MaltaHip Project: What's Next?

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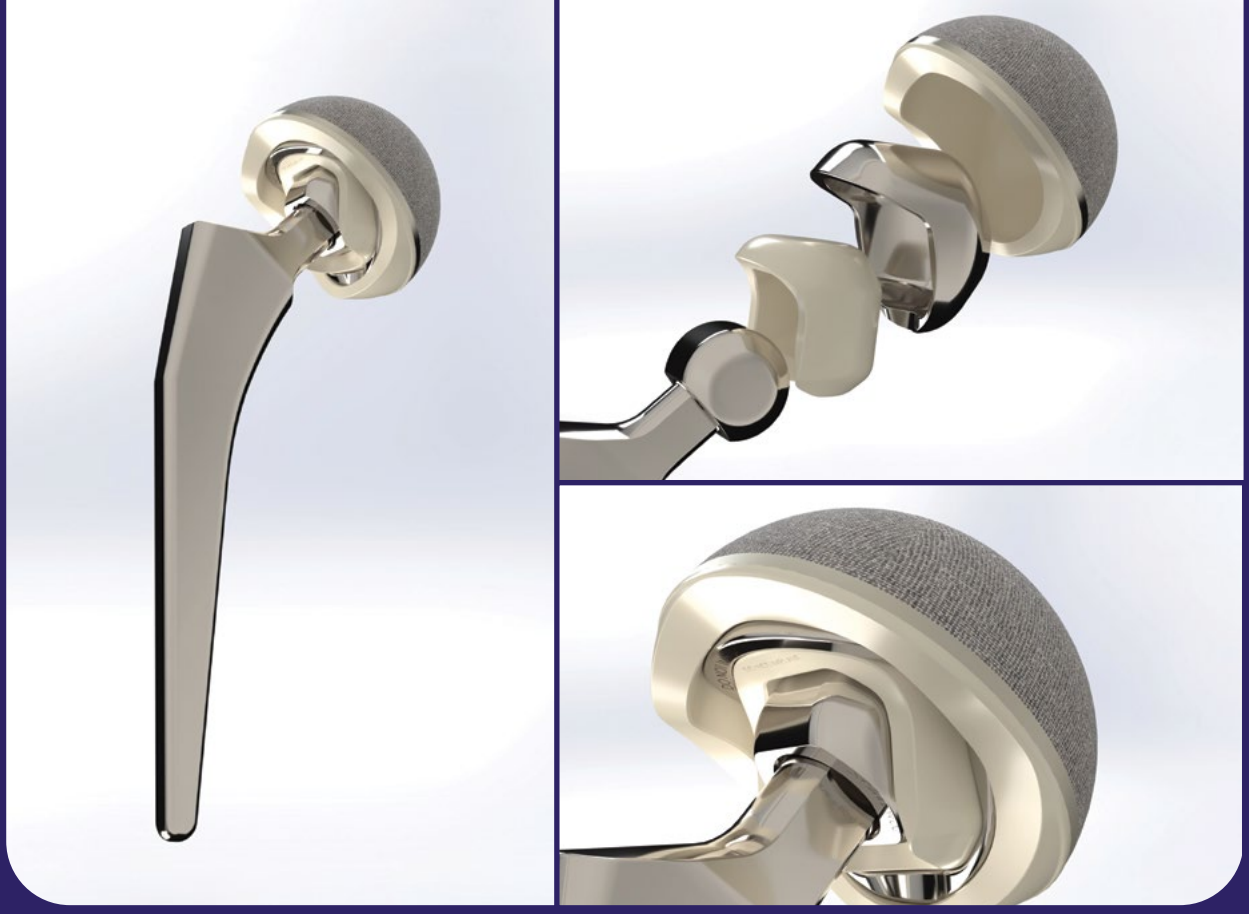
*When the **MaltaHip** project was first introduced, it marked a rethinking of hip replacement. Now, with successful early testing, new international partnerships, and a growing pipeline of funding, that leap is well on its way to becoming a globally significant reality.*

From its inception, the MaltaHip project aimed to address some of the persistent challenges associated with traditional hip implants in the ever-evolving field of medical devices. Requiring an interdisciplinary approach, the project brought together Prof. Pierre Schembri-Wismayer (Department of Anatomy); Prof. Ing. Pierluigi Mollicone (Department of Mechanical Engineering); and Prof. Ing. Joseph Buhagiar, Dr Ing. Donald Dalli, Dr Leonardo Fanton, and Prof. Ing. Bertram Mallia (Department of Metallurgy and Materials Engineering). This multifaceted team from the University of Malta, now collaborating with Garland Surgical Ltd – a UK-based start-up company – is working towards a solution for the millions suffering from joint-related issues worldwide.

FROM LAB TO REAL-WORLD READINESS

Research is the backbone of innovative technology development. However, without guidance on the criteria that must be met, it is hard for researchers and entrepreneurs to know the optimal moment to bring their ideas and products to market. Technology readiness levels (TRLs) – a ranking system originally developed by NASA – was designed to do just that. The TRL system assists in evaluating and managing



Photorealistic renderings of the prosthetic hip joint
Images courtesy of the MaltaHip Team

the progression of new technologies from concept to deployment. It ranges from level 1 (basic research) to level 9 (fully proven technology in real-world use), and has specific criteria required at each stage to advance to the next.

For MaltaHip, the journey has progressed from TRL 3–4 (university prototype testing) to TRL 6 (refined prototype successfully tested in cadaveric implantation). Reaching even TRL 3 was no easy feat, explains Buhagiar, one of the MaltaHip inventors. The researchers had to design and build a custom machine that replicates all the movements of the hip joint while applying a variable load to simulate body weight. These initial wear-simulation tests were performed to 'see if the sizing was correct, if the parts were moving correctly, and to identify any obvious problems,' says Buhagiar. 'As everything was functional, we could proceed to the next step.'

Once it was clear that the proof-of-concept was viable, the UM research team – with the assistance of EMPAV Engineering Ltd, a Maltese manufacturing engineering workshop – produced additional prototype prostheses that met all the functional criteria for a hip replacement. This prototype was then sent to EndoLab® in Germany, a facility specialising in biomechanical testing. There, MaltaHip surpassed expectations. Following simulations mimicking millions of gait cycles (the cyclic pattern of movement that occurs while walking), the device exhibited significantly less wear than traditional commercial hip implants. In fact, in some cases, the wear was too minimal to measure. This result alone demonstrated that the prosthesis could handle high loads without degradation, while also suggesting longer-lasting use – a factor that could redefine standards in orthopaedic care. At this time, MaltaHip was no longer just an innovative concept.

What are the next steps?

'We incorporated Garland Surgical Ltd to further develop what was a promising proof-of-concept project into a commercially viable hip replacement system. We raised initial funding of around €1.5 million to further develop the implant design into a device that would suit a global population – addressing the three key limitations of the existing available implants: namely, reduction of wear, stability, and range of motion,' explains Simon Mifsud, CEO of Garland Surgical Ltd.

'Now that we've completed the initial verification of the latest prototype, we are raising more funds to complete product development. This will allow us to complete something called the design history file – organised documentation of all the product design

The Garland Team, supported by their Clinical Advisors, Board Members, NLC Health Ventures, and Engineering Consultants at the MaltaHip Revision System Cadaveric Testing Lab (West Midlands Surgical Training Centre, Coventry)

Photo courtesy of the Garland Team

and development processes – and then begin the regulatory clearance needed to sell it worldwide.'

A SMARTER DESIGN, PROVEN BY SCIENCE

What explains the exceptional wear resistance at the heart of MaltaHip's novel design? A considerable difference from all of the traditional hip replacements, which simulate the ball-and-socket nature of the human joint, lies in 'the molecular behaviour of the used polymeric materials in the prosthetics,' says Schembri-Wismayer. Unlike current implants on the market, the unidirectional curvilinear articulations of the MaltaHip allow the molecular chains in the polymer components to align in a single direction under pressure. This alignment reduces a common phenomenon known as 'cross-shear' and significantly improves resistance to degradation.

During the initial cadaveric implantation performed by orthopaedic surgeons, the device's excellent mobility was also confirmed – their impression being jovially relayed by Schembri-Wismayer as 'even allowing the "patient" to do yoga (another proof of its range of motion)'. These real-world assessments are key to demonstrating that the device can support not only routine activities, but also higher mobility demands, such as sports or physically active lifestyles.'

SERVING A GLOBAL POPULATION

Manufacturers develop a full range of implant sizes to accommodate anatomical differences across gender and ethnicity – MaltaHip is no exception. However, the company's commitment to inclusive design goes far beyond size alone. 'Traditional implants last for a maximum of 25 years if they're placed well and use the current state of the art, which is based on a regular ball-and-socket replication of the natural hip,' states Mifsud. 'But those hip replacements have been developed in the same basic format for 120 years, and their longevity has only increased by 10 to 15 years – thanks to improvements in surgical technique and surgical approach, as well as advances in material technology.'

'This is a major concern when it comes to younger patients,' he adds. 'They don't have much choice now. They will either bear discomfort, chronic pain, and restricted mobility, or undergo surgery knowing that traditional implants may last only 20 to 25 years – meaning multiple revision surgeries over the course of their lifetime.' However, even for those who choose to undergo a hip replacement, there remains a risk of dislocating the new joint, especially within the first 12 months post-operation. This can impact not only their activity levels, but also their overall health.

'Due to its design, the MaltaHip prosthetic cannot be dislocated easily. That means the patient is able to perform daily activities like tying a shoelace, sitting cross-legged, or swinging their affected leg out of bed without dislocating their hip after surgery. These are things we all take for granted. They will also be able to pursue their interests, whether that's playing tennis, practising yoga or

The MaltaHip Team

Top: Prof. Ing. Joseph Buhagiar (Project Leader), Prof. Pierre Schembri-Wismayer (Main Inventor) and Prof. Ing. Pierluigi Mollicone (Inventor)

Bottom: Dr Ing. Donald Dalli (Inventor), Prof. Ing. Bertram Mallia (Collaborator) and Dr Leonardo Fanton (Research Support Officer IV)

surfing; they can feel confident in their implant,' Mifsud points out. By offering greater longevity and a lower risk of failure, MaltaHip provides a viable option for younger patients who want to reclaim their mobility and quality of life early – without sacrificing long-term outcomes.

The Team also highlighted a final point about the device's long-term value. Culturally, certain ethnicities require a larger range of motion than others – for example, some Asian and Middle Eastern populations sit cross-legged or in a squatting position to socialise or pray. With a standard hip replacement, this can be risky. 'With our device, we believe they will be able to do that. This device has been designed to suit a global population, addressing a lot of the current health inequalities in hip replacements,' Mifsud notes.

STRATEGIC INVESTMENT IN MALTA

Beyond medical innovation, MaltaHip is becoming a symbol of successful technology transfer and international collaboration. Garland Surgical Ltd has recently opened a subsidiary in Malta, establishing operations at the Malta Life Sciences Park and securing grant support from Malta Enterprise. This includes R&D funding, business development incentives, and hiring local engineering talent, including Dalli – one of the original MaltaHip inventors.

These investments are not just a win for the project; they represent a vote of confidence in Malta's growing biotech and medtech sectors. With UM retaining shares in the company and serving as an R&D partner, the MaltaHip project is also a textbook case of how academia and industry can work hand-in-hand to build globally competitive products.

While much has been achieved, there is still a long road ahead. Garland Surgical Ltd is currently raising a £3.5 million seed round to complete its design history file – the cornerstone document required for medical regulatory approval. Following that, the company will begin rigorous production-level testing on multiple implant sizes and prepare for regulatory submissions to meet the criteria for TRL 7.

MaltaHip is not just an invention – it is a reinvention of what orthopaedic medicine can achieve. With its roots firmly planted in research from the University of Malta and its branches reaching into global markets, it offers a rare fusion of innovation, inclusivity, and impact. As Garland Surgical Ltd advances clinical and commercial development, the MaltaHip project may well become one of the island's most remarkable contributions to global health.

Scan the QR code to read more about the MaltaHip Project