Measuring the functional and clinical effectiveness of a passive dynamic ankle foot orthosis when used to rehabilitate complex limb salvage post lower limb blast trauma

Nicole Bennett

School of Health and Society

University of Salford, Manchester, UK

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III. List of abbreviations

The following table describes the significance of various abbreviations used throughout the thesis and the page on which each one is defined or first used is also given.

Abbreviation	Meaning	Page
DMRC	defence military rehabilitation centre	Xiii
OETT	orthotic education training trust	Xiii
PD AFO	passive dynamic ankle foot orthosis	Xv
PROM	patient reported outcome measure	Xv
LEFS	lower extremity functional scale	Xv
FAOS	foot and ankle outcome score	Xv
GPS	gait profile score	Xv
IED	improvised explosive device	1
EPIC	european prospective investigation into cancer and nutrition	1
AFO	ankle foot orthosis	2
3D	three dimensional	5
WW1	world war one	6
WW2	world war two	6
MOD	ministry of defence	7
AVM	anti-vehicle mine	7
GC	gait cycle	17
GRF	ground reaction force	20
NAO	national audit office	22
NHS	national health service	22
MESI	mangled extremity syndrome index	27
PSI	predictive salvage index	27

MESS	mangled extremity severity score	27
NISSA	nerve ischemia soft tissue skeletal shock and age	27
LSI	limb salvage index	27
LEAP	lower extremity assessment project	27
RTA	road traffic accident	29
METALS	military extremity trauma amputation limb salvage study	29
SMFA	short musculoskeletal function assessment	30
PTSD	post-traumatic stress disorder	31
ISO	international standards organisation	33
FFO	functional foot orthosis	35
IDEO	intrepid dynamic exoskeletal orthosis	39
CFI	centre for the intrepid	40
BOB	british off-loading brace	41
GRAFO	ground reaction ankle foot orthosis	45
EVA	ethylene vinyl acetate	49
AFO-FC	ankle foot orthosis footwear combination	56
SVA	shank to vertical angle	56
EMG	electromyography	59
PLS	posterior leaf spring	64
VR-12	veterans RAND 12-item health survey	69
VAS	visual analogue scale	69
ADL	activities of daily living	70
HSO	higher scientific officer	74
IDT	interdisciplinary team	75
MODREC	ministry of defence research ethics committee	79

ADMR	academic department military research	80
MFCL	medicare functional classification level	85
ASIS	anterior superior iliac spine	88
PSIS	posterior superior iliac spine	88
LED	light emitting diode	94
CAST	calibrated anatomical systems technique	94
CGM	conventional gait model	103
MAP	movement analysis profile	105
SD	standard deviation	107
QOL	quality of life	107
MCID	minimal clinically important difference	116
COM	centre of mass	158
COP	centre of pressure	163
GDI	gait deviation index	171
GGI	gillette gait index	171
CTEV	congenital talipes equinovarus	174

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V. Abstract

Summary: Studies suggest passive dynamic ankle foot orthoses (PD AFO) are effective at improving gait and patient reported outcomes measures (PROM) in personnel who have undergone limb salvage due to blast trauma. Studies using PD AFOs have included able bodied and personnel with variable clinical presentations. This study examines if PD AFO use improves gait and PROMs in personnel injured by the same blast mechanism with similar unilateral deck slap blast injuries.

Introduction: Rehabilitation outcomes following limb salvage are reported as substandard, with personnel frequently demonstrating poor functional and psychosocial outcomes. There has been a call for advancements in orthotics to support limb salvage patients eager to preserve their lower limb, yet function at high levels of mobility. PD AFOs are used to improve clinical outcomes. Studies have shown that when combined with exercise rehabilitation PD AFOs can decrease biomechanical pain, improve physical activity and enable return to work in high functioning adults.

Method: The study consisted of 12 individuals who had sustained “deck slap” injuries caused by high energy blast trauma. Kinematic, kinetic and temporal spatial parameters were measured walking with and without their PD AFO at a self-selected speed. Participants completed the Lower Extremity Functional Scale (LEFS) and the Foot and Ankle Outcome Score (FAOS) pre and post PD AFO provision. The mean and standard deviation was calculated for each test measure and statistical analysis was conducted using R version 3.5.3.

Results: Use of a PD AFO significantly improved each participant’s mean PROM score and user’s propulsive capability. Participant’s gait profile score (GPS) also improved when using the PD AFO.

Conclusion: This study suggests that unilateral PD AFO use can improve gait parameters and PROMs in injured personnel who have sustained unilateral blast trauma.

Chapter 1: Introduction

British military operations in Afghanistan and Iraq resulted in many personnel suffering severe injury or loss of life[1]. Improvements in personal protection, enhanced prehospital care, and rapid aero evacuation to medical facilities capable of providing optimised resuscitation and limb salvage surgery have resulted in an unprecedented number of personnel surviving battlefield injuries[2]. These advancements have enabled limbs that would have, at one time, required immediate amputation, to now be deemed salvageable[3]. The injured limb(s) have often suffered multiple severe fractures, widespread vascular injuries and peripheral nerve damage requiring extensive, and sometimes multiple surgical reconstructions and re-vascularisation. Although the salvaged limb appears intact, its' function capability can be severely compromised[4].

A difficult question that emerges from such advancements is: Does salvaging the limb achieve the best outcome for the injured patient? The decision to amputate or attempt salvage of injured limbs is a subject of much debate[5-8]. This decision often emerges in the presence of high-energy lower extremity trauma, such as battlefield injuries caused by improvised explosive devices (IED)[5], as the injuries sustained are clinically complex[2]. The debate predominantly centres on pain management and function.

As a result of their injuries, individuals with lower limb trauma are often predisposed to living a sedentary lifestyle, further increasing the development of obesity and increasing the risk of type 2 diabetes mellitus and cardiovascular disease[9]. Regular physical activity and/or structured exercise is now widely established as an important strategy in improving mental health, preventing obesity and chronic diseases such as type 2 diabetes mellitus and developing cardiovascular disease in the general population[10-12]. Recent findings from the multi-centre European Prospective Investigation into Cancer and Nutrition (EPIC) study suggest that inactivity is in fact the single largest contributor to mortality rather than obesity[13]. This is clinically very important because the consequences of chronic pain and reduced physical function after lower-limb

trauma may predispose an individual to live a more sedentary lifestyle, regardless of their pre-injury activity levels.

Individuals who experience high energy lower extremity trauma and undergo limb salvage frequently demonstrate poor functional and psychosocial outcomes[6; 8; 14-17] with ongoing pain being a determining factor in the short to long term. Amputation, however, presents significant long-term health concerns, as post-traumatic lower limb amputees have been shown to have an increased morbidity and mortality from cardiovascular disease[18; 19]. Poor limb salvage outcomes over the past decade have led to an increase in the number of injured personnel seeking elective amputation on average 18 months after initial limb salvage surgery[20]. Personnel with deck-slap blast injuries, for example, are at a higher risk of amputation[20]. Deck-slap is a military colloquial term for a pattern of fractures seen to the calcaneus, talus and distal end of tibia, due to an explosion from an IED underneath a military vehicle[2]. The explosion beneath the armoured vehicle creates powerful shockwaves which cause the floor of the vehicle to rapidly deflect, transmitting high upward forces. Personnel tend to be sitting at the moment of impact[21] and therefore the force generated from these shockwaves is transferred to the incumbents lower limbs causing extensive damage to bones, soft tissues and blood vessels within the foot and ankle.

Anecdotally there has been a call for advancements in technology from medics and injured personnel to support lower-limb salvage patients eager to preserve their lower limb(s) yet function at high levels of mobility. Empirically, at the Defence Medical Rehabilitation Centre (DMRC) Headley Court, the use of “conventional” orthoses, such as custom functional foot orthoses, stock ankle braces and thermoplastic custom Ankle Foot Orthoses (AFO) of various designs, were not having a positive impact on reducing the elective amputation rates in this patient group. On account of this, orthotists who treat injured US and UK military personnel began utilising a specifically designed passive dynamic ankle foot orthosis[5] (PD AFO) (Figure 1-1) manufactured from advanced composites to try and achieve this advancement. Studies[22; 23] have suggested that when combined with exercise rehabilitation, injured personnel

using this PD AFO demonstrate improved functional outcomes and reduced elective amputation rates[24].

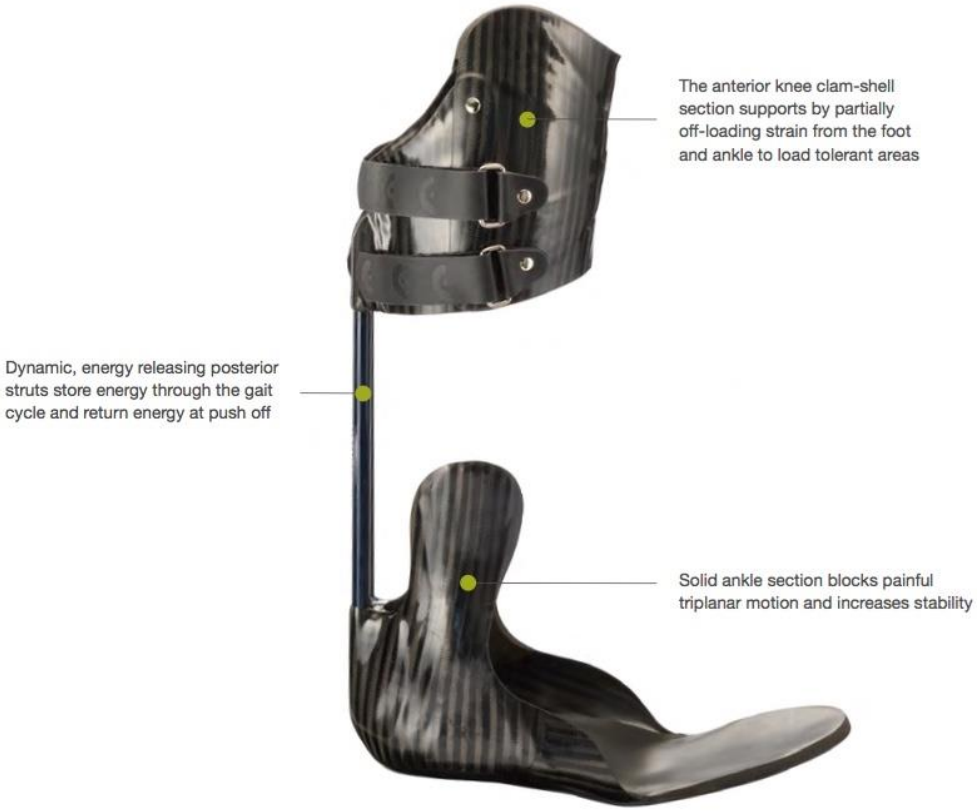

Figure 1-1 Example of the PD AFO (Source: Blatchford private clinic website[25])

In a recent US systematic review[5] of 487 PD AFO users, it was suggested that PD AFO provision combined with exercise rehabilitation enabled return to work, recreation and physical activity, and decreased pain in high functioning patients. In an 8-week integrated PD AFO and rehabilitation study [22] to improve function and pain outcomes, 41 of 50 users initially considering amputation favoured a limb salvage management plan utilising the PD AFO instead and, importantly, this was sustained for 2 years follow-up. After 8 weeks use of a PD AFO the participants appeared to have improved outcomes in all physical performance and PROMs. No study to date, however, has compared PD AFOs to other custom made AFO designs. The UK and US PD AFOs used by military personnel are of the same design, as the US military provided training to the DMRC Headley Court clinical team. The only difference is the fabrication

method, and this is described later in this thesis. Only this PD AFO design (Figure 1-1) is discussed in this thesis.

1.1 Rationale for the study

The use of PD AFOs at Defence Medical Rehabilitation Centre (DMRC) Headley Court has grown organically since 2014, as the clinical need for a high activity AFO was necessary to assist the young limb salvage population emerging at this time. Improving the functional capability of this injured cohort served in persuading both personnel and medics that elective amputation was not the only option for severely injured limb salvage patients to lead an active lifestyle without significant pain.

1.2 The study objectives

The objective of this study was to evaluate how injured participants, who sustained deck-slap injuries (calcaneal, talus and distal end of tibia complex fractures) whilst serving in Afghanistan, walked both with and without their prescribed PD AFO. Participants walking with the PD AFO were also compared to a military specific able-bodied control group. A further objective was to evaluate the participants' validated patient reported outcome measures (PROMs) used to measure quality of life pre and post provision of a PD AFO and associated rehabilitation.

1.3 Structure of the thesis

This thesis is set out in five chapters in addition to this chapter.

Chapter 2 will review the existing literature related to conflict injuries, in particular deck-slap injuries caused by IED blast trauma. It will discuss limb salvage, and review the literature surrounding the clinical outcomes of both salvage and amputation. It will progress onto discuss orthotic intervention for deck slap injuries to improve clinical outcomes, with a focus on PD AFO design used to treat this participant group.

The method of data collection and biomechanical analysis will be described in Chapter 3, whilst Chapter 4 will present the three-dimensional (3D) gait analysis and PROMs results. Chapter 5 will discuss these results focused around 4 hypotheses and present a summary of the study highlighting limitations and suggestions for future research considerations in this area. Chapter 6 provides all appendices and references.

Chapter 2: Literature review

This literature review begins by discussing combat injuries in recent conflicts and considers the factors that have led to a rise in complex limb salvage within the military. The review explores the true complexity of blast trauma and why the clinical need for advanced orthoses capable of allowing users a higher level of activity has grown. It will discuss conventional orthotic solutions for the traumatically injured limb and present the background underpinning how the use of passive dynamic ankle foot orthoses (PD AFO) within the injured military community has strived to improve pain and functional outcomes. PD AFOs provide a potential solution for injured personnel to engage in a more active lifestyle and ultimately avoid elective amputation where possible.

2.1 Combat injuries spanning the 20th and 21st century

Since World War 1 (WW1), explosive weapons and fragmentation devices have accounted for over 70% of all deaths and injuries to combatants in conflict[26]. Survivability from battlefield injuries has increased from 70% in World War 2 (WW2) to 89% more recently in Iraq[26]. This has been attributed to a number of factors including improved body armour that protects the torso, along with modern medical resuscitative strategies and shorter casualty evacuation times[27]. Therefore, a greater number of critically injured casualties are surviving to reach field hospitals within war zones[27].

The conflict in Afghanistan started in 2001 as a counter insurgency operation, which continued as such throughout the conflict[28]. In contrast, UK operations in Iraq started in 2003 as conventional warfare against a well organised army, but evolved into counter insurgency measures against irregular forces[29]. This shift from conventional to asymmetric warfare and insurgency changed the weapons used by those forces opposing the coalition, and the types of wounds British personnel sustained[30]. However, despite the significant differences in the type of conflicts and weapons used, the pattern of wounding to the body remains largely unchanged[29]. Typically, head and neck injuries account for one fifth of all injuries sustained, and unprotected extremities account for 68% of all injuries, a

percentage consistent with battlefield injuries sustained since world war 2[29]. Injuries to the torso, however, do appear to have decreased following the introduction of combat armour in the 1970s[29].

Specific data on all injuries sustained by UK personnel in Afghanistan (Operation Herrick) has been published by the Ministry of Defence (MOD)[31] . In total 7,800 individuals were admitted into the UK's field hospital in Afghanistan between April 2006 and November 2014. Of all admissions 4220 were the result of injures (50% battle injuries and 50% not related to conflict) and 3,347 of natural causes. The patients were a mix of personnel and Afghanistan civilians. The report states that, of the 10,371 injuries treated at the hospital, 44% were to the extremities, with 27% respectively to the lower limb. The number of injuries to the lower extremities is less than previously documented in the literature[1; 29] and this may be due to the fact the hospital data also involved the local civilian population.

It has been reported that, of the lower limb injuries sustained, one third were fractures, with 82% reported as open fractures[3; 26]. Mortality from isolated combat extremity injuries was 10%[3]. Therefore, these lower limb blast injuries are not typically life threatening to personnel but are a source of on-going morbidity.

2.1.1 The growth of improvised explosive devices (IEDs)

Counter insurgency combat in Iraq and Afghanistan was plagued by the insurgents' signature weapons, the improvised explosive device (IED) and anti-vehicle mine (AVM) [1-7], which caused 60% of all injuries sustained[1].

This thesis focuses on the effects of IEDs and AVMs used against military vehicles, as this was the mechanism of injury of all participants within this study.

The United Nations defines an IED as a bomb fabricated in an improvised manner incorporating destructive, lethal, noxious, pyrotechnic, or incendiary chemicals[32]. IEDs are triggered by a variety of means such as remote control,

infrared or magnetic triggers, trip wires or pressure-sensitive plates as shown in (Figure 2-1).

Explosions that occur in an enclosed space, such as inside an armoured, vehicle are associated with a higher incidence of primary blast lung injury and burns[33]. This environment is more likely to lead to severe injuries when compared to open air explosions[34]. Explosions to personnel whilst in a enclosed space cause the highest number of severe injuries and casualties requiring surgical intervention[35]. Furthermore, the incidence of lower limb injury in enclosed spaces is 81% compared with 52% in open spaces[33]. Standing passengers within armed vehicles suffer more severe foot and ankle injuries, higher amputation rates and poorer return to work rates than seated passengers[28]

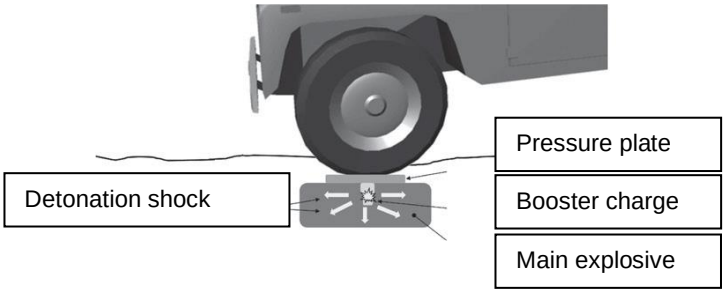

Figure 2-1 IED triggered by vehicle upon pressure plate[33]

2.2 Blast injury classification

IEDs have a significant demoralising effect on our nation's service personnel as they are a source of inflicting life changing injuries on personnel and causing devastating damage to much needed military equipment[36]. The blast injury wounds they cause are classified according to the mechanism by which they are produced, and their effect on the skeletal system[26].

Primary blast injuries are caused by the pressure waves from the explosive which pass through the victim[30]. This leads to cellular disruption, soft tissue destruction and bone micro fractures[26].

Secondary blast injuries are caused by projectiles, and can be subdivided into primary and secondary fragmentation[26]. Primary fragmentation is from the IED

weapon itself, such as metal nails that were placed within it. Secondary fragmentation, however, is generated from the environment, such as rocks or automobile parts [20; 26; 30]. Secondary fragmentation increases the risk of infection, both short and long term, as the environmental fragments can contaminate the wound[3; 26; 30; 37; 38].

Tertiary blast injuries occur as a result of the bodily displacement of the occupant or impact against a solid structure[26]. Tertiary blast effects cause the most significant injuries in an under vehicle IED/AVM explosion, accounting for 96% of all injuries [20; 33]. The injuries sustained are very similar to those seen ordinarily in civilian blunt trauma. Severe axial loading of the lower limbs from underfloor explosions[2; 20; 26; 30; 33; 39], or being thrown by the explosion and landing on the feet, typically result in calcaneal fractures[26].

2.2.1 Fracture classifications

A fracture, as defined by the Oxford dictionary, is a crack or break in a hard object or material, typically a bone[40]. Fractures of the bone can be categorised as displaced, non-displaced, open or closed[41]. Displaced and non-displaced fractures refer to the way in which the bone breaks. In a displaced fracture, the bone snaps into two or more parts and moves, so that the two ends are not aligned[41]. In a non-displaced fracture, the bone cracks either part or all of the way through, but does not move and maintains its correct alignment[41]. A closed fracture is when the bone breaks, but there is no puncture or open wound to the skin[41]. An open fracture is one in which the bone breaks through the skin, even though it may recede back into the wound and not be visible through the skin[41]. If the bone is in many pieces, it is called a comminuted fracture[41], which is complex to treat and is the most common type seen in blast trauma[2; 3; 26; 39].

The Gustilo-Anderson open fracture classification system is the most commonly used classification system for open fractures[3; 38]. It was created by Ramon Gustilo and Anderson in 1976[42]. Gustilo et al.[43] subsequently modified their classification system into its current form in 1984, as seen in (Table 2-1).

Table 2-1 The modified Gustilo-Anderson classification[41]

I	A fracture with a clean laceration <1cm in length, caused by low velocity trauma and minimal contamination.
II	A fracture with a laceration > 1cm in length lacking any severe soft tissue damage or devitalised tissue.
IIIA	A fracture with extensive soft tissue loss. Adequate coverage of fracture by soft tissue despite extensive cutaneous laceration or flaps, or high energy trauma regardless of the size of the wound.
IIIB	More extensive injury and contamination of the soft tissue, periosteal stripping, and soft tissue gaps present with exposed bone, will likely require either local soft tissue flap or free flap for coverage.
IIIC	Any open fracture with an arterial injury requiring repair regardless of degree of soft tissue disruption.

The Gustilo-Anderson classification system provides a framework, guides treatment and facilitates communication regarding fractures[44]. IIIB and IIIC classifications are the most severe open fractures and are commonly associated with blast trauma [2; 3].

2.3 IED blast injuries: the scale of lower extremity injuries

In Iraq and Afghanistan, IEDs were the leading cause of death among all nations' troops operating in this region from 2001-2014[21].

The US joint theatre trauma registry has recorded all injuries to coalition forces sustained during these conflicts and it estimates 29,941 injuries have occurred to 10,989 personnel in total (excluding fatalities). Specifically highlighting foot and ankle injuries, the report outlines that there were 298 dislocations, 701 crush injuries, 1089 open wounds and 336 partial foot amputations[30]. Disappointingly, this study does not discuss the number of fractures sustained.

Owens et al.[7] describe battle injuries sustained by US military personnel by evaluating a cohort of battle injuries from October 2001-January 2005 in both Iraq and Afghanistan. IED blast injuries were the most prevalent mechanism of injury, representing 36%, followed by gunshot wounds at 16% [7; 30]. Extremity injuries to at least one limb accounted for 82% of all injuries, 22% of which damaged the foot and ankle complex. Of these foot and ankle injuries

sustained, 76% were open fractures [7; 30], the Gustilo-Anderson classification of these fractures was not reported. This study clearly highlights the particular risk IEDs present to the foot and ankle complex of all military forces operating in counter insurgency style conflict.

IED injuries are not only reserved to military personnel; civilians also sustain injury in warfare and at the hands of terrorist activity. Frykberg et al.[45] report that out of 220 terrorist incidents from across the world, 85% of 3357 casualties required surgery from soft tissue extremity injuries, with or without fractures. Similarly, the risks to the foot and ankle remain high, as civilians are twice as likely to injure their lower limbs in a landmine blast compared to any other part of the body[36; 46]. Whilst this research study is very much military focussed, the same injury patterns can be seen in a general population and therefore the results of the study may be translatable to civilian rehabilitation.

2.3.1 IED blast trauma: foot and ankle injuries

Hindfoot and ankle fractures pose a challenge to orthopaedic surgeons, as fractures caused by high energy transfer are complex, and although seen in civilian trauma they are not observed as frequently[47]. Modern day sophisticated IED's have led to increased numbers of calcaneal fractures that are substantially more comminuted, open and with significant soft-tissue injury [39].

Over the 11 years of conflict in Iraq and Afghanistan, 114 UK personnel sustained 134 hindfoot injuries[47]. The calcaneus was the most frequently injured bone and occurred in isolation in 48% of cases (Table 2-2). The Gustilo-Anderson classification was not published in this study.

Table 2-2 Injury pattern by bone[47]. Personnel with isolated fractures of the tibial plafond, tarsals and metatarsals were not included in this analysis.

Fracture	Total number of British personnel (%)	Number of fractures that were isolated (%)
Calcaneus	116 (87)	64 (48)
Talus	38 (28)	11 (8)
Coexisting tibial plafond	33 (25)	-
Coexisting tarsal	61 (46)	-
Coexisting metatarsal	53 (40)	-

2.3.1.1 IED blast trauma: calcaneal fractures

McKay's cadaveric modelling of blast injuries found that the calcaneus tends to fracture first with an underfoot compressive load[48]. Yoganandan et al.[49] concluded that loads at approximately 8 times body weight (greater than 6.2kN) were sufficient to cause intra-articular calcaneal fractures in 50% of clinical cases[49]. Calcaneal alignment, as one third of the foot tripod, is critical to maintain appropriate length, width, and height to allow for near normal shoe wear and gait[50].

From March 2003 to August 2010, 583 US military personnel sustained a calcaneal fracture during both the Afghanistan and Iraq conflict[38]. Of those injured 102 sustained an open fracture, 45% of which had a Gustilo and Anderson classification of IIB or IIC with the type of fracture unspecified. Of the open fractures sustained 65% occurred whilst inside a military vehicle[38]. The most commonly associated fracture after the calcaneus was the talus, occurring in 48%, and the tibia in 43% of personnel. A quarter of those injured had bilateral fracture patterns.

This hindfoot (typically calcaneal) fracture pattern caused by under vehicle IED blasts is colloquially referred to within the military as a deck-slap injury[39]. Recent conflicts in Iraq and Afghanistan have seen a resurgence of deck-slap injuries to the foot, which have not been described on such a large scale since WW2[39]. Therefore, understanding this mechanism of injury and the consequent injury patterns is vital to understanding the clinical complexities surrounding the clinical treatment of these personnel.

2.4 History of deck-slap injuries

Military surgeons first described “deck-slap” injuries during WW2, as the use of highly explosive mines increased dramatically throughout this period, both at sea and during ground combat[39]. For the first time in history, multiple combatant nations possessed large fleets of steel ships and submarines[39] and, equally, the weaponry to disable these large structures. Below deck explosions caused force to be transmitted across rigid steel decks into the lower extremities of the sailors above[39; 51].

Keating in 1944 quoted, *“the deck rose suddenly beneath the feet of those injured, and the force transmitted upwards through the skeleton produced a series of injuries including fractures of the os calcis, tibia and knee. Compression fractures of the lumbar and thoracic vertebral bodies sometimes occur”*[52].

A British Surgeon, Brigadier General Rowley Bristow, during WW2 noted, *“Fractures of the os calcis are more common than in peacetime. They are produced by landmines, by a bomb which goes off between decks, and have occurred also in men who slide down the side of a sinking ship and hit their heels against the projecting bilge on the hull”*[53].

Barr et al.[54] confirmed these findings in the US, concluding that 30% of US naval casualties from mine attacks during the Normandy invasions sustained a fractured calcaneus[2].

2.4.1 Modern day deck-slap injuries

In recent conflicts the deflection of the military vehicle floor caused by an IED explosion mirrors that of the maritime deck deflection reported in WW2[2]. As the consequential injury is similar, hindfoot fractures sustained in this manner are referred to as deck-slap injuries.

Ramasamy et al.[2] reported on 40 deck-slap calcaneal fractures sustained by British personnel between January 2006 and December 2008. He found that 83% had subtalar joint compromise, 68% calcaneocuboid joint injuries and 63%

of personnel had injuries to both joints[2]. Of the injured in this UK study, 52.5% suffered a midfoot injury and 27.5% a forefoot injury at the same time as the calcaneal fracture[2]. Only 10% had a calcaneal fracture in isolation[2]. Additionally, the tibia was also fractured in 67.5% of British personnel, demonstrating that deck-slap injury patterns span multiple bones and joint articulations; therefore they are of particular concern[2]. In this study 58% had an open fracture documented as either IIIB or IIIC, with the IIC fractures faring worst, with 91.7% necessitating immediate amputation.

2.4.1.1 Associated spinal fractures

In the UK, between January 2006 and December 2008, 30% of personnel sustained a spinal fracture following deck-slap injury[2]. The incidence of spinal injury is similar to the 21% reported in people who have fallen greater than two storeys from a building[55]. Therefore, patients who clinically present with deck-slap injuries have an increased risk of spinal fractures, which further complicates their rehabilitation and recovery. Of the 12 participants in this study 2 suffered a spinal fracture following deckslap injury.

2.5 Deck-slap: anatomy of the foot

Deck-slap injuries most commonly injure the hindfoot and the distal end of the tibia [2; 20; 30]. Injuries to the calcaneus are associated with the highest complication rate [56; 57].

The functional transverse subdivisions of the normal pedal skeleton are divided, based on functional and clinical criteria as follows[58].

- Hindfoot (calcaneus and talus)
- Midfoot (cuboid, navicular, three cuneiforms and five metatarsals)
- Forefoot (proximal, middle and distal phalanges)

Blast injuries are not easy to predict, and often all transverse subdivisions of the foot are injured. This thesis will predominantly discuss the functional hindfoot in relation to deck-slap injuries.

When the calcaneus and talus are disrupted following a blast injury (Figure 2-2), the shape of the hindfoot bones are severely distorted and compromised. Bony outgrowth and fragmentation often occur with healing (Figures 2-3, 2-4). As the calcaneus and talus are integral to weight bearing, damage to these bones causes significant immediate disability. The talus has only a limited area of penetrable bone available for vascular perforation. This feature, combined with small nutrient vessels, variations in intraosseous anastomoses and a lack of collateral circulation, predispose the talus to osteonecrosis when its vascular supply is disturbed[50]. This is particularly problematic after fracture or dislocation due to impact[50].

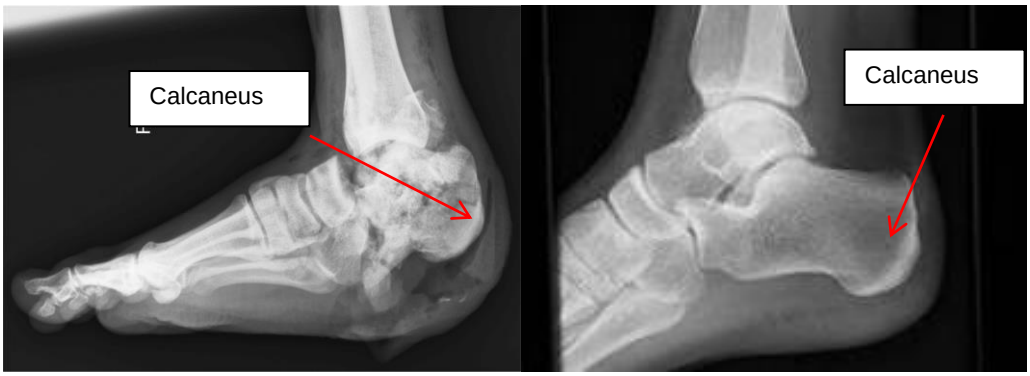

Figure 2-2 Left: X-ray of a highly comminuted calcaneal fracture following IED deck-slap blast. Right: X-ray of a normal hindfoot[2]

Function is severely compromised when a blast displaces hindfoot skeletal anatomy, as the calcaneus and talus are integral to both the subtalar and talocrural joints[59; 60].

2.5.1 Subtalar and talocrural joints

Ordinarily the talocrural and subtalar joints are the pivot between the calcaneus and the tibia, which share a mechanical coupling relationship via the talus. Therefore, movements of the calcaneus can contribute to movement of the tibia, for example inversion of the calcaneus by 20^{o} results in external tibial rotation of the tibia by 10^{o} during closed chain movement[61].

Traditionally the subtalar joint was described as an individual torque absorber, and the ankle as a hinge which only delivers sagittal motion[62]. However, the

work of Lundgren et al.[63] has since shown that the talocrural and subtalar joints work together in tandem to provide frontal and transverse motion in the foot, demonstrating a complex coupling relationship[63].

Damage, therefore, to any of the bones that form these important joints will most certainly affect the functional capability of the lower limb, in particular dorsiflexion/plantarflexion of the ankle joint and inversion/eversion of the subtalar joint. Intra articular bone loss from the calcaneus resulting from blast injuries frequently require subtalar joint fusion[50]. It can prove very difficult restoring the talocalcaneal relationship following a calcaneal mal union. Therefore, patients with a displaced calcaneal fracture may derive better long-term results from subtalar joint fusion[64]. Although reliable rates have not been published, the prevalence of patients subsequently undergoing a subtalar arthrodesis post severe calcaneal fracture is reported as high [65-67].

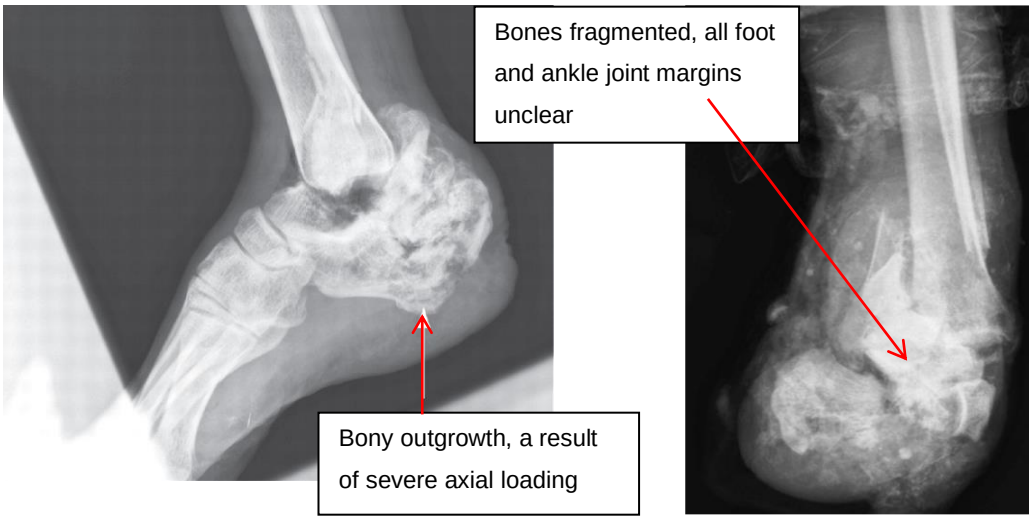

Figure 2-3 Comminuted fractured calcaneus, caused by primary and secondary blast mechanism[26].

Figure 2-4 Complex lower limb injury of 29 bones following IED blast[26]

2.5.2 Deck-slap: soft tissue disruption

Often the most significant muscle group disrupted as a result of a deck-slap injury is the Triceps Surae, as it inserts into the calcaneus through the Achilles tendon[2]. Damage to the structure of the calcaneus affects the ability of the Triceps Surae to provide active ankle plantarflexion, knee flexion and controlled

shank inclination in gait[60; 68]. The deep fascia of the foot forms the plantar aponeurosis that extends from the calcaneus bone to the phalanges of the toes[60]. The plantar fascia provides shock absorption and supports the longitudinal arch, as well as enclosing the flexor tendons of the foot[60; 68]. Significant disruption to the calcaneus can damage the fibrous tissues of the plantar fascia. All structures (plantar aponeurosis, long/short plantar ligament and spring ligament) that support the medial longitudinal arch insert into the calcaneus[69]. Additionally, the short plantar ligament attaches directly to the calcaneus[60; 68], therefore the lateral arch can also be disrupted as a direct result of deck-slap blast trauma.

The plantaris, extensor/flexor digitorum brevis, abductor hallucis/digiti minimi, quadratus plantae and perineal retinaculum muscles can also be disrupted, as they too insert into the calcaneus and primarily control movement of the toes and prevent peroneal subluxation[68].

Disruption to bone, nerves and soft tissue within the foot and ankle has a profound effect on gait. In understanding gait, the convention described by Perry et al.[70], ensures a consistent approach is undertaken.

2.5.2.1 Normal gait

Human locomotion involves smooth advancement of the human body through space with the least mechanical and physiological energy expenditure[71; 72]. It is the mechanism by which the human body is transported using coordinated and complex systematic and symmetric actions[71]. Human locomotion is typified by several events which occur in a rhythmic and repetitive pattern[73].

The gait cycle (GC) is the period of time between any two identical events in the walking cycle. Any identical event could be selected as the start of the GC because the various events follow each other repeatedly and smoothly. In most text, the preferred start and end point of each GC is initial contact[70; 73]. The stance phase, on average, accounts for 62% of the gait cycle at normal walking speed[74]

Each GC is divided into two phases[70],

1. Stance Phase - The period of which the foot is in contact with the ground
2. Swing Phase - The period of which the foot is off the ground and travelling in a forward motion.

Perry further divides the GC according to three functional tasks; weight acceptance, single limb support and limb advancement. These are further divided into 8 gait events as shown in (Figure 2-5).

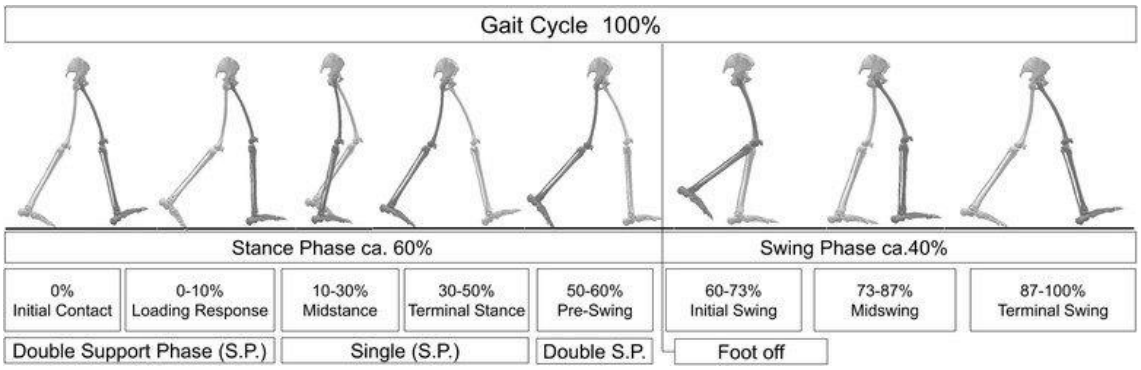

Figure 2-5 Classification of a normal gait cycle as classified by Perry et al[70]

Although almost all books on clinical gait analysis advocate Perry's sub-division of the GC[75; 76], there are some problems associated with it. For example, initial contact is clearly an instant and not a phase, and using the terminology mid stance is misleading as this event does not occur in the middle of stance[77]. Despite its' limitations, this thesis will use this widely understood terminology whilst discussing all gait events.

2.5.3 The effect of deck-slap injuries on walking

Injured personnel typically display an antalgic gait pattern with a lack of pre swing push off and propulsion in gait as a result of deck-slap injuries[5; 78]. As the primary ankle dorsiflexors, such as tibialis anterior, originate proximally on the tibia and insert into the first metatarsal and the first cuneiform, they are less likely to be damaged as part of a deck-slap injury. Typically deck slap fractures are focally at the hind foot[2]. Anecdotally deck slap injured personnel walk with reduced speed and a shortened stride length on the injured side. The injured

limb spends more time in swing phase than stance phase to put as little weight through the injured limb as possible. The injured foot and ankle joint appear stiff, and lower limb muscle weakness is evident due to deconditioning. Often increased knee flexion is visible throughout stance phase with a lack of pre swing hip extension, and reduced motion in the torso and upper limbs as the patient braces before each step.

The precise cause of the lack of push off and propulsion seen in those with deck slap injuries is difficult to truly ascertain. Increasingly experts have concluded that much of what was thought to be understood about propulsion is oversimplified or simply incorrect[79]. Ankle propulsion in gait has always conventionally been discussed as an event that starts at pre-swing and is primarily due to triceps surae activity However Chen et al.[80] disagrees with this theory. Chen attributes more importance to the events which occur during loading response[80]. During loading response, the heel lever forces the foot to the floor and the shank is pulled forward from a reclined position to a vertical position. This motion appears to be propulsive.

Baker[81] has concluded that when focusing on just the limb in order to categorically answer this question, it would require some form of induced acceleration analysis to ascertain what muscles are acting to accelerate the segments. Until such times this can be determined, all that can be exemplified is that during the transition from stance to swing the limb is both pushed forwards by the action of the plantar flexors pushing the plantar foot against the ground and pulled forwards at the thigh by the hip flexors[81].

The triceps surae supports the body while it translates over the ankle joint, restraining it from falling[82]. Damage therefore grossly affects lower limb stability and alignment; during single support on the injured side as, if weak, the knee and hip will adopt an increased flexed position. Honeine et al.[82] have shown triceps surae is not solely responsible for the generation of propulsion in gait directly. However, it seems plausible that damage to the triceps surae could compromise gait propulsion as, indirectly, triceps surae activity controls step length and walking speed[82], factors which affect propulsion.

Additionally, damage to the medial longitudinal arch reduces stability in the foot during toe off, and does not enable the foot to engage any propulsive force generated throughout stance[69]. Damage to the articular joint surfaces of the subtalar and talocrural joints could lead to both a reduced range of plantarflexion and dorsiflexion in the ankle joint, and inversion/eversion in the subtalar joint[20]. This could have a profound effect on the position of the ground reaction force (GRF) throughout the gait cycle, leading to instability and inappropriate gait timing and inefficiency[83].

Deck slap injuries fall under a category of injuries that contribute to "limb salvage". Limb salvage is defined as the returning of a limb to a state of reasonable functionality after severe trauma that might otherwise result in amputation[84].

2.5.4 Limb salvage surgery

Acute management of the injured limb is undertaken to preserve and salvage bones, muscles, nerves, blood vessels and skin (Table 2-3)[3; 85]. Quick evacuation to hospital, application of a well-fitting tourniquet quickly and early, aggressive wound debridement and irrigation are the cornerstone of any effort to salvage a severe open extremity wound[86].

Table 2-3 Cornerstones of limb salvage surgery[3]

Debridement	Removes all non-viable tissue, and is essential in allowing the open wound to heal with reduced risk of infection[50].
Soft tissue injury	The magnitude of soft tissue injury present dictates if limb salvage is possible, and is more significant in determining this compared to bony injury or loss[50].
Blood flow	Restoring blood flow is the initial primary concern in theatre. The arterial tree must be repaired or reconstructed promptly to ensure appropriate revascularisation of the injury site[85]. Failure to perform prompt repair leads to almost inevitable future amputation.[3; 85; 87]
Bone	All dysvascular and non-articular bone is removed before the wound is closed[50]. Once closed surgery to reconstruct and realign bones begins, as the area can tolerate the inflammatory response associated with surgery[87]. Diaphyseal loss to bone is salvaged using several techniques such as bone grafting, tissue transfer, and limb lengthening. Osseous loss, or loss of articular surfaces is more complex and often leads to distraction osteogenesis or fusion[50]. External fixation has been the treatment of choice by most surgeons in the management of open fractures[37]. The external fixator provides control of axial length, rotational and coronal alignment of the distal tibia, ankle and hindfoot[30]. [3; 85; 87]

Plantar soft tissue wounds to the foot are known to be a negative outcome predictor for limb salvage[88], tissue coverage is rarely sensate and is often not cosmetically appealing[85]. Skin grafts often change the shape of the foot and, as a result, shoe and orthosis fitting can be problematic. Muscles damaged by the blast cannot be replaced, and although surgeons can replace bulk and coverage or perform tendon transfers, it may not be possible to restore muscle function to pre-injury levels[85]. Repair, reconstruction and grafting of damaged nerves are possible; however the results are varied and rarely restore pre-injury function[85].

2.5.5 Risk of infection and amputation

Infection is always a risk of any surgery including limb salvage. However open fractures are associated with a higher incidence of infection; in particular those caused by IED blasts[2; 3; 21].

Deep tissue infection is reported in 10-39% of all combat open calcaneal fractures[38] in particular, with military wounds being more likely to be contaminated compared to civilian wounds, despite antibiotic use[37]. Quick administration of antibiotics has a significant beneficial influence on the incidence of infection[89]. Collective reports confirm that most military blast wounds are heavily contaminated with 3-4 different species of bacteria as compared with only one species found in most civilian wounds[42; 90; 91]. The rate of infection in the salvaged limb with specific deck-slap injuries is 42%, with studies reporting osteomyelitis in 13% of deck slap open fractures[2]. This leads to personnel experiencing foot and ankle pain, swelling and tenderness, which makes rehabilitation difficult.

The natural history of open calcaneal fractures often includes infection and amputation[38]. The overall amputation rate for combat casualties following an open hindfoot fracture is 42%[38], with civilian studies reporting between 7.1% and 22%[92]. Dickens et al.[38] in the US report that 18% of amputations due to blast trauma were performed immediately at the field hospital with 15.4% performed within 24 hours, and 27% between 24 hours to 12 weeks post injury.

Ramasamy et al.[20] in the UK report on amputation rates due to deck slap injuries. Of the personnel in the study 45% had an amputation post injury and 61% of those limbs amputated were considered unsalvageable and were amputated at the field hospital in Afghanistan. A delayed amputation for chronic pain (mean, 19.5 months post injury) was required for 10% of the personnel in the study.

2.6 Financial implications of trauma

Major trauma is a serious public health problem; it is the leading cause of death in all groups under 45 years of age and a significant cause of short and long-term morbidity[93]. The National Audit Office (NAO) estimate that there are at least 20,000 cases of major trauma each year in England resulting in 5,400 deaths and many others resulting in permanent disabilities requiring long-term care[93].

The NAO estimate that trauma costs the National Health Service (NHS) between £0.3 and £0.4 billion a year in immediate treatment[93]. This does not include the cost of any subsequent hospital treatments, rehabilitation, home care support, or informal carers. In addition, the NAO estimate that the annual lost economic output as a result of major trauma is between £3.3 billion and £3.7 billion[94].

The cost of limb salvage to the UK military has not been published. However, Edwards et al.[95] estimates that the 40-year cost of the UK Afghanistan lower limb amputee cohort is £288 million. This figure estimates the cost of trauma care, rehabilitation and prostheses. Financially, the cost of trauma care and ongoing rehabilitation, and equipment for injured personnel from the Iraq and Afghanistan conflicts is significantly high and will be for generations.

2.6.1 Cost of limb salvage vs amputation

The most recent cost/benefit analysis demonstrates equal 2 year costs between limb salvage and amputation[96]. However, a 3 fold differential exists for the lifetime cost of the amputee group due to the ongoing cost of prosthetic

componentry[96]. Chung et al.[97] in the US reports that the economic cost over 40 years of lower limb amputation is thought to be $350,465 compared to $133,704 for limb salvage surgery[97]. This is expected to increase as prosthetic limbs continue to technologically advance[87 95].

Economically, therefore, amputation has been shown to be the more costly solution long term for any treating health care service[96]. The decision to salvage or to amputate a limb is complex and multi-faceted and will be discussed in more detail later in this thesis.

2.7 Limb salvage rehabilitation

The British Society of Rehabilitation Medicine defines rehabilitation as the process of assessment, treatment and management with ongoing evaluation, by which the individual (and their family/carers) are supported to achieve their maximum potential for physical, cognitive, social and psychological function, participation in society, and quality of living[98]. Rehabilitation of the limb salvage patient is a series of treatments designed to facilitate the process of recovery from injury, to as optimal a condition as possible. Without such input, patients are unlikely to return to their maximum levels of function, which has significant implications for them, their formal and informal carers, and society as a whole[99].

2.7.1 Stage one: early rehabilitation phase in DMRC Headley Court

Basic principles of physically rehabilitating a salvaged limb begin with as early mobilisation as possible[3], in line with standard treatment protocols at DMRC Headley Court. Often the complexity of the injury requires the patient to be non-weight bearing for a considerable period of time, commonly between 6-12 weeks[100]. During this period of non-weight bearing, the injured patients' physiotherapist is concerned with maintaining joint mobility, muscle strength and conditioning, sitting balance and training transfers as well as treatments with non-weight-bearing conditions, such as hydrotherapy (dependant on wound healing)[101].

The occupational therapist advises on bed posture, mattress types, aids for independent daily self-care, wheelchair-dependency training and meaningful activities that can be performed while wheelchair dependant[101]. The interdisciplinary team also pay close attention to wound and scar management to promote healing, in addition to psychological support.

Occasionally following injury or surgery, nerves can be disrupted which can lead to the skin becoming hypersensitive to touch. This is treated in therapy with desensitisation[102] to re-educate the skin to tolerate both texture and pressure. Nerve damage can also lead to the foot being insensate[69], therefore the patient could also be at risk of developing pressure sores as a result. As part of rehabilitation, the patient is educated to self-manage this as much as possible under the watchful eyes of the clinical team. Preventative strategies, such as using pressure relieving mattresses, are utilised when needed. More proximal joints, that may be minimally affected by the original injury, will require early range of motion exercises to prevent contractures through disuse and development of frozen joints[3]. Cardiovascular exercise can also be undertaken whilst non-weight bearing by utilising static hand bikes or weights. This improves blood flow, which in turn improves the flow of oxygen and the release of cortisone, which is thought to improve wound healing[103].

2.7.2 Stage two rehabilitation in DMRC Headley Court

Typically, after 6-12 weeks, the patient will begin partial or touch weight bearing, as sanctioned by their orthopaedic surgeon, dependant on healing. This can be referred to as the second stage of physical rehabilitation[101]. The patient is advised to only allow reduced weight through the injured side, and this is self-managed by the patient using bilateral crutches. During this period the patient can begin using equipment like the anti-gravity treadmill[104]. This treadmill allows for mobilisation without crutches and promotes natural gait patterning which aids the re-education of gait post injury[105]. Once the orthopaedic surgeon deems the injury healed (typically after 12 weeks post injury) the patient may progress to full weight bearing[100]. At this time, they begin working on more functional physical rehabilitation (Figure 2-6). This also includes negotiating

stairs and uneven terrain. Occupational therapy becomes more vocationally driven[101].

Figure 2-6 Patients undergoing group rehabilitation (Source: Image taken by MDT team at DMRC Headley Court)

2.7.3 Stage three: rehabilitation for high activity in DMRC Headley Court

The last phase of physical rehabilitation involves working on high activity tasks, if deemed clinically appropriate, such as returning to sports (Figure 2-7). A programme based on plyometric techniques[106] is undertaken to achieve this. Patients who have undergone limb salvage require the same running rehabilitation as amputees to maximise their potential and avoid further injury.

Figure 2-7 Example of study participant running as part of rehabilitation at DMRC Headley Court. (Source: Daily Express 14th Feb 2016[107])

In a civilian setting rehabilitation services do differ nationally, and often amputees receive greater access and therapy time in comparison to the limb salvage patient[14; 108; 109]. The NHS Clinical Advisory Group recommend that improving rehabilitation should specifically be given more priority, and rehabilitation is one of the biggest considerations informing trauma care pathway redesign[98; 110].

2.8 Limb salvage vs. amputation: the dilemma

One of the most difficult challenges that both medics and patients with severe lower extremity injury face is the decision on whether to amputate or to attempt/continue with limb salvage. At the centre of the decision is the patient, and the focus should be on that individual's expected functional outcome, and ability to return to employment and family life as soon as possible. This debate has generated much controversy in the literature with studies supporting advantages of both approaches[6; 85; 109; 111]. Many scoring systems have been developed to try to assist surgeons with this complex decision-making process, through predicting the likelihood of salvage success.

2.8.1 Limb salvage scoring systems

Scoring systems have been developed retrospectively by analysing large databases to try to identify factors that might predict the need for an amputation (Table 2-4). Each scoring system has a critical score that, once reached, indicates that the patient would be best served with a primary amputation. A summary of 5 limb salvage scoring systems that have been developed are found below.

Table 2-4 Limb salvage scoring systems

1985	Mangled Extremity Syndrome Index (MESI)[112]	First reported scoring system Never widely used as deemed too complex and includes the upper limb[3]
1987	Predictive Salvage Index (PSI)[113]	Determined limb survival was related to warm ischemia time, the level of arterial injury and the muscle and bone injury Definitions of each grade were not given, thus it has never been widely used[3]
1990	Mangled Extremity Severity Score (MESS)[114]	Determined that patients with sciatic or posterior tibial nerve disruption were most likely to require amputation Is the most commonly used in clinical practice [115]
1991	Limb Salvage Index (LSI)[116]	Concluded a Gustilo IIIC injury with a nerve injury is an absolute indication for amputation Not utilised in clinical practice as requires very detailed documentation and examination, which makes it practically difficult in a busy clinical setting
1994	Nerve, ischemia, soft tissue, skeletal, shock and age (NISSA) score[117]	The authors included nerve injury, but separated out the skeletal and soft tissue components of the MESS It has been reported that these modifications improved the sensitivity of this score from 63% to 81%. This score is used in clinical practice.

The Lower Extremity Assessment Project (LEAP) conducted the largest study to date, evaluating the 5-limb salvage scoring systems prospectively across 556 injured limbs. It concluded that a low score on each was predictive of limb salvage. However, a high score did not necessarily predict the need for amputation using any of the scoring systems[8].

No scoring system has produced repeatable, reliable results when used to analyse retrospective patient cohorts[118; 119]. Therefore, at this time there is no scoring system that can be applied with confidence to determine if it is best to amputate or salvage severely injured limbs to gain the best clinical outcome.

These scoring systems do, however, give medics a thought process which can aid in the decision-making process, and provide a common language to report and communicate complex clinical information.

2.9 Introduction to limb salvage clinical outcomes

Functional and physical outcomes are poor for patients who have suffered traumatic injury to the lower limb and have undergone salvage reconstruction[6; 16; 20; 120]. Limb salvage in the early stages of rehabilitation places a greater burden on the patient due to prolonged stays in hospitals, greater numbers of surgical procedures and a delay to initial rehabilitation compared to amputation[121]. The clinical outcomes that limb salvage patients experience are important to understand, as the most common reason for desiring a late amputation is on-going pain and dissatisfaction with the function of the salvaged limb[122].

When comparing clinical outcomes in both civilian and military populations, most studies have compared patients' functional, psychosocial and pain outcomes, as well as their ability to return to employment post injury. Surgeons clinically would define a poor clinical outcome[28] as:

1. Persistent chronic infection (osteomyelitis or wound infection) 12 months after injury
2. Delayed fracture healing more than 12 months after injury
3. Symptomatic post traumatic osteoarthritis[123]
4. The need for an amputation

There have only been a very small number of long-term studies evaluating the clinical outcomes of limb salvage patients in comparison to amputees[6; 8].

2.9.1 Clinical outcomes in civilian populations

The LEAP study was a multi-centre study of severe lower extremity trauma in the US civilian population between 1994 -1997. Functional outcomes were gathered at 2- and 7-year follow-ups for 601 patients. The LEAP Group found

no difference in functional or psychosocial outcomes at 2 years in 95% of patients who sustained high energy lower limb trauma treated with either limb salvage or amputation[120]. These outcomes persisted for at least 7 years post injury[124] and at both follow ups functional and psychosocial outcomes were rated as poor.

The LEAP study group also found that high pain intensity, sleep and rest dysfunction, elevated levels of depression and anxiety at 3 months post discharge were strong predictors of chronic pain at 7 years[125]. Chronic pain may partially explain the poor functional outcomes and low return to work rates[81, 82] as well as high levels of anxiety and depression[6] previously reported in this population. The civilian return to work rate is 40% at a mean 76 months post injury[92].

In 2009 Potter et al.[65] investigated the long-term functional outcomes after operative treatment for intra-articular fractures of the calcaneus in civilian trauma. Validated functional questionnaires were completed by 73 patients on average 12.8 years after injury. The group were split into those who were injured from a fall and those who were injured in a road traffic accident (RTA). The group injured in an RTA had less favourable outcome scores compared to those injured in a fall[65]. However, the height of the fall was not documented, therefore it cannot be determined if this group sustained less energy transfer at the point of impact and thus the disparity in the results[65].

2.9.2 Clinical outcomes in US military population

The Military Extremity Trauma Amputation/Limb Salvage study (METALS)[6] was published in 2013 by the US military. It is the largest published study which reports on the outcomes of amputation versus limb salvage within military cohorts. This observational study presents the clinical outcomes of 324 personnel injured whilst serving in Iraq and Afghanistan on average 38.6 months (range, 6.8 to 69.7 months) post injury.

Overall, all participants reported moderate to high levels of disability, except for upper limb and hand function. The injured personnel scored significantly poorer

than population norms in the Short Musculoskeletal Function Assessment (SMFA) used to determine overall function. Both unilateral and bilateral amputees were deemed to have greater functional ability compared to unilateral limb salvage patients, although the differences were not always significant[6].

Amputees were 2.6 times more likely to engage in higher activity pursuits compared to limb salvage patients (Table 2-5), with only 38% of all personnel in the METALS study engaged in any kind of sports and recreational activity[6]. The barriers to this for limb salvage patients are not described in this study. Pain continues to interfere with 20% of all patients' daily activities, with the unilateral limb salvage group experiencing the highest level of daily pain[6] (Table 2-5).

Melcer et al.[14] similarly found that post injury amputees and limb salvage patients attend pain clinic appointments equivalently. However, as rehabilitation progresses, amputees typically attend pain clinics less often than limb salvage patients. Both studies appear to suggest on average the rate of pain experienced is higher in the limb salvage group[6; 14].

Table 2-5 METALS study clinical outcomes: Paffenbarger Physical Activity Questionnaire, The Revised Center for Epidemiologic Studies Depression Scale, Chronic Pain Grade Scale[6]

	All Patients	Unilateral Amputation	Unilateral Salvage	Bilateral Amputation	Amputation and Salvage	Bilateral Salvage
Number of participants	324	113	126	39	30	16
Engaged in vigorous sports or recreational activities %	38	45.1	26.2	48.7	50	31.2
Depressive symptoms %	38.3	40.7	43.6	25.6	23.3	37.5
Working/on active duty %	43.7	43.4	48	30.8	36.7	56.2
With pain interfering with daily activity %	19.9	17.1	27	10.3	16.7	12.5

The METALS study[6] reports that neither the amputation level nor the timing of amputation was significantly associated with the outcomes in the amputee group. This contradicts other studies [38 14; 122] which suggest delayed amputation

in the limb salvage patient leads to significantly more revision surgeries, prolonged infections, increased pain and higher rates of psychological diagnoses.

Whilst amputees and limb salvage patients appear to suffer from depression equally, amputees are significantly more likely to screen for post-traumatic stress syndrome (PTSD) comparatively[6]. Those who had delayed amputation and limb salvage have similar rates of PTSD and reported substance abuse, but the incidence of this significantly reduces in those amputated immediately post injury[14]. This would suggest delaying amputation has a significant effect on an individual's mental health.

A meta-analysis conducted by Busse and the orthopaedic trauma working group[17] state that generally if at 2 years post injury a limb salvage patient has not returned to work, the likelihood that they will is less than 50%[17]. These return to work rates are similar to those in the METALS study[6]. Although not statistically significant, METALS found limb salvage patients more likely to return to work compared to amputees. No study has presented the return to work rates linked to amputation level or defined the complex injuries of the limb salvage patient for comparison.

2.9.3 Clinical outcomes in UK military population

The UK military outcomes from blast trauma are as similarly poor as the US studies[2; 20; 28]. Ramasamy et al.[20] presented the outcomes of IED foot and ankle blast injuries in the UK between 2006-2008[20] (Figure 2-8). Nearly 3 years post injury, 74% of injured limbs had clinical symptoms requiring on going rehabilitation, surgical intervention and analgesia.

Poor clinical outcomes have been reported in 75% of patients with deck-slap injuries 3 years following injury[2]. Functional measures (such as the chronic pain grade scale) used in these studies are global in nature. Given that a substantial proportion of the patients in this study had bilateral injuries, the use of global scores makes it difficult to directly compare the limb salvage and amputee populations, unlike the US publications[20].

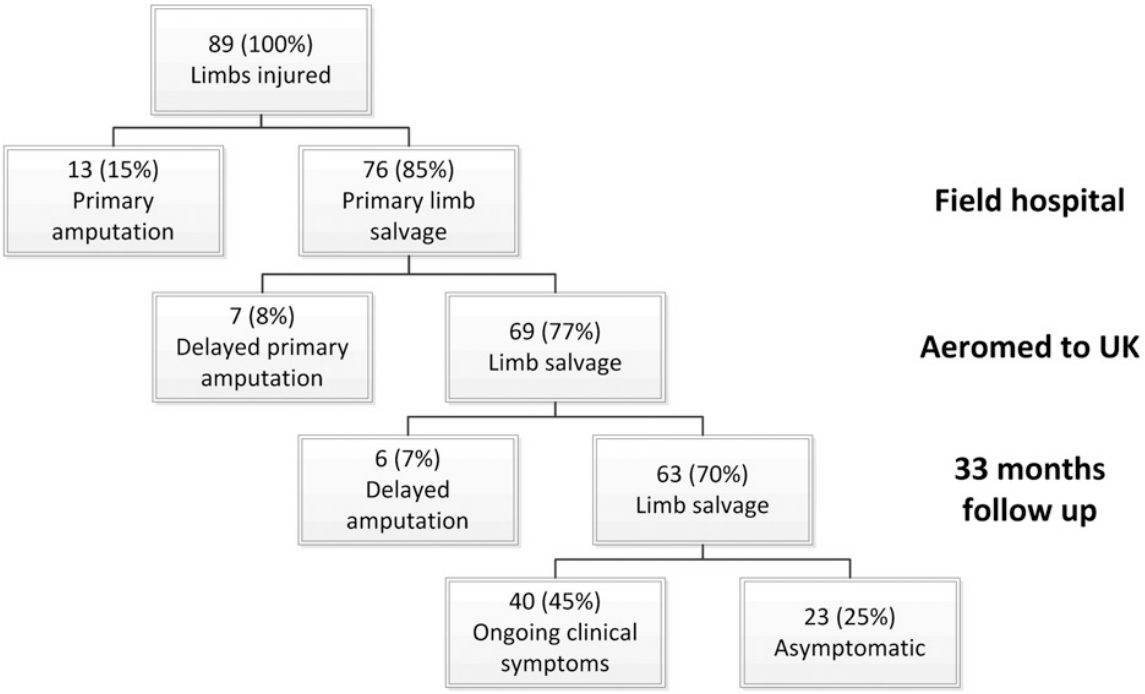

Figure 2-8 Flowchart depicting the outcomes of UK foot and ankle blast injuries[20]

In the same study, Ramasamy reported that only 14% of personnel who sustained a foot and ankle injury due to blast trauma were able to return to pre-injury occupational roles, which falls to 5% in those personnel with deck-slap injuries[2]. It is likely that the reduced return to work rates reported within the military are related not only to the severity of the injuries sustained, but also to the higher occupational demands placed upon active service personnel compared to civilians.

Ladlow et al.[15] found similar results to the METALS group: unilateral amputees have a functional advantage over limb salvage patients and delaying amputation has no bearing on functional ability[15]. However, Ladlow et al.[15] contradict Melcer et al.[14] as this UK study found mental health outcomes were comparable with general population norms[15].

In conclusion, the larger military studies conclude that, on average, three years post injury those treated with amputation appear to have better functional outcomes than those treated with limb salvage[6; 14; 15]. This contradicts the LEAP civilian study which concluded that the functional outcomes of amputees and limb salvage patients are the same at two years post injury[120]. The research

therefore suggests that the clinical and functional outcomes experienced by the limb salvage patients are sub-standard, particularly in military personnel injured by blast mechanisms. The evidence has therefore promoted elective amputation as a very credible option for patients with injuries similar to the participants in this study.

These poor limb salvage outcomes have anecdotally led to a call for advancements in orthotics to support lower-limb salvage patients eager to preserve their lower limb, yet function at high levels of mobility.

2.10 Orthotic treatment in the limb salvage patient

2.10.1 Conventional orthotic treatment for traumatic fractures

Orthotics is a specialty within the medical field concerned with the design, manufacture and application of externally applied devices onto the body[69; 126]. They are formally termed orthoses, but sometimes called splints or braces to lay people.

An orthosis is defined by the International Standards Organisation (ISO) as '*an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system*'[127].

The orthotist is the healthcare professional responsible for the design and provision of orthoses[126].

When traumatic blast injuries are sustained to the foot and ankle, the normal function of the skeletal and neuromuscular systems are disrupted. Orthoses can assist to improve pain, function and prevent further deformity to these systems post injury, to improve the injured patient's quality of life[69]. Fractures and dislocations resulting from blast trauma can be difficult to treat due to the involvement of osseous, soft tissue, vascular and nerve structures[3; 30].

It is important to recognise that many variations of injury can occur in blast trauma, therefore each patient must be thoroughly assessed as to their individual joint motion, sensation, strength and functional deficits[128] globally. It is

also important to understand that these injuries can cause long term morphological changes, so the need to review and reassess patients regularly is crucial and best practice[129].

2.10.2 Hindfoot fractures: morphological changes and body impairments

Morphological changes are often present post hindfoot fracture and orthoses can often assist as shown in (Table 2-6). The morphological change to the structure of the foot after trauma is often linked to body impairments, which influence function. Orthoses can be used to improve these functional deficits as a result of body impairments as outlined in (Table 2-7).

Table 2-6 Typical morphological changes seen in hindfoot blast trauma

Morphological Changes	Why this occurs	Problems this may present	Possible orthotic solution
Calcaneal Spur	Due to displacement of bone a single piece of sharp bone maybe present on the calcaneus[130].	This can be associated with pain if on the plantar surface, as it is directly loaded or rubs on footwear if posterior[130; 131]. Possible entrapment of the nerve to abductor digiti minimi causing heel pain[131]	Functional foot orthoses (FFO) [130; 132; 133] to redistribute planar pressure. Silicone heel pads to provide cushioning.[130; 134]
Incongruity of the subtalar joint	62% of all calcaneal fractures produce distortion in the subtalar joint as the articular surface is most likely compromised[130]. The blast injury can displace the subtalar joint. A varus deflection typically occurs in deck-slap injuries as most injuries are sustained whilst sitting[20] The hindfoot is therefore typically resting in a varus position at the point of impact[130]	Post-traumatic arthritis of the subtalar joint[135] leading to pain and discomfort. Reduced hindfoot shock absorbency- as subtalar joint range of motion into pronation maybe compromised[69] Compliance on uneven terrain, lack of subtalar joint pronation leads to a lack of flexibility within the midtarsal joint to accommodate for uneven terrain[69]. Excessive subtalar joint pronation, as a result of the talus shifting laterally[69] Propulsion, If the subtalar joint is restricted the coupling motion between the midtarsal joint is affected. The subtalar joint may not be able to supinate and subsequent locking of the midtarsal joint to generate a rigid lever for propulsion in terminal stance[59; 69; 136].	FFO's to improve shock absorbency using shock absorbing materials[69; 130]. FFO's to control velocity of pronation and redistribute planar pressure[69]. A semi flexible FFO can be used to reduce excessive over pronation[69; 130] FFO's allow normal plantarflexion of the first ray, stabilising the forefoot and improving the foot's ability to propel[69; 130]. A lateral forefoot wedge can also assist the transfer of weight onto the medial forefoot[128] in terminal stance for 3rd rocker. Immobilisation of the subtalar and midtarsal joint can help to reduce pain if arthritic. This can be achieved using an Ankle Foot Orthosis (AFO)[69; 137]. A rocker sole with a compensating heel elevator can be used[69] in combination with a carbon fibre Morton's extension plate[138] . This can help to facilitate late stance push off if FFO's are not effective in improving the midtarsal joints ability to provide a rigid forefoot lever for propulsion when subtalar supination is compromised.

Morphological Changes	Why this occurs	Problems this may present	Possible orthotic solution
Reduced height of the foot or leg.	Displacement of bone as well as the addition of metalwork post-surgical procedures, can lead to the foot or the limb being longer or shorter than before[130; 139].	Pelvic obliquity, low back pain, imbalance[140] and possible split size footwear.	Provide a shoe raise internally or externally to address the leg length discrepancy[69; 140]. Possible provision of a toe filler insole and rocker sole[130] if the foot length difference is significant to optimise shoe fitting and ensure 3rd rocker happens at the correct pivot point within the footwear.
Widening or narrowing of the calcaneus	The blast injury has displaced the bone possibly changing the width of the hindfoot	If a significant change it can be difficult to wear traditional footwear[130]	Provide custom or modular orthopaedic footwear to fit the abnormally shaped hindfoot[130]. Lowering the heel quarter of the shoe as the malleoli maybe in a different position[130]

Table 2-7 Typical body impairments seen in hindfoot blast trauma[130]

Body impairment	Why this has occurred	Orthotic solution	Effect on gait (anecdotally)
Impaired muscle balance	Positional changes of muscle attachments due to distortion of bone[130]. This may cause the Lengthening of tendons which results in weakening of contractile forces required for optimal muscle function[130; 141]. Additionally, poor proprioceptive control of actions by antagonistic contraction maybe seen, the most significant being the triceps surae[130]. Muscle shortenings due to direct trauma, adhesions, scarring or bedrest ankle inactivity post trauma[142] could also lead to muscle imbalance.	AFO that provides either a dorsal stop or significant resistance to dorsiflexion thus ensuring control of gait kinematics. Ensuring hip extension occurs at terminal stance in the absence of strong plantar flexor power[143-145]. AFO That controls the limb in swing phase and prevents drop foot[69]. AFO with the ankle angle set to the length of the gastrocnemius with the knee extended and foot dorsiflexed. Shank to vertical angle at mid stance is typically 10-12°to achieve 2nd-3rd rockers in gait.[144; 146; 147]. The final position is fine tuned in clinic by an orthotist. Orthosis which provides energy return from terminal stance to pre swing to facilitate plantarflexion power, a dynamic AFO[148; 149]. An orthosis which prevents excessive ankle and knee flexion (if appropriate), as this does not allow the triceps surae to contract and assist with what power remains, as its tendon is not under tension[144]. Resting AFO that resists excessive plantarflexion to reduce the risk of muscle contractures, particularly the soleus and gastrocnemius[150].	Lengthening of tendons in triceps surae leads to an increased shank inclination during mid stance with resultant increased ankle dorsiflexion. This creates a lack of an extension moment at the knee and the hip in mid stance through terminal stance[83]. Shortening of the tendons in triceps surae can prevent initial contact being with the heel and the ankle maybe in a fixed equinus position[83] making the injured limb effectively longer. This can lead to ground clearance difficulties in swing phase with increased flexion seen in the hip and or knee to compensate. As ankle dorsiflexor range is restricted there may be increased motion through the midfoot (midfoot break).

Body impairment	Why this has occurred	Orthotic solution	Effect on gait (anecdotally)
Impaired muscular function around the hindfoot	Incongruity of the subtalar joint and widening of the calcaneus can impinge on the peroneal tendons[130]. The peroneals are the dynamic lateral stabilisers of the ankle[151]. Pain upon tensing these tendons can lead to instability of the hindfoot[151] as well as structural damage.	FFO with lateral posting to increase the subtalar valgus moment. This encourages hindfoot supination to relieve pressure on the peroneal tendons and help improve stability[128; 130; 152; 153]. Kinesiology taping to improve ankle stability[154] Orthopaedic footwear can also be considered to restore ankle stability if very unstable[130].	Antalgic gait often presents with reduced single support time on the injured side with associated shortening of stride length and general gait asymmetry.
Weakening of the subtalar plate	The subtalar plate acts as the long arm of a lever during push off in terminal stance, as during re-supination with tensing of the plantar aponeurosis, the individual bony links of the plate become interlocked, preventing bending forces[130]. The resultant force in the subtalar joint upon interlocking causes pain, by acting on incongruent joint surfaces[130]. The subtalar plate may not be able to interlock as it's subjected to bending forces at its weakest point, the midtarsal joint[130].	Stiffening of the shoe and addition of a rocker sole helps to reduce strain on the midtarsal joint[69; 130]. Firm FFO's can also be used to support the midtarsal joint in terminal stance to counteract the bending forces upon it[69; 130].	Weakening of the subtalar plate causes a reduced efficiency of push off[130] and potential to develop a mid-foot break to enable push off in terminal stance.

Many structural changes occur to the foot and ankle following blast trauma, and a detailed patient assessment focusing on lower limb muscle power and joint range of motion is important to determine which orthotic treatment may be beneficial to improve pain and biomechanical function. There is no published research that outlines typical muscle power, joint ranges of motion or gait kinetics and kinematics in patients who have undergone limb salvage, and this thesis is the start of this documentation.

2.10.2.1 Orthoses used in blast trauma

There have been limited publications on the use of orthoses in lower limb foot and ankle trauma rehabilitation. Only 2 civilian papers known to the author have been published that discuss possible orthotic treatment of the hindfoot post high-energy traumatic injury[128; 130]. Prior to conflicts in Iraq and Afghanistan there is no literature regarding the orthotic treatment of the foot and ankle due to blast trauma. The only orthosis mentioned in the literature, which has claimed to successfully treat patients who have sustained foot and ankle blast injuries, is the Intrepid Dynamic Exoskeletal Orthosis (IDEO™) (Figure 2-9). Over 20 papers[5; 22; 24; 122; 155-170] have been published either by, or in connection to, the US military on the effectiveness of this orthotic design between 2009 and 2018.

2.11 Intrepid dynamic exoskeletal orthosis (IDEO™)

The IDEO™ (Figure 2-9) is best described as a custom made, Passive-Dynamic Ankle Foot Orthosis (PD AFO) [4; 22; 156; 159; 161; 169; 171-173]. A PD AFO provides users with a dynamic response[173], i.e. a force that produces motion which is not powered or providing mechanical assistance. It provides energy return using an energy storing composite strut[158; 171; 173] coupled with appropriate AFO trim lines and manufacturing material. PD AFOs, like all AFOs, are commonly prescribed to manipulate the GRF and normalise gait kinematics.

Figure 2-9 IDEO™ [174]

The IDEO™ was developed by the prosthetic department at the Centre for the Intrepid (CFI), Brook Army Medical Centre, San Antonio, Texas, USA, and in 2009 first appeared in the literature[171]. The IDEO™ was developed to address impairments created by lower limb blast trauma, such as diminished plantarflexion and propulsive force, decreased weight acceptance and compromised joint stability[5; 22; 171]. The overriding goal was to enable limb salvage patients to lead a more active lifestyle and, where appropriate, be able to take part in higher levels of activity without resultant pain[171] .

2.11.1 Clinical need for the IDEO™

The CFI began treating limb salvage patients from Iraq and Afghanistan in 2008; previously the service had only provided prostheses. Individuals transferring into the CFI were typically prescribed non-custom plastic AFOs or prefabricated carbon fibre AFOs, which were not deemed functionally adequate by patients and therapy staff[171]. At this time, lower limb stock orthoses were not designed for variable sports and recreation, often a primary rehabilitation goal when treating a young military population[22; 156].

Plastic stock AFOs do not provide adequate strength when high training loads are applied during high activity[175] and prefabricated carbon AFOs cannot be used whilst squatting and offer limited triplanar foot and ankle control[176].

Therefore, there was a growing clinical need for a custom AFO design that offered injured personnel the ability to be more active, and by doing so reduce the elective amputation rates within the limb salvage community that were ever growing[22; 24].

Other than stock plastic AFOs and prefabricated carbon fibre AFOs as published[159], it is unknown if the US military utilised any form of custom AFO before embarking on IDEO™ development. It is therefore unknown how a custom AFO of any design or material would perform against the IDEO™ as this, to date, has never been published.

As the clinical success of this orthotic design became clear through further US publications[22; 156; 159], evidence was growing that the IDEO™ design was appearing to provide limb salvage patients with an orthosis capable of enabling users to be more functional[159]. For this reason, DMRC Headley Court in the UK began investigating this design to treat its similarly injured limb salvage population.

2.12 UK PD AFO: British off-loading brace (BOB)

The orthotic service at DMRC Headley Court began supplying an identically designed PD AFO to the IDEO™ in 2013 post training from the US military rehabilitation team. The IDEO™ is a trademarked name and so the UK version of this orthotic design within DMRC Headley Court was colloquially named the British Off-loading Brace (BOB)[177].

Throughout this thesis the term PD AFO will be used to define the orthosis used at DMRC Headley Court and by the participants in this study, not BOB. A PD AFO is the more technically correct name for such an orthosis.

Blatchford is the prosthetic and orthotic service contractor to the Ministry of Defence (MOD), and in 2013 it did not have the capability to manufacture the PD AFO internally, and so from 2013-2016 the PD AFO was manufactured by Orthotic Composites Ltd. Blatchford developed this capability in November 2016, and so from that date to the present day the PD AFO has been

manufactured by Blatchford following the same manufacture process utilising the same composite materials.

Blatchford has since released this style of PD AFO to the wider UK orthotics market (civilian) under the product name Momentum®. The Momentum® (Figure 2-10) has been available since 2016 within both the private sector and the NHS, although adoption within the NHS anecdotally has been limited due to cost.

At the time of writing, the Momentum® costs the NHS £1,825 to purchase and £3,800 + VAT in the private sector, inclusive of clinical time. IDEO™ costs to the US military are not published. However, anecdotally Hanger in the US market provide the same style PD AFO, marketed as the Exosym™, at an approximate cost of $10,000. This includes the orthosis and a week of residential rehabilitation with a physiotherapist.

Figure 2-10 Momentum® PD AFO (Source: Blatchford private clinic website)[25]

Since 2014, 74 personnel have been supplied a PD AFO of this design at DMRC Headley Court and 11 of these personnel went on to have an elective amputation within 18 months of using the orthosis. Of the 11 patients, 8 chose elective amputation post use of the PD AFO and the other 3 patients clinically were advised to have an amputation, due to recurrent deep infection that was not responding to antibiotic treatment.

The US military have provided clinical training to orthotists for the use of the IDEO™, but only to US military centres and global military allies such as the UK. Therefore, the design and clinical use of the IDEO™ and DMRC Headley Court's PD AFO are known by the researcher to be the same.

There is, however, 1 key difference between the UK's PD AFO and the IDEO™, and this is how the orthosis is manufactured[23].

2.12.1 Manufacturing difference between the IDEO™ and the BOB (referenced in this thesis as a PD AFO)

The US military favour a composite infusion manufacturing technique, also referred to as wet lamination[178]. This involves laying up dry weaved carbon fibre, aralon and aramid onto a dry plaster of Paris positive cast. At room temperature, hardener is added by hand to acrylic resin. This resin mixture, referred to as "the matrix"[179], is then poured into the lamination and manually threaded through the composite fibres evenly whilst a vacuum is applied. The resin undergoes an exothermic reaction and sets to form the finished orthosis. This type of manufacture is relatively cheap and quick to fabricate, producing strong orthoses. However, the manufactured product can often be heavy, as the resin to carbon ratio is high[179].

The process is reliant on manual steps, so there is little control of variables. However, in practice, repeatable and quality results are achieved because the technicians manufacturing are highly skilled and experienced in lamination. This method is standard practice globally for the manufacturing of carbon fibre prosthetic sockets[69; 179] (Figure 2-11).

Figure 2-11 Prosthetic socket lamination (Source: Picture taken by thesis author in prosthetics department, DMRC Headley Court)

The UK PD AFO is manufactured using composite materials (aramid and carbon fibre), which are machine pre-impregnated with resin, colloquially referred to as “pre preg”. This reduces and standardises the resin (matrix) content within the orthosis, which leads to a lighter and thinner orthosis without compromising on strength[179-182]. The composite fibres are laid up onto a positive cast over a very thin layer of plastic (Figure 2-12). Anecdotally this protects the composite from the moisture in the cast. The volume of composite fibre layers is dependent on the weight and activity level of the patient.

Figure 2-12 Unidirectional carbon fibre being applied onto a PD AFO (Source: picture taken by thesis author at Blatchford manufacturing facility in Sheffield)

Additionally, pre-preg orthoses are cured in a vacuum assisted oven at a controlled temperature. The manufacturing process is therefore less reliant on manual intervention, ensuring fewer variables occur and a high-quality product is achieved consistently. A negative consequence of this method is that it cannot be adjusted once the final orthosis is complete, as the resin content is very low[179], unlike orthoses manufactured using wet lamination with a higher resin content that can be heated a little, if required, to allow the shape to be adjusted[179]. Pre-preg manufacturing is more expensive and takes longer, however it produces lighter, stronger and thinner orthoses[180; 181], and for these reasons is the manufacturing technique favoured by DMRC Headley Court presently for all PD AFO designs.

2.13 IDEO™ / PD AFO design

This thesis will now discuss each component of the IDEO™ (PD AFO) design and outline its importance in relation to function.

2.13.1 Knee section

The proximal ground reaction cuff at the knee is designed to redistribute and deflect pressure away from the painful foot and ankle area, and transfer this load to tolerant areas around the knee, such as the patella tendon and the medial tibia flare[183]. This strategy effectively reduces axial loading of the ankle and foot during stance phase[69].

The IDEO™, therefore, behaves similarly to a conventional ground reaction ankle foot orthosis (GRAFO) in that the knee section increases the proximal lever arm, and helps to control tibial progression through mid-stance, as it acts as a dorsal stop (dorsiflexion limiter)[184]. An orthosis that limits the degree of dorsiflexion can control the tibia and increase stance limb stability in terminal stance. Like a GRAFO, it transfers the ground reaction force though a solid ankle to the anterior tibial cuff, creating a mechanical plantarflexion moment at the ankle. This supports the internal plantarflexion moment that could be reduced, for example, secondary to weak plantarflexor muscles. The

plantarflexion moment results in an external knee extension moment through the mid and terminal phases of stance. This occurs as the tibia is limited from excessive inclination. Knee flexion is therefore limited, and the ground reaction is able to fall in front of the knee, creating an external knee extensor moment thereby restoring the plantarflexion-knee extension couple[185; 186]. This design provides maximum resistance to dorsiflexion, as recommended by Lehmann et al[187] for stance phase stability.

The anterior knee cuff is set in approximately 10° of knee flexion to load some of the users' body weight onto the anterior shell at the medial tibial flare and patellar tendon bar areas during stance phase[69]. The design features of the knee section are found below (Table 2-8).

Table 2-8 Knee design features

Design Feature	Importance
Total surface bearing on the proximal anterior tibia area of the limb, below the knee.	To redistribute pressure around this area, careful not to create areas of discomfort due to high pressure on bony prominences[69].
Patellar tendon notch	To increase load in this pressure tolerant area[69]
Flared distally on the proximal tibial area	To reduce high forces along the tibial shaft
Dropped trim line around medial and lateral hamstring tendons posteriorly	To improve comfort when the knee is flexed[69].
Rivet opening/ strap closure	Ensures strong fixation of the anterior shell
Manufactured with carbon fibre twill and unidirectional fibres	Provides a rigid, strong, yet lightweight orthosis[179; 182; 188; 189].

The proximal knee cuff and the rigid foot and ankle section are attached by two dynamic composite struts (clever bones™). The clever bones™ are available in four strengths and are distributed by Ossur as a dynamic prosthetic pylon system, typically for geriatric amputees. Clever bones™ have, therefore, been adapted for use in a PD AFO and not originally designed for this purpose.

2.13.2 Posterior strut section

The clever bones™ are trimmed to size and laminated directly into the IDEO™. This thesis will focus on the use of clever bones within PD AFO design. Other commercially available struts such as the carbon ankle seven (Ottobock),

posterior dynamic element (Fabtech) and the dynamic strut AFO (Coyote Design) will not be discussed. The use of posterior struts in a PD AFO is reported to enhance transition through midstance, releasing energy in the form of spring assistance between terminal stance and pre swing[190]. The strut is thought to provide an internal plantarflexion moment to supplement insufficient plantar flexor strength[165] between terminal stance and pre swing. The design features of the posterior strut are shown below (Table 2-9)

Table 2-9 Clever bone™ design features

Design Feature	Importance
Carbon fibre with a polyurethane core.	Carbon fibre is a composite material that provides energy return[182]. The posterior struts are compressed and deflect from initial contact through to terminal stance. They claim to return the stored energy to the user at pre swing which helps to facilitate increased push off[159; 182.] The polyurethane core gives the strut further flexibility.
Round shape	Anecdotally provides some torque compliance compared to a flat strut design[171]
Two struts	Improves strength.
Laminated into the foot and knee sections	Anecdotally creates a stronger fixation and reduces the risk of breakages compared to modular struts that utilise metal bolts and mounting plates.

In the literature there has been some experimentation with the IDEO™ posterior struts. The Littig strut, which originates from a dynamic hip disarticulation system, has been compared to Clever Bones™. The clinical team at the CFI report an increased energy return, torsional dynamics and general responsiveness using Clever Bones™ rather than the Littig strut system[171]. There are no other struts in the literature that have been tested against Clever Bones™ in IDEO™ design.

2.13.3 Ankle and foot section

The design features of the rigid ankle and foot section are outlined below (Table 2-10).

Table 2-10 Ankle and foot design features

Design feature	Importance
Rigid in all areas, including the full-length forefoot.	The inherent rigidity of an AFO has shown to play an essential role in determining its biomechanical function, and needs to be optimal to positively influence gait[191; 192]. The rigidity (lack of material deformation) allows force to transmit through the foot section and up into the posterior struts of the AFO when loaded. The rigidity in the ankle and full length footplate enables the external dorsiflexion moment between mid-stance and terminal stance to be resisted, which influences the position of the GRF in relation to the knee and hip joints[193]. The full length footplate maximises the foot lever length, shifting the GRF as far anterior to the knee as possible during terminal stance for stability[193]. It provides maximum triplanar control to the foot and ankle, stabilising the foot and ankle joints, reducing excessive movement[69]. Empirically this can reduce pain when joint integrity is compromised[137].
Forefoot rocker- Either designed into the plantar surface of the PD AFO footplate or added to the participant's footwear	As the forefoot section of the AFO is rigid a rocker is necessary to enable the user to use the third rocker during walking[69].
Trim lines on the apex or distal to the metatarsophalangeal joints	Serves to help strengthen the forefoot and reduce the risk of breakages. This area of the orthosis is subjected to high stress during high activity[69].
Trim lines at the malleoli can sweep behind the apex.	The material is strong enough to trim behind the malleoli and avoid pressure on bony prominences without deformation of the material[182].
Medial and lateral supramalleolar trim line extensions	Provide enhanced ankle stability when carrying out more complex functional activity as the varus and valgus control areas have a greater surface area in contact with the limb.
Manufactured with advanced composite materials, carbon twill, unidirectional and aramid.	Provide a rigid, strong yet lightweight orthosis to optimise performance[179; 180; 182; 189]. Aramid in the foot plate provides the orthosis with impact resistance to tolerate peak forces for high activity[189].

The foot and ankle section is typically fixed in a plantarflexed ankle angle alignment. Therefore a heel elevator made from urethane foam is placed under the heel[158; 159] to accommodate for this position, aligning the plantar surface of the PD AFO to a 90 degree angle to the shank, ensuring the heel remains in contact with the floor when weight bearing.

2.13.4 Heel elevator

The heel elevator (Figure 2-13) is made from a polyurethane rubber[158]. Anecdotally, polyurethane heel elevators are more durable than conventionally

used high density ethylene vinyl acetate (EVA) heel elevators, and do not bottom out as readily. Polyurethane is, however, slightly heavier[194].

The heel elevator's height is fine-tuned in combination with the patient's footwear pitch, in line with tuning principals to be discussed in 2.15.4. The heel elevator is thought to provide shock absorbency[159] at initial contact through loading response, if made by the heel, which aims to decrease impact on the joints of the injured limb. The cushioned heel strives to accommodate for the lack of subtalar joint pronation whilst in the PD AFO. Facilitating load acceptance provides a more fluid transition from initial contact to loading response as the tibia advances over the foot towards mid stance.

Figure 2-13 Example of a polyurethane heel elevator (Source: picture taken by author in orthotic department at DMRC Headley Court)

2.13.5 Ankle angle

The ankle angle of an AFO can be described as the angle of the foot relative to the shank in the sagittal plane of the AFO. This angle is measured as the angle between the line of the lateral border of the foot (base of 5th metatarsal head to the base of the heel) and the line of the shank. It is described in degrees of dorsi-flexion or plantar flexion, with plantigrade describing a neutral position[193].

The foot and ankle section of the IDEO™ is typically set with the ankle angle in plantarflexion[159], the exact angle of which is patient specific and not included in any IDEO™ published literature. A plantarflexed ankle position increases the degree of strut deflection and associated energy return from midstance through to pre swing[159]. It also reduces the risk of tibio talar impingement[171] and accommodates for possible shortening of the Achilles tendon post injury due to both trauma and/or a sedentary lifestyle. Setting the ankle in a plantarflexed

position allows for improved forefoot loading during agility and running activities[159]. Whilst empirically plantarflexing the foot 5-10° does appear to provide the best fixed position for high functional activities on the injured side, it does require the contralateral side to also be raised at the heel to ensure a leg length discrepancy is not introduced. This could lead to shortening of the Achilles tendon if used long term[195], although there are no long-term studies to determine this. The desired ankle angle is always captured in the negative cast by the orthotist.

2.14 Casting for a PD AFO

There is no published research on specific casting methods for the IDEO™, therefore casting information is based on the researcher's experience and training received by the US military team responsible for the IDEO™.

2.14.1 Determining the ankle angle and foot pitch

The orthotist determines the ankle position and pitch of the foot within the PD AFO individually for each patient by assessing the following factors in (Table 2-11) to make this clinical judgement.

Table 2-11 Determinants for selecting PD AFO ankle angle

Ankle angle determinants	Importance
Pain	Does a particular ankle position relieve discomfort? Increased ankle dorsiflexion can cause anterior ankle impingement pain in patients with a compromised talocrural joint[196] post trauma. Anecdotally it is more likely a plantarflexed ankle position will reduce pain in those with previous hindfoot trauma.
Range of motion	Joint restrictions will limit the ankle angle options available for casting
Calf muscle length	The PD AFO must accommodate both gastrocnemius and soleus length as described by Owen et al.[144] and Eddison et al.[197]. Setting the angle of the ankle in the PD AFO without regard to the tri-jointed requirements of the gastrocnemius can result in insufficient length being available to allow knee and hip extension during the Gait Cycle[198]. In addition, an overstretched gastrocnemius in terminal stance will reduce the possibility of optimum force production in the calf complex[198]. If the correct length of the musculotendinous unit is not accommodated for within the PD AFO, bony foot deformities caused by enforced supination or pronation within the PD AFO can occur[144]. The lever arm ratio between the ankle and the knee at 40% of the Gait Cycle is 2:3, so small changes in the ankle angle are amplified at the knee[198]. Both gastrocnemius and soleus length should be routinely monitored in clinic.

Ankle angle determinants	Importance
Function	Higher levels of activity such as running may benefit biomechanically from a more plantar flexed ankle angle in the orthosis to improve forward progression from terminal stance to pre swing[199] similar to the theory behind prosthetic running blade alignment (Figure 2-14). This allows the blade to compress and return the energy in a force vector that propels the runner forward at a desired speed[199]. However, an increased plantarflexion angle can make standard footwear fitting difficult and introduce a leg length imbalance that must be considered

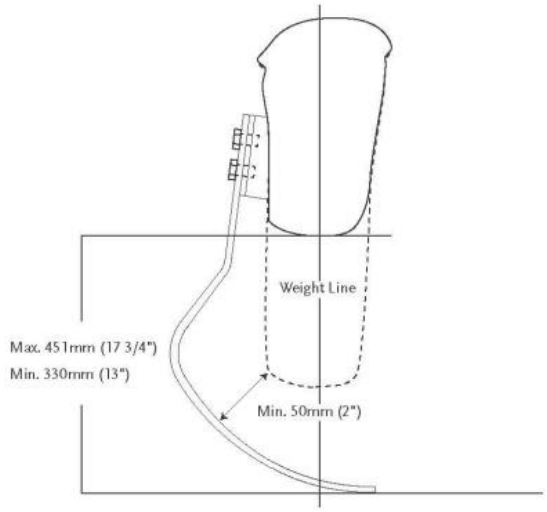

Figure 2-14 Example of prosthetic running blade bench alignment[199] (Source: Ossur)

2.14.1.1 Determining forefoot flexibility

Optimally the forefoot of the PD AFO will incorporate a roll over shape with extension of the toes[165; 171]. This allows for a solid metatarsal contact that increases proprioception, ensures isolated bending of the posterior struts[200] and facilitates the third rocker of gait from mid stance to terminal stance[159]. The orthotist determines 1st ray range of motion and the tightness of the plantar fascia to ensure the forefoot can accommodate this position comfortably.

A rocker sole is added to the participant's footwear if a reduced ROM in the 1st ray or tight plantar fascia is identified, as in all solid AFO design[201]. This allows for the user to advance through the third rocker of gait.

2.14.2 Patient positioning for casting

Patients are cast using a casting jig (Figure 2-15) to enable the orthotist to set the appropriate ankle angle and pitch of the foot within the negative cast. The use of a casting jig is the AFO casting method taught by Ottobock Healthcare[202].

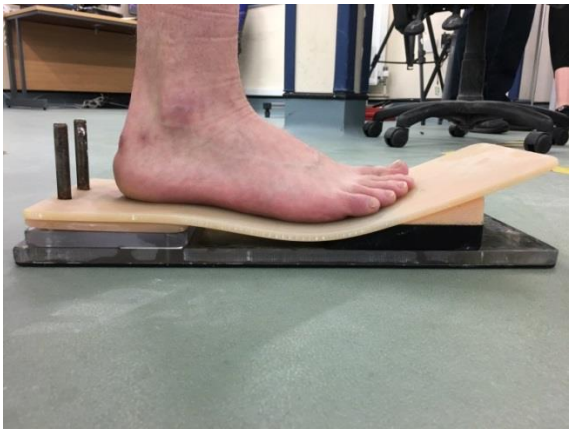

Figure 2-15 The PD AFO casting jig (Source: Picture of a non-injured foot taken by thesis author at DMRC Headley Court)

A forefoot wedge is positioned from the metatarsal heads forward (Figure 2-15) to create the forefoot rollover shape. A flexible plastic is positioned over the heel raises and forefoot wedge on the casting jig to create a smooth surface for casting upon.

Arm rails can be used to stabilise the patient, and a block placed under the non-injured limb to account for the leg length inequality the casting jig introduces. Patients are asked to stand fully upright and look forward, with the injured limb positioned ahead (Figure 2-16). The aim is to cast with the knee in 2-5° flexion (as discussed in 2.13.1) and this is achieved by asking the patient to keep their "knee soft" during casting. Anecdotally this casting position ensures best alignment of the PD AFO, as it allows for optimal positioning of the patient's centre of gravity as shown in (Figure 2-16) compared to standing with their limbs side by side[203]. It also ensures that the calf and, in turn, the posterior struts are not reclined. Empirically, casting is undertaken fully weight bearing if the joints of the foot and ankle present as stiff in nature. The stiffness of the ankle is determined in the physical examination. While open chain the orthotist

moves the ankle through its possible passive ROM, both with the knee flexed and extended to determine the true range of motion of the ankle joint in the sagittal plane. The subtalar and midtarsal joints where held in a neutral alignment by the orthotist during testing, and the angulation measured using a goniometer and recorded in the participants clinical records.

If full mobility is available in the foot and ankle joints and on full weight bearing excess midfoot pronation is evident, casting is undertaken semi weight bearing, if not the patient is cast standing.

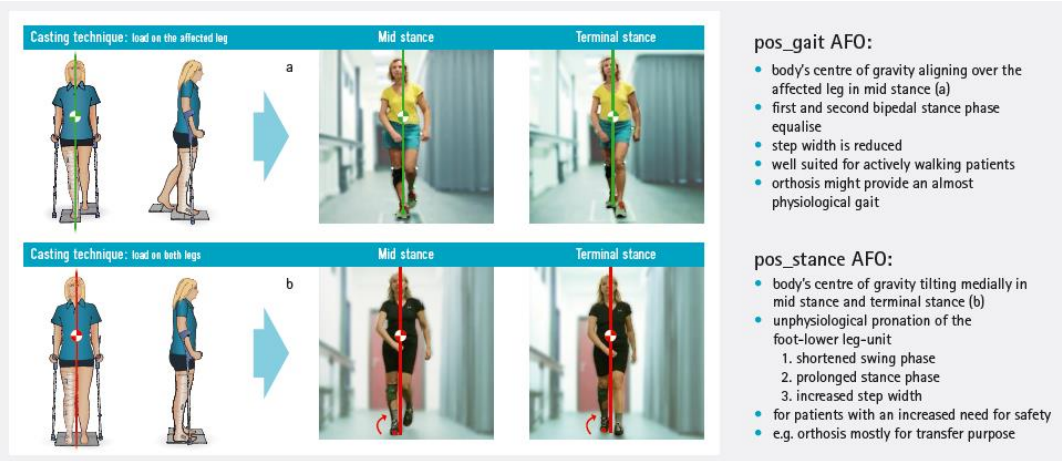

Figure 2-16 Optimal casting position (Fior & Gentz poster[204])

The hindfoot/forefoot alignment is corrected where possible by the orthotist in casting. Pressure is applied to the cast in line with the control systems shown in (Figure 2-17). If a fixed deformity is present, appropriate medial/lateral posting is added to the orthosis intrinsically[69]. In the transverse plane the foot and ankle section relative to the knee cuff is cast externally rotated. This correlates with the patient's natural external tibial torsion and toe out. The normal range of tibial torsion in adults is approximately 20° external[69].

2.15 Orthotic design control systems

Ankle-foot orthoses (AFOs) are commonly prescribed in an attempt to manipulate the GRF and normalise kinetics and kinematics. There are 4 distinct

control systems incorporated into the IDEO™ design, as with all conventional solid ankle AFOs as shown below (Figure 2-17).

Plantarflexion control	**Dorsiflexion control**
Force at the posterior calf (Fp) and metatarsal heads (Fd) counter the stabilising force applied by the shoe closure (Fc)	Force at the proximal tibia applied by a rigid cuff or a soft strap (Fp) and a force applied by the toe box of the shoe (Fd). The counter stabilising force is
Valgus/Eversion control	**Varus/Inversion control**
Force applied along the 5th metatarsal (Fd), At the proximal lateral calf band (Fp) and above and below the medial malleoli (Fc)	Force applied along the shaft of the 1st metatarsal (Fd), at the proximal medial calf (Fp) and above and below the lateral malleoli (Fc)

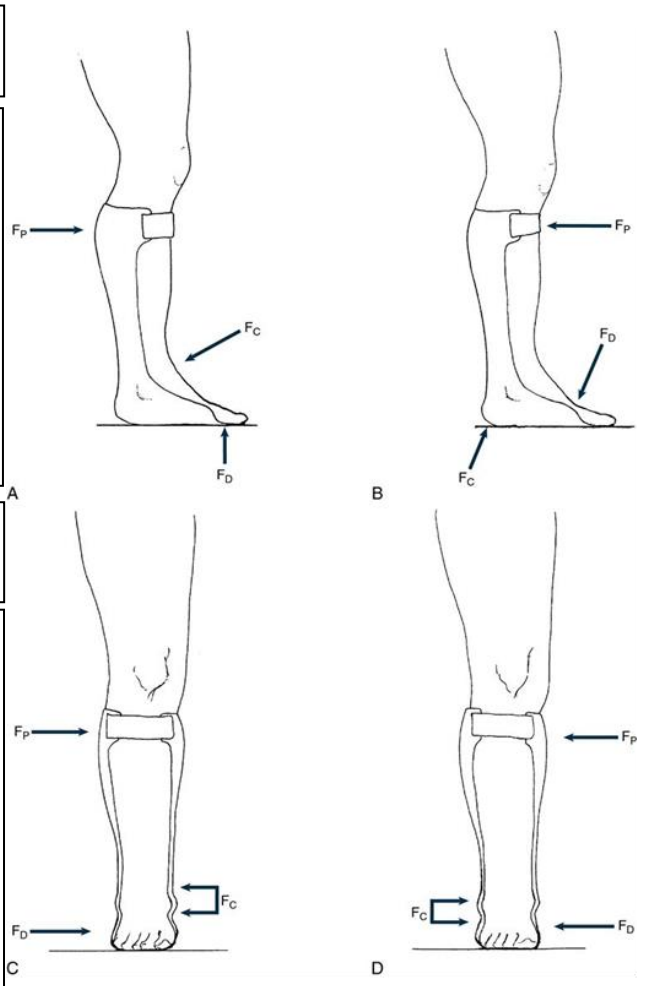

Figure 2-17 The four force systems utilised in Solid Ankle Foot Orthosis design[69]

2.15.1 Standard procedure for fitting a PD AFO

2.15.1.1 Use of a class I compression sock

All users of PD AFOs are provided with a below knee class I compression sock[171] (Figure 2-18). The sock provides an interface which stabilises the soft tissues between the PD AFO and the patient's limb[171]. Ankle motion is important in maintaining good lower limb venous return[205] and to ensure the ankle is fixated in the PD AFO, a compression sock is applied to improve

venous return and reduce the risk of swelling within the orthosis that could affect fit[206].

Figure 2-18 Compression sock (Source: picture taken by thesis author at DMRC Headley Court)

2.15.2 PD AFO diagnostic fitting

All UK PD AFO users have a diagnostic fitting. Diagnostic PD AFOs (Figure 2-19) are manufactured in ThermoLyn® clear[207]. The transparency of this thermoplastic permits verification of the fit and prevents skin discolouration on the residual limb[207]. The thermoplastic has a minor shrinkage of 1% and is a trusted material to provide a reliable diagnostic fit[207].

The diagnostic PD AFO is used both statically and dynamically between parallel bars. Empirically the material is brittle, so caution must be used when testing dynamically. The diagnostic fit stage is necessary to identify any ill-fitting areas of the brace prior to completion, as once cured composite orthoses offer limited adjustment[179].

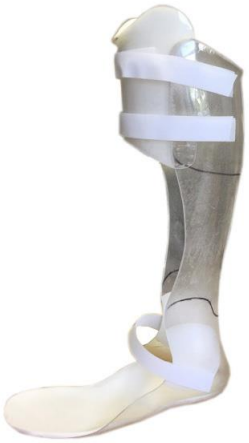

Figure 2-19 Example of a diagnostic PD AFO (Source: Picture taken by thesis author at DMRC Headley Court)

2.15.3 PD AFO Biomechanical optimisation

The term biomechanical optimisation is used to encompass the whole process of designing, aligning and tuning an ankle foot orthosis and footwear combination (AFO-FC)[208]. It is imperative that all AFOs are aligned and tuned to optimise the ground reaction force (GRF) during gait[146]. AFO-FC tuning appears to optimise gait in the paediatric cerebral palsy population, and from these studies[193; 209-211] It can be deduced that during mid stance an element of shank inclination is required during healthy walking. There are no studies specifically which investigate tuning of AFOs in the management of limb salvage patients who utilise composite PD AFOs, as studies to date have focussed on the neurologically impaired, utilising thermoplastic AFOs[193; 197; 209; 211-214].

2.15.4 Importance of AFO-FC tuning

Tuning an AFO-FC is widely recognised as an essential aspect of clinical practice[215]. AFO-FC tuning can be defined as the process whereby fine adjustments are made to the design of an AFO-FC to optimise its' performance during a particular activity[211]. It involves the manipulation of the shank to vertical angle (SVA) by the addition of heel elevators to the users' footwear and in some cases, the addition of other modifications, including rockers, flares and SACH (solid ankle cushioned heel) heels to optimise the entry and exit from mid-stance, and influence the GRF in the sagittal plane[211].

The shank angle to floor measure of an AFO-FC is the prime determinant of gait rather than the ankle angle of the AFO[144; 146; 208]. The SVA is described as inclined if the shank is inclined forward from the vertical and reclined if the shank is reclined backward from the vertical. It is described in degrees from the vertical, vertical being 0 degrees, and is measured statically in relaxed stance. Although the shank to vertical angle is determined statically, Eddison et al.[214] has shown this correlates to the dynamic measurement during gait.

A shank to vertical angle of 10-12° inclined has been shown to be central to the production of stability in stance, both in normal and pathological gait[144]. This is the position that brings the centre of the knee joint directly over the middle of the foot at mid stance, which aids the AFO user's ability to progress into a typical position during terminal stance[144]. It also facilitates ballistic movement of the thigh, pelvis and trunk[144]. Soleus restrains the forward movement of the shank and momentum carries the thigh, pelvis and trunk forward to extend the knee[144]. Furthermore, this position facilitates appropriate GRF alignment to the knee and hip, converting external moments from flexion to extension at the knee and hip which creates stability[213].

Therefore, bench aligning a patient's AFO-FC with a shank to vertical angle of 10-12° (as measured with a goniometer) is an optimum position to start AFO fitting in clinic[144]. Gait should then be observed dynamically using the AFO-FC and ideally instrumented gait analysis[193] or a video vector system used to determine the true position of the GRF in stance. Particular attention should be paid to the GRF position in single support to ensure it is anterior to the knee, which generates an external knee extension moment[83]. Alteration of the shank to floor angle by just a few degrees can influence the alignment of the GRF to the joints in standing and gait considerably[146].

Issuing a sub-optimal AFO-FC to a patient may have an immediate pernicious effect on function and in the longer term it may contribute to deterioration[193]. PD AFOs should therefore always be tuned in line with best practice guidelines[215].

2.16 Biomechanics of gait using the IDEO™

IDEO™ users adopt various gait adaptations to utilise this orthosis successfully[165; 200 78], anecdotally the most commonly observed stance and swing phase gait deviations using a PD AFO are listed below. They are typically seen on initial use and, with tailored rehabilitation, typically improve over time[216].

- Full knee extension and medial rotation of the foot on initial contact with the heel
- Inconsistent step length
- Rapid progression through initial contact and loading response
- Decreased load acceptance through toes in terminal stance
- Poor trunk control/proximal weakness, resulting in sway and forward inclination of the trunk through stance phase
- Decreased propulsion in pre swing through initial swing

The restriction of ankle joint range within the IDEO™ leads to deficits, such as reduced plantarflexion, dorsiflexion and ankle power generation[170; 217]. To overcome these deficiencies in mechanical power and the limitations of ankle motion, other joints, such as the hip, may compensate by increasing the acceleration of the hip flexors during the transition from stance to swing phase to maintain a steady walking speed[78].

When used in able bodied participants, Arch et al.[165] has shown that a PD AFO creates a compensatory premature increase in the internal plantarflexion moment[165], typically occurring between 20 and 70% of stance. However, this study utilises the PD AFO without footwear and previous work by Owen et al.[208] describe the importance of the AFO and footwear combination in relation to kinematic and kinetic gait analysis outcomes. Furthermore, the shank to vertical angle of the PD AFOs was set at 0° to the bench, therefore at mid stance the PD AFO would have been reclined rather than inclined as described in 2.15.4. The sagittal plane alignment of the PD AFO may have impacted on the premature increase in the internal plantarflexion moment reported.

The sagittal plane alignment of any AFO is crucial and has a significant effect on lower limb joint kinematics and kinetics[166; 168; 200] A plantar flexed alignment may reduce the demand on the knee and ankle extensors, which suggests a greater reliance on a PD AFO[166; 200]. Brown et al. [166] studied the sagittal plane alignment of the IDEO™ and concluded that 75% of participants preferred their IDEO™ ankle angle in a more plantar flexed ankle position than initially prescribed by their orthotist. It was suggested that the reduced demand on these key muscle groups was a possible factor as to why this preference occurred[166]. It would seem logical to suggest pain may also have been a factor, although this was not specifically mentioned in the study.

2.16.1 Biomechanical significance of the posterior strut stiffness

The biomechanical effects of changing the stiffness of the energy storing struts in the IDEO™ have been investigated in 4 separate studies[4; 168; 172; 173]. Advanced additive manufacturing techniques, such as selective laser sintering, has enabled researchers to manufacture energy storing struts in a very precise and controlled manner for testing[168].

Harper et al.[168] tested 3 struts on a group of IDEO™ users; the patient's prescribed strut, a strut 20% firmer and a strut 20% less firm. They found that the range of motion within the ankle joint increased when using a more compliant strut whilst walking on flat terrain. This suggests that if pain is caused by ankle joint motion the use of a firmer strut should be considered by the orthotist to limit ankle movement.

Electromyography (EMG) data has shown an increase in medial gastrocnemius activity when a more compliant strut is utilised[168]. Furthermore a strut with a lower bending axis also increases gastrocnemius recruitment[170]. This indicates that when less support is offered by an orthosis, and a strut with a bending axis closer to the patient's anatomical ankle joint is employed, the triceps surae is more active in late stance[168; 170] within the PD AFO. This is beneficial as it retains activity in the triceps surae in gait and reduces the risk of atrophy and

oedema[218]. A similar non-military study reporting on triceps surae activity within an AFO found similar results[219]. No significant change was seen in the ankle or hip moments or work during walking on flat terrain[4; 168; 170]. However, there was an increase in knee flexion, when using the most compliant strut[4; 168]. Ranz et al.[170] hypothesised that the kinematic and kinematics of gait would change if the bending axis of the posterior struts was located closer to the anatomical ankle axis. However, on investigation this hypothesis was rejected, and this suggests the bending axis of the struts may not be as clinically important as first thought.

During running, strut stiffness does not influence joint angles, moments or powers in unilateral IDEO™ users[173]. When walking uphill compared to flat terrain, hip power generation increases during late stance when using the IDEO™[172] and it is likely that the increase is due to a compensatory strategy because of reduced ankle and knee power generation whilst using the IDEO™ [172]. Furthermore, it seems likely that the fixed ankle position and greater control and manipulation of the GR whilst walking uphill played a role in this result.

There are limited studies that observe hip strategies whilst walking uphill in an AFO. However, there has been one such study which also demonstrates increased hip power generation when using a homoplastic AFO utilising a composite posterior strut, compared to a conventional homoplastic posterior leaf spring AFO[220]. Limb salvage patients readily adapt and compensate to different dynamic strut stiffness when walking and running[173] and the change in strut compliance appears to have no effect on the metabolic cost of walking[4].

Overall results would appear to suggest that varying strut stiffness does not consistently achieve different results. Strut stiffness is not as clinically significant as originally thought[4; 168; 172; 173] and patient preference should dictate the choice of strut[5]. This, in clinical practice, is challenging, as the Clever Bones™ are laminated into the PD AFO and therefore cannot be changed without fully remaking the entire PD AFO. The testing of multiple struts is therefore not practical using clever bones™ as the cost of multiple orthoses prohibits this.

2.16.2 Biomechanical significance of the heel elevator

The urethane foam heel elevator strives to accommodate for the fixed plantarflexed ankle position, enabling initial contact to be with the heel[158]. It allows a degree of compression which helps to provide some shock absorbency upon loading response and smooths the transition from initial contact to early mid stance in early stance[158; 171]. While the heel elevator is not attached to the IDEO™, it is an integral part of the system (Figure 2-20). The height and material of the heel elevator has a direct effect on the loading of the foot as well as gait kinematics.

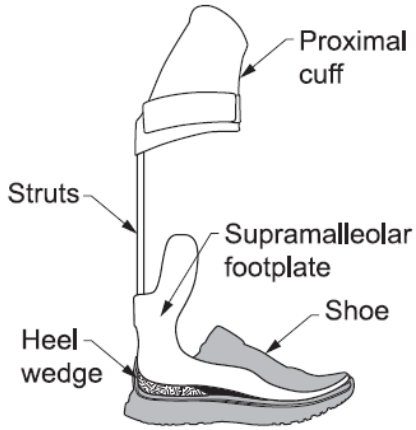

Figure 2-20 Heel elevator position inside the shoe under the PD AFO[158]

Ikeda et al.[158] reported that IDEO™ users prefer a heel elevator at a height that produces an internal ankle dorsiflexion (loading response) and external knee extension (terminal stance) moment closest in time to the gait cycle of able-bodied individuals. Ikeda et al.[158] also report that 2cm was found to be the optimal height of the heel elevator. No specific ankle angle was published in this study, so it is difficult to understand why 2cm was found to be optimal. The height of the heel elevator required is determined by the PD AFO ankle angle in line with fine tuning AFO principals[144; 146; 147], the footwear pitch, and any existing leg length discrepancies that require accommodation.

2.17 Amputation rates in patients who have been prescribed an IDEO™

The severity of lower limb injuries at the hands of blast trauma precludes to a late amputation rate post limb salvage of approximately 10-15%[7; 221]. Hill et al.[24] retrospectively examined historical clinical records of 624 service personnel provided with an IDEO™ at the CFI between 2009-2014[5]. The referring injury categories for the participants are shown below (Table 2-12).

Table 2-12 Referring Injury Diagnosis Categories, IDEO™, CFI 2009-2014[24]

Injury type	Description	Percentage of participants %
Ankle	Pilon fractures, fusions, post traumatic osteoarthritis	25
Tibia	Fractures, excludes pilon fractures	17.5
Nerve injury below the knee	Functional deficit below the knee	16.4
Hindfoot	Fusions, post traumatic osteoarthritis	14.2
Soft Tissue	Compartment syndrome, Achilles tendon injuries, quadriceps injuries	5.9
Midfoot/Forefoot	Foot pain, forefoot/midfoot post traumatic osteoarthritis, toe amputation	3.8
Other	Osteomyelitis, late effects of fracture, nerve injury above knee	17.4

Of the 624 participants in this study, 20% went on to have an amputation after referral for IDEO™ provision, 84% of which were within the 12 months following provision[5; 24].

Personnel with midfoot/forefoot injuries, soft tissue injuries and hindfoot injuries experienced the highest proportions of amputation post IDEO™ use[5; 24]. Those with a compromised ankle joint and nerve injuries below the knee demonstrated the lowest amputation rate at the CFI[5; 24](Figure 2-21). Nearly 58% of the injuries were at, or could influence, the functionality of the ankle joint[5; 24]

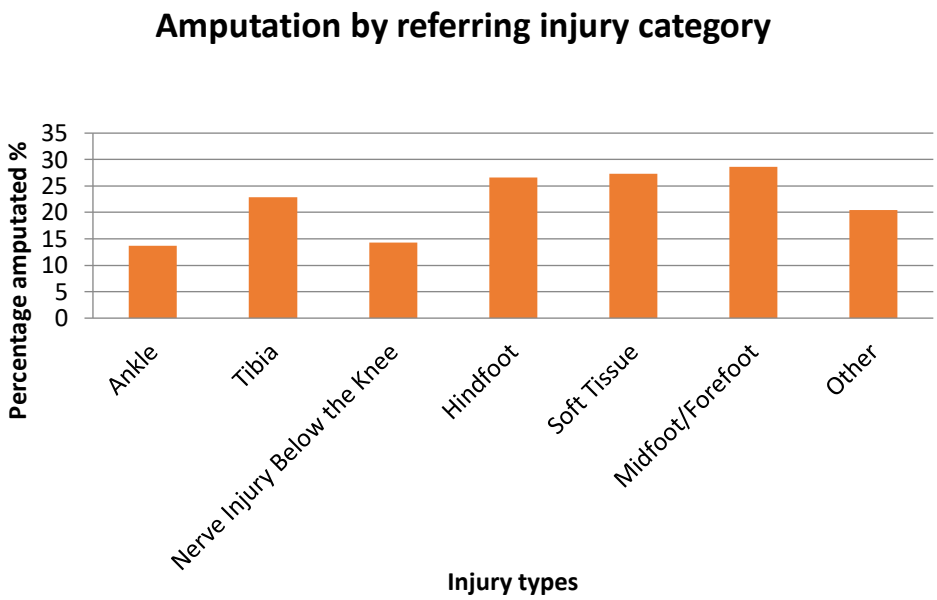

Figure 2-21 Proportion of amputations by referring injury category[24]

In a prospective observational study of IDEO™ users who completed a residential rehabilitation programme at the CFI, 60% had considered amputation prior to embarking on the programme[22]. The most common reasons given by personnel for this were the inability to run and jump (88%), mechanical pain (86%) and weakness (68%). At the end of the 8-week programme following treatment, the number of participants considering amputation fell to 18%[22]. Unfortunately, it is unknown if the participants continued with IDEO™ use long term, as no follow up study was completed.

2.17.1 Biomechanics of gait IDEO™ vs amputation

There are no gait analysis studies in the literature that compare the gait of IDEO™ or PD AFO users to limb salvage gait without any orthosis. This thesis is the first to present such an analysis.

In addition, there are no publications that compare the gait of any PD AFO user without their orthosis against other styles of AFO, custom or prefabricated. There are, however, 2 studies that have looked at the gate of IDEO™ users vs unilateral trans-tibial amputees[78; 217].

Esposito et al.[222] found 2 notable variances when examining the gait of IDEO™ users versus unilateral trans-tibial amputees wearing energy storing prosthetic feet. Amputees exhibited reduced knee flexor and extensor internal moment and power generation[78; 223], whilst IDEO™ users exhibited reduced ankle power generation and ankle ROM[78]. The lack of ankle power generation around the ankle in IDEO™ users[78] is largely due to the limited ability to deform the orthosis.

Mangan et al.[217] reports that amputees utilising energy storing prosthetic feet present with a more dynamic gait compared to IDEO™ users with stride parameters and ankle mechanics more equally matched to the able bodied. Limb salvage personnel exhibit a slower cadence and reduced stance time compared to amputees[217]. The study, however, does not make clear how long each participant had been using their IDEO™ or prosthesis, or how much rehabilitation they had received prior to testing. It would have been useful to understand if the participants were established users, as this would have helped strengthen the results.

2.18 Comparison of functional outcomes of the IDEO™ compared to other AFO's

The IDEO™ has only been tested functionally against two styles of prefabricated AFO, a Blue Rocker (Figure 2-22), and a thermoplastic Posterior Leaf Spring (PLS) (Figure 2-23). Both are commonly used prefabricated AFOs[159]. They are, however, very different from an IDEO™.

Figure 2-22 Bluerocker® (Source: Allard)[224]

Figure 2-23 Posterior Leaf Spring (PLS) (Source: Chaneco)[225]

The PLS is thermoplastic and therefore has different material characteristics[164]. It has no anterior knee cuff attached, a flexible forefoot, and is designed to warp at the ankle due to the trim lines allowing some ankle ROM, particularly dorsiflexion. This allows for significantly less control over the GR relative to the limb.

The Bluerocker® is made from composite materials and, as the anterior knee and foot plate offer some rigidity, this design does offer improved ground reaction force control compared to the PLS. However, the Bluerocker® does not have a posterior strut designed to deflect and provide energy return, so again it behaves differently in comparison to the IDEO™[164].

In the 2012 study by Patzkowski et al.[159], 18 personnel conducted physical function tests such as the 40-yard dash, 4 square step test and sit to stand test. All functional measures improved when wearing the IDEO™ compared to the other AFOs. All patients reported that the IDEO™ was the most comfortable orthosis tested, although this is not surprising as the IDEO™ is a custom-made orthosis. Custom made AFOs are individually shaped to the user and are often padded, whereas stock orthoses are typically manufactured to a more generic lower limb shape and come in a small number of sizes. Therefore, when both are compared against one another in a population group with complex lower limb trauma injuries, you would expect the custom made AFOs to be more comfortable as the geometry of the foot is less likely to be a standard shape that

conforms to the use of stock AFO products. The participant's footwear within this study was not specified.

As the orthoses tested against the IDEO™ are so inherently different from a biomechanical perspective, no conclusion from this study can be drawn to determine the effectiveness of the IDEO™ design on functional performance against other AFOs. In addition, this study makes no reference to any of the orthoses sagittal plane alignments or footwear, and as studies have shown this has a significant effect on functional effectiveness[144; 158; 166]. The study, however, does highlight the significant improvement in patient outcomes within the CFI clinical service since the IDEO™ was implemented, compared to the use of stock orthoses previous utilised[159].

2.18.1 Disadvantages of the IDEO™

No journal paper published from 2009-2018 has outlined any specific disadvantages of the IDEO™ other than reduced power generation and range of motion around the ankle[78].

Anecdotally the IDEO™ presents users with the same disadvantages as more commonly used AFOs. Finding footwear large enough to accommodate the orthosis is a common difficulty, with patients typically being advised to find wide and deep sport trainers with as large a heel pitch as possible to help reduce the height of the heel elevator required to appropriately fine tune the IDEO™[144]. Some tasks can be more difficult as users have reduced sensation on the plantar surface of the foot, like driving a car. Many remove their orthoses before such tasks, which can be time consuming and frustrating. Patients often report AFOs in general to be bulky and uncosmetic[226].

A further disadvantage is that all AFOs that restrict and immobilise ankle range of motion may increase a risk of disuse atrophy in lower limb musculature[218], and therefore the use of the IDEO™ could expedite muscle atrophy in lower limb musculature below the knee. This is important as, empirically, patients with deck-slap injuries often present with functional muscle power in their injured limb (greater than 3 on the Oxford scale[227]).

While there are no published breakage rates for any AFOs available, it would seem plausible that the IDEO™ would be at risk of breakage as some patients use it for repetitive high activity. Although the use of carbon fibre provides a lightweight orthotic solution it doesn't lend itself to easy adjustment, and this can lead to increased remakes and a shorter lifespan of the orthosis if the patient's limb changes volume over time.

Composite custom PD AFOs, such as the Momentum®, are not commonly used within orthotic services in the UK, resulting in only a small number of clinicians and technicians experienced in applying and manufacturing them. Accessibility to expertise is therefore problematic for user's dependant on patient's geography. The Momentum® PD AFO is not readily available in the NHS due to cost, and a lack of clinical expertise and confidence applying it. It is predominantly supplied within the MOD and the private market in the UK. Training courses at DMRC Headley Court have been run for NHS clinicians with the goal of sharing PD AFO knowledge and improving the capability of NHS services to support personnel upon discharge from HM Armed forces.

2.19 Rehabilitation using the IDEO™

Injured service personnel are a unique clinical population who are accustomed to being incredibly physically fit and being able to participate in a large variety of highly demanding athletic and recreational activities. Once injured, many personnel will intensively focus on returning to their previous combat duties, and it is therefore vitally important that rehabilitation be tailored to maximise the personnel's potential success.

The US military provide the IDEO™ to clinically appropriate personnel alongside a specific "return to run programme"[22; 159; 171] based on sports medicine. This is a two-week intensive course which focuses on key components of rehabilitation, strength, agility and speed[159]. Initially participants work on strength and power with an emphasis on functional patterns. Strengthening begins in bilateral stance and progresses to lunging or split squat patterns. Eccentric strengthening is considered vitally important in building sufficient strength for

deceleration while running or playing sports[171]. Strength can be tested using isokinetic testing equipment. It has been reported that post IDEO™ provision and subsequent rehabilitation knee extensor strength can improve by up to 300%[171]. Knee extensor strength is believed to improve due to the ability to recruit proximal muscles, as the distal section of the limb is stabilised in the IDEO™[172]. Additionally, the improvement in strength may be attributable to the training effect and the increased use of the limb, as the user is more able in the IDEO™[171].

Agility and plyometric training is also initiated during the programme, allowing personnel to become comfortable loading the injured limb, and to work linearly in all 3 planes of motion to develop the multidirectional movement patterns that the IDEO™ allows[171]. Advanced plyometric work is undertaken utilising jumps, hops, and bounds[171] to allow the user to feel and harness the energy return from the IDEO™.

Recent evidence in uninjured participants suggest that strengthening and plyometric training may have a correlation to an improved running economy[228; 229]. Personnel are taught to run with a forefoot strike posture when using the IDEO™[171]. Due to the ankle typically being fixed in a plantarflexed position, it is thought that a forefoot strike patterning improves the energy return from the orthosis during high activity. Enabling this requires good knee control to reduce the risk of excessive knee hyperextension.

Recent evidence also suggests runners that make initial contact with their forefoot may have a lower impact transient compared to those who make initial contact with their heel[230] and therefore potentially decrease the impact stress that the injured limb is exposed to. Running biomechanics in the IDEO™ have not been investigated in detail, and the long-term potential consequences to musculoskeletal health are unclear.

2.19.1 Clinical outcomes of IDEO™ users

The return to run programme has been shown to improve physical performance, pain, and patient reported outcomes[5]. In 2012, 84 US personnel took part in a study[22] which tested participants without the IDEO™ before induction into an 8-week rehabilitation programme. They were tested again at week 4 without the IDEO™, as the first 4 weeks of the programme are without the orthosis while it is being manufactured. The participant was then provided with an IDEO™ and tested again after 4 weeks of rehabilitation using the IDEO at week 8. The short musculoskeletal function assessment[231] (SMFA), the veterans rand 12 health survey[232] (VR-12), and the visual analogue pain scale[233] (VAS) were used as patient reported outcome questionnaires. All patient outcome scores improved between 23-35% by week 8[22].

The following functional tests were used in this study:

- The 4-square step test
- Timed 12 stair ascent
- Self-selected walking velocity
- 20 metre shuttle run

No significant improvement was recorded from week 0-4 for all functional tests without the IDEO™. However, during weeks 4-8 significant improvements were seen post supply of the IDEO™. As no significant improvements were seen during weeks 0-4, it implies that the impact of the IDEO™ was the key driver that improved the participant's outcomes (Figure 2-24). As there is no IDEO™ group who were supplied the orthosis only, without participating in the 2-week rehabilitation programme, there is no way of accurately measuring how successful the programme is in improving results in this study. However, Blair et al.[156] demonstrated the benefit of the IDEO™ when supplied alongside a rehabilitation programme compared to those who only received the IDEO™[156]. Since the 84 participants presented with a wide range of physical impairments, it is difficult to draw conclusions from this study regarding predictive success of the IDEO™ with a particular injury profile.

Sheean et al.[167] examined a subset of the 84 participants, 12 who had an ankle joint fusion and possibly a subtalar joint fusion (exact number not specified), and 11 patients who underwent subtalar joint fusion only. The subtalar joint only group demonstrated significant improvements with the IDEO™ in both patient reported and physical performance outcomes whereas the ankle fusion group saw significant improvement in the physical performance measures, but not the patient reported outcomes[167]. Patient reported pain scores were generally improved with IDEO™ use, with pain reduced by 23-35%[22].

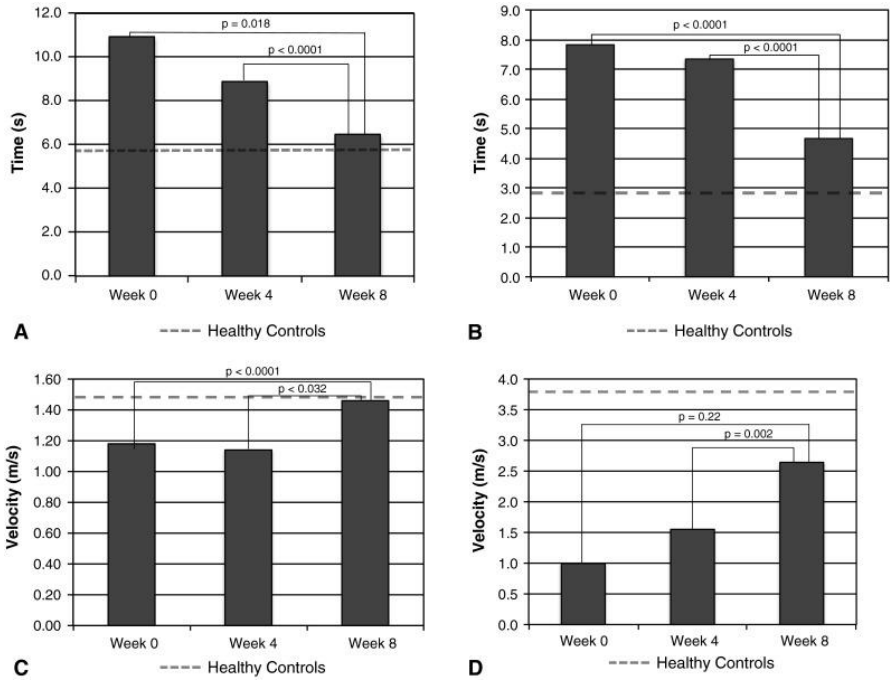

Figure 2-24 Mean Physical Functional Measures at week 0, 4 and 6 (Bedigrew et al) [22]

A) Time for the 4 square step test (effect size 4.5 seconds, 41%); (B) Time for the timed stair ascent (effect size 3.2 seconds, 40%); (C) Speed for the self-selected walking velocity (effect size 0.3 m/s, 24%); and (D) Speed for the 20-m shuttle run (effect size 1.6 m/s, 165%).

2.19.2 Clinical outcomes of PD AFO users at DMRC Headley Court

Ladlow et al.[23] published the first and only study to evaluate the medium-term (mean 34±11 months) effect of a PD AFO on functional and psychosocial outcomes in the UK. Retrospective levels of mobility, activities of daily living (ADL), anxiety, depression and pain were evaluated in a heterogeneous group of 23 injured UK servicemen after PD AFO provision. This data was then compared to limb salvage military data gathered prior to PD AFO availability[15].

Before PD AFO availability, 74% of limb salvage patients could walk with or without walking aids and 4% could run independently[15]. Post provision of the PD AFO and rehabilitation this increased to 91% and 57% respectively[23]. PD AFO users were also able to walk greater distances over a 6-minute walk test and these distances were in keeping with the able bodied[23]. This study suggests that most PD AFO users plateaued in function with the orthosis after the 2nd admission i.e. after 6 weeks of residential rehabilitation using the orthosis[23]. PD AFO users reported improvement and, importantly, no deterioration in their pain status, alongside unchanged levels of 'none to minimal' depression and anxiety[23]. There was a twofold increase in the number of personnel reporting 'no pain' without the PD AFO at follow-up (13%–31%). Those who received MDT rehabilitation after PD AFO provision were better able to 'control their pain' when wearing and not wearing their brace compared with patients who did not receive residential rehabilitation after PD AFO fitting[23]. The group of PD AFO users were comparable to below knee military amputees regarding function, quality of life and pain status[23]. When compared to previous limb salvage personnel who did not utilise a PD AFO, a significant improvement to function, quality of life and pain status was reported[15; 23].

Direct comparisons of the limb salvage group to previous literature is difficult due to the vast range of surgical procedures encompassed within the term "salvage" and the limited number of studies in this patient population using an PD AFO[23; 78]. Even though the sample size is small and there is a lack of control group, the results from this first UK study are encouraging.

2.19.3 PD AFO summary

The IDEO™ was first introduced to increase function, return to duty rates, and reduce elective amputation rates following lower extremity trauma and limb salvage[5]. Moderate evidence[4; 22; 156; 159; 167-169; 171; 172; 234-236] from 12 studies support 4 empirical evidence statements in personnel under 40 years of age, injured with high-energy lower extremity trauma, potentially confounded by post-traumatic ankle osteoarthritis, using an IDEO™, and participating in residential rehabilitation following limb salvage surgery[5].

Empirical evidence statements[5]

1. May allow return to active duty for a limited population of high functioning users[156; 167; 169; 171; 235; 236]
2. May allow return to exercise, recreation and physical activity, and decreased pain for a limited population of high functioning users[22; 159; 169; 171; 235; 236]
3. Results in improved agility, power and speed, compared with no-brace or conventional off the shelf bracing alternatives[159]
4. IDEO strut stiffness should be considered with respect to patient preference only[168; 172; 234]

While research available on PD AFO designs such as the IDEO™ is encouraging, there are large gaps in the literature. Most published research uses small sample sizes that exhibit selection bias. The participant injury groups are often very mixed clinically, as is the inevitable nature of reporting on lower limb trauma. This vast variation makes it difficult to draw any conclusion from the data.

PD AFOs such as the IDEO™ have not been tested compared to other custom-made orthotic designs. Only comparisons have been made to off the shelf orthoses[159] whose material and function are very different biomechanically to composite PD AFOs. There is no published baseline gait analysis data on blast injury limb salvage patients, only data utilising PD AFOs or prostheses.

Additionally, there are no long-term studies that look at the implications of partaking in high activity sport post limb salvage. PD AFOs were ultimately prescribed within the military to provide severely injured personnel with an alternative to amputation that would allow them to lead the active lifestyle they desire. Had the PD AFO not been provided, many would have opted for elective amputation both in the UK and the USA. However, the long-term effects of using a PD AFO on joint health are unknown. Therefore, one cannot say with certainty this was a better long-term clinical solution for this patient group.

Previous studies have examined the gait of PD AFO users, but this study is novel as it presents the functional gait differences in individuals with and without a PD AFO. By presenting the gait analysis and PROM's results, this thesis will strive to answer the following research question and hypotheses:

Research Question: Does a PD AFO improve gait and functional outcomes of injured military personnel who have undergone unilateral limb salvage?

Hypothesis 1: PD AFO use will improve the patient reported outcomes of injured military personal that have undergone unilateral limb salvage.

Hypothesis 2: PD AFO use will improve participants propulsion through midstance and terminal stance of gait in both the injured and uninjured limb.

Hypothesis 3: PD AFO use will improve participants stability through stance phase of gait.

Hypothesis 4: PD AFO use will improve the gait profile score of both the injured and uninjured limb.

Chapter 3: Methodology

3.1 Chapter overview

This chapter outlines the retrospective study design, from provision of the PD AFO following the typical Headley Court pathway, and the process that was implemented to compare the kinematics, kinetics and temporal spatial parameters of gait in participants when walking with and without a PD AFO. Furthermore, the chapter outlines the approach used to gather patient reported outcome measures (PROMs) before and after provision of the PD AFO.

The recruitment strategy of the study is described, and a detailed description of the orthosis is presented.

The procedures undertaken to estimate the motion between the body segments and calculate the desired biomechanical outcomes are described, and the parameters used to answer the hypotheses presented.

Finally, the statistical techniques employed to determine any statistical significance or effect in the biomechanical data and PROMs are presented.

3.1.1 PD AFO service summary

All participants attended the orthotic clinic at DMRC Headley Court and were fitted with a PD AFO between 2014 and 2016. In accordance with standard clinic practice at DMRC Headley Court, all participants were invited to answer PROM questionnaires (Appendix A and B) pre and post-provision of the PD AFO.

Participants also attended the onsite gait laboratory for gait analysis post supply of their orthosis. All gait analysis sessions were undertaken by both the researcher/orthotist and the local Higher Scientific Officer (HSO) who managed the clinical sessions in the gait laboratory. This process was in line with the department's standard clinical delivery for all PD AFO users. Kinematic, kinetic and temporal spatial data were collected both during walking with and without the PD AFO. In both test conditions the participants were shod.

3.1.2 An overview of the current clinical DMRC Headley Court PD AFO pathway to provision

A patient is referred for fitting of a PD AFO by the consultant-led interdisciplinary team (IDT). The patient is assessed by an orthotist and if deemed clinically appropriate a PD AFO is offered as a form of treatment to reduce pain and/or improve biomechanical function. The local clinical criteria for provision of a PD AFO are outlined in Table 3.1.

Table 3-1 Inclusion and exclusion criteria for provision of PD AFO at DMRC Headley Court

Inclusion criteria	Exclusion criteria
Patient exhibits biomechanical pain to the foot/ankle, that is not responding well to standard rehabilitation treatment protocols.	Planned surgery.
Plateau in functional ability post rehabilitation input, and level of function is deemed suboptimal.	Open wounds or poor skin quality in the area of the orthosis.
Sufficient hip, knee and trunk control to have controlled use of the PD AFO, and benefit from the energy returning properties.	History of recurrent ulceration.
Patient has a nerve injury presenting with weakness (less than 3 Oxford scale) in the plantar flexor muscles.	Significant oedema that can't be managed successfully with medication or clinical compression hosiery.
Patient has the desire to take part in high level activities such as running, and the patient's physiotherapist and rehabilitation consultant are satisfied that the patients has adequate hip and knee control as well as no medical reasons why the patient can't peruse such endeavours.	Severe knee cruciate ligament insufficiency, as PD AFO's design encourages a greater knee extension moment[69].

If after physical assessment the patient consents to treatment, the individual is cast and a custom-made PD AFO manufactured for them.

At the assessment the patient is asked to complete 2 validated PROMs questionnaires, the foot and ankle outcome score (FAOS) (Appendix A) and the lower extremity functional scale (LEFS) (Appendix B).

The PD AFO is supplied to the patient typically 6 weeks after the initial assessment/casting appointment in line with manufacturers' lead times. It is common that the PD AFO requires fine adjustment to improve comfort and fit with use, and this takes place within the first 3 weeks of fitting.

3.1.3 Evaluation of the PD AFO

All PD AFO users attend the gait laboratory, ideally at the end of their second admission post-supply to collect kinematic, kinetic and temporal spatial gait data. This, on average, is 8-9 weeks post supply of the PD AFO (Figure 3-1), as this is when a plateau in functional improvement using a PD AFO is typically seen[23].

The PD AFO 3D gait analysis session was the only time the participants in this study visited the gait laboratory.

Data were collected both shod with and without the PD AFO and used to measure changes in the patients' gait. The data are also used clinically to check the PD AFO alignment and help highlight any potential areas in gait that could benefit from re-education or improved muscle control work in therapy.

Whilst it is appreciated that a 3D gait analysis appointment shortly after provision of the PD AFO may be more beneficial for fine tuning purposes, the overall goal of gathering data is to measure the changes in gait and therefore it is deemed more appropriate to allow the PD AFO user time to suitably adapt to the orthosis. Having 2 gait analysis sessions was deemed to be too difficult to achieve for every PD AFO user due to staff and gait laboratory resources.

The patient and their treating clinical team are invited to a feedback session post data collection with the HSO within 3 weeks. This ensures that the patient is not only engaged with the process but values the gait analysis clinical session undertaken.

3.2 An overview of the PD AFO rehabilitation pathway

Admission to DMRC Headley Court is typically for 3 weeks of residential rehabilitation followed by 3 weeks leave at home before the next admission block (Figure 3-1). During admission each patient follows their own personalised timetable. The timetable is split into hourly slots from 08.00-16.00 and each treating professional books an hour slot with the patient as required.

The IDT team consists of; rehabilitation consultants, physiotherapists occupational therapists, prosthetists/orthotists, exercise and rehabilitation instructors, social workers, mental health practitioners, podiatrists and nursing staff.

As the patient progresses with rehabilitation the gaps between each 3-week admission block increases. The admission block requirements are planned by the patient's rehabilitation consultant. On average, patients who have sustained a complex trauma are treated at DMRC Headley Court for 2-5 years prior to discharge from HM Armed Forces. All medical care thereafter is conducted in a civilian setting, most commonly in NHS hospitals.

While the service aims for 3D gait analysis to be undertaken around 8-9 weeks post provision of the PD AFO, the timing of the gait laboratory session is determined by several factors such as:

- Patient availability at DMRC Headley Court
- Laboratory availability
- Researcher/orthotist and physiotherapist agreement that the patient has made enough progress utilising their PD AFO, and that the patient's gait patterning using the PD AFO has plateaued. The patient must attend residential rehabilitation for at least 3 weeks before 3D gait analysis will be considered

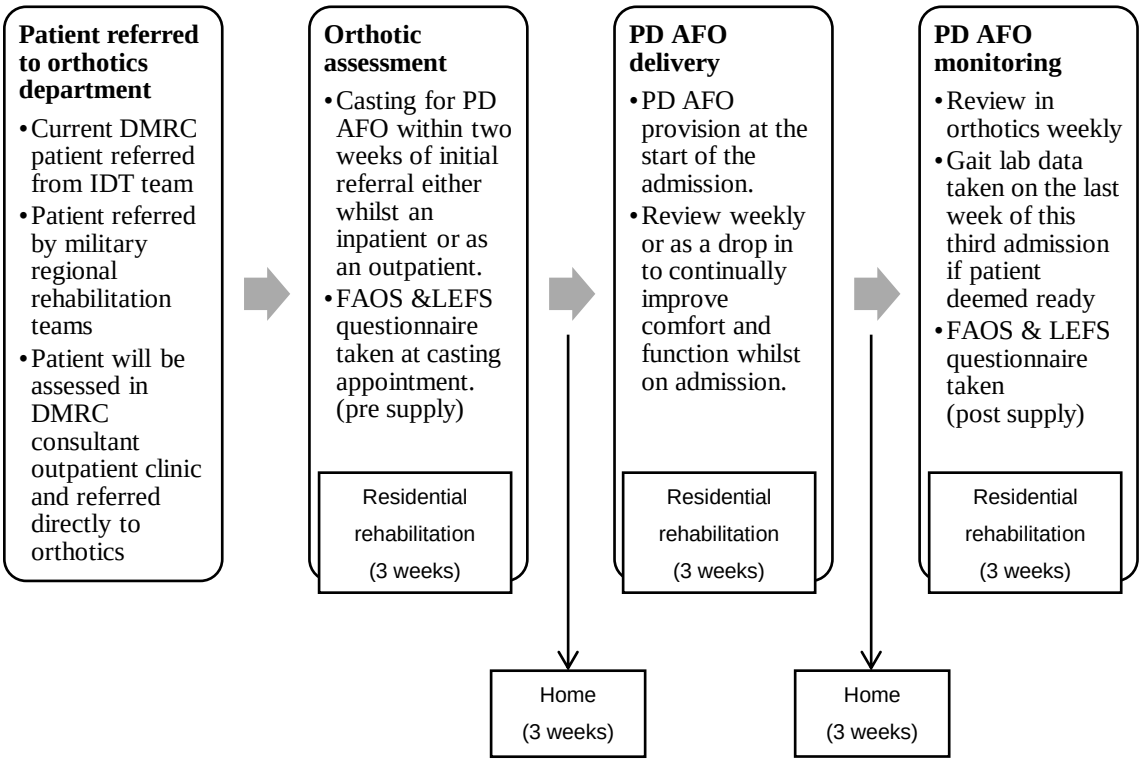

Figure 3-1 Patient journey to PD AFO provision and associated rehabilitation structure

3.3 Study inclusion/exclusion criteria

Inclusion criteria

- Sustained a complex hindfoot fracture in Afghanistan due to the detonation of an improvised explosive device (IED). The calcaneus must have been fractured and diagnosed by x ray
- Participant was referred to orthotics for a PD AFO and had sustained a unilateral injury.
- Participant was referred in response to rehabilitation plateauing due to ongoing biomechanical pain in the foot and ankle
- Orthopaedic consultant was not planning any further surgery currently
- Participant was capable of walking without walking aids for at least 10 minutes continuously, both with and without the PD AFO. Doing so did

not cause severe onset of pain which would have been harmful to the individual

- Compliant with rehabilitation

Exclusion criteria

- Known history of neurological condition including brain or spinal cord injury
- Known history of peripheral nerve injury
- Participant sustained other lower limb traumatic injuries that are still causing pain or deformity
- Diagnosed lower limb or trunk musculoskeletal degeneration prior to traumatic injury

3.4 Ethical approval and data management

It is necessary to obtain ethical approval to comply with the “declaration of Helsinki and committee for proprietary medicinal products note for guidance on good clinical practice for trials of medicinal products”[237]. Ethical approval was sought and gained from both Salford University (Appendix E) and the Ministry of Defence research ethics committee (MODREC) (Appendix F). Ethical approval was sought to use retrospective data that had been collected as part of the clinical orthotics service offering. MODREC was approved on 20/03/2016 reference number: 690/MODREC/15, and Salford ethics approved on 29/11/2016 reference number: HSCR16-69. The MODREC application was for a larger project of which my MRes was a small part. Therefore, there is 8 months gap between each application.

Once consent was provided, participants were given a unique participant identification code. All stored data uses this code only and does not contain personal details. The code is specific to this study with no other identifying data. A list linking participant identification codes to participant names is securely maintained on “DII” which is the Ministry of Defence secure defence intranet. It is password protected.

All data from the LEFS/FAOS questionnaires have been entered onto a Microsoft Excel spread sheet, which is stored within the DII research department folder. This is also password protected. Paper records of the LEFS/FAOS and consent forms for each participant are stored in the participant's clinical records, as it forms part of their clinical care. Files are kept in a secure building, in a locked cabinet in line with local policies.

In accordance with current MOD policy and UK trials regulations guidelines, consent forms and all other paper and electronic records will be securely stored in the research archive on the Academic Department of Military Rehabilitation (ADMR) for 15 years. Arrangements for confidential destruction of other material will be made after 5-years according to the ADMR policy.

3.5 Recruitment of participants

Participants were invited to take part in this study if they met the inclusion/exclusion criteria above. Out of the 46 personnel fitted with a PD AFO at Headley Court, 12 personnel were identified as the only suitable participants Due to the nature of blast trauma very few patients had isolated injuries of a unilateral nature at the foot and ankle, and many patients presented with lower limb nerve damage, traumatic brain injury and bilateral lower limb injuries.

The 12 users who met the inclusion criteria were written to and invited to consent for their data to be used within this study (Figure 3-2). It was made clear within the consent form (Appendix C) that allowing use of their data was entirely voluntary. Participants' clinical treatment or care would not be affected, should they not wish their data to be used for this purpose. All 12 participants were provided with a participant information sheet (Appendix D) in the same letter and invited to ask questions. All participants were informed that they could retract consent at any time without explanation and this would not affect their clinical care at DMRC Headley Court. All 12 participants who were invited to participate consented to be part of this study and no participants withdrew during the study.

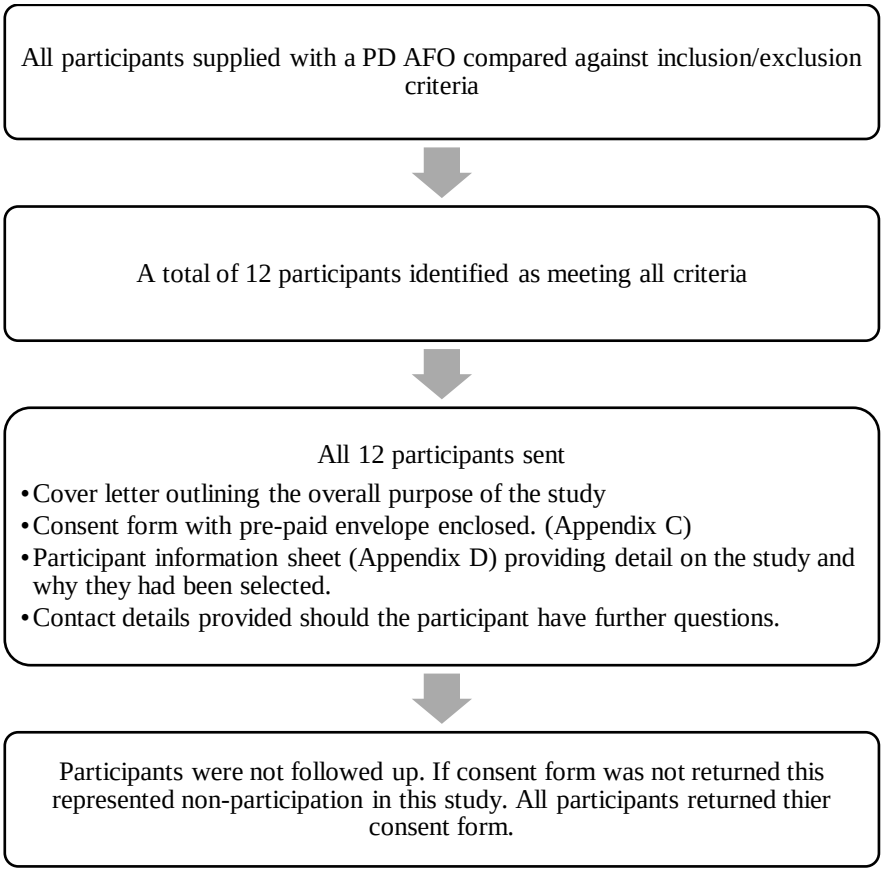

Figure 3-2 Recruitment process

3.6 Testing of orthotic intervention

3.6.1 Ankle angle of participants PD AFOs

All 12 participants in this study were assessed and cast by the researcher/orthotist and the ankle angle selected was determined as outlined in 2.14.1. All 12 participants had an ankle angle fixed in the PD AFO of between 5-10° plantar flexed (Table 3-2).

Table 3-2 Ankle angle of each participant's PD AFO

Participant	Plantarflexion angle of PD AFO as cast (°)	Reason for set ankle angle
AP02	10	Tightness in calf musculature and position deemed least painful on weight bearing.
AP03	8	Tightness in calf musculature
AP06	5	Position deemed least painful on weight bearing.

AP07	5	Tightness in calf musculature and position deemed least painful on weight bearing.
AP08	8	Tightness in calf musculature and position deemed least painful on weight bearing.
AP09	8	Position deemed least painful on weight bearing.
AP10	10	Position deemed least painful on weight bearing.
AP11	5	Position deemed least painful on weight bearing.
AP12	5	Position deemed least painful on weight bearing.
AP17	12	Tightness in calf musculature
AP19	8	Tightness in calf musculature and position deemed least painful on weight bearing.
AP20	5	Position deemed least painful on weight bearing.

The ankle angle was always set into the negative cast and never rectified into the positive cast thereafter. Empirically, rectifying the desired ankle angle into the positive cast inevitably changes the overall shape and depth of the foot within the orthosis. Ultimately if the positive cast is adjusted in this way the fit of the PD AFO is more likely to be suboptimum, as it introduces a greater degree of potential human error into the manufacture process. While this has not been verified in a clinical study it is widely considered good clinical practice within the orthotics industry.

All participants' PD AFO had a neutral hindfoot to forefoot alignment as captured in the cast, no intrinsic posting was utilised by the researcher/orthotist due to fixed varus or valgus deformities[69].

3.6.2 Participant preparation for casting

Cling film and stockinet were wrapped around the injured limb to protect the skin from casting materials. A cutting strip was positioned lateral to the knee, sweeping down the front of the anterior tibia and ankle. This allows for good shaping around the anterior knee section, necessary to identify the patella tendon location (Figure 3-3).

The following bony prominences were marked with indelible pencil; margins of the 1st metatarsophalangeal joint, margins of the base of the 5th metatarsal, margins of the medial and lateral malleoli, margins of the fibular head, margins

of the patella and either side of the patella tendon distal to the patella, margins of the medial and lateral tibial flares, and clinically appropriate areas for that individual patient, such as specific areas of scar tissue or location of metalwork superficial to the surface of the skin.

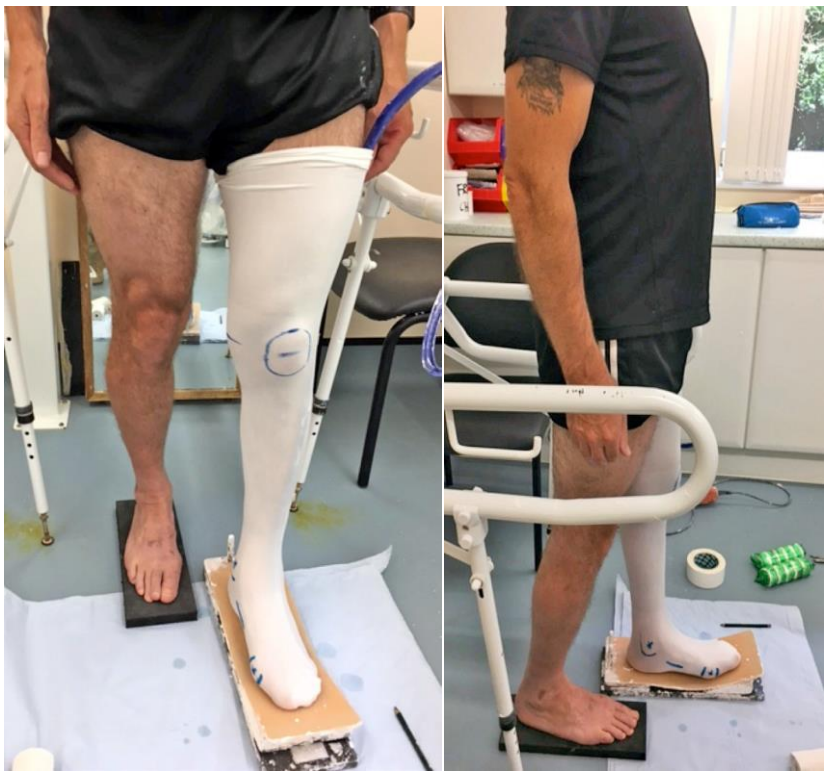

Figure 3-3 Study participant demonstrating the PD AFO casting set up (Source: Picture taken by thesis author at DMRC Headley Cout)

3.6.3 Casting of participants

All 12 participants were cast using Cellacast Xtrsa® (Ottobock), a fibreglass fabric bandage impregnated with polyurethane resin. This material was favoured as it anecdotally creates a stronger cast that is less likely to deform in transit to the manufacturer's laboratory, and it is less messy in clinic compared to conventional plaster of paris.

The researcher/orthotist always wrapped from above the knee downwards, as with limited time until the bandage sets the orthotist required greater time to ensure that the cast had an optimum foot position. Controlling the foot and ankle is technically and physically more challenging within the casting environment compared to shaping around the knee, as there are many joints

which require control. Therefore, starting the cast at the knee and working downwards is easier in practice. Once the knee section was wrapped it was shaped, and the patella tendon identified in the cast by the researcher's thumbs. The wrap was extended downwards around the foot, and the limb positioned into the identified favourable position (ankle angle and width of standing base) identified as optimum pre-casting, as described in 2.14.2. All participants were cast standing as described in 2.14.2. No participants presented with a flexible pes planus foot type empirically, unsuitable for this casting technique.

Once the fibreglass bandage had cured, the cast was removed using an oscillating saw. The researcher checked each cast's alignment in the coronal, sagittal and transverse planes to ensure it was satisfactory. The cast was then sealed ready for transit to the manufacturer, along with measurements and specification information.

3.6.4 Measurements

The following measures were taken from the participant's limb and sent with the negative cast to the manufacturer (Figure 3-4). These were taken with a calibrated tape measure and callipers.

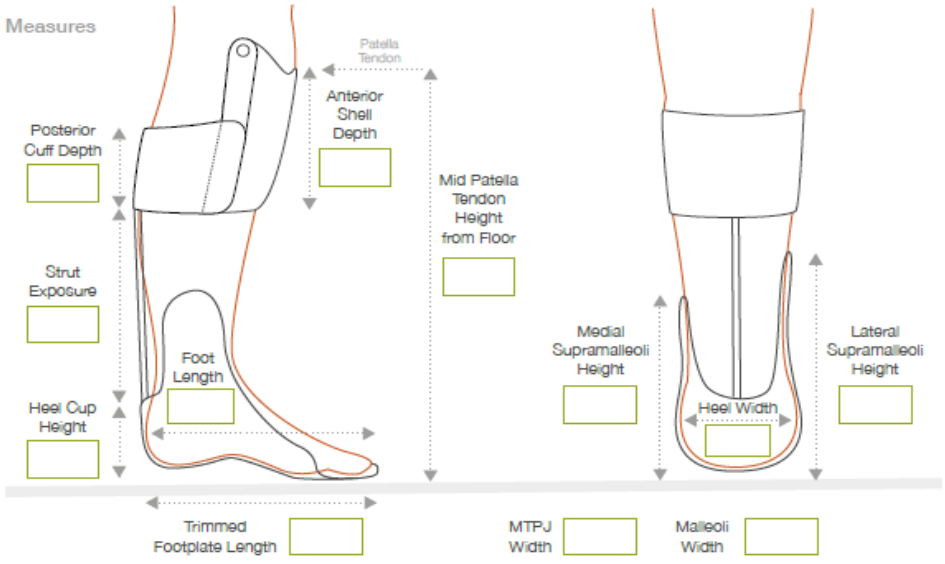

Figure 3-4 PD AFO Manufacturing measures (Source: Blatchford Momentum® clinicians ordering form- internal document)

3.8 Specification of AFO

3.8.1 Strut selection

The researcher/orthotist provided the manufacturer with the weight, height and activity level of the patient. The researcher/orthotist uses an adapted version of the Medicare functional classification level[238] (MFCL) (Table 3-3) to define the patients activity level. This information dictates what strength of posterior strut is selected and the number of composite layers in the foot and ankle section of the PD AFO, as discussed in 2.13.3. All participants in this study were either defined as K-level 3 or K-level 4.

Table 3-3 Medicare Functional Classification Level (MFCL) Definitions[238]

K-level 0	Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis/orthosis does not enhance quality of life or mobility
K-level 1	Has the ability or potential to use a prosthesis/orthosis for transfers or ambulation on level surfaces at a fixed cadence. Typical of the limited and unlimited household ambulator.
K-level 2	Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
K-level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who can traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic/orthotic use beyond simple locomotion.
K-level 4	Has the ability or potential for prosthetic/orthotic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic/orthotic demands of the child, active adult, or athlete.

The criteria used for strut selection was provided to DMRC Headley Court by the Centre for the Intrepid (CFI). It has not been scientifically tested or verified but has been adopted as best practice until such times it has been tested (Table 3-4). Large struts were used in 7 participants PD AFOs and medium struts used in the 5 remaining participants.

Table 3-4 Strut selection chart (Source: Clinical team at the CFI)

Patient weight	Walking only	Walking and running
<55kg	Small	Medium
55kg-85kg	Medium	Large
85kg-100kg	Large	Extra Large
>100kg	Extra Large	Extra Large (consider triple strut)

3.8.2 Dimensions of the PD AFO

The length of each PD AFO is depended on the height of the patient and their clinical requirements. For each of the 12 participants their PD AFO measured as follows +/- 2cm (Table 3-5).

Table 3-5 Dimensions of the participants PD AFO

PD AFO section	Length of section
Length of strut exposure	20cm
Depth of anterior knee cuff	12cm
Depth of posterior knee cuff	10cm
Height of lateral and medial supra malleolar section (from floor to distal tip of)	18cm
Depth of Heel cup	12cm

3.8.3 Rectification of the PD AFO

The manufacturer filled the negative cast with plaster of paris and the following rectification was carried out to the positive cast as standard (Table 3-6):

Table 3-6 Standard cast rectification

Cast removal	Cast build up
Patella tendon- 12mm	Distal end of tibia- 8mm
Medial and lateral flares of the tibia- 5mm	Medial and lateral malleoli- 3mm
Take 5mm off calf bulk soft tissue	Navicular- 3mm
	Fibular head- 4mm
	Return curve on the posterior calf

3.8.4 Manufacture of the participants' PD AFO

In this study 10 PD AFOs were manufactured by Orthotic Composites Ltd and 2 by Chas A Blatchford and Sons Ltd. All 12 PD AFOs worn by the participants were manufactured as described in 2.12.1. All were finished with 6mm Poron® padding on the anterior knee cuff and 3mm Poron® padding on the malleoli, navicular and footplate areas. Each had a gloss finish on the outer composite layer to allow for easier donning of footwear. All used a rivet to hold the anterior knee section in place and a velcro® strap to close the knee section into position. No ankle or toe straps were used.

3.9 Fitting of the participant's PD AFO

All participants had a diagnostic fitting 2 weeks after casting, followed 6 weeks later with the final supply of their composite PD AFO. This was in line with the manufacturers' lead times. The process of fitting the participants' diagnostic and definitive PD AFO was the same.

3.9.1 Static fitting

Firstly, the class I compression sock, as described in 2.15.1.1, was donned by the participant, and the PD AFO applied whilst sitting. Final trim lines were marked, and any immediate areas of sub-optimal fit noted. The researcher/orthotist trimmed the PD AFO to fit into the participant's footwear and adjusted the orthosis as required to optimise initial fit.

3.9.2 Bench alignment

The PD AFO was then bench aligned following principals discussed in 2.15.4. A heel elevator, as discussed in 2.13.4, was positioned inside the shoe under the heel of the PD AFO to bring the shank to vertical angle to 10-12°[193] (Figure 3-5). This was measured by the researcher/orthotist using a goniometer to deem the optimum position to start dynamic testing[193]. The heel elevator, therefore, was at a variable height for each participant, as the height of the elevator was dependant on the ankle angle of the PD AFO, the pitch of the participant's

footwear (heel-sole differential[193]) and any prior true leg length discrepancies already identified on assessment.

Figure 3-5 Optimal PD AFO bench alignment (10-12° shank to vertical[193]) (Source: picture taken by thesis author at DMRC Headley Court)

All participants used their own sports trainers with a standard pitch of between 10-15mm; footwear was not standardised. This study had no budget to purchase footwear for each participant to make footwear provision consistent; therefore, patients used their own trainers. No adaptations were made to any of the participants' trainers. A heel elevator was made for the participant's sound side at the height required to ensure the pelvis was level when standing wearing the PD AFO and footwear combination on the injured side.

3.9.3 Determining leg length

Leg length was determined using two methods:

- Standing - The researcher/orthotist located both the participant's anterior superior iliac spines (ASIS) and posterior superior iliac spines (PSIS) on the pelvis and assessed visually if these were level[239], making sure that the knees were not flexed. Blocks of 5mm were used, if needed, to determine any shortening present. This was carried out with the PD AFO in situ, with the participant wearing their trainers and appropriate heel elevators bilaterally.

- Supine - The researcher/orthotist measured both limbs with a calibrated tape measure from the ASIS to the apex of the medial malleoli[240] ensuring that the knee was neither flexed or hyperextended.

Dynamic fitting did not start until the lengths of the patient's limbs were deemed equal with the PD AFO, footwear and appropriate heel elevators in situ.

3.9.4 Dynamic fitting

The participant was initially invited to walk between parallel bars and feedback on the comfort of the PD AFO. Any necessary adjustments that were required to improve the fit and comfort of the PD AFO were undertaken by the researcher/orthotist.

The participant was encouraged, if possible, to roll over through the PD AFO and load both limbs equally, opening their stride length gradually. Empirically, to benefit from the spring-like characteristics of the PD AFO, the participant must load the PD AFO sufficiently.

Both the researcher/orthotist and the participant's physiotherapist observed the participant's gait visually, focusing on the functional tasks of gait, such as weight acceptance, single limb support and swing limb advancement in both the coronal and sagittal plane[239]. The participant's foot, knee and hip positions were noted, and any gait deviations evident were discussed to identify if they were caused by the PD AFOs alignment, or if caused by other factors such as poor muscle control, for example. The participant's gait was also recorded on the physiotherapy department's Apple iPad™. This enabled the clinical team to watch the participant's gait in slow motion and allow for retrospective visual analysis.

Fine tuning[193] was carried out at the fitting appointment and at subsequent review appointments within the orthotics department to optimise PD AFO function using video vector.

Advice was provided verbally to participants on the care and wear of their PD AFO, as well as a department written information leaflet.

3.10 Instrumentation

3.10.1 Summary of motion analysis equipment

Measurements were made with an optoelectronic motion capture system (Vicon, Oxford, UK) with 10 T-Series Vicon cameras and 4 strain gauge force plates (AMTI, Watertown, MA, USA) embedded within a 10m walkway. Kinematic data were collected at 120Hz and ground reaction forces at 1200Hz. Standard video was captured in both the sagittal and coronal planes as an assurance measure to support or verify any anomalies in the captured 3D kinematic data if required.

3.10.2 System calibration and lab coordinate system set up

The purpose of calibration is to minimise any measurement uncertainty by ensuring the accuracy of the gait analysis equipment prior to testing. The system calibration incorporates data derived from the force plates and data generated from the camera measurement system. Both the calibrated force plates and camera system provide an accurate measurement of the motion data of tracking markers and ground reaction forces (GRF). The camera system was calibrated using an Active Wand (Vicon). The L-frame on the Active Wand contains 4 markers: 2 markers are attached to form the X-axis and another 2 markers determine the Y-axis (Figure 3-6).

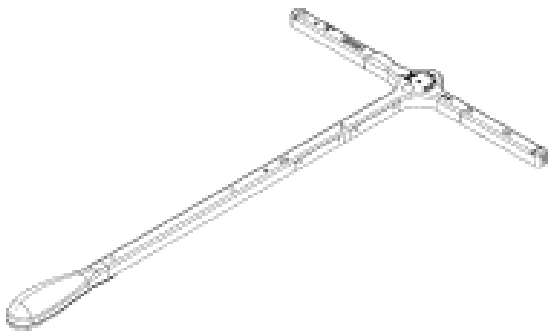

Figure 3-6 Active Wand used to calibrate the T- Series Vicon camera system (Source :Vicon)[241]

To calibrate, the Active Wand was placed at the original corner of force plate 1, with the X and Y axis aligned with the 2 sides of the force plates. The Active Wand's reference structure determined the laboratory coordinate system. In this study the X-axis was set as anterior-posterior, the Y-axis was set along a medial-lateral direction and the Z-axis was the vertical axis. The Active Wand was waved by the researcher inside the measurement volume, (between all the cameras), in all 3 directions. This procedure ensures that all the data capture space will be calibrated with the Active Wand and provides the system with accurate distances. The camera system signals when each camera is correctly calibrated, and the Active Wand is weaved until all 10 cameras are confirmed to be calibrated. The gait analysis lab at DMRC Headley Court is pictured below (Figure 3-7).

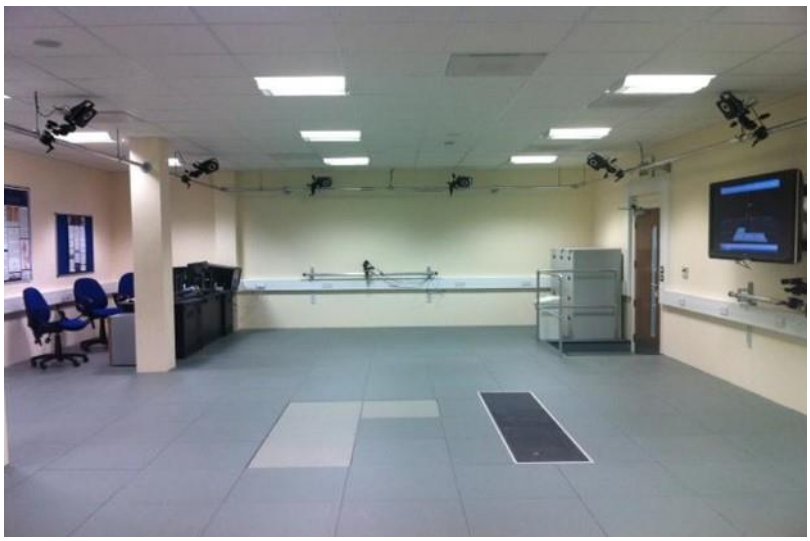

Figure 3-7 The gait laboratory at DMRC Headley Court (Source: picture taken by thesis author at DMRC Headley Court)

3.10.3 Force plate set up

In the laboratory 4 force plates were used to capture 1 full gait cycle, capturing at a frequency of 1200Hz with a threshold for detection of 10N. All force plates were level with the laboratory floor, aligned in the same direction as one another, and had a medial-lateral offset between adjacent plates to allow for lateral sway and step width. The gait laboratory was calibrated according to manufacturers guidelines.

Calibrating the force plates is important, as any errors in the parameter settings of the force plates can lead to incorrect values of joint kinetics. To ensure accuracy of the force plate measurements and their settings in the laboratory coordinate system (the exact position and orientation), a CalTester device[242] (which consists of a rod with 2 conical tips, five wands with retroreflective markers, a force application bar and a base plate) was used. The CalTester test procedure that was undertaken is described below in (Figure 3-8).

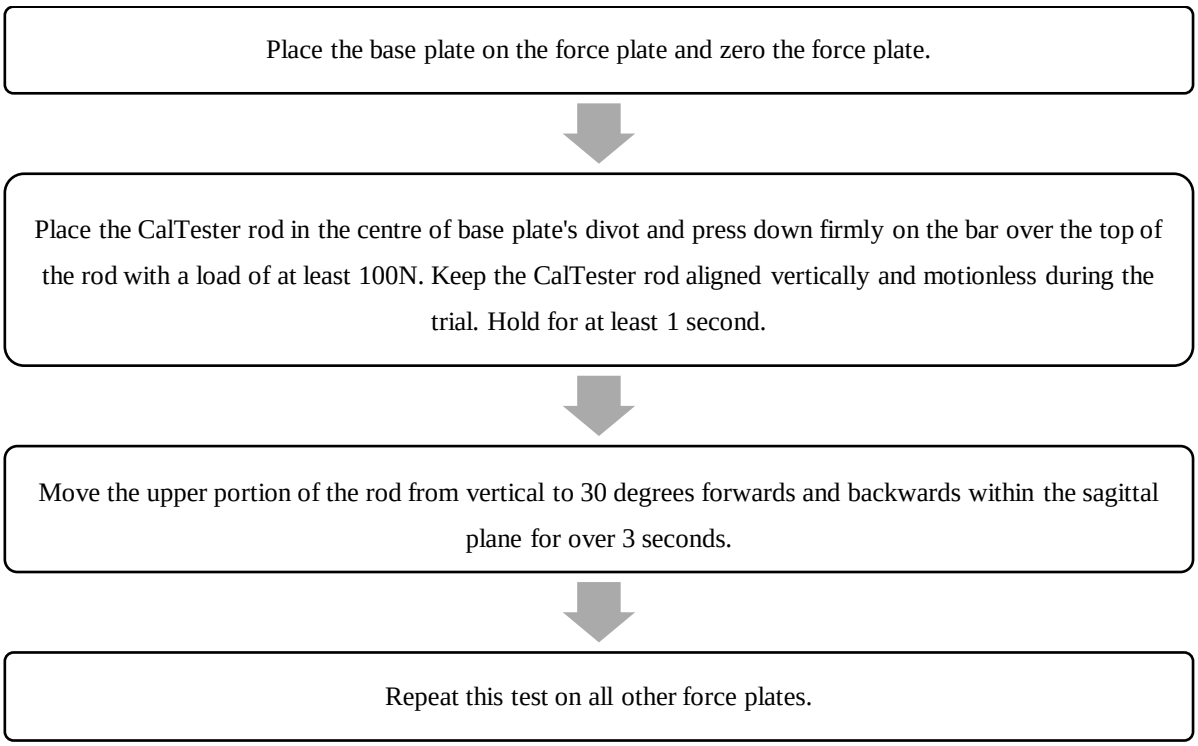

Figure 3-8 CalTester test procedure

Once the Caltester data collected were processed in CalTesterPlus (Visual 3D) software, the results were compared to a threshold that was in line with the University of Salford's lab standards:

1. A GRF orientation error of 1%
2. A 3mm location error of the X, Y and Z COP, in line with Salford universities lab standards

If the results fell above these thresholds, the Vicon system and force plates were re-calibrated and the Caltester test was repeated until the results were satisfactory.

3.11 Participant preparation

3.11.1 Anthropometric measurements

On arrival to the gait laboratory the participant was requested to change into shorts. The following anthropometric measurements were taken following written informed consent for the 3D gait analysis session (Table 3-7).

Table 3-7 Anthropometric measures

Measurement	Method	Unit recorded
Height	Stadiometer	cm
Mass	Medical grade scales	kg
Bilateral leg length	Measure taken from ASIS to the apex of the medial malleoli using a calibrated tape measure, with the participant lying supine on a flat plinth.	cm
Bilateral knee joint width	Callipers	cm
Shoulder offset	Callipers	cm

All anthropometric measures were recorded into the participant's medical records and stored in line with local MOD policy.

3.11.2 Gait analysis markers

To track the movement of the participant's body during walking, the motion capture system detects the position of several 14mm retro-reflective markers that are attached to both the participant's skin and the PD AFO using double sided sticky tape.

The markers were placed onto specific locations of the participant's body (Table 3-8), and this allowed for the system to approximate the location of the participant's anatomical landmarks and, more specifically, the underlying bony anatomy.

In this study, the placement of the lower limb reflective markers was based upon previous studies of amputee gait (Protocol: 272/PPE/11) conducted at DMRC Headley Court[246; 247]. This lower limb marker set is the standard model used at Salford University and was selected so that a direct comparison between the walking ability of below knee amputees, and the individuals who had lower limb salvage surgery (who wear a PD AFO) could be made in the future. All participants in this study had the same markers applied using the same model.

The system uses this information to define a virtual model and it tracks the movement of the pelvis, thigh, shank and foot segments during walking. The infrared light from each camera's light emitting diodes (LED) reflects off the markers to obtain the 2-dimensional (2D) co-ordinates of the markers on the participant's body. Data from the system's calibration procedure identify the locations of the cameras relative to a laboratory-fixed co-ordinate frame[243]. This was used to combine all the cameras' 2D co-ordinates to obtain the markers' 3D co-ordinates.

3.11.3 Calibrated anatomical systems technique (CAST)

The process of using markers attached to skin can result in inaccuracies due to movement of the skin under the marker whilst the patient is moving. To minimise skin movement whilst testing, a method known as the Calibrated Anatomical Systems Technique (CAST) was developed[127; 244]. Cappozzo et al.[127; 245] describes that markers over fleshy areas of the body experience more skin movement compared to markers over bony prominences. However, the bony prominence markers are necessary to define the ends of human segments and joints in order to approximate the location of underlying bones. Markers over fleshy areas are referred to as 'technical markers' and define a technical co-ordinate frame. The markers over bony prominences are referred to as 'anatomical markers' and define an anatomical co-ordinate frame. Assuming body segments are rigid, the spatial relationship can be determined between an anatomical frame and a technical frame on the same body segment during a

static trial. The CAST protocol was used in this study to minimise the effect of soft tissue artefact leading to marker displacement errors.

3.11.4 Marker placement

Each participant had 39 technical, and 32 anatomical markers placed on the landmarks outlined in (Table 3-8). Clusters of 3 or 4 markers on a rigid plate (Figure 3-9) were used as part of the technical marker set, instead of individual markers, as an additional means of reducing skin-movement (CAST protocol), therefore reducing inaccuracies. Although the gathering of full body data was in line with standard clinical service delivery, this study will only discuss the lower limb data gathered.

All the markers were applied with double-sided medical tape whilst the participant was standing, to reduce the risk of the markers on the skin moving relative to the bone as the participant transcends from sitting or lying to standing[77]. All participants were asked to inform the researcher should this be too uncomfortable, and they were informed they could sit down at any time, as a seat was made available. All participants felt they were able to do this, and no participant asked to sit down during positioning of the markers.

Table 3-8 Marker set locations

Marker Type	Segment	Right	Left	Placement	Markers
Anatomical	Head	Mastoid Process Occipital Protuberance	Mastoid Process	Placed on a band that was wrapped around the participants head	3
	Shoulder	Distal tip of the acromion process	Distal tip of the acromion process		2
	Elbow	Medial Humeral Epicondyle Lateral Humeral Epicondyle	Medial Humeral Epicondyle Lateral Humeral Epicondyle		4
	Wrist Hand	Medial Styloid Process Lateral Styloid Process 2nd Metacarpelphalangeal Joint	Medial Styloid Process Lateral Styloid Process 2nd Metacarpelphalangal Joint		6
	Pelvis	Anterior Superior Iliac Spine Posterior Superior Iliac Spine	Anterior Superior Iliac Spine Posterior Superior Iliac Spine		4
	Thorax	Clavicle (sternal end) Xiphoid Process T2 T10	Clavicle (sternal end)		5
	Knee	Medial Femoral Epicondyle Lateral Femoral Epicondyle	Medial Femoral Epicondyle Lateral Femoral Epicondyle		4
	Ankle	Medial Malleolus Lateral Malleolus	Medial Malleolus Lateral Malleolus		4
	Foot	Posterior Calcaneus Lateral Calcaneus 1st, 2nd & 5th Metatarsal Head	Posterior Calcaneus Lateral Calcaneus 1st, 2nd & 5th Metatarsal Head	Placed over the participant's footwear. The heads of the metatarsals felt through the participants trainers.	10

Marker Type	Segment	Right	Left	Placement	Markers
Technical	Forearm	Mid Forearm Cluster (x3)	Mid Forearm Cluster (x3)	Placed centrally on the outer aspect of the forearm	6
	Arm	Mid Upper Arm Cluster (x3)	Mid Upper Arm Cluster (x3	Placed centrally on the outer aspect of the forearm	6
	Thorax	Back Marker		Tracker to determine participants direction of travel	1
	Thigh	Mid Thigh Anterior Cluster (x3) Mid Thigh Posterior	Mid Thigh Anterior Cluster (x3) Mid Thigh Posterior	Posterior marker placed centrally on the thigh	8
	Shank	Tibial Cluster (x4)	Tibial Cluster (x4)	Positioned laterally on the lower third of the calf	8

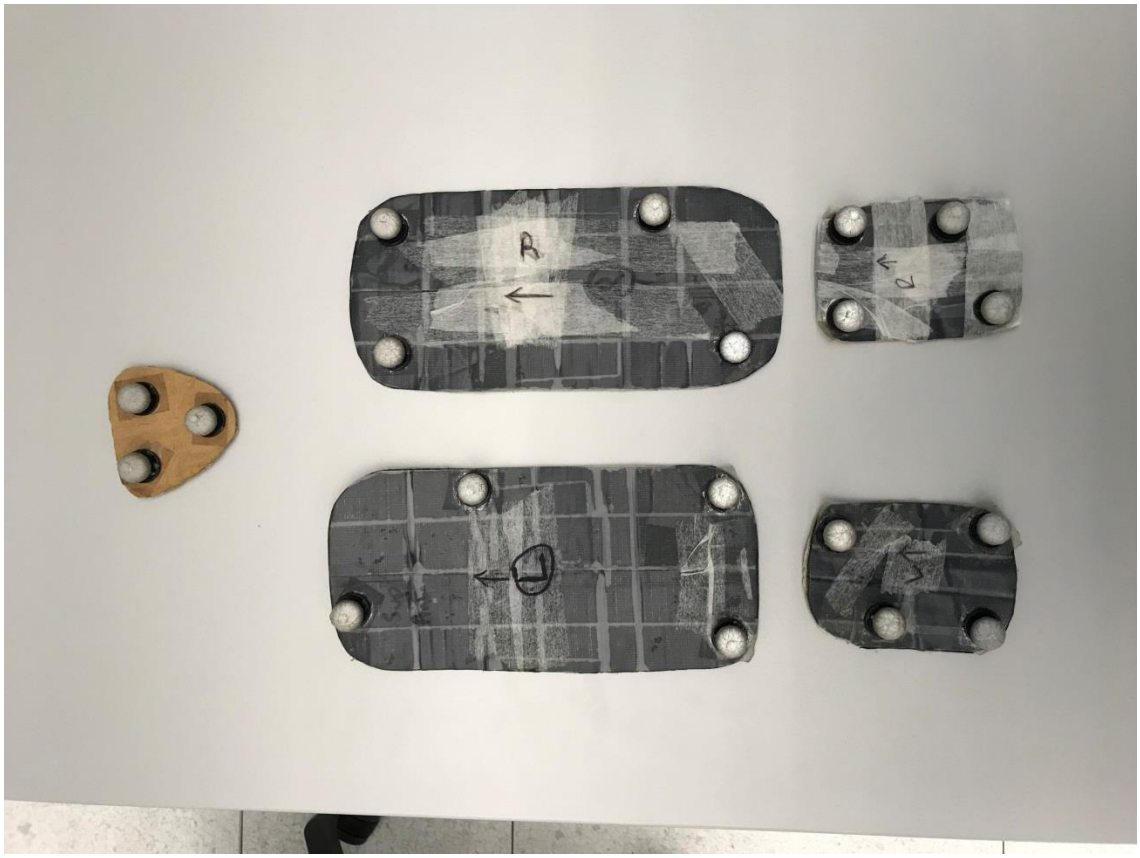

Figure 3-9 Examples of the thigh and tibial clusters (Source: Picture taken by thesis author at DMRC Headley Court)

On the limb wearing the PD AFO, markers were attached onto the orthosis that overlay the required bony landmarks. This included the medial and lateral malleoli and the medial and lateral femoral condyles. The distances from the bony landmarks to the PD AFO were not recorded and not always equal. However, this was not considered to be problematic as Vicon finds the centre point of these markers.

3.12 Motion analysis data collection

3.12.1 Test conditions

Two conditions were tested.

1. The participant walking while wearing their PD AFO in their own trainers, with a rubber heel elevator as prescribed inside both trainers

2. The participant walking without their PD AFO, with the same trainers. No heel elevators were inside the footwear unless a diagnosed leg length discrepancy was present. This was therefore addressed with adequate heel elevators prior to testing

On the injured limb the trainer was on average 1-2 sizes larger than the participant's regular shoe size to accommodate for the PD AFO comfortably. Participants had split sized trainers. When walking without the orthosis no allowance was made for the slightly larger shoe on the injured side, the shoe was secured to the foot tightly. All participants tested wore their PD AFO daily and walked to the testing session in their PD AFO; therefore, testing always began with the PD AFO in situ.

3.12.2 The test procedure: gathering the data

Following placement of all markers to the orthosis and body (Figure 3-10), a static standing trial was recorded to calculate the location of joint centres. The participant was then instructed to walk at a comfortable self-selected speed up and down the gait laboratory for 5 minutes to acclimatise to the test condition. The participant was invited to practise walk several times along the gait lab to define an appropriate starting point for them individually at each end. Starting from an optimum position improved the participant's ability to step on each of the force plates consistently without adopting an unnatural gait pattern and targeting the force plates. The participant was not instructed to strike a particular point on the force plate.

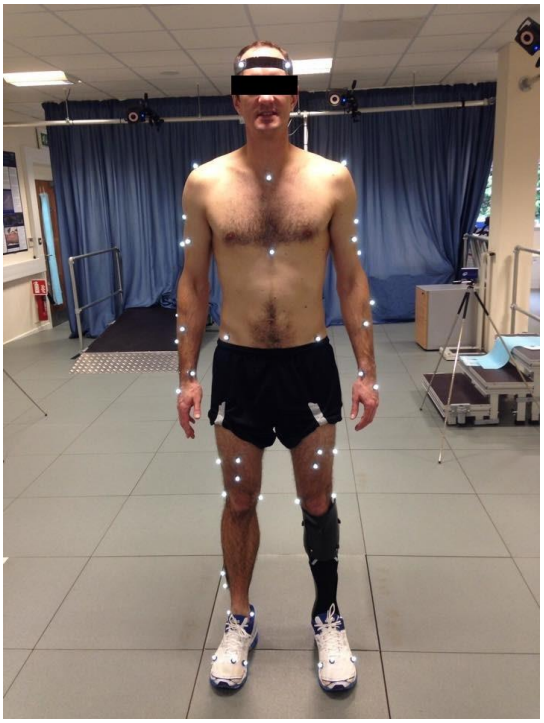

Figure 3-10 Participant ready to begin the first testing condition (Source: Picture taken by thesis author at DMRC Headley Court)

Chairs were placed at either end of the gait laboratory so, if required, the participant could rest between trials for 2 minutes. However, no participant required the use of the chairs to rest during testing. Once ready to record, the participant walked up and down the clinic room at a self-selected speed until 10 suitable walking trials were collected for both the right and the left leg. A suitable trial was defined as clear force plate contact (with 1 foot only) throughout the gait cycle. The participant's foot was required to strike the force plate completely (contain initial contact through to toe off) to qualify as a successful walking trial.

Once testing was underway, if any anatomical markers fell off they were not repositioned. Had a tracking marker fallen off this would have been repositioned during testing and a new static trial captured. During data capture, if a foot was not completely inside the force plate perimeter the trial was discarded, due to resultant errors in the recorded GR force data.

The participant had a rest on a chair between each test condition. The PD AFO was removed, and their trainer re-donned on the injured side. Markers on the

injured lower limb were repositioned matching the contralateral side, and any markers that had either fallen off previously or appeared loose were reattached securely. The participant was given 5 minutes to acclimatise to this test condition. Once again, a static trial was collected and, once ready, the participant walked up and down the clinic room across the force plates at a self-selected speed until 10 walking trials for both the right and the left leg were collected. The procedures for both test conditions were the same.

All markers were then removed, and the participant was invited to ask any questions and asked about any pain experienced during the session. All participants reported discomfort during walking without their PD AFO, however, this was not any greater than the discomfort experienced normally when the PD AFO was not used. The participant was then thanked for their time and they left the gait analysis laboratory wearing their PD AFO.

3.12.3 Data processing

After data collection, the passive reflective markers were labelled and then automatically digitised in Vicon Nexus. Gaps less than 10 frames in trajectory were filled using a polynomial interpolation cubic spline. After labelling, all digitalised data was exported to C3D files. The exported C3D files from Vicon Nexus were streamed and further processed in Visual3D™ (C-Motion, Rochelle, USA, V6) software for data modelling, filtering and analysis.

3.13 Motion analysis data analysis

3.13.1 Software for processing kinetic and kinematic data

A model specific to the height and mass of each participant was created and labelled which contained pelvis, thigh, shank and a rigid foot segment. Gait events were determined from force plates with initial contact marking the start and end of the gait cycle.

3.13.2 Determining lower limb joint centres and segments

In the Visual3D software, the coda pelvis model was used to build the pelvis segment that was determined by both the ASIS and PSIS (Figure 3-11).

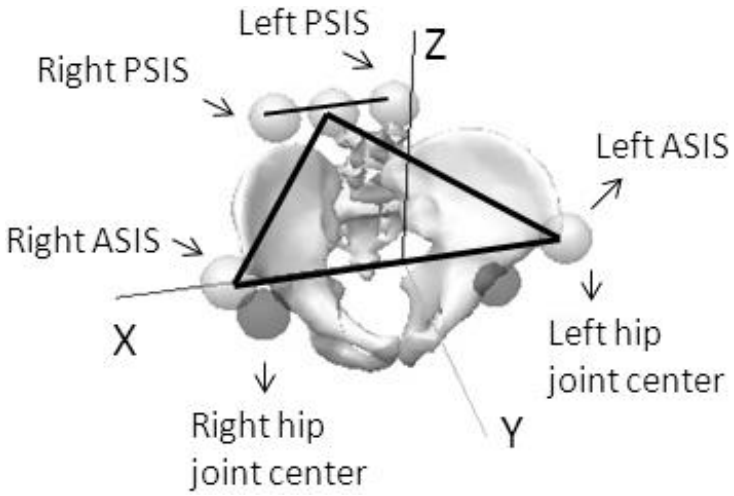

Figure 3-11 The creation of Visual3D pelvis[248]

The hip joint centre was determined mathematically by the software using the positions of the ASIS and PSIS markers, and a regression equation proposed by Bell et al.[249]. The joint centre of the knee was determined to be the midpoint of the distance between the medial and lateral epicondyles of the femur. The joint centre of the ankle was determined to be the midpoint of the distance from the medial to lateral malleolus. Then the left thigh segment was created by using the left hip centre, and the left medial and lateral femoral epicondyles. The four tracking markers were used to track the segment, but not to define it. The right thigh segment was also built in the same way. The tibia was defined by the medial and lateral epicondyle markers, and the malleoli markers. The tibial cluster tracked the segment in space. Similarly, both foot segments were built by projecting the midpoint of the medial and lateral malleoli, in addition to the midpoint of the 1st and 5th metatarsal head markers projected onto the floor. These were tracked by all the markers on the foot.

3.13.3 Gait model

The biomechanical model was a modified cast version. The inertial parameters for each segment were based upon the recommendations from De Leva et

al.[250]. A local co-ordinate system was defined for each segment and an X-Y-Z cardan sequence applied. This described sagittal plane motion around an x axis, coronal plane motion around the y axis and transverse plane around the z axis. This model was used to calculate how the joints were moving (joint kinematics), the relationship between ground reaction forces measured from force plates and joint movement (joint moment).

Joint kinematics were calculated for the pelvis, hip, knee and ankle joints using inverse kinematics, as termed by Lu and O'Connor in 1999[251]. The use of inverse kinematics produces a linked segment rigid body model[252] and an optimisation technique was used to fit this model to the measured marker positions, generally using some weighted least-squares fit cost function[252].

Utilising this method allowed for specific constraints to be applied at the joints of the virtual model so to limit rotation and or translation. The pelvis in this study permitted six degrees of freedom, but only sagittal, coronal and transverse plane rotation was permitted at all other joints This was the method chosen as it is the same method that was used to gather the normative data presented as control in this study, and has been used in previous studies at DMRC Headley Court[246]. Although inverse kinematic models have not been subject to the same rigorous validation as conventional gait models (CGM)[252], they do provide a predictive approach to modelling soft tissue artefact and are compatible with advanced musculoskeletal modelling techniques.

This study did not utilise the CGM as this utilises wand markers, which have been shown to be less effective at accounting for soft tissue artefact[253]. Wand markers used have been shown to be inaccurate around the hip[252; 254; 255]. Additionally, the CGM foot model does not provide a comprehensive picture of the foot's complex motion in gait [252]. Although CGMs in a clinical setting are quicker and easier to use, providing clinically meaningful information in a well validated and standardised way[252], this study adopted inverse kinematics as this was how the normative data was processed at DMRC Headley Court by the HSO[246; 247] prior to this study and allowed for comparison.

3.13.4 The calculations of the joint angle, joint moment and temporal spatial parameters

Joint angles were calculated using the cardan sequence X-Y-Z (X represents flexion/extension; Y represents abduction/adduction and Z represents internal/external rotation) according to the relative position between the labelled segments.

All moments in this study, were calculated as internal moments and normalised to body mass and reported in Nm/kg. Mathematically, the external moments are equal and opposite to the internal moment, which can be calculated with inverse dynamics[256].

Power generated at joints of the lower limb were also calculated at specific time points during the gait cycle and reported in Watts/kg. Power can either be generated through concentric muscle activity, or absorbed through eccentric muscle activity or elongation of soft tissue[257]. Power graphs can, however, be affected by joints above and below, due to the action of bi/tri articular muscles[258].

Temporal and spatial parameters were calculated within Visual 3D. All data was normalised to represent 0-100% of the gait cycle and exported as an ASCII file for extraction of specific parameters. Microsoft excel was used to process the data and create the gait graphs within this thesis.

3.13.5 Gait parameters selected to answer studies hypotheses.

Empirically, patients who have experienced deck-slap injuries walk with an antalgic gait pattern, as described in 2.5.3. The functional capability of the uninjured limb can be impaired as a result, as injured personnel increase their reliance on the sound limb for support in a similar way to unilateral amputees[259-261]. No study has looked directly at the rates of low back pain in custom AFO users. However, studies on amputees have shown that this asymmetry of loading has been linked to several associated comorbidities, including the prevalence of lower back pain[262; 263] and osteoarthritis[262; 263]. Hence, it is

important to understand how both the injured and uninjured limb behave with and without PD AFO use, and how this compares to normative data.

In order to answer the gait element of the research question and subsequent hypotheses, parameters of gait were selected which best enable this and are presented (Table 3.9).

Table 3-9 Researcher's selected gait parameters to answer hypothesis 2-4

Hypotheses	Measures	Relevance
Hypothesis 2: Propulsion	Temporal spatial: walking speed, step length and cadence Ankle kinematics- sagittal plane Ankle moments- sagittal plane Hip moments- sagittal plane Hip power- sagittal plane Ankle powers Anterior-posterior GRF	Lack of pre swing propulsion is a common gait deficiency prevalent in blast trauma limb salvage[5; 159; 171; 173]. PD AFO's are believed to improve propulsion[5]. These measures will help investigate if these claims are substantiated for this group of participants.
Hypothesis 3: Stability	Vertical GRF Temporal spatial: stride length, width, double support time, stance time and % gait cycle when toe off occurred Hip kinematics- sagittal plane Foot progression angle Knee kinematics- sagittal plane Knee moments- sagittal plane	AFO's are often prescribed to improve gait stability by controlling the GRF[69; 144]. The GRF, kinematic and temporal spatial measures selected will strive to determine if a PD AFO affects participants stability.
Hypothesis 4: Gait profile score (GPS)/Movement analysis profile (MAP)	GPS/MAPS Hip kinematics - coronal and transverse plane Pelvis kinematics - sagittal, coronal and transverse plane	Lower limb kinematics is important as any potential stiffness/restriction or excessive range of motion can have a detrimental effect on gait. It can be a determinant of inefficient walking and can increase energy expenditure[264]. It may cause abnormal loading of the limbs which could contribute to the development of low back pain or lower limb osteoarthritis[265]. Kinematic data is used to form the MAPS which in turn allows the overall gait of participants to be compared[266].

3.13.5.1 Presentation of gait data

All gait parameters selected facilitate data comparison and allow for clinical interpretation[245; 267; 268]. All parameters are presented in tables within the results

section of this thesis. Graphs showing the following results are presented in the results section (Tables 3-10), kinematic (joint angle), kinetic (moment) gait, ankle power and the vertical and anterior-posterior GRF.

Table 3-10 Joint angle and moment gait graphs present in this thesis

	Sagittal Plane		Coronal Pane		Transverse Plane	
	Kinematics	**Kinetics**	**Kinematics**	**Kinetics**	**Kinematics**	**Kinetics**
Pelvic	✓		✓		✓	
Hip	✓	✓	✓		✓	
Knee	✓	✓				
Ankle	✓	✓				
Foot					✓	

3.13.6 Visualisation of the gait graph data

Although specific peak parameters are useful to compare between groups, they can be limiting as they only represent specific points within a gait cycle. The use of gait graphs allows for differences to be seen across the entire gait cycle for each test condition. Data for each lower limb joint were plotted in a graphical format, as demonstrated in (Figure 3-12).

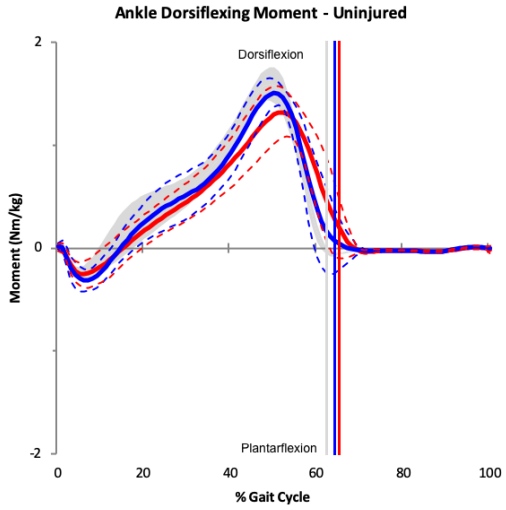

Figure 3-12 Example of gait graph in this study

Each test condition is shown in the gait graph. The red line is shod without the PD AFO and the blue line is while wearing the PD AFO. The standard deviation

for each is plotted in a dotted line. This data is plotted against control data[246; 247], shown as a grey band. It is presented as 1 standard deviation (SD) above and below the mean of the control data for each joint. The vertical line represents the % of the gait cycle where toe off occurred for both test conditions and for the control group.

Control data were taken from a study undertaken at DMRC Headley Court[246] conducted by the same HSO who assisted in this study's data collection. The data includes only able-bodied military personnel who had been asymptomatic regarding pain in their lower limbs for at least 6 months prior to testing. All were without previous major joint, soft tissue surgery or neurological conditions and therefore might be considered a match for the pre-injury status of this study's participants[246; 247].

Statistical parametric mapping was not used in this study to examine changes throughout the whole gait cycle. Rather, peak variables of gait were selected to answer the hypotheses, as deemed more appropriate measures by the researcher in measuring the effect of the PD AFO on specific parameters.

3.13.7 Patient reported outcome measures (PROMs)

Each participant was invited to complete 2 standardised and specific functional outcome questionnaires pre and post fitting of the PD AFO. These questionnaires were the Lower Extremity Functional Scale (LEFS) and the Foot and Ankle Outcome Score (FAOS). These questionnaires are routinely used at DMRC Headley Court and deemed a useful tool for identifying pain and functional ability[269-271]. These questionnaires are considered to not cause distress or upset to the participant.

3.13.8 Lower extremity functional scale (LEFS)

The LEFS asks the participant about how they cope with activities of daily living (ADL). This includes balance (non-vestibular), coordination, functional mobility, life participation, occupational performance, quality of life (QoL), range of motion and strength. The participant grades each question from 1-5. A score of

1 represents extreme difficulty conducting this activity, and a score of 5 represents no difficulty at all. The maximum score is 80, which would indicate a very high level of function and the minimum detectable change for the LEFS is 9 points. The scores pre and post fitting of the PD AFO were compared. The LEFS appears to detect meaningful change better than the well documented SP-36 physical function subscale, often reported in the literature[269]. The LEFS is a reliable and validated patient reported outcome measure[269; 272; 273] and it takes approximately 5 minutes to complete.

3.13.9 The foot and ankle outcome score (FAOS)

The FAOS assesses a participant's perception about how their foot and ankle injury is affecting their quality of life. It includes questions on pain, symptoms, ADL, function in sports and recreational activity and how the participant has managed these in the last week. It requires participants to score each question between 0 and 4. A score of 0 indicates extremely bad symptoms, and a score of 4 indicates no symptoms. It is a reliable and validated patient reported outcome measure[274-277] and takes approximately 10 minutes to complete.

This questionnaire provides a combined score, as well as the ability to evaluate each subsection. This is a globally validated[275; 276; 278; 279] patient reported outcome measure that has a subsection related specifically to sport and recreation in relation to the ankle. The ability to return to sport post injury is greatly important to predominantly young male military personnel treated at DMRC Headley Court, and therefore it was important to gather outcomes in relation to this specifically.

3.13.10 PROM data collection procedure

The process used to gather PROMs for all participants in this study was identical and follows standard treatment protocols at DMRC Headley Court (Figure 3-13).

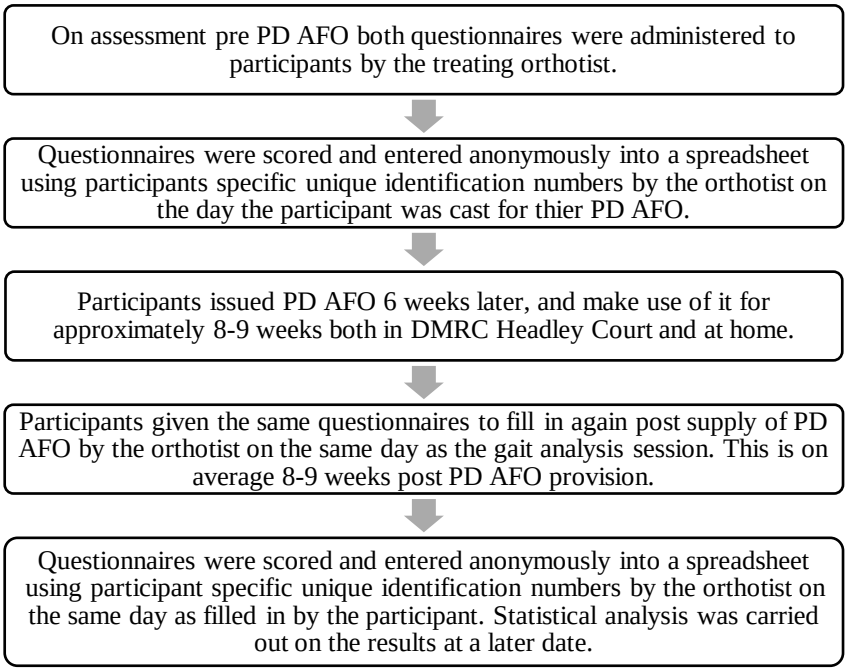

Figure 3-13 Patient reported outcomes questionnaire process

3.14 Statistical Testing

Statistical analysis was conducted using R version 3.5.3, a free software environment for statistical computing and graphics. Specific parameters were extracted, as described above, for each participant and both test conditions compared. The mean and standard deviation was calculated across all ten walking trials per limb for each participant in both test conditions. For comparison, all participants' data was first checked for normal distribution using Shapiro-Wilk tests. The data were then tested for homogeneity of variance using either F-tests (for normally distributed data) or Fligner-Killeen tests (for non-normal data). When the data was normally distributed and presented homogeneity of variance, statistically significant differences between the shod and PD AFO test conditions were identified with paired t-tests or unpaired t-tests between the injured limb wearing the PD AFO and controls. Paired t-tests were used for the PROM responses. For non-normal data, statistically significant differences were identified using either Wilcoxon tests (for data with equal variances) or Kruskal-Wallis tests (for data with unequal variances). Statistical significance was defined as $p<0.05$.

In addition, effect size calculations were performed to evaluate Cohen's d[280]. A meaningful change was defined as a medium effect size or higher. A d value of 0.5 was defined as a medium effect size[280], 0.8 was a large effect size[280], 1.2 was a very large effect size[281].

Chapter 4: Results

4.1 Chapter overview

This chapter begins by outlining the demographics of each participant. It then goes on to discuss specific gait data (highlighted in 3.13.5) systematically in relation to the following hypotheses.

Research Question: Does a PD AFO improve gait and functional outcomes of injured military personnel who have undergone unilateral limb salvage?

Hypothesis 1: PD AFO use will improve the patient reported outcomes of injured military personnel that have undergone unilateral limb salvage.

Hypothesis 2: PD AFO use will improve a participant's propulsion through midstance and terminal stance of gait in both the injured and uninjured limb.

Hypothesis 3: PD AFO use will improve a participant's stability during the stance phase of gait.

Hypothesis 4: PD AFO use will improve the gait profile score of both the injured and uninjured limb.

Hypothesis 1 and 2 were chosen for this study as they are key claims in the literature surrounding PD AFOs and therefore warrant exploration. Hypothesis 3 was chosen as it is a common goal in lower limb orthotic treatment, and hypothesis 4 may help to understand the overall function of PD AFOs in gait.

The temporal and spatial parameters are the mean data of each test condition for all 12 participants. The primary and secondary kinematic and kinetic gait parameters presented are based on the mean of the 10 walking trials conducted for 9 participants for both test conditions. The kinetic and kinematic data for 3 of the participants had to be withdrawn from the study during the analysis phase as the data were compromised. There were errors with some markers and data capture on the force plates for these 3 participants. The results section of this thesis was written after the researcher left her position at DMRC Headley Court as the hospital had relocated to the Midlands, and therefore was unable to

retrieve this data from the VICON software installed in the gait lab on site. The kinematic and kinetic data for AP12, 17 and 19 was therefore discarded for presentation in the results. As the compromise related to marker placement it was deemed satisfactory to include the temporal spatial data for these participants.

Tables of the temporal and spatial parameters, kinematic and kinetic data are presented alongside all standard deviations, range of the mean value, as well as all corresponding p-values and d-values available. In addition to providing data in tabular form, gait graphs for kinematics and kinetics are also presented as described in 3.13.6.

Control data was available for kinematic and kinetic parameters as complete in this thesis. However, no control ground reaction force data was made available to the researcher, and only a small number of temporal spatial parameters were available to use.

The chapter also presents the results of the PROMs used in this study for all 12 participants.

4.2 Participant demographics

The demographics of the 12 participants are detailed in (Table 4-1). All participants were male with an average age of 32±8 years when the PD AFO was initially supplied. They had an average height of 185cm and weight of 95kg. Only 3 participants had a full range of motion (20° dorsiflexion to 50° plantarflexion)[68] available at the ankle joint on assessment by the researcher (measured visually using a goniometer). All other participants had some degree of restriction at the ankle joint when tested passively. All participants sustained IED blast trauma (deck slap) with a calcaneal fracture. Only 1 participant had a calcaneal fracture in isolation; all other participants fractured more than 1 lower limb bone, as shown in (Table 4-1).

In this study 9 participants sustained an open fracture, 7 of which were classified by Gustilo-Anderson as IIIC, the most severe. The 3 closed fractures

were classified as IIIA. Post trauma joint fusion had been performed on 4 participants on the injured side. On average the clinical gait analysis session took place 16±10 weeks post provision of the PD AFO. It was noted that 4 participants waited more than 20 weeks until the gait analysis session was undertaken. Patient availability at DMRC Headley Court was the reason for 3 of the participants waiting more than 20 weeks, and for 1 participant it took 41 weeks, as he required hospitalisation for a reason unrelated to his lower limb, and subsequently took longer to rehabilitate with the PD AFO.

Table 4-1 Participant demographics

	Height (cm)	Weight (Kg)	Age when PD AFO supplied (Years)	Ankle ROM (DF-PF°)	Fracture location(s)	Open or Closed Fracture(s)	Gustilo-Anderson classification	Surgical fusion post injury	Time between PD AFO provision and gait analysis (Weeks)
AP02	183	101	28	5DF-25PF	Calcaneus, medial malleolus	Open	IIIC	None	12
AP03	187	99	36	3DF-25PF	Calcaneus, distal end of tibia, talus	Open	IIIB	None	9
AP06	177	79	28	10DF-30PF	Calcaneus, cuboid, base of 5th metatarsal	Closed	IIIA	None	9
AP07	184	87	42	5DF-30PF	Calcaneus, distal end of tibia, talus	Open	IIIC	None	10
AP08	189	93	45	5DF-25PF	Calcaneus, distal end of tibia, talus	Open	IIIC	Subtalar joint	11
AP09	185	75	27	Full	Calcaneus	Closed	IIIA	None	10
AP10	191	84	34	Full	Calcaneus, cuboid	Closed	IIIB	Triple arthrodesis	20
AP11	181	112	30	Full	Calcaneus, C6, T7	Open	IIIB	None	22
AP12	178	78	23	5DF-30PF	Calcaneus, lisfranc, distal end of tibia, fibula	Open	IIIC	None	11

	Height (cm)	Weight (Kg)	Age when PD AFO supplied (Years)	Ankle ROM (DF-PF°)	Fracture location(s)	Open or Closed Fracture(s)	Gustilo-Anderson classification	Surgical fusion post injury	Time between PD AFO provision and gait analysis (Weeks)
AP17	193	115	23	3DF-25PF	Calcaneus, distal end of tibia, talus, fibula, base of 5th metatarsal	Open	IIIC	Subtalar joint	41
AP19	184	113	43	3DF-25PF	Calcaneus, cuboid, distal end of tibia	Open	IIIC	Subtalar joint	9
AP20	189	100	28	10DF-30PF	Calcaneus, cuboid, base of 5th metatarsal	Open	IIIC	None	24
Mean±SD Range	185±5 177 to193	95±14 75 to 115	32±8 23 to 45	-	-	Open 9 Closed 3	IIIA 3 IIIC 7 IIIB 2 IIIB 3	Fusion- 4 No fusion to 8	16±10 9 to 41

4.3 Patient Reported Outcome Measures (PROM) results to answer hypothesis 1

4.3.1 Lower Extremity Functional Scale (LEFS)

There was a significant change demonstrated in the participants' mean pre and post LEFS score (p=<0.001) with a very large effect size (1.51) (Figure 4-1). The mean LEFS score pre provision of the PD AFO was 38 (SD=15) and the mean LEFS score post provision of the PD AFO was 54 (SD=10). The minimal clinically important difference (MCID) for the change in the LEFS score is 9 (Appendix B), which was achieved post provision of the PD AFO in 10 of the 12 participants (Table 4-2). The mean change in LEFS score was 19 (SD= 12). The coefficient of variation for the change score was 0.63.

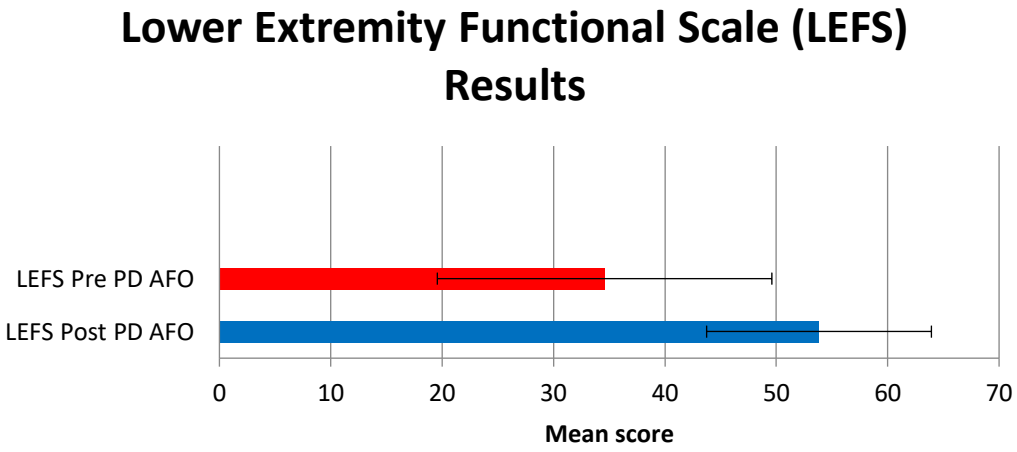

Figure 4-1 Mean (LEFS) scores pre and post provision of a PD AFO. Error bars show standard deviation, (N=12)

Table 4-2 A comparison of the LEFS scores and the minimal clinically important difference.

Inclusive of SD, range and p value. Score =80, higher scores represent higher levels of function. (N=12)

	AP02	**AP03**	**AP06**	**AP07**	**AP08**	**AP09**	**AP10**	**AP11**	**AP12**	**AP17**	**AP19**	**AP20**	**Mean±SD Range**	***p value Cohens d***
LEFS score Pre provision of PD AFO	36	46	41	20	28	48	24	70	35	15	16	36	38±15 15 to 70	0.001 1.51
LEFS score Post provision of PD AFO	51	52	59	43	54	60	71	69	58	45	34	50	54±10 34 to 71	
LEFS (MCID) (>9 = Significant)	15	6	18	23	26	12	47	-1	23	30	18	14	19±12 -1 to 47	

4.3.2 Foot and ankle outcome score (FAOS)

All subsections of the FAOS (symptoms, pain, ADL, QOL, and sports and recreation) demonstrated a significant change between the pre and post PD AFO scores as a cohort ($p<0.01$) (Figure 4-2). This was also reflected in the effect size, as the sports and recreation subsection demonstrated a very large effect size (2.04) and all other subsections demonstrate a large effect size (between 0.8-1.2) (Table 4-3). In this study 11 participants reported an improvement to their symptoms post supply of the PD AFO and 1 participant (AP03) reported their symptoms did not change. Improvement to pain post supply of the PD AFO was reported in 10 participants and 1 participant (AP20) reported that their pain did not change. A participant AP11 reported that use of the PD AFO made pain worse. Additionally, 11 participants reported an improvement in carrying out activities of daily living, 1 participant (AP11) reported the PD AFO made carrying out activities of daily living more difficult. Improvements to quality of life were reported in 9 participants post supply of the PD AFO. The remaining 2 participants (AP03 and AP19) reported that use of the PD AFO did not change their quality of life and 1 participant (AP11) reported use of the PD AFO declined their quality of life. All 12 participants reported that their ability to engage in sports and recreation improved post use of the PD AFO; this represented the largest score differential (30) between the pre and post mean scores.

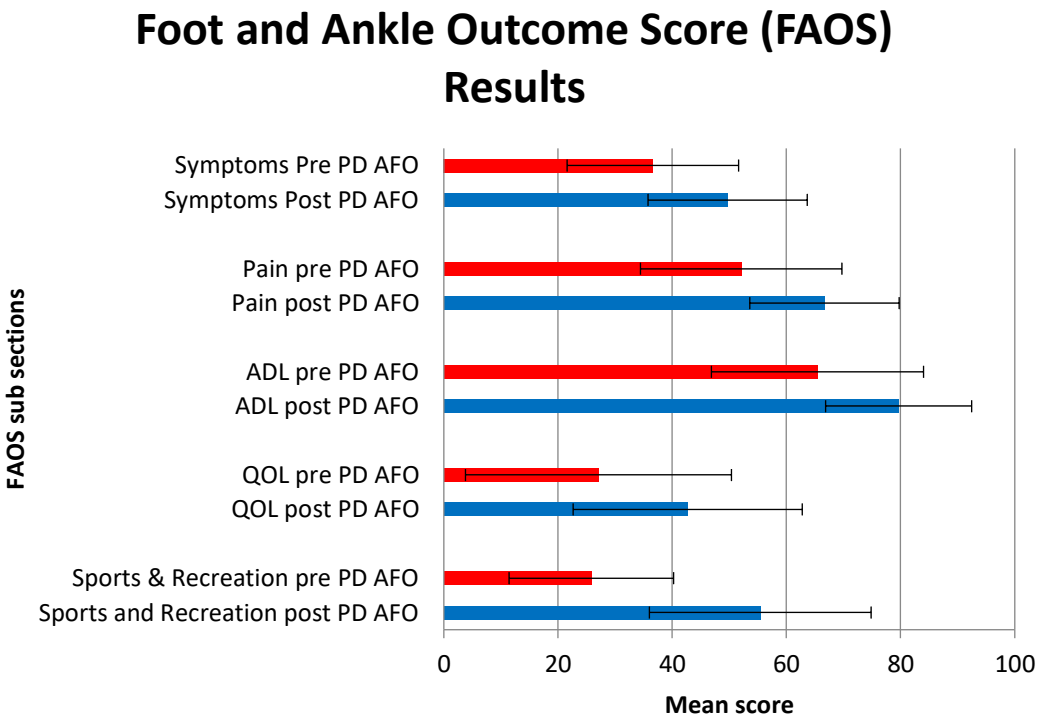

Figure 4-2 Mean (FAOS) scores for each sub section of the questionnaire pre and post provision of a PD AFO Error bars show standard deviation. (N=12)

Table 4-3 A comparison of the FAOS pre and post subsection scores and the subsequent changes for all participants, inclusive of SD, range and p value. (N=12)

FAOS sub sections	**AP02**	**AP03**	**AP06**	**AP07**	**AP08**	**AP09**	**AP10**	**AP11**	**AP12**	**AP17**	**AP19**	**AP20**	**Mean Score±SD Range**	***p values Cohens d***
Symptoms Pre Score	14	46	32	43	50	39	21	54	36	57	18	21	37±15 14 to 64	0.01 0.98
Symptoms Post Score	39	46	43	54	61	57	75	64	46	64	25	29	50±14 25 to 75	
Symptoms change	25	0	11	11	11	18	54	10	10	7	7	8	14±14 0 to 54	
Pain pre score	47	69	47	50	53	64	36	83	50	28	22	75	52±18 22 to 83	0.00 1.05
Pain post score	67	78	72	64	67	78	81	75	64	44	36	75	67±13 36 to 81	
Pain change	19	8	25	14	14	14	44	-8	14	17	14	0	15±13 -8 to 44	
ADL pre score	44	84	68	66	57	88	54	99	74	41	37	74	65±19 37 to 99	0.00 1.01
ADL post score	72	85	75	75	79	90	99	97	87	54	60	82	80±13 54 to 99	
ADL change	28	1	7	9	22	1	44	-1	13	13	24	9	14±13 -1 to 44	
QOL pre score	13	63	19	19	19	38	6	75	50	0	0	25	27±23 0 to 75	0.01 0.97
QOL post score	31	63	63	31	31	56	56	69	56	19	0	38	43±20 0 to 69	
QOL change	19	0	44	13	13	19	50	-6	6	19	0	13	16±17 -6 to 50	
Sports & recreation pre score	10	35	25	25	20	55	15	45	25	20	0	35	26±14 0 to 55	0.00 2.04

FAOS sub sections	AP02	AP03	AP06	AP07	AP08	AP09	AP10	AP11	AP12	AP17	AP19	AP20	Mean Score±SD Range	*p values* *Cohens d*
Sports and recreation post score	45	70	40	45	70	70	80	85	60	30	20	50	55±19 20 to 85	
Sports and recreation change	35	35	15	20	50	15	65	40	35	10	20	15	30±17 10 to 65	

4.4 Parameters to investigate hypothesis 2: propulsion in gait

4.4.1 Temporal spatial parameters

The temporal and spatial data showed an increased walking speed of the participants when the PD AFO was worn on the injured limb (Table 4-4). However, this did not show a significant (>0.05) difference (p= 0.10) when compared to shod alone but does show a large effect size (0.84). When the PD AFO was worn, cadence increased and was closer to control data. However, this did not show a significant difference (p=0.25) but does demonstrate a very large effect size (1.24). The participants' stride length increased when wearing the PD AFO and this did show a significant increase (p =0.03) and a large effect size (1.17). The participants using the PD AFO walked faster and had a longer stride length compared to controls.

Table 4-4 A comparison of the mean temporal and spatial parameters: walking speed and cadence of participants with and without a PD AFO compared to available control data.

Parameter	**Without PD AFO** **Mean ± SD** **Range**	**With PD AFO** **Mean ± SD** **Range**	**Control Group[271]** **Mean** **Range**
Self-Selected Walking Speed (meters per second)	1.17±0.34	1.40±0.18	1·29
	0.71 to 1.81	1.20 to 1.81	1·25 to 1·33
p value	0.1		N/A*
Cohen's d	0.84		N/A*
Cadence (steps per second)	94±15.21	109±13.45	106
	75 to 117	90 to 137	101 to 110
p value	0.25		N/A*
Cohen's d	1.24		N/A*
Stride length (meters)	1.36±0.22	1.56±0.11	N/A*
	0.99 to 1.78	1.35 to 1.78	N/A*
p value	0.03		N/A*
Cohen's d	1.17		N/A*

*This data was unavailable

4.4.2 Anterior/posterior ground reaction force

Use of the PD AFO significantly increased the anterior-posterior ground reaction force peak at pre swing (propulsive force) (AP2). (p=0.004) and (p=0.02) respectively, and both the uninjured and injured limb demonstrated a very large effect size (1.87) and (1.45 respectfully) (Table 4-5). The anterior-posterior peak at loading response (AP1) also increased in both the uninjured and injured limb when the PD AFO was worn. However, this was not deemed a significant change (p=0.11) and (p=0.28) respectfully. This is also referred to as the braking force, which corresponds to the deceleration period of the support phase. Whilst this didn't demonstrate a significant change, a medium effect size (0.61) is shown in the injured limb and a large effect size in the uninjured limb (0.91).

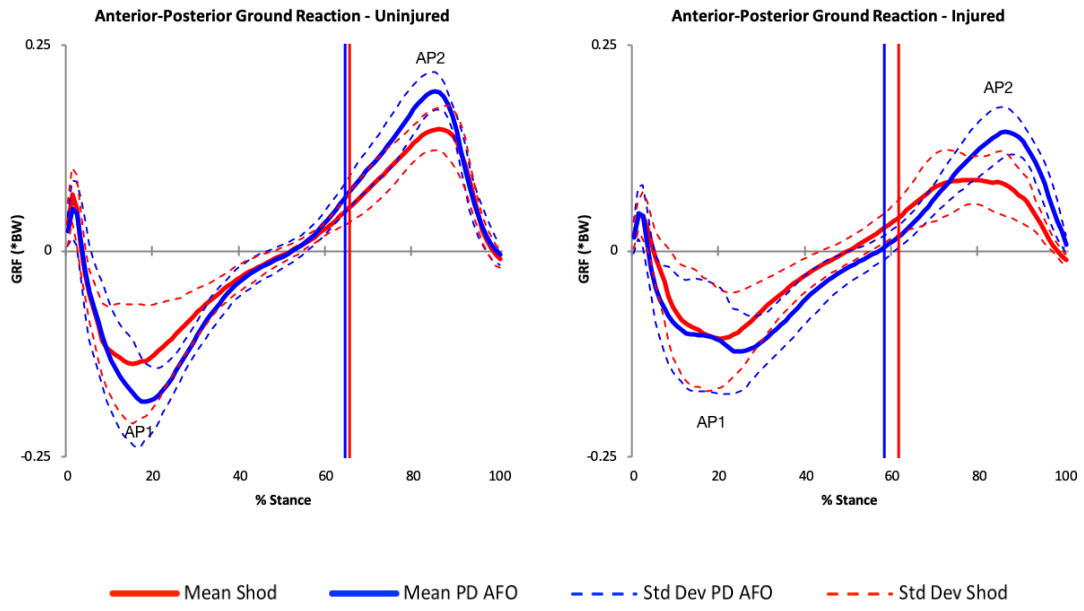

Figure 4-3 Anterior-posterior ground reaction during the two testing conditions for both the injured and uninjured limb.

Table 4-5 A comparison of the mean, SD, and range of the anterior-posterior ground reaction for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb	
	Without PD AFO	**With PD AFO**	**Without PD AFO**	**With PD AFO**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**
	Range	**Range**	**Range**	**Range**
AP1 (***** body weight)	-0.14±0.05	-0.18±0.06	-0.11±0.06	-0.12±0.04
	-0.25 to -0.10	-0.28 to -0.14	-0.19 to -0.03	-0.22 to -0.07
p value	0.11		0.28	
Cohen's d	0.91		0.61	
AP2 (***** body weight)	0.15±0.03	0.19±0.02	0.09±0.04	0.14±0.03
	0.12 to 0.19	0.17 to 0.24	0.04 to 0.15	0.11 to 0.19
p value	0.004		0.02	
Cohen's d	1.87		1.45	

4.4.3 Ankle power

The ankle joint power demonstrated a significant change in both the maximum power absorption between mid-stance and terminal stance (p=0.001) (Table 4-6), and the maximum power generation at pre swing (p=0.009) between the injured limb whilst wearing the PD AFO and the control group. The ankle power generation and absorption of the control group though gait was significantly greater than the injured limb whilst wearing a PD AFO. Whilst not demonstrating a significant change (p=0.80), the maximum ankle power absorption did slightly increase in the injured limb whilst participants wore the PD AFO. The uninjured limb's ankle power absorption was also very similar for both test conditions. The maximum power generation at pre swing increased on the uninjured limb whilst wearing the PD AFO and demonstrated a large effect size (0.92). However, this decreased on the injured limb whilst wearing the PD AFO (p=0.43) and showed a medium effect size (0.54).

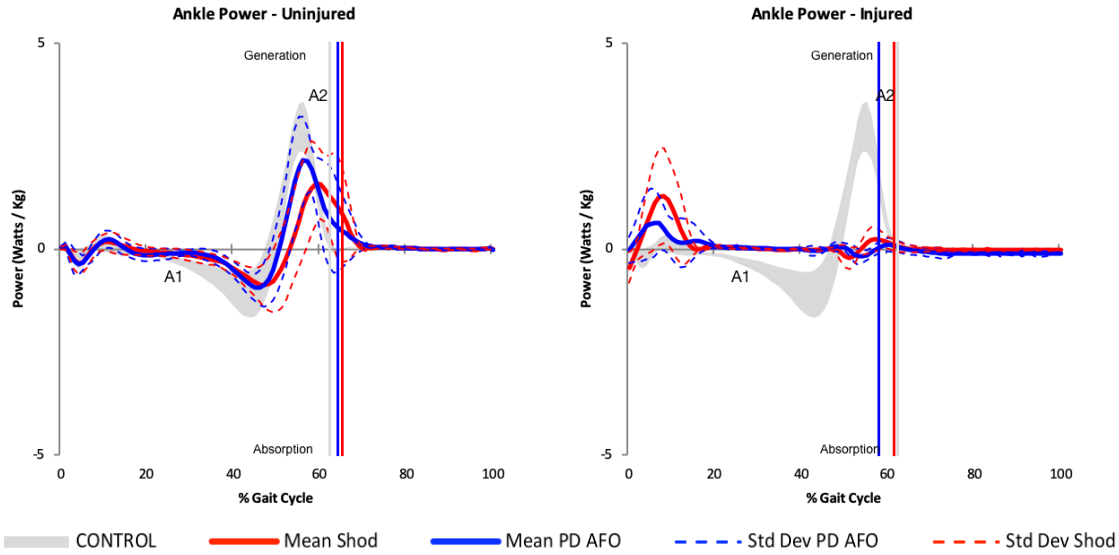

Figure 4-4 Ankle power during the two testing conditions for both the injured and uninjured limb.

Table 4-6 A comparison of the mean, SD, and range of ankle power for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
A1 maximum power absorption: mid-stance-terminal stance (15-40%GC) (Watts/Kg)	-0.81±0.50	-0.93±0.41	-0.02±0.55	-0.05±0.47	-1.30± 0.53
	-1.63 to -0.48	-1.71 to -0.64	-1.39 to -0.15	-1.74 to -0.39	-1.62 to 0.58
p value	0.96		0.80		0.001*
Cohen's d	0.04		0.16		3.32
A2 maximum power generation: pre swing (50-60%GC) (Watts/Kg)	1.86±1.09	2.65±0.64	0.34±0.31	0.21±0.15	3.21± 0.69
	0.48 to 3.33	1.97 to 3.84	0.06 to 0.79	0.04 to 0.42	2.26 to 4.34
p value	0.20		0.43		0.009*
Cohen's d	0.92		0.54		2.84

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.4.4 Ankle moments

The sagittal plane external ankle moment showed a significant difference (p=0.03 and p= 0.02) respectively in both the dorsiflexing and plantarflexing moment on the injured limb between the 2 test conditions (Table 4-7). The peak dorsiflexing and plantarflexing moments on the injured limb for both test

conditions demonstrated a very large effect (1.21) and (1.32) respectfully. There was a significant difference (p=0.04) in the plantarflexing moment on the uninjured limb between the 2 test conditions, with a large effect size (1.06). The dorsiflexing moment for the uninjured limb for each test condition did not demonstrate a significant change (p=0.17). Whilst the value of the dorsiflexing moment increased by 0.05Nm/kg it was not a significant difference. There was no significant difference between the sagittal plane moments of the injured limb using the PD AFO compared to control.

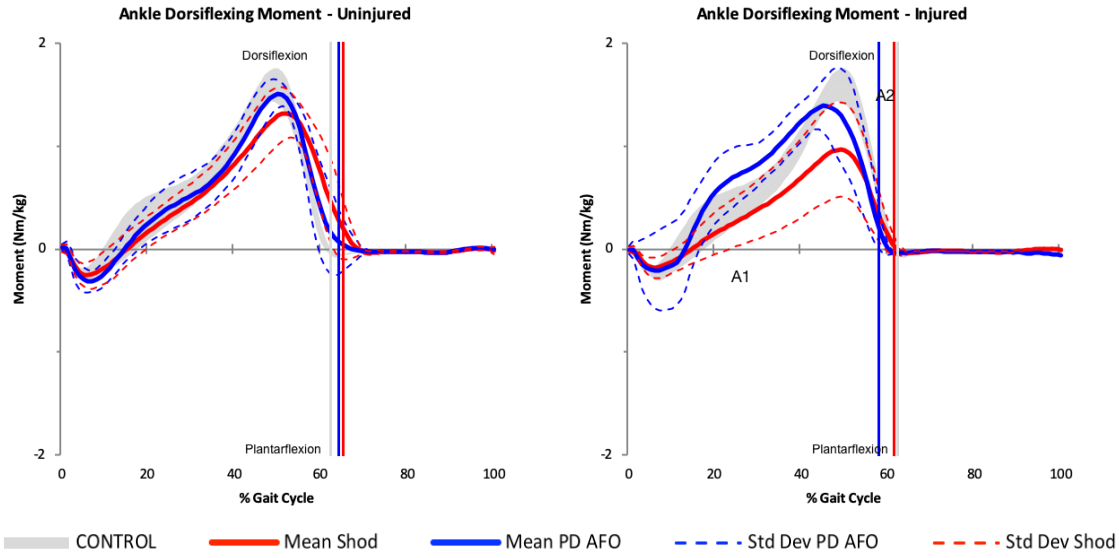

Figure 4-5 Sagittal plane external ankle moment during the two testing conditions for both the injured and uninjured limb.

Table 4-7 A comparison of the mean, SD, and range of sagittal plane ankle moments for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[235]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Peak dorsiflexing moment in loading response (Nm/kg)	-0.29±0.11	-0.34±0.10	-0.21±0.1	-0.36±0.15	-0.25 ±0.1
	-0.55 to -0.20	-0.54 to -0.23	-0.33 to -0.15	-0.56 to -0.07	-0.41 to -0.22
p value	0.17		0.03		0.11*
Cohen's d	0.42		1.21		0.89
Peak plantarflexing moment in late stance (Nm/kg)	1.38±0.24	1.57±0.09	1.02±0.48	1.53±0.24	1.61 ±0.33
	0.86 to 1.60	1.42 to 1.70	0.02 to 1.48	1.11 to 1.87	1.29 to 1.78
p value	0.04		0.02		0.64*
Cohen's d	1.06		1.32		0.24

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.4.5 Ankle kinematics

The sagittal plane ankle kinematics on both the injured and uninjured limb demonstrated a plantar flexed position upon initial contact for both test conditions (Figure 4-6). The control group's ankle angle at initial contact in the sagittal plane is slightly dorsiflexed (1.8°). When participants wear the PD AFO, the uninjured limb's initial contact angle is closer to plantigrade and controls. The injured limb, at initial contact when using the PD AFO, remains in an increased plantar flexed position (-6.4°). The changes in the ankle at initial contact for all test conditions are not significant (>0.05) (Table 4-8) but do demonstrate a medium effect size on the injured limb (0.78). The participants' peak ankle dorsiflexion angle in gait remained similar for both test conditions on the uninjured limb. A significant change (p=0.001) is shown in the injured limb's peak dorsiflexion angle comparing both test conditions. When using the PD AFO, the ankle remains in a plantar flexed position throughout the GC in the sagittal plane. In late stance the peak ankle angle of plantarflexion increased in the uninjured limb when the PD AFO was worn. This was not deemed significant (p=0.08) but demonstrated a large effect size (0.89). The injured limb's peak plantarflexion angle in late stance was very similar for both test

conditions and did not show a significant change (p=0.80). The sagittal plane range of motion in the ankle through the GC did show a significant change for both test conditions in both the uninjured and injured limb (p=0.05) and (p=<0.001) respectfully. The uninjured limb's mean range of motion in the ankle joint increased by 3° when the PD AFO was worn on the injured limb and compared more comparatively to control. The injured limb's ankle range of motion decreased by 7.6° when using the PD AFO. When the PD AFO was worn on the injured limb, the uninjured limb demonstrated an improvement in the timing of peak plantarflexion at pre swing.

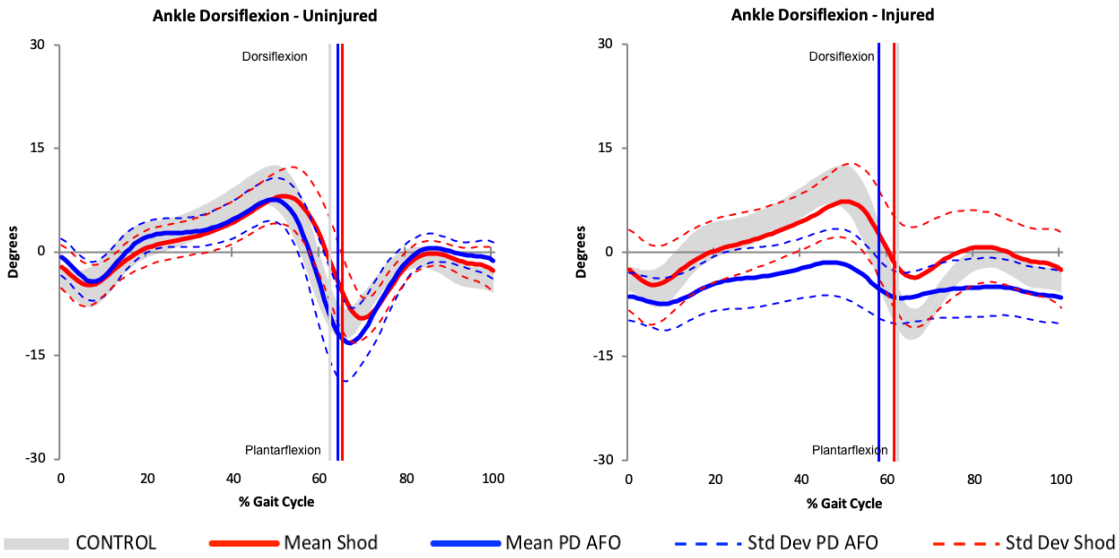

Figure 4-6 Sagittal plane ankle motions during the two testing conditions for both the injured and uninjured limb.

Table 4-8 A comparison of the mean, SD, and range of sagittal plane ankle motion for the two test conditions for both the injured and uninjured limb, compared to available control data.

Parameter	Un-injured limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Angle at Initial contact (°) (dorsiflexion +ve)	-2.12±3.09	-0.75±2.64	-2.58±6.06	-6.40±3.43	1.8 ±2.6
	-7.13 to 1.74	-5.43 to 2.74	-10.21 to 10.00	-12.09 to -2.30	1.2 to 6.5
p value	0.35		0.12		0.10*
Cohen's d	0.48		0.78		0.96
Peak dorsiflexion (°)	8.8±3.8	8.2±3.1	6.8±4.5	-0.7±3.9	10.1 ±2.8
	3.1 to14.1	2.1 to 12.0	1.0 to 12.1	-8.2 to 3.9	6.2 to 15.6
p value	0.72		0.001		<0.001*
Cohen's d	0.18		1.84		3.19
Peak plantarflexion in pre swing (°) (50-60%GC)	-10.7±3.3	-14.4±4.7	-3.6±7.2	-8.35±4.0	-10.7 ±2.2
	-16 to -7.5	-24.5 to -9.6	-14.7 to -1.6	-14.4 to -3.2	-13.7 to -6.4
p value	0.08		0.8		0.09*
Cohen's d	0.89		0.33		0.89
Range of motion through full gait cycle (°)	19.6±3.0	22.6±3.0	15.2±2.3	7.6±2.7	20.7 ±3.1
	12.4 to 21.9	16.8 to 26.6	12.1 to 19.1	4.9 to 13.1	16.5 to 26.2
p value	0.05		<0.001		<0.001*
Cohen's d	1.0		2.36		4.93

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.4.6 Hip moment

The sagittal plane hip moments showed a significant difference (p=0.01) and very large effect size (1.51) between the peak extending moment of the uninjured limb with and without the PD AFO (Table 4-9). The hip extending moments increased in the uninjured and injured limbs when participants used their PD AFO, and this was comparable with controls. The injured limb did not show a significant change (p=0.07) but did demonstrate a large effect size (0.91). The peak hip flexing moment of the uninjured and injured limb increased when using the PD AFO. This demonstrated a significant difference (p=0.04) on the injured limb and no significant difference on the uninjured limb (p=0.06).

Both the uninjured and injured limb demonstrates a large effect size, (0.95) and (1.05) respectively. An increase in the hip flexing moment was also seen in the uninjured limb when the PD AFO was worn. However, this was not deemed significant (p=0.06). There was a medium effect size shown between the peak hip flexing and extending moments of the injured limb (0.62) and (0.57) respectively whilst wearing the PD AFO compared to controls.

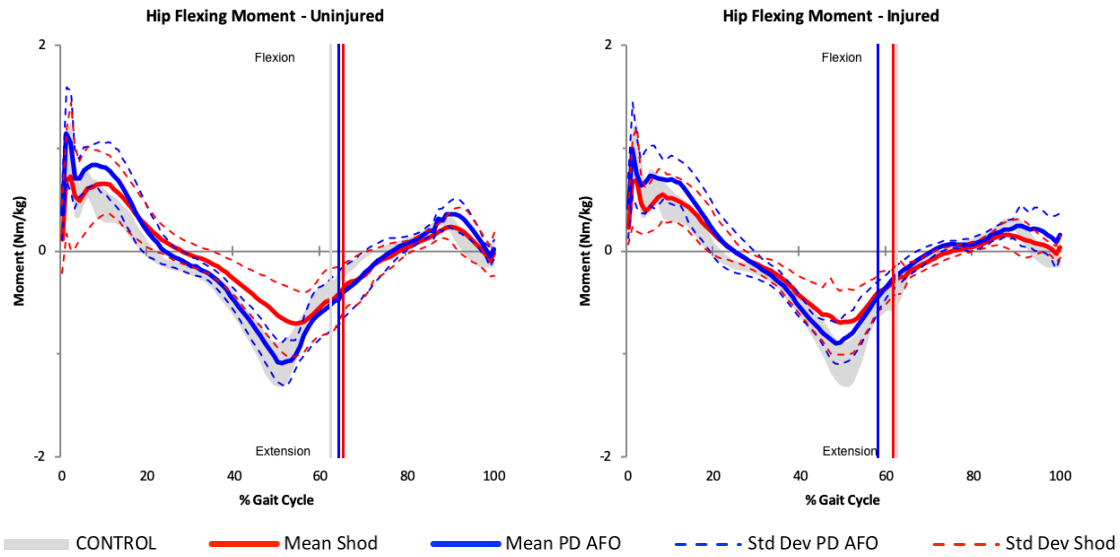

Figure 4-7 Sagittal plane external hip moments during the two testing conditions for both the injured and uninjured limb.

Table 4-9 A comparison of the mean, SD, and range of sagittal plane hip moments for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Peak extending moment (Nm/kg)	-0.83±0.29	-1.18±0.16	-0.83±0.19	-0.97±0.12	-0.99 ±0.34
	-1.26 to -0.49	-1.41 to -0.90	-1.11 to -0.54	-1.25 to -0.84	-1.33 to 0.70
p value	0.01		0.07		0.23*
Cohen's d	1.51		0.91		0.57
Peak flexing moment (Nm/kg)	0.73±0.50	1.14±0.30	0.69±0.35	0.99±0.33	1.08 ±0.42
	0.36 to 1.73	0.91 to 1.87	0.37 to 1.42	0.75 to 1.62	0.48 to 1.45
p value	0.06		0.04		0.17*
Cohen's d	0.95		1.05		0.62

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.4.7 Hip Power

The maximum hip power generation during loading response increased on both the injured and uninjured limb when the PD AFO was worn. Whilst both increased, neither was statistically significant (p=0.09) (p=0.54) respectively (Table 4-10). However, the change on the injured limb did represent a large effect size (1.07). When wearing the PD AFO, both the injured and uninjured limbs generated greater power at loading response than able-bodied controls. The injured limb generates 40% more power and the uninjured limb 34% more power compared to controls.

The maximum hip power absorption at midstance increased on the uninjured limb and decreased on the injured limb when the PD AFO was worn. Neither was statistically significant (p=0.29) (p=0.70). This represented a medium effect size (0.69) on the uninjured limb and a small effect size on the injured limb (0.40). There was a statistically significant difference between injured limb using the PD AFO and controls (p=<0.001).

The maximum power generation during pre-swing and initial swing increased on both the injured and uninjured limb when the wearing the PD AFO. Whilst this increase was not statistically different, the effect size on the uninjured limb was very large (1.22). When utilising the PD AFO, the peak maximum power generation during pre-swing and initial swing on the uninjured limb was still 33% lower than able-bodied controls and 40% lower than controls on the injured side.

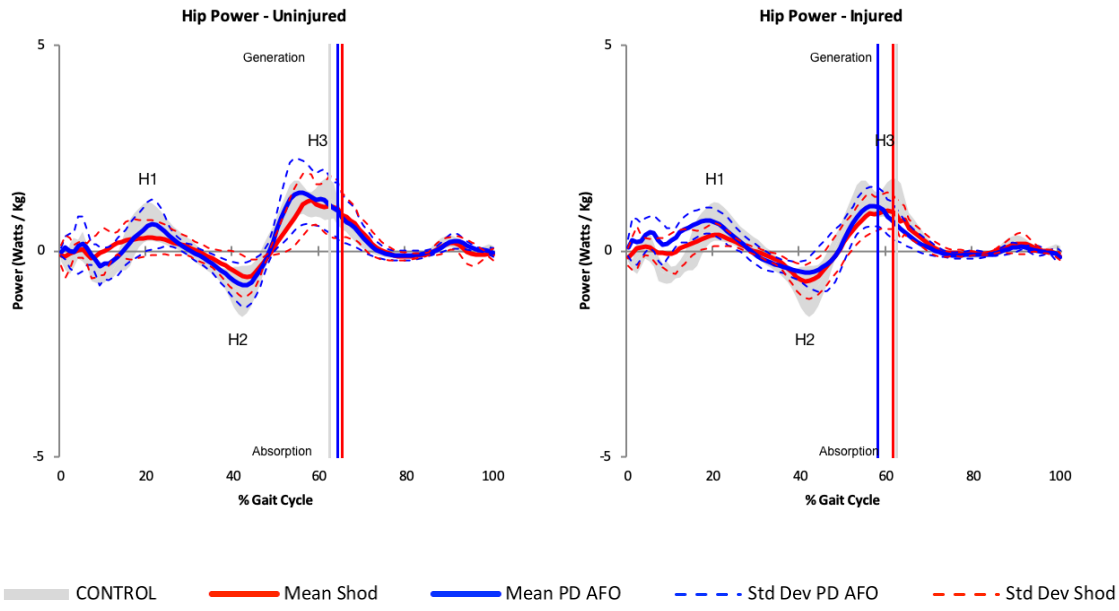

Figure 4-8 Hip powers during the two testing conditions for both the injured and uninjured limb.

Table 4-10 A comparison of the mean, SD, and range of hip moments for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[235]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
H1 maximum power generation during loading response: (0-10%GC) (Watts/Kg)	0.53±0.36	0.76±0.38	0.49±0.28	0.83±0.33	0.50±0.30
Range	0.5 to 1.10	0.31 to 1.30	0.10 to 1.04	0.37 to 1.40	0.10 to 1.44
p value	0.54		0.09		0.40
Cohen's d	0.02		1.07		0.51
H2 maximum power absorption during midstance: (10-30%GC) (Watts/Kg)	-0.68±0.42	-0.79±0.39	-0.75±0.30	-0.60±0.33	-0.8 ±0.30
Range	-1.40 to -0.21	-1.47 to -0.21	-1.33 to -0.45	-1.29 to -0.09	-1.65 to -0.14
p value	0.29		0.7		<0.001*
Cohen's d	0.69		0.48		2.74
H3 maximum power generation during pre-swing and initial swing (50-70%GC) (Watts/Kg)	0.82±0.18	0.90±0.19	0.65±0.17	0.73±0.23	1.2±0.50
Range	0.12 to 1.90	0.04 to 2.29	0.07 to 1.61	0.02 to 1.66	0.06 to 1.95

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[235]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
p value	0.09		0.91		0.25
Cohen's d	1.22		0.07		0.71

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.5 Parameters to investigate hypothesis 3: stability in gait

4.5.1 Temporal spatial parameters: With and without the PD AFO

The temporal and spatial data showed no difference in stride width for each test condition (Table 4-11). Double support time is reduced when the PD AFO is worn, but this reduction did not demonstrate a significant change (p=0.25) but does show a medium effect size (0.57).

Table 4-11 A comparison of the mean temporal and spatial parameters: stride length, stride width, double support time of participants with and without a PD AFO compared to available control data.

Parameter	Without PD AFO	With PD AFO	Control Group Jarvis et al[282]
	Mean ± SD	Mean ± SD	Mean
	Range	Range	Range
Stride Width (meters)	0.14±0.02	0.14±0.02	0·12
	0.10 to 0.17	0.10 to 0.16	0·11 to 0·13
p value	0.16		N/A*
Cohen's d	0.35		N/A*
Double Support Time (Seconds)	0.32±0.15	0.26±0.05	N/A*
	0.18 to 0.47	0.19 to 0.37	N/A*
p value	0.25		N/A*
Cohen's d	0.57		N/A*

*This data was unavailable

4.5.2 Temporal spatial parameters: uninjured vs injured limb

The step length on both the injured and uninjured limb increased when using a PD AFO. This did not show a significant difference, (p=0.06) (p=0.14)

respectively but showed a large effect size on the injured limb (0.84) and a very large effect size on the uninjured limb (1.24) (Table 4-12). The step length when wearing the PD AFO was closer to the control group compared to without the PD AFO. Stance time decreased when participants used the PD AFO. This did not show a significant change but demonstrated a medium effect size on the uninjured limb (0.69) and a large effect size on the injured limb (0.95). The swing time increased when the PD AFO was worn, but again this did not show a significant change, nor a meaningful change in the effect size. Toe off occurred sooner in the gait cycle for both the injured and uninjured limb when wearing the PD AFO. The injured limb showed a significant change (p=0.03) in the timing that toe off occurred between test conditions, 62.2% (shod) and 57.7% (PD AFO) respectively, and this demonstrated a large effect size (1.13).

Table 4-12 A comparison of the mean temporal and spatial parameters: step length, stance length, swing time and % gait cycle toe off occurs of participants with and without a PD AFO compared to available control data.

Parameter	**Un-injured Limb**		**Injured Limb**		**Control Group**
	Without PD AFO	**With PD AFO**	**Without PD AFO**	**With PD AFO**	**Jarvis et al[282]**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	**Mean**
	Range	**Range**	**Range**	**Range**	**Range**
Step Length (meters)	0.66±0.13	0.78±0.05	0.69±0.12	0.77±0.09	0.74
	0.42 to 0.87	0.71 to 0.87	0.56 to 0.90	0.68 to 0.92	0.70 to 0.78
p value	0.06		0.14		N/A*
Cohen's d	1.24		0.84		N/A*
Stance Time (seconds)	0.81±0.15	0.73±0.07	0.76±0.15	0.65±0.05	N/A*
	0.61 to 1.04	0.62 to 0.84	0.54 to 0.99	0.55 to 0.72	N/A*
p value	0.45		0.09		N/A*
Cohen's d	0.69		0.95		N/A*
Swing Time (seconds)	0.40±0.07	0.40±0.04	0.46±0.08	0.48±0.05	N/A*
	0.31 to 0.55	0.33 to 0.44	0.38 to 0.62	0.43 to 0.58	N/A*
p value	0.83		0.5		N/A*
Cohen's d	0.10		0.33		N/A*

Parameter	Un-injured Limb		Injured Limb		Control Group
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[282]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean
	Range	Range	Range	Range	Range
% Gait cycle at point of toe off	66.6±4.08	64.6±3.35	62.2±4.73	57.7±3.02	N/A*
	60.4 to 70.9	61.8 to 72.0	55.2 to 72.1	50.5 to 60	N/A*
p value	0.30		0.03		N/A*
Cohen's d	0.54		1.13		N/A*

*This data was unavailable

4.5.3 Vertical ground reaction force

The use of the PD AFO significantly increased the 2 peaks of the vertical ground reaction force (p=0.04), (p=0.01) and (p=0.03) respectively, in both the uninjured and injured limbs (Table 4-13). Use of the PD AFO also decreased the trough of the vertical ground reaction force for both the uninjured and the injured limb. The decrease of the trough was significant on the injured limb (p=0.03) and demonstrated a very large effect size (1.23).

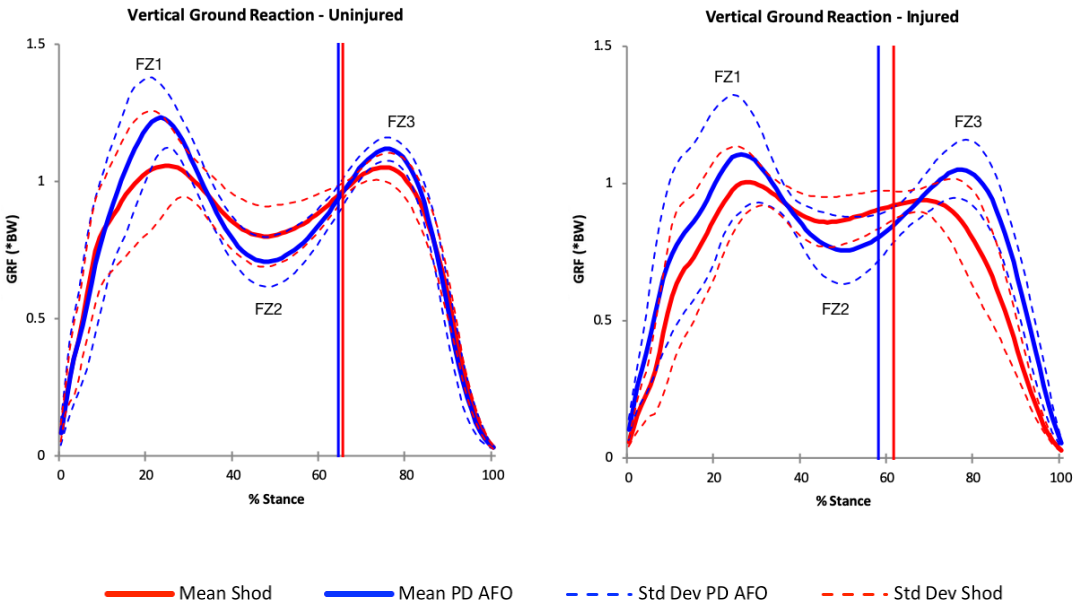

Figure 4-9 Vertical ground reaction during the two testing conditions for both the injured and uninjured limb.

Table 4-13 A comparison of the mean, SD, and range of the vertical ground reaction force for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb	
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range
FZ1 (* body weight)	1.15±0.17	1.27±0.10	1.06±0.09	1.16±0.14
	0.98 to 1.45	1.03 to 1.49	0.94 to 1.19	1.00 to 1.44
p value	0.04		0.04	
Cohen's d	1.23		1.10	
FZ2 (* body weight)	0.76±0.10	0.85±0.08	0.75±0.08	0.82±0.10
	0.71 to 0.95	0.61 to 0.87	0.74 to 0.93	0.59 to 0.91
p value	0.06		0.03	
Cohen's d	1.09		1.23	
FZ3 (* body weight)	1.05±0.06	1.13±0.04	0.91±0.11	1.06±0.11
	1.00 to 1.11	1.06 to 1.21	0.72 to 1.06	0.83 to 1.19
p value	0.01		0.03	
Cohen's d	1.53		1.29	

4.5.4 Hip kinematics- sagittal plane

The sagittal plane hip kinematics demonstrated a significant change (p=0.03) in the injured limbs range of motion comparing both test conditions (Table 4-14). Both the injured and uninjured limbs range of motion in the hip increased when the PD AFO was worn, and this increase was more comparable to controls. For both conditions, both limbs at initial contact were in a flexed position at the hip joint. Wearing the PD AFO slightly increased the flexion angle at initial contact bilaterally, but this was not deemed significant (p=0.54 and p=0.17). Conversely the injured limb does demonstrate a medium effect size change in the initial contact angle (0.64). The peak extension angle of the hip in the GC decreased slightly on the injured limb when wearing the PD AFO but increased on the uninjured limb for the same test condition.

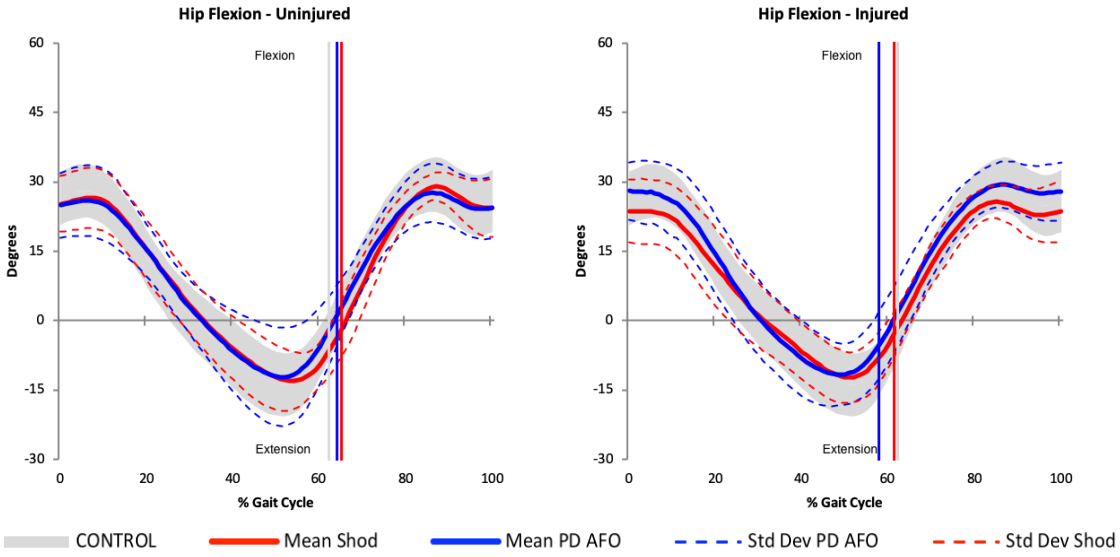

Figure 4-10 Sagittal plane hip motion during the two testing conditions for both the injured and uninjured limb.

Table 4-14 A comparison of the mean, SD, and range of sagittal plane hip motion for the two test conditions (injured and uninjured limb), compared to available control data.

Parameter	Un-injured limb		Injured limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Flexion angle at initial contact (°)	25.25±6.02	27.00±5.84	23.62±6.79	28.00±6.17	26.4 ±5.7
	16.28 to 34.50	20.28 to 34.93	11.85 to 31.06	20.34 to 35.60	21.3 to 38.9
p value	0.54		0.17		0.90*
Cohen's d	0.29		0.64		0.26
Peak extension (°)	14.0±6.3	15.5±4.7	13.0±5.5	12.8±6.6	14.1 ±6.7
	5.7 to 25.8	8.3 to 21.2	6.3 to 18.1	1.7 to 23	4.3 to 28.4
p value	0.54		0.92		0.68*
Cohen's d	0.29		0.05		0.20
Range of motion through full gait cycle (°)	44.1±5.9	46.8±3.7	40.6±2.9	44.5±3.8	-44.2 ± 2.6
	36.2 to 49.2	39.6 to 52.1	35.4 to 44.0	37.9 to 49.3	-49.7 to -39.5
p value	0.27		0.03		0.86*
Cohen's d	0.54		1.16		0.09

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.5.5 Foot progression angle

The foot kinematics in the transverse plane demonstrated that there were no significant differences (p=0.92) (shod) and (p=0.93) (PD AFO) respectively in the foot progression angle between the 2 test conditions, nor was there a meaningful effect size change (Table 4-15). The foot remained in an externally rotated position throughout stance. Additionally, there was no significant difference between the injured limb wearing the PD AFO and controls (p=0.78).

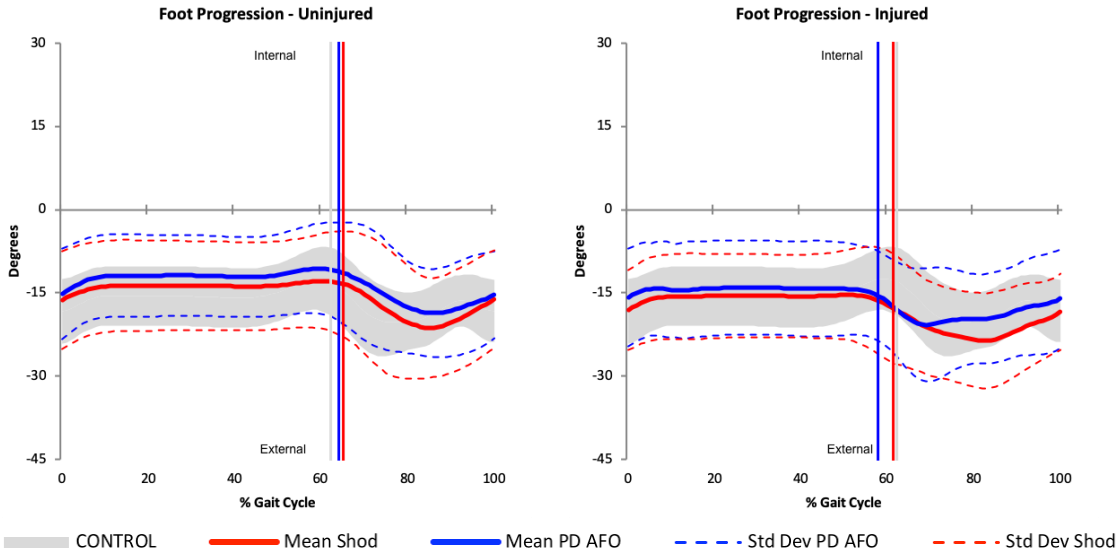

Figure 4-11 Transverse plane foot progression during the two testing conditions for both the injured and uninjured limb.

Table 4-15 A comparison of the mean, SD, and range of foot progression angle for the two test conditions for both the injured and uninjured limb, compared to available control data.

Parameter	Un-injured limb		Injured limb		Control
	Without PD AFO Mean ± SD Range	With PD AFO Mean ± SD Range	Without PD AFO Mean ± SD Range	With PD AFO Mean ± SD Range	Jarvis et al[246] Mean ± SD Range
Average external foot progression (°)	22.4±10.4	20.0±8.75	25.6±9.8	22.3±9.5	16.4±5.2
	3.7 to 34.5	6.3 to 33.6	9.3 to 41.1	7.2 to 40.8	12.8 to 25.3
p value	0.92		0.93		0.78*
Cohen's d	0.40		0.05		0.13

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.5.6 Knee moments

The sagittal plane knee moments did not show any significant differences (p=<0.05) for each test condition (Table 4-16). Whilst the sagittal plane knee flexing moments increased in both the uninjured and injured limb when participants were wearing the PD AFO, this did not represent a significant difference (p= 0.23 and p=0.35) respectively. However, a medium effect size is shown in the peak knee flexing moment of the uninjured limb (0.62). Furthermore, the knee flexing moment on both the uninjured and injured limb was greater than the control group both with and without use of the PD AFO. Use of the PD AFO increased the knee extending moments compared to without the PD AFO. Whilst this showed no significant difference, the uninjured limb demonstrated a medium effect size (0.71).

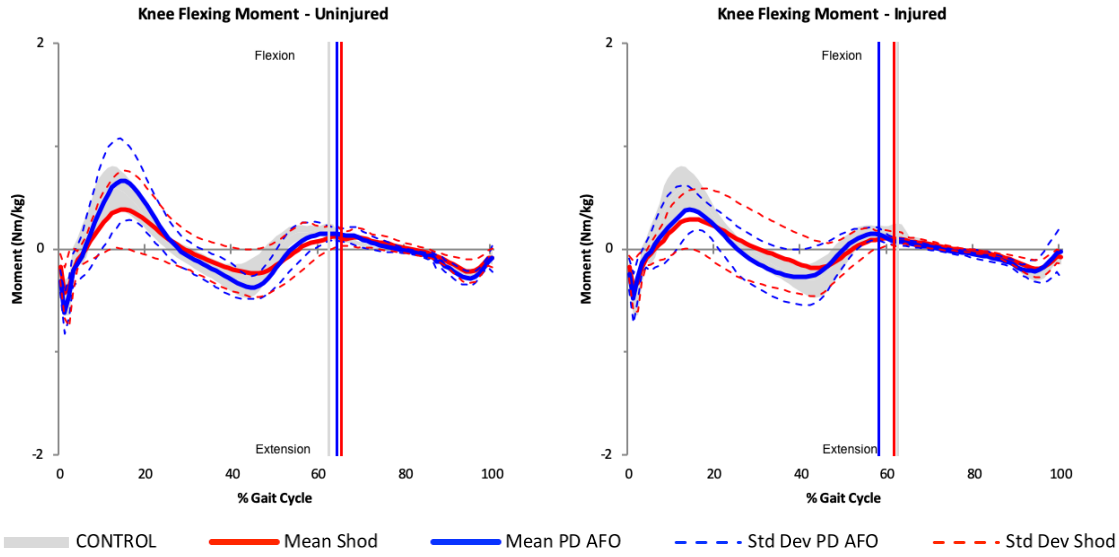

Figure 4-12 Sagittal plane knee external moment during the two testing conditions for both the injured and uninjured limb.

Table 4-16 A comparison of the mean, SD, and range of sagittal plane knee moments for the two test conditions (both the injured and uninjured limb), compared to available control data.

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Peak Flexing Moment (Nm/kg)	0.48±0.33	0.71±0.40	0.42±0.28	0.54±0.21	0.38 ±0.17
	0.06 to 1.06	0.39 to 1.47	0.11 to 0.94	0.30 to 0.96	0.11 to 0.62

Parameter	Un-Injured Limb		Injured Limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
p value	0.23		0.35		0.25*
Cohen's d	0.62		0.46		0.59
Peak Extending Moment (Nm/kg)	-0.27±0.25	-0.42±0.15	-0.26±0.21	-0.32±0.24	-0.61 ±0.22
	-0.64 to 0.02	-0.61 to -0.20	-0.50 to 0.13	-0.58 to 0.17	-0.81 to -0.22
p value	0.15		0.58		0.71*
Cohen's d	0.71		0.28		0.19

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.5.7 Knee kinematics

The knee kinematics in the sagittal plane demonstrated that there were no significant (p=<0.05) changes in the peak flexion angles or initial contact angles for each test condition (Table 4-17). On initial contact, the uninjured and injured limb like controls were in slight extension without wearing the PD AFO. When participants were wearing the PD AFO, the uninjured limb remained in slight extension upon initial contact, but the injured limb using the PD AFO was in slight flexion (3.3°). The peak knee flexion angle, both in early stance and swing, increased in the uninjured and injured limb when the PD AFO was worn, and both were more similar to able-bodied controls compared to without the PD AFO. Whilst no significant changes were shown, there was a large effect size demonstrated in the uninjured limb ankle at initial contact between both test conditions (0.89). Additionally, both the uninjured and the injured limb demonstrated a medium effect size change in the peak flexion angle in swing (0.58) and (0.71) respectively.

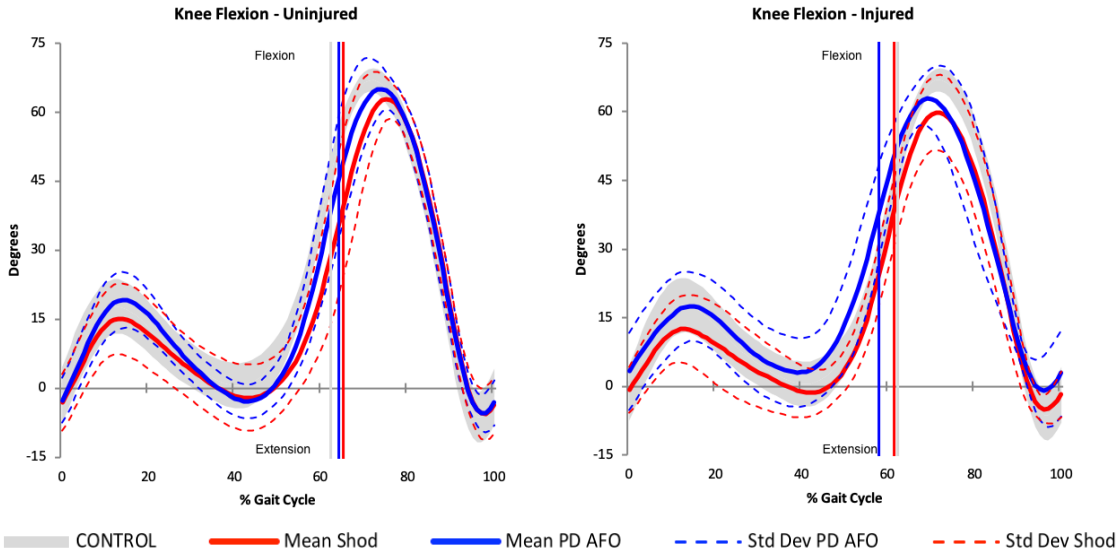

Figure 4-13 Sagittal plane knee motion during the two testing conditions for both the injured and uninjured limb.

Table 4-17 A comparison of the mean, SD, and range of sagittal plane knee motion for the two test conditions for both the injured and uninjured limb, compared to available control data.

Parameter	Un-injured limb		Injured limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Angle at initial contact (°) (Flexion +ve)	-3.05±6.1	-2.68±4.9	-0.72±5.0	3.30±8.4	-1.4 ±6.0
	-15.71 to 4.35	-9.31 to 5.38	-5.19 to 10.82	-5.25 to 20.35	-12.0 to -9.1
p value	0.89		0.34		0.13*
Cohen's d	0.07		0.58		0.65
Peak flexion early stance (°) (0-20%)	15.47±7.9	19.59±6.1	13.54±6.9	18.90±8.0	17.9 ±5.9
	3.70 to 24.53	12.91 to 27.8)	6.18 to 27.76	7.63 to 33.06	7.8 to 29.2
p value	0.23		0.15		0.76*
Cohen's d	0.58		0.71		0.15
Peak flexion in swing (°)	64.4±5.0	66.7±3.7	60.2±8.1	65.1±3.5	67 ±2.6
	54.7 to 70.1	60.4 to 71.3	43.2 to 71.2	58.6 to 71.5	62.7 to 70.6
p value	0.3		0.08		0.19*
Cohen's d	0.58		0.71		0.15

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.6 GPS, MAPS and hip/pelvic kinematics to answer hypothesis 4

4.6.1 Hip kinematics: coronal and transverse plane

The coronal plane hip kinematics showed a significant change (p=0.03) in the injured limbs peak adduction angle comparing both test conditions. The peak adduction angle on the injured limb increased by 3.2° when using the PD AFO and demonstrated a large effect size (1.16) (Table 4-18). The uninjured limb only increased slightly (1.3°) for the same test condition and was not deemed a significant change (p=0.75). The peak hip abduction angle increased on the uninjured limb when the PD AFO was worn by 2.2° but decreased in the injured limb by 0.5° for the same test condition. Neither was considered significant changes (p= 0.24 and p=0.79), respectively, but a medium effect size (0.79) was shown on the injured limb.

The transverse plane hip kinematics demonstrated no significant differences (<0.05) for each test condition. A medium effect size (0.63) was demonstrated in the peak internal rotation of the uninjured limb between both test conditions. When participants walked without the PD AFO both the injured and uninjured limbs remained in external rotation throughout the GC. When participants wore the PD AFO, the injured limb remained in external rotation throughout the GC, but the uninjured limb exhibited a peak internal rotation angle of 1.2° during terminal stance.

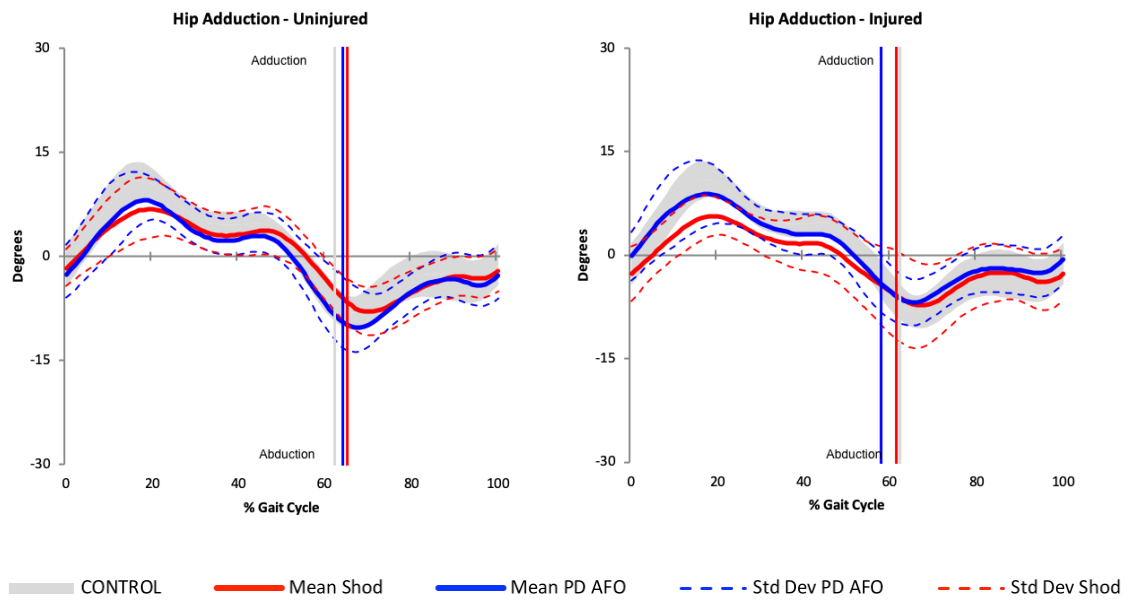

Figure 4-14 Coronal plane hip motion during the two testing conditions for both the injured and uninjured limb.

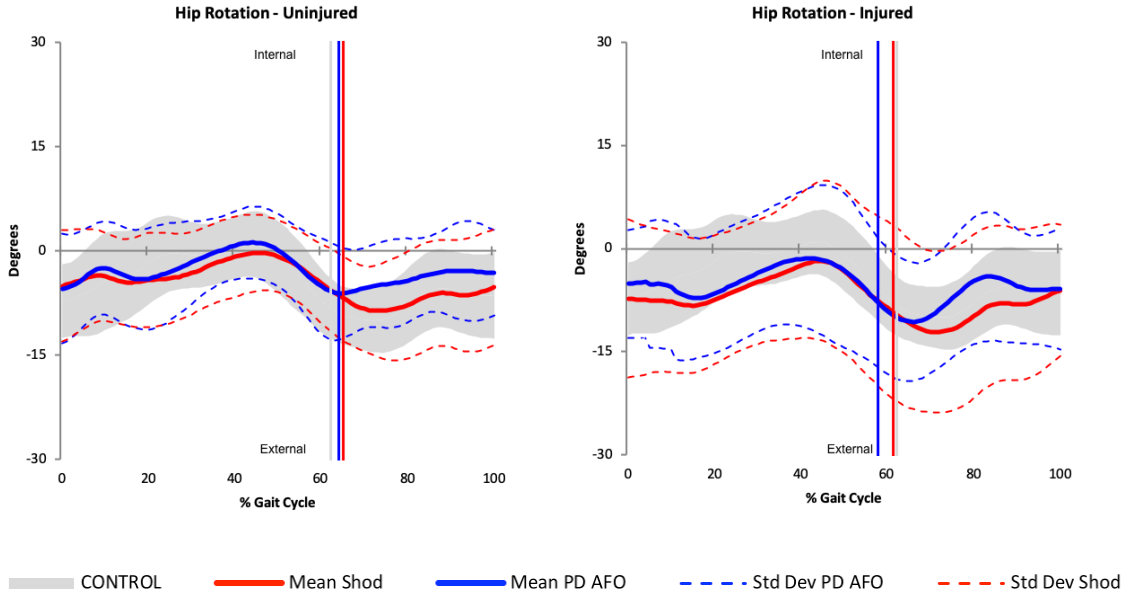

Figure 4-15 Transverse plane hip motion during the two testing conditions for both the injured and uninjured limb.

Table 4-18 A comparison of the mean, SD, and range of coronal and transverse plane hip motion for the two test conditions (injured and uninjured limb), compared to available control data.

Parameter	Un-injured limb		Injured limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Peak adduction (°)	6.8±5.1	8.1±3.5	5.7±2.1	8.9±3.8	11.1 ±2.5
	2.5 to 16.1	3.4 to 15.2	2.9 to 9.6	2.0 to 12.9	6.9 to 14.6
p value	0.75		0.03		0.78*
Cohen's d	0.15		1.16		0.26
Peak abduction (°)	-8.0±2.1	-10.2±3.8	-7.3±5.9	-6.8±3.2	-8.6 ±2.5
	-12.0 to -5.5	-17.4 to -4.4	-18.3 to -1.0	-12.7 to -2.9	-12.4 to -4.4
p value	0.24		0.79		0.90*
Cohen's d	0.58		0.13		0.06
Peak internal rotation (°) (Internal +ve)	-0.3±5.9	1.2±4.9	-1.8±6.6	-1.4±7.8	1.5 ± 3.7
	-6.6 to 7.8	-3.8 to 9.4	-2.9 to 11.7	-9.9 to 15.1	-4.7 to 8.6
p value	0.95		0.81		0.89*
Cohen's d	0.63		0.25		0.07
Peak external rotation (°)	-8.6±6.9	-6.1±5.5	-12.1±7.4	-10.6±8.9	-10.7 ± 3.8
	-21.9 to -2.0	-18.3 to -3.0	-24.5 to 0.5	-29.6 to 2.6	-17.5 to -3.9
p value	0.20		0.60		0.42*
Cohen's d	0.03		0.12		0.39

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.6.2 Pelvic kinematics

The sagittal plane pelvic kinematics demonstrated a significant difference (p=0.02) in the range of pelvic tilt, when comparing the injured limb wearing the PD AFO (7.7°) and the control group (8.9°) (Table 4-19). The injured limb's range of pelvic tilt remained the same for both test conditions (7.7°). The uninjured limb's range of pelvic tilt increased when wearing the PD AFO from 5.9° to 6.5° respectively, however this was not deemed significant (p=0.33). The pelvis on the uninjured and injured limb for both test conditions remained anteriorly tilted throughout the GC.

The coronal plane pelvic kinematics did not show any significant differences (p=<0.05) for both test conditions. The maximum upwards, downwards and

range of pelvic obliquity increased in both the uninjured and injured limbs when the PD AFO was worn; this was comparable to controls.

The transverse plane pelvic kinematics did not show any significant differences (p=<0.05) for both test conditions. However, a large effect size (0.85) was demonstrated on the range of pelvic rotation utilised by the uninjured limb between both test conditions. The uninjured and injured limb demonstrated a greater range of pelvic rotation when the participants wore the PD AFO. This increased by 0.4° on the uninjured limb and 1.6° on the injured limb. Both the injured and uninjured limbs in both test conditions demonstrated a greater range of pelvic rotation compared to controls. With and without use of the PD AFO, the internal rotation of the pelvis on the uninjured limb remained the same. The injured limb's internal rotation of the pelvis only increased by 0.2° when the PD AFO was used, but this demonstrated a medium effect size (0.62) and all angles were similar to controls.

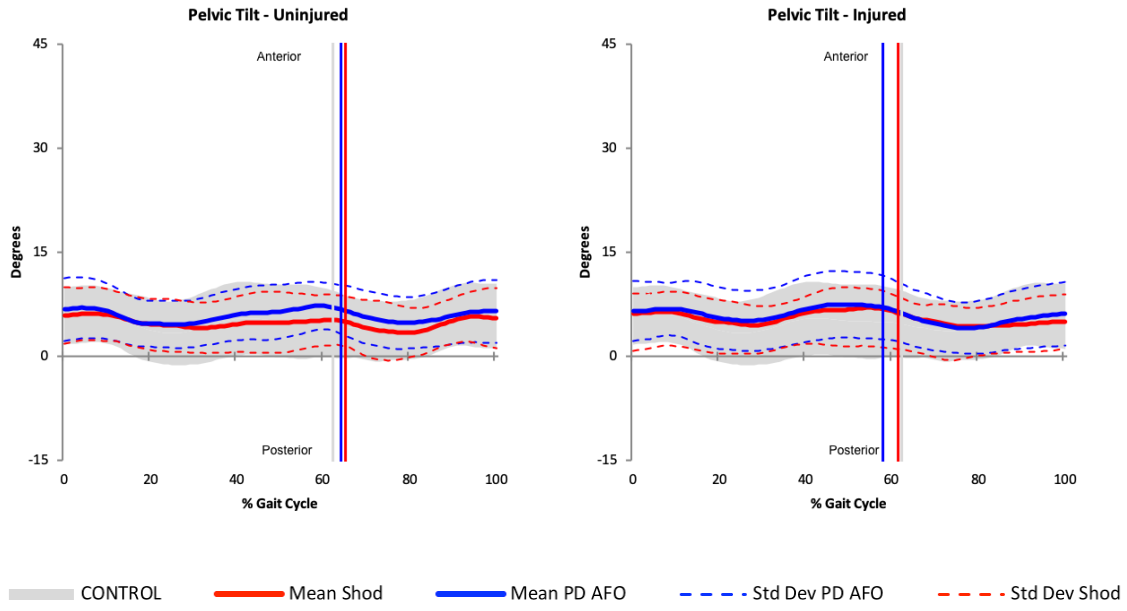

Figure 4-16 Sagittal plane pelvic motion during the two testing conditions for both the injured and uninjured limb

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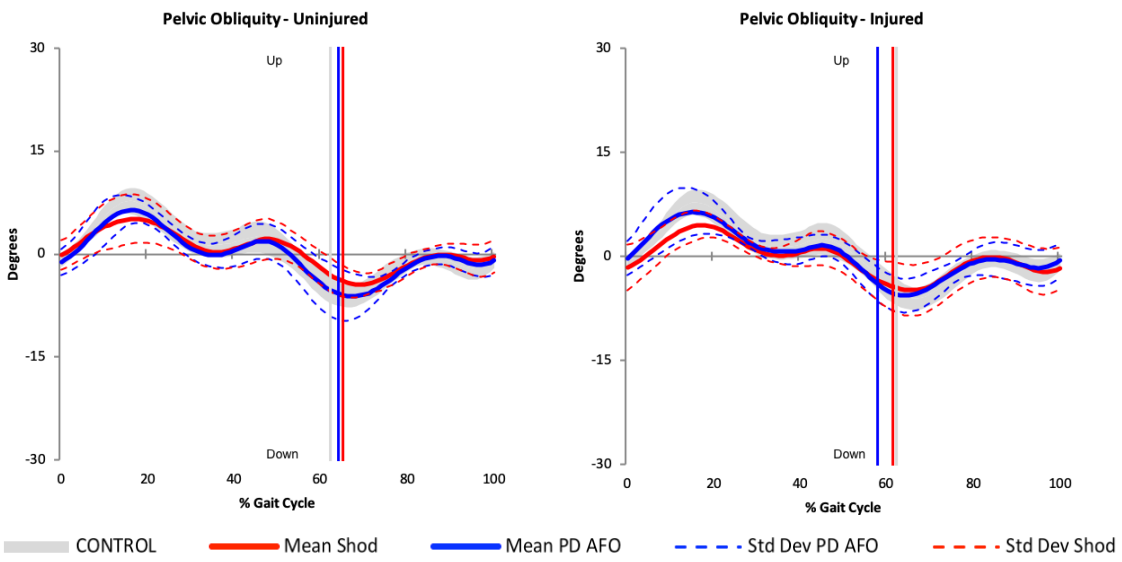

Figure 4-17 Coronal plane pelvic motion during the two testing conditions for both the injured and uninjured limb.

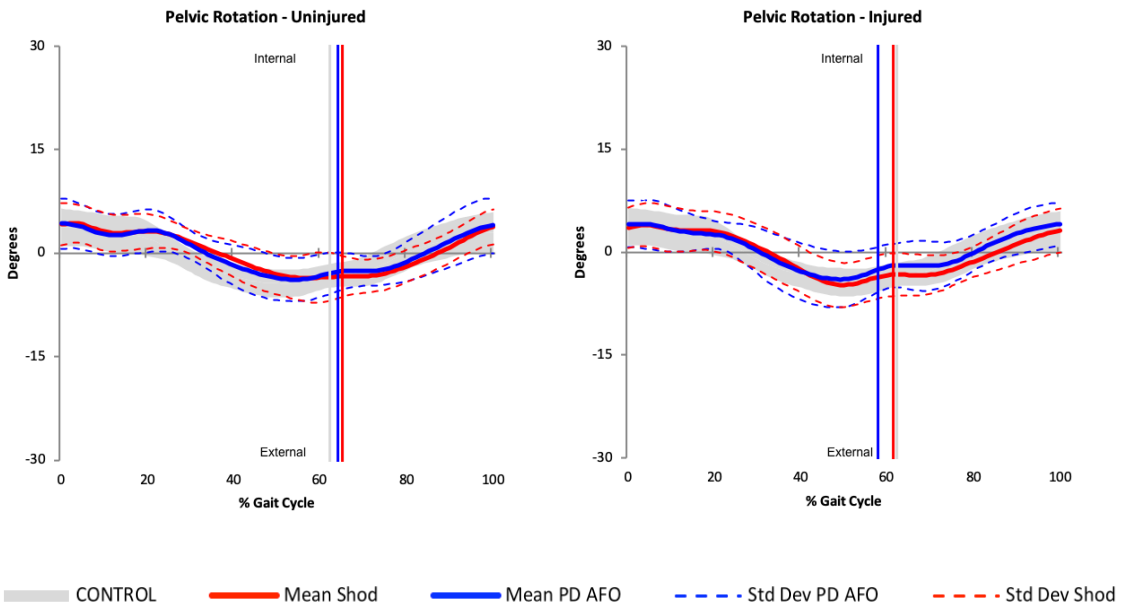

Figure 4-18 Transverse plane pelvic motion during the two testing conditions for both the injured and uninjured limb.

Table 4-19 A comparison of the mean, SD, and range of sagittal, coronal and transverse plane pelvic motion for the two test conditions (injured and uninjured limb), compared to available control data.

Parameter	Un-injured limb		Injured limb		Control
	Without PD AFO	With PD AFO	Without PD AFO	With PD AFO	Jarvis et al[246]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
Maximum anterior tilt (°)	6.1±3.6	7.3±3.2	7.0±2.9	7.5±3.7	6.2 ±3.1
	2.2 to 7.4	3.8 to 7.9	3.7 to 6.7	2.4 to 7.6	5.5 to 8.6
p value	0.56		0.49		0.94*
Cohen's d	0.40		0.29		0.64
Range of anterior/posterior tilt (°)	5.9±1.4	6.5±1.0	7.7±3.0	7.7±3.0	8.9 ± 4.2
	2.6 to 8.3	5.1 to 7.7	5.0 to 14.9	4.9 to 14.7	3.9 to 15.1
p value	0.33		0.89		0.02*
Cohen's d	0.47		0.01		1.18
Max pelvic obliquity (pelvis up) (°)	6.4±3.5	7.0±2.0	5.4±1.9	7.4±3.0	7.8 ± 4.5
	1.6 to 11.1	5.0 to 11.4	3.0 to 8.5	2.7 to 13.0	5.3 to 11.1
p value	0.64		0.13		0.67*
Cohen's d	0.22		0.76		0.20
Max pelvic obliquity (pelvis down) (°)	5.5±1.9	7.0±2.8	6.2±3.7	6.8±1.6	6.3 ± 1.8
	3.0 to 8.6	2.3 to 11.5	1.0 to 13.0	4.6 to 9.5	2.9 to 8.6
p value	0.22		0.71		0.57*
Cohen's d	0.60		0.18		0.31
Range of pelvic up/down tilt (°)	11.7±4.6	14.0±4.2	11.7±4.7	14.1±3.0	12.1 ± 4.1
	8.0 to 19.7	9.6 to 22.9	6.9 to 20.3	9.5 to 19.6	9.3 to 16.3
P value	0.33		0.21		1.0*
Cohen's d	0.47		0.62		0.00
Maximum internal rotation (°)	4.3±2.3	4.3±3.3	3.9±2.8	4.1±3.4	4.2 ± 2.6
	2.8 to 8.7	1.8 to 12.4	1.4 to 6.3	2.5 to 13.0	0.2 to 7.8
Cohen's d	0.04		0.60		0.87
Range of pelvic rotation (°)	10.6±3.7	11.0±4.8	10.9±3.4	12.5±5.3	9.2 ± 2.7
	6.3 to 16.0	4.8 to 20.5	6.3 to 16.3	6.1 to 20.8	5.9 to 14.2
p value	0.85		0.47		0.16
Cohen's d	0.04		0.60		0.87

*The p value in the control column relates to the injured limb wearing the PD AFO vs control (able bodied)

4.7 Gait profile score (GPS) and movement analysis profile (MAP)

Use of the PD AFO improved the GPS score for both the uninjured and injured limb, although this did not demonstrate a significant difference (p=0.42) (p=0.98), nor a meaningful change in the effect size (Table 4-20). No significant differences were shown in the mean injured and uninjured GPS scores for each of the gait parameters, shown. Use of the PD AFO increased the pelvic tilt, pelvic rotation, and hip flexion/extension GPS scores in both the injured and uninjured limb (Table 4-21). Use of the PD AFO decreased the pelvic obliquity, hip adduction/adduction, hip rotation and foot progression GPS scores in both the injured and uninjured limb. Use of the PD AFO decreased the knee flexion/extension and ankle dorsiflexion/plantar flexion GPS scores on the uninjured limb but increased the GPS score on the injured limb. A large effect size (0.8-1.2) was shown on the injured limb's hip adduction/abduction, hip rotation and knee flexion/extension GPS score, (0.93) (0.93) and (0.86) respectively. The largest effect size in the GPS score for the uninjured limb was hip rotation (0.91). The controls' GPS score for each of the gait parameters was less than the injured limb, both with and without use of the PD AFO, and less than the uninjured limb with and without the PD AFO for all parameters except pelvic tilt. The GPS score for controls' pelvic tilt (3.7) was greater than the uninjured limb, both with and without the PD AFO (3.46) and (3.05) respectively. There was a significant difference (p=0.01) and a very large effect size (1.33) between the overall GPS score of the controls (3.9) and the participants, when using the PD AFO (6.28).

Table 4-20 A comparison of the mean, SD, and range of the overall gait profile scores (GPS) of the uninjured and injured limb during gait with and without use of the PD AFO.

Parameter	Without PD AFO Mean ± SD Range	With PD AFO Mean ± SD Range	Control Mean ± SD Range
GPS uninjured limb	6.18±2.5	5.99±1.8	N/A*
	3.4 to 11.8	4.0 to 8.7	N/A*
p value	0.42		N/A*
Cohen's d	0.39		N/A*
GPS injured limb	6.21±3.3	5.31±1.7	N/A*
	3.3 to 10.4	3.6 to 9.1	N/A*
p value	0.98		N/A*
Cohen's d	0.01		N/A*
GPS overall	6.61±2.1	6.28±2.1	3.9±1.2
	4.1 to 10.2	3.7 to 10.0	2.0 to 6.3
p value	0.74		0.01
Cohen's d	0.16		1.33

*This data was unavailable

Table 4-21 A comparison of the mean, SD, and range of the gait variability scores (GVS) of the uninjured and injured limb during gait with and without use of the PD AFO for 9 kinematic gait parameters.

Parameter	Uninjured		Injured		Control
	Without PD AFO Mean ± SD Range	With PD AFO Mean ± SD Range	Without PDAFO Mean ± SD Range	With PD AFO Mean ± SD Range	Jarvis et al[247] Mean ± SD Range
Pelvic anterior/posterior tilt	3.05±2.1	3.46±1.7	2.88±1.5	3.96±1.7	3.7±2.6
	0.9 to 6.6	1.3 to 6.7	1.2 to 6	1.0 to 6.7	0.9 to 8.7
p value	0.13		0.56		0.79
Cohen's d	0.21		0.67		0.12
Pelvic obliquity (up/down tilt)	2.52±0.8	2.15±0.9	2.84±0.7	2.23±0.9	1.5±0.6
	1.5 to 4.1	1.2 to 3.6	1.8 to 4	1.2 to 3.7	0.6 to 2.5
p value	0.37		0.12		0.07
Cohen's d	0.44		0.77		0.93
Pelvic internal/external rotation	2.80±0.7	2.95±1.0	2.83±1.1	3.08±0.9	2.0±0.7
	2.0 to 3.9	1.7 to 4.4	1.7 to 4.7	1.1 to 4.1	0.7 to 3.3
p value	0.71		0.60		0.02
Cohen's d	0.18		0.25		1.25
Hip flexion/extension	5.63±1.9	5.89±4.0	5.47±3.1	6.28±2.9	4.8±3.4

Parameter	Uninjured		Injured		Control
	Without PD AFO	With PD AFO	Without PDAFO	With PD AFO	Jarvis et al[247]
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Range	Range	Range	Range	Range
	3.0 to 8.8	2.8 to 15.6	1.4 to 10.7	2.1 to 11.8	1.4 to 11.4
p value	0.49		0.58		0.33
Cohen's d	0.08		0.27		0.46
Hip adduction/abduction	3.71±1.2	3.74±1.2	4.65±1.3	3.36±1.5	2.4±0.8
	1.7 to 4.7	1.3 to 5.0	2.8 to 6.8	2.2 to 7.0	1.3 to 3.5
p value	0.96		0.07		0.09
Cohen's d	0.02		0.93		0.88
Hip internal/external rotation	6.09±2.4	5.96±2.6	8.20±7.3	7.56±5.0	4.6±2.2
	2.9 to 9.6	2.6 to 9.2	2.3 to 26.2	2.8 to 17.5	1.4 to 6.9
p value	0.91		0.93		0.17
Cohen's d	0.05		0.10		0.79
Knee flexion/extension	9.14±4.5	6.08±3.9	7.33±3.6	7.66±6.2	4.1±2.1
	3.4 to 15.9	3.3 to 14.8	3.3 to 12.1	2.9 to 21.4	2.4 to 8.9
p value	0.08		0.86		0.05
Cohen's d	0.72		0.06		0.78
Ankle dorsiflexion/plantarflexion	3.99±1.0	3.49±1.3	5.33±2.8	6.33±3.0	2.2±0.9
	2.5 to 5.3	2.1 to 6.7	2.2 to 12.3	3.4 to 11.9	1.2 to 3.7
p value	0.38		0.49		0.00
Cohen's d	0.43		0.42		2.00
Foot progression internal/external	9.06±5.5	7.60±4.6	7.93±4.5	7.21±5.1	4.6±2.6
	2.7 to 16.5	2.2 to 15.2	2.8 to 15.6	2.2 to 16.4	1.4 to 9.2
p value	0.55		0.93		0.40
Cohen's d	0.29		0.15		0.66

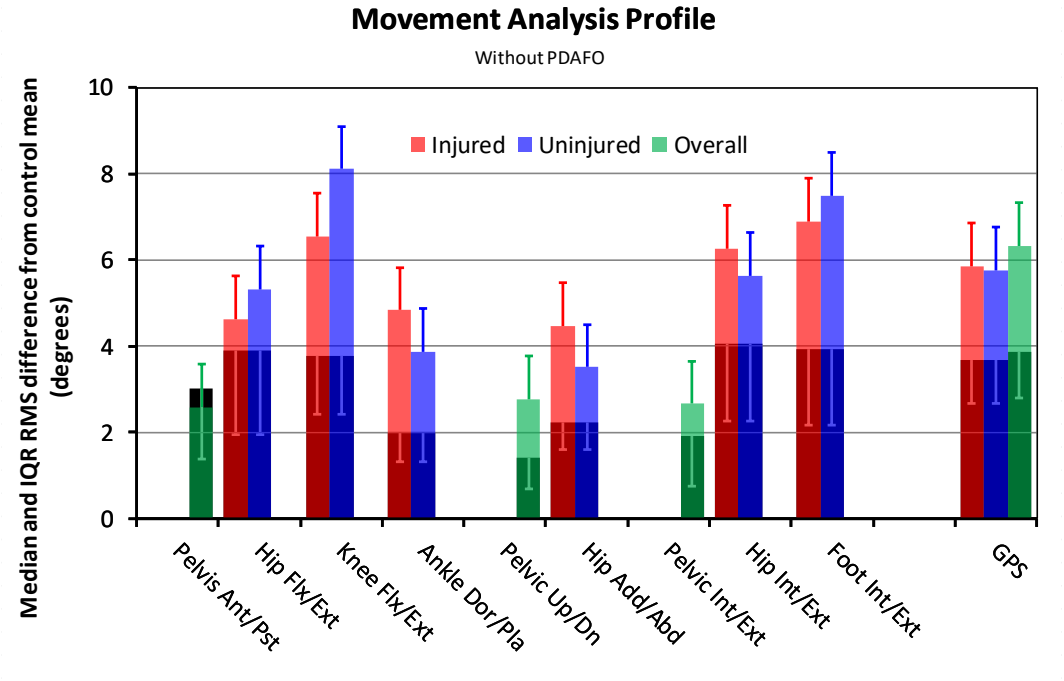

Figure 4-19 Gait profile score and movement analysis profile in the injured and uninjured limb without the PD AFO during gait

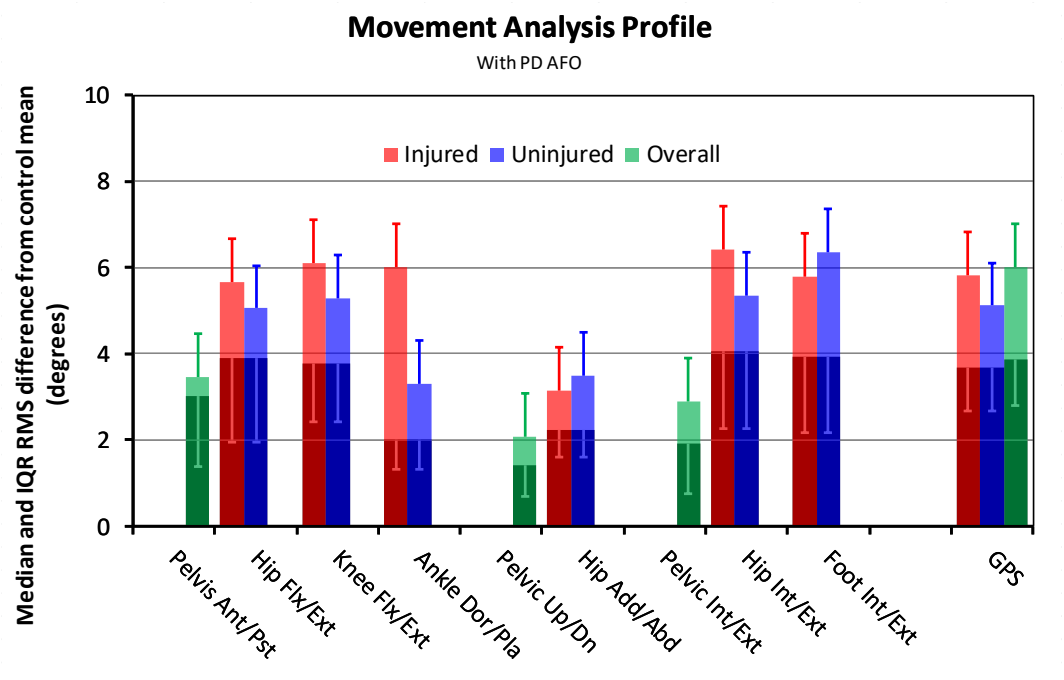

Figure 4-20 Gait profile score and movement analysis profile in the injured and uninjured limb with the PD AFO during gait

Chapter 5: Discussion

5.1 Introduction to discussion

The aim of this thesis was to investigate if a PD AFO improved gait and functional outcomes when worn by injured personnel who sustained unilateral deck slap injuries during the Afghanistan conflict. Improvement was defined using both PROM and biomechanical outcomes to test 4 hypotheses.

Hypothesis 1: PD AFO use will improve the patient reported outcomes of participants.

Hypothesis 2: PD AFO use will improve participants propulsion through terminal stance of gait in both the injured and uninjured limb.

Hypothesis 3: PD AFO use will improve the participants stability through the stance phase of gait.

Hypothesis 4: PD AFO use will improve the gait profile score of both the injured and uninjured limb.

All prior studies using this style of PD AFO have been conducted on military personnel of a similar age and predominantly injured due to high-energy blast trauma sustained in Afghanistan. Therefore, prior PD AFO studies have included participants similar to this study's cohort. This is the first study, to the author's knowledge, that presents gait parameters of participants with deck slap injuries specifically. Prior work has grouped participants together that present with a wider profile of lower limb injuries caused by various mechanisms.

This study builds on an important limitation of prior gait studies using PD AFOs, as it presents the study cohort without use of a PD AFO, which is novel. The hypotheses set out in chapter 2 (and listed above) will now be examined.

5.2 Hypothesis 1: PD AFO use will improve the patient reported outcomes of participants

Overall, the mean patient reported outcome measures (PROM) scores for both the foot and ankle outcome score (FAOS) and the lower extremity functional

scale (LEFS) improved when the PD AFO was worn, and both represented a significant difference with an extra-large effect size. However, in this study 1 participant (AP11) consistently reported lower scores when wearing the PD AFO across both the LEFS and all sections of the FAOS, apart from the ability to engage in sports and recreation (Table 4-3). It may be of interest to note that participant AP11, alongside AP08, AP17 and AP19, all went on to have elective amputation within 18 months of being provided with the PD AFO. AP08 cited a lack of functional capability as his main driver in seeking elective amputation and this is reflected in his poor activities of daily living (ADL) and quality of life (QoL) scores. AP17 and AP19 cited both pain and reduced function as the main reasons for amputation, and whilst the PD AFO improved scores in this area the scores remained low, as seen in (Table 4-3). AP11 also cited pain and function as the main reasons for amputation, although AP11's FAOS scores suggest his pain and functional levels were not as significantly impacted by his injuries, compared to the other participants. For example, in the cohort, AP11 scored the least level of pain pre-PD AFO fitting. It seems clear from the results, PD AFO use did not improve pain and function for AP11, as both areas scored worse after use of the orthosis. It must also be noted that the PROM results are only 2 snap shots of participants' opinions on 2 separate days. Use of the PD AFO anecdotally increased participants' ability to be more active, and therefore the post PD AFO results were taken during a period of greater physical activity, which could have itself created some compensatory increased musculoskeletal pain. Consequently, these results cannot accurately predict which participants would have gone on to elective amputation, as this decision is made over an 18-month period. The PROMS merely provide an indication of participants' opinions on a given day before and after PD AFO treatment.

When looking at the PROMs results alongside the participant demographics, AP11, AP17 and AP19 all weighed greater than 110kg and were the three heaviest participants in the cohort. Heavier individuals exert greater forces through the lower limb when mobilising[283]. Therefore, maintaining a lighter body weight would be advantageous to PD AFO users in reducing the load going through the damaged structures of the foot, both when the PD AFO is in situ and when walking shod. It has been shown that even with the firmness of the

carbon fibre footplate, plantar pressures do reduce on the injured limb when PD AFOs are worn, particularly in the forefoot[284].

However, it stands to reason that this increased stature may have contributed to these participants' on-going foot and ankle discomfort due to the increased loading of the foot, although this alone does not account for why wearing the PD AFO exacerbated AP11's pain. All 4 of these participants had a Gustilo-Anderson classification fracture IIIC, with a restricted range of motion (ROM) in their ankle joint. AP11 had the greatest restriction to ROM and was the only participant to also have sustained spinal fractures. As the PD AFO restricts foot and ankle movement, the restriction in a participant's ROM does not directly affect an individual's functional capability in the PD AFO, nor does it present a reason as to why AP11 found using the PD AFO more painful in gait.

AP11's spinal fractures were fully healed before he began using a PD AFO, and the participant did not report any back pain or discomfort with the PD AFO rubbing. While AP08, AP17 and AP19 all had post injury subtalar joint fusion, prior studies on similarly aged military users, who have sustained trauma have suggest, that PD AFO users who have undergone subtalar fusion often report favourable outcomes post PD AFO use[167].

Further to this, Ikeda et al. also report improvement in PROMs gathered from personnel with prior fusions[285]. Therefore, the presence of fusion alone does not allude to why these participants did not continue with PD AFO beyond 18 months. AP11 and AP17 were delayed in undergoing rehabilitation for both clinical complications and personal reasons. The benefits of rehabilitation alongside PD AFO provision are well documented[22; 23; 157; 171].

As discussed previously, the reasons as to why elective amputation is sought by an individual is complex. The underlying reason for participant AP11 choosing amputation over continued PD AFO use is not fully understood (as it is personal to AP11). However, it would seem apparent that the functional capability of the orthosis and its ability to reduce pain was suboptimum for this participant. This also applies to the other participants who sought elective amputation within 18 months of use. The US military report an amputation rate

of 20% in all of its IDEO™ users within 12 months of provision[24]. Anecdotally the UK military amputation rate for all PD AFO users is not dissimilar at approximately 15%. In this study the amputation rate was higher at 33%. Deck slap injuries are some of the most complex blast injuries to the foot and ankle to treat[2] and this amputation rate is reflective of the complexity of this study cohort's injury profile.

Following prescription and provision of a PD AFO, all mean subsection scores of the FAOS (symptoms, pain, activities of daily living, quality of life, and sports and recreation) improved by 35%, 29%, 23%, 59%, and 112% respectively. No prior PD AFO study has used the FAOS as a PROM, but other patient reported outcome measures, for example, the short musculoskeletal function assessment (SMFA), veterans rand 12 and the visual analogue scale, have been reported on users of the IDEO™ and all are in agreement that PD AFO use improved outcomes[22]. The FAOS was found to be the second most commonly used foot and ankle PROM in orthopaedic practice in a 2017 systematic review[286]. The FAOS has been used in a limited number of studies utilising orthoses but, as the orthoses in question were prefabricated[287; 288], they are not comparable with this study. The FAOS has not been used in prior PD AFO published research. The FAOS was selected for use in this study as it had a detailed sports and recreation sub section. As discussed previously, many personnel rate the ability to engage in sport as crucial to their recovery post injury and therefore the FAOS allowed for this information to be captured and compared. The other PROMs used in prior PD AFO studies do not capture this so readily.

A minimal clinically important difference (MCID) is defined as the smallest difference in score from the domain of interest based on patients' perception as being beneficial[286]. Practically, this means the smallest change in a treatment outcome that an individual patient would identify as important, and which would indicate a change in the patient's management. It provides a threshold value that has become the most important psychometric parameter for interpreting change over time[286]. As the MCID is affected by the patient population and only one study has been conducted on the FAOS on a patient cohort with mixed

ankle and hind-foot complications[286], the MCID suggested (pain 25.3, symptoms 11.2, ADL 20.0, Sports 36.8, QOL 32.7) has not been used for comparison in this study.

The most important subsections of the FAOS for this studies cohort relate to pain and the ability to engage in high activity. These areas have been presented in IDEO™ literature. It is well documented that deck slap injuries are associated with increased pain[20; 33], and this study reports an average improvement of 28% in FAOS pain scores post provision of the PD AFO. This agrees with Ladlow et al.[23] who report a twofold increase in the number of personnel reporting 'no pain' (13%–31%) after utilising a PD AFO at follow-up (mean 34±11 months). Ladlow el al. also report that, by the second admission of residential rehabilitation at DMRC Headley Court (on average 9 weeks post provision), all PD AFO users were able to 'control their pain', and there was an incremental increase in the number of personnel reporting 'no pain' symptoms at all (6%–38%)[23]. This result is comparable to a previous study of below knee amputees[15] and is twofold greater than previously reported pain levels in the limb salvage population prior to PD AFO availability[15]. There are no long-term studies on the clinical outcomes of PD AFO users. This study by Ladlow et al.[23] is the longest period in which clinical outcomes were gathered by PD AFO users.

While many US journals have discussed the IDEO™ and its positive impact on pain management in limb salvage patients, there have only been 2 US studies that have used a PROM to measure this[22; 285]. Ikeda et al.[285] reported on the PROMs of 99 IDEO™ users, 54 of which were personnel with previous fractures, and therefore more comparable with this studies population. They used a numerical pain scale (0-10) and found, post IDEO™ provision, the personnel's pain decreased by 71% in the fracture population, which is greater than the minimal clinically important difference of 1 point or 15% for chronic musculoskeletal pain[289]. The evidence, therefore, strongly suggests that the use of PD AFOs can reduce pain in the foot and ankle complex of those who have undergone complex limb salvage.

In a young military population, the ability to engage in sports and recreational activity is important, as physical fitness is an important part of military life.

Through injury, if this ability is taken away, it can be detrimental to a person's sense of self and often elective amputation is sought consequently [236]. In this study the FAOS sports subsection scores improved by a factor of 1.1 when the PD AFO was worn. This was a significant change and represented a very large effect size. This subsection of the FAOS asks about a participant's ability to squat, jump, kneel, run and twist/pivot on the injured limb. These results agree with the published literature that reports a 24-166% improvement in physical performance when comparing personnel pre shod and post IDEO™ provision. Post PD AFO provision personnel were able to engage in exercise, recreation and physical activity which otherwise wasn't possible[22; 159; 171; 236]. Studies on personnel who underwent limb salvage prior to the clinical availability of PD AFOs confirm this level of activity was not reported before PD AFOs were utilised[15].

It seems plausible that using a dynamic yet supportive composite AFO, which could provide pain relief and ankle stability, coupled with timely and appropriate rehabilitation, could contribute to the apparent success of PD AFOs in enabling personnel with limb salvage injures to be more functional. It has been shown that entering rehabilitation too late, or not at all, reduces the magnitude of effect to both physical performance and perceptive measures[22]. Therefore, this suggests rehabilitation alongside provision is highly important in being able to achieve high levels of function when using PD AFOs.

The LEFS has previously been used in a broad range of lower limb research, including participants with ankle fractures[290] and osteoarthritis[291]. When participants in this study wore their PD AFO, the mean LEFS score improved by 42%. This was statistically significant and represented a very large effect size.

Ikeda et al.[285] reported on IDEO™ users LEFS scores. The group examined a diverse cohort of participants, 11 of whom were personnel who had previously sustained fractures to the foot and ankle and were therefore most comparable to this study. Of the personnel who sustained fractures, an improvement of 129% in the LEFS score was reported post supply of the IDEO™, which was statistically significant. This implies that the cohort in Ikeda et al.'s study were functionally more able than this study cohort, shod prior to PD AFO supply. Both

studies agree that PD AFO use significantly improves LEFS scores, and therefore functionality.

In summary, direct comparisons between the PROM findings of this study and those from the IDEO™ studies must be made with caution due to different rehabilitation approaches between the UK and US military rehabilitation teams, clinical presentations unique to each patient and the measurement tools utilised; however, collectively both militaries report significant improvements in injured personnel's pain[22; 285], general functionality /quality of life[285] and the ability to engage in sport post PD AFO utilisation short term[22; 23; 236; 285]. This study further supports these findings.

Hypothesis 1: Supports the hypothesis that PD AFO use will improve the patient reported outcomes of participants.

5.3 Hypothesis 2: PD AFO use will improve participant propulsion through terminal stance of gait in both the injured and uninjured limb.

The strategy used to generate power for forward propulsion in walking and running has been highlighted as a marker of successful gait[292]. Propulsion in this hypothesis is defined as the ability to aid the body's forward momentum/progression and not just the ability of the muscles that act on the ankle to generate active power. Literature suggests that PD AFOs improve the ability of users to generate propulsion in terminal stance [159; 236]. Increased walking speed[293], cadence and step length[294] are all considered signs of a more propulsive gait pattern. The mean increased walking speed, cadence and step length presented in this study post PD AFO use (Table 4-4) is consistent with IDEO™ users in the literature[159; 161].

Ground reaction forces are important biomechanical measures to analyse, as they reflect the motion of the body's centre of mass (COM). Studies suggest the anterior-posterior ground reaction force component (A-P GR) may represent an appropriate method for measuring the coordinated task of forward propulsion of the limb during walking[295; 296]. In this study, the A-P GR mean peak at pre swing is significantly increased on both the injured and uninjured limb when wearing

the PD AFO (Table 4-5), with the mean peak values and shape of the graphs presented being similar to those of IDEO™ users and able bodied controls[4; 78; 172]. As an increase in walking speed and step length[295] can be associated with an increase in the peak AP GR values at pre swing, it is difficult to accurately ascertain how much of the propulsive acceleration seen in (Figure 4-3) is due to the use of a PD AFO and not just the effect of speed.

Schwartz et al.[297] studied the effect of speed on gait and concluded that both the peak braking force and the peak propulsive force increase at higher walking speeds[297]. This finding is in agreement with Sun et al.[298], who suggested there is a consistent correlation between GR propulsive forces and walking speed. Sun et al.[298] tested participants walking at 3 speeds, with only 1 being faster than self-selected walking speed. Schwartz et al.[297] tested 5 walking speeds, 2 of which were faster than self-selected walking speed. Furthermore Sun et al.[298] tested adult males, whereas Schwartz et al.[297] tested children aged 4-17. As Schwartz tested more variations in walking speeds and a greater number of participants (although children), it seems more likely that any trends would be easier to determine from this work. For this reason, this study has used the work of Schwartz et al.[297] as its' basis for determining the impact of speed on gait variables. The mean walking speed of the participants in this study correspond with the "free and fast" speeds of the Schwartz[297] study. Therefore, the A-P propulsive force in this study is likely to have been impacted by the change in mean participants speed. Although the mean walking speed increased by 0.23m/s (20%) using the PD AFO, this was not deemed a statistically significant change. The mean peak braking GR and mean peak propulsive GR on the uninjured limb appear to increase symmetrically with and without the PD AFO (Figure 4-3). However, the injured limb does not demonstrate such a symmetrical increase in the mean braking A-P GR peaks with and without use of the PD AFO. This non-uniform increase in the peaks suggests the PD AFO may be having an influence on the A-P GR. The mean peak propulsive GR on the injured limb increases 25% more than the uninjured limb at the same speed. This is to be expected, as the injured limb has a lower baseline value when shod compared to the uninjured limb, leading to a higher percentage increase for the same change in GR.

It must also be noted the generation of propulsion is multifaceted and that all factors that could influence this cannot be explored in this thesis. One such factor is the possible contribution of the Achilles tendon within the PD AFO. Studies have shown that the tendon is loaded when walking in an AFO (stock product)[299]. However, it is unclear if the tendon is actively contributing to propulsion whilst in a rigid composite PD AFO around the ankle, where the movement/deflection is happening in posteriorly mounted composite struts attached to the PD AFO. The increase in the self-selected mean walking speed, for example, is reflective of the drawbacks of applying statistics to small participant samples. The results show a 20% increase in self-selected walking speed when the PD AFO is worn, yet this is not deemed a significant change but represents a large effect size. For this reason, caution must be applied when analysing the significance of the gait analysis data using p value in isolation. This is always true when testing a small sample size.

The mean peak ankle dorsiflexor moment increased significantly (Figure 4-5) in both the uninjured limb 0.19 Nm/kg (14%) and the injured limb 0.51 Nm/kg (50%) when using the PD AFO. The mean ankle power generation on the injured limb significantly decreased by 0.13 Watts/Kg (38%) whilst wearing the PD AFO (Figure 4-4), suggesting the power was absorbed by the orthosis. Previous work in this area has failed to reach a definitive conclusion. Some studies suggest that increasing walking speed by increasing stride length does not result in a linear increase in the peak ankle dorsiflexing moment at pre swing[300; 301]. This is contradictory to prior work examining the change in kinetics with walking speed, which suggests walking speed does influence ankle kinetics linearly[298]. Furthermore, stride length has been shown to be the most important factor when looking at changes in moments in the sagittal plane, rather than walking speed alone[302]. Ardestani et al.[302] have shown that increasing cadence to increase overall walking speed has little effect on resultant joint moments, but increasing stride length in order to increase speed has a significant effect[302].

The 50% increase in mean ankle dorsiflexor moment on the injured limb when using the PD AFO is expected, as the injured limb has a lower baseline value when shod compared to the uninjured limb, leading to a higher percentage

increase for the same change in GR. It could be proposed that participants achieve this due to the influence of the PD AFO assisting the limb in its' capability to behave more propulsively, and not just as a result of the change in the participants mean walking speed, which is not statistically significant.

There is much contention in the literature regarding how best to manage the speed-mediated effects with respect to joint moments[303]. Classically, studies have used instrumented treadmills, or asked participants to walk at a pre-determined speed as well as a self-selected walking speed to control for this variable. However, this can often lead to altered gait patterns, which do not reflect participants normal gait[304]. Although the increase in walking speed within this study was not significant, it may still be influencing the results. It was the researcher's preference to allow participants to self-select their own walking speed to ensure the gait patterns presented were representative of how the participants walked on a flat surface in everyday life, and the limitations of this are discussed further in chapter 6.

By design, the PD AFO limits the ankle's range of motion in the sagittal plane. Previous literature on thermoplastic AFOs suggest that significant plantarflexor strength is required to deform AFOs and generate propulsion[305]. A theory is that restriction to ankle ROM provided by AFOs diminishes plantarflexor output and the generation of forward propulsion[301] by restricting ankle plantarflexion. This study contradicts this as, although the mean power generated around the injured limbs ankle is diminished by use of a solid ankle AFO design (like prior studies[301; 305]), the study participants in PD AFOs were still able to generate increased propulsion in gait, shown in the A-P GR graph (Figure 4-3).

In addition to the ankle, the hip has a significant role in generating propulsion. The participants' mean peak hip extension moment increased marginally by 0.14 Nm/kg (17%), and the mean hip power generated during pre-swing increased by 0.3 Nm/kg (12%) on the injured limb whilst wearing the PD AFO. This was not statistically significant and represents a lesser increase in the mean hip extension moment compared to the uninjured limb when the PD AFO was worn, which increased by 0.32 Nm/kg (42%). Both the injured and the uninjured limb had the same mean hip extension moment of 0.83 Nm/kg without

use of the PD AFO and so, unlike other results, they can be directly compared having started at the same value. Studies show that an increase in walking speed does influence and increase moments around the hip in the sagittal plane[298; 300; 302]. Furthermore, it is consistent with simulation analysis showing that the bilateral hamstrings contribute to forward propulsion in early and mid-stance in healthy walkers[306; 307] and that the sound limb's rectus femoris and biarticular hamstrings contribute to forward propulsion post-stroke to recoup for the lack of plantarflexor output[308]. Previous studies have shown that amputees use similar hip strategies to compensate for reduced ankle propulsion[309]. The study participants' mean hip power generation in late stance, mean hip extension moment and mean peak extension only increased by 12%, 17% and 2% respectively, which suggests that the PD AFO was potentially able to provide greater assistance with ankle propulsion than previous reported studies[308; 309] that do not utilise composite orthoses or posterior strut design. The hip was not required to overcompensate for a lack of propulsion on the injured side when the PD AFO was utilised by the participants. In summary, unlike thermoplastic AFOs[301], composite PD AFOs appear to provide improved dorsiflexor moments during late stance that supplement plantarflexor strength[200] and aid propulsion[4; 78; 172].

Often, studies neglect to discuss or focus on the impact that using an orthosis unilaterally has on the sound contralateral limb and its' ability to generate both propulsive and breaking forces. Morgenroth et al.[310] found in trans tibial amputees that increased push off on the prosthetic side reduced contralateral knee adduction moments and the loading impulse. It is suggested that gait abnormalities, in particular gait asymmetry, can cause excess mechanical loading on the intact knee and hip, which may increase the risk of developing osteoarthritis [262; 311; 312]. It can be concluded that when the PD AFO was worn, gait abnormalities on the sound limb reduced and the limb performed closer to able-bodied controls. This is reflected in the GPS (Table 4-20) that shows the uninjured limbs' overall GPS improved by 3% when the PD AFO was worn. This implies that it is possible that the risk of developing osteoarthritis may reduce slightly with PD AFO use in the unilaterally injured and, overall, lower limb joint health may improve as a result of PD AFO use. However, to conclude, this

would warrant further investigation around the degree of gait asymmetry, which is outside the scope of this thesis.

In summary, the evidence in prior studies and the results of this study agree and suggest that PD AFOs do increase a user's ability to generate propulsion in late stance.

Hypothesis 2: Hypothesis supports that PD AFO use will improve participants' propulsion through terminal stance of gait in both the injured and uninjured limb.

5.4 Hypothesis 3: PD AFO use will improve participant stability through stance phase of gait.

The original 6 determinants of gait were defined by Saunders et al.[72] in 1953 and have since been deemed by some to be too simplistic or even incorrect, and have led to much debate on their relevance clinically within the gait analysis community[313]. Why we walk the way we do is complex and, in 2009, Richard Baker suggested that the following determinants may be more appropriate and clinically meaningful in determining successful gait[313]:

- One's ability to support bodyweight against gravity
- One's ability to achieve toe clearance and adequate step length
- One's ability to achieve a smooth transition from one stride to the next while preserving the momentum of the passenger unit
- One's ability to conserve energy

Measuring these determinants is complex and requires not only gait analysis data but a full clinical assessment as well as comprehensive electromyography (EMG) results. This study examined some of the gait variables that contribute to gait stability, but it is acknowledged that the amount of data required to discuss this in full is vast, and beyond the scope of this thesis.

In walking, these determinants can conflict with one another as, in order to generate forward momentum, it is necessary to displace the COM to a position in front of the centre of pressure (COP). Moving the COM to a position that is

not directly above the base of support places the body in a potentially unstable position[314].

As described in section 2.5, blast trauma can significantly disrupt and damage the anatomy of the foot and ankle, and this in turn can have a detrimental effect on an individual's stability in gait. Trauma can cause sensation loss, which can result in reduced proprioceptive feedback and lead to gait instability[315]. This is in addition to muscle and tendon damage, which can make muscle innervation reduced or mistimed, leading once again to compromised lower limb stability.

A lack of lower limb stability may increase the risk of trips and falls, causing secondary injury and possibly lead to the development of a "fear of falling". This fear can subsequently cause an individual to limit their activity, which can reduce mobility, further muscle weakness and increased risk of future falls[316].

Literature around stability predominately discusses geriatrics who are more likely to walk slowly, have a shorter stride length, a wider base of support and spend a greater proportion of the gait cycle in double-leg support[317]. Paradoxically these same gait alterations are believed to increase stability during walking[318; 319]. Research on measuring general gait stability is confined to studies of the able bodied, elderly, toddlers and those with vestibular deficiency. Therefore, caution must be applied when comparing to young personnel who have sustained unilateral foot and ankle trauma. Studies have also shown there to be a link between the influence of fear and motor behaviour[320]. Maki et al.[317] suggests that gait parameter changes are stabilising fear-related adaptations, rather than direct risk factors that increase the likelihood of falling. Therefore, it is suggested that an individual's emotional state can also influence stability and the factors of influence are not solely biomechanical.

Previous studies have shown that temporal spatial parameters can improve with AFO use[187; 321; 322]. In this study, the mean participant's double support time reduced by 0.06s (19%) when the PD AFO was worn, and the mean step length increased by 0.08m (12%) with a large effect size on the injured limb and 0.12m (18%) with a very large effect size on the uninjured limb. This did not, however,

represent a significant result. This agrees with Haight et al.[172] who report similar reductions in double support time and increase in step length with IDEO™ users. As the participants walked faster with a greater step length, spent less time in double support and had a unchanged mean stride width, it suggests the participants made fewer stabilizing fear-related adaptations when wearing the PD AFO[317], and use of the orthosis improved participants ability to walk. However, this doesn't provide a true reflection of stability in gait, as studies[322-325] show that variability of parameters (in particular stride length) is a better indicator of gait performance stability. To accurately determine this, each participant would need to be examined individually and not as a cohort, as the variability between subject is likely to mask the effects of the PD AFO. Investigating each individual participant is outside the scope of this thesis and is recommended for future work.

The vertical GR component represents a summation of forces from all segments of the body during locomotion, and can provide a representation of COM control[326]. Since postural stability is defined as the body's ability to maintain its' COM within its base of support[327], the vertical GR may provide information about an individual's postural control during walking, and the individual's ability to support their own body weight. Indeed, studies that have investigated vertical GR during walking suggest that the second peak force at push-off decreases in magnitude[328] and in variability[329] in people assumed to be less stable during locomotion. Instability during walking may, therefore, manifest as increased displacement of the body's COM within a constantly changing base of support and a reduced second vertical peak in the vertical GR. In this study use of the PD AFO improved the shape of the vertical GR graphs for both the uninjured and injured limb, with more defined twin peaks (Figure 4-9). The injured limb with PD AFO use improved the mean timing of the twin peaks, in that they have greater symmetry with the twin peak timings of the uninjured limb. Stansfield et al.[330] concluded that in normal gait the second vertical peak of the vertical GF should be a minimum of 110% of body weight. It has been suggested that failing to meet this assumes an individual is having difficulty in supporting their body weight in late stance, which in turn suggests a level of gait instability[328]. In this study, with PD AFO use, the mean uninjured limb in late

stance supports 113% of body weight, which is an 8% improvement compared to gait without use of the PD AFO on the uninjured limb. The injured limb, however, in push off supports 91% of body weight without use of the PD AFO, and this improves to 106% of body weight when the PD AFO is worn. This implies that use of a PD AFO improves the mean injured and uninjured limbs' ability to support body weight at late stance. It helps to prepare the body for weight transfer to the leading limb and improves stability accordingly.

The effect of walking speed on the vertical GR must also be considered. Schwartz et al.[297] investigated the impact of five speeds on the vertical GR of 83 participants and found that at slow and normal walking speeds, the vertical GR displays a characteristic "double-hump" shape, with 2 peaks of approximately the same magnitude. As walking speed becomes faster, while both peaks increase, its' influence on the 'weight acceptance' peak is more pronounced than it is on the 'push off' peak[297]. The participants mean walking speed in this study corresponds with the "free and fast" speeds reported in the study by Schwartz et al.[297]. Therefore, the significant changes seen in the second peak of the mean vertical GR (FZ3) (Table 4-9) on both the injured and uninjured limb are greater than would be expected if they were purely due to a change in speed. This strongly implies that the result is not due to the 20% increase in walking speed but is a result of the PD AFO allowing participants to support their body weight more effectively and, in turn, improve their gait stability.

The foot progression angle (FPA) is affected by femoral anteversion, tibiofemoral torsion, the position of all lower limb joints, including the pelvis and the shape of the foot. It is an indicator of the rotational malalignment of the lower extremity[331; 332]. The FPA or "toe-out angle" is defined by the orientation of the longitudinal axis of the foot in the transverse plane with respect to the direction of progression during gait[333]. Established normative values for FPA magnitude range from 5-9º in older and younger healthy adults[334], and an accepted criterion for excessive external FPA ('toe-out angle') is a FPA greater than 10±5º. Previous studies show that an excessive internal or external foot progression angle not only results in various muscular and skeletal problems[335;

[336], but can also affect stability and the risk of falls[314], as described by Bozbas et al.[314].

Study participants presented bilaterally with a FPA suggestive of an excessive external toe out angle, with the injured foot exhibiting a greater toe out angle (25.6°±9.8) compared to the uninjured limb (22.4°±10.4) when shod. This is likely a compensation to increase participants' base of support to, in turn, improve stability. Use of the PD AFO appeared to reduce mean out-toeing in the uninjured limb by 2.4° (11%) and the injured limb by 3.3° (13%), which brought the angulation value closer to normative values[334]**,** although neither reduction was considered statistically significant. Between test conditions, the following markers on the injured limb are repositioned as part of removing the PD AFO for the shod test condition:

1. The medial and lateral malleolus and the shank tibial cluster are all repositioned.
2. The markers on the participants' trainers remained in situ. On account of this there is a higher probability of resulting errors due to reduced reproducibility.

Locating bony landmarks on the medial and lateral malleoli through a composite PD AFO is difficult to accurately repeat and, although the same researcher moved the markers during each participant's session, the FPA results could be misleading and inaccurate.

The FPA has not been reported in previous PD AFO studies. However, a study that examined those who had sustained distal tibial fractures concluded that post trauma, individuals are more likely to walk with an increased FPA on the injured side[337], and while the evidence is limited and paediatric in focus, it does concur with this study that fractures to the foot and ankle can potentially predispose individuals to an increased external toe out angle.

Very few studies have reported on changes to the FPA with AFO use. Danino et al.[338] noted that unilateral AFO use did not appear to change the FPA, but bilateral AFO use did reduce participants toe out angle. In contrast, Kim et al.[339] noted AFO use increased the external toe out angle. While both studies

disagree with this study, and are worthy to note, the studies are examining AFO use in those with cerebral palsy[338] and stroke[339]. As the FPA can be influenced by spasticity around the hip, for example, caution is applied when comparing studies where participants present with pathologies that affect the central nervous system. Furthermore, none of these studies discuss the sagittal plane alignment of the AFOs. If the AFOs utilised are not suitably aligned to provide forward inclination of the shank, as discussed in 2.16.3, then the participant may have to externally rotate their foot during mid-stance to terminal stance to enable transition to pre-swing if the participants Achilles tendon is tight and they lack adequate ankle range of motion into dorsiflexion[144]. This adaptation is commonly described as a midfoot break, and participants have to gain dorsiflexion through their midfoot to transition to pre-swing with an externally rotated foot[340]. Often, crucial sagittal plane alignment details and specific design properties of AFOs are not present in the literature[341] and this makes it very difficult to verify the kinematic results in the literature, as they are interdependent on one another. On account of this, little is known about how PD AFO use truly affects the FPA. This study suggests that PD AFO use in unilateral deckslap injuries reduces the FPA and this, in turn, suggests improved stability**[314]** for this cohort. Although as the marker placement at the ankle between test conditions could introduce reproducibility errors as discussed, this conclusion must be taken with caution.

Hip extension commonly peaks at 10° around 50% of the gait cycle at terminal stance while the knee is approximately 5° flexed and the shank and thigh are inclined[144]. This position of the limb with the quasi stiffness of the ankle permits maximum hip extension with the GR alignment anterior to the knee and posterior to the hip, which helps to create stabilising knee and hip extension moments[144]. Such stability of the stance leg in terminal stance facilitates what Owen et al.[144] describes as the “Big V” of terminal stance. Achieving the “Big V” position produces stretching and strengthening in particular of the hamstrings, hip flexors and gastrocnemius[144]. Therefore, hip extension capability is crucial to the creation of the “Big V” and therefore stability in stance.

PD AFO users in this study demonstrated a reduced mean peak hip extension angle on the injured limb during stance compared to controls, and this finding is supported by other studies of IDEO™ users[4; 78; 168; 172]. This result is unexpected, as walking speed and stride length increased with PD AFO use and, therefore, it would have been expected ordinarily that hip extension would increase linearly, as described by Schwartz et al.[297]. As no prior PD AFO study exists that examines the gait of users prior to PD AFO utilisation, there are no prior studies for comparison to examine the impact of PD AFOs on hip extension. This study suggests unilateral PD AFO use does not greatly influence the mean peak hip extension angle of participants in terminal stance, as both the changes to the injured and uninjured limb were no greater than 1.5° even with an increase in walking speed when the PD AFO was worn. While using the PD AFO, the mean knee angle on the injured limb remains flexed at around 40% of the gait cycle when then knee should be extending. The results (Figure 4-13) show that the mean knee angle remains flexed throughout the gait cycle on the injured limb when wearing the PD AFO. This compromises the creation of the “Big V” and in turn makes it difficult for the injured limb to reach a greater angle of hip extension. Haight et al.[172] is the only study that reports on knee extension in IDEO™ users and found that the posterior strut stiffness had a significant effect on knee kinematics. The more compliant the posterior strut the greater the knee flexion in gait, with a reduction in the peak knee extension angle in stance[172]. The IDEO™ users exhibited greater knee extension in terminal stance than this study presents and were closer to able bodied controls[172; 247]. It is possible that the PD AFO posterior struts used in this study were more compliant than those presented by Haight el al[172]., but without having each participant’s weight, height, lower limb muscle power status and original IDEO™ prescription, this cannot be ascertained or compared.

Moreover, it is possible that there were participants in this study who were wearing a PD AFO/footwear combination with too great a shank-to-vertical angle (greater than 12°) on the day of testing, as the footwear worn to the gait analysis testing could have been different to the footwear used during the initial PD AFO fitting with the orthotist. This sagittal plane alignment would prevent the knee from reaching full extension at pre swing.

This rationale is also suggested in the kinematic sagittal plane ankle results, which shows mean toe off on the injured limb occurs earlier when the PD AFO is worn. Toe off typically occurs around 62% of the gait cycle[342] and, when using the PD AFO, the cohort's injured limb appeared to reach toe off sooner at 57.7%. This can be a sign of "drop off", as is the increased knee flexion described when the PD AFO is worn. Toe off also occurs early in the gait cycle at faster walking speeds[297], so this may be influencing the result. On examination, AP08 and AP02 exhibited excessive knee flexion in terminal stance when wearing the PD AFO, with both participants' knees remaining between 15-20° flexed. Consequently, AP08 had the earliest toe off at 50% of the gait cycle and AP02 was also early at 59%, but these participants did not present with the fastest walking speed.

A participant's muscle strength and ability to activate the gluteus maximus muscle must also be considered. During initial contact, the gluteus maximus contributes to hip extension and controls the rate of hip flexion[343]. Ineffective functioning can compromise hip stability and gait. A change in the muscle firing patterns in gluteus maximus has direct implications for rehabilitation of lower limb dysfunction[344]. An antalgic gait pattern like the participants in this study may lead to muscle inhibition or atrophy and, if the activation of gluteus maximus is delayed, pelvic stability may become compromised[344]. Jonkers et al.[345] concluded that when the gluteus maximus isn't functioning, hip extension initiation is prevented and a prolonged stance phase knee flexion in gait is witnessed. A lack of gluteal activation is often reported post lower limb trauma[344], and this dysfunction in gluteal activation may be contributing to the lack of hip extension[344], as seen in this study.

This study suggests that use of a PD AFO appears to reduce the ability to gain adequate knee extension in terminal stance to create stance phase stability on the injured side and, therefore, the limb is deemed less stable. This is not supported by the literature, and on closer examination as results presented in this study are the mean of all 9 participants the results have been affected particularly by AP02 and AP08's excessive knee flexion in gait. What cannot be

determined is whether weakness in proximal musculature such as the gluteals also played a role in this result, as EMG data were not recorded for participants.

In conclusion, the vertical GF suggests a PD AFO provides increased stability and all other parameters investigated either suggest a lack of stability when using the PD AFO or are inconclusive.

Hypothesis 3: Hypothesis rejected: support the alternative hypothesis that PD AFO use will improve participants' base of support.

5.5 Hypothesis 4: PD AFO use will reduce the gait profile score of both the injured and uninjured limb

The Gait Profile Score (GPS) is a single index measure in degrees that summarises the overall deviation of kinematic gait data relative to normative data[266]. It simplifies complex kinematic gait data by providing clinicians with a very general measure to compare kinematic gait features Comprehensive indices, such as the GPS that express a shift towards normality, as the effect of wearing an orthosis are regarded as effective by the International Classification of Functioning, Disability and Health framework in providing evidence of the efficiency of orthotic intervention[346].

The GPS can be subdivided to provide gait variable scores (GVS) of nine key component kinematic gait variables, which are presented as a Movement Analysis Profile (MAP)[266]. It was selected for use in this study, as it is unrelated to an individual's specific pathological state. It also has the advantage of subdividing into GVS and MAP, which are not present in other summary measures such as the Gillette Gait Index (GGI)[347] and the Gait Deviation Index (GDI)[348]. The GGI has further limitations in that the 16 parameters used to calculate it are a mix of gait variables and temporal-spatial parameters, with no clear rationale as to why they are specifically used[77]. The results produced also appear to be sensitive to the choice of control data utilised[349]. The GDI was developed to address the limitations in the GGI and has successfully been applied to patients with a range of different conditions and pathologies[77]. There is a very strong linear correlation between the GDI and the GPS (r=0.995)[77],

and the GPS was selected for this study as the MAP visualisation makes the interpretation of the results easier.

The GPS provides clinicians with a score for each limb, as well as an overall score combining the hip, knee and ankle variables from both limbs, and the pelvic variables from one. A typical GPS for the control population is 5.3°±1.4. In this study, when participants wore the PD AFO, the overall GPS reduced on both the uninjured and injured limb by 0.19° and 0.9°, respectively. The MCID reported for the GPS is 1.6°[350], so whilst the change in the GPS overall represents a reduction, and therefore suggests gait kinematics improved with PD AFO use, this did not demonstrate a "clinically important difference" as the reduction angle was less than 1.6°[350]. Discretion must be applied when using this MCID value within the context of this study, as the 1.6° was evaluated for children with cerebral palsy and therefore a completely different clinical presentation to this study population.

Anecdotally in clinic, the gait patterns of children with cerebral palsy are vastly more varied than those with unilateral deck slap injures to the foot and ankle. Therefore, it is suggested that the MCID for participants in this study would be less than 1.6°. When comparing the injured limb using the PD AFO to controls, there was a significant difference in the GPS overall with a very large effect size. The GPS of the injured limb was less affected by the PD AFO than the GPS overall. This likely reflects the compensation mechanisms on the contralateral side during walking with the PD AFO, and has also been reported in previous studies presenting unilateral foot and ankle pathology, such as clubfoot[351]. P values and Cohen's d were only calculated for the injured limb wearing the PD AFO vs controls, which is consistent with the rest of the data within this thesis. The uninjured limb vs control was not explored.

Before the GPS can be evaluated, the effect of varying walking speeds on the results must be considered. Walking at different speeds has been shown to affect gait patterns of healthy individuals[297], as well as those with conditions such as Parkinson's disease[352] that cause individuals to walk more slowly than healthy controls. As the GPS could be influenced by either the participants physical condition or their walking speed (or both), possibly this may hinder the

ability of the GPS to quantify the exact effect of a disorder or intervention on the gait pattern. In this study, the walking speed of the participants when shod is different to the control group who walk faster by 0.12 m/s (10%). The participants walked faster with the PD AFO compared to the control group by 0.11m/s (8%). Fukuchi et al[343] studied the effect of speed on the GPS and concluded that gait speed significantly affects the GPS. They compared the gait data of participants who had previously had a stroke, and walked very slowly, to the standard GPS with normative data from a standard (and quicker) speed. The authors then compared the same participant data to predicted normative data with matched speeds, called the GPSv. Up to 1º of difference was found between the GPS results and GPSv results, showing that a mismatch between patient walking speeds and the normative data for the GPS can influence the results by up to 1º attributable to speed alone. Considering the minimal clinically significant difference for the GPS is 1.6°[340], if the patient group are also walking at a different speed to the control group then the MCID may be as high as 2.6°.

If this is the case, then it is possible that the GPS is not sensitive enough to detect variations in the unilateral foot and ankle blast trauma population presented in this thesis. As discussed previously, the GPS can be broken down to provide the GVS, based on nine kinematic variables and this in turn forms a MAP, which visualises the magnitude of the deviation of those nine variables across the gait cycle. The MAPs for each test condition in this study are presented in (Figure 4.19 and 4.20) and are more useful for identifying individual impairments that make up the GVS and are, therefore, a useful rehabilitative tool.

Use of a PD AFO improved the participants' sagittal plane ankle dorsiflexion/plantarflexion GVS on the uninjured limb by 0.5° (12.5%). This did not demonstrate a significant difference and the effect size was small. Schwartz et al.[297] has shown an increase in gait speed does produce an exponential increased in the peak plantarflexion angle at pre swing. Therefore, the changes in the GVS may be linked to the increase in walking speed. When the PD AFO was worn, the uninjured limbs' timing of push off improved and was closer to

control. Possibly when walking shod, the participants were delaying push off, spending longer on the uninjured limb for both stability and to reduce discomfort.

The injured limb demonstrated a reduced GVS score when the PD AFO was worn, declining by 1° (19%). This did not represent a statistically significant change with a small effect size. It should be noted that the GPS examines 101 data points for every stride, therefore the negative kinematic effect of the PD AFO on the ankle (limiting ROM) will be present at all 101 data points, which leads inevitably to the GPS at the ankle presenting very negatively. A very large effect size and a statistically significant change was found between the sagittal plane ankle dorsiflexion/plantarflexion GVS on the injured limb using the PD AFO compared to control 4.1° (65%) (Table 4-21). As described above with the uninjured limb, speed will be affecting the dorsiflexion/plantarflexion GVS. The results suggest that use of a PD AFO (whilst not significant) does negatively affect the sagittal kinematics of the ankle on the limb wearing the PD AFO. This is in line with expectations, as the PD AFO significantly restricts ankle motion as part of its design, as discussed in 2.13.3 and, therefore, would be expected to negatively affect this GPS.

There has been little use of the GPS/MAP in the literature on participants without a neurological condition, and no studies have been presented on AFO users without a neurological condition. This has made comparison to the limb salvage cohort in this study challenging. The only study available on GVS in participants with orthopaedic lower limb impairments is a study by Manousaki et al.[351], who reported on children with unilateral idiopathic congenital talipes equinovarus (CTEV). This study reported the CTEV foot to have a sagittal plane ankle dorsiflexion/plantarflexion GVS of 6.5±3.2[351]. With only 1 study for comparison on children with potentially very different skeletal anatomy, the only conclusion that can be made is that the CTEV foot behaves like a “normal” foot, as the GPS score is within normal limits (5.3°±1.4)[77]. Possibly the GPS is not sensitive enough to pick up gait impairments in the unilateral CTEV patient. Removing the sagittal plane ankle dorsiflexion/plantarflexion GVS from the MAP improves the overall GPS by 0.18° (4%). Therefore, the effect of this variable on

the participants overall gait whilst shod is low. However, when using the PD AFO, participants had a 0.29° (7%) improvement in the overall GPS when the sagittal plane ankle dorsiflexion/plantarflexion GVS was removed, but this still did not result in a MCID as the change remained less than 1.6°. As a PD AFO restricts both plantarflexion and dorsiflexion at the ankle, it was expected that the GVS on the injured limb would represent the largest score change comparing both test conditions, as shown in studies on participants with unilateral clubfoot[351]. However, the largest change on the injured limb was in the coronal plane adduction/abduction of the hip with a score differential of 1.29, and this was unexpected.

The coronal plane hip adduction/abduction GVS on the injured limb improved by 1.29° (28%) when the PD AFO was worn. Schwartz et al.[297] reports that walking speed changes have a direct effect on the coronal plane hip peak adduction/abduction angles in gait. Therefore, while a GVS improvement is seen, these results must be viewed with caution due to the effect of speed. The result suggests there was less vertical displacement of the femur relative to the pelvis on the injured limb when wearing the PD AFO, and this is much closer to control. When shod, the injured limb is more abducted, and this could be due to the pelvis being higher on the uninjured side. Participants demonstrated increased knee flexion on the injured limb when shod (Figure 4-13), which would create a limb that is effectively shorter, and this could account for this result. This shod walking pattern is likely compensating for pain or is to help with ground clearance. PD AFO users are required to use a heel elevator under the PD AFO, as described in 2.13.4. The result suggests the heel elevator set up for the cohort whilst using the PD AFO did not introduce any obvious leg length discrepancies, and this set up contributed to the improvement seen in the hip adduction/abduction GVS score on the injured side.

The uninjured limb worsened marginally by 0.03° (1%) when the PD AFO was worn, and appears to be more abducted at push off, but it is difficult to ascertain why (Figure 4-14). As discussed, speed does affect hip adduction/abduction kinematics with both peak adduction at early midstance and peak abduction at pre swing increasing linearly[297]. On the uninjured limb the peak adduction angle

only increased by 1%, and therefore the increase in speed is not reflected in this peak. PD AFO users typically wear a heel elevator under the uninjured limb to ensure no leg length discrepancy is introduced as a result. Consequently, this practice could increase the risk of leg length discrepancies being introduced by either inaccuracies in the clinician's estimations of the required heel elevators, participants leaving heel elevators in the uninjured shoe accidently when not wearing the PD AFO or participants forgetting to don the prescribed heel elevators when the PD AFO is worn. It has already been suggested that it is possible that some of the participants could have been using different footwear or heel elevator combinations provided when the PD AFO was first supplied, and this would, in turn, affect the coronal plane hip adduction/abduction GVS. However, there is no clear evidence of this in the hip adduction/abduction kinematics results.

The coronal plane pelvic up/down tilt GVS improved on both the uninjured and injured limb by 0.37° (15%) and 0.61° (21%) respectively when the PD AFO is worn. However, neither represented a significant change. Schwartz et al[297] showed that increased walking speed does affect pelvic coronal plane kinematics[297]. This result could also be influenced by the ability of the hip abductors and the gluteal musculature to stabilise the pelvis[68]. This result is directly linked to the adduction/abduction of the hip, as it is measured from the same point (the horizontal line of the pelvis), which has already been discussed.

The transverse plane pelvic internal/external GVS for both the uninjured and injured limb worsened when participants used the PD AFO by 0.15° (5%) and 0.25° (9%) respectively, although neither represent a significant change. The injured limb wearing the PD AFO compared to control represented a significant change. Possibly the increase in pelvic rotation compared to control is due to the pelvis compensating rotationally for the lack of foot and ankle compliance on the injured side whilst the PD AFO is worn. Additionally, once again, walking speed has been shown to affect transverse plane pelvic kinematics[297] and, therefore, the transverse plane pelvic internal/external GVS results must be viewed with discretion. The transverse plane hip internal/external GVS improved when the PD AFO was worn by 0.13° (2%) on the uninjured limb and

0.64° (8%) on the injured limb, but these were not statistically significant. Schwartz has shown that speed does influence the transverse plane hip kinematics, in particular the peak external rotation at pre swing[297], but only at higher speeds. At lesser speeds, whilst the peak angles increase, they do not increase exponentially[297]. The participants' change in walking speed when the PD AFO is worn may, therefore, be influencing the transverse plane hip internal/external GVS results.

The sagittal plane pelvic anterior/posterior tilt GVS score worsened on the uninjured limb by 0.41° (13%), and 1.08° (38%) on the injured limb when the PD AFO was worn. Walking speed has also been shown to increase pelvic anterior tilt, in particular at higher walking speeds[297]. As the PD AFO restricts ankle ROM in the sagittal plane, possibly the pelvis is overcompensating by increasing the anterior tilt of the pelvis. The PD AFO holds the ankle in a fixed plantarflexed alignment, with both the injured and uninjured limb utilising heel elevators to compensate for this (Figure 2-20). Use of heel elevators shifts the COM anteriorly and this, in turn, typically causes individuals to have an increased anteriorly tilted pelvis with an increased lumbar lordosis to compensate for this shift in the individual's weight line for stability[353]. It is possible the use of heel wedges contributed to this result, as well as the effect of walking speed.

The sagittal plane hip flexion/extension GVS worsened on the uninjured limb by 0.26° (5%) and 1.08° (15%) on the injured limb when the PD AFO was worn, although neither represented a significant difference. This GVS is directly linked to the position of the pelvis, as the degree of hip flexion and extension is measured off the pelvis. Schwartz et al.[297] showed that increasing walking speed increases the peak hip flexion and extension angles in gait and, therefore, the change in GVS in this study is highly likely to have been influenced by this change in speed between the test conditions.

The sagittal plane knee flexion/extension GVS score improved on the uninjured limb by 3.06° (34%) and worsened on the injured limb by 0.33° (4%) when the PD AFO was worn, but neither represented a significant change. Once again, the participants' increased walking speed whilst using the PD AFO would have

impacted on this result[297]. The improvement on the uninjured limb is more than anticipated and represents a medium effect size. It is likely as a result of the increased ankle power seen in (Figure 4-4) while the increase in power distally is driving the increased knee flexion.

The transverse plane foot progression GVS improved by 1.46° (16%) on the uninjured limb and 0.72° (9%) on the injured limb. Schwartz et al.[297] reported that increased walking speed only affects the foot progression angle around the time of toe off, and not at any other time in the gait cycle. Therefore, the increase seen in walking speed is having only a small effect on this GVS result. PD AFO use does appear to reduce the external rotation of the foot in gait (Figure 4-11), bringing the angulation closer to able-bodied control. However, as discussed previously, the markers around the ankle are repositioned on the brace during testing and this could lead to greater placement error of the markers as a result.

This study's results are partially in agreement with previous literature in patients with Ehlers–Danlos syndrome[354; 355], which reports that pelvic tilt and foot progression angle show no significant change[354] and significant differences are only seen in the ankle joint kinematics[355]. However, most literature in this area[356-358] presents participants with conditions of the central nervous system and therefore present with spasticity acting upon the joint kinematic results. It would not be clinically appropriate to compare any of these studies to this study, as isolated foot and ankle trauma is not comparable to such neuro presentations. Also, the studies that use participants with Ehlers-Danlos syndrome are not utilising AFOs and are affected by a systemic condition that presents global body disability again, this is not directly comparable clinically to the participants in this study.

The most comparable study found which utilised the GPS/MAP was a study on children with CTEV[351]. This study agrees that their largest deviant GVS variable was in the ankle plantar/dorsiflexion angle. However, they also report the foot progression angle as significantly deviated too. Our study found the foot progression angle changes in GVS were not significant and showed only a

medium effect size. This CTEV study did not perform any statistical analysis for the GVS and, therefore, again comparisons are difficult.

In summary as the GPS can provide a global estimation of gait deviation, which may be related to pathology, it has the potential to be a valuable complement to a more detailed analysis of kinematics. However, in this study as patients' walking speed was not controlled, and walking speed clearly affects the kinematic results of the lower leg[297], it has been difficult to draw definitive conclusions from these results. It is also questionable whether the GPS is sensitive enough to see meaningful change in those with only a unilateral foot and ankle condition. This coupled with a relatively small number of study participants has made it difficult to show any statistically meaningful change in the GPS for the study cohort.

Hypothesis 4: Hypotheses supports that PD AFO use reduces the gait profile score of both the injured and uninjured limb.

5.6 Scope and boundaries of the study

The scope of the investigation was to examine the gait of personnel who had similar injuries sustained by the same mechanism of trauma, walking on flat indoor terrain with and without a specifically designed PD AFO. This is novel, as prior PD AFO studies that have examined clinical outcomes have recruited participants with a wide range of clinical presentations, making it difficult to draw conclusions from the data in order to influence clinical practice. This study presents the gait of PD AFO users without use of the orthosis shod, and this aspect of the study is particularly different from previous work. This research is not intended to clarify or propose prescription criteria or treatment algorithms for PD AFOs. No other orthoses were tested, only this 1 PD AFO design; therefore, this study is not intended to present PD AFOs as the only clinical solution that could be utilised for this injured patient group.

5.7 Limitations

A limitation of this study is that the researchers and participants could not be blinded to the treatment used, as only one orthosis (PD AFO) was tested. The

results of the PROMS could, therefore, be affected by the placebo effect. Collection and interpretation of the PROMS data was completed without the knowledge of the gait analysis results, and the researcher (although offered) did not have to provide any assistance or explanation to participants when answering the PROMS questions. The biomechanical data was collected using fully automated measuring tools. Therefore, researcher bias was low.

The footwear used by participants was not standardised. The data were originally collected as part of our standard clinical service and it was appropriate at the time to capture participants in their own footwear. All participants were using similar lace up sports trainers, but the pitch and heel cushion properties, for example, may have varied slightly between participants, and this has not been accounted for. When required, participants wore split size footwear to accommodate the PD AFO and the effect of this has also not been considered.

Whilst the ankle angle of the PD AFO was documented, the exact shank to vertical angle (SVA) prior to gait analysis testing was not recorded, and this was an error by the researcher. The researcher assumed that participants would attend the gait clinic wearing the PD AFO in the same footwear and using the same heel elevators prescribed when the orthosis was initially supplied. The researcher did not verify this prior to gait analysis testing. As the SVA influences sagittal plane kinematics it would have been useful to have this data to further understand the study's results. Additionally, only 1 orthotist was involved with the provision and fine-tuning of each participant's PD AFO. Therefore, the findings of this study are limited to 1 clinician's clinical practice. The treating orthotist/researcher is an experienced clinician working as a state registered orthotist for 15 years.

A further limitation to this study is the lack of documentation around the knee and hip muscle powers of each participant, and the lack of electromyography (EMG) data to verify muscle function. This would have been helpful to understand if muscle weakness, due to a more sedentary lifestyle post-trauma, contributed to any of the results seen in this study.

This study examined participants walking in a gait laboratory, which is not a “real world” environment. Participants walking speed was not controlled. However, the researcher did not want to introduce any abnormal gait compensations by trying to restrict injured personnel’s speed. It was more clinically appropriate to allow individuals to walk at a speed they felt comfortable with, as their lower limb injures were extensive.

The sample size in this study was small (n=12) as the inclusion criteria were strict and the UK population of PD AFO users within the military is small. US military outcome studies do contain larger sample sizes and range from n=10 to n=146 as they have greater numbers of PD AFO users within their service. They also recruit participants with a wide range of injuries; for example they include those with deckslap fractures alongside those with peripheral nerve injuries. It was important to keep the inclusion criteria strict in this study to ensure participants compared were as similar as possible regarding their lower limb injury profile, which is difficult in the trauma injured population. Furthermore, this study only looked at a male military cohort who had access to extensive rehabilitation. This study is generalised to this demographic and caution must be applied when comparing to a civilian population.

5.8 Future works

Future studies should further look to examine gait of PD AFO users and, importantly, include comparisons to other custom made composite AFOs that are made to the same cast and fine-tuned appropriately. Previously, PD AFOs have only been compared functionally to prefabricated AFOs of differing materials and trim lines. A dose response study should also be undertaken, whereby small changes are made systematically to the PD AFO design and tested to determine the mechanism of action of each change.

Future work should also include the addition of strain gauges to the posterior struts of PD AFOs to determine how much the struts deflect and the effect of this on gait. Electromyography of the lower limb should also be performed during gait to understand how use of PD AFOs improves the ability of the limb

to generate forward momentum. Statistical parametric mapping could also be used to further examine gait patterns in more detail.

There is also a need to further understand the effects of rehabilitation on the quality of gait and clinical outcomes achieved. No studies have gathered gait analysis at time points along PD AFO user's rehabilitation journey to understand if a "training effect" is present, which would support the need for orthotic PD AFO users to have tailored physiotherapy as part of any intervention. In addition, there are no long-term studies of PD AFO users, as this specific PD AFO design has only been used in the US since 2009 and the UK since 2014.

5.9 Conclusion

The aim of this thesis was to explore the use of a specifically designed PD AFO that utilises a posteriorly mounted pair of composite struts in UK military personnel who had sustained unilateral complex hindfoot trauma. The literature review identified that no prior work had reported gait analysis of PD AFO users shod alone, and studies reporting clinical outcomes were often presenting personnel with a diverse range of injuries together. It was hypothesised that the PD AFO would improve participant clinical outcome, and this would be demonstrated through improvements in participants' PROM scores and selected gait variables, as well as their GPS.

It is apparent from the results in this thesis that PD AFOs use can improve pain, quality of life and the ability to engage in a more active lifestyle. Using a PD AFO can aid the body's ability to generate forward progression and rely less on hip compensations to achieve this forward momentum. This research supports evidence that suggests that PD AFOs can improve gait and clinical outcomes in patents with unilateral hindfoot fractures with ongoing biomechanical pain that is not responding to conventional rehabilitative interventions.

Chapter 6: References and Appendices

6.1 Appendix A FAOS questionnaire

FAOS FOOT & ANKLE SURVEY

Todays date: _____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your foot/ankle. This information will help us keep track of how you feel about your foot/ankle and how well you are able to do your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms
These questions should be answered thinking of your foot/ankle symptoms during the **last week**.

S1. Do you have swelling in your foot/ankle?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Do you feel grinding, hear clicking or any other type of noise when your foot/ankle moves?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S3. Does your foot/ankle catch or hang up when moving?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S4. Can you straighten your foot/ankle fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

S5. Can you bend your foot/ankle fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

Stiffness
The following questions concern the amount of joint stiffness you have experienced during the **last week** in your foot/ankle. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

S6. How severe is your foot/ankle stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S7. How severe is your foot/ankle stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

P1. How often do you experience foot/ankle pain?

Never	Monthly	Weekly	Daily	Always
□	□	□	□	□

What amount of foot/ankle pain have you experienced the **last week** during the following activities?

P2. Twisting/pivoting on your foot/ankle

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P3. Straightening foot/ankle fully

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P4. Bending foot/ankle fully

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P5. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P6. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P7. At night while in bed

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P8. Sitting or lying

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

P9. Standing upright

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your foot/ankle.

A1. Descending stairs

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

A2. Ascending stairs

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your foot/ankle.

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A5. Bending to floor/pick up an object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining foot/ankle position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your foot/ankle.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your foot/ankle.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

SP2. Running

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

SP3. Jumping

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

SP4. Twisting/pivoting on your injured foot/ankle

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

SP5. Kneeling

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

Quality of Life

Q1. How often are you aware of your foot/ankle problem?

Never	Monthly	Weekly	Daily	Constantly
□	□	□	□	□

Q2. Have you modified your life style to avoid potentially damaging activities to your foot/ankle?

Not at all	Mildly	Moderatly	Severely	Totally
□	□	□	□	□

Q3. How much are you troubled with lack of confidence in your foot/ankle?

Not at all	Mildly	Moderately	Severely	Extremely
□	□	□	□	□

Q4. In general, how much difficulty do you have with your foot/ankle?

None	Mild	Moderate	Severe	Extreme
□	□	□	□	□

Thank you very much for completing all the questions in this questionnaire.

Questionnaire and User's Guide can be downloaded from: www.koos.nu

6.2 Appendix B LEFS

EMORY HEALTHCARE
EMORY PHYSICAL THERAPY

Lower Extremity Functional Scale (LEFS)

Source: Binkley JM, Stratford PW, Lott SA, Riddle DL. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties, and clinical application. North American Orthopaedic Rehabilitation Research Network. *Phys Ther*. 1999 Apr;79(4):371-83.

The Lower Extremity Functional Scale (LEFS) is a questionnaire containing 20 questions about a person's ability to perform everyday tasks. The LEFS can be used by clinicians as a measure of patients' initial function, ongoing progress and outcome, as well as to set functional goals.

The LEFS can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities. It can be used to monitor the patient over time and to evaluate the effectiveness of an intervention.

Scoring instructions

The columns on the scale are summed to get a total score. The maximum score is 80.

Interpretation of scores

- The lower the score the greater the disability.
- The minimal detectable change is 9 scale points.
- The minimal clinically important difference is 9 scale points.
- % of maximal function = (LEFS score) / 80 * 100

Performance:

- The potential error at a given point in time was +/- 5.3 scale points.
- Test-retest reliability was 0.94.
- Construct reliability was determined by comparison with the SF-36. The scale was found to be reliable with a sensitivity to change superior to the SF-36.

Instructions

We are interested in knowing whether you are having any difficulty at all with the activities listed below **because of your lower limb problem** for which you are currently seeking attention. Please provide an answer for **each** activity.

Today, *do you* or *would you* have any difficulty at all with:

Activities	Extreme difficulty or unable to perform activity	Quite a bit of difficulty	Moderate difficulty	A little bit of difficulty	No difficulty
1. Any of your usual work, housework or school activities.	0	1	2	3	4
2. Your usual hobbies, recreational or sporting activities.	0	1	2	3	4
3. Getting into or out of the bath.	0	1	2	3	4
4. Walking between rooms.	0	1	2	3	4
5. Putting on your shoes or socks.	0	1	2	3	4
6. Squatting.	0	1	2	3	4
7. Lifting an object, like a bag of groceries from the floor.	0	1	2	3	4
8. Performing light activities around your home.	0	1	2	3	4
9. Performing heavy activities around your home.	0	1	2	3	4
10. Getting into or out of a car.	0	1	2	3	4
11. Walking 2 blocks.	0	1	2	3	4
12. Walking a mile.	0	1	2	3	4
13. Going up or down 10 stairs (about 1 flight of stairs).	0	1	2	3	4
14. Standing for 1 hour.	0	1	2	3	4
15. Sitting for 1 hour.	0	1	2	3	4
16. Running on even ground.	0	1	2	3	4
17. Running on uneven ground.	0	1	2	3	4
18. Making sharp turns while running fast.	0	1	2	3	4
19. Hopping.	0	1	2	3	4
20. Rolling over in bed.	0	1	2	3	4
Column Totals:	0	1	2	3	4

6.3 Appendix C Participant consent form

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Title of Study: The effectiveness of a PD AFO in limb salvage patients as a treatment option.

Ministry of Defence Research Ethics Committee Reference: 690MoDREC15

☐ The nature aims and risks of the research have been explained to me. I have read and understood the Information for Participants (v3 04/10/2016) and understand what is expected of me. All my questions have been answered fully to my satisfaction.

☐ I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately without having to give a reason. I also understand that I may be withdrawn from it at any time, and that in neither case will this be held against me in subsequent dealings with the Ministry of Defence.

☐ I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.

☐ I agree to volunteer as a participant for the study described in the information sheet and give full consent.

☐ This consent is specific to the study described in the Information for Participants attached and shall not be taken to imply my consent to participate in any subsequent study or deviation from that detailed here.

☐ I understand that in the event of my sustaining injury, illness or death as a direct result of participating as a volunteer in Ministry of Defence research, I or my dependants may enter a claim with the Ministry of Defence for compensation under the provisions of the no-fault compensation scheme, details of which are attached.

☐ I agree to be contacted by the researchers of this investigation if they request the use of my data towards other studies in addition to this study.

Participant's Statement:

I _____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the

Participant Information Sheet about the project and understand what the research study involves.

Signed Date

Witness Name

Signature

Investigator's Statement:

I _____

confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the Participant.

Signed Date

AUTHORISING SIGNATURES

The information supplied above is to the best of my knowledge and belief accurate. I clearly understand my obligations and the rights of research participants, particularly concerning recruitment of participants and obtaining valid consent.

Signature of Chief Investigator

…… Date

Name and contact details of Independent Medical Officer (if appropriate):

Name and contact details of Chief Investigator:

6.4 Appendix D Participant information sheet

This participant information sheet is to be provided to all patients who we are requesting to use their gait analysis and outcome data for my MSc (Res).

PARTICIPANT INFORMATION SHEET

Study title

The effectiveness of a Passive Dynamic Ankle Foot Orthosis (PD AFO) in limb salvage patients as a treatment option.

Invitation to take part

You were fitted with a PD AFO whilst on rehabilitation at DMRC Headley Court. As you are aware it is normal practise at DMRC Headley Court to undergo gait analysis and fill in outcome surveys during your clinical treatment when supplied with a PD AFO. During your rehabilitation you consented to us gathering this data from you. We would like to use the data captured during your time at DMRC Headley Court towards a study evaluating the PD AFO and its effectiveness for those with similar injuries to yourself. You should only consent for the use of your data towards this study if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to let us use your data for this research study, it is important for you to understand why the research is being done. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you would like to take part, please let us know if you have been involved in any other study during the last year.

What is the purpose of the research?

The overall aim of this research study is to determine how useful the PD AFO is to you and how your walking ability did or did not improve when you were wearing the PD AFO. This will help us to determine its use in treating complex lower limb injures.

Who is doing this research?

The research is being undertaken by Mrs Nicole Bennett

Why have I been invited to take part?

You have been asked if we can use your data as you are a patient aged between 18-50 years old who has a lower limb injury. As part of your rehabilitation at DMRC Headley Court you have been prescribed and fitted with a PDAFO by the multidisciplinary team. You are currently receiving on-going or have received rehabilitation at DMRC Headley Court and have consented to undergoing gait analysis and completing outcome measures as part of your clinical care.

Do I have to take part?

No, you do not have any obligation to allow us to use your data and neither your medical care nor employment will be affected by such a decision.

What will I be asked to do?

As we already have the data you are not required to do anything further. We just wish your consent to use the gait analysis data of you walking with and without your BOB as well as the LEFS and FAOS outcome surveys which were taken before, and we provided you with a BOB. If you would like a copy of these to refresh your memory which questionnaires, they were then please contact us. We may like to contact you in the future to ask to use your data towards additional research projects. If you are happy with this, please consent to this on the consent form as stated.

What is the device or procedure that is being tested?

The device that is being tested is a PD AFO which is a custom Ankle Foot Orthoses (AFO) made from composite materials.

What are the benefits of taking part?

The benefit of allowing us to use your data is that your data will help us evaluate a brace that we currently prescribe to personnel with complex lower limb injuries. If we can understand more about the impact it has on personnel's lives and the difference in your gait, we will be better informed about how best to provide it. As clinicians we will be better placed to prescribe evidence-based treatments and to share this information with NHS teams for supporting veterans and civilians alike.

What are the possible disadvantages and risks of taking part?

There are no disadvantages to allowing us to use your data.

Can I withdraw from the research and what will happen if I don't want to carry on?

You may at any time withdraw the use of your data without giving a reason. If you ever require any further explanation, please do not hesitate to ask.

Are there any expenses and payments which I will get?

No. There are no payments. All data collection has already taken place when you were an in-patient at DMRC Headley Court.

Will my taking part or not taking part affect my Service career or medical care?

No

Whom do I contact if I have any questions or a complaint?

Anish Kurien, Research and Innovation Manager, University of Salford Contactable via Tel: 0161 295 7012 /2280 or email address a.kurien@*salford*.ac.uk

What happens if I suffer any harm?

You will suffer no harm as we only wish to use your data that we already have as part of your clinical treatment whilst at DMRC Headley Court.

What will happen to any samples I give?

You will not be required to give any samples.

Will my records be kept confidential?

Any data will remain confidential as to your identity: if it can be specifically identified with you, your permission will be sought in writing before it will be published. Other material, which cannot be identified with you, will be published or presented at meetings with the aim of benefiting others. You may ask Mrs Nicole Bennett or Dr Hannah Jarvis for copies of all papers, reports, transcripts, summaries and other published or presented material. All information will be subject to the current conditions of the Data Protection Act 1998.

Experimental records, including paper records and computer files, will be held for a minimum of 15 years in conditions appropriate for the storage of personal information. You have right of access to your records at any time

Who is organising and funding the research?

The research study is being organised by the University of Salford and ADMR at DMRC Headley Court.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MoDREC). Ethics has also been approved from the University of Salford.

Further information and contact details.

Name and contact details of Local Investigators: Mrs Nicole Bennett, Prosthetics and Orthotics department, DMRC Headley Court, Epsom, Surrey, KT18 6JW. Tel: 07590713780

Compliance with the Declaration of Helsinki.

This study complies, and always will comply, with the Declaration of Helsinki[1] as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.

6.5 Appendix E Ethics approval: Ministry of Defence

Ministry of Defence
Research Ethics Committee

From the Chairman
Professor Allister Vale MD
National Poisons Information Service (Birmingham Unit),
City Hospital, Birmingham B18 7QH

Telephone: 0121 507 4123
e-mail:allistervale@npis.org

Dr Hannah Jarvis
Military Performance Analysis
Research Laboratory,
ADMR,
Headley Court,
Epsom,
Surrey
KT18 6JW

Our Reference:
690/MODREC/15

Date: 20 March 2016

Dear Dr Jarvis,

The effectiveness of the British Off-loading Brace (BOB) in limb salvage patients

Thank you for submitting your revised Application 690 with tracked changes, and with a covering letter with responses to my own letter. The revised protocol has been approved by the Officers of MODREC ex-Committee.

I wish you and your colleagues a successful study. In due course please send the Secretariat a final report containing a summary of the results so that these can be filed in accordance with the arrangements under which MODREC operates. Please would you also send a brief interim report in one year's time if the study is still ongoing.

This approval is conditional upon adherence to the protocol – please let me know if any amendment becomes necessary.

Yours sincerely

Allister Vale

Allister Vale MD FRCP FRCPE FRCPG FFOM FAACT FBTS FBPhS FEAPCCT Hon FRCPSG

cc, Professor David Jones, Professor David Baldwin, Secretariat

6.6 Appendix F Ethics approval: University of Salford

University of Salford MANCHESTER

Research, Innovation and Academic Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

29 November 2016

Dear Nicole,

RE: ETHICS APPLICATION–HSCR16-69 - Measuring the clinical effectiveness of the British Off-loading Brace (BOB), using both clinical gait analysis and validated functional outcome measures for 12 patients who have sustained limb salvage post IED Blast.

Based on the information you provided, I am pleased to inform you that application HSCR16-69 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,

Sue McAndrew
Chair of the Research Ethics Panel

6.7 References

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