A case series of the ReAktiv™ posterior dynamic element (PDE) orthosis on ankle trauma

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Abstract

Background:

Injuries sustained during High Energy Trauma (HET) often require complex surgery and extensive rehabilitation and can result in long-term issues such as pain, loss of function and limitations in physical activity. The ReAktiv Posterior Dynamic Element™ orthosis is a custom-made Passive-Dynamic Ankle-Foot-Orthosis (PDAFO) that aims to alter impact and loading through the foot and ankle, reducing pain and allowing users to return to high levels of physical activity. The aim of this study was to conduct a case series on the clinical effectiveness of the ReAktiv PDE orthosis on pain and function for people that had sustained a HET injury to the lower limb.

Methods: This case series retrospectively reviewed the results of three patients that had received the ReAktiv PDE Orthosis as a treatment intervention to alleviate pain and improve physical function following a HET injury to the ankle. To determine any changes in pain all participants completed the LEFS and completed a 2MWT prior to receiving the orthosis as part of the initial assessment. The PDQ and PSEQ were completed at the final fitting of the orthosis (2 weeks) and provided a baseline measure of how much the pain from their injury affected them on a day-to-day basis. A 6-week physiotherapy-led rehabilitation programme was established to help patients with gait retraining, functional movement patterns and returning to physical activity.
Physical function was assessed using the 2MWT, FSST, TSA and SLB. The questionnaires (LEFS, PDQ, PSEQ) were re-recorded at the conclusion of the rehabilitation programme to determine any self-reported changes in pain since receiving the orthosis. All physical tests were re-recorded at the conclusion of the rehabilitation programme (6-weeks).

Results: The ReAktiv PDE orthosis shows promise in improving self-reported pain levels in those who have sustained HET injuries to the ankle. Tracking of pain prior to receiving the orthosis, and again at the conclusion of the rehabilitation programme was recorded on 1 participant. The PDQ and PSEQ showed an improvement when using the orthosis and how much pain interfered with their life. The LEFS was recorded on two participants and showed improvement with both participants reporting a higher score at the conclusion of rehabilitation with the orthosis compared to baseline with no orthosis. Physical walking performance improved as indicated by the improvement seen in the 2MWT. Improvement in mobility and balance, measured through recording of the FSST, TSA and the SLB test at the commencement and conclusion of the rehabilitation programme was also seen.

Conclusion: The ReAktiv PDE orthosis shows potential as a treatment option to improve pain levels and walking performance in those who have sustained a unilateral, HET injury to the lower limb. In addition to the application of the orthosis, the use of a 6-week physiotherapy-led rehabilitation programme, recorded further improvements in walking performance, physical mobility and balance. Further research conducted on a larger and more diverse cohort of ReAktiv PDE orthosis wearers, would help to determine the significance of the orthosis design on pain and physical performance, and the impact that the rehabilitation programme has on pain and physical function. Long-term follow up of users would also indicate whether the improvements that have been obtained during this short timeframe are sustained in the long-term or whether participants experience regression due to further deterioration to their injured limb.

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Attestation of Authorship

"I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning."

Sarah Gardner:

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This dissertation was approved by Auckland University of Technology Ethics Committee (AUTEC), ethics application 21/137 (29/06/2021)

Chapter 1: Introduction

1.1 High Energy Trauma (HET) Injuries

HET injuries are those that occur following a significant traumatic event such as motor vehicle/bike accident, impact injury, fall from height, sports, gunshot wounds, or shrapnel injury (Peterson et al., 2021). HET injuries are prevalent and account for approximately 250,000 hospitalisations in the United States of America (US) every year (Highsmith et al., 2016). Due to the damage that occurs to the limb and the complexity of the injuries sustained in a HET injury, initial treatment often requires surgical intervention rather than conservative treatment and can result in either an amputation of the affected limb or extensive limb salvage (Highsmith et al., 2016). Initially the short-term complications associated with limb salvage following HET injuries can include pain, impairment (reduced joint range of motion), functional deficits (gait, balance, muscle power and loading ability) and disability (Highsmith et al., 2016). The impact of HET injuries on a person's ability to work are significant, with approximately 50% of people returning to work 24 months post-injury (Bosse et al., 2002). Over time, the long-term complications associated with these injuries can include chronic pain, post-traumatic arthritis, ongoing impairment, and functional deficits which can contribute to delayed amputation of the affected limb.

1.2 Traumatic ankle injuries

The Ministry of Health (2021) reported that the occurrence of fractures of the lower leg, including the ankle, requiring hospitalisation in New Zealand adults (20 – 64 years) for the year 2019 was approximately 4,903. The highest rates of low-energy, acute lateral ankle fractures occurs in adolescents younger than 19 years (Beck et al., 2020) and older adults, particularly females (Toole et al., 2015). These are usually due to a fall or an inversion injury of the ankle and are referred to as a low-energy trauma (mono-trauma). The structures damaged in these events may be isolated to a closed fracture of the fibular. Ankle fractures that occur due to high energy trauma (poly-trauma), such as motor vehicle accidents (MVA) or falls from height often result in damage to multiple structures of the ankle and may involve misalignment of the foot and ankle. As a result, surgical intervention is typically indicated when the congruency of the ankle joint mortise or ankle joint stability is compromised (Briet et al., 2017).

1.2.1 Classification of ankle injuries

Classification systems for ankle injuries are used to describe the mechanism of injury, the severity of injury, and to help to guide treatment. The Lauge-Hansen classification for ankle injuries (Table 1.1) is based on cadaveric studies, describing the rotational forces acting on the ankle and associated fracture presentation (Lauge-Hansen, 1948). It is one of the most widely used and accepted ankle fracture classification systems (Tartaglione et al., 2015). Unlike other classification systems, the Lauge-Hansen classification system is based on both radiographic criteria and the mechanism of trauma and can help to determine whether and what type of surgical intervention is necessary (Tartaglione et al., 2015).

Table 1.1 Lauge-Hansen Classification	
Supination-Adduction (SAD)	1. Transverse fracture of the distal fibula 2. Vertical fracture of the medial malleolus
Supination – External Rotation (SER)	1. Injury of anterior inferior tibiofibular ligament 2. Oblique/spiral fracture to distal fibula 3. Injury to posterior inferior tibiofibular ligament or avulsion of posterior malleolus 4. Medial malleolus transverse fracture or disruption of deltoid ligament
Pronation – Abduction (PAB)	1. Medial malleolus fracture or injury to the deltoid ligament 2. Injury of the anterior inferior tibiofibular ligament 3. Transverse or comminute fracture of the fibula proximal to the tibial plafond
Pronation – External Rotation (PER)	1. Medial malleolus fracture or injury to the deltoid ligament 2. Injury of the anterior inferior tibiofibular ligament 3. Oblique or spiral fracture of fibula proximal to the tibial plafond 4. Injury of the posterior inferior tibiofibular ligament or avulsion of posterior malleolus

Note. From "Classifications in Brief: Lauge-Hansen Classification of Ankle Fractures" by J.P. Tartaglione, A.J. Rosenbaum, M. Abousayed and J.A. DiPreta (2015), *Clinical Orthopaedics and Related Research, 473*: (10), https://www.ncbi.nlm.nih.gov/pubmed/25900357. Copyright by 2022 The Association of Bone and Joint Surgeons.

A limitation of the Lauge-Hansen classification is that it was initially created to guide direct closed reduction of the ankle, with the goal of reversing the mechanism of injury by putting the foot and ankle back into the original position. However, this assumes the mechanism of trauma which is often unreliable or unknown, and with the advancement of modern-day radiology and surgical fixation techniques, this concept is now of less importance (Boszczyk et al., 2018).

The Danis-Weber classification (Table 1.2) first published in 1972, groups ankle fractures based on radiographic criteria only by taking into consideration the position of the distal fibular fracture in relation to the syndesmosis (Tartaglione et al., 2015). It is frequently used by orthopaedic surgeons because of its simplicity and excellent inter-observer agreement (Vieira Cardoso et al., 2021). However, one of its limitations is that it does not consider the structures on the medial side of the ankle (Han et al., 2020). Fractures are classified as Type A, B or C. Type A is typically below the level of the syndesmosis, with syndesmosis and deltoid ligaments intact. Type B occurs at the level of the ankle joint, with possible injury to the syndesmosis complex. Type C fractures occur above the syndesmosis complex and can result in complete disruption of the syndesmosis ligaments, and an unstable ankle mortise (Vieira Cardoso et al., 2021).

An additional classification system, the AO Foundation/Orthopaedic Trauma Association (AO/OTA) classification, is a reliable system to characterise the type and severity of Ankle fractures but does not always provide enough information about damage to the medial and posterior malleoli (Pfluger et al., 2022). It is considered to be an advanced classification system that is often considered too complex and difficult to learn and apply, which affects its inter-observability and reproducibility (Olczak et al., 2021). Although there are limitations to both the Lauge-Hansen and Danis-Weber classification systems, they both continue to be widely used amongst medical professionals and in the literature to categorise fractures and to interpret mechanism of injury and trauma.

Table 1.2 Danis-Weber Classification of Ankle Fractures	
A	Below the level of the syndesmosis
	Usually, transverse
	Tibiofibular syndesmosis intact
	Deltoid ligament intact
	Medial malleolus occasionally fractured
	Usually stable if medial malleolus intact
B	Distal extent at the level of the syndesmosis, may extend some distance proximally
	Usually, spiral
	Tibiofibular syndesmosis usually intact, but widening of the distal tibiofibular joint (especially on stressed views) indicates syndesmotic injury
	Medial malleolus may be fractured
	Deltoid ligament may be torn, indicated by widening of the space between the medial malleolus and talar dome
	Variable stability; dependent on the status of medial structures and syndesmosis; may require ORIF
	Can be further classified as
	B1: Isolated
	B2: Associated with a medial lesion (malleolus or ligament)
	B3: Associated with a medial lesion and fracture of the posterolateral tibia
C	Above the level of the syndesmosis
	Tibiofibular syndesmosis disruption with widening of the distal tibiofibular articulation
	Medial malleolus fracture or deltoid ligament injury often present
	Fracture may arise as proximally at the level of the fibular neck and not visualized on ankle films, requiring knee or full-length tibia-fibula radiographs (Maisonneuve fracture)
	Unstable; usually requires ORIF
	Weber C fractures can be further classified as
	C1: Diaphyseal fracture of the fibula, simple
	C2: Diaphyseal fracture of the fibula, complex
	C3: Proximal fracture of the fibula

Note. From "Classifications in Brief: Lauge-Hansen Classification of Ankle Fractures" by J.P. Tartaglione, A.J. Rosenbaum, M. Abousayed and J.A. DiPreta (2015), *Clinical Orthopaedics and Related Research, 473*: (10), https://www.ncbi.nlm.nih.gov/pubmed/25900357. Copyright by 2022 The Association of Bone and Joint Surgeons.

1.2.2 Poly-trauma fractures

Poly-trauma fractures are often associated with high-energy trauma (HET) such as motor vehicle accidents (MVA) and can cause severe damage within the foot-ankle complex. The mechanism of trauma usually results in a supination-adduction or pronation-abduction movement, in conjunction with high energy impact and direct force (Briet et al., 2017).

Briet et al. (2017) looked at the differences in classification and trauma mechanisms between mono and poly-trauma patients with ankle fractures. In this study, they found there was a significant difference in not only the trauma mechanism, intensity, number of open fractures and number of surgically fixed fractures, but also the classification of the ankle fractures between the mono and poly trauma patients. Poly-trauma was more likely to be associated with a supination-adduction, or pronation-abduction injury, with a high energy impact (HET) and direct force, such as those occurring following motor vehicle accidents and falls from heights (Briet et al., 2017).

In these poly-trauma HET ankle injuries, the resulting damage to structures in a supination-adduction type fracture would likely correspond with a Danis-Weber Type A or B fracture with Lauge-Hansen stage 1-2. A pronation-abduction type fracture would likely correspond with a Danis-Weber Type B or C fracture, with Lauge-Hansen stage 1-3.

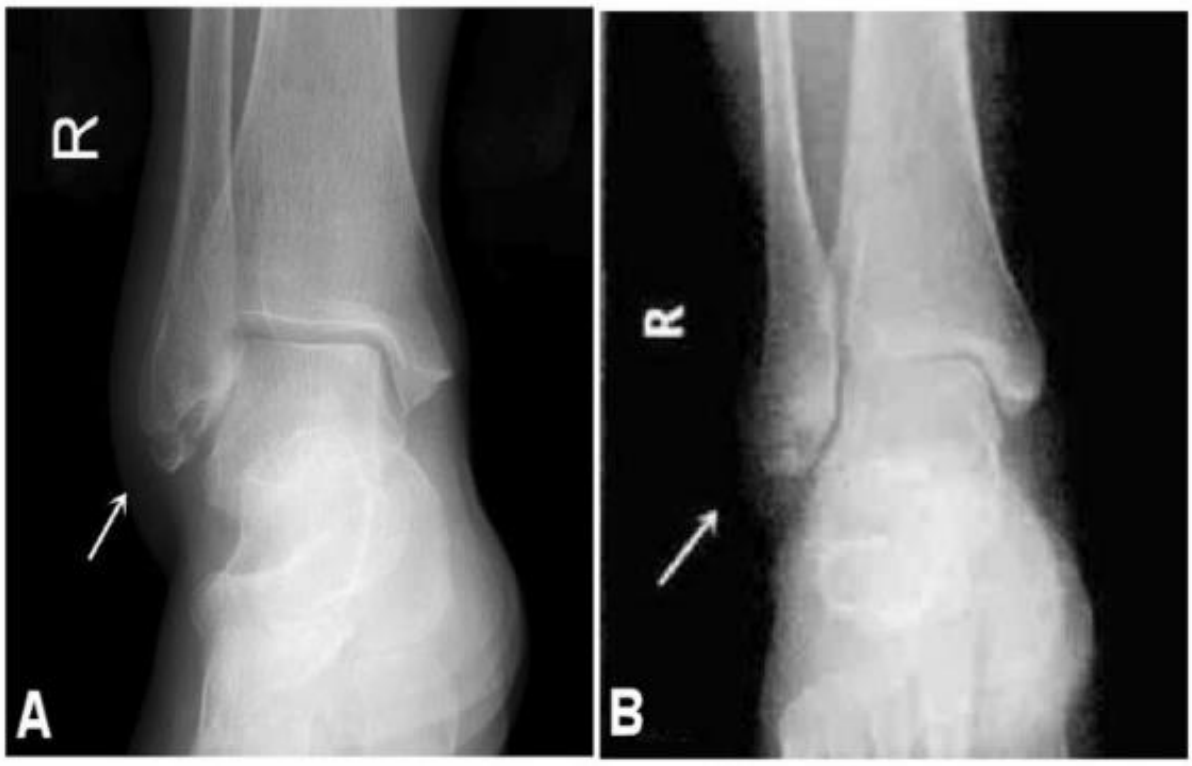

Figure 1.1 Supination – Adduction fracture

X-rays showing Supination-Adduction fracture. In both images A & B the arrows indicate the Lateral malleolus fracture with the fracture line below the inferior tibiofibular joint level.

From “Radiographic analysis of adult ankle fractures using combined Danis-Weber and Lauge-Hansen classification systems” by S.M. Han and T.H Wu et al (2020) *Scientific Reports, 10* (1), p.3. (https://doi.org/10.1038/s41598-020-64479-2). Copyright by The Author(s) 2020.

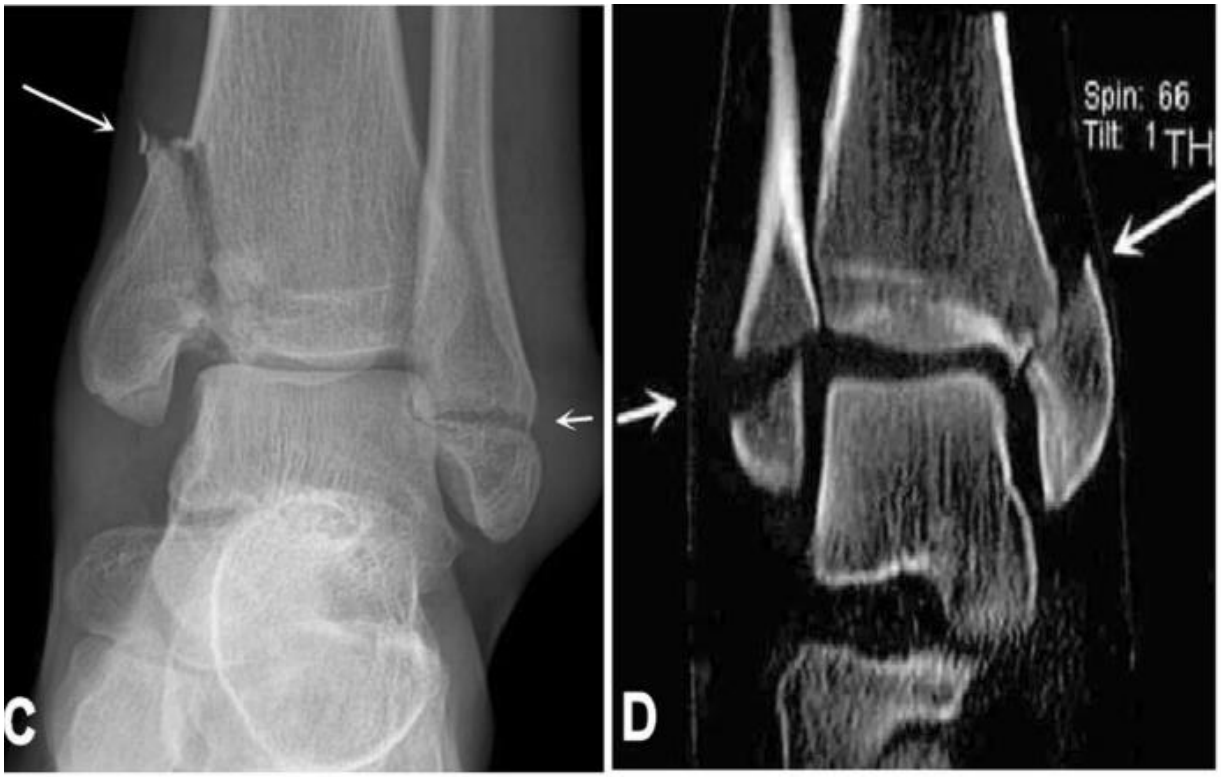

Figure 1.2 Supination – Adduction fracture

Supination – Adduction fracture. In images C & D, this is a Danis-Weber Type A stage 2 and Lauge-Hansen stage 2. The lateral malleolus fracture line is transverse and below the inferior tibiofibular joint level. The medial malleolus fracture is higher than the lateral malleolus fracture with the medial malleolus fracture being vertical or oblique.

From “Radiographic analysis of adult ankle fractures using combined Danis-Weber and Lauge-Hansen classification systems” by S.M Han and T.H Wu et al (2020), *Scientific Reports, 10* (1), p.3. (https://doi.org/10.1038/s41598-020-64479-2). Copyright by The Author(s) 2020.

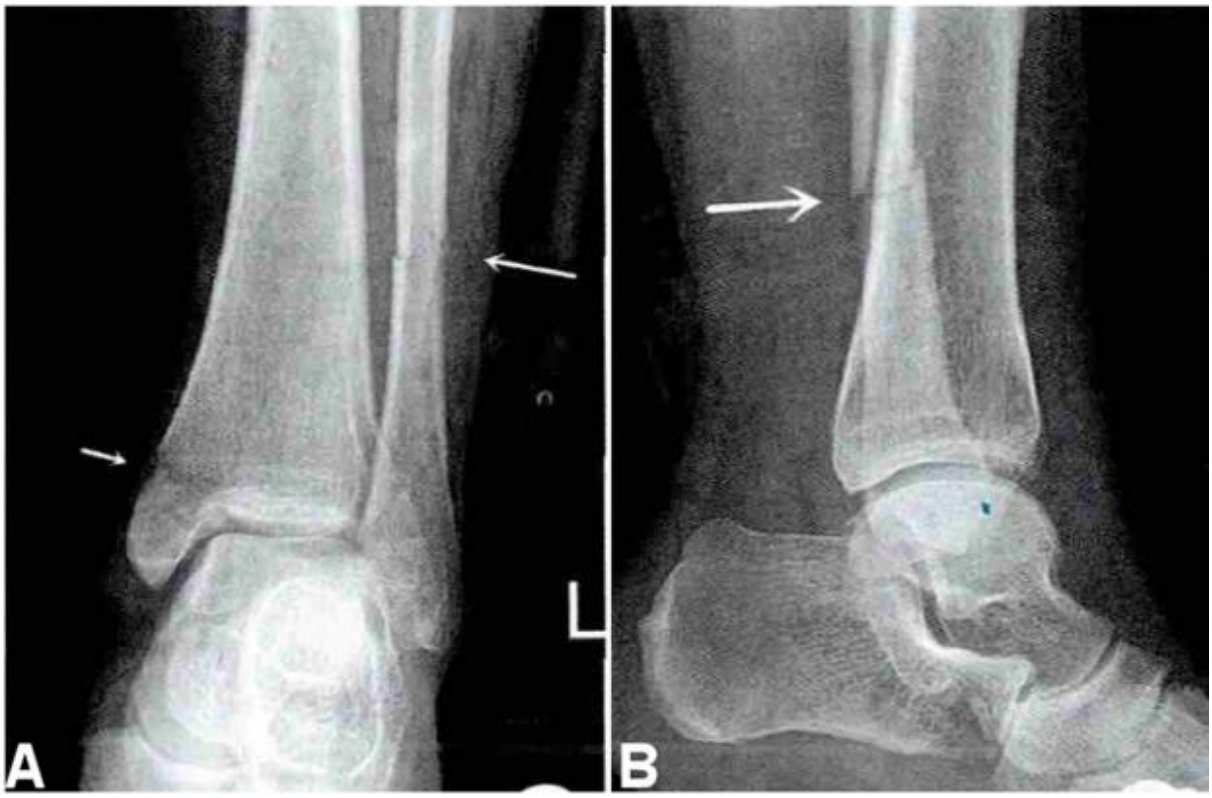

Figure 1.3 Pronation – Abduction fracture

Pronation-Abduction fracture. Image A and image B of a medial malleolus fracture, which is above the lower tibiofibular syndesmosis. Also present is a fibular fracture. Fractures are indicated by the arrows. This is stage 3 of the Lauge-Hansen classification and Danis-Weber Type C.

From "Radiographic analysis of adult ankle fractures using combined Danis-Weber and Lauge-Hansen classification systems" by S.M Han and T.H Wu et al (2020), *Scientific Reports, 10* (1), p.5. (https://doi.org/10.1038/s41598-020-64479-2). Copyright by The Author(s) 2020.

1.2.3 Management of HET injuries

1.2.3.1 Surgical Intervention

In a systematic review by Larsen et al. (2019) of 1237 patients who had either surgical or conservative treatment for non-displaced, ankle fractures, whether the ankle fracture is best managed surgically or conservatively to be inconclusive. Both interventions carry risks. Conservative risks include muscle atrophy, stiffness, swelling of ankle joint and cartilage degeneration, malalignment, non-union and prolonged immobilisation. Surgical risks include risk of infection, deep vein thrombosis, reoperation, failure of hardware, amputation and mortality. They also found no significant difference in health-related quality of life, pain or development of osteoarthritis with either intervention.

Surgical intervention is often required following HET injuries affecting the ankle where there is often misalignment, instability and loss of congruity of the ankle joint (Martijn et al., 2021). To obtain anatomical alignment as well as stability of the fractured bones, the repositioning and surgical fixation of the fracture with screws, plates or pins is considered more effective than what could be achieved conservatively and can help to facilitate earlier weightbearing and mobilisation (Larsen et al., 2019).

In a systematic review by Ribeiro de Avila et al. (2018) patients treated surgically for unstable ankle fractures appear to report less functionality and lower physical capacity, compared with those who have not sustained an ankle fracture. In this study they found that these limitations could last for long periods and impact on patient's quality of life. This is similar to findings by Jonkergouw et al. (2021) who found that patients who had sustained poly-trauma injuries often showed higher pain and lower performance levels than those without foot and ankle injuries. HET injuries often involve complex wounds that are further complicated by severe soft tissue loss, pain, nerve injury, and volumetric muscle loss (Hsu & Bosse, 2012). The challenges for surgeons managing these injuries can also place considerable restraints on post-surgical rehabilitation (Patzkowski, Owens, et al., 2012a)

Surgical treatment of ankle fractures aims to achieve stability, anatomic reduction and congruity of the ankle joint by means of open reduction and internal fixation (Martijn et al., 2021). Up to 50% of surgically treated patients show suboptimal functional results with residual complaints at long-term follow up. A frequent complaint is persistent pain, which can have a large impact on the day-to-day functioning of the patient. Injury to the medial deltoid ligament complex can result in shifting of the talus, leading to altered ankle joint kinematics and instability. It is hypothesised that the presence of Osteochondral Lesion's (OCL) following ankle trauma may greatly contribute to residual pain (Martijn et al., 2021). An OCL is a term given when there is indication that both cartilage and underlying subchondral bone are affected and can include chondral lesions and subchondral cysts. The incidence of OCL's after ankle fractures is 45.1%, and amongst all OCL's the talus is the location with the highest incidence (42.7%), followed by the fibula (31.2%), medial malleolus (29.4%) and the tibial plafond (16.6%) (Martijn et al., 2021).
Martijn et al. (2021) looked at ankle fractures and the high incidence of OCLs, primarily on the talus. The talus plays a significant part in the load bearing structure of the ankle, helping to transfer weight and pressure across the ankle joint. It has no muscular or tendinous attachments and therefore the blood supply is mostly extraosseous (Parekh & Kadakia, 2021). Due to this poor blood supply, it is susceptible to osteonecrosis and delayed healing time following injury. Approximately 75% of all

cases of talar osteonecrosis are secondary to traumatic injury with over 90% of trauma related osteonecrosis cases due to talar neck fractures (Parekh & Kadakia, 2021, p. 267). Conservative treatment of OCL includes casting immobilisation, use of a walking/moon boot, bone stimulation and physical therapy. Early arthritic changes and failure to return to a previous level of activity are often reported in patients who receive nonoperative management (Wang et al., 2021). There is also a lack of consensus amongst the literature regarding duration of conservative treatment, method of immobilisation, weightbearing status and physical therapy protocols (Rungprai et al., 2017). Once conservative treatment has failed, operative management is adviced however this also carries inherent risks and has its own limitations (Wang et al., 2021).

1.3 Introduction to Ankle-Foot-Orthoses (AFO)

To combat changes that have occurred following a HET injury, ankle-foot-orthoses (AFO) and/or prosthetics are commonly used by people that have sustained HET injuries (Mangan et al., 2016). AFOs are an external brace used to modify foot and ankle function and have traditionally been designed for those with neurological disorders with the goal to either restrict movement, aid stability or assist with ambulation (Patzkowski et al., 2011). A person who has undergone limb salvage would potentially be fitted with an AFO, whereas a prosthetic is an external device that replaces an absent limb segment and would be fitted to those who have undergone an amputation (Healy et al., 2018).

Despite the use of prosthetics or AFOs for HET injuries, an individual's level of function post-injury is likely to be worse than pre-injury levels. The post-injury level of function is also influenced by whether the person undergoes limb salvage or amputation. Greater levels of asymmetry are seen in those fitted with an AFO compared to those fitted with a prosthesis following HET injuries (Mangan et al., 2016). Reduced stance time on the affected leg is observed in those fitted with an AFO, suggestive of an antalgic gait pattern due to residual pain. Other compensations include decreased walking speed, foot drop, uneven step length, knee hyperextension, hip hiking, and leg circumduction (Brown et al., 2017; Mangan et al., 2016). Other studies examining HET cohorts have reported that those fitted with a prothesis were more likely to return to pre-injury activities compared to those fitted with an AFO (Patzkowski et al., 2011). These findings suggest that those undergoing amputation display a more symmetrical gait pattern and may be more likely to return to pre-injury activity levels compared to those undergoing limb salvage. The decision to amputate or pursue limb salvage is complex and multi-factorial, with patients that once required amputation now routinely managed with limb salvage, giving more options to the patient and surgical team (Russell

Esposito et al., 2017). Unfortunately, it is difficult to predict which patients will thrive after surgery and rehabilitation, or whom despite initial attempts to salvage the limb will inevitably proceed with a delayed amputation due to complications such as infection, non-union, chronic pain or limitations in function (Russell Esposito et al., 2017). In a study of 569 people that had undergone limb salvage or amputation, Boose et al found that severe levels of disability were still present 2 and 7-years post-injury (Bosse et al., 2002). Issues such as continued activity limitation, weakness and pain are considered to be the three primary factors that play a role in a patient's decision to abandon the limb salvage pathway and undergo a late amputation of the limb (Bedigrew et al., 2014). The use of an external bracing device such as an AFO, may be the only option for managing complex pain and restricted mobility in those patients that decline amputation or where amputation is not a viable option.

Figure 1.4 Thermoplastic Swedish Leaf Spring AFO

From *massonshealthcare.com.au,* n.d. (https://uploads-ssl.webflow.com/5e38a47f18e5f9a2de23959c/5ee199cf06d3a8549981de03_90SAFO.jpg). Copyright by Massons Healthcare.

Figure 1.5 Prosthetic limbs

Below Knee Prosthetic used to replace the lower limb following amputation.

From *Ottobockus.com*, n.d. (*https://media.ottobock.com/_web-site/prosthetics/lower-limb/running_system_3s80/images/32017_d3_317546_2177472-169-col-form_free_1_1_teaser_fallback.jpg*). Copyright by 2022 Ottobock.

1.4 Classification of AFOs

1.4.1 Prefabricated AFOs

AFOs are often used to help restore a more normal and safer walking pattern because they can assist in providing lateral stability to the ankle in stance phase, facilitate toe clearance in swing phase and promote heel strike (Rao & Aruin, 2016). AFOs are available in a variety of materials and come as either an off-the-shelf or custom-made orthopaedic device. An off-the-shelf AFO is pre-designed to meet a set range of requirements and is available in a range of standardised sizes and shapes to best fit the wearer. AFOs can also be manufactured from different materials such as polypropylene plastic, carbon fibre laminate or carbon fibre. Practitioners then select the appropriate device for patients based on the treatment objectives that they are trying to achieve such as improve ambulation, balance or stability (Holtkamp et al., 2017).

1.4.2 Custom-made AFO's

Custom-made AFOs are designed and tailored to a user's specific needs and physiology and when an off-the-shelf AFO does not fit correctly or meet the specific functional requirements of the user (Holtkamp et al., 2017). Due to the diverse population of users that require AFOs, custom-made designs can include a range of materials that alter the flexibility/stiffness of the device, and therefore the amount of assistance that the brace provides (Totah et al., 2017).

Figure 1.6 Custom-made hinged Ankle-Foot-Orthosis

Custom-Made Ankle-Foot-Orthosis with a hinged ankle joint to allow for some dorsiflexion.

From customorthotic.ca./ankle-foot-orthosis/ by Custom Orthotic Design, n.d. (https://www.customorthotic.ca/wp-content/uploads/2021/07/Hinged-AFO.png). Copyright 2021 Custom Orthotic Design Group.

In recent years, carbon fibre has been utilised to produce custom AFOs that hold spring-like properties, which potentially enable the storage of energy at the beginning of stance phase and return energy at the end of the stance phase, helping to reduce the need for compensation during gait (Bregman et al., 2012). The successful use of carbon fibre and advancement in prosthetic design and technology for patients who have undergone amputation, has greatly influenced the design of AFOs and led to the development of more dynamic, energy storing and return devices which can be

utilised for those with not only neurological deficits, but also those who have experienced HET injuries (Patzkowski, Blanck, et al., 2012).

Figure 1.7 Off-the-shelf Carbon fibre Ankle-Foot Orthosis.

From *Ottobock.com,* n.d. (https://www.ottobock.com/en-us/product/28U23). Copyright by 2022 Ottobock.

1.5 Intrepid Dynamic Exoskeletal Orthosis (IDEO) Brace

The Intrepid Dynamic Exoskeletal Orthosis (IDEO) (Figure 1.8) is a custom-made, energy-storing, carbon fibre orthosis which holds the foot and ankle in an optimal alignment to reduce pain and maximise function. It was developed specifically for trauma patients after limb salvage (Hsu et al., 2017). The altered positioning of the foot and ankle is designed to enable the wearer to perform high-level, dynamic activities such as running, jumping, and other physical activity (Hsu et al., 2017). The IDEO offers an alternative treatment intervention when compared to conventional AFOs by increasing the function of the injured limb and allowing patients to achieve relatively high levels of mobility, whilst simultaneously reducing pain levels (Hill et al., 2016).

Patzkowski et al. (2011) and colleagues observed that those who had undergone amputation of the lower limb, often at the time of injury or shortly thereafter, were often able to return to physical activity quicker than those who had undergone limb salvage. The advancement in the designs and materials used in prosthetic limbs compared to AFO's was hypothesised to be a major contributing factor to this difference in rehabilitation outcomes. In their cohort of military personnel who had

sustained HET to the lower limb, nearly 40% initially requested amputation of the limb due to pain and activity limitations, following the fitting of the IDEO and undergoing a rehabilitation program, 83% of the cohort countermanded the request for amputation (Patzkowski, Owens, et al., 2012b).

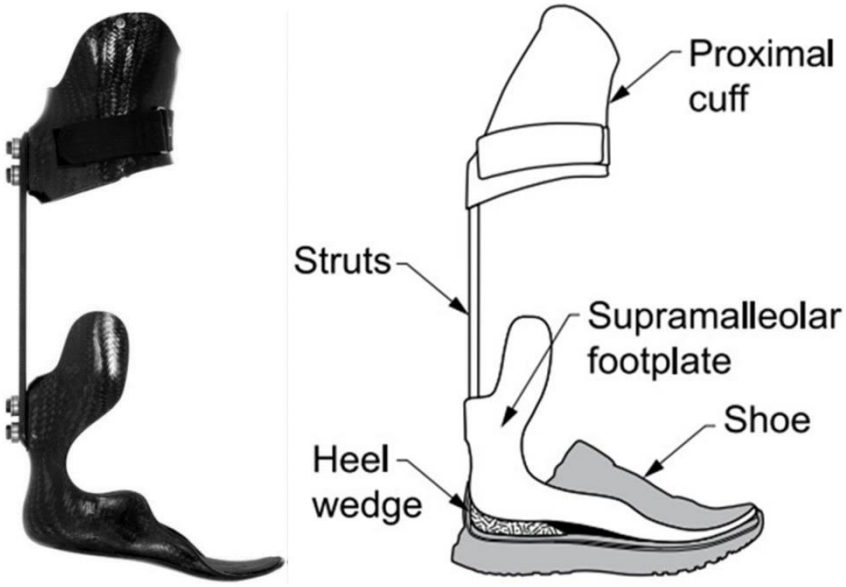

Figure 1.8 IDEO brace and schematic of IDEO brace

From "Gait biomechanics following lower extremity trauma: Amputation vs. reconstruction" by E. Esposito Russell and D.J. Stinner et al (2017), *Gait and Posture, 54,* p. 168 (https://www.ncbi.nlm.nih.gov/pubmed/28314214). Copyright 2017 by Elsevier B.V.

Schematic of the IDEO brace.

From "Effects of altering heel wedge properties on gait with the Intrepid Dynamic Exoskeletal Orthosis" by A.J. Ikeda and J.R Fergason et al (2017), Prosthetics *and Orthotics International, 42(*3), p. 266 (https://www.ncbi.nlm.nih.gov/pubmed/28870146). Copyright 2017 by The International Society for Prosthetics and Orthotics.

The IDEO consists of a full-length rigid foot plate, dynamic posterior strut and a proximal ground reaction cuff (Ikeda et al., 2019). The IDEO is similar in design to a prosthetic running foot, with the use of carbon fibre allowing the brace to store and return energy after loading, that simulates the power of the gastrocnemius and soleus muscles during normal gait (Hsu & Bosse, 2012).

Figure 1.9 Prosthetic carbon running foot

Examples of a prosthetic carbon running foot the "Cheetah Xplore ®" by Össur.

From *Össur.com,* 2022. (https://www.ossur.com/en-us/prosthetics/feet/cheetah-xplore). Copyright 2022 Össur.

The proximal cuff is fashioned in the style of a patellar tendon bearing prosthesis, it has a posterior attachment to the proximal aspect of the carbon fibre strut. The distal supra-malleolar AFO provides medial and lateral support to the ankle joint and foot and attaches to the distal end of the carbon fibre strut. The foot plate design allows for an increase in deflection of load, and storage of energy within the brace. During gait, as the tibia progresses forwards from mid to terminal stance, the foot plate design allows for more increased loading on the forefoot, which during high impact running and agility activities helps to reduce load through the ankle complex (Patzkowski, Blanck, et al., 2012). Bedigrew et al. (2014) evaluated 84 military service members who had sustained lower extremity HET during four weeks of physical therapy without the IDEO, followed by four weeks with it. They found patients improved in all physical performance measures (dynamic balance, timed stair ascent, self-selected walking speed and 20m shuttle run) with the timed stair ascent obtaining statistically significant results (p=0.01). Patient reported outcomes (Short Musculoskeletal Function Assessment, Veterans Rand 12 item health survey, Visual Analog pain scale) also improved whilst using the IDEO. One limitation of the IDEO brace is that it is only accessible to people within the US.

1.6 ReAktiv PDE Orthosis

The Reaktiv PDE orthosis is a passive-dynamic, custom-made, modular, carbon fibre AFO similar in concept to the IDEO. Its design and intended purpose are very similar however, it is more widely accessible to those who are not based within the US. The ReAktiv PDE orthosis consists of a custom-made proximal cuff and full-length rigid SMO foot piece but uses a Posterior Dynamic Element (PDE) Modular Composite Spring System (Fabtec™ systems, USA) that is selected based on the height, weight, activity level and degree of unloading that is needed from the orthosis. Selection of a stiffer PDE is correlated with higher levels of activity and/or unloading. The use of a modular design also allows for select parts of the brace to be redesigned or adjusted to reflect changes in activity levels, changes in leg shape due to muscle gain or loss and/or swelling and oedema, or in the event of damage where single parts can be replaced rather than the need for a complete new orthosis.

Figure 1.10 (a) ReAktiv PDE Orthosis and (b) Runner using a ReAktiv PDE Orthosis

(a) The ReAktiv PDE Orthosis. Image obtained from fabtechsystems.com, 2022. (https://fabtechsystems.com/Reaktiv-Modular-Dynamic-Bracing/). Copyright 2022 Fabtech Systems, LLC.

(b) From "A modified passive-dynamic ankle-foot orthosis: can it prevent amputation and arthrodesis in patients with ankle-foot trauma?" by N. Jonkergouw and L. de Kruijff (2021), *Archives Orthopaedic Trauma Surgery,* p. 2. https://www.ncbi.nlm.nih.gov/pubmed/34319472. Copyright 2021 The Author(s).

There have been a small number of studies from 2011 to 2019 that have looked at the IDEO and its use on Military personnel who sustained HET injuries during military conflict. To date only two studies have been published using a ReAktiv PDE orthosis or Passive Dynamic AFO. There are no studies at present that compare the IDEO and ReAktiv PDE orthosis. A summary of these studies has been included in Table 1.3.

Table 1.3 Summary of Literature on IDEO and ReAktiv PDE orthosis

Author	Year	Sample size	Gender	Median Age	Time since injury	Rehab	Mechanism of trauma	Injury	Symptoms	Outcome and brace used
Patzkowski et al	2011	1	M	29	>2 years	12mths RTR	MVA	Ankle fracture, bone loss	N/A	IDEO, Return to combat duty
Owens et al	2011	10	M	28.8	N/A	9mths RTR	IED, GSW	Fractures to tibial shaft, calc and distal fibular	Reduced rom at ankle and foot	IDEO, Return to high level function
Patzkowski et al	2012	16	M	28	N/A	RTR	10 MVA, 4 blast, 2 GSW	Fractures to ankle and calc, pilon fractures	Post-traumatic arthritis at subtalar joint +/- tibiotalar joint	IDEO 44% return to active duty, 13% to combat
Patzkowski et al	2012	17	M	31.4	>2 years	RTR	4 GSW, 5 MVA, 4 blast, 2 fall	Fractures to ankle and calc, avascular necrosis of talus, nerve, other	N/A	IDEO Return to active duty
Patzkowski et al	2012	18	M	31	N/A	3mths	6 blast, 4 GSW, 4 MVA	Fractures to ankle and tibia, nerve injury	Pain, foot drop	IDEO, Improvement in FSST and TSA
Blair et al	2014	146	M	31.5	>2 years	RTR	85 blast, 31 GSW, 17 MVA	Fractures ankle, tibia, fibula, calc, talus	Pain, functional limitations	IDEO, 51.3% return to duty
Bedigrew et al	2014	84	79 M, 5 F	N/A	>2 years	2mths	MVA, fall	N/A	Mechanical pain, stiffness	IDEO, Improvement in FSST and TSA
Harper et al	2014	13	M	29.4	N/A	N/A	MVA, blast	Fractures ankle, tibia, fibular, tissue loss, neuropathy	Ankle muscle weakness Functional limitations	IDEO, If AFO stiffness decreased by 20% = ankle rom increased, but minimal effect on overall walking performance
Sheean et al	2014	122	M	26	>2 years	RTR	IED	Reconstruction/fusions, transtibial amputations	Disability, loss of ROM, psychosocial issues	IDEO, Poor RTD outcomes following amputation and rearfoot reconstruction. Psychosocial issues higher in limb salvage group.

Haight et al	2015	24	M	29.3	N/A	8mths	5 blast, 3 MVA, 3 GSW, 1 fall	Fractures to ankle, tibia, fibular, foot, soft tissue loss	Reduced ROM and weakness	IDEO users able to walk uphill at speed and strides equivalent to able body controls
Hill et al	2016	624	573 M, 28 F	30	N/A	N/A	HET – not specified	139 ankle, 96 tibia, 91 nerve, 226 other	Pain, functional limitations	80% avoided amputation and elected to continue to use IDEO
Mangan et al	2016	10	M	25.03	>2 years	RTR	HET – not specified	Injury to lower leg, ankle, foot	N/A	IDEO, Amputees walk with a gait closer to non-injured controls than those having limb salvage
Russell-Esposito et al	2017	24	23 M, 1 F	29.4	N/A	7mths	Blast, GSW, MVA	Fractures to ankle, tibia, fibular, neuropathy, tissue loss	Functional limitations	Improved walking speed similar to uninjured controls when in IDEO
Hsu et al	2017	91	81 M, 10 F	36.2	>1 year	RTR	HET – not specified	Severe lower extremity injury	Pain, functional limitations	IDEO, Improved self-efficacy, avoid amputation
Wilken et al	2018	20	M	31.8	>2 years	RTR	Blast, GSW, MVA, fall	N/A	N/A	Improved TSA, SLS, FSST compared to no IDEO use
Ikeda et al	2019	99	M	N/A	>2 years	RTR	Not specified	N/A	Fractures, nerve injury, post-traumatic arthritis	LEFS with IDEO better than without
Mazzone et al	2019	30	28 M, 2 F	30.9	>2 years	RTR	MVA, IED, fall, other	Fractures to ankle, tibia, fibular, foot	Pain	Improved high-level multidirectional mobility using the IDEO
Ladlow et al	2019	65	M	33	>2 years	MDT rehab	IED, GSW, MVA, fall, other	Fractures, nerve damage	Pain, functional limitations, psychosocial issues	Improved function and psychosocial outcomes when using a PDAFO and MDT rehab
Jonkergouw et al	2021	17	13 M, 4 F	38.2	>2 years	MDT rehab	Not specified	Fractures to ankle/calc	Pain, loss of function and mobility	Improved physical performance, reduced pain using ReAktiv PDE orthosis

RTR; Return to Run, RTD; Return to Duty, MVA; Motor Vehicle Accident, GSW; Gun Shot Wound, IED; Improvised Explosive Device, HET; High Energy Trauma, LEFS; Lower Extremity Functional Scale, TSA; Timed Stair Ascent, STS; Sit to Stand test, FSST; Four Square Step Test, IDEO; Intrepid Dynamic Exoskeletal Orthosis, PDAFO; Passive Dynamic Ankle Foot Orthosis, AFO; Ankle Foot Orthosis, MDT; Multi-Disciplinary Team

All studies were conducted predominantly on military personnel who sustained severe HET injuries. Across these studies, the most common causes of trauma were explosions (either IED or blast injuries), MVA, gunshot wounds or high impact falls (Parachute). The sample size for the studies were relatively small ranging from 1 to 146 participants and were predominantly male (n=639) with only 3 studies including females (n=8). The average age range across the studies was 25.7 years. The predominant injuries sustained were fractures to the ankle (n=230), tibia and fibula (n=198), calcaneus and talus (n=185), these were often accompanied with massive soft tissue loss and in some cases nerve damage. As a result of these injuries, the most common symptoms reported in participants were pain, loss of function, reduced range of movement at the ankle, and muscle weakness particularly plantarflexion.

Most studies used participants who had completed the "Return to Run" (RTR) rehabilitation programme as part of their recovery from injury. The RTR program is a dynamic, high intensity rehabilitation program designed to return military patients undergoing limb salvage to high-level physical function (Bedigrew et al., 2014). The time that participants had been in their IDEO brace ranged from 8 weeks to more than 2 years. The time since initial injury varied across all studies but generally appeared to be greater than 2 years. The primary objectives varied from assessing a participant's ability to return to active military duty, comparison of the IDEO to a prosthetic limb and its effects on gait kinematics, the effect of IDEO posterior strut stiffness and the effect this has on gait and the assessment and measure of function through LEFS, single leg stance (SLS), self-selected walking speed, timed stair ascent (TSA), four-square step test (FSST).

Use of the IDEO showed improvements in the FSST, TSA, SLS and multidirectional mobility compared to no brace (Mazzone et al., 2019; Patzkowski, Blanck, et al., 2012; Wilken et al., 2018). Using the IDEO allowed users to walk at speeds and stride lengths equivalent to able bodied controls (Haight et al., 2015; Russell Esposito et al., 2017). There were also reported improvements in both LEFS (Ikeda et al., 2019) and self-efficacy scores (Hsu et al., 2017). Within the studies that focused on military cohorts and a return to duty, five studies reported some or all participants able to return to either active combat duty or a return to duty. In those that "returned to duty" this may not have been in the same role as prior to their injury, and so the physical demands required for the role may also have differed (Blair, 2014; Owens et al., 2011; Patzkowski et al., 2011; Patzkowski, Owens, et al., 2012a).

1.7 Conclusion

HET injuries affecting the ankle and lower limb are complex and have a significant impact on the individuals rate of recovery and long-term physical abilities. Those that have suffered a HET injury and undergone limb salvage typically have worse outcomes than those who have undergone amputation. For those that have sustained a HET injury to the ankle, tibia, fibula, calcaneus or talus and been fitted with a passive dynamic AFO (either IDEO or ReAktiv PDE orthosis), these braces show promise in improving pain (Ikeda et al., 2019) self-efficacy (Hsu et al., 2017) and physical function (Meeker et al., 2022; Patzkowski, Blanck, et al., 2012; Wilken et al., 2018) at times similar to pre-injury levels. The use of these devices warrants further investigation in the general population given that the predominant research to date has been conducted on military cohorts. At present there is limited data available on the use of either the IDEO or the ReAktiv PDE orthosis in the general population who have sustained HET injuries to the ankle.

Chapter 2: Aims

There were two aims of this study, firstly to conduct a case series on the clinical effectiveness of the ReAKtiv PDE orthosis on pain and function for people that had sustained a HET injury to the lower limb. Secondly, to determine the effectiveness of a physiotherapy-led rehabilitation programme to further improve walking speed whilst using the ReAktiv PDE orthosis.

Chapter 3: Methods

3.1 Ethical approval

Ethical approval was obtained from the Auckland University of Technology Ethics Committee (21/137) (**Appendix A**). All participants were provided with a participant information sheet (**Appendix B**) and written informed consent (**Appendix C**) prior to study entry.

3.2 Participants

Patients that had had received a ReAktiv PDE orthosis for a HET injury were recruited from the Bigfoot Podiatry Clinic (Auckland, Aotearoa New Zealand). Those eligible to participate were identified by the practice manager, who then sent the participant information sheet and consent form to potential participants.

3.2.1 Inclusion Criteria

Participants included in the study were those aged 18 years or older, who had received the ReAktiv PDE orthosis as part of their treatment following HET during 2019 - 2021.

3.2.2 Exclusion Criteria

Patients were excluded from the study if they had received the ReAktiv PDE orthosis for management of a congenital ankle injury such as talipes-equinovarus, had any neuromuscular conditions or history of falls.

3.2.3 Intervention

Patients were fitted with a custom-made ReAktiv PDE orthosis following referral from an Orthopaedic surgeon for the orthosis. The initial appointment consisted of a thorough taking of the patient history and all treatments to date (including surgeries) to the affected limb. The patients' chief complaints such as pain, loss of function, restricted mobility and effects on day-to-day life were discussed.

Physical assessment looked at the available range of motion in the foot (talonavicular joint, mid-tarsal joint and 1st Metatarsophalangeal joint) and ankle (subtalar joint and talocrural joint) both non-weightbearing and weightbearing, alignment of the lower limb, areas of scarring or skin grafts that remain sensitive to touch, gait assessment (including a 2MWT) and current compensations to manage pain or restriction of movement. Footwear was also discussed as some participants required

specific footwear for work and some styles of footwear are not compatible with the orthosis due to style/fit. Outcome measures (PDQ and PSEQ) were recorded at this session to ascertain a baseline measure of pain prior to receiving the orthosis.

An above knee fibreglass cast was taken of the affected leg. With the patient sitting on a chair with the knee flexed at 90° and the foot positioned on an EVA wedge with an angle of approximately 10° to simulate vertical shoe angle (VSA). The ankle was positioned so that the tibia was vertical to the knee, whilst maintaining 90° of flexion. Any subtalar joint valgus correction that could be applied was done manually, prior to casting so that the alignment of the foot, ankle and knee was optimal. Measurements of the fibular length, circumference of the calf and ankle, and foot length were also recorded in millimetres (mm).

A prescription for the orthosis indicating the desired style, design, strut stiffness, closure system, strength of lamination required, and activity level of wearer was sent with a scanned cast of the leg (using TechMed™ 3D software) to Masson's Healthcare in Melbourne, Australia for fabrication.
On receipt of the final orthosis the patient was contacted for a fitting, where the orthosis was checked for fit primarily at the proximal calf piece to ensure there was a snug fit to the leg, and at the foot piece to ensure it would fit into footwear. The orthosis was also checked to ensure there was adequate padding and no noticeable discomfort on any bony prominences or scar tissue. Patients were then instructed on how to don/doff the orthosis and to fit it into footwear. They then progressed to walking in the orthosis in the clinic with the instructions to "Walk with your knee slightly flexed, with pressure against the shin. Imagine you are walking more on the ball of your foot rather than heel-toe. There will be a "sweet-spot" in this position which is the optimal position of the orthosis where you should feel supported and pain in the ankle should be minimal".

Any questions were answered, patients were then rebooked for a review 2 weeks later for another check prior to beginning the rehabilitation programme. During this time a referral was made to the lead Physiotherapist for the "ReAktivate rehabilitation program". Upon receiving the referral, the physiotherapist would make the appropriate requests for funding from ACC (if applicable) and contact the patient directly to discuss location and times for rehab sessions. At the review, if there were any changes or adjustments that needed to be made to the orthosis such as additional padding or trimming of the orthosis for comfort or footwear, it was done at the time of the appointment. Rehabilitation was initially conducted at Crossfit North Harbour due to its large, spacious indoor area which included stairs, stationary bikes, numerous free weights and the ability to have exclusive use

of it for the rehabilitation sessions. The initial session consisted of musculoskeletal screening, assessment of any existing compensation patterns such as reduced stance time on the affected leg, uneven stride length, hip hiking, leg circumduction or knee hyperextension. Rerecording of patient outcomes (PDQ, PSEQ, LEFS) and the 2MWT, as well as baseline measure of function tests TSA, SLB and FSST was also performed. Establishment of goals and expectations for the rehab programme and an initial home exercise plan was started focusing on mobility exercises to manage adaptations to new loading patterns when wearing the orthosis. Any issues they were having with the orthosis were discussed and passed on to the Podiatrist if required. Subsequent rehab sessions were done once a week for six-weeks with each session tailored to the individual's ability and goals. Session two focussed on sagittal plane movements and both strength and balance, gait retraining, progression of home exercise programme combining mobility, strength and balance. Session three focussed on coronal plane movements, progression of exercises and gait retraining (as appropriate) to incorporate more directions. Session four focussed on multidirectional and combined movements, progression of exercises to incorporate all dimensions of movement. Session five moved onto more dynamic/plyometric exercises such as early stage jumping, skipping, return to running (if appropriate background strength achieved and in line with participant goals). If not part of participants goals, then focus was more on progression of previous sessions and focus on consistency of movements rather than intensity. At the final session all outcome measures were rerecorded to see any changes or improvements.

3.3 Extraction of Information

Following informed consent, the participant's clinical records were accessed by the practice manager, who extracted information including age (years), gender (male, female, other), ethnicity (Pakeha/European, Māori, Pacific Island, Asian), injury (type of injury, classification) and surgical history.

3.4 Outcomes

Outcomes were assessed at baseline (prior to receiving the orthosis), at two-weeks (the commencement of the rehabilitation programme), and at eight-weeks (the conclusion of the rehabilitation programme). Patient-reported outcomes were PDQ, PSEQ and LEFS. Measures of lower limb function were two-minute walk test, four-square step test, timed stair ascent and single leg balance.

3.4.1 Pain

Pain was assessed using two patient reported outcome measures; the Pain Disability Questionnaire (PDQ) which measures disability and function and is based on previous clinical research which indicates there is a link between biopsychosocial factors and the development of pain and disability (Giordano et al., 2012). (**Appendix D)**. The questionnaire consists of 15 questions, with scores ranging from 0 (No problems) to 10 (Greatly interferes) and records a score out of 150, the higher the total score the more interference pain has on their life. It has excellent test-retest reliability (Anagnostis et al., 2004).

The Pain Self-Efficacy Questionnaire (PSEQ) is one of the most frequently used self-efficacy questionnaires in a clinical setting for musculoskeletal disorders (Dube et al., 2021) (**Appendix E)**. It consists of 10 questions aimed at assessing the confidence of people with persistent pain to achieve different activities despite their pain. Each question records a score of 0 (not at all confident) and 6 (completely confident), with a total score out of 60. A high score indicates stronger self-efficacy beliefs. The PSEQ has excellent test-retest reliability (Dube et al., 2021).

3.4.2 Function

Lower limb function was assessed using the Lower Extremity Functional Score (LEFS) (Binkley et al., 1999) (**Appendix F)**. The LEFS has been shown to be a valid and reliable self-reported questionnaire (Ikeda et al., 2019). It consists of 20 common activities of daily living, which patients report on the perceived ease or difficulty performing. The highest score is 80, indicating no difficulty and the lowest score 0, indicating extreme difficulty or inability to perform activities.

3.4.3 Two Minute Walk Test

Functional exercise capacity was measured using the two-minute walk test (2MWT) due to its use as a reliable and valid measure for those with lower extremity injuries and/or amputations (Newton et al., 2016). In previous research it achieved comparable results to the 12-minute walk test upon which it is based, and is therefore an appropriate test choice for early-stage rehabilitation, especially for those whom 12 minutes of walking may cause excessive loading and pain to an injured limb (Newton et al., 2016).

The 2MWT was conducted on a level surface with two markings 20m apart. Participants were given written and verbal instructions. Participants were instructed to walk as quickly as possible, covering as much distance as possible within two minutes. Participants could stop and rest during the test if

required and were allowed to walk using any usual mobility aids. Timing was recorded from the commencement of the verbal instruction “three, two, one, go” and concluded at two minutes with the instruction “stop now”. The distance covered was then measured to the nearest metre and recorded.

3.4.4 Single-Leg Balance Test

Balance was measured using the Single-Leg Balance (SLB) test a commonly used test to assess standing balance, more often in older adults to assess falls risk and is considered to have good test-retest reliability (Bohannon & Tudini, 2018). The SLB has been used by previous studies assessing the use of the IDEO brace (Mazzone et al., 2019). The test began on the countdown “three, two, one, go” where participants would be required to stand on one leg for as long as they could. Participants must have the non-weightbearing limb off the ground but could position the limb at their discretion for balance, the limb needed to remain a minimum of 15cm (approximately) off the ground. The time was stopped as soon as the non-weightbearing foot touched the ground, and the number of seconds recorded. Participants were able to rest as needed in-between tests, but for no longer than two minutes. Participants were given a maximum of three attempts on each leg, the time was measured in seconds for their braced leg and the best of the three attempts recorded for analysis. An increase in time was indicative of improvement in performance. Participants were given both written and verbal instructions.

3.4.5 Timed Stair Ascent

Lower limb mobility and power was assessed using the Timed Stair Ascent (TSA) (Wilken et al., 2018). The TSA has been shown to have good test-retest reliability (Northgraves et al., 2016). Participants ascended a flight of nine steps as quickly as possible while touching every step with at least one of their feet. Time was recorded in seconds and began on the word “go” and stopped when both feet were on the top step. Participants were given three attempts, with the fastest of these recorded. The TSA was only recorded whilst in the ReAktiv PDE orthosis and at the commencement and conclusion of the rehabilitation programme.

3.4.6 Four-Square Step Test

The Four-Square Step Test (FSST) was used to assess dynamic balance and mobility due to its high interrater and test-retest reliability (Sawers et al., 2020). The FSST was conducted using four 2.5cm diameter plastic poles arranged in a cross-shape on a level surface. Participants began in the left rear square and stepped over each object as they moved forwards, sidestepped to the right, backwards

and sidestepped to the left, before reversing the pattern finishing where they started in the left rear square. Participants were instructed to move as quickly as possible, while facing in the same direction and always keeping one foot on the floor. Timing was started when the participants foot was placed in the box in front of them and stopped when both feet were placed in the square where they began. Participants were given three attempts, with the fastest of these recorded. Participants were allowed to rest in between attempts. The FSST was conducted at the commencement and conclusion of the rehabilitation programme.

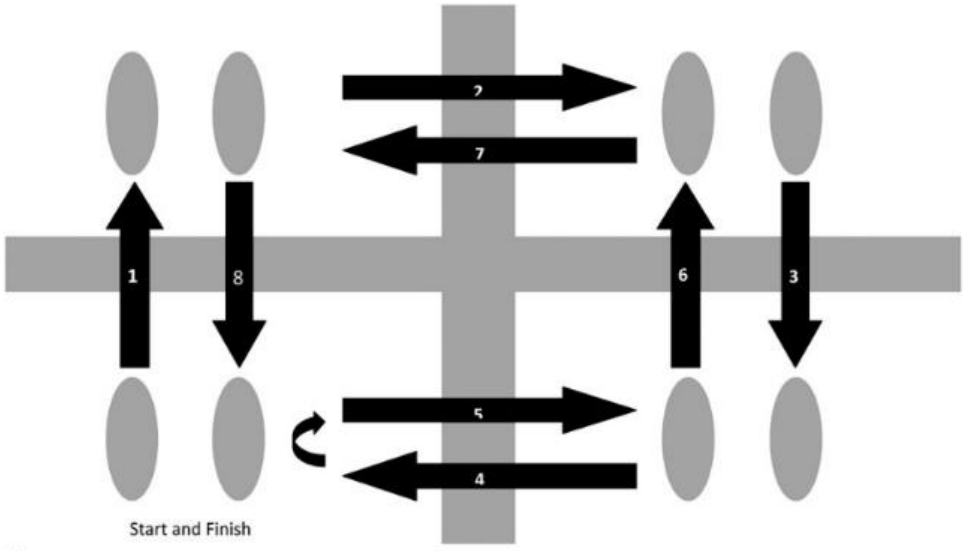

Figure 1.11 Four-square step test

Schematic representation of the four-square step test

From "Comparative effect of Orthosis Design on Functional Performance" by J.C. Patzkowski and R.V. Blanck, 2012, *The Journal of Bone and Joint Surgery*, (94), p. 510. Copyright 2012 by The Journal of Bone and Joint Surgery.

3.5 Data Analysis

Clinical and demographic data were presented in a table with side-by-side results of each of the functional outcomes pre and post intervention for each participant, as well as bar graphs for the functional outcomes to show change over time.

Chapter 4: Results

4.1 Introduction

Five potential participants were identified by the clinic practice manager as those who had received the ReAktiv PDE orthosis as part of their treatment. These participants were sent an invitation to participate in the research study initially via email. After four weeks, if there had been no response, a second follow up invitation to participate in the research was sent via mail. Of the five potential participants initially identified, three consented to participate (Figure 4.1).

Figure 1.12 Schematic drawing of recruitment process

4.2 Participant characteristics

Participant characteristics are featured below in Table 1.4.

Table 1.4 Participant Characteristics

Age	Gender	Ethnicity	Injury	Classification	Surgical history	Post-surgical complications
43	Male	Pakeha/European	MVA – Motorbike	Severe Weber A fracture + dislocation of ankle	ORIF, bone grafts, arthroscope (to remove osteophytes)	Spontaneous STJ fusion, post-traumatic arthritis
54	Male	Pakeha/European	Fall from height	Osteochondral injury medial talar dome and moderate partial tear deltoid ligament. Medullary infarction posterior distal tibia, chronic partial tear anterior syndesmotic ligament	Arthroscope, retrograde drilling of medial talus	
50	Male	Pakeha/European	MVA – Motorbike	Talus fracture (undiagnosed) subsequently developed avascular necrosis and post-traumatic arthritis	ORIF, ankle fusion, bone grafting at talonavicular joint	Broken metalware and non-union of the ankle, post-traumatic arthritis
MVA; motor vehicle accident, ORIF: open reduction internal fixation						

4.3 Measures of function

4.3.1 Pain Self-Efficacy Questionnaire

Table 1.5 Pain self-efficacy questionnaire results recorded at baseline and six-weeks post-intervention

Participant	Baseline	Six-weeks
#1	N/A	N/A
#2	42/60	47/60
#3	N/A	N/A
N/A: Data not available		

4.3.2 Pain Disability Questionnaire

Table 1.6 Pain Disability questionnaire results recorded at baseline and six-weeks post-intervention

Participant	Baseline	Six-weeks
#1	N/A	N/A
#2	67/150	63/150
#3	36/150	N/A
N/A: Data not available		

4.3.3 Lower Extremity Functional Scale

Table 1.7 LEFS score recorded at baseline prior to receiving the brace and two-weeks and six-weeks post intervention

Participant	Baseline	Two-weeks	Six-weeks
#1	50/80	61/80	75/80
#2	32/80	46/80	39/80
#3	45/80	N/A	N/A
N/A: Data not available			

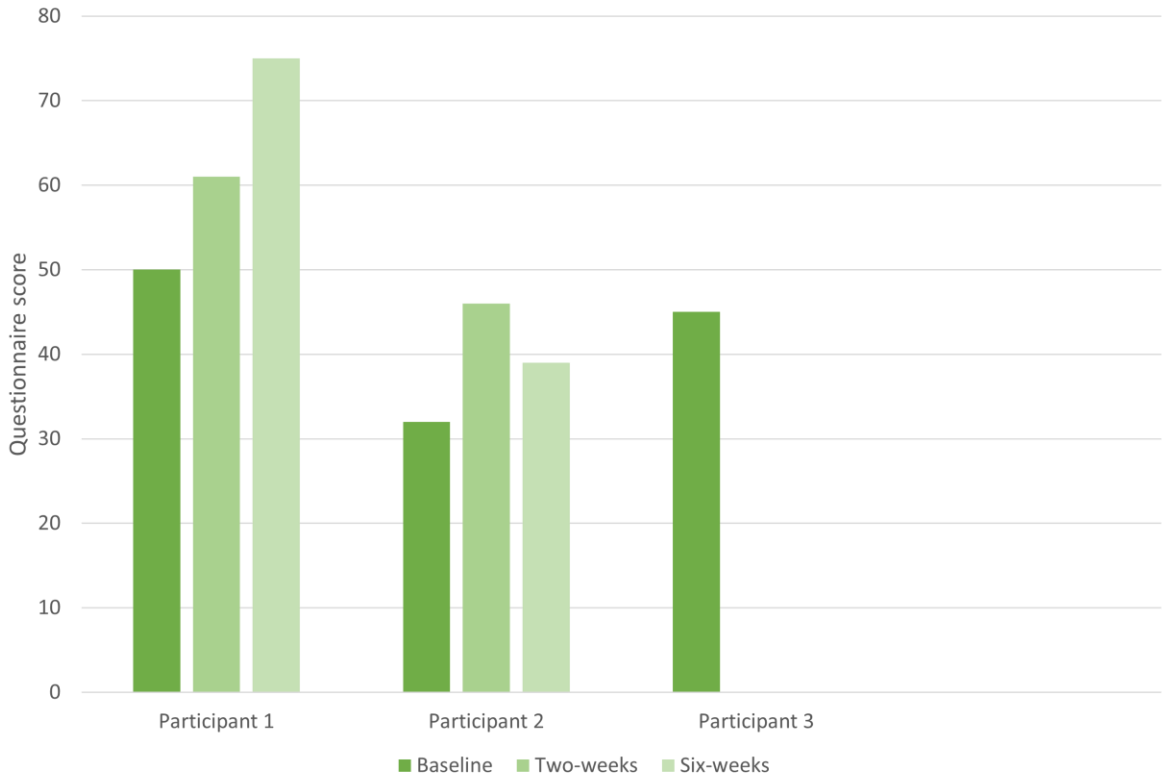

Figure 1.13 Lower Extremity Functional Scale

Lower Extremity Functional Scale (LEFS) indicating the scores obtained for the 3 participants at baseline, two-weeks and six-weeks.

4.3.4 Two-Minute Walk Test (2MWT)

Table 1.8 2MWT recorded at baseline with no brace and at two-weeks and six-weeks post receiving brace

Case	Baseline (No brace)	Two-weeks (with brace)	Six-weeks (with brace)
#1	220m	255m	300m
#2	235m	160m	249m
#3	114m	130m	N/A
N/A: Data not available			

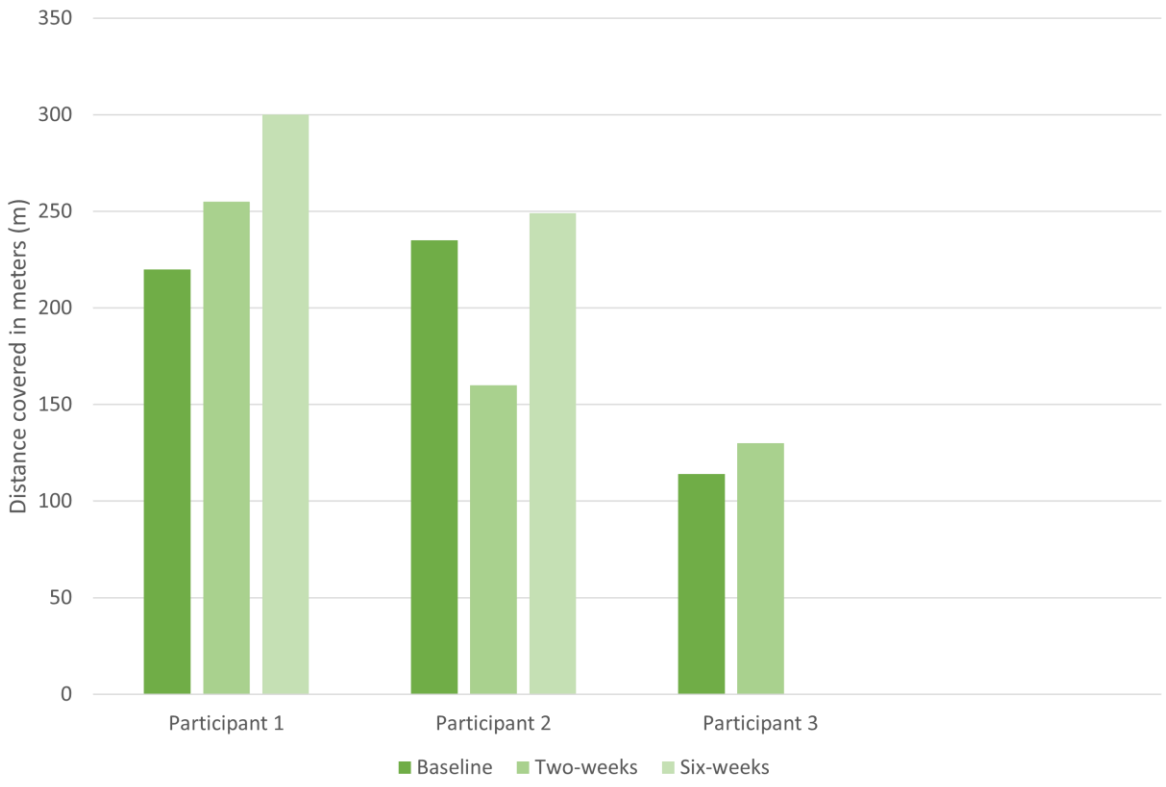

Figure 1.14 Two-minute walk test

Two-Minute Walk test indicating the scores obtained for the 3 cases at baseline, two-weeks and six-weeks. The distance covered is measured in meters (m).

4.3.5 Four-square step test (FSST)

Table 1.9 FSST recorded at two-weeks and six-weeks post-receiving the brace

Participant	Two-weeks (with brace)	Six-weeks (with brace)
#1	6.0s	4.0s
#2	9.0s	8.53s
#3	7.4s	N/A
N/A: Data not available		

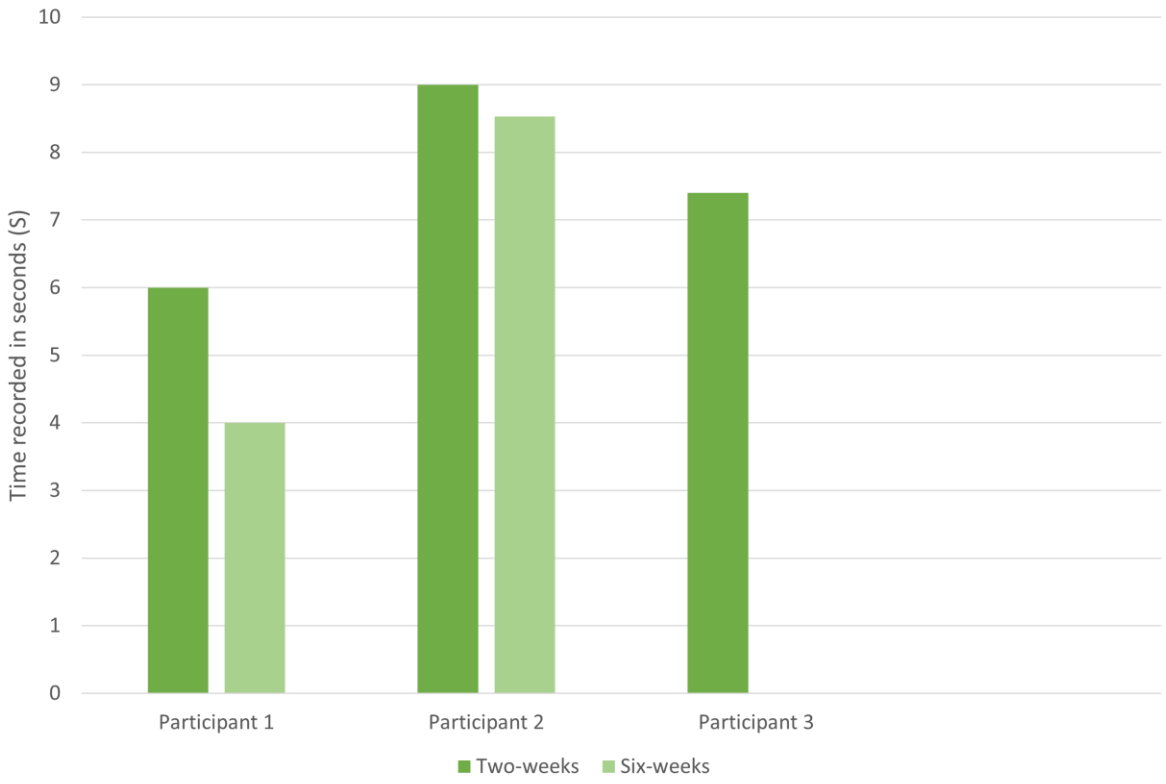

Figure 1.15 Four-square step test

Four-square step test indicating the scores obtained by the 3 cases at two-weeks and six-weeks. Time was measured in seconds (s).

4.3.6 Timed Stair Ascent (TSA)

Table 1.10 TSA measured using the brace at two-weeks and six-weeks

Participant	Two-weeks (with brace)	Six-weeks (with brace)
#1	6.0s	4.8s
#2	8.0s	6.56s
#3	13.3s	N/A
N/A: Data not available		

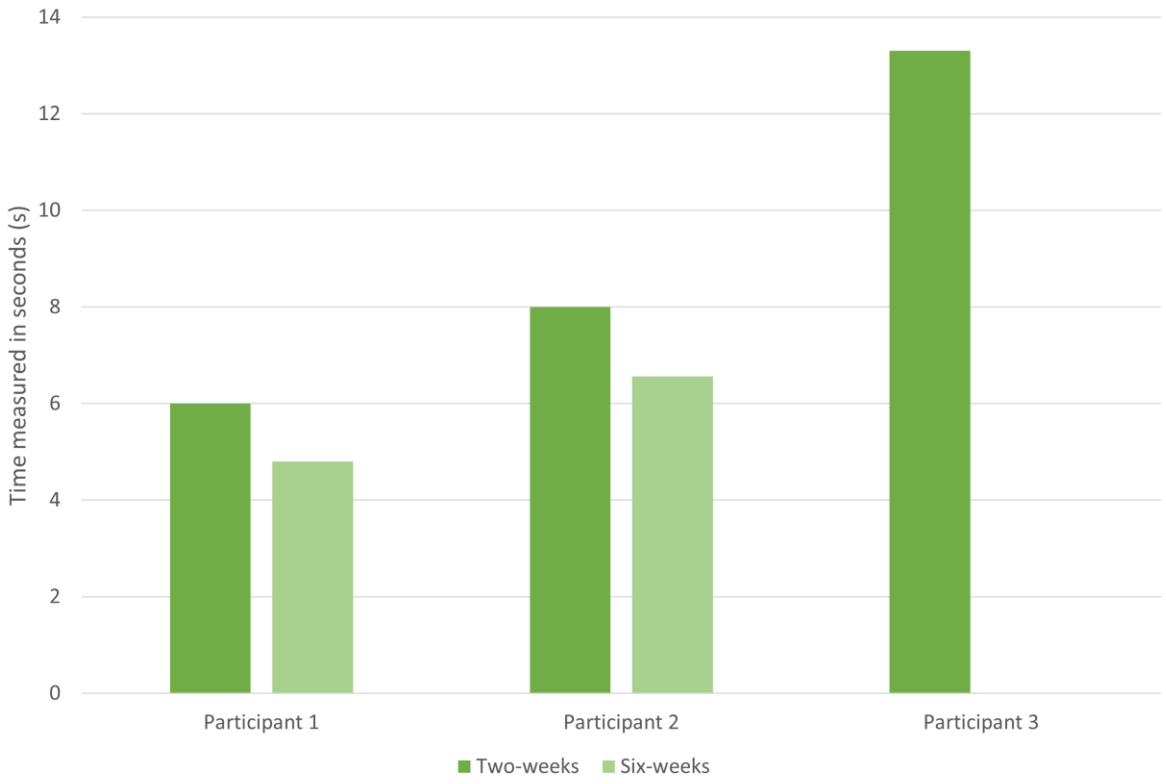

Figure 1.16 Timed Stair Ascent

Timed Stair Ascent indicating the scores obtained by the 3 cases at two-weeks and six-weeks. Time was measured in seconds (s).

4.3.7 Single Leg Balance (SLB)

Table 1.11 SLB measured using the brace and two-weeks and six-weeks

Case	Two-weeks (with brace)	Six-weeks (with brace)
#1	14.0s	46.0s
#2	3.0s	4.0s
#3	4.7s	N/A
N/A: Data not available		

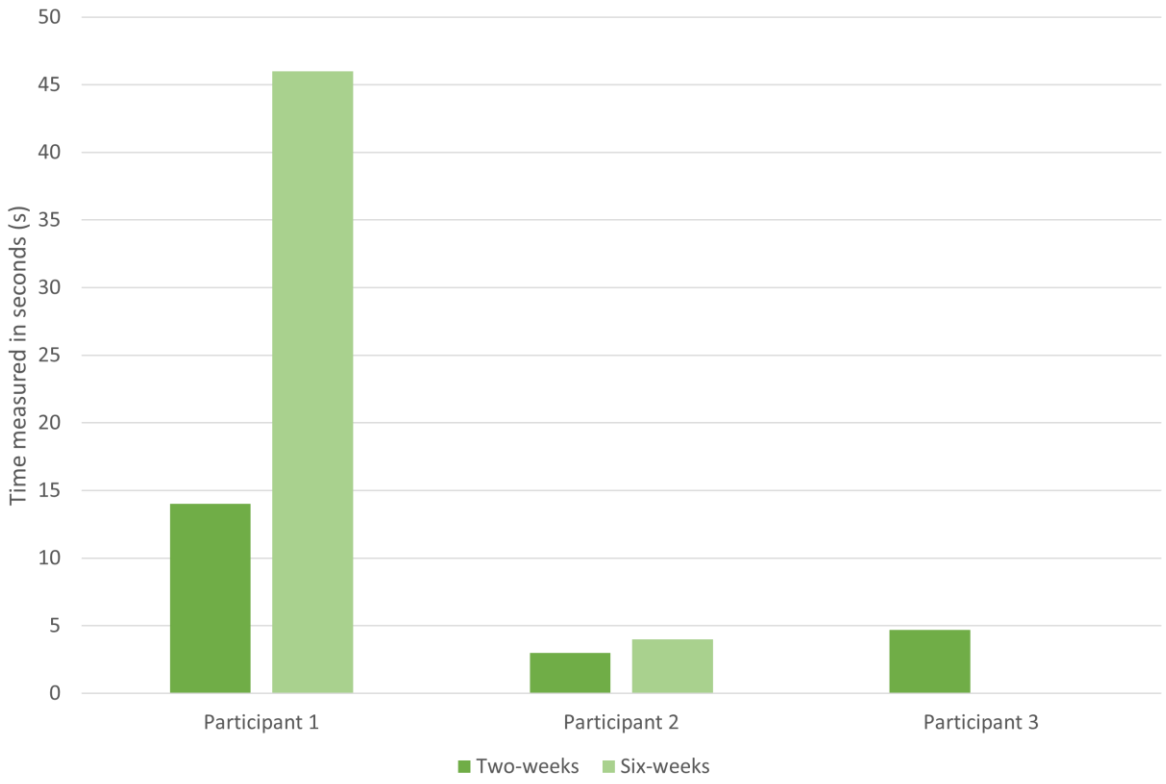

Figure 1.17 Single Leg Balance

Single Leg Balance indicating the scores obtained by the 3 cases at two-weeks and six-weeks. Time was measured in seconds (s).

Chapter 5: Discussion

5.1 Participants

The participants included in this study had sustained unilateral HET injury via MVA or falls that caused severe damage to the foot, ankle and lower limb. These injuries were associated with a range of complications including non-union, subchondral cysts and post-traumatic arthritis. These post-injury complications are commonly associated with HET injuries (Briet et al., 2017). The primary complaint for all participants was pain in the ankle when weightbearing and with activity, however this was only measured later in the study utilising the Pain and Disability Questionnaire (PDQ) and Pain Self-Efficacy Questionnaire (PSEQ) on one participant at both baseline and completion of the rehabilitation. The next most common complaint was reduced mobility due to stiffness and loss of movement at the ankle. These symptoms have been reported in other HET cohorts, with 80% of people reporting pain and 64% reporting stiffness in the injured limb (Bedigrew et al., 2014). Results from this study has shown that for a small number of participants the use of the ReAktiv PDE orthosis could help to improve pain levels during day-to-day functional activities, as well as the confidence to do these activities despite pain.

5.2 Pain

Improvements in pain were seen in the one participant with full-data at the six-week follow up. The intended design of the orthosis allows for a reduced amount of weight and force through the ankle joint as it transfers the load more anteriorly onto the tibia and forefoot (Owens et al., 2011). This alteration of force may be a factor in the reduction in pain observed. The material properties and stiffness of the orthosis provides stability and alignment to the weakened and damage joint structures, whilst also helping with generation of momentum and propulsion through its storage and energy return in gait. This combination of design and materials allows wearers to return to higher levels of physical function and activity whilst reducing further damage to the ankle and helping to improve pain levels and mobility.

5.3 Function

In this small study, the LEFS improved with the use of the ReAktiv orthosis over the six-week period for one participant. There was variation in the magnitude of this improvement, with some participants exceeding the minimally important difference of the LEFS (9 to 12 points) (Binkley et al., 1999). These improvements for this participant are similar to the results obtained by Ikeda et al.

(2019) who reported a 26-point difference in their study on 99 participants when walking with an IDEO brace, compared to participants without a brace.

Dingemans et al. (2017) conducted a study on the LEFS questionnaire on 1,014 healthy visitors and staff at 4 hospitals. The median score across this healthy population was 76. This suggests that subjects with HET injuries can return to levels of function consistent with healthy individuals who had not sustained a HET injury. This is of important clinical significance as it indicates that for certain individuals, the use of a passive-dynamic AFO (IDEO or ReAktiv PDE Orthosis) may potentially enable them to return to a level of pre-injury functionality. Improvements of this magnitude were seen at two-weeks for most participants, however, were not always maintained at six-weeks. This may reflect the complexity of HET injuries and their long-standing impact on participants (Chong et al., 2021). Baseline scores for the LEFS ranged from 32-50 points indicative of reduced function. This is consistent with previous research by Chong et al. (2021) who looked at LEFS post ankle fracture fixation, where median scores recorded at 2 years and 5 years post-surgery were 71 and 66 respectively, indicating that there will be a potential further reduction in functional outcome following ankle fracture fixation over time.

5.3.1 Two-Minute Walk Test

Improvements in walking distance were seen in the 2MWT when wearing the ReAktiv PDE orthosis compared to not wearing the orthosis. For the 2 participants that completed the rehabilitation programme, the six-week 2MWT results exceeded the normative data for age-matched individuals as reported by Bohannon et al. (2015). These improvements are consistent with other studies reporting improvements in walking distance. Jonkergouw et al. (2021) reported a significant increase in six-minute walk test scores in a military cohort that had sustained HET injuries, after six weeks of using the ReAktiv PDE orthosis. Ladlow et al. (2019) reported significant improvements in walking distance at 12-months following the provision of a passive dynamic AFO. The increases in walking distance may be attributed to the improvements in pain seen in these cohorts. In a study by Faraji (2022) looking at pain associated with combat related lower limb injuries leading to foot and ankle disorders, ankle pain accounted for 72.9% of reported pain in a cohort of 809 war veterans. With abnormalities and compensation in gait and joint loading occurring over time due to the injuries sustained in combat, it was hypothesised that this further contributed to ongoing joint pain and degeneration. Hsu et al. (2019) also reported decreased walking speed, step length and cadence, as well as trunk asymmetry in patients following ankle fractures.

5.3.2 Four Square Step Test

There was improvement seen in the FSST over the duration of the rehabilitation programme. These results are consistent with Bedigrew et al. (2014) who reported a reduction in FSST time at eight-weeks after the provision of an IDEO brace. Normative data for the FSST in healthy populations ranges from 6.3 to 6.9 seconds (Torlak & Moffat, 2014). This suggests that the improvements seen in the participants from this study are consistent with healthy people, without a history of HET injuries. These improvements in the FSST could be attributed to the design of the orthosis and its ability to allow loading of the device through more pressure tolerant areas of the leg, such as the proximal cuff or the medial and lateral support gained at the foot and ankle from the SMO foot piece (Ikeda et al., 2019).

5.3.3 Timed Stair Ascent

Improvements in the timed stair ascent at follow-up were consistent with previous work by Bedigrew et al. (2014). These improvements may be due to a reduction in pain levels and improvement in ankle stability, as well as assistance with propulsion whilst using the ReAktiv PDE orthosis. In a study by Bedigrew et al. (2014) whose cohort of 31 IDEO users recorded times of 6.2 seconds at commencement of rehabilitation and 4.2 seconds at week 8, indicate an improvement in stair ascent whilst using the IDEO brace. When comparing follow-up scores to healthy populations, Nightingale et al. (2014) reported that the average time to ascend 10 steps was 0.59 seconds per/step. Participants in this study ranged from 0.66-0.88 seconds per/step at initial testing and 0.53-0.72 seconds per/step at follow-up, suggesting that some participants reached a level of function similar to healthy cohorts.

5.3.4 Single-Leg Balance

The improvements in SLB time after six-weeks are a novel finding. Mazzone et al. (2019) reported that an IDEO brace did not improve SLB time at six-weeks in a naval cohort. This could be attributed to the injury sustained, the shape of the brace foot piece, footwear worn during testing, brace stiffness and this not being considered a priority during rehabilitation in this cohort. During the 6-week rehabilitation programme with the ReAktiv PDE orthosis emphasis was made on practicing SLB in the orthosis to help contribute to an improvement in overall functional outcomes.

A decrease in ankle dorsiflexion following trauma or fracture has previously been shown to affect dynamic postural control in individuals (Albin et al., 2019). This loss of movement at the ankle after

traumatic injury, reduces the ability of the foot to make corrections and adjustments, and the consequences of this can include a reduced gait speed and poorer functional outcomes such as balance (Albin et al., 2019). In a study by Hsu et al. (2019) those who had sustained an ankle fracture were more likely to exhibit greater trunk movement asymmetry (in a vertical direction), and reduced walking speed, step length and cadence compared to healthy individuals. This reduction in walking speed, cadence and smaller step lengths can contribute to a higher risk of falls and a decline in mobility (Papp et al., 2021).

5.4 Limitations

This study is not without limitations. There was a very small pool of participants that were eligible for this study. Additionally, not all completed the rehabilitation program after the orthosis was dispensed affecting some of the data that was able to be collected, and therefore making it difficult to interpret whether the rehabilitation programme had any additional impact on the outcomes measured whilst using the ReAktiv PDE orthosis. The time required off work and ease of access to the location where the rehabilitation was conducted was a barrier for some participants who relied on taxis or public transport for travel. Government forced lockdowns related to the COVID-19 response also meant some aspects of the participants rehabilitation sessions were conducted virtually rather than face to face. Some participants were also happy with the improvements that they had made and noted in their day-to-day activities, that they did not feel the need to participate further in the rehabilitation programme. Like previous studies (Blair et al., 2014; Owens et al., 2011; Patzkowski et al., 2011; Patzkowski, Owens, et al., 2012b; Wilken et al., 2018) using similar orthoses, our cohort also consisted of only males, with no females in the practice database eligible for inclusion.

Aesthetics of the orthoses could be a possible issue for future users, such as mentioned in previous research by Phillips et al. (2011) who looked at the views of AFO users with Charcot-Marie-Tooth disease. They found that males and females had quite different views on the most important characteristics of AFO's and therefore whether this correlated with compliance in wearing the device. For males the biggest disadvantage of using AFO's was the lack of mobility in tight spaces, which affected the functional use of an AFO, followed by discomfort, and restriction of movement and lack of flexibility. In contrast, for females some of the biggest disadvantages were more related to a lack of AFO design choice e.g., not fit for purpose, restriction of shoe options due to fit or having to wear prescription shoes/boots, drawing attention to the disability, as well as the weight of the brace and poor fit.

Chapter 6: Future Directions and implications for clinical practice

6.1 Future directions

The improvements to pain and function seen with the ReAktiv PDE orthosis for people with HET injuries, warrants further exploration into effects in other populations with midfoot and /or rearfoot pathology. Potential groups to explore include those with congenital conditions such as Talipes Equinovarus (clubfoot) and long-term conditions such as ankle arthritis which result in significant structural changes to the rearfoot.

The majority of studies investigating the effects of the IDEO brace and ReAktiv PDE orthosis have reported improvements in patient-reported outcomes and global measures of lower limb function, however, the mechanism behind these improvements requires further investigation. Lab-based biomechanical studies evaluating changes in force and lower limb kinematics may help to improve understanding of these mechanisms. Tracking the LEFS, PDQ and PSEQ measures in participants that received the brace at 2 and 5-years post-fitting would provide an indication of the orthoses long-term effectiveness, given that previous research has shown that there will be a potential reduction in function over time for those who have undergone ankle fracture fixation. This information will help make clinical decision-making more accurate around the suitability of the ReAktiv PDE orthosis as a treatment intervention for potential patients.

The high cost of the IDEO/ReAktiv PDE orthosis due to its size, complexity and design mean that it is not financially accessible for all prospective patients, such as those not eligible for funding. The cost of the ReAktiv PDE orthosis ($4500 NZD) and associated rehabilitation ($1100 NZD) may be a barrier for prospective users. All participants in this study had their orthosis funded though Accident Compensation Corporation (ACC). Additionally, a significant portion of the rehabilitation programme was also funded by ACC. With no easily accessible local manufacturing in NZ for these orthosis and reliance on overseas facilities, this increases the overall cost of the brace with the additional charges such as importation and duty costs, shipping and currency rates further impacting the overall cost and accessibility to the orthosis. A potential solution to this would be to train existing, locally based, skilled carbon fibre fabricators in how to manufacture the ReAktiv PDE orthosis. In New Zealand we have a number of skilled fabrication facilities that already use carbon fibre for manufacturing of boats/yachts, movie special effects and costumes and other custom work. It is possible that with

some additional training, people in this industry could be able to locally produce the ReAktiv PDE orthosis.

The design and material choices such as 3D printing of the orthosis, where the orthosis could be more highly customised for the patient's comfort, activity level, age, weight, gender, occupation, pain and injury is also an avenue that warrants further investigation. In a recent systematic review comparing 3D printed AFO's to traditional AFO's for foot drop, they found that the biomechanical effects and the material properties were found to be very similar. The mechanical stiffness and energy dissipation of the 3D printed AFO's were similar to that found in pre-fabricated carbon fibre AFO's (Wojciechowski et al., 2019). Whether 3D printing would result in the same success as custom made carbon fibre braces such as the IDEO/ReAktiv PDE orthosis is an area worthy of future investigation.

6.2 Implications for clinical practice

Unlike the IDEO, the fabrication of the ReAktiv PDE orthosis can be manufactured at any orthosis/prosthesis facility by appropriately skilled and trained Orthotists/Technicians. There are no restrictions as to where the location of these facilities can be. Although this provides greater access to the orthosis for both prescribers and users, in New Zealand we currently have a severe labour shortage of qualified Orthotists, which impacts the accessibility to the orthosis. According to a publication by the Health Workforce Advisory Committee (2001) on the New Zealand Health Workforce, as per the 1996 census there were only 135 Orthotists and/or Prosthetists working across the private and public sector. There is also no current education or training establishment for this profession in New Zealand. As a result of this labour shortage, we lack appropriately skilled manufacturers in New Zealand to be able to produce these types of devices locally. Instead, we rely on manufacturers in Australia and overseas to be able to provide these types of custom-made devices for us.

The consequences of a chronic injury are multi-factorial and affect both participation in the labour market but also productivity. In the "Fit-for-work" report Bevan et al. (2012) found that the odds of participating in the labour force in New Zealand are 31.5% lower for those people with a chronic condition, and musculoskeletal disorders represented the second largest category of conditions resulting in claims for a sickness benefit behind psychiatric and psychological conditions. In 2009/10

the Accident Compensation Corporation of New Zealand spent $147, 452, 564 on work-related musculoskeletal entitlement claims.

Podiatrists solely work on the lower limb and will often encounter patients that have sustained severe injuries to the lower extremity in their private practice and are well positioned to be able to prescribe and provide AFO's for a range of neurological and musculoskeletal conditions.

From the small cohort of people with HET injuries in this study, the improvements seen whilst using the ReAktiv PDE orthosis allowed participants with significant reductions in function to return to a higher level of mobility and functionality. These improvements in pain and function, may have significant benefits for those that have previously been unable to work or partake in physical activities due to their HET injury. Despite the small number of participants, what makes this work novel is that it was undertaken in a non-military population following ankle trauma. There may be further scope for the potential use of the ReAktiv PDE orthosis in other population groups that suffer significant foot and ankle pathology (such as arthritis and Talipes-Equino-Varus).

Chapter 7: Conclusions

The primary aim of this study was to determine the effectiveness of the ReAktiv PDE orthosis as a potential treatment modality for people that had suffered significant injury to the ankle following HET and who post-surgery continued to have issues with pain and reduced function and mobility.

Improvements in patient-reported pain and function were seen with the use of the ReAktiv PDE orthosis. This was indicated by the results reported in both the PDQ and PSEQ, as well as improvements reported in the LEFS, with 1 participant exceeding the minimally important difference and recording a score similar to non-injured, healthy individuals. Results from the physical tests (2MWT, FSST, TSA, SLB) also showed improvements when using the brace compared to not using the brace.

Study data has shown that for some in this population group, the use of the ReAktiv PDE orthosis could help to improve pain levels during everyday functional activities as well as the confidence to do these functional day-to-day activities despite pain. This work is of clinical importance as it provides an additional treatment modality that could be used on those people who have suffered a HET injury to the ankle and who continue to experience pain and limitations in physical function and/or for whom surgical intervention is no longer an option. In some circumstances, it may allow users of the brace to return to the same or similar levels of activity prior to injury.

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Appendices

Appendix A: Ethical Approval

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

11 June 2021

Michael Frecklington
Faculty of Health and Environmental Sciences

Dear Michael

Re Ethics Application: **21/137 ReAktive™ Brace as a treatment for ankle trauma: a retrospective case series**

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application has been approved for three years until 10 June 2024.

Standard Conditions of Approval

1. The research is to be undertaken in accordance with the Auckland University of Technology Code of Conduct for Research and as approved by AUTEC in this application.
2. A progress report is due annually on the anniversary of the approval date, using the EA2 form.
3. A final report is due at the expiration of the approval period, or, upon completion of project, using the EA3 form.
4. Any amendments to the project must be approved by AUTEC prior to being implemented. Amendments can be requested using the EA2 form.
5. Any serious or unexpected adverse events must be reported to AUTEC Secretariat as a matter of priority.
6. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the AUTEC Secretariat as a matter of priority.
7. It is your responsibility to ensure that the spelling and grammar of documents being provided to participants or external organisations is of a high standard and that all the dates on the documents are updated.

AUTEC grants ethical approval only. You are responsible for obtaining management approval for access for your research from any institution or organisation at which your research is being conducted and you need to meet all ethical, legal, public health, and locality obligations or requirements for the jurisdictions in which the research is being undertaken.

Please quote the application number and title on all future correspondence related to this project.

For any enquiries please contact ethics@aut.ac.nz. The forms mentioned above are available online through http://www.aut.ac.nz/research/researchethics

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: nz_sarahg@outlook.com; matthew.carroll@aut.ac.nz;

Appendix B: Participant Information sheet

Participant Information Sheet

Date Information Sheet Produced:

28 April 2021

Project Title

ReAktive™ Brace as a treatment for ankle trauma: a retrospective case series

An Invitation

Kia Ora my name is Sarah Gardner and I am working with Mike Frecklington to undertake a research project as part of a Master of Health Practice Qualification. I am inviting adults to participate in a study about the ReAktive™ brace they wear because of sustaining an ankle injury. This will involve me reviewing your clinical records to obtain measurements about your injury and tests you undertook whilst wearing the brace. This information sheet will help you decide if you would like to take part in the study. Before you decide you may want to talk to other people about the study such as family/whānau or friends. If you agree to taking part in the study, please sign the Consent form. If you decide you do not want to participate in the study, you can withdraw at any time prior to the completion of data collection.

What is the purpose of this research?

The purpose of this research is to evaluate the ReAktive™ brace as a treatment for ankle injuries. This study will also contribute to the requirements of a MHPrac degree for a student (Sarah Gardner). The findings of this research may be used for academic publications and presentations.

How was I identified and why am I being invited to participate in this research?

This project invites participants over 20 years of age, who have received a ReAktive™ brace as a treatment for an ankle injury. Your consent is required before you can participate.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

You will not need to attend any appointments as part of this study. We will obtain information relating to your age, gender, ethnicity, injury and tests you undertook whilst wearing the brace from your clinical records.

What are the discomforts and risks, and how will these be alleviated?

There are minimal risks, except that your clinical records will be accessed. These will only be accessed by the person will be the clinical administrator. The decision to take part or to not take part in this study will not impact on your clinical care.

What are the benefits?

This study will support research into the use of bracing for traumatic ankle injuires, with the findings potentially being of interest to health care professionals treating people that have sustained traumatic ankle injuries. Your participation will also be assisting a student in gaining their MHPrac qualification.

How will my privacy be protected?

The information collected during this research is confidential to the researcher and project supervisor. Information will be stored securely at AUT University for up to six years, after which it will be destroyed. Any reporting of this study will not include an information that could identify you. A summary of the findings can be requested by you following the completion of the research.

Appendix C: Consent form

Consent Form

Project title: ***ReAktive™ Brace as a treatment for ankle trauma: a retrospective case series***

Project Supervisor: ***Mike Frecklington***

Researcher: ***Sarah Gardner***

- ○ I have read and understood the information provided about this research project in the Information Sheet dated 28 April 2021.
- ○ I have had an opportunity to ask questions and to have them answered.
- ○ I agree to have my clinical notes relating to my injury and brace accessed and understand that this information will be de-identified and shared with the researcher and that this information will only be used for academic purposes.
- ○ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.
- ○ I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.
- ○ I agree to take part in this research.
- ○ I wish to receive a summary of the research findings (please tick one): Yes○ No○

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

.....

.....

.....

.....

Date:

Approved by the Auckland University of Technology Ethics Committee on 11th June 2021 AUTEC Reference number 21/137

Note: The Participant should retain a copy of this form.

Appendix D: Pain Disability Questionnaire

EVEXIA
HEALTH & PERFORMANCE

Pain Disability Questionnaire (PDQ)

Provider: Kirsten Rose

Today's date: _____

Instructions

Instructions: These questions ask your views about how your pain now affects how you function in everyday activities. Please answer every question and mark ONE number on EACH question that best describes how you feel.

1. Does your pain interfere with your normal work inside and outside the home?

☐ 0 : Work normally ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Unable to work at all

2. Does your pain interfere with personal care (such as washing, dressing, etc.)?

☐ 0 : Take care of myself completely ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Need help with all my personal care

3. Does your pain interfere with your traveling?

☐ 0 : Travel anywhere I like ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Only travel to see doctors

4. Does your pain affect your ability to sit or stand?

☐ 0 : No problems ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Can not sit/stand at all

5. Does your pain affect your ability to lift overhead, grasp objects, or reach for things?

☐ 0 : No problems ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Can not do at all

6. Does your pain affect your ability to lift objects off the floor, bend, stoop, or squat?

☐ 0 : No problems ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Can not do at all

7. Does your pain affect your ability to walk or run?

☐ 0 : No problems ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Can not walk/run at all

8. Has your income declined since your pain began?

☐ 0 : No decline ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Lost all income

9. Do you have to take pain medication every day to control your pain?

☐ 0 : No medication needed ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : On pain medication throughout the day

10. Does your pain force your to see doctors much more often than before your pain began?

☐ 0 : Never see doctors ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : See doctors weekly

11. Does your pain interfere with your ability to see the people who are important to you as much as you would like?

☐ 0 : No problem ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Never see them

12. Does your pain interfere with recreational activities and hobbies that are important to you?

☐ 0 : No interference ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Total interference

13. Do you need the help of your family and friends to complete everyday tasks (including both work outside the home and housework) because of your pain?

☐ 0 : Never need help ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Need help all the time

14. Do you now feel more depressed, tense, or anxious than before your pain began?

☐ 0 : No depression/tension ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Severe depression/tension

15. Are there emotional problems caused by your pain that interfere with your family, social and or work activities?

☐ 0 : No problems ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 : Severe problems

Appendix E: Pain Self-Efficacy Questionnaire

EVEXIA
HEALTH & PERFORMANCE

Pain Self Efficacy Questionnaire (PSEQ)

Provider: Kirsten Rose

Today's date: _____

Instructions

Please rate how confident you are that you can do the following things at present, despite the pain. To indicate your answer chose one of the numbers on the scale for each item, where 0 = not at all confident and 6 = completely confident. Remember, this questionnaire is not asking whether of not you have been doing these things, but rather how confident you are that you can do them at present, despite the pain.

1. I can enjoy things, despite the pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

4. I can cope with my pain in most situations.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

5. I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work).

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

7. I can cope with my pain without medication.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

8. I can still accomplish most of my goals in life, despite the pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

9. I can live a normal lifestyle, despite the pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

10. I can gradually become more active, despite the pain.

☐ 0 : Not at all confident ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 : Completely confident

Appendix F: Lower Extremity Functional Scale

EVEXIA
HEALTH & PERFORMANCE

Lower Extremity Functional Scale (LEFS) (Binkley, JM; Stratford PW. et al.)

Provider: Kirsten Rose

Today's date: _____

Instructions

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.

1. Today, do you or would you have any difficulty at all with: 1. Any of your usual work, housework or school activities.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

2. Today, do you or would you have any difficulty at all with: 2. Your usual hobbies, recreational or sporting activities.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

3. Today, do you or would you have any difficulty at all with: 3. Getting into or out of the bath.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

4. Today, do you or would you have any difficulty at all with: 4. Walking between rooms.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

5. Today, do you or would you have any difficulty at all with: 5. Putting on your shoes or socks.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

6. Today, do you or would you have any difficulty at all with: 6. Squatting.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

7. Today, do you or would you have any difficulty at all with: 7. Lifting an object, like a bag of groceries from the floor.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

8. Today, do you or would you have any difficulty at all with: 8. Performing light activities around your home.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

9. Today, do you or would you have any difficulty at all with: 9. Performing heavy activities around your home.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

10. Today, do you or would you have any difficulty at all with: 10. Getting into or out of a car.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

11. Today, do you or would you have any difficulty at all with: 11. Walking 2 blocks.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

12. Today, do you or would you have any difficulty at all with: 12. Walking a mile.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

13. Today, do you or would you have any difficulty at all with: 13. Going up or down 10 stairs (about 1 flight of stairs).

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

14. Today, do you or would you have any difficulty at all with: 14. Standing for 1 hour.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

15. Today, do you or would you have any difficulty at all with: 15: Sitting for 1 hour .

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

16. Today, do you or would you have any difficulty at all with: 16: Running on even ground.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

17. Today, do you or would you have any difficulty at all with: 17: Running on uneven ground.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

18. Today, do you or would you have any difficulty at all with: 18: Making sharp turns while running fast.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

19. Today, do you or would you have any difficulty at all with: 19: Hopping.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty

20. Today, do you or would you have any difficulty at all with: 20: Rolling over in bed.

☐ 0: Extreme difficulty or unable to perform activity ☐ 1: Quite a bit of difficulty ☐ 2: Moderate difficulty ☐ 3: A little bit of difficulty ☐ 4: No difficulty