Chapter 1

Introduction

"You are never dedicated to something you have complete confidence in. No one is fanatically shouting that the sun is going to rise tomorrow. They know it's going to rise tomorrow. When people are fanatically dedicated to political or religious faiths or any other kinds of dogmas or goals, it's always because these dogmas or goals are in doubt."

Robert M Pirsig, 1974\(^1\) (p 155)

1.1 BACKGROUND TO THE THESIS

The plantar fascia is a strong connective tissue structure that spans the plantar surface of the foot from the inferior heel to the toes.\(^2\) If damaged, degeneration of the fascia occurs and symptoms develop - this condition is most often referred to as plantar fasciitis.\(^3\)

Plantar fasciitis is one of the most common foot complaints, affecting approximately one in ten people at some time in their life.\(^4\) It is particularly prevalent in runners and people who are overweight,\(^5\)-\(^10\) however it is also consistently reported in people with systemic, inflammatory arthritis.\(^11\)-\(^18\) Although there are little good quality epidemiological data available, the following highlight the prevalence of this condition.

It has been estimated that:

- More than two million Americans receive treatment for plantar fasciitis each year.\(^19\)
- Fifteen percent (15\%) of adult foot complaints requiring professional care in the United States are for plantar heel pain.\(^20\)
Plantar fasciitis makes up one quarter of all foot injuries\textsuperscript{21} and up to 8\% of overall injuries to runners and sports people.\textsuperscript{22-24} One American orthotic laboratory found that one in every eight orthotic prescriptions were associated with heel spur related symptoms.\textsuperscript{25}

The symptoms associated with plantar fasciitis usually occur at the plantar fascial attachment to the heel\textsuperscript{26} (Figure 2.1), and while usually self limiting,\textsuperscript{27} the resultant pain and disability can have a significant impact on a person’s quality of life.\textsuperscript{28}

**Figure 2.1** Diagram of the plantar fascia illustrating the most likely area to become painful and tender.

![Diagram of the plantar fascia illustrating the most likely area to become painful and tender.](image)

Diagram from MediClip CD: *Manual Medicine* \textsuperscript{29}

Plantar fasciitis is generally considered to be responsive to conservative treatment.\textsuperscript{8, 30} However, no individual modality has a sufficient amount of evidence to support its use in clinical practice. This is largely due to most trials so far either grouping multiple treatments together\textsuperscript{31} or being poor in quality.\textsuperscript{4, 32} This is no more evident than with the use of foot orthoses - a widely advocated long-term treatment.\textsuperscript{25, 33-45} Although a handful of randomised controlled trials have recently been published,\textsuperscript{19, 46-48} the conclusions of these trials are susceptible to bias because the investigators have generally not followed rigorous randomised controlled trial methods (e.g. appropriate...
randomisation and allocation concealment). In addition, no trial has yet evaluated foot orthoses for longer than three months; therefore the question of whether there is a long-term advantage of certain orthoses is unanswered. Further trials are needed that incorporate rigorous methods and measure outcomes over a longer timeframe.

1.2 AIM OF THE THESIS

The aim of this thesis was to evaluate the short and long-term effectiveness of foot orthoses in the treatment of plantar fasciitis.

1.3 OBJECTIVES OF THE THESIS

To achieve the aforementioned aim, the following objectives were developed:

- Critically review the literature relating to plantar fasciitis, foot orthoses, patient-based health status and randomised controlled trial methodology.
- Survey the podiatry profession in Australia and New Zealand to determine what foot orthoses were most commonly prescribed.
- Compare foot-specific health status measures to determine which were most appropriate when evaluating orthoses in the treatment of plantar fasciitis.
- Conduct a pragmatic randomised controlled trial evaluating the effectiveness of foot orthoses in the treatment of plantar fasciitis. Both the survey and the comparison of health status measures informed the randomised controlled trial.
1.4 OUTLINE OF THE THESIS

This thesis contains six chapters:

Chapter 1 introduces the problem to be studied and discusses the background relating to its investigation. In addition, this chapter provides the broad aims and objectives of the thesis.

Chapter 2 critically reviews the literature relating to the thesis, including prior research relating to plantar fasciitis, with specific reference to treatment with foot orthoses. In addition, there is discussion of health outcome assessment, instruments used to measure foot-specific health status, and randomised controlled trial methodology.

Chapter 3 presents the findings from a survey of the orthosis prescribing habits of 617 podiatrists in Australia and New Zealand. Although this chapter presents a stand-alone study, the results informed Chapter 5.

Chapter 4 provides an investigation of two questionnaires used to measure foot-specific health status. This chapter includes a trial on 17 participants that compared the two questionnaires in a clinical setting. Like Chapter 3, this chapter presents a stand-alone study that informed Chapter 5.

Chapter 5 presents and discusses a randomised controlled trial of 135 participants. This trial evaluated the effectiveness of three types of foot orthoses in the treatment of plantar fasciitis over a 12 month period. This is the main study of this thesis.

Chapter 6 summarises and draws together the results from Chapters 3, 4 and 5 and then makes overall conclusions relating to their findings.
Chapter 2

Literature review

2.1 INTRODUCTION

This chapter reviews the literature related to this thesis. Firstly, an overview of plantar fasciitis - the condition studied in Chapters 4 and 5 - is presented. Secondly, the treatment of plantar fasciitis with foot orthoses - the primary focus of this thesis - is analysed in detail. In addition to discussing the mechanism of action of foot orthoses, this section also critically reviews the literature evaluating their effectiveness as a treatment for plantar fasciitis. The third section presents an overview of patient-based health status assessment, thus providing the necessary background to how orthotic effectiveness was assessed in Chapters 4 and 5. Lastly, randomised controlled trial methodology is discussed, providing a rationale for the type of trial used in Chapter 5. Conclusions from the literature reviewed are then made supplying the overall foundations for the subsequent investigations.

2.2 PLANTAR FASCIITIS

2.2.1 Introduction

The plantar fascia, or plantar aponeurosis, is a tough, fibrous, connective tissue structure that spans the plantar surface of the foot from the inferior heel to the toes. If this structure is damaged, degeneration of the fascia occurs and symptoms develop - this condition is most often referred to as plantar fasciitis. A general introduction including the prevalence of plantar fasciitis was included in Chapter 1: Introduction.

2.2.2 Terminology associated with plantar fasciitis

There are many conditions that cause similar symptoms to plantar fasciitis, and as a result, there are many different names associated with it. Two main sorts of descriptors
Descriptors incorporating the general location of pain, such as subcalcaneal pain\textsuperscript{49, 50} or heel pain\textsuperscript{51-53} have been used often in the past. More recently, the term plantar heel pain has also gained some acceptance.\textsuperscript{26, 54-57} All of the above are appropriate generic terms to describe pain located in the plantar heel region, particularly if a firm diagnosis cannot be made. However, Rome\textsuperscript{56} reports there are nearly 30 different conditions cited in the literature as potential causes of pain in the plantar heel. Therefore, each of the above terms can be used to describe the general location of pain either prior to diagnosis or if a definitive diagnosis is too difficult to ascertain.

The second sort of descriptor identifies specific anatomical structures. Heel spur syndrome was used relatively often during the 1980s\textsuperscript{58, 59} and 1990s,\textsuperscript{60, 61} although it is used infrequently today as spurs can be present in people who have no heel pain.\textsuperscript{62} Two studies have also concluded that plantar heel spurs do not always form at the attachment of the plantar fascia to the calcaneus.\textsuperscript{20, 63} Thus, heel spur syndrome is not an appropriate term to use for the symptoms associated with plantar fasciitis.

Currently, the term plantar fasciitis is the most widely used in the literature.\textsuperscript{3, 12, 19, 27, 31, 44, 48, 64-67} It is specific to one structure - the plantar fascia - rather than numerous structures included under terms like plantar heel pain. Further, plantar fasciitis is generally accepted as the primary cause of heel pain.\textsuperscript{26, 55} Therefore, providing diagnosis is possible, the term plantar fasciitis is most appropriate and will be used in this thesis (some of the difficulties related to diagnosis are discussed later in 2.2.7 Diagnosis of plantar fasciitis).

2.2.3 Anatomy of the plantar fascia

The plantar fascia is a broad structure that spans between the medial calcaneal tubercle and the proximal phalanges of the toes.\textsuperscript{2} There is still some debate as to whether it is deep fascia or an aponeurosis, although both Sarrafian\textsuperscript{2} and Draves\textsuperscript{68} refer to it as the plantar aponeurosis. The Dorland’s Medical Dictionary\textsuperscript{69} defines an aponeurosis as:
“(i) a white, flattened or ribbon-like tendinous expansion, serving mainly to connect a muscle with the parts that it moves, (ii) a term formerly applied to certain fasciae”. Further, it defines the plantar aponeurosis as: bands of fibrous tissue radiating toward the bases of the toes from the medial process of the tuber calcanei; also called the plantar fascia. For the purpose of this thesis, however, the term plantar fascia will be used to link to the clinical condition plantar fasciitis.

The plantar fascia is made up of predominantly longitudinally oriented collagen fibres\textsuperscript{70} that are highly non-compliant.\textsuperscript{71} There are three distinct structural components: the medial component, the central component, and the lateral component (Figure 2.2). The central component is the largest and most prominent.\textsuperscript{2}

**Figure 2.2** Anatomical diagram illustrating the components of the plantar fascia.

![Diagram from Draves\textsuperscript{68}](image)
The central component originates from the posteromedial aspect of the calcaneal tuberosity and runs distally to separate at the forefoot into five slips that insert in a complex fashion into the digits.\textsuperscript{2} Insertions occur into both the deep transverse ligament and proximal phalanges, as well as superficially into the skin of the interdigital web area.\textsuperscript{72} Perry\textsuperscript{70} describes the basic design as “a broad nonelastic strap firmly attached to the calcaneus, with its opposite end wrapped around the convex surface of the highly mobile MP joints” (p 14). The central component is the thickest and strongest of the three,\textsuperscript{68} and importantly, is the structure that is associated with the symptoms of plantar fasciitis. The lateral component originates from the lateral process of the calcaneal tuberosity, covers the abductor digiti minimi muscle, and inserts onto the base of the fifth metatarsal.\textsuperscript{2} The relatively thin medial component covers the abductor hallucis muscle and runs distally and medially to blend into the periosteum of the navicular, the medial cuneiform and plantar surface of the first metatarsal.\textsuperscript{68, 73}

In younger people the plantar fascia is also intimately related to the Achilles tendon,\textsuperscript{74} with a continuous fascial connection between the two from the distal aspect of the Achilles to the origin of the plantar fascia at the calcaneal tubercle. However, the continuity of this connection decreases with age to a point that in the elderly there are few, if any connecting fibres.\textsuperscript{74} There are also distinct attachments of the plantar fascia and the Achilles tendon to the calcaneus so the two do not directly impact on each other.\textsuperscript{75} Nevertheless, there is an indirect relationship whereby if the toes are dorsiflexed, the plantar fascia tightens via the windlass mechanism (explained in 2.2.4 Biomechanics of the plantar fascia). If a tensile force is then generated in the Achilles tendon it will increase tensile strain in the plantar fascia.\textsuperscript{76} Clinically, this relationship has been used as a basis for treatment for plantar fasciitis, with stretches\textsuperscript{19} and night stretch splinting\textsuperscript{77, 78} being applied to the gastrocnemius/soleus muscle unit\textsuperscript{a}.

2.2.4 Biomechanics of the plantar fascia

The plantar fascia contributes to support of the arch of the foot by acting as a tie-rod, where it undergoes tension when the foot bears weight.\textsuperscript{79} Out of all the structures that

\textsuperscript{a} This stretch is often referred to as the Achilles tendon stretch, however the stretch is necessarily applied to the soleus and gastrocnemius as well as the Achilles tendon.
stabilise the arch of the foot, the plantar fascia contributes the most stability.\(^8^0\) One biomechanical model estimated it carries as much as 14% of the total load of the foot.\(^8^1\) As a result it is a strong structure that can normally withstand high forces. In an experiment using cadavers, Kitaoka et al\(^8^2\) found that failure of the plantar fascia averaged at loads of 1189 ± 244 Newtons. Interestingly, failure most often occurred at the proximal attachment to the calcaneus, which is consistent with the usual location of symptoms (i.e. in plantar fasciitis).

Complete rupture or surgical release of the plantar fascia leads to a decrease in arch stiffness\(^8^3\) and a significant collapse of the longitudinal arch of the foot.\(^8^4\)–\(^8^9\) Arangio and colleagues\(^9^0\) produced a model that predicted such conditions would result in a 17% increase in vertical displacement and a 15% increase in horizontal elongation of the foot when it was loaded at 683 Newtons. Surgical release also significantly increases both stress in the plantar ligaments\(^8^9\)\(^9^1\) and plantar pressures under the metatarsal heads.\(^9^2\)

Although most of the figures mentioned above are from either cadaver studies or investigations using models, they highlight the relatively large load the plantar fascia is subjected to while contributing to the structural integrity of the foot.

The plantar fascia also has an important role in dynamic function during gait. Gefen\(^9^3\) found the plantar fascia continuously elongated during the contact phase of gait. It went through rapid elongation before and immediately after mid-stance, reaching a maximum of 9% to 12% elongation between mid-stance and toe-off. During this phase the plantar fascia behaves like a spring, which may assist in conserving energy.\(^9^4\)\(^9^5\) In addition, the plantar fascia has a critical role in normal mechanical function of the foot, contributing to the ‘windlass’ mechanism.\(^8^5\)\(^9^6\) When the toes are dorsiflexed in the propulsive phase of gait, the plantar fascia becomes tense, resulting in elevation of the longitudinal arch and shortening of the foot.\(^7^6\) (Figure 2.3).
Figure 2.3 The effect of dorsiflexing the toes on arch height.

Diagram from Hicks\textsuperscript{96}

Hicks\textsuperscript{96} likened this mechanism to a cable being wound around the drum of a windlass (Figure 2.4); the plantar fascia being the cable, the metatarsal head the drum, and the handle, the proximal phalanx.

Figure 2.4 The windlass mechanism.

Diagram from Brown\textsuperscript{97}
Therefore, the plantar fascia has a number of roles, the most important of these including supporting the arch of the foot and contributing to the windlass mechanism.

### 2.2.5 Pathophysiology of plantar fasciitis

The plantar fascia can become damaged when it is subjected to high loads. Often this damage occurs as a result of a series of relatively small insults (i.e. microtrauma or fatigue failure), any one of which would be insufficient to cause injury on its own. If, however, the ensuing strain on the fascia continues, an overload injury occurs; most often at the attachment of the fascia to the calcaneus. Continued microtrauma leads to chronic inflammation, which causes collagen degeneration with subsequent, but often inadequate, repair. Gross changes such as fascial thickening, tears and oedema can be viewed non-invasively with diagnostic ultrasound or magnetic resonance imaging. In addition, bone marrow oedema may occasionally be present at the calcaneal attachment. Interestingly, although plantar fasciitis has always been thought of as an inflammatory condition, a recent study that histologically examined samples of plantar fascia removed during surgery in 50 cases of chronic plantar fasciitis found no evidence of inflammation present. The authors suggested the disorder was associated with degenerative changes, and would be best classified as fasciosis rather than fasciitis. Histological findings included myxoid degeneration with fragmentation and degeneration of the plantar fascia and increased vascularisation in the adjacent bone marrow.

In the past, much has also been written about the contribution of plantar calcaneal spurs to the pain associated with plantar fasciitis. For many years there was general agreement that an association between spurs and plantar heel pain or plantar fasciitis existed; however spurs can be present in people who have no heel pain, and those with pain do not always have spurs. Further, McCarthy and Gorecki demonstrated that plantar heel spurs could form at sites other than the attachment of the plantar fascia to the calcaneus (e.g. the origin of flexor digitorum longus muscle). They went on to suggest that spurs were a result, not the cause of inflammation. Similarly, Kumai & Benjamin found that plantar calcaneal spurs formed superior to the plantar
fascial enthesis. They concluded spurs are not a result of traction from the plantar fascia but may be a consequence of degenerative changes that occur in the plantar fascial enthesis. Interestingly, there is also a higher incidence of plantar calcaneal spurs in people diagnosed with osteoarthritis.\textsuperscript{118}

The relationship between spurs and plantar fasciitis should not be underestimated, however, as there is an increased incidence of spurs in people with plantar heel pain. One case-control study\textsuperscript{54} compared the incidence of heel spur in 82 people with heel pain and 400 controls without heel pain. The incidence of heel spur was 65.9\% in participants with heel pain versus 15.5\% in participants without heel pain (Odds Ratio 10.5, 95\% confidence interval 6.2 to 17.9\textsuperscript{119}). Notwithstanding these findings, the presence of a plantar calcaneal spur is generally not considered diagnostic of plantar fasciitis. Calcaneal spurs appear to be a related finding rather than an essential feature of plantar fasciitis.

2.2.6 Aetiology of plantar fasciitis

There are many causes of plantar fasciitis, from systemic disease to local factors. Originally, venereal diseases such as gonorrhoea\textsuperscript{120-122} were thought to be the primary aetiology. This theory was later questioned,\textsuperscript{111-113, 123, 124} however it was not until 1957 that Du Vries\textsuperscript{114} proposed heel spurs and heel pain were primarily caused by mechanical factors in the foot. Around this time, inflammatory arthropathies, such as ankylosing spondylitis,\textsuperscript{11} were also suggested to be a cause of heel pain. Since then a number of studies have found an association with inflammatory arthropathies and calcaneal spurs.\textsuperscript{12-18, 125}

It is now recognised that many conditions cause pain similar to plantar fasciitis. Heel pain guidelines developed by the American College of Foot and Ankle Surgeons\textsuperscript{57} indicate there are five broad aetiological categories: mechanical, traumatic, neurological, arthritic and other. More specifically, almost 30 different factors have been cited as causing plantar heel pain (i.e. pain similar to the proximal form of plantar fasciitis).\textsuperscript{56}
The factors that have been consistently cited include:

- Incorrect training methods and footwear.\(^8, 9, 126, 127\)
- Decreased ankle dorsiflexion\(^3, 7, 10, 128\) and biomechanical anomalies.\(^3, 64, 126\)
- Increased weight\(^6\) and increased body mass index.\(^9, 10, 129, 130\)
- Sustained standing.\(^10, 19\)

Interestingly, some of these factors have been investigated in runners as well, although none appear to be good predictors of who will develop plantar fasciitis.\(^5, 131-135\) This may simply indicate that the stress from running on its own is great enough to cause plantar fasciitis.

All of the above factors fall into the mechanical category in the heel pain guidelines outlined above. Excessive mechanical stress is currently accepted as being the primary cause of plantar fasciitis.\(^31, 65, 67, 99, 136, 137\) Biomechanical anomalies such as high-arched,\(^138\) or more commonly, excessively pronated feet\(^3, 64, 114, 126, 139\) have been suggested to be factors that contribute to such stress. Tightness of the plantar fascia in high-arched feet prevents normal shock absorption and stress dissipation, resulting in additional stress at the fascial attachment to the calcaneus.\(^3, 138\) In contrast, excessive pronation causes elongation of the foot, which consequently stretches the plantar fascia.\(^139, 140\) Taking this one step further, Scherer\(^41\) suggested that closed chain rearfoot pronation causes the forefoot to supinate, placing tension on the plantar fascia. This tension prevents the windlass mechanism from activating properly during the propulsive phase of gait.\(^141, 142\) Considered more broadly, any condition (even weight gain) that stretches the plantar fascia in a repetitive fashion has the potential to cause microtrauma and subsequent degeneration.

A number of researchers have also investigated the distribution of force and plantar pressure under the heel in people with plantar fasciitis.\(^143-148\) It is plausible to expect that pain under the heel may alter the timing or distribution of pressure under the affected foot, however this has not been found in all studies.\(^144-146\) Interestingly, Wearing and colleagues\(^147, 148\) incorporated what they thought was the most sensitive method - measurement of the position of the centre of pressure - and found that people
with plantar fasciitis had lower hindfoot and greater midfoot impulses. They also found a previously unidentified increase in digital loading, which they suggested could have a protective role.\textsuperscript{148} As the existing research provides conflicting results, further research is needed. Plantar pressure technology, therefore, has had little impact so far with respect to uncovering the cause or effect of plantar fasciitis.

In conclusion, it is most likely that a combination of the above factors cause plantar fasciitis.\textsuperscript{133} Although little good quality evidence exists, mechanical overload is widely accepted as being the primary cause. One or more of these may initially be present at a sub-clinical level only to be pushed ‘over the edge’ when another factor is added; Nigg\textsuperscript{98} referred to this level (i.e. the level that needs to be reached for symptoms to develop) as the \textit{critical limit}. Although not the focus of this thesis, further well-designed research is needed to evaluate the role these factors play in plantar fasciitis.

2.2.7 Diagnosis of plantar fasciitis

The diagnosis of plantar fasciitis is based primarily on the history and physical findings.\textsuperscript{27, 137, 149} Two groups are most likely to be affected: one is predominantly aged between 40 and 60 years and overweight, and the second contains younger people that are relatively active, particularly runners.\textsuperscript{97, 150} Symptoms typically develop over a number of weeks or months, and there is generally no history of trauma.\textsuperscript{137, 149} The pain is characteristically worse when arising from bed in the morning, tends to reduce after a few steps, may then be felt during the day after inactivity, and often worsens again by the evening.\textsuperscript{12, 27, 36, 59, 149, 151, 152} Although not usually disabling, a person with plantar fasciitis may develop a limp.\textsuperscript{153} Most people do not take time off work,\textsuperscript{30} although it often limits activity,\textsuperscript{130} and occasionally it may be severe enough to enforce a sedentary lifestyle.\textsuperscript{28}

The site of pain is typically the anteromedial region of the heel, however it can also be more distal in the medial longitudinal arch.\textsuperscript{31} Palpation over the course of the fascia reveals pain at its attachment to the medial calcaneal tubercle or distally within its central band.\textsuperscript{26, 150} Some authors suggest this pain may become more pronounced if tension is added to the fascia via dorsiflexion of the hallux.\textsuperscript{149, 154}
A thorough history and clinical examination is generally all that is required to diagnose plantar fasciitis. Medical imaging, including X-rays, technetium bone scans (scintigraphy), ultrasonography and magnetic resonance imaging are sometimes considered useful. X-rays are mainly used to confirm whether a plantar calcaneal spur is present, although they are also valuable to rule out more sinister or systemic causes of heel pain (e.g. tumour or inflammatory arthritis). The other imaging modalities at this stage have not become commonplace in the clinical or research setting as they are generally too expensive to use in routine practise and there is no evidence that performing such tests changes clinical outcomes.

Although diagnosis of plantar fasciitis is usually straight forward, it can be more complex. As stated previously, nearly 30 differential diagnoses of pain underneath the heel have been cited in the literature. Two in particular have been frequently mentioned: nerve entrapment and alterations in heel pad thickness and compressibility. Care is required to differentiate these from plantar fasciitis, particularly entrapment of the first branch of the lateral plantar nerve (also referred to as the nerve to the abductor digiti quinti muscle). In contrast to plantar fasciitis, nerve entrapment tends to present more as burning, radiating pain and is often not as severe first thing in the morning or after periods of rest. However, due to the close proximity of the nerve with the fascial attachment to the calcaneus, differentiation can be complex (Figure 2.5). If one structure (nerve or plantar fascia) is inflamed it can predispose to inflammation in the other.
Figure 2.5 Proximity of the first branch of the lateral plantar nerve (nerve to the abductor digiti quinti muscle) to the attachment of the plantar fascia to the calcaneus.

The pain associated with fat pad atrophy (loss of thickness and compressibility) tends to be more centrally located in the plantar heel than pain associated with plantar fasciitis. Most research to date has used specialised equipment (e.g. ultrasonography or tissue compressibility devices) to diagnose reduced thickness or compressibility. However, there is no evidence of the diagnostic utility of this technology. Diagnosis can be made clinically, although it is difficult determining the point at which a heel pad loses sufficient compressibility and thickness to become problematic. Therefore, a clinical diagnosis of fat pad atrophy is usually only made in those individuals who have marked loss of thickness or compressibility.

With the above in mind, it is acknowledged that differential diagnosis of plantar fasciitis can be difficult. The use of medical imaging, electrodiagnostic tests and biopsy have not been shown to alter clinical outcomes, so practitioners and researchers need to accept a relatively pragmatic approach. Clearly it would be ideal if all conditions that cause pain in the plantar heel, including plantar fasciitis, could be differentiated in a cheap and convenient manner - unfortunately this is unrealistic in the majority of
clinical settings. However, a thorough history and physical examination using the techniques outlined above should usually differentiate plantar fasciitis from other conditions. The reality of clinical practice dictates that this is what clinicians do on a day-to-day basis.

2.2.8 Treatment of plantar fasciitis

There are a variety of reported treatments for plantar fasciitis, ranging from conservative to surgical. Conservative management is reportedly very successful, although there have been few randomised controlled trials.\(^8, 30, 185\) Despite this concern, Cornwall and McPoil\(^31\) suggest that non-surgical or conservative treatment can be classified into three broad categories according to the treatment aims: (i) reduction of pain and inflammation, (ii) reduction of tissue stress, and (iii) restoration of muscle strength and flexibility. The following treatments have been recommended for each category (for completeness some studies cited below have shown no beneficial effect).

(i) Reduction of pain and inflammation:

- Rest/reduction in activities.\(^{26, 99, 186-188}\)
- Ice and anti-inflammatory medication.\(^8, 99, 187-190\)
- Massage.\(^{36, 190}\)
- Therapeutic ultrasound.\(^{191}\)
- Low-intensity laser.\(^{192}\)
- Iontophoresis.\(^{193, 194}\)
- Herbal medicine.\(^{195, 196}\)
- Acupuncture.\(^{197}\)

(ii) Reduction of tissue stress:

- Footwear.\(^8, 9, 127\)
- Strapping/padding.\(^{35, 36, 136, 187, 198-203}\)
- Heel cups/heel cushions.\(^{49, 185, 204}\)
- Foot orthoses.\(^{19, 25, 33-48}\)
- Casting/bracing.\(^{205, 206}\)
(iii) Restoration of muscle strength and flexibility:

- Exercises, including stretching the gastrocnemius/soleus muscle complex. 99, 190, 207, 208
- Night stretch splints. 77, 78, 209-217

Plantar fasciitis may have a natural history of resolution without intervention. To date, there have been no studies to determine the self-limiting nature of this condition. With this in mind, it has been reported that up to 90% of patients using conservative treatments will become symptom free within 12 months. 8, 30 It has been suggested the longer a person has plantar fasciitis the more resistant it can be to treatment. 218

Resistant cases may require more invasive treatments such as injection therapy (either local anaesthetic 219 or more commonly corticosteroid 220-225 ), extracorporeal shock wave therapy, 226-236 or surgery. 237-248 A period of at least 6 to 12 months of conservative treatment is recommended prior to progressing to these more invasive procedures. 57, 152, 243, 249

Good quality evidence supporting individual treatments for plantar fasciitis is lacking. Two recent systematic reviews by Crawford and colleagues 4, 32 found study quality to be generally poor. Thankfully, this situation has begun to change, with a number of rigorous trials published in recent years. 222, 250-252 Researchers must adopt similar methodology to that used in these trials. Until more high quality trials exist conclusions about the different treatments used for plantar fasciitis will be difficult to make.

Research relating to extracorporeal shock wave therapy can be used to demonstrate the importance of well-designed studies. Most studies suggesting a beneficial effect for this treatment are case series reports 227-235 or poor quality randomised controlled trials. 226, 253

These studies consistently reported clinically important beneficial effects of extracorporeal shock wave therapy. In contrast, recent, good-quality randomised controlled trials have demonstrated extracorporeal shock wave therapy to be no better than placebo. 250-252
Until evaluations using rigorous, randomised controlled trial methodology are conducted, good evidence of the beneficial effect of conservative treatments for plantar fasciitis will not exist. It is important to note, however, that an absence of evidence does not mean evidence of absence;\textsuperscript{254} the absence of high quality randomised controlled trials simply indicates the effect is not yet known.\textsuperscript{255, 256}

\subsection*{2.2.9 Summary}

The plantar fascia spans the plantar surface of the foot from the calcaneus to the toes. It is responsible for supporting the foot, as well as contributing to energy conservation and dynamic function via the windlass mechanism. The fascia is prone to damage when an excessive repetitive load is applied to it - the resulting clinical presentation is referred to as \textit{plantar fasciitis}. This common foot complaint is thought to be caused by many different factors, although the most frequently proposed factors are obesity, excessive standing or ambulating, and certain musculoskeletal anomalies. Conservative management, including stretching the calf muscles, strapping and orthoses, is generally considered effective; however there is a fundamental lack of evidence for many commonly employed treatments. Further rigorous, randomised controlled trials evaluating the effect of these commonly used modalities are required.
2.3 FOOT ORTHOSES IN THE TREATMENT OF PLANTAR FASCIITIS

2.3.1 Introduction

As discussed previously (2.2.8 Treatment of plantar fasciitis), foot orthoses are one of the primary conservative treatments used in the management of plantar fasciitis. Accordingly, there have been numerous articles published concerning their mechanism of action and their effectiveness. This section reviews the literature concerning the use of foot orthoses for plantar fasciitis. Firstly, the common issues related to researching orthoses will be introduced. Then, the mechanism of action of foot orthoses with respect to the plantar fascia will be discussed, followed by a detailed review of the effectiveness of foot orthoses in the treatment of plantar fasciitis.

2.3.2 Issues related to researching foot orthoses

Foot orthoses are widely used to treat a variety of foot and foot-related conditions. Consequently, there has been a significant volume of literature published relating to their use. Nevertheless, due to the nature of orthotic therapy, there are many complexities associated with researching their effects. Such complexities include:

- The variability in patient profile and subsequent rationale for orthotic prescription.
- Diversity in the philosophy of orthotic function.
- Variability in orthotic prescription.
- Inconsistency in the manufacture of the device, including the type of material used.
- The research methodology used, including issues associated with attempting to blind patients and clinicians to a device they can see; problems with attempting to create a “placebo”; problems associated with footwear interactions.
- The outcomes measured.

Due to these difficulties, orthotic research is often viewed negatively - by both clinicians and researchers - because it is not representative of current clinical practise (the clinicians) or because it lacks methodological rigour (the researchers). This is a
consistent criticism of clinically based research and offers a good example of the conflicting nature of research outcomes versus clinical outcomes. In addition, although much of the literature supports the use of foot orthoses, there is also a considerable amount of research that is inconclusive or refutes the effect of orthoses.\textsuperscript{261, 262} While this is confusing, discrepancy in results can, in part, be attributed to the different methodologies used by the authors and the varying quality of the research. These issues will be covered in greater detail later in this section.

A further issue is the terminology associated with orthoses. The term ‘foot orthosis’ includes a myriad of devices that are used, in some manner, to affect the function of the foot. Historically, the development of foot orthoses and their subsequent prescription has often been in response to new understandings or assumptions associated with paradigms of foot function. In addition, practitioners’ previous clinical experience, both positive and negative, has had a bearing on prescription habits. As a consequence, there is considerable variation in the types of orthoses prescribed between practitioners. This is further compounded by a lack of good quality research evaluating the effects that different types of foot orthoses have on foot pathologies. Clearly, it is difficult to develop consistent terminology for orthotic prescriptions when conclusive scientific evidence is not available and practitioners prescribe different devices, often even for the same condition.

Universal terminology for orthotic prescription has been identified as problematic in attempting discourse on almost any aspect of orthotic therapy.\textsuperscript{263} Orthoses have previously been categorised in a number of ways, the two most common being: (i) soft/flexible, semi-rigid and rigid\textsuperscript{264-266} and (ii) accommodative and functional.\textsuperscript{267} More recently, the Australian Podiatry Council developed guidelines for orthotic therapy, which included six different types of orthosis\textsuperscript{268} (Table 2.1).
Table 2.1 Orthotic types taken from the Australian Podiatry Council’s ‘Clinical Guidelines for Orthotic Therapy Provided by Podiatrists’.268

| (i) | Cushioning orthosis |
| (ii) | Pressure relief orthosis |
| (iii) | Pre-moulded/pre-formed/prefabricated orthosis |
| (iv) | Moulded non-cast orthosis |
| (v) | Moulded cast (no posting) orthosis |
| (vi) | Functional (customised kinetic) orthosis |

While the limitations of these guidelines are acknowledged, they are the first of their kind to be developed, validated and published. Further they are the first guidelines adopted by a national professional body.

Whatever the terminology used, it is generally still confusing, particularly to people with limited experience in the field. At this stage there is no right or wrong method to name orthoses. Therefore, to manage the varied terminology available the following will be done in this thesis:

- When a research article is discussed the terminology used in that article will be used.
- Certain qualifiers will be added if that terminology is unclear and if the prescription described in the method has enough detail to clarify what type of device has been used.
- Footnotes will be used where necessary to describe certain devices.
- In Chapters Three, Four and Five, orthosis terminology will conform to the terminology recommended by the Australian Podiatry Council’s ‘Clinical Guidelines for Orthotic Therapy Provided by Podiatrists’.268

### 2.3.3 Mechanism of action of foot orthoses

Evaluating the mechanism of action of foot orthoses is complex and has provided many challenges for researchers. Despite advances in technology, there is still a great deal to learn.260, 269-271 With plantar fasciitis, it is believed that foot orthoses reduce strain in the
fascia, allowing the opportunity for healing. Two broad methods have been used to investigate this: either plantar fascial strain has been assessed directly or surrogate measures that reportedly have a relationship with strain in the fascia (e.g. rearfoot pronation) have been evaluated.\textsuperscript{139, 140} Surrogate measures include kinematics, kinetics or plantar pressures, and electromyography. These three measures will be discussed first, followed by a review of the research that has evaluated plantar fascial strain directly.

2.3.3.1 Kinematics

The analysis of the kinematic effect of foot orthoses has received a great deal of attention, although the majority of research relates to foot function in general rather than plantar fasciitis. Nevertheless, it is worth reviewing these studies because any decrease in rearfoot pronation with orthoses should reduce strain in the plantar fascia.\textsuperscript{139, 140} Most early investigations used static radiographic measurement, however two-dimensional, and more recently three-dimensional, motion analysis has been increasingly used.

One of the earliest attempts to quantify the mechanism of action of foot orthoses involved the use of static radiographic measurement. Most studies focused on children and were designed to evaluate whether foot orthoses had a ‘corrective’ effect on the posture of growing feet over time.\textsuperscript{272-276} More recently, a study using 22 children and adults evaluated the immediate postural changes of foot orthoses.\textsuperscript{277} This study is of interest because if orthoses produce an immediate improvement in rearfoot pronation they should also reduce strain in the plantar fascia.\textsuperscript{139, 140} When compared to no intervention, foot orthoses did improve radiographic angles representative of foot pronation (i.e. foot pronation reduced). However, while improvement was statistically significant, none of the angles measured improved more than 4°. Moreover, the relevance of static radiographic measures is questionable, as it is now widely accepted that static measures of the foot have little correlation to dynamic function.\textsuperscript{278-281}

Due to this limitation, radiographic studies have been superseded by two and three-dimensional motion analysis, which have focused largely on dynamic rearfoot motion.
These techniques allow dynamic evaluation and, in the case of three-dimensional motion analysis, they provide a more accurate representation of the three-dimensional motion that normally occurs during gait. A summary of the results from these studies is presented in Tables 2.2 and 2.3.
Table 2.2 Summary of two-dimensional (2-dimensional) motion analysis studies evaluating the effect of anti-pronatory foot orthoses on rearfoot pronation.

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of study</th>
<th>Participant numbers</th>
<th>Types of orthoses</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bates et al²⁸³</td>
<td>2-dimensional video analysis (marker system not stated)</td>
<td>n=6</td>
<td>&quot;Rigid&quot; (customised - made from a cast)</td>
<td>4° reduction in maximum calcaneal eversion (not statistically significant)</td>
</tr>
<tr>
<td>Rodgers &amp; Leveau²⁸⁴</td>
<td>2-dimensional video analysis (skin markers for the leg, and shoe markers to represent calcaneal bisection)</td>
<td>n=29</td>
<td>&quot;Semi-rigid&quot; (customised - made from a cast)</td>
<td>1° reduction in maximum calcaneal eversion – left foot only (statistically significant)</td>
</tr>
<tr>
<td>Smith et al²⁸⁵</td>
<td>2-dimensional video analysis (skin markers for the leg, and shoe markers to represent calcaneal bisection)</td>
<td>n=11</td>
<td>&quot;Soft&quot; or &quot;semi-rigid&quot; (customised - made from a cast)</td>
<td>1° reduction in maximum calcaneal eversion (statistically significant for semi-rigid but not significant for soft)</td>
</tr>
<tr>
<td>Baitch et al²⁸⁶</td>
<td>2-dimensional video analysis (skin markers)</td>
<td>n=13</td>
<td>&quot;Standard balance&quot; or &quot;inverted balance&quot; (customised - made from a cast)</td>
<td>2° - 4° reduction in maximum tibiocalcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>Brown et al²⁸⁷</td>
<td>2-dimensional video analysis (skin markers)</td>
<td>n=24</td>
<td>&quot;Arch supports&quot; or &quot;biomechanical&quot; (customised - made from a cast)</td>
<td>1° reduction in maximum calcaneal eversion (not statistically significant)</td>
</tr>
<tr>
<td>Stell &amp; Buckley²⁸⁸</td>
<td>2-dimensional video analysis (skin markers for the leg, and shoe markers to represent calcaneal bisection)</td>
<td>n=30</td>
<td>Either &quot;casted&quot; (customised) or &quot;non-casted&quot;</td>
<td>3° - 5° reduction in maximum calcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>Genova et al²⁸⁹</td>
<td>2-dimensional video analysis (skin markers for the leg, and a plastic marker moulded to the calcaneus)</td>
<td>n=13</td>
<td>&quot;Soft&quot; or &quot;semirigid&quot;</td>
<td>2° reduction in maximum calcaneal eversion (statistically significant)</td>
</tr>
</tbody>
</table>
Table 2.3  Summary of three-dimensional (3-dimensional) motion analysis studies evaluating the effect of anti-pronatory foot orthoses on rearfoot pronation.

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of study</th>
<th>Participant numbers</th>
<th>Types of orthoses</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novick et al</td>
<td>3-dimensional motion analysis (skin markers)</td>
<td>n=21</td>
<td>“rigid” (customised - made from a cast)</td>
<td>4˚ reduction in maximum calcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>McCulloch et al</td>
<td>3-dimensional motion analysis (skin markers)</td>
<td>n=10</td>
<td>“functional” (customised - made from a cast)</td>
<td>3˚ reduction in maximum calcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>Eng &amp; Pierrynowski</td>
<td>3-dimensional motion analysis (skin markers)</td>
<td>n=10</td>
<td>“Flat Spenco insole posted medially in the hindfoot and forefoot with rubber wedges”</td>
<td>1˚ - 3˚ reduction in maximum calcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>Kitaoka et al</td>
<td>3-dimensional magnetic tracking system (sensors attached to bone)</td>
<td>n=14 (feet from cadavers)</td>
<td>Two “commonly prescribed prefabricated arch supports”</td>
<td>Typically &lt;1˚ increase in maximum calcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>Nigg et al</td>
<td>3-dimensional motion analysis (skin markers)</td>
<td>n=12</td>
<td>Schering Plough prefabricated “inserts” - five different densities</td>
<td>&lt; 4˚ reduction in maximum calcaneal eversion (statistically significant)</td>
</tr>
<tr>
<td>Stacoff et al</td>
<td>3-dimensional motion analysis (intra-cortical bone pins)</td>
<td>n=5</td>
<td>“medial” - multiple different-angled cork wedges mounted onto the shoe insole</td>
<td>1˚ - 3˚ reduction in maximum calcaneal eversion (not statistically significant)</td>
</tr>
<tr>
<td>Kitaoka et al</td>
<td>3-dimensional magnetic tracking system (sensors attached to bone)</td>
<td>n=9 (feet from cadavers)</td>
<td>Two “prefabricated arch supports” (same as previous study)</td>
<td>Approximately 0˚ - 1˚ increase in maximum calcaneal eversion (not statistically significant)</td>
</tr>
<tr>
<td>Mundermann et al</td>
<td>3-dimensional motion analysis (skin markers)</td>
<td>n=21</td>
<td>Flat (control) insole, insole with medial rearfoot and forefoot posts, neutral shell custom-moulded orthosis with no posting, neutral shell custom-moulded orthosis with medial rearfoot and forefoot posts</td>
<td>Insole with posting reduced maximum rearfoot eversion by 2˚ (statistically significant). Neutral shell orthosis with and without posting did not significantly reduce maximum rearfoot eversion.</td>
</tr>
</tbody>
</table>
Although many of the reductions in rearfoot pronation reported in these trials were statistically significant, the findings were on average, small. For example, mean improvements in the amount of maximum calcaneal eversion are generally in the order of 1° to 4° (i.e. the orthoses tested support the calcaneus in a less everted position by 1° to 4°). Whether small changes like these are important - that is, leading to improved clinical outcomes - is yet to be answered. Further research is needed to ascertain this.

In addition to investigating rearfoot movement specifically, other researchers have evaluated it indirectly by investigating the affect foot orthoses have on internal tibial rotation. Due to the subtalar joint coupling mechanism between the foot and leg, any reduction in rearfoot pronation will lead to a reduction in internal tibial rotation.\textsuperscript{297-300} Tibial rotation is easier to investigate than calcaneal position because researchers do not have to be concerned about footwear covering the heel\textsuperscript{b}. A summary of the results from studies evaluating internal tibial rotation is presented in Table 2.4.

\textsuperscript{b} To properly view calcaneal motion when using footwear either a window needs to be cut out of the heel counter or a moulded calcaneal bisector that extends out of the shoe is used to represent the calcaneus. Alternatively a bisection of the heel of the shoe has been used, however this is a less accurate reflection of calcaneal motion.\textsuperscript{301}
Table 2.4 Summary of studies evaluating the effect of anti-pronatory foot orthoses on internal tibial rotation.

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of study</th>
<th>Participant numbers</th>
<th>Types of orthoses</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cornwall &amp; McPoil</td>
<td>2-dimensional video analysis</td>
<td>n=2 (case studies)</td>
<td>A range of orthoses including an “inflatable arch support”, an “accommodative orthosis”, and a “rigid orthosis”</td>
<td>1” - 3” reduction in maximum internal tibial rotation</td>
</tr>
<tr>
<td>Nawoczenski et al</td>
<td>3-dimensional motion analysis</td>
<td>n=20</td>
<td>“Semi-rigid” (customised - made from a cast)</td>
<td>2” reduction in maximum internal tibial rotation (statistically significant)</td>
</tr>
<tr>
<td>Nigg et al</td>
<td>3-dimensional motion analysis</td>
<td>n=12</td>
<td>Schering Plough prefabricated “inserts” - five different densities</td>
<td>&lt; 5” reduction in maximum internal tibial rotation (statistically significant)</td>
</tr>
<tr>
<td>Stacoff et al</td>
<td>3-dimensional motion analysis</td>
<td>n=5</td>
<td>“medial” - multiple-different angled cork wedges</td>
<td>1” - 3” reduction in maximum internal tibial rotation (statistically significant)</td>
</tr>
<tr>
<td>Nester et al</td>
<td>3-dimensional motion analysis</td>
<td>n=12</td>
<td>“anti-pronatory” (10˚ ethyl vinyl acetate medial wedge with arch filler)</td>
<td>4” reduction in maximum internal shank (leg) rotation (statistically significant)</td>
</tr>
<tr>
<td>Mundermann et al</td>
<td>3-dimensional motion analysis</td>
<td>n=21</td>
<td>Flat (control) insole, insole with medial rearfoot and forefoot posts, neutral shell custom-moulded orthosis with no posting, neutral shell custom-moulded orthosis with medial rearfoot and forefoot posts Insole with posting, neutral shell orthosis, and neutral shell orthosis with posting reduced maximum tibial rotation less than 1” (statistically significant)</td>
<td></td>
</tr>
<tr>
<td>Nester et al</td>
<td>3-dimensional motion analysis</td>
<td>n=15</td>
<td>“medially wedged” (10˚ ethyl vinyl acetate medial wedge with arch filler)</td>
<td>3” reduction in maximum internal shank (leg) rotation (statistically significant)</td>
</tr>
</tbody>
</table>

All these studies arrived at similar conclusions - that orthoses significantly decrease internal tibial rotation. Therefore, these results support the findings mentioned previously that foot orthoses reduce rearfoot pronation. Like calcaneal eversion the mean decrease in internal rotation was small - in the region of 1˚ to 4˚. While this
magnitude of change is small, Nawoczenski and colleagues\textsuperscript{303} point out that the 2° decrease in their study represents a reduction of up to 30\% in the overall range of motion of the tibia from heel contact to the time at which the tibia is maximally internally rotated. However, once again, whether this change is clinically important has yet to be determined by appropriate research.

Interestingly, in addition to finding small mean changes in rearfoot pronation, Nigg and colleagues evaluated the kinematic changes of each individual participant in their studies, finding the orthotic effects were unsystematic across all participants.\textsuperscript{293,294} They proposed the concept of each individual having a “preferred movement path”, with an orthosis either supporting or even counteracting it.\textsuperscript{306} They went on to suggest orthosis construction should be individualised to optimise this preferred path, ultimately affecting muscle efficiency, comfort and performance. Nester and colleagues also suggest orthoses may have additional effects on the soft tissues of the lower limb, which may explain their documented clinical success.\textsuperscript{305}

A further issue to consider is that change in rearfoot motion may not be the most sensitive or important variable to measure when evaluating the effect of foot orthoses on the plantar fascia. A better measure may be that of arch height (e.g. navicular height) or even foot length. As mentioned previously (2.2.4 Biomechanics of the plantar fascia) if the foot pronates, the height of the arch decreases and the foot elongates, placing increased strain on the plantar fascia.\textsuperscript{139,140} Therefore, if orthoses had the desired affect, then arch height would increase and the foot would shorten, consequently relieving strain in the plantar fascia. Kitaoka and co-workers evaluated this possibility using cadavers by assessing the effect on arch height of two different prefabricated foot orthoses.\textsuperscript{292,295} These studies are summarised in Table 2.5.
Table 2.5 Summary of three-dimensional (3-dimensional) motion analysis studies evaluating the effect of anti-pronatory foot orthoses on arch height.

<table>
<thead>
<tr>
<th>Author</th>
<th>Type of study</th>
<th>Participant numbers</th>
<th>Types of orthoses</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kitaoka et al</td>
<td>3-dimensional magnetic tracking</td>
<td>n=14 (feet from</td>
<td>Two “commonly prescribed prefabricated arch supports”</td>
<td>0.5 - 1.6 mm increase in arch height (statistically significant)</td>
</tr>
<tr>
<td></td>
<td>system</td>
<td>cadavers)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kitaoka et al</td>
<td>3-dimensional magnetic tracking</td>
<td>n=9 (feet from</td>
<td>Two “prefabricated arch supports” (same as previous study)</td>
<td>0.3 - 0.7 mm increase in arch height (statistically significant)</td>
</tr>
<tr>
<td></td>
<td>system</td>
<td>cadavers)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clearly, although there was a statistically significant increase in arch height with the orthoses, the increase was very small, raising the issue again as to whether this increase is clinically worthwhile.

Most of the studies mentioned above used orthoses made from relatively firm materials, such as thermoplastics, cork and ethyl vinyl acetate. Studies using softer, more compressive materials like orthopaedic felt have found similar findings.\(^{307, 308}\)

However, due to compression of the softer material (i.e. felt) the initial changes in pronation are not maintained over time. Even after short periods of exercise (10 to 20 minutes), the original decrease in pronation (i.e. decreased internal tibial rotation and increased navicular height) gained from a felt orthosis significantly diminishes.\(^{307, 308}\)

One of these studies\(^{308}\) demonstrated an initial increase of navicular height of 8.0 mm (much bigger than more rigid orthoses - refer back to Table 2.5) but found that with exercise this increase diminished towards that of orthoses made from rigid materials. Again, it is not known whether the 3.6 mm increase in navicular height at 20 minutes measured in this study is enough to lessen strain in the plantar fascia. It is plausible that it would, although with increased exercise time and further compression of the felt, the orthotic effect may be short-lived.

Clearly, material selection is an important component of foot orthoses if the desired goal is to reduce pronation in the long-term. Unfortunately, insufficient evidence exists
to be certain about which orthotic materials are most appropriate when treating plantar fasciitis. Due to the myriad of orthotic materials and prescriptions available, further research is needed that evaluates prescription variables, including material selection, to determine the most appropriate combinations.

2.3.3.2 Kinetics and plantar pressures

In the past decade the use of sophisticated equipment to measure plantar pressures has become popular. Instruments such as the F-Scan, EMED/PEDAR, Musgrave and Kistler force platform are now widely used in research on foot function. While most studies have focused on the effect foot orthoses have on force and plantar pressure in the forefoot of people with diabetes\textsuperscript{309-313} or rheumatoid arthritis,\textsuperscript{314-316} some have focused on the temporal effects of foot orthoses in samples with more general musculoskeletal pathologies.\textsuperscript{317-319} It is plausible that changing the timing of force and pressure under the foot may have a positive affect, particularly with heel pain caused by plantar fasciitis. However, the results are conflicting, possibly due to differences in the type of equipment used to measure plantar pressures, as well as in the orthoses studied.

In a study using an electrodynogram system, Bennett et al\textsuperscript{317} evaluated the affect of a Root-style customised orthosis on 22 participants who had consulted a podiatry clinic for musculoskeletal complaints. They found the time to maximum or peak pressure at the lateral forefoot was 5% to 7% earlier with the orthoses. Cornwall and McPoil\textsuperscript{318} used a PEDAR system on 10 “healthy” participants to evaluate the affect of a prefabricated device. In contrast to Bennett et al,\textsuperscript{317} they found initiation of loading at the medial forefoot was significantly earlier with the orthosis - loading began at 3% of the stance phase versus 18% without orthoses. In a similar study to Bennett et al,\textsuperscript{317} Reed and colleagues\textsuperscript{319} also used an electrodynogram system on 27 participants who were about to receive orthoses for a variety of musculoskeletal complaints. They found initiation of loading at the medial forefoot was delayed by approximately 7% using both Root and inverted-style customised foot orthoses. More importantly, they found approximately a 5% decrease in the duration of loading under the heel, which corresponds to the site where the symptoms of plantar fasciitis most commonly occur. While there is disagreement in these studies with respect to the location of the change in
timing, it is clear foot orthoses alter timing of plantar pressures in the foot. The variation in location of these changes may be dependent on the type of device used or the technology (electrodynogram versus PEDAR) used to measure force.

In addition to these temporal effects, traditional Root theory of foot function\textsuperscript{320, 321} suggests that anti-pronatory foot orthoses should also lead to the foot being repositioned in a less pronated position. This in turn should increase force and pressure at the lateral forefoot. As a consequence of this more supinated position, the foot would also shorten, resulting in decreased strain on the plantar fascia.\textsuperscript{139, 140} To investigate this theory, Redmond et al\textsuperscript{322} evaluated two different foot orthoses using a PEDAR system in 22 healthy participants who were excessively pronated. The two devices included a\textit{flat insole} with a $6^\circ$ medial (varus) rearfoot wedge and a modified Root-style\textit{customised orthosis} (moulded to a model of the foot) with a $6^\circ$ rearfoot varus post. They found there was no shift in forces from medial to lateral, as would be expected with these types of device. However, the customised device markedly reduced force in the heel and forefoot, redistributing it towards the midfoot. For example in the heel, maximum force and the force-time integral reduced by 8% and 11% respectively. In contrast, maximum force and the force-time integral increased by 20% and 54% respectively in the midfoot. Due to the contoured shape of the customised orthosis, plantar pressures decreased in both the heel and the midfoot due to the increased area the force was applied. Whether these effects are beneficial is not known at this stage, although it is plausible that such changes may be valuable in cases of plantar heel pain where the proximal aspect of the plantar fascia is inflamed at its attachment to the calcaneus.

Finally, some researchers have attempted to evaluate the effect of foot orthoses on the centre-of-pressure.\textsuperscript{323-328} It has been suggested that the centre-of-pressure should shift laterally with anti-pronatory orthoses, however the relationship between centre-of-pressure and foot function is still far from understood. With this in mind, most researchers have assessed whether there is a medial-lateral shift in the centre of pressure with orthoses,\textsuperscript{323, 325, 326, 328} while two studies have focused on the timing or velocity of the centre of pressure.\textsuperscript{324, 327} The results so far are somewhat equivocal with some studies finding there are changes with orthoses\textsuperscript{323-325, 328} while others found no
Therefore, further research is needed before any conclusions can be made.

2.3.3.3 Electromyography

There have only been two studies published to date on the effects of foot orthoses on electromyographic activity of muscles in the leg (both studies used surface electromyography). Tomaro and co-workers\textsuperscript{329} evaluated the effect of customised foot orthoses on electromyographic activity of the tibialis anterior, peroneus longus and gastrocnemius muscles in 10 participants. They found a significant, albeit small, increase (2.6\% mean increase) in the duration of tibialis anterior activity with orthoses. Nawoczenski and Ludewig\textsuperscript{330} studied amplitude, rather than duration, of electromyographic activity in 12 runners. They found a statistically significant increase (37.5\% mean increase) in amplitude in tibialis anterior muscle activity with customised foot orthoses.

Although the data from surface electrodes is difficult to interpret, these studies suggest further research using electromyography may be worthwhile. It would be of particular interest to examine whether foot orthoses influence the tibialis posterior muscle.\textsuperscript{2} The primary action of tibialis posterior is to supinate the rearfoot and support and stabilise the medial longitudinal arch.\textsuperscript{2} Therefore, activity of tibialis posterior should also have an affect on strain in the plantar fascia.\textsuperscript{139,140} Unfortunately, this muscle is difficult to access, even with intramuscular electromyography.\textsuperscript{330}

2.3.3.4 Plantar fascial strain

All of the studies mentioned previously measured variables that do not directly indicate strain in the plantar fascia. It can only be inferred that altering rearfoot motion or arch height, for example, leads to a decrease in plantar fascial strain. Direct strain measurement in live humans would be the ideal method to evaluate the effect foot orthoses have, however due to the invasiveness of this procedure it is unlikely to be done. The next best method, although not ideal, would be to use cadavers. Kogler and colleagues did precisely that in two studies\textsuperscript{331,332} where they implanted a transducer that
measured strain in the fascia of cadaveric limbs. In the first study they evaluated the
effect of different foot orthoses in seven cadaveric limbs\textsuperscript{331} and in the second study they
examined the effect of different medial and lateral wedging configurations in nine
cadaveric limbs.\textsuperscript{332} They found that some orthoses significantly reduced strain in the
plantar fascia, while others did not. For example the UCBL orthosis\textsuperscript{c} reduced strain by
up to 5\%, whereas the functional foot orthosis increased strain slightly by up to 1\%
depending on the load applied. Likewise, lateral forefoot wedging significantly
decreased strain in the fascia (by about 1\%), while medial forefoot wedging increased
strain. It is clear from this research, that some orthoses have the ability to reduce
plantar fascial strain in cadavers. Whether this translates to the dynamic environment of
a live human remains to be investigated, although it appears likely it would. Finally, it
is not known if such small decreases in strain would be enough to improve the clinical
outcome for someone with plantar fasciitis.

2.3.3.5 \textit{Summary}

There is still a great deal to be learnt about the effect foot orthoses have on foot function
in general, as well as their effect on the function of the plantar fascia specifically. The
cadaver research by Kogler and colleagues suggests that some foot orthoses reduce
strain in the plantar fascia; an assumption long held by clinicians. This may be due to a
small reduction in the amount of rearfoot pronation, however simple support of the arch
cannot be ruled out. Whatever the primary mechanism, any assistance in preventing the
foot from elongating will lessen strain on the plantar fascia. Alternatively, reducing
plantar pressures around the heel or affecting clinically worthwhile changes in lower
limb muscle activity, may also reduce strain. Irrespective of the mechanism of action,
there is a more fundamental question to address and that is whether foot orthoses are
indeed useful in the treatment of plantar fasciitis. The next section explores this
question.

\textsuperscript{c} UCBL = University of California Biomechanics Laboratory
2.3.4 Effectiveness of foot orthoses in the treatment of plantar fasciitis

This section is in press and will be published in the Journal of the American Podiatric Medical Association.

There has been an abundance of articles published over the past 30 years on the effectiveness of foot orthoses in the treatment of plantar fasciitis. The vast majority suggest orthoses are highly effective in reducing the symptoms associated with this condition. One of the earlier quantitative methods of assessing outcomes of orthotic therapy was to either retrospectively evaluate patients’ satisfaction or self-reported symptom improvement using a questionnaire. Most studies have evaluated customised or prescription orthoses, finding that patient satisfaction and symptom relief is generally very high. The main findings from these studies were that self-reported symptom relief ranged from 70% to 94% and patient satisfaction from 83% to 91%. Details of these studies are contained in Table 2.6.
### Table 2.6 Summary of orthosis studies evaluating patient satisfaction or self-reported symptom relief.

<table>
<thead>
<tr>
<th>Author</th>
<th>Number of patients approached / respondents (response rate)</th>
<th>Types of orthoses</th>
<th>Period respondents wore orthoses</th>
<th>Patient satisfaction (continued use of orthoses)</th>
<th>Symptom relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blake and Denton</td>
<td>180 / 115 (64%)</td>
<td>“Root technique” or “inverted technique” (customised - made from a cast)</td>
<td>Up to 1 year</td>
<td>Not reported (not reported)</td>
<td>70% indicated orthoses had “definitely helped”</td>
</tr>
<tr>
<td>Donatelli et al</td>
<td>81 / 53 (65%)</td>
<td>“functional semi-rigid” (customised - made from a cast)</td>
<td>Up to 2 years</td>
<td>91% satisfied or very satisfied (94% still using orthoses)</td>
<td>94% indicated they experienced pain relief</td>
</tr>
<tr>
<td>Gross et al</td>
<td>500 / 347 (69%)</td>
<td>“orthotic shoe insert”</td>
<td>Up to 8 years</td>
<td>Not reported (90% still using orthoses)</td>
<td>76% indicated “complete resolution or great improvement”</td>
</tr>
<tr>
<td>Moraros et al</td>
<td>527 / 453 (86%)</td>
<td>“prescription foot orthoses”</td>
<td>14 weeks</td>
<td>83% satisfied (not reported)</td>
<td>95% indicated “fully or partially resolved”</td>
</tr>
</tbody>
</table>

However, none of these studies controlled for the use of other treatments (e.g. ice, physical therapy, etc.) or compared orthoses to no treatment. These are potential confounders because other treatments could have caused the result reported by respondents, or the condition may have improved over time even without treatment. Furthermore, patient satisfaction often evaluates satisfaction with service quality rather than being related to treatment outcome. Finally, assessment of symptoms or satisfaction is not broad enough to expose the full impact of the condition on a person. For example, a respondent could have no symptoms because they have limited their activities - often ones they enjoy - rather than due to a direct pain-relieving effect of orthoses. As a result of these methodological flaws, evidence from these studies is considered to be weak.
The majority of other literature on the effects of orthoses is also of generally poor quality, being either personal opinion or case series. Case series have concluded that foot orthoses are highly effective, however none of these studies satisfy the requirements for good evidence. An example previously presented, that of extracorporeal shock wave therapy (2.2.8 Treatment of plantar fasciitis), can be used to illustrate this point. Earlier non-randomised trials all reported extracorporeal shock wave therapy to be effective in treating plantar fasciitis. Rigorous, randomised controlled trials, however, found it to be no more effective than placebo. Clearly, the same could be true for any treatment, including foot orthoses. Therefore, when evaluating the effectiveness of foot orthoses in the treatment of plantar fasciitis it is important to focus on the available randomised controlled trials - that is, the best possible evidence available. With this in mind, the databases Medline, Cinahl, PubMed, Science Direct were searched for articles relating to foot orthoses and plantar fasciitis. In addition a hand search was performed using the references from those articles identified above and a systematic review from the Cochrane Library. Utilising this method, randomised controlled trials were identified, and all such trials were included in this review.

There have been six published randomised controlled trials to date evaluating foot orthoses for the treatment of plantar fasciitis. A detailed evaluation of these trials is presented below. First though it is worth highlighting that the first of these trials was published in 1997, so use of this methodology to evaluate orthoses for this condition is still relatively new. In this context, it is important to note that all suffer from certain methodological flaws. Therefore, their findings need to be discussed alongside their strengths and weaknesses.

Two of the six trials have evaluated the effect of magnetic insoles on plantar heel pain and these will be discussed first. Caselli and colleagues evaluated the effect of relatively soft insoles with and without magnetic foil in 34 participants with heel pain. Participants were assessed before treatment and after four weeks using the Foot Function Index. No significant difference was found between the two groups - the overall mean score (0 best - 100 worst) decreased from 34 to 31 for the magnetic foil
insole and from 29 to 28 for the standard insole. Therefore, it was concluded that the magnetic foil offered no advantage over the plain insole. This study did not follow key recommendations for conducting rigorous randomised controlled trials (discussed further in section 2.5: Randomised Controlled Trail Methodology) and was generally of poor quality.

A recent, more rigorous trial by Winemiller and coworkers also evaluated the effect of cushioning insoles with and without static bipolar magnets in 101 participants with plantar heel pain. No significant differences were found between the two groups after four and eight weeks of treatment. The overall mean visual analogue pain scale scores decreased from 6.9 to 3.9 for the nonmagnetic insole and from 6.7 to 3.9 for the magnetic insole at 8 weeks. Like the trial by Caselli and colleagues, it was concluded that magnets do not provide additional benefits compared to nonmagnetic insoles for the treatment of plantar heel pain. Therefore, there is no evidence to support the use of magnets for plantar fasciitis.

The other four trials have not included magnetic insoles, focusing instead on comparing customised foot orthoses to prefabricated or over-the-counter devices. Both these devices are commonly used in practise by podiatrists in Australia and New Zealand. The comparison of customised and prefabricated foot orthoses has arisen because of the difference in cost between them. A substantial amount of money is spent each year on foot orthoses - one United Kingdom study in 1994 reported the annual budget for orthoses in the National Health Service was UK£12 million. The issue of cost effectiveness of foot orthoses is further highlighted by a number of surveys and audits being conducted in the UK in the past ten years. Clearly cost is an important issue, but equally important is whether customised or prefabricated devices are more effective. The following randomised trials have attempted to evaluate the effectiveness of these devices.

Lynch and co-workers investigated the effect of foot orthoses in a three-arm trial of 85 participants. The three interventions were: (i) a mechanical treatment consisting of low-Dye taping and functional foot orthoses, (ii) an anti-inflammatory treatment consisting
of a corticosteroid injection followed by non steroidal anti-inflammatory drugs, and (iii) an accommodative viscoelastic heel cup. After three months the mechanical treatment was found to provide better relief of symptoms and fewer dropouts than the other groups. Visual analogue pain scores improved 44 mm for the mechanical group, 34 mm for anti-inflammatory group and 22 mm for the accommodative group. Nevertheless, this trial evaluated quite different treatment regimes, and the functional foot orthoses group had the added short-term treatment of taping.

Concentrating more on the effect of orthoses alone, Turlik et al\textsuperscript{47} evaluated functional foot orthoses against another type of generic heel pad in 55 participants. They found after approximately three months that functional foot orthoses obtained better outcomes on all measures. However, the researchers used outcome measures that did not have demonstrated validity or reliability. Moreover, certain methodological issues (e.g. allocation concealment) that could have led to bias were not addressed or reported on in all of the above studies, making the findings dubious. These issues are highlighted below in Table 2.8.

In a larger, multi-centre trial, Pfeffer and colleagues\textsuperscript{19} evaluated five treatments, including a silicone insert, a rubber insert, a felt insert, a customised orthosis and a stretching-only group (all orthosis groups also received stretching) in 200 participants. After 8 weeks, they found the prefabricated (over-the-counter) groups performed significantly better than the customised group and the stretching-only group. Pain scores (0 best - 100 worst) from the Foot Function Index improved 22.9 points for all the prefabricated groups combined versus 16.9 points for the customised and 17.2 for stretching only). The study design for this trial was generally in accordance with good research practice, although the researchers’ experience with prescription foot orthoses appeared to be minimal. As such their experience with casting and prescription for the customised orthoses could be questioned. For example, the authors’ state that “each centre had reviewed a Prolab instructional video on casting technique” prior to the commencement of the trial, indicating they may have been unfamiliar with the casting and prescription techniques normally used for customised foot orthoses. In contrast, it is most likely that the other randomised controlled trials utilised experienced clinicians.
Nonetheless this study provides a useful test of the effects of prefabricated orthoses, and demonstrates a slightly better outcome of stretching and prefabricated orthoses compared to stretching alone.

Finally, a recent study by Martin et al\textsuperscript{48} evaluated custom-made orthoses against over-the-counter arch supports and tension night splints in 193 participants. At 12 weeks, there was no significant difference in pain reduction between the groups. Visual analogue pain scores for pain during the day improved 34 mm for the custom-made group, 32 for the over-the-counter group and 28 for the tension night splint. Pain scores rating the pain upon the first step of the day improved 53 mm for both the custom-made and the over-the-counter groups and 61 mm for the tension night splint. Interestingly, the custom-made group had less dropouts compared to the other groups: 16\% for custom-made versus 27\% for over-the-counter versus 29\% for the tension night splints. Although this is the largest study to-date (initial recruitment), indicating good statistical power and therefore less likely to commit a Type II error\textsuperscript{d}, there were some methodological issues, including a very high dropout rate (24\%) that may have biased the study’s results.

A comparison of the four studies that focused on prefabricated versus customised orthoses is presented in Tables 2.7 and 2.8. Table 2.7 summarises general information about these trials (e.g. aims, participants, interventions and findings) whereas Table 2.8 reports on whether or not they followed important methodological recommendations (e.g. prospective sample size calculation, allocation concealment, intention to treat analysis).

\textsuperscript{d} Type II error: when the null hypothesis is accepted incorrectly, concluding that no significant difference exists between treatment groups when in fact there is one.\textsuperscript{349} This is largely dependent on sample size. A small sample size is less likely to detect a significant effect. In contrast, a large sample size is more likely to detect a significant effect, however this difference may not necessarily be clinically relevant. A prospective sample size calculation should be performed to ensure a statistically significant result is detected when a clinically meaningful difference is present.
Table 2.7  Summary of randomised trials comparing prefabricated and customised foot orthoses in the management of plantar fasciitis.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Aim of Study</th>
<th>Interventions</th>
<th>Participant numbers</th>
<th>Intervention period</th>
<th>Results (outcomes are group means)</th>
</tr>
</thead>
</table>
| Lynch et al   | To compare the individual effectiveness of three types of conservative therapy in the treatment of plantar fasciitis | 1. Anti-inflammatory therapy (corticosteroid injection and NSAIDs)  
2. Accommodative viscoelastic heel cup  
3. Mechanical (low-Dye taping and then a functional foot orthosis) | 103 recruited -35 anti-inflammatory -33 accommodative -35 mechanical | 3 months            | The mechanical treatment was significantly more effective than either the anti-inflammatory group or the accommodative group.  
-mechanical group decreased 44 mm on VAPS score compared to 34 mm for the anti-inflammatory group and 22 mm for the accommodative group. |
| Turlik et al  | To evaluate the effectiveness of generic heel pads and functional foot orthoses in relieving symptoms of heel spur | 1. Dr Fabricant's Sports Heel Pad  
2. Functional foot orthosis | 60 recruited -34 heel pad -26 functional orthosis | Unclear – at least 3 months | The functional orthosis performed significantly better on all outcome measures.  
-unvalidated non-parametric outcome measures.  
-participants using functional orthosis also used less adjunctive therapies (e.g. NSAIDs). |
| Pfeffer et al | To compare the results of nonoperative treatments for proximal plantar fasciitis (heel pain syndrome) | 1. Stretching only  
2. Custom foot orthosis  
3. Silicone heel pad (Bauerfiend)  
4. Rubber heel cup (Tuli’s™)  
5. Felt insert (Bauerfiend Orthotic™)  
NB. All orthosis/insert groups also stretched | 236 recruited -46 stretching only -42 custom orthosis -51 silicone heel pad -50 rubber heel cup -47 felt insert | 8 weeks             | Significantly better improvement in the prefabricated insert groups compared to the stretching-only and custom orthosis groups.  
-22.9 point improvement in pain for prefabricated devices compared to 16.9 for customised and 17.2 for stretching.  
-percentage improved in each group were: (1) silicone heel pad, 95%; (2) rubber insert, 88%; (3) felt insert, 81%; (4) stretching only, 72%; (5) custom orthosis, 68% |
| Martin et al  | To evaluate the effectiveness of three mechanical modalities in the treatment of plantar fasciitis | 1. Over-the-counter arch support (Foot Soldiers, Professional Footcare International)  
2. Custom-made foot orthosis  
3. Night splint (AliMed™, Inc) | 255 recruited -85 over-the-counter arch support -85 custom-made orthosis -85 night splint | 3 months            | No significant difference noted between groups with respect to first-step pain or pain felt during the day.  
-first step pain reduced 53 mm for the custom and over-the-counter, and 61 for the night splint. |

Abbreviations: NSAIDs = Non Steroidal Anti-Inflammatory Drugs, VAPS = Visual Analogue Pain Scale
Table 2.8 Methodological comparison of randomised trials using prefabricated and customised foot orthoses in the management of plantar fasciitis.

<table>
<thead>
<tr>
<th>Author</th>
<th>Prospective sample size calculation</th>
<th>Sample size at beginning &amp; end of trial</th>
<th>Dropout (%)</th>
<th>Appropriate randomisation and allocation concealment</th>
<th>Patients blinded to treatment</th>
<th>Validated outcome measures</th>
<th>Health status/quality of life measures</th>
<th>Intention-to-treat analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lynch et al⁴⁶</td>
<td>Not stated</td>
<td>Beginning: 103 End: 85</td>
<td>17%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Yes - VAPS only</td>
<td>No</td>
<td>Not stated</td>
</tr>
<tr>
<td>Turlik et al⁴⁷</td>
<td>Not stated</td>
<td>Beginning: 60 End: 55</td>
<td>8%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>No</td>
<td>No</td>
<td>Not stated</td>
</tr>
<tr>
<td>Pfeffer et al¹⁰</td>
<td>Not stated</td>
<td>Beginning: 236 End: 200</td>
<td>15%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Yes - one domain of Foot Function Index</td>
<td>No - only pain domain of Foot Function Index</td>
<td>Yes</td>
</tr>
<tr>
<td>Martin et al⁴⁸</td>
<td>Not stated</td>
<td>Beginning: 255 End: 193</td>
<td>24%</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Yes - VAPS only</td>
<td>No</td>
<td>Not stated</td>
</tr>
</tbody>
</table>

**Abbreviations:** VAPS = Visual Analogue Pain Scale
Clearly there are many methodological issues that have not been addressed in these trials (these issues are discussed below in 2.5 Randomised controlled trial methodology). With these limitations in mind, the evidence suggests foot orthoses produce small beneficial reductions in pain and disability in people with plantar fasciitis. However, what is less clear is whether prefabricated or customised orthoses are most effective. Most of the trials have focused on the question of how effective customised devices are compared to prefabricated devices. Some trials have demonstrated customised orthoses provide better outcomes,\textsuperscript{46,47} while others either show no difference\textsuperscript{48} or that prefabricated orthoses perform better.\textsuperscript{19} Interestingly, the two largest trials\textsuperscript{19,48} - and arguably the best designed from a methodological standpoint - demonstrated either no difference, or that the prefabricated orthoses tested performed better than the customised orthoses tested. The trial by Pfeffer and colleagues\textsuperscript{19} even found that the customised device they evaluated was no better than stretching alone.

Therefore, while there are discrepancies relating to the effect of orthoses in these trials, the evidence so far suggests that certain prefabricated orthoses performed as well, and in some circumstances better than customised orthoses. This is an important finding because one of the most crucial issues relating to foot orthoses is their cost. Clearly, if two devices have similar effectiveness, however one costs less, then the less expensive device is more cost-effective. The cost of prefabricated foot orthoses is often much less than customised or prescription orthoses. Therefore, if a prefabricated orthosis is as effective as a customised orthosis that costs more, then the prefabricated device provides better value for money. Although, the cost of fitting and modifying (i.e. professional expertise) prefabricated orthoses needs to be considered when assessing their overall cost.

If patients obtain good outcomes from prefabricated devices then prescribing fully customised, prescription orthoses with every possible modification may be unnecessary. If customised orthoses are no more effective over a given period, then the only justification for them would be if there was evidence demonstrating prefabricated devices had a reduced effect over time and needed to be replaced more often. As yet
though, the issue of whether prefabricated orthoses are more cost-effective has not been properly evaluated.

2.3.5 Summary

Foot orthoses are a common form of treatment for plantar fasciitis. They attempt to decrease the stress on the injured plantar fascia, preventing reinjury and thereby promoting healing. While many reports recommend foot orthoses for this condition, there is limited good quality research evaluating their effectiveness. Six randomised controlled trials have evaluated different types of foot orthoses for the treatment of plantar fasciitis, four of which have compared prefabricated and customised devices. Each trial has methodological strengths and weaknesses, so caution is needed when interpreting their results. Nevertheless, the evidence suggests that foot orthoses produce small reductions in pain and disability associated with plantar fasciitis. At this stage it is not possible to conclude either prefabricated or customised orthoses are better, nor can it be suggested that customised orthoses are better over time and therefore have a cost advantage. Further good quality randomised controlled trials are needed to provide evidence for which orthoses are most effective, and importantly, which are the most cost-effective.
2.4 ASSESSMENT OF PATIENT-BASED HEALTH STATUS

2.4.1 Introduction

Evaluating the effect of treatments is an essential component of any clinical trial, including those trials evaluating treatments for musculoskeletal disorders. Traditionally, clinician-based measures were used, essentially placing little emphasis on an appraisal from the person being treated. Consequently, decisions regarding the effect of treatment were based on the health professional’s judgement, rather than on the patient’s (also referred to within the literature as ‘consumer’s’) appraisal of their own health. A common example from medicine is that of measuring tumour size as the primary outcome of success of a treatment. However, it is not necessarily the case that a diminution in tumour size correlates to a good therapeutic outcome. Indeed, in reality, side effects of treatment can have a negative impact on the individual’s quality of life, both in the short and long term. This clinician-based focus is a historical problem in medicine and medical research where patient input had traditionally been considered too subjective. Bias towards clinician-based measures also exists in professions that care for foot and foot-related problems. Examples from the podiatry, orthopaedic and physiotherapy literature include measuring arch height, frontal plane calcaneal position or plantar pressures. Again, very little is known about the actual relationship between these objective measures and quality of life.

Due to the limitations of these measures, health outcome assessment has recently focused more on the concept of ‘health’ rather than disease. The World Health Organisation’s (WHO) definition of ‘health’ is that which is “not merely the absence of disease or infirmity, but a state of complete physical, mental, and social well-being”. Clearly, this definition of health is more holistic and consumer-centred than clinician-based measures. Accordingly, ‘health status’ measurement has developed to include a broader account of ‘health’, which encompasses the consumer’s perspective of their health.

More recently, health status measurement has incorporated the notion of health-related quality of life, which is an important, and some would argue fundamental, measure of
the impact of a disease or abnormality on an individual. Health-related quality of life characterises and measures what consumers experience as a result of health care. Emphasis is taken away from the disease process, while highlighting ill-health, which captures a broader view of the person and the impact of a condition on their life. Measurement of health-related quality of life is usually by self-report, and includes such areas as functional ability, social functioning, psychological well-being, somatic sensation (e.g. pain), and life satisfaction.

Measuring health status via self-reported questionnaire is a complex area that is developing rapidly. These questionnaires or instruments pose relevant questions relating to a person’s quality of life. Each question or item is then scored individually or added together to form a summary score. Scores can also be weighted to place more importance on certain sections of the instrument. In addition, many questionnaires group items together into like areas, known as domains (e.g. ‘pain’, ‘function’, ‘vitality’, etc.). Domains can also be scored individually or combined to give an overall numerical score of health and well-being, although this feature is not available for all instruments. Questionnaire development is a science of its own and rigorous methods should be employed to develop an instrument that will measure appropriately and accurately. Questions and their grouping into domains need to be developed using sound measurement principles, including item inclusion, psychometrics, validity and reliability testing. Appropriate development will ensure that instruments measure what they are supposed to measure and that they do so in a reproducible manner.

Health status measures can be categorised under two broad areas; (i) generic measures, which assess universal aspects of general health and well-being, and (ii) specific measures, which assess a specific medical condition or region of the body. It is generally accepted that when measuring health status, both a generic and a specific measuring instrument should be used as they measure distinct but complimentary aspects of patients’ health. Generic instruments allow some commonality of measurement, and as such, comparison between different conditions. However, due
to their non-specific nature, they are generally less responsive to change compared with specific instruments.\textsuperscript{363}

While there are many generic instruments to measure health status or health-related quality of life (e.g. the Sickness Impact Profile\textsuperscript{367, 368} and the Nottingham Health Profile\textsuperscript{369}), the most commonly used example is the 36-Item Short-Form Health Survey (SF-36) developed during the Medical Outcomes Study.\textsuperscript{370} It has been widely validated in many countries (including Australia) and against a variety of medical conditions,\textsuperscript{371-382} and is one of the most widely used instruments to measure health.

There are also a large number of instruments that relate to specific conditions, such as measures for rheumatoid arthritis\textsuperscript{383} and ankylosing spondylitis.\textsuperscript{384, 385} Few, however, relate explicitly to the foot. This may explain why, until recently, research evaluating foot problems has either used surrogate outcomes such as biomechanical measures or measures like patient satisfaction and pain scales - measures that have associated problems. There is little evidence to show biomechanical measures are actually linked to outcomes. Patient satisfaction tends to measure satisfaction with service quality rather than effectiveness of treatments and outcomes for the consumer.\textsuperscript{337, 338} Pain scales only assess one aspect of health, rather than the relatively broad investigation that health status assessment achieves.

Future outcomes research relating to foot problems clearly needs to incorporate health status or health status measurement. Both generic measures, like the widely used SF-36, as well as specific measures need to be included. The SF-36 has already been used in research related to common musculoskeletal disorders\textsuperscript{386, 387} and, specifically, problems of the foot.\textsuperscript{250, 388} Only two foot-specific questionnaires were available at the time of this study: the Foot Function Index and the Foot Health Status Questionnaire. Due to the relative obscurity of these two instruments, a summary of both is presented below.
2.4.2 The Foot Function Index

The Foot Function Index was designed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction in a rheumatoid arthritis population. During its validation it was examined for test-retest reliability, internal consistency, and construct and criterion validity. It has good test-retest reliability (intraclass correlation coefficients ranging from 0.69 to 0.87) and a high degree of internal consistency (Cronbach’s $\alpha$ ranging from 0.73 to 0.95). The pain domain (subscale) has also been shown to be a reliable side-to-side measure in orthopaedic intervention trials, where the foot that is not operated on serves as an internal control. The Foot Function Index was originally developed to assess the effect of foot orthoses on foot pathology in people with rheumatoid arthritis, however its developers suggest its use need not be restricted to this group. In fact, three recent studies have used the Foot Function Index in research unrelated to rheumatoid arthritis; although in each study the authors changed the questionnaire in some way without investigating the effect on validity or reliability.

The Foot Function Index has three domains or subscales: Activity Limitation, Pain and Disability (Appendix 1). Each domain contains a number of questions (five for Activity Limitation, nine for Pain, and nine for Disability) beside which respondents place a mark representing their responses on a visual analogue scale (see Figure 2.6 for an example from the Pain domain). The visual analogue scale ranges from the lowest end of the spectrum (e.g. “No pain”) to the highest end of the spectrum (e.g. “Worst pain imaginable”) and has corresponding verbal anchors at these extremes. If the respondent was not involved or did not perform the activity in question, he or she would answer the question not applicable (NA), which removes that question from the scoring.

Figure 2.6 An example of the style of question used in the Foot Function Index (taken from the Pain domain).

<table>
<thead>
<tr>
<th>HOW SEVERE WAS YOUR FOOT PAIN:</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. At its worst?..............No pain_____________________________imaginable_____</td>
<td>Worst pain</td>
</tr>
</tbody>
</table>
After completion, each question is scored by measuring the mark placed by the respondent on the visual analogue scale and then assigning a score between 0 and 9 to it (i.e. 10 equal segments on the visual analogue scale). Once each question is scored, the scores are added and then divided by the number of applicable questions in that domain (NA questions are not scored and therefore do not enter into this equation). This is repeated for each domain and then an overall Foot Function Index can be computed by adding each of the domain scores then dividing by three (i.e. three domains). The scores for each domain range from 0 - 100, with 0 representing the best and 100 representing the worst possible scenario. Similarly, the overall Foot Function Index score ranges from 0 - 100.

2.4.3 The Foot Health Status Questionnaire

The Foot Health Status Questionnaire was primarily developed to assess subjects undergoing surgical treatment for common foot conditions, however it was validated (content, criterion and construct validity) across a wide spectrum of pathologies including skin, nail and musculoskeletal disorders. It has a high test-retest reliability (intraclass correlation coefficients ranging from 0.74 to 0.92) and high degree of internal consistency (Cronbach’s $\alpha$ ranging from 0.85 to 0.88).$^{394}$ Although it was originally designed with surgical outcomes in mind, it can be used to assess general foot conditions, such as skin conditions and musculoskeletal pain.$^{394-397}$

The Foot Health Status Questionnaire has four domains: Pain, Function, Footwear and General Foot Health (Appendix 2). Again, each domain has a series of questions (four for Pain, four for Function, three for Footwear, and two for General Foot Health); however in contrast to the Foot Function Index, each question has a series of responses (e.g. “None”, “Very Mild”, “Mild”, “Moderate”, “Severe”) to which the participant circles the most appropriate response (see Figure 2.7 for an example from the Pain domain).
Figure 2.7 An example of the style of question used in the Foot Health Status Questionnaire (taken from the Pain domain).

1. What level of foot pain have you had during the past week? (circle number)
   None..........................................................1
   Very Mild..................................................2
   Mild.........................................................3
   Moderate..................................................4
   Severe....................................................5

The score for each question is then entered into a computer program (The Foot Health Status Questionnaire, Version 1.03), which then transforms the raw results and sums them into each domain. Like the Foot Function Index, the scores range from 0 - 100, however 100 represents the best and 0 represents the worst scenario - this is opposite to the Foot Function Index.

2.4.4 Summary

Health status assessment is an important and rapidly developing area of health outcome assessment. Its measurement emphasises the manifestations of an illness and its treatment from the consumer’s perspective. Measurement of health status is carried out by self-reported questionnaires that have undergone appropriate development, including validity and reliability testing. Health status instruments fall into one of two categories, either generic or specific. There are many generic instruments available, however the SF-36 is one of the most commonly used in clinical trials. With respect to the foot, there were two validated instruments available at the time of this study, the Foot Function Index and the Foot Health Status Questionnaire.
2.5 RANDOMISED CONTROLLED TRIAL METHODOLOGY

Part of this section has been published in the Journal of the American Podiatric Medical Association.398

2.5.1 Introduction

Randomised controlled trial methodology has been reported in medical science since the 1940’s, although its initial use may have occurred 50 years earlier.399-401 A randomised controlled trial is considered the gold-standard when evaluating the efficacy or effectiveness of a treatment.350, 402-407 There are two key features to a randomised controlled trial, which in its simplest form includes: (i) there is a comparison of a group receiving an intervention and one which does not, and (ii) there is random allocation into those groups.407 More complex trials can be performed where multiple interventions are compared.

The main aim of using randomised controlled trial methodology is to ensure as much as possible that the characteristics of the participants (people who receive the interventions) at the beginning of the trial are similar across groups.406 As a consequence, if appropriate randomisation and concealment are carried out, bias, or systematic unwanted effects, will be minimised.407 In order to appreciate the power of randomised controlled trials, it is important to explore these issues further.

2.5.2 Random allocation

The key feature of randomised controlled trials is random allocation of participants to groups. This feature promotes comparability among the study groups.408 such that known and unknown prognostic variables will be similar.405 Common methods to achieve randomisation include consulting a random number table (supplied in many statistical textbooks) or by using a computer program to generate a random number sequence.406 There are different forms of randomisation including simple randomisation, blocked randomisation (where randomisation occurs in equally sized blocks of participants), stratified randomisation (where randomisation is based on
prognostic variables) and adaptive randomisation (where allocation probabilities change as the study progresses).\textsuperscript{405} For most studies, simple or blocked randomisation is usually appropriate, however for multi-centre trials randomisation may need be stratified by centre.\textsuperscript{405}

Once the allocation sequence is determined it must be concealed from the person or people recruiting participants for the trial.\textsuperscript{409,411} This prevents a potential bias in recruitment. For example, a recruiter who knows which group the next participant is to be allocated to could exclude participants from the trial if he or she had little faith in the allocated treatment. This may occur if the next potential recruit is a particularly difficult case and the investigator thinks they may respond poorly to the allocated treatment, for example the control group. Ultimately, this could cause imbalance in the groups because the control group will not contain these difficult cases.

\section*{2.5.3 Bias}

In any clinical evaluation, it is essential that research methodologies ensure that the effect of a treatment on patients is directly attributable to that treatment, and not to other extraneous causes. For example, one common problem in clinical trials - even controlled trials - is that, unknowingly, researchers may influence or bias the outcome of a study.\textsuperscript{409,410,412} Such bias can distort the results or conclusions away from the truth, the end result being an underestimation or exaggeration of the effects of an intervention.\textsuperscript{406} Some of the more common biases that may occur will now be covered.

\subsection*{2.5.3.1 Selection bias}

Selection bias can arise if the investigators systematically manipulate enrolment into the trial.\textsuperscript{342,406} For example, selection bias will occur if patients are selected using non-random methods or if they self-select themselves into groups.\textsuperscript{413} This may make the recruits unrepresentative of the population with the condition being studied (i.e. it affects the external validity or generalisability of the trial). Selection bias can be minimised by careful sampling procedures and strict adherence to inclusion and exclusion criteria.\textsuperscript{413}
2.5.3.2 Allocation bias

Allocation bias is a type of selection bias. It occurs when the processes of allocating participants to groups leads to differences in the baseline characteristics of those groups. For example, if a researcher thinks a potential recruit may not do well with the treatment allocated to them, the researcher may exclude them from the study or postpone their enrolment until they are certain they will receive the intervention they believe to be most beneficial. Allocation bias can be prevented by appropriate randomisation and concealment of the allocation schedule from recruiters. This should be possible in all trials.

2.5.3.3 Assessment bias

Investigators’ or participant’s assessment of their response to treatment may be biased if they lack objectivity. For example, if an investigator is aware of the group a participant has been allocated to he or she may distort or misclassify the outcome measured. Participants may also under or over-report exposures or not report the outcomes being measured accurately. Assessments, therefore, must be as accurate and objective as possible. Measurements should be appropriate, objective and collected using standardised procedures. Objectivity can also be ensured by “blinding” of assessors, and sometimes also by blinding of participants.

2.5.3.4 Ascertainment bias

This form of bias occurs when the results or conclusions of the trial are distorted by the knowledge of which intervention each participant is receiving. For example, if the intervention for each participant is known, investigators may alter the types of co-intervention offered to participants or distort the outcomes being measured.

2.5.3.5 Inappropriate handling of withdrawals, dropouts and protocol violations

If the investigators know the intervention a participant received then they may alter the way in which they handle a participant who withdraws, drops out or violates the study
protocol. For example, the investigator may ignore a participant’s breach of protocol or allow a participant to withdraw less easily if they know what intervention they have been allocated. Drop-out rates are discussed further below (2.5.5 Other issues).

Assessment bias, ascertainment bias and inappropriate handling of participants can all be minimised by appropriate blinding. However, blinding of both the investigators and the participants is not possible in all trials. For example, it is difficult in trials where the intervention is a physical therapy, such as foot orthoses. Appropriate reporting of the methods used in clinical trials (refer to section 2.5.6 Reporting randomised controlled trials) will also minimise these forms of bias.

2.5.3.6 Publication bias

Publication bias occurs when a trial is published or not published because of the direction of its findings. For example, studies that have a positive result are more likely to be published and trials finding no difference between groups are, on average, less likely, or will take longer, to be published.

2.5.3.7 Stopping rules

Bias can occur if a trial is stopped inappropriately. For example, it would be inappropriate if investigators are aware of the outcomes of each intervention and continue recruiting only until they obtain a positive result. A pre-specified sample size (discussed in 2.5.4 Sample size) should be determined and data collection should generally continue until that target has been reached.

2.5.4 Sample size

Researchers should conduct a prospective power analysis and sample size calculation to decrease the chance of Type II errors. There should be an appropriate number of patients recruited into the trial to be able to detect clinically important effects. Sample size can be estimated using readily available tables and nomograms, or calculated using appropriate formulae.
2.5.5 Other issues

A range of other issues influences the validity and usefulness of clinical trials. These include:

- The primary outcome measures should be both valid and reliable.\textsuperscript{349,413}
- Appropriate outcome measures should be used,\textsuperscript{417} including those that measure patient-based health status as they offer a broader investigation of the effect of an intervention compared to surrogate outcome measures.\textsuperscript{357} A more detailed review of health status assessment is covered in the previous section (Section 2.4 Assessment of patient-based health status) of this literature review.
- The dropout rate must be reported and should be kept to a minimum; studies with substantial loss to follow-up should be viewed with caution.\textsuperscript{418} Excessive dropout may lead to distortion of results, particularly if more dropouts have occurred in one group.
- An intention-to-treat analysis should be conducted as the primary analysis. With this type of analysis outcome measures are obtained regardless of compliance with the trial protocol and data from all participants are analysed according to allocation even if the participants had adverse events or unexpected outcomes.\textsuperscript{419-422} Intention-to-treat analysis maintains the balance of confounders (reducing variability between groups)\textsuperscript{419} and provides a more pragmatic estimate of the benefit of a treatment.\textsuperscript{423}
- If a pragmatic trial is planned, then interventions, clinicians and study protocols should represent common practice as much as possible to ensure external validity and generalisability.\textsuperscript{424}

In addition, the interests of participants must be safeguarded by ensuring approval by an appropriate institutional ethics committee, guided by the Declaration of Helsinki.\textsuperscript{425}

2.5.6 Reporting randomised controlled trials

Bias may also occur during the dissemination process; both on the part of the authors and the readers of articles reporting randomised controlled trials. For example, insufficient information may be supplied in the article for readers to judge whether the
study is of good quality. To rectify this, researchers and editors involved in the area began developing guidelines for reporting clinical trials.\textsuperscript{426, 427} This concerted effort culminated in 1996, when a report was presented in the Journal of the American Medical Association titled \textit{Improving the Quality of Randomized Controlled Trials: The Consolidated Standards of Reporting Trials (CONSORT) Statement}.

This statement aimed to ensure accurate and complete reporting of the design, conduct, analysis and generalisability of trials; thus ensuring the highest possible standards are met when clinical trials are published. To facilitate this process, a checklist was also developed with items ranging from the title and abstract, to methodological issues and reporting of results. In addition, a flow diagram was suggested to illustrate the progress of participants through the trial.

The CONSORT statement has since been revised\textsuperscript{429-432} and is widely recognised as the benchmark for appropriately reporting randomised controlled trials. It has been endorsed or recommended by many journals including the \textit{British Medical Journal}, the \textit{Journal of the American Medical Association}, the \textit{New England Journal of Medicine} and \textit{The Lancet}. Following these recommendations will ensure researchers provide adequate details of a trial, thus providing clinicians and other researchers with sufficient information to judge whether the findings are reliable. This is important when making decisions about incorporating findings into clinical practice.\textsuperscript{433}

\subsection*{2.5.7 Summary}

Randomised controlled trials are considered the gold-standard when evaluating the efficacy or effectiveness of interventions. Nevertheless, if there is insufficient attention to detail and protocol, results of such trials can be biased or contain errors. Issues such as inadequate allocation concealment, selection bias and inappropriate handling of dropouts can all cause bias. In addition, not adhering to general standards in research, such as using valid and reliable outcome measures will also cause inaccurate results, and outcome analyses that do not follow the intention-to-treat principle may cause distortion of a study’s findings. Finally, it is widely accepted that when reporting the results of randomised controlled trials the recommendations outlined in the CONSORT statement are followed.
2.6 CONCLUSIONS

The plantar fascia is responsible for supporting the foot, as well as contributing to energy conservation and dynamic function via the windlass mechanism. It is prone to damage when an excessive repetitive load is applied to it. The clinical condition that represents this damage is referred to as plantar fasciitis. Many treatments have been suggested with one of the most common being foot orthoses. However, most of the research relating to their use is of poor quality. Further rigorous, randomised controlled trials evaluating the effect of foot orthoses on plantar fasciitis are required. Appropriate methodology using a pragmatic approach will provide results that have minimal bias and are generalisable to the population of interest. In addition, patient-based health status should be evaluated to understand the effect of foot orthoses from the patient’s perspective.
Chapter 3

Foot orthosis prescribing habits of Australian and New Zealand podiatrists

3.1 INTRODUCTION

This chapter presents the findings from a survey of members of the Australian Podiatry Association and the New Zealand Society of Podiatrists. The survey was conducted to investigate the orthotic prescription habits of Australian and New Zealand podiatrists. The results of this survey have been published in the Journal of the American Podiatric Medical Association.  

3.2 BACKGROUND

There are many different types of foot orthoses ranging from cushioning insoles to ‘customised’ or ‘functional’ foot orthoses made from a plaster cast of the patient’s foot. Although this range is extensive, podiatrists - who are the primary providers of foot health care - have for the past twenty to thirty years relied on customised foot orthoses as a primary therapy to treat a range of foot and foot related conditions. However, in the past 10 years ‘pre-fabricated’ or ‘off-the-shelf’ foot orthoses have begun to be used more frequently; primarily due to these devices being relatively quick and cheap compared to customised orthoses. Unfortunately, there are a myriad of different types of pre-fabricated foot orthoses, as there are different styles of customised foot orthoses. Furthermore, there are many different materials that orthoses can be made from.

Due to the variety of devices currently used by practitioners, it was considered important to investigate the types of orthoses podiatrists were prescribing and, if possible, determine what prescription variables a ‘typical’ customised foot orthosis
consisted of. This was necessary as a clinical trial comparing commonly used foot orthoses for the treatment of plantar fasciitis was planned. The results from this survey, therefore, informed the method of the randomised controlled trial in Chapter 5.

3.3 AIM

To evaluate the orthotic prescription habits of podiatrists in Australia and New Zealand.

3.4 RESEARCH QUESTIONS

The following were the primary research questions of this study. For podiatrists who are members of the Australian Podiatry Association or New Zealand Society of Podiatrists:

1. What types of foot orthoses are most commonly prescribed?

2. What is a typical prescription for a customised foot orthosis?

3.5 METHOD

3.5.1 Participants

Participants for this research project included members of the Australian Podiatry Association and the New Zealand Society of Podiatrists.

3.5.2 Terminology

Universal terminology for orthotic prescription has been identified as problematic in discourse on almost any aspect of orthotic therapy. For the purpose of this survey the following cast and orthotic categories and abbreviations have been used. General
orthotic types were taken from the Australian Podiatry Council’s⁶ ‘Clinical Guidelines for Orthotic Therapy Provided by Podiatrists’²⁶⁸ (Table 3.1). Prior to this study, all podiatrists who were members of the Australian Podiatry Association and New Zealand Society of Podiatrists were supplied with a copy of this document, including definitions of the different categories of orthoses.

Table 3.1 Orthotic types as per the Australian Podiatry Council’s ‘Clinical Guidelines for Orthotic Therapy Provided by Podiatrists’.²⁶⁸

<table>
<thead>
<tr>
<th>(i)</th>
<th>Cushioning orthosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ii)</td>
<td>Pressure relief orthosis</td>
</tr>
<tr>
<td>(iii)</td>
<td>Pre-moulded/pre-formed/pre-fabricated orthosis</td>
</tr>
<tr>
<td>(iv)</td>
<td>Moulded non-cast orthosis</td>
</tr>
<tr>
<td>(v)</td>
<td>Moulded cast (no posting) orthosis</td>
</tr>
<tr>
<td>(vi)</td>
<td>Functional (customised kinetic) orthosis</td>
</tr>
</tbody>
</table>

Without doubt, the most inconsistency within orthosis terminology originates with category (vi) above, the ‘functional (customised kinetic) orthosis’. For simplicity this will be referred to as *customised foot orthosis*. Within this category there are different styles that have been previously described by authors. All these styles are categorised under the broad classification of customised foot orthoses, however there are some important differences between them. The *Root* customised foot orthosis was originally described by Root³²¹ and is generally balanced so the bisection of the heel is vertical and any forefoot to rearfoot anomaly is supported. The *modified Root* customised foot orthosis is generally balanced so the heel is held in a position that will align the subtalar joint in neutral (i.e. in the neutral calcaneal stance position) as described by Hice.⁴³⁵ Other devices and modifications mentioned in this chapter are those that have been previously described by the original authors (e.g. the *inverted* customised foot orthosis⁴³⁷,⁴⁵²).

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⁶ The Australian Podiatry Council is the peak representative body for podiatry in Australia and is made up of the Australian Podiatry Associations from each State. It is now known as the Australasian Podiatry Council.
In addition, there are also different techniques for obtaining a negative cast or impression of the foot (as discussed in 3.7.2 Most commonly prescribed foot orthoses). The neutral suspension cast is that which has previously been described by Root et al.\textsuperscript{453} and the direct pressure or Langer cast technique is that which has been previously described by Langer and Wernick.\textsuperscript{454}

### 3.5.3 The Questionnaire

A questionnaire was developed using the expertise of six podiatrists, with a range of clinical experience from 3 to 20 years. These podiatrists had worked in a variety of settings where foot orthoses were utilised, including hospital and private practice, orthotic laboratories, education of student podiatrists and policy relating to the podiatry profession (e.g. competency standards\textsuperscript{263} and clinical guidelines for orthoses\textsuperscript{268}). In addition, the educational and employment backgrounds of these podiatrists included a range of States in Australia, as well as the United Kingdom and New Zealand.

The resulting questionnaire was subsequently piloted on 40 registered podiatrists across all States of Australia and New Zealand. After analysis of the responses and feedback, the questionnaire was further developed and refined to the format used in this research project - a 23-item questionnaire (Appendix 3). The questionnaire included sections on demographics, quantity of orthoses prescribed, assessment methods, types of orthoses prescribed, casting methods, style of customised foot orthoses, additions/materials, and manufacturing habits.

### 3.5.4 Procedure

The questionnaire was distributed via the *Australasian Journal of Podiatric Medicine* (Vol. 32, No. 3) and posted to all members of the Australian Podiatry Association and the New Zealand Society of Podiatrists. To maximise response rate, a reply-paid envelope was included and a reminder notice was published in the following issue of the journal (Vol. 32, No. 4). In addition, five state, national and international conferences were targeted to further improve the response rate from members who had not completed the questionnaire previously. Prior to distribution, the research project was
approved by the University of Western Sydney Macarthur Ethics Review Committee (Human Subjects): Approval no. 1998/087 (Appendix 4).

### 3.5.5 Statistical analysis

Data were statistically analysed using the computer program Statistical Package for the Social Sciences (SPSS), Version 9.0. Data were analysed using cross-tabulations and statistical analysis was performed using the Pearson’s chi-square test. Fischer’s exact test was used where the sample size in a cell was small. Statistical significance was set at the conventional level of $p<0.05$.

### 3.6 RESULTS

#### 3.6.1 Response Rate

Six hundred and seventeen eligible responses were received corresponding to a 41% response rate. Sixty percent of the respondents were female and 40% male. Fifty-four respondents (approximately 9%) did not prescribe any type of foot orthosis, therefore the study sample for analysing orthotic prescriptions was 563 (Table 3.2). Ninety-three percent of the study sample were from Australia and 7% were from New Zealand.

**Table 3.2** Distribution of eligible members and respondents who prescribed foot orthoses across the two countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of eligible members (N=1505)</th>
<th>No. of respondents who prescribed foot orthoses (N=563)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>1394</td>
<td>521 (37%)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>111</td>
<td>42 (38%)</td>
</tr>
</tbody>
</table>
3.6.2 Types of foot orthoses prescribed

Seventy-two percent of respondents indicated that they prescribe customised foot orthoses ‘most often’, with pre-fabricated foot orthoses being the next ‘most often’ prescribed category (Figure 3.1). However, respondents from New Zealand prescribed three times as many pre-fabricated foot orthoses compared to Australian respondents ($\chi^2=19.78$, df=1, p<0.001).

**Figure 3.1** Percentage of respondents that utilised different types of foot orthosis ‘most often’ (N=563).

Of those who prescribed customised foot orthoses, the majority prescribed modified Root customised foot orthoses (52%), with the next most common style of device being the Root style (Figure 3.2).
Figure 3.2 Percentage of respondents that utilised different styles of customised foot orthosis ‘most often’ (n=442).

The remainder consisted of inverted and other techniques such as the DC wedge. With respect to the most commonly prescribed customised foot orthosis (the modified Root style), half the respondents balanced the positive cast to the neutral calcaneal stance position (NCSP) and the rest either balanced the cast with the heel vertical or utilised some other method (Table 3.3).
**Table 3.3** Results of respondents’ positive cast balancing protocols for customised foot orthoses.

<table>
<thead>
<tr>
<th>Orthosis style</th>
<th>Response</th>
<th>% within each style</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root style (n=303)</td>
<td>balance to vertical</td>
<td>54</td>
</tr>
<tr>
<td></td>
<td>balance to NCSP</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>other</td>
<td>9</td>
</tr>
<tr>
<td><em>modified Root style (n=422)</em></td>
<td>balance to vertical</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td><em>balance to NCSP</em></td>
<td><em>50</em></td>
</tr>
<tr>
<td></td>
<td>other</td>
<td>11</td>
</tr>
<tr>
<td>Inverted style (n=302)</td>
<td>&lt;20° inversion</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>20-25° inversion</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>&gt;25° inversion</td>
<td>12</td>
</tr>
</tbody>
</table>

NCSP = neutral calcaneal stance position  
*indicates the most commonly prescribed customised foot orthosis
3.6.3 Types of casting utilised

Neutral suspension casting was the most commonly utilised technique (58%) for obtaining a cast of the foot prior to manufacturing customised foot orthoses (Figure 3.3). Most other respondents employed the direct pressure or Langer technique.

Figure 3.3 Percentage of respondents that utilised different negative cast techniques ‘most often’ (n=539).
3.6.4 Materials and manufacturing

The vast majority of respondents used polypropylene ‘most often’ for the orthotic shell material (Figure 3.4) and ethyl vinyl acetate ‘most often’ for the rearfoot posting material (Figure 3.5).

Figure 3.4 Percentage of respondents that utilised different orthotic shell materials ‘most often’ (n=524).

Figure 3.5 Percentage of respondents that utilised different rearfoot post materials ‘most often’ (n=527).
Seventy percent of respondents utilised a commercial orthotic laboratory ‘most of the time’ or ‘always’ (Figure 3.6), with 20% indicating they do not use a commercial laboratory. The respondents who never used a commercial laboratory either manufactured the orthoses themselves or utilised technicians within their practice.

**Figure 3.6** Percentage of respondents indicating how often they utilised a commercial orthotic laboratory to manufacture their foot orthoses (n=562).

There were significant differences in manufacturing habits between males and females, with males being twice as likely to manufacture foot orthosis themselves ($\chi^2=10.69$, df=4, $p=0.030$). Consequently, there was a significant difference in the proportion of males and females utilising commercial orthotic laboratories ($\chi^2=9.21$, df=3, $p=0.027$). Seventy-four percent of females utilised a commercial laboratory ‘most of the time’ or ‘always’, while for males this figure was only 63%.
3.7 DISCUSSION

3.7.1 Generalisability of the survey findings

Although a large number of useable responses were returned (617), this represents only 41% of the potential sample. While the low response rate is acknowledged, it is consistent with response rates from non-directed questionnaires in health professions generally\textsuperscript{455-457} and in podiatry specifically.\textsuperscript{458} Notwithstanding the low response rate, many of the results from this questionnaire were unambiguous, indicating that further responses would be unlikely to change the results.

The gender split for respondents is consistent with the 1992 national podiatric medicine labour force data,\textsuperscript{459} indicating that approximately two thirds of the total work force was female (68%). The slightly lower rate of females in this survey (60%) may be explained by a decrease in the number of female graduates in the six to seven years since the labour force data was collected. This is supported by further data in the labour force report which showed that in 1992, 70% of graduates were female, however by 1994 this had fallen to 59% and in 1995, only 53% of undergraduate enrolments were females.

3.7.2 Most commonly prescribed foot orthoses

With respect to the most commonly prescribed foot orthosis, the results are clear. The vast majority of respondents prescribed customised foot orthoses ‘most often’. In fact, respondents were six times more likely to prescribe customised foot orthoses than pre-fabricated foot orthoses, which were the second most commonly prescribed orthoses. Further, those respondents who did prescribe customised foot orthoses indicated that the modified Root style was the most commonly prescribed customised foot orthosis style. Further, the majority of respondents balanced the modified Root style orthosis to the NCSP. The modified Root style was prescribed approximately two and a half times as often as the second most common customised foot orthosis, the Root style. Prior to manufacturing cast-type orthoses, most respondents utilised the neutral suspension casting technique to obtain a negative cast, although the direct pressure or Langer technique was also reasonably common. With respect to materials, over 80% of
respondents used polypropylene for the orthotic shell material and ethyl vinyl acetate for the rearfoot post material. Finally, the majority of respondents utilised a commercial orthotic laboratory to manufacture their foot orthoses ‘most of the time’ or ‘always’.

From these results, a profile of a typical foot orthosis prescribed by podiatrists in Australia and New Zealand can be developed. This orthosis utilises the modified Root style and is balanced to the neutral calcaneal stance position. It is made with a polypropylene shell and has an ethyl vinyl acetate rearfoot post applied. Typically, podiatrists take a neutral suspension cast prior to manufacture and use the service of a commercial orthotic laboratory to fabricate their orthoses. As previously discussed, due to the unambiguous nature of these findings, it is unlikely that the results would change even if more responses had been received. Therefore, although cautious of the generalisability of these findings, it is likely that this style of orthosis is representative of the most commonly prescribed device in Australia and New Zealand.

It is interesting to note the level of use of commercial orthotic laboratories by podiatrists. As commercial orthotic laboratories are a relatively recent phenomenon, the high level of use reported in this study has developed rapidly. However, this growth rate is likely to ease, given that the majority of practitioners are already utilising laboratories. Perhaps not surprisingly, males were twice as likely to manufacture their own foot orthoses, compared to females who were more likely to utilise a commercial orthotic laboratory.

Although practitioners still appear to be prescribing customised foot orthoses most often, respondents clearly indicated that pre-fabricated foot orthoses are the second most commonly prescribed devices. With the need to utilise cost-effective modalities, pre-fabricated foot orthoses may increase their share of the market in the future, however further research is needed to evaluate their effectiveness in comparison to other orthoses. Of interest here is that respondents from New Zealand were more likely to prescribe pre-fabricated foot orthoses than Australian respondents, which begs the question, “are their outcomes from orthotic therapy any different to the outcomes experienced in Australia?” Whether this greater use of pre-fabricated foot orthoses is
good or bad is impossible to determine without appropriate trials. This research that is needed to determine which styles of foot orthosis provide the best outcome at the least cost to the patient.

3.7.3 Limitations of this study

There are several limitations of this study that need to be recognised. Firstly, the response rate was low, therefore it is difficult to generalise the findings to the entire podiatric profession in Australia and New Zealand. However, the key findings from this study with respect to the substantiation required for Chapter 5 are clear and apparent, indicating that further responses probably would not affect the findings. Secondly, there is the possibility that participants may not respond honestly to this self-reported questionnaire; however the survey was anonymous and participants were unaware of how the results were to be compiled, so there was little motive for dishonesty. Thirdly, there may be a response bias for those who prescribe orthoses often compared those who do so infrequently. Finally, due to variations in terminology in orthotic therapy, some respondents may not have been familiar with terms utilised in this questionnaire and as such may have misunderstood certain questions and responses.

3.7.4 Directions for future research

Although the aim of this study was to evaluate orthosis prescription habits and use the findings to inform the randomised controlled trial in Chapter 5, two issues arose from this research that deserve further investigation. Firstly, there were differences in prescription habits between the countries and between males and females. It would be interesting to determine what the precursors are to these differences. Secondly, further research is required to compare Australia and New Zealand to other countries, such as the United States and the United Kingdom where similar scopes of practice exist. This would provide useful information regarding the most commonly prescribed foot orthosis in those countries and would make available data to compare variations in prescription.
3.7.4 Summary with reference to the primary research questions

At the beginning of this study two primary research questions were presented. Both questions are now answered below using a brief synopsis of the findings discussed in detail above. For podiatrists in Australia and New Zealand:

1. The customised foot orthosis was the type of orthosis most commonly prescribed, followed by the prefabricated foot orthosis.

2. The typical customised prescription was a modified Root style foot orthosis, balanced to the neutral calcaneal stance position, made with a polypropylene shell and with an ethyl vinyl acetate rearfoot post applied. To manufacture this device, most practitioners utilised a neutral suspension cast and employed the service of a commercial orthotic laboratory.

3.8 CONCLUSION

The types of foot orthoses prescribed most often by podiatrists in this survey were customised, followed by pre-fabricated. At the time of this survey the typical customised prescription was a modified Root style foot orthosis, balanced to the neutral calcaneal stance position, made with a polypropylene shell and with an ethyl vinyl acetate rearfoot post applied. These foot orthoses were utilised in the randomised controlled trial contained in Chapter 5.
Chapter 4

A comparison of two foot-specific health status instruments

4.1 INTRODUCTION

This chapter presents the findings from a comparison of two instruments designed to measure foot-specific health status: the Foot Function Index and the Foot Health Status Questionnaire. The results of this evaluation have been published in the journal Foot & Ankle International.\textsuperscript{460}

4.2 BACKGROUND

Evaluating the outcomes of an intervention can be a difficult and complex process; nevertheless outcomes assessment is an important tool to measure the effect of any treatment. While the field of health outcome assessment encompasses a vast array of measures, more recent developments have begun to focus on health status. This has now advanced to the point that health status can be utilised as a primary outcome measure.

Professions dealing with the foot have not escaped this evolutionary process, and consequently two foot-specific health status questionnaires have been developed and used in clinical trials: the Foot Function Index and the Foot Health Status Questionnaire. However, prior to using these questionnaires in such clinical trials, an evaluation of their suitability is required: it was the intention of this project to compare these two questionnaires.
4.3 AIM

The aim of this project was to compare available foot-specific health status measures to determine which was the most appropriate to evaluate the effectiveness of foot orthoses in the treatment of people with plantar fasciitis.

4.4 RESEARCH QUESTION

The following was the primary research question of this study:

1. Which foot-specific health status instrument, the Foot Function Index or the Foot Health Status Questionnaire, is most appropriate (i.e. ease of use, responsiveness, limitations, etc.) when evaluating the effectiveness of foot orthoses in the treatment of plantar fasciitis?

4.5 METHOD

A small clinical trial was conducted to measure change in health status of participants with plantar fasciitis treated with foot orthoses. The study compared performance of the two questionnaires. No attempt was made to assess the efficacy of the foot orthoses.

4.5.1 Study design

This clinical trial utilised a single factor, one-group pretest-posttest design. This study design was appropriate for comparing available, validated, foot-specific health status questionnaires (the Foot Function Index and the Foot Health Status Questionnaire).

4.5.2 Participants

Participants were recruited from a sports medicine centre and from a university teaching clinic in the Sydney metropolitan area. People were invited to participate in the study if they had consulted these clinics with pain in the arch or heel of the foot and
demonstrated clinical signs and symptoms consistent with plantar fasciitis. They were excluded if they had any relevant endocrine, neurological or musculoskeletal conditions that could have affected the plantar fascia. The project was approved by the University of Western Sydney Ethics Review Committee (Human Subjects) - Protocol Number 98/75 (Appendix 5). Informed consent was obtained from all participants prior to recruitment into the project.

4.5.3 Treatment

The treatments used in this project were customised, prescription foot orthoses. Either the investigator or a podiatrist employed in private practice assessed the participants and decided on the prescription. Neutral suspension casts were obtained of both feet and the corresponding casts were balanced to the neutral calcaneal stance position using the principles of Hice. Prescription variables included a 4.5mm polypropylene shell and a 350 - 400 kg/m² ethyl vinyl acetate rearfoot post. The orthoses were sent to a commercial orthotic laboratory for manufacture. This style of orthosis has been found to be the most widely utilised device in Australia and New Zealand. It is important to reiterate that it was not the aim of this study to evaluate the effectiveness of the orthoses per se, but instead, the application of the two outcome measures.

4.5.4 Outcomes measures

All participants were assessed by the investigator prior to and four weeks after receiving the foot orthoses. The following outcome measures were used.

4.5.4.1 The Foot Function Index

The Foot Function Index was designed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction in a rheumatoid arthritis population. As mentioned in Section 2.4.2, during its validation it was examined for test-retest reliability, internal consistency, and construct and criterion validity. It has good test-retest reliability (intraclass correlation coefficients ranging from 0.69 to 0.87) and a high degree of internal consistency (Cronbach’s α ranging from 0.73 to 0.95). The Foot Function Index was originally developed to assess the effect of foot orthoses.
on foot pathology in people with rheumatoid arthritis, however its developers suggest its use need not be restricted to this group.\textsuperscript{391,392}

\subsection*{4.5.4.2 The Foot Health Status Questionnaire}

The Foot Health Status Questionnaire was primarily developed to assess subjects undergoing surgical treatment for common foot conditions, however it was validated (content, criterion and construct validity) across a wide spectrum of pathologies including skin, nail and musculoskeletal disorders. As mentioned in Section 2.4.3, it has a high test-retest reliability (intraclass correlation coefficients ranging from 0.74 to 0.92) and high degree of internal consistency (Cronbach’s $\alpha$ ranging from 0.85 to 0.88).\textsuperscript{394} Although it was originally designed with surgical outcomes in mind, it can be used to assess general foot conditions, such as skin conditions and musculoskeletal pain.\textsuperscript{394-397}

\subsection*{4.5.5 Statistical Analyses}

Data were statistically analysed using the computer program Statistical Package for the Social Sciences (SPSS), Version 10.0. All data were initially explored using the descriptive function in SPSS and were visually inspected using histograms and distribution curves to check for gross departures from normality. In addition, skewness and kurtosis values were assessed and statistical tests for normalcy (Kolmogorov-Smirnov and Shapiro-Wilk) were performed. Certain domains in both questionnaires were significantly skewed, indicating the data should not be analysed using parametric tests. Consequently, comparisons between the before and after scores from the questionnaires were made using the Wilcoxon Signed Rank Sum Test.\textsuperscript{349} The medians and 95\% confidence intervals of the difference between the before and after scores were generated using Minitab Version 14.1. Statistical significance was set at the conventional level of $p<0.05$. All other analyses are qualitative in nature and are interpretations by the investigator.
4.6 RESULTS

There were 13 females and 4 males who participated in the study. Participant characteristics are summarised in Table 4.1.

Table 4.1 Participant characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>44.6</td>
<td>± 10.5</td>
<td>24-72</td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>83.4</td>
<td>± 20.9</td>
<td>47-130</td>
</tr>
<tr>
<td>Height (metres)</td>
<td>1.67</td>
<td>± 0.08</td>
<td>1.50-1.81</td>
</tr>
<tr>
<td>BMI (kilograms/metre$^2$)</td>
<td>29.9</td>
<td>± 6.9</td>
<td>20.9-46.6</td>
</tr>
</tbody>
</table>

BMI = body mass index

Pain levels improved after treatment with the foot orthoses whether measured with the Foot Function Index or the Foot Health Status Questionnaire. When measured with the Foot Function Index the mean pain level (0=best and 100=worst) improved from 44.5 (±18.1) before treatment to 25.8 (±21.7) after treatment. Similarly, although using reversed scoring (100=best and 0=worst), the mean pain level using the Foot Health Status Questionnaire improved from 35.0 (±21.9) before treatment to 66.0 (±19.0) after treatment.

To demonstrate the effect of the foot orthoses from a statistical viewpoint, medians before and after treatment are presented below for each domain of the Foot Function Index and the Foot Health Status Questionnaire (Table 4.2). In addition, the median of the difference between before and after the orthotic intervention and the 95% confidence interval are shown, as is the result from the Wilcoxon Signed Rank Sum Test.
Table 4.2 Change in scores for the Foot Function Index and Foot Health Status Questionnaire due to orthotic intervention (N=17).

**Foot Function Index** (Score ranges from 0-100), NB: the lower the result the better.

<table>
<thead>
<tr>
<th></th>
<th>Median before treatment (inter-quartile range)</th>
<th>Median after treatment (inter-quartile range)</th>
<th>Median of the change between before and after</th>
<th>95% Confidence Interval</th>
<th>Z-Value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity Limitation</td>
<td>15.0 (3.5-24.0)</td>
<td>4.0 (0.0-22.0)</td>
<td>5.5</td>
<td>-2.0 to 13.0</td>
<td>-1.321</td>
<td>0.186</td>
</tr>
<tr>
<td>Pain*</td>
<td>43.0 (31.5-60.0)</td>
<td>20.0 (6.5-50.0)</td>
<td>19.0</td>
<td>6.0 to 29.0</td>
<td>-3.007</td>
<td>0.003</td>
</tr>
<tr>
<td>Disability*</td>
<td>33.0 (3.5-47.5)</td>
<td>11.0 (0.0-36.0)</td>
<td>16.0</td>
<td>3.5 to 28.0</td>
<td>-2.386</td>
<td>0.017</td>
</tr>
<tr>
<td>Foot Function Index*</td>
<td>32.0 (17.0-41.0)</td>
<td>12.0 (4.0-31.0)</td>
<td>14.0</td>
<td>7.0 to 22.0</td>
<td>-2.960</td>
<td>0.003</td>
</tr>
</tbody>
</table>

**Foot Health Status Questionnaire** (score ranges from 0-100), NB: the higher the result the better.

<table>
<thead>
<tr>
<th></th>
<th>Median before treatment (inter-quartile range)</th>
<th>Median after treatment (inter-quartile range)</th>
<th>Median of the change between before and after</th>
<th>95% Confidence Interval</th>
<th>Z-Value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot Pain*</td>
<td>35.6 (12.5-52.2)</td>
<td>71.9 (48.1-71.9)</td>
<td>-30.6</td>
<td>-41.3 to -20.6</td>
<td>-3.517</td>
<td>0.000</td>
</tr>
<tr>
<td>Foot Function*</td>
<td>50.0 (31.3-50.0)</td>
<td>75.0 (65.6-93.8)</td>
<td>-25.0</td>
<td>-40.6 to -9.4</td>
<td>-2.772</td>
<td>0.006</td>
</tr>
<tr>
<td>Footwear*</td>
<td>25.0 (20.8-37.5)</td>
<td>33.3 (25.0-58.3)</td>
<td>-8.3</td>
<td>-16.7 to 0.0</td>
<td>-2.188</td>
<td>0.029</td>
</tr>
<tr>
<td>General Foot Health*</td>
<td>25.0 (0.0-25.0)</td>
<td>25.0 (25.0-72.5)</td>
<td>-17.5</td>
<td>-30.0 to -6.3</td>
<td>-2.681</td>
<td>0.007</td>
</tr>
</tbody>
</table>

*Statistically significant at p<0.05

NB. The two questionnaires have reversed scoring (i.e. 0 is the best score for the Foot Function Index and 100 is the best score for the Foot Health Status Questionnaire). Therefore, for the Foot Health Status Questionnaire a negative median of the change between before and after indicates improvement.
The foot orthoses led to an improvement in all three domains for the Foot Function Index, as well as the overall Foot Function Index score. However, the *Activity Limitation* domain was not statistically significant. In contrast, all four domains of the Foot Health Status Questionnaire significantly improved. Boxplots graphically display the improvements in the domains for both questionnaires (Figures 4.1 and 4.2).

**Figure 4.1** Box plots with interquartile range before and after treatment for each domain of the Foot Function Index (N=17).

Act. Lim. = Activity Limitation
Overall FFI = Overall Foot Function Index

**NB.** For the Foot Function Index, a *decrease* in the result from before to after indicates an improvement (i.e. opposite to the Foot Health Status Questionnaire).
4.7 DISCUSSION

The aim of this study was to compare and contrast the Foot Function Index and the Foot Health Status Questionnaire for measuring health status in participants receiving foot orthoses for plantar fasciitis. Although quantitative results have been presented in the results section, some of the more qualitative issues surrounding the administration and results obtained from these questionnaires are also discussed. Further discussion is drawn from experience gained conducting a larger clinical trial (Chapter 5) where over
700 individual assessments were made over the course of the twelve month trial. There are five main discussion areas:

### 4.7.1 Administration

While both questionnaires are relatively easy to administer, the Foot Health Status Questionnaire has some distinct advantages. The Foot Health Status Questionnaire was designed and validated on an Australian population (an advantage when used on Australian participants), whereas the Foot Function Index was designed and validated on a North American population. The instructions and wording of the Foot Health Status Questionnaire were written for participants with a relatively low level of English comprehension - Year Nine Australian Education System, approximately age 14 (Bennett PJ, Personal Communication, 1999) and formulated in a manner that is easy to understand. As such, respondents generally find it easier to complete. Further, the font utilised in the Foot Health Status Questionnaire is quite large, compared to the small font of the Foot Function Index, thus allowing people with mild visual impairment to easily read the text.

In contrast, it was beneficial to initially explain the method of questioning in the Foot Function Index, and then allow the respondent to read the instructions and complete the questionnaire. Without this brief explanation, respondents often found, in particular, the visual analogue scale method of answering confusing: while not a major concern, it does require more of the clinician’s/researcher’s time. Nevertheless, once a participant has completed the Foot Function Index a few times it becomes easier.

The Foot Health Status Questionnaire uses a different system where responses are provided in the form of a phrase (e.g. none, mild, moderate, etc.), which alters throughout the questionnaire. As the phrases change from question to question, the respondent must focus more on reading each response. In addition, respondents very occasionally indicate their response to be between two answers (i.e. between mild and moderate) or circle both, which can be problematic if not picked up before they complete the questionnaire. While the instructions are fairly clear, it is suggested the
wording on the Foot Health Status Questionnaire answers could be changed to something like ‘circle one number for each question below’ to alleviate this problem.

Finally, a section with relevant questions from the SF-36 (generic health status measure), as well as a section for patient demographics, characteristics and co-morbidities is included in the Foot Health Status Questionnaire. In contrast, the Foot Function Index does not include any of these, therefore other questionnaires would need to be completed, thus increasing respondent burden.

4.7.2 Responsiveness

The results from this project demonstrated that there was an improvement in all domains for both the Foot Function Index and the Foot Health Status Questionnaire following treatment with foot orthoses. Although all domains improved, the improvement in the Activity Limitation domain for the Foot Function Index was not significant, indicating either that this domain was less responsive to change than other domains or that orthoses produced smaller changes in activity limitation than in pain and disability.

When assessing the only domain that is directly comparable between the two instruments, that of Pain, the median effect size (i.e. before minus after) and the 95% confidence interval of that median are very similar, indicating responsiveness in this domain for the two questionnaire is comparable. However, the issue of responsiveness needs to be evaluated in the context of the specificity of the questionnaires to particular patient populations. It is pertinent to remember that the Foot Function Index was originally designed to measure the impact of foot pathology on function in terms of pain, disability and activity restriction, and that the original development occurred with people with rheumatoid arthritis in mind.\textsuperscript{389, 392} Taking this into account, it may be better suited to conditions that cause a greater degree of disability than more general musculoskeletal disorders such as plantar fasciitis.

In addition, a concern arose with the Foot Health Status Questionnaire: the General Foot Health domain may not be very discriminating between patients due to the limited
number of questions (there are only two questions in this domain). This may explain the result obtained for this domain where there were many participants clustered on a few scores, possibly indicating an inability of this domain to discriminate between participants who have similar, but not exactly the same, general foot health.

In summary, the Foot Health Status Questionnaire and the Foot Function Index demonstrated similar responsiveness in the sample evaluated, particularly in the domain of Pain. However, one domain in the Foot Function Index, Activity Limitation, did not demonstrate significant change, and therefore its relevance in measuring the effect of foot orthoses on plantar fasciitis is questionable. The findings from this project cannot be extrapolated to using the questionnaires in people with higher degrees of activity limitation, where the Foot Function Index may perform better than the Foot Health Status Questionnaire.

4.7.3 Scoring

The Foot Function Index has one area of concern in the Activity Limitation domain whereby a participant measured over time can inadvertently provide markedly different scores even though their actual activity limitation has not changed to the extent indicated. There are two interrelated issues associated with this: (i) the relevance of some of the questions to people suffering from plantar fasciitis, and, (ii) the impact of marking these question ‘NA’ (not applicable) on the overall score for this domain.

The Activity Limitation domain has five questions of which the first two relate to how much of the time did the respondent use walking aids such as a cane or crutches. These two questions are often answered NA by people with little activity limitation. The next two questions (questions three and four) relate to how much of the time the respondent ‘stay indoors’ or ‘stay in bed’ due to their foot problem. In participants who have a condition such as plantar fasciitis where such questions may not be relevant, there are potentially two ways in which they can respond: they can mark the questions as NA or they can score it as zero on the visual analogue scale. While questions answered NA are taken out of the final overall score for that domain, questions marked as zero will be included as a zero out of nine score for that domain. Clearly, this will alter the overall
scoring. In contrast to the previous questions, the final question (question five: “how much of the time did you limit your activities because of foot problems?”) is marked by most people with plantar fasciitis, rather than indicating NA.

A problem arises if on one occasion the participant marks questions three and/or four (‘staying indoors’ and ‘staying in bed’) with NA, then on the next occasion marks one or both with a score of zero. This alters the overall score for this domain even though the condition may have changed little. This potentially indicates poor consistency for this domain for people who do not have marked activity limitation.

This problem is of less concern in the other domains (Pain and Disability) as there are nine questions (potential score of 81) that are answered by the majority of respondents. Even if they are not, one or two questions either answered with a score or marked NA have less of an effect on the overall domain score. Further testing in a population with less activity limitation than the rheumatoid arthritis group utilised for the original validity and reliability testing may be needed to objectively evaluate this concern.

Interestingly, in the original validation process, Budiman-Mak and colleagues found that the Activity Limitation domain had less internal consistency compared with the domains of Pain and Disability. They went on to state that, “it would be useful to test the Foot Function Index in a population of individuals with degenerative joint disease of the feet to help clarify the usefulness of the Activity Limitation sub-scale” (p 570).

When developing and validating a similar scale, the Ankle Arthritis Scale, which adapted the Foot Function Index to the ankle, the researchers elected not to utilise the Activity Limitation domain due to this finding.

4.7.4 Footwear

The Foot Health Status Questionnaire contains a domain relating to footwear, which is an important area to assess when evaluating foot problems. Many anomalies in the lower extremity, or treatments relating to them, can have a significant impact on footwear. In particular, when evaluating the effect of foot orthoses - which invariably take up room in the shoe - it is important to assess their effect on footwear. An example
of this would be if the orthoses cause a marked improvement in foot-health, but
constrained the person to wearing one pair of shoes which they did not like wearing.
When evaluating shoe-wearing populations, the footwear domain is fundamental when
assessing other disorders where there is marked orthopaedic deformity (e.g. hallux
valgus, digital deformities, etc.).

A summary of the above discussion is contained in the Table 4.3.
Table 4.3. Comparison of the Foot Function Index (FFI) and the Foot Health Status Questionnaire (FHSQ).

<table>
<thead>
<tr>
<th></th>
<th>Applicability</th>
<th>Domains measured</th>
<th>Validity/Reliability</th>
<th>Can be used on its own</th>
<th>Ease of use</th>
<th>Areas of concern</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FFI</strong></td>
<td>Applicable to patients with moderate to severe foot conditions (e.g. people with rheumatoid arthritis)</td>
<td>(i) <strong>Activity Limitation</strong></td>
<td><strong>Valid</strong> internal, construct and criterion validity -validated on a rheumatoid arthritis population(^{389}) <strong>Reliable</strong> -ICCs ranging from 0.69 to 0.87(^{389})</td>
<td>Yes</td>
<td>Fair</td>
<td>Reliability of Activity Limitation domain for respondents with little activity limitation - due to lack of validation in this clinical group (requires expanded validation).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(ii) <strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>Fair</strong> -small font can be difficult to read -visual analogue scale can be confusing at first for respondents</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(iii) <strong>Disability</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>Lack of discrimination in the General Foot Health domain - respondents tend to cluster on certain values (may require further questions in this domain)</strong></td>
</tr>
<tr>
<td></td>
<td>(can also create an overall FFI by combining the above three domains)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FHSQ</strong></td>
<td>Applicable to patients with a broad spectrum of foot conditions</td>
<td>(i) <strong>Pain</strong></td>
<td><strong>Valid</strong> content, criterion and construct validity -more extensive validation than FFI, including skin, nail and musculoskeletal disorders (as well as foot surgery)(^304) <strong>Reliable</strong> -ICCs ranging from 0.74 to 0.92(^304)</td>
<td>Yes</td>
<td>Good</td>
<td><strong>Lack of discrimination in the General Foot Health domain - respondents tend to cluster on certain values (may require further questions in this domain)</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(ii) <strong>Function</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(iii) <strong>Footwear</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(iv) <strong>General Foot Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4.7.5 Other Questionnaires

Measurement of health outcomes is a rapidly growing area of research. At the time of this study there were few rigorously validated foot-specific health status measures in the public domain, however others have recently appeared. These include, The Foot Disability Questionnaire,462 The Rowan Foot Pain Assessment Questionnaire (ROFPAQ),463 which focuses on pain; and the American Academy of Orthopaedic Surgeons Foot and Ankle Questionnaire464 which has not been extensively validated yet. Being relatively new, these questionnaires have had limited use thus far.

4.7.6 Limitation of this study

As the study was conducted on a small sample presenting to just two clinics, care is needed assessing the generalisability of the treatment effect. Nevertheless, the specific aim of this study was to evaluate two foot-specific health status questionnaires, not the effect of foot orthoses per se.

4.7.7 Summary with reference to the primary research question

At the beginning of this study one primary research question was presented. This question will now be answered using a brief synopsis of the findings discussed in detail above. The Foot Health Status Questionnaire is the most appropriate foot-specific health status instrument when used to evaluate the effectiveness of foot orthoses in the treatment of plantar fasciitis. It has been well validated, is easy to administer and complete, is responsive to change, and also evaluates footwear and general health. In contrast, the Foot Function Index is generally not as easy to administer, does not evaluate footwear and general health, and there is the potential for inconsistent scoring in the Activity Limitation domain when dealing with respondents who do not have marked activity limitation.
4.8 CONCLUSION

At the time of this study, the Foot Health Status Questionnaire was found to be the preferred questionnaire when evaluating effects of foot orthoses on people suffering from plantar fasciitis. From this finding it was decided to use the Foot Health Status Questionnaire as the primary outcome measure in the randomised controlled trial contained in Chapter 5.
Chapter 5

Effectiveness of three types of foot orthoses in the treatment of plantar fasciitis: A single blind, randomised controlled trial

5.1 INTRODUCTION

This chapter presents the findings from a randomised controlled trial that evaluated the effectiveness of three types of foot orthoses in the treatment of plantar fasciitis.

5.2 BACKGROUND

The randomised controlled trial presented in this chapter was informed by findings from Chapters 3 and 4. From the survey conducted in Chapter 3, certain types of orthosis were found to be commonly prescribed and these were incorporated into this trial. In particular, a typical customised orthotic prescription was profiled; ensuring the customised orthosis used was most representative of the type of device prescribed by Australian and New Zealand podiatrists in practice. Similarly, Chapter 4 demonstrated that the Foot Health Status Questionnaire was the most appropriate health status instrument available to assess foot orthoses in the treatment of plantar fasciitis; therefore this questionnaire was used as the primary health status measure for the randomised controlled trial.

5.3 AIM

To evaluate the short and long-term effectiveness of foot orthoses (particularly customised and prefabricated foot orthoses) in the treatment of plantar fasciitis.
5.4 RESEARCH QUESTIONS

The following were the primary research questions of this study. In people with plantar fasciitis:

1. Are customised foot orthoses more effective at improving pain after 3 months than prefabricated or sham orthoses?

2. Are customised foot orthoses more effective at improving pain after 12 months than prefabricated or sham orthoses?

3. Are customised foot orthoses more effective at improving function after 3 months than prefabricated or sham orthoses?

4. Are customised foot orthoses more effective at improving function after 12 months than prefabricated or sham orthoses?

5.5 METHOD

5.5.1 Ethics approval

Ethics approval was gained through the University of Western Sydney Macarthur Ethics Review Committee (Human Subjects) - Protocol No.: 99/012 (Appendix 6).

5.5.2 Sample

5.5.2.1 Participants

One hundred and thirty six participants were recruited into the randomised controlled trial. To assist recruitment two media releases were sent to local newspapers, which published articles on the research project. Recruitment occurred from April 1999 to July 2000 and data collection was completed in September 2001.
5.5.2.2 *Inclusion criteria*

Inclusion into the research project was contingent on participants fulfilling the following criteria:

(i) 18 years of age or older.
(ii) Able to complete the health status measurement instruments.
(iii) Had symptoms consistent with plantar fasciitis for at least four weeks.

Plantar fasciitis was diagnosed from a clinical assessment based on the following criteria:

(i) Pain was reproduced by palpation of the plantar fascia or its origin at the medial calcaneal tubercle.
(ii) Pain was sharp and localised but not radiating.
(iii) Pain was worse when first standing or walking in the morning or after rest.
(iv) Pain reduced initially after first standing, but worsened with increased activity.

5.5.2.3 *Exclusion criteria*

(i) Previous plantar fascial surgery.
(ii) Previous osseous foot surgery.
(iii) Corticosteroid injection within the past three months.
(iv) Previous lower limb trauma causing structural imbalance (e.g. ankle fracture).
(v) Osseous abnormality (e.g. tarsal coalition).
(vi) Inflammatory arthritis (e.g. ankylosing spondylitis).
(vii) Metabolic disorders (e.g. diabetes).
(viii) Neurological disorders (e.g. Charcot-Marie-Tooth disease).

5.5.2.4 *Sample Size*

A prospective sample size calculation was performed using a previously published nomogram. As there were no data available from previous clinical trials of a similar nature, a difference between orthoses of 20 points on the Pain domain of the Foot
Health Status Questionnaire was chosen as a clinically important difference to detect. Standard deviations were derived from the trial in Chapter 4 and were set at 20. A sample size of 120 participants (i.e. 40 per group) provided 80% power to detect a 20 point difference at an alpha level of 0.05. To allow for participants dropping out of the trial, a sample size of between 130 and 140 was nominated. The final sample size recruited was 136, which was also adequate to detect a 13 point difference in function.

5.5.3 Setting

The trial was conducted at the University of Western Sydney Uniclinic.

5.5.4 Randomisation protocol

Participants were allocated to groups according to the output from a computer-generated randomisation process using Microsoft® Excel 97 (simple randomisation was performed). The allocation sequence was housed in a secure location (a lockable, combination safe) in the University of Western Sydney Podiatry Clinic and was not available to the investigator who recruited the participants. After recruiting a participant and completing all baseline assessments (i.e. after the initial appointment), the investigator obtained that participant’s allocation by phoning or e-mailing the reception staff at the clinic.

5.5.5 Blinding

This trial utilised single blinding where the participants were unaware of the type of orthosis allocated to them. Orthoses were made to appear as similar as possible given the constraints of materials (5.5.6 Clinical protocol). Each participant had impressions or casts of their feet taken at the initial appointment and were advised they would receive an orthosis that was moulded specifically to their feet. Prior to allocation, participants were only informed that they would receive a soft, medium or hard orthosis. They were not provided with any other information such as whether the devices were prefabricated or customised.
Due to difficulty blinding a physical therapy, such as foot orthoses, the investigator was not blinded. Although this was a potential source of bias, the main outcome measures (the Foot Health Status Questionnaire and the SF-36) were self-reported questionnaires. The data from these were quantitative and there was no subjective interpretation by the investigator conducting the assessment. Further, the participants completed the outcome measures at the beginning of each appointment before interacting with the researcher. Therefore, bias was minimised as much as possible given the physical constraints of researching this form of therapy.

5.5.6 Clinical protocol

5.5.6.1 Appointment 1 (Initial appointment)

Participants were informed of the procedures via a Participant Information Sheet. After reading the Information Sheet any questions relating to the study were answered. Participants then signed a Consent Form after which they completed the outcome instruments as outlined previously (5.5.7 Outcome measures). Each participant was then assessed using a standardised assessment (Appendix 7) by the investigator, who conducted all assessments over the course of the trial. Participant characteristics, such as weight, height, and duration of symptoms were obtained. In addition, certain biomechanical measurements, such as neutral calcaneal stance position, were included to assist with orthotic prescription. These were performed using a standard tractograph and angle finder as previously outlined in the literature\textsuperscript{465, 466} and were informed by the survey findings in Chapter 3.

Following completion of the assessment, neutral position plaster casts\textsuperscript{453} of both feet were taken by the investigator: these impressions or models of the feet were later used to fabricate the foot orthoses or size the Formthotics\textsuperscript{TM}. The feet were then cleaned and dried. A modified version of ‘Low-Dye’ taping\textsuperscript{467} was then applied (using 3.8 centimetre Leuko\textsuperscript{®} Sports Tape) to assist with immediate symptoms. Participants were advised to leave the tape on for three to five days.

At the end of the initial appointment each participant was given two educational brochures (Your podiatrist talks about heel pain and Choosing a cross-training shoe -
Appendices 8 and 9) that explained plantar fasciitis and its treatment, including appropriate triceps surae stretches and footwear. Participants were then given a further appointment two to three weeks later.

Following this appointment, and after the participant had departed, allocation to one of three groups (sham, prefabricated or customised) as per the allocation sequence (5.5.4 Randomisation protocol) was performed. Once the participant was allocated to a group, the orthoses were fabricated for that individual in the intervening two to three weeks.

The sham foot orthosis (Figure 5.1) was fabricated by moulding 6 mm, soft (120 kg/m$^3$) ethyl vinyl acetate over an unmodified cast of the foot. The ethyl vinyl acetate was heated in a small industrial oven to 140º Celsius for two to three minutes and then moulded over the cast using a standard orthotic vacuum press. These devices were manufactured at the University of Western Sydney Podiatry Orthoses Laboratory by the investigator and a technician. The sham orthosis was included so as to have a group receiving an orthosis that provided minimal structural support, however it is not a device that would be manufactured in practice.

**Figure 5.1** The sham orthosis and unmodified plaster cast.
The *prefabricated* foot orthosis (Figure 5.2) was a blue ¾ length Formthotic™ (retail mould) supplied by Footscience International (Christchurch, New Zealand). This prefabricated device is widely used by podiatrists and other health professionals in Australia and New Zealand. They were dispensed using the manufacturer’s instructions (i.e. heat moulded in the shoes with the talonavicular joint held by the participant in congruency). To achieve this the investigator used a standard Footscience International heat-moulding machine. The orthoses were placed in the shoes, which were then positioned over the heat outlets of the machine. A constant stream of warm air was then applied for a pre-set amount of time via the controls on the control panel (as per the manufacturer’s instructions). Once complete, the participant placed his or her feet in the shoes, making sure the Formthotics™ remained in place. They then stood up, and with the assistance of the investigator, their talonavicular joints were placed in congruency. They remained in this position while the devices cooled and moulded to the shape of their feet - this took approximately one to two minutes.

**Figure 5.2** The *prefabricated* orthosis and neutral suspension cast.
The customised foot orthosis (Figure 5.3) was fabricated using principles described by Hice. This style of customised orthosis is commonly referred to as a modified Root device as it is a slight modification from the original Root functional foot orthosis. To fabricate the device, the neutral suspension cast was sent to a commercial orthotic laboratory (The Orthotic Laboratory, Melbourne, Australia). The laboratory manufactured the orthoses in a standard fashion and then mailed the finished devices back to the investigator.

**Figure 5.3** The customised orthosis and modified plaster cast.

All devices were made to look as similar as possible (i.e. colour and shape) given the confines of the materials used in the study (Figures 5.4 and 5.5). A comparison of the materials and specifications of the three orthoses is made in Table 5.1.
Figures 5.4 and 5.5  Superior (top figure) and inferior (bottom figure) views of the three orthoses.
Table 5.1  Comparison of materials and specifications for the orthoses.

<table>
<thead>
<tr>
<th>Orthosis</th>
<th>Cast modifications</th>
<th>Shell material</th>
<th>Shell borders</th>
<th>Post material and grind</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sham</td>
<td>Nil.</td>
<td>Soft 120 kg/m³ ethyl vinyl acetate.</td>
<td>Medial border - bisection of 1st metatarsal.</td>
<td>None - ground into inferior aspect of shell.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lateral border - lateral aspect of foot.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Distal border - 10-15 mm proximal to 1st metatarsal head and 5-10 mm proximal to the fifth metatarsal head.</td>
<td>Inferior surface ground parallel with forefoot (i.e. 0°) with no pronatory motion.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Heel cup height - approximately 12.0 mm.</td>
<td>Heel ground to 1-2 mm thickness.</td>
</tr>
<tr>
<td>Prefabricated</td>
<td>Nil - cast not required (orthosis moulded with the talonavicular joint congruent).</td>
<td>Firm density polyethylene foam.</td>
<td>Pre-ground by manufacturer - available in extra small, small, medium, large and extra large (borders similar to sham and customised orthosis).</td>
<td>None - ground into inferior aspect of shell.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Medial and anterior borders occasionally ground to fit foot or shoe.</td>
<td>No grind required, already present.</td>
</tr>
<tr>
<td>Customised</td>
<td>As per Hice⁴³⁵ - intrinsic posting to balance cast in the neutral calcaneal stance position.</td>
<td>4.5 mm polypropylene (semi-rigid, thermoelastic) - shell fitted with a thin vinyl top-cover.</td>
<td>Medial border - bisection of 1st metatarsal.</td>
<td>400 kg/m³ ethyl vinyl acetate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lateral border - lateral aspect of foot.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Distal border - 10-15 mm proximal to 1st metatarsal head and 5-10 mm proximal to the fifth metatarsal head.</td>
<td>Inferior surface ground parallel with forefoot (i.e. 0°) with no pronatory motion.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Heel cup height - approximately 12.0 mm.</td>
<td>Heel ground to 1-2 mm thickness.</td>
</tr>
</tbody>
</table>

NB: No external advertising (e.g. logos) were present on any of the orthoses.
5.5.6.2 Appointment 2 (Issue appointment)

Two to three weeks after the initial appointment the participant returned and the allocated orthoses were dispensed by the investigator. A standardised form was used to collect relevant data (Appendix 10). A handout was given to the participant that provided relevant information about the orthoses (Appendix 11). For the purpose of this analysis, the second appointment was classified as the baseline appointment for the outcome measures as this is when treatment (i.e. the orthoses) began. All outcome measures were completed at the beginning of this appointment.

5.5.6.3 Appointments 3 and 4 (1 and 3 month follow-up)

Participants returned 1 month after receiving the foot orthoses to review their progress and to ensure the orthoses were comfortable. The outcome measures were completed again at the beginning of this appointment. A standardised form was used to collect other relevant data (Appendix 12). If the participant had any concerns at this stage, the investigator attempted to rectify them once they had completed the outcome measures. For example, participants may have reported the orthoses were uncomfortable. If this were the case they were adjusted accordingly (e.g. shortening the orthosis to stop discomfort beneath the metatarsal heads), however no adjustments were made that changed the inherent function of the device (e.g. to the balance or posting of the device). The 3 month follow-up (Appointment 4) essentially repeated the previous appointment. Data were collected as per Appointment 3 and adjustments were made to orthoses that were uncomfortable.

5.5.6.4 Appointments 5 and 6 (6 and 12 month follow-up)

For the 6 and 12-month follow-ups the health status measures were mailed to the participants. An extra questionnaire was also sent (Appendix 13) and a reply-paid envelope was included to facilitate the return of the questionnaires. For participants who did not reply within 2 weeks, a follow-up phone call was made to encourage them to complete the outcome measures and the questionnaires were re-sent if necessary.
This marked the end of data collection for the randomised controlled trial. Table 5.2 provides an overview of the activities undertaken at each of the above appointments.
Table 5.2  Outline of the activities undertaken at each appointment.

<table>
<thead>
<tr>
<th>Appointment</th>
<th>Outcomes measured</th>
<th>Initial assessment</th>
<th>Plaster casts taken</th>
<th>Low-Dye taping applied</th>
<th>Stretching exercises prescribed</th>
<th>Plantar fasciitis and footwear literature</th>
<th>Orthoses dispensed with instructions</th>
<th>Orthotic adjustment made if required</th>
</tr>
</thead>
</table>
| **Appointment 1**  
(initial appointment) | ✓                  | ✓                  | ✓                   | ✓                      | ✓                               | ✓                                        |                                     |                                     |
|                | (at clinic)      |                    |                     |                        |                                 |                                          |                                     |                                     |
| **Appointment 2**  
(issue appointment - baseline) | ✓                  |                    |                     |                        |                                 |                                          |                                     | ✓                                   |
|                | (at clinic)      |                    |                     |                        |                                 |                                          |                                     |                                     |
| **Appointment 3**  
(1 month follow-up appointment) | ✓                  |                    |                     |                        |                                 |                                          |                                     | ✓                                   |
|                | (at clinic)      |                    |                     |                        |                                 |                                          |                                     |                                     |
| **Appointment 4**  
(3 month follow-up appointment) | ✓                  |                    |                     |                        |                                 |                                          |                                     | ✓                                   |
|                | (at clinic)      |                    |                     |                        |                                 |                                          |                                     |                                     |
| **Appointment 5**  
(6 month follow-up appointment) | ✓                  |                    |                     |                        |                                 |                                          |                                     |                                     |
|                | (sent to participant) |                |                     |                        |                                 |                                          |                                     |                                     |
| **Appointment 6**  
(12 month follow-up appointment) | ✓                  |                    |                     |                        |                                 |                                          |                                     |                                     |
|                | (sent to participant) |                |                     |                        |                                 |                                          |                                     |                                     |
5.5.7 Outcomes measures

5.5.7.1 Primary Outcomes

The primary outcome measures were the Pain and Function domains of the Foot Health Status Questionnaire at 3 and 12 months.

5.5.7.2 Secondary Outcomes

Secondary outcomes included:

- The Pain and Function domains of the Foot Health Status Questionnaire at 1 and 6 months.
- The Footwear and General Foot Health domains of the Foot Health Status Questionnaire at 1, 3, 6 and 12 months.
- Four domains of the Short Form-36 (commonly known as the SF-36). The domains were (i) Physical Function, (ii) General Health, (iii) Vitality and (iv) Social Functioning. These four domains are combined with the Foot Health Status Questionnaire and were found in its original development and validation to be most relevant to foot problems.\(^{394}\)
- A four-point scale of perceived improvement. Participants were asked, “Did the foot orthoses help?” to which they answered: (i) yes, a lot, (ii) yes, a little, (iii) no, not at all, or (iv) no, made it worse.

NB: the Foot Health Status Questionnaire and the SF-36 have been discussed in detail previously in 2.4 Assessment of patient-based health status. The Foot Health Status Questionnaire data were scored using the computer program, The Foot Health Status Questionnaire, Version 1.03. The SF-36 data were scored using a non-commercial, validated syntax derived from the Statistical Package for the Social Sciences (SPSS), Version 8.0.
5.5.8 Statistical analysis

Data were analysed using the computer program Statistical Package for the Social Sciences (SPSS), Version 10.0. All data were initially explored using descriptive statistics and continuous data were visually inspected using histograms and distribution curves to check for gross departures from normality. In addition, skewness and kurtosis values were assessed. To compare continuous outcome data (e.g. the Foot Health Status Questionnaire and SF-36 data) a linear regression approach to analysis of covariance (ANCOVA) was used. The baseline outcome measure (e.g. pain at baseline) for the three groups was used as a covariate. Data were analysed using the intention to treat principle. Statistical significance was set at the conventional level of p<0.05.

5.5.9 Protocol for non-responsive participants and stopping rules

If a participant had no relief of symptoms with the allocated orthosis the outcome measures at that point in time were compared to those at baseline. An a priori decision was made that if the outcome measures had not improved (i.e. 0% improvement in pain) or had worsened, the participant was offered alternative treatment (no statistical comparisons were made during this process).

Due to the interventions being relatively harmless, and that orthoses have been used for many years without major complications, no formal stopping rules were developed. As such, the trial was expected to run the full 12 months (i.e. each participant would be treated for 12 months).

5.6 RESULTS

The results are presented in the following order. Firstly, the baseline characteristics of the three groups are provided (Table 5.3). This is followed by a participant flow diagram (Figure 5.6) demonstrating the progression of participants through the 12 months of the trial. After this, comparisons of effectiveness are made between the three groups. The primary outcomes comparing the three orthoses are presented first, followed by the secondary outcomes.
5.6.1 Baseline characteristics

Baseline characteristics of the three groups are provided below in Table 5.3.

**Table 5.3** Baseline characteristics. Values are means (± standard deviations) unless otherwise stated.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sham (n=45)</th>
<th>Prefabricated (n=44)</th>
<th>Customised (n=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years</strong></td>
<td>48.5 (± 9.6)</td>
<td>47.3 (± 11.6)</td>
<td>49.2 (± 12.0)</td>
</tr>
<tr>
<td><strong>Number of women (%)</strong></td>
<td>30 (67)</td>
<td>25 (57)</td>
<td>34 (74)</td>
</tr>
<tr>
<td><strong>Height in centimetres</strong></td>
<td>168.3 (± 8.6)</td>
<td>168.6 (± 9.4)</td>
<td>165.9 (± 7.5)</td>
</tr>
<tr>
<td><strong>Weight in kilograms</strong></td>
<td>83.5 (± 14.0)</td>
<td>93.5 (± 18.0)</td>
<td>83.2 (± 16.6)</td>
</tr>
<tr>
<td><strong>Body Mass Index in kilograms/metre²</strong></td>
<td>29.6 (± 4.9)</td>
<td>32.9 (± 6.1)</td>
<td>30.3 (± 6.1)</td>
</tr>
<tr>
<td><strong>Number of feet affected (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One foot</td>
<td>22 (49)</td>
<td>23 (52)</td>
<td>25 (59)</td>
</tr>
<tr>
<td>Both feet</td>
<td>23 (51)</td>
<td>21 (48)</td>
<td>19 (41)</td>
</tr>
<tr>
<td><strong>Area of plantar fascia affected</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number affected proximally (%)</td>
<td>37 (82)</td>
<td>33 (75)</td>
<td>36 (78)</td>
</tr>
<tr>
<td>Number affected elsewhere (%)</td>
<td>8 (18)</td>
<td>11 (25)</td>
<td>10 (22)</td>
</tr>
<tr>
<td><strong>Hours on feet per day - self-reported</strong></td>
<td>9 (± 3)</td>
<td>9 (± 3)</td>
<td>9 (± 3)</td>
</tr>
<tr>
<td><strong>Median period of symptoms in months (range)</strong></td>
<td>12 (1-240)</td>
<td>11 (2-360)</td>
<td>12 (2-360)</td>
</tr>
</tbody>
</table>

1FHSQ = Foot Health Status Questionnaire (0 corresponds to the worst foot health, 100 the best)

| **SF-36 (0-100 points)**                           |                 |                      |                    |
| Foot Pain                                          | 45.1 (± 20.6)   | 42.1 (± 20.0)        | 48.4 (± 20.9)      |
| Foot Function                                      | 68.2 (± 26.8)   | 56.1 (± 27.3)        | 62.2 (± 22.0)      |
| Footwear                                           | 42.0 (± 26.0)   | 39.2 (± 29.6)        | 40.6 (± 24.4)      |
| General Foot Health                                | 31.4 (± 21.4)   | 30.2 (± 28.3)        | 32.9 (± 24.6)      |

2SF-36 = Short Form-36 (0 corresponds to the worst health, 100 the best)
Baseline participant characteristics were reasonably similar across all three groups. Notable exceptions to this were: the mean weight was higher in the prefabricated group, and the median period of symptoms was slightly less in the prefabricated group. Nonetheless, because appropriate randomisation and allocation concealment occurred, these differences can only be attributed to chance.
5.6.2 Progression of participants through the trial

Progression of participants over the 12 months of the trial is presented in Figure 5.6.

Figure 5.6 Participant flow diagram.

Patients screened at initial appointment (N=147) → Participants initially randomised (N=136) →

11 patients not randomised because of: pain due to conditions other than plantar fasciitis (n=5); current use of anti-inflammatory (n=1); symptoms so mild as to not register on outcome measures (n=1); tibialis posterior tendon injury (n=1); systemic arthropathy (n=1); diabetes (n=1); possible neurological disorder (n=1)

Randomised to SHAM foot orthoses (n=46) → Baseline – Issue (n=45) dropout (n=1, *see box at bottom of diagram) →

1 month review (n=45) → 3 month review (n=44) dropout (n=1) → 6 month review (n=44) → 12 month review (n=43) dropout (n=1)

Randomised to PREFABRICATED foot orthoses (n=44) → Baseline – Issue (n=44) →

1 month review (n=44) → 3 month review (n=44) → 6 month review (n=44) → 12 month review (n=43) dropout (n=1)

Randomised to CUSTOMISED foot orthoses (n=46) → Baseline – Issue (n=46) →

1 month review (n=46) → 3 month review (n=45) dropout (n=1) → 6 month review (n=45) → 12 month review (n=45)

*One participant withdrew from the trial (due to illness) prior to receiving treatment and without knowing which intervention she had been allocated. No baseline data were available.
Non-compliance with the protocol was minimal for the first 3 months of the trial, however as expected the numbers increased by 6 and 12 months. Numbers of participants in each group who were non-compliant are shown below in Table 5.4.

Table 5.4 Numbers of participants in each group who were non-compliant with the protocol.

<table>
<thead>
<tr>
<th>Time</th>
<th>Sham (n=45)</th>
<th>Prefabricated (n=44)</th>
<th>Customised (n=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3 months</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>6 months</td>
<td>9</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>12 months</td>
<td>12</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>

NB: Non-compliance with protocol included participants: taking anti-inflammatory medication, being given a corticosteroid injection, using alternative foot orthoses or a night stretch splint.

5.6.3 Primary outcomes

All three groups experienced improvements in pain and function at 3 and 12 months compared to baseline. The mean scores for pain and function for each group are presented in Figures 5.7 and 5.8 below.
Figure 5.7  Foot Health Status Questionnaire *pain* scores at baseline, 3 months and 12 months (mean ± standard error).

Figure 5.8  Foot Health Status Questionnaire *function* scores at baseline, 3 months and 12 months (mean ± standard error).
Significant differences were found between the sham orthosis and the other two orthoses for function scores at 3 months (prefabricated and customised improved more than sham). The following summarises the results presented in Table 5.5:

- The prefabricated group reported a greater improvement in function scores at 3 months of 8.4 points (95% confidence interval 1.0 to 15.8) compared to the sham ($t = 2.258$, $p = 0.026$).
- The customised group reported a greater improvement in function scores at 3 months of 7.5 points (95% confidence interval 0.3 to 14.7) compared to the sham ($t = 2.065$, $p = 0.041$).
- There was no difference in function scores at 3 months between the customised and the prefabricated orthoses.
- There were no differences in function scores at 12 months between any of the orthoses.
- There were no differences in pain scores at 3 and 12 months between any of the orthoses.

### Table 5.5 Comparison of the effect of the treatments for the primary outcomes.

<table>
<thead>
<tr>
<th>Outcome/time</th>
<th>Orthoses compared</th>
<th>Adjusted difference between means (95% CI)</th>
<th>t statistic</th>
<th>P value (*Significant at p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FHSQ - Pain @ 3 months</td>
<td>Prefab. vs. Sham</td>
<td>8.7 (-0.1 to 17.6)</td>
<td>$t = 1.947$</td>
<td>0.054</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>7.4 (-1.4 to 16.2)</td>
<td>$t = 1.670$</td>
<td>0.097</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>1.3 (-7.6 to 10.2)</td>
<td>$t = 0.294$</td>
<td>0.769</td>
</tr>
<tr>
<td>FHSQ - Pain @ 12 months</td>
<td>Prefab. vs. Sham</td>
<td>2.2 (-5.6 to 10.0)</td>
<td>$t = 0.533$</td>
<td>0.581</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>-0.1 (-7.8 to 7.7)</td>
<td>$t = -0.020$</td>
<td>0.984</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>2.3 (-5.6 to 10.1)</td>
<td>$t = 0.573$</td>
<td>0.568</td>
</tr>
<tr>
<td>FHSQ - Function @ 3 months</td>
<td>Prefab. vs. Sham</td>
<td>8.4 (1.0 to 15.8)</td>
<td>$t = 2.258$</td>
<td>0.026*</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>7.5 (0.3 to 14.7)</td>
<td>$t = 2.065$</td>
<td>0.041*</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>0.9 (-6.3 to 8.1)</td>
<td>$t = 0.249$</td>
<td>0.804</td>
</tr>
<tr>
<td>FHSQ - Function @ 12 months</td>
<td>Prefab. vs. Sham</td>
<td>5.5 (-2.0 to 13.0)</td>
<td>$t = 1.455$</td>
<td>0.148</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>4.3 (-3.0 to 11.6)</td>
<td>$t = 1.169$</td>
<td>0.244</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>1.2 (-6.1 to 8.5)</td>
<td>$t = 0.320$</td>
<td>0.749</td>
</tr>
</tbody>
</table>

FHSQ = Foot Health Status Questionnaire  
CI = confidence interval
### 5.6.4 Number needed to treat for primary outcomes

To compliment the analysis of the primary outcomes, numbers needed to treat were also calculated. Improvements from baseline of greater than 75% for pain and 33% for function were deemed clinically important. These levels were classified as ‘beneficial outcomes’ and participant’s data were subsequently dichotomised to reflect those who achieved them. These figures were chosen by taking into account improvement from the mean baseline score of the participants for pain (approximately 45) and function (approximately 60) to a result of 80 on either score - this magnitude of improvement was classified as being a ‘beneficial outcome’ from a clinical standpoint. Estimates of the number needed to treat (for benefit or harm) are presented in Table 5.6. Given that significant results were only found at 3 months (see Table 5.5), numbers needed to treat are only given for this timeframe. More extensive analysis, including the numbers and percentages of participants who achieved greater than a 75% improvement for pain and a 33% improvement in function, plus the absolute risk reductions are included in Appendix 14.

**Table 5.6** Number needed to treat (NNT) plus 95% confidence interval (CI)\(^f\) for pain and function at 3 months (*indicates a statistically significant difference in treatment effect).

<table>
<thead>
<tr>
<th>FHSQ domain/time</th>
<th>Sham vs. Prefabricated</th>
<th>Sham vs. Customised</th>
<th>Prefabricated vs. Customised</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain @ 3 months</td>
<td>NNT = 6</td>
<td>NNT = -138</td>
<td>NNT = -6</td>
</tr>
<tr>
<td></td>
<td>(95% CI -27 to 3)</td>
<td>(95% CI -5 to 6)</td>
<td>(95% CI -3 to 35)</td>
</tr>
<tr>
<td>Function @ 3 months</td>
<td>NNT = 6(^*)</td>
<td>NNT = 4(^*)</td>
<td>NNT = 12</td>
</tr>
<tr>
<td></td>
<td>(95% CI -26 to 3)</td>
<td>(95% CI 21 to 2)</td>
<td>(95% CI -9 to 4)</td>
</tr>
</tbody>
</table>

NB: A positive NNT indicates a beneficial outcome by the second orthosis, while a negative number indicates a harmful outcome by the second orthosis. A positive NNT can be referred to as NNT(benefit) and a negative NNT can be referred to as NNT(harm).\(^{470}\)

FHSQ = Foot Health Status Questionnaire

\(^f\) For number needed to treat (NNT) the confidence interval may not include the NNT value.\(^{470}\)
5.6.5 Secondary outcomes

5.6.5.1 Foot Health Status Questionnaire

Significant differences in general foot health scores were found between the customised and the sham orthoses at 1 month (customised improved more than sham) and between the sham orthosis and the other two orthoses at 3 months (prefabricated and customised improved more than sham). The following summarises the results presented in Table 5.7:

- The customised group reported a greater improvement in general foot health scores at 1 month of 11.0 points (95% confidence interval 2.5 to 19.4) compared to the sham ($t = 2.562$, $p = 0.012$).
- The prefabricated group reported a greater improvement in general foot health scores at 3 months of 12.7 points (95% confidence interval 2.8 to 22.6) compared to the sham ($t = 2.525$, $p = 0.013$).
- The customised group reported a greater improvement in general foot health scores at 3 months of 14.8 points (95% confidence interval 5.0 to 24.6) compared to the sham ($t = 2.975$, $p = 0.003$).

Table 5.7 Comparison of the effect of the treatments on the Foot Health Status Questionnaire (secondary outcomes).

<table>
<thead>
<tr>
<th>Outcome/time</th>
<th>Orthoses compared</th>
<th>Adjusted difference between means (95% CI)</th>
<th>$t$ statistic</th>
<th>$P$ value (*Significant at $p&lt;0.05$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prefab. vs. Sham</td>
<td>4.9 (-2.1 to 11.9)</td>
<td>$t = 1.389$</td>
<td>0.167</td>
</tr>
<tr>
<td>FHSQ - Pain</td>
<td>Custom vs. Sham</td>
<td>6.6 (-0.3 to 13.6)</td>
<td>$t = 1.892$</td>
<td>0.061</td>
</tr>
<tr>
<td>@ 1 month</td>
<td>Prefab. vs. Custom</td>
<td>-1.7 (-8.7 to 5.3)</td>
<td>$t = -0.482$</td>
<td>0.630</td>
</tr>
<tr>
<td>FHSQ - Pain</td>
<td>Prefab. vs. Sham</td>
<td>2.1 (-6.0 to 10.3)</td>
<td>$t = 0.528$</td>
<td>0.599</td>
</tr>
<tr>
<td>@ 6-months</td>
<td>Custom vs. Sham</td>
<td>5.6 (-2.4 to 13.7)</td>
<td>$t = 1.387$</td>
<td>0.168</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>-3.5 (-11.6 to 4.7)</td>
<td>$t = -0.844$</td>
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<tr>
<td>FHSQ - Function</td>
<td>Prefab. vs. Sham</td>
<td>4.2 (-2.6 to 11.0)</td>
<td>$t = 1.231$</td>
<td>0.221</td>
</tr>
<tr>
<td>@ 1 month</td>
<td>Custom vs. Sham</td>
<td>5.9 (-0.8 to 12.5)</td>
<td>$t = 1.753$</td>
<td>0.082</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>-1.6 (-8.3 to 5.0)</td>
<td>$t = -0.488$</td>
<td>0.626</td>
</tr>
<tr>
<td>Outcome/time</td>
<td>Orthoses compared</td>
<td>Adjusted difference between means (95% CI)</td>
<td>t statistic</td>
<td>P value (*Significant at p&lt;0.05)</td>
</tr>
<tr>
<td>-------------------</td>
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<tr>
<td><strong>FHSQ - Function</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 6 months</td>
<td>Prefab. vs. Sham</td>
<td>5.1 (-2.4 to 12.6)</td>
<td>( t = 1.346 )</td>
<td>0.181</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>5.0 (-2.3 to 12.3)</td>
<td>( t = 1.359 )</td>
<td>0.176</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>0.1 (-7.3 to 7.4)</td>
<td>( t = 0.021 )</td>
<td>0.984</td>
</tr>
<tr>
<td><strong>FHSQ - Shoes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 1 month</td>
<td>Prefab. vs. Sham</td>
<td>0.7 (-5.4 to 6.7)</td>
<td>( t = 0.221 )</td>
<td>0.825</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>-2.1 (-8.1 to 3.9)</td>
<td>( t = -0.696 )</td>
<td>0.488</td>
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<td></td>
<td>Prefab. vs. Custom</td>
<td>2.8 (-3.2 to 8.8)</td>
<td>( t = 0.914 )</td>
<td>0.362</td>
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<tr>
<td><strong>FHSQ - Shoes</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 3 months</td>
<td>Prefab. vs. Sham</td>
<td>3.3 (-3.5 to 10.0)</td>
<td>( t = 0.964 )</td>
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<td>Custom vs. Sham</td>
<td>-1.4 (-8.1 to 5.2)</td>
<td>( t = -0.421 )</td>
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<td>Prefab. vs. Custom</td>
<td>4.7 (-2.0 to 11.4)</td>
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<td><strong>FHSQ - Shoes</strong></td>
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<td></td>
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<td>@ 6 months</td>
<td>Prefab. vs. Sham</td>
<td>3.7 (-3.4 to 10.8)</td>
<td>( t = 1.028 )</td>
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<tr>
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<td>Custom vs. Sham</td>
<td>1.6 (-5.4 to 8.7)</td>
<td>( t = 0.455 )</td>
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<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>2.1 (-5.0 to 9.2)</td>
<td>( t = 0.582 )</td>
<td>0.562</td>
</tr>
<tr>
<td><strong>FHSQ - Shoes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 12 months</td>
<td>Prefab. vs. Sham</td>
<td>2.0 (-6.6 to 10.6)</td>
<td>( t = 0.465 )</td>
<td>0.643</td>
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<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>-3.1 (-11.6 to 5.4)</td>
<td>( t = -0.721 )</td>
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<tr>
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<td>Prefab. vs. Custom</td>
<td>5.1 (-3.4 to 13.7)</td>
<td>( t = 1.185 )</td>
<td>0.238</td>
</tr>
<tr>
<td><strong>FHSQ - General Foot Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 1 month</td>
<td>Prefab. vs. Sham</td>
<td>5.1 (-3.5 to 13.6)</td>
<td>( t = 1.174 )</td>
<td>0.243</td>
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<td>Custom vs. Sham</td>
<td>11.0 (2.5 to 19.4)</td>
<td>( t = 2.562 )</td>
<td>0.012*</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>-5.9 (-14.4 to 2.6)</td>
<td>( t = -1.366 )</td>
<td>0.174</td>
</tr>
<tr>
<td><strong>FHSQ - General Foot Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 3 months</td>
<td>Prefab. vs. Sham</td>
<td>12.7 (2.8 to 22.6)</td>
<td>( t = 2.525 )</td>
<td>0.013*</td>
</tr>
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<td></td>
<td>Custom vs. Sham</td>
<td>14.8 (5.0 to 24.6)</td>
<td>( t = 2.975 )</td>
<td>0.003*</td>
</tr>
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<td>Prefab. vs. Custom</td>
<td>-2.1 (-12.0 to 7.8)</td>
<td>( t = -0.419 )</td>
<td>0.676</td>
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<tr>
<td><strong>FHSQ - General Foot Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 6 months</td>
<td>Prefab. vs. Sham</td>
<td>9.6 (-1.3 to 20.4)</td>
<td>( t = 1.750 )</td>
<td>0.082</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>10.2 (-0.5 to 21.0)</td>
<td>( t = 1.888 )</td>
<td>0.061</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>-0.6 (-11.4 to 10.2)</td>
<td>( t = -0.117 )</td>
<td>0.907</td>
</tr>
<tr>
<td><strong>FHSQ - General Foot Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>@ 12 months</td>
<td>Prefab. vs. Sham</td>
<td>5.9 (-4.9 to 16.8)</td>
<td>( t = 1.087 )</td>
<td>0.279</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>8.3 (-2.4 to 19.0)</td>
<td>( t = 1.535 )</td>
<td>0.127</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>-2.4 (-13.1 to 8.4)</td>
<td>( t = -0.433 )</td>
<td>0.665</td>
</tr>
</tbody>
</table>

FHSQ = Foot Health Status Questionnaire
CI = confidence interval
5.6.5.2 *Short Form-36 (SF-36)*

Significant differences were found between the custom and the sham orthoses for *general health* scores at 3 months and 12 months (customised improved more than sham). In addition, there were significant differences between the sham orthosis and the other two orthoses for *vitality scores* at 1 month (prefabricated and customised improved more than sham) and between the custom and the other two orthoses for *vitality scores* at 3 months (customised improved more than prefabricated and sham).

The following summarises the results presented in Table 5.8:

- The customised group reported a greater improvement in general health scores at 3 months of 6.0 points (95% confidence interval 1.2 to 10.8) compared to the sham \((t = 2.488, p = 0.014)\).
- The customised group reported a greater improvement in general health scores at 12 months of 6.2 points (95% confidence interval 1.3 to 11.0) compared to the sham \((t = 2.519, p = 0.013)\).
- The prefabricated group reported a greater improvement in vitality scores at 1 month of 7.8 points (95% confidence interval 2.1 to 13.5) compared to the sham \((t = 2.716, p = 0.007)\).
- The customised group reported a greater improvement in vitality scores at 1 month of 8.4 points (95% confidence interval 2.7 to 14.0) compared to the sham \((t = 2.933, p = 0.004)\).
- The customised group reported a greater improvement in vitality scores at 3 months of 12.0 points (95% confidence interval 5.5 to 18.4) compared to the sham \((t = 3.674, p = 0.000)\).
- The prefabricated group reported a lesser improvement in vitality scores at 3 months of -6.7 points (95% confidence interval -13.2 to -0.2) compared to the customised \((t = -2.043, p = 0.043)\).
Table 5.8 Comparison of the effect of the treatments on the SF-36 (secondary outcomes).

<table>
<thead>
<tr>
<th>Outcome/time</th>
<th>Orthoses compared</th>
<th>Adjusted difference between means (95% CI)</th>
<th>t statistic</th>
<th>P value (*Significant at p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36 - Physical function @ 1 month</td>
<td>Prefab. vs. Sham</td>
<td>1.7 (-4.3 to 7.7)</td>
<td>t = 0.565</td>
<td>0.573</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>1.9 (-4.0 to 7.9)</td>
<td>t = 0.639</td>
<td>0.524</td>
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<tr>
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<td>Prefab. vs. Custom</td>
<td>-0.2 (-6.2 to 5.8)</td>
<td>t = -0.067</td>
<td>0.946</td>
</tr>
<tr>
<td>SF-36 - Physical function @ 3 months</td>
<td>Prefab. vs. Sham</td>
<td>4.7 (-1.7 to 11.1)</td>
<td>t = 1.445</td>
<td>0.151</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>1.9 (-2.9 to 9.8)</td>
<td>t = 1.086</td>
<td>0.280</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>1.2 (-5.2 to 7.6)</td>
<td>t = 0.374</td>
<td>0.709</td>
</tr>
<tr>
<td>SF-36 - Physical function @ 6 months</td>
<td>Prefab. vs. Sham</td>
<td>1.7 (-5.5 to 8.8)</td>
<td>t = 0.459</td>
<td>0.647</td>
</tr>
<tr>
<td></td>
<td>Custom vs. Sham</td>
<td>2.0 (-5.1 to 9.1)</td>
<td>t = 0.570</td>
<td>0.570</td>
</tr>
<tr>
<td></td>
<td>Prefab. vs. Custom</td>
<td>-0.4 (-7.5 to 6.7)</td>
<td>t = -0.104</td>
<td>0.917</td>
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<tr>
<td>SF-36 - Physical function @ 12 months</td>
<td>Prefab. vs. Sham</td>
<td>6.0 (-3.0 to 15.1)</td>
<td>t = 1.323</td>
<td>0.188</td>
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<tr>
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<td>Custom vs. Sham</td>
<td>4.7 (-4.2 to 13.6)</td>
<td>t = 1.036</td>
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<tr>
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<td>Prefab. vs. Custom</td>
<td>1.4 (-7.6 to 10.3)</td>
<td>t = 0.300</td>
<td>0.764</td>
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<tr>
<td>SF-36 - General Health @ 1 month</td>
<td>Prefab. vs. Sham</td>
<td>1.9 (-2.5 to 6.3)</td>
<td>t = 0.861</td>
<td>0.391</td>
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<td>Custom vs. Sham</td>
<td>1.8 (-2.5 to 6.2)</td>
<td>t = 0.834</td>
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<td>Prefab. vs. Custom</td>
<td>0.1 (-4.3 to 4.5)</td>
<td>t = 0.039</td>
<td>0.969</td>
</tr>
<tr>
<td>SF-36 - General Health @ 3 months</td>
<td>Prefab. vs. Sham</td>
<td>2.7 (-2.2 to 7.6)</td>
<td>t = 1.103</td>
<td>0.272</td>
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<td>Custom vs. Sham</td>
<td>6.0 (1.2 to 10.8)</td>
<td>t = 2.488</td>
<td>0.014*</td>
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<tr>
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<td>Prefab. vs. Custom</td>
<td>-3.3 (-8.1 to 1.5)</td>
<td>t = -1.365</td>
<td>0.175</td>
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<tr>
<td>SF-36 - General Health @ 6 months</td>
<td>Prefab. vs. Sham</td>
<td>0.6 (-4.7 to 6.0)</td>
<td>t = 0.237</td>
<td>0.813</td>
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<td>Custom vs. Sham</td>
<td>2.1 (-3.2 to 7.3)</td>
<td>t = 0.769</td>
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<td>Prefab. vs. Custom</td>
<td>-1.4 (-6.7 to 3.9)</td>
<td>t = -0.527</td>
<td>0.599</td>
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<tr>
<td>SF-36 - General Health @ 12 months</td>
<td>Prefab. vs. Sham</td>
<td>4.6 (-0.3 to 9.6)</td>
<td>t = 1.870</td>
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<tr>
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<td>Custom vs. Sham</td>
<td>6.2 (1.3 to 11.0)</td>
<td>t = 2.519</td>
<td>0.013*</td>
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<td>Prefab. vs. Custom</td>
<td>-1.5 (-6.4 to 3.3)</td>
<td>t = -0.621</td>
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<td>SF-36 - Vitality @ 1 month</td>
<td>Prefab. vs. Sham</td>
<td>7.8 (2.1 to 13.5)</td>
<td>t = 2.716</td>
<td>0.007*</td>
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<tr>
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<td>Custom vs. Sham</td>
<td>8.4 (2.7 to 14.0)</td>
<td>t = 2.933</td>
<td>0.004*</td>
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<tr>
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<td>Prefab. vs. Custom</td>
<td>-0.5 (-6.2 to 5.1)</td>
<td>t = -0.187</td>
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</table>
### Outcome/time

<table>
<thead>
<tr>
<th>Orthoses compared</th>
<th>Adjusted difference between means (95% CI)</th>
<th>t statistic</th>
<th>P value (*Significant at p&lt;0.05)</th>
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</thead>
<tbody>
<tr>
<td><strong>SF-36 - Vitality</strong> @ 3 months</td>
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</tr>
<tr>
<td>Prefab. vs. Sham</td>
<td>5.3 (-1.2 to 11.8)</td>
<td><em>t</em> = 1.599</td>
<td>0.112</td>
</tr>
<tr>
<td>Custom vs. Sham</td>
<td>12.0 (5.5 to 18.4)</td>
<td><em>t</em> = 3.674</td>
<td>0.000*</td>
</tr>
<tr>
<td>Prefab. vs. Custom</td>
<td>-6.7 (-13.2 to -0.2)</td>
<td><em>t</em> = -2.043</td>
<td>0.043*</td>
</tr>
<tr>
<td><strong>SF-36 - Vitality</strong> @ 6 months</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Prefab. vs. Sham</td>
<td>6.4 (-0.5 to 13.2)</td>
<td><em>t</em> = 1.845</td>
<td>0.067</td>
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<tr>
<td>Custom vs. Sham</td>
<td>6.5 (-0.2 to 13.3)</td>
<td><em>t</em> = 1.909</td>
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<tr>
<td>Prefab. vs. Custom</td>
<td>-0.2 (-7.0 to 6.7)</td>
<td><em>t</em> = -0.045</td>
<td>0.965</td>
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<tr>
<td><strong>SF-36 - Vitality</strong> @ 12 months</td>
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<td></td>
</tr>
<tr>
<td>Prefab. vs. Sham</td>
<td>3.4 (-3.8 to 10.5)</td>
<td><em>t</em> = 0.933</td>
<td>0.353</td>
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<td>Custom vs. Sham</td>
<td>5.1 (-1.9 to 12.1)</td>
<td><em>t</em> = 1.433</td>
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<td>Prefab. vs. Custom</td>
<td>-1.7 (-8.8 to 5.3)</td>
<td><em>t</em> = -0.487</td>
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<tr>
<td><strong>SF-36 - Social functioning</strong> @ 1 month</td>
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<td></td>
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<tr>
<td>Prefab. vs. Sham</td>
<td>2.4 (-5.0 to 9.9)</td>
<td><em>t</em> = 0.646</td>
<td>0.520</td>
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<tr>
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<td>1.1 (-6.2 to 8.4)</td>
<td><em>t</em> = 0.299</td>
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<td>1.3 (-6.1 to 8.7)</td>
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<td><strong>SF-36 - Social functioning</strong> @ 3 months</td>
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<td>Prefab. vs. Sham</td>
<td>1.6 (-6.8 to 10.0)</td>
<td><em>t</em> = 0.376</td>
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<td>Custom vs. Sham</td>
<td>2.2 (-6.1 to 10.5)</td>
<td><em>t</em> = 0.519</td>
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<td>Prefab. vs. Custom</td>
<td>-0.6 (-8.9 to 7.8)</td>
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<td><strong>SF-36 - Social functioning</strong> @ 6 months</td>
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<tr>
<td>Prefab. vs. Sham</td>
<td>3.1 (-6.1 to 12.3)</td>
<td><em>t</em> = 0.656</td>
<td>0.513</td>
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<td>Custom vs. Sham</td>
<td>-1.9 (-11.0 to 7.2)</td>
<td><em>t</em> = -0.415</td>
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<td>Prefab. vs. Custom</td>
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<tr>
<td><strong>SF-36 - Social functioning</strong> @ 12 months</td>
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<tr>
<td>Prefab. vs. Sham</td>
<td>-3.2 (-13.1 to 6.7)</td>
<td><em>t</em> = -0.637</td>
<td>0.525</td>
</tr>
<tr>
<td>Custom vs. Sham</td>
<td>-1.9 (-11.6 to 7.9)</td>
<td><em>t</em> = -0.378</td>
<td>0.706</td>
</tr>
<tr>
<td>Prefab. vs. Custom</td>
<td>-1.3 (-11.1 to 8.5)</td>
<td><em>t</em> = -0.265</td>
<td>0.791</td>
</tr>
</tbody>
</table>

SF-36 = Short Form - 36  
CI = confidence interval  

5.6.5.2 *Four-point scale of perceived improvement*

A four-point ordinal scale was also used to determine participant’s perceived improvement with the interventions. The responses to the question “Did the foot orthoses help?” were: (i) Yes, a lot, (ii) Yes, a little, (iii) No, not at all, and (iv) No, made it worse. The results from this question at 1, 3, 6 and 12 months are presented below in Figures 5.9 to 5.12.
Figure 5.9  Percentage of participants in each group who indicated their symptoms had improved at 1 month.

Figure 5.10  Percentage of participants in each group who indicated their symptoms had improved at 3 months.

NB: The response “Missing” includes those not wearing orthoses.
**Figure 5.11** Percentage of participants in each group who indicated their symptoms had improved at *6 months*.

![Bar chart showing percentage of participants in each group who indicated their symptoms had improved at 6 months.]

NB: The response “Missing” includes those not wearing orthoses.

**Figure 5.12** Percentage of participants in each group who indicated their symptoms had improved at *12 months*.

![Bar chart showing percentage of participants in each group who indicated their symptoms had improved at 12 months.]

NB: The response “Missing” includes those not wearing orthoses.
5.7 DISCUSSION

5.7.1 Baseline Characteristics

The trial recruited 136 participants, however one dropped out before receiving her orthoses (i.e. she was unaware of the type of device allocated) and was consequently removed from the analysis. Of the remaining 135 participants, 89 were female and 46 were male. The mean age was 48.3 years (± 11.1) indicating that from this sample the most likely time to attend a treatment for management of plantar fasciitis is late in the fifth decade of life. This is similar to other trials that have evaluated foot orthoses in the treatment of plantar fasciitis. Increased body weight has been implicated previously in the development of plantar fasciitis. Although this trial did not attempt to evaluate the correlation between weight and plantar fasciitis, the mean body mass index of participants (30.9 ± 5.9) was in the obese range supporting the link between body mass and plantar fasciitis.

Approximately half (47%) of participants had both feet involved, with the remainder having only the left or right foot affected (27% and 26% respectively). The majority (79%) had their main focus of pain in either the plantar heel or proximal aspect of the plantar fascia, with the remainder having pain only in the central portion (one participant had pain in the entire fascia, including the plantar heel). The mean self-reported number of hours on feet per day was 8.7 (± 3.1) and the most frequent time participants reported having symptoms was 12 months with a range from 1 to 360 months. These findings are similar to other randomised controlled trials. It should be noted that duration of symptoms might be longer than normal as patients with more long-standing pain may self-select for trials of this nature (i.e. an advertised clinical trial at a university clinic).

5.7.2 Drop-outs and non-compliance

One participant withdrew before receiving her orthoses and prior to the investigator obtaining her baseline data. Her data were subsequently omitted from all further
analysis. Otherwise, only four participants (3%) dropped out of the trial or were lost to follow-up. Each group had at least one person drop-out by the end of the trial.

At 12 months, 12 people in the sham group, 11 in the prefabricated group and 8 in the customised group had deviated from the study protocol by not complying fully with the intervention. Interestingly, the sham group had a steady increase in non-compliance over the twelve months, whereas the other two groups had relatively large increases at certain times. The customised group had five extra non-compliant participants between 3 and 6 months, but then trailed off at eight cases at 12 months. In contrast, the prefabricated group had seven extra non-compliant participants between 6 and 12 months. This might suggest the pre-fabricated devices were not as effective after 12 months as they were earlier on, however this is speculative.

5.7.3 Primary Outcomes

The results from the analysis of the primary outcomes favoured the prefabricated and the customised foot orthoses, both of which improved function more at 3 months compared to the sham foot orthosis. The prefabricated orthosis improved function 8.4 points more (95% confidence interval 1.0 to 15.8, p=0.026) and the customised orthosis 7.5 points more (95% confidence interval 0.3 to 14.7, p=0.041) than the sham foot orthoses (ANCOVA adjusted). Although some findings were statistically significant, the differences between group outcomes were relatively small and it is not clear if these estimates are large enough to be clinically important. When assessing the upper confidence limit the effect would most likely be considered clinically important, however the lower confidence limit approaches zero, suggesting an effect that would most likely be not clinically important. No other significant differences were found in any other variables (pain at 3 and 12 months, function at 12 months) for the primary outcomes.

Interestingly, although both devices improved function more than the sham device at 3 months, there was no significant difference in pain between the three orthoses. Participants who were allocated the sham orthosis may have experienced a reduction in their pain by altering their function, rather than the orthosis having a direct effect on
pain. (The correlation coefficient for the change in pain at 3 months vs. the change in function at 3 months is 0.65.) By reducing activity levels participants would have reported worse function scores, but subsequently lessened their pain. This highlights one of the key advantages to assessing health status more broadly using health status measures, rather than only assessing pain. Most previous trials evaluating foot orthoses for the treatment of plantar fasciitis have only assessed pain.19,46-48

The numbers needed to treat and the 95% confidence intervals for pain and function at 3 and 12 months provide support to the primary outcome findings above. Prior to discussing these findings it should be noted that the smaller the treatment effect (i.e. as the absolute risk reduction approaches zero) the number needed to treat becomes difficult to interpret in a clinically meaningful way.470 An absolute risk reduction of zero translates to a number needed to treat of infinity. With this in mind, the most important numbers need to treat for the primary outcomes in this trial are those associated with changes in function at 3 months, where a significant treatment effect was detected.

The number needed to treat was determined from those participants who experienced an improvement in function by greater than 33% from their baseline measure; this was classified as a beneficial outcome. Compared to the sham device, one additional ‘beneficial outcome’ in function was achieved by treating 6 people with a prefabricated foot orthosis for 3 months. With the customised foot orthosis, only 4 people would need to be treated for the same outcome. These figures are compatible with that which is considered an effective treatment, generally considered to be in the range of 2 to 5.472 Not surprisingly, given that there was no statistical difference between prefabricated and customised orthoses, the number needed to treat between these two devices was 12, indicating that for one additional ‘beneficial outcome’ in function with the customised device, you would need to treat 12 people for 3 months.

Unlike the prefabricated and customised orthoses, the sham was designed to have little structural effect and is a device that would not normally be used in practice. There are two reasons why it would not normally be used. Firstly, due to the time involved in making the sham orthosis, it would be more expensive to fabricate than the
prefabricated device. To fabricate the sham requires the following: a neutral suspension cast (impression) of the foot, creation of a positive cast from the negative cast, the shell material to be heated then moulded over the cast, and finally, grinding of the shell material to the desired shape. Secondly, the prefabricated orthosis is significantly easier to use, providing an almost immediate treatment for the patient. Notwithstanding these reasons, the sham foot orthosis provided an interesting comparison to the prefabricated and the customised devices, which are both designed to provide significant structural support for the foot.

Of most interest, therefore, are the comparisons between prefabricated and customised foot orthoses. As the primary outcome analysis clearly shows, there were no significant differences between the prefabricated and the customised foot orthoses in any of the variables measured, even after 12 months of use. This finding suggests the prefabricated foot orthosis used in this trial (a blue ¾ length Formthotic™) performed as well as the customised foot orthosis (a modified Root balanced to the neutral calcaneal stance position). This is an important finding due to the cost associated with the devices. A prefabricated Formthotic™ orthosis similar to the one used in this trial retails for approximately A$40 (plus fees for consultation, etc.), although practitioners charge between A$75 to $150 to the patient to allow for fitting and professional expertise. In contrast, a customised orthoses generally retails for between A$250 and $400 (plus fees for consultation, casting, etc.).

5.7.4 Secondary Outcomes

The secondary outcome analysis evaluated the remaining data from the Foot Health Status Questionnaire, as well as the four domains of the SF-36. In addition, between-group comparisons were also made using the four-point scale of perceived improvement. It should be pointed out before discussing the findings from the secondary outcomes that the primary outcome analysis provides the most important and statistically rigorous results of this randomised controlled trial. Due to the large number of inferential tests conducted in the secondary outcome analysis (84 tests) it is prone to Type 1 error. At the significance level set (p<0.05), this number of tests could have resulted in up to four significant results being found purely by chance. Nevertheless, it
provides further information, which largely supports the analysis of the primary outcomes.

Analysis of the remaining Foot Health Status Questionnaire variables provide a similar picture to the data from the primary outcomes. The prefabricated and customised orthosis groups improved more in general foot health at 3 months compared to the sham group. The prefabricated group improved 12.7 points more (95% confidence interval 2.8 to 22.6, p=0.013) and the customised group improved 14.8 points more (95% confidence interval 5.0 to 24.6, p=0.003) compared to the sham group. In addition, the customised group also improved more than the sham group for general foot health at the earlier time point of 1 month (11.0 points, 95% confidence interval 2.5 to 19.4, p=0.012).

When evaluating the data from the SF-36 the customised group improved 6.0 points more (95% confidence interval 1.2 to 10.8, p=0.014) at 3 months and 6.2 points more (95% confidence interval 1.3 to 11.0, p=0.013) at 12 months for general health compared to the sham group. In addition, for vitality at 1 month the prefabricated group improved 7.8 points more (95% confidence interval 2.1 to 13.5, p=0.007) and the customised group improved 8.4 points more (95% confidence interval 2.7 to 14.0, p=0.004) than the sham group. The customised group also improved 12.0 points more (95% confidence interval 5.5 to 18.4, p=0.000) than the sham for vitality at 3 months. Interestingly, the customised also performed 6.7 points more (95% confidence interval 0.2 to 13.2, p=0.043) than the prefabricated group for vitality at 3 months, although this magnitude of effect is the smallest of all the significant results and may not be clinically important.

Taking these results and the findings from the primary outcome analysis into account, it is apparent that the sham orthosis did not perform as well as the prefabricated or the customised orthosis in the short-term (i.e. up to 3 months). However, the effect sizes are relatively small, so the clinical importance of these results is not clear. Like the degree of uncertainty with the primary outcomes, the 95% confidence intervals range from values that would most likely not be clinically important to ones that would be. Surprisingly, in comparison to the Foot Health Status Questionnaire results, the SF-36
findings show the customised orthosis performed better than the sham device for the General Health domain at 3 and 12 months, while the prefabricated orthosis did not. Further, the customised orthosis showed greater improvement compared to the prefabricated device for the Vitality domain at 3 months. These differences between the prefabricated and customised orthoses were not found with the primary outcomes and most likely mean little. Although the results suggest the customised orthoses when compared to the prefabricated orthoses may have some benefits for general health, but not foot-specific general health. Additional trials where the primary outcomes are generic health status instruments are needed to study this further.

Finally, the data from the four-point improvement scale again support the findings from the primary outcome analysis. Generally there was little difference between the devices, although the short-term results indicate that the prefabricated and customised orthoses had more participants respond that the orthoses helped ‘a lot’. For example, at 1 month the sham group had 58% of participants responding that the orthoses had helped ‘a lot’ compared to 61% for the prefabricated and 67% for the customised. At 3 months the figures were 60% for the sham compared to 71% for the prefabricated and 76% for the customised. Interestingly, the percentage of respondents in each group indicating they had improved (either ‘a lot’ or ‘a little’) was similar between groups, however the sham device had a higher percentage that responded ‘a little’ compared to the other two groups. Similar to the analysis of the primary outcomes, the groups demonstrated little difference at 6 and 12 months. Like all previous analyses, these findings add support to improvement occurring in the short-term (up to 3 months), but not in the long-term.

5.7.5 Strengths and limitations of this study

There are a number of strengths of this study. This study used the gold-standard methodology - a randomised controlled trial - to evaluate the effectiveness of three different foot orthoses in the treatment of plantar fasciitis. This methodology provides the highest form of evidence when comparing treatments. In addition, appropriate randomisation and allocation concealment were conducted, further minimising bias. This trial also used rigorously validated outcome measures, including the most
appropriate foot-specific questionnaire and a generic health status questionnaire. The foot orthoses used were representative of the types of devices commonly used in clinical practise as found in the survey in Chapter 3. Finally, all other protocols were similar to clinical practise. Therefore, the results should have good generalisability.

There are several limitations of this project that need to be taken into account. Firstly, although this trial was randomised it was not double blind (i.e. the assessor was not blinded to the treatment the participants received). It is widely recognised that to reduce observer bias it is best to blind the assessors. Nevertheless, when dealing with physical therapies such as foot orthoses, it is difficult blinding the assessors because the therapy can be seen and at times may require adjustment if it is uncomfortable. Although, one very rigorous randomised trial that evaluated foot orthoses for people with rheumatoid arthritis in the United States did achieve double-blinding. To minimise observer bias as much as possible in this trial (i.e. the trial contained in this thesis), self-reported outcome measures were used and these were completed at the beginning of each appointment (the participant completed the outcome measures immediately upon entering the consulting room).

Secondly, because this trial and the studies that preceded it were conducted in Australia, care is needed when generalising the results to participants outside of Australia. The baseline characteristics of the participants in this trial, however, are similar to previous trials in the United States, so the results should be reproducible in that country. A further limitation is that only one practitioner (the investigator) consulted the participants, so different results may occur with other practitioners. Finally, it is not possible to advocate that the sham device was totally inert (i.e. a placebo); it may, in reality, be beneficial. Further testing would be required to ascertain this, which unfortunately was not possible for this thesis. For example, kinematic and plantar pressure analysis may be worthwhile to evaluate what effect, if any, the soft, sham device has.
5.7.6 Directions for future research

There are a number of research projects that could be performed which would relate to the findings of this study. Firstly, this randomised trial did not set out to investigate the minimal clinically important difference of the health status measures used. It is uncertain whether the between-group effects in this study are clinically important; therefore trials that specifically investigate the minimal clinically important difference of the Foot Health Status Questionnaire would be highly worthwhile. Using Cohen’s suggested effect sizes (i.e. difference in group means divided by their common standard deviation), the effects of the orthoses used in this trial would generally be classified as small to medium. However, this method, although widely used, may be too simplistic, so more research is needed using appropriate methodology.

If future randomised trials are conducted the results could be made as widely generalisable as possible by utilising multiple clinicians at a number of sites. Ideally, these would also be conducted in multiple countries as well (i.e. international, multi-centre randomised controlled trials). Double-blinding would clearly also be advantageous, however the complexity achieving this makes double-blinding a costly exercise.

A further issue that remains unresolved from this trial is how much of an effect the sham device has when used in the treatment of plantar fasciitis. Further research evaluating the biomechanical effects as well as its effectiveness from the patient’s perspective would be worthwhile. A study comparing it to an insole with no known effect (e.g. a flat, non-cushioning insole) would be required. This issue was given thought during the design of this trial (i.e. Chapter 5), however the investigator thought that participants would be too knowledgeable about foot orthoses and would realise that a flat, non-cushioning insole was not an active treatment.

This as well as other trials have shown no difference between prefabricated and customised foot orthoses when used to treat people with plantar fasciitis; therefore evaluations comparing different types of prefabricated orthoses should now be considered. In addition, whether the orthoses are posted (i.e. wedged at the rearfoot or
forefoot) would be worth investigating given the supposed mechanism of action of foot orthoses (discussed in 2.3.4 Mechanism of action of foot orthoses). Finally, a UCBL orthoses has been found to be more effective than other foot orthoses in reducing strain in the plantar fascia in cadavers\textsuperscript{331} so future research could evaluate this device as well.

5.7.7 Summary with reference to the primary research questions

At the beginning of this study four primary research questions were presented. Each question is now answered below using a brief synopsis of the findings discussed in detail above. In people with plantar fasciitis:

1. The customised foot orthosis was not more effective at improving pain after 3 months compared with the prefabricated or sham orthoses.

2. The customised foot orthosis was not more effective at improving pain after 12 months compared with the prefabricated or sham orthoses.

3. The customised foot orthosis was more effective at improving function after 3 months compared with the sham orthosis, but it was not more effective than the prefabricated orthosis (the prefabricated orthosis was also more effective than the sham orthosis).

4. The customised foot orthosis was not more effective at improving function after 12 months compared with the prefabricated or sham orthoses.

5.8 CONCLUSION

This trial shows that, in the short-term treatment of people with plantar fasciitis, customised and prefabricated orthoses (of the type used in this trial) have only marginally greater therapeutic effects than sham orthoses which are not expected to control foot motion. In the long-term there are no differences in therapeutic effect. Finally, there is no apparent difference in therapeutic effect between customised and prefabricated orthoses when used for the treatment of plantar fasciitis.
Chapter 6

Conclusion

6.1 BACKGROUND

Plantar fasciitis is a common foot condition that can have a marked affect on a person’s quality of life. Many treatments have been suggested to alleviate the pain and disability associated with this condition, with foot orthoses being one of the most common. However, the research relating to the use of orthoses is generally of poor quality and no trials have evaluated their effectiveness for longer than three months. Existing trials have also limited their assessment to pain only, rather than investigating health status more broadly. The aim of this thesis was, therefore, to evaluate the short and long-term effectiveness of foot orthoses in the treatment of plantar fasciitis. To do so, a series of three studies were conducted, with the first two informing the final study. A pragmatic approach was used throughout the thesis to ensure the results are as generalisable as possible to the population of interest. An overview of each study will now be presented.

6.2 OVERVIEW OF THE STUDIES

The aim of the first study in this thesis (Chapter 3) was to investigate orthosis prescribing habits of podiatrists in Australia and New Zealand. This survey found that the most commonly prescribed foot orthoses were customised and prefabricated. A ‘typical’ customised prescription consisted of: a modified Root style orthosis, balanced to the neutral calcaneal stance position, with the shell made from polypropylene and an ethyl vinyl acetate rearfoot post applied. These foot orthoses were included in the randomised controlled trial conducted in Chapter 5.

The aim of the second study (Chapter 4) was to compare two foot-specific health status questionnaires: the Foot Function Index and the Foot Health Status Questionnaire. The Foot Health Status Questionnaire was found to be the preferred questionnaire when
evaluating effects of foot orthoses on people suffering from plantar fasciitis. It has been well validated, is easy to administer and complete, is responsive to change, and also evaluates footwear and general health. In contrast, the Foot Function Index is generally not as easy to administer, does not evaluate footwear and general health, and there is the potential for inconsistent scoring in the Activity Limitation domain when dealing with respondents who do not have marked activity limitation. Therefore, the Foot Health Status Questionnaire was identified as the preferred questionnaire to evaluate patients treated with foot orthoses for plantar fasciitis and was subsequently used as the primary outcome measure in the randomised controlled trial conducted in Chapter 5.

The final study (Chapter 5) evaluated the short and long-term effectiveness of foot orthoses in the treatment of plantar fasciitis. By incorporating the findings from Chapter 3, typical prefabricated and customised foot orthoses were investigated. In addition, a sham device was included to evaluate the prefabricated and customised devices against a device designed to provide little structural support. Participants with plantar fasciitis were randomly allocated one of the three orthoses. At 3 months, estimates of treatment effect on function favoured prefabricated and customised orthoses over the sham orthosis. Compared to the sham orthosis, function was 8.4 points (0 - 100 scale) better for the prefabricated orthosis (95% CI 1.0 to 15.8; p=0.026) and 7.5 points better for the customised orthosis (95% CI 0.3 to 14.7; p=0.041). These effects are statistically significant, however it is not clear if they are large enough to be clinically important. There were no other significant between-group effects on primary outcomes. These results suggest provision of appropriate orthoses may produce a short-term benefit in function for people with plantar fasciitis. As there were no differences between the prefabricated and customised orthoses over 12 months the cheaper prefabricated orthosis is recommended.

6.3 CONCLUSIONS

The studies presented in this thesis have added to the knowledge about foot orthoses and plantar fasciitis. In particular, the randomised controlled trial conducted in Chapter 5 contributes to the body of evidence relating to the treatment of plantar fasciitis with foot
orthoses. With reference to the aims of each study in this thesis, the following conclusions can be made:

- Customised foot orthoses were the most commonly prescribed devices by members of the Australian Podiatry Association and the New Zealand Society of Podiatrists.
- The next most commonly prescribed foot orthoses were prefabricated orthoses.
- The most commonly prescribed customised device was a modified Root style orthosis balanced to the neutral calcaneal stance position, with the shell made from polypropylene and an ethyl vinyl acetate rearfoot post applied.
- At the time the study was conducted the Foot Health Status Questionnaire was the most appropriate foot-specific health status measure to evaluate foot orthoses in the treatment of plantar fasciitis.
- In the short-term treatment of plantar fasciitis (i.e. at 3 months), the prefabricated and customised orthoses used in this thesis\(^8\) were more effective than a sham device at improving function although it is not clear whether the magnitude of their effect is clinically important.
- In the long-term treatment of plantar fasciitis (i.e. at 12 months), there was no difference in effectiveness between the sham, prefabricated and customised orthoses used in this thesis.
- Over a 12 month intervention period there were no differences in effectiveness between the prefabricated and customised orthoses used in this thesis and therefore, the cheaper prefabricated orthosis is recommended.

\(^8\) The sham orthosis was made from soft, 120 kg/m\(^3\) ethyl vinyl acetate orthosis and were moulded on an unmodified cast of the participant’s foot. The prefabricated orthosis was a blue ¾ length Formthotic\(^{TM}\) and was moulded directly to the participant’s foot with the talo-navicular joint held congruent. The customised orthosis was a semi-rigid, posted, modified Root orthosis balanced to the neutral calcaneal stance position.
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Appendix 1

THE FOOT FUNCTION INDEX
FOOT PAIN AND DISABILITY INDEX

Name: ___________________________  ID: _______  Date: ___ / ___  Total Score: ____________

ACTIVITY LIMITATION

The line next to each item represents how often you did something in the past week. On the far left is "None of the time" and on the far right is "All of the time". Place a mark on the line to indicate how often you performed the following activities in the past week because of your foot. Mark NA on the line to the far right of the item if you did not perform this activity during the past week.

EXAMPLE: How much of the time did you:

0. Wear shoes when walking in the house?  None of the time  All of the time

A. HOW MUCH OF THE TIME DID YOU:  Score/NA

1. Use a cane, crutches or a walker indoors?  None of the time  All of the time

2. Use a cane, crutches or a walker outdoors?  None of the time  All of the time

3. Stay indoors most of the day because of foot problems?  None of the time  All of the time

4. Stay in bed most of the day because of foot problems?  None of the time  All of the time

5. Limit your activities because of foot problems?  None of the time  All of the time
Name: ___________________________  ID: ______  Date: ______

PAIN

The line next to each item represents the amount of pain you typically had in each situation. On the far left is "No pain" and on the far right is "The worst pain imaginable". Place a mark on the line to indicate how bad your foot pain was in each of the following situations during the past week. If you were not involved in one or more of these situations, mark that item NA.

B. HOW SEVERE WAS YOUR FOOT PAIN:  

<table>
<thead>
<tr>
<th>Item</th>
<th>No pain</th>
<th>Worst pain imaginable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. At its worst?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>2. Before you get up in the morning?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>3. When you walked barefoot?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>4. When you stood barefoot?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>5. When you walked wearing shoes?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>6. When you stood wearing shoes?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>7. When you walked wearing orthotics?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>8. When you stood wearing orthotics?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
<tr>
<td>9. At the end of the day?</td>
<td>No pain</td>
<td>Worst pain imaginable</td>
</tr>
</tbody>
</table>

____ / ____ = ____ %
**DISABILITY**

The line next to each item represents the amount of difficulty you had performing an activity. On the far left is "No Difficulty" and on the far right is "So difficult unable". Place a mark on the line to indicate how much difficulty you had performing each activity because of your feet during the past week. If you did not perform an activity during the past week, mark that item NA.

**C. HOW MUCH DIFFICULTY DID YOU HAVE:**

<table>
<thead>
<tr>
<th>Activity Description</th>
<th>No Difficulty</th>
<th>So difficult unable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Walking around the house?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>2. Walking outside on uneven ground?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>3. Walking four or more blocks?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>4. Climbing stairs?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>5. Descending stairs?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>6. Standing on tip toes?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>7. Getting out of a chair?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>8. Climbing up or down curbs?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
<tr>
<td>9. Walking fast or running?</td>
<td>No difficulty</td>
<td>So difficult unable</td>
</tr>
</tbody>
</table>
Appendix 2

THE FOOT HEALTH STATUS QUESTIONNAIRE
Thank you for taking the time to fill out this important questionnaire.

The answers you provide will help researchers, doctors and surgeons to better understand how to care for foot problems.

The questionnaire is very simple and there are no right or wrong answers.

The information you provide will be kept strictly confidential.
FOOT HEALTH QUESTIONNAIRE

INSTRUCTIONS

This questionnaire asks for your views about your foot health.

Answer every question by circling your answer. All answers are confidential. If you are unsure about how to answer a question please give the best answer you can.

The following questions are about the foot pain you have had during the past week.

1. What level of foot pain have you had during the past week? (circle number)

   None...................................................... 1
   Very Mild............................................. 2
   Mild..................................................... 3
   Moderate............................................. 4
   Severe.................................................. 5

(circle a number for each question below)

DURING THE LAST WEEK

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Occasionally</th>
<th>Fairly</th>
<th>Many Times</th>
<th>Very Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. How often have you had foot pain?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>3. How often did your feet ache?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>4. How often did you get sharp pains in your feet?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>
These questions are about how much your feet interfere with activities you might do during a typical day.
(circle a number for each question below)

**DURING THE LAST WEEK .....**

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Have your feet caused you to have difficulties in your work or activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Were you limited in the kind of work you could do because of your feet?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**DURING THE LAST WEEK .....**

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. How much does your foot health limit you in walking?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. How much does your foot health limit you in climbing stairs?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

9. How would you rate your overall foot health  
(circle number)

- Excellent........................................................................1
- Very good..........................................................................2
- Good.................................................................................3
- Fair..................................................................................4
- Poor..................................................................................5
The following questions are about the shoes that you wear. Please circle the response which best describes your situation.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree Nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. It is hard to find shoes that do not hurt my feet</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. I have difficulty in finding shoes that fit my feet</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. I am limited in the number of shoes I can wear</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

13. In general, what condition would you say your feet are in? (circle number)

   Excellent ................................................. 1
   Very Good ................................................. 2
   Good ....................................................... 3
   Fair ....................................................... 4
   Poor ....................................................... 5

Turn to next page please
14. In general would you say your health is

(circle one)

- Excellent ........................................... 1
- Very good ......................................... 2
- Good .................................................. 3
- Fair .................................................... 4
- Poor .................................................... 5

15. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

<table>
<thead>
<tr>
<th>ACTIVITIES</th>
<th>Yes, Limited A Lot</th>
<th>Yes, Limited A Little</th>
<th>No, Not Limited At All</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>c. Lifting or carrying groceries</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>d. Climbing several flights of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>e. Climbing one flight of stairs</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>f. Bending, kneeling or stooping</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>g. Walking more than a kilometre</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>h. Walking several blocks</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>i. Walking one block</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>j. Bathing or dressing yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

16. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(circle one)

- Not at all ........................................................................ 1
- Slightly ........................................................................... 2
- Moderately ........................................................................ 3
- Quite a bit ......................................................................... 4
- Extremely .......................................................................... 5
17. These questions are about how you feel and how things have been with you during the past four weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the Time</th>
<th>A good Bit of the Time</th>
<th>Some of the Time</th>
<th>A little of the Time</th>
<th>None of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Did you feel full of life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>b. Did you have a lot of energy?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>c. Did you feel worn out?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>d. Did you feel tired?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

18. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All of the time</td>
<td>1</td>
</tr>
<tr>
<td>Most of the time</td>
<td>2</td>
</tr>
<tr>
<td>Some of the time</td>
<td>3</td>
</tr>
<tr>
<td>A little of the time</td>
<td>4</td>
</tr>
<tr>
<td>None of the time</td>
<td>5</td>
</tr>
</tbody>
</table>

19. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

<table>
<thead>
<tr>
<th></th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don’t Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I seem to get sick a little easier than other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>b. I am as healthy as anybody I know</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>c. I expect my health to get worse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>d. My health is excellent</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
The following questions ask you about general information we need to complete this health survey. The questions relate to information about your current situation.

20. Full Name:_________________________

21. Address:_____________________________ Postcode:____

22. Date of Birth:_________ Tick Sex: Male □ Female □

23. What is the date when you filled out this survey? Please write here →

24. Do you take any medicine prescribed by your doctor for any of the following conditions; (please tick the appropriate box/s)

   Diabetes □ Hormone Replacement Therapy □
   Arthritis □ High Cholesterol □
   Blood Pressure □ Chronic Pain □
   Heart Troubles □ Sleeping Problems □
   Asthma □ Stress □

   Any other conditions you take medicine for, please list ....... 1. 2.

For the next questions please tick either YES or NO in the boxes

25. Are you a pensioner or health care card holder? YES □ NO □

26. Do you smoke cigarettes? YES □ NO □

27. Do you do any regular physical exercise? YES □ NO □

28. Do you have private health insurance? YES □ NO □

29. What is the date for your scheduled foot operation?________

30. What type of foot problem are you having the operation for (tick box/s)

   □ Bunion (Big toe) □ Hammertoe □ Clawtoe □ Neuroma (Mortons)
   □ In grown toenail □ Plantar Wart Removal □ Other ____________
31. Have you completed a trade certificate or any other educational qualification since leaving school?

Yes ☐ No ☐

32. If your answer is yes, What is the highest qualification you have completed since leaving school? (for example, trade certificate, bachelor degree, associate diploma etc)

please write here; ______________________________________

33. Please tick the box which comes closest to the TOTAL amount of income received by ALL members of your household last year (including pensions, allowances and investments).

PER YEAR

$1 - 2,079 ☐
$2,080 - 4,159 ☐
$4,160 - 6,239 ☐
$6,240 - 8,319 ☐
$8,320 - 10,399 ☐
$10,400 - 15,599 ☐
$15,600 - 20,799 ☐
$20,800 - 25,999 ☐
$26,000 - 31,199 ☐
$31,200 - 36,399 ☐
$36,400 - 41,599 ☐
$41,600 - 51,999 ☐
$52,000 - 77,999 ☐
$78,000 or more ☐

PLEASE PUT THIS IN THE ENVELOPE PROVIDED AND POST IT.

THANK YOU
Appendix 3

FOOT ORTHOSIS PRESCRIPTION QUESTIONNAIRE
Foot Orthoses Prescription Questionnaire

IMPORTANT

If you do not prescribe foot orthoses, I am still interested in your input.

My name is Karl Landorf – I am presently enrolled in a Master of Science (Hons) (Health) at the University of Western Sydney, Macarthur. As part of my research, I am interested in the orthotic prescription habits of podiatrists in Australia and New Zealand. To this end, I would appreciate you spending a short period of time completing the following questionnaire. Not only will your input assist me, I envisage the results will also be beneficial for the profession.

If you do not prescribe foot orthoses:

Please, if you do not prescribe any foot orthoses, I am still interested in your input. Complete the first 6 questions of this questionnaire, then return it in the reply-paid envelope. This will take about 1 minute to complete.

If you do prescribe foot orthoses:

If you do prescribe foot orthoses, please complete the questions requested beginning at question 1. Once you have finished, return the questionnaire in the reply-paid envelope. The questionnaire should only take five to ten minutes to complete.

Thankyou for your time.

Karl Landorf
Dip App Sc (Pod), Grad Dip Ed

This questionnaire is being conducted by Karl Landorf from the University of Western Sydney, Macarthur. The Australian Podiatry Council, Australian Podiatry Associations and the New Zealand Society of Podiatrists Inc. are not associated with this questionnaire, the data collection or analysis of the data in any way. All enquiries regarding this research can be directed to Karl Landorf (phone: 02 4620 3758, fax: 02 4620 3792, e-mail: k.landorf@uws.edu.au). For ethical issues, see contact details on the final page.
Foot Orthoses Prescription Questionnaire

1. What is your gender?
   - [ ] Female
   - [ ] Male

2. How many years have you been practising as a podiatrist?
   - [ ] <5 years
   - [ ] 5 to 9 years
   - [ ] 10 to 20 years
   - [ ] >20 years

3. Where did you obtain your original undergraduate qualification in podiatry/chiroprapy?
   - [ ] Qld.
   - [ ] NSW
   - [ ] Vic.
   - [ ] South Aust.
   - [ ] Western Aust.
   - [ ] New Zealand
   - [ ] United Kingdom
   - [ ] Other

   If you have ticked “Other”, please specify:

4. What country do you currently practise in?
   - [ ] Australia
   - [ ] New Zealand

5. If you practise in Australia, what Australian state or territory do you mainly practise in?
   - [ ] Qld.
   - [ ] NSW
   - [ ] ACT
   - [ ] Vic.
   - [ ] Tas.
   - [ ] South Aust.
   - [ ] Western Aust.
   - [ ] NT

6. Do you prescribe foot orthoses?
   - [ ] No

   If you answered "No", please stop here and return the questionnaire in the reply-paid envelope - thankyou for your participation.

   - [ ] Yes

   If you answered "Yes", please continue.

7. In your practice, what percentage of patients have conditions that you prescribe foot orthoses for?
   - [ ] <25%
   - [ ] 25%-49%
   - [ ] 50%-75%
   - [ ] >75%
8. Overall, which of the following would best describe your approach to clinical assessment prior to prescribing foot orthoses?

☐ Quantification (i.e. biomechanical measurements)
☐ Visual assessment (e.g. eyeballing)
☐ Combination of Quantification and Visual
☐ Other

If you have ticked "Other", please specify:

9. What techniques do you use when assessing a patient prior to prescribing foot orthoses? (Tick more than one box if required)

☐ Static clinical measurements
☐ Manual muscle testing
☐ Treadmill and video analysis
☐ Plantar pressure analysis (e.g. EDG)
☐ Other

If you have ticked "Other", please specify:

10. What biomechanical measuring instruments do you commonly use? (Tick more than one box if required)

☐ I do not take measurements
☐ Tractograph
☐ Forefoot measuring device
☐ Gravity goniometer
☐ Inclinometer (roof level)
☐ Other

If you have ticked "Other", please specify:

11. Of the following, which do you find the most useful clinical indicator when prescribing foot orthoses?

☐ Neutral calcaneal stance position (NCSP)
☐ Resting calcaneal stance position (RCSP)
☐ Difference between NCSP and RCSP
☐ Forefoot position
☐ Other

If you have ticked "Other", please specify:

12. Of the foot orthoses you prescribe, what type do you prescribe most often?

☐ Cushioning orthosis
☐ Pressure relief orthosis
☐ Pre-moulded or pre-formed or pre-fabricated orthosis
☐ Moulded non-cast orthosis
☐ Moulded cast orthosis (no posting)
☐ Functional (customised kinetic) foot orthosis

NB. The above categories have been taken from the Australian Podiatry Council's 'Clinical Guidelines for Orthotic Therapy Provided by Podiatrists; May 1998'. A Functional (customised kinetic) foot orthosis is the term used for a rigid, cast and posted (balanced) foot orthosis; for example, a Root style orthosis.
13. Prior to manufacturing cast orthoses, what type of negative plaster cast (impression) do you take most often?

- [ ] I do not prescribe cast orthoses
- [ ] Neutral suspension cast
- [ ] Neutral cast (Direct pressure or Langer)
- [ ] Semi-weight bearing cast
- [ ] Other

If you answered "I do not prescribe cast orthoses", please go to question 22.

If you have ticked "Other", please specify:

14. If you prescribe functional (customised kinetic) foot orthoses, what style of device do you prescribe most often?

- [ ] I do not prescribe functional (customised kinetic) foot orthoses
- [ ] Root
- [ ] Modified Root
- [ ] Blake Inverted
- [ ] Other

If you answered "I do not prescribe functional (customised kinetic) foot orthoses", please go to question 22.

If you have ticked "Other", please specify:

15. If you prescribe Root style orthoses do you:

- [ ] I do not prescribe Root style orthoses
- [ ] Balance the cast to vertical
- [ ] Balance the cast to the neutral calcaneal stance position
- [ ] Other

If you have ticked "Other", please specify:

16. If you prescribe modified Root style orthoses do you:

- [ ] I do not prescribe Modified Root style orthoses
- [ ] Balance the cast to vertical
- [ ] Balance the cast to the neutral calcaneal stance position
- [ ] Other

If you have ticked "Other", please specify:

17. If you prescribe Blake Inverted style orthoses what is the most common angle you balance to:

- [ ] I do not prescribe Blake Inverted orthoses
- [ ] <20°
- [ ] 20-25°
- [ ] >25°

18. When prescribing functional (customised kinetic) foot orthoses, how often do you prescribe an extrinsic rearfoot post?

- [ ] Never
- [ ] Sometimes
- [ ] Most of the time
- [ ] Always
19. When prescribing functional (customised kinetic) foot orthoses, what material do you use most often?

☐ Polypropylene
☐ Rohadur-like material
☐ Carbon-fibre/graphite
☐ Ortholen/sub-ortholen
☐ Other

If you have ticked "Other", please specify:

20. When prescribing an extrinsic rearfoot post, what material do you use most often?

☐ Ethyl vinyl acetate (EVA)
☐ Acrylic (methyl methacrylate)
☐ Cork
☐ Other

If you have ticked "Other", please specify:

21. When prescribing an extrinsic rearfoot post, do you prescribe motion in the post?

☐ Yes, always
☐ Sometimes
☐ Rarely
☐ Never
☐ Unsure

22. Which of the following best describes your orthotic manufacturing habits?

☐ Send orthoses to a commercial orthotic laboratory
☐ Manufacture orthoses yourself
☐ Manufacture some yourself and send some to a commercial laboratory
☐ Manufacture orthoses in your practice using technicians
☐ Other

If you have ticked "Other", please specify:

23. If you use a laboratory to manufacture your orthoses, how often do you use them?

☐ I do not use an orthotic laboratory
☐ Sometimes
☐ Most of the time
☐ Always

Please place your finished questionnaire in the reply-paid envelope and return it at your earliest possible convenience.

Thank you for your participation in this questionnaire.

This research project has been approved by the University of Western Sydney Macarthur Ethics Review Committee (Human Subjects). Any complaints about this research may be directed to the Ethics Committee through the Executive Officer, Kokila De Silva, phone (02) 4620 3641. Any complaint you make will be treated in confidence and investigated fully and you will be informed of the outcome.
Appendix 4

ETHICAL APPROVAL: CHAPTER 3
Ethics Review Committee (Human Subjects)

CERTIFICATE OF APPROVAL

To: Mr Karl Landorf and Ms Anne-Maree Keenan,
Faculty of Health

Telephone: (02) 4620 3758

Date: 14 October 1999

Project Title: Foot orthotic prescription habits amongst
Australian and New Zealand podiatrists

Protocol No: 98/087

The Ethics Review Committee (Human Subjects) has renewed its approval of
the above protocol.

The Principal Investigator is required to:

(a) provide an Annual Report on matters including:
    - security of records
    - compliance with approved consent procedures and
documentation.

(b) to report to the Committee immediately anything that might affect
    ethical acceptance of the protocol, including:
    - adverse effects on subjects/participants;
    - proposed changes in the protocol;
    - unforeseen events that might affect continued ethical acceptability
      of the project.

The protocol is approved until 31 December 1999 subject to the protocol
complying with the above. It should be noted that it is the responsibility of the
first named investigator for ensuring ethical practice in research and for
compliance with the above requirements.

The above protocol number must be quoted in all future correspondence
regarding this protocol.

Dr Mary Hawkins
Chair
Ethics Review Committee (Human Subjects)
Appendix 5

ETHICAL APPROVAL: CHAPTER 4
Date: 28 August, 1998

To: Student
    Karl Landorf
    Faculty of Health
    UWSM - Campbelltown

Supervisor
    Anne - Maree Keenan & Dr. Louise Rushworth
    Faculty of Health
    UWSM - Campbelltown

Telephone: (02) 4620 3335 & (02) 9817
            (02) 4620 3758
            1218

Fax: (02) 4620 3792 & (02) 9816
     (02) 4620 3792
     2447

Project Title: Pilot project to trial three patient-based outcome measuring instruments

Protocol No. 98/75

The Ethics Review Committee (Human Subjects) at its meeting of 12 August 1998 approved the above protocol.

The Principal Investigator is required
a) to provide an Annual report on matters including
   * security of records
   * compliance with approved consent procedures and documentation
b) to report to the Committee immediately anything that might affect ethical acceptance of the protocol, including
   * adverse effects on subjects/participants
   * proposed changes in the protocol
   * unforeseen events that might affect continued ethical acceptability of the project.

The protocol is approved until 28 August 1999 subject to the protocol complying with the above.

It should be noted that it is the responsibility of the first-named investigator for ensuring ethical practice in research and for compliance with the above.

The above Protocol number must be quoted in all future correspondence regarding this protocol.

Mr. Harry Mayfield
CHAIR,
ETHICS REVIEW COMMITTEE (HUMAN SUBJECTS)
Ethics Review Committee (Human Subjects)

CERTIFICATE OF APPROVAL

Date: 13 April 1999

To: Mr Karl Landorf, Faculty of Health
    Ms Anne-Maree Keenan, Faculty of Health
    Dr R Louise Rushworth, Faculty of Health

Telephone: (02) 4620 3758       Fax: (02) 46203792

Project Title: A Trial to Evaluate the Effectiveness of Three Different Insoles (Foot Orthoses) on Arch and Heel Pain

Protocol No: 99/012

The Ethics Review Committee (Human Subjects) has approved the above protocol.

The Principal Investigator is required to:

(a) provide an Annual Report on matters including:
    - security of records
    - compliance with approved consent procedures and documentation.

(b) to report to the Committee immediately anything that might affect ethical acceptance of the protocol, including:
    - adverse effects on subjects/participants;
    - proposed changes in the protocol;
    - unforeseen events that might affect continued ethical acceptability of the project.

The protocol is approved until 30 June 2000 subject to the protocol complying with the above. It should be noted that it is the responsibility of the first named investigator for ensuring ethical practice in research and for compliance with the above requirements.

The above protocol number must be quoted in all future correspondence regarding this protocol.

Mr Harry Mayfield
Chair
Ethics Review Committee (Human Subjects)
Appendix 7

APPOINTMENT 1 (INITIAL) ASSESSMENT FORM
SUBJECTIVE

Name: ___________________________ Date of initial examination: ___________________________

Address: ___________________________

Phone no.: ___________________________

Age: ________ Years Sex: Female □ Male □

Height: ________ Metres Weight: ________ Kilograms

Occupation: ___________________________

Activities (eg. walking, running, sports): ___________________________

Activity Level (eg. how many times per week do you participate in sport etc.?): ___________________________

Where are you symptoms?:

Mark area on diagram

Describe your symptoms (eg. sharp/dull, burning/piercing): ___________________________

When do you get the symptoms?: ___________________________

Does anything make the symptoms better or worse?: ___________________________

Check list
☐ Information sheet
☐ Consent form
☐ Assessment form
☐ FHSQ & VAS

☐ Plaster casts
☐ Strapping
☐ Heel pain brochure
☐ Footwear advice

196
How long have you had your symptoms for?:

Do you know how the symptoms started?:

Do you have any other symptoms elsewhere in your feet/legs/body?:

Further questions from the researcher?

**OBJECTIVE**

Pain/discomfort where? (palpate):

Is pain worse when extending the hallux?: Yes ☐ No ☐

Foot morphology

- Flat ☐
- Low arched ☐
- Normal ☐
- High arched ☐

Orthopaedic Problems

- Hammer/claw toes ☐
- HAV ☐
- HL/HR ☐
- Other ☐ please specify...

Biomechanical Assessment

<table>
<thead>
<tr>
<th>Left</th>
<th>Inv/ev</th>
<th>RCSP</th>
<th>Inv/ev</th>
<th>Right</th>
<th>Inv/ev</th>
<th>NCSP</th>
<th>Inv/ev</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Navicular Drop</td>
<td></td>
<td>1st MTJ dorsiflexion</td>
<td></td>
<td>STJ ROM</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ankle Jt. dorsiflexion</td>
<td></td>
<td>MTJ ROM</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>mm</td>
<td>ILD</td>
<td>mm</td>
</tr>
</tbody>
</table>

Other comments:

Check list

- Information sheet
- Consent form
- Assessment form
- FHSQ & VAS

- Plaster casts
- Strapping
- Heel pain brochure
- Footwear advice

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STRETCHES AND EXERCISE
Prepare properly before exercising. Warm-up before running or walking, and do some stretching exercises afterward.

Pace yourself when you participate in athletic activities. If overweight, try non weight-bearing activities such as swimming or cycling.

KEEP THE CALF MUSCLES FLEXIBLE

ADDITIONAL CONTROL
Your podiatrist may also use taping or strapping to provide extra support for your foot. Orthoses (shoe inserts) specifically made to suit your needs may be also be prescribed.

How your podiatrist can help
Podiatrists are highly skilled foot health professionals trained to deal with the prevention, diagnosis, treatment and rehabilitation of medical and surgical conditions of the feet and lower limbs. Podiatrists have completed a Bachelor of Podiatry or higher degree, and are continually upgrading their skills and knowledge through further education and training.

Regular visits to your podiatrist can help prevent recurrences of heel pain and other associated foot problems.

Where can I find a podiatrist?
Refer to your Yellow Pages™ for a list of podiatrists in your area, or contact the Australian Podiatry Association in your state.

Many health funds in Australia provide cover for podiatry services on their ancillary tables and government funded services are available through the Department of Veterans' Affairs, some public hospitals and community health centres.

*This information should not be used as a substitute for podiatric or medical attention.

MY PODIATRIST IS:
Heel Pain

Heel pain is one of the most common conditions treated by podiatrists. It is often a message from the body that something is in need of medical attention. Pain that occurs right after an injury or early in an illness may play a protective role, often warning us about the damage we have suffered.

Who gets heel pain?

The greatest incidence of heel pain is seen in middle-aged men and women. It is also seen in those who take part in regular sporting activities and those significantly overweight and on their feet a lot. Heel pain can also occur in children, usually between 8 and 13, as they become increasingly active in sporting activities.

The causes of heel pain

While heel pain has many causes, it is usually the result of faulty biomechanics (abnormalities in the way we walk). This can place too much stress on the heel bone and the soft tissues attached to it.

The stress may also result from injury, or a bruise incurred while walking, running or jumping on hard surfaces; wearing poorly constructed footwear; or being significantly overweight.

Systemic diseases such as arthritis and diabetes can also contribute to heel pain.

Common complications

HEEL SPUR
A common cause of heel pain is the heel spur, a bony growth under the heel bone. There are no visible features on the heel, but a deep painful spot can be found in or around the middle of the sole of the heel (see diagram).

Approximately 10 per cent of the population may have heel spurs without any pain.

Heel spurs result from strain on the muscles of the foot. This may result from biomechanical imbalance, a condition occurring in many people.

PLANTAR FASCITIS
Both heel pain and heel spurs are frequently associated with an inflammation of the long band of tissue that connects the heel and the ball of the foot. The inflammation of this arch area is called plantar fascitis.

The inflammation may be aggravated by shoes that lack appropriate support, especially in the arch area, and by the chronic irritation that sometimes accompanies an athletic lifestyle.

OTHER CAUSES OF HEEL PAIN
- Excessive rolling in of the feet when walking.
- An inflamed bursa (bursitis), a small, irritated sack of fluid at the back of the heel.
- A neuroma (a nerve growth).
- Other soft-tissue growths.
- Heel bumps or ‘pump bumps’, a bone enlargement at the back of the heel bone.
- Bruises or stress fractures to the heel bone.

Overcoming the problem

If pain and other symptoms of inflammation – redness, swelling, heat – persist, you should limit normal daily activities and consult your local podiatrist.

Your podiatrist may conduct a number of x-rays to look for heel spurs or fractures.

TREATMENT
Early treatment might involve exercise and shoe recommendations, taping or strapping and anti-inflammatory medication (such as aspirin). Taping or strapping supports the foot, placing stressed muscles in a restful state and preventing stretching of the plantar fascia. Other physical therapies may also be used, including ice-packs and ultra-sounds.

These treatments will effectively treat the majority of heel and arch pain without the need for surgery.

Only a relatively few cases of heel pain require surgery. If required, surgery is usually for the removal of a spur, but also may involve release of the plantar fascia, removal of a bursa, or a removal of a neuroma or other soft-tissue growth.

RECOVERY
Your recovery will depend on the cause of your heel pain and your individual health. If you are suffering with a heel spur or plantar fascitis, it normally takes about six to eight weeks for a healthy individual to fully recover. That is when the injured area is fully rested or properly strapped.

Preventing future problems

FOOTWEAR
Wear shoes that fit well – front, back and sides – and have shock-absorbent soles, rigid uppers and supportive heel counters. Do not wear shoes with excessive wear on heels or soles.
Appendix 9

BROCHURE: CHOOSING A CROSS-TRAINING SHOE
8 DURABILITY
Most walking shoes have leather uppers and some use mesh for ventilation and flexibility. The most durable outsoles are made of rubber.

9 FOR A COMFORTABLE FIT
Your feet elongate and spread upon impact when you walk. Long walks in warm weather can expand your feet up to a half size, so don’t buy shoes that are too tight fitting.
For length, there should be a space the width of your thumbnail between the end of the shoe and the tip of your longest toe on your longer foot. Make sure you can wriggle your toes freely. The heel should be snug, but comfortable. Always have your feet remeasured every time you buy new shoes since aging and injuries can change your foot size.

10 THE ATHLETE’S FOOT HAS TRAINED FIT TECHNICIANS TO FIT YOU CORRECTLY
They’re trained in basic foot anatomy and physiology, so they can recognise your foot type and match you with the type of shoe that will suit you best.
They’ll also measure both your feet (because your left and right are often slightly different).

11 FAMOUS SHOE COMPANIES GET US TO TEST THEIR NEW MODELS
Nike, Reebok, Rockport and many other top brands send their latest designs to our Research and Development Centre in the USA, for us to test.
We put each new model through a ten week test period, with people of all ages, weights and sporting abilities, then evaluate it for durability, stability, cushioning, and suitability for different foot types.
So the shoe companies get the benefit of our unbiased criticism and input, which helps them improve their product.
Our slogan below is a fact.
1 WALK IN COMFORT
There are several factors to consider when choosing a walking shoe. These include your particular walking style or ‘action’, your foot type and the kind of walking you do. Power and fitness walkers, for example, need more cushioning and support. Olympic walkers need flexibility. Off trail walkers need stability and traction.
Weigh up all features of walking shoes carefully.
No matter what kind of walking you do, if you achieve the right balance of these features you’ll walk in comfort with less chance of injury.

2 KNOW HOW YOU WALK
Everybody has a unique walking ‘action’. Around 50% of the population have flat feet that tend to roll inwards too much, which causes strain on ankles, knees and hips. Others have high arches (around 20%) that send a shock up through your legs as you walk. Take a look at your old walking shoes and you may see a tell-tale pattern.

If your sole is worn towards the inside and the upper is overhanging the sole, you’re rolling inwards more than normal. Which means your foot is flatter than average.

If all the wear is towards the outside of the sole, and the upper bulges out that way, you don’t roll in enough.

3 SHOE SHAPE
Flat feet generally need a shoe with a straight last*. High arched walkers can compensate their foot and leg motion with more curved and cushioned shoes, depending on the severity of the problem.
Our trained Fit Technicians can match you to a shoe model that is designed to help make your walking ‘action’ more comfortable.

4 CUSHIONING
If you walk at a good pace you can experience shock through your legs that is equal to double your weight. Therefore, a shoe with good cushioning is important.
Better shoes have shock absorbing materials in the midsoles (see photo) and heels and some have innovative technologies that are very effective. If you have high arches you will have the greatest need for cushioning.

5 REMOVABLE INSOLE
This not only provides comfort but added cushioning as well. For both of these reasons, it’s a good idea to replace the insole halfway through the life of your shoes, generally after six months. However, each individual should determine this for themselves.

6 INTERNAL SUPPORT FEATURES
Support is important for any walker, especially if you’re a trail or off-trail walker.
Different brands use different internal support features.

Most use contoured midsoles which allow the foot to sit right down inside the moulded sole unit for additional support.

7 EXTERNAL SUPPORT FEATURES
External support features include a firm resistant heel counter, foot frame and variable lacing. A firm heel counter will help increase rearfoot control and maximise heel stability.
For additional stability many shoes now offer a foot frame. This unit supports the upper and cradles the foot.
There are a number of lacing techniques available which will help customise the fit of the shoe. Brands which have recognised this provide additional eyelets on the upper for variable lacing.
Appendix 10

APPOINTMENT 2 (ISSUE) ASSESSMENT FORM
Issue Form

Name:
Address:
Phone no.:

Date of issue appointment:  
Note any changes from initial assessment

Change in weight: Kilograms  
Weight: Kilograms

Occupation:

How many hours on feet: Hours per day

Changes in activities (eg. walking, running, sports):

Changes in activity level (eg. how many times per week do you participate in sport etc.?):

Did the strapping help?  
Yes, a lot  
Yes, a little  
No, not at all  
No, made it worse

Where are your symptoms?:

Mark area on diagram

Have any other symptoms developed elsewhere in your feet/legs/body? Since the last appointment:

Further questions from the researcher?

Check list
☐...FHSQ
☐...VAS
☐...Issue assessment
☐...Orthoses instructions
☐...Appointment for 2/52
Appendix 11

INSTRUCTIONS FOR WEARING FOOT ORTHOSES
Instructions for Using Foot Orthoses

Introduction
You have now received your orthoses; please take some time to read the following information.

Adjustment period
The investigators involved with this project have formulated a prescription to improve your foot mechanics/symptoms. It will take a short period of time to adjust to the orthoses - this is normal.

1. Begin by wearing your orthoses for one hour on the first day, two hours on the second day, three hours on the third day etc. Therefore, you will gradually increase the wearing time by approximately one hour per day.

2. If you have any pain or discomfort during the adjustment period (feet, legs, hip, back) reduce the time you wear the orthoses. Some individuals will take longer to adjust to their orthoses than others.

3. Adults will generally be able to use their orthoses for a full day within two to three weeks.

Footwear
1. You may need to purchase new footwear to accommodate or allow your orthoses to function properly. Low-heeled, lace-up shoes with a deep, supportive heel-counter are most suitable: running or walking shoes are ideal.

2. Running shoes will often have removable insoles. These may need to be removed to allow the orthoses to function correctly.

3. Your orthoses can be transferred from one pair of shoes to another providing they have a similar heel height. Orthoses are balanced to suit a pair(s) of shoes. You would have already discussed this with the investigator of this research project.

4. If your orthoses squeak in your shoes, apply talcum powder to the inside of the heel seat of the shoe (i.e. between the orthosis and the shoe).

5. If you have any questions regarding footwear, please ask the investigator.

Sport
Make sure you can comfortably wear your orthoses all day, every day, for at least one week, before playing sport or running in them. This will minimise the risk of blistering, ankle sprains etc.
Follow-up Appointments

It is important that you return in approximately two to four weeks so your progress can be monitored. An appointment will be made for you to assess your progress.

If you have any questions or concerns, please contact the chief investigator on phone: (02) 4620 3758; fax (02) 4620 3792; e-mail: k.landorf@uws.edu.au. If you are having problems contacting the chief investigator try the UWSM student Podiatry Clinic, phone: 02 4620 3700.

Additional Instructions
Appendix 12

APPOINTMENTS 3 AND 4 (1 AND 3 MONTH) ASSESSMENT FORM
<table>
<thead>
<tr>
<th><strong>Name:</strong></th>
<th><strong>Date of RV appointment:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Address:</strong></td>
<td><strong>Note any changes from initial assessment</strong></td>
</tr>
<tr>
<td><strong>Phone no.:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Change in weight:</strong> Kilograms</td>
<td><strong>Weight:</strong> Kilograms</td>
</tr>
<tr>
<td><strong>Occupation:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>How many hours on feet:</strong> Hours per day</td>
<td></td>
</tr>
<tr>
<td><strong>Changes in activities</strong> (eg. walking, running, sports):</td>
<td></td>
</tr>
<tr>
<td><strong>Changes in activity level</strong> (eg. how many times per week do you participate in sport etc.?):</td>
<td></td>
</tr>
<tr>
<td><strong>Did the foot orthoses help?</strong></td>
<td><strong>Yes, a lot</strong></td>
</tr>
<tr>
<td><strong>Where are your symptoms?:</strong></td>
<td></td>
</tr>
</tbody>
</table>

```
Mark area on diagram
```

```
Have any other symptoms developed elsewhere in your feet/legs/body? Since the last appointment:
```

**Further questions from the researcher?**

**Outcome**

- [ ] Continue
- [ ] Adjust FOs and continue
- [ ] Withdraw from the study

**Check list**

- [ ] FHSQ
- [ ] VAS
- [ ] RV assessment
- [ ] Outcome noted above
- [ ] Appointment for
Appendix 13

APPOINTMENTS 5 AND 6 (6 AND 12 MONTH) QUESTIONNAIRE
Extra Questions

Please complete the following questions by ticking the appropriate box. Be as honest as possible when answering the questions; there are no right or wrong answers.

1. Are you still wearing the foot orthoses (orthotics/inserts)
   - Yes
   - No ➔ Go to Qu. 4

2. Are the foot orthoses still helping?
   - Yes, a lot
   - Yes, a little
   - No, not at all
   - No, made it worse

3. How often do you wear your foot orthoses?
   - All the time
   - As much as possible
   - Sometimes
   - Only when I remember
   - Other

4. Are you still doing your stretching exercises?
   - Yes, every day
   - Yes, most days
   - Only when I remember
   - No
   - Other

5. Are you taking any anti-inflammatory medication?
   - Yes
   - No

6. Are you using any other treatments for your feet?
   - Yes
   - No

7. Have you been satisfied with your foot orthoses?
   - Highly satisfied
   - Satisfied
   - Neutral
   - Unsatisfied
   - Highly unsatisfied

8. Would you recommend the treatment (i.e. the foot orthoses you received) to a friend suffering from arch or heel pain?
   - Highly recommend
   - Recommend
   - Neutral
   - Not recommend
   - Definitely not recommend

In case I need to contact you, is it likely that your address or phone number will change in the next 6 months?
   - Yes
   - No

Thankyou for completing this questionnaire
Appendix 14

DATA FOR NUMBER NEEDED TO TREAT
Calculation of number needed to treat for pain and function at 3 and 12 months (for pain improvement >75% and function improvement > 33%)

<table>
<thead>
<tr>
<th></th>
<th>1. Sham (n=45)</th>
<th>2. Prefab (n=44)</th>
<th>3. Custom (n=46)</th>
<th>ARR - Absolute Risk Reduction</th>
<th>NNT - Number Needed to Treat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td>No</td>
</tr>
<tr>
<td>Pain @ 3/12 &gt;/=75%</td>
<td>15</td>
<td>33.3</td>
<td>22</td>
<td>50.0</td>
<td>15</td>
</tr>
<tr>
<td>Pain @ 12/12 &gt;/=75%</td>
<td>24</td>
<td>53.3</td>
<td>26</td>
<td>59.1</td>
<td>20</td>
</tr>
<tr>
<td>Function @ 3/12 &gt;/=33%</td>
<td>17</td>
<td>37.8</td>
<td>24</td>
<td>54.5</td>
<td>29</td>
</tr>
<tr>
<td>Function @ 12/12 &gt;/=33%</td>
<td>19</td>
<td>42.2</td>
<td>25</td>
<td>56.8</td>
<td>31</td>
</tr>
</tbody>
</table>

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Effectiveness of foot orthoses in the treatment of plantar fasciitis

Karl B. Landorf

Thesis submitted for the Award of Doctor of Philosophy (Health)
School of Exercise and Health Sciences
University of Western Sydney

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- David Matthews and Wendy Lees for their editorial assistance.

Finally, to my parents and family for providing the opportunities to even contemplate this thesis.
Declaration

I hereby declare that this thesis is my own work and to the best of my knowledge it contains no materials previously published or written by another person, except where due acknowledgement is made. I have not submitted this material, either in full or in part, for a degree at this or any other institution.
Abstract

Aim

To evaluate the short and long-term effectiveness of foot orthoses in the treatment of plantar fasciitis.

Design

Three studies were undertaken in the thesis, the first two informing the third.

The aim of the first study was to establish prescription habits of Australian and New Zealand podiatrists in order to ascertain the most commonly prescribed foot orthoses. A questionnaire was mailed to all members of the Australian Podiatry Association and the New Zealand Society of Podiatrists.

The purpose of the second study was to establish the most appropriate outcome measure to assess the effectiveness of foot orthoses in the treatment of plantar fasciitis. This trial utilised a one-group pretest-posttest design to compare two validated, foot-specific health status questionnaires (the Foot Function Index and the Foot Health Status Questionnaire).

Finally, the main study, a pragmatic single-blind randomised controlled trial, was conducted to evaluate the effectiveness of three types of foot orthoses in the treatment of plantar fasciitis.

Setting

The questionnaire was administered as a postal survey. The second study, evaluating two foot-specific health status questionnaires was conducted at a university-based clinic and a private clinic. The randomised controlled trial was conducted at a university-based clinic.
Participants

In the first study, 1505 podiatrists were sent the orthosis prescription questionnaire, with 563 useable responses. In the second study, 17 patients with symptoms consistent with plantar fasciitis were assessed with the health status questionnaires over the course of four weeks of treatment. In the randomised controlled trial, 135 participants who met the inclusion and exclusion criteria for plantar fasciitis were evaluated for a 12 month period. Participants were randomly allocated to receive either a sham (an unmodified soft, 120 kg/m$^3$ ethyl vinyl acetate orthosis), prefabricated (a blue $\frac{3}{4}$ length Formthotic™) or a customised orthosis (a semi-rigid, posted, modified Root orthosis balanced to the neutral calcaneal stance position).

Outcome measures

The primary outcome measure for the randomised controlled trial was the Foot Health Status Questionnaire. Secondary outcome measures included the SF-36 and a four-point scale of improvement.

Results

The results of the orthosis prescription questionnaire indicated that customised orthoses were the most commonly prescribed type of device, followed by prefabricated orthoses. The most common style of customised orthosis was a modified Root device, posted to the neutral calcaneal stance position. This device and a prefabricated orthosis were included in the randomised controlled trial as the two active interventions.

The comparison of two foot-specific health status measures indicated that the most appropriate measure was, as indicated above, the Foot Health Status Questionnaire.

In the main study (i.e. the randomised controlled trial), estimates of treatment effect on function favoured the prefabricated and customised orthoses over the sham orthosis after three months of treatment. Compared to the sham orthosis, function (0-100 scale)
was 8.4 points better for the prefabricated orthosis (95% CI 1.0 to 15.8; p=0.026) and 7.5 points better for the customised orthosis (95% CI 0.3 to 14.7; p=0.041). These effects are statistically significant, but it is not clear if they are large enough to be clinically important. There were no other significant between-group effects on the primary outcome measure.

Conclusion

Provision of appropriate foot orthoses produces small short-term benefits in function for people with plantar fasciitis, but no effect is apparent at 12 months.
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