# Improving outcomes following complex foot and ankle injuries

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## Declaration of Originality

The work presented in this thesis is my own and all other is appropriately referenced.

## Copyright Declaration



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December 2020

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# Abstract

Foot and ankle injuries are severely disabling for military personnel who are conditioned to undertake impact activities. Following injury, performance and patient-reported outcomes have been shown to improve for amputees compared to limb-salvage military patients. A novel custom-made ankle foot orthosis may provide improved outcomes for limb-salvage patients. Initial results with the orthosis demonstrate improved performance and patient-reported outcomes at 2-year follow-up and a reduction in the number of personnel pursuing amputation. The orthosis, however, does not work for all foot and ankle injuries. This work sought to define the indications for prescription and create a clinical decision tool to facilitate evidence-based prescription.

The outcomes for UK military personnel with complex foot and ankle injuries who underwent rehabilitation prior to the introduction of the orthosis were investigated. Over 50% of the cohort underwent amputation with improved performance outcomes for amputees compared to limb-salvage patients. Following the introduction of the orthosis, a reduction in amputation and improvement in physical performance measures were seen. Patients with a pain-specialist diagnosis of chronic pain did not benefit from prescription of the orthosis, whereas patients with primarily a nerve injury diagnosis did.

Using injury characteristics alone, however, was found to be unable to predict outcome for all injured personnel. Therefore, biomechanical measures were examined. Gait analysis of patients prior to prescription of an orthotic was conducted. Patients with a negative symmetry index of more than 20% for power generation at pre-swing were found to benefit from prescription of the orthosis in the absence of an ipsilateral injury.

This is the most complete investigation of UK personnel prescribed a novel orthosis following foot and ankle injury. This analysis facilitated the production of a clinical decision tool. The tool now requires validation and can be used to counsel foot and ankle injury patients on whether they may benefit from prescription of this orthosis.

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# Abbreviations

| Abbreviation | Explanation |
|---|---|
| 6-MWT | 6-Minute Walk Test |
| AAOP | American Academy of Orthotists and Prosthetists |
| ADL | Activities of Daily Living |
| AFO | Ankle Foot Orthosis |
| AIS | Abbreviated Injury Severity Scale |
| AO/OTA | Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association |
| BBImperial | Body Builder Imperial Model |
| BMI | Body Mass Index |
| BOB | Bespoke Offloading Brace |
| BPI | Brief Pain Inventory |
| CESD-R | Revised Centre for Epidemiologic Studies Depression Scale |
| CFO | Carbon Fibre Spring Orthosis |
| CGM | Conventional Gait Model |
| CHAMP | Comprehensive High-level Activity Predictor |
| CoP | Centre of Pressure |
| CRPS | Chronic Regional Pain Syndrome |
| DMRC | Defence Medical Rehabilitation Centre |
| EQ-5D | European Quality of Life- 5 Dimensions |
| EQ-5D-5L | European Quality of Life – 5 Dimensions – 5 Levels |
| F&A | Foot and Ankle Score |
| FASS | Foot and Ankle Severity Scale |
| FE | Finite Element Modelling |
| FSST | Four Square Step Test |
| GA | Gustilo and Anderson |
| GAD | Generalised Anxiety Disorder |
| GAD-7 | Generalised Anxiety Disorder-7 |
| GPAF | Globally Poor Ankle Function |

Abbreviations

| | |
|---|---|
| GSW | Gunshot Wound |
| HELET | High Energy Lower Extremity Trauma |
| IDEO | Intrepid Dynamic Exoskeletal Orthosis |
| IED | Improvised Explosive Device |
| ISS | Injury Severity Score |
| LEAP | Lower Extremity Assessment Project |
| LEFS | Lower Extremity Functional Scale |
| LS | Limb Salvage |
| MCS | Mental Component Score |
| MDT | Multi-disciplinary Team |
| METALS | Military Extremity Trauma Amputation/Limb Salvage study |
| MFA | Musculoskeletal Functional Assessment |
| NISS | New Injury Severity Score |
| OA | Osteoarthritis |
| ORIF | Open Reduction Internal Fixation |
| OUTLET | Outcomes after Severe Distal Tibia, ankle, and/or foot trauma: Comparison of Limb Salvage Versus Transtibial Amputation Study |
| PCS | Physical Component Score |
| PDAFO | Passive Dynamic Ankle Foot Orthosis |
| PHQ-9 | Patient Health Questionnaire-9 |
| PHP | Post-hoc Power |
| PiG | Plug-in Gait |
| PLS | Posterior Leaf Spring |
| PPM | Physical Performance Measure |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| PROMS | Patient reported outcome measures |
| PTB | Patella Tendon Bearing |
| PTOA | Post Traumatic Osteoarthritis |
| PTSD | Post-Traumatic Stress Disorder |
| pyCGM2.3 | Python Conventional Gait Model 2.3 |
| RoM | Range of Movement |

Abbreviations

| | |
|---|---|
| RTA | Road Traffic Accident |
| RTR CP | Return to Run Clinical Programme |
| SD | Standard Deviation |
| SF-12 | Short Form-12 |
| SF-36 | Short Form-36 |
| SI | Symmetry Index |
| SIP | Sickness Impact Profile |
| SMFA | Short Musculoskeletal Functional Assessment |
| SSWV | Self-selected Walking Velocity |
| TBI | Traumatic Brain Injury |
| TSA | Timed Stair Ascent |
| TTA | Trans-tibial amputation |
| UCBL | University of California Biomechanics Laboratory |
| UK | United Kingdom |
| US | United States |
| VAS | Visual Analogue Scale |
| VR-12 | Veterans Rand-12 |

# Chapter 1: Introduction

## 1.1. Scope of thesis

This thesis concerns the analysis of outcomes of complex foot and ankle injuries sustained by Service Personnel and predicting outcome with the use of a novel custom passive dynamic ankle foot orthosis.

## 1.2. General introduction

The conflicts in Iraq and Afghanistan have seen the use of Improvised Explosive Devices (IEDs) as the insurgents' *modus operandi* (Edwards, 2016). Whether caused by underfoot explosions whilst on foot patrol or due to rapid deformation of the floor of the vehicle in under-vehicle blasts, these types of foot and ankle injuries are recognised to be severely disabling (A. Ramasamy, 2013). Furthermore, improvements in personal protection equipment and medical resuscitation have seen an unprecedented number of casualties surviving, but at the cost of severe musculoskeletal injuries and consequent long term disability (Jowan G. Penn-Barwell, 2015; Hill, 2016). Over 80% of wounded Service Personnel in recent conflicts sustained at least one extremity injury. Frequently these are of high severity, with 82% of extremity fractures open (Owens, 2007). While these injuries make up the 'worst-case scenario,' we know that severe foot and ankle injuries occurring as a result of High Energy Lower Extremity Trauma (HELET) often result in poor outcomes (MacKenzie, 2005). In addition to blast injuries, Service Personnel sustain complex foot and ankle injuries during military training and recreational activities, resulting in an increasing burden of foot and ankle injured personnel despite the return to contingency operations.

Treatment of complex foot and ankle injuries can be with either Limb Salvage (LS) surgery or amputation. Civilian literature suggests that outcomes following severe foot and ankle injuries are poor regardless of whether LS or amputation are pursued. Data from the Lower Extremity Assessment Project (LEAP) found no difference in patient reported outcomes at two years in those sustaining HELET treated with either LS or amputation, but worse outcomes than population norms (Ellington, 2013). This persisted for seven years post injury and a high prevalence of chronic pain was reported in both groups (MacKenzie, 2005, 2006; Castillo, 2006).

The LEAP study specifically excluded military patients due to access to advanced rehabilitation pathways and prosthetics. Doukas et al found that for military patients following HELET, amputation resulted in improved patient reported outcome measures compared to LS patients (Doukas, 2013). It was hypothesised LS patients would benefit from external augmentation of the foot and ankle, in the form of an orthosis, combined with an advanced rehabilitation pathway. In an attempt to improve outcomes for military LS patients the Department of Defence in the United States (US) designed a custom made Passive Dynamic Ankle Foot Orthosis (PDAFO) called the Intrepid Dynamic Exoskeletal Orthosis (IDEO) (Patzkowski, 2011). The United Kingdom (UK) military have introduced a PDAFO called the Bespoke Offloading Brace (BOB), to the rehabilitation pathway for injured Service Personnel. Initial outcomes with the IDEO and BOB appear promising however outcomes beyond two years are not known; some patients still progress to amputation, and an unknown number abandon the orthosis. To prevent painful and ultimately futile rehabilitation with the BOB, it is necessary to understand the clinical and biomechanical indications for use.

## 1.3. Aim

The aim of this thesis is to present novel experimental clinical and biomechanical data that will provide the fundamental theoretical underpinnings for an evidence based clinical decision tool for the prescription of the IDEO and BOB devices in complex foot and ankle injuries.
In order to achieve this aim, the objective is to analyse clinical and biomechanical data of Service Personnel following injury.

## 1.4. Thesis organisation

This thesis is composed of three main sections: Section A, ‘Complex Foot and Ankle Injuries’, Section B, ‘Clinical Research’, and Section C, ‘Biomechanical Research’.

### 1.4.1. Section A: Complex foot and ankle injuries

Chapter 2 is a systematic review of the literature concerning LS and amputation outcomes since LEAP and examines the question of superiority of outcomes in either amputation or LS for both civilian and military personnel. Having established that outcomes for LS in military

personnel are inferior to amputees, Chapter 3 examines the anatomy of the foot and ankle, gait analysis methodology, and changes to gait following injury. In an attempt to improve outcomes for military LS patients' Chapter 4 reviews the ankle foot orthoses available following trauma, specifically assessing the options to allow individuals to return to running and impact activities. Chapter 5 examines current research concerning the BOB and IDEO, highlighting the current evidence base on the mechanism of action and basis for prescription of the devices. This establishes the requirement for the creation of a clinical decision tool which is the focus of Section B.

### 1.4.2. Section B: Clinical research

Section B will present the clinical research undertaken by the author on foot and ankle injury cohorts that is the experimental foundation of this thesis. In Chapter 6 the outcome of UK Service Personnel with complex foot and ankle injuries prior to the introduction of the BOB is explored. Chapter 7 builds on this theme by assessing the outcomes of UK Service Personnel with complex foot and ankle injuries prescribed the BOB. Establishing clear benefit data for nerve injury patients, Chapter 8 presents a larger cohort and examines the outcome of US Service Personnel with a nerve injury rehabilitated with the IDEO.

### 1.4.3. Section C: Biomechanical analysis

Having established the clinical indications for prescription, and developing further granularity to the clinical decision tool, Section C investigates biomechanical analysis options for inclusion in the tool. Chapter 9 explores gait analysis in a healthy individual wearing the BOB to establish a biomechanical model to process historic gait data and to investigate the effect of the BOB on proximal joints. Chapter 10 uses the biomechanical model found in the previous Chapter to analyse the gait of a foot and ankle injured cohort with known outcomes with the BOB in order to establish gait changes for use in the clinical decision tool. Chapter 11 is a summary of the pertinent findings and outcomes of the experimental work, key analyses, and presents a proposed clinical decision tool. The thesis concludes discussing and highlighting areas for further work.

# Chapter 2: Limb salvage surgery: progress since the Lower Extremity Assessment Project

## 2.1. Introduction

The decision to salvage or amputate a mangled lower limb following trauma is not an easy one. In 1987 Hansen declared in his editorial, that LS surgery following Gustilo and Anderson (GA) Type 3C tibial fractures leaves patients, 'divorced, demoralized and destitute' (Hansen, 1987). This led to research in the early nineteen nineties looking at outcomes for traumatic amputees. In 1993, Pierce et al found the notion that traumatic amputees had superior outcomes unsupportable (Pierce, 1993). LS followed by secondary amputation if required was recommended instead of primary amputation. Despite ongoing research, by the turn of the millennium, there was no consensus in the literature of the best treatment for the mangled lower extremity. Consequently, there was a need for an evidence base to elucidate which management option, amputation or LS, would provide the best outcome for patients.

The LEAP was a North American based, multi-centre prospective longitudinal study, aiming to answer the question of whether amputees or LS patients had better outcomes following HELET (MacKenzie, 2000). LEAP followed up 545 patients for 2-years including 149 primary amputations, 38 secondary amputations and 358 LS patients (Bosse, 2002). At 2-year follow up, there was no statistically significant difference in the Sickness Impact Profile (SIP) (Bergner, 1981) (the primary outcome measure) between the primary, secondary amputation, and LS groups, and functional outcomes were similar after adjustment for variables. The LEAP authors concluded that self-efficacy, low education level and, involvement in a disability compensation claim, were the most significant factors for low SIP scores regardless of treatment. Furthermore, both groups did worse than population norms. At 7-year follow up there had been a deterioration of SIP scores however there was still no significant difference between the groups and outcomes remained worse than population norms (MacKenzie, 2005). Outcome of LEAP results can be found in Table 2-1.

| | Limb salvage | Amputation | Overall |
|---|---|---|---|
| **Functional outcome** | No stated walking speed | Below knee amputees fastest walking speed of amputee cohort | No difference in walking speed |
| **Pain** | 82% | 65% | Higher prevalence of chronic pain in LS cohort |
| **Return to work** | 49% 2 years<br>62% 7 years | 53% 2 years<br>47% 7 years | No statically significant difference |
| **Failure rate of LS** | 3.9% | n/a | |
| **Re-operation** | 19.1% | 5.4% | Re-operation rate higher for LS cohort |
| **Re-hospitalisation** | 47.5% | 33.9% | Re-hospitalisation more common in LS cohort |
| **Complication rate** | 37.7% (6 months) | 24.8% (3 months) | Higher rate for LS cohort |
| **Infection** | 25% | 33% | No statistically significant difference |
| **PROM – SIP score** | 12.6 | 11.8 | No statistically significant difference |
| **Factors associated with poor outcome regardless of treatment** | Rehospitalization for a major complication<br>Lower educational level<br>Non-white race<br>Poverty<br>Lack of private health insurance<br>Poor social support network<br>Low self-efficacy<br>Smoking<br>Involvement in litigation claim | | |
| **Predictors of patient satisfaction** | Return to work<br>Depression<br>Physical functioning element of SIP<br>Self-selected walking speed<br>Pain intensity | | |

*Table 2-1: Summary of LEAP results.*

The LEAP finished recruiting over 20 years ago in June 1997, in which time multiple advances have been made in microsurgery, limb salvage techniques, and the management of complex trauma patients, including lessons learnt from the introduction of Major Trauma Centres in the UK (Bosse, 2002; Ong, 2010; Stammers, 2013; Blair, 2016). Improvement in lower limb prosthetic design has also enhanced outcomes for lower limb amputees (Kistenberg, 2014). The LEAP excluded military patients, however the burden of HELET seen during recent conflicts have led to a large amount of HELET research examining LS techniques and pathways,

resulting in advanced prosthetics for military amputees, fuelled by the desire to maintain function in high demand military casualties (MacKenzie, 2000).

Whilst the outcomes between LS and amputation have been equivocal, these developments may have tipped the balance towards one of these treatment options. Therefore, there exists a need to identify if either modern LS techniques or advancements in prosthetic care have influenced outcomes for civilians or military personnel following HELET.

## 2.2. Aim

The aim of this systematic review is to examine the literature relating to outcomes from LS and amputation following HELET since 2005, when LEAP reported the 7-year follow-up results, for both civilians and military personnel. It is hypothesised that, due to the greater availability of advanced prosthetics within the military population, military amputees will have superior functional outcomes compared to military LS patients. It is also hypothesised that for civilian patients, outcomes will remain unchanged regardless of treatment received.

## 2.3. Methods

A literature search was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines using MEDLINE to identify all research related to outcomes in LS and amputation following HELET. The search was built on combinations of the following terms: limb salvage, amputation, functional outcome, mangled extremity, lower limb, trauma, combat, and civilian. The dates were limited to 01 January 2006 until 30 April 2019. Additionally, references of full articles reviewed were screened for missed publications.

### 2.3.1. Inclusion

The highest level of evidence available was used, which included prospective and retrospective cohort observational studies. Papers were included if they referred to:

- Human adults over 16 years old
- Lower limb trauma
- LS and/or amputation

- More than 20 patients
- Minimum 12-months follow up

### 2.3.2. Exclusion

Systematic reviews, meta-analyses, case reports, letters and opinion papers were excluded. Papers were excluded if they were not available in English or did not focus on HELET, for example oncology and chronic vascular disease. Papers were excluded if the full text was not available through the journal or had been retracted. Papers were also excluded, if, when reporting upper and lower limb amputation outcomes, it was not possible to differentiate between the groups. Papers undertaking subgroup analyses of the LEAP cohort were also excluded. Papers were excluded if they examined outcomes following rehabilitation with a bespoke novel orthosis, the IDEO or BOB, not currently widely available. These studies are presented in more detail in Chapter 5.

### 2.3.3. Data Analysis

Data was collected on:

- The number of patients
- Gender
- Age
- Follow up period
- Functional outcomes
- Pain
- Return to work rates
- Failure rate of LS
- Reasons for delayed amputation
- Re-operation rates
- Infection rates
- Length of hospital stay and rehabilitation
- Patient reported outcomes
- Factors associated with poor outcome

After initial review of the papers, it was evident that the heterogeneous nature and reporting of the research precluded the possibility of a meta-analysis in combination with a systematic review. Therefore, papers were grouped into broad categories to enable comparison. Literature results are reported as all amputees compared to LS patients, then sub divided into literature concerning civilian then military cohorts with any differences highlighted.

#### 2.3.4. Quality Assessment

The quality of each paper was assessed using the American Academy of Orthotists and Prosthetists (AAOP) State-of-the-Science Evidence Report Guidelines Protocol (American Academy of Orthotists and Prosthetists, 2008). Each study was classified according to the study design guidelines recommended in the AAOP guidelines and the Quality Assessment Form was used to score each study. Each study was given an internal and external validity score and an overall score. Internal validity was classified as high with 0-3 threats, moderate with 4-6 threats, or low with 7 or more threats. For external validity, studies were rated as high with 0 to 2 threats, moderate with 3-5 threats, or low with 6 or more threats (Highsmith, 2016). For the overall score, studies were rated as high with 0 to 6 threats, moderate with 7 to 12 threats, or low with 13 or more threats.

## 2.4. Results

#### 2.4.1. Study retrieval and characteristics

The search numbers can be seen in Figure 2-1. The initial search revealed 1378 papers. After removal of duplicates (291) and studies not available in English (65), 1022 studies remained. After removal of studies based on a title not in keeping with the inclusion criteria, 129 abstracts were reviewed. In keeping with the inclusion criteria, 35 papers were selected from abstract review for full text review. An additional 22 studies were selected from references. Eighteen studies were excluded on full text review. Four were not trauma related, two did not have more than 12-months follow up, three included less than 20 subjects, three did not include a functional outcome, one related to only transfemoral amputees, and five were meta-analyses or systematic reviews. Therefore, 39 papers were included of variable quality (Table 2-2).

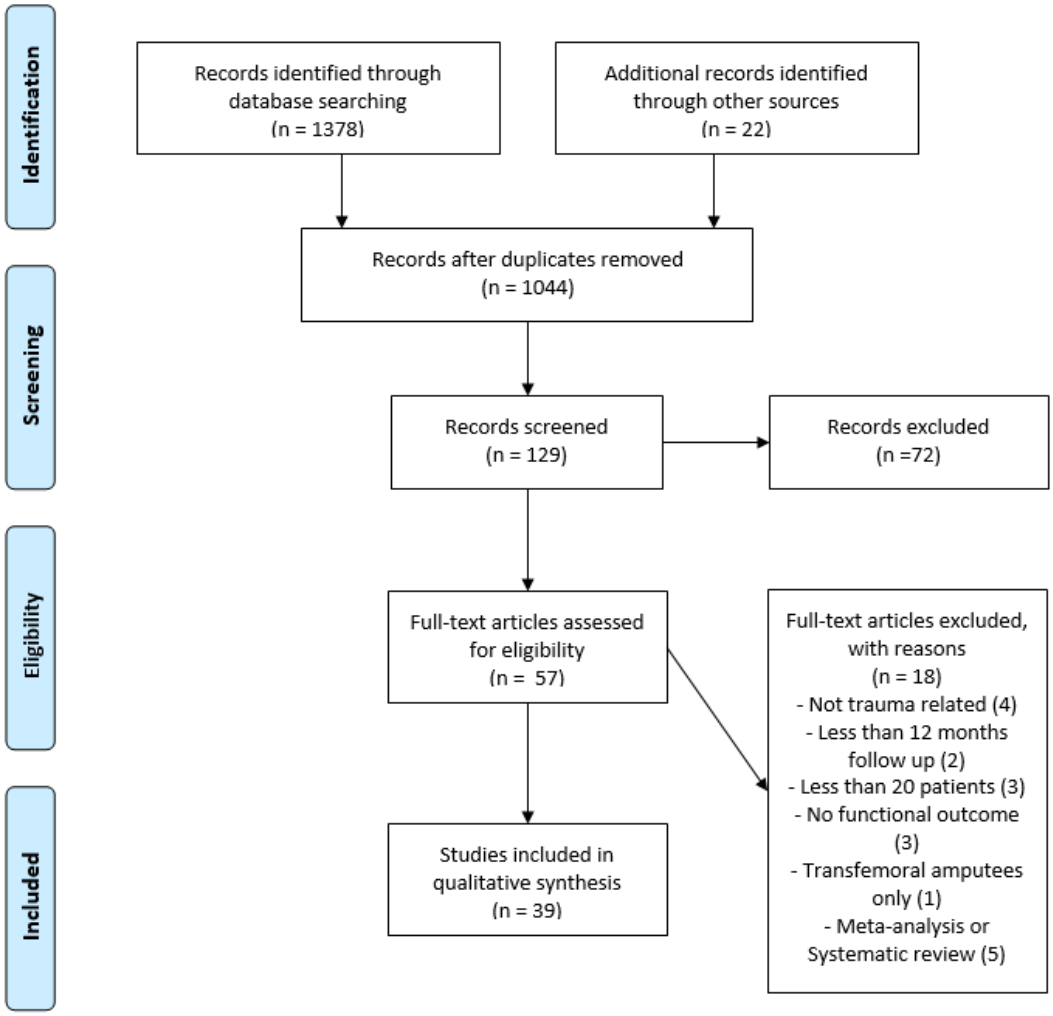


*Figure 2-1: PRISMA 2009 Flow Diagram*

| Paper | Study design | LS group | Amputation group | Follow up (Months) | Outcome Measures | Results | Quality of paper |
|---|---|---|---|---|---|---|---|
| A comparison of four-year health outcomes following combat amputation and limb salvage (Melcer, 2017) | Retrospective observational cohort study. | 107 | Primary 440<br>Secondary 78 | 48 | Wound complications, Physical health complications coded electronically, ICD code for psych | Late amputees had higher rates of osteomyelitis and wound infections in the second year of follow up. PTSD increased in all groups over 4 years, particularly in the 2nd year. | High |
| A comparison of health outcomes for combat amputee and limb salvage patients injured in Iraq and Afghanistan wars (Melcer, 2013) | Retrospective observational cohort study. | 117 | Primary 587<br>Secondary 84 | 12 | Mental health outcomes, patient reported pain as well as pain clinic use | Slightly higher rates of HO and infection in primary amputation compared to LS, highest rate in secondary amputation. Primary amputation lowest PTSD, highest rates in secondary amputation. Similar pain clinic use for all groups in first 30 days then secondary amputation had largest pain clinic use then LS. | High |
| Comparison of 6-minute walk test performance between male Active Duty soldiers and servicemembers with and without traumatic lower-limb loss (Linberg, 2013) | Retrospective case control study. | 0 | 118 | 36 | 6-MWT | 6-MWT time reduced for military amputees compared to those without limb loss. | High |

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| Influence of immediate and delayed lower limb amputation compared with lower limb salvage on functional and mental health outcomes post rehabilitation in the UK Military (Ladlow, 2016) | Retrospective case control study. | 21 | Primary 64<br>Secondary 15 | 12 | 6-MWT, Run independently, ADL, PHQ9, GAD7 | 6-MWT improved for amputees over LS (p=0.05). No difference in mental health outcomes. More pain reported in LS group than amputees. | High |
| Long-term, patient centered outcomes of lower extremity vascular trauma (Perkins, 2018) | Retrospective observational cohort study. | 437 | Primary 49<br>Secondary 90 | 72 | SF-36 and QoL | No difference between groups. | High |
| Medium term outcomes following limb salvage for severe open tibia fracture are similar to trans-tibial amputation (J. G. Penn-Barwell, 2015) | Retrospective observational cohort study. | 30 | Secondary 18 | 49 | SF-36 | No difference between groups. | Moderate |
| Outcomes following limb salvage after combat hindfoot injury are inferior to delayed amputation at five | Retrospective observational cohort study. | 62 | Secondary 28 | 64 | AAOSF&A, SF-12 | SF-36 PCS improved for amputees compared to LS patients (p=0.0351). | Moderate |

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| years (Bennett, 2018) | | | | | | | |
| Outcomes of IED foot and ankle blast injuries (A. Ramasamy, 2013) | Retrospective observational cohort study. | 63 | Primary 20<br>Secondary 6 | 33 | Ongoing clinical symptoms and return to work | 66 limbs had clinical symptoms at follow up requiring ongoing surgical intervention, rehab or analgesia. | High |
| Short term physical and mental health outcomes for combat amputee and nonamputee extremity injury patients (Melcer, 2013) | Retrospective observational cohort study. | 274 | Primary 382 | 24 | Mental health outcomes using ICD-10 diagnosis | Amputees had double the risk of infection and anaemia. Amputees had higher risk of mood, sleep, pain and post-concussion syndrome. Amputees reduced risk of PTSD. | High |
| The Military Extremity Trauma Amputation/Limb Salvage (METALS) Study (Doukas, 2013) | Retrospective observational cohort study. | 142 | Primary 195<br>Secondary 26 | 37 | SMFA, Depression, PTSD, chronic pain | SMFA improved for amputees compared to LS patients, amputees higher participation in vigorous sport and lower rates of PTSD. | Moderate |
| Patient based outcomes and quality of life after salvage wartime extremity vascular injury (Scott, 2014) | Retrospective observational cohort study. | 181 | Primary 22<br>Secondary 11 | 61 | SF-36 | Older age (>40), educational status, Rank <E7 were statistically significant for unfavourable outcomes (poor SF36). | High |
| Better mental component of quality of life in | Retrospective cross-sectional study. | n/a | 38 | 288 | SF-36 | Reduced role physical for amputees compared to controls ($p<0.01$) but improved mental component scores ($p<0.05$). | High |

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| amputee (Karami, 2012) | | | | | | | |
| Functional Outcomes of Unilateral Lower Limb Amputee Soldiers in Two Districts of Sri Lanka (Gunawardena, 2015) | Retrospective case control study. | n/a | 461 | 36 | SF-36 | Worse SF-36 outcomes for amputees compared to non-amputees ($p<0.001$) | High |
| Late amputation may not reduce complications or improve mental health in combat-related lower extremity limb salvage patients (Krueger, 2015) | Retrospective case series. | n/a | 44 | 12 | Mental health outcomes using ICD-10 codes | Late amputation does not improve mental health outcomes for patients. | Moderate |
| Long term outcomes of patients undergoing war related amputations of the foot and ankle (Ebrahimzadeh, 2007) | Retrospective case series. | n/a | Primary 17<br>Secondary 10 | 204 | Mental Health, pain diagnoses and return to work | Long term physical and psychological issues which impact QoL compared to population norms. | Moderate |

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| Long-term outcomes of unilateral transtibial amputations (Ebrahimzadeh, 2013) | Retrospective case series. | n/a | Primary 57<br>Secondary 39 | 204 | Mental Health, pain diagnoses and return to work | High rates of back and knee pain reported amongst amputees and higher rate of psych diagnoses than general population. | Moderate |
| Midterm health and personnel outcomes of recent combat amputees (Melcer, 2010) | Retrospective case series. | n/a | 382 | 24 | Mental health outcomes using ICD-10 diagnosis | Two-thirds of the cohort had at least one mental health diagnosis. | High |
| Quality of life among veterans with war-related unilateral extremity amputation: a long-term survey in a prothesis centre in Iran (Taghipour, 2009) | Retrospective cross-sectional study. | n/a | 141 | 252 | SF-36 | SF-36 worse than population norms. | High |
| The outcome of British combat amputees in relation to military service (Dharm-Datta, 2011) | Retrospective case series. | n/a | 41 | 28 | SF-36 and functional activity assessment | Physical component scores below population norm whilst mental component scores same as population norm. | High |
| Unilateral lower limb loss following combat injury medium term outcomes in British | Retrospective case series. | n/a | 39 | 40 | SF-36 | Improved SF-36 scores with increasing residual limb length. | Moderate |

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| military amputees (Bennett, 2013) | | | | | | | |
| Unilateral lower limb loss: prosthetic device use and functional outcomes in service members from Vietnam war and OIF/OEF conflicts (Gailey, 2010) | Retrospective cohort study. | n/a | 350 | 36 | Functional capacity and health status | More mental health diagnoses in recent war related amputees. | Moderate |
| Outcome of lower limb amputees at Cotonou (Chigblo, 2019) | Prospective case series. | n/a | 70 | 38 | TUG, Classification of Pohjolainen, Houghton's score | Quality of life worse than population norms. | High |
| A prospective study of the outcome of patients with limb trauma following the Haitian earthquake in 2010 at one and two year (Delauche, 2013) | Prospective case series. | 106 | Primary 30<br>Secondary 169 | 24 | Satisfaction and SF-36 | Less satisfaction amongst amputees at 2 years however more amputees felt cured. No difference in outcome but SF-36 worse than reference population norms. | Moderate |
| Amputation versus conservative treatment in severe open lower-limb fracture: A functional and | Retrospective cohort study. | 27 | 24 | 24 | SF-36, walking distance | Physical Component Score improved for amputees compared to LS ($p<0.001$). | Moderate |

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| quality-of-life study (Fioravanti, 2018) | | | | | | | |
| Is amputation a viable treatment option in lower extremity trauma? (Barla, 2017) | Retrospective cohort study. | 16 | 20 | 34 | SF-12, walking distance, Houghton score | More complications, operations, and hospital stays in LS group. Amputees had a longer walking distance and evidence of more complete recovery, but no difference in QoL between the two groups. | High |
| Long term outcomes after high energy open tibial fractures: Is a salvaged limb superior to prosthesis in terms of physical function and quality of life? (Frisvoll, 2019) | Retrospective cohort study. | 66 | Primary 66<br>Secondary 16 | 65 | SF-36, 6-MWT, VAS for satisfaction | No difference in SF-36 or 6-MWT between amputees and LS. | Moderate |
| Long term quality of life in trauma patient following the full spectrum of tibial injury (Giannoudis, 2009) | Retrospective cohort study | 108 | Primary 13<br>Secondary 9 | 37 | VAS, EQ5D | Pain more frequent in LS patients, no QoL differences between LS or amputation. | Moderate |
| Predictors of amputation in high energy forefoot and midfoot | Retrospective cohort study. | 119 | 27 | 12 | EQ5D, VAS | No difference in QoL measures between groups. | Moderate |

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| injuries (Working, 2017) | | | | | | | |
| Complex tibial fractures are associated with lower social classes and predict early exit from employment and worse patient-reported QOL: a prospective observational study of 46 complex tibial fractures treated with a ring fixator (Elsoe, 2018) | Prospective case series. | 46 | n/a | 20 | EQ5D-5L, KOOS, OMAS, MDI, VAS pain | QoL worse than population norms. | Moderate |
| Factors Influencing Functional Outcomes After Distal Tibia Shaft Fractures (Vallier, 2012) | Prospective individual randomised trial. | 86 | n/a | 22 | FFI, MFA | QoL worse than population norms. | High |
| Functional outcomes of posttraumatic lower limb salvage: A pilot study of anterolateral thigh perforator flaps | Retrospective case series. | 28 | 14 | 18 | SMFA | Patient preference for LS over amputation. | Moderate |

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| versus muscle flaps (Rodriguez, 2009) | | | | | | | |
| Management of severe open tibial fractures: The need for combined orthopaedic and plastic surgical treatment in specialist centres (Naique, 2006) | Retrospective cohort study. | 70 | Primary 2<br>Secondary 3 | 14 | Enneking limb score | QoL less than population norms. | Moderate |
| Outcome after complex trauma of the foot (Kinner, 2011) | Retrospective case series. | 50 | Primary 11<br>Secondary 7 | 48 | AOFAS, SF-12, VAS (F&S scale) | Most patients suffer occupational limitations and impairment of ADLs regardless of treatment. | Moderate |
| Outcome following open reduction and internal fixation of open Pilon fractures (Boraiah, 2010) | Retrospective case series. | 58 | 1 | 34 | SF-36 | QoL worse than population norms. | Moderate |
| Outcome of 28 open Pilon fractures with injury severity-based fixation (Danoff, 2015) | Retrospective case series. | 28 | n/a | 38 | SMFA, AAOSF&AQ, customised short questionnaire | QoL worse than population norms. | High |
| Patient reported health related quality of life early outcomes at 12 | Retrospective cohort study. | 91 | Primary 1 | 12 | SF-12 | QoL worse than population norms. | Moderate |

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| months after surgically managed tibial plafond fracture (Bonato, 2017) | | | Secondary 2 | | | | |
| Results and Outcomes After Operative Treatment of High-Energy Tibial Plafond Fractures (Harris, 2006) | Retrospective case series. | 76 | n/a | 26 | FFI, MFA, and general health status | QoL worse than population norms. | Moderate |
| The impact of Trauma-centre care on functional outcomes following major lower-limb trauma (MacKenzie, 2008) | Retrospective cross-sectional study. | 925 | n/a | 12 | SF-36, MFA, CESD-R | QoL worse than population norms. | High |
| Risk factors for infection and amputation following open, combat related calcaneal fractures (Dickens, 2013) | Retrospective observational cohort study. | 59 | Primary 28<br>Secondary 15 | 48 | VAS, Tegner activity level | Outcomes for amputees better than LS. | High |

*Table 2-2: Summarised results of papers included in systematic review. ICD=international classification of disease, PTSD=post-traumatic stress disorder, HO=heterotopic ossification, 6-MWT=6-minute walk test, ADL=activities of daily living, PHQ-9=patient health questionnaire-9, GAD-7=general anxiety disorder-7, SF-36=short form-36, SF-12=short form-12, QoL=quality of life, AAOSF&A=American association of orthopaedic surgeons foot and ankle score, PCS=physical component score, SMFA=short musculoskeletal functional assessment, TUG=timed up and go, VAS=visual analogue scale, EQ5D=EuroQoL 5D, KOOS=knee injury and osteoarthritis outcome score, OMAS=Olerud-Molander ankle score, MDI=major depression inventory, FFI=foot function index, MFA=musculoskeletal functional assessment, AOFAS=American Orthopaedic foot and ankle score, CESD-R=centre for epidemiological studies depression scale-revised.*

All studies were retrospective (35 studies), except four which were prospective. Similar to findings of a review by Busse et al from 2007, patients with the most severe injuries undergo amputation (Busse, 2007). The retrospective nature of the included studies presents an inherent bias. Additionally, there was no randomisation in any of the trials, patients were categorised based on the treatment received rather than randomised into treatments. Conclusions on treatment recommendations must be considered in the context of the retrospective study design. Seventeen of the studies looked at a civilian population and 22 at a military population. The included studies reported on LS or amputation in isolation or compared cohorts of patients with primary amputation, secondary (delayed) amputation, or LS.

### 2.4.2. Internal and External Validity

Table 2-3 shows the quality assessment of each study. Only one study demonstrated high internal validity. Moderate internal validity was demonstrated in 18 studies with points lost on lack of randomisation, failure to calculate an effect size, and lacking statistical power for conclusions drawn. Twenty studies demonstrated low internal validity with issues concerning not only lack of effect size and statistical power, but also high attrition rates (>20%) and unequal attrition between comparison groups. External validity was improved over internal validity with all but one study rating high. Overall, 19 studies were high quality and 20 moderate quality.

| | | Internal Validity | | | | | | | | | | | | | | | | | | | External Validity | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Author (Year) | Study | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | Total | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | Total |
| Melcer (2017) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | x | x | Moderate | x | x | x | x | x | x | x | x | High |
| Melcer (2013) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | x | x | Moderate | x | x | x | x | x | x | x | x | High |
| Linberg (2013) | O2 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Ladlow (2016) | O2 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Perkins (2018) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Penn-Barwell (2015) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | x | High |

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| Bennett (2018) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | x | High |
| Ramasamy (2013) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Dickens (2013) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Melcer (2013) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Doukas (2013) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | x | High |
| Scott (2014) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | x | x | x | x | High | x | x | x | x | x | x | x | x | High |
| Karami (2012) | O3 | n/a | n/a | n/a | n/a | n/a | | x | | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Gunaward ena (2006) | O2 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |

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| Krueger (2015) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | | | x | Low | x | x | x | x | x | x | x | x | High |
| Ebrahimzadeh (2007) | O5 | n/a | n/a | n/a | n/a | n/a | | x | | | | | | | x | | | | x | Low | x | x | | x | x | x | x | x | High |
| Ebrahimzadeh (2009) | O5 | n/a | n/a | n/a | n/a | n/a | | x | | | | | | | x | | | | x | Low | x | x | | x | x | x | x | x | High |
| Melcer (2010) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Taghipour (2009) | O3 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Dharm-Datta (2011) | O5 | n/a | n/a | n/a | n/a | n/a | | x | | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |
| Bennett (2013) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | x | High |
| Gailey (2010) | O1 | n/a | n/a | n/a | n/a | n/a | | x | | | | | | | x | | x | | x | Low | x | x | x | x | x | x | x | x | High |
| Chigblo (2019) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |

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| Delauche (2013) | O5 | n/a | n/a | n/a | n/a | n/a | | x | | | | | | x | x | | | | x | Low | x | x | x | x | x | x | x | High |
| Fioravanti (2018) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | | x | | x | | x | Low | x | x | | x | x | x | x | High |
| Barla (2017) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | High |
| Frisvoll (2019) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | | x | x | x | x | x | High |
| Giannoudis (2009) | O1 | n/a | n/a | n/a | n/a | n/a | | x | | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | High |
| Working (2017) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | High |
| Elsoe (2018) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | | | x | Low | x | x | x | x | x | x | x | High |
| Vallier (2012) | E5 | n/a | n/a | n/a | n/a | x | x | x | x | | x | | | x | x | | x | x | x | Moderate | x | x | x | x | x | x | x | High |
| Rodriguez (2009) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | | x | x | x | x | High |
| Naique (2006) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | | | | | x | Low | x | x | | x | x | x | x | High |
| Kinner (2011) | O5 | n/a | n/a | n/a | n/a | n/a | | x | | | | | | x | x | | x | | x | Low | x | | | x | x | x | x | High |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Boraiah (2010) | O5 | n/a | n/a | n/a | n/a | n/a | | | | | | | x | x | | x | | x | Low | x | | x | x | x | x | x | x | High |
| Danoff (2014) | O5 | n/a | n/a | n/a | n/a | n/a | | x | x | | | x | x | x | x | | x | | x | Moderate | x | | x | x | x | x | x | x | High |
| Bonato (2017) | O1 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | | x | x | | x | | x | Low | x | x | x | x | x | x | x | x | High |
| Harris (2006) | O5 | n/a | n/a | n/a | n/a | n/a | | x | | | | x | x | x | | | x | | x | Low | x | x | x | x | x | x | x | x | High |
| Mckenzie (2008) | O3 | n/a | n/a | n/a | n/a | n/a | | x | x | | | | x | x | x | | x | | x | Moderate | x | x | x | x | x | x | x | x | High |

*Table 2-3: Quality assessment of included studies. X represents where item is present. O1=Cohort study, O2=Case-control study, O3=Cross-sectional study, O4=Qualitative study, O5=Case series, O6=Case study. N/A is not applicable where the validity item cannot be assessed due to the type of study. Internal validity items, 1=comparison or control group used, 2=groups formed by random assignment, 3=groups comparable at baseline, 4=groups handled the same way, 5=control/comparison group appropriate, 6=intervention(s) blinded, 7=inclusion criteria appropriate, 8=exclusion criteria appropriate, 9=protocol addresses fatigue and learning, 10=protocol addresses accommodation and washout, 11=attrition explained and less than 20%, 12=attrition equal between groups, 13=outcome measures reliable, 14=statistical analysis appropriate, 15=effect size reported, 16=statistical significance reported, 17=statistical power adequate, 18=free from conflicts of interest. External validity items, 1=sample characteristics adequately described 2=sample representative of the target population, 3=outcome measures adequately described 4=outcome measures valid for this study, 5=intervention adequately described 6=findings clinically significant/relevant, 7=conclusions placed in context of literature, 8=conclusions supported by findings.*

### 2.4.3. Patient and Injury Characteristics

All patients included in this systematic review sustained traumatic lower limb injuries. The studies report on a total of 12,779 patients, predominately male (83.7%) with a median age of 30-years (range 20-55). The military cohort was statistically younger than the civilian cohort (28.6; SD 6.7 vs 42.1; SD 5.3, p<0.001 (*t-test*)). Mean follow up was 54-months (range 12 to 288 months) with no significant difference between follow up of the military or civilian cohorts (73.7; SD 81.8 vs 28.1; SD 14.5, p=0.03 (*t-test*)).

### 2.4.4. Functional outcomes

The aim of LS and amputation is to restore function to allow individuals to ambulate. Included studies used a variety of measures to assess functional outcome. These included walking distances, the use of walking aids, and results of the 6-Minute Walk Test (6-MWT). Overall, improved walking distances were reported for amputees compared to LS patients. Combining data from the only studies to use the 6-MWT examining 52 amputees and 52 LS patients, the 6-MWT distance for amputees is improved over LS patients (528.61m; SD 80.76 vs 488.96m; SD 66.37, p=0.0074 (*t-test*)) (Ladlow, 2016; Frisvoll, 2019).

Examining the civilian cohort, Barla et al (high quality study) found significantly longer (better) walking distances for amputees compared to LS patients, with more amputees able to walk greater than 5km compared to LS patients (15 v 4, p=0.0064 (*Fisher's exact test*)) and amputees demonstrated a reduced requirement for walking aids compared with LS patients (3 v 8, p=0.033 (*Fisher's exact test*)) (Barla, 2017). In contrast, Frisvoll et al (moderate quality study) found no difference in 6-MWT distance for amputees compared to LS patients (449m v 493m; p=0.286 (*t-test*)) (Frisvoll, 2019).

In military patients, Ladlow et al (high quality study) found improved outcomes for amputees compared to LS patients in physical functioning in the form of the 6-MWT (p=0.006 (*ANOVA*)) and ability to undertake Activities of Daily Living (ADL) (p<0.05 (*t-test*)), regardless of whether the amputation was early (primary) or delayed (secondary) (Ladlow, 2016). Although improved over LS patients, the 6-MWT distance was significantly reduced for amputees compared with uninjured personnel (661m v 761m respectively p<0.001) (Linberg, 2013).

Based on the evidence from high quality studies, amputation appears to provide superior functional outcomes in the form of 6-MWT and walking distance, compared to LS. Despite the assessment of overall high quality for the studies, the outcomes are based on small cohorts of patients lacking power calculations.

### 2.4.5. Pain

An assessment of which treatment method results in reduced pain is likely to aid in functional recovery. Overall, the evidence from the included studies appears to suggest long-term pain is an issue regardless of treatment method. It is reported as having a prevalence of 26-55% in the studies with civilian patients following LS surgery at minimum 12-month follow up (Danoff, 2015; Bonato, 2017). Vallier et al (high quality study) report a trend towards increased long term pain for LS patients treated with an intramedullary nail compared to plate fixation however statistical significance is not found (54% v 27%; p=0.08 (*t*-test)) (Vallier, 2012). Fioravanti et al (moderate quality study) found mechanical pain was more prevalent in LS patients (20/27 LS patients v 5/24 amputees), however neuropathic pain was more prevalent in amputees (18/24 amputees v 7/27 LS patients) (Fioravanti, 2018). Pain was more likely if patients were involved in a compensation claim, in keeping with LEAP findings, or suffered an Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) type B or C injury (Giannoudis, 2009; Bonato, 2017). Frisvoll et al and Working et al (both moderate quality studies) found there was no statistically significant difference in reported pain between LS patients and amputees but pain was reported more frequently for both groups than population norms (Working, 2017; Frisvoll, 2019).

Long-term follow up for more than 15-years for US military transtibial amputees revealed a number of chronic pain issues including stump pain, back pain, and contralateral knee pain (Ebrahimzadeh, 2013). Initially similar rates of pain-clinic use in US military LS patients and amputees were reported however, pain-clinic use increased with time for late (delayed, secondary) amputees following failed LS (Melcer, 2013). In studies examining a UK military cohort, ongoing pain issues were reported in a large number of LS patients, with pain cited as a reason for delayed amputation (A. Ramasamy, 2013; Ladlow, 2016; Bennett, 2018). Doukas

et al (moderate quality study) found in their study of a US military cohort no difference in pain interference reported regardless of treatment received (Doukas, 2013).

Pain is an issue for HELET patients regardless of treatment with ongoing long-term pain issues reported in moderate and high-quality research studies for both civilian and military patients. Due to the variety of methods used to assess pain, it has not been possible to find an overall rate, but evidence from multiple studies demonstrates that pain is an issue for patients regardless of treatment with no statistical difference found between the cohorts within studies.

### 2.4.6. Return to work

If function can be restored with either LS or amputation (with subsequent use of prosthetics), patients may be able to return to work. Overall, the median return-to-work rate was 61%. The return-to-work rate for the LS civilian cohort was 66% (range: 53-95%) returning at the same level or lighter duties (Harris, 2006; Naique, 2006; Rodriguez, 2009; Kinner, 2011; Vallier, 2012; Danoff, 2015; Bonato, 2017; Elsoe, 2018). A similar return-to-work rate was found in the only study reporting return-to-work rates looking at civilian amputees with 64% returning to employment at the same level or lighter duties (Chigblo, 2019). Three studies (two moderate and one high quality) directly compare civilian LS and amputee return-to-work rates and found them statistically similar, ranging from 48-73% (Barla, 2017; Fioravanti, 2018; Frisvoll, 2019). Seven studies report return-to-work rates for military personnel following HELET with a median of 63% (range 38-69%) returning at the same level or to lighter duties and no difference found between amputees and LS populations (Ebrahimzadeh, 2007, 2013; Taghipour, 2009; Gailey, 2010; Melcer, 2010; Dharm-Datta, 2011; Gunawardena, 2015). The return-to-work rate is therefore not different regardless of treatment received following HELET for LS or amputees.

## 2.4.7. Clinical outcomes

### *2.4.7.1. Failure rate of Limb Salvage*

The definition for failure of LS varies between papers, as does the definition for primary amputation. Where stated, the definition of secondary or late amputation has been used as a proxy for failure of LS. The median LS failure rate for all included studies is 9%.

Examining the literature on civilian cohorts, the median LS failure rate is 3.3%. The highest rate was reported following the Haitian earthquake, at 55%. In the same study, the primary amputation rate is significantly lower than the secondary rate at 10%. There is no definition for primary and secondary amputation provided in the study, and the apparently low primary amputation rate may be due to the definition of primary amputation being only that which occurs at point of wounding (Delauche, 2013). Barla et al define early amputation as less than 90-days and do not report any delayed amputations in their cohort of 42 patients (Barla, 2017). Whereas a rate of 4% is found at 14-month follow-up, when defining secondary amputation as not the first procedure in a civilian population (Naique, 2006). With the same definition a higher LS failure rate of 11% at 4-years is reported (Kinner, 2011). Both studies are of moderate quality however, the latter looked specifically at complex foot injuries as opposed to all lower limb injuries and had a longer follow-up, which may explain the higher LS failure rate reported.

Looking at studies concerning military cohorts, the median LS failure rate was higher than reported in civilian literature at 13.5%. Defining secondary amputation as more than 24-hours after injury an LS failure rate of 17% is reported (Perkins, 2018). A lower rate of 4% is reported with a definition of more than 30-days for failed LS (Scott, 2014). Three studies define primary amputation as within 90-days of injury reporting a higher LS failure rate at 6-10% rising to 12% at 4-year follow up (Doukas, 2013; Melcer, 2013, 2017). Using a definition of more than 12-weeks post injury, a US study reports an LS failure rate of 15% (Dickens, 2013). This rate is similar to a UK study reporting an LS failure rate at 15% however delayed amputation is not defined (Ladlow, 2016). A higher secondary amputation rate is reported of 32% when defining secondary amputation as occurring after the first three surgical procedures (J. G. Penn-Barwell, 2015). A similar rate of 31% is found looking specifically at hindfoot injuries, again

with a definition of after the first three surgical procedures (Bennett, 2018). A third UK paper only reports 7% of the cohort requiring secondary amputation at 18-months post injury (A. Ramasamy, 2013).

Due to the range of definitions and the heterogenous LS population, it is not possible to surmise an LS failure rate. It appears to be between 0 and 55% for civilians and 4-32% for military patients. Moderate quality evidence suggests a higher rate of failed LS for foot and ankle injuries compared to all lower limb injuries.

#### *2.4.7.2. Reason for delayed amputation*

Most studies do not state the reason for secondary amputation; in those that do the most common reason was pain (50%-69%) (Naique, 2006; A. Ramasamy, 2013; Krueger, 2015; Ladlow, 2016; Bennett, 2018; Perkins, 2018). Other stated reasons include dissatisfaction with functional ability (14%-58%) (Krueger, 2015; Ladlow, 2016; Bennett, 2018; Perkins, 2018), infection (7-20%) (Giannoudis, 2009; Bennett, 2018; Perkins, 2018), and non-viable soft tissue (Boraiah, 2010; Kinner, 2011; Bonato, 2017).

#### *2.4.7.3. Re-operation*

The need for recurrent operations after the primary procedure can be disruptive to patients, delay rehabilitation, and prevent return to work. The median reoperation rate was 0.48 (range 0-4.15) operations per patient.

Analysing reoperation rates for the LS civilian population, no difference was found in the use of a plate or nail for extra-articular tibial fractures (27% v 24% p=0.4 (*t-test*)) (Vallier, 2012). A reoperation rate of 10% is reported for complex foot and ankle fractures (Harris, 2006; Boraiah, 2010; Kinner, 2011). Naique et al found that LS patients managed at a specialist centre had a decreased reoperation rate compared to those managed at a local centre (48%), however the rate of reoperation in the specialist centre is not clearly stated and significance is not presented (Naique, 2006). Comparatively, for the civilian amputee population, Delauche et al report a 30% stump revision rate but fail to report the reoperation rate for the LS cohort (Delauche, 2013). Fioavanti et al, Frisvoll et al, and Barla et al, all found an increased

reoperation rate for LS patients compared to amputees however only Fioavanti et al report a statistically significant difference in the reoperation rate (Barla, 2017; Fioravanti, 2018; Frisvoll, 2019).

For military amputees, additional procedures are reported to be between 3.5 and 4.8 per patient (range 1-15) with a lower re-operation rate in patients undergoing primary vs secondary amputation, however the significance of this finding is not reported (Bennett, 2013; Ebrahimzadeh, 2013).

It is not clear whether there is a higher reoperation rate following LS or amputation. Given that a reoperation rate of 10-50% is reported in the literature patients should be advised that up to 50% will require at least one further procedure following either management option.

*2.4.7.4. Infection*

Similar to re-operation rates, the recurrence of infection after the primary procedure may be problematic for individuals following lower limb trauma, requiring repeated visits to see healthcare professionals in either the primary or secondary care setting. The median reported infection rate was 17% (range 0-77%).

Significantly higher rates of infection in civilian LS patients compared to amputees were reported in two studies (17/27 vs 8/24 $p<0.001$ (*$chi^2$ test*) (Fioravanti, 2018) and 6 vs 15 $p<0.001$ (*Student's t-test*) (Barla, 2017) respectively). Similar rates of deep infection were found by Frisvoll et al study (Frisvoll, 2019). Conversely, survivors of the Haitian earthquake appeared to have higher rates of infection following amputation than LS patients; this may be due to the severity of injuries or level of healthcare available (Delauche, 2013).

The infection rate following blast injury in military LS patients was noted to be higher with increasing GA classification (A. Ramasamy, 2013). Additionally, 45% of LS patients had ongoing clinical symptoms at 33 months follow up including sequalae due to infection. A culture positive wound infection was identified in 46% of calcaneal fractures following blast injury managed with LS with increasing Injury Severity Score (ISS) and GA classification predictive of increased incidence of infection (Dickens, 2013). The rate of infection following

LS was reported at 2.5-9% superficial and 1.3-14% deep, with no stated definition of the difference between superficial and deep (Harris, 2006; Naique, 2006; Boraiah, 2010; Melcer, 2010; Kinner, 2011; Danoff, 2015). Ongoing infection was also reported in patients that underwent amputation, albeit rates were reduced from the pre amputation rate (Krueger, 2015). Higher rates of infection in amputees (early and late) compared to LS patients ($p<0.05$ (*chi² test*)) both in the short term and in the first four years post injury were found in military patients (Melcer, 2013, 2017). It was again noted that increasing ISS was associated with an increased risk of infection signifying that infection is more likely in those with worse injuries. Examining just amputees, a 30% superficial infection rate was reported and 19% chronic infection rate in a cohort of amputees at 2 years post amputation (Melcer, 2010).

It is not clear whether infection is more common in amputees or LS patients. There appears to be a trend towards increased infection in LS patients when compared with amputee populations. The lack of definition of infection in the included studies precludes finding an overall rate for the populations for comparison. Rates of infection in studies examining just amputees appear higher than the rates for amputees in comparison studies calling into question inclusion criteria and definitions (Melcer, 2010; Barla, 2017; Fioravanti, 2018).

#### *2.4.7.5. Length of hospital stay and rehabilitation time*

Although hospital stay and rehabilitation time is a measure of outcome following LS or amputation, little is reported in the included literature. The Houghton scale, a measure of success of rehabilitation following amputation, is noted to be improved in younger civilian amputees and those with more distal amputations (Barla, 2017; Chigblo, 2019). In military patients undergoing optimal rehabilitation, the LS group had a shorter rehabilitation time compared to unilateral amputees ($p=0.009$ (*t-test*)) and bilateral amputees ($p=0.001$ (*t-test*)) (Ladlow, 2016). In the same study, the delayed-below knee amputation group or failed LS patients required significantly greater rehabilitation time than the successful LS group ($p=0.05$ (*t-test*)) (Ladlow, 2016). Given the paucity of information it is not possible to draw conclusions on which treatment option results in decreased hospital stay and rehabilitation time.

*2.4.7.6. Patient reported outcome measures*

A variety of patient reported outcome measures (PROMs) are used in the included studies. Overall, three studies (two moderate and one high quality studies) on civilian cohorts' report improved outcomes for amputees, three report no difference (two moderate and one high quality studies) and one (moderate quality) reports improved outcomes for LS patients. Using the 36-Item Short Form Survey (SF-36) amputation has superior physical outcomes over LS (Giannoudis, 2009; Barla, 2017; Fioravanti, 2018). The European Quality of Life – 5 Dimensions (EQ-5D) demonstrates that patients with GA 3B/C injuries undergoing LS report problems with pain and in carrying out normal activities more frequently than amputees (Giannoudis, 2009). Three further studies using the SF-36, Short Fotm-12 (SF-12), and EQ-5D examining civilian cohorts comparing LS and amputation report no difference in PROMs regardless of treatment, LS or amputation (Barla, 2017; Working, 2017; Frisvoll, 2019). Only one civilian study concludes that LS has superior PROMs over amputation examining a Haitian civilian population, with improved Role Emotional domain of the SF-36 compared to amputees and LS psychologically preferred by patients (Delauche, 2013).

For military patients, four studies (two moderate and two high quality) report improved PROMs for amputees, three (all high quality) report no difference and one (high quality) reported improved outcomes for LS patients. Doukas et al (moderate quality study) found Short Musculoskeletal Functional Assessment (SMFA) scores were improved in all domains for amputees compared to LS patients (Doukas, 2013). Similarly, in the same study, significant improvements were noted in the Role Physical, Bodily Pain and Mental Component Score (MCS) domains of the SF-36 when comparing amputees with LS patients. Amputees also had an improved pain domain of the EQ-5D and improved Visual Analogue Scale (VAS) score compared with LS patients ($p<0.05$ (*t-test*)) (Karami, 2012; Dickens, 2013). For hind foot injuries specifically, VAS, Tegner activity levels, and the Physical Component Score (PCS) of the SF-12 were all improved for amputees compared to LS patients (Dickens, 2013; Bennett, 2018). The SF-36 was not noted to be different between LS patients and amputees in two military comparative studies and one further military study concluded that with rates of Post-Traumatic Stress Disorder (PTSD) similar in both cohorts, there was no difference in outcomes between treatment methods (J. G. Penn-Barwell, 2015; Melcer, 2017; Perkins, 2018). Similar to civilian studies, only one military study concluded that LS was better based on patient-

reported outcomes in short-term follow-up, with amputees at an increased risk of mood, sleep, pain, and post-concussion syndromes (Melcer, 2013).

Therefore, due, in part, to the variety of PROMs used, it has not been possible to conclude in either civilian or military populations which treatment option results in better outcomes. The largest military study does suggest that, for military patients, patient-reported outcomes in the form of the SMFA are improved for amputees.

Similar to LEAP, most of the research reporting patient-reported outcomes, 20 papers in total (10 military and 10 civilian), conclude that patient-reported outcomes are worse than population norms regardless of treatment. Utilising the SF-36 and SF-12 the PCS is consistently noted to be lower than population norms however the MCS is noted, particularly in military cohorts, to be at or above population norms for both LS and amputees (MacKenzie, 2008; Taghipour, 2009; Boraiah, 2010; Dharm-Datta, 2011; Kinner, 2011; Bennett, 2013; Scott, 2014; Gunawardena, 2015; Bonato, 2017). The European Quality of Life – 5 Dimensions – 5 Levels (EQ-5D-5L) is also noted to be below population norms (Elsoe, 2018) as are the Musculoskeletal Functional Assessment (MFA) and SMFA with the exception, as expected, of the arm and hand domains (Harris, 2006; MacKenzie, 2008; Vallier, 2012; Doukas, 2013; Danoff, 2015). The Foot Function Index is also noted to be below population normal reference values (Harris, 2006; Vallier, 2012). Diagnosis of psychiatric conditions were noted to be higher than reference populations with an impact on quality of life reported and ongoing or new diagnoses of psychiatric conditions despite delayed amputation which was thought may prevent the onset (Ebrahimzadeh, 2007, 2013; Melcer, 2010; Krueger, 2015). Therefore, regardless of treatment option, HELET results in a life changing injury with ongoing impact on quality of life.

### 2.4.8. Factors associated with poor outcome

Although there is little consensus across the studies as to factors associated with poor outcome, worse functional outcomes are reported with AO/OTA C3 fractures (intra-articular, comminuted, distal tibia) (Harris, 2006). These fracture patterns are also likely to result in reports of moderate to severe persistent pain (Bonato, 2017) and have ongoing infection (Boraiah, 2010). Ongoing infection is also reported in association with an ipsilateral talar

fracture (p=0.006), forefoot fracture (p=0.01), higher Injury Severity Score (ISS) (p=0.03), and more severe GA fracture type (p=0.042) (Dickens, 2013). Independently, the presence of infection results in worse functional outcome scores (Danoff, 2015).

In keeping with the LEAP, patients who are unemployed are more likely to complain of ongoing pain, specifically ankle and knee pain regardless of fixation method (Vallier, 2012). Increased social support and higher educational attainment are reported to result in improved SMFA and SF-36 regardless of treatment (Taghipour, 2009; Doukas, 2013; Scott, 2014). Older age resulted in worse SMFA and SF-36 and higher reports of pain regardless of treatment (Doukas, 2013; Scott, 2014). Female gender trends towards worse functional scores but does not reach significance (Vallier, 2012) and more women are found to report problematic pain (Giannoudis, 2009). Patients of any gender, if involved in a compensation claim, are more likely to have moderate to severe pain (Bonato, 2017).

Involvement of the hindfoot resulted in poorer PROMs (SF-12 and VAS) (Kinner, 2011) and a negative Bohler's angle on initial radiograph, coexisting talus and calcaneal fractures, a tibial plafond fracture in addition to a hindfoot fracture, were all predictive of a poor Foot and Ankle (F&A) score (Bennett, 2018). The more proximal the amputation the worse the PCS of the SF-36 (Bennett, 2013) and it is also reported that worse soft tissue injuries resulted in poorer patient reported outcomes (SF-12 and VAS) (Kinner, 2011). The geographical location of treatment also has an impact on the outcome for patients with treatment at a level one trauma centre resulting in improved functional scores (Naique, 2006; MacKenzie, 2008).

Again, there is little consensus on factors predictive of the need for amputation however, there is an increased incidence of amputation with increasing numbers of foot and ankle fractures (p=0.015), an open injury (p<0.001), increasing GA grade (p<0.001), the presence of a vascular injury (p<0.001), and the loss of sensation to any surface of the foot (p<0.001) (Working, 2017). Loss of sensation was not noted to be predictive in a different study and was also refuted by the LEAP study (Dickens, 2013). Further risk factors include ipsilateral forefoot fractures (p<0.0001), a talar fracture (p<0.0001), plantar wounds (p<0.0001), and a culture-positive wound infection (p<0.0001), as well as an increasing wound size (A. Ramasamy, 2013; Dickens, 2013). Severe soft tissue injury (p<0.0001), uncompensated shock (p<0.0001),

ischaemic time of more than 6-hours ($p<0.0001$), and increasing ISS are also found to increase the incidence of amputation following HELET (Ladlow, 2016; Perkins, 2018).

## 2.5. Discussion

Following review of the included studies, there is no correlation between the management option for HELET and overall outcomes. Similar to the LEAP, based solely on patient-reported outcomes, this review shows that there is no difference between the two treatment options for civilian populations (Table 2-4). Consistent with the LEAP, this review also shows that outcomes for HELET patients are worse than population norms, regardless of treatment. LEAP assessed self-selected walking velocity and found no difference between the LS and amputee cohorts. The literature reviewed here examined walking distance as opposed to walking speed. Walking distance was found to be improved for amputees for both civilian and military populations, but as speed was not assessed no comment can be made on the correlation with self-selected walking velocity (SSWV) and satisfaction found by the LEAP.

| | **LEAP** | **Civilian cohort** | **Military cohort** |
|---|---|---|---|
| **Functional outcome** | No difference in walking speed | Improved walking distance for amputees | Improved walking distance for amputees |
| **Pain** | Higher prevalence of chronic pain in LS cohort | No difference | No difference |
| **Return to work** | No statically significant difference | No difference | No difference |
| **Failure rate of LS** | 3.9% | 3.3% | 13.5% |
| **Re-operation** | Re-operation rate higher for LS cohort | No clear difference | No clear difference |
| **Infection** | No statistically significant difference | Trend towards higher rates for LS cohort | Higher rate in LS cohort |
| **PROM** | SIP - No statistically significant difference | SF-12 and SF-36 no clear difference | SMFA improved for amputees |

*Table 2-4: Comparison of LEAP results with included literature.*

The LEAP excluded military patients, therefore examining the military literature in isolation there is a trend towards improved PROMs and functional outcomes for amputees. In the largest study of military patients, Doukas et al concluded that PROMs in the form of the SMFA are superior for amputees (Doukas, 2013). The authors attribute improved outcomes to the advanced rehabilitation pathways and novel prosthetics available exclusively to military

amputees. The study is limited by more than a 20% attrition rate and a statistically significant difference was found between the follow up rate of LS patients and amputees, favouring amputees; the results in isolation should be interpreted in light of this bias (Doukas, 2013). The improved outcomes are however also supported by three other military-cohort comparative studies, two of high quality. Improved outcomes for military amputees found here may have been biased and limited by the statistically younger military population included in this review. Amputation may be favoured by young active personnel to allow for prosthetic fitting and return to impact activity not required by an older, civilian population (Aravind, 2010; Owens, 2011; Patzkowski, 2011). The advances in lower limb prosthetic design and improvements in military specific rehabilitation pathways may account for the improved outcomes for military amputees seen in some of the studies included in this systematic review compared to civilians (Kistenberg, 2014). The included studies do not follow up amputees for sufficiently long enough to ascertain whether early improvements in PROMs are sustained with advancing age. Furthermore, the older population of civilians examined in this review do not demonstrate the same superior PROMs following amputation. It is not clear whether this is due to the difference in age or a difference in required minimum functional levels for military and civilian cohorts. Long term health risks associated with amputation must be considered, especially in light of the averagely younger military population for whom there is a substantial amount of time living with the amputation and associated health burdens. These include but are not limited to musculoskeletal complications and cardiovascular risks independent of the potentially reduced mobility inherent following amputation. Arguably, there is a need to find a solution to improve mobility and augment function for LS patients to prevent amputation and bring PROMs up to the same level as amputees, or potentially population norms.

There is no consensus in the literature on the definition of primary amputation and failed LS or secondary amputation. The LEAP analysed amputation occurring in the first three months after injury compared to amputation occurring after the first three months (Bosse, 2002). This definition of 3 months is consistent with subsequent studies describing the definition as 90 days or 12 weeks (Dickens, 2013; Doukas, 2013; Melcer, 2013, 2017). Although no definition has been agreed in either clinical or research communities, a definition of 3 months is gaining the largest body of evidence, particularly in the US. Agreement of a definition would allow for

direct comparison of studies examining outcomes, especially in light of the heterogenous injury patterns for included cohorts of lower limb patients.

The LS failure rate reported in this review is noted to be higher for military patients than civilians or that reported in LEAP. This may be due to the mechanism of injury for military patients. Blast injury accounts for the majority of injuries for military patients included in this review, as opposed to road traffic collisions or falls from height seen in the civilian literature. Blast injury has been shown to have worse outcomes compared to civilian injury mechanisms due to the polytrauma nature of injury and consequent increased ISS (Doucet, 2011). Infection rates may also be higher due to environment in which the injury was sustained leading to inevitable amputation.

Similar to previous reviews, the functional outcomes utilised in included studies vary widely with no single functional assessment used by all studies (Hawkins, 2014). The LEAP used the SIP (Bergner, 1981) however no studies included in this review used this measure rendering direct comparisons difficult. The SF-36 or SF-12 is the most frequently used measure in this review. Like the SIP the SF-36 and SF-12 are not specific to lower limb injuries but have been used extensively in the literature when looking at outcomes for amputees (Condie, 2006; Penn-Barwell, 2011). The EQ-5D and VAS used by included studies are also not specific to the lower limb. Post-operative outcome, regardless of treatment, is linked to function and none of the aforementioned PROMs specifically measure lower limb function (Momoh, 2013). The SMFA includes more questions relating to the lower limb than the previously mentioned outcome measures and is used by six studies. The SMFA allows for comparison with the Outcomes after Severe Distal Tibia, ankle, and/or foot trauma: Comparison of Limb Salvage Versus Transtibial Amputation (OUTLET) study, a prospective study looking at outcomes following severe foot and ankle injuries (Bosse, 2017). OUTLET uses the SMFA as the primary outcome measure. OUTLET concedes that the SMFA is not lower limb specific but highlights that it is extensively validated and includes a mobility and bother index. OUTLET has finished recruiting, enrolling 596 patients (510 LS patients and 86 amputees) (Bosse, 2017; Reider, 2018). The full results are not published, however, early presented results suggest that patients with severe calcaneal and ankle injuries would have had better outcomes with amputation than LS (Reider, 2018). This is similar to findings in a subgroup analysis of LEAP

patients with foot and ankle injuries which found that patients treated with free flaps and/or ankle arthrodesis had inferior outcomes compared with standard below knee amputation (Ellington, 2013). The literature presented in this review concerning military cohorts analysing foot and ankle injuries also supports this finding (A. Ramasamy, 2013; Dickens, 2013; Bennett, 2018).

The LEAP concluded that in the civilian sector LS costs less over a lifetime than amputation (MacKenzie, 2007). Neither the LEAP nor this review were able to demonstrate a difference in functional outcomes between LS and amputation for the civilian cohort. Economically therefore, where LS is possible, it should be trialled followed by amputation if required (Saddawi-Konefka, 2008; Chung, 2009). This view is supported by Ladlow et al, who found similar functional outcomes in patients treated with early and delayed amputation following failed LS (Ladlow, 2016). This implies that attempted LS does not functionally adversely affect patients. Melcer et al however found that, over a four-year follow up period, mental health outcomes were worse for failed LS patients; this was supported by Krueger et al (Krueger, 2015; Melcer, 2017). Although, high levels of anxiety and depression have also been found in post-traumatic amputees regardless of timing of amputation (Mckechnie, 2014). LS has however, been found to be psychologically more acceptable than amputation (Akula, 2011). Therefore, although patients may not be harmed by a trial of LS functionally, the trial may impact their mental health, although equally, amputation may adversely impact mental health.

The limitations of this review include the lack of meta-analysis due to the heterogenous nature of the included literature. The lost to follow-up rate of the included studies was high, up to 41%, and therefore not only is bias present in studies due to the lack of randomisation, it is also present due to the high attrition rate. The internal validity of the studies adds to the potential for bias with only one study rated high quality for internal validity. To overcome deficiencies in the literature, sufficiently powered randomised studies are required looking at subsets of lower limb HELET patients, with consistent outcome reporting, to answer the question of whether LS or amputation results in improved outcomes for patients. Randomised controlled trials for LS and amputation are not practical, although they may be scientifically desirable, therefore the pragmatic approach of longitudinal prospective observational studies

is preferable. These require large cohorts to allow for meaningful statistical analysis. The attempted subgroup analysis seen in the LEAP due to the heterogenous cohort recruited including unilateral and bilateral injuries, along with injuries at various levels of the lower limb, must be viewed with certain scepticism as the original study was not powered for these calculations. OUTLET has attempted to overcome this with a specific study examining foot and ankle injuries, but formal peer reviewed results are still awaited and evidence-based guidance on amputation or LS for foot and ankle injuries cannot be produced without these results. In light of the potential long-term health complications associated with amputation and the lack of clear appropriately powered evidence for treatment following severe foot and ankle injuries, technological advances in materials, microprocessors, and rehabilitation, should be investigated to find ways to improve outcomes for LS patients to prevent amputation.

## 2.6. Conclusion

In conclusion, LS and amputation are equivocal in civilian literature. Military patients, particularly with foot and ankle injuries, demonstrate improved PROMs and walking distances following amputation. The literature suggests that this may be due, in part, to improved rehabilitation pathways and prosthetic design available to military amputees. There is scope for research to improve outcomes for LS patients by reviewing rehabilitation pathways and devices available to augment function. The observed technological advances in prosthetic design may lend themselves to orthotic design. If orthotics can be improved to augment function for LS patients, and allow young active personnel to return to impact activities, PROMs for LS patients may be brought in line with amputees, or even exceed amputees and match population norms. This is desirable to prevent amputation where possible and the potential for long term health complications. To enable advances in orthotic design, pathological gait following HELET must be examined to understand deficiencies and function requiring augmentation. The next Chapter will concentrate on the analysis of gait with a focus on the deficiencies present in gait following injury.

# Chapter 3: Gait and gait changes following lower limb trauma

## 3.1. Introduction

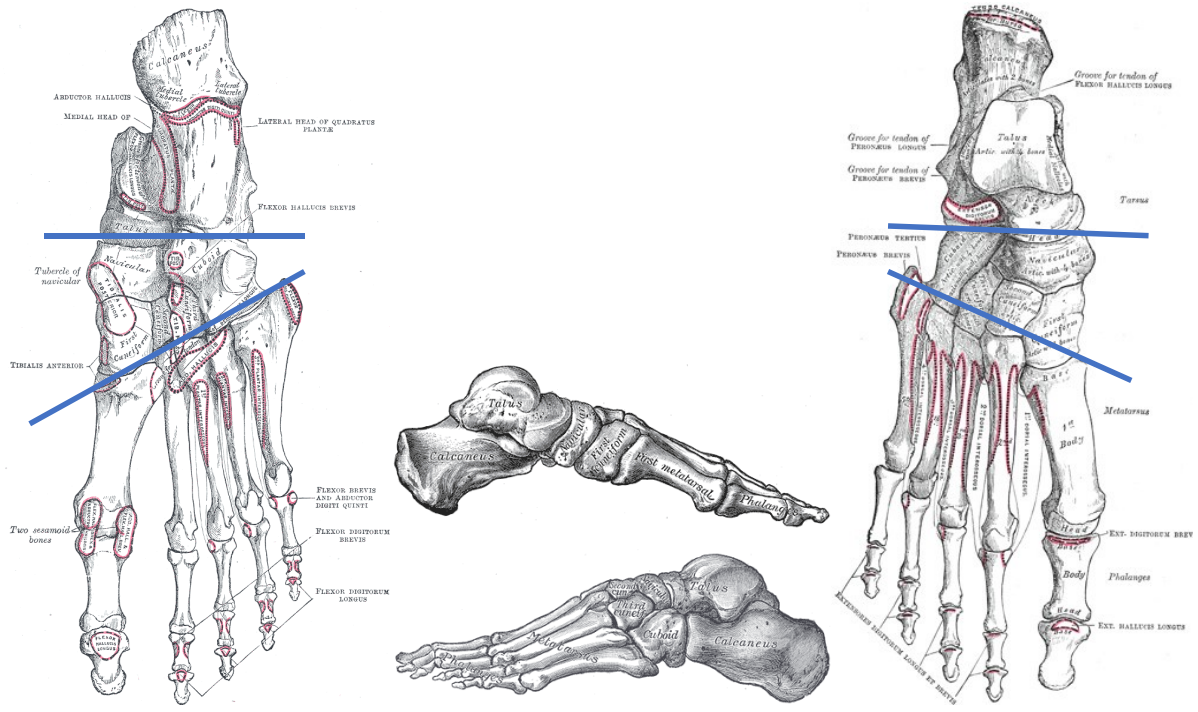
Chapter 2 concluded that outcomes for both LS patients and amputees are worse than population norms. Specifically for military patients, functional and patient-reported outcomes are superior for amputees compared to LS patients (Doukas, 2013; Ladlow, 2016). As a consequence of poor functional outcomes for Service Personnel following LS, return to military service rates are also poor (A. Ramasamy, 2013; Bennett, 2018). The superior functional performance of amputees has led some LS patients to request elective amputation in an attempt to increase their functional performance (Aravind, 2010; Owens, 2011). Where possible, it is desirable to avoid amputation due to secondary health concerns (Gailey, 2008). World War II follow-up studies of amputees demonstrate increased risk of low back pain, osteoarthritis (OA), and cardiovascular disease (Hrubec, 1980; Modan, 1998). Cardiovascular complications are not necessarily the consequence of inactivity, but due to underlying haemodynamic changes (Rose, 1987; Yekutiel, 1989). Change in arterial flow (shear stress, circumferential strain, and reflected waves) proximal to the amputation site is hypothesised to cause increased cardiovascular disease in amputees. This has been evidenced by an increased risk of cardiovascular complications in bilateral amputees compared to unilateral lower limb amputees despite similar activity levels (Naschitz, 2008).

To avoid elective amputation following LS it is necessary to improve the functional performance of LS patients, bringing their outcomes in line with amputees, or if possible, population norms. To investigate how to improve outcomes for LS patients an understanding of the complications experienced by LS patients is needed. LS patients commonly complain of nerve injury deficits, chronic pain, instability, and muscle wasting impacting on functional performance (Eiser, 2001; Pollak, 2008; Shawen, 2010; Ursone, 2010; Grogan, 2011; Russell Esposito, 2014). Additionally, limited function in walking, running, and other activities has been reported (Bosse, 2002; Mackenzie, 2004; Doukas, 2013). These changes can be seen in the gait of individuals following trauma and consequent LS.

The aim of this Chapter is to explain the reasons for the functional deficits experienced by LS patients as a result of trauma. This Chapter will review the functional anatomy of the foot and ankle and present the principles in analysing normal and pathological gait.

## 3.2. Anatomy of the foot and ankle

The foot is made up of 26 bones excluding the 2 sesamoid bones (Figure 3-1) (Gray, 2009). The ankle joint known as the talocrural joint is comprised of the talus in the ankle mortise (tibiotalar, fibulotalar, and tibiofibular joints) (Ieong, 2020). The hind foot is made up of the calcaneus and talus bones. The subtalar joint is the connection between the calcaneus and talus. The midfoot is formed at the transverse midtarsal joint made up of the talus, navicular, calcaneus, and cuboid. The midfoot is finished by the lateral, intermediate and medial cuneiform bones. The forefoot is comprised of the metatarsal bones and phalanges.



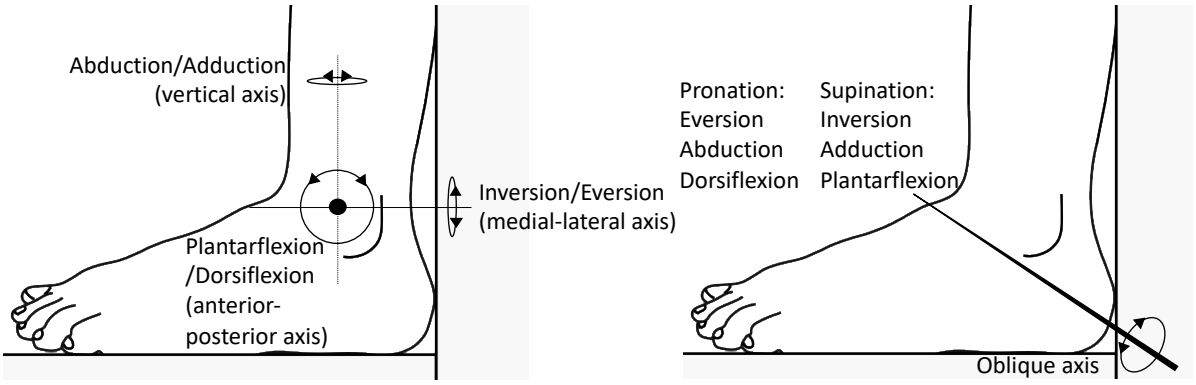

a b C

*Figure 3-1 : Osteology of the foot. 1a: Inferior (plantar) view. 1b: Medial and lateral views. 1c: Superior (dorsal) view. Solid lines approximately demarcate hindfoot, midfoot and forefoot. Image reproduced from Gray's Anatomy 1918 (out of copyright).*

The foot has several adaptations to aid with gait. The heel, comprised of the calcaneus, is rounded and the heel pad is filled with fluid, connective tissue, and fat to act as a shock

absorber during gait (Chan, 1994). Continual alterations during gait in foot shape accommodate changes in the environment (Chan, 1994). There are two sesamoid bones located under the head of the first metatarsal which sit in the flexor hallucis brevis and help to distribute force during gait (Chan, 1994). The bones of the foot are connected via ligaments, which along with the muscles of the foot, form two longitudinal arches (medial and lateral) and a transverse arch. The arches provide support to the foot and allow the foot to be both mobile and rigid, a key ability to enable walking (Mann, 1980; Chan, 1994). The joints that constitute the foot and ankle make gait possible providing the kinetic linkage between the body and the ground allowing the foot and ankle to bear weight (Brockett, 2016).

Movements of the ankle-foot complex are; inversion/eversion which occurs primarily at the subtalar joint; (Michael, 2008) dorsiflexion/plantar flexion (sagittal plane up and down) which occurs primarily at the talocrural joint; abduction/adduction (transverse plane); and anterior/posterior translation (Figure 3-2) (Wiley, 2013). A combination of these movements allows for supination and pronation. Supination is achieved through inversion, plantarflexion and adduction whilst pronation is achieved through dorsiflexion, eversion and abduction (Brockett, 2016). Normal ankle range of motion varies depending on ethnicity and age, as well as whether the foot is weight bearing (Grimston, 1993). Ankle range of motion is from 10-20$^{o}$ of dorsiflexion to 40-55$^{o}$ of plantarflexion reduced to 30-40$^{o}$ total range of motion during gait (7-10$^{o}$ dorsiflexion and 20$^{o}$ plantarflexion) (Grimston, 1993; Winter, 1995; Waters, 1999).




a b

*Figure 3-2: Movement at the ankle joint. 2a) Fundamental movements 2b) Applied combination of movements around an oblique axis.*

Plantar and dorsiflexion occur with movement of the talus in the ankle mortise (talocrural joint). This is composed of the tibia and medial malleolus, the tibiofibular syndesmosis and the fibular with lateral malleolus extension. The talus is wedge shaped and wider anteriorly than posteriorly (Figure 3-3). During dorsi and plantarflexion the axis of movement shifts in the frontal plane due to slide of the talus (Figure 3-4). In a neutral or dorsiflexed position, the axis runs lateral, posterior and **plantar** to medial, anterior and **dorsal**. In a plantarflexed position the axis shifts slightly and runs lateral, posterior, and **dorsal** to medial, anterior, and **plantar**. Dorsiflexion is combined with slight abduction and eversion (pronation) whilst plantarflexion is combined with inversion and adduction (supination) (Figure 3-2 and Figure 3-4). Therefore movement occurs in more than one plane due to the slide of the talus in the joint (Sarrafian, 1993).

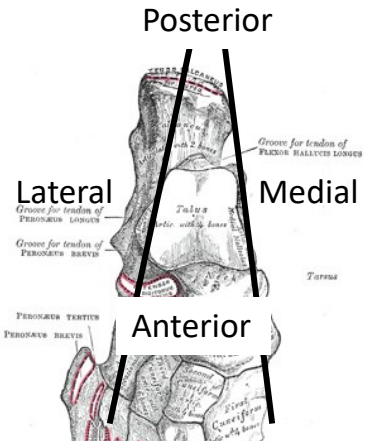



*Figure 3-3: Wedge shaped talus with wider portion anteriorly. Image reproduced from Gray's Anatomy 1918 (out of copyright).*

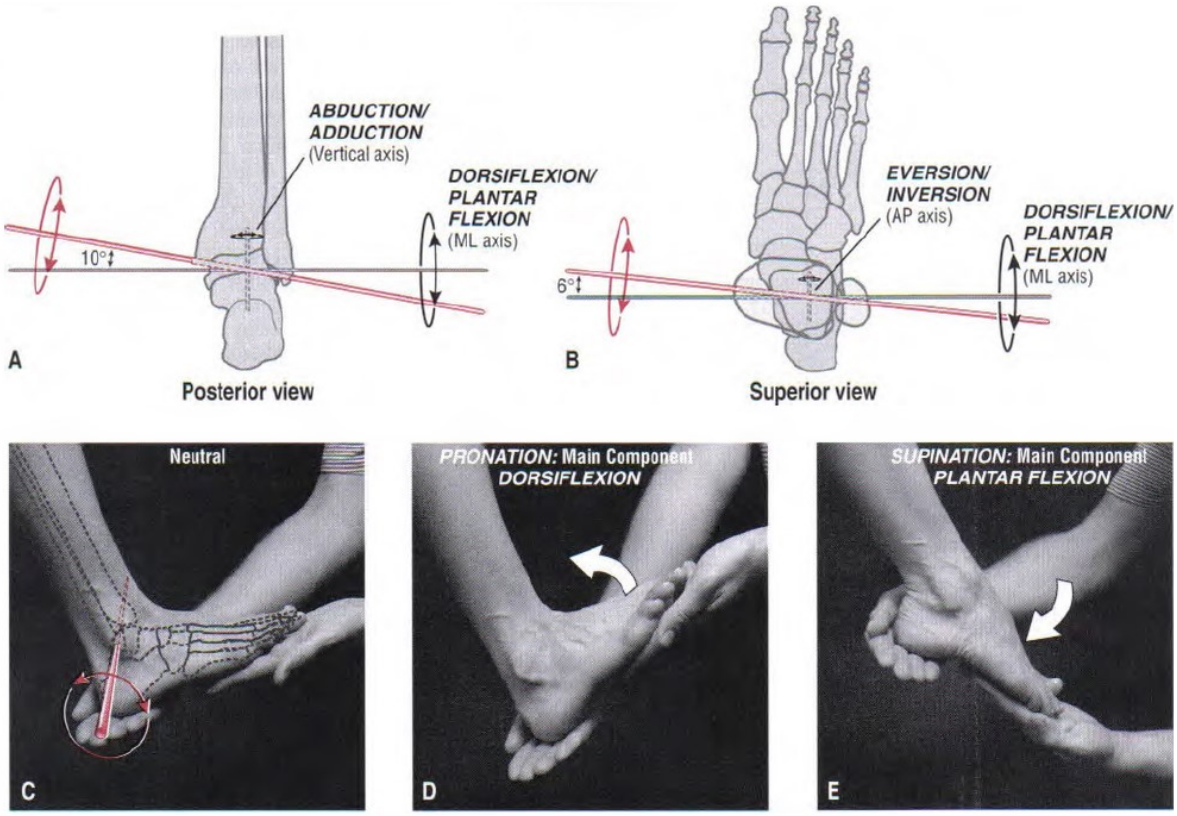



*Figure 3-4: Orientation of axis during plantarflexion and dorsiflexion. (A and B) In neutral or dorsiflexion the axis runs lateral, posterior, and plantar to medial, anterior, and dorsal. (E) In plantarflexion the axis shifts in the frontal plane to run lateral, posterior and dorsal to medial, anterior, and plantar. There is a see-saw motion of the axis. Image reproduced with permission of the rights holder, Elsevier.*

Inversion and eversion along with abduction and adduction occur at the subtalar joint. The axis of rotation runs obliquely through the joint (Figure 3-5). Inversion is almost double eversion as the lateral malleolus and thick deltoid ligament limit movement (Irvine, 1993).

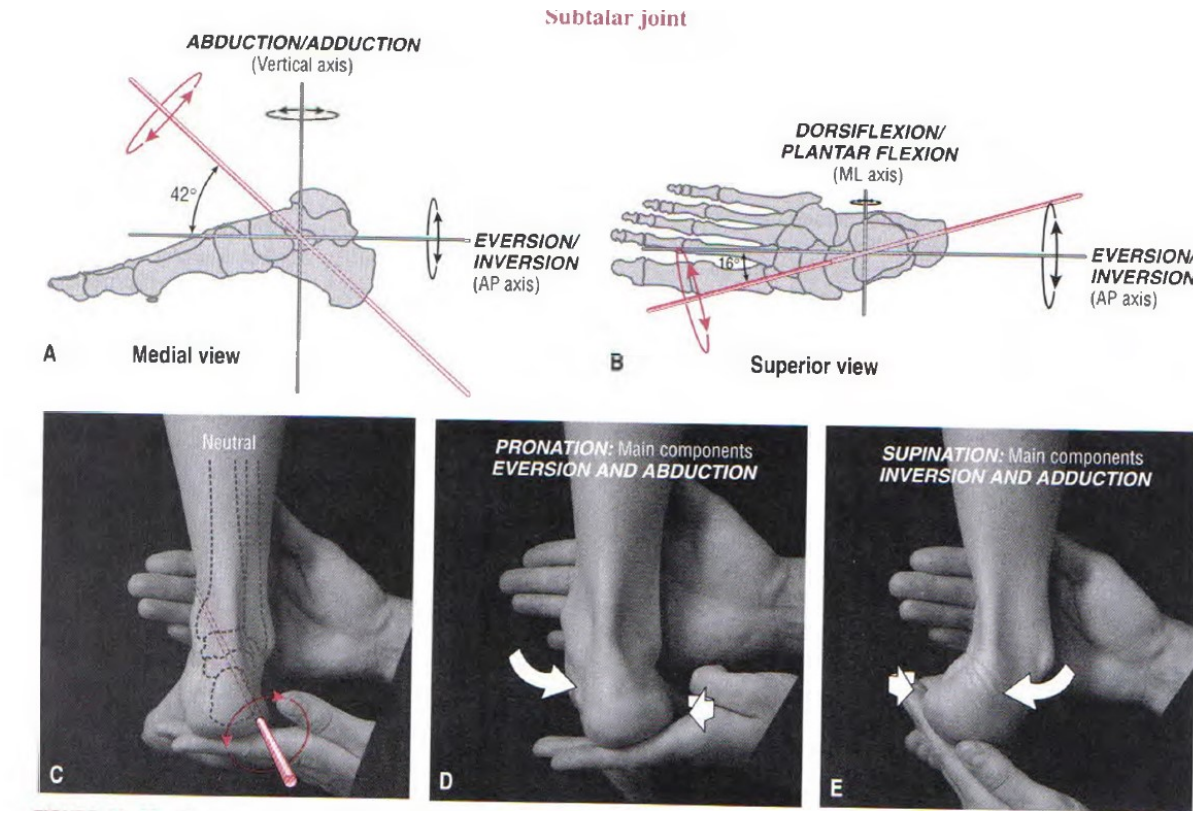



*Figure 3-5: Movements at the subtalar joint. The oblique axis is shown in red. Image reproduced with permission of the rights holder, Elsevier.(Irvine, 1993)(Irvine, 1993)(Irvine and Neumann, 1993)(Irvine and Neumann, 1993)(Irvine and Neumann, 1993)(Irvine and Neumann, 1993)(Irvine and Neumann, 1993)(Irvine and Neumann, 1993)<sup>98</sup>*

The transverse tarsal joint (Chopart's joint) is comprised of the talonavicular and calcaneocuboid joints. The calcaneocuboid joint is relatively rigid in comparison to the talonavicular joint. Movement at the transverse tarsal joint rarely occurs in isolation. It is the combined movement of the transverse tarsal joint with the subtalar joint that contributes to pronation and supination (Figure 3-5). Supination at the midfoot range of motion is approximately twice that of the range of motion for pronation (Irvine, 1993).

There are twelve extrinsic muscles in the leg which contribute to movement of the foot (Figure 3-6) (Brockett, 2016). Plantarflexion is achieved using the plantarflexor muscles

namely the Gastrocnemius, Soleus, and Plantaris muscles. These are supplied by the tibial nerve and are contained in the superficial posterior compartment of the leg. Contributions to plantarflexion (and inversion) are also made by the muscles of the deep posterior compartment also supplied by the tibial nerve, Tibialis Posterior, Flexor Digitorum Longus, and Flexor Hallucis Longus. Dorsiflexion is achieved using the dorsiflexor muscles located in the anterior compartment of the leg, supplied by the deep peroneal nerve. The dorsiflexors are Tibialis Anterior, Extensor Hallucis Longus, and Extensor Digitorum Longus. Tibialis Anterior also contributes to inversion along with Tibialis Posterior (Vloka, 2001). Eversion (and plantarflexion) is achieved using the muscles in the lateral compartment of the leg, Peroneus Longus and Brevis, supplied by the superficial peroneal nerve. The superficial and deep peroneal nerves are branches of the common peroneal nerve which is vulnerable to injury as it winds around the neck of the proximal fibula (Poage, 2016; Garrett, 2020).

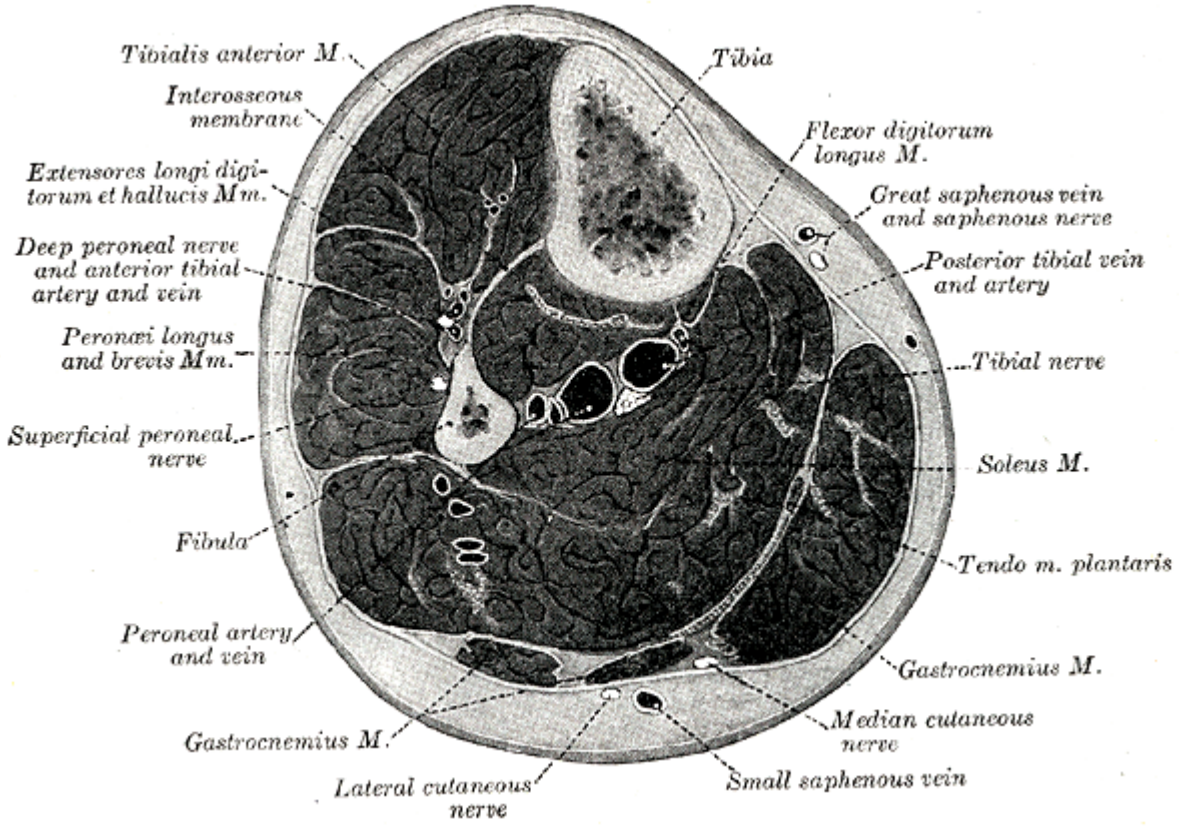



*Figure 3-6: Muscle of the lower leg. Image reproduced from Gray's Anatomy 1918 (out of copyright).*

## 3.3. Gait

Gait is the bipedal forward propulsion of the centre of mass of the body. It involves a repetitive sequence which moves the body forward and provides stability (J Perry, 1992).

### 3.3.1. The gait cycle

Human gait begins with heel strike and the transfer of weight from one foot to the next (Figure 3-7) (J Perry, 1992). One leg provides stability and the other swings through to propel the body forward. This process is then repeated. Gait is divided into stance and swing phases (Taborri, 2016). Conventionally, the gait cycle begins at heel strike on one side and ends with heel strike on the same side. Heel strike to heel strike represents 100% of the gait cycle. In pathological gait the heel may not be the first part of the foot to contact the ground, to account for this, the gait cycle is more accurately described from initial contact with the ground with one foot until initial contact with the same foot, regardless of whether initial contact is made with the heel or another part of the foot.

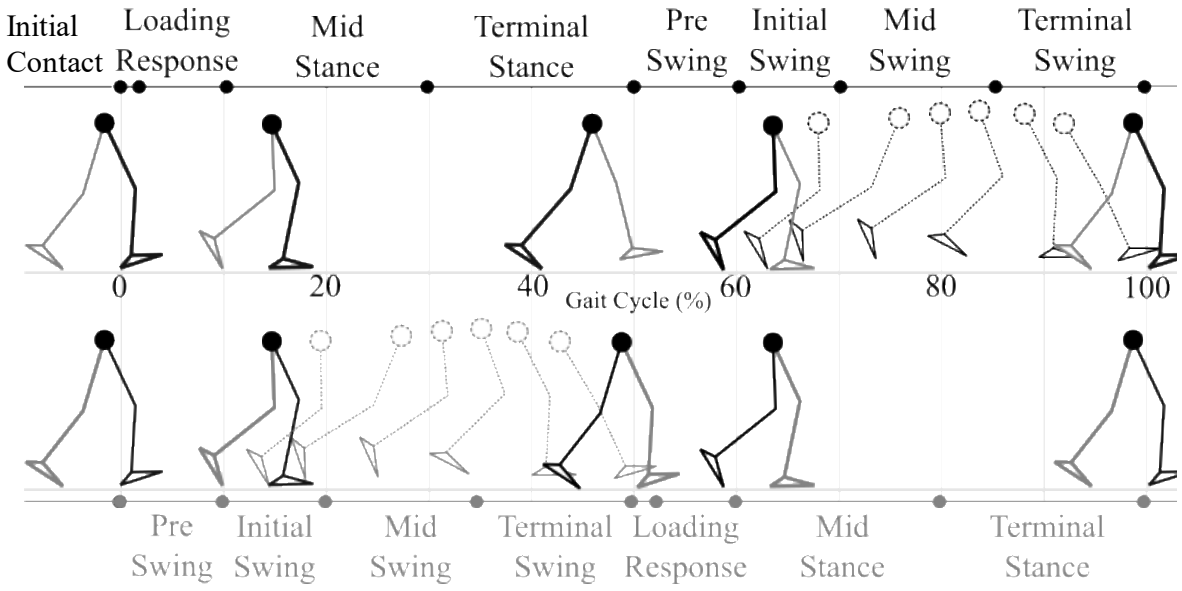



*Figure 3-7: Gait cycle in eight phases.*

Normal unobserved gait speed is approximately 1.37m/s for men and 1.23m/s for women, (Finley, 1970) which equates to approximately 4.5 and 3.6 km/h respectively (Chan, 1994). At this speed the stance phase accounts for approximately 60% of the gait cycle (Mann, 1980).

The stance phase begins at heel strike (initial contact) and ends at toe off. The swing phase accounts for the other 40% of the gait cycle. This begins at toe off and ends at heel strike (initial contact). During the swing phase the foot is not in contact with the ground. For approximately 11% of the gait cycle a double leg support phase occurs. This begins when one leg contacts the ground at heel strike and the other leg is in the toe off phase but has not yet left the ground.

### *3.3.2.* Phases of gait

Subdividing the gait cycle into phases enables diagnosis of abnormalities to be confined to certain points in the gait cycle. There are several different ways to sub-divide the gait cycle depending on the granularity required (Table 3-1 and Figure 3-7).

| **Granularity** | **Gait Phases** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Two Phases | Stance | | | | | Swing | | |
| Three Phases | First Rocker | Second Rocker | | | | Swing | | |
| Four Phases | Heel Strike | Flat Foot | Heel Off | | | Swing | | |
| Five Phases | Heel Strike | Flat Foot | Heel Off | Toe Off | | Swing | | |
| Six Phases (1) | Initial Contact | Loading Response | Mid Stance | Terminal Stance | Pre-Swing | Swing | | |
| Six Phases (2) | Loading response | Mid Stance | Terminal Stance | Pre-Swing | | Swing 1 | Swing 2 | |
| Seven Phases | Loading response | Mid Stance | Terminal Stance | Pre-Swing | | Initial Swing | Mid Swing | Terminal Swing |
| Eight Phases | Initial Contact | Loading Response | Mid Stance | Terminal Stance | Pre-Swing | Initial Swing | Mid Swing | Terminal Swing |
| Eight phases gait (%) | 0-2 | 2-12 | 12-31 | 31-50 | 50-60 | 60-73 | 73-85 | 85-100 |
| Gait (%) | 0 | | | | | 60 | | 100 |

*Table 3-1: Subdivisions of the gait cycle based on granularity required.*

Examining the eight phases in more detail (see 'eight phases gait (%)' in Table 3-1 and Figure 3-7), initial contact accounts for the first 2% of the gait cycle and occurs during the double limb support phase (J Perry, 1992). In normal gait, initial contact is made with the heel. During this phase impact deceleration occurs. Phase 2 is the loading response which accounts for the next 10% of the gait cycle and is also contained in the double leg support phase (J Perry, 1992). During this phase shock absorption, stability, and forward progression occur. Phase 3 is mid-

stance and is the first phase of single leg support. The mid-stance phase accounts for the next 19% of the gait cycle. During this phase the body centre of mass progresses over a stationary foot (J Perry, 1992). The fourth phase is terminal stance which accounts for a further 19% of the gait cycle during which the heel rises. During this phase the body centre of mass progresses beyond the supporting foot (J Perry, 1992). The fifth phase is pre-swing which accounts for 10% of the gait cycle and is once again in the double leg support phase as the opposite side has made contact with the ground. There is a 'push' during pre-swing to prepare the leg to swing through (J Perry, 1992). The sixth phase is initial swing which accounts for 13% of the gait cycle. This phase begins as the foot is lifted from the ground. Initial swing is followed by the seventh phase, mid swing. The mid-swing phase accounts for a further 12% of the gait cycle and ensures the foot continues to travel forward and clears the floor (J Perry, 1992). The final 15% of the gait cycle occurs during the eight phase, terminal swing. During this phase limb advancement is completed and the limb is prepared for initial contact (J Perry, 1992).

The stance phase can also be divided into 4 rockers accounting for the pivot system which allows for progression of body weight in a forward direction (Jacquelin Perry, 1992):

1. Heel rocker – the first rocker occurs when the heel strikes the floor through to flat foot. There is controlled deceleration of the foot using the dorsiflexors and acceptance of the body weight. This rocker occurs around the 'rounded' calcaneum.
2. Ankle rocker – this second rocker occurs as the body weight moves forward and the tibia advances in front of the ankle foot complex.
3. Forefoot – this third rockers occurs as the centre of pressure reaches the metatarsal heads and the heel rises. The rocker occurs around the metatarsals.
4. Toe rocker – the fourth rocker occurs as the toes 'push' to accelerate the limb forward.

The 4 rockers explain the movement of the centre of pressure (CoP). The CoP begins at the heel on the lateral aspect and progresses across the plantar aspect of the foot through the rockers, to the head of the first metatarsal at toe off (toe rocker) (Figure 3-8) (Chan, 1994).

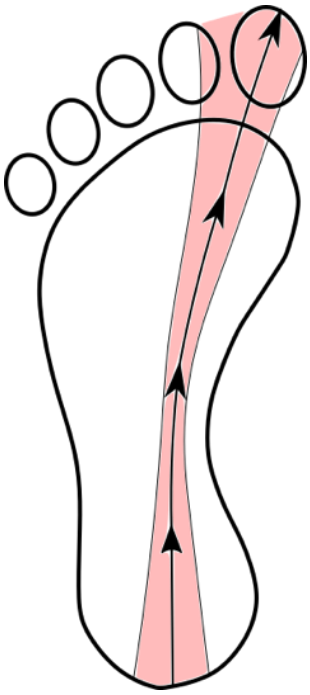


*Figure 3-8: Centre of Pressure progression during gait, starting at the heel at initial contact and progressing anteriorly and medially until toe off.*

### 3.3.3. Normal Gait

Human locomotion involves walking upright with straight knees and hips, the most economical way to walk, and allows for efficiency over long distances (Kramer, 1998). Bipedal gait usually begins between 12 and 18-months old and by the age of 5-7 years the components which contribute to gait are set with little variation (Dubin, 2014). All components of gait work to minimise vertical movement of the individual's centre of gravity to optimise efficiency of energy expenditure and contribute to the correct placement of the foot (Dubin, 2014). Gait can be considered to be a series of balance and losses of balance to move the body forward. After each movement forward, balance must be regained with foot placement (Irvine, 1993). Gait is not a passive movement and the musculature must be used to maintain continual forward propulsion.

As described, normal human gait begins with heel strike (J Perry, 1992) which is distinct from other animals who all make initial contact with the forefoot (Simonsen, 2014). The normal position of the forefoot to the floor at heel strike is 20-25 degrees (J Perry, 1992). In this position the foot is slightly plantarflexed or neutral, the knee is extended, and the hip is flexed

to approximately 30 degrees (J Perry, 1992). Following heel strike, controlled plantarflexion of the forefoot occurs via the eccentric action of the tibialis anterior and the toe extensors (the muscles of the anterior compartment of the leg supplied by the deep peroneal nerve). Rotation occurs around the heel (calcaneum) to allow for the forefoot to contact the ground. The talocrural joint and slightly supinated subtalar joints plantarflex and pronate as the forefoot is lowered to the ground. The knee flexes further as the weight begins to transfer forward (J Perry, 1992).

From the point of heel strike until toe off the movements of the foot and lower limb are based around the principle of a closed kinematic chain. This is as opposed to during swing when movements are based around an open kinematic chain. During an open kinematic chain, the calcaneus pronates and supinates about the talus through the subtalar joint. During a closed kinematic chain, the relative lack of freedom of the foot, which is constrained by the floor, results in the transfer of movement from the foot to the lower limb. The talus pronates and supinates about the fixed calcaneus and the movements of the lower limb are internal and external rotation of the tibia around the fixed foot.

On contact with the ground the foot is flexible and unlocked (Table 3-2). The medial longitudinal arch depresses and resistance of the lowering of the arch acts to absorb shock. Flexibility allows the foot to be lowered to the ground and adapt to uneven terrain. Flexibility is achieved by eversion (pronation) at the subtalar joint during a closed kinematic chain and internal rotation of the tibia and fibula at heel strike. The talonavicular and calcaneocuboid joints are ‘unlocked’, and a cushioning effect is created. External rotation of the leg occurs during mid and late stance with plantarflexion of the foot. The hindfoot inverts (supinates) increasing midfoot rigidity in the arch which has the effect of ‘locking’ the foot at the talonavicular and calcaneocuboid joints, to allow it to act a ridged lever for toe off (Chan, 1994). The foot is also stabilised by the ‘windlass’ effect of the medial longitudinal arch. This occurs as a result of the plantar fascia acting on the proximal phalanges. As the toes extend during toe off, the plantar fascia becomes tense and the medial longitudinal arch provides further stability to the rigid lever required at toe off.

| **Gait Phase** | Stance – closed chain | | | | | | Swing – open chain | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Tibia** | Internally rotating | | Externally rotating | | | | Internally rotating | | | | |
| **STJ** | Everting | | | Inverting | | | Everting | | | | |
| **Midfoot** | Increasing flexibility | | | Increasing stability | | | Increasing flexibility | | | | |
| **Gait Cycle (%)** | 0 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 |

*Table 3-2: Rotation and movement of lower leg and foot during a closed kinematic chain for stance and open kinematic chain for swing throughout the gait cycle resulting in changes in stability and flexibility. STJ=subtalar joint.*

The foot and ankle complex must have enough mobility to allow for all phases of gait to occur. If flexibility is lost, deviations at proximal joints occur to allow gait to continue. Just prior to swing, maximal plantarflexion has occurred of 20 degrees. The foot dorsiflexes 10 degrees during the initial phase of swing, recovering half of the plantarflexion achieved at toe off (J Perry, 1992). The foot continues to dorsiflex through the swing phase to a neutral position until heel strike occurs (J Perry, 1992). For normal walking the ankle requires approximately 10 degrees of dorsiflexion and 20 degrees of plantarflexion (Irvine, 1993).

There are four fundamentals for efficient walking (Jacquelin Perry, 1992):

1. Stability to accept and support weight during the stance phase
2. Foot clearance during the swing phase
3. Positioning of the foot for initial contact and loading
4. Mobility at the foot, ankle, knee, and hip for stride length

Efficient walking is achieved by the interplay of the hip, knee, and foot and ankle joints. Normal gait relies on muscle power to aid in energy conservation to produce efficient forward propulsion (Waters, 1999). Saunders et al (Saunders, 1953) proposed 'the six determinants of gait' theory which is still widely quoted today. Advanced gait analysis, however, has largely refuted the claims of Saunders that pelvic and knee actions prevented the vertical excursion of the centre of gravity to reduce energy expenditure (Gard, 1997; Kerrigan, 2001). Multiple further studies have further discredited the theory (Kuo, 2010). Instead, the inverted pendulum model of walking has been popularised. Energy efficiency is obtained through energy exchange and therefore there is little mechanical work (Cavagna, 1977). The stance and swing leg work like pendulums thereby reducing energy required (Mochon, 1980). This

theory was further developed to explain why walking costs energy and is the basis for the dynamic walking model (McGeer, 1990). The dynamic walking model states that as the heel makes contact with the ground energy is lost; this is referred to as a collision cost (Kuo, 2010). Energy input is required to reduce the loss from step-to-step transition. This energy loss can be compensated for by increased push (plantarflexion) at toe off, pre-emptive to the collision loss (Kuo, 2002). Pathology of the foot and ankle, and musculature of the lower limb, causes deviations in gait resulting in loss of these energy efficiency mechanisms. Loss of these mechanisms makes gait harder and results in deviation at proximal joints.

### 3.3.4. Gait Analysis

Gait analysis involves the description of skeletal motion (Westblad, 2002). It is the instrumented measurement of gait and interpretation of the associated movements (Baker, 2006). It provides measurements of joint kinetics and kinematics (Baker, 2006). Kinematic measurement is the movement of the body in space (joint angles) and kinetics concern the forces that cause that movement (ground reaction force, power, moment/torque). Gait can be analysed in several different ways. The simplest is observational gait analysis (Berger, 1992) which allows for the assessment of:

- Spatial descriptors (Figure 3-9)
    - Step length (one foot to the next)
    - Stride length (the same foot from initial contact to initial contact)
    - Step width
    - Foot angle (toe out)
- Temporal descriptors
    - Cadence (steps/min)
    - Stride time (time of gait cycle)
    - Step time
    - Walking speed or velocity (m/s)
- Trunk rotation
- Arm swing

Comparing right and left step length is a useful tool when assessing gait symmetry.

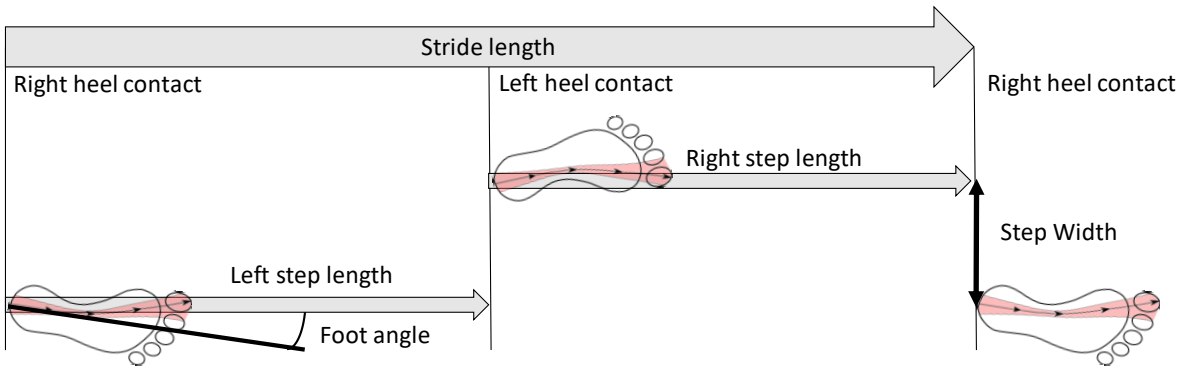



*Figure 3-9: Spatial descriptors of gait*

There are many more advanced approaches to assessing gait depending on the required output (Taborri, 2016). Gait assessment can be invasive or non-invasive. Examples of non-invasive gait assessment include footswitches and foot pressure insoles, as well as automated three-dimensional gait assessment methods. Invasive methods include the placement of intra-cortical pins. These methods are more accurate as soft tissue artefact is removed, however gait may be adjusted when pins are placed and the process may be painful (Westblad, 2002; Barton, 2011). Other options include the assessment of cadavers using fluoroscopic techniques and MRI (de Asla, 2006; Kozanek, 2009).

Footswitches and foot pressure insoles are the gold standard for gait phase detection (Taborri, 2016). These methods provide information on length of stance phase and swing phase. Instrumented insoles, such as the Pedar® system, also provide information on the progression of the centre of pressure. Gait analysis using automated three-dimensional systems with force plates in a gait lab is the gold standard for kinematic data (Brockett, 2016; Taborri, 2016). It also provides information on kinetics and gait phase. Joint angles are determined by motion analysis and gait phase is determined by the force plates which register heel strike and toe off.

Automated three-dimensional gait assessment systems involve the placement of skin markers on bony landmarks which are used to calculate 3-D spatial coordinates based on rigid body dynamics (Westblad, 2002). Markers are illuminated stroboscopically and a camera is used to detect the marker. If more than two cameras are able to detect the marker, then a position

can be determined (Cappozzo, 2005). Markers are between 9 and 25 mm in diameter (Baker, 2006). Systems are reliable with accuracy within 1mm (Chiari, 2005). The more cameras the more accurate the data and the easier it is to process after capture (Jacquelin Perry, 1992). No less than 60Hz is required, with most systems using 100-120Hz to allow for capture of complex movements. In modern systems markers can be labelled in real time improving accuracy, whereas traditionally markers were labelled after the data was captured. The information of the position of the marker can be used to provide outputs including joint kinetics and kinematics (Baker, 2006).

Several different models are offered for calculation and interpretation of these results. The Vicon system (Oxford) is the most widely used system in the UK. It uses the Vicon Clinical Manager (VCM) Plug-in Gait (PiG) model to process data providing kinematic data and if force plates are used, kinetic data (Baker, 2006). It is based on the conventional gait model (CGM) originally developed in both Newington Children's hospital and the Helen Hayes Hospital (McGinley, 2009). It has been widely used in research and is considered robust. Although reliability has been assessed by numerous studies the accuracy of results has been subject to far less research (McGinley, 2009). A large degree of variability has been demonstrated when analysing results of the same subject from different gait labs (Kadaba, 1989, 1990; Noonan, 2003; McGinley, 2009). Reliability within labs is however much better. Error comes from either incorrect calibration due to incorrect marker placement or errors by the system in detection of markers due to lab set up (Westblad, 2002). Error can also occur if the incorrect marker set up is used for a particular model. For example, the PiG model requires placement of markers on the lateral aspect of the thigh and tibia, equidistance with reference to the anterior-posterior position, although the superior inferior position is less important. If markers are not placed centrally errors can accumulate in the model outputs with more distal joint calculations. Error also stems from soft tissue artefacts with the movement of markers on bony landmarks due to the soft tissues (Baker, 2006; Barton, 2011). To minimise error the correct biomechanical model must be chosen based on the lab set up, the marker set used on the individual, and the familiarity of the researchers with the software. Where appropriate a combination of biomechanical models may be required to provide the most accurate results with different models used for different gait variables.

To ensure accuracy of data, gait data can be compared to normative data sets matched to the biomechanical model used to process the data for kinematics and kinetics. Gait analysis is used clinically to provide an objective measure of the deviation of pathological gait from normal gait (Pinzone, 2014), although it must be recognised that in a gait lab idealised gait may occur from the subject who is focusing on their gait pattern and may not represent their usual everyday gait pattern over uneven terrain with external distractions (Baker, 2006).

Data for a 'healthy' individual is presented in Figure 3-10. Gait analysis data is presented as joint angles (Figure 3-10a) for the ankle, knee, and hip. Angle data is usually presented as sagittal angles as this represents the most reliable data with minimal soft tissue artefact (Duffell, 2014). Sagittal data for the ankle angles represents dorsi (positive data in graphs) and plantarflexion (negative data in graphs), and for the hip and knee, flexion and extension. Sagittal plane data is also provided for internal joint moments.

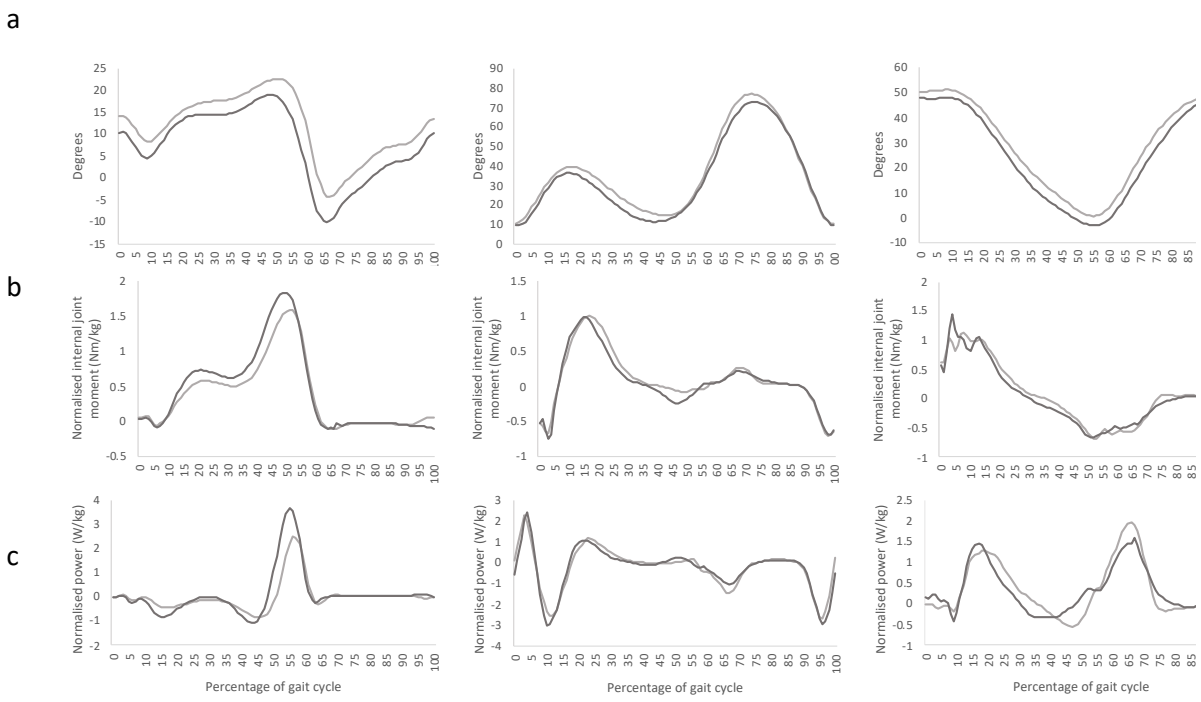



*Figure 3-10: Healthy gait data. a) ankle, knee and hip angles. b) ankle, knee and hip internal joint moments. c) ankle, knee and hip power data. Light grey lines represent left, and dark grey lines represent right.*

Ankle moments (Figure 3-10b) demonstrate dorsiflexor moment at heel strike. The forefoot is then lowered to the ground by the action of the dorsiflexors. Plantarflexor moment then dominates (positive movement in Figure 3-10b) as the leg shank progresses forward resulting

in progression of the centre of mass. Plantarflexor moment continues up until toe off when dorsiflexion takes over to allow for toe clearance during the swing phase (negative movement in Figure 3-10b).

Ankle power can also be measured (Figure 3-10c). When the value is negative this corresponds to the plantarflexors working eccentrically. The most power is generated by the plantarflexors prior to toe off during the toe rocker phase at the end of double leg support (Brockett, 2016).

When assessing a subject's gait, it is necessary to distinguish gait adaptations due to pathology and the adaptations due to walking speed. Increased walking speed affects joint kinematics, ground reaction forces, and muscle activity (van der Linden, 2002; Nymark, 2005). At slow speeds a straight leg in early stance supports the centre of mass against gravity whereas with increased speed Vasti and Soleus provide this support with a flexed knee (Liu, 2008). Analysis of gait and comparison to normative values must be undertaken with matched gait speed. It is not enough to undertake comparison of SSWV without knowledge of the speed, as walking speed mismatch occurs between SSWV of pathological and normal gait. Comparison of kinetics and kinematics to reference data or control groups must be matched to velocity where possible (Schreiber, 2018, 2019).

When assessing gait in the literature, symmetry has been assumed between the left and right leg. This results in studies either presenting only the results for the left or right or combining the results of the left and right for a given gait variable. Clinically, this has led to the assumption that a finding of asymmetry in gait is pathological (Sadeghi, 2000). Symmetry of gait has been defined as the perfect agreement of the left and right limb (Soudan, 1982; Hannah, 1984; Herzog, 1989; Eng, 1995; Vaughan, 1999) or when no statistically significant difference exists between the left and right (Hamill, 1984; Gundersen, 1989; Griffin, 1995; Hesse, 1997). Although symmetry has been demonstrated using these definitions, visual inspection of Figure 3-10 (assessing a healthy individual) reveals that there is not perfect agreement between the left and right. A degree of asymmetry has been noted to be entirely normal during gait with each limb acting in a different role during the phases of gait, either supporting or propelling the body (Riley, 1977; Herzog, 1989; Õunpuu, 1989; Sadeghi, 2000).

To quantify asymmetry and allow for the normative reference range to be found, and hence understand what is pathological, various symmetry indices have been proposed. The simplest is the symmetry index (SI) introduced by Robinson et al (Robinson, 1987) which has been used to assess both pathological and normal gait (Herzog, 1989; Becker, 1995).

$$SI = \frac{X_R - X_L}{½(X_R + X_L)} \ 100\%$$

$X_R$ represents any gait variable for the right and $X_L$ the same gait variable for the left. If the number is positive, then the right has a greater magnitude and if the number is negative then the left has a greater magnitude. If the number is 0% then there is perfect agreement between the left and right. Literature examining gait symmetry has reported up to 20% of gait asymmetry in healthy populations (Herzog, 1989; Jeleń, 2008).

## 3.4. Pathological gait following trauma

Injury, resulting in the loss of any of the components required for walking, produces adaptive mechanisms to continue movement enabling forward progression of gait (Jacquelin Perry, 1992). Any injury which compromises the use of muscles or joints in the lower limb can produce inefficient gait which can require up to twice the energy of normal gait (Waters, 1999). Patients will therefore perform substitutions during the gait cycle to compensate for any disturbance in normal gait to attempt to minimise the increase in energy required (De Visser, 2003). The ability to compensate will depend on the degree of disability (Waters, 1999).

As described in the previous Chapter, LS surgery is performed for complex injuries to the foot and ankle. Limb salvage populations are heterogenous with potentially numerous injuries resulting in gait deviations. Post LS surgery, despite efforts intraoperatively to minimise abnormalities, gait has been noted to change. Slower walking speed has been observed and the inability to maintain adaptive mechanisms under visual and cognitive distraction is evident (de Visser, 1998). This may be due to the loss of proprioception which cannot be compensated for other than with visual cues. Certain gait deviations post LS surgery are predictive of outcome. Slower preferred walking speed, a lengthened stride time, a deterioration of balance control, and a concomitant involvement of the knee joint are all associated with longer LS recovery times (Hertel, 1996; de Visser, 1998; De Visser, 2000).

A functionally acceptable level of gait without an aid, which allows for basic independent living, can be gained by 15-months post limb salvage surgery. This gait pattern is recognisably disturbed by external distraction due to the need to concentrate on each step and the aforementioned decrease of proprioception; gait therefore requires increased energy and concentration (De Visser, 2003). Normal or minimal required walking speed is defined as >1.2 m/s (>4 ft/s). This is an appropriate speed based on both limb salvage and amputee outcomes, and is equivalent to average healthy unobserved walking speed (Isakov, 2000; De Visser, 2003). Full functional return however requires speeds of 1.3-1.5 m/s (4.4-4.9 ft/s) (Dietmair, 2009). The most significant factors predicting inability to walk faster than 1.2 m/s (4 ft/s), after LS surgery, on flat ground, are <50° of plantar flexion of the involved ankle, nonreciprocal stair climbing, and knee flexion strength of grade <4 ($p<0.05$) (Archer, 2006). Daily activities require patients to be able to walk on more than just flat ground and they should be able to perform dual-tasks without deterioration in gait pattern or balance (de Visser, 2001; De Visser, 2003). Additionally, military patients may wish to attain more than just ambulation with a desire to return to running and sports participation therefore necessitating potential augmentation (Owens, 2011).

As stated, LS surgery is performed for complex foot and ankle injuries with multiple underlying pathologies. Gait deviations can therefore affect the stance and/or swing phase of gait (Dubin, 2014). Gait deviations as a result of LS surgery can be categorised as due to (Jacquelin Perry, 1992):

1. Deformity
2. Muscle weakness
3. Pain

LS surgery may also necessitate ankle or hindfoot fusion. Therefore, for the purposes of this Chapter, gait deviations because of ankle or hindfoot fusion will also be discussed. A summary of the gait changes due to pathology, categorised by stages of the gait cycle, can be found in Table 3-3 at the end of the Chapter.

### 3.4.1. Deformity

Deformity occurs when there is insufficient range of movement (RoM) at the foot and ankle joints to allow for the required movements during gait (Jacquelin Perry, 1992). This may occur as a result of muscle contractures following trauma, skin grafting, or as a result of prolonged disuse after injury (Hof, 2001). Contractures can be classified as either elastic or rigid. Elastic contractures are common following disuse and can be overcome with a force less than body weight. Rigid contractures require more than body weight to move and hence cannot be overcome during gait.

An elastic plantarflexion contracture will allow for the foot to be placed flat during gait however may result in the toe contacting the ground during the swing phase as the power of the dorsiflexors cannot overcome the resistance. This type of contracture may result in gait abnormalities and adaptations like those seen with weakened dorsiflexors (see Figure 3-12). To overcome the plantarflexor deformity, an external force is required to keep the foot in a more dorsiflexed position. This can be achieved with the use of an external ankle foot orthosis (AFO). Conversely, a rigid plantarflexion contracture prevents the foot from being placed flat on the ground without compromising tibial advancement (Figure 3-11). To compensate and allow tibial advancement with a flat foot, the knee must flex early, and the heel must also rise early. Surgical intervention is required to release the rigid contracture and an AFO can be used to provide sagittal support ensuring correct heel placement and controlled lowering of the toes to the ground.

Dorsiflexor contractures result in normal heel contact but an inability to lower the forefoot to the floor. To compensate and achieve a flat foot during midstance, the knee must flex during loading response and there is excessive tibial advancement during mid stance. There is also a prolonged heel contact period during terminal stance (Figure 3-14). The swing phase is unaffected. Gait adaptations are not dissimilar to those seen with weakened plantarflexors during the stance phase (see Figure 3-11). To aid in appropriate timing, an AFO can be used. This helps to normalise gait pattern by providing support for sagittal movements of the foot and ankle.

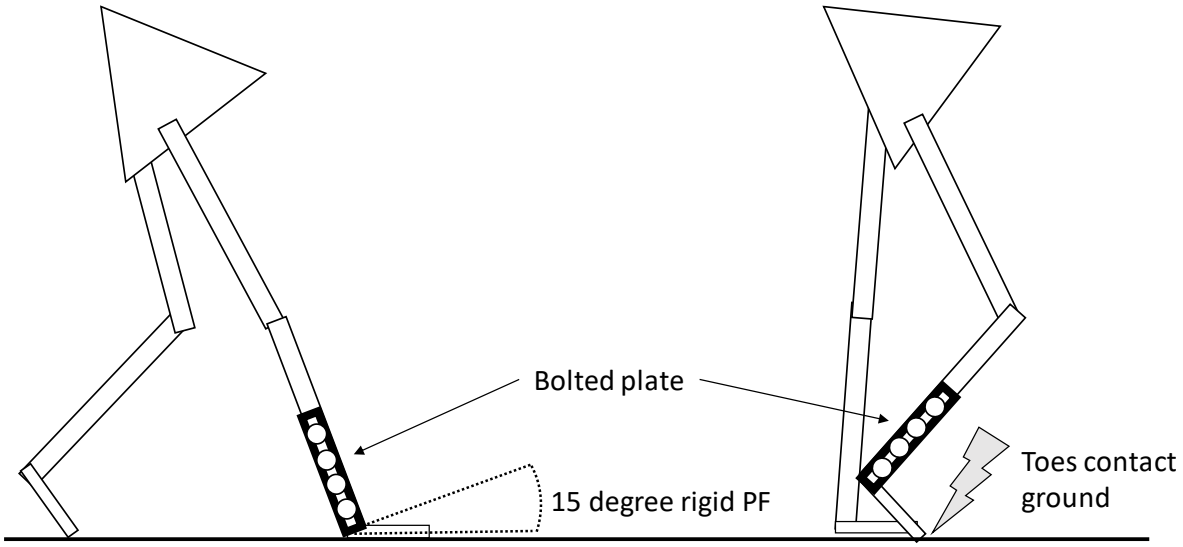



*Figure 3-11: 15-degree plantarflexion contracture. If the contracture is elastic, then it can be overcome during gait. If it is rigid as in this diagram, (marked by bolted plate) it cannot be overcome during gait and tibial progression does not occur. With both elastic and rigid contractures, increased hip flexion is required for toe clearance during swing to prevent the toes contacting the ground. PF=plantarflexion.*

### 3.4.2. Weakness of ankle dorsiflexors and/or plantarflexors

Weakness of ankle dorsiflexors (tibialis anterior, extensor hallucis longus, and extensor digitorum longus) results in either a slapping sound as the forefoot contacts the floor or in foot drop (Marciniak, 2013). Foot drop can be due to sciatic nerve neuropathy impacting the common peroneal nerve, injury to the common peroneal nerve as it winds round the fibula at the knee, deep peroneal nerve neuropathy, or a central polyneuropathy. Impairment of the dorsiflexors is most evident at initial contact, loading response, and mid swing. Dorsiflexor weakness prevents an individual from placing the heel effectively at the start of gait (Figure 3-12). Alternatively, the heel may be placed but the foot slaps to the floor with rapid plantarflexion. If initial contact is made with the toes there is uncontrolled lowering of the heel to the ground (Figure 3-12). The heel rocker is compromised and the pattern of loading deviates from normal (Jacquelin Perry, 1992). The individual can also not slow the progression of the centre of mass after foot placement during the loading response phase (Liu, 2006). The remaining phases of stance are unaffected by weakened dorsiflexors. The swing phase is however compromised.

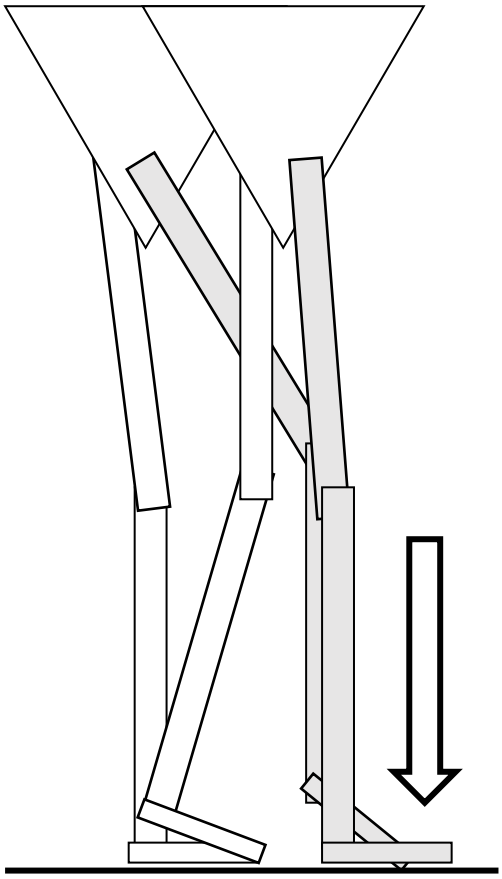


*Figure 3-12: Foot drop gait. Forefoot contact with the ground at initial contact due to impairment of dorsiflexors. Rapid drop of the heel to flat foot.*

Foot drop effectively creates a long limb as the individual is unable to dorsiflex the foot during the swing phase of gait in a similar way to a plantarflexor contracture (Figure 3-11) and the toes may contact the ground. To compensate for weakened dorsiflexors it is necessary to attempt to shorten the limb during the swing phase. This is achieved through a steppage gait, or circumduction and abducting the limb. A steppage gait involves a flexed knee and hip to attempt to shorten the limb during swing. This requires muscle activation and is inefficient. Alternatively, circumduction and abduction move the limb away from the midline of the body and by leaning the body away from the limb allows for the limb to be effectively shortened. Ultimately, weakness of the dorsiflexors may lead to contracture of the plantarflexors due to lack of stretching.

Gait analysis of sagittal ankle angles on an individual with weakened dorsiflexors demonstrates initial contact in a plantarflexed position and asymmetry of angles throughout the gait cycle with reciprocal gait compensations on the contralateral side (Figure 3-13).

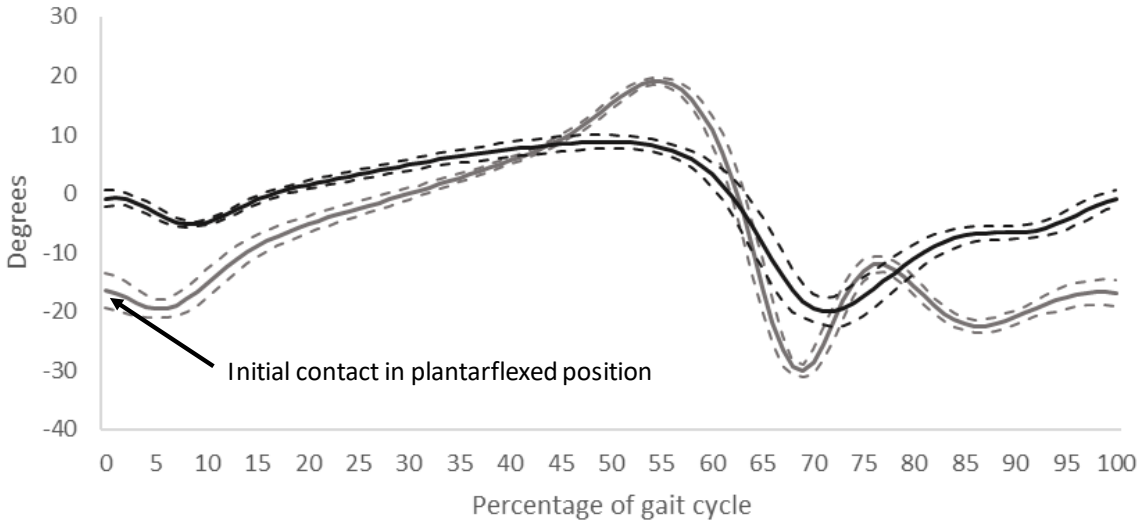



*Figure 3-13: Ankle sagittal angles throughout the gait cycle. The grey line represents the side with dorsiflexor weakness, and the black line represents the uninjured side with reciprocal gait compensations. The initial contact angle on the injured side demonstrates plantarflexion and contact with the toes.*

Injury to the Common Peroneal Nerve will result in not only weak dorsiflexors but also weak evertors of the foot (Peroneus Longus and Brevis). The lateral compartment of the leg containing the evertors of the foot is supplied by the superficial peroneal nerve, a branch of the common peroneal nerve (Garrett, 2020). This makes accommodation over uneven ground difficult and over time may result in *pes varus* leaving the foot in a fixed supinated position. The combined weakness of the dorsiflexors and evertors of the foot may lead to *per equinovarus* (Irvine, 1993).

Plantarflexor function is important in generating forward propulsion during terminal stance and toe-off (Neptune, 2001; Liu, 2008). Gastrocnemius and Soleus power are both vital in gait. The plantarflexes work to support the leg and trunk throughout single-leg stance and working oppositely to provide forward progression during late stance (Neptune, 2001; Liu, 2006). Soleus function is particularly important as walking speed increases (Liu, 2008). The plantarflexors are supplied by the tibial nerve. If the tibial nerve is damaged patients are

unable to progress their centre of mass in a controlled way from the hindfoot to the forefoot (Sutherland, 1980). Initial contact is made with the heel. The foot is lowered to the floor during loading response by the actions of the unaffected dorsiflexors. The plantarflexor muscles are then unable to slow the progression of the tibia during midstance. This places the ankle into excessive dorsiflexion. The knee flexes and the quadriceps fire to attempt to compensate resulting in further premature progression of the centre of mass. The weak plantarflexors allow for inappropriate ankle dorsiflexion due to unopposed action. Subjects cannot initiate pre-swing or generate power through toe off and the knee remains flexed (Figure 3-14) (Neptune, 2001).

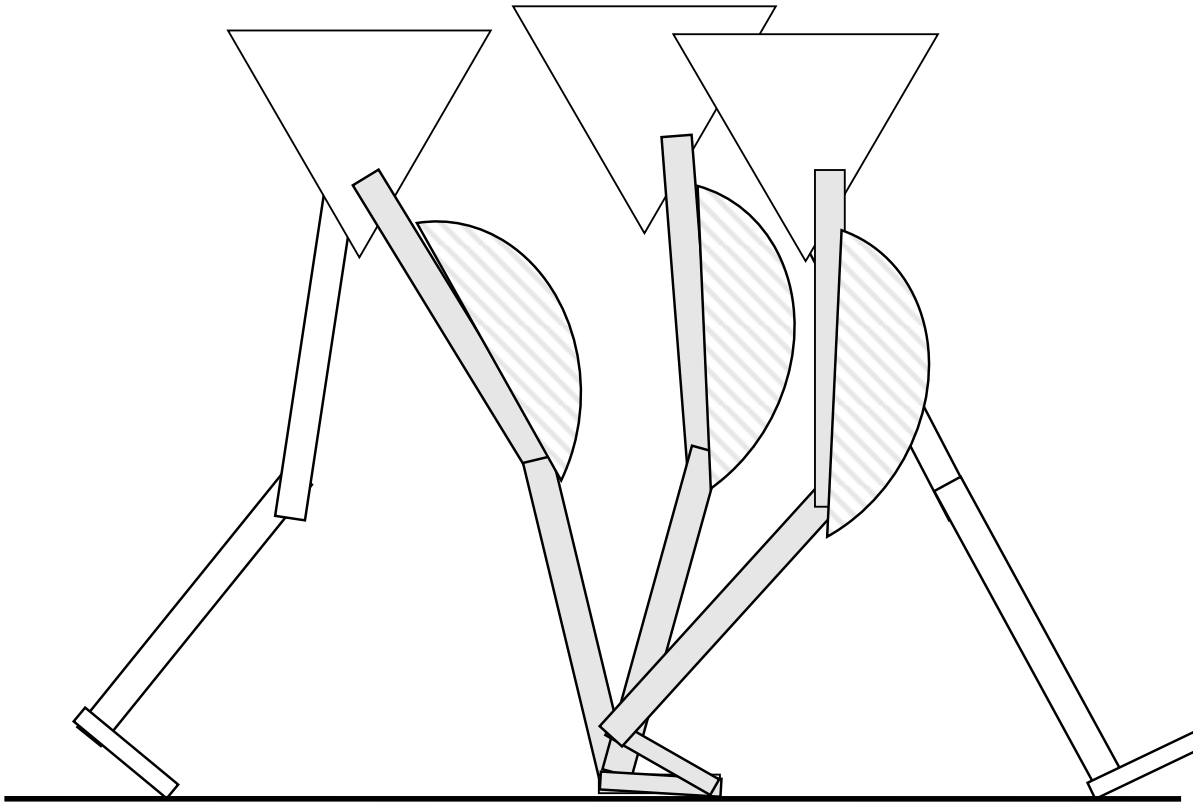


*Figure 3-14: Weakness of the plantarflexors results in unopposed action of the dorsiflexors. Early and uncontrolled tibial advancement occurs. The quadricep muscles flex the knee inappropriately. A late heel rise occurs only once the weight has been transferred to the other limb as reduced strength is required to raise the heel with sharing of load.*

To accommodate for plantarflexor weakness, individuals slow their gait, increase stance phase dorsiflexion and knee flexion on the weakened side, and decrease the percentage of the gait cycle spent on the affected side (Sutherland, 1980). This makes gait inefficient as the quadricep muscles must work concentrically, requiring additional energy expenditure and an

increased burden is placed on more proximal joints (Nadeau, 1999; Kuo, 2002; Lewis, 2008; Collins, 2010). Forward progression of the body is also slowed as stability is favoured over speed (Liu, 2008). To increase the speed and efficiency, an increase in hip flexor muscle activity is required to compensate for the weakened ankle plantarflexor muscles (Nadeau, 1999; Lewis, 2008). With increasing speed this compensation mechanism is overwhelmed and there is an increase in energy expenditure of about 20% (Saunders, 1953; Waters, 1999; Collins, 2010). Individuals are also not able to lift the heel of the affected side until the centre of mass has been transferred to the other limb, therefore double support time is increased (Figure 3-14) (Sutherland, 1980). Poor power generation is noted particularly at pre-swing on the injured side when undertaking gait analysis (Figure 3-15). The power generation demonstrates abnormal timing and is reduced compared to the uninjured (sound) side with asymmetry noted.

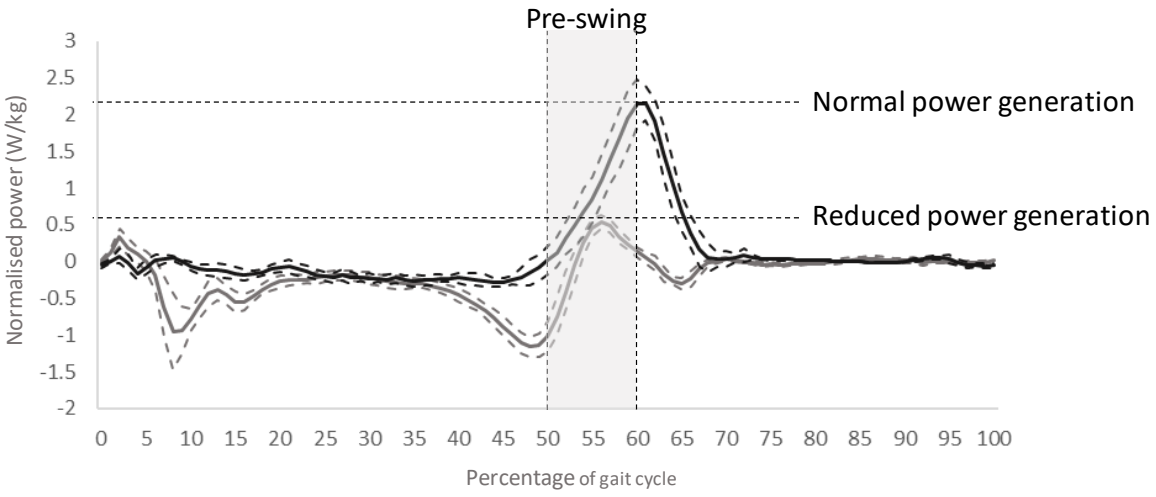



*Figure 3-15: Ankle power generation throughout the gait cycle, grey line represents the injured side, demonstrating poor power generation with abnormal timing at pre-swing. The black line represents the sound side demonstrating normal power generation building during pre-swing.*

Weakness in either the plantarflexors or dorsiflexors requires an external force to support the foot and augment function. Support can be provided by a passive AFO which ensures controlled lowering of the foot to the ground and support to sagittal plane movements. For weakness in plantarflexion action a dynamic AFO is required to store and return energy, augmenting function.

### 3.4.3. Mechanical Pain with loading the hindfoot/midfoot

Mechanical pain on loading of the foot and ankle is pain, which is present only on loading the foot, not at rest. Mechanical pain may be due to OA of the ankle joints. Degenerative arthritis of the ankle is rarer than that of the knee and hip (Barg, 2013). OA of the foot and ankle is more commonly caused by post-traumatic changes (Brockett, 2016). Incongruency in the joint line following fracture results in excessive contact stress at the joint and exceeds the capacity of the cartilage to repair (Saltzman, 2005). Following fracture of the ankle, post-traumatic OA has been shown to develop in 12-18 months (Lindsjö, 1981). Arthritic or degenerative processes at the ankle joint, subtalar joint, or midfoot joints will result in stance gait changes. These changes will shorten the stance phase of gait as the individual attempts to limit the amount of time spent on the painful limb (Murray, 1967; Stauffer, 1977; Fish, 1993; Khazzam, 2006; Valderrabano, 2007). Spending less time on the limb has the effect of reducing the load passing through the joint (Mündermann, 2005). Shortening the stance phase on the affected side results in lengthening the stance phase on the unaffected limb compared to controls and producing asymmetric gait (Barton, 2011). Double leg support time remains unchanged (De Visser, 2000). Gait is slower and there is a reduced ankle range of motion compared to healthy controls (Barton, 2011). There is particularly reduced sagittal plane ankle joint RoM secondary to pain resulting in reduced dorsiflexion and the foot held in a plantarflexed position in the stance and swing phase (Stauffer, 1977). With the ankle held in 15 degrees of plantarflexion the joint is at its most relaxed position with limited pressure placed on the joint capsule (Jacquelin Perry, 1992). Sagittal plane motion demonstrates the greatest reduction in RoM compared to controls, however all ankle RoM is reduced (Khazzam, 2006; Valderrabano, 2007). Particularly with regards to the hindfoot, there is reduced external rotation and reduced eversion from the loading response through to terminal stance (de Asla, 2006; Khazzam, 2006; Kozanek, 2009). Knee movement is also reduced by approximately $10^{o}$ (Philippe, 2008).

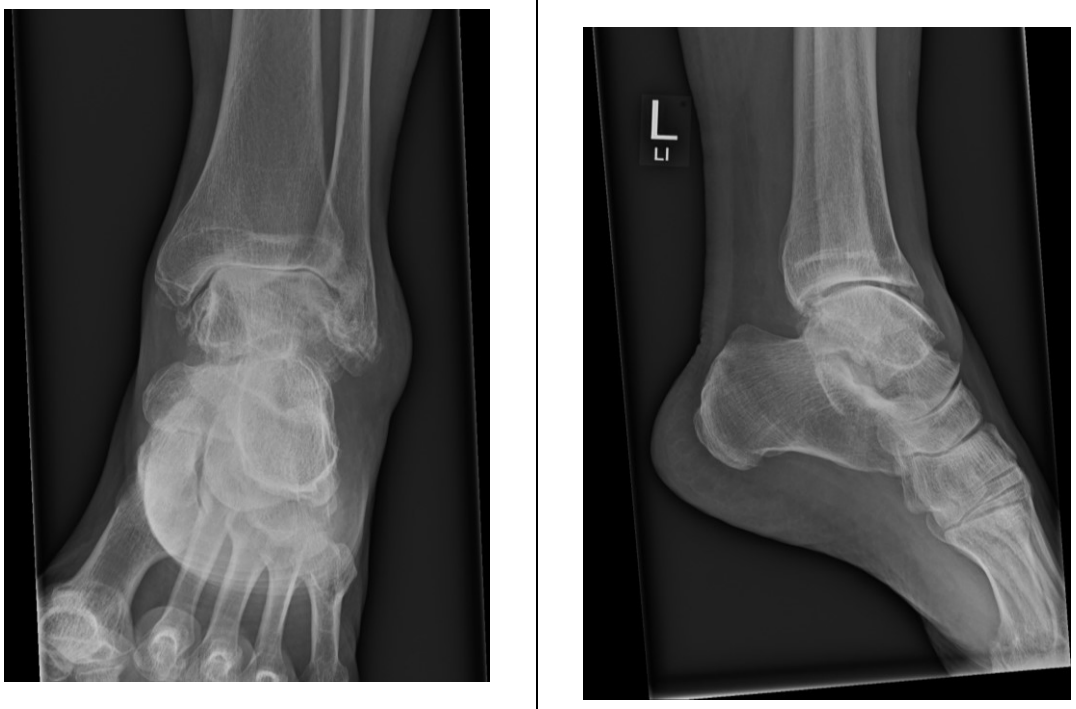
To overcome problems with pain during gait, patients often attempt to hold the pathological joint still. If the joint does not move, then pain is reduced. This can be achieved with surgical intervention using arthrodesis (fusion) techniques. Alternatively, external support can be placed around the foot and ankle in the form of an AFO to hold the painful joint or joints in a

static position during gait. To reduce pain further a load sharing device like a patella tendon bearing (PTB) AFO may be useful.

### 3.4.4. Ankle or hindfoot fusion

Arthrodesis (fusion) is the gold standard of treatment for end-stage ankle (Figure 3-16) or subtalar arthritis, as it relieves pain by preventing movement at the joint. Following ankle arthrodesis reduced pain has resulted in increased walking speed and symmetry of gait phases (Hahn, 2012; Ieong, 2020).

a

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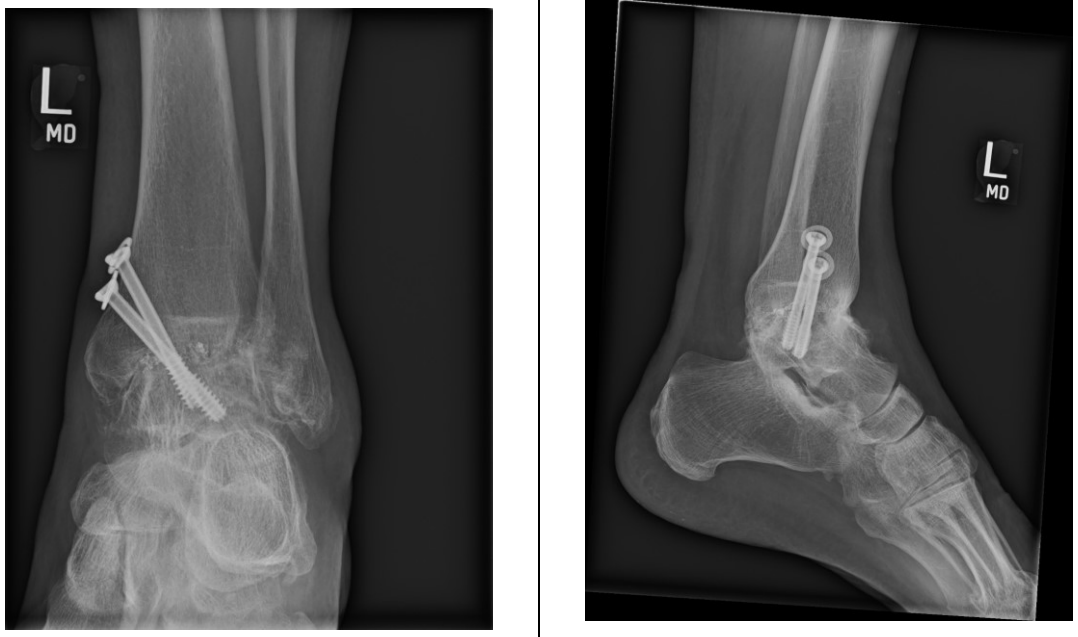


*Figure 3-16: Ankle arthritis radiographs and arthrodesis. a) Ankle arthritis with joint space narrowing and sclerosis. b) Fusion achieved with two screws. Reproduced with permission of the rights holder, Mr A Ramasamy.*

Gait changes following fusion include a reduced RoM of the ankle joint (Figure 3-17), altered ankle moment, and gait inefficiencies (Coester, 2001; Valderrabano, 2003). Patients have been noted to walk at speeds of 84% of the speed of controls following arthrodesis, with a 3% greater energy requirement, and a 10% reduction in gait efficiency (Waters, 1988, 1999).

Gait speed is noted to be reduced due to reduced cadence and stride length (Thomas, 2006). Of note, other studies have found speed to be reduced due only to reduced stride length with cadence similar to controls (Mazur, 1979; Beyaert, 2004). This disparity demonstrates variability between individual compensation mechanisms. Gait speeds are however notably increased for individuals post fusion compared to pre-operative levels (Mazur, 1979; Wu, 2000; Beyaert, 2004; Thomas, 2006; Philippe, 2008). Following fusion hypermobility of the midfoot may occur to compensate for the relative lack of motion at the ankle and/or subtalar joints (Waters, 1999; Brodsky, 2013; Chopra, 2014). There is also reduced hindfoot movement in the sagittal plane (Mazur, 1979; Wu, 2000; Thomas, 2006). These changes result in increased dorsiflexion stresses on the surrounding joints leading to degenerative arthritis at these joints (Coester, 2001; Fuchs, 2003).

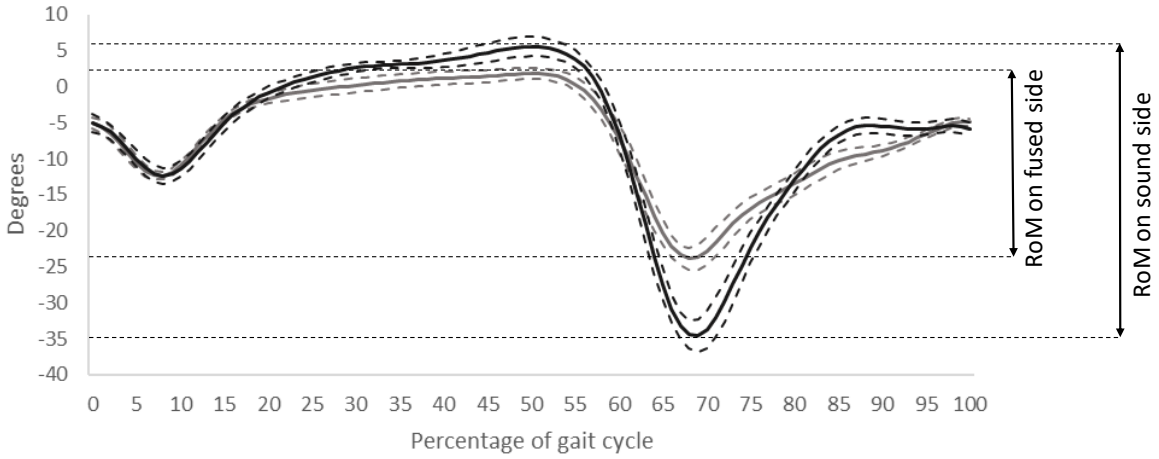


*Figure 3-17: Ankle sagittal angles during the gait cycle. Grey line represents fused side with reduced range of movement (RoM) compared to sound side.*

Patients continue to demonstrate asymmetrical gait after fusion due to a shorter stance phase on the affected side (Figure 3-18) (Philippe, 2008; Chopra, 2014). Following fusion, patients attempt to compensate for gait changes by altering knee flexion during stance compared to controls (Philippe, 2008). The knee must hyper-extend during the first rocker of gait to allow for the foot to be placed flat to the floor after heel strike due to a lack of flexibility at the fused joint (Mazur, 1979). The knee then flexes during midstance and once again hyper-extends during late stance (Mazur, 1979; Wu, 2000; Beyaert, 2004). The heel also lifts early to allow

for forward progression of the tibia (Beyaert, 2004). Following fusion there is a global reduction and forward shift in vertical ground reaction force with a reduced first peak due to early heel lift (Beyaert, 2004; Barton, 2011). Power generation at pre-swing is also reduced compared to the sound side (Figure 3-18). Despite all these changes, fusion improves gait over pre-op levels but does not restore it to normal levels (Philippe, 2008; Hahn, 2012).

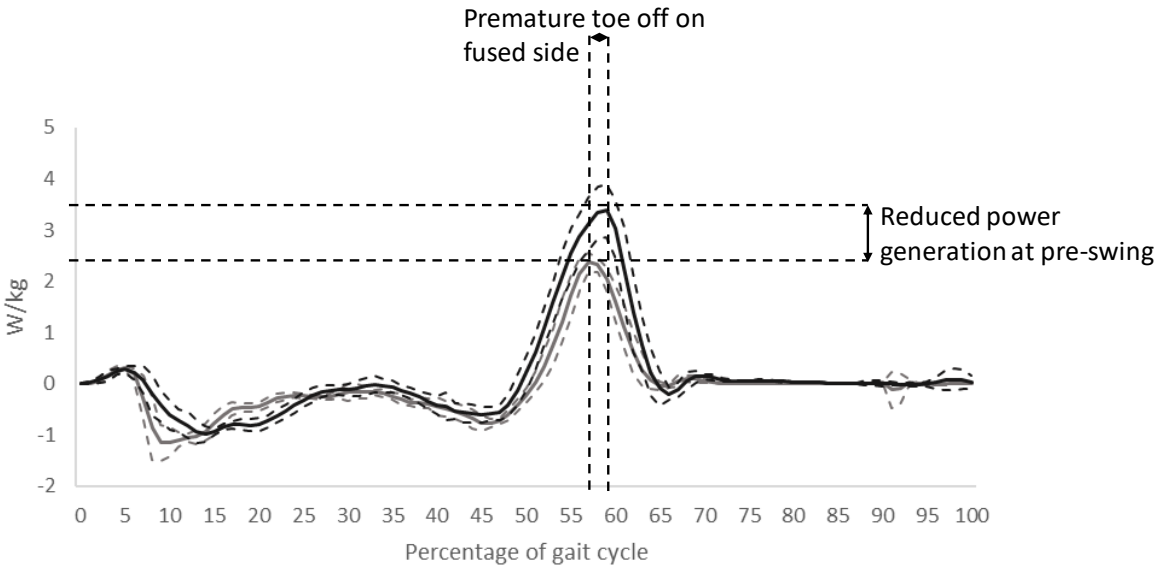


*Figure 3-18: Ankle power data throughout the gait cycle. Grey line represents fused side, black line represents sound side. Reduced power generation at pre-swing is noted on the fused side compared to the sound side. Premature toe off on the sound side is also noted demonstrating asymmetry through the stance phase.*

Although patients report reduced pain following fusion, there is limited return to impact sporting activity including running (Kerkhoff, 2017). To aid in power generation during terminal stance and pre-swing following arthrodesis a dynamic AFO can be applied to aid with power for toe off and to improve timing. Several types of lower limb orthoses exist, and the correct type will depend on the degree of augmentation and ultimate functional outcome required, including the need to return to sporting activity.

## 3.5. Summary

A summary of deviations from normal gait due to pathology is shown in Table 3-3.

| | | | Stance | | | Swing | | |
|---|---|---|---|---|---|---|---|---|
| **Pathology** | **Initial contact** | **Loading response** | **Mid-stance** | **Terminal stance** | **Pre-swing** | **Initial swing** | **Mid-swing** | **Terminal swing** |
| **Elastic DF deformity** | Heel strike | Increased knee flexion | Increased knee flexion | Delayed heel rise | Decreased power | Delayed | Normal | Normal |
| **Elastic PF deformity** | Toe strike | Yields to body weight, delayed heel contact | Normal or inhibited tibial advancement | Premature heel rise | Normal | Normal | Increased knee flexion to prevent toe contact with the ground | Unable to dorsiflex foot for initial contact |
| **DF weakness** | Toe strike, or heel strike with rapid drop of toes | Rapid heel drop or flat foot | Normal | Normal | Normal | Normal | Increased knee flexion to prevent toe contact with the ground | Unable to dorsiflex foot for initial contact |
| **PF weakness** | Normal | Normal | Normal or increased knee flexion | Delayed or no heel off | Delayed heel off | Normal or slightly delayed | Normal | Normal |
| **Hindfoot pain** | Toe strike as foot held at 15 degrees PF to reduce pain | Shortened loading response to reduce time spent on painful limb | Shortened | Normal | Normal | Lengthened | Lengthened | Lengthened |
| **Midfoot pain** | Heel strike | Shortened loading response to reduce time spent on painful limb | Shortened | Shortened | Reduced power due to pain when plantar fascia tightens | Lengthened | Lengthened | Lengthened |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Ankle fusion** | Heel strike | Increased knee flexion | Increased knee flexion | Normal or delayed heel rise | Sustained heel contact | Normal | Normal | Normal |
| **Hindfoot fusion** | Heel strike | Increased knee flexion | Increased knee flexion | Delayed heel rise | Sustained heel contact | Normal | Normal | Normal |

*Table 3-3: Summary of deviation from normal gait due to pathology. DF=dorsiflexion PF=plantarflexion*

## 3.6. Conclusion

Military personnel complain of reduced function and ability to participate in impact activities following LS surgery. Functional deficit and consequent deviations from normal gait are dependent on the injury or combination of injuries sustained. Gait is a complex process, and any injury may alter gait parameters. Common functional deficits include weakness of dorsi/plantarflexors resulting in a reduced ability to propel the body forward at the end of the stance phase of gait and modifications in the swing phase to avoid the toes contacting the ground. Adaptations to compensate for these changes are energy intensive. Individuals need something to augment function to prevent the toes from colliding with the ground and to increase toe off push and power generation. Patients also suffer with mechanical pain of the hindfoot and/or midfoot. To reduce pain, patients limit movement of the limb and hold the foot in 15 degrees of plantar flexion which results in toe contact rather than heel contact at the beginning of gait and pain on push off at the end of the stance phase. These individuals need an intervention to prevent movement of the joint to decrease pain and to augment function.

It is desirable to overcome these functional limitations regardless of cause and return individuals to pain free, efficient gait to prevent amputation. Although definitive surgical treatment such as arthrodesis may prevent pain, gait is altered and becomes inefficient; therefore, running may not be possible. Military personnel wish to return to running, sports participation, and impact activities. This may be possible with external augmentation in the form of an orthosis. Orthosis design varies depending on required external support. Ultimately a device must provide support of sagittal motion at the ankle and augment power. If the orthosis supports sagittal range of motion and augments power, it may be possible to return individuals to functional activities including running and military service. In the next Chapter the role of foot and ankle orthoses following trauma is examined with an emphasis on which orthoses have the required support and ability to augment, in order to return military personnel to an increased functional level.

# Chapter 4: The role of orthoses following foot and ankle trauma

## 4.1. Introduction

Chapter 2 demonstrated that military amputees show superior functional and patient reported outcomes compared to LS patients (Doukas, 2013; Ladlow, 2016). Chapter 3 highlighted pathological gait abnormalities occurring as a result of foot and ankle injury. Deformity, weakness of plantar or dorsiflexors, and mechanical pain, as well as functional deficits consequent of arthrodesis and nerve injury, are present in LS-patient populations following HELET. Functional outcomes are further reduced by resultant slower gait, asymmetry due to pain or functional deficit, and energy inefficiency. Consequently, return to military-duty rates are poor for LS patients and individuals struggle to participate in impact sporting activities including running (Sheean, 2014; Kerkhoff, 2017). Conversely, amputees were found to be more likely to engage in vigorous sporting activity than LS patients (Doukas, 2013).

In the UK, wounded Service Personnel rehabilitate at a centralised rehabilitation centre, the Defence Medical Rehabilitation Centre (DMRC). Regardless of injury or treatment, personnel are rehabilitated together, albeit with a bespoke package specific to the individual's injury. LS patients interact freely and rehabilitate alongside amputees affording personnel direct comparison of amputee and LS outcomes and rehabilitation timelines. Due to advances in prosthetic design and rehabilitation pathways, amputees often report improved pain and function in the early stages of rehabilitation compared to LS patients (Fergason, 2010; Ladlow, 2016). Consequently, LS patients have requested elective amputation in an attempt to accelerate improvements in functional and pain outcomes (Owens, 2010). Although improvements are seen for amputees compared to LS patients in the short-term, as highlighted in Chapter 3 it is desirable to avoid elective amputation due to long-term secondary health concerns.

Military personnel wish to return to running and sports participation following lower limb trauma and therefore a solution is required to augment function to allow LS patients to achieve outcomes in line with amputees, or population norms (Patzkowski, 2011).

Furthermore, military LS patients have cited activity limitation as a decision factor for elective amputation (Krueger, 2015). Therefore, augmentation of function for LS patients is important to prevent progression to amputation (Aravind, 2010; Owens, 2011; Patzkowski, 2011).

As highlighted in the previous Chapter, LS patients may suffer from weakness of plantar and/or dorsiflexors requiring support of sagittal plane ankle RoM and augmentation of power generation at pre-swing to improve functional outcomes. Additionally, where mechanical pain is present, load sharing during stance may also be required to offload the joint, and in some cases, this will need to be combined with limitations in the painful RoM, and power augmentation. The solution to aid LS patients may be an orthotic providing external augmentation whilst retaining the lower limb and avoiding amputation. AFOs are commonly prescribed for patients with conditions affecting the lower limb and are used for long-term treatment and short-term rehabilitation.

For amputees, technological advances in prosthetics over the past decade have been better than those seen in orthotics. LS patients requiring orthotics to augment function have been left wanting (Butowicz, 2017). The aim of this Chapter is to present the range of orthotics available for LS patients and discuss their applicability to the functional deficits present in military LS-patients with a view to returning Service Personnel to duty and impact activities including running.

## 4.2. Orthoses

The fundamental aim for civilians following lower limb trauma is to achieve functional weight bearing and allow for independent ambulation (De Visser, 2000, 2003; Archer, 2006; Crowe, 2019). Optimal outcomes for military HELET patients additionally include return to sporting activities, which can only be achieved in LS-patients through co-ordinated rehabilitation and where necessary, augmentation with orthoses. Orthoses are used in patients with functional deficits at the foot and ankle to improve gait and performance (Desloovere, 2006; Van Gestel, 2008; Bregman, 2010; Jeanne C Patzkowski, 2012). AFOs cover a wide range of different types with a variety of functions. These include supporting the foot and ankle, restricting painful motion, improving gait stability, ensuring toe clearance during the swing phase of gait,

assisting diminished ankle function, and improving gait efficiency (Lehmann, 1987; Churchill, 2003; Harper, 2014; Lusardi, 2016; Russell Esposito, 2017; Pongpipatpaiboon, 2018). These changes improve function and enable users to accomplish more of their ADLs (Churchill, 2003; Wiley, 2013). AFOs also prevent further injury in patients with ankle instability preventing progression to secondary injuries and protect underlying vulnerable tissue (Greene, 1990; Surve, 1994; Lusardi, 2013; Wiley, 2013; Crowe, 2019).

### 4.2.1. How do orthoses work?

An AFO is any orthosis that crosses the ankle joint but is distal to (does not cross) the knee (Fox, 2019). AFOs work on different parts of the gait cycle depending on design. The ideal orthosis should (Lusardi, 2016):

- Meet the individual's mobility goals
- Maximise stance stability
- Minimise abnormal alignment
- Aid swing clearance
- Pre-position the limb for heel strike at initial contact
- Reduce energy inefficiencies

The component parts of an AFO include a foot plate, lower spans or ankle trimline (ankle support), strut, upper spans or proximal trimline, and cuff or closure (Figure 4-1). The foot plate sits in the shoe and is attached to the ankle trim line. The ankle trim line can either be continuous with the foot plate or include an articulating joint. The struts continue proximally and attach to the proximal trim line. Although shoes alone may improve gait following trauma in the absence of orthoses, a further improvement in outcomes are seen with the addition of an AFO (Churchill, 2003).

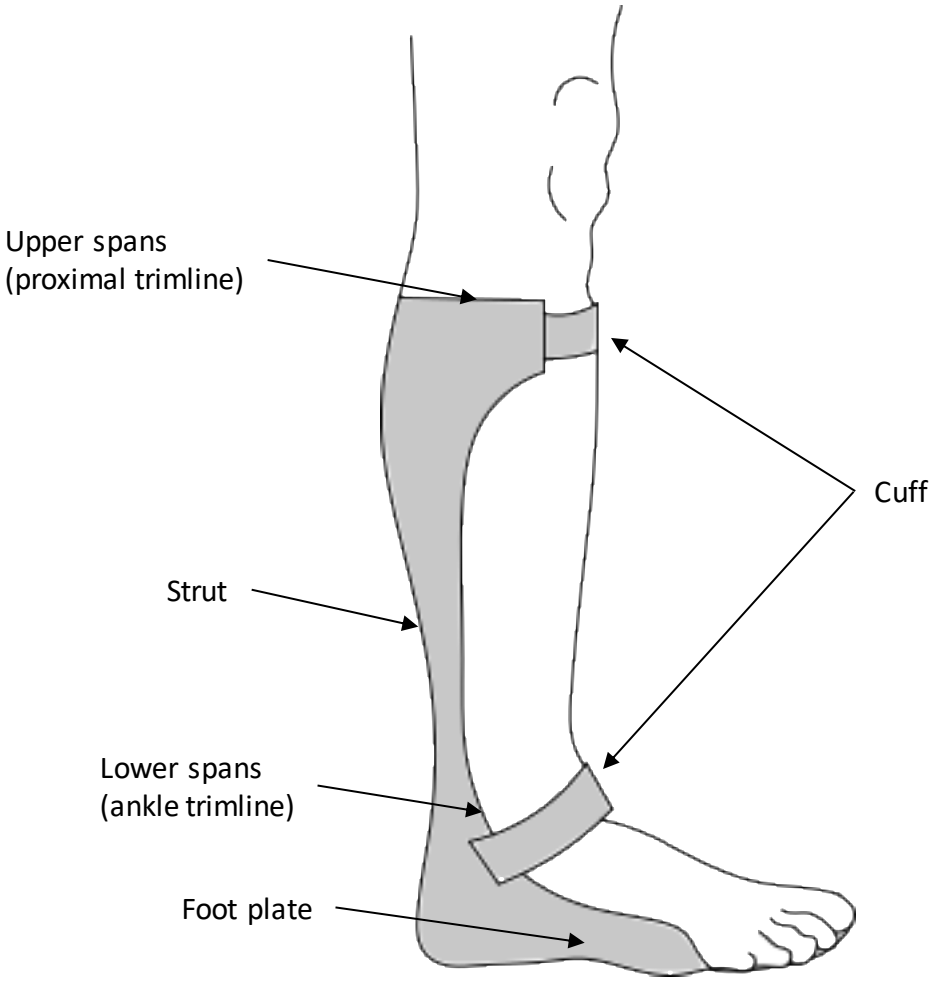


*Figure 4-1: Component parts of an ankle foot orthosis (AFO).*

The effect of an orthosis is dependent on the materials used, the assembly of the component parts, and the fit to the individual (Condie, 2008). Traditionally AFOs were made from leather, then plastics and more recently carbon fibre and other composite materials. AFOs can be custom built, bespoke to the patient or prefabricated. Prefabricated orthoses are cheaper and are usually immediately available however may cause fit problems for patients with an abnormal foot or lower leg shape. This may be particularly problematic for blast injury military patients who have abnormal lower leg shape or multiple skin grafts. Bespoke AFOs provide a more accurate and intimate fit and are modifiable to the individual's needs which may be beneficial for military LS patients. Bespoke AFOs are more expensive and take longer to procure.

### 4.2.2. What types of orthoses are available?

AFOs are either passive or functional (using motors to enable movement). Features to correct foot ankle deformities in passive AFOs are provided by the shape, material properties, and the thickness of the material used (Sumiya, 1996a, 1996b; Major, 2004; Bartonek, 2007a). Passive AFOs fall into two further broad categories: static or dynamic.

### 4.2.3. Static

Static orthoses prevent any motion at the ankle joint and dynamic orthoses allow some motion in the sagittal plane. All AFOs aim to provide sufficient support with minimal compromise of forward progression.

#### *4.2.3.1. Solid*

Solid AFOs are usually made from thermoplastics which are thin and light. Solid AFOs are comprised of a foot plate, ankle trimline, strut, proximal trimline and a superior cuff (Figure 4-2). Solid fixed AFOs provide most support and prevent movement in all planes at the ankle joint however they compromise forward progression of the tibia. Simple static AFOs hold the foot in position to allow for heel strike, aiding in control of forefoot descent, and support the forward movement of the body by increasing stability at the ankle in the mediolateral directions (Sumiya, 1996b; Neptune, 2001; Harper, 2014). Solid AFOs are of use for patients with dorsiflexor weakness who additionally require medial and lateral support. This level of support however comes at the cost of compromise of the rockers of gait. The first rocker of gait is compromised as the forefoot cannot be lowered to the ground in isolation, instead it lowers to the ground in a fixed position advancing the tibia concurrently causing abnormal knee flexion. The proximal cuff prevents the tibia moving further forward and therefore the second rocker is compromised. The final two rockers are compromised by the fixed angle at the ankle resulting in premature heel lift and reduced power generation at toe off (Delafontaine, 2017).

##### 4.2.3.1.1. Posterior shell orthosis

The most common solid AFO is the posterior shell orthosis (Figure 4-2). The posterior shell orthosis is a moulded sheet of plastic fitted to the leg posteriorly with a continuous foot plate.

The heel is held in place by the heel cup and the shoes. There is a strap proximally to hold the orthosis in position and apply a counter force distal to the knee (Figure 4-3). The flexibility allowed at the ankle can be changed based on the ankle trimlines (Sumiya, 1996b). If the aim is to completely limit ankle range of movement then the trim lines need to be extended anterior of the malleoli (Elattar, 2018). Conversely, if subtalar motion restriction is the main aim then the trim line can be posterior to the malleoli (Elattar, 2018). This prevents movement in the subtalar joint, allowing movement only in the talocrural joint potentially reducing subtalar joint pain (Sumiya, 1996b).

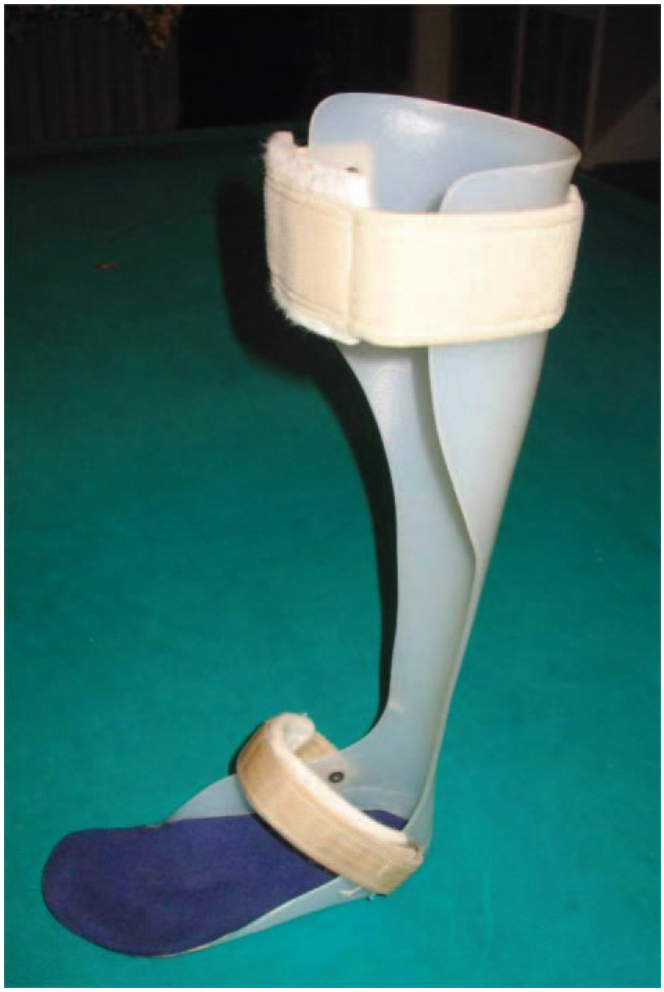

*Figure 4-2: Solid ankle foot orthosis. Reproduced with permission of the copyright holder, Sage Publishing.*

A posterior shell fixed orthosis is of use for patients with foot drop. Control of unopposed plantarflexion (foot drop) is provided during the swing phase of gait via a fulcrum applied over the dorsal aspect of the foot by either a strap or the laces/enclosure of the shoe, opposed by

the foot plate (Figure 4-3A). To counter dorsiflexion during stance the heel cup provides the counter force whilst opposing forces are applied over the distal and proximal anterior aspect of the leg by the shoe enclosure and proximal cuff respectively (Figure 4-3B). This is the basic mechanism of all AFOs of a similar design regardless of material used for manufacture.

An improvement in gait speed of 12% is seen following the addition of a solid AFO (Bregman, 2010). The gait is still recognisably abnormal with ongoing, though reduced, compensation mechanisms noted (Pongpipatpaiboon, 2018). By supporting the foot in dorsiflexion, orthoses decrease body vertical displacement during gait seen with a steppage gait and hence improve efficiencies (Lehmann, 1969; Danielsson, 2004).

Solid AFOs can be uncomfortable to wear secondary to increases in pressure due to the solid nature (Bishop, 2009). They are also of limited benefit when running as the plastic deforms too readily and there is minimal power augmentation (Major, 2004). To be of use for military patients the AFO would require modification to provide not only sagittal range of motion support but also mid stance offloading in the presence of mechanical pain, power augmentation at toe off, and material changes would be required to allow for impact activities.

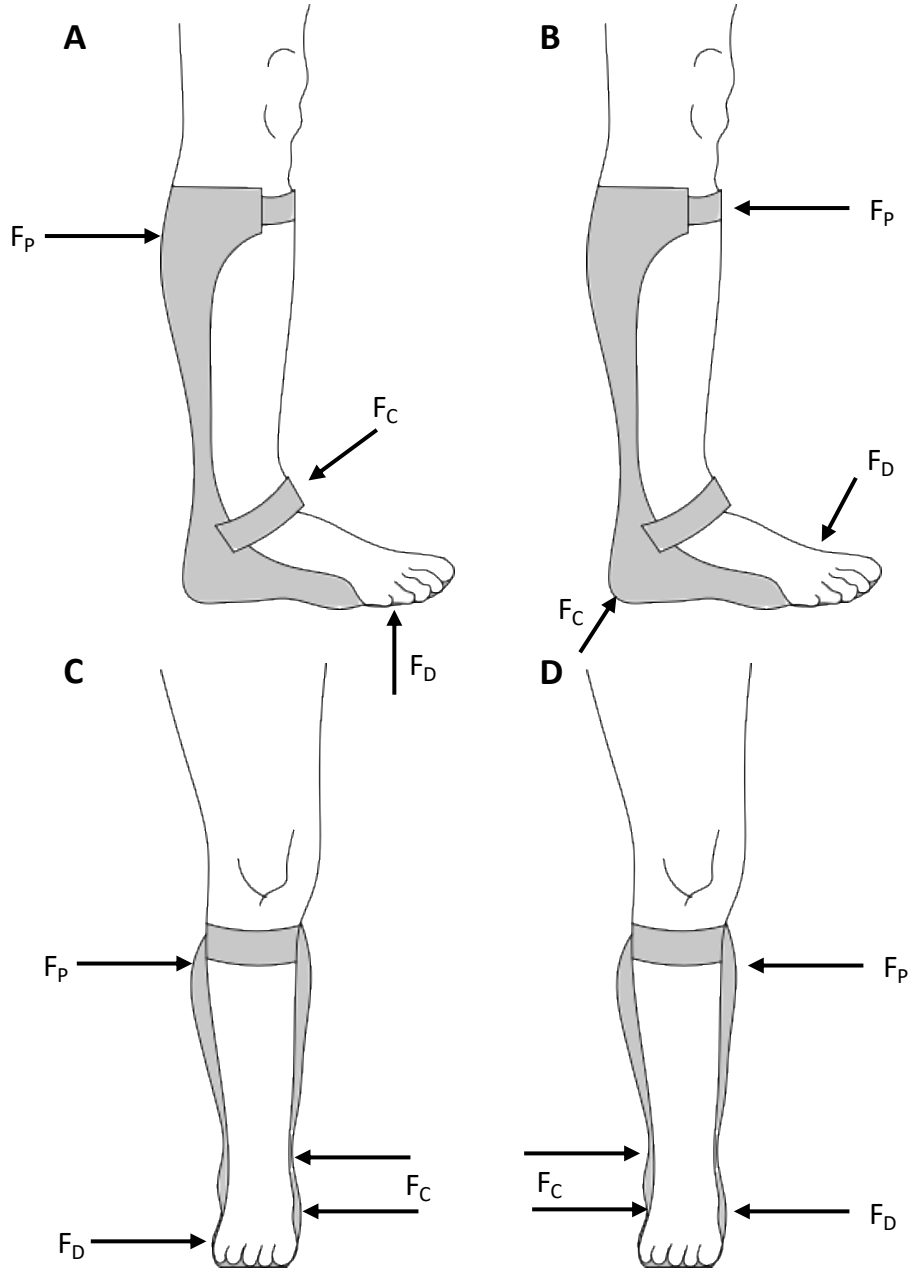


*Figure 4-3: Forces acting on a solid AFO. A: Plantarflexion control system during swing phase. Proximal force ($F_P$) at the posterior calf, with a distal force ($F_D$) at the metatarsal heads. The counter force ($F_C$) is supplied by the enclosure of the shoe (e.g. laces). B: Dorsiflexion control during stance phase. The $F_P$ is applied anterior to the proximal cuff, the $F_D$ is applied dorsally over the metatarsal heads by the shoe enclosure and the Fc is applied by the heel cup of the AFO. C: To prevent eversion during stance the $F_P$ and $F_D$ are applied by the lateral shell of the AFO whilst the $F_C$ is applied by the medial malleoli trim line. D: To prevent inversion the $F_P$ and $F_D$ forces are supplied by the medial proximal and distal shell of the AFO whilst the $F_C$ is applied by the lateral malleoli trim line* (Lusardi, 2016).

#### 4.2.3.1.2. Anterior floor reaction AFO

A modified type of solid AFO is the anterior floor reaction AFO (Figure 4-4). The anterior floor reaction AFO utilises the ankle plantar flexion-knee extension couple to prevent hyper flexion

at the knee seen with the posterior shell orthosis. The plantar flexion-knee extension couple occurs when a slightly plantar flexed ankle creates an extension moment at the knee aiding with knee control. It is most useful in lower limb trauma patients with nerve damage resulting in weakened dorsiflexion, or weakened quads (Harrington, 1983). It works in a similar way to a posterior shell AFO but with improved kinematics and kinetics during mid to late stance. The resulting knee extension moment is determined by the length of the foot plate and degree of plantar flexion the foot plate is set in. Padding anterior to the patella region is required for comfort due to the anterior nature of the force (Harrington, 1983). Commercial examples include the Anterior Leaf Spring. These orthoses, like the posterior shell AFO previously described, do not allow for running or impact activities.


*Figure 4-4: An anterior floor reaction AFO. This can be manufactured from thermoplastic or carbon fibre as in the picture. The anterior floor reaction AFO has a stiff long foot plate and is set in slight plantarflexion. The plantar flexion-knee extension mechanism is utilised in mid to late stance to extend the knee. There is padding anterior to the tibia for comfort. The anterior ankle trim lines provide added stability and prevent medial lateral movement at the ankle joint. Reproduced with permission of the Copyright holder, Elsevier.*

#### 4.2.3.1.3. Patella tendon bearing AFO

Another example of a modified solid AFO is the patella tendon bearing AFO (PTB-AFO). The PTB-AFO is a fixed AFO providing offloading of the ankle joint by preferentially placing the forces through the patella tendon and thus reducing axial loading of the distal limb during the stance phase of gait. A reduction in axial load reduces pain at the ankle joint. The anterior shell proximally has a patella bar and a medial and lateral flare. These are designed to hold some weight. The anterior shell is set at $10^{o}$ of flexion to take load which is transmitted down the struts to bypass the ankle and reduce axial loading through the ankle. This technique can be very useful for patients with post-traumatic OA to reduce mechanical pain. The PTB-AFO can also be of use in patients with tissue damage due to trauma which needs to be bypassed (Titus, 1975). The PTB-AFO relies on the knee being normal and muscle power also not being impaired, therefore cannot be used in patients with proximal nerve damage post trauma. Although a PTB-AFO provides the mid-stance offloading required by some LS-patients, and provides the sagittal RoM support required, it does not provide power augmentation and as with all other thermoplastic solid AFOs the lack of flexibility and energy return means it is not suitable for military patients wishing to return to impact activities.

### 4.2.4. Dynamic

In comparison to solid AFOs, dynamic AFOs have the potential to allow sagittal plane motion of the ankle. This is achieved by minimising the thermoplastic or other material trimlines in the ankle region to limit rigidity, altering the material to allow for flexibility, or by adding a mechanical joint. Dynamic AFOs also have the potential to provide proprioceptive feedback from the ground via the dynamic footplate (Elattar, 2018). Dynamic AFOs permit a variable amount of dorsiflexion during the stance phase whilst restricting plantarflexion during the swing phase of gait. Restricting plantarflexion during the swing phase allows the toe to clear the floor, whilst allowing for dorsiflexion during stance allows for more physiological ankle rockers of gait during stance.

#### *4.2.4.1. Thermoplastic Dynamic AFO*

There are two types of thermoplastic dynamic AFO: the flexible-rigid AFO and the articulated AFO. The flexible-rigid AFO is made from materials which can bend therefore the degree of

flexibility can be modified based on need via material and trim lines. The flexible-rigid AFO can be classed as flexible, semi-rigid, and rigid. The more flexible of these AFOs allow for some progression of the tibia however power generation at toe off is still reduced due to a block to plantarflexion (Hamdan, 2018).

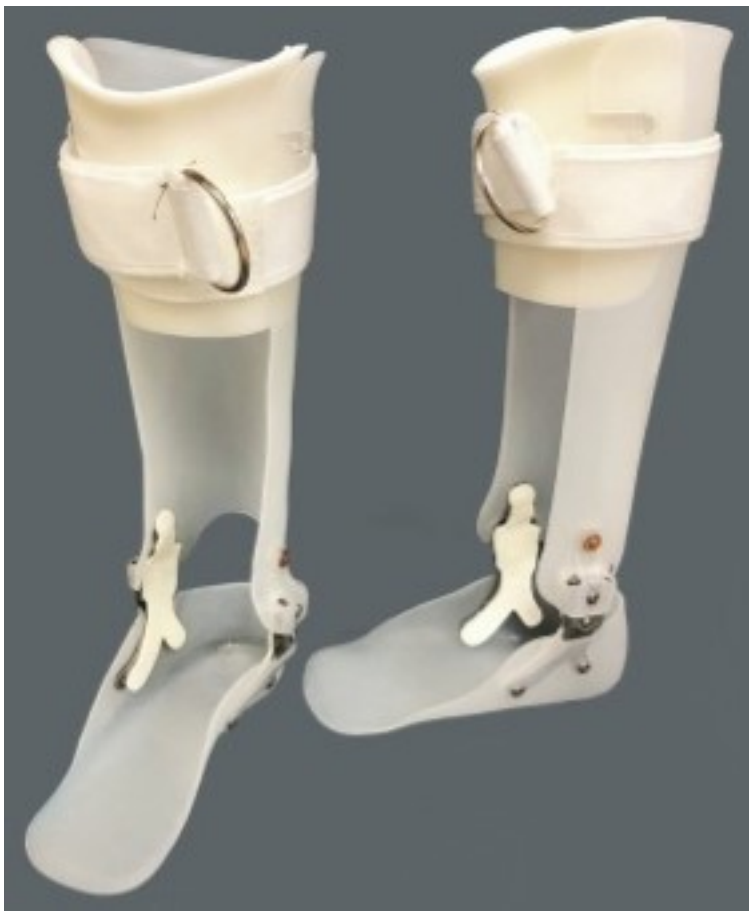

*Figure 4-5: Articulated AFO with a hinge at the ankle. The axis of the joint is aligned as closely as possible to the bending axis of the physiological ankle joint. This should reduce torque and shear forces. Reproduced with permission of the copyright holder, Elsevier.*

The articulated thermoplastic AFO is a modified version of the fixed AFO which incorporates a hinge at the ankle, with the advantage of allowing stretching of the Achilles to prevent spasticity (Figure 4-5) (Middleton, 1988). A hinge joint allows for some motion at the ankle during gait to augment function and allow forward propulsion of the tibia (Wolf, 2008). This type of AFO augments function in the second rocker and smooths out gait. The hinge joint can be allowed to provide free motion of the ankle or can be made with a block to prevent plantar or dorsi flexion as required. This type of orthosis is good for restoring functional gait

following trauma for patients with dorsiflexor weakness. It is also particularly useful for patients with subtalar arthritis as motion is controlled in the coronal plane, but normal ankle (talocrural joint) function can be retained. As the ankle can move, an articulated AFO is not useful if the ankle joint is also arthritic. An articulated AFO does not allow for running nor does it augment power for patients with plantarflexor weakness and therefore is not of use for military patients wishing to return to impact activities (Elattar, 2018).

If subtalar joint arthritis is the main complaint the University of California Biomechanics Laboratory (UCBL) orthosis may be of use. This dynamic AFO controls postural flexible deformities by holding the hindfoot in a neutral position, this stiffens and locks the transverse tarsal joints by keeping the calcaneus in a neutral position limiting pronation and forefoot abduction (Elattar, 2018). The UCBL can also have a supra-malleolar extension to support ankle motion in the presence of drop foot and control sagittal motion (Lusardi, 2016). Like the dynamic AFOs, this does not provide support in running nor impact activities.

#### *4.2.4.2. Posterior leaf spring AFO*

The Posterior Leaf Spring (PLS) AFO (Figure 4-6) is made of a flexible material to allow for some ankle motion during gait. Motion is allowed by trim lines posterior to the malleoli, allowing tibial advancement whilst preventing excessive foot drop during swing (Ounpuu, 1996; Churchill, 2003). The name suggests it may help to overcome the reduction in power generation seen in solid AFOs, by utilising a leaf spring action. A leaf spring action occurs when the AFO is deformed during stance. This energy is stored and returned at pre-swing. The amount of energy stored depends on the material used and the amount of deformation. The energy return from plastic is minimal but may provide a small amount of assistance (Sumiya, 1996b). Research demonstrates however that the PLS does not allow for elastic spring deformation and therefore does not augment push off (Ounpuu, 1996; Wolf, 2008). In fact, it has been shown to reduce energy production at terminal stance when compared with barefoot walking (Ounpuu, 1996).

The PLS does not control the hindfoot as well as a solid device due to the flexibility. Allowing movement of the hindfoot may result in pain for patients post trauma or in the presence of OA. To overcome this movement, the trim lines can be cut to include the malleoli to produce

a modified PLS which provides more mediolateral stability whilst allowing some flexibility however clearly sacrificing degrees of flexibility to achieve this. The PLS is not suitable for running or impact activities providing no energy return and absorbing energy during midstance (Ounpuu, 1996).

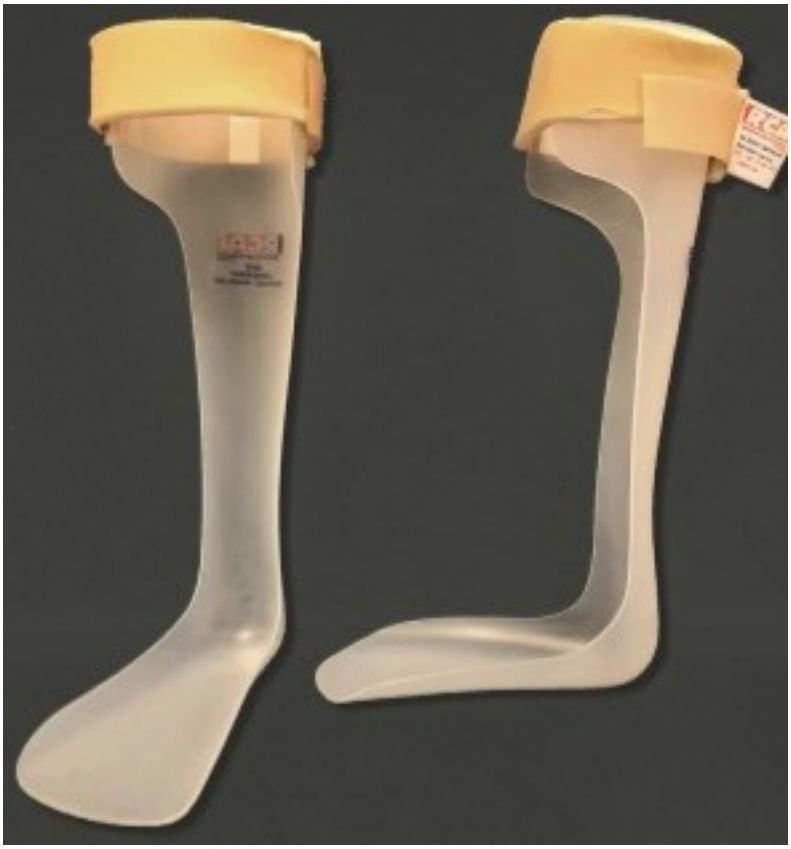

*Figure 4-6: Posterior Leaf Spring orthosis. The PLS ensures correct positioning of the foot and initial contact and ensures the first two rockers of gait are supported. Reproduced with permission of the copyright holder, Elsevier.*

#### *4.2.4.3. Carbon fibre spring orthoses (CFOs)*

To overcome deficiencies in the PLS, dynamic orthoses can be made of materials which store and return energy using the spring mechanism. Carbon fibre is often used as it significantly increases energy return, augmenting push-off (Wolf, 2008). In mid and terminal stance, the leaf spring mechanism is loaded as the tibia progresses forward and this is returned at push off in pre-swing, constituting up to 62% of ankle push off (Wolf, 2008). The addition of carbon fibre to an orthosis provides strength whilst being relatively thin and light (Nicol, 2017). One example of a CFO is the Dual Carbon Fibre Spring orthosis (Figure 4-7) which is based on a PLS

design. It uses the calf and foot sections of the PLS but joins them together with a carbon fibre strut which is designed to act via the leaf spring mechanism (Lusardi, 2016).

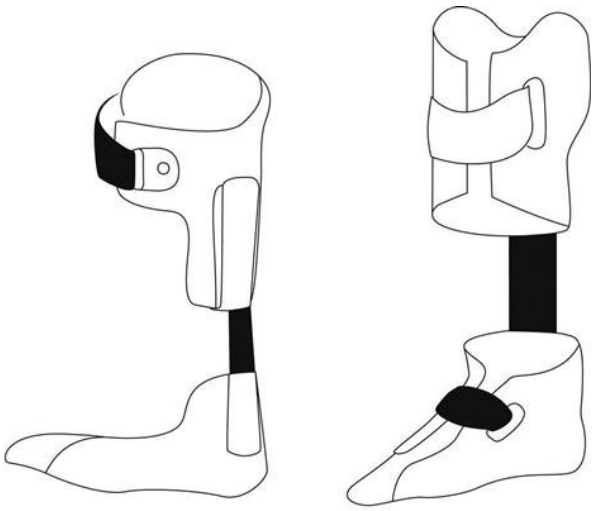

*Figure 4-7: CFO with PLS calf and foot components connected by a carbon fibre strut. The CFO provides dorsiflexion assistance during the swing phase of gait. The carbon fibre struct also acts to absorb energy during the stance phase of gait via deformation and return the energy at pre-swing to augment toe off. Reproduced with permission of the copyright holder, Elsevier.*

CFOs allow motion which can be bespoke to an individual's needs and deficits. Depending on the deficit, a CFO can hold the foot in a neutral position if dorsiflexion is compromised, or provide push-off due to plantar flexor weakness (Bartonek, 2007a). In mid-stance the forward progression of the tibia loads the spring and this elastic energy is returned in toe off to augment function (Wolf, 2008; Harper, 2014). More physiologically normal ankle and knee kinematics have been noted in gait studies for CFO wearers in comparison to classic hinged orthoses (Wolf, 2008). Carbon-fibre AFOs demonstrate improved ankle RoM and power generation over a classic PLS which is of use if the patient has plantar flexor weakness following trauma (Desloovere, 2006; Bartonek, 2007b). Carbon-fibre demonstrates high stiffness at low loads but may yield at higher loads. If higher loads are necessary further augmentation may be required than provided by a CFO (Major, 2004). These types of orthoses are of use in trauma patients and are promising for military patients providing sagittal ankle RoM support and power augmentation. They do not however provide offloading during mid-stance for patients with mechanical pain, and the interface between the carbon fibre and

thermo plastic, proximally and distally, is a weak point and running is therefore not recommended.

#### *4.2.4.4. Dorsiflexion assist designs*

To overcome breakage problems with the Dual carbon fibre spring orthosis and to allow running, entirely carbon fibre designs exist. Dorsiflex assist designs are commercially available orthoses comprising of an anterior shin plate and a medially located upright with a foot plate. These prefabricated devices are made entirely from carbon fibre or other composite materials and pre-position the foot for heel strike. They augment function in patients with loss of anterior compartment musculature power (dorsiflexors) which may be secondary to trauma and provide some medial/lateral support due to instability of the ankle. Due to the shape, they allow forward progression of the tibia and provide some assistance in toe off whilst allowing for adequate clearance during swing. A commercial example is the BlueRocker (Allard International, Helsingborg, Sweden) (Figure 4-8). It is prefabricated and therefore not bespoke which may be problematic for some military patients following LS due to abnormalities in lower limb shape. The BlueRocker is made of carbon fibre with a pretibial shell and extension which runs along the lateral aspect of the leg and ankle to connect to a foot plate (Jeanne C Patzkowski, 2012). It can be used for foot drop and to aid with limb proprioception. The BlueRocker is one example of a dorsiflex assist device but there is no evidence in the literature to support this design of orthosis over any other dorsiflex assist devices for the same indication (Nicol, 2017). The BlueRocker can be used for running and may be a solution for military patients with weakness of dorsi/plantarflexion to enable return to physical activity. It does not however provide sagittal ankle RoM support, nor offloading during stance for individuals with mechanical pain.

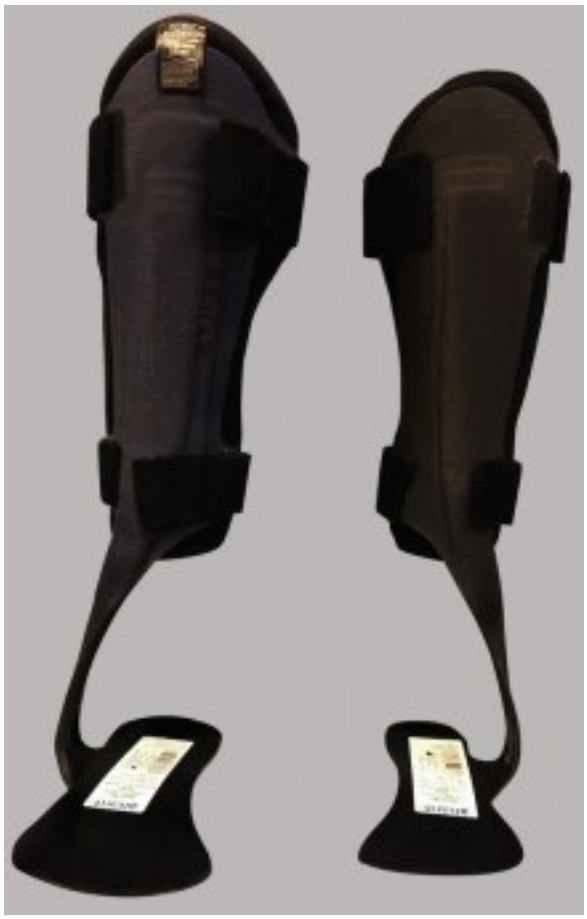

*Figure 4-8: BlueRocker orthosis. Pretibial shell, carbon fibre spring over lateral aspect of the ankle, distal footplate also made of carbon fibre. Reproduced with permission of the copyright holder, Elsevier.*

#### *4.2.4.5. Passive-Dynamic Ankle Foot Orthosis (PDAFO)*

To overcome apparent weaknesses in the designs of the previously mentioned orthoses the PDAFO was created (Patzkowski, 2011). The PDAFO is a custom-made orthosis manufactured from carbon fibre with posteriorly mounted struts, and a proximal ground-reaction cuff (Figure 4-9). At initial contact the PDAFO positions the foot for heel contact which is useful for patients with dorsiflexor weakness. During loading response, the PDAFO allows for the foot to be placed flat and there is a small amount of tibial advancement which is also useful for patients with dorsiflexor weakness. During both phases the PDAFO works as a passive device like the previously mentioned thermoplastic solid AFOs. There is a distal supramalleolar component to provide stability at the ankle not present in the BlueRocker (Jeanne C Patzkowski, 2012). During mid stance the PDAFO acts as a 'load sharing' or 'load redirecting' device in a similar way to a PTB device. This limits the loads passing axially through

the ankle joint and either shares or redistributes that load in an anterior direction. This aids with pain relief in the case of ankle arthritis. The orthosis also functions in a similar way to an anterior floor reaction brace utilising the ankle plantar flexion-knee extension couple to prevent hyper flexion at the knee. During terminal stance the PDAFO acts as an energy storing orthosis, similar to a CFO, with the structs deforming to store energy and returning the energy at pre-swing to augment function at toe off (Desloovere, 2006; Bartonek, 2007b; Wolf, 2008; Russell Esposito, 2017). A PDAFO acts to substitute function of soleus but not gastrocnemius to provide plantar flexion moments during mid and late stance, returning the energy at toe off (Arch, 2016). Augmented energy return is useful for patients with plantarflexor weakness. During swing the PDAFO holds the foot in a neutral position to prevent the toes contacting the ground and ensures the foot is appropriately positioned for initial contact, again aiding patients with dorsiflexor weakness.

*Figure 4-9: Passive Dynamic Ankle Foot Orthosis (PDAFO). This is the Intrepid Dynamic Exoskeletal Orthosis (IDEO).*

The PDAFO has been demonstrated to be of use in a heterogeneous population of injured personnel including those with weakness in plantar and dorsiflexion, mechanical pain on loading of the hind and mid foot, and following ankle and/or subtalar fusion. The literature

demonstrates that a PDAFO is better than no AFO, the traditional PLS AFO, and the BlueRocker. There is reduced energy expenditure (Danielsson, 2004), improved ankle RoM and push-off (Desloovere, 2006; Van Gestel, 2008), and improved stride length (Bartonek, 2007b) providing restoration of functional gait above any other AFO (Wolf, 2008; Jeanne C Patzkowski, 2012).

Commercially available examples of a PDAFO are the IDEO, BOB, and Reaktiv (Jeanne C Patzkowski, 2012; Ladlow, 2019). These are noted to improve ability to undertake sport participation, return to running, and military duty above other available AFOs following trauma (Owens, 2011).

### 4.2.5. Functional

Powered functional AFOs are made from thermoplastic with a carbon fibre shell and hinge joint with the addition of artificial pneumatic muscles via EMG (Ferris, 2006). They are useful for patients with muscle weakness, but do not solve mechanical pain issues as they do not provide offloading. Powered AFOs improve push-off and reduce the energy of walking compared to conventional options (Collins, 2010). Powered AFOs are not of use to restore running or impact activities, and therefore currently provide little benefit to restore function following trauma in a military population but may represent an area of focus for future research.

### 4.2.6. Summary of AFOs

| Type of orthosis | Category of orthosis | Action | Indication | Material |
|---|---|---|---|---|
| Fixed AFO | Static | Control ankle position throughout stance for stability and prevent toe contact during swing | - Dorsiflexor weakness<br>- Pain in the ankle and subtalar joints | Thermoplastic |
| Anterior floor reaction | Static | Provide stability in stance | - Weakness at knee | Thermoplastic |
| PTB-AFO | Static | Offload weight from the ankle joint | - Pain at the ankle joint | Thermoplastic |
| Hinged AFO | Dynamic | Toe clearance in swing, position foot, allow for tibial advancement | - Dorsiflexor weakness | Thermoplastic |
| UCBL | Dynamic | Stabilise subtalar and tarsal joints | - Pain in midfoot<br>- Rigid foot deformity | Thermoplastic |
| PLS | Dynamic | Assist toe clearance in swing, pre-position foot | - Dorsiflexor weakness<br>- Mild plantarflexor weakness | Thermoplastic |
| CFO | Dynamic | Assist toes clearance, pre-position for initial contact provide elastic energy at toe off | - Dorsiflexor weakness<br>- Plantarflexor weakness | Carbon fibre |
| Dorsiflexion assist | Dynamic | Assist toes clearance, pre-position for initial contact provide elastic energy at toe off and allow tibial advancement | - Dorsiflexor weakness<br>- Plantarflexor weakness | Carbon fibre |
| PDAFO | Dynamic | Assist toes clearance, pre-position for initial contact provide elastic energy at toe off and allow tibial advancement with offloading from patellar tendon bearing aspect | - Dorsiflexor weakness<br>- Plantarflexor weakness<br>- Pain<br>- Ankle and/or subtalar fusion | Carbon fibre |

*Table 4-1: Summary of the features of AFOs.*

## 4.3. What evidence is there that they improve outcome, and which is best for military patients following trauma?

Simple thermoplastic AFOs, both rigid and hinged, have been shown to improve outcomes for stroke patients with improved kinematics and independence of ADLs (Leung, 2003; Fatone, 2007). There is however a paucity of literature relating to improvements for trauma patients

following LS with AFOs. Initial improvements in function with solid thermoplastic AFOs allow individuals to achieve independence with ADLs but do not allow for return to high impact activities (Patzkowski, 2011). AFOs like the CFO incorporate carbon fibre and demonstrate improvements for children with plantarflexor weakness (Desloovere, 2006; Bartonek, 2007b, 2007a; Wolf, 2008). They still do not allow for a return to impact activity for military personnel due to the weaknesses in connection between the plastic proximal and distal components and carbon fibre struts. Consequently, the all carbon fibre design options present in the dorsiflexion assist devices like the BlueRocker and the PDAFOs are of interest as they provide augmentation of power generation whilst allowing for impact activities. Additionally, the design of the PDAFO may allow for a degree of offloading in mid-stance and provides sagittal ankle RoM support.

The BlueRocker provides a positive loading response, results in energy return, along with stability at the knee, but does not provide substantial ankle RoM support other than preventing foot drop (Nicol, 2017). The BlueRocker was compared to the IDEO and to the PLS and no brace. Functional outcomes were improved for patients when wearing the IDEO compared to the other options (Jeanne C Patzkowski, 2012). Although all three (the BlueRocker, IDEO, and PLS) have been used for patients following trauma, if a patient has ankle instability and weakness, the literature suggests that the IDEO outperforms the other two orthoses. The IDEO was also preferred by patients, it could be worn for longer with comfort, and demonstrated potentially more energy return to augment function (Jeanne C Patzkowski, 2012). Not only does the IDEO allow patients to run it also improves running efficiency combined with appropriate rehabilitation (Patzkowski, 2011; Ladlow, 2019; Yoder, 2019). Additionally the IDEO allows patients to return to sports participation as well as military duty (Owens, 2011; Blair, 2014).

Other potential options of AFO design for running have been presented in the literature including a prototype report of an AFO of dorsal design tested on one patient. It demonstrated good results with prolonged use over one year allowing running without discomfort but lacks the comprehensive support and evidence base of a PDFAO (Bishop, 2009; Highsmith, 2016).

A greater understanding of the functional deficits following injury which gain most benefit from a PDAFO would aid in accurate prescription to military personnel to enable return to high impact activities and potentially military duty. The bespoke design and prescription process is currently qualitative, involving trial and error, despite efforts to attempt to provide an evidence base (Arch, 2016). This risks over prescription to individuals potentially benefiting from a more traditional, less engineered AFOs. Consideration should be made as to the individual deficiency, the aetiology, and patient specific factors when prescribing to ensure prescription of the correct orthosis (Crowe, 2019).

## 4.4. Conclusion

This review has highlighted that there are numerous AFOs available to augment function following lower limb injury. The correct choice of AFO depends on injury pattern and required functional level. Most options presented here do not allow for a return to running and sports participation. Of those options that do allow for high impact activities, the PDAFO appears to be the most viable option for military patients to return to running and military duty. The next Chapter will examine the PDAFO in more detail to gain an understanding of the current research foci and research deficiencies.

# Chapter 5: Review of IDEO and BOB

## 5.1. Introduction

In the context that some military patients following LS are requesting elective amputation due to perceived poor function and patient-reported outcomes, Chapter 4 explored external augmentation options used in an attempt to improve outcomes (Owens, 2010). Chapter 4 focused on AFOs available to LS patients, specifically those to aid in the return to sporting activity. Based on that review, it was concluded that a PDAFO may be a solution to allow military LS patients to return to impact activities.

An increased number of military LS patients were seen following recent conflicts in both Iraq and Afghanistan. As highlighted in Chapter 4, combined rehabilitation of amputees and LS patients in both the UK DMRC and equivalent American centres, enabled LS patients to directly compare rehabilitation timelines and outcomes with amputee counterparts. Amputees reported improved pain and function in the early stages of rehabilitation compared to LS patients (Fergason, 2010; Ladlow, 2016). LS rehabilitation not only resulted in poorer functional and patient reported outcomes compared to amputees, but if LS was unsuccessful and a delayed amputation required, rehabilitation times were significantly longer than for successful LS (Ladlow, 2016). The rehabilitation difficulties experienced by LS patients resulted in the American Department of Defence investigating options for improved rehabilitation pathways. This resulted in the creation of an orthosis, based on the design of a prosthetic energy storage carbon fibre foot, to augment function in LS patients wishing to undertake high impact activities (Owens, 2011; Highsmith, 2016). This design was shared with UK rehabilitation specialists and a similar device was created for UK military personnel. The IDEO used in the US and the BOB used in the UK, are carbon fibre PDAFOs which have allowed some LS patients to return to advanced functional activities such as running and jumping (Bishop, 2009; Owens, 2011; Russell Esposito, 2015, 2017). These orthoses were designed to overcome limitations in joint stability and power; hence overcome the consequent problems with gait, and pain (Owens, 2011; Patzkowski, 2011; Bedigrew, 2014; Brown, 2017).

Most of the literature pertains to the IDEO which has been in use in the US for longer than the UK BOB and has been procured to more patients. Throughout this Chapter the PDAFO will be referred to as the IDEO, but conclusions can equally be applied to the BOB. Firstly, it is necessary to understand how the IDEO works. Secondly, considering the prolonged rehabilitation timelines for failed LS patients, it is important to ascertain whether the IDEO represents a viable treatment option for LS patients to improve outcomes and thereby potentially prevent amputation. Finally, it is necessary to establish for whom the IDEO works, in order to prevent painful and potentially futile rehabilitation. The aim of the Chapter is to establish the mechanism of action of the IDEO, whether the IDEO improves outcomes, and whether it is possible to predict who will benefit from the prescription of this type of orthosis.

## 5.2. IDEO mechanism of action?

The IDEO is an energy storage and return orthosis, initially reported in the literature in 2011 with the BOB in use in the UK since 2014. Both the IDEO and BOB (Figure 5-1) are made from carbon fibre and are composed of a footplate, supramalleolar component, posterior strut, and proximal cuff (Patzkowski, 2011). The IDEO footplate is made from a combination of carbon fibre, Kevlar, and high-strength aralon stockinette (Patzkowski, 2011). The IDEO is made from a wet lay-up technique using composite fibres and acrylic resin. Fracture of the orthosis due to fatigue has been reported (Patzkowski, 2011). To combat the fracture and fatigue problems, the BOB material composition is different to that of the IDEO using pre-impregnated carbon fibre with epoxy resin (Ladlow, 2019).


*Figure 5-1: The Bespoke Offloading Brace (BOB). The BOB is comprised of a foot plate continuous with a supramalleolar extension. The proximal cuff acts to bear weight through the patella tendon and is cut higher anteriorly, medially, and laterally, than posteriorly to allow for knee flexion.*

The IDEO works in several different ways (Table 5-1). It was designed to combine the benefits of different orthoses, working together to help LS patients with complex injury patterns (Patzkowski, 2011).

| Phase of Gait | Name of phase | % of gait cycle | Action | Comment |
|---|---|---|---|---|
| 1 | Initial contact | 0-2 | The IDEO/BOB positions the foot for heel/midfoot contact (depending on walking or running) | This is useful for patients with dorsiflexor weakness |
| 2 | Loading response | 2-12 | The IDEO/BOB allows for the foot to be placed flat and there is a small amount of tibial advancement | This is useful for patients with dorsiflexor weakness |
| 3 | Mid-stance | 12-31 | The IDEO/BOB acts as a 'load sharing' or 'load redirecting' device in a similar way to a patella tendon bearing device. This limits the loads passing axially through the ankle joint and either shares or redistributes that load in an anterior direction | This aids with pain relief in the case of ankle arthritis |
| 4 | Terminal stance | 31-50 | The IDEO/BOB acts as an energy storing orthosis (like a carbon fibre spring orthosis) with the structs deforming to store energy | This aids patients with plantar flexor weakness or following fusion |
| 5 | Pre-swing | 50-60 | the IDEO/BOB returns energy to augment function at toe off | This aids patients with plantar flexor weakness or following fusion |
| 6 | Swing phase | 60-100 | The IDEO/BOB holds the foot in a dorsiflexed position to prevent the toe contacting the ground and ensures the foot is appropriately positioned for initial contact | This helps patients with dorsiflexor weakness |

*Table 5-1: Mechanism of action of the IDEO/BOB during the gait cycle.*

At initial contact the footplate and ankle trimlines (with supramalleolar extension) of the IDEO position the foot for heel contact and during loading response ensure controlled lowering of the forefoot to the ground (Bedigrew, 2014). This is like a solid thermoplastic AFO and is of use in patients with dorsiflexion weakness. Also like a simple thermoplastic AFO the ankle is constrained, held in optimal alignment and supported to prevent excessive movement. This will benefit patients with ankle arthritis, but the constraint compromises the heel rocker of gait (Ikeda, 2019). To overcome this the IDEO has a roller shaped heel which allows for a more normalised heel rocker of gait (Janisse, 2008; Mazzone, 2019). A wedge in also worn under

the heel on both the IDEO limb and sound limb to prevent imbalance and exaggerated abrupt centre of mass transitions during the rockers of gait. Changing the heel wedge height alters loading of the foot. When 2 and 3 cm wedges are used there is a less abrupt transition in the CoP from loading response to flat foot than when a 1 cm wedge is worn. This is preferred by patients and results in a more normalised pattern of gait. The 2 cm wedge results in the closest timings in gait to able bodied individuals but does not completely normalise gait (Ikeda, 2018).

The IDEO is not only of use to patients with dorsiflexion weakness. The foot plate and supramalleolar extension function in a similar way to a UCBL orthosis with a supramalleolar extension (see Chapter 4 for more detail). The UCBL keeps the calcaneus in a neutral position limiting pronation and forefoot abduction, thus stiffening and locking the transverse tarsal joint (Elattar, 2018). The supramalleolar extension stops excessive movement at the ankle joint. The UCBL has been shown to be of use in patients with midfoot and subtalar joint arthritis. The similarity of the IDEO foot plate to the UCBL means LS patients should expect to gain the same benefit in the presence of midfoot, subtalar joint, and talocrural joint arthritis (Thompson, 1992; Huang, 2006).

During midstance stability is provided by the foot plate and supramalleolar extension and there is offloading, or load sharing, provided by the proximal cuff. The proximal cuff acts in a similar way to a PTB orthosis (see Chapter 4 for more detail). A PTB orthosis offloads distal joints by preferentially loading through more proximal areas. This reduces axial load at the foot and ankle, loading instead at the patella tendon area and supracondylar regions (Osborne, 2014; Ladlow, 2019). This is achieved by a PTB bar positioned anteriorly in the proximal cuff. The consequent offloading or load sharing effect is indicated in patients who experience pain in the ankle joint during stance. By minimising ankle movement and offloading the ankle joint, patients with ankle joint arthritis should experience decreased pain.

The foot and ankle component merges into a posterior strut(s). This is a similar design to the CFO. The CFO uses a polyproline foot plate and proximal cuff with a carbon fibre strut joining the two (see Chapter 4 for more detail). The joints between the polyproline and carbon fibre

represent weak points preventing running. To allow running and overcome breakage problems the IDEO is make entirely of carbon fibre. Similar to the CFO, the posterior strut of the IDEO is flexible and has the potential to store energy during gait when deformed by the foot plate acting as a lever (Ikeda, 2019). As the wearer progresses through stance, the strut deforms, demonstrating column buckling and storing energy (Wach, 2018). Energy is then returned at pre-swing to assist toe-off in patients with weakened plantar flexors (Patzkowski, 2011; Ikeda, 2019; Schmidtbauer, 2019; Stewart, 2020). The stiffness of the struts determine whether the ankle is held in a neutral position, provides stability, and allows for energy return (Sumiya, 1996b; Bregman, 2010; Harlaar, 2010). The literature concerning AFOs demonstrates greater stiffness results in reduced ankle plantarflexion, dorsiflexion and total RoM of the ankle joint (Totah, 2019). IDEO trials examining stiffness variation have demonstrated decreased stiffness results in increased ankle RoM and increased gastrocnemius muscle activity to provide plantarflexion power not provided by the orthosis (Harper, 2014). A decrease in stiffness of the IDEO also results in decreased support and the need for proximal joints to compensate when walking (Russell Esposito, 2014). Biomechanical parameters of running remained unchanged over a range of stiffnesses (Russell Esposito, 2015). Additionally, similar to changes in heel wedge size, changes in stiffness do not normalize gait compared to controls (Russell Esposito, 2014). During gait individuals are able to compensate for changes in stiffness therefore patient preference appears more important than the absolute stiffness (Harper, 2014; Russell Esposito, 2014, 2015; Arch, 2015; Haight, 2015).

As well as stiffness, the bending axis of the strut varies the IDEO function. A lower bending axis increases ankle RoM and power generation which may be of benefit to those individuals who are able to tolerate ankle movement pain free but require assistance with plantarflexion power (Russell Esposito, 2017). Self-selected running speeds however, were not noted to be different by alteration in the vertical strut bending axis (Russell Esposito, 2017). Although bending axis variation effects the peak ankle and knee joint kinetics and kinematics, the changes do not meet minimal detectable change levels therefore clinical relevance is unlikely. The bending axis is likely to be clinically less relevant than other potentially modifiable features (Ranz, 2016). Patients prefer the middle bending axis when trialled against a high or

low axis and similar to stiffness, patient preference seems most important (Russell Esposito, 2017).

The alignment of the foot plate (plantarflexed , neutral, or dorsiflexed) impacts how the foot strikes the ground as well as how the device stores and returns energy (Schmidtbauer, 2019). Alignment also affects knee and ankle moments and powers (Schmidtbauer, 2019). Energy storage and return is decreased by a plantarflexed alignment; 15% less peak ankle power absorption is noted as the plantarflexors are not stretched consequently a neutral position may be beneficial for patients who require plantarflexion assistance (Schmidtbauer, 2019). Increasing plantarflexion however may reduce quadriceps-muscle fatigue and be of use in patients with quadriceps-muscle weakness secondary to injury (Schmidtbauer, 2019). A plantarflexed alignment is however preferred by most patients despite the measured reduction in power (Brown, 2017; Schmidtbauer, 2019). Alignment changes of ±3 degrees resulted in significant differences in gait kinetics and kinematics. Foot plate alignment may be one of the most important component when prescribing a PDAFO (Brown, 2017; Schmidtbauer, 2019). The studies examining foot plate alignment to date however do not link outcome of continued use, abandonment, or amputation, with use of the IDEO, nor do they provide advice on prescription of foot plate alignment for the variety of pathologies prescribed the IDEO. Although gait changes are noted, further research is required to establish optimal foot plate alignment, linked to outcome, to enable evidence-based prescription.

Completing the gait cycle, during swing the foot is held in a neutral position by the IDEO to prevent the toes clashing with the ground. This feature is again like a simple thermoplastic AFO and is useful for patients with foot drop due to dorsiflexor weakness.

Both the IDEO and BOB are bespoke to the individual with component parts chosen based on the required size of the IDEO. The size is determined by individual weight and planned activity. The current prescription guidelines for the BOB can be found in Table 5-2. This layup guide was developed by trial and error and therefore it may be necessary to adjust the layup by providing varied strut stiffness, foot plate alignment, heel wedge height, depending on patient required performance, outcome, and preference as noted above (Harper, 2014). The

decision of whether an individual requires a small, medium, large, or extra-large, is made by the orthotist as there are no evidence-based guidelines.

| All Bespoke offloading braces | Patellar tendon bearing – 3 Twill and 3UD cross or frame<br>Calf – 4 Twill and 3UD under strut and 3UD over strut | |
|---|---|---|
| **Size (patient weight)** | **Ankle** | **Foot** |
| Small (<55kg) | 3 Twill and 4UD | 3 Twill and 4 Kevlar and 5 Full length UD, 2 step back |
| Medium (55-85kg) | 3 Twill and 5UD | 3 Twill and 4 Kevlar and 6 Full length UD, 2 step back |
| Large (85-100kg) | 3 Twill and 6UD | 3 Twill and 4 Kevlar and 8 Full length UD, 2 step back |
| Extra-large (>100kg) | 4 Twill and 6UD | 4 Twill and 4 Kevlar and 10 Full length UD, 2 step back |

*Table 5-2: Lay-up configuration prescription by activity and patient weight. UD = unidirectional.*

The IDEO specifically (as opposed to the BOB) is initially fabricated with removable struts which can be changed to allow for variable stiffness and bending axis. This has the benefit of allowing the IDEO to be truly bespoke. Once an individual has finished rehabilitation a final IDEO is made with the desired struts incorporated. Due to the use of different struts in the UK design (BOB) they are integrated from the beginning and cannot be modified without a new orthosis being fabricated.

The IDEO potentially benefits patients with dorsiflexor weakness and/or plantarflexor weakness due to a variety of pathologies as well as mechanical ankle and/or subtalar joint pain. As noted in Chapter 3, patients with pathology demonstrate a variety of gait adaptations. Gait biomechanics when walking and running therefore warrant investigation to understand the effect of the IDEO on the foot and ankle joints, as well as the more proximal joints.

Gait spatiotemporal parameters have been noted to change with use of the IDEO. Walking velocity during gait analysis is noted to improve with use of the IDEO and is comparable to controls (Osborne, 2014; Russell Esposito, 2017; Quacinella, 2019, 2019). As previously noted, elective amputation has been requested by LS patients due to perceived improvements in outcomes for amputees. It is not clear whether the IDEO results in speeds similar to amputees or whether amputees walk faster. Russell Esposito et al found no statistical difference in

speeds for LS patients wearing an IDEO, unilateral transtibial amputees (TTA), and controls (p=0.107) (Russell Esposito, 2017). Conversely Mangan et al (Mangan, 2016) found TTAs walk faster than LS patients wearing an IDEO (p=0.036). Ultimately, speeds comparable to uninjured controls are required and have been demonstrated with use of the IDEO. Cadence has also been demonstrated to improve when wearing the IDEO, as has stride length (Osborne, 2014; Quacinella, 2019, 2019).

Specifically examining joint kinematics, ankle RoM on the limb wearing the IDEO has been found to be decreased compared to the unaffected side, and to controls, when walking (Figure 5-2) and climbing stairs (Aldridge Whitehead, 2016; Russell Esposito, 2017). This is to be expected considering the constrained position the IDEO holds the foot and ankle in and highlights that benefit may be gained for patients with talocrural joint pathologies requiring movement at the joint to be constrained. The peak plantarflexion angle in early stance has also been found to be statistically less on the unaffected side compared to controls, but all other ankle angles were similar to controls (Russell Esposito, 2017). Similarly, knee and hip angles were largely similar to controls on the unaffected limb. On the affected limb knee and hip range of motion were decreased compared to controls, but other angle measures were not (Russell Esposito, 2017). It is important to ascertain whether kinematics of proximal joints on the affected limb, and unaffected limb are altered by use of the IDEO to prevent injury at proximal or contralateral joints with long-term use. To date, no studies have examined the proximal joints on the affected limb and unaffected limb in and out of the IDEO for the same cohort, therefore it is not currently possible to conclude whether use of the IDEO induces changes in angles which may result in injury of proximal joints with long-term use. Additionally, there are no studies linking observed changes in kinematics with long-term outcome with the IDEO.

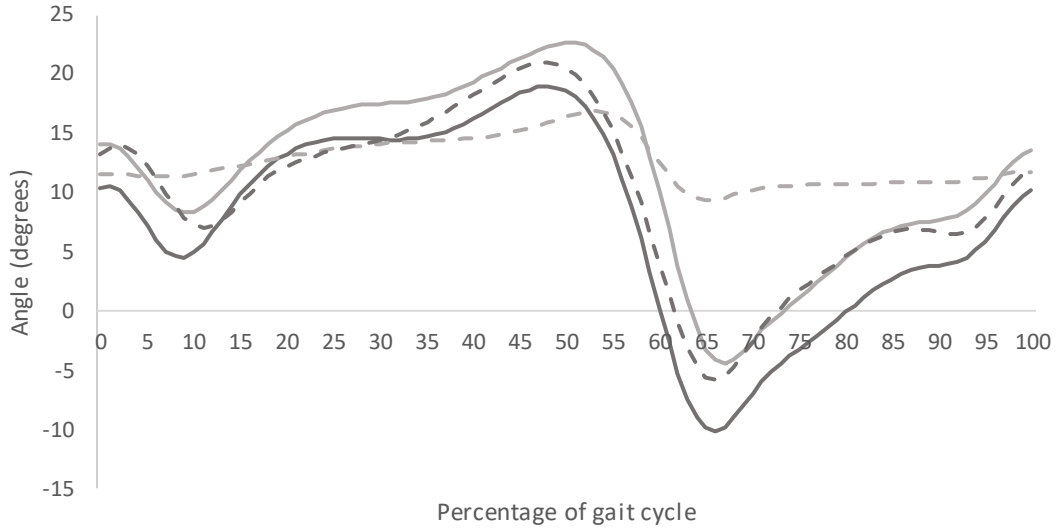


*Figure 5-2: Ankle plantarflexion (-)/dorsiflexion (+) angles during gait. Solid lines represent no IDEO, dotted lines represent IDEO condition. Dark grey lines represent sound limb. Light grey lines represent injured side. Reduction in ankle joint range of motion is noted on the limb wearing the IDEO.*

Offloading as well as energy storage and return are thought to be provided by the IDEO due to similarities in design to the PTB orthosis and the CFO respectively. Offloading has only been investigated in one study, finding decreased peak plantar flexor pressures on the IDEO side for the forefoot and toes (63.8% decrease; $p<0.05$ (*Wilcoxon signed-rank test*)), and increased plantar pressure on the unaffected side (23.7% increase; $p<0.05$ (*Wilcoxon signed-rank test*)) (Stewart, 2020). The contribution of the component parts of the IDEO to the observed offloading was not investigated but the decreased pressure on the IDEO side demonstrates patients with mechanical pain may benefit from prescription. Investigating power data to establish the effect of energy storage and return, power generation at pre-swing was reduced on the IDEO wearing side compared to controls and compared to the unaffected limb (Russell Esposito, 2017). This pattern is also seen in TTAs wearing a carbon fibre prosthesis thought to function in a similar way, but the implications have not been investigated. Despite power generation levels being lower than for controls, LS patients wearing the IDEO are walking at comparable speeds to controls. Comparable power generation may not be required to attain the required functional outcome. Only one study examining one individual has looked at power generation on the affected side in and out of the orthosis and found no change in power generation at the ankle when wearing the orthosis, although power generation on the

unaffected side was increased (Osborne, 2014). This contradicts other studies examining the IDEO which found, although the IDEO does not entirely replicate plantarflexion strength, it does augment it, specifically soleus function (Arch, 2015, 2016). The small number of individuals included in the studies may account for the differences between studies and the different biomechanical metrics investigated. It is therefore not clear what role the IDEO plays in assisting power generation. Given that one of the aims of the IDEO is to improve outcomes for LS patients with plantarflexion weakness, attempting to replicate CFO benefits but additionally allowing running, quantifying the required power generation for LS patients and power return capability of the IDEO is desirable. Additionally, studies investigating the offloading capacity and capability are required to ascertain to what extent the IDEO offloads, or load shares during stance.

The IDEO was designed to undertake impact activities including running. Studies examining gait when running have found that the orthosis limb lands in a more plantarflexed position than the sound side which may have important implications for long term use due to gait asymmetries (Haight, 2015; Schmidtbauer, 2019). Consequently, patients may require running training in the IDEO to ensure correct foot placement using a midfoot strike. Correct placement can be learned through biomechanical feedback training (Yoder, 2019). Midfoot or forefoot strike when running wearing the IDEO is preferable to a heel strike gait. If the wearer strikes the floor with the heel the slightly plantarflexed foot position imposed by the foot plate results in a sudden extensor moment at the knee potentially resulting in injury (Patzkowski, 2011). The return to run clinical programme (RTR CP) offered in the US includes gait training to aid in correct foot placement as well as nutrition, physical therapy, and a psychological element (Ikeda, 2019).

Gait is not normalised for IDEO users compared to controls with regards to kinematics and kinetics. Increased loading on the unaffected side and less time spent on the orthotic limb is noted resulting in ongoing asymmetries during walking and running (Russell Esposito, 2015; Mangan, 2016; Russell Esposito, 2017). Although benefit in gait velocity is gained from use of the IDEO it is not derived through normalisation of gait.

It has been established that the IDEO works by combining the benefits of a simple thermoplastic AFO, a PTB orthosis, and a CFO, whist allowing impact activities with improved material design in the carbon fibre lay-up. Although modifications in heel wedge thickness, foot plate alignment, strut stiffness, and bending axis have been investigated for changes in gait kinetics and kinematics, patient preference appears to be most important with none of the modification demonstrating significant changes in gait parameters. Now that the mechanism of action of the IDEO has been discussed, it is important to establish whether the IDEO works for LS populations to allow a return to impact activities, and improve patient reported outcomes.

## 5.3. Does the IDEO work?

The primary aim of the IDEO is to improve outcomes for LS patients, attempting to bring them in line with amputee populations, or where possible, healthy controls. This should enable patients with lower limb injuries to return to sporting activity and running. In the US the IDEO is therefore provided to individuals in combination with the RTR CP. This is an 8-week rehabilitation programme run by the Centre for the Intrepid and involves strength training, physiotherapy, agility training, and running training (Patzkowski, 2011). Owens et al reported 8 of 10 (80%) wearers of the IDEO were able to return to running after completion of the RTR CP at the 8-week point where they were unable to run prior to the programme (Owens, 2011). Patzkowski et al also report 81% (13 of 16) of patients were able to return to running following completion of the RTR CP (Jeanne C. Patzkowski, 2012b). Both studies demonstrate 80% of wearers able to run after optimal rehabilitation with the orthosis. This is better than rates of independent running reported in the literature for military unilateral amputees following optimal rehabilitation of 50% (Ladlow, 2016). To achieve a return to running, the IDEO should improve agility, power, and speed.

Statistically significant improvements of between 25 and 41% have been demonstrated in measures of agility in the form of the four square step test (FSST) and 20% in the Illinois Agility test following 8 weeks of RTR CP (Bedigrew, 2014; Crowell, 2016; Sheean, 2016; Potter, 2018). Assessing measures of strength and power, statistically significant improvements of between 20 and 40% have been found using the timed stair ascent (TSA), and a 25% improvement in

the sit to stand 5 times test (Bedigrew, 2014; Crowell, 2016; Potter, 2018). The use of the IDEO and RTR CP brought the FSST results in line with population norms (Wilken, 2012). The TSA results were between 50 and 100% slower than military population norms and the sit to stand 5 times test was up to 25% slower than military population norms (Wilken, 2012). The sit to stand 5 times results were however comparable with amputee populations (Halsne, 2018). The IDEO also resulted in improved outcomes in the FSST, TSA, and sit to stand 5 times tests compared with other orthoses, namely the PLS, BlueRocker, and no brace ($p<0.05$ (*t-test*)) (Jeanne C Patzkowski, 2012).

SSWV was noted to improve by 0.3 m/s to 1.49 m/s ($p<0.0001$ (*t-test*)) when wearing the IDEO compared to not wearing the IDEO in a study by Bedigrew et al examining 84 patients (Bedigrew, 2014). This brought outcomes of SSWV in line with healthy controls and was faster than the 1.25 m/s reported in the literature for unilateral TTAs (Russell Esposito, 2017). Potter et al did not see an improvement in SSWV in their study of 81 patients however SSWV was reported to be 1.5 m/s before and after the RTR CP which is in keeping with healthy controls (Potter, 2018).

Improvements were not just seen in walking speed but also in running speed. Bedigrew et al report a 1.6 m/s ($p=0.002$ (*t-test*)) improvement in running speed with use of the IDEO after the RTR CP bringing speeds to 2.6m/s. Potter et al also reported an improvement after the RTR CP with speeds of 2.2 m/s improved to 2.8 m/s (Potter, 2018). Neither of these bring speeds in line with healthy controls which are reported to be 3.8 m/s nor with amputee populations reported as 3.5 m/s when wearing carbon fibre protheses (Sanderson, 1996; Bedigrew, 2014). Improvements in running were however superior to wearing the PLS and BlueRocker orthoses ($p<0.05$(*t-test*)) (Jeanne C Patzkowski, 2012).

Use of the IDEO for LS patients has demonstrated an improvement in measures of agility, strength and power, as well as improved walking and running speeds. These improvements are not consistently brought up to healthy population levels and for running speeds are not as good as for amputees. Overall, the IDEO does however appear to improve functional outcomes for LS patients.

As well as enabling return to running, the IDEO must be acceptable to patients and not cause more pain. Where possible, wearers of the IDEO should report less pain. As with functional outcome, the IDEO aims to improve patient reported outcomes to the same level as amputees, and where possible healthy controls. A variety of PROMs and methods to assess pain are reported in the literature concerning the IDEO. The Lower Extremity Functional Scale (LEFS) was noted to statistically improve in a study by Ikeda et al (29.7 +/- 16.6 no IDEO v 59.5 +/- 13.6 with IDEO), however only 26 of 156 (17%) patients completed the LEFS pre and post prescription (Ikeda, 2019). This represents a potential bias in reporting and the results must be considered in this context. A further three studies have however also found improvement in LEFS with use of the IDEO which are above minimal detectable change levels (Osborne, 2014; Crowell, 2016; Yoder, 2019). Another lower extremity specific outcome measure used to assess improvement with the IDEO is the foot and ankle outcome score which demonstrated improvement in all domains after optimal rehabilitation in one patient (Osborne, 2014).

The SMFA is a commonly used PROM for musculoskeletal conditions, it is not specific to the lower limb but assess overall musculoskeletal health. The SMFA was noted to improve in all domains, expect the arm/hand domain, following completion of the RTR CP in a cohort of 84 patients with a variety of functional deficits (Bedigrew, 2014). The SMFA was conducted at 2-year follow-up in 31 patients and noted to remain significantly improved (Bedigrew, 2014). Similarly, a study of 64 IDEO users with a variety of functional deficits found improvement in all domains of the SMFA with the exception of the arm/hand domain at 12-month follow-up (Potter, 2018). These improvements brought SMFA results at 12-month follow-up in line with unilateral lower limb amputee populations, but neither cohorts were in line with population norms (Doukas, 2013).

Pain was scored out of 10 by Ikeda et al and noted to improve from pre prescription at 5.2 to 1.7 post prescription ($p<0.05$) (Ikeda, 2019). Using the VAS, Bedigrew et al report a statistically significant improvement in pain score after completion of the RTR CP with this improvement sustained for 2-years (Bedigrew, 2014). Improvements are seen in PROMs and in measures of pain with use of the IDEO with improvements sustained for 2-years (the longest follow-up).

Importantly, use of the IDEO brought SMFA scores in line with amputee populations, although it should be noted that neither population reports outcomes in line with population norms.

Improvements in functional and patient reported outcomes may enable a return to duty for Service Personnel. Return to duty rates in the UK following complex foot and ankle injuries have previously been reported as poor at 14% (A. Ramasamy, 2013). An improvement in return to duty rates for military personnel using the IDEO following HELET has been reported in the literature with an increased proportion returning compared to amputees (33.2% IDEO v 12.3% amputees). A higher proportion of IDEO users returned after completing the RTR CP than those who did not complete the RTR CP (51.3% v 12.9% respective p=0.0001) (Blair, 2014). The reported return to duty rate of 51.3% is higher than the literature reported amputee return to duty rate in the US of 43.4% and the US return to duty rate of LS patients prior to the introduction of the IDEO, reported as 48% (Doukas, 2013; Blair, 2014). It is however clear that the IDEO, although improving return to duty rates, does not enable all LS patients to return to duty despite the functional and patient reported outcome improvements previously noted.

Along with improving return to running and impact activities, a secondary aim of the IDEO is to prevent amputation. The IDEO has resulted in patients previously considering amputation opting to pursue LS. Out of 50 patients previously considering amputation, 41 pursued LS in one study (Bedigrew, 2014) and 8 of 13 in another, with 2 of 13 undecided, and 3 pursuing amputation (Jeanne C Patzkowski, 2012). There is a 20% amputation rate following use of the IDEO reported in the literature for all indications (Hill, 2016) and a 5% amputation rate reported when excluding those who are clinically unstable (patients with infection, those with non-union, and those requiring more surgery) (Higgins, 2010; Potter, 2018). Therefore, although the IDEO appears to work, it does not work for all patients with some pursuing amputation. It should be noted that none of the published literature concerning the IDEO reports on individuals who abandon the IDEO and either opt for surgical management (other than amputation) or the use of an alternate orthosis. Anecdotally abandonment of the BOB has been reported in the UK and the lack of reporting of abandonment rates in the US literature concerning the IDEO represents an obvious weakness and bias.

The IDEO therefore improves outcomes for a heterogenous cohort of LS patients, improving functional and patient reported outcome measures, as well as reducing elective amputation and improving return to duty rates. It appears that demonstrated benefits are derived through the combined actions of the IDEO working in the same way as a simple thermoplastic AFO, a PTB orthosis, and a CFO. Benefit would be expected for patients with dorsiflexor weakness and/or plantarflexor weakness due to a variety of pathologies as well as mechanical ankle and/or subtalar joint pain. Although abandonment rates of the IDEO have not been reported, amputation rates have. It is important to establish which diagnoses gain benefit from the IDEO and which still result in amputation.

## 5.4. For whom does the IDEO work?

Most of the published literature concerns populations prescribed the IDEO for all indications. These include following fracture, nerve injury, arthritis, fusion, Achilles pathology, spinal cord injury, ankle/foot dislocation, compartment syndrome, partial foot amputation, necrotising fasciitis, and stroke (Ikeda, 2019). Hill et al reported in their study examining the injury characteristics of IDEO users, injuries around the ankle (Pilon fractures, post-traumatic OA, and fusion) represented the greatest proportion of users (25%) (Hill, 2016). Pilon fractures and post-traumatic OA are likely to result in mechanical pain during stance and therefore use is consistent with mechanism of action. Fusion results in decreased power generation at toe off and again is consistent with IDEO mechanism of action. Tibia fractures, nerve injuries, and hindfoot injuries characterised the next highest user diagnoses (17.5%, 16.4%, and 14.2% respectively). Tibia fractures may result in pain, similarly hindfoot injuries may also, therefore as with post-traumatic OA, these diagnoses are in keeping with the IDEO working for patients with mechanical pain during stance. Nerve injuries may result in either dorsi or plantarflexor weakness, both may benefit from the mechanism of action of the IDEO. Although Hill et al did not report IDEO abandonment rates they did investigate elective amputation rates, a surrogate for failure with the IDEO. Amputation was more common in patients with a diagnosis of midfoot/forefoot pain or post-traumatic OA, soft tissue injuries, and hindfoot injuries (28.6%, 27.3%, and 26.6% respectively) (Hill, 2016). It is not clear from the stated mechanism of action of the IDEO as to why these diagnoses would still result in amputation. The mid/forefoot is held still by the IDEO however if trimlines were not sufficient at the

forefoot, potentially movement may occur and hence benefit not achieved. The IDEO is unlikely to help with soft tissue injuries but should have helped with hindfoot injuries. Hill et al found the lowest rates of elective amputation were in patients with a nerve injury or ankle injury (both 14%) (Hill, 2016). Although the injury and amputation rates were characterised by this study, functional outcome was not assessed. It is not possible to predict from this study who will perform well with the IDEO and continue to use it, who will perform badly and abandon the IDEO, and who will require elective amputation. Potter et al found elective amputation was more common in IDEO users who reported greater dysfunction at baseline (as measured by the SMFA), had a diagnosis of PTSD or depression, and had pain (Potter, 2018). They did not however report the injury profile of patients requiring amputation, nor whether any functional assessment predicted amputation. These two studies highlight that amputation is less likely with a nerve injury, or injury around the ankle joint, but more likely with pain, diagnoses at the mid/forefoot, and a psychological diagnosis including PTSD.

To attempt to overcome the heterogenous nature of the reported cohorts, Potter et al grouped patients into functional deficits (Potter, 2018). This allowed for outcomes to be assessed regardless of injury, focusing instead on what the patient was unable to do as a consequence of the injury. The functional deficit categories can be found in Table 5-3. Unfortunately the study did not attempt to link outcome measures with the functional deficits therefore no comment can be made from the study on which functional deficits benefit from prescription of the IDEO and has resulted in a call for prescription guidelines based on functional deficit (Younger, 2018).

| |
|---|
| Weakness of ankle dorsiflexors and/or plantarflexors resulting from leg injury |
| Limited ankle dorsiflexion and/or plantarflexion resulting from leg injury |
| Mechanical pain with loading to hindfoot/midfoot |
| Ankle or hindfoot fusion or candidate for ankle or hindfoot fusion |
| Candidate for amputation secondary to ankle/foot impairment |

*Table 5-3: Functional deficit categories used to attempt to overcome the heterogenous nature of foot and ankle injured populations.*

Examining who the IDEO works for in more detail, studies have looked at functional outcomes in specific cohorts of patients finding outcomes improvement in post-traumatic OA, ankle and subtalar fusion, Pilon fractures, and outcomes following all lower limb fractures (Jeanne C.

Patzkowski, 2012b; Sheean, 2016; Mazzone, 2019; Quacinella, 2019). The weakness of all these studies is small cohort size and short follow-up time. Two patients with a common peroneal nerve injury have been examined with the IDEO and improvements in gait and ability to run independently found but the cohort is too small to draw conclusions on whether the IDEO should be prescribed to nerve injury patients (Quacinella, 2019). The consequent weakness present in common peroneal nerve patients would be in keeping with the mechanism of action of the IDEO but a larger study is required.

Examining 16 patients with post-traumatic OA of the ankle or subtalar joint, a reduction in request for amputation was seen from 38% to 6% after completion of the RTR CP, and 81% of patients could run, 75% jump, and 44% had returned to military duties (Jeanne C. Patzkowski, 2012b). The authors concluded that the RTR CP and IDEO may be used as an alternative or adjunct to arthrodesis in the presence of symptomatic post-traumatic OA (Jeanne C. Patzkowski, 2012b). The stated mechanism of action of the IDEO is in keeping with benefit provided to patients with talocrural or subtalar joint arthritis as these joints are restricted in movement, and offloading occurs, both potentially reducing pain. Looking at using the IDEO as an adjunct following arthrodesis, Sheean et al compared outcomes with an ankle fusion +/- subtalar fusion and just a subtalar fusion, finding statistically significant improvements in both groups in the FSST and TSA, but improvements in VAS were only seen for patients with an isolated subtalar fusion (Sheean, 2016). Statistically significant improvements were however seen for both groups in SSWV (Sheean, 2016). Looking at PROMs statistically significant improvements in all domains of the SMFA were found in the cohort of patients with isolated subtalar fusion following completion of the RTR CP but not in patients with an ankle fusion +/- subtalar fusion (Sheean, 2016). The authors concluded the IDEO works for both cohorts of patients, stating the lack of statistical improvement in the patient reported outcomes for the ankle fusion +/- subtalar fusion cohort was due to good pre-prescription levels and the functional gains should not be ignored (Sheean, 2016). Functional improvements for patients following fusion may be gained due to the energy storage and return ability of the IDEO, gait studies, including running are required to confirm this hypothesis.

Spatiotemporal parameters of gait were examined for patients following Pilon fractures and use of the IDEO finding 3 of the included 7 patients were able to return to deployment with

the IDEO and improvements in walking speed from 1.1 m/s to 1.3 m/s (p=0.01 (*t-test*)) but none of the other spatiotemporal metrics (Quacinella, 2019). In this small study the authors conclude that the cost of the IDEO cannot be justified for the small improvement in speed however functional and patient reported outcome measures are not reported and may demonstrate improvements above and beyond those seen in spatiotemporal parameters. The study is also not in keeping with Hill et al who found Pilon fracture patients were amongst the most common users of the IDEO and injuries around the ankle had the smallest elective amputation rates following use of the IDEO (Hill, 2016). Examining a variety of healed lower limb fractures resulting in ankle and or foot pain in 30 patients (including Pilon fractures), Mazzone et al found improvement in the Comprehensive High-level Activity Mobility Predictor (CHAMP) test ($p<0.05$ (*ANCOVA*)) with improvements above the minimal detectable change value for patients using the IDEO, demonstrating agility improvement following the RTR CP (Mazzone, 2019). The subsets of the test including the Illinois agility test and Edgren sidestep test, also tests of agility, did not demonstrate statistically significant improvement but the authors conclude the IDEO and RTR CP work for LS patients following fracture with resultant foot and ankle pain to improve agility. The authors did not report any amputations in their cohort, and consistent with the rest of the literature did not report any patients abandoning the IDEO. The authors highlight the role the RTR CP plays in combination with the IDEO.

It is not possible from the literature to establish whether the improvements in function and patient reported outcomes are as a result of the IDEO or the RTR CP. No study has examined LS outcomes following just the RTR CP with no IDEO. One study has examined outcomes of the RTR CP and IDEO comparing them to just prescription of the IDEO and found improved outcomes for patients undertaking the RTR CP with the IDEO (Blair, 2014). Further studies are required to establish the role played by the IDEO in improving outcomes compared to physical therapy in the form of the RTR CP alone.

It has been established in this section that the IDEO have been prescribed for a variety of indications and for pathologies and injuries that are not a result of HELET, the original intended use (Mazzone, 2019). Sporting injury at the foot and ankle accounts for the largest cohort of injuries for limited or reduced military duties and medical discharge in the US. It

therefore makes sense to extend the use beyond patients with injuries caused by HELET (Songer, 2000; Ruscio, 2010). It has also been established that the IDEO does not work for all patients. Approximately 20% progress to amputation. Additionally, an unknown number abandon the orthosis. Where sub-group analysis has occurred, the IDEO has been demonstrated to provide improvement for patients with ankle and/or subtalar arthrodesis and post-traumatic OA of the ankle and/or subtalar joint. It may also provide benefit for nerve injuries, but the numbers are currently too small to draw conclusions and the outcome of pain following lower limb fractures is also not clear with contradictions found in the outcome measures used and between studies.

The only systematic review concerning the IDEO found some improved outcomes for Service Personnel under 40 years of age following HELET with or without post-traumatic OA to allow return to active duty, exercise, recreational activity, and improvements in agility (Highsmith, 2016). This was particularly true when used in combination with the RTR CP (Blair, 2014).

Although it is apparent that the IDEO works for some patients it is not clear which groups of patients it will provide benefit to. Outcomes are also limited to maximum 2-year follow up and there are no prospective trials or randomised control trials. Studies additionally include small cohorts and sub-group analysis further diminishes statistical power. The prescription of the IDEO is currently lacking an evidence base linking injury, functional deficit, and outcome (Schmidtbauer, 2019).

## 5.5. Conclusion

The quality of the literature concerning the IDEO and BOB has been noted to be poor with a lack of blinding, poor reporting of exclusion criteria and no reporting of effect size (Highsmith, 2016). The literature mainly reports a heterogenous patient population with little attempt to identify which injury patterns benefit most from prescription or whether gait characteristics pre-prescription, can be used to predict outcome with the orthosis (Jeanne C. Patzkowski, 2012a; Bedigrew, 2014; Hill, 2016; Brown, 2017; Russell Esposito, 2017; Potter, 2018; Younger, 2018; Mazzone, 2019; Quacinella, 2019; Schmidtbauer, 2019). Further gaps exist in research concerning the offloading capacity and capability of the orthosis, and the energy

storage and return capacity (Stewart, 2020). Also, there is little consensus on which outputs or endpoints should be measured and how much physical therapy is necessary as part of the RTR CP (Highsmith, 2016; Potter, 2018; Ikeda, 2019).

The IDEO improves functional and patient-reported outcome measures whilst preventing amputation in some patients. It is evident that the current IDEO design does not have a clear evidence base for prescription. The impact of use of the IDEO on proximal and contralateral lower limb joints has also not been established.

In order to understand which patients benefit from prescription of the BOB, and to build an evidence base for prescription, the next two Chapters will examine the outcomes for LS patients in the UK prior to the routine use of the BOB and the outcomes with the BOB. Specifically, injury pattern and functional deficit will be used to attempt to predict outcome with the view to create a clinical decision tool for prescription.

# Chapter 6: Outcomes of UK limb salvage patients prior to the introduction of a novel orthosis

## 6.1. Introduction

The previous Chapter concluded that the IDEO/BOB improves outcomes for some military personnel with a lower limb injury. It also demonstrated however that the IDEO/BOB does not improve outcomes for all; approximately 20% progress to amputation and an unknown number abandon the orthosis. The literature concerning the IDEO/BOB, available to date, includes a heterogenous population of foot and ankle injury patients (Highsmith, 2016). The heterogenous nature of the studied cohorts does not allow for evidence-based prescription of the IDEO/BOB. There are demands from military and civilian clinicians for a clinical decision tool to allow for evidence based prescription of the IDEO/BOB (Younger, 2018). An evidence-based clinical decision tool would enable timely, informed prescription and potentially prevent futile rehabilitation. In order to create a clinical decision tool, the outcomes of UK military personnel prior to the introduction of the orthosis, at the end of 2014, must be established as a baseline. This can be used as a comparison for further research concerning outcomes with the BOB to ascertain whether functional and patient-reported outcomes improve with use of the BOB and enable the creation of a clinical decision tool.

The DMRC was the single point of rehabilitation for military personnel repatriated injured from Iraq and Afghanistan. The facility, which was originally located at Headley Court, Surrey and since relocated to Stanford Hall, Loughborough, provides inpatient rehabilitation delivered by a multi-disciplinary team (MDT). The DMRC also provides treatment for all Service Personnel requiring inpatient rehabilitation regardless of mechanism of injury. As mentioned in previous Chapters, the DMRC rehabilitation model means that amputees and LS patients rehabilitate together, as do combat and non-combat injured personnel. Patients are therefore able to compare subjectively their outcomes to other inpatients regardless of injury or treatment. The DMRC undertook research in 2015 investigating the outcomes of immediate amputees, delayed amputees due to failed LS, and LS patients (Ladlow, 2016). They found that functional outcomes were worse for LS patients compared to amputees and that rehabilitation timelines were longest for failed LS patients requiring delayed amputation.

Data was collected on the outcome of lower limb injury patients, but outcome was not linked to injury pattern. It is not possible from this research to link injury pattern with functional and patient reported outcome, and progression to amputation.

The aim of this Chapter is to investigate the outcomes of military personnel who underwent LS surgery and were rehabilitated at the DMRC prior to the introduction of the BOB in the UK in late 2014. The primary objective is to look for predictors of delayed amputation due to failed LS. The secondary objective is to establish functional and patient reported outcomes for LS patients and delayed amputees.

## 6.2. Method

A retrospective analysis was undertaken of all patients who had completed LS rehabilitation at DMRC from January 2013 – January 2015, prior to the routine use of the BOB. A convenience sample was used of all patients who completed LS rehabilitation in the time frame. Patients were defined as requiring LS rehabilitation based on inclusion criteria used in the Military Extremity Trauma Amputation/Limb Salvage (METALS) study (Doukas, 2013). Patients were included if they had sustained an injury of the leg below the knee requiring intervention. Detail of inclusion and exclusion criteria can be found in Table 6-1.

| **Inclusion criteria** | **Exclusion criteria** |
|---|---|
| *Conservative intervention* | Non-UK military |
| Plaster of Paris cast | Immediate lower limb amputation |
| *Operative intervention* | |
| Revascularisation | |
| Bone graft | |
| Plastic surgery intervention for wound coverage | |
| Nerve repair | |
| Compartment syndrome treatment | |
| Gustilo Anderson Type III fracture | |
| Severe foot injuries (mangled foot) | |

*Table 6-1: Inclusion and exclusion criteria*

Basic demographic data were collected on age at incident, body mass index (BMI), and smoking status. Mechanism of injury data were classified as blast, gunshot wound (GSW), road traffic accident (RTA), fall from height, and sporting/training injury. Data from time of

injury was collected on the side of injury, injury sustained, the Injury Severity Score (ISS), and the New Injury Severity Score (NISS). Both the ISS and NISS are measures of injury severity using the Abbreviated Injury Severity Scale (AIS). The AIS is an injury-scoring system with a scale of 1 – 6 in a single body region with 1 representing a minor injury and 6 an injury which is almost always fatal. As it only measures one body region in isolation, the AIS is not of practical use in a multiply injured patient. The ISS was introduced in 1974 based on work by Baker et al (Baker, 1974) to enable a single score to be assigned to a multiply injured patient. The ISS is calculated as the sum of the squares of the highest AIS score for the three most severely injured body regions. There are six defined body regions: the head and neck, face, chest, abdomen and pelvic contents, extremities and pelvic girdle, and external. The score ranges from 1 to 75. If any region is scored as 6 then an ISS of 75 is automatically assigned. The ISS, although still calculated, has largely been replaced by the NISS. The NISS is calculated by the sum of the squares of the AIS of the three most severe injuries, regardless of the body region (Osler, 1997). This has the advantage of being more sensitive to polytrauma patients with multiple severe injuries in the same body region. Major trauma is defined by a NISS > 15 (Russell, 2011).

Data was collected on the anatomical regions injured classified as forefoot, midfoot, hindfoot, ankle, and lower leg as well as the injury sustained. To enable comparison of a heterogenous population of foot and ankle injuries, patients were classified by the functional deficit caused by the injury. The functional deficit was divided into one of 5 categories based on work by Potter et al (Potter, 2018) (Table 6-2).

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|---|
| 1. Weakness of ankle dorsiflexors and/or plantar flexors resulting from leg injury |
| 2. Limited ankle dorsiflexion and/or limited ankle plantar flexion resulting from leg injury |
| 3. Mechanical pain with loading to hindfoot/midfoot |
| 4. Ankle or hindfoot fusion or candidate for ankle or hindfoot fusion |
| 5. Candidate for amputation secondary to ankle/foot impairment e.g. osteomyelitis |

*Table 6-2: Functional deficit by type*(Potter, 2018)

Injuries were also classified by the Foot and Ankle Severity Scale (FASS) which is divided into impairment (FASS-I) and severity (FASS-S) (Manoli, 1997). Severity is scored from 1-6 with 1 representing minimal injury and 6 a currently untreatable injury. Impairment is scored from

0-6 with 0 representing no residual signs and symptoms of the injury and 6 representing total impairment. Injuries of the foot and ankle (Table 6-3) were assigned a FASS-S and FASS-I by 10 experienced surgeons and final scores were agreed by a committee. The resultant FASS-S and FASS-I for each injury gives an idea of how treatable an injury is and the expected long-term impairment. An injury with a high FASS-S but low FASS-I is very treatable and long-term disability should not be expected. The FASS has been demonstrated to be a better predictor of outcome in military lower limb injuries than the AIS (M. A. Ramasamy, 2013). Data were also collected on the treatment received as well as complications including non-union and osteomyelitis. The primary outcome measure was progression to amputation.

| Injury | FASS-S | FASS-I |
|---|---|---|
| Ankle sprain-medial (deltoid) | 1 | 0 |
| Fibular fracture, diaphysis, undisplaced | 1 | 0 |
| Great toe fracture, phalanx, single, undisplaced | 1 | 0 |
| Laceration-dorsal, skin, subq. | 1 | 0 |
| Lateral malleolus fracture-undisplaced | 1 | 0 |
| Lesser toe fracture, single, displaced | 1 | 0 |
| Lesser toe fracture, single, undisplaced | 1 | 0 |
| Lesser toe fractures, multiple, undisplaced | 1 | 0 |
| Medial malleolus fracture, undisplaced | 1 | 0 |
| Laceration-plantar, skin subq. | 1 | 1 |
| Sesamoid fracture(s), single or multiple, undisplaced | 1 | 1 |
| Calcaneal fracture, nonarticular, undisplaced | 2 | 0 |
| Great toe fracture, phalanges, multiple, undisplaced | 2 | 0 |
| Metatarsal fracture, first, undisplaced | 2 | 0 |
| Ankle sprain, lateral (anterior talofibular/calcaneofibular) | 2 | 0 |
| Bimalleolar fracture, undisplaced | 2 | 1 |
| Fibular fracture, diaphysis, displaced | 2 | 1 |
| Great toe fractures, phalanx, single, displaced | 2 | 1 |
| Interphalangeal joint dislocation, first | 2 | 1 |
| Interphalangeal joint dislocation, single, two through five | 2 | 1 |
| Interphalangeal joint dislocations-multiple | 2 | 1 |
| Laceration, dorsal, skin, subq., muscle/tendon | 2 | 1 |
| Laceration, plantar, skin, subq., muscle/tendon | 2 | 1 |
| Lesser toe fracture, multiple, displaced | 2 | 1 |
| Maisonneuve fracture (upper fibula, ankle sprain, undisplaced) | 2 | 1 |
| Medial malleolus fracture-displaced | 2 | 1 |
| Metatarsal fracture, single, second through fifth, undisplaced | 2 | 1 |
| Achilles tendon laceration/rupture | 3 | 1 |
| Ankle dislocation without fracture, displaced | 3 | 1 |
| Calcaneal fracture-nonarticular-displaced | 3 | 1 |
| Great toe fractures, phalanges, multiple, displaced | 3 | 1 |
| Lateral malleolus fracture with deltoid ligament tear, displaced | 3 | 1 |
| Metatarsal fracture, first, displaced | 3 | 1 |
| Metatarsal fracture, single, second through fifth, displaced | 3 | 1 |
| Metatarsal fractures, multiple, undisplaced | 3 | 1 |
| Metatarsophalangeal joint dislocation, first | 3 | 1 |
| Metatarsal joint dislocation, single, two through five | 3 | 1 |
| Talar fracture, head, undisplaced | 3 | 1 |
| Talar fracture, neck, undisplaced | 3 | 1 |
| Tarsal bone fracture, cuboid, undisplaced | 3 | 1 |
| Tarsal bone fracture, cuneiform(s), undisplaced | 3 | 1 |
| Tarsal bone fracture, navicular, undisplaced | 3 | 1 |
| Tibial fracture, diaphysis, undisplaced | 3 | 1 |
| Tibial-fibular fracture, diaphysis, undisplaced | 3 | 1 |
| Tibial-fibular fracture, metaphysis, nonarticular | 3 | 1 |
| Bimalleolar fracture-displaced | 3 | 1 |
| Single unsalvageable 2nd to 5th toes | 3 | 1 |
| Calcaneal fracture, articular, undisplaced | 3 | 2 |
| Maisonneuve fracture/dislocation (upper fibula, ankle displacement), displaced | 3 | 2 |
| Metatarsophalangeal joint dislocations, multiple | 3 | 2 |
| Nerve laceration, other nerve (except tibial nerve) | 3 | 2 |
| Proximal tibiofibular joint dislocation with ankle ligament disruption | 3 | 2 |
| Sesamoid fracture(s), displaced | 3 | 2 |

| | | |
|---|---|---|
| Syndesmotic ligament tear (distal tibiofibular joint disruption)-displaced | 3 | 2 |
| Talar fracture, body, undisplaced | 3 | 2 |
| Tarsal bone fracture, cuneiform(s), displaced | 3 | 2 |
| Tarsal bone fracture, navicular, displaced | 3 | 2 |
| Tarsal bone fracture, cuboid, displaced | 3 | 2 |
| Trimalleolar fracture < 33% posterior malleolus, undisplaced | 3 | 2 |
| Trimalleolar fracture> 33% posterior malleolus, undisplaced | 3 | 2 |
| Compartment syndrome, leg (isolated) | 4 | 1 |
| Tibial fracture, diaphysis, displaced | 4 | 1 |
| Unsalvageable great toe (distal to IP joint) | 4 | 1 |
| Compartment syndrome, foot (isolated) | 4 | 2 |
| Metatarsal fractures, multiple, displaced | 4 | 2 |
| Multiple unsalvageable 2nd to 5th toes | 4 | 2 |
| Talar fracture head-displaced | 4 | 2 |
| Tarsal bone dislocation (navicular, cuboid, cuneiform) | 4 | 2 |
| Subtalar dislocation (talocalcaneal), medial | 4 | 2 |
| Tibial Pilon fracture-undisplaced | 4 | 2 |
| Trimalleolar fracture < 33% posterior malleolus-displaced | 4 | 2 |
| Unsalvageable great toe (distal to MP joint) | 4 | 2 |
| Calcaneal fracture, articular, displaced | 4 | 3 |
| Subtalar dislocation (talocalcaneal)-lateral | 4 | 3 |
| Talar fracture-neck-displaced | 4 | 3 |
| Talotarsal (Chopart's) dislocation | 4 | 3 |
| Tibial-fibular fracture, diaphysis, displaced | 5 | 2 |
| Talar fracture, body, displaced | 5 | 3 |
| Talus fracture with dislocation of fragment | 5 | 3 |
| Tarsometatarsal (Lisfranc) dislocation | 5 | 3 |
| Tarsometatarsal (Lisfranc) fracture/dislocation | 5 | 3 |
| Trimalleolar fracture> 33% posterior malleolus, displaced | 5 | 3 |
| Unsalvageable forefoot (needs immediate mid-tarsal amputation) | 5 | 3 |
| Nerve laceration-tibial nerve | 5 | 4 |
| Unsalvageable forefoot (distal to Lisfranc's Joint) | 6 | 3 |
| Unsalvageable foot (needs immediate amputation) | 6 | 3 |
| Tibial Pilon fracture-displaced | 6 | 4 |
| Add for compartment syndrome, leg (associated with other injuries) | 1 | 1 |
| Add for compartment syndrome, foot (associated with other injuries) | 1 | 1 |
| Add for open dislocation | 1 | 1 |
| Add for open fracture | 1 | 1 |

*Table 6-3: Foot and Ankle Severity Scale* (Manoli, 1997).

The secondary outcome measures were a comparison of functional, and patient reported outcomes between LS patients and amputees. Functional outcome at discharge was assessed using the 6-Minute Walk Test (6-MWT). This is a standard assessment used in the rehabilitation setting with known normative data for a military population (Wilken, 2012). The 6-MWT was performed indoors on a flat 20 m surface. Patients were requested to walk back and forth around cones spaced 20 m apart as many times as possible in the 6-minute time allowance. The distance was then recorded. Patient reported outcome measures were recorded using the Generalised Anxiety Disorder-7 (GAD-7) questionnaire and Patient Health Questionnaire-9 (PHQ-9). The former is a measure of anxiety and the latter a measure of depression. These assessment tools were chosen as they are used widely during rehabilitation at the DMRC with published comparative data in both the UK and US (Ladlow, 2016; Potter, 2018). Results of the GAD-7 can be interpreted as mild, moderate and severe at cut off points 5, 10 and 15 respectively, out of a total score of 21 (Spitzer, 2006). Similarly, the PHQ-9 has cut off points of 5, 10, 15, and 20 representing mild, moderate, moderately severe, and severe depression (Kroenke, 2001).

Patients were also assessed based on the DMRC Outcome Measure (Ladlow, 2016). This 4-part score is assigned by healthcare practitioners. It assesses patients based on their mobility, ADLs, mental health support, and pain status. Details of the scoring system and interpretation can be found in Table 6-4. This is not a validated measure. The retrospective nature of this analysis necessitates the use of data collected at the time of rehabilitation. The DMRC score was the only score of function collected as standard. It is compiled from assessment by the MDT and the patient therefore provides a wholistic view of progress. It provides scores for similar domains to the SMFA used extensively in the literature for LS-patients and amputees potentially enabling comparison.

| Measure | Scoring | Interpretation |
|---|---|---|
| Mobility | 1 = able to run independently | Assessed by physiotherapist |
| | 2 = able to walk independently | |
| | 3 = able to walk with the use of aids | |
| | 4 = requires a wheelchair | |
| Activities of daily living | 1 = able to perform independently | Assessed by occupational therapist with patient's subjective opinion |
| | 2 = able to perform with an aid or adaptation | |
| | 3 = requires assistance with some tasks | |
| | 4 = requires assistance with all tasks | |
| Mental Health Support | 1 = not receiving mental health support | Assessed by mental health team |
| | 2 = currently receiving mental health support | |
| Pain status | 1 = no pain | Patient reported outcome |
| | 2 = controlled pain | |
| | 3 = uncontrolled pain | |

*Table 6-4: DMRC Outcome Measures* (Ladlow, 2016).

Outcome measures were compared between those pursing LS and those undergoing delayed amputation. Delayed amputation (failed LS) was defined as amputation occurring more than 3-months (>90 days) after the original injury, consistent with the METALS definition (Doukas, 2013).

### 6.2.1. Statistical analysis

Data were assessed for normative distribution. Where normally distributed, mean and standard deviation (SD) were reported. If data were skewed, median and range were reported. Comparisons between categorical data were made using the chi-square test. The student's t-test was used to compare means of scale data. A p value of 0.05 was set for significance. Post-hoc power (PHP) calculations were undertaken; a test was deemed to be appropriately powered with a PHP >0.8.

## 6.3. Results

Twenty-eight patients, all male, were eligible for inclusion in the study. Mean age at time of incident was 27 years (SD 5.5 years). The mean BMI at time of discharge was 28 kg/m$^2$ (SD

3.3). 61% were non-smokers, 14% ex-smokers, and 25% current smokers. Blast injury accounted for the largest proportion of mechanisms of injury (Figure 6-1). Of those injured by blast (15), 9 (60%) were mounted and the rest dismounted.

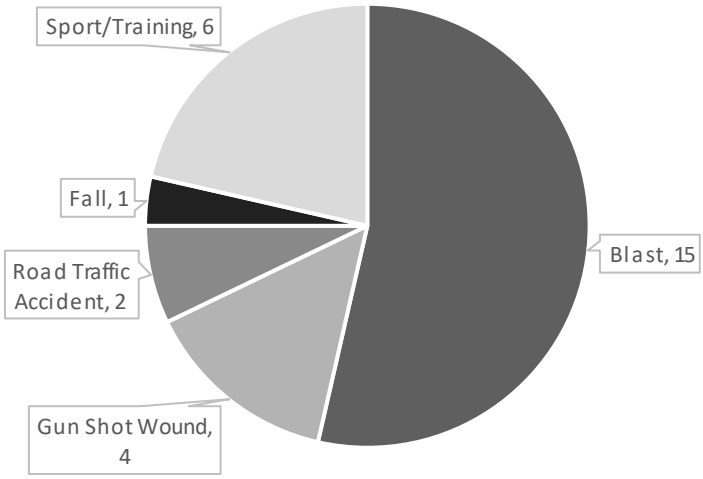



*Figure 6-1: Mechanism of Injury of included personnel (n=28)*

Left sided injuries were found in 13 patients, right in 12, and 3 patients sustained bilateral LS injuries. The median ISS was 4 (range 1 – 29) and the median NISS was 5.5 (range 1 – 34). There were 5 patients with a NISS of >15 signifying major trauma.

Ankle fractures accounted for the largest proportion of injuries (Figure 6-2). Of the 13 ankle fractures sustained, 9 were intra-articular and 4 were extra articular. Examining the talus and calcaneus fractures in more details, 1 talus fracture was extra articular, 1 was intra articular, extending into the subtalar joint, and 3 were intra-articular extending into the ankle joint. For the calcaneus, 4 were intra articular and 1 was extra articular. There were 3 open tibia fractures and 4 closed tibia fractures. Mechanical pain on loading of the hind/midfoot accounted for the greatest proportion of functional deficits (Figure 6-3).

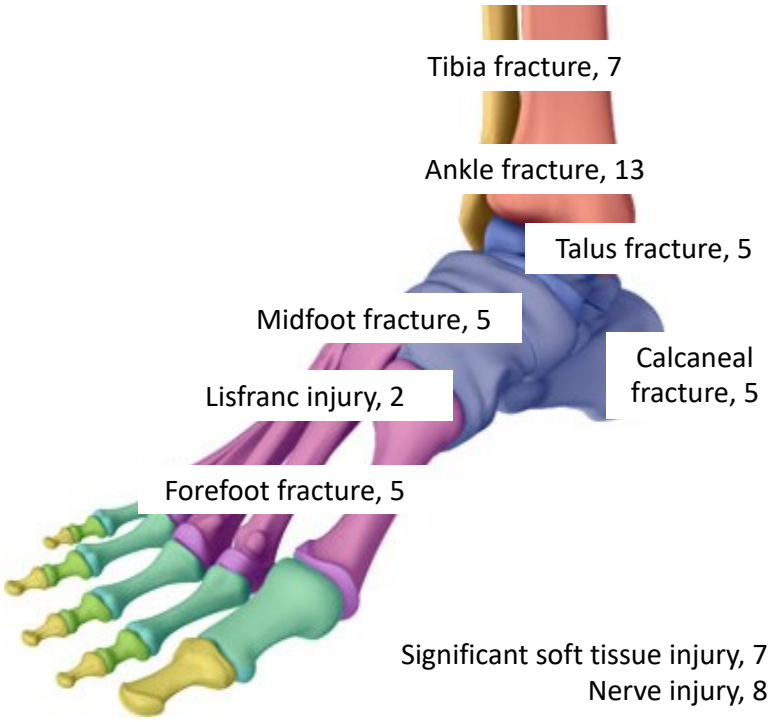



*Figure 6-2: Injury sustained. The total number adds up to more than the total number of included personnel as individuals sustained more than one injury.*

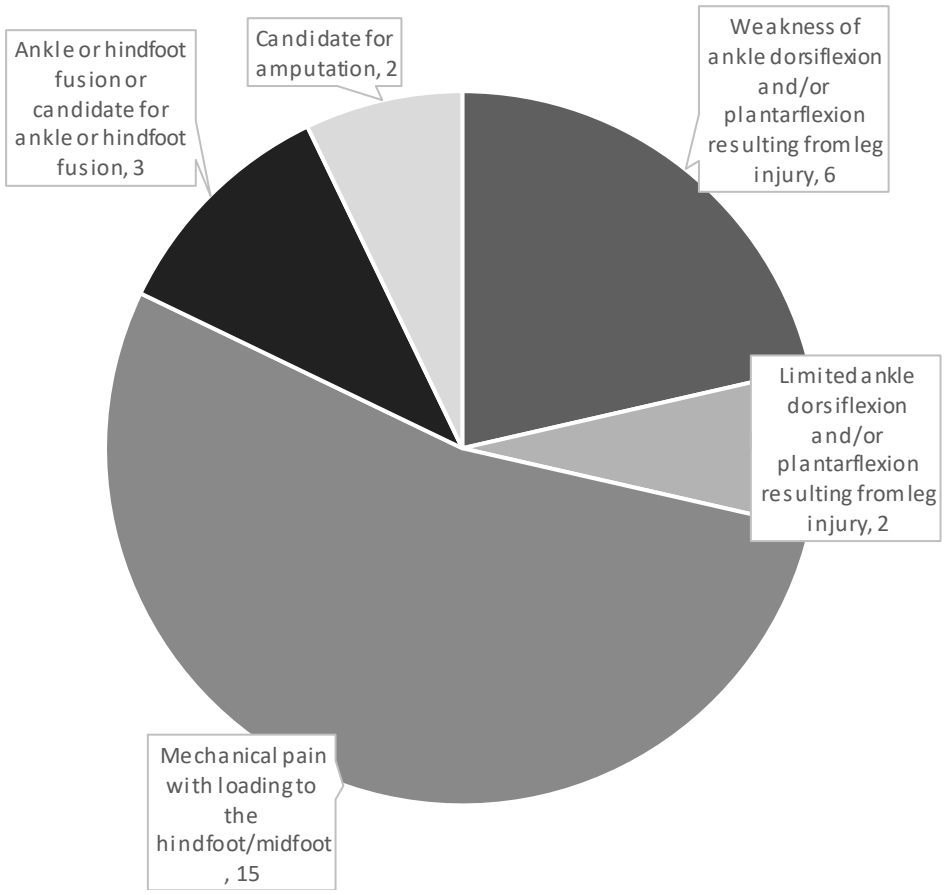



*Figure 6-3: Functional deficit following lower limb injury*

The median FASS-S was 4 and median FASS-I was 3 (Figure 6-4).

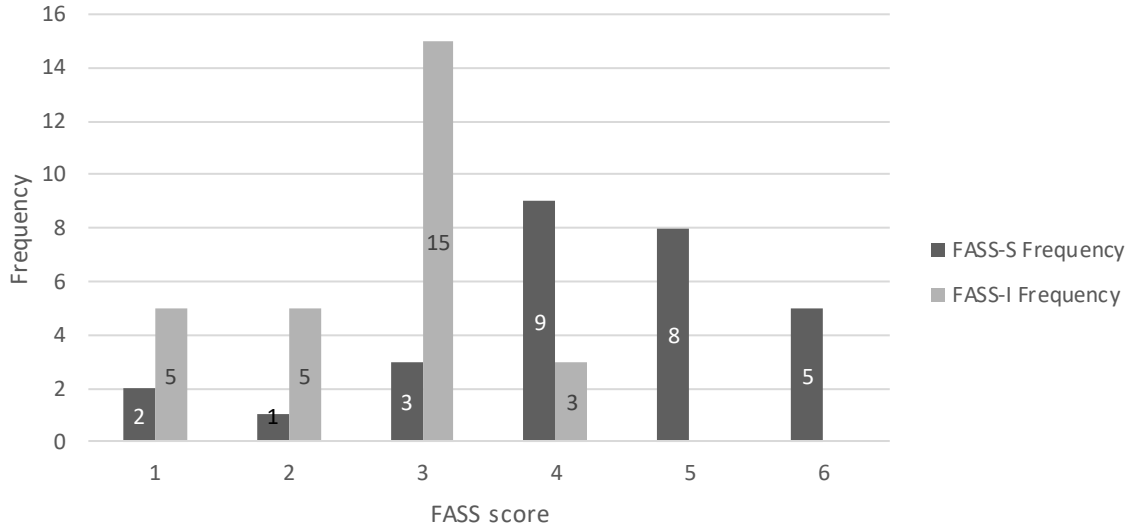



*Figure 6-4: Foot and ankle severity scale distribution*

Examining treatment, most patients underwent open reduction internal fixation (ORIF) (53.6%). The rest had debridement +/- skin graft (17.9%), conservative management (10.7%), intra-medullary nail (10.7%), External-Fixation (3.6%), and K-wire fixation (3.6%). Three patients underwent a secondary arthrodesis. Eight patients experienced non-union, seven of these were infected and one was aseptic. Fifteen of the cohort (53.6%) underwent delayed amputation at median 10-months (range 6-16 months) post injury. There was no statistically significant difference between the age (p=0.697), BMI (p=0.71) or smoking status (p=0.274) of delayed amputees compared to LS patients.

### 6.3.1. Predictors of amputation

Delayed amputation was more frequent in personnel with a sport/training mechanism of injury (p=0.01, PHP = 0.805) (Figure 6-5).

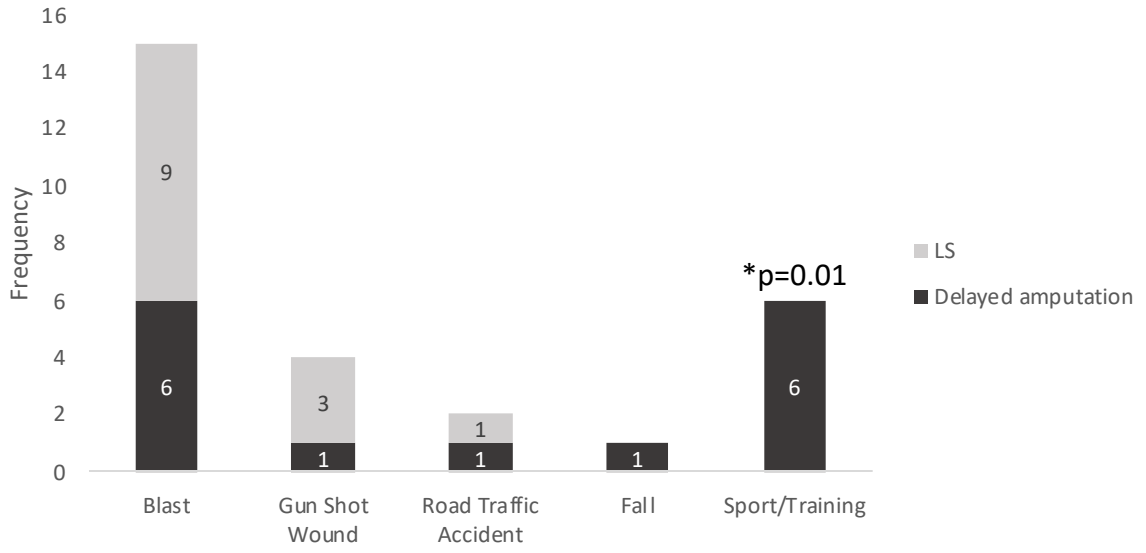



*Figure 6-5: Outcome by mechanism of injury.*

The ISS and NISS were not statistically different between delayed amputees and LS-patients (p=0.692 and p=0.9 respectively). The outcome by injury sustained can be seen in Figure 6-6. Of the 9 intra-articular ankle fractures, 8 progressed to amputation which was found to be statistically significant (p=0.016, PHP = 0.782). An extra articular ankle fracture was not predictive of outcome. Intra and extra articular talus and calcaneal fractures were also not predictive of outcome. A closed tibial fracture was statistically significant for LS (p=0.02, PHP = 0.668) with all 4 patients with a closed tibial fracture pursuing LS.

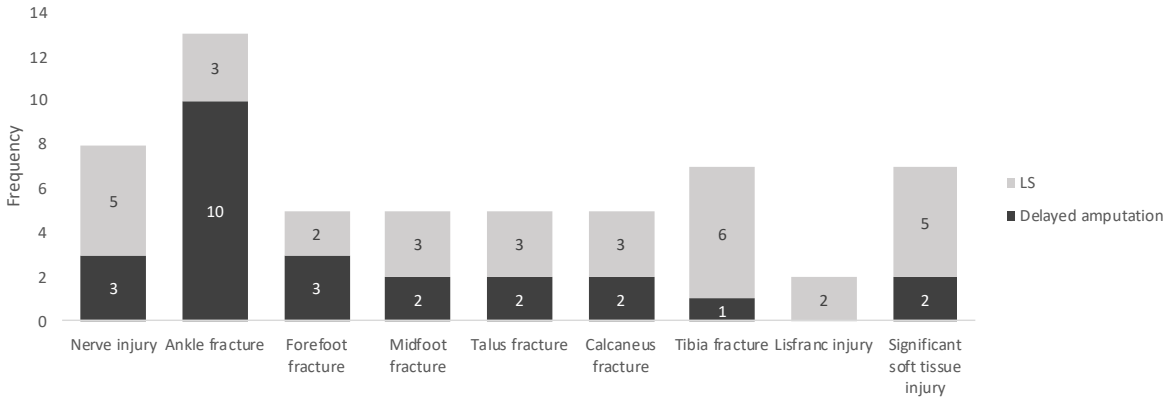



*Figure 6-6: Outcome by injury sustained.*

To ascertain whether an increasing number of foot and ankle injuries on the same side were predictive of outcome, the cohort were assessed based on number of injuries on one side of, ankle fracture, hindfoot fracture, midfoot fracture, forefoot fracture, and a nerve injury (Figure 6-7). This was not noted to be statistically significant. Those who did not sustain any of these injuries (noted in Figure 6-7 as 0) had either an isolated ligament injury or a significant soft tissue injury.

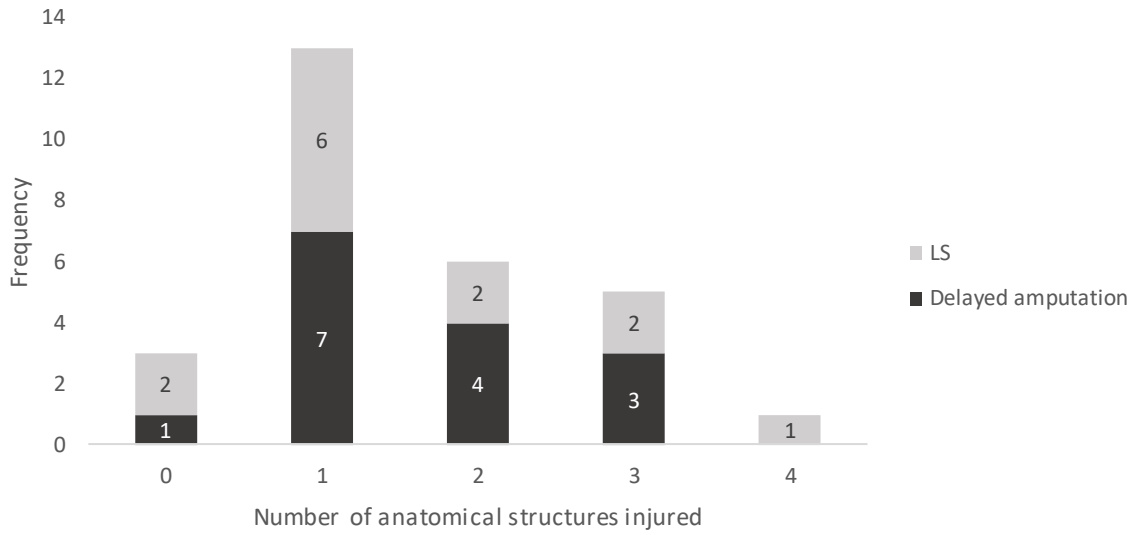



*Figure 6-7: Outcome by number of anatomical structures injured on one side of nerve injury, ankle fracture, hindfoot fracture, midfoot fracture and/or forefoot fracture.*

Examining the functional deficit (Figure 6-8), amputation was less frequent in those with weakness of ankle dorsiflexion and/or plantarflexion however this was not statistically significant. There was no correlation between outcome of delayed amputation compared with LS and the FASS (Figure 6-9).

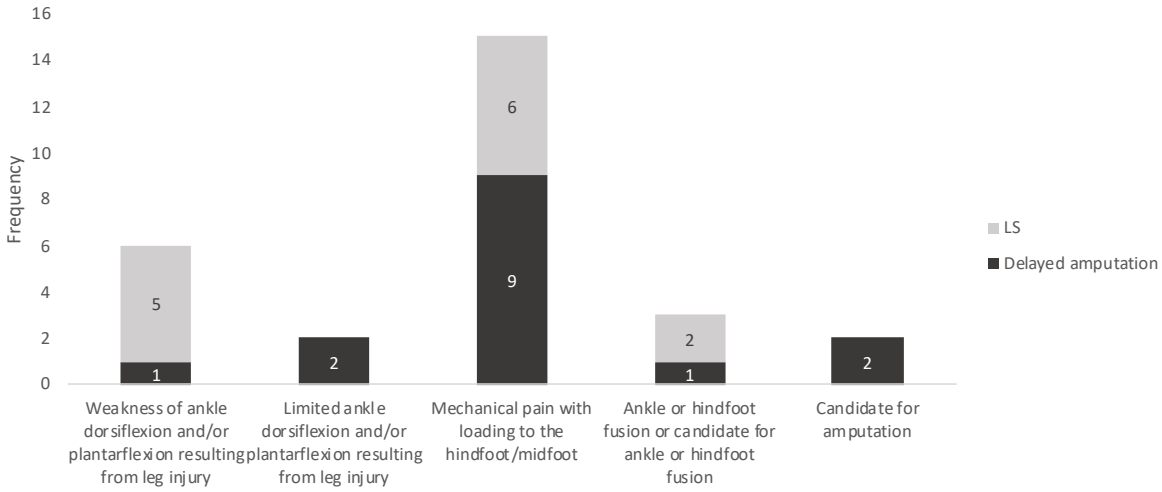
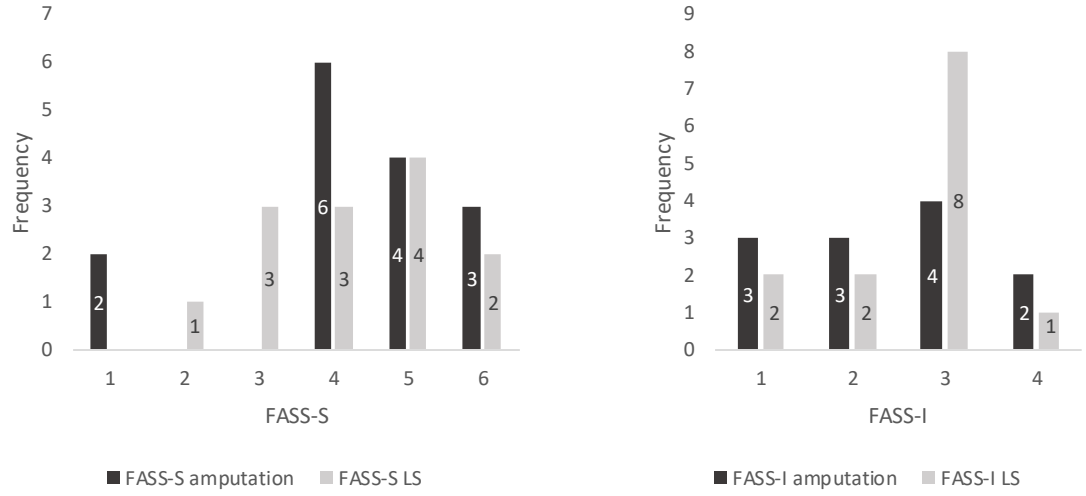



*Figure 6-8: Outcome by functional deficit.*




a b

*Figure 6-9: Foot and ankle severity scale distribution by outcome. a) FASS-S b) FASS-I.*

Treatment overall was not predictive of outcome. Six patients underwent fasciotomy, 3 in each group. All 8 patients with an intra articular ankle fracture resulting in delayed amputation were treated with an ORIF, the only patient with an intra-articular ankle fracture not to have an amputation was treated with an external-fixator due to concomitant soft tissue injury. This was not found to be statistically significant.

Post operatively, 10 patients developed osteomyelitis, 7 in the delayed amputation group and 3 in the LS group, this was not found to be significant (p=0.208). Nine patients were diagnosed with chronic pain by a pain specialist, 7 in the delayed amputation group and 2 in the LS group, this was also not found to be significant (p=0.08). Eight patients developed non-union, 7 in the delayed amputation group and 1 in the LS group. This was found to be statistically significant (p=0.038, PHP = 0.648) with non-union predictive of the need for amputation.

### 6.3.2. Functional outcomes of LS patients and amputees

The mean 6-MWT distance (Figure 6-10) for LS patients was 472.3m (SD 109.7) and for delayed amputees was 595.3m (SD 89.3) following amputation with the difference found to be statistically significant (p=0.003, PHP = 0.883). Amputees were able to walk further in 6 minutes than LS patients on discharge. Examining the 6-MWT distance by functional deficit there was no statistically significant difference between the distance walked for patients with weakness of plantar/dorsiflexors, mechanical pain, or fusion (weakness v mechanical pain p=0.221, weakness v fusion p=0.354, mechanical pain v fusion p=0.051). Comparing the functional deficits of LS-patients to the amputee population however revealed no statistical difference in distance walked for patients with mechanical pain compared to amputees, but patients with weakness of dorsiflexors and/or plantarflexors and patients who had a fusion both walked statistically shorter distances than amputees (p=0.008, PHP = 0.807 and p=0.003, PHP = 0.921 respectively) (Figure 6-11).

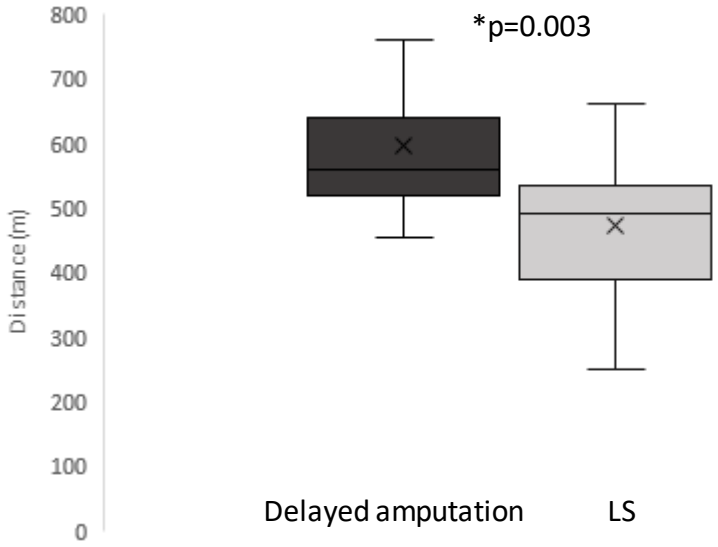



*Figure 6-10: 6-MWT distance for delayed amputees and LS after optimal rehabilitation at the DMRC.*

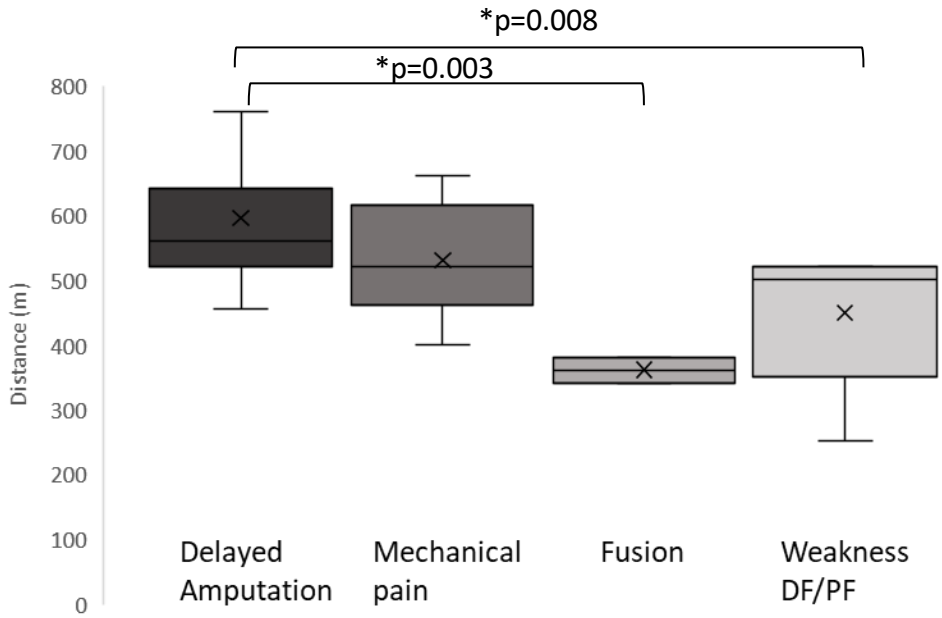



*Figure 6-11: 6-MWT distance for amputees and LS patients based on functional deficit.*

### 6.3.3. Patient reported outcome measures of LS patients and amputees

Results for the GAD-7 and PHQ-9 can be found in Figure 6-12 analysed by outcome of amputation or LS. No statistically significant difference was found between either GAD-7 or PHQ-9 when analysed based on outcome.

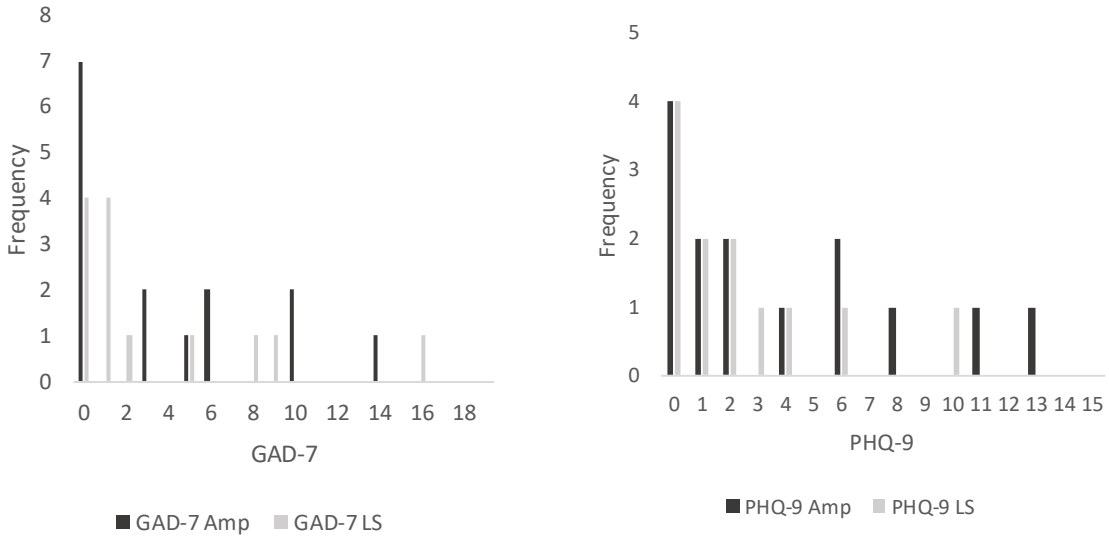



*Figure 6-12: GAD-7 and PHQ-9 by outcome of amputation or LS.*

Analysing the GAD-7 based on cut off points, 3 amputees and 3 LS-patients had mild Generalised Anxiety Disorder (GAD), 3 amputees and no LS-patients had moderate GAD, and one LS-patient had severe GAD. Analysing the cut off points for PHQ-9, 3 amputees and 1 LS-patient had mild depression, 2 amputees and 1 LS-patient had moderate depression, and 1 amputee and 1 LS-patient had moderately severe depression. The sub-categorisations were not found to be statistically significant comparing LS and delayed amputation.

The DMRC grading (Figure 6-13) reveals that LS-patients require more assistance with mobility (p=0.007, PHP = 0.839). Seven delayed amputees could run independently, whilst only 1 LS-patient was able to run independently. A similar number between groups (who cannot run independently) were able to walk independently, (8 amputees and 9 LS patients), and an additional 3 LS-patients required aids to walk. No statistical difference between the groups was found with reference to ADLs and no statistically significant difference was found in mood consistent with the GAD-7 and PHQ-9 scores above. Statistically, more LS-patients

reported pain than amputees (p=0.035, PHP = 0.585) with 7 amputees and 2 LS-patients reporting no pain and 2 LS patients reporting uncontrolled pain.

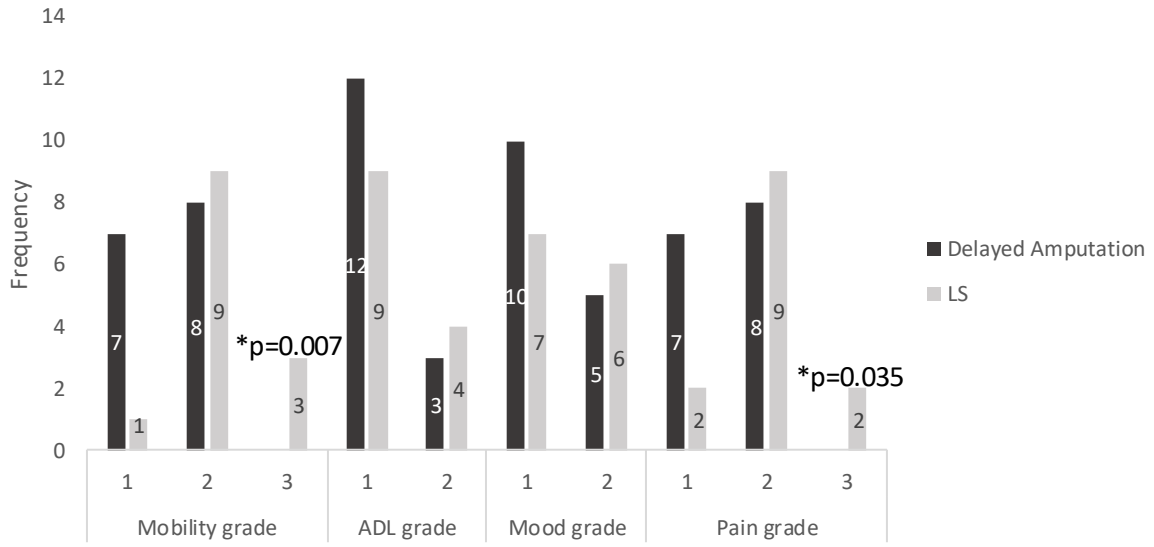



*Figure 6-13: DMRC outcome measure results for delayed amputees and LS patients.*

## 6.4. Discussion

The results demonstrate that 54% of the cohort underwent delayed amputation. This is higher than the median LS failure rate found in Chapter 2 of 3.3% for civilians and 13.5% for military personnel. This relatively high percentage may be due to the cohort representing the worst severity of the military lower limb injuries. The cohort may be subject to bias as a convenience sample of those referred for advanced inpatient rehabilitation was used. The cohort is also relatively small with only 28 patients included.

It is desirable to avoid delayed amputation where possible as discussed in Chapter 3, to prevent secondary health concerns of low back pain, OA, and cardiovascular disease (Hrubec, 1980; Modan, 1998; Gailey, 2008). The amputation rate found here of 54% however represents the outcome following optimal gold standard military rehabilitation prior to the introduction of the BOB at the DMRC and can be used as a comparison when examining outcomes for LS-patients prescribed the BOB. It will be necessary to establish whether use of the BOB reduces delayed amputation by improving functional outcomes.

Statistically significant risk factors for delayed amputation were a sporting mechanism of injury, intra-articular ankle fracture, and non-union. These factors have not previously been associated with delayed amputation. Only the mechanism of injury, however, demonstrated sufficient power on the post-hoc power analysis to be an independent risk factor for delayed amputation. As shown in Chapter 2, pain is associated with failure of LS and non-union may be associated with pain (Naique, 2006; A. Ramasamy, 2013; Krueger, 2015; Ladlow, 2016; Bennett, 2018; Perkins, 2018). Of note however, a chronic pain diagnosis was not found here to be statistically significant when investigating associations with LS failure. Non-union did not demonstrate sufficient power and the small cohort size may account for a statistical significance found in non-union but not in chronic pain. Also shown in Chapter 2, infection is associated with failure of LS and 6 of the 7 patients with a non-union resulting in delayed amputation had an associated infection, only one was aseptic. The presence of non-union may be a factor in progression to amputation, however, this study does not have sufficient statistical power to conclude that non-union is an independent risk factor for amputation.

The study shows that delayed amputation was more common in those with a sporting or training mechanism of injury. Individuals who sustained complex lower limb injuries as a result of combat operations may have undergone primary amputation, therefore those with injuries as a result of sporting or training accidents may represent the next most complex injuries. Alternatively, this result may be a product of the combined rehabilitation model at the DMRC. Personnel who have injured themselves whilst undertaking military sporting or training exercises are rehabilitated next to amputees who have sustained amputations on operations. If amputees are seen to have improved functional outcomes, this may drive LS-patients to request amputation. The psychological drivers surrounding rehabilitation and amputation are out of the scope of this thesis but warrant future investigation.

An intra-articular ankle fracture was found to be statistically predictive of amputation, however, similar to non-union, lacked post-hoc power. An intra-articular ankle fracture may represent a risk factor for amputation due to the disrupted joint line and onset of post-traumatic OA which has been found to arise within 18-months of injury. The consequent pain, like non-union, has been demonstrated to be a driving factor in amputation. Similar to non-

union, this study lacks post-hoc power to conclude that an intra-articular ankle fracture is independently associated with amputation.

A closed tibial fracture was shown to be predictive of LS, although due to small numbers this study lacks statistical post-hoc power to conclude an independent association. Closed tibial fracture may result in a less complex injury making LS more likely. An undisplaced diaphyseal tibial fracture is assigned a FASS of 3-1, whereas a worse case displaced trimalleolar fracture is assigned a FASS of 5-3. The more serious injury with greater impairment predictive of delayed amputation.

An improved 6-MWT distance was achieved by amputees compared to LS-patients. Amputees were able to walk on average 121 m further in 6-minutes than LS-patients. This is above the minimal detectable change of 45 m reported in the literature (Resnik, 2011). Improved 6-MWT distance for amputees compared to LS patients is consistent with Barla et al who found superior walking distances for civilian amputees compared to LS patients (t-test $p<0.006$) (Barla, 2017). Delayed amputees walked a mean of 595.3 m (SD 89.3) in 6-minutes. This is less than the norm for able bodied active military personnel of 724.9 m (SD 84.1) (Wilken, 2012) and also less than the average for military TTAs reported in the literature as 661 m (SD 87) (Linberg, 2013). The amputee result found here however falls within the standard deviation of the latter study. The amputee result of 595.3 m is comparable to average 6-MWT distances recorded at the DMRC for patients who have undergone immediate below knee amputation of 598 m (SD 63) (Ladlow, 2016). This demonstrates that for functional outcome, the trial of LS prior to amputation has not affected performance. For LS patients the mean 6-MWT distance of 472 m is above 459 m, the lower value for age-matched healthy civilian controls (Chetta, 2006). Specifically, the statistical difference was found for LS patients with weakness of dorsi/plantarflexors and those following fusion. These may represent groups warranting further investigation for benefit with the BOB.

The results of this study also demonstrate that more amputees can run independently than LS-patients. Functional performance is an important determinant for LS-patients when considering amputation (Aravind, 2010). An inability to run independently after LS rehabilitation may be a factor driving individuals towards elective amputation. Additionally,

LS-patients required aids to mobilise which (other than prosthetics) were not required in the delayed amputee cohort, further highlighting superior functional outcomes for amputees. This was also found by Barla et al where LS-patients required more walking aids than amputees (t-test $p<0.03$) (Barla, 2017).

The results of this study demonstrate a higher burden of pain in the LS cohort compared to the amputee cohort. However, this result lacks statistical power in post-hoc power analysis. Increased pain is consistent with the literature which shows ongoing pain as a common complaint for LS-patients (Danoff, 2015; Bonato, 2017). Pain is also cited as a reason for elective amputation in a number of studies following complex foot and ankle injuries (Naique, 2006; A. Ramasamy, 2013; Krueger, 2015; Ladlow, 2016; Bennett, 2018; Perkins, 2018).

Improved outcomes for amputees is in keeping with other military studies, assessing patient reported outcome using the SMFA (Doukas, 2013). The SMFA provides an overall score and sub-category scores for mobility, arm/hand function, ADLs, and emotional status (Swiontkowski, 1999). Three of these 4-categories are similar to the DMRC score (mobility, ADLs, and emotional status). METALS found significantly better SMFA scores for amputees compared to LS patients and this is also represented in this study using the DMRC score. Both of these results are contrary to the LEAP which found no difference in the SIP scores at 2 and 7-years regardless of treatment option (MacKenzie, 2005). The LEAP excluded military patients who have access to dedicated rehabilitation centres in the form of the DMRC. The METALS study highlights the potential role of dedicated rehabilitation centres as a reason for the difference in outcomes between the METALS study and the LEAP study. It is not possible to extricate the role the DMRC and similar centres play, both positively and potentially negatively, in the rehabilitation of Service Personnel.

Using the PHQ-9 in this study, 32.1% of the cohort reported symptoms of depression with no difference between depression levels in amputees or LS-patients. The METALS study found 38.3% of reported depression using the Revised Centre for Epidemiologic Studies Depression Scale (CESD-R) whilst the LEAP found 37.6% of the cohort scored for depression at 2-years on the Brief Symptom Inventory (McCarthy, 2003; Doukas, 2013). The results are not dissimilar

between studies and demonstrate a higher level of depression than in the UK able-bodied population aged over 16-years of 19.7% (National Statistics, 2020).

There are a few limitations of this study. Firstly, this study includes a small cohort taken from a convenience sample. There are therefore a number of potential biases present including the study examining the most severe injuries and a lack of statistical power for drawn conclusions. This is a convenience sample of all patients discharged over a 2-year period prior to the introduction of the BOB and larger numbers were not available. Conclusions must therefore be understood in the context of the small sample size and retrospective nature of the data analysis. Data was only available at discharge from the DMRC with no comparative data prior to rehabilitation therefore it is not possible to conclude whether the rehabilitation provided at the DMRC improved the outcomes. The outcomes of those individuals who underwent primary amputation are also not examined and comparisons cannot be made. The aim of this study however was to find the outcome of LS patients prior to routine use of the BOB, and this has been achieved. The results can act as a baseline after discharge from the gold-standard of rehabilitation care at that point in time. Additionally, the DMRC use an outcome measure which has not been validated beyond the rehabilitation centre. It is however similar in several subcategories to the SMFA. The DMRC tool benefits from providing an MDT derived measure combined with a patient-derived measure. Future research looking at the BOB cohort should include the SMFA to provide a validated outcome score and allow comparison with the METALS study. It should also use the DMRC outcome score where available to allow for comparison with this study.

## 6.5. Conclusion

In conclusion, in this convenience sample of lower limb injury patients rehabilitated at the DMRC, over 50% of patients underwent delayed amputation following a lower limb injury. Predictors of amputation were a sporting/training mechanism of injury and functional outcomes were improved for amputees compared to LS-patients. Particularly functional outcomes were improved for amputees compared to LS patients with weakness of dorsi/plantarflexion and following fusion. There is therefore scope for improvement in outcomes for LS patients to prevent amputation, improve walking and running outcomes, and

improve reported pain. The addition of external augmentation for LS patients in the form of the BOB may be one solution to improve rehabilitation pathways for LS patients and prevent progression to amputation. To be successful the BOB needs to bring functional outcomes in line with amputees or, where possible, military population norms. It also needs to reduce the delayed amputation rate. In the next Chapter the outcomes for patients prescribed the BOB at the DMRC are examined. The feasibility to produce a clinical decision tool for the prescription of the BOB from current data is also assessed.

# Chapter 7: Outcome with the Bespoke Offloading Brace for UK military personnel

## 7.1. Introduction

Prior to the introduction and routine use of the BOB at the DMRC over 50% of the LS-patients underwent delayed amputation. A sporting/training mechanism of injury was found to be the only significant predictor of the need for amputation (Chapter 6). Similar to the findings in Chapter 2, patients who underwent delayed amputation had superior functional outcomes compared to those who pursued LS. There is therefore scope to improve functional outcomes for LS-patients and attempt to prevent progression to amputation.

Chapters 4 and 5 established that outcomes for LS-patients may be improved using the IDEO/ BOB. These orthoses are designed to overcome weakness in dorsiflexion and plantarflexion, improve upon decreased joint stability, and aid in propulsion by storing energy during the stance phase of gait and returning it at toe off (Owens, 2011; Patzkowski, 2011; Bedigrew, 2014). Short-term results are promising with 41 of 50 patients who were previously considering amputation pursuing LS after using the IDEO (Bedigrew, 2014). Improved functional and patient-reported outcomes, sustained for maximum 2-year follow-up, have also been reported with use of the IDEO (Bedigrew, 2014).

Although positive outcome results have been found in a heterogenous LS population, the literature demonstrates that not all patients benefit from prescription of the IDEO. Approximately 20% of users still progress to amputation with pain cited as the most common reason; an unknown number abandon the IDEO (Hill, 2016). The BOB costs approximately £1,500 for military personnel and rehabilitation timelines following prescription can be long. To prevent potentially painful, costly, protracted, and ultimately futile rehabilitation with the BOB, it is desirable to understand the clinical indications – or contraindications – for prescription. As described in Chapter 5, only a handful of studies have investigated outcomes with the IDEO for specific clinical indications and even then, they are limited due the small cohort numbers. Improvement in outcomes for patients following ankle and/or subtalar fusion (Sheean, 2016), post-traumatic OA (Jeanne C. Patzkowski, 2012b), and common

peroneal nerve injury have been demonstrated in small studies (Quacinella, 2019). To date, no study has produced clear indication criteria for prescription of the IDEO/BOB. Furthermore, outcomes have only been followed up for a maximum of 2-years.

## 7.2. Aim

The aim of this study is to investigate an association between medium term outcome with the BOB and injury for UK military personnel. Specific objectives are to establish:

1. if the BOB improves functional and patient-reported outcomes for LS-patients;
2. predictors of elective amputation following use of the BOB; and
3. predictors for ongoing use of the BOB.

It is hypothesised that:

1. patients with Chronic Regional Pain Syndrome (CRPS) or neuropathic pain will abandon the BOB and require amputation;
2. patients with primarily a nerve injury will continue to use the BOB;
3. patients with an ankle and/or subtalar fusion will continue to use the BOB;
4. overall outcome with the BOB can be predicted from injury pattern or functional deficit.

## 7.3. Method

This study was registered and approved by the Military Medical Directorate and Ministry of Defence Research Ethics Committee (1005MODREC19). All UK military patients who had been prescribed a BOB via the DMRC were identified from a prospective database. Patients were included if they had sustained an injury of the leg below the knee requiring intervention. Detail of inclusion and exclusion criteria can be found in Table 7-1.

| **Inclusion criteria** | **Exclusion criteria** |
|---|---|
| *Conservative intervention* | Non-UK military |
| Plaster of Paris cast | Reside outside the UK at follow-up |
| Significant/central nerve injury | Significant mental health problems |
| *Operative intervention* | |
| Revascularisation | |
| Bone graft | |
| Plastic surgery intervention for wound coverage | |
| Nerve repair | |
| Compartment syndrome treatment | |
| Gustilo Anderson Type III fracture | |
| Severe foot injuries (mangled foot) | |
| Brostrom repair/another ligament repair | |

*Table 7-1: Inclusion and exclusion criteria of study examining clinical outcomes with the BOB.*

Clinical records held at the DMRC, Queen Elizabeth Hospital, Birmingham, and primary health care records for the individuals were scrutinised. The most recent general practice or secondary care entry was used as a surrogate marker for follow-up. Demographic data including age, BMI, and smoking status was recorded. Information relating to the injury was documented including mechanism of injury, side of injury, ISS, and NISS (see previous Chapter for detailed explanation of the ISS and NISS). Data was collected on the anatomical injury location, injury pattern, and functional deficit. As in the previous Chapter, the functional deficit was divided into one of 5-categories based on work by Potter et al (Table 7-2) (Potter, 2018). The functional deficit enables comparison between patients with various injuries, overcoming the heterogenous nature of the cohort and enables comparison with the literature.

| |
|---|
| 1. Weakness of ankle dorsiflexors and/or plantar flexors resulting from leg injury |
| 2. Limited ankle dorsiflexion and/or limited ankle plantar flexion resulting from leg injury |
| 3. Mechanical pain with loading to hindfoot/midfoot |
| 4. Ankle or hindfoot fusion or candidate for ankle or hindfoot fusion |
| 5. Candidate for amputation secondary to ankle/foot impairment |

*Table 7-2: Functional deficit by type used to overcome heterogenous nature of foot and ankle injured population prescribed the BOB* (Potter, 2018).

Injuries were also classified by the FASS which is divided into impairment (FASS-I) and severity (FASS-S) (Manoli, 1997). The FASS has been demonstrated to be a better predictor of outcome in military lower limb injuries than the AIS (A. Ramasamy, 2013). A detailed description of the FASS can be found in the previous Chapter. It was also noted whether patients had an

associated ligament, vascular or nerve injury, as well as the treatment received. Complications were recorded including non-union and progression to Chronic regional Pain Syndrome (CRPS)/neuropathic pain. CRPS was noted if an individual had been referred for a specialist pain consultant opinion and a diagnosis of CRPS made. Neuropathic pain was noted if an individual had been referred for specialist pain intervention with a neuropathic pain diagnosis made. These two diagnoses were recorded as chronic pain. The primary outcome recorded was delayed amputation. The secondary outcome recorded was ongoing use of the BOB for those with retained limbs.

Performance with the BOB was assessed pre prescription and post rehabilitation using the 6-MWT. This is a standard assessment used in the rehabilitation setting with known normative and minimal detectable change data for a military population (Wilken, 2012).

PROMs were recorded pre prescription and post rehabilitation with the BOB, using the GAD-7 and PHQ-9. These assessment tools were chosen as they are used widely during rehabilitation at the DMRC with published comparative data in both the UK and US (Ladlow, 2016; Potter, 2018). A full description of both can be found in the previous Chapter. The Brief Pain Inventory (BPI) and VAS for pain were also documented as these tools are used in the literature looking specifically at foot and ankle trauma (Bosse, 2017). Patients also completed the SMFA to assess perceived functional performance with the BOB (Swiontkowski, 1999). The SMFA is a measure of functional status. An overall function index and bother index are obtained along with scores for mobility, arm/hand function, daily activities, and emotional status. Data can be compared to standardised population norms and the SMFA is used in the METALS study allowing for military comparison (Doukas, 2013). As noted in the previous Chapter, the SMFA has not previously been collected for patients at the DMRC. To obtain the score, patients who had not progressed to amputation were contacted as part of this study. Patients were also assessed, as in Chapter 6, based on the DMRC Outcome Measure (Ladlow, 2016). This 4-part score is assigned by healthcare practitioners. It assesses patients based on their mobility, ADLs, mental health support, and pain status. Details of the scoring system and interpretation can be found in Table 7-3. The retrospective nature of this study necessitated the use of measures routinely recorded at the DMRC prior to the introduction of the BOB and since introduction. Outcome with the BOB was recorded based on whether the patient was

still using the BOB at most recent follow up and analysis was undertaken to attempt to predict outcome with the BOB.

| Measure | Scoring | Interpretation |
|---|---|---|
| Mobility | 1 = able to run independently | Assessed by physiotherapist |
| | 2 = able to walk independently | |
| | 3 = able to walk with the use of aids | |
| | 4 = requires a wheelchair | |
| Activities of daily living | 1 = able to perform independently | Assessed by occupational therapist with patient's subjective opinion |
| | 2 = able to perform with an aid or adaptation | |
| | 3 = requires assistance with some tasks | |
| | 4 = requires assistance with all tasks | |
| Mental Health Support | 1 = not receiving mental health support | Assessed by mental health team |
| | 2 = currently receiving mental health support | |
| Pain status | 1 = no pain | Patient reported outcome |
| | 2 = controlled pain | |
| | 3 = uncontrolled pain | |

*Table 7-3: DMRC Outcome Measures for patients rehabilitated following injury. The score is divided into 4 domains and assigned by either a health care practitioner or via a patient reported outcome.*

### 7.3.1. Statistical Analysis

Data were assessed for normative distribution using the Shapiro-Wilk test. Where normally distributed, mean and standard deviation (SD) are reported. If data were skewed, median and range are reported. Comparison between categorical data were made using the chi-square test. The student's t-test was used to compare means of scale data for normally distributed data, and non-parametric tests were used for skewed data. A p value of 0.05 was set for significance. Post-hoc power (PHP) calculations were undertaken; a test was deemed to be appropriately powered with a PHP > 0.8.

## 7.4. Results

60 patients have been provided with a BOB via the DMRC as of August 2018. Five patients were excluded; four reside outside the UK therefore there is no follow up data available, and one patient was excluded due to significant underlying mental health problems preventing

contact for outcome data. An additional individual was lost to follow up. There were therefore 54 records available for analysis.

### 7.4.1. Demographics

All patients were male with a mean age at incident of 28.5 years (SD 6.5). The mean BMI was 28.10 kg/m$^2$ (SD 3.19). 53.7% were non-smokers, 27.8% ex-smokers and 18.5% current smokers. Median follow-up since injury was 96.5 months (range 47-382).

### 7.4.2. Injury details

Sport/military training and blast accounted for the largest proportion of injuries by mechanism (Figure 7-1). Of the blast-injury cohort, there was an even split of mounted and dismounted blast injury with 8 mounted and 8 dismounted at time of injury.

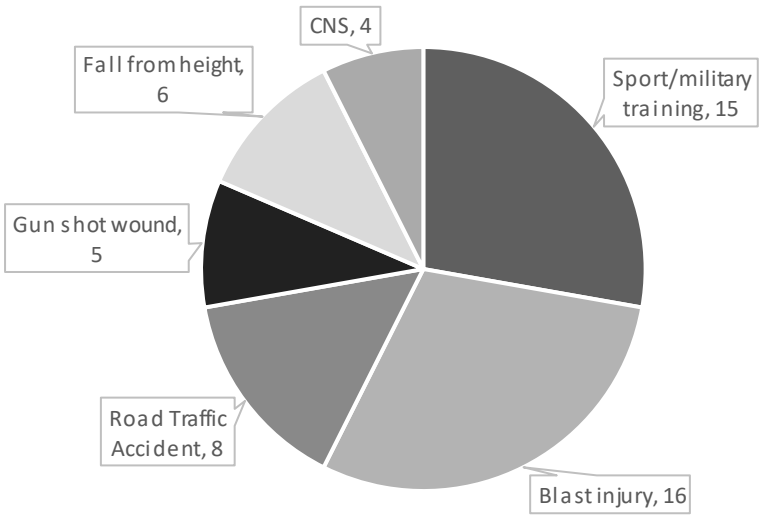



*Figure 7-1: Mechanism of Injury for cohort (n=54). The number next to the category is the raw number of personnel from the cohort. CNS = Central Nervous System.*

The side of injury requiring a BOB was the left in 48% of cases and right 48% with 4% (n = 2) bilateral. The median ISS was 4 (range 1-21) and NISS was 12 (range 1-24). There were 9 patients with a NISS of >15, indicting major trauma.

The injuries sustained can be seen in Figure 7-2. Of the 14 ankle fractures sustained, 12 were intra-articular. Looking at the hindfoot injuries, 18 of the 19 calcaneal fractures were intra-articular and 13 of the 17 talus fractures were intra-articular. Of the 13 tibia fractures sustained, 9 were open injuries.

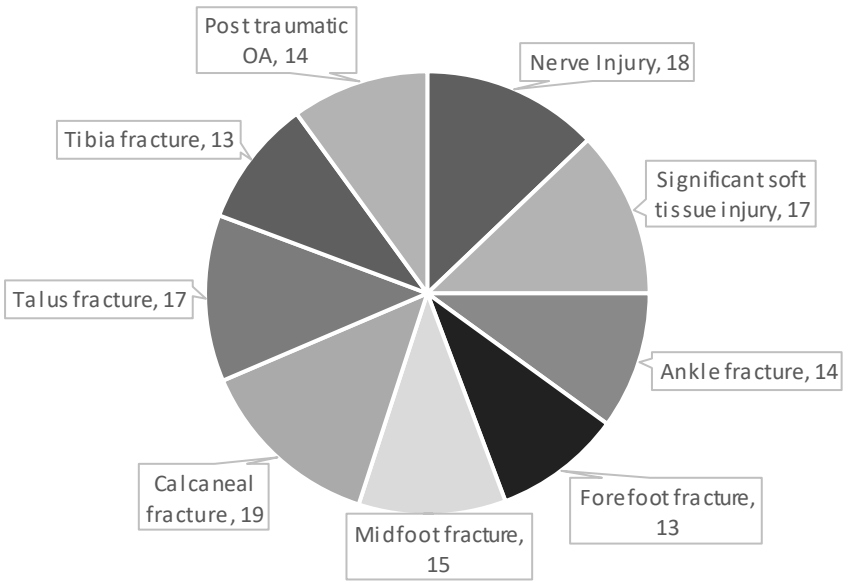



*Figure 7-2: Injury sustained. The total number of injuries adds up to more than the total number of included personnel as individuals sustained more than one injury.*

Mechanical pain on loading of the hind or mid foot accounted for the greatest proportion of functional deficits (Figure 7-3). Candidates for amputation included individuals with chronic osteomyelitis or non-union.

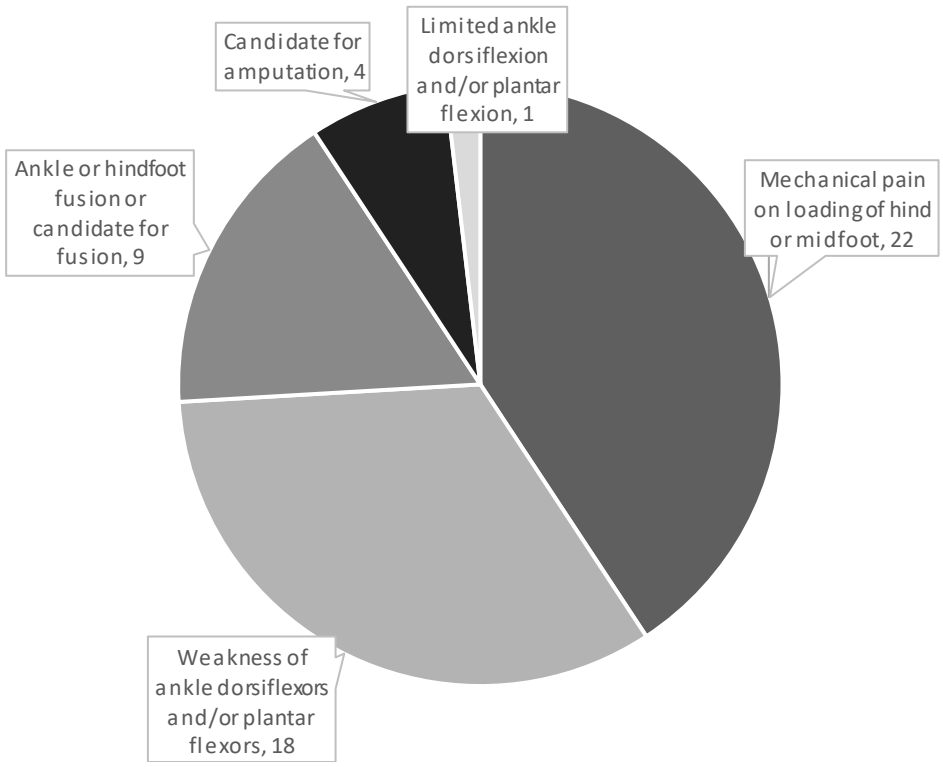



*Figure 7-3: Functional deficit following lower limb injury and prescribed a BOB. N=54, number next to category is raw number of personnel.*

The median FASS-S was 4 (range 2-6) and median FASS-I was 2 (range 0-4) (Figure 7-4). 20 (37%) patients sustained concomitant ligament injuries, 2 (3.7%) patients sustained a vascular injury, and 18 (31.5%) patients sustained an associated or primary nerve injury.

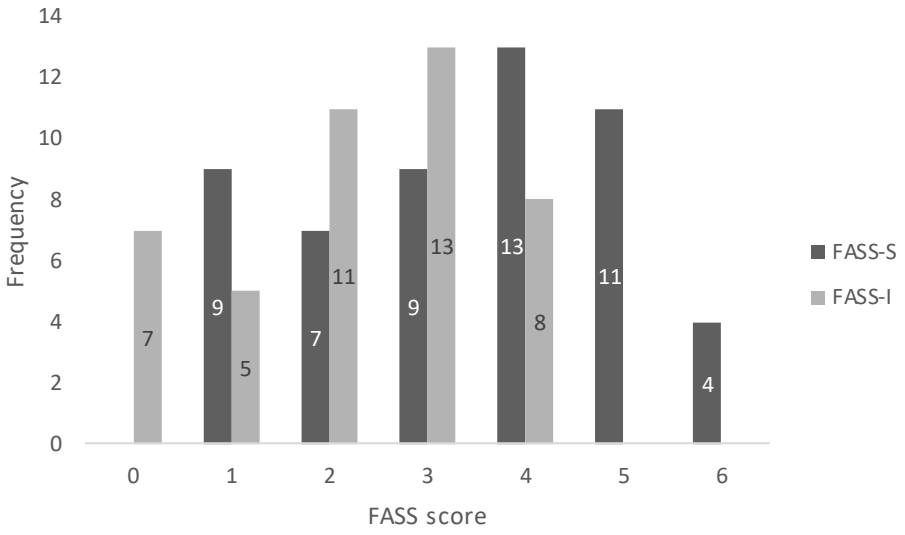



*Figure 7-4: Foot and Ankle Severity Scale results.*

### 7.4.3. Treatment and complications

The majority of patients underwent an ORIF as treatment for their injury (Figure 7-5). This represents the primary management although patients may have undergone several subsequent operations.

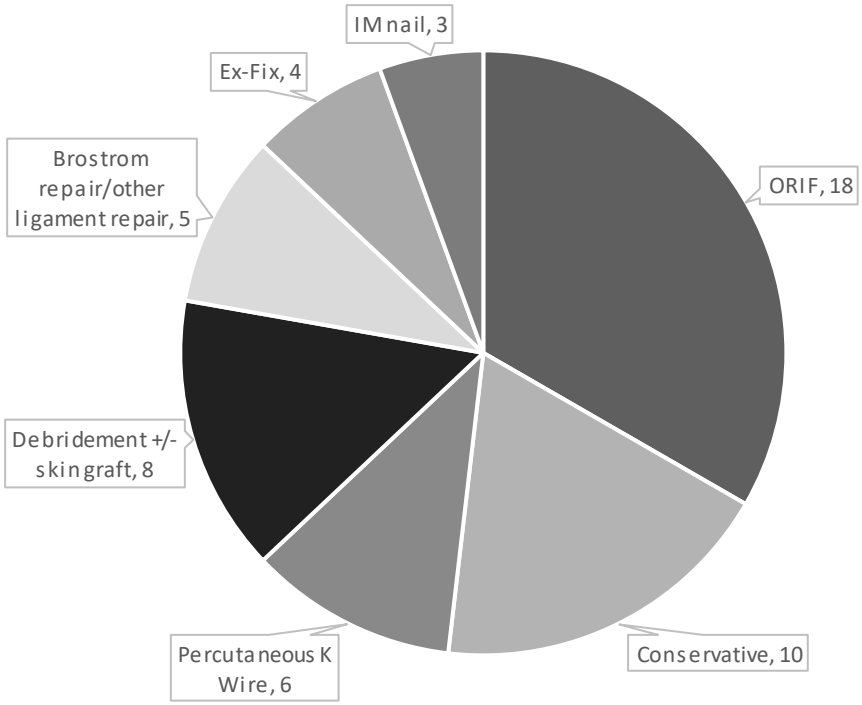



*Figure 7-5: Treatment for lower limb injury. IM nail = intra-medullary nail, Ex-Fix = external-fixator, ORIF = Open Reduction Internal Fixation.*

Sixteen (28.6%) patients underwent attempted fusion as a secondary procedure. Sixteen (28.6%) patients suffered non-union, of which 6 patients had an infected non-union. An additional 5 (9%) patients had a delayed union. Chronic pain was diagnosed in 9 (16.7%) patients and 20 (37%) patients had a psychiatric diagnosis including PTSD or GAD. Prior to use of the BOB, 25 (46%) patients were considering amputation, 14 (26%) were not, and for 15 (28%) patients it is not known whether they were considering amputation. Thirteen (24%) patients progressed to amputation; these are discussed further in a later section (Amputation).

### 7.4.4. Performance assessment

Median follow-up since prescription of the BOB was 63-months (range 27-82). The mean 6-MWT distance prior to use of the BOB was 369.43 m (SD 104.59) and with the BOB was 490.22 m (SD 98.81) with a mean improvement of 130.37 m (SD 100.1) (Figure 7-6). Comparison of pre and post use mean distance demonstrated a statistically significant improvement ($p<0.001$, PHP = 0.980) and an improvement above the minimal detectable change for military personnel of 81.25 m (Wilken, 2012). Statistically significant improvements in 6-MWT distance (Figure 7-7) were seen for individuals with weakness of dorsi and/or plantarflexion ($p<0.001$, PHP = 0.992) and individuals following fusion ($p<0.001$, PHP = 0.994). The improvement in 6-MWT distance for patients with mechanical pain was not found to be significant ($p=0.063$) and neither was the change for candidates for amputation ($p=0.591$).

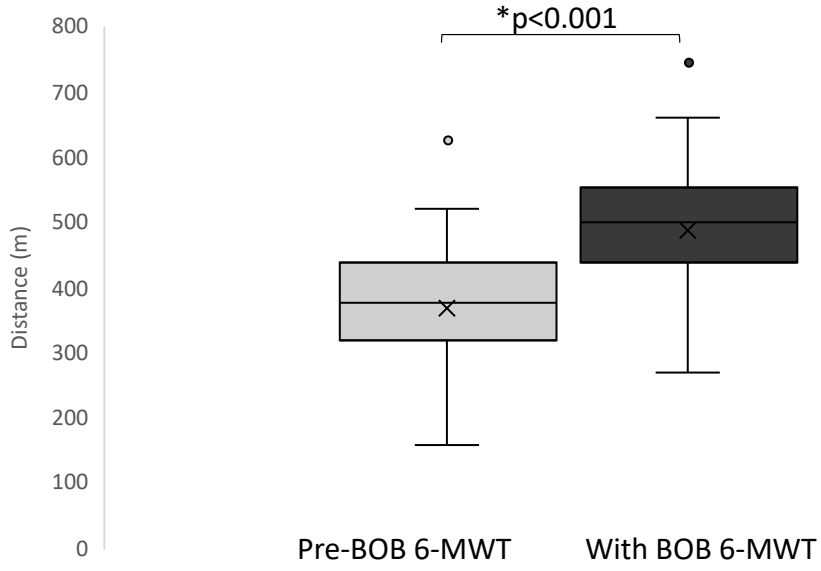



*Figure 7-6: 6-Minute Walk Test distance before and after BOB use.*

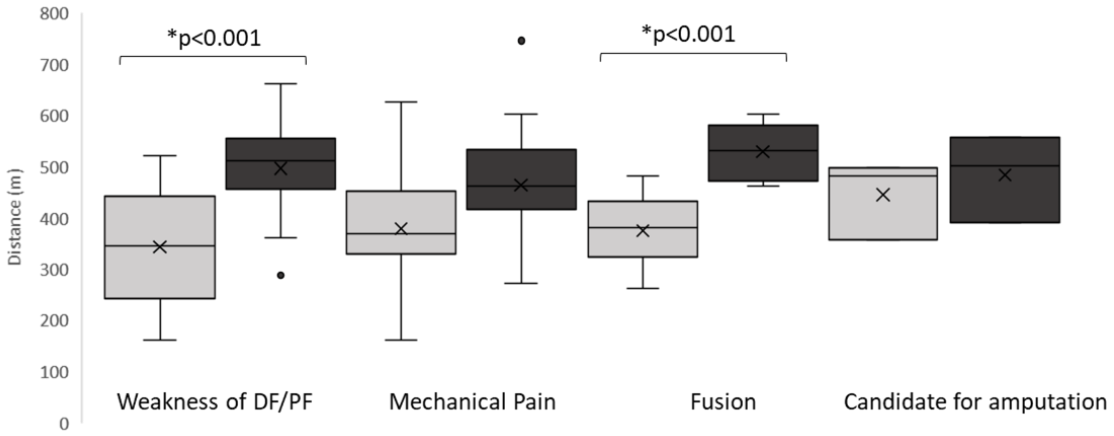



*Figure 7-7: Change in 6-Minute Walk Test distance from pre-BOB prescription (light grey) to with BOB (dark grey) by functional deficit. DF=dorsiflexion PF=plantarflexion.*

### 7.4.5. Patient reported outcome measures

Thirty (55.6%) patients had a pre- and post-BOB use GAD-7 and PHQ-9 recorded. The median pre use GAD-7 was 3 (range 0-21) and post use was 3.5 (range 0-21). A change in the number of patients in each category (mild, moderate and severe) pre-BOB use and with BOB use was seen but this was not statistically significant (Table 7-4). The median pre use PHQ-9 was 5 (range 0-27) and post use was 5 (range 0-27). Similar to GAD-7, although changes were seen in the number of people in each category before and after use of the BOB, these were not statistically significant (Table 7-5).

| | **Pre-BOB** | **With-BOB** |
|---|---|---|
| **Mild GAD-7** | 4 | 10 |
| **Moderate GAD-7** | 9 | 4 |
| **Severe GAD-7** | 1 | 3 |

*Table 7-4: Categories of GAD-7 pre-BOB use and post-BOB use.*

| | **Pre-BOB** | **With-BOB** |
|---|---|---|
| **Mild PHQ-9** | 6 | 9 |
| **Moderate PHQ-9** | 8 | 4 |
| **Moderately severe PHQ-9** | 4 | 3 |
| **Severe PHQ-9** | 2 | 3 |

*Table 7-5: Categories of PHQ-9 pre-BOB use and post-BOB use*

Thirty-two patients had a BPI and 39 has a VAS assessment completed pre- and post-BOB use (Table 7-6) with a statistically significant improvement in both BPI interference and VAS.

| **PROM** | **Pre BOB use** | **Post BOB use** |
|---|---|---|
| **BPI Interference*** | 5.15 (2.53) | 4.37 (2.47) |
| **BPI Severity** | 3.67 (2.20) | 3.59 (2.05) |
| **VAS**** | 56.95 (16.36) | 71.33 (17.44) |

*Table 7-6: Patient reported outcome measures reported with SD *Statistical significance <0.05 **statistical significance <0.001.*

Twenty-three (56%) patients completed the SMFA (amputees at time of completion excluded) (Table 7-7 and Figure 7-8). The median time of prescription of the first BOB to completion of the SMFA was 51-months (range 24-73).

| | |
|---|---|
| SMFA Daily Activities | 34.37 (20.75) |
| SMFA Emotional Status | 47.24 (23.42) |
| SMFA Arm and Hand Function | 4.19 (6.09) |
| SMFA Mobility | 39.03 (20.36) |
| SMFA Function Index | 31.52 (15.87) |
| SMFA Bother Index | 38.86 (25.91) |

*Table 7-7: SMFA results for LS patients with BOB at median 51-months post prescription of the BOB.*

Figure 7-8 shows the results of the SMFA compared to normative data, the METALS study LS cohort (Doukas, 2013), and a cohort of LS-patients treated with the IDEO at 12-months follow up (Potter, 2018). The data from this study is statistically worse in all but the arm/hand function domain of the SMFA ($p<0.0001$) from normative data. Comparing the data in this study to the METALS study data, there is no statistical difference (mobility ($p=0.42$), ADL ($p=0.10$), Emotion ($p=0.84$), arm/hand ($p=0.07$), function index ($p=0.55$)). Statistical differences are found when comparing this data to the study by Potter et al at 12-months follow-up in all but the arm/hand domain (mobility ($p=0.008$), ADL ($p=0.003$), emotion ($p=0.014$), arm/hand ($p=0.79$) function index ($p=0.01$)) (Potter, 2018).

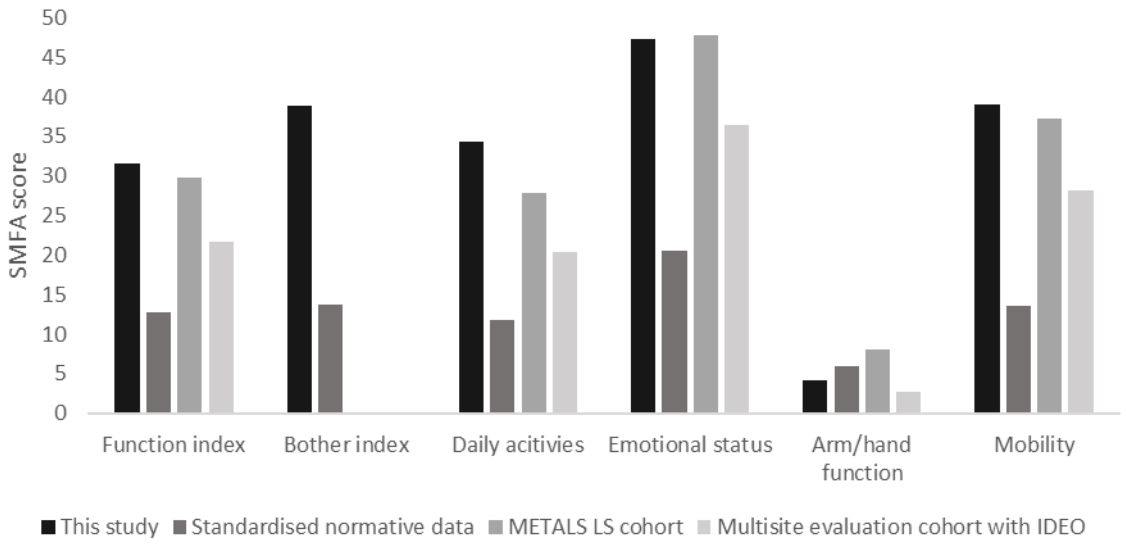



*Figure 7-8: SMFA of this study compared to normative data, the METALS LS cohort* (Doukas, 2013)*, and a LS cohort from the Multisite evaluation with the IDEO* (Potter, 2018).

Following use of the BOB, 23 individuals had a DMRC score available for analysis. Examining the mobility score, 14 were able to run independently, 7 walk independently, and 2 required walking aids. Looking at the ADL score, 18 were independent and 5 required aids or adaptations. Examining the pain score, 5 reported no pain, 16 reported controlled pain, and 2 uncontrolled pain.

## 7.4.6. Outcome predictors

### *7.4.6.1. Amputation*

Thirteen patients have progressed to amputation (24%). The reasons for progression to amputation were chronic pain (n = 8), infection (3), non-union (1), and unrelated trauma (1). There was no difference in mean age at time of injury between those who retained their injured limb and those who required elective amputation (28.3-years *vs*. 28.9-years respectively; p=0.781). There was also no significant difference in the mean BMI of each group (27.99 kg/m$^2$ v 28.48 kg/m$^2$; p=0.629) and no difference in smoking status (p=0.614).

#### 7.4.6.1.1. Injury details

Patients progressing to amputation trialled the BOB for a mean of 10.4 months compared to 38.4 months for patients retaining their limbs (p<0.001). There was no significant difference in mechanism of injury (p=0.522) or injury sustained (Figure 7-9), except if a nerve injury was sustained, amputation was less likely (p=0.002, PHP = 0.994). The ISS and NISS were not statistically different between the two groups (p=0.986 and p=0.827 respectively).

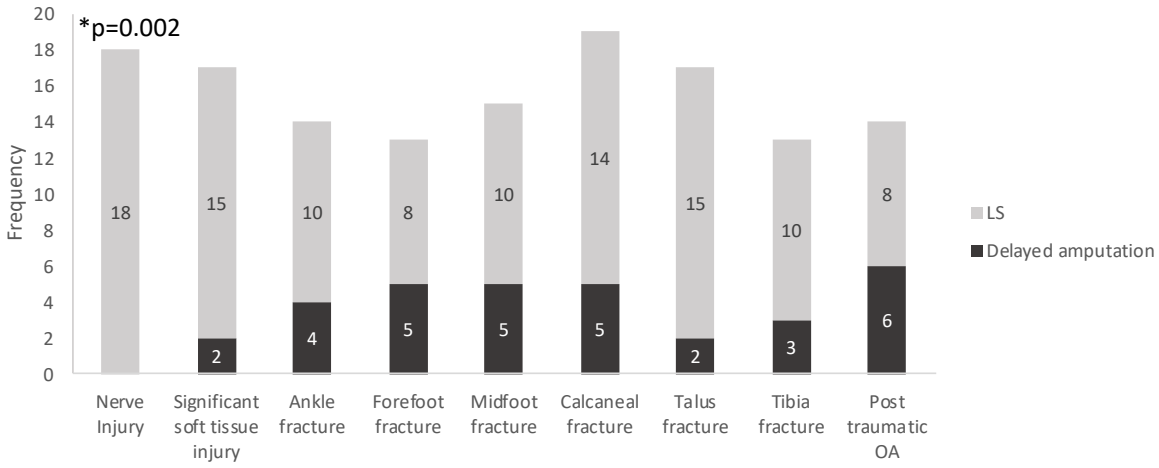



*Figure 7-9: Injury sustained grouped by outcome of delayed amputation or limb salvage (LS), OA=osteoarthritis.*

To ascertain whether an increasing number of foot and ankle injuries on the same side were predictive of amputation, the cohort were assessed based on number of injuries on one side of: ankle fracture, hindfoot fracture, midfoot fracture, forefoot fracture, and a nerve injury (Figure 7-10). This was not noted to be statistically significant. Those who did not sustain any of these injuries (noted in Figure 7-10 as 0) had either an isolated ligament injury or a significant soft tissue injury. Ligament, vascular, and significant soft tissue injuries were also not predictive of need for amputation (p=0.328, p=0.99, p=0.137 respectively).

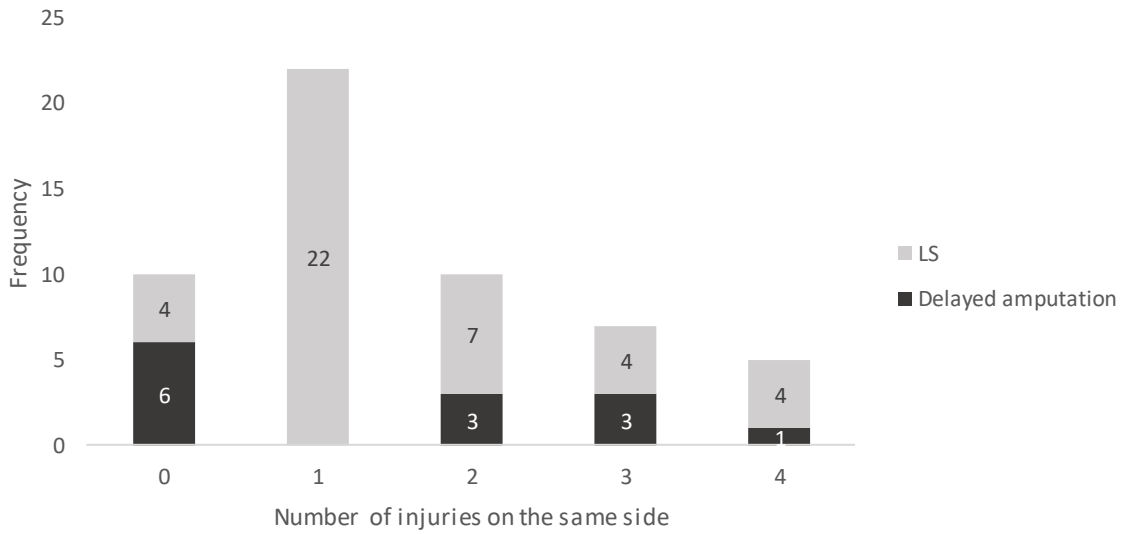



*Figure 7-10: Outcome by number of injuries on the ipsilateral side of: nerve injury, ankle fracture, hindfoot fracture, midfoot fracture and/or forefoot fracture on the same side, LS=limb salvage.*

The functional deficit was not shown to predict need for amputation. Those patients, however, who, due to the nature of their injury or subsequent developments (for example osteomyelitis), were candidates for amputation when they began the BOB trial, were statistically more likely to have an elective amputation (p=0.005, PHP = 0.838). The FASS-S and FASS-I were not predictive of need for amputation (p=0.792 and p=0.846 respectively).

#### 7.4.6.1.2. Treatment and complications

Treatment was not predictive of need for amputation (p=0.154) nor were a subsequent ankle or subtalar arthrodesis (p=0.170) or a diagnosis of post-traumatic OA (p=0.075). There was however a reduction in the number of patients with post-traumatic OA who were considering amputation (n = 8) and pursued amputation (n=6). Non-union was not predictive of the need for amputation (p=0.334). Patients with a chronic pain diagnosis were more likely to require amputation (p<0.001, PHP = 0.999) (Table 7-8).

| | Pain diagnosis | No pain diagnosis |
|---|---|---|
| LS | 1 | 40 |
| Delayed amputation | 9* | 4 |

*Table 7-8: Outcome of LS or amputation after BOB trial with chronic pain, defined as pain specialist diagnosed CRPS or neuropathic pain. *p<0.001, LS=limb salvage.*

Patients requiring delayed amputation were more likely to have a psychiatric diagnosis including PTSD and GAD (p=0.002, PHP = 0.961) (Table 7-9).

| | Psychiatric diagnosis | No psychiatric diagnosis |
|---|---|---|
| LS | 10 | 31 |
| Delayed amputation | 10* | 3 |

*Table 7-9: Outcome of LS or amputation after BOB trial with psychiatric diagnosis. *p=0.002, LS=limb salvage.*

#### 7.4.6.1.3. Performance assessments

The 6-MWT distance when initially prescribed the BOB (Figure 7-11) was not statistically significantly different between LS patients and those who required amputation (372.88 m SD 106.97 v 358.4 m SD 101.2; p=0.707). Those who required amputation, however, had a statistically significantly reduced 6-MWT when they abandoned the BOB compared with LS patients (433.50 m SD 98.43 v 508.52 m SD 93.24; p=0.035, PHP = 0.567).

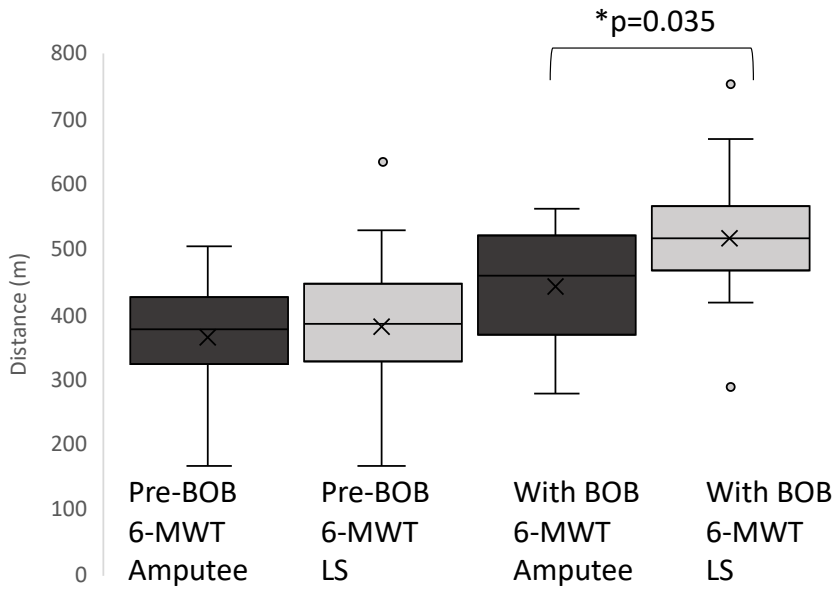



*Figure 7-11: 6-Minute Walk Test distance pre-BOB and with BOB use, grouped by LS and delayed amputation (distance in m). LS=limb salvage, BOB=bespoke offloading brace, 6-MWT=6-Minute Walk Test.*

#### 7.4.6.1.4. Patient reported outcome measures

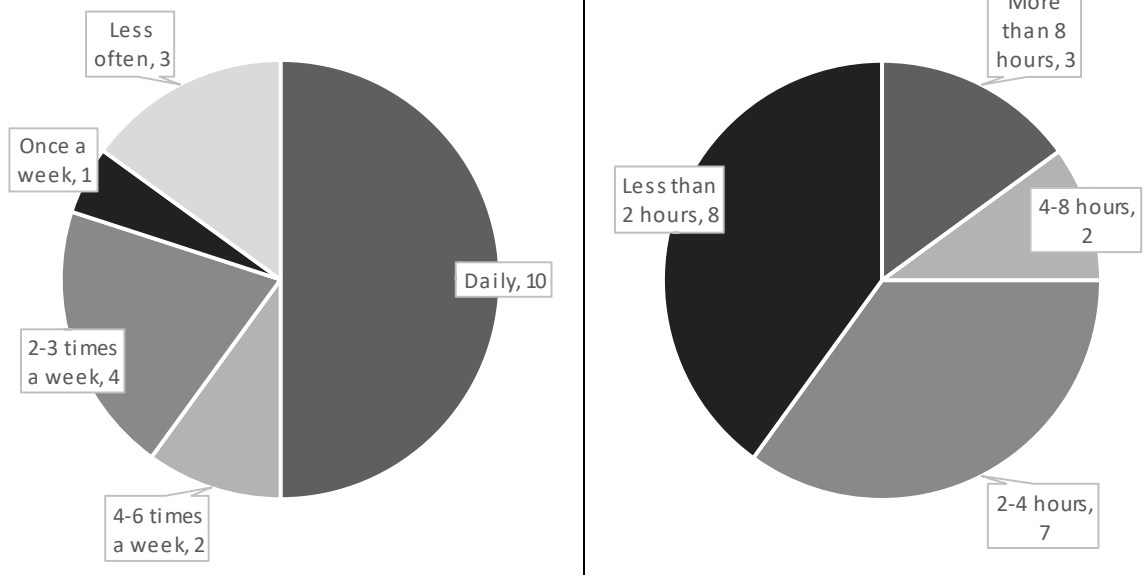
Examining patient reported outcomes, the GAD-7 and PHQ-9 were both statistically significantly worse for individuals who progressed to amputation at prescription of the BOB and at follow-up than LS-patients (Table *7-10*). There was no significance in the BPI and VAS.

| | **Pre BOB** | | | **With BOB** | | |
|---|---|---|---|---|---|---|
| | LS | Delayed Amputation | Significance (power) | LS | Delayed Amputation | Significance (power) |
| GAD-7 | 3 (0-12) | 13 (2-21) | 0.017 (0.965) | 2.5 (0-16) | 11 (2-21) | 0.007 (0.900) |
| PHQ-9 | 4 (0-19) | 18 (1-27) | 0.008 (0.962) | 4 (0-22) | 13.5 (1-27) | 0.024 (0.785) |

*Table 7-10: Pre BOB and with BOB GAD-7 and PHQ-9 grouped by outcome of LS or delayed amputation. LS=limb salvage, GAD-7=Generalised Anxiety Disorder-7, PHQ-9=patient healthcare questionnaire-9, BOB=Bespoke Offloading Brace.*

### *7.4.6.2. BOB Use*

Twenty-seven patients continue to use the BOB for variable periods of the day whilst 27 patients have abandoned it (including 13 patients who have progressed to amputation). Therefore, 66% of those who have retained their limbs wear the orthosis. The results in this section relate to those who have retained their limbs (41 patients). For those who wear the BOB and have recorded usage data, most wear it daily for less than 4 hours (Figure 7-12).




A B

*Figure 7-12: BOB use data. A) frequency of use of BOB B) Length of time BOB worn on each occasion*

For those who have abandoned the BOB, the most frequent reason for abandonment was that the BOB was no longer required due to operative intervention or improvement in injury, followed by pain when wearing the BOB (Figure 7-13).

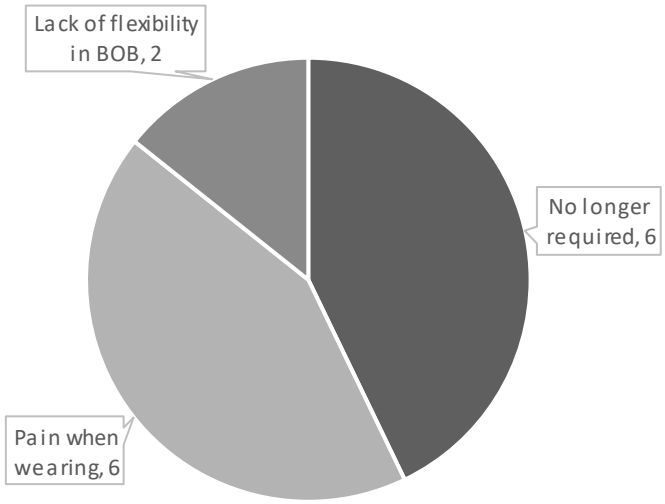



*Figure 7-13: Reasons for BOB abandonment after trial.*

The two groups (BOB wearers (group A) and those who have abandoned the BOB (group B)) were similar in age at incident (group A 27.8-years v group B 29.4-years; p=0.454), BMI (group A 28.29kg/$m^2$ v group B 27.41kg/$m^2$; p=0.414), and smoking status (p=0.846).

#### 7.4.6.2.1. Injury details

It was not possible to predict continued use with mechanism of injury (p=0.465). The ISS and NISS were not significantly different between the two groups (p=0.628 and p=0.688 respectively). The anatomical location of injury was not significantly different between groups A and B, nor was the number of injuries sustained on the same side. Examining the injury sustained in more detail, there was a trend towards continued use of the BOB for isolated nerve injury patients, but this did not reach significance. Twelve patients suffered injuries that resulted in only nerve dysfunction below the knee (e.g. trauma at or above the knee resulting in a nerve injury). Nine of the 12 (75%) were in group A and the three patients in group B had multi-ligament injuries at the knee precluding the ability to run or wear the BOB due to discomfort. Four patients had central neurological conditions (e.g. cauda equina sequalae)

and all four were in group A. The presence of post-traumatic OA was not different between groups A and B; 5 patients in group A had post-traumatic OA and 3 in group B (p=0.824). The presence of a Pilon fracture was not different between groups A and B, with 3 individuals in group A and 3 in group B (p=0.393). It was not possible to predict continued use of the BOB by functional deficit (p=0.874). The FASS-S and FASS-I scores were not different between groups A and B (p=0.147 and p-0.441 respectively), neither was a vascular injury (p=0.628) nor ligamentous injury (p=0.879).

#### 7.4.6.2.2. Treatment and complications

Whether a patient had undergone fusion was not statistically significant between groups A and B (p=0.750). The treatment received was also not significant between groups A and B (p=0.322).

There was no difference between groups A and B in the context of non-union (p=0.883). Only one patient had chronic pain (after removal of the amputee cohort) and they were in group B. The presence of a psychiatric diagnosis was not different between groups A and B (p=0.447). Twelve patients who were previously considering amputation pursued LS after using the BOB, with eight continuing to use the BOB. The other 4 had operative intervention and no longer required the BOB.

#### 7.4.6.2.3. Performance assessment

The improvement in 6-MWT distance was not significantly different between groups A and B (174.44 m v 113.1 m; p=0.148). Pre-BOB prescription, patients in group A walked 360.29 m (SD 107.54) and those in group B walked 396.91 m (SD 106.64) (p=0.366) improving to 509.32 m (SD 87.36) and 507.25 m (SD 105.92) (p=0.953) respectively which were not found to be statistically significant. Examining the 6-MWT distance by functional deficit, there was a statistically significant improvement in distance for those with a weakness of dorsi/plantarflexion in group A (313.0 SD 117.61 v 527.14 SD 62.11; p<0.001, PHP = 0.992) but this was not seen in group B (386.2 SD 109.3 v 471.5 SD 129.29; p=0.318). There was no statistically significant improvement for either group A or B with mechanical pain (p=0.285 and p=0.288 respectively), and both groups A and B saw statistically significant improvements

in 6-MWT distance following fusion (group A 392 m SD 83.19 v 548 m SD 57.62; p=0.009, PHP = 0.590 and group B 325 m SD 7.07 v 506m SD 48.08; p=0.034, PHP = 0.659).

#### 7.4.6.2.4. Patient reported outcome measures

The pre-prescription BPI interference was statistically higher (worse) for group A compared to group B (5.47 SD 2.32 v 3.27 SD 2.96; p=0.028, PHP = 0.610). The BPI interference after prescription of the BOB was not statistically different between groups (p=0.909). Similarly, the pre prescription BPI severity was higher (worse) for group A (4.1 SD 2.16 v 2.36 SD 1.83; p=0.03, PHP = 0.599) but there was no statistically significant difference between groups in the BPI severity score after prescription of the BOB (p=0.976). There was no statistically significant difference in the GAD-7 (pre-prescription p=0.183, with BOB-use p=0.332), PHQ-9 (pre-prescription p=0.289, with BOB-use p=0.276), and VAS (pre-prescription p=0.405, with BOB-use p=0.9) between groups A and B.

There was no significant difference between the SMFA in all domains of those in group A and in group B (SMFA ADL p=0.776, SMFA emotional status p=0.506, SMFA arm and hand p=0.776, SMFA mobility p=0.825, SMFA functional index p=0.875, SMFA bother index p=0.681). Looking at the DMRC score following trial of the BOB, 11 of 16 (69%) patients in group A were able to run independently whilst 2 of 6 (33%) in group B were able to run independently. 4 of 5 in group A were able to walk independently if they could not run independently whilst 3 of 4 in group B were able to walk independently. A walking aid was required by 1 person in group A and 1 in group B. These results were not statistically significant (DMRC mobility p=0.269). Looking at the ADL DMRC score following trial of the BOB, 12 of 16 (75%) patients in group A were able to perform ADLs independently whilst 5 of 6 (83.3%) in group B were able to. The remaining patients in each group required an aid or adaptation to perform ADLs. This was also not statistically significant (ADL p=0.762). Uncontrolled pain was reported by 1 of 16 (6.25%) patients in group A and 1 of 6 (16.7%) in group B. This was also not statistically significant (pain p=0.705). No patients in either group required mental health support.

## 7.5. Discussion

### 7.5.1. Does the BOB improve outcomes for LS-patients?

An aim of this study was to examine the outcomes of LS-patients treated at the DMRC after introduction of the BOB. With use of the BOB this study has demonstrated a decrease in elective amputation rates from 54% reported at the DMRC prior to the introduction of the BOB to 24%. The study has also demonstrated that the BOB has prevented amputation with 25 patients considering amputation prior to trial of the BOB and 13 pursuing amputation. An amputation rate of 24% is consistent with the IDEO literature reporting an 18-20% amputation rate with use of the IDEO at maximum 2-year follow up. Therefore, this study adds medium-term outcomes to the evidence that in some cases the IDEO/BOB can be used to prevent amputation (Bedigrew, 2014; Hill, 2016).

This study has demonstrated a statistically significant improvement in functional outcomes for LS-patients using the BOB consistent with literature concerning the IDEO (Bedigrew, 2014). This study suggests that those who gain the most benefit from the BOB have the largest gains in physical performance, seen with LS-patients demonstrating a significantly improved 6-MWT distance compared to patients who required an elective amputation after trialling the BOB. The 6-MWT distance demonstrated a statistically significant improvement above minimal detectable change values for military personnel. The 6-MWT distance also demonstrated an improvement compared to LS outcomes for patients prior to the introduction of the BOB of 472.3 m seen in the previous Chapter, but this difference was not statistically significant ($p=0.26$). Patients using the BOB still have worse 6-MWT distances than amputees reported in the previous Chapter as 595.3 m, and in the literature as 661 m (Linberg, 2013). The results for LS patients with the BOB are however above 459 m which is the minimum required for community ambulation (Chetta, 2006; Linberg, 2013). Patients with weakness of dorsi and/or plantarflexors or following fusion demonstrated particularly poor outcomes in the previous Chapter with improvements seen for both groups in this study. Similarly, however, neither group demonstrated 6-MWT distances in line with the amputee distances reported in the previous Chapter and the literature. Therefore, although the BOB improves outcomes for LS patients, it does not bring functional outcomes in the form of the

6-MWT in line with military unilateral below knee amputees, nor military able-bodied personnel reported as 724.9 m (Wilken, 2012).

PROMs were also seen to improve with use of the BOB, with an improvement in both VAS and BPI interference consistent with the IDEO literature (Bedigrew, 2014; Ikeda, 2019). Use of the BOB may reduce pain in LS-patients by restricting movement at the painful foot and ankle joints, and possibly by providing offloading or load sharing during stance. Despite improvements in pain, the SMFA results were below reported population norms and were similar to the results seen in the METALS study in the US prior to the introduction of the IDEO (Doukas, 2013). This appears to imply that the BOB does not improve SMFA results for LS-patients using the BOB above the levels seen prior to introduction of the IDEO. The SMFA results seen here were not as good as those reported in the literature for a population of military patients using the IDEO at 12-months follow-up (Potter, 2018). There are a few possible explanations for this difference. Firstly, the SMFA results reported by Potter et al were taken at 12-months post prescription whereas in this study the results were collected at median 51-months post prescription and therefore the improvement seen by Potter et al may not be sustained in the longer-term (Potter, 2018). The exclusion criteria used in the Potter paper meant all clinically unstable patients were excluded, as were patients who abandoned the IDEO. The differences between SMFA data may therefore be due to different inclusion criteria. As the SMFA has not previously been collected for UK LS patients, it is not possible to establish whether it improved from pre-prescription to post BOB trial. The DMRC outcome score, however, demonstrated an increase in the number of LS-patients able to run independently from one prior to the introduction of the BOB (Chapter 6) to 14 with the BOB. Return to running is one of the aims of the BOB and may help to explain the reduction in elective amputations seen with personnel pursuing LS if they can run independently. Although the BOB improves patient-reported outcomes in the form of the VAS and BPI which were measured pre and post prescription, the SMFA can only be compared to the literature and does not demonstrate an improvement upon the results of the METALS study (Doukas, 2013).

### 7.5.2. Predictors of amputation

Prior to the introduction of the BOB, a sporting/training mechanism of injury was predictive of amputation for UK LS patients following optimal rehabilitation at the DMRC (Chapter 6). Following rehab with the BOB, this was shown to not be predictive of progression to amputation. Instead, a pain-specialist diagnosis of CRPS or neuropathic pain, a diagnosis of a psychiatric condition, and, in keeping with this, a poor GAD-7 and PHQ-9 were all predictive of the need for amputation. This has also been shown by Potter *et a*l. who found that patients who progressed to amputation after trial of the IDEO were more likely to have a psychiatric diagnosis (Potter, 2018). They also found that pain was commonly cited as the reason for amputation. Patients who required amputation demonstrated reduced 6-MWT distances with the BOB compared to those patients who pursued LS, however post-hoc power analysis demonstrated that this statistical test was not appropriately powered. The 6-MWT distance for those who required delayed amputation was less than the distance achieved by delayed amputees reported in the previous chapter, and for immediate amputees at the DMRC reported as 598 m (Ladlow, 2016). The combined rehabilitation at the DMRC affords patients the ability to compare their outcomes directly with LS and amputee patients. The poor functional outcomes for patients with the BOB who progressed to amputation may also account, in part, for the decision to progress to amputation. Although the BOB did not completely prevent amputation, only 13 of the 25 patients originally considering amputation ultimately pursued amputation. This demonstrates that use of the BOB may help to prevent amputation in some patients.

Particularly for nerve-injury patients, use of the BOB was noted to be predictive of preventing amputation, which may be due to good functional outcomes seen by patients with weakness of dorsi and/or plantarflexors. Additionally, there was a trend towards nerve-injury patients continuing to use the BOB. Those who abandoned the BOB, did so due to ipsilateral injuries at the knee preventing use of the BOB. Therefore, the BOB may work for nerve injuries where there is not an ipsilateral concomitant injury preventing use. The numbers presented in this study, similar to others in the literature, are insufficient to draw conclusions on whether patients with a nerve injury resulting in foot and ankle deficits consistently gain benefit from use of the BOB. Hill et al report that 91 patients have been prescribed the IDEO for a nerve injury, with a nerve injury representing the lowest rate of progression to amputation (Hill,

2016). Long-term outcomes of patients with the IDEO in the US, where there are larger numbers, require investigation to establish whether nerve injury can be used in a clinical decision tool for prescription.

### 7.5.3. Predictors of ongoing use of the BOB

This is the first study to report on the number of patients who abandon the BOB. There are no studies in the literature looking at ongoing use and abandonment of the IDEO. All studies report only on the outcomes of those patients who continue to use the IDEO. Having established that a third of patients abandon the BOB, this chapter aimed to link outcome with the BOB to the initial injury. The literature demonstrates good outcomes with the IDEO for patients following ankle and/or subtalar fusion therefore it was hypothesised that individuals with an ankle and/or subtalar fusion would continue to use the BOB (Sheean, 2016). This has not been demonstrated and fusion cannot be used as a predictor for ongoing use of the BOB. Functional outcomes were however improved for patients following fusion in keeping with the literature (Sheean, 2016). The improvement in likely due to the energy storage and return provided by the BOB to aid with forward propulsion during both walking and running. It has also not been possible to link functional deficit with ongoing use of the BOB despite the functional gains seen for both fusion patients and those with weakness of dorsi and/or plantarflexors. A larger study is required with appropriate statistical power to draw conclusions on use of the BOB in patients following fusion.

Patients with predominantly mechanical pain of the mid/hindfoot during stance did not demonstrate statistically significant improvements in the 6-MWT distance and post traumatic osteoarthritis, a cause of mechanical pain, was not predictive of ongoing use of the BOB. Patients may have abandoned the BOB due to the demonstrated poor functional gains. A 25% reduction was however seen in the number of people requesting and then pursuing amputation in the presence of post traumatic osteoarthritis. These gains were not as great as reported in the literature where there was a reduction from 6 patients requesting to only 1 pursuing amputation (Jeanne C. Patzkowski, 2012b). The only study in the literature looking at outcomes for post traumatic osteoarthritis with the IDEO contains only 16 patients with both ankle-joint arthritis and/or subtalar joint arthritis. The offloading or load sharing offered by the BOB, combined with restriction of movement of the foot and ankle, implies that the

BOB should work for patients with post-traumatic osteoarthritis, and hence mechanical pain. To investigate this, larger studies looking specifically at patients using the BOB with confirmed ankle or subtalar joint post traumatic osteoarthritis (PTOA) are necessary. Patients included in this study have sustained polytrauma and therefore abandonment of the BOB may be due to other injuries. With return to contingency operations in the military, although polytrauma may unfortunately continue to occur, the majority of injuries are likely to be isolated. PTOA may therefore predominate and research to improve outcomes for these patients will be increasingly important. Additionally, research into PTOA of the ankle and/or subtalar joints may add a clinical indication for use in civilian populations and potentially delay progression to fusion in young patients. Similar to the literature, this study did not demonstrate ongoing use of the BOB following a Pilon fracture, and lower limb fracture could not be used to predict outcome with the BOB (Mazzone, 2019; Quacinella, 2019).

It should be noted that although the BOB did not work for all LS patients, there was no deterioration in the GAD-7 or PHQ-9 for patients who trialled and abandoned the BOB. Additionally, 6 patients abandoned the BOB as they no longer required it due to either operative intervention (other than amputation) or the ability to run without the BOB. This implies that although it is desirable to predict who will benefit from use of the BOB to prevent prolonged unsuccessful rehabilitation, mental health does not deteriorate with trial of the BOB. Furthermore, if delayed amputation is required after trail of the BOB, the 6-MWT distance demonstrated in the previous Chapter of 595.3 m for delayed amputees, is not different to the distance for immediate amputees seen at both the DMRC and in the literature (Linberg, 2013). Therefore, the evidence suggests that a trial with the BOB resulting in delayed amputation would not result in worse functional outcomes than immediate amputation.

Although injury pattern and functional deficit could not be used to predict outcome, the BPI interference and severity were both noted to be statistically higher (worse) for patients who continued to use the BOB (group A) than those who abandoned the BOB (group B). It may be that group A perceived they had the most to gain from use of the BOB. Not all patients had a BPI available therefore this significance is based off a small subset of the cohort, but nonetheless, it implies that if a patient is not experiencing sufficient pain of severity to cause interference, they may not gain benefit from prescription of the BOB. Future prospective

work concerning the IDEO and BOB should include investigation of the BPI to ascertain whether this may be of use in a clinical decision tool.

It was not possible to interrogate thoroughly the medical records of individuals who had abandoned the BOB and left the military; this would have allowed to ascertain whether they used an alternate AFO. Once personnel have left the military, care is transferred to the NHS where access to records is problematic. Orthotic records were only available up until the point of discharge from service unless personnel continued to use the BOB. Where individuals were not contactable, ongoing orthosis use other than for the BOB remains unknown. It may be that the BOB provided too much support and individuals abandoned the BOB in preference for a less engineered AFO. Future studies should investigate whether alternate AFOs are preferred by individuals for whom the BOB does not provide intended benefit.

### 7.5.4. Limitations

A weakness of this study is that it is retrospective and therefore attracts all the usual disadvantages and biases of a retrospective observational cohort study. The data set is also not complete with not all patients completing the performance assessments and patient-reported outcome measures before and after using the BOB. All efforts were made to attempt to provide a complete data set but as with other retrospective follow-up studies concerning military cohorts following limb salvage and those concerning use of the IDEO, a follow-up rate of patient-reported outcomes over 50% is not unusual (Doukas, 2013; Bennett, 2018; Ikeda, 2019). This study contains a similar number of participants to the largest studies examining clinical outcomes with the IDEO (maximum 84 patients in the literature concerning IDEO outcomes) (Bedigrew, 2014). Like other literature concerning the IDEO, however, this study has required subgroup analyses to achieve the aims resulting in smaller numbers in each cohort. Larger prospective studies are required to conclusively establish outcomes but, in the UK, there are only a limited number of LS patients who require prescription of the BOB and therefore this is the most complete follow-up study of these patients possible. A future multi-national study may be required to provide sufficient numbers of patients for an appropriately powered study.

This is the first study to look at not only progression to amputation but also abandonment rates of the BOB. It represents the longest follow up study of patients with the IDEO/BOB in the literature. Unlike previous studies it also attempts to look for not just predictors of amputation, but also predictors of ongoing use of the BOB to try to create a clinical decision tool for prescription. Similar to previous studies, this study has demonstrated that a chronic pain diagnosis (defined as pain specialist diagnosed CRPS or neuropathic pain) is predictive of amputation, and the only patient to have a chronic pain diagnosis in the cohort who retained their limb abandoned the BOB (Potter, 2018). It has also demonstrated a trend towards ongoing use of the BOB for nerve-injury patients with a larger study required to draw further conclusions.

Despite attempts to overcome the heterogenous nature of foot and ankle injury patients using the functional deficit, it has not been possible to link injury pattern alone with outcome with the BOB. It may be that a different aspect of outcome following foot and ankle injuries will enable prediction. There is a growing body of evidence examining gait changes and the IDEO. Chapter 3 established the possible gait deficiencies present following foot and ankle injury. Studies examining gait with the IDEO have been presented in Chapter 5. There is a lack of evidence examining gait prior to the prescription of the IDEO/BOB and investigating a link to outcome with the BOB. Given that the BOB aids with gait by supporting the foot and ankle in patients demonstrating pathological gait, analysis of gait kinetics and kinematics prior to the prescription of the BOB therefore need to be examined in order to establish whether it is possible to produce a clinical decision tool to predict outcome from metrics of gait.

## 7.6. Conclusion

In conclusion, the BOB reduces elective amputation rates from 54% to 24% and prevents amputation in a proportion of LS patients. Although the BOB provides benefit to many LS patients, it is not currently possible to predict which patients will benefit from the prescription of a BOB. Patients with a chronic pain diagnosis, defined as pain-specialist diagnosed CRPS or neuropathic pain, do not gain benefit from prescription of the BOB. Patients with a nerve injury may gain benefit but larger studies are required to investigate the trend demonstrated. Given that the BOB is used to aid in walking and running, a study investigating gait patterns

prior to prescription of the BOB is warranted to ascertain whether gait metrics are predictive of ongoing use of the BOB. Gait patterns will be the focus of Chapters 9 and 10. Prior to that, a more detailed study on patients with nerve injuries prescribed the IDEO is presented in the following chapter.

# Chapter 8: Nerve injuries

**This chapter has been published in part:**

Franklin N, Hsu JR, Wilken J, McMenemy L, Ramasamy A, Stinner DJ. *Advanced Functional Bracing in Lower Extremity Trauma: Bracing to Improve Function*. Sports Med Arthrosc. 2019 Sep;27(3):107–11.

## 8.1. Introduction

The aim of this thesis is to produce a clinical decision tool for prescription of the BOB to prevent futile and painful rehabilitation in LS-patients who will not gain benefit from use. So far in this thesis it has been established that the BOB does not work for patients in the presence of a diagnosis of chronic pain, including CRPS or pain specialist diagnosed neuropathic pain (Figure 8-1) (Chapter 7).

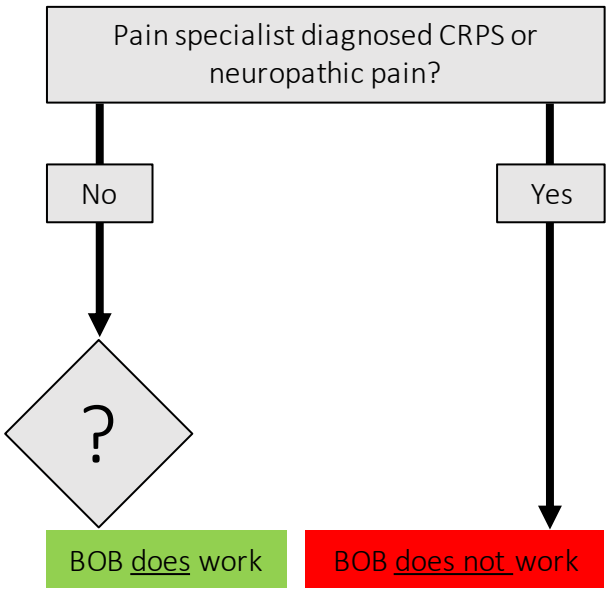



*Figure 8-1: Clinical decision tool for prescription of the BOB, currently it is not possible to predict outcome for all patients prescribed the BOB.*

Chapter 6 established that patients with weakness of dorsi and/or plantarflexors had poor functional outcomes in the form of the 6-MWT when compared to amputees. Chapter 7 demonstrated that with use of the BOB, patients with weakness of dorsi and/or plantarflexors have a statistically significant improvement in the 6-MWT distance above minimal detectable

change levels. A statistically significant improvement was only seen for individuals who continued to use the BOB, not for individuals who abandoned the BOB. A nerve injury results in weakness of dorsi and/or plantarflexors. The previous Chapter also showed that a nerve injury was predictive of LS, with no patients requiring elective amputation in the presence of a nerve injury. There was also a trend towards ongoing use of the BOB for nerve-injury patients, where an ipsilateral concomitant injury was not present. In an effort to understand further indications for prescription of the BOB, the previous Chapter concluded that a larger study is needed to establish the outcomes for patients using the BOB with a nerve injury resulting in dysfunction at the foot and ankle. The previous Chapter represented the most complete follow-up study of nerve-injury patients prescribed the BOB in the UK. To enable a larger study, follow-up of patients prescribed the IDEO in the US must be undertaken.

The IDEO was introduced in the US prior to the introduction of the BOB. By 2014 the IDEO had been prescribed to over 600 patients (Hill, 2016). Analysis of the injury patterns of those prescribed an IDEO demonstrated that 91 patients (16.4% of the study cohort) had a nerve injury resulting in functional deficit at the foot and ankle (Hill, 2016). Patients with a nerve injury demonstrated some of the lowest amputation rates (14.3%) (Hill, 2016). Hill et al only looked at injury characteristics and amputation rates, they did not provide any data on functional or PROMs. Quacinella et al report on the spatiotemporal and gait kinematics, as well as the CHAMP score, of two patients with a common peroneal nerve injury resulting in foot drop following knee dislocation (Quacinella, 2019). They concluded that the IDEO provided significant benefit following common peroneal nerve injury however a larger study was required (Quacinella, 2019). To date there have been no studies examining the functional and PROMs, for specifically nerve injury patients, following completion of the RTR CP and use of the IDEO. All patients prescribed the IDEO participate in the RTR CP. As described in Chapter 5, the RTR CP is an 8-week sports medicine derived rehabilitation programme designed to ensure the individual gains maximum benefit from the IDEO (Owens, 2011; Patzkowski, 2011). The RTR CP measures success using PROMs and physical performance measures (PPMs) (Bedigrew, 2014). Combination of the RTR CP and IDEO has been demonstrated to provide superior results in terms of return to duty and improved PPMs and PROMs sustained for 2-years than LS without the IDEO (Bedigrew, 2014; Blair, 2014). The results of nerve injury patients however have not been examined in isolation. Knowledge of outcomes for nerve

injury patients would provide an evidence base for indication of use of the BOB and potentially inclusion in a clinical decision tool.

Working with American colleagues at the 'Brooke Army Medical Centre' and the 'Extremity Trauma and Amputation Centre of Excellence', a cohort of nerve-injury patients was identified who had completed the RTR CP. This Chapter presents work published in part in Sports Medicine and Arthroscopy Review in 2019 (Franklin, 2019).

## 8.2. Aim

The aim of the Chapter is to investigate the outcomes of patients prescribed an IDEO with a nerve injury. It is hypothesised that individuals with a nerve injury will gain benefit from prescription of the IDEO with improvements in both PROMs and PPMs. It is also hypothesised, based on trends noted in the previous Chapter, that a nerve injury will result in amputation rates less than those seen in the literature for all LS patients of 20% (Bedigrew, 2014).

## 8.3. Method

Patients with a nerve injury at or proximal to the knee were identified from a cohort of patients prescribed the IDEO as part of the IRB-approved prospective longitudinal observational cohort study of the IDEO. Inclusion criteria were nerve injury at or proximal to the knee and completion of the 8-week RTR CP.

Patients with a nerve injury proximal to the knee may have a variety of distal weaknesses depending on the level of the nerve injury. To overcome these differences and allow comparisons, patients were divided into groups based on functional deficits of plantarflexion and dorsiflexion strength grades (Table 8-1).

| **Group** | **Plantarflexion Grade** | **Dorsiflexion Grade** |
|---|---|---|
| Normal/Near normal | 4-5 | 4-5 |
| Foot drop | 4-5 | 0-3 |
| Globally poor ankle function (GPAF) | 0-3 | 0-3 |

*Table 8-1: Plantarflexion and dorsiflexion strength grades for each function group.*

To ensure consistency in strength grading between examiners, a cut off of ≤3/5 was chosen as it represents the point at which the individual has the inability to move against resistance. Foot drop was therefore defined when an individual has a dorsiflexion grade of ≤3/5. Globally poor ankle function (GPAF) was the term chosen to represent an individual with a power grade of ≤3/5 in both dorsiflexion and plantarflexion.

Outcome with the IDEO was assessed based on physical and patient-reported outcome measures. The PROMs collected include the Veterans Rand 12 (VR-12), a measure of physical functioning based on the Short Form-12. In addition to physical functioning it also assesses pain, general health, and mental health (Schalet, 2015). The VR-12 is expressed as a physical score (VR-12P) and a mental score (VR-12M). The VAS is also collected as part of the VR-12. The second PROM collected was the SMFA which is a measure of how bothersome the individual finds their injury as well as their perceived level of function (Swiontkowski, 1999). The SMFA is made up of several domains as described in Chapter 7. These domains are ADLs, emotion, arm and hand function, mobility, function, and bother. PPMs include the FSST, 20-m shuttle run, SSWV, and the TSA. These measures were chosen as they assess a variety of physical abilities including mobility, dynamic balance, and power. They have also been previously validated in healthy Service Personnel providing military cohort norms for reference (Wilken, 2012). The FSST is a measure of mobility and dynamic balance. To undertake the FSST, the participant steps sequentially over 4 1-inch sticks laid in a cross on the ground; forward, to the right, back and to the left. Participants are timed to complete one evolution (Wilken, 2012). The 20-m shuttle run is a timed run of 20-m. The TSA requires the participant to ascend 12 stairs as quickly as possible without using the handrail, it is a measure of power (Wilken, 2012). The SSWV is a measure of how quickly an individual naturally walks 15m without instruction and is measured in seconds. These measures are taken as part of the RTR CP at time point week 0 (baseline) and week 8 to demonstrate progress. The secondary outcome of interest was progression to amputation. Electronic healthcare records, radiographs, operation notes, and prosthetic service records were reviewed to ensure all patients with an amputation were identified. The most recent follow up with a healthcare provider acted as a surrogate for time to follow up.

Data were collected on patient demographics including age, sex, time from injury to follow up, and time from injury to beginning the RTR CP. Data were also collected on mechanism of injury, injury sustained, concomitant injuries, level of nerve injury, and progression to amputation. Concomitant injury data included traumatic brain injury (TBI). TBI is a spectrum including mild traumatic brain injury (m-TBI) which is routinely collected as part of the Joint Theatre Trauma Registry and may result in delayed rehabilitation due to progression to post concussive syndrome (Prince, 2017).

### 8.3.1. Statistical Analysis

Independent sample t-tests were used to compare baseline function between groups of function. Paired t-tests were used to compare patient reported outcome measures and patient performance measures at the start and completion of the RTR CP. A p value of $<0.05$ was set for significance. Post-hoc power (PHP) calculations were undertaken; a test was deemed to be appropriately powered with a PHP $>0.8$.

## 8.4. Results

Thirty-eight patients with a nerve injury were identified. Eight patients were excluded as they had not completed the RTR CP. The demographics and injury details for the cohort of 30 patients can be seen in Table 8-2.

| | |
|---|---|
| Age (years) | 30 (range 21-52) |
| Sex | Male (100%) |
| Time from injury to most recent follow-up (months) | 25 (range 4 – 83) |
| Time from injury to starting the RTR CP (months) | 18 (range 2 – 60) |
| Level of nerve dysfunction/injury | Common Peroneal 13 |
| | Sciatic 12 |
| | Spine 5 |
| Function group | Normal/Near normal 3 |
| | Foot drop 17 |
| | GPAF 9 |
| | Undocumented 1 |
| Mechanism of injury | Blast 8 |
| | Gunshot wound 7 |
| | Fall 4 |
| | Road Traffic Accident 4 |
| | Other 7 |
| Injury sustained | Penetrating/soft tissue loss 16 |
| | Knee dislocation 5 |
| | Spinal Injury 5 |
| | Iatrogenic/Tumour 2 |
| | Fracture 2 |
| Current smoker | 8 (27%) |
| Concomitant injuries | TBI (including m-TBI) 11 (36%) |
| | Burns 2 (7%) |

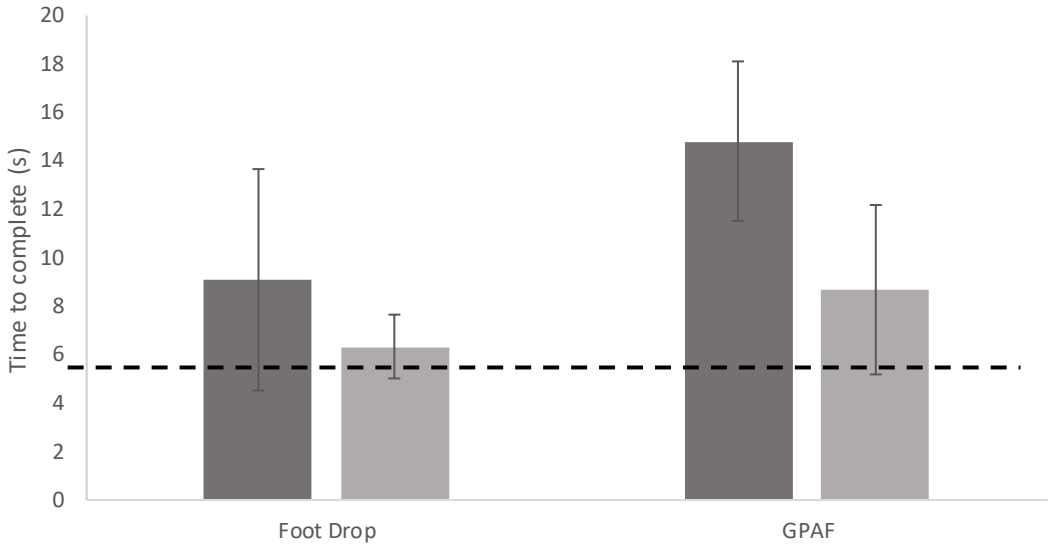
*Table 8-2: Demographic and injury details for cohort of 30 nerve injury patients who completed the 8-week RTR CP. m-TBI = mild Traumatic Brain Injury. RTR-CP = return to run clinical programme.*

Comparing the foot-drop group (n=17) with the GPAF group (n=9) (Table 8-3), at baseline there were statistical differences in the PPMs FSST, 20m-shuttle run, and TSA, with worse results for the GPAF group. There were also statistical differences in the ADL, mobility, function, and bother domains of the SMFA, as well as the physical domain of the VR-12. In all instances, the GPAF group were slower or scored worse demonstrating poorer physical function and a worse perception of function. All these statistical differences, except for the SMFA function and bother domains, were appropriately powered.

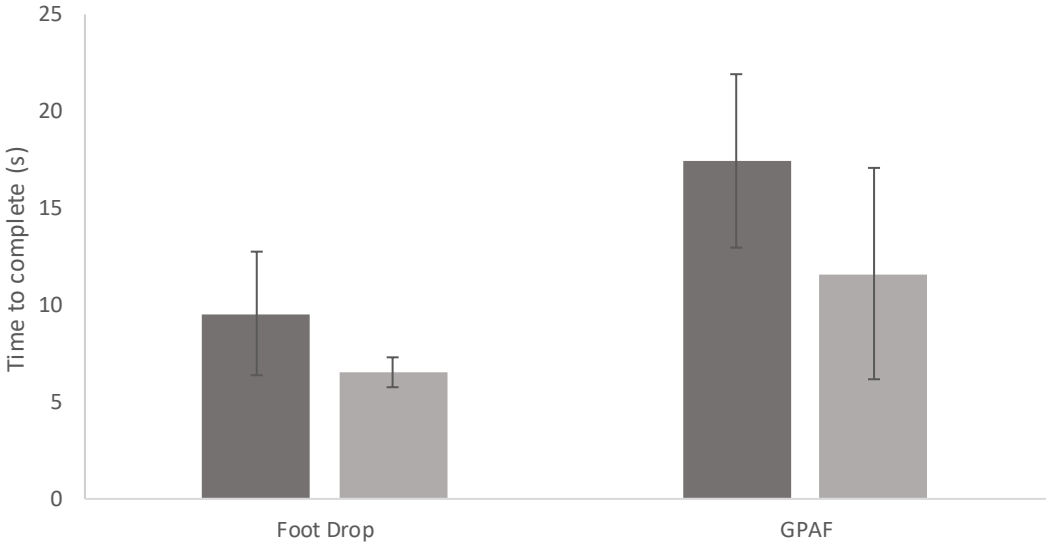
| | Foot drop | | | | | | GPAF | | | | | | Baseline comparison of foot drop and GPAF | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Week 0 | SD | Week 8 | SD | p | Power | Week 0 | SD | Week 8 | SD | p | Power | p | Power |
| Physical performance measures | | | | | | | | | | | | | | |
| FSST (s) | 9.1 | 4.6 | 6.3 | 1.3 | 0.01 | 0.76 | 14.8 | 3.3 | 8.7 | 3.5 | 0.001 | 0.99 | 0.003 | 0.95 |
| Shuttle (s) | 9.5 | 3.2 | 6.5 | 0.8 | 0.002 | 0.95 | 17.4 | 4.5 | 11.6 | 5.5 | 0.018 | 0.75 | 0.009 | 0.90 |
| SSWV (s) | 8.7 | 2.8 | 6.4 | 1.8 | 0.01 | 0.77 | 10.3 | 2.5 | 7.3 | 1.9 | 0.015 | 0.77 | 0.14 | 0.33 |
| TSA (s) | 7.3 | 4.1 | 4.3 | 1.1 | 0.015 | 0.72 | 12.7 | 4.2 | 7.1 | 4 | 0.004 | 0.94 | 0.004 | 0.89 |
| SMFA domains | | | | | | | | | | | | | | |
| ADL | 23.1 | 22.7 | 19.4 | 13.4 | 0.28 | 0.18 | 50.8 | 12.3 | 30.1 | 8.9 | 0.003 | 0.99 | 0.002 | 0.98 |
| Emotional status | 38.6 | 25.8 | 34.8 | 15.8 | 0.4 | 0.12 | 49.9 | 19.6 | 45.6 | 18.7 | 0.26 | 0.18 | 0.26 | 0.23 |
| Arm/hand | 8.1 | 20 | 8.4 | 19.2 | 0.65 | 0.07 | 14.5 | 22.8 | 10.4 | 46.2 | 0.10 | 0.36 | 0.46 | 0.10 |
| Mobility | 33.4 | 18.4 | 27.1 | 10.8 | 0.11 | 0.36 | 53.3 | 11.1 | 33.9 | 10.2 | 0.002 | 0.97 | 0.007 | 0.92 |
| Function | 25.5 | 19.2 | 22 | 11.8 | 0.2 | 0.23 | 42.8 | 12.5 | 29.6 | 8.1 | 0.001 | 0.98 | 0.02 | 0.78 |
| Bother | 24.9 | 24.9 | 19.7 | 16.4 | 0.2 | 0.24 | 44.4 | 16.5 | 28.4 | 10.1 | 0.012 | 0.81 | 0.04 | 0.66 |
| VR-12 | | | | | | | | | | | | | | |
| VR-12P | 39.2 | 7.7 | 41.9 | 8.4 | 0.06 | 0.47 | 27.4 | 5.9 | 39.7 | 6.1 | 0.001 | 0.98 | 0.001 | 0.99 |
| VR-12M | 52.3 | 11.3 | 51.6 | 8.7 | 0.72 | 0.64 | 48.1 | 8.3 | 48.1 | 7.8 | 0.99 | 0.05 | 0.34 | 0.18 |
| VAS | 2.4 | 2.6 | 2.1 | 2.1 | 0.45 | 0.11 | 4.2 | 1.7 | 2.5 | 0.9 | 0.07 | 0.45 | 0.08 | 0.57 |

*Table 8-3: Patient reported outcome measures and physical performance measures at baseline and at 8 weeks on completion of the RTRCP for patients in the foot drop group and the GPAF group. Comparison within group is made between baseline and 8 weeks, and between groups at baseline. Shaded squares demonstrate statistical differences p<0.05.*

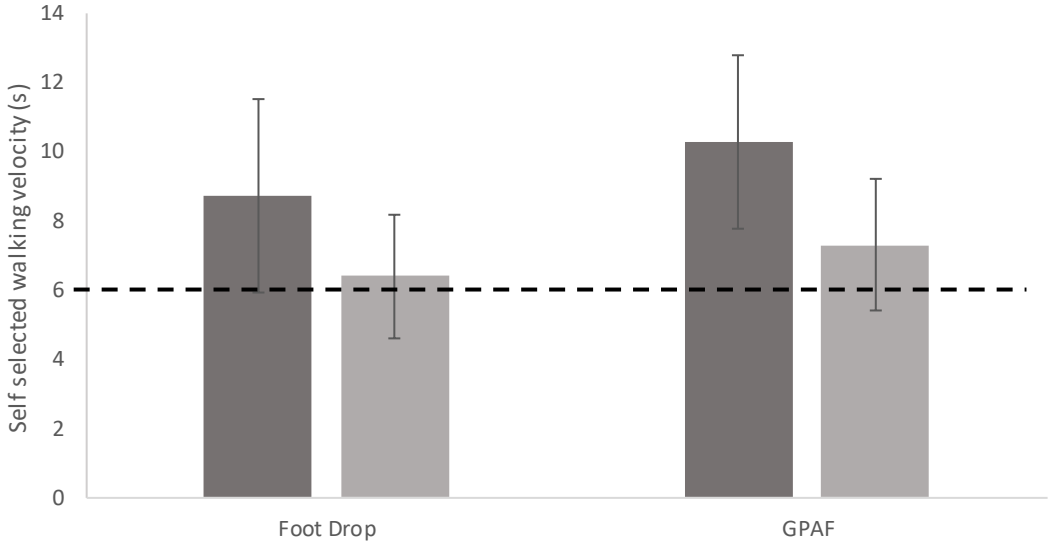
a


20
18
16
14
12
10
8
6
4
2
0
Time to complete (s)
Foot Drop
GPAF

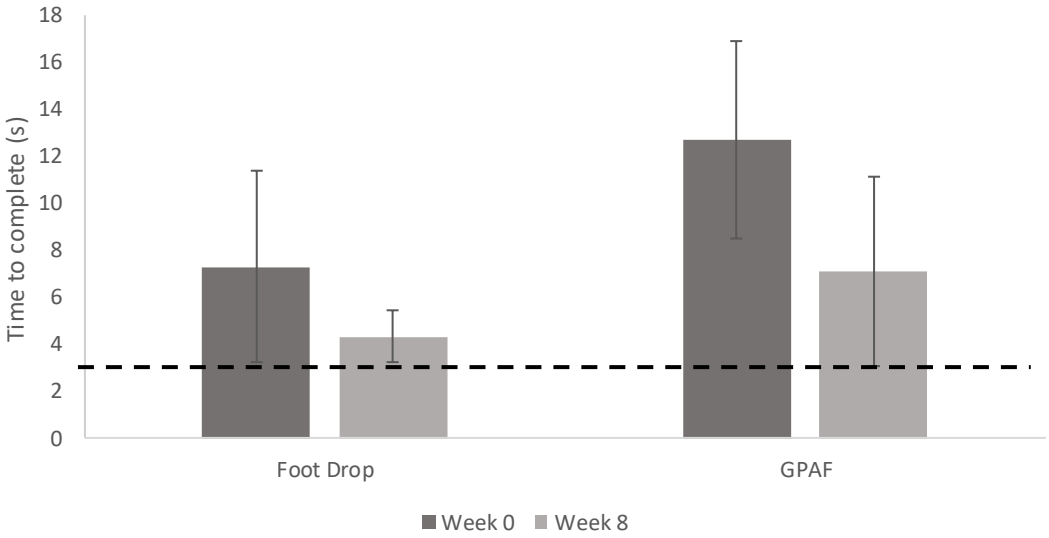
b


25
20
15
10
5
0
Time to complete (s)
Foot Drop
GPAF

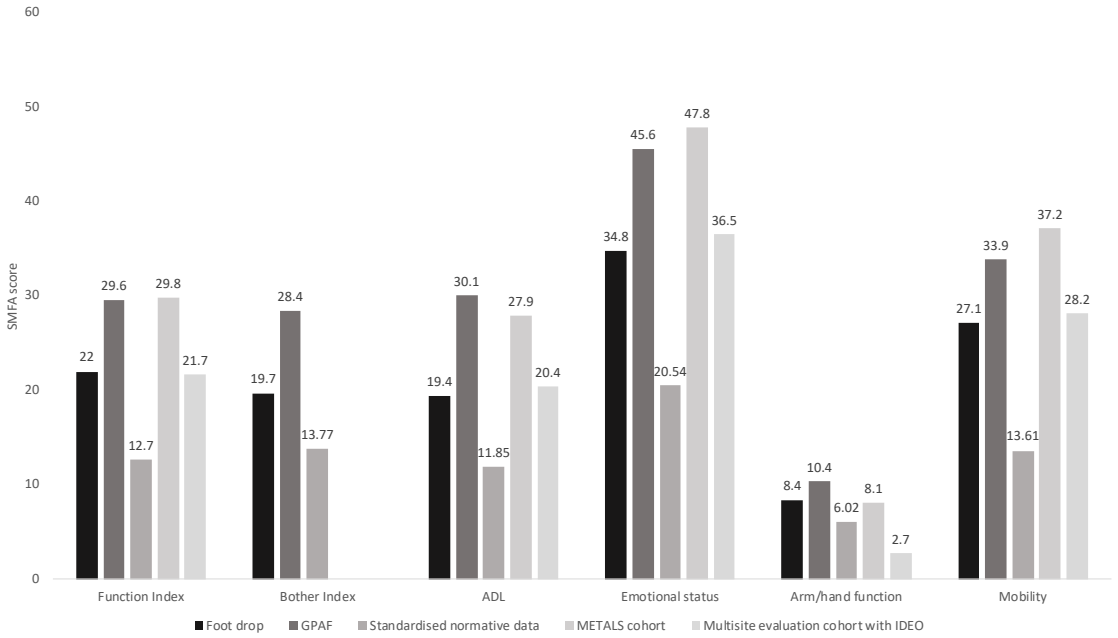
c


Self selected walking velocity (s)
14
12
10
8
6
4
2
0
Foot Drop
GPAF

d


Time to complete (s)
18
16
14
12
10
8
6
4
2
0
Foot Drop
GPAF
Week 0
Week 8

e




f

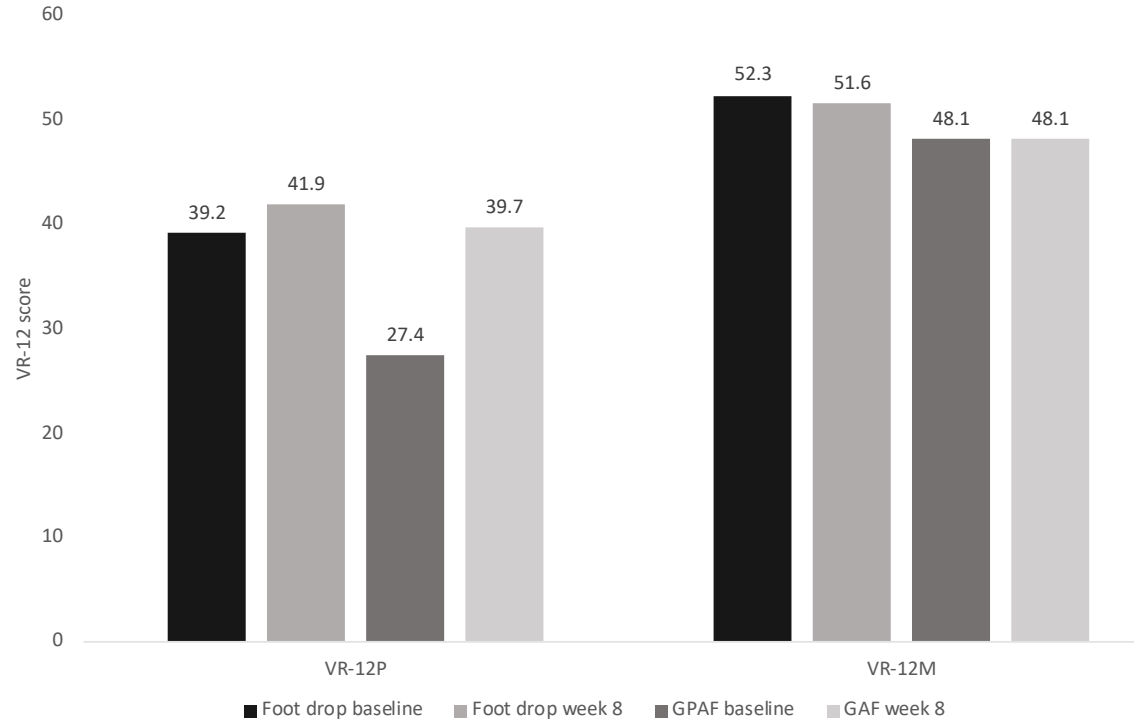



*Figure 8-2: Performance measures for the foot drop group and GPAF group at baseline (week 0) and week 8 on completion of the RTR CP a) Four Square Step Test b) 20m shuttle run c) self-selected walking velocity of 15m d) timed stair ascent e) SMFA data f) VR-12. The dashed line represents military population norms for uninjured males ages 18-43 (a, c, d)* (Wilken, 2012)*and population norms for the VR-12 (f)* (Selim, 2009)*. The shuttle run does not have a known military population norm value.*

### 8.4.1. Foot Drop

The PPMs and PROMs at baseline (week 0) and on completion of the RTR CP can be found in Table 8-3 and compared to military population norms in Figure 8-2. On completion of the RTR CP with the IDEO, patients in the foot drop group demonstrated statistically significant improvement in all PPMs (FSST, 20m-shuttle run, SSWV, and TSA). The improvements seen in the FSST and SSWV brought the foot drop group in line with reference data levels for healthy military populations. Although improvements were seen in almost all PROMs, these were not found to be significant. The SMFA results are similar, with the exception of the arm/hand domain, to the results from a study by Potter et al looking at outcomes for all patients with the IDEO at 12-month follow-up (Potter, 2018). The VR-12 results for the foot drop group bring outcomes in line with population norms for both mental and physical results.

### 8.4.2. Globally poor ankle function group

Like the foot-drop group, patients in the GPAF group also experienced improvement in all PPMs at the end of the 8-week RTR CP. Additionally, statistically significant improvements were found in the ADL, mobility, function, and bother domains of the SMFA. Statistically significant improvements were also seen in the VR-12P domain which brought outcomes from well below population norms to the same level.

Post-hoc power analysis reveals that the foot drop group was only appropriately powered ($p>0.8$) in the 20m shuttle run test. The GPAF group were appropriately powered in all domains of the SMFA and VR-12 where significance was found, as well as in the FSST and TSA.

### 8.4.3. Amputation

Two patients (7%) underwent amputation during the follow up period. Both patients were in the GPAF group. One patient experienced recurrent ulceration distal to the knee due to complete loss of sensation. He underwent amputation at 2 years 3 months following completion of the RTR CP. The second patient had a diagnosis of Chronic Regional Pain Syndrome and underwent amputation 1 year 5 months following completion of the RTR CP. At average 2 years follow up, all patients continue to use the IDEO for variable periods of the day except for the two patients who have progressed to amputation.

## 8.5. Discussion

After completion of the RTR CP with the IDEO, patients with foot drop and GPAF demonstrated improvement in PPMs and PROMs. This demonstrates that the IDEO and RTR CP work to improve outcomes for nerve injury patients.

### 8.5.1. Foot drop group

After completion of the RTR CP the foot drop group demonstrated improvements in PPMs bringing outcomes close to military population norms. Although the study was only sufficiently powered for the 20m-shuttle run, the PPM improvements are consistent with findings by Bedigrew et al. concerning physical improvements for a heterogenous population of IDEO users and therefore it can be concluded that use of the IDEO improves outcomes for patients with foot drop (Bedigrew, 2014).

Although a number of different options exists for the treatment of patients with foot drop, specifically for patients with a traumatic peroneal nerve palsy, operative intervention has been demonstrated to have poor outcomes due to reduced resolution rates (Masakado, 2008; Poage, 2016). In older, less active patient populations, tendon transfers have demonstrated success, however with persistent post-operative plantarflexion power loss, risk of tendon rupture, and post-operative continued used of an orthosis (Ho, 2014; Johnson, 2015; Poage, 2016). For a previously fit and active military population, this study demonstrates a non-operative intervention option to improve PPMs and therefore allow impact activities without the associated risks of surgery. This study adds to the body of evidence that the IDEO and RTR CP improve outcomes for LS patients.

Improvements were also seen in the PROMs with VR-12P outcomes in line with population norms. Although a statistical improvement in SMFA was not seen for patients in the foot-drop group, week 8 results were better than the SMFA results reported for 126 limb salvage patients without the IDEO (ADL 19.4 v 27.9, emotional status 34.8 v 47.8, mobility 27.1 v 37.2, Function 22 v 29.8) (Doukas, 2013). Although this study was not appropriately powered to report on statistical improvements in the SMFA, the results of the SMFA seen here for foot-

drop patients are similar to the results for the Multisite evaluation carried out by Potter et al looking at outcomes with the IDEO at 12-months follow-up (Potter, 2018). The foot drop group started with better scores at baseline than the GPAF group and therefore the bottoming and ceiling effects inherent in the SMFA may explain the lack of statistical improvement. This study therefore demonstrates that patients with foot drop benefit from prescription of the IDEO and the RTR CP.

### 8.5.2. GPAF group

The GPAF group demonstrated statistically significant improvements in all PPMs and the SSWV with the IDEO was close to population norms. It should be noted that, despite a statistically significant improvement in all PPMs for the GPAF group, the results for the other PPMs were worse than population norms, heterogenous studies examining IDEO populations, and transtibial amputees (Wilken, 2018). Patients in the GPAF group demonstrated a higher disability level at baseline relative to the foot drop group and military population norms and therefore results may continue to improve with ongoing use of the IDEO beyond the 8-week point when results were collected.

The IDEO supports the foot and ankle at the 'initial contact' and 'loading response' phases of gait, ensuring appropriate positioning of the foot. This is true of traditional AFOs used for patients with dorsiflexion weakness and may explain the improvements seen in the foot drop group. Additionally the IDEO stores energy during stance and returns this energy at pre-swing, augmenting power for patients with concomitant plantarflexion weakness (Russell Esposito, 2014; Ranz, 2016). This may explain the physical performance improvements seen for patients with GPAF in this study and the improvements for patients specifically with weakness of dorsi and/or plantarflexors seen in the previous Chapter.

Improvements were also seen for the GPAF group in PROMs. At baseline, the GPAF group demonstrated self-reported difficulties with ADLs, mobility, function, and found these more bothersome than individuals with foot drop. The mechanism of action of the IDEO, providing increased stability and power augmentation, enabled improvements in all these domains. Despite statistically significant improvements in the SMFA results for the GPAF group the results after completion of the RTR CP were similar to the results for LS patients prior to the

introduction of the IDEO seen in the METALS study (Doukas, 2013). The GPAF group began at a lower baseline therefore had potentially larger gains to make in the 8-weeks. As with the PPMs the results may continue to improve and may be comparable to the multisite evaluation study at 12-months follow-up (Potter, 2018).

The VR-12 score also improved for the GPAF group bringing the physical component score in line with population norms from a baseline well below population norms. At a population level, a 1 point increase in the Veterans Rand Score has been estimated to reflect a 6% reduction in total health care expenditures, 5% decrease in pharmacy expenditures, 9% decrease in hospital inpatient visits, 4% fewer medical provider visits, and a 5% lower rate of hospital outpatient visits (Group, 2006). Patients with GPAF demonstrated improvements of greater than 12 points on average following the RTR CP. The potential societal, financial, and care savings are therefore large.

### 8.5.3. Amputation

This study found that only 2 patients progressed to amputation and the rest continued to use the IDEO for variable periods of the day. Hill et al in their study of injury and outcome with the IDEO reported a 14.3% amputation rate with nerve injuries and IDEO use (Hill, 2016). 14.3% is higher than the 6.7% seen here, and higher than the rate seen in the previous Chapter, with no nerve injury patients undergoing amputation. Previous IDEO literature has included a heterogenous cohort of patients with polytrauma, whereas this study attempted to use a homogenous cohort. Where patients experience multiple injuries, progression to amputation may be a consequence of one of the other injuries. Patients may also abandon the IDEO due to a concomitant ipsilateral injury preventing use. No patients abandoned the IDEO in this study and only 2 patients required amputation, therefore there are insufficient numbers to ascertain whether a concomitant ipsilateral injury with a nerve injury is significant in predicting outcome of ongoing use or abandonment of the IDEO. One patient in this study progressed to amputation with CRPS. This is in keeping with findings in the previous Chapter and published work, that the IDEO does not work for patients with CRPS and CRPS is a predictive factor for amputation (Potter, 2018).

### 8.5.4. Limitations

Due to the relatively small cohort of patients prescribed the BOB in the UK, it has been necessary to use a cohort of patients from the US wearing the IDEO. In the US, patients participate in the RTR CP which is not available in the UK. Patients at the DMRC in the UK do however undergo intensive physio, bespoke to their injury, in the months leading up to prescription of the BOB, and once received. Any differences between the IDEO and the BOB in fabrication are minor and aim to combat breakage issues seen in the US and increase the longevity of use of the BOB. Therefore, the results from this Chapter can be used to draw conclusions on the development of the clinical decision tool for prescription of the BOB.

This study was only appropriately powered for statistical analysis of the GPAF group. As previously described in this thesis, the cohorts available for analysis following prescription of the BOB are small and sub-group analysis further diminishes statistical power. This is the largest study to undertake analysis of a group of patients prescribed the IDEO for a single indication. All attempts have been made to assess the improvements appropriately. Despite the lack of power for the foot-drop group, results have been demonstrated to be in line with healthy population norms. Additionally, the study was appropriately powered for conclusions drawn about improvements in both PPMs and PROMs for the GPAF cohort.

The follow-up for the PPMs and PROMs was only at the 8-week point on completion of the RTR CP. Potter et al have demonstrated an ongoing improvement in PROMs at 6-month and 12-months follow-up with IDEO use (Potter, 2018). Therefore, it is reasonable to expect improvements in PPMs and PROMs to continue. Although the cohort were followed up for an average of 18 months post completion of the RTR CP, this was to look for the elective amputation rate and PPMs and PROMs were not collected. A longer follow-up period would strengthen this study, but this is an American cohort and therefore this is not currently practicable.

Taking into consideration the results of this and the previous Chapter, it has been established that the BOB works for patients with predominantly a nerve injury resulting in dorsi and/or plantarflexion weakness. It has also been established that the BOB doesn't work for patients

with a diagnosis of chronic pain. There still exist a group of patients for whom it is not possible to predict outcome with the BOB.

## 8.6. Conclusion

Patients with a nerve injury causing either foot drop or GPAF, requiring augmentation to undertake impact activities, will benefit from prescription of the BOB combined with rehabilitation. Although both chronic pain and nerve injury are predictors of outcome with the BOB, it is currently not possible to predict outcome for all patients prescribed the BOB. The next Chapter will investigate gait as a discriminator for inclusion in the clinical decision tool.

# Chapter 9: Gait pilot study

## 9.1. Introduction

The previous Chapters have established which clinical indications can be used in a decision tool for prescription of the BOB. This is summarised in the flowchart of Figure 9-1. Despite efforts to establish a link between injury patterns and outcome with the BOB, there is still a number of patients for whom it is not possible to predict outcome. The previous clinical Chapters have focused on functional outcomes in the form of PPMs and questionnaire-based PROMs. As highlighted in Chapter 5, and the previous Chapters, there is a growing body of evidence investigating biomechanical gait changes in the IDEO. Gait studies enable objective assessment of walking ability and allow comparison of gait between individuals. Chapter 3 explained the common gait deficiencies present following LS and Chapters 4 and 5 highlighted the role ankle foot orthoses, particularly the IDEO/BOB, play in augmenting gait for LS patients. All studies to date investigating gait and the IDEO have focused on gait in the IDEO, but none investigate gait for LS patients prior to prescribing the IDEO.

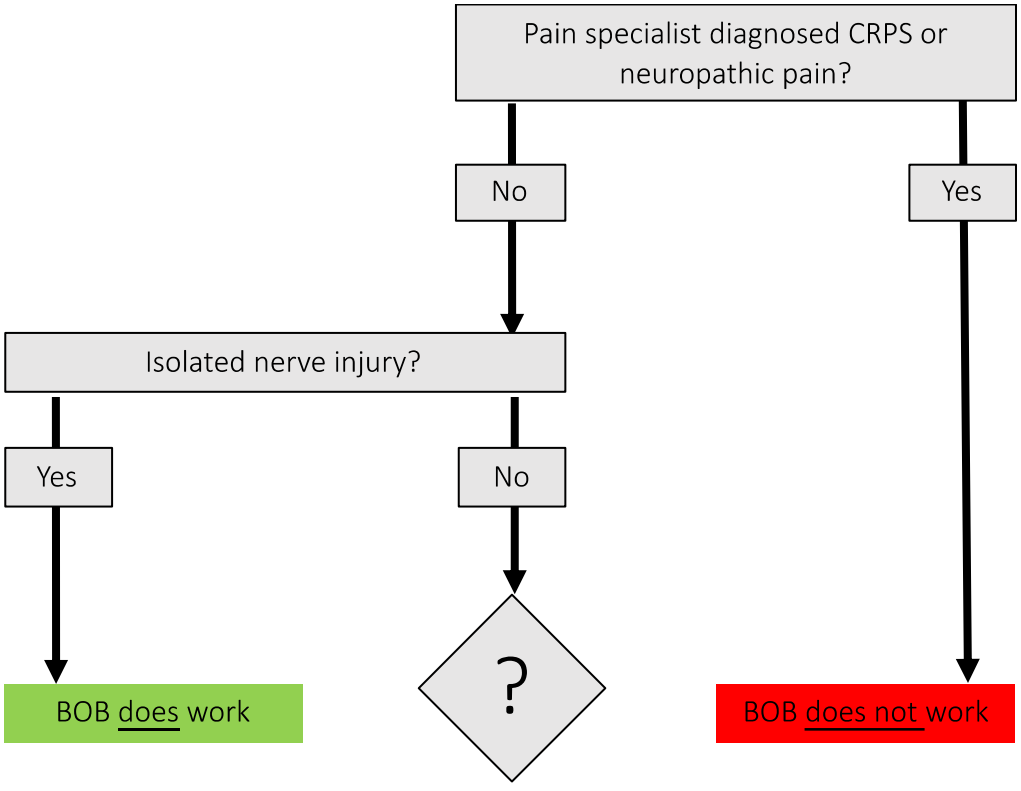



*Figure 9-1: Clinical indications included in clinical decision tool. There is still a number of patients for whom it is not possible to predict outcome with the BOB.*

### 9.1.1. Gait changes with the BOB

Gait studies examining patients in the IDEO have established a statistically significant reduction in ankle RoM and ankle power generation at pre-swing compared to controls (Russell Esposito, 2014, 2017). IDEO gait studies do not link the observed gait changes to outcomes with the IDEO. There are also no studies examining gait changes in and out of the IDEO/BOB for the same patient; all studies compare statistical differences between the affected limb wearing the IDEO and either the unaffected limb or controls. In order to understand IDEO/BOB induced gait changes it is necessary to investigate the gait of an individual in and out of the BOB, looking at statistical differences assessed against minimal detectable change values (Wilken, 2012). The first aim of this Chapter is to investigate gait in and out of the BOB in a healthy volunteer in order to understand BOB induced gait changes.

### 9.1.2. Gait biomechanical analysis

Furthermore, to create a clinical decision tool, investigation of gait of patients with known outcomes, prescribed a BOB is required. Unpublished work from the DMRC highlights a number of patients undergoing lower limb rehabilitation (for whom outcomes are known (presented in Chapter 7) had their gait assessed prior to prescription of the BOB.

The gait analysis used the standard DMRC gait lab set up for markers (Figure 9-4). These data have not previously been analysed and to be of use raw data must be processed with the correct biomechanical model. Multiple biomechanical models exist, each resulting in varying outputs with respect to angles, moment, and power (Ferrari, 2008; Gorton, 2009; Duffell, 2014). Variability has also been found when the same model is used at different gait labs (Gorton, 2009). Three different biomechanical models are of interest for this Chapter, the PiG, the Python Conventional Gait Model 2.3 (pyCGM2.3), and the Body Builder Imperial Model (BBImperial).

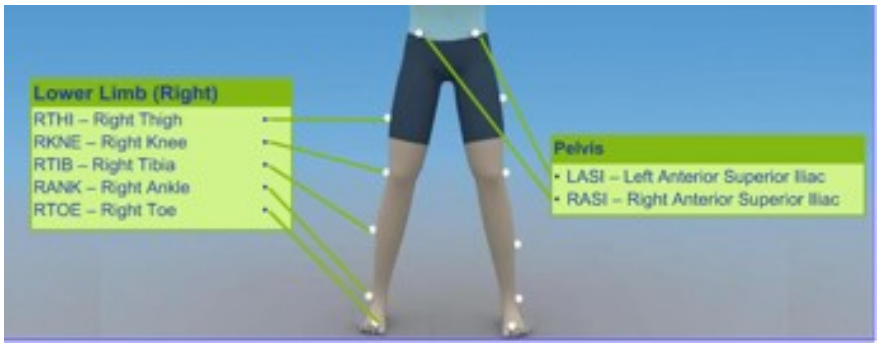
Both the PiG and pyCGM2.3 are based on the CGM. The CGM was originally developed at both the Newington Children's Hospital and the Helen Hayes Hospital, before being incorporated into Vicon and PiG (Kadaba, 1989; McGinley, 2009). PiG assumes that all joints

in the lower limb are ball and socket joints capable of three rotational degrees of freedom. Relative translation at the knee and ankle is not considered as it was assumed that the soft tissue artefact from markers would result in more movement than the possible relative translation at these joints (Leboeuf, 2019). For PiG the seven segments of the lower limb (pelvis, two femurs, two tibias and two feet) are linked in an open chain. Results of the distal segments in an open chain are dependent on the results of the proximal segment (Leboeuf, 2019). This makes the model simple but results in proximal errors compounded distally (Cappozzo, 1995).

Despite the potential for errors due to the open chain set up, PiG has been validated by numerous clinical studies and is considered to be particularly robust (McGinley, 2009). The longevity of use of PiG combined with validation outside the initiating centres is a clear strength. Although the repeatability of the model has been well validated, the accuracy of the results has been subject to far less scrutiny (McGinley, 2009). This is a criticism of most models used for gait analysis, where reproducibility of results is favoured above accuracy. This may be due to the lack of a gold standard against which to compare the results (Leboeuf, 2019).

The PiG model uses a configuration of 16 markers placed on the skin (Figure 9-2). The position of the markers for the PiG model are different to the DMRC set up (Figure 9-4a). The most significant weakness of the PiG model occurs with misplacement of the thigh and tibia markers (Vicon Motion Systems, 2016). In PiG these markers need to be placed equidistant in the anterior-posterior location, so they sit in the lateral midline of the thigh or tibia. Error in placement results in large errors in angle output (Duffell, 2014; Vicon Motion Systems, 2016). Not only do errors occur at the joints associated with the misplaced markers, but due to the open chain set up, with distal segments dependent on the proximal results, errors are compounded distally. PiG also approximates the joint centre locations, as opposed to directly measuring from the markers, introducing further potential error (Leboeuf, 2019).

a

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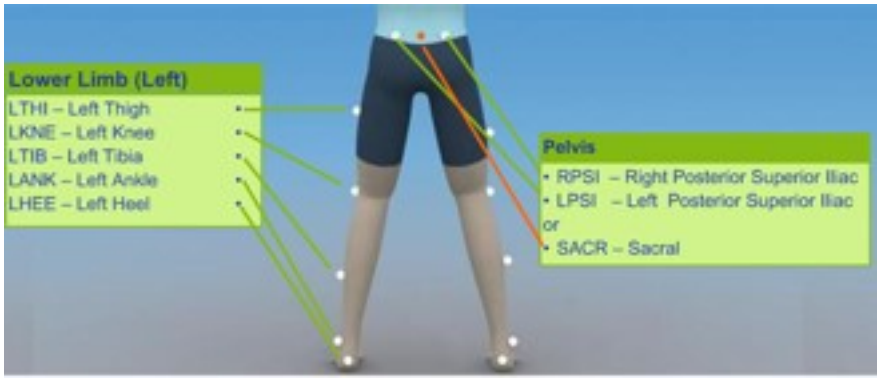


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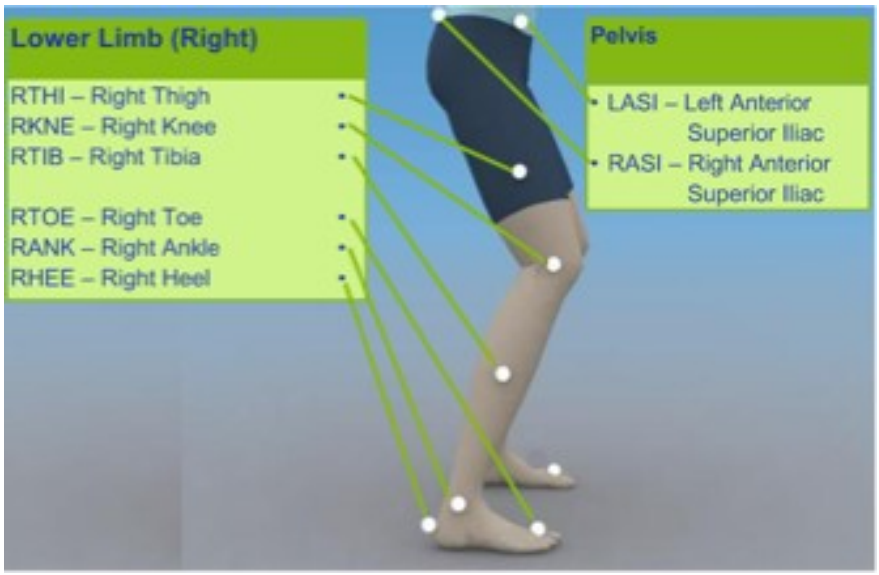



*Figure 9-2: Vicon Plug-in Gait marker set-up. a) anterior view b) posterior view c) lateral view. Of note, the THI and TIB markers anterior-posterior position is crucial for establishing the orientation of the knee and ankle flexion axis.*(Vicon Motion Systems, 2016) *Reproduced with permission of Vicon.*

Although validated through multiple trials, the previously mentioned weaknesses and technological advancement since the inception of the CGM in the 1970's has led researchers to question whether adaptation would result in increased clinical relevance (Leboeuf, 2019).

This led to the creation of the pyCGM2 and evolution of pyCGM2.3. The pyCGM2.3 allows for the use of clusters on the thigh and tibia to represent these segments, whilst maintaining the strengths of using a CGM-derived model. The pyCGM2.3 also uses inverse kinematics to minimise weighted mean square differences. Inverse kinematics is a mathematical process using the position of the rigid joint segments to calculate the joint angles. This is opposed to forward kinematics where the joint angles are used to calculate the position of the rigid joint segments. The latter results in potentially more errors than the former. Despite the use of inverse kinematics, the cluster marker placement on the thigh and tibia is still required to be accurate as one of the markers in each of the clusters provides the same function as the thigh and tibia marker found in the PiG model (Leboeuf, 2019). Inaccurate placement in the anterior-posterior direction results in the same errors as seen in the PiG model. The DMRC marker-placement set up does not ensure the thigh and tibia markers are placed in a central position with regards to anterior-posterior referencing, although in some cases they may have been. Therefore, both the PiG and pyCGM2.3 have the potential to contain errors in the joint angles and joint rotations generated, due to the inaccurate placement of markers.

The third option is the BBImperial model (Figure 9-3). The BBImperial model uses clusters to calculate kinematics but does not use clusters to identify joint centres (Cleather, 2010). The medial and lateral knee and ankle markers are used during the static calibration only and the clusters are used during the dynamic trials. This has the advantage of allowing for placement of the clusters anywhere on the segment so as not to impede the individual's gait (Duffell, 2014). This model also closely aligns to the DMRC marker setup. It has the added advantage of not using the open-chain model found in CGM-derived biomechanical models and therefore may overcome the weaknesses highlighted with proximal errors compounded distally. The BBImperial model has the disadvantage, however, of processing neither gait spatiotemporal parameters nor joint power data. Therefore, a second aim of this Chapter is to assess all three potential biomechanical models which may be used to process the DMRC gait data and select the most appropriate.

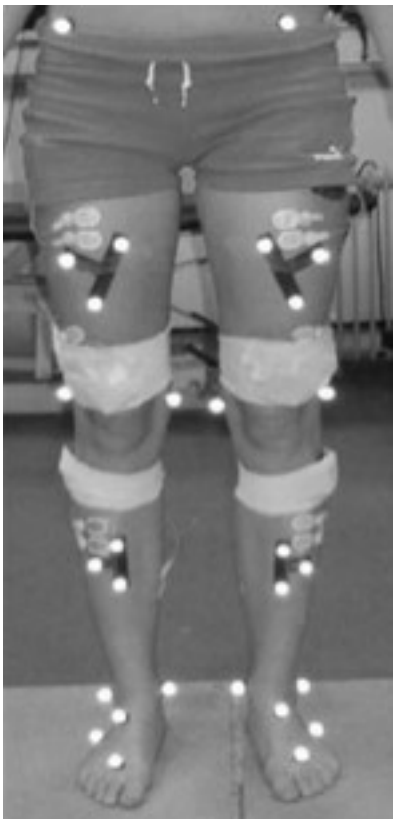


*Figure 9-3: Marker set up for the BBImperial model with clusters on the thigh and tibia* (Duffell, 2014). *Markers are placed on the Anterior superior iliac spines (ASIS) bilaterally, the Posterior superior iliac spines (PSIS) bilaterally, clusters on the thigh shanks, medial and lateral femoral condyles bilaterally, tibia shanks bilaterally, medial and lateral malleoli bilaterally, over the 2nd metatarsal, 5th metatarsal, and the heel, bilaterally. Reproduced with permission of the copyright holder, Sage.*

Gait studies concerning the IDEO have demonstrated a reduction in ankle RoM and power generation at pre-swing (Russell Esposito, 2014, 2017). The mechanism of action of the BOB is to support the foot and ankle, and augment function. The foot and ankle kinetics and kinematics are therefore of most interest in selecting an appropriate model. To use the DMRC historic gait data, the most appropriate biomechanical model must be selected based on foot and ankle biomechanics.

### 9.1.3. Proximal joints

For ongoing use of the BOB in rehabilitation, it would be desirable to know whether the BOB affects proximal joints. Knowledge of this would guide clinicians, informing them of possible changes in knee and hip joints with ongoing use of the BOB. Differences have been noted, between BOB users and controls, in proximal joint angles, with a decrease in knee RoM and

hip flexion during stance (Russell Esposito, 2014). Compared to the contralateral limb, however, statistically significant differences of proximal joints have not been noted between the affected and unaffected limbs of the same individual when wearing the IDEO (Russell Esposito, 2017). No studies have looked at changes in proximal joint angles in and out of the BOB in the same individual to establish the effect of the BOB on proximal joints. If the proximal joints do not demonstrate any deviation when the BOB is being worn, it can be concluded that they are not adversely impacted by use of the BOB and therefore a trial is unlikely to cause adverse consequences from the perspective of the proximal lower limb joints. Therefore, the third and final aim of this Chapter is to investigate the impact of the BOB on proximal joints in a healthy volunteer to assess for statistically significant kinetic and kinematic differences at the knee and hip when wearing the BOB.

## 9.2. Method

A male volunteer who was 39-years-old, had a mass of 79.7 kg and height 1.79 m was used as a healthy control. He had no known gait deviations or chronic injuries to his lower limbs. He walked without an AFO and did not require any modifications to his shoes. A BOB was fabricated for the individual by the lead orthotist at the DMRC. The left leg was chosen for fitting of the BOB although there was no known injury to either side. A standard lay up for the BOB was used based on the individual's height and weight. The highest activity level was chosen for lay-up (see Chapter 5 for further information about the fabrication of the BOB).

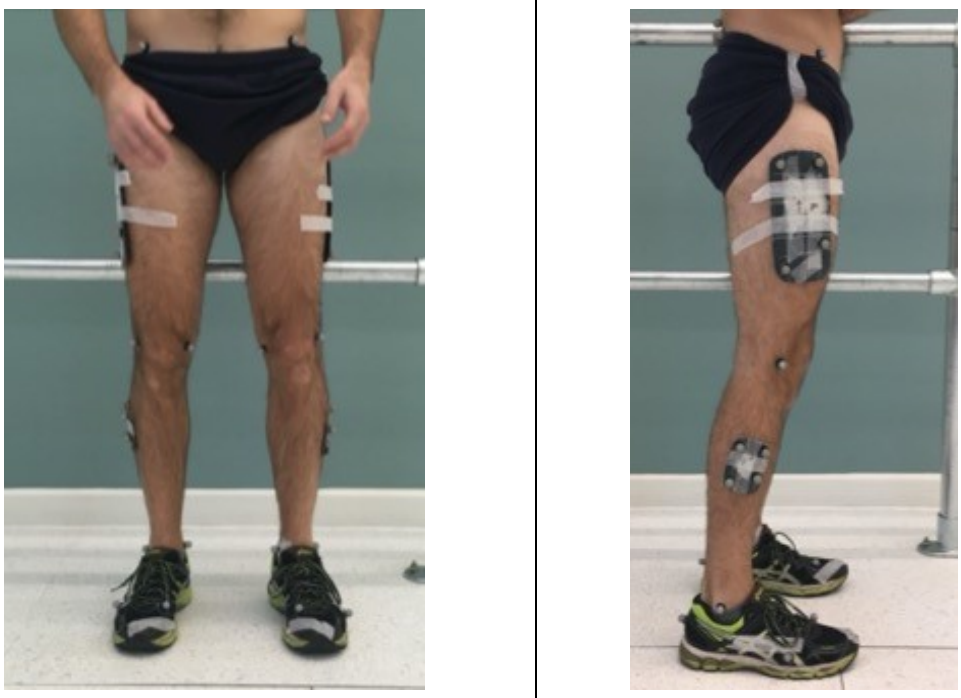
The gait-lab set up consisted of a 20-camera optoelectric motion capture system (100Hz; Vicon Motion Systems Ltd, Oxford, UK) over a 20m walkway. This was synchronized with six force plates (1000Hz; Kistler, Advanced Mechanical Technology Inc, MA, USA) embedded in the floor. Force plates were calibrated and 'zero'd' at set up. Thirty-seven lower limb retro-reflective markers were placed on the pelvis, thigh, knee, tibia, ankle, and foot. This marker set is the standard lower limb set up for the DMRC (Figure 9-4a). Data was collected on the subject's height, weight, leg length (measured from the anterior superior iliac spine to medial malleolus), knee width, and ankle width. Model inputs can be found in Table 9-1. The BBImperial Model only requires the height and weight.

| | **PiG** | | | | **pyCGM2.3** | | | |
|---|---|---|---|---|---|---|---|---|
| | Shod | | BOB | | Shod | | BOB | |
| **Input** | Left | Right | Left | Right | Left | Right | Left | Right |
| Leg Length (mm) | 918 | 910 | 915 | 911 | 910 | 910 | 912 | 912 |
| Thigh Rotation (°) | 0 | 0 | 36 | 17 | 0 | 0 | 0 | 0 |
| Knee Width (mm) | 106 | 102 | 112 | 105 | 105 | 105 | 108 | 108 |
| Ankle width (mm) | 84 | 88 | 82 | 85 | 85 | 85 | 83 | 83 |
| Sole delta (mm) | 0 | 0 | 5 | 5 | 0 | 0 | 0 | 0 |

*Table 9-1: Subject measurement data input for each biomechanical model for gait analysis. Thigh rotation positive number is internal and negative number is external. Rotation is added to attempt to overcome the misplacement of the thigh and tibia markers where required. Sole delta is added where required to compensate for the thickness of the shoe sole. PiG = Plug in Gait, pyCGM2.3 = Python Conventional Gait Model 2.3.*

Two experimental conditions were tested. The first condition was wearing just trainers (shod) (Figure 9-4a) and the second condition was wearing trainers and the BOB on the left leg (BOB) (Figure 9-4b). Due to inclusion of the BOB in the shoe it was necessary for the healthy subject to wear different trainers on each foot, his usual trainer on the right and a trainer one size bigger on the left. Data will be presented for the right and left shod condition (R shod and L shod) and for the right and left BOB condition with the BOB worn just on the left leg (R BOB (L) and L BOB (L)). The individual completed a static trial followed by ten walking trials at a self-selected walking velocity for each of the testing conditions; shod and BOB. In order to not introduce gait alterations, no precise instructions were given about speed of walking. The subject wore the BOB over a period of 5 days prior to the gait trials to become accustomed with walking in the BOB. The individual completed ten practice trials in each condition (shod and BOB) prior to the experimental trials to become accustomed to the gait lab and change in experimental condition.

a



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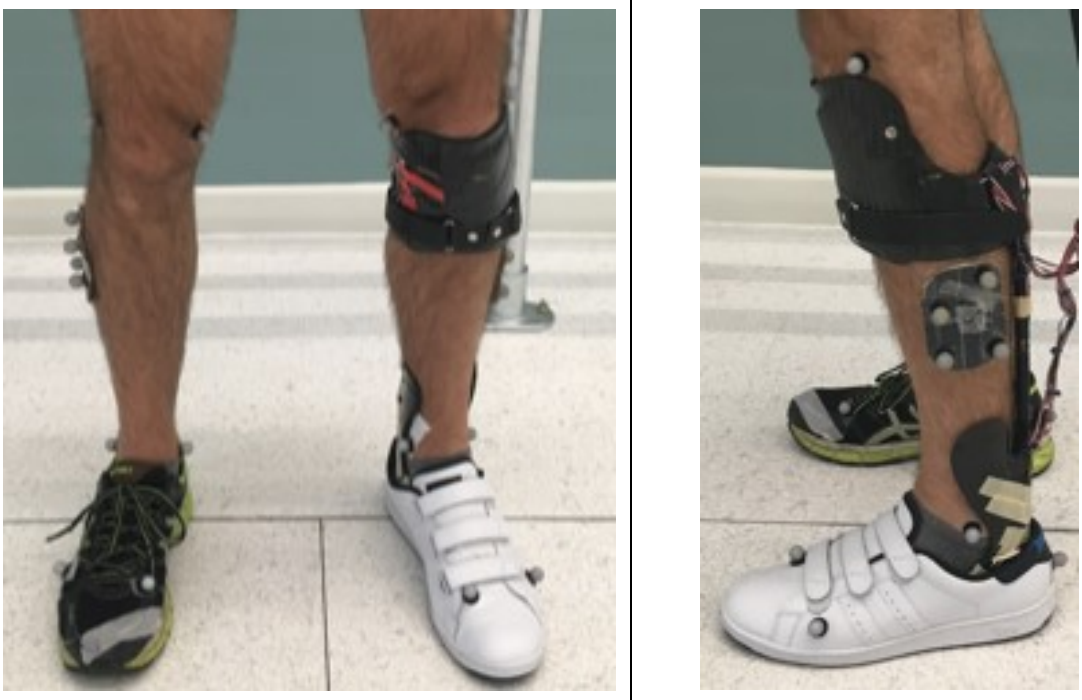


*Figure 9-4: a) DMRC Marker set up for lower limbs viewed anteriorly and laterally. Clusters placed on the thigh and tibia are not in the lateral midline. They are placed asymmetrically superior inferior to allow Vicon Nexus to identify left from right. b) DMRC marker set up with the BOB on the left leg. The marker placement has not changed despite the addition of the BOB. The BOB is cut inferior to the medial and lateral femoral condyles therefore the markers are placed in the normal position, the tibia is exposed, and the cluster can be placed (the superior inferior location with reference to the contralateral limb allows Vicon Nexus to distinguish left from right), and the ankle trim lines allow placement of the medial and lateral malleoli markers. The remaining marker placement, proximal and distal, remain unchanged also. The left trainer is different to the right as the BOB necessitates wearing a shoe one size larger.*

Nexus Vicon (Oxford, UK) was used to crop each trial to one gait cycle (initial contact of current cycle to initial contact of the next) on the right and left side. Data was filtered using Woltring smoothing (15 Hz cut off). To enable comparison of the three models, the data was processed with PiG (detailed methodology for PiG can be found online) (Vicon Motion Systems, 2019), pyCGM2.3 (detailed methodology for pyCGM2.3 can be found online) (*The CGM 2.i Project - CGM2.i*, no date), and the BBImperial Model (detailed methodology can be found (Long, 2017)). Gait cycle spatiotemporal parameters, lower limb joint angles (x, y, and z), joint moment data (x, y, and z), and power data, were extracted from each model (BBImperial does not provide spatiotemporal or power data, and moment data is only calculated for the stance phase of gait). The data was interpolated using a bespoke Matlab (Matlab 2019a, The MathWorks) script to 101 points normalised to 100% of the gait cycle. Ten trials in each condition (shod and BOB) were undertaken. Outputs for each limb are calculated independent of the contralateral limb. Therefore, spatiotemporal data may be different for the left and right side in each condition if, for example, one leg swings through faster than the other. Twenty-four dependent measures of peak angles, moments, powers, and ranges of motion were analysed for each model (Table 9-2), consistent with IDEO gait literature (Russell Esposito, 2017).

| **Angle** | **Moment** | **Power** |
|---|---|---|
| <u>Ankle</u> | | |
| Peak DF stance | Peak DF - loading response | Ankle abs - loading response |
| Peak PF - initial swing | Peak PF - terminal stance | Ankle abs - terminal stance |
| Ankle ROM | | Peak ankle gen - pre-swing |
| <u>Knee</u> | | |
| Knee flex - initial contact | | Peak knee gen - early mid stance |
| Peak knee flex - loading | Peak knee ext - loading response | |
| Peak knee ext - stance | Peak knee flex - terminal stance | |
| Peak knee flex - swing | | |
| Knee ROM | | |
| <u>Hip</u> | | |
| Peak hip flex - stance | Peak hip ext - stance | Peak hip gen - loading response |
| Peak hip ext - stance | Peak hip flex - terminal stance | |
| Peak hip flex - swing | | Peak hip abs - terminal stance |
| Hip ROM - sagittal | | |

*Table 9-2: 24 dependent measures of gait. Peak angles, moments, powers, and ranges of motion. DF = dorsiflexion, PF = plantarflexion, ROM=range of motion, flex = flexion, ext = extension, abs=absorption, gen=generation.*

### 9.2.1. Selecting the biomechanical model

For a healthy individual with no underlying injury, gait is assumed to be symmetrical in the shod condition, defined as no statistically significant differences above minimal detectable change values, between the left and right side (Hamill, 1984). To establish which biomechanical model is most appropriate to use to process the spatiotemporal, angles, moment, and power data for the historic gait data presented in the next Chapter each of the dependent measures of gait will be assessed for symmetry in the shod condition. The chosen biomechanical model for spatiotemporal, angle, moment, and power data, will demonstrate the least number of statistical differences in the shod condition at the ankle between the left and the right side. Firstly, the spatiotemporal data will be compared for the PiG and pyCGM2.3 models. The number of statistically different measures in the shod condition will be analysed between left and right. In a healthy individual asymmetry should not be found, therefore if it is found through statistical differences, a lack of sensitivity in the model will be assumed. The model with the least statistically significant differences for the spatiotemporal data will be chosen as it will be assumed to contain the least errors. The angle and moment data will be assessed in the same way for all three models and finally the power data will be assessed for the PiG and pyCGM2.3 models. Since each gait model will be assessed for spatiotemporal, angle, moment, and power data, it may be that a different model is chosen to process each of the variables in the next Chapter.

### 9.2.2. Assessing BOB induced gait changes at the foot and ankle

To assess BOB induced gait changes at the foot and ankle, the chosen biomechanical model will be used to compare the shod and BOB conditions for statistically significant differences in spatiotemporal, angle, moment, and power data at the foot and ankle. Where present, statistically significant differences will demonstrate BOB induced changes.

### 9.2.3. Assessing BOB induced gait changes at proximal joints

To assess BOB induced gait changes at proximal joints, the chosen biomechanical model will be used to compare shod and BOB conditions. Similar to changes at the foot and ankle, the knee and hip angle, moment, and power data will be concluded to demonstrate BOB-induced

gait changes if statistically significant differences are found between the shod and BOB conditions.

### 9.2.4. Statistical analysis

Data was assessed for normality using the Shapiro-Wilk test. Data was found to be normally distributed. To assess each model, a mean of the ten trials for each limb under each condition (shod and BOB) was taken. Results are presented as mean ± standard deviation. T-tests were used to assess differences in gait for the 24 dependent measures. Independent t-tests were used for comparison of the ipsilateral side in the shod and BOB condition, whilst paired t-tests were used for comparison between sides (left and right) in each condition. A significance level of p=0.01 was set. Results found to be statistically significant were then assessed against published minimal detectable change values for angle, moment, and power data for the same walking speed (Wilken, 2012). As explored in Chapter 3, walking speed has an impact on gait, altering angle, moment, and power data; therefore, minimal detectable change values must be used for a matched walking speed.

## 9.3. Results

### 9.3.1. Gait cycle spatiotemporal parameters

Gait-cycle spatiotemporal parameters for the two CGM derived biomechanical models under each condition can be seen in Table 9-3. Using the standard BBImperial model, it is not possible to output gait spatiotemporal parameters.

#### *9.3.1.1. PiG*

**Cadence** was not significantly different using the PiG model between left and right in the shod condition (p=0.62) and between left and right in the BOB condition (p=0.08). It was significantly less in the BOB compared to the shod condition in the left leg (p<0.001) and the right (p<0.001). **Walking speed** is not significantly different in the shod condition between the left and right (p=0.72) or BOB condition between the left and right (p=0.74), but the left leg in the BOB condition is significantly slower than the left leg in the Shod condition (p<0.001) and the right leg in the BOB condition is significantly slower than the right leg in the Shod

condition (p<0.001). **Stride time** is significantly slower between the right leg in the BOB condition and the right leg in the Shod condition (p<0.001) and the left leg in the BOB condition compared to the left leg in the Shod condition (p<0.001). **Step time** was significantly lower in the left leg in the BOB condition compared to the that in the Shod condition (p<0.001); this was not observed on the right side (p=0.11). **Single support time** on the right leg in the BOB condition is statistically different to the Shod condition (p<0.001); this is not observed on the left. **The step length** in the BOB condition is significantly less on the right than the left (p<0.001); no statistical difference is noted in step length in the shod condition.

*9.3.1.2. pyCGM2.3*

**Cadence** is not different using the pyCGM2.3 model between the left and right in the shod condition (p=0.76) and left and right in the BOB condition (p=0.03). Cadence for the left leg in the BOB condition is significantly less than the left leg in the Shod (p<0.001) and the right leg in the BOB condition is significantly less than the right leg in the Shod condition (p<0.001). **Walking speed** is not significantly different between the left leg in the Shod condition and the right leg in the Shod condition (p=0.85) and left leg in the BOB condition compared to the right leg in the BOB condition (p=0.70), but the left leg in the BOB condition is significantly slower than the left leg in the Shod condition (p=0.001) and the right leg in the BOB condition is significantly slower than the right leg in the Shod condition (p<0.001). **Stride time** is significantly more on both left and right comparing the BOB condition to the Shod condition (p<0.001). **Step time** is significantly different on the left and right, comparing the BOB condition to the shod condition (p<0.001). The step time is significantly different for the left leg in the BOB condition compared to the shod condition (p<0.001) and within the BOB condition between left and right (p=0.002), this is not observed in the Shod condition. **Opposite foot contact** is significantly more in the BOB condition on the right compared to the Shod condition on the right (p=0.002), this is not observed on the left. **Foot-off percentage** is more on the right for the BOB condition than the right leg for the Shod condition (p=0.003), and the foot off percentage is also more for the right leg in the BOB condition compared to the left leg in the BOB condition (p<0.001). **Single support time** on both the left and right is significantly more for the BOB condition than the Shod condition (p=0.003 and p<0.001 respectively). **Step length** on the is significantly longer for the Shod condition than the BOB condition (p=0.006) and the left step length is significantly longer for the BOB condition than

the right for the BOB condition (p<0.001). **The limp index** is significantly different for the right BOB condition compared to the right Shod condition (p=0.001) and the limp index is significantly different between the right and left side for the BOB condition (p=0.002).

| | PiG | | | | pyCGM2.3 | | | |
|---|---|---|---|---|---|---|---|---|
| | **L Shod** | **R Shod** | **L BOB** | **R BOB** | **L Shod** | **R Shod** | **L BOB** | **R BOB** |
| **Cadence (steps/min)** | 116.3 (3.03) | 117.2 (4.65) | 106.9* (3.35) | 109.4* (2.72) | 117.1 (4.6) | 117.7 (4.0) | 107.3* (3.7) | 110.4* (2.1) |
| **Walking Speed (m/s)** | 1.7 (0.07) | 1.7 (0.09) | 1.5* (0.08) | 1.5* (0.07) | 1.7 (0.1) | 1.7 (0.1) | 1.5* (0.08) | 1.5* (0.07) |
| **Stride Time (s)** | 1.0 (0.03) | 1.0 (0.04) | 1.1* (0.04) | 1.1* (0.03) | 1.0 (0.04) | 1.0 (0.04) | 1.1* (0.04) | 1.1* (0.02) |
| **Step Time (s)** | 0.5 (0.01) | 0.5 (0.03) | 0.6* (0.02) | 0.5 (0.54) | 0.5 (0.02) | 0.5 (0.02) | 0.6* (0.02) | 0.5§ (0.02) |
| **Opposite Foot Off (%)** | 10.2 (3.44) | 10.6 (1.19) | 11.6 (1.35) | 10.4 (1.48) | 10.9 (2.3) | 11.0 (0.7) | 11.3 (1.3) | 10.5 (0.74) |
| **Opposite Foot Contact (%)** | 50.5 (0.68) | 49.3 (1.17) | 50.3 (1.68) | 50.8 (0.93) | 50.2 (1.18) | 49.2 (0.8) | 50.1 (1.65) | 51.3* (1.35) |
| **Foot Off (%)** | 61.0 (1.79) | 59.7 (3.80) | 60.5 (1.63) | 61.6 (1.59) | 61.6 (1.1) | 61.2 (0.8) | 60.3 (1.19) | 62.9*§ (1.45) |
| **Single Support (s)** | 0.4 (0.03) | 0.4 (0.01) | 0.4 (0.03) | 0.4* (0.02) | 0.4 (0.01) | 0.4 (0.0) | 0.4* (0.03) | 0.4* (0.02) |
| **Double Support (s)** | 0.2 (0.04) | 0.2 (0.05) | 0.2 (0.02) | 0.2 (0.02) | 0.2 (0.03) | 0.2 (0.02) | 0.2 (0.02) | 0.2 (0.01) |
| **Stride Length (m)** | 1.7 (0.05) | 1.7 (0.07) | 1.7 (0.06) | 1.6 (0.05) | 1.7 (0.06) | 1.7 (0.07) | 1.7 (0.05) | 1.6 (0.06) |
| **Step Length (m)** | 0.9 (0.04) | 0.8 (0.04) | 0.9 (0.02) | 0.8§ (0.04) | 0.9 (0.04) | 0.8 (0.04) | 0.9 (0.03) | 0.8*§ (0.05) |
| **Step Width (m)** | 0.1 (0.02) | 0.1 (0.01) | 0.1 (0.02) | 0.1 (0.02) | 0.1 (0.01) | 0.1 (0.01) | 0.1 (0.02) | 0.1 (0.02) |
| **Limp Index** | 1.03 (0.07) | 0.97 (0.06) | 0.99 (0.05) | 1.03 (0.05) | 1.02 (0.04) | 0.99 (0.02) | 0.98 (0.05) | 1.06*§ (0.05) |

*Table 9-3: Gait cycle parameters. Mean (SD). *significant difference to shod condition §significant difference to left in same condition.*

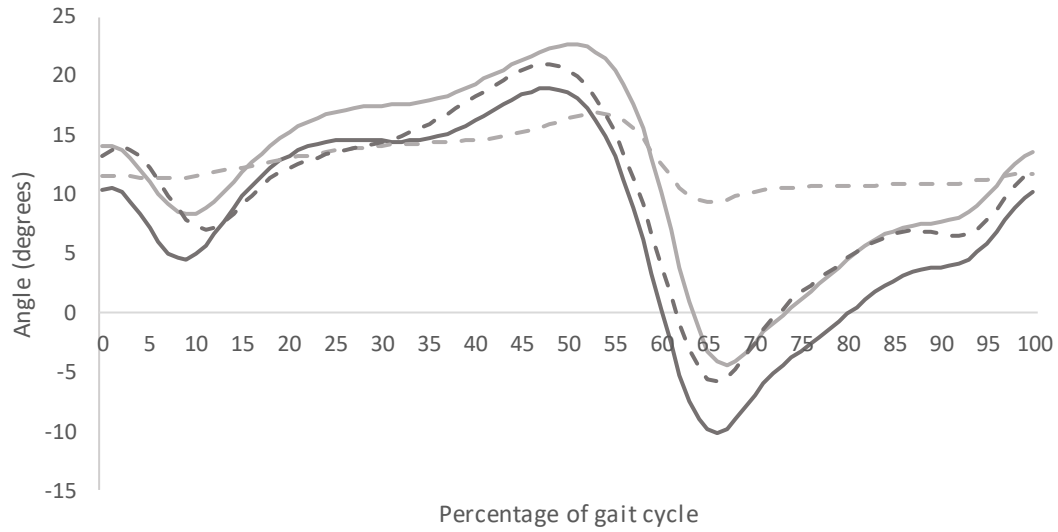
Comparing the PiG and pyCGM2.3 models, similar statistical differences were found with regards to cadence, walking speed, and stride time comparing the left side in and out of the BOB, and the right side in the shod condition and the BOB condition. All statistically significant differences found using the PiG model are also seen in the pyCGM2.3 model. In addition, the pyCGM2.3 model found inter-limb statistically significant differences in the BOB condition for step time, foot off, and limp index. No statistically significant differences, as expected in a healthy subject, are present in the shod condition in either model.

## 9.3.2. Angles

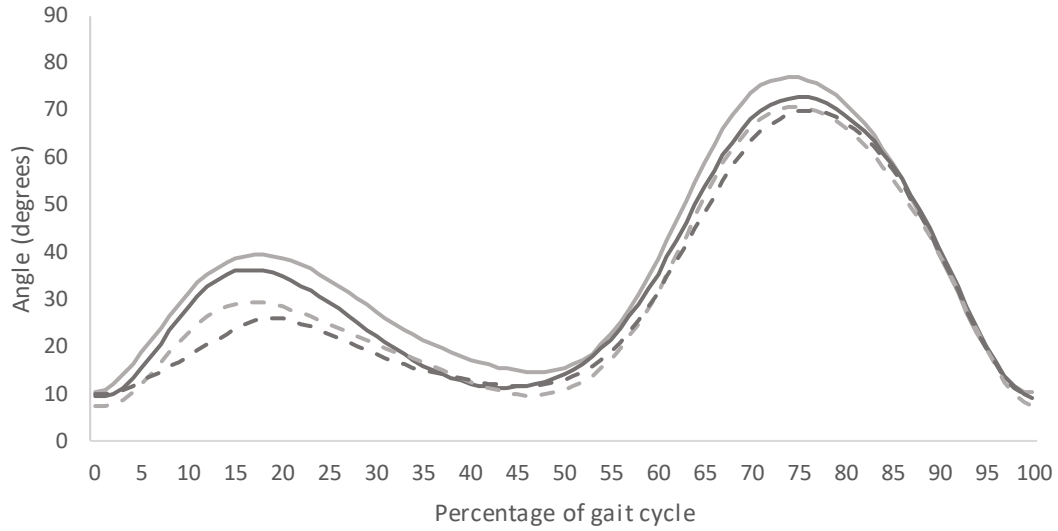
### *9.3.2.1. PiG*

The ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension angles calculated using the PiG model can be seen in Figure 9-5 and summary data can be found in Table 9-4.

a




b



c

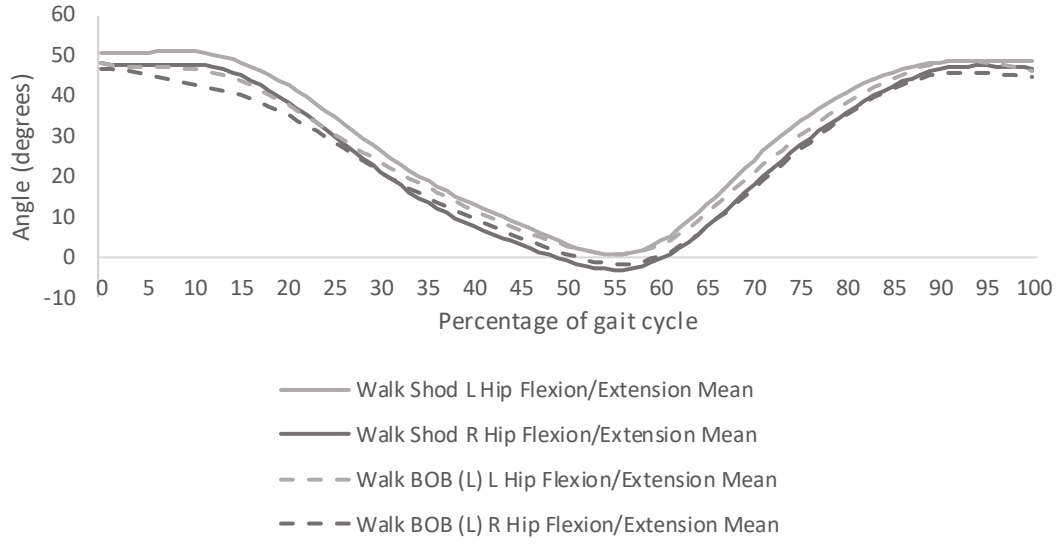



*Figure 9-5: PiG model. Mean of 10 trials Shod and BOB condition angles (a) ankle plantarflexion (-)/dorsiflexion (+) angles (b) knee flexion/extension angles (c) hip flexion/extension angles.*

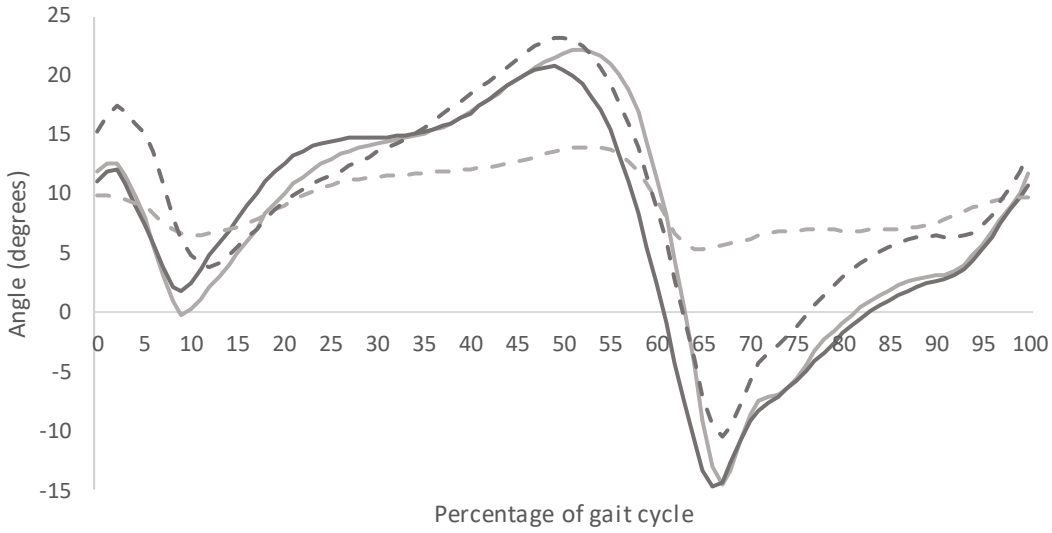
| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| | **Left** | **Right** | **Left** | **Right** |
| **Peak DF stance** | 22.71 (0.60) | 19.03 (1.02)$^{\S}$ | 16.97 (0.84)$^{*\#}$ | 21.14 (0.68)$^{\S\# *}$ |
| **Peak PF - initial swing** | -4.56 (1.26) | -10.22 (1.34)$^{\S\#}$ | 9.23 (0.83)$^{*\#}$ | -6.24 (0.83)$^{\S\# *}$ |
| **Ankle ROM** | 27.26 (1.26) | 29.25 (0.84)$^{\S}$ | 7.74 (0.73)$^{*\#}$ | 27.37 (1.03)$^{\S\#}$ |
| **Knee flex - initial contact** | 10.27 (0.72) | 9.36 (0.70) | 7.51 (1.14) | 10.05 (1.66) |
| **Peak knee flex - loading** | 46.63 (2.69) | 42.49 (3.25)$^{\S}$ | 39.23 (4.82)$^{*\#}$ | 37.93 (3.91) |
| **Peak knee ext - stance** | 10.25 (0.69) | 9.00 (0.70)$^{\S}$ | 6.40 (0.85)$^{*}$ | 9.25 (1.10)$^{\S}$ |
| **Peak knee flex - swing** | 77.03 (1.15) | 72.73 (0.97)$^{\S}$ | 70.78 (1.29)$^{*\#}$ | 70.03 (1.09)$^{*}$ |
| **Knee ROM** | 66.79 (0.46) | 63.73 (0.28)$^{\S\#}$ | 64.37 (0.44)$^{*}$ | 60.78 (-0.01)$^{\S\# *}$ |
| **Peak hip flex - stance** | 51.29 (3.11) | 48.47 (1.29) | 48.11 (1.48) | 46.70 (1.67) |
| **Peak hip ext - stance** | 0.68 (1.30) | -3.14 (1.06)$^{\S}$ | 0.52 (1.23) | -1.83 (0.71)$^{\S *}$ |
| **Peak hip flex - swing** | 49.07 (2.17) | 47.56 (0.83) | 48.92 (0.99) | 45.89 (1.35)$^{\S}$ |
| **Hip ROM - sagittal** | 48.38 (0.87) | 50.70 (-0.23) | 48.40 (-0.24) | 47.72 (0.64)$^{*}$ |

*Table 9-4: Summary of PiG model output for ankle, knee, and hip angles during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod $^{\S}$Right and left statistically different in same condition. $^{\#}$Difference above minimal detectable change. DF=dorsiflexion PF=plantarflexion RoM=range of movement ext=extension flex=flexion.*

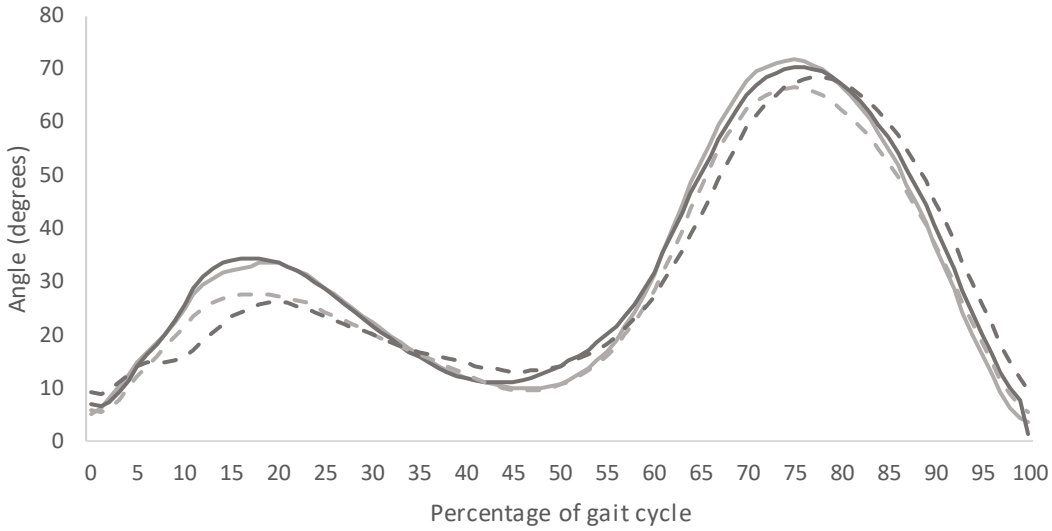
*9.3.2.2. pyCGM2.3*

The pyCGM2.3 model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension angles can be seen in Figure 9-6 and summary data can be found in Table 9-5.

a




b



c

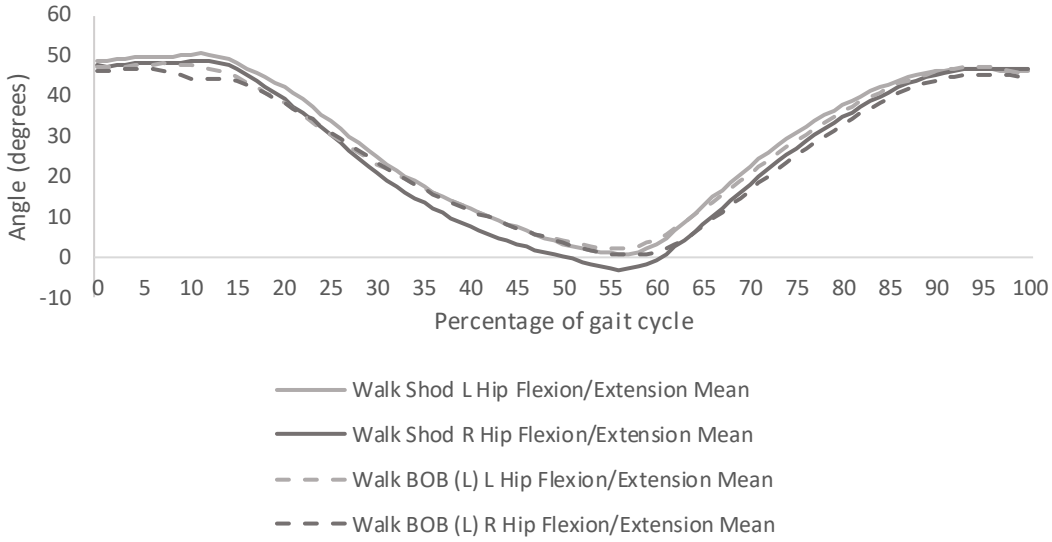



*Figure 9-6: pyCGM2.3 model. Mean of 10 trials Shod and BOB condition angles (a) ankle plantarflexion (-) /dorsiflexion (+) angles (b) knee flexion/extension angles (c) hip flexion/extension angles.*

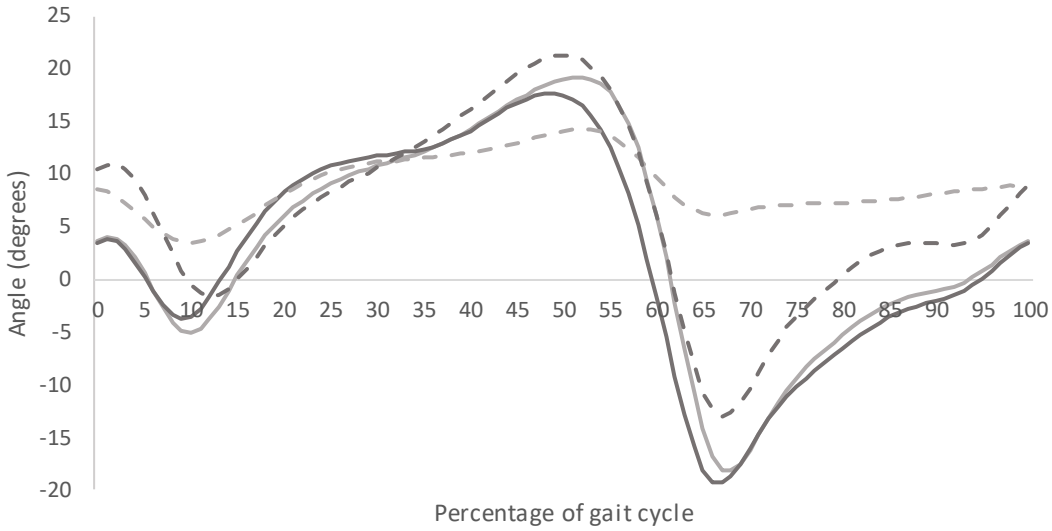
| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| | **Left** | **Right** | **Left** | **Right** |
| **Peak DF stance** | 22.20 (0.77) | 20.80 (1.19)[§] | 14.09 (0.89)[*#] | 23.30 (0.69)[§#*] |
| **Peak PF - initial swing** | -15.02 (1.14) | -15.12 (1.54) | 5.17 (0.76)[*#] | -11.16 (1.00)[§#*] |
| **Ankle ROM** | 37.22 (1.20) | 35.92 (1.26) | 8.92 (0.76)[*#] | 34.46 (1.05) [§#] |
| **Knee flex - initial contact** | 10.33 (3.37) | 9.19 (1.24) | 8.14 (0.90) | 11.34 (2.09)[§] |
| **Peak knee flex - loading** | 30.69 (3.76) | 32.52 (2.08) | 25.92 (2.61)[*] | 20.44 (1.69)[§*] |
| **Peak knee ext - stance** | 8.71 (1.44) | 9.02 (1.32) | 6.31 (1.12)[*] | 10.63 (1.35)[§] |
| **Peak knee flex - swing** | 71.70 (1.50) | 70.47 (0.97) | 66.65 (1.29)[*] | 68.64 (1.02)[§*] |
| **Knee ROM** | 62.98 (1.62) | 61.45 (1,78) | 60.34 (1.99) | 58.01 (1.61) [*] |
| **Peak hip flex - stance** | 50.87 (4.17) | 49.03 (1.86) | 48.11 (2.16) | 46.93 (1.78) |
| **Peak hip ext - stance** | 3.41 (1.47) | 0.20 (1.03)[§] | 4.09 (1.72) | 3.50 (0.72)[*] |
| **Peak hip flex - swing** | 46.85 (2.31) | 47.04 (1.50) | 47.37 (0.92) | 45.38 (1.43)[§] |
| **Hip ROM - sagittal** | 47.46 (4.07) | 48.83 (2.47) | 44.02 (3.39) | 43.43 (1.80)[*] |

*Table 9-5: Summary of pyCGM2.3 model output for ankle, knee, and hip angles during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod [§]Right and left statistically different in same condition. [#]Difference above minimal detectable change. DF=dorsiflexion PF=plantarflexion RoM=range of movement ext=extension flex=flexion.*

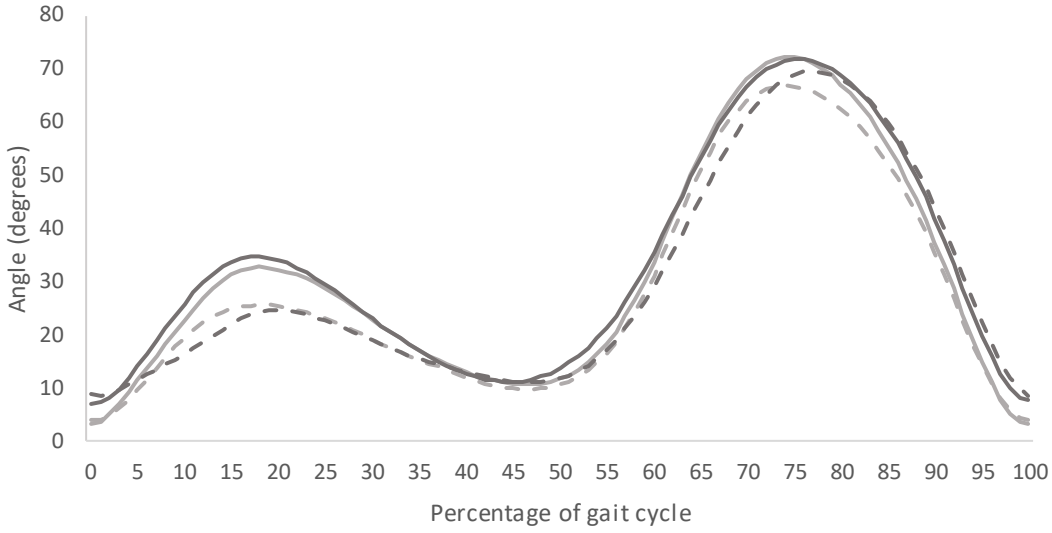
*9.3.2.3. Bodybuilder Imperial Model*

The BBImperial model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension angles can be seen in Figure 9-7 and summary data can be found in Table 9-6.

a




b



c

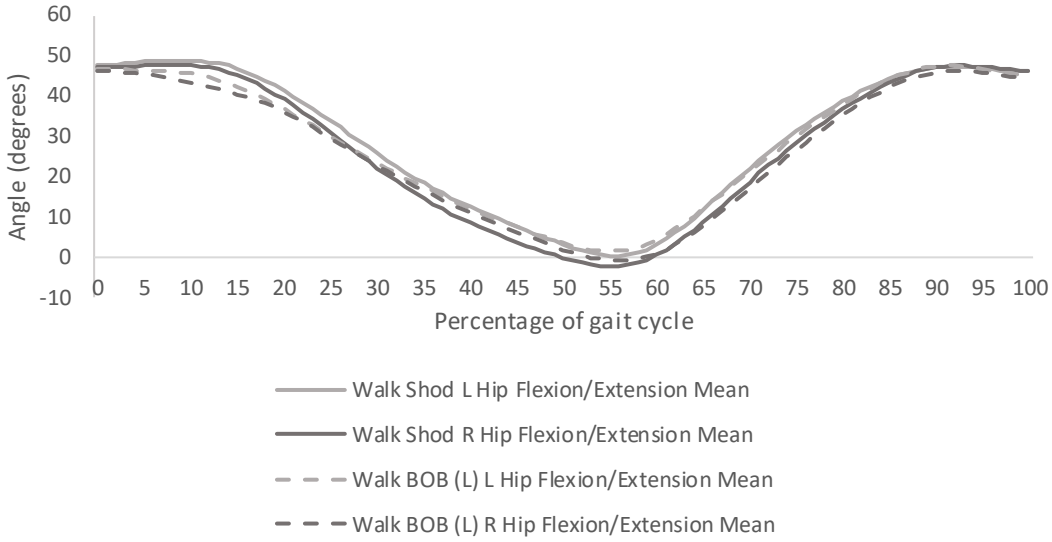



*Figure 9-7: Bodybuilder Imperial model. Mean of 10 trials Shod and BOB condition angles (a) ankle plantarflexion (-) /dorsiflexion (+) angles (b) knee flexion/extension angles (c) hip flexion/extension angles.*

| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| | **Left** | **Right** | **Left** | **Right** |
| **Peak DF stance** | 19.33 (0.98) | 17.60 (1.08)[§] | 14.26 (0.89)[*#] | 21.40 (0.56) [*§#] |
| **Peak PF - initial swing** | -18.74 (1.11) | -19.71 (1.59) | 6.06 (0.62) [*#] | -13.40 (1.15) [*# §#] |
| **Ankle ROM** | 38.07 (1.50) | 37.31 (1.48) | 8.20 (0.69) [*#] | 34.80 (0.92) [*§#] |
| **Knee flex - initial contact** | 6.94 (1.66) | 9.67 (1.01) [§] | 5.99 (0.90) | 10.15 (1.64) [§] |
| **Peak knee flex - loading** | 28.64 (2.86) | 31.30 (2.45) | 23.31 (2.57) | 19.59 (2.07) [*# §] |
| **Peak knee ext - stance** | 6.94 (1.66) | 9.49 (0.76) [§] | 5.77 (0.95) | 9.30 (1.27) [§] |
| **Peak knee flex - swing** | 72.14 (1.57) | 71.81 (0.94) | 67.05 (1.18) [*] | 69.65 (1.00) [*§] |
| **Knee ROM** | 65.20 (1.59) | 62.32 (1.34) [§] | 61.28 (1.63) [*#] | 60.35 (1.66) [§] |
| **Peak hip flex - stance** | 48.85 (3.53) | 47.85 (1.75) | 46.55 (1.84) | 45.84 (1.75) |
| **Peak hip ext - stance** | 3.10 (1.76) | -0.20 (0.98) [§] | 3.56 (2.02) | 1.88 (0.97) [*] |
| **Peak hip flex - swing** | 47.45 (2.30) | 47.52 (1.13) | 47.59 (0.88) | 46.29 (1.22) |
| **Hip ROM - sagittal** | 45.75 (2.78) | 48.05 (2.40) | 42.98 (3.34) | 43.96 (2.15) |

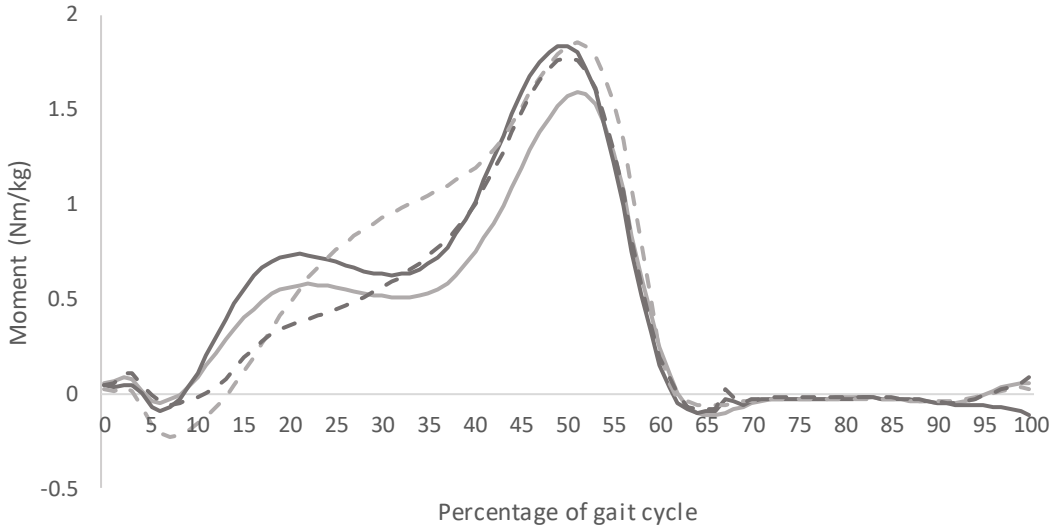
*Table 9-6: Summary of Bodybuilder Imperial model output for ankle, knee, and hip angles during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod [§]Right and left statistically different in same condition. [#]Difference above minimal detectable change. DF=dorsiflexion PF=plantarflexion RoM=range of movement ext=extension flex=flexion.*

## 9.3.3. Moment data

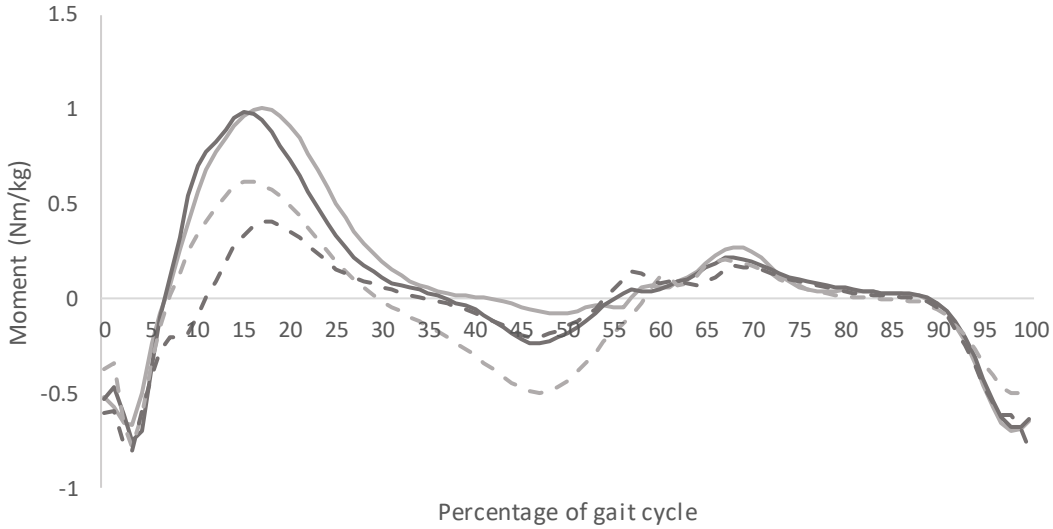
### *9.3.3.1. PiG*

The PiG model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension moment data can be seen in Figure 9-8 and summary data can be found in Table 9-7.

a




b



c

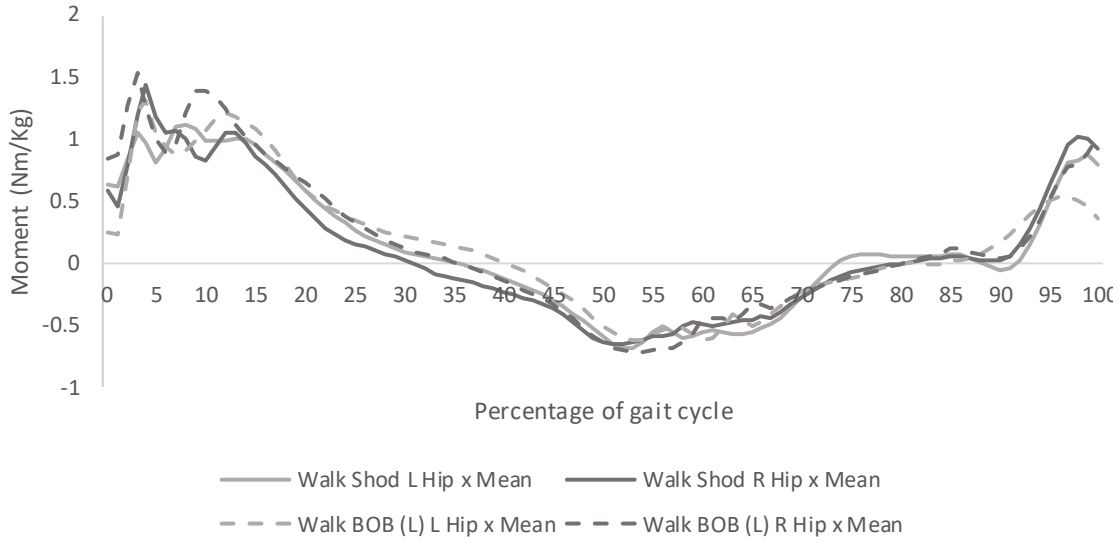



*Figure 9-8: PiG model. Mean 10 trials Shod and BOB condition internal joint moment (+ moment) with BOB data (a) ankle plantarflexion (+)/dorsiflexion (-) (b) knee flexion/extension (c) hip flexion/extension.*

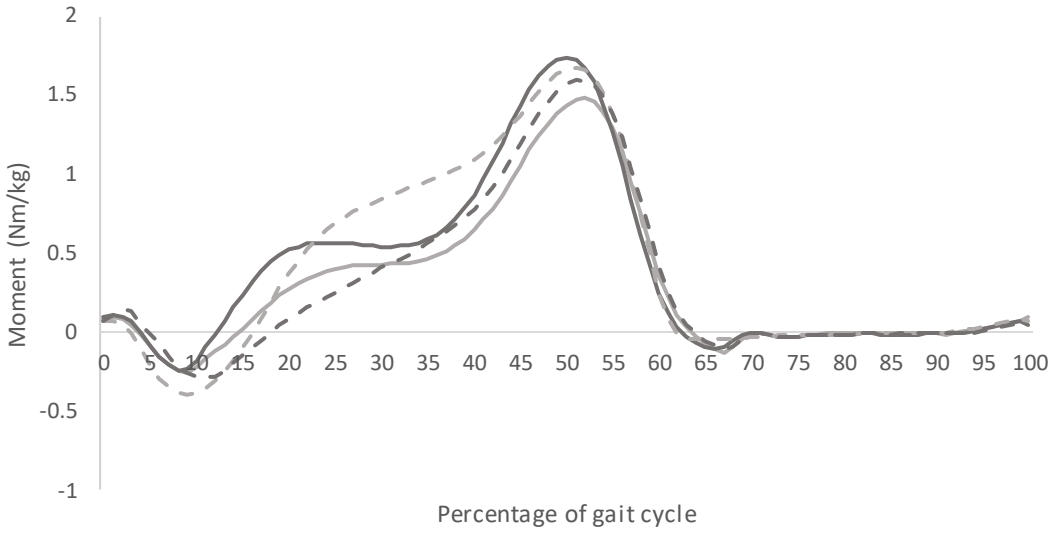
| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| *Moments (Nm/kg)* | **Left** | **Right** | **Left** | **Right** |
| **Peak DF - loading response** | -0.06 (0.04) | -0.10 (0.050) | -0.24 (0.03)$^{*\#}$ | -0.07 (0.01)$^{\S\#}$ |
| **Peak PF - terminal stance** | 1.62 (0.16) | 1.85 (0.12) | 1.02 (0.94) | 1.78 (0.07) |
| **Peak knee ext - loading response** | 1.02 (0.16) | 1.01 (0.14) | 0.62 (0.08)$^{*\#}$ | 0.42 (0.11)$^{*\#}$ |
| **Peak knee flex - terminal stance** | -0.70 (0.10) | -0.86 (0.09)$^{\S\#}$ | -0.90 (0.16) | -0.89 (0.11) |
| **Peak hip ext - stance** | 1.23 (0.11) | 1.53 (0.21)$^{\S\#}$ | 1.56 (0.25) | 1.60 (0.23) |
| **Peak hip flex - terminal stance** | -0.58 (0.05) | -0.52 (0.11) | -0.62 (0.16) | -0.54 (0.08) |

*Table 9-7: Summary of PiG model output for ankle, knee, and hip internal joint moments (+ moment with BOB) during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod $^{\S}$Right and left statistically different in same condition. $^{\#}$Difference above minimal detectable change. DF=dorsiflexion PF=plantarflexion ext=extension flex=flexion.*

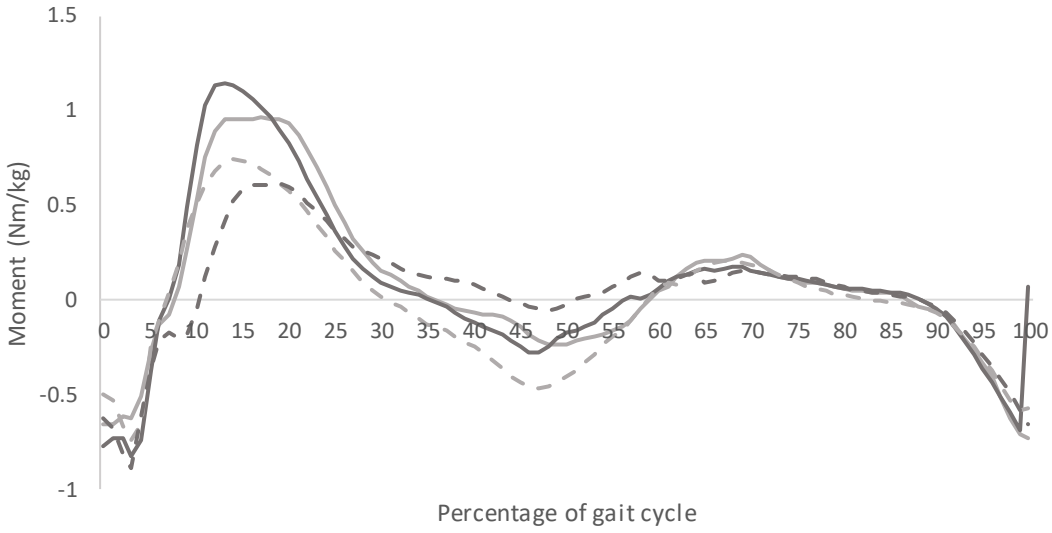
*9.3.3.2. pyCGM2.3*

The pyCGM2.3 model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension moment data can be seen in Figure 9-9 and summary data can be found in Table 9-8.

a




b



c

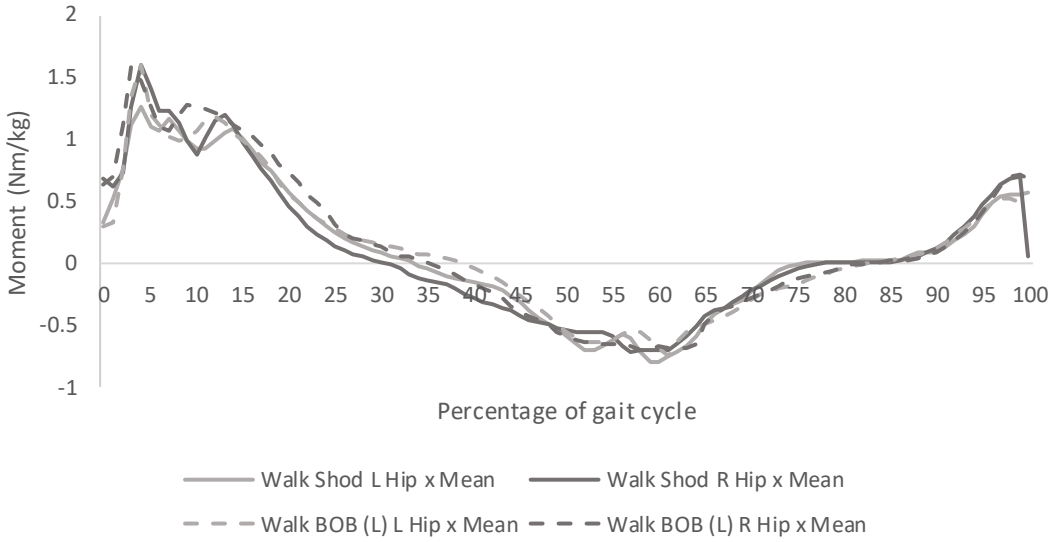



*Figure 9-9: pyCGM2.3 model. Mean 10 trials Shod and BOB condition internal joint moment data (+ moment) (a) ankle plantarflexion/dorsiflexion (b) knee flexion/extension (c) hip flexion/extension.*

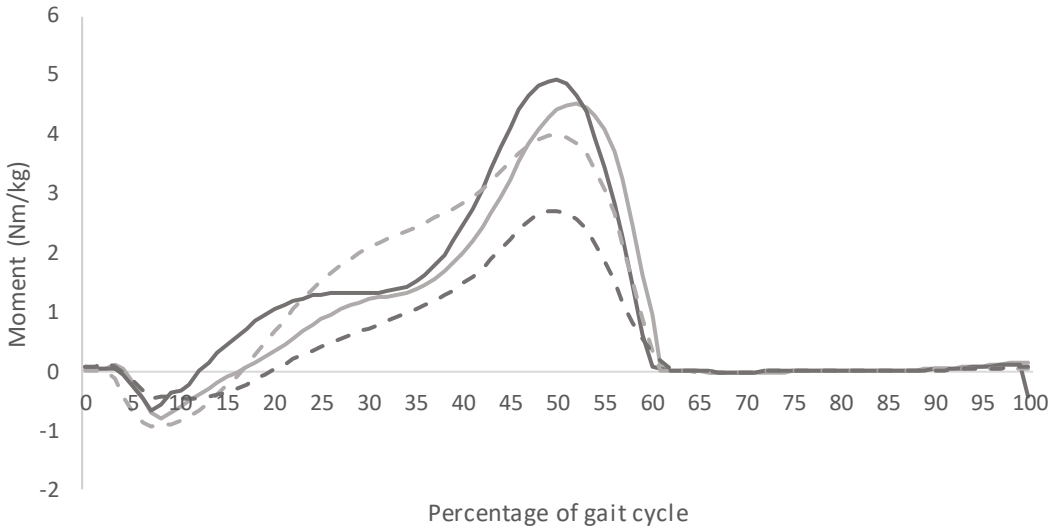
| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| *Moments (Nm/kg)* | **Left** | **Right** | **Left** | **Right** |
| **Peak DF - loading response** | -0.26 (0.08) | -0.26 (0.09) | -0.42 (0.05)$^{*\#}$ | -0.30 (0.03)$^{\S\#}$ |
| **Peak PF - terminal stance** | 1.49 (0.07) | 1.74 (0.11)$^{\S\#}$ | 1.70 (0.09)$^{*\#}$ | 1.60 (0.05)$^{\S}$ |
| **Peak knee ext - loading response** | 0.99 (0.15) | 1.15 (0.15) | 0.76 (0.08) | 0.63 (0.10)$^{*\#}$ |
| **Peak knee flex - terminal stance** | -0.26 (0.07) | -0.29 (0.09) | -0.47 (0.11)$^{*\#}$ | -0.07 (0.04)$^{\S\# *\#}$ |
| **Peak hip ext - stance** | 1.37 (0.12) | 1.67 (0.25) | 1.78 (0.37) | 1.66 (0.26) |
| **Peak hip flex - terminal stance** | -0.84 (0.07) | -0.74 (0.10) | -0.75 (0.10) | -0.73 (0.06) |

*Table 9-8: Summary of pyCGM2.3 model output for ankle, knee, and hip internal joint moments (+ moment) during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod $^{\S}$Right and left statistically different in same condition. $^{\#}$Difference above minimal detectable change. DF=dorsiflexion PF=plantarflexion ext=extension flex=flexion.*

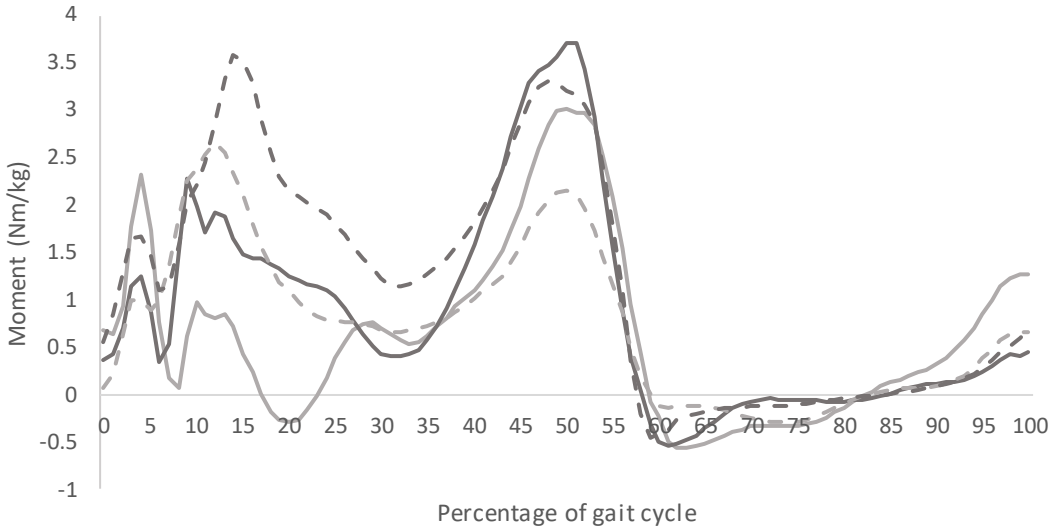
*9.3.3.3. Bodybuilder Imperial model*

The BBImperial model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension moment data can be seen in Figure 9-10 and summary data can be found in Table 9-9. The BBImperial model calculates moments for the stance phase only.

a




b



c

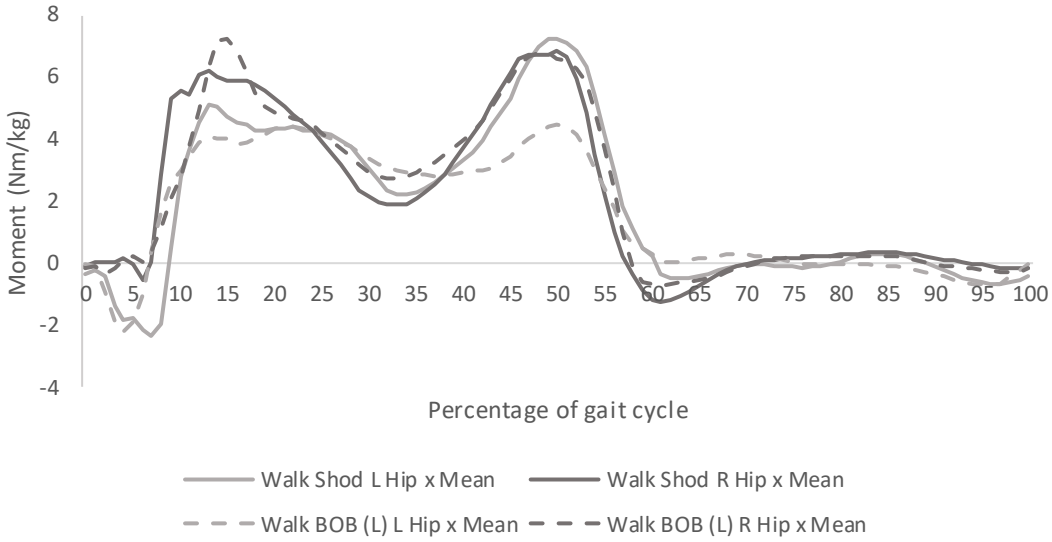



*Figure 9-10: Bodybuilder Imperial model. Mean 10 trials Shod and BOB condition internal joint moment (+ moment) data (a) ankle plantarflexion/dorsiflexion (b) knee flexion/extension (c) hip flexion/extension.*

| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| *Moments (Nm/kg)* | **Left** | **Right** | **Left** | **Right** |
| **Peak DF - loading response** | -0.80 (0.15) | -0.70 (0.15) | -0.99 (0.21) | -0.51 (0.11) §# |
| **Peak PF - terminal stance** | 4.53 (0.12) | 4.93 (0.24) §# | 4.04 (0.30) | 2.78 (0.52) §# *# |
| **Peak knee ext - loading response** | 2.49 (0.55) | 2.55 (0.37) | 2.84 (0.32) | 3.66 (0.47) §# *# |
| **Peak knee flex - terminal stance** | -0.72 (0.27) | -0.51 (0.20) | -0.16 (0.12) *# | -0.64 (0.50) |
| **Peak hip ext - stance** | 7.34 (0.20) | 7.04 (0.50) | 5.06 (0.64) *# | 7.57 (0.74) §# |
| **Peak hip flex - terminal stance** | 0.14 (0.71) | -1.20 (0.45) §# | 0.27 (0.38) | -1.04 (0.92) §# |

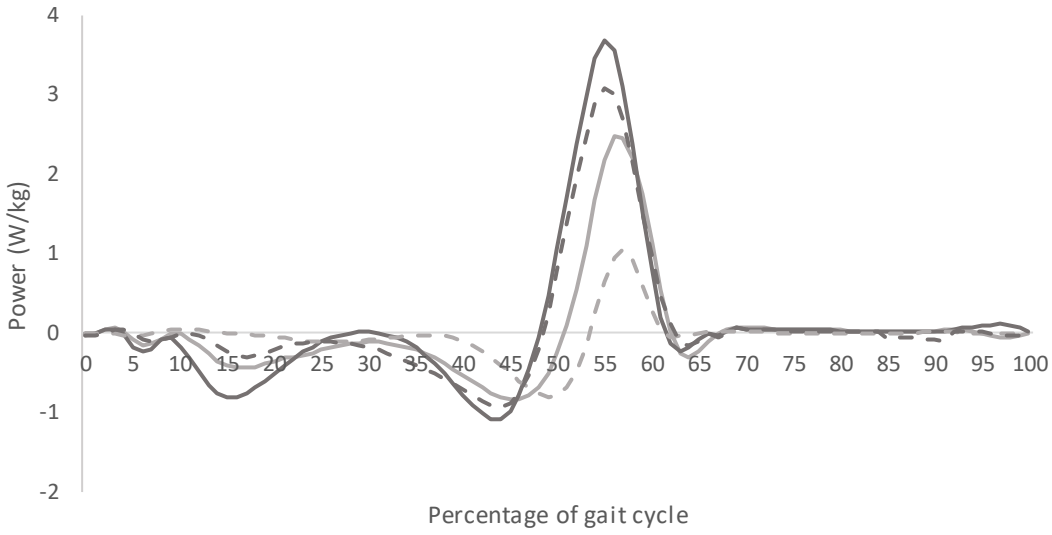
*Table 9-9: Summary of Bodybuilder Imperial model output for ankle, knee, and hip internal joint moments during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod §Right and left statistically different in same condition. #Difference above minimal detectable change. DF=dorsiflexion PF=plantarflexion ext=extension flex=flexion.*

## 9.3.4. Power

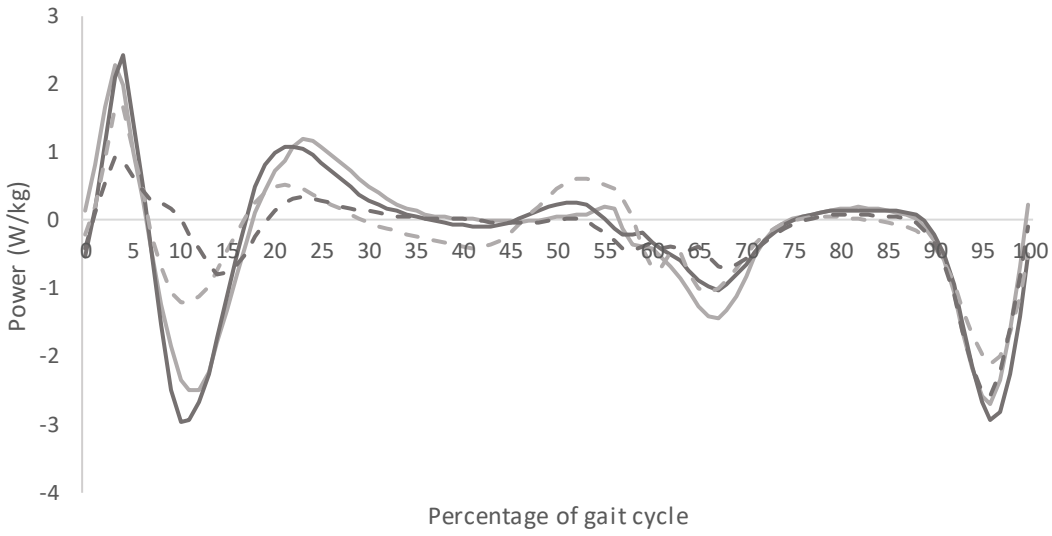
### *9.3.4.1. PiG*

The PiG model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension power data can be seen in Figure 9-11 and summary data can be found in Table 9-10.

a




b



c

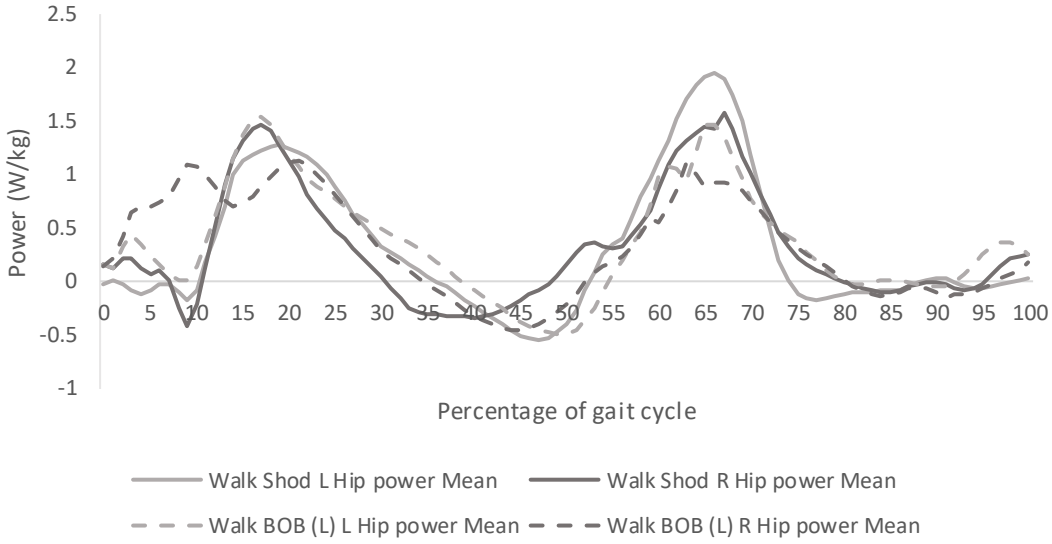



*Figure 9-11: PiG model. Mean 10 trials Shod and BOB condition joint power data (a) ankle plantarflexion/dorsiflexion (b) knee flexion/extension (c) hip flexion/extension.*

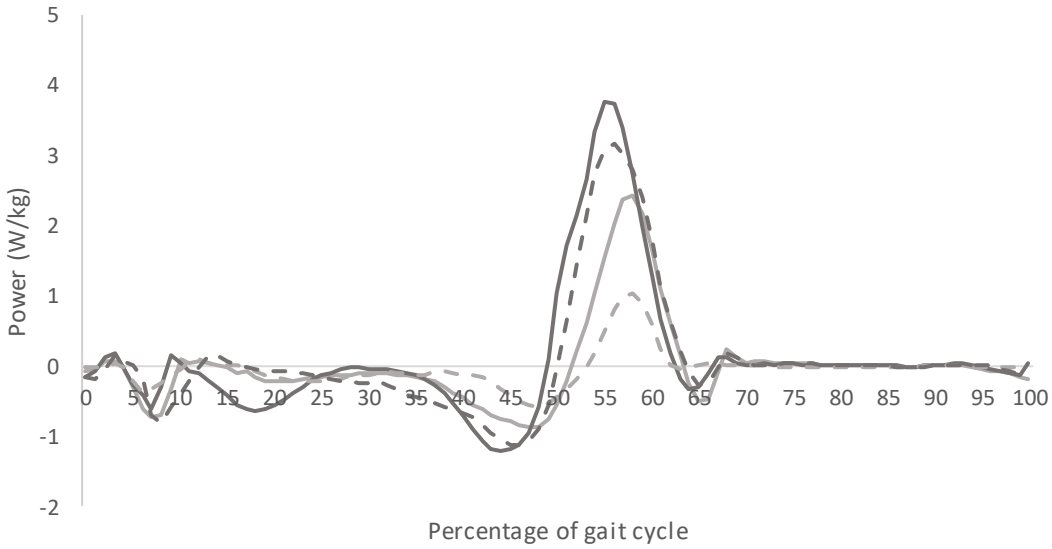
| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| W/kg | **Left** | **Right** | **Left** | **Right** |
| **Ankle abs - loading response** | -0.49 (0.17) | -0.83 (0.15)$^{\S}$ | -0.06 (0.03)$^{*}$ | -0.31 (0.12)$^{\S *}$ |
| **Ankle abs - terminal stance** | -0.93 (0.13) | -1.15 (0.14) | -0.78 (0.11) | -0.96 (0.10)$^{\S}$ |
| **Peak ankle gen - pre-swing** | 2.70 (0.53) | 3.76 (0.45)$^{\S}$ | 1.12 (0.23)$^{*}$ | 3.18 (0.30)$^{\S}$ |
| **Peak knee gen - early mid stance** | 2.36 (0.22) | 2.66 (0.52) | 1.90 (0.37) | 1.14 (0.33)$^{\S *}$ |
| **Peak hip gen - loading response** | 1.33 (0.20) | 1.49 (0.32) | 1.60 (0.23) | 1.27 (0.23) |
| **Peak hip abs - terminal stance** | -0.58 (0.20) | -0.38 (0.08) | -0.54 (0.09) | -0.49 (0.04) |

*Table 9-10: Summary of PiG model output for ankle, knee, and hip power data during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod $^{\S}$Right and left statistically different in same condition. Abs=absorption gen=generation.*

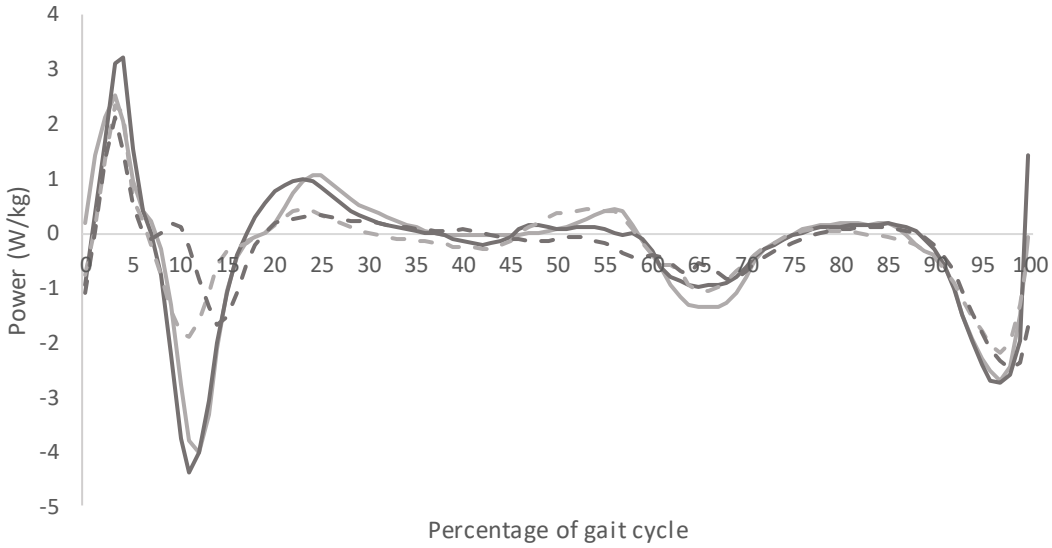
*9.3.4.2. pyCGM2.3*

The pyCGM2.3 model ankle dorsiflexion/plantarflexion, knee flexion/extension, and hip flexion/extension power data can be seen in Figure 9-12 and summary data can be found in Table 9-11.

a




b



c

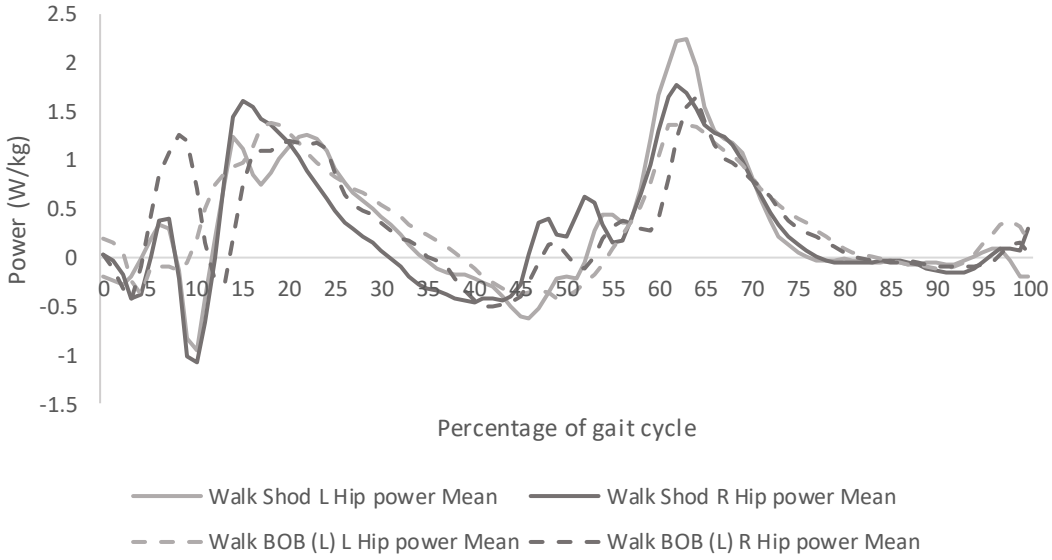



*Figure 9-12: pyCGM2.3 model Mean 10 trials Shod and BOB condition joint power data (a) ankle plantarflexion/dorsiflexion (b) knee flexion/extension (c) hip flexion/extension.*

| | **Walk Shod** | | **Walk BOB (L)** | |
|---|---|---|---|---|
| W/kg | **Left** | **Right** | **Left** | **Right** |
| **Ankle abs - loading response** | -0.95 (0.42) | -0.86 (0.12) | -0.39 (0.14) | -1.00 (0.25)§ |
| **Ankle abs - terminal stance** | -0.94 (0.13) | -1.26 (0.12)§ | -0.61 (0.26) | -1.16 (0.13)§ |
| **Peak ankle gen - pre-swing** | 2.57 (0.13) | 3.83 (0.39)§ | 1.10 (0.20)* | 3.26 (0.25)§ |
| **Peak knee gen - early mid stance** | 2.93 (0.44) | 3.61 (0.65) | 3.13 (0.81) | 2.27 (0.35)* |
| **Peak hip gen - loading response** | 1.46 (0.31) | 1.67 (0.33) | 1.48 (0.27) | 1.52 (0.30) |
| **Peak hip abs - terminal stance** | -0.62 (0.17) | -0.53 (0.07) | -0.53 (0.09) | -0.56 (0.11) |

*Table 9-11: Summary of pyCGM2.3 model output for ankle, knee, and hip power data during the gait cycle in both Shod and BOB conditions. *BOB condition statistically different to Shod §Right and left statistically different in same condition. Abs=absorption gen=generation.*

## 9.4. Discussion

### 9.4.1. Biomechanical model selection

One of the aims of this study was to analyse three biomechanical models and assess which should be used to provide results for spatiotemporal, angle, moment, and power data for the historic gait data to be presented in the next Chapter.

*9.4.1.1. Spatiotemporal data*

Comparing the PiG and pyCGM2.3 models, there were no statistically significant differences found in the shod condition for either models. This is to be expected as statistically significant differences would imply asymmetry of gait which should not be found for a healthy individual with no underlying pathology. Although in the BOB condition more parameters were shown to be statistically significantly different using the pyCGM2.3 model than the PiG model, it is not possible to use the BOB condition to select a model, as symmetry may not be expected. Therefore, the model chosen for spatiotemporal data will be decided based on which model is chosen for angles or moment or power data.

*9.4.1.2. Angle data*

Using the PiG model, the ankle initial contact angle is between 10 and 15$^{o}$ dorsiflexion (14.0 ± 0.8$^{o}$ Left Shod, 10.4 ± 1.2$^{o}$ Right Shod). Reference data suggests initial contact in non-pathological gait should be between 5$^{o}$ of plantarflexion (-5$^{o}$) and 5$^{o}$ of dorsiflexion (Jacquelin Perry, 1992). A small degree of plantarflexion calculated at swing is also found (-4.7$^{o}$ Left shod and -10.2$^{o}$ Right shod). Reference data suggests this should be between -10$^{o}$ and -20$^{o}$. The range of movement (RoM) calculated by PiG is not however different from published normal data due to the larger dorsiflexion angle at initial contact. Ankle RoM is reported in the literature to be 19.4 – 28$^{o}$ in keeping with the 27 – 29$^{o}$ found with this model (J Perry, 1992). Examining the shod condition, statistically significant differences are found between the left and right for peak dorsiflexion during stance and range of movement, as well peak plantar flexion with the difference above minimal detectable change values.

The initial contact angles are above the reference values of -5 to 5$^{o}$ for the pyCGM2.3 model (11.8 ± 1.6$^{o}$ Left Shod, 11.0 ± 1.1$^{o}$ Right Shod). The RoM is also greater than reference data (34-37$^{o}$ compared to 27-29$^{o}$). Statistically significant differences are found in the reported peak dorsiflexion at stance between the left and right side in the shod condition. The initial contact angle for the ankle in the Shod condition for the BBImperial model is similar to published reference data. In the BBImperial model the initial contact angle is 3.44 ± 1.32$^{o}$ on the left and 3.39 ± 0.86$^{o}$ on the right. This is consistent with the -5 to 5$^{o}$ reported in the

literature (Kadaba, 1990; Jacquelin Perry, 1992). The RoM at the ankle is larger than reported reference values and a statistically significant difference is found in the shod condition of the peak dorsiflexion angle.

Both the pyCGM2.3 and BBImperial models demonstrate one statistically significant difference in the shod condition. Additionally, the BBImperial model demonstrates initial contact angle data in keeping with published reference data therefore the BBImperial model will be used to process joint angles in future studies. The initial contact angle for the PiG and pyCGM2.3 models were higher than the reference data and both appeared higher than the visually measured angle found from the videos of gait of approximately 5$^{o}$. The standard deviation is small implying the results are consistent. This may be due to placement of the thigh and tibia markers which must be placed centrally on the lateral aspect of the limb with reference to the anterior and posterior aspect of the leg, as these are used to calculate knee and ankle angles. It is theorised the higher calculated initial contact results are because of errors compounded distally due to the placement of the thigh and tibia markers and open chain set up of these models. The use of a different marker set and calculation method in the BBImperial model is likely to explain the normal initial contact angle compared to the other two models and the reduction in the number of statistically significant differences of dependent measures in the shod condition. Despite the efforts of the pyCGM2.3 to overcome compounded errors due to the open chain model design these were still found in this study (Leboeuf, 2019).

#### *9.4.1.3. Moment data*

The PiG model does not demonstrate statistically significant differences for either of the ankle measurements presented in dorsiflexion and plantarflexion in the shod condition. This is likely due to the normal ankle RoM when compared to reference data as the moment, and then power data, are calculated from the change in angle (this is explained in more detail in Proximal joints). The pyCGM2.3 model demonstrates statistically significant differences at one of the ankle measurements above minimal detectable change levels in the shod condition, whilst the BBImperial model also shows statistically significant differences in the shod condition at the same ankle measurement. The PiG model demonstrates the least

number of statistically significant differences at the ankle for moment data in the shod condition, therefore in future Chapters, the PiG model will be used to calculate moment data.

#### *9.4.1.4. Power data*

The PiG derived power data demonstrates statistically significant differences at two of the three measurements used, ankle power absorption during loading response, and peak ankle power generation at pre-swing in the shod condition. Neither of these differences are above minimal detectable change values. The pyCGM2.3 also demonstrates statistically significant differences at two of the three reported measurements for ankle power in the shod condition, at ankle power absorption at terminal stance and peak ankle generation of power at pre-swing. Again, neither of these differences are above minimal detectable change values. Both models demonstrate statistically significant differences at two of the three measured power parameters. As the PiG model is being used to calculate moment data, and the power data is dependent on the moment data calculations, the PiG model will also be used to calculate power data. Furthermore, as spatiotemporal gait data is a product of the PiG model when used to calculate moment and power data, the PiG model will also be used to obtain spatiotemporal data.

In summary, the results show that the PiG model should be used to calculate the gait cycle spatiotemporal parameters, moment data, and power data demonstrating the least statistically differences between the right and left in the shod condition. For angle data, the BBImperial model should be used.

### 9.4.2. BOB induced gait changes at the foot and ankle

The study presented in this Chapter set out to compare the gait of the same individual in and out of the BOB to assess BOB induced gait changes at the foot and ankle and proximal joints. This is the first study to assess gait in and out of the BOB for the same individual, all other studies assess the gait of the limb in the IDEO compared to the contralateral limb, or to controls (Russell Esposito, 2014, 2017). Walking speed and cadence were found to be statistically slower in the BOB condition than the shod condition. The speed reported of 1.5 m/s is the same as found for patients using the IDEO after the return to run clinical

programme (Potter, 2018). The addition of the BOB reduced walking speed in the healthy individual. This is contrary to published literature looking at the IDEO which has found no difference in walking speed during gait studies between IDEO wearers and controls, and improvements in functional outcomes in the form of self-selected walking velocity with the addition of the IDEO (Russell Esposito, 2017; Potter, 2018). The reduction in speed is likely due to the healthy volunteer not requiring the BOB and not being trained in its use over a prolonged period. Although every effort was made for the wearer to become accustomed with use, he had not undergone a rehabilitation package with the BOB and therefore had no formal training.

Of note, mean walking speed in both the shod and BOB conditions (1.5 m/s – 1.7 m/s) is faster than the literature-reported average healthy individual self-selected walking velocity (1.2 m/s) (Jacquelin Perry, 1992). The individual was asked to walk at a comfortable pace without direction or guidance. His walking pace was higher than standard walking speed. Wilken et al (Wilken, 2012) who looked at minimal detectable change values for gait also report a higher self-selected walking velocity of 1.31 m/s (SD 0.17 m/s) in healthy adults than Perry's reported walking speed of 1.2 m/s but it is slower than the 1.7 m/s (SD 0.1 m/s) seen here. With increasing walking speed, increased differences are seen in the gait with regards to joint angle, moment, and power (Wilken, 2012; Schreiber, 2018). It is therefore important to try to compare, as far as possible, data recorded at similar walking speeds. The minimal detectable change data for gait is available in 4 different walking speeds, therefore data was compared to the closest walking speed (Wilken, 2012). This will also be required in future studies. Cadence, walking speed, stride time, and step time, demonstrated the most consistent differences between the shod and BOB condition, therefore these spatiotemporal gait parameters will be reported in the next Chapter.

A reduction in ankle RoM has been reported in the literature for individuals wearing the IDEO compared to the contralateral limb and to controls (Russell Esposito, 2014, 2017). Examining the ankle angle data in the BOB, it is evident that once wearing the BOB, almost all variability in the sagittal plane at the ankle is lost. The RoM is reduced to 7.74$^{o}$ for the PiG model, 8.9$^{o}$ for the pyCGM2.3 model, and 8.2$^{o}$ for the BBImperial model. This is less than the published literature looking at ankle RoM in the IDEO reported between 11.9$^{o}$ in a stiff IDEO and 13.38$^{o}$

in a compliant IDEO (Russell Esposito, 2014). The stiffness of the IDEO/BOB impacts the possible degree of RoM at the ankle during walking. The different fabrication methods of the IDEO and BOB may result in stiffness differences between the IDEO and BOB. This would explain the differences in RoM seen between this study and gait studies examining the IDEO. Although decreased compared to the literature, the RoM results add to the literature demonstrating a statistical reduction in ankle RoM when wearing the IDEO/BOB compared to the contralateral limb, controls, and now with this study, the same limb in and out of the BOB (Russell Esposito, 2014, 2017). All reported ankle-dependent angles were statistically less in the BOB compared to the same limb out of the BOB. It has still not been established what impact the ankle angle changes have on the outcome with the IDEO/BOB; further studies examining gait in and out of the BOB for pathological populations are required to assess the impact of these gait changes on function.

When considering the use of gait in the creation of a clinical decision tool, ankle angles out of the BOB are more likely to demonstrate variability compared to in the BOB, as when in the BOB the limb is supported at a fixed angle with little RoM. Additionally, the aim of the thesis is the creation of a clinical decision tool to decide who will benefit from prescription of the BOB. This will be used prior to prescription, therefore biomechanical indications for use out of the BOB are required. In order to find these, gait parameters prior to prescription for patients with known outcomes will be examined in the next Chapter.

The plantarflexion moment data at the ankle is not statistically different in the PiG model across the two conditions. This is consistent with the literature looking at the IDEO compared to the contralateral limb and to controls (Russell Esposito, 2014, 2017). Also consistent with the literature, in the BOB condition, the limb wearing the BOB has a statistically significantly increased (more negative) internal joint moment, above minimal detectable change values, compared to the same limb in the shod condition, and to the contralateral limb in the BOB condition. This can be explained by the method used to calculate the moment data. The RoM at the ankle joint has been shown to be reduced in the BOB-wearing limb compared to the same limb in the shod condition and to the contralateral limb in the BOB condition. Due to the smaller RoM, the rate of change of ankle angle throughout the gait cycle is also less. This is equal to the angular velocity and is calculated by differentiation of the ankle angle with

respect to time (Equation 1). The angular velocity, $\omega$, (the rotational speed at which the foot dorsiflexes or plantar flexes) (Equation 1), is given by the change in the ankle angle, $d\theta$, over the change in time, $dt$. The angular acceleration, $a$, experienced by the ankle joint is given by the rate of change of angular velocity throughout the gait cycle. This is found by differentiating the angular velocity of the angle with respect to time, where $\alpha$ is the angular acceleration (Equation 2).

$$\frac{d\theta}{dt} = \omega$$

*Equation 1: angular velocity.*

$$\frac{d^2\theta}{dt^2} = \frac{d\omega}{dt} = \alpha$$

*Equation 2: angular acceleration.*

The total moment, $M_T$, experienced by the ankle joint is then given by Equation 3, where *I* is the moment of inertia which is dependent on the lengths and predicted masses of the joint segments entered into the model. This total moment is formed from several moments acting about this joint, as seen in Equation 4; the total ankle moment, $M_{total}$, is the sum of the moments from the joint reaction moment from the tibia $M_{JRM}$, the external ground reaction moment that is acting on the foot, $M_{GRM(acting\ on\ foot)}$, and the internal joint moment from muscles and ligaments, $M_{IJM}$.

$$M_T = I\alpha$$

*Equation 3: Total moment.*

$$M_T = M_{JRM} + M_{GRM(acting\ on\ foot)} + M_{IJM}$$

*Equation 4: Total ankle moment.*

During gait, the interest is in the internal joint moment (and the implication this has on the work done by muscles). This is the moment that is calculated by the biomechanical models, by rearranging Equation 4 to give Equation 5. The joint reaction moment, $M_{JRM}$ is calculated

using segmental velocities, and the external ground reaction moment, $M_{GRM(acting\ on\ foot)}$, from the force plates.

$$M_{IJM} = M_T - M_{JRM} + M_{GRM(acting\ on\ foot)}$$

*Equation 5: Internal joint moment from muscles and ligaments.*

PiG calculates $M_{IJM}$, however $M_{GRM}$ acts on both the BOB and the lower limb (so is $M_{GRM(acting\ on\ foot\ and\ BOB)}$). Therefore, it is not possible to calculate $M_{IJM}$ with the addition of the BOB; instead, it is only possible to calculate the sum of internal joint moment plus that within the BOB, $M_{IJM} + M_{IB}$ , as shown in Equation 6.

$$M_{IJM} + M_{IB} = M_T - M_{JRM} + M_{GRM(acting\ on\ foot)}$$

*Equation 6: The internal joint moment of the ankle with the addition of the BOB.*

Smaller (more negative) moment values are therefore likely to be due to the lower angular acceleration as this reduces the total moment and therefore reduces the internal joint moment that is calculated. It is not possible to say what proportion of the value calculated for the internal joint moment is from the moment within the BOB, and what the actual internal joint moment generated from the muscles is. To directly ascertain the contribution of the BOB to the moment, further work is required to characterise the BOB; this will require instrumenting the BOB and using invasive muscular measurements to accurately quantify each components contribution. Additionally, as with the changes in ankle RoM, it is not possible from this study to conclude what impact the changes in ankle moment with the BOB have on functional outcomes. To understand the association between moment changes and the clinical outcome, gait assessment of pathological patient populations in and out of the BOB are required in a cohort with known outcomes with the BOB.

Consistent with literature looking at power data comparing the IDEO limb to the contralateral limb and to controls, this study has found a reduction in power generation at the ankle during pre-swing in the limb wearing the BOB compared to the contralateral limb and to the shod condition (Russell Esposito, 2014, 2017). This also agrees with studies looking at other types

of ‘spring-like’ orthoses where up to a 63% reduction in power generation has been reported in the literature, believed to be due to the limited ability of the individual to deform the IDEO during walking (Bregman, 2012; Russell Esposito, 2017). The reported power data is intrinsically linked to the internal joint moment and angular velocity. The equation used to calculate power during normal gait is given in Equation 7, with power, P, equal to the internal joint moment, $M_{IJM}$, multiplied by the angular velocity at that joint, $\omega$.

$$P = M_{IJM} \cdot \omega$$

*Equation 7: Power.*

As mentioned, when wearing the BOB, it is not possible to calculate $M_{IJM}$ therefore the power calculation in the BOB condition is given by Equation 8 , where the equivalent moment, $M_{eq}$, is equal to the sum of the internal joint moment and the moment within the BOB: $M_{eq} = M_{IJM} + M_{IB}$.

$$P = M_{eq} \cdot \omega$$

*Equation 8: Power calculation in the BOB condition.*

As with the moment data, a decrease in angular acceleration seen in the BOB condition, results in a decrease in power output. Therefore, the power absorption and generation will decrease as a result of wearing the BOB, although only the power generation was found to be statistically significant. Again, the impact on functional outcome cannot be concluded from this study and larger studies of IDEO/BOB wearing populations with instrumented orthoses and gait analysis in and out of the orthosis, are required to draw conclusions.

To assess the gait of pathological populations prior to prescription of the BOB, the ankle angles will be assessed. As the moment and power data are intrinsically linked, and in keeping with reported literature concerning IDEO wearing populations, the power dependent measures demonstrating statistically significant differences between the BOB and shod condition, will also be analysed. Additionally, for the development of the clinical decision tool, angles and power are both dependent measures that are widely understood by clinicians and can easily be explained to patients.

### 9.4.3. Proximal joints

A further aim of this Chapter was to examine the effect of the BOB on the proximal joints of the lower limb. The right side, not wearing the BOB in the BOB condition, demonstrates changes in angles at the ankle which are statistically significant and above minimal detectable change values, when compared to the right side in the shod condition. This is true for all models used to process the data. The literature has demonstrated a reduction in plantarflexion in early stance in the unaffected limb when wearing the IDEO compared to controls, but differences of the other measures have not previously been shown (Russell Esposito, 2017). This study has used a healthy individual who does not usually wear the BOB and has not gone through a formalised rehabilitation regime wearing the BOB. Differences in the contralateral limb may be due to induced gait deviations due to the lack of experience and formalised training. Previous studies have not shown a difference in the contralateral limb compared to controls, however there are no other studies looking at gait in and out of the BOB for the same individual that would allow direct comparisons.

Examining the knee-joint data, the flexion angle at initial contact is not different between the BOB and shod conditions. Russell Esposito et al have previously noted a statistical difference between the IDEO-wearing limb knee flexion at initial contact compared to controls, and found the contralateral limb also different to controls (Russell Esposito, 2017). This has not been shown here for the same individual in and out of the BOB. The peak knee flexion during loading and peak knee extension in stance are noted to be different between BOB and shod conditions, but not above minimal detectable change values for the BBImperial model. The knee RoM is noted to be reduced between the BOB and shod conditions, particularly on the side wearing the BOB. This is consistent with the literature, demonstrating a reduction in knee RoM in the IDEO-wearing limb compared to the contralateral limb and compared to controls (Russell Esposito, 2017). Changes in the knee RoM are likely due to the contact of the proximal cuff of the BOB on the posterior aspect of the thigh triggering early extension of the knee. Additionally, the stiffness of the IDEO has been shown to alter the amount of knee flexion required, with a stiffer IDEO requiring more knee flexion and a compliant IDEO requiring less to maintain overall limb stiffness (Russell Esposito, 2014). As previously stated, it is not possible to compare the stiffness of the BOB used in this study with the literature as

manufacturing processes are different, potentially leading to differences in stiffness. Previous studies have highlighted a difference in the hip-joint angles for both the IDEO-wearing limb and the contralateral limb compared to controls (Russell Esposito, 2017). This has not been shown in this study for the same individual in and out of the BOB where differences are not above minimal detectable change values.

With the exception of moment data for knee extension during loading response, which is altered by the observed changes in angles, the moment and power data at the knee and hip joints is not noted to be different between shod and BOB conditions, further adding to the evidence found for IDEO-wearing populations compared to controls that the use of the BOB does not impact proximal joints (Russell Esposito, 2017).

Although this is only one healthy volunteer, the small changes at the knee in angles, and no detectable change at the hip, points to a finding that the BOB does not cause changes in more proximal joints and hence can be trialled without concern of unintended consequences at other joints. Further studies involving larger numbers of healthy volunteers would be required to confirm this finding alongside studies of individuals with pathological gait.

### 9.4.4. Limitations

This Chapter has several limitations. Firstly, the volunteer is a healthy individual who does not require the BOB. Therefore, the gait data in the BOB may not be representative of a pathological gait population who have undergone rehabilitation with the BOB. The individual had no formal training with the BOB and the reduction in knee joint flexion during swing may be as a consequence of a lack of training. This is however the first study to examine gait in and out of the BOB for the same individual, adding to the literature concerning gait in the IDEO compared to the contralateral limb and to controls. The comparison of the three models was also only done on one individual's data, a larger population may have found different amounts of deviation between the models. Ten trials in each condition for each limb were used to attempt to minimise variation of results where possible. Despite the use of only one individual, it has been possible to establish the most appropriate model to use for analysis moving forward. Ideally, the marker set used for gait analysis would be chosen for the

biomechanical model intended to process the data. As the intention is to process historically collected gait data, this was not pre-emptively possible.

## 9.5. Conclusion

In conclusion, this Chapter has established that the BBImperial model will be used to process angle data and the PiG model will be used to process all other gait data for the historic data set provided by the DMRC. This Chapter adds to the literature demonstrating ankle angle, moment, and power changes in the BOB-wearing limb compared to the same limb out of the BOB. The Chapter has demonstrated that moment and power changes noted in the BOB are a consequence of a reduction in ankle-angle range of movement but that further studies are required to establish the contribution of the BOB to moment and power changes. The Chapter has also shown that the BOB does not induce gait deviation at proximal joints in one individual. Larger scale studies on patients with pathological gait are required to ascertain the long-term impact of BOB use on proximal joints. The next Chapter will look at historic pathological gait data prior to prescription of the BOB in order to understand the contribution gait data can make to produce a clinical decision tool.

# Chapter 10: Historic UK Gait data

## 10.1. Introduction

Previous Chapters have found that patients with a pain-specialist diagnosis of CRPS or neuropathic pain abandon the BOB. It has also been established that patients with predominantly a nerve injury will gain benefit from use of the BOB (Figure 10-1). Clinical indications alone, however, have not been able to produce a clinical decision tool for prescription of the BOB. There is still a number of patients for whom it is not possible to predict whether prescribing the BOB will provide long-term benefit. The previous Chapter investigated gait changes in and out of the BOB for a healthy volunteer. Peak dorsiflexion at stance, peak plantarflexion at initial swing, and ankle range of motion were all found to be statistically smaller, above minimal detectable change values, in the limb wearing the BOB compared to the same limb not wearing the BOB. Additionally, power changes were noted for the individual when wearing the BOB compared to not wearing the BOB, with a statistically significant reduction in ankle power absorption at loading response and power generation at pre-swing. These changes have all also been demonstrated in biomechanical gait studies investigating IDEO-wearing populations comparing the IDEO limb to the contralateral limb and to controls (Russell Esposito, 2014, 2017).

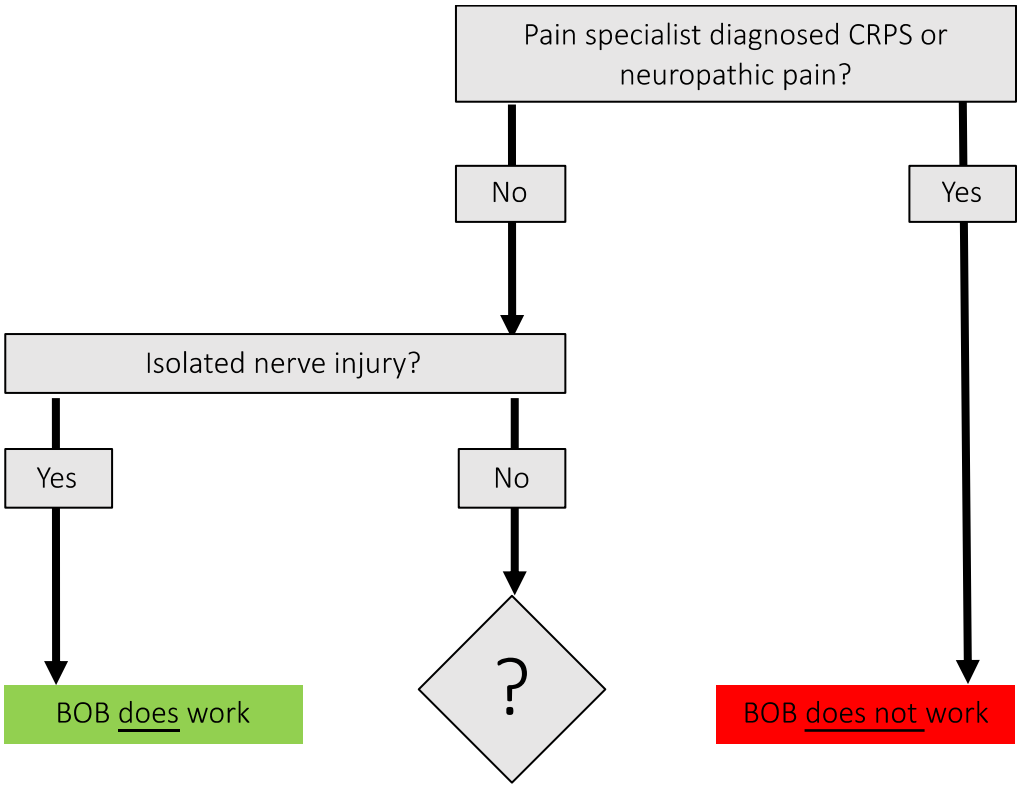



*Figure 10-1: Clinical decision tool with known indications. For a number of personnel with foot and ankle injuries, it is still not possible to predict outcome.*

Although changes in gait for IDEO wearing populations have been established, there are no studies looking at the gait of IDEO/BOB wearing populations prior to prescription of the orthosis and linking this to outcome. In order to create a clinical decision tool, gait for patients with known outcomes with the BOB requires investigation. Specifically investigating gait prior to prescription of the BOB and the aforementioned dependent measures known to change once a BOB has been prescribed; ankle angles, power absorption at loading response, and peak ankle power generation at pre-swing. The previous Chapter highlighted that a number of patients undergoing lower limb rehabilitation prescribed the BOB at the Defence Medical Rehabilitation Centre (DMRC), with known outcomes presented in Chapter 7, had their gait assessed prior to prescription. This data has not previously been processed or analysed.

The aim of this Chapter is to analyse the historic gait data collected at the DMRC to ascertain whether it is possible to predict from gait which patients will continue to use the BOB, and

which will abandon the BOB. This will allow for the completion of the clinical decision tool in Figure 10-1.

Of particular interest when assessing the dependent measures is power generation at pre-swing. Energy storage and return provided by the IDEO/BOB is particularly useful for patients with plantarflexor weakness, for example nerve injury patients, as seen in Chapter 8. In healthy subjects, ankle plantarflexors supply 50-80% of power generation during normal walking, which is significantly reduced due to pathology (Winter, 1983; Russell Esposito, 2017; Fickey, 2018). Reduction in power adversely affects gait and has been found to be one of the prime determinants of poor gait outcome following limb-salvage surgery prior to the introduction of the BOB (Robinson, 1991). Normal power generation at the ankle during pre-swing was found in the previous Chapter and in the literature to be approximately 2-4 W/kg (Winter, 1983; Russell Esposito, 2014, 2017; Fickey, 2018). The literature does not define a level for 'poor' ankle power generation, however, studies have found a reduction of between 43 and 63% in pathological populations (Winter, 1983; Russell Esposito, 2017). For the purpose of this study, in light of no standardised definition, poor ankle-power generation will be defined as less than 65% of the lower limit for healthy individuals, therefore less than 0.7 W/kg. In light of the positive outcome for nerve injury patients found in Chapter 8, the understood mechanism of action of the BOB, and statistical differences in power generation at pre-swing found for an individual wearing and not wearing the BOB, it is this dependent metric that is of most interest when considering gait for individuals prior to prescription of the BOB.

Although gait studies enable an objective assessment of walking ability, variability in raw data has been found between gait labs and biomechanical models (Ferrari, 2008; Gorton, 2009; Duffell, 2014). For a clinical decision tool including gait to be widely used, it is necessary to include a normalised measure of gait. In the previous Chapter investigating the gait of a healthy individual, statistically significant differences in gait were not expected. As described in Chapter 3, it has been argued that for healthy individuals with no underlying pathology, gait is symmetrical (Hannah, 1984; Eng, 1995; Vaughan, 1999). Symmetry of gait was defined in the previous Chapter as no statistically significant difference between the left and right side (Hamill, 1984). In pathological gait populations statistically significant differences between

the injured and sound limb are expected. Therefore, to quantify the degree of asymmetry in pathological gait populations, a symmetry index (SI) can be used (Robinson, 1987):

$$SI = \frac{X_I - X_S}{½(X_I + X_S)} \quad 100\%$$

Where $X_I$ is any gait variable for the injured side and $X_S$ is the same gait variable for the sound side. If the result is 0% the injured and sound sides are perfectly symmetrical. If the result is positive, then the result for the injured side is larger and if the result is negative then the sound side is larger. Literature examining gait kinetics has reported up to 20% of gait asymmetry in healthy populations as normal (Herzog, 1989; Jeleń, 2008). Both statistical differences between the injured and sound side, and the SI could be used in a clinical decision tool as they are normalised to the individual and do not require comparison of raw data between gait labs. There are no studies to date, quantifying asymmetry of gait in pathological populations prior to prescription of the BOB and linking this to outcomes.

The gait-dependent measures found in the previous Chapter and in the literature, which demonstrate statistical difference between not wearing the BOB and wearing the BOB will be investigated for a foot and ankle injury population prior to prescription of the BOB.
It is hypothesised that:

1. Individuals who continue to use the BOB will have a negative SI whilst those who abandon the BOB will have an SI between ±20% representing a normal SI, or a positive SI.
2. A statistically significant difference will be found between the SI for those who continue to use the BOB and those who abandon the BOB.

## 10.2. Method

Gait data was collected between March 2014 and June 2017 at Headley Court, DMRC. All individuals were recruited as part of the 'Effectiveness of the British Offloading Brace (BOB) in limb salvage patients' study (MoDREC reference: 690/MODREC/15). Inclusion criteria were:

- Age 18-50 years
- Current serving personnel

- A complex fracture, nerve injury, or chronic injury to the foot and ankle complex requiring prescription of the BOB
- Able to walk 10m at one time before rest without severe pain.

Exclusion criteria included:

- medical recommendation not to participate in research
- patient deemed unable to cognitively consent
- undergoing active treatment for a mental health disorder.

The gait lab comprised of a 10m walkway with 10 T-series Vicon cameras (Vicon, Oxford, UK) and 4 embedded force plates (AMTI, Watertown, MA, USA). Kinematic data was collected at 120 Hz and force plate data at 1200 Hz. A static standing trial was recorded for each participant to locate the joint centres. Participants were asked to walk at a self-selected walking velocity, with 5 practice trials prior to the capture of 10 trials. Individuals usually requiring the use of a walking aid undertook their trials with their usual aid.

The same method for processing the gait data, as presented in the previous Chapter, was used. The PiG model was used to acquire the gait parameters to enable comparison with minimal detectable change values matched to speed. It was also used to acquire power data. The BBImperial model was used to calculate joint angles. Ten gait cycles on the injured and sound side were processed per person, interpolated using a bespoke MatLab (MatLab 2019a, MathWorks) script normalised to 101 points representing 100% of the gait cycle. The mean average and standard deviation (SD) were found at each point. The injured leg was compared to the sound leg for each individual. Power data were scaled to body mass. The cohort were split into two groups. Group A included those patients who continued to use the BOB and group B included those patients who abandoned the BOB. Angle data was analysed to find peak dorsiflexion at stance, peak plantarflexion at initial swing, and ankle range of motion. Power data was analysed to find the peak ankle power absorption at loading response and power generation at pre-swing.

### 10.2.1. Statistical methods

All data are reported as mean (SD) comparing the sound and injured limb. A statistical significance of p=0.05 was set. Data were assessed for normality using the Shapiro-Wilk test.

Data with a normal distribution were analysed using a paired t-test comparing the sound side to the injured side to identify significant interlimb differences. Data which were not normally distributed were analysed using the Wilcoxon signed-rank test. All data were compared to established minimal detectable change values based on matched walking speed (Wilken, 2012). Statistical comparisons of the symmetry index were undertaken using an independent two-tailed t-test. Significant outliers were removed for statistical analysis between groups A and B.

## 10.3. Results

### 10.3.1. Demographics

Twenty-one patients were identified, original files were found for 19, and on review one individual did not have an available static file to calibrate the model against and was therefore excluded, leaving 18 patients. Of the 18 patients, two were excluded from analysis, one had an amputation for an unrelated reason following an accident whilst wearing the BOB and the other had an amputation for chronic infected non-union where the BOB was prescribed as a temporising measure. These two were excluded as neither of these patients could be described as having abandoned the BOB due to reasons the BOB could correct. The cohort therefore includes 16 patients, 11 in group A and 5 in group B (Table 10-1).

| ID | Injury | Pain specialist diagnosis | Nerve Injury | Amputation |
|---|---|---|---|---|
| **Group A – Continued use of BOB** | | | | |
| 1 | Comminuted calc # | N | N | N |
| 2 | Comminuted talus & calc # | N | N | N |
| 3 | Comminuted calc # & subluxed cuboid | N | N | N |
| 4 | Central nerve injury | N | Y | N |
| 5 | Comminuted tib/fib #, cuneiform # & calc # | N | N | N |
| 6 | Sciatic nerve damage | N | Y | N |
| 7 | Ankle # dislocation, calc & talus #, subluxed navicular and cuboid | N | N | N |
| 8 | Tibial and calc # | N | N | N |
| 9 | Tib/fib, calc, talus, cuboid, navicular and multiple forefoot # | N | N | N |
| 10 | Tib/fib #, nerve injury | N | Y | N |
| 11 | Tib/fib, calc & navicular # | N | N | N |
| **Group B – Abandoned the BOB** | | | | |
| 12 | Knee # dislocation, nerve injury | N | Y | N |
| 13 | Calc # | Y | N | Y |
| 14 | Osteochondral defect of the talus | N | N | N |
| 15 | NOF, Tib & calc # | N | N | N |
| 16 | Tib/fib # | N | N | N |

*Table 10-1: Injuries sustained by each individual prescribed a BOB with gait analysis data available. Calc = calcaneum, tib = tibia, fib = fibula, # = fracture, NOF = neck of femur.*

Examining the cohort in more detail, using the previously established clinical decision tool for the BOB (Figure 10-2), one of the cohort had a diagnosis of CRPS and therefore would be predicted to abandon the BOB and did (group B, 13). Two of the cohort had isolated nerve injuries with no other injury and would be predicted to continue to wear the BOB (group A, 4 and 6) and did. A further two patients had nerve injuries with concomitant injuries on the ipsilateral side. One patient continued to the use the BOB (group A, 10) and the other did not (group B, 12) due to problems with the BOB impinging on an injury at the knee.

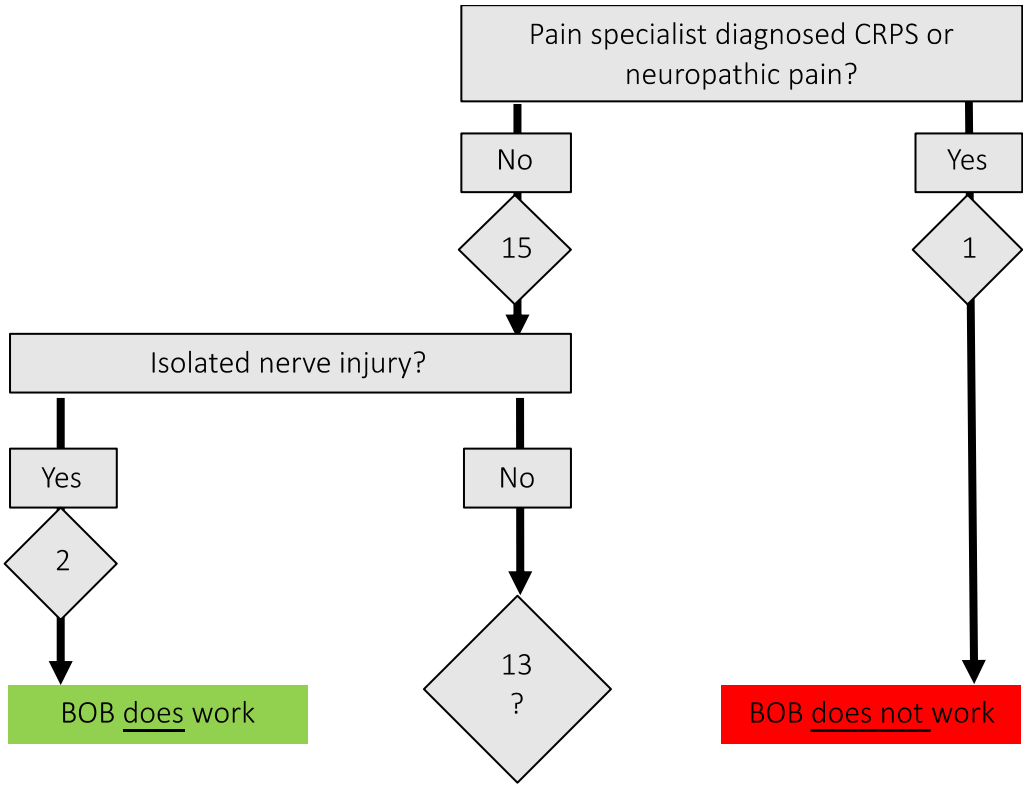



*Figure 10-2: Utility of current clinical decision tool for 16 individuals included in gait study. The current tool is not able to predict outcome for 13 of the cohort.*

### 10.3.2. Gait parameters

The gait spatiotemporal parameters can be seen in Table 10-2 and Table 10-3. There was no statistically significant difference between the injured and sound side between groups A and B.

| | | Group A | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | | 9 | | 10 | | 11 | |
| | | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S |
| Cadence | steps/ min | 115.11 (5.94) | 112.92 (2.94) | 107.78 (1.99) | 107.90 (1.95) | 108.14 (1.96) | 108.14 (2.08) | 84.48 (4.01) | 85.20 (3.33) | 112.35 (3.75) | 112.19 (2.30) | 91.03 (1.94) | 93.01 (3.10) | 101.71 (1.22) | 102.53 (1.97) | 79.37 (3.24) | 79.82 (3.86) | 100.19 (3.03) | 99.42 (2.73) | 69.76 (3.53) | 71.17 (4.33) | 96.38 (3.17) | 96.63 (2.07) |
| Walking Speed | m/s | 1.34 (0.06) | 1.35 (0.08) | 1.26 (0.04) | 1.26 (0.03) | 1.31 (0.03) | 1.31 (0.03) | 0.90 (0.06) | 0.90 (0.05) | 1.39 (0.07) | 1.39 (0.05) | 0.98 (0.04) | 1.00 (0.03) | 1.19 (0.04) | 1.18 (0.04) | 0.83 (0.06) | 0.83 (0.06) | 1.02 (0.04) | 1.03 (0.03) | 0.48 (0.05) | 0.48 (0.05) | 1.02 (0.06) | 1.02 (0.06) |
| Stride Time | s | 1.04 (0.05) | 1.06 (0.03) | 1.11 (0.02) | 1.11 (0.02) | 1.11 (0.02) | 1.11 (0.02) | 1.42 (0.07) | 1.41 (0.06) | 1.07 (0.04) | 1.07 (0.02) | 1.32 (0.03) | 1.29 (0.04) | 1.18 (0.01) | 1.17 (0.02) | 1.51 (0.06) | 1.51 (0.07) | 1.20 (0.04) | 1.21 (0.03) | 1.72 (0.09) | 1.69 (0.11) | 1.25 (0.04) | 1.24 (0.03) |
| Step Time | s | 0.54 (0.04) | 0.51* (0.03) | 0.56 (0.02) | 0.55 (0.01) | 0.56 (0.01) | 0.55 (0.02) | 0.70 (0.03) | 0.72 (0.05) | 0.55 (0.02) | 0.51 (0.02) | 0.71 (0.02) | 0.61 (0.02) | 0.62 (0.01) | 0.56* (0.01) | 0.76 (0.04) | 0.75 (0.05) | 0.61 (0.03) | 0.59 (0.02) | 0.86 (0.11) | 0.85 (0.03) | 0.64 (0.04) | 0.60 (0.03) |

*Table 10-2: Gait parameters for individuals in group A. Injured (I) and Sound (S) side compared. *p<0.05. Shaded cells highlight statistical difference between injured and sound side.*

| | | Group B | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 12 | | 13 | | 14 | | 15 | | 16 | |
| | | I | S | I | S | I | S | I | S | I | S |
| Cadence | steps/ min | 99.23 (3.07) | 98.73 (3.15) | 80.89 (3.05) | 79.62 (2.05) | 120.62 (2.48) | 119.98 (3.05) | 107.63 (2.58) | 107.33 (1.95) | 109.57 (1.14) | 110.15 (1.52) |
| Walking Speed | m/s | 1.16 (0.05) | 1.16 (0.04) | 0.84 (0.07) | 0.81* (0.07) | 1.45 (0.04) | 1.45 (0.04) | 1.28 (0.03) | 1.27 (0.03) | 1.41 (0.02) | 1.42 (0.02) |
| Stride Time | s | 1.21 (0.04) | 1.22 (0.04) | 1.49 (0.05) | 1.51 (0.04) | 1.00 (0.02) | 1.00 (0.03) | 1.12 (0.03) | 1.12 (0.02) | 1.10 (0.01) | 1.09 (0.02) |
| Step Time | s | 0.61 (0.02) | 0.60 (0.03) | 0.73 (0.04) | 0.77* (0.02) | 0.51 (0.02) | 0.49 (0.01) | 0.56 (0.01) | 0.55 (0.02) | 0.55 (0.02) | 0.54 (0.02) |

*Table 10-3: Gait parameters for individuals in group B. Injured (I) and Sound (S) side compared. *p<0.005. Shaded cells highlight statistical difference between injured and sound side.*

## 10.3.3. Ankle angles

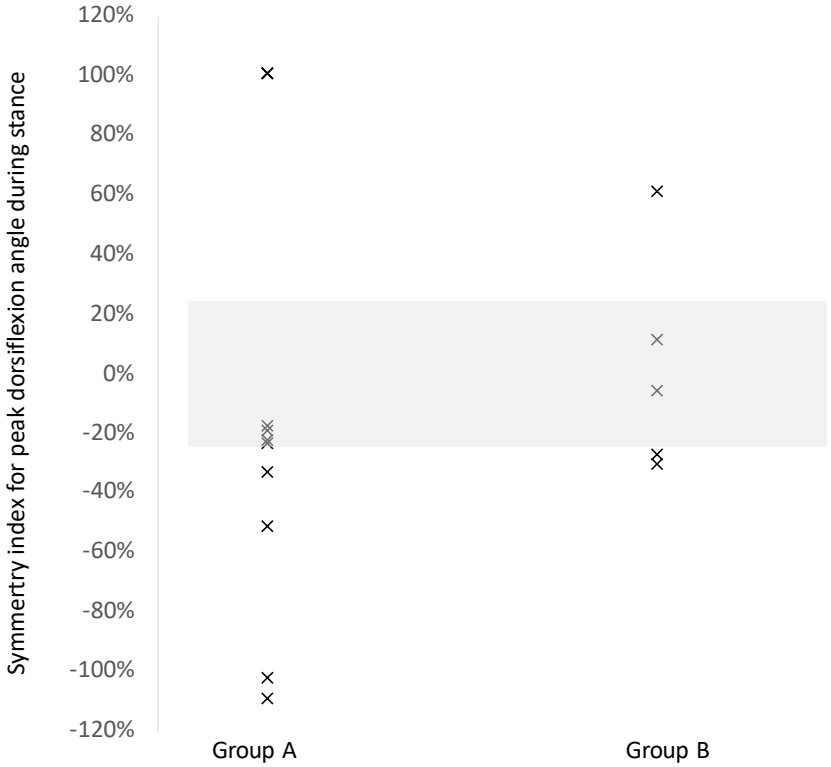
| | Group A | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | | 9 | | 10 | | 11 | |
| | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S |
| Peak DF Stance | 16.55 (0.72) | 19.11 (0.53) | 11.94 (1.03) | 12.05 (3.16) | 1.93 (0.74) | 5.62 (1.31) | 7.01 (2.67) | 3.69 (1.21) | 18.62 (0.25) | 16.75 (1.20) | 19.22 (0.54) | 8.89* (1.11) | 15.26 (1.04) | 18.99* (0.42) | 9.26 (0.91) | 8.42 (1.36) | 16.69 (0.42) | 18.31 (0.82) | 16.56 (1.29) | 9.97* (1.30) | 15.48 (0.71) | 14.54 (1.00) |
| Peak DF Stance SI | -14.36% | | -0.92% | | -97.75% | | 62.06% | | 10.57% | | 73.5% | | -21.78% | | 9.5% | | -9.26% | | 49.68% | | 6.26% | |
| Peak PF swing | -6.30 (1.23) | -10.75* (1.00) | -17.17 (1.08) | -23.03* (2.46) | -24.07 (1.43) | -34.73* (2.15) | -19.18 (3.74) | -29.65* (3.38) | -4.07 (1.86) | -12.81* (5.04) | -30.49 (0.40) | -20.85* (2.27) | -14.48 (1.83) | -7.79* (3.01) | -9.97 (3.59) | -24.47* (4.78) | -1.69 (1.38) | -12.94* (2.62) | -27.64 (6.89) | -9.19* (2.29) | -5.73 (1.09) | -11.97* (1.79) |
| Peak PF swing SI | -52.2% | | -29.15% | | -36.26% | | -42.88% | | -103.55% | | 37.55% | | 60.08% | | -84.20% | | -153.79% | | 100.19% | | -70.51% | |
| Ankle RoM | 22.86 (0.88) | 29.86* (0.88) | 29.11 (1.17) | 35.08* (2.93) | 25.99 (1.62) | 40.35* (2.36) | 26.20 (2.54) | 33.34* (3.50) | 22.69 (2.00) | 29.55* (4.96) | 49.71 (0.76) | 29.74* (1.60) | 29.74 (1.49) | 26.77 (3.07) | 19.23 (3.54) | 32.89* (3.98) | 18.38 (1.41) | 31.25* (2.54) | 44.20 (7.48) | 19.15* (2.93) | 21.21 (1.38) | 26.5* (2.34) |
| Ankle RoM SI | -26.56% | | -18.60% | | -43.29% | | -23.98% | | -26.26% | | 50.27% | | 10.51% | | -52.42% | | -51.86% | | 79.08% | | -22.18% | |

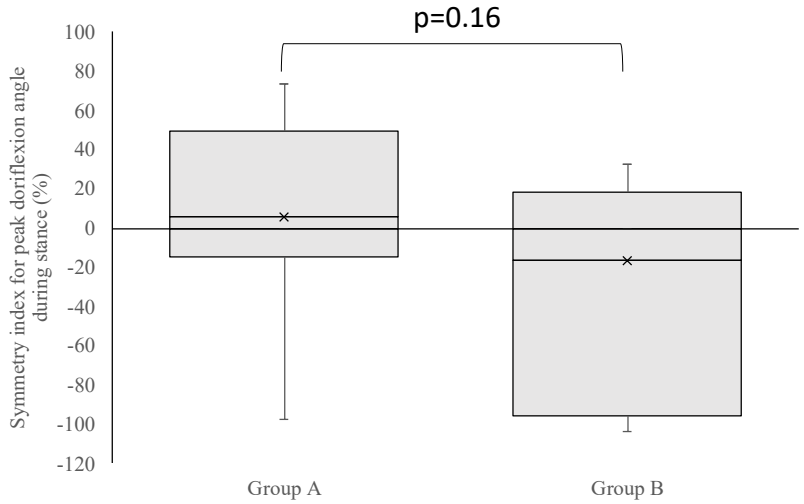
*Table 10-4: Mean (SD) peak kinematics (degrees) at the ankle for group A. DF = dorsiflexion. PF= plantarflexion. RoM = range of movement. I=injured side, S=sound side. *and shading represents p<0.05 and above minimal detectable change between injured and sound side.*

| | Group B | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 12 | | 13 | | 14 | | 15 | | 16 | |
| | I | S | I | S | I | S | I | S | I | S |
| Peak DF Stance | 10.45 (0.70) | 10.14 (0.61) | 4.51 (2.51) | 11.64* (1.34) | 4.69 (0.45) | 3.36 (2.02) | 2.26 (0.80) | 7.09* (1.35) | 11.77 (1.51) | 13.84 (1.53) |
| Peak DF Stance SI | 3.01% | | -88.30% | | 33.04% | | -103.32% | | -16.17% | |
| Peak PF swing | -37.76 (1.14) | -28.34* (1.38) | -24.98 (2.50) | -11.00* (5.41) | -28.44 (1.54) | -33.66* (1.97) | -26.49 (2.16) | -32.05* (1.93) | -15.86 (1.33) | -15.05 (1.20) |
| Peak PF swing SI | 28.50% | | 77.71% | | -16.81% | | -19.00% | | 5.24% | |
| Ankle RoM | 48.21 (1.46) | 38.48* (1.38) | 29.49 (1.36) | 22.63 (5.46) | 33.13 (1.47) | 37.03 (2.10) | 28.74 (2.34) | 39.14* (2.16) | 27.63 (1.23) | 28.90 (0.98) |
| Ankle RoM SI | 22.45% | | 26.32% | | -11.12% | | -30.64% | | -4.49% | |

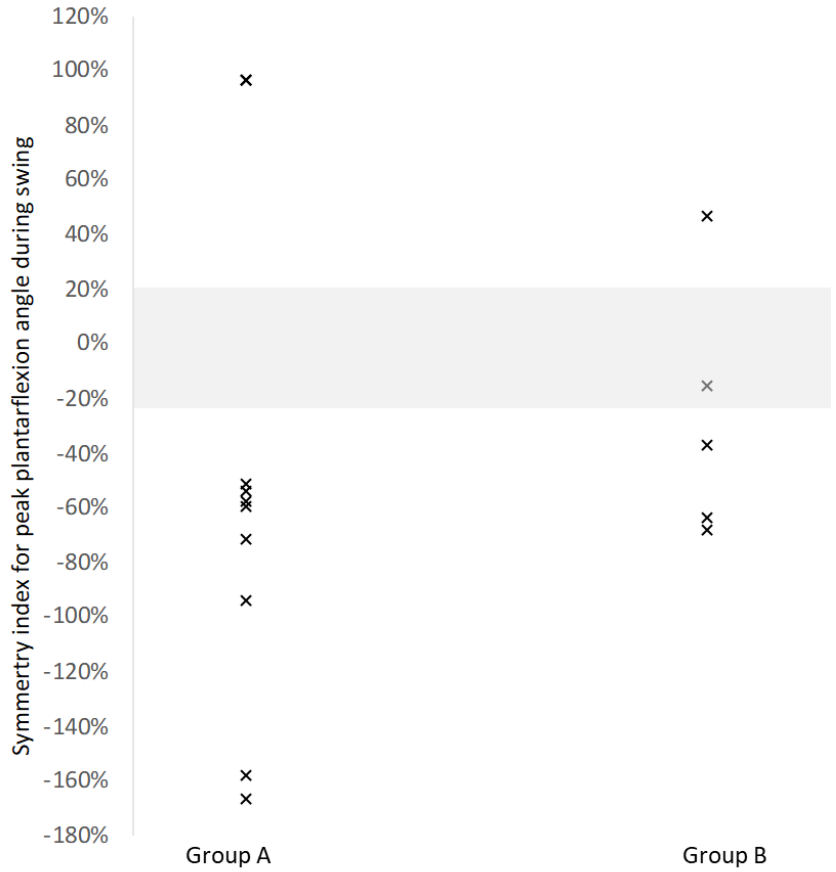
*Table 10-5: Mean (SD) peak kinematics (degrees) at the ankle out of the BOB for individuals in group B. DF = dorsiflexion. PF= plantarflexion. RoM = range of movement. I=injured side, S=sound side. *and shading represents p<0.05 and above minimal detectable change between injured and sound side.*

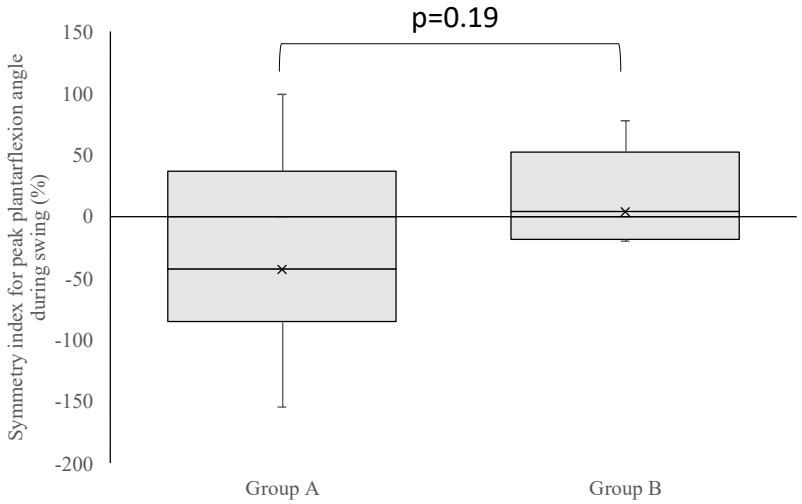
a


Symmertry index for peak dorsiflexion angle during stance
120%
100%
80%
60%
40%
20%
0%
-20%
-40%
-60%
-80%
-100%
-120%
Group A
Group B


p=0.16
Symmetry index for peak doriflexion angle during stance (%)
100
80
60
40
20
0
-20
-40
-60
-80
-100
-120
Group A
Group B

b


120%
100%
80%
60%
40%
20%
0%
-20%
-40%
-60%
-80%
-100%
-120%
-140%
-160%
-180%
Symmertry index for peak plantarflexion angle during swing
Group A
Group B


p=0.19
150
100
50
0
-50
-100
-150
-200
Symmetry index for peak plantarflexion angle during swing (%)
Group A
Group B

c

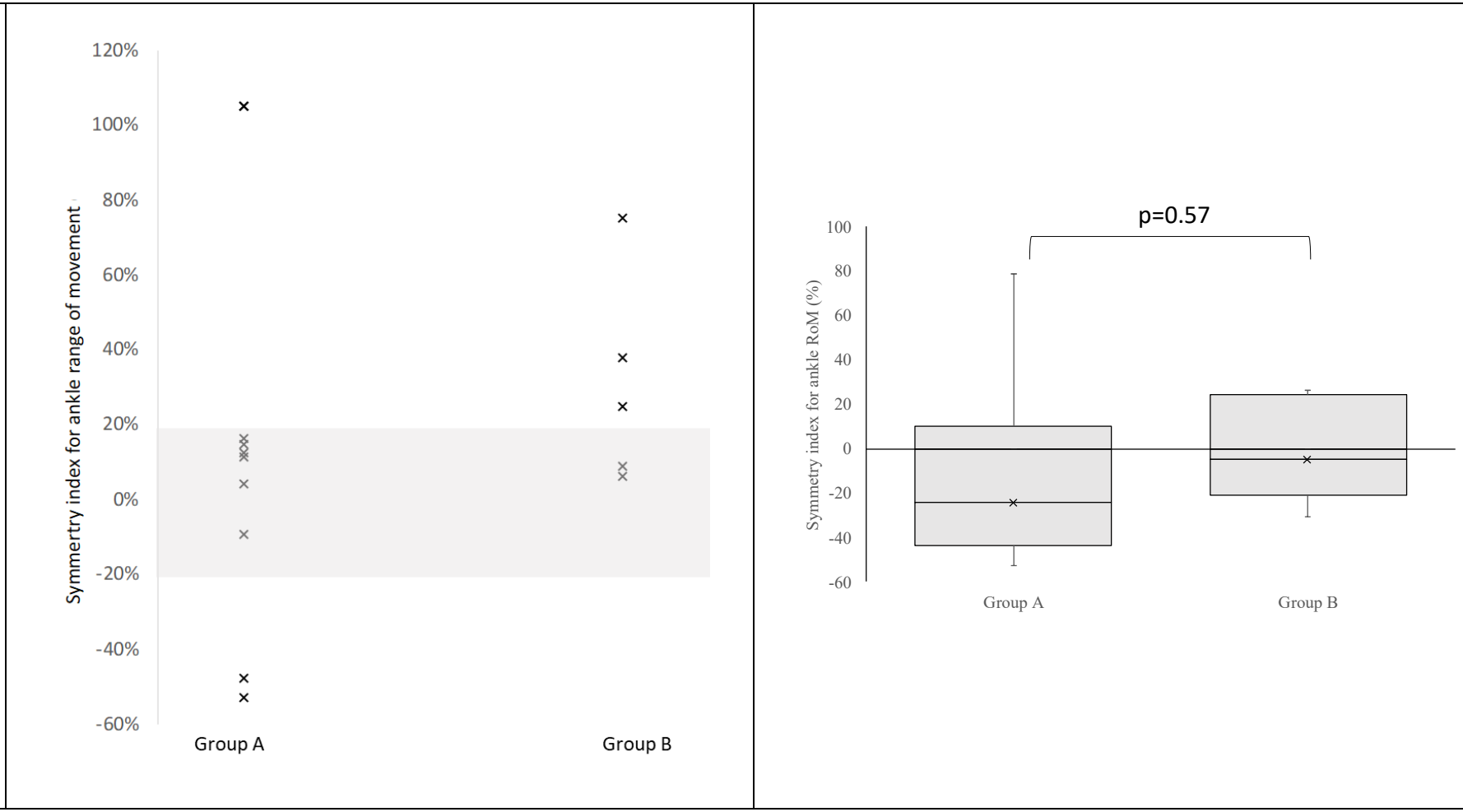



*Figure 10-3: a) Symmetry index for peak dorsiflexion angle during stance b) symmetry index for peak plantarflexion angle during swing c) symmetry index for ankle range of movement. Shaded area represents +20% and -20% normal variability.*

The peak dorsiflexion angle during stance did not demonstrate a symmetry index different from the defined normal range with the majority of patients falling within the +20% region (Figure 10-3a). All patients in group A demonstrated a statistically significant difference between the injured and sound side for the peak angle of plantarflexion achieved during swing, whilst all but one patient in group B also demonstrated this. Three patients in group B also demonstrated symmetry indices within the normal limits whereas no one in group A did (Table 10-4 and Table 10-5 and Figure 10-3b). All but one patient in group A demonstrated a statistically significant difference in ankle range of motion, however, only two patients in group B demonstrated this. The symmetry indices were not found to be statistically different between groups A and B for the measured angles.

### 10.3.4. Power data

The ankle-power absorption during loading response did not demonstrate any consistent statistically significant differences between group A and B (Table 10-6 and Table 10-7), and the symmetry index was not found to be statistically different (Figure 10-4a). A statistically significant difference between groups A and B was found for the symmetry index for peak power generation at pre-swing (Figure 10-4b). Group A has a larger negative SI than group B. Seven individuals in group A demonstrated a statistically significant difference in peak ankle power generation at pre-swing. Two of the five individuals in group B demonstrated statistical differences of ankle power generation at pre-swing.

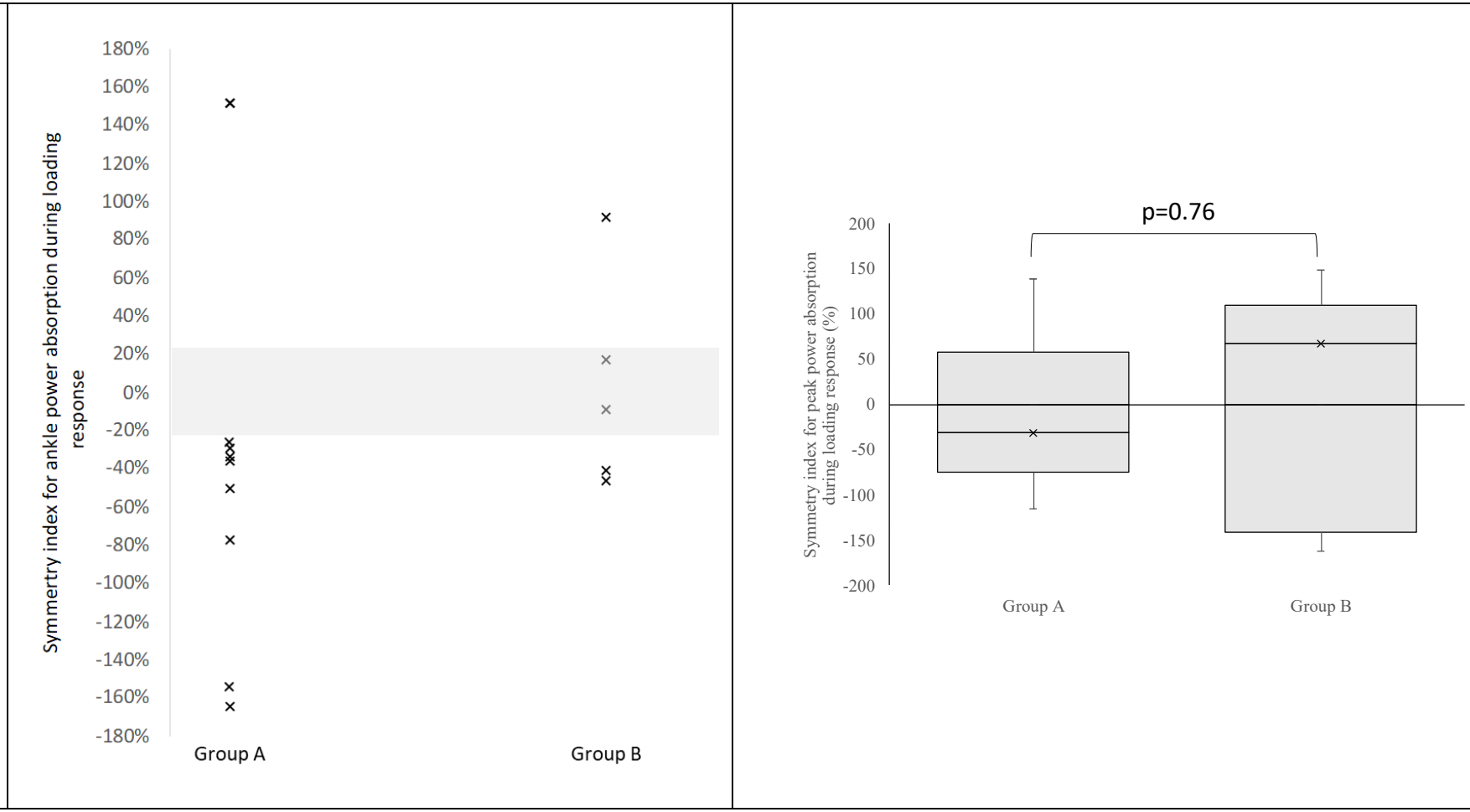
| | Group A | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | | 9 | | 10 | | 11 | |
| | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S | I | S |
| Ankle absorption loading response | -0.33 (0.31) | -0.18 (0.34) | -0.58 (0.08) | -1.27 (2.11) | -1.37 (0.22) | -0.75* (0.25) | -0.29 (0.12) | -0.52* (0.07) | -0.16 (0.14) | -0.33 (0.22) | -1.10 (0.32) | -0.20* (0.05) | -0.58 (0.10) | -0.74 (0.37) | -0.08 (0.10) | -0.11 (0.09) | -0.08 (0.03) | -0.30* (0.06) | -0.49 (0.82) | -1.24 (1.12) | -0.29 (0.06) | -0.20 (0.04) |
| Ankle absorption loading response SI | 58.82% | | -74.59% | | 58.49% | | -56.79% | | -69.39% | | 138.46% | | -24.24% | | -31.58% | | -115.79% | | -86.71% | | 36.73% | |
| Peak ankle generation pre-swing | 0.48 (0.98) | 1.95 (0.96) | 1.53 (0.06) | 2.04* (0.30) | 2.44 (0.13) | 3.44* (0.47) | 0.99 (0.51) | 1.58* (0.51) | 1.78 (0.47) | 3.51* (0.82) | 0.57 (0.06) | 1.94* (0.40) | 0.69 (0.05) | 3.17* (2.36) | 0.93 (0.38) | 1.29 (0.18) | 1.52 (0.39) | 2.07 (0.30) | 0.24 (0.27) | -0.02 (0.12) | 1.79 (0.19) | 2.56* (0.58) |
| Peak ankle generation pre-swing SI | -120.9% | | -28.57% | | -34.01% | | -45.91% | | -65.41% | | -109.16% | | -128.5% | | -32.43% | | -30.64% | | 236.36% | | -35.4% | |

*Table 10-6: Mean (SD) peak power data (W/kg) at the ankle for individuals in group A. I=injured side, S=sound side, SI=symmetry index. *and shading represents p<0.05 and above minimal detectable change between injured and sound side.*

| | Group B | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | 12 | | 13 | | 14 | | 15 | | 16 | |
| | I | S | I | S | I | S | I | S | I | S |
| Ankle absorption loading response | -1.61 (0.24) | -0.24* (0.03) | -0.24 (1.16) | -2.34 (1.80) | -0.23 (0.08) | -0.91 (1.74) | -0.69 (0.07) | -0.34* (0.12) | -2.13 (4.57) | -1.00 (2.18) |
| Ankle absorption loading response SI | 148.11% | | -162.79% | | -119.30% | | 67.96% | | 72.20% | |
| Peak ankle generation pre-swing | 3.36 (0.22) | 5.00* (0.60) | 1.63 (0.40) | 0.91 (0.44) | 3.59 (1.45) | 4.22 (0.95) | 2.43 (0.07) | 3.76* (0.26) | 2.57 (1.04) | 2.50 (0.78) |
| Peak ankle generation pre-swing SI | -39.22% | | 56.69% | | -16.13% | | -42.97% | | 2.76% | |

*Table 10-7: Mean (SD) peak power data (W/kg) at the ankle for individuals in group B. I=injured side, S=sound side, SI=symmetry index. *and shading represents p<0.05 and above minimal detectable change between injured and sound side.*

a


Symmetry index for ankle power absorption during loading response
180%
160%
140%
120%
100%
80%
60%
40%
20%
0%
-20%
-40%
-60%
-80%
-100%
-120%
-140%
-160%
-180%
Group A
Group B
p=0.76
Symmetry index for peak power absorption during loading response (%)
200
150
100
50
0
-50
-100
-150
-200
Group A
Group B

b

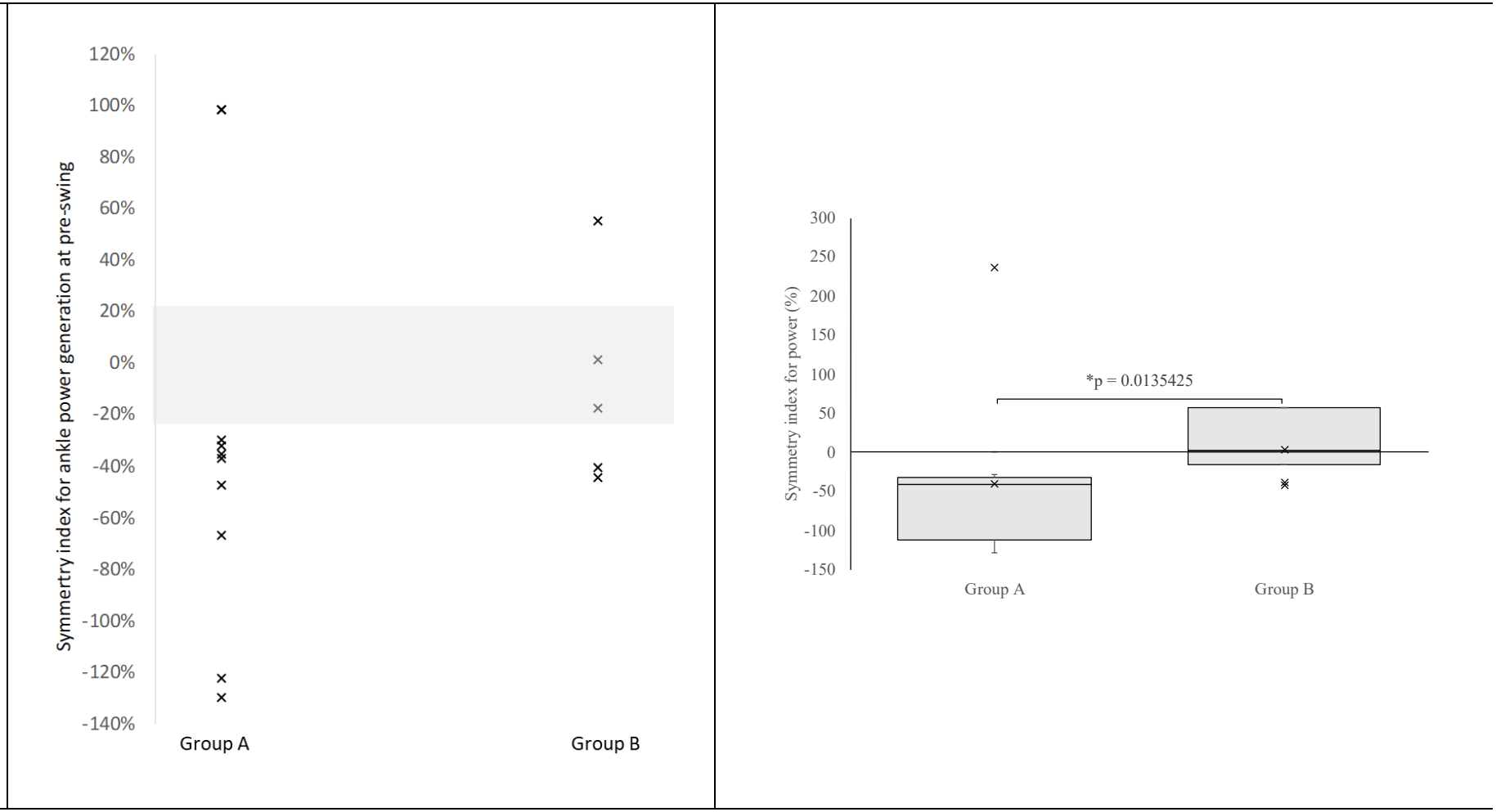



*Figure 10-4: a) symmetry index for ankle power absorption during loading b) symmetry index for ankle power generation at pre-swing. The shaded area represents +20% and -20% normal variability.*

## 10.4. Discussion

The aim of this study was to analyse the historic gait data collected at the DMRC to ascertain whether it was possible to predict from gait which patients will continue to use the BOB, and which will abandon the BOB. The statistically significant dependent measures of gait from Chapter 9 were analysed for asymmetry in a pathological population prior to prescription of the BOB. Although asymmetry has been found in a number of those measures, the only statistically significant difference in the SI between group A and group B was found in power generation at pre-swing.

This study has found that the BOB works for individuals specifically with an SI which is more negative than -20% of ankle power generation at pre-swing between the injured and sound side with the magnitude of power generation on the injured side smaller than that on the sound side. All, bar one, of group A demonstrated a negative SI for power generation at pre-swing. The one individual who did not demonstrate a negative SI for pre-swing, demonstrated bilaterally poor power generation of -0.02 and 0.24 W/kg. This is less than literature-reported norms and the definition of poor power generation established for this study. Therefore, although there was a positive SI, this result is erroneous as both sides demonstrated poor power generation. None of group B demonstrated poor power generation at pre-swing on the injured side, whilst four of Group A did, and all bar one of Group A had power generation of less than 2 W/kg, the lowest end of reference data. As discussed previously, power generation is generally reduced in pathological gait and it would be beneficial to quantify the reduction required to gain benefit from the BOB. Due to the small sample size, it is not possible to quantify a value for power generation below which the BOB will be beneficial. Further studies are required instrumenting the BOB and limb to assess which patients will gain most from the prescription of the BOB. It may be that for some patients, a less engineered AFO is more appropriate. Furthermore, one of the individuals in group B (16) demonstrated symmetrical gait and power with values largely in keeping with population norms and reference data. It may be that the negative outcome was as a result of too much support provided by the BOB, when an alternate AFO may have been more appropriate (see Chapter 4 for an explanation of orthoses).

The results are less conclusive for those in group B. There were only 5 individuals who abandoned the BOB with gait data available. One of the individuals had a nerve injury and an ipsilateral knee injury. Although he demonstrated a negative SI for peak ankle power generation at pre-swing and therefore would be expected to do well with the BOB by the aforementioned criteria, the knee injury prevented use of the BOB due to the fit of the proximal cuff. One other individual in group B demonstrated a negative SI for power generation at pre-swing. He abandoned the BOB due to pain at the hip as a result of an injury sustained at the same time as that at the foot and ankle. Both individuals also demonstrated power generation on the injured side of more than 2 W/kg. The other three in group B demonstrated a normal or positive SI for power generation at pre-swing. This leads to the conclusion that an SI which is more negative than -20% for power generation at pre-swing is predictive of outcome in the absence of an ipsilateral injury preventing use of the BOB. If poor power generation is demonstrated bilaterally the BOB may also work regardless of the SI. This conclusion is based on a small sample size and a larger cohort is required to refine and confirm this statement.

The previous Chapter and literature examining the BOB/IDEO has found use of the orthosis results in reduction in ankle-power generation at pre-swing compared to the contralateral limb, controls, and the same limb out of the BOB (Russell Esposito, 2014, 2017). Considering the poor power generation demonstrated by pathological patients presented in this study in group A, it would be expected that use of the BOB augments function at push off. This is not achieved, however, through an increase in power generation. The BOB restricts overall ankle range of motion and therefore as described in the previous Chapter; power generation is also reduced. It is thought instead, that function is augmented by reduced ankle work as opposed to augmentation of net ankle push-off (Bregman, 2012). This may explain the improvement seen in patients with a nerve injury presented in Chapter 8. A nerve injury may result in weakened dorsiflexors, therefore the need for additional support at initial contact, loading response, and during the swing phase of gait. Or a nerve injury might result in reduced plantarflexor power hence reduction of both push off and centre of mass transition during gait (Zelik, 2016). A nerve injury may also result in both deficits (globally poor ankle function). To support and augment gait due to these deficiencies, a device would need to support the foot and ankle during the initial phases of gait, store energy during stance, and then return

energy at push off. The BOB acts in both these ways. The passive support is similar to a simple plastic AFO but, combined with power storage, is unique to the BOB and IDEO. Energy storage has been shown in mechanical testing where the IDEO demonstrates buckling of the struts under compressive load with strut deflection, which is thought to contribute to the storage of energy during gait (Wach, 2018). During patient testing with the IDEO, energy return at pre-swing has been shown to augment function (Russell Esposito, 2014; Ranz, 2016). This explains the benefit gained from the BOB for individuals with a nerve injury and the patient in group A studied here.

Neither the spatiotemporal data nor angles revealed any pattern for prediction of outcome with the BOB. Slower walking speed and lengthened stride time have previously been reported in the literature following ankle trauma and are associated with increased recovery time following limb salvage surgery (De Visser, 2000; Hsu, 2019). Six Individuals in group A and 2 individuals in group B demonstrated walking speed of less than 1.2 m/s out of the BOB (a recognised cut off for assessment of patients after limb-salvage surgery) (Archer, 2006). This is in keeping with literature findings that approximately 45% of patients will walk slower than 1.2 m/s after rehabilitation without use of a BOB (Archer, 2006). Examining stride time, 4 individuals in group A and 1 in group B demonstrated prolonged stride times of approximately 1.5 seconds consistent with norms reported for individuals post limb-salvage surgery (De Visser, 2000). Further studies are required examining a pathological cohort in the BOB to ascertain whether use of the BOB improves these spatiotemporal parameters.

### 10.4.1. Limitations

This is the first study to look at gait pre-prescription and outcome with the BOB or IDEO. All other studies examine clinical and injury characteristics or functional deficit to predict outcome (Potter, 2018). The strengths of this study include using the sound limb and comparing it to the injured limb with a symmetry index. As discussed in Chapter 9, the absolute values generated by different gait labs and models vary. The SI does not require comparison to normative data nor comparison to absolute values, hence the gait lab used to capture, and the model used to process the data, should not impact on the use of this parameter in a clinical decision tool. Access to gait lab facilities are widely available at military inpatient rehabilitation facilities. This is not however the case in NHS clinical settings.

Although the SI allows for comparison between gait labs, a force plate and access to a gait lab is required to generate power data. Therefore, it would be desirable to establish gait parameters which do not require assessment in a formal gait lab or the use of a force plate. These options will be discussed and explored further in the next chapter.

The study is limited to the cohort of patients with gait data collected at time of prescription. There are insufficient numbers for firm conclusions to be drawn on gait parameters which predict a negative outcome with the BOB. Although a larger cohort than presented here have been prescribed the BOB (Chapter 7), once an individual has undergone rehabilitation and worn the BOB for a period of time, the gait may have changed. Therefore, it would not have added to the study to bring back individuals at a later date. Furthermore, individuals who have abandoned the BOB have progressed to amputation, may now be wearing an alternate AFO, or have undergone operative procedures, further altering gait, making their current gait irrelevant. The clinical decision tool must therefore be assessed against a larger cohort of wearers of the BOB or IDEO with known clinical outcomes and gait data available prior to prescription. As such, a prospective trial is required to assess the success of, and enhance, the clinical decision tool in predicting outcome with the BOB.

## 10.5. Conclusion

In this thesis so far, it has been established that (Figure 10-5):

1. the BOB does not work for patients with a pain specialist diagnosis of CRPS or neuropathic pain, at the foot and ankle;
2. the BOB works for individuals with an isolated nerve injury;
3. if the individual has an SI for ankle power generation at pre-swing which is more negative than -20%, then the BOB will work, if a more proximal injury is not present on the ipsilateral side;
4. if a negative SI is not found in power generation at pre-swing but poor power generation (<0.7W/kg) is noted bilaterally, then the BOB may also provide benefit.

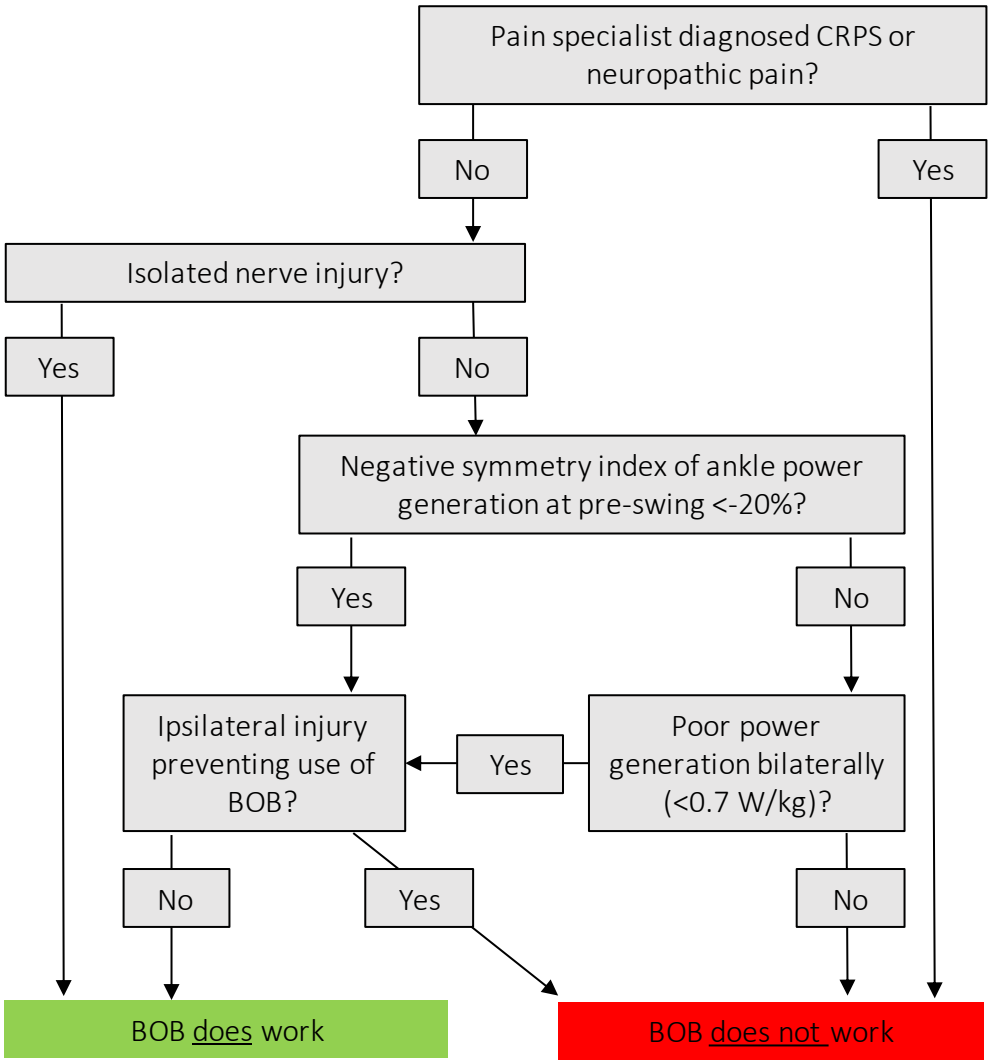



*Figure 10-5: Proposed clinical decision tool for prescription of the BOB now requiring further validation and refinement.*

In conclusion, this study has demonstrated that in addition to clinical indications for use of the BOB, gait analysis can be used to predict outcome. It is now necessary to use the proposed clinical decision tool to assess success in prediction of outcome with the BOB on a different retrospective cohort and to undertake a prospective trial.

# Chapter 11: Summary, Discussion, and Future Work

## 11.1. Summary

Complex foot and ankle injuries are common following battlefield injury. They are also sustained as a result of military training and recreational activities. These injuries may occur as a result of HELET and are treated with either LS or amputation. Either treatment results in outcomes that are worse than population norms for both civilians and military personnel. Specifically, for military personnel, patient-reported and performance outcomes are superior for amputees compared to LS patients. Military LS patients rehabilitated alongside amputees complain of increased rehabilitation timelines, perceive their outcomes to be worse, and consequently request elective (delayed) amputation.

In order to allow military personnel, following LS to undertake impact activities, orthotic devices may be prescribed. Simple thermoplastic AFOs, PTB orthoses, and CFOs appear inadequate for use for impact activities due to weaknesses in the materials from which they are made. The AFO most likely to return military personnel to impact activities was found to be a PDAFO. A PDAFO combines the design features of a simple thermoplastic AFO, a PTB orthosis, and a CFO, whilst being made of carbon fibre thus overcoming the weakness in material design. Two of the most prevalent PDAFOs are the IDEO used in the US and the BOB used in the UK. These orthoses were designed to improve patient-performance outcomes for military personnel following LS and attempt to prevent amputation.

By combining the benefits of other AFO designs, the IDEO/BOB has the potential to work for a wide variety of foot and ankle pathologies. The IDEO has been used extensively in the US, however, outcomes beyond 2-years have not been reported and specific clinical indications for use are unknown. Furthermore, although the IDEO improved performance and patient-reported outcomes, some patients still progressed to amputation and an unknown number abandoned the IDEO. There are no studies investigating outcomes using the BOB in the UK. To improve outcomes for military LS patients, this thesis focused on the development of an evidence-based clinical decision tool for the prescription of the IDEO and BOB devices in complex foot and ankle injuries with the vision of preventing painful and futile rehabilitation.

Outcome data for military personnel in the UK following optimum rehabilitation before the introduction of the BOB was collected: performance outcomes in the form of the 6-MWT for LS patients were worse than patients undergoing delayed amputation. There was a delayed amputation rate of over 50% with a sporting/training mechanism of injury predictive of the need for amputation. Following the introduction of the BOB, the rate of delayed amputation reduced by half to 24%. Risk factors for amputation were found to be a pain-specialist diagnosis of CRPS or neuropathic pain and a psychiatric diagnosis including PTSD. Two-thirds of LS patients who were prescribed the BOB continued to use it at mean 63-months follow-up. Pain-specialist diagnosed CRPS or neuropathic pain were found to be the only statistically significant indicators for the abandonment of the BOB.

Also noted, was a trend towards ongoing use of the BOB for individuals with a nerve injury, however, UK numbers were too small to draw statistical conclusions. A cohort of American military personnel who were prescribed the IDEO was also examined to investigate further patients with a nerve injury and improvements in patient-reported and performance outcomes were found. An amputation rate of 7% was seen with 2 patients requiring amputation for CRPS and recurrent ulceration. It was therefore concluded that prescription of the IDEO benefits individuals with predominantly a nerve injury resulting in weakness at the foot and ankle.

A small fraction of BOB patients with pain-specialist diagnosed CRPS, neuropathic pain, and nerve-injury patients contributed to the BOB use/abandonment cohort. Within the data set however, there is a large cohort of patients for whom it was not possible to predict whether the PDAFO would work for them based on their injury pattern or functional deficit. Therefore, the gait pattern of those prescribed a BOB, before usage, was investigated to ascertain whether it was possible to predict ongoing use or abandonment of the BOB using biomechanical markers.

A biomechanical model was chosen to analyse gait before prescription of the BOB. In gait analysis of a healthy individual wearing the BOB, it was shown that the BOB does not induce proximal joint gait deviations. Consequently, it was concluded, although further work is

required in a larger cohort, the BOB can be prescribed without concern of inducing injury in proximal joints.

Subsequently, the gait of the LS-patient population prior to prescription of the BOB was analysed. Using the symmetry index, it was found that a negative symmetry index of greater than -20% for power generation at pre-swing was predictive of ongoing use of the BOB. Notably, in the absence of a negative symmetry index, poor power generation, (defined as less than 0.7 W/kg, bilaterally), was also found to be predictive of ongoing use. Additionally, it was shown that a proximal injury on the ipsilateral limb may result in abandonment of the BOB despite a negative symmetry index for power generation at pre-swing.

The conclusions that have been demonstrated in this thesis sanction the creation of a data-driven, evidence-based clinical decision tool to support outcome prediction when considering using the IDEO/BOB. Specifically, it is designed to support clinician decision making when prescribing the IDEO/BOB to a prospective patient. The tool is presented in decision-tree form in Figure 11-1.

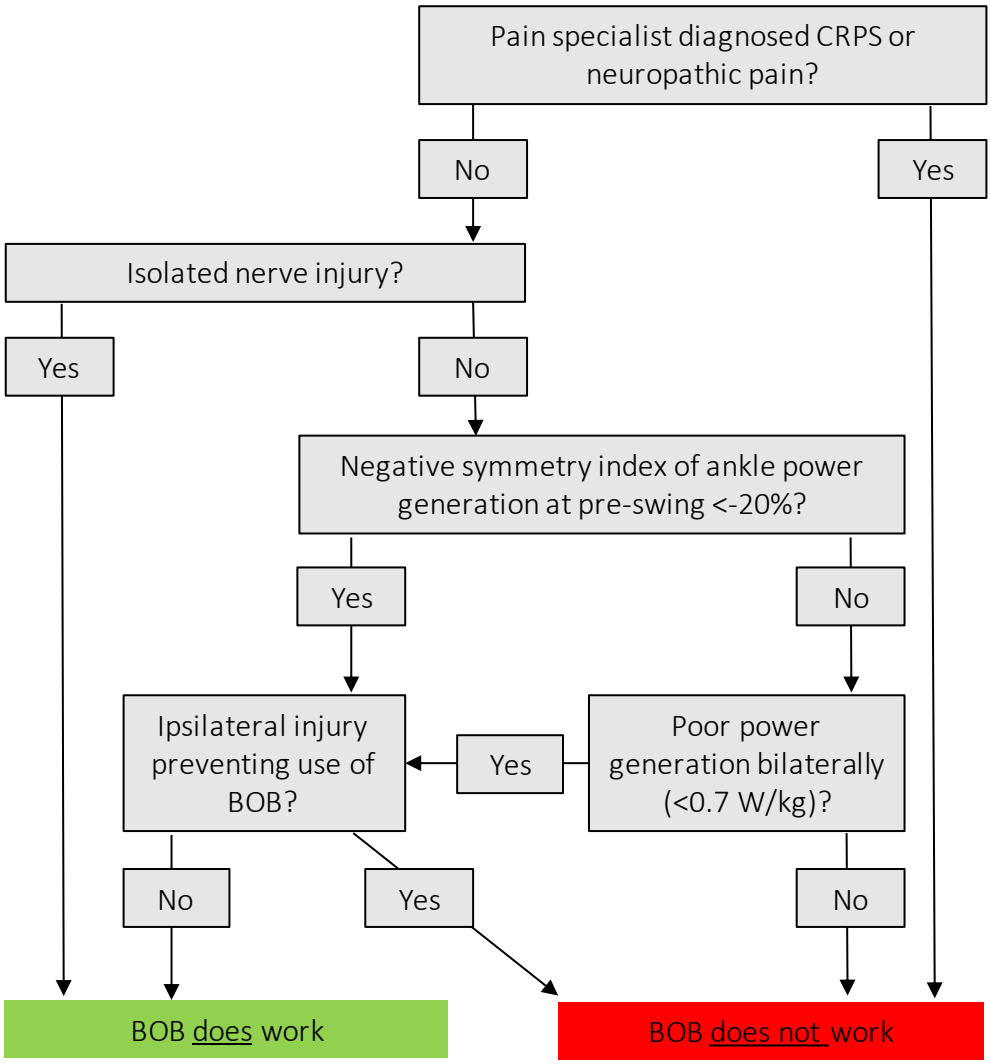



*Figure 11-1: Clinical decision tool for the prescription of the BOB and IDEO.*

## 11.2. Discussion and future work

### 11.2.1. Clinical decision tool

The clinical decision tool uses clinical and biomechanical criteria to predict who will benefit from prescription of the IDEO/BOB. Creation of the clinical tool was based on all patients prescribed the BOB in the UK, and a cohort of American patients prescribed the IDEO for nerve injuries. The balance of the available evidence from a detailed review and the results of this work specifically for the BOB/IDEO indicate that use of this orthotic is unlikely to benefit patients with a pain-specialist diagnosis of CRPS or neuropathic pain (Potter, 2018).

Treatment options available for patients with CRPS are limited and this study has found that a high proportion resort to amputation. The literature proposes, that even with amputation, complications persist (Krueger, 2015). The IDEO was designed to attempt to prevent amputation and although Bedigrew et al found a reduction in amputation rate consistent with the results of this work (Chapter 7), reasons for progression to amputation despite the use of IDEO were not defined (Bedigrew, 2014). The authors report that prior to introduction of the IDEO, 50 patients were considering amputation, with pain being the most common reason for the request (86%). Potter et al similarly found pain the most common reason for amputation in their study concerning outcomes with the IDEO (Potter, 2018). The evidence supports the assertion in this thesis, that patients with pain-specialist diagnosed CRPS or neuropathic pain may not benefit from use of the IDEO/BOB and these patients may ultimately progress to amputation, although a positive outcome cannot be guaranteed.

In order to investigate the outcomes of patients with a nerve injury prescribed the orthosis, a cohort of American patients prescribed the IDEO was used. This included patients with either foot drop or GPAF. Improvements in both patient-reported and physical performance measures were noted, especially for patients with GPAF. Limitations in the American data prevented the analysis of long-term follow-up results beyond the end of the RTR CP. Despite this, the evidence presented here suggests that the IDEO/BOB works for patients with predominately a nerve injury. Specifically, the mechanical support offered by the IDEO/BOB at initial contact and loading response combined with the energy storage and return is likely to explain the benefit seen by the nerve-injury cohort.

Foot and ankle injury patients prescribed the IDEO and BOB sustain heterogenous injury patterns. Despite efforts to overcome this confounding factor by grouping patients into functional deficits, it was not possible to predict outcomes for all foot and ankle patients using purely clinical data. It is postulated that with a larger study, functional deficit may allow for prediction of outcome with the IDEO/BOB. Work in the US investigating the outcomes of 81 patients, as part of the multisite evaluation of prescription of the IDEO trial, presents a potential opportunity to increase granularity on functional deficits and outcomes with the IDEO, in patients with ongoing follow-up beyond 12-months (Potter, 2018). Additionally, appropriately powered studies examining patients with homogenous injury deficits caused by

non-battlefield injury would be beneficial with the move away from the high intensity kinetic battles seen in both Iraq and Afghanistan. It is likely that future patients who will benefit from prescription of the IDEO/BOB will have sustained injuries not just from battlefield injury but also sporting/training mechanisms as well as experiencing chronic injuries in the form of PTOA.

This work, having reached the limit of what clinical data could currently offer, also integrated biomechanical data sets into the methodology; achieved by investigating the gait of a patient cohort prior to prescription of the BOB. Previous studies have demonstrated a statistically significant reduction in ankle RoM when wearing the IDEO compared to the contralateral limb and controls (Russell Esposito, 2014, 2017).The published reduction in ankle RoM findings was reinforced in this study for a healthy individual in and out of the BOB. Intrinsically linked to this reduction, moment and power data have also been found to change when wearing the IDEO/BOB, specifically with a reduction in ankle-power generation at pre-swing. The findings from the gait pilot study were further investigated in a pathological population prior to prescription of the BOB. Investigating power generation at pre-swing, it was found that a negative symmetry index which is more negative than -20% was predictive of ongoing use of the BOB. There was one exception to this, an individual with poor power generation bilaterally, who gained benefit. According to these findings, two individuals with negative symmetry indices would have been predicted to gain benefit from the use of the BOB, but ultimately abandoned it due to ipsilateral proximal injuries.

This is the first clinical decision tool for the prescription of the IDEO/BOB, refined and tested with the addition of biomechanical questions concerning power generation at pre-swing. Integration of the symmetry index was added as it can be calculated regardless of the raw data produced by different biomechanical models and gait labs, widely generalising its use across labs and researchers, as a powerful tool to acquire and process data.

Due to the lack of evidence in the literature, for this study a poor power generation level of less than 0.7 W/kg was set; however further work Is required to increase the evidence base and refine this metric with a larger cohort. Beneficial not just for use with the clinical decision

tool but also to provide a defined standard against which future gait studies could be compared.

A systematic review has previously attempted to provide empirical evidence statements for the prescription of the IDEO finding that, for patients under the age of 40 who have sustained lower limb trauma as a result of HELET, the IDEO in combination with the RTR CP, may allow some individuals to return to duty, recreational activities, and improve agility, power, and speed (Highsmith, 2016). The statement, however, was not specific on the indication for prescription, nor did it identify those patients for whom the IDEO would not work, thus resulting in abandonment or amputation. Like the empirical evidence statement, the work presented here has been specific to a relatively young military cohort and therefore the clinical decision tool is unlikely to be transferable to an older or civilian population.

Further studies are required to increase confidence in the validity of the clinical decision tool. The American patient cohort, with known outcomes with the IDEO, can and should be assessed using the tool. This would require a retrospective analysis against all patients prescribed the IDEO at a single institution, (as was conducted in this study with the inclusion of all patients prescribed the BOB at the DMRC). All patients would need to have undergone gait analysis before prescription of the IDEO, for this tool to be used, which may limit the number of people who could be included. Additionally, adequate analysis of patients who abandon the IDEO but do not progress to amputation is consistently missing from the IDEO literature, therefore It would also be necessary to include in the analysis exactly how many individuals abandon the IDEO.

In addition to corroborating and refining the tool with retrospective cohorts using IDEO data, a prospective trial is required to ascertain the validity of the clinical decision tool. When considering an individual for prescription of the IDEO/BOB, the tool should be used to record whether the individual is predicted to continue to use the orthosis or abandon it. Specifically, for a prospective trial, the individual should be blinded to the prediction. In theory, the tool could be used to counsel patients about the likely outcome with the IDEO/BOB, this may result in the individual behaving differently with the IDEO/BOB and alter the observable data. For a prospective trial, the individual must be blinded to the prediction, and the clinician

prescribes as they usually would. To enable double-blinding of the prediction, an online platform could be used to record whether the individual has a pain-specialist diagnosis of CRPS, neuropathic pain, a nerve injury, a negative symmetry index of power generation at pre-swing, poor power generation at pre-swing bilaterally, and an ipsilateral injury, along with other pertinent information. The individual and clinician would not know whether ongoing use or abandonment is predicted and therefore outcome results would not be affected. The outcome of ongoing use or abandonment with the IDEO/BOB should then ideally be collected at 6-month intervals. This type of prospective trial requires international collaboration as the numbers prescribed the IDEO/BOB in each country are relatively small. The use of an online platform for data collection would significantly aid in international and, multicentre data input. The results would increase the evidence base behind prescription, refine and add confidence to the validity of the clinical decision tool. This being the case future patients can be appropriately counselled on whether the IDEO/BOB is the correct orthosis to aid in their return to impact activities. It is then logical to extend the trial beyond a young military population extending its clinical application to civilian and older populations wishing to undertake impact activities following HELET.

For the clinical decision tool to be of use to as many clinicians as possible it would be desirable to move away from biomechanical markers that require the use of a gait lab. With evolving technologies companies such as Vicon are introducing app-based gait analysis technologies. These technologies allow for gait to be recorded on a mobile device and output kinematic data. As part of a prospective study, use of app-based gait-analysis technology would allow for evaluation of a larger cohort of LS patients, particularly those without access to a gait lab. The use of machine learning could be introduced to attempt to elicit predictors of outcome which do not require the use of a formal gait lab. App-based gait results can also be compared with formal gait-lab outputs (where available) to begin to move away from the confinements of static gait labs towards a mobile technology which can be used on deployment by military clinicians. With larger cohorts, the ankle RoM, which is supported and reduced when the IDEO/BOB is worn and is used as part of the calculations for moment and power data, may be found to be predictive of outcome.

### 11.2.2. Indication for use of the BOB

This thesis initially examined a specific cohort of patients with LS as a result of HELET. It then became evident from the clinical indications for those prescribed the BOB at the DMRC that HELET was not the only indication. Patients were prescribed the BOB for several pathologies, including injuries sustained as a result of ligamentous sporting injuries and following the onset of post-traumatic OA.

With the return to contingency following the conflicts in Iraq and Afghanistan, the military is dealing with considerably fewer blast-injury patients and although HELET still occurs during military training and in everyday life, it is likely patients with alternate injury patterns will be looking for assistance in returning to impact activities. The IDEO/BOB has demonstrated good outcomes for patients with a nerve injury. This need not be traumatic, with benefits gained for patients with central nervous system dysfunction, for example following cauda equina or tumour. A larger prospective trial may be able to conclude for which specific indications the IDEO/BOB should be prescribed.

In this work, the outcomes of patients who continued to use the BOB and those who abandoned the BOB were explored in detail. As presented in Chapter 7, patients with chronic non-union or osteomyelitis are unlikely to gain long-term benefit from the use of the BOB and will progress to amputation. Some of these patients may, however, benefit from the use of the BOB as a temporising measure. In these patients, the BOB may provide short-term benefit prior to elective amputation. Further studies examining the patient-reported outcomes for pain and physical functioning for this specific subset of patients would be required to investigate potential short-term improvements.

Other foot and ankle injuries not examined in this thesis may also gain benefit from prescription of the BOB, for example, Achilles injuries. Following this type of injury, the BOB may offer a defined degree of offloading during walking as part of a staged rehabilitation programme. This provides the added bio-mechanical advantage of allowing a small amount of stretching of the Achilles during rehabilitation to prevent excessive stiffness. If offloading can be quantified, the BOB could be modified to provide tuned percentage weight offloading in rehabilitation following not just Achilles injuries but other trauma and surgery. To enable

use in these cohorts of patients, a better understanding of the mechanism of action of the BOB is required, specifically the offloading capacity and capability.

### 11.2.3. Mechanism of action of the BOB

To understand whether the BOB could provide benefit for patients requiring offloading, the exact mechanism of action of the BOB must be better understood. The original design was based around a carbon fibre running blade prosthesis used by amputees. The prosthesis design was incorporated with a PTB orthosis and CFO, both of which also provide the benefits seen from a simple thermoplastic AFO. By combining the designs, clinical benefit was seen, however, the exact mechanism of action was not understood. The proximal cuff is thought to provide similar benefits seen with a PTB orthosis, providing offloading or load sharing during stance. This would lead to the conclusion that the IDEO/BOB will provide benefit for patients with mechanical pain during stance, for example, caused by osteoarthritis in the talocrural and/or subtalar joints. The literature has found some benefit for patients with OA from a prescription of the IDEO in combination with the RTRCP with improvements seen in participation in impact activities (Jeanne C. Patzkowski, 2012b). The improvements in participation in impact activities did not result in changes in spatiotemporal characteristics and in Chapter 7 the presence of OA was not found to predict an outcome with the BOB (Quacinella, 2019). This thesis presented only a limited cohort of patients with PTOA, some of whom have concomitant injuries due to polytrauma. A study is required examining the outcomes of personnel with isolated PTOA. To understand which patients will benefit from the load sharing provided by the IDEO/BOB, further studies are required examining the proportion of load carried by the device. Initial investigations using plantar pressures have demonstrated a decrease in peak pressures in the affected foot wearing the IDEO, specifically at the forefoot and toes (Stewart, 2020). To take this work forward, the IDEO/BOB struts require instrumentation using, for example, strain gauges to quantify the load through them. Plantar pressures in and out of the IDEO/BOB can then be compared to the strut data when walking to attempt to quantify the load sharing. The data gained from these experiments can then be used to build computational models. A computational model of the orthotic would allow for alterations of the design or materials of the IDEO/BOB and provide expected changes to the load sharing capacity without having to manufacture and test the orthosis with each change. This would allow for in-silico tuning of the IDEO/BOB for optimum load sharing

and opens up the possibility of providing offloading of a specific percentage of a patient's weight. This would potentially result in the IDEO/BOB being indicated for rehabilitation following foot and ankle injuries and surgery, where reduced weight bearing is required.

Currently, the private cost of manufacture of the orthosis with a one-week rehabilitation package is £3,800 (+VAT) making widespread use of the BOB for post-operative rehabilitation in the NHS unaffordable. Understanding the mechanical properties of the orthosis and the mechanism of action may allow for use of a more cost-effective material. Trialling of different material and designs using computational modelling may allow for a similar orthosis to be designed, providing tuned offloading, at a much-reduced cost.

In addition to offloading, the BOB aids patients with weakness of power generation at pre-swing in a similar fashion to a CFO. Despite research into strut stiffness during walking and running, it does not appear to be the stiffness of the struts which is responsible for observed improvements in outcomes (Russell Esposito, 2014, 2015). Although patients with reduced ankle-power generation at pre-swing require augmentation, this may not be as a direct result of increased power from the IDEO/BOB, but instead as a result of reduced work at the ankle joint.

### 11.2.4. Moments and power data

To understand the ability of the IDEO/BOB to augment function for patients with reduced plantarflexor power, the correct biomechanical measure must be chosen. Traditionally, gait is assessed for moment and power data. In an orthosis, although widely reported, the moment and power data of the ankle are not being explicitly measured. The addition of the IDEO/BOB restricts the ankle joint movement, which as explained in Chapters 9 and 10, is intrinsically linked to the method in which moment and subsequently power data are calculated. The moment result which is calculated when an orthosis is worn is the sum of the internal joint moment plus the orthosis moment. Similarly, the power data, therefore, is a combination of both the ankle and orthosis data. To gain a better understanding of the role the orthosis plays at pre-swing, an instrumented IDEO/BOB is required to determine the energy storage and return capability and capacity. It is also necessary to undertake concurrent EMG gait studies to assess the contribution of the IDEO/BOB and muscles to gait. *In vivo*

studies of this kind have not been undertaken with the IDEO/BOB. One study has looked at the IDEO integrated into a healthy musculoskeletal model in OpenSim, finding that the IDEO provides plantarflexor moments in mid and late stance to supplement the power of the plantarflexors (Arch, 2016). This is in keeping with the findings in this thesis however further studies are required to quantify the amount of augmentation provided and to allow for tuning of the IDEO/BOB. If successful, it would be possible to customise the IDEO/BOB to the exact amount of augmentation required to prevent excessive support, avoiding over-engineering. Alternatively, where appropriate, a different AFO can be designed with the correct amount of augmentation for the individual. Furthermore, experiments looking at the degree of offloading provided, and energy storage and return may allow for an orthosis to be designed or a different AFO selected to aid those who abandon the BOB.

Computational modelling using both Finite Element (FE) and musculoskeletal modelling present options to provide bespoke rehabilitation options to injured personnel. Orthotic designs can be tuned using FE and knowledge of an individual's anatomy, geometry, injury, and muscular strength could be combined with musculoskeletal modelling to prescribe a bespoke orthosis. With enough additional study, as outlined above, it will be possible to supersede the clinical decision tool with computational modelling alone.

This thesis has demonstrated that up to a third of those who retain their limbs still abandon the BOB. In some cases, this may be because the BOB does not provide enough support, and in other cases, because it provides too much support. It follows that further experiments may allow for truly custom-designed orthoses to be produced to aid with the specific pathologies of patients and for changes to be made as pathologies evolve with time.

### 11.2.5. Rehabilitation

Both the IDEO and BOB are prescribed as part of a rehabilitation package. In the UK, the BOB was introduced into already established rehabilitation pathways and consequently, the only difference between the rehabilitation provided to those in Chapters 6 and 7 is the addition of the BOB. This is not true of the American literature where the RTR CP was created to be delivered with the IDEO. Consequently, it is not possible to say whether improvements in patient-reported and physical performance outcomes are as a result of the IDEO, or the RTR

CP, or unique to the combination of the two. Return to duty rates have been shown to improve for individuals who undertook the RTR CP along with prescription of the IDEO as opposed to being prescribed the IDEO without a formalised rehabilitation pathway (Blair, 2014). There are, however, no studies looking at the outcomes for LS patients in America undertaking the RTR CP and comparing them to individuals undertaking the RTR CP with an IDEO, or with an alternate AFO. The results of such a study could guide rehabilitation specialists in the UK looking to improve outcomes for patients with foot and ankle injuries that do not require the BOB or those who require a different AFO. It may also be possible to create a new pathway for foot and ankle injury patients for whom it is not clear from the clinical decision tool whether prescription of the BOB will help; a package similar to the RTR CP could be delivered along with a staged approach of orthosis prescription, from a simple thermoplastic AFO to PTB, CFO, Reaktiv or Phatbrace as indicated, and then to the BOB if required.

In addition to a prospective trial investigating the outcomes of personnel with the IDEO/BOB using the clinical decision tool, it would be desirable to also investigate the outcomes of individuals using other AFOs as part of rehabilitation packages. This data would allow for a more complete clinical decision tool to be designed. Clinical and biomechanical data could be used to establish which AFO, from a simple thermoplastic AFO through to the IDEO/BOB, would be most appropriate. This would provide evidence of the level of support required for different injury and gait patterns; it may also potentially allow individuals to change orthosis as pathologies evolve with time. App-based gait technologies could be used to assess which biomechanical markers predict the need for an orthotic. In turn predictors of which orthotic (from a simple thermoplastic AFO to a PDAFO) achieve the desired functional and clinical outcome could also be investigated. Although large numbers of patients would be required in such a study, including all military patients with foot and ankle deficiencies referred for an orthosis would allow a better understanding of the clinical and biomechanical indications for different levels of augmentation.

The IDEO/BOB was designed to enable personnel to undertake impact activities and return to running. Ultimately, any orthosis prescribed to an individual as part of a rehabilitation package must achieve the goals of that individual. Consequently, a patient with an injury at

the foot and ankle may also wish to change orthosis based on their requirements for physical activity which may change with advancing years, type of job, and other co-morbidities.

### 11.2.6. Proximal joints

To fully understand the role that the BOB can play in rehabilitation, the impact on proximal joints must be investigated. Alterations in angles and loading of proximal joints may induce injury or may slow the progression of pathologies. Use of the BOB may not only provide offloading at the foot and ankle but also at more proximal joints which may in some cases slow the progression of osteoarthritis. Or use of the BOB may unduly load proximal joints resulting in acceleration of OA at proximal joints preferentially over the foot and ankle.

It is important to understand the impact of the orthosis on proximal joints as large deviations in gait at the knee and hip may result in long-term injury. There are no studies concerning the IDEO looking specifically at the effect of the IDEO on proximal joints. Studies reporting gait data for IDEO-wearing populations, comparing the results to the contralateral limb and controls, have found changes in knee flexion based on the stiffness of the IDEO. When a stiffer IDEO is worn the knee flexes more, and when a more compliant IDEO is worn the knee flexes less (Russell Esposito, 2014). Statistically significant differences above minimal detectable change values between the IDEO0-wearing limb and the contralateral limb have not been found (Russell Esposito, 2017). Here, statistically significant differences above minimal detectable change values were not found at proximal joints for a healthy individual in and out of the BOB. The knee range of movement on the limb wearing the BOB was reduced; this was presumed to be due to the BOB impacting the posterior thigh inducing early extension in an individual who was healthy and consequently had not been through rehabilitation wearing the BOB. Changes at the pelvis and spine were not investigated as part of the gait analysis used in this thesis and have not been looked at in the literature. In the absence of significant deviations at the knee and hip, it can be assumed that deleterious deviations at the spine are not induced. To fully understand proximal joint changes for an IDEO/BOB-wearing population it is necessary to undertake a larger study of individuals in and out of the orthosis and examining the proximal joints for changes, including the spine and arm swing. If, as in Chapter 9, gait deviations are not found, a trial of the BOB can be undertaken without concern of long-term consequences on the proximal joints.

### 11.2.7. Limitations

Although this thesis provides a complete picture of the UK BOB cohort rehabilitated at the DMRC the numbers are small. This limits the strength of the conclusions drawn. Larger numbers may have allowed for more confidence in the conclusions concerning clinical indications for use. Due to the relatively small number of patients prescribed a BOB in the UK, it is necessary to undertake a prospective trial in combination with other countries, for example, the DoD in the US prescribing the IDEO.

The role of psychiatric diagnoses has also not been explored in this thesis. Rehabilitation for military personnel following injury alongside colleagues who have sustained amputations requires further attention. LEAP found that self-efficacy played a key role in outcomes following HELET for civilian patients and this was also found for military patients in the METALS study (McCarthy, 2003; Doukas, 2013). Consequently, although this thesis concentrated on the clinical and biomechanical indications for ongoing use of the BOB, it cannot be excluded that psychology did not play a role in patient perception of their progress with the BOB and so with the decision whether they continue using it. The thesis used patient-reported outcome measures to understand the patient perception of use; however, as with several other studies examining limb salvage populations and using patient-reported outcome measures, approximately a third of the cohort were lost to follow up. The bias this may have caused in the analysis is not clear. It may be that patients who did not respond are doing well and therefore do not feel the need to engage further with healthcare services or it may be that those who are doing badly did not engage. Every effort, within the protocol approved by the MoD ethics committee, was made to contact the cohort to provide a complete data set. Where people could not be contacted, and where available, the DMRC outcome measure was used as a proxy due to the similar domains to the SMFA domains.

Furthermore, numbers for the cohort presented in Chapter 10 were limited by the number of personnel who had their gait assessed prior to prescription of the BOB. Larger numbers, particularly in the cohort who abandoned the BOB would have been beneficial. It was not however possible to bring people back once rehabilitation with the BOB was completed or at a later stage as gait may change with the use of the BOB or individuals may be using alternate

orthoses or had surgical intervention. To overcome this, a retrospective study of patients prescribed the IDEO in the US, with known outcomes, and available gait analysis prior to prescription is suggested.

### 11.2.8. Conclusion

Experimentally based on a combination of patient functional outcomes and biomechanical data, this thesis has proposed and developed a clinical decision tool for the prescription of the IDEO/BOB. This tool can now be used to help in decision making and counselling of patients with foot and ankle injuries in order to prevent futile painful rehabilitation. Moving forward, it is the recommendation of the author, that the tool be tested on larger retrospective cohorts and used on a prospective cohort to further refine and validate it. More work is required to quantify the offloading capacity and capability of the IDEO/BOB as well as the energy storage return function. A better understanding of these factors will allow for the prescription of a customised orthosis based on underlying pathology and gait augmentation requirements. The IDEO/BOB provides clinical benefits for patients with foot and ankle injuries and allows patients with nerve injuries and asymmetry of power generation at pre-swing, to return to impact activities at median 63-months follow-up. The clinical decision tool developed and presented in this work is a significant step forward in the evidence and knowledge base, provides accessible advice to the clinician, fully focused on the individual patient to delivering tailored personalised prescriptions, ultimately intending to achieve better outcomes for an active population who have many productive years ahead of them.

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