (simulated) electrical domains. While only a subset of the intended monitoring functions was physically realised, the simulation of additional parameters during evaluations confirmed the feasibility of extending the framework. In this way, adProLiSS supports a pathway towards predictive maintenance, ensuring that both clinical users and technical staff are equipped with timely, consequence-aware information on prosthesis operational health.

8.4.7 Patient-Prosthesis Management System

PPMS role

The Patient–Prosthesis Management System (PPMS), technically implemented and described in Section 8.2.2, was also demonstrated as part of the scenario evaluations. While Section 8.2.2 detailed its architecture, data flow, and code-level integration, the present section highlights its applied role during demonstrations and the way it supported stakeholder interaction.

PPMS integrates sensor & patient inputs

During the ulcer detection (Section 8.4.1), weight distribution monitoring (Section 8.4.2), fall assist (Section 8.4.3), and maintenance alerts (Section 8.4.4) scenarios, the PPMS provided the primary stakeholder-facing interface. Real-time events from the Raspberry Pi were logged to dedicated worksheets and displayed as visual indicators (e.g. green-to-red transitions), timestamped event logs, and annotated data entries. Patient-reported inputs from the portal (Section 8.4.5) were also surfaced within the PPMS, allowing prosthetists, physiotherapists, and engineers to view subjective experiences alongside sensor-derived events.

Dashboard: unified, real time, traceable

In practice, the PPMS served as the central demonstration dashboard:

- It consolidated heterogeneous sensor data streams into a unified view;
- It enabled real-time awareness of prosthesis health (socket conditions, gait balance, fall events, maintenance needs);
- It logged both automated alerts and patient-generated observations, ensuring traceability of evolving needs.

PPMS provides structured consequence feedback

By situating all relevant data within a role-based interface, the PPMS illustrated how adProLiSS can move beyond raw data collection to provide structured, consequence-aware feedback directly to clinical and technical stakeholders. The usability and effectiveness of the PPMS were subsequently assessed through stakeholder evaluations, as reported in Chapter 9.

8.4.8 Consequence-Driven Co-Design Support Tool

CD-CST role

The Consequence-Driven Co-Design Support Tool (CD-CST), whose technical development and integration were detailed in Section 8.2.3, was also demonstrated during the evaluation scenarios. Whereas Section 8.2.3 focused on its architecture, ontology integration, and scripting logic, the present section emphasises its applied use by stakeholders during demonstrations.

Stakeholder use: select, check, add smart systems

The CD-CST was presented to amputees, prosthetists, physiotherapists, and engineers as an interactive environment for collaboratively configuring prosthesis sub-systems. Stakeholders used the tool to:

- Select components from the prosthesis library (liner, socket, knee, and foot/ankle), visualising their specifications and functional roles;
- Receive automated compatibility checks, where inappropriate pairings (e.g. a high-mobility sports blade with a K1 mobility-level amputee) were flagged as errors.
- Add smart systems such as pressure or gait monitoring sensors, which in turn defined the aftercare services required for that amputee.

Simulated reasoning & PPMS links

Although certain AI-driven consequence reasoning functions were simulated rather than fully implemented, the tool successfully conveyed how ontology-encoded knowledge could inform design choices and highlight potential mismatches before final configuration. Demonstrations also showcased the link to the PPMS, whereby the prosthetist, physiotherapist, or engineer could review a patient's current prosthesis digitally before initiating modifications.

CD-CST supports shared decision making

As a demonstration platform, the CD-CST highlighted how adProLiSS supports shared decision-making, enhances amputee awareness of available options, and provides clinicians with consequence-based reasoning during design consultations. Its usability and perceived value were subsequently evaluated through stakeholder feedback, as discussed in Chapter 9.

8.4.9 Summary of Demonstration Scenarios

The preceding subsections detailed a series of demonstration scenarios designed to validate the adProLiSS implementation across its physical, digital, and knowledge layers. Each scenario targeted a specific aspect of prosthesis use, ranging from ulcer risk detection to weight distribution monitoring, fall response, maintenance scheduling, and the capture of amputee feedback. Additional subsections demonstrated the role of the PPMS and CD-CST as stakeholder-facing applications. To consolidate these examples and highlight their alignment with the layered framework, Tables 8.1-8.2 provide a structured summary of the case-based demonstration scenarios, and the implementation platform. The table maps each scenario to the sensors employed, the associated knowledge rules derived from the PLCCKMF, the operational triggers defined within the system workflow, and the resulting outputs in the PPMS, PushBullet notifications, and CD-CST. This integrated overview emphasises how the scenarios collectively illustrate the feasibility of consequence-aware, stakeholder-centred prosthesis management.

Table 8.1: Case-based Demonstration Scenarios

Scenario	Physical Inputs (Sensor / Modules)	Knowledge Rule/s (PLCCKMF)	Operational Event / Trigger	Application Outputs
8.4.1 Ulcer Risk Detection	Socket FSR + Temperature + Humidity sensor (co-located)	*UlcerRiskCondition*: Pressure > 80kPa, Temp > 37°C, Humidity > 70%	Threshold violation → classify as *Ulcer Risk*	PPMS: alert + log; PushBullet: message to amputee; CD-CST: not linked
8.4.2 Weight Distribution Monitoring	Sole FSRs (heel, forefoot)	*WeightDistributionCondition*: imbalance beyond threshold	Prolonged imbalanced load on sensors	PPMS: balance indicator + log; PushBullet: posture correction message; CD-CST: not linked
8.4.3 Fall Assist & Emergency Response	Thigh FSR (impact) + GPS module	*FallEvent*: sudden impact + location	Impact above threshold	PPMS: event log with force + location; PushBullet: notification to next-of-kin; CD-CST: not linked
8.4.4 Maintenance & Service Alerts	Knee servo encoder (cycle count, angles)	*MaintenanceCondition*: >100 cycles	Cycle threshold exceeded	PPMS: maintenance alert; PushBullet: reminder to amputee; CD-CST: could be linked for lifecycle planning
8.4.5 Amputee Evolving Needs	Patient portal (manual entry in Google Sheet)	*AmputeeFeedbackCondition*: patient logs concern	New log entry	PPMS: notes visible to prosthetist / physio / engineer; PushBullet: not used; CD-CST: can incorporate in design review
8.4.6 Sub-System Operational Parameters	Pylon FSR (overload) + Servo encoder feedback	*OverloadCondition*: load > limit; *ActuationMismatchCondition*: commanded vs achieved angle mismatch	Excessive sustained load; encoder mismatch	PPMS: stress alert, angle deviation log; PushBullet: optional notification; CD-CST: not linked

Table 8.2: Implementation Platforms

Scenario	Physical Inputs (Sensor / Modules)	Knowledge Rule/s (PLCCKMF)	Operational Event / Trigger	Application Outputs
8.4.7 Patient–Prosthesis Management System	Data imported from all sensors	Knowledge applied through thresholds	Data aggregated and visualised	PPMS: central hub with traffic-light indicators, logs, notes; PushBullet: linked
8.4.8 Consequence-Driven Co-Design Tool	Library of prosthesis elements + smart system options (from PPMS)	*CompatibilityCondition*: e.g. mismatch of K-level vs component	Stakeholders select incompatible configuration	CD-CST: alerts/warnings; PPMS: linked for patient case data

8.5 Implementation Challenges and Limitations

Actuation & fabrication constraints

The physical prototyping process posed several constraints, particularly regarding actuation and fabrication. Servo motors provided a feasible means to simulate knee articulation but lacked the torque and responsiveness of clinical-grade actuators, limiting the realism of gait replication. Similarly, the prosthesis covers were fabricated using PLA on a desktop 3D printer. While this approach supported rapid iteration and modularity, the material properties fell short of those required for long-term durability, wear resistance, and cosmetic finish in patient-ready prostheses. Power supply presented a further limitation, as the prototype was predominantly operated on mains electricity, with battery integration only partially explored.

Sensor reliability & calibration limits

Sensor reliability was another challenge. Force-sensitive resistors (FSRs) provided useful load distribution data but exhibited variability and sensitivity to alignment, while inertial measurement units (IMUs) suffered from drift over extended use. Socket-based temperature and humidity sensors proved effective for simulating ulcer risk, but their readings were susceptible to environmental noise, and calibration against reference instruments was required. Moreover, several intended monitoring parameters, such as battery voltage, motor current draw, and motor thermal load, were simulated rather than physically implemented due to resource and time constraints.

Computing & data management challenges

From a computing perspective, the Raspberry Pi platform enabled multi-sensor integration, actuation, and communication through Python scripting, but it was limited in terms of real-time responsiveness. The reliance on wireless communication introduced occasional connectivity interruptions, which were manageable in controlled demonstrations but could present risks in real-world deployment. The choice of Google Sheets as the backbone for data management and visualisation ensured accessibility and rapid development, yet this platform was not designed for high-frequency data streams or long-term medical record compliance, highlighting a scalability limitation.

The stakeholder-facing platforms, the PPMS and CD-CST, successfully demonstrated how information could be structured, visualised, and shared, but both were implemented as research prototypes rather than production systems. The PPMS interface relied on Google Sheets for display logic, offering usability but lacking the security and robustness required for clinical environments. The CD-CST, while effective in allowing stakeholders to explore prosthesis configurations and consequences, used a manually curated library and simulated reasoning rules. The full integration of ontology-driven inference and aftercare element libraries remains an area for future refinement.

Evaluation via controlled simulation

Evaluation-specific constraints also shaped the implementation. Demonstration scenarios relied on controlled simulations rather than live use by amputees, reflecting ethical and safety considerations. Certain events, such as fall detection, motor overheating, or service alerts, were triggered manually or through scripted simulations. Furthermore, the evaluation cohort was necessarily limited in scale, with participation constrained by stakeholder availability. These choices were appropriate for feasibility testing but also illustrate the gap between prototype demonstration and large-scale clinical validation.

Scalability gaps

Finally, questions of generalisability and scalability remain. The system was applied to a single lower-limb prosthesis prototype, and while the underlying adProLiSS framework is extensible to other prosthesis types, this was not tested within the present study. Similarly, the modular design and cloud-based backbone demonstrate adaptability but are not yet optimised for regulatory, clinical, or industrial adoption. Addressing these limitations will be essential in moving from research proof-of-concept to practical, real-world deployment.

8.6 Chapter Conclusion

Framework realised as layered system

This chapter translated the adProLiSS framework from concept to a working system by implementing a sensor-integrated prosthesis prototype, embedded computing and data flow on a Raspberry Pi, and two stakeholder platforms, the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST). The Physical Layer combined IMUs, FSRs, temperature–humidity sensors, strain sensing, GPS, and an actuated knee module within modular, 3D-printed covers; the

Operational Layer orchestrated data capture, rule checks, event generation, and notifications; and the Application Layer rendered consequence-aware insights to clinicians, engineers, and amputees via PPMS and CD-CST. The Knowledge Layer (PLCCKMF) underpinned the system, specifying what to measure and how to interpret it through formal and structured rules (e.g. ulcer risk, weight imbalance, fall events, use-based maintenance).

Eight demos validate integration

Eight demonstrations evidenced end-to-end operation: ulcer risk, weight distribution, fall assist, maintenance alerts, amputee daily needs, sub-system operational monitoring, and the stakeholder-facing roles of PPMS and CD-CST. These scenarios showed how layered integration yields actionable, consequence-aware outputs (alerts, logs, dashboards, configuration checks) and how simulated elements (e.g. battery/thermal monitoring) can validate workflows prior to hardware completion.

Prototype constraints vs clinical readiness

The chapter also surfaced implementation constraints (consumer-grade sensors, PLA covers, mains power, Google Sheets backbone) and scope choices (simulated sensors/reasoning where appropriate). These do not diminish the contribution; rather, they delineate the boundary between a research-grade prototype and a deployable clinical system. With the integrated build in place, Chapter 9 evaluates stakeholder usability, perceived value, and scenario effectiveness, using the demonstrations and platforms implemented here as the empirical basis.

Part C

Solution Evaluation, Discussion and Conclusion

9

9 Evaluation of the adProLiSS Framework: Stakeholder-Centred Prototype Demonstrations

This chapter presents a formative, stakeholder-centred evaluation of the Adaptive Prosthesis Life-Cycle Service System Framework (adProLiSS). Building on the conceptual and implementation work detailed in earlier chapters, this chapter investigates how adProLiSS functions when deployed in lab-based demonstrations.

The evaluation specifically addresses Research Questions 4 through 7, which explore the effectiveness, applicability, and stakeholder reception of the framework. Conducted through live, one-to-one prototype demonstrations with multiple stakeholder groups, this research aims to capture technical, practical, and emotional responses to the framework's consequence-driven, ontology-based approach to prosthesis development and aftercare. Mixed-methods data collection, including pre- and post-demonstration questionnaires and observational field notes, provide the empirical foundation for this chapter.

9.1 Evaluation Objective and Research Alignment with adProLiSS Hypothesis

Evaluation aim: test adProLiSS hypothesis

This chapter evaluates the core contributions of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) by assessing how its conceptual principles and supporting tools perform in realistic demonstration settings. The primary aim is to test the extent to which the adProLiSS Framework, including its Methodology, the Patient-Prosthesis Management System (PPMS), the Consequence-Driven Co-Design Support Tool (CD-CST), and the modular physical prototype, aligns with its core hypothesis, namely that an ontology-driven, consequence-aware product–service system can enhance time efficiency, cost-effectiveness, functionality, user comfort, emotional well-being, and aftercare quality for amputees and their stakeholders.

Four evaluation goals defined

From this, the following evaluation goals were derived:

1. Assess how adProLiSS supports stakeholder communication and consequence reasoning across the prosthesis life-cycle.
2. Evaluate the usability and interpretability of the PPMS and CD-CST as operational tools.
3. Determine the framework's ability to support adaptive, stakeholder-centred prosthesis design through digital monitoring and modularity.
4. Explore stakeholder perceptions of emotional and functional benefits linked to consequence awareness and co-design processes.

Evaluation addresses RQs & ethics compliance

The evaluation directly addresses the research questions defined in Chapter 3 by examining whether the proposed solution addresses critical weaknesses identified in conventional prosthesis design, development and aftercare, including fragmented knowledge flows, limited stakeholder participation, and reactive consequence management. Ethical approval for all demonstration activities was granted by the University Research Ethics Committee (Reference: 8507_23042021_Nicholas Patiniott), and participants were informed of the study's purpose and their right to withdraw at any time. Verbal informed consent was obtained for all sessions, with all data anonymised and stored securely in accordance with GDPR and institutional data protection policies.

9.2 Evaluation Context: Stakeholder Roles and Demonstrated Use-Cases

This section outlines the participating stakeholders, the demonstration context, and the specific prototype scenarios used to test how adProLiSS performs in realistic but controlled conditions. While primarily framed as a formative prototype demonstration (Lim, Stolterman and Tenenberg, 2008), the evaluation draws on participatory design principles (Sanders and Stappers, 2008), and incorporates structured expert input inspired by the Delphi Technique (Landeta, Barrutia and Lertxundi, 2011). This combined approach aligns with the Descriptive Study second phase of the Design Research Methodology (DRM) (Blessing, Chakrabarti and Wallacce, 1995; Blessing and Chakrabarti, 2009), ensuring that systematic, multi-stakeholder feedback directly informs whether the proposed solution addresses the core research questions.

9.2.1 Stakeholder Profiles and Recruitment Rationale

26 participants across stakeholder groups

The evaluation involved multiple stakeholder groups directly connected to the prosthesis life-cycle, ensuring a diverse range of professional and lived experience perspectives. These groups represent the primary decision-makers and users directly involved in the prosthesis life-cycle, from design and prescription to daily use and aftercare. In total, 26 participants were engaged:

- **Amputees (n = 5):** Lower-limb amputees with varying levels of amputation/disarticulation from hip to lower leg.

- **Prosthetists (n = 7):** Including 4 practising prosthetists from the Orthotics and Prosthetics Unit at St. Luke’s Hospital and 3 postgraduate students enrolled in the MSc Prosthetics and Orthotics programme.

- **Physiotherapists (n = 5):** Professionals supporting amputees through rehabilitation, gait retraining, and long-term aftercare.

- **Rehabilitation Specialist (n = 1):** A medical doctor specialising in physical and rehabilitative medicine.

- **Engineers (n = 8):** Practitioners and researchers with backgrounds in product development, assistive device design, medical device engineering, and design research.

These groups represent the primary decision-makers and users directly involved in the proposed prosthesis life-cycle, from design and prescription through daily use and aftercare. Most evaluation sessions were conducted at the Concurrent Engineering Research Unit (CERU) at the University of Malta, where the physical prototype was set up for live demonstration. In cases where participants could not travel to CERU (~20%) because for instance they lived abroad, the same content was delivered off-site using video demonstrations and explanatory materials to ensure consistency across sessions. All sessions were conducted as one-to-one meetings between the researcher and a single participant, creating a focused environment for in-depth demonstration, observation, and individualised feedback.

9.2.2 Ontology-Grounded Demonstrated Scenarios and Smart System Features

Evaluation via use-case scenarios & platforms

The evaluation centred on a series of carefully defined prototype scenarios that illustrate how adProLiSS integrates physical design, digital monitoring, consequence reasoning, and stakeholder decision support. These scenarios demonstrated the practical implementation of the Custom Prosthesis Development Frame, the Prosthesis Adaptation Frame, and the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame described in Chapter 4.

The core demonstrated prototype scenarios are divided into two categories: a) **Use-case-based system features**, where showcase how the adProLiSS framework responds to real-world patient conditions and system status, thereby embodying the frameworks consequence-aware principles; b) **Implementation platforms**, which are the stakeholder-facing tools enabling usability, interaction and decision-making support throughout the prosthesis life-cycle. A compiled list of the demonstration scenarios is shown in Table 9.1

Use-case-based system features:

1. **Evolving Health Issues: Socket Ulcer Detection -** Demonstrates how embedded sensors monitor residual limb interface pressure, temperature and humidity within the socket, triggering alerts in the PPMS and sending notifications to a dedicated patient mobile device.

2. **Evolving Weight Distribution Monitoring -** Demonstrating how gait dynamics and load distribution data are uploaded live to the PPMS for real-time visualisation and stakeholder follow-up.

3. **Evolving Daily Use Situations: Fall Assist and Emergency Response -** Simulating impact detection with automated GPS-based localisation, PPMS updates on force of impact, and live alerts sent to designated family members indicating that the patient requires assistance.

4. **Evolving Maintenance and Service Alerts -** Illustrates how prosthesis sub-systems autonomously trigger maintenance alerts and update service schedules in the PPMS based on internal health diagnostics.

5. **Handling Amputee Evolving Daily Needs -** Showing how amputees can log daily feedback, concerns, or satisfaction reports. These feeding directly into the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame, which can also be viewed in the PPMS.

6. **Monitoring of Prosthesis Sub-system Evolving Operational Parameters -** Simulating how for instance unusual pylon stress readings or excessive

current thresholds trigger service alerts and support pre-emptive interventions.

Implementation platforms:

7. **Patient–Prosthesis Management System (PPMS):** A secure, role-based interface that displays prosthesis status, sub-system diagnostics, real-time sensor data, and notifications. An example of such notifications is a visual traffic light indicator (where green is good, and red indicates an issue) for immediate condition awareness.

8. **Consequence-Driven Co-Design Support Tool (CD-CST):** A web-based prototype, where users select prosthesis and aftercare elements from a structured library. The system provides real-time feedback on compatibility (e.g. flagging mismatches between user K-level and selected component) and simulates consequence-aware suggestions using encoded production rules.

Table 9.1: Summary of Demonstration Scenarios

Scenario #	Scenario	Framework Component	Consequence Type	Stakeholders Involved
1	Socket Ulcer Detection	PPMS, Sensors	Clinical (preventable harm)	Amputee, Prosthetist
2	Weight Distribution Monitoring	PPMS	Functional (gait optimisation)	Physiotherapist, Engineer
3	Fall Detection & Emergency Response	PPMS, CD-CST	Safety (emergency)	Amputee, Rehabilitation Specialist
4	Maintenance Alerts	PPMS	Operational (system reliability)	Engineer, Prosthetist
5	Amputee Feedback Logging	PPMS, Knowledge Modelling	Emotional / Experiential	Amputee, Prosthetist
6	Excessive Stress Alerts	PPMS & Ontology Rules	Structural / Usage	Engineer, Prosthetist
7	PPMS	PPMS	Systematic (cross-stakeholder co-ordination)	Prosthetist, Physiotherapist, Engineer
8	CD-CST Consequence Driven Design	CD-CST	Improved design	Amputee, Prosthetist, Physiotherapist

Note: In line with the role definitions established in Chapter 6, the term "prosthetist" is used here to denote the clinical authority and lead designer responsible for prosthesis configuration and prescription decisions.

Additionally, the physical prototype's modularity was demonstrated to show how components can be reconfigured to meet different patient requirements, reinforcing the practical feasibility of the modular product architecture described in Chapter 4.

9.3 Evaluation Methodology: Protocoled, Data Capture and Demonstration Consistency

Each evaluation session followed a consistent, structured flow:

a) **Introduction and Context Setting:** The participant received a concise verbal explanation of the research problem, the motivation for developing the adProLiSS framework, and the specific aims of the demonstration.

b) **Pre-Demonstration Questionnaire:** Prosthetists, amputees, and physiotherapists completed a baseline questionnaire capturing their perspectives on their current roles, emotional states, and levels of satisfaction with present-day prosthesis services. This provided a basis for before-and-after comparison. Engineers did not complete the pre-demonstration questionnaire, as their role is not typically integrated in current aftercare workflows.

c) **Presentation and Explanation:** A PowerPoint presentation outlined the adProLiSS framework, its conceptual architecture, the closed-loop methodology, and how the integrated tools (PPMS, CD-CST) operationalise consequence-driven co-design and aftercare.

d) **Live Demonstration:** Each participant observed or interacted with the physical prototype as it simulated the defined scenarios, supported by the

PPMS and the basic CD-CST interface. Demonstrations included live alerts, data uploads, mobile notifications, and example system responses.

e) **Post-Demonstration Questionnaire:** Participants then completed a structured questionnaire including Likert scale items, multiple-choice questions, and open comment sections. The questions were designed to capture technical, practical, and emotional perspectives on how adProLiSS and its tools improve or reshape key aspects of prosthesis development and aftercare.

f) **Observational Notes:** During and after each session, the researcher recorded field notes to capture spontaneous feedback, participant questions, behavioural cues, and emerging themes not covered by the structured questionnaire.

Data collection, ethics & limitations

Questionnaire data were collected using Google Sheets or paper forms (which were then digitised) and securely stored on the University of Malta servers. All responses were anonymised and handled in line with the university's research ethics and GDPR compliance policies. While the structured procedure ensured consistency and reliability across sessions, it is also important to acknowledge limitations inherent in the sample size and stakeholder reach achieved during this study. This study draws inspiration from principles of the Delphi Technique by engaging a diverse panel of stakeholders and systematically collecting expert input, it was designed as a formative, prototype-focused evaluation. Its aim was to demonstrate and test the practical viability of the adProLiSS framework and its core tools through realistic, single-round scenarios rather than a full iterative consensus-building process. This approach aligns with the developmental stage of the research, providing empirical insights to refine the framework for future implementation and validation. This structured, multi-stakeholder, mixed-method evaluation provides the empirical foundation for the subsequent analysis and discussion sections, which examine how well the adProLiSS framework and its enabling tools address the research hypothesis

Delphi inspired formative evaluation approach and stakeholder needs. All raw evaluation data are compiled and reported in an internal technical report archived at the University of Malta (Patiniott, 2025).

Scenario-based demonstrations reflect system integration

The decision to structure the evaluation around scenario-based demonstrations was made to better reflect the integrated, multi-stakeholder nature of the adProLiSS framework. Rather than isolating features for individual testing, each scenario embodied multiple interacting components, sensor feedback, system logic, stakeholder engagement, and patient-specific context, allowing participants to evaluate realistic system behaviours in a situated manner. This approach is supported in the healthcare domain by (Haynes, Purao and Skattebo, 2009; Kneale *et al.*, 2017), who argue that context-specific intervention evaluation provides deeper insights into implementation potential and stakeholder impact. (Michailidou, 2017) similarly highlights that scenario-driven engagement facilitates inclusive and meaningful co-design in user-centred innovation. From an engineering systems perspective, (Wang *et al.*, 2024) further reinforces this methodological choice, demonstrating how situation modelling in complex systems enables the capture of emergent behaviours and non-linear interdependencies. Together, these works support the use of scenario-based evaluation as a scientifically rigorous method for assessing integrated frameworks like adProLiSS, where the value of each component emerges from its dynamic interplay with others across the prosthesis life-cycle.

Literature supports scenario-based evaluation

9.4 Challenges, Limitations and Contextual Constraints of Stakeholder Evaluations

Small, locally constrained sample size

As with any prototype-based stakeholder evaluation, certain constraints shaped the scope and generalisability of this study's findings. The primary limitation concerns the relatively small stakeholder sample sizes, especially within the local Maltese context where the total pool of qualified prosthetists, practising physiotherapists specialising in amputee care, and amputees is inherently limited. Despite proactive recruitment and outreach efforts, including attempts to engage international participants, it was only possible to secure limited overseas input. Logistical, time, and follow-up constraints prevented broader international expansion of the sample.

Findings are indicative, not generalisable

This constraint does not undermine the formative value of the results but does mean that findings should be understood as indicative rather than statistically generalisable. In applied design research, smaller, well-selected samples are widely recognised as sufficient for generating actionable insight when the goal is to evaluate prototypes or explore stakeholder perceptions in depth (Creswell, 2013; Tipton *et al.*, 2017; Vasileiou *et al.*, 2018a). Moreover, mixed-method triangulation, using questionnaires with both Likert-type scales and open-ended qualitative questions, combined with direct observation, helps strengthen the credibility and trustworthiness of the conclusions (Blessing and Chakrabarti, 2009; Indrayan and Mishra, 2021).

Mixed-method triangulation boosts credibility

Context rich insights despite limits

In this sense, the sample size reflects the pragmatic reality of engaging with a small, specialised prosthetics community and the practical constraints associated with recruiting clinicians, engineers, and prosthesis users for live demonstrations, rather than an attempt at strict geographic representativeness. While many participants were drawn from the Maltese healthcare and research context, a subset of contributors resided outside Malta and participated remotely. These participants were included based on their direct involvement in prosthesis design, rehabilitation, or lived prosthesis use, and were selected for the relevance of their expertise and experience to the prosthesis life-cycle under investigation.

Accordingly, the findings are not intended to be statistically generalisable to a specific national population. Instead, they provide robust, context-rich evidence to assess whether the adProLiSS framework can address the identified research problem and support improved communication, consequence reasoning, and stakeholder-centred design in practice.

9.5 Evaluation Criteria Derived from Hypothesis and Consequence Mapping

Primary evaluation criteria

The following evaluation criteria, derived from the hypothesis, were used to assess the success and practical value of adProLiSS in supporting its stated goals. Each criterion was chosen to test a specific aspect of the framework's claim to enhance **time efficiency, cost-effectiveness, functional customisation, user comfort, emotional well-being, and aftercare**, these being core elements of the research hypothesis.

Within this evaluation design, emotional well-being is not treated as a broad psychological construct but as the amputee's affective responses to prosthesis use and aftercare. This includes confidence, trust, satisfaction, or frustration associated with prosthesis performance and its supporting services. Framing emotion in this way follows design research perspectives that define emotion as a fundamental dimension of user experience (Desmet, 2007, 2015), while also building on (Farrugia, 2017) doctoral work, which formalised emotional consequences arising from design commitments and life-phase system interactions. Including emotional well-being as a criterion therefore ensures that the evaluation of adProLiSS captures not only functional and technical outcomes but also experiential consequences central to amputees' quality of life.

Secondary criteria

Grounded in the hypothesis and consequence mapping, the following secondary six criteria were formulated to provide a structured means of evaluating adProLiSS. Each criterion tests a specific claim regarding its ability to enhance efficiency, functionality, comfort, collaboration, adaptability, and emotional support:

1. **Consequence Awareness**: Did participants become more aware of intended or unintended consequences?
2. **Decision Support**: Did the tools help inform or clarify decision-making?
3. **System Usability**: Were the PPMS and CD-CST perceived as intuitive, accessible, and informative?

4. **Stakeholder Collaboration**: Did the framework promote cross-role understanding and communication?
5. **Adaptability**: Was the system perceived as responsive to changing patient or stakeholder needs?
6. **Emotional Response**: Did participants report increased confidence, trust, or reduced anxiety?

These criteria were assessed via mixed-method triangulation, combining self-reports, observational data, and content analysis of open responses.

Together, these criteria map onto the hypothesised outcomes of improved prosthesis life-cycle management in terms of time, cost, functionality, comfort, and emotional and aftercare support. The criteria were assessed via mixed-method triangulation, combining self-reports, observational data, and content analysis of open responses.

9.6 Empirical Findings from Stakeholder Engagement

Evaluation findings: 24 participants, mixed methods

This section presents the empirical findings from the stakeholder-centred evaluation of the adProLiSS framework. Data were collected from 24 participants, amputees, prosthetists, physiotherapists, rehabilitation specialists, and engineers, through a combination of structured questionnaires, 5-point Likert-scale responses, ranging from (Extremely beneficial) to (Not at all beneficial), open-ended feedback, and observational field notes during the live demonstrations. For reporting clarity, rehabilitation specialists were grouped with prosthetists, as they adopt a holistic perspective on prosthesis management, encompassing functional performance, user adaptation, and long-term rehabilitation strategy rather than isolated sub-system concerns.

Results structured scenario – by – scenario

Rather than structuring the results around individual evaluation criteria in isolation (criterion-by-criterion analysis), the findings are presented scenario-by-scenario. This structure mirrors how the demonstrations were conducted, each scenario

Captures integrative, multi-criteria stakeholder responses

illustrated multiple system behaviours and provoked multi-dimensional stakeholder responses. Presenting the results per scenario avoids repetition and better reflects the integrative nature of the adProLiSS framework, where functional, emotional, and procedural outcomes are often triggered simultaneously. Cross-criteria reflections are included within each scenario to capture this complexity without fragmenting the stakeholder experience across disjointed sections.

Within each scenario subsection, findings are structured as follows:

1. Stakeholder Perspectives – including representative quotes;
2. Cross-Criteria Performance – integrating both quantitative ratings and qualitative interpretations;
3. Graphical Reference – linking to figures (Figures 9.1 to 9.7) that visualise the rating distribution per criterion;
4. Observational Notes – summarising researcher observations during the live demonstrations.

This structure reflects the integrated and consequence-aware nature of the adProLiSS framework, where system features are not siloed by function but work in tandem to meet evolving amputee and stakeholder needs.

9.6.1 Evolving Health Issues: Socket Ulcer Detection

Socket sensors monitor ulcer risk factor

This scenario evaluated the integration of pressure, temperature, and humidity sensors within the prosthetic socket to detect early conditions that may lead to skin ulceration. Sensor data was continuously monitored by the prosthesis microcontroller and locally processed to identify thresholds associated with tissue irritation. When risk conditions were met, alerts were automatically triggered, synchronised with the Patient–Prosthesis Management System (PPMS), and pushed to the amputee's mobile device, ensuring rapid, bidirectional awareness.

Alerts auto-synced to PPMS & mobile devices

Shortens response time vs traditional care

From a life-cycle perspective, this mechanism shortens the response time between symptom onset and stakeholder action, removing the reliance on scheduled follow-ups or delayed user reports. In traditional settings, early-stage ulceration often goes unnoticed until pain or skin breakdown occurs, by which point intervention may require socket redesign, wound treatment, or prosthesis withdrawal. The adProLiSS framework repositions this process as one of real-time prevention, enabling proactive care before complications escalate.

Proactive, real-time ulcer detection

i. Stakeholder Perspectives and Role-Specific Value:

Clinicians see reduced reliance on user reporting

Prosthetists noted that the system could reduce dependency on amputee communication alone, particularly for users with low sensitivity or cognitive impairments. One prosthetist highlighted that such an early detection system is *"especially beneficial in patients with altered sensory systems, as it enables patients to take timely action to prevent ulcer formation and seek assistance with socket management and use"*. Another emphasised the long-term impact of undetected ulcers, explaining that they *"mostly affect the ability of the patient to wear the prosthesis, sometimes causing them to lose weeks of their life or further amputation"*. These reflections underline the clinical relevance of proactive ulcer detection in preserving prosthesis usability and patient mobility.

Undetected ulcers risk prosthesis downtime & mobility loss

Alerts justify reassessment & continuity of care

Physiotherapists highlighted how gait deterioration from ulcer-related discomfort often goes unreported, undermining rehabilitation. They agreed the alert mechanism could justify clinical reassessments between sessions, enhancing care continuity.

Real-time alerts boost confidence & prevent complications

Amputees expressed strong appreciation for the ability to receive real-time alerts regarding internal socket risks, noting that this feature increased their confidence in using the prosthesis. One participant remarked, *"I'd rather know immediately than walk another week with it and end up needing treatment",* reflecting the value of early notification in preventing avoidable complications. This sentiment aligns with broader stakeholder feedback that proactive sensing transforms the user's role from passive recipient to active participant in prosthesis care.

Calibration & thresholds need refinement, but aid design transparency

Engineers focused on the sensor calibration stability and alert thresholds, questioning false positives and the interpretability of alerts in edge cases. However, they agreed on the value of such diagnostic transparency for future socket designs.

ii. Cross-Criteria Performance

Faster detection, strong consensus

Time Efficiency: All participants emphasised the benefit of accelerated detection, enabling earlier intervention and reducing prosthesis downtime due to severe ulceration or re-fabrication. Specifically, *66.67% of participants rated the time-saving benefit as very high*, while the remaining *33.33% rated it as high*, indicating a strong consensus on the scenario's effectiveness in minimising delays.

Reduced hospitalisation & re-fabrication costs

Cost Efficiency: The system was seen to reduce the overall financial burden associated with hospitalisation, socket replacement, extended rehabilitation, and time lost by both users and clinical staff. *41.67% of participants rated the cost-saving benefit as very high, while 58.33% rated it as high*, indicating widespread recognition of its economic value.

Sensors & automated alerts seen as robust

Functionality: The integration of the sensors and the automated logic linking real-time data to alerts was highlighted as a functional strength of the system. Evaluation scores reflected this, with *50% of participants rating its functional impact as very high, and the remaining 50% as high*, demonstrating balanced and consistent support across roles.

Proactive mitigation valued

User Comfort: participants appreciated the system's ability to proactively mitigate discomfort by addressing early signs of pressure or irritation, rather than reacting once damage had occurred. Here, *79.17% of participants rated the comfort benefit as very high, and 20.83% as high*, suggesting strong alignment between clinical intentions and user experience.

Transparent monitoring eased anxiety

Emotional Well-being: All participants remarked on how transparent monitoring reduced anxiety by making internal socket health visible and actionable. *70.83% of* *participants assigned a very high rating, while 29.17% selected high*, reinforcing the emotional reassurance offered by the system.

Alerts & PPMS boosted traceability & collaboration

Aftercare Quality: The scenario also demonstrated how sensor-triggered alerts, logged and visualised through the PPMS, enhanced the traceability and continuity of aftercare. This supported more responsive, data-driven collaboration among stakeholders. *79.17% of participants rated this benefit as very high, and 20.83% as high*, confirming its perceived value in structured, adaptive aftercare management.

These quantitative evaluations are visually summarised in Figure 9.1, which presents the distribution of stakeholder ratings across all six criteria for the Socket Ulcer Detection scenario.

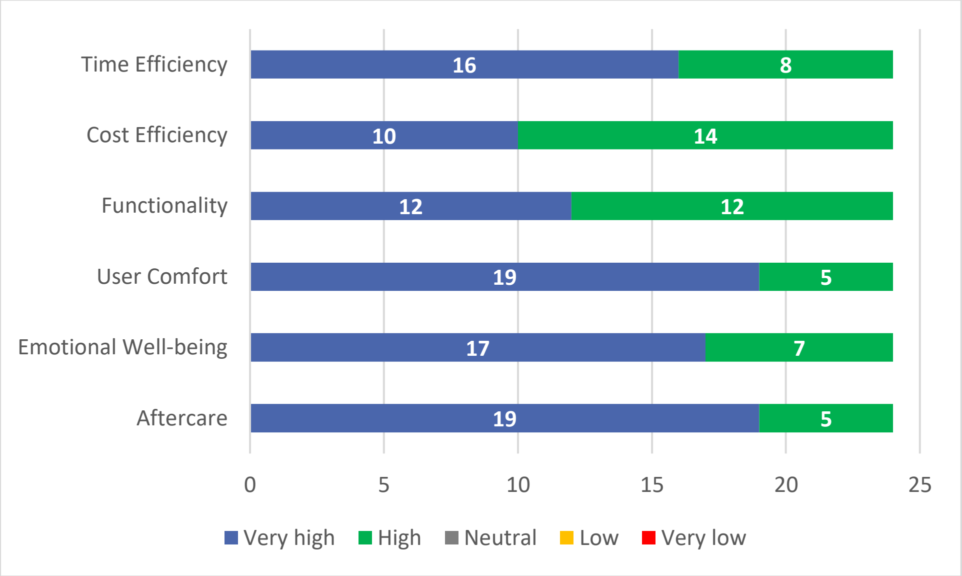


Figure 9.1: Stakeholder-perceived benefits across six evaluation criteria for the Socket Ulcer Detection scenario.

iii. Observational Notes

During the demonstration, participants showed strong engagement with the system's real-time feedback capabilities. Physiotherapists noted that the visual feedback displayed on the PPMS dashboard could complement traditional gait assessments, particularly for patients with limited verbal communication. Amputees responded positively to the mobile notifications, with several highlighting that early alerts would enable them to manage socket discomfort proactively before requiring clinical intervention. This leading to amputees feeling more empowered.

9.6.2 Evolving Weight Distribution Monitoring

This scenario involved pressure sensors embedded in the sole of the prosthetic foot, near the heel and ball, to detect weight imbalance. Simulated pressure changes were monitored by the microcontroller and logged into the Patient–Prosthesis Management System (PPMS), where deviations from normal distribution triggered alerts.

The feature enables early detection of compensatory behaviours linked to socket misalignment, muscular fatigue, or rehabilitation issues. By allowing stakeholders to visualise biomechanical deviations between clinical sessions, adProLiSS enhances care continuity. Traditionally, such problems remain unnoticed until discomfort is reported or visible decline occurs. Continuous monitoring shifts gait assessment from occasional checks to a persistent, proactive process.

i. Stakeholder Perspectives and Role-Specific Value

Data driven insights for clinical action viewed as beneficial

Prosthetists recognised the value of gait pattern alerts in identifying potential socket fit issues or lower-limb misalignments before they escalated into user complaints or required technical interventions. One prosthetist noted that, *“We usually depend on patient reports or visual assessment in clinic. This gives us more objective information to act on”*, highlighting the shift from subjective evaluations to data-driven insights.

Fine tuning of rehabilitation & earlier re-assessment

Physiotherapists were particularly responsive to this scenario, highlighting how objective gait data can enhance their ability to fine-tune rehabilitation programmes and justify re-evaluation before the next scheduled session. One physiotherapist noted that this could be used to help in teaching an amputee how to walk, reducing the possibility that amputees learn bad habits from the onset of rehabilitation.

Stance monitoring seen as beneficial

Increased sense of security & trust

Amputees also expressed appreciation for the ability to have their stance patterns monitored, especially in cases where minor discomforts might not be consciously perceived or reported. As one participant remarked, *"It's reassuring to know that changes in how I stand can be picked up even if I don't notice them myself, and tell me to correct my posture"*, reflecting a sense of increased security and trust in the system's continuous monitoring.

Use of ML for predictive imbalance patterns

Engineers suggested the addition of machine learning techniques to find a pattern in weight distribution imbalance of the amputee to predict cause and future imbalance patterns.

ii. Cross-Criteria Performance

Real-time alerts support posture correction & good standing habits

Time Efficiency: Participants broadly agreed that real-time weight distribution monitoring would allow amputees to correct their posture and promote 'good habits' while standing. This would reduce the need for prolonged physiotherapy sessions. *While 83.33% of participants provided a positive rating overall*, 50% rated the time-saving benefit as very high, 33.33% as high, and 16.67% as neutral.

Fewer complications & clinic visits lead to long-term savings

Cost Efficiency: By mitigating the risk of long-term musculoskeletal complications and reducing the frequency of clinic visits and extended therapy, the system was perceived to offer long-term cost savings in aftercare. Among participants, *20.83% rated the cost benefit as very high, 58.33% as high*, and 20.83% as neutral.

Continuous monitoring gives dynamic picture of prosthesis-use interaction

Functionality: Participants noted that continuous monitoring allowed for a dynamic understanding of prosthesis-user interaction and posture. Repeated weight imbalance alerts would indicate that physical adjustments would be needed. This shift towards continuous functionality evaluation was positively received, with *54.17% rating it as very high, 29.17% as high,* and 16.67% as neutral.

Alerts prompt alignment, socket adjustment before discomfort escalates

User Comfort: While the impact was more indirect compared to the socket ulcer scenario, many participants acknowledged that alerts prompted timely socket or alignment adjustments that helped avoid the development of discomfort. As such, the system was seen to contribute to sustained comfort over time through improved weight distribution. Ratings were *58.33% very high, 33.33% high*, and 8.33% neutral.

Monitoring reassures amputees by flagging deviations unnoticed by user

Emotional Well-being: The monitoring system offered reassurance that deviations would be flagged even if not consciously perceived. This reduced anxiety and enhanced confidence. *50% of participants reported very high benefit, 41.67% high*, and 8.33% neutral.

PPMS visualisation supports team co-ordination & continuity of care

Aftercare Quality: Weight imbalance visualised within the PPMS as trend data, can support better co-ordination between prosthetists, physiotherapists, and engineers. This functionality was identified as a strength in enhancing continuity and coherence in aftercare decisions. Overall, *62.5% of participants rated aftercare quality benefit as very high, 33.33% as high*, and 4.17% as neutral.

The full distribution of responses across all six evaluation criteria is shown in Figure 9.2.

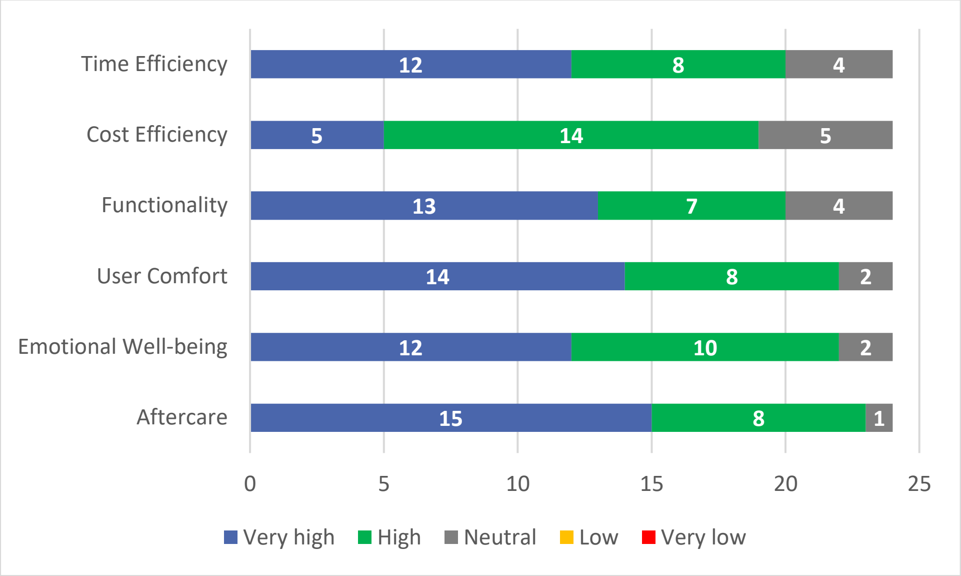


Figure 9.2: Stakeholder evaluation of Weight Distribution Monitoring scenario

iii. Observational Notes

Several participants inquired about the potential to integrate this module with rehabilitation goal-setting dashboards or virtual learning environments. They suggested that enabling amputees to visualise their weight distribution in real-time could serve as an effective educational tool during gait training and prosthesis use instruction.

9.6.3 Evolving Daily Use Situations: Fall Assist and Emergency Response

Fall detection & notification

This demonstration scenario focused on the adProLiSS system's capacity to detect falls and initiate immediate notifications to both clinical stakeholders and caregivers. Once a fall was detected, simultaneous alerts were automatically triggered: alerts were logged in the Patient–Prosthesis Management System (PPMS) and sent to pre-registered emergency contacts.

Unlike traditional fall management, which relies on the amputee self-reporting the event after it occurs or only following up when injuries become evident, this system enables near real-time recognition and co-ordination. The demonstration highlighted how this function can act as a critical safety net for amputees, especially those living alone or in remote locations, by reducing delays in response and facilitating better post-fall medical planning.

i. Stakeholder Perspectives and Role-Specific Value

Valued detailed fall context for targeted reconfiguration

Prosthetists expressed strong interest in using fall detection data to identify underlying mechanical triggers such as knee instability or foot misalignment, with the aim of informing prosthesis reconfiguration or due to environmental conditions. One prosthetist noted, *"Falls are a major problem. Having an inbuilt system that can detect, record and inform on how the fall happened would allow us to properly react to any arising problem"*. This was seen as a significant improvement over current practices that often lack detailed context surrounding fall incidents.

Faster intervention & structured rehab

Physiotherapists emphasised the link between real-time fall alerts and injury prevention. They pointed out that timely detection could enable faster intervention and more structured post-fall rehabilitation. As one physiotherapist explained, *"We often only hear about falls when the damage is already done. This allows for immediate support and tracking the frequency of such events".* The system was therefore viewed as a valuable mechanism for preventing re-injury and enabling more context-sensitive therapy adjustments.

Improved confidence

Amputees responded favourably to the reassurance provided by the automatic alert system. Many indicated that it increased their confidence during daily activities, particularly in potentially risky environments such as stairs or outdoor terrain. One participant remarked, *"I feel more secure knowing that if I were to have an accident, assistance would be more readily available*". This sentiment was echoed in the field notes, which recorded a general sense of improved safety and autonomy.

Improved diagnostic ability

Engineers discussed the technical challenges of fine-tuning the fall detection algorithm, particularly in reducing false positives without compromising responsiveness. Nonetheless, they acknowledged the diagnostic value of timestamped fall logs that combine kinematic and impact data, which could support post-event analysis and iterative system improvement.

ii. Cross-Criteria Performance

Reduced delays between fall & notification

Time Efficiency: The system significantly eliminated delays between fall occurrence and stakeholder notification, enabling faster emergency response and co-ordinated follow-up. 87.5% of participants agreed that the automatic alert mechanism would improve response time and reduce the risk of delayed intervention, with *45.83% rating the time-saving benefit as very high, 41.67% as high*, and only 12.5% as neutral. This reflects broad consensus on the system's potential to accelerate crisis management and reduce prolonged prosthesis downtime following a fall.

Reduced medical expenses

Cost Efficiency: Falls often result in unplanned emergency care, hospitalisation, or extended rehabilitation, all of which carry substantial cost implications. Participants acknowledged that early intervention enabled by the alert system could prevent hospital admissions and minimise related healthcare expenses. 95.83% of participants agreed with this view, with *58.33% rating the cost benefit as very high and 37.5% as high*. Only 4.17% remained neutral, suggesting widespread confidence in the economic advantages of real-time fall detection

Reframes prosthesis as an active safety monitor

Functionality: The integration of fall detection was seen as a leap forward in prosthesis functionality. Rather than acting purely as a mechanical aid, the prosthesis was reframed as an active safety monitor capable of real-time incident management. 100% of participants acknowledged this improvement, with *75% rating it as a very high functionality enhancement and 25% as high*. This feedback shows a shift toward perceiving the prosthesis as a smarter, context-aware system.

Improved confidence

User Comfort: While the system does not directly influence physical comfort in the same way as socket design, it contributes to comfort indirectly by promoting confidence in movement. The reduction of fear-driven cautionary behaviours, such as overly guarded walking, was seen as reducing unnecessary muscular strain. 83.34% of participants agreed the system contributed positively to comfort, with *54.17% selecting very high, 29.17% high*, and 16.67% neutral.

Reduced anxiety, greater independence

Emotional Well-being: Amputees and clinicians consistently reported a sense of increased psychological security, especially among users who had previously experienced falls. The ability to receive immediate support following an incident contributed to reduced anxiety and greater independence. 91.67% of participants reported emotional benefits, with *54.17% rating it as very high, 37.5% high*, and 8.33% neutral.

Fall logs in PPMS enable traceable care planning

Aftercare Quality: By logging fall events into the PPMS and enabling review by clinical staff, the system enhanced the traceability of incidents. Participants noted the added value of correlating falls with other alerts such as gait anomalies or stress readings. This allowed for more precise care planning and proactive risk mitigation. 91.67% of participants affirmed the improvement in aftercare quality, with *62.5% indicating a very high benefit, 29.17% high*, and only 4.17% neutral.

Figure 9.3 illustrates the stakeholder evaluations across all six criteria for this use case.

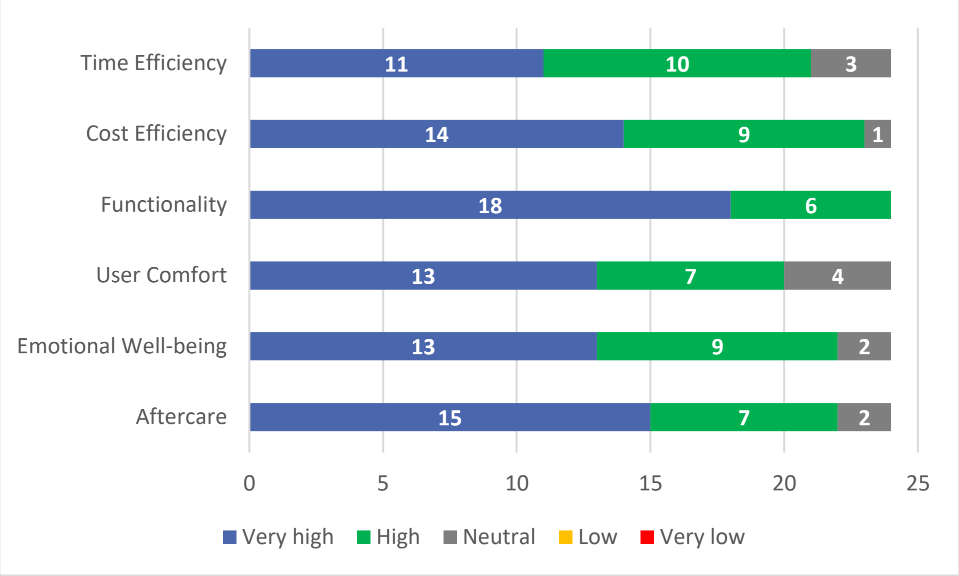


Figure 9.3: Stakeholder evaluation of the Fall Assist and Emergency Response

iii. Observational Notes

The need for configurable escalation protocols, for instance, contacting different stakeholders based on fall severity, was also noted as a potential improvement.

9.6.4 Evolving Maintenance and Service Alerts

Embedded monitoring triggers maintenance alerts

This scenario demonstrated how the adProLiSS system uses embedded sensor data to monitor wear conditions in key prosthesis sub-systems and automatically trigger service alerts when defined thresholds are breached. Parameters such as knee cycle counts were used to infer material fatigue, wear-and-tear, or impending failure of components like the knee actuator or socket attachment. These alerts were displayed within the Patient–Prosthesis Management System (PPMS) and simultaneously forwarded to relevant stakeholders.

Unlike conventional maintenance models that rely on fixed servicing schedules or user-reported issues, the adProLiSS framework introduces predictive servicing capabilities. Maintenance is no longer reactive but becomes condition-based, increasing prosthesis availability while reducing the risk of unexpected failure.

i. Stakeholder Perspectives and Role-Specific Value

Prosthetists valued real-time data for preventative, pre-scheduled maintenance

Prosthetists emphasised that the system could enable a more structured and preventive approach to prosthesis upkeep. One noted, *"We often only learn of problems when the prosthesis fails or the amputee complains. This lets us stay ahead"*. Real-time access to wear indicators was seen as a valuable tool for pre-scheduling maintenance before breakdowns disrupted the user's routine. Another prosthetist added, *"Having real-time data on wear helps us schedule maintenance efficiently and limit downtime"*. These remarks reinforced the system's value in enhancing service responsiveness and extending the prosthesis life-cycle.

Physiotherapists linked alerts to uninterrupted rehabilitation & adaptive therapy planning

Physiotherapists, though not typically involved in direct technical servicing, viewed the maintenance alert system as a contributor to therapy continuity. They noted that unexpected prosthesis failure often delays or interrupts rehabilitation progress, leading to setbacks in muscle conditioning or gait correction. Early alerts, by contrast, allow the therapy plan to proceed uninterrupted. Some also expressed interest in using alert data to adapt physiotherapy intensity or timing, particularly in cases where wear-related discomfort may affect gait dynamics before a failure occurs.

Amputees felt empowered & reassured by proactive maintenance alerts

Amputees responded positively to the idea of receiving direct alerts for system servicing. This empowered them to engage proactively with maintenance processes rather than waiting for faults to become apparent through function loss. One participant commented, *"I feel more confident knowing that my prosthesis is in good working order"*, reflecting how alert systems contributed to peace of mind and better personal planning. Participants also appreciated the reduction in frustrating breakdowns that might interfere with daily mobility or employment.

Engineers highlighted adaptive, data-driven diagnostics enabling pre-emptive servicing

Engineers praised the shift towards condition-based diagnostics. They highlighted that combining real-time sensor data with historical usage patterns, such as terrain type, weight load, and frequency of use, could enable adaptive maintenance scheduling tailored to individual use profiles. One engineer noted, *"The objective* *data can now be compared with stakeholder subjective remarks, making problem identification more accurate"*. Another stated, *"Pre-emptive maintenance can now be done rather than reactive maintenance"* indicating that the system could help reduce emergency repairs and optimise service intervals.

ii. Cross-Criteria Performance

Proactive alerts reduce downtime & speed up diagnostics

Time Efficiency: By pre-emptively identifying wear conditions, the system significantly reduced prosthesis downtime caused by unexpected failures. Participants noted that this proactive detection also accelerated the diagnostic process during servicing. In total, 79.2% of participants reported a positive impact, with *37.5% rating the benefit as very high, 41.67% as high*, and 20.83% as neutral. The reduced need for reactive investigations was seen as a key contributor to more efficient maintenance workflows.

All participants recognised strong cost savings from preventative alerts

Cost Efficiency: Avoiding major component failure through early alerts translated into tangible financial savings. All participants (100%) acknowledged this as a major cost-saving mechanism in prosthesis maintenance, with *70.83% rating the benefit as very high and 29.17% as high*. Reducing emergency interventions, unscheduled replacements, and redundant clinic visits were highlighted as clear advantages

Real-time diagnostics improves safety & extends device lifespan

Functionality: The ability to monitor mechanical and electrical sub-system states in real-time was regarded as a functional upgrade to the prosthesis. Participants emphasised that this not only preserved device integrity but extended the operational lifespan while ensuring safety. Among participants, *75% rated the benefit to functionality as very high, with the remaining 25% marking it as high*.

Pre-scheduled maintenance reduces discomfort from gradual wear

User Comfort: Participants noted that pre-scheduled maintenance would improve user comfort by eliminating the discomfort and uncertainty often associated with progressive component degradation. *45.83% of participants described the benefit as very high, 41.67% as high*, while 12.5% remained neutral. Early alerts were credited with preventing physical discomfort caused by subtle wear-related imbalances.

Alerts reassures amputees, reding anxiety & boosting trust

Emotional Well-being: The psychological security of knowing the system would "warn them" before a failure occurred was repeatedly mentioned by amputees. This sense of reliability reduced anxiety and increased trust in the prosthesis. *62.5% of participants rated the emotional benefit as very high, 25% as high,* and 12.5% as neutral.

Logged alerts improve traceability, co-ordination, & aftercare personalisation

Aftercare Quality: The PPMS's ability to log triggered alerts, intervention records, and service intervals was seen as vital to improving the traceability and co-ordination of maintenance. Participants particularly valued how this supported more personalised aftercare routines. *70.83% rated the contribution to aftercare as very high, 20.83% as high,* and 8.33% as neutral. Several participants proposed extending this traceability to inform long-term prosthesis improvement cycles.

Figure 9.4 provides a consolidated overview of participant ratings across all six performance dimensions.

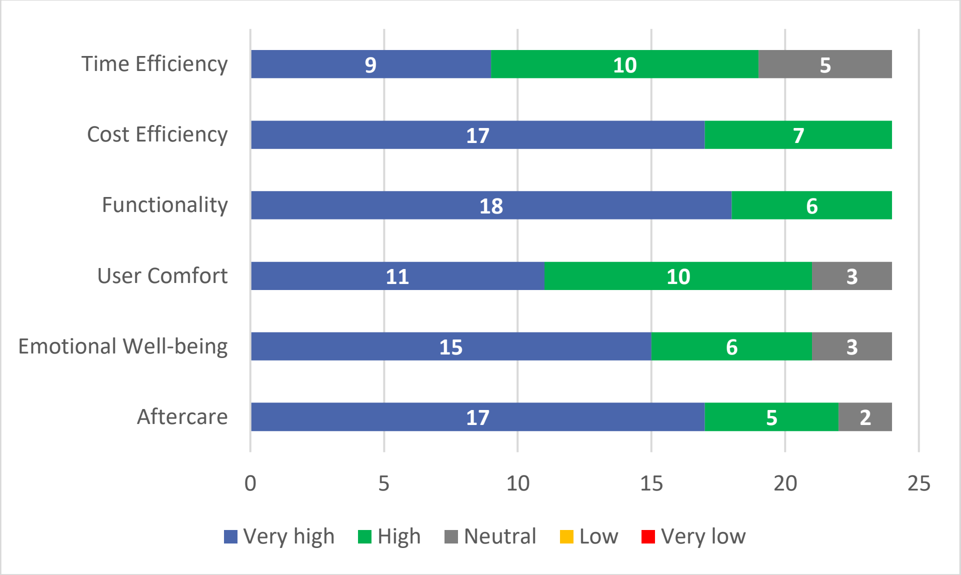


Figure 9.4: Stakeholder-perceived benefits of the maintenance alert system

iii. Observational Notes

Prosthetists and physiotherapists commented on the utility of integrating these alerts into the amputee's routine clinical file, while engineers discussed how environmental parameters (e.g. temperature, humidity) could be factored into more refined predictive models. Prosthetists responded positively to the traffic-light alert icons, which were seen as intuitive indicators of urgency.

9.6.5 Handling Amputee Evolving Daily Needs

Amputees can log daily feedback into PPMS, capturing discomfort or emotional stress

This scenario focused on the ability of the adProLiSS framework to capture real-time user feedback during daily prosthesis use. Unlike sensor-derived alerts, this mechanism enables amputees to directly report discomfort, anomalies, or changes in physical or emotional states via the PPMS interface. Users could submit free-text feedback, which would then be timestamped and stored in the PPMS.

Reactive to adaptive care

This scenario demonstrates how the prosthesis service system can be made more adaptive by moving away from centralised, reactive models of issue detection. Rather than waiting for scheduled check-ups or relying exclusively on sensor data, stakeholders will be continuously informed of evolving user needs, which may otherwise go unnoticed in traditional care models.

i. Stakeholder Perspectives and Role-Specific Value

Prosthetists value user-logged experiences

Prosthetists emphasised that the direct logging of user-reported experiences provided a more holistic understanding of prosthesis performance and the amputee's experience. One prosthetist remarked, *"This provides a more detailed history of what the amputee is experiencing, allowing us to better understand what issues they are facing"*. This enhanced visibility enabled more targeted socket adjustments, better alignment decisions, and stronger justification for mid-cycle clinical intervention.

Physiotherapists saw logs as early indicators of rehab setbacks

Physiotherapists valued the feature for its potential to flag early signs of rehabilitation setbacks or emotional strain occurring between sessions. They noted that patterns such as frequent reports of fatigue, frustration, or reduced activity levels could act as proxies for underlying biomechanical or psychosocial challenges. As one physiotherapist explained, *"More detailed and personalised therapy sessions can be carried out based on current problems that the amputee is facing"*. This input was seen to enhance both the timing and focus of therapeutic adjustments.

Amputees felt empowered & reassured

Amputees expressed strong support for the feature, describing it as a source of empowerment and reassurance. They appreciated being able to report concerns immediately, without waiting for scheduled appointments or needing to justify a clinical visit. One amputee commented, *"Sometimes something feels off, but it's not enough to call in. With this system I can log it straight away"*, while another added, *"This gives me peace of mind. I know that what I feel won't be forgotten or dismissed"*. These responses indicated that the feature improved emotional engagement and reduced the psychological burden of delayed communication.

Feedback useful to supplement sensor data, supporting root-cause analysis & design refinement

Engineers viewed amputee-logged feedback as a supplementary data stream for diagnosing design inconsistencies or operational anomalies not captured by embedded sensors. They suggested that mapping these qualitative reports to specific prosthesis configurations could enable root-cause analysis and continuous improvement in future designs. In this way, user feedback was not only clinically useful but also contributed to engineering refinement across the life-cycle.

ii. Cross-Criteria Performance

Faster action on reported issues, reducing delays in diagnosis & care

Time Efficiency: Instead of relying solely on scheduled appointments, clinicians could act upon emerging urgent issues as they were reported, significantly reducing delays in diagnosis and resolution. This was reflected in stakeholder evaluations, with *20.83% of participants rating the time-saving benefit as very high, 62.5% as high*, and only 16.67% expressing a neutral view.

Earlier, low-cost interventions prevent escalation into expensive critical actions

Cost Efficiency: By enabling earlier, low-cost interventions, such as minor socket padding, suspension adjustments, or activity modifications, the system was seen to prevent escalation into more complex and costly clinical actions. Participants viewed this as a cost-effective way of intervening before problems compounded. This view was supported by *29.17% rating the cost-saving impact as very high, 50% as high*, and 20.83% remaining neutral.

Capture of subjective feedback improves system functionality

Functionality: The ability to capture subjective experience as part of system input was viewed as a functional enhancement. Participants noted that certain issues, such as intermittent inability or user frustration, would not typically be reported. The inclusion of this human-centred data stream was seen to make the framework more context-aware and responsive. *50% of participants rated this improvement in functionality as very high, with an additional 37.5% assigning a high score*, and 12.5% neutral.

Immediate reporting of discomfort prevents long-term tolerance of issues, maintain comfort

User Comfort: Immediate reporting of discomfort was viewed as a feature that indirectly improved long-term comfort. By avoiding the build-up of unreported irritation or misalignment, users felt less compelled to tolerate issues unaided. *29.17% rated the comfort benefit as very high, 54.17% as high*, and 16.67% neutral, suggesting broad endorsement across clinical and user groups.

Amputees felt emotionally validated

Emotional Well-being: This feature was valued for its psychological and physical impact. Amputees described the ability to share experiences without needing to justify them in a clinical setting as emotionally validating. The shift from reactive to proactive communication fostered a sense of autonomy, with *70.83% rating this impact as very high and the remaining 29.17% as high*, indicating unanimous recognition of emotional benefit

Integration of user reports into PPMS enhances personalised, responsive aftercare quality

Aftercare Quality: Participants agreed that incorporating amputee-reported experiences into the Patient–Prosthesis Management System (PPMS) significantly improved the quality of aftercare. The ability to track recurring issues, link them with environmental or behavioural triggers, and adjust aftercare accordingly was seen to foster a more personalised and responsive service. This was reflected in the scores, with *54.17% of participants indicating a very high impact, 33.33% high*, and 12.5% neutral.

These results are visually summarised in Figure 9.5, which illustrates the distribution of stakeholder ratings across all six criteria for this demonstration scenario.

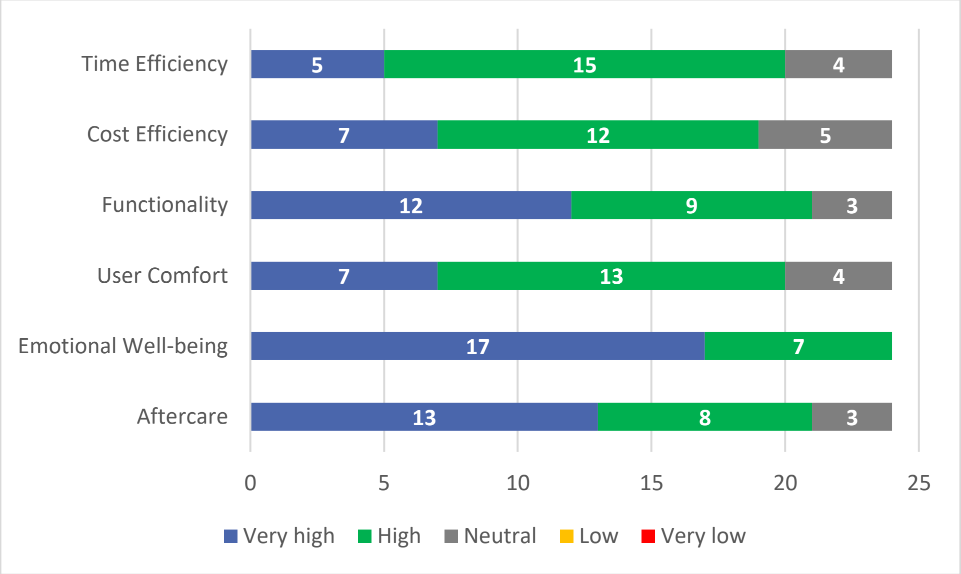


Figure 9.5: Stakeholder evaluation scores for the Amputee Daily Feedback Logging scenario

iii. Observational Notes

Amputees valued simple interface; clinicians saw triage potential; engineers suggested issue-priority scoring. Widely praised for emotional and ethical value

During the demonstration, amputees actively engaged with the feedback interface. Several participants commented on the importance of simplicity and clarity in the interface design. Prosthetists and physiotherapists discussed setting notification thresholds (e.g. alerting after two consecutive reports of a specific issue). Engineers suggested future integration to assign priority scores to types of issues into thematic categories for faster triage. Clinicians also noted that feedback logs could be used to pre-screen patients prior to appointments, enabling more focused consultations. Overall, this use case was among the most positively received from an emotional and ethical standpoint, with participants highlighting the benefit of a system that "listens" as well as "measures".

9.6.6 Monitoring of Prosthesis Sub-system Evolving Operational Parameters

Sub-system stress & power monitored in real-time

This scenario demonstrated the monitoring of internal sub-system metrics such as mechanical stress, power consumption, and electrical loads, parameters typically invisible to clinical teams but crucial for technical maintenance. Simulated anomalies in pylon stress and motor current triggered alerts, which were logged in the PPMS and relayed to engineers for intervention.

Maintenance becomes proactive

Such parameters are usually checked only during workshop inspections or after faults arise. The adProLiSS framework replaces this reactive approach with real-time monitoring, enabling predictive maintenance and early anomaly detection. This is especially critical in modular or sensor-rich prostheses, where undetected failures can compromise system performance and user safety.

By tracking evolving operational parameters, the system supports proactive maintenance, reduces repair costs, and enhances prosthesis reliability and user continuity.

i. Stakeholder Perspectives and Role-Specific Value

Prosthetists noted that stress alerts enable early detection of wear / strain

Prosthetists noted the clinical value of understanding component strain in relation to user-specific behaviour. They explained that stress-related alerts could serve as early indicators of alignment issues that may propagate into structural failures. One prosthetist remarked that the ability to detect wear conditions early *"gives us a heads-up before damage occurs"* while another emphasised, *"We can now see how wear accumulates over time rather than just fixing it after it breaks"*.

Physiotherapists notes that stress / load data can direct therapy adjustments

Physiotherapists saw potential in correlating prosthesis stress data, such as pylon loading or joint strain, with rehabilitation activities. They suggested that repeated high loads during certain tasks could indicate therapy plan revisions or trigger personalised movement guidance. One physiotherapist stated, *"This can educate the patient, especially an active one engaged in work or leisure, regarding the loads they can carry and their limitations, helping to minimise risk of failure"*.

Amputees felt this supports behaviour adjustments

Amputees expressed interest in understanding how their daily activity patterns might influence prosthesis wear, especially among those who engage in high-impact or non-standard movements. Several participants mentioned that having visibility into operational parameters would empower them to adjust their behaviour to prevent damage.

Engineers praised automated diagnostics & PPPMS visualisation, enabling predictive maintenance & fault tracing

Engineers were particularly enthusiastic about the shift toward automated fault identification, coupled with contextual visualisation on the PPMS dashboard. They highlighted the ability to isolate specific stress zones and trace recurring threshold breaches over time as a major advancement for diagnostic precision. The move away from reliance on user complaints or physical inspections was seen as a foundational step toward predictive maintenance and adaptive system tuning.

ii. Cross-Criteria Performance

Early alerts reduce manual diagnostics & emergency downtime

Time Efficiency: Monitoring internal operational thresholds was strongly endorsed for its ability to facilitate earlier intervention, reducing time spent on manual diagnostics, prolonged inspection, or emergency downtime. Most participants agreed on the time-saving potential, with *66.67% rating the benefit as very high, 29.17% as high*, and only 4.17% expressing a neutral view

Pre-emptive servicing avoids major repairs & replacements

Cost Efficiency: By detecting overstress or electrical anomalies before component failure occurs, the system minimises the need for expensive repairs, full replacements, or urgent appointments. This pre-emptive servicing strategy was positively received with *79.17% rating it as very high benefit, 16.67% high*, and 4.17% neutral.

Prosthesis reframed as adaptive diagnostic tool

Functionality: The continuous tracking of operational parameters was seen as a significant enhancement to prosthesis functionality. The feature elevates the device from being a passive mechanical system to an adaptive, diagnostic tool capable of addressing degradation. *A strong 87.5% of stakeholders rated this as a very high functional benefit, while the remaining 12.5% considered it high*.

Indirect benefit through smoother, disruptive-free operation

User Comfort: Although not directly tied to comfort, the maintenance of optimal mechanical and electrical conditions prevents disruptions, such as irregular movement, or noise, that could compromise the user's physical experience. Here, *45.83% of participants reported a very high impact, 33.33% a high impact*, and 20.83% were neutral.

Reassurance from internal fault monitoring

Emotional Well-being: Participants noted the psychological reassurance gained from knowing the system could detect faults early. Amputees, in particular, commented that visibility into the prosthesis's "internal status" eased the worry of unexpected breakdowns. This was reflected in the responses: *45.83% selected very high, 50% high*, and 4.17% neutral.

PPMS visualises data for predictive care & design improvement

Aftercare Quality: The PPMS's ability to store and visualise historical stress and current readings was praised for its role in long-term aftercare. The data could be used to schedule more accurate maintenance, monitor wear patterns, and inform future design improvements. *70.83% of participants rated this contribution as very high, 25% as high*, and 4.17% as neutral.

Figure 9.6 presents the breakdown of stakeholder responses for each evaluation dimension.

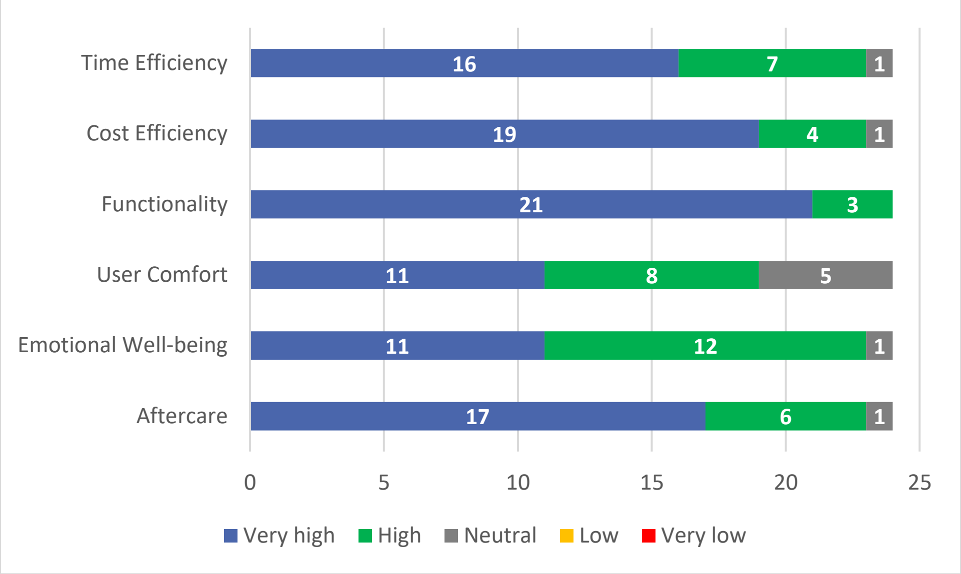


Figure 9.6: Stakeholder perceived benefit of monitoring prosthesis operational parameters

iii. Observational Notes

During the demonstration, engineers exhibited a strong interest in integrating this feature with service history logs, in addition to feeding this data into predictive models or digital twins of the prosthesis to simulate future failure points. Prosthetists noted that alert frequency should be balanced to avoid "alert fatigue," especially when borderline thresholds are frequently crossed but do not yet require intervention.

Overall, the scenario demonstrated the adProLiSS framework's capacity to incorporate low-level technical diagnostics into the broader prosthesis service system, aligning engineering foresight with clinical and user needs.

9.6.7 Patient-Prosthesis Management System

PPMS as central dashboard

The Patient–Prosthesis Management System (PPMS) functions as a central interface within the adProLiSS framework, unifying sensor data, stakeholder input, and service events into a role-specific dashboard. It was demonstrated as a digital workspace for prosthetists, physiotherapists, and engineers, enabling access to real-time alerts (e.g. pressure, stress, fall detection), patient histories, and collaborative aftercare tools via a colour-coded interface.

Consolidates fragmented records into one system, improving continuity & traceability across the prosthesis life-cycle

The PPMS addresses the fragmentation common in traditional prosthesis management, where patient data, device records, and service logs are often dispersed across clinics and formats. By consolidating this information, it allows stakeholders to make informed, co-ordinated decisions across disciplines and locations. In doing so, the PPMS enhances continuity across the prosthesis life-cycle, supporting traceability from early design through to long-term aftercare. Its integration into adProLiSS enables real-time knowledge to inform timely, cost-effective, and collaborative responses to evolving patient needs.

i. Stakeholder Perspectives and Role-Specific Value

PPMS centralises patient-prosthesis records, making follow-up more efficient & enabling longitudinal insight

Prosthetists and physiotherapists immediately identified the clinical advantages of having a consolidated, real-time view of patient–prosthesis interactions through the PPMS. The system's ability to centralise alerts, sensor readings, and historical notes on adjustments or rehabilitation outcomes was seen as transformative for care co-ordination. One clinician noted, *“You usually get this kind of information by chasing files or calling around. Having it here makes follow-up much more efficient, allowing us to provide better holistic care”*. Another added, *“This would provide a detailed patient-prosthesis history, allowing us to see past problematic patterns”* highlighting the tool's potential to support more longitudinally informed decision-making.

Improved traceability as a route to more responsive & personalised care

Amputees, while not having unrestricted access to the full PPMS interface, responded positively to the idea that their clinicians could now access a more structured and up-to-date history of their prosthesis use and related alerts. In practice, amputees interacted with the PPMS through a role-restricted, patient-facing portal, which allowed them to record qualitative feedback and selected aspects of their prosthesis use, while clinical interpretation and system-wide oversight remained the responsibility of the prosthetist. Several participants remarked that this enhanced traceability would likely improve the quality and timeliness of the service they receive. The perception that clinicians are better informed, based on continuous data rather than fragmented reports, was viewed as a step toward more responsive and personalised care. Amputees expressed increased confidence that their evolving needs would no longer be overlooked due to missing or outdated information in traditional documentation systems.

PPMS links sensor anomalies with service logs & conditions, supporting diagnostic & design refinement

Engineers utilised the PPMS primarily to interpret technical alerts and correlate them with maintenance logs and usage history. The capacity to trace sensor anomalies back to specific servicing events or environmental conditions enabled more accurate diagnostics and improved system design iterations. As one engineer explained, *"This provides a more detailed and updated history of the prosthesis, making problem solving more accurate through objective data".*

ii. Cross-Criteria Performance

PPMS speeds up case management by consolidating data across roles

Time Efficiency: The PPMS would reduce delays by consolidating data from multiple disciplines into a unified interface. Stakeholders no longer needed to request updates separately or rely solely on verbal reports, which had previously slowed decision-making. A strong majority (87.5%) agreed that the PPMS improved time efficiency in managing prosthesis-related cases, *with 54.17% rating the benefit as very high, 33.33% as high*, and 12.5% as neutral.

Faster resolutions & lower admin / clinical costs

Cost Efficiency: By streamlining communication, avoiding redundant assessments, and reducing fragmentation of information, the PPMS was seen to lower both administrative and clinical costs. Participants felt that fewer repeat diagnostics, faster resolution of issues, and more efficient co-ordination could be achieved. Again, 87.5% of participants recognised a cost-saving benefit, *with 58.33% indicating very high benefit, 29.17% high*, and 12.5% neutral.

Centralises alerts, configurations, logs & feedback; stronger collaboration

Functionality: The PPMS integrates sensor alerts, prosthesis configuration records, service logs, and user feedback. This centralisation enhances functional precision in prosthesis management and enables multi-role collaboration. While the functionality was generally well received, ratings reflected a more moderate distribution: *37.5% very high, 45.83% high*, and 16.67% neutral.

Indirect benefit through faster issue resolution

User Comfort: Though indirectly related, the PPMS was credited with facilitating quicker identification and resolution of discomfort-related issues, which ultimately supported enhanced comfort during use. Participants' perceptions were varied, with *33.33% indicating very high benefit, 41.67% high*, and 25% neutral.

Reassurance through traceability & follow-up visibility

Emotional Well-being: Amputees and clinicians alike highlighted the psychological reassurance provided by the PPMS. The ability to track what issues had been logged and what follow-up actions were in place helped reduce anxiety and increased trust in the system. This emotional benefit was reflected in the ratings: *66.67% very high, 29.17% high*, and 4.17% neutral.

Enables personalised, traceable multi-stakeholder care

Aftercare Quality: The PPMS was widely considered an improvement in aftercare coordination. Its ability to maintain a traceable history of interventions, enable asynchronous collaboration, and document all stakeholder actions was seen as critical to delivering high-quality, personalised care. *66.67% of participants rated this benefit as very high, 29.17% as high*, and 4.17% as neutral.

Figure 9.7, which visualises the distribution of stakeholder responses.

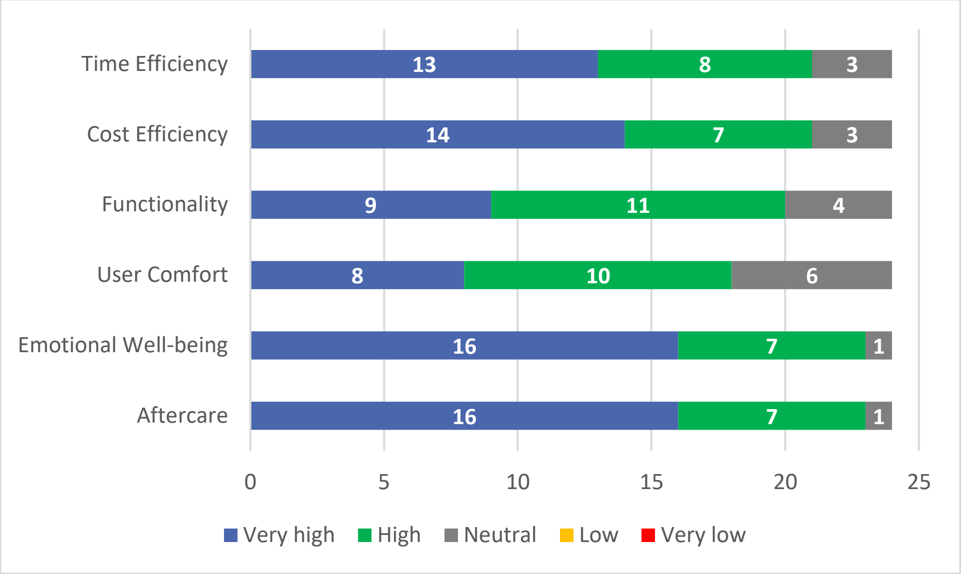


Figure 9.7: Stakeholder Evaluation of the Patient–Prosthesis Management System

iii. Observational Notes

During demonstrations, multiple clinicians praised the simplicity of the PPMS interface, particularly traffic-light visual alerts, and historical event logs. Engineers suggested that future iterations could include predictive analytics dashboards for anticipating faults before thresholds are breached.

Overall, the PPMS exemplified how digital infrastructure can centralise prosthesis life-cycle management, empowering diverse stakeholders to act more efficiently, transparently, and collaboratively.

9.6.8 Consequence-Driven Co-Design Tool

CD-CST simulates consequences of design decision

The Consequence-Driven Co-Design Support Tool (CD-CST) functions as an interactive digital simulation platform that allows stakeholders to visualise, reason about, and test the downstream consequences of prosthesis design decisions prior to implementation. Embedded within the adProLiSS framework, the CD-CST was demonstrated as a tool that integrates ontological rules, historical stakeholder feedback, and prosthesis life-cycle data to simulate both expected and unintended outcomes associated with specific component selections, socket designs, or service actions.

Enables stakeholders to test what-if scenarios, improving design & aftercare decisions

Rather than relying solely on tacit experience or trial-and-error adjustments during fittings and aftercare, the CD-CST provides a knowledge-driven environment where stakeholders can collaboratively explore what-if scenarios. This not only improves decision-making during the early design phases but also supports faster resolution of aftercare challenges by mapping design alternatives to historical outcomes and inferred consequences.

i. Stakeholder Perspectives and Role-Specific Value

Prosthetists value forward simulation to reduce trial-and-error adjustments & preserve comfort

Prosthetists appreciated the ability to simulate reconfiguration option, such as selecting different knee sub-systems or alterations to socket design, before implementing changes that would otherwise require user re-adjustment. One prosthetist noted, *"It's a much smarter way to approach adjustments; we can test different possible solutions before committing. It has the potential of reducing physical alterations"*. This forward simulation was seen as reducing trial-and-error and preserving patient comfort during transitional phases.

Clinicians highlight improved communication & visual justification of decisions for amputees

Both **prosthetists** and **physiotherapists** identified the tool as a valuable medium for improved communication and shared decision-making. In particular, it was found useful for justifying complex component choices or aftercare interventions to the amputee in an accessible, visually-supported manner. The ability to present cause–effect relationships in an intuitive format was viewed as a major benefit when discussing adjustments during follow-up sessions.

Amputees feel more involved & respected, with design shaped around their needs

Amputees engaged with the tool during co-design sessions. Participants remarked that they felt more in control and that their lived experiences were being directly translated into the design rationale. One amputee explained that, *"for once it feels like the design is being shaped around me, not the other way around"*. Several others echoed this sentiment, indicating that the process made them feel heard and respected in ways they had not previously experienced.

Engineers see CD-CST as reducing design learning curve

Engineers praised the CD-CST for its ability to compress the design learning curve by highlighting interdependencies between mechanical configuration, physiological impact, and emotional consequences. As one engineer explained, *"This type of design support can help visualise downstream effects that we may otherwise miss"*. Another noted its strength during early-stage development, saying, *"It's highly beneficial at the conceptual design phase to support the designer in clearly implementing and catering for user requirements"*. Engineers also noted that the tool could be used retrospectively to diagnose issues or refine existing configurations.

ii. Cross-Criteria Performance

Reduces trial-and-error cycles

Time Efficiency: By reducing physical trial-and-error cycles and enabling more informed initial decisions, the CD-CST was widely viewed as shortening the time required for post-deployment adjustments. A total of 87.5% of participants agreed that the tool could accelerate setup refinement, with *33.33% rating it as providing very high benefit, 37.5% as high benefit*, and 29.17% as neutral. Notably, some participants remarked that while the design phase itself may take longer due to the increased number of configuration options, this trade-off was justified by the reduction in physical alterations and fewer adjustment iterations during later stages.

Reduces unsuitable choices, lowering rework & visit costs

Cost Efficiency: Avoiding unsuitable configurations at an early stage was seen as a major cost-saving factor, reducing the likelihood of rework, unnecessary component purchases, and repeated clinic visits. A strong 95.83% of participants recognised the long-term cost benefits of a simulation-led approach, with *62.5% reporting very high benefit, 25% high benefit*, and 12.5% neutral.

Optimises design trade-offs in real-time

Functionality: By allowing stakeholders to explore and balance competing design requirements in real-time, the CD-CST enabled prosthesis configurations that better aligned with specific user needs and system limitations. *58.33% of participants rated its contribution to functionality as very high, 33.33% as high*, and 8.33% remained neutral, highlighting the tool's role in optimising performance outcomes from the outset

Upfront tailoring reduces later discomfort

User Comfort: Participants noted that the CD-CST enhanced user comfort not by directly addressing physical discomfort, but by enabling a better design process that accounted for individual needs from the outset. The ability to simulate different configurations and visualise their impact allowed clinicians and engineers to tailor solutions more precisely, ensuring that potential discomfort could be mitigated before implementation. As a result, *54.17% of participants reported a very high impact on comfort, 37.5% indicated a high benefit*, and 8.33% remained neutral.

Co-design fosters empowerment & trust

Emotional Well-being: The tool's co-design philosophy was frequently mentioned by amputees as emotionally empowering. Participants valued being able to visualise how their feedback influenced design, fostering a stronger sense of control and trust in the clinical process. *62.5% of participants reported very high emotional benefit, 33.33% indicated high*, and only 4.17% felt neutral about its impact.

Design logic remains traceable, aiding re-fits & long-term care

Aftercare Quality: participants felt that the CD-CST would enhanced aftercare quality. These records allowed for traceable design logic, informed future re-fittings, and supported more nuanced aftercare strategies tailored to evolving user needs. *66.67% of participants reported a very high benefit, 29.17% high benefit*, and 4.17% neutral.

The results pertaining to how participants perceived the CD-CST are shown in Figure 9.8.

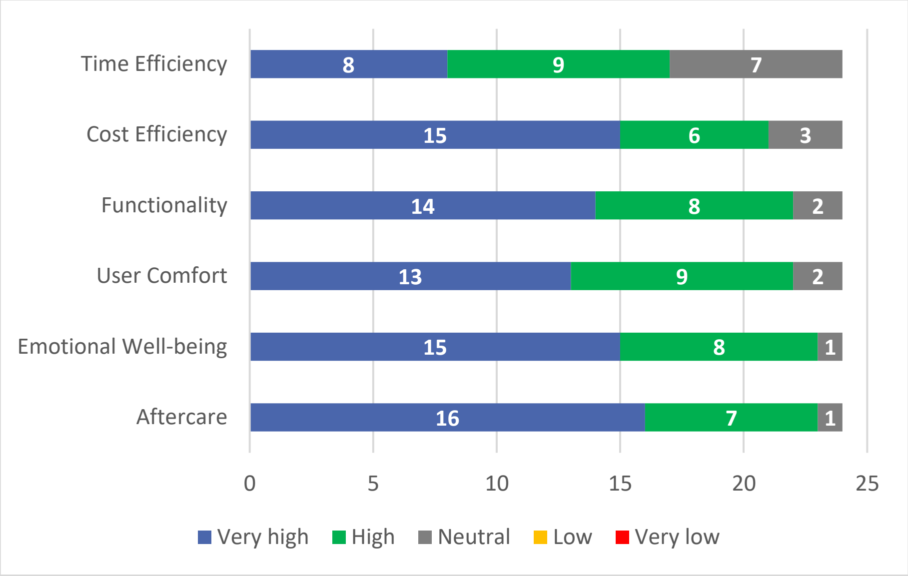


Figure 9.8: Stakeholder-rated performance of the Consequence-Driven Co-Design Tool

iii. Observational Notes

Several participants continued discussing CD-CST simulation features even after their evaluation time ended, particularly those from engineering and design backgrounds. Clinicians remarked on the educational value of the tool, noting its potential in training junior staff. Meanwhile, amputees responded positively to the tool's ability to provide visual explanation of design decisions, making them feel more included and reassured.

The CD-CST was thus validated as a forward-facing tool for simulation-led collaboration, embedding consequence-awareness into the heart of prosthesis design and service delivery.

9.7 Synthesis and Discussion of Stakeholder Evaluation Findings

The empirical findings presented in Section 9.6 indicate a clear alignment between the hypothesised benefits of the adProLiSS framework and the observed stakeholder experiences across all demonstrated scenarios. By triangulating structured Likert-scale responses, observational field notes, and direct stakeholder quotations, the evaluation offers both quantitative substantiation and qualitative depth. This section discusses the key patterns that emerged, contrasts them with the baseline perceptions identified during pre-evaluation consultations, and highlights areas of particularly strong convergence or divergence.

a) Systemic Improvements Across Criteria

Observation of improvements across all six evaluation criteria

Across all scenarios, participants consistently reported marked improvements in the six core evaluation criteria: time efficiency, cost efficiency, functional performance, user comfort, emotional well-being, and aftercare quality. Notably, several system components, particularly the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST), demonstrated cross-cutting benefits. These tools were frequently cited as enabling more responsive, transparent, and co-ordinated care delivery.

Ulcer detection, fall alerts, & PPMS show biggest time gains

Time efficiency improvements were most strongly noted in the ulcer detection, fall response, and PPMS-related scenarios, with stakeholders emphasising reduced diagnostic lag and faster follow-up co-ordination. Similarly, cost efficiency gains were attributed to the transition from reactive to predictive service logic, as seen in the maintenance alerts, stress monitoring, and CD-CST design optimisation workflows. The evaluation findings substantiate the design rationale presented in Chapter 4, confirming that a shift from episodic, stakeholder-triggered care to continuous, system-supported monitoring improves responsiveness, personalisation, and long-term prosthesis management.

Maintenance, monitoring & CD-CST show biggest cost savings

b) Design Rationality and Functional Enhancement

CD-CST shoed how upfront simulation reduces long-term adjustments

The demonstration of the CD-CST was particularly impactful in illustrating the framework's capability for consequence-based simulation and co-design. Participants noted that while the addition of simulation steps could increase initial design time, it drastically reduced post-deployment adjustments, leading to a net functional gain and time-cost benefit. These responses suggest that the framework successfully implements the balance between up-front configurational effort and downstream service reduction, echoing key principles of Product-Service System design and Integrated Product Development (see Chapter 5).

Functionality-related feedback also underscored the value of real-world performance monitoring. Both gait-related and sub-system stress monitoring features were seen as important enhancements that extend functionality beyond what is currently achievable in traditional prosthesis practice. This confirms the relevance of embedding cyber-physical system capabilities within the prosthesis life-cycle, as argued in Chapter 4 and 7.

c) Psychosocial and Emotional Dimensions

Evaluation highlighted emotional benefits

The evaluation also reinforced the importance of addressing non-technical dimensions such as user comfort and emotional well-being. In scenarios such as feedback logging and fall detection, amputees frequently cited increased reassurance, confidence, and perceived inclusion in their own care journey. Emotional well-being was most improved in cases where users could visualise system activity or track clinical responsiveness, factors which previously contributed to anxiety or perceived neglect.

Improvement in prosthesis experience by addressing evolving user needs

Importantly, these findings support the broader hypothesis that an ontology-based service framework can enhance the overall prosthesis experience by addressing evolving user and system needs. In particular, the results reinforce the value of capturing not just objective sensor data, but also emotional and experiential feedback within service logic, allowing the system to adapt to subjective realities that are otherwise difficult to quantify. The knowledge modelling approaches discussed in Chapter 7 enabled the capture of these softer data points, and the PPMS provided the semantic and operational infrastructure to support traceability and longitudinal learning.

d) Aftercare Quality and Stakeholder Integration

adProLiSS strengthens aftercare via

A defining strength of the adProLiSS framework was its capacity to improve aftercare quality through integration, traceability, and cross-stakeholder visibility.

integration, traceability & shared visibility

The PPMS in particular was regarded as a major improvement over existing fragmented practices, consolidating patient history, service events, alerts, and stakeholder input into a single ecosystem. Engineers, prosthetists, and physiotherapists emphasised the value of shared access to real-time, evidence-based decision-support tools.

Amputees felt benefit indirectly though better co-ordination & responsiveness

While amputees did not directly interact with the PPMS interface, their perception of improved care co-ordination and tailored responsiveness indicates that the system's impact is felt across the stakeholder chain. This validates the framework's multi-role architecture, as introduced in Chapters 5 and 8, and confirms the value of modular, role-sensitive system design.

e) Comparison with Pre-Evaluation Expectations

Observations noted in pre-evaluation questionnaire

Although a direct comparison with pre-evaluation responses must account for differences in sample composition and question framing, several observations can be made. Prior to system demonstration, stakeholders, particularly prosthetists and physiotherapists, expressed significant frustration with poor data traceability, siloed workflows, and insufficiently personalised care. They also showed interest in conceptual tools that could support configuration decisions and history tracking, though they were sceptical about their feasibility or practicality.

Post-evaluation, improvements noted through adProLiSS

The evaluation results demonstrate that the adProLiSS framework not only met these initial expectations but exceeded them in several areas, particularly with respect to real-time alerts, co-design transparency, and integrated feedback capture. The transformation from conceptual aspiration to operational prototype was widely recognised and appreciated, lending further credibility to the ontology-driven and consequence-aware design logic underpinning the framework.

f) Limitations and Future Considerations

It is important to acknowledge that some limitations remain. Feedback from engineers was robust during the demonstration, no engineering stakeholders were included in the pre-evaluation phase due to availability constraints, potentially limiting longitudinal comparison in this group.

Additionally, some stakeholders raised concerns about data overload or false alerts, particularly in relation to fall detection and sub-system stress monitoring. These signal the need for continuous refinement of threshold logic and adaptive filtering, which may be addressed in future iterations of the system.

g) Conclusion of the Discussion

Overall, the stakeholder evaluation substantiates the core thesis of this work: that a consequence-aware, ontology-driven service system framework can improve prosthesis design and aftercare outcomes across technical, clinical, and emotional domains. The empirical findings strongly support the viability of the adProLiSS framework as a scalable, multi-role, and knowledge-intensive system capable of adapting to the evolving needs of both amputees and prosthesis sub-systems. These insights form a critical foundation for the concluding reflections in Chapter 10, which will situate these contributions within the broader landscape of engineering design, healthcare delivery, and prosthesis research.

10

10 Discussion of Findings and Conclusions

Chapter 10 provides thesis-wide discussion & concluding synthesis

This chapter provides the overarching discussion and concluding synthesis of the research presented in this thesis. While Chapter 9 evaluated the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) through stakeholder-centred prototype demonstrations and examined the performance of its supporting tools, the present chapter situates those findings within the wider objectives of this research. The purpose here is to move beyond the immediate evaluation results and to integrate the outcomes of Chapters 1 through 9 into a coherent whole.

Revisits aims & RQs, critically reflects on contributions & limitations, & state final conclusion

Accordingly, this chapter fulfils three functions. First, it offers a thesis-wide discussion that revisits the research aim, hypothesis, and questions, and interprets the findings in light of both the literature and the identified problem landscape. Second, it reflects critically on the conceptual, methodological, and practical contributions of the work, including its strengths, weaknesses, and boundary conditions. Third, it states the final conclusions of the research, highlighting the contributions to knowledge, practice, and policy, together with the study's limitations and directions for future work.

The chapter is structured as follows. Section 10.1 presents the overarching discussion, organised around the aim, hypothesis, and research questions, followed by positioning relative to the literature, contributions, implications, and critical reflections. Section 10.2 delivers the conclusions of the thesis, including the resolution of the hypothesis, the principal contributions, limitations, avenues for future research, and final remarks.

10.1 Discussion of Findings

Links findings to aims, hypothesis, & RQs

This section discusses the main findings of this research in relation to the stated aims, hypothesis, and research questions. It synthesises the conceptual, methodological, and practical outcomes of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) and situates them within the wider literature on prosthesis design, aftercare, and product–service system frameworks. The discussion is structured into five parts.

Discussion structure

First, the conceptual and methodological contributions of the research are outlined, highlighting how consequence awareness and ontology-driven reasoning advance the state of the art in prosthesis life-cycle management (Section 10.1.1). Second, these contributions are interpreted in light of the seven research questions defined in Chapter 3, clarifying how each was addressed through the design, implementation, and evaluation of adProLiSS (Section 10.1.2). Third, the framework is positioned within the wider literature, with explicit comparisons to existing approaches in engineering design, healthcare ontologies, and digital support systems (Section 10.1.3). Fourth, the discussion turns to the conceptual and methodological contributions in greater depth, consolidating their significance for engineering design and healthcare practice (Section 10.1.4). Fifth, the practical implications for amputees, clinicians, engineers, and service providers are considered alongside a critical internal evaluation of strengths and weaknesses (Section 10.1.5).

Highlights contributions while acknowledging limitations

The discussion concludes with an appraisal of the framework's validation, boundary conditions, and generalisability (Section 10.1.6). Together, these subsections provide a balanced interpretation of the findings, acknowledging both the contributions and the current limitations of adProLiSS, and setting the stage for the synthesis and conclusions presented in Section 10.2.

10.1.1 Revisiting Aim, Hypothesis, and Research Questions

Research aim: develop, implement & evaluate adProLiSS to meet evolving amputee needs

The overarching aim of this research was to develop, implement, and evaluate a service system framework capable of addressing the evolving needs of amputees across the prosthesis life-cycle. This was addressed through the design and deployment of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS), an ontology-based, consequence-aware framework intended to overcome the limitations of current prosthesis design and aftercare practices.

The central hypothesis of the thesis posited that:

Research hypothesis

The amputee's overall 'prosthesis experience' can be improved in terms of time efficiency, cost efficiency, functionality, comfort, emotional well-being, and aftercare quality if a 'Prosthesis Life-Cycle Ontology' -based Service System Framework is adopted across life-cycle phases, catering for the evolving needs of both amputees and prosthesis sub-systems.

Seven RQs guided inquiry

To test this hypothesis, seven research questions (RQ1–RQ7) were defined in Chapter 3. These questions covered the activities, stakeholders, tools, and critical phases of the prosthesis life-cycle (RQ1–RQ3), the specifications and elements required for a product–service system approach (RQ4–RQ5), its applicability across prosthesis types (RQ6), and its evaluation and potential computational implementation (RQ7). Together, these questions structured the research inquiry and provided a systematic means of determining whether the aim and hypothesis could be achieved.

The following section (10.1.2) addresses each research question in turn, synthesising the evidence gathered across the thesis and demonstrating how the collective findings support the resolution of the hypothesis.

10.1.2 Addressing the Research Questions

The seven research questions (RQ1–RQ7) defined in Chapter 3 provided the structure for this research and guided the development, implementation, and evaluation of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS). Each is addressed below, with supporting evidence drawn from the preceding chapters.

RQ1 – What are the activities that are involved in developing a prosthetic device?

Activities of current approaches, fragmented, tacit & reactive

This research mapped the prosthesis life-cycle into a sequence of activities encompassing design, development, delivery, adaptation, and aftercare, which were identified in Chapter 3 through literature analysis and stakeholder input. While these activities exist in current practice, they are often fragmented, tacit, and reactive. In contrast, Chapters 5 and 6 translated them into the adProLiSS framework and methodology, where they are made explicit, consequence-aware, and knowledge-driven. The evaluation in Chapter 9 confirmed the practical relevance of these activities, as demonstrated in prototype scenarios such as socket ulcer detection, weight distribution monitoring, and maintenance alerts.

Activities are interdependent across domains, require integrated & traceable knowledge flows

Finding: Prosthesis development and aftercare involve interdependent activities distributed across clinical, engineering, and user domains, requiring integrated knowledge flows and traceability mechanisms to ensure adaptability.

RQ2 – Who is involved in the different prosthesis life-cycle phases, and what tools, methods and/or systems are used?

Stakeholders, tools, methods & systems identified

Chapter 3 established the core stakeholder groups (amputees, prosthetists, physiotherapists and engineers) and the fragmented nature of their current tools and practices. Chapters 5 and 6 addressed this by embedding multi-stakeholder integration into the adProLiSS framework, supported by the Patient-Prosthesis Management System (PPMS) and Consequence-Driven Co-Design Support Tool (CD-CST). The evaluation in Chapter 9 confirmed that stakeholders recognised the value of these tools in improving communication, decision-making, and knowledge reuse.

Structured ontology-based tools enable shared consequence knowledge & decision traceability

Finding: Effective prosthesis design and aftercare require structured involvement of diverse stakeholders, supported by ontology-driven tools that provide common access to consequence knowledge and decision traceability.

RQ3 – Which activities and/or systems in the prosthesis life-cycle phases drive high cost, poor quality, long development cycles, or difficulty adapting to amputees' evolving needs?

Identification of high cost activities

Chapters 3 and 4 highlighted the problems caused by fragmented knowledge exchange, reliance on tacit expertise, and reactive adjustments. Chapter 9 demonstrated that adProLiSS addresses these issues through proactive consequence reasoning, modular product-service integration, and early detection of risks (such as ulcer formation, mechanical stress, fall events).

Explicit knowledge capture & consequence simulation reduce cost & quality issues

Finding: The most critical activities are those where tacit, unrecorded decisions accumulate (socket design, fitting, and aftercare), as they drive cost escalation, inefficiencies, and reduced quality. These issues are mitigated within adProLiSS by embedding explicit knowledge capture and consequence simulation.

RQ4 – What specifications should a PSS approach have to result in improved time efficiency, cost efficiency, functionality, user comfort, emotional well-being and aftercare quality?

PSS requirements identified

Chapter 5 defined the requirements of a prosthesis-specific PSS framework: ontology-driven knowledge structures, consequence awareness, stakeholder integration, modularity, and traceability. Chapter 6 translated these into methodological steps, and Chapter 8 implemented them through the PPMS, CD-CST, and physical prototype. Evaluation results (Chapter 9) showed improvements in perceived time efficiency, cost efficiency, functionality, user comfort, and emotional well-being.

Knowledge integration required for prothesis PSS

Finding: A PSS approach for prosthesis design must integrate semantic knowledge modelling, consequence reasoning, and service-system principles to deliver measurable benefits across functional and emotional domains.

RQ5 – What elements should such a PSS approach framework involve?

Identified elements: PLXXKMF, closed-loop methodology, PPMS & CD-CST, modular prototypes

Chapters 5–7 defined these elements: i) an ontology-based knowledge base, the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF), ii) a closed-loop methodology linking design to aftercare, iii) digital support tools (PPMS, CD-CST), and iv) modular physical/digital prototypes. Evaluation confirmed that these elements supported usability, interpretability, and stakeholder communication.

Essential elements identified

Finding: The essential elements of a prosthesis life-cycle PSS framework are an ontology-based knowledge base, integrated digital tools, and modular hardware and software components that jointly enable adaptive, stakeholder-centred care (prosthetists, physiotherapists, amputees and engineers).

RQ6 – Is the proposed PSS framework applicable to all ranges of prosthesis?

Ontology designed for generalisability

While the implementation in Chapters 8–9 focused on lower-limb prostheses, the ontology and methodology were deliberately structured for generalisability. The evaluation highlighted stakeholder agreement that the framework principles (knowledge structuring, consequence reasoning, stakeholder integration) are transferrable to other prosthesis types, though practical validation was limited to the lower-limb context.

Conceptually applicable across prosthesis

Finding: The adProLiSS framework is conceptually applicable to the full range of prostheses, but empirical evidence is currently limited to lower-limb prototypes; further research is needed to validate broader applicability.

RQ7 – How can the proposed ontology-based service system framework be evaluated to assess its effectiveness, applicability and scalability?

Method of evaluation

Chapter 9 demonstrated that the framework can be evaluated through formative, scenario-led, stakeholder-centred demonstrations, supported by pre/post questionnaires and qualitative feedback. The research also highlighted that while evaluation via a single case study was appropriate for this formative stage, future multi-site and multi-device studies are required for validation. The PPMS and CD-CST show feasibility for computational implementation, but further development is needed for large-scale deployment.

Finding: The framework is best evaluated through staged, scenario-based demonstrations, evolving towards computational implementation and multi-device validation as the tools mature.

To provide a clear overview of how the research questions were addressed across the thesis, Table 10.1 maps each RQ to the methods and chapters where it was investigated, the key sources of evidence, and the principal findings. This tabular synthesis demonstrates the coherence of the research design and ensures that the resolution of the hypothesis can be explicitly traced back to the research objectives.

Table 10.1: Mapping of Research Questions to Methods, Evidence, and Findings

RQ	Method / Chapters	Evidence	Main Finding
RQ1 – What are the activities that are involved in developing a prosthetic device?	Literature review, stakeholder input (Chapter 3); Framework (Chapter 5); Methodology (Chapter 6); Evaluation (Chapter 9)	Figure 3.2 Prosthetic Device Product Development Descriptive Model	Prosthesis development and aftercare involve interdependent activities across design, delivery, adaptation, and aftercare. In adProLiSS, these are made explicit, structured, and consequence-aware rather than tacit and reactive.
RQ2 – Who is involved in the different prosthesis life-cycle phases, and what tools, methods and /or systems are used?	Stakeholder analysis (Chapter 3); adProLiSS framework (Chapters 5–6); Evaluation (Chapter 9)	Stakeholder tables (Chapter 3); PPMS/CD-CST descriptions (Chapter 8); Likert results Chapter 9)	Multi-stakeholder involvement (amputees, prosthetists, physiotherapists, engineers) is essential. adProLiSS supports them via ontology-based tools (PPMS, CD-CST) that enhance communication, decision-making, and traceability.
RQ3 – Which activities and/or systems in the prosthesis life-cycle phases drive high cost, poor quality, long development cycles, or difficulty adapting to amputees' evolving needs?	Problem analysis (Chapters 3–4); Framework responses (Chapters 5–6); Evaluation (Chapter 9)	Stakeholder interviews and evidence (Chapters 3–4); Framework responses (Chapters 5–6); Demonstrator evaluation (Chapter 9)	The most critical phases are socket design, fitting, maintenance and aftercare, where tacit knowledge dominates. adProLiSS mitigates these through explicit consequence capture, simulation, and modularity, reducing inefficiencies and risks.
RQ4 – What specifications should a Product-Service System (PSS) approach have to result in improved time efficiency, cost efficiency, functionality, user comfort, emotional well-being and aftercare?	Framework requirements (Chapter 5); Methodology (Chapter 6); Implementation (Chapter 8); Evaluation (Chapter 9)	Figures 5.2, 6.1 (framework & methodology); PPMS & CD-CST prototypes (Chapter 8); Likert graphs (Chapter 9.6)	Required specifications are: ontology-based knowledge backbone, consequence awareness, stakeholder integration, modularity, and traceability. Demonstrations showed measurable improvements across all six evaluation criteria.
RQ5 – What elements should such a PSS framework involve?	Framework design (Chapter 5); Methodology (Chapter 6); PLCCKMF (Chapter 7); Prototypes (Chapter 8); Evaluation (Chapter 9)	Ontology diagrams (Chapter 7); Digital Tool implementations (PPMS, CD-CST) (Chapter 8); Stakeholder feedback (Chapter 9)	Essential elements are: i) ontology-based knowledge backbone (PLCCKMF), ii) closed-loop life-cycle methodology, iii) digital tools (PPMS, CD-CST), iv) modular physical/digital prototypes. Together they enable adaptive, stakeholder-centred care.
RQ6 – Is the proposed PSS framework applicable to all ranges of prosthesis?	Framework generalisation (Chapters 5–7); Demonstrators (Chapters 8–9)	Ontology general structures (Chapter 7); Stakeholder perceptions (Chapter 9 interviews/comments)	The framework is conceptually transferrable to upper-limb and other prostheses. Evidence to date is limited to lower-limb prototypes; broader validation is required.
RQ7 – How can the proposed ontology-based service system framework be evaluated to assess its effectiveness, applicability and scalability?	Evaluation design (Chapter 9); CD-CST instantiation, PPMS (Chapters 8–9)	Demo scenarios (Chapter 9); Questionnaire results (Chapter 9); CD-CST web prototype (Chapter 8)	Formative, scenario-led, stakeholder-centred evaluation proved effective. adProLiSS is feasible as a computational tool (PPMS + CD-CST), but requires scaling to multi-site and multi-device validation.

10.1.3 Positioning in the Literature

Address gaps defined in Chapter 2

The findings of this research can be situated against the gaps and limitations identified in Chapter 2, where the state of the art in prosthesis development, aftercare, and knowledge management was reviewed. That review highlighted four persistent issues: i) fragmented and discipline-specific approaches to prosthesis development, with limited integration of design and aftercare; ii) a lack of Product–Service System (PSS) applications tailored to healthcare and prosthesis life-cycle contexts; iii) limited uptake of ontology-driven approaches for structuring heterogeneous prosthesis knowledge; and iv) the absence of systematic methods for incorporating stakeholder knowledge and consequence reasoning into decision-making. The Adaptive Prosthesis Life-Cycle Service System (adProLiSS) directly addresses these gaps by combining PSS principles, ontology-based knowledge structuring, digital tool implementation, and stakeholder-centred evaluation into a unified framework.

a. Product–Service Systems (PSS) and Prosthesis Design

PSS mainly applied in manufacturing, while healthcare use limited & little focus on prosthesis life-cycles

As discussed in Chapter 2, PSS literature has primarily developed in industrial and manufacturing contexts, with emphases on life-cycle costing, value-in-use, and product–service integration (Goedkoop, 1999; Tukker, 2004; Baines *et al.*, 2017; Paschou *et al.*, 2020). Applications in healthcare have been limited, often focusing on service delivery optimisation rather than embedding PSS principles into the design and adaptation of assistive technologies. Studies such as (Mourtzis *et al.*, 2018) have demonstrated the benefits of PSS for manufacturing adaptability, yet few attempts have been made to extend these concepts to prosthesis life-cycles.

Application of adProLiSS to prostheses and its benefits

This research advances the field by operationalising PSS principles within a prosthesis-specific framework. The adProLiSS framework demonstrates how life-cycle integration can enhance not only cost and time efficiency but also functionality, comfort, emotional well-being, and aftercare quality. In doing so, it provides empirical evidence that PSS, when ontology-driven and stakeholder-centred, can serve as a powerful paradigm for healthcare devices where long-term adaptability is critical.

b. Ontology-Driven Systems and Knowledge Modelling

Existing healthcare aid interoperability but remain limited to clinical workflows. None yet extended to prosthesis design and aftercare

The literature reviewed in Chapter 2 identified the growing role of ontologies in healthcare and engineering design, with examples such as the UiA eHealth ontology (Chatterjee *et al.*, 2021) and the ADCATER ontology (Cocco *et al.*, 2024). These efforts illustrate the potential of semantic modelling for interoperability, reasoning, and decision support. However, existing healthcare ontologies largely focus on clinical workflows or medical data exchange and have not been extended to prosthesis design and aftercare.

PLCCKMF: prosthesis specific ontology, filling gap in structured decision support for design & aftercare

The adProLiSS framework contributes by introducing the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF), an ontology tailored to the prosthesis life-cycle domain that formalises consequence knowledge across physical, functional, emotional, systemic, and semantic domains. Unlike prior ontologies, PLCCKMF explicitly integrates stakeholder perspectives and experiential consequence knowledge, enabling outcomes that are intended or unintended, and interacting or non-interacting, to be formally represented, analysed, and acted upon. This fills a significant gap identified in Chapter 2: the absence of a structured, reusable knowledge base for prosthesis decision-making across design and aftercare phases.

c. Digital Twins, AI, and Smart Aftercare Systems

Current approaches focus on device-centric optimisation

As noted in Chapter 2, digital twin and AI-based approaches are gaining traction in healthcare and wearable systems(Tao, Qi, *et al.*, 2019; Tao, Zhang, *et al.*, 2019; Fuller *et al.*, 2020). For instance, digital twins have been explored for orthopaedics and rehabilitation planning, while AI-driven prosthesis systems focus on gait prediction and control optimisation. While promising, these approaches often remain device-centric and do not integrate semantic knowledge structures or consequence reasoning across multiple stakeholders.

Improvements through adProLiSS

In contrast, adProLiSS situates digital prototypes (e.g. PPMS, CD-CST) within an ontology-driven service system. This allows not only for monitoring and data-driven feedback but also for traceable reasoning about design and aftercare consequences. By embedding consequence awareness and stakeholder knowledge into digital tools, adProLiSS extends beyond monitoring or prediction to support reflective, multi-actor decision-making. This positions the research as complementary to digital twin and AI approaches, offering a semantic and service-oriented layer that enhances their applicability to complex healthcare contexts.

d. Human- and Stakeholder-Centred Design

Stakeholder input valued, but tacit knowledge rarely formalised in prosthesis design & aftercare

The literature on participatory and human-centred design (Howard, Culley and Dekoninck, 2008; Sanders and Stappers, 2008; Steen, Manschot and De Koning, 2011b; Vink *et al.*, 2019) emphasises the value of involving diverse stakeholders in healthcare technology development. However, as highlighted in Chapter 2, many studies stop at descriptive accounts of user or clinician experiences, without providing systematic methods for integrating their knowledge into design and aftercare processes. Furthermore, stakeholder knowledge often remains tacit, unrecorded, and inaccessible across disciplines.

adProLiSS embeds stakeholder knowledge, improving communication, transparency & decision traceability

The adProLiSS framework advances this discourse by embedding stakeholder knowledge directly into its ontology and supporting tools, namely the PPMS and the CD-CST. The PPMS captures patient and clinician experiences in a structured, reusable format, while the CD-CST enables consequence-driven simulations that integrate multidisciplinary perspectives. Evaluation results in Chapter 9 confirm that this approach improved communication, transparency, and decision traceability, thereby addressing a gap in the literature on operationalising stakeholder integration beyond qualitative accounts.

adProLiSS offers paradigm shift with improvements in prosthesis experience

By bridging these four streams of literature, PSS, ontology-driven systems, digital twins and AI, and stakeholder-centred design, adProLiSS represents a paradigm shift in prosthesis research. It provides an integrated, consequence-aware framework that addresses systemic inefficiencies documented in prior studies (Healy *et al.*,

2020) while extending conceptual advances in PSS and ontology research into the healthcare domain. The evaluation evidence (Chapter 9) substantiates that the framework not only addresses gaps identified in the literature but also delivers measurable improvements in prosthesis experience, positioning ontology-driven PSS as a viable model for future healthcare innovation.

10.1.4 Conceptual and Methodological Contributions

Research contributions: conceptual & methodological

This research delivers both conceptual and methodological contributions that extend the state of the art in prosthesis design, aftercare, and knowledge-driven service systems. The conceptual contributions advance the theoretical framing of prosthesis life-cycle management, while the methodological contributions provide novel approaches for structuring, implementing, and evaluating adaptive service-system solutions.

PLCCKMF: scalable ontology that formalises diverse consequence knowledge, embedding stakeholder perspectives for reusable, traceable prosthesis decision-making

The PLCCKMF (Chapter 7, Figure 7.1) constitutes an ontology tailored to the prosthesis life-cycle domain. It formalises heterogeneous consequence knowledge across physical, functional, emotional, systemic, and semantic domains, while also distinguishing intended and unintended as well as interacting and non-interacting outcomes. By embedding stakeholder perspectives into this structured ontology, the PLCCKMF provides a reusable and extensible conceptual backbone that guides prosthesis design and aftercare decisions. As argued in Chapter 4, such a computational ontology was essential because manual approaches cannot accommodate the volume, diversity, and interdependencies of consequence knowledge across multiple patient profiles. This ensures scalability, tractability, and decision traceability in ways that traditional methods cannot achieve. This ensures that consequence knowledge can be systematically reused and acted upon across diverse prosthesis cases.

Extends PSS by embedding consequence awareness as a design principle

A second conceptual contribution lies in the integration of consequence awareness into product–service system (PSS) thinking. Whereas existing PSS research has primarily emphasised life-cycle costing and value-in-use within manufacturing and industrial contexts, this research extends the paradigm to prosthesis development and aftercare by positioning consequence awareness as a core design principle (Chapter 5, Figure 5.2). This conceptual shift ensures that life-cycle decisions are guided not only by technical and economic considerations but also by the experiential outcomes of amputees and other stakeholders.

Frames prosthesis design as a multi-stakeholder service system

A third conceptual contribution concerns the development of a stakeholder-centred service framework. Previous approaches to prosthesis design and aftercare often treated stakeholder groups in isolation. In contrast, the Adaptive Prosthesis Life-Cycle Service System (adProLiSS) conceptualises the prosthesis experience as a multi-stakeholder service system (Chapter 5, Sections 5.1.2–5.1.5). By aligning amputees, prosthetists, physiotherapists, engineers, and designers within a common ontology-driven framework, the research advances a new way of understanding prosthesis design as a collaborative and consequence-aware process.

Introduces closed-loop life-cycle methodology

Beyond these conceptual advances, the thesis also delivers significant methodological contributions. One such contribution is the development of a closed-loop life-cycle methodology (Chapter 6, Figure 6.1). This stepwise approach integrates prosthesis design, adaptation, and aftercare into a continuous process, operationalising consequence capture, knowledge structuring, and decision traceability (Chapter 6, Table 6.1a–b). In doing so, it supports iterative improvement across all phases of the prosthesis life-cycle.

Scenario-based demonstrations as a formative evaluation model for complex, multi-stakeholder healthcare systems

A second methodological advance is the introduction of scenario-based demonstration and evaluation (Chapter 9, Sections 9.2–9.6). Here, physical prototypes, digital tools, and stakeholder engagement were combined to create demonstrator scenarios that captured both quantitative (Likert-scale) and qualitative (open-ended) feedback. This represents a novel evaluation model for complex, multi-stakeholder service systems in healthcare, providing a mechanism for formative testing under lab-based conditions.

Implementation of digital tools into clinical & engineering workflows

A third methodological contribution relates to the development and integration of digital tools. Two systems were designed and implemented: The Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST) (Chapter 8, Sections 8.2.2–8.2.3). The PPMS supports structured consequence logging, maintenance alerts, and the recording of patient-reported experiences for clinician review, while the CD-CST enables consequence simulation and multi-stakeholder decision exploration. Their integration demonstrates a methodological pathway for embedding ontology-driven reasoning into both clinical and engineering workflows.

Formalisation of tacit knowledge

A final methodological contribution lies in the formalisation of stakeholder and technical knowledge into ontology fragments and rules. The PLCCKMF (Chapter 7), supported by structured taxonomies and Semantic Web Rule Language (SWRL) rules, exemplifies how tacit stakeholder knowledge can be transformed into explicit, machine-interpretable formats. This enables consequence reasoning and provides a foundation for adaptive service delivery.

Collectively, these contributions advance conceptual & methodological foundations for adaptive prosthesis service systems

Taken together, these conceptual and methodological contributions advance both academic understanding and practical implementation of adaptive service systems for prosthesis life-cycles. Conceptually, the research establishes consequence awareness and stakeholder integration as core tenets of prosthesis life-cycle management. Methodologically, it demonstrates how ontologies, digital tools, and scenario-based evaluations can be combined into a coherent framework capable of improving knowledge flows, decision traceability, and patient outcomes.

To consolidate these contributions, Table 10.2 maps each one to its location within the thesis and highlights its significance. This tabular synthesis provides a concise reference, demonstrating how the contributions are grounded in earlier chapters and clarifying their academic and practical value.

Table 10.2: Conceptual and Methodological Contributions of the Research

	Contribution	Where in Thesis	Significance
Conceptual	Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF)	Chapter 7; Figure 7.1	Provides an ontology-based knowledge backbone tailored to prosthesis life-cycles, formalising consequences (intended/unintended; interacting/non-interacting) across physical, functional, emotional, systemic, and semantic domains.
	Integration of Consequence Awareness into PSS	Chapter 5, Figure 5.2; Section 5.1	Extends Product–Service System research into prosthesis design and aftercare, embedding consequence awareness as a core design principle alongside cost and technical considerations.
	Stakeholder-Centred Service Framework	Chapter 5, Sections 5.1.2–5.1.5	Reconceptualises prosthesis design and aftercare as a multi-stakeholder service system, aligning amputees, clinicians, engineers, and designers within a shared ontology-driven framework.
Methodological	Closed-Loop Life-Cycle Methodology	Chapter 6, Figure 6.1; Table 6.1	Provides a structured process for iterative adaptation, integrating consequence capture, knowledge structuring, and decision traceability across prosthesis life-cycle phases.
	Scenario-Based Demonstration and Evaluation	Chapter 9, Sections 9.2–9.6	Introduces a novel evaluation approach using scenario-led demonstrations, combining prototypes with stakeholder feedback to assess time efficiency, cost efficiency, functionality, user comfort, emotional well-being, and aftercare quality.
	Digital Tool Development (PPMS and CD-CST)	Chapter 8, Sections 8.2.2–8.2.3	Demonstrates methodological integration of ontology-driven reasoning into practice through digital systems for consequence logging (PPMS) and consequence simulation (CD-CST).
	Knowledge Formalisation through Ontology and Rules	Chapter 7	Advances methodological practice by transforming tacit stakeholder knowledge into explicit, machine-interpretable formats via ontology fragments, taxonomies, and SWRL rules.

Collectively, these contributions establish both a theoretical and methodological foundation for adaptive, ontology-driven service systems in prosthesis life-cycle management. Conceptually, the research advances the field by positioning consequence awareness and multi-stakeholder integration as central design principles. Methodologically, it demonstrates how ontologies, digital tools, and scenario-based evaluations can be combined into a coherent process that improves knowledge flows, decision traceability, and patient outcomes. The following section extends this discussion by considering the practical implications of these contributions, together with a critical reflection on their strengths and weaknesses.

10.1.5 Practical Implications and Internal Critique

Contribution have practical implications but require critical reflection on strengths & weaknesses

The conceptual and methodological contributions outlined above carry a number of implications for practice in prosthesis design, clinical aftercare, and service delivery. At the same time, critical reflection is required to acknowledge the strengths and weaknesses of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS), ensuring a balanced appraisal of its value and limitations.

Amputees become active contributors through consequence capture, improving intervention speed, comfort, & trust

The first set of practical implications concerns amputees themselves. By embedding consequence capture into the Patient–Prosthesis Management System (PPMS), amputees are no longer passive recipients of prosthesis care but active contributors of experiential knowledge. Demonstration scenarios such as ulcer detection and weight distribution monitoring (Chapter 9, Sections 9.6.1–9.6.8) showed that structured consequence feedback can shorten intervention times, reduce discomfort, and enhance trust in the care process.

Clinicians gain decision-traceability tools (PPMS, CD-CST), enabling preventive care and stronger multidisciplinary collaboration.

For prosthetists and physiotherapists, adProLiSS offers a structured means to simulate design alternatives with other stakeholders, and as a means of decision traceability through the combined use of PPMS and the Consequence-Driven Co-Design Support Tool (CD-CST). These tools reduce reliance on tacit knowledge, support the early identification of potential problems, and improve multidisciplinary communication. In practice, this enables clinicians to adopt a preventive rather than reactive stance, thereby shifting aftercare towards predictive maintenance and evidence-based adaptation.

CD-CST enables simulation of design alternatives, reducing physical implementation cycles & improving outcomes

From the perspective of engineers and designers, the adProLiSS framework provides opportunities to simulate design alternatives and explore consequence pathways before physical prototyping. The CD-CST, in particular, allows design teams to anticipate the stakeholder impacts of material, geometry, or control-system changes. This supports consequence-driven design decisions that reduce development cycles and costs, while improving functional and emotional outcomes for end-users.

Shifts prosthesis management to adaptive, knowledge-driven service aligned with value-based care

At the level of service providers and policy, adProLiSS highlights the potential of adopting product–service system thinking in clinical procurement and rehabilitation services. By emphasising long-term outcome monitoring and consequence traceability, the framework encourages providers to reframe prosthesis management as an adaptive, knowledge-driven service rather than a one-off product delivery. This aligns with ongoing healthcare policy trends that emphasise interoperability, accountability, and value-based care.

Multi-stakeholder integration, ontology-driven knowledge base, functional tools (PPMS, CD-CST), & scenario-led validation showing multi-criteria benefits

Alongside these practical implications, a balanced critique reveals both strengths and weaknesses of the framework. Among the strengths, adProLiSS achieves genuine multi-stakeholder integration by bringing together amputees, prosthetists, physiotherapists, and engineers within a single framework, thereby bridging gaps between disciplines that traditionally operated in isolation. Its ontology-driven knowledge base, the PLCCKMF, ensures that consequence knowledge is structured, reusable, and machine-interpretable, reducing reliance on tacit expertise and enabling decision traceability. In addition, the development of PPMS and CD-CST demonstrates how conceptual models can be translated into functional tools that deliver tangible benefits in practice. Finally, the scenario-led validation provided empirical evidence that the framework can improve time and cost efficiency, functionality, user comfort, emotional well-being, aftercare quality, and stakeholder collaboration across multiple life-cycle phases.

Early-stage PPMS/CD-CST, limited AI reasoning, small sample size, ontology maintenance challenges, & digital literacy barriers

The weaknesses of adProLiSS must also be acknowledged. The PPMS and CD-CST remain at a formative stage of development. While functional for demonstration purposes, they require further refinement for deployment in clinical environments. In particular, as noted in Chapter 8, the AI reasoning capabilities of the CD-CST were not yet fully implemented, with current demonstrations relying on simplified scenario logic rather than fully autonomous inference. The evaluation was necessarily limited in sample size and geography, which constrains the ability to generalise findings to broader populations. However, as justified in Chapter 9 (Creswell, 2013; Tipton *et al.*, 2017; Vasileiou *et al.*, 2018b), the depth and representativeness of the stakeholder sample remain scientifically valid for exploratory research of this type. Another weakness concerns ontology maintenance: as consequence knowledge expands, systematic methods for updating and validating the ontology will be necessary to prevent complexity and inconsistencies. Finally, the framework assumes a baseline level of digital literacy among amputees and clinicians, which may not always be present in practice, and which could constrain adoption unless appropriate training or user interface refinements are introduced.

adProLiSS shows promise with measurable benefits but needs refinement, validation, & infrastructural support for large-scale adoption

Taken together, the practical implications demonstrate that adProLiSS has the potential to enhance the daily realities of amputees, clinicians, engineers, and service providers, while the internal critique highlights areas that must be addressed for large-scale adoption. To complement this narrative discussion, Table 10.3 provides a structured synthesis of the key strengths and weaknesses, together with their practical implications. This tabular overview makes explicit both the benefits already evidenced and the areas requiring further development. Overall, the reflections presented here position adProLiSS as both a promising and a developing approach: robust enough to provide measurable benefits in formative evaluations, yet still requiring refinement, broader validation, and infrastructural support for real-world integration.

Table 10.3: Strengths and Weaknesses of adProLiSS and Their Practical Implications

		Implications
Strengths	Multi-stakeholder integration across amputees, clinicians, engineers, and designers	Enhances communication, transparency, and collaborative decision-making across life-cycle phases
	Ontology-driven knowledge base (PLCCKMF) providing structured, reusable consequence knowledge	Reduces reliance on tacit expertise; enables decision traceability and adaptive care pathways
	Practical tool support via PPMS and CD-CST	Demonstrates how conceptual models can be operationalised into usable systems with tangible clinical and design benefits
	Scenario-led validation demonstrating improvements in time efficiency, cost efficiency, functionality, user comfort, emotional well-being, aftercare quality, and stakeholder collaboration	Provides empirical evidence of multi-dimensional benefits and motivates further investment in adaptive service systems
Weaknesses	Prototype maturity (TRL) – PPMS and CD-CST are early-stage	Requires further development, validation, and refinement before large-scale clinical adoption
	Evaluation scope (sample size & geography) – limited generalisability, though scientifically valid for exploratory research	Broader studies are needed to confirm findings across different populations and healthcare contexts
	Ontology maintenance challenges as knowledge base expands	Ongoing governance and updating mechanisms are needed to sustain accuracy and usability
	Dependency on digital literacy among amputees and clinicians	Training and support mechanisms will be necessary to ensure equitable adoption

adProLiSS strengthens prosthesis life-cycle management with PPMS & CD-CST but requires refinement, scaling, & ontology maintenance for wider adoption

Overall, the strengths of adProLiSS demonstrate its potential to improve communication, traceability, and outcome quality across the prosthesis life-cycle, while also offering practical tool support through PPMS and CD-CST. At the same time, the identified weaknesses point to clear priorities for future refinement: advancing prototype maturity, scaling evaluation across broader populations, establishing ontology maintenance mechanisms, and addressing digital literacy gaps. Taken together, these reflections show that adProLiSS is both a robust and a developing approach, capable of delivering measurable benefits in its current form, yet still evolving towards full clinical and industrial integration.

10.1.6 Validity, Boundary Conditions, and Generalisability

Study boundaries reflect doctoral scope

While this research achieved its stated objectives, certain boundaries of scope and scale shape the extent to which findings can be generalised. These limitations do not undermine the validity of the work, but they define the natural context of a doctoral study and point to areas where further development and investigation are needed. In particular, they reflect trade-offs between depth and breadth, prototype maturity and proof-of-concept, and localised evaluation versus large-scale generalisability. Table 10.4 summarises the key limitations and outlines corresponding directions for future work.

Taken together, the limitations presented here should not be read as weaknesses of the framework itself but as natural boundaries of a doctoral investigation. Each one points directly to an actionable line of enquiry for future research, whether scaling evaluation, advancing prototype maturity, or establishing ontology governance. In this way, adProLiSS is positioned not as a finished endpoint but as a demonstrable foundation and a springboard for further integration into healthcare practice at scale. The following section synthesises these findings, bringing together the conceptual, methodological, and practical contributions into a unified conclusion.

Table 10.4: Research Limitations and Corresponding Future Work

Limitation	Implication	Future Work
Focus on lower-limb prostheses only	Findings cannot be assumed to transfer directly to upper-limb prostheses or other assistive devices.	Extend the framework and evaluation to upper-limb prostheses and explore adaptability to other rehabilitation technologies.
Evaluation sample size and geography – small, localised but scientifically justified (see Chapter 9).	Limits generalisability across broader populations and healthcare systems.	Conduct multi-centre, cross-cultural evaluations with larger and more diverse stakeholder groups.
Prototype maturity and scope, PPMS and CD-CST were functional demonstrators, not full clinical systems. The AI reasoning layer of the CD-CST was not yet fully implemented.	Interoperability, security, and regulatory compliance remain outside current scope.	Advance prototypes to higher TRLs, complete AI reasoning integration, integrate with hospital IT systems, and align with standards such as HL7/FHIR (Ayaz *et al.*, 2021).
Ontology governance not fully established	Risk of inconsistency as consequence knowledge expands.	Develop systematic governance processes, including expert panels, version control, and automated validation.
Educational applications only partially explored	Potential value for training clinicians and designers not fully developed.	Extend adProLiSS into an educational simulator for consequence-aware prosthesis design and aftercare training.

10.2 Conclusions

This section synthesises the overall findings of the thesis and reflects on their implications for theory, practice, and future research. Whereas Section 10.1 discussed the contributions, practical implications, and limitations of adProLiSS in detail, this section distils those insights into a set of clear conclusions. It begins by revisiting the central hypothesis and the research questions, confirming how they have been addressed through the design, implementation, and evaluation of the framework (Section 10.2.1). The wider contributions to knowledge, practice, and policy are then summarised (Section 10.2.2), followed by a concise account of the research limitations (Section 10.2.3) and avenues for future work (Section 10.2.4). The chapter closes with final remarks that position adProLiSS within the broader trajectory of engineering design and prosthesis care (Section 10.2.5).

10.2.1 Hypothesis Resolution and Main Findings

The findings of this research support this hypothesis, stated above in Section 10.1.1. Through the design, implementation, and evaluation of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS), measurable improvements were demonstrated across the six core criteria of the prosthesis experience, alongside enhanced stakeholder collaboration and decision traceability.

Time and cost gains: early detection & preventive maintenance reduced delays, costly repairs, & unnecessary clinical visits

With respect to *time efficiency*, demonstration scenarios such as early ulcer detection and automated maintenance alerts showed that structured consequence capture could shorten clinical response times and reduce delays in prosthesis adaptation (Chapter 9, Figures 9.1 and 9.4). Similarly, *cost efficiency* was addressed through both system-driven mechanisms, such as preventive maintenance protocols, and stakeholder contributions, such as informed user reporting. Together, these reduced the risk of costly repairs and avoidable clinical visits (Chapter 9, Section 9.6.2).

Functionality & comfort improved through stress/load monitoring & pressure distribution feedback, enabling targeted adaptations

Improvements were also observed in *functional performance*, where prototype demonstrations confirmed that consequence-aware feedback, such as mechanical stress and electrical load monitoring, directly supported the optimisation of prosthesis function. In terms of user comfort, the integration of consequence knowledge relating to socket pressure and weight distribution (Chapter 9, Section 9.6.2 and 9.6.3) enabled targeted adaptations that improved daily wearability.

Emotional reassurance & adaptive aftercare enhanced via PPMS communication & closed-loop processes

The research further highlighted benefits for emotional well-being, with stakeholder feedback emphasising that improved communication, transparency, and the sense of being “listened to” through PPMS enhanced confidence and reduced anxiety (Chapter 9, Section 9.6.5). The quality of aftercare was similarly enhanced, as the closed-loop process embedded in adProLiSS ensured that aftercare was adaptive rather than reactive, thereby supporting continuity of care and proactive interventions.

Stakeholder collaboration improved through shared knowledge & consequence simulation, reducing fragmented communication

An additional finding emerged beyond the predefined evaluation criteria, namely stakeholder collaboration. The framework facilitated more effective cross-disciplinary interaction between amputees, clinicians, engineers, and designers, made possible through shared knowledge structures and consequence simulation (Chapter 9, Section 9.6.7). This reflects a significant shift from fragmented communication practices towards a more integrated model of prosthesis life-cycle management.

Findings validate thesis: ontology-based, consequence-aware framework enhances efficiency, comfort, well-being, aftercare, & collaboration

Taken together, these findings confirm that an ontology-driven, consequence-aware service framework can enhance the prosthesis experience in terms of time, cost efficiency, comfort, functionality, emotional well-being, aftercare quality, and user-centred outcomes. The research thus validates the central proposition of this thesis: that structuring heterogeneous consequence knowledge and embedding it into adaptive service processes enables more effective, collaborative, and responsive prosthesis life-cycle management.

10.2.2 Contributions to Knowledge, Practice, and Policy

Contribution extend to knowledge, practice & policy beyond hypothesis validation

This research has generated contributions that extend beyond the resolution of its central hypothesis, advancing both theoretical knowledge and practical approaches to prosthesis life-cycle management. The contributions can be grouped into three broad domains: knowledge, practice, and policy.

Extends PSS theory from manufacturing to prosthesis care, incorporating comfort, emotion, & aftercare

From a *knowledge perspective*, the thesis advances the academic discourse on product–service systems (PSS), ontologies, and consequence-aware prosthesis design and aftercare technologies. While existing PSS literature has been primarily rooted in manufacturing and industrial contexts, this research demonstrates how PSS principles can be reinterpreted and applied to the prosthesis domain, where outcomes are measured not only in terms of cost and performance but also in relation to user comfort, emotional well-being, and aftercare quality. The development of the Prosthesis Life-Cycle Consequence Knowledge Modelling Frame (PLCCKMF) represents a significant theoretical advancement, offering a domain-

Introduces PLCCKMF as a domain-specific ontology embedding stakeholder perspectives into structured consequence knowledge

specific ontology that formalises consequences across multiple domains and embeds stakeholder perspectives into structured knowledge representations. As argued in Chapter 4, the computational nature of this ontology is essential: manual approaches cannot accommodate the scale, diversity, and interdependencies of consequence knowledge across multiple patient profiles and prosthesis cases. By ensuring scalability, tractability, and traceability, the ontology enables insights to be reused and extended in ways not feasible through traditional methods. By combining consequence awareness with ontology-driven reasoning, the thesis extends both PSS theory, ontology research and engineering design knowledge, showing how heterogeneous forms of knowledge can be made interoperable, reusable, and traceable across life-cycle phases.

Ontology-based reasoning ensures scalability, reusability, & traceability of heterogeneous knowledge across life-cycle phases

adProLiSS delivers practical tools, embedding consequence knowledge into daily workflows

In *terms of practice*, the thesis provides methodological and technological innovations that have direct implications for prosthetists, physiotherapists, engineers, designers and amputees. The Adaptive Prosthesis Life-Cycle Service System (adProLiSS) translates conceptual models into operational tools, most notably through the Patient–Prosthesis Management System (PPMS) and the Consequence-Driven Co-Design Support Tool (CD-CST). These tools exemplify how structured consequence knowledge can be embedded into everyday practice, enabling clinicians to move from reactive to proactive aftercare, engineers and designers to simulate consequence pathways during development, and amputees to play a more active role in shaping their own prosthesis experience. The scenario-led evaluations presented in Chapter 9 demonstrated that these tools are capable of improving time and cost efficiency, functional outcomes, user comfort, emotional well-being, and aftercare quality, while also fostering improved collaboration across stakeholder groups. Taken together, these practical contributions show that adProLiSS is not merely a conceptual framework but a demonstrable approach for improving service delivery in prosthesis care.

Scenario-led evaluations confirm benefits across efficiency, comfort, aftercare, & stakeholder collaboration

Positions prosthesis management as a PSS with focus on monitoring,

At the *level of policy and systems integration*, the research highlights implications for healthcare service design and procurement. By framing prosthesis management as a product–service system, the thesis emphasises the importance of long-term traceability, & adaptive support

monitoring, consequence traceability, and adaptive support. These elements align with emerging policy trends that emphasise value-based care, interoperability, and accountability in health technology management. Although full-scale integration with standards such as HL7/FHIR and regulatory frameworks was beyond the scope of this doctoral research, the ontology-driven foundation of adProLiSS offers a clear trajectory for alignment with such standards in the future. In this sense, the thesis contributes not only to academic and clinical practice but also to broader debates about how health systems can adopt adaptive, knowledge-based service models that extend beyond the point of device delivery to encompass the entire life-cycle of care.

Contributions span knowledge, practice, & policy, advancing adaptive, ontology-driven prosthesis management

In summary, the contributions of this research span theoretical, methodological, and systemic domains. It extends knowledge by formalising consequence-aware ontologies for prosthesis life-cycles, advances practice by delivering and evaluating digital tools that operationalise this knowledge, and contributes to policy discussions by demonstrating how PSS principles can be embedded into healthcare service delivery. Collectively, these contributions strengthen the scientific and practical foundations for a new generation of adaptive, ontology-driven prosthesis management systems, demonstrating how computational ontologies can scale consequence knowledge across cases and contexts while maintaining traceability and rigour.

10.2.3 Limitations of the Research

Study focused on lower-limb prostheses with small, localised evaluations; broader studies needed for generalisation

Like any doctoral study, this research was shaped by boundaries of scope, resources, and methodological choices. The focus was primarily on lower-limb prostheses, which allowed for depth of inquiry but limited the ability to generalise findings directly to upper-limb prostheses or other assistive technologies. The evaluations conducted with amputees, prosthetists, physiotherapists, and designers were necessarily small in scale and geographically localised, though scientifically justified for exploratory research. While these evaluations demonstrated the feasibility and potential impact of adProLiSS, larger and more diverse studies will be required to confirm the generalisability of the findings.

Prototypes remain early-stage; ontology governance & clinical integration require further development

Another limitation lies in the maturity of the developed prototypes. The PPMS and CD-CST were implemented at an early technology readiness level, suitable for demonstration and formative evaluation but not yet optimised for routine clinical integration. Similarly, while the PLCCKMF provided a robust foundation, systematic processes for ontology governance and long-term maintenance were not fully developed within this thesis. These boundaries do not undermine the contributions of the research but define its natural limits as a doctoral research.

10.2.4 Future Work

Future work: scale evaluations across larger, more diverse populations & healthcare contexts

The research presented in this thesis lays the groundwork for multiple avenues of extension. Scaling evaluations is an immediate priority, with future studies involving larger, more diverse participant groups across different healthcare systems and cultural contexts. This would extend the validation of adProLiSS across broader populations and healthcare contexts.

Advance PPMS & CD-CST maturity: IT integration, regulatory compliance, AI reasoning, & interactive bi-directional care features

A second line of future work involves advancing prototype maturity. The PPMS and CD-CST require further technical development to reach higher technology readiness levels, including integration with hospital IT infrastructures, compliance with regulatory standards, and improved user interfaces to ensure accessibility for clinicians and amputees alike. Completing the integration of the CD-CST’s AI reasoning layer will also be essential, enabling the tool to autonomously infer and simulate consequence pathways rather than relying solely on predefined scenarios. Future developments could also extend PPMS into a bi-directional communication platform, enabling clinicians to provide feedback or guidance directly through the system. This would transform PPMS from a monitoring tool into a more interactive service channel, supporting adaptive care pathways in real time.

Establish ontology governance: expert review, version control, reasoning validation, & expansion to upper-limb and rehabilitation contexts

Further attention is also needed to establish robust ontology governance. Processes for updating, validating, and expanding the PLCCKMF should be developed, including methods for expert review, version control, and automated reasoning validation. Expanding the ontology to incorporate upper-limb prosthesis knowledge and broader rehabilitation contexts would further enhance its applicability.

Advance consequence reasoning: ontologies, hybrid reasoning, ML, symbolic integration, & links to cyber-physical systems

A further scientific avenue lies in the advancement of consequence reasoning itself. While this research demonstrated the feasibility of ontology-driven consequence capture and SWRL-based reasoning, future work could explore more sophisticated approaches such as probabilistic ontologies (Carvalho, Laskey and Costa, 2017), hybrid reasoning frameworks, or the integration of machine learning with symbolic representations (D'Amato, 2020). Such work would enable the modelling of uncertainty, the prediction of emergent consequences, and the tighter coupling of adProLiSS with cyber-physical prosthesis systems and digital twin architectures (Bruynseels, de Sio and van den Hoven, 2018).

Use digital tools as simulators for training clinicians, designers, and engineers in consequence-aware prosthesis design

Finally, the framework holds potential as an educational and training platform. By adapting the digital tools into consequence-driven simulators, adProLiSS could support the training of clinicians, designers, and engineers, thereby extending its impact beyond immediate clinical care to the broader ecosystem of prosthesis design and service delivery.

10.2.5 Final Remarks

adProLiSS reframes prosthesis management as an adaptive, integrated service system

This thesis has presented the design, development, and evaluation of the Adaptive Prosthesis Life-Cycle Service System (adProLiSS), an ontology-based, consequence-aware framework that rethinks prosthesis management as an integrated service system. By combining structured knowledge representation with practical digital tools and stakeholder-centred evaluation, the research has demonstrated how prosthesis design and aftercare can be transformed from fragmented, reactive processes into a coherent, adaptive, and collaborative endeavour.

Contributions span theory, method, & practice, embedding consequence awareness, ontologies, & digital tools into prosthesis life-cycle care

The contributions of this work span theory, method, and practice. Conceptually, it positions consequence awareness as a core principle of product–service system design for prostheses. Methodologically, it formalises stakeholder knowledge into reusable ontologies and decision-support processes. Practically, it demonstrates measurable improvements in time and cost efficiency, functionality, comfort, emotional well-being, and aftercare quality. Taken together, these contributions show that the evolving needs of amputees and prosthesis sub-systems can be addressed more effectively when engineering design is integrated with service thinking and knowledge-driven support.

Scope: lower-limb focus & prototypes, but provides a rigorous foundation for scaling

While the research was necessarily bounded to lower-limb prostheses, early-stage prototypes, and exploratory evaluations, it provides a scientifically rigorous and practically demonstrable foundation that can be extended and scaled.

Principles extend beyond prosthesis care, towards adaptive, knowledge-driven healthcare design systems

Looking forward, the principles advanced here, ontology-based consequence modelling, stakeholder-centred service integration, and adaptive knowledge-based design, hold potential far beyond the immediate domain of prosthesis care. They point towards a broader paradigm for engineering design in healthcare: one where technologies are conceived not as static artefacts but as evolving service systems, responsive to human needs and enriched by structured knowledge exchange.

Prosthesis care must be adaptive to evolving amputee needs

Ultimately, the central contribution of this thesis lies in demonstrating that prosthesis design and aftercare must be conceived not as static processes, but as adaptive systems capable of responding to the evolving needs of amputees over time.

adProLiSS shows design progress is measured in quality of life, not only technical performance

In conclusion, this thesis has shown that progress in prosthesis care is not measured solely in technical performance but in the quality of life it enables. By embedding consequence knowledge at the heart of service-system thinking, adProLiSS demonstrates that engineering design can shape better human experiences across the life-cycle of care.

References

3D printing prosthetics: Meet the real revolution (2024). Available at: https://www.sculpteo.com/en/3d-learning-hub/applications-of-3d-printing/3d-printed-prosthetics/ (Accessed: March 11, 2024).

Abrams, D.P. (2002) *Consequence-Based Engineering Approaches for Reducing Loss in Mid-America*.

Alcayaga, A., Wiener, M. and Hansen, E.G. (2019) “Towards a framework of smart-circular systems: An integrative literature review,” *Journal of Cleaner Production*, 221, pp. 622–634. Available at: https://doi.org/10.1016/J.JCLEPRO.2019.02.085.

Alessa, M. *et al.* (2022) “The Psychosocial Impact of Lower Limb Amputation on Patients and Caregivers,” *Cureus*, 14(11). Available at: https://doi.org/10.7759/CUREUS.31248.

Amsan, A.N., Nasution, A.K. and Ramlee, M.H. (2019) *A Short Review on the Cost, Design, Materials and Challenges of the Prosthetics Leg Development and Usage*.

Anderson, C.B. *et al.* (2022) “Improving shared decision-making for prosthetic care: a qualitative needs assessment of prosthetists and new lower-limb prosthesis users,” *Prosthetics and orthotics international*, 47(1), p. 26. Available at: https://doi.org/10.1097/PXR.0000000000000142.

Anderson, C.B., Fatone, S. and Christiansen, C.L. (2024) “A Narrative Review of Prosthesis Design Decision Making After Lower-Limb Amputation for Developing Shared Decision-Making Resources,” *Current physical medicine and rehabilitation reports*, 12(1), p. 26. Available at: https://doi.org/10.1007/S40141-024-00432-Y.

Andreasen, M. and Hein, L. (2000) “Integrated Product Development,” *IPU, Lundtofte* [Preprint].

Andreasen, M.M.. and Hein, L.. (1987) “Integrated product development,” p. 205. Available at: https://books.google.com/books/about/Integrated_Product_Development.html?id=8rdgPwAACAAJ (Accessed: September 24, 2025).

Andreasen, M. and Mortensen, N. (1997) “Basic Thinking patterns and working methods for multiple DFX,” *1997* [Preprint].

An OMG Systems Modelling Language (2017). OMG Standards Development Organisation. Available at: http://www.omg.org/spec/SysML/20161101.

Arabian, A. *et al.* (2016) “Global social acceptance of prosthetic devices,” in *GHTC 2016 - IEEE Global Humanitarian Technology Conference: Technology for the Benefit of Humanity, Conference Proceedings*. Institute of Electrical and Electronics Engineers Inc., pp. 563–568. Available at: https://doi.org/10.1109/GHTC.2016.7857336.

Argote, L. and Miron-Spektor, E. (2014) “Organizational Learning: From Experience to Knowledge.” Available at: https://doi.org/10.2307/41303106.

Asiedu, Y. and Gu, P. (1998) “Product life cycle cost analysis: State of the art review,” *International Journal of Production Research*, 36(4), pp. 883–908. Available at: https://doi.org/10.1080/002075498193444.

Aurich, J.C., Fuchs, C. and Wagenknecht, C. (2006) “Life cycle oriented design of technical Product-Service Systems,” *Journal of Cleaner Production*, 14(17), pp. 1480–1494. Available at: https://doi.org/10.1016/J.JCLEPRO.2006.01.019.

Ayaz, M. *et al.* (2021) “The Fast Health Interoperability Resources (FHIR) Standard: Systematic Literature Review of Implementations, Applications, Challenges and Opportunities,” *JMIR Medical Informatics*, 9(7), p. e21929. Available at: https://doi.org/10.2196/21929.

Bailey, K.D.. (1994) *Typologies and taxonomies : an introduction to classification techniques*. Sage Publications.

Baines, T. *et al.* (2017) “Servitization: revisiting the state-of-the-art and research priorities,” *International Journal of Operations and Production Management*, 37(2), pp. 256–278. Available at: https://doi.org/10.1108/IJOPM-06-2015-0312.

Baines, T. and Lightfoot, H.W. (2014) “Servitization of the manufacturing firm: Exploring the operations practices and technologies that deliver advanced services,” *International Journal of Operations and Production Management*, 34(1), pp. 2–35. Available at: https://doi.org/10.1108/IJOPM-02-2012-0086.

Baines, T.S. *et al.* (2007) “State-of-the-art in product-service systems,” *http://dx.doi.org/10.1243/09544054JEM858*, 221(10), pp. 1543–1552. Available at: https://doi.org/10.1243/09544054JEM858.

Bates, T.J., Fergason, J.R. and Pierrie, S.N. (2020) “Technological Advances in Prosthesis Design and Rehabilitation Following Upper Extremity Limb Loss,” *Current Reviews in Musculoskeletal Medicine*, 13(4), p. 485. Available at: https://doi.org/10.1007/S12178-020-09656-6.

Batty, M. (2018) “Digital twins,” *https://doi.org/10.1177/2399808318796416*, 45(5), pp. 817–820. Available at: https://doi.org/10.1177/2399808318796416.

Baxter, D. *et al.* (2008) “A framework to integrate design knowledge reuse and requirements management in engineering design,” *Robotics and Computer-Integrated Manufacturing*, 24(4), pp. 585–593. Available at: https://doi.org/10.1016/J.RCIM.2007.07.010.

Beckley, A., Ton, Y. and Wong, C.K. (2025) *Lower Limb Amputations: Epidemiology and Assessment*, *PM&R Knoweldge*. Available at: https://now.aapmr.org/lower-limb-amputations-epidemiology-and-assessment/?utm_source=chatgpt.com (Accessed: September 26, 2025).

Belani, H., Solic, P. and Perkovic, T. (2022) “Towards Ontology-Based Requirements Engineering for IoT-Supported Well-Being, Aging and Health.” Available at: https://doi.org/10.1109/REW56159.2022.00019.

Biddiss, E. and Chau, T. (2007) “Upper-limb prosthetics: Critical factors in device abandonment,” *American Journal of Physical Medicine and Rehabilitation*, 86(12), pp. 977–987. Available at: https://doi.org/10.1097/PHM.0B013E3181587F6C.

Bikakis, A. and Antoniou, G. (2010) “Rule-based contextual reasoning in ambient intelligence,” *Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics)*, 6403 LNCS, pp. 74–88. Available at: https://doi.org/10.1007/978-3-642-16289-3_8.

Bjögvinsson, E., Ehn, P. and Hillgren, P.A. (2012) "Design things and design thinking: Contemporary participatory design challenges," *Design Issues*, 28(3), pp. 101–116. Available at: https://doi.org/10.1162/DESI_a_00165.

Blessing, L., Chakrabarti, A. and Wallacce, K. (1995) "A Design Research Methodology," in *International Conference on Engineering Design ICED95*, pp. 22–24.

Blessing, L.T.M. and Chakrabarti, A. (2009) "DRM: A Design Reseach Methodology," *DRM, a Design Research Methodology*, pp. 13–42. Available at: https://doi.org/10.1007/978-1-84882-587-1_2.

Blij, M. (2024) *The Art of Moulding a Prosthetic Socket*. Available at: https://www.orfit.com/prosthetics-orthotics/blog/moulding-a-prosthetic-socket (Accessed: March 11, 2024).

Blomqvist, E., Hammar, K. and Presutti, V. (2016) *Engineering Ontologies with Patterns-The eXtreme Design Methodology*.

Bodell, F.K. *et al.* (2025) "Design knowledge for digital health implementation: a scoping review based on citation analysis," *Design Science*, 11, p. e31. Available at: https://doi.org/10.1017/DSJ.2025.10022.

Bolock, A. el, Abdelrahman, Y. and Abdennadher, S. (2020) *Character Computing*. Edited by A. El Bolock, Y. Abdelrahman, and S. Abdennadher. Cham: Springer International Publishing (Human–Computer Interaction Series). Available at: https://doi.org/10.1007/978-3-030-15954-2.

Borg, J.C. (1999) *Design Synthesis For Multi-X-A "Life-Cycle Consequence Knowledge" Approach*.

Borg, J.C. and Farrugia, L. (2014) *Life-Cycle Interactions for Modelling Human Emotions A Foundation for Developing "Design for Emotion" Support Tools*.

Borg, J.C., Yan, X.T. and Juster, N.P. (2000) "Exploring decisions' influence on life-cycle performance to aid 'design for Multi-X,'" *AI EDAM*, 14(2), pp. 91–113. Available at: https://doi.org/10.1017/S0890060400142015.

Borst, P., Akkermans, H. and Top, J. (1997) "Engineering ontologies," *International Journal of Human-Computer Studies*, 46(2–3), pp. 365–406. Available at: https://doi.org/10.1006/IJHC.1996.0096.

Boukhris, A., Fritzsche, A. and Möslein, K. (2017) "Co-creation in the Early Stage of Product-service System Development," in *Procedia CIRP*. Elsevier B.V., pp. 27–32. Available at: https://doi.org/10.1016/j.procir.2017.03.316.

Brandt, J. (2021) "An operational perspective of the changing prosthetics & orthotics landscape," *Canadian Prosthetics and Orthotics Journal*. Canadian Online Publication Group. Available at: https://doi.org/10.33137/CPOJ.V4I2.35996.

Brauckmann, V. *et al.* (2024) "Report on Prosthetic Fitting, Mobility, and Overall Satisfaction after Major Limb Amputation at a German Maximum Care Provider," *Applied Sciences (Switzerland)*, 14(16), p. 7274. Available at: https://doi.org/10.3390/APP14167274/S1.

Brown, T. (2008) *Design Thinking*. Available at: www.hbr.org.

Bruynseels, K., de Sio, F.S. and van den Hoven, J. (2018) “Digital Twins in health care: Ethical implications of an emerging engineering paradigm,” *Frontiers in Genetics*, 9(FEB). Available at: https://doi.org/10.3389/fgene.2018.00031.

Buchgeher, G. *et al.* (2021) “Knowledge Graphs in Manufacturing and Production: A Systematic Literature Review,” *IEEE Access*, 9, pp. 55537–55554. Available at: https://doi.org/10.1109/ACCESS.2021.3070395.

Burkart, N. and Huber, M.F. (2021) “A Survey on the Explainability of Supervised Machine Learning,” *Journal of Artificial Intelligence Research*, (70), pp. 245–317. Available at: https://jair.org/index.php/jair/article/view/12228/26647?utm_source=chatgpt.com (Accessed: September 24, 2025).

Buzzi, M. *et al.* (2012) “3D modelling and knowledge: Tools to automate prosthesis development process,” *International Journal on Interactive Design and Manufacturing*, 6(1), pp. 41–53. Available at: https://doi.org/10.1007/s12008-011-0137-5.

Calabrese, L. *et al.* (2023) “What Is Hidden behind Amputation? Quanti-Qualitative Systematic Review on Psychological Adjustment and Quality of Life in Lower Limb Amputees for Non-Traumatic Reasons,” *Healthcare 2023, Vol. 11, Page 1661*, 11(11), p. 1661. Available at: https://doi.org/10.3390/HEALTHCARE11111661.

Calvo, R.A. and D’Mello, S. (2010) “Affect detection: An interdisciplinary review of models, methods, and their applications,” *IEEE Transactions on Affective Computing*, 1(1), pp. 18–37. Available at: https://doi.org/10.1109/T-AFFC.2010.1.

Carvalho, R.N., Laskey, K.B. and Costa, P.C.G. (2017) “PR-OWL – a language for defining probabilistic ontologies,” *International Journal of Approximate Reasoning*, 91, pp. 56–79. Available at: https://doi.org/10.1016/J.IJAR.2017.08.011.

Ceschin, F. (2014) “Product-service system innovation: A promising approach to sustainability,” *SpringerBriefs in Applied Sciences and Technology*, 17, pp. 17–40. Available at: https://doi.org/10.1007/978-3-319-03795-0_2/COVER.

Chadwell, A. *et al.* (2020) “Technology for monitoring everyday prosthesis use: a systematic review,” *Journal of NeuroEngineering and Rehabilitation*, 17(1), p. 93. Available at: https://doi.org/10.1186/S12984-020-00711-4.

Chandrasegaran, S.K. *et al.* (2013) “The evolution, challenges, and future of knowledge representation in product design systems,” *Computer-Aided Design*, 45(2), pp. 204–228. Available at: https://doi.org/10.1016/J.CAD.2012.08.006.

Charmaz, K. (2014) “Constructing Grounded Theory A Practical Guide through Qualitative Analysis.” Available at: https://www.scirp.org/reference/referencespapers?referenceid=3294104 (Accessed: September 26, 2025).

Chatterjee, A. *et al.* (2021) “An automatic ontology-based approach to support logical representation of observable and measurable data for healthy lifestyle management: Proof-of-concept study,” *Journal of Medical Internet Research*, 23(4). Available at: https://doi.org/10.2196/24656.

Clarke, L., Ridgewell, E. and Dillon, M.P. (2024) “Development of a Core Outcome Set for users and funders of lower-limb prosthetic interventions (PI-COS): a step to inform the benefits measured in prosthetic health economic evaluations,” *Disability and rehabilitation*, 46(19), pp. 4407–4419. Available at: https://doi.org/10.1080/09638288.2023.2275279.

Cocco, L. *et al.* (2024) *Ontology-driven Data Management Design in Healthcare Domain. The ADCATER Experience.* Available at: https://tinyurl.com/4h95yvav.

Colombo, G. *et al.* (2010) “A new design paradigm for the development of custom-fit soft sockets for lower limb prostheses,” *Computers in Industry*, 61(6), pp. 513–523. Available at: https://doi.org/10.1016/J.COMPIND.2010.03.008.

Cooper, R.G. (1990) “Stage-gate systems: A new tool for managing new products,” *Business Horizons*, pp. 44–54. Available at: https://doi.org/10.1016/0007-6813(90)90040-I.

Cost of a Prosthetic Leg - 2023 Healthcare Costs (2024). Available at: https://health.costhelper.com/prosthetic-legs.html (Accessed: March 11, 2024).

Couturier, P. *et al.* (2014) “Tracking the consequences of design decisions in mechatronic Systems Engineering,” *Mechatronics*, 24(7), pp. 763–774. Available at: https://doi.org/10.1016/j.mechatronics.2014.03.004.

Cowan, N. (2010) “The magical mystery four: How is working memory capacity limited, and why?,” *Current Directions in Psychological Science*, 19(1), pp. 51–57. Available at: https://doi.org/10.1177/0963721409359277.

Creswell, J.W. (2013) *Qualitative inquiry & research design. Choosing Among Five Approaches*.

Creswell, J.W. and Plano Clark, V.L. (2018) *Designing and Conducting Mixed Methods Research (3rd ed.).* Available at: https://www.scirp.org/reference/referencespapers?referenceid=2697821 (Accessed: September 27, 2025).

Customized Comfortable Sockets (2025) *Georgia Pprosthetics*. Available at: https://www.georgiaprosthetics.com/customized-comfortable-sockets (Accessed: March 11, 2024).

D’Amato, C. (2020) “Machine Learning for the Semantic Web: Lessons learnt and next research directions,” *Semantic Web*, 11(1), pp. 195–203. Available at: https://doi.org/10.3233/SW-200388.

Darr, T., Klein, M. and McGuinness, D.L. (1998) *Special Issue: Configuration Design*. Available at: https://www.cambridge.org/core.

Desmet, P. (2003) “A Multilayered Model of Product Emotions,” *The Design Journal*, 6(2), pp. 4–13. Available at: https://doi.org/10.2752/146069203789355480.

Desmet, P. (2004) “Measuring emotion: Development and application of an instrument to Measure Emotional Responses to Products.” Available at: https://www.researchgate.net/publication/313757692_Measuring_emotion_Development_and_application_of_an_instrument_to_Measure_Emotional_Responses_to_Products (Accessed: September 30, 2025).

Desmet, P. (2007) *Framework of Product Experience*, *www.ijdesign.org International Journal of Design*. Available at: www.ijdesign.org.

Desmet, P. (2015) *Design for Mood: Twenty Activity-Based Opportunities to Design for Mood Regulation*, *International Journal of Design*. Available at: www.ijdesign.org.

Dillingham, T.R., Pezzin, L.E. and MacKenzie, E.J. (2002) “Limb amputation and limb deficiency: Epidemiology and recent trends in the United States,” *Southern medical journal*, 95(8), pp. 875–883. Available at: https://doi.org/10.1097/00007611-200208000-00018.

Donnelley, C.A. *et al.* (2021) “Cost Analyses of Prosthetic Devices: A Systematic Review,” *Archives of Physical Medicine and Rehabilitation*, 102(7), pp. 1404-1415.e2. Available at: https://doi.org/10.1016/J.APMR.2021.02.010.

Donnelly, K. (2006) *SNOMED-CT: The advanced terminology and coding system for eHealth*, *Studies in Health Technology and Informatics*. Available at: https://www.researchgate.net/publication/6701249_SNOMED-CT_The_advanced_terminology_and_coding_system_for_eHealth (Accessed: July 1, 2025).

Duffy, A.H.B. *et al.* (1993) “Design co-ordination for concurrent engineering,” *Journal of Engineering Design*, 4(4), pp. 251–265. Available at: https://doi.org/10.1080/09544829308914785.

Duffy, A. and O’Donnell, F.J. (1998) *A Design Research Approach*. Available at: https://www.researchgate.net/publication/2824982_A_Design_Research_Approach (Accessed: July 6, 2023).

Eckert, C., Maier, A. and McMahon, C. (2005) “Communication in design,” in *Design Process Improvement: A Review of Current Practice*. Springer London, pp. 232–261. Available at: https://doi.org/10.1007/978-1-84628-061-0_10.

Eidmann, A. *et al.* (2023) “Demographics and Etiology for Lower Extremity Amputations—Experiences of an University Orthopaedic Center in Germany,” *Medicina (Lithuania)*, 59(2). Available at: https://doi.org/10.3390/medicina59020200.

Erkoyuncu, J.A. *et al.* (2009) “Uncertainty challenges in service cost estimation for product-service systems in the aerospace and defence industries.” Available at: https://www.researchgate.net/publication/284959506_Uncertainty_challenges_in_service_cost_estimation_for_product-service_systems_in_the_aerospace_and_defence_industries (Accessed: September 23, 2025).

Fan, J., Han, F. and Liu, H. (2014) “Challenges of Big Data analysis,” *National Science Review*. Oxford University Press, pp. 293–314. Available at: https://doi.org/10.1093/nsr/nwt032.

Farrugia, L. (2017) *Emotional “Design for X” A Human and Life Phase Systems Meetings Consequence Knowledge Approach*.

Feigenbaum, E.A. (1984) “Knowledge engineering. The applied side of artificial intelligence,” *Annals of the New York Academy of Sciences*, 426(1), pp. 91–107. Available at: https://doi.org/10.1111/J.1749-6632.1984.TB16513.X.

Fuller, A. *et al.* (2020) “Digital Twin: Enabling Technologies, Challenges and Open Research,” *IEEE Access*, 8, pp. 108952–108971. Available at: https://doi.org/10.1109/ACCESS.2020.2998358.

Gailey, R.S. *et al.* (2002) “The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee’s ability to ambulate,” *Archives of physical medicine and rehabilitation*, 83(5), pp. 613–627. Available at: https://doi.org/10.1053/APMR.2002.32309.

Gaver, W. (2009) “Designing for emotion (among other things),” *Philosophical Transactions of the Royal Society B: Biological Sciences*, 364(1535), pp. 3597–3604. Available at: https://doi.org/10.1098/rstb.2009.0153.

Ghailani, A. Al *et al.* (2025) “Exploring the Role of Psychological Support and Social Factors in Resilience Among Traumatic Amputees in North Batinah, Oman: Mixed Methodology,” *Middle East Journal of Rehabilitation and Health Studies 2025 12:2*, 12(2), p. e159966. Available at: https://doi.org/10.5812/MEJRH-156590.

Gholizadeh, H. *et al.* (2014) “Transtibial prosthesis suspension systems: Systematic review of literature,” *Clinical Biomechanics*, 29(1), pp. 87–97. Available at: https://doi.org/10.1016/j.clinbiomech.2013.10.013.

Giacomin, J. (2014) “What is human centred design?,” *Design Journal*, 17(4), pp. 606–623. Available at: https://doi.org/10.2752/175630614X14056185480186.

Goedkoop, M. (1999) “Product Service systems, Ecological and Economic Basics.” Available at: https://www.researchgate.net/publication/293825611_Product_Service_systems_Ecological_and_Economic_Basics (Accessed: September 28, 2025).

Gregor, S. and Hevner, A.R. (2013) “Positioning and Presenting Design Science Research for Maximum Impact1,” *Management Information Systems Quarterly*, 37(2), pp. 337–355. Available at: https://doi.org/10.25300/MISQ/2013/37.2.01.

von Grop, T. and Adams, E. (2024) *Design for Emotion - Trevor van Gorp, Edie Adams - Google Books*. Available at: https://books.google.com.mt/books?hl=en&lr=&id=8lgSs1GoPN8C&oi=fnd&pg=PP2&dq=Van+Gorp,+T.+and+Adams,+E.,+2012.+Design+for+emotion&ots=mV8MINDsO3&sig=JstPXCNwu3uph62fK6QhyHfzdOQ&redir_esc=y#v=onepage&q=Van%20Gorp%2C%20T.%20and%20Adams%2C%20E.%2C%202012.%20Design%20for%20emotion&f=false (Accessed: March 11, 2024).

Gruber, T. (1993) *What is an Ontology?* Available at: http://tomgruber.org.

Hafner, B.J. *et al.* (2007) “Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition From Mechanical to Microprocessor Control of the Prosthetic Knee,” *Archives of Physical Medicine and Rehabilitation*, 88(2), pp. 207–217. Available at: https://doi.org/10.1016/j.apmr.2006.10.030.

Hafner, B.J. *et al.* (2023) “Development of an item bank for measuring prosthetic mobility in people with lower limb amputation: The Prosthetic Limb Users Survey of Mobility (PLUS-M),” *PM & R : the journal of injury, function, and rehabilitation*, 15(4), pp. 456–473. Available at: https://doi.org/10.1002/PMRJ.12962.

Harkins, C.S., McGarry, A. and Buis, A. (2013) “Provision of prosthetic and orthotic services in low-income countries: a review of the literature,” *Prosthetics and orthotics international*, 37(5), pp. 353–361. Available at: https://doi.org/10.1177/0309364612470963.

Hartson, R. and Pyla, P. (2019) “The Nature of UX Design,” *The UX Book*, pp. 261–277. Available at: https://doi.org/10.1016/B978-0-12-805342-3.00012-6.

Haynes, S.R., Purao, S. and Skattebo, A.L. (2009) “Scenario-based methods for evaluating collaborative systems,” *Computer Supported Cooperative Work*, 18(4), pp. 331–356. Available at: https://doi.org/10.1007/S10606-009-9095-X.

Healy, A. *et al.* (2020) “A scoping literature review of studies assessing effectiveness and cost-effectiveness of prosthetic and orthotic interventions,” *Disability and rehabilitation. Assistive technology*, 15(1), pp. 60–66. Available at: https://doi.org/10.1080/17483107.2018.1523953.

Heath, T. and Bizer, C. (2011) “Linked Data: Evolving the Web into a Global Data Space,” *Synthesis Lectures on the Semantic Web: Theory and Technology*, 1(1), pp. 1–121. Available at: https://doi.org/10.2200/S00334ED1V01Y201102WBE001.

Highsmith, M.J., Andrews, C.R., *et al.* (2016a) “ Gait Training Interventions for Lower Extremity Amputees: A Systematic Literature Review ,” *Technology & Innovation*, 18(2), pp. 99–113. Available at: https://doi.org/10.21300/18.2-3.2016.99.

Highsmith, M.J., Andrews, C.R., *et al.* (2016b) “Gait Training Interventions for Lower Extremity Amputees: A Systematic Literature Review,” *Technology and innovation*, 18(2–3), pp. 99–113. Available at: https://doi.org/10.21300/18.2-3.2016.99.

Highsmith, M.J., Kahle, J.T., *et al.* (2016) “Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews,” *Journal of rehabilitation research and development*, 53(2), pp. 157–184. Available at: https://doi.org/10.1682/JRRD.2015.03.0046.

Hitzler, P., Krotzsch, M. and Rudolph, S. (2009) *Foundations of Semantic Web Technologies*, *CRC Press*. Available at: https://www.researchgate.net/publication/235720532_Foundations_of_Semantic_Web_Technologies (Accessed: August 3, 2025).

Hogan, A. *et al.* (2021) “Knowledge Graphs,” *ACM Computing Surveys*, 54(4), p. 71. Available at: https://doi.org/10.1145/3447772.

Horgan, O. and MacLachlan, M. (2004) “Psychosocial adjustment to lower-limb amputation: A review,” *Disability and Rehabilitation*, pp. 837–850. Available at: https://doi.org/10.1080/09638280410001708869.

Horridge, M. and Patel-Schneider, P.F. (2012) *OWL 2 Web Ontology Language Manchester Syntax*. Available at: https://www.w3.org/TR/owl2-manchester-syntax/ (Accessed: August 2, 2025).

Horrocks, I. *et al.* (2004) *SWRL: A Semantic Web rule language combining OWL and RuleML*. Available at: http://www.w3.org/Submission/2004/SUBM-SWRL-20040521/Latestversion:http://www.w3.org/Submission/SWRL/.

Howard, T.J., Culley, S.J. and Dekoninck, E. (2008) “Describing the creative design process by the integration of engineering design and cognitive psychology literature,” *Design Studies*, 29(2), pp. 160–180. Available at: https://doi.org/10.1016/J.DESTUD.2008.01.001.

Huang, H.H. *et al.* (2024) “Integrating Upper-Limb Prostheses with the Human Body: Technology Advances, Readiness, and Roles in Human-Prosthesis Interaction,” *Annual Review of Biomedical Engineering*, 26(1), pp. 503–528. Available at: https://doi.org/10.1146/ANNUREV-BIOENG-110222-095816/CITE/REFWORKS.

Huet, G. *et al.* (2007) “Knowledge Loss in Design Reviews,” in T. S, T. M, and R. P (eds.). Springer. Available at: www.EngineeringEBooksPdf.com.

Indrayan, A. and Mishra, A. (2021) “The importance of small samples in medical research,” *Journal of Postgraduate Medicine*, 67(4), pp. 219–223. Available at: https://doi.org/10.4103/jpgm.JPGM_230_21.

Isaksson, O., Larsson, T.C. and Rönnbäck, A.Ö. (2009) “Development of product-service systems: Challenges and opportunities for the manufacturing firm,” *Journal of Engineering Design*, 20(4), pp. 329–348. Available at: https://doi.org/10.1080/09544820903152663.

Jagyasi, P. (2020) *3D Printed Prosthetics: The Pros and Cons*. Available at: https://drprem.com/tech/3d-printed-prosthetics-the-pros-and-cons/ (Accessed: March 11, 2024).

Jones, H. *et al.* (2021) “Co-creation and User Perspectives for Upper Limb Prosthetics,” *Frontiers in Neurorobotics*, 15, p. 689717. Available at: https://doi.org/10.3389/FNBOT.2021.689717.

Jones, H. *et al.* (2022) “Towards User-Centred Prosthetics Research Beyond the Laboratory,” *Frontiers in Neuroscience*, 16, p. 863833. Available at: https://doi.org/10.3389/FNINS.2022.863833/BIBTEX.

Jordan, M.I. and Mitchell, T.M. (2015) “Machine learning: Trends, perspectives, and prospects,” *Science*, 349(6245), pp. 255–260. Available at: https://doi.org/10.1126/SCIENCE.AAA8415.

Jo, S.-H. *et al.* (2021) “Psychiatric understanding and treatment of patients with amputations,” *Journal of Yeungnam Medical Science*, 38(3), pp. 194–201. Available at: https://doi.org/10.12701/YUJM.2021.00990.

Ju, N. *et al.* (2021) “A user-driven approach to prosthetic upper limb development in Korea,” *Healthcare (Switzerland)*, 9(7). Available at: https://doi.org/10.3390/healthcare9070839.

Kambanou, M.L. (2020a) “Life Cycle Costing: Understanding How It Is Practised and Its Relationship to Life Cycle Management—A Case Study,” *Sustainability 2020, Vol. 12, Page 3252*, 12(8), p. 3252. Available at: https://doi.org/10.3390/SU12083252.

Kambanou, M.L. (2020b) “Life cycle costing: Understanding how it is practised and its relationship to life cycle management-A case study,” *Sustainability (Switzerland)*, 12(8), p. 3252. Available at: https://doi.org/10.3390/SU12083252.

Kambanou, M.L. and Lindahl, M. (2016) “A Literature Review of Life Cycle Costing in the Product-Service System Context,” *Procedia CIRP*, 47, pp. 186–191. Available at: https://doi.org/10.1016/J.PROCIR.2016.03.054.

Keet, C.M. (2018) *An Introduction to Ontology Engineering*.

Kitamura, Y. and Mizoguchi, R. (2003) “Ontology-based description of functional design knowledge and its use in a functional way server,” *Expert Systems with Applications*, 24(2), pp. 153–166. Available at: https://doi.org/10.1016/S0957-4174(02)00138-0.

Klute, G.K. *et al.* (2011) “Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: Effect on fit, activity, and limb volume,” *Archives of Physical Medicine and Rehabilitation*, 92(10), pp. 1570–1575. Available at: https://doi.org/10.1016/j.apmr.2011.05.019.

Kneale, L. *et al.* (2017) “Using scenarios and personas to enhance the effectiveness of heuristic usability evaluations for older adults and their care team,” *Journal of Biomedical Informatics*, 73, pp. 43–50. Available at: https://doi.org/10.1016/j.jbi.2017.07.008.

Kooiman, V.G.M. *et al.* (2023) “Testing and evaluation of lower limb prosthesis prototypes in people with a transfemoral amputation: a scoping review on research protocols,” *Journal of NeuroEngineering and Rehabilitation*. BioMed Central Ltd. Available at: https://doi.org/10.1186/s12984-023-01125-8.

Kulkarni, P.G. *et al.* (2023) “Overcoming Challenges and Innovations in Orthopedic Prosthesis Design: An Interdisciplinary Perspective,” *Biomedical Materials & Devices (New York, N.y.)*, 2(1), p. 1. Available at: https://doi.org/10.1007/S44174-023-00087-8.

Kumar, D. *et al.* (2023) “Psychological adjustments among lower limb amputees in North Indian population: A cross-sectional study,” *Industrial Psychiatry Journal*, 32(2), pp. 323–327. Available at: https://doi.org/10.4103/IPJ.IPJ_199_22.

Lambrix, P. and Tan, H. (2006) “SAMBO-A system for aligning and merging biomedical ontologies,” *Web Semantics*, 4(3), pp. 196–206. Available at: https://doi.org/10.1016/J.WEBSEM.2006.05.003.

Landeta, J., Barrutia, J. and Lertxundi, A. (2011) “Hybrid Delphi: A methodology to facilitate contribution from experts in professional contexts,” *Technological Forecasting and Social Change*, 78(9), pp. 1629–1641. Available at: https://doi.org/10.1016/j.techfore.2011.03.009.

Langley, D.J. (2022) “Digital Product-Service Systems: The Role of Data in the Transition to Servitization Business Models,” *Sustainability 2022, Vol. 14, Page 1303*, 14(3), p. 1303. Available at: https://doi.org/10.3390/SU14031303.

Lathouwers, E. *et al.* (2023) “Therapeutic benefits of lower limb prostheses: a systematic review,” *Journal of NeuroEngineering and Rehabilitation*, 20(1), pp. 1–27. Available at: https://doi.org/10.1186/S12984-023-01128-5/FIGURES/4.

Leason, I. *et al.* (2022) “An opportunity for inclusive and human-centred design,” *British Dental Journal*, 233(8), pp. 607–612. Available at: https://doi.org/10.1038/s41415-022-5101-1.

Lee, D.R.C. *et al.* (2024) “A clinical comparison of a digital versus conventional design methodology for transtibial prosthetic interfaces,” *Scientific Reports*, 14(1), pp. 1–18. Available at: https://doi.org/10.1038/S41598-024-74504-3;SUBJMETA.

Liao, S.H. (2005) “Expert system methodologies and applications-a decade review from 1995 to 2004,” *Expert Systems with Applications*, 28(1), pp. 93–103. Available at: https://doi.org/10.1016/J.ESWA.2004.08.003.

Li, H., Yu, L. and He, W. (2019) “The Impact of GDPR on Global Technology Development,” *Journal of Global Information Technology Management*. Taylor and Francis Inc., pp. 1–6. Available at: https://doi.org/10.1080/1097198X.2019.1569186.

Lim, Y.K., Stolterman, E. and Tenenberg, J. (2008) “The anatomy of prototypes: Prototypes as filters, prototypes as manifestations of design ideas,” *ACM Transactions on Computer-Human Interaction*, 15(2). Available at: https://doi.org/10.1145/1375761.1375762.

Manz, S. *et al.* (2022) “A review of user needs to drive the development of lower limb prostheses,” *Journal of NeuroEngineering and Rehabilitation*. BioMed Central Ltd. Available at: https://doi.org/10.1186/s12984-022-01097-1.

Matschewsky, J., Kambanou, M.L. and Sakao, T. (2018) “Designing and providing integrated product-service systems–challenges, opportunities and solutions resulting from prescriptive approaches in two industrial companies,” *International Journal of Production Research*, 56(6), pp. 2150–2168. Available at: https://doi.org/10.1080/00207543.2017.1332792.

Matschewsky, J., Lindahl, M. and Sakao, T. (2020) “Capturing and enhancing provider value in product-service systems throughout the lifecycle: A systematic approach,” *CIRP Journal of Manufacturing Science and Technology*, 29, pp. 191–204. Available at: https://doi.org/10.1016/j.cirpj.2018.08.006.

Maussang, N., Zwolinski, P. and Brissaud, D. (2009) “Product-service system design methodology: from the PSS architecture design to the products specifications,” *Journal of Engineering Design*, 20(4), pp. 349–366. Available at: https://doi.org/10.1080/09544820903149313.

Ma, W.J., Husain, M. and Bays, P.M. (2014) “Changing concepts of working memory,” *Nature Neuroscience*, pp. 347–356. Available at: https://doi.org/10.1038/nn.3655.

McGuinness, D.L. and van Harmelen, F. (2004a) *OWL Web Ontology Language Overview*, *W3C*. Available at: https://www.w3.org/TR/owl-features/ (Accessed: July 1, 2025).

McGuinness, D.L. and van Harmelen, F. (2004b) *Web Ontology Language Overview: W3C Recommendation | Request PDF*. Available at: https://www.researchgate.net/publication/240410049_Web_Ontology_Language_Overview_W3C_Recommendation (Accessed: July 1, 2025).

McMahon, C. and Van Leeuwen, J. (2009) “Guest Editorial: Special Issue: Developing and using engineering ontologies,” *Artificial Intelligence for Engineering Design, Analysis and Manufacturing: AIEDAM*, pp. 1–2. Available at: https://doi.org/10.1017/S0890060409000067.

Meier, H., Roy, R. and Seliger, G. (2010) “Industrial Product-Service Systems—IPS2,” *CIRP Annals*, 59(2), pp. 607–627. Available at: https://doi.org/10.1016/J.CIRP.2010.05.004.

Melles, M., Albayrak, A. and Goossens, R. (2021) “Innovating health care: Key characteristics of human-centered design,” *International Journal for Quality in Health Care*, 33, pp. 37–44. Available at: https://doi.org/10.1093/intqhc/mzaa127.

Meulenbelt, H.E.J. *et al.* (2006) “Skin problems in lower limb amputees: a systematic review,” *Disability and rehabilitation*, 28(10), pp. 603–608. Available at: https://doi.org/10.1080/09638280500277032.

Michailidou, I. (2017) *Design the experience first: A scenario-based methodology for the design of complex, tangible consumer products*.

Michalowski, M. *et al.* (2021) “A Health eLearning Ontology and Procedural Reasoning Approach for Developing Personalized Courses to Teach Patients about Their Medical Condition and Treatment,” *International Journal of Environmental Research and Public Health*, 18(14), p. 7355. Available at: https://doi.org/10.3390/IJERPH18147355.

Mihailović, J., Stošić, B. and Milutinović, R. (2025) “A product-service system as a responsible innovation,” *Journal of Responsible Innovation*, 12(1), p. 2519899. Available at: https://doi.org/10.1080/23299460.2025.2519899.

Miller, T.A. *et al.* (2020) “Impact of Time to Receipt of Prosthesis on Total Healthcare Costs 12 Months Postamputation,” *American Journal of Physical Medicine & Rehabilitation*, 99(11), p. 1026. Available at: https://doi.org/10.1097/PHM.0000000000001473.

Miller, T.A. *et al.* (2023) “Factors that influence time to prosthesis receipt after lower limb amputation: A Cox proportional hazard model regression,” *PM&R*, 15(4), pp. 474–481. Available at: https://doi.org/10.1002/PMRJ.12781.

Minaya, P.E., Avella, L. and Trespalacios, J.A. (2024) “Synthesizing three decades of digital servitization: a systematic literature review and conceptual framework proposal,” *Service Business*, 18(2), pp. 193–222. Available at: https://doi.org/10.1007/S11628-024-00559-X/FIGURES/5.

Mishra, A. (2014) “Lower Limb Amputations,” in. Available at: https://www.researchgate.net/publication/272487981.

Mittermeyer, S.A., Njuguna, J.A. and Alcock, J.R. (2011) “Product-service systems in health care: Case study of a drug-device combination,” *International Journal of Advanced Manufacturing Technology*, 52(9–12), pp. 1209–1221. Available at: https://doi.org/10.1007/s00170-010-2766-4.

Mizoguchi, R. and Borgo, S. (2025a) “An Ontology of Representation,” *Applied Ontology*, 20(2), pp. 137–152. Available at: https://doi.org/10.1177/15705838251337943.

Mizoguchi, R. and Borgo, S. (2025b) “An Ontology of Representation,” *Applied Ontology*, 20(2), pp. 137–152. Available at: https://doi.org/10.1177/15705838251337943.

Mont, O.K. (2002) “Clarifying the concept of product-service system,” *Journal of Cleaner Production*, 10(3), pp. 237–245. Available at: https://doi.org/10.1016/S0959-6526(01)00039-7.

Mourtzis, D. *et al.* (2018) “A Lean PSS design and evaluation framework supported by KPI monitoring and context sensitivity tools,” *International Journal of Advanced Manufacturing Technology*, 94(5–8), pp. 1623–1637. Available at: https://doi.org/10.1007/S00170-017-0132-5.

Musen, M.A. (2015) “The Protégé Project,” *AI Matters*, 1(4), pp. 4–12. Available at: https://doi.org/10.1145/2757001.2757003.

Nasteski, V. (2017) “An overview of the supervised machine learning methods,” *HORIZONS.B*, 4, pp. 51–62. Available at: https://doi.org/10.20544/horizons.b.04.1.17.p05.

Ng, I.C.L., Maull, R. and Yip, N. (2009) “Outcome-based contracts as a driver for systems thinking and service-dominant logic in service science: Evidence from the defence industry,” *European Management Journal*, 27(6), pp. 377–387. Available at: https://doi.org/10.1016/J.EMJ.2009.05.002.

Nickerson, R.C., Varshney, U. and Muntermann, J. (2013) “A method for taxonomy development and its application in information systems,” *European Journal of Information Systems*, 22(3), pp. 336–359. Available at: https://doi.org/10.1057/EJIS.2012.26.

Nico, W. (1997) *Construction of Engineering Ontologies for Knowledge Sharing and Reuse*.

Noblet, T. *et al.* (2019) “Amputation in Trauma—How to Achieve a Good Result from Lower Extremity Amputation Irrespective of the Level,” *Current Trauma Reports*, 5(1), pp. 69–78. Available at: https://doi.org/10.1007/S40719-019-0159-1/FIGURES/3.

Nonaka, I. and Takeuchi, H. (1995) “Knowledge-Creating Company,” *Knowledge-Creating Company*, (December 1991), pp. 3–19. Available at: https://global.oup.com/academic/product/the-knowledge-creating-company-9780195092691 (Accessed: September 3, 2025).

Norman, D. (2002) *The_Design_of_Everyday_Things_Don_Norman*.

Nugent, K. *et al.* (2025) “How has body image been evaluated among people with lower limb loss? A scoping review,” *Disability and rehabilitation*, 47(1), pp. 33–46. Available at: https://doi.org/10.1080/09638288.2024.2335646.

O’Banion, L.A. *et al.* (2022) “Lower extremity amputation protocol: a pilot enhanced recovery pathway for vascular amputees,” *Journal of Vascular Surgery Cases, Innovations and Techniques*, 8(4), p. 740. Available at: https://doi.org/10.1016/J.JVSCIT.2022.08.003.

O’Keeffe, B. and Rout, S. (2019) “Prosthetic Rehabilitation in the Lower Limb,” *Indian Journal of Plastic Surgery : Official Publication of the Association of Plastic Surgeons of India*, 52(1), p. 134. Available at: https://doi.org/10.1055/S-0039-1687919.

Olaya-Mira, N. *et al.* (2025) “Methods to assess lower limb prosthetic adaptation: a systematic review,” *Journal of NeuroEngineering and Rehabilitation*. BioMed Central Ltd. Available at: https://doi.org/10.1186/s12984-024-01530-7.

Ortiz-Escobar, L.M. *et al.* (2023) “Assessing the implementation of user-centred design standards on assistive technology for persons with visual impairments: a systematic review,” *Frontiers in Rehabilitation Sciences*. Frontiers Media SA. Available at: https://doi.org/10.3389/fresc.2023.1238158.

Ottobock | Microprocessor Knees: Trust, Move, Live. (2024). Available at: https://www.ottobock.com/en-gb/prosthetics/microprocessor-knees (Accessed: March 11, 2024).

Oussous, A. *et al.* (2018) “Big Data technologies: A survey,” *Journal of King Saud University - Computer and Information Sciences*. King Saud bin Abdulaziz University, pp. 431–448. Available at: https://doi.org/10.1016/j.jksuci.2017.06.001.

Pahl, G. *et al.* (2007) *Engineering Design A Systematic Approach*. Edited by K. Wallace and L. Blessing. Springer.

Pannunzio, V., Kleinsmann, M. and Snelders, D. (2019) “Three approaches to design engineering in the health domain: A systemic perspective,” *Proceedings of the Design Society: International Conference on Engineering Design*, 2019-August, pp. 1005–1014. Available at: https://doi.org/10.1017/DSI.2019.106.

Paschou, T. *et al.* (2020) “Digital servitization in manufacturing: A systematic literature review and research agenda,” *Industrial Marketing Management*, 89, pp. 278–292. Available at: https://doi.org/10.1016/J.INDMARMAN.2020.02.012.

Pastorino, R. *et al.* (2019) “Benefits and challenges of Big Data in healthcare: An overview of the European initiatives,” *European Journal of Public Health*, 29, pp. 23–27. Available at: https://doi.org/10.1093/eurpub/ckz168.

Patel, J. *et al.* (2022) “Perioperative Care Pathways in Low- and Lower-Middle-Income Countries: Systematic Review and Narrative Synthesis,” *World journal of surgery*, 46(9), pp. 2102–2113. Available at: https://doi.org/10.1007/S00268-022-06621-X.

Patiniott, N. *et al.* (2022) “Towards a Product Service System Framework for Lower Limb Prosthetic Devices,” *Proceedings of the Design Society*, 2, pp. 1341–1350. Available at: https://doi.org/10.1017/PDS.2022.136.

Patiniott, N. *et al.* (2023) “Elements of a Prescriptive and Adaptive Prosthesis Development Service Framework,” *Proceedings of the Design Society*, 3, pp. 1605–1614. Available at: https://doi.org/10.1017/PDS.2023.161.

Patiniott, N. (2025) *A “Prosthesis Life-Cycle Ontology” - Based Service System Framework to Cater for Amputees’ Evolving Needs: Compiled evaluation responses and raw data (Internal Report No CERU/ITR/01/2025)*. Available at: https://drive.google.com/file/d/1dZuRS3DIaQj17wF3qg4rFKpsAsVGhq0O/view?usp=drive_link (Accessed: November 28, 2025).

Patiniott, N. and Borg, J.C. (2025) “Advancing Prosthesis Design: Ontology Driven Multi-Disciplinary Framework for Evolving Amputee Needs,” in *Proceedings of the Design Society ICED25*.

Peerdeman, B. *et al.* (2011) “Myoelectric forearm prostheses: State of the art from a user-centred perspective,” *Journal of Rehabilitation Research and Development*, 48(6), pp. 719–737. Available at: https://doi.org/10.1682/JRRD.2010.08.0161.

Peery, J.T., Ledoux, W.R. and Klute, G.K. (2005) “Residual-limb skin temperature in transtibial sockets,” *Journal of Rehabilitation Research and Development*, 42(2), pp. 147–154. Available at: https://doi.org/10.1682/JRRD.2004.01.0013.

Pezzin, L.E., Dillingham, T.R. and Mackenzie, E.J. (2000) *Rehabilitation and the Long-Term Outcomes of Persons With Trauma-Related Amputations*, *Arch Phys Med Rehabil*.

Pine, J.B. (1993) “Mass Customisation: The New Frontier in Business Competition,” *Australian Journal of Management*, 17(2), pp. 271–283. Available at: https://doi.org/10.1177/031289629301700206.

Pourabdollahian, G. and Copani, G. (2015) “Development of a PSS-oriented business model for customized production in healthcare,” in *Procedia CIRP*. Elsevier B.V., pp. 492–497. Available at: https://doi.org/10.1016/j.procir.2015.02.158.

Prosthetic FAQs for the New Amputee – Amputee Coalition (2021). Available at: https://amputee-coalition.org/resources/prosthetic-faqs-for-the-new-amputee/?utm_source=chatgpt.com (Accessed: September 21, 2025).

Prosthetics Costs: The High Price of Prosthetic Limbs (2025). Available at: https://www.disabled-world.com/assistivedevices/prostheses/prosthetics-costs.php (Accessed: March 11, 2024).

Prosthetics Process | Hanger Clinic (2024). Available at: https://hangerclinic.com/patients/new-patients/prosthetics-process/ (Accessed: March 11, 2024).

Ramstrand, N. *et al.* (2024) "Designing feelings into lower-limb prostheses – A kansei engineering approach to understand lower-limb prosthetic cosmeses," *Journal of Rehabilitation and Assistive Technologies Engineering*, 11, p. 20556683241289936. Available at: https://doi.org/10.1177/20556683241289938.

Raschke, S.U. (2022) "Limb Prostheses: Industry 1.0 to 4.0: Perspectives on Technological Advances in Prosthetic Care," *Frontiers in Rehabilitation Sciences*. Frontiers Media SA. Available at: https://doi.org/10.3389/fresc.2022.854404.

Raval, N. *et al.* (2024) "Cost-effectiveness of lower limb prosthetic devices for mobility in older adults with dysvascular amputations," *Journal of the International Society of Physical and Rehabilitation Medicine*, 7(2), pp. 54–59. Available at: https://doi.org/10.1097/PH9.0000000000000031.

Reason, P. and Bradbury, H. (2008) *SAGE Handbook of Action Participative Inquiry and Practice*.

Reim, W., Parida, V. and Örtqvist, D. (2015) "Product-Service Systems (PSS) business models and tactics - A systematic literature review," *Journal of Cleaner Production*, 97, pp. 61–75. Available at: https://doi.org/10.1016/J.JCLEPRO.2014.07.003.

Rekant, J.S. *et al.* (2020) "Amputee, clinician, and regulator perspectives on current and prospective upper extremity prosthetic technologies," *medRxiv*, p. 2020.08.07.20170209. Available at: https://doi.org/10.1101/2020.08.07.20170209.

Rivera, J.A. *et al.* (2024) "Estimating Recent US Limb Loss Prevalence and Updating Future Projections," *Archives of Rehabilitation Research and Clinical Translation*, 6(4), p. 100376. Available at: https://doi.org/10.1016/J.ARRCT.2024.100376.

Robert, G., Donetto, S. and Williams, O. (2021) "Co-designing healthcare services with patients," *In The Palgrave Handbook of Co-Production of Public Services and Outcomes . Palgrave Macmillan, Cham.*, pp. 313–333.

Rodrigues, D., Carvalho, L. and Pinto, C. (2025) "Lower-Limb Amputees and Family Caregivers: Challenges, Needs, and Strategies for Empowerment—A Qualitative Study," *Nursing Reports*, 15(5), p. 166. Available at: https://doi.org/10.3390/NURSREP15050166/S1.

Rofizah Johari, N. *et al.* (2025) *REDEFINING PROSTHETIC DEVICES: AESTHETIC CONSIDERATIONS IN USER-CENTERED DESIGN FOR LOWER LIMB PHYSICAL DISABILITIES*, *International Journal for Studies on Children, Women, Elderly and Disabled*. Available at: https://www.cuelogic.com/blog/user-centered-design.

Roozenburg, N.F.M. and Eekels, J. (1995) “Product Design: Fundamentals and Methods.”

Roșca, A.C. *et al.* (2021) “Psychological Consequences in Patients With Amputation of a Limb. An Interpretative-Phenomenological Analysis,” *Frontiers in Psychology*, 12, p. 537493. Available at: https://doi.org/10.3389/FPSYG.2021.537493/BIBTEX.

Russell, S.J. and Norvig, P. (2021) *Artificial Intelligence A Modern Approach*. Available at: https://www.scirp.org/reference/referencespapers?referenceid=3352205 (Accessed: July 2, 2025).

Russell, S. and Norvig, P. (1995) *Artificial Intelligence A Modern Approach*. Second Edition.

Sakao, T. and Shimomura, Y. (2007) “Service Engineering: a novel engineering discipline for producers to increase value combining service and product,” *Journal of Cleaner Production*, 15(6), pp. 590–604. Available at: https://doi.org/10.1016/J.JCLEPRO.2006.05.015.

Salem, H. *et al.* (2021) “A systematic review of the applications of Expert Systems (ES) and machine learning (ML) in clinical urology,” *BMC Medical Informatics and Decision Making*, 21(1), p. 223. Available at: https://doi.org/10.1186/S12911-021-01585-9.

Salgado Manrique, J.S. and Cifuentes-De la Portilla, C. (2025) “Exploring Opportunities for Advancements in Lower Limb Socket Fabrication and Testing: A Review,” *Biomechanics*, 5(3), p. 64. Available at: https://doi.org/10.3390/BIOMECHANICS5030064.

Sanders, E.B.N. and Stappers, P.J. (2008) “Co-creation and the new landscapes of design,” pp. 799–809. Available at: https://doi.org/10.1080/15710880701875068.

Sanders, J.E. and Fatone, S. (2011) “RESIDUAL LIMB VOLUME CHANGE: SYSTEMATIC REVIEW OF MEASUREMENT AND MANAGEMENT,” *Journal of rehabilitation research and development*, 48(8), p. 949. Available at: https://doi.org/10.1682/JRRD.2010.09.0189.

Sansoni, S. *et al.* (2015) *The Aesthetic Appeal of Prosthetic Limbs and the Uncanny Valley: The Role of Personal Characteristics in Attraction*, *International Journal of Design*. Available at: https://www.researchgate.net/publication/276881700_The_Aesthetic_Appeal_of_Prosthetic_Limbs_and_the_Uncanny_Valley_The_Role_of_Personal_Characteristics_in_Attraction (Accessed: July 6, 2023).

Sansoni, S., Wodehouse, A. and Buis, A. (2014) “THE AESTHETICS OF PROSTHETIC DESIGN: FROM THEORY TO PRACTICE,” in *Dubrovnik-Croatia*. Available at: www.pixeldiva.co.uk.

Sansoni, S., Wodehouse, A. and Buis, A. (2015) *A new design system of below-limb prostheses The role of a visual prosthetic designer*. Available at: https://www.researchgate.net/publication/282576255_A_new_design_system_of_below-limb_prostheses_The_role_of_a_visual_prosthetic_designer (Accessed: July 21, 2023).

Sarker, I.H. (2022) “AI-Based Modeling: Techniques, Applications and Research Issues Towards Automation, Intelligent and Smart Systems,” *SN Computer Science*, 3(2). Available at: https://doi.org/10.1007/s42979-022-01043-x.

Schaffalitzky, E. *et al.* (2012) “Developing consensus on important factors associated with lower limb prosthetic prescription and use,” *Disability and Rehabilitation*, 34(24), pp. 2085–2094. Available at: https://doi.org/10.3109/09638288.2012.671885.

Scherer, K.R. (2005) “What are emotions? and how can they be measured?,” *Social Science Information*, 44(4), pp. 695–729. Available at: https://doi.org/10.1177/0539018405058216.

Scherer, K.R. and Moors, A. (2019) “The Emotion Process: Event Appraisal and Component Differentiation,” *Annual Review of Psychology*, 70, pp. 719–745. Available at: https://doi.org/10.1146/ANNUREV-PSYCH-122216-011854.

Scherer, K.R., Schorr, A. and Johnstone, T. (2001) *Appraisal Considered as a Process of Multilevel Sequential Checking*, *Appraisal Processes in Emotion*. Oxford University PressNew York, NY. Available at: https://doi.org/10.1093/OSO/9780195130072.003.0005.

Schlieder, C. *et al.* (2020) “A decade of Semantic Web research through the lenses of a mixed methods approach,” *Semantic Web*, 11(6), pp. 979–1005. Available at: https://doi.org/10.3233/SW-200371.

Da Silva Júnior, W.C., De Oliveira, M.A.V. and Bonvent, J.J. (2015) “Conception, design and development of a low-cost intelligent prosthesis for one-sided transfemoral amputees,” *Revista Brasileira de Engenharia Biomedica*, 31(1), pp. 62–69. Available at: https://doi.org/10.1590/2446-4740.0647.

Sinha, R., Van Den Heuvel, W.J.A. and Arokiasamy, P. (2011) “Factors affecting quality of life in lower limb amputees,” *Prosthetics and Orthotics International*, 35(1), pp. 90–96. Available at: https://doi.org/10.1177/0309364610397087,.

Slattery, P., Saeri, A.K. and Bragge, P. (2020) “Research co-design in health: A rapid overview of reviews,” *Health Research Policy and Systems*. BioMed Central Ltd. Available at: https://doi.org/10.1186/s12961-020-0528-9.

Soellner, S. *et al.* (2024) “Industrial service innovation: Exploring the transformation process to digital servitization in industrial goods companies,” *Industrial Marketing Management*, 117, pp. 288–303. Available at: https://doi.org/10.1016/J.INDMARMAN.2024.01.009.

Spoladore, D. and Pessot, E. (2021) “Collaborative ontology engineering methodologies for the development of decision support systems: Case studies in the healthcare domain,” *Electronics (Switzerland)*, 10(9). Available at: https://doi.org/10.3390/electronics10091060.

Spoladore, D., Tosi, M. and Lorenzini, E.C. (2024) “Ontology-based decision support systems for diabetes nutrition therapy: A systematic literature review,” *Artificial Intelligence in Medicine*. Elsevier B.V. Available at: https://doi.org/10.1016/j.artmed.2024.102859.

Stacey, P.K. and Tether, B. (2014) *Designing Emotion--Centred Product Service Systems: the Case of a Cancer Care Facility*, *Working Paper series*. Available at: http://www.lums.lancs.ac.uk/publications.

Steen, M. (2013) “Co-design as a process of joint inquiry and imagination,” *Design Issues*, 29(2), pp. 16–28. Available at: https://doi.org/10.1162/DESI_a_00207.

Steen, M., Manschot, M. and De Koning, N. (2011a) “Benefits-of-Co-design-in-Service-Design-Projects,” *International Journal of Design*, 5(2), pp. 53–60.

Steen, M., Manschot, M. and De Koning, N. (2011b) “Benefits-of-Co-design-in-Service-Design-Projects,” *International Journal of Design*, 5(2), pp. 53–60.

Studer, R., Benjamins, V.R. and Fensel, D. (1998a) “Knowledge engineering: Principles and methods,” *Data & Knowledge Engineering*, 25(1–2), pp. 161–197. Available at: https://doi.org/10.1016/S0169-023X(97)00056-6.

Studer, R., Benjamins, V.R. and Fensel, D. (1998b) “Knowledge Engineering: Principles and methods,” *Data and Knowledge Engineering*, 25(1–2), pp. 161–197. Available at: https://doi.org/10.1016/S0169-023X(97)00056-6.

Sun, Y. and Carmichael, D.G. (2018) “Uncertainties related to financial variables within infrastructure life cycle costing: a literature review,” *Structure and Infrastructure Engineering*, 14(9), pp. 1233–1243. Available at: https://doi.org/10.1080/15732479.2017.1418008.

Swami, V., Einon, D. and Furnham, A. (2006) “The leg-to-body ratio as a human aesthetic criterion,” *Body Image*, 3(4), pp. 317–323. Available at: https://doi.org/10.1016/J.BODYIM.2006.08.003.

Sweller, J., Ayres, P. and Kalyuga, S. (2011) “Cognitive Load Theory.” Available at: https://doi.org/10.1007/978-1-4419-8126-4.

Tan, C.F. *et al.* (2016) *The application of expert system: A review of research and applications*, *ARPN Journal of Engineering and Applied Sciences*. Available at: https://www.researchgate.net/publication/309256481_The_application_of_expert_system_A_review_of_research_and_applications (Accessed: September 25, 2025).

Tao, F., Zhang, H., *et al.* (2019) “Digital Twin in Industry: State-of-the-Art,” *IEEE Transactions on Industrial Informatics*, 15(4), pp. 2405–2415. Available at: https://doi.org/10.1109/TII.2018.2873186.

Tao, F., Qi, Q., *et al.* (2019) “Digital Twins and Cyber–Physical Systems toward Smart Manufacturing and Industry 4.0: Correlation and Comparison,” *Engineering*, 5(4), pp. 653–661. Available at: https://doi.org/10.1016/j.eng.2019.01.014.

Thibaut, A. *et al.* (2022) “Impact of microprocessor prosthetic knee on mobility and quality of life in patients with lower limb amputation: a systematic review of the literature,” *European Journal of Physical and Rehabilitation Medicine*, 58(3), p. 452. Available at: https://doi.org/10.23736/S1973-9087.22.07238-0.

Tichem, M. (1997) *A Design Co-ordination Approach to Design for X*.

Tipton, E. *et al.* (2017) “Implications of Small Samples for Generalization: Adjustments and Rules of Thumb,” *Evaluation Review*, 41(5), pp. 472–505. Available at: https://doi.org/10.1177/0193841X16655665,.

Triberti, S. *et al.* (2017) “Developing emotional design: Emotions as cognitive processes and their role in the design of interactive technologies,” *Frontiers in Psychology*, 8(OCT), p. 1773. Available at: https://doi.org/10.3389/fpsyg.2017.01773.

Tukker, A. (2004) “Eight types of product–service system: eight ways to sustainability? Experiences from SusProNet,” *Business Strategy and the Environment*, 13(4), pp. 246–260. Available at: https://doi.org/10.1002/BSE.414.

Tukker, A. (2015) “Product services for a resource-efficient and circular economy – a review,” *Journal of Cleaner Production*, 97, pp. 76–91. Available at: https://doi.org/10.1016/J.JCLEPRO.2013.11.049.

Turner, S., Belsi, A. and McGregor, A.H. (2021) “Issues Faced by Prosthetists and Physiotherapists During Lower-Limb Prosthetic Rehabilitation: A Thematic Analysis,” *Frontiers in Rehabilitation Sciences*, 2. Available at: https://doi.org/10.3389/FRESC.2021.795021.

Turner, S. and McGregor, A.H. (2020) “Perceived Effect of Socket Fit on Major Lower Limb Prosthetic Rehabilitation: A Clinician and Amputee Perspective,” *Archives of Rehabilitation Research and Clinical Translation*, 2(3), p. 100059. Available at: https://doi.org/10.1016/J.ARRCT.2020.100059.

Ulrich, K.T.. and Eppinger, S.D.. (2016) *Product design and development*. McGraw-Hill Education.

Unterkalmsteiner, M. and Abdeen, W. (2023) “A compendium and evaluation of taxonomy quality attributes,” *Expert Systems*, 40(1). Available at: https://doi.org/10.1111/exsy.13098.

Varaganti, P. and Seo, S. (2024) “Recent Advances in Biomimetics for the Development of Bio-Inspired Prosthetic Limbs,” *Biomimetics 2024, Vol. 9, Page 273*, 9(5), p. 273. Available at: https://doi.org/10.3390/BIOMIMETICS9050273.

Vargo, S.L. and Lusch, R.F. (2008) “Service-dominant logic: Continuing the evolution,” *Journal of the Academy of Marketing Science*, 36(1), pp. 1–10. Available at: https://doi.org/10.1007/s11747-007-0069-6.

Varsavas, S.D. *et al.* (2022) “A review of parameters affecting success of lower-limb prosthetic socket and liners and implementation of 3D printing technologies,” *Materials Today: Proceedings*, 70, pp. 425–430. Available at: https://doi.org/10.1016/J.MATPR.2022.09.280.

Vasantha, G.V.A. *et al.* (2012) “A review of product-service systems design methodologies,” *Journal of Engineering Design*, 23(9), pp. 635–659. Available at: https://doi.org/10.1080/09544828.2011.639712.

Vasileiou, K. *et al.* (2018a) “Characterising and justifying sample size sufficiency in interview-based studies: Systematic analysis of qualitative health research over a 15-year period,” *BMC Medical Research Methodology*, 18(1). Available at: https://doi.org/10.1186/s12874-018-0594-7.

Vasileiou, K. *et al.* (2018b) “Characterising and justifying sample size sufficiency in interview-based studies: Systematic analysis of qualitative health research over a 15-year period,” *BMC Medical Research Methodology*, 18(1). Available at: https://doi.org/10.1186/s12874-018-0594-7.

Venable, J., Pries-Heje, J. and Baskerville, R. (2016) “FEDS: A Framework for Evaluation in Design Science Research,” *European Journal of Information Systems*, 25(1), pp. 77–89. Available at: https://doi.org/10.1057/EJIS.2014.36;JOURNAL:JOURNAL:TJIS20;CTYPE:STRING:JOURNAL.

Vink, J. *et al.* (2019) “Reshaping mental models – enabling innovation through service design,” *Journal of Service Management*, 30(1), pp. 75–104. Available at: https://doi.org/10.1108/JOSM-08-2017-0186.

Walsh, H., Dong, A. and Tumer, I. (2019) “Towards a theory for unintended consequences in engineering design,” in *Proceedings of the International Conference on Engineering Design, ICED*. Cambridge University Press, pp. 3411–3420. Available at: https://doi.org/10.1017/dsi.2019.348.

Wanamaker, A.B., Andridge, R.R. and Chaudhari, A.M.W. (2017) “When to biomechanically examine a lower-limb amputee: A systematic review of accommodation times,” *Prosthetics and Orthotics International*. SAGE Publications Inc., pp. 431–445. Available at: https://doi.org/10.1177/0309364616682385.

Wanamaker, A.B., Andridge, R.R. and Chaudhari, A.M.W. (2020) “Costs Associated with Lower- and Upper-Limb Amputation Over the First 4 Years with a Prosthesis,” *Journal of Prosthetics and Orthotics*, 32(2), pp. 81–92. Available at: https://doi.org/10.1097/JPO.0000000000000310.

Wang, J. *et al.* (2024) “Situation modeling and evaluation for complex systems: A case study of satellite attitude control system,” *Advanced Engineering Informatics*, 61, p. 102505. Available at: https://doi.org/10.1016/J.AEI.2024.102505.

Wan, Y. *et al.* (2024) “Making knowledge graphs work for smart manufacturing: Research topics, applications and prospects,” *Journal of Manufacturing Systems*, 76, pp. 103–132. Available at: https://doi.org/10.1016/J.JMSY.2024.07.009.

What to consider when it’s time for a new prosthetic knee (2024). Available at: https://www.ottobock.com/en-gb/what-to-consider (Accessed: March 11, 2024).

What to Expect: The Months After Amputation Surgery (no date). Available at: https://www.hortonsoandp.com/what-to-expect-the-months-after-amputation-surgery-recovery/ (Accessed: March 11, 2024).

WHO (2017) *STANDARDS FOR PROSTHETICS AND ORTHOTICS WHO*. Available at: http://apps.who.int/bookorders.

Wieringa, R.J. (2014) “Design science methodology: For information systems and software engineering,” *Design Science Methodology: For Information Systems and Software Engineering*, pp. 1–332. Available at: https://doi.org/10.1007/978-3-662-43839-8/COVER.

Wilkinson, C.R. and De Angeli, A. (2014) “Applying user centred and participatory design approaches to commercial product development,” *Design Studies*, 35(6), pp. 614–631. Available at: https://doi.org/10.1016/j.destud.2014.06.001.

Wyss, D. *et al.* (2015) “Priorities in lower limb prosthetic service delivery based on an international survey of prosthetists in low- and high-income countries,” *Prosthetics and orthotics international*, 39(2), pp. 102–111. Available at: https://doi.org/10.1177/0309364613513824.

Xing, K., Rapaccini, M. and Visintin, F. (2017) “PSS in Healthcare: An Under-Explored Field,” in *Procedia CIRP*. Elsevier B.V., pp. 241–246. Available at: https://doi.org/10.1016/j.procir.2017.03.068.

Xu, K. and Qin, S. (2023) “An Interdisciplinary Approach and Advanced Techniques for Enhanced 3D-Printed Upper Limb Prosthetic Socket Design: A Literature Review,” *Actuators 2023, Vol. 12, Page 223*, 12(6), p. 223. Available at: https://doi.org/10.3390/ACT12060223.

Xu, L. Da, Xu, E.L. and Li, L. (2018) “Industry 4.0: State of the art and future trends,” *International Journal of Production Research*, 56(8), pp. 2941–2962. Available at: https://doi.org/10.1080/00207543.2018.1444806.

Yin, R.K. (2018) *Case Study Research and Applications Design and Methods*. 6th ed. Thousand Oaks. Available at: https://www.scirp.org/reference/referencespapers?referenceid=2914980 (Accessed: September 26, 2025).

Yip, M.H., Phaal, R. and Probert, D.R. (2015) “Characterising product-service systems in the healthcare industry,” *Technology in Society*, 43, pp. 129–143. Available at: https://doi.org/10.1016/j.techsoc.2015.05.014.

Yuan, B. *et al.* (2023) “The global burden of traumatic amputation in 204 countries and territories,” *Frontiers in Public Health*, 11, p. 1258853. Available at: https://doi.org/10.3389/FPUBH.2023.1258853/BIBTEX.

Ziegler-Graham, K. *et al.* (2008) “Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050,” *Archives of Physical Medicine and Rehabilitation*, 89(3), pp. 422–429. Available at: https://doi.org/10.1016/J.APMR.2007.11.005.

Appendix 1 – Formal Stakeholder Questionnaires

Questionnaire about leg prosthesis

The aim of this questionnaire is to better understand the current issues about the current issues amputees, who are about to receive a prosthesis or have already received a prosthesis, face. The information gained from this questionnaire would facilitate my research into prosthesis by having a better understanding of your needs and desired improvements for a prosthesis. This will enable me to manufacture a prototype prosthesis.

Amputee Background

Question 1: Please select the age group that best fits your current age.

- 18-25
- 26-40
- 41-65
- Over 65

Question 2: Please select your gender.

- Male
- Female
- Other

Question 3: What type of amputation do you have?

- Above the knee
- Below the knee

Question 4: If you have a prosthesis, how long have you had your prosthesis?

Ownership of prosthesis

Question 5: If you had to own or are already in possession of a prosthesis, what are your key requirements? You may tick a maximum of three (3).

- Improved mobility to do a few daily tasks (eg walking, going up stairs)
- Advanced improved mobility ie can do complex tasks (eg cycling)
- Aesthetically pleasing (looks good)
- Emotionally pleasing (eg makes you happy, boosts your confidence)
- Comfort
- Ease of wearing and removing
- Cost
- User adjustments (eg for fitting into different shoes)
- Easy maintenance

- Ability of upgrading with new or improved features (eg smoother motor)

Question 6: How does the idea of wearing and owning a prosthesis make you feel?

- Very happy (it makes up for my lost limb)
- Happy
- Neutral
- Sad
- Very sad (as it reminds me of my lost limb)

Question 7: For the type of requirements indicated above, what would be an acceptable price range that you would be willing to pay for a new prosthesis?

- €50 - €250
- €250 - €500
- €500 - €750
- above €750

Question 8: Instead of purchasing a prosthesis, would it make any difference if you had to subscribe to a service that provides you with a prosthesis matching your needs, for an annual fee? To provide an example of the concept of the service, it will cost in the range of €75-€100 per annum and will include one functional prosthesis matching your physical requirements and two maintenance services. For an additional fee, the service will allow you to temporarily change your prosthesis for specific events/activities (eg cycling).

- Definitely Yes
- Yes
- Not sure
- No
- Definitely No
- Other: ________________________________

Question 9: Please state why you like or dislike the service described in the above question.

Innovative Prosthesis Design

Question 10: Would you prefer your new prosthesis to have an artificial look or a more 'life like' look?

Artificial	Partially artificial	Neutral	Partially life like	Totally life like

Question 11: As an amputee, do you have a support system (eg family or friends or therapist)?

- Yes
- No

Question 12: If your answer to the above question was Yes, please state your support system and why you find them beneficial. If your answer to the above question was No, please state your reason for not using a support system.

Question 13: Should a new prosthesis design depend on having the support of family/friends /therapists? (eg help with putting on or removing the prosthesis, requiring assistance while walking with the prosthesis)

- Definitely Yes
- Ideally Yes
- Neutral
- Ideally No
- Definitely No

Question 14: Do you see any benefits, even at an extra cost, for your prosthesis to offer smart features? Smart features may be (but are not limited to) functions to monitor battery levels and with sound alerts; step count; ability to change colour or pattern; auto adjustable shock absorbers tuned with GPS; fall monitor with alerts to loved ones?

- Definitely Yes
- Yes
- Neutral
- No
- Definitely No

Question 15: Do you have other ideas for features? Please elaborate on the need of such a feature.

Question 16: Would you like the ability to perform minor adjustments on your prosthesis?

- Definitely Yes
- Yes
- Neutral
- No
- Definitely No

Question 17: Please give a brief explanation to your answer for the above question.

Question 18: Is there any other issue, problem or feature that you would like to discuss that has not been mentioned in this questionnaire? If yes, please give an explanation.

Questions for current prosthesis users

Question 19: Do you find that the whole process of obtaining a prosthesis, consisting of a number of steps, including being measured and fitted the prosthesis to be adequate?

- Yes
- Not sure
- No

Question 20: Please provide brief reasons to clarify your answer above.

Question 21: In total, how costly (estimate) was the whole process (practitioners plus prosthesis itself) of obtaining your specific prosthesis?

- Publicly funded free service
- Cost less than €500 (USD 600)

- Between €500 (USD 600) and €1000 (USD 1200)
- Between €1000 (USD 1200) and €2000 (USD 2400)
- More than €2000 (USD 2400)

Question 22: Does your current prosthesis give you the mobility that you require? Please give a brief explanation.

Question 23: Does your current prosthesis cause you any discomfort or pain? If yes, please give a brief description to help us understand if this can be eliminated in future prosthesis designs.

Final Section

Question 24: Is there an issue with your current prosthesis that you would like to improve and why? You can refer to more than one issue.

Question 25: If you would like to be updated on our work and/or informed about trying on a prototype, feel free to provide name and contact details.

Prosthetist Questionnaire

This questionnaire is being done to better understand the needs/issues that you encounter while dealing with leg related amputees.

Prosthetist Details

Question 1: Please select your gender

- Male
- Female
- Other

Question 2: How long have you been practicing your profession?

- experience < 5 years
- 5 years < experience < 10 years
- 10 years < experience < 15 years
- Experience > 15 years

Question 3: Have you worked in any other countries besides Malta?

- Yes
- No

Question 4: If the answer to the above question was Yes, please list which countries you have worked in.

Question Regarding Amputees

Question 5: What is the most common type of amputation that you deal with?

- Below the knee
- Above the knee
- Other ________________

Question 6: For above the knee amputees, what is the most common age group that you deal with?

- 0 - 18
- - 25
- 25 - 40
- 40 - 65
- over 65
- Other _____________

Question 7: Are the majority of AK cases disease or accident related?

- Disease
- Accident

- Other __________

Question 8: If disease related, please specify which are the most common diseases.

Question 9: Are the majority of your patients male or female?

- Male
- Female
- Other

Question 10: What are the most common prosthesis issues that your clients encounter? (eg socket comes loose, too much wear and tear on the knee joint)

Prosthesis Development Service

This section is intended to understand the steps and challenges encountered by prosthetists when prescribing a prosthesis to amputees.

Question 11: Please select common steps involved in recommending and providing a prosthesis (you can select more than one)

- Get to know the client and his/her case
- Take biometric data
- Ask them how much they want to spend
- Ask them for their mobility goals
- Recommend one or two prosthesis options
- Order off the shelf parts (eg artificial knee joint)
- Make casting and let it dry
- Assemble off the shelf and cast parts together
- Check that prosthesis developed fits well
- Spray or give the casting a colour

Question 12: Which from the above steps take you more time and/or are challenging? Please clarify why. (maximum 2 steps)

Question 13: For an above the knee amputee, what is the most common type of prosthesis that you would recommend for an active person? Please give a brief explanation.

Question 14: For an above the knee amputee, what is the most common type of prosthesis that you would recommend for a more sedate person? Please give a brief explanation.

Question 15: Are you satisfied with the standard prosthesis sub-systems available? (eg knee joint and ankle)

- Very satisfied
- Satisfied
- Neutral
- Disappointed
- Very disappointed

Question 16: Please give a brief explanation for your answer to the above question.

Question 17: Please give a brief explanation to your answer for the above question.

Question 18: How regularly do current patients come for maintenance, adjustments or to replace parts on their prosthesis?

- Very often
- Often
- Neutral
- Occasionally
- Almost never

Question 20: Please state the reason for the answer for the above question.

Question 21: Is there a long time between a patient being measured for the prosthesis and the patient being fitted with the prosthesis?

- Yes
- No

Question 22: With regards to the above question, please give a time frame.

Question 23: Do you find that the current service system of being measured, obtaining and fitting of the prosthesis to be adequate?

- Yes
- No

Question 24: If the answer to the above question was Yes, please briefly explain why. If the answer to the above question was no, please give a brief description of where you would like to see improvements.

Opinion on improved prothesis design

This section focuses on obtaining feedback from prosthetists based on their years of experience of working with amputees. Prosthetists can here make recommendations of new design features in prosthesis that will help both their patients as well as themselves.

Question 25: What improvements or new features would you want to see on future prosthesis?

Question 26: Do your patients prefer their prosthesis to have an artificial look or a more life like look?

Artificial   Partially artificial   Neutral   Partially life like   Totally life like

Question 27: Do your patients have a support system (eg family or friends or therapists)?

- Yes
- No

Question 28: If your answer to the above question was yes, please state the support system they use

Question 29: Should a new prosthesis design depend on having the support of family/friends /therapists? (eg help with putting on or removing the prosthesis, help to pay for the prosthesis, requiring assistance while walking with the prosthesis)

- Definitely Yes
- Ideally Yes
- Neutral
- Ideally No
- Definitely No

Question 30: Do you see any benefits, even at an extra cost, for the prosthesis to offer smart features? Smart features may be (but are not limited to) facilities to monitor battery levels and have with sound alerts; step count; ability to change colour or pattern; auto adjustable shock absorbers tuned with GPS, fall monitor with alerts to loved ones?

- Definitely Yes
- Yes
- Neutral
- No
- Definitely No

Question 31: Do you have an ideas for smart features? Please elaborate

Question 32: Instead of purchasing a prosthesis, would it make any difference if you had to subscribe to a service that provides you with a prosthesis matching your needs, for an annual fee? To provide an example of the concept of the service, it will cost in the range of €75-€100 per annum and will include one functional prosthesis matching your physical requirements and two maintenance services. For an additional fee, the service will allow you to change your prosthesis for specific events/activities (eg cycling).

- Definitely Yes
- Yes
- Neutral
- No
- Definitely No

Question 33: Please state why you like or dislike the service described in the above question.

Question 34: Do you think that your patients should have the ability to perform minor adjustments to their own prosthesis?

- Definitely Yes
- Yes
- Neutral
- No
- Definitely No

Question 35: With regards to the above question, please give a brief explanation.

Final section

Question 36: Is there any other issue, problem or feature that you would like to discuss that has not been mentioned in this questionnaire? If yes, please give an explanation.

Appendix 2 - Aesthetic Differences of Lower Limbs between Men and Women

Abstract

This report shall outline a study conducted to observe and assess the aesthetic differences in lower limbs between men and women. It is believed that by completing this study, the PREMIER Team would gain enough knowledge to accurately design two sets of above knee prosthesis that have a closer relationship to the anatomical dimensions of both the male and female human legs. With this knowledge, 3D designs can be explored and designed using Inventor such that the prototype prosthesis may have more accurate and aesthetically proportions.

Introduction

It is clearly known that humans are a bipedal species and that we rely solely on our two legs to walk. While the general function and positioning of the joints are the same for both men and women, their aesthetic ratios are different. Males usually tend to be larger than females, and therefore have more muscle in the thighs and calves, while women tend to be slimmer and more petite. These differences are subtle and are normally taken for granted. However, since the PERMIER Team is currently underway in designing 3D prothesis using Inventor, it is important that these subtle differences in ratios be known such that the team can accurately cater for the different needs of the different amputees. It is therefore hoped that this study will give the team enough information and foresight to be able to design prosthesis that are suitable for both the male and female forms.

The Importance of Aesthetic Appeal

The aesthetic design of prosthetics has only recently begun to be observed and researched, specifically the dependent relationship of aesthetic attraction and the link to human limb resemblance (Sansoni et al 2015). A recent study conducted by Sansoni et al (2015) has shown that there is a relationship between the level of attraction of the prosthesis to the amputee depending on how life-like or how unrealistic the prosthetic is. This has been referred to as the Uncanny Valley (UV). This study showed that in general, the more realistic the prosthesis, the more the amputees were finding the prosthetic to be aesthetically pleasing. However, this was only the case up to a certain extent. Prosthetics that were hyper realistic were shown to have less aesthetic appeal as it was a stark reminder of what the amputees had lost. Figure 1 gives a graphical representation of the UV.

There are three main areas to note in the UV graph are:

- The First Area – is the first section of the graph that shows very little resemblance to the human anatomy and it therefore has a very low attraction level
- The Second Area - this second section (seen as a peak) has a medium level of human resemblance and also has a medium attraction level
- The Third Area (seen as a trough) depicts an area that has high human resemblance but however has a negative impact on attraction level

Additionally, an internal study was carried out by the PREMIER Team which also showed that initially the amputees prefer a more realistic, but not hyper realistic, prosthesis. After a prolonged period, and after the amputees have become accustomed to wearing the prosthesis, they tend to favour a less life like look as opposed to a hyper realistic prosthesis. This further confirms the theory behind the UV.

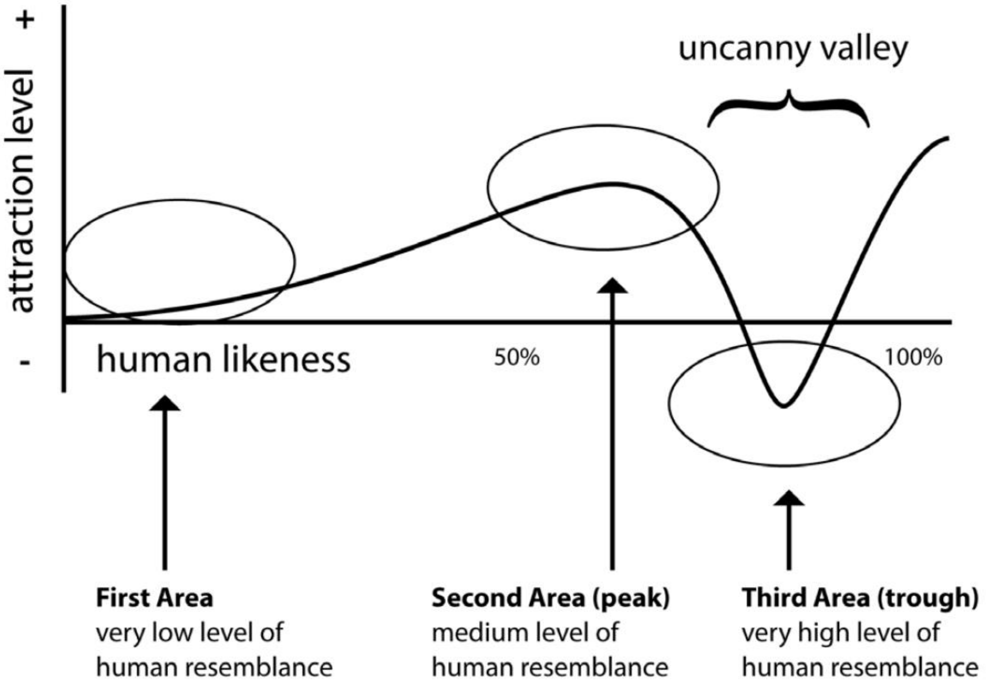


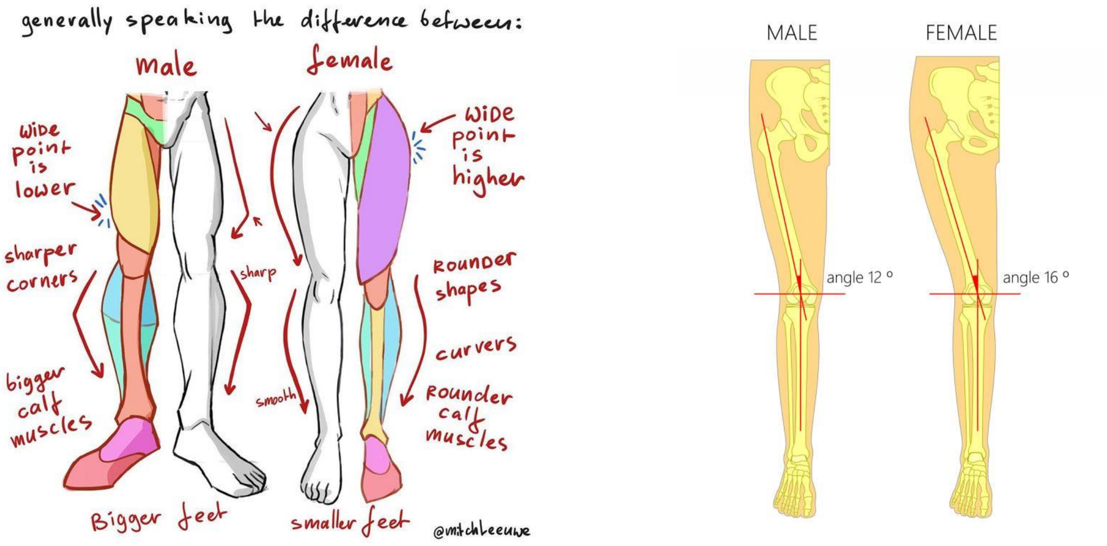
Figure 1: Graphical representation of the Uncanny Valley

There are other factors which contribute to the amputee liking or disliking the aesthetics of their prosthesis. Age and gender also play a significant part of what the amputee would like with regards to the aesthetic look of their prosthesis.

It is therefore believed that if it becomes possible to merge the realistic look with something more modern looking, there would be a much higher acceptance of the prosthesis in terms of aesthetic appearance, as this would generate more positive emotions. However, to do that, one must first understand the aesthetic differences that there are between male and female lower limbs.

Comparison of Ratios of Male vs Female Lower Limbs

In this section of the report, an aesthetic comparison of the male and female lower limbs shall be made. This comparison shall be made by observing anatomical sketches shown in Figure 2. Figure 2a give a colourful representation of the muscle differences of both the male and female limbs. When it comes to the quadriceps muscle group it is shown that the female muscle group is wider at the top end of the muscle, giving the impression of wider hips, while that of the man is slimmer at the top and wider at the bottom of the muscle group that is closer to the knee. Also note that the female quadriceps are more curvaceous while that of the male is more linear and with a sharp angle. In a similar fashion, it can be seen that the calf muscle of the female is also curved while that of the male is angular and in a vertical diamond shape. Additionally, the calf muscles of the male is larger and wider. Figure 2b depicts anatomical structures of both the male and female lower limbs. However, this sketch clearly highlights the difference between the deflection angle of the femur, where that of the male is at 12 degrees and that of the female is 16 degrees. The difference in the deflection angle is what accentuates the female quadriceps muscles giving them a wider hip.



a) *b)*

Figure 2: Anatomical sketches of the lower limbs; a) depicting a visual sketch; b) showing the different deflection angle

Images taken form pinterst.com and breakingmuscle.com

In addition to anatomical sketches, one can compare the visual differences in photos of male and female calves. Figure 3 shows a frontal view of a females (left) and males (right) shin and calf muscles. One can clearly see that the female calf muscle is curved with that of the male has a vertical diamond shape. From this image, it can also be noted that the feet of the male (right) are larger than that of the female (left).

Figure 3: Shows the difference between the female (left) and male (right) shins and calve muscles

In a study conducted by Viren Swami et al (2006) it was found that the human leg-to-body ratio (LBR) is different for both male and female. The study has shown that the physical attractiveness for men was to have a short LBR while that for women was a longer LBR.

Conclusion

While brief, this report has shown that there are significant ratios between the male and female lower limbs anatomy, the diamond shaped calf muscle of the male and the wide top of the quadriceps of the female. Additionally, it was noted that the males have larger muscles than the females due to the males having larger body mass. Therefore, when designing the 3D models, it would be a good idea to preserve these ratios while adding a modern flair to the designs, making the prosthesis more aesthetically pleasing. At the same time, one must consider the size of the prosthesis and that it is not too bulky that it causes problems when the amputee tries to wear certain types of clothing.

Reference

Sansoni, S., Wodehouse, A., McFadyen, A.K. and Buis, A., 2015. The aesthetic appeal of prosthetic limbs and the uncanny valley: The role of personal characteristics in attraction. International Journal of Design, 9(1), pp.67-81.
Viren Swami, Dorothy Einon, Adrian Furnham, The leg-to-body ratio as a human aesthetic criterion, Body Image, Volume 3, Issue 4, 2006, Pages 317-323, ISSN 1740-1445, https://doi.org/10.1016/j.bodyim.2006.08.003.
https://www.pinterest.com/pin/420594052705447429/
https://breakingmuscle.com/the-difference-between-male-and-female-biomechanics-in-strength-training/
https://www.shutterstock.com/image-photo/male-female-legs-on-sofa-close-579937297

Appendix 3 – Pre-evaluation Questionnaires

Amputee Questionnaire

This questionnaire seeks to identify the challenges that you, as an amputee, face, with regards to your prosthesis and the aftercare service that you receive, from the initial consultation to discuss your requirements, through your ongoing usage of the prosthesis.

Section 2 – Amputee Background

1) Please select the age group that best suits you.
    - 18 to 25 years
    - 26 to 40 years
    - 41 to 65 years
    - Over 65

2) Which of the following cases matches with you?
    - Above the knee
    - Below the knee but above the ankle
    - Ankle / foot
    - Above the elbow
    - Below the elbow but above the wrist
    - Wrist / hand

3) For how many years have you been an amputee?
    - Less than 1 year
    - Between 1 year and 5 years
    - Between 5 years and 10 years
    - Between 10 years and 15 years
    - More than 15 years

4) For how many years have you been wearing a prosthesis?
    - Less than 1 year
    - Between 1 year and 5 years
    - Between 5 years and 10 years
    - Between 10 years and 15 years
    - More than 15 years

5) How many prostheses have you had to date?
    - 1
    - 2
    - 3
    - 4

  - 5
  - More than 5

6) What has been the average life time of your prosthetics?
  - Less than 1 year
  - Between 1 and 2 years
  - Between 2 and 3 years
  - Between 3 and 4 years
  - Between 4 and 5 years
  - More than 5 years

7) Was the reason for amputation due to an illness / disease or through an accident?
  - Illness / disease
  - Accident

8) If you selected illness/disease in the previous question, please specify which one it is.

9) Kindy select the stakeholders that are present during your consultations.
  - Amputee
  - Amputee family member
  - Prosthetist
  - Prosthesis Technician
  - Physiotherapist

<u>Section 4 – Amputee Issues and Requirements</u>

10) Do you encounter any of the following issues when having your consultations? Select as many as required.
  - Bad communication between amputee and prosthetist
  - The outcome (positive and negative effects) of the proposed prosthesis is not clear to amputee and/or prosthetist
  - Limited selection of standard sub-system parts (such as a knee sub-system or an ankle sub--system)
  - Limited sub-system parameter information (such as number of times the knee can flex/extend)
  - Lack of aesthetic options
  - The proposed prosthetic solution presented to you is not clear
  - Do you feel that your needs cannot be met due to current limitations in the service?
  - Choices are impacted by the level of aftercare that is available

11) Kindly list any other issues that are present during your consultations. Kindly list the issues in order of significance, starting with the one that has the greatest impact as issue 1.

12) What the typical duration between the initial consultation and measurement for your prosthesis, and the subsequent fitting appointment when you are presented with the prosthesis?
- Same day
- 1 week
- 2 weeks
- 3 weeks
- 4 weeks
- More than 4 weeks

13) When an issue with your prosthesis arises, how long do you typically wait from the time you request an appointment to when you are seen by your prosthetist?
- Same day
- 1 week
- 2 weeks
- 3 weeks
- 4 weeks
- More than 4 weeks

14) Please identify 5 of the most common issues that you encounter while wearing your prosthesis? Kindly list the issues in order of significance, starting with the one that has the greatest impact as issue 1.

15) Please identify 5 of the most common issues that you encounter with regards to the aftercare service that you receive? Kindly list the issues in order of significance, starting with the one that has the greatest impact as issue 1.

16) How frequently do you suffer from ulcers?
- Every few weeks
- Every month
- Around every 2 months
- Around every 3 months
- Every 3 to 6 months
- More than every 6 months

17) How satisfied are you with the current process of obtaining a prosthesis and the aftercare that you receive?
- Very satisfied
- Satisfied
- Neutral
- Dissatisfied
- Very dissatisfied

18) Please provide a brief explanation for your response to the above question.

Section 5 – Improvements

19) Would you like the ability to perform minor adjustments to your prosthesis? For instance, adjustments could include modifying the angle of ankle inclination to ensure a better fit within a shoe.
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

20) In your opinion, would a smart prosthesis capable of collecting data be beneficial in improving your ability to make informed design decisions with your prosthetist, both in the development of services for your aftercare and in the design of your new prosthetic devices? Examples of data are step count, detection of ulcers, wear and tear on prosthesis.
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

21) Please identify up to five types of data you consider important to collect, providing a brief explanation for each. Kindly prioritise the data types in order of significance, starting with the one that has the greatest impact as item 1.

22) What smart features, beyond data collection, do you believe would enhance your experience? Please give a brief explanation to your answers. An example of smart features are sounds and alerts, fall monitors, auto adjustable shock absorbers, LED display

23) During your consultations with your prosthetist, would you consider an interactive tool, such as a computer program or mobile application, that enables you to visualise changes to your prosthesis and its sub-systems, along with their effects and outcomes related to your prosthesis maintenance and your aftercare services, to be beneficial?

- Definitely yes
- Yes
- Neutral
- No
- Definitely no

24) If you were required to make minor adjustments to your prosthesis (such as modifying the angle of ankle inclination for a better fit within your shoe), would you find an interactive tool helpful in assisting you with these adjustments?

- Definitely yes
- Yes
- Neutral
- No
- Definitely no

Final Section

25) How satisfied are you with your prosthesis and the aftercare that you receive?

- Very satisfied
- Satisfied
- Neutral
- Dissatisfied
- Very dissatisfied

26) Are there any changes to your prosthesis and/or your aftercare services that you would like to implement?

27) Are there any other problems that you encounter throughout your prosthesis experience that have not been discussed in the questionnaire?

Prosthetist Questionnaire

This questionnaire seeks to identify the challenges you, as a prosthetist, encounter in delivering the necessary services to amputees. The questions are designed to explore potential issues across the entire care journey, from the initial consultation to discuss prosthesis requirements, through to ongoing aftercare during the prosthesis's usage

By participating, you will not only contribute to advancing prosthetic design and aftercare but also gain insights into innovations that can enhance clinical practices and improve user experiences and outcomes. Your perspective as a healthcare professional, as well as your experience and expertise will help shape the future of smart prosthetics and patient aftercare.

Section 1 – Prosthetist Details

2) How long have you been practicing your profession?
    - Less than 5 years
    - Between 5 and 10 years
    - Between 10 and 15 years
    - More than 15 years

3) Have you worked in any other countries besides Malta?
   Yes / No

4) If you have worked in another country, please list the country/ies that you have worked in.

Section 2 – Questions regarding Amputees

5) Please rank the types of amputations you most frequently encounter, with 1 indicating the most common and 6 indicating the least common.

	1	2	3	4	5	6
Above the knee						
Below the knee but above the ankle						
Ankle / Foot						
Above the elbow						
Below the elbow but above the wrist						
Wrist / Hand						

6) What is the most common age group that you deal with for lower limb amputation?
    - 18 to 25
    - 26 to 40
    - 41 to 65
    - Above 65

7) Are the majority of lower limb amputations related to illnesses and diseases or are the accident related?
    - Illness / Disease
    - Accident

8) If illness or disease is the primary cause of amputation, please list the 3 most common conditions.

Section 3 - Questions related to current issues

9) Select which issues are prevalent during the initial consultation with the amputee. Select as many as required.
    - Bad communication between amputee and prosthetist
    - The outcome (positive and negative effects) of the proposed prosthesis is not clear to amputee and/or prosthetist
    - Limited selection of standard sub-system parts (such as a knee sub-system or an ankle sub--system)
    - Limited sub-system parameter information (such as number of times the knee can flex/extend)
    - Lack of aesthetic options
    - Amputee involvement is limited due to amputee's inability to understand the proposed prosthetic solution
    - Choices are impacted by the level of aftercare that the amputee can receive

10) What additional issues, not mentioned in the previous question, do you encounter during the initial consultation?

11) Please select all applicable stakeholders involved in the initial consultation with the amputee.
    - Amputee
    - Amputee family member
    - Prosthetist
    - Prosthesis Technician
    - Physiotherapist

12) Please list any other stakeholders present during the initial consultation that were not mentioned in the previous question.

13) What is the typical duration between the initial consultation and measurement of the amputee for a prosthesis, and the subsequent fitting of the prosthesis?
    - Same day
    - 1 week
    - 2 weeks
    - 3 weeks
    - 4 weeks
    - More than 4 weeks

14) How frequently do amputees come for maintenance and adjustments to their prosthesis?
    - Multiple times a week
    - Every week
    - Every 2 weeks
    - Every 4 weeks
    - Every 6 weeks
    - More than 6 weeks

15) Please identify up to five of the most prevalent challenges encountered in amputee aftercare and prosthesis maintenance and give a brief explanation. Examples of such challenges include frequent ulcer development or insufficient access to specialised facilities for amputees. Kindly list the challenges in order of significance, starting with the one that has the greatest impact as issue 1.

Section 4 – Questions related to the aftercare services provided

16) How satisfied are you with the current services in place to provide an amputee with a prosthesis, the maintenance of the prosthesis and the aftercare services available?
    - Very satisfied
    - Satisfied
    - Neutral
    - Dissatisfied
    - Very dissatisfied

17) Please give a brief explanation to your above answer.

18) In your opinion what changes to the current services would improve your ability to prove a service to amputees?

19) In your opinion, would a smart prosthesis capable of collecting data be beneficial in improving your ability to make informed design decisions, both in the development of services for amputees and in the design of new prosthetic devices? Examples of data are step count, detection of ulcers, wear and tear on prosthesis.
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

20) Please identify up to five types of data you consider important to collect, providing a brief explanation for each. Kindly prioritise the data types in order of significance, starting with the one that has the greatest impact as item 1.

21) What smart features, beyond data collection, do you believe would enhance your ability to deliver improved prosthetic designs and services within your profession? Please give a brief explanation to your answers. An example of smart features are sounds and alerts, fall monitors, auto adjustable shock absorbers, LED display

22) Do you consider an interactive tool, such as a computer program or mobile application, that enables the visualisation of the prosthesis and its sub-systems, along with their effects and outcomes related to prosthesis maintenance and amputee aftercare, to be beneficial?
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

23) Throughout the prosthesis life-cycle, the amputee and their prosthesis interact with various stakeholders (e.g., prosthetists, prosthesis technicians, physiotherapists), each contributing expertise gained through their professional experience. In your opinion, should these stakeholders also be actively involved in the prosthesis decision-making process during the initial consultation?
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

24) In your opinion, should amputees have the capability to perform minor adjustments to their prosthesis? For instance, adjustments could include modifying the angle of ankle inclination to ensure a better fit within a shoe.
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

25) Considering that the amputee can now receive guidance from an interactive tool on performing minor adjustments, do you believe they should be permitted to make these adjustments independently?
- Definitely yes
- Yes
- Neutral
- No
- Definitely no

Final Section

26) Are there any other problems that you encounter in your profession that have not been discussed in the questionnaire?

Physiotherapist Questionnaire

This questionnaire seeks to identify the challenges you, as a physiotherapist, encounter while delivering the necessary services to amputees. The questions are designed to explore potential issues across the entire care journey, from the initial consultation to discuss prosthesis requirements, through to ongoing aftercare during the prosthesis's usage

By participating, you will not only contribute to advancing prosthetic design and aftercare but also gain insights into innovations that can enhance clinical practices and improve user experiences and outcomes. Your perspective as a healthcare professional, as well as your experience and expertise will help shape the future of smart prosthetics and patient aftercare.

Section 2 – Physiotherapist Details

27) How long have you been practicing your profession?
    - Less than 5 years
    - Between 5 and 10 years
    - Between 10 and 15 years
    - More than 15 years

28) Have you worked in any other countries besides Malta?
    Yes / No

29) If you have worked in another country, please list the country/ies that you have worked in.

Section 3 – Questions regarding Amputees

30) Please rank the types of amputations you most frequently encounter, with 1 indicating the most common and 6 indicating the least common.

	1	2	3	4	5	6
Above the knee						
Below the knee but above the ankle						
Ankle / Foot						
Above the elbow						
Below the elbow but above the wrist						
Wrist / Hand						

31) What is the most common age group that you deal with for lower limb amputation?

- 18 to 25
- 26 to 40
- 41 to 65
- Above 65

32) Are the majority of lower limb amputations related to illnesses and diseases or are the accident related?

- Illness / Disease
- Accident

33) If illness or disease is the primary cause of amputation, please list the 3 most common conditions.

34) Are there significant differences in the physiotherapy regimens for amputees based on whether the amputation resulted from an illness or disease compared to an accident?

- Yes
- No

35) If you selected yes in the previous question, kindly list up to 5 of the most significant differences. Please list the challenges in order of significance, starting with the one that has the greatest impact as issue 1.

Section 4 - Questions related to current issues

36) On average how often does an amputee come in for a physiotherapy session?

- More than once a week
- Once a week
- Every 2 weeks
- Every 3 weeks
- Every 4 weeks
- Between 4 to 6 weeks
- Between 6 to 8 weeks

- More than every 8 weeks

37) To what degree do you find that amputees are clearly able to discuss the issues that they are having?
    - Very clear
    - Clear
    - Neutral
    - Unclear
    - Very unclear

38) Do you feel you have sufficient information regarding how patients utilise their prostheses in daily life and the challenges they encounter, to effectively tailor physiotherapy sessions to the specific needs of each individual amputee?
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

39) List up to 5 of the most relevant issues that you encounter while dealing with the amputees during their physiotherapy sessions. Please list the challenges in order of significance, starting with the one that has the greatest impact as issue 1.

Section 5 – Questions related to the aftercare services provided

40) Do you think a smart prosthesis will be beneficial in terms of collecting data about the amputee's mobility and performance, to allow you to make more informed decisions when prescribing the physiotherapy to the amputee? An example of such data would be how many steps the amputee has taken throughout the day and at what speed the steps were taken, or how sedentary the amputee has been throughout the day.
    - Definitely yes

- Yes
- Neutral
- No
- Definitely no

41) List up to 5 other smart features in a smart prosthesis that would help you in providing a better service to the amputee. Please list the smart features in order of significance, starting with the one that has the greatest impact as smart feature 1.

42) Would you find an interactive tool, integrated with a smart prosthesis, that provides data on the amputee's movements and identifies irregular patterns beneficial in adjusting the physiotherapy regimen to address current challenges?
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

43) Do you believe physiotherapists should be involved in the initial consultation between the amputee and the prosthetist to facilitate the development of a more effective prosthesis solution and better tailored aftercare for the amputee?
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

Final Section

44) Are there any other problems that you encounter in your profession that have not been discussed in the questionnaire?

Prosthetist & Orthotics Student Questionnaire

This questionnaire seeks to identify the challenges you, as a P&O student, encounter in delivering the necessary services to amputees. The questions are designed to explore potential issues across the entire care journey, from the initial consultation to discuss prosthesis requirements, through to ongoing aftercare during the prosthesis's usage

By participating, you will not only contribute to advancing prosthetic design and aftercare but also gain insights into innovations that can enhance clinical practices and improve user experiences and outcomes. Your perspective as a healthcare professional, as well as your experience and expertise will help shape the future of smart prosthetics and patient aftercare.

Section 2 – Prosthetist Details

45) Kindly give a brief background of your past and present courses.

46) Have you had any working placements in any other countries besides Malta?
Yes / No

47) If you have worked in another country, please list the country/ies that you have worked in.

Section 3 – Questions regarding Amputees

48) Please rank the types of amputations you most frequently encounter, with 1 indicating the most common and 6 indicating the least common.

	1	2	3	4	5	6
Above the knee						
Below the knee but above the ankle						
Ankle / Foot						
Above the elbow						
Below the elbow but above the wrist						
Wrist / Hand						

49) What is the most common age group that you deal with for lower limb amputation?
   - 18 to 25
   - 26 to 40
   - 41 to 65
   - Above 65

50) Are the majority of lower limb amputations related to illnesses and diseases or are the accident related?
   - Illness / Disease
   - Accident

51) If illness or disease is the primary cause of amputation, please list the 3 most common conditions.

Section 4 - Questions related to current issues

52) Select which issues are prevalent during the initial consultation with the amputee. Select as many as required.
   - Bad communication between amputee and prosthetist
   - The outcome (positive and negative effects) of the proposed prosthesis is not clear to amputee and/or prosthetist
   - Limited selection of standard sub-system parts (such as a knee sub-system or an ankle sub--system)
   - Limited sub-system parameter information (such as number of times the knee can flex/extend)
   - Lack of aesthetic options
   - Amputee involvement is limited due to amputee's inability to understand the proposed prosthetic solution
   - Choices are impacted by the level of aftercare that the amputee can receive

53) What additional issues, not mentioned in the previous question, do you encounter during the initial consultation?

54) Please select all applicable stakeholders involved in the initial consultation with the amputee.
- Amputee
- Amputee family member
- Prosthetist
- Prosthesis Technician
- Physiotherapist

55) Please list any other stakeholders present during the initial consultation that were not mentioned in the previous question.

56) What is the typical duration between the initial consultation and measurement of the amputee for a prosthesis, and the subsequent fitting of the prosthesis?
- Same day
- 1 week
- 2 weeks
- 3 weeks
- 4 weeks
- More than 4 weeks

57) How frequently do amputees come for maintenance and adjustments to their prosthesis?
- Multiple times a week
- Every week
- Every 2 weeks
- Every 4 weeks
- Every 6 weeks
- More than 6 weeks

58) Please identify up to five of the most prevalent challenges encountered in amputee aftercare and prosthesis maintenance and give a brief explanation. Examples of such challenges include frequent ulcer development or insufficient access to specialised facilities for amputees. Kindly list the challenges in order of significance, starting with the one that has the greatest impact as issue 1.

Section 5 – Questions related to the aftercare services provided

59) How satisfied are you with the current services in place to provide an amputee with a prosthesis, the maintenance of the prosthesis and the aftercare services available?
    - Very satisfied
    - Satisfied
    - Neutral
    - Dissatisfied
    - Very dissatisfied

60) Please give a brief explanation to your above answer.

61) In your opinion what changes to the current services would improve your ability to prove a service to amputees?

62) In your opinion, would a smart prosthesis capable of collecting data be beneficial in improving your ability to make informed design decisions, both in the development of services for amputees and in the design of new prosthetic devices? Examples of data are step count, detection of ulcers, wear and tear on prosthesis.
    - Definitely yes
    - Yes
    - Neutral
    - No
    - Definitely no

63) Please identify up to five types of data you consider important to collect, providing a brief explanation for each. Kindly prioritise the data types in order of significance, starting with the one that has the greatest impact as item 1.

64) What smart features, beyond data collection, do you believe would enhance your ability to deliver improved prosthetic designs and services within your profession? Please give a brief explanation to your answers. An example of smart features are sounds and alerts, fall monitors, auto adjustable shock absorbers, LED display

65) Do you consider an interactive tool, such as a computer program or mobile application, that enables the visualisation of the prosthesis and its sub-systems, along with their effects and outcomes related to prosthesis maintenance and amputee aftercare, to be beneficial?

- Definitely yes
- Yes
- Neutral
- No
- Definitely no

66) Throughout the prosthesis life-cycle, the amputee and their prosthesis interact with various stakeholders (e.g., prosthetists, prosthesis technicians, physiotherapists), each contributing expertise gained through their professional experience. In your opinion, should these stakeholders also be actively involved in the prosthesis decision-making process during the initial consultation?

- Definitely yes
- Yes
- Neutral
- No
- Definitely no

67) In your opinion, should amputees have the capability to perform minor adjustments to their prosthesis? For instance, adjustments could include modifying the angle of ankle inclination to ensure a better fit within a shoe.

- Definitely yes
- Yes
- Neutral
- No
- Definitely no

68) Considering that the amputee can now receive guidance from an interactive tool on performing minor adjustments, do you believe they should be permitted to make these adjustments independently?

- Definitely yes
- Yes
- Neutral
- No
- Definitely no

Final Section

69) Are there any other problems that you encounter in your profession that have not been discussed in the questionnaire?

Appendix 4 – Evaluation Questionnaires

Novel Prosthesis Development and Aftercare Service Evaluation – Amputee Perspective

This questionnaire aims to assess the effectiveness and impact of the smart prosthesis and its supporting framework based on the demonstration you will observe. The questions are designed to gather feedback on various aspects such as time efficiency, cost-effectiveness, functionality, emotional response, comfort, and aftercare. By participating, you will not only contribute to advancing prosthetic design and aftercare but also gain insights into innovations that can enhance clinical practices and improve user experiences and outcomes. Your perspective as a patient, as well as your experience will help shape the future of smart prosthetics and patient aftercare.

Brief Amputee Background

1. Please select an option from below that best suits you.
    - Male
    - Female

2. Kindly select the age bracket that best suits you.
    - Between 18 to 24 years old
    - Between 25 to 40 years old
    - Between 41 to 55 years old
    - Between 56 to 70 years old
    - More than 71 years old

3. How long have you been an amputee? Select the option that best suits you.
    - Between 0 to 5 years
    - Between 6 to 10 years
    - Between 11 to 15 years
    - Between 16 to 20 years
    - More than 20 years

Section 1: Falls and Recovery

This section pertains to the demonstration showcasing amputee falls and recovery time.

Section 1.1 Frequency and Recovery from Falls

4. In general, when you fall, are you able to pick yourself up and continue walking ordo you need assistance?
    - I am able to pick myself up and carry on walking
    - I am unable to pick myself up and require assistance

Section 1.2 Assistance Time for Falls

5. If you require assistance to get up from a fall, how long does it typically take for help to arrive?

- Between 1 and 5 minutes
- Between 5 and 10 minutes
- Between 10 and 15 minutes
- Greater than 15 minutes

Section 1.3 Automated Alert Systems

6. To what extent would you find an automated system that alerts your family members or caregivers with your location when you fall to be useful?

Highly useful				Not at all useful
1	2	3	4	5
○	○	○	○	○

Section 1.4 Recording Pain and Discomfort

7. To what extent would you consider recording any pain or discomfort and the cause of a fall as part of your patient history to help healthcare professionals?

Yes, definitely				No, definitely not
1	2	3	4	5
○	○	○	○	○

8. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

9. Are there any comments or suggestions that you would like to mention in regards tothe questions asked in this section?

Section 2: Prosthesis maintenance

This section pertains to the demonstration showcasing prosthesis maintenance and functionality.

Section 2.1 Frequency of Maintenance

10. How regularly do you take your prosthesis in for a general maintenance?

Very frequently Not at all

1	2	3	4	5
○	○	○	○	○

Section 2.2 Severity of Prosthesis Problems

11. How severe are the problems you typically encounter with your prosthesis?

Very severe				Not at all severe
1	2	3	4	5
○	○	○	○	○

Section 2.3 Automated Maintenance Detection

12. To what extent do you think an automated system that detects prosthesis maintenance issues would be beneficial in terms of maintaining functionality, reducing cost and reducing down-time?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

13. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

14. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 3: Early Detection of Ulcers

This section pertains to the demonstration of ulcer formation and detection

Section 3.1 Frequency of Ulcers

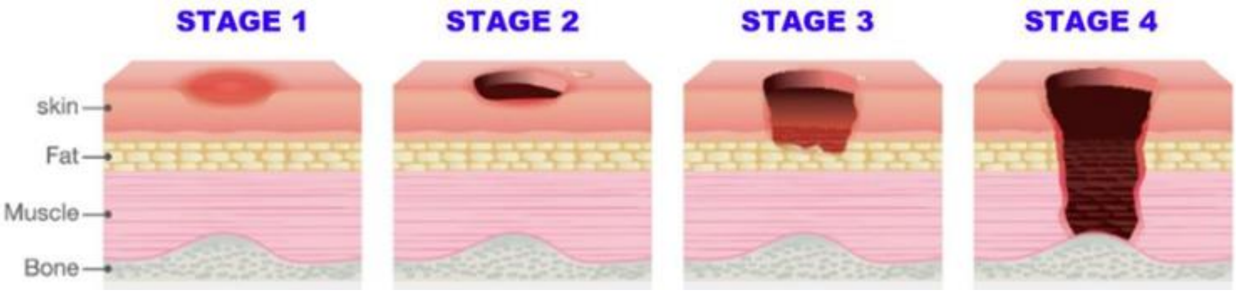
15. How frequently do you suffer from socket related ulcers?

Very frequently				Not at all

1	2	3	4	5
○	○	○	○	○

Section 3.2 Stage of Ulcer Development

16. At what stage did you notice that you have an ulcer?



- Stage 1 - Beginning
- Stage 2 - Mild
- Stage 3 - Medium
- Stage 4 - Severe

Section 3.3 Appointment Wait Time

17. Upon recognizing the presence of an ulcer, what is the typical wait time between scheduling an appointment and the actual consultation with your healthcare professional?
    - Less than 1 week
    - Between 1 and 2 weeks
    - Between 2 and 3 weeks
    - Between 3 and 4 weeks
    - Greater than 4 weeks

Section 3.4 Prosthesis Use During Ulcer Healing

18. To what extent do you think an automated detection system to detect ulcers at an early stage would be beneficial to you?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

19. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

20. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 4: Weight Distribution Imbalance

This section pertains to the demonstration showcasing postural imbalance that occurs while amputees are standing still and favouring their healthy leg.

Section 4.1 Favouring the Healthy Leg

21. How often do you realise that you favour your healthy leg while standing still?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

22. To what extent does the weight imbalance from favouring your healthy leg cause additional stress and/or pain to your health leg and/or lower back?

High effect				No effect at all
1	2	3	4	5
○	○	○	○	○

Section 4.2 Body Stress from Weight Imbalance

23. To what extent would you find an automated system to alert you to your bad posture to be useful in maintaining correct body posture and reducing complications from weight imbalance?

Highly effective				No effect at all
1	2	3	4	5
○	○	○	○	○

24. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

25. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 5: Excessive Stress Alerts

This section pertains to the demonstration showcasing the stresses exerted on the prosthesis and the generated alerts.

5.1 Prosthesis Failure Due to Stress

26. How often does your prosthesis fail due to excessive stress?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 5.2 Monitoring Prosthesis Stress

27. To what extent do you feel that a prosthesis stress monitor would help maintain its health, prolong its lifespan, and reduce costs?

Significantly				Not at all
1	2	3	4	5
○	○	○	○	○

28. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

29. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 6: Amputee Feedback and Aftercare

This section pertains to the demonstration about amputee feedback

Section 6.1 Stakeholder Communicating Issues

30. How often do you want to inform healthcare professionals about daily issues with your prosthesis but are unable to do so?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 6.2 Logging Daily Feedback

31. To what extent would you find the ability to record and submit your daily prosthesis related feedback to be beneficial to you for your aftercare and emotional support?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

32. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

33. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 7: Patient-Prosthesis Management System

This section pertains to demonstrated Patient-Prosthesis Management System

Section 7.1 Adequacy of Medical History

34. To what extend do you feel that you have an adequate prosthesis-related medical history?

Very good history				No history
1	2	3	4	5
○	○	○	○	○

Section 7.2 Detailed Patient-Prosthesis History

35. To what extent would a detailed prosthesis medical history would be to enable healthcare professionals to provide better, personalised aftercare?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 7.3 Patient-Prosthesis Management System

36. To what extent do you think the Patient-Prosthesis Management System would provide detailed history needed for improved healthcare service?

High improvement				No improvement at all
1	2	3	4	5
○	○	○	○	○

37. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

38. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Novel Prosthesis Development and Aftercare Service Evaluation – Prosthetist Perspective

This questionnaire aims to assess the effectiveness and impact of the novel Prosthesis Development and Aftercare Service. The questions are designed to gather feedback on various aspects such as time efficiency, cost-effectiveness, functionality, emotional response, comfort, and aftercare. By participating, you will not only contribute to advancing prosthetic design and aftercare but also gain insights into innovations that can enhance clinical practices and improve user experiences and outcomes. Your perspective as a healthcare professional, as well as your experience and expertise will help shape the future of smart prosthetics and patient aftercare.

Brief Prosthetist Background

1. Please select an option from below that best suits you.
    - Male
    - Female

2. Kindly select the best age bracket that suits you.
    - Between 18 to 24 years old
    - Between 25 to 40 years old
    - Between 41 to 55 years old
    - Between 56 to 70 years old

3. How long have you been practicing as a prosthetist?
    - Between 0 to 5 years
    - Between 6 to 10 years
    - Between 11 to 15 years
    - Between 16 to 20 years
    - More than 20 years

Section 1: Falls and Recovery

This section pertains to the demonstration showcasing amputee falls and recovery time.

Section 1.1 Frequency and Recovery from Falls

4. To what extent are you informed about your patient's falls?

I am always informed				I am not at all informed
1	2	3	4	5
○	○	○	○	○

Section 1.2 Assistance Time for Falls

5. To what extent would you find the information about the time it takes for your patient to receive assistance after a fall to be useful in providing better aftercare?

Highly useful				Not at all useful
1	2	3	4	5
○	○	○	○	○

Section 1.3 Automated Alert Systems

6. To what extent do you believe an automated alert system that informs family members or caregivers of a patient's fall would be beneficial in providing quicker assistance?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 1.4 Recording Pain and Discomfort

7. To what extent would it be useful for you to have access to a patient's recorded pain and discomfort following a fall?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

8. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

<u>Section 2: Prosthesis maintenance</u>

This section pertains to the demonstration showcasing prosthesis maintenance and functionality.

Section 2.1 Frequency of Maintenance

9. How often do your patients make appointments for their prosthesis or socket to undergo maintenance?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 2.2 Severity of Prosthesis Problems

10. In general, how severe are the prosthesis problems reported by your patients?

Very severe				Not at all severe
1	2	3	4	5
○	○	○	○	○

11. Does the severity of the problem increase the time, effort and cost to fix?

Very, very				No, not at all
1	2	3	4	5
○	○	○	○	○

Section 2.3 Automated Maintenance Detection

12. To what extent would an automated system that detects maintenance issues help you address problems before they become severe?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

13. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation

<u>Section 3: Early Detection of Ulcers</u>

This section pertains to the demonstration of ulcer formation and detection

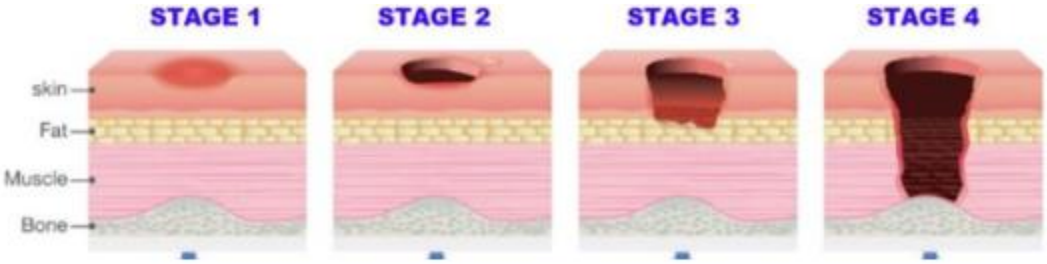
Section 3.1 Frequency of Ulcers

14. How frequently do your patients come in for socket adjustments due to ulcer formations?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 3.2 Stage of Ulcer Development

15. In general, what is the most common stage of ulcer that you see in your patients when they first approach you with their ulcers?



- Stage 1 - Beginning
- Stage 2 - Mild
- Stage 3 - Medium
- Stage 4 - Severe

Section 3.3 Appointment Wait Time

16. How long does it typically take for your patients to walk comfortably with their prosthesis after ulcer treatment?
    - Less than 1 week
    - Between 1 and 2 weeks
    - Between 2 and 3 weeks
    - Between 3 and 4 weeks
    - Greater than 4 weeks

Section 3.4 Prosthesis Use During Ulcer Healing

17. To what extent do you think an automated system to detect ulcers at an early stage be beneficial in terms of time and cost?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

18. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation

Section 4: Weight Distribution Imbalance

This section pertains to the demonstration showcasing postural imbalance that occurs while amputees are standing still and favouring their healthy leg.

Section 4.1 Favouring the Healthy Leg

19. How often do your patients complain of pain on their good side due to favouring their healthy leg while standing?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 4.2 Body Stress from Weight Imbalance

20. To what extent do you think an automated system to alert the amputee on their bad posture to be useful in maintaining correct body posture and reducing complications from weight imbalance?

Highly effective				Not at all effective
1	2	3	4	5
○	○	○	○	○

21. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

Section 5: Excessive Stress Alerts

This section pertains to the demonstration showcasing the stresses exerted on the prosthesis and the generated alerts.

5.1 Prosthesis Failure Due to Stress

22. How often do prostheses fail due to excessive stress caused by your patients?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 5.2 Monitoring Prosthesis Stress

23. To what extent do you feel that a prosthesis stress monitor would help maintain its health, prolong its lifespan, and reduce costs?

Significantly				Not at all
1	2	3	4	5
○	○	○	○	○

24. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation

Section 6: Amputee Feedback and Aftercare

This section pertains to the demonstration about amputee feedback

Section 6.1 Stakeholder Communicating Issues

25. How often are you able to discuss daily prosthesis issues with your patients?

Very often				Not at all
1	2	3	4	5
○	○	○	○	○

Section 6.2 Logging Daily Feedback

26. To what extent do you think that the ability for patients to record and submit their daily prosthesis related and emotional feedback would improve patient care?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

27. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation

<u>Section 7: Patient-Prosthesis Management System</u>

This section pertains to demonstrated Patient-Prosthesis Management System

Section 7.1 Adequacy of Medical History

28. To what extent is patient prosthesis related history readily available?

Highly available				Not at all available
1	2	3	4	5
○	○	○	○	○

Section 7.2 Detailed Patient-Prosthesis History

29. To what extent would a detailed and up-to-date patient history allow you to provide better and more personalised aftercare?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 7.3 Patient-Prosthesis Management System

30. To what extent do you believe the Patient-Prosthesis Management System would offer detailed and updated patient history needed for better care?

High improvement				No improvement at all
1	2	3	4	5
○	○	○	○	○

31. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation

Section 8: Final Section

32. Are there any comments / suggestions / feedback that you would like to share that you have not yet mentioned?

Novel Prosthesis Development and Aftercare Service Evaluation – Physiotherapist Perspective

This questionnaire aims to assess the effectiveness and impact of the novel Prosthesis Development and Aftercare Service. The questions are designed to gather feedback on various aspects such as time efficiency, cost-effectiveness, functionality, emotional response, comfort, and aftercare. By participating, you will not only contribute to advancing prosthetic design and aftercare but also gain insights into innovations that can enhance clinical practices and improve user experiences and outcomes. This showcasing how technology can support rehabilitation and facilitate smoother patient integration. Your perspective as a healthcare professional, as well as your experience and expertise will help shape the future of smart prosthetics and patient aftercare.

Brief Physiotherapist Background

1. Please select an option from below that best suits you.
    - Male
    - Female

2. Kindly select the age bracket that best suits you.
    - Between 0 to 5 years
    - Between 6 to 10 years
    - Between 11 to 15 years
    - Between 16 to 20 years
    - More than 20 years

3. How long have you been practicing as a physiotherapist working with amputees?
    - Between 0 to 5 years
    - Between 6 to 10 years
    - Between 11 to 15 years
    - Between 16 to 20 years
    - More than 20 years

Section 1: Falls and Recovery

This section pertains to the demonstration showcasing amputee falls and recovery time.

Section 1.1 Frequency and Recovery from Falls

4. To what extent do you receive information about patient falls?

I am always informed				I am not at all informed
1	2	3	4	5
○	○	○	○	○

Section 1.2 Assistance Time for Falls

5. To what extent does knowing how long it takes for a patient to get assistance after a fall help you in creating more effective physiotherapy recovery plans?

Highly useful				Not at all useful
1	2	3	4	5
○	○	○	○	○

Section 1.3 Automated Alert Systems

6. To what extent do you think an automated fall alert system would help in designing more targeted and effective physiotherapy sessions?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 1.4 Recording Pain and Discomfort

7. To what extent would having detailed records of a patient's pain and discomfort following a fall to improve their aftercare service?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

8. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

9. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 2: Prosthesis maintenance

This section pertains to the demonstration showcasing prosthesis maintenance and functionality.

Section 2.1 Frequency of Maintenance

10. Does the frequency of prosthesis maintenance affect the amount of physiotherapy needed for your patients?

Yes, definitely				No, not at all
1	2	3	4	5
○	○	○	○	○

Section 2.2 Severity of Prosthesis Problems

11. Does the severity of prosthesis problems increase the physiotherapy required for patients?

Yes, definitely				No, not at all
1	2	3	4	5
○	○	○	○	○

Section 2.3 Automated Maintenance Detection

12. To what extent would a regularly maintained prosthesis, that uses an automated detection system, be effective in reducing the amount of physiotherapy needed?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

13. With regards to the questions asked in this section, do you think that the proposed solutions can improve amputees' overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

14. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 3: Early Detection of Ulcers

This section pertains to the demonstration of ulcer formation and detection

Section 3.1 Frequency of Ulcers

15. How frequently do amputees’ need physiotherapy due to ulcer related issues?

Very frequently				Not at all
1	2	3	4	5
○	○	○	○	○

Section 3.2 Stage of Ulcer Development

16. Do you find that amputees who suffer from ulcers become more sedentary and inactive, thus requiring more physiotherapy to become active again?

Yes definitely				No, not at all
1	2	3	4	5
○	○	○	○	○

Section 3.3 Appointment Wait Time

17. Does the wait time for ulcer treatment affect the physiotherapy plan for patients?
    - Yes, longer wait times means that the amputee will require more physiotherapy
    - No, the waiting time does not require the amputee to have more physiotherapy

Section 3.4 Prosthesis Use During Ulcer Healing

18. To what extent do you believe an early detection system for ulcers would reduce the amount of physiotherapy needed for recovery?

High reduction				No reduction at all
1	2	3	4	5
○	○	○	○	○

19. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

20. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 4: Weight Distribution Imbalance

This section pertains to the demonstration showcasing postural imbalance that occurs while amputees are standing still and favouring their healthy leg.

Section 4.1 Favouring the Healthy Leg

21. How often do patients complain of pain on their good side and/or lower back due to weight distribution imbalance, and thus require additional physiotherapy?

Very often				No at all
1	2	3	4	5
○	○	○	○	○

Section 4.2 Body Stress from Weight Imbalance

22. To what extent do you believe an alert and reminder system for weight balance would indirectly reduce the need for physiotherapy due to bad posture related issues?

Highly beneficial				No at all beneficial
1	2	3	4	5
○	○	○	○	○

23. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

24. Are there any other comments or suggestions that you would like to mention in regards to the questions mentioned in this section?

Section 5: Excessive Stress Alerts

This section pertains to the demonstration showcasing the stresses exerted on the prosthesis and the generated alerts.

5.1 Prosthesis Failure Due to Stress

25. To what extent does excessive stress failures in prostheses result in additional physiotherapy needs for your patients?

High impact, significant physio required				No impact, additional physio not required
1	2	3	4	5
○	○	○	○	○

Section 5.2 Monitoring Prosthesis Stress

26. To what extent do you believe that a prosthesis stress monitor can reduce the need for physiotherapy due to fewer prosthesis failures?

Highly beneficial				No at all beneficial
1	2	3	4	5
○	○	○	○	○

27. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

28. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 6: Amputee Feedback and Aftercare

This section pertains to the demonstration about amputee feedback

Section 6.1 Stakeholder Communicating Issues

29. How frequently are you able to discuss daily physio and mobility issues with your patients?

Very frequently				No at all
1	2	3	4	5
○	○	○	○	○

Section 6.2 Logging Daily Feedback

30. To what extent do you think patient-submitted daily feedback would be beneficial for tailoring physiotherapy care?

Highly beneficial				No at all beneficial
1	2	3	4	5
○	○	○	○	○

31. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions? Please give a brief explanation.

32. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Section 7: Patient-Prosthesis Management System

This section pertains to demonstrated Patient-Prosthesis Management System

Section 7.1 Adequacy of Medical History

33. Is patient prosthesis related history readily available to you?

Highly available				No at all available
1	2	3	4	5
○	○	○	○	○

34. How detailed is the available patient history, to allow you to provide more targeted and personalise physiotherapy?

Highly detailed				No at all detailed
1	2	3	4	5
○	○	○	○	○

Section 7.2 Detailed Patient-Prosthesis History

35. To what extent would a detailed patient history allow you to provide better and more personalised physiotherapy services?

Highly beneficial				No at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 7.3 Patient-Prosthesis Management System

36. To what extent do you believe the Patient-Prosthesis Management System would provide the detailed history needed for better physiotherapy aftercare service?

Highly improvement				No improvement at all
1	2	3	4	5
○	○	○	○	○

37. With regards to the questions asked in this section, do you think that the proposed solutions can improve the amputee's overall experience and aftercare in terms of time, cost, functionality, comfort and emotions?

38. Are there any comments or suggestions that you would like to mention in regards to the questions asked in this section?

Novel Prosthesis Development and Aftercare Service Evaluation – Engineer / Product Designer Perspective

This questionnaire forms part of an academic evaluation of a novel Prosthesis Development and Aftercare Service Framework. The purpose of this study is to assess the perceived effectiveness and impact of the framework across key domains, including time efficiency, cost-effectiveness, functional performance, user comfort, emotional response, and quality of aftercare.

Integral to the demonstration is a digital design support tool developed to assist stakeholders, particularly engineers and product designers, in visualising the downstream implications of their design decisions across the prosthesis life-cycle. This tool, in conjunction with the broader ontology-driven service framework and smart prosthesis system, aims to promote more informed, collaborative, and human-centred design and development practices.

Your participation, as a professional in product design, is essential to evaluating the utility and relevance of this integrated approach, and to identifying ways it may support improved prosthesis outcomes and aftercare service provision.

Brief Engineer / Product Designer Background

1. Please select the option from below that best suits you.

    - Male
    - Female

2. Please select the age bracket that best suits you.

    - Between 18 to 24 years old
    - Between 25 to 40 years old
    - Between 41 to 55 years old
    - Between 56 to 70 years old

3. Please select the engineering professional background that best suits you.

    - Academic
    - Industrial Design
    - Clinical Engineer
    - Medical Devices
    - Design Engineer
    - Product Management
    - Other: ____

4. How many years of experience do you have in product design?

    - Between 0 to 5 years
    - Between 6 to 10 years

- Between 11 to 15 years
- Between 16 to 20 years
- More than 20 years

5. Have you previously been involved in designing healthcare-related products or assistive technologies? If yes kindly give a brief explanation of your experience.

- Yes
- No

6. Prior to this demonstration, how familiar were you with prosthetic devices and their development process?

Highly familiar	Familiar	Somewhat familiar	Vaguely familiar	Not at all familiar
1	2	3	4	5
○	○	○	○	○

7. To what extent are you familiar with product service system design frameworks or ontology-based systems?

Highly familiar	Familiar	Somewhat familiar	Vaguely familiar	Not at all familiar
1	2	3	4	5
○	○	○	○	○

Section 1: Evaluation of the Demonstrated Product Service System Framework and Design Tool

8. To what extent do you believe the digital design tool demonstrated could support informed decision-making in prosthesis development?

Highly useful				Not at all useful
1	2	3	4	5
○	○	○	○	○

9. To what extent do you believe that the demonstrated framework and design tool helped communicate the consequences of design decisions in the following area:

   a. Time efficiency
   b. Cost effectiveness
   c. Functionality / maintenance requirements
   d. User comfort and fit

e. Emotional well-being of the user
f. Aftercare procedures

	Very well 1	2	3	4	Not at all well 5
a	○	○	○	○	○
b	○	○	○	○	○
c	○	○	○	○	○
d	○	○	○	○	○
e	○	○	○	○	○
f	○	○	○	○	○

10. To what extent do you believe that integrating real-world data (e.g. from smart prosthesis) into the design process enhances understanding of post-deployment product performance?

Strongly agree 1	Agree 2	Neutral 3	Disagree 4	Strongly disagree 5
○	○	○	○	○

11. How effective was the design tool and demonstration in helping you to visualise and understand the impact of design decisions with real-world outcomes?

Highly effective 1	2	3	4	Not at all effective 5
○	○	○	○	○

12. To what extent do you believe that the system effectively supports consequence-driven learning, where long-term impacts of early-stage decisions could be visualised or anticipated?

Strongly agree 1	Agree 2	Neutral 3	Disagree 4	Strongly disagree 5
○	○	○	○	○

13. To what extent do you believe that the design framework was useful in facilitating a cross-disciplinary design perspective (e.g. collaboration with clinicians, users, and other stakeholders)?

Highly beneficial 1	2	3	4	Not at all beneficial 5
○	○	○	○	○

14. To what extent do you believe this framework supports more efficient product development (such as a prosthesis)?

Highly beneficial 1	2	3	4	Not at all beneficial 5
○	○	○	○	○

15. Which features of the demonstrated tool/framework were particularly beneficial for the design process?

16. Could any of these features be applied to non-medical or unrelated product domains? Give a brief explanation for your answer.

Definitely yes				Definitely not
1	2	3	4	5
○	○	○	○	○

Section 2: Scenario-Based Design Reflections

Section 2.1: Falls and Safety Design Implications

17. To what extent would the ability to detect and log sudden failures or unsafe conditions (e.g. such as when a patient falls) be beneficial in helping design better solutions (e.g. prioritising safety features in design or balance related design choices)?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 2.2: Prosthesis Maintenance

18. To what extent would automated detection of mechanical issues be beneficial for long term durability and maintainability of the prosthesis?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

19. To what extent does early detection of mechanical stress influence your component selection?

Very much				Not at all
1	2	3	4	5
○	○	○	○	○

20. To what extent would automated detection of mechanical issues help balance initial cost with long-term performance?

Very much				Not at all
1	2	3	4	5
○	○	○	○	○

Section 2.3: Early Detection of Ulcers

21. To what extent do you think that the early detection of pressure related socket ulcers would be beneficial in providing the ability to design better solutions to improve user comfort (e.g. in terms of socket design, material choice)?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

22. To what extent would such feedback support more modular or user-specific product iterations?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

Section 2.4: Weight Distribution Imbalance

23. To what extent do you think the continuous monitoring of performance (e.g. user posture and gait) would be beneficial if used to guide future design iterations?

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

24. To what extent would this reduce the redesign and iterative testing cycles of the product (e.g. such as the prosthesis)?

High reduction				No reduction at all
1	2	3	4	5
○	○	○	○	○

Section 2.5: Excessive Stress Alerts

25. To what extent do you think a stress monitor would help in:

    a. Maintaining prosthesis functionality
    b. Prolong prosthesis life span
    c. Reduce maintenance costs

	Very well 1	2	3	4	Not at all well 5
a	○	○	○	○	○
b	○	○	○	○	○
c	○	○	○	○	○

Section 2.6: Amputee Feedback and Aftercare

26. To what extent do you think recorded feedback from the user (e.g. frustration, stress, or disengagement during use) would be beneficial in providing you with additional information to better help during the design process?

Highly beneficial 1	2	3	4	Not at all beneficial 5
○	○	○	○	○

27. To what extent would insights into emotional engagement be beneficial in selecting specific design choices?

Highly beneficial 1	2	3	4	Not at all beneficial 5
○	○	○	○	○

Section 2.7: Patient-Prosthesis Management System

28. To what extent do you think an up-to-date patient-prothesis history would be beneficial in providing you with additional information during the design process?

Highly beneficial 1	2	3	4	Not at all beneficial 5
○	○	○	○	○

<u>Section 3: Relevance to ‘Your’ Design Practice</u>

29. To what extent could you envisage incorporating a similar design and consequence visualisation approach into design workflow in different areas? Please give a brief explanation as to your reasoning.

Yes Definitely				Definitely not
1	2	3	4	5
○	○	○	○	○

30. In your opinion, which stages of the product development cycle would benefit most from this kind of ontology-based, data-informed framework?

- Concept generation
- Requirements specification
- Prototyping
- Testing and validation
- Post-deployment monitoring
- Other: ____

31. What additional data or features would you find useful to be integrated into this design support system?

<u>Section 4: Human-Centred Design and Aftercare Consideration</u>

32. To what extent do you think stress monitoring or emotional response logging would affect your approach to user experience design?

High effect				No effect at all
1	2	3	4	5
○	○	○	○	○

33. To what extent do you think the framework and the supporting systems are able to cater for the evolving physical and emotional needs of the prosthesis user? Please give a brief explanation.

Highly beneficial				Not at all beneficial
1	2	3	4	5
○	○	○	○	○

34. To what extent does the framework and design tool support emotionally aware design?

High support				No support at all
1	2	3	4	5
○	○	○	○	○

35. To what extent do you think that product designers should be involved in designing for aftercare services, not just the physical product? Please give a brief explanation to your reasoning.

Highly involved				Not at all involved
1	2	3	4	5
○	○	○	○	○

36. To what extent did this demonstration change your perspective on the designer’s role in long term user experience and healthcare outcomes? Please give a brief explanation.

Yes Definitely				Definitely not
1	2	3	4	5
○	○	○	○	○

Section 5: Overall Assessment and Future Use

37. To what extent do you think the potential of this ontology driven framework and digital tool in improving:

    a. Design decision quality
    b. Collaboration among stakeholders
    c. Efficiency of the prosthesis development cycle
    d. Quality of aftercare services

	High improvement 1	2	3	4	No improvement 5
a	○	○	○	○	○
b	○	○	○	○	○
c	○	○	○	○	○
d	○	○	○	○	○

38. What are the most impactful elements of the smart prosthesis framework from your design perspective and why? Please give a brief explanation.

39. To what extent would you consider adopting a framework and design tool like this if it were generalised for use in other domains beyond prosthesis, such as in your area of expertise? Please give a brief explanation.

Yes Definitely 1	2	3	4	Definitely not 5
○	○	○	○	○

40. What improvements or additional capabilities would you recommend for the tool or the framework to better support design work?

41. Any additional comments, feedback or suggestions?

Appendix 5 – Pier Reviewed Papers

1) Patiniott, N. *et al.* (2022) 'Towards a Product Service System Framework for Lower Limb Prosthetic Devices', *Proceedings of the Design Society*, 2, pp. 1341–1350. doi:10.1017/pds.2022.136.

2) Patiniott, N. *et al.* (2023) 'ELEMENTS OF A PRESCRIPTIVE AND ADAPTIVE PROSTHESIS DEVELOPMENT SERVICE FRAMEWORK', *Proceedings of the Design Society*, 3, pp. 1605–1614. doi:10.1017/pds.2023.161.
   Awarded the Reviewers' Favorite Award as decided by the ICED23 awards committee

3) Patiniott, N., Vella, P. C., Borg, J. C., Gatt, A., Francalanza, E., Paetzold-Byhain, K., & Zammit, J. P. (2023, September). Towards an Ontology For a Smart and Adaptive Prosthesis Service System Framework. Conference on Integrated Systems in Medical Technologies (ISMT), Erlangen. 32-37.

4) Patiniott, N. *et al.* (2024) 'An AI-based prosthesis framework fostering an adaptive amputee healthcare service', *Proceedings of the Design Society*, 4, pp. 2187–2196. doi:10.1017/pds.2024.221.

5) Patiniott, N. *et al.* (2025) 'Advancing prosthesis design: ontology driven multi-disciplinary framework for evolving amputee needs', *Proceedings of the Design Society*, 5, pp. 349–358. doi:10.1017/pds.2025.10049.

6) Patiniott, N. et al. (2025) 'Ontological Modelling for Consequence-Driven Learning: A Human-Centred Simulation Approach to Smart Prothesis Design and Education', Proceedings of the International Conference on Engineering and Product Design Education, pp. 3005-4753. Doi: 10.35199/EPDE.2025.29

7) Patiniott, N., Borg, J., Farrugia, P., Mercieca, A., Gatt, A., & Casha, O. (2025). Design and Implementation of an Ontology-Driven Cyber–Physical Prosthesis Service System for Personalised and Adaptive Care. Applied Sciences, 15(23), 12637. https://doi.org/10.3390/app152312637