An Investigation on the effect of Custom-made orthoses in Combination with Physiotherapy Management in the Treatment of Non-Specific Mechanical Low Back Pain

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Abstract

An investigation on the effect of Custom-made foot orthoses in Combination with Physiotherapy Management in the Treatment of Non-Specific Mechanical Low Back Pain

Aim

The aim of this study was to investigate whether there would be significant effect on pain, disability, as well as on kinematic and spatiotemporal data during gait at heel strike, midstance, and toe-off when prescribing custom-made foot orthoses in combination with 6-week physiotherapy intervention in individuals diagnosed with Non-Specific Mechanical Low Back Pain.

Research Design and Method

This research project was a Quantitative, Postpositivist, and Quasi-experimental study which investigated the effects of custom-made foot orthoses in combination with physiotherapy management in the treatment of Non-Specific Mechanical low back pain. 20 participants were recruited and divided into two equal groups; quantitative data was collected from Comparison Group A, who underwent 6-weeks physiotherapeutic intervention, and Experimental Group B, who were provided with custom-made foot orthoses in addition to the physiotherapeutic intervention. Data collected at baseline and following a six-week intervention period included the Oswestry Disability Index Questionnaire score, the Visual Analog scale score, lower limb, pelvic kinematics, and spatiotemporal data obtained from Gait Analysis testing using Vicon Optoelectronic Motion Capture System. Statistical analyses were consequently carried out to evaluate the effects of combining custom-made foot orthoses with six-weeks physiotherapy intervention in the treatment of Non-Specific Mechanical low back pain.

Results

In both Group A and Group B, there was a statistically significant improvement in pain and disability ($p=<0.05$), but the improvement was not statistically significantly different between the two groups. Significant Kinematic changes were noted in both groups, with changes in the pelvis noted only in Group B, and Spatiotemporal data were noted. An increase in Walking Speed was noted in Group A and a decrease in Cadence, a decrease in single support and stride time in Group B. It was also noted that Group B became closer to Normative Data post-intervention.

Conclusion

The findings in the present study indicate that both 6-week physiotherapy intervention only and 6-week physiotherapy intervention combined with custom-made foot orthoses are effective in reducing pain and disability in the management of Non-Specific Mechanical Low Back Pain. However, the orthoses group exhibited a trend towards more normalization of the gait pattern, which, in the long term, could translate into an added benefit for the patient. However, this will need to be investigated further. Both types of interventions should be considered in the management of Low Back Pain patients who also present with altered foot biomechanics.

Keywords: Non-Specific Mechanical Low Back Pain, Pain, Disability, Kinematics, Orthoses, Physiotherapy

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Chapter 1 Introduction

1.1. Background

Low back pain is a leading cause of disability and is well documented to be a prevalent health problem. Its occurrence is in similar proportions in all cultures, and it is found that it interferes with quality of life and work performance, Low Back Pain is also the most common reason for medical consultations. The World Health Organisation (WHO) showed that it is present in similar proportions in several countries, contrasting with the previous belief that it was a problem primarily confined to western countries. There is a reported lifetime prevalence of 94% of people living with Low Back Pain, which is considered as a high prevalence, and that about 23% of the reported Low Back Pain is chronic, where 11-12% of the population has reported disability related to Low Back Pain. Few cases of back pain are due to specific/non-mechanical causes; most cases are non-specific/mechanical. (Balague et al.2011)

Acute back pain is the most common type of low back pain, which is usually self-limiting, and lasts less than four to six weeks. Chronic back pain is a more complex problem, which often has a solid psychological overlay: work dissatisfaction, boredom, and a generous compensation system contribute to it. (Balague et al.2011)

The WHO (2013) estimated that low back pain is one of the top ten disability-adjusted life years which causes diseases and injuries, and that it is higher than Human Immunodeficiency Virus, road injuries, tuberculosis, lung cancer, chronic obstructive pulmonary disease, and preterm birth complications. WHO also points out that the lifetime prevalence of non-specific mechanical low back pain, which is the most common type of low back pain, is estimated to be at 60-70% in industrialized countries. It also points out

that the prevalence of low back pain will increase as the world population ages due to its relation to the deterioration of the intervertebral discs in the spine.

The impact of low back pain on socioeconomic status was also discussed in the 2013 Background Paper. It discusses how such impact is especially in relation to work loss, since low back pain is recognised as one of the leading causes of activity limitation and work absence. This results in an economic burden on individuals, families, communities, industry, and governments. In fact, following several studies in Europe, it has been found that in the United Kingdom, Low Back Pain was identified as the most common cause of disability, especially in young adults, where more than 100 million workdays are collectively low per year. (WHO, 2013)

The most recent documented statistical evidence of the situation of how Low Back Pain impacts the Maltese Population was published by Cuschieri et al. (2020), who looked at data dated back to 2015 from the Maltese European Health Interview Survey Database. The European Health Interview Survey is a study in which information on health-related issues is systematically collected. The latter's outcome is not currently accessible; therefore, it is not possible to see more comprehensive and recent updates on the prevalence of low back pain and its associated disabilities in the Maltese population. Nevertheless, from the 2015 database, as well as from the paper written by Cuschieri et al.(2015), it is clear that low back pain imposes a substantial burden on the Maltese population and level of disability in relation to it, with a total of 23,649 Maltese living with Low Back Pain, with females experiencing a higher Low Back pain burden when compared to males.

Chuter et al. (2014) explains how foot function is one of the aetiological mechanisms suggested that affect the development of low back pain. This can be attributed to excessive foot pronation or supination, leading to kinematic angles and gait changes. Orthoses have traditionally been prescribed to reduce such effects. Nevertheless, foot orthoses are not currently considered in international and national guidelines for managing Non-Specific Low Back Pain.

This was also the case in the European Guidelines for the Management of Chronic Non-Specific Low Back Pain (2006), which provides evidence-based guidelines to provide a set of recommended treatments for chronic non-specific mechanical low back pain. These guidelines recommend conservative management such as physiotherapy in relation to supervised exercise therapy and educational interventions, but no mention is made to the prescription of custom-made foot orthoses. The latter could be due to the limited amount of research done on the matter up to 2006, as the European Guidelines have not been updated since. However, as may be evidenced in Chapter 2 of this dissertation, more trials were carried out after 2006 to investigate the effectiveness of prescribing custom-made foot orthoses in the management of low back pain. Despite varying results, most studies showed a positive effect on low back pain when prescribing custom-made foot orthoses (Soo-Hyun Kim et al.,2015; Castro-Mendez et al., 2012; Kwang Yang Park, 2017; Rosner et al., 2013).

In fact, Kim et al. (2016) explained how orthoses intervention influences lower extremity movement pattern by means of mechanical control and biofeedbackThat is because orthoses increase foot stability by means of providing contact for weight-bearing across a more significant part of the sole of the foot. This may decrease the rotational

forces on the lower limbs. Another way orthoses assist in decreasing pain is by providing an increased sensory input from the sole surface, which would also result in the stimulation of proprioceptive receptors. A decreased perception of pain might relax tight muscular structures and reduce muscle tension asymmetry. Therefore, most clinicians, notably podiatrists, link the use of custom-made foot orthoses with the relief of Low Back pain, reasoning that back pain may be related to the disruption of biomechanics and disruption of the kinetic chain. (Kim et al.,2016)

1.2. Justification of the Study

As discussed in the next chapter, the literature search yielded findings on the effects of custom-made foot orthoses on low back pain, or the effects of physiotherapeutic interventions on low back pain, separately. This was also pointed out by Castro-Mendez et al.(2012) in their study. They pointed out that low back pain was not entirely eliminated following the four weeks intervention with custom-made foot orthoses. Their results indicated that a more extended intervention period might have been required or that other factors needed to be evaluated. Participants were instructed not to receive any other medical, podiatry, or physiotherapy treatment during the study, which makes room for further research on the outcome should any of these exclusion criteria be combined with the prescription of custom-made biomechanical foot orthoses. In fact, following Castro-Mendez et al.(2012) recommendations, the literature search yielded no results answering the research question of this dissertation. Therefore, further investigations are required on this matter.

This can also be applied in the context that mechanical low back pain affects up to 94% of the population in western countries, with 11-12% ending with disabilities due to low back pain. Therefore, this study aimed to evaluate alternative, possibly more effective means to help manage mechanical low back pain and associated disability that affects the quality of life.

1.4. Research Question

What are the effects on pain, disability, and lower limb kinematics when prescribing custom-made foot orthoses in combination with physiotherapy intervention in individuals diagnosed with Non-Specific Mechanical Low Back Pain?

1.5. Aim

This dissertation aimed to investigate whether there would be significant effect on pain, disability, as well as on kinematic and spatiotemporal data during gait at Heel Strike, Midstance and Toe off, when prescribing custom-made foot orthoses in combination with 6 week physiotherapy intervention in individuals diagnosed with Non-Specific Mechanical Low Back Pain.

1.6. Objectives

Objectives of this research study are:

i. To compare outcomes in pain measured by the Visual Analog Scale between the two different types of treatment methods in the management of Non-Specific Mechanical low back pain between the two experiment groups, where one of the groups had a 6-week physiotherapeutic

intervention, and the other group had a 6-week physiotherapeutic intervention combined with custom-made foot orthoses.

ii. To investigate outcome in disability measured by the Oswestry Disability Index between the two different types of treatment methods in the management of mechanical low back pain between the two experiment groups where one of the groups had a 6-week physiotherapeutic intervention, and the other group had a 6-week physiotherapeutic intervention combined with custom-made foot orthoses.

iii. To investigate the kinematic and spatiotemporal data biomechanical changes at heel strike, midstance, and toe-off during the gait cycle before and after intervention in two experiment groups where one of the groups had a 6-week physiotherapeutic intervention, and the other group had a 6-week physiotherapeutic intervention combined with custom-made foot orthoses.

iv. To compare the kinematic and spatiotemporal data biomechanical changes at heel strike, midstance, and toe-off during the gait cycle between two experiment groups where one of the groups had a 6-week physiotherapeutic intervention, and the other group had a 6-week physiotherapeutic intervention combined with custom-made foot orthoses.

1.7. Hypothesis

1.7.1. Primary Hypothesis.

Alternative Hypothesis: custom-made foot orthoses in combination with 6-week physiotherapy management result in statistically significant differences in pain, disability, kinematic and spatiotemporal outcomes in managing Non-Specific Mechanical Low Back Pain.

Null Hypothesis: custom-made foot orthoses in combination with 6-week physiotherapy management do not result in statistically significant differences in pain, disability, kinematic and spatiotemporal outcomes in managing Non-Specific Mechanical Low Back Pain.

1.7.2. Secondary Hypotheses. The Secondary Hypotheses are required to answer the Primary Hypothesis in relation to:

1.7.2.1. Comparison Before and After in Experimental Group A and Experiment Group B separately.

The **null hypothesis** states that there are no significant differences between Oswestry Disability Index Mean results, Visual Analog Scale Mean Results, Kinematic and Spatiotemporal Data at Heel Strike, Midstance and Toe Off within the gait analysis mean results in Comparison Group A subjects Before Intervention and Oswestry Disability Index Mean results, Visual Analog Scale Mean Results, Kinematic and Spatiotemporal

Data at Heel Strike, Midstance and Toe Off within the gait analysis mean results in Comparison Group A subjects After Intervention.

The **alternative hypothesis** states that there are significant differences between Oswestry Disability Index Mean results, Visual Analog Scale Mean Results, Kinematic and Spatiotemporal Data at Heel Strike, Midstance and Toe Off within the gait analysis mean results in Comparison Group A subjects Before Intervention and Oswestry Disability Index Mean results, Visual Analog Scale Mean Results, Kinematic and Spatiotemporal Data at Heel Strike, Midstance and Toe Off within the gait analysis mean results in Comparison Group A subjects After Intervention.

The above is also applicable for Experiment Group B.

1.7.2.2. Comparison between Comparison Group A and Experiment group B.

The **Null Hypothesis** states that there is no significant difference in Visual Analog Scale difference, Oswestry Disability Index difference; and Kinematic and Spatiotemporal Data difference at Heel Strike, Midstance and Toe off between Comparison Group A and Experiment Group B.

The **Alternative Hypothesis** states that there is a significant difference in Visual Analog Scale difference, Oswestry Disability Index difference; and Kinematic and Spatiotemporal Data difference at Heel Strike, Midstance and Toe off between Comparison Group A and Experiment Group B.

1.8. Layout of the dissertation

This dissertation constitutes of six different chapters, which are as follows:

Chapter 1: Presents background on the study. This is done by explaining the context of the implications of Low Back Pain in our society, gaps found in the literature regarding the research question, as well as the measures taken within this dissertation in order to address such gaps. In this chapter, one also finds the aim, objective, and hypotheses.

Chapter 2: This chapter includes an extensive literature review utilizing keywords associated with the research question and the subject being investigated in this study. The keywords mainly included Low Back Pain (non-specific/musculoskeletal), custom-made foot orthoses, physiotherapy, 3D-gait analysis. The selection of such keywords reflected the aim of this dissertation and yielded any scientific evidence available on the subject. This helped to identify any gaps and other research questions that have been presented from such literature.

Chapter 3: This chapter includes an in-detail breakdown of the methodology, theoretical framework, and research design used to answer the research question. In this chapter, one also finds a critical analysis on the reliability and validity of the study, as well on the research tools used, including the Visual Analog Scale, Oswestry Disability Index, and the Vicon 3d-gait Analysis.

Chapter 4: In this chapter, one finds the presentation of the results following the data collection. This is followed by the statistical analysis grouped according to the treatment

outcome in relation to pain (using the VAS) and disability (using the ODI) between the two groups. Statistical analysis also includes the kinematic and spatiotemporal data (collected via the 3d-gait Analysis).

Chapter 5: In this chapter, one finds a discussion of the results presented in chapter 4, in relation to the available literature. Here one will also find the limitations of the study, recommendations for practice and future research, and dissemination of the findings.

Chapter 6: In this chapter, one finds concluding remarks and summary of the salient points that emerged from the discussion and results.

Chapter 2 Literature Review

2.1. Search Strategy

A literature review was conducted to discuss findings and conclusions of literature on Orthoses in the management of Low back pain, Physiotherapy intervention with additional orthoses, and Physiotherapy intervention in Low Back Pain. Two sources of information were used: electronic and non-electronic sources. This review focused on studies published between the years 2000-2020—databases used primarily included PubMed, Cochrane, HyDi, and Google Scholar.

Before the literature search was performed, the research terms were defined. Terms were combined with Boolean Operators, which are simple words (AND, OR, NOT or AND NOT) used as conjunctions to combine or exclude keywords in a search, resulting in order to reduce or expand the number of search results yielded, in order to have more focused and relevant literature. Table 1. below represents the salient terms used during the literature search.

Table 1 Salient search terms used to carry a comprehensive literature search, in combination with the use of Boolean operators to link different keywords.

Primary Keywords	Secondary Keywords	Tertiary Keywords
Low Back Pain Mechanical Low Back Pain Custom-made foot orthoses Physiotherapy Physical Therapy Non-specific Low Back Pain Exercise Therapy Gait Lab Analysis Vicon Gait Analysis Oswestry Disability Index Visual Analog Scale	Pathogenesis Epidemiology Prevalence Incidence Risk Factors Pathophysiology Management Treatment Lower Limb Foot Posture Pelvic floor Biomechanics	Barriers Limitations Functional Acute Sub-acute Chronic Specific Effects Tools Assessment

It was also noted that there are alternative keywords to the ones initially identified in research articles, such as Physical Therapy instead of Physiotherapy. Using such additional terms helped to identify a more broadened search. Therefore, articles were still identified even if there was a slight variation in terminology. This was done by using MeSH by Pubmed.

Other search criteria were applied for search results to yield the English language only articles, which were sourced from reputable library and electronic journals, and the publication year from 2000 or later. Exceptions were made by including older articles that explained a historical context or when new literature on the specific subject was sparse.

Studies found through the above search engine criteria were then analysed by means of Critical appraisal skills program (CASP) tools, which is a set of 8 critical appraisal tools to methodologically review a study design, sample size, and recruitment techniques.

2.2. Low Back Pain

2.2.1. Definition of Low Back pain.

The World Health Organisation (2013) defines Low Back pain as “pain and discomfort below the costal margin and above the inferior gluteal folds, with or without referred leg pain.” It also keeps on explaining how it can be experienced in various types of pain including aching, burning, stabbing, sharp or dull, well-defined, or vague, with intensity ranging from mild to severe. The pain may begin suddenly or might have gradual progression. The lower back is the part of the back between the 12th rib and the top of the

legs, and that it is constituted of vertebrae, discs, nerves, muscles, and ligaments. (Royal Berkshire NHS, 2019)

Low Back Pain is often described in temporal terms, which include

- acute (pain that persists less than 4 weeks),
- subacute (pain that lasts 4-12weeks) and
- chronic (pain that persists more than 12 weeks).

Pergolizzi and LeQuang (2020) also point out a less systematic but arguably more realistic paradigm of Low Back Pain classification, which refers to certain cases where individuals report episodic Low Back Pain, characterized by remissions relapses with periodic flares. The latter might be described as a type of chronic Low Back Pain.

2.2.2. Definition of Non-specific Mechanical Low Back Pain.

Low back pain can be either Specific or non-specific low back pain. Asher (2021) states that non-specific Low back pain is typically mechanical in nature, meaning that it is brought about due to movement, muscle imbalances, wear and tear on joints, and other contributing factors. Royal Berkshire NHS (2019) also explains how non-specific low back pain is also referred to as Mechanical Low back pain because this kind of Low Back Pain is related to movement, activity, and posture.

Non-specific Mechanical low back pain is not attributed to recognisable, known specific pathology, including infection, tumour, osteoporosis, ankylosing spondylitis,

fracture, inflammatory process, radicular syndrome or cauda equina syndrome. (WHO,2013)

2.2.3. Causes of Non-specific Mechanical Low Back Pain.

The majority of causes of Low back pain are non-specific, including individual characteristics, working conditions, awkward static/dynamic working postures, manual handling/lifting, lifestyle, and psychological factors. (WHO,2013)

Kim et al.(2016) refers to Pelvic Malalignment Syndrome as one of the causes of Non-specific Mechanical Low Back Pain. It is associated with biomechanical changes, especially weight-bearing and asymmetries of muscle tension strength and joint ranges affecting soft tissues and joints. According to Ishida et al. (2012), this is also referred to as pelvic crossed syndrome; Lower crossed syndrome, or distal crossed syndrome. It is caused by muscle strength imbalances in the lower segment, where constant muscular changes occur since muscles are shortened or lengthened in relation to each other, within a specific pattern of weakness and tightness that cross between the dorsal and ventral sides of the body.

Gordon and Bloxham (2016) explain how the Pelvic Cross syndrome consists of decreased flexibility, with shortening of the hip flexor and back extensor muscles, hamstrings shortening and weakening of the abdominal muscles. This will, in turn, cause additional mechanical stress to the joints and soft tissue of the lumbar spine and cause lumbar lordosis, which is an excessive inward curve, decreased lumbopelvic movement, and posterior tilt of the pelvis. As Kim et al.(2016) further develop, the above will affect pelvis transfers loads which are generated by body weight and gravity during standing, walking,

and sitting. This will result in pelvic malalignment, rotational malalignment, and decreased pelvic obliquity, where one hip is higher than the other.

Therefore, symptoms of such a syndrome include:

i. Persistent foot, leg or low back pain that is activity-dependent

ii. Curvature of the spine

iii. Asymmetrical muscle bulk or strength

iv. Decreased ability to turn the body in a particular direction.

Kim et al.(2016) state that Malalignment syndrome is commonly treated using biomechanical foot orthoses to address the above-mentioned biomechanical malalignments in the lower extremity kinetic chain; where the treatment aim is to restore the normal structure and function of the spine and pelvis, which will in turn realign the pelvis. The role of foot orthoses is further discussed in section 2.3 below.

2.2.4. Low Back Pain measurement tools.

This section discussed the validity and reliability of the outcome measures used in this study, the Visual Analog Scale and Oswestry Disability Index.

2.2.3.1. Validity and reliability of the Visual Analog Scale (VAS).

Hawker et al. (2011) described the VAS as a self-administered, single-item, continuous scale comprised of a 10 centimeters (100mm) line, which can either be horizontal or vertical, which is most commonly anchored by “no pain” at score 0 and “worst pain”(score

100 or 10), reporting the current pain intensity or the pain intensity in the previous 24-hours with a perpendicular line to the VAS. Hawker et al. (2011) explain how a higher score indicates greater pain intensity.

Algahdir et al. (2017) looked into the test-retest reliability, validity, and minimum detectable change of the VAS, NRS, and VRS in the measurement of arthritic knee pain. The need for such a study was since all the three pain rating scales have shown good validity and reliability for assessing pain intensity, but further research was necessary to determine the most reliable and valid tool. This study recruited 121 subjects who were asked to complete all the scales with brief instructions beforehand. They had to repeat the second time around after 24hours to determine test-retest reliability. Two independent examiners were involved in the two sessions. The outcome of this study showed that although all the three scales showed good test-retest reliability and good correlation between the three, the VAS was considered the most stable, with the smallest margin of error in the measurement of knee pain. This showed that the VAS has good internal validity.

2.2.3.2. Validity and reliability of the Oswestry Disability Index.

The Oswestry Disability Index is a self-assessment questionnaire, which will provide a percentage score level of function in activities of daily living in those living with low back pain, and who are undergoing treatment. The score reflects the perceived level of disability in 10 everyday activities of daily living.

Vianin (2008) determines the psychometric characteristics, which are the validity, reliability, and responsiveness of the tool. According to Vianin (2008), the latter are the final determinants to determine whether such a questionnaire is suitable for a clinically

useful measure. This systematic review breaks down the psychometric characteristics to conclude that the Oswestry Disability Index is a valid, reliable, and responsive condition-specific assessment tool. The author did so as follow;

A. Validity: reviewed how other research papers correlated the ODI with other outcome measurements which are also aimed at measuring the disability caused by low back pain, which included: the Pain Disability Index, the Low Back Outcome Score, the Manniche Scale, the Aberdeen Score, and the Curtin Scale. A functional evaluation was carried out with the ODI, which determined that the ODI "shows a good construct validity because it is consistent with some and was used as the standard comparison for other outcome measures assessing LBP-induced disability." (Vianin, 2008)

B. Consistency: Vianin (2008) referred to Roland & Fairbank (2002) and Fairbank & Pynsent (2000) regarding internal consistency. Following a review of the latter, it showed that the consistency of the ODI is of acceptable level, and within the Cronbach α ranges of 0.71 to 0.87.

C. Responsiveness: The responsiveness of the ODI is high, as measured with the most common method of responsiveness measurement found in the current literature search, which was a receiving operating characteristic curve. The area under the curve can be used as a quantitative method to assess actual change. It can be interpreted as the portability of identifying subjects that have undergone true improvement. Therefore, this method of measuring responsiveness can also be used to estimate the minimum clinically significant difference.

Another paper that looked into the responsiveness of the Oswestry Disability Index was by Cleland et al. (2011). This paper provided a systematic review of the responsiveness of patient-reported health outcomes measures for the evaluation of low back pain, including

the ODI out of the total of 43 measures that were identified. This paper pointed out that most of the papers reviewed consisted of participants undergoing physical and interventional therapies from clinical practice and clinical trials. From the 43 measures, Cleland et al.(2011) determined that the Roland Morris Disability Questionnaire and the Oswestry Disability Index were the most comprehensively validated measures with respect to responsiveness.

D. Test-retest ability: from the systematic review Vianin (2008) determined that the ODI has test-retest reliability is high. Values ranged from r=0.83 to 0.99 and varied according to the time interval between measurements. He also pointed out that the more spaced out the ODI measure was repeated, the lower the score.

As mentioned above, Cleland et al.(2011) determined how both the Roland Morris Disability Questionnaire and the ODI are valid validated measures. Chiarotto et al.(2016) looked into determining which of the measurements has better measurement properties for measuring physical functioning in non-specific low back pain by means of a systematic review and meta-analysis. Out of the nine reviewed articles, it was determined that the ODI displayed better test-retest reliability and smaller measure of physical functioning. In contrast, the other test was concluded to have better construct validity. Despite these differences, the paper concluded that there are no strong reasons to prefer either one or the other to measure the physical functioning in participants with non-specific low back pain.

2.2.4. Management of Low Back Pain.

Pergolizzi and LeQuang (2020), in their Narrative Review, pointed out that the primary objectives of rehabilitation of LBP patients are to control pain, restore function, assure no future functional deficits in order to preserve employment and productivity, in order to prevent Low Back Pain to become chronic. They also stated that one of the most significant challenges in managing Low Back Pain is that it is broad and affects a heterogeneous population, which leads to the fact that the combination and interdisciplinary approaches to Low Back Pain management are considered helpful in many cases.

In their paper, Pergolizzi and LeQuang (2020) point out that rehabilitation management may be selected based on a patient-centric model, which means that patients' needs are reviewed holistically, considering the multiple factors that might be contributing to their chronic Low back pain. "Treatment based classification (TBC) attempts to triage the care for patients with LBP by grouping them at the first level (first contact with a healthcare provider for acute LBP) or second level (in rehabilitation)" (Pergolizzi & LeQuang, 2020)

According to the TBC paradigm, there are three main categories of rehabilitation:

i. Symptomatic Care: aims for the care in the acute stages of a new or recurrent episode of Low Back pain, with strong symptomatic features.

ii. Movement Control: aims to care for patients with moderate pain and disability.

iii. Functional Control: aims to care for patients with mild low back pain to alleviate their functional deficits.

Apart from the above three main categories, Pergolizzi and LeQuang (2020) point out the importance of taking another important factor of Low Back Pain which is the psychosocial factors, which includes anxiety, job dissatisfaction, catastrophizing beliefs, and depression.

Different types of Low Back Pain rehabilitation include the following:

i. Physical Therapy and Exercise: which is considered ineffective for acute Low Back Pain but effective for patients with subacute or chronic Low Back Pain. This type of rehabilitation includes McKenzie management, Pilates, Yoga, stability exercises, and aerobic exercise. These are further discussed in section 2.5.1. below.

ii. Spinal manipulation: This is a technique where practitioners manually apply a controlled thrust (that is, a force of a specific magnitude or degree in a specific direction) to a joint of your spine.

iii. Cognitive Behavioral Therapy (CBT) addresses the psychosocial contributors to chronic Low Back Pain. A systematic review by Hajihasani et al. (2019) where CBT was combined with physical therapy interventions showed an improvement in pain and disability in patients with chronic Low Back pain, which subsequently improved their quality of life.

iv. Mindfulness Meditation: This includes progressive muscle relaxation techniques, where participants are encouraged to relax, become mindful of various body parts, and consciously relax the body areas. This technique was found to be effective in patients suffering from mild low back pain.

v. Custom Orthoses: which targets the modification of the structural and functional characteristics of the neuromuscular and skeletal systems via foot posture. Further discussion of such a rehabilitation modality can be found in section 2.4. below.

vi. Bracing: mostly indicated for scoliosis patients, but little evidence is present whether bracing is beneficial with patients with mechanical chronic low back pain.

vii. Hot and cold therapy: A 2006 Cochrane Review of superficial heat or cold for low back pain, stated that evidence to support the common practice of superficial heat and cold for low back pain is limited, and that there is moderate evidence that heat therapy provides short term reduction in pain and disability in a population with both acute and subacute Low Back Pain. It also pointed out that exercise further reduces pain and improves function.

viii. Kinesiology Tape: Nelson (2016) concluded that Kinesio taping is not a substitute for traditional physical therapy or exercise but may be most effective as an additional form of therapy. Kinesio taping may help improve range of motion, muscular endurance, and motor control.

ix. Patient education: Patient education involves pain information, self-management techniques, and understanding biopsychosocial contributors to Low Back Pain.

x. Traction: is a form of rehabilitation therapy that has been falling out of favour when compared to other recent forms of treatments. Especially since systematic reviews such as Wegner et. al. (2013), have found that traction has little effect on pain intensity, function, global improvement or ability to return to work for patients with Low Back Pain.

xi. Rest: Pergolizzi and LeQuang (2020) discussed how bed rest was once a frequent recommendation given to patients complaining of Back Pain, but that presently most clinicians favour early activity and exercise over rest, when indicated. In fact, physical

therapy and specific exercises, further discussed in section 2.5.1. below are recommended by many clinicians, with or without pharmacological therapy.

2.3. Foot Posture and Biomechanics

Foot biomechanics have been widely referred to in relation to the knee joint and how their changes via the use of orthoses are used to treat certain knee joint conditions such as Osteoarthritis. However, little evidence is present to determine the effect size of such foot postures on more proximal joints like the hip and pelvis. This was further discussed in this section.

2.3.1 The relationship between Low Back Pain, Foot Posture and Gait.

As previously stated, low back pain is a highly prevalent worldwide problem, with multiple causes and risk factors contributing to it, such as age, female sex, low educational status, obesity, occupation, and psychosocial factors. Apart from these well-established risks and causes, Menz et al. (2013) explored whether postural variations such as decreased lumbar lordosis and leg length discrepancy are suspected risk factors since they alter the stresses placed on the soft tissues structures around the spine. This also implicates the involvement of abnormal foot posture and function, with research indicating that individuals with low back pain are more likely to have altered foot biomechanics.

In their study, Menz et al. (2013) explored such a relationship using objective biomechanical measurements, like the MatScan system, which involved walking over a pressure mat. Results of this study showed that although they found no significant relation between altered foot posture and low back pain when in a static position, their findings suggested that the dynamic foot function of the foot during gait may influence low back

pain, due to the kinematic interaction of the lower extremity. He also explained that part of the normal components of gait is foot pronation during the early stages of the stance phase of gait, where the calcaneus everts while the talus adducts and the plantar flexes resulting in a corresponding internal rotation of the tibia which will affect the internal rotation of the femur; and how this internal rotation of the femur will result in anterior pelvic tilt due to the tight fibrous connection provided by the sacroiliac joint. Then he explored the possibility of how excessive foot pronation may result in compensatory movements of the proximal joints, resulting in applying greater forces on the lumbo-pelvic region, which may contribute to the development of low back pain.

Although Menz et al.(2013) found little to no association between pronated foot function and low back pain in their study except in women, they pointed out that the limitations of their study may have contributed to this outcome. Such limitations included not differentiating between low back pain types, intensity, and duration of symptoms and limiting their investigation to kinetic data rather than kinematic involvement of more proximal structures. Such kinematic involvements and changes on the pelvis and low back with the alteration of foot posture were explored by papers such Kim et al.(2017) and KwangYang Park(2017) utilizing 3d gait analysis systems, as well as previously by gait analysis by the naked eye, as done by Danenberg & Giuliano (2000), which are further discussed in section 2.4.3 of this chapter.

A study that looked into the kinematic changes in the spine and pelvic alignment was carried out by Betsch et al., 2011, which was also referenced by Menz et al.(2013) above. This study looked into how different foot positions (inner and outer margin increased, positive and negative heel height) immediately affected pelvic position and spinal posture,

utilizing the Raster stereography Method which creates a 3d model of the back, in 51 participants, which were healthy and with no previous history of low back pain which lasted more than two days. Results of such study showed that positive and negative heel heights, as well as an increase of the outer margin, resulted in significant changes of the pelvic tilt and torsion and that it did not differ between genders (unlike Menz et al., 2013).

Another paper that looked into one of the possible etiologies of Low back pain related to abnormal foot function is by Castro-Mendez et al. (2021). They specifically explored abnormal subtalar pronation (which is the rotation that occurs in an excessive way at the subtalar joint, or supination). This excessive rotation at the subtalar joint results in an increased internal rotation of the tibia, and femur, and on pelvic rotation. This was done by investigating the effect size of reducing low back pain by manipulating foot posture with foot orthoses. Further discussion on the latter can be found in the section 2.4 below.

2.4. Podiatry and Foot Orthoses

2.4.1. Podiatry and biomechanics.

The NHS (2021) defines Podiatrists as “healthcare professionals who have been trained to diagnose and treat abnormal conditions of the feet and lower limbs.” Such conditions include toenail problems, corns, calluses, verrucas, altered foot biomechanics, bunions, heel pain, blisters, gout as well as sports injuries.

The term Biomechanics refers to the study of forces that act against the body and how these affect movement. Podiatrists specifically target the study of movement in the ankle, toes, and foot in relation to the forces that impact them. (Terris, 2018)

With the development of theories such as the Sagittal Plane Facilitation of Howard Dananberg (1986, 2000), the Rotational Equilibrium Theory of Kevin Kerby (1992), and the Mechanical Tissues Stress Model of McPoil and Hunt (1995) broadened the inclusion of biomechanics involvement in podiatry management for new therapeutic and clinical analysis opportunities. (Kirby & Van Gheluwe, 2009)

2.4.2. Foot Orthoses

The International Organization for Standardization define orthoses as a "device used to modify the structural and functional characteristics of the neuromuscular and skeletal systems" (ISO, 2007). There are many types of orthoses, one of which is foot orthoses.

Kim et al.(2016) explained how management with orthoses can be influential on the pattern of movement of the lower extremity due to mechanical control and biofeedback. That is because orthoses increase foot stability by means of providing contact for weight-bearing across a more significant part of the sole of the foot. This in turn, would decrease the occurrence of overpronation or oversupination of the foot, especially during gait. Once such alignment is achieved, it may decrease the rotational forces on the lower limbs. Another way orthoses assist in decreasing pain is by providing an increased sensory input from the sole surface, which will also result in the stimulation of proprioceptive receptors. A decreased perception of pain might result in relaxation of tight muscular structures and therefore reduce muscle tension asymmetry.

Foot orthoses are generally broadly categorised into two types:

i. Prefabricated: which have a generic contour and can be purchased over the counter from pharmacies, health professionals or shoe stores.

ii. Custom-made foot orthoses: which are manufactured from a cast, impression or scan of an individual's foot.

2.4.2.1. Clinical Analysis.

The introduction of biomechanical principles in podiatric practice led to a steady evolution of clinical examination, including:

i. Gait observation initially started by observation by the naked eye, which evolved into slow motion video analyses, which further evolved into 3d Gait analysis using motion capture systems such as the Vicon System (Oxford Metrics) utilized in this study.

ii. Plantar foot pressure: which was initially monitored using an inked footprint, which then further developed into pressure mapping and pressure sensors.

iii. Measurement of the lower joints ranges: including the hip, knee and foot, as well as isolated deformities of the leg and foot which related to functional gait analysis. One of the most used, validated tools for such measurement is the Foot Posture Index (Redmond et al., 2006).

(Kirby & Van Gheluwe, 2009)

2.4.2.1.1. Validity and reliability of the Foot Posture Index (FPI-6).

The Foot Posture Index was developed by Redmond et al.(2006). It was validated by means of comparison with a previous existing tool called the Rose's Valgus Index, determination of inter-item reliability, factor analysis, and benchmarking against three-dimensional kinematic models of the lower limb. From the results, after performing the

tests on 36 subjects, six criteria were proposed. The final conclusion was that the assessment is quick and simple to perform and allows multiple segments, multiple plane evaluation that offers some advantages over existing clinical measures of foot posture.

Redmond et al.(2008) also investigated the normative values of the Foot Posture Index, by means of a systematic analysis. A search was carried out using online databases (including Medline, Embase, PubMed) and internet search engines for studies relating to the use of the FPI, and the authors were contacted for the original, anonymised datasets. This resulted in 1648 individual participants from 16 studies. The aim of the study was to establish normative reference values. The data collected included age, gender, pathology, FPI scores, and BMI index. This study extrapolated a set of population norms for children, adults, and older people, from a large healthy population sample. It also concluded that the foot posture is related to age and the presence of pathology, but not influenced by gender or BMI.

A more recent study by McLaughlin et al. (2016) tested the inter-examiner reliability between inexperienced clinicians when using the Foot Posture Index. This study concluded that there is high inter-rater reliability between inexperienced examiners, as long as they have a background in musculoskeletal assessment. Therefore, the test is not only limited for use with professionals who specialise in dealing with the foot/ankle complex. They arrived at this conclusion by recruiting 83 participants who were university students, and all were assessed by two inexperienced examiners with a musculoskeletal understanding using the FPI-6 checklist.

From the above research, it can be concluded that the FPI-6 is a reliable clinical tool used to quantify standing foot posture, and determine whether the foot is pronated, neutral or supinated, and that has good inter-rater reliability, even in between inexperienced examiners.

2.4.2.1.2. Gait analysis.

Tao et al.(2012) explained how gait analysis is the systematic study of human locomotion, and such analysis involves the measurement, description, and assessment of quantities that characterise human locomotion. By means of gait analysis, the kinematic and kinetic parameters of the gait cycle can be determined.

The gait pattern can be further divided into phases in order to be able to more directly identify the functional significance of the different motions generated by the individual joints and segments.

A.The Gait Cycle

Phases of the gait cycle include:

i. Initial contact: Also known as heel strike, is when the foot touches the ground. The joint posture present at this moment will determine the limb's loading response pattern. This phase involves 30 degrees of hip flexion (by means of rectus femoris), full knee extension (by contraction of the quadriceps), ankle dorsiflexion to neutral (supinated 5degrees), and then into ankle plantar flexion. This is followed by knee flexion up to 5degrees (by contraction of the Hamstrings), which increases as the plantar flexion of the heel is increased by means of eccentric contraction of the tibialis anterior.

ii. Loading response: This phase with the initial double-stance period and is also known as foot flat. This phase begins with initial foot contact and continues until the other limb is lifted for swing. During this phase the foot rolls into pronation to absorb the impact, while hip extends, caused by a contraction of the adductor magnus and gluteus maximus muscles. There is also knee flexion 15 to 20 degrees, and ankle plantarflexion increased 10-15degrees.

iii. Midstance: This is the phase of the first half of the single-limb support interval. In this phase one finds that the leg repositions over the stationary foot by means of ankle dorsiflexion, while at the same time the knee extends after reaching maximal flexion. The hip extends by contraction of the gluteus muscle, while the ankle becomes supinated and dorsiflexed. The contralateral limb is elevated and continues until the body weight is aligned over the forefoot which is in contact with the ground. At this moment the body transitions from force absorption to forward force propulsion.

iv. Terminal Stance: This phase is also known as heel-off, and it completes the single-limb support phase. In this phase, the foot is preparing for the toe-off and swing phase. During this phase, there would be heel-off while the contralateral limb strikes the ground. During this phase the body weight moves ahead of the forefoot. In fact, this phase begins when the heel leaves the ground, and the body weight is then divided over the metatarsal heads. During this phase, there would be 10-13degrees of hip hyperextension, which then goes into flexion, the knee becomes flexed (0-5 degrees), and the ankle supinates and plantar flexes.

v. Pre-Swing: This phase is also known as the toe-off phase and as the second double-stance interval in the gait cycle. It begins with the initial foot contact by means of heel strike of the contralateral limb and ends with the ipsilateral toe-off. This prepares the limb

for the swing phase. During this phase, the hip becomes less extended, and the knee is flexed 35-40degrees, and ankle plantar flexion increases to 20 degrees.

vi. Initial Swing: this phase is approximately one-third of the swing period. During this phase the hip extends to 10 degrees, followed by flexion due to contraction of the iliopsoas muscles 20 degrees with lateral rotation, the knee flexes to 40 to 60 degrees and the ankle progressed from plantar flexion to dorsiflexion, in order to end in a neutral position.

vii. Mid-swing: This phase begins when the swinging limb is opposite the stance limb, and it ends when the swinging limb is forward and the tibia is vertical. The knee is allowed to extend in response to gravity (by contraction of the sartorius muscle), while the ankle continues dorsiflexion to neutral.

viii. Terminal Swing: This is the final phase of the swing phase which begins with a vertical tibia and ends when the heel strikes the floor. During this phase the knee would be locked in extension.

(PhysioPedia (2021); Tao et al.(2012))

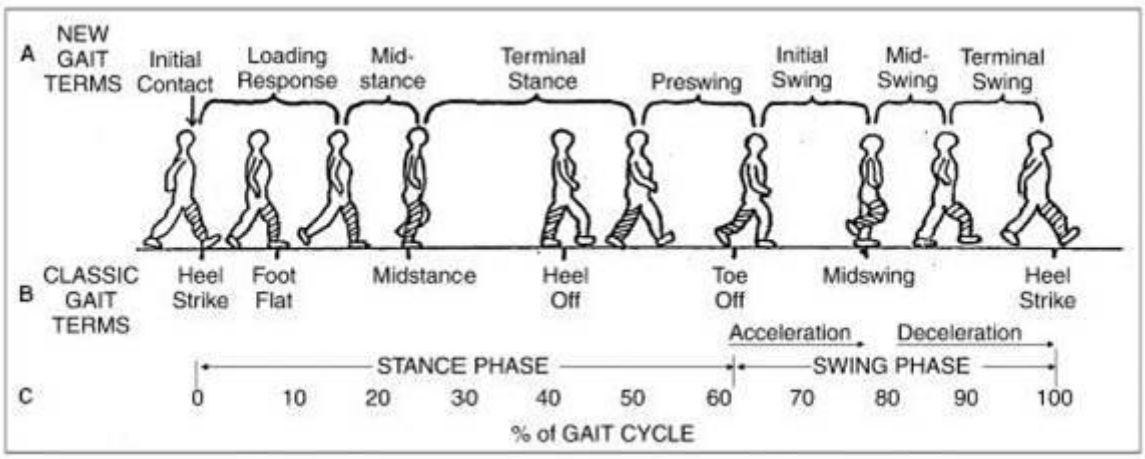


Figure 1 The Gait Cycle as illustrated by PhysioPedia (2021)

B. Kinematic Data

According to Baker (2013) “Kinematics describe the way the body moves”. This is explained by means of segments of major bone structures, such as the pelvis, femur, and tibia, where each of these segments is assumed to be a rigid body, meaning that the segment itself does not change shape during walking.

Most gait analysis systems, including the Oxford Vicon Motion Analysis is based on the interpretation of the joint angles. A co-ordinate system is used to understand what the joint angles represent and allows the orientation of each segment to be described. This is known as segment kinematics. This is almost always defined by a vertical axis (upwards) and a horizontal axis pointing in the direction of walking (x or y axis). Therefore, joint kinematics describes the orientation of one segment with respect to an adjacent segment.

In three-dimensional kinematics, a third axis is considered, the z-axis, to form a coordinate system which is composed of three mutually perpendicular axes (x, y and z), where one is considered as the primary axis. These axes are also described by means of anatomical planes where the forward and upward axis is the segment sagittal plane (flexion and extension), the upward and lateral axis is the segment coronal plane (abduction and adduction) and the forward and lateral axis is the segment transverse plane (internal and external rotation).

C. Spatiotemporal Data

According to Baker (2013), fundamentally, “the gait cycle is a pattern of movement in which the feet are moved forwards alternately while the rest of the body moves forward

over these." Tables 2 and 3 below show the definitions of the spatial and temporal parameters that constitute a gait cycle.

Table 2 Spatial Parameters and their definition (Baker, 2013)

Spatial Parameter	Definition
Step	Is the movement of one foot in front of the other
Stride	Is when a step of one foot is followed by another step of the contralateral limb
Foot contact	Is when one foot makes contact with the floor, and by convention this is when the gait cycle starts and finishes when the same limb makes contact with the ground again. This is also sometimes known as heel strike.
Step length	Is the distance that one part of the foot travels in front of the same part of the contralateral foot during each step
Stride length	Is the distance that one part of a foot travels between the same instant in two consecutive gait cycles. On average the stride length for one side must be equal to the contralateral side, since if not, the individual would not be walking in a straight line. Measured in metres.
Step width	Is a measure of the mediolateral separation of the feet. The measurement of the step width is dependent on the point of the foot used as the basis of measurement. In three-dimensional gait analysis, this is usually measured by the distance between the ankle joint centres

Table 3 Temporal Parameters and their definition (Baker, 2013)

Temporal Parameter	Definition
Stride time	Is the duration of one gait cycle. By convention the stride time is the time taken between successive foot strikes on the same side
Cadence	Is the number of cycles in a specified time, which is measured as steps/minutes
Support	Is divided into the single support, which is when only one limb is in contact with the ground for 60-72% of the stance phase, and double support, which is when both limbs are in contact with the ground for 24-30% of the stance phase.
Step time	Is sometimes defined similarly to stride time, especially when measures of gait symmetry are useful.
Walking speed	Is the distance travelled in a given time, and it is related to cadence and stride length. Measured in metres/second

2.4.2.1.2.1 Three-Dimensional Motion Capture Systems.

Research on gait analysis has been carried out since the late 19th century, and it was applied in the area of biomedical engineering resulting in the introduction of video camera systems. (Tao et al.,2012)

A. The Oxford VICON motion System

Vicon is one of the key players in optoelectronic motion capture systems based on markers. The trademark is often used as a proprietary eponym for optoelectronic motion capture systems. This is greatly utilized to perform gait analysis in hospitals and allows the quantification of angular measurements of pelvic, hip, knee, and ankle rotations during gait.

It is considered as a passive-marker optical system, where one or more cameras capture the light reflected by the markers placed on various anatomical points in order to be able to generate 2D or 3D movement analysis. The Vicon Bonita Cameras use one or more near-infrared cameras that operate at a rate of 240 or 250fps. Each camera contains a lens and a strobe, where the strobe is an array of near-infrared light-emitting diodes (LEDs) that surround the lens. As a result, the retro-reflective markers reflect the light emitted by the strobe back to the lens (Feng & Max, 2014)

B. Validity and reliability of the Three-Dimensional Motion Capture Analysis

I. Inter-rater and Intra-rater validity and reliability

The system was introduced to the market approximately 30 years ago. Tsushima et al.(2003) commented how despite the more extensive use of such systems, there was still lack of reliability testing of such systems. The aim of their paper was to determine the test-retest and intertester reliability of kinematic measurement in a 3-d gait analysis system, specifically the VICON system. The system available during the period of this study was the VICON140, and since then, multiple new updates of the system have been available. The researcher explained how "Reliability refers to the repeatability or reproducibility of measurement procedures" (Tsushima et al., 2003). They continued to explain that one can find two major factors that influence the latter, which are people variability that perform the test, and measurement errors which include marker placement, localisation of bony landmarks, marker movement with skin movement, and the accuracy of the system itself.

To fulfill their aim, they recruited 6 participants without any significant contraindications, and the marker placements were performed by two senior physical therapists. The study consisted of a repeated measures design. This included two testing sessions per day on two separate tests in order to test for intra-subject reliability, test-retest reliability, and inter-tester reliability. This study made use of the system available at the present time, the Vicon140 3d motion analysis system (Oxford Metrics Ltd., Oxford, Uk). The system consisted of 4 infrared cameras, opposed to the current updated systems of 13-16cameras. Both current systems, and this older system made use of a 10m walkway and same 15 markers placements for the lower limbs, which was referred to as the VCM model, which is equivalent to the current Plugin-gait lower limb marker placement at the moment,

although a Full body marker placement was developed later on. In both the VCM and Plugin-gait (VICON Documentation, 2020) the markers are as follows: sacrum (between the Posterior Superior Iliac Spines), bilateral anterior superior iliac spines, lateral thighs, the axis of the knee joints, the lateral calf, lateral malleoli, Achilles tendon, and the second metatarsal heads.

Results for this study showed that there was a high level of test-retest and inter-tester reliability when using standardized marker placement methods and procedures. This means that there was not a lot of variation in data collected when the tests were repeated within one session to the next with reattached markers, and when the markers were attached by a different therapist in the same day. This shows that with a standardized, well understood marker placement, there would be reduced margin of error in between trials. Even though there was a high level of standardisation in these aspects, this paper still noted the level of error to be used in future studies for further investigation. It noted that the intra-subject reliability in 5 trials without marker reattachment was higher than the latter two. A point that was raised by the paper was that the pelvic tilt had a higher margin of error, and decreased reliability. They went on to explain that the latter might have been due to two factors which include miscalculation in the system, or the pelvic tilt during gait was very small making it difficult to calculate.

Baker (2013) further described how inaccuracy in pelvic marker placement can affect results obtained. He explained how one of the primary consequences of placing on the anterior superior spine markers too high will affect the pelvic obliquity graphs, since one side would be recorded as too high. This will in turn affect the report of Hip adduction, since hip adduction is the orientation on the thigh relative to the pelvic. Marker placements

will have a smaller effect on the Pelvic tilt, since it would increase slightly anterior pelvic tilt and negligible effect on Pelvic rotation. Nevertheless, if the orientation of the pelvis changes, then it will affect the estimated position of the hip joint, and therefore also affect more distal joints/segments orientation. On the other hand, more distal joints/segments would not affect the orientation of the pelvis readings.

II. Accuracy and Error Margin

A more recent study by Kim et al.(2017) investigated a more applicable use of the Vicon system. They looked into how orthoses would influence these changes by means of a 12-camera VICON motion analysis system which is three-dimensional gait analysis designed by Oxford Metrics, Oxford, UK. From the gait analysis, kinematic and kinetic data were collected under three set conditions which include walking barefoot, walking with flat insoles in shoes, and walking with biomechanical foot orthoses in shoes. Even though in 2003, Tsushima et al.(2003), discussed how results showed that the pelvic tilt had a higher margin of error, and decreased reliability, Kim, et al.(2017) focused a lot of their study on pelvic rotation and malalignment but made no reference to this possible margin of error, nor to the 2003 paper, previously referred to.

Another recent study that also looked into the error margin of marker placement was carried out by Merriaux et al.in 2017. This study did not require subject recruitment since it used robotic equipment to test the margin of error of marker placement. The study constituted both static and dynamic tests. Results showed that the system error was less than 2mm.

Overall, studies show that the Vicon 3D Gait Analysis is a valid and reliable test for gait analysis, with minimal margin of error of marker placement with good inter-tester and test-retest reliability.

2.4.2.2. Therapeutic Interventions.

Kirby & Van Gheluwe (2009) pointed out that the growing biomechanical influence in clinical podiatry, resulted in the introduction of new functional orthoses based on dynamic controls instead of static support. These were based on the following theories and techniques:

i. The Functional Root Orthoses: This was developed by Dr. Merton Root, between 1958 and 1959. This involved casting feet in a non-weight bearing "STJ-neutral" position in order to standardize and compare one foot to another. Root developed criteria to define a normal foot, and how altering the subtalar joint using orthoses, would in turn affect the motion of the midtarsal joint. (Kennedy,2018)

ii. Kirby Heel Skive orthoses: which involves the shaving of some plaster from the medial heel to increase the ground reaction forces under the medial side of the Subtalar joint axis. (Kennedy,2018) This creates a varus wedging effect within the heel cup of the custom foot orthoses. This extrinsic rearfoot posting helps to maintain rear foot stability. This allows for increased ground reaction forces on the medial plantar side of the calcaneus. This will decrease the eversion of the heel. Therefore, this technique will improve pronation, by generating a force to result in supinatory movements during gait. (SOLO labs, 2017)

iii. Kinetic Wedge: is an adaptation designed by Dananberg, which involves the use of a cut out under the first metatarsal head. This allows the first ray to plantarflex more freely.

This is generally used in the presence of Functional Hallux limitus, which is a condition in which there is adequate dorsiflexion of the first metatarsophalangeal joint when an individual is non-weight bearing but is characterised by limited dorsiflexion of the first metatarsophalangeal joint during gait.

2.4.3. The Relationship between Low Back Pain and Orthoses

As previously discussed, Podiatrists link the use of custom-made foot orthoses with the relief of Low Back pain, reasoning that back pain may be related to the disruption of biomechanics and disruption of the kinetic chain. In fact in 2016, Kim et al. were amongst the first to look into the effects on gait when prescribing biomechanical foot orthosis to individuals with malalignment syndrome by means of a three-dimensional gait analysis. This was done by means of Comparative Experimental Quantitative research. 10 participants were recruited by means of convenient sampling (1:4 Male:female ratio, with an age range of 20-57 years) that have pelvic malalignment with/without low back pain.

In this study (Kim et.al., 2016), looked into how orthoses would influence these changes by means of a 12-camera VICON motion analysis system which is three-dimensional gait analysis designed by Oxford Metrics, Oxford, UK. From the gait analysis, kinematic and spatiotemporal data were collected under three set conditions which include walking barefoot, walking with flat insoles in shoes, and walking with biomechanical foot orthoses in shoes. The results of such a study were compared using Anova on SPSS, showed that the use of biomechanical foot orthoses can correct pelvic asymmetry, as well improve

walking speed when wearing orthoses, which further information was given in section 2.2.3. above.

The authors of the study itself pointed out its limitations as a study, which despite the fact that awareness of limitations helps with future research, these limitations still reduce its reliability and validity of results to a certain extent. These limitations included: the small sample size and lack of a follow- up study. Despite the latter, it was still a good study, with a reliable methodology which can be followed and evaluated in future studies, with good and in detailed explanation of steps taken and, on the execution, making it easy to replicate. Another aspect noted about this study was that there was only a passing mention of the varus or valgus abnormalities of the rearfoot, with no expansion of the way these were measured or diagnosed and how that affected the customisation of the biomechanical foot orthoses.

The role of excessive foot pronation on low back pain was previously studied by Castro-Mendez et al.(2021) by means of a randomized, double- blinded, clinical trial that included a sample of 105 participants with excessive subtalar pronation and chronic low back pain. Participants recruited underwent the FPI-6 (Foot Posture index) to assess and evaluate the foot rotation, which is a validated tool of assessment. Those participants that scored >+6 in the Foot Posture Index were recruited, and they were divided into two groups where one served as a control group with placebo foot orthoses, and the other as the experiment group with custom-made foot orthoses. Both Groups underwent the same testing for Low Back Pain, which included the Visual Analog Scale and the Oswestry's disability Index Questionnaire for Lower back pain, which both are validated tools. These were measured at the moment of inclusion and after 4 weeks of using the orthoses.

Using a 95% confidence interval, results by Castro-Mendez et al.(2021) showed a significant improvement in self-reported back pain in the experiment group that used the custom-made foot orthoses. In contrast, the control group showed no significant difference when using the placebo insoles with $p<0.001$, showing a statistical difference in LBP between the two groups following the 4 weeks intervention period.

Although there was such a significant positive difference in Low back Pain, the Castro-Mendez et al.(2021) still pointed out that pain was not eliminated completely following the 4 weeks intervention, which might indicate that a more extended intervention period might have been required or that other factors needed to be evaluated. In fact, for this study, participants were instructed not to receive any other medical, podiatry or physiotherapy treatment during the study, which makes room for further research on the outcome should any of these exclusion criteria be combined with the prescription of custom-made biomechanical foot orthoses. All in all, this study is well constructed, with a reliable and detailed methodology, with a large enough sample size that can represent the total population, which resulted in valid results, making it a valid pillar for future research.

KwangYang Park (2017) is another paper that looked into the effects of wearing orthoses on pelvic alignment which was published after Kim et al.(2016). The major difference was that the population was that of 15 college students diagnosed with flatfoot in their 20s, whereas in Kim et al.(2016) the age difference was broader, and the foot rotation was not only focused on the flat foot. A major similarity is that both papers used the VICON gait analysis system in order to assess pelvic rotation, and symmetry between left and right. The subjects were instructed to do 5 trials pre and post-test (wearing the orthoses), and the

average of these results were taken. The significant difference at p= 0.05, results showed that statistically significant difference was found in the pelvic angles right versus left prior wearing the orthoses, but this was not the case after wearing the orthoses which results in no statistically significant difference between the right and left pelvic angles.

Another positive result from this research is that the total pelvic angle decreased significantly after wearing the orthoses. The methodology in this study was very clearly explained and broken down but lacks in certain aspects which affects its validity and reliability as a research paper. Reliability is decreased since the population size is very small, and also of a specific age group, and therefore it does not represent the total population. Therefore, the results obtained from this study cannot be generalised. Due to this, other studies are required in this regard. Also, the author of the paper did not pinpoint any of its limitations, thus making it less informative to the reader and also questionable whether the researcher was aware of these research limitations when conducting this study. The reliability is compromised due to the fact that information on which plane of pelvic angles they were investigating, which also affects the reproducibility and future comparison of such a study.

Another point that was limiting in the studies above, is that all the research papers mentioned above all studied the immediate and/or short-term effects of custom-made foot orthoses. In 2000, Danenberg and Giuliano (2000), published a paper with the title ‘Chronic Low-Back Pain and its response to custom-made foot orthoses.’ In this study, Danenberg and Giuliano (2000), recruited 32 subjects with a long history of chronic low back pain, which have been treated unsuccessfully by other means and were considered to reach the medical endpoint for their long-standing pain.

The aim of the study was to find whether altered gait biomechanics and, if treated with custom-made foot orthoses, would affect the biomechanics of the lower back resulting in alleviation of back pain. Each subject was asked to complete the Quebec Back Pain Disability scale questionnaire, which is a self-administered questionnaire to assess each subject's level of functional disability due to back pain. This questionnaire was repeated for a total of 3 times including before treatment, wearing orthoses for 1 month and wearing the orthoses for at least 6 months. Subjects also underwent a gait analysis assessment using a dual-direction slow-motion video assessment, as well as an in-shoe pressure analysis with the F-scan system.

Data collected from both the latter tools were used to create the custom-made foot orthoses, along with other physical examinations, and these were again repeated following the assignment of the orthoses and the pre-set times. Results of this study showed that there was a significant decrease in low back pain post-prescribing custom-made foot orthoses and that this remains so for longer periods of time, showing that prescribing insoles will both decrease the intensity of pain and the rate of recurrence. Despite being an older study, thus some might dispute its relevance to the current days, there are not many other (more recent) papers that target the long-term effects of custom-made foot orthoses, and for that reason that it is still relevant to research to make reference to today. It is also a reliable and valid study, which can be replicated due to the detail in describing every step of the research. Although this paper has every step explained in detail, it provided little information on how subjects were recruited and how ethical permission was obtained to carry out such research. One can say that this paper is one of the pioneers of gait research

before the gait plug-in model started to be used to assess the effectiveness of orthoses as well as other treatment modalities.

Danenberg & Giuliano (2000), in their introduction, also stated that custom-made foot orthoses were more effective than standard care of low back pain including spinal manipulation, physical therapy, therapeutic injections and surgery. The latter was a research focus of Cambron et al.(2017) in the study that investigated the efficacy of the orthoses with and without chiropractic treatment for chronic low back pain. The study included 225 subjects which were randomly divided into one of the groups. Subjects underwent a 6-week intervention period, and a 12-week follow-up visit. The level of back pain was measured using a pain rating scale and low back disability was measured using the Oswestry Disability Index. These were measured at baseline, 6 weeks, 12 weeks, and after an additional 3,6, and 12 months. The latter shows that, like Danenberg & Giuliano (2000), this study investigated the long-term effects of custom-made foot orthoses. Results showed that Low Back Pain improved with custom-made foot orthoses when compared with the control/non-intervention group, and that adding a chiropractor intervention further improved Low Back Pain scores. The results of this study are reliable and valid due to a large sample population, with a detailed descriptive reliable methodology and detailed scrutinization of the results obtained with comparison of results with other studies and research.

A less recent, smaller scaled study carried out by Rosner et al. (2013) also investigated the effects custom foot orthoses on pain, disability, recurrence of spinal fixation, and muscle dysfunction in 41 adults with low back pain patients, receiving a chiropractic intervention. The difference was that the intervention was carried out for 4 weeks, instead

of the longer term as mentioned in the previously described study by Cambron et.al (2017).

Rosner et al. (2013) aim in this study was to evaluate whether there is a better outcome using shoe inserts combined with chiropractic intervention, by also making a comparison between the custom orthoses and sham orthoses. The subjects were recruited via a telephone interview, then those eligible within the exclusion criteria, with a history of low back pain of one month or greater, were divided into 2 groups. Both groups underwent 5 weeks of chiropractic intervention but were assigned custom orthoses and sham orthoses respectively. At the end of the study the subjects from both groups were asked about their compliance in wearing insoles by asking them questions on length of wear during the day, whether they found the insoles helpful and whether they encountered any difficulty in wearing them. Since the subjects were blinded throughout the process which type of orthoses they were given, they were also asked which type of orthoses they thought that they were assigned. The clinician was also blind to the latter.

From this, it came out that 80% of the subjects with the custom-made insoles believed that the insoles were the corrective ones, but on the other hand, even 65% of the other experiment group with the sham insoles reported the same. Rosner et al. (2013) discusses that both groups resulted in significant improvement in back pain following both the chiropractor intervention and shoe insert, but there was no significant difference in outcomes between the sham and custom-made foot orthoses, which is opposite to results yielded by Castro-Mendez et.al. (2017). Despite this, results still showed greater improvement in the custom- made orthoses group than the sham group, when both wore them consistently, but this was not statistically significant. This might be indicative of a

placebo effect by the orthoses, which one can find further discussed in the paper Sadler et al (2013) below.

Rosner et al. (2013) attempted, as previously described, to assess whether compliance of use affected the overall treatment outcome and preservation of longevity of the effect of the chiropractic session. It also stated when the effect of chiropractic intervention was assessed between one session and the other, it showed that the effectiveness decreased with time, but that results indicate the possibility that the length of effectiveness was prolonged by using inserts. Results of the study were not enough to support the difference between the subjects that wore their orthoses most of the day or not. The researchers contributing to the study gave a thorough description of all the limitations that could have affected the results and lack of significance of the outcomes. Being a smaller population than the study carried out by Cambron et.al (2017) decreases the validity, and also due to the shorter intervention gives no indication on the effects in case of a longer intervention period. Despite the latter, Rosner et al. (2013) raised valid points and suggestions for future research on the effects of custom-made foot orthoses in relation to patient's compliance, and also the effects of orthoses on spinal muscles activation.

Despite Rosner et al. (2013) looked into the effects of orthoses and chiropractic intervention on low back pain subjects and also made an attempt to evaluate whether length of wear affected the final outcomes, they did not specify whether subjects recruited were majority of the time standing or sitting during the day. This is also the truth about all the studies mentioned above.

The study that looked into the effects of custom orthoses on standing workers was actually carried out prior to this study in 2005 by John Zhang. This study, like Rosner et al.(2013) and Cambron et.al(2017), looked into the effects on the treatment outcome with Chiropractic treatment and prescription of orthoses, but treatment outcome in this paper is not exclusive to only the effect on back pain, but also on the lower extremities. For this study, 32 subjects were recruited with a standing job of at least 6 hours during the day, and that they reported lower limb, foot or/and spinal pain or discomfort.

These 32 subjects were divided into 3 groups: Comparison Group A with just orthoses, Experiment group B with both orthoses and chiropractic intervention and a control group which did not receive any intervention. The outcome measure used in this paper was the Foot and Ankle Outcome Scores (FAOS), which was a tool developed to assess foot and ankle related problems by looking into the level of pain, symptoms, activities of daily living, function in sports and recreation, and foot/ankle quality of movement. Despite this being the only outcome measure used, this paper still made a discussion on how the results reflect in the case of back pain. It should be noted again that spinal discomfort was one of the inclusion criteria. In the discussion, the researcher stated that since the results of this study showed a significant improvement in the participants of Experiment group B undergoing both interventions, that this would be translated to improvement in low back pain when linked to previous studies like Danenberg & Giuliano (2000), also mentioned above.

This association with back pain from this study seemed not backed up by the study itself, and that there was a gap between the participant's recruitment inclusion criteria, and the discussion, since in between there was no reference to an outcome to actually test back

pain/spinal discomfort. Another limitation noted in this study, which was also not pointed out by the author, was the sample size which was then further made smaller when divided into 3 groups. Due to the small sample size and lack of description of the sample demographics, it makes this study unreliable and not valid to represent the general population. Apart from these limitations, this study did consist of a control group, which the other studies lacked, as well as a detailed description of the methodology and linking of results with previous research. Therefore, it would have been easily reproducible with a larger sample size for a possible larger effect size.

Williams (2013) investigated the patients' perspective when prescribing custom-made foot orthoses for the management of low back pain. After 16 weeks post intervention participants underwent conversational style interviews. From these interviews it was identified that the participants identified issues in their daily lives, such as having only one pair and therefore having to swap them around. Despite these issues, patients still adhered most of the time of using them, since they noticed other benefits when using the custom-made insoles such as improved posture and pain. Another factor that contributed to their adherence was the whole assessment process which helped in their understanding on the relationship between foot biomechanics and low back pain. Therefore, it showed how education, and good explanation helped with patient adherence to the intervention.

Seo and Park (2014) investigated the effects of custom-made foot orthoses on changes in spatiotemporal data in 20 college students who have been diagnosed with flat feet. The participants' spatiotemporal data parameters, specifically step time, step length, stride time, stride length and gait velocity, were measured using the VICON Motion System (Vicon,Oxford,UK) before and after wearing the orthoses, and results were compared. Results of this study showed that there was a decrease in step time and stride time and

increase in stride length and gait velocity when participants were wearing the custom-made foot orthoses.

2.5. Physiotherapy

Physiotherapy is described by the World Physiotherapy as “a health care profession concerned with human function and movement and maximising physical potential. It is concerned with identifying and maximising quality of life and movement potential within the spheres of promotion, prevention, treatment/intervention, and rehabilitation.” (Physiopedia, 2021)

During the research stage of different studies, these three different titles were referred to, primarily: physiotherapy, physical therapy and kinesiotherapy. They all were referring to the same professional entity.

2.5.1. The relationship between Physiotherapy and Low Back Pain.

Studies results such as Betsch et al. (2011) showed a significant correlation between foot posture alteration and pelvic movement. However, they could not exclude whether results were affected by muscular imbalances and differences in ranges of movement and pointed out that this required further investigation. This was also pointed out by Castro-Mendez et al. (2012) who pointed out that although there was a significant decrease in low back pain following their intervention, there was no complete resolution. Due to that, they also suggest that further investigation on such influences on low back pain are required.

In fact, modification of lumbo-pelvic movement was also investigated in the context of physiotherapy intervention by Laird et al (2012), and this review aimed to investigate the effect of physiotherapeutic intervention on movement patterns with people suffering from low back pain, and the resulting relationship between changes in movement and pain\activity limitation. The movement patterns measured by reviewed trials were classified into three main groups, which were: (i) specific trunk muscle activity patterns where research papers investigated the effectiveness between specific exercise vs general exercise; (ii) 'flexion relaxation response' changes by the use of electrical and EMG input of specific muscular activity, and (iii) various aspects of lumbo-pelvic kinematics and postural patterns, including core stabilisation, movement normalisation and postural correction. From their review Laird et al (2012) pointed out that movement-based interventions were not consistent in findings of effectiveness, and there were also inconsistent findings where pain was improved when there were changes in movement patterns. Laird et al (2012) pointed out that further research was required to further study the different types of movement-based interventions, their level of effectiveness, and how that effectiveness comes about.

Schembri et al. (2014) another paper that investigated the effects of movement-based intervention specifically on core re-education which is a local Maltese study. This study looked into the effectiveness and longevity of the effectiveness of core exercises vs traditional exercises in 120 participants suffering from low back pain. In order to assess this, the participants were divided into 3 groups, where Group A was the control group which received individual sessions on posture re-education, Group B underwent modified Pilates intervention and group C received traditional exercises, which constituted similar exercises as the modified Pilates group without teaching them how to engage the core

muscles and stabilisers. All three groups received posture re-education and back care advice. Assessment tools included the Oswestry Disability Index and Visual Analog Scale. Following 6 weeks intervention, all 3 groups showed significant improvement in the scores, but in Group B, the modified Pilates group, the difference was more significant. Following 6 months intervention Group B continued to improve, whereas the other groups started to regress. Therefore, from this paper it was concluded that core-stability exercises have better long-term effects than traditional back exercises. This study has a very reliable and reproducible methodology due to the detail that it was explained and defined, although the sample population is not indicative of whether it was representative to the total population since the total population size is unknown.

A more recent systematic review by Gatchel and Bloxham (2016) reviewed 39 trials that looked into the different types of exercises given to patients suffering with Non-specific Chronic Low Back Pain and their effectiveness. The different exercise intervention that were reviewed included:

i. Aerobic Exercise - especially moderate intensity exercise which means 40-60% of the maximum heart rate, should be promoted for low back pain rehabilitation. This is more effective when accompanied with behavioural treatment and multidisciplinary treatment programmes.

ii. Muscular Strength or Stabilisation Exercises - Gatchel & Bloxham (2016) explain how research shows how improving stability of the spine and increased the strength of the abdominal muscles results in effective decrease in low back pain. Accompanied with a muscular strength programme would be even more effective than core muscular strength alone.

iii. Flexibility training - improving flexibility of the lumbar spine and hamstrings significantly reduce chronic low back pain. That is because research has shown that improvement in the lumbar flexibility can result in an increased spinal range of motion, which in turn can help to reduce back pain. Care has to be taken not to perform exercises that will result in increase in pain.

iv. Conventional Physiotherapy - which showed less effectiveness when compared with core exercises and aerobic exercise

v. Passive treatment including ultrasound and no physical activity - which showed no improvement when compared to other interventions

The general conclusion by Gatchel & Bloxham (2016) was that exercise intervention which targets muscular strength, flexibility and aerobic fitness are beneficial in the management of Non-Specific Chronic low back pain but not for acute low back pain. That is because patients with acute low back pain recover in 4-6weeks even without treatment, and exercise should be avoided during this acute phase due to swelling of the affected area. Nonetheless they pointed out that due to the fact that non-specific low back pain is multifactorial, no single exercise programme is optimal and that a variety may be needed in the treatment of such patients. In fact further research is required to combine all interventions, and their added effectiveness.

2.5.2. The relationship between Physiotherapy, Low Back Pain and Gait Analysis.

As seen in the 2000 research paper by Dananberg, et al. (2000) and other papers discussed above, they stated that the use of orthoses resulted in gait modification. This notion of gait

modification was also investigated in the context of exercise-centered intervention using pilates. This was investigated by Limba da Fonseca et al. (2009). This study targeted the pilates method since it involves specific training of deep abdominal muscles, since they are associated with the low back pain when they are weak and dysfunctional. The deep abdominal muscles are also commonly referred to as the core muscles, which are composed of transversus abdominis, multifidus and pelvic-floor muscles. This correlates with more recent findings by Schembri et al. (2014), discussed above, that found that physiotherapeutic intervention on core re-education showed a positive significant improvement in low back pain.

These notions were investigated via a single-blind randomised controlled trial, where a total of 28 individuals were recruited. The participants were divided into two groups, consisting of a control group with 11 healthy individuals with no complaints of back pain, and the experiment group consisted of 17 participants complaining of moderate low back pain, with or without referred lower limb pain. The experiment group was further divided into two groups, where one group did not undergo any intervention and the other underwent 15 sessions of pilates intervention. Assessment included that all participants had to walk on a Gaitway System instrumented treadmill with a force platform that holds a piezoelectric sensor system by Kistler Inc. which values represent values of active forces in the body, which produces a resultant in the vertical direction and weight distribution during gait, and the resultant effects were assessed at different speeds, from preferred speeds to faster ones.

Results showed that there was no significant statistical difference in vertical forces between the control and low back pain group, but that there was a statistical difference

between the pilates pre- and post-pilates intervention and no statistical difference in the non-pilates group. There was also a significant decrease in the Visual Analog scale score, resulting in decreased low back pain in the pilates group, but not in the non-pilates group. Results indicated that pain distribution in people with low back pain has a different influence on the gait analysis. It was noticed that when participants walked at their preferred speed, those with referred leg pain decreased the amount of force imposed on their painful leg.

From the results, it was concluded that pilates was beneficial in relieving pain and improving weight distribution in low back pain patients and that this benefit contributed to the enhanced stability of the lumbar-spine segments by means of pilates. This study has a very reliable and reproducible methodology due to the detail that it was explained and defined, with the exception that the questionnaire for low back pain was not specified which was used. Due to the small sample size, results do not represent the more significant population, and therefore the results cannot be generalised. Still, the results indicate that pilates and core retraining can be beneficial for low back pain and improved gait, and that further research is required on the subject.

Krekoukias et al. (2021) was the only literature paper found that evaluated kinetic and kinematic characteristics during gait analysis and gait symmetry, using optoelectronic system following physiotherapeutic intervention in 75 participants with chronic low back pain because of degenerated disc disease. The participants were divided into three groups, where each group received five sessions (once per week) either of manual therapy, or sham treatment, or classic physiotherapy (which includes stretching exercises, TENS, massage). Before the intervention, it was noted that there was increased rotation of the pelvic and

increased gait asymmetry during walking. Following the intervention period, only the group that received manual therapy showed a tendency towards symmetry between right and left side during gait, especially in pelvic rotation, but the paper discussed no further change in gait characteristics, apart from reduction in pain and disability post intervention. It is also important to note that this paper did not consider changes more distally than the pelvic during gait.

No other studies were found in relation to kinematic and kinetic changes following a physiotherapeutic intervention in relation to low back pain, or any other condition using a 3d gait lab system, such as the VICON system. Therefore, research and data are limited to the present day on this behalf.

2.5.3.The relationship between Physiotherapy, Low Back Pain and Orthoses.

Zhang(2005), Rosner et al.(2013) and Cambron et al.(2017) all looked into the effects of chiropractic intervention specifically when combined with the use of orthoses in the treatment of low back pain. As previously mentioned, from the literature search, there were no results with research papers about the effects of physiotherapeutic intervention combined with orthoses in the treatment of non-specific/mechanical low back pain.

Robert Ferrari (2013) investigated how reported disability, by means of the Oswestry Disability Index, due to chronic low back pain following a motor vehicle collision is affected when prescribing custom-made foot orthoses. Sixty-six participants complaining of more than 3 months of chronic low back pain following a motor vehicle collision were

recruited. Thirty patients received a prescribed tailored exercise therapy program in addition to analgesics and education, and thirty-four patients received the same therapy in addition with custom foot orthoses. All participants completed the Oswestry Disability Index pre- and post- 8-week intervention. Results from this study showed that although both groups improved, the group that were prescribed the orthoses had lower scores.

Another paper that looked on the effects of physiotherapeutic intervention combined with orthoses was investigated in the case of patellofemoral pain, which is defined as "idiopathic pain arising from the anterior knee/patellofemoral region that is of otherwise unknown origin" (Vincenzino et al., 2008) This could be related to Kim et al.(2016) relation that he made in his paper to malalignment syndrome, and the effect of biomechanical changes, including asymmetry in muscle tension, strength, weight-bearing, and range of motion of joints which also include the knees. Despite no direct correlation being made in the literature between the two papers, both can be referenced for further research on the effects of custom-made foot orthoses when combined with physiotherapeutic intervention.

Vincenzino et al.(2008) carried out a randomised single-blinded clinical trial, in order to investigate the clinical efficacy of foot orthoses in the management of patellofemoral pain syndrome. They recruited 176 participants with anterior or posterior knee pain which is non-traumatic in origin and was present for at least six weeks. These participants were divided into three groups, where one group received physiotherapy intervention only, another group received only flat inserts and the other group received physiotherapy intervention combined with foot orthoses. Main outcome measures investigated global improvement, severity of usual and worst pain over the previous week, anterior knee pain

scale, and functional index questionnaire, which were performed at 6, 12 and 52 weeks. This study concluded that the short-term effect of custom-made foot orthoses, despite being superior to flat inserts, still did not result in a better outcome when combined with physiotherapy intervention, when compared to the group that received physiotherapy intervention only.

2.6. Conclusion and Gaps in Literature

In this chapter, the high prevalence of non-specific mechanical low back pain has been discussed. A lot of literature indicates that malalignment syndromes, altered biomechanics, as well as various mechanical stresses are some of the most common causes of Non-specific Mechanical Low Back Pain. (Pergolizzi & LeQuang, 2020; Ashe, 2021; Kim et.al., 2016; Gordon & Bloxham,2016)

From the aforementioned scientific research that has been carried out over approximately the past 10 years that looked into the effects of physiotherapy (Laird et.al.,2012; Schembri et.al.,2014; Gatchel & Bloxham,2016) and foot orthoses (Kim et.al,2016; Castro-Mendez et.al.,2012; Kwan Yang Park, 2017; Dananberg & Giuliano,2000; Cambron et.al.,2017; Rosner et.al.,2013) on Non-Specific Mechanical Low Back Pain, only one paper looked into the combined effects of physiotherapy intervention with custom-foot orthoses in the treatment of low back pain (Ferrari ,2013). Still, the latter only looked into the outcome of perceived disability by means of the Oswestry Disability Index, excluding the effect on pain, kinematic and spatiotemporal data as outcomes, as well as only looked into chronic low back pain with a definite cause, that caused due to a motor vehicle collision.

Therefore, no research was found that studied the outcome of the combined effects of physiotherapy and custom-made foot orthoses on pain, disability, kinematic and spatiotemporal data changes by means of a 3d- gait analysis system. Only one paper was found that looked into the spatiotemporal data following Pilates intervention in patients with low back pain (Limba da Fonseca et al.,2009). This means that there was limited data to compare with the outcomes of this dissertation. This further shows the gap in research on this topic, and the need of this dissertation's research question to fill that gap.

Most scientific research discussed above showed a positive effect on outcome on Non-specific mechanical back pain with either of the individual interventions except for Rosner et al.(2013) which did not show a statistically significant improvement between participants that underwent chiropractic intervention combined with custom-made foot orthoses vs participants that underwent chiropractic intervention combined with sham orthoses. Nevertheless, the latter was a small-scale study, with multiple limitations which were listed in the study itself which might have affected the outcome of results. These trends were taken into consideration when reviewing the results of this dissertation.

The next chapter is an overview and justification of the methodological approach adopted and the methods used to achieve the aims and objective of this study.

Chapter 3 Methodology

This research project was a Quantitative, Postpositivist and Quasi-experimental study that investigated the effects of custom-made foot orthoses in combination with physiotherapy management in the treatment of Non-Specific Mechanical low back pain. Quantitative data was collected from Comparison Group A and Experimental Group B. The data collected included the score of the Oswestry Disability Index Questionnaire, the score of the Visual Analog scale, as well as results from the Gait Analysis testing by means of the Vicon System. Statistical analysis and discussion were carried out to evaluate the effects of combining custom-made foot orthoses with six-weeks physiotherapy intervention in the treatment of Non-Specific Mechanical low back pain.

3.1. Research Design

Creswell (2009) explains that research design refers to the plan and procedure required to carry out research. This involves making decisions from broad assumptions, which lead to detailed methods of how data is collected, analysed and interpreted. He further explains how there are three types of designs which include: quantitative, qualitative and mixed methods, which are defined as follows:

i. Qualitative Research is defined as a method of looking into more depth and understanding the meaning of individuals or groups related to a social or human problem, by means of an interpretive and naturalistic approach to the subject matter. The process to carry out qualitative research involves forming of questions and procedures, which leads to the typical collection of data within the participants' setting. This is followed by data analysis which inductively builds from particulars to general themes, and interpretations of the meaning of the data is extrapolated by the researcher. (Ataro,2020; Aspergs & Corte, 2019; Creswell, 2009)

ii. Quantitative Research Design is defined as a means for testing objective theories by examining the relationship among variables. The measurement of the variables involves the using of instruments in order to collect numerical data which can be analysed by using statistical procedures. This type of research involves the inquiry of assumptions about testing theories deductively, taking bias in consideration, controlling alternative explanations, and finally being able to generalise and replicate the findings. (Berg, 2001)

Following review of all the above designs, a quantitative approach was identified as the design best to answer the research question of this dissertation, due to the involvement of measurement of numerical variables through the collection of data from the Visual Analog Scale, Oswestry Disability Index, and Kinematic Data from the gait analysis system. That was because a need was identified to assess whether prescribing custom-made foot orthoses in combination with physiotherapeutic intervention would affect the outcome of treatment in participants with low back pain. This reflects a postpositivist approach which is further discussed in section 3.1.2.1 below. Table 4 below explains the strengths, limitations, and the justification for using a quantitative approach for this dissertation.

iii. Mixed Methods Research is a type of research design that combines or associates both qualitative and quantitative forms for a broader understanding of the subject matter. It involves the philosophical assumptions, the use of qualitative and quantitative approaches, and the mixing of both approaches in a study. (Shoonenboom & Johnson,2017)

Table 4 *Strengths, limitations, and justification of a Quantitative approach (based Creswell,2009)*

Strengths	Limitations	Justification
-Results of an adequate sample can be generalised to the entire population -Focuses on a single concept -Provides objective and numerical data -Use of Validated and Reproducible tools, therefore the study is reproducible, valid, and reliable.	-lacks the multidimensional investigation of a problem like e.g., the socioeconomic and psychological implications of low back pain.	To answer the research questions includes the following: • Creating a specific hypothesis • Collection of data to support or refute the hypothesis. • The identification of factors that influence an outcome. • The utility of an intervention • Understanding the best predictors of outcomes

3.1.2. Research Design Components.

Wright et al.(2016) explain that the key to a good quality research design involves the alignment of the researcher's worldview, which includes ontology and epistemology, with the research methodology and method used for data collection, analysis, and interpretation. According to Creswell (2009) when choosing a Research Design (as explained in section 3.1.) there are three components to take into consideration for the Framework of the chosen design. These three components include the Philosophical Paradigms, Selected Strategies of Inquiry, and the Research Method, which are discussed separately in detail below.

3.1.2.1. Philosophical Paradigms.

The Paradigms/ worldviews are a general orientation and beliefs about the world and the nature of the research that a researcher holds, which are shaped by the discipline area of the student, the beliefs of the advisers and faculty in a students' area, and past research

experience. This will shape the research approach chosen, type of research question asked, and also method of data collection and analysis. It will also influence a researcher to embrace one of the three research designs, by means of 4 different paradigms which include:

- pragmatism,
- constructivism,
- advocacy/participatory
- postpositivism (Wright et.al., 2016; Creswell, 2009)

3.1.2.1.1. Overview of the Paradigms

i. Pragmatic Paradigms

Pragmatism is a paradigm that is based on actions, situations, and consequences rather than pre-existing conditions. In this paradigm, researchers focus on the research problem and use all the approaches available to understand the problem, instead of focusing on methods. This is applicable in the case of mixed methods research that makes use of both quantitative and qualitative assumptions for their research. (Evans et.al.,2011) Since this dissertation answered the research question in a quantitative approach only, pragmatism was not applicable.

ii. The Social Constructivist Paradigm

In this paradigm, the research's intent is to make sense of (or interpret) the meaning others have about the world. In the Social Constructivist Paradigm, the research doesn't start with a theory, but instead the researcher generates or inductively develops a theory or pattern of meaning. These meanings are varied and multiple, therefore the researcher is led to look

for complexity of views rather than narrowing meaning into a few categories or ideas. This paradigm theorises that personal experience cannot be excluded from knowledge and that reality is constructed by the individuals. Therefore, this type of paradigm is more relevant to qualitative research, which tends to involve more open-ended questions so that the participants can share their views. (Ataro, 2020; Creswell, 2009; Whitman, 1993) Since this dissertation intent was not to interpret personal experience to answer the research question, Social Constructivist Paradigm was not applicable.

iii. The Advocacy and Participatory Paradigm

This is another paradigm which is typically related to qualitative research, but it can also sometimes be a foundation to quantitative research. Creswell (2009) states that an advocacy/participatory worldview holds that research inquiry needs to be intertwined with politics and a political agenda. This paradigm focuses on the needs of marginalized groups of groups and individuals. Baum et al.(2006) further explains how this paradigm reflects questioning about the nature of knowledge, and how much that knowledge can represent the interests of society. Since this dissertation intent was not focused on interpreting politics and a political agenda in marginalised groups in society to answer the research question, advocacy/participatory worldview was not applicable.

iv. Postpositivism Paradigm

The quantitative approach for this dissertation was based on a postpositivist theoretical framework. This paradigm or philosophical view can also be referred to as positivist/postpositivist research, empirical science and postpositivism. This type of paradigm is more representative of quantitative research rather than qualitative research.

Phillips & Burbules (2000) explain postpositivists as a paradigm that holds a deterministic philosophy in which causes determine effects or outcomes.

PostPositivists studies investigate problems that reflect the need to identify and assess the cause that influences outcomes. An example of the latter can be done via experiments. It is based on observation and measurement of the objective reality. Therefore, the scientific method, which is the accepted approach to research by postpositivists, includes that the research begins with a theory. This is to be followed by collection of data, by means of numeric and objective measures, that either supports or refutes the theory, and finally makes necessary revisions and conducts additional tests.

3.1.2.2. Strategies of Inquiry.

Following the selection whether a study is qualitative, quantitative, or mixed methods, the researcher further goes into choosing the strategy of inquiry for the specific chosen design. They are also known as ‘approaches to inquiry’ or ‘research methodologies. Creswell (2009) explains that strategies of inquiry are types of qualitative, quantitative, and mixed methods models that specify direction for procedures in a research design.

Qualitative strategies include:

i. Ethnography which studies an intact cultural group in a natural setting over a period of time by collecting, primarily, observational and interview data.

ii. Grounded theory in which the theory must derive from data, which is different from other forms of research which suggest that data should be collected in order to test a

theory. Such theory is especially useful when there is little knowledge or understanding about a problem.

iii. Case Studies where researchers explore in depth a program, event, activity, process, or one or more individuals.

iv. Phenomenological research which is a strategy that involves identifying the essence of human experiences about a phenomenon as described by participants.

iv. Narrative Research looks into the study of lives of individuals and asks one or more individuals to provide stories about their lives.

(Austin.Z. & Sutton, 2014)

Mixed Methods Strategies include:

i. Sequential Mixed methods involve seeking to elaborate on or expand on the findings of one method with another method.

ii. Concurrent Mixed Methods look into the converging and merging quantitative and qualitative data in order to provide a comprehensive analysis of the research problem.

iii. Transformative mixed methods use a theoretical lens as an overarching perspective within a design that contains both quantitative and qualitative data.

(Shoonenboom.J. & Johnson, 2017)

Quantitative strategies include:

i. Non-experimental designs such as survey research. In the case of the latter, they provide a numeric description of trends, attitudes or opinions of a population by studying a sample of that population. In this type of design, Creswell (2009) further explains how it includes

cross-sectional and longitudinal studies using questionnaires or structured interviews for data collection.

ii. Experimental research determines whether a specific treatment influences an outcome. This is investigated by providing a specific treatment to one group and withholding it from another, to determine how both groups performed on an outcome. Experimental designs include two types of experiments which are, True Experiments and Quasi-Experimental Designs. True Experiments include random assignment of students to treatment conditions, whereas quasi-experimental designs are non-randomised (Keppel,1991)

In fact, the Experimental design of this study was identified to be quasi-experimental, since it includes two groups, but participants have not been randomly assigned to either group (refer to Section 3.3 for further explanation on Convenient Sampling method used). In fact, quasi-experimental participants are not-randomly assigned.

Table 5 Strengths, limitations, and justification of a Quasi-experimental Research Design (based on Creswell,2009)

Strengths	Limitations	Justification
-More flexibility in the recruitment of participants -Ethical Considerations in order not to withhold treatment for patients with Low Back Pain until a group of patients are available in order to obtain a randomised sample. -More financially viable -Higher internal validity than other non-experimental designs	-Due to the fact that it lacks randomisation, it reduces the reliability and validity of the study -In randomised trials, the two experiments group are considered equivalent, but in a quasi-experimental design they would not be	-Aims to establish a cause-and-effect relationship between variables -Allows an experiment to be carried out without being having randomization and/or control group Therefore, due to the nature of participants that were recruited for this study, convenient sampling was more suitable.

3.1.2.3. Research Method.

Creswell (2009) points out that the third major element in the framework of a research is the specific research methods used. These research methods include forms of data, analysis, and interpretation that researchers propose for the study they are carrying out.

The research method of this dissertation is investigated more detail below starting from section 3.2 onwards.

3.2. Sampling

Beck (2013) explains how the sensitivity of an experiment is defined by the probability of rejecting a false null hypothesis. This is affected by three factors: the significance level, the effect size of the given intervention, and finally the sample size. Out of these three factors, the researcher only has control over the sample size. That is because the

significance level is selected before the study, and the effect size is dependent on the effectiveness of any intervention given in the study. This is known as Priori Power Estimation.

Kadam & Bhalerao (2010) explains that sampling is a basic statistical principle with which the sample size is defined before starting a clinical study to decrease the element of bias when interpreting results. To understand more what sampling is, they also differentiated between these three terms:

i. Population, which is defined as a complete set of people, e.g., patients living with Non-specific Mechanical Low Back pain

ii. Target Population, which is a subset of individuals with a specific clinic and demographic characteristics that are determined by the inclusion and exclusion criteria of the study

iii. Sample population, is a portion of the target population that adequately represents the population to be able to generalise results in order to be representative of the population.

3.2.1. Sampling Technique.

Taherdoost (2016) explains how sampling techniques can be divided into two types:

i. Probability or random sampling which means that every potential participant in the population has an equal chance of being included in the sample. Types of probability sampling include simple random, stratified random, cluster sampling, systematic sampling and multi-stage sampling. Probability sampling has the least bias.

ii. non-probability or non-random sampling is defined as a method in which not all members of the population have an equal chance of being selected for the study, or equal chance to be recruited in one experiment group or the other. Types of non-probability sampling includes:

- *Quota sampling* is a technique where participants are chosen on predetermined characteristics in order that the total sample will have equal distribution of characteristics as the wider population.
- *Snowball sampling* is a technique that recruits a small number of participants which will help and encourage other potential participants to participate in the study, to increase the sample size.
- *Convenience sample* is a technique used to recruit participants that are not often readily and easily available. Further explanation on this type of sampling is found in section 3.3.1.1. below.
- *Purposive or judgemental sampling* occurs when settings, persons or events are deliberately selected in order to provide important information that would not have been able to be otherwise obtained.

3.2.1.1. Convenient Sampling.

For this dissertation, once screening and informed consent were obtained, the recruited participants that fit into the inclusion and exclusion criteria, discussed in section 3.2.3., were divided using Non-Probability Convenient Sampling into two groups, Comparison Group A (participants in this group would receive only physiotherapy intervention) and Experiment Group B (participants in this group would receive both physiotherapy and custom-made orthoses interventions).

According to Etikan et al. (2016), the main goal of convenience sampling is to collect information from participants who are easily accessible to the researcher. Etikan et al.(2016) continues to describe the limitations of such an approach, due to the presence of bias, as well as the presence of outliers. They also point out that the researcher does not know how well a convenience sample will represent the population regarding the traits. (Etikan et.al., 2016). Thus, this limits the generalisation of the research outcomes and results.

Taking the latter into consideration, a Simple Randomised Sampling would have been a much more ideal option. However, according to Banerjee and Chaudhury (2010), "a sample may be defined as random if every individual in the population being sampled has an equal likelihood of being included. Random sample is the basis of all good sampling techniques and disallows any method of selection based on volunteering or the choice of groups of people known to be cooperative." This corresponds with the Nice guidelines (2019) which define the term on similar terms and adding that this "means that each individual (or each group in the case of cluster randomisation) has the same chance of having each intervention" (Nice,2019)

Since in this project, participants were recruited by means of a consultant's referral to the Physiotherapy Outpatients over the data collection period, referrals are sporadic, meaning that subjects cannot be recruited all in one go and therefore not able to be randomly distributed. This would result in enrolment restrictions resulting in participants not resembling the patients in practice thus reducing the ability to generalise the final results. The solution for this was the use of Convenient Sampling.

3.2.2. Sample Size Estimation.

According to Sage Research Methods (2008), a sample size can be defined in two main ways.

- Designated sample size, which is the number of sample units selected for contact or data collection.
- Final sample size which is the number of completed data collection from which subjects data was actually collected. The final sample size discussion can be found in section 3.2.2.2.

Kadam & Bhalerao (2010) pointed out that the sample size of a study depends on the following factors:

- Level of significance/confidence level is the 'p' value determined prior to starting a study. The 'p' value signifies the level of acceptance by the researcher that results obtained are not due to chance. The 'p' value for this dissertation is of $p<0.05$ or significance level of 95%. So the researcher accepted that there is a 5% chance of making a Type I error to get 'a false positive', meaning that a difference is determined when no actual difference exists. The latter is represented as alpha (α)

- Power of the study is when the researchers predetermine the false negative rate that they are willing to accept to make their study adequately powered to accept or reject the null hypothesis accurately. This is predetermined because a researcher may fail to detect a difference in results when there is a difference in results, and this is known as the Type II Error. The accepted error for most studies is 80%.

- Effect size which is the difference between the value of the variable between experiment groups, or between the control and the test group. This can be further differentiated as absolute difference or relative difference. This can be estimated from previously reported studies. If studies found that the effect size is large between experiment groups then the sample size required for the study is less, and if the effect size between the groups is small, the sample size required is larger.

- Event rate in the population is the prevalence rate of a condition in a population, which is the proportion of individuals within a population that have a particular disorder, illness or attributes within a specific period of time, or at a specific point in time. This is estimated from previous reported studies. Mechanical/non-specific Low Back pain is that of 60-70% in industrialised countries. (WHO, 2013)

- Standard deviation/margin of error in the population is the measure of dispersion or variability in the data. The larger the standard variation, the larger the sample size. On the other hand, the more a sample is homogeneous, the lesser the standard variation, and therefore a smaller sample size might be required. In the case of this dissertation the variation between the participants is large, therefore according to this a larger sample size was required.

3.2.2.1. Calculating the designated sample size.

Cuschieri et al.(2020) obtained Data from the Maltese European Health Interview Survey dataset for 2015 for self-reported 12 months of chronic low back pain with associated limitations amongst the Maltese population. They found that 6.3% of the Maltese Population, meaning 27,006 individuals, live with Low back Pain. This value represents an estimate of the Total Population of individuals suffering from Low back Pain in Malta.

In the case of this dissertation, the Target population was being considered. This included the patients that are referred to St. Luke's Musculoskeletal Physiotherapy Outpatients by means of referrals, sent by a consultant, for Non-Specific Mechanical Low back pain. Another factor for patients to be eligible for the study was that the patients needed to meet the inclusion and exclusion criteria found in section 3.2.3.1. below.

Unfortunately, since there was limited statistical data with the required information of the inclusion and exclusion criteria, and since patients are referred via a referral system which varies over time, it was not possible to estimate the target population. Therefore, since the Target Population was not available, it was not possible to estimate the Sample Population.

To determine the target population size, reference was made to similar studies (Castro-Mendez et.al.,2012; Soo-Hyun et.al.,2017; Dananberg & Giuliano, 2000; Rosner et.al.,2013) to see what their sample population was. The sample population of such

studies ranged from 10-60 participants. Therefore, the designated sample size of this dissertation was estimated to be 50 participants in each experiment group.

3.2.2.2. Final Sample Size.

Sage Research Methods (2008) pointed out that the final sample size may be smaller than the designated sample.

This was the case of this study, which resulted in the collection of 10 participants in Comparison Group A and 10 participants in experiment group B. Reasons for this difference between the designated sample size and the final sample size were mostly related to participants recruitment phase, as follows:

- Due to the covid-19 pandemic, outpatients were restricted both at the general hospital where patients are seen by the consultants, and at the St.Luke's Physiotherapy outpatients in order to minimise patient to patient contact in waiting areas. This resulted in decreased population, resulting in not reaching the designated sample size, thus having a decreased final sample size
- Ineligibility of patients referred to St. Luke's Musculoskeletal physiotherapy outpatients.
- Patients who refused to participate in the study, which resulted in a decreased response rate

3.2.3.1. Inclusion and exclusion Criteria.

A set of inclusion and exclusion criteria was established to recruit an accessible population sample which is representative of the target population and thus maintain internal validity.

A. Inclusion Criteria: Information was obtained from the Physiotherapy Assessment by the Intermediaries. The criteria include:

i. 18-60 years old, that was because a lot of the reviewed papers made use of that average age range (Kim , 2015; Danenberg & Giuliano., 2000) Dananberg& Giuliano (2000) also noted that the follow-up phase of their study age range of the participants that attended was between 37-65 years of age, which indicated increase in compliance in that age range.

ii. Non-specific Mechanical Low back pain, defined as low back pain caused by the placing of abnormal stress and strain on the muscles of the vertebral column, and not attributable to a recognizable, known specific pathology. Refer to section 2.1 for further information of the definition of these criteria.

iii. Both Male or Female participants to be included

iv. Foot Posture Index >+5 and <-1, which indicated whether subjects had a significant amount of pronation or supination (refer to section 3.4.1.1. for more information regarding this assessment criteria).

v. 6 weeks or more with Non-specific Mechanical Low Back Pain, which included patients with acute on chronic (subacute), and chronic pain subjects. Refer to section 2.1 for further information of the definition of these criteria.

B. Exclusion Criteria: Information was obtained from the Physiotherapy Assessment by the Intermediaries. The criteria include:

i. Low Back Pain present for less than 6 weeks, which excluded subjects with acute onset of back pain. That is because it has been found that individuals

with acute low back pain recover in 4 to 6 weeks with or without treatment. Therefore, there would be no added benefit in completing an intervention programme, both physiotherapy and prescribing of orthoses. (Gordon & Bloxham, 2016)

ii. Foot Posture Index between 0 and +5, which excluded subjects without excessive pronation or supination, refer to section 3.4.1.1. for more information regarding this assessment criteria.

iii. Neurological Dysfunction such as cerebrovascular accident, due to the fact that they may contribute to altered gait or pain sensation, which would have been difficult to dissociate from symptoms of mechanical, non-specific back pain.

iv. Recent Surgery or Childbirth, that was due to the fact that following childbirth there would be associated weakness in the pelvic floor muscles (Dietz & Wilson, 2005), and following surgery the body would require recovery time, and pain reported would be difficult to be distinguished whether it is due to mechanical, non-specific back pain or due to the recent surgery, which would results in inconsistency of results.

v. Pregnancy since any low back pain symptoms usually go away after giving birth.

vi. Systemic Problems (Cancer, Cardiac, Vascular). That was because like in the case of Cancer which could be pressing on the vertebral column and/or spinal cord, which might result in nerve and muscular compression resulting in pain. (NIH,2020)

vii. Diabetes, that is because diabetic patients have a higher risk for foot ulcers development (Diabetes UK, 2019)

viii. Known Psychological Problems (Including depression). That is because psychological problems can influence how closely one focuses on their pain as well as their perception of its severity. (NIH,2020)

ix. Fibromyalgia since it amplifies painful sensations and is characterised by widespread musculoskeletal pain with associated fatigue, sleep, memory and mood issues. (Mayoclinic, 2020)

x. Specific Low Back Pain, is when there is a definite diagnosis for the cause of low back pain, including:

- Inflammatory Conditions including Rheumatoid Arthritis and Ankylosing Spondylitis
- Herniated Discs which result in nerve or spinal cord compression. A herniated disc occurs when one or more intervertebral discs become compressed and bulge outwards.
- Spondylosthesis is when there is displacement of the vertebra, in the lumbar region resulting in nerve compression
- Fractures, can be traumatic or secondary to other disorders such as osteoporosis or tumour
- Osteoporosis which is a progressive decline in bone density, which increases the risk for fractures.
- Cauda Equina Syndrome is when a ruptured herniated disk compresses the spinal cord, resulting in possible neurological damage if left untreated. (NIH,2020)

3.3. Reliability and Validity of the study

Creswell (2009) states that "validity and reliability of scores on instruments lead to meaningful interpretations of data."

He further explained that Validity is whether the scores from a measure represent the variable that is intended to be measured. There are three traditional forms of validity to look for, which are:

i. Content Validity – that investigates whether the measuring tool selected measures the variable intended to be measured, for example: The Visual Analog Scale is a pain scale which will indicate the difference in pain in participants suffering from Mechanical Low Back Pain before and after intervention, where pain is the measured variable.
ii. Predictive or Concurrent Validity –where predictive validity demonstrates an outcome measure which is predicting a future outcome measure vs concurrent validity which is when a test correlates well with a measure that has been previously validated.
iii. Construct Validity – is whether the outcome measure is measuring the intended outcome, for example: that the Oswestry Disability Index is measuring the disability in individuals suffering with low back pain.

(Creswell, 2009)

Patino & Ferreira (2018) state that the validity of study also refers to how well the outcome of the study represents the true findings among a similar larger population outside

of the study. They also explain how there are two types of validity, which are internal validity and external validity.

Price et al.(2015) state that reliability refers to the consistency of a measure. There are three types of reliability:

i. Test-retest reliability - measures the consistency of results when you repeat the same test on the same sample at a different point in time.
ii. Internal Consistency – assesses the correlation between multiple items in a test that are intended to measure the same construct. Like for example, the multiple questions in the Oswestry Disability Index all are measurement to the level of disability in individuals suffering from Low Back Pain.
iii. Inter-Rater Reliability – is the extent to which two or more examiners (raters or observers) produce consistent results between them.

All the above are taken into consideration when discussing the validity and reliability of the outcome measures used in this dissertation. (Refer to section 3.7.)

3.3.1. Internal Validity.

Patino & Ferreira (2018) define Internal Validity "as the extent to which the observed results represent the truth in the population we are studying, and thus are not due to methodological errors."

In the case of this dissertation Internal Validity signifies that the results obtained from the sample population with participants living with Non-Specific Mechanical Low Back pain, represent the same results in the total population of individuals suffering from Non-Specific Mechanical Low Back Pain. Therefore, it means that the results obtained were not due to errors like TypeI error to get 'a false positive' due to reasons like errors in measurement, or selection criteria, or not using reliable and validated outcome measures.

Should there be a lack of internal validity, it implies that the results of the study deviate from the truth. Therefore, one cannot draw any conclusion, or generalise findings to the total population. Without internal validity, it would be irrelevant to analyse the external validity of the study.

Patino & Ferreira (2018) state that to ensure internal validity the researcher must carefully plan the research design, involving adequate recruitment strategies, sampling method, data collection, analysis and sample size.

3.3.2. External Validity.

Once internal validity of the study has been determined, it implies that one can start analysing the External Validity of the study, and whether the results from an intervention can be practically applied in a clinical setting.

Steckler & McLeroy (2008) explain that External Validity is when there is causal relationship between variables, and whether that relationship can be generalized to

different measures, persons, settings and times. They further explain how external validity is influenced by these four categories:

i. Study participant recruitment, selection procedures, participation rates, and the representative nature at the levels of individuals, professionals/individuals who are carrying out the intervention and the delivery settings. For example, highly selective inclusion and exclusion criteria would reduce the external validity of a study, since these criteria are not easily reproducible in clinical practice (Rothwell, 2006) For this study, the inclusion and exclusion criteria were selected to mitigate as much as possible participants with specific low back pain, in order for the sample population to be representative as much as possible to the population of individuals suffering from non-specific mechanical Low Back Pain. Another way that external validity was ensured was by recruiting professionals that in their daily jobs they work with patients with low back pain. On the other hand, the convenient sampling method, as part of a non-randomised selection in this quasi-experimental design, affects the external validity since it decreased the generalisation to a bigger population.

ii. Consistency of implementation of the same protocol, methods, settings, and time across the entirety of the research. External Validity was maintained by having a definite Research Method.

iii. Impact on a variety of outcomes, especially those important to populations, practitioners, and decisionmakers. This includes examples like quality of life, program costs, side-effects from intervention. That is because the latter may affect participants' consistency, decrease recruitment potential, and affect drop-out rates. To improve External validity, all these were well-

explained in the recruitment letters, as well as making sure that it is free of charge to participants, as well as minimal to no side-effects.

iv. Outcome measure and follow-up also affect external validity since it also depends on whether the outcomes of the intervention are clinically relevant. (Rothwell, 2006) This is also dependent on the generalisability of the sample recruited, and since this study was a quasi-experimental design with convenient sampling, External validity was unavoidably affected.

Patino & Ferreira (2018) states that external validity can be increased by using broader inclusion criteria for the target population to represent more the total population, and by investigating interventions that are practical and easily applied to a clinical setting.

For this dissertation external validity was ensured by using interventions that are already used in clinical practice, and the investigation involved using outcome measures to measure the collective effect when these interventions were combined.

3.4. Ethical Considerations

Creswell (2009) states that "Researchers need to protect their research participants; develop a trust with them; promote the integrity of research; guard against misconduct and impropriety."

For this dissertation to concur with the World Medical Association Declaration of Helsinki (2013), an ethics proposal form was compiled and sent to the Faculty Research Ethics Committee (FREC) and the University of Malta Research Ethics Committee (UREC) for

approval. The proposal was accepted by both committees. Permission to conduct the study was also obtained from the Karen Grech Rehabilitation Hospital (KGH) Research Ethics Committee, KGH Data protection officer, KGH Chief Executive Officer, KGH Chief Operation officer, Manager of Physiotherapy Services at St. Luke's Outpatients, and Clinical Lead at Physiotherapy Outpatients. Consent forms for participants' participation were created in both English and Maltese. The procedure to obtain consent from subjects was as follows:

1. Physiotherapists working at St. Luke's Physiotherapy Outpatients acted as intermediaries.
2. Patients referred to St.Luke's Physiotherapy Outpatients by their respective consultant with a clinical diagnosis of Mechanical Low Back Pain, were approached, assessed and recruited by the intermediary.
3. The intermediary assessed the potential participants by means of a standard physiotherapy assessment of Low Back Pain, and by means of the Foot Posture Index.
4. The intermediary was the one to obtain an informed consent from the potential participants that fit into the inclusion and exclusion criteria, after they gave a detailed verbal and written description of what the study entailed.

Participants were given a detailed verbal and written (which was available in English and Maltese, depending on the participant's preference) description regarding the purpose of this study (refer to Appendix 4). On acceptance, written consent was obtained, where it was made clear that all information would remain confidential, and personal data would be

destroyed upon completion of the study. In fact, each participant was coded with a number, which was solely known by the researcher, as entailed by the World Medical Association Declaration of Helsinki (WMA, 2013). It was made clear that participants had a right to withdraw at any stage of the research process, where all information would be omitted from the study and discarded. It was ensured that participants were not deceived in any way and were not at risk of any harm during the study (refer to Appendix 1-4 for Ethical Approvals).

3.5. Participants Recruitment

Physiotherapists working at St. Luke's Physiotherapy Outpatients acted as Intermediaries. As intermediaries they assessed the potential participants by means of a standard physiotherapy assessment of Low Back Pain, and by means of the Foot Posture Index. Those patients that fit into the inclusion and exclusion criteria, were approached by the same intermediary to obtain informed consent. Once screening and informed consent was obtained, the recruited participants were divided by means of convenient sampling (refer to section 3.2.3.1 above) into two groups (Comparison Group A: 10 participants would undergo the standard physiotherapy intervention for 6 weeks; experiment group B: 10 participants would undergo standard physiotherapy intervention for 6 weeks, as well as being provided with custom-made foot orthoses).

3.6.1. Assessment tools

3.6.1.1. Foot Posture Index (FPI-6).

The FPI-6 is a clinical tool used to quantify standing foot posture, and determine whether the foot is pronated, neutral or supinated, between a scale of -12 to +12. The tool was used

as a means of eligibility to be a subject of the study, since the subjects with pronated or supinated feet would require orthoses whilst those with neutral foot posture would not. During assessment, the patient had to stand in a relaxed stance position with double limb support, hands on the side and looking straight ahead. Refer to appendix 5 for the table of assessment of FPI-6.

Assessment of the foot posture constituted of the following 6 validated criteria, and each criterion was graded between -2 and +2 based on the observations and palpation by the intermediary:

i. Talar Head Palpation

ii. Supra and infra lateral malleoli curvature (Viewed from behind)

iii. Calcaneal Frontal plane position (viewed from behind)

iv. Prominence in region of the TaloNavicular Joint (Viewed at an angle from inside)

v. Congruence of the medial longitudinal arch (viewed from inside)

vi. Abduction/Adduction of forefoot on rearfoot (view from behind)

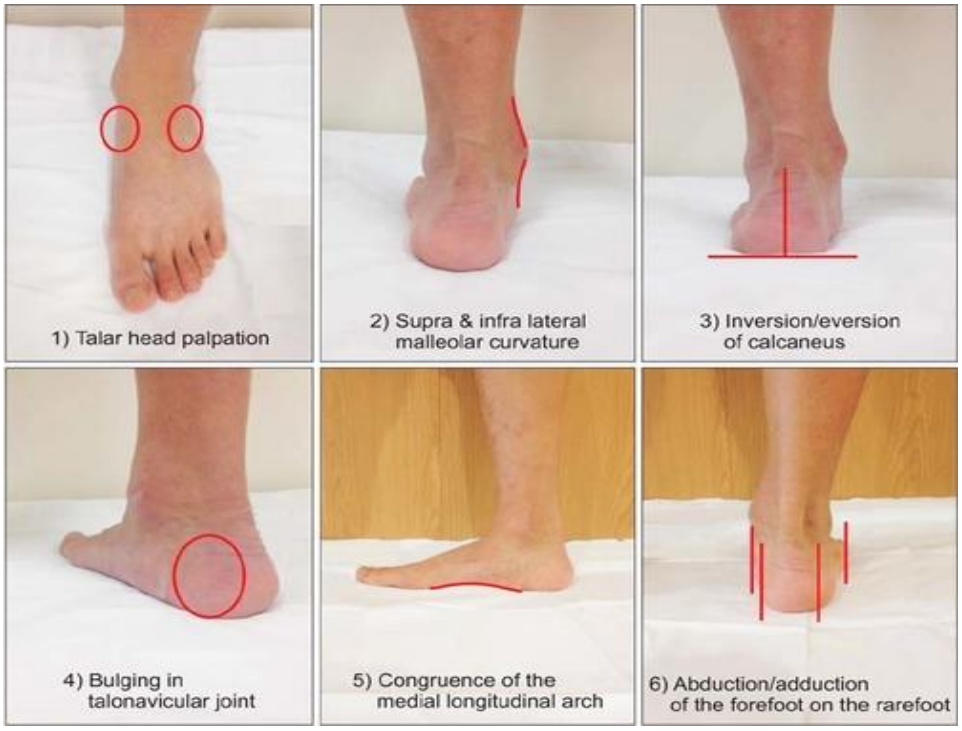


Figure 2 Illustrating the 6-FPI criteria. Obtained from Hanifan et al.(2020).

The score of the criteria was calculated. If the value was between zero and +5 it meant that the foot posture of the subject was neutral and therefore not eligible to be recruited in the study. If values between +6 to +9 indicated a mildly pronated foot, +10 to +12 indicated a highly pronated foot, whereas with values less than -1 indicate a supinated posture (Hanifan et.al.,2020) Further detail on the validity and reliability of this tool were previously discussed in Chapter 2.

3.7. Data Collection

The data collection period was conducted between October 2020 and September 2021. During this period, participants were recruited individually according to the Referral system at St. Luke's Physiotherapy Outpatients. The patients referred with Non-Specific Mechanical Low Back Pain were assessed and recruited by the intermediaries.

Gait Lab Analysis Assessment, Oswestry Disability Index Questionnaire and Visual Analog scale were assessed in a period of a maximum of one week after intermediary assessment. Participants underwent intervention for the duration of six weeks, and the tests were repeated at the end of the intervention period. The data collection was done by the Researcher.

3.7.2. Research Tools.

This study included the use of three types of research tools in order to provide quantitative data with regards to three aspects of Non-Specific Mechanical Low Back Pain, including pain, disability and gait analysis. The validity and reliability of such tools were also previously discussed in Chapter 2.

Vianin (2008) further explained how for an outcome measure to be determined as clinically relevant, it must be sensitive to change over time and responsive to measuring change over time of what is relevant information to the patients/subjects.

3.7.2.1. Visual Analog Scale

> *"The patient's self-report is the most accurate and reliable evidence of the existence of pain and its intensity, and this holds true for patients of all ages, regardless of communication or cognitive deficits."* (Karcioglu et al, 2008)

In fact, recruited subjects were asked to mark their current pain level on the Visual Analog scale (VAS). The VAS is a unidimensional measure of pain intensity which is accessible via the public domain. Subjects were asked to mark on a straight horizontal line, of fixed

length of 100mm, with the point that they felt represented their perception of their current level of pain. The score is determined by measuring the distance where the participant has put the point from the edge (no pain/ 0 point). The Visual Analog scale is available in the public domain with no cost. The Visual Analog Scale is presented in Appendix 5.

3.7.2.2. Oswestry Disability Index.

The recruited subjects were asked to fill out the Oswestry low back pain disability questionnaire, which is a self-assessment questionnaire, which will provide a percentage score level of function in activities of daily living in those suffering from low back pain and are undergoing treatment. The score reflects the perceived level of disability in 10 everyday activities of daily living. The subject had to score 6 statements from 0 to 5 (5 being the worst score). Vianin (2008) explains how "Oswestry Disability Index (ODI) is one of the most commonly used outcome measures for individuals with low back pain." The Oswestry Disability Index questionnaire is presented in Appendix 6

3.7.2.3. Gait Lab Analysis.

Instrumented 3D Gait Analysis was conducted at the Clinical Biomechanics Laboratory at the Faculty of Health Sciences by the Researcher. The version of the instrumented 3D Gait Analysis used was VICON 8.1. Retroreflective markers were attached to the anatomical locations on the body, as illustrated in Figure 4, using the medical grade tape, as dictated by the Plugin-Gait model (Vicon). This is greatly utilized to perform gait analysis in

hospitals and allows the quantification of angular measurements of pelvis, hip, knee, and ankle rotations during gait.

The researcher received training by a qualified physiotherapist working within the Gait Analysis lab within the General Hospital of Malta.

3.7.2.3.1. Data collection.

i. The Set-up

The gait analysis was conducted using a 16-camera VICON motion analysis system (Oxford Metrics, Oxford UK).

On both test days, a full calibration of the system including all cameras in the Vicon system was conducted using an active wand as per manufacturer instructions. This is an important step as this sets up a “calibrated volume” in which the capture of movement would take place.

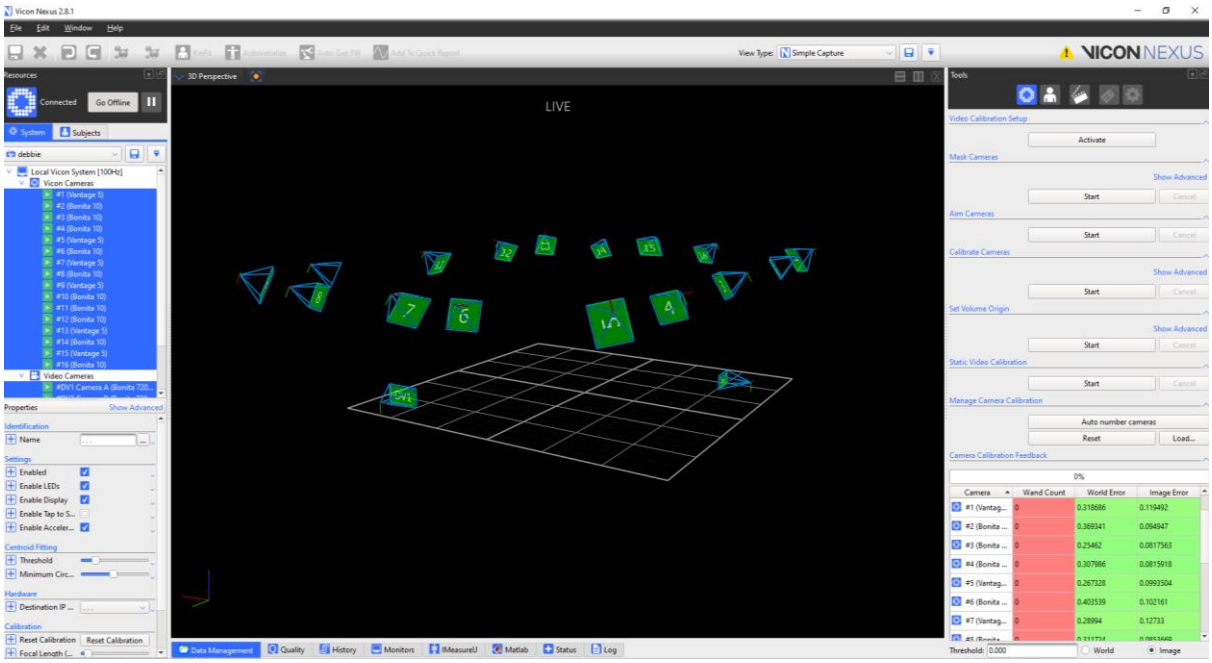


Figure 3 Illustrates the Calibration screen on Vicon © Nexus Programme Version 2.8

ii. Preparing the Subject

Upon arrival, the participant was introduced to the test-setup and the process of positioning the reflective markers. Each participant was also assigned a pseudonym, and all personal data was inputted in a separate file using the pseudonym. All files were stored separately from any subsequent data acquired during the session, and electronic files were further protected by means of a password to access them, as per ethics and data protection requirements.

Before starting the preparation for the Gait Analysis, the participants were requested to fill out the Oswestry Disability Index Questionnaire (where the participant had the choice between the English and Maltese Version), as well as mark the on the Visual Analog Scale.

Following the first two tests, preparations for the gait analysis included collecting anthropometric measurements, which consisted of weight, height, knee width, leg length, ankle width, and distance between the anterior sacroiliac spine. This data is required for the VICON Plugin Gait model.

Eighteen 9-mm-diameter reflective markers were used and placed over the following anatomic locations – according to the Vicon "Plug-in-Gait" (PIG) model: superior iliac spines (ASIS) x2, posterior superior iliac spine (PSIS) x2, lateral epicondyle of the knee joints x2, lateral malleolix2, achilles tendon x2, second metatarsals x2, and lateral aspects of the thigh and calf segments x4. For the latter, wands were used to improve rotational measures for the thigh/femoral and calf/tibial segments. Refer to Figure 4 for the marker placement illustration.

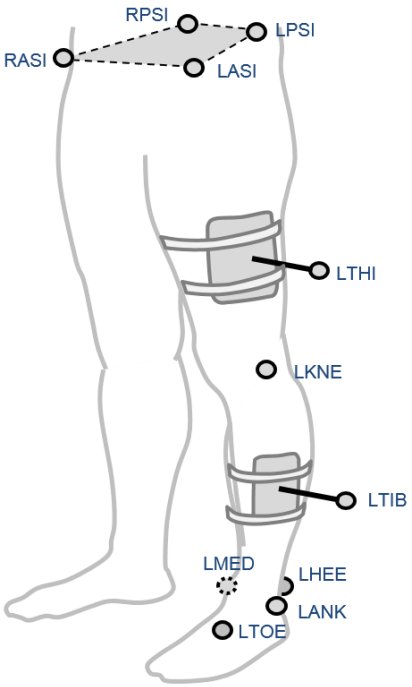


Figure 4 *illustrates the marker placement for the Plug-in gait model with the Oxford Vicon System© obtained from https://pycgm2.github.io/pages/CGM10.html*

Data was captured in two sessions, where the days were selected according to the availability of the participants to attend. Before recording, the system had to be calibrated using an Active Wand Vicon, for the cameras to be adjusted and focused on the 10 meters walkway. All movement captures were performed according to the manufacturer's instructions.

Before the gait analysis captures, a static trial was conducted to establish relationships between the markers in a static position for each subject in the initial anatomical position. Subject was also instructed to walk a few times along the 10m walkway at a normal comfortable speed to get accustomed to it.

Data was collected under the following conditions listed in table 6:

Table 6 Data collection conditions

Group A - Physiotherapy Intervention only	Group B - Physiotherapy and Orthoses
Initial Visit: Fill out Oswestry Disability Index Questionnaire and Visual Analog Scale Gait Analysis: Condition 1: with shoes (no insoles)	Initial visit: Fill out Oswestry Disability Index Questionnaire and Visual Analog Scale Gait Analysis: Condition 1: with shoes (no insoles) Condition 2: with shoes and insoles
After 6 weeks intervention: Fill out Oswestry Disability Index Questionnaire and Visual Analog Scale	After 6 weeks intervention: Fill out Oswestry Disability Index Questionnaire and Visual Analog Scale

Gait Analysis: Condition 1: with shoes (no insoles)	Gait Analysis: Condition 1: with shoes (no insoles) Condition 2: with shoes and insoles

For each condition, six trials were acquired for each subject walking at a self-selected speed, and the mean of the data collected was calculated.

iii. Data Collected from Gait Analysis

From the gait analysis captures kinematic in all three planes (Frontal, Sagittal and Coronal planes) and spatiotemporal data were collected, as listed in table 7 below. The kinematic data of each was collected at heel strike, midstance, and toe-off.

Table 7 Kinematic and Spatiotemporal data

Spatiotemporal Data			Kinematic Data
Cadence	Opposite Foot Off	Step Time	Pelvic tilt ,Obliquity and Rotation
Double Support	Opposite Foot Contact	Stride Length	Hip Flexion/Extension, Abduction/Adduction and Rotation
Foot off	Single Support	Stride Time	Knee Flexion/Extension, Abduction/Adduction and Rotation
Limb Index	Step Length +Width	Walking Speed	Ankle Dorsiflexion/Plantarflexion, Abduction/Adduction and Rotation

v. Gait Data analysis

Motion captures and modelling of all trials were performed using VICON ©Nexus 2.8 software. All gap-filling was done manually using “Rigid body” and “Pattern fill” where necessary, as well as trajectory data was filtered using a Woltering filter (mean square error of 10 mm squared). Kinematic and Spatiotemporal data were then computed using POLYGON© software. Gait patterns were obtained by averaging the data of five different cycles of gait for each participant.

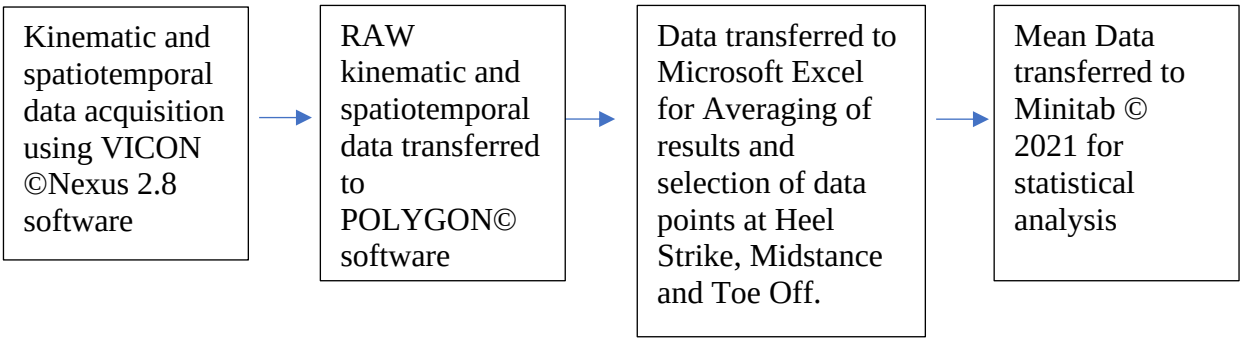


Figure 5 Illustrates Flow Chart for Data Processing

3.7.3. Follow-up data collection phase.

The follow-up phase was post 6 weeks intervention, with a pre-set date, and participants were reminded 2 weeks before and a day before via phone call or message.

On the day of the follow-up, the researcher welcomed the participant, and general verbal feedback on their experience and compliance to the interventions was obtained. This was followed up by repeating the outcome measures of the Visual Analog Scale, the Oswestry Disability Index Questionnaire, and the gait lab analysis. Participants were requested to bring similar attire and ideally the same footwear as the first assessment session for the latter.

The outcome measures detailed before were repeated identically and systematically and by the same researcher as the pre-intervention session to prevent inter-rater reliability.

3.8. Interventions

3.8.1. Physiotherapy Intervention.

The physiotherapist assessed the participant who presented with mechanical low back pain and identified the exclusion and inclusion criteria as specified in section 3.3.3.1. The physiotherapy assessment aimed to identify impairments that may have contributed to the onset of the low back pain, as well as evaluate the probability of developing persistent pain. Factors that were assessed include: weakness, stiffness, posture, and external factors which could possibly affect any of the latter.

Following the physiotherapeutic assessment, the physiotherapist constructed an individualised intervention programme for the participant, which included both interventions during the scheduled sessions, as well as a home exercise programme within the six-weeks of intervention.

Treatment for all participants was based on the combination of two or more of these principles, based on the need of the participant in question: pain relief (by means of electrotherapy, manual therapy, heat modalities or acupuncture), core and abdominal muscles engagement (in order to improve and strengthen lumbar spine and pelvic floor muscles), managing muscular imbalances by means of strengthening and stretching

exercises, postural education, and general back care education, as well as prevention of recurrence.

A more detailed discussion and overview of the above assessment and discussion were previously discussed in Chapter 2. All procedures followed the accepted protocols normally carried out at the St.Luke's Physiotherapy outpatients.

3.8.2. Custom-made foot orthoses Intervention.

The podiatrist prescribed, manufactured, and dispensed the custom-made foot orthoses according to each participant's needs prior the start of the 6 weeks intervention period of physiotherapeutic intervention.

Following an assessment by the podiatrist of the foot biomechanics, a scan of the foot was taken using the Paromed © system, which is a laser scanner used to capture the contours of the participants' feet, to ensure accurate and comfortable fitting of orthoses produced. This

Figure 6 Illustrates a photo of one of the EVA insoles made with High Density EVA for one of the participants

is a standardized system used by podiatrists and orthotist in hospitals to manage foot deformities. From the 3D scan, custom-made foot orthoses were modelled using the PCS modelling system and manufactured using Low/Medium/High density ethylene-vinyl acetate (EVA), depending on the type of corrections which were required by the participant. Orthoses utilized dual-density EVA, of ShoreA50 (medium density) for the posterior aspect of the foot and Shore A 30 (Low Density) for the forefoot. A medial heel post of 5^{o} was incorporated for participants with pronation (FPI>+5 to FPI +9), whilst a Kirby Heel Skive was incorporated for those participants with FPI >+10, as per standard practice.

The podiatrist also provided the participants with education on use of the orthoses, and also on appropriate footwear to be used. The participant was instructed to slowly increase the time of use of the orthoses starting with 2hours wearing time and increase 2 hours per day. The participant was also advised to contact the podiatrist should he/she encounter any issues with the custom-made foot orthoses following the accustom-period, like increase of symptoms or onset of new symptoms, so that the podiatrist could provide a review and the insoles were corrected accordingly.

3.8.3. Participants' Compliance.

The World Health Organisation (2013) defines compliance/adherence as "the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider." Argent et al.(2018) further developed this definition into "the extent to which an

individual corresponds with the quantity and quality of exercise, as prescribed as the healthcare professional."

Martin et al.(2005) points out that patient decreased compliance to treatment can be a threat to health and wellbeing, and this will result in an appreciable economic burden as well. They even put to light the fact that in some disease conditions, more than 40% of patients sustain significant risks by misunderstanding, forgetting, or ignoring healthcare advice. This percentage increases up to 70% when the preventative or treatment regimens are complex, and/or require lifestyle changes, and the modification of existing habits. This includes lifestyle changes such as exercise, which frequently poses significant difficulties for patients. They also point out that studies have shown that exercise programs tend to be more successful in supervised exercise programs rather than home-based programs.

In fact, Argent et al.(2018) point out that compliance to home exercise programmes in rehabilitation is estimated to be around 50%. They also pointed out that despite such a low estimate of adherence, they noted that adherence has been poorly defined in most of the research papers, and that such papers measuring adherence lack validated and reliable tools to measure level of adherence.

Argent et al.(2018) discussed factors that may help to improve patient compliance with the prescribed exercise regimen:

i. Positive Feedback: when the physiotherapist provides positive feedback, and performance of the exercise and progression of symptoms monitored, it was noted that patients would be more compliant. For this dissertation, patients were monitored with follow-up sessions either physically or over

the phone to check in on patients' progress. When the follow-up is done physically, the physiotherapist is more able to check patients' ability to perform an exercise correctly. Generally, the easier the patient does a prescribed exercise in a follow-up session, the more the patient has been compliant with the given regime.

ii. Goal Setting: it is extensively used to motivate and encourage adherence.

iii. Education: education is multifactorial and can affect perceived barriers and the patients' beliefs/perceived threats. Regarding the management of low back pain, education is based on core control during daily activities, postural re-education, work environment, sedentary vs physical activity ratio, prolonged hours in the same position, lifestyle, handling heavyweights, and other lifestyle changes. Education also involves explaining to the patient the source of their pain in simple terms whenever possible and indicated.

iv. Personalised Exercise Programme: Evidence shows that when an exercise programme is tailored to a patients' needs and daily life, that there would be increased compliance.

v. Written information: In fact, in this dissertation participants were given a written home-exercise programme with images, and the number of sets and repetitions also written down by their physiotherapist. This was done to mitigate the chance of decreased adherence due to misunderstanding, and forgetfulness.

3.9. Statistical Analysis

Minitab Statistical Software© (2021) was used for statistical analysis. After analysing the normal distribution of data, using the Shapiro-wilk test, the independent t-test was used to compare mean difference in before and after results of the three research tools between Comparison Group A and Experiment Group B, and the Paired sample t-test was used to compare the Before and After mean results of the 3 research tools in each group separately. 95% level of confidence was used throughout.

Hypothesis testing refers to the procedure used to reject or accept statistical hypotheses (which is an assumption about a population parameter). Such testing is used since it is impractical to examine entire populations for a research study, and therefore a sample is used. A null hypothesis shows that results obtained are random and by chance, whereas in the alternative hypothesis shows that results obtained are not random. One can either accept or reject the null hypothesis.

3.7.1. Determining Normal Distribution of Data.

A Normal distribution represents the distribution of many random variables as a symmetrical bell-shaped graph. It is important because it describes the statistical behaviour of a population. The shape of the normal distribution is determined by the mean and the standard deviation. It determines the probability of whether a randomly selected score from a sample will be less than or equal to a specified value. Normally distributed data of a

sample is a requirement in order to choose between parametric and non-parametric statistical tests.

The Shapiro- Wilk test was used as a normality test. This is because according to Ghasemi and Zahedias (2012), this test is recommended as the best choice for testing the normality of data. The reason for this, is because when compared to K-S test, which is the most popular test of normality, the Shapiro-Wilk test has more sensitivity to correctly reject or accept the null hypothesis and thus detecting whether a sample has a normal distribution or not. If the p-value calculated by the test is less than the significance level of 0.05 then the null hypothesis (that all the values were sampled from a population that follows a Gaussian distribution) is rejected and thus concluding that the sample gathered doesn't have a normal distribution. Also, according to Ghasemi and Zahedias (2012), the recommended sample size when using such a test is less than 50. Since the sample size of the samples in this dissertation are 10 participants for Comparison Group A and 10 participants Experiment Group B, this is a good test to determine the distribution of this data.

Data will be graphically presented using Q-Q Plots. Q-Q plots compare sample data to statistical population. If the data points of the sample data reflect that of the statistical population, it signifies that sample data is normally distributed. The more offset the two set of data are, the further away the sample data is from a Gaussian distribution.

3.7.2. Independent sample t-test (assuming unequal variance).

An Independent Sample T-test (assuming unequal variance) is used when the mean of the same variable is being compared between two different samples/ groups. (Kim, 2019) Both samples/groups must have a normal distribution which will be determined by the Shapiro-

Wilk test as explained above. In the case that one or both samples do not have a normal distribution the Mann-Whitney test is to be used instead.

The Independent Sample t-test is used when the direction of the two groups is unknown whether it is a positive or negative example: the age means in the Comparison Group A can be smaller or larger than the age mean in the Experiment Group. The assumption that there is unequal variance was made since the test would be stricter when accepting or rejecting the null hypothesis.

The Independent t-test was used for both Anthropometric data (age and FPI) analysis and Outcome Measures Mean Difference between Group A and Group B.

3.7.3. Paired Sample t-test.

A Paired Sample t-test is used when the mean of the same variable is being compared within the same sample/ group. (Kim, 2015) The group must have a normal distribution which will be determined by the Shapiro-Wilk test as explained above. In the case that one or both samples do not have a normal distribution the Wilcoxon Signed-rank test is to be used instead.

The Paired Sample t-test was used to see whether there was statistical difference in Before and After Intervention in the mean scores of the research tools, Oswestry Disability Index, Visual Analog Scale and Kinematic and Spatiotemporal data results, in both Comparison Group A and Experiment Group B subjects. It was also used to compare FPI index

between left and right limbs, to determine whether there is a statistical difference. The latter was done for both Group A and Group B.

3.7.4. Statistical Comparison with Normative Data.

Kinematic Data was compared with pre-existing Normative Kinematic data collected by the Faculty of Health Science, Department of Podiatry, in the Biomechanics Gait Laboratory, in 2018, which is a standard operating procedure in such laboratories. The Normative Data collection involved 44 participants between 18-55 years old, that were selected to participate in the data collection, and they did not have any neurological, orthopaedic, or musculoskeletal conditions (including low back pain); did not have leg length discrepancies above 1cm; did not have any malformations, bunions, severe valgus/varus. Participants FPI index -1 to +6 were included, therefore participants with severe overpronation/oversupination were excluded. Normative data was collected for both Males and Females.

The One-Sample t-test was used to compare the Kinematic angle variable at Heel Strike, Midstance and Toe off for both Group A and Group B, with Normative data, if data is normally distributed. In the case that one or both samples do not have a normal distribution the One-Sample Wilcoxon signed-rank test was used instead. According to Liang et al. (2019), the One-Sample t-test is used to compare one group’s average value toa single number (which is a known population). In this case, the known population is the Normative Data of the Kinematic data collected by the Faculty of Health Science, Department of Podiatry, in the Biomechanics Gait Laboratory, in 2018.

The comparison with Normative Data was investigated to evaluate the changes in Kinematic Data collected post-intervention in Comparison Group A receiving only Physiotherapy Management, and in Experiment Group B receiving both Physiotherapy management in combination with custom-made foot orthoses, and whether either of the intervention became less statistically significant to the Normative Data. This yielded further input on the effectiveness of either interventions on normalising the kinematic angles during gait.

Chapter 4 Results and Statistical Analysis

In this chapter, the demographic data and the Visual Analog Scale data, Oswestry Disability Index data, Kinematic and Spatiotemporal data gathered during the data collection process were compiled to produce descriptive statistical graphs and statistical analysis tests using Minitab Statistical Software (2021).

4.1. Descriptive statistics of the study population

A total of twenty participants fit in the inclusion and exclusion criteria discussed in chapter 3 and successfully participated in this study to form two groups, Group A which was the group that received physiotherapy management only, and Group B which was the group that received both physiotherapy and custom-made foot orthoses management

The relevant demographic data to the purpose of this study was retrieved from the Participant Data sheet (refer to appendix 4) of each participant taking part in this study, including the sample population age, gender, and FPI score.

4.1.1. Age and Gender.

Ten participants were recruited to form Group A, 70% were female (N =7) whilst 30% were male (n=3) The mean age was 34.1 years with a standard deviation of 13.7.

Ten participants were recruited to form Group B, where 30% were female (n=3) whilst 70% were male (n=7) The mean age was 36.18 years with a standard deviation of 11.91.

4.1.1.1. Normality Analysis of Age.

Using the Shapiro-Wilk statistical test, it was determined whether the age of the participants in Group A and Group B are normally distributed as illustrated in the

Probability Plots in Figures 3 and 4 below. The null hypothesis states that the data is normally distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

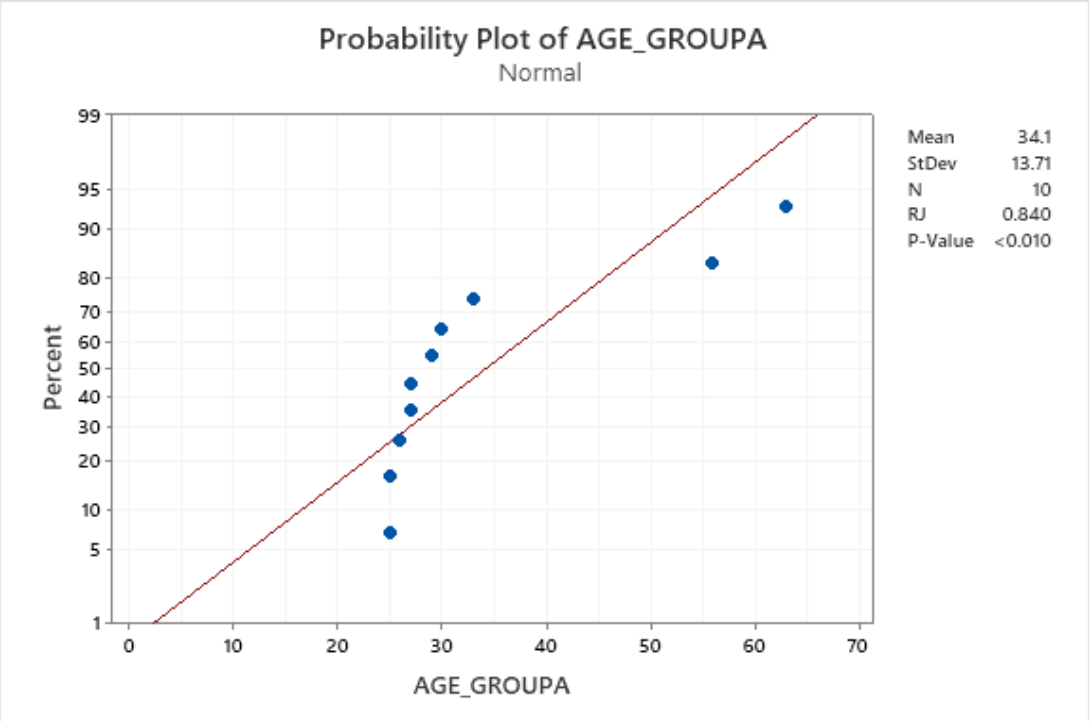


Figure 7 *illustrates the probability plot for the Age of participants in Group A*

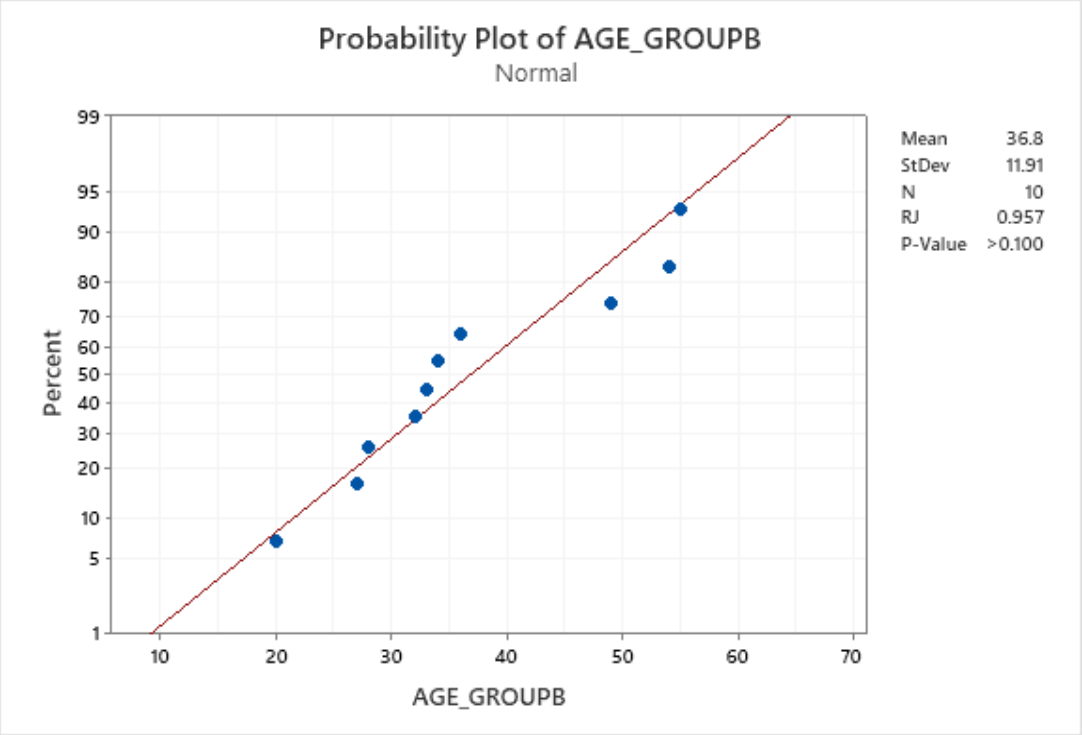


Figure 8 illustrates the probability plot for the Age of participants in Group B

With a 95% level of confidence, the above plots demonstrate that the p-value exceeds 0.05 in Group B with a p-value of 0.1, but the p-value is less than 0.05 in Group A with a p-value of 0.01. This signifies that the null hypothesis has been rejected, and so the alternative hypothesis has been accepted; therefore data is normally distributed in Group B; but the null hypothesis has been accepted, and so the alternative hypothesis has been rejected; therefore data is not normally distributed in Group A. Therefore, parametric tests such as the independent test cannot be used for further statistical examination of this data. Instead, the Mann-Whitney test was selected as the non-parametric statistical test.

4.1.2.3. Determining the Statistical Difference of the Age of the participants between Group A and Group B.

Since the Shapiro-Wilk test demonstrated that the data is not normally distributed in one of the groups, the Mann-Whitney test was used, and the results are illustrated in Table 8 and

Figure 9. Histograms were used to graphically represent the data being statistically analysed, where Group A is depicted using a blue solid line and Group B is depicted using a dotted red line.

The null hypothesis states that there is no significant difference between age in Comparison Group A and age in Experiment Group B subjects. The alternative hypothesis states that there is a significant difference between age in Comparison Group A and age in Experiment Group B subjects.

Table 8 illustrates the calculated p-value of Age Group A vs Group B

Median	p-value	<0.05	Null Hypothesis
A:28 B:33.5	0.326	No	Accepted

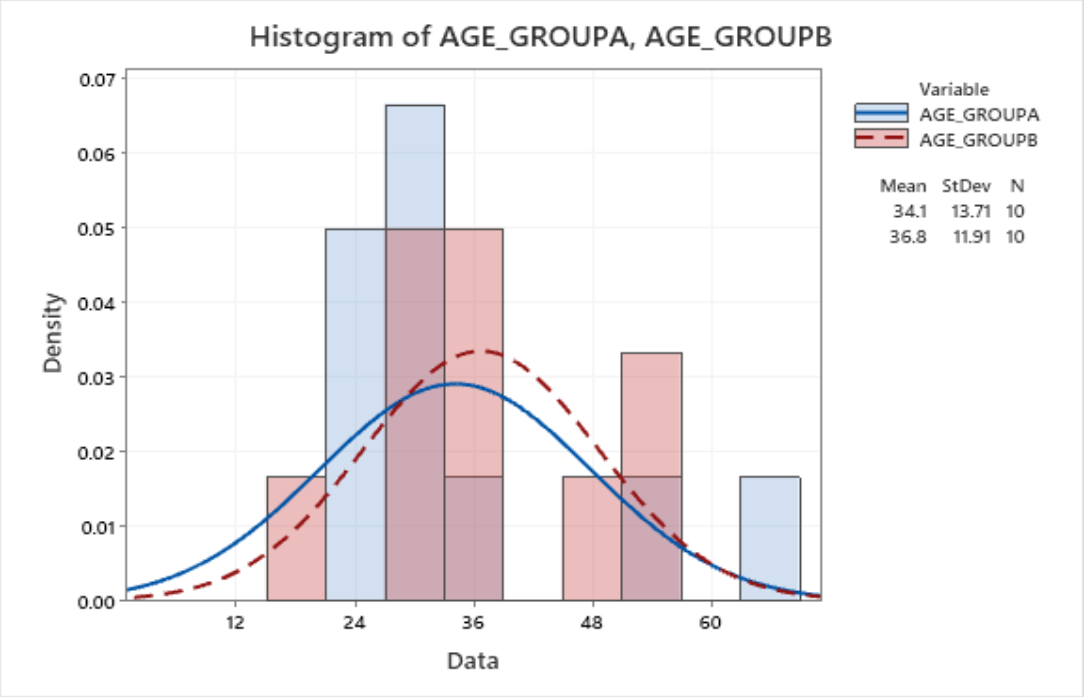


Figure 9 illustrates the Histogram plot of the Mann-Whitney test of Age Group A vs Group B

With a 95% level of confidence, the above plots demonstrate that the p-value exceeds 0.05, with a p-value of 0.326. This signifies that the null hypothesis has been accepted, and so the alternative hypothesis has been rejected. This means that there is no statistical difference in age between the two groups.

4.1.2. Foot Posture Index.

Ten participants were recruited for both Group A and Group B. FPI scores are illustrated in the table below.

Table 9 *Presents the FPI mean scores and Standard Deviation*

Group	Limb side	Mean Score	Standard deviation
A	Right	7.7	1.636
	Left	7.4	1.838
B	Right	8.2	1.687
	Left	8.6	1.776

4.1.2.1. Normality Analysis

Using the Shapiro-Wilk statistical test, it was determined whether the FPI index scores of Group A and Group B are normally distributed for both left and right lower limbs as illustrated in the Probability Plots below. The null hypothesis states that the data is normally distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

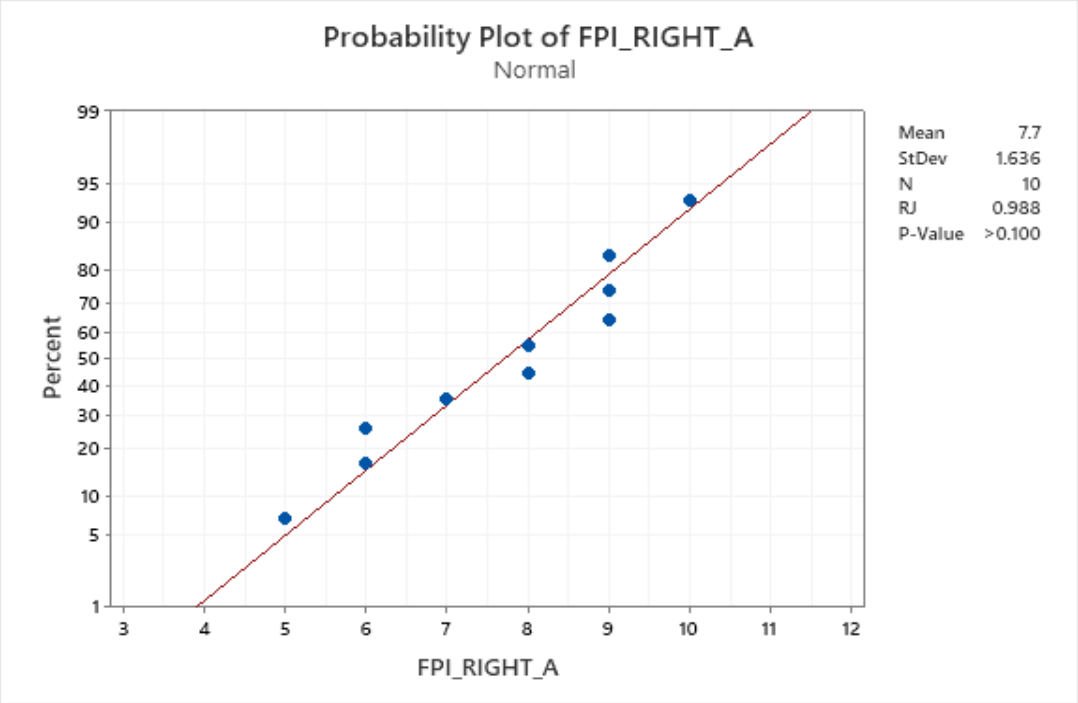


Figure 10 illustrates the probability plot for the FPI scores in Group A Right limb

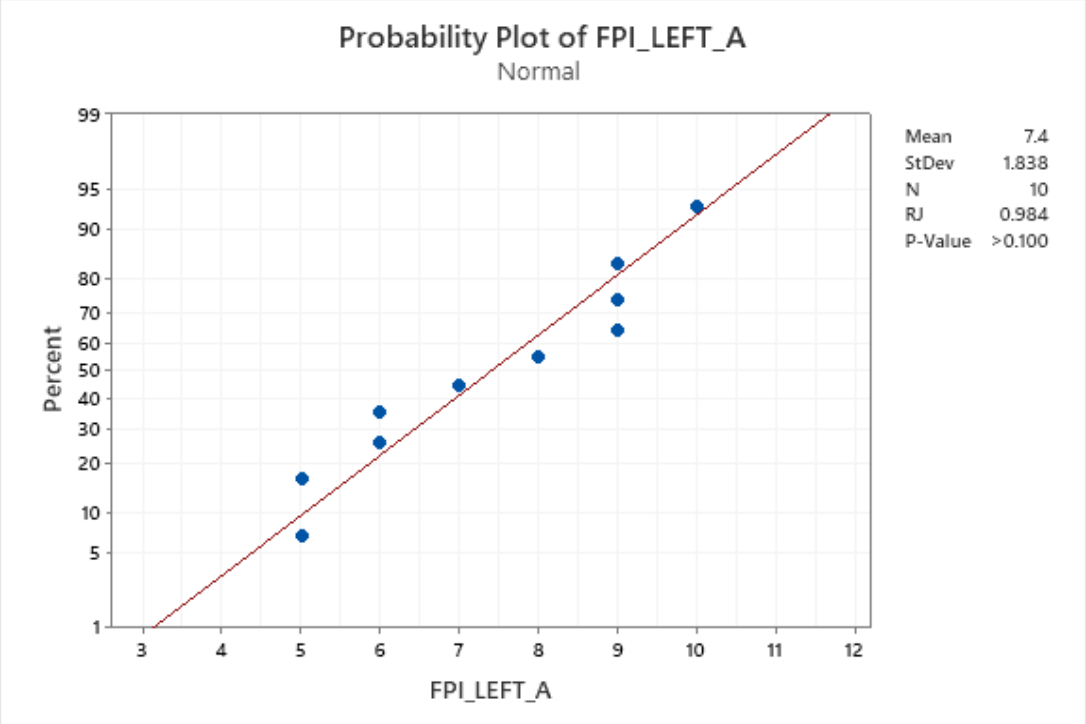


Figure 11 illustrates the probability plot for the FPI scores in Group A Left limb

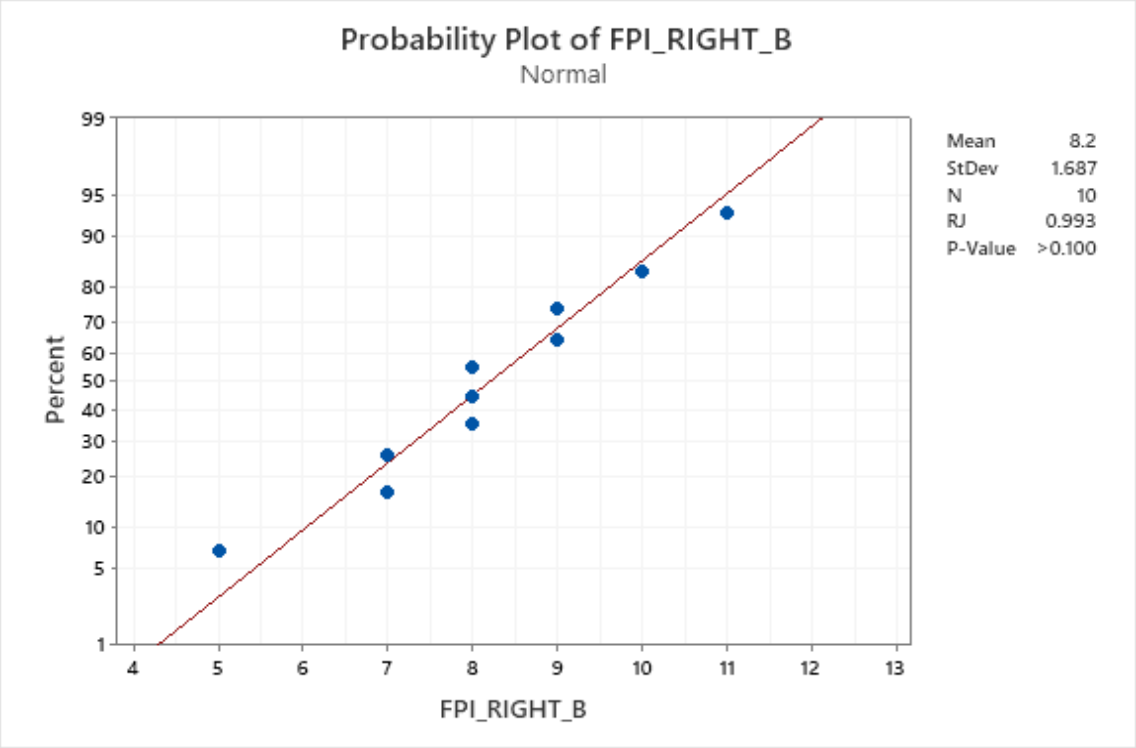


Figure 12 *illustrates the probability plot for the FPI scores in Group B Right limb*

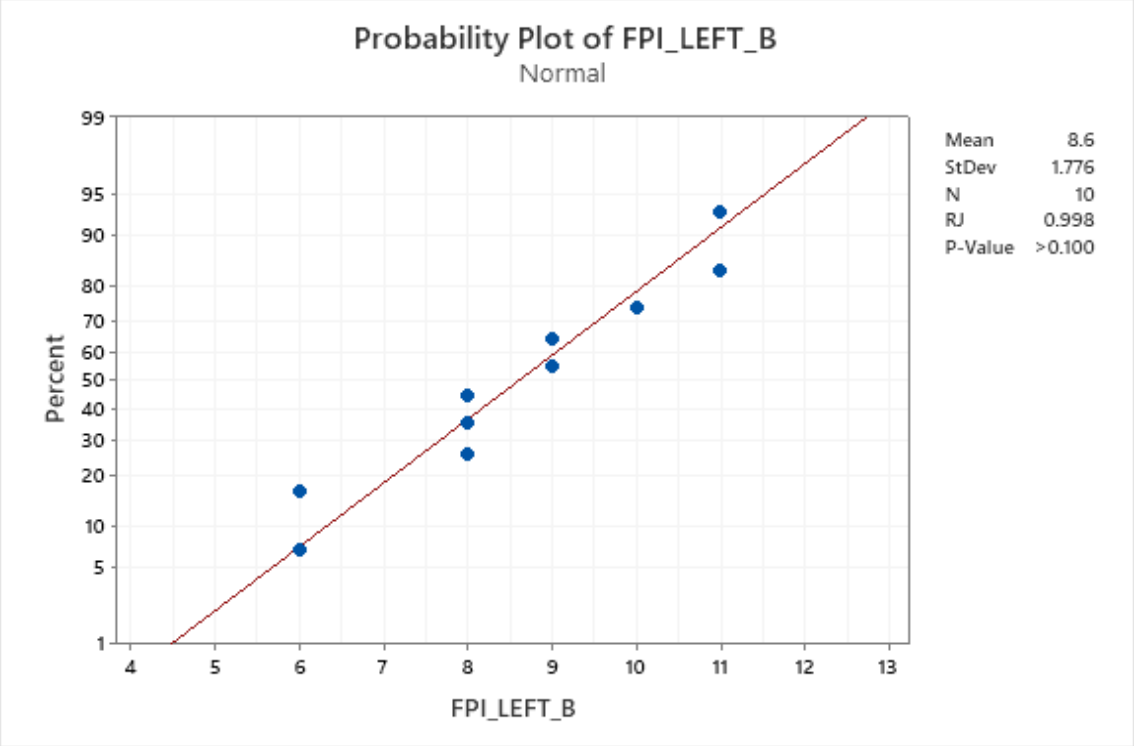


Figure 13 *illustrates the probability plot for the FPI scores in Group B Left Limb*

With a 95% level of confidence, the above plots demonstrate that in both groups and both limbs the p-value exceeds 0.05, with a p-value of 0.1 for both left and right lower limbs in both Groups A and B. This signifies that the null hypothesis has been rejected, and so the alternative hypothesis has been accepted therefore data is normally distributed. Therefore, parametric tests such as the independent test and the paired sample t-test can be used for further statistical examination of this data.

4.1.2.2. Determining the Statistical Difference between Left and Right limbs FPI scores in both Group A and Group B.

Since the Shapiro-Wilk test demonstrated that the data is normally distributed, the Paired sample t-test was used, and the results are illustrated below, for Group A and B. Histograms were used to graphically represent the data being statistically analysed.

The null hypothesis states that there is no significant difference between FPI scores between Left and right in Comparison Group A and between Left and Right in Experiment Group B subjects. The alternative hypothesis states that there is a significant difference between FPI scores between Left and right in Comparison Group A and between Left and Right in Experiment Group B subjects.

Table 10 *illustrates the calculated p-value of Right vs Left FPI scores in Group A and B separately.*

Group	Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
A	0.3	+/-0.949	0.343	no	Accepted
B	-0.4	+/-1.647	0.462	no	Accepted

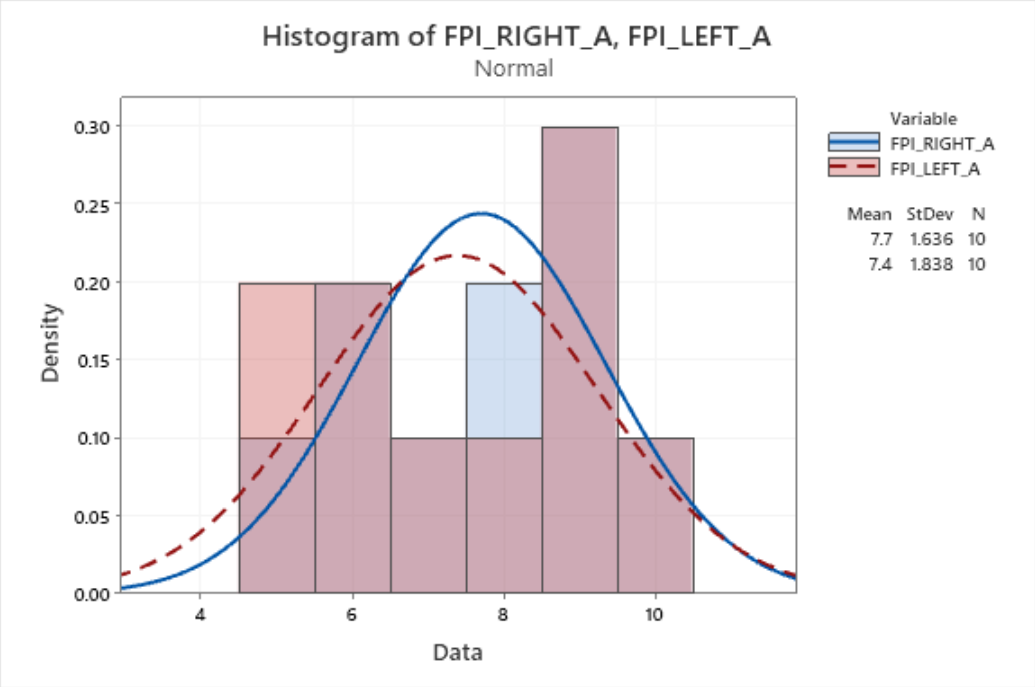


Figure 14 illustrates the Histogram plot of the Paired sample T-test of Right vs Left FPI scores in Group A

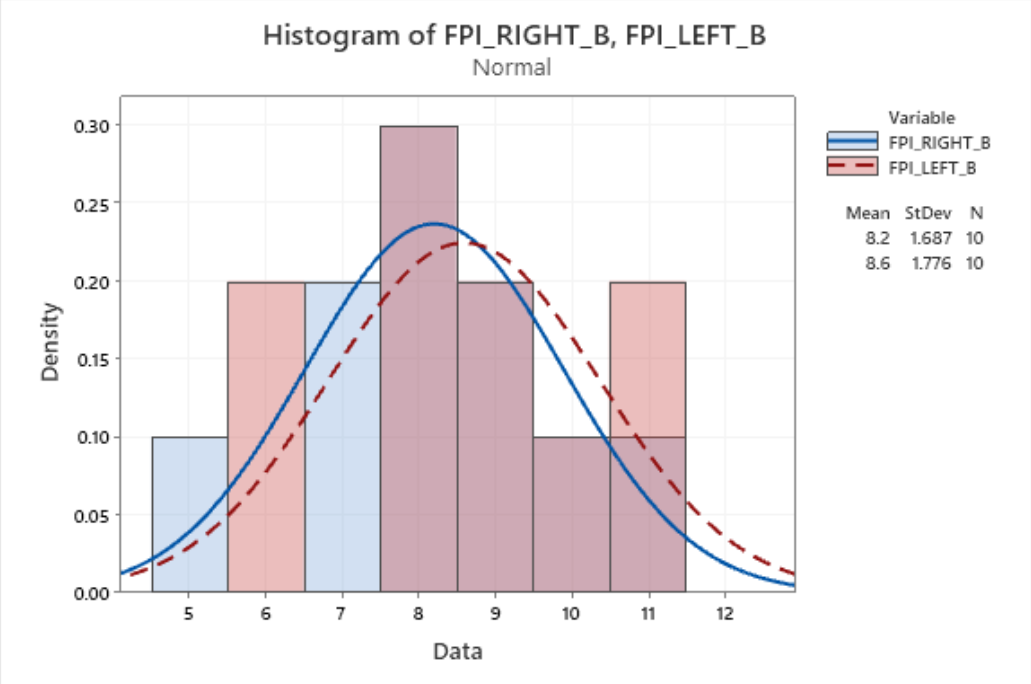


Figure 15 illustrates the Histogram plot of the Paired sample T-test of Right vs Left FPI scores in Group B

With a 95% level of confidence, the above plots demonstrate that the p-value outcome in Group A and Group B is that of 0.34 and 0.46, meaning that it is larger than 0.05. That means that the null hypothesis is accepted. The alternative hypothesis is rejected, showing

that there is not a statistically significant difference between Left and Right FPI scores in both Group A and Group B. This means that since there is no statistical difference between the contralateral limbs, there is no need to distinguish between the two, and they can be statistically processed collectively hence forth.

4.1.2.3. Determining the Statistical Difference between Group A and Group B Right FPI score; and Group A and Group B Left FPI score.

Since the Shapiro-Wilk test demonstrated that the data is normally distributed, the Independent two tailed t-test (assuming unequal variance) was used, and the results are illustrated below.

i. The null hypothesis states that there is no significant difference between Group A Right FPI scores and Group B Right FPI scores. The alternative hypothesis states that there is a significant difference between Group A Right FPI scores and Group B Right FPI scores.

ii. The null hypothesis states that there is no significant difference between Group A Left FPI scores and Group B Left FPI scores. The alternative hypothesis states that there is a significant difference between Group A Left FPI scores and Group B Left FPI scores.

Table 11 *illustrates the calculated p-value of Group A Right vs Group B Right FPI scores*

Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
A:7.70 B:8.20	A: +/-1.64 B: +/-1.69	0.510	No	Accepted

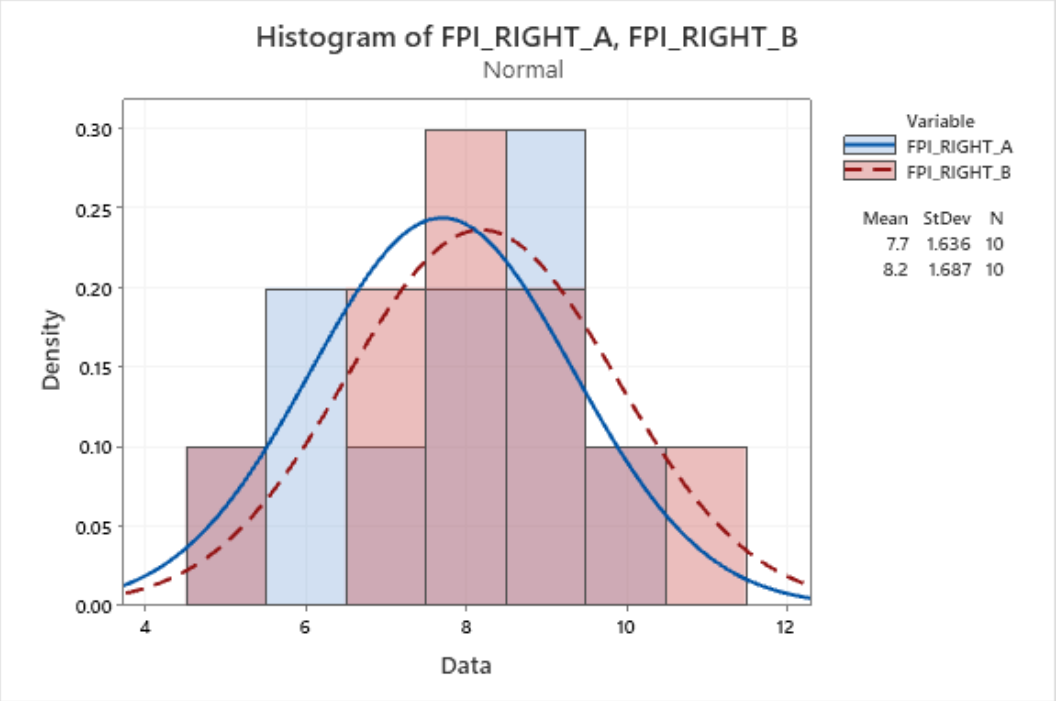


Figure 16 illustrates the Histogram plot of the Independent sample T-test of Group A Right vs Group B Right FPI scores

Table 12 *illustrates the calculated p-value of Group A Left vs Group B Left FPI scores*

Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
A:7.40 B:8.60	A: +/-1.84 B: +/-1.78	0.156	No	Accepted

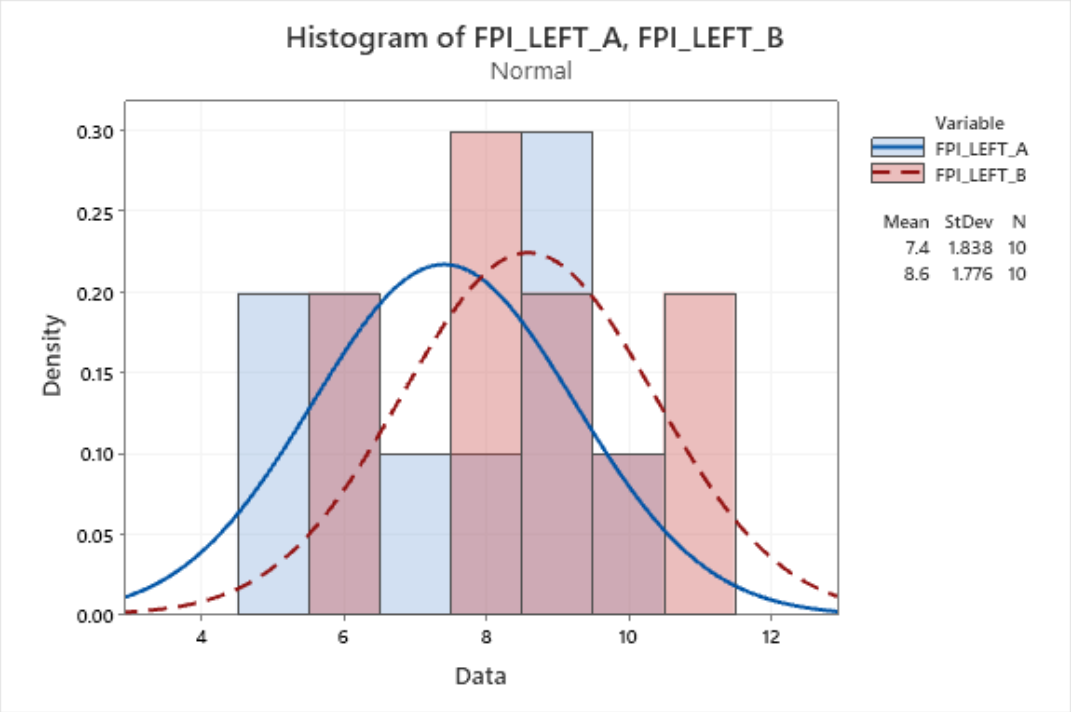


Figure 17 illustrates the Histogram plot of the Independent sample T-test of Group A Left vs Group B Left FPI scores

With a 95% level of confidence, the above plots demonstrate that the p-value outcomes are that of 0.51 and 0.16 meaning that in both cases the p-value is larger than 0.05. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference between Group A and Group B FPI scores.

4.2. Statistical analysis

After analysing the normal distribution of data, statistical tests were conducted to compare the difference in the before and after results of the three research tools between Comparison Group A and Experiment Group B, and to compare the before and after results of the three research tools in each group separately. Refer to chapter 3 for the description of the statistical tests used.

4.2.1. Statistical analysis of the Visual Analog Scale.

4.2.1.1. Determining the normal distribution.

The Shapiro-Wilk test was used to assess the normality assumption of score distribution for each group of participants (n=10) separately as illustrated below in the Probability plots. The null hypothesis states that the data is normally distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

4.2.1.1.1. Normality Analysis of Before and After scores in Group A and Group B.

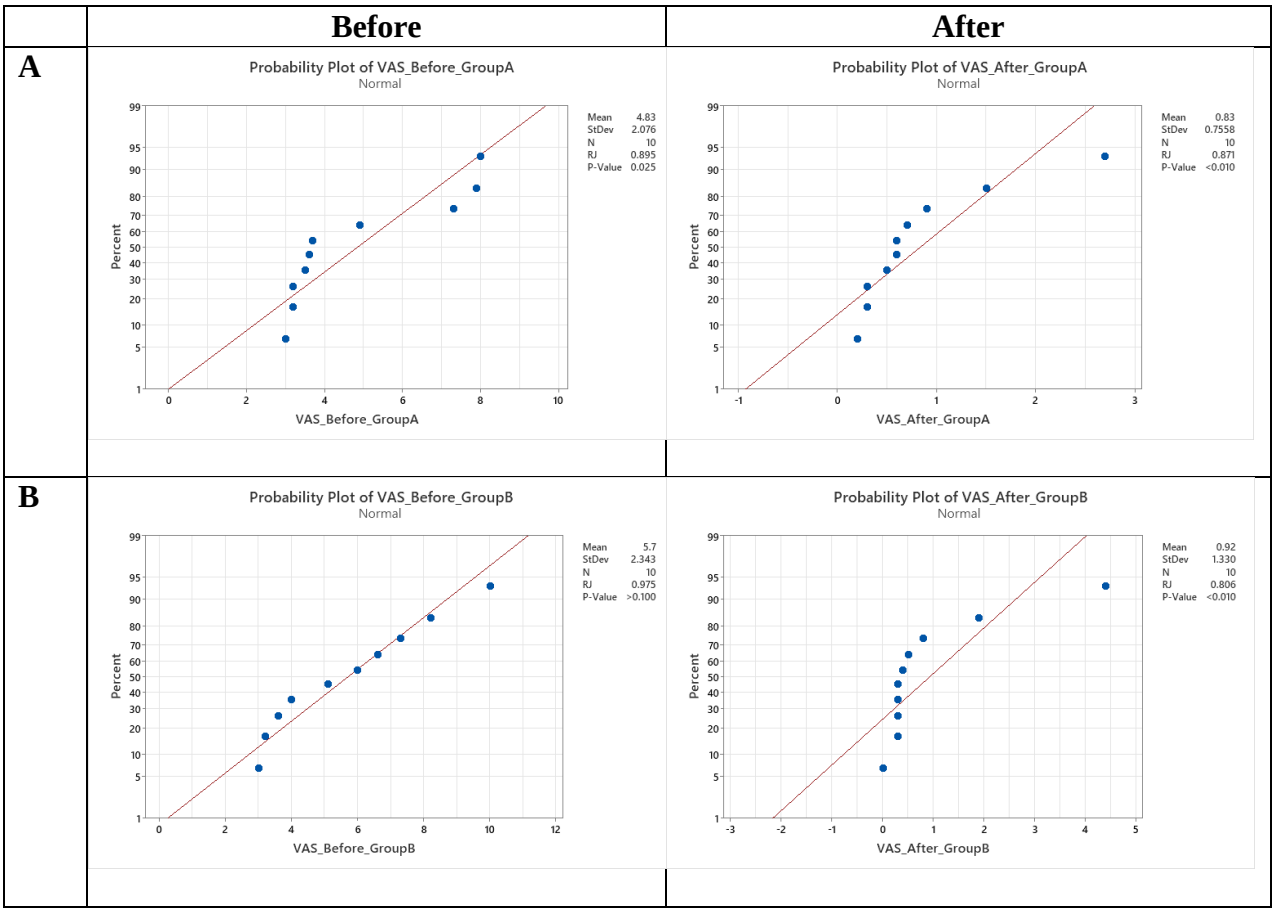


Figure 18 Illustrates the Probability Plots for Before and After VAS scores in Group A and Group B

With a 95% level of confidence the above plots demonstrate that in Group A Before and After the p-value is 0.025 and <0.01 respectively, meaning that it is less than 0.05,

therefore the Null Hypothesis is rejected, signifying that the data set is not evenly distributed. Therefore, non-parametric tests are required to evaluate the data further statistically.

On the other hand, with a 95% level of confidence the above plots demonstrate that in Group B Before and After the p-value is >0.1 in Group B, meaning that it is greater than 0.05, therefore the Null Hypothesis is accepted, signifying that the data set is evenly distributed; but a p-value of <0.01 in Group A, means that it is less than 0.05, therefore the Null Hypothesis is rejected, signifying that the data set is not evenly distributed. Therefore, non-parametric tests are required to evaluate the data further statistically.

4.2.1.1.2. Normality Analysis of Group A Difference and Group B Difference Before and After intervention.

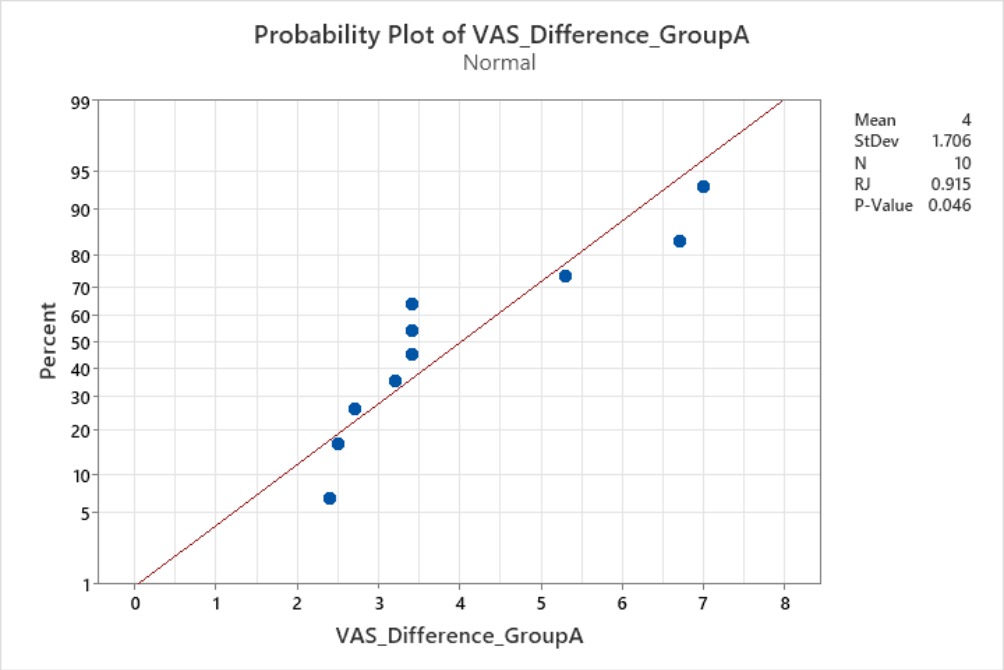


Figure 19 *illustrates the probability plot for the Visual Analog scale scores in Group A*

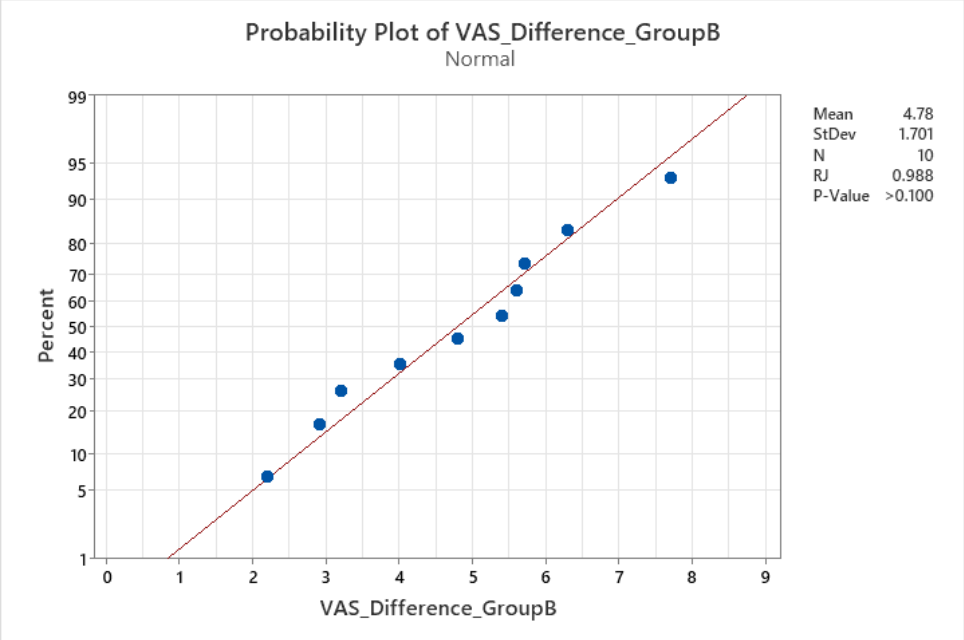


Figure 20 *illustrates the probability plot for the visual analog scale scores in group B*

With a 95% level of confidence, the above plots demonstrate that the p-value is 0.046 and >0.1, respectively for group A and group B. This signifies that the data is not normally distributed in Group A, but it is normally distributed in Group. Therefore, non-parametric tests have to be used for further statistical examination of this data.

4.2.1.2. Statistical analysis of before and after in Comparison Group A and Experiment group B separately.

Since the Shapiro-Wilk test demonstrated that the data is not normally distributed, the Wilcoxon Signed-rank test was used, and the results are illustrated below, for Group A and B. Histograms were used to graphically represent the data being statistically analysed, the Before is depicted using a blue solid line and the After is depicted using a dotted red line, for both Group A and Group B.

i. The null hypothesis states that there is no significant difference between Visual Analog Scale results in Comparison Group A Subjects Before Intervention and Visual Analog Scale results in Comparison Group A Subjects After Intervention. The alternative hypothesis states that there is a significant difference between Visual Analog Scale results in Comparison Group A Subjects Before Intervention and Visual Analog Scale results in Comparison Group A Subjects After Intervention.

ii. The null hypothesis states that there is no significant difference between Visual Analog Scale results in Experiment Group B Subjects Before Intervention and Visual Analog Scale results in Experiment Group B Subjects After Intervention. The alternative hypothesis states that there is a significant difference between Visual Analog Scale results in Experiment Group B Subjects Before Intervention and Visual Analog Scale results in Experiment Group B Subjects After Intervention.

Table 13 illustrates the statistical values of the statistical tests of the VAS scores Before and After intervention in Group A and Group B separately

Group	Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
A	4.00	+/-1.706	0.006	yes	Rejected
B	4.78	+/-1.701	0.006	yes	Rejected

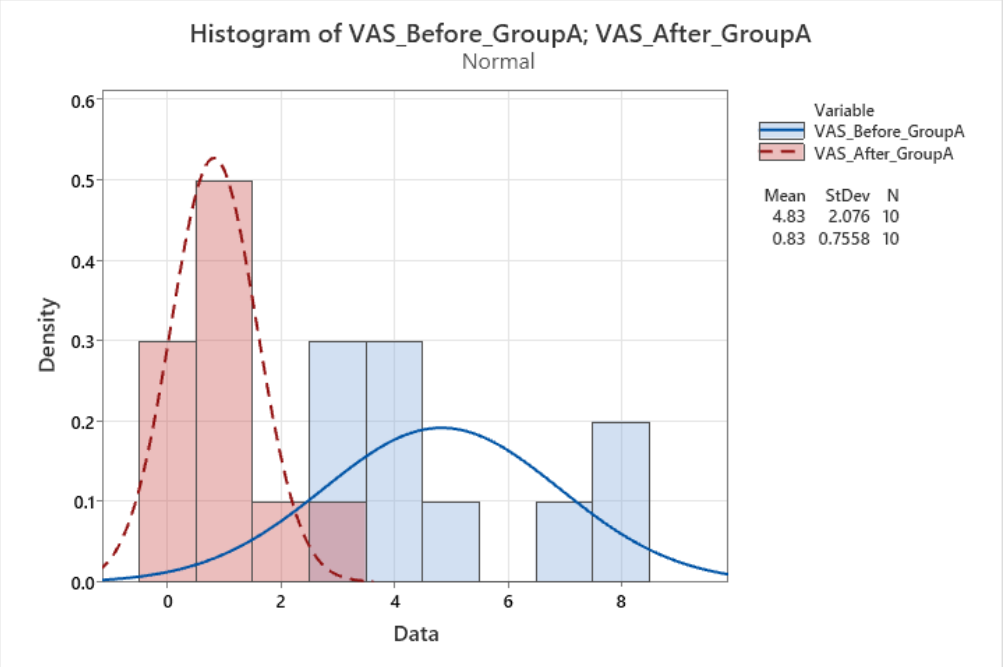


Figure 21 *illustrates the Histogram plot of the Wilcoxon Signed-rank test of the VAS score comparison Before and After intervention in Group A.*

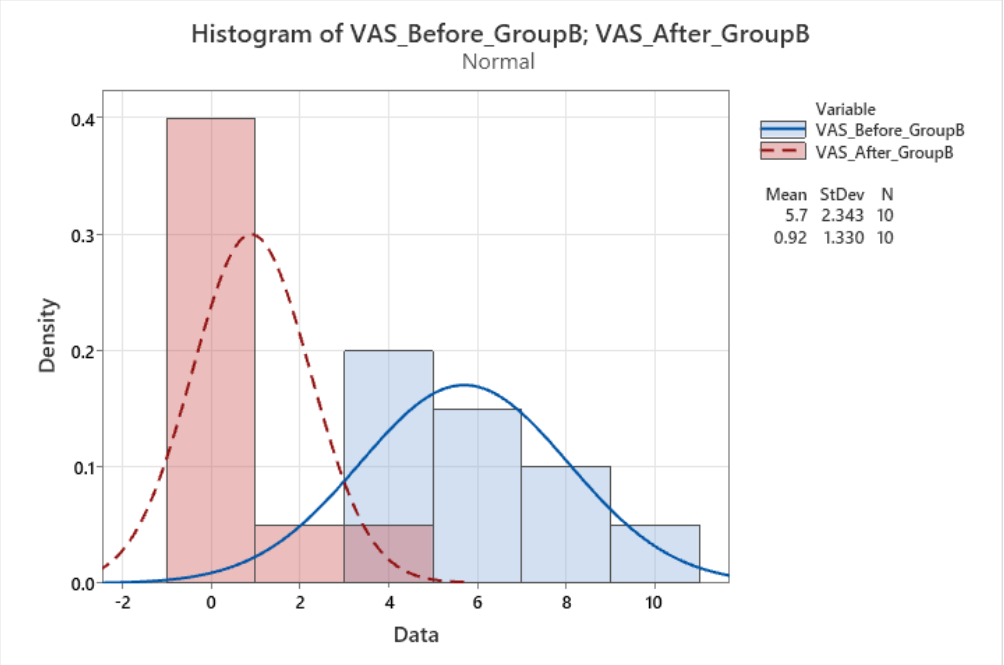


Figure 22 illustrates the Histogram plot of the Wilcoxon Signed-rank test of the VAS score comparison Before and After intervention in Group B.

With a 95% level of confidence, the above plots demonstrate that the p-value outcome in both groups is that of 0.006 meaning that it is smaller than 0.05. That means that the null

hypothesis is rejected, and that the alternative hypothesis is accepted, showing that there is significant difference before and after intervention in both groups. This means that in both groups the value of the visual analog scale score decreased significantly, therefore indicating an improvement in Low Back Pain with both interventions.

4.2.1.2. Statistical analysis of before and after intervention difference in VAS scores between Group A and Group B.

Since the Shapiro-Wilk test demonstrated that the data is not normally distributed, the Mann-Whitney test was used, and the results are illustrated below. Histograms were used to graphically represent the data being statistically analysed, Group A is depicted using a blue solid line and Group B is depicted using a dotted red line.

The null hypothesis states that there is no significant difference between Visual Analog Scale difference in results in Comparison Group A subjects and Visual Analog Scale difference results in Experiment Group B subjects. The alternative hypothesis states that there is a significant difference between Visual Analog Scale difference in results in Comparison Group A subjects and Visual Analog Scale difference results in Experiment Group B subjects.

Table 14 illustrates the statistical values of before and after intervention difference in VAS scores between Group A and Group B

Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
A:4.00 B: 4.78	A: +/-1.71 B: +/-1.70	0.364	No	Accepted

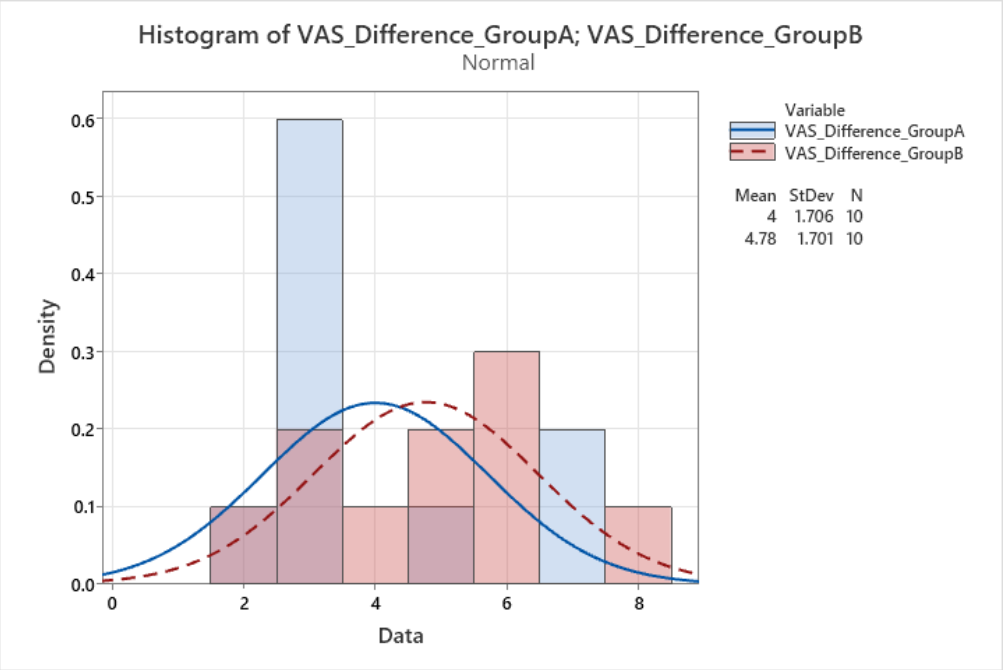


Figure 23 illustrates the Histogram plot of before and after intervention difference in VAS scores between Group A and Group B

With a 95% level of confidence, the above plots demonstrate that the p-value outcome is that of 0.364 meaning that it is larger than 0.05. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference before and after intervention difference in VAS scores between Group A and Group B.

Although there is not a statistically significant difference in the treatment outcome between the groups, in the Histogram plot seen above, one can notice that the difference is greater Group B, meaning that there was more improvement in pain levels in individuals with low back pain, when compared to Group A.

4.2.2. Statistical analysis of the Oswestry Disability Index.

4.2.2.1. Determining the normal distribution.

The Shapiro-Wilk test was used to assess the normality assumption of score distribution for each group of participants (n=10) separately as illustrated below in the Probability plots presented below. The null hypothesis states that the data is normally distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

4.2.1.1.1. Normality Analysis of Before and After scores in Group A and Group B.

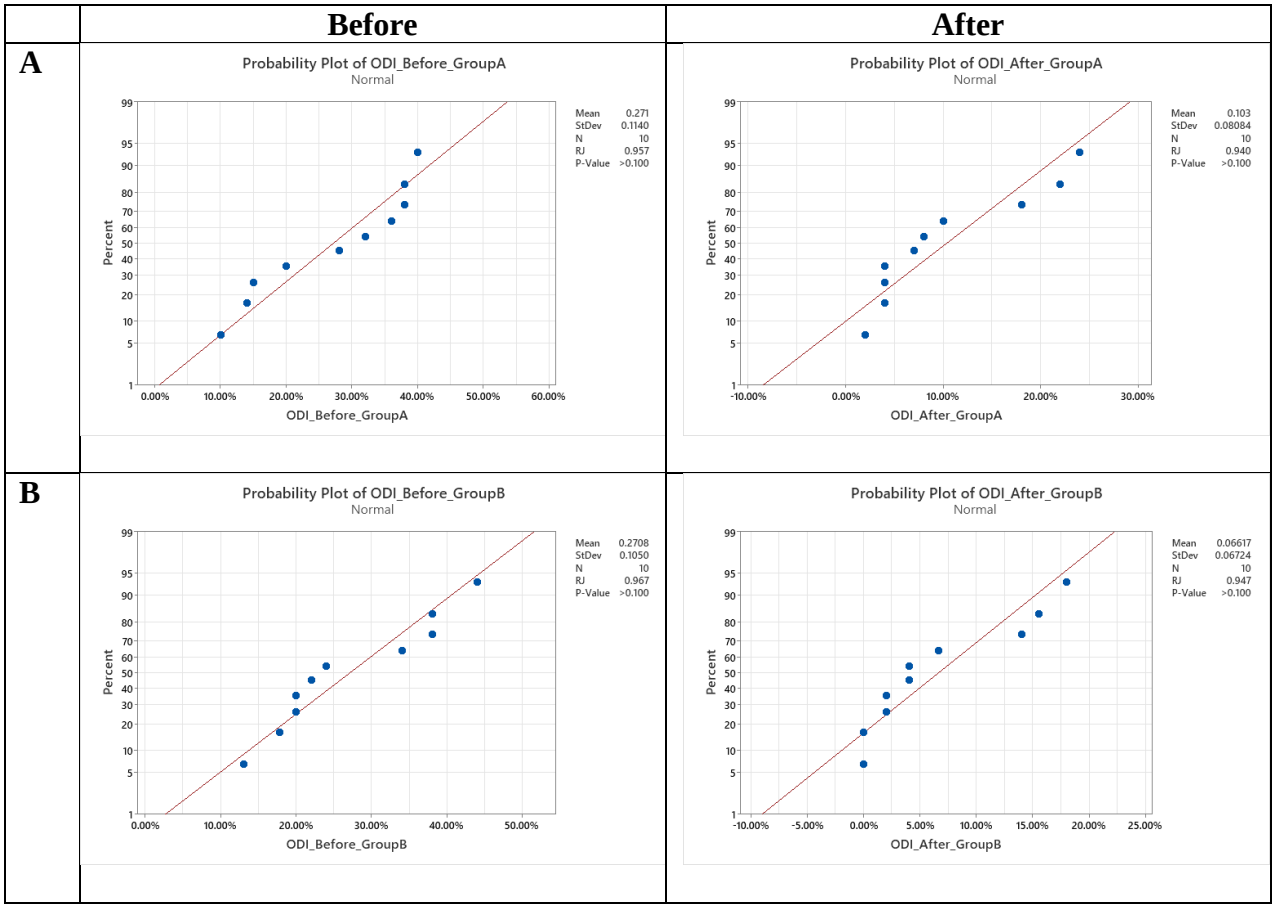


Figure 24 Illustrates the Probability Plots for Before and After ODI scores in Group A and Group B

With a 95% level of confidence, the above plots demonstrate that in both groups the p-value exceeds 0.05, 0.079 and 0.898, respectively for group A and group B. This signifies that the data is normally distributed. Therefore, parametric tests such as the independent test and the paired sample t-test can be used for further statistical examination of this data.

4.2.1.1.2. Normality Analysis of Group A Difference and Group B Difference Before and After intervention.

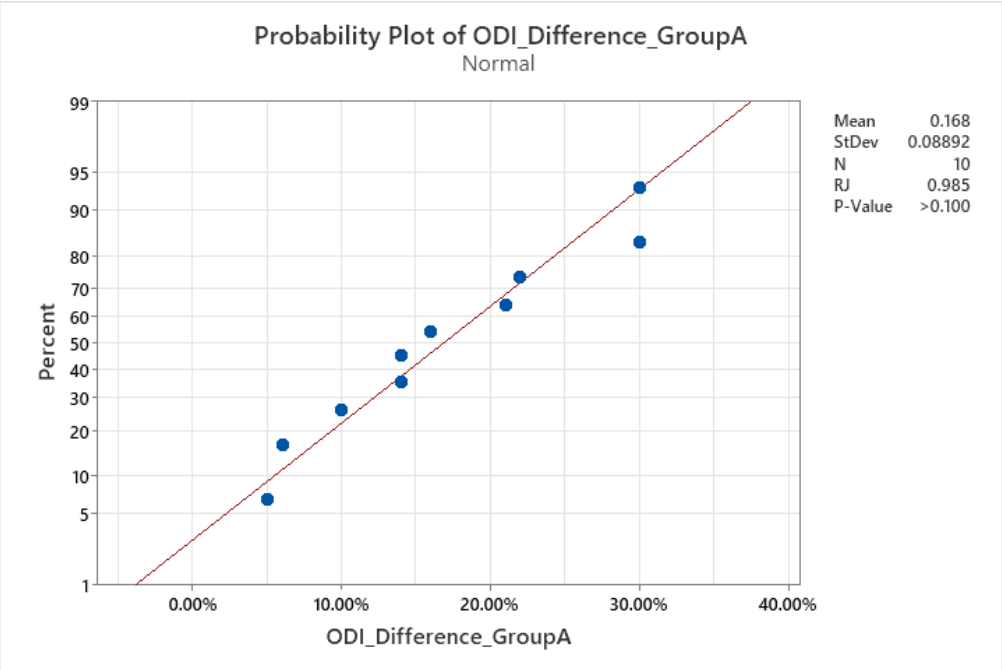


Figure 25 illustrates the probability plot for the Oswestry Disability Index Score Difference in Group A

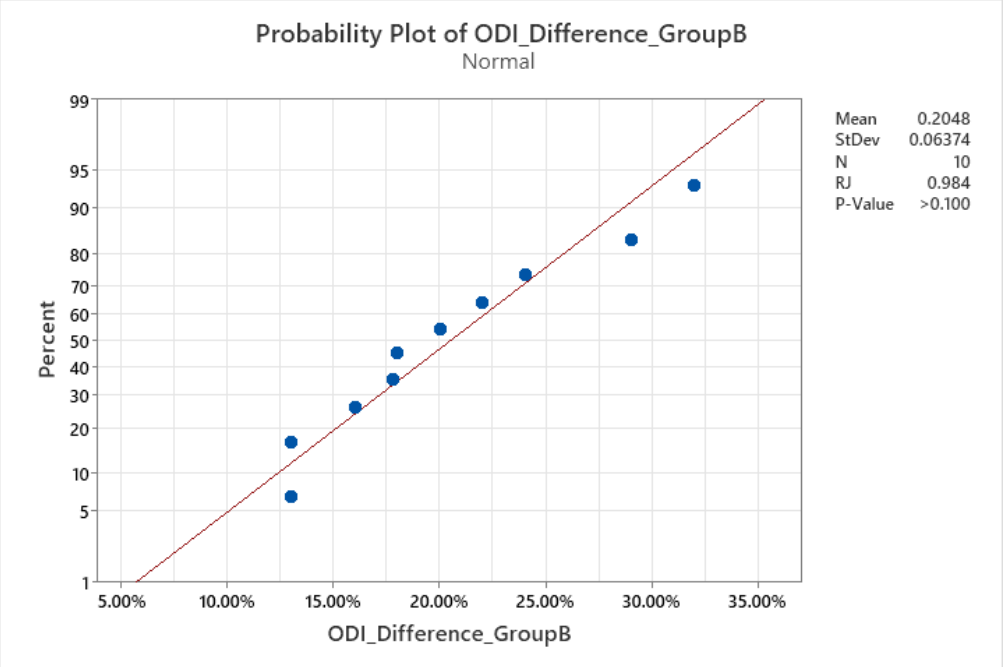


Figure 26 illustrates the probability plot for the Oswestry Disability Index Score Difference in Group B

With a 95% level of confidence, the above plots demonstrate that in both groups the p-value exceeds 0.05, >0.1 for both group A and group B. This signifies that the data is normally distributed since the Null Hypothesis has been accepted. Therefore, parametric tests such as the independent test and the paired sample t-test can be used for further statistical examination of this data.

4.2.1.2. Statistical analysis of before and after in Comparison Group A and Experiment Group B separately.

Since the Shapiro-Wilk test demonstrated that the data is normally distributed, the Paired sample t-test was used, and the results are illustrated below, for Group A and B. Histograms were used to graphically represent the data being statistically analysed, the Before is depicted using a blue solid line and the After is depicted using a dotted red line, for both Group A and Group B.

i. The null hypothesis states that there is no significant difference between Oswestry Disability Index Mean results in Comparison Group A Subjects Before Intervention and Oswestry Disability Index Mean results in Comparison Group A Subjects After Intervention. The alternative hypothesis states that there is a significant difference between Oswestry Disability Index Mean results in Comparison Group A Subjects Before Intervention and Oswestry Disability Index Mean results in Comparison Group A Subjects After Intervention.

ii. The null hypothesis states that there is no significant difference between Oswestry Disability Index Mean results in Experiment Group B Subjects Before Intervention and Oswestry Disability Index Mean results in Experiment Group B subjects After Intervention. The alternative hypothesis states that there is a significant difference between Oswestry Disability Index Mean results in Experiment Group B Subjects Before Intervention and Oswestry Disability Index Mean results in Experiment Group B subjects After Intervention.

Table 15 illustrates the statistical values of the Paired sample T-test of the ODI score Before and After intervention in Group A and Group B separately

Group	Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
A	0.168	+/-0.089	0.000	Yes	Rejected
B	0.205	+/-0.063	0.000	Yes	Rejected

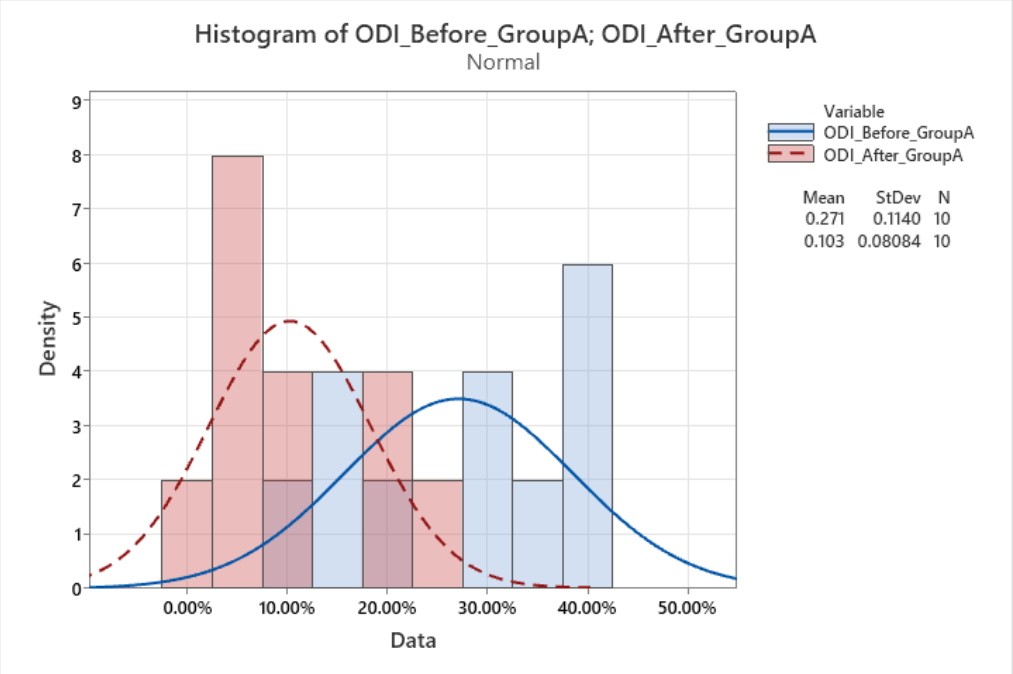


Figure 27 illustrates the Histogram plot of the Paired sample T-test of the ODI score comparison Before and After intervention in Group A.

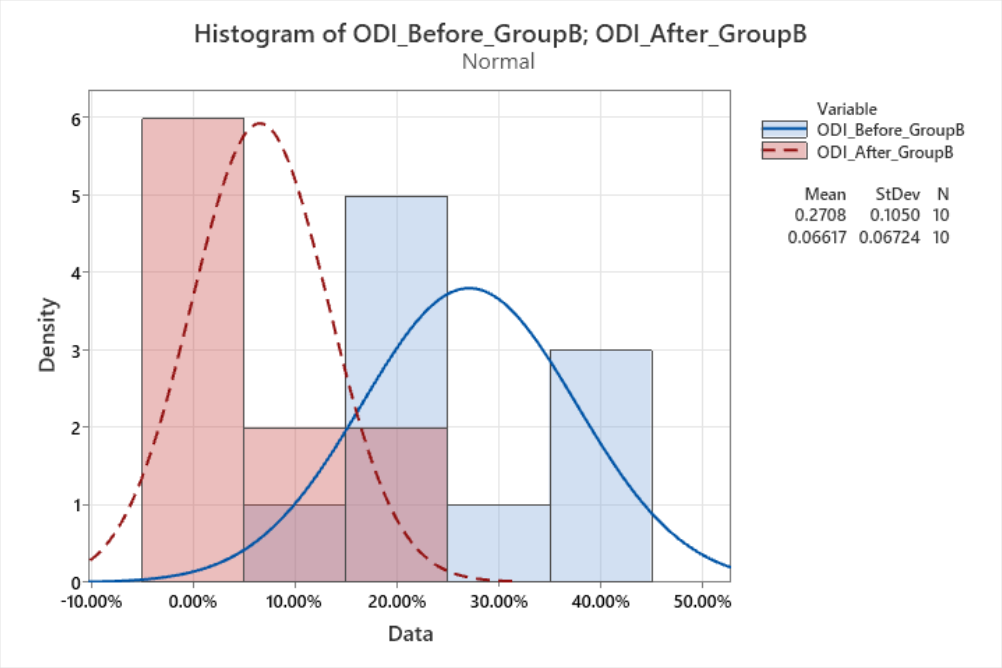


Figure 28 illustrates the Histogram plot of the Paired sample T-test of the ODI score comparison Before and After intervention in Group B.

With a 95% level of confidence, the above plots demonstrate that the p-value outcome in both groups is that of 0.000 for Group A and 0.000 for Group B, meaning that it is smaller

than 0.05. That means that the null hypothesis is rejected, and that the alternative hypothesis is accepted, showing that there is significant difference before and after intervention in both groups. Therefore, in both groups, the value of the Oswestry Disability Index score decreased significantly, therefore indicating an improvement in perceived disability due to Low Back Pain with both interventions.

4.2.1.2. Statistical analysis of before and after intervention difference in ODI scores between Group A and Group B.

Since the Shapiro-Wilk test demonstrated that the data is normally distributed, the Independent two tailed t-test (assuming unequal variance) was used, and the results are illustrated below. Histograms were used to graphically represent the data being statistically analysed, Group A is depicted using a blue solid line and Group B is depicted using a dotted red line.

The null hypothesis states that there is no significant difference between Oswestry Disability Index difference in results in Comparison Group A subjects and Oswestry Disability Index difference in results in Experiment Group B subjects. The alternative hypothesis states that there is a significant difference between Oswestry Disability Index difference in results in Comparison Group A subjects and Oswestry Disability Index difference in results in Experiment Group B subjects.

Table 16 illustrates the statistical values of before and after intervention difference in ODI scores between Group A and Group B

Mean	Standard Deviation	p-value	<0.05	Null Hypothesis
0.168 0.205	A +/-0.089 B +/- 0.064	0.304	No	Accepted

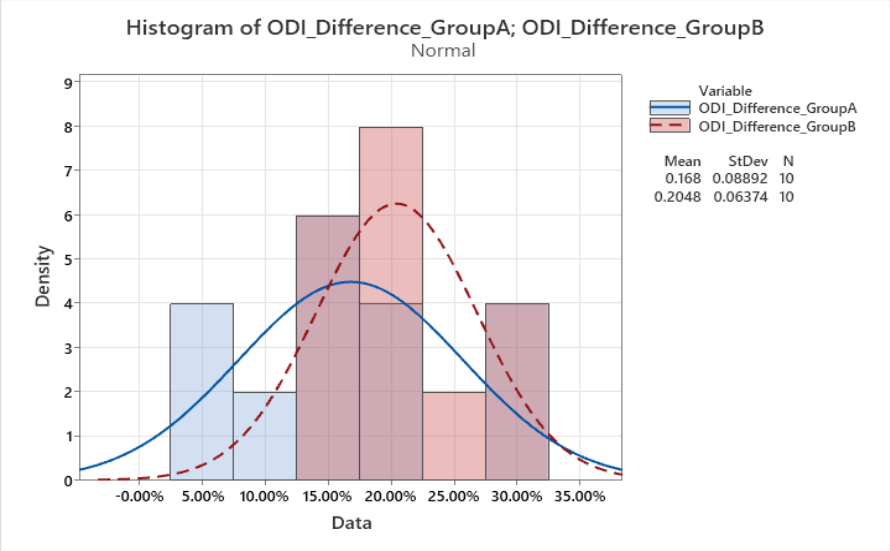


Figure 29 illustrates the Histogram plot of before and after intervention difference in ODI scores between Group A and Group B

With a 95% level of confidence, the above plots demonstrate that the p-value outcome is that of 0.304, meaning that it is larger than 0.05. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention difference in ODI scores between Group A and Group B.

Although there is not a statistically significant difference in the treatment outcome between the groups, in the Histogram plot above, one can notice that the difference is

greater in Group B, meaning that there was more improvement in perceived disability levels in individuals with low back pain, when compared to Group A.

4.2.3. Statistical analysis of the Kinematic and Spatiotemporal Data In Group A.

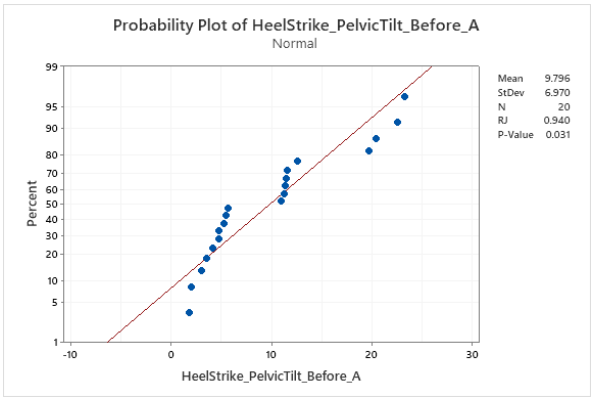
The Shapiro-Wilk test was used to determine the normal distribution of Kinematic and Spatiotemporal Data before and after intervention in Group A (n=20) as explained above in section 4.2.3.2. If data was normally distributed, the Paired Sample t-test was used to analyse the data, whereas if the data was not normally distributed the Wilcoxon signed-rank test was used to analyse the data. Histograms were used to graphically represent the data being statistically analysed, where Group A Before is depicted using a blue solid line and Group A After is depicted using a dotted red line, as represented in the Figure below. The same was repeated for Experiment Group B (n=20), as explained below.

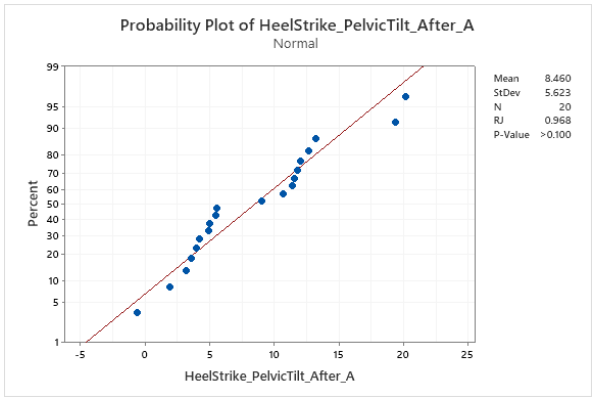
4.2.3.1. Determining the normal distribution.

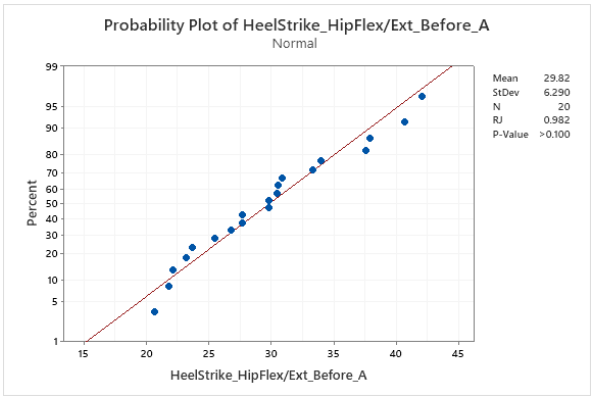
The Shapiro-Wilk test was used to assess the normality assumption of score distribution for each group of participants separately as illustrated below in the Probability plots for Kinematic and Spatiotemporal Data. The null hypothesis states that the data is normally distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

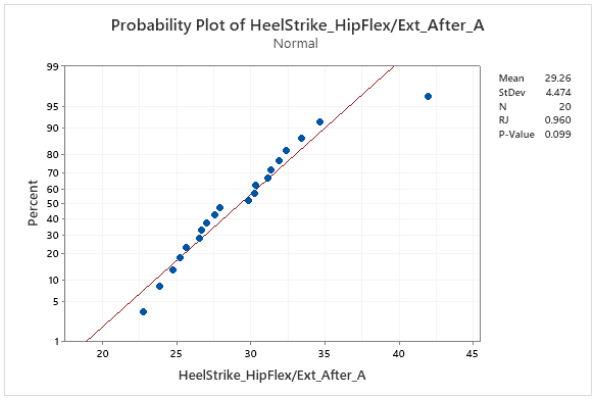
4.2.3.1.1. Kinematic Data.

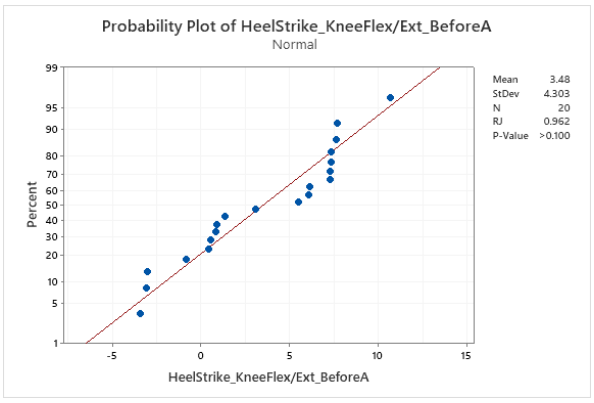
Before **After**

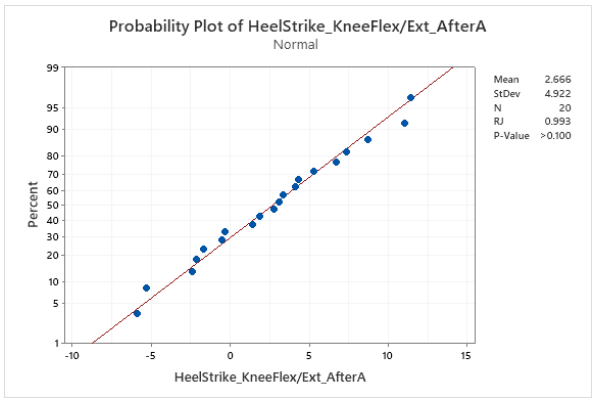


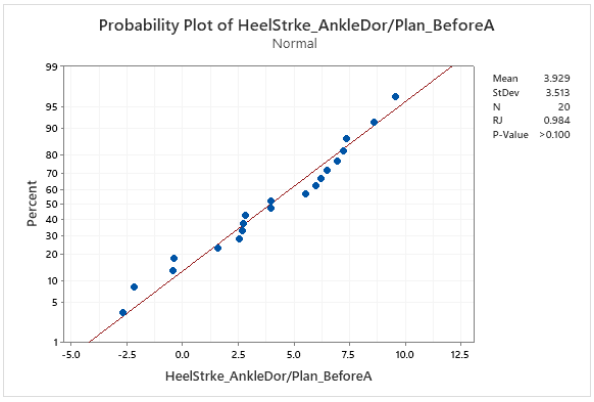


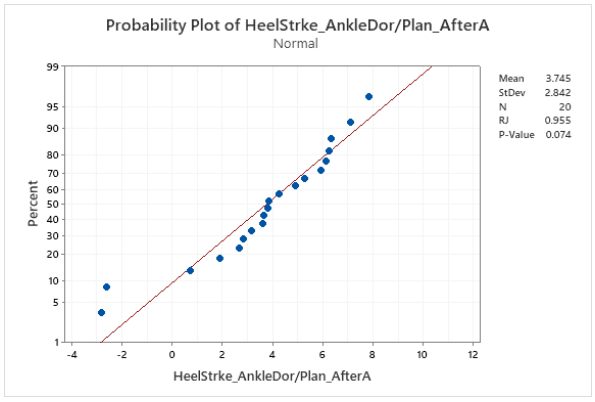


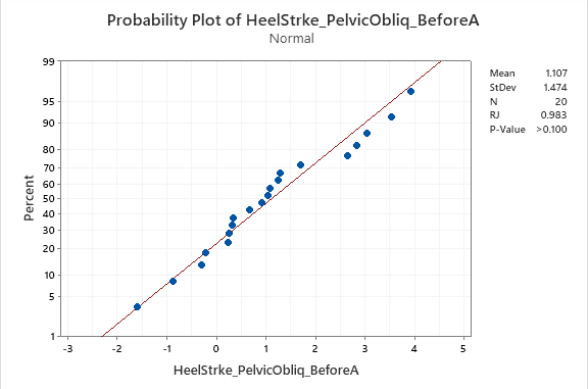


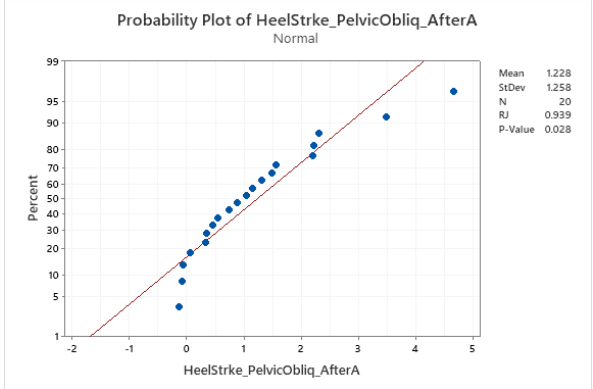


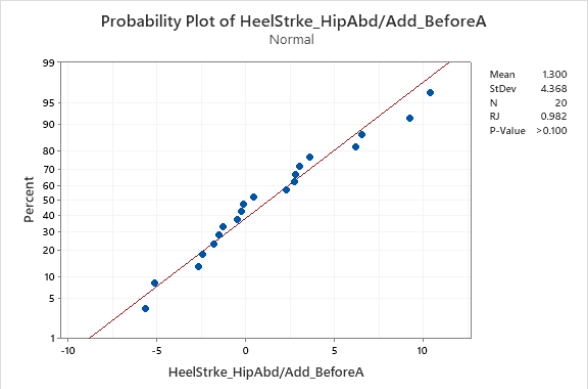


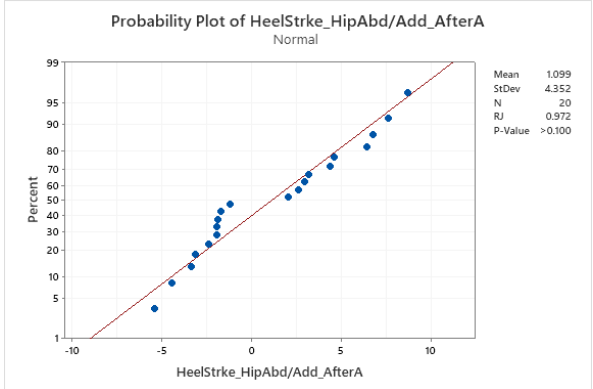


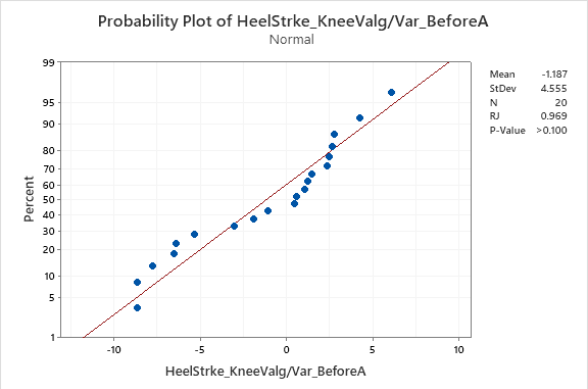


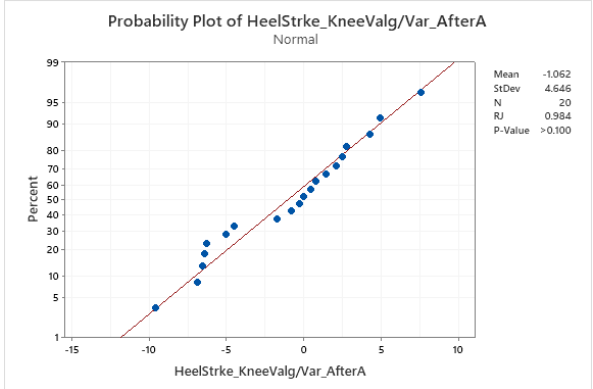

Probability Plot of HeelStrke_PelvicObliq_BeforeA
Normal
Mean 1.107
StDev 1.474
N 20
RJ 0.983
P-Value >0.100
Percent
HeelStrke_PelvicObliq_BeforeA

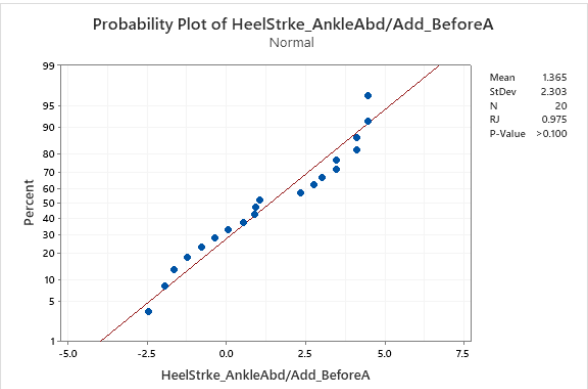

Probability Plot of HeelStrke_PelvicObliq_AfterA
Normal
Mean 1.228
StDev 1.258
N 20
RJ 0.939
P-Value 0.028
Percent
HeelStrke_PelvicObliq_AfterA

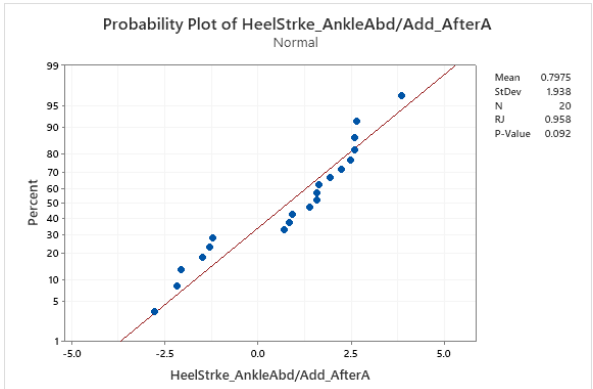

Probability Plot of HeelStrke_HipAbd/Add_BeforeA
Normal
Mean 1.300
StDev 4.368
N 20
RJ 0.982
P-Value >0.100
Percent
HeelStrke_HipAbd/Add_BeforeA

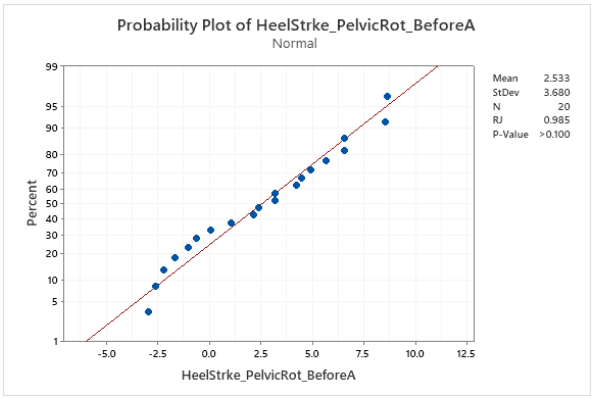

Probability Plot of HeelStrke_HipAbd/Add_AfterA
Normal
Mean 1.099
StDev 4.352
N 20
RJ 0.972
P-Value >0.100
Percent
HeelStrke_HipAbd/Add_AfterA

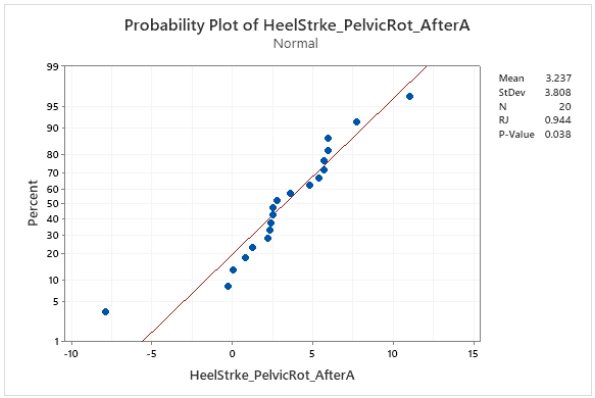

Probability Plot of HeelStrke_KneeValg/Var_BeforeA
Normal
Mean -1.187
StDev 4.555
N 20
RJ 0.969
P-Value >0.100
Percent
HeelStrke_KneeValg/Var_BeforeA

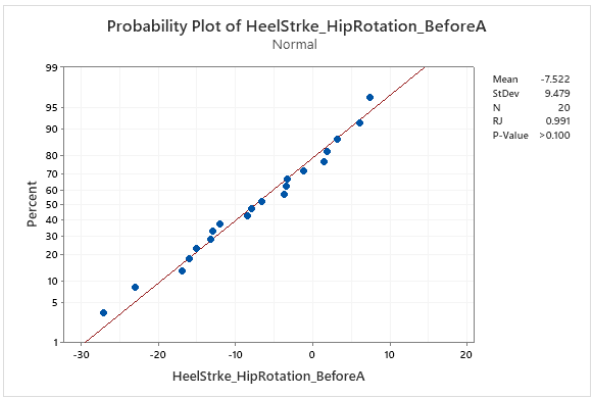

Probability Plot of HeelStrke_KneeValg/Var_AfterA
Normal
Mean -1.062
StDev 4.646
N 20
RJ 0.984
P-Value >0.100
Percent
HeelStrke_KneeValg/Var_AfterA

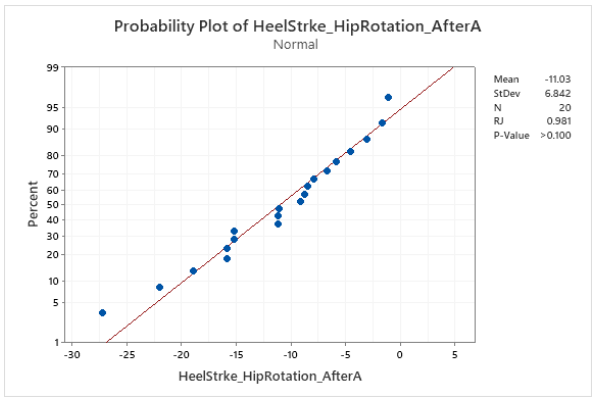

Probability Plot of HeelStrke_AnkleAbd/Add_BeforeA
Normal
Mean 1.365
StDev 2.303
N 20
RJ 0.975
P-Value >0.100
Percent
HeelStrke_AnkleAbd/Add_BeforeA

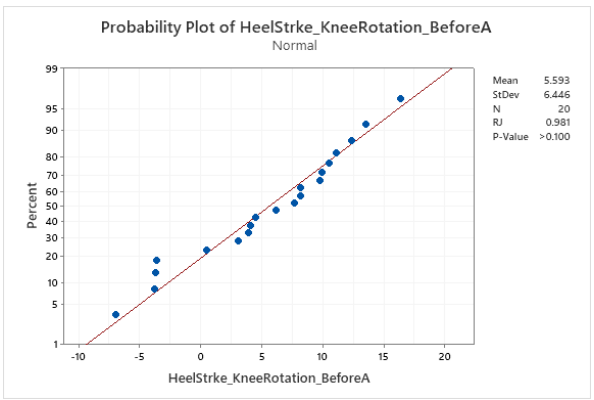

Probability Plot of HeelStrke_AnkleAbd/Add_AfterA
Normal
Mean 0.7975
StDev 1.938
N 20
RJ 0.958
P-Value 0.092
Percent
HeelStrke_AnkleAbd/Add_AfterA

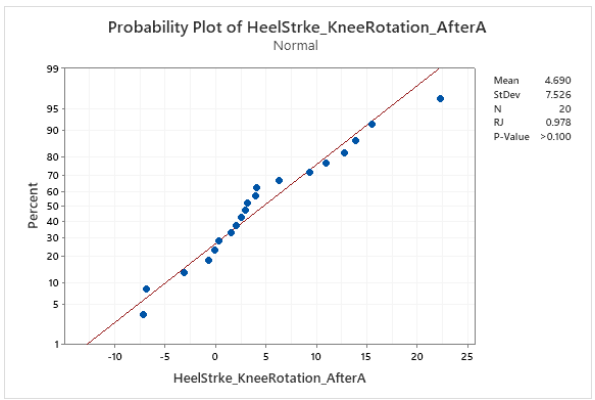


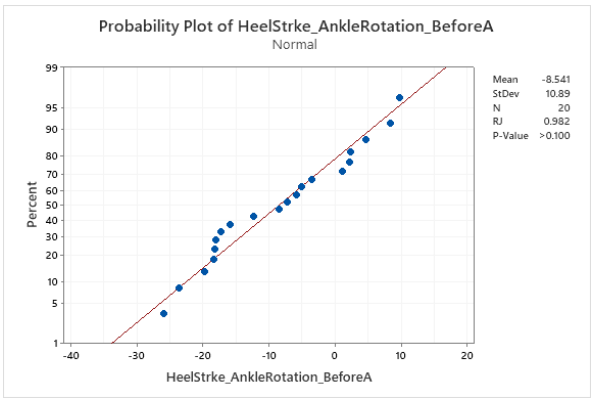












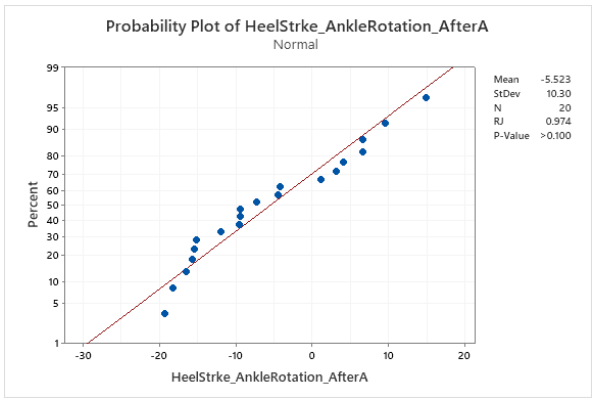


Figure 30 illustrates the normality analysis of before and after intervention at Heel Strike in Group A

With a 95% level of confidence, the above plots demonstrate that the majority of angles the p-value exceeds 0.05, for both Before and After intervention in Group A. This signifies that the data is normally distributed since the Null Hypothesis has been accepted. Therefore, parametric tests such as the Paired Sample t-test can be used for further statistical examination of this data. This is except for Pelvic Tilt Before (p-value 0.031), Pelvic Obliquity After (p-value 0.028) and Pelvic Rotation After (p-value 0.038), since the p-values are less than 0.05, therefore the Null Hypothesis has been rejected, while the Alternative Hypothesis has been accepted. This meant that the data for these angles are not normally distributed, and non-parametric statistical tests were needed for further statistical examination. Further breakdown of the p-values can be found below.

Table 17 p-value for the Normal Distribution for Kinematic Data at Heel Strike of Group A Before and After Intervention

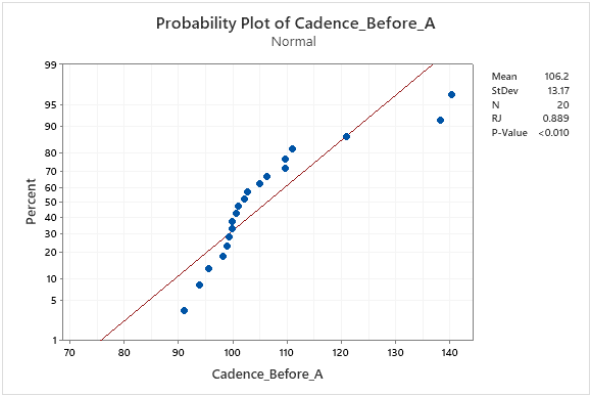
	Before			After		
Angle	p-value	<0.05	Null Hypothesis	p-value	<0.05	Null Hypothesis
Pelvic Tilt	0.031	Yes	Rejected	>0.1	No	Accepted
Hip Flex/Ext	>0.1	No	Accepted	0.099	No	Accepted
Knee Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Dorsi/Plantar	>0.1	No	Accepted	0.074	No	Accepted
Pelvic Obliquity	>0.1	No	Accepted	0.028	Yes	Rejected
Hip Abd/Add	>0.1	No	Accepted	>0.1	No	Accepted
Knee Valg/Var	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Abd/Add	>0.1	No	Accepted	0.092	No	Accepted
Pelvic Rotation	>0.1	No	Accepted	0.038	Yes	Rejected
Hip Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Knee Rotation	>0.1	No	Accepted	>0.1	No	Accepted

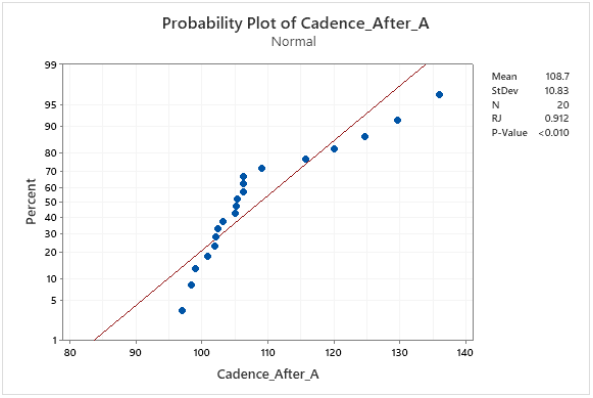
Ankle Rotation	>0.1	No	Accepted	>0.1	No	Accepted

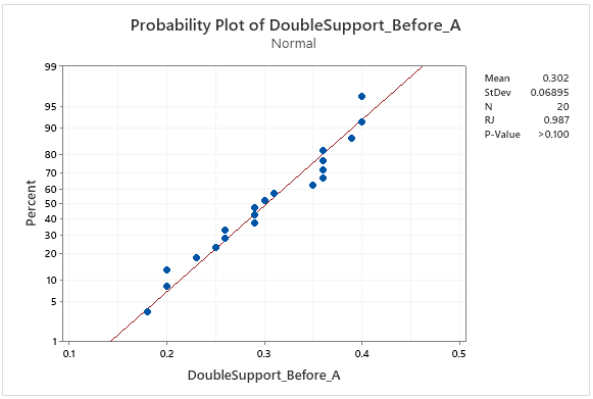
The above Statistical Analysis was then repeated for Midstance and Toe Off. Refer to Appendix 7-8 for the Probability Plots and Analysis of Data.

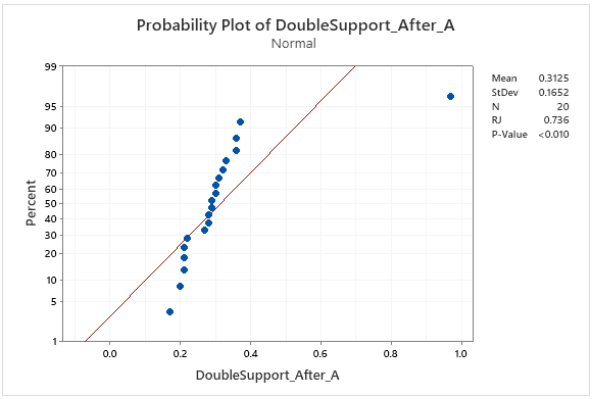
4.2.3.2.2. Spatiotemporal Data.

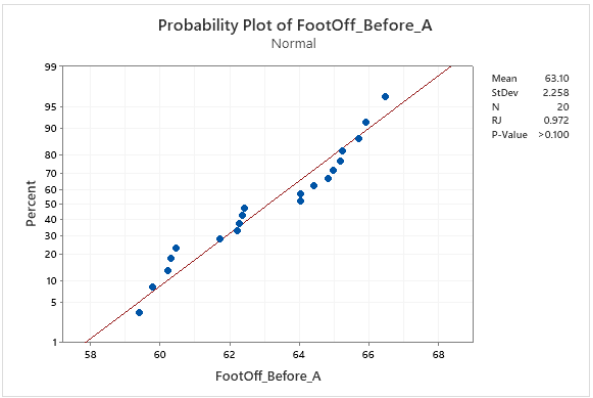
Before **After**

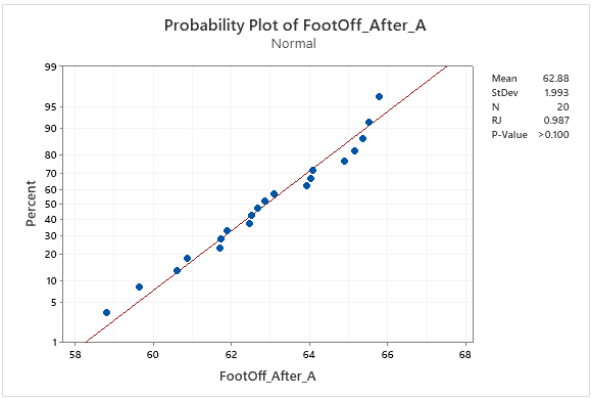


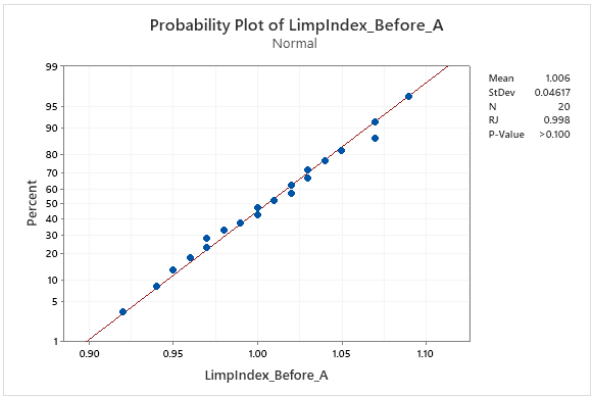


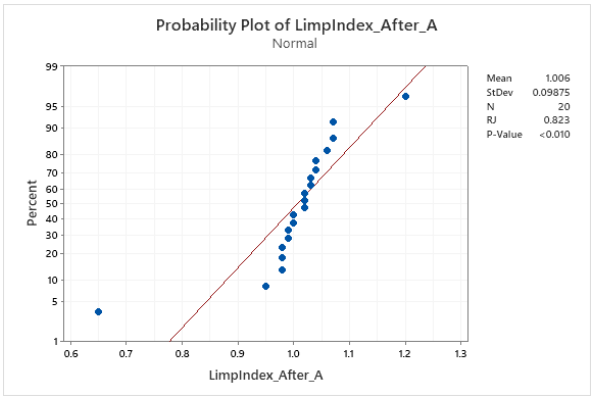


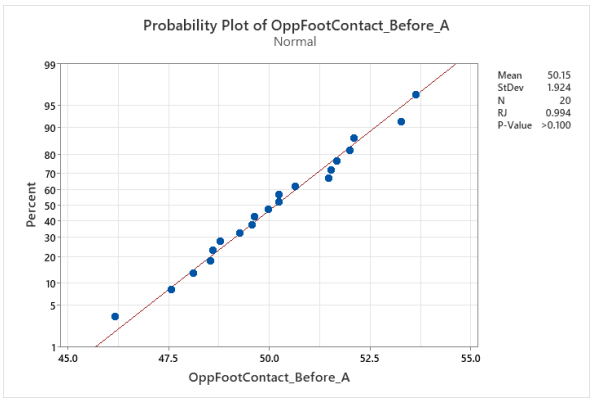


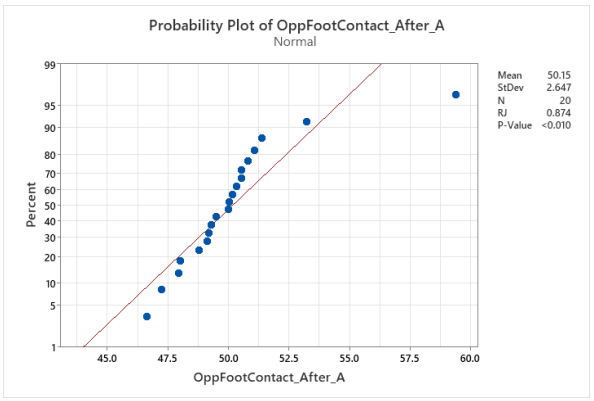


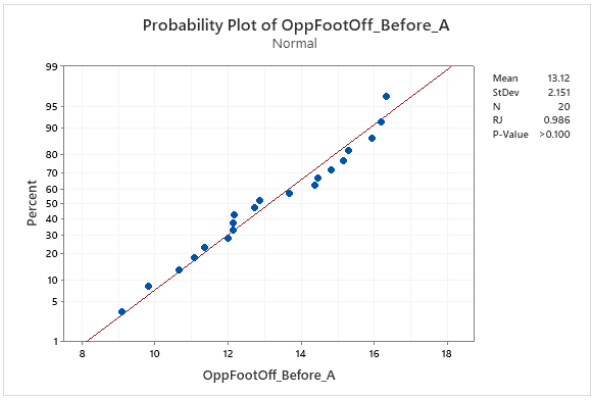


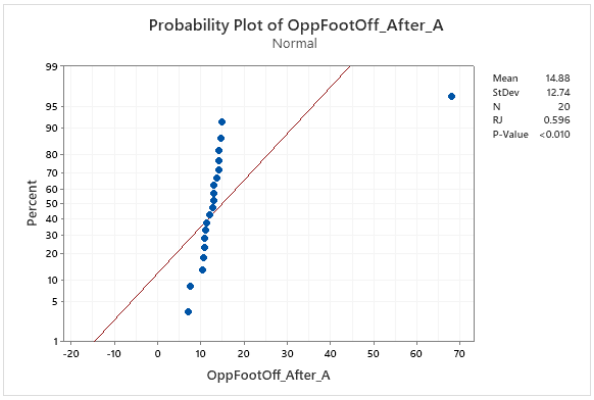

Probability Plot of LimpIndex_Before_A
Normal
Mean 1.006
StDev 0.04617
N 20
RJ 0.998
P-Value >0.100
Percent
LimpIndex_Before_A

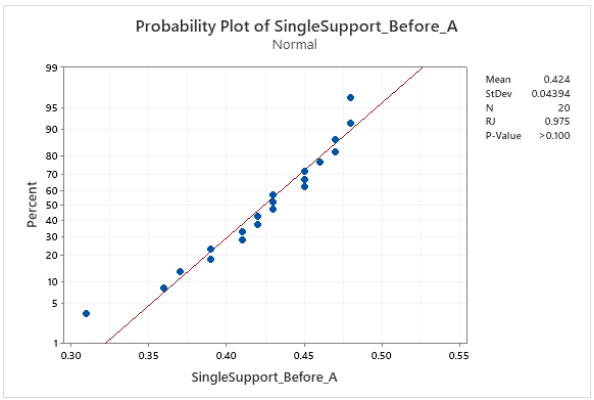

Probability Plot of LimpIndex_After_A
Normal
Mean 1.006
StDev 0.09875
N 20
RJ 0.823
P-Value <0.010
Percent
LimpIndex_After_A

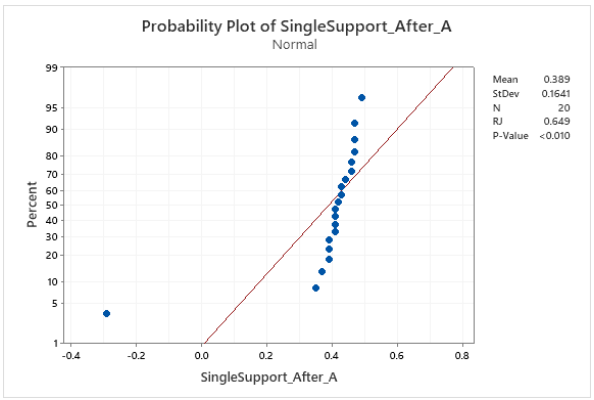

Probability Plot of OppFootContact_Before_A
Normal
Mean 50.15
StDev 1.924
N 20
RJ 0.994
P-Value >0.100
Percent
OppFootContact_Before_A

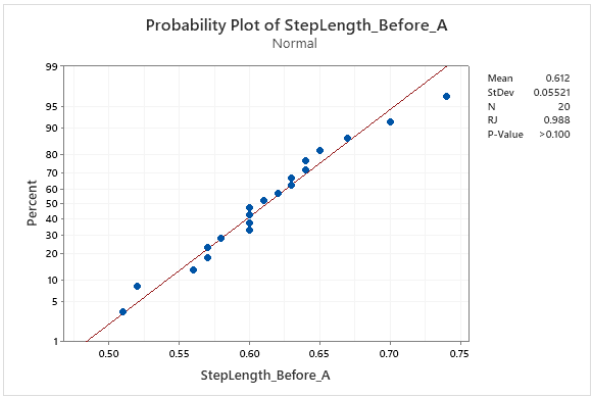

Probability Plot of OppFootContact_After_A
Normal
Mean 50.15
StDev 2.647
N 20
RJ 0.874
P-Value <0.010
Percent
OppFootContact_After_A

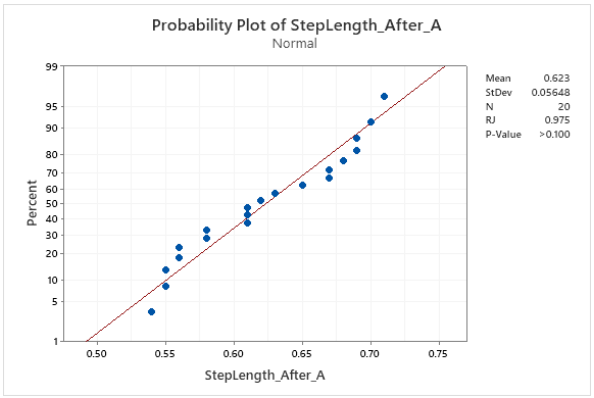

Probability Plot of OppFootOff_Before_A
Normal
Mean 13.12
StDev 2.151
N 20
RJ 0.986
P-Value >0.100
Percent
OppFootOff_Before_A

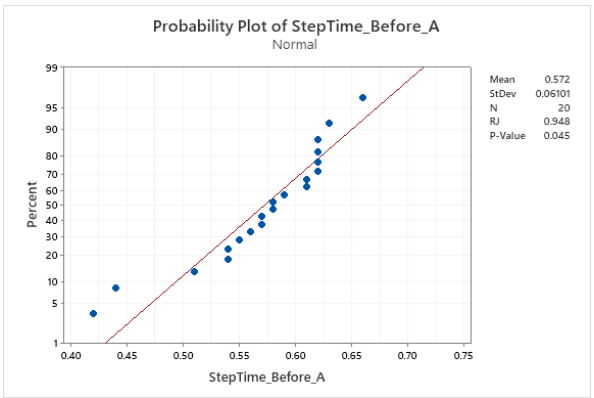

Probability Plot of OppFootOff_After_A
Normal
Mean 14.88
StDev 12.74
N 20
RJ 0.596
P-Value <0.010
Percent
OppFootOff_After_A

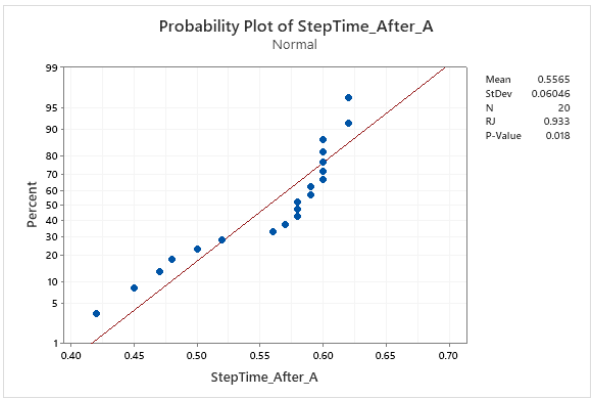

Probability Plot of SingleSupport_Before_A
Normal
Mean 0.424
StDev 0.04394
N 20
RJ 0.975
P-Value >0.100
Percent
SingleSupport_Before_A

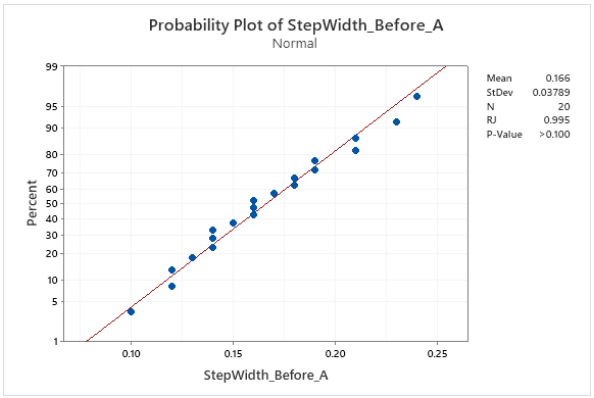

Probability Plot of SingleSupport_After_A
Normal
Mean 0.389
StDev 0.1641
N 20
RJ 0.649
P-Value <0.010
Percent
SingleSupport_After_A

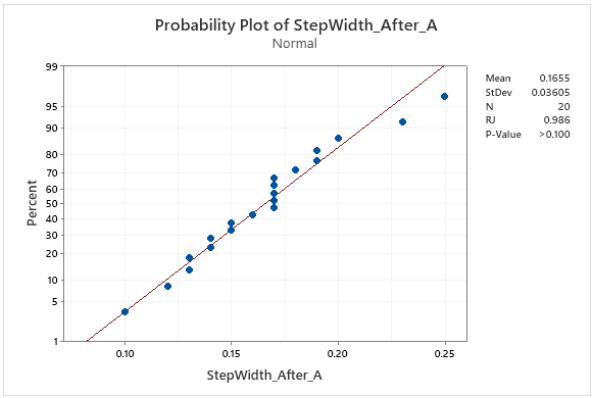

Probability Plot of StepLength_Before_A
Normal
Mean 0.612
StDev 0.05521
N 20
RJ 0.988
P-Value >0.100
Percent
StepLength_Before_A

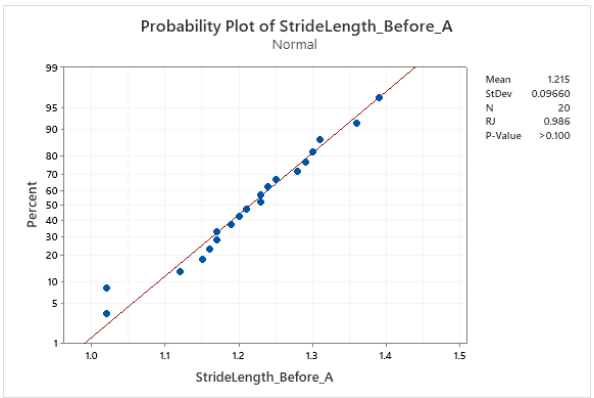

Probability Plot of StepLength_After_A
Normal
Mean 0.623
StDev 0.05648
N 20
RJ 0.975
P-Value >0.100
Percent
StepLength_After_A

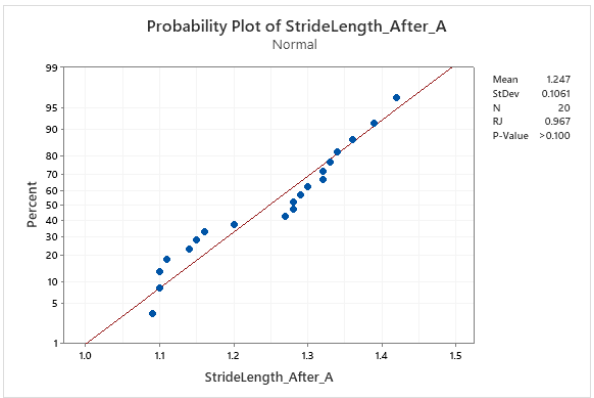

Probability Plot of StepTime_Before_A
Normal
Mean 0.572
StDev 0.06101
N 20
RJ 0.948
P-Value 0.045
Percent
StepTime_Before_A


Probability Plot of StepTime_After_A
Normal
Mean 0.5565
StDev 0.06046
N 20
RJ 0.933
P-Value 0.018
Percent
StepTime_After_A


Probability Plot of StepWidth_Before_A
Normal
Mean 0.166
StDev 0.03789
N 20
RJ 0.995
P-Value >0.100
Percent
StepWidth_Before_A


Probability Plot of StepWidth_After_A
Normal
Mean 0.1655
StDev 0.03605
N 20
RJ 0.986
P-Value >0.100
Percent
StepWidth_After_A


Probability Plot of StrideLength_Before_A
Normal
Mean 1.215
StDev 0.09660
N 20
RJ 0.986
P-Value >0.100
Percent
StrideLength_Before_A


Probability Plot of StrideLength_After_A
Normal
Mean 1.247
StDev 0.1061
N 20
RJ 0.967
P-Value >0.100
Percent
StrideLength_After_A

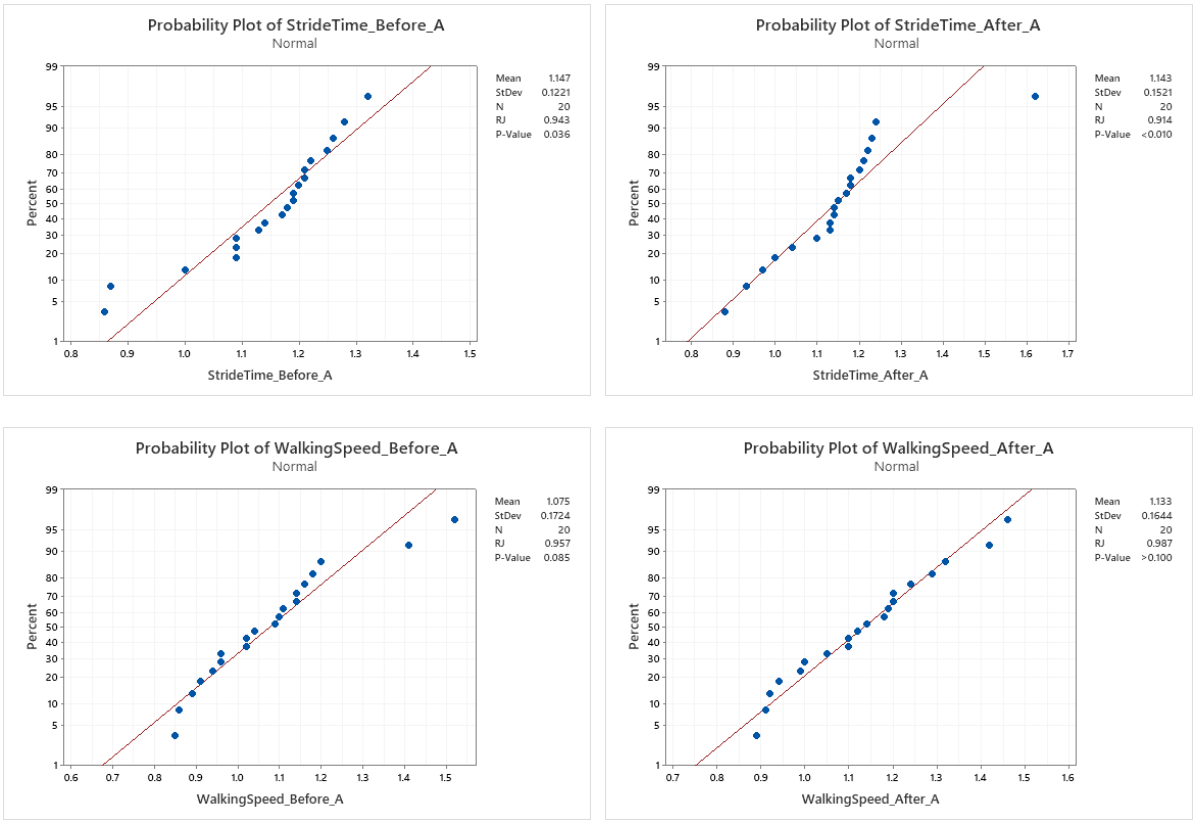


Figure 31 illustrates the probability plots for the Spatiotemporal Data Before and After intervention in Group A

With a 95% level of confidence, the above plots demonstrate that for both Before and After intervention in Group A there is a mix of p-values which either exceed or are less than 0.05. This signifies that not all the data is normally distributed, since the Null Hypothesis has not been accepted in several spatiotemporal data. Therefore, both parametric tests such as the Paired Sample t-test and non-parametric tests such as the Wilcoxon Signed-rank test must be used for further statistical examination of this data.

Table 18 p-value for the Normality values for Spatiotemporal Data of Group A Before and After Intervention

	Before			After		
Data	p-value	<0.05	Null Hypothesis	p-value	<0.05	Null Hypothesis
Cadence	<0.01	Yes	Rejected	<0.01	Yes	Rejected
Double Support	>0.1	No	Accepted	<0.01	Yes	Rejected
Foot Off	>0.1	No	Accepted	>0.1	No	Accepted
Limp Index	>0.1	No	Accepted	<0.01	Yes	Rejected
Opposite Foot Contact	>0.1	No	Accepted	<0.01	Yes	Rejected
Opposite Foot Off	>0.1	No	Accepted	<0.01	Yes	Rejected
Single Support	>0.1	No	Accepted	<0.01	Yes	Rejected
Step Length	>0.1	No	Accepted	>0.1	No	Accepted
Step Time	0.045	Yes	Rejected	0.018	Yes	Rejected
Step Width	>0.1	No	Accepted	>0.1	No	Accepted
Stride Length	>0.1	No	Accepted	>0.1	No	Accepted
Stride time	0.036	Yes	Rejected	<0.01	Yes	Rejected
Walking Speed	0.085	No	Accepted	>0.1	No	Accepted

4.2.3.2. Statistical Analysis of the Kinematic Data Before and After intervention in Group A.

The null hypothesis states that there is no significant difference between Kinematic results at heel strike, midstance and toe-off within the gait analysis mean results in Comparison Group A subjects Before Intervention and Kinematic Mean results in Comparison Group A subjects After Intervention. The alternative hypothesis states that there is a significant difference between Kinematic results at heel strike, midstance, and toe-off within the gait

analysis mean results in Comparison Group A Subjects Before Intervention and Kinematic Mean results in Comparison Group A subjects After Intervention. If the p-value is <0.05, the Null Hypothesis is rejected, whereas the Alternative Hypothesis is accepted.

Table 19 *Illustrates the Kinematic Data Statistical Analysis for Heel Strike Group A*

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon signed-rank test	0.113	no	accepted
Hip Flex/ext	Paired Sample t-test	0.518	no	accepted
Knee Flex/ext	Paired Sample t-test	0.335	no	accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.751	no	accepted
Pelvic Obliquity	Wilcoxon signed-rank test	0.695	no	accepted
Hip Abd/Add	Paired Sample t-test	0.745	no	accepted
Knee Valg/Var	Paired Sample t-test	0.709	no	accepted
Ankle Abd/Add	Paired Sample t-test	0.09	no	accepted
Pelvis Rotation	Wilcoxon signed-rank test	0.24	no	accepted
Hip Rotation	Paired Sample t-test	0.079	no	accepted
Knee Rotation	Paired Sample t-test	0.658	no	accepted
Ankle Rotation	Paired Sample t-test	0.09	no	accepted

With a 95% level of confidence, the above table demonstrate that the p-value outcome is larger than 0.05 in all angles at Heel Strike. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Kinematic scores between Group A at Heel Strike. Refer to Appendix 13 for the Histogram of the Kinematic Angles of Group A before and after intervention at Heel Strike.

Table 20 Illustrates the Kinematic Data Statistical Analysis for Midstance Group A

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon signed-rank test	0.563	no	accepted
Hip Flex/ext	Paired Sample t-test	0.442	no	accepted
Knee Flex/ext	Paired Sample t-test	0.732	no	accepted
Ankle Dorsi/Plantar	Wilcoxon signed-rank test	0.185	no	accepted
Pelvic Obliquity	Paired Sample t-test	0.366	no	accepted
Hip Abd/Add	Paired Sample t-test	0.573	no	accepted
Knee Valg/Var	Paired Sample t-test	0.961	No	accepted
Ankle Abd/Add	Paired Sample t-test	0.047	yes	rejected
Pelvis Rotation	Wilcoxon signed-rank test	0.951	no	accepted
Hip Rotation	Paired Sample t-test	0.041*	yes	rejected
Knee Rotation	Wilcoxon signed-rank test	0.72	no	accepted
Ankle Rotation	Paired Sample t-test	0.162	no	accepted

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most angles at Midstance. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Kinematic scores in Group A at Midstance. This is except for Ankle Abd/Add with a p-value of 0.047 and Hip Rotation with a p-value of 0.041. Since in both cases the p-value is smaller than 0.05 the Null Hypothesis is rejected, and the alternative hypothesis is accepted. Therefore, showing that there is statistical difference at those angles at Midstance Before and After intervention in Group A. As illustrated in Figures below, one can see that the dotted red line which represents the after showed a left shift more towards the zero, for both Ankle Abduction/Adduction and Hip Rotation, meaning that the ankle decreased Adduction and

became more neutral, and Hip rotation decreased Internal Rotation, and became more neutral.

Refer to Appendix 14 for the rest of the Histogram plots of the Kinematic Angles of Group A before and after intervention at Midstance.

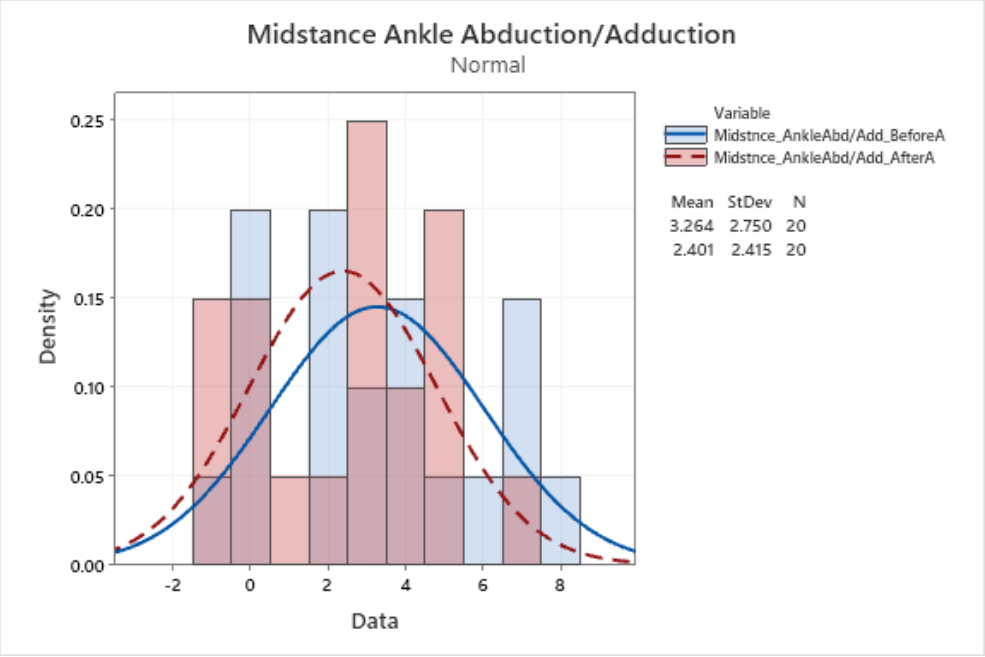


Figure 32 Illustrates the Histogram for Ankle Abduction at Midstance for Before and After in Group A

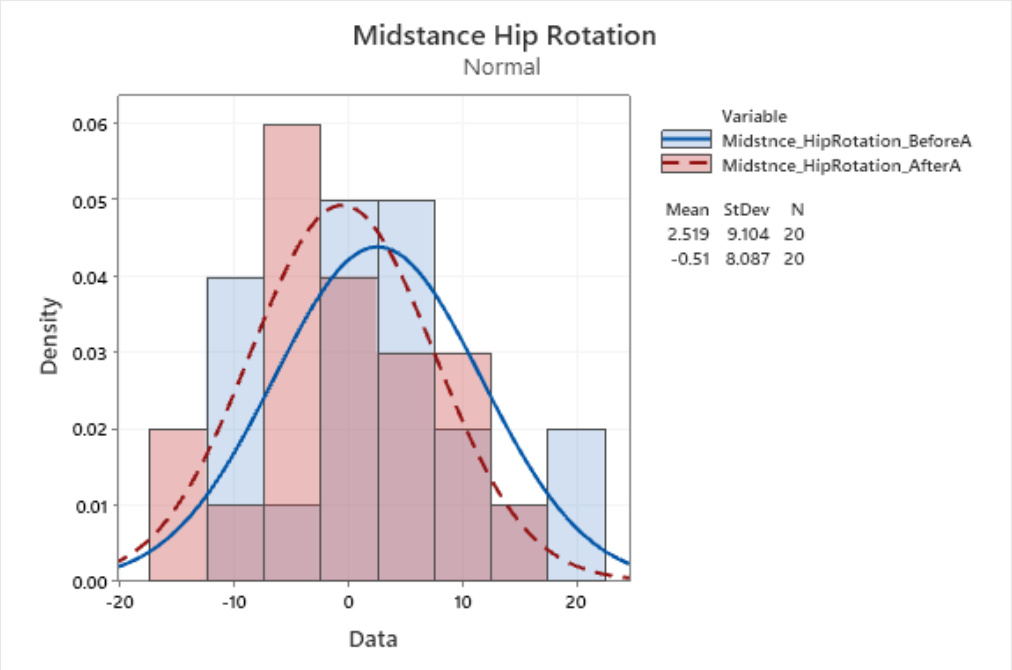


Figure 33 Illustrates the Histogram for Hip Rotation at Midstance Before and After for Group A

Refer to Appendix 15 for the Histograms of the Kinematic Angles of Group A before and after intervention at Midstance.

Table 21 Illustrates the Kinematic Data Statistical Analysis for Toe Off Group A

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon signed-rank test	0.198	no	accepted
Hip Flex/ext	Paired Sample t-test	0.129	no	accepted
Knee Flex/ext	Paired Sample t-test	0.999	no	accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.527	no	accepted
Pelvic Obliquity	Paired Sample t-test	0.362	no	accepted
Hip Abd/Add	Paired Sample t-test	0.896	no	accepted
Knee Valg/Var	Paired Sample t-test	0.025	yes	rejected
Ankle Abd/Add	Paired Sample t-test	0.018*	yes	rejected
Pelvis Rotation	Paired Sample t-test	0.708	no	accepted
Hip Rotation	Paired Sample t-test	0.032*	yes	rejected
Knee Rotation	Paired Sample t-test	0.692	no	accepted
Ankle Rotation	Wilcoxon signed-rank test	0.059	no	accepted

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most angles at Toe Off. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Kinematic scores between Group A at Toe Off. This is except for Knee Valgus/Varus with a p-value of 0.025, Ankle Abd/Add with a p-value of 0.018 and Hip Rotation with a p-value of 0.032. Since in all three cases the p-value is smaller than 0.05 the Null Hypothesis is rejected, and the alternative hypothesis is accepted. Therefore, showing that there is statistical difference at those angles at Toe Off

Before and After intervention in Group A. As illustrated in Figures below, one can see that the dotted red line which represents the after showed a left shift more towards the zero, for Knee Valgus/Varus, Ankle Abduction/Adduction and Hip Rotation, meaning that the knee decreased in varus and became more neutral, ankle decreased Adduction and became more neutral, and Hip rotation decreased Internal Rotation, and became more neutral.

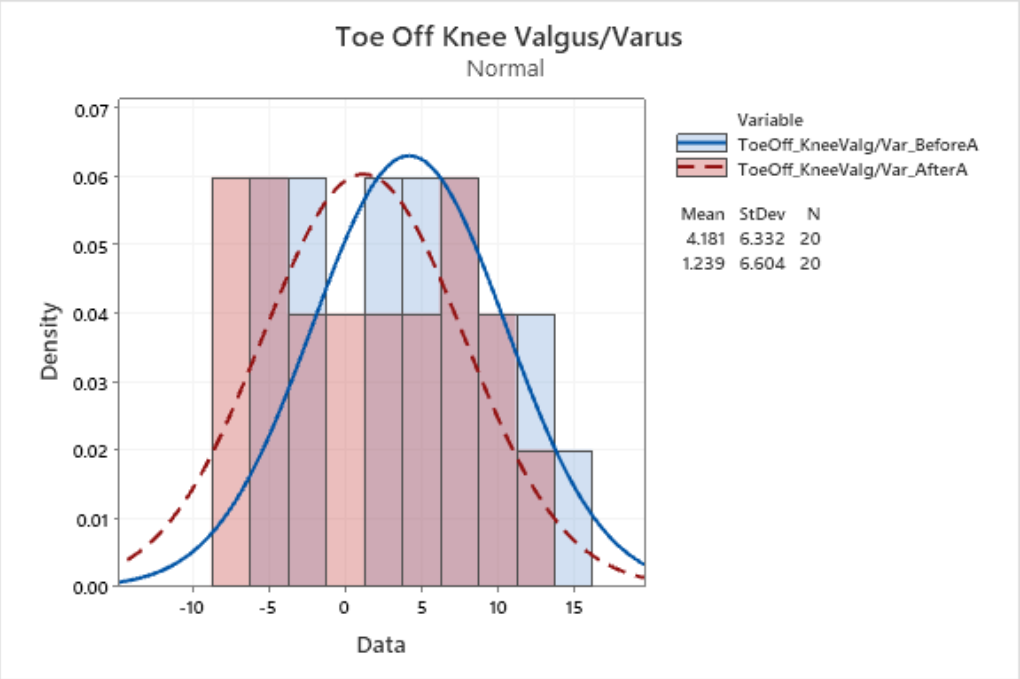


Figure 34 *Illustrates the Histogram Plot for Knee Valgus/Varus at Toe Off in Group A*

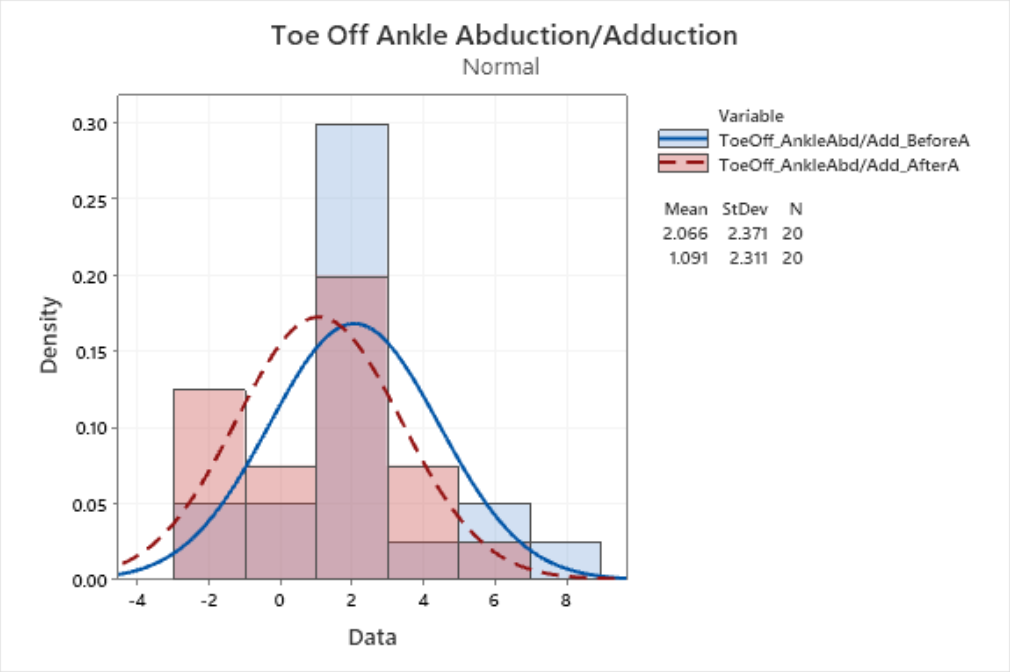


Figure 35 *Illustrates the Histogram Plot for Ankle Abduction/Adduction at Toe Off in Group A*

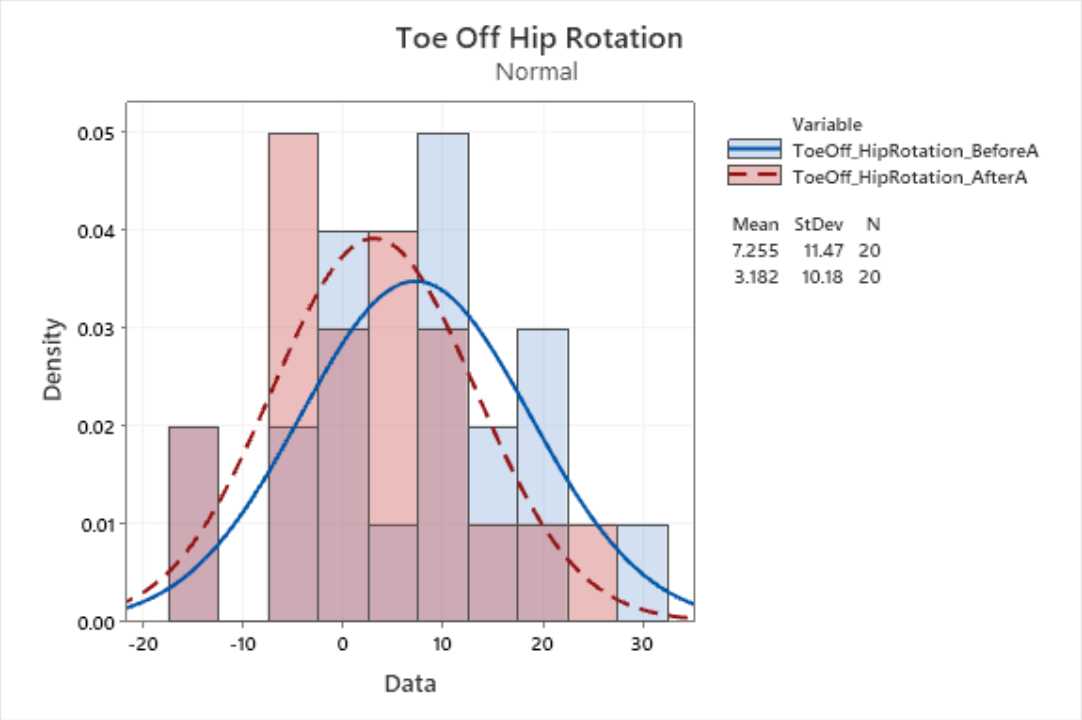


Figure 36 *Illustrates the Histogram Plot for Hip Rotation at Toe Off in Group A*

Refer to Appendix 16 for the Histograms of the of Kinematic Angles of Group A before and after intervention at Toe Off.

4.2.3.2.1. Statistical Analysis of the Kinematic Data Before and After intervention in Group A with Normative Data.

The Shapiro-Wilk test was used to determine the normal distribution of each Kinematic Data as explained above in section 4.2.3.2. If data was normally distributed, the One-Sample t-test was used to analyse the data, whereas if the data was not normally distributed the One-sample Wilcoxon signed-rank test was used to analyse the data, to compared with the Normative Data. Further details on the Normative Data can be found in Chapter 3.

The Null Hypothesis states that there is no significant difference between Before and After the intervention of Group A kinematic angles at Heel Strike, Midstance and Toe-Off, when compared with Normative Data. The Alternative Hypothesis states that there is a significant difference between Before and After intervention of Group A kinematic angles at Heel Strike, Midstance and Toe-Off, when compared with Normative Data.

Table 22 Illustrates the p-values at Heel Strike, Midstance and Toe Off Before and After intervention in Group A compared with Normative Data

Angle	Heel strike PValue Before	Heel strike PValue After	Midstance p-value Before	Midstance p-value After	Toe off PValue Before	Toe off PValue After
Pelvic Tilt	0.029	0.001	0.668	0.173	0.723	0.263
Hip Flex/ex	0.037	0.002	0.00	0.00	0.691	0.185
Knee Flex/ex	0.00	0.00	0.001	0.001	0.00	0.00
Ankle Dorsi/Plantar	0.053	0.036	0.00	0.00	0.00	0.00

Pelvic Obliquity	0.00	0.00	0.006	0.00	0.006*	0.099*
Hip Abd/Add	0.002	0.001	0.08	0.038	0.022	0.023
Knee Valg/Var	0.00	0.00	0.182	0.192	0.122	0.664
Ankle Abd/Add	0.00	0.00	0.260*	0.786*	0.003*	0.124*
Pelvis Rotation	0.00	0.00	0.658	0.621	0.057	0.037
Hip Rotation	0.012	0.00	0.036*	0.396*	0.009*	0.149*
Knee Rotation	0.734	0.416	0.575	0.641	0.592	0.960
Ankle Rotation	0.00	0.00	0.00	0.00	0.00	0.001

From Table above, one can note that in Heel Strike of Group A is no statistically significant difference in Kinematic Angles both Before and After intervention when compared with Normative Data. Most angles were statistically significantly different from the Normative data, both before and after the intervention, since p-values were lower than 0.05 therefore, the Null Hypothesis was rejected. This was except for Knee rotation, since in both before and after, data was not statistically significantly different than normative data, since p-values exceeded 0.05 in both cases, and therefore the Null Hypothesis was accepted.

During Midstance it was noted that Hip rotation before intervention was statistically significantly different than Normative Data with a p-value of 0.036. This means that the Null Hypothesis was rejected, while the Alternative Hypothesis was accepted since the p-value was smaller than 0.05. On the other hand, after the intervention, it was noted that Hip Rotation p-value went up to 0.396, therefore since it exceeds 0.05, the Null

Hypothesis has been accepted, signifying that Hip Rotation After Intervention was statistically significantly different than the Normative Data. The same trend for Hip Rotation was noted again at Toe Off, with p-values of 0.009 and 0.149, for Before and After intervention for Group A respectively.

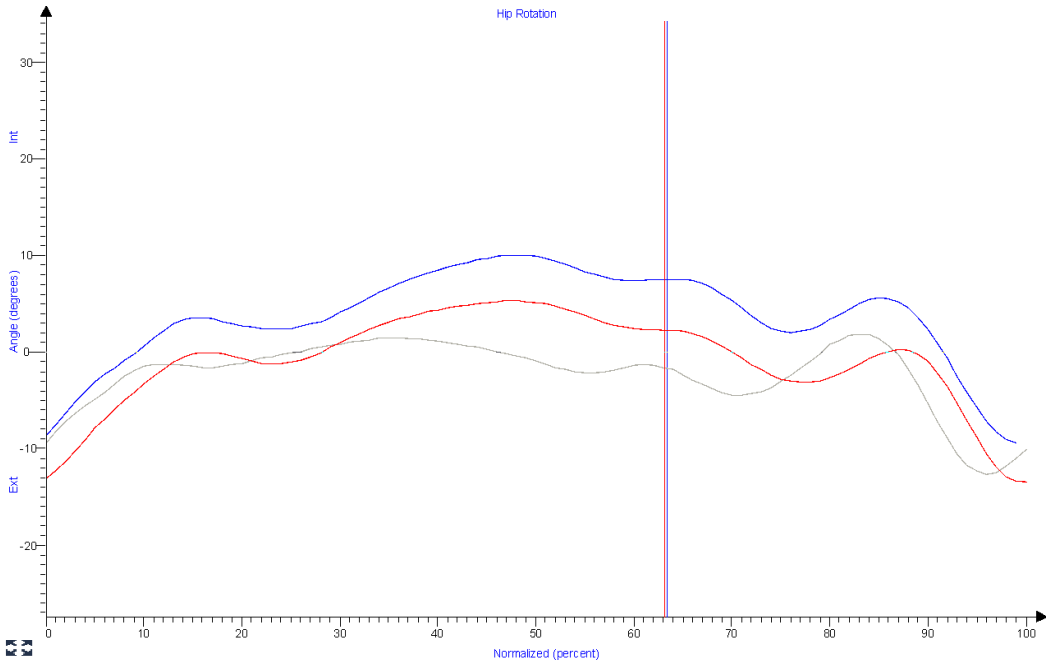


Figure 37 Polygon Graph of the Gait Cycle of Hip Rotation in Group A Before (blue) and After (red) with Normative Data (grey)

Similarly, at Toe off, it was noted that Ankle Abduction/Adduction before intervention was statistically significantly different than Normative Data with a p-value of 0.03. This means that the Null Hypothesis was rejected, while the Alternative Hypothesis was accepted since the p-value was smaller than 0.05. On the other hand, after intervention, it was noted that Ankle Abduction/Adduction p-value went up to 0.124, therefore since it exceeds i0.05, the Null Hypothesis has been accepted, signifying that Ankle Abduction/Adduction After Intervention was statistically significantly different than the Normative Data. The same trend for Ankle Abduction/Adduction was noted again at Midstance, with p-values of 0.26 and 0.786, for Before and After intervention for Group A respectively. Although the before was still statistically difference from the Normative

Data, the After had a greater p-value signifying that the data became more like the Normative Data.

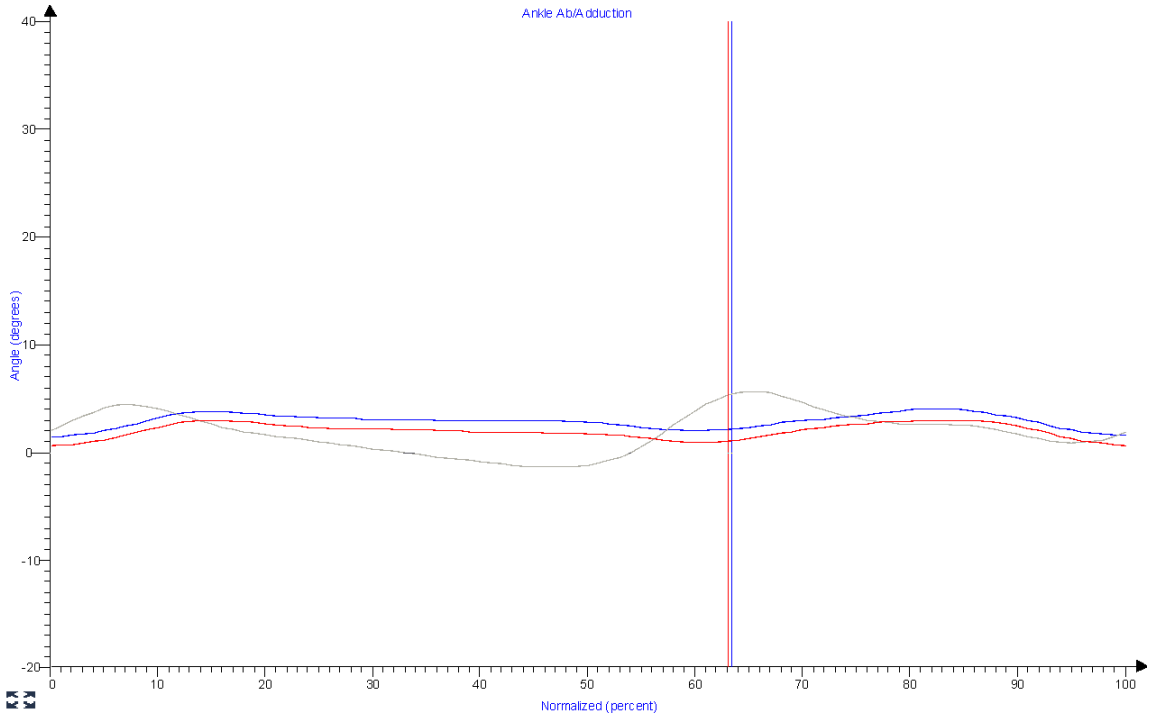


Figure 38 Polygon Graph of the Gait Cycle of Ankle Abduction/Adduction in Group A Before (blue) and After (red) with Normative Data (grey)

4.2.3.3. Statistical Analysis of the Spatiotemporal Data Before and After Intervention in Group A.

The null hypothesis states that there is no significant difference between Spatiotemporal Results in Comparison Group A Subjects Before Intervention and Spatiotemporal Results in Comparison Group A Subjects After Intervention. The alternative hypothesis states that there is a significant difference between Spatiotemporal Results in Comparison Group A Subjects Before Intervention and Spatiotemporal Results in Comparison Group A Subjects After Intervention.

Table 23 *Illustrates the spatiotemporal data p-value before and after intervention in Group A*

Data	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Wilcoxon signed-rank test	0.089	No	Accepted
Double Support	Wilcoxon signed-rank test	0.098	No	Accepted
Foot Off	Wilcoxon signed-rank test	0.696	No	Accepted
Limp Index	Wilcoxon signed-rank test	0.823	No	Accepted
Opposite Foot Contact	Wilcoxon signed-rank test	0.162	No	Accepted
Opposite Foot Off	Wilcoxon signed-rank test	0.501	No	Accepted
Single Support	Paired Sample t-test	0.333	No	Accepted
Step Length	Wilcoxon signed-rank test	0.26	No	Accepted
Step Time	Wilcoxon signed-rank test	0.26	No	Accepted
Step Width	Paired Sample t-test	0.905	No	Accepted
Stride Length	Paired Sample t-test	0.032*	No	Accepted
Stride Time	Wilcoxon signed-rank test	0.36	No	Accepted
Walking Speed	Paired Sample t-test	0.02*	Yes	Rejected

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most Spatiotemporal Data. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Spatiotemporal Data scores between Group A Before and After. This is except for Stride Length with a p-value of 0.032 and Walking Speed with a p-value of 0.02, which are smaller than 0.05; therefore the Null Hypothesis is rejected, and the Alternative Hypothesis is accepted, signifying that there is a statistically significant difference Before and After intervention Spatiotemporal Data in Group A.

As illustrated in Figure below, one can see that the dotted red line which represents the after showed a Right shift in both Strike Length and Walking Speed.

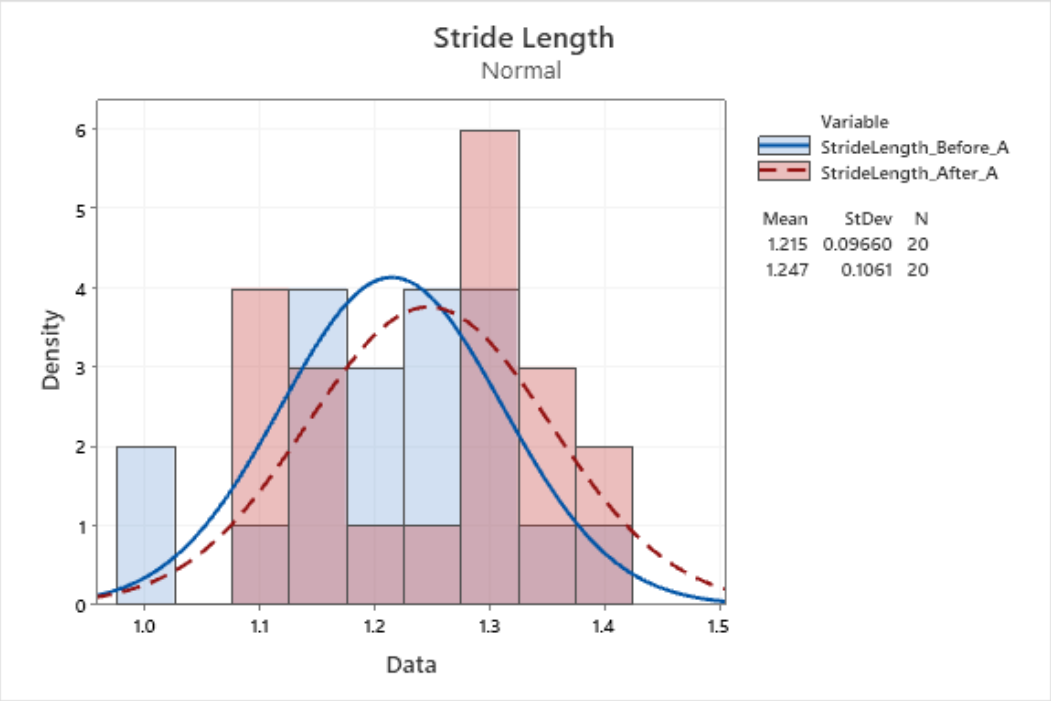


Figure 39 Illustrates the Hisotgram Plot of Stride Length before and after intervention in Group A

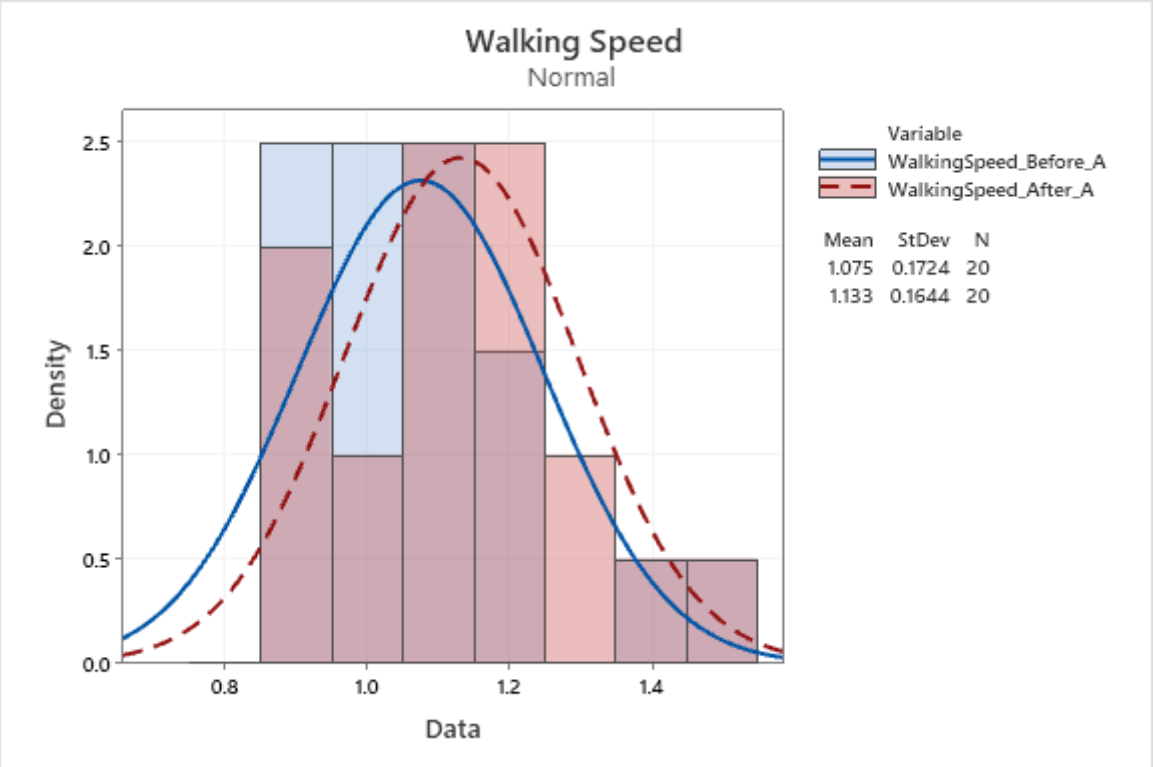


Figure 40 Illustrates the Hisotgram Plot of Walking Speed before and after intervention in Group A

Refer to Appendix 16 for the rest of the Histogram plots of the Spatiotemporal Data of Group A before and after intervention.

4.2.4. Statistical Analysis of the Kinematic Data Before without insoles and After with insoles in Group B.

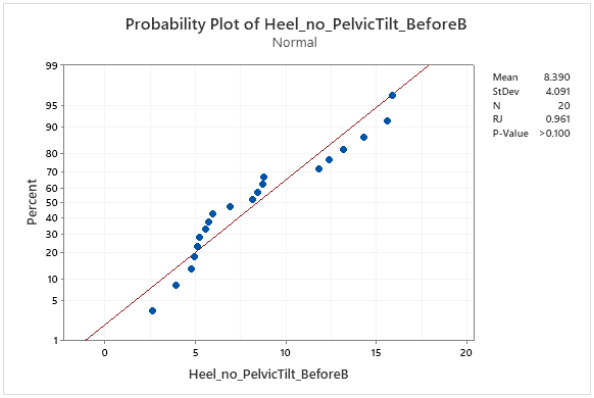
The Shapiro-Wilk test was used to determine the normal distribution. If data was normally distributed, the Paired Sample t-test was used to analyse the data, whereas if the data was not normally distributed the Wilcoxon signed-rank test was used to analyse the data. Histograms were used to graphically represent the data being statistically analysed, where Group B Before is depicted using a blue solid line and Group B After is depicted using a dotted red line, as represented below. The same was repeated for Comparison Group A, as explained above.

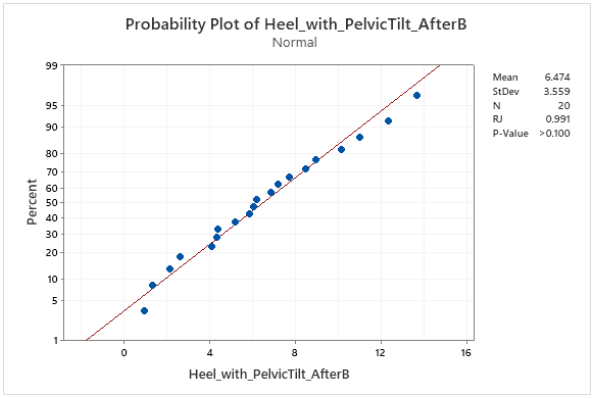
4.2.4.1. Determining the normal distribution.

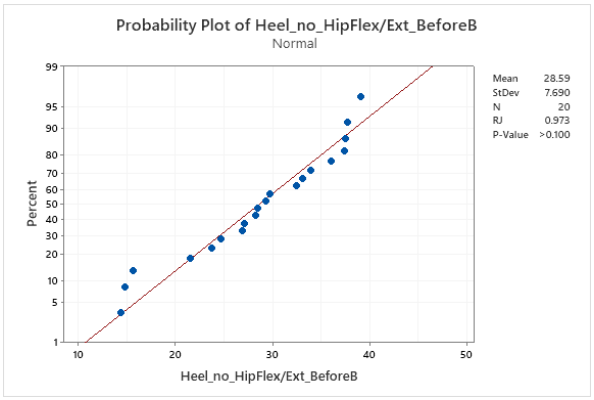
The Shapiro-Wilk test was used to assess the normality assumption of score distribution for each group of participants separately as illustrated below in the Probability plots for Kinematic and Spatiotemporal Data. The null hypothesis states that the data is normally distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

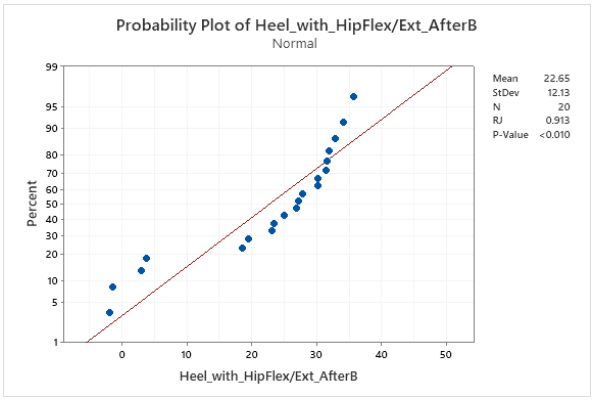
4.2.3.1.1. Kinematic Data.

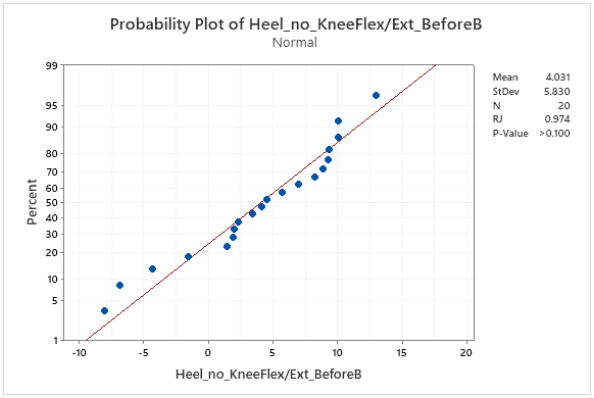
Before without insoles | **After with insoles**

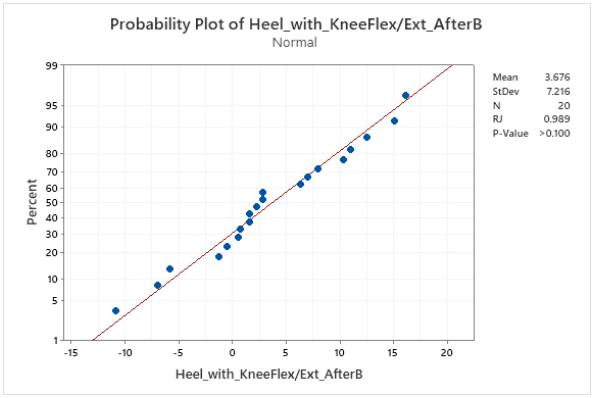


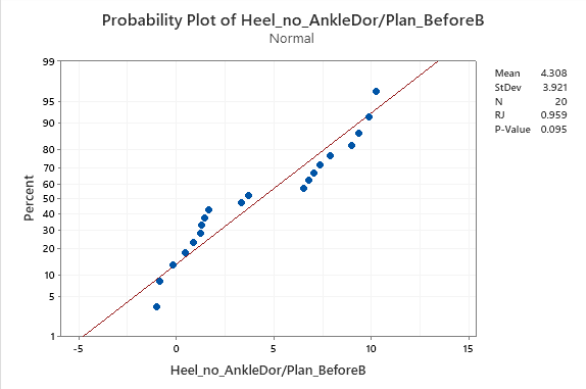


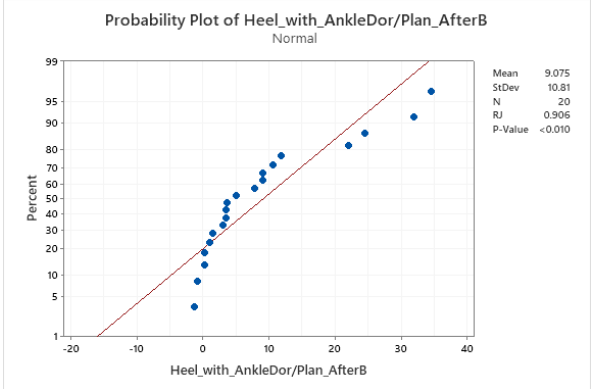


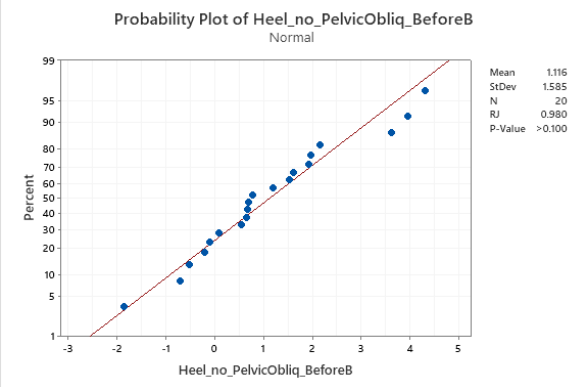


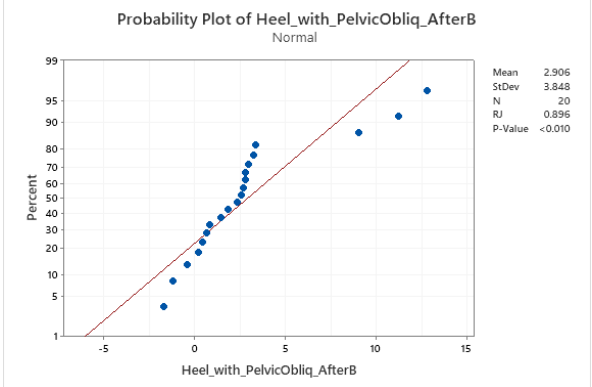


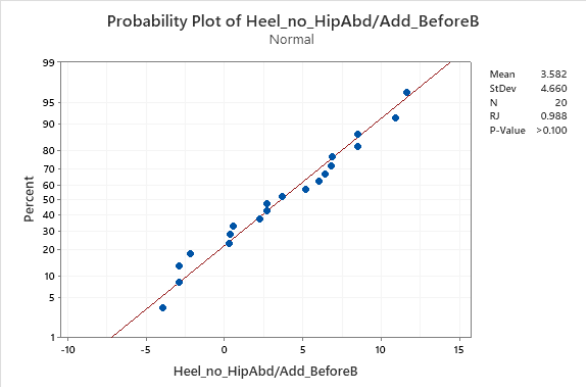


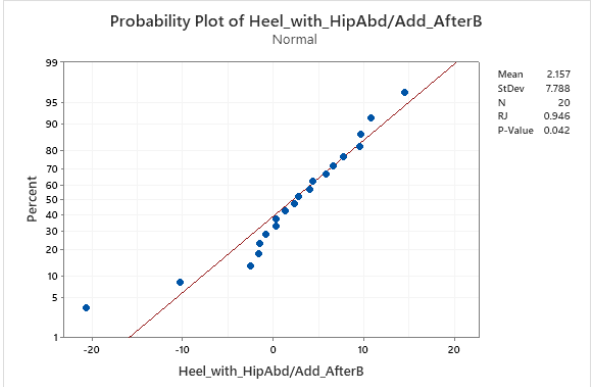

Probability Plot of Heel_no_AnkleDor/Plan_BeforeB
Normal
Mean 4.308
StDev 3.921
N 20
RJ 0.959
P-Value 0.095
Percent
Heel_no_AnkleDor/Plan_BeforeB

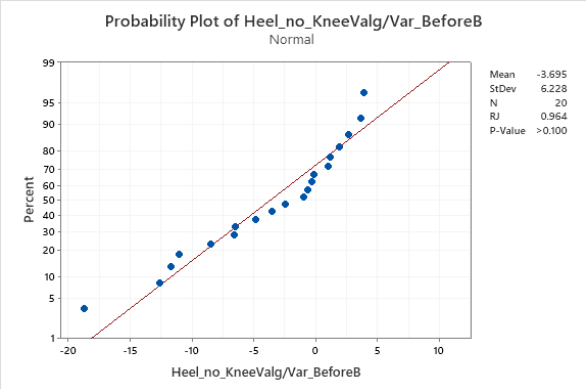

Probability Plot of Heel_with_AnkleDor/Plan_AfterB
Normal
Mean 9.075
StDev 10.81
N 20
RJ 0.906
P-Value <0.010
Percent
Heel_with_AnkleDor/Plan_AfterB

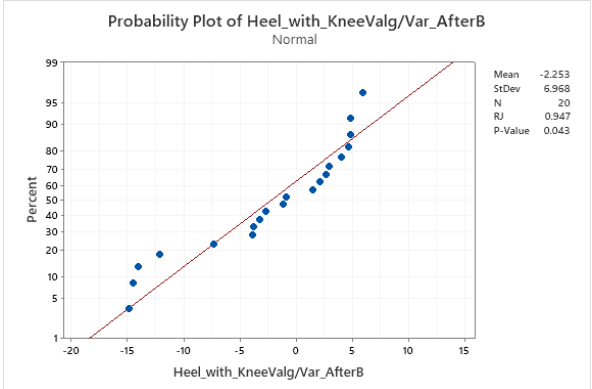

Probability Plot of Heel_no_PelvicObliq_BeforeB
Normal
Mean 1.116
StDev 1.585
N 20
RJ 0.980
P-Value >0.100
Percent
Heel_no_PelvicObliq_BeforeB

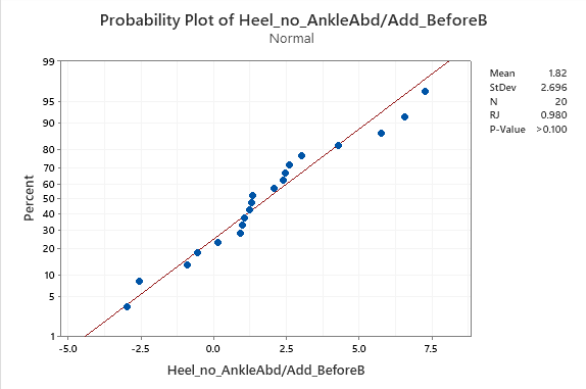

Probability Plot of Heel_with_PelvicObliq_AfterB
Normal
Mean 2.906
StDev 3.848
N 20
RJ 0.896
P-Value <0.010
Percent
Heel_with_PelvicObliq_AfterB

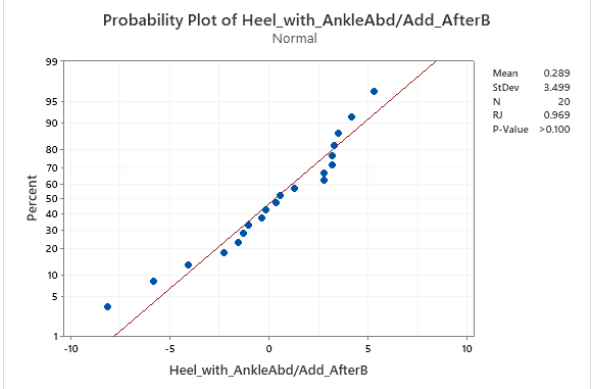

Probability Plot of Heel_no_HipAbd/Add_BeforeB
Normal
Mean 3.582
StDev 4.660
N 20
RJ 0.988
P-Value >0.100
Percent
Heel_no_HipAbd/Add_BeforeB

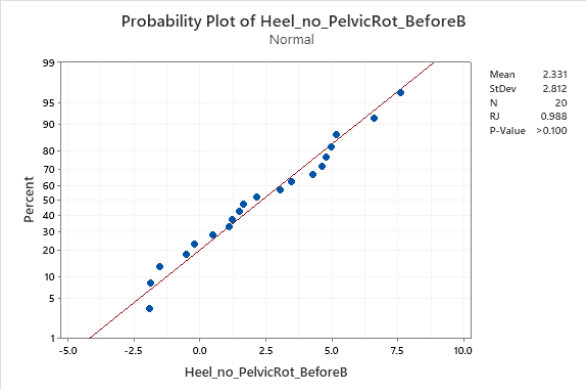

Probability Plot of Heel_with_HipAbd/Add_AfterB
Normal
Mean 2.157
StDev 7.788
N 20
RJ 0.946
P-Value 0.042
Percent
Heel_with_HipAbd/Add_AfterB


Probability Plot of Heel_no_KneeValg/Var_BeforeB
Normal
Mean -3.695
StDev 6.228
N 20
RJ 0.964
P-Value >0.100
Percent
Heel_no_KneeValg/Var_BeforeB


Probability Plot of Heel_with_KneeValg/Var_AfterB
Normal
Mean -2.253
StDev 6.968
N 20
RJ 0.947
P-Value 0.043
Percent
Heel_with_KneeValg/Var_AfterB


Probability Plot of Heel_no_AnkleAbd/Add_BeforeB
Normal
Mean 1.82
StDev 2.696
N 20
RJ 0.980
P-Value >0.100
Percent
Heel_no_AnkleAbd/Add_BeforeB


Probability Plot of Heel_with_AnkleAbd/Add_AfterB
Normal
Mean 0.289
StDev 3.499
N 20
RJ 0.969
P-Value >0.100
Percent
Heel_with_AnkleAbd/Add_AfterB


Probability Plot of Heel_no_PelvicRot_BeforeB
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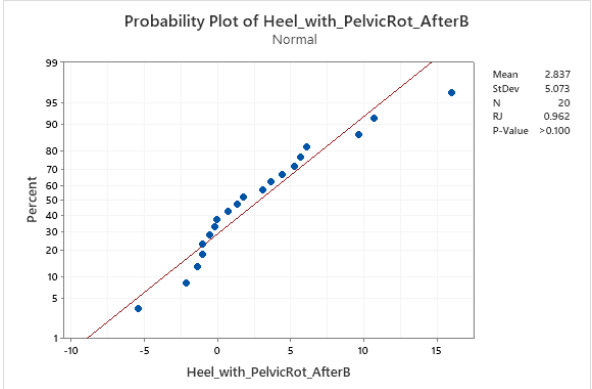
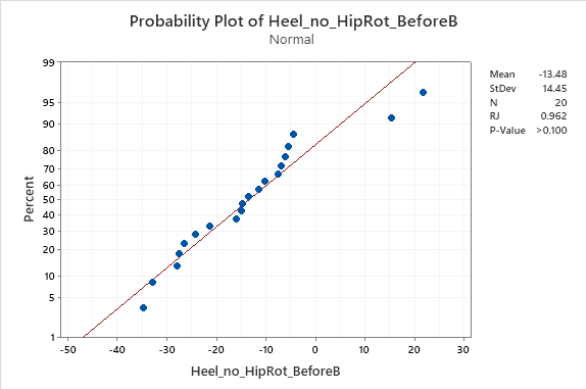
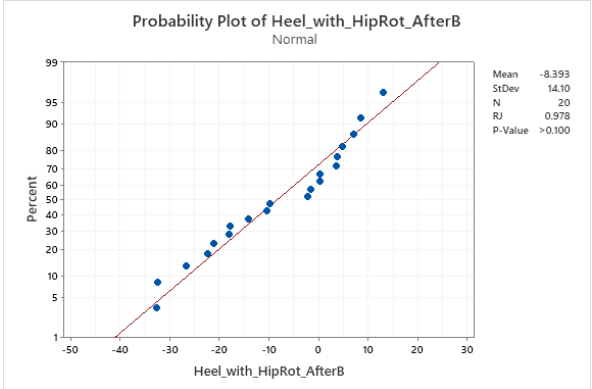
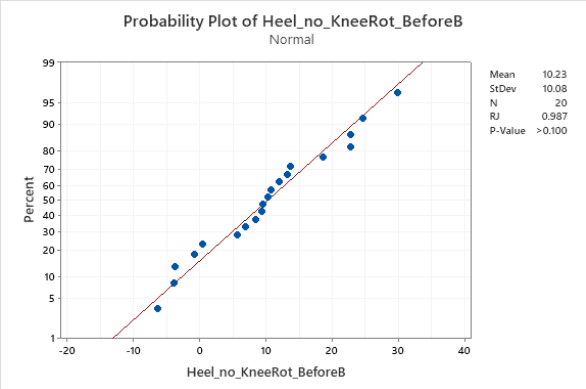
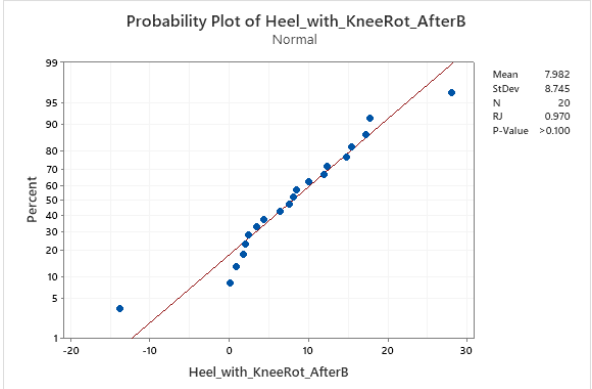
Mean 2.331
StDev 2.812
N 20
RJ 0.988
P-Value >0.100
Percent
Heel_no_PelvicRot_BeforeB


Probability Plot of Heel_with_PelvicRot_AfterB
Normal
Mean 2.837
StDev 5.073
N 20
RJ 0.962
P-Value >0.100
Percent
Heel_with_PelvicRot_AfterB


Probability Plot of Heel_no_HipRot_BeforeB
Normal
Mean -13.48
StDev 14.45
N 20
RJ 0.962
P-Value >0.100
Percent
Heel_no_HipRot_BeforeB


Probability Plot of Heel_with_HipRot_AfterB
Normal
Mean -8.393
StDev 14.10
N 20
RJ 0.978
P-Value >0.100
Percent
Heel_with_HipRot_AfterB


Probability Plot of Heel_no_KneeRot_BeforeB
Normal
Mean 10.23
StDev 10.08
N 20
RJ 0.987
P-Value >0.100
Percent
Heel_no_KneeRot_BeforeB


Probability Plot of Heel_with_KneeRot_AfterB
Normal
Mean 7.982
StDev 8.745
N 20
RJ 0.970
P-Value >0.100
Percent
Heel_with_KneeRot_AfterB

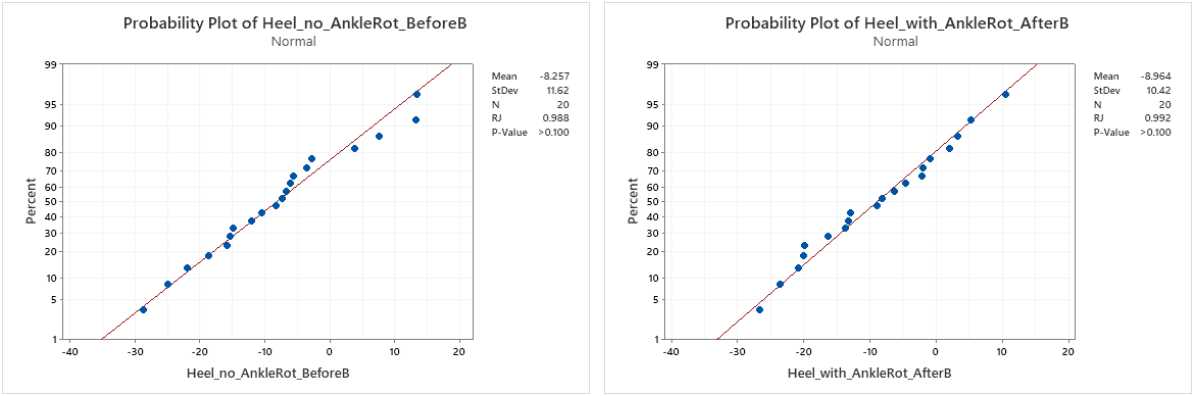


Figure 41 Illustrates the Probability Plots for Kinematic Data Before without insoles and After with Insoles at Heel Strike in Group B

With a 95% level of confidence, the above plots demonstrate that some angles p-value exceeds 0.05, for both Before and After intervention in Group B. This signifies that the data is normally distributed since the Null Hypothesis has been accepted. Therefore, parametric tests such as the Paired Sample t-test can be used for further statistical examination of this data. While the other angles p-values are less than 0.05, therefore the Null Hypothesis has been rejected, while the Alternative Hypothesis has been accepted. This meant that the data for these angles are not normally distributed, and non-parametric statistical tests were needed for further statistical examination.

Table 24 p-value for the Normality Analysis for Kinematic Data at Heel Strike of Group B Before and After Intervention

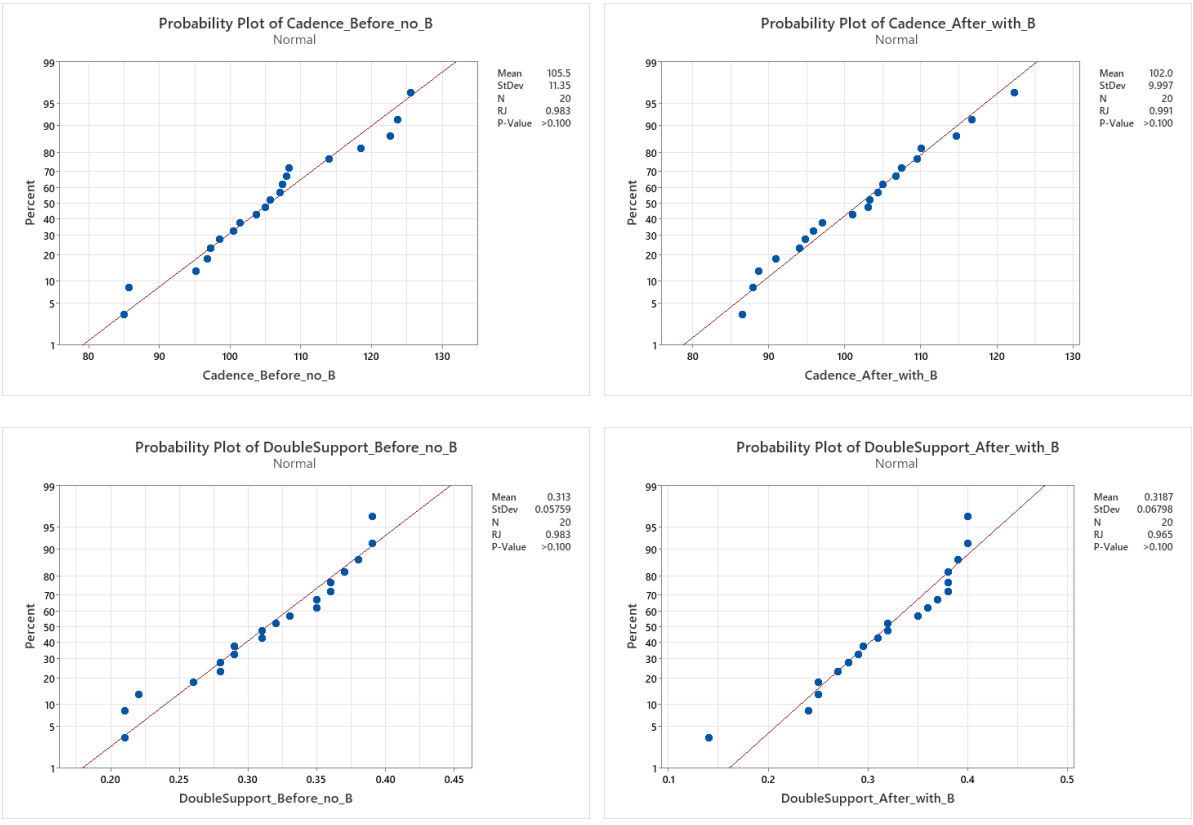
	Before			After		
Angle	p-value	<0.05	Null Hypothesis	p-value	<0.05	Null Hypothesis
Pelvic Tilt	>0.1	No	Accepted	>0.1	No	Accepted
Hip Flex/Ext	>0.1	No	Accepted	<0.01	Yes	Rejected
Knee Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Dorsi/Plantar	0.095	No	Accepted	<0.01	Yes	Rejected
Pelvic Obliquity	>0.1	No	Accepted	<0.01	Yes	Rejected

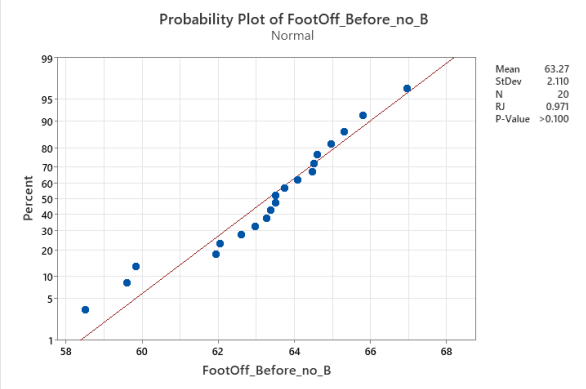
Hip Abd/Add	>0.1	No	Accepted	0.042	Yes	Rejected
Knee Valg/Var	>0.1	No	Accepted	0.043	Yes	Rejected
Ankle Abd/Add	>0.1	No	Accepted	>0.1	No	Accepted
Pelvic Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Hip Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Knee Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Rotation	>0.1	No	Accepted	>0.1	No	Accepted

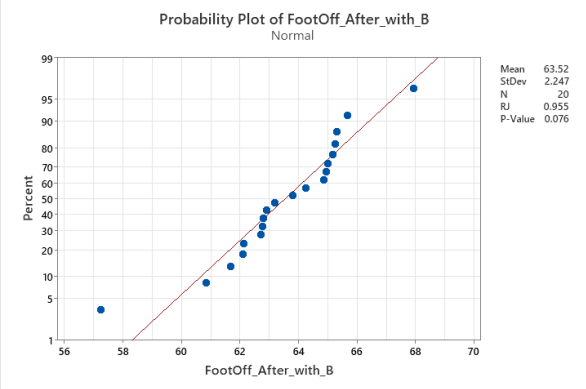
The above Statistical Analysis was then repeated for Midstance and Toe Off. Refer to Appendix 9-10 for the Probability Plots and Analysis of Data.

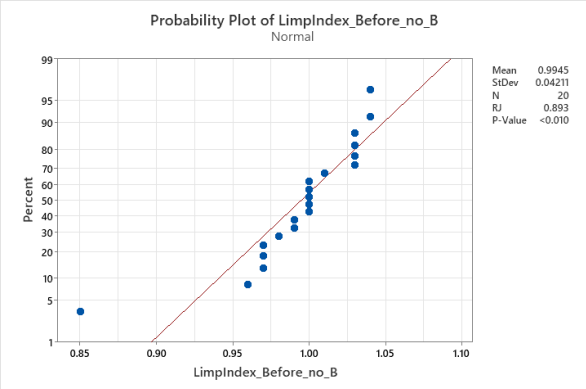
*4.2.3.2.2. Spatiotemporal Data***.**

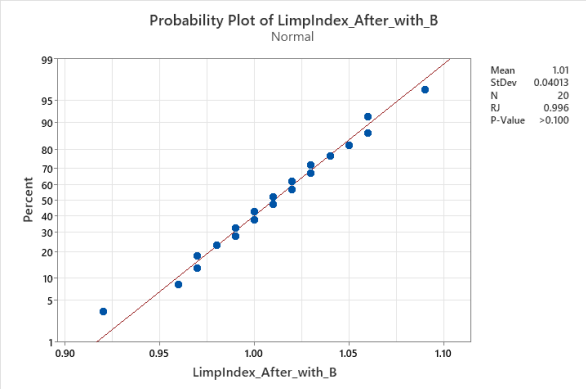
Before without insoles **After with insoles**

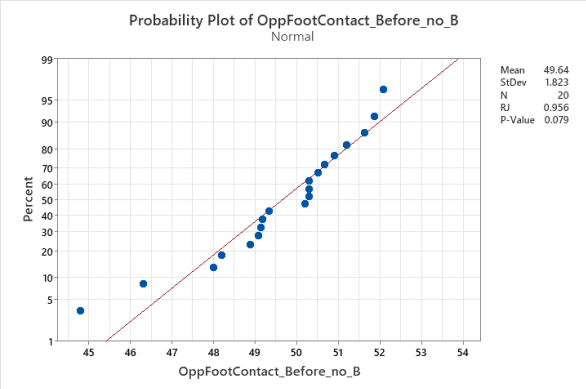


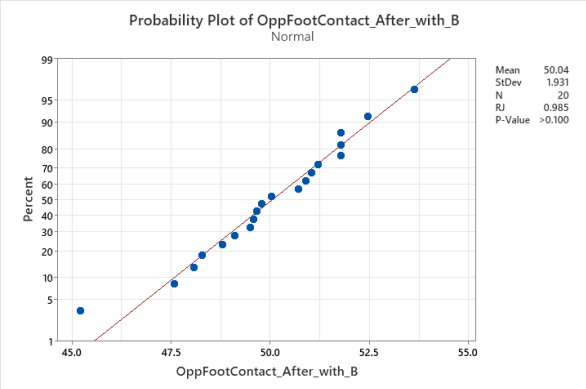

Probability Plot of FootOff_Before_no_B
Normal
Mean 63.27
StDev 2.110
N 20
RJ 0.971
P-Value >0.100
Percent
FootOff_Before_no_B

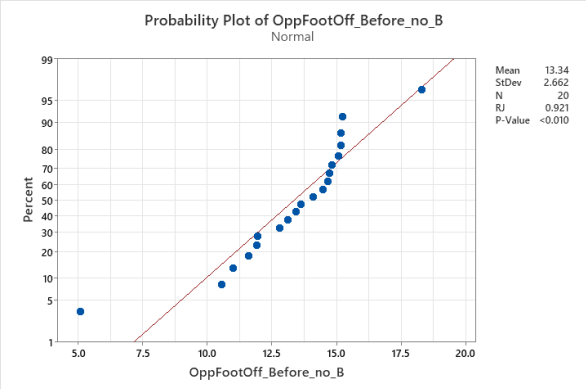

Probability Plot of FootOff_After_with_B
Normal
Mean 63.52
StDev 2.247
N 20
RJ 0.955
P-Value 0.076
Percent
FootOff_After_with_B

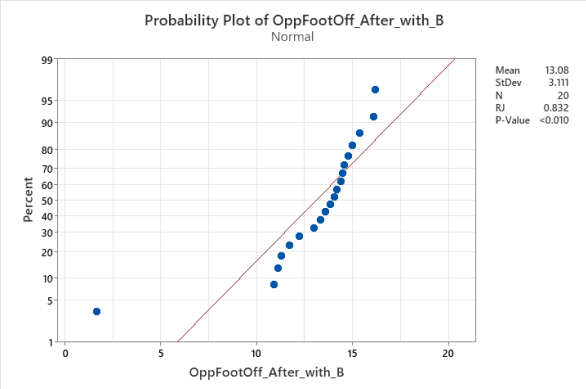

Probability Plot of LimpIndex_Before_no_B
Normal
Mean 0.9945
StDev 0.04211
N 20
RJ 0.893
P-Value <0.010
Percent
LimpIndex_Before_no_B

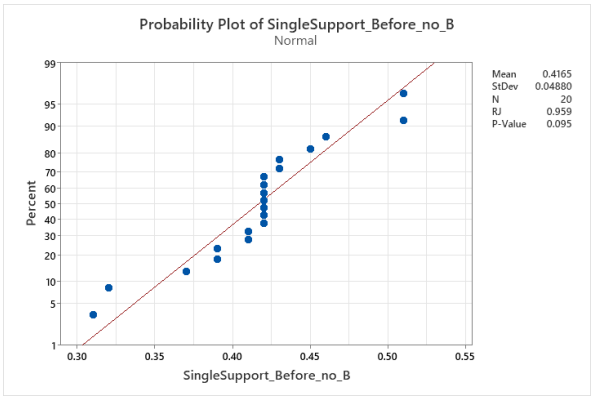

Probability Plot of LimpIndex_After_with_B
Normal
Mean 1.01
StDev 0.04013
N 20
RJ 0.996
P-Value >0.100
Percent
LimpIndex_After_with_B

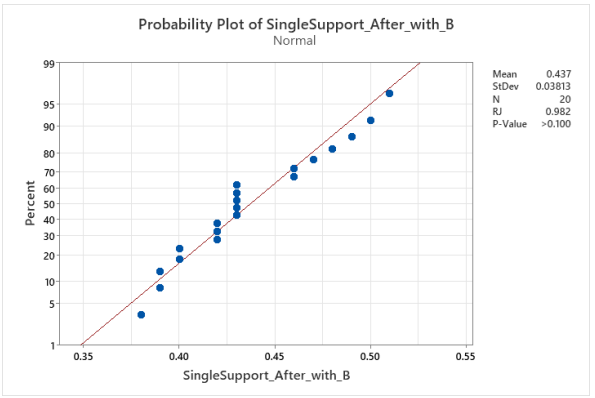

Probability Plot of OppFootContact_Before_no_B
Normal
Mean 49.64
StDev 1.823
N 20
RJ 0.956
P-Value 0.079
Percent
OppFootContact_Before_no_B

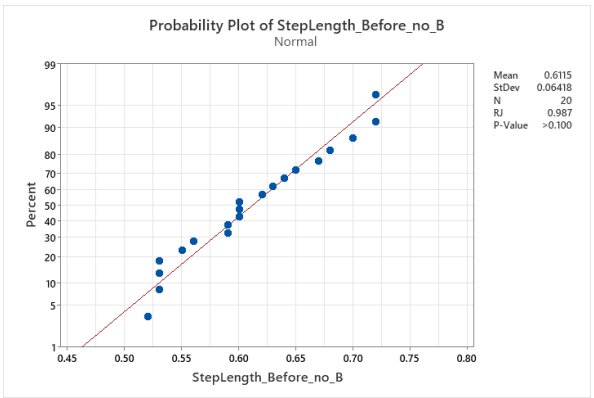

Probability Plot of OppFootContact_After_with_B
Normal
Mean 50.04
StDev 1.931
N 20
RJ 0.985
P-Value >0.100
Percent
OppFootContact_After_with_B

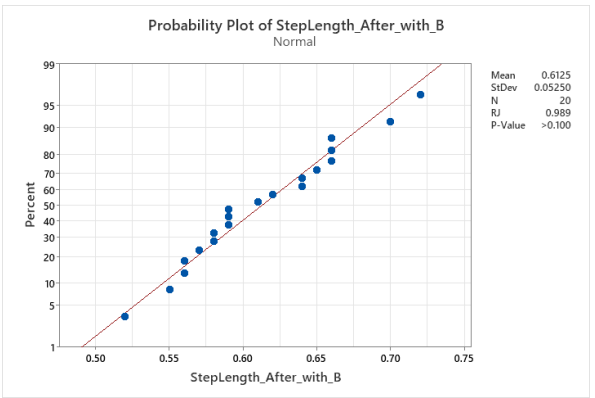

Probability Plot of OppFootOff_Before_no_B
Normal
Mean 13.34
StDev 2.662
N 20
RJ 0.921
P-Value <0.010
Percent
OppFootOff_Before_no_B

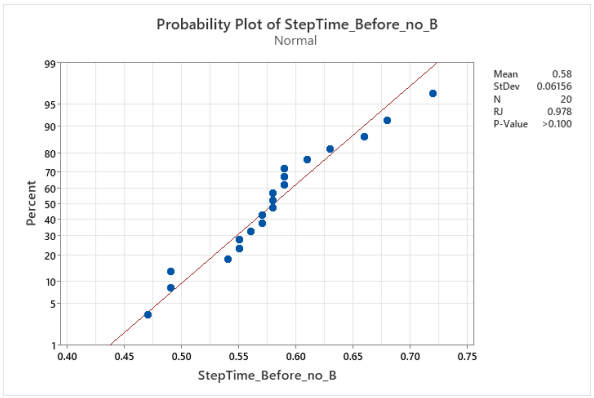

Probability Plot of OppFootOff_After_with_B
Normal
Mean 13.08
StDev 3.111
N 20
RJ 0.832
P-Value <0.010
Percent
OppFootOff_After_with_B

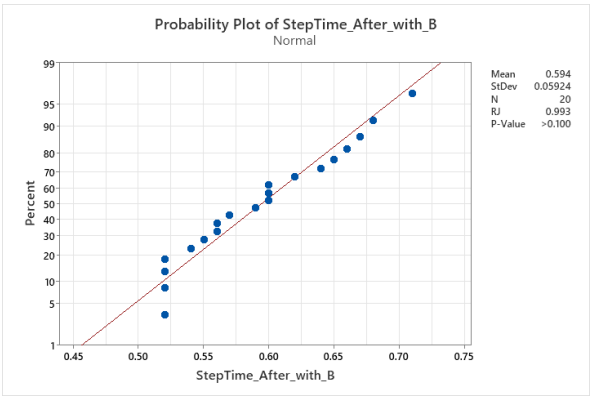

Probability Plot of SingleSupport_Before_no_B
Normal
Mean 0.4165
StDev 0.04880
N 20
RJ 0.959
P-Value 0.095
Percent
SingleSupport_Before_no_B

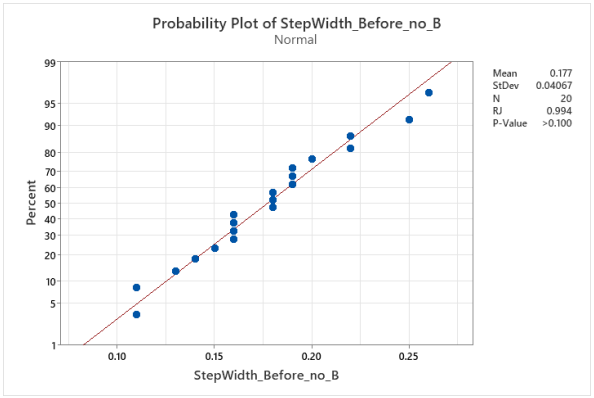

Probability Plot of SingleSupport_After_with_B
Normal
Mean 0.437
StDev 0.03813
N 20
RJ 0.982
P-Value >0.100
Percent
SingleSupport_After_with_B

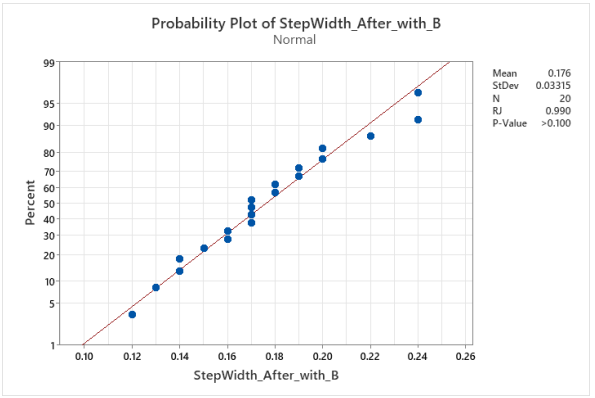

Probability Plot of StepLength_Before_no_B
Normal
Mean 0.6115
StDev 0.06418
N 20
RJ 0.987
P-Value >0.100
Percent
StepLength_Before_no_B


Probability Plot of StepLength_After_with_B
Normal
Mean 0.6125
StDev 0.05250
N 20
RJ 0.989
P-Value >0.100
Percent
StepLength_After_with_B


Probability Plot of StepTime_Before_no_B
Normal
Mean 0.58
StDev 0.06156
N 20
RJ 0.978
P-Value >0.100
Percent
StepTime_Before_no_B


Probability Plot of StepTime_After_with_B
Normal
Mean 0.594
StDev 0.05924
N 20
RJ 0.993
P-Value >0.100
Percent
StepTime_After_with_B


Probability Plot of StepWidth_Before_no_B
Normal
Mean 0.177
StDev 0.04067
N 20
RJ 0.994
P-Value >0.100
Percent
StepWidth_Before_no_B


Probability Plot of StepWidth_After_with_B
Normal
Mean 0.176
StDev 0.03315
N 20
RJ 0.990
P-Value >0.100
Percent
StepWidth_After_with_B

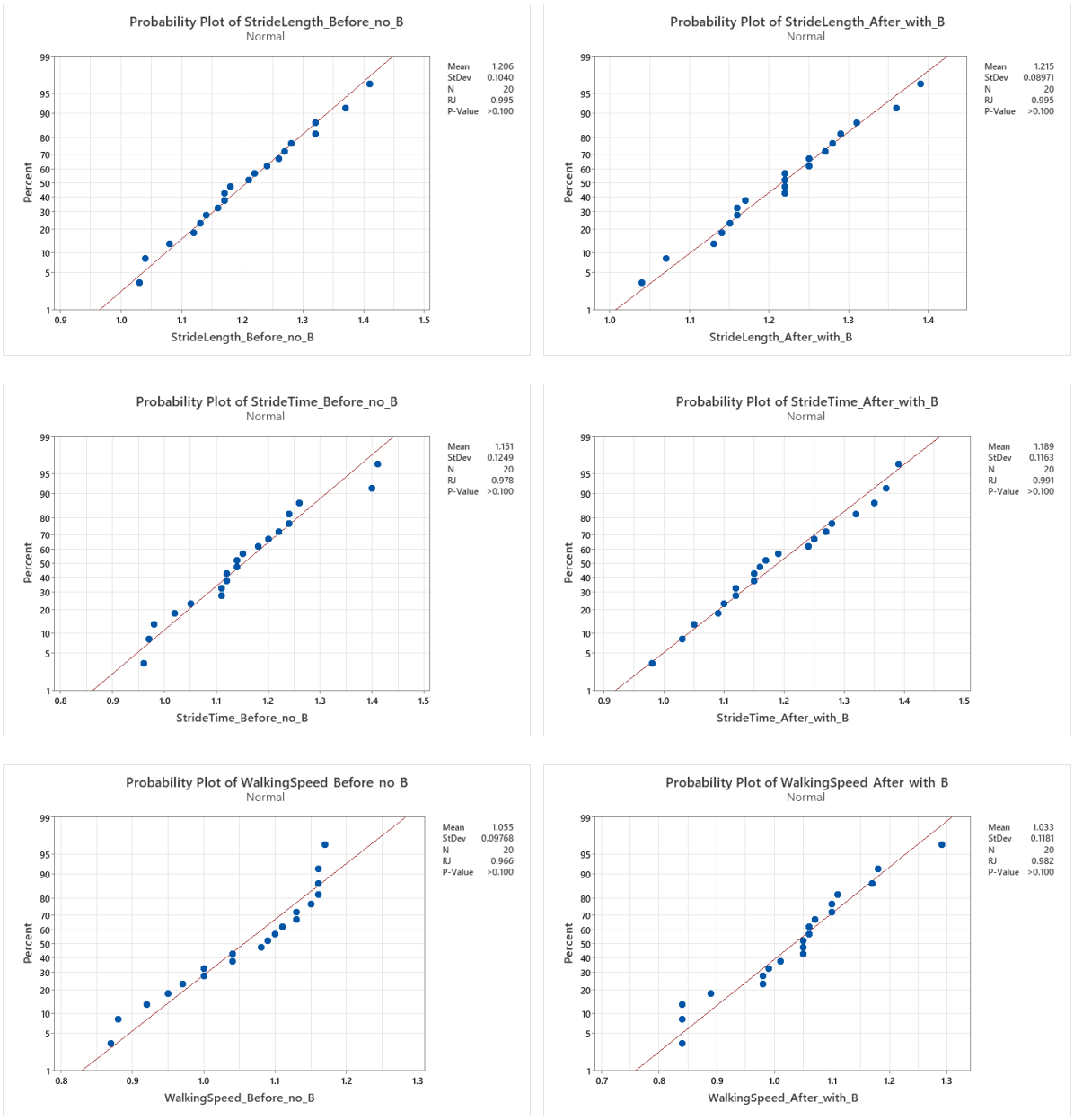


Figure 42 Illustrates the Probability Plots for Spatiotemporal Data Before without insoles and After with Insoles at Heel Strike in Group B

With a 95% level of confidence, the above plots demonstrate that for both Before without insoles and After with insoles intervention in Group B there is a mix of p-values that either exceed or are less than 0.05. This signifies that not all the data is normally distributed since the Null Hypothesis has not been accepted in a number of spatiotemporal data, although in this case, most of the above data are normally distributed. Therefore, both parametric tests

such as the Paired Sample t-test and non-parametric tests such as the Wilcoxon Signed-rank test must be used for further statistical examination of this data.

Table 25 p-value for the Normality Analysis for Spatiotemporal Data of Group B Before and After Intervention

	Before			After		
Data	p-value	<0.05	Null Hypothesis	p-value	<0.05	Null Hypothesis
Cadence	>0.1	No	Accepted	>0.1	No	Accepted
Double Support	>0.1	No	Accepted	>0.1	No	Accepted
Foot Off	>0.1	No	Accepted	0.076	No	Accepted
Limp Index	<0.01	Yes	Rejected	>0.1	No	Accepted
Opposite Foot Contact	0.079	No	Accepted	>0.1	No	Accepted
Opposite Foot Off	<0.01	Yes	Rejected	<0.01	Yes	Rejected
Single Support	0.095	No	Accepted	>0.1	No	Accepted
Step Length	>0.1	No	Accepted	>0.1	No	Accepted
Step Time	>0.1	No	Accepted	>0.1	No	Accepted
Step Width	>0.1	No	Accepted	>0.1	No	Accepted
Stride Length	>0.1	No	Accepted	>0.1	No	Accepted
Stride time	>0.1	No	Accepted	>0.1	No	Accepted
Walking Speed	>0.1	No	Accepted	>0.1	No	Accepted

4.2.4.2. Statistical Analysis of the Kinematic Data Before without insoles and After with insoles in Group B.

The null hypothesis states that there is no significant difference between Kinematic results at Heel Strike, Midstance and Toe-Off within the gait analysis results in Experiment Group B Subjects Before Intervention and Kinematic results in Experiment Group B Subjects

After Intervention. The alternative hypothesis states that there is a significant difference between Kinematic results at Heel Strike, Midstance and Toe Off within the gait analysis results in Experiment Group B Subjects Before Intervention and Kinematic results in Experiment Group B Subjects After Intervention.

Table 26 *Illustrates the Kinematic Data Statistical Analysis for Heel Strike Group B*

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.113	No	Accepted
Hip Flex/ext	Wilcoxon Signed-Rank Test	0.173	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.835	No	Accepted
Ankle Dorsi/Plantar	Wilcoxon Signed-Rank Test	0.240	No	Accepted
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.055	No	Accepted
Hip Abd/Add	Wilcoxon Signed-Rank Test	0.808	No	Accepted
Knee Valg/Var	Wilcoxon Signed-Rank Test	0.14	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.116	No	Accepted
Pelvic Rotation	Paired Sample t-test	0.650	No	Accepted
Hip Rotation	Paired Sample t-test	0.209	No	Accepted
Knee Rotation	Paired Sample t-test	0.284	No	Accepted
Ankle Rotation	Paired Sample t-test	0.818	No	Accepted

With a 95% level of confidence the above table demonstrates that the p-value outcome is larger than 0.05 in all angles at Heel Strike. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Kinematic scores between Group

B at Heel Strike. Refer to Appendix 17 for the Histogram of the Kinematic Angles of Group B before and after intervention at Heel Strike.

Although the Pelvic Obliquity angle during Heel Strike did not statistically show significant difference before and after, the p-value (0.083) is close to 0.05 when compared to the other angles. Therefore, more information could be provided from the Histogram Plot below, where it can be noted that the red line is shifted towards right, and the value is more positive. This signifies that the opposite side of the pelvis is higher than before intervention.

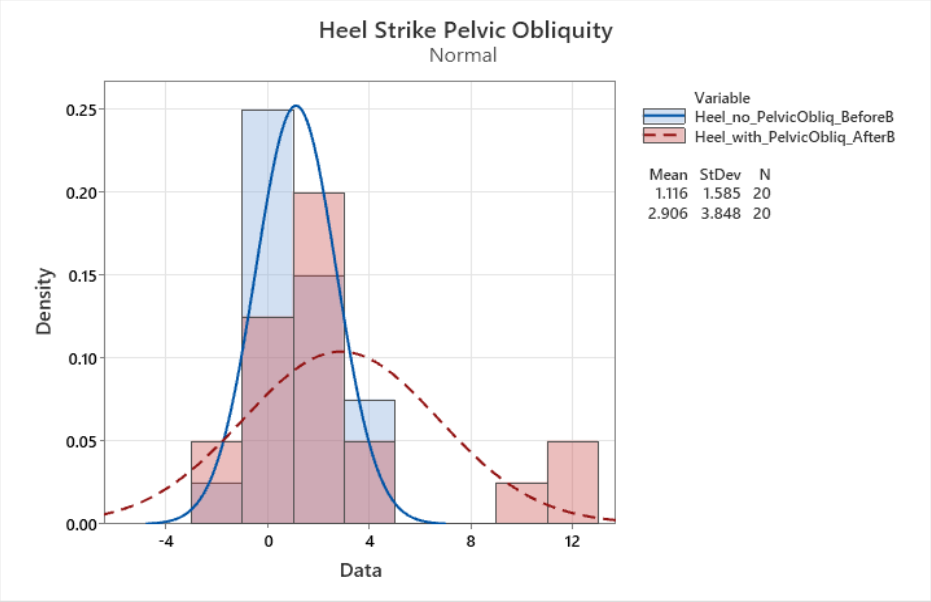


Figure 43 *Illustrates the Histogram Plot for Pelvic Obliquity for Before and After in Group B*

Table 27 Illustrates the Kinematic Data Statistical Analysis for Midstance Group B

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon Signed-Rank Test	0.05*	Yes	Rejected
Hip Flex/ext	Paired Sample t-test	0.249	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.839	No	Accepted

Ankle Dorsi/Plantar	Paired Sample t-test	0.046*	Yes	Rejected
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.76	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.453	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.083	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.15	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.162	No	Accepted
Hip Rotation	Paired Sample t-test	0.3	No	Accepted
Knee Rotation	Paired Sample t-test	0.399	No	Accepted
Ankle Rotation	Paired Sample t-test	0.732	No	Accepted

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most angles at Midstance. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Kinematic scores in Group B at Midstance. This is except for Pelvic Tilt with a p-value of 0.05; and Ankle Dorsiflexion/Plantarflexion with a p-value of 0.046. Since in both cases the p-value is smaller than 0.05 the Null Hypothesis is rejected, and the alternative hypothesis is accepted. Therefore, showing that there is statistical difference at those angles at Midstance Before and After intervention in Group B.

As illustrated in the Histogram plots below, one can see that the dotted red line which represents the after showed a left shift more towards the zero, for Pelvic Tilt, meaning that the Pelvis decreased in anterior tilt and became more neutral in the Sagittal Plane. On the other hand, one can see that the dotted red line which represents the after showed a right

shift in Ankle Dorsiflexion/Plantarflexion in the Sagittal Plane. This signifies that there was an increase in dorsiflexion during Midstance after intervention.

Refer to Appendix 18 for the rest of the Histogram plots of the Kinematic Angles of Group B before and after intervention at Midstance.

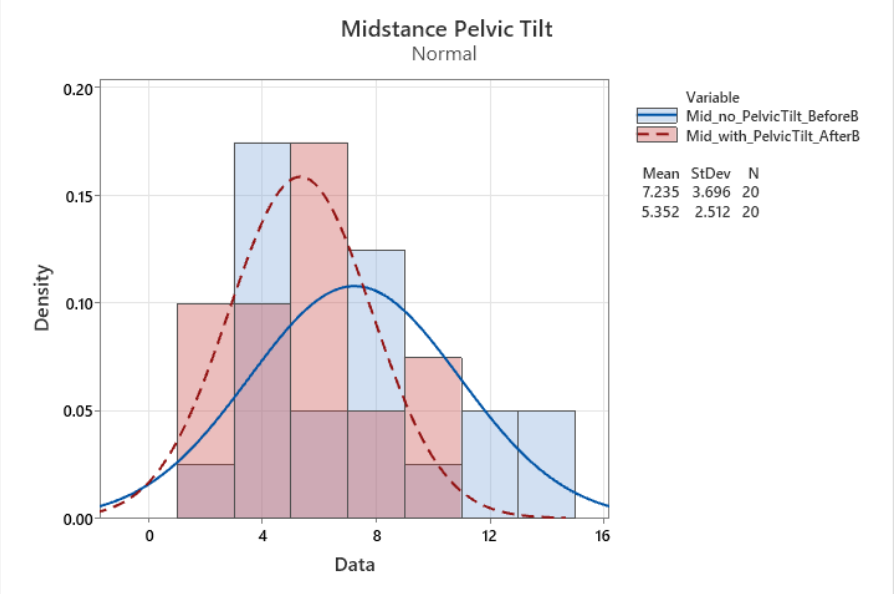


Figure 44 *Illustrates the Histogram Plot for Pelvic Tilt at Midstance before and after intervention in Group B*

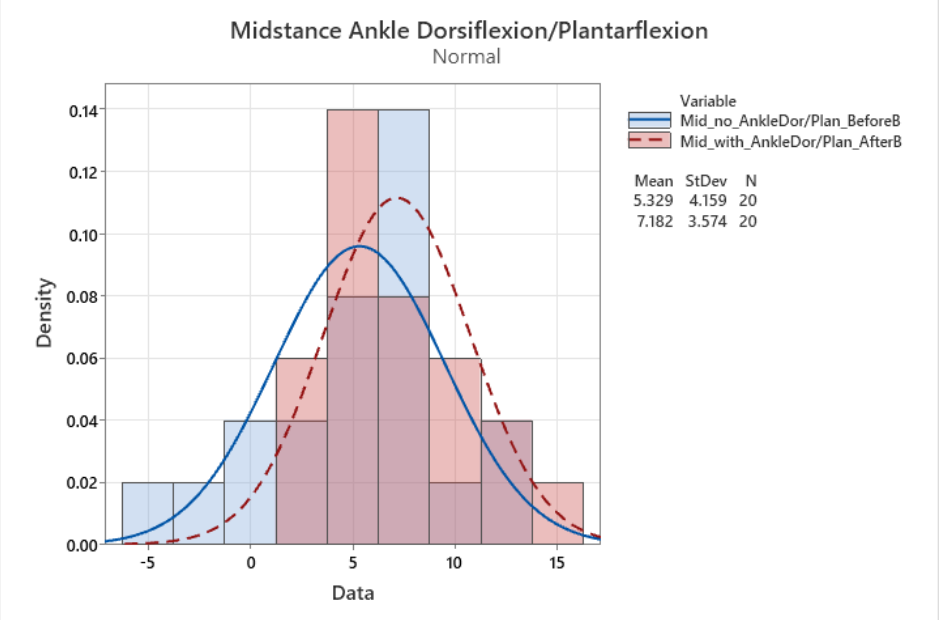


Figure 45 Illustrates the Histogram Plot for Ankle Dorsiflexion/Plantarflexion at Midstance before and after intervention in Group B

Although the Knee Valgus/Varus angles during Midstance did not statistically show significant difference before and after, and the p-value (0.083) is close to 0.05 when compared to the other angles, one can look at the Histogram Plot below and note that the red line is shifted towards right and closer to zero value. This signifies that there was a decreased in valgus of the knee and the knee became more neutral in the Coronal Plane.

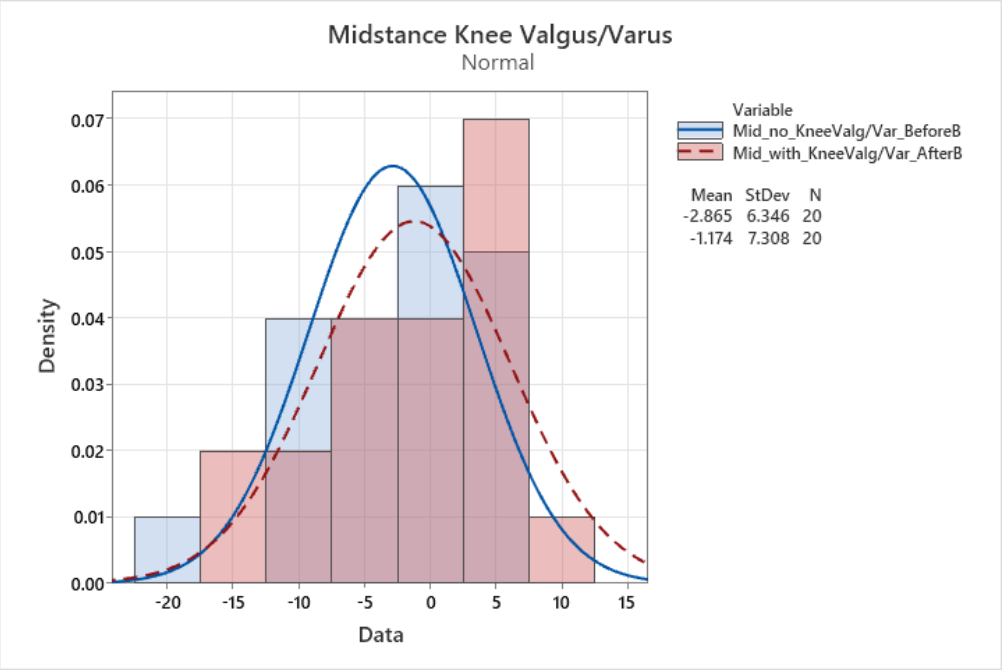


Figure 46 Illustrates the Histogram Plot for Knee Valgus/Varus at Midstance before and after intervention in Group B

Refer to Appendix 18 for the Histograms of the of Kinematic Angles of Group B before and after intervention at Midstance.

Table 28 Illustrates the Kinematic Data Statistical Analysis for Toe Off Group B

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon Signed-Rank Test	0.059	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.462	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.022*	Yes	Rejected
Ankle Dorsi/Plantar	Wilcoxon Signed-Rank Test	0.444	No	Accepted

Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.151	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.071	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.004*	Yes	Rejected
Ankle Abd/Add	Paired Sample t-test	0.98	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.150	No	Accepted
Hip Rotation	Paired Sample t-test	0.518	No	Accepted
Knee Rotation	Paired Sample t-test	0.192	No	Accepted
Ankle Rotation	Paired Sample t-test	0.489	No	Accepted

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most angles at Toe Off. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Kinematic scores in Group B at Toe Off. This is except for Knee Flexion/Extension with a p-value of 0.022; and Knee Valgus/Varus with a p-value of 0.004. Since in both cases, the p-value is smaller than 0.05 the Null Hypothesis is rejected, and the alternative hypothesis is accepted. Therefore, showing that there is a statistical difference at those angles at Toe Off Before and After intervention in Group B.

As illustrated in the Histogram plots in Figures below, one can see that the dotted red line which represents the after, showed a left shift more towards the zero, for Knee Flexion/Extension, meaning that the knee decreased in Knee flexion in the Sagittal Plane. On the other hand, one can see that the dotted red line which represents the after showed a right shift in Knee Valgus/Varus in the Coronal Plane. This signifies that there was an increase in Knee Varus during Toe Off after intervention.

Refer to Appendix 19 for the Histograms of the of Kinematic Angles of Group B before and after intervention at Toe Off.

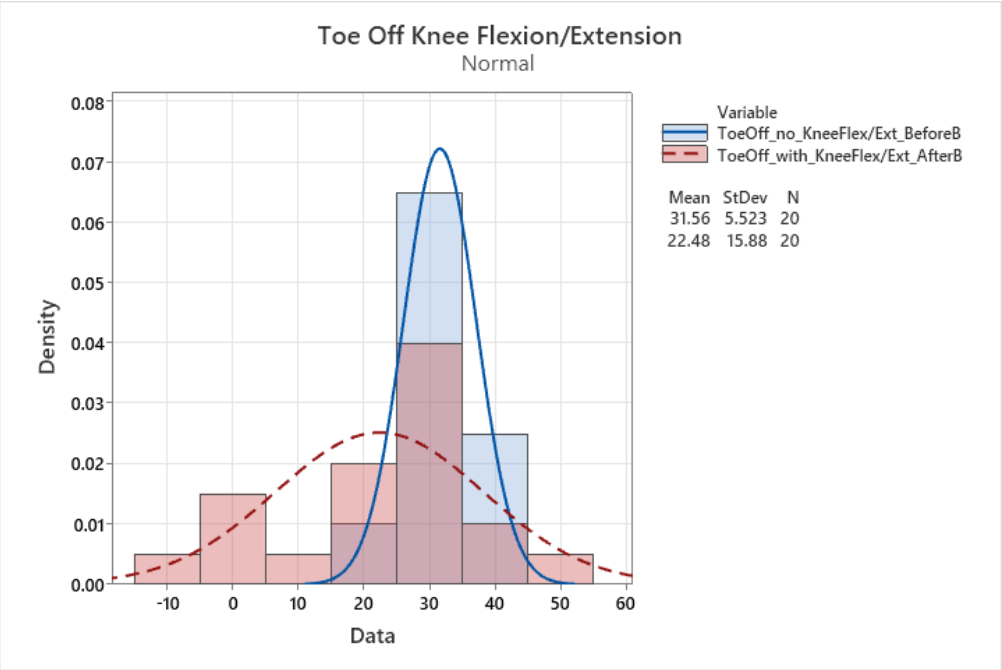


Figure 47 *Illustrates the Histogram Plot of Knee Flexion/Extension at Toe off for Group B*

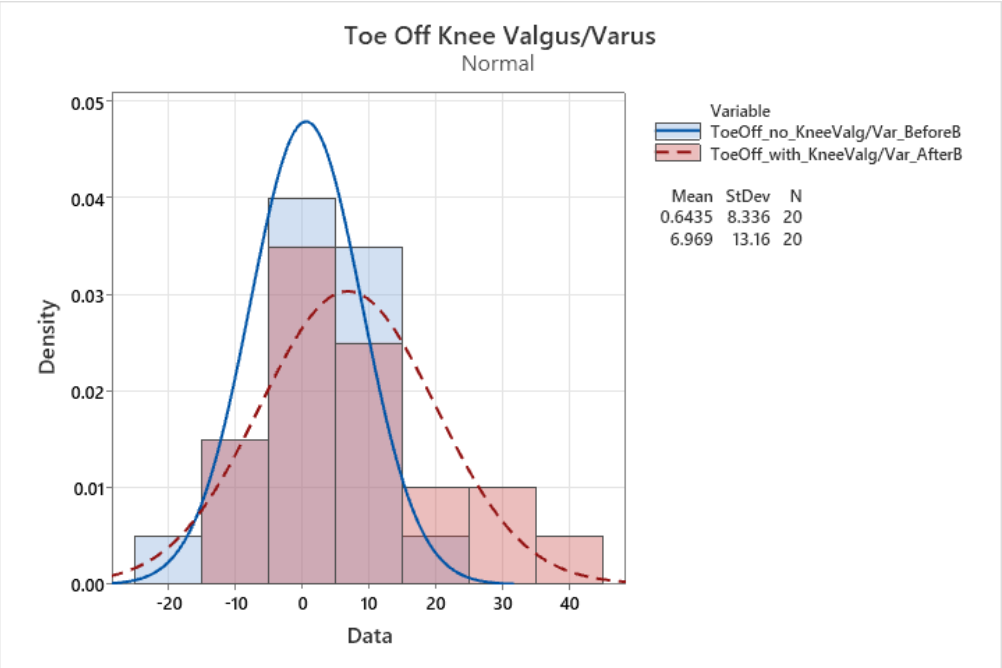


Figure 48 *Illustrates the Histogram Plot of Knee Valgus/Varus at Toe off for Group B*

Although the Pelvic Tilt and Hip Abduction/Adduction angles during Toe Off did not statistically show significant difference before and after, and the p-value (0.059 and 0.071 respectively) is close to 0.05 when compared to the other angles, one can look at the Histogram Plot below for further analysis. One can note that the red line is shifted towards left and closer to zero value for the Pelvic tilt, therefore there was a decrease in posterior tilt, and more towards neutral in the Sagittal Plane. For Hip Abduction/Adduction the red line is shifted towards the right, therefore more positive, meaning that there was decrease of Hip Abduction in the Coronal Plane.

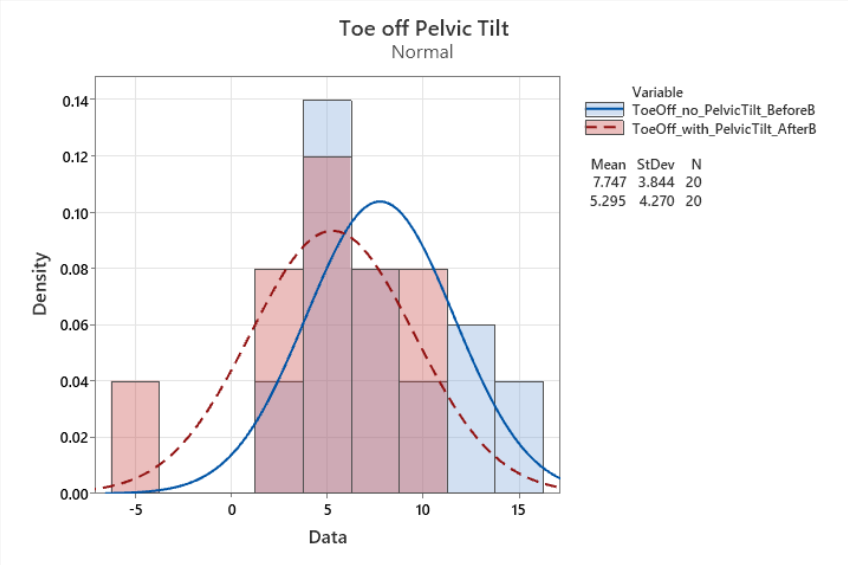


Figure 49 *Illustrates the Histogram Plot of Pelvic Tilt at Toe off before and after intervention in Group B*

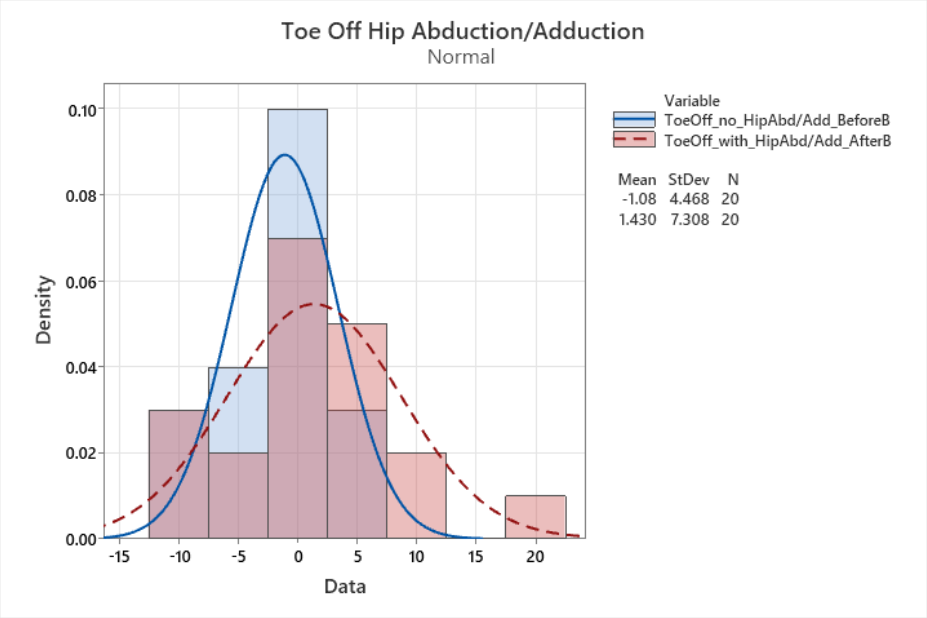


Figure 50 *Illustrates the Histogram Plot for Hip Abduction/Adduction at Toe off before and after intervention in Group B*

4.2.4.2.1. Statistical Analysis of the Kinematic Data Before and After intervention in Group B with Normative Data.

The Shapiro-Wilk test was used to determine the normal distribution of each Kinematic Data as explained above in section 4.2.3.2. If data was normally distributed, the One-Sample t-test was used to analyse the data, whereas if the data was not normally distributed the One-sample Wilcoxon signed-rank test was used to analyse the data, to compared with the Normative Data. Further details on the Normative Data can be found in Chapter 3.

The Null Hypothesis states that there is no significant difference between Before without insoles and after with insoles of Group B kinematic angles at Heel Strike, Midstance and Toe Off, when compared with Normative Data. The Alternative Hypothesis states that

there is a significant difference between Before without insoles and after with insoles of Group B kinematic angles at Heel Strike, Midstance and Toe Off, when compared with Normative Data.

Table 29 Illustrates the p-values at Heel Strike, Midstance and Toe Off Before and After intervention in Group A compared with Normative Data

Angle	Heel strike PValue Before	Heel strike PValue After	Midstance PValue Before	Midstance PValue After	Toe off PValue Before	Toe off PValue After
Pelvic Tilt	0.001	0.00	0.00	0.00	0.240	0.001
Hip Flex/ex	0.02	0.00	0.006	0.002	0.761	0.514
Knee Flex/ex	0.00	0.00	0.00	0.00	0.00	0.009
Ankle Dorsi/Plantar	0.034	0.022	0.00	0.00	0.000	0.000
Pelvic Obliquity	0.00	0.00	0.001*	0.641*	0.000*	0.455*
Hip Abd/Add	0.288	0.198	0.001	0.015	0.650	0.255
Knee Valg/Var	0.000	0.000	0.003*	0.066*	0.512	0.1
Ankle Abd/Add	0.000	0.000	0.162*	0.555*	0.002	0.013
Pelvic Rotation	0.00	0.00	0.385*	0.945*	0.07*	0.778*
Hip Rotation	0.002*	0.046*	0.675	0.683	0.425	0.116
Knee Rotation	0.082*	0.345*	0.042*	0.095*	0.093*	0.408*
Ankle Rotation	0.000	0.000	0.00	0.00	0.00	0.00

From Table above, one can note that in Heel Strike of Group B there is no statistically significant difference in Kinematic Angles both Before and After intervention when compared with Normative Data. Most angles were statistically significantly different from the Normative data, both before and after intervention, since p-values were lower than 0.05

therefore the Null Hypothesis was rejected. This was except for Knee rotation, since in both before and after, data was not statistically significantly different than normative data, since p-values exceeded 0.05 in both cases, and therefore the Null Hypothesis was accepted.

Although Hip rotation at Heel Strike both before and after p-values were less than 0.05, therefore statistically significant different from Normative Data, it can be noted that the p-value became larger in the After, therefore signifying that the data became less statistically significantly different than Normative Data Post Intervention. Similarly for Knee Rotation, although at Heel Strike both before and after p-values were more than 0.05, therefore not statistically significant different from Normative Data, it can be noted that the p-value became larger in the After, therefore signifying that the data became even more statistically significantly different than Normative Data Post Intervention.

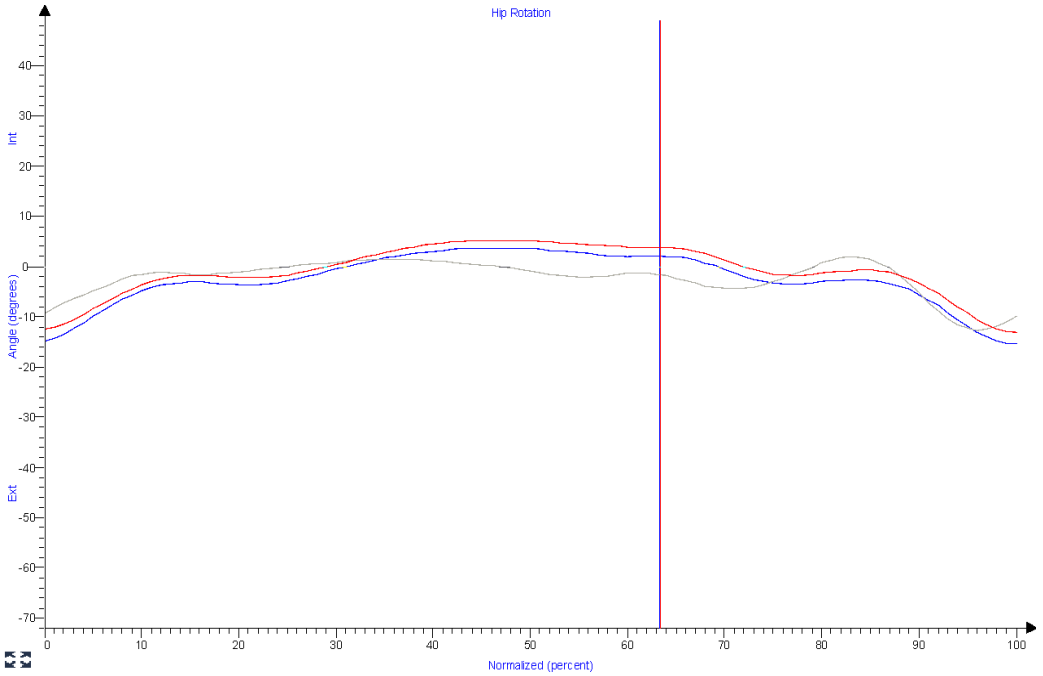


Figure 51 Polygon Graph of the Gait Cycle of Hip Rotation in Group B Before (blue) and After (red) with Normative Data

During Midstance it was noted that Pelvic Obliquity, Knee Valgus/Varus and Knee Rotation before intervention were statistically significantly different than Normative Data with a p-values of 0.001, 0.003 and 0.042 respectively. This means that the Null Hypothesis was rejected, while the Alternative Hypothesis was accepted since the p-value was smaller than 0.05. On the other hand, after intervention, it was noted that Pelvic Obliquity, Knee Valgus/Varus and Knee Rotation p-values went up to 0.641, 0.066 and 0.095 respectively. Therefore, since they exceed p-value 0.05, the Null Hypothesis has been accepted, signifying that Pelvic Obliquity, Knee Valgus/Varus and Knee Rotation After Intervention were statistically significantly different than the Normative Data. The same trend for Pelvic Obliquity and Knee Rotation was noted again at Toe Off, with p-values of 0.000 before and 0.455 after; and 0.093 before and 0.408 after respectively, in Group B. In the case of Knee Rotation at Toe Off, although both before and after p-values were more than 0.05, therefore not statistically significantly different from Normative Data, it can be noted that the p-value became larger in the After, therefore signifying that the data became even more statistically significantly different than Normative Data Post Intervention.

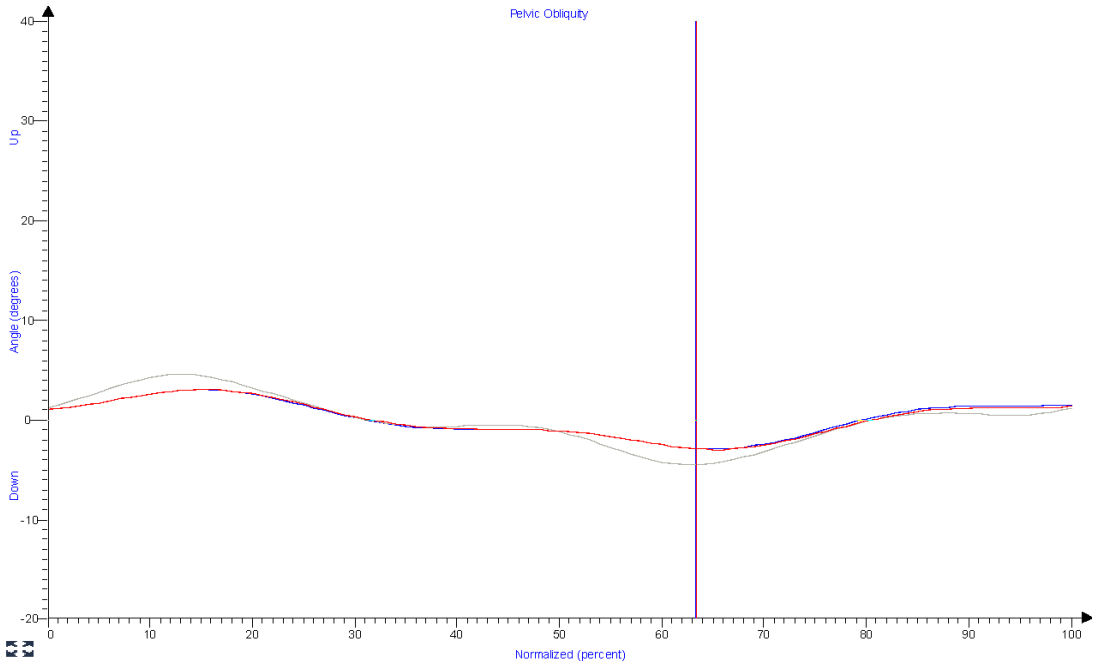


Figure 52 Polygon Graph of the Gait Cycle of Pelvic Obliquity in Group B Before (blue) and After (red) with Normative Data

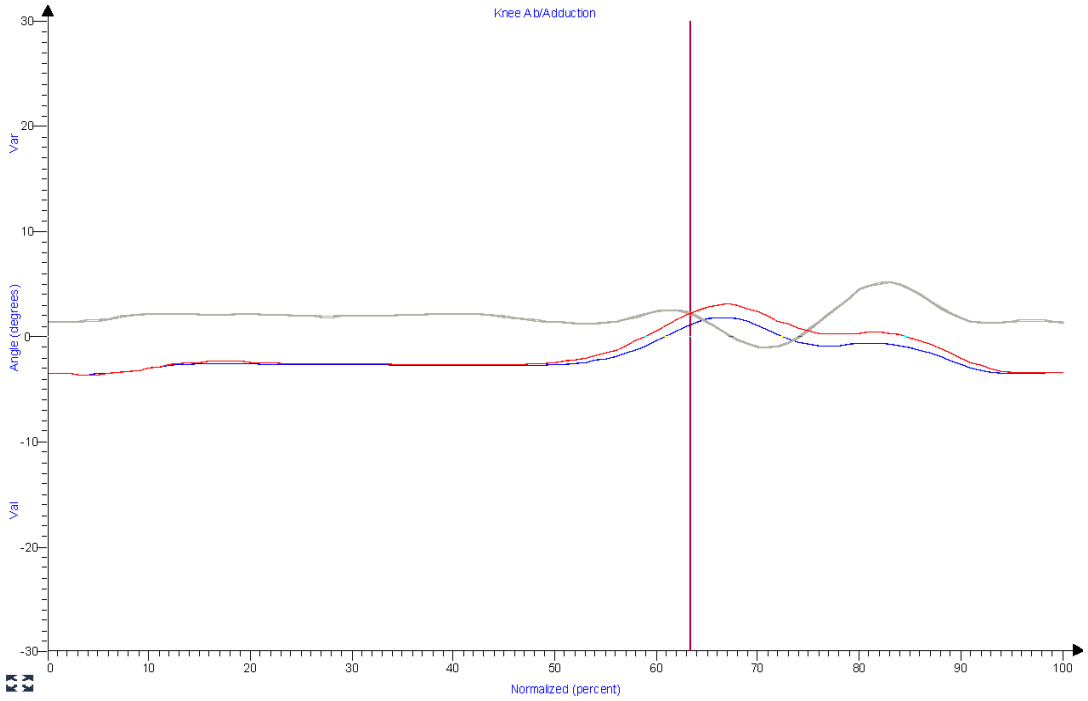


Figure 53 Polygon Graph of the Gait Cycle of Knee Abduction/Adduction in Group B Before (blue) and After (red) with Normative Data

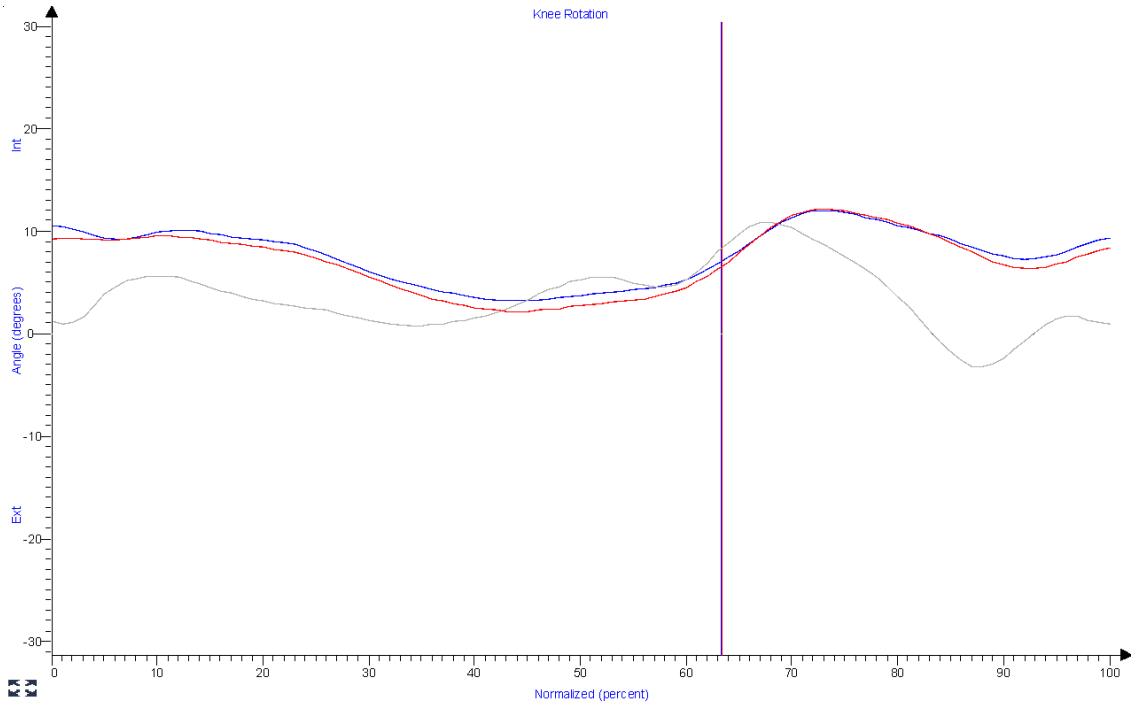


Figure 54 Polygon Graph of the Gait Cycle of Knee Rotation in Group B Before (blue) and After (red) with Normative Data

A similar trend can also be noted for Ankle Abduction/Adduction and Pelvic Rotation. Although at Midstance both before and after p-values (0.162 and 0.385 respectively) were more than 0.05, therefore not statistically significant different from Normative Data, it can be noted that the p-value (0.555 and 0.945 respectively) became larger in the After, therefore signifying that the data became even more statistically significantly different than Normative Data Post Intervention. The same trend for Pelvic Rotation was noted at Toe off with p-values 0.07 for the before and 0.778 for the after.

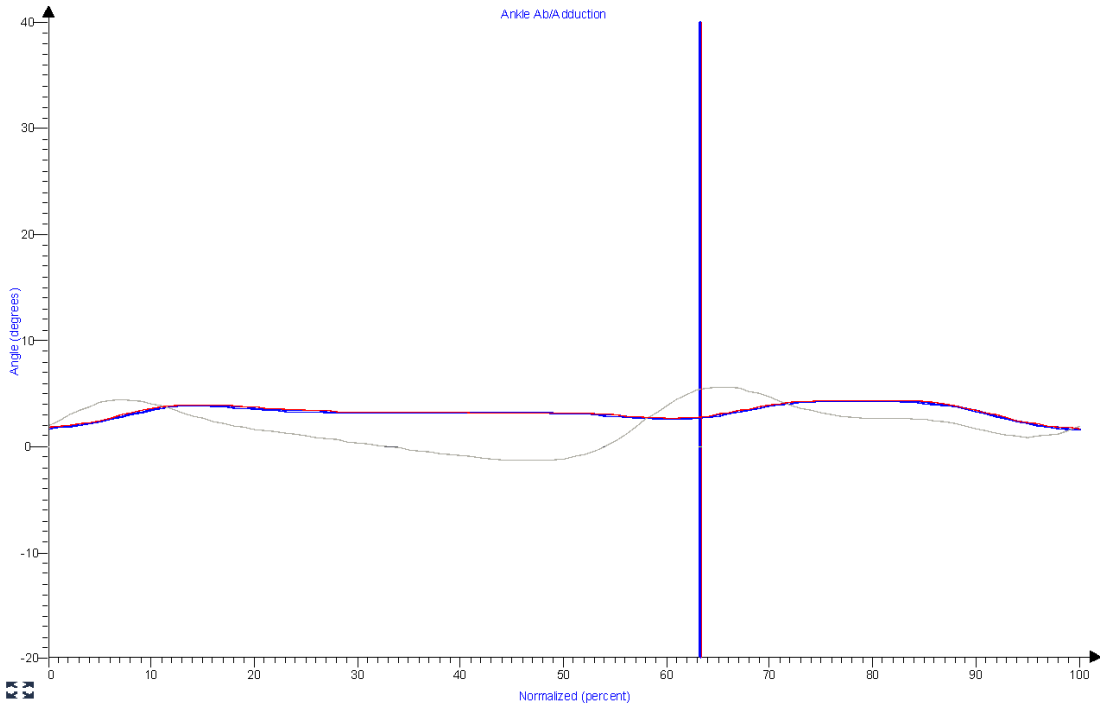


Figure 55 *Polygon Graph of the Gait Cycle of Ankle Abduction/Adduction in Group B Before (blue) and After (red) with Normative Data*

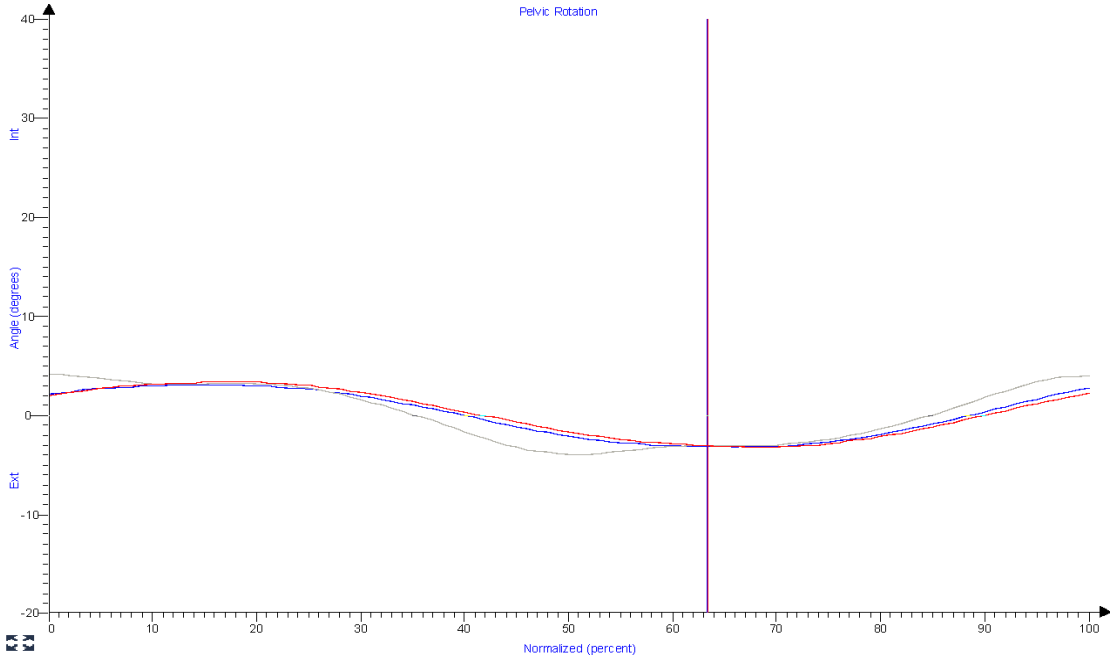


Figure 56 Polygon Graph of the Gait Cycle of Pelvic Rotation in Group B Before (blue) and After (red) with Normative Data

4.2.4.3. Statistical Analysis of the Spatiotemporal Data Before without insoles and After with insoles in Group B.

The null hypothesis states that there is no significant difference between Spatiotemporal Results in Experiment Group B Subjects Before Intervention and Spatiotemporal Results in Experiment Group B Subjects After Intervention. The alternative hypothesis states that there is a significant difference between Spatiotemporal Results in Experiment Group B Subjects Before Intervention and Spatiotemporal Results in Experiment Group B Subjects After Intervention.

Table 30 *Illustrates the spatiotemporal data p-value before and after intervention in Group B*

Data	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Paired Sample t-test	0.023*	Yes	Rejected
Double Support	Paired Sample t-test	0.571	No	Accepted
Foot Off	Paired Sample t-test	0.707	No	Accepted
Limp Index	Wilcoxon signed-rank test	0.433	No	Accepted
Opposite Foot Contact	Paired Sample t-test	0.568	No	Accepted
Opposite Foot Off	Wilcoxon signed-rank test	0.723	No	Accepted
Single Support	Paired Sample t-test	0.022*	Yes	Rejected
Step Length	Paired Sample t-test	0.916	No	Accepted
Step Time	Paired Sample t-test	0.107	No	Accepted
Step Width	Paired Sample t-test	0.858	No	Accepted
Stride Length	Paired Sample t-test	0.479	No	Accepted
Stride Time	Paired Sample t-test	0.011*	Yes	Rejected
Walking Speed	Paired Sample t-test	0.173	No	Accepted

With a 95% level of confidence the above table demonstrates that the p-value outcome is larger than 0.05 in most Spatiotemporal Data. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in before and after intervention in Spatiotemporal Data scores between Group B Before without insoles and After with insoles. This is except for Cadence with a p-value of 0.023; Single Support with a p-value of 0.022; and Stride Time with a p-value of 0.011, which in all three cases the p-value is smaller than 0.05, therefore the Null Hypothesis is rejected, and the Alternative Hypothesis is accepted signifying that there is a statistically significant difference Before and After intervention Spatiotemporal Data in Group B.

As illustrated below, one can see that the dotted red line which represents the after showed that in Cadence, the dotted red line shifted to the left, meaning that after intervention there was a decrease in steps/min. In the case of single support and stride time, the dotted red line shifted to the right, meaning that in both cases there was an increase in Single Support and increase in Stride Time after a combination of 6-weeks physiotherapeutic intervention and custom-made foot orthoses intervention.

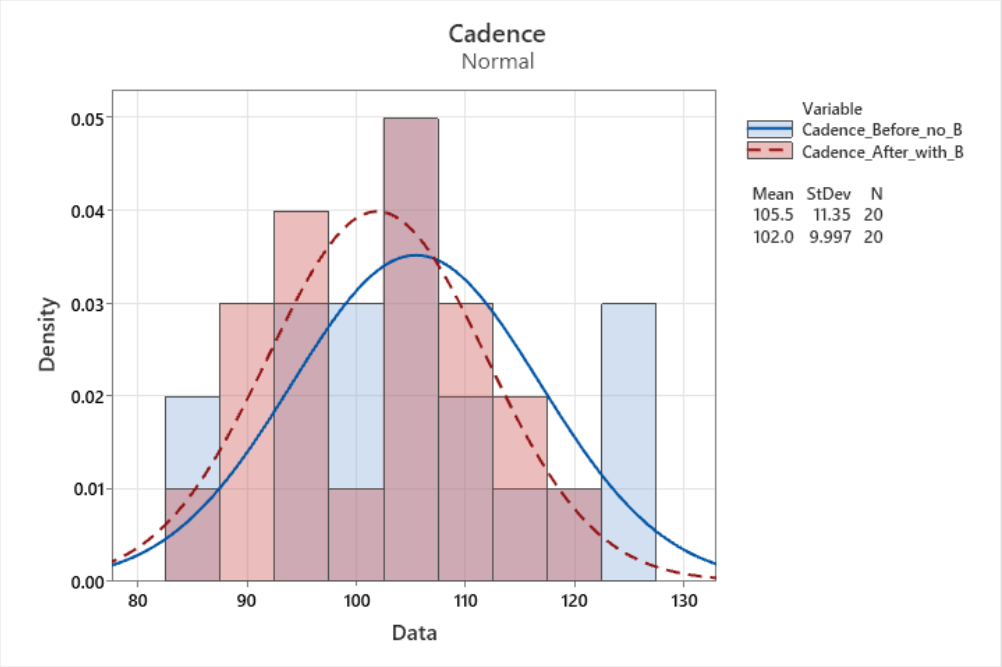


Figure 57 Illustrates the Histogram for Cadence Group B

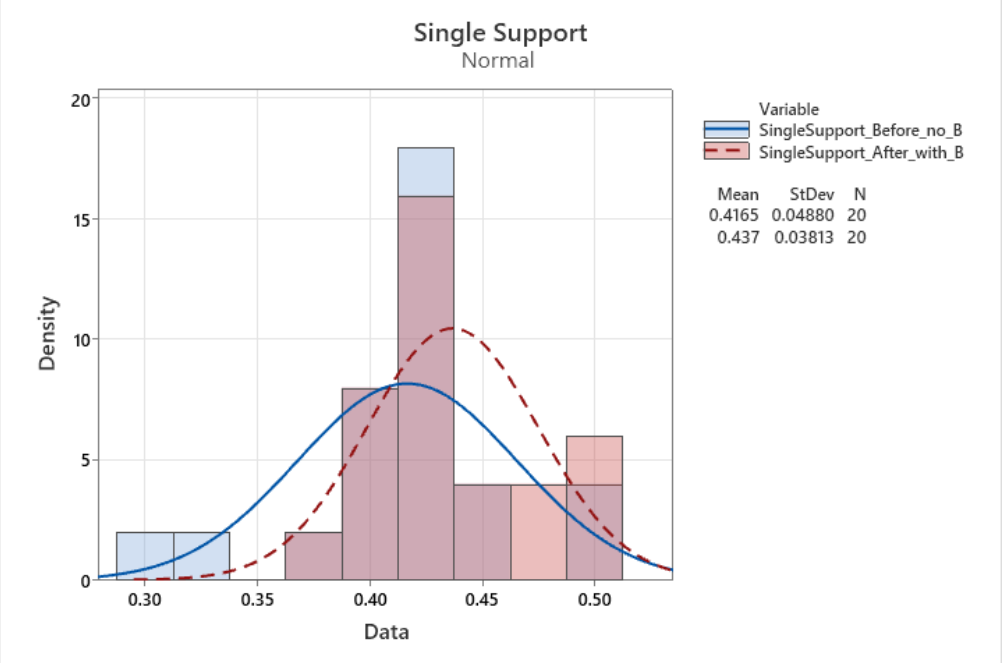


Figure 58 Illustrates the Histogram Plot for Single Support Group B

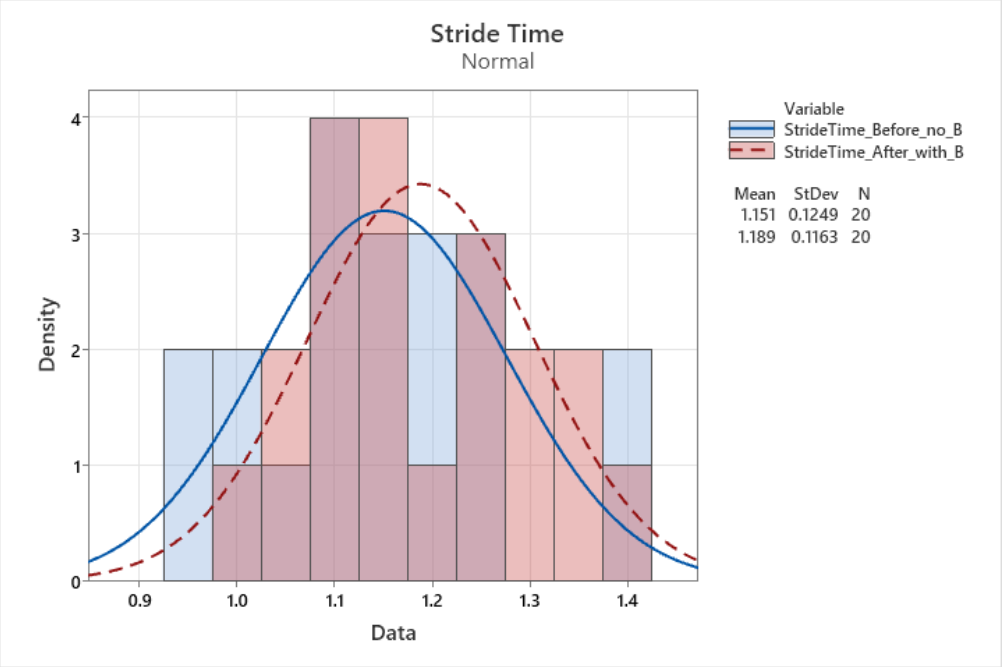


Figure 59 *Illustrates the Histogram Plot for Stride Time Group B*

4.2.5. Statistical Analysis of the Kinematic Angles Difference between Group A and Group B.

The Shapiro-Wilk test was used to determine the normal distribution of each Spatiotemporal Data as explained above in section 4.2.3.2. If data was normally distributed, the Independent Sample t-test (assuming unequal variance) was used to analyse the data, whereas if the data was not normally distributed the Mann-Whitney test was used to analyse the data. Histograms were used to graphically represent the data being statistically analysed, where Group A Difference is depicted using a blue solid line and Group B Difference is depicted using a dotted red line.

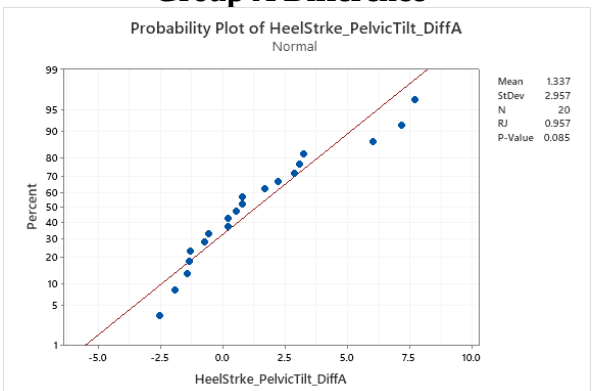
4.2.5.1. Determining the normal distribution.

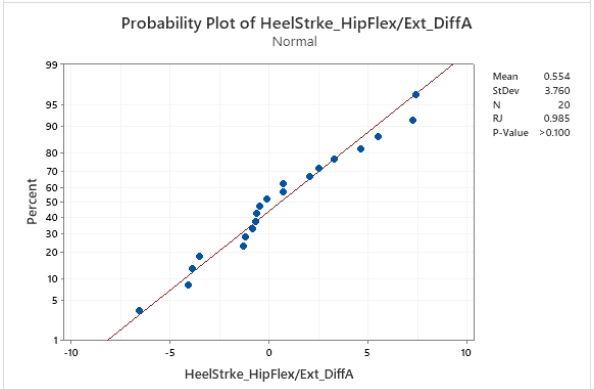
The Shapiro-Wilk test was used to assess the normality assumption of score distribution for each group of participants separately as illustrated below in the Probability plots for Kinematic and Spatiotemporal Data. The null hypothesis states that the data is normally

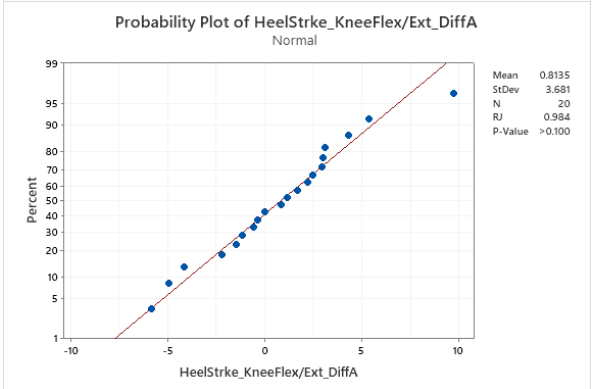
distributed when p-value is >0.05. The alternative hypothesis states that the data is not normally distributed when p-value is <0.05.

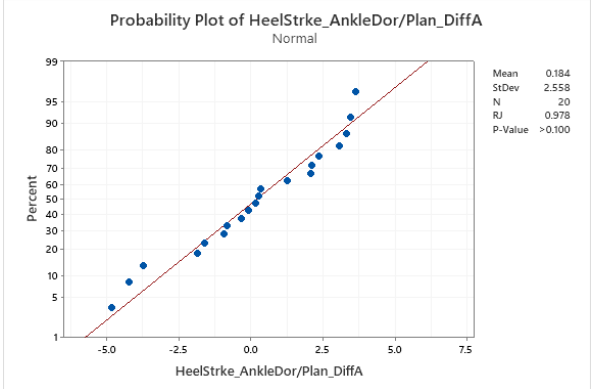
4.2.5.1.1. Kinematic Data.

Group A Difference

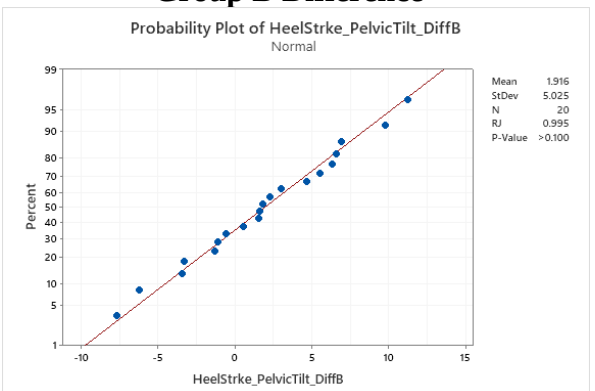


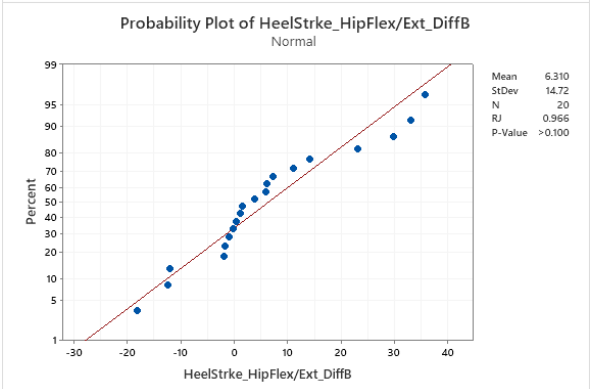


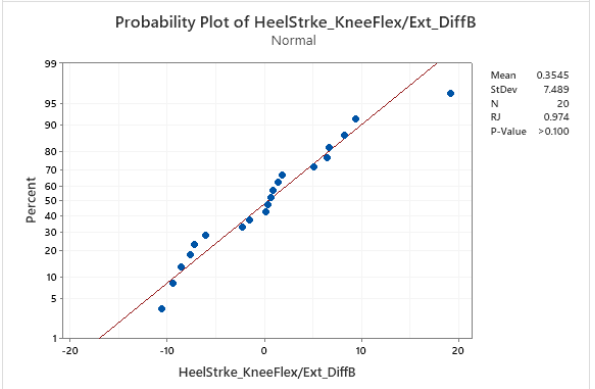


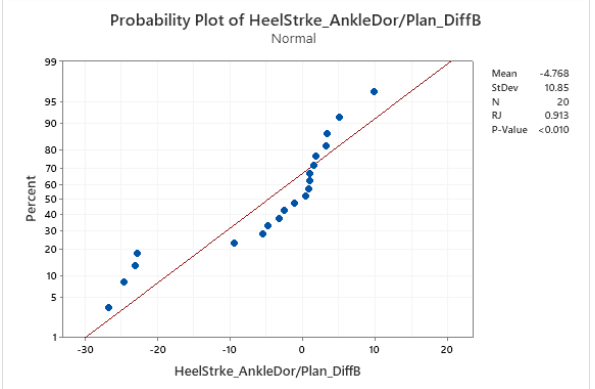


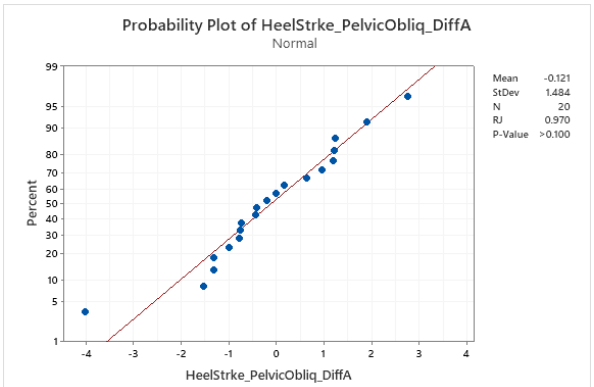
Group B Difference

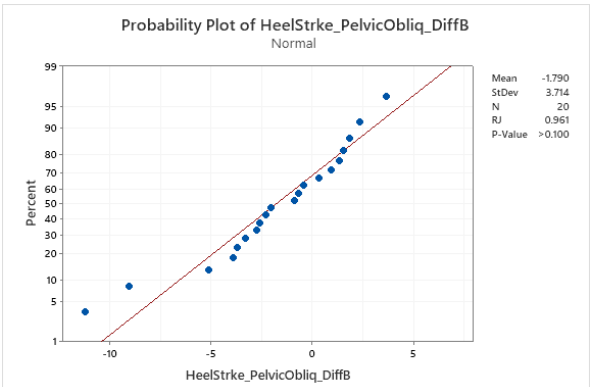


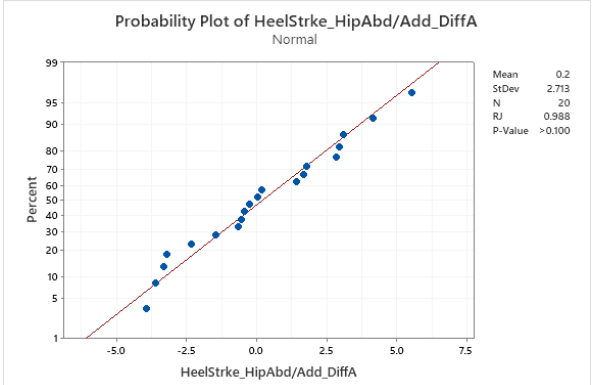


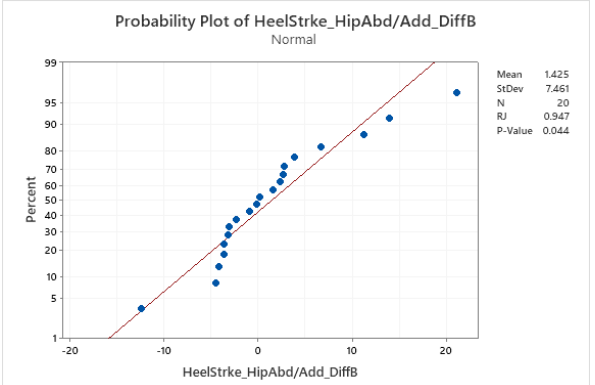


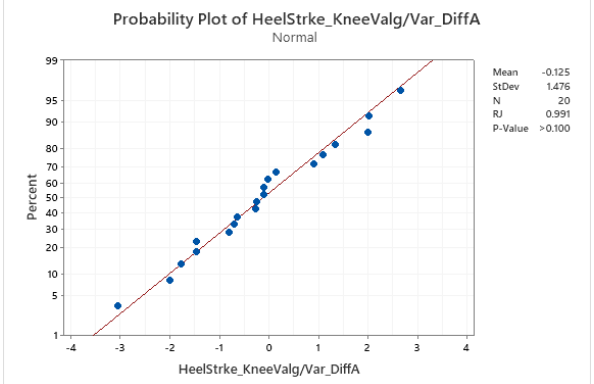


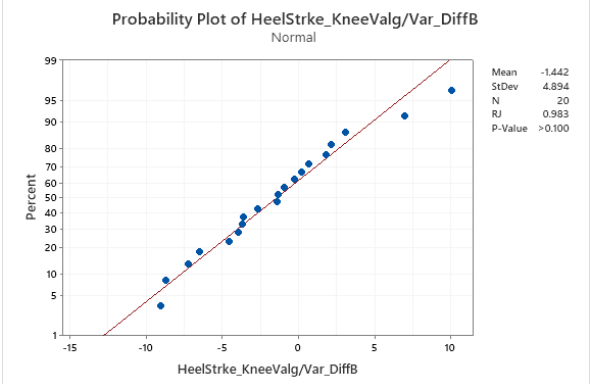

Probability Plot of HeelStrke_PelvicObliq_DiffA
Normal
Mean -0.121
StDev 1.484
N 20
RJ 0.970
P-Value >0.100
Percent
HeelStrke_PelvicObliq_DiffA

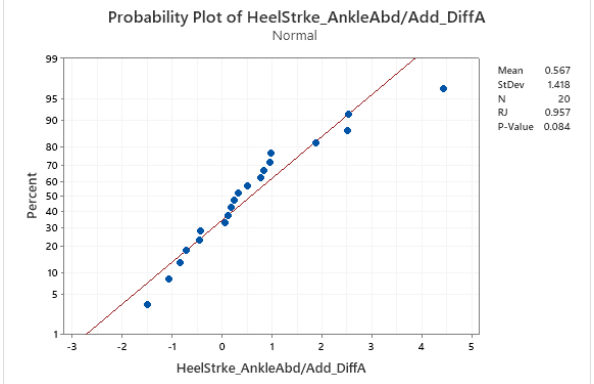

Probability Plot of HeelStrke_PelvicObliq_DiffB
Normal
Mean -1.790
StDev 3.714
N 20
RJ 0.961
P-Value >0.100
Percent
HeelStrke_PelvicObliq_DiffB

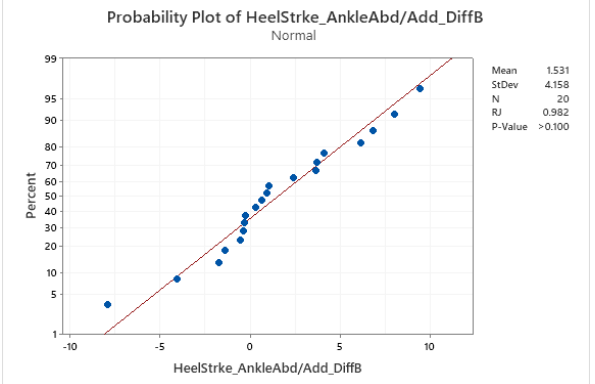

Probability Plot of HeelStrke_HipAbd/Add_DiffA
Normal
Mean 0.2
StDev 2.713
N 20
RJ 0.988
P-Value >0.100
Percent
HeelStrke_HipAbd/Add_DiffA


Probability Plot of HeelStrke_HipAbd/Add_DiffB
Normal
Mean 1.425
StDev 7.461
N 20
RJ 0.947
P-Value 0.044
Percent
HeelStrke_HipAbd/Add_DiffB


Probability Plot of HeelStrke_KneeValg/Var_DiffA
Normal
Mean -0.125
StDev 1.476
N 20
RJ 0.991
P-Value >0.100
Percent
HeelStrke_KneeValg/Var_DiffA


Probability Plot of HeelStrke_KneeValg/Var_DiffB
Normal
Mean -1.442
StDev 4.894
N 20
RJ 0.983
P-Value >0.100
Percent
HeelStrke_KneeValg/Var_DiffB


Probability Plot of HeelStrke_AnkleAbd/Add_DiffA
Normal
Mean 0.567
StDev 1.418
N 20
RJ 0.957
P-Value 0.084
Percent
HeelStrke_AnkleAbd/Add_DiffA


Probability Plot of HeelStrke_AnkleAbd/Add_DiffB
Normal
Mean 1.531
StDev 4.158
N 20
RJ 0.982
P-Value >0.100
Percent
HeelStrke_AnkleAbd/Add_DiffB

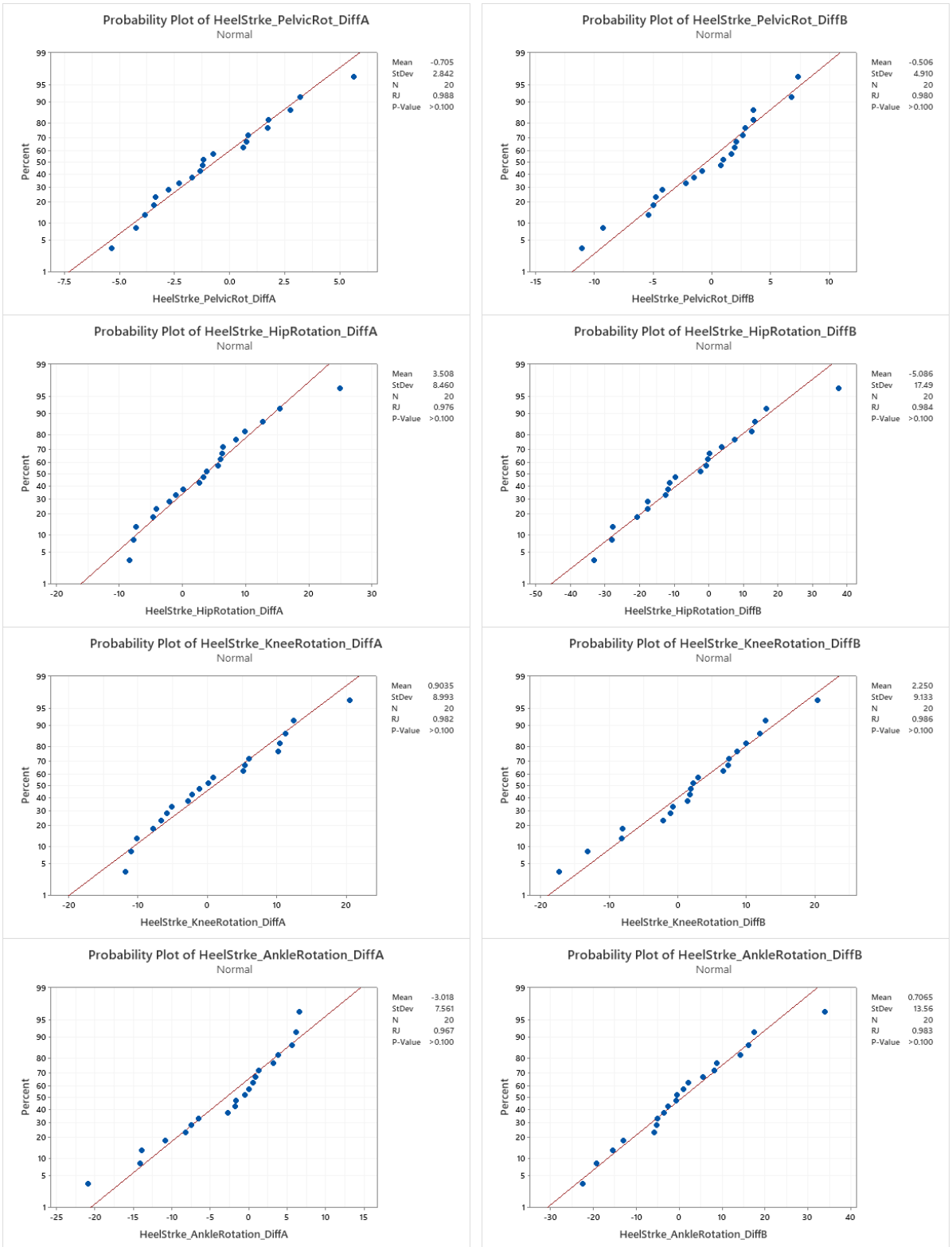


Figure 60 Illustrates the Probability Plots for Normal Distribution of Kinematic Data of Group A Difference and Group B Difference at Heel Strike

With a 95% level of confidence the above plots demonstrate that most of the p-values exceed 0.05, for both Group A and Group B. This signifies that the data is normally

distributed since the Null Hypothesis has been accepted. Therefore, parametric tests such as the Independent Sample t-test (assuming unequal variance) can be used for further statistical examination of this data. Except for Ankle Dorsiflexion/Plantarflexion (p-value <0.01) and Hip Abduction/Adduction (p-value 0.044) with p-values that are less than 0.05, therefore the Null Hypothesis has been rejected, while the Alternative Hypothesis has been accepted. This meant that the data for these angles are not normally distributed, and non-parametric statistical tests were needed for further statistical examination. Further breakdown of the p-values can be found in Table below.

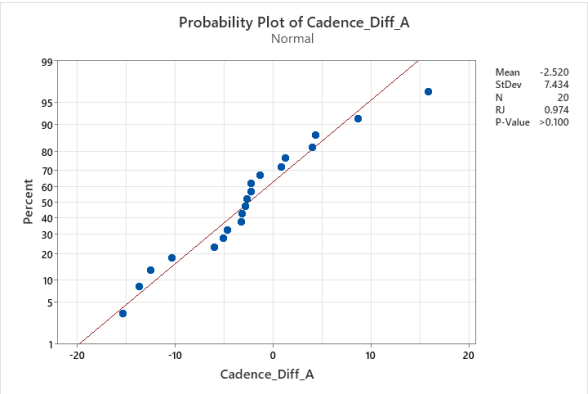
Table 31 *Illustrates the p-values of Kinematic Data Group A Difference and Group B Difference at Heel Strike*

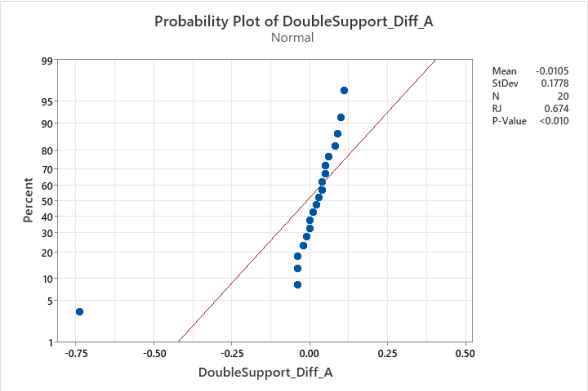
	Group A			Group B		
Angle	p-value	<0.05	Null Hypothesis	p-value	<0.05	Null Hypothesis
Pelvic Tilt	0.085	No	Accepted	>0.1	No	Accepted
Hip Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Knee Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Dorsi/Plantar	>0.1	No	Accepted	<0.01	Yes	Rejected
Pelvic Obliquity	>0.1	No	Accepted	>0.1	No	Accepted
Hip Abd/Add	>0.1	No	Accepted	0.044	Yes	Rejected
Knee Valg/Var	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Abd/Add	0.084	No	Accepted	>0.1	No	Accepted
Pelvic Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Hip Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Knee Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Rotation	>0.1	No	Accepted	>0.1	No	Accepted

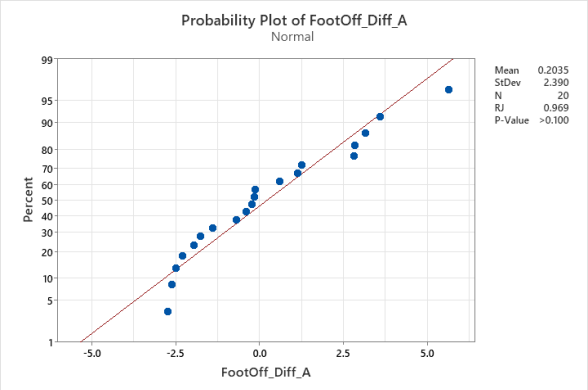
The above Statistical Analysis was then repeated for Midstance and Toe Off. Refer to Appendix 18-19 for the Probability Plots and Analysis of Data.

4.2.5.1.1. Spatiotemporal Data.

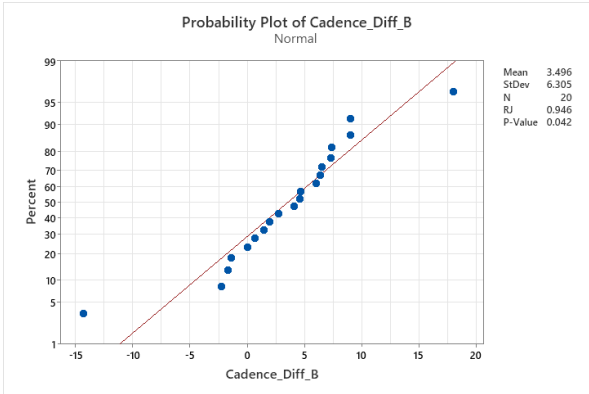
Group A

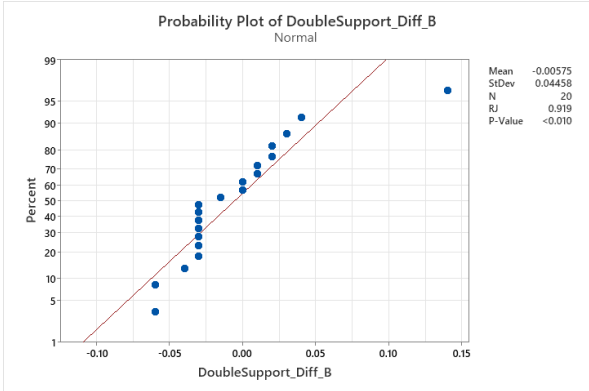


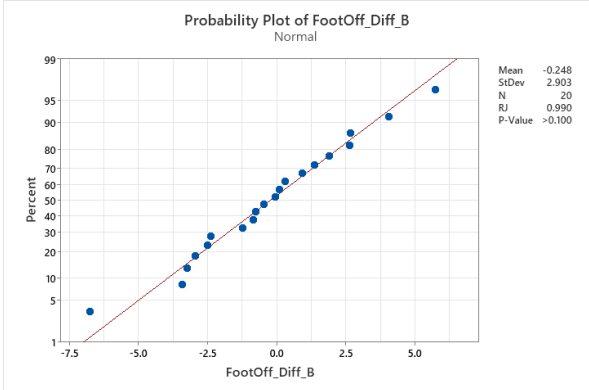


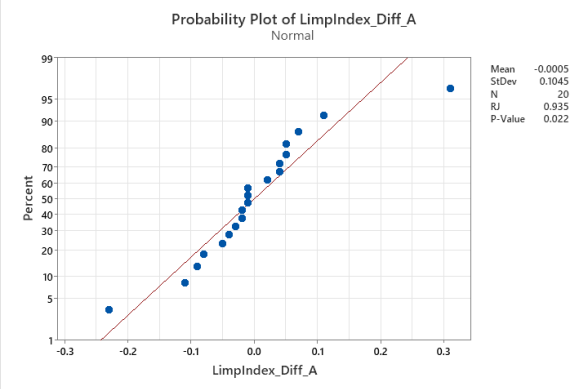


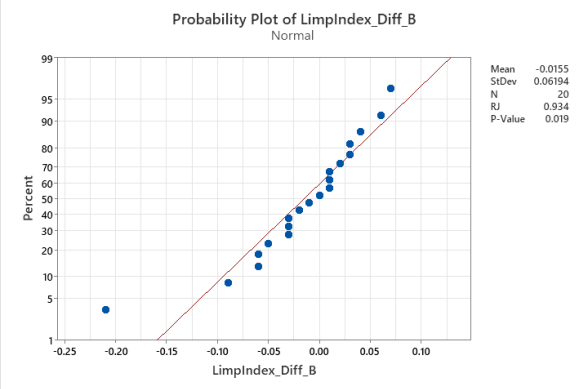
Group B

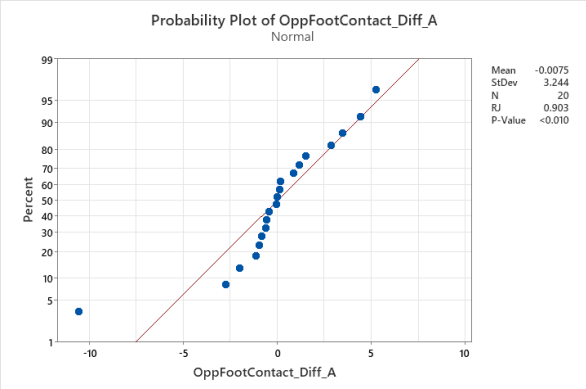


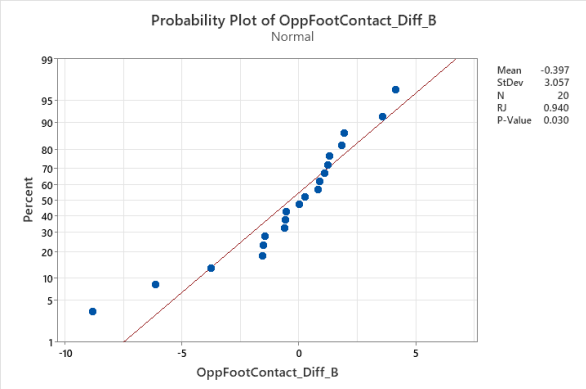


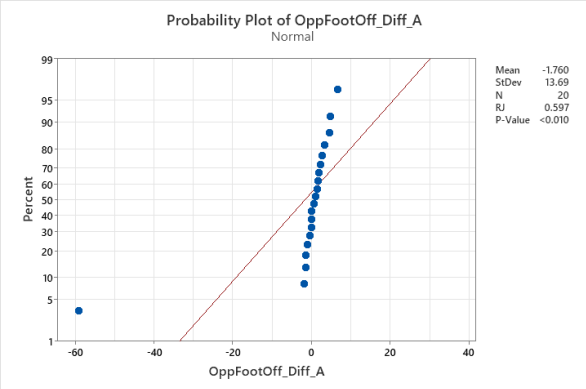


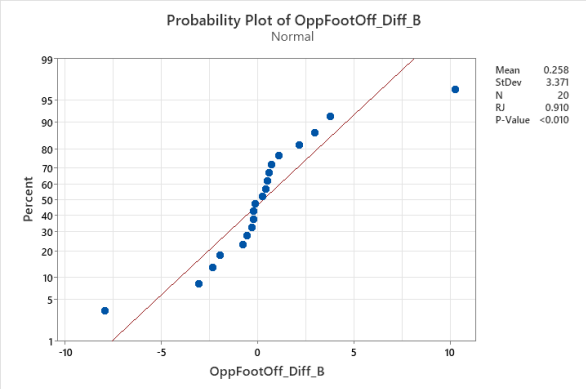

Probability Plot of LimpIndex_Diff_A
Normal
Mean -0.0005
StDev 0.1045
N 20
RJ 0.935
P-Value 0.022
Percent
LimpIndex_Diff_A

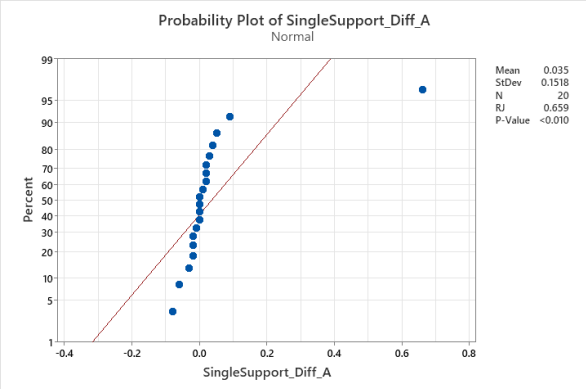

Probability Plot of LimpIndex_Diff_B
Normal
Mean -0.0155
StDev 0.06194
N 20
RJ 0.934
P-Value 0.019
Percent
LimpIndex_Diff_B

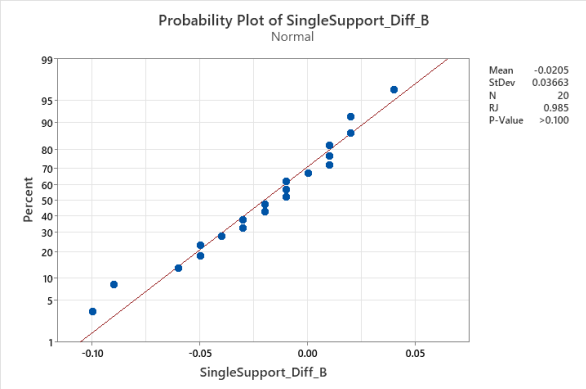

Probability Plot of OppFootContact_Diff_A
Normal
Mean -0.0075
StDev 3.244
N 20
RJ 0.903
P-Value <0.010
Percent
OppFootContact_Diff_A

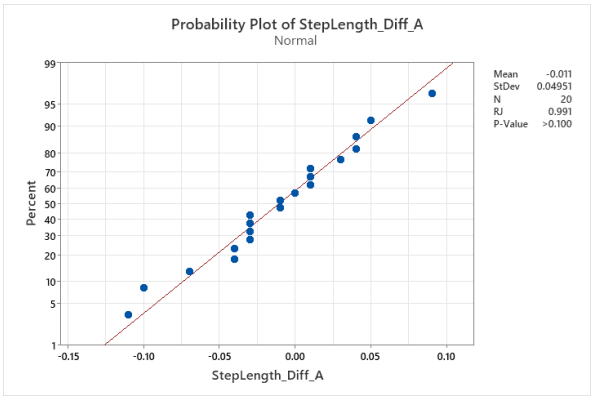

Probability Plot of OppFootContact_Diff_B
Normal
Mean -0.397
StDev 3.057
N 20
RJ 0.940
P-Value 0.030
Percent
OppFootContact_Diff_B

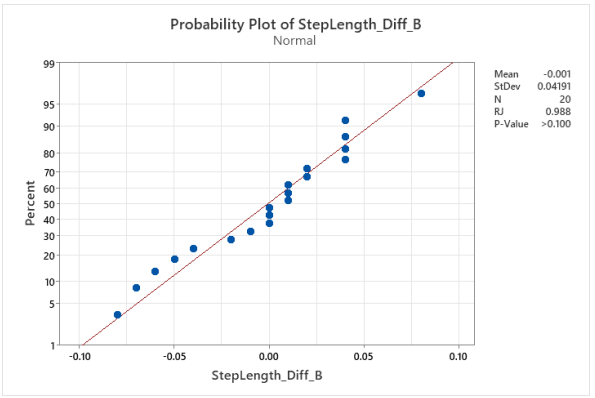

Probability Plot of OppFootOff_Diff_A
Normal
Mean -1.760
StDev 13.69
N 20
RJ 0.597
P-Value <0.010
Percent
OppFootOff_Diff_A

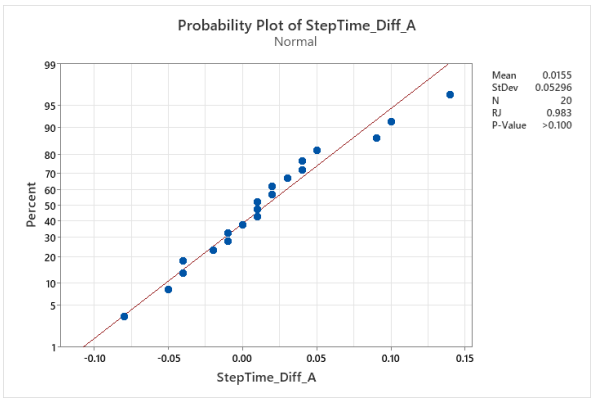

Probability Plot of OppFootOff_Diff_B
Normal
Mean 0.258
StDev 3.371
N 20
RJ 0.910
P-Value <0.010
Percent
OppFootOff_Diff_B

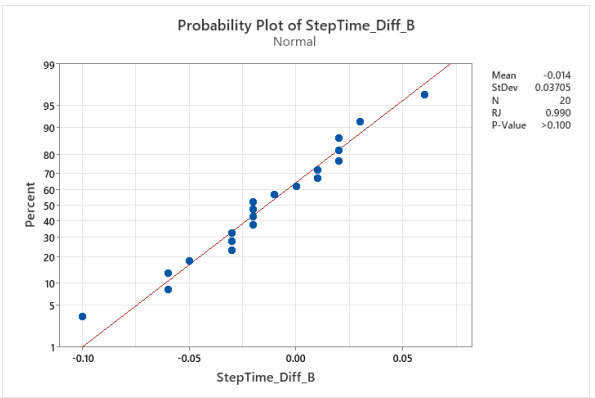

Probability Plot of SingleSupport_Diff_A
Normal
Mean 0.035
StDev 0.1518
N 20
RJ 0.659
P-Value <0.010
Percent
SingleSupport_Diff_A

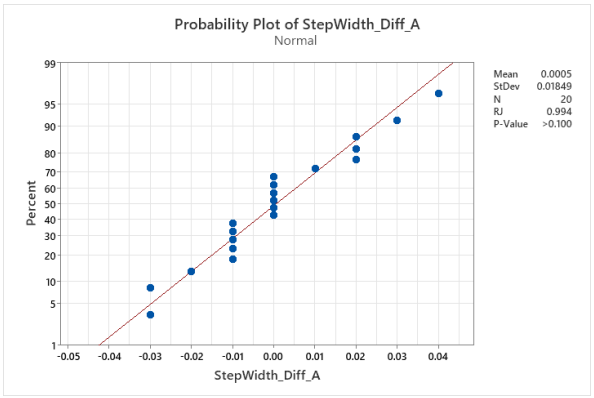

Probability Plot of SingleSupport_Diff_B
Normal
Mean -0.0205
StDev 0.03663
N 20
RJ 0.985
P-Value >0.100
Percent
SingleSupport_Diff_B

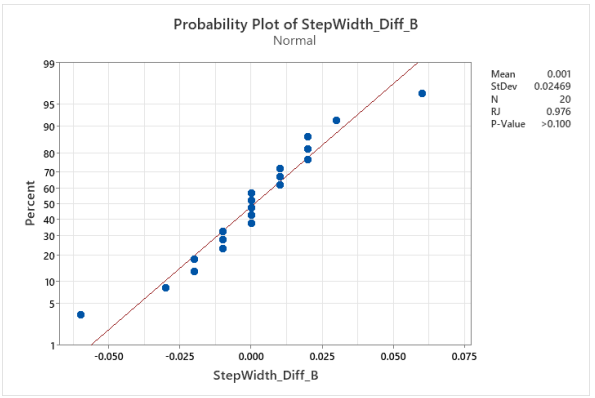

Probability Plot of StepLength_Diff_A
Normal
Mean -0.011
StDev 0.04951
N 20
RJ 0.991
P-Value >0.100
Percent
StepLength_Diff_A

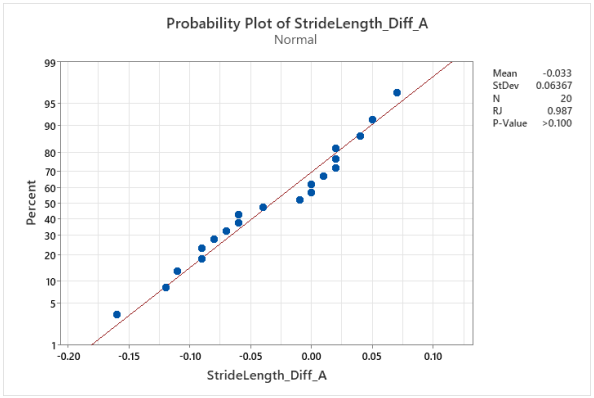

Probability Plot of StepLength_Diff_B
Normal
Mean -0.001
StDev 0.04191
N 20
RJ 0.988
P-Value >0.100
Percent
StepLength_Diff_B

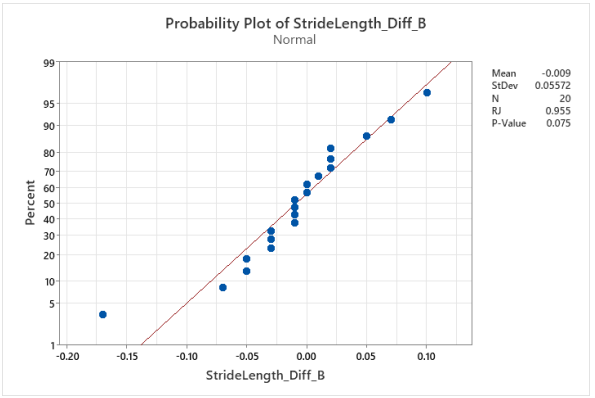

Probability Plot of StepTime_Diff_A
Normal
Mean 0.0155
StDev 0.05296
N 20
RJ 0.983
P-Value >0.100
Percent
StepTime_Diff_A


Probability Plot of StepTime_Diff_B
Normal
Mean -0.014
StDev 0.03705
N 20
RJ 0.990
P-Value >0.100
Percent
StepTime_Diff_B


Probability Plot of StepWidth_Diff_A
Normal
Mean 0.0005
StDev 0.01849
N 20
RJ 0.994
P-Value >0.100
Percent
StepWidth_Diff_A


Probability Plot of StepWidth_Diff_B
Normal
Mean 0.001
StDev 0.02469
N 20
RJ 0.976
P-Value >0.100
Percent
StepWidth_Diff_B


Probability Plot of StrideLength_Diff_A
Normal
Mean -0.033
StDev 0.06367
N 20
RJ 0.987
P-Value >0.100
Percent
StrideLength_Diff_A


Probability Plot of StrideLength_Diff_B
Normal
Mean -0.009
StDev 0.05572
N 20
RJ 0.955
P-Value 0.075
Percent
StrideLength_Diff_B

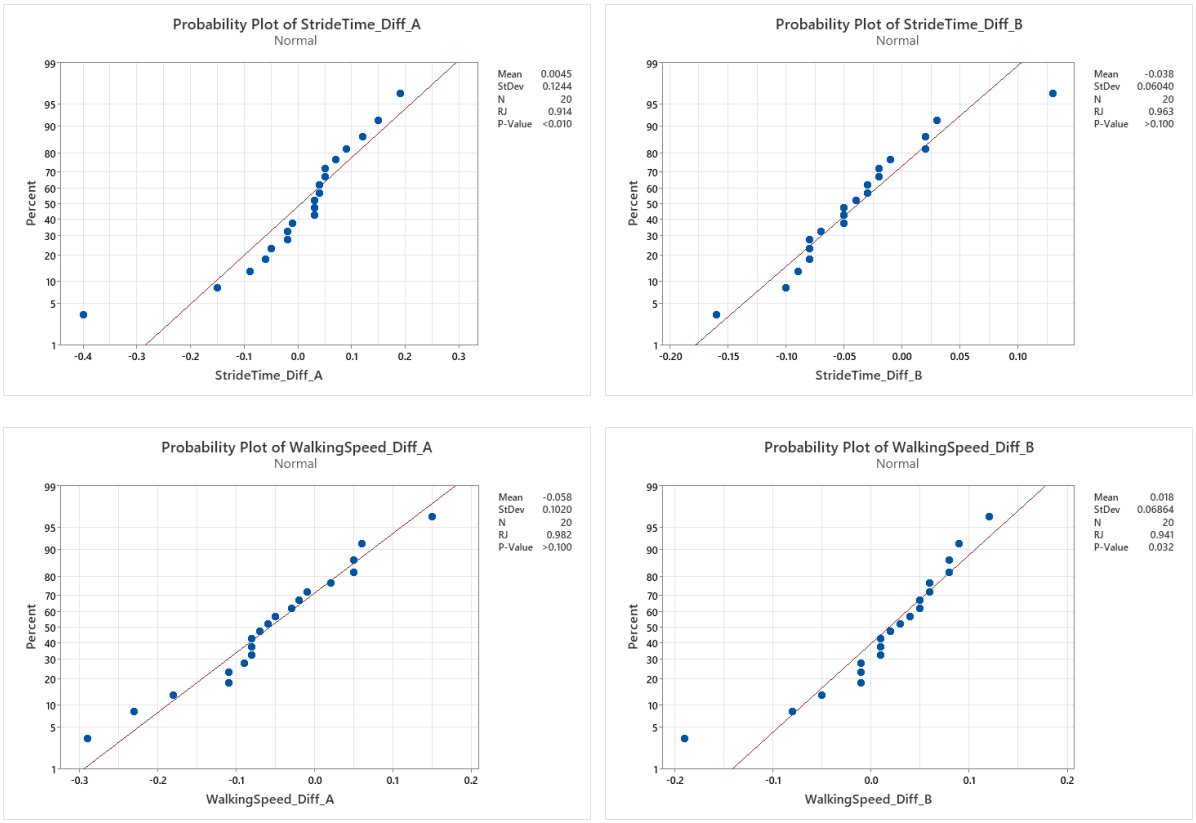


Figure 61 *Illustrates the Probability Plots for Normal Distribution of Spatiotemporal Data of Group A Difference and Group B Difference at Heel Strike*

With a 95% level of confidence, the above plots demonstrate that for both Group A and Group B Before and After intervention Difference, there is a mix of p-values, which either exceed or are less than 0.05. This signifies that not all the data is normally distributed since the Null Hypothesis has not been accepted in a few spatiotemporal data. Therefore, both parametric tests such as the Independent Sample t-test (assuming unequal variance) and non-parametric tests such as the Mann-Whitney test have to be used for further statistical examination of this data.

Table 32 Illustrates the p-values of Spatiotemporal Data Group A Difference and Group B Difference at Heel Strike

	Group A			Group B		
Data	p-value	<0.05	Null Hypothesis	p-value	<0.05	Null Hypothesis
Cadence	>0.1	No	Accepted	0.042	Yes	Rejected
Double Support	<0.01	Yes	Rejected	<0.01	Yes	Rejected
Foot Off	>0.1	No	Accepted	>0.1	No	Accepted
Limp Index	0.022	Yes	Rejected	0.019	Yes	Rejected
Opposite Foot Contact	<0.01	Yes	Rejected	0.03	Yes	Rejected
Opposite Foot Off	<0.01	Yes	Rejected	<0.01	Yes	Rejected
Single Support	<0.01	Yes	Rejected	>0.1	No	Accepted
Step Length	>0.1	No	Accepted	>0.1	No	Accepted
Step Time	>0.1	No	Accepted	>0.1	No	Accepted
Step Width	>0.1	No	Accepted	>0.1	No	Accepted
Stride Length	>0.1	No	Accepted	0.075	Yes	Rejected
Stride time	<0.01	Yes	Rejected	>0.1	No	Accepted
Walking Speed	>0.1	No	Accepted	0.032	Yes	Rejected

4.2.4.2. Statistical Analysis of the Kinematic Data between Group A Difference and Group B Difference between before and after intervention.

The null hypothesis states that there is no significant difference between Kinematic results at Heel Strike, Midstance and Toe Off within the gait analysis results in Comparison Group A Difference and Kinematic results in Experiment Group B Difference. The

alternative hypothesis states that there is a significant difference between Kinematic results at Heel Strike, Midstance and Toe Off within the gait analysis results in Comparison Group A Difference and Kinematic results in Experiment Group B Difference

Table 33 Illustrates the Kinematic Data Statistical Analysis for Heel Strike between Group A and Group B difference

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Independent Sample t-test	0.66	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.105	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.808	No	Accepted
Ankle Dorsi/Plantar	Mann-Whitney test	0.31	No	Accepted
Pelvic Obliquity	Independent Sample t-test	0.074	No	Accepted
Hip Abd/Add	Mann-Whitney test	0.946	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.262	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.337	No	Accepted
Pelvic Rotation	Independent Sample t-test	0.876	No	Accepted
Hip Rotation	Independent Sample t-test	0.058	No	Accepted
Knee Rotation	Independent Sample t-test	0.641	No	Accepted
Ankle Rotation	Independent Sample t-test	0.292	No	Accepted

With a 95% level of confidence the above table demonstrates that the p-value outcome is larger than 0.05 in all angles at Heel Strike. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in the difference in Kinematic scores before and after intervention between Group A and Group B at Heel Strike.

Although the Pelvic Obliquity angle and Hip Rotation during Heel Strike did not statistically show significant difference before and after, the p-values (0.074 and 0.058

respectively) are close to 0.05 when compared to the other angles. Therefore, more information could be provided from the Histogram Plot below, where it can be noted that the red line is shifted towards left, and the value is more negative in both cases. This signifies that the opposite side of the pelvis is lower in the Coronal Plane and that the hip is more internally rotated in the Transverse Plane than before intervention.

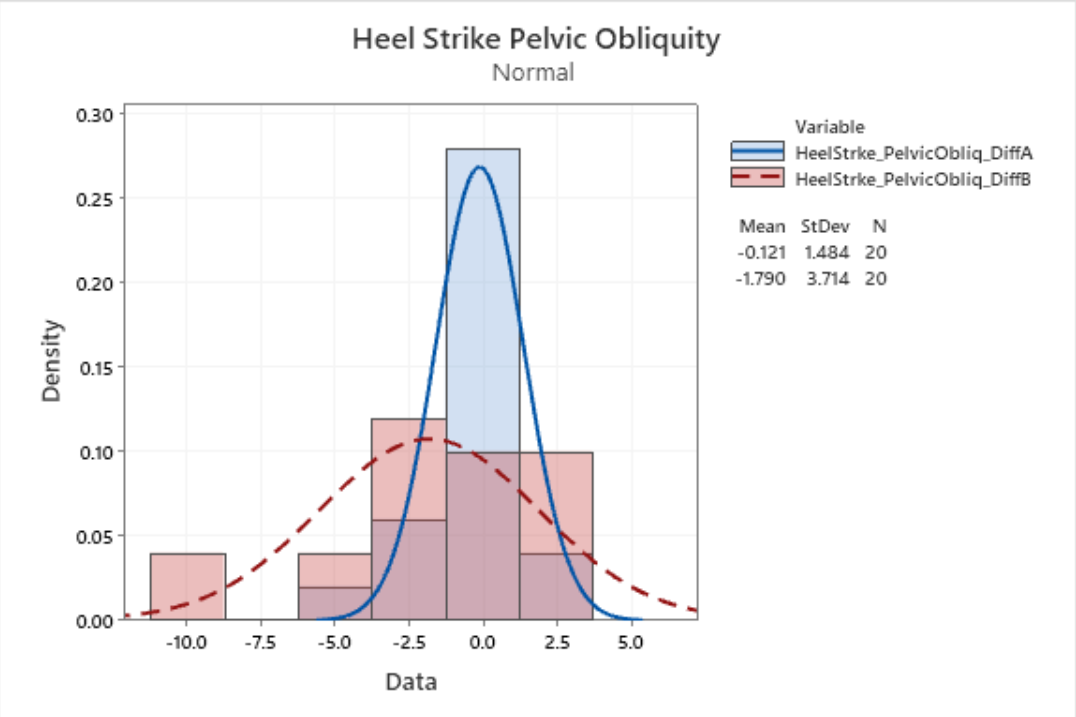


Figure 62 illustrates the Histogram Plot for Pelvic Obliquity at Heel Strike of Group A Difference vs Group B Difference

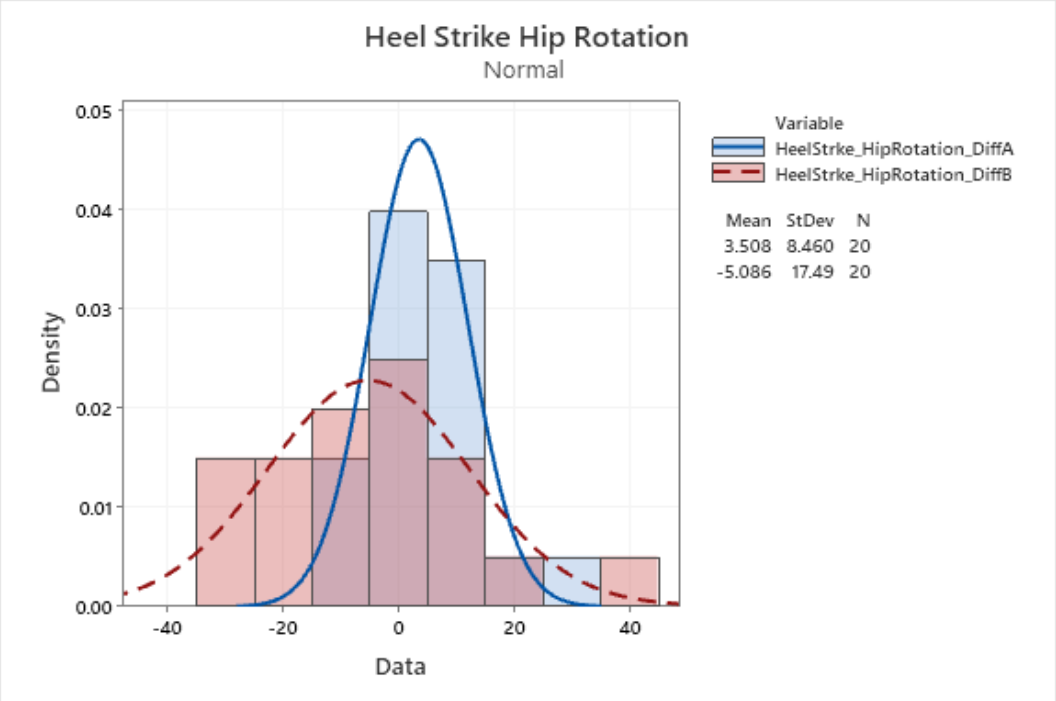


Figure 63 illustrates the Histogram Plot for Hip Rotation at Heel Strike of Group A Difference vs Group B Difference

Refer to Appendix 23 for the rest of the Histogram plots of the Kinematic Angles at Heel Strike.

Table 34 Illustrates the Kinematic Data Statistical Analysis for Midstance between Group A and Group B difference

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Mann-Whitney test	0.25	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.589	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.719	No	Accepted
Ankle Dorsi/Plantar	Mann-Whitney test	0.02*	Yes	Rejected
Pelvic Obliquity	Mann-Whitney test	0.048*	Yes	Rejected
Hip Abd/Add	Mann-Whitney test	0.85	No	Accepted
Knee Valg/Var	Mann-Whitney test	0.525	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.699	No	Accepted
Pelvic Rotation	Independent Sample t-test	0.202	No	Accepted

Hip Rotation	Independent Sample t-test	0.038*	Yes	Rejected
Knee Rotation	Independent Sample t-test	0.695	No	Accepted
Ankle Rotation	Independent Sample t-test	0.184	No	Accepted

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most angles at Midstance. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in the difference in Kinematic scores before and after intervention between Group A and Group B at Midstance. This is except for Ankle Dorsiflexion/Plantarflexion with a p-value of 0.02; Pelvic Obliquity with a p-value of 0.048 and Hip Rotation with a p-value of 0.038. Since in all cases, the p-value is smaller than 0.05 the Null Hypothesis is rejected, and the alternative hypothesis is accepted. Therefore, showing that there is statistical difference in the difference in Kinematic scores before and after intervention between Group A and Group B.

As illustrated in the Histogram plots below, one can see that the dotted red line which represents Group B showed a left shift in all three angles. Therefore, more dorsiflexion is noted in the Sagittal Plane; a lower opposite side of the Pelvis in the Coronal Plane and more external rotation in the Transverse Plane in Group B when compared to Group A.

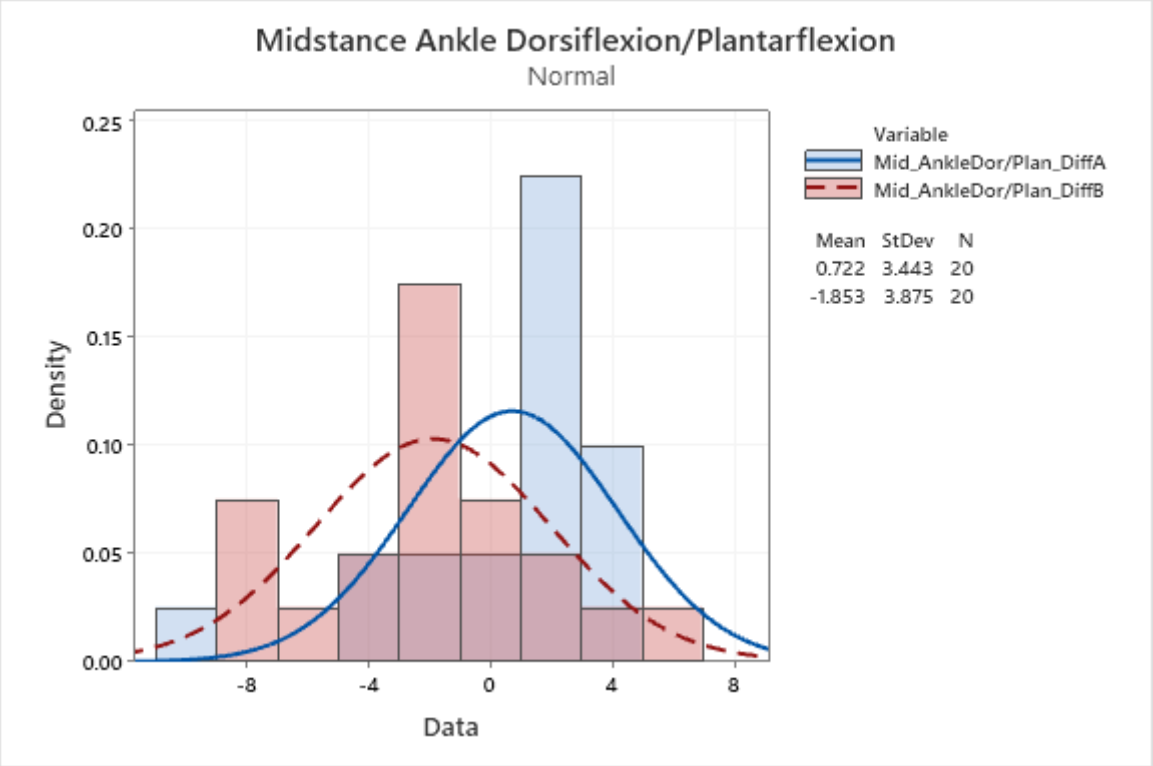


Figure 64 illustrates the Histogram Plot for Ankle Dorsiflexion/Plantarflexion at Midstance of Group A Difference vs Group B Difference

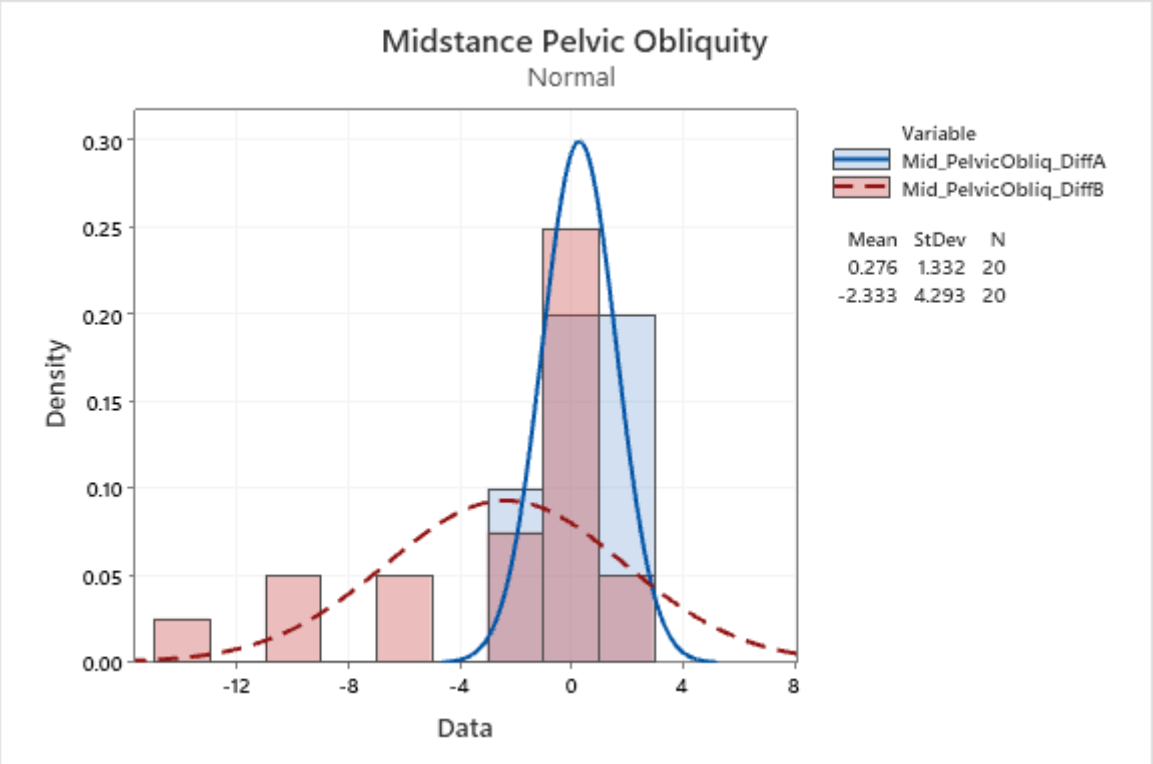


Figure 65 illustrates the Histogram Plot for Pelvic Obliquity at Midstance of Group A Difference vs Group B Difference

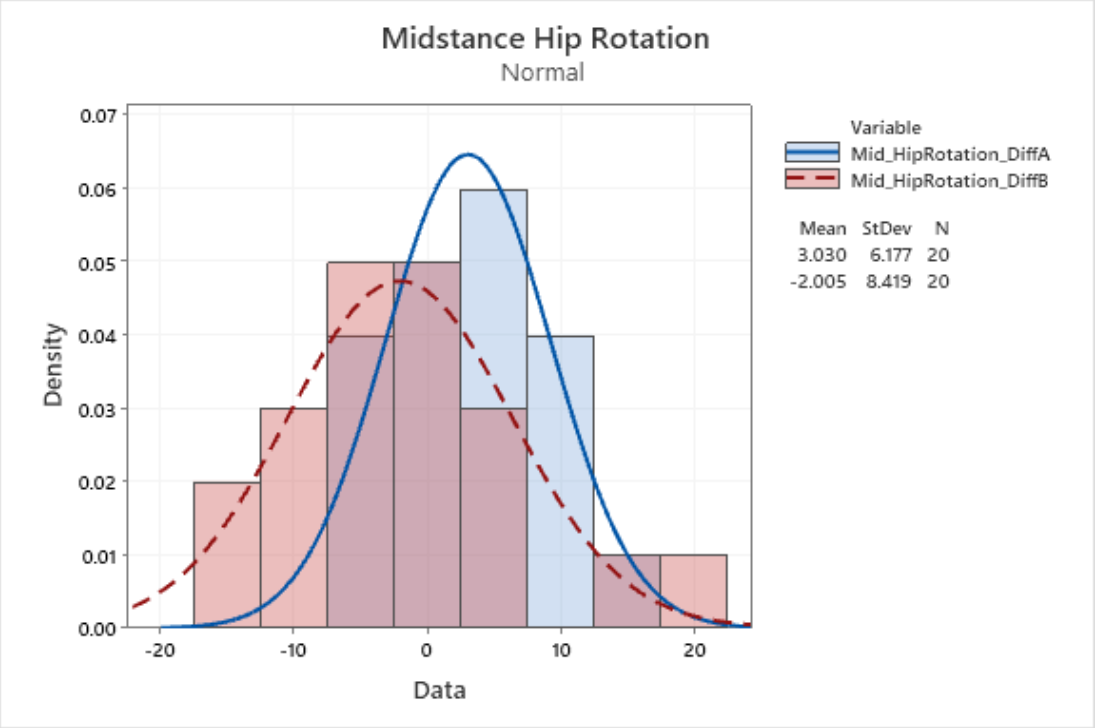


Figure 66 illustrates the Histogram Plot for Hip Rotation at Midstance of Group A Difference vs Group B Difference

Refer to Appendix 24 for the rest of the Histogram plots of the Kinematic Angles at Midstance.

Table 35 Illustrates the Kinematic Data Statistical Analysis for Toe Off between Group A and Group B difference

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Independent Sample t-test	0.597	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.522	No	Accepted
Knee Flex/ext	Mann-Whitney test	0.057	No	Accepted
Ankle Dorsi/Plantar	Independent Sample t-test	0.466	No	Accepted
Pelvic Obliquity	Mann-Whitney test	0.441	No	Accepted
Hip Abd/Add	Mann-Whitney test	0.148	No	Accepted
Knee Valg/Var	Mann-Whitney test	0*	Yes	Rejected
Ankle Abd/Add	Independent Sample t-test	0.169	No	Accepted
Pelvic Rotation	Mann-Whitney test	0.224	No	Accepted

Hip Rotation	Independent Sample t-test	0.078	No	Accepted
Knee Rotation	Independent Sample t-test	0.697	No	Accepted
Ankle Rotation	Independent Sample t-test	0.029*	Yes	Rejected

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most angles at Toe Off. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference in the difference in Kinematic scores before and after intervention between Group A and Group B at Toe Off. This is except for Knee Valgus/Varus with a p-value of 0.00; and Ankle Rotation with a p-value of 0.029. Since in both cases the p-value is smaller than 0.05 the Null Hypothesis is rejected, and the alternative hypothesis is accepted. Therefore, showing that there is statistical difference in the difference in Kinematic scores before and after intervention between Group A and Group B at Toe Off.

As illustrated in the Histogram plots below, one can see that the dotted red line which represents Group B showed a left shift for Knee Valgus/Varus, meaning that there was less Knee Valgus in the Coronal Plane in Group B when compared to Group A. On the other hand, for ankle rotation, one can see that the dotted red line which represents Group B showed a right shift in the graph, meaning that there was less internal rotation in Transverse Plane in Group B when compared to Group A.

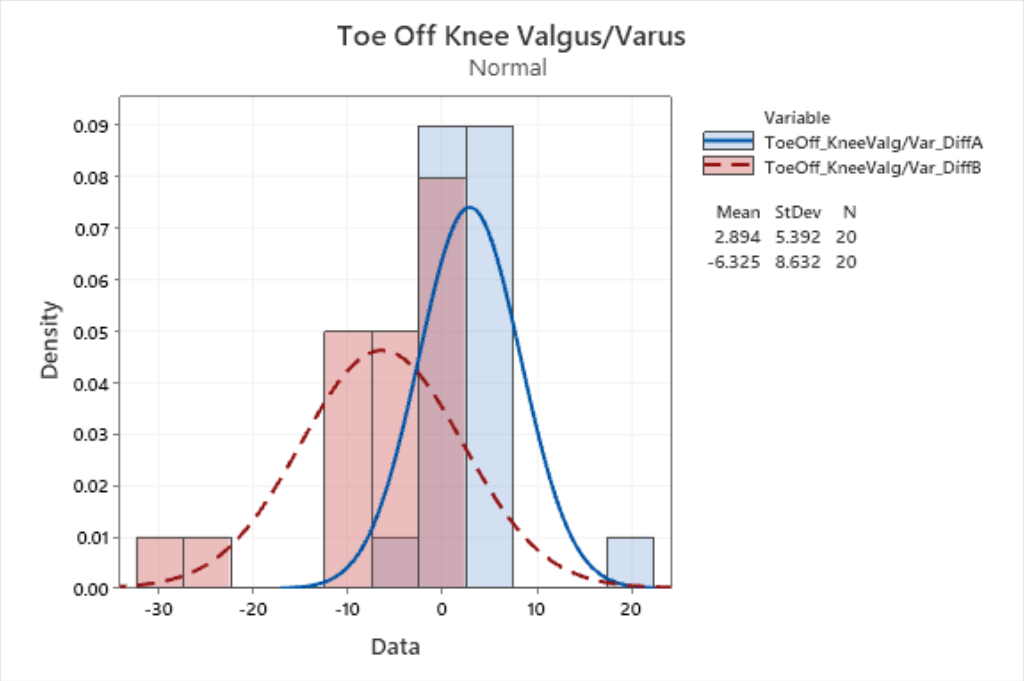


Figure 67 illustrates the Histogram Plot for Knee Valgus/Varus at Toe Off of Group A Difference vs Group B Difference

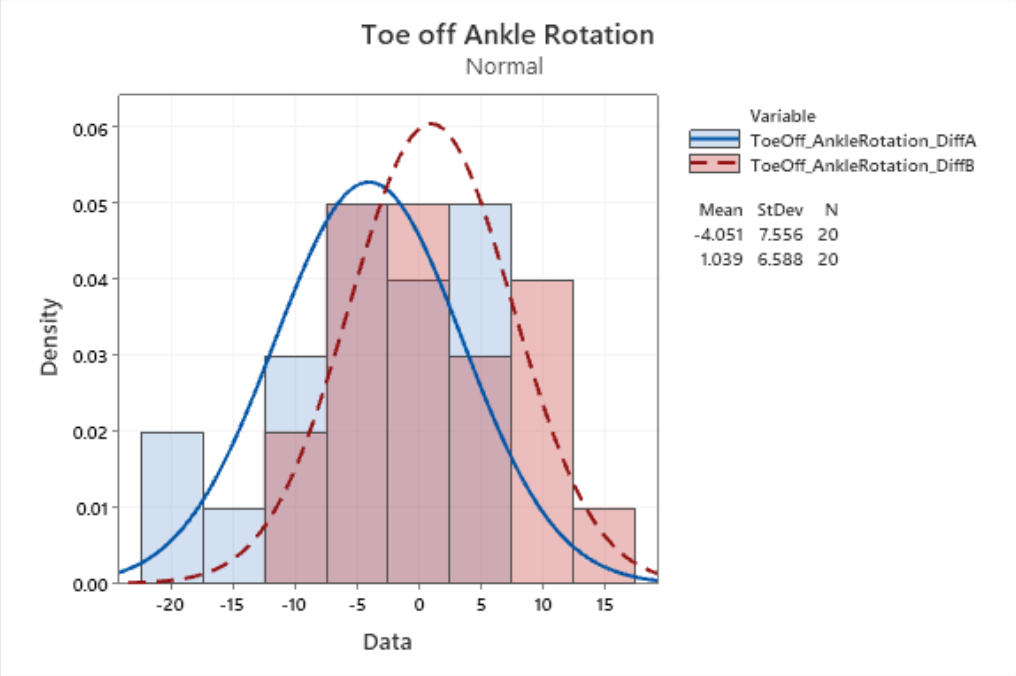


Figure 68 illustrates the Histogram Plot for Ankle Rotation at Toe Off of Group A Difference vs Group B Difference

Although the Knee Flexion/Extension and Hip Rotation angles during Toe Off did not statistically show significant difference before and after, since the p-value (0.057 and 0.078 respectively) is close to 0.05 when compared to the other angles, one can look at the Histogram Plot below for further analysis. Where one can note that the red line is shifted

towards right for the Knee Flexion/Extension. For Hip Rotation the red line is shifted towards the left, therefore meaning that there was decrease of Hip External Rotation in the Transverse Plane.

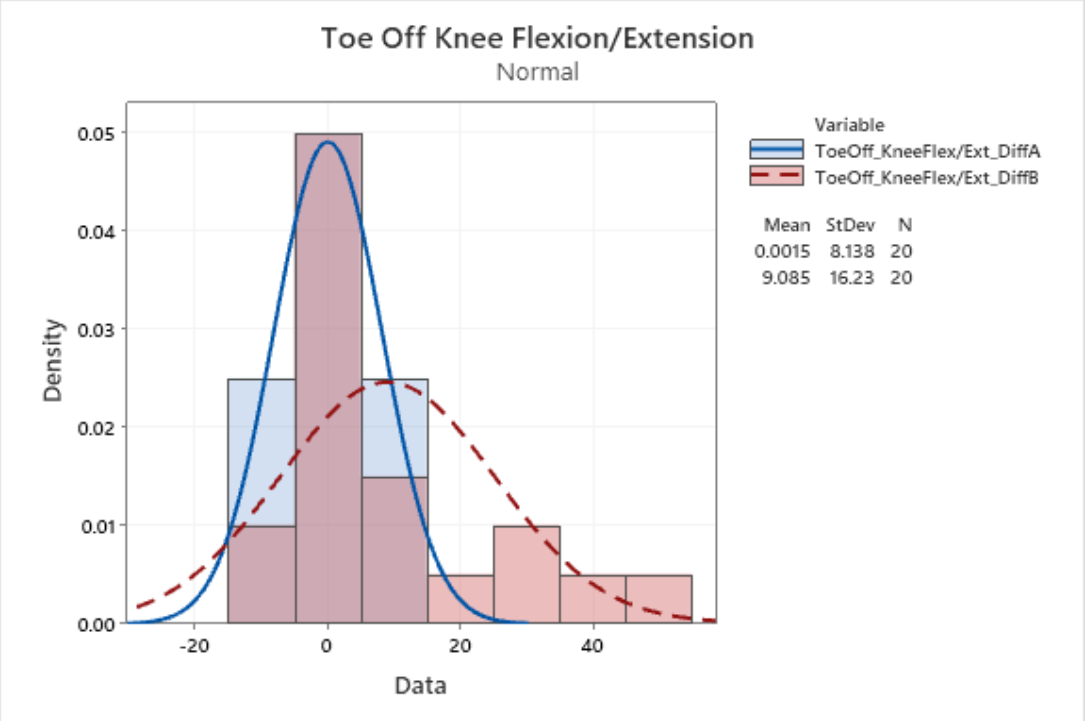


Figure 69 illustrates the Histogram Plot for Knee Flexion/Extension at Toe Off of Group A Difference vs Group B Difference

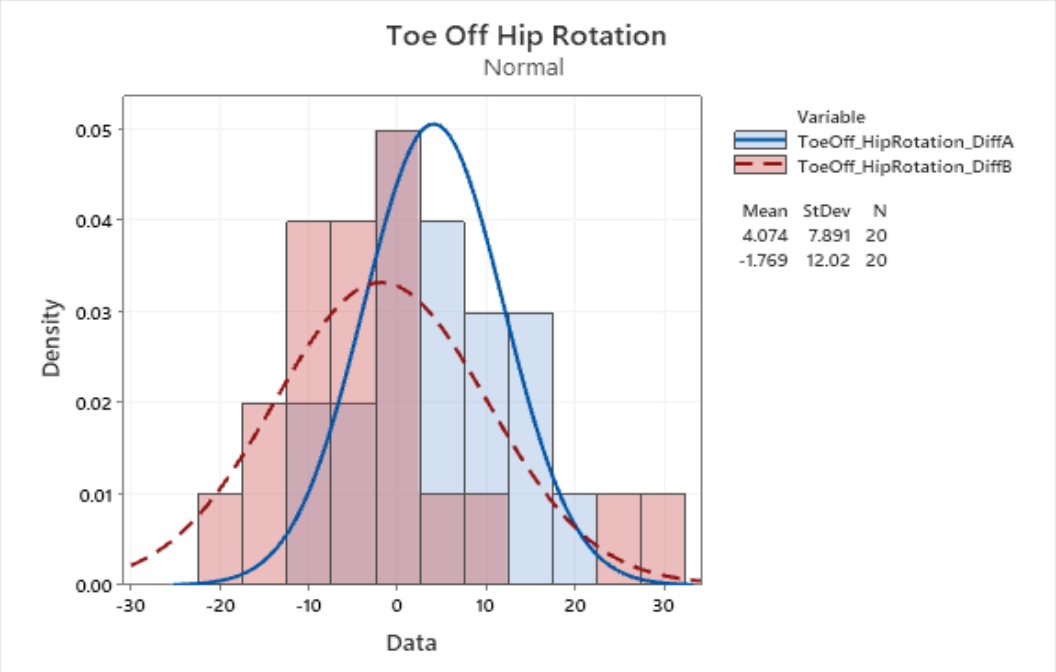


Figure 70 illustrates the Histogram Plot for Hip Rotation at Toe Off of Group A Difference vs Group B Difference

Refer to Appendix 25 for the rest of the Histogram plots of the Kinematic Angles at Toe Off.

4.2.3.3. Statistical Analysis of the Spatiotemporal Data Before without insoles and After with insoles Intervention in Group B.

The null hypothesis states that there is no significant difference between Spatiotemporal Results in Comparison Group A Subjects Before Intervention and After Intervention Difference and Spatiotemporal Results in Experiment Group B Subjects Before Intervention and After Intervention Difference. The alternative hypothesis states that there is a significant difference between Spatiotemporal Results in Comparison Group A Subjects Before Intervention and After Intervention Difference and Spatiotemporal Results in Experiment Group B Subjects Before Intervention and After Intervention Difference.

Table 36 Illustrates the Spatiotemporal Data Statistical Analysis for Group A and Group B difference

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Mann-Whitney test	0.02*	Yes	Rejected
Double Support	Mann-Whitney test	0.059	No	Accepted
Foot Off	Independent Sample t-test	0.595	No	Accepted
Limp Index	Mann-Whitney test	0.776	No	Accepted
Opposite Foot Contact	Mann-Whitney test	0.946	No	Accepted
Opposite Foot Off	Mann-Whitney test	0.317	No	Accepted
Single Support	Mann-Whitney test	0.052	No	Accepted
Step Length	Independent Sample t-test	0.495	No	Accepted
Step Time	Independent Sample t-test	0.049*	Yes	Rejected
Step Width	Independent Sample t-test	0.943	No	Accepted
Stride Length	Independent Sample t-test	0.212	No	Accepted

Stride time	Mann-Whitney test	0.014*	Yes	Rejected
Walking Speed	Mann-Whitney test	0.005*	Yes	Rejected

With a 95% level of confidence, the above table demonstrates that the p-value outcome is larger than 0.05 in most Spatiotemporal Data. That means that the null hypothesis is accepted, and that the alternative hypothesis is rejected, showing that there is not a significant difference between Group A Before Intervention and After Intervention Difference and Spatiotemporal Results in Group B Before Intervention and After Intervention Difference. This is except for Cadence with a p-value of 0.02; Step Time with a p-value of 0.049, Stride time with a p-value of 0.014 and Walking Speed with a p-value of 0.005 which in all cases the p-value is smaller than 0.05, therefore the Null Hypothesis is rejected, and the Alternative Hypothesis is accepted signifying that there is a statistically significant difference between Group A Before Intervention and After Intervention Difference and Spatiotemporal Results in Group B Before Intervention and After Intervention Difference.

As illustrated in Figures below, one can see that the dotted red line which represents Group B, showing graphically the Difference in Intervention in Group A and Group B.

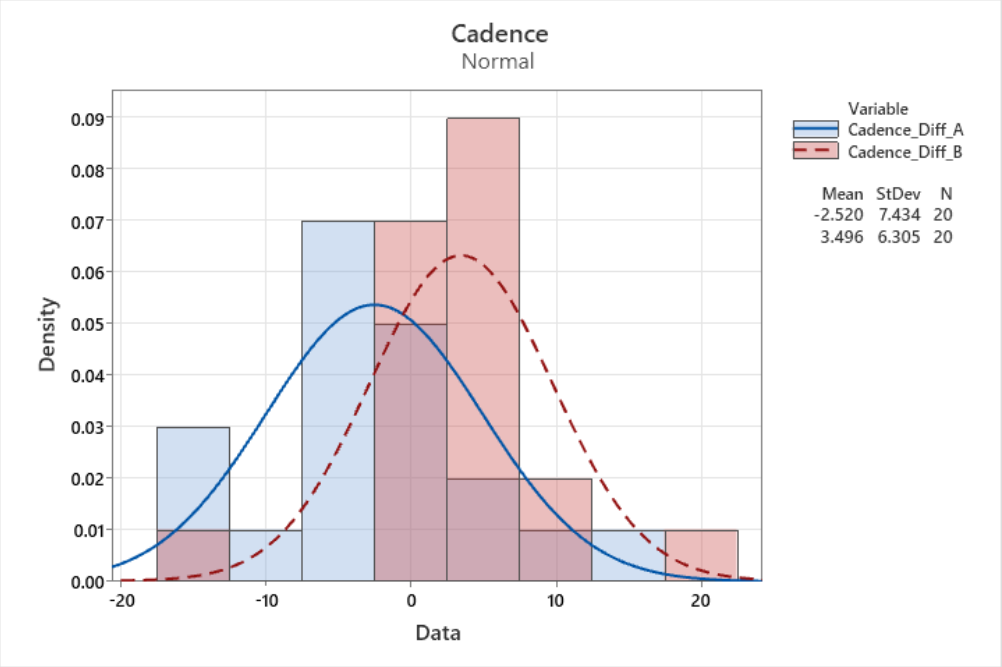


Figure 71 illustrates the Histogram Plot of Cadence of Group A Difference vs Group B Difference

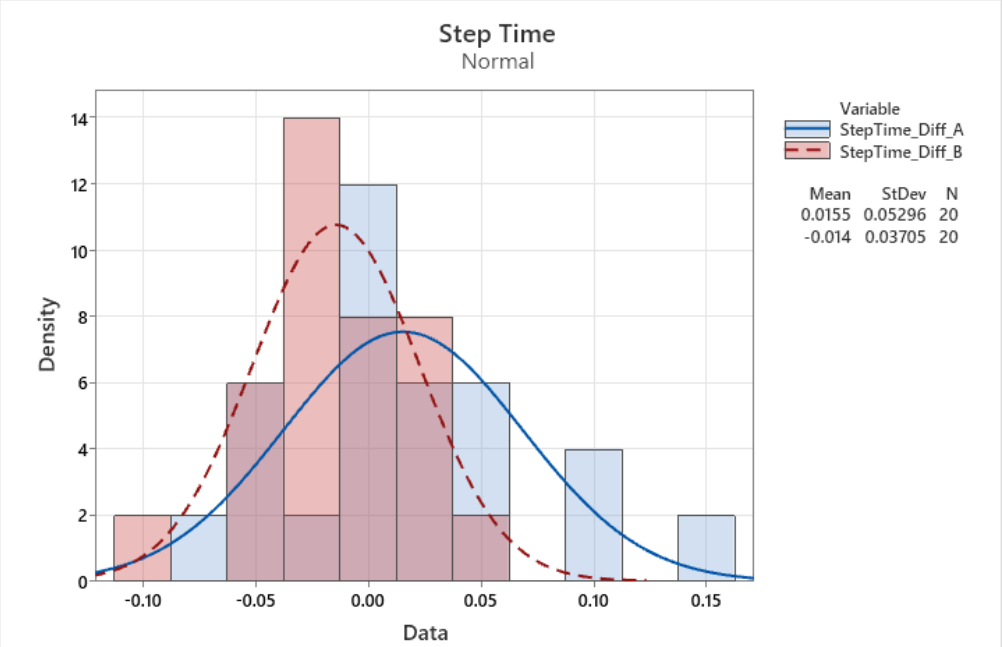


Figure 72 illustrates the Histogram Plot of Step Time of Group A Difference vs Group B Difference

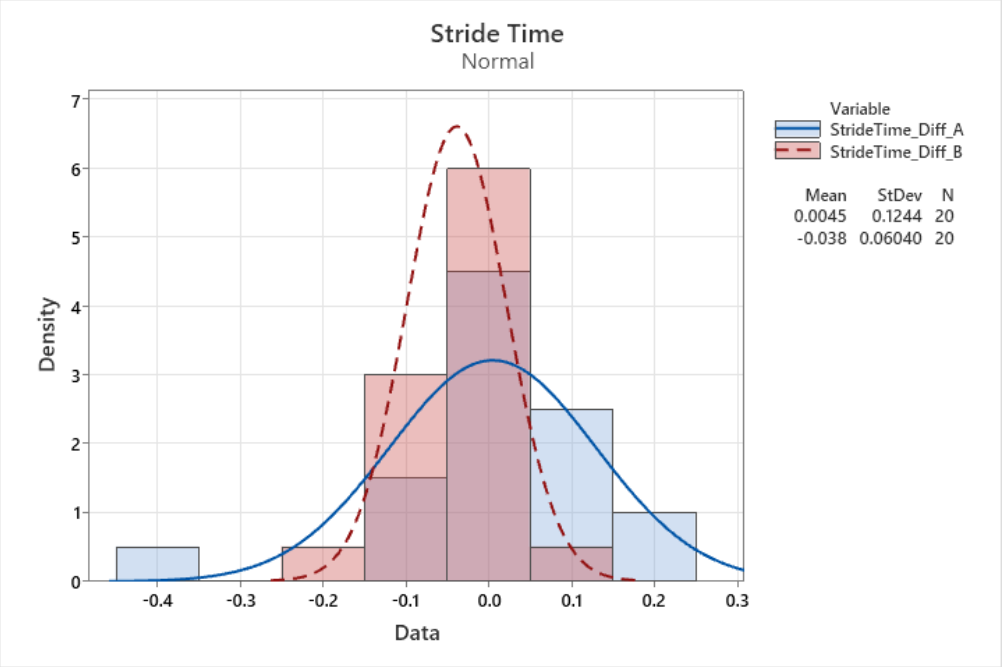


Figure 73 illustrates the Histogram Plot of Stride Time of Group A Difference vs Group B Difference

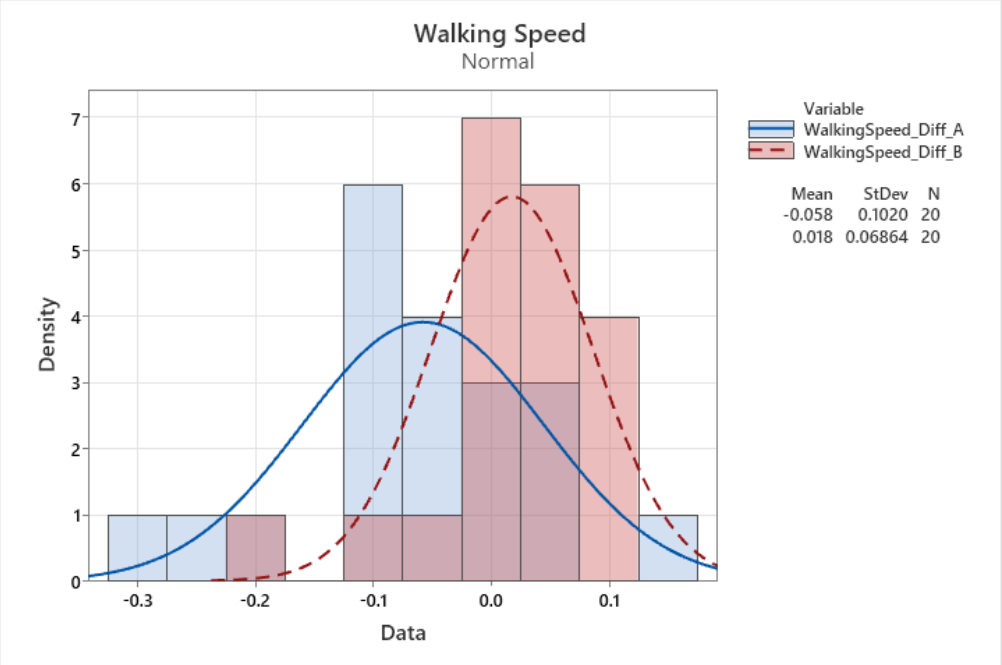


Figure 74 *illustrates the Histogram Plot of Walking Speed of Group A Difference vs Group B Difference*

Refer to Appendix 26 for the rest of the Histogram plots of the Spatiotemporal Data of Group A Before Intervention and After Intervention Difference and Spatiotemporal Results in Group B Before Intervention and After Intervention Difference.

4.3. Additional Statistical Analysis

Additional Statistical Analysis complementary to the above results can be found attached in the Appendices. A summary of such results include:

i. There is no statistically significant difference between Group A Before intervention and Group B before no insoles before intervention at Heel Strike, Midstance and Toe Off. Same for Spatiotemporal Data. This comparison shows that there was no statistically significant difference at baseline measurement before intervention between the two Groups. Refer to Appendices 31-34.

ii. There is no statistically significant difference between Group A After intervention and Group B After intervention with no insoles at Heel Strike, Midstance and Toe Off. Refer to Appendices 35-38.

iii. There is no statistically significant difference at Heel Strike between Group B Before no insoles and Group B before with insoles. At Midstance a significant difference was found in Pelvic Obliquity (p-value = 0.05), where it became more neutral and Ankle Rotation (p-value =0.023) where it became less externally rotated and more neutral, as seen in the Histogram Plots. Although the Pelvic Tilt p-value was that of 0.055, therefore Null Hypothesis Accepted since p-value >0.05, it was still very close to rejecting the Null Hypothesis, and the Histogram Plots showed that there was a decrease in anterior pelvic rotation when participants were assessed with custom-made foot orthoses. At Toe Off a statistically significant difference was found at Ankle Dorsiflexion/Plantarflexion with p-value of 0.002, where an increase in dorsiflexion was noted in the Histogram Plots. This comparison shows the immediate effect of custom-made foot orthoses prior

6-weeks intervention. There was no statistically significant difference in Spatiotemporal Data. Refer to Appendices 39-43.

iv. Statistical Analysis of Group B before with insoles vs after with insoles, resulted that a statistically significant difference at Heel Strike was found in Knee Valgus/Varus (p-value = 0.05), where there was a decrease in Valgus and Hip Rotation (p-value =0.025) where it became less externally rotated and more neutral, as seen in the Histogram Plots. Although the Pelvic Obliquity p-value was that of 0.055, therefore Null Hypothesis Accepted since p-value >0.05, it was still very close to rejecting the Null Hypothesis, and the Histogram Plots showed that the difference from the contralateral side of the pelvis became more neutral. At Midstance a statistically significant difference was found at Hip Flexion/Extension with p-value of 0.049, where a decrease in Hip flexion was noted in the Histogram Plots. At Toe Off a significant difference was found in Knee Valgus/Varus (p-value = 0.004), where there was a decrease in Valgus. Although the Pelvic Tilt p-value was that of 0.057, and Knee Flexion/Extension p-value of 0.052, therefore Null Hypothesis Accepted since p-value >0.05, they both were still very close to rejecting the Null Hypothesis, and the Histogram Plots showed that there was a decrease in Anterior Pelvic Tilt and a decrease in Knee Flexion. When comparing to normative values, it showed that Group B After intervention with insoles became closer to Normative Data than Group B with insoles before intervention. This comparison showed the difference between the immediate effect of custom-made foot orthoses, in relation to after 6-week physiotherapeutic and custom-made foot orthoses

intervention. There was no statistically significant difference in Spatiotemporal Data. Refer to Appendices 44-48.

v. There is no statistically significant difference at Heel Strike between Group B After no insoles and Group B After with insoles. At Midstance a significant difference was found in Pelvic Obliquity (p-value = 0.005), where it became more neutral, Ankle Dorsiflexion/Plantarflexion (p-value =0.001) where it became more dorsiflexed, and Knee Rotation (p-value = 0.048) where it became less internally rotated, as seen in the Histogram Plots. Although the Knee Valgus/Varus p-value was that of 0.058, therefore Null Hypothesis Accepted since p-value >0.05, it was still very close to rejecting the Null Hypothesis, and the Histogram Plots showed that there was a decrease in knee valgus in Group B after with insoles. At Toe Off a statistically significant difference was found at Knee Flexion/Extension with p-value of 0.041, where a decreased in Knee Flexion was noted in the Histogram Plots. This showed the difference in Kinematic changes between without and with insoles after 6-weeks of intervention. There was no statistically significant difference in Spatiotemporal Data. Refer to Appendices 49-53.

Chapter 5 Discussion

Excessive foot pronation has been linked to Low Back Pain since it may cause malalignment of the lower extremity. Castro-Mendez et al.(2021) further explained how it includes decreased range of ankle inversion, decreased knee flexion range, increased knee internal rotation, increased hip internal rotation and increase in pelvic tilt. Additionally, in pronation, the foot is dorsiflexed, everted, and abducted (Brockett & Chapman, 2016). In this research, it was noted that from the Foot Posture Index, all participants resulted in a positive FPI value, meaning that they all demonstrated an overpronated foot posture. So, discussions below will mainly be focused on overpronation biomechanics.

As previously discussed, the question whether custom-made foot orthoses and physiotherapy intervention are effective in the management of Non-Specific Mechanical Low Back pain has been questioned in literature separately (Custom-made foot orthoses and Low Back Pain literature: Castro-Mendez et al.(2021); Kim (2016); KwangYangPark (2017); Rosner et al.(2013); Menz et al.(2013); Betsch et al.(2011); and Physiotherapy and Low Back Pain literature: Lair et al.(2012); Schembri et al.(2014); Glatchel & Bloxham (2016); Limba da Fonseca et al.(2009)). No literature was found investigating both interventions combined and their effectiveness in management of Non-Specific Musculoskeletal Low Back Pain.

The purpose of this research was to investigate whether there would be significant effects on pain, disability, as well as on kinematic and spatiotemporal data when prescribing custom-made foot orthoses in combination with 6-week physiotherapy intervention in individuals living with Non-Specific Mechanical Low Back Pain. The effectiveness of the interventions was investigated based on these outcome measures: Visual Analog Scale for

measurement of pain; Oswestry Disability Index for measurement of disability; and Oxford Vicon 3d gait analysis for Kinematic and Spatiotemporal Data Measurements.

Following Statistical Analysis in Chapter 4, results showed that:

i. Both Group A, in which participants only received the 6 weeks physiotherapy intervention, and Group B, in which participants received both custom-made foot orthoses and 6 weeks physiotherapy intervention, showed a significant improvement on pain and disability after intervention. Results showed that Group B improved more than Group A although there was no statistically significant difference between Group A and Group B improvement.

ii. Results also showed significant kinematic differences in both Group A, and Group B after intervention; but significant kinematic changes in the pelvis were noted only in Group B. Both groups demonstrated changes in all three planes, i.e., Sagittal, Coronal and Transverse, mostly at Midstance and Toe off during the gait cycle.

iii. When Kinematic Data was compared with normative data, it was found that in Group A, most angles were statistically different from Normative data both Before and After intervention, except at Midstance, it was found that Hip Rotation was statistically significantly different from Normative data before intervention but became not statistically significantly different from Normative data after 6 weeks physiotherapeutic intervention. The same with Ankle Abduction/Adduction at Toe Off. In Group B at Midstance, it was found that Pelvic Obliquity, Knee Valgus/Varus and Knee Rotation were statistically significantly different from Normative data before intervention but became not statistically significantly different from Normative data after 6 weeks physiotherapeutic and custom-made foot orthoses intervention. The same was noted at Toe Off for Pelvic Obliquity.

iv. Spatiotemporal Data Analysis showed that in Group A, participants showed increase in stride length and walking speed post intervention, whereas in Group B, a statistically significant difference was in Cadence data, where there was a decrease in steps per minute, and increase in single support data and stride time data, after a combination of 6-weeks physiotherapeutic intervention and custom-made foot orthoses.

5.1. Review of Findings

The following sections critically discuss the results of this research and compare findings to current literature.

5.1.1. Visual Analog Scale and Oswestry Disability index.

Both Group A and Group B showed a significant improvement on pain and disability before and after intervention. Results showed that Group B improved more than Group A although there was no statistically significant difference between Group A and Group B improvement. The cause for the latter, could be that the sample size was too small, to yield a significant difference statistically.

These results are congruent to similar studies that investigated effectiveness of custom-made foot orthoses and physiotherapy management separately on pain and disability (Castro-Mendez et al.(2021); Ferrari (2013); Rosner et al.(2013) and Schembri et al.(2014)). It must be emphasized, however, that no studies were found in the literature that investigated the effectiveness of both interventions combined in the management of Non-Specific Mechanical Low Back Pain.

Castro-Mendez et al.(2021) showed that there was a significant improvement post 4 weeks intervention with orthoses but pointed out that pain was not eliminated completely by the end of the intervention period. This was also the case in this research, where post-6 weeks intervention, although both groups significantly improved, none of the participants scored 0 on both the Visual Analog Scale and Oswestry Disability Index.

Two other papers that showed congruent results on the Oswestry Disability index were by Ferrari (2013) and Rosner et al.(2013). Both papers concluded that reported disability improved post intervention, with the difference that Ferrari (2013) investigated the effectiveness of custom-made foot orthoses combined with physiotherapy management in participants with chronic low back pain post motor vehicle collision, and Rosner et al.(2013) investigated the combined effectiveness of chiropractic intervention with custom-made foot orthoses/sham orthoses in the management of Chronic Low Back Pain. The latter concluded that although chiropractic intervention combined with orthoses management resulted in significant difference in disability scores, the participants were not able to distinguish whether they were prescribed the sham or the custom-made foot orthoses, and therefore this raised the question on whether there was an element of a placebo effect.

Congruent results were also found regarding physiotherapy management only, in relation to Visual Analog Scale and Oswestry Disability Index. Schembri et al.(2014) looked into the effects of movement-based intervention specifically on core re-education in a local Maltese study. In this study, a comparison was made between core training vs traditional strengthening exercises vs education. In all three groups, the participants showed

significant improvement in pain and disability scores, but after 6 months follow up it was found that the group with the modified pilates sessions kept on progressing, whereas the other group participants experienced a regression. In the case of this dissertation, physiotherapists customised physiotherapy intervention for each participant based on multiple therapies including core stability, strengthening exercises, education, and pain relief.

5.1.2. Kinematic Data.

Results of this research demonstrated that significant kinematic differences were found in both Group A, and Group B. Despite this, it was noted that significant kinematic changes in the pelvis were noted only in Group B, but both groups demonstrated changes in all three planes, i.e., Sagittal, Coronal and Transverse, mostly at Midstance and Toe off during the gait cycle.

Significant differences in kinematic Data in Group A after 6 weeks physiotherapy intervention, where p-value was <0.05, were found at Midstance where there was a decrease in hip rotation, and ankle adduction, while at Toe Off there was also a decrease in hip rotation and ankle adduction, and a decrease in knee varus, where it became more neutral.

The resultant changes are possible corrective changes to what Castro-Mendez et al.(2021) listed as biomechanical changes caused by foot overpronation. In group A, a 6-week physiotherapeutic intervention mainly helped to decrease the increased internal hip

rotation caused by an overpronated foot. Since Brockett & Chapman (2016) pointed out that pronation is characterised by abduction of the foot, it would be assumed that correction would also involve a decrease in abduction, but results of this research for Group A showed a decrease in Varus, and more towards a neutral position. A possible explanation for this is since, clinically, patients with overpronation, who do not have orthoses or other foot corrections, will tend to attempt to correct their overpronating posture by adducting the foot and go more into supination to try and neutralise the ankle joint. The latter would explain why kinematic change in adduction was reported by the VICON 3d gait lab system, instead of ankle abduction as expected with an overpronated foot. No literature was found in relation to kinematic changes following a combined 6-week physiotherapeutic intervention and custom-made foot orthoses in relation to non-specific mechanical Low Back Pain, or any other condition using a 3d gait lab system, such as the Oxford VICON system. Therefore, data obtained in this research could not be related to current literature.

A small exception to the latter is a 2021 paper by Krekoukias et.al., which investigated the kinetic, kinematic and gait symmetry during gait analysis using an optoelectronic system in 75 participants with chronic low back pain because of degenerated disc disease, post three types of physiotherapeutic intervention. The interventions being compared were manual therapy, sham treatment and classic physiotherapy (which included stretching exercises, TENS, and massage). This paper discussed how before intervention, it was noted that there is an increased rotation of the pelvis and decrease in gait symmetry during walking. According to the researcher, these altered gait characteristics, with special focus on pelvic kinematics, may have been due to changes in proprioception of the lumbar region, in the differentiation of motor control, in increased muscular activity of the

paraspinal muscles and the pain/posture avoidance. Following the 5-week intervention period, only the group that received manual therapy showed a tendency towards gait symmetry in pelvic rotation, but no further change in gait characteristics were noted, apart from pain and disability reduction. Despite this it is important to note that this paper did not consider changes in the more distal joints.

Significant difference in kinematic Data in Group B before and After 6 weeks physiotherapy intervention and prescription of custom-made foot orthoses where p-value was <0.05 was found that at Midstance there was a decrease in Pelvic tilt, meaning there was a decrease in anterior tilt of the pelvis, and an increase in dorsiflexion at the ankles. At Toe Off there was decreased knee flexion and knee valgus.

Despite this, only a small amount of literature was found that investigated the effect of kinematic data by custom-made foot orthoses only. One such paper was by Kwang Yang Park (2017) which showed that there was a significant decrease of the pelvic angle at midstance and midswing of the gait cycle when 15 college students diagnosed with flat feet wore orthoses, in comparison to when not wearing orthoses. This correlates with the findings of this research, which also found a decrease in pelvic tilt at midstance when wearing custom-made foot orthoses. Kwang Yang Park (2017) also found that the pelvic angle also decreased after wearing an orthotic, although the difference was not significant. This differentiated from this research, since left and right were not compared since there was no statistically significant difference in the baseline value of the Foot Posture Index.

Another paper that showed similar results was by Kim et al.(2016) which collected kinematic data from participants with malalignment syndrome. The difference between Kim et al.(2016), and Kwang Yang Park (2017) and this dissertation was that kinematic data was only collected at peak value, instead of the various stages of the gait cycle.

Nonetheless data showed that the peak pelvic tilt and obliquity angles were significantly greater when wearing orthoses, when compared to barefoot. Although in this research, there was no statistically significant difference in Pelvic Obliquity at Heel Strike, Midstance or Toe Off, it was noted that Pelvic Obliquity at Heel Strike with a p-value of 0.083, was closer to p-value 0.05 than the other kinematic angles at Heel Strike. Kim et al.(2016) also found a difference in increased knee adduction, which correlates with this research result which showed a decrease in knee abduction (therefore increase in knee adduction) during toe off. Kim et al.(2016) also found significant differences in hip flexion/extension, knee flexion/extension and rotational angles when wearing orthoses, although there was no definition of the direction of the change, therefore cannot be compared with this dissertation data.

The above changes were further backed up by statistically evaluating the before and after intervention difference between Group A and Group B. Significant difference in kinematic Data where p-value was <0.05 was found that at Midstance where there was a more dorsiflexion, less pelvic obliquity, and more internal rotation in Group B, when compared with Group A. While at Toe Off there was less Knee Valgus, and less internal rotation in Group B, when compared with Group A. No significant different changes were noted at Heel Strike.

5.1.2.1. Comparing Kinematic Data with Normative Data.

Further statistical analysis of the Kinematic data obtained in this research was carried out by comparing the data obtained with Normative data (which properties and source were explained in Chapter 3). Participants in the Normative Data Set did not have altered foot biomechanics, and no complaints of non-specific mechanical Low Back Pain. Therefore, it stands to reason that data collected from participants with altered foot biomechanics and complaining of low back pain, would be statistically significantly different, before any intervention, from the Normative data; and that data should not be statistically significantly different from Normative Data after intervention. This yielded further input on the effectiveness of either interventions on normalising the kinematic angles during gait.

In Group A, at Heel Strike, most angles were statistically different from Normative data both Before and After intervention, except for Knee Rotation since both Before and After intervention data were not statistically different from normative data. This could signify that Knee Rotation changes at Heel Strike, is not a characteristic in individuals complaining of Non-Specific Mechanical Low Back Pain. At Midstance, it was found that Hip Rotation was statistically significantly different from Normative data before intervention but became not statistically significantly different from Normative data after 6 weeks physiotherapeutic intervention. The same with Ankle Abduction/Adduction at Toe Off.

Like in Group A, in Group B at Heel Strike, most angles were statistically different from Normative data both Before and After intervention, except for Knee Rotation since both

Before and After intervention data were not statistically different from normative data. This further indicates that Knee Rotation changes at Heel Strike, may not be a characteristic in individuals complaining of Non-Specific Mechanical Low Back Pain. Similarly to Group A, at Heel Strike it could also be noted that although Hip Rotation before and after intervention showed data which was statistically significantly different from Normative data, the p-value changed from 0.002 to 0.046, which shows that after intervention the p-value of Hip rotation became closer to 0.05, therefore closer to Normative Data. This could indicate that although Hip rotation was not found to be statistically significantly different at Heel Strike before and after intervention in Group B, it still had an improvement and became closer to Normative Data after Intervention, where it became less externally rotated, whereas in Group A a decrease in internal rotation was noted. A similar pattern was seen with Knee Rotation, indicating a decrease in internal rotation, and closer to Normative data after intervention, although still not statistically significantly different from Normative Data both before and after 6 weeks physiotherapeutic intervention and custom-made foot orthoses.

Group B at Midstance, it was found that Pelvic Obliquity, Knee Valgus/Varus and Knee Rotation were statistically significantly different from Normative data before intervention but became not statistically significantly different from Normative data after 6 weeks physiotherapeutic and custom-made foot orthoses intervention. The same was noted at Toe Off for Pelvic Obliquity. At Toe Off although Knee Rotation was not statistically significantly different from the Normative Data both before and after intervention, it can be noted that the p-value after intervention became larger, therefore indicating that the Knee rotation data of Group B at Toe Off became more like the Normative data after intervention than before intervention.

The interpretation of the above data could signify that since in both Visual Analog Scale and Oswestry Disability Index in both Group A and Group B showed a significant improvement from before to after intervention, it indicates that 6-weeks physiotherapeutic intervention affected Hip rotation, and Ankle Abduction/Adduction; and with combination of 6-weeks physiotherapeutic intervention and custom-made foot orthoses it affected Pelvic Obliquity, knee valgus/varus and knee rotation, where the data became not statistically significantly different from Normative Data. These results could also be highly indicative that altered Hip Rotation, Ankle Abduction/Adduction, Knee Rotation, Pelvic Obliquity and Knee Valgus/Varus are contributing characteristics to Non-Specific Mechanical Low Back Pain.

On another note, Pelvic Rotation before and after intervention both in Group A and Group B were compared to the Normative Data, where in both instances they were not statistically significantly different from Normative Data, indicating that possibly Pelvic Rotation is not a characteristic change during gait in individuals with Non-Specific Mechanical Low Back Pain. This is opposed to what Krekoukias et al. (2021) found in their research paper, that Pelvic Rotation was altered before intervention during gait, and improved post physiotherapeutic intervention.

The above results showed that Experiment Group B, which received both Physiotherapy Management and Custom-made foot orthoses, became more like the normative data than Comparison Group A, which received Physiotherapy Management only. This implied that prescribing Physiotherapy Management in combination with Custom-made foot Orthoses was more effective in normalising gait in individuals suffering from Non-Specific

Mechanical Low Back Pain. The significance of this is that since the individuals in the Normative Data sample did not have any reports of Low Back Pain, the fact that data of this study, especially that of Group B, became less statistically significantly different than the Normative Data, meant that the normalisation of gait possibly resulted in decreasing Low Back Pain.

5.1.5. Spatiotemporal Data.

Results of this research demonstrated that significant Spatiotemporal data differences were found in both Group A, and Group B after 6-weeks Intervention.

In Group A, a statistically significant difference was found in the Stride Length and Walking Speed Spatiotemporal data, where it was found that participants' stride length and walking speed increased post 6-weeks physiotherapeutic intervention. Although no current literature was found investigating changes in Spatiotemporal Data before and after physiotherapeutic intervention in individuals with Non-Specific Mechanical Low Back Pain, Ellen (2007) found that individuals with low back pain walk at a slower pace than healthy individuals. This is backed up by Fonseca et al.(2009) who investigated force distribution during gait at different speeds post-Pilates intervention in individuals with low back problems. The latter found that post-Pilates intervention there was more equal weight distribution at faster walking speed. This correlates with the Spatiotemporal findings of Group A in this study, where there was an increase in walking speed after 6-weeks physiotherapeutic intervention.

In Group B, a statistically significant difference was in Cadence data, where there was a decrease in steps per minute after a combination of 6-weeks physiotherapeutic intervention and custom-made foot orthoses. A statistically significant difference post- intervention when compared to data collected before intervention, was also found in Single Support Data and Stride Time data, where in both cases an increase was noted after intervention.

No literature was found on the effect of custom-made insoles in combination with physiotherapeutic intervention on spatiotemporal data in individuals suffering with Non-Specific Mechanical Low Back Pain. Therefore, these findings were compared with results found by Kim (2017), who found that there was an increase in stride length, step length and walking speed, when participants with malalignment syndrome wore biomechanical foot orthoses. He also found that there were no other gait parameters which were statistically different between wearing orthoses, and not wearing them. Change in Spatiotemporal data was also investigated by Seo and Park (2014), whose paper investigated the effects of foot orthoses on spatiotemporal data changes of healthy college students in their 20s with flat feet. Results of the latter showed that the step and stride times of both feet significantly decreased when with foot orthoses, and their stride length and gait velocity significantly increased, which contradict results obtained from this dissertation. A possible reason why data between Seo and Park (2014) results, and this study results differ could be since post intervention in Group B a decrease in knee flexion was noted.

This was further investigated by Allet et.la. (2011), to understand the influence of stride frequency and stride length on joint moments and plantar pressures in 20 healthy young adults, who were instructed to walk at a specific walking speed, with variable stride

lengths. They found that with decreasing stride length, there is a decrease in knee extension. Therefore, since stride length affects the stride time, an increase in stride length would increase the stride time. This would indicate in relation to Group B Spatiotemporal and Kinematic results, that with an increase in Knee Extension/ decrease in Knee flexion, there was an associated increase in Stride time (due to an increase in stride length, although in this study it did not yield statistically significant difference after intervention in Group B).

5.2. Clinical Relevance of Findings

The significant improvement in pain and disability post-intervention in both Group A and Group B, showed that both 6-weeks of individualised physiotherapeutic intervention only, and 6-weeks of individualised physiotherapeutic intervention combined with custom-made foot orthoses were effective in improving pain and disability outcomes. Although there was not a statistically significant difference in the pain and disability outcome between Group A and Group B, Group B still had a larger improvement when compared to Group A.

These results were further correlated with significant kinematic and spatiotemporal changes found in both Group A and Group B. It was noted that Group B kinematic data got more approximated to Normative data, which consisted of a group of individuals which were healthy, without altered foot biomechanics, and not diagnosed with Non-Specific Mechanical Low Back Pain. This signifies that the participants in Group B post-intervention, with 6-week individualised physiotherapeutic intervention in combination with custom-made foot orthoses, demonstrated a normalised gait pattern. Therefore, this

can imply that such intervention results in normalisation of gait, which can be also beneficial in the management of other biomechanical conditions which are affected by altered foot posture.

From the FPI data, Group A had a mean of 7.40 (sd +/-1.84) and Group B had a mean of 8.60 (sd +/-1.78) indicating that all participants had overpronated feet. Furthermore, from the FPI data comparison between Group A and Group B, as well as, from the additional statistical analysis discussed in Section 4.3, it was concluded that there was no significant difference in foot posture and kinematic angles between all the participants in both groups before any intervention was given. Therefore, the baseline for both groups was the same, further emphasising the difference in data post-intervention, which was due to the effectiveness of the different interventions, as well as further emphasising that overpronation has a possible link with Non-Specific Mechanical Low Back Pain.

Furthermore, such results can be indicative on what structures both types of interventions affected, which in turn affected pain and disability in the individuals with Non-Specific Mechanical Low Back pain. Therefore, such findings can serve as an added guideline when formulating the intervention for such patients.

Another significant implication is that such findings further promote the importance of including a multidisciplinary approach in patient's care of Non-Specific Mechanical Low Back Pain within a clinical care setting, where professionals learn to identify more when it is required to refer to other professionals from a more holistic patient care. Leeftink et.al. (2020) explained how a multidisciplinary plan in health care is one of the emerging

research fields that is applicable to many healthcare settings with similar underlying characteristics. In their review, Leeftink et.al. (2020) give the example that during rehabilitation care, a patient requires appointments with multiples therapists from different disciplines, such as a physiotherapist, psychologist, and dietician. Such multidisciplinary approach is determined as an essential holistic view for optimising the care chain from a patient and provider perspective. Therefore, it can be extrapolated that the outcome results of this dissertation, further contributed to enforce the importance of a more multidisciplinary approach, involving both physiotherapy and custom-made foot orthoses management by other therapists such a podiatrist, when caring for patients diagnosed with Non-Specific Mechanical Low Back Pain, for a more patient-centred and holistic care. This involves that therapists dealing with such patients, can identify altered foot posture in relation to the back problem, and effectively communicate and refer when necessary for the prescription of cutom-made foot orthoses.

5.3. Recommendations for Practice and Future Research

This study uniquely identified the effects of combined custom-made foot orthoses with physiotherapeutic intervention in individuals with Non-Specific Mechanical Low Back Pain, by investigating the effect on pain by means of the Visual Analog Scale, disability by means of the Oswestry Disability Index, as well as Kinematic and Spatiotemporal Data using a 3d gait analysis of the Oxford Vicon System.

Taking into consideration the limitations of the study, discussed below, repeating this study with large-scale studies with long-term follow-up are recommended, and combined studies of EMG of lumbosacral and lower limb muscles are needed to confirm the effect of

custom-made foot orthoses and physiotherapeutic intervention on the correction of Kinematic and Spatiotemporal Data. Furthermore, Kinetic data evaluation would provide further insight on force direction and distribution during gait.

Another recommendation is to further investigate the effectiveness of prescribing custom-made foot orthoses in the management of other biomechanical conditions resulting in pain, and disability.

Furthermore, future studies can include further investigating the need of educating therapists involved in the management of Non-Specific Mechanical Low Back Pain patients regarding the identification of altered foot posture and its involvement in the aetiology of low back pain, followed by the appropriate referral to professionals, such as podiatrists, for further in detail assessment of the altered foot biomechanics, and foot orthoses prescription. Another suggestion for future research is the evaluation of the perception of professionals, with special focus on physiotherapists, on the use of foot orthoses as part of the management of Low Back Pain. These two suggestions will further help in the recommendation of updating present guidelines with regards to the management and referral pathways of Non-Specific Mechanical Low Back Pain.

5.4. Limitations

Puhan et al. (2012) explained how unbiased discussion of research limitations represents an important part of scientific evaluation and progress. The identified limitations should include the description of the potential limitation, explanations of the implication of such limitations, as well as provide alternative approaches, while also including what steps were

taken to mitigate the limitation. “A study’s limitations should place research findings within their proper context to ensure readers are fully able to discern the credibility of the study's conclusion and can generalize findings appropriately.” (Ross & Bibler Zaidi,2019)

The limitations of this study are outlined at the different stages of the research process (Ross & Bibler Zaidi, 2019):

i. Study Design: This part of the study involves decisions which are made by the researcher, including the research design, philosophical paradigms and the research method. The latter includes the chosen sampling method, which is one of the limitations which can be pointed out in this dissertation. These limitations can be classified into conscious decisions which have been taken by the researcher, like for example the choosing of convenient sampling over the golden standard of a randomised control trial, and the unconscious limitations that were unpredictable, like for example the occurrence of the Covid-19 pandemic right in the middle of the data collection period. Refer to section 3.3. for further explanation on the limitations encountered during sampling, and the steps taken to mitigate the limitations.

Limitations in a study design also include the inclusion and exclusion criteria, which further influence the sampling method. The inclusion and exclusion criteria of this dissertation are listed in section 3.3.3.1. These are also known as delimitations, and usually are part of the conscious deciding process of when the researcher is constructing a research design. These may represent a systematic bias intentionally introduced into the study design or instrument by the researcher.

ii. Data collection: study limitations can also be introduced during data collection, and these can be classified as follows:

a. Self- selection bias: Following the process of creating the study design, this dissertation encountered the limitation that data used was collected only from participants who decided to enrol in the study. Ethical participants recruitment means that the eligible individuals have the freedom of choice to decide whether to be involved in the data collection. This influenced the final generalisation of data, since the participants that accepted to participate in the study via the intermediary do not necessarily represent the general population. This limitation was difficult to mitigate due to the freedom of choice of the individual, and there were plenty of factors that may influence an individual to participate in the study or not. To try and increase the chances of an eligible individual to give consent to be part of the study, was by giving informative letters, and explanations in regards what the study entails by the intermediaries, and by reducing as much as possible the number of sessions that a participant was needed to attend for data collection.

b. Social-Desirability Bias: This is when there is the possibility that participants give biased input by responding to questions they think are what the researcher is looking for rather than their authentic response. This was kept in mind during data analysis of the Oswestry Disability Index questionnaire. In order to mitigate such a limitation, the participant was reassured that there was no correct answer, and to feel comfortable to answer what best describes their pain. Nonetheless such self-reported data could have still led to a certain degree of inaccuracy due to the social desirability bias.

Another limitation in relation to this, is the subjectivity of the Visual Analog scale and the Oswestry Disability index since they are both self-reported tests. Apart from the social-disability bias, the pain perception of the individuals needed to be considered. That is

because pain perception influences pain threshold/tolerance and how each participant interprets their own pain intensity and resulting disability. This resulted in the self-reported information with the two tests not proportional to their description and reproduction of pain during the initial assessment.

Hawthorne effect: which is also called the Observer Effect, is caused when the participants in a study change their behaviour since they know that they are being watched. (Glen, 2021) This was noted to be the case during Gait Lab data collection, where the participants were required to walk along a 10m walkway in front of the research. Despite being instructed to walk at their chosen comfortable pace and style of walk, it was noted that participants still walked differently than their usual walk. It was noted that there was a little bit of social desirability bias, since they attempted to walk in what they believed was the correct way to walk. In order to mitigate such a limitation, the participant was advised to walk while not observed by the research along the walkway, and when data collection started more walks than required were captured in order to give time for the participant to feel more at ease, and their gait more normalised to their usual.

Horns or Halo effect: Sedgwick & Greenwood (2015) point out that the researcher may bias the data collected by allowing a first impression of the participant to be influenced by a single characteristic or impression of another characteristic either unfavourably (horns effect) or favourable (halo effect). In this dissertation, such a limitation was mitigated since data collected were either self-reported, or via the Vicon gait lab which is an objective measure which the researcher cannot influence.

iii. Data Analysis: it is when a study limitation may arise because of the type of statistical analysis carried out. This is like in the case of when using convenience sampling, some studies may not follow the basic principles of inferential statistical analyses when compared to a randomised trial. It is in fact a limitation of this dissertation that a convenient sampling method was used, and further explanation on this and how this limitation was mitigated can be found in section 3.3.3.

iv.Study results: is when the limitations of any research study are related to validity of the study results, which specifically pose threats to internal or external validity of the research outcome. Internal validity refers to reliability or accuracy of the study results, while external validity relates to the generalizability of results from the study's sample to the larger,target population.

(Ross & Bibler Zaidi,2019)

This dissertation limitation that threatened internal validity included effects of events external to the study, like the COVID-19 pandemic, which resulted in decreased recruitment of participants due to reasons explained in section 3.3. This further led to threats to external validity of this dissertation. That is because of a smaller sample size, and limited sampling population (due to COVID-19) where it made it more difficult to generalise the results from the study to its larger population. To mitigate such an unpredictable limitation, the data collection period was made longer to attempt to collect a bigger sample size.

Chapter 6 Conclusion

The aim of this study was to investigate whether there would be significant effect on pain, disability, as well as on Kinematic and Spatiotemporal data when prescribing custom-made foot orthoses in combination with 6-week physiotherapy intervention in individuals diagnosed with Non-Specific Mechanical Low Back Pain.

No current literature was found that investigated the above aim, but most current literature has reported positive outcomes when only prescribing custom-made foot orthoses with changes in pelvis kinematics, spatiotemporal data with faster walking speeds, decreased stride time and stride length; and improvement in pain and disability (Castro-Mendez et al.(2021); Kim (2016); KwangYangPark (2017); Rosner et al.(2013); Menz et al.(2013); Betsch et al.(2011))

Similar positive outcomes on pain and disability was found in current literature that investigated only outcomes following physiotherapeutic interventions Lair et al (2012); Schembri et al.(2014); Glatchel & Bloxham (2016)), with only one paper that looked into the gait kinematic changes post-physiotherapeutic intervention for chronic low back pain. The latter resulted in manual therapy that influences pelvic rotation. (Krekoukias et al.2021) One paper was found that investigated the force distribution during gait post-Pilates intervention, which resulted in more equal weight distribution and faster walking speed. (Limba da Fonseca et al.2009) Unfortunately, no current literature found looked into kinematic changes more distally than the pelvis, and more detailed spatiotemporal data, and gait characteristics change in Non-Specific Mechanical Low Back Pain, post physiotherapy intervention.

This study demonstrated significant differences and improvement in pain, and disability after both physiotherapy intervention, and after physiotherapy intervention combined with custom-made foot orthoses, as well as significant change in kinematic and spatiotemporal data with both types of intervention.

The novelty of this study was the investigation of the effect of combined intervention of physiotherapy with custom-made foot orthoses, on pain and disability outcomes, which were then related with kinematic and spatiotemporal data, as well as comparison was made with kinematic normative data.

A key finding in this study is the kinematic angles which were corrected following both interventions, and how in Group B (after 6-weeks physiotherapeutic intervention combined with custom-made foot orthoses) became more similar to the Normative Data, when compared to Group A. Also, Group B kinematics provided more corrective kinematics related to kinematic changes resultant of altered foot biomechanics, specifically overpronation, when compared with Group A, with higher effect on the pelvic angles, which were not affected after physiotherapy intervention only in Group A.

The findings in the present study indicate that, as regards pain and disability, both 6-week physiotherapy intervention only, and 6-week physiotherapy intervention combined with custom-made foot orthoses are effective in the management of Non-Specific Mechanical Low Back Pain. However, the orthoses group exhibited a trend towards more normalization of the gait pattern which, in the long term, could translate into an added benefit for the patient. This, however, will need to be investigated further. Both types of

interventions should be considered in the management of Low Back Pain patients who also present with altered foot biomechanics.

The clinical implication of such findings includes the need of a more effective multidisciplinary approach to Non-Specific Mechanical Low Back Pain, where therapists include altered foot posture assessment in relation to the Low Back Pain, by means of observation and the use of tools such at the FPI-6 assessment tool. Such assessment would be followed up by proper communication and referral system to the professional specialised in the examination of foot posture and prescription of foot orthosis, such as podiatrists. As seen in the results of this study, such combination therapy, yielded better results in Low back Pain outcomes, as well as more normalisation of gait.

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Appendices

Appendix 1: Email from FREC approving study

Dear Deborah
Thank you for sending the amendments. I confirm that your application is now approved and you may proceed with data collection.

Please remember to liaise with Ms Christabel Vella as you need to send her the following documents:

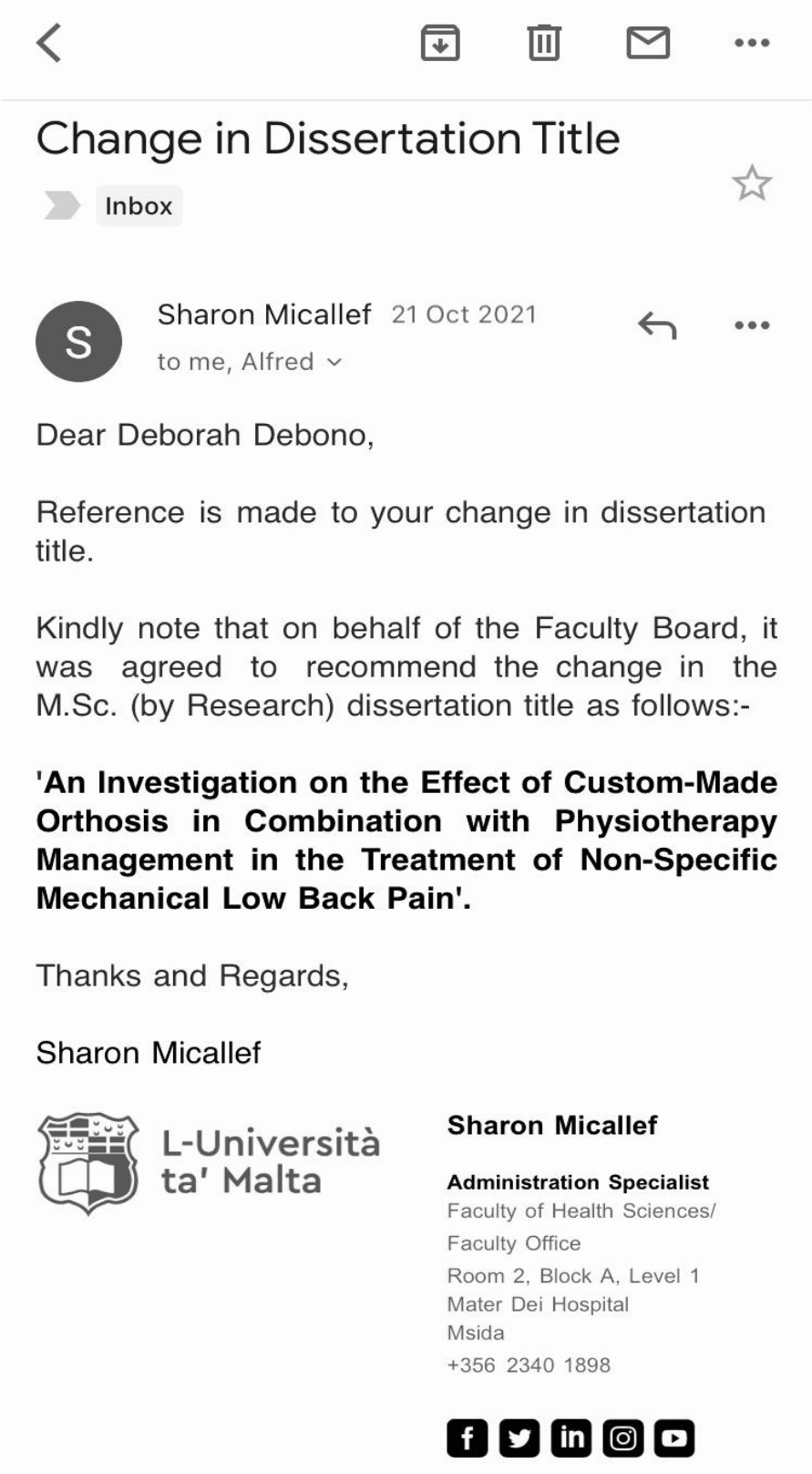
1. A soft copy of these documents **merged in ONE pdf document**:
   a) the revised pages only made in Word using track changes.
   b) the endorsement email from your supervisor.
   c) the endorsement email from Dr Ritienne Grima.

2. An updated soft copy of the appendices in a zipped file **(without track changes)**.

Best wishes
Ritienne Grima

Ritienne Grima Ph.D
Senior lecturer
Head, Department of Communication Therapy
Chairperson, Faculty Research Ethics Committee
Faculty of Health Sciences
University of Malta
Tel.: (+356) 2340 1142

Appendix 2: Approval for Change in Title of Dissertation



Change in Dissertation Title

Inbox

Sharon Micallef 21 Oct 2021

to me, Alfred

Dear Deborah Debono,

Reference is made to your change in dissertation title.

Kindly note that on behalf of the Faculty Board, it was agreed to recommend the change in the M.Sc. (by Research) dissertation title as follows:-

'An Investigation on the Effect of Custom-Made Orthosis in Combination with Physiotherapy Management in the Treatment of Non-Specific Mechanical Low Back Pain'.

Thanks and Regards,

Sharon Micallef

L-Università ta' Malta

Sharon Micallef

Administration Specialist
Faculty of Health Sciences/
Faculty Office
Room 2, Block A, Level 1
Mater Dei Hospital
Msida
+356 2340 1898

Appendix 3: Permission Forms and Intermediary Forms

Consent to conduct research

Dear Mr.Borg ,

My name is Deborah Debono. I am a postgraduate student reading for a Master's degree at the University of Malta, and a physiotherapist by profession. I am writing to request permission to include patients referred with Mechanical Low Back Pain to Musculoskeletal Physiotherapy Outpatients by yourself in a research study I am conducting, within the time frame of September 2019 - June 2021. This study is being conducted as part of my postgraduate dissertation.

The aim of the study is to investigate whether there are added benefits of prescribing insoles combined with physiotherapy intervention, in patients suffering from non-specific low back pain who also require foot orthoses because of pronated or supinated feet. The study will consist of two groups. Both groups will undergo the standard physiotherapy treatment at Musculoskeletal Outpatients St. Luke's, but only one group would be prescribed custom made orthoses. Participants from each group would be randomly selected. Any research outcome would be documented, and a discussion will be done on the outcome of prescribing custom-made insoles when combined with physiotherapy intervention, in patients suffering from low back pain.

Patients referred with low back pain to the Musculoskeletal outpatients are going to be assessed by a physiotherapist. Those patients who fit into the inclusion and exclusion criteria will be recruited once an informed consent is obtained from each participant. Those

who refuse to participate will be omitted from the study, which however will not affect services received by the patient within the Musculoskeletal Outpatients.

It is also important to point out, that any intervention carried out in this study will be free of charge to the participant.

Participants will be asked to carry out the following:

1. A 3D gait analysis at Clinical Biomechanics Laboratory at the Faculty of Health Sciences (Mater Dei Hospital). The participants' walking pattern will be analysed using a 10 metre walkway with retroreflective markers attached to major anatomical points on the legs and back. The system to be used is the Plugin-Gait model (Vicon), which is greatly utilised to perform gait analysis in hospitals. The participants will be requested to attend for this analysis twice in order for the researcher to be able to see the participants' progress through time.

2. Be randomly selected for the prescription of custom-made foot orthoses. Participants will have to attend an extra session for assessment and foot measurement by a podiatrist at Mater Dei Hospital, and then make use of insoles prescribed for a period of 6 weeks. An appointment to the participant shall be given at a later date.

3. Fill out a Visual Analog Scale and the Oswestry Low Back Pain Disability Questionnaire, which are the tools to be used to determine the level of pain and how the pain is affecting the participants' daily life by ticking and marking the most appropriate answers, at the beginning and the end of the study. .

4. Both groups of participants will undergo a 6 weeks standard intervention of physiotherapy treatment with a standard program of management of low back pain at the Musculoskeletal Outpatients at St.Luke's. This will be accompanied by a home exercise program, and a documentation format to monitor compliance and any issues with this program.

The participant would be properly instructed, with a good explanation, on the study and on how the above procedure shall be carried out. The interventions and tests shall be carried out on separate days throughout the span of approximately eight weeks of the total participation period. Physiotherapy assessment and intervention to be carried out at Musculoskeletal Outpatients at St. Luke's, while the other testing will be carried out at the Clinical Biomechanics Laboratory at the Faculty of Health Sciences (Mater Dei Hospital).

It is going to be made clear to the patient that the decision whether or not the participant takes part of the is voluntary.

The participant may withdraw at any time from the study without consequences of any kind or loss of benefits to which he/she is otherwise entitled. He/she has the right to refuse to answer any questions he/she does not wish to answer.

Any information that is obtained in connection with this study and that can lead to the identification of the participant will remain confidential and will be disclosed only with the participant's permission or as required by law.

Thank you for taking your time to read this consent form and for giving your consent to conduct this research. Should you require any additional clarifications, I may be contacted at the below email, or my supervisor Dr Alfred Gatt at alfred.gatt@um.edu.mt

Ms. Deborah Debono
B.Sc (Hons) in Physiotherapy
deborah.debono.11@um.edu.mt

19 9 19

Date

Signature

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Permission to Recruit Patients for Master's by Research Project

Esposito Ivan at Health-MDH 20 June 2019 at 06:58
To: Deborah Debono <deborah.debono.11@um.edu.mt>

Dear Ms Debono
I have no objections.
Regards
Ivan Esposito

From: Deborah Debono [deborah.debono.11@um.edu.mt]
Sent: 19 June 2019 23:17
To: Esposito Ivan at Health-MDH
Subject: [EXTERNAL] - Permission to Recruit Patients for Master's by Research Project

Dear Mr. Esposito,

I hope that this email finds you well.

I am Deborah Debono,a physiotherapist by profession, and currently I am reading for a Masters by research with the title 'An investigation on the effects of custom-made orthoses in combination with physiotherapy management in the treatment of mechanical low back pain'.

I am sending this email to you because I kindly require your signed permission in order to recruit patients referred by yourself to the physiotherapy outpatients at St. Luke's Hospital with mechanical low back pain diagnosis.

For further information in regards to the research design, kindly refer to the attached letter of information and consent. Should you very kindly accept to give me your permission to recruit subjects referred by yourself, an electronic signature on the document attached or a reply with your consent to this email would suffice.

Should you wish to further discuss the above please do not hesitate to contact me either by replying to this email, calling on 99841828 or by setting up a meeting if you wish.

I would also like to take the opportunity to thank you for your time, and consideration amidst your busy schedule.

Kind regards,

Deborah Debono

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Fwd: Permission to recruit participants for Master's By Research Project

Fiorini Anthony at Rehabilitation Services-Health 12 August 2019 at 13:14
To: Deborah Debono <deborah.debono.11@um.edu.mt>
Cc: Messina Roberta at Rehabilitation Services-Health

Dear Ms Debono,

The members of the Research Committee of KGH have agreed that you can proceed with your planned study at the hospital.

Anthony Fiorini
Consultant
Health-Rehabilitation Services

t +356 22081829 e https://health.gov.mt
Kindly consider your environmental responsibility before printing this e-mail

MINISTRY FOR HEALTH
ST LUKE'S HOSPITAL, PJAZZA SAN LUQA,
PIETA', MALTA

From: Deborah Debono [mailto:deborah.debono.11@um.edu.mt]
Sent: Monday, 29 July 2019 23:11
To: Fiorini Anthony at Rehabilitation Services-Health
Subject: [EXTERNAL] - Fwd: Permission to recruit participants for Master's By Research Project

---------- Forwarded message ---------
From: **Deborah Debono** <deborah.debono.11@um.edu.mt>
Date: Sun, 23 Jun 2019 at 16:17
Subject: Permission to recruit participants for Master's By Research Project
To:

Dear Dr. Fiorini,

I hope that this email finds you well.

I am Deborah Debono (physiotherapist), currently reading for a Master's by Research with the title 'An investigation on the effects of custom-made orthoses in combination with physiotherapy management in the treatment of mechanical low back pain'.

I am sending this email to you because I kindly require your signed permission in order to recruit patients referred to the physiotherapy outpatients at St. Luke's with low back pain.

For further information in regards to the research design, kindly refer to the attached letter of information and consent. Should you very kindly accept to give me your permission to recruit subjects referred to the outpatients, an electronic signature on the document attached or a reply with your consent to this email would suffice.

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Fwd: Permission to recruit participants for Master's By Research Project

Bugeja Charles at Rehabilitation Services-Health 3 September 2019 at 09:30
To: Deborah Debono <deborah.debono.11@um.edu.mt>

Dear Deborah

Permission granted on my behalf

Charles

Charles Bugeja
Head of Operations
Rehabilitation Services
Rehabilitation Hospital

t +356 22081861 e https://health.gov.mt
Maltese Presidency of the Council of the EU www.eu2017.mt

MINISTRY FOR HEALTH
ST LUKE'S HOSPITAL, PJAZZA SAN LUQA,
PIETA', MALTA

From: Deborah Debono <deborah.debono.11@um.edu.mt>
Sent: Friday, 16 August 2019 14:14
To: Bugeja Charles at Rehabilitation Services-Health

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L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Fwd: Permission to recruit participants for Master's By Research Project

Stephen Zammit 28 August 2019 at 09:36
To: Deborah Debono <deborah.debono.11@um.edu.mt>

Permission granted.

Best of luck in your study.

Regards,

Stephen

Steward Malta

Stephen Zammit
Executive Director, Karin Grech Hospital
https://www.stewardmalta.org/
Guardamangia Hill, Pieta', Malta, PTA1312

From: Deborah Debono <deborah.debono.11@um.edu.mt>
Sent: Wednesday, 28 August 2019 09:27
To: Stephen Zammit
Subject: Fwd: [EXTERNAL] - Fwd: Permission to recruit participants for Master's By Research Project

[Quoted text hidden]

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Permission to Recruit Patients for Master's by Research Project

Gatt Alexander A at Health-MDH 23 June 2019 at 09:53
To: Deborah Debono <deborah.debono.11@um.edu.mt>

Dear Ms Debono

I consent to this project

Best wishes

Alex Gatt

From: Deborah Debono <deborah.debono.11@um.edu.mt>
Sent: 19 June 2019 23:19
To: Gatt Alexander A at Health-MDH
Subject: [EXTERNAL] - Permission to Recruit Patients for Master's by Research Project

Dear Mr. Gatt,

I hope that this email finds you well.

I am Deborah Debono,a physiotherapist by profession, and currently I am reading for a Masters by research with the title 'An investigation on the effects of custom-made orthoses in combination with physiotherapy management in the treatment of mechanical low back pain'.

I am sending this email to you because I kindly require your signed permission in order to recruit patients referred by yourself to the physiotherapy outpatients at St. Luke's Hospital with mechanical low back pain diagnosis.

For further information in regards to the research design, kindly refer to the attached letter of information and consent. Should you very kindly accept to give me your permission to recruit subjects referred by yourself, an electronic signature on the document attached or a reply with your consent to this email would suffice.

Should you wish to further discuss the above please do not hesitate to contact me either by replying to this email, calling on 99841828 or by setting up a meeting if you wish.

I would also like to take the opportunity to thank you for your time, and consideration amidst your busy schedule.

Kind regards,

Deborah Debono

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Fwd: Consent to Recruit Participants for Master's By Research

Schembri Jesmond M at Rehabilitation Services-Health 5 September 2019 at 08:26
To: "deborah.debono.11@um.edu.mt" <deborah.debono.11@um.edu.mt>
Cc: Cassar Marcette at Rehabilitation Services-Health

Dear Deborah,

Permission granted to recruit patients for your study from the physiotherapy outpatients at St. Luke's.

Good luck!

Regards

Jesmond

Jesmond Schembri
Advanced Allied Health Practitioner (Physiotherapy)
Physiotherapy Services
Rehabilitation Hospital Karin Grech

t +356 22082024 / 22082023
e [redacted] | https://health.gov.mt
Maltese Presidency of the Council of the EU www.eu2017.mt

MINISTRY FOR HEALTH
ST LUKE'S HOSPITAL, PJAZZA SAN LUQA,
PIETA', MALTA

Kindly consider your environmental responsibility before printing this e-mail

From: Deborah Debono [mailto:deborah.debono.11@um.edu.mt]
Sent: Wednesday, 04 September 2019 08:34
To: Schembri Jesmond M at Rehabilitation Services-Health
Subject: [EXTERNAL] - Fwd: Consent to Recruit Participants for Master's By Research

---------- Forwarded message ---------
From: **Deborah Debono** <deborah.debono.11@um.edu.mt>
Date: Sun, 4 Aug 2019 at 16:59
Subject: Consent to Recruit Participants for Master's By Research
To:

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

RE: [EXTERNAL] - Fwd: Permission to recruit participants for Master's By Research Project

Messina Roberta at Rehabilitation Services-Health 16 August 2019 at 14:25
To: Deborah Debono <deborah.debono.11@um.edu.mt>
Cc: Fiorini Anthony at Rehabilitation Services-Health

Dear Ms.Debono

Thank you for your email. I hereby forward approval as Data Protection Officer. Kindly note that you are to abide by all clauses in the Data Protection Act including the sections related to Research. You are to ensure that the officer in charge of the section that you are retrieving information from is updated on the progress of your research at all times. You are to declare the retention time for the data collected prior to starting data collection. Do not hesitate to contact me should you require any further guidance.

Regards

Roberta Messina

DPO

KGH

Roberta Messina
Principal Pharmacist
Rehabilitation Hospital
Rehabilitation Services

t +356 22085010
https://health.gov.mt | www.publicservice.gov.mt

MINISTRY FOR HEALTH

ST LUKE'S HOSPITAL, PJAZZA SAN LUQA, PIETA', MALTA

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

Request to conduct research at the Clinical Biomechanics Laboratory at the Faculty of Health Sciences.

Cynthia Formosa 4 October 2019 at 09:54
To: Deborah Debono <deborah.debono.11@um.edu.mt>

Dear Deborah

No objection from my end to use our facilities for your data collection.

regards

CF
Professor Cynthia Formosa PhD FFPM RCPS (Glasg.)
Head/Associate Professor
Podiatry Department
Faculty of Health Sciences
Block A, Level 1
Mater Dei Hospital
University of Malta

Tel - 23401838

[Quoted text hidden]

Request to be an intermediary

Dear Ms. Cardona,

My name is Deborah Debono. I am a postgraduate student at the University of Malta, and a physiotherapist by profession. I am writing to request your assistance to be an intermediary in a research study at St. Luke's Musculoskeletal Physiotherapy Outpatients, within the time frame of September 2019 - September 2021. This study is conducted as part of my postgraduate dissertation.

The aim of the study is to investigate the effects of prescribing insoles combined with physiotherapy intervention, in patients suffering from mechanical low back pain. The study will consist of two groups. Both groups will undergo the standard physiotherapy treatment at St. Luke's Physiotherapy Musculoskeletal Outpatients, but only one group would be prescribed custom-made orthosis. Participants from each group would be randomly selected. Any research outcome would be documented, and a discussion will be done on the outcome of prescribing custom-made insoles when combined with physiotherapy intervention, in patients suffering from mechanical low back pain.

Patients referred with musculoskeletal low back pain to the Musculoskeletal outpatients are going to be assessed by a physiotherapist. Those patients which fit into the inclusion and exclusion criteria will be recruited once an informed consent is obtained from each participant. Those who refuse to participate will be omitted from the study and still be given an appointment within the standard time frame and waiting time within the Musculoskeletal Outpatients.

It is also important to point out, that any intervention carried out in this study will be free of charge to the participant.

As an intermediary you will be carrying out the following:

1. In the first session, assess whether the patient referred is eligible to be a subject in the research by ticking the exclusion and inclusion criteria list that is going to be provided. As the intermediary, it will also involve recruiting the eligible patients as subjects. As part of this process, you will also learn to use the Foot Posture Index prior the experiment period as part of the inclusion and exclusion criteria examination.

2. Carry out a 6 weeks standard intervention of physiotherapy treatment with a standard program of management of low back pain at the St. Luke's Physiotherapy Musculoskeletal Outpatients, based mainly on core stability exercises, education and general back exercises (including stretching and strengthening). This will be accompanied by a home exercise program.

3. Explain to the participant the following information:

i. Verbal explanation of the information letter and consent form. This would include an explanation on the interventions and tests. These shall be carried out on separate days throughout the span of approximately eight weeks of the total participation period.

ii. That the participation in this study is voluntary, and to be made clear to the participant that the decision whether or not the he/she takes part of the study will not affect

the services that the patient normally receives. Explaining that the participant may withdraw at any time from the study without consequences of any kind or loss of benefits to which he/she is otherwise entitled. He/she has the right to refuse to answer any questions he/she does not wish to answer.

iii. Any information that is obtained in connection with this study and that can lead to the identification of the participant will remain confidential and will be disclosed only with the participant's permission or as required by law.

Thank you for taking your time to read this consent form to be an intermediary in this study.

Ms. Deborah Debono
B.Sc (Hons) in Physiotherapy
deborah.debono.11@um.edu.mt

23/8/11

Signature

Date

Request to be an intermediary

Dear Ms. Pace Gouder,

My name is Deborah Debono. I am a postgraduate student at the University of Malta, and a physiotherapist by profession. I am writing to request your assistance to be an intermediary in a research study at St. Luke's Musculoskeletal Physiotherapy Outpatients, within the time frame of September 2019 - September 2021. This study is conducted as part of my postgraduate dissertation.

The aim of the study is to investigate the effects of prescribing insoles combined with physiotherapy intervention, in patients suffering from mechanical low back pain. The study will consist of two groups. Both groups will undergo the standard physiotherapy treatment at St. Luke's Physiotherapy Musculoskeletal Outpatients, but only one group would be prescribed custom-made orthosis. Participants from each group would be randomly selected. Any research outcome would be documented, and a discussion will be done on the outcome of prescribing custom-made insoles when combined with physiotherapy intervention, in patients suffering from mechanical low back pain.

Patients referred with musculoskeletal low back pain to the Musculoskeletal outpatients are going to be assessed by a physiotherapist. Those patients which fit into the inclusion and exclusion criteria will be recruited once an informed consent is obtained from each participant. Those who refuse to participate will be omitted from the study and still be given an appointment within the standard time frame and waiting time within the Musculoskeletal Outpatients.

It is also important to point out, that any intervention carried out in this study will be free of charge to the participant.

As an intermediary you will be carrying out the following:

1. In the first session, assess whether the patient referred is eligible to be a subject in the research by ticking the exclusion and inclusion criteria list that is going to be provided. As the intermediary, it will also involve recruiting the eligible patients as subjects. As part of this process, you will also learn to use the Foot Posture Index prior the experiment period as part of the inclusion and exclusion criteria examination.

2. Carry out a 6 weeks standard intervention of physiotherapy treatment with a standard program of management of low back pain at the St. Luke's Physiotherapy Musculoskeletal Outpatients, based mainly on core stability exercises, education and general back exercises (including stretching and strengthening). This will be accompanied by a home exercise program.

3. Explain to the participant the following information:

i. Verbal explanation of the information letter and consent form. This would include an explanation on the interventions and tests. These shall be carried out on separate days throughout the span of approximately eight weeks of the total participation period.

ii . That the participation in this study is voluntary, and to be made clear to the participant that the decision whether or not the he/she takes part of the study will not affect

the services that the patient normally receives. Explaining that the participant may withdraw at any time from the study without consequences of any kind or loss of benefits to which he/she is otherwise entitled. He/she has the right to refuse to answer any questions he/she does not wish to answer.

iii. Any information that is obtained in connection with this study and that can lead to the identification of the participant will remain confidential and will be disclosed only with the participant's permission or as required by law.

Thank you for taking your time to read this consent form to be an intermediary in this study.

Ms. Deborah Debono
B.Sc (Hons) in Physiotherapy
deborah.debono.11@um.edu.mt

22/8/19

Signature

Date

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

Request to be an intermediary in Research

Lesley Farrugia Zahra 3 October 2019 at 10:15
To: Deborah Debono <deborah.debono.11@um.edu.mt>

I accept Thanks
Ms.Lesley Farrugia

From: Deborah Debono <deborah.debono.11@um.edu.mt>
Sent: Wednesday, October 2, 2019 10:52 PM
To:
Subject: Request to be an intermediary in Research

[Quoted text hidden]

L-Università ta' Malta

Deborah Debono <deborah.debono.11@um.edu.mt>

Request to be an Intermediary in Research

Pauline Fenech 5 October 2019 at 09:01
To: Deborah Debono <deborah.debono.11@um.edu.mt>

Yes, I accept.

Pauline Fenech

Pauline Fenech
M.Sc. Sports Physiotherapy (Bath)
B.Sc., SRP.
MSOMM , MAPPI.

[Quoted text hidden]

Appendix 4: Participants Consent Form and Information Letter in Maltese and English; and Participant Data Sheet

Formula ta' Informazzjoni għall-Parteċipanti

Għażiż/a Parteċipant/a,

Jiena Deborah Debono, fil-preżent qed insegwi 'Master's By Research'. Bħala parti mir-rekwiżiti tal-kors, qed nagħmel riċerka bit-titlu, **Inveztigazzjoni fuq l-effett tas-sulletti apposta magħquda ma' trattament tal-fizjoterapija f'kaz ta' uġiegħ mekaniku fiċ-ċintorin tad-dahar.** L-għan ta' dan l-istudju hu li ninvestiga l-effett ta' meta tikkombina sulletti magħmula speċifikament għalik ma' trattament tal-fizjoterapija f'kaz ta' uġiegħ mekaniku fiċ-ċintorin tad-dahar. Is-sehem tiegħek f'dan l-istudju jista' jgħin biex ikollna aktar għarfien dwar jekk hemmx benefiċċju li persuna jigi preskrit sulletti apposta għaliha mizjud ma' trattament tal-fizjoterapija fil-kura ta' uġiegħ mekaniku taċ-ċintorin tad-dahar. Kull informazzjoni miġbura tintuża biss għall-għan jew l-għanijiet ta' dan l-istudju.

Bħala parteċipant/a inti se tintalab tieħu sehem f'dan l-istudju sabiex ninvestigaw livell ta'uġiegħ, funzjoni fil-ħajja ta'kuljum u l-qagħada ta' kif timxi. Jekk taċċetta li tieħu sehem inti tintalab sabiex tiltaqa' mar-riċerkatriċi, Deborah Debono, għal zewġt jew tliet appuntamenti, fil-laboratorju tal-Biomekanika fil-Fakulta tax-Xjenza tas-saħħa (Mater Dei Hospital), li ser jingħataw skont f'liema grupp tar-riċerka tkun imqassam. Dawn il-laqgħat ser jieħdu madwar siegħa.

Parteċipanti ħa jkunu maqsuma f'żewġ gruppi skont minn jiġi l-ewwel fl-appuntamenti li jkunu għadhom vojta. Din id-divizjoni ħa sseħħ billi jigu mogħtija appuntamenti għat-testijiet ta' qabel t-trattament u għas-sulletti mill-intermedjarji f'appuntamenti u ħinijiet li jkunu indikati.

Waqt din il-laqgħa, ha tkun mitlub tagħmel dawn l-affarijiet fil-presenza tar-riċerkatriċi,

1. Analizi tal-mixja tiegħek 3D, fejn il-mixja tiegħek ser tigi ezaminata f'tul ta' 10 metri. Ħa jkollok marki reflettivi mwaħħlin ma' punti anatomiċi fuq ġismek. Is-sistem li ħa tkun uzata jismiha 'Plugin-Gait Model (Vicon)'. Din is-sistema hija uzata frekwentament fl-isptarijiet biex janalizzaw il-mixja tal-persuna.

Għal din l-analizi ħa tkun mitlub biex tattendi għal total ta'darbtejn biex nkunu nistgħu naraw il-progress tiegħek. Ħa tkun mitlub biex tilbes qalziet qasir u flok taċ-ċingi. Ħa tkun mitlub ukoll biex tilbes l-istess par ta' zarbun tal-ġiri għal zewg appuntament, li ser jsiru f'ġranet separati. Il-laboratorju ta' fejn ser issir din l-analizi ha jkun mizmum b'temperatura. Huwa importanti ukoll li tigi nfurmat li l-laboratorju fejn ser issr l-analizi jikkonsist f'tlettax l-kamera li ħa jkun qiegħdin jiġbru nformazzjoni mill-marki mwaħħlin f'punti diversi fuq ġismek, u minn zewg kameras li jirrekordjaw l-video. Izzommx lura li tinformani jekk ma

tkunx tixtieq li tidher fil-video dak inhar tal-analizi. Jekk taċċetta li tipparteċipa fir-riċerka, imma dakinhar tal-appuntament ma tkunx tista tattendi, hu ħsieb li tinforma minn qabel permess tal-kuntatti li jinstabu hawn taħt.

2. Jekk tkun magħzul biex tipparteċipa fil-grupp li ha jingħata s-sulletti, ħa tkun mitlub tattendi sessjoni oħra biex issir ezami tas-saqajn minn podjatrista fis-Sptar Mater Dei. Meta jingħataw is-sulletti, ħa tkun mitlub biex tagħmel uzu minnhom kif ħa jkun spjegat matul iz-zmien kollhu tar-riċerka. Għall-ezami ħa tkun mitlub biex tilbes l-istess zarbun li ħa tuza' għall-ezami tal-mixja, kif ġie spjegat hawn fuq, kif ukoll l-iktar zarbun li tuza' ta' kuljum u zarbun tal-ġiri. Jekk dakinhar ma tkunx tista tattendi, hu hsieb li tinforma minn qabel permess tal-kuntatti li jinstabu hawn taht.

3. Timla 'Visual Analog Scale' u 'Oswestry Low Back Pain Disability Questionnaire'. Dawn huma għodda uzati biex jiddertimaw l-livell tal-uġiegħ, u kif dak l-uġiegħ qiegħed jaffettwa l-ħajja tiegħek ta' kuljum billi timmarka l-iktar tweġibiet li japplikaw. Dawn iz-zewg testijiet ħa jsiru għal total ta' darbtejn, u ħa jkunu magħquda mas-sessjonijiet oħra. Allura, mhux ħa jkun hemm bzonn li tattendi sessjonijiet zejda biex tagħmel dawn.

4. Iz-zewg gruppi tal-parteċipanti ħa jgħaddu minn sitt gimgħat t' intervenzjoni tipika tal-fizjoterapija għall-kura taċ-ċintorin tad-dahar fid-dipartiment tal-Fizjoterapija fl-isptar ta' San Luqa. Dan it-trattament ħa jkun akkompanjat b'programm t'ezerċezzji li jsiru d-dar. Matul dawn is-sitt gimgħat, ħa tagħmel korrespondenza mal-fizjoterapista tiegħek fuq appuntamenti u trattament.

M'intix obbligat/a li twieġeb il-mistoqsijiet kollha u tista' twaqqaf l-istudju fi x'ħin trid mingħajr ma tagħti l-ebda raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqek u l-informazzjoni li tingabar mingħandek tinħażen b'mod anonimu . Nassigurak li se tinżamm il-kunfidenzjalità matul l-istudju kollu u l-identità tiegħek u kull informazzjoni personali miġbura mhuma se jiġu żvelati mkien fit-teżi, ir-rapporti, il-preżentazzjonijiet u/jew il-pubblikazzjonijiet li jistgħu jirriżultaw minnha. Kull tagħrif miġbur se jiġi psewdonomizzat, jiġifieri id-data kollha se tkun protetta permezz ta' sistema ta' kodiċi u miżmuma separatament mill-informazzjoni personali. Ir-Riċerkatriċi u s-Superviżur akkademiku biss ser ikollhom aċċess għall-informazzjoni miġbura u dan bi skop ta' verifika, filwaqt li l-eżaminaturi se jkollhom biss aċċess għal data kkodifikata. L-awdjo rrekordjat u d-data kollha se jinħażnu fuq il-kompjuter personali tar-Riċerkatur/Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, il-materjal stampat se jinqafel f'post sigur.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija għażla għal kollox volontarja u inti ħieles/ħielsa li taċċetta jew tirrifjuta li tieħu sehem mingħajr ma jkun hemm konsegwenzi fil-konfront tiegħek. Se tingħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex tkun tista' taċċessahom fil-futur. Barra minn hekk, skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, inti għandek id-dritt li taċċessa, tirretifika, u fejn japplika titlob sabiex titħassar id-data li tikkonċerna lilek. L-informazzjoni personali kollha se titħassar hekk kif jintemm dan l-istudju ta' riċerka u jkunu ppubblikati r-riżultati miksuba.

Grazzi ħafna tal-ħin u s-sehem tiegħek f'dan l-istudju. F'każ li jkollok xi mistoqsijiet jew tixtieq tiċċara xi ħaġa, tista' ċċempilli fuq . jew tibgħatli email fuq deborah.debono.11@um.edu.mt. Tista' wkoll tikkuntattja lis-Superviżur Dr. Alfred Gatt fuq alfred.gatt@um.edu.mt jew ċċempel fuq 23401153.

Dejjem tiegħek,

_____

Ms. Deborah Debono

_____

Dr. Alfred Gatt

Formula ta' Kunsens tal-Parteċipanti

Inveztigazzjoni fuq l-effett tas-sulletti apposta magħquda ma' trattament tal-fizjoterapija f'kaz ta' uġiegħ mekaniku fiċ-ċintorin tad-dahar

Jien, hawn taħt iffirmat/a, nagħti l-kunsens tiegħi biex nieħu sehem fl-istudju mmexxi minn Deborah Debono. L-għan ta' dan id-dokument hu li jiġu speċifikati t-termini tal-parteċipazjoni tiegħi f'dan l-istudju ta' riċerka.

1. Jien ingħatajt informazzjoni miktuba u verbali dwar l-għan tal-istudju u l-mistoqsijiet kollha twieġbu.
2. Nifhem li se nkun qed nipparteċipa fi studju, fejn ir- Riċerkatriċi ħa j/tinvestiga ninvestiga l-effett ta' meta tikkombina sulletti maghmula specifikament ghalik ma' trattament tal-fizjoterapija f'kaz t'uġiegħ mekaniku fiċ-ċintorin tad-dahar
3. Naf li l-istudju se jieħu madwar siegħa u li ħa jkolli bzonn nattendi għal darbtejn/tlett darbiet. Nifhem, li l-laqgħa se ssir fil-Laboratorju tal-biomekanika klinika fil-Fakulta tax-Xjenza tas-saħħa f'Mater Dei, u li l-appuntamenti ħa jkunu mogħtija skont f'liema grupp ħa tkun mqassam.
4. Naf ukoll li se ssir kodifikazzjoni tad-data u din se tinżamm separatament mill-informazzjoni personali.
5. Naf ukoll li r- Riċerkatriċi u s-Superviżur akkademiku huma l-uniċi persuni li se jkollhom aċċess għal din l-informazzjoni għal skop ta' verifika, filwaqt li l-eżaminaturi se jkollhom aċċess għal data kkodifikata biss.
6. Barra min hekk, naf li dak kollhu li jkun irrekordjat u d-data se jinħażnu fuq il-kompjuter personali tar-Riċerkatriċi permezz ta' kodifikazzjoni tad-data (data encryption) u li hi protetta b'password. Barra minn hekk, naf li l-materjal stampat se jitqiegħed f'post sikur u se jinżamm sakemm joħorġu r-riżultati.
7. Naf li l-identità tiegħi u l-informazzjoni personali mhuma se jinkixfu mkien fit-teżi, fir-rapporti, fil-preżentazzjonijiet u/jew fil-pubblikazzjonijiet li jistgħu jirriżultaw minnha.
8. Nifhem ukoll li jien liberu/a li naċċetta, nirrifjuta jew inwaqqaf il-parteċipazzjoni f'kull ħin bla ma nagħti raġuni. Dan mhux ħa jkollu riperkussjonijiet negattivi fuqi. Nifhem ukoll li la darba nirtira minn dan l-istudju, l-informazzjoni miġbura se tinżamm b'mod anonimu.
9. Nifhem ukoll li l-kontribuzzjoni tiegħi ser isservi biex jista' jgħin biex jkun hemm aktar għarfien dwar jekk hemmx benefiċċju li persuna jigi preskrit sulletti apposta għalih mizjud ma' trattament tal-fizjoterapija fil-kura ta' uġiegħ mekaniku taċ-ċintorin tad-dahar.
10. Nifhem ukoll, li skont ir-Regolamenti Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika aktar il-provvedimenti relevanti tar-regolamenti msemmija, jiena għandi d-dritt li naċċessa, nirretifika, u fejn japplika nitlob sabiex titħassar id-data li tikkonċernani.

11. Naf ukoll li meta jintemm l-istudju u r-riżultati jkunu ppubblikati, l-informazzjoni personali miġbura titħassar.
12. Fl-aħħar nett, naf ukoll li se ningħata kopja tal-ittra ta' informazzjoni u tal-formula ta' kunsens sabiex inkun nista' naċċessahom fil-futur.
13. Jien qrajt u fhimt il-punti u d-dikjarazzjonijiet f'din il-formula. Inħossni sodisfatt/a bit-tweġibiet li ngħatajt għall-mistoqsijiet li kelli, u qed naċċetta minn jeddi li nipparteċipa f'dan l-istudju.

Parteċipant:_____

Firma:_____

Data:_____

Numru ta' Kuntatt: _____

Isem is-Superviżur tar-ricerkja: Dr. Alfred Gatt

Firma: _____

alfred.gatt@um.edu.mt
23401153

Isem ir-Riċerkatriċi: Ms. Deborah Debono

Firma: _____

deborah.debono.11@um.edu.mt

Participants` Information Sheet

Dear Participant,

My name is Deborah Debono and I am currently reading for a Master's by Research at the University of Malta. As part of my course requirements I am conducting a research study entitled, **An investigation on the effect of custom-made orthoses in combination with physiotherapy management in the treatment of mechanical low back pain.** The aim of this study is to investigate the effect when combining custom-made insoles with physiotherapeutic management in Mechanical Low back Pain. Your participation in this study would help us gain a better understanding about whether there are any added benefits when prescribing custom-made insoles in addition to physiotherapy treatment in the treatment of Mechanical low back pain. Furthermore, all data collected from this research shall be used solely for the purpose of this study.

You are being invited to participate in a study which will investigate level of pain, daily life function and walking pattern before and after 6-week intervention. If you agree to participate, you will meet the researcher, Deborah Debono, two/three times, at the Clinical Biomechanics Laboratory at the Faculty of Health Sciences (Mater Dei Hospital). Appointments shall be given according to which group you have been randomly allotted to. Duration of the sessions are approximately one hour.

Participants will be divided into two groups on a first come basis to the different pre-set appointment slots available. This division will be carried out by giving the participants appointments, prior starting the intervention period, for pre-testing and for the fitting of the insoles by the intermediaries on the preset times and days.

During the visit, the following will be carried out in the presence of the researcher,

1. Carry out a 3D gait analysis testing, where your walking pattern will be analysed using a 10-metre walkway with reflective markers attached to anatomical points on your body. The system to be used is the Plugin-Gait model (Vicon), which is greatly utilised to perform gait analysis in hospitals.

You will be requested to attend for this analysis in total of two times in order to be able to see your progress through time. For this analysis, you will also be required to wear shorts and a vest top. It will also be required to wear the same pair of running shoes on the two

separate days that the analysis is to be carried out. The gait analysis lab would be set at a comfortable temperature. It is important to note that the gait analysis lab consists of 13 cameras that get information only from the attached markers, and two video recording cameras. Feel free to inform myself or the co-researcher, should you not wish to be video recorded on the day. Should you have accepted to participate, and not be able to attend on the day, kindly inform beforehand by means of the contact details found below.

2. Should you be randomly selected for the prescription of custom made insoles, you will have to attend an extra session for assessment and foot measurement by a podiatrist at Mater Dei Hospital, and then make use of the prescribed insoles as instructed, throughout the entirety of the study. You will be requested to come with the same footwear that you will be wearing for the gait analysis lab, as explained above, as well as your most commonly used footwear in your daily life and a pair of running shoes. Should you not be able to attend, kindly inform beforehand by means of the contact details found below.

3. Fill out a Visual Analog Scale, and Oswestry Low Back Pain Disability Questionnaire. These are the tools used to determine the level of pain and how the pain is affecting your daily life by ticking and marking the most appropriate answers. These are to be done in total of two times, and it is going to be combined with other sessions. Therefore, you will not be required to attend any extra sessions in order to carry these out.

4. Both groups of participants will undergo a six weeks standard intervention of physiotherapy treatment with a standard program of management of low back pain at the Musculoskeletal Outpatients at St. Luke's Hospital. This will be accompanied by a home exercise program. During these six weeks, you will be corresponding with your respective physiotherapist regarding appointment and treatment.

You are not obliged to participate in this study or to answer all the questions and you may withdraw from the study at any time without giving a reason. Furthermore, withdrawal from the study will not have any negative repercussions on you and any data collected will be stored anonymously. I can assure you that confidentiality will be maintained throughout the study and that your identity and personal information will not be revealed in any publications, reports or presentations arising from this research. All data collected will be pseudonymised meaning that the data will be assigned codes and that this data will be stored securely and separately from any codes and personal data. This data may only be accessed by the researcher and the academic supervisor. Examiner(s) will have access to coded data only. The video-recordings and data files

will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard.

Participation in this study is completely voluntary and you are free to accept or refuse to take part without giving a reason. A copy of the information sheet and consent form will be provided for future reference. As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, to access, rectify and where applicable ask for the data concerning you to be erased. Once the study is completed and the results are published, the data will be retained in anonymous form. Any personal details will be destroyed.

Thank you for your time and consideration. Should you have any questions or concerns do not hesitate to contact me on or by e-mail **deborah.debono.11@um.edu.mt** or my supervisor Dr. Alfred Gatt on **alfred.gatt@um.edu.mt** or on 23401153.

Yours Sincerely,

Deborah Debono	Dr. Alfred Gatt
Researcher	Research Supervisor

Participants` Consent Form

An investigation on the effect of custom-made orthoses in combination with physiotherapy management in the treatment of mechanical low back pain

I, the undersigned, give my consent to take part in the study conducted by Deborah Debono. The purpose of this document is to specify the terms of my participation in this research study.

1. I have been given written and verbal information about the purpose of the study and all questions have been answered.
2. I understand that I have been invited to participate in a study, in which the researcher will ask questions and perform tests to investigate the effect when combining custom-made insoles with physiotherapeutic management in Mechanical Low back Pain.
3. I am aware that the meeting will take approximately one hour for two to three times. I understand that the meeting is to be conducted at the Clinical Biomechanics Laboratory at the Faculty of Health Sciences (Mater Dei Hospital) and that appointments shall be given according to which group you have been randomly allotted to.
4. I am aware that the data collected will be coded and that this data will be stored securely and separately from any codes and personal data.
5. I am aware that the researcher and the academic supervisor/s are the only persons who have access to this data. Examiners will have access to coded data only.
6. I am also aware that the coded video-recordings and data files will be stored on the researcher`s personal computer that is password protected and in an encrypted format. Any material in hard-copy form will be placed in a locked cupboard and kept until results are published.
7. I am aware that my identity and personal information will not be revealed in any publications, reports or presentations arising from this research.
8. I also understand that I am free to accept, refuse or stop participation at any time without giving any reason. This will have no negative repercussions on myself and that any data collected form me will be stored anonymously.
9. I also understand that my contribution will serve to help gain a better understanding about whether there are any added benefits when prescribing custom-made insoles in addition to physiotherapy treatment in the treatment of Mechanical low back pain.
10. I understand that under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased.

11. I also understand that once the study is completed and results are published the data will be retained in anonymous form. Any personal details will be destroyed.
12. I will be provided with a copy of the information letter and consent form for future reference.
13. I have read and understood the points and statements of this form. I have had all the questions answered to my satisfaction, and I agree to participate in this study.

Participant: _____

Signature: _____

Date: _____

Contact Number:_____

_____ _____

Ms.Deborah Debono
Researcher
deborah.debono.11@um.edu.mt

Dr. Alfred Gatt
Research Supervisor
alfred.gatt@um.edu.mt
23401153

PARTICIPANT DATA SHEET

DATE and time	
GROUP A or B	
Consent form	
Subject vicon label	
Next vicon appointment (6weeks)	
DATA COLLECTION	
FPI index	
OSWESTRY SCORE	
VAS	
AGE	
Anthropometric DATA (millimetres)	
Height	
Weight	
Leg length	
Glenohumeral Offset	
Elbow width	
Wrist width	
Hand thickness	
ASIS width	
Knee width	
Ankle width	
Sole Delta	

SUBJECT NAME: _____ CONTACT NUMBER:_____

Appendix 5: Visual Analog Scale and Foot Posture Index

DATE:_____

VISUAL ANALOG SCALE

Subject Number: _____ A/B

Session: ____

SUBJECT NAME: _____

FOOT POSTURE INDEX FPI-6

Subject Number: _____ A/B DATE: _____

	COMPONENT	PLANE	SCORE 1 Date_____ Comment_____		SCORE 2 Date_____ Comment_____		SCORE 3 Date_____ Comment_____	
			Left *(-2 to +2)*	*Right* *(-2 to +2)*	*Left* *(-2 to +2)*	*Right* *(-2 to +2)*	*Left* *(-2 to +2)*	*Right* *(-2 to +2)*
Rearfoot	Talar head palpation	*Transverse*						
Rearfoot	Curves above and below lateral malleoli.	*Frontal/ trans*						
Rearfoot	Inversion/eversion of the calcaneus	*Frontal*						
Forefoot	Bulge in the region of the TNJ	*Transverse*						
Forefoot	Congruence of the medial longitudinal arch	*Sagittal*						
Forefoot	Abduction/adduction of the forefoot on the rear foot (too-many-toes).	*Transverse*						
	TOTAL							

SUBJECT NAME: _____

Appendix 6: Oswestry Disability Index in English and Maltese, and approvals for use

Mapi Research Trust

User agreement Special Terms

Mapi Research Trust, a non-for-profit organisation subject to the terms of the French law of 1st July 1901, registered in Carpentras under number 453 979 346, whose business address is 27 rue de la Villette, 69003 Lyon, France, hereafter referred to as "MRT" and the User, as defined herein, (each referred to singularly as a "Party" and/or collectively as the "Parties"), do hereby agree to the following User Agreement Special and General Terms:

Mapi Research Trust
PROVIDE™
27 rue de la Villette
69003 Lyon
France
Phone: +33 (0)4 72 13 66 66

Recitals

The User acknowledges that it is subject to these Special Terms and to the General Terms of the Agreement, which are included in Appendix 1 to these Special Terms and fully incorporated herein by reference. Under the Agreement, the Questionnaire referenced herein is licensed, not sold, to the User by MRT for use only in accordance with the terms and conditions defined herein. MRT reserves all rights not expressly granted to the User.

The Parties, in these Special Terms, intend to detail the special conditions of their partnership.

The Parties intend that all capitalized terms in the Special Terms have the same definitions as those given in article 1 of the General Terms included in Appendix 1.

In this respect, the Parties have agreed as follows:

Article 1. Conditions Specific to the User

Section 1.01 Identification of the User

User Name	Deborah Debono
Legal Form	Student
Address	
Country	Malta
Email address	deborah.debono.11@um.edu.mt
Telephone number	

Section 1.02 Identification of the Questionnaire

Title	Oswestry Disability Index (ODI)
Author(s)	Fairbank J
Owner	Fairbank Jeremy
Copyright	ODI © Jeremy Fairbank, 1980. All Rights Reserved.
Original bibliographic references	Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000 Nov 15;25(22):2940-52; discussion 2952. (PubMed Abstract) Baker DJ, Pynsent PB and Fairbank JCT (1989) The Oswestry Disability revisited. In Roland Jenner JR (eds) Back pain: New approaches to rehabilitation and education. Manchester University Press.pp174-186 Fairbank JCT, Couper J, Davies JB, O'Brien JP. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy. 1980;66:271-273 (PubMed) Stokes OM. Answer to the Letter to the Editor of L. Denteneer et al. concerning "Do we have the right PROMs for measuring outcomes in lumbar spinal surgery?" by O.M. Stokes et al., Eur Spine J (2017) 26:816-824 (PubMed)

Article 2. Rights to Use

Section 2.01 Context of the Use of the Questionnaire

The User undertakes to only use the Questionnaire in the context of the Study as defined hereafter.

Context of Use	Clinical project or study
Title	An investigation on the effect of custom-made orthoses in combination with physiotherapy management in the treatment of mechanical low back pain
Disease or condition	non specific Low back pain
Type of research	Clinical trial
Questionnaire used as primary endpoint	Yes
Number of patients expected	still to be determined
Number of submissions to the questionnaire for each patient	two to three times
Term of clinical follow-up for each patient	not applicable
Start	01/2019
End	09/2021
Mode of administration	Paper administration

Section 2.02 Conditions for Use

The User undertakes to use the Questionnaire in accordance with the conditions for use defined hereafter.

(a) Rights transferred
Acting in the Owner's name, MRT transfers the following limited, non-exclusive rights, to the User (the "Limited Rights")
(i) to use the Questionnaire, only as part of the Study; this right is made up exclusively of the right to communicate it to the Beneficiaries only, free of charge, by any means of communication and by any means of remote distribution known or unknown to date, subject to respecting the conditions for use described hereafter; and

(ii) to reproduce the Questionnaire, only as part of the Study; this right is made up exclusively of the right to physically establish the Questionnaire or to have it physically established, on any paper, electronic, analog or digital medium, and in particular documents, articles, studies, observations, publications, websites whether or not protected by restricted access, CD, DVD, CD-ROM, hard disk, USB flash drive, for the Beneficiaries only and subject to respecting the conditions for use described hereafter; and

(iii) Should the Questionnaire not already have been translated into the language requested, the User is entitled to translate the Questionnaire or have it translated in this language, subject to informing MRT of the same beforehand by the signature of a Translation Agreement indicating the terms of it and to providing a copy of the translation thus obtained as soon as possible to MRT.

The User acknowledges and accepts that it is not entitled to amend, modify, condense, adapt, reorganise the Questionnaire on any medium whatsoever, in any way whatsoever, even minor, without MRT's prior specific written consent.

(b) Specific conditions for the Owner

The Owner has intended to transfer a part of the copyright on the Questionnaire and/or the Documentation to MRT in order to enable MRT to make it available to the User for the purpose of the Study, subject to the User respecting the following Owner's requirement: for all new studies, version 2.1a of the Questionnaire must be used.

The User therefore undertakes to respect these special terms.

(c) Specific conditions for the Questionnaire

- Use in Individual clinical practice or Research study / project

The User undertakes never to duplicate, transfer or publish the Questionnaire without indicating the Copyright Notice.

In the case of use of an electronic version of the Questionnaire in commercial studies / projects, the User undertakes to respect the following special obligations:

- In case of use of an e-vendor, User shall check with Mapi Research Trust that e-vendor has signed the necessary License Agreement with Mapi Research Trust before starting the development of the electronic version of the Questionnaire
- Cite the reference publications
- Insert the Owner's copyright notice on all pages/screens on which the Questionnaire will be presented
- Mention the following information: "The Questionnaire contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: www.proqolid.org"

- For the first migration of the Questionnaire (generally the original version) into a specific electronic device

- Review of screenshots:

After implementation of the Questionnaire into the device, the user/e-provider will generate screen captures (screenshots) of the original questionnaire as displayed in the device. These will be reviewed by Mapi to check that they are consistent with the original paper version in terms of presentation, content and completion except for specific instructions related to the electronic administration. Corrections that may be needed will be reported to the user/e-provider. In this case, screenshots after correction

will be generated for another round of review by Mapi until all screenshots are approved.

- Usability testing:

Usability testing is a methodology which aims to examine whether respondents are able to use a device and associated software as intended. Major issues of concern in usability testing typically include device complexity, navigation and response selection for example.

The objective of this investigation is to ensure that the electronic version of the questionnaire as included in the device meets usability criteria, focusing on functional aspects and respondents' understanding of instructions. Usability testing consists in interviews with patients where patients will complete the electronic version of the Questionnaire on the device and comment on their understanding of the instructions, ease of use and handiness of the device. A Usability testing report presenting results will be produced. If any changes are recommended, these will be implemented by the user/e-provider. If issues raised by respondents are rated as major, the user/e-provider may need to perform additional developments and another round of interviews may be needed.

The review of screenshots and usability testing are mandatory. These steps shall be performed exclusively by Mapi and shall be sponsored by the User.

- For the migration of other language versions of the Questionnaire on an existing certified specific electronic device

- Update version

After the electronic device original version of the Questionnaire is fully ready, the Questionnaire's language versions developed for paper administration will be updated to reflect the changes in wording of instructions implemented in the electronic device original version of the questionnaire.

Native speakers of the languages will reflect the changes made to the electronic device original version of the Questionnaire and will provide English equivalents of all changes made for Mapi's quality control.

- Review of screenshots:

After implementation of the Questionnaire into the device, the user/e-provider will generate screen captures (screenshots) of the original questionnaire as displayed in the device. These will be reviewed by Mapi to check that they are consistent with the original paper version in terms of presentation, content and completion except for specific instructions related to the electronic administration. Corrections that may be needed will be reported to the user/e-provider. In this case, screenshots after correction will be generated for another round of review by Mapi until all screenshots are approved.

The update of version and review of screenshots are mandatory. These steps shall be performed exclusively by Mapi and shall be sponsored by the User.

- Use in a publication or on a website with unrestricted access:

In the case of a publication, article, study or observation on paper or electronic format of the Questionnaire, the User undertakes to respect the following special obligations:

- not to include any full copy of the Questionnaire, but a protected version with the indication "sample copy, do not use without permission"
- to indicate the name and copyright notice of the Owner
- to include the reference publications of the Questionnaire
- to indicate the details of MRT for any information on the Questionnaire as follows: "contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org "

- to provide MRT, as soon as possible, with a copy of any publication regarding the Questionnaire, for information purposes
- to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

- Use for dissemination:

- On a website with restricted access:

In the case of publication on a website with restricted access, the User may include a clean version of the Questionnaire, subject to this version being protected by a sufficiently secure access to only allow the Beneficiaries to access it.

The User undertakes to also respect the following special obligations:

- to indicate the name and copyright notice of the Owner
- to include the reference publications of the Questionnaire
- to indicate the details of MRT for any information on the Questionnaire as follows: "contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org "
- to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

- On promotional / marketing documents

In the case of publication on promotional/marketing documents, the User undertakes to respect the following special obligations:

- to indicate the name and copyright notice of the Owner
- to include the reference publications of the Questionnaire
- to indicate the details of MRT for any information on the Questionnaire as follows: "contact information and permission to use: Mapi Research Trust, Lyon, France – Internet: https://eprovide.mapi-trust.org "
- to provide MRT, as soon as possible, with a copy of any publication regarding the Questionnaire, for information purposes
- to submit the screenshots of all the Pages where the Questionnaire appears to MRT before release to check that the above-mentioned requirements have been respected.

For any other use not defined herein, please contact MRT for the specific conditions of use and access fees (if applicable).

Article 3. Term

MRT transfers the Limited Rights to use the Questionnaire as from the date of delivery of the Questionnaire to the User and for the whole period of the Study.

Article 4. Beneficiaries

The Parties agree that the User may communicate the Questionnaire in accordance with the conditions defined above to the Beneficiaries involved in the Study only, in relation to the Study defined in section 2.01.

Article 5. Territories and Languages

MRT transfers the Limited Rights to use the Questionnaire on the following territories and in the languages indicated in the table

below:

Questionnaire	Language
ODI	English for the UK

Article 6. Price and Payment Terms

The User undertakes in relation to MRT to pay the price owed in return for the availability of the Questionnaire, according to the prices set out below, depending on the languages requested and the costs of using the Questionnaire, in accordance with the terms and conditions described in section 6.02 of the General Terms included in Appendix 1.

Agreed and acknowledged by

Deborah Debono

26-Nov-2018

ODI version 2.1a

This questionnaire is designed to give us information as to how your back (or leg) trouble affects your ability to manage in everyday life.
Please answer every section. Mark one box only in each section that most closely describes you today.

Section 1 - Pain intensity

- ○ I have no pain at the moment.
- ○ The pain is very mild at the moment.
- ○ The pain is moderate at the moment.
- ○ The pain is fairly severe at the moment.
- ○ The pain is very severe at the moment.
- ○ The pain is the worst imaginable at the moment.

Section 2 - Personal care (washing, dressing, etc.)

- ○ I can look after myself normally without causing extra pain.
- ○ I can look after myself normally but it is very painful.
- ○ It is painful to look after myself and I am slow and careful.
- ○ I need some help but manage most of my personal care.
- ○ I need help every day in most aspects of self care.
- ○ I do not get dressed, wash with difficulty and stay in bed.

Section 3 - Lifting

- ○ I can lift heavy weights without extra pain.
- ○ I can lift heavy weights but it gives extra pain.
- ○ Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- ○ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- ○ I can lift only very light weights.
- ○ I cannot lift or carry anything at all.

Section 4 - Walking

- ○ Pain does not prevent me walking any distance.
- ○ Pain prevents me walking more than one mile.
- ○ Pain prevents me walking more than a quarter of a mile.
- ○ Pain prevents me walking more than 100 yards.

ODI - United Kingdom/English - Mapi Institute.
ODI_AU2.1a_eng-GBort.doc

- ○ I can only walk using a stick or crutches.
- ○ I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- ○ I can sit in any chair as long as I like.
- ○ I can sit in my favourite chair as long as I like.
- ○ Pain prevents me from sitting for more than 1 hour.
- ○ Pain prevents me from sitting for more than half an hour.
- ○ Pain prevents me from sitting for more than 10 minutes.
- ○ Pain prevents me from sitting at all.

Section 6 - Standing

- ○ I can stand as long as I want without extra pain.
- ○ I can stand as long as I want but it gives me extra pain.
- ○ Pain prevents me from standing for more than 1 hour.
- ○ Pain prevents me from standing for more than half an hour.
- ○ Pain prevents me from standing for more than 10 minutes.
- ○ Pain prevents me from standing at all.

Section 7 - Sleeping

- ○ My sleep is never disturbed by pain.
- ○ My sleep is occasionally disturbed by pain.
- ○ Because of pain I have less than 6 hours sleep.
- ○ Because of pain I have less than 4 hours sleep.
- ○ Because of pain I have less than 2 hours sleep.
- ○ Pain prevents me from sleeping at all.

Section 8 - Sex life (if applicable)

- ○ My sex life is normal and causes no extra pain.
- ○ My sex life is normal but causes some extra pain.
- ○ My sex life is nearly normal but is very painful.
- ○ My sex life is severely restricted by pain.
- ○ My sex life is nearly absent because of pain.
- ○ Pain prevents any sex life at all.

Section 9 - Social life

- ○ My social life is normal and causes me no extra pain.
- ○ My social life is normal but increases the degree of pain.
- ○ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- ○ Pain has restricted my social life and I do not go out as often.
- ○ Pain has restricted social life to my home.
- ○ I have no social life because of pain.

Section 10 - Travelling

- ○ I can travel anywhere without pain.
- ○ I can travel anywhere but it gives extra pain.
- ○ Pain is bad but I manage journeys over two hours.
- ○ Pain restricts me to journeys of less than one hour.
- ○ Pain restricts me to short necessary journeys under 30 minutes.
- ○ Pain prevents me from travelling except to receive treatment

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Result

Your ODI = [ ] %

Consent to use the Maltese Translation of the Oswestry Disability Index

Dear Mr. Owen Sant' Angelo,

My name is Deborah Debono. I am a postgraduate Student from the University of Malta, and a physiotherapist by profession. I am writing this letter to request permission to use the Maltese Translation of the Oswestry Disability Index, which was translated by yourself in 2000, within the time frame of September 2019 - June 2021. I would also like to ask permission to put small modifications to the already existing version in order to be up to date with the current recommended version of the ODI 2.1. This study is conducted as part of my postgraduate dissertation.

The aim of the study is to investigate the added benefits of prescribing insoles combined with physiotherapy intervention, in patients suffering from mechanical low back pain. The study will consist of two groups. Both groups will undergo the standard physiotherapy treatment at St. Luke's Musculoskeletal Physiotherapy Outpatients, but only one group would be prescribed custom made orthosis. Participants in each group would be randomly selected. Any research outcome would be documented, and a discussion will be done on the outcome of prescribing custom made insoles with physiotherapy intervention, in patients suffering from low back pain. Participants will be asked to carry out the Questionnaire for two times in total in the pre and post intervention.

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Thank you for taking your time to read this consent form and for giving your consent to conduct this research.

Ms. Deborah Debono
B.Sc (Hons) in Physiotherapy
deborah.debono.11@um.edu.mt

22/3/19

Date

Signature

The Oswestry Low Back Pain Disability Questionnaire

Data:___/___/_____

Dawn il-mistoqsijiet huma magħmula biex jagħtu informazzjoni dwar kif l-problemi f'dahrek (jew f'saqajk) jaffetwak kif inti tghix l-ħajja tiegħek ta' kuljum. Jekk joġgħbok irrispondi kull sezzjoni. Immarka biss kaxxa wahda f'kull sezzjoni li l-aktar tixbaħ il-problema tiegħek illum.

Qawwa ta l-uġiegħ
[] M'għandi l-ebda uġiegħ bħalissa.
[] L-uġiegħ huwa ftit bħalissa.
[] L-uġiegħ huwa moderat bħalissa.
[] L-uġiegħ huwa ftit qawwi bħalissa.
[] L-uġiegħ huwa hafna qawwi bħalissa.
[] L-uġiegħ huwa l-agħar li jista' jkun bħalissa.

Kura Personali
[] Nista nieħu ħsieb tiegħi nnifsi mingħajr ma nweġġa'.
[] Nista nieħu ħsieb tiegħi nnifsi iżda nweġġa'.
[] Meta nieħu ħsieb tiegħi nnifsi, nweġġa' u jkolli noqgħod attent /a.
[] Għandi bżonn ftit għajnuna iżda nista' nagħmel ħafna mill-affarijiet.
[] Għandi bżonn l-għajnuna kuljum għal-ħafna bżonnijiet personali.
[] Ma nistax nilbes, ninħasel b'diffikulta' u noqgħod fis-sodda.

Tqandil
[] Nista' nerfa affarijiet tqal mingħajr ma nweġġa'.
[] Nista' nerfa affarijiet tqal iżda nweġġa'.
[] Ma nistax nerfa affarijiet tqal mill-art, iżda nista nerfagħhom minn fuq mejda.
[] Nista' nerfa affarijiet mhux daqshekk tqal, jew ħfief.
[] Nista' nerfa affarijiet ħfief biss.
[] Ma nista' nerfa jew inġorr xejn.

Mixi
[] Nista' nimxi fit-tul mingħajr ma nweġġa.
[] Minħabba l-uġiegħ ma nistax nimxi aktar minn zewg kilometri (mil).
[] Minħabba l-uġiegħ ma nistax nimxi aktar minn kilometru (nofs mil).
[] Minħabba l-uġiegħ ma nistax nimxi aktar minn nofs kilometru (kwart ta' mil).
[] Meta nimxi, jkolli nuża l-bastun jew il-krozzi.
[] Inkun fis-sodda ħafna u jkolli nitkaxkar sal-kamra tal-banju.

Meta Npoġġi
[] Nista' npoġġi fuq liema siġġu li rrid u għal kemm ħin irrid.
[] Nista' noqgħod biss fis-siġġu favorit tiegħi għal kemm ħin irrid.
[] Minħabba l-uġiegħ ma nistax indum bil-qegħda aktar minn siegħa.
[] Minħabba l-uġiegħ ma nistax indum bil-qegħda aktar minn nofs siegħa.
[] Minħabba l-uġiegħ ma nistax indum bil-qegħda aktar minn aktar għaxar minuti.
[] Minħabba l-uġiegħ ma nistax inpoġġi.

Meta Noqgħod bil-Wieqfa
[] Nista' noqgħod bil-wieqfa kemm irrid mingħajr ma nħoss uġiegħ.
[] Nista' noqgħod bil-wieqfa kemm irrid iżda nħoss l-uġiegħ.
[] Minħabba l-uġiegħ ma nistax indum bil-wieqfa aktar minn siegħa.
[] Minħabba l-uġiegħ ma nistax indum bil-wieqfa aktar minn nofs siegħa.

[] Minħabba l-uġiegħ ma nistax indum bil-wieqfa aktar minn għaxar minuti.
[] Minħabba l-uġiegħ ma nistax noqgħod bil-wieqfa.

L-Irqad
[] Norqod tajjeb tul il-lejl kollu.
[] Norqod tajjeb biss jekk nieħu xi pilloli.
[] Norqod inqas minn sitt siegħat anki jekk nieħu l-pilloli.
[] Norqod inqas minn erba' siegħat anki jekk nieħu l-pilloli.
[] Norqod inqas minn sagħtejn anki jekk nieħu l-pilloli.
[] Minħabba l-uġiegħ ma norqod xejn.

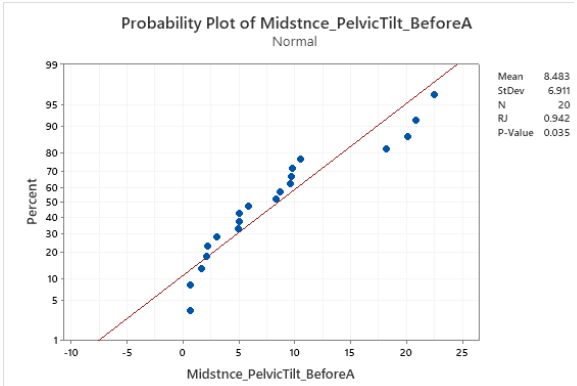
Ħajja Sesswali
[] Il-ħajja sesswali tiegħi hija normali mingħajr ma nħoss uġiegħ.
[] Il-ħajja sesswali tiegħi hija normali iżda nhoss xi uġiegħ.
[] Il-ħajja sesswali tiegħi hija kważi normali iżda nweġġa' ħafna.
[] Il-ħajja sesswali tiegħi hija ristretta ħafna minħabba l-uġiegħ.
[] Il-ħajja sesswali tiegħi kważi ma teżistix minħabba l-uġiegħ.
[] Il-ħajja sesswali tiegħi hija nieqsa għal kollox minħabba l-uġiegħ.

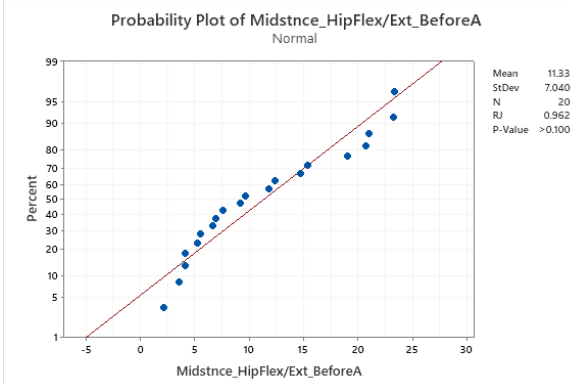
Ħajja Soċjali
[] Il-ħajja soċjali tiegħi hija normali u ma tikkaġunax uġiegħ.
[] Il-ħajja soċjali tiegħi hija normali iżda nħoss xi wġiegħ.
[] Ma nistax nieħu sehem f'affarijiet li jitolbu aktar enerġija e.ż. sport.
[] Ma tantx noħroġ minħabba l-uġiegħ.
[] Inqatta l-ħin tiegħi d-dar minħabba l-uġiegħ.
[] Il-ħajja soċjali tiegħi hija nieqsa għal kollox minħabba l-uġiegħ.

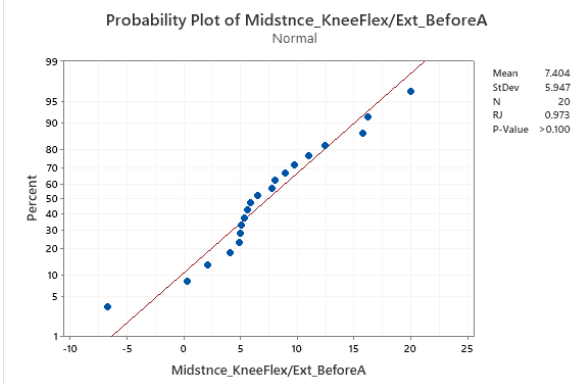
Vjaġġar
[] Nista' nivjaġġa kullimkien mingħajr ma nħoss uġiegħ.
[] Nista' nivjaġġa kullimkien iżda nħoss xi uġiegħ.
[] Kapaci nivjaġġa għal aktar minn sagħtejn iżda nweġġa ħafna.
[] Minħabba l-uġiegħ, ma nistax nivjaġġa aktar minn siegħa.
[] Minħabba l-uġiegħ, ma nistax nivjaġġa aktar minn nofs siegħa.
[] Ma nistax nivjaġġa minħabba l-uġiegħ, ħlief għal kura u terapija.

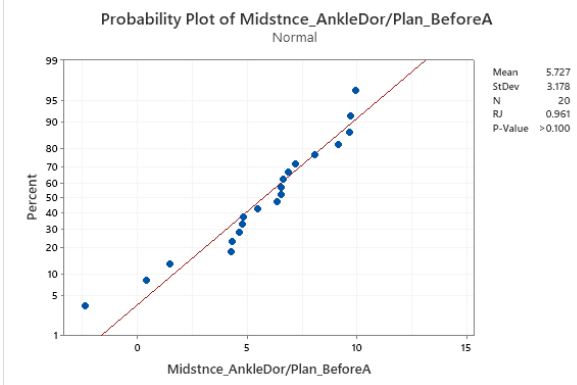
Appendix 7: Normality Testing of Data – Group A Kinematic Data at Midstance

Before

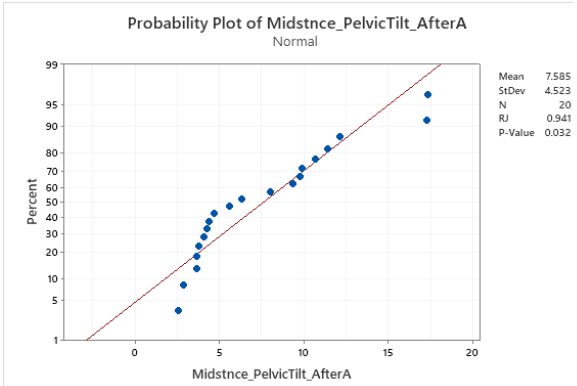


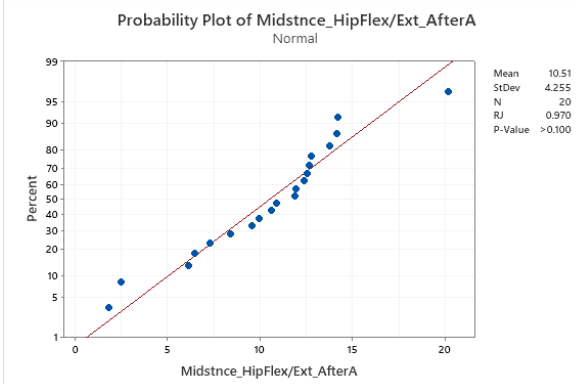


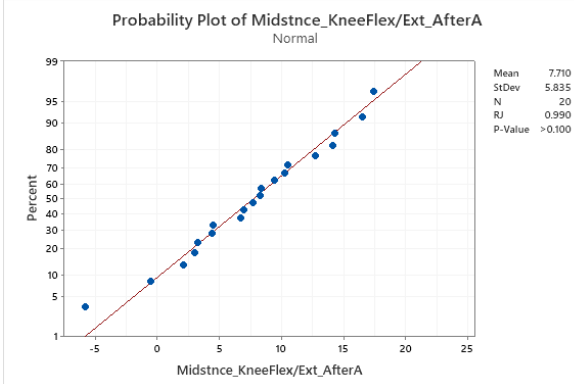


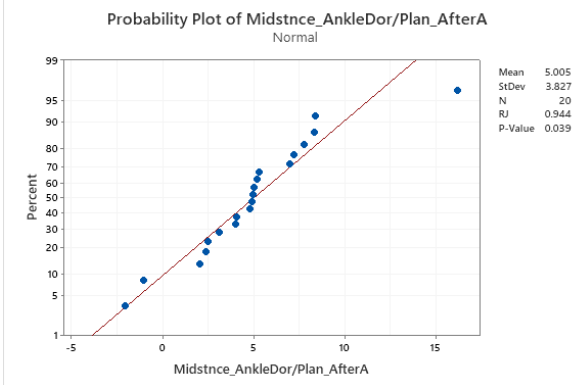


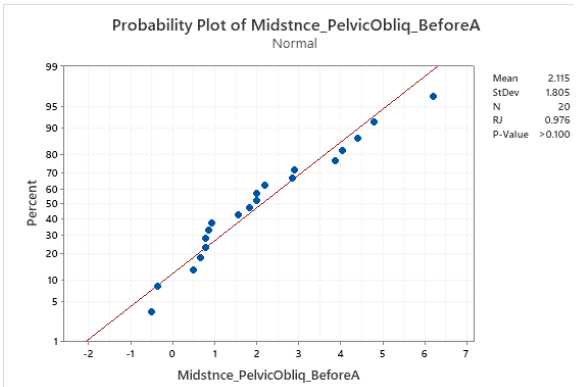
After

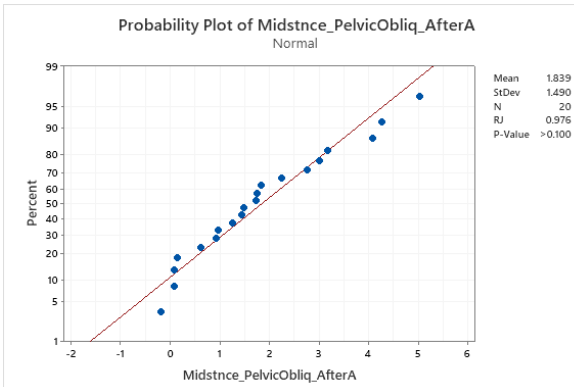


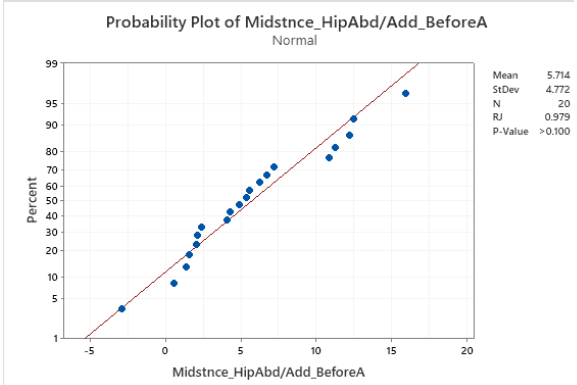


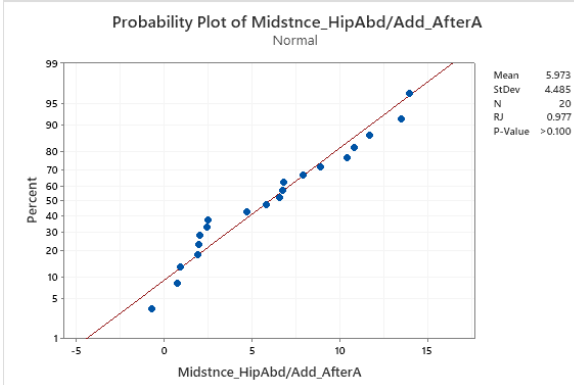


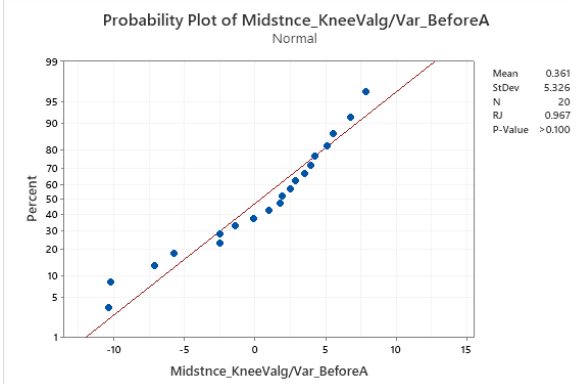


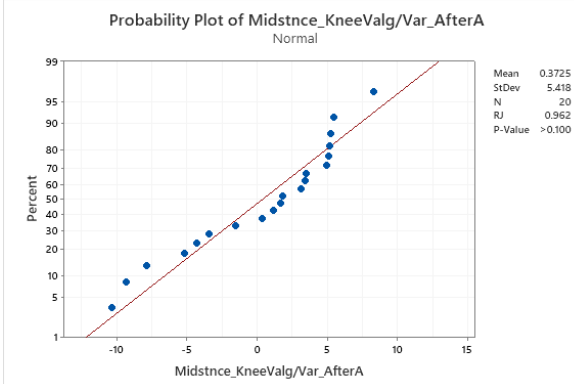

Probability Plot of Midstnce_PelvicObliq_BeforeA
Normal
Mean 2.115
StDev 1.805
N 20
RJ 0.976
P-Value >0.100
Percent
Midstnce_PelvicObliq_BeforeA

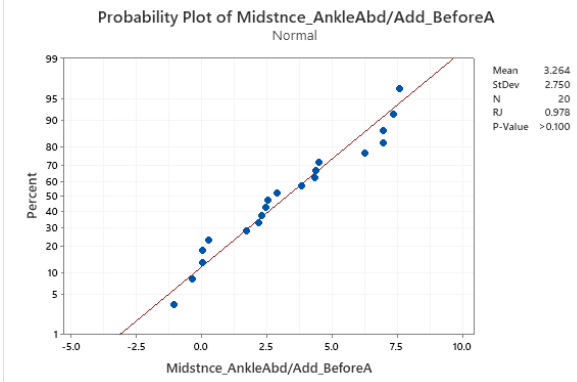

Probability Plot of Midstnce_PelvicObliq_AfterA
Normal
Mean 1.839
StDev 1.490
N 20
RJ 0.976
P-Value >0.100
Percent
Midstnce_PelvicObliq_AfterA

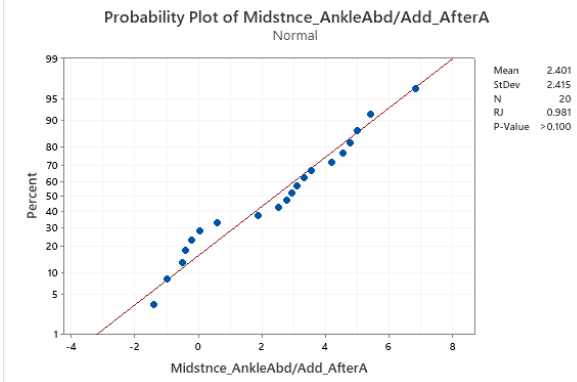

Probability Plot of Midstnce_HipAbd/Add_BeforeA
Normal
Mean 5.714
StDev 4.772
N 20
RJ 0.979
P-Value >0.100
Percent
Midstnce_HipAbd/Add_BeforeA

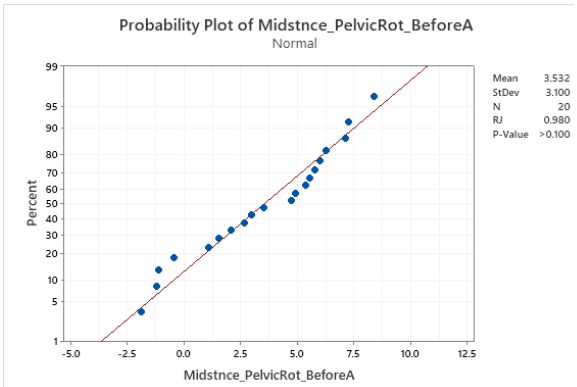

Probability Plot of Midstnce_HipAbd/Add_AfterA
Normal
Mean 5.973
StDev 4.485
N 20
RJ 0.977
P-Value >0.100
Percent
Midstnce_HipAbd/Add_AfterA

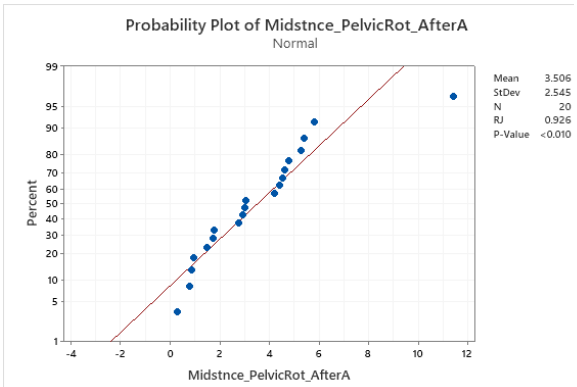

Probability Plot of Midstnce_KneeValg/Var_BeforeA
Normal
Mean 0.361
StDev 5.326
N 20
RJ 0.967
P-Value >0.100
Percent
Midstnce_KneeValg/Var_BeforeA

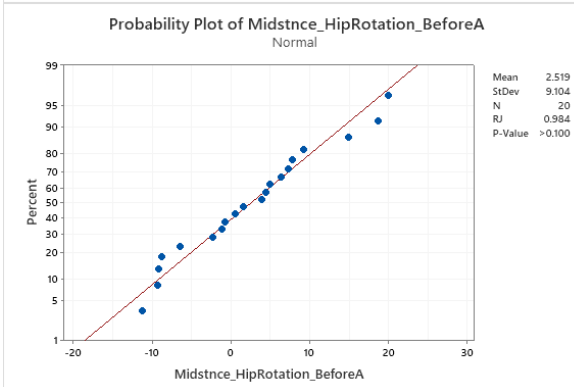

Probability Plot of Midstnce_KneeValg/Var_AfterA
Normal
Mean 0.3725
StDev 5.418
N 20
RJ 0.962
P-Value >0.100
Percent
Midstnce_KneeValg/Var_AfterA

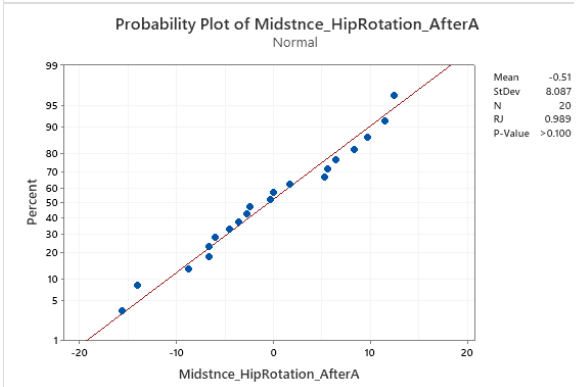

Probability Plot of Midstnce_AnkleAbd/Add_BeforeA
Normal
Mean 3.264
StDev 2.750
N 20
RJ 0.978
P-Value >0.100
Percent
Midstnce_AnkleAbd/Add_BeforeA

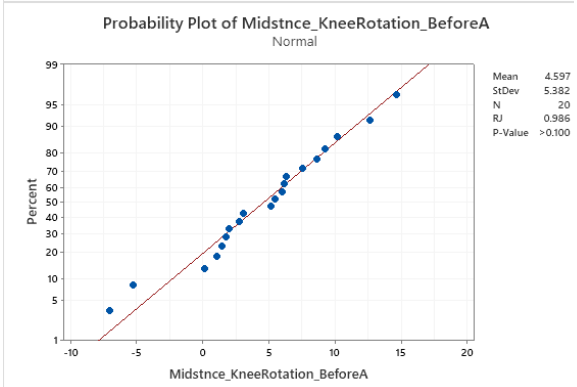

Probability Plot of Midstnce_AnkleAbd/Add_AfterA
Normal
Mean 2.401
StDev 2.415
N 20
RJ 0.981
P-Value >0.100
Percent
Midstnce_AnkleAbd/Add_AfterA

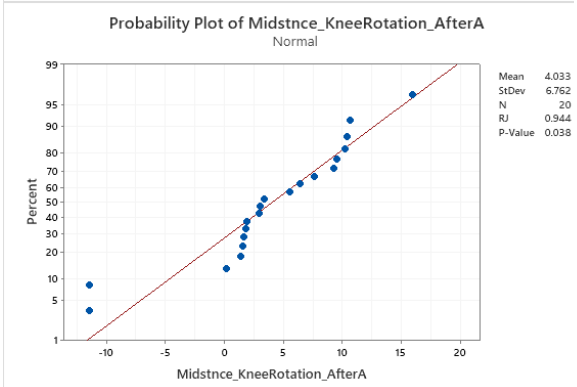

Probability Plot of Midstnce_PelvicRot_BeforeA
Normal
Mean 3.532
StDev 3.100
N 20
RJ 0.980
P-Value >0.100
Percent
Midstnce_PelvicRot_BeforeA

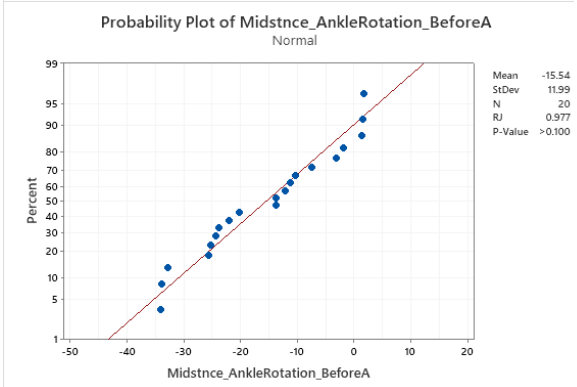

Probability Plot of Midstnce_PelvicRot_AfterA
Normal
Mean 3.506
StDev 2.545
N 20
RJ 0.926
P-Value <0.010
Percent
Midstnce_PelvicRot_AfterA

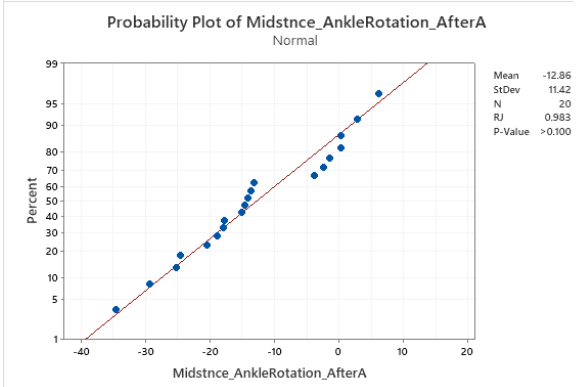

Probability Plot of Midstnce_HipRotation_BeforeA
Normal
Mean 2.519
StDev 9.104
N 20
RJ 0.984
P-Value >0.100
Percent
Midstnce_HipRotation_BeforeA


Probability Plot of Midstnce_HipRotation_AfterA
Normal
Mean -0.51
StDev 8.087
N 20
RJ 0.989
P-Value >0.100
Percent
Midstnce_HipRotation_AfterA


Probability Plot of Midstnce_KneeRotation_BeforeA
Normal
Mean 4.597
StDev 5.382
N 20
RJ 0.986
P-Value >0.100
Percent
Midstnce_KneeRotation_BeforeA


Probability Plot of Midstnce_KneeRotation_AfterA
Normal
Mean 4.033
StDev 6.762
N 20
RJ 0.944
P-Value 0.038
Percent
Midstnce_KneeRotation_AfterA

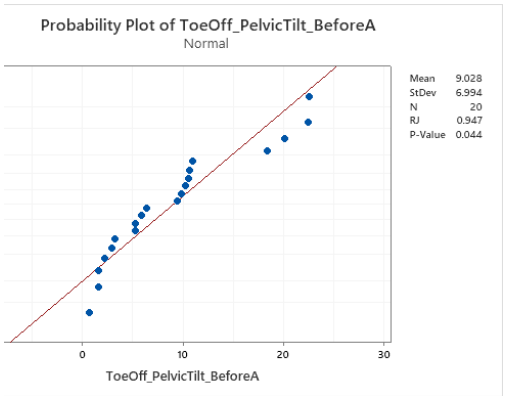

Probability Plot of Midstnce_AnkleRotation_BeforeA
Normal
Mean -15.54
StDev 11.99
N 20
RJ 0.977
P-Value >0.100
Percent
Midstnce_AnkleRotation_BeforeA

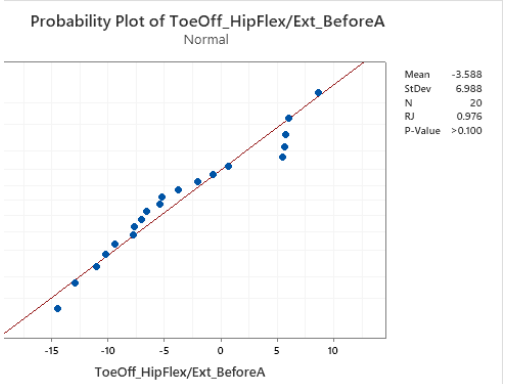

Probability Plot of Midstnce_AnkleRotation_AfterA
Normal
Mean -12.86
StDev 11.42
N 20
RJ 0.983
P-Value >0.100
Percent
Midstnce_AnkleRotation_AfterA

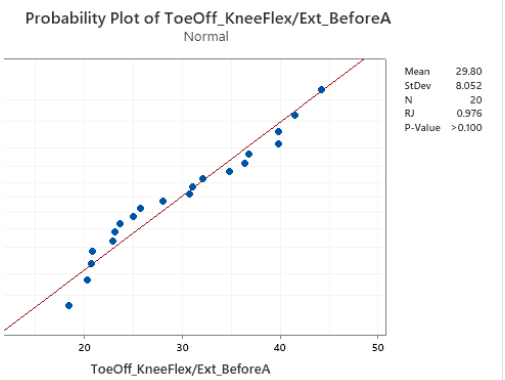
	Before			After		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.035	Yes	Rejected	0.032	Yes	Rejected
Hip Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Knee Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Dorsi/Plantar	>0.1	No	Accepted	0.039	Yes	Rejected
Pelvic Obliquity	>0.1	No	Accepted	>0.1	No	Accepted
Hip Abd/Add	>0.1	No	Accepted	>0.1	No	Accepted
Knee Valg/Var	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Abd/Add	>0.1	No	Accepted	>0.1	No	Accepted
Pelvic Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Hip Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Knee Rotation	>0.1	No	Accepted	0.038	Yes	Rejected
Ankle Rotation	>0.1	No	Accepted	>0.1	No	Accepted

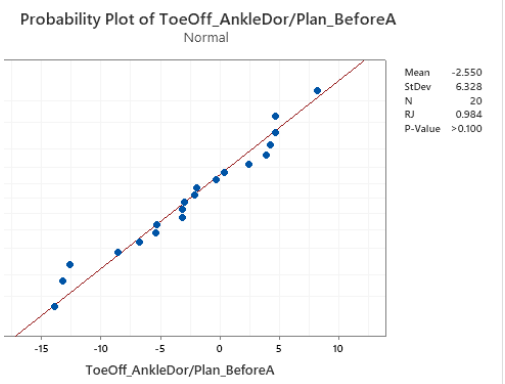
Appendix 8: Normality Testing of Data – Group A Kinematic Data at Toe Off

Before

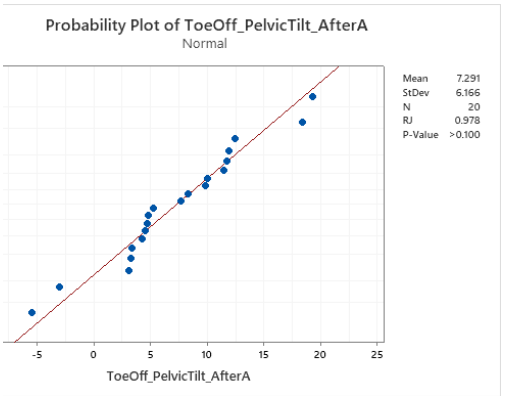


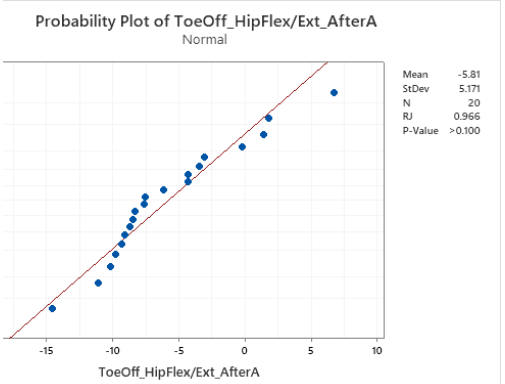


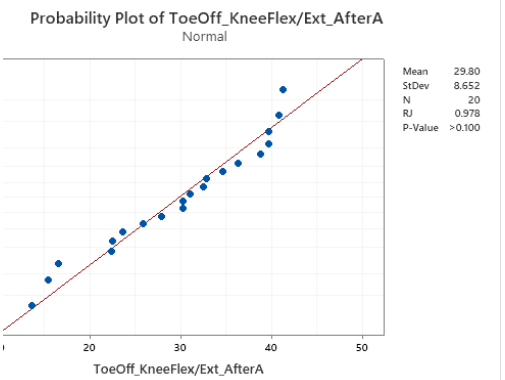


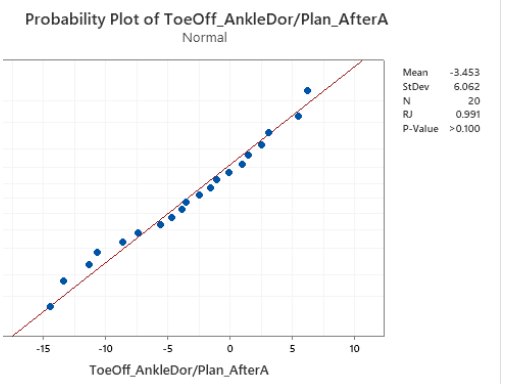


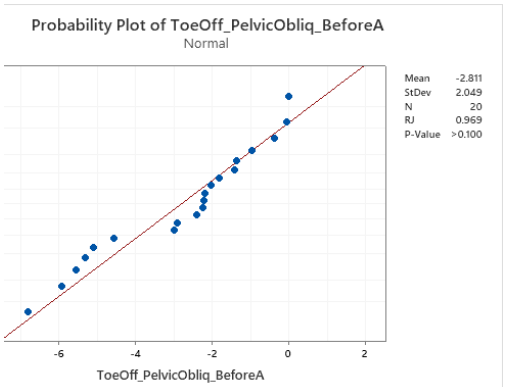
After

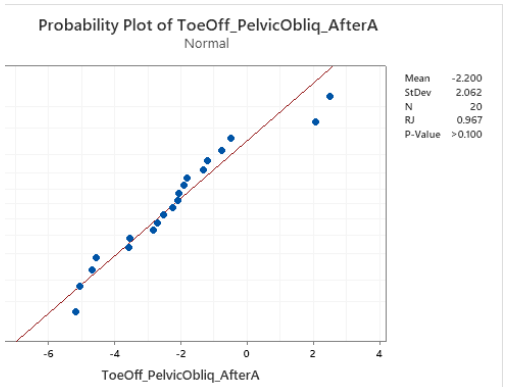


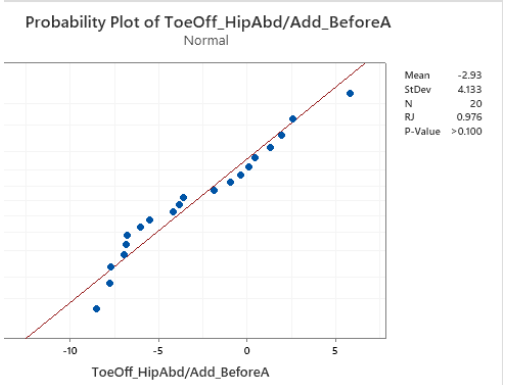


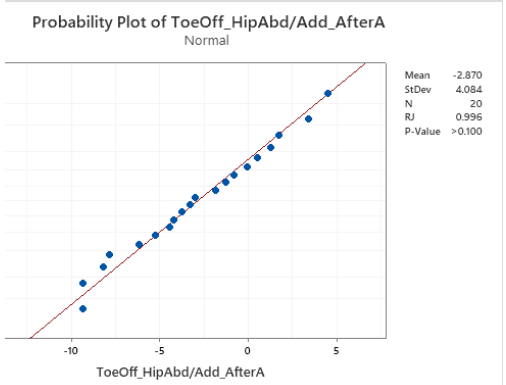


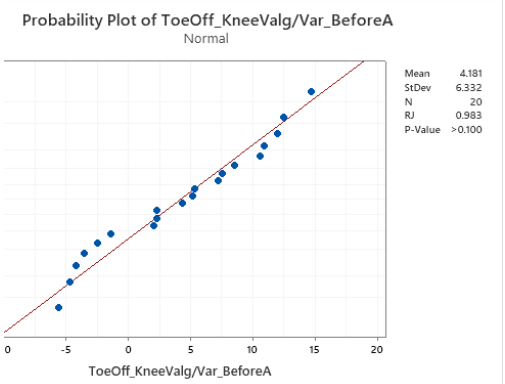


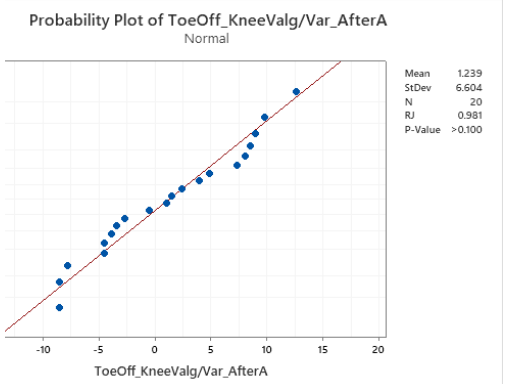

Probability Plot of ToeOff_PelvicObliq_BeforeA
Normal
Mean -2.811
StDev 2.049
N 20
RJ 0.969
P-Value >0.100
-6
-4
-2
0
2
ToeOff_PelvicObliq_BeforeA

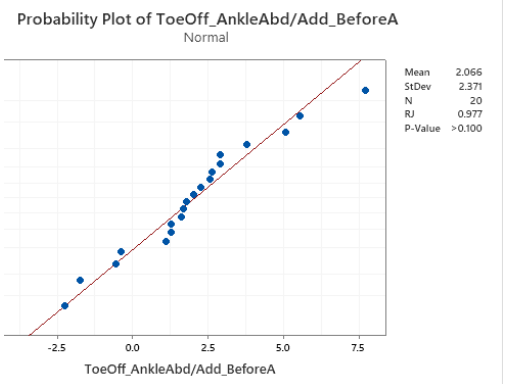

Probability Plot of ToeOff_PelvicObliq_AfterA
Normal
Mean -2.200
StDev 2.062
N 20
RJ 0.967
P-Value >0.100
-6
-4
-2
0
2
4
ToeOff_PelvicObliq_AfterA

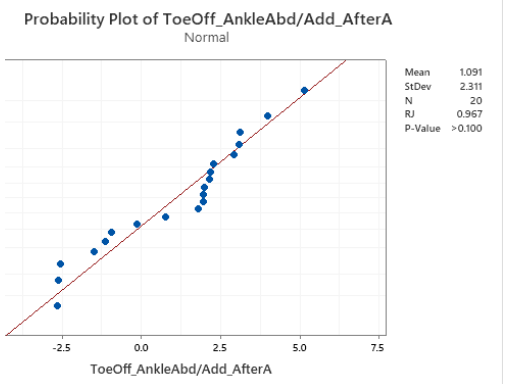

Probability Plot of ToeOff_HipAbd/Add_BeforeA
Normal
Mean -2.93
StDev 4.133
N 20
RJ 0.976
P-Value >0.100
-10
-5
0
5
ToeOff_HipAbd/Add_BeforeA

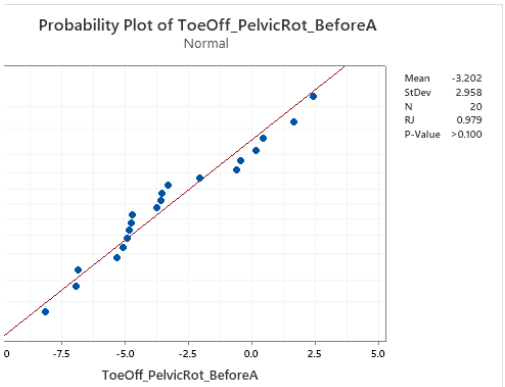

Probability Plot of ToeOff_HipAbd/Add_AfterA
Normal
Mean -2.870
StDev 4.084
N 20
RJ 0.996
P-Value >0.100
-10
-5
0
5
ToeOff_HipAbd/Add_AfterA

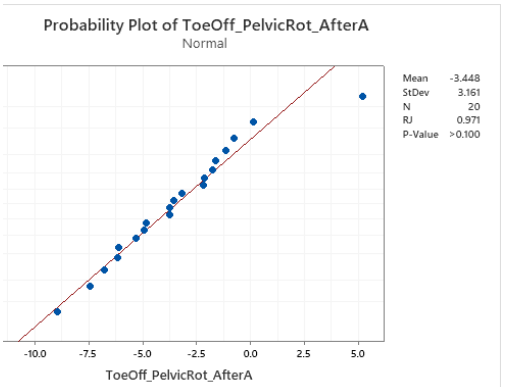

Probability Plot of ToeOff_KneeValg/Var_BeforeA
Normal
Mean 4.181
StDev 6.332
N 20
RJ 0.983
P-Value >0.100
0
-5
0
5
10
15
20
ToeOff_KneeValg/Var_BeforeA

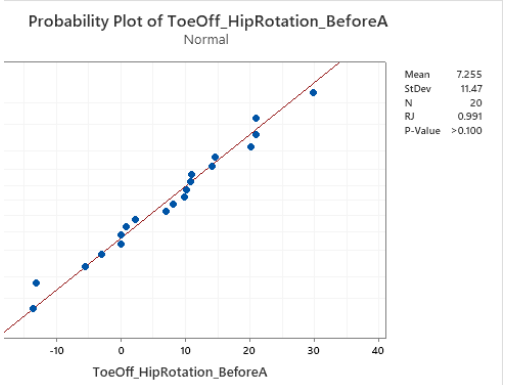

Probability Plot of ToeOff_KneeValg/Var_AfterA
Normal
Mean 1.239
StDev 6.604
N 20
RJ 0.981
P-Value >0.100
-10
-5
0
5
10
15
20
ToeOff_KneeValg/Var_AfterA

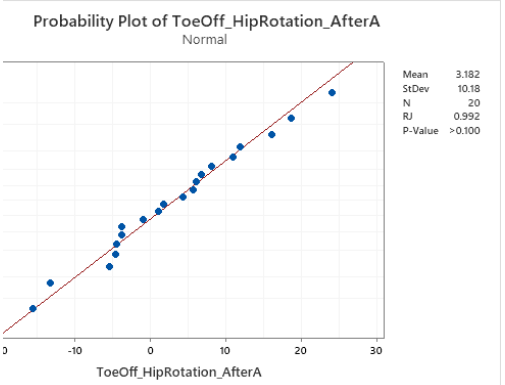

Probability Plot of ToeOff_AnkleAbd/Add_BeforeA
Normal
Mean 2.066
StDev 2.371
N 20
RJ 0.977
P-Value >0.100
-2.5
0.0
2.5
5.0
7.5
ToeOff_AnkleAbd/Add_BeforeA

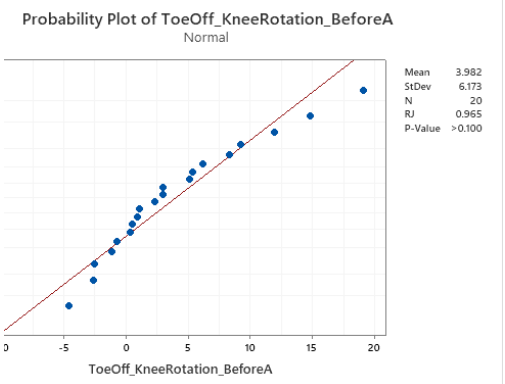

Probability Plot of ToeOff_AnkleAbd/Add_AfterA
Normal
Mean 1.091
StDev 2.311
N 20
RJ 0.967
P-Value >0.100
-2.5
0.0
2.5
5.0
7.5
ToeOff_AnkleAbd/Add_AfterA

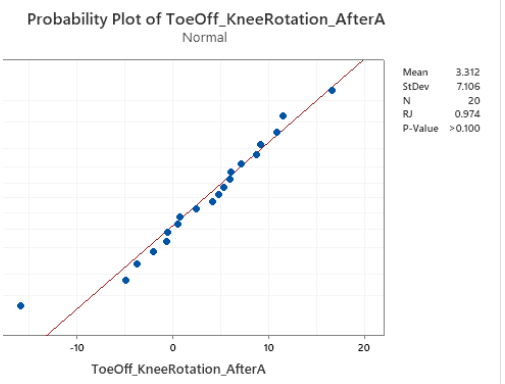

Probability Plot of ToeOff_PelvicRot_BeforeA
Normal
Mean -3.202
StDev 2.958
N 20
RJ 0.979
P-Value >0.100
ToeOff_PelvicRot_BeforeA

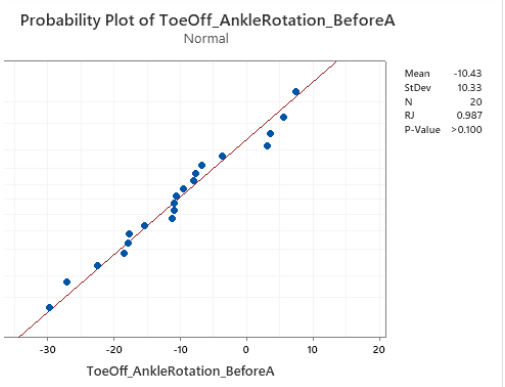

Probability Plot of ToeOff_PelvicRot_AfterA
Normal
Mean -3.448
StDev 3.161
N 20
RJ 0.971
P-Value >0.100
ToeOff_PelvicRot_AfterA

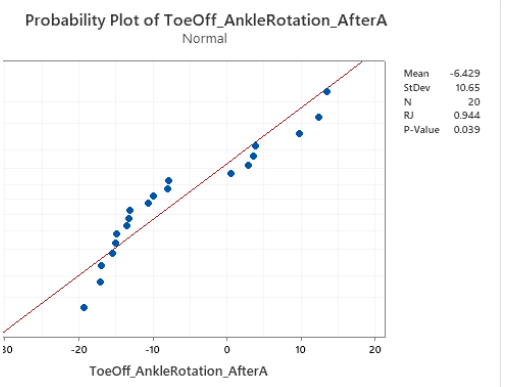

Probability Plot of ToeOff_HipRotation_BeforeA
Normal
Mean 7.255
StDev 11.47
N 20
RJ 0.991
P-Value >0.100
ToeOff_HipRotation_BeforeA


Probability Plot of ToeOff_HipRotation_AfterA
Normal
Mean 3.182
StDev 10.18
N 20
RJ 0.992
P-Value >0.100
ToeOff_HipRotation_AfterA


Probability Plot of ToeOff_KneeRotation_BeforeA
Normal
Mean 3.982
StDev 6.173
N 20
RJ 0.965
P-Value >0.100
ToeOff_KneeRotation_BeforeA


Probability Plot of ToeOff_KneeRotation_AfterA
Normal
Mean 3.312
StDev 7.106
N 20
RJ 0.974
P-Value >0.100
ToeOff_KneeRotation_AfterA

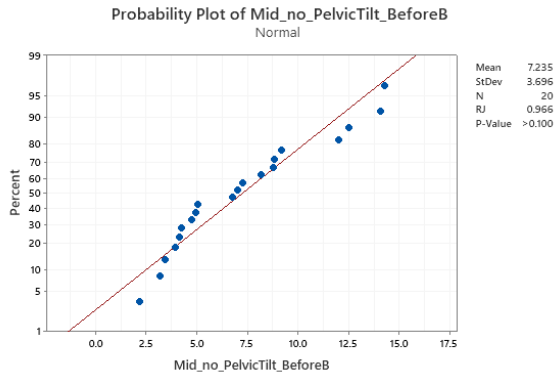

Probability Plot of ToeOff_AnkleRotation_BeforeA
Normal
Mean -10.43
StDev 10.33
N 20
RJ 0.987
P-Value >0.100
ToeOff_AnkleRotation_BeforeA

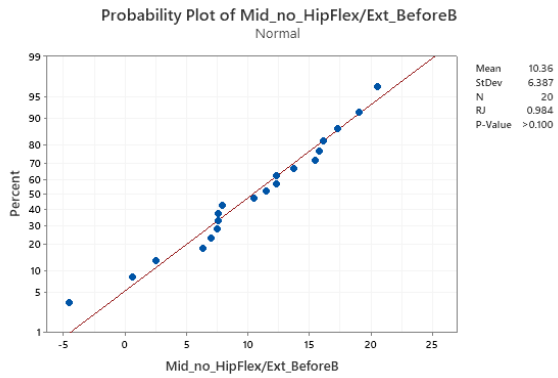

Probability Plot of ToeOff_AnkleRotation_AfterA
Normal
Mean -6.429
StDev 10.65
N 20
RJ 0.944
P-Value 0.039
ToeOff_AnkleRotation_AfterA

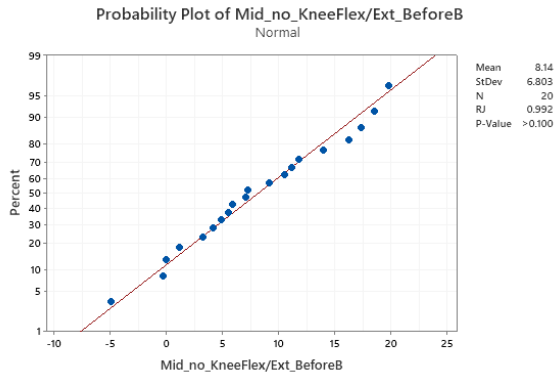
	Before			After		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.044	Yes	Rejected	>0.1	No	Accepted
Hip Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Knee Flex/Ext	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Dorsi/Plantar	>0.1	No	Accepted	>0.1	No	Accepted
Pelvic Obliquity	>0.1	No	Accepted	>0.1	No	Accepted
Hip Abd/Add	>0.1	No	Accepted	>0.1	No	Accepted
Knee Valg/Var	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Abd/Add	>0.1	No	Accepted	>0.1	No	Accepted
Pelvic Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Hip Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Knee Rotation	>0.1	No	Accepted	>0.1	No	Accepted
Ankle Rotation	>0.1	No	Accepted	0.039	Yes	Rejected

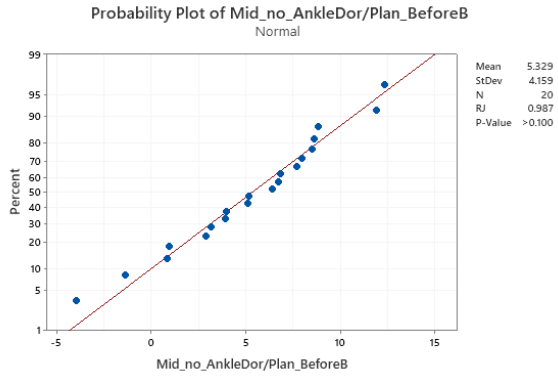
Appendix 9: Normality Testing of Data – Group B Kinematic Data at Midstance

Before without Insoles

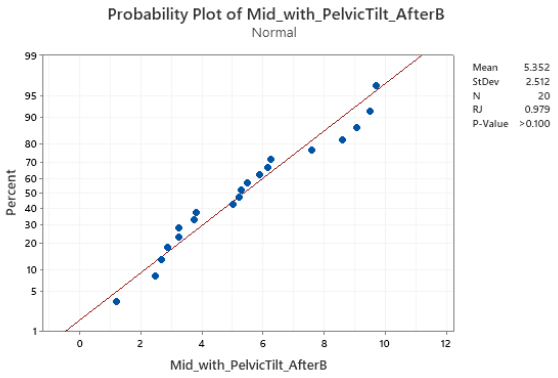


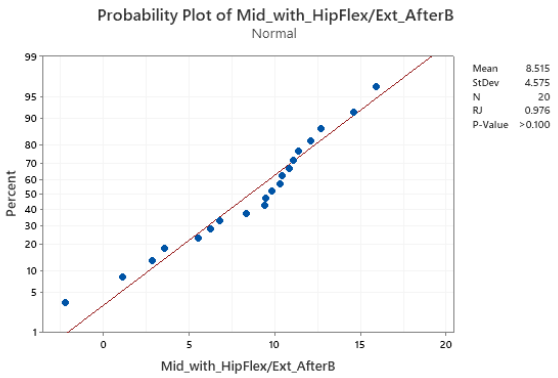


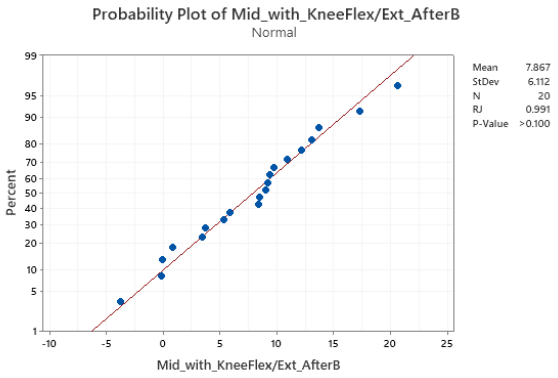


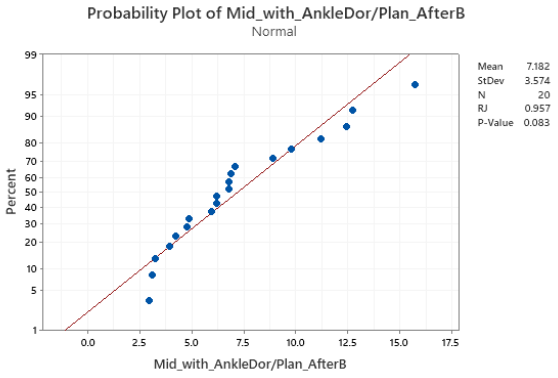


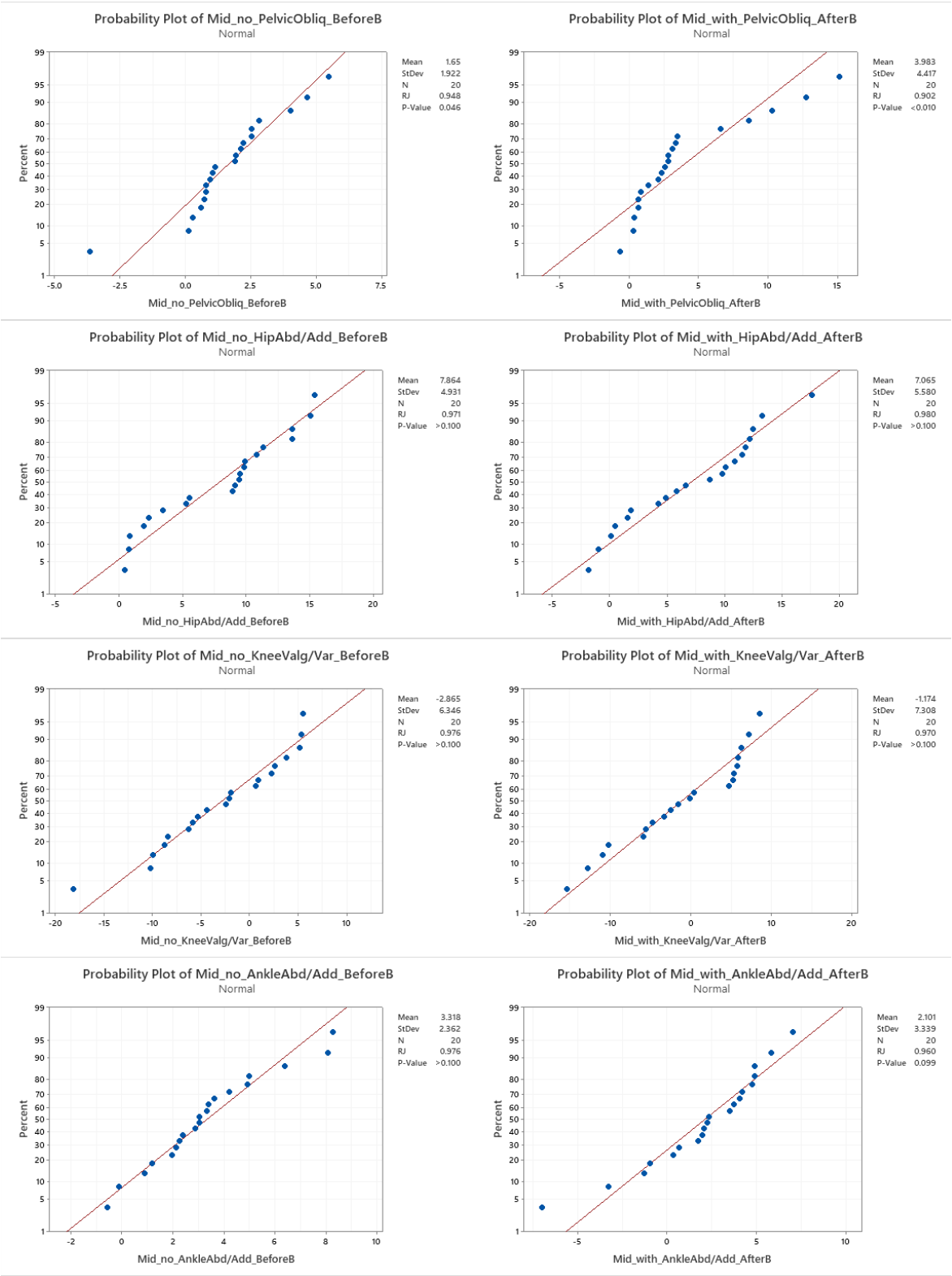
After with Insoles

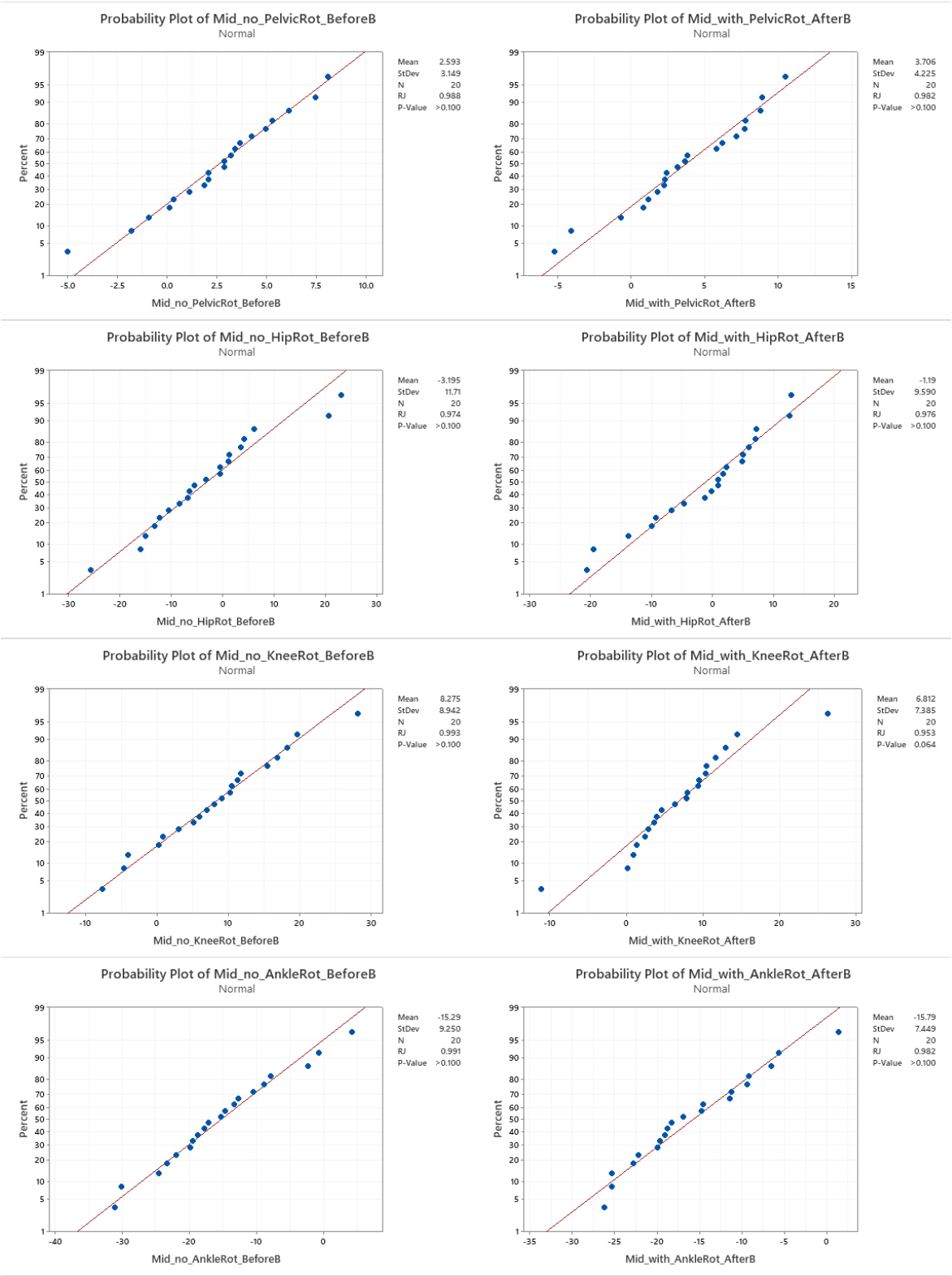








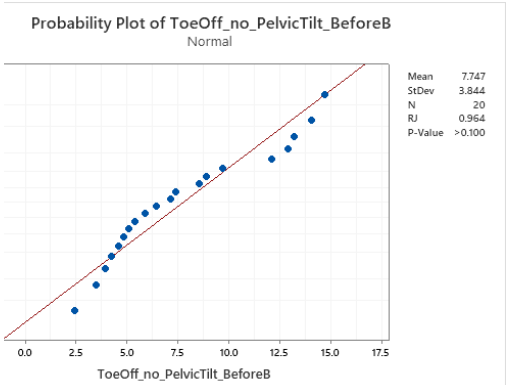

Probability Plot of Mid_no_PelvicObliq_BeforeB
Normal
Mean 1.65
StDev 1.922
N 20
RJ 0.948
P-Value 0.046
Percent
Mid_no_PelvicObliq_BeforeB
Probability Plot of Mid_with_PelvicObliq_AfterB
Normal
Mean 3.983
StDev 4.417
N 20
RJ 0.902
P-Value <0.010
Percent
Mid_with_PelvicObliq_AfterB
Probability Plot of Mid_no_HipAbd/Add_BeforeB
Normal
Mean 7.864
StDev 4.931
N 20
RJ 0.971
P-Value >0.100
Percent
Mid_no_HipAbd/Add_BeforeB
Probability Plot of Mid_with_HipAbd/Add_AfterB
Normal
Mean 7.065
StDev 5.580
N 20
RJ 0.980
P-Value >0.100
Percent
Mid_with_HipAbd/Add_AfterB
Probability Plot of Mid_no_KneeValg/Var_BeforeB
Normal
Mean -2.865
StDev 6.346
N 20
RJ 0.976
P-Value >0.100
Percent
Mid_no_KneeValg/Var_BeforeB
Probability Plot of Mid_with_KneeValg/Var_AfterB
Normal
Mean -1.174
StDev 7.308
N 20
RJ 0.970
P-Value >0.100
Percent
Mid_with_KneeValg/Var_AfterB
Probability Plot of Mid_no_AnkleAbd/Add_BeforeB
Normal
Mean 3.318
StDev 2.362
N 20
RJ 0.976
P-Value >0.100
Percent
Mid_no_AnkleAbd/Add_BeforeB
Probability Plot of Mid_with_AnkleAbd/Add_AfterB
Normal
Mean 2.101
StDev 3.339
N 20
RJ 0.960
P-Value 0.099
Percent
Mid_with_AnkleAbd/Add_AfterB

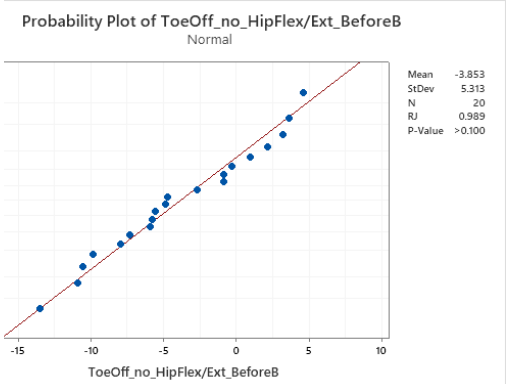

Probability Plot of Mid_no_PelvicRot_BeforeB
Normal
Mean 2.593
StDev 3.149
N 20
RJ 0.988
P-Value >0.100
Percent
Mid_no_PelvicRot_BeforeB
Probability Plot of Mid_with_PelvicRot_AfterB
Normal
Mean 3.706
StDev 4.225
N 20
RJ 0.982
P-Value >0.100
Percent
Mid_with_PelvicRot_AfterB
Probability Plot of Mid_no_HipRot_BeforeB
Normal
Mean -3.195
StDev 11.71
N 20
RJ 0.974
P-Value >0.100
Percent
Mid_no_HipRot_BeforeB
Probability Plot of Mid_with_HipRot_AfterB
Normal
Mean -1.19
StDev 9.590
N 20
RJ 0.976
P-Value >0.100
Percent
Mid_with_HipRot_AfterB
Probability Plot of Mid_no_KneeRot_BeforeB
Normal
Mean 8.275
StDev 8.942
N 20
RJ 0.993
P-Value >0.100
Percent
Mid_no_KneeRot_BeforeB
Probability Plot of Mid_with_KneeRot_AfterB
Normal
Mean 6.812
StDev 7.385
N 20
RJ 0.953
P-Value 0.064
Percent
Mid_with_KneeRot_AfterB
Probability Plot of Mid_no_AnkleRot_BeforeB
Normal
Mean -15.29
StDev 9.250
N 20
RJ 0.991
P-Value >0.100
Percent
Mid_no_AnkleRot_BeforeB
Probability Plot of Mid_with_AnkleRot_AfterB
Normal
Mean -15.79
StDev 7.449
N 20
RJ 0.982
P-Value >0.100
Percent
Mid_with_AnkleRot_AfterB

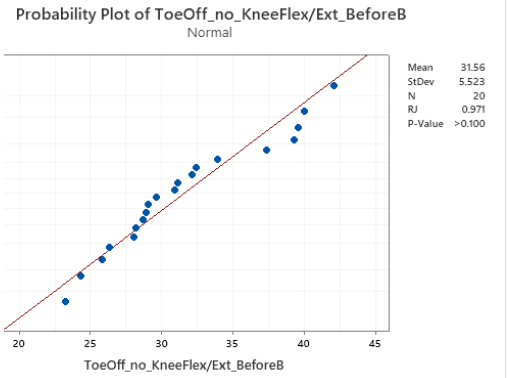
	Before without Insoles			After with insoles		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	>0.1	no	Accepted	>0.1	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Dorsi/Plantar	>0.1	no	Accepted	0.083	no	Accepted
Pelvic Obliquity	0.046	yes	Rejected	<0.01	yes	Rejected
Hip Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Knee Valg/Var	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Abd/Add	>0.1	no	Accepted	0.099	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Hip Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Knee Rotation	>0.1	no	Accepted	0.064	no	Accepted
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

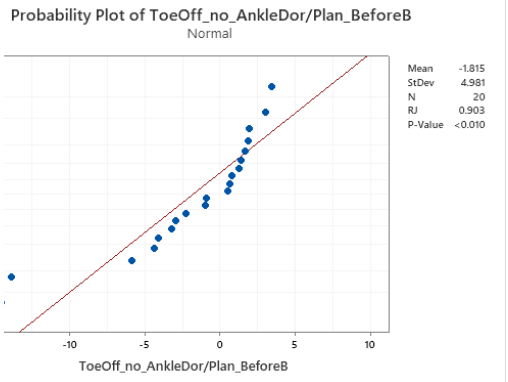
Appendix 10: Normality Testing of Data – Group B Kinematic Data at Toe Off

Before without Insoles

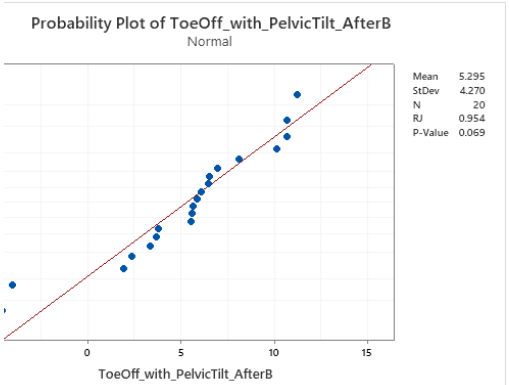


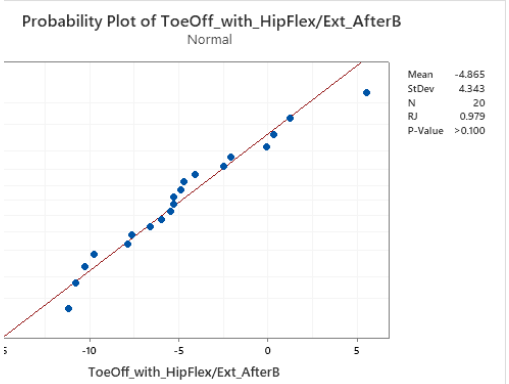


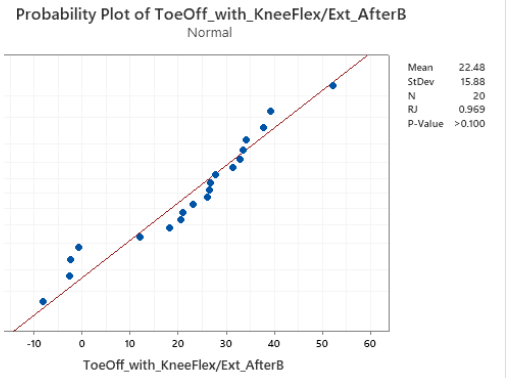


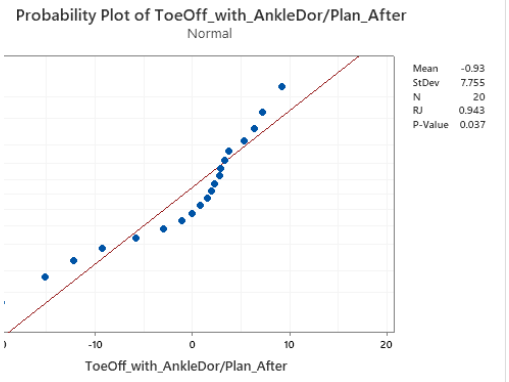


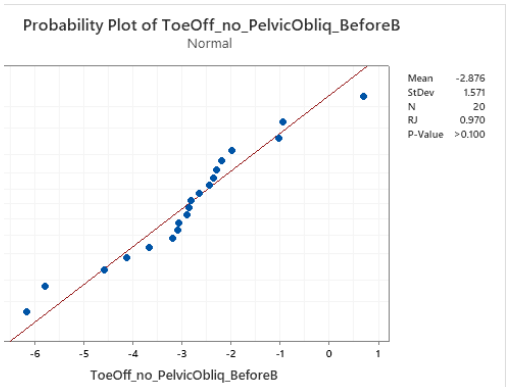
After with Insoles

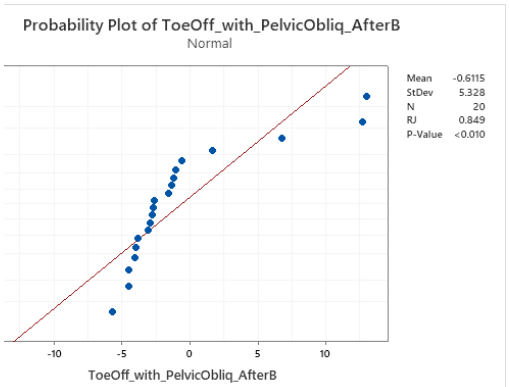


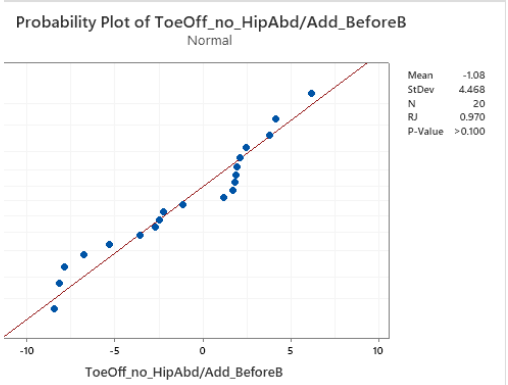


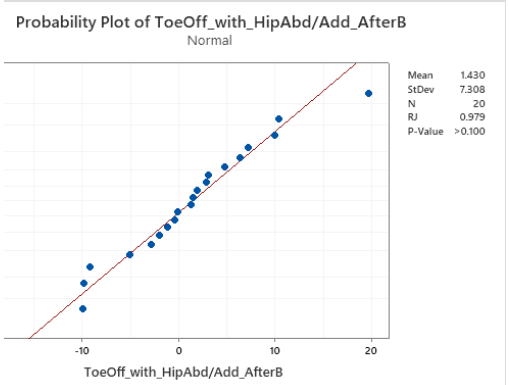


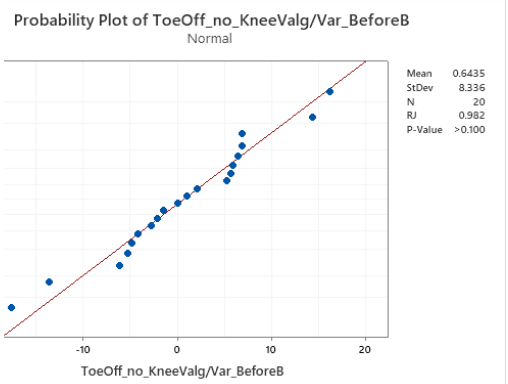


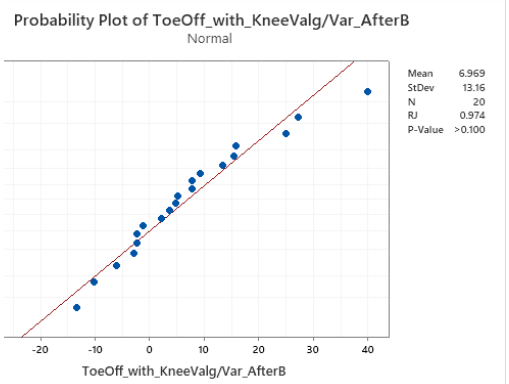

Probability Plot of ToeOff_no_PelvicObliq_BeforeB
Normal
Mean -2.876
StDev 1.571
N 20
RJ 0.970
P-Value >0.100
-6 -5 -4 -3 -2 -1 0 1
ToeOff_no_PelvicObliq_BeforeB

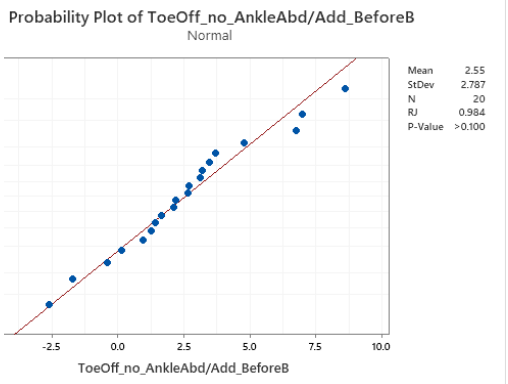

Probability Plot of ToeOff_with_PelvicObliq_AfterB
Normal
Mean -0.6115
StDev 5.328
N 20
RJ 0.849
P-Value <0.010
-10 -5 0 5 10
ToeOff_with_PelvicObliq_AfterB

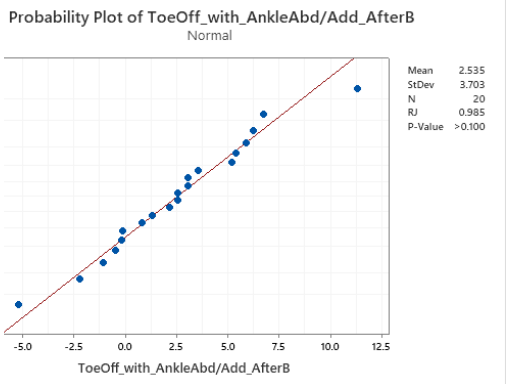

Probability Plot of ToeOff_no_HipAbd/Add_BeforeB
Normal
Mean -1.08
StDev 4.468
N 20
RJ 0.970
P-Value >0.100
-10 -5 0 5 10
ToeOff_no_HipAbd/Add_BeforeB

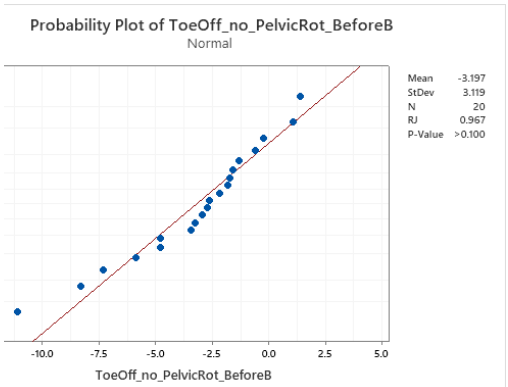

Probability Plot of ToeOff_with_HipAbd/Add_AfterB
Normal
Mean 1.430
StDev 7.308
N 20
RJ 0.979
P-Value >0.100
-10 0 10 20
ToeOff_with_HipAbd/Add_AfterB

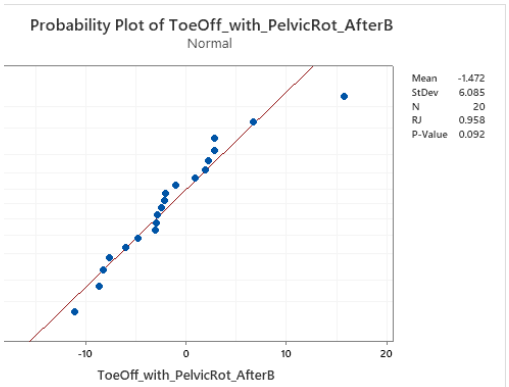

Probability Plot of ToeOff_no_KneeValg/Var_BeforeB
Normal
Mean 0.6435
StDev 8.336
N 20
RJ 0.982
P-Value >0.100
-10 0 10 20
ToeOff_no_KneeValg/Var_BeforeB

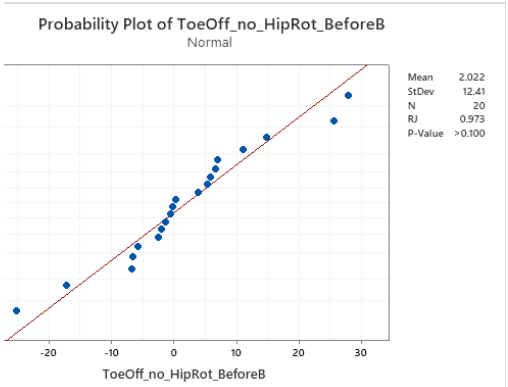

Probability Plot of ToeOff_with_KneeValg/Var_AfterB
Normal
Mean 6.969
StDev 13.16
N 20
RJ 0.974
P-Value >0.100
-20 -10 0 10 20 30 40
ToeOff_with_KneeValg/Var_AfterB

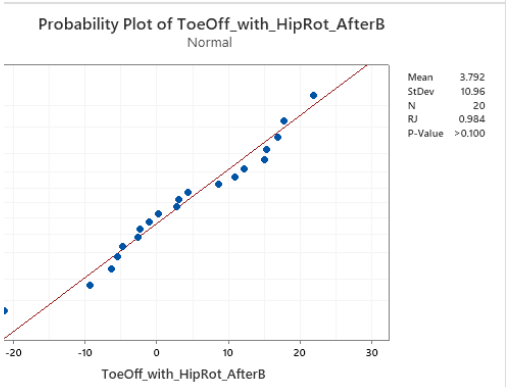

Probability Plot of ToeOff_no_AnkleAbd/Add_BeforeB
Normal
Mean 2.55
StDev 2.787
N 20
RJ 0.984
P-Value >0.100
-2.5 0.0 2.5 5.0 7.5 10.0
ToeOff_no_AnkleAbd/Add_BeforeB

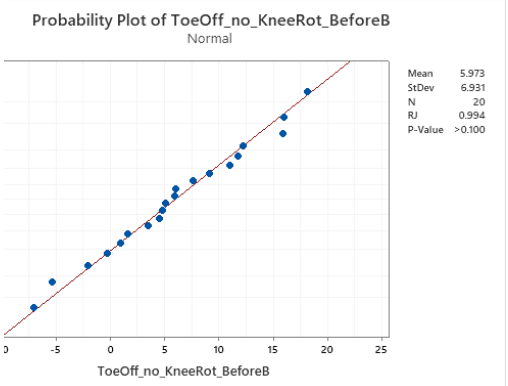

Probability Plot of ToeOff_with_AnkleAbd/Add_AfterB
Normal
Mean 2.535
StDev 3.703
N 20
RJ 0.985
P-Value >0.100
-5.0 -2.5 0.0 2.5 5.0 7.5 10.0 12.5
ToeOff_with_AnkleAbd/Add_AfterB

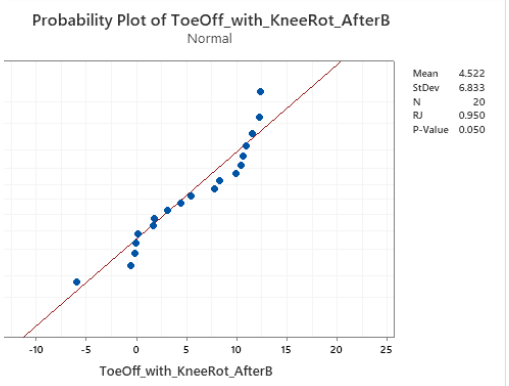

Probability Plot of ToeOff_no_PelvicRot_BeforeB
Normal
Mean -3.197
StDev 3.119
N 20
RJ 0.967
P-Value >0.100
-10.0 -7.5 -5.0 -2.5 0.0 2.5 5.0
ToeOff_no_PelvicRot_BeforeB

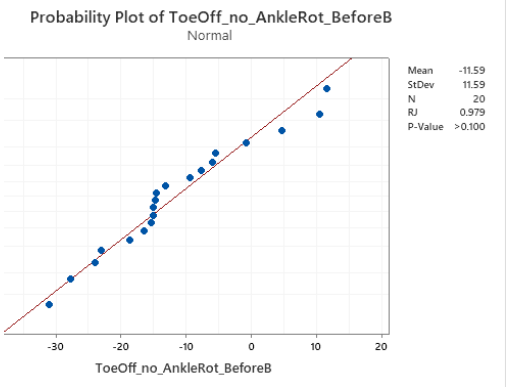

Probability Plot of ToeOff_with_PelvicRot_AfterB
Normal
Mean -1.472
StDev 6.085
N 20
RJ 0.958
P-Value 0.092
-10 0 10 20
ToeOff_with_PelvicRot_AfterB

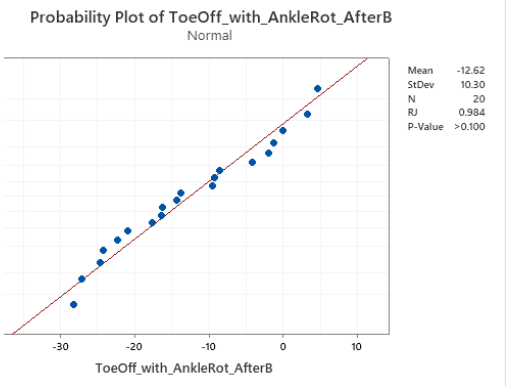

Probability Plot of ToeOff_no_HipRot_BeforeB
Normal
Mean 2.022
StDev 12.41
N 20
RJ 0.973
P-Value >0.100
-20 -10 0 10 20 30
ToeOff_no_HipRot_BeforeB


Probability Plot of ToeOff_with_HipRot_AfterB
Normal
Mean 3.792
StDev 10.96
N 20
RJ 0.984
P-Value >0.100
-20 -10 0 10 20 30
ToeOff_with_HipRot_AfterB


Probability Plot of ToeOff_no_KneeRot_BeforeB
Normal
Mean 5.973
StDev 6.931
N 20
RJ 0.994
P-Value >0.100
-5 0 5 10 15 20 25
ToeOff_no_KneeRot_BeforeB


Probability Plot of ToeOff_with_KneeRot_AfterB
Normal
Mean 4.522
StDev 6.833
N 20
RJ 0.950
P-Value 0.050
-10 -5 0 5 10 15 20 25
ToeOff_with_KneeRot_AfterB

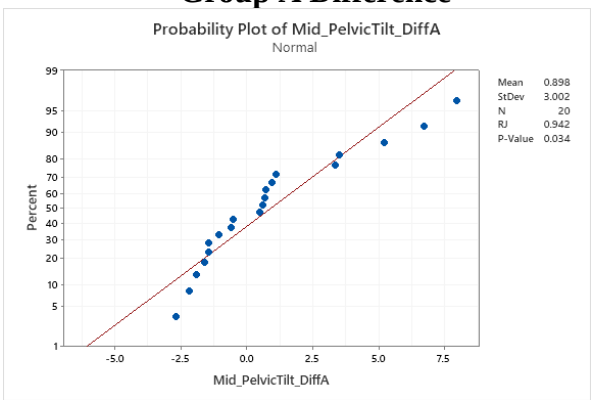

Probability Plot of ToeOff_no_AnkleRot_BeforeB
Normal
Mean -11.59
StDev 11.59
N 20
RJ 0.979
P-Value >0.100
-30 -20 -10 0 10 20
ToeOff_no_AnkleRot_BeforeB

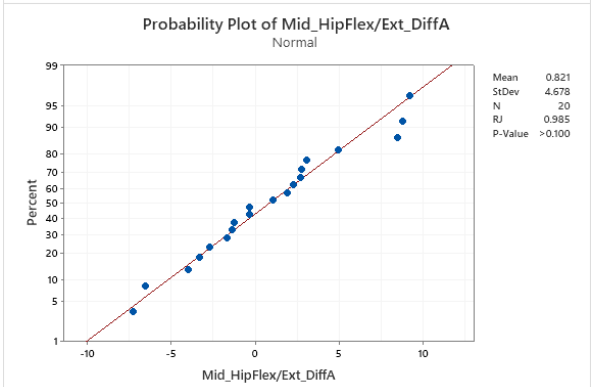

Probability Plot of ToeOff_with_AnkleRot_AfterB
Normal
Mean -12.62
StDev 10.30
N 20
RJ 0.984
P-Value >0.100
-30 -20 -10 0 10
ToeOff_with_AnkleRot_AfterB

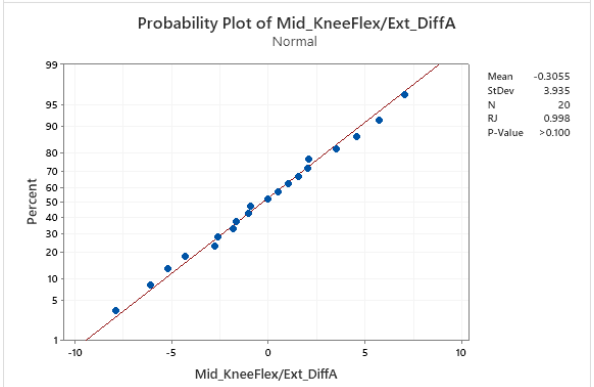
	Before without Insoles			After with insoles		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	>0.1	no	Accepted	0.069	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Dorsi/Plantar	<0.01	yes	Rejected	0.037	yes	Rejected
Pelvic Obliquity	>0.1	no	Accepted	<0.01	yes	Rejected
Hip Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Knee Valg/Var	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	0.092	no	Accepted
Hip Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Knee Rotation	>0.1	no	Accepted	0.05	no	Accepted
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

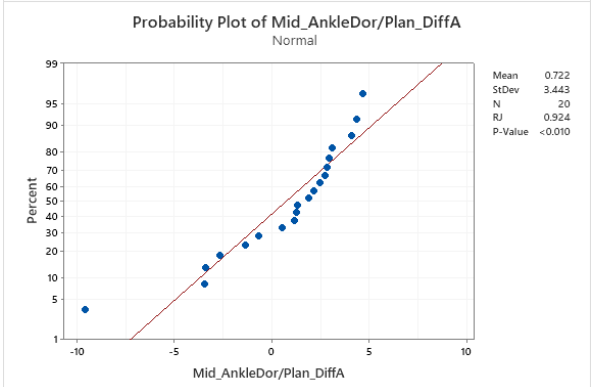
Appendix 11: Normality Testing of Data – Group A and B Difference at Midstance

Group A Difference

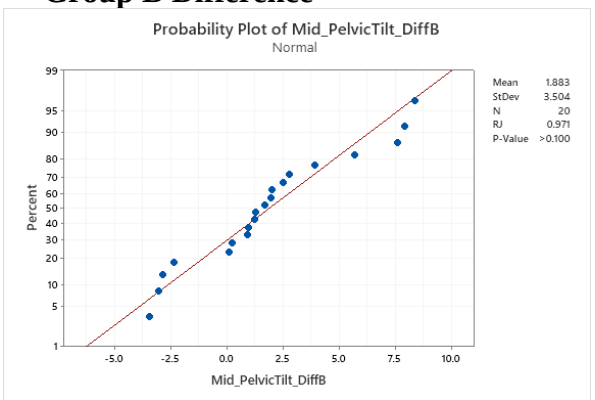


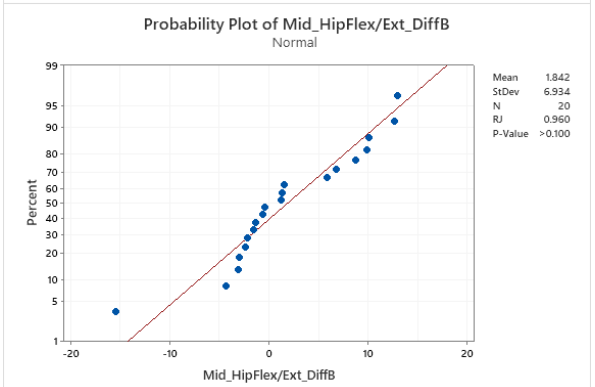


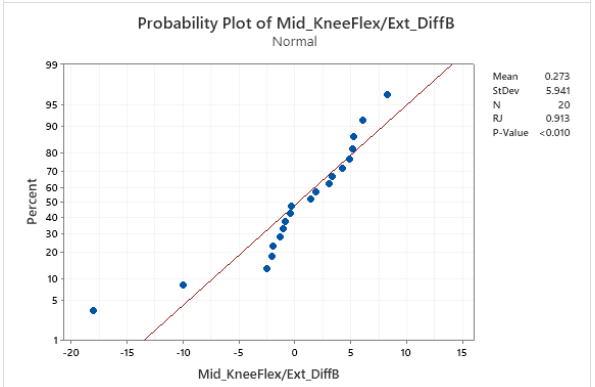


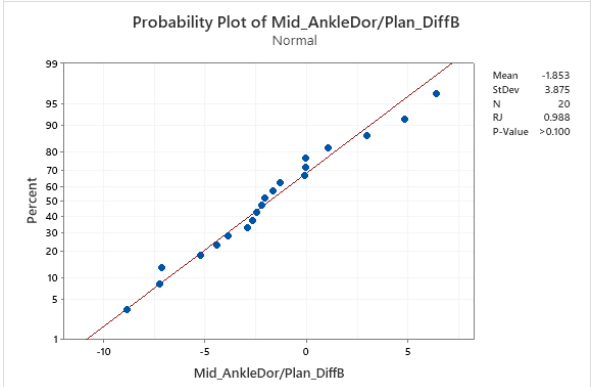


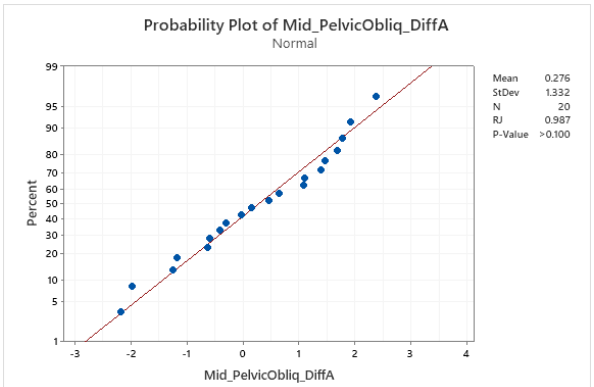
Group B Difference

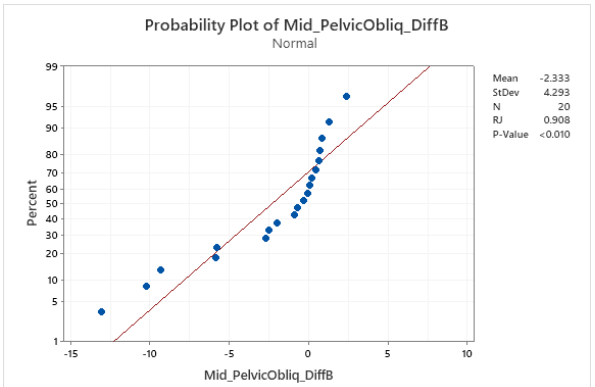


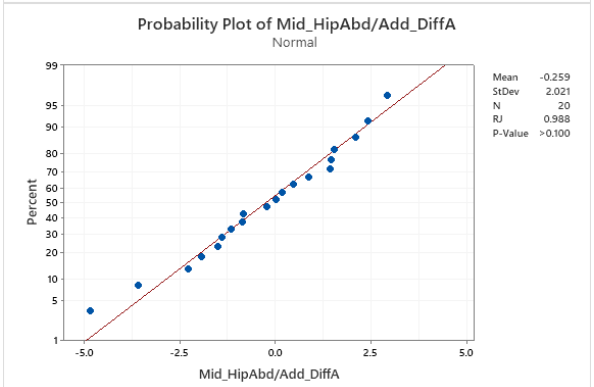


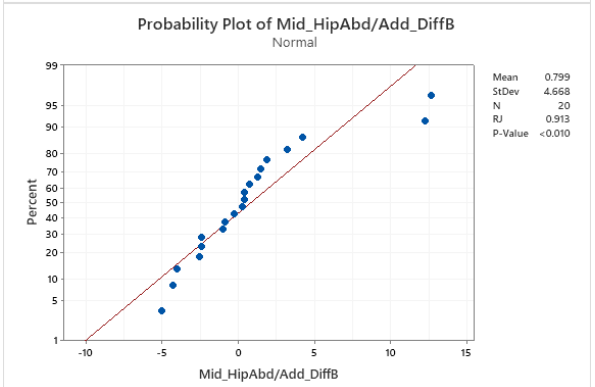


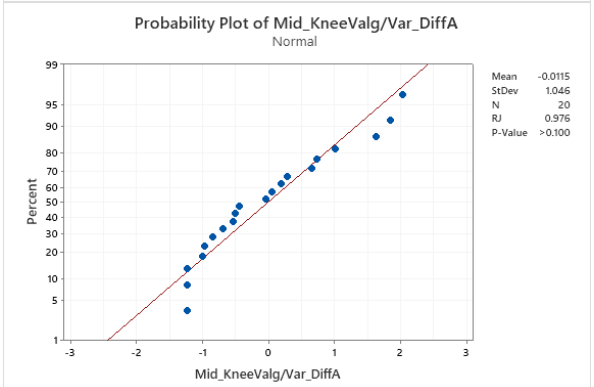


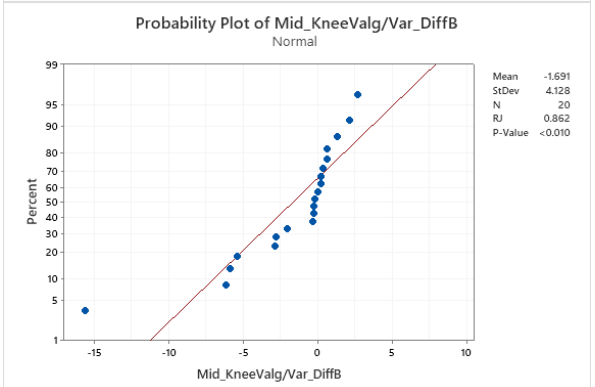

Probability Plot of Mid_PelvicObliq_DiffA
Normal
Mean 0.276
StDev 1.332
N 20
RJ 0.987
P-Value >0.100
Percent
Mid_PelvicObliq_DiffA

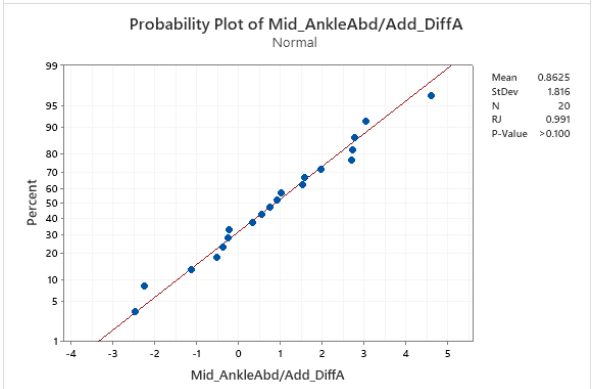

Probability Plot of Mid_PelvicObliq_DiffB
Normal
Mean -2.333
StDev 4.293
N 20
RJ 0.908
P-Value <0.010
Percent
Mid_PelvicObliq_DiffB

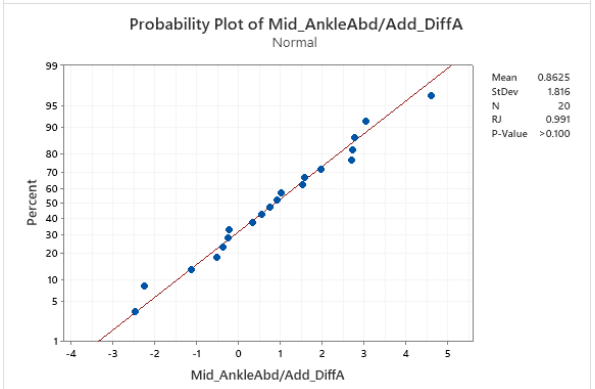

Probability Plot of Mid_HipAbd/Add_DiffA
Normal
Mean -0.259
StDev 2.021
N 20
RJ 0.988
P-Value >0.100
Percent
Mid_HipAbd/Add_DiffA

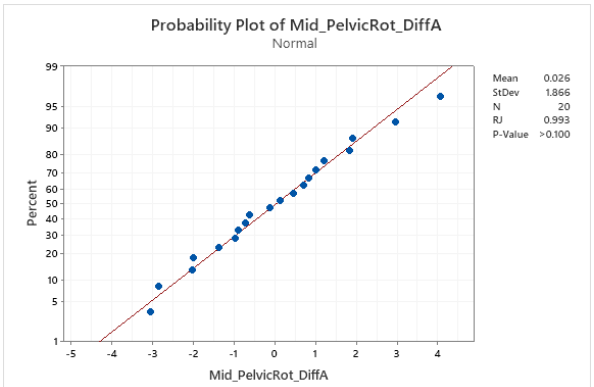

Probability Plot of Mid_HipAbd/Add_DiffB
Normal
Mean 0.799
StDev 4.668
N 20
RJ 0.913
P-Value <0.010
Percent
Mid_HipAbd/Add_DiffB

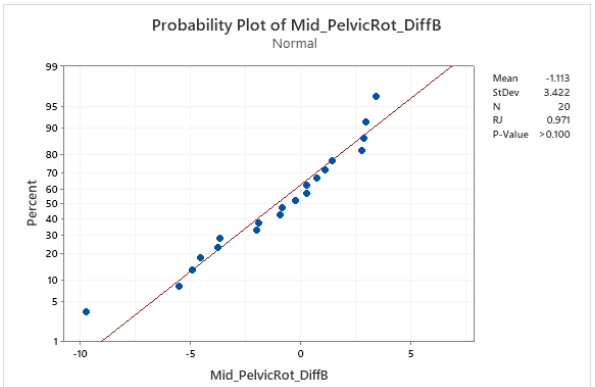

Probability Plot of Mid_KneeValg/Var_DiffA
Normal
Mean -0.0115
StDev 1.046
N 20
RJ 0.976
P-Value >0.100
Percent
Mid_KneeValg/Var_DiffA

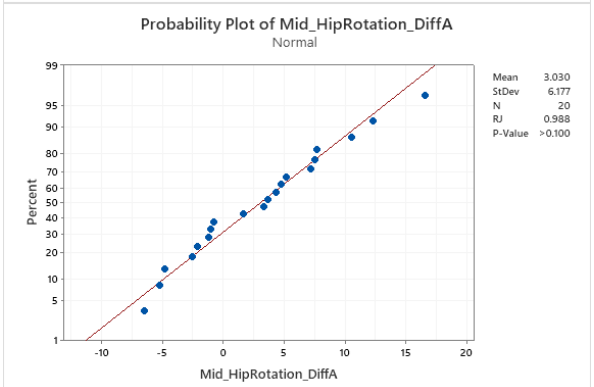

Probability Plot of Mid_KneeValg/Var_DiffB
Normal
Mean -1.691
StDev 4.128
N 20
RJ 0.862
P-Value <0.010
Percent
Mid_KneeValg/Var_DiffB

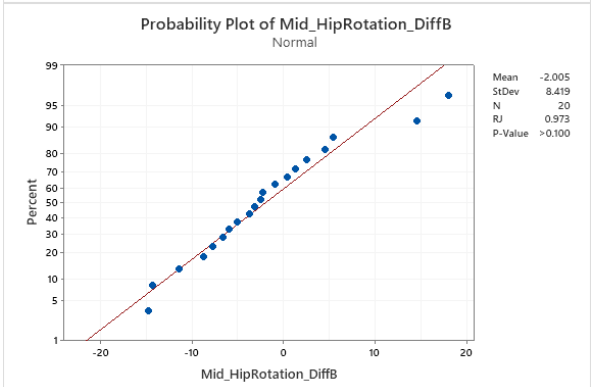

Probability Plot of Mid_AnkleAbd/Add_DiffA
Normal
Mean 0.8625
StDev 1.816
N 20
RJ 0.991
P-Value >0.100
Percent
Mid_AnkleAbd/Add_DiffA

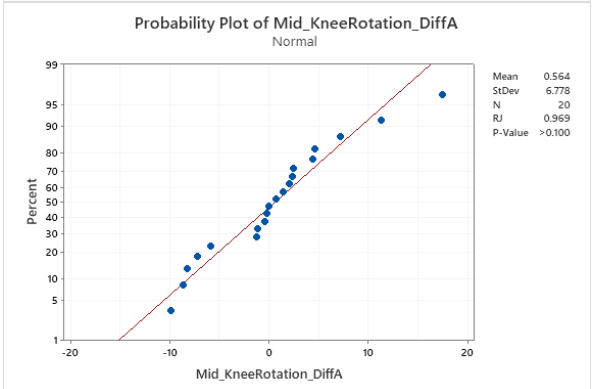

Probability Plot of Mid_AnkleAbd/Add_DiffA
Normal
Mean 0.8625
StDev 1.816
N 20
RJ 0.991
P-Value >0.100
Percent
Mid_AnkleAbd/Add_DiffA

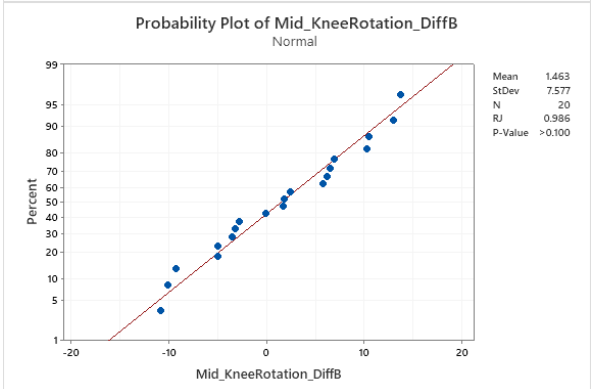

Probability Plot of Mid_PelvicRot_DiffA
Normal
Mean 0.026
StDev 1.866
N 20
RJ 0.993
P-Value >0.100
Percent
Mid_PelvicRot_DiffA

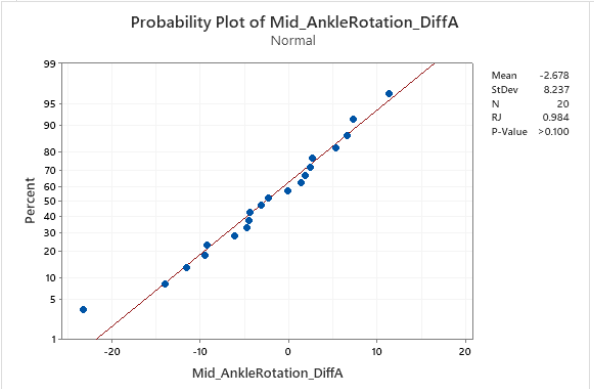

Probability Plot of Mid_PelvicRot_DiffB
Normal
Mean -1.113
StDev 3.422
N 20
RJ 0.971
P-Value >0.100
Percent
Mid_PelvicRot_DiffB

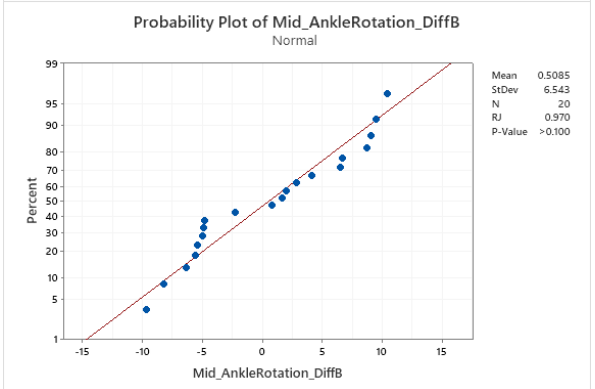

Probability Plot of Mid_HipRotation_DiffA
Normal
Mean 3.030
StDev 6.177
N 20
RJ 0.988
P-Value >0.100
Percent
Mid_HipRotation_DiffA


Probability Plot of Mid_HipRotation_DiffB
Normal
Mean -2.005
StDev 8.419
N 20
RJ 0.973
P-Value >0.100
Percent
Mid_HipRotation_DiffB


Probability Plot of Mid_KneeRotation_DiffA
Normal
Mean 0.564
StDev 6.778
N 20
RJ 0.969
P-Value >0.100
Percent
Mid_KneeRotation_DiffA


Probability Plot of Mid_KneeRotation_DiffB
Normal
Mean 1.463
StDev 7.577
N 20
RJ 0.986
P-Value >0.100
Percent
Mid_KneeRotation_DiffB

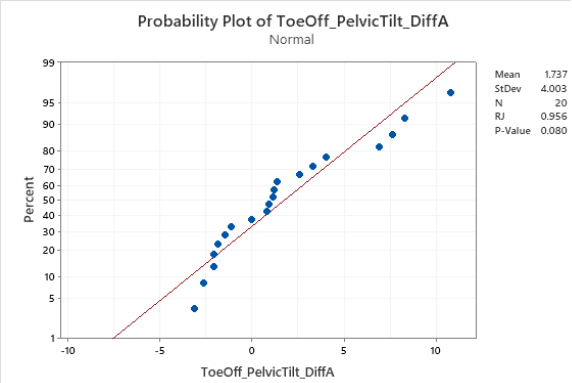

Probability Plot of Mid_AnkleRotation_DiffA
Normal
Mean -2.678
StDev 8.237
N 20
RJ 0.984
P-Value >0.100
Percent
Mid_AnkleRotation_DiffA

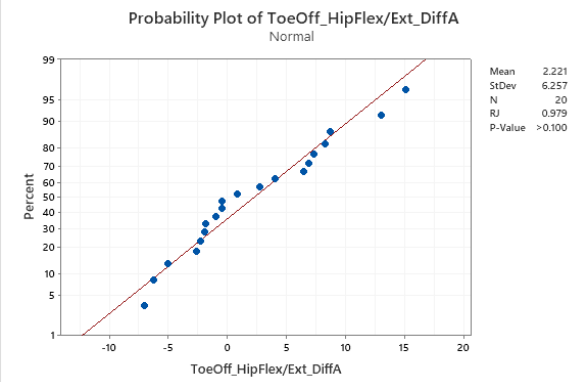

Probability Plot of Mid_AnkleRotation_DiffB
Normal
Mean 0.5085
StDev 6.543
N 20
RJ 0.970
P-Value >0.100
Percent
Mid_AnkleRotation_DiffB

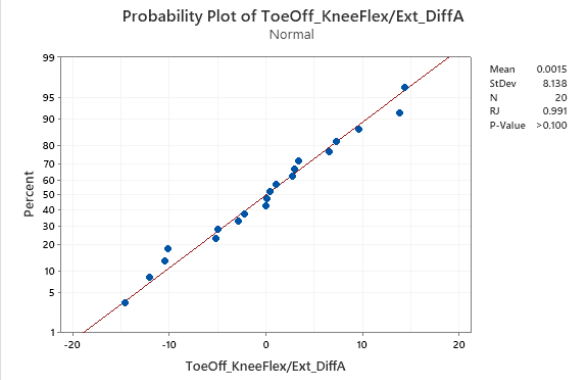
	Group A Difference			Group B Difference		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.034	Yes	Rejected	>0.1	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	>0.1	no	Accepted	<0.01	yes	Rejected
Ankle Dorsi/Plantar	<0.01	yes	Rejected	>0.1	no	Accepted
Pelvic Obliquity	<0.01	yes	Rejected	<0.01	yes	Rejected
Hip Abd/Add	>0.1	no	Accepted	<0.01	yes	Rejected
Knee Valg/Var	>0.1	no	Accepted	<0.01	yes	Rejected
Ankle Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Hip Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Knee Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

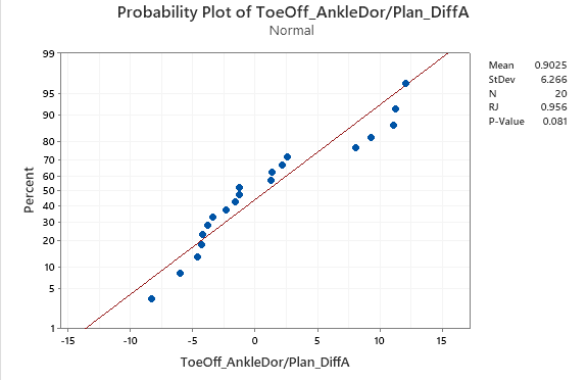
Appendix 12: Normality Testing of Data – Group A and B Difference at Toe Off

Group A Difference

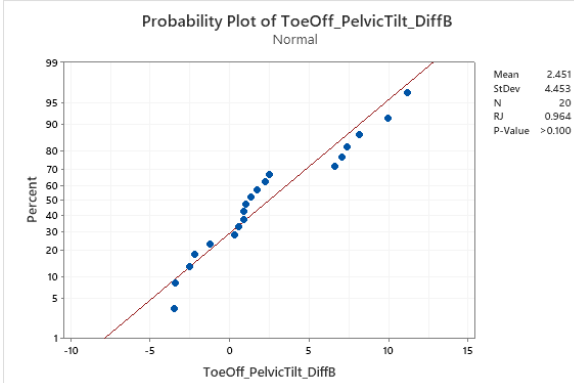


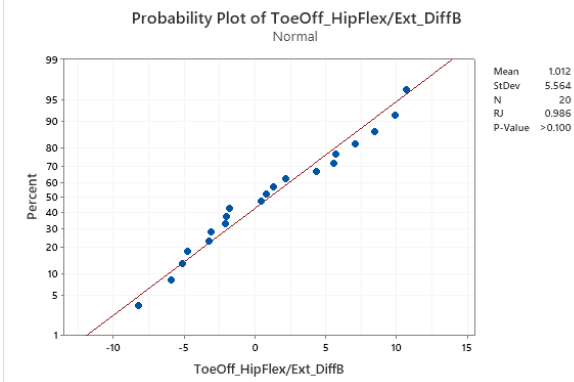


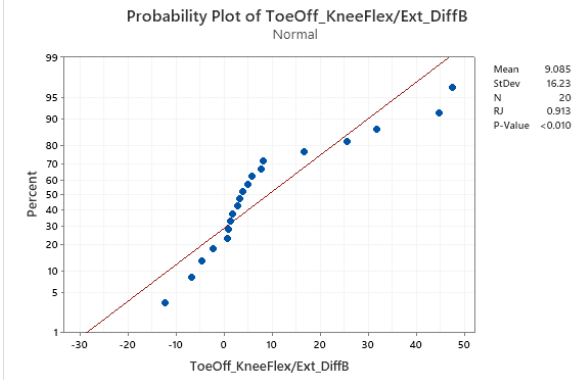


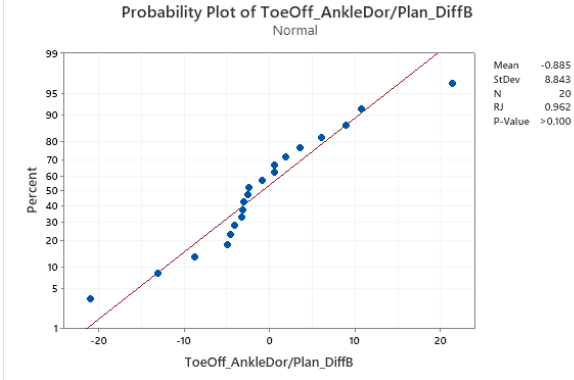


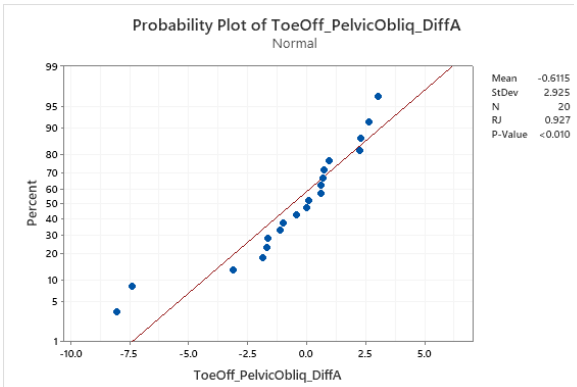
Group B Difference

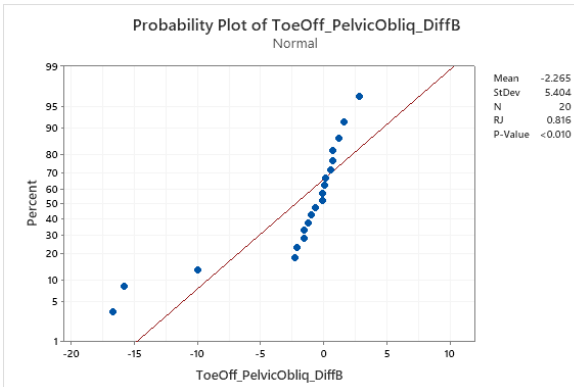


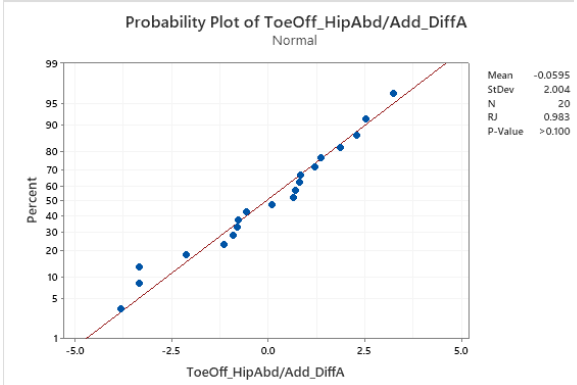


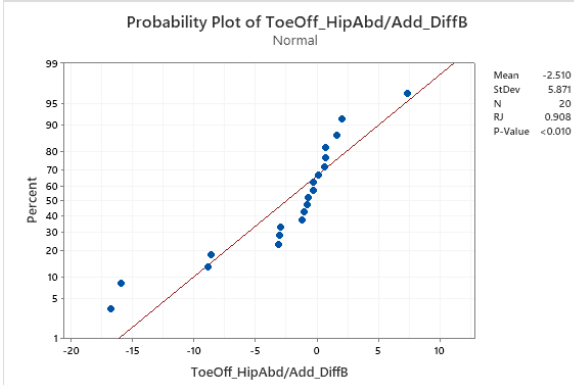


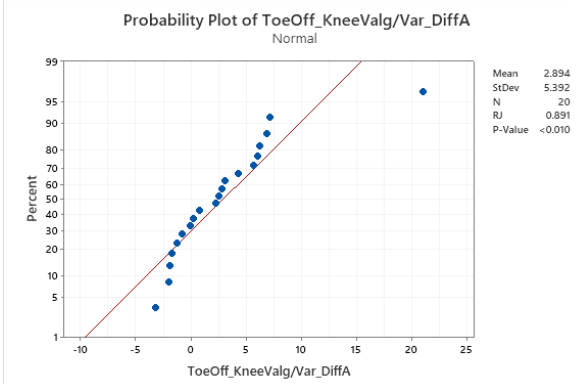


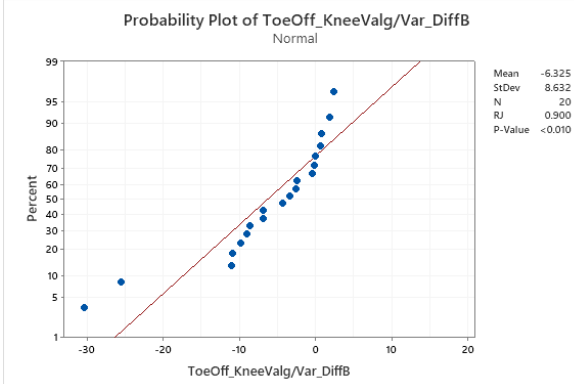

Probability Plot of ToeOff_PelvicObliq_DiffA
Normal
Mean -0.6115
StDev 2.925
N 20
RJ 0.927
P-Value <0.010
Percent
ToeOff_PelvicObliq_DiffA

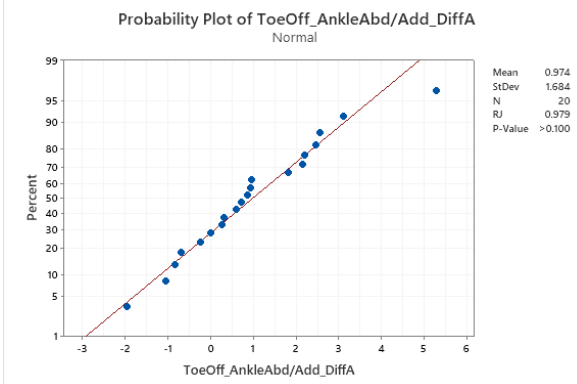

Probability Plot of ToeOff_PelvicObliq_DiffB
Normal
Mean -2.265
StDev 5.404
N 20
RJ 0.816
P-Value <0.010
Percent
ToeOff_PelvicObliq_DiffB

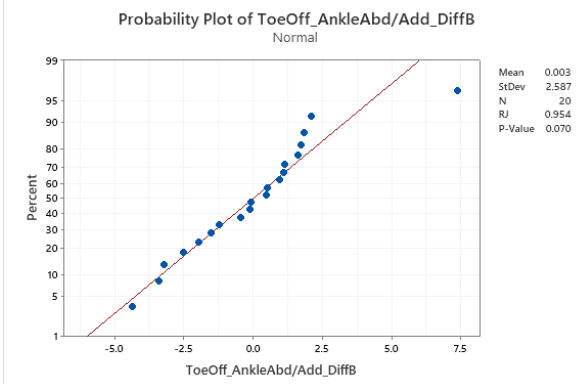

Probability Plot of ToeOff_HipAbd/Add_DiffA
Normal
Mean -0.0595
StDev 2.004
N 20
RJ 0.983
P-Value >0.100
Percent
ToeOff_HipAbd/Add_DiffA

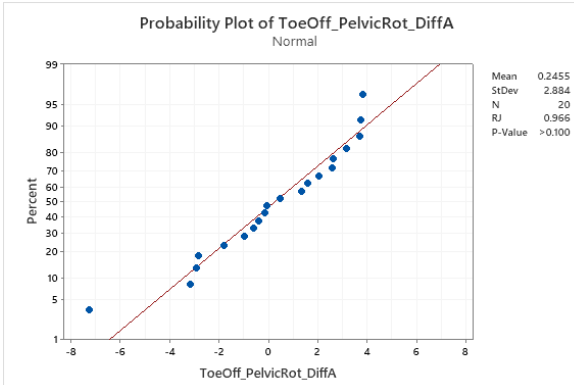

Probability Plot of ToeOff_HipAbd/Add_DiffB
Normal
Mean -2.510
StDev 5.871
N 20
RJ 0.908
P-Value <0.010
Percent
ToeOff_HipAbd/Add_DiffB

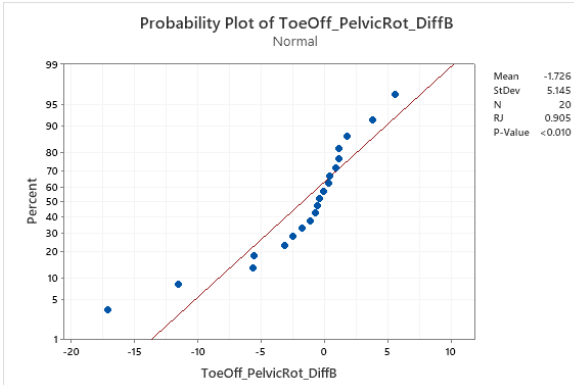

Probability Plot of ToeOff_KneeValg/Var_DiffA
Normal
Mean 2.894
StDev 5.392
N 20
RJ 0.891
P-Value <0.010
Percent
ToeOff_KneeValg/Var_DiffA

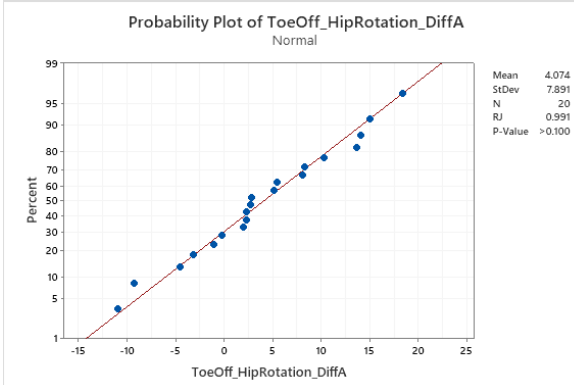

Probability Plot of ToeOff_KneeValg/Var_DiffB
Normal
Mean -6.325
StDev 8.632
N 20
RJ 0.900
P-Value <0.010
Percent
ToeOff_KneeValg/Var_DiffB

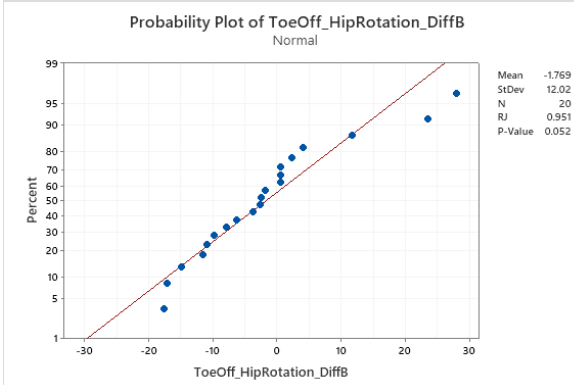

Probability Plot of ToeOff_AnkleAbd/Add_DiffA
Normal
Mean 0.974
StDev 1.684
N 20
RJ 0.979
P-Value >0.100
Percent
ToeOff_AnkleAbd/Add_DiffA

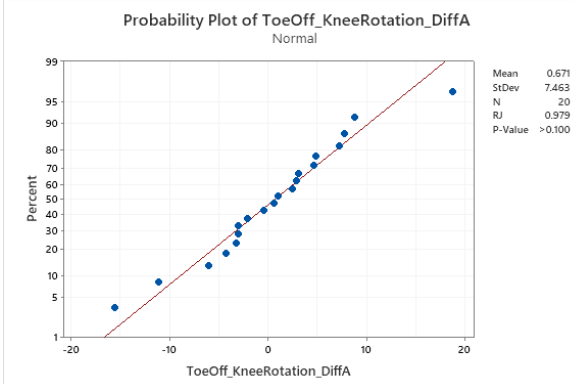

Probability Plot of ToeOff_AnkleAbd/Add_DiffB
Normal
Mean 0.003
StDev 2.587
N 20
RJ 0.954
P-Value 0.070
Percent
ToeOff_AnkleAbd/Add_DiffB

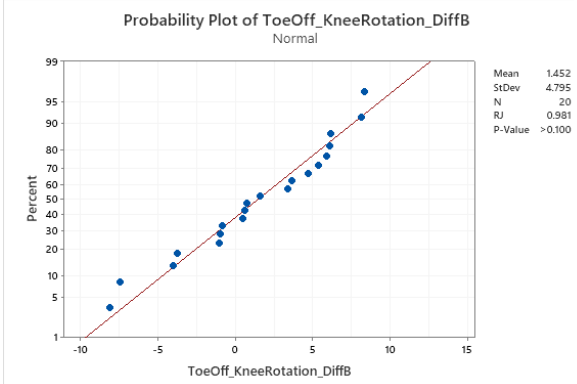

Probability Plot of ToeOff_PelvicRot_DiffA
Normal
Mean 0.2455
StDev 2.884
N 20
RJ 0.966
P-Value >0.100
Percent
ToeOff_PelvicRot_DiffA

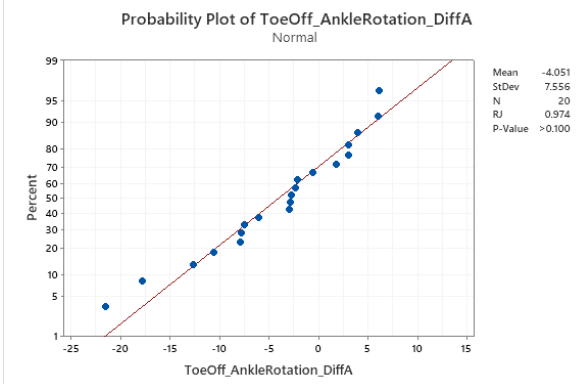

Probability Plot of ToeOff_PelvicRot_DiffB
Normal
Mean -1.726
StDev 5.145
N 20
RJ 0.905
P-Value <0.010
Percent
ToeOff_PelvicRot_DiffB

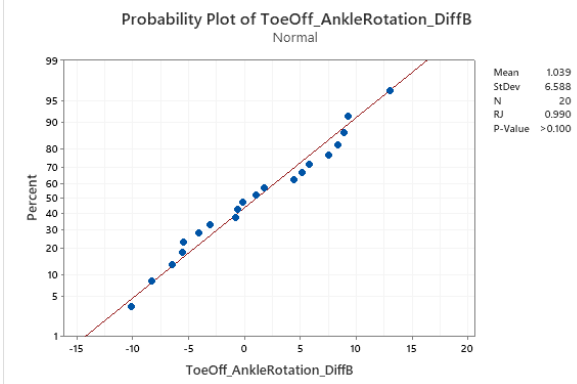

Probability Plot of ToeOff_HipRotation_DiffA
Normal
Mean 4.074
StDev 7.891
N 20
RJ 0.991
P-Value >0.100
Percent
ToeOff_HipRotation_DiffA


Probability Plot of ToeOff_HipRotation_DiffB
Normal
Mean -1.769
StDev 12.02
N 20
RJ 0.951
P-Value 0.052
Percent
ToeOff_HipRotation_DiffB


Probability Plot of ToeOff_KneeRotation_DiffA
Normal
Mean 0.671
StDev 7.463
N 20
RJ 0.979
P-Value >0.100
Percent
ToeOff_KneeRotation_DiffA

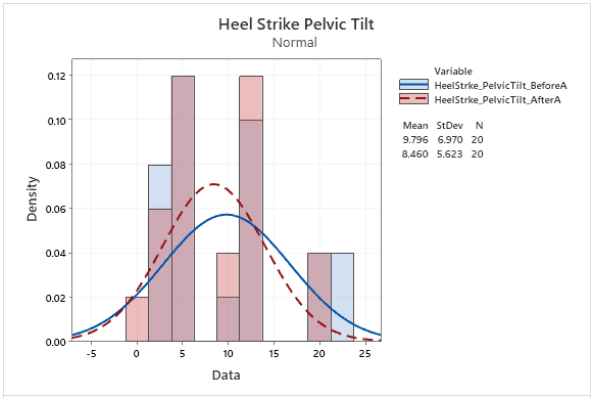

Probability Plot of ToeOff_KneeRotation_DiffB
Normal
Mean 1.452
StDev 4.795
N 20
RJ 0.981
P-Value >0.100
Percent
ToeOff_KneeRotation_DiffB

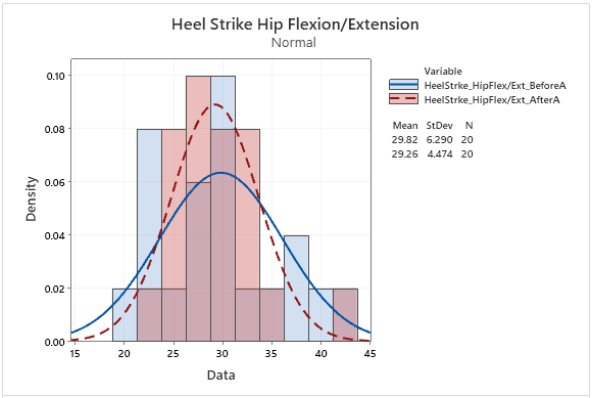

Probability Plot of ToeOff_AnkleRotation_DiffA
Normal
Mean -4.051
StDev 7.556
N 20
RJ 0.974
P-Value >0.100
Percent
ToeOff_AnkleRotation_DiffA

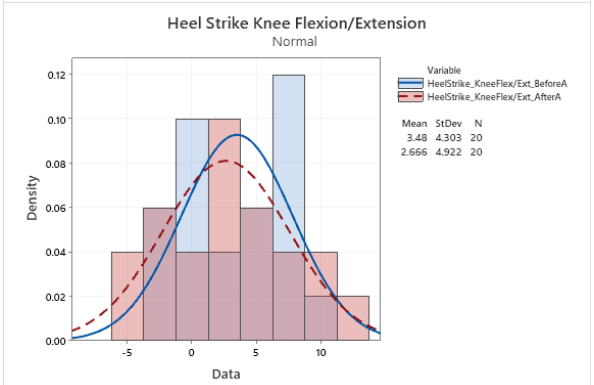

Probability Plot of ToeOff_AnkleRotation_DiffB
Normal
Mean 1.039
StDev 6.588
N 20
RJ 0.990
P-Value >0.100
Percent
ToeOff_AnkleRotation_DiffB

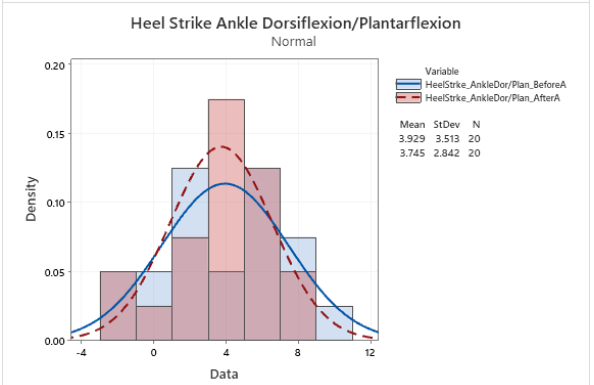
	Group A Difference			Group B Difference		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.08	no	Accepted	>0.1	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Dorsi/Plantar	0.081	no	Accepted	>0.1	no	Accepted
Pelvic Obliquity	<0.01	yes	Rejected	<0.01	yes	Rejected
Hip Abd/Add	>0.1	no	Accepted	<0.01	yes	Rejected
Knee Valg/Var	<0.01	yes	Rejected	<0.01	yes	Rejected
Ankle Abd/Add	>0.1	no	Accepted	0.07	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	<0.01	yes	Rejected
Hip Rotation	>0.1	no	Accepted	0.052	no	Accepted
Knee Rotation	>0.1	no	Accepted	0.05	no	Accepted
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

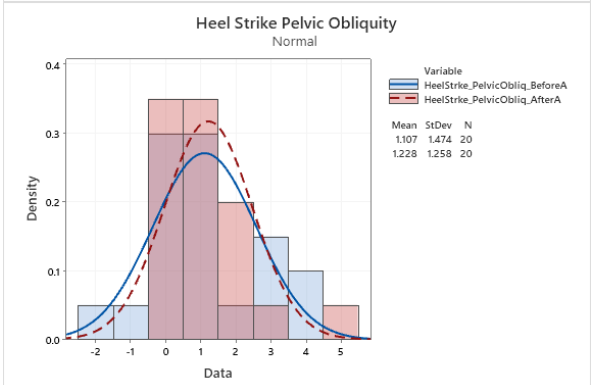
Appendix 13: Group A Before and After Kinematic Data Histograms at Heel Strike

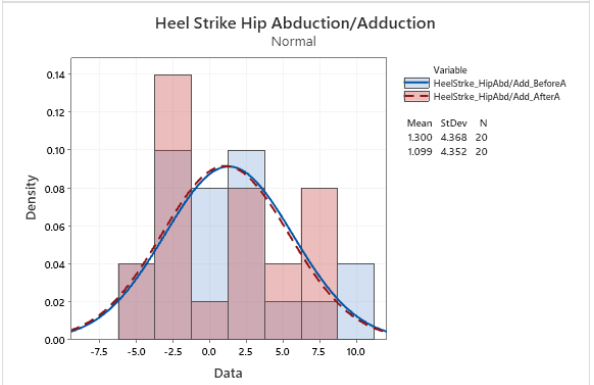


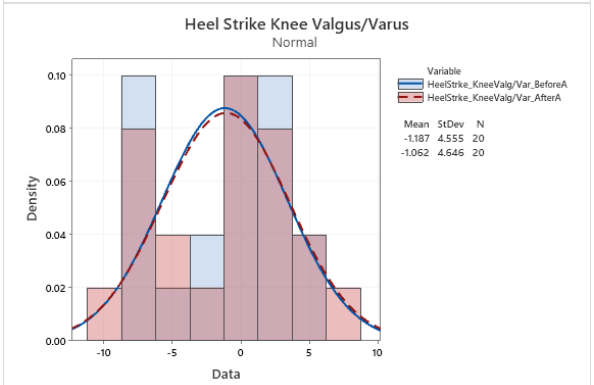


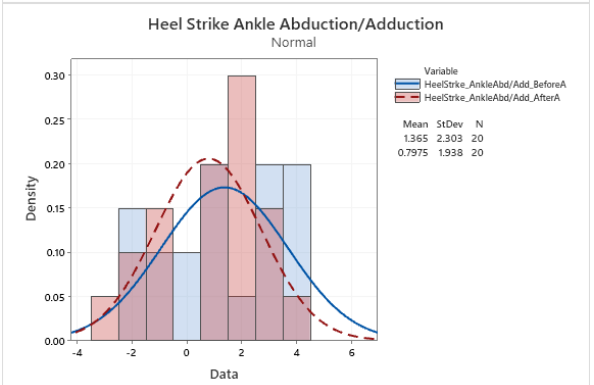


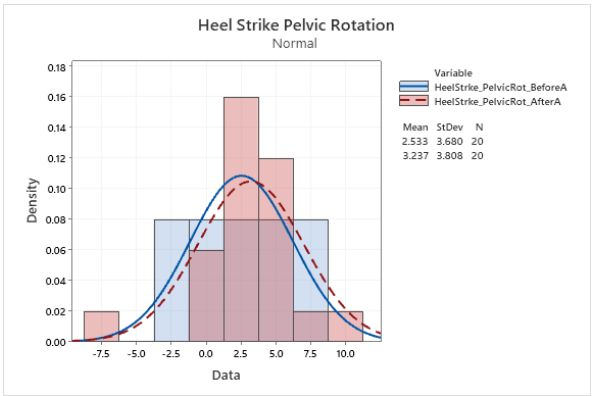


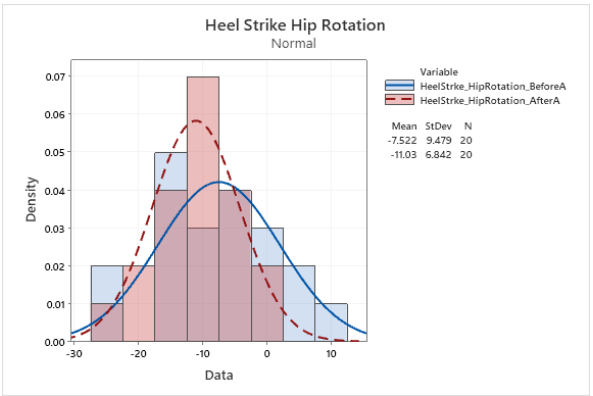


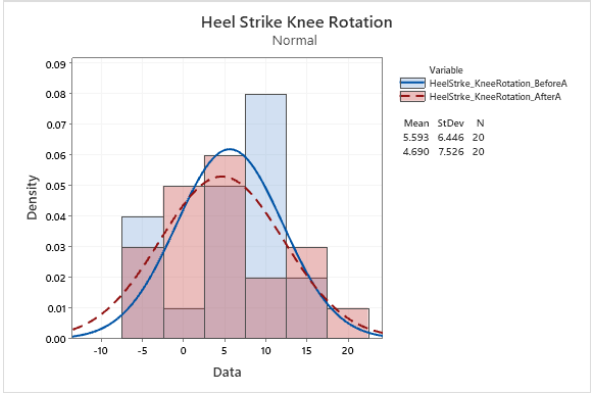


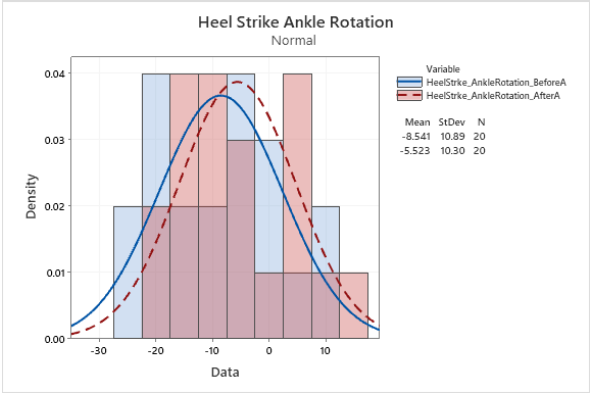




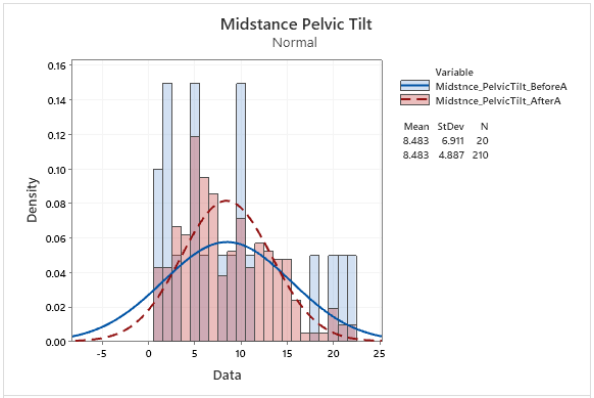

Heel Strike Pelvic Rotation
Normal
Density
Data
Variable
HeelStrke_PelvicRot_BeforeA
HeelStrke_PelvicRot_AfterA
Mean StDev N
2.533 3.680 20
3.237 3.808 20

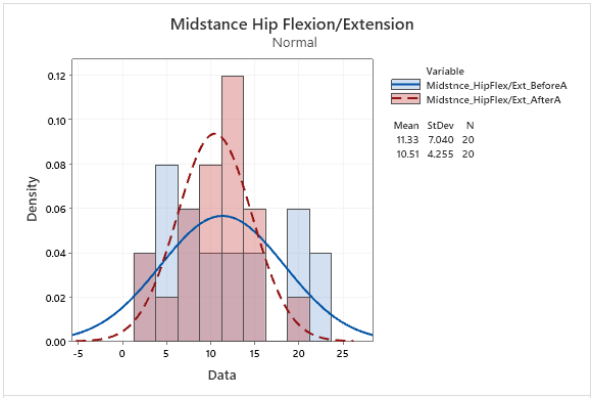

Heel Strike Hip Rotation
Normal
Density
Data
Variable
HeelStrke_HipRotation_BeforeA
HeelStrke_HipRotation_AfterA
Mean StDev N
-7.522 9.479 20
-11.03 6.842 20

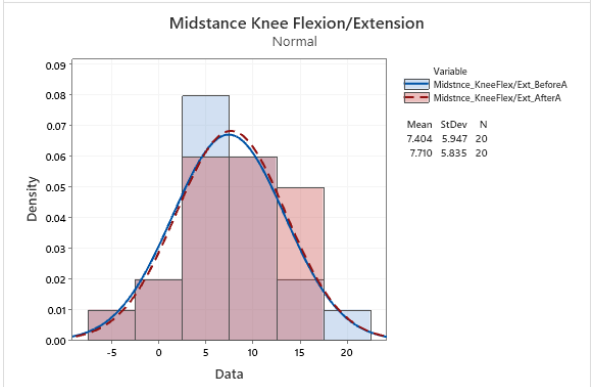

Heel Strike Knee Rotation
Normal
Density
Data
Variable
HeelStrke_KneeRotation_BeforeA
HeelStrke_KneeRotation_AfterA
Mean StDev N
5.593 6.446 20
4.690 7.526 20

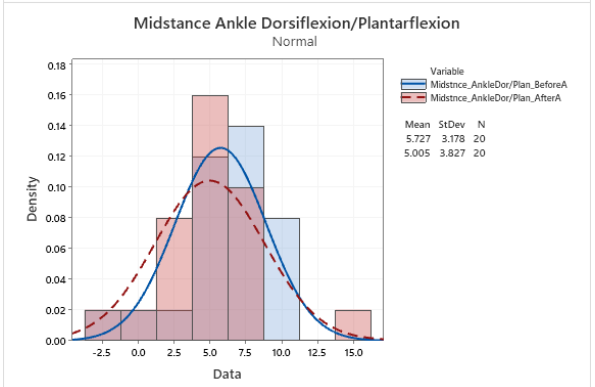

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
HeelStrke_AnkleRotation_BeforeA
HeelStrke_AnkleRotation_AfterA
Mean StDev N
-8.541 10.89 20
-5.523 10.30 20

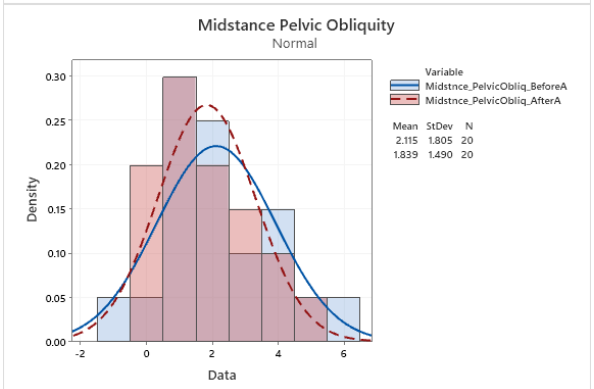
Appendix 14: Group A Before and After Kinematic Data Histograms at Midstance

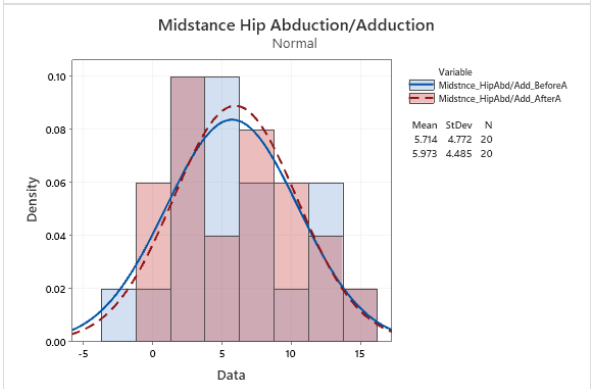


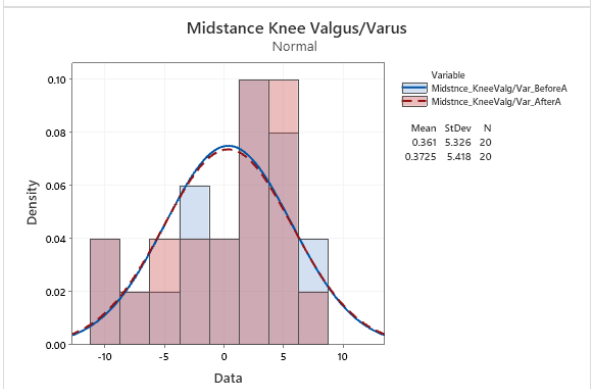


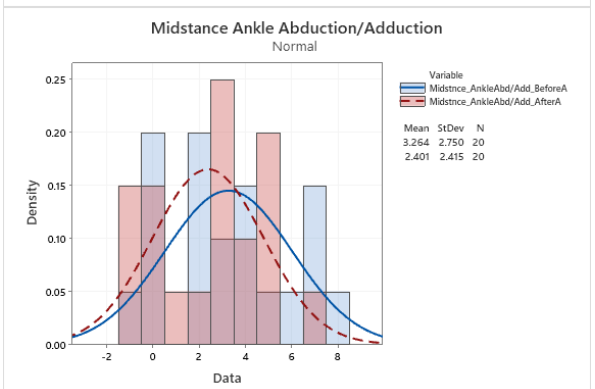


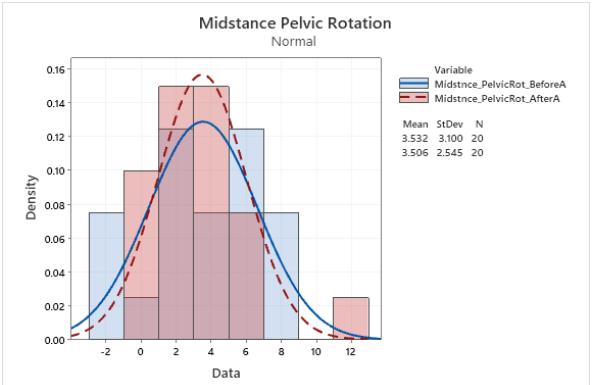


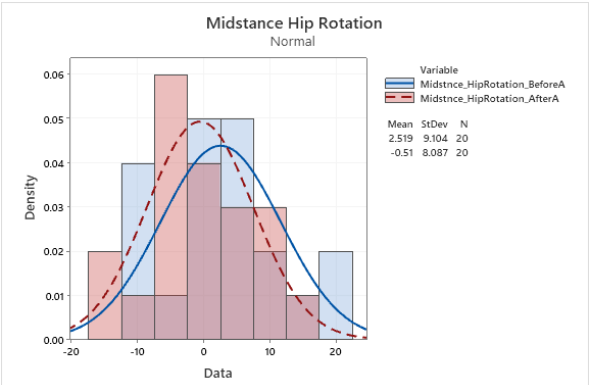


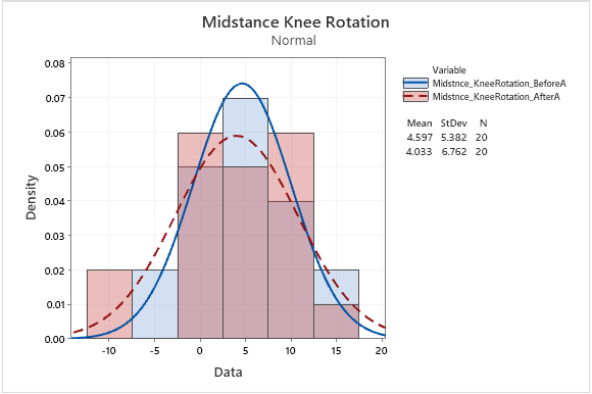


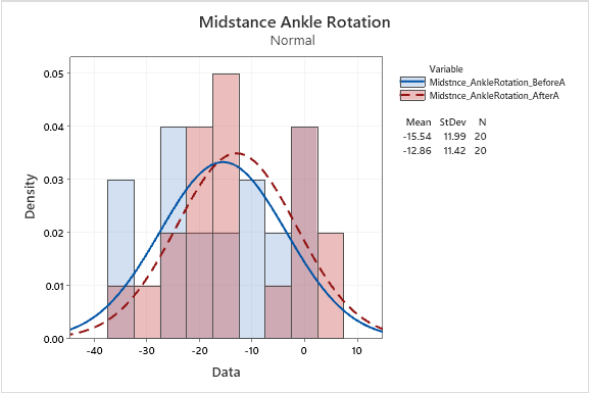




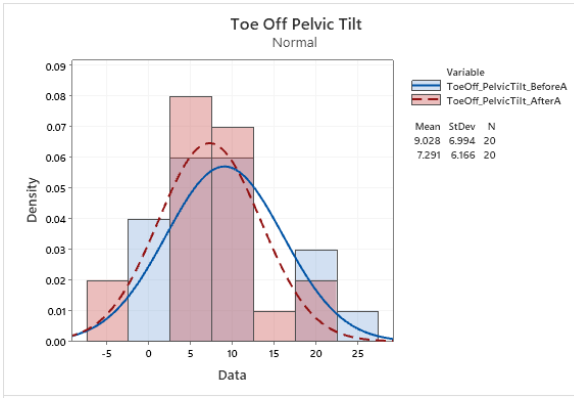

Midstance Pelvic Rotation
Normal
Density
Data
Variable
Midstnce_PelvicRot_BeforeA
Midstnce_PelvicRot_AfterA
Mean StDev N
3.532 3.100 20
3.506 2.545 20

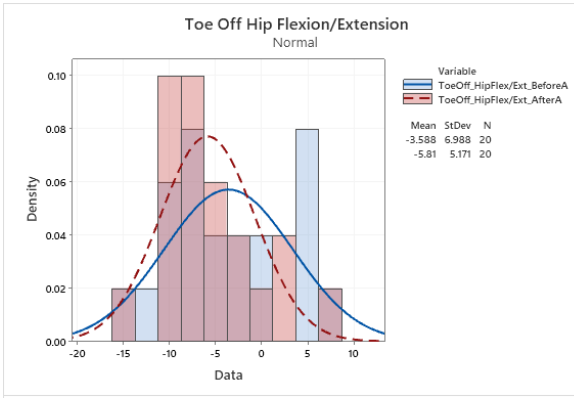

Midstance Hip Rotation
Normal
Density
Data
Variable
Midstnce_HipRotation_BeforeA
Midstnce_HipRotation_AfterA
Mean StDev N
2.519 9.104 20
-0.51 8.087 20

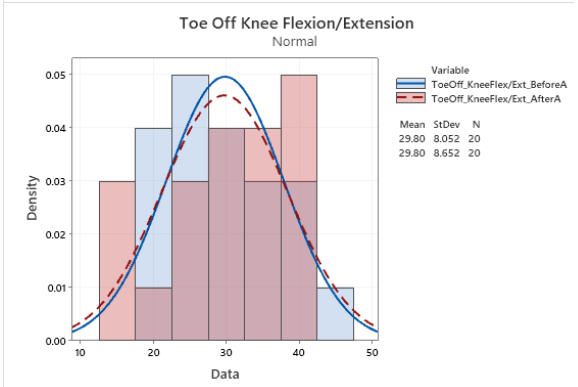

Midstance Knee Rotation
Normal
Density
Data
Variable
Midstnce_KneeRotation_BeforeA
Midstnce_KneeRotation_AfterA
Mean StDev N
4.597 5.382 20
4.033 6.762 20

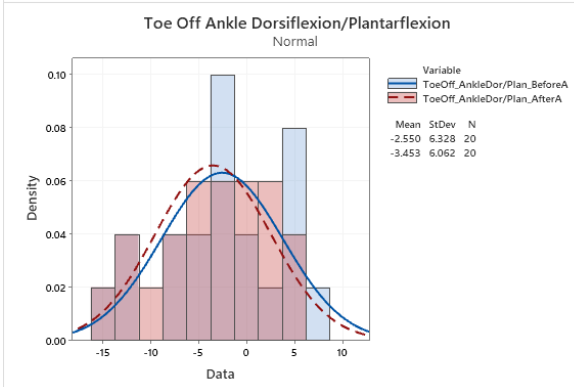

Midstance Ankle Rotation
Normal
Density
Data
Variable
Midstnce_AnkleRotation_BeforeA
Midstnce_AnkleRotation_AfterA
Mean StDev N
-15.54 11.99 20
-12.86 11.42 20

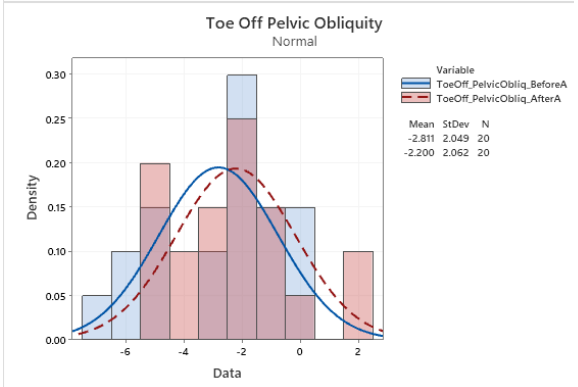
Appendix 15: Group A Before and After Kinematic Data Histograms at Toe Off

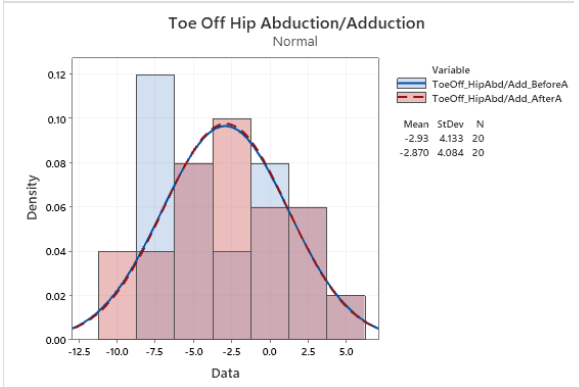


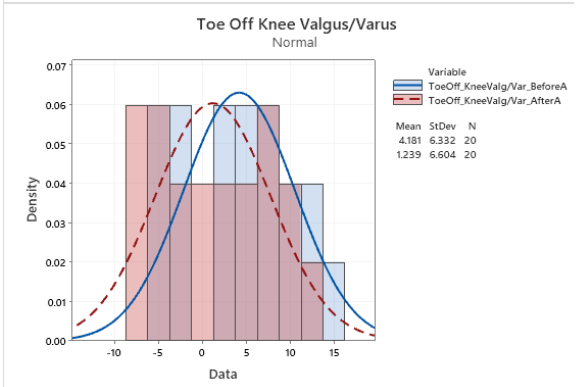


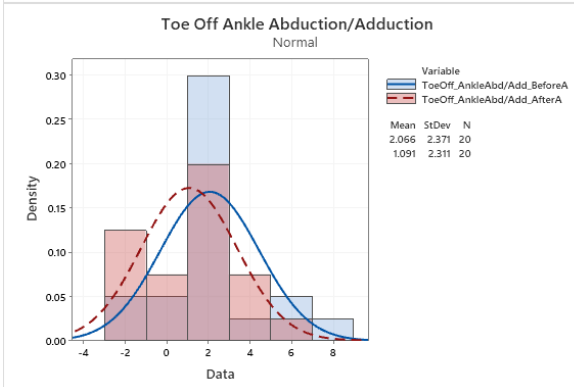


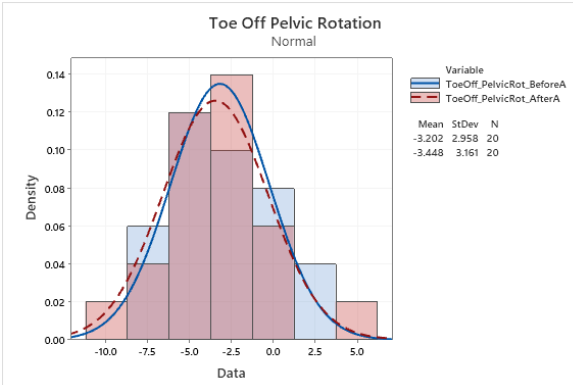


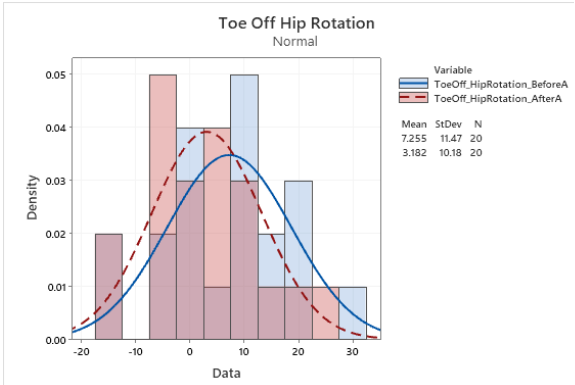


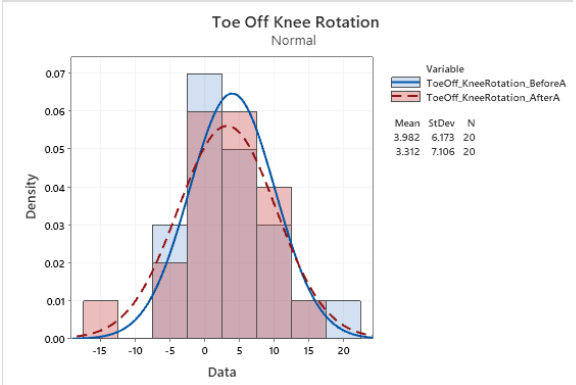


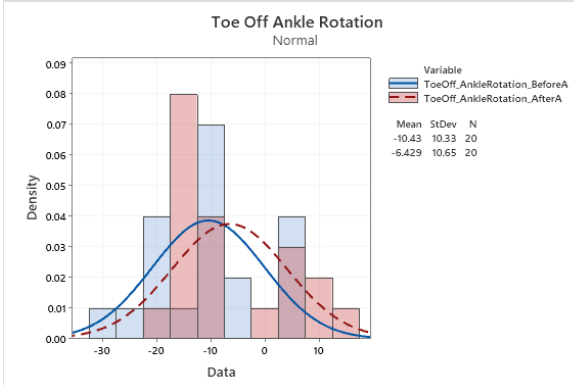




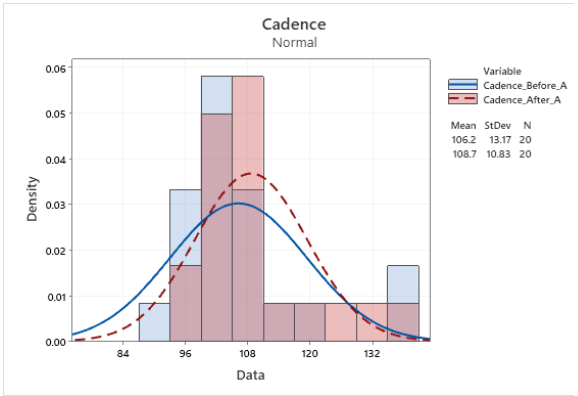

Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_PelvicRot_BeforeA
ToeOff_PelvicRot_AfterA
Mean StDev N
-3.202 2.958 20
-3.448 3.161 20

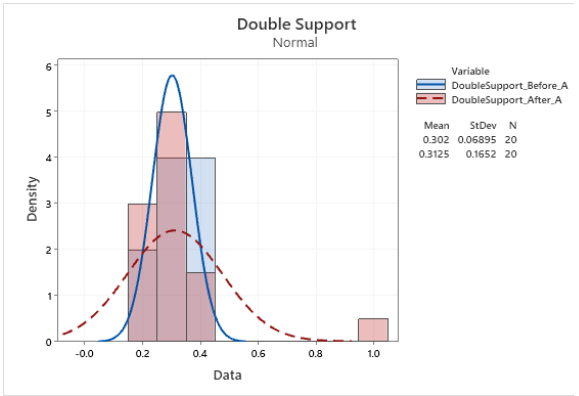

Toe Off Hip Rotation
Normal
Density
Data
Variable
ToeOff_HipRotation_BeforeA
ToeOff_HipRotation_AfterA
Mean StDev N
7.255 11.47 20
3.182 10.18 20

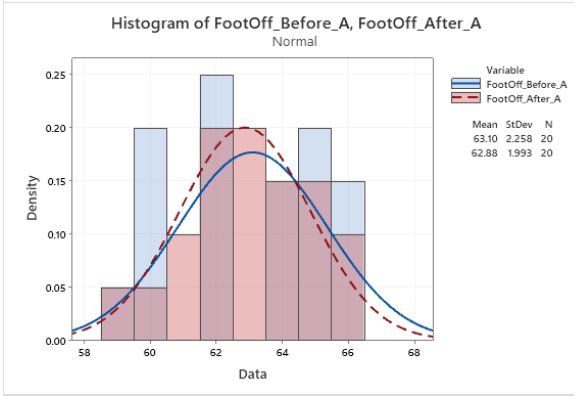

Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_KneeRotation_BeforeA
ToeOff_KneeRotation_AfterA
Mean StDev N
3.982 6.173 20
3.312 7.106 20

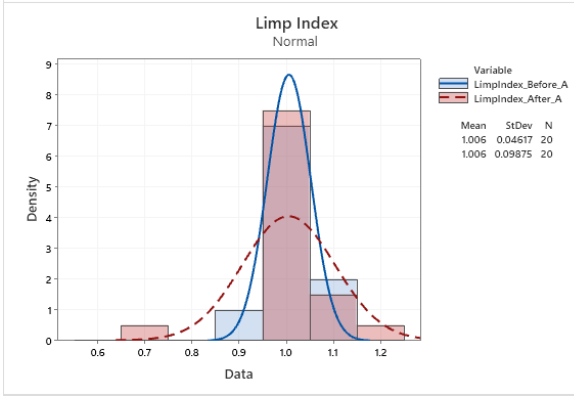

Toe Off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_AnkleRotation_BeforeA
ToeOff_AnkleRotation_AfterA
Mean StDev N
-10.43 10.33 20
-6.429 10.65 20

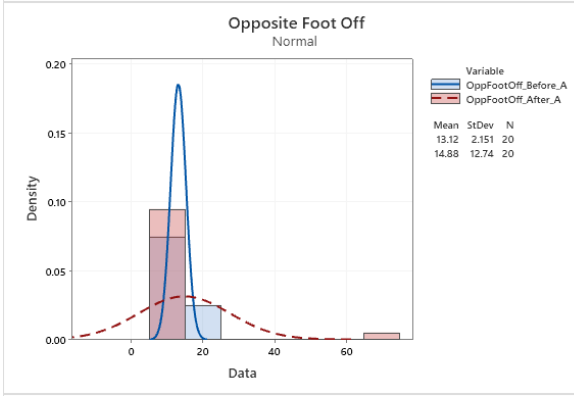
Appendix 16: Group A Spatiotemporal Data Histograms

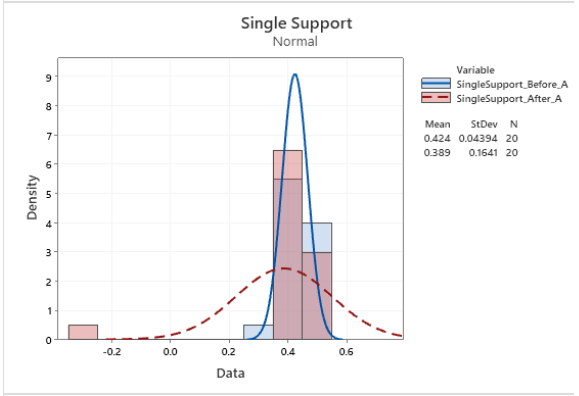


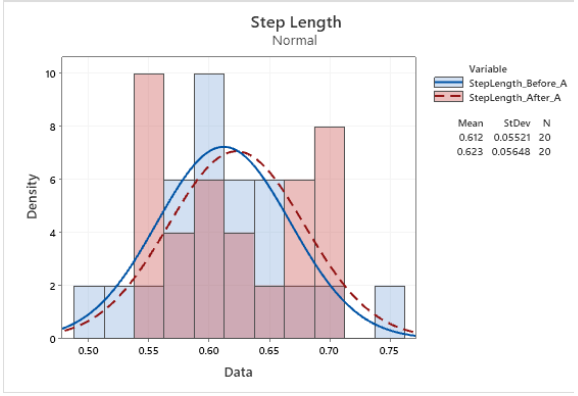


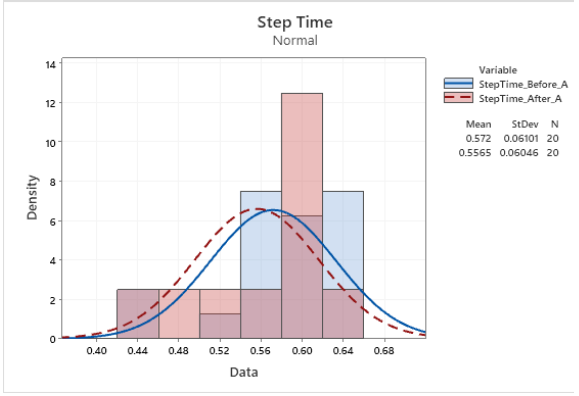


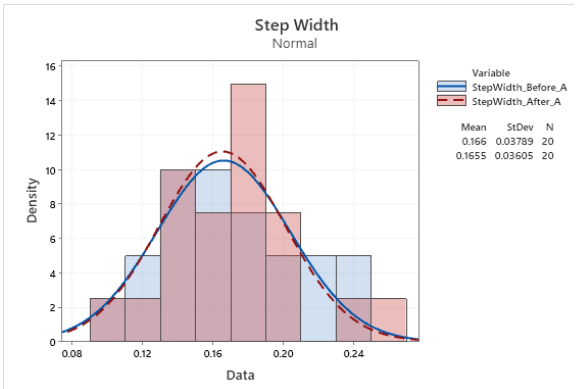


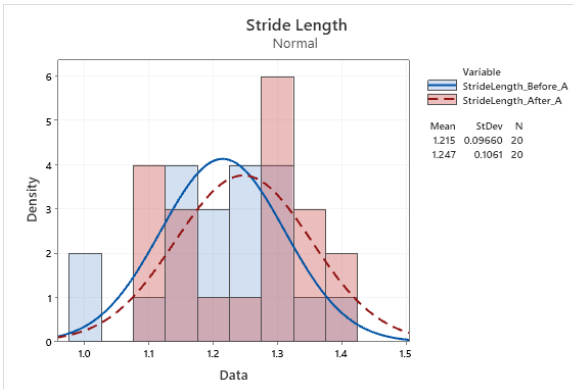


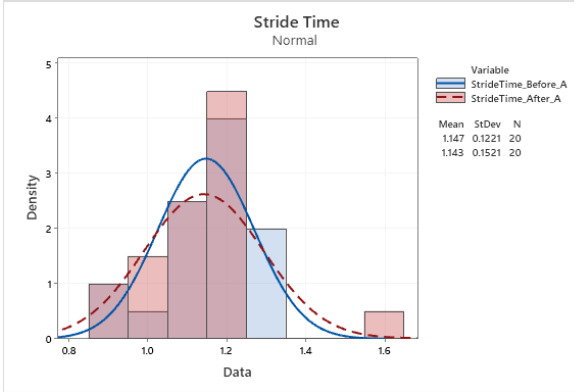


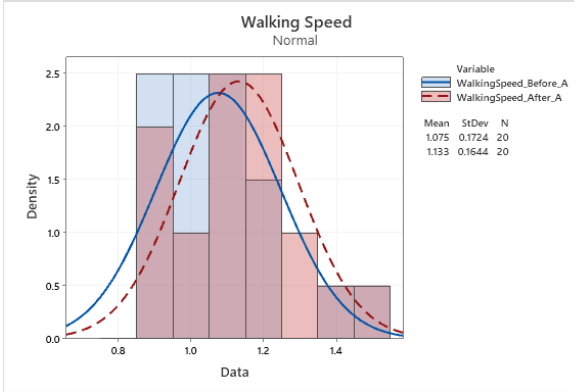





Step Width
Normal
Density
Data
Variable
StepWidth_Before_A
StepWidth_After_A
Mean StDev N
0.166 0.03789 20
0.1655 0.03605 20

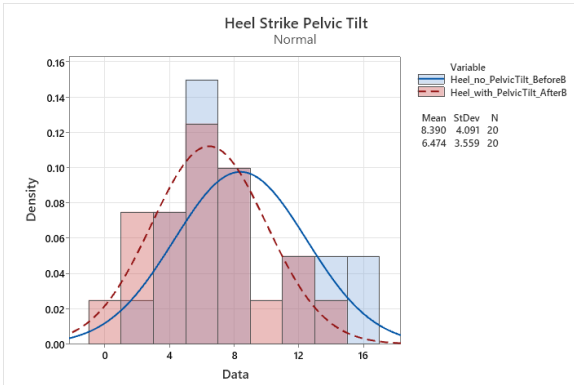

Stride Length
Normal
Density
Data
Variable
StrideLength_Before_A
StrideLength_After_A
Mean StDev N
1.215 0.09660 20
1.247 0.1061 20

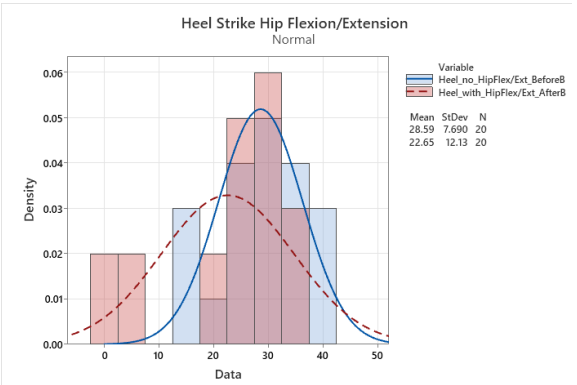

Stride Time
Normal
Density
Data
Variable
StrideTime_Before_A
StrideTime_After_A
Mean StDev N
1.147 0.1221 20
1.143 0.1521 20

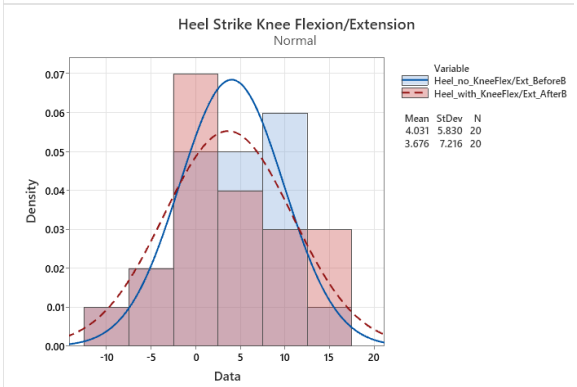

Walking Speed
Normal
Density
Data
Variable
WalkingSpeed_Before_A
WalkingSpeed_After_A
Mean StDev N
1.075 0.1724 20
1.133 0.1644 20

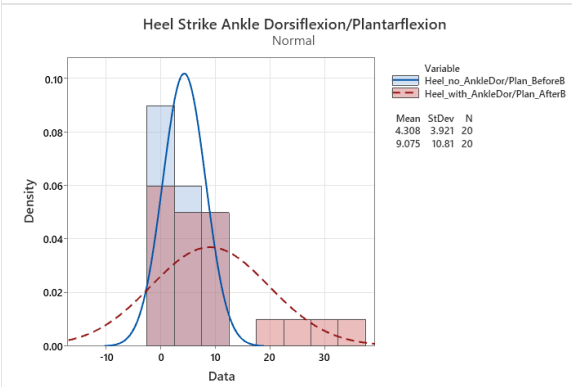
Appendix 17: Group B Before no insoles and After with insoles Kinematic Data

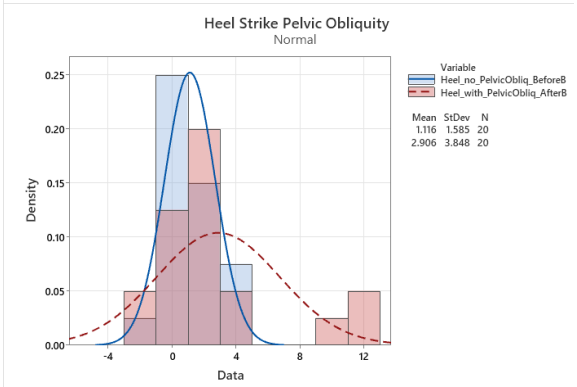
Histograms at Heel Strike

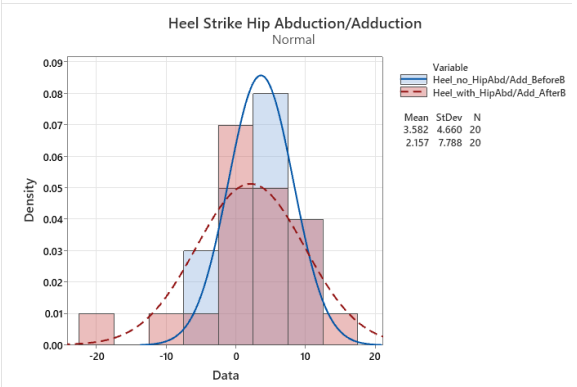


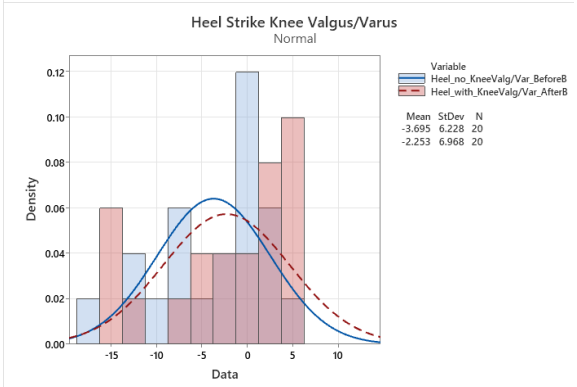


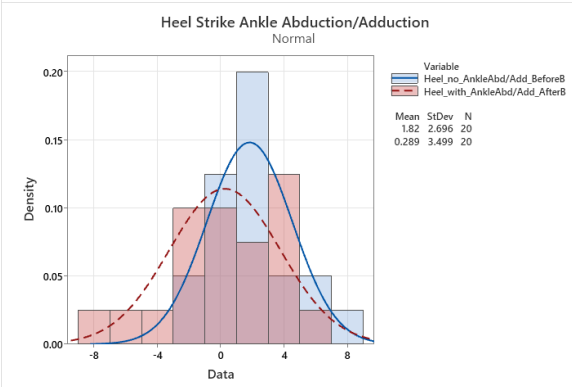


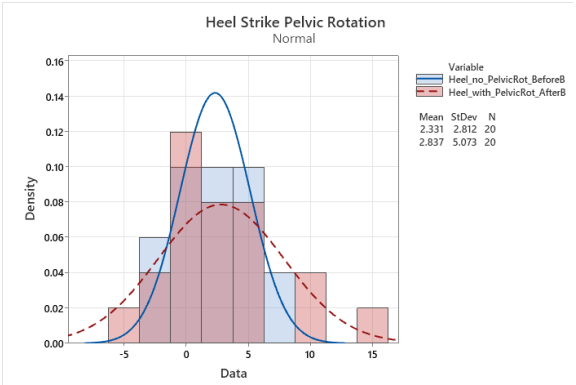


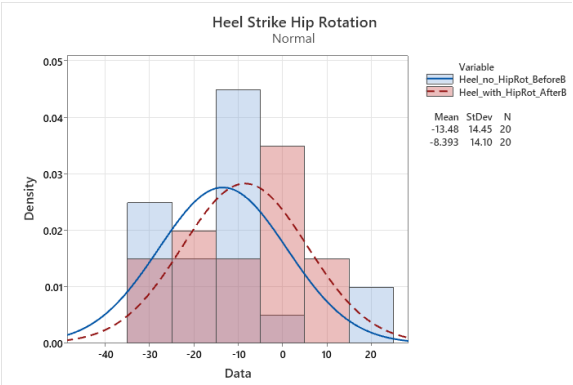


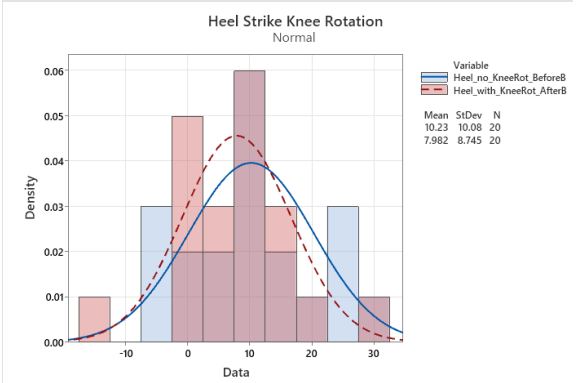


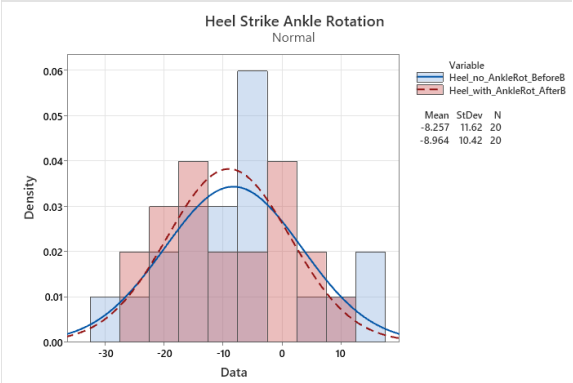





Heel Strike Pelvic Rotation
Normal
Density
Data
Variable
Heel_no_PelvicRot_BeforeB
Heel_with_PelvicRot_AfterB
Mean StDev N
2.331 2.812 20
2.837 5.073 20

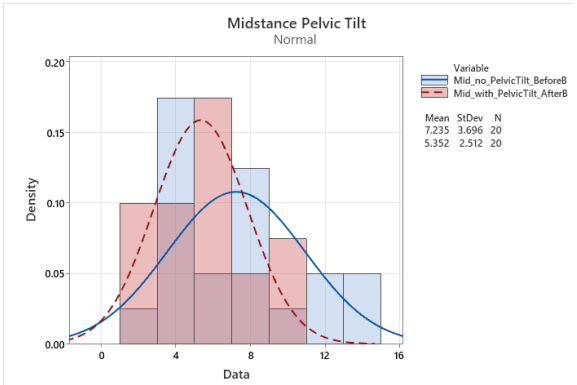

Heel Strike Hip Rotation
Normal
Density
Data
Variable
Heel_no_HipRot_BeforeB
Heel_with_HipRot_AfterB
Mean StDev N
-13.48 14.45 20
-8.393 14.10 20

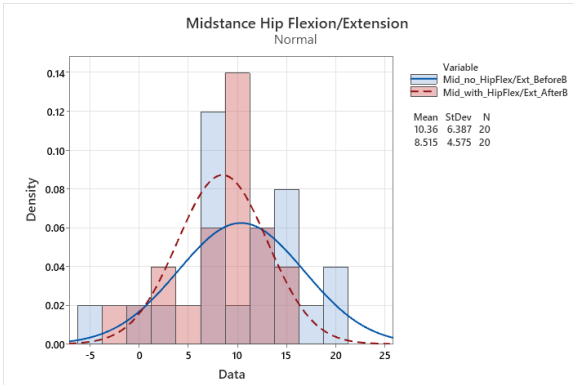

Heel Strike Knee Rotation
Normal
Density
Data
Variable
Heel_no_KneeRot_BeforeB
Heel_with_KneeRot_AfterB
Mean StDev N
10.23 10.08 20
7.982 8.745 20

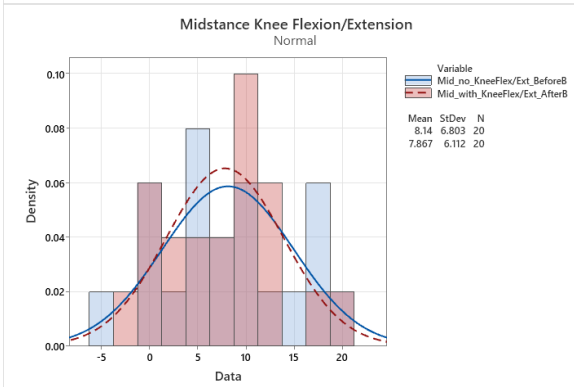

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
Heel_no_AnkleRot_BeforeB
Heel_with_AnkleRot_AfterB
Mean StDev N
-8.257 11.62 20
-8.964 10.42 20

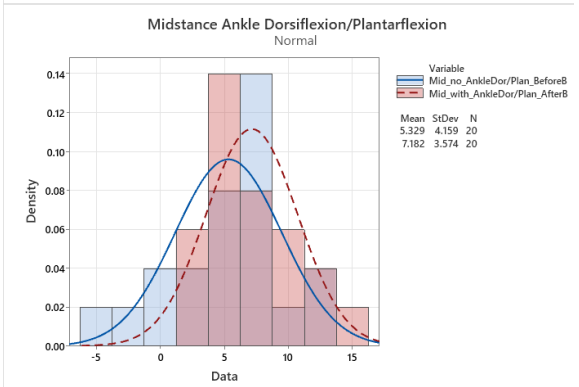
Appendix 18: Group B Before no insoles and After with insoles Kinematic Data

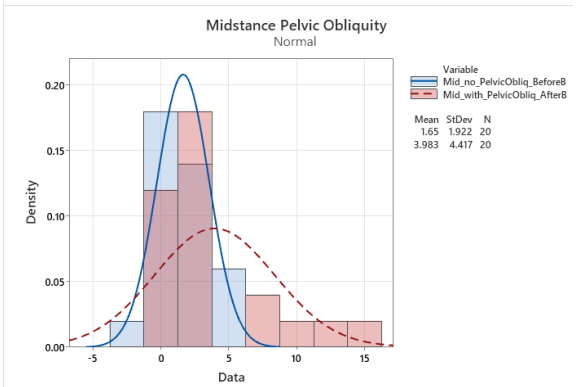
Histograms at Midstance

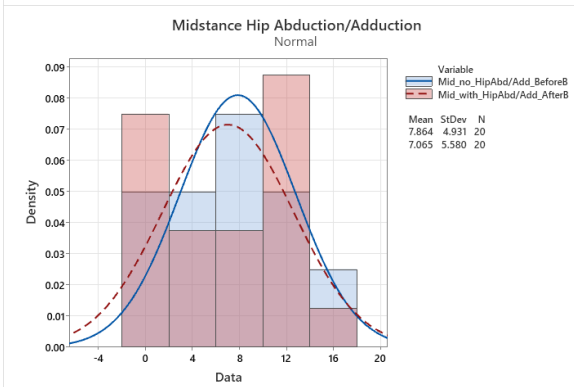


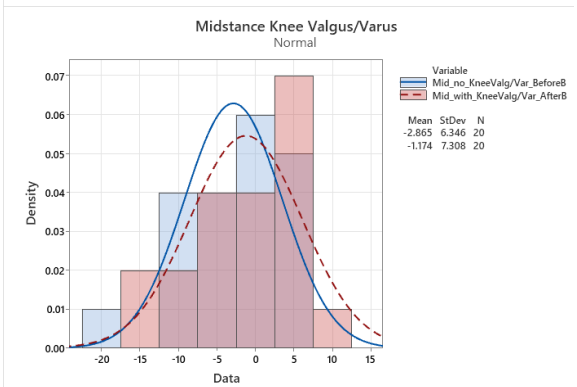


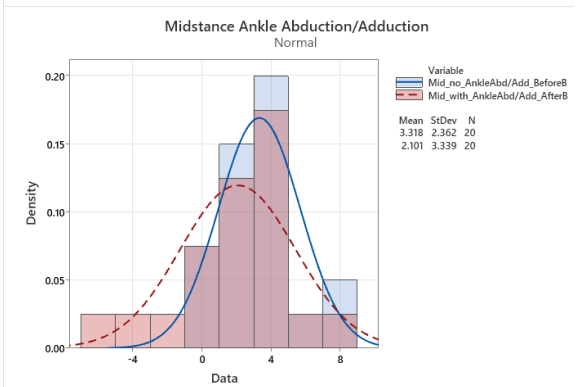


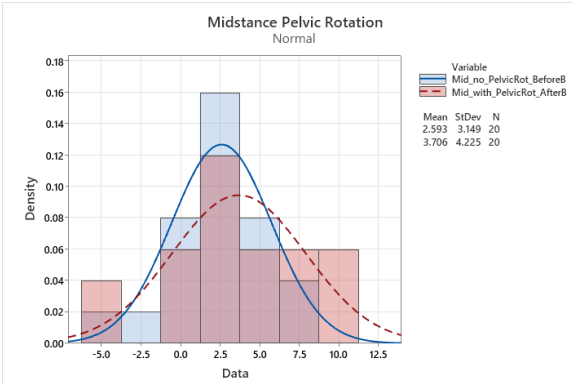


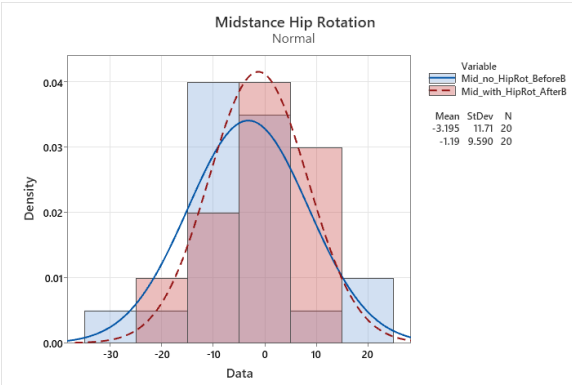


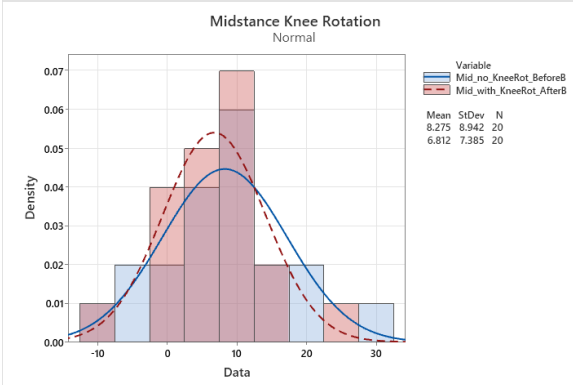


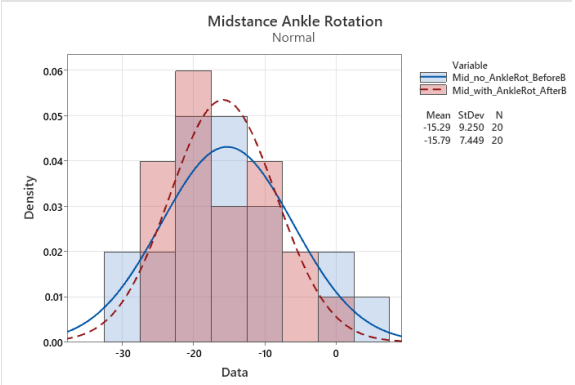





Midstance Pelvic Rotation
Normal
Density
Data
Variable
Mid_no_PelvicRot_BeforeB
Mid_with_PelvicRot_AfterB
Mean StDev N
2.593 3.149 20
3.706 4.225 20

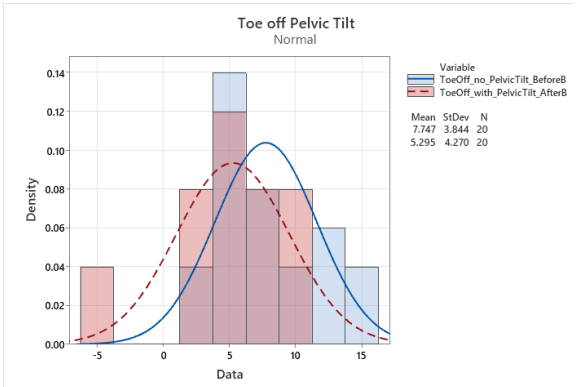

Midstance Hip Rotation
Normal
Density
Data
Variable
Mid_no_HipRot_BeforeB
Mid_with_HipRot_AfterB
Mean StDev N
-3.195 11.71 20
-1.19 9.590 20

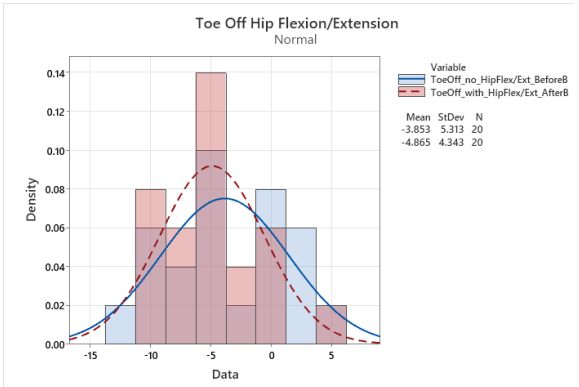

Midstance Knee Rotation
Normal
Density
Data
Variable
Mid_no_KneeRot_BeforeB
Mid_with_KneeRot_AfterB
Mean StDev N
8.275 8.942 20
6.812 7.385 20

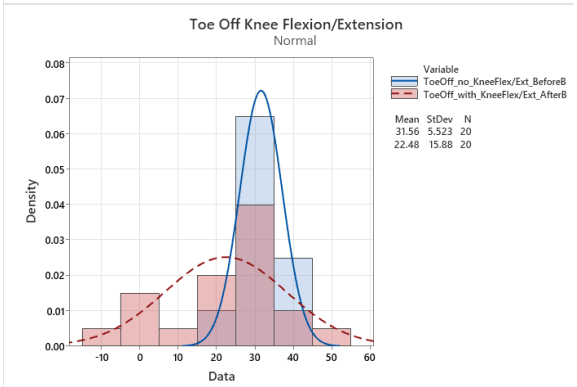

Midstance Ankle Rotation
Normal
Density
Data
Variable
Mid_no_AnkleRot_BeforeB
Mid_with_AnkleRot_AfterB
Mean StDev N
-15.29 9.250 20
-15.79 7.449 20

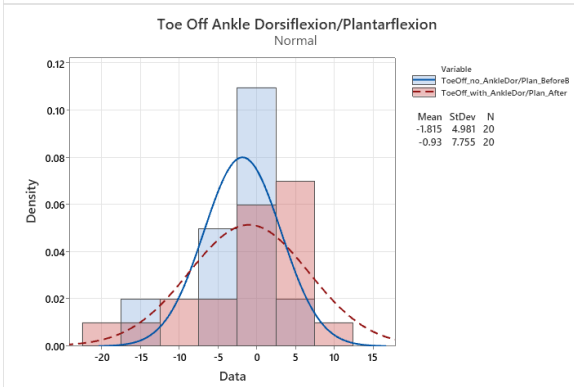
Appendix 19: Group B Before no insoles and After with insoles Kinematic Data

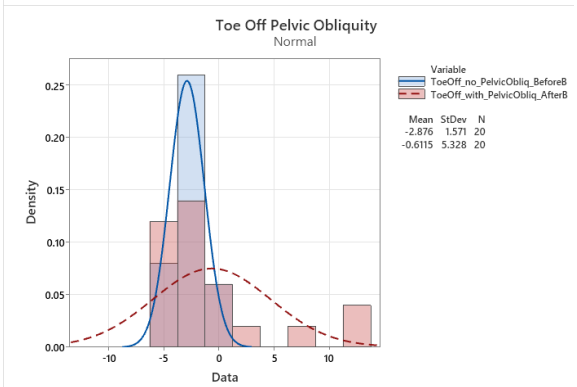
Histograms at Toe Off

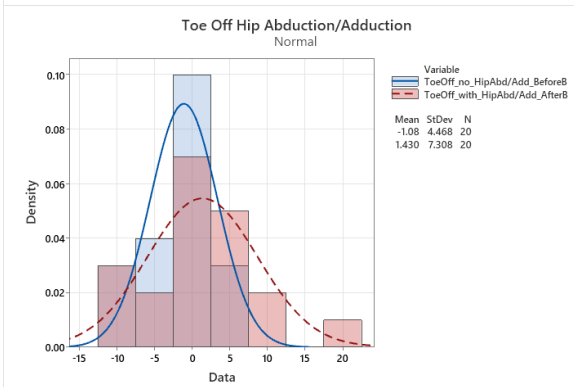


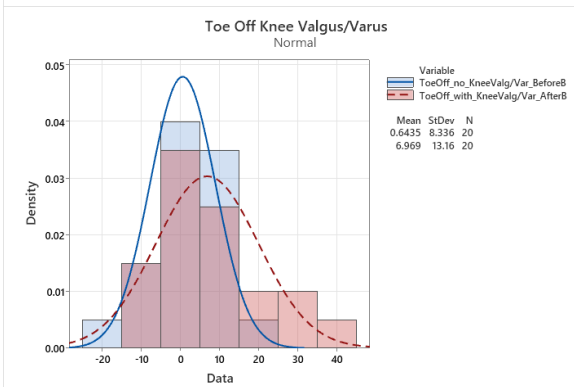


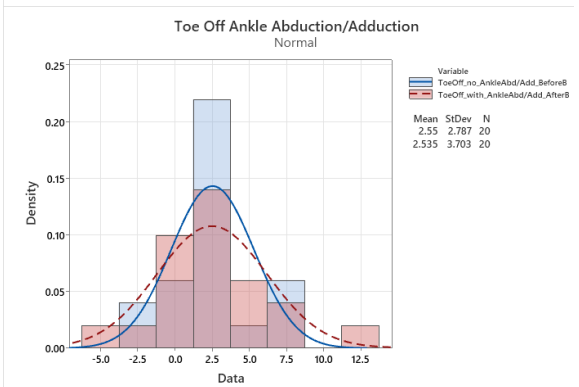


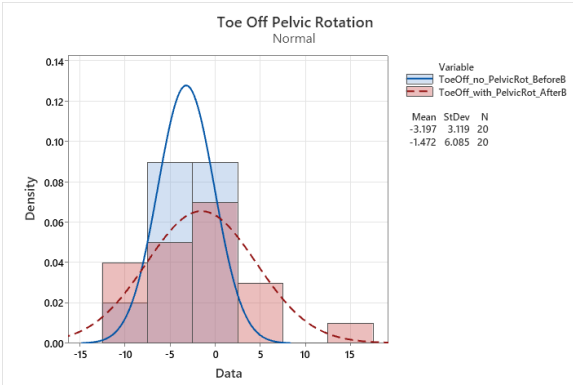


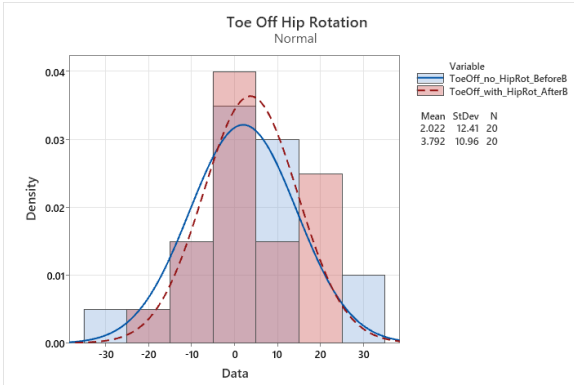


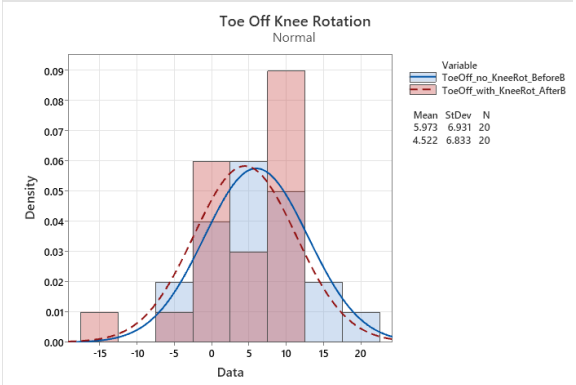


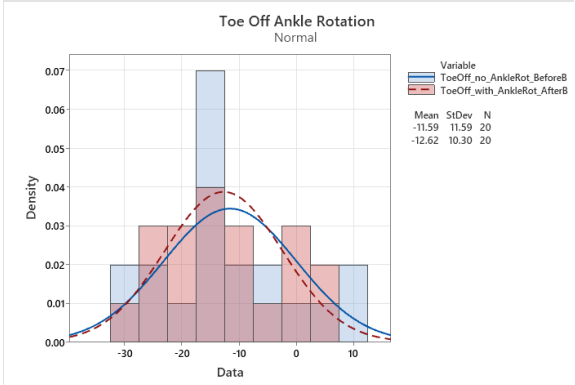





Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_no_PelvicRot_BeforeB
ToeOff_with_PelvicRot_AfterB
Mean StDev N
-3.197 3.119 20
-1.472 6.085 20

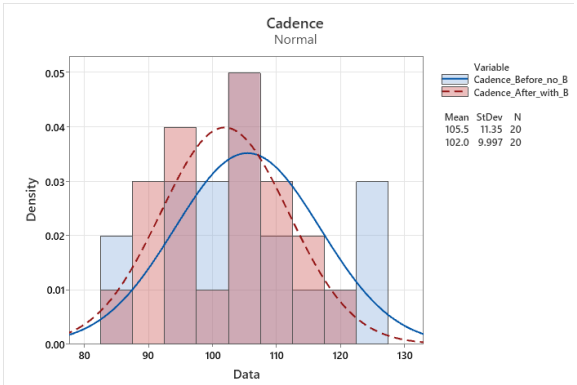

Toe Off Hip Rotation
Normal
Density
Data
Variable
ToeOff_no_HipRot_BeforeB
ToeOff_with_HipRot_AfterB
Mean StDev N
2.022 12.41 20
3.792 10.96 20

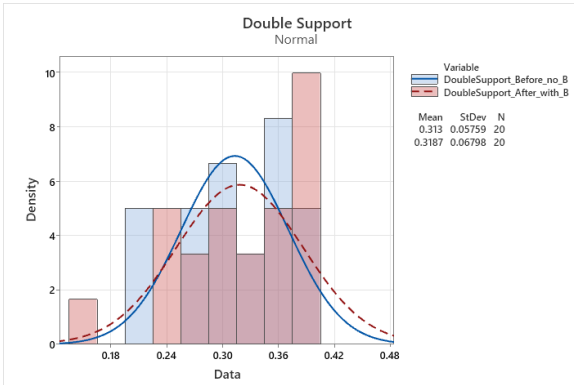

Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_no_KneeRot_BeforeB
ToeOff_with_KneeRot_AfterB
Mean StDev N
5.973 6.931 20
4.522 6.833 20

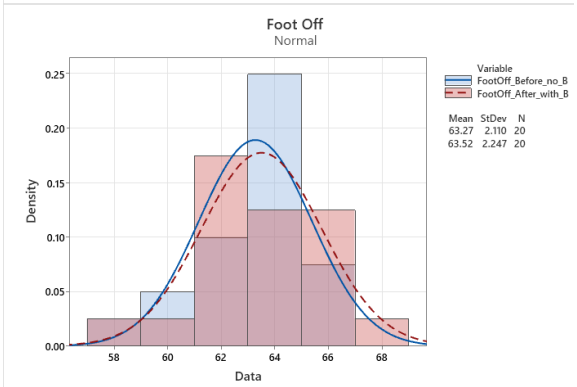

Toe Off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_no_AnkleRot_BeforeB
ToeOff_with_AnkleRot_AfterB
Mean StDev N
-11.59 11.59 20
-12.62 10.30 20

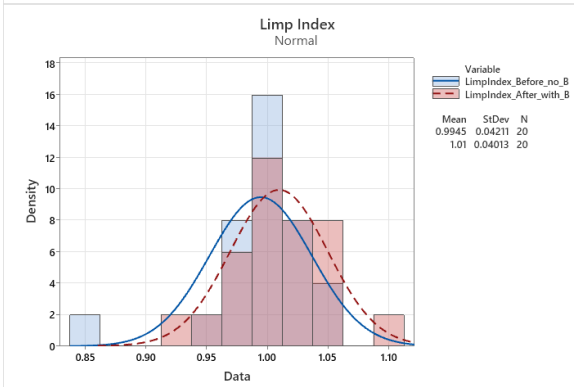
Appendix 20: Group B before no insoles vs after with insoles Spatiotemporal Data

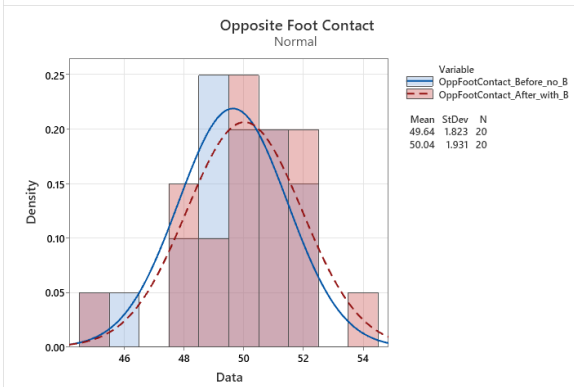
Histograms

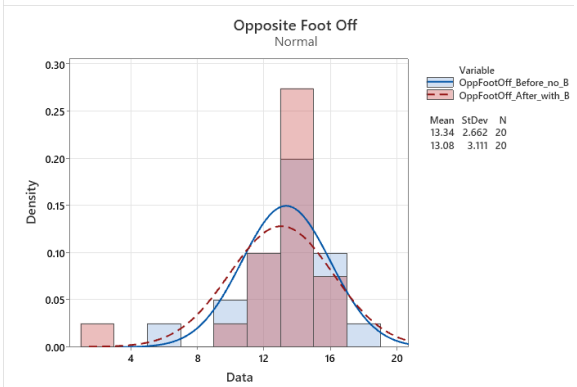


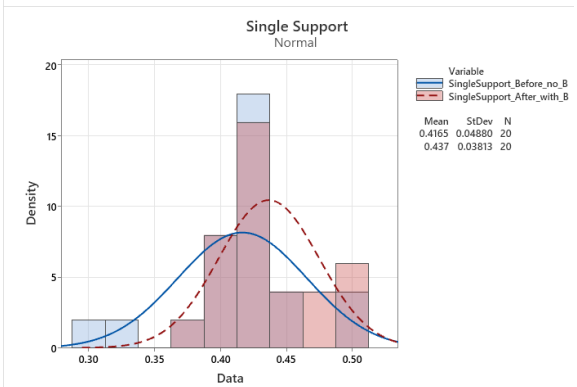


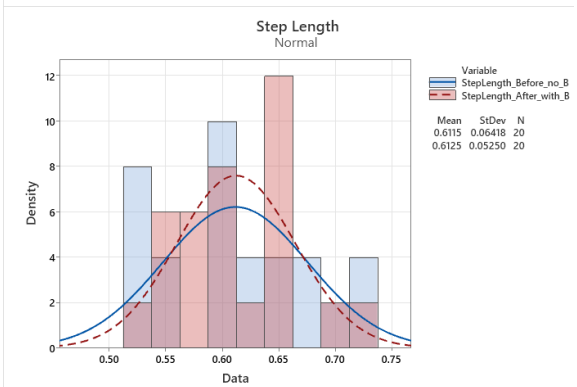


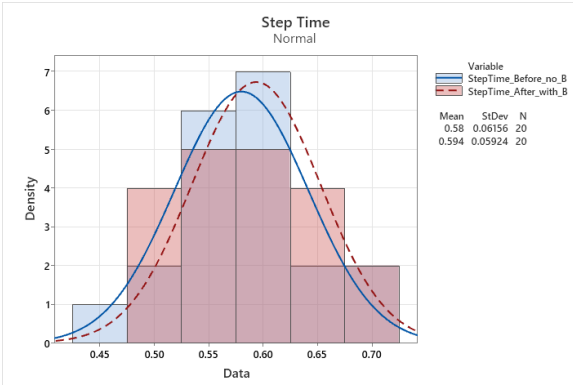


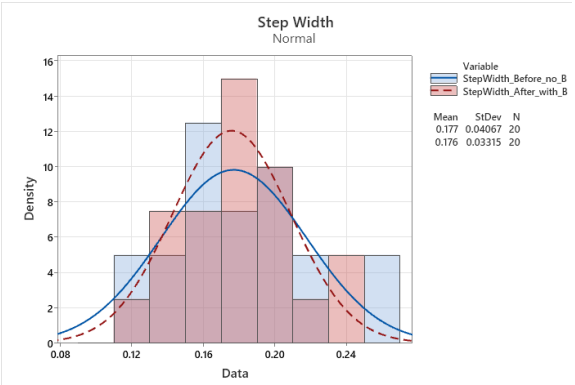


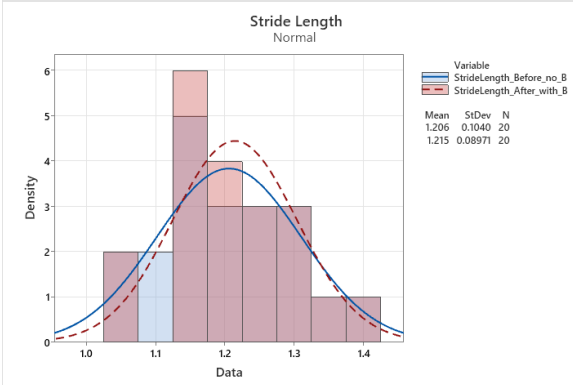


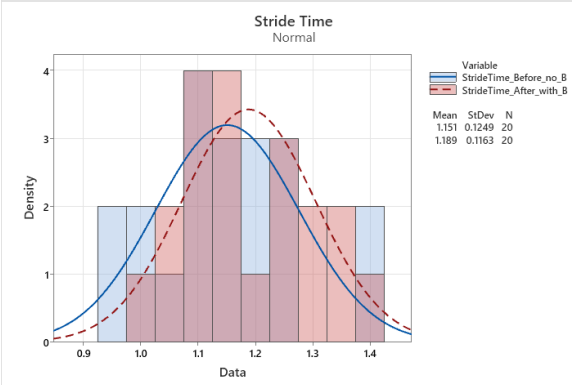


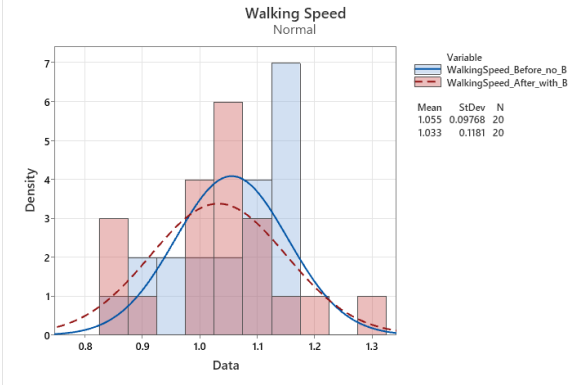



Step Time
Normal
Density
Data
Variable
StepTime_Before_no_B
StepTime_After_with_B
Mean StDev N
0.58 0.06156 20
0.594 0.05924 20

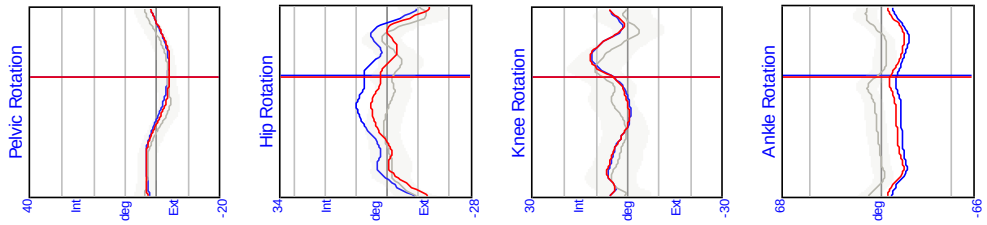

Step Width
Normal
Density
Data
Variable
StepWidth_Before_no_B
StepWidth_After_with_B
Mean StDev N
0.177 0.04067 20
0.176 0.03315 20

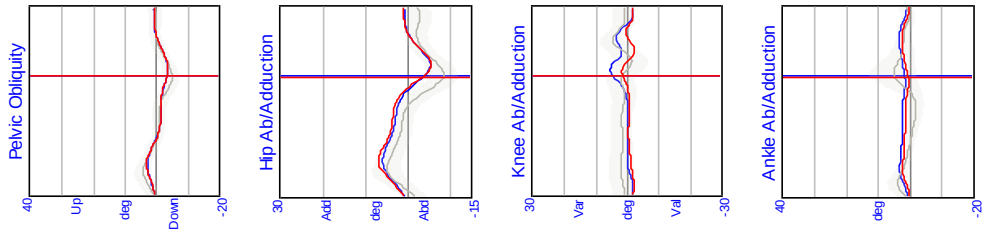

Stride Length
Normal
Density
Data
Variable
StrideLength_Before_no_B
StrideLength_After_with_B
Mean StDev N
1.206 0.1040 20
1.215 0.08971 20

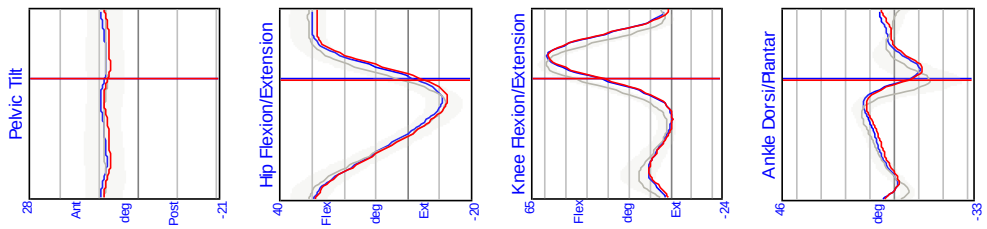

Stride Time
Normal
Density
Data
Variable
StrideTime_Before_no_B
StrideTime_After_with_B
Mean StDev N
1.151 0.1249 20
1.189 0.1163 20


Walking Speed
Normal
Density
Data
Variable
WalkingSpeed_Before_no_B
WalkingSpeed_After_with_B
Mean StDev N
1.055 0.09768 20
1.033 0.1181 20

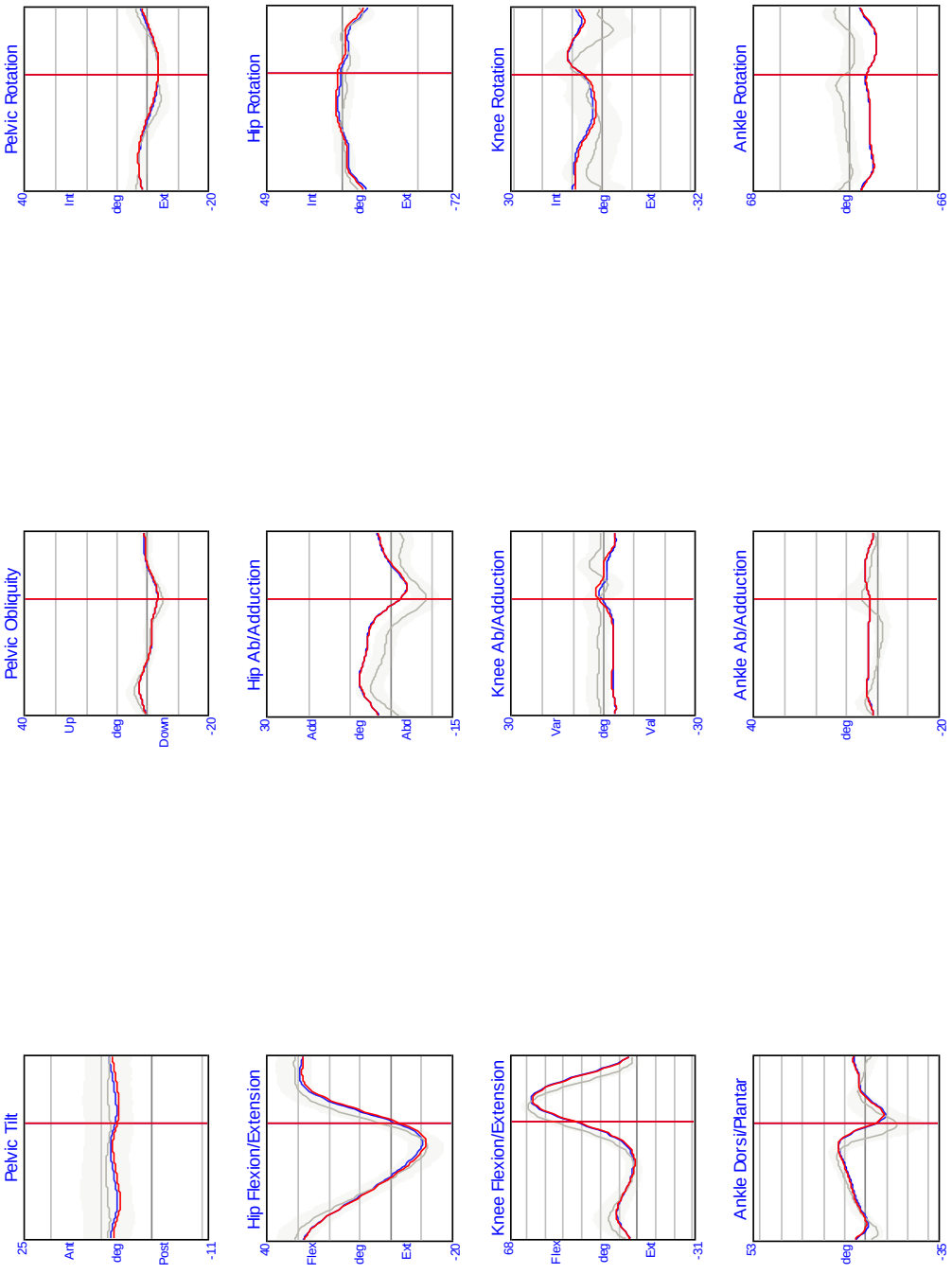
Appendix 21: Group A Polygon Graphs



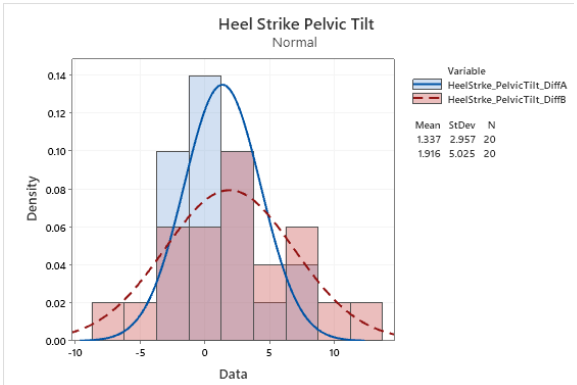


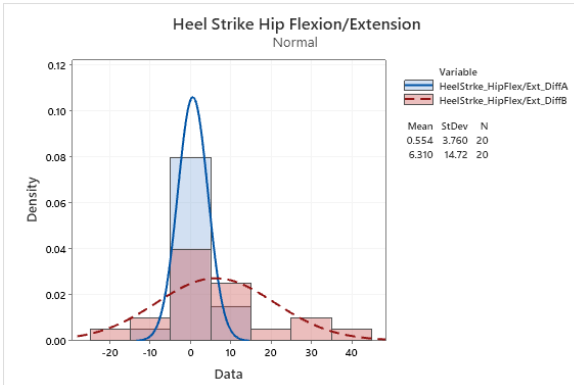


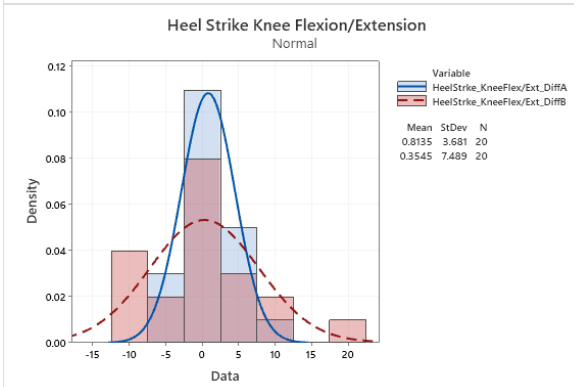
Appendix 22: Group B Polygon Graphs

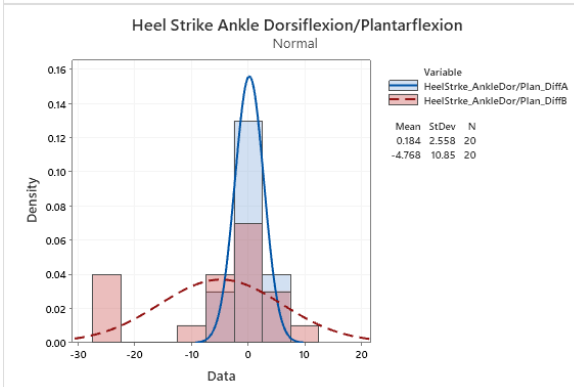


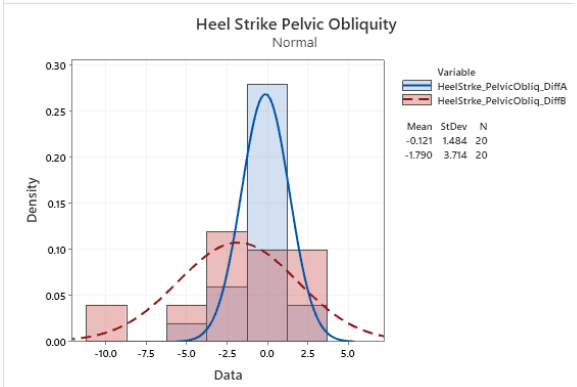
Appendix 23: Group A Difference vs Group B difference Kinematic Data Histogram Plots at Heel Strike

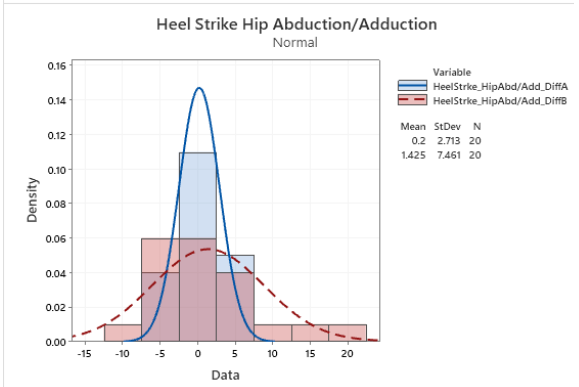


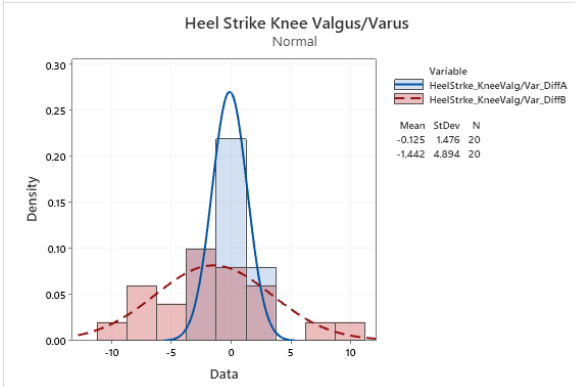


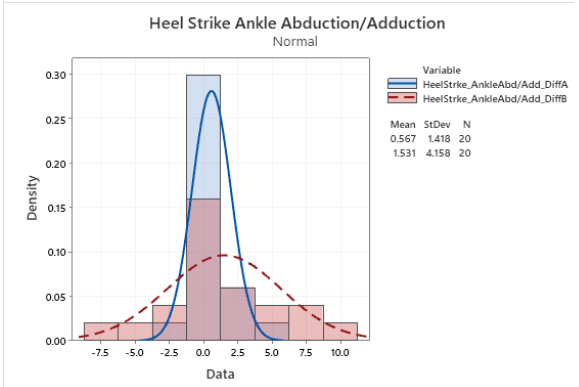


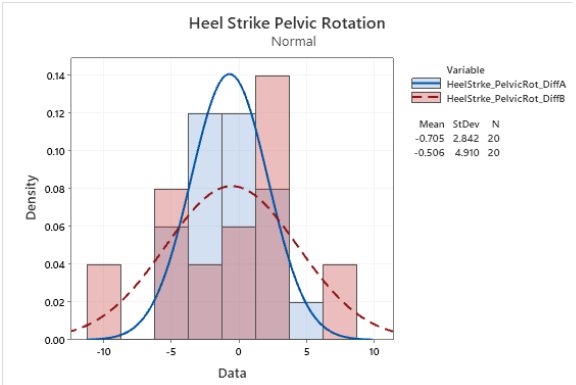


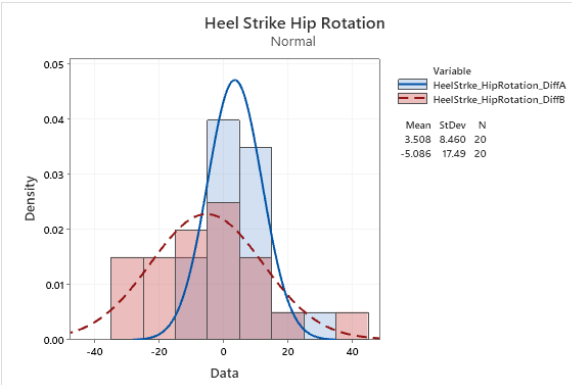


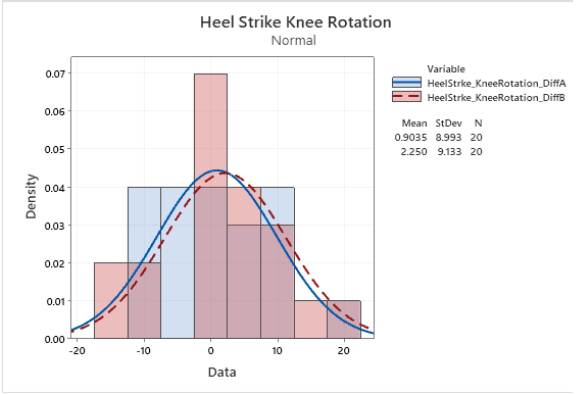


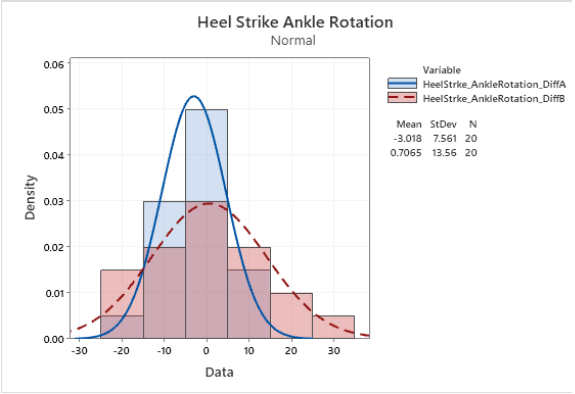




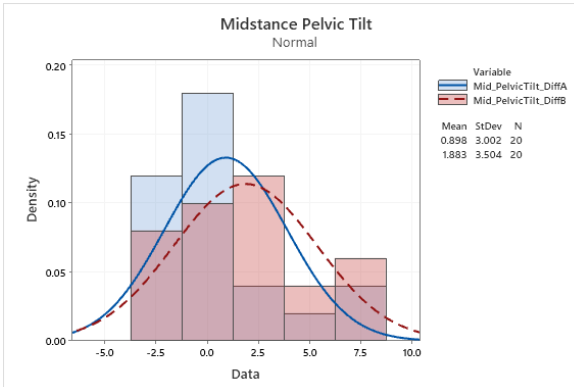

Heel Strike Pelvic Rotation
Normal
Density
Data
Variable
HeelStrke_PelvicRot_DiffA
HeelStrke_PelvicRot_DiffB
Mean StDev N
-0.705 2.842 20
-0.506 4.910 20

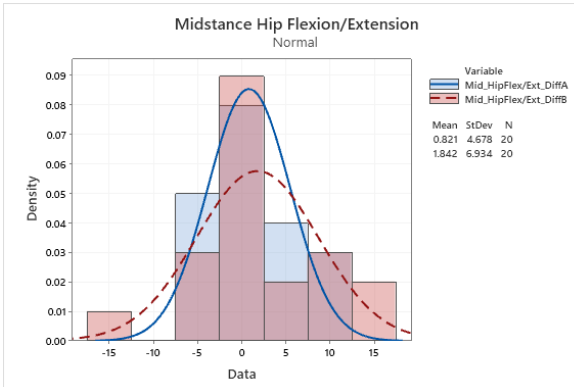

Heel Strike Hip Rotation
Normal
Density
Data
Variable
HeelStrke_HipRotation_DiffA
HeelStrke_HipRotation_DiffB
Mean StDev N
3.508 8.460 20
-5.086 17.49 20

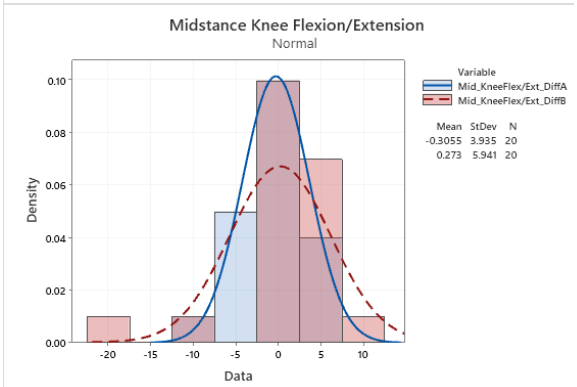

Heel Strike Knee Rotation
Normal
Density
Data
Variable
HeelStrke_KneeRotation_DiffA
HeelStrke_KneeRotation_DiffB
Mean StDev N
0.9035 8.993 20
2.250 9.133 20

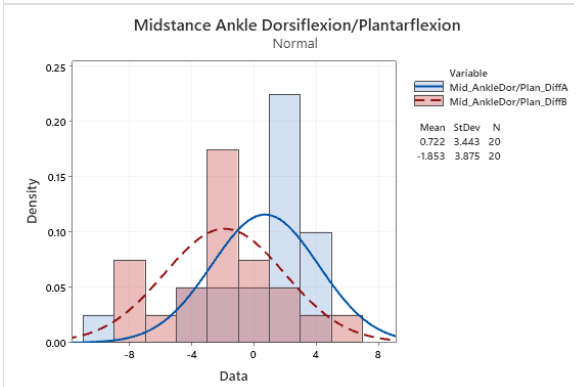

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
HeelStrke_AnkleRotation_DiffA
HeelStrke_AnkleRotation_DiffB
Mean StDev N
-3.018 7.561 20
0.7065 13.56 20

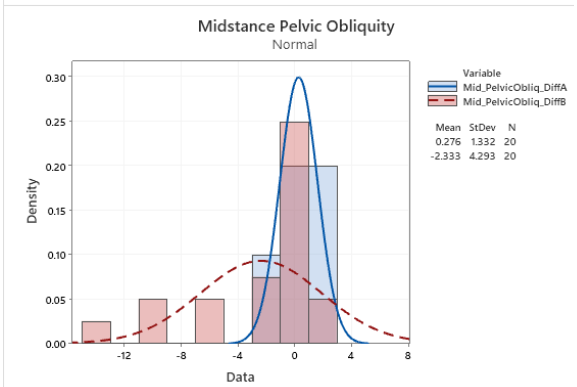
Appendix 24: Group A Difference vs Group B difference Kinematic Data Histogram Plots at Midstance

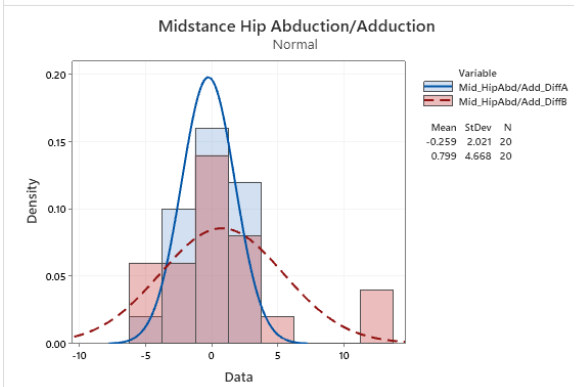


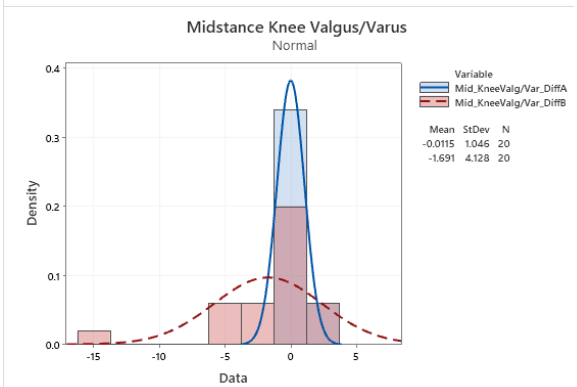


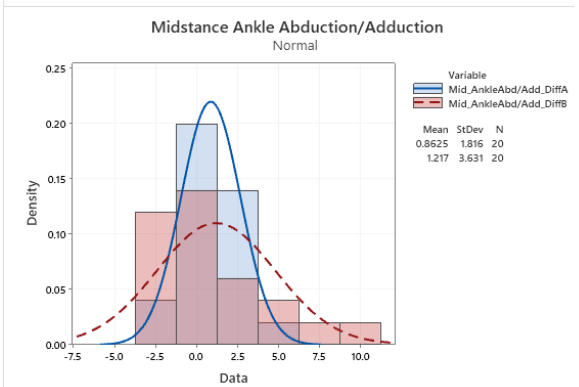


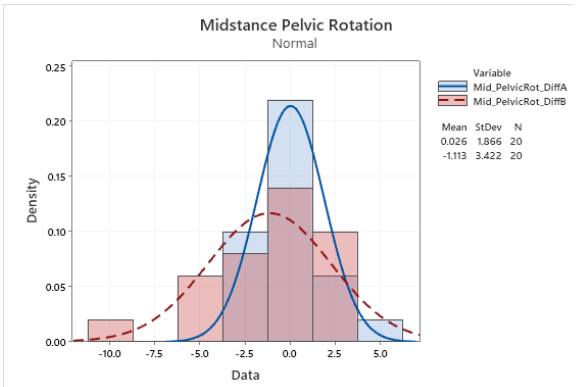


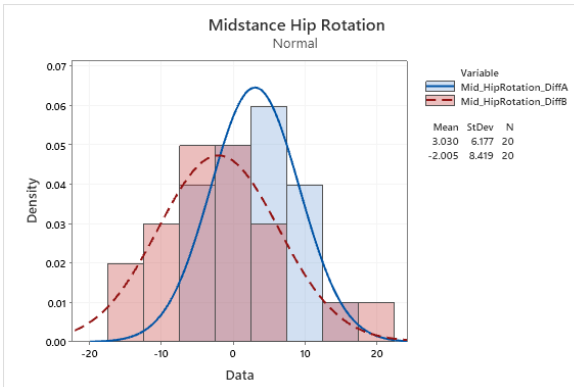


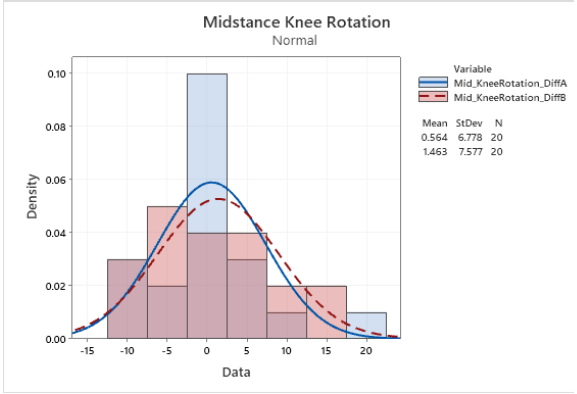


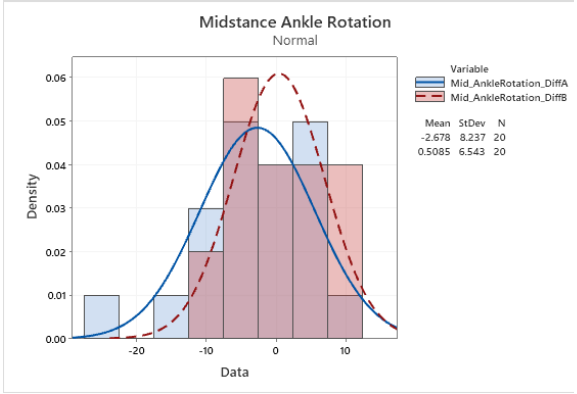




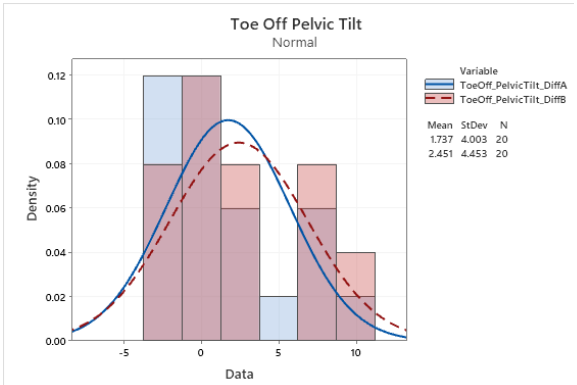

Midstance Pelvic Rotation
Normal
Density
Data
Variable
Mid_PelvicRot_DiffA
Mid_PelvicRot_DiffB
Mean StDev N
0.026 1.866 20
-1.113 3.422 20

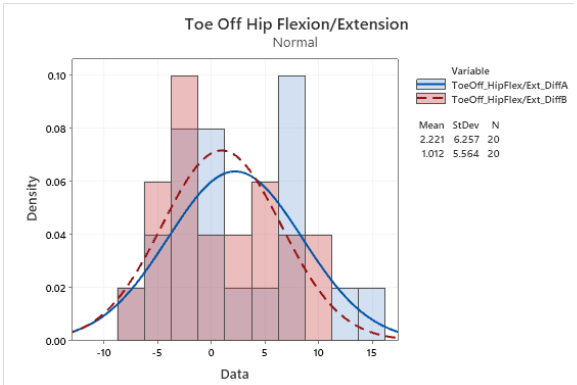

Midstance Hip Rotation
Normal
Density
Data
Variable
Mid_HipRotation_DiffA
Mid_HipRotation_DiffB
Mean StDev N
3.030 6.177 20
-2.005 8.419 20

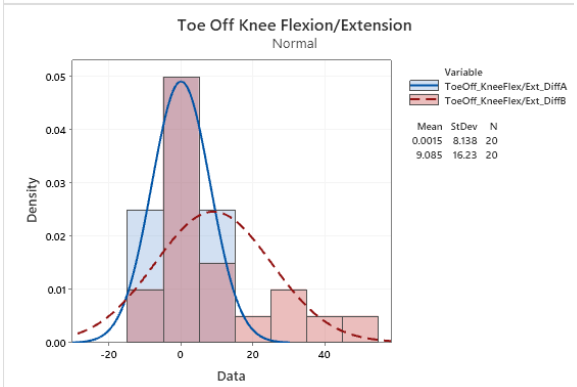

Midstance Knee Rotation
Normal
Density
Data
Variable
Mid_KneeRotation_DiffA
Mid_KneeRotation_DiffB
Mean StDev N
0.564 6.778 20
1.463 7.577 20

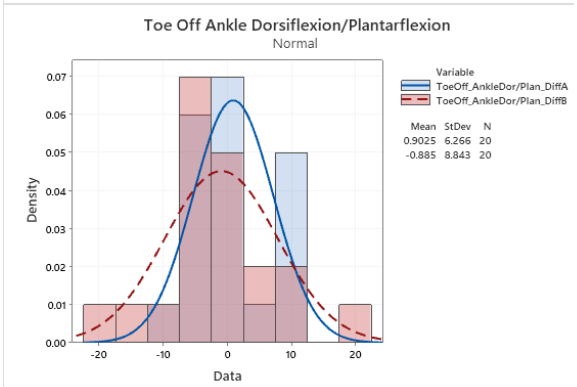

Midstance Ankle Rotation
Normal
Density
Data
Variable
Mid_AnkleRotation_DiffA
Mid_AnkleRotation_DiffB
Mean StDev N
-2.678 8.237 20
0.5085 6.543 20

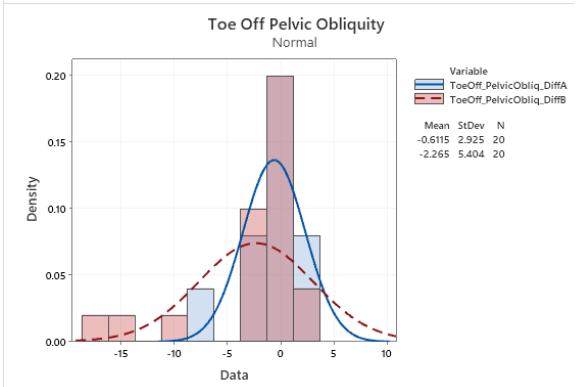
Appendix 25: Group A Difference vs Group B difference Kinematic Data Histogram Plots at Toe Off

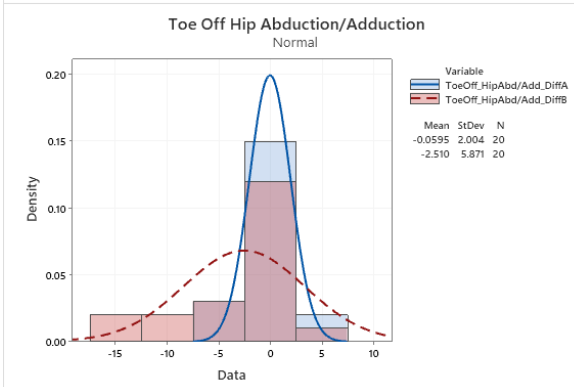


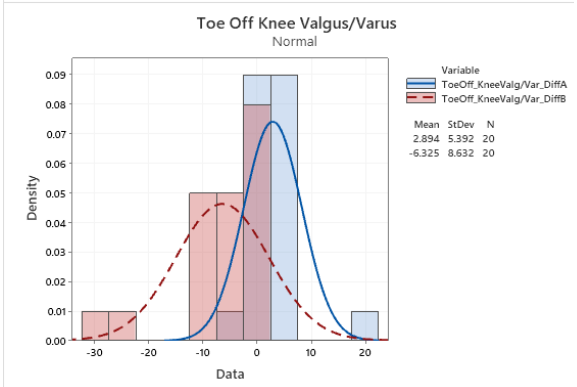


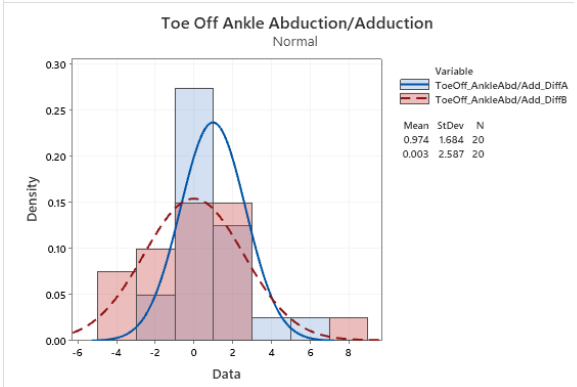


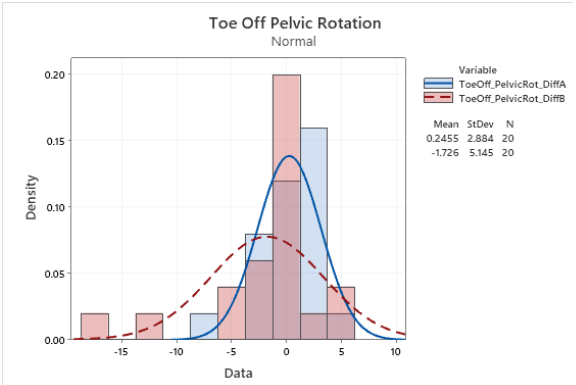


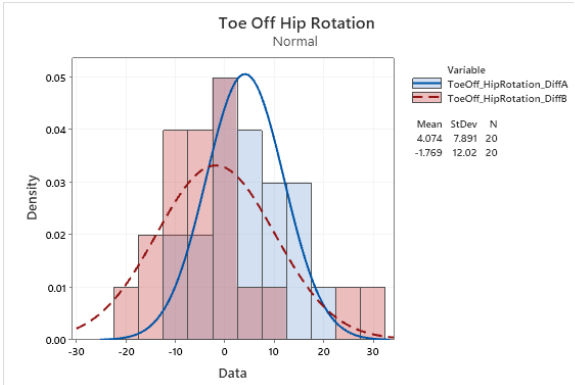


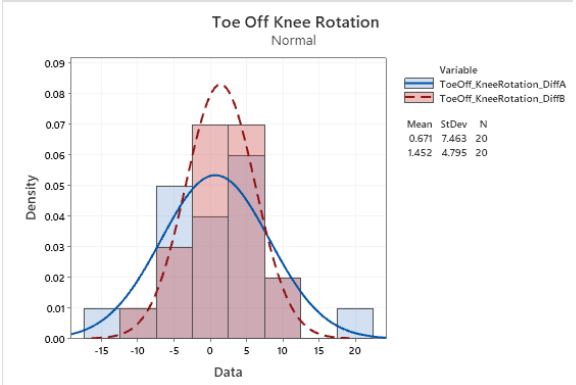


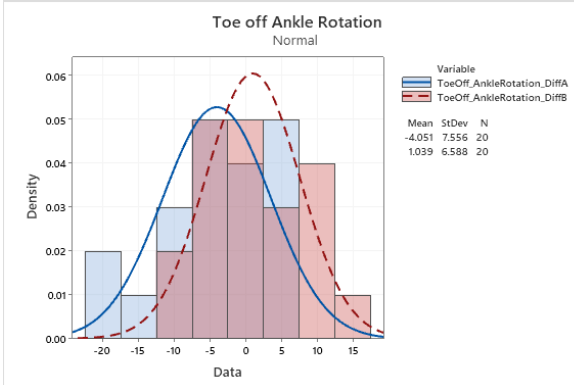





Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_PelvicRot_DiffA
ToeOff_PelvicRot_DiffB
Mean StDev N
0.2455 2.884 20
-1.726 5.145 20

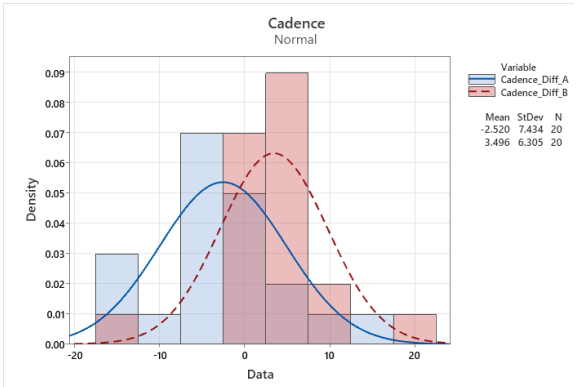

Toe Off Hip Rotation
Normal
Density
Data
Variable
ToeOff_HipRotation_DiffA
ToeOff_HipRotation_DiffB
Mean StDev N
4.074 7.891 20
-1.769 12.02 20

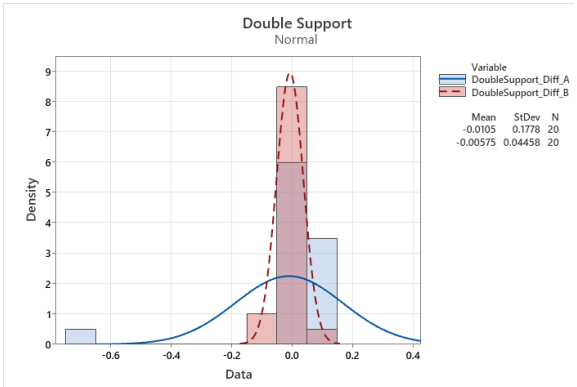

Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_KneeRotation_DiffA
ToeOff_KneeRotation_DiffB
Mean StDev N
0.671 7.463 20
1.452 4.795 20

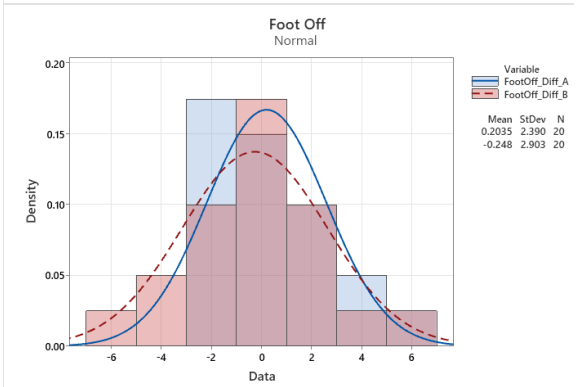

Toe off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_AnkleRotation_DiffA
ToeOff_AnkleRotation_DiffB
Mean StDev N
-4.051 7.556 20
1.039 6.588 20

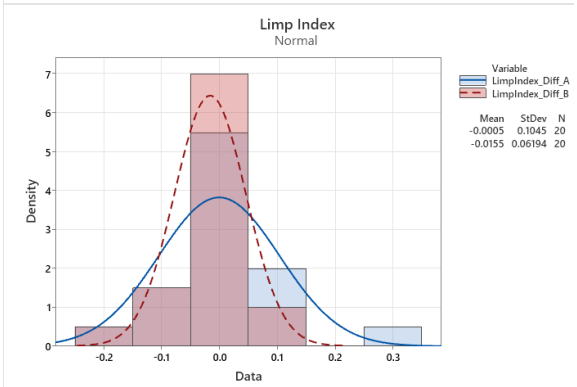
Appendix 26: Group A Difference vs Group B difference Spatiotemporal Data

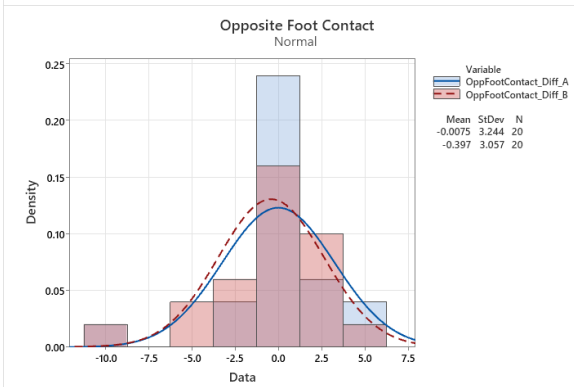
Histogram Plots

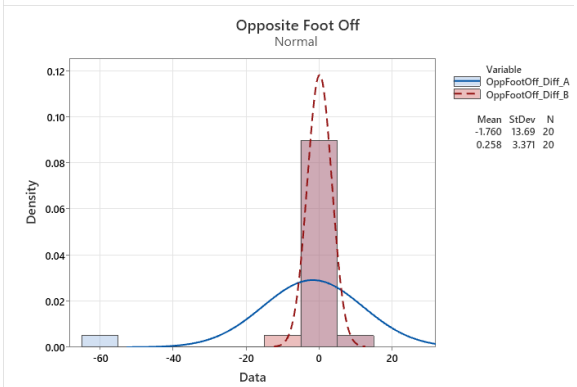


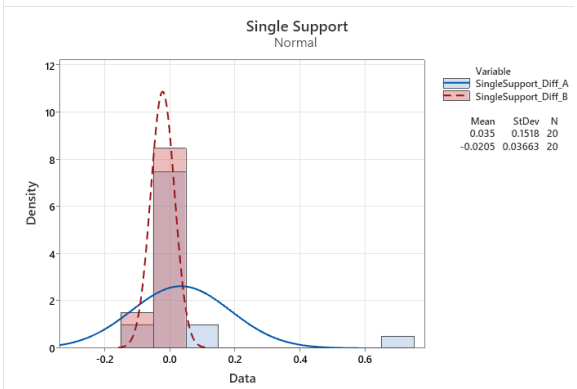


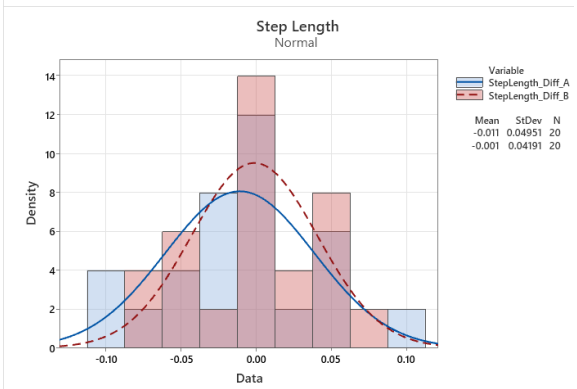


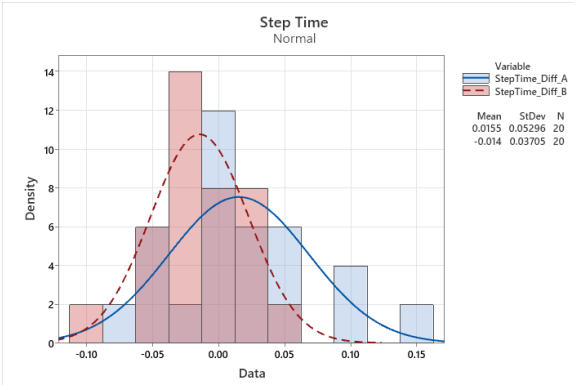


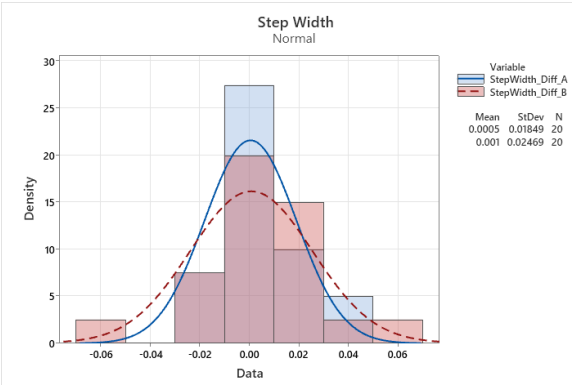


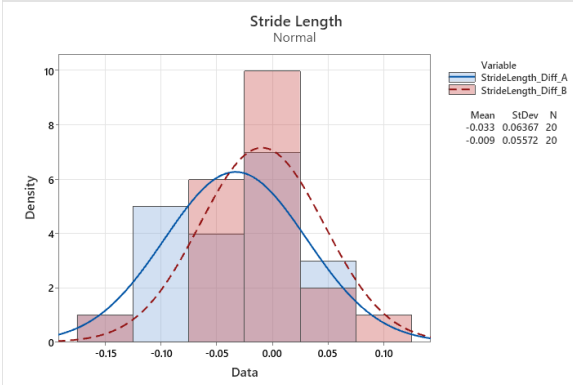


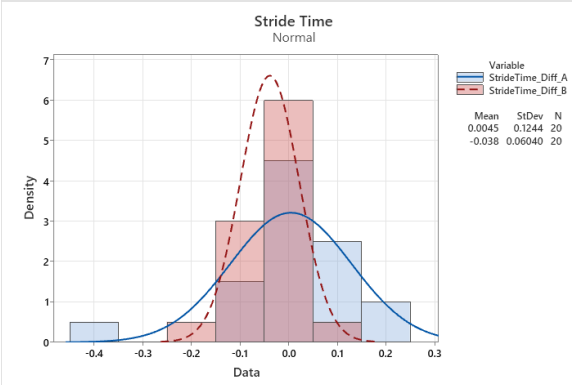


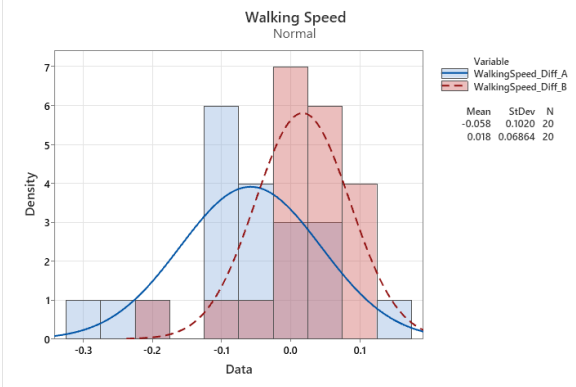



Step Time
Normal
Density
Data
Variable
StepTime_Diff_A
StepTime_Diff_B
Mean StDev N
0.0155 0.05296 20
-0.014 0.03705 20


Step Width
Normal
Density
Data
Variable
StepWidth_Diff_A
StepWidth_Diff_B
Mean StDev N
0.0005 0.01849 20
0.001 0.02469 20


Stride Length
Normal
Density
Data
Variable
StrideLength_Diff_A
StrideLength_Diff_B
Mean StDev N
-0.033 0.06367 20
-0.009 0.05572 20

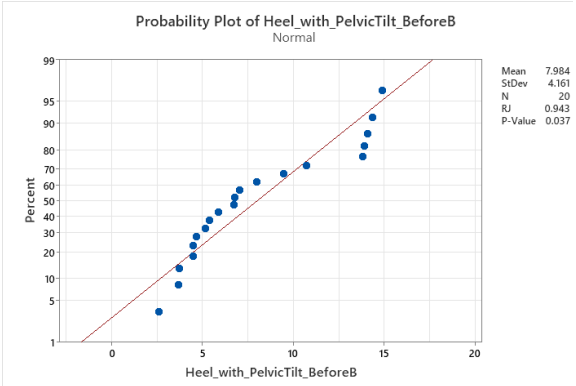

Stride Time
Normal
Density
Data
Variable
StrideTime_Diff_A
StrideTime_Diff_B
Mean StDev N
0.0045 0.1244 20
-0.038 0.06040 20

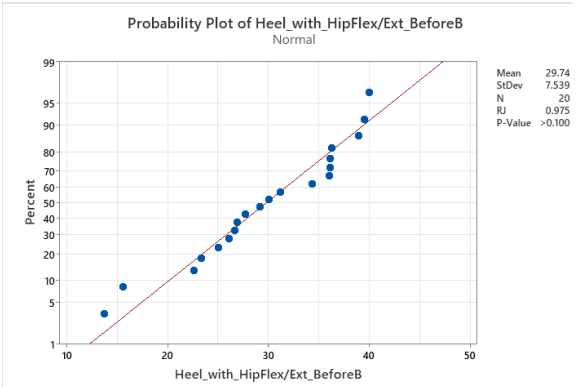

Walking Speed
Normal
Density
Data
Variable
WalkingSpeed_Diff_A
WalkingSpeed_Diff_B
Mean StDev N
-0.058 0.1020 20
0.018 0.06864 20

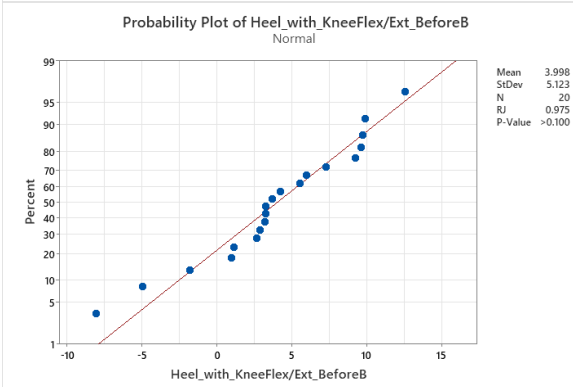
Appendix 27: Additional Statistical Analysis – Normality Testing of Data – Group B

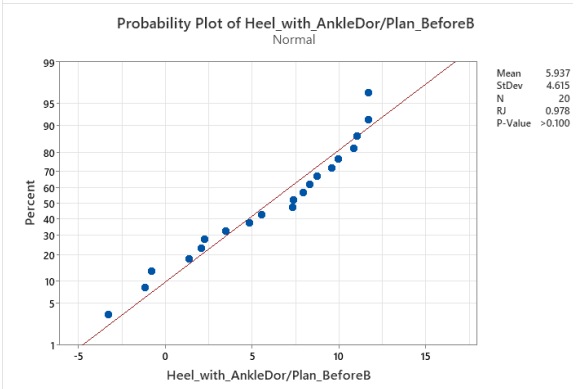
Before with insoles and After no insoles at Heel Strike

Before with Insoles

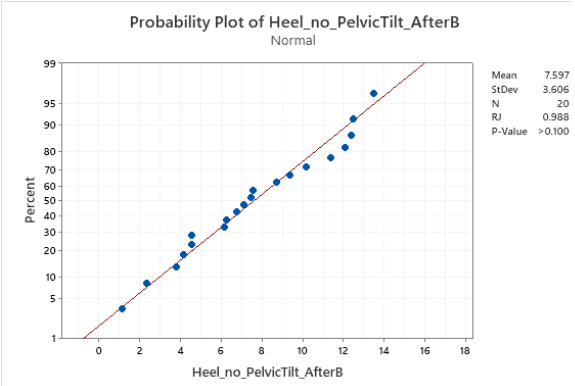


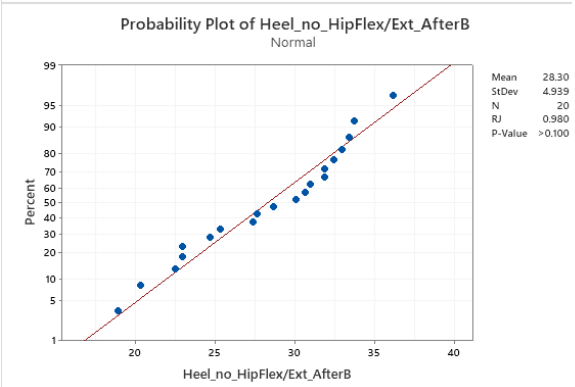


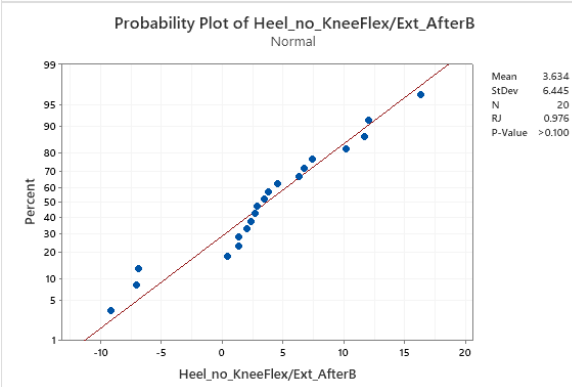


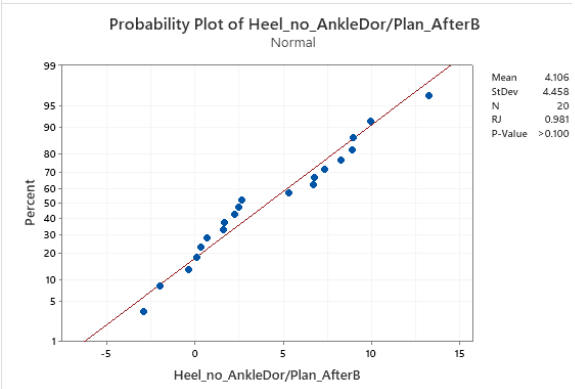


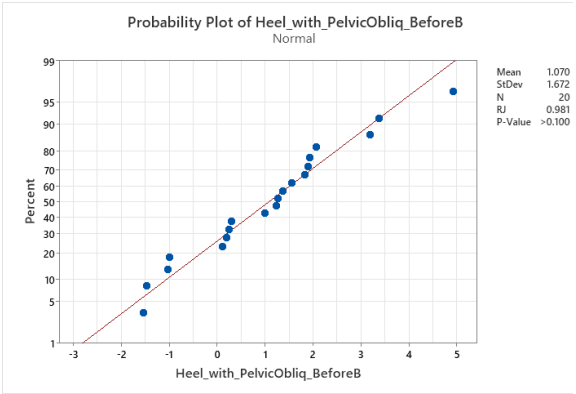
After No insoles

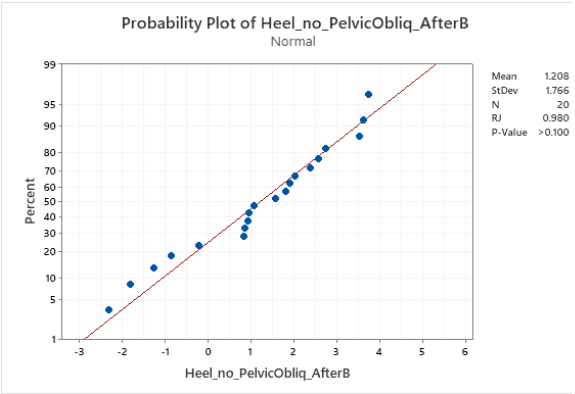


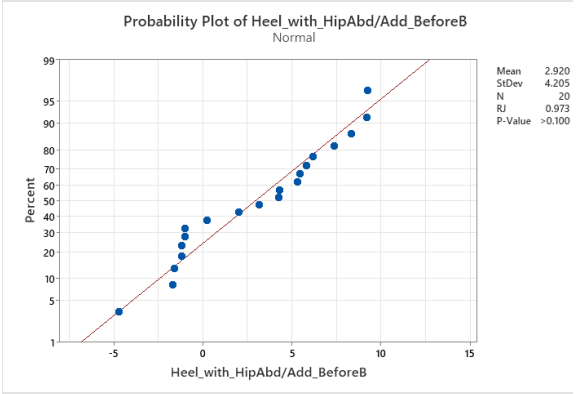


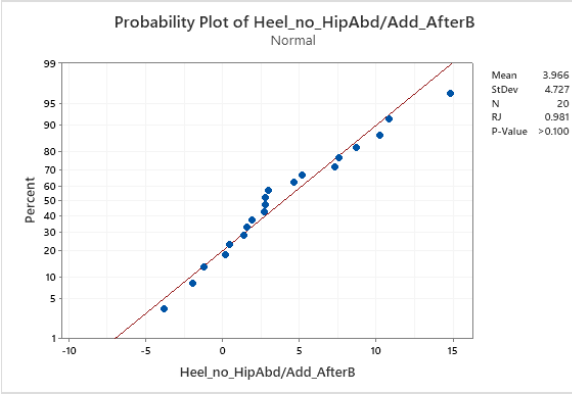


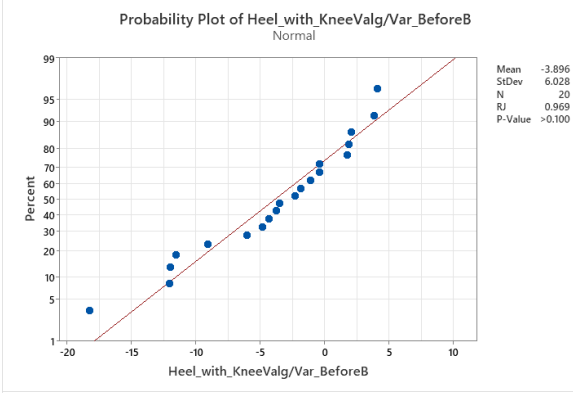


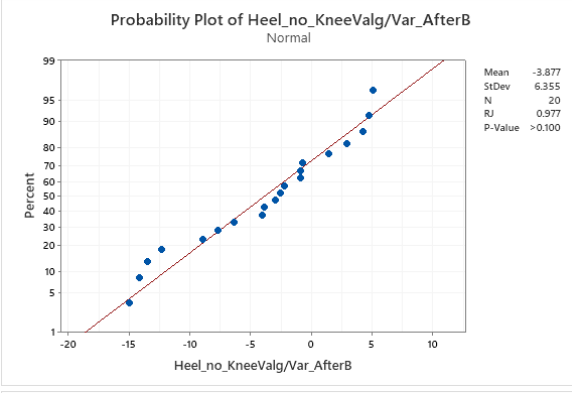

Probability Plot of Heel_with_PelvicObliq_BeforeB
Normal
Mean 1.070
StDev 1.672
N 20
RJ 0.981
P-Value >0.100
Percent
Heel_with_PelvicObliq_BeforeB

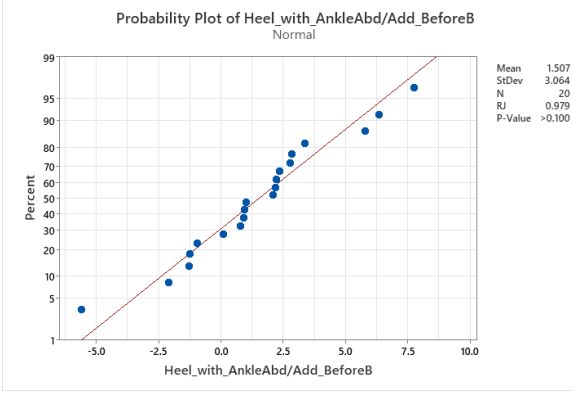

Probability Plot of Heel_no_PelvicObliq_AfterB
Normal
Mean 1.208
StDev 1.766
N 20
RJ 0.980
P-Value >0.100
Percent
Heel_no_PelvicObliq_AfterB

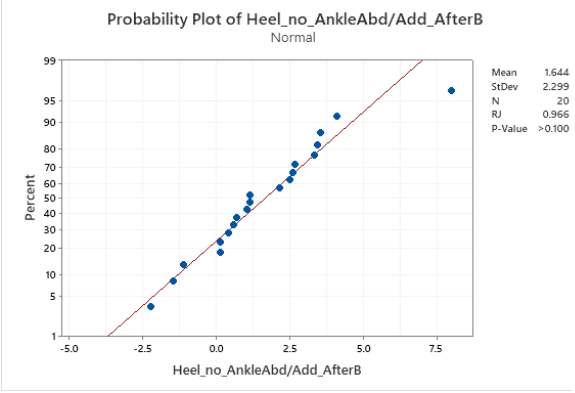

Probability Plot of Heel_with_HipAbd/Add_BeforeB
Normal
Mean 2.920
StDev 4.205
N 20
RJ 0.973
P-Value >0.100
Percent
Heel_with_HipAbd/Add_BeforeB

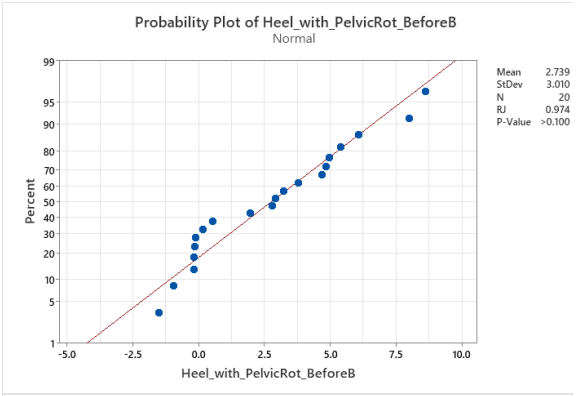

Probability Plot of Heel_no_HipAbd/Add_AfterB
Normal
Mean 3.966
StDev 4.727
N 20
RJ 0.981
P-Value >0.100
Percent
Heel_no_HipAbd/Add_AfterB

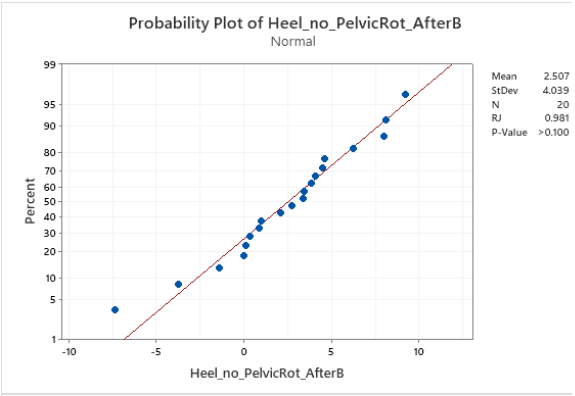

Probability Plot of Heel_with_KneeValg/Var_BeforeB
Normal
Mean -3.896
StDev 6.028
N 20
RJ 0.969
P-Value >0.100
Percent
Heel_with_KneeValg/Var_BeforeB

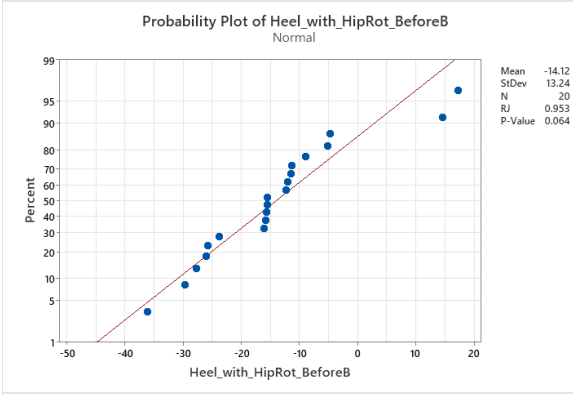

Probability Plot of Heel_no_KneeValg/Var_AfterB
Normal
Mean -3.877
StDev 6.355
N 20
RJ 0.977
P-Value >0.100
Percent
Heel_no_KneeValg/Var_AfterB

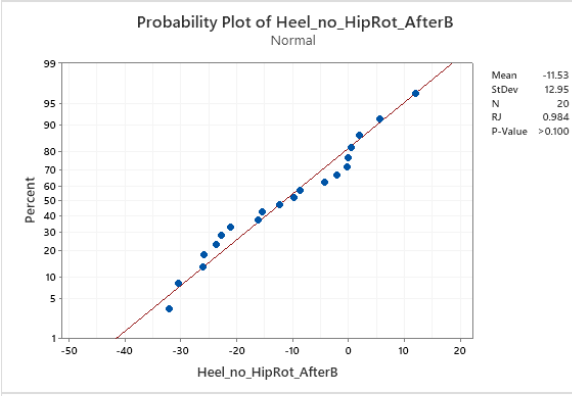

Probability Plot of Heel_with_AnkleAbd/Add_BeforeB
Normal
Mean 1.507
StDev 3.064
N 20
RJ 0.979
P-Value >0.100
Percent
Heel_with_AnkleAbd/Add_BeforeB

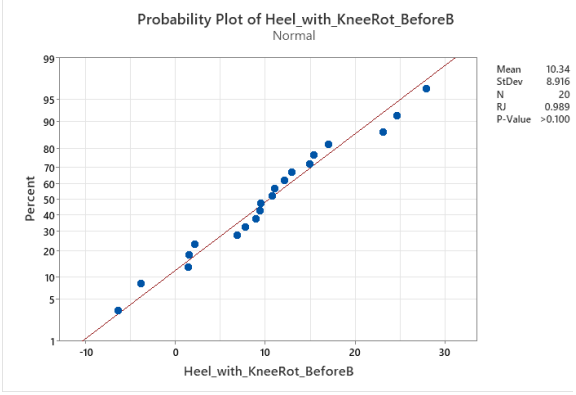

Probability Plot of Heel_no_AnkleAbd/Add_AfterB
Normal
Mean 1.644
StDev 2.299
N 20
RJ 0.966
P-Value >0.100
Percent
Heel_no_AnkleAbd/Add_AfterB

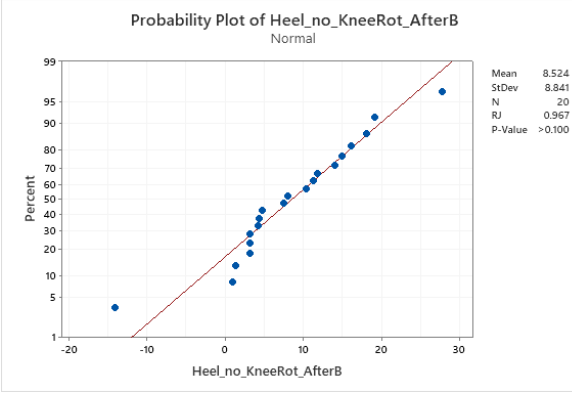

Probability Plot of Heel_with_PelvicRot_BeforeB
Normal
Mean 2.739
StDev 3.010
N 20
RJ 0.974
P-Value >0.100
Percent
Heel_with_PelvicRot_BeforeB

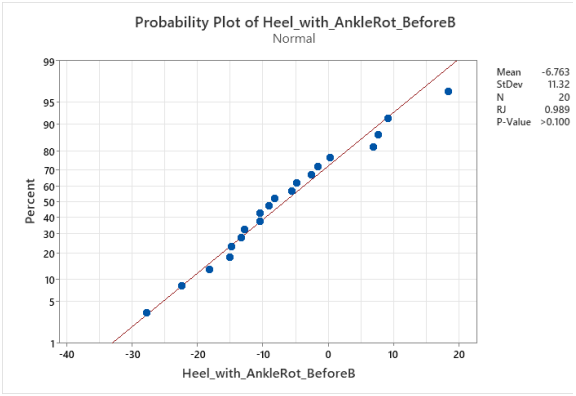

Probability Plot of Heel_no_PelvicRot_AfterB
Normal
Mean 2.507
StDev 4.039
N 20
RJ 0.981
P-Value >0.100
Percent
Heel_no_PelvicRot_AfterB

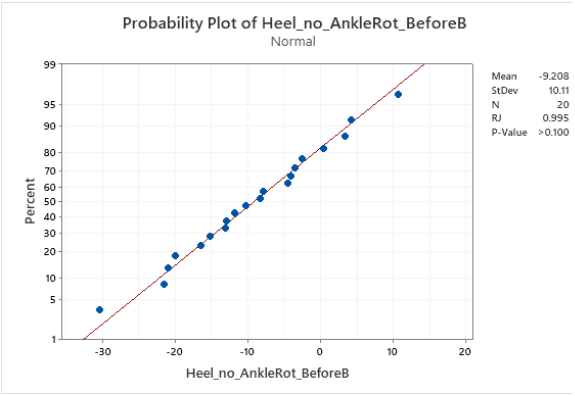

Probability Plot of Heel_with_HipRot_BeforeB
Normal
Mean -14.12
StDev 13.24
N 20
RJ 0.953
P-Value 0.064
Percent
Heel_with_HipRot_BeforeB


Probability Plot of Heel_no_HipRot_AfterB
Normal
Mean -11.53
StDev 12.95
N 20
RJ 0.984
P-Value >0.100
Percent
Heel_no_HipRot_AfterB


Probability Plot of Heel_with_KneeRot_BeforeB
Normal
Mean 10.34
StDev 8.916
N 20
RJ 0.989
P-Value >0.100
Percent
Heel_with_KneeRot_BeforeB


Probability Plot of Heel_no_KneeRot_AfterB
Normal
Mean 8.524
StDev 8.841
N 20
RJ 0.967
P-Value >0.100
Percent
Heel_no_KneeRot_AfterB


Probability Plot of Heel_with_AnkleRot_BeforeB
Normal
Mean -6.763
StDev 11.32
N 20
RJ 0.989
P-Value >0.100
Percent
Heel_with_AnkleRot_BeforeB

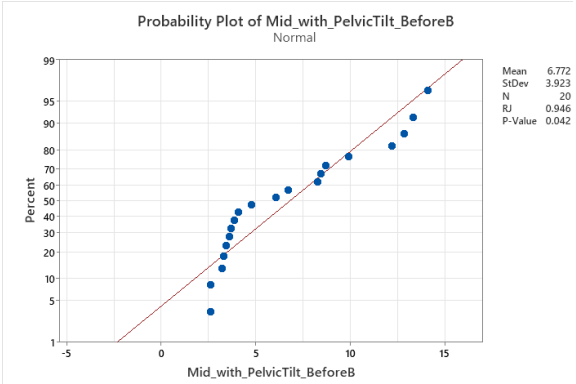

Probability Plot of Heel_no_AnkleRot_BeforeB
Normal
Mean -9.208
StDev 10.11
N 20
RJ 0.995
P-Value >0.100
Percent
Heel_no_AnkleRot_BeforeB

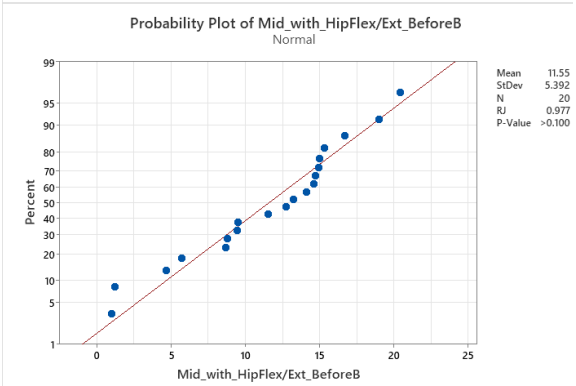
	Before with Insoles			After without Insoles		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.037	Yes	Rejected	>0.1	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Dorsi/Plantar	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Obliquity	>0.1	no	Accepted	>0.1	no	Accepted
Hip Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Knee Valg/Var	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Hip Rotation	0.064	no	Accepted	>0.1	no	Accepted
Knee Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

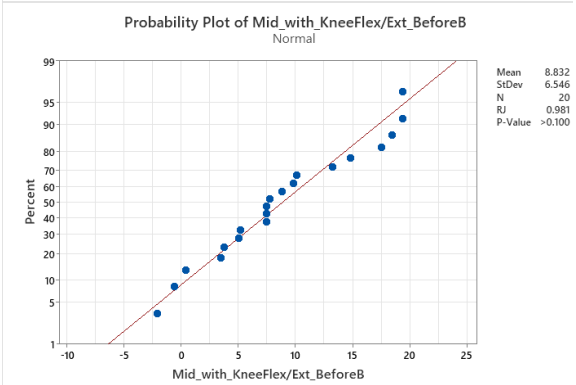
Appendix 28: Additional Statistical Analysis – Normality Testing of Data – Group B

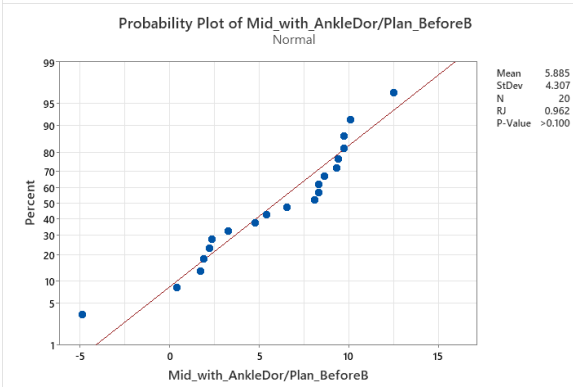
Before with insoles and After no insoles at Midstance

Before with Insoles

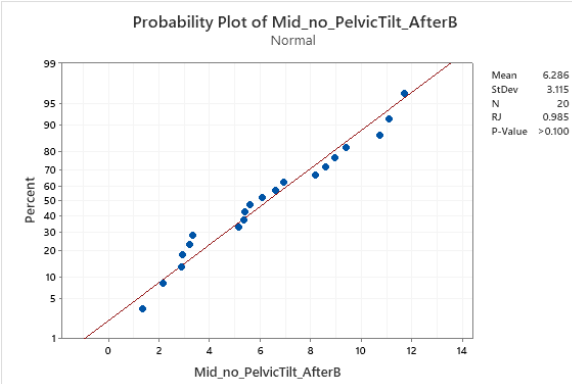


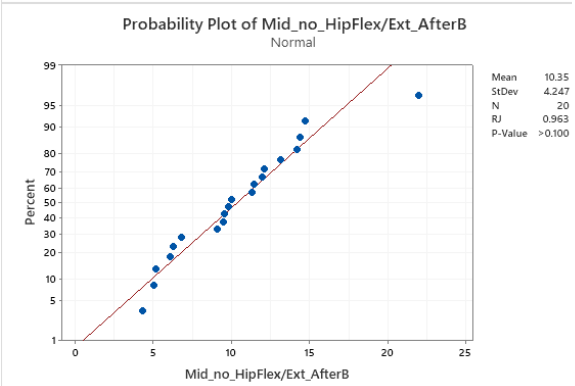


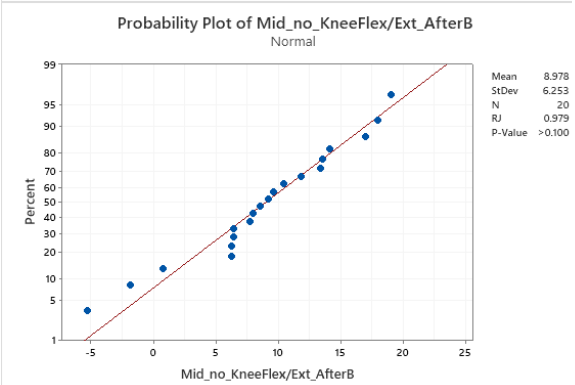


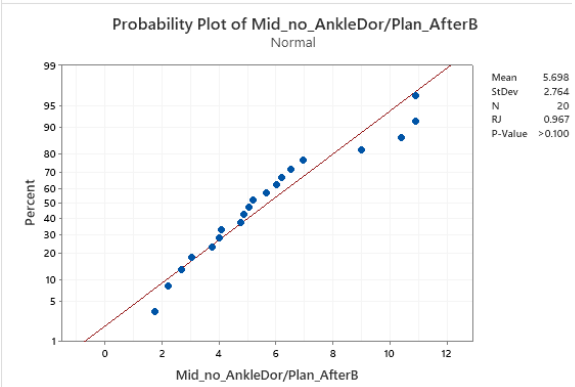


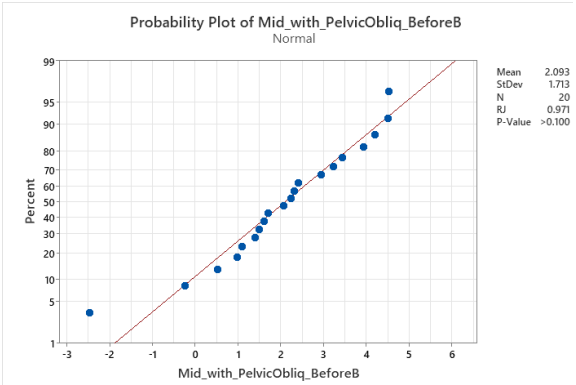
After no insoles

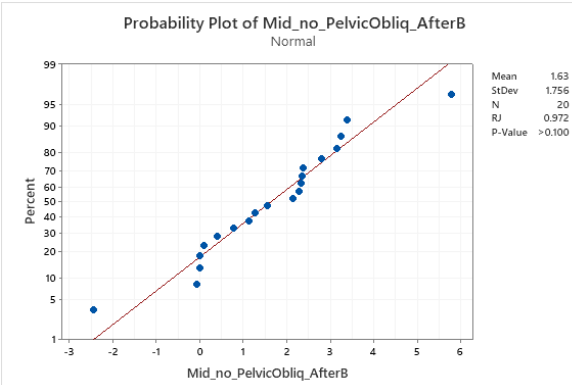


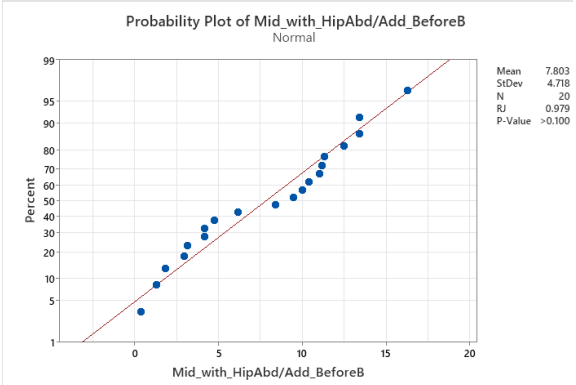


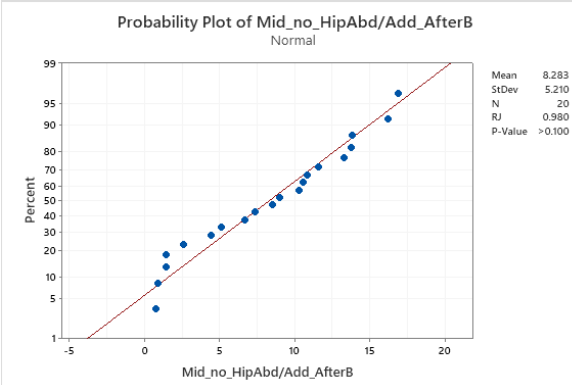


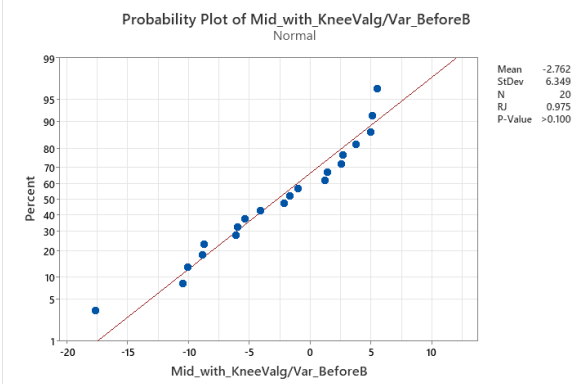


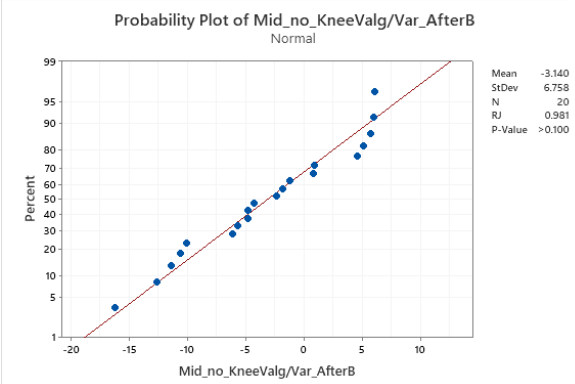

Probability Plot of Mid_with_PelvicObliq_BeforeB
Normal
Mean 2.093
StDev 1.713
N 20
RJ 0.971
P-Value >0.100
Percent
Mid_with_PelvicObliq_BeforeB

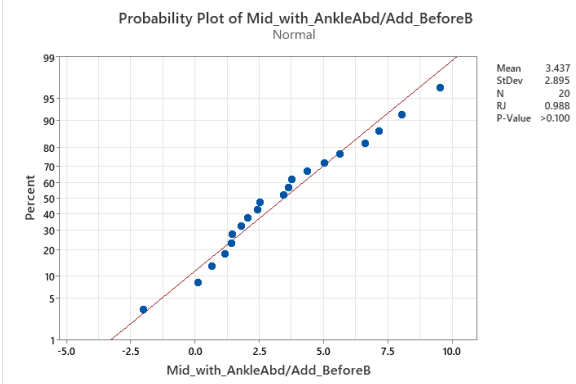

Probability Plot of Mid_no_PelvicObliq_AfterB
Normal
Mean 1.63
StDev 1.756
N 20
RJ 0.972
P-Value >0.100
Percent
Mid_no_PelvicObliq_AfterB

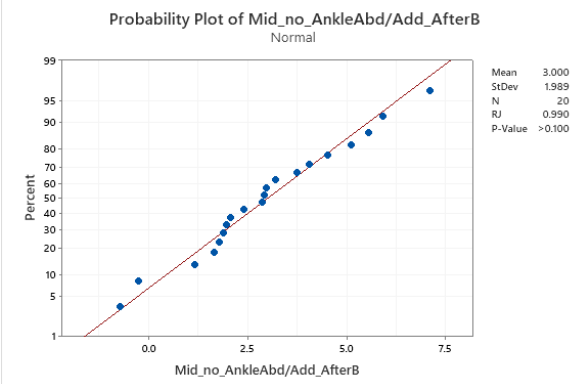

Probability Plot of Mid_with_HipAbd/Add_BeforeB
Normal
Mean 7.803
StDev 4.718
N 20
RJ 0.979
P-Value >0.100
Percent
Mid_with_HipAbd/Add_BeforeB

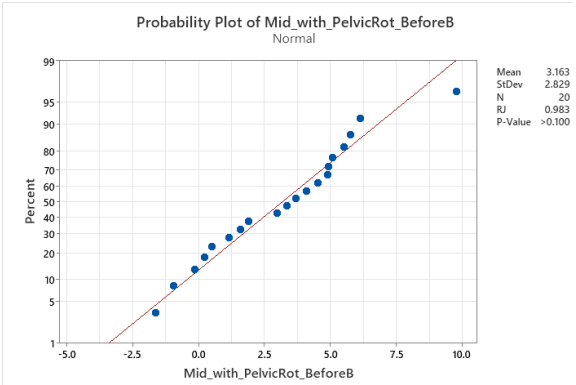

Probability Plot of Mid_no_HipAbd/Add_AfterB
Normal
Mean 8.283
StDev 5.210
N 20
RJ 0.980
P-Value >0.100
Percent
Mid_no_HipAbd/Add_AfterB

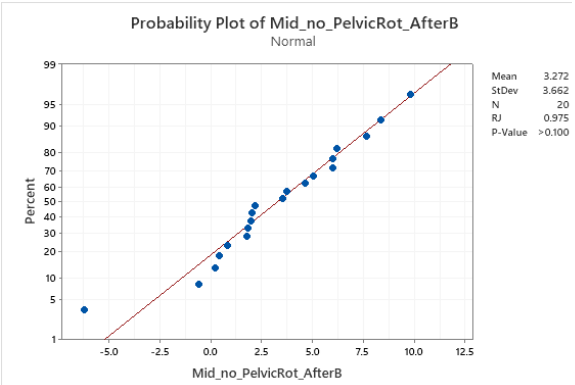

Probability Plot of Mid_with_KneeValg/Var_BeforeB
Normal
Mean -2.762
StDev 6.349
N 20
RJ 0.975
P-Value >0.100
Percent
Mid_with_KneeValg/Var_BeforeB

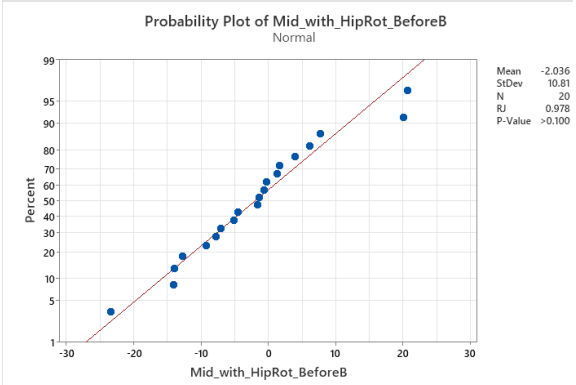

Probability Plot of Mid_no_KneeValg/Var_AfterB
Normal
Mean -3.140
StDev 6.758
N 20
RJ 0.981
P-Value >0.100
Percent
Mid_no_KneeValg/Var_AfterB

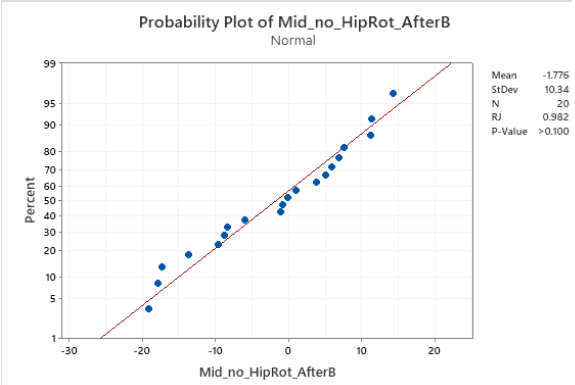

Probability Plot of Mid_with_AnkleAbd/Add_BeforeB
Normal
Mean 3.437
StDev 2.895
N 20
RJ 0.988
P-Value >0.100
Percent
Mid_with_AnkleAbd/Add_BeforeB

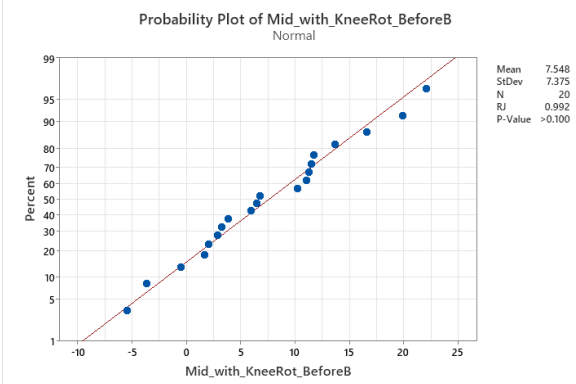

Probability Plot of Mid_no_AnkleAbd/Add_AfterB
Normal
Mean 3.000
StDev 1.989
N 20
RJ 0.990
P-Value >0.100
Percent
Mid_no_AnkleAbd/Add_AfterB

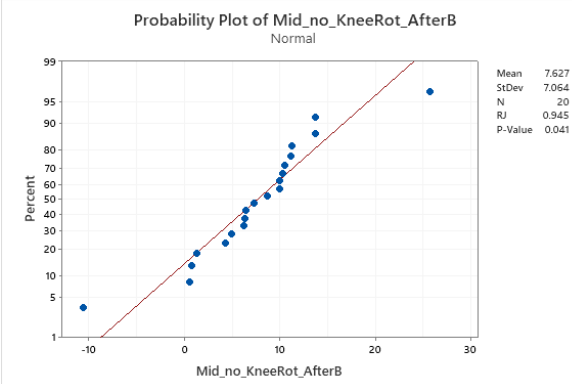

Probability Plot of Mid_with_PelvicRot_BeforeB
Normal
Mean 3.163
StDev 2.829
N 20
RJ 0.983
P-Value >0.100
Percent
Mid_with_PelvicRot_BeforeB

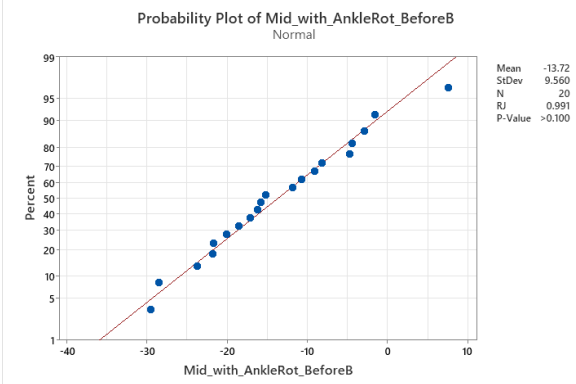

Probability Plot of Mid_no_PelvicRot_AfterB
Normal
Mean 3.272
StDev 3.662
N 20
RJ 0.975
P-Value >0.100
Percent
Mid_no_PelvicRot_AfterB

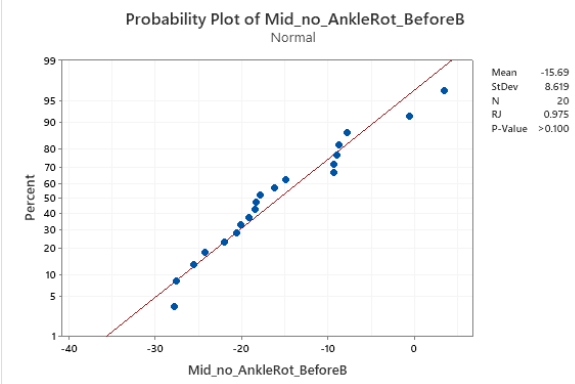

Probability Plot of Mid_with_HipRot_BeforeB
Normal
Mean -2.036
StDev 10.81
N 20
RJ 0.978
P-Value >0.100
Percent
Mid_with_HipRot_BeforeB


Probability Plot of Mid_no_HipRot_AfterB
Normal
Mean -1.776
StDev 10.34
N 20
RJ 0.982
P-Value >0.100
Percent
Mid_no_HipRot_AfterB


Probability Plot of Mid_with_KneeRot_BeforeB
Normal
Mean 7.548
StDev 7.375
N 20
RJ 0.992
P-Value >0.100
Percent
Mid_with_KneeRot_BeforeB


Probability Plot of Mid_no_KneeRot_AfterB
Normal
Mean 7.627
StDev 7.064
N 20
RJ 0.945
P-Value 0.041
Percent
Mid_no_KneeRot_AfterB


Probability Plot of Mid_with_AnkleRot_BeforeB
Normal
Mean -13.72
StDev 9.560
N 20
RJ 0.991
P-Value >0.100
Percent
Mid_with_AnkleRot_BeforeB

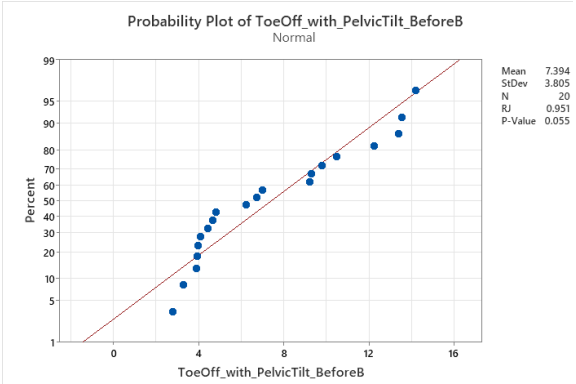

Probability Plot of Mid_no_AnkleRot_BeforeB
Normal
Mean -15.69
StDev 8.619
N 20
RJ 0.975
P-Value >0.100
Percent
Mid_no_AnkleRot_BeforeB

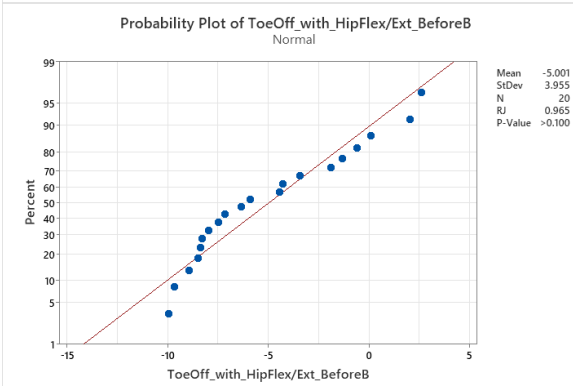
	Before with Insoles			After without Insoles		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.042	Yes	Rejected	>0.1	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Dorsi/Plantar	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Obliquity	>0.1	no	Accepted	>0.1	no	Accepted
Hip Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Knee Valg/Var	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Hip Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Knee Rotation	>0.1	no	Accepted	0.041	no	Accepted
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

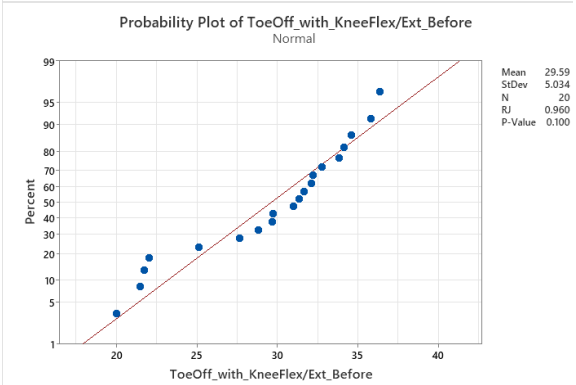
Appendix 29: Additional Statistical Analysis – Normality Testing of Data – Group B

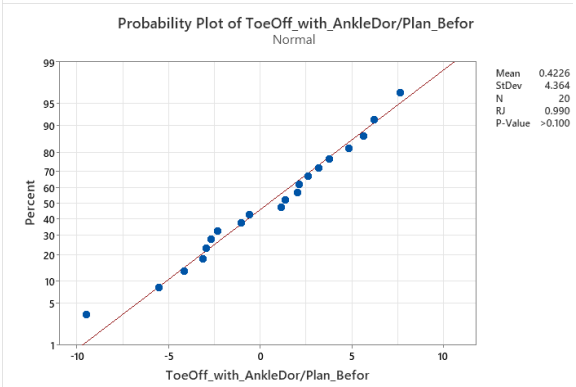
Before with insoles and After no insoles at Toe Off

Before with Insoles

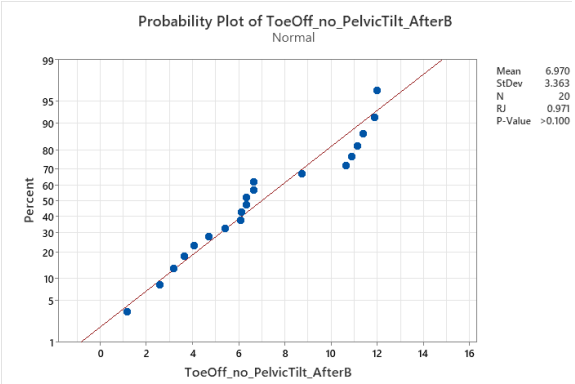


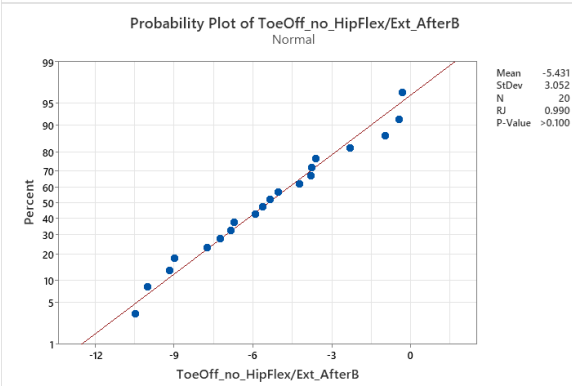


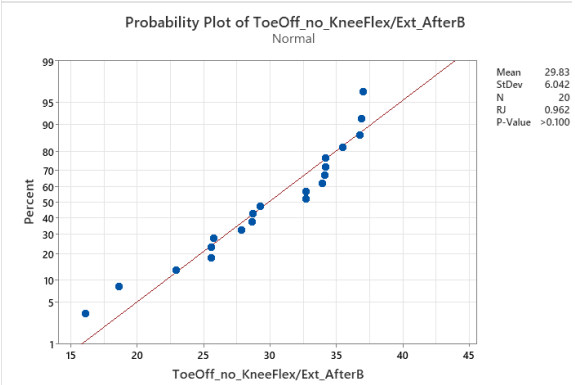


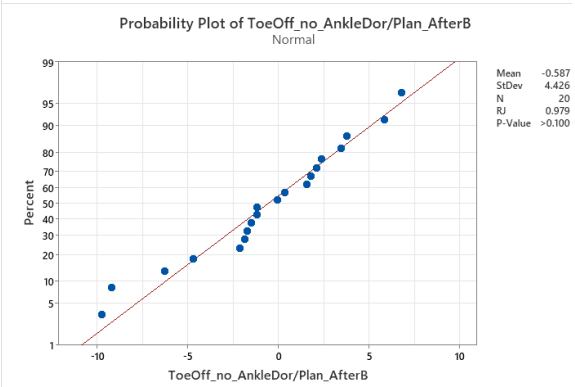


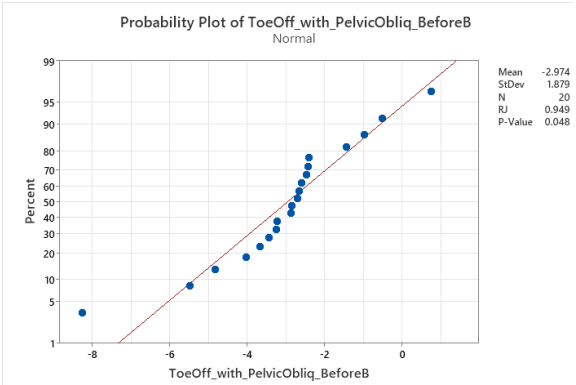
After No insoles

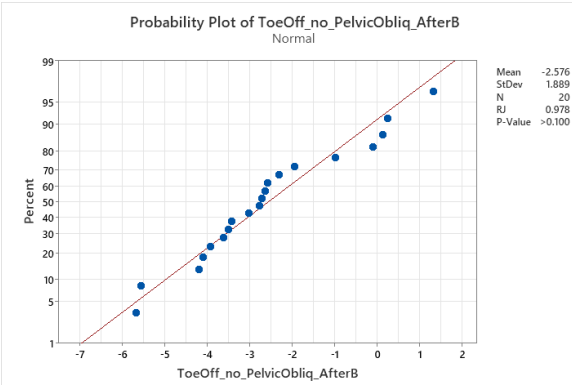


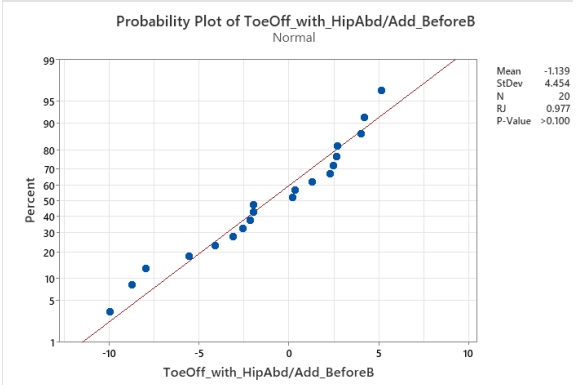


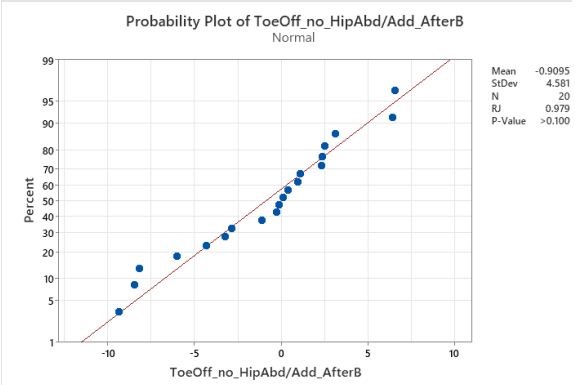


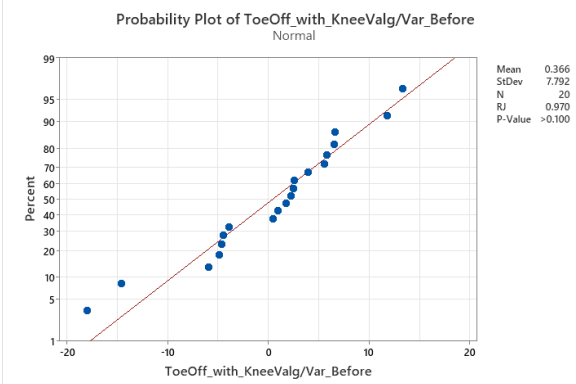


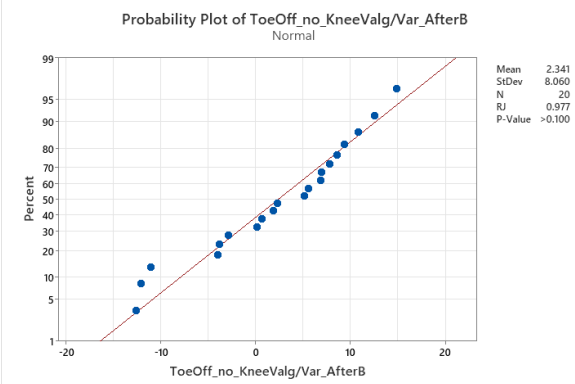

Probability Plot of ToeOff_with_PelvicObliq_BeforeB
Normal
Mean -2.974
StDev 1.879
N 20
RJ 0.949
P-Value 0.048
Percent
ToeOff_with_PelvicObliq_BeforeB

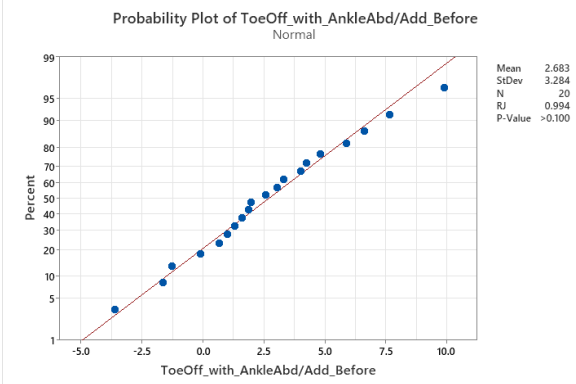

Probability Plot of ToeOff_no_PelvicObliq_AfterB
Normal
Mean -2.576
StDev 1.889
N 20
RJ 0.978
P-Value >0.100
Percent
ToeOff_no_PelvicObliq_AfterB

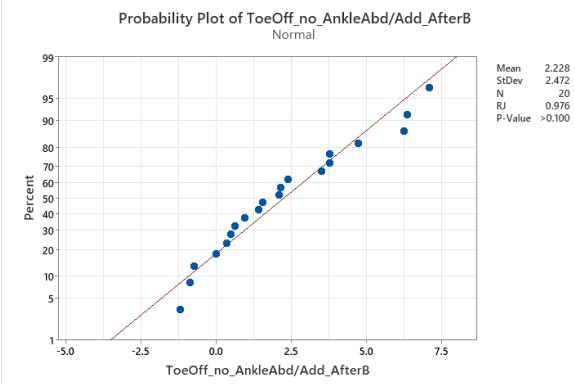

Probability Plot of ToeOff_with_HipAbd/Add_BeforeB
Normal
Mean -1.139
StDev 4.454
N 20
RJ 0.977
P-Value >0.100
Percent
ToeOff_with_HipAbd/Add_BeforeB

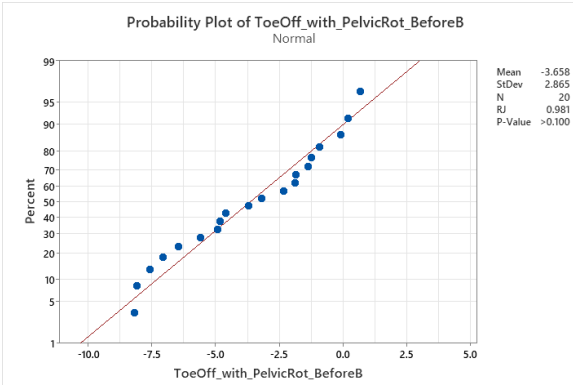

Probability Plot of ToeOff_no_HipAbd/Add_AfterB
Normal
Mean -0.9095
StDev 4.581
N 20
RJ 0.979
P-Value >0.100
Percent
ToeOff_no_HipAbd/Add_AfterB

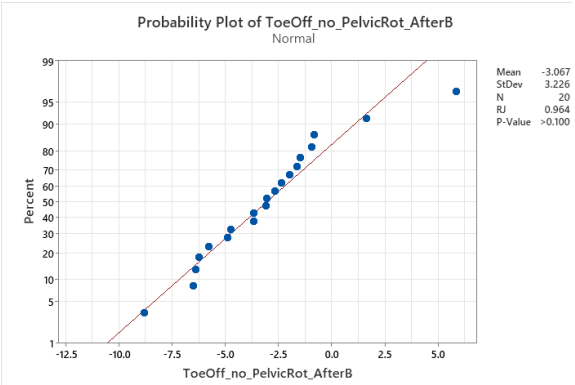

Probability Plot of ToeOff_with_KneeValg/Var_Before
Normal
Mean 0.366
StDev 7.792
N 20
RJ 0.970
P-Value >0.100
Percent
ToeOff_with_KneeValg/Var_Before

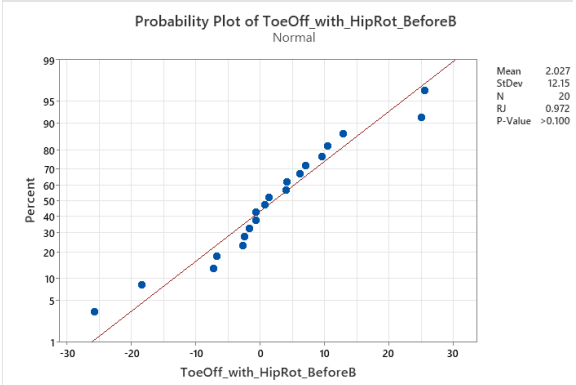

Probability Plot of ToeOff_no_KneeValg/Var_AfterB
Normal
Mean 2.341
StDev 8.060
N 20
RJ 0.977
P-Value >0.100
Percent
ToeOff_no_KneeValg/Var_AfterB

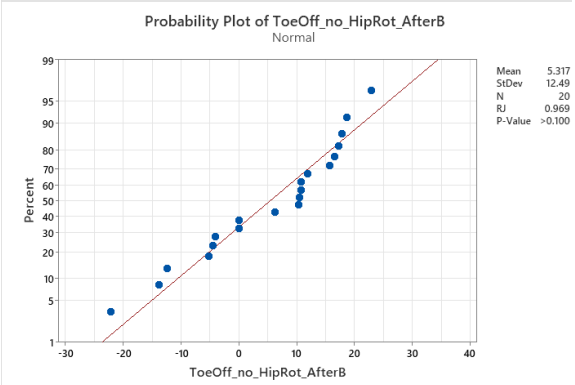

Probability Plot of ToeOff_with_AnkleAbd/Add_Before
Normal
Mean 2.683
StDev 3.284
N 20
RJ 0.994
P-Value >0.100
Percent
ToeOff_with_AnkleAbd/Add_Before

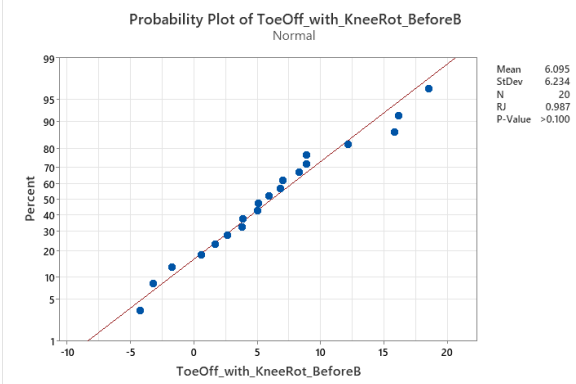

Probability Plot of ToeOff_no_AnkleAbd/Add_AfterB
Normal
Mean 2.228
StDev 2.472
N 20
RJ 0.976
P-Value >0.100
Percent
ToeOff_no_AnkleAbd/Add_AfterB

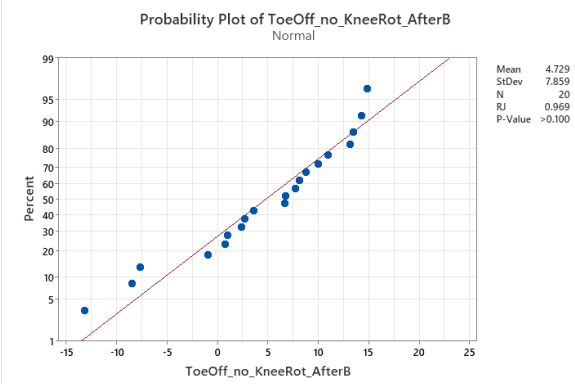

Probability Plot of ToeOff_with_PelvicRot_BeforeB
Normal
Mean -3.658
StDev 2.865
N 20
RJ 0.981
P-Value >0.100
Percent
ToeOff_with_PelvicRot_BeforeB

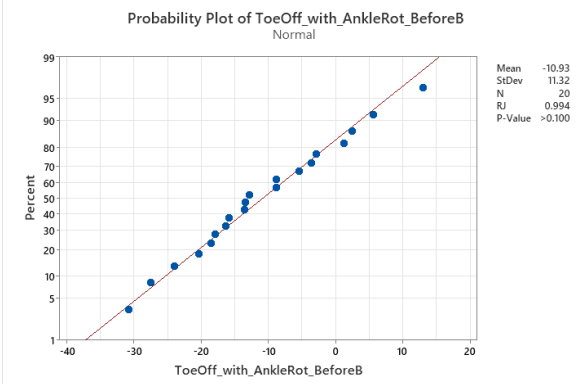

Probability Plot of ToeOff_no_PelvicRot_AfterB
Normal
Mean -3.067
StDev 3.226
N 20
RJ 0.964
P-Value >0.100
Percent
ToeOff_no_PelvicRot_AfterB

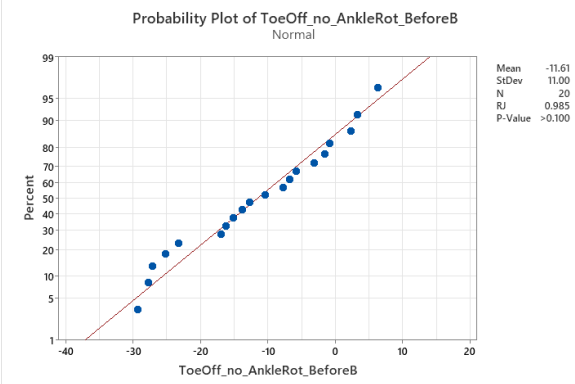

Probability Plot of ToeOff_with_HipRot_BeforeB
Normal
Mean 2.027
StDev 12.15
N 20
RJ 0.972
P-Value >0.100
Percent
ToeOff_with_HipRot_BeforeB


Probability Plot of ToeOff_no_HipRot_AfterB
Normal
Mean 5.317
StDev 12.49
N 20
RJ 0.969
P-Value >0.100
Percent
ToeOff_no_HipRot_AfterB


Probability Plot of ToeOff_with_KneeRot_BeforeB
Normal
Mean 6.095
StDev 6.234
N 20
RJ 0.987
P-Value >0.100
Percent
ToeOff_with_KneeRot_BeforeB


Probability Plot of ToeOff_no_KneeRot_AfterB
Normal
Mean 4.729
StDev 7.859
N 20
RJ 0.969
P-Value >0.100
Percent
ToeOff_no_KneeRot_AfterB


Probability Plot of ToeOff_with_AnkleRot_BeforeB
Normal
Mean -10.93
StDev 11.32
N 20
RJ 0.994
P-Value >0.100
Percent
ToeOff_with_AnkleRot_BeforeB

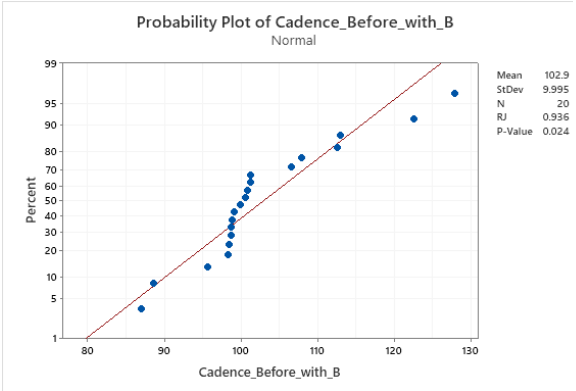

Probability Plot of ToeOff_no_AnkleRot_BeforeB
Normal
Mean -11.61
StDev 11.00
N 20
RJ 0.985
P-Value >0.100
Percent
ToeOff_no_AnkleRot_BeforeB

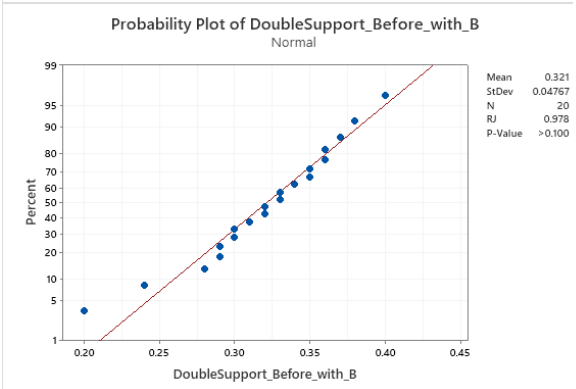
	Before with Insoles			After without Insoles		
Angle	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Pelvic Tilt	0.055	no	Accepted	>0.1	no	Accepted
Hip Flex/Ext	>0.1	no	Accepted	>0.1	no	Accepted
Knee Flex/Ext	0.1	no	Accepted	>0.1	no	Accepted
Ankle Dorsi/Plantar	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Obliquity	0.048	yes	Rejected	>0.1	no	Accepted
Hip Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Knee Valg/Var	>0.1	no	Accepted	>0.1	no	Accepted
Ankle Abd/Add	>0.1	no	Accepted	>0.1	no	Accepted
Pelvic Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Hip Rotation	>0.1	no	Accepted	>0.1	no	Accepted
Knee Rotation	>0.1	no	Accepted	0.041	yes	Rejected
Ankle Rotation	>0.1	no	Accepted	>0.1	no	Accepted

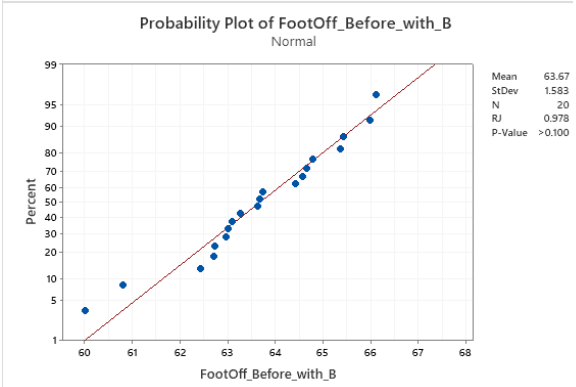
Appendix 30: Additional Statistical Analysis – Normality Testing of Data – Group B

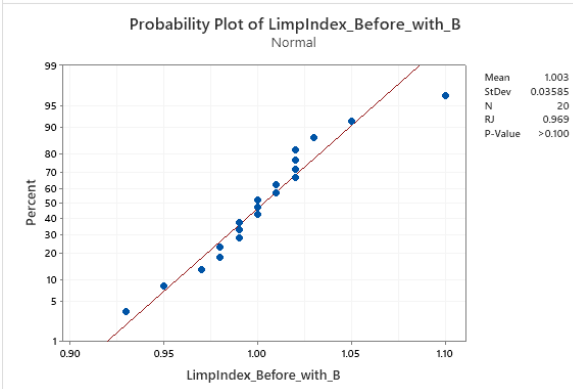
Before with insoles and After no insoles Spatiotemporal Data

Before With insoles

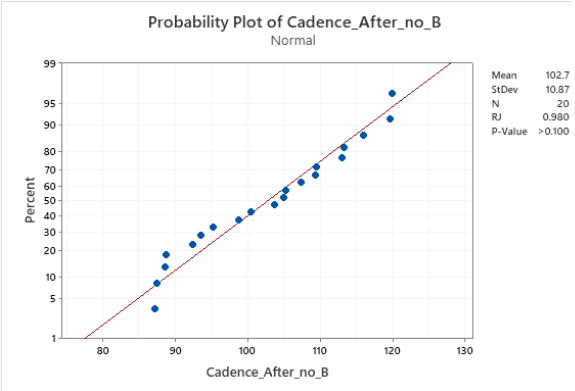


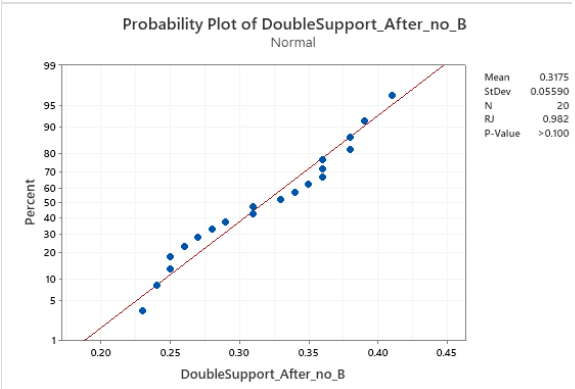


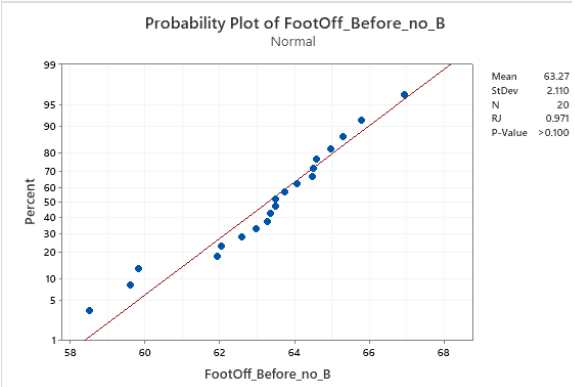


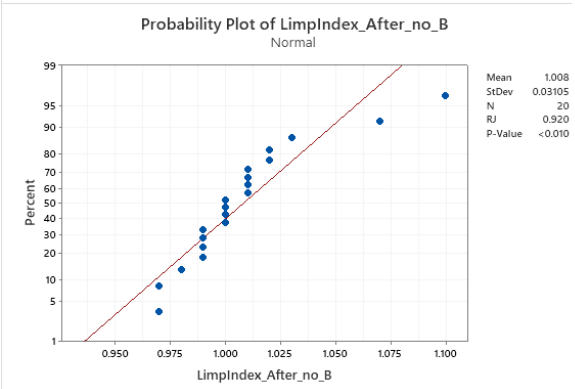


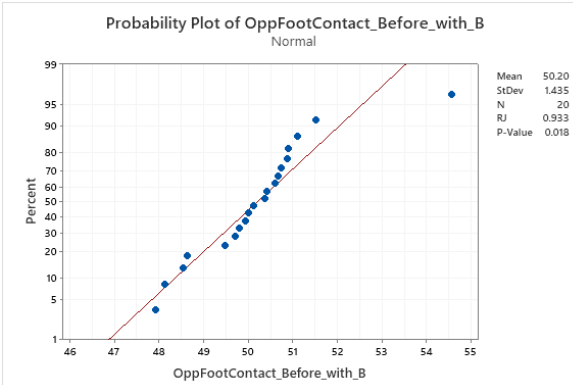
After without Insoles

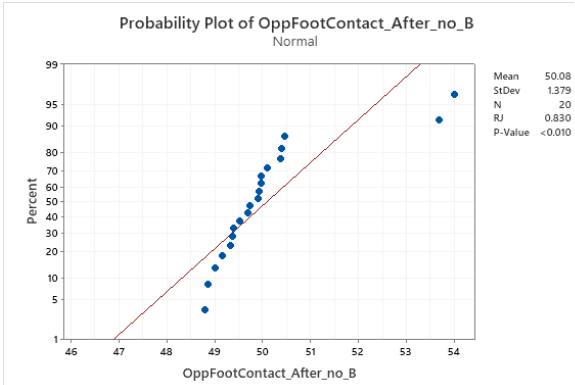


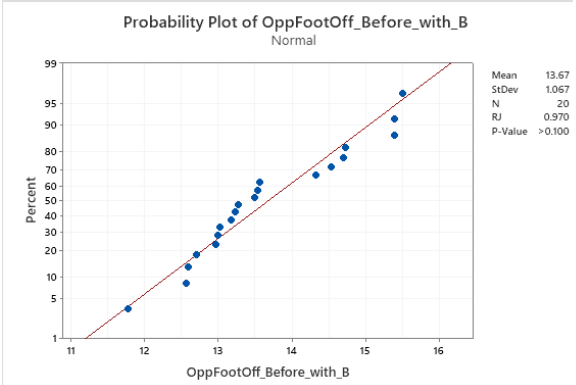


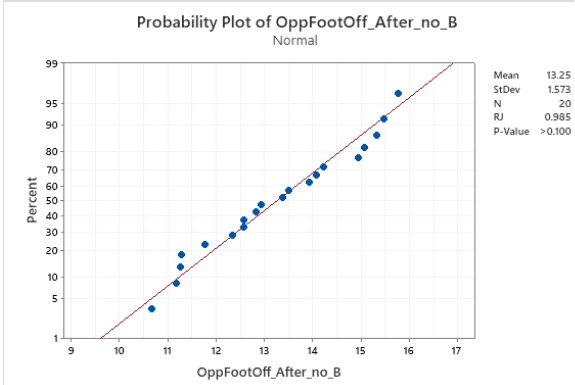


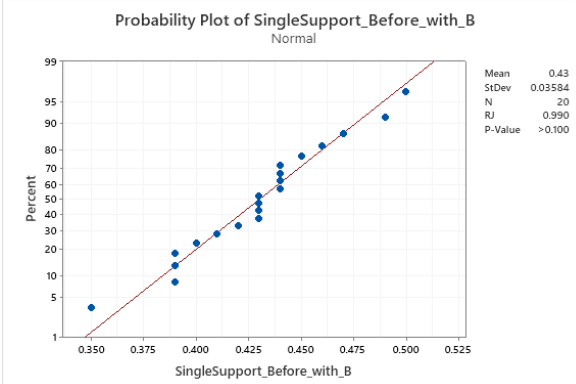


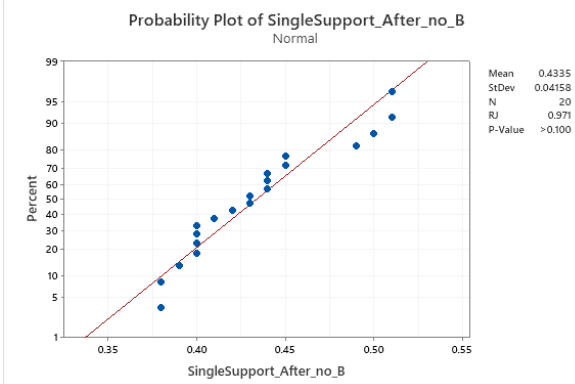

Probability Plot of OppFootContact_Before_with_B
Normal
Mean 50.20
StDev 1.435
N 20
RJ 0.933
P-Value 0.018
Percent
OppFootContact_Before_with_B

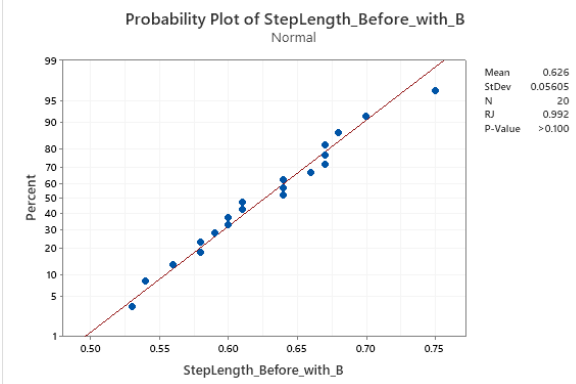

Probability Plot of OppFootContact_After_no_B
Normal
Mean 50.08
StDev 1.379
N 20
RJ 0.830
P-Value <0.010
Percent
OppFootContact_After_no_B

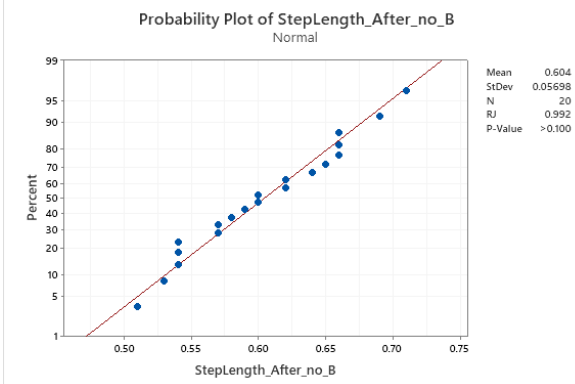

Probability Plot of OppFootOff_Before_with_B
Normal
Mean 13.67
StDev 1.067
N 20
RJ 0.970
P-Value >0.100
Percent
OppFootOff_Before_with_B

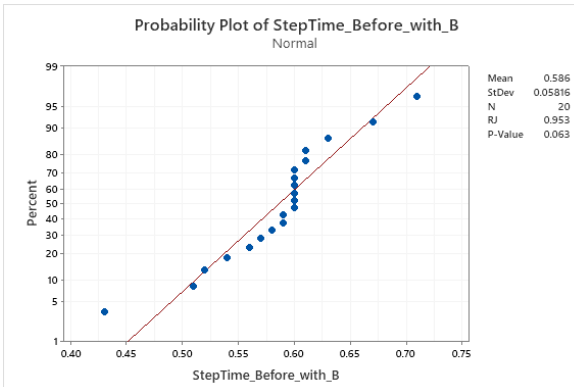

Probability Plot of OppFootOff_After_no_B
Normal
Mean 13.25
StDev 1.573
N 20
RJ 0.985
P-Value >0.100
Percent
OppFootOff_After_no_B

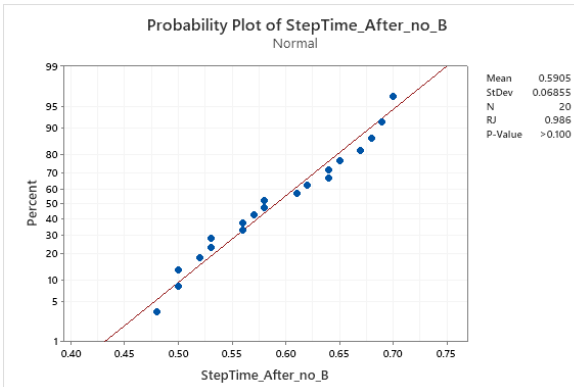

Probability Plot of SingleSupport_Before_with_B
Normal
Mean 0.43
StDev 0.03584
N 20
RJ 0.990
P-Value >0.100
Percent
SingleSupport_Before_with_B

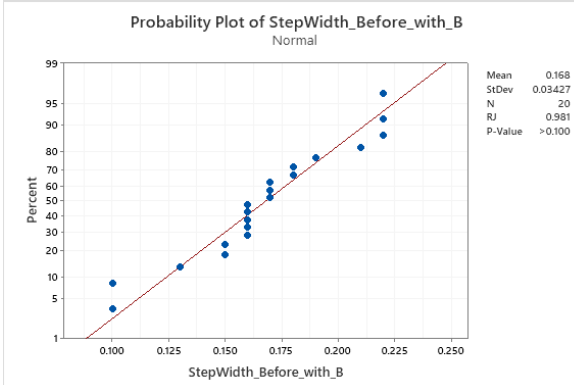

Probability Plot of SingleSupport_After_no_B
Normal
Mean 0.4335
StDev 0.04158
N 20
RJ 0.971
P-Value >0.100
Percent
SingleSupport_After_no_B

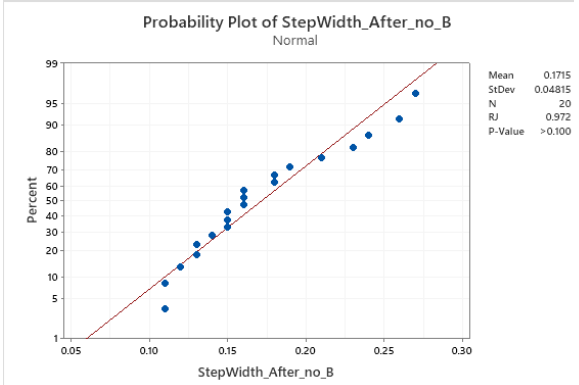

Probability Plot of StepLength_Before_with_B
Normal
Mean 0.626
StDev 0.05605
N 20
RJ 0.992
P-Value >0.100
Percent
StepLength_Before_with_B

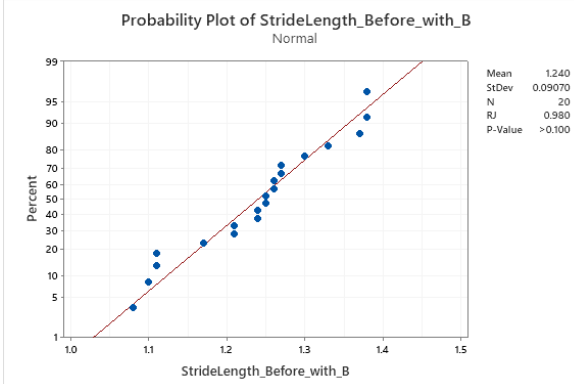

Probability Plot of StepLength_After_no_B
Normal
Mean 0.604
StDev 0.05698
N 20
RJ 0.992
P-Value >0.100
Percent
StepLength_After_no_B

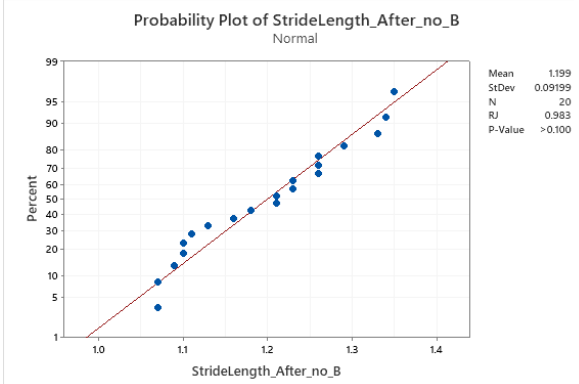

Probability Plot of StepTime_Before_with_B
Normal
Mean 0.586
StDev 0.05816
N 20
RJ 0.953
P-Value 0.063
Percent
StepTime_Before_with_B

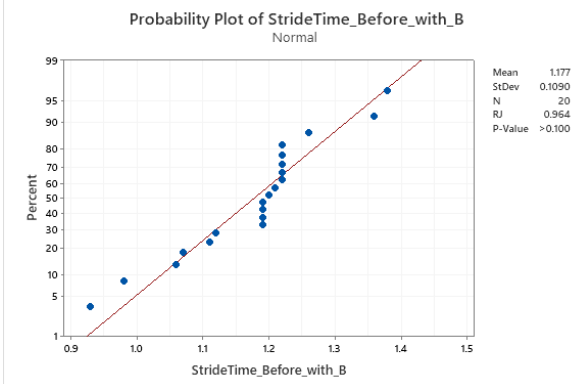

Probability Plot of StepTime_After_no_B
Normal
Mean 0.5905
StDev 0.06855
N 20
RJ 0.986
P-Value >0.100
Percent
StepTime_After_no_B

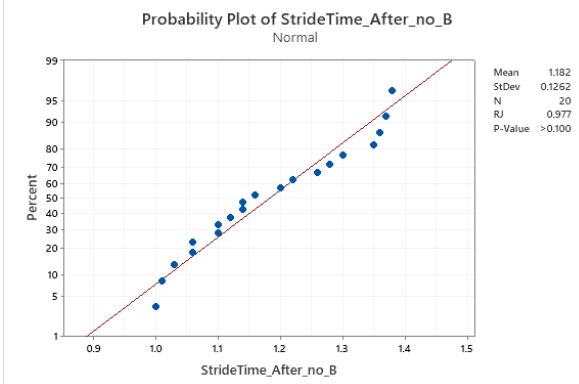

Probability Plot of StepWidth_Before_with_B
Normal
Mean 0.168
StDev 0.03427
N 20
RJ 0.981
P-Value >0.100
Percent
StepWidth_Before_with_B

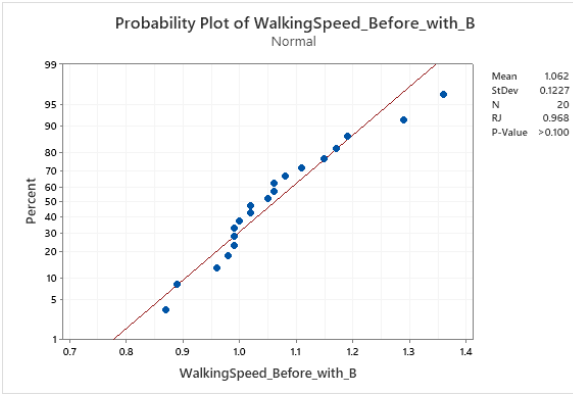

Probability Plot of StepWidth_After_no_B
Normal
Mean 0.1715
StDev 0.04815
N 20
RJ 0.972
P-Value >0.100
Percent
StepWidth_After_no_B

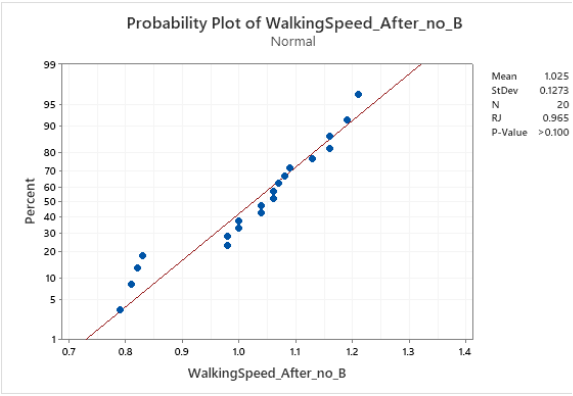

Probability Plot of StrideLength_Before_with_B
Normal
Mean 1.240
StDev 0.09070
N 20
RJ 0.980
P-Value >0.100
Percent
StrideLength_Before_with_B


Probability Plot of StrideLength_After_no_B
Normal
Mean 1.199
StDev 0.09199
N 20
RJ 0.983
P-Value >0.100
Percent
StrideLength_After_no_B


Probability Plot of StrideTime_Before_with_B
Normal
Mean 1.177
StDev 0.1090
N 20
RJ 0.964
P-Value >0.100
Percent
StrideTime_Before_with_B


Probability Plot of StrideTime_After_no_B
Normal
Mean 1.182
StDev 0.1262
N 20
RJ 0.977
P-Value >0.100
Percent
StrideTime_After_no_B





	Before with Insoles			After without insoles		
	P value	<0.05	Null Hypothesis	P value	<0.05	Null Hypothesis
Cadence	0.04	Yes	Rejected	>0.1	No	Accepted
Double Support	>0.1	No	Accepted	>0.1	No	Accepted
Foot Off	>0.1	No	Accepted	>0.1	No	Accepted
Limp Index	>0.1	No	Accepted	<0.01	Yes	Rejected
Opposite Foot Contact	0.018	Yes	Rejected	<0.01	Yes	Rejected
Opposite Foot Off	>0.1	No	Accepted	>0.1	No	Accepted
Single Support	>0.1	No	Accepted	>0.1	No	Accepted
Step Length	>0.1	No	Accepted	>0.1	No	Accepted
Step Time	0.063	No	Accepted	>0.1	No	Accepted
Step Width	>0.1	No	Accepted	>0.1	No	Accepted
Stride Length	>0.1	No	Accepted	>0.1	No	Accepted
Stride Time	>0.1	No	Accepted	>0.1	No	Accepted
Walking Speed	>0.1	No	Accepted	>0.1	No	Accepted

Appendix 31: Additional Statistical Analysis – Group A before vs Group B before no insoles Kinematic Analysis Heel Strike

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Mann-Whitney test	0.892	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.584	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.736	No	Accepted
Ankle Dorsi/Plantar	Independent Sample t-test	0.75	No	Accepted
Pelvic Obliquity	Independent Sample t-test	0.984	No	Accepted
Hip Abd/Add	Independent Sample t-test	0.119	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.115	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.569	No	Accepted
Pelvis Rotation	Independent Sample t-test	0.847	No	Accepted
Hip Rotation	Independent Sample t-test	0.133	No	Accepted
Knee Rotation	Independent Sample t-test	0.093	No	Accepted
Ankle Rotation	Independent Sample t-test	0.937	No	Accepted

Appendix 32: Additional Statistical Analysis – Group A before vs Group B before no insoles Kinematic Analysis at Midstance

Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Mann-Whitney test	0.871	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.649	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.718	No	Accepted
Ankle Dorsi/Plantar	Independent Sample t-test	0.736	No	Accepted
Pelvic Obliquity	Mann-Whitney test	0.655	No	Accepted
Hip Abd/Add	Independent Sample t-test	0.169	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.09	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.947	No	Accepted
Pelvis Rotation	Independent Sample t-test	0.348	No	Accepted
Hip Rotation	Independent Sample t-test	0.094	No	Accepted
Knee Rotation	Independent Sample t-test	0.125	No	Accepted
Ankle Rotation	Independent Sample t-test	0.941	No	Accepted

Appendix 33: Additional Statistical Analysis – Group A before vs Group B before no insoles Kinematic Analysis and Histogram Plots at Toe Off

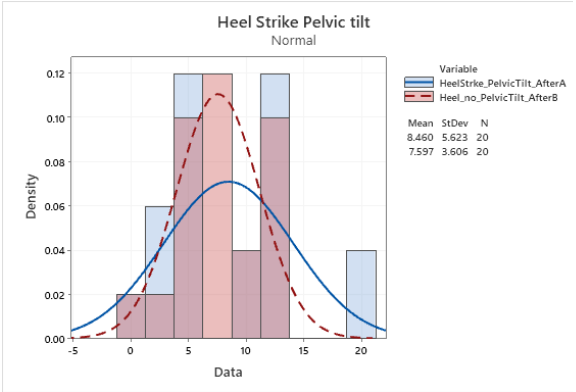
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Mann-Whitney test	0.935	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.893	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.425	No	Accepted
Ankle Dorsi/Plantar	Mann-Whitney test	0.735	No	Accepted
Pelvic Obliquity	Independent Sample t-test	0.910	No	Accepted
Hip Abd/Add	Independent Sample t-test	0.182	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.14	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.557	No	Accepted
Pelvis Rotation	Independent Sample t-test	0.996	No	Accepted
Hip Rotation	Independent Sample t-test	0.174	No	Accepted
Knee Rotation	Independent Sample t-test	0.344	No	Accepted
Ankle Rotation	Independent Sample t-test	0.741	No	Accepted

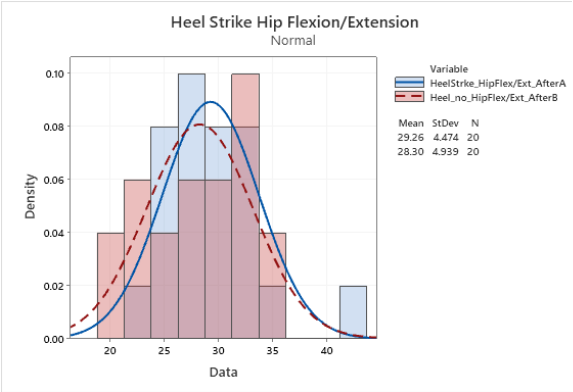
Appendix 34: Additional Statistical Analysis – Group A before vs Group B before no insoles Spatiotemporal Data

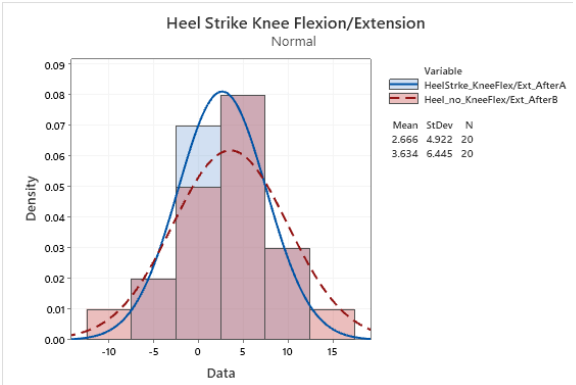
	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Mann-Whitney test	0.766	No	Accepted
Double Support	Independent Sample t-test	0.587	No	Accepted
Foot Off	Independent Sample t-test	0.8	No	Accepted
Limp Index	Mann-Whitney test	0.646	No	Accepted
Opposite Foot Contact	Independent Sample t-test	0.398	No	Accepted
Opposite Foot Off	Mann-Whitney test	0.745	No	Accepted
Single Support	Independent Sample t-test	0.613	No	Accepted
Step Length	Independent Sample t-test	0.979	No	Accepted
Step Time	Mann-Whitney test	0.989	No	Accepted
Step Width	Independent Sample t-test	0.382	No	Accepted
Stride Length	Independent Sample t-test	0.790	No	Accepted
Stride Time	Mann-Whitney test	0.715	No	Accepted
Walking Speed	Independent Sample t-test	0.663	No	Accepted

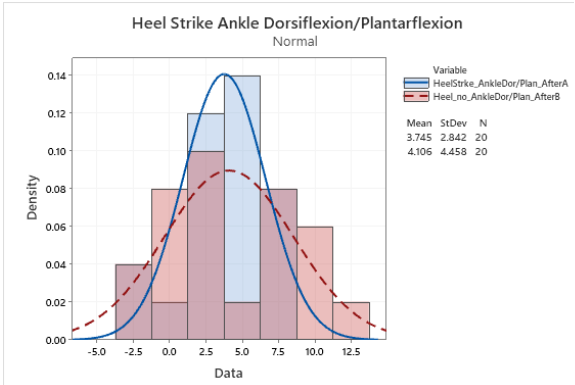
Appendix 35: Additional Statistical Analysis - Group A After vs Group B after no insoles Kinematic Histogram Plots and Analysis at Heel Strike

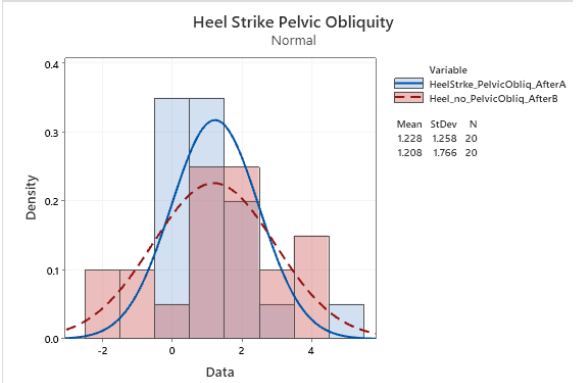
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Independent Sample t-test	0.567	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.521	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.597	No	Accepted
Ankle Dorsi/Plantar	Independent Sample t-test	0.762	No	Accepted
Pelvic Obliquity	Mann-Whitney test	0.598	No	Accepted
Hip Abd/Add	Independent Sample t-test	0.053	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.119	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.216	No	Accepted
Pelvis Rotation	Mann-Whitney test	0.579	No	Accepted
Hip Rotation	Independent Sample t-test	0.968	No	Accepted
Knee Rotation	Independent Sample t-test	0.148	No	Accepted
Ankle Rotation	Independent Sample t-test	0.261	No	Accepted

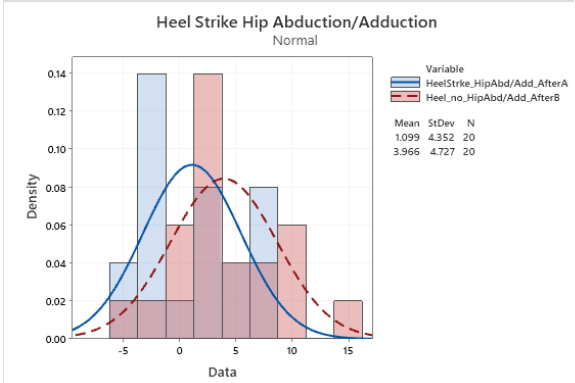


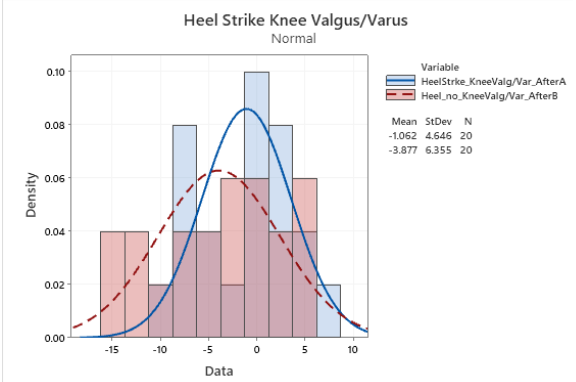


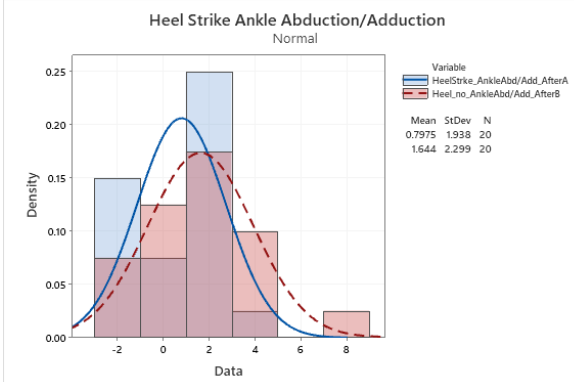

Heel Strike Knee Flexion/Extension
Normal
Density
Data
Variable
HeelStrke_KneeFlex/Ext_AfterA
Heel_no_KneeFlex/Ext_AfterB
Mean StDev N
2.666 4.922 20
3.634 6.445 20

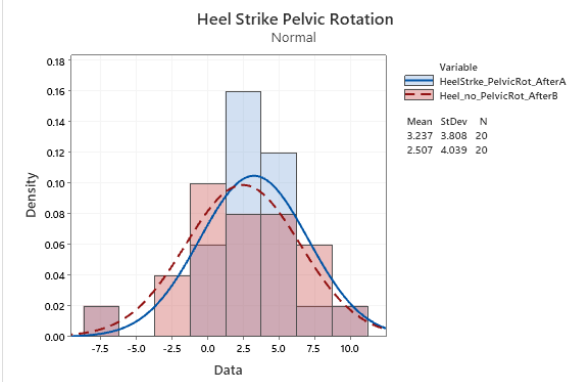

Heel Strike Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
HeelStrke_AnkleDor/Plan_AfterA
Heel_no_AnkleDor/Plan_AfterB
Mean StDev N
3.745 2.842 20
4.106 4.458 20

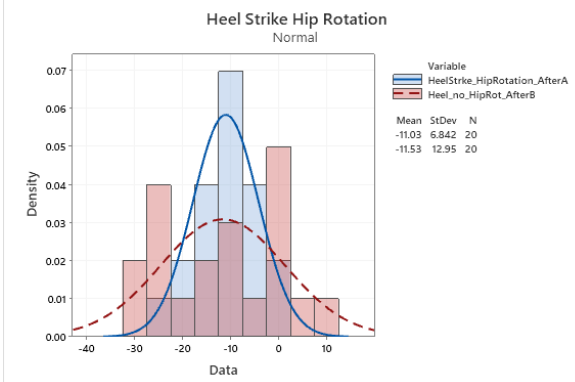

Heel Strike Pelvic Obliquity
Normal
Density
Data
Variable
HeelStrke_PelvicObliq_AfterA
Heel_no_PelvicObliq_AfterB
Mean StDev N
1.228 1.258 20
1.208 1.766 20

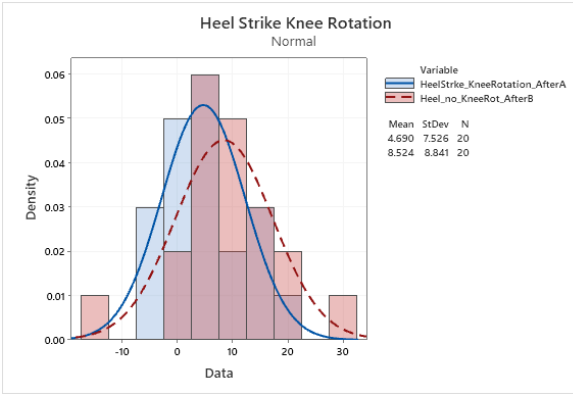

Heel Strike Hip Abduction/Adduction
Normal
Density
Data
Variable
HeelStrke_HipAbd/Add_AfterA
Heel_no_HipAbd/Add_AfterB
Mean StDev N
1.099 4.352 20
3.966 4.727 20

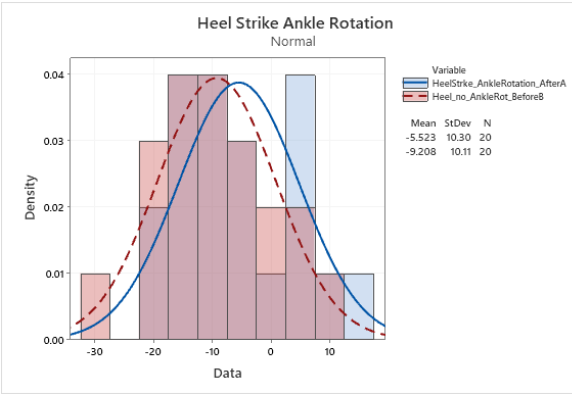

Heel Strike Knee Valgus/Varus
Normal
Density
Data
Variable
HeelStrke_KneeValg/Var_AfterA
Heel_no_KneeValg/Var_AfterB
Mean StDev N
-1.062 4.646 20
-3.877 6.355 20


Heel Strike Ankle Abduction/Adduction
Normal
Density
Data
Variable
HeelStrke_AnkleAbd/Add_AfterA
Heel_no_AnkleAbd/Add_AfterB
Mean StDev N
0.7975 1.938 20
1.644 2.299 20


Heel Strike Pelvic Rotation
Normal
Density
Data
Variable
HeelStrke_PelvicRot_AfterA
Heel_no_PelvicRot_AfterB
Mean StDev N
3.237 3.808 20
2.507 4.039 20

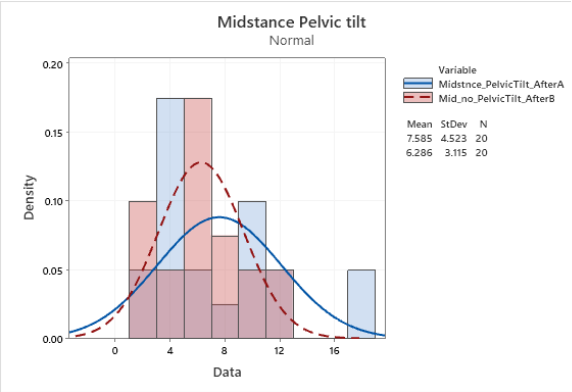

Heel Strike Hip Rotation
Normal
Density
Data
Variable
HeelStrke_HipRotation_AfterA
Heel_no_HipRot_AfterB
Mean StDev N
-11.03 6.842 20
-11.53 12.95 20

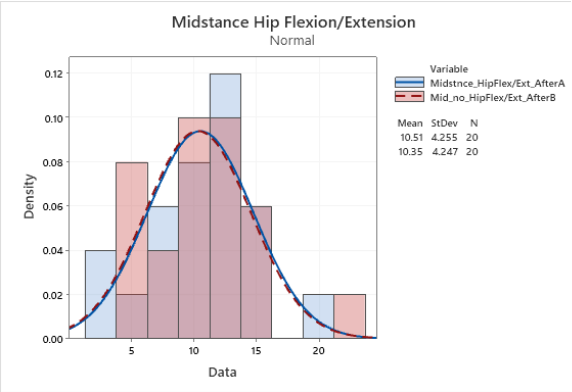

Heel Strike Knee Rotation
Normal
Density
Data
Variable
HeelStrke_KneeRotation_AfterA
Heel_no_KneeRot_AfterB
Mean StDev N
4.690 7.526 20
8.524 8.841 20

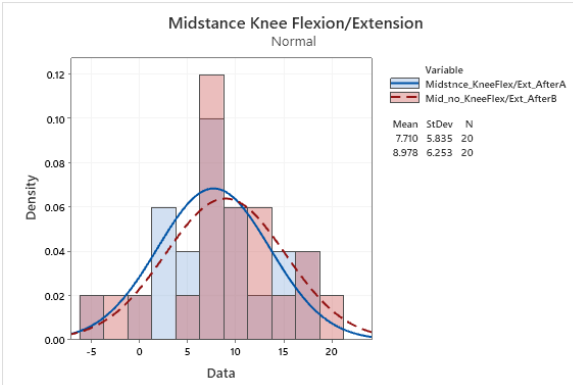

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
HeelStrke_AnkleRotation_AfterA
Heel_no_AnkleRot_BeforeB
Mean StDev N
-5.523 10.30 20
-9.208 10.11 20

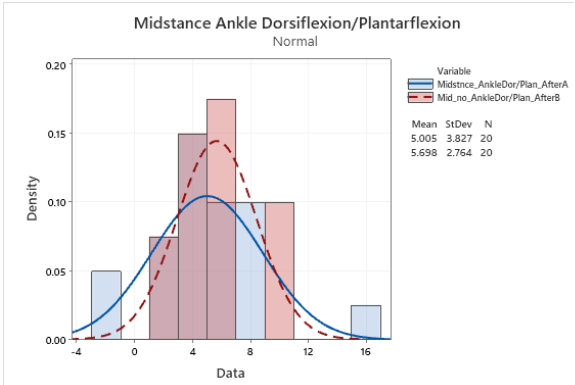
Appendix 36: Additional Statistical Analysis - Group A After vs Group B after no insoles Kinematic Histogram Plots and Analysis at Midstance

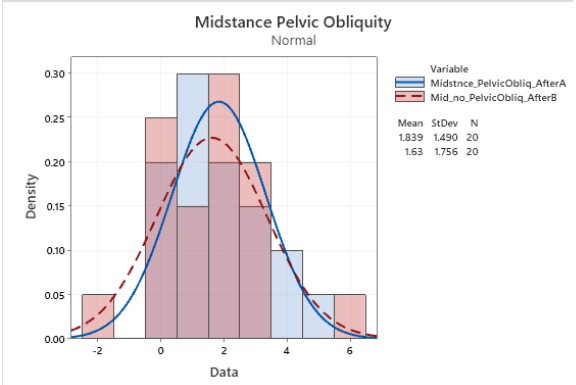
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Mann-Whitney test	0.508	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.906	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.511	No	Accepted
Ankle Dorsi/Plantar	Independent Sample t-test	0.552	No	Accepted
Pelvic Obliquity	Mann-Whitney test	0.687	No	Accepted
Hip Abd/Add	Independent Sample t-test	0.141	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.078	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.397	No	Accepted
Pelvis Rotation	Mann-Whitney test	0.925	No	Accepted
Hip Rotation	Independent Sample t-test	0.669	No	Accepted
Knee Rotation	Mann-Whitney test	0.108	No	Accepted
Ankle Rotation	Independent Sample t-test	0.383	No	Accepted

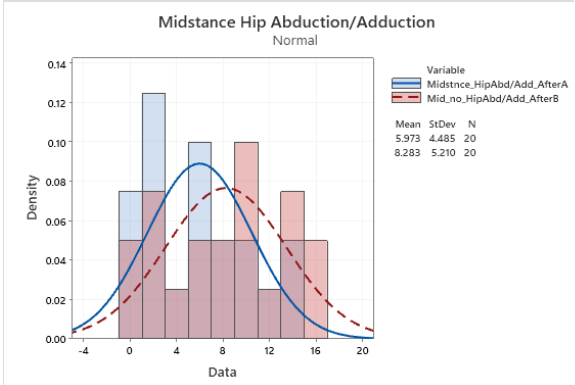


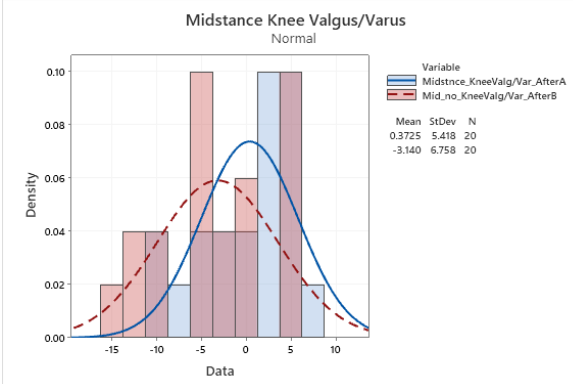


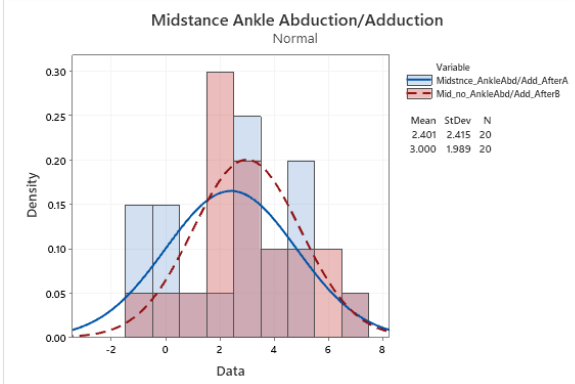

Midstance Knee Flexion/Extension
Normal
Density
Data
Variable
Midstnce_KneeFlex/Ext_AfterA
Mid_no_KneeFlex/Ext_AfterB
Mean StDev N
7.710 5.835 20
8.978 6.253 20

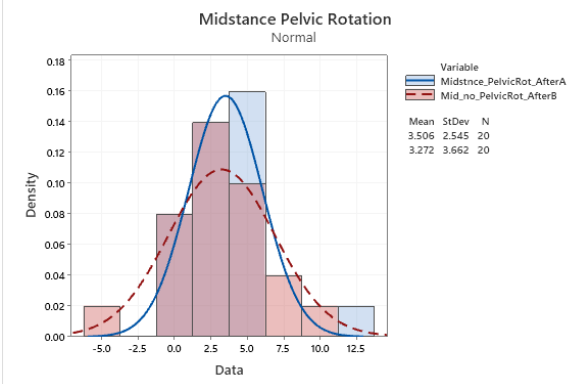

Midstance Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
Midstnce_AnkleDor/Plan_AfterA
Mid_no_AnkleDor/Plan_AfterB
Mean StDev N
5.005 3.827 20
5.698 2.764 20

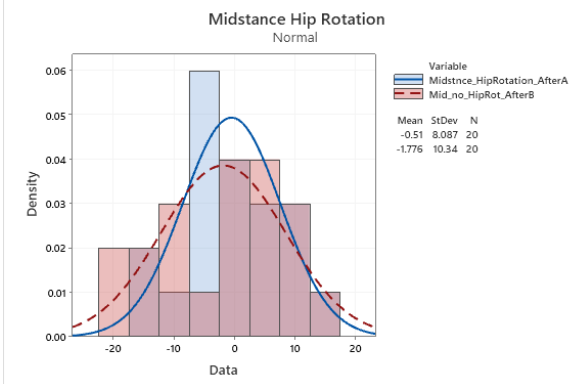

Midstance Pelvic Obliquity
Normal
Density
Data
Variable
Midstnce_PelvicObliq_AfterA
Mid_no_PelvicObliq_AfterB
Mean StDev N
1.839 1.490 20
1.63 1.756 20

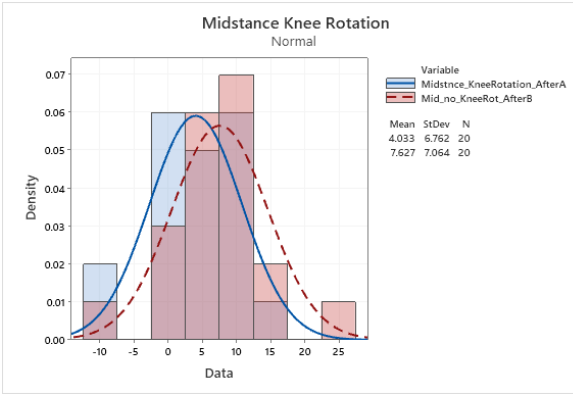

Midstance Hip Abduction/Adduction
Normal
Density
Data
Variable
Midstnce_HipAbd/Add_AfterA
Mid_no_HipAbd/Add_AfterB
Mean StDev N
5.973 4.485 20
8.283 5.210 20

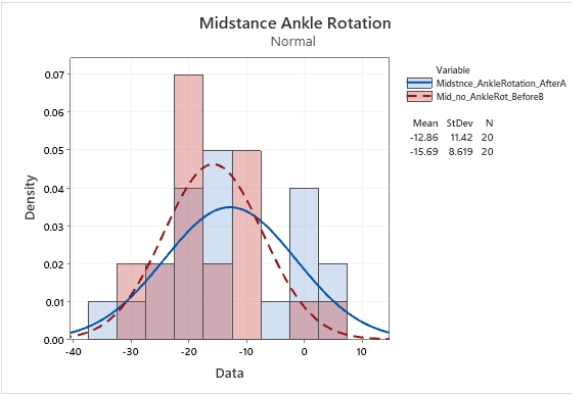

Midstance Knee Valgus/Varus
Normal
Density
Data
Variable
Midstnce_KneeValg/Var_AfterA
Mid_no_KneeValg/Var_AfterB
Mean StDev N
0.3725 5.418 20
-3.140 6.758 20


Midstance Ankle Abduction/Adduction
Normal
Density
Data
Variable
Midstnce_AnkleAbd/Add_AfterA
Mid_no_AnkleAbd/Add_AfterB
Mean StDev N
2.401 2.415 20
3.000 1.989 20


Midstance Pelvic Rotation
Normal
Density
Data
Variable
Midstnce_PelvicRot_AfterA
Mid_no_PelvicRot_AfterB
Mean StDev N
3.506 2.545 20
3.272 3.662 20

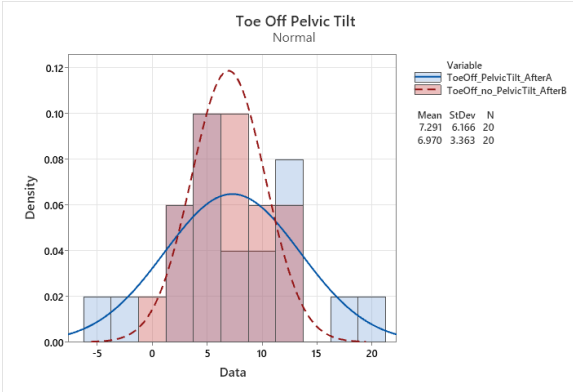

Midstance Hip Rotation
Normal
Density
Data
Variable
Midstnce_HipRotation_AfterA
Mid_no_HipRot_AfterB
Mean StDev N
-0.51 8.087 20
-1.776 10.34 20

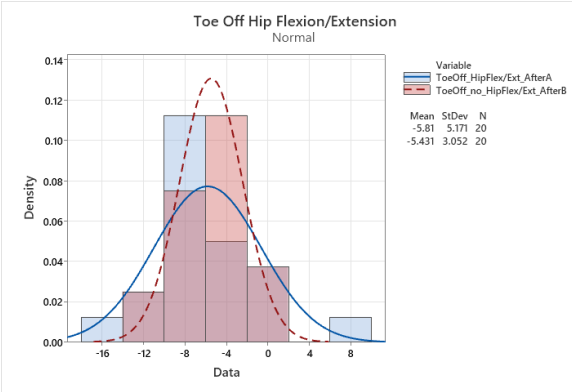

Midstance Knee Rotation
Normal
Density
Data
Variable
Midstnce_KneeRotation_AfterA
Mid_no_KneeRot_AfterB
Mean StDev N
4.033 6.762 20
7.627 7.064 20

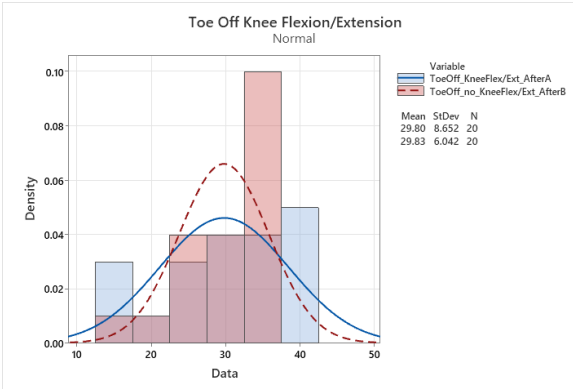

Midstance Ankle Rotation
Normal
Density
Data
Variable
Midstnce_AnkleRotation_AfterA
Mid_no_AnkleRot_BeforeB
Mean StDev N
-12.86 11.42 20
-15.69 8.619 20

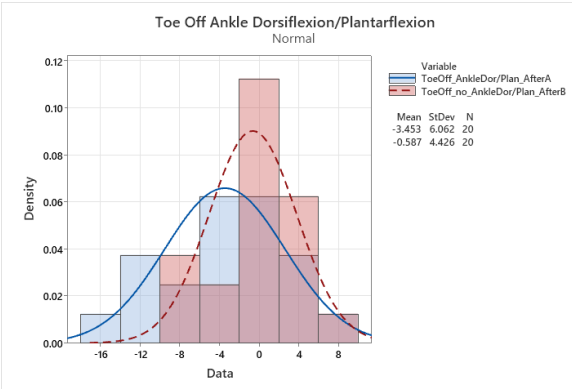
Appendix 37: Additional Statistical Analysis - Group A After vs Group B after no insoles Kinematic Histogram Plots and Analysis at Toe Off

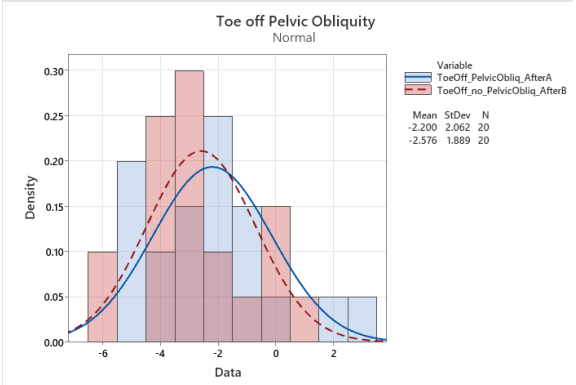
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Independent Sample t-test	0.84	No	Accepted
Hip Flex/ext	Independent Sample t-test	0.78	No	Accepted
Knee Flex/ext	Independent Sample t-test	0.988	No	Accepted
Ankle Dorsi/Plantar	Independent Sample t-test	0.097	No	Accepted
Pelvic Obliquity	Independent Sample t-test	0.551	No	Accepted
Hip Abd/Add	Independent Sample t-test	0.161	No	Accepted
Knee Valg/Var	Independent Sample t-test	0.639	No	Accepted
Ankle Abd/Add	Independent Sample t-test	0.141	No	Accepted
Pelvis Rotation	Independent Sample t-test	0.709	No	Accepted
Hip Rotation	Independent Sample t-test	0.557	No	Accepted
Knee Rotation	Independent Sample t-test	0.553	No	Accepted
Ankle Rotation	Mann-Whitney test	0.273	No	Accepted

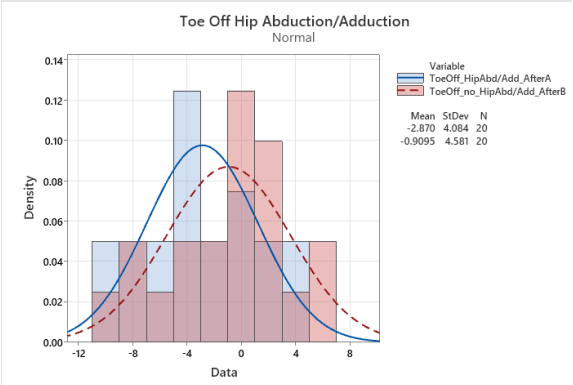


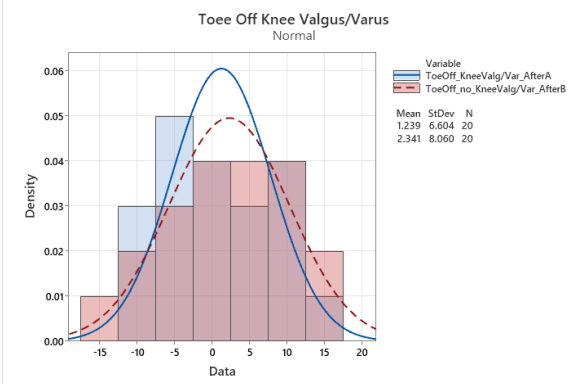


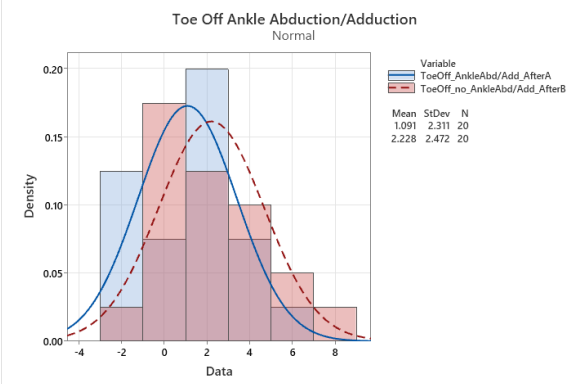

Toe Off Knee Flexion/Extension
Normal
Density
Data
Variable
ToeOff_KneeFlex/Ext_AfterA
ToeOff_no_KneeFlex/Ext_AfterB
Mean StDev N
29.80 8.652 20
29.83 6.042 20

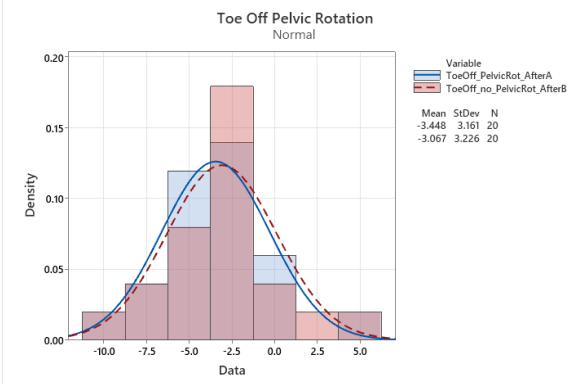

Toe Off Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
ToeOff_AnkleDor/Plan_AfterA
ToeOff_no_AnkleDor/Plan_AfterB
Mean StDev N
-3.453 6.062 20
-0.587 4.426 20

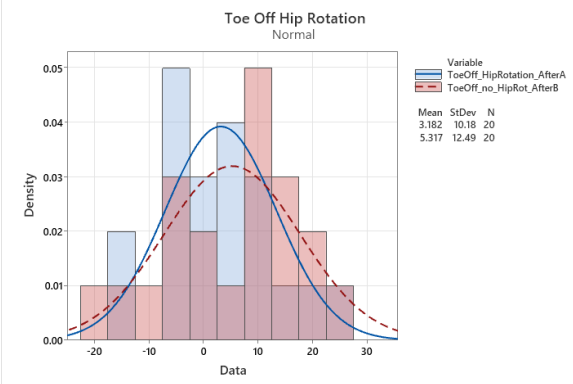

Toe off Pelvic Obliquity
Normal
Density
Data
Variable
ToeOff_PelvicObliq_AfterA
ToeOff_no_PelvicObliq_AfterB
Mean StDev N
-2.200 2.062 20
-2.576 1.889 20

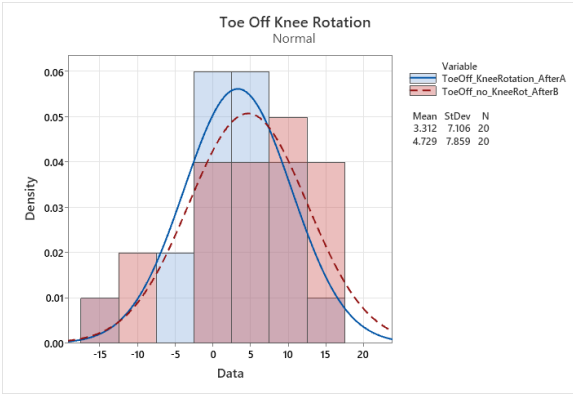

Toe Off Hip Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_HipAbd/Add_AfterA
ToeOff_no_HipAbd/Add_AfterB
Mean StDev N
-2.870 4.084 20
-0.9095 4.581 20

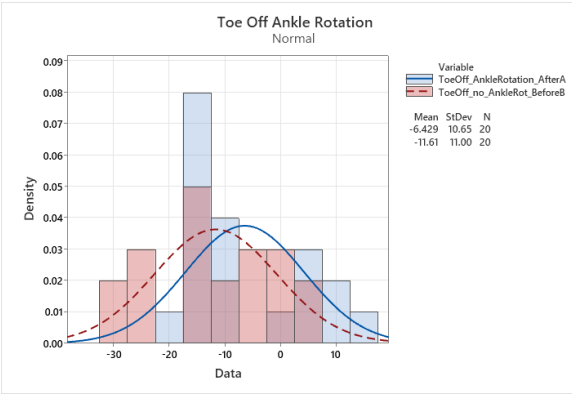

Toee Off Knee Valgus/Varus
Normal
Density
Data
Variable
ToeOff_KneeValg/Var_AfterA
ToeOff_no_KneeValg/Var_AfterB
Mean StDev N
1.239 6.604 20
2.341 8.060 20


Toe Off Ankle Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_AnkleAbd/Add_AfterA
ToeOff_no_AnkleAbd/Add_AfterB
Mean StDev N
1.091 2.311 20
2.228 2.472 20


Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_PelvicRot_AfterA
ToeOff_no_PelvicRot_AfterB
Mean StDev N
-3.448 3.161 20
-3.067 3.226 20


Toe Off Hip Rotation
Normal
Density
Data
Variable
ToeOff_HipRotation_AfterA
ToeOff_no_HipRot_AfterB
Mean StDev N
3.182 10.18 20
5.317 12.49 20


Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_KneeRotation_AfterA
ToeOff_no_KneeRot_AfterB
Mean StDev N
3.312 7.106 20
4.729 7.859 20

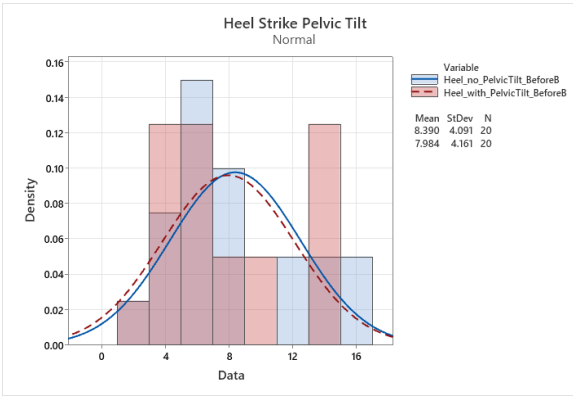

Toe Off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_AnkleRotation_AfterA
ToeOff_no_AnkleRot_BeforeB
Mean StDev N
-6.429 10.65 20
-11.61 11.00 20

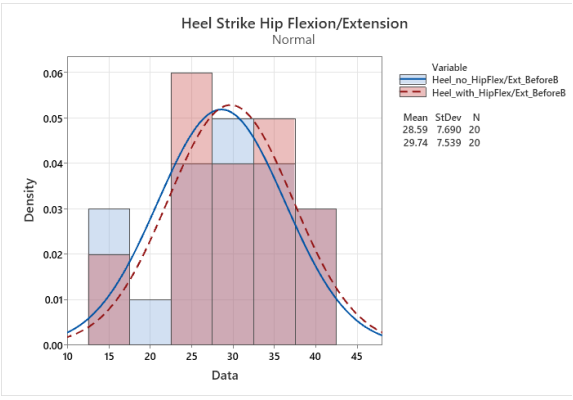
Appendix 38: Additional Statistical Analysis - Group A After vs Group B after no insoles Spatiotemporal Data

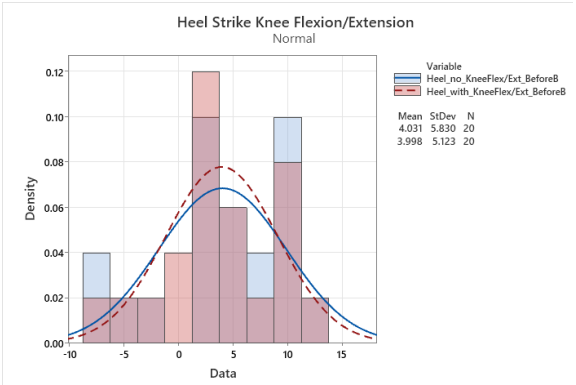
	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Mann-Whitney test	0.224	No	Accepted
Double Support	Mann-Whitney test	0.133	No	Accepted
Foot Off	Independent Sample t-test	0.252	No	Accepted
Limp Index	Mann-Whitney test	0.43	No	Accepted
Opposite Foot Contact	Independent Sample t-test	0.917	No	Accepted
Opposite Foot Off	Mann-Whitney test	0.208	No	Accepted
Single Support	Mann-Whitney test	0.508	No	Accepted
Step Length	Independent Sample t-test	0.296	No	Accepted
Step Time	Mann-Whitney test	0.212	No	Accepted
Step Width	Independent Sample t-test	0.658	No	Accepted
Stride Length	Independent Sample t-test	0.131	No	Accepted
Stride Time	Mann-Whitney test	0.401	No	Accepted
Walking Speed	Independent Sample t-test	0.026	Yes	Rejected

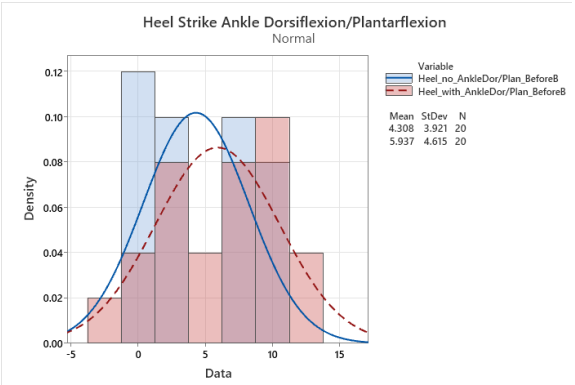
Appendix 39: Additional Statistical Analysis – Group B before no insoles vs before with insoles Kinematic Analysis and Histogram Plots at Heel Strike

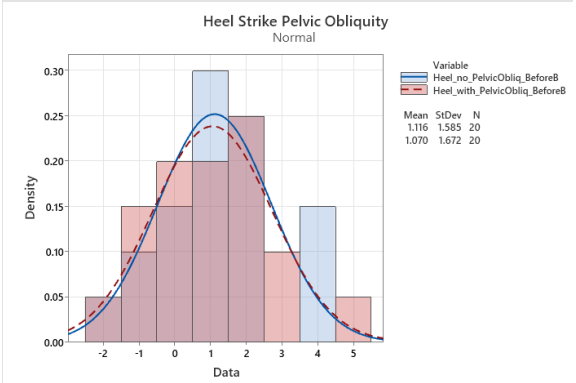
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon Signed-Rank Test	0.56	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.566	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.982	No	Accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.185	No	Accepted
Pelvic Obliquity	Paired Sample t-test	0.927	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.483	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.865	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.688	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.582	No	Accepted
Hip Rotation	Paired Sample t-test	0.798	No	Accepted
Knee Rotation	Paired Sample t-test	0.938	No	Accepted
Ankle Rotation	Paired Sample t-test	0.618	No	Accepted

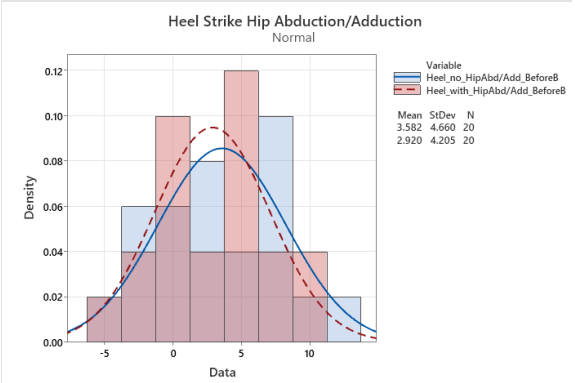


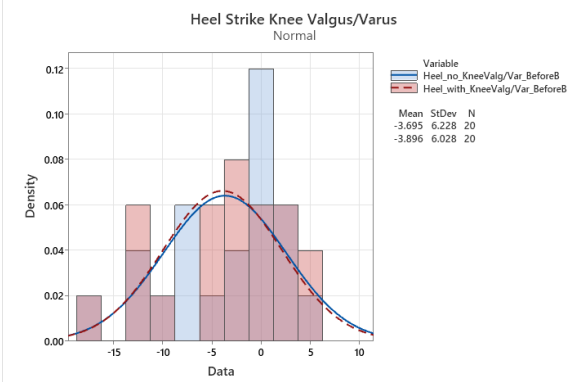


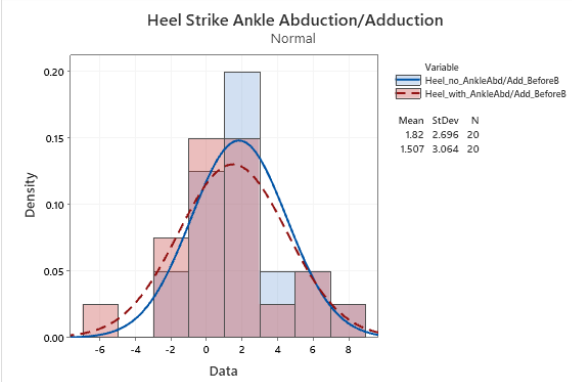

Heel Strike Knee Flexion/Extension
Normal
Density
Data
Variable
Heel_no_KneeFlex/Ext_BeforeB
Heel_with_KneeFlex/Ext_BeforeB
Mean StDev N
4.031 5.830 20
3.998 5.123 20

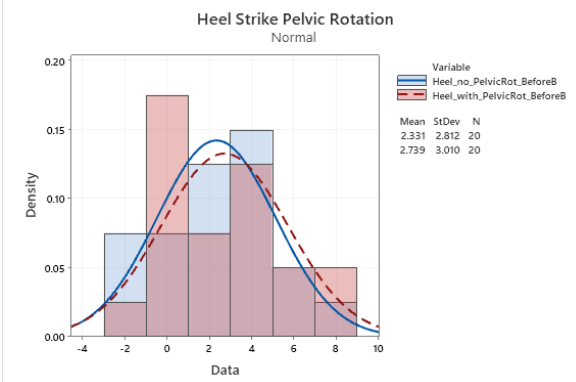

Heel Strike Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
Heel_no_AnkleDor/Plan_BeforeB
Heel_with_AnkleDor/Plan_BeforeB
Mean StDev N
4.308 3.921 20
5.937 4.615 20

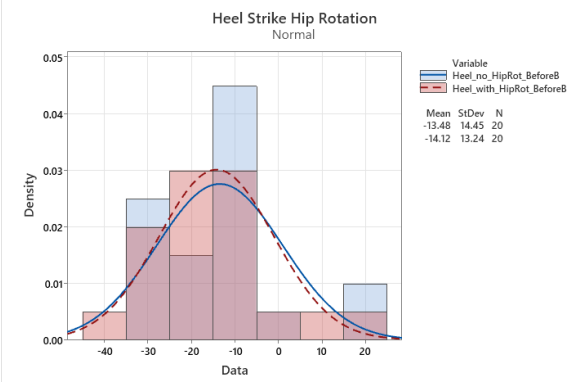

Heel Strike Pelvic Obliquity
Normal
Density
Data
Variable
Heel_no_PelvicObliq_BeforeB
Heel_with_PelvicObliq_BeforeB
Mean StDev N
1.116 1.585 20
1.070 1.672 20

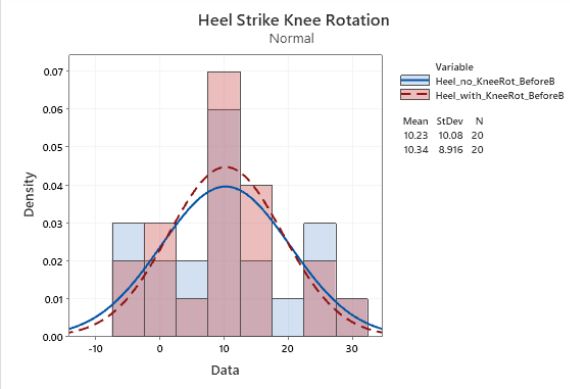

Heel Strike Hip Abduction/Adduction
Normal
Density
Data
Variable
Heel_no_HipAbd/Add_BeforeB
Heel_with_HipAbd/Add_BeforeB
Mean StDev N
3.582 4.660 20
2.920 4.205 20

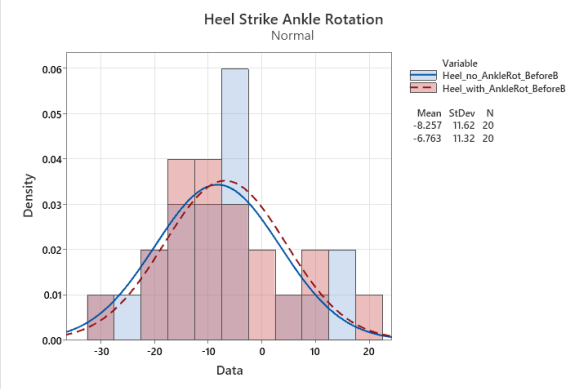

Heel Strike Knee Valgus/Varus
Normal
Density
Data
Variable
Heel_no_KneeValg/Var_BeforeB
Heel_with_KneeValg/Var_BeforeB
Mean StDev N
-3.695 6.228 20
-3.896 6.028 20


Heel Strike Ankle Abduction/Adduction
Normal
Density
Data
Variable
Heel_no_AnkleAbd/Add_BeforeB
Heel_with_AnkleAbd/Add_BeforeB
Mean StDev N
1.82 2.696 20
1.507 3.064 20


Heel Strike Pelvic Rotation
Normal
Density
Data
Variable
Heel_no_PelvicRot_BeforeB
Heel_with_PelvicRot_BeforeB
Mean StDev N
2.331 2.812 20
2.739 3.010 20

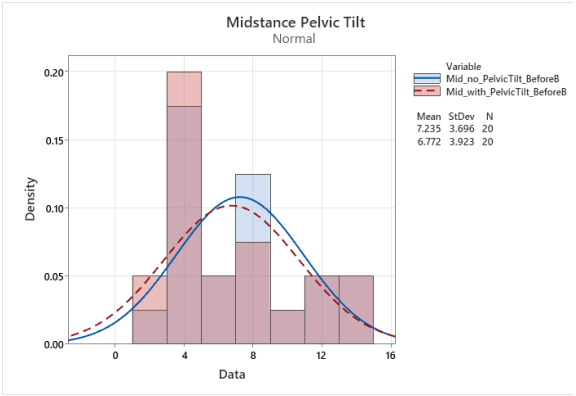

Heel Strike Hip Rotation
Normal
Density
Data
Variable
Heel_no_HipRot_BeforeB
Heel_with_HipRot_BeforeB
Mean StDev N
-13.48 14.45 20
-14.12 13.24 20

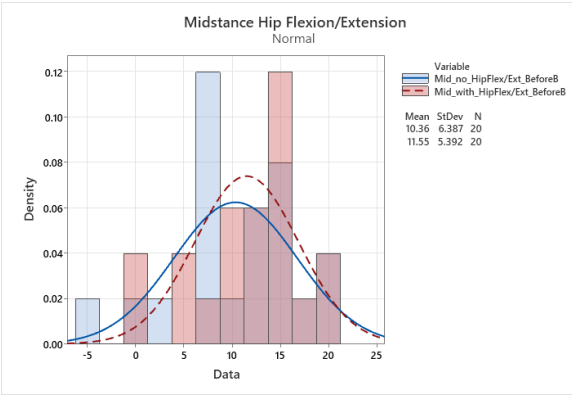

Heel Strike Knee Rotation
Normal
Density
Data
Variable
Heel_no_KneeRot_BeforeB
Heel_with_KneeRot_BeforeB
Mean StDev N
10.23 10.08 20
10.34 8.916 20

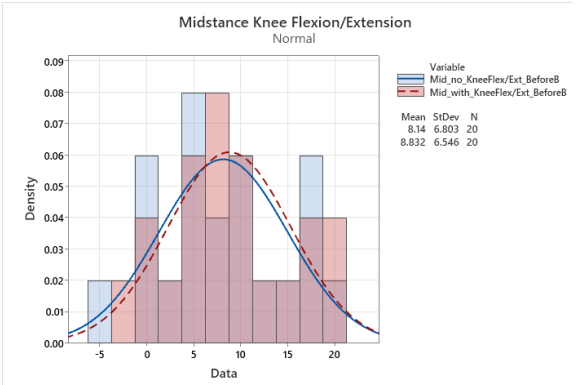

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
Heel_no_AnkleRot_BeforeB
Heel_with_AnkleRot_BeforeB
Mean StDev N
-8.257 11.62 20
-6.763 11.32 20

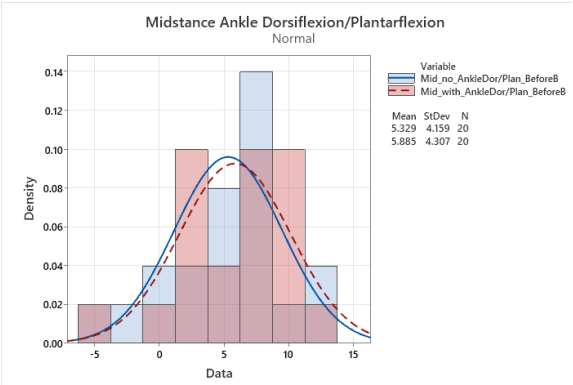
Appendix 40: Additional Statistical Analysis – Group B before no insoles vs before with insoles Kinematic Analysis and Histogram Plots at Midstance

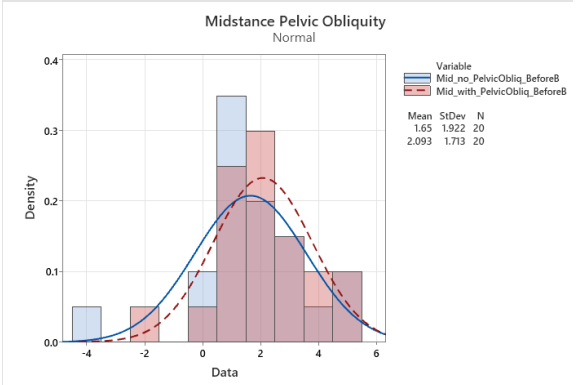
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon Signed-Rank Test	0.055*	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.116	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.109	No	Accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.145	No	Accepted
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.05*	Yes	Rejected
Hip Abd/Add	Paired Sample t-test	0.85	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.310	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.589	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.170	No	Accepted
Hip Rotation	Paired Sample t-test	0.356	No	Accepted
Knee Rotation	Paired Sample t-test	0.422	No	Accepted
Ankle Rotation	Paired Sample t-test	0.023*	Yes	Rejected

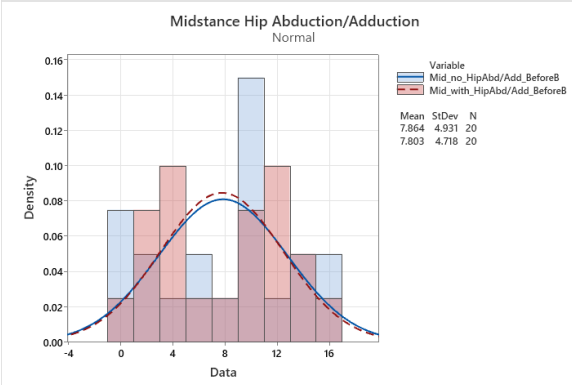


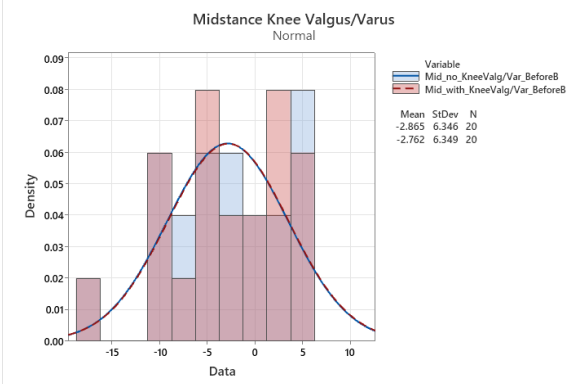


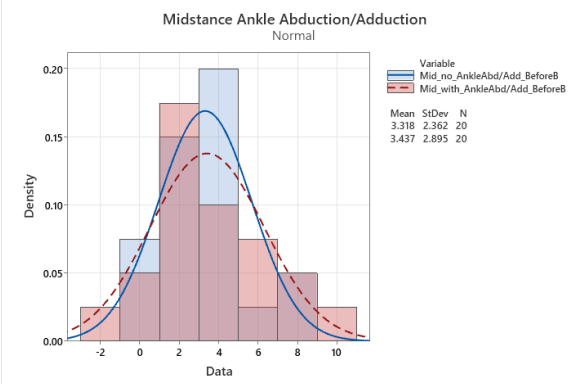

Midstance Knee Flexion/Extension
Normal
Density
Data
Variable
Mid_no_KneeFlex/Ext_BeforeB
Mid_with_KneeFlex/Ext_BeforeB
Mean StDev N
8.14 6.803 20
8.832 6.546 20

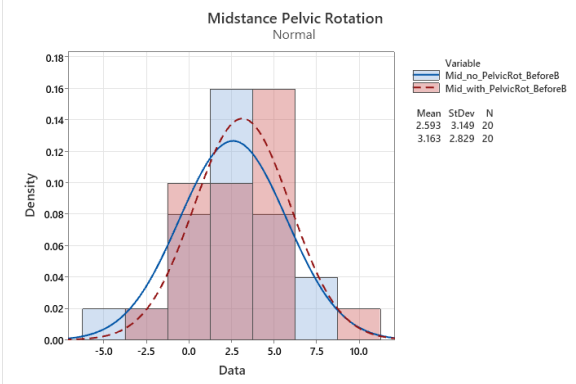

Midstance Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
Mid_no_AnkleDor/Plan_BeforeB
Mid_with_AnkleDor/Plan_BeforeB
Mean StDev N
5.329 4.159 20
5.885 4.307 20

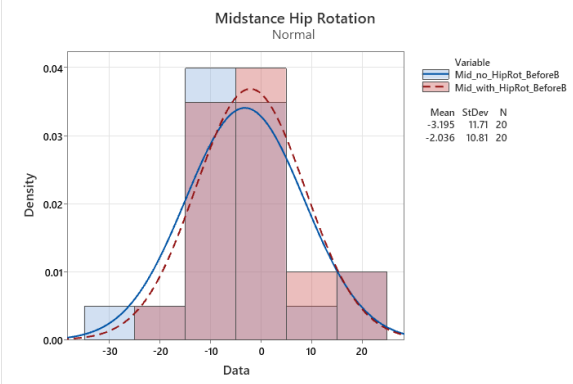

Midstance Pelvic Obliquity
Normal
Density
Data
Variable
Mid_no_PelvicObliq_BeforeB
Mid_with_PelvicObliq_BeforeB
Mean StDev N
1.65 1.922 20
2.093 1.713 20

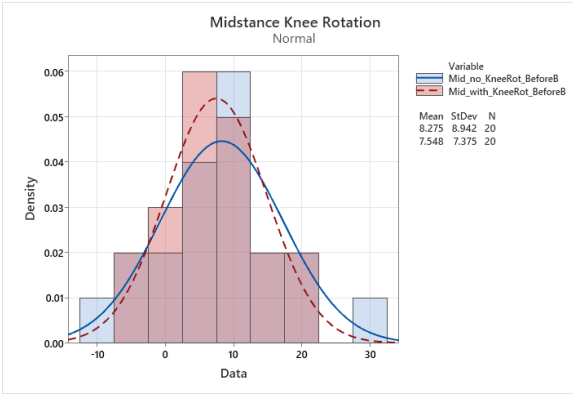

Midstance Hip Abduction/Adduction
Normal
Density
Data
Variable
Mid_no_HipAbd/Add_BeforeB
Mid_with_HipAbd/Add_BeforeB
Mean StDev N
7.864 4.931 20
7.803 4.718 20

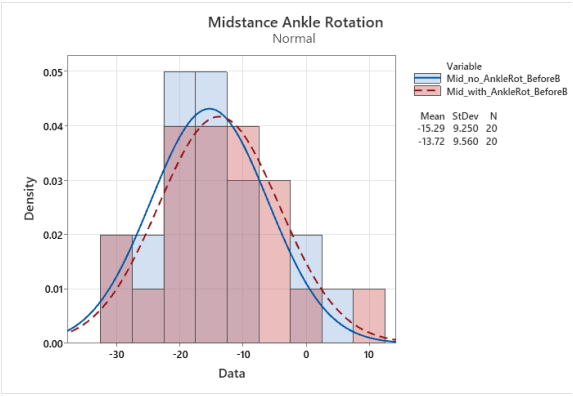

Midstance Knee Valgus/Varus
Normal
Density
Data
Variable
Mid_no_KneeValg/Var_BeforeB
Mid_with_KneeValg/Var_BeforeB
Mean StDev N
-2.865 6.346 20
-2.762 6.349 20


Midstance Ankle Abduction/Adduction
Normal
Density
Data
Variable
Mid_no_AnkleAbd/Add_BeforeB
Mid_with_AnkleAbd/Add_BeforeB
Mean StDev N
3.318 2.362 20
3.437 2.895 20


Midstance Pelvic Rotation
Normal
Density
Data
Variable
Mid_no_PelvicRot_BeforeB
Mid_with_PelvicRot_BeforeB
Mean StDev N
2.593 3.149 20
3.163 2.829 20

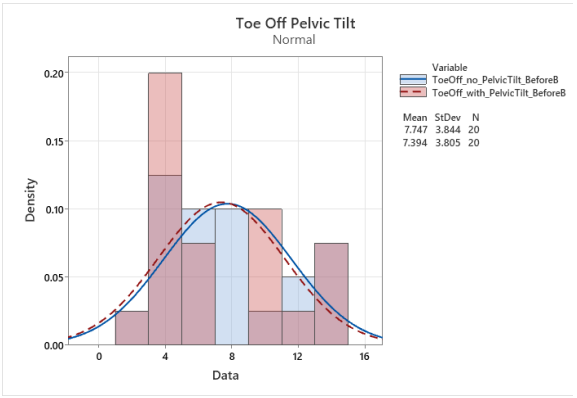

Midstance Hip Rotation
Normal
Density
Data
Variable
Mid_no_HipRot_BeforeB
Mid_with_HipRot_BeforeB
Mean StDev N
-3.195 11.71 20
-2.036 10.81 20

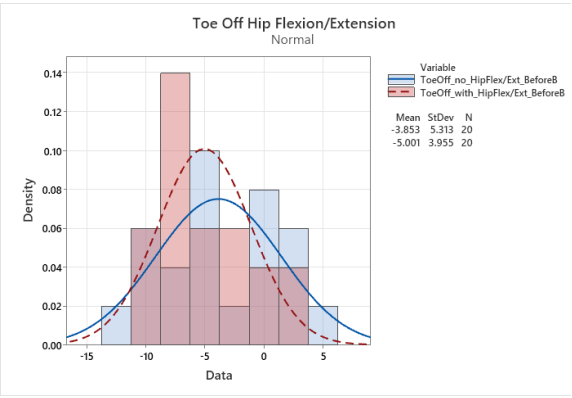

Midstance Knee Rotation
Normal
Density
Data
Variable
Mid_no_KneeRot_BeforeB
Mid_with_KneeRot_BeforeB
Mean StDev N
8.275 8.942 20
7.548 7.375 20

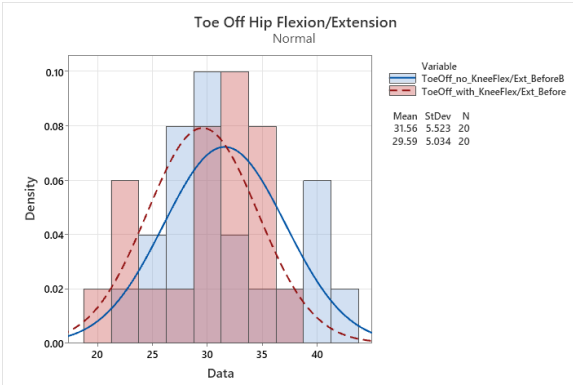

Midstance Ankle Rotation
Normal
Density
Data
Variable
Mid_no_AnkleRot_BeforeB
Mid_with_AnkleRot_BeforeB
Mean StDev N
-15.29 9.250 20
-13.72 9.560 20

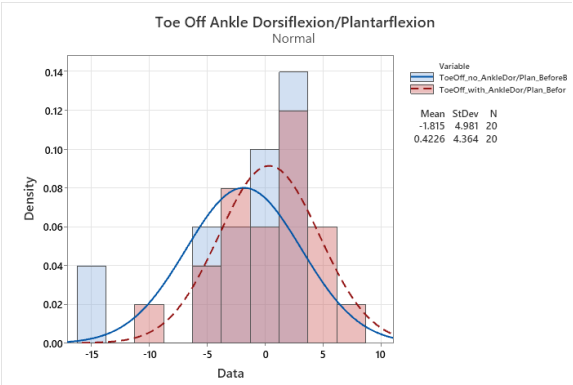
Appendix 41: Additional Statistical Analysis – Group B before no insoles vs before with insoles Kinematic Analysis and Histogram Plots at Toe Off

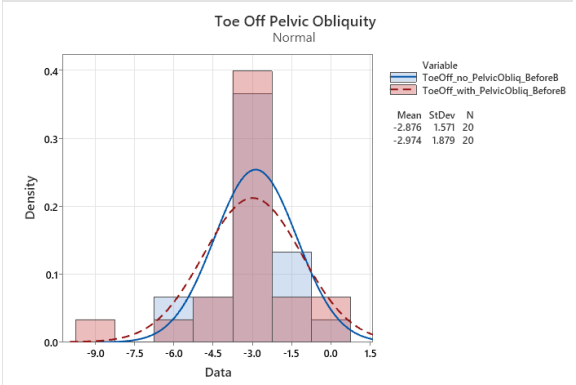
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.142	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.157	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.101	No	Accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.022*	Yes	Rejected
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.808	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.873	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.652	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.595	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.284	No	Accepted
Hip Rotation	Paired Sample t-test	0.996	No	Accepted
Knee Rotation	Paired Sample t-test	0.861	No	Accepted
Ankle Rotation	Paired Sample t-test	0.48	No	Accepted

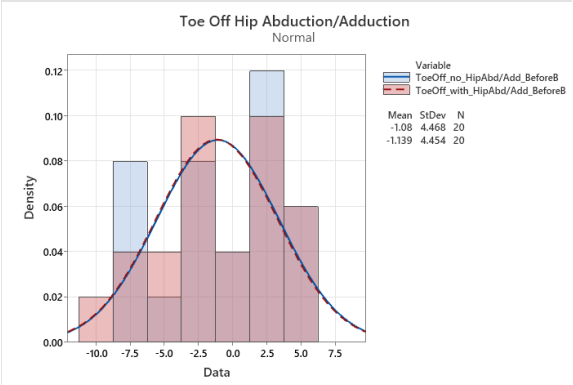


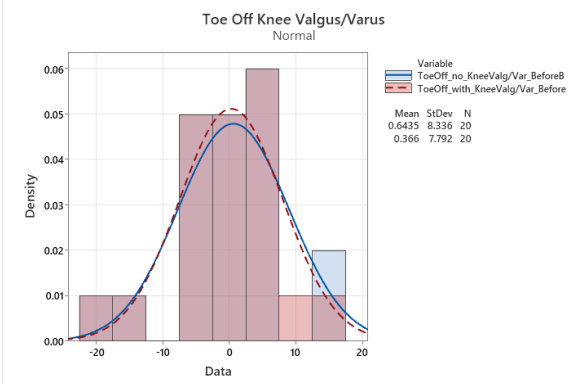


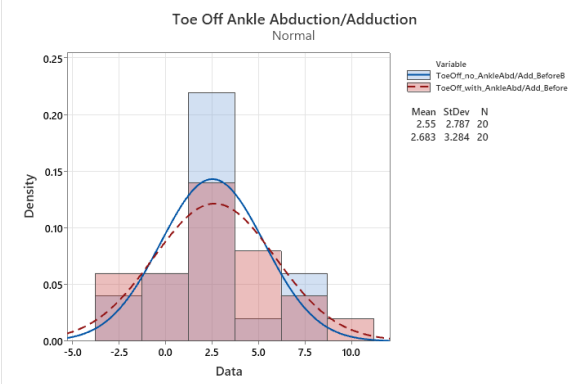

Toe Off Hip Flexion/Extension
Normal
Density
Data
Variable
ToeOff_no_KneeFlex/Ext_BeforeB
ToeOff_with_KneeFlex/Ext_Before
Mean StDev N
31.56 5.523 20
29.59 5.034 20

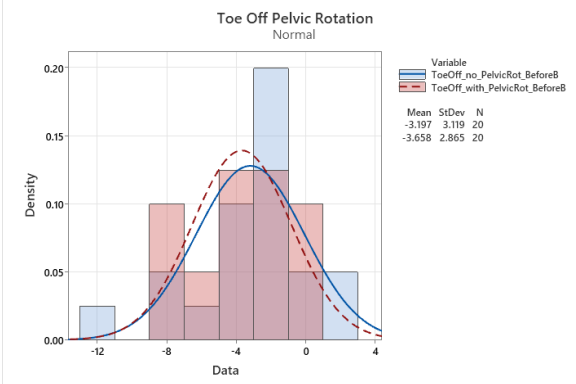

Toe Off Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
ToeOff_no_AnkleDor/Plan_BeforeB
ToeOff_with_AnkleDor/Plan_Befor
Mean StDev N
-1.815 4.981 20
0.4226 4.364 20

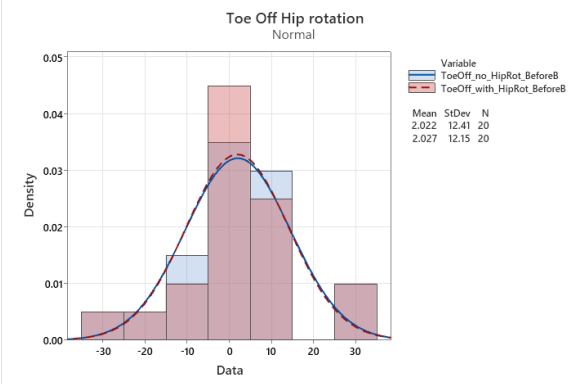

Toe Off Pelvic Obliquity
Normal
Density
Data
Variable
ToeOff_no_PelvicObliq_BeforeB
ToeOff_with_PelvicObliq_BeforeB
Mean StDev N
-2.876 1.571 20
-2.974 1.879 20

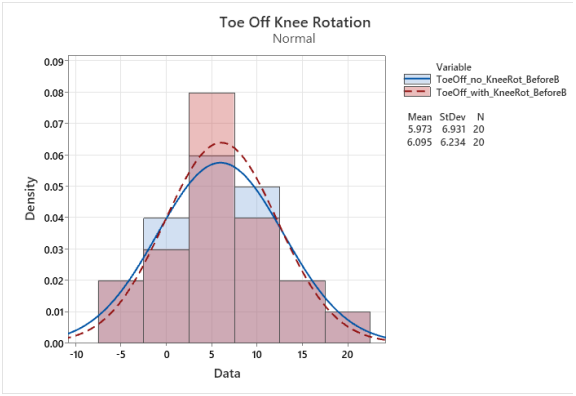

Toe Off Hip Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_no_HipAbd/Add_BeforeB
ToeOff_with_HipAbd/Add_BeforeB
Mean StDev N
-1.08 4.468 20
-1.139 4.454 20

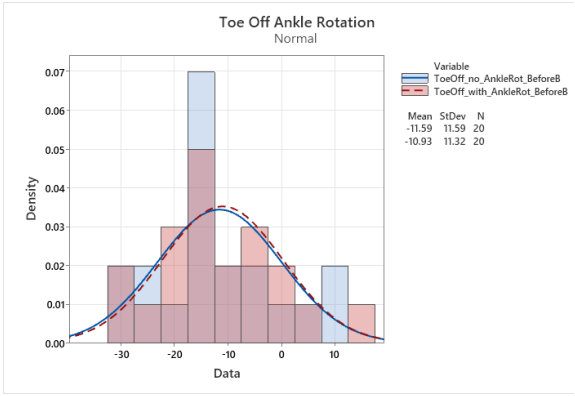

Toe Off Knee Valgus/Varus
Normal
Density
Data
Variable
ToeOff_no_KneeValg/Var_BeforeB
ToeOff_with_KneeValg/Var_Before
Mean StDev N
0.6435 8.336 20
0.366 7.792 20


Toe Off Ankle Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_no_AnkleAbd/Add_BeforeB
ToeOff_with_AnkleAbd/Add_Before
Mean StDev N
2.55 2.787 20
2.683 3.284 20


Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_no_PelvicRot_BeforeB
ToeOff_with_PelvicRot_BeforeB
Mean StDev N
-3.197 3.119 20
-3.658 2.865 20


Toe Off Hip rotation
Normal
Density
Data
Variable
ToeOff_no_HipRot_BeforeB
ToeOff_with_HipRot_BeforeB
Mean StDev N
2.022 12.41 20
2.027 12.15 20


Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_no_KneeRot_BeforeB
ToeOff_with_KneeRot_BeforeB
Mean StDev N
5.973 6.931 20
6.095 6.234 20


Toe Off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_no_AnkleRot_BeforeB
ToeOff_with_AnkleRot_BeforeB
Mean StDev N
-11.59 11.59 20
-10.93 11.32 20

Appendix 42: Additional Statistical Analysis – Group B before no insoles vs before with insoles Kinematic Data compared with Normative Data

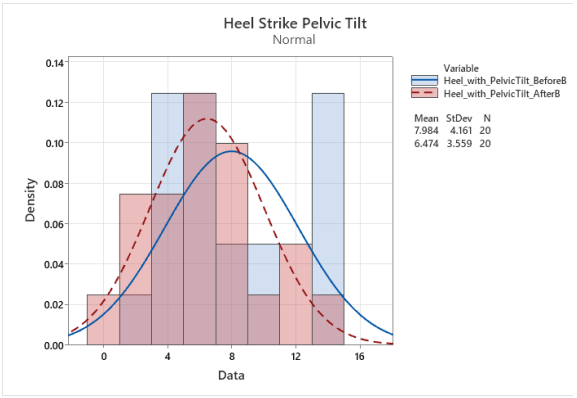
Angle	Heel strike PValue Before	Heel strike PValue After	Midstance PValue Before	Midstance PValue After	Toe off PValue Before	Toe off PValue Before
Pelvic Tilt	0.001	0.001	0.104	0.029	0.203	0.097
Hip Flex/ex	0.02	0.071*	0.000	0.000	0.761	0.388
Knee Flex/ex	0.00	0.00	0.006	0.012	0.000	0.000
Ankle Dorsi/Plantar	0.034	0.002	0.00	0.00	0.000	0.000
Pelvic Obliquity	0.00	0.00	0.05	0.001	0.000	0.002
Hip Abd/Add	0.281	0.071	0.001	0.001	0.65	0.608
Knee Valg/Var	0.00	0.00	0.003	0.003	0.512	0.393
Ankle Abd/Add	0.00	0.00	0.162	0.182	0.002	0.004
Pelvis Rotation	0.00	0.00	0.385	0.929	0.07	0.011
Hip Rotation	0.002	0.000	0.675	0.986	0.425	0.415
Knee Rotation	0.082	0.046	0.042	0.040	0.093	0.054
Ankle Rotation	0.00	0.00	0.000	0.000	0.00	0.00

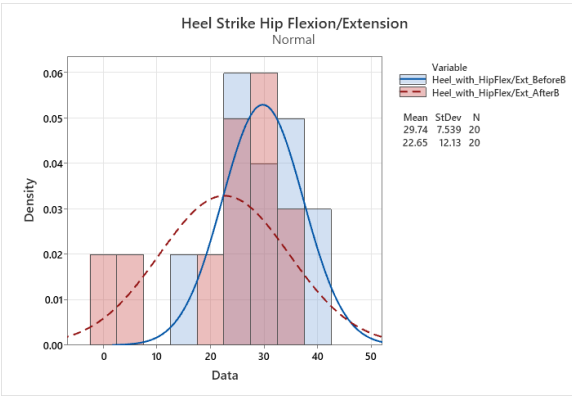
Appendix 43: Additional Statistical Analysis – Group B before no insoles vs before with insoles Spatiotemporal Data

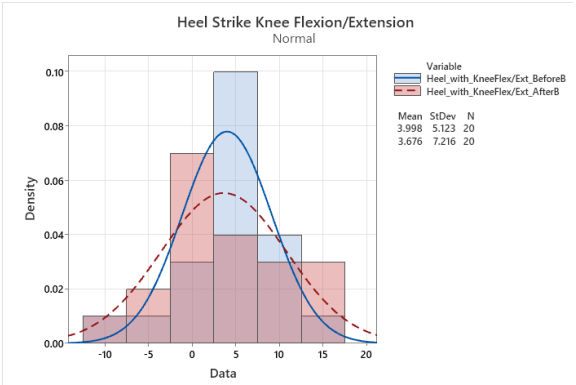
	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Wilcoxon Signed-Rank Test	0.588	No	Accepted
Double Support	Paired Sample t-test	0.532	No	Accepted
Foot Off	Paired Sample t-test	0.290	No	Accepted
Limp Index	Wilcoxon Signed-Rank Test	0.5	No	Accepted
Opposite Foot Contact	Wilcoxon Signed-Rank Test	0.323	No	Accepted
Opposite Foot Off	Wilcoxon Signed-Rank Test	0.695	No	Accepted
Single Support	Paired Sample t-test	0.113	No	Accepted
Step Length	Paired Sample t-test	0.151	No	Accepted
Step Time	Paired Sample t-test	0.609	No	Accepted
Step Width	Paired Sample t-test	0.08	No	Accepted
Stride Length	Paired Sample t-test	0.067	No	Accepted
Stride Time	Paired Sample t-test	0.259	No	Accepted
Walking Speed	Paired Sample t-test	0.827	No	Accepted

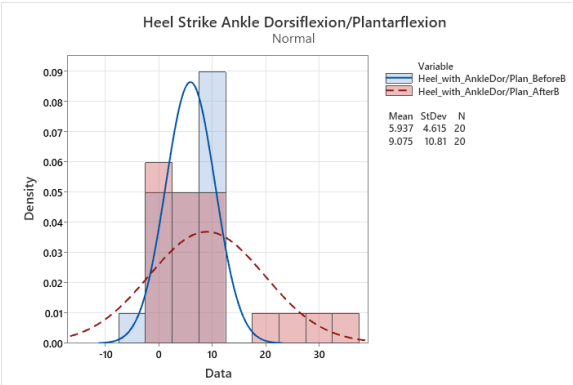
Appendix 44: Additional Statistical Analysis – Group B before with insoles vs after with insoles Kinematic Analysis and Histogram Plots at Heel Strike

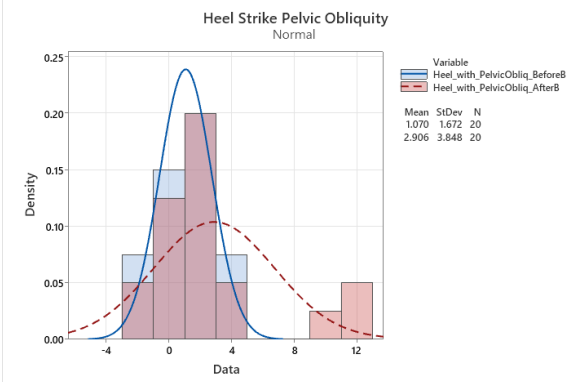
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.104	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.095	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.758	No	Accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.255	Yes	Rejected
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.055*	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.323	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.05*	Yes	Rejected
Ankle Abd/Add	Paired Sample t-test	0.202	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.919	No	Accepted
Hip Rotation	Paired Sample t-test	0.025*	Yes	Rejected
Knee Rotation	Paired Sample t-test	0.171	No	Accepted
Ankle Rotation	Paired Sample t-test	0.259	No	Accepted

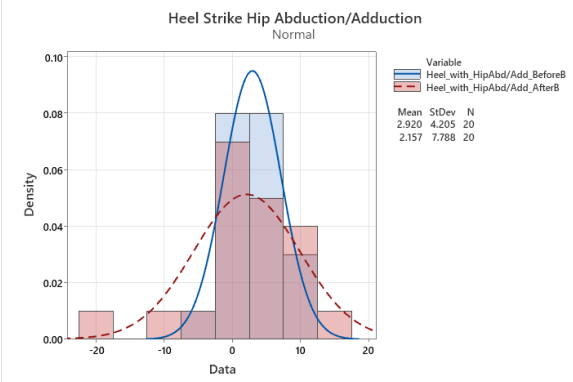


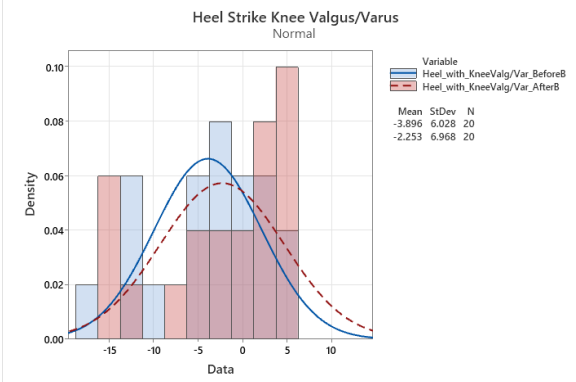


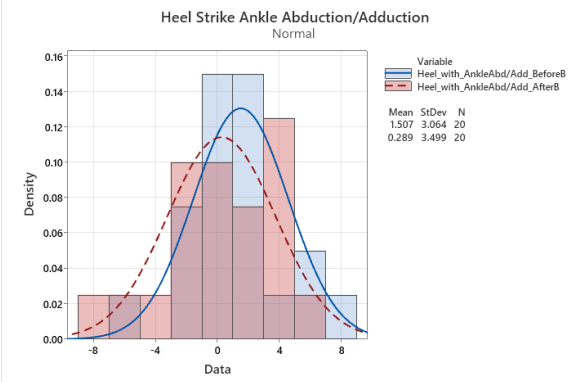

Heel Strike Knee Flexion/Extension
Normal
Density
Data
Variable
Heel_with_KneeFlex/Ext_BeforeB
Heel_with_KneeFlex/Ext_AfterB
Mean StDev N
3.998 5.123 20
3.676 7.216 20

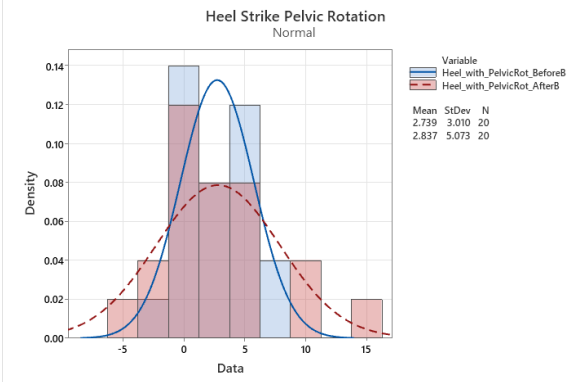

Heel Strike Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
Heel_with_AnkleDor/Plan_BeforeB
Heel_with_AnkleDor/Plan_AfterB
Mean StDev N
5.937 4.615 20
9.075 10.81 20

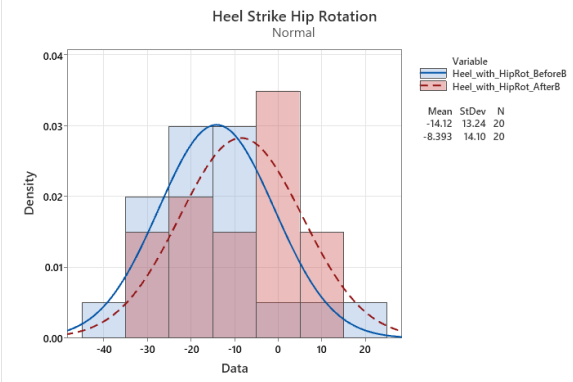

Heel Strike Pelvic Obliquity
Normal
Density
Data
Variable
Heel_with_PelvicObliq_BeforeB
Heel_with_PelvicObliq_AfterB
Mean StDev N
1.070 1.672 20
2.906 3.848 20

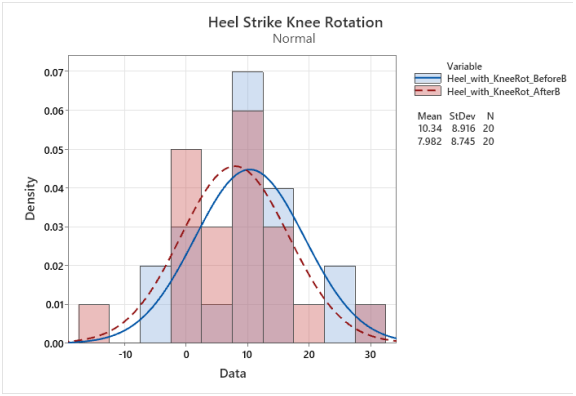

Heel Strike Hip Abduction/Adduction
Normal
Density
Data
Variable
Heel_with_HipAbd/Add_BeforeB
Heel_with_HipAbd/Add_AfterB
Mean StDev N
2.920 4.205 20
2.157 7.788 20

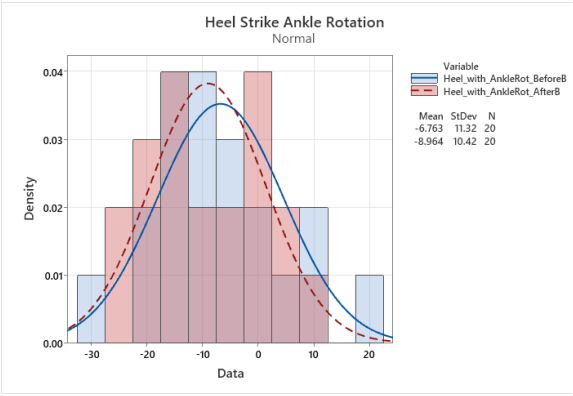

Heel Strike Knee Valgus/Varus
Normal
Density
Data
Variable
Heel_with_KneeValg/Var_BeforeB
Heel_with_KneeValg/Var_AfterB
Mean StDev N
-3.896 6.028 20
-2.253 6.968 20


Heel Strike Ankle Abduction/Adduction
Normal
Density
Data
Variable
Heel_with_AnkleAbd/Add_BeforeB
Heel_with_AnkleAbd/Add_AfterB
Mean StDev N
1.507 3.064 20
0.289 3.499 20


Heel Strike Pelvic Rotation
Normal
Density
Data
Variable
Heel_with_PelvicRot_BeforeB
Heel_with_PelvicRot_AfterB
Mean StDev N
2.739 3.010 20
2.837 5.073 20

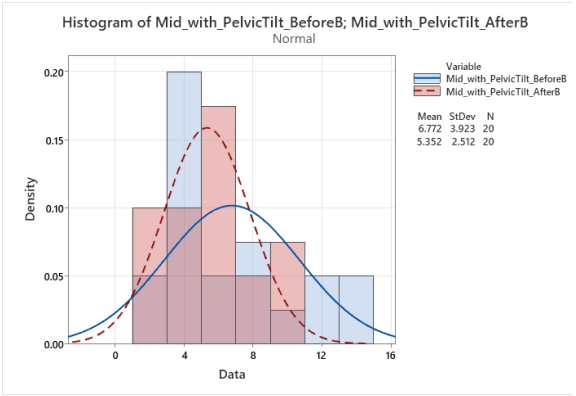

Heel Strike Hip Rotation
Normal
Density
Data
Variable
Heel_with_HipRot_BeforeB
Heel_with_HipRot_AfterB
Mean StDev N
-14.12 13.24 20
-8.393 14.10 20

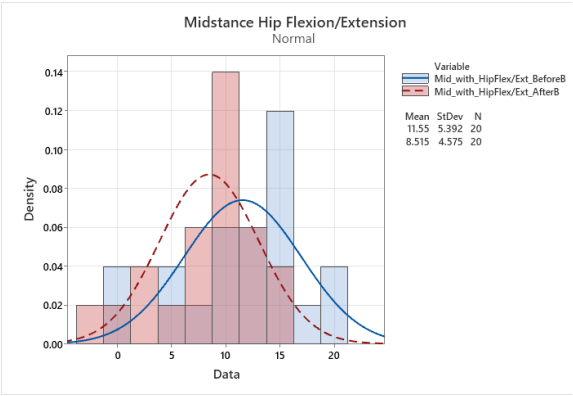

Heel Strike Knee Rotation
Normal
Density
Data
Variable
Heel_with_KneeRot_BeforeB
Heel_with_KneeRot_AfterB
Mean StDev N
10.34 8.916 20
7.982 8.745 20

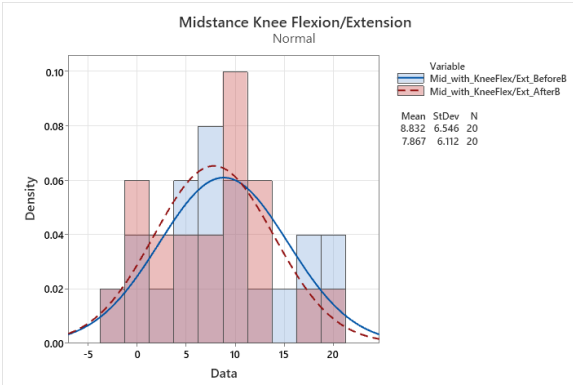

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
Heel_with_AnkleRot_BeforeB
Heel_with_AnkleRot_AfterB
Mean StDev N
-6.763 11.32 20
-8.964 10.42 20

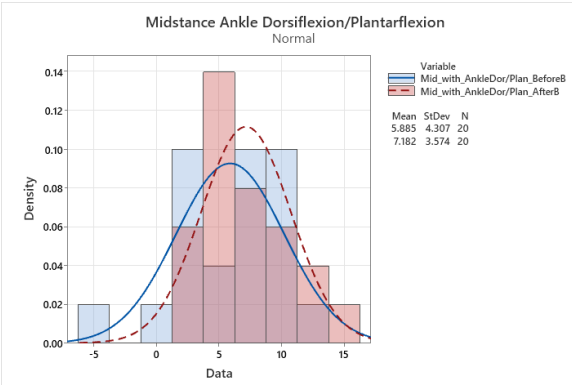
Appendix 45: Additional Statistical Analysis – Group B before with insoles vs after with insoles Kinematic Analysis and Histogram Plots at Midstance

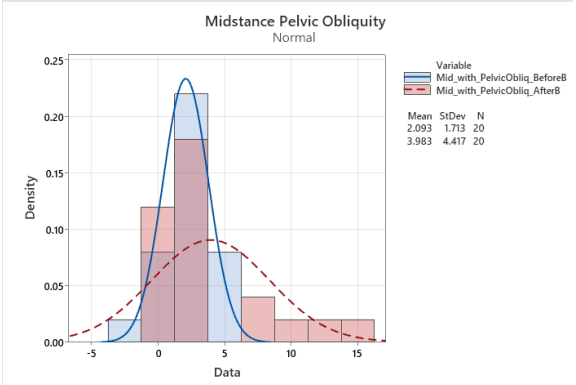
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Wilcoxon Signed-Rank Test	0.173	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.049*	Yes	Rejected
Knee Flex/ext	Paired Sample t-test	0.458	No	Accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.176	No	Accepted
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.198	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.501	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.108	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.144	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.491	No	Accepted
Hip Rotation	Paired Sample t-test	0.691	No	Accepted
Knee Rotation	Paired Sample t-test	0.658	No	Accepted
Ankle Rotation	Paired Sample t-test	0.215	No	Accepted

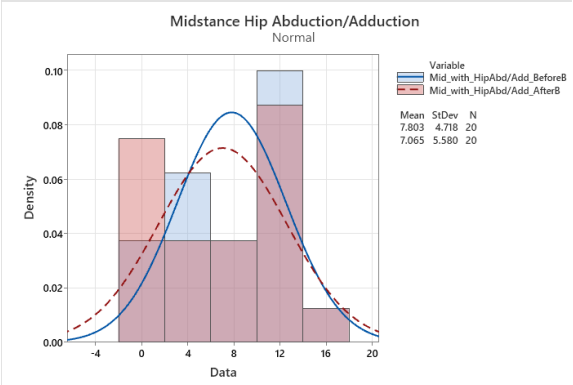


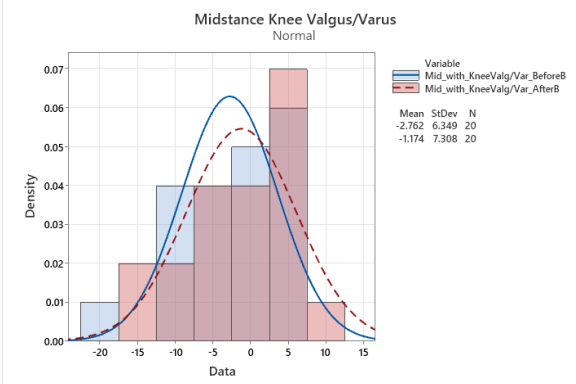


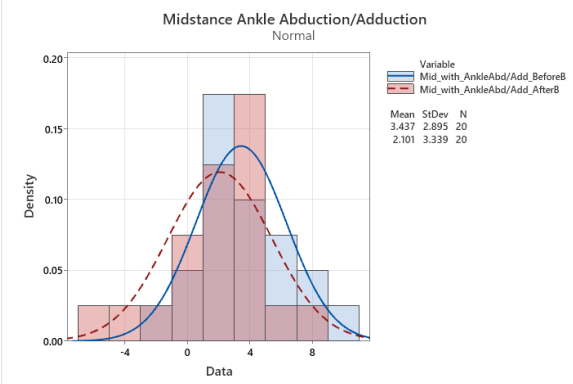

Midstance Knee Flexion/Extension
Normal
Variable
Mid_with_KneeFlex/Ext_BeforeB
Mid_with_KneeFlex/Ext_AfterB
Mean StDev N
8.832 6.546 20
7.867 6.112 20
Density
Data

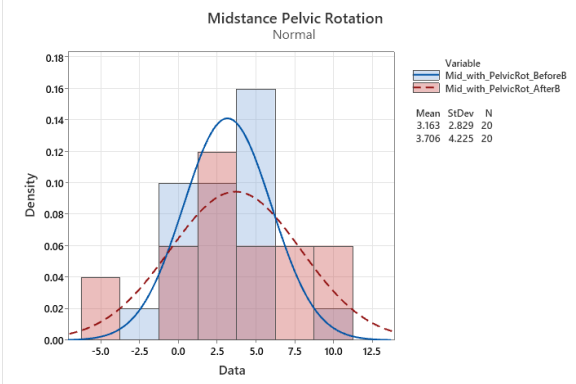

Midstance Ankle Dorsiflexion/Plantarflexion
Normal
Variable
Mid_with_AnkleDor/Plan_BeforeB
Mid_with_AnkleDor/Plan_AfterB
Mean StDev N
5.885 4.307 20
7.182 3.574 20
Density
Data

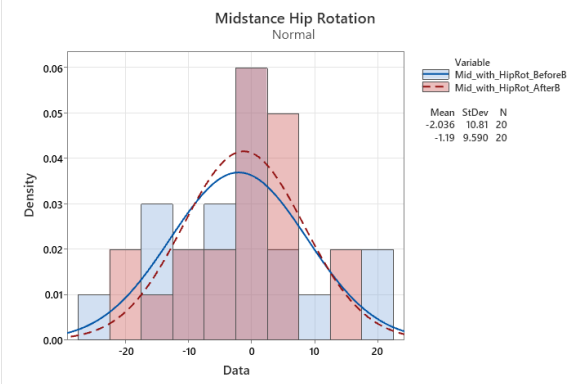

Midstance Pelvic Obliquity
Normal
Variable
Mid_with_PelvicObliq_BeforeB
Mid_with_PelvicObliq_AfterB
Mean StDev N
2.093 1.713 20
3.983 4.417 20
Density
Data

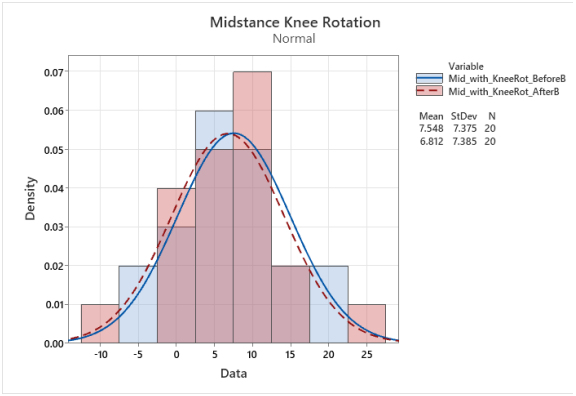

Midstance Hip Abduction/Adduction
Normal
Variable
Mid_with_HipAbd/Add_BeforeB
Mid_with_HipAbd/Add_AfterB
Mean StDev N
7.803 4.718 20
7.065 5.580 20
Density
Data

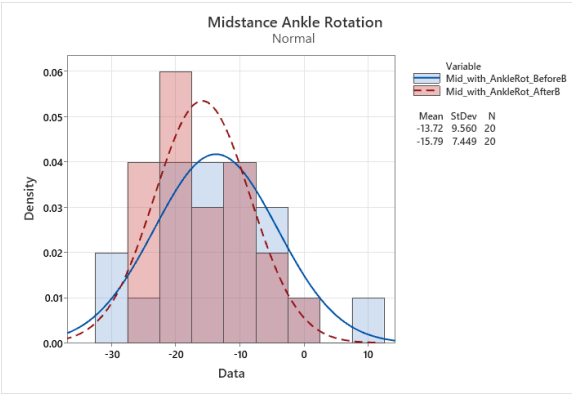

Midstance Knee Valgus/Varus
Normal
Variable
Mid_with_KneeValg/Var_BeforeB
Mid_with_KneeValg/Var_AfterB
Mean StDev N
-2.762 6.349 20
-1.174 7.308 20
Density
Data


Midstance Ankle Abduction/Adduction
Normal
Variable
Mid_with_AnkleAbd/Add_BeforeB
Mid_with_AnkleAbd/Add_AfterB
Mean StDev N
3.437 2.895 20
2.101 3.339 20
Density
Data


Midstance Pelvic Rotation
Normal
Variable
Mid_with_PelvicRot_BeforeB
Mid_with_PelvicRot_AfterB
Mean StDev N
3.163 2.829 20
3.706 4.225 20
Density
Data

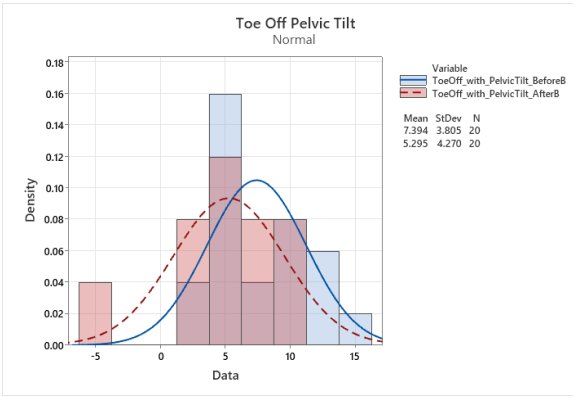

Midstance Hip Rotation
Normal
Variable
Mid_with_HipRot_BeforeB
Mid_with_HipRot_AfterB
Mean StDev N
-2.036 10.81 20
-1.19 9.590 20
Density
Data

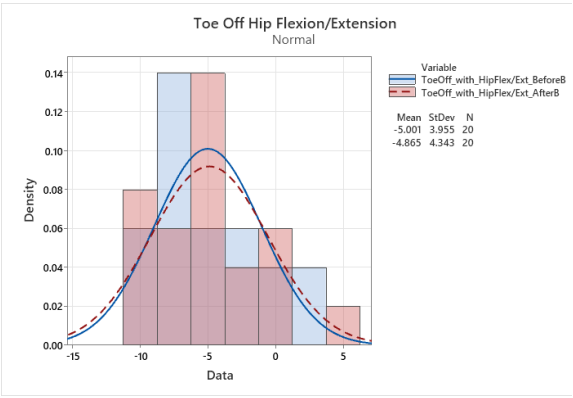

Midstance Knee Rotation
Normal
Density
Data
Variable
Mid_with_KneeRot_BeforeB
Mid_with_KneeRot_AfterB
Mean StDev N
7.548 7.375 20
6.812 7.385 20

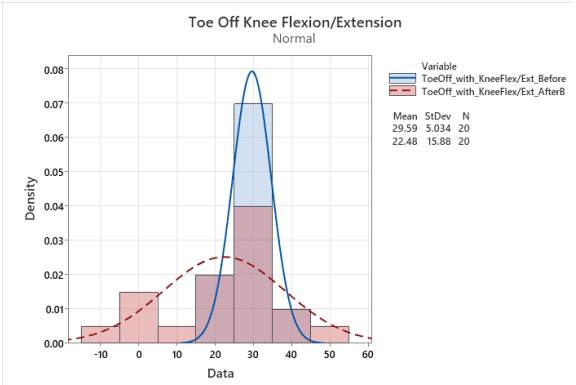

Midstance Ankle Rotation
Normal
Density
Data
Variable
Mid_with_AnkleRot_BeforeB
Mid_with_AnkleRot_AfterB
Mean StDev N
-13.72 9.560 20
-15.79 7.449 20

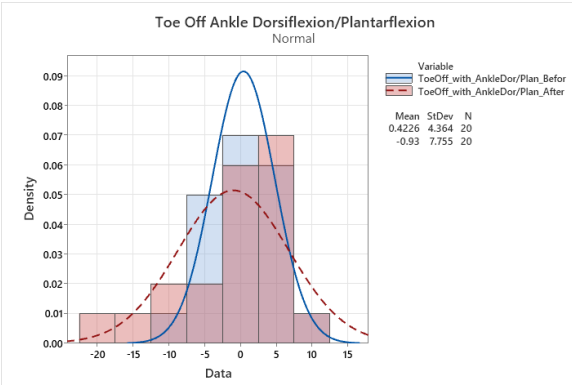
Appendix 46: Additional Statistical Analysis – Group B before with insoles vs after with insoles Kinematic Analysis and Histogram Plots at Toe Off

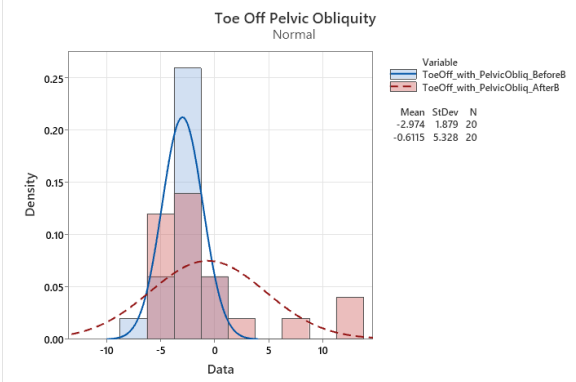
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.057*	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.910	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.052*	No	Accepted
Ankle Dorsi/Plantar	Wilcoxon Signed-Rank Test	0.695	No	Accepted
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.067	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.082	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.004*	Yes	Rejected
Ankle Abd/Add	Paired Sample t-test	0.806	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.094	No	Accepted
Hip Rotation	Paired Sample t-test	0.497	No	Accepted
Knee Rotation	Paired Sample t-test	0.173	No	Accepted
Ankle Rotation	Paired Sample t-test	0.312	No	Accepted

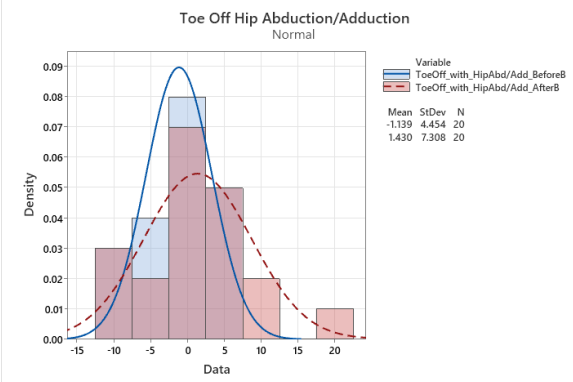


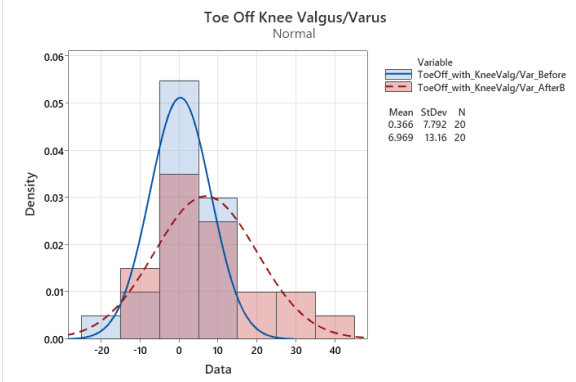


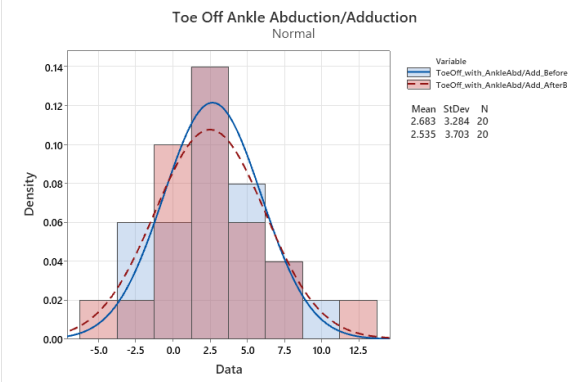

Toe Off Knee Flexion/Extension
Normal
Density
Data
Variable
ToeOff_with_KneeFlex/Ext_Before
ToeOff_with_KneeFlex/Ext_AfterB
Mean StDev N
29.59 5.034 20
22.48 15.88 20

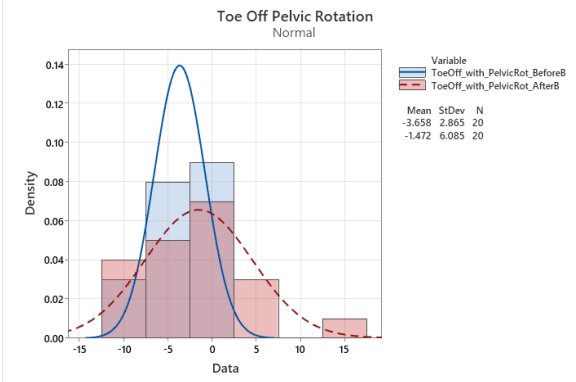

Toe Off Ankle Dorsiflexion/Plantarflexion
Normal
Density
Data
Variable
ToeOff_with_AnkleDor/Plan_Befor
ToeOff_with_AnkleDor/Plan_After
Mean StDev N
0.4226 4.364 20
-0.93 7.755 20

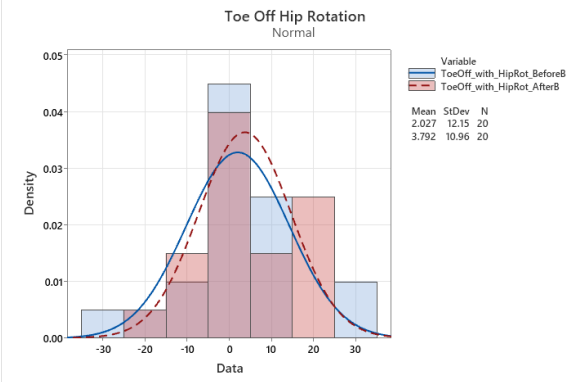

Toe Off Pelvic Obliquity
Normal
Density
Data
Variable
ToeOff_with_PelvicObliq_BeforeB
ToeOff_with_PelvicObliq_AfterB
Mean StDev N
-2.974 1.879 20
-0.6115 5.328 20

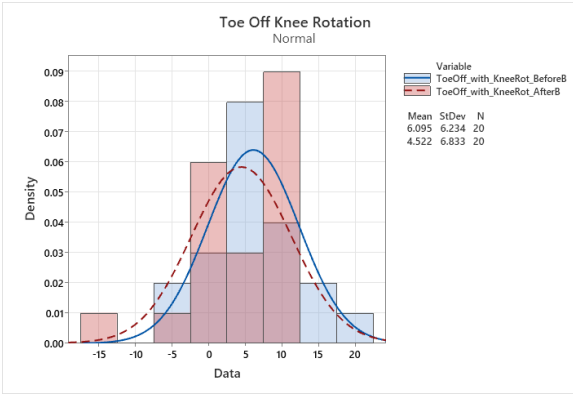

Toe Off Hip Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_with_HipAbd/Add_BeforeB
ToeOff_with_HipAbd/Add_AfterB
Mean StDev N
-1.139 4.454 20
1.430 7.308 20

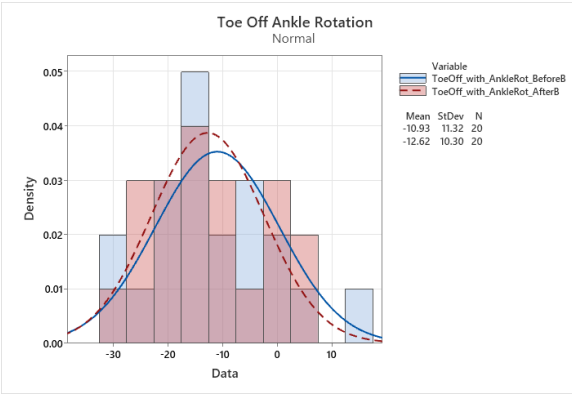

Toe Off Knee Valgus/Varus
Normal
Density
Data
Variable
ToeOff_with_KneeValg/Var_Before
ToeOff_with_KneeValg/Var_AfterB
Mean StDev N
0.366 7.792 20
6.969 13.16 20


Toe Off Ankle Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_with_AnkleAbd/Add_Before
ToeOff_with_AnkleAbd/Add_AfterB
Mean StDev N
2.683 3.284 20
2.535 3.703 20


Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_with_PelvicRot_BeforeB
ToeOff_with_PelvicRot_AfterB
Mean StDev N
-3.658 2.865 20
-1.472 6.085 20


Toe Off Hip Rotation
Normal
Density
Data
Variable
ToeOff_with_HipRot_BeforeB
ToeOff_with_HipRot_AfterB
Mean StDev N
2.027 12.15 20
3.792 10.96 20


Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_with_KneeRot_BeforeB
ToeOff_with_KneeRot_AfterB
Mean StDev N
6.095 6.234 20
4.522 6.833 20


Toe Off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_with_AnkleRot_BeforeB
ToeOff_with_AnkleRot_AfterB
Mean StDev N
-10.93 11.32 20
-12.62 10.30 20

Appendix 47: Additional Statistical Analysis – Group B before with insoles vs after with insoles Kinematic Analysis compared with Normative Data

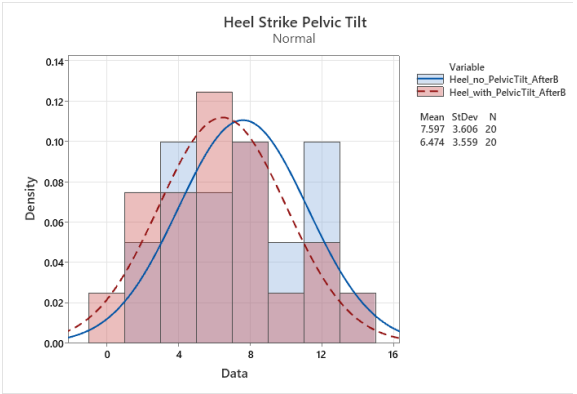
Angle	Heel strike PValue Before	Heel strike PValue After	Midstance PValue Before	Midstance PValue After	Toe off PValue Before	Toe off PValue Before
Pelvic Tilt	0.001	0.00	0.029	0.0	0.097	0.001
Hip Flex/ex	0.071	0.00	0.0	0.0	0.388	0.514
Knee Flex/ex	0.0	0.0	0.012	0.002	0.00	0.009
Ankle Dorsi/Plantar	0.002	0.022	0.0	0.0	0.00	0.00
Pelvic Obliquity	0.00	0.00	0.005	0.542*	0.002	0.455*
Hip Abd/Add	0.071	0.198	0.001	0.015	0.608	0.225
Knee Valg/Var	0.00	0.000	0.003	0.066*	0.393	0.1
Ankle Abd/Add	0.0	0.0	0.187	0.555	0.004	0.013
Pelvis Rotation	0.0	0.0	0.929	0.613	0.011	0.778*
Hip Rotation	0.00	0.046	0.986	0.683	0.415	0.116
Knee Rotation	0.046	0.345*	0.040	0.095*	0.054	0.408*
Ankle Rotation	0.0	0.0	0.0	0.0	0.0	0.0

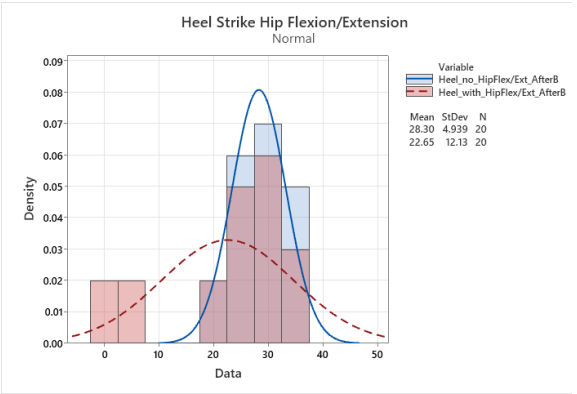
Appendix 48: Additional Statistical Analysis – Group B before with insoles vs after with insoles Spatiotemporal data

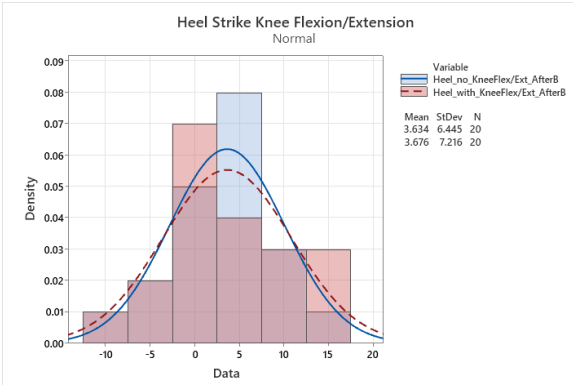
	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Wilcoxon Signed-Rank Test	0.723	No	Accepted
Double Support	Paired Sample t-test	0.873	No	Accepted
Foot Off	Paired Sample t-test	0.820	No	Accepted
Limp Index	Paired Sample t-test	0.635	No	Accepted
Opposite Foot Contact	Wilcoxon Signed-Rank Test	0.668	No	Accepted
Opposite Foot Off	Wilcoxon Signed-Rank Test	0.779	No	Accepted
Single Support	Paired Sample t-test	0.465	No	Accepted
Step Length	Paired Sample t-test	0.133	No	Accepted
Step Time	Paired Sample t-test	0.563	No	Accepted
Step Width	Paired Sample t-test	0.138	No	Accepted
Stride Length	Paired Sample t-test	0.06	No	Accepted
Stride Time	Paired Sample t-test	0.627	No	Accepted
Walking Speed	Paired Sample t-test	0.344	No	Accepted

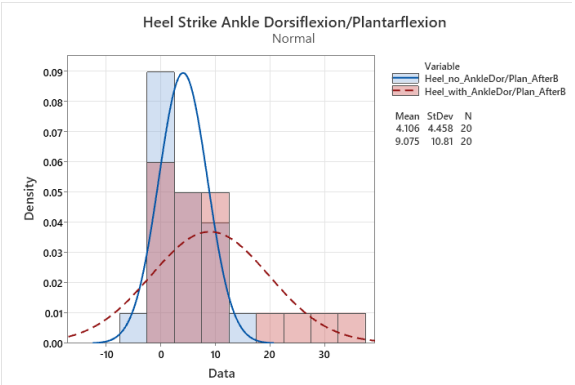
Appendix 49: Additional Statistical Analysis – Group B after no insoles vs after with insoles Kinematic Analysis and Histogram Plots at Heel Strike

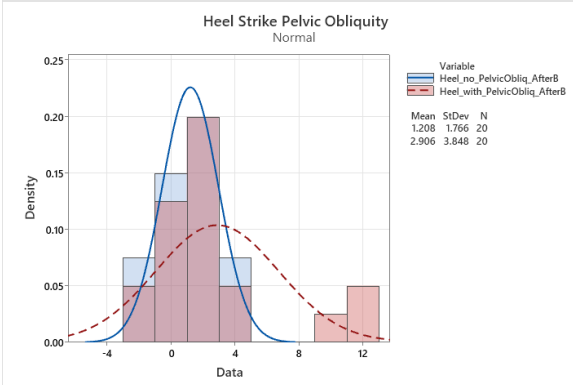
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.215	No	Accepted
Hip Flex/ext	Wilcoxon Signed-Rank Test	0.057	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.981	No	Accepted
Ankle Dorsi/Plantar	Wilcoxon Signed-Rank Test	0.156	No	Accepted
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.087	No	Accepted
Hip Abd/Add	Wilcoxon Signed-Rank Test	0.514	No	Accepted
Knee Valg/Var	Wilcoxon Signed-Rank Test	0.211	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.114	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.763	No	Accepted
Hip Rotation	Paired Sample t-test	0.259	No	Accepted
Knee Rotation	Paired Sample t-test	0.7	No	Accepted
Ankle Rotation	Paired Sample t-test	0.924	No	Accepted

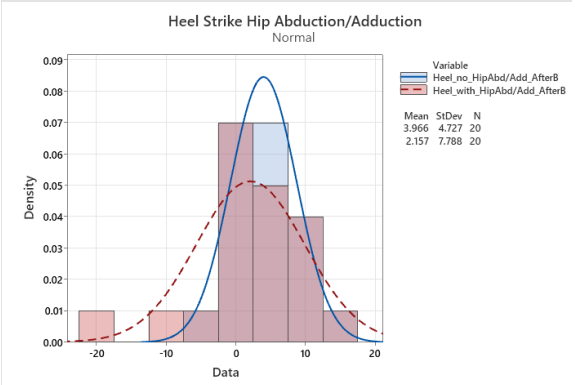


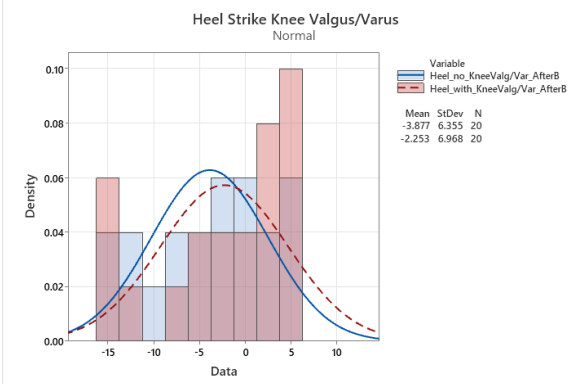


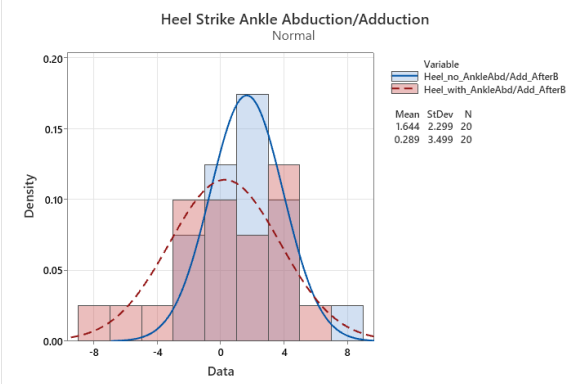

Heel Strike Knee Flexion/Extension
Normal
Variable
Heel_no_KneeFlex/Ext_AfterB
Heel_with_KneeFlex/Ext_AfterB
Mean StDev N
3.634 6.445 20
3.676 7.216 20
Density
Data

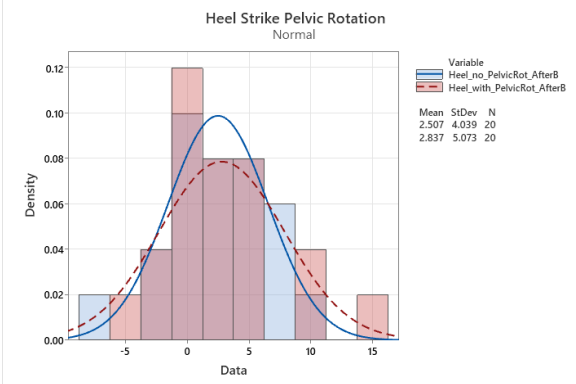

Heel Strike Ankle Dorsiflexion/Plantarflexion
Normal
Variable
Heel_no_AnkleDor/Plan_AfterB
Heel_with_AnkleDor/Plan_AfterB
Mean StDev N
4.106 4.458 20
9.075 10.81 20
Density
Data

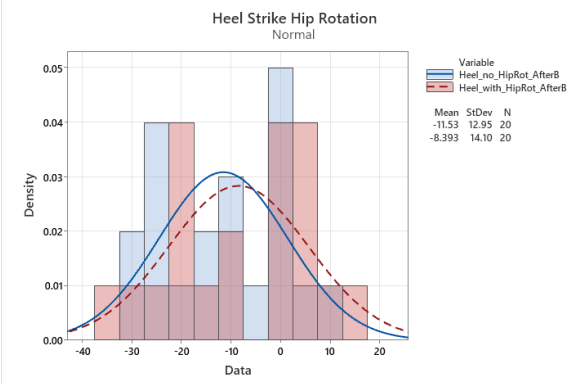

Heel Strike Pelvic Obliquity
Normal
Variable
Heel_no_PelvicObliq_AfterB
Heel_with_PelvicObliq_AfterB
Mean StDev N
1.208 1.766 20
2.906 3.848 20
Density
Data

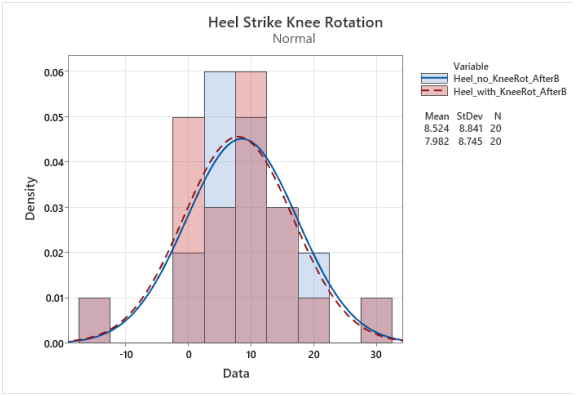

Heel Strike Hip Abduction/Adduction
Normal
Variable
Heel_no_HipAbd/Add_AfterB
Heel_with_HipAbd/Add_AfterB
Mean StDev N
3.966 4.727 20
2.157 7.788 20
Density
Data

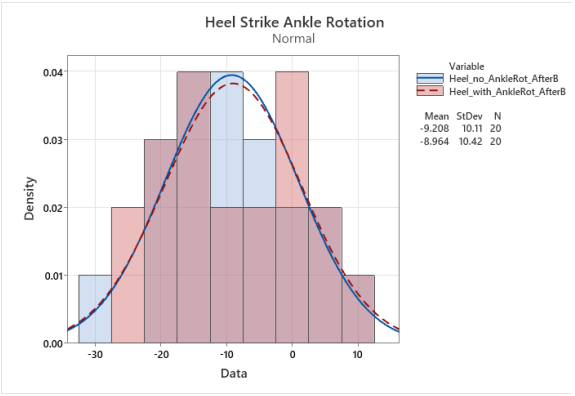

Heel Strike Knee Valgus/Varus
Normal
Variable
Heel_no_KneeValg/Var_AfterB
Heel_with_KneeValg/Var_AfterB
Mean StDev N
-3.877 6.355 20
-2.253 6.968 20
Density
Data


Heel Strike Ankle Abduction/Adduction
Normal
Variable
Heel_no_AnkleAbd/Add_AfterB
Heel_with_AnkleAbd/Add_AfterB
Mean StDev N
1.644 2.299 20
0.289 3.499 20
Density
Data


Heel Strike Pelvic Rotation
Normal
Variable
Heel_no_PelvicRot_AfterB
Heel_with_PelvicRot_AfterB
Mean StDev N
2.507 4.039 20
2.837 5.073 20
Density
Data

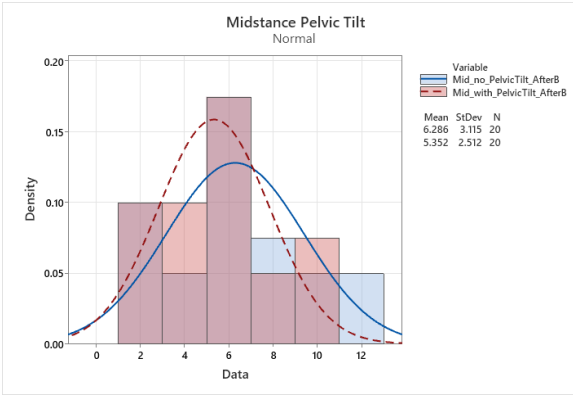

Heel Strike Hip Rotation
Normal
Variable
Heel_no_HipRot_AfterB
Heel_with_HipRot_AfterB
Mean StDev N
-11.53 12.95 20
-8.393 14.10 20
Density
Data

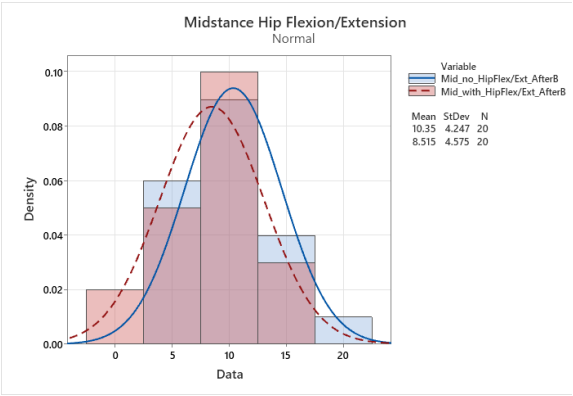

Heel Strike Knee Rotation
Normal
Density
Data
Variable
Heel_no_KneeRot_AfterB
Heel_with_KneeRot_AfterB
Mean StDev N
8.524 8.841 20
7.982 8.745 20

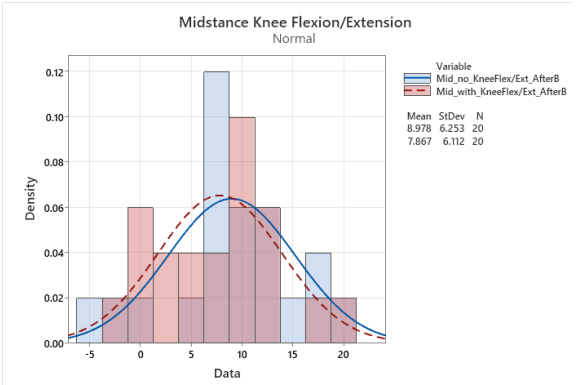

Heel Strike Ankle Rotation
Normal
Density
Data
Variable
Heel_no_AnkleRot_AfterB
Heel_with_AnkleRot_AfterB
Mean StDev N
-9.208 10.11 20
-8.964 10.42 20

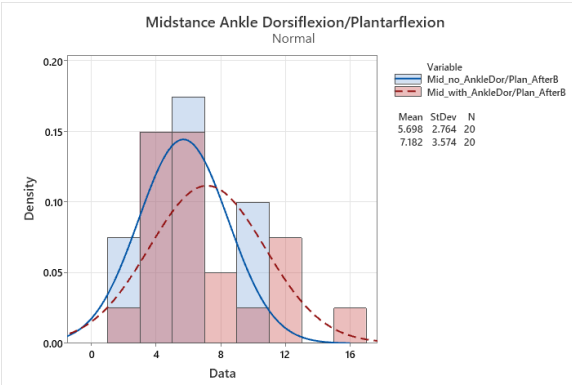
Appendix 50: Additional Statistical Analysis – Group B after no insoles vs after with insoles Kinematic Analysis and Histogram Plots at Midstance

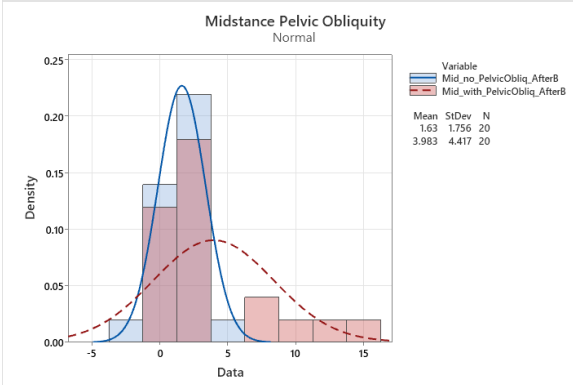
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.111	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.121	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.210	No	Accepted
Ankle Dorsi/Plantar	Paired Sample t-test	0.001*	Yes	Rejected
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.005*	Yes	Rejected
Hip Abd/Add	Paired Sample t-test	0.269	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.058*	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.172	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.448	No	Accepted
Hip Rotation	Paired Sample t-test	0.491	No	Accepted
Knee Rotation	Wilcoxon Signed-Rank Test	0.048*	Yes	Rejected
Ankle Rotation	Paired Sample t-test	0.86	No	Accepted

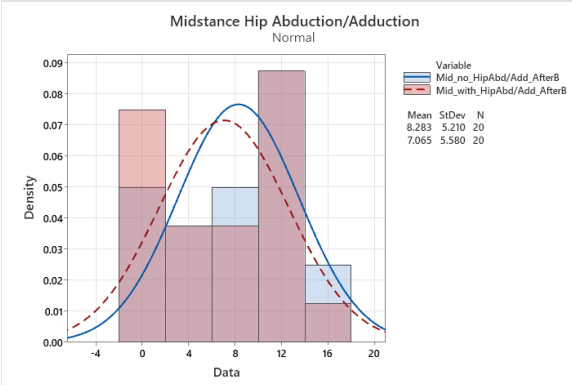


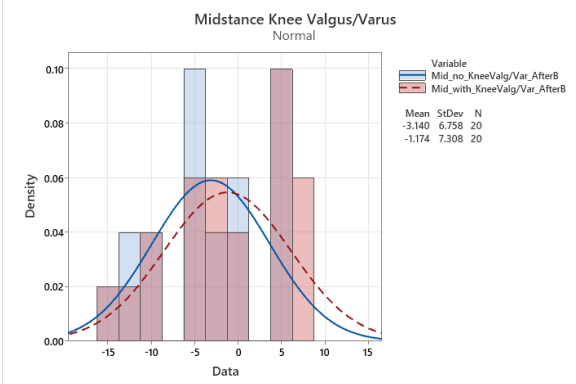


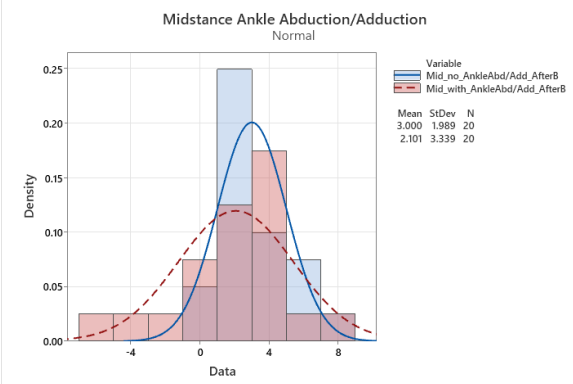

Midstance Knee Flexion/Extension
Normal
Variable
Mid_no_KneeFlex/Ext_AfterB
Mid_with_KneeFlex/Ext_AfterB
Mean StDev N
8.978 6.253 20
7.867 6.112 20
Density
Data

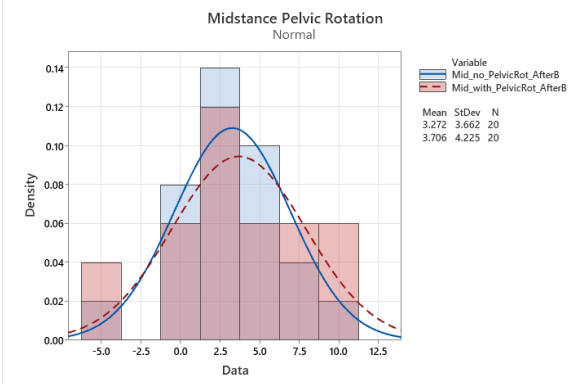

Midstance Ankle Dorsiflexion/Plantarflexion
Normal
Variable
Mid_no_AnkleDor/Plan_AfterB
Mid_with_AnkleDor/Plan_AfterB
Mean StDev N
5.698 2.764 20
7.182 3.574 20
Density
Data

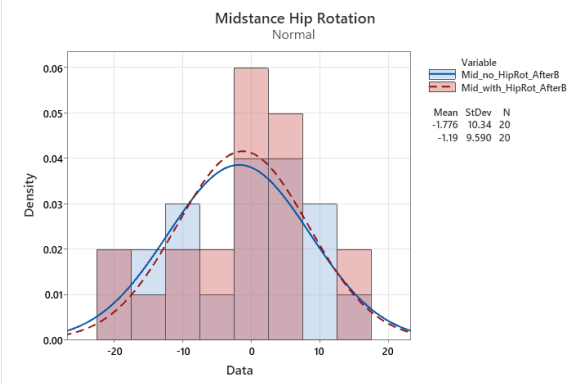

Midstance Pelvic Obliquity
Normal
Variable
Mid_no_PelvicObliq_AfterB
Mid_with_PelvicObliq_AfterB
Mean StDev N
1.63 1.756 20
3.983 4.417 20
Density
Data

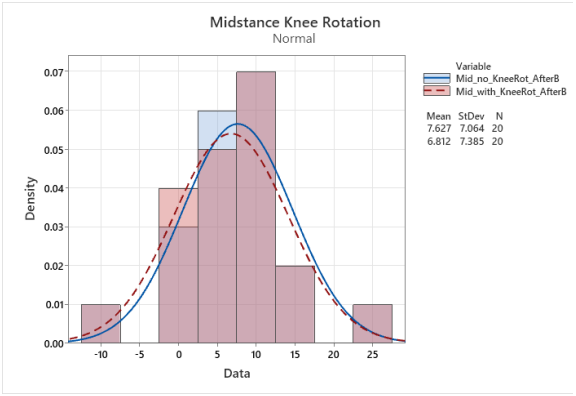

Midstance Hip Abduction/Adduction
Normal
Variable
Mid_no_HipAbd/Add_AfterB
Mid_with_HipAbd/Add_AfterB
Mean StDev N
8.283 5.210 20
7.065 5.580 20
Density
Data

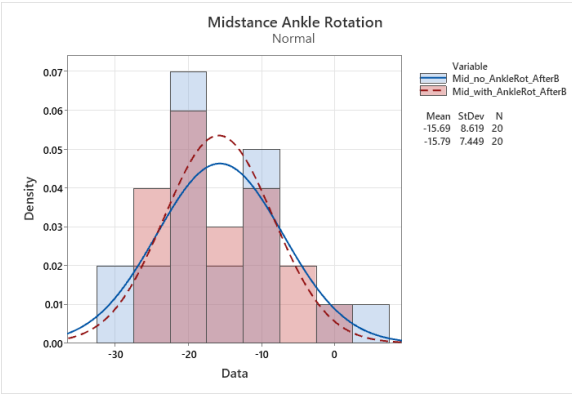

Midstance Knee Valgus/Varus
Normal
Variable
Mid_no_KneeValg/Var_AfterB
Mid_with_KneeValg/Var_AfterB
Mean StDev N
-3.140 6.758 20
-1.174 7.308 20
Density
Data


Midstance Ankle Abduction/Adduction
Normal
Variable
Mid_no_AnkleAbd/Add_AfterB
Mid_with_AnkleAbd/Add_AfterB
Mean StDev N
3.000 1.989 20
2.101 3.339 20
Density
Data


Midstance Pelvic Rotation
Normal
Variable
Mid_no_PelvicRot_AfterB
Mid_with_PelvicRot_AfterB
Mean StDev N
3.272 3.662 20
3.706 4.225 20
Density
Data

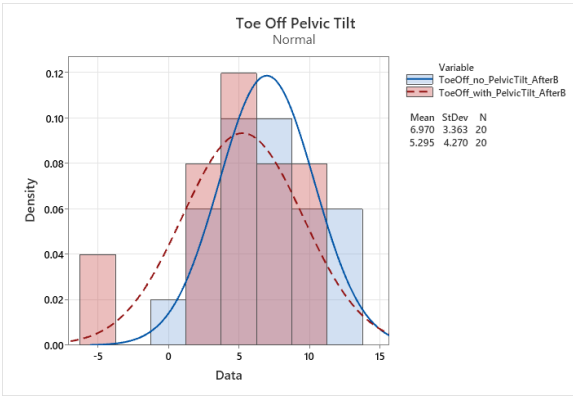

Midstance Hip Rotation
Normal
Variable
Mid_no_HipRot_AfterB
Mid_with_HipRot_AfterB
Mean StDev N
-1.776 10.34 20
-1.19 9.590 20
Density
Data

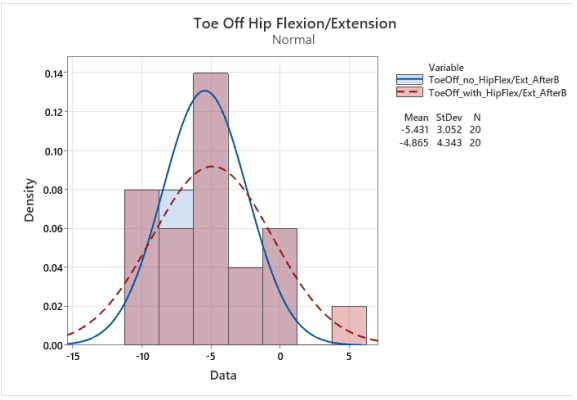

Midstance Knee Rotation
Normal
Density
Data
Variable
Mid_no_KneeRot_AfterB
Mid_with_KneeRot_AfterB
Mean StDev N
7.627 7.064 20
6.812 7.385 20

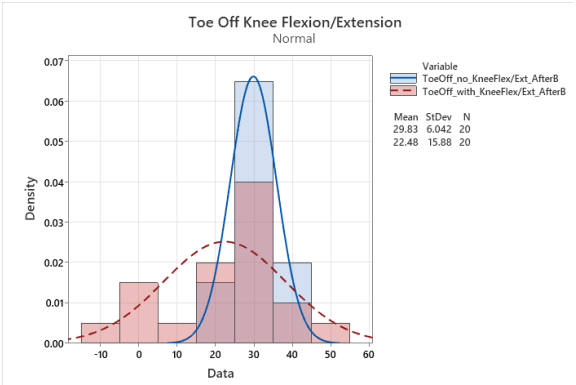

Midstance Ankle Rotation
Normal
Density
Data
Variable
Mid_no_AnkleRot_AfterB
Mid_with_AnkleRot_AfterB
Mean StDev N
-15.69 8.619 20
-15.79 7.449 20

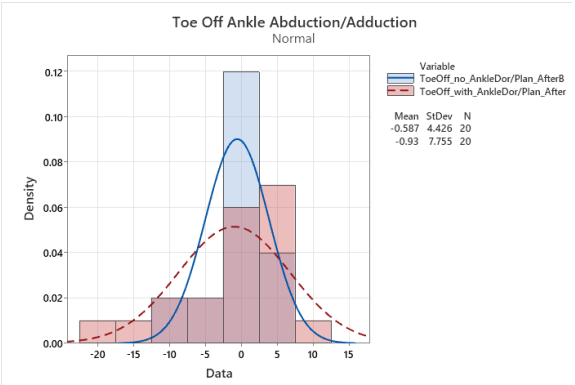
Appendix 51: Additional Statistical Analysis – Group B after no insoles vs after with insoles Kinematic Analysis and Histogram Plots at Toe Off

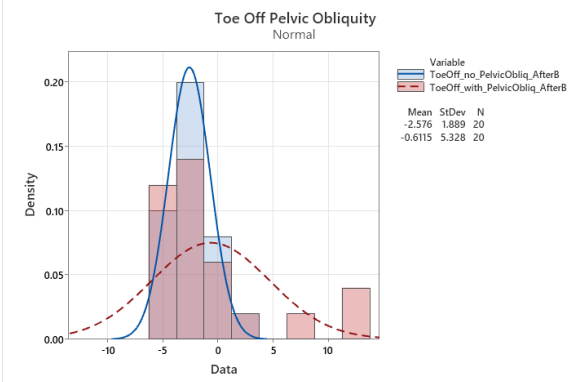
Angle	Statistical test	p-value	<0.05	Null Hypothesis
Pelvic Tilt	Paired Sample t-test	0.152	No	Accepted
Hip Flex/ext	Paired Sample t-test	0.565	No	Accepted
Knee Flex/ext	Paired Sample t-test	0.041*	Yes	Rejected
Ankle Dorsi/Plantar	Wilcoxon Signed-Rank Test	0.723	No	Accepted
Pelvic Obliquity	Wilcoxon Signed-Rank Test	0.723	No	Accepted
Hip Abd/Add	Paired Sample t-test	0.081	No	Accepted
Knee Valg/Var	Paired Sample t-test	0.055*	No	Accepted
Ankle Abd/Add	Paired Sample t-test	0.534	No	Accepted
Pelvis Rotation	Paired Sample t-test	0.2	No	Accepted
Hip Rotation	Paired Sample t-test	0.296	No	Accepted
Knee Rotation	Paired Sample t-test	0.837	No	Accepted
Ankle Rotation	Paired Sample t-test	0.264	No	Accepted

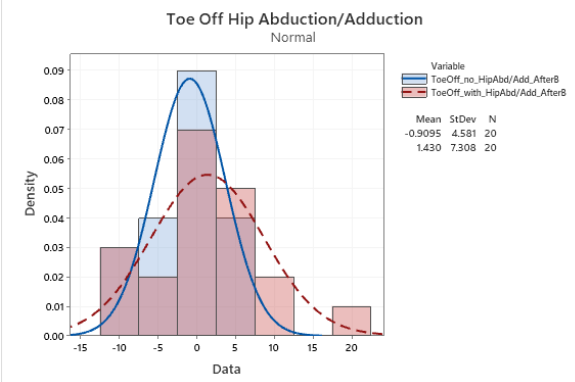


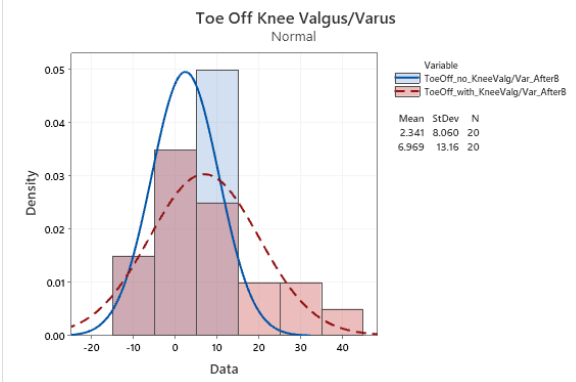


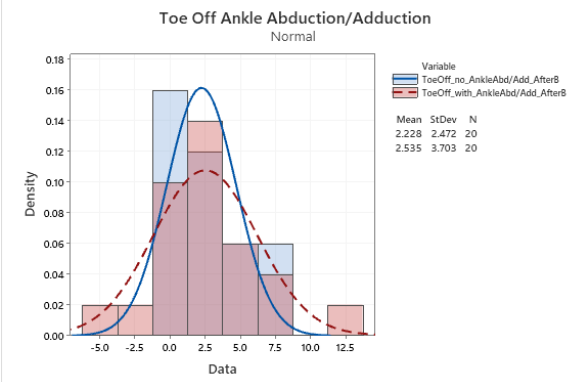

Toe Off Knee Flexion/Extension
Normal
Density
Data
Variable
ToeOff_no_KneeFlex/Ext_AfterB
ToeOff_with_KneeFlex/Ext_AfterB
Mean StDev N
29.83 6.042 20
22.48 15.88 20

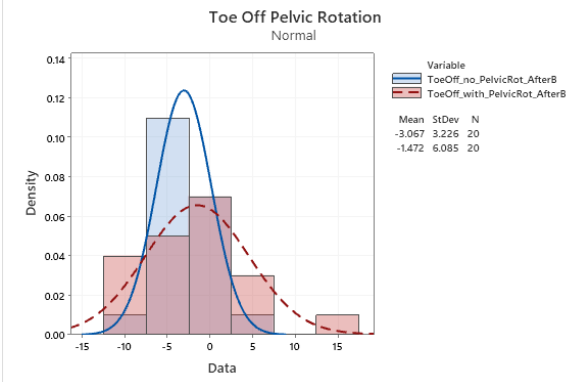

Toe Off Ankle Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_no_AnkleDor/Plan_AfterB
ToeOff_with_AnkleDor/Plan_After
Mean StDev N
-0.587 4.426 20
-0.93 7.755 20

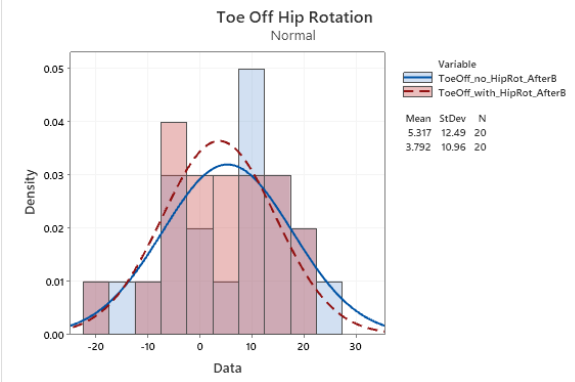

Toe Off Pelvic Obliquity
Normal
Density
Data
Variable
ToeOff_no_PelvicObliq_AfterB
ToeOff_with_PelvicObliq_AfterB
Mean StDev N
-2.576 1.889 20
-0.6115 5.328 20

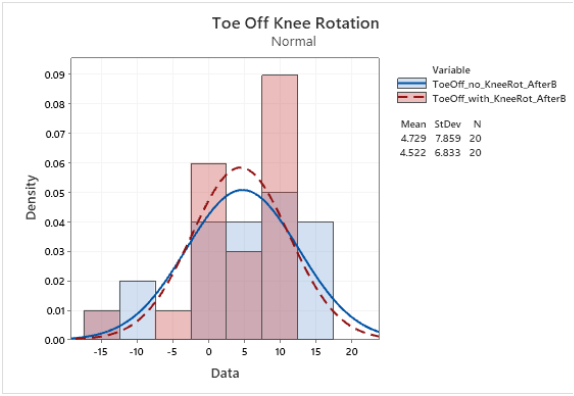

Toe Off Hip Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_no_HipAbd/Add_AfterB
ToeOff_with_HipAbd/Add_AfterB
Mean StDev N
-0.9095 4.581 20
1.430 7.308 20

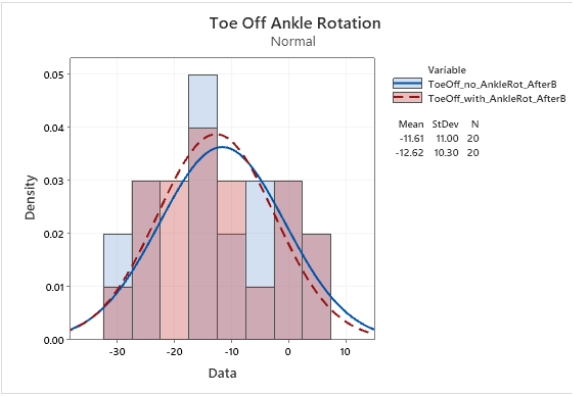

Toe Off Knee Valgus/Varus
Normal
Density
Data
Variable
ToeOff_no_KneeValg/Var_AfterB
ToeOff_with_KneeValg/Var_AfterB
Mean StDev N
2.341 8.060 20
6.969 13.16 20


Toe Off Ankle Abduction/Adduction
Normal
Density
Data
Variable
ToeOff_no_AnkleAbd/Add_AfterB
ToeOff_with_AnkleAbd/Add_AfterB
Mean StDev N
2.228 2.472 20
2.535 3.703 20


Toe Off Pelvic Rotation
Normal
Density
Data
Variable
ToeOff_no_PelvicRot_AfterB
ToeOff_with_PelvicRot_AfterB
Mean StDev N
-3.067 3.226 20
-1.472 6.085 20


Toe Off Hip Rotation
Normal
Density
Data
Variable
ToeOff_no_HipRot_AfterB
ToeOff_with_HipRot_AfterB
Mean StDev N
5.317 12.49 20
3.792 10.96 20


Toe Off Knee Rotation
Normal
Density
Data
Variable
ToeOff_no_KneeRot_AfterB
ToeOff_with_KneeRot_AfterB
Mean StDev N
4.729 7.859 20
4.522 6.833 20


Toe Off Ankle Rotation
Normal
Density
Data
Variable
ToeOff_no_AnkleRot_AfterB
ToeOff_with_AnkleRot_AfterB
Mean StDev N
-11.61 11.00 20
-12.62 10.30 20

Appendix 52: Additional Statistical Analysis – Group B after no insoles vs after with insoles Kinematic Analysis compared with Normative Data

Angle	Heel strike PValue Before	Heel strike PValue After	Midstance PValue Before	Midstance PValue After	Toe off PValue Before	Toe off PValue Before
Pelvic Tilt	0.0	0.0	0.003	0.000	0.02	0.001
Hip Flex/ex	0.0	0.0	0.0	0.0	0.092	0.514
Knee Flex/ex	0.0	0.0	0.011	0.002	0.00	0.009
Ankle Dorsi/Plantar	0.087	0.022	0.0	0.0	0.00	0.00
Pelvic Obliquity	0.0	0.0	0.0	0.614*	0.012	0.455*
Hip Abd/Add	0.485	0.198	0.001	0.015	0.781	0.225
Knee Valg/Var	0.00	0.0	0.003	0.066*	0.805	0.1
Ankle Abd/Add	0.0	0.0	0.324	0.555	0.002	0.013
Pelvis Rotation	0.0	0.0	0.951	0.613	0.111	0.778
Hip Rotation	0.003	0.046	0.897	0.683	0.061	0.116
Knee Rotation	0.233	0.345	0.017	0.095*	0.404	0.408
Ankle Rotation	0.0	0.0	0.0	0.0	0.0	0.0

Appendix 53: Additional Statistical Analysis – Group B after no insoles vs after with insoles Spatiotemporal Data

	Statistical test	p-value	<0.05	Null Hypothesis
Cadence	Paired Sample t-test	0.342	No	Accepted
Double Support	Paired Sample t-test	0.883	No	Accepted
Foot Off	Paired Sample t-test	0.963	No	Accepted
Limp Index	Wilcoxon Signed-Rank Test	0.836	No	Accepted
Opposite Foot Contact	Wilcoxon Signed-Rank Test	1.0	No	Accepted
Opposite Foot Off	Wilcoxon Signed-Rank Test	0.455	No	Accepted
Single Support	Paired Sample t-test	0.477	No	Accepted
Step Length	Paired Sample t-test	0.105	No	Accepted
Step Time	Paired Sample t-test	0.574	No	Accepted
Step Width	Paired Sample t-test	0.407	No	Accepted
Stride Length	Paired Sample t-test	0.034*	No	Accepted
Stride Time	Paired Sample t-test	0.392	No	Accepted
Walking Speed	Paired Sample t-test	0.369	No	Accepted