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An investigation into the effects of metatarsal padded insoles in the management of painful plantar corns

Grace Parfitt

A thesis submitted to the University of Huddersfield in partial fulfilment of the requirements for the degree of Doctor of Philosophy.

Human and Health Sciences
University of Huddersfield

September 2019

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Abstract

Background

The management of painful plantar corns form a key aspect of routine podiatric care. Existing research focuses on treatments to remove the corn rather than interventions that address the causative factors responsible for its development. Treatments aimed at removing corn tissue, including standard treatment of sharp scalpel debridement and enucleation, are associated with short lived outcomes for patients necessitating repetitive podiatric intervention. Since pressure is regarded as an important factor in the development of corns, the literature focuses around implementation of pressure-relieving strategies alongside corn removal treatments, to improve patient outcomes by preventing recurrence. Metatarsal padded insoles are commonly used by podiatrists to reduce pressure in the management of corns, yet there is currently no research available supporting this clinical practice. This research aimed to address this gap in the literature by investigating a currently ambiguous issue in routine podiatric practice: do metatarsal aperture padded insoles, in conjunction with debridement, improve patient outcomes significantly more than sharp debridement alone in the management of corns?

Methods

A pragmatic, parallel group, randomised controlled pilot trial was conducted, whereby 30 participants were allocated to receive either sharp scalpel debridement alone (control group, n = 15) or sharp scalpel debridement alongside a metatarsal padded insole (intervention group, n = 15). The primary outcomes measured were the presence of an

improved plantar corn at six months following treatment and time-to-resolution. Secondary outcomes were; pain, foot disability, and health-related quality of life.

Prior to conducting a proof of concept pilot study, several preliminary investigations were undertaken to determine the type of forefoot padded insole to be tested, which involved: extensive analysis of the research regarding forefoot pads, a survey to investigate current practice, compressional stiffness testing of materials, patients' perspective of metatarsal padded insoles, and pressure analysis.

Results

The preliminary investigations determined that the preferable insole for reducing pressure at the forefoot was a metatarsal pad made from a medium-density polyurethane material. Further to this, an aperture at the site of the corn should provide greater reductions in pressure.

Results of the pilot study showed that a larger-scale study is feasible with recommendations, including; recruitment strategies, efficacy of expanding the study over multiple sites using multiple researchers, and extending the evaluation from six to 12 months. At six months 29% (4/14) of the corns had completely resolved in the control group compared with 13% (2/16) in the intervention group (p = 0.793). Partial resolution (a greater than 50% reduction in baseline area measurement) occurred in 50% of the participants in both control (n = 7) and intervention (n = 8) groups. Time-to-resolution was greater in the intervention group than those in the control ($\chi^2_{(1)}$ = 0.325; p = 0.569). The intervention group showed a greater reduction in mean pain of 23 mm, in comparison to 17 mm in the

control, when compared to baseline mean scores (62 mm (SD 21 mm), 47 mm (SD 30 mm), respectively).

Conclusion

These preliminary investigations have emphasised that a larger-scale study evaluating metatarsal padded insoles is feasible and warranted to determine if this common intervention is effective in managing painful plantar corns. Findings from the pilot suggest that there is no significant difference in resolution rates and time-to-resolution between those receiving debridement and insole therapy to those receiving debridement alone. Conclusions should not be drawn from these findings as considerable imbalances between participants at baseline were found, which could have substantially impacted on the effectiveness of the treatment. Future research should continue to investigate treatments that address the cause of corn development, rather than simply the removal of the lesion to improve outcomes for patients.

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List of Abbreviations

DM Diabetes mellitus

EVA Ethelene Vinyl Acetate

HRQoL Health-related quality of life

IPJ Interphalangeal joint

MTPJ Metatarsophalangeal joint

MFPDI Manchester foot pain and disability index

NIHR National Institute for Health Research

NHS National Health Service

NICE National Institute for Health and Care Excellence

OTC Over the counter

PPP Peak plantar pressure

QOL Quality of life

RA Rheumatoid arthritis

RCT Randomised controlled trial

ROM Range of motion

SREP School Research Ethics Panel

SSD Sharp scalpel debridement

UK United Kingdom

VAS Visual Analogue Scale

WHO World Health Organisation

Chapter 1 - Introduction

Hyperkeratotic lesions, namely calluses and corns, are a common skin complaint amongst the general population with the latest epidemiological review highlighting a self-reported prevalence of up to 48% (Farndon, Vernon, & Parry, 2006). A corn, described in the literature as a well-circumscribed and sharply demarcated area of hyperkeratosis, is thought to be the latter stage of callus development and often leads to increased pain for the patient due to the parakeratotic central core (Singh, Bentley, & Trevino, 1996). Although corns are commonly perceived as a minor skin complaint, they habitually cause foot pain and immobility (Garrow et al., 2000; Menz, Tiedemann, Kwan, Plumb, & Lord, 2006). The repercussions of foot pain can be far-reaching, impacting not only in painful mobility but also in restriction of independence, especially in the older population of 65 years and above (Menz, 2008; Menz & Morris, 2005). This could cascade into a series of events leading to deterioration in general health and wellbeing (Landorf et al., 2013).

The location of the corn is thought to impact upon the quality of life (QOL) experienced by the patient. In a survey it was found that patients with plantar corns, occurring beneath the metatarsophalangeal joints (MTPJs), had a substantially lower QOL than those with dorsal and inter-digital corns. This is a result of the MTPJs being weight-bearing joints, leading to pain during gait (Farndon, Concannon, & Stephenson, 2015).

Currently there are no National Institute for Health and Care Excellence (NICE) guidelines available for podiatrists to refer to when managing corns in clinical practice. Several treatment options are available for use, including: sharp scalpel debridement (SSD) and

enucleation, emollients, keratolytics, surgery and offloading devices. However, these options are not supported by substantial high-quality evidence. The research evidence of these treatment options will be discussed in further detail in Chapter 2.

SSD and enucleation is the 'usual' treatment to manage corns and accounts for up to 75% of a podiatrist's workload, yet this clinical decision is primarily based on anecdotal and non-randomised trials (Landorf et al., 2013; Redmond, Allen, & Vernon, 1999; Siddle et al., 2013). One of the major limitations of SSD and enucleation is the high recurrence rate of the corn and associated pain experienced by the patient. Patients are compelled to return frequently for repeated treatments, which can be frustrating, not to mention costly in time and resources for the service provider and patient (Farndon et al., 2013). In an attempt to overcome this, offloading devices, such as strapping and padding, insoles and functional orthoses are being prescribed routinely to help provide more curative relief for patients with plantar corns (Balanowski & Flynn, 2005; Potter & Potter, 2000). Several studies have identified that plantar lesions occur in areas of high plantar pressure (Jackson, Binning, & Potter, 2004; Mueller et al., 2003; Potter & Potter, 2000). It is assumed that by offloading, the excessive pressure will subsequently decrease the mechanical stress and irritation at the site, reducing patient pain, prevent recurrence, or slow the process of hyperkeratosis and corn development (Grouios, 2004).

Despite their frequent use in clinical practice, there is currently no research evidence available that has evaluated the efficacy of metatarsal padded insoles for the management of plantar corns, which is emphasised later in Chapter 2 (Bevans & Bosson, 2010). Numerous research has been conducted investigating the pressure-relieving abilities of forefoot

devices and materials for healthy patients without hyperkeratosis (Hähni, Hirschmüller, & Baur, 2016; Lee, Landorf, Bonanno, & Menz, 2014). This evidence is explored and critically discussed in Chapter 3. The extensive options available, and the lack of research evaluating the use of metatarsal pads in patients with painful hyperkeratosis, makes it challenging for podiatrists when prescribing insoles in practice. This leads to the delivery of inconsistent care and clinicians trialling insoles, which is costly, time consuming, and can be subjective.

To ensure patients are receiving optimal care, this project aims to investigate the uncertainty of whether incorporating metatarsal padded insoles provides any additional benefit alongside the usual treatment of SSD and enucleation. This could potentially enhance patient QOL and satisfaction if the process of corn development is prolonged and pain is reduced further. Treatment intervals could possibly be lengthened, which may well assist in decreasing the cost and demands on National Health Service (NHS) resources. Further research evidence evaluating the effectiveness of the fundamental aspects of podiatric care is essential, particularly in the current climate where the limited-funding resources are increasingly being directed towards evidence-based management to support service provision (Potter & Potter, 2000).

This introductory chapter examines the theory behind hyperkeratosis, its pathophysiology, the determinants behind its formation, and the consequences which impact upon a patient's QOL. Service provision for the management of corns is discussed, inclusive of its limitations in the prevailing healthcare climate. The chapter will proceed to outline the current treatment of corns in practice, treatment limitations, and the reasoning behind

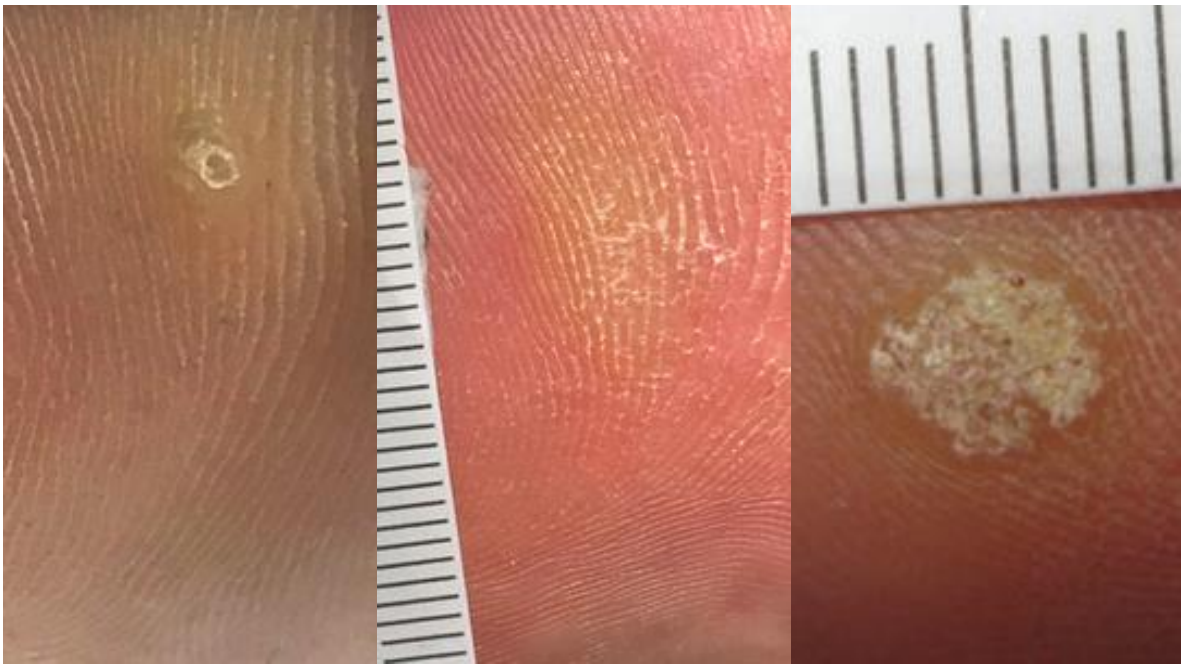
investigating metatarsal padded insoles. Finally, an overview of the structure of this thesis is provided.

1.1 Defining and diagnosing corns

Hyperkeratosis is a term used to describe conditions of the skin, such as corns, calluses, and verruca pedis, resulting from increased proliferation of the stratum corneum layer. A corn is a well-delimited focal area of hyperkeratosis (Singh et al., 1996). An accurate diagnosis can usually be made on clinical presentation through observations and palpation of the base of the corneum layer. It is important to differentiate between a corn, callus and verruca pedis, as this influences the choice of management. A corn is distinguished from an area of callus by its visible, translucent, central parakeratotic core, resulting from more focal mechanical forces and stresses occurring at the site. On direct pressure this core presses into the dermis causing pain and sometimes inflammation (Singh et al., 1996).

Corns and verrucae can be more difficult to distinguish, and in some rare cases may require a biopsy to establish a diagnosis (Tollafield, 2017). In comparison to a corn, a verruca is caused by the human papilloma virus (HPV). They are usually painless, and unlike a corn they do not present with pain on direct pressure, although can present with pain upon the 'pinch' test. The skin striations are forced around a verruca, in contrast to a corn in which the striations run up to the lesion. Other factors to consider when making a clinical diagnosis are: verrucae can occur on non-weight-bearing areas, punctuate capillaries are visible, and the patient may have a previous history of verrucae. Figure 1-1, below, demonstrates these differences between a plantar corn, callosity and verruca.

Figure 1-1: Image of a corn (a), a callus (b) and a verruca (c).



a) b) c)

Heloma is frequently used to describe a corn, which is derived from the Greek term “helus” meaning a stone-shaped wedge (Grouios, 2004). Various types of corns are described in the literature based on their anatomical location and characteristics (Freeman, 2002). Since this project focused on evaluating the effectiveness of metatarsal padded insoles, only hard corns (heloma durum), neurovascular corns (heloma neurovasculare) and fibrous corns were included, as these corns occur over the MTPJs. Heloma durum are most common, which appear as a dry firm mass of hyperkeratosis. Heloma neurovasculare and fibrous corns differ to a heloma durum due to their greater complexity and pain experienced, which makes them notorious for their lack of response to treatment (Grouios, 2004). Heloma neurovasculare contain blood vessels and nerve tissue. Debridement is difficult and usually unsuccessful due to the associated pain, inflammation, and the high likelihood of haemorrhage. Fibrous corns are chronic, where the hyperkeratotic tissue has attached

deeper into the layers of the skin causing greater pain, and are thought to be a result of a lack of treatment, or longstanding unsuccessful treatment (Freeman, 2002).

1.2 Epidemiology

Corns and calluses are a widespread problem amongst the general population, with research reporting a prevalence of between 15-77%, demonstrated in Table 1-1 (Benvenuti, Ferrucci, Guralnik, Gangemi, & Baroni, 1995; Ebrahim, Sainsbury, & Watson, 1981).

Table 1-1: Summary of the literature reporting the prevalence of corns and calluses.

Study	Population studied	Number of participants	Number of participants with corns, or both corns and calluses (%)
Ebrahim et al. (1981)	Hospitalised, aged ≥ 60 years	100	30 (30%) both
Brodie, Rees, Robbins, and Wilson (1988)	Community, aged ≥ 65 years	200	30 (15%) corns
Cartwright and Henderson (1986)	Community, aged ≥ 65 years	543	293 (54%) both
Black and Hale (1987)	Community, aged ≥ 65 years	733	117 (16%) corns
Elton and Sanderson (1986)	Community of North Manchester	1153	300 (26%) corns
White and Mulley (1989)	Community, aged ≥ 80 years	96	65 (68%) both
Benvenuti et al. (1995)	Community, aged ≥ 65 years	459	298 (65%) both
Robbins, Roth, and Villanueva (1996) [1994 data]	Homeless in US	51	29 (57%) both

Robbins et al. (1996) [1995 data]	Homeless in US	30	15 (50%) both
Helfand, Cooke, Wallinskey, and Demp (1998)	Community, aged ≥ 65 years	417	196 (47%) both
Munro and Steele (1998)	Community, aged ≥ 65 years	128	23 (17%) corns
Menz and Lord (2001)	Community, aged ≥ 75 years	135	42 (31%) both
Dawson et al. (2002)	Females without knee problems	96	59 (62%) corns
Springett, Whiting, and Marriot (2003)	Employees of a large organisation in SE England	499	327 (65%) both
Dunn et al. (2004)	Community, aged ≥ 65 years	784	455 (58%) both
Garrow, Silman, and Macfarlane (2004)	Community sample in North West England	3417	1059 (31%) both
Helfand (2004)	Community, aged ≥ 65 years	1000	770 (77%) both
Spink, Menz, and Lord (2009)	Community, aged ≥ 70 years	301	180 (60%) both
Bennett (2012)	New referrals to podiatry in Australia	392	67 (17%) both

Accurately establishing the prevalence across the general population remains difficult, hence the large range reported. Some study designs rely on participants self-reporting the lesions rather than professional diagnosis, which questions the internal validity and reliability of the estimated prevalence (Farndon et al., 2009). Studies in which participants self-reported their foot complaints found lower incidences than those in which the foot was professionally assessed (Farndon et al., 2006). The majority of the literature targets specific sections of the population, typically those aged 65 years and over, rather than a cross-section of the general population. A large cross-sectional study evaluating the wider

population would be beneficial to better understand hyperkeratosis prevalence and prevent inaccurate estimations in the general population.

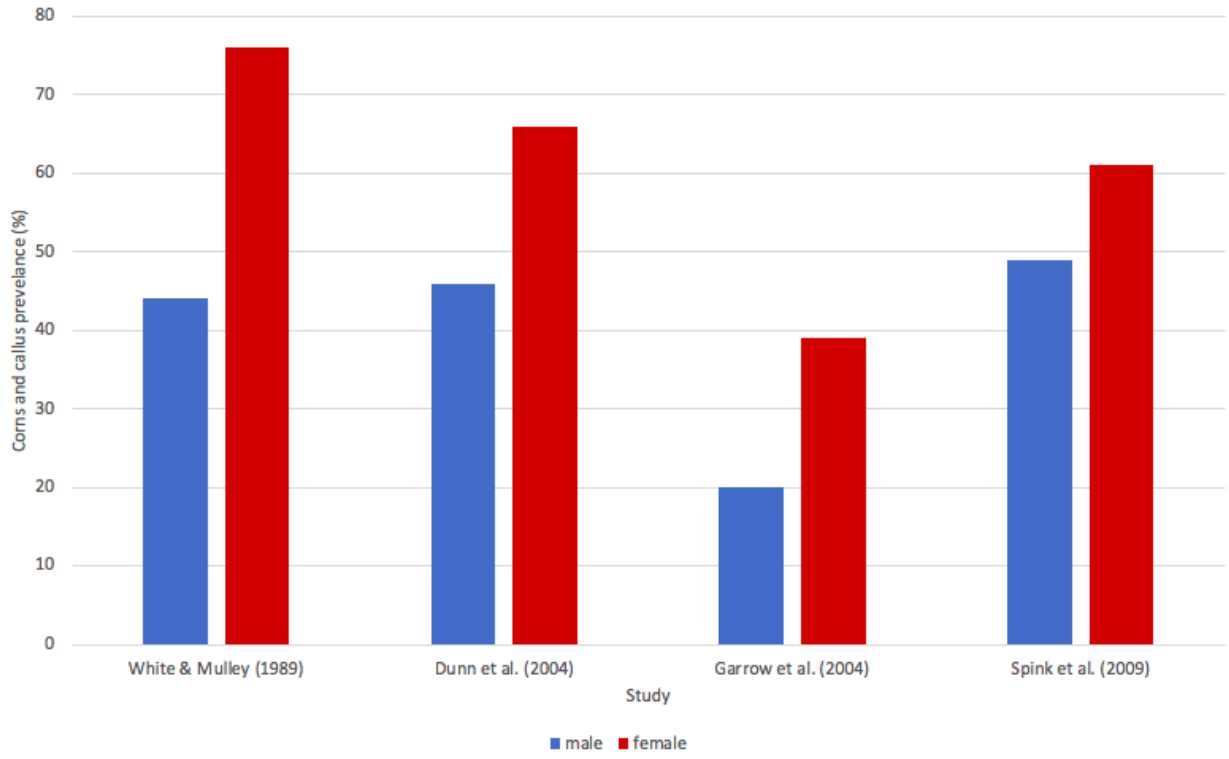
After reviewing the literature, several factors have been identified as being influential in the development of corns, including age, gender and activity level. Many studies have demonstrated that the prevalence of corns and calluses is higher in those aged 65 years and above (Garrow et al., 2000; Helfand, 2004; Spink et al., 2009; Springett, Deane, & Dancaster, 1997). This is due to the associated skin changes and possible co-morbidities which leads to alterations in the ability to tolerate the forces across the foot leading to the development of hyperkeratosis (Menz & Lord, 2001). This could provide an explanation to why the majority of the literature investigating corns and calluses focuses on the older population.

It is important to note, however, that other populations have also been found to have high occurrence rates, such as in the homeless (Robbins et al., 1996) and athletes (Adams, 2002; Grouios, 2004). Robbins et al. (1996) suggest that the lack of appropriate foot hygiene, hosiery and footwear in the homeless population could explain the high prevalence in this demographic, which is a growing concern. Research has suggested a link between the development of hyperkeratosis and increased pressure at the site (Menz, Zammit, & Munteanu, 2007; Potter & Potter, 2000). Activity level could therefore have an impact on the amount of pressure at the site and the production of hyperkeratosis, hence the high prevalence in athletes. Further to this, reviewing the literature highlighted a greater incidence of corns and calluses in those living independently within the community (Benvenuti et al., 1995; Spink et al., 2009; Springett et al., 2003), in comparison to those hospitalised and in residential care (Black & Hale, 1987; Ebrahim et al., 1981). Populations

based in the community and workplace are likely to be more physically active than those in hospital and nursing homes.

Several studies report that the prevalence of corns is greater in females than males, as illustrated in Figure 1-2 (Dunn et al., 2004; Garrow et al., 2000; Spink et al., 2009; White & Mulley, 1989). Other epidemiological studies do not report on the incidence separately.

Figure 1-2: Reported gender differences in corn and callus prevalence within the literature.



Research implies this is due to their choice of footwear (Dawson et al., 2002; López López et al., 2015). A survey of 356 women, aged between 20 and 60 years, found that 88% wore shoes that were considerably narrower than their feet (Frey, Thompson, Smith, Sanders, & Horseman, 1993). Women are more likely to wear footwear that has a narrower toe box

with a higher heel counter, in comparison to men. Wearing footwear with an elevated heel has been shown to increase the peak pressures at the forefoot substantially, elevating the production of keratinocytes, and leading to corn and callus formation (Yung-Hui & Wei-Hsien, 2005). In addition to ill-fitting footwear, the prevalence of toe and hallux valgus deformities are found to be higher in females than males (Menz et al., 2007). Menz et al. (2007) found that those presenting with plantar hyperkeratosis were significantly more likely to have hallux valgus and at least one lesser toe deformity than those without hyperkeratosis.

Racial differences in prevalence have also been reported within the literature. Dunn et al. (2004) found a significantly higher prevalence of corn and callus development in the African American population (70%), in comparison to Puerto Rican (34%) and Non-Hispanic White (58%) populations ($n = 784$, $p = 0.001$).

Corns typically occur on either the plantar aspect of the MTPJs or dorsum of the interphalangeal joints (IPJs) (Stephenson, Farndon, & Concannon, 2016). Plantar corns frequently occur over the third and fourth metatarsal. Several studies have highlighted the metatarsal area of the forefoot to be the most prevalent location of foot pain (Garrow et al., 2004; Hill, Gill, Menz, & Taylor, 2008; Menz et al., 2006).

1.3 Pathophysiology and aetiology

The pathophysiology and aetiology of corns and calluses requires further investigation as its mechanisms are not fully clear (Menz, 2008; Spink et al., 2009). Hyperkeratosis is a complex process that results in the thickening of the stratum corneum layer due to an increased production of keratinocytes and a decrease in desquamation. This process is the normal protective mechanism of the skin to compensate for repetitive or excessive intermittent mechanical stress occurring at the site, such as pressure and shearing forces (Grouios, 2004). This physiological hyperkeratosis increases the surface area of the skin as a protective barrier, thereby preventing damage to the deeper tissues by dissipating the forces. However, hyperkeratosis becomes pathological when the production of keratinised tissue, the corn or callus, becomes excessive and symptomatic. It is not fully understood why pathological hyperkeratosis (corns and calluses) occurs in some individuals and not others. The aetiology is widely assumed to be multi-factorial in origin. Pressure and shearing forces are key causative factors thought to contribute to its development, and are discussed in the literature (Hamatani et al., 2016).

1.3.1 Pressure

Several studies have shown that peak plantar pressures (PPPs) are substantially greater in participants with plantar hyperkeratosis than those without (Duffin, Kidd, Chan, & Donaghue, 2003; Pataky et al., 2002; Potter & Potter, 2000). Menz et al. (2007) compared the plantar pressures of those with and without hyperkeratosis in 292 participants from the older population. Over half of the participants had plantar hyperkeratosis (n = 151, 52%), of which demonstrated significantly higher PPPs for the second MTPJ ($p = 0.001$) and third to the fifth MTPJ ($p = 0.009$). The mean increases in pressure at the forefoot were 9-12% in

participants with hyperkeratosis. Potter and Potter (2000) reported similar findings, although the difference in raised pressures recorded for participants with plantar hyperkeratosis was considerably higher (a 25% increase). The cross-sectional design of the papers leads to difficulties in determining whether the hyperkeratosis is a result of the increased pressure or *vice versa*. Plantar pressures have been shown to reduce significantly following the removal of the hyperkeratosis through SSD in patients with diabetes mellitus (DM), demonstrated in Table 1-2 (Pataky et al., 2002; Pitei, Foster, & Edmonds, 1999; Young et al., 1992).

Table 1-2: The reported reduction in pressure following debridement of hyperkeratosis in patients with DM.

Study	**Number of participants**	**Peak Plantar Pressure (PPP)**		
		Before Debridement	***After Debridement***	***p-value***
Young et al. (1992)	17	14.2 kg cm^{-2}	10.3 kg cm^{-2}	$p < 0.001$
Pitei et al. (1999)	Group 0 = 6 Group A = 10 Group B = 8	Group 0 = 374.8 kPa Group A = 351.7 kPa Group B = 241.0 kPa	Group 0 = 251.0 kPa Group A = 240.5 kPa Group B = 176.2 kPa	Group 0 $p = 0.14$ Group A $p < 0.05$ Group B $p = 0.05$
Pataky et al. (2002)	13	340 kPa	141 kPa	$P < 0.005$

(Pitei et al. (1999, p. 253) defined groups as: Group 0 – patients presenting with callus for first time, with no history of ulceration; Group A – history of ulceration, requiring callus debridement every 6-8 weeks; Group B – history of ulceration, requiring callus debridement every 3-4 weeks.)

This literature suggests that hyperkeratosis causes increased pressure at the site, and once removed plantar pressure decreases in patients with DM. It could be that the hyperkeratosis

acts as a 'foreign body' and contributes to additional forces at the site causing increased pain. Although up to 30% of pressure was shown to be reduced in the studies, Young et al. (1992) did find that 6 of the 43 sites evaluated increased in pressure after debridement, which were all located below the metatarsal heads. This has great importance, as corns predominantly develop in this location (Farndon et al., 2015).

Other studies have evaluated plantar pressure in patients with hyperkeratosis without the presence of DM, focusing on those with rheumatoid arthritis (RA) or the older population who are otherwise healthy (Araguas Garcia & Corbi Soler, 2018c; Davys et al., 2005; Landorf et al., 2013; Woodburn, Stableford, & Helliwell, 2000). The findings in these studies generally contradict the research that investigated pressure changes in diabetic subjects and is highlighted in Table 1-3.

Table 1-3: Peak pressure changes following debridement of hyperkeratosis in populations without DM.

Study	**Population**	**Number of participants**	**Peak plantar pressure (PPP) (kPa)**		
			Before debridement	***After debridement***	***p-value***
Woodburn et al. (2000)	RA	14	254	285	p = 0.14
Davys et al. (2005)	RA	19	828	817	Not provided
Landorf et al. (2013)	Healthy, ≥ 65 years	41	215.8	215.8	Not provided
Araguas Garcia and Corbi Soler (2018b)	Healthy, ≥ 65 years	48	357.4	213.7	p = 0.05

The findings by Woodburn et al. (2000) support the notion that hyperkeratosis is caused by increased pressure due to the reported increase in pressure at the site following removal in patients with RA. Landorf et al. (2013) found no reported change to PPP, which could suggest that pressure does not advance in the presence of hyperkeratosis in healthy individuals. Interestingly, Araguas Garcia and Corbi Soler (2018b) reported similar findings to those studies evaluating diabetic subjects (Pataky et al., 2002; Pitei et al., 1999; Young et al., 1992).

The discrepancies amongst the studies presented in Tables 1-2 and 1-3 could be attributed to a number of factors. The studies target different populations with contrasting inclusion criteria, therefore making it difficult to pool the data. For example, Pitei et al. (1999) included participants with DM, and neuropathy and a history of ulceration, whereas the sample by Pataky et al. (2002) involved diabetic participants without neuropathy. All the studies used to investigate plantar pressures in the various populations use a multitude of equipment, such as F-scan, EMED Pedar Novel GmbH, and Musgrave Footprint analysis. Although all are widely accepted tools for accurately measuring plantar pressures, the sensor technologies differ in size and possibly receptiveness, which may have impacted on the results. Some have the ability to measure the foot-shoe interface, which could provide a more realistic assessment of plantar pressure in everyday life (Catalfamo, Moser, Ghoussayni, & Ewins, 2008; Veves, Manes, Murray, Young, & Boulton, 1993).

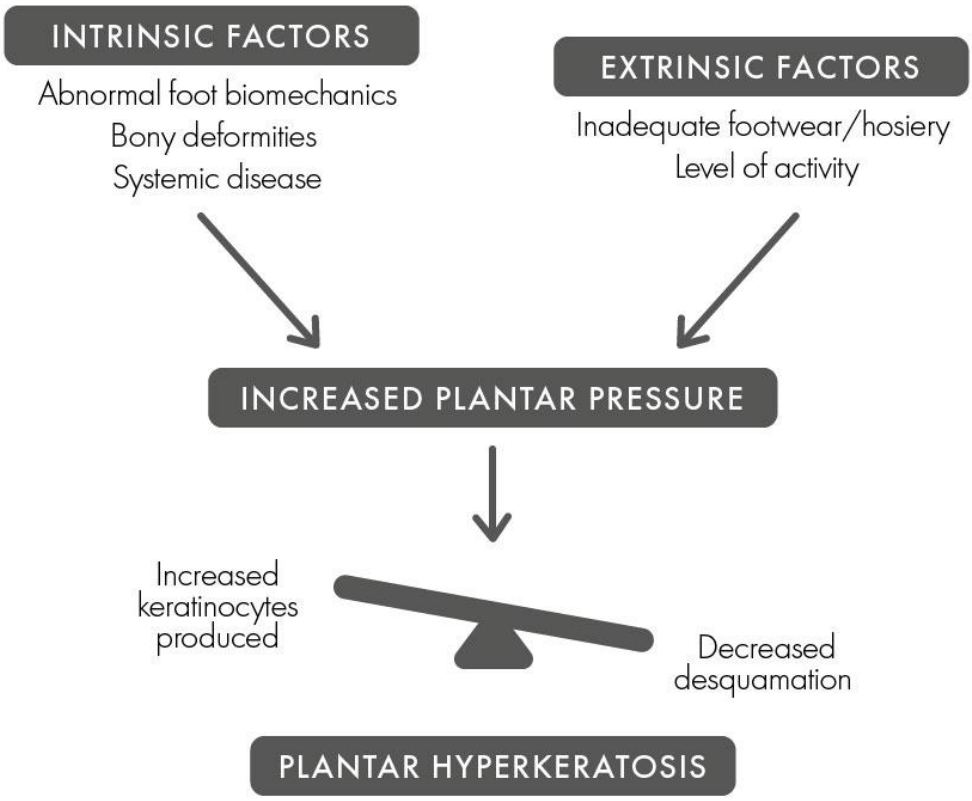
Despite the conflicting findings, hyperkeratosis could still be attributed to raised pressures, as it may be associated with a positive feedback mechanism, where hyperkeratosis, once

formed, may act as a ‘foreign body’ leading to additional increases in pressure (Menz et al., 2007).

1.3.2 Contributory factors that increase forefoot plantar pressure

Many factors have been identified in the literature that increase pressure at the forefoot, and are thought to in turn to contribute to the development of corns and calluses. These intrinsic and extrinsic factors are highlighted in Figure 1-3, and help to provide some justification to support the underlying assumption of raised pressure as a cause of hyperkeratosis. These intrinsic and extrinsic factors will be considered when collecting the demographics of participants recruited to this study.

Figure 1-3: Contributory factors thought to cause plantar hyperkeratosis as a result of increased pressure.



1.3.2.1 Abnormal foot biomechanics

It is widely assumed within the literature that abnormal foot biomechanics influence the formation of mechanically induced corns and calluses due to the associated increased pressures at the site(s). However, studies investigating this hypothesis are scarce and date to 1999 (Bevans & Bowker, 1999).

Bevans and Bowker (1999), compared the foot structure and function in patients with diabetes with forefoot plantar calluses (n = 22), diabetic subjects without forefoot calluses

(n = 20), and non-diabetic subjects with forefoot calluses (n = 17). The two groups with calluses more frequently presented with equinus, forefoot invertus and forefoot evertus. Functional differences in the talocrural, subtalar, and the first MTPJ were found between participants with calluses and those without ($p < 0.0001$). Assessments of talocrural joint dorsiflexion with the knee extended was significantly greater in those with diabetes and no calluses (88.8°) compared to those with diabetes and calluses (91.8°), and non-diabetic subjects with calluses (91.5°), $p = 0.03$. Other research has shown similar findings that ankle dorsiflexion is significantly reduced in those subjects with calluses ($p = 0.003$) (Hamatani et al., 2016). Sufficient ankle joint dorsiflexion of 5-10° from the 90° leg and foot relationship, is necessary in the mid-phase of gait to provide stability (Young, Nix, Wholohan, Bradhurst, & Reed, 2013). Those with limited dorsiflexion, known as having ankle equinus, obtain the necessary motion elsewhere resulting in alterations to the normal gait pattern. Lavery, Armstrong, and Boulton (2002) found that patients with ankle equinus are up to three times more likely to have significantly raised peak forefoot plantar pressures than those with a normal range of movement ($n = 1666$, $p = 0.0001$).

Bevans and Bowker (1999) discovered that as part of an assessment of the first MTPJ, the mean relaxed and maximum dorsiflexed positions of the hallux were significantly greater in the group without calluses in comparison to the others with calluses ($p = 0.0013$ and 0.0015, respectively). A minimum of 65° range of movement at the first MTPJ is essential for toe-off, and any limitations to this motion are likely to result in compensatory mechanisms and increased pressures at the associated sites, in particular the IPJ of the first (Birke, Cornwall, & Jackson, 1988).

Bevans and Bowker (1999) found that mean eversion was significantly greater in the two groups with calluses than the non-callus group ($p = 0.0001$). After discriminant function analysis it was found to be the strongest predictor for callus formation ($p < 0.0001$).

It is important to note that the differences in function, reported by Bevans and Bowker (1999), between the two callus groups (with and without diabetes) and the non-callus group (who have diabetes) are not related to the presence of diabetes. This is because no significant differences in these functions were found between the two groups with calluses. Differences were found between the glycated haemoglobin test ($HbA1_c$), as expected. The non-diabetic group with calluses had scores significantly lower (6.6%, $p = 0.001$) than the two diabetic groups with calluses (8.8%) and without (9.8%), who understandably showed similar results. The study did not record the location of the calluses, which could have helped provide some knowledge of the abnormal mechanics in relation to the formation of the calluses in a typical area.

Those with abnormal foot mechanics, including, limited dorsiflexion at the ankle joint and first MTPJ, and those in an everted and pronated foot position, are more likely to develop plantar corns and calluses due to the increase in pressures occurring at the forefoot. This will be kept in mind when designing the methodology for the project.

1.3.2.2 Bony deformities

The high prevalence of bony deformities of the foot in patients with plantar corns and calluses is well documented (Menz & Lord, 2001; Spink et al., 2009). In the study by Menz and Lord (2001), 73% of participants with plantar hyperkeratosis (n = 42) were more likely to

present with severe hallux valgus than those with mild, moderate, or no deformity (27%). Similarly in 2009, Spink et al. observed a significantly greater number of cases of hallux valgus, classified as moderate to severe, in participants with plantar hyperkeratosis than those without ($p = 0.01$). The changes in the plantar pressure distribution during gait as a result of the deformity provide an explanation for the formation of the hyperkeratosis (Nix, Vicenzino, Collins, & Smith, 2013). There is great disparity amongst the literature evaluating the pressure distributions in patients with and without hallux valgus. Some studies demonstrate a significantly greater pressure under the medial aspect of the forefoot than the lateral in participants with hallux valgus and vice versa (Bryant, Tinley, & Singer, 2000; Martínez-Nova et al., 2010; Mickle, Munro, Lord, Menz, & Steele, 2011b; Wen et al., 2012). Many of the studies did not identify participants who experienced pain with the deformity. Subjects experiencing pain at the joint may adopt an antalgic gait pattern to offload the painful area, which could help explain the inconsistencies reported amongst the studies (Crosbie & Burns, 2007). Nix et al. (2013) argue that the different stages of hallux valgus progression may explain the inconsistencies in pressure distributions reported in their systematic review. In response to this, Koller et al. (2014) reported the plantar pressure characteristics of different regions of the foot in relation to the severity of hallux valgus. It was found that as the angle of the hallux valgus deformity increases the pressure load is shifted from the medial to the lateral aspect of the foot.

Toe deformities, namely claw and hammer, are assumed to contribute to the development of hyperkeratosis. Menz and Lord (2001) identified that from a sample of 135 community-dwelling older subjects, those with digital deformity and digital lesions were more likely to have plantar hyperkeratosis (29% in comparison to 7%, $p < 0.01$). The extension of the MTPJ

that occurs as a result of the toe deformity exposes the metatarsal head to further pressures during gait; however, this has only been shown in diabetic subjects with neuropathy (Bus, Maas, de Lange, Michels, & Levi, 2005). Bus et al. (2005) found that diabetic participants with neuropathy and claw/hammer deformity had peak pressures 1.7 times higher under the MTPJ area than diabetic neuropathic participants without deformity.

1.3.2.3 Systemic disease(s)

DM and RA are discussed within the literature in relation to raised forefoot loading and subsequent hyperkeratosis formation (Mueller et al., 2003; Siddle et al., 2013). A meta-analysis of 16 studies concluded that patients with DM are subject to higher forefoot pressures, due to the complication of peripheral neuropathy (Fernando et al., 2013). Several structural changes can occur in patients with neuropathy, and have been identified in the literature as a possible precursors for increased pressure, which include: plantar tissue thickness, stiffness, toe deformity, pes cavus and reduced range of movement (Mueller et al., 2003). A hierarchical multiple regression analysis was conducted to predict PPPs beneath the metatarsal heads (Klaesner, Hastings, Zou, Lewis, & Mueller, 2002; Mueller et al., 2003). Hammer toe deformity and plantar tissue thickness were found to be the most influential factors in pressure loading at the forefoot. This is in line with other research evidence that has demonstrated raised pressures under the MTPJ area in the presence of hammer toe deformity, which significantly increases the likelihood of forefoot ulceration (Bus et al., 2005; Lavery, Armstong, Vela, Quebedeaux, & Flesichl, 1998). Abouaesha, van Schie, Griffiths, Young, and Boulton (2001) measured the plantar tissue thickness and forefoot pressures in 157 patients with diabetes, reporting that higher peak forefoot pressures were significantly associated with a reduced plantar tissue thickness beneath the first ($r < -0.26$, p

< 0.001) and the second to fifth metatarsal heads ($r < -0.605$, $p < 0.0001$); similar findings were reported by Mueller et al. (2003).

The latest review of foot problems presenting in patients with RA shows that approximately 24-77% are affected by hyperkeratosis (Stolt, Suhonen, & Leino-Kilpi, 2017). Patients with RA are associated with the development of moderate-to-severe deformities and reduced mobility at the joints of the foot (Siddle et al., 2013; Woodburn et al., 2000). Hallux valgus is the most frequent deformity, with studies reporting a prevalence of up to 65% in patients with RA (Stolt et al., 2017). Other common deformities include: hammer and claw toes, metatarsal head depression, and spur formation. A cross-sectional study of 172 participants with RA found that PPPs were 20% higher in regions with forefoot deformity (Konings-Pijnappels et al., 2019).

1.3.2.4 Inappropriate footwear

Inappropriate footwear is considered to be a major contributing factor in the development of corns and calluses (Burns, Leese, & McMurdo, 2002; Menz & Morris, 2005; Perez-Pico, Marcos-Tejedor, Iglesias-Sanchez, & Acevedo, 2018; Schwarzkopf, Perretta, Russell, & Sheskier, 2011). Inappropriate footwear is outlined as: ill-fitting (shoes that are an incorrect shape or size for the foot), lacking fastenings, interfering with normal foot function (for example; unstable or raised heel), having irregularities within the shoe (for example, seams), and shoes worn in situations for which they are not designed (Grouios, 2004; Vernon et al., 2007).

Menz and Morris (2005) recruited 176 participants, aged 62 years and over, in an investigation of the associations between ill-fitting footwear and the presence of corns. It was found that the presence of corns was significantly associated with inadequate width and area for both indoor and outdoor shoes ($p < 0.01$). Palomo-López et al. (2017) found comparable results, reporting that in a sample of 100, 61% presented with hyperkeratosis and 57% of participants were wearing unsuitable footwear. In a study by López López et al. (2015), 83% of the 100 participants aged 65 years and over, were found to be wearing incorrectly fitted shoes that showed a difference in size between left and right feet. Similar findings were shown in the study by Schwarzkopf et al. (2011), which evaluated shoe size mismatch in the general population ($n = 235$), and found that 34.9% of participants wore ill-fitting shoes. The research implies that adequate footwear shape and size could help avoid corns and calluses.

Several studies have reviewed the plantar pressure changes when wearing various types of footwear, including: high-heeled shoes, flat ballet pumps, and running shoes (Yin, Pan, Sun, & Chen, 2016; Yung-Hui & Wei-Hsien, 2005). It has been found that the majority of women wear narrow footwear with a raised heel (Frey et al., 1993; Mandato & Nester, 1999). Several research studies have shown that raising the height of the shoe's heel causes the foot to pronate and forces the pressure from the rearfoot to the forefoot (Karimi, Razaghi, & Sumikura, 2018; Yin et al., 2016; Yung-Hui & Wei-Hsien, 2005). Mandato and Nester (1999), analysed 35 women using the F-scan in-shoe pressure system, and compared the forefoot pressures when wearing trainers, a shoe with a 5.1 cm heel, and a 7.6 cm heel. Forefoot plantar pressures increased by 63% when participants changed from wearing trainers to the 5.1 cm heels, which increased by a further 30% when the 7.6 cm heels were

worn. Research has shown that toe box shape can greatly impact upon the level of pressure at the forefoot (Branthwaite, Chockalingam, & Greenhalgh, 2013; Branthwaite, Chockalingam, Greenhalgh, & Chatzistergos, 2014). Branthwaite et al. (2013) found that the round-shaped toe box resulted in significantly less forefoot pressures in comparison to the square- and pointed-shaped toe box, particularly the at the first and fifth MTPJs ($p = 0.017$, and $p < 0.001$ respectively). In terms of forefoot pressures, normal cushioned trainers are more beneficial for running than flat, racing-style running trainers which have been found to increase forces under the foot by nearly 11% (Queen, Abbey, Wiegerinck, Yoder, & Nunley, 2009).

Observations of shoe-wearing habits indicated that a large proportion of the population wear ill-fitting footwear, particularly in the older population of 65 years and above, in which up to 83% of footwear has been reported as inappropriate (López López et al., 2015; Menz & Morris, 2005; Palomo-López et al., 2017; Perez-Pico et al., 2018). Chantelau and Gede (2002) collected anthropometric data from 568 participants, and reported that more than two thirds of the feet measured were broader than the size of normal footwear available on the market. This could help to explain the high prevalence of poorly fitting footwear, despite the knowledge that this could contribute to corn development and foot pain. A national standard using 11 criteria has been devised to recognise healthy footwear, which is now being applied in certain retailers (Vernon et al., 2007). This set of criteria could also be used by healthcare professionals when providing footwear advice. The role of footwear appraisal in the prevention and management of corns is essential, given the association found between the high prevalence of hyperkeratosis and the wearing of inappropriate footwear (Burns et al., 2002; Menz & Morris, 2005; Palomo-López et al., 2017).

1.3.2.5 Level of activity

The repetitive stress occurring at the forefoot during walking, and in other physical activity, is thought to contribute to hyperkeratosis formation, particularly in patients with bony deformities, abnormal foot mechanics and ill-fitting footwear, due to additional mechanical overload at the tissue site (Young et al., 1992). Studies investigating the prevalence of corns and calluses have found an increased prevalence in populations who are considerably more active (Benvenuti et al., 1995; Spink et al., 2009; Springett et al., 2003).

During the later phase of stance, greater pressures and forces of up to 414 kPa can arise under the forefoot to allow for push-off (Kelly, 1998; Kwon & Mueller, 2001). Several studies have identified that the magnitude and duration of the physical activity influences peak forefoot pressures (Burnfield, Jorde, Augustin, Augustin, & Bashford, 2007). Increased walking and running speed has been found to significantly increase forefoot plantar pressures by up to 33% (Burnfield et al., 2007; Fourchet, Taiar, & Millet, 2013).

The duration and intensity of physical activity is linked to skin breakdown and hyperkeratosis, particularly in those with diabetes and neuropathy (Kwon & Mueller, 2001). In now-controversial research by Kosiak (1959), it was found that ulcers in anaesthetised dogs were caused by either excessive pressures applied for a short duration (500 mm Hg for 2 hours) or low pressures applied for a long duration (150 mm Hg for 10-12 hours). Reducing forefoot pressures during walking has become a primary focus for researchers in order to help reduce skin breakdown, particularly in those with diabetes. This is achieved through footwear modifications and orthoses. Sage, Webster, and Fisher (2001) performed a

retrospective analysis on 233 participants with diabetic foot ulcers, and found that the presence of hyperkeratosis in 192 (82%) participants preceded foot ulceration. No research currently exists which has investigated the benefits of incorporating forefoot padded insoles in patients with hyperkeratosis without ulceration. This therefore provides justification for this research.

Overall, it is clear from reviewing the literature that increased compressive pressures, occurring at the forefoot, due to the several factors identified, have a role to play in the development of corn and callus formation. The differences in the peak pressure changes reported in the literature following debridement suggest that corn and callus formation may not be solely attributed to raised pressures (Pataky et al., 2002; Pitei et al., 1999; Woodburn et al., 2000; Young et al., 1992).

1.3.3 Shear

It is hypothesised within the literature that, in addition to the increased compressive pressures, horizontal shearing forces may contribute to the formation of corns and calluses at the forefoot (Hamatani et al., 2016). Research investigating the shearing forces at the forefoot during walking is limited, in comparison to the wealth of evidence available evaluating pressure. The ability to accurately measure plantar shear poses many technical difficulties, which has acted as a barrier to conducting valuable research (Taketoshi, Masako, Hiroshi, Makoto, & Hiromi, 2012). A review of the literature shows that several methods and pieces of equipment are used to measure shear. Some methods only allow the assessment of one aspect of gait, and do not allow triaxial force measurements, leading to some studies recording variables in separate gait cycles (Yavuz, Botek, & Davis, 2007; Yavuz,

Tajaddini, Botek, & Davis, 2008). The sensors that attach to the plantar skin in some of the studies are thick (2.3 mm) (Tappin & Robertson, 1991). Participants may therefore alter their walking during the testing to accommodate the sensor, thereby making walking more comfortable and prevent any damage to the skin. This can directly interfere with the forces between the foot and ground interface, affecting the internal validity of the findings. There have been some recent advancements in the measurement of shearing forces (Taketoshi et al., 2012). Taketoshi et al. (2012) developed an in-shoe measurement system, ShokacChip, which is based on F-scan pressure-distribution-sensor sheets and shear-sensor sheets. The system is advantageous due to its thin insole which has the ability to measure both compressive forces and shear simultaneously.

The only research available investigating shearing forces as a factor for corn formation evaluates participants with diabetes, due to the significant likelihood of ulceration in those with corns and calluses (Sage et al., 2001). Hamatani et al. (2016) utilised the ShokacChip equipment developed in 2012 and were the first to compare forefoot shearing forces in diabetic participants with and without calluses (n = 69). Peak shear stress during propulsion was found to significantly increase by 1.32 times in participants with forefoot calluses when compared to those without ($p = 0.03$). Similar to the pressure studies, as discussed above, it is difficult to determine whether the presence of the callus is a result of the increased shear, or *vice versa*. Amemiya et al. (2016) recorded the shear and pressure forces at the forefoot in participants with hyperkeratosis that was subsequently debrided and evaluated after one month in comparison to those without hyperkeratosis. It was found that corn and callus formation under the second metatarsal head was associated with higher shear and pressure forces. The ShokacChip equipment, used in both of these studies, requires special

measurement shoes to be worn by the participants which does not reflect the shearing patterns in the participants' typical footwear (Hamatani et al., 2016).

Other research is available that has investigated shearing forces occurring at the forefoot in individuals without plantar hyperkeratosis. Yavuz et al. (2008) compared peak shear pressures of 35 participants with and without DM (n = 15 and n = 20, respectively). Peak shear pressure was significantly greater by 33.7% in participants with diabetes than those without ($p = 0.014$). This is likely due to the neuropathy associated with the condition. Studies have demonstrated that peak pressure (compressive forces) generally occurs more medially than peak shearing, and is much greater in magnitude (Hosein & Lord, 2000; Perry, Hall, & Davis, 2002).

Whilst shearing is assumed to be a factor involved in the development of corn formation, further research is required to determine the extent of its involvement. Technology should continue to advance in the area to take measurements in a more realistic and accurate way. There is a greater amount of research evidence in support of compressive pressure causing hyperkeratosis. Compressive forces have been found to be 6 times greater than shear forces in the forefoot during walking (Hamatani et al., 2016; Hosein & Lord, 2000). The plantar metatarsal padded insoles used in this research project, which are used to manage painful corns, will focus primarily on reducing the compressive forces.

1.4 Impact of corns

The formation of plantar hyperkeratosis is a normal protective response to excessive pressure. However, it can become pathological if it continues to develop causing undesirable symptoms for patients (Farndon et al., 2009; Springett et al., 2003). The main symptom reported by patients is pain during walking, which is often described as a burning, throbbing, stabbing and shooting pain (Caselli et al., 1997). The pain is exacerbated in corns due to the central parakeratotic core pressing into the dermis (Grouios, 2004).

Foot pain, particularly in the older population, can have a detrimental effect on mobility and independence. Several studies have found a high positive correlation between foot pain and disability in activities of daily living, functional limitation and an increased risk of falling (Leveille, Wagner, et al., 1998; Menz & Lord, 2001). Menz and Lord (2001), evaluated balance and functional ability in the older population (n = 135), comparing those with plantar hyperkeratosis (n = 42) and those without (n = 93). It was found that those with plantar hyperkeratosis performed significantly worse in various tests, miscalculated assessments of balance, and took longer to complete important functional tasks. Co-ordination stability was one of these key tests where those with plantar hyperkeratosis found it more challenging to adjust their body position within their equilibrium, hence the higher error score reported of 10.9 compared to 7.4 ($p < 0.05$).

Patients with plantar hyperkeratosis who have DM are at an increased risk of developing an ulceration (Murray, Young, Hollis, & Boulton, 1996; Nishide et al., 2009; Potter & Potter, 2000). In a study of 65 participants, a relative risk of 11 was found for participants developing an ulcer beneath an area of callus than those without such an area (Murray et

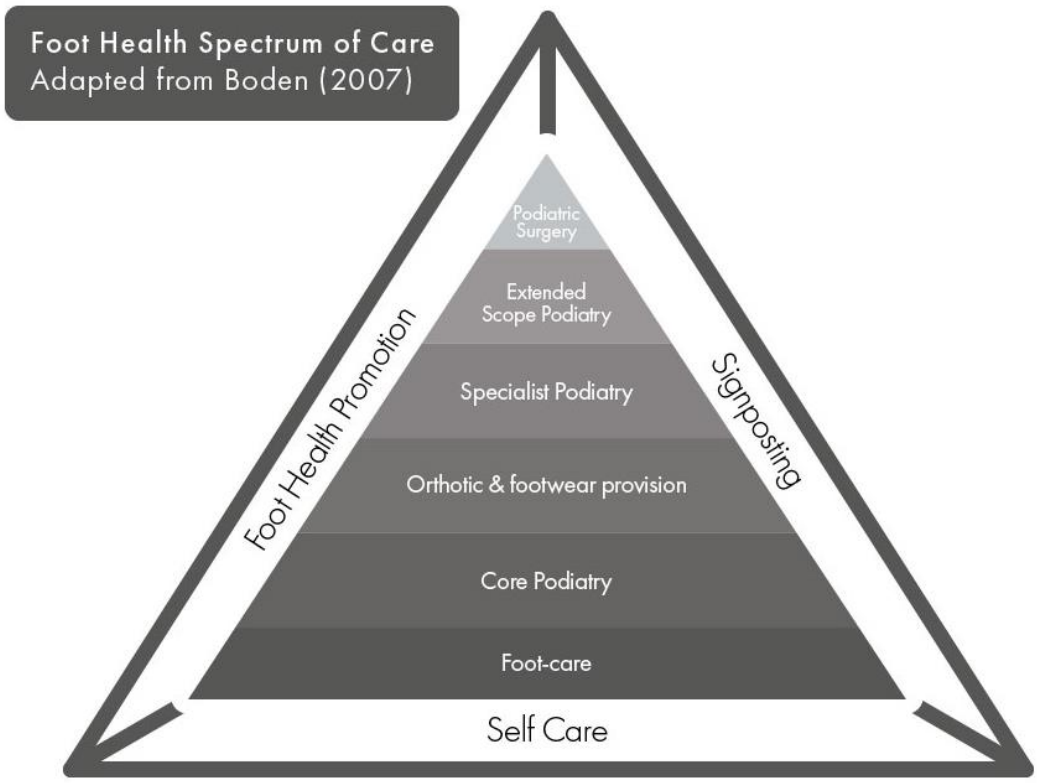
al., 1996). This could be attributed to the continuation of excessive mechanical stresses occurring at the site due to a lack of treatment, causing damage to the deeper tissues, but also could be attributed to the additional pressures caused by the hyperkeratosis itself (Potter & Potter, 2000). Pressures that become too great for the skin to withstand result in breakdown, allowing a portal for infection (Dawber, Bristow, & Turner, 2001). The repercussions of ulcer formation in these high-risk groups are significant, impacting on morbidity and mortality rates (Murray et al., 1996).

Plantar corns are often chronic in nature and are renowned for being difficult to treat successfully, especially fibrous and neurovascular corns (Grouios, 2004). Patients are forced to attend for frequent treatments as pain is reported to return following the 'usual' treatment after only two weeks (Landorf et al., 2013). Plantar corns, therefore, not only impact on the patients' lives by incurring pain and disability over a long period of time, but can also become a costly burden. It would be beneficial to further understand the impact of corns from a patient's perspective, as currently no qualitative research evidence is available.

1.5 Service provision for corn management

The current function of podiatry services is based primarily around core podiatry, demonstrated in Figure 1-4.

Figure 1-4: Pyramid of podiatry care.

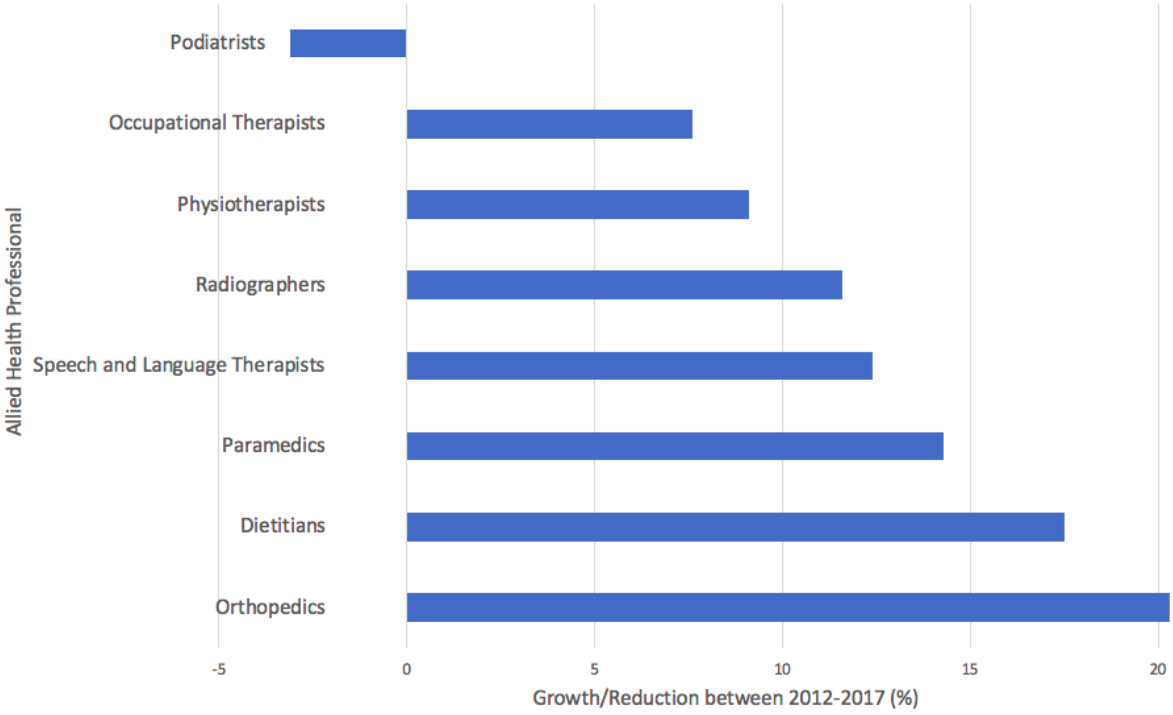


The majority of the management of corns falls within core podiatry, unless these lesions in a high-risk patient deteriorate and become a risk for ulceration, amputation and increased mortality (Murray et al., 1996). Diabetic patients with neuropathy and plantar hyperkeratosis are strongly associated with ulceration if plantar loading is not managed effectively (Young et al., 1992; Potter & Potter, 2000). The severe deformity associated with RA patients leading to abnormal pressures and plantar hyperkeratosis can often require signposting away from core podiatry to more specialist services for bespoke footwear, orthoses and surgery (Siddle et al., 2013).

Podiatry services in the NHS are in increasing demand – a demand which outweighs the provision and resources allocated (Vernon et al, 2007). Only approximately 3.6% of the

general population are able to seek treatment by NHS podiatrists (College of Podiatry, 2015). The reported prevalence of corns and calluses in the general population ranges between 15-77%, and is particularly high in those aged 65 years and above, those with DM and/or RA, and those who are more physically active (Balanowski & Flynn, 2005; Bevans & Bowker, 1999; Menz et al., 2007; Siddle et al., 2013; Spink et al., 2009). NHS podiatry services are unable to accommodate this high prevalence, which is likely to continue to increase due to the ageing population and the increase in number of those with DM (Spink et al., 2009). Alongside this, the number of podiatrists in the NHS has fallen by 3% between 2012-2017 due to reduced funding, in contrast to other allied health professional groups which are growing, as shown in Figure 1-5 (Public Health England, 2017).

Figure 1-5: The growth/reduction of allied health professionals in the NHS between 2012-2017.



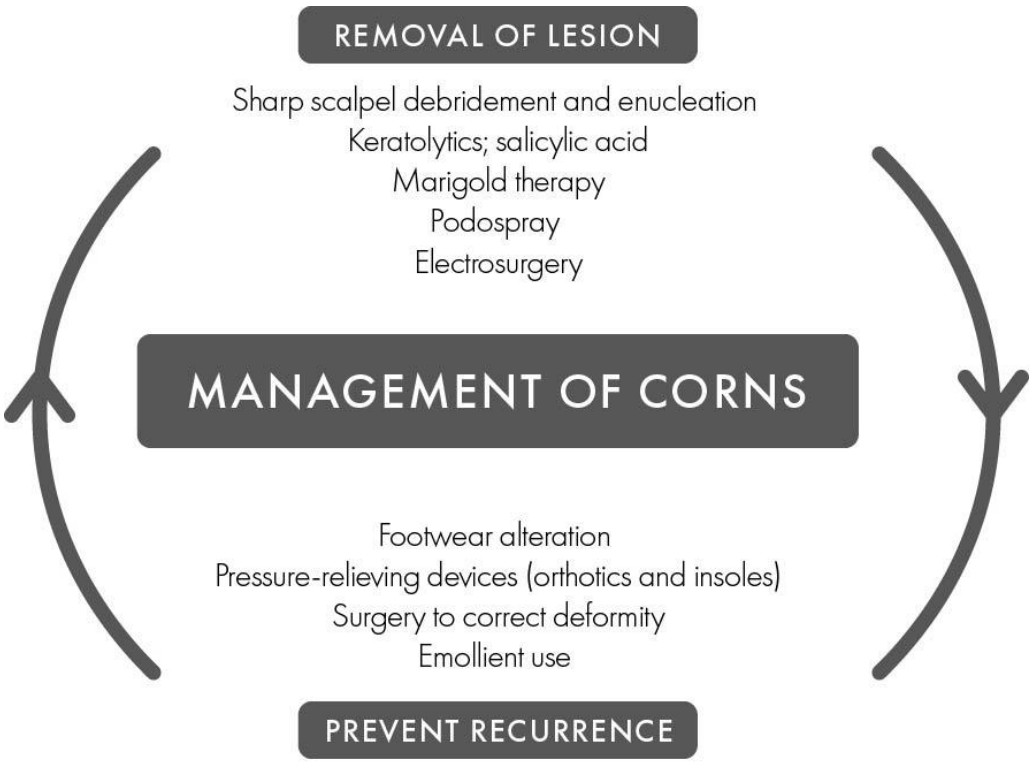
(Data taken from Public Health England (2017))

The smaller workforce has resulted in patients of a lower risk category subsequently being discharged to accommodate high-risk patients. Patients discharged from NHS podiatry are forced to seek treatment privately. A survey of 616 podiatrists working in private practice found that the majority of patients attending the clinic presented with corns and calluses (Farndon, 2016). On the contrary, Campbell et al. (2002) found that 42% of patients with moderate-to-severe hyperkeratosis who were experiencing pain did not access treatment from a podiatrist. This could be due to the cost implications for patients associated with accessing private care. Campbell (2007) conducted a logistic regression analysis on 343 patients who had been discharged from NHS podiatry services due to their low-risk status. It was found that approximately 15% of these participants, once discharged, progressed into a higher-risk category due to deterioration in foot health, particularly those with increased age. This highlights the importance of investigating the effectiveness of treatment options providing long-term outcomes for patients, thereby helping to maximise the efficiency of podiatry services, and, by optimising management plans and preventative measures, reduce where possible the occurrence and recurrence of symptoms, and shorten the length of treatment intervals (Vernon et al., 2007). Given the high prevalence of corns, their associated complications, and difficulties with the provision of treatment, research is necessary to establish whether metatarsal padded insoles, as a pressure-relieving strategy, improve patient care by reducing recurrence rates or extending the time between recurrences. This further justifies the necessity of this project.

1.6 Overview of the management of plantar corns

The following provides a brief overview of the interventions used in practice. Chapter 2 explores these treatments further by critically appraising the research evidence that evaluates their efficacy in managing plantar corns. There are currently no NICE guidelines available for the management of corns or calluses. The aim of treatment is to firstly remove the lesion to alleviate pain and secondly to prevent recurrence of the corn by establishing the cause. Figure 1-6 presents the interventions used in practice in relation to these aims.

Figure 1-6: An overview of the management of corns.

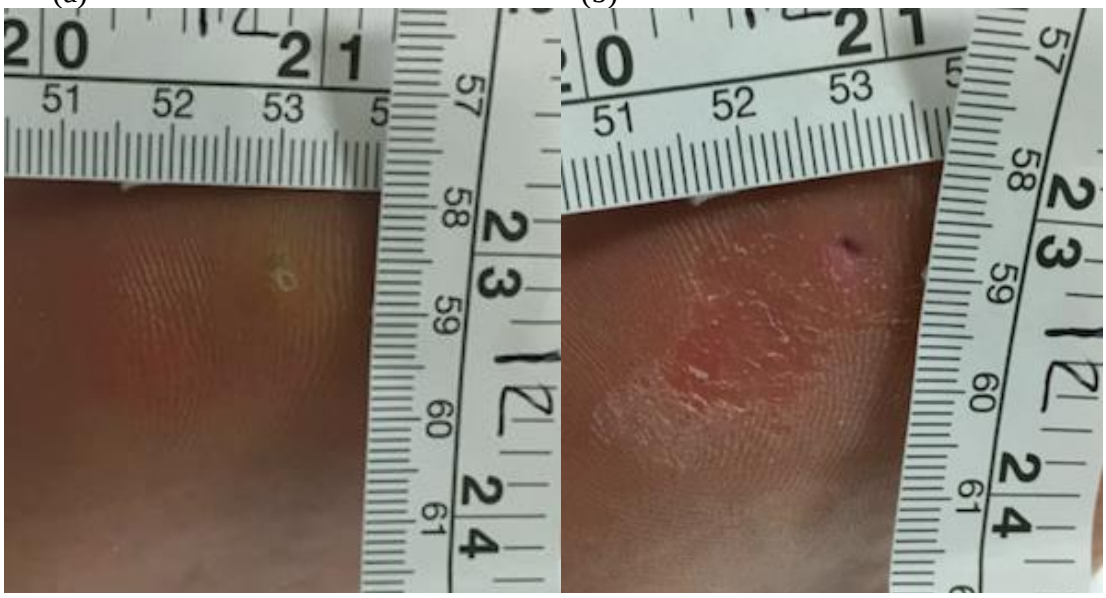


SSD and enucleation is the most frequent treatment utilised in podiatry practice for the management of corns (Farndon et al., 2006). This involves paring the devitalised

hyperkeratotic tissue and the central core of the corn (the nucleus) using a scalpel by a podiatrist, shown in Figure 1-7.

Figure 1-7: Image to illustrate corn before (a) and after (b) SSD and enucleation.

(a) (b)



The success of debridement is short-lived; Landorf et al. (2013) reported that pain and lesion recurrence returned within 4 weeks. In patients with fibrous and neurovascular corns, sufficient SSD and enucleation can be difficult due to their complexity, as it involves deeper tissue with nerve and vascular elements (Grouios, 2004). Debridement itself can cause pain for these patients. This and the short-lived effects of SSD and enucleation has led to the use of different methods to aid lesion removal in these patients, including the use of a podospray and electrosurgery under local analgesia. A podospray is a device that utilises a jet of water to reduce friction, and cools the skin to facilitate the removal of the tissue with a bur. Electrosurgery uses a probe to heat the tissue cells, which evaporates the fluid

causing separation of the keratinised tissue from the dermis (Anderson & Burrow, 2002; Bevans & Bosson, 2010). The podiatrist is then able to enucleate the tissue more easily.

Medicaments are also implemented in practice to remove the lesion and reduce or eliminate the pain. The most researched of these are salicylic acid and marigold therapy. Salicylic acid is available in different concentrations, and acts by hydrating the stratum corneum to promote desquamation, and therefore corn enucleation (Potter & Potter, 2000). It can be applied by a healthcare professional or the patient themselves, due its availability over the counter. Marigold, *Tagetes erecta*, is thought to have anti-keratotic and anti-inflammatory properties. It is applied to the skin by a health care professional with the use of a semi-compressed felt pad, demonstrated in Figure 1-8 (Khan & Evans, 1996; Khan & Khan, 2000).

Figure 1-8: Application of marigold therapy with semi-compressed felt metatarsal pad.

The padding, highlighted in Figure 1-8, is thought to assist in the healing of the corn by temporarily offloading the pressure from the site, whilst retaining the medicament. The literature accentuates the importance of combining pressure-relieving strategies with lesion removal (Potter & Potter, 2000; Woodburn et al., 2000). This is because the development of plantar hyperkeratosis is thought to be due to elevated pressures as a result of certain intrinsic and extrinsic factors, as discussed previously (Grouios, 2004). There is an underlying assumption that by restoring the plantar pressure to levels similar to those found in individuals without hyperkeratosis, the cycle of hyperkeratosis formation will be broken, thereby preventing recurrence.

One of the primary methods to offload pressure from the metatarsal heads is through the use of a forefoot pad, such as a metatarsal pad with or without an aperture and dome. This can be a temporary measure by directly applying it to the skin, lasting two to four days, or alternatively more long-term, by incorporating the device into an insole or orthotic. Several studies have demonstrated that forefoot pads, added on to an insole, can significantly reduce PPP by up to 43% (Jackson et al., 2004; P. Lee et al., 2014; Lin et al., 2013; Lott, Hastings, Commean, Smith, & Mueller, 2006). The pads can be custom moulded or prefabricated, with a vast array of materials are available from which to construct the pad. There is a clear opening for this study, as currently no research evidence is available to determine if these metatarsal padded insoles, in combination with SSD and enucleation, are more effective in managing plantar corns than the usual treatment of SSD and enucleation alone.

The standard treatment of SSD and enucleation should also involve footwear advice and the use of emollients from the podiatrist, where appropriate. Inadequate footwear has been shown to raise forefoot pressures, which is thought to contribute to hyperkeratosis formation (Burns et al., 2002; Menz & Morris, 2005; Perez-Pico et al., 2018). Management should, therefore, routinely include footwear appraisal and advice, where necessary, to ensure patients are wearing appropriate footwear that is of the correct size and shape (Vernon et al., 2007). Studies have shown that the hydration levels of the skin are decreased in those with hyperkeratosis, which reduces the desquamation rate, leading to a build-up of keratinocytes (Bouwstra et al., 2003; Wu, van Osdol, & Dauskardt, 2006). The frequent application of an emollient could assist in encouraging a balance between the production and desquamation of keratinocytes by re-hydrating the skin. SSD and enucleation alongside footwear appraisal and emollient advice will be regarded as the standard treatment for corn management in this research study.

1.7 Purpose of the study

A large proportion of the population are affected by corns, which not only cause pain for patients, but also increase the demands on already-strained podiatry services. A large survey of 1,856 podiatrists practising in the UK reported that over one quarter of the patients on that day presented with corns and calluses (Farndon, 2016). The impact of corns in the older population and those with diabetes, where prevalence is high, can lead to more severe complications by impacting on their QOL. Forefoot ulceration has been shown to occur beneath an area of hyperkeratosis in over 82% of patients with diabetes (Sage et al., 2001). Preventing corn formation or delaying its recurrence is vital.

Studies have demonstrated that the effects of the standard treatment of debridement are short-lived, reporting corn recurrence rates and associated pain within 4 weeks following treatment (Landorf et al., 2013). This usual treatment is insufficient, given that the majority of NHS services offer a standard 3-month minimum wait for an appointment, and that many patients accessing the NHS who are classified as low risk are being discharged. Treatment needs to focus on addressing the cause as well as removing the lesion. The cause of hyperkeratosis and corn formation is still not fully understood; however, strong associations have been found between hyperkeratosis formation and excessive pressures occurring at the site, due to a number of intrinsic and extrinsic factors (Grouios, 2004). The literature emphasises the importance of combining pressure-relieving strategies, such as, metatarsal pads, alongside removal of the lesion to assist in breaking the cycle of hyperkeratosis formation (Potter & Potter, 2000). There is currently no evidence to state whether incorporating a metatarsal padded insole will aid improvements in patient outcomes beyond those of SSD and enucleation alone. This supports the necessity for this research, which may assist in improving the quality of management plans for patients with plantar corns, an improvement which may subsequently prevent the recurrence of these complications and the lesions themselves. It will enhance podiatric knowledge, and could also help to support the widespread anecdotal clinical practice being undertaken without validated research evidence to support the use of metatarsal padded insoles in practice.

1.8 Primary aim and objectives

The primary aim of this research was to investigate the inclusion of a metatarsal padded insole alongside SSD in improving patient-related outcomes in the management of plantar corns.

To assist in achieving the aim, the following objectives were set:

1. To identify the type of forefoot pads currently being prescribed in practice for managing plantar corns.
2. To establish the compressional stiffness of various orthotic materials available for use in managing plantar corns.
3. To determine patients' perspectives of the materials available for use in managing plantar corns.
4. To investigate whether the chosen plantar metatarsal aperture pad reduces the plantar pressure from the forefoot.
5. To evaluate the effectiveness of SSD and enucleation, with patient education alone.
6. To evaluate the effectiveness of SSD and enucleation, with patient education and the inclusion of a plantar metatarsal aperture pad.

1.9 Overview of the thesis

Following this introduction to the thesis, Chapter 2 will critically review and appraise the available literature that has evaluated treatments for managing corns and calluses. It aims to identify the gap in the literature regarding the use of metatarsal pads in corn management. Different outcome measures used in the studies to analyse the efficacy of the treatment interventions are highlighted, which helped design the methodology of this

research project. Chapter 3 presents a meta-analysis that was conducted to estimate the efficacy of the usual treatment of sharp scalpel debridement, when compared to any comparative, in management of painful hyperkeratosis.

Since there are no previous studies that have investigated the efficacy of metatarsal padded insoles for the management of corns, the study required two key parts:

Part 1: Insole selection

To identify the preferred metatarsal padded insole that was used for the evaluation, a thorough review of the literature available investigating the pressure-relieving properties of the different types, materials and designs was conducted alongside several small-scale investigations to further support the decision-making process of the insole selection. Part 1 of the study is presented and discussed in Chapter 4.

Part 2: Proof of concept pilot study

This involved an evaluation of the selected insole alongside the 'usual' treatment of SSD in comparison to debridement only, in a proof of concept pilot study to test feasibility and acceptability, and to consider how this could be incorporated into a future, larger RCT study.

The methodology used for the pilot study to evaluate the selected plantar metatarsal padded insole is outlined and justified in Chapter 5. The results of the pilot study are then presented in Chapter 6, highlighting the findings of the primary and secondary outcomes measured.

Discussion of the results then follows in Chapter 7, exploring the findings in relation to other research, the potential use of the findings, considering the strengths and limitations and the ability to conduct the study on a larger scale.

To conclude the thesis, Chapter 8 summarises the main findings of the research study, and highlights how it contributes to clinical practice.

1.10 Summary

This chapter has introduced the theory surrounding hyperkeratosis and has emphasised that the pathophysiology and aetiology is still not yet fully understood. It is clear that excessive compressive pressures occurring at the site, due to a number of intrinsic and extrinsic factors, are highly likely to lead to corn formation. The impact of corn formation on the patient and podiatry services has been explored. An overview of the treatment interventions for managing plantar corns has been outlined, demonstrating that the standard treatment involves SSD and enucleation. The short-lived effects of SSD and enucleation have been highlighted, which includes; pain and lesion recurrence within 4 weeks. The question of whether the use of metatarsal padded insoles alongside the usual SSD and enucleation would provide any additional benefit in the management of corns has been proposed. Attempting to answer this question will enhance podiatric knowledge, and if the inclusion of metatarsal padded insoles is found to provide additional benefits, it could lead to improved care for patients with painful plantar corns, and may assist in reducing the demands on NHS podiatry services.

The subsequent chapter explores and critically appraises the literature that has investigated the efficacy of the treatment interventions used in the management of corns.

Chapter 2 - Literature review of the treatments for plantar corns

This chapter presents a review of the literature, exploring and analysing studies that have investigated the effectiveness of various interventions used to treat and manage painful hyperkeratosis, including corns. This review identifies if any of the methods used in these studies to control and measure the various variables would be appropriate to implement in this research project. This chapter further justifies the necessity for conducting this investigation to evaluate the use of plantar metatarsal padded insoles alongside sharp scalpel debridement (SSD) and enucleation for the management of painful plantar corns.

2.1 Search method and strategy

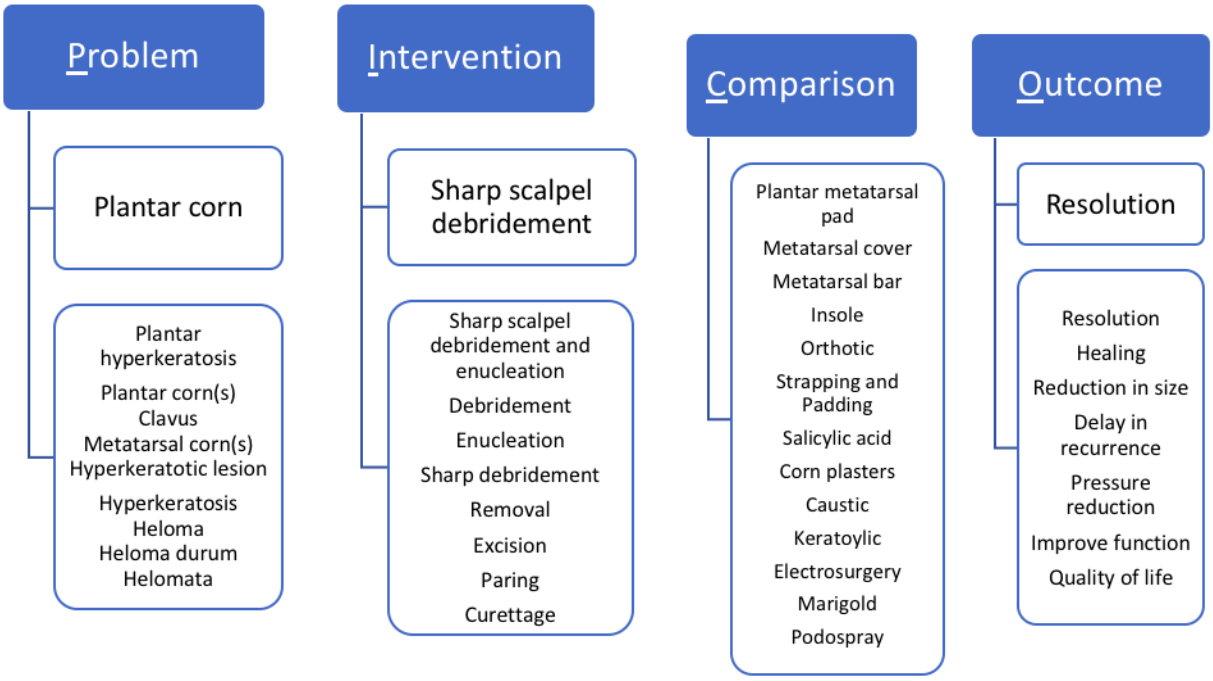
To identify the effectiveness of treatments available for managing plantar corns, a systematic approach was used to conduct the literature review to generate a thorough account of the evidence available (Ridley, 2012). The aim of the search strategy was to target all papers that focused on investigating any treatment used to manage painful plantar hyperkeratosis that included both corns and callosities. Whilst corns should be distinguished from calluses due to the focal parakeratotic centre of the former, the pathology and aetiology, which have been discussed in Chapter 1, overlap considerably (Grouios, 2004). By widening the search to include both hyperkeratotic lesions, a comprehensive analysis of the research could be conducted, preventing pertinent evidence from being excluded from the review (Gough, Oliver, & Thomas, 2017). For instance, although the standard treatment for corns and calluses is SSD, most of the research evidence evaluating this modality investigates painful calluses rather than corns (Woodburn et al., 2000). This evidence would still be applicable in clinical practice when devising an

evidence-based management plan. Additionally, the terminology for hyperkeratosis within the literature is ill defined and is often interchangeable (Freeman, 2002). Some research may also evaluate treatment modalities for both corns and calluses due to their crossover, therefore narrowing the search to solely include corns could prove restrictive.

All avenues for accessing possible relevant research evidence was explored, including library catalogues, bibliographical databases, and open access databases, to ensure the review verified the credibility and validity of the findings (Ridley, 2012). The library catalogues searched were the Consortium of University Research Libraries [CURL] and the National British Library integrated catalogue. The following electronic databases were examined: Allied and Complementary Medicine [AMED] (1985-present), Centre of Reviews and Dissemination Database [CRD] (1994-March 2015), Cochrane Library, Cumulative Index to Nursing and Allied Health Literature [CINAHL] (1982-present), Embase (1947-present), Evidence Search, and MEDLINE (1966-present). This search was initially carried out in 2014, and has been continuously updated until September 2019 to ensure all papers were identified during the writing of the thesis. No date restrictions were applied, but only papers in English were retrieved as there was no translation service available.

Before reviewing the databases and catalogues, an exhaustive search term list was produced using the PICO (Problem, Intervention, Comparison, and Outcome) model to help maximise the recovery of evidence by identifying key concepts to assist in breaking down the search (da Costa Santos, de Mattos Pimenta, & Nobre, 2007). Figure 2-1 illustrates the four components of PICO, with the matched keywords for the search and a list of the synonyms recognised for each.

Figure 2-1: Summary of search terms using the PICO template.



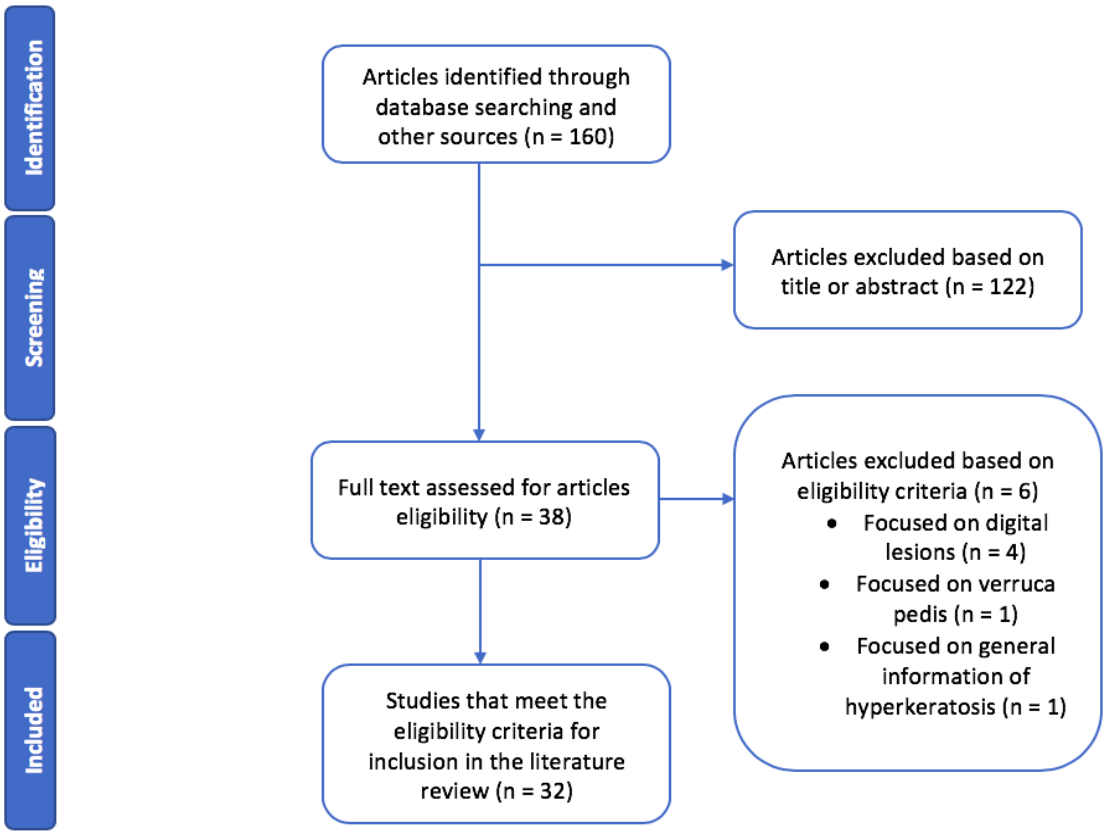
To further improve the search strategy, Boolean operators were used, such as “OR” to connect synonyms for each concept, and “AND” to link the four components together for the search (Ridley, 2012). In this instance, it was not necessary to use any truncations or wildcard operators. When searching each electronic database and catalogue, the search strategy was entered in line with their own operators. Alongside the keyword searching, the strategy also included searching for subject headings relating to the key terms (da Costa Santos et al., 2007).

In addition to searching through the various databases and library catalogues, “snowball” methods were also incorporated. This included exploring the references from the primary articles retrieved and pursuing the electronic tracking on the databases and journals. These methods are found to be advantageous in identifying applicable research that is ordinarily

difficult to locate, as well as establishing the efficiency of the search strategies (Greenhalgh & Peacock, 2005).

The selection process for the articles included in the literature review is illustrated in Figure 2-2.

Figure 2-2: Flow diagram of the literature review selection process, adapted from the PRISMA flowchart (Moher, 2009).



A total of 160 papers were retrieved from the searches due to the comprehensive nature of the design of the search strategy. Inevitably a large proportion of these articles recovered had no relevance to the management of plantar hyperkeratosis as the search terms used

were highly subjective. The results for each search were manually screened for relevance, examining the title and abstract, which eliminated 122 articles. The full texts of 38 articles were assessed for eligibility. Articles which failed to meet the inclusion criteria of treatment for the management of plantar hyperkeratosis or corns were excluded (n = 6). These exclusions focused on: evaluating treatments for verrucae pedis, general information on corns, and evaluating lesions on the dorsal aspect of the foot. The search strategy resulted in the inclusion of a range of study types, including randomised controlled trials (RCTs), case studies, and non-experimental designs.

2.2 Search results

Following the comprehensive search and selection process, a total of 33 papers were suitable for inclusion in the review, which were subsequently discussed and explored. A range of treatment modalities were evaluated, including: SSD (n = 12), keratolytics (n = 4), hydrocolloid dressings (n = 2), marigold therapy (n = 3), bleomycin injection (n = 1), electrosurgery (n = 6), surgical punch incision (n = 1), and orthotic therapy (n = 4). The studies focusing on orthotic therapy investigated flat cushioned insoles and custom-moulded insoles (Caselli et al., 1997; Colagiuri, Marsden, Naidu, & Taylor, 1995; Duffin et al., 2003; Timson & Spooner, 2005). No studies were found to have evaluated the use of insoles with a metatarsal pad alongside SSD in the management of plantar corns, revealing an opening for the proposed project.

All final papers were critically appraised using the Critical Appraisal Skills Programme (CASP) tool to help ensure all pertinent issues were assessed when appraising the research (The Critical Appraisal Skills Programme, 2019).

2.3 The standard treatment of SSD

SSD and enucleation is the usual treatment for managing hyperkeratosis, including corns and calluses (Farndon et al., 2013). This routine treatment is considered to be an integral part of practice, with researchers emphasising that it constitutes approximately 70% of a podiatrist's workload (Potter & Potter, 2000).

A total of 12 studies were found to have evaluated the effectiveness of debridement in managing hyperkeratosis, including corns (Araguas Garcia & Corbi Soler, 2018a, 2018b; Balanowski & Flynn, 2005; Davys et al., 2005; Gijon-Nogueron, Garcia-Paya, Ortega-Avila, Paez-Moguer, & Cervera-Marin, 2015; Landorf et al., 2013; Pataky et al., 2002; Pitei et al., 1999; Redmond, Landorf, & Keenan, 2009; Siddle et al., 2013; Woodburn et al., 2000; Young et al., 2013). There was disparity among the papers in relation to their design methodology, sample targeted, and outcome measures used.

One common outcome was that of reduction of pain associated with the hyperkeratosis. The same method to measure pain was adopted by all studies using the horizontal 100 mm Visual Analogue Scale (VAS). This VAS is widely used as it is simple to understand and quick to administer. Previous studies have found the scale to be sensitive in assessing the effects of treatments, and scores have been found to be reproducible (Kelly, 1998). Substantial

reductions in pain were reported immediately following debridement when compared to baseline measurements in various case series, as shown in Table 2-1 (Araguas Garcia & Corbi Soler, 2018b; Gijon-Nogueron et al., 2015; Redmond et al., 1999).

Table 2-1: Summary of the case studies investigating pain levels (mm) before and immediately after debridement.

Study	**Number of participants**	**Pre-debridement (mm) mean (SD) or median (IQR)**	**Post-debridement (mm) mean (SD) or median (IQR)**	**p-value**
Redmond et al. (1999)	79	69 (4-100)	9.5 (0-84)	Not provided
Woodburn et al. (2000)	8	59 (37-76)	24 (12-43)	0.01
Balanowski and Flynn (2005)	21	37 (32)	12 (21)	0.001
Gijon-Nogueron et al. (2015)	34	77 (9.9)	9 (8)	0.001

In spite of the significant reductions in pain of up to 68 mm on the VAS reported in the case series, Table 2-2 demonstrates that three RCTs also found a decrease in reported pain in control groups (Araguas Garcia & Corbi Soler, 2018b; Davys et al., 2005; Landorf et al., 2013).

Table 2-2: Summary of the RCTs investigating pain levels (mm), before and immediately after debridement.

Study	**Number of Participants**	**Pre-debridement (mm) mean (SD) or median (IQR)**		**Post-debridement (mm) mean (SD) or median (IQR)**		**p-value**
		Control	*Intervention*	*Control*	*Intervention*	
Davys et al. (2005)	38	43 (12-66)	36 (12-66)	3 (-17-1)	3 (-10-1)	0.48
Landorf et al. (2013)	80	47 (21)	55 (21)	20 (19)	16 (16)	0.124
Araguas Garcia & Corbi Soler (2018b)	98	55 (16)	56 (16)	44 (14)	16 (11	0.001

All of the control groups of the RCTs involved sham debridement, where the scraping action against the skin was imitated by use of the blunt edge of a scalpel without lesion removal. It is difficult to determine whether improvements in control groups were due to a perceived or true placebo effect (Ernst & Resch, 1995), which may affect the internal validity of the findings and conclusions. Previous research has suggested medical devices included in the sham technique enhance the placebo effect (Kaptchuk, Goldman, Stone, & Stason, 2000). The gratitude effect could explain the reductions in pain demonstrated in control groups; Redmond et al. (1999) argued that palliative podiatric treatments, such as debridement, are notably associated with this effect. The positive attitude of the participants towards receiving professional treatment could have directly affected reported pain levels following the treatment, which could affect the internal validity of results (Layous et al., 2017). In the latest Ipsos MORI Veracity Index poll, over 90% stated that they trusted the actions of healthcare professionals (Ipsos, 2018), leading to an assumption that patients expect an intervention will have a beneficial effect when administered by a healthcare professional.

Despite using the same standardised method for the control groups (sham debridement), the results of the studies analysing pain following debridement that use a control group for comparison are contradictory. Both Davys et al. (2005) and Landorf et al. (2013) reported no significant differences in pain scores between the sham and SSD groups following treatment ($p = 0.48$ and $p = 0.124$, respectively); however, Araguas Garcia and Corbi Soler (2018b) found a significant difference ($p < 0.001$). These conflicting findings could be attributed to a number of factors, including the placebo and gratitude effects, the differences in samples targeted, and the methods used for debridement. Davys et al. (2005) targeted patients with rheumatoid arthritis (RA), in contrast to the other two studies, which focused on the older

population who were otherwise healthy. Disease-specific characteristics may exist alongside the plantar hyperkeratosis, such as synovitis of the MTPJs, which could contribute to the participant's forefoot pain. This may influence the effects of debridement if pain experienced is not solely attributed to plantar hyperkeratosis, thereby affecting the internal validity of results and conclusions. Both Araguas Garcia and Corbi Soler (2018b) and Davys et al. (2005) designated one experienced practitioner to carry out all of the debridement for repeatability purposes, whereas Landorf et al. (2013) had multiple student podiatrists performing the treatments. Arguably, an experienced practitioner may have debrided further hyperkeratosis (i.e., not just plantar), which could influence pain levels experienced by the SSD group.

Despite these conflicting findings in the RCTs, it seems clear that the removal of hyperkeratosis by SSD is associated with substantial, immediate pain relief. When reviewing the literature, including the case series, in participants aged 65 years and above who were otherwise healthy, reductions in pain of between 25 and 68 mm on the 100 mm VAS were found (Araguas Garcia & Corbi Soler, 2018a; Balanowski & Flynn, 2005; Gijon-Nogueron et al., 2015; Landorf et al., 2013; Redmond et al., 1999). The reported immediate reductions in pain are far less pronounced in the studies targeting those with RA, with pain scores decreasing between 3 and 35 mm on the scale, following debridement. The pain relief observed, however, has been shown to be short-lived, with pain returning in up to four to six weeks due to recurrence of the hyperkeratotic lesion (Davys et al., 2005; Landorf et al., 2013). Indeed Landorf et al. (2013) found a 71% reduction in pain on the 100 mm VAS immediately following real debridement, yet the clinical effect was found to diminish over time; at three weeks the difference in mean pain from baseline was 55%, and 29% at six

weeks. The data suggest that SSD in isolation may not be valuable in the short term, but could potentially provide cumulative benefits in the long term, when used in combination with other treatment options.

A combined therapeutic approach with and without regular SSD over a period of 18 months in 65 participants with RA was undertaken by Siddle et al. (2013). The combined therapeutic approach was in accordance with clinical practice, which consisted of education and self-management advice, bespoke prescription foot orthoses, footwear provision or advice, physiotherapy, and steroid injection therapy, as required. There are criticisms of this approach, as although interventions were available to all participants, there was no standardisation of the type and number of treatments provided to participants. For instance, steroid injection therapy, which is known to reduce pain, was implemented if deemed necessary by the practitioner. As a result there was little homogeneity between the groups, making it difficult to assess the internal validity of findings and conclusions. Nonetheless, the study did have relatively high ecological validity, as treatments resembled real-life practice, being carried out in a clinical environment. However, details of how many treatments were actually provided to participants would have been beneficial. Siddle et al.'s (2013) data demonstrated significantly improved changes in pain within each group at 18 months. Their SSD and therapeutic intervention group showed an improvement in pain of 16.9 mm on a VAS, when comparing pain at baseline and at 18 months (95% confidence interval (CI) 9.4 to 24.4, $p < 0.001$), and their control group without debridement showed a 17.5 mm reduction in pain (95% CI 9.4 to 25.5, $p < 0.001$). The differences reported between groups for pain were found to be non-significant, suggesting that SSD, when used alongside other therapies, provides no additional benefits over the other therapies alone. Since over

70% of recruits (n = 187) were excluded during the screening process for not meeting the criteria, the results from Siddle et al. (2013) may only be applicable for low-risk populations with RA. Despite its limitations, the study is useful for demonstrating the potential efficacy of other therapies, including orthotic therapy, over the usual debridement treatment in reducing pain.

In addition to self-reported pain, the effects of debridement on static balance and functional ability have been investigated (Balanowski & Flynn, 2005; Landorf et al., 2013). This is of importance; it is well documented that painful foot problems, including corns, in older people are highly associated with an increased risk of falling, reduced mobility, and decreased quality of life (Farndon et al., 2015). The tests used to measure balance and functional ability, such as the ascent and descent of eight stairs, are widely accepted methods and have been verified for their reliability and sensitivity (Brauer, 2013; Menz & Lord, 2001). Balanowski and Flynn (2005) conducted a case series, targeting the older population with plantar hyperkeratosis who were otherwise healthy. They found significant improvements in balance when comparing pre- and post-debridement scores for all three functional tests: the ascent and descent of eight stairs ($p < 0.001$), the alternate step-up test ($p = 0.001$), and the six metre walk ($p = 0.001$). This significance remained at the one-week follow-up, which is in line with previous assumptions that the more the hyperkeratosis has built up, the greater the likelihood of a reduction in proprioception and function (Menz & Lord, 2001). In contrast, the RCT by Landorf et al. (2013) found non-significant improvements in the functional ability tests immediately following debridement and at six weeks. Balanowski and Flynn (2005) did not include a control group for comparison. It is therefore possible that the changes in functional ability observed by Balanowski and Flynn

(2005) could be due to non-intervention effects, such as the influence of demand characteristics. In this way, participants may have predicted the researchers' hypothesis and altered their performance in the functional tests to conform to these expectations. Further research is required to address the uncertainty of the effects of debridement on balance and functional ability.

The effects of debridement on gait, which is affected due to the impact painful hyperkeratosis has on mobility, particularly in the older population, have been investigated (Araguas Garcia & Corbi Soler, 2018a; Gijon-Nogueron et al., 2015). Gijon-Nogueron et al. (2015) were the first to explore this lack of understanding via a single-arm proof-of-concept study on 34 participants with plantar hyperkeratosis. Various spatial and temporal aspects of gait were measured before and after debridement, including: cadence, step duration, stride length, and gait cycle length. Interestingly, there were no significant changes found to any of the gait parameters measured, consistent with the findings by Araguas Garcia and Corbi Soler (2018a), who also found no differences when compared to the sham debridement group. Both studies implemented the same standardised methods using the Win-Track system (MEDICAPTEURS Technology), which is valued for its ability to capture reliable and accurate data (Ramachandra, Maiya, & Kumar, 2012).

Although SSD does not appear to influence the kinematics of gait, studies have shown that the treatment has repercussions on the kinetic variables of gait, including peak maximum force and peak plantar pressure (PPP). Pressure is an area of particular interest for many researchers, since it is thought to play a key role in the development of hyperkeratosis and has been found to be a major factor in causing ulceration in high-risk patients with diabetes

mellitus (DM) (Araguas Garcia & Corbi Soler, 2018a; Young et al., 1992). The findings of the studies investigating the effects of debridement on PPP are contradictory, as discussed in Chapter 1. Those studies investigating the effects of pressure in patients with DM have found that PPP reduces by up to 30% following debridement (Pataky et al., 2002; Pitei et al., 1999; Young et al., 1992); however, the majority of studies that have investigated patients with RA or those with plantar hyperkeratosis who are otherwise healthy have found no significant differences in PPP following debridement (Davys et al., 2005; Landorf et al., 2013; Woodburn et al., 2000). A possible reason to explain the conflicting findings could be that the participants in the studies targeting those with DM could have had diabetic sensory neuropathy. Participants with sensory loss would continue to walk on the hyperkeratotic lesions, whereas those with normal sensation (without DM) would have avoided walking on sites prior to debridement by altering their gait to avoid pain. The most recent study by Araguas Garcia and Corbi Soler (2018a) targeted the older population with hyperkeratosis who were otherwise healthy, and found a significant reduction in peak pressure when comparing pressures before (357 kPa) and after (214 kPa) debridement, which is consistent with Pataky et al. (2002), Young et al. (1992), and Pitei et al. (1999), who investigated patients with DM ($p = 0.05$). Despite the conflicting evidence, it is still assumed that raised pressures contribute to the development of hyperkeratosis, since lesions return within four weeks following debridement. There is an underlying assumption that once the hyperkeratosis has formed this may in itself act as a 'foreign body', increasing pressures further at the site, hence the discrepancies found in the studies. These studies that investigated the effects of debridement on pressure concluded that debridement of hyperkeratosis should coincide with pressure-relieving strategies to help improve management success. This is achieved by reducing underlying pressures, and in turn

breaking the cycle of hyperkeratosis development to prevent recurrence, or at least slow its formation (Pitei et al., 1999; Potter & Potter, 2000).

After reviewing the literature evaluating the effectiveness of SSD, there is some evidence to support its use in routine clinical practice for managing plantar hyperkeratosis, including corns (Araguas Garcia & Corbi Soler, 2018b; Landorf et al., 2013). Debridement has been shown to provide immediate pain relief in patients with painful hyperkeratosis (Araguas Garcia & Corbi Soler, 2018b; Gijon-Nogueron et al., 2015; Redmond et al., 1999). When these beneficial effects are compared against a control sham debridement group the evidence is contradictory. Although the RCTs show reductions in pain immediately following real debridement, Davys et al. (2005) and Landorf et al. (2013) found the difference in pain improvement between the SSD and sham debridement group was non-significant ($p = 0.48$ and $p = 0.124$, respectively), in contrast to Araguas Garcia and Corbi Soler (2018a) who reported significant reductions in pain between the two groups, in favour of those receiving SSD ($p < 0.001$). Variations in findings could be explained by differences in the samples studied, and/or the method of debridement, which was either performed by one qualified podiatrist or by multiple student podiatrists, depending on the study. Other factors involved in this routine podiatric treatment that could play a fundamental role in the success of debridement include social interaction, the practitioner's inter-personal relationship with the patient, and the patient's perceptions of attending an appointment for professional treatment (Farndon et al., 2009; Matricciani & Jones, 2015). Currently there are no studies that qualitatively evaluate the efficacy of debridement by exploring patients' perspectives, which would be beneficial to help support its continued use in clinical practice.

Generally, pain relief associated with debridement has been shown to be short-lived, lasting no longer than six weeks, emphasising the necessity of investigating the long-term effects of SSD and its use alongside other interventions, such as orthotic therapy, to help prevent recurrence. Siddle et al. (2013) found no additive benefit of SSD at 18 months when compared to a combined therapy, which included custom-moulded orthotics, in patients with RA. They emphasised that research is required to assess the effectiveness of cheaper alternative insoles, rather than custom-moulded orthotics, for patients with RA. This is particularly essential where NHS funding is limited, since current evidence focuses on these bespoke devices, which are expensive and time consuming to produce (Vernon et al., 2007). The current project aims to investigate the effectiveness of a simple insole with a plantar metatarsal pad, which is an alternative and potentially more cost-effective device.

2.4 Other conservative treatments

The apparent short-lived therapeutic effects of debridement for the treatment of corns and callosities has led to the development and evaluation of other treatment modalities, such as keratolytics, marigold therapy, hydrocolloid dressings, and intralesional bleomycin injections. Keratolytics, namely salicylic acid, are the most commonly used alternative, available to the general public over the counter (OTC) for self-application, or by professional application from a podiatrist. Farndon et al. (2013) conducted a large RCT investigating the long- and short-term effectiveness of salicylic acid corn plasters in comparison to the usual treatment of SSD. At the three-month review, 34% (n = 32) of the 95 participants who had received corn plaster treatment were found to have a resolved corn, in contrast to 21% (n = 20) of the 94 participants in the debridement group (p = 0.044). At the 12-month evaluation,

the time taken for the corn to return to baseline size was significantly longer in the corn plaster group (mean difference = 0.40, 95% CI 0.24 to 0.65, $p < 0.001$). One independent podiatrist, who was 'blind' to the treatment group, assessed all the participants' corns at the three-month follow-ups, thus decreasing the chance of the results being influenced by researcher bias, thereby improving the consistency of assessment amongst participants.

Additionally, Farndon et al. (2013) measured self-reported pain using the 100 mm VAS, and found that pain was significantly less in the corn plaster group at three months when compared to the debridement group (mean difference = 1.0, 95% CI -1.5 to -0.6, $p < 0.001$). Interestingly, in the study by Gijón-Noguerón et al. (2017), where pain levels were only analysed in the short term, the debridement group were found to have significantly reduced pain levels at six weeks in comparison to the salicylic acid group ($p < 0.001$). The studies cannot be compared, as the salicylic acid treatment and regimen differed: Gijón-Noguerón et al. (2017) used Callivoro Marthand salicylic acid plasters, which also contain benzocaine and are not available in the UK. They concluded that the usual treatment of SSD achieves better outcomes in terms of pain and functionality than the Callivoro Marthand plasters in the short term.

The Carnation corn plasters, evaluated by Farndon et al. (2013), are widely available OTC in the UK. The product was evaluated with the treatment being applied by a podiatrist in a clinical environment, rather than by the patient in their own home. The treatment regimen by Farndon et al. (2013) involved the podiatrist assessing the corn site on a weekly basis for a maximum of four weeks, and applying the corn plaster if the corn remained present. This does not reflect the everyday practice of treatment in the general public, where Carnation

plasters would routinely be applied by the general public in their home, rather than by a healthcare professional, who is experienced at assessing and targeting the affected area to minimise skin irritations and tissue breakdown. The inexperienced patient may in reality continue to apply the product once the corn has resolved, and may incorrectly apply the plaster to healthy tissue, which could lead to complications, such as tissue breakdown.

Whilst the sample size in the Farndon et al. (2013) study was large (n = 202), it included only a small cross-section of the population that experience corns. Participants were excluded from the study if they had a significant systemic comorbidity, including DM, RA, peripheral arterial disease (PAD), peripheral neuropathy, and skin conditions such as eczema and psoriasis. Several studies have demonstrated the prevalence of hyperkeratosis in patients with RA and DM to be high, due to these patients being exposed to raised pressures at the forefoot as a result of complications associated with their condition(s) (Fernando et al., 2013). The findings and conclusions of the study (Farndon et al., 2013) may therefore not be representative of the general wider population with corns. Despite the limitations of their study, Farndon et al. (2013) demonstrate that salicylic acid plasters are a safe and effective alternative to the usual treatment of debridement when applied by a podiatrist on low-risk patients.

The biophysical effects of common OTC keratolytics on the skin have also been studied in comparison to debridement (Hashmi, Nester, Wright, & Lam, 2016). This included assessments of skin hydration, elasticity, and texture after treatment using one of the following: Balsan Callus Removal Lotion (KOH 40%), Wartner Corn and Callus Removal Pen (TCA, concentration unknown), or SSD. Hashmi et al. (2016) found improvements in all

outcome measures by week three; the debridement group, however, was found to have significant improvements in all measures immediately following treatment ($p < 0.01$). The items of equipment used to measure these outcomes, including the Corneometer CM 825, Cutometer 580 MPA, and Visioscan VC 98, have been previously tested and approved for their intra- and inter-tester reliability (Hashmi, Wright, Nester, & Lam, 2015). Measuring biophysical outcomes increases the clinical understanding of the action of keratolytics and debridement on the properties of the skin; however, these do not match the direct goals of treatment pertinent to patients.

Evidence to support the use of salicylic acid plasters in clinical practice when applied by a podiatrist on low-risk patients has been explored (Farndon et al., 2013), showing salicylic acid plasters can be considered as an alternative to SSD in low-risk patients, with 53% (n = 23) of the 43 participants still having a corn present at 12 months.

Further research is required to investigate additional alternatives to help improve treatment outcomes for patients with painful corns. Keratolytics, such as salicylic acid plasters, are not applicable for the majority of patients with corns, and therefore do not provide a suitable and effective alternative to the usual treatment of debridement for these patients. Previous studies have investigated other alternatives which are appropriate for high-risk populations with corns, including marigold therapy and hydrocolloid dressings.

Three studies were located in the literature that evaluated the use of marigold therapy for the management of plantar corns (Khan & Evans, 1996; Khan & Khan, 2000; Khan, Potter, & Birch, 1996). Participants in Khan et al.'s (1996) RCT (n = 30) received one of the following:

marigold therapy with a protective aperture pad, placebo marigold therapy with a pad, or active marigold therapy alone. The results demonstrated significant reductions in the size of hyperkeratotic lesions in the group given marigold therapy with protective padding, compared to the group given the marigold placebo ($p < 0.001$). A significant difference was also found between the group receiving marigold therapy with protective padding and those receiving marigold therapy alone ($p < 0.001$). Multiple comparisons were performed during the analysis due to the three-arm design. This raises the family-wise error rate, as it was unclear whether the study accounted for this, thus affecting the internal validity of the results. The effects of the treatment were only analysed after four weeks, as opposed to Khan and Khan's (2000) study, where they found the plantar corn resolved at two months and remained absent at a 12-month follow up. Whilst the literature provides some evidence to support the use of marigold in practice, further research is necessary to compare the effect of marigold treatment against the standard SSD. It is unclear what additional benefits marigold therapy can provide to patients, if any.

It has been proposed that hydrocolloid dressings may help to aid in the healing of corns by creating an occlusive moist environment, hydrating the hyperkeratotic tissue, and making it more pliable to withstand the mechanical stresses at the site (Petersen, Beck, Reumert, & Steensgaard, 1991; Springett et al., 1997). Table 2-3 summarises the key findings of two studies that have investigated the use of hydrocolloid occlusion in the management of painful corns.

Table 2-3: Resolution rates of the evidence available evaluating the use of hydrocolloid dressings in the treatment of plantar corns.

Study (year)	***Study design***	***Number of participants***	***Follow-up***	***Number of corns resolved***	***p-value***
Petersen et al. (1991)	RCT SSD + hydrocolloid vs SSD alone	**Intervention group** 15 **Control group** 13	6 months	**Intervention group** 4 (27%) **Control group** 5 (38%)	0.79
Springett et al. (1997)	Case series	14	5 weeks	3 (21%)	Not provided

Studies by Petersen et al. (1991) and Springett et al. (1997) utilised different hydrocolloid dressings with varying treatment regimens (Duoderm and HydroCure, respectively). Both studies found similar resolution rates. However, when compared against debridement and enucleation in the RCT by Petersen et al. (1991), no additive value from the hydrocolloid occlusion was noted at six months. In this RCT the debridement and enucleation treatment in both groups was given on a fortnightly basis for 12 weeks. This does not reflect standard clinical practice, where repeat debridement may occur at up to 12 weeks following initial treatment (Farndon et al., 2009). Although hydrocolloids have more benefits over keratolytic treatments, since they are easy to apply and are deemed suitable for high-risk

patients, further research is required to establish their efficacy in the long term as a viable alternative to SSD and enucleation.

Intralesional bleomycin injections are occasionally used to manage verrucae pedis; Lee, Landorf, Bonanno, and Menz (2014) proposed that injections could be used to help treat corns due to the proapoptotic effects the bleomycin has on keratinocytes. In this RCT, M. Lee et al. (2014) compared debridement and intralesional bleomycin injection against debridement alone in 50 participants from the military with painful plantar corns. The results demonstrate the superior benefits experienced by the group who received the bleomycin injection, including greater resolution rates of 37%, in comparison to 10% in the SSD group. It is worth noting that the military population are subject to high-intensity weight-bearing exercise regimens and wear the same standardised footwear, unlike the general population, which could influence corn occurrence. Nonetheless this treatment could provide an effective alternative to the standard treatment for plantar corns. However, further research is required to analyse the effects of bleomycin injections in the wider population, outside of the military, who are affected by plantar corns.

2.5 Surgical intervention

Surgery can include either removal of the lesion or correction of bony prominences and deformities that cause abnormal mechanical stresses at the site, including metatarsal shortening, metatarsal head excision, or floating osteotomy (Grouios, 2004; Singh et al., 1996). The studies found in the literature evaluate the removal of lesions through electrosurgery (Anderson & Burrow, 2002; Bevans & Bosson, 2010; Smith & Morrison, 1990;

Whinfield & Forster, 1997; Wilkinson & Kilmartin, 1998) and punch incision (Güngör, Bahçetepe, & Topal, 2014).

The resolution rates reported by the studies evaluating the efficacy of electrosurgery are shown in Table 2-4.

Table 2-4: Resolution rates found by the studies evaluating electrosurgery.

Study (year)	***Number of participants (drop-outs)***	***Follow-up***	***Number of corns resolved***
Smith and Morrison (1990)	66	Unknown	52 (79%)
Wilkinson and Kilmartin (1998)	61	Mean 55 months	24 (39%)
Anderson and Burrow (2002)	30 (1) 35 corns	5 months	15 (52%)
Bevans and Bosson (2010)	59 (5)	6 months	Electrosurgery: 9 (26%) SSD: 1 (4%)

Following electrosurgery, the resolution rates ranged between 26-79% (Bevans & Bosson, 2010; Smith & Morrison, 1990). The high disparity amongst the findings could be due to the differences in the type and location of corns evaluated: fibrous and neurovascular corns located on the plantar aspect are renowned for being typically more painful and resistant to treatment (Farndon et al., 2013). Smith and Morrison (1990), who reported the highest resolution rate, evaluated mainly lesions on the digits and do not specify the type of corns treated, in comparison to Bevans & Bosson (2010), who focus on more complex lesions. In addition, Smith and Morrison (1990) used a retrospective design, whereby the researchers reviewed the patients' records from six years previous to gather the data. Caution is required with the results, due to the risk of potential confounding variables affecting their internal validity. For example, the post-operative care received may have differed between participants, including the provision of insoles following surgery to assist in healing for one patient and not another. When conducting the follow-up assessment, the time period after which the lesion was regarded as resolved was different in every case. Short follow-up periods could have led to inaccurate resolution rates, as the normal process of hyperkeratosis is 28 days.

Pain levels, assessed using the 100 mm VAS, were found to have reduced significantly following electrosurgery, when compared to baseline ($p < 0.01$) (Bevans & Bosson, 2010; Whinfield & Forster, 1997). Whinfield and Forster (1997) found a significant reduction in pain of 58% at the 12-month follow-up ($p < 0.01$). The study, however, had a large drop-out rate of 32.5% ($n = 13$), which raises the question as to whether these participants experienced a decrease, increase, or had no change in their pain from the corn following treatment. This could potentially have great implications for the internal validity of the

findings. The researchers eliminated all the data from the 13 participants that were lost to follow-up, among whom eight were lost to follow-up due to the VAS being “spoilt” (Whinfield & Forster, 1997, p. 226). This casts further doubt over whether the participants fully understood how to complete the questionnaire, or whether the information was stored and managed appropriately. Although Whinfield and Forster (1997) found that electrosurgery significantly improved pain scores, it is unclear whether these reductions are greater than those found after SSD and enucleation treatment due to the lack of comparative control group.

Bevans and Bosson's (2010) study is the only RCT available to compare the treatment outcomes in those receiving electrosurgery with the standard SSD and enucleation treatment. Whilst a significant reduction in pain was reported in the intervention group from baseline (75 mm, SD 19 mm) to the six-month follow-up (37 mm, SD 31 mm), there was no significant difference found in the SSD group (60 mm to 46 mm, $p = 0.12$). These differences in pain between the groups from baseline to six months were not statistically analysed in comparison to one another, raising doubts as to whether the electrosurgery provided significantly better outcomes than those receiving the usual treatment of SSD and enucleation.

Preliminary investigations have been conducted assessing the use of the punch incision surgical technique in the removal of painful corns, and have demonstrated some positive findings (Güngör et al., 2014; Sacchidanand, Mallikarjuna, Purohit, & Sujaya, 2012).The case series by Güngör et al. (2014) evaluated 17 corns, finding that 13 had resolved at the six-month evaluation. Two independent dermatologists, who were not involved in the research,

compared the photographs pre- and post-debridement, commenting on the presence of the corn. This helped to control for researcher bias, which could have potentially impacted on the internal validity of the findings. Further research is required to investigate the effectiveness of this technique in comparison to other treatment modalities, and whether there are any complications associated with its use.

Whilst there is some evidence available to support the use of surgical interventions, such as electrosurgery, in managing painful corns, it is important to recognise the limitations of these studies, as discussed above. Although electrosurgery and punch incision techniques are considered to be relatively low-trauma procedures, they are not a viable option for a large proportion of the population with painful corns. Those with conditions that may lead to impaired wound healing, pacemakers, or metal implants are deemed unsuitable for these treatments (Bevans & Bosson, 2010). One of the main disadvantages of the treatments is the inconvenience imposed on patients' everyday lives following the procedure, as it is recommended to rest and attend for regular reviews whilst the wound heals. Patients with corns already experience a great level of disruption to their everyday lives due to the associated pain. Anderson and Burrow's (2002) study found that the daily activities of 63% of the 30 participants were affected due to the pain experienced from the corns, which were located on the plantar metatarsal area and/or the dorsum of the digits. This should be acknowledged, since plantar lesions are considered more challenging to manage, due to the greater complexity of the procedure and the possibility of increased healing times due to weight-bearing forces (Smith & Morrison, 1990). The greater the complexity of the electrosurgery, the greater the potential impact on practitioner confidence in referring patients for the procedure, performing the procedure itself, and educating patients about

the treatment. Consequently, with low practitioner experience being a factor, this could have major implications for the availability and success rate of the treatment within Trusts across the United Kingdom.

It is widely accepted that the effectiveness of electrosurgery and punch incision techniques rely primarily on their ability to remove a greater amount of parakeratotic tissue without pain, in comparison to the standard treatment of SSD and enucleation (Bevans & Bosson, 2010). The treatment does not address the external excessive stresses and forces that occur at the site of the corn, factors which are assumed to be the primary cause of the lesion (Potter & Potter, 2000). This could help explain why, in their long-term follow-up study, Wilkinson and Kilmartin (1998) found lower resolution rates than the other research studies, that is, the affected area was exposed to excessive pressure for longer, leading to the process of hyperkeratinisation for protection (Spink, Menz, & Lord, 2009). Undoubtedly, this has led to these studies concluding that offloading through the use of orthoses following the removal of the lesion is of importance (Bevans & Bosson, 2010; Whinfield & Forster, 1997).

2.6 Pressure-relieving strategies to prevent recurrence

In conjunction with the standard treatment of SSD and enucleation to remove the corn, it is common for podiatrists to provide patients with some form of pressure relief to assist in preventing the recurrence of the lesion. In the short term, a hypoallergenic metatarsal felt pad with an aperture at the site of the corn is often applied directly to the patient. The pad lasts no longer than one week (Yates & Merriman, 2009). Despite this treatment being an

established method described for corn management in most podiatry textbooks, the literature search identified no research evidence that has evaluated the effectiveness of this adhesive felt padding for managing plantar corns (Dawber et al., 2001; Frowen & Brewster, 2010; Menz, 2008). Felt padding has, however, been shown to be beneficial in the healing of diabetic foot ulcerations beneath the metatarsal heads by offloading pressure at the site of the wound. Nubé et al. (2006) demonstrated a 73% reduction in wound size in 15 participants after four weeks of applying adhesive felt padding.

Since the assumed effects of the adhesive felt padding for corns last no longer than one week unless the padding is reapplied, other therapies are adopted, including: foam cushioned insoles, insoles with a metatarsal forefoot pad, custom-made foot orthoses, and footwear modifications. Four studies have evaluated the use of foam cushioned insoles and custom-made foot orthoses in managing painful calluses (Caselli et al., 1997; Colagiuri et al., 1995; Duffin et al., 2003; Timson & Spooner, 2005). Colagiuri et al. (1995) evaluated the effects of a rigid customised orthotic made from Rohadur on diabetic participants with calluses over a period of 12 months. A total of 20 participants were randomly allocated to receive either usual debridement treatment (n = 11) or the rigid orthotic (n = 9). Improvement of the callused area was assessed by evaluating photographs at baseline and at the 12-month review, using a classification system to grade the severity of the callosity from one to three. A significant improvement in the callus grade from baseline to 12 months was found in the orthotic group ($p = 0.02$), in comparison to the debridement group. A subjective ordinal scale was used to classify the callus from the photographs taken. Classifying a callus using two-dimensional photographs also poses challenges, as the depth and density of the callus cannot be established without the use of other measures

(Tollafield, 2017). Other quantitative methods would have been beneficial to assist in evaluating the efficacy of the rigid custom-moulded insoles, such as a VAS to assess pain, and lesion measurements to help quantify changes in calluses more thoroughly.

It is unclear whether the rigid customised orthotic evaluated by Colagiuri et al. (1995) reduced pressure at the site of the callus, which would help explain the improvements seen in the calluses. Duffin et al. (2003) investigated the effects of flat cushioned insoles and semi-rigid customised orthotics in reducing high PPPs on 34 diabetic adolescents with and without calluses. Significant reductions in PPPs were found when participants' values without an insole were compared to those wearing: a cushioned insole ($p = 0.001$), customised semi-rigid orthoses ($p = 0.05$), and a combination of the two aforementioned devices together ($p < 0.001$). Further to these primary investigations, Duffin et al. (2003) reviewed the presence of callosities at 12 months through simple observation. A total of six of the 23 diabetic adolescents who continued to wear the semi-rigid orthotics had plantar calluses at baseline; two of these six were found to have resolved at the 12-month follow-up. In the 67 participants who did not wear an orthotic, seven had calluses at baseline, which were still present at 12 months. The study did not evaluate the calluses quantitatively: no measurements are provided to highlight the severity of the calluses in relation to pain or size. It is unclear whether the calluses that remained showed any signs of improvement and/or deterioration due to the lack of assessments carried out. It is also unclear whether the two callosities that resolved were of any significance to the adolescents. The study also failed to record whether the participants applied any other treatments to the plantar calluses during the 12-month period, which raises the question of whether the resolution was solely due to the orthotic therapy.

There is a lack of clarity as to why only 23 of the 34 subjects continued to wear the semi-rigid orthotic for the 12-month follow-up period in the study by Duffin et al. (2003). Colagiuri et al. (1995) and Duffin et al. (2003) provide no details of the compliance rate of the participants receiving the orthotic therapy during the studies. This is important, as the more the participants wore the insoles, the greater the potential effect on the calluses. A variable compliance rate could influence the internal validity of the results. In addition, the researchers do not report on the durability of the orthotics, or whether any had to be replaced during the 12-month study period. This has direct implications for clinical practice, as the associated cost of each orthotic was relatively expensive, with Colagiuri et al. (1995) reporting that the rigid insoles cost £75 per pair. Any additional replacement(s) further impacts upon the benefits and cost-effective compared to the standard treatment. Whilst the studies by Colagiuri et al. (1995) and Duffin et al. (2003) have their limitations, their findings help to provide some insight into the possible efficacy of customised orthotic therapy in managing plantar calluses in patients with diabetes.

In comparison to Colagiuri et al. (1995) and Duffin et al. (2003), Caselli et al. (1997) excluded participants with diabetes, recruiting those with painful plantar hyperkeratosis who were otherwise healthy (n = 60). Participants were randomly allocated to receive one of: SSD followed by no insole, SSD with a Viscoped (prefabricated) insole, or SSD with a Poron insole. The study had a high drop-out rate of 42% (n = 25). At the four-week evaluation 16 remained in the Viscoped group, 12 in the Poron group, and 7 in the SSD only group. There was no explanation as to why 42% of participants were lost at follow-up, which raises concerns, as it could suggest issues with compliance with wearing the insoles due to their

comfort and/or inconvenience. It is unknown whether these participants experienced any improvements with the treatments.

Caselli et al. (1997) measured the differences in foot function index (FFI) scores at baseline and at four weeks. All three groups showed an improvement in foot function: the Viscoped group improved by 60%, the greatest observed in the three groups; the Poron group improved by 43%; and the SSD only group by 10%. The study did not statistically compare these differences in improvement found between groups, making it difficult to determine whether including an insole, either Viscoped or Poron, into the management of hyperkeratosis was worthwhile in comparison to SSD alone. Budiman-Mak, Conrad, and Roach (1991) evaluated the use of the FFI questionnaire used by Caselli et al. (1997). A strong positive correlation was found between the total FFI score and actual clinical measures of foot pathology, measured by foot joint count, walking time, and grip strength, indicating the index has criterion validity. Further quantitative measures of hyperkeratosis are required to gain a greater understanding of the effectiveness of the combined insole therapy and SSD, in comparison to SSD alone, such as reporting the resolution rate by taking accurate measurements of the corn size and associated pain. Timson and Spooner (2005) analysed the efficacy of flat ethylene vinyl acetate (EVA) insoles, with an aperture at the site of the plantar callus, in relieving pain. Participants were randomly allocated to receive either SSD (n = 13) or insole therapy (n = 12). Pain was measured using the 100 mm VAS both pre- and post-treatment, and after six weeks. Whilst pain scores were found to be reduced immediately after treatment and at the six-week evaluation in both groups, these reductions were significantly greater in the insole group ($p < 0.001$). Apertures in all the insoles measured 18 mm in diameter. Although this standardised the insole used in the

study, in practice the sizes of calluses vary between individuals, which could influence the effects on pain reported should the aperture be greater or smaller than the lesion, thereby impacting on the findings of the study (Farndon et al., 2013; Freeman, 2002). The number of participants included in the evaluation was relatively small, which makes inferences in accepting or rejecting the null hypothesis difficult to establish. Furthermore, the analysis may not be representative of the target population. Purposive sampling was used to recruit participants who had painful calluses that had not previously been treated, which could explain the relatively low mean age of those included (48 years, SD = 14.8), as those who had received prior treatment of their calluses were more likely to be older. The exclusion of this demographic limits the applicability of the findings.

Despite the flaws and limitations of the studies by Timson and Spooner (2005) and Caselli et al. (1997), the findings highlight that insole therapy could possibly improve pain and foot function in participants with painful hyperkeratotic lesions, beyond the effects of SSD and enucleation. Due to the short-lived effects of debridement found in various studies, it would be beneficial to investigate the long-term use of insoles in conjunction with debridement on plantar hyperkeratosis beyond four to six weeks (Davys et al., 2005; Landorf et al., 2013).

The Viscoped insole used in the study by Caselli et al. (1997) that demonstrated the greatest improvements in foot function included a metatarsal dome within the device, and can be purchased OTC at approximately £55. Several studies have demonstrated that forefoot pads, including a metatarsal bar and dome, are clinically effective at reducing pressure at the metatarsals in healthy individuals without hyperkeratosis (Deshaies et al., 2011; Jackson et al., 2004; P. Lee et al., 2014). Caselli et al. (1997) are the only researchers to have

investigated the use of a forefoot padded insole in the management of hyperkeratosis. Whilst Timson and Spooner (2005) have investigated the use of apertures in flat insoles, surprisingly insoles with a metatarsal pad and aperture at the site of the corn have not previously been evaluated, yet they are frequently used in practice and described in the majority of podiatric textbooks for managing painful hyperkeratosis (Frowen & Brewster, 2010; Menz, 2008). The lack of knowledge and the widespread anecdotal clinical practice, undertaken without validated research evidence to support the intervention, clearly illustrates the need for further investigation to evaluate the effectiveness of incorporating a metatarsal padded insole alongside SSD. This will enhance podiatric knowledge and lead to improved care for patients with plantar corns.

2.7 Summary

This literature review has explored the current evidence base for managing painful hyperkeratosis, including corns. The papers identified date from the 1990s to 2018, demonstrating that the topic area – the management of plantar hyperkeratosis, including corns – is still of great importance and interest as it remains a salient problem for practitioners to date. The review emphasises that although there are a range of methods available to manage hyperkeratosis, the optimal treatment is yet to be identified. SSD continues to be the standard treatment, despite limited evidence to support its use (Davys et al., 2005; Landorf et al., 2013). The next chapter reviews the randomised controlled trials that have been conducted to estimate the effectiveness of sharp scalpel debridement for managing painful hyperkeratosis, which provides further justification for the project.

Chapter 3 – Sharp scalpel debridement for painful hyperkeratosis: a meta-analysis

Further to the comprehensive review of the literature a meta-analysis was conducted to assess the overall effect of treatments for painful hyperkeratosis, where appropriate. This meta-analysis presents the efficacy of sharp scalpel debridement (SSD) when compared to any comparator. The literature review highlighted that minimal research evidence has been conducted investigating the effects of other treatments, such as salicylic acid, electrosurgery, and insole therapy. A meta-analysis determining whether an effect exists on each of these alternative treatments was not possible. SSD is the standard routine treatment for painful hyperkeratosis, but there is limited high-quality evidence to support its frequent use. The aim of the meta-analysis was to estimate the efficacy of this routine treatment by combining data derived from the literature review in the previous chapter.

3.1 Methods

3.1.1 Study eligibility

Studies were assessed against the following predetermined selection criteria:

- *Study Design:* only randomised controlled trials (RCTs) were considered for inclusion.
- *Study population*: adults, aged 18 years and older with painful hyperkeratosis who were otherwise healthy.
- *Intervention*: the meta-analysis focused on SSD, which is the usual treatment for hyperkeratosis.
- *Comparator*: studies that directly compared SSD against any other alternative treatment or with sham debridement were considered for inclusion.

- *Outcome measures*: primary outcomes of the meta-analysis were pain (using the 100 mm visual analogue scale (VAS)), complete resolution of the lesion, and peak plantar pressure. The literature review identified these outcomes as commonly used measures of treatment effects for painful hyperkeratosis within the literature.

3.1.2 Search method and strategy

The systematic search strategy was outlined in Chapter 2, which highlights the databases examined and search terms using the PICO model (Problem, Intervention, Comparison, and Outcome).

3.1.3 Quality assessment

To assess the risk of bias the Cochrane Collaboration tool was used to assess the quality of trials included in the meta-analysis (Julian et al., 2011). Studies were stratified as low, unclear, or high risk dependent upon the following criteria: selection bias (sequence generation and allocation concealment), performance bias (blinding of participants and researchers), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), and reporting bias (selective outcome reporting).

3.1.4 Data analysis

A meta-analysis was performed to pool outcome data using Stata statistical software (Version 14 I/C) for statistical analysis of selected studies. Analyses were stratified by treatment modality (SSD versus any comparator). For the purpose of the analysis SSD is referred to as the control and any other comparative treatment is referred to as the treatment. Heterogeneity of the studies was assessed using the Cochrane's Q statistic (I^2).

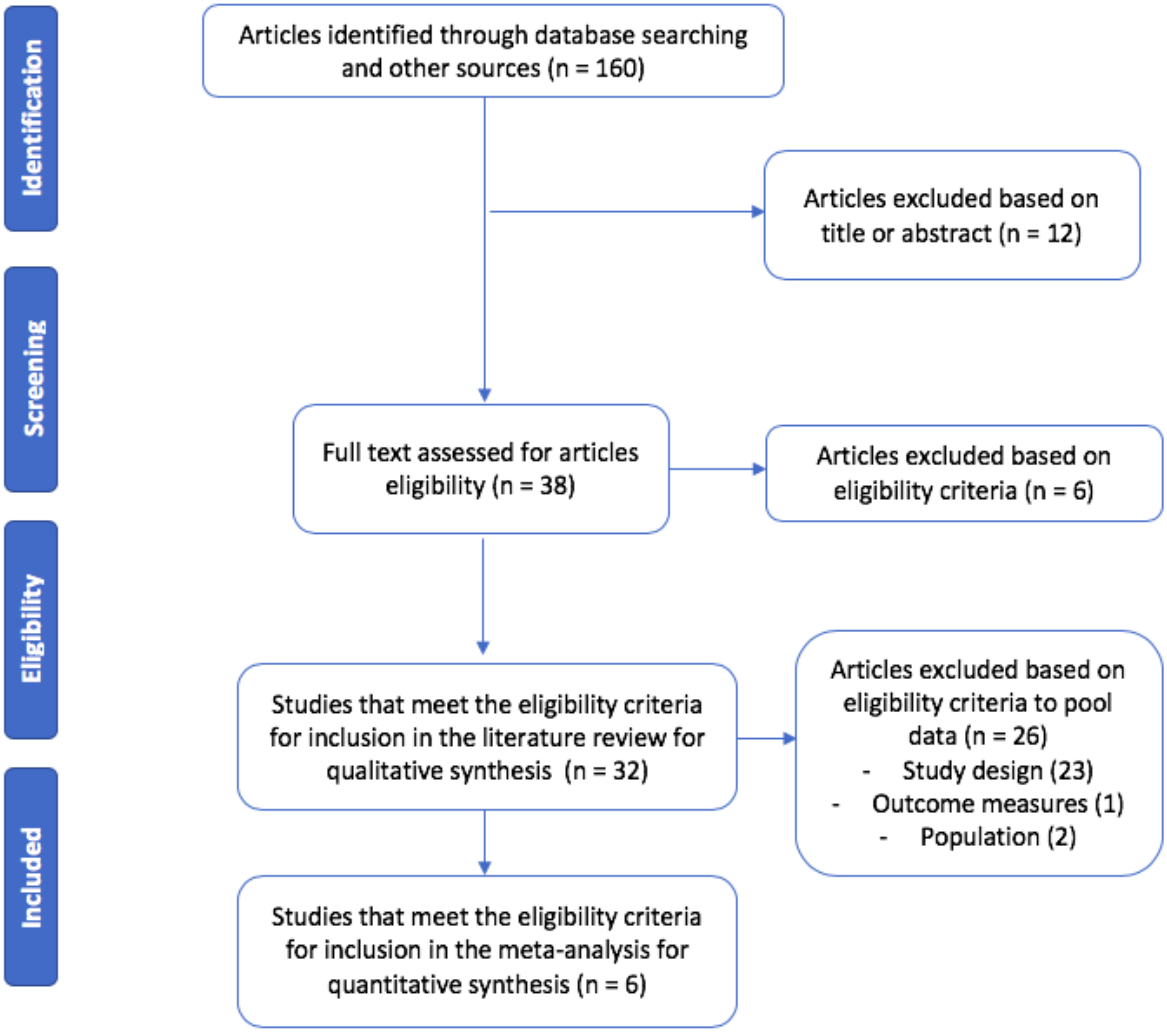
An I^2 value greater than 75% indicated substantial heterogeneity. A random-effects model was used to estimate the amount of variance in effect across studies. For dichotomous outcome data (presence of a resolved lesion), risk ratios were used to report the pooled effect with a confidence interval of 95%. A p value of less than 0.05 was considered statistically significant. Forest plots were used to present overall effect of the data.

3.2 Results

3.2.1 Study selection

The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow chart presented in Figure 2-2 within Chapter 2 was revised for the meta-analysis. Figure 3-1 highlights the selection process for articles included in the meta-analysis.

Figure 3-1 Flow diagram of the meta-analysis selection process, adapted from the PRISMA flowchart (Moher, 2009)



Of the 32 studies evaluated in the literature review, Chapter 2, a total of 26 were excluded from the subsequent meta-analysis. The studies were predominantly excluded from the meta-analysis due to their methodological design (n = 26), as only RCTs were included within the analysis. Two studies (Davys et al., 2005; Siddle et al., 2013) were excluded as their sample population included participants with rheumatoid arthritis (RA), in comparison to the other studies sample who were otherwise healthy. Treatment effects on participants

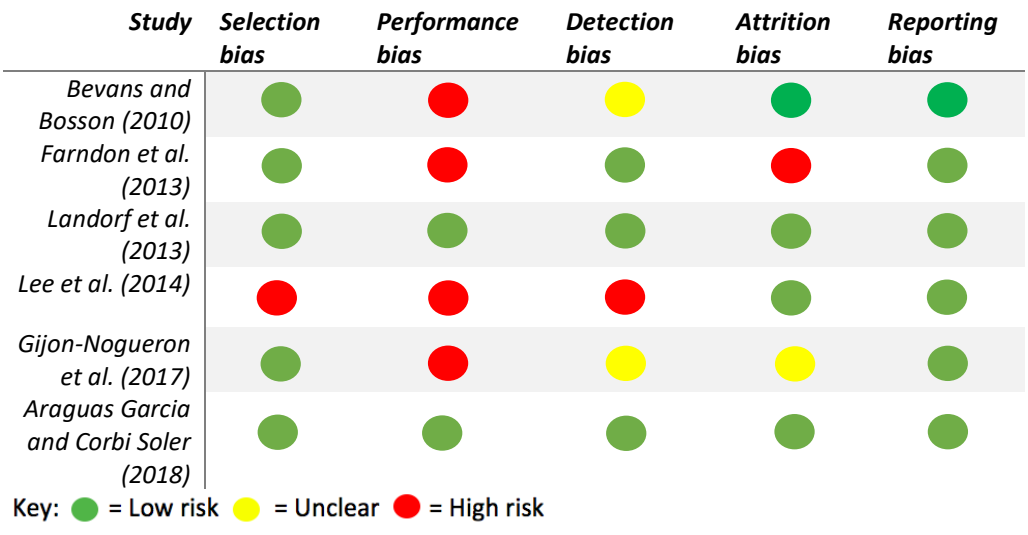
with RA could differ, due to the complications associated with the condition that could exacerbate pain and gait alterations, which could influence the process of hyperkeratinisation (Siddle et al., 2013). Conducting a separate meta-analysis for these two studies was not appropriate as follow up periods differed from four weeks (Davys et al., 2005) and 18 months (Siddle et al., 2013). Petersen et al., (1991) did not meet the inclusion criteria, as the instrument tool to measure the patients' pain was not comparable to the 100 mm VAS, which is more widely adopted within the research evidence due to its validity and reliability (Hasenstein et al., 2017).

From the six studies selected for inclusion, five meta-analyses were conducted. The treatment outcomes analysed were pain (immediately and six weeks after treatment), complete resolution of the corn (three and six months after treatment), and peak plantar pressure (immediately after treatment).

3.2.2 Risk of bias of included studies

Risk of bias was assessed in the six studies included, illustrated in Table 3-1.

Table 3-1 Risk bias assessment of the studies included in the analysis

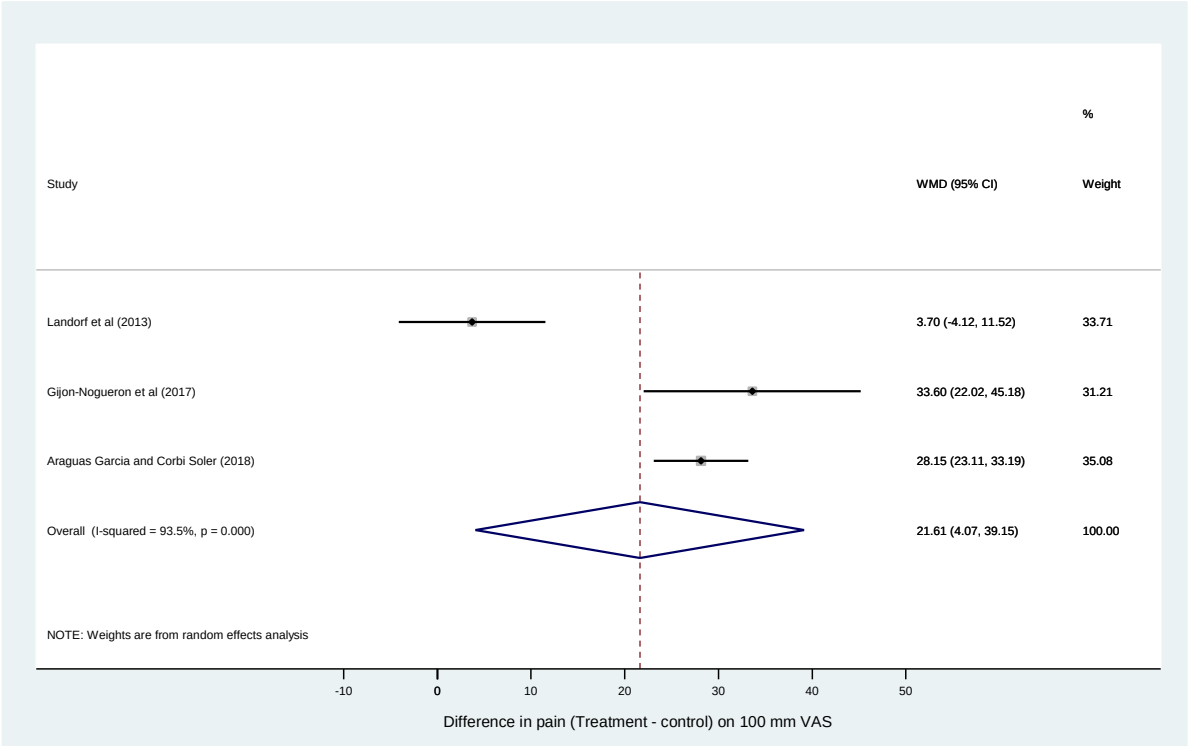


The generation of allocation sequence and concealment was adequate in the majority of the studies included in the analysis (n = 5, 83%). The potential risk of performance bias was considered to be high amongst 67% (n = 4) of the studies, due to the difficulties in blinding the participant and clinician to the intervention. Two of the studies (33%) were able to blind participants when SSD treatment was compared against a sham debridement as a screen was placed between the participant and clinician performing the treatment (Landorf et al., 2013; Araguas Garcia et al., 2018). Three of the trials included (50%) blinded the outcome assessors to the treatment allocation. The potential risk of bias likely to be introduced by missing outcome data and selective reporting was assessed as low (n = 4, 67% and n = 6, 100%, respectively).

3.2.3 Pain immediately after treatment

Three studies (Landorf et al., 2013; Gijon-Nogueron et al., 2017; Araguas Garcia and Corbi Soler, 2018) considered the effect of an intervention to assess pain immediately after treatment in randomized controlled trials, measuring pain based on a 100 mm VAS reported by study participants. A random effects meta-analysis conducted on study data revealed that the synthesized estimate for the unstandardised difference in means between treatment and control groups (treatment – control) was 21.6 points (95% confidence interval 4.1 to 39.1). A Z-test for overall effect revealed evidence that this difference was statistically significant at the 5% significance level (Z=2.41, p=0.016). Cochran's Q test revealed evidence for statistical heterogeneity ($\chi 2$ (2)=30.58; p<0.001). The I^2 statistic was 93.5%, indicating high statistical heterogeneity. The τ^2 statistic (between-study variance) was 221.7. Results are summarized in a forest plot (Figure 3-2).

Figure 3-2 Forest plot for meta analysis of pain immediately after treatment

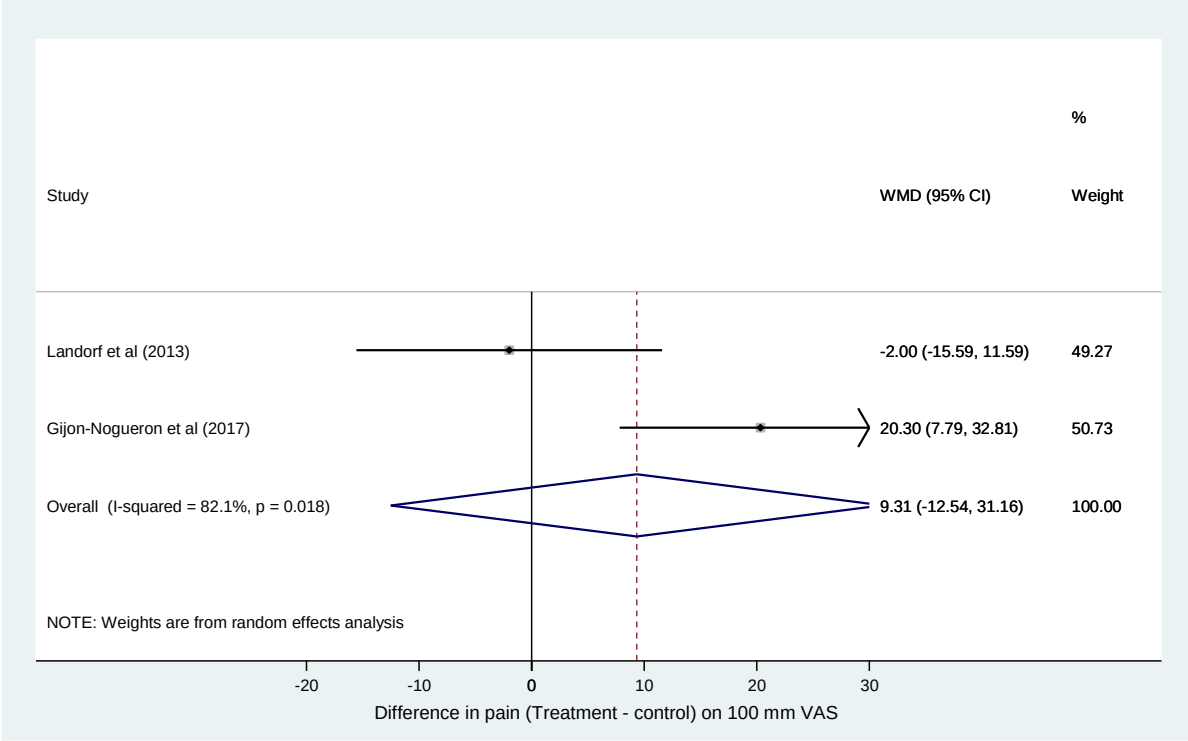


3.2.4 Pain six weeks post treatment

Two studies (Landorf et al., 2013; Gijon et al. 2017) considered the effect of an intervention to assess pain six weeks post treatment in randomised controlled trials, measuring pain based on a 100 m VAS reported by study participants. A random effects meta-analysis conducted on study data revealed that the synthesized estimate for the unstandardised difference in means between treatment and control groups (treatment – control) was 9.3 points (95% confidence interval -12.5 to 31.2). A Z-test for overall effect revealed no evidence that this difference was statistically significant at the 5% significance level (Z = 0.84, p = 0.404). Cochran's Q test revealed evidence for statistical heterogeneity ($\chi 2$ (1)=5.60; p = 0.018). The I^2 statistic was 82.1%, indicating high statistical heterogeneity. The

τ^2 statistic (between-study variance) was 204.2. Results are summarized in a forest plot (Figure 3-3).

Figure 3-3 Forest plot for meta analysis of pain six weeks after treatment

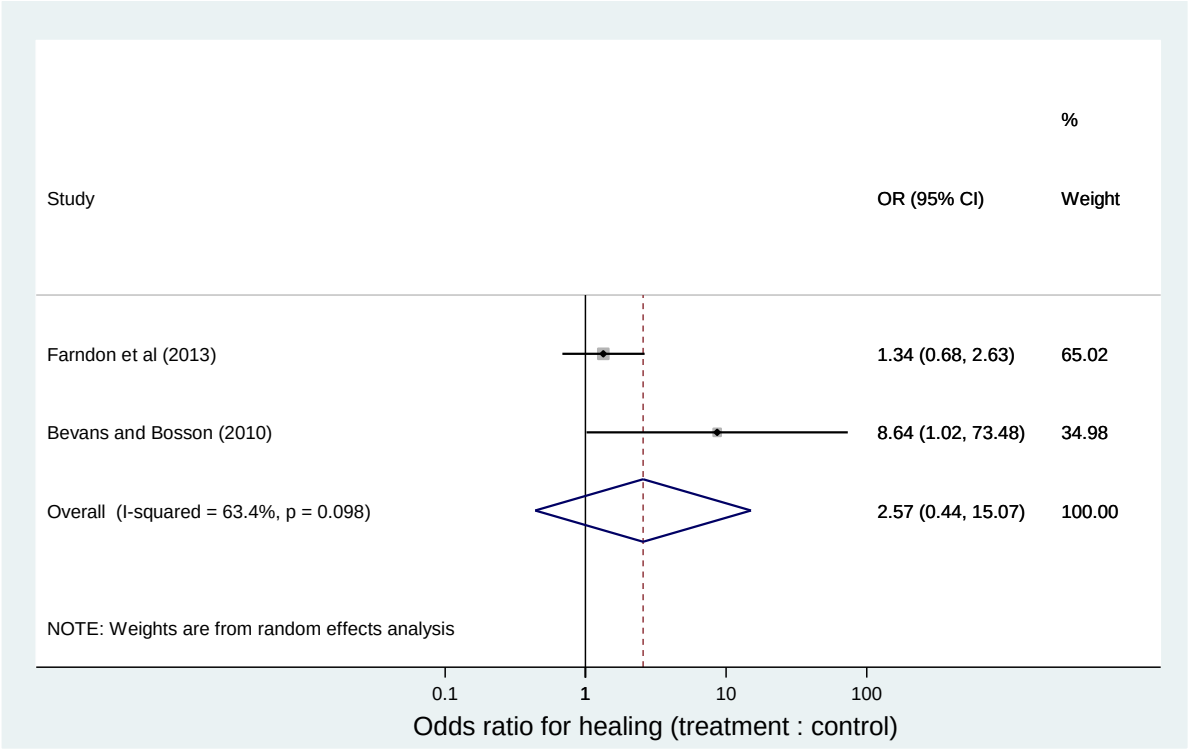


3.2.5 Complete resolution at three months

Two studies (Bevans & Bosson, 2010; Farndon et al., 2013) considered the effect of an intervention to assess proportion of corn resolution by three months in randomised controlled trials. A random effects meta-analysis conducted on study data revealed that the synthesised estimate for the odds ratio between the treatment and control groups (treatment : control) was 2.57 (95% confidence interval 0.44 to 15.07). A Z-test for overall effect revealed no evidence that this difference was statistically significant at the 5% significance level (Z=1.05, p=0.295). Cochran's Q test revealed evidence for statistical

heterogeneity (χ2 (1)=2.73; p=0.098). The I^2 statistic was 63.4%, indicating moderate statistical heterogeneity. The τ^2 statistic (between-study variance) was 1.1. Results are summarized in a forest plot (Figure 3-4).

Figure 3-4 Forest plot for a meta analysis for complete resolution at three months

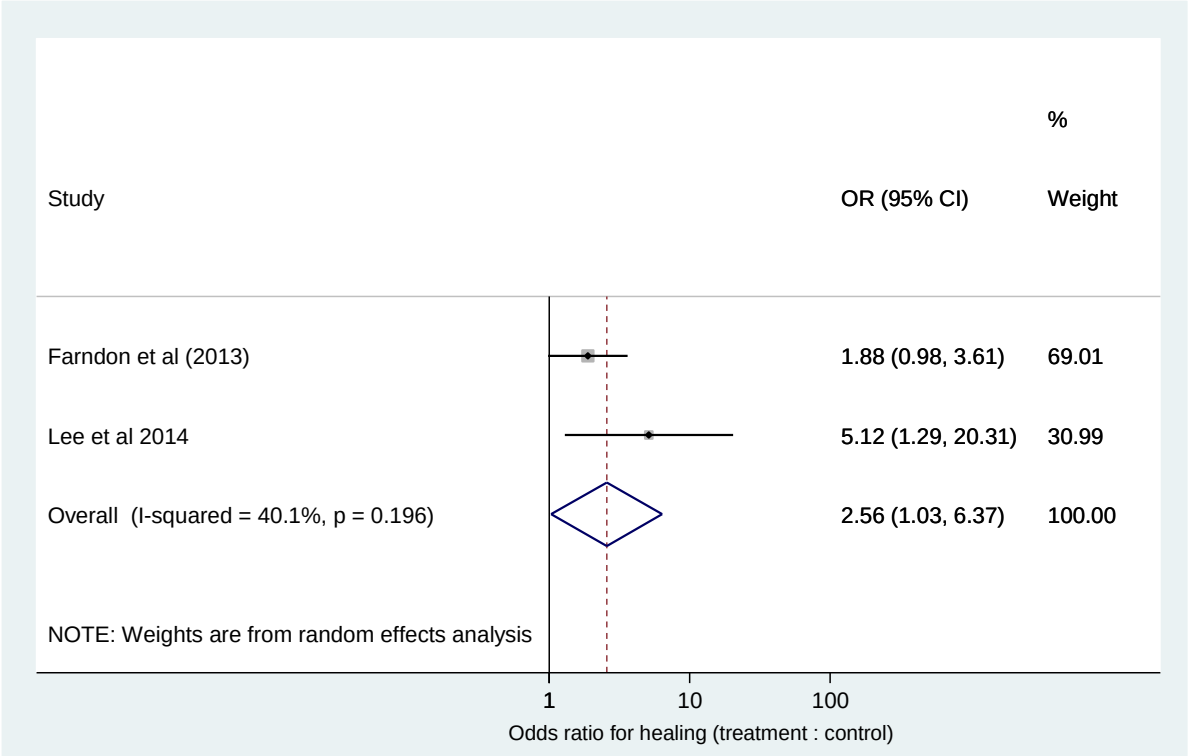


3.2.6 Complete resolution at six months post treatment

Two studies (Farndon et al., 2013; Lee et al., 2014) considered the effect of an intervention to assess proportion of corn resolution by six months in randomised controlled trials. A random effects meta-analysis conducted on study data revealed that the synthesised estimate for the odds ratio between the treatment and control groups (treatment : control) was 2.56 (95% confidence interval 1.03 to 6.37). A Z-test for overall effect revealed evidence that this difference was statistically significant at the 5% significance level (Z=2.03, p=0.043). Cochran's Q test revealed evidence for statistical heterogeneity (χ2 (1)=1.67; p=0.196). The

I^2 statistic was 40.1%, indicating moderate statistical heterogeneity. The τ^2 statistic (between-study variance) was 0.2. Results are summarized in a forest plot (Figure 3-5).

Figure 3-5 Forest plot for meta analysis of complete resolution at six months after treatment

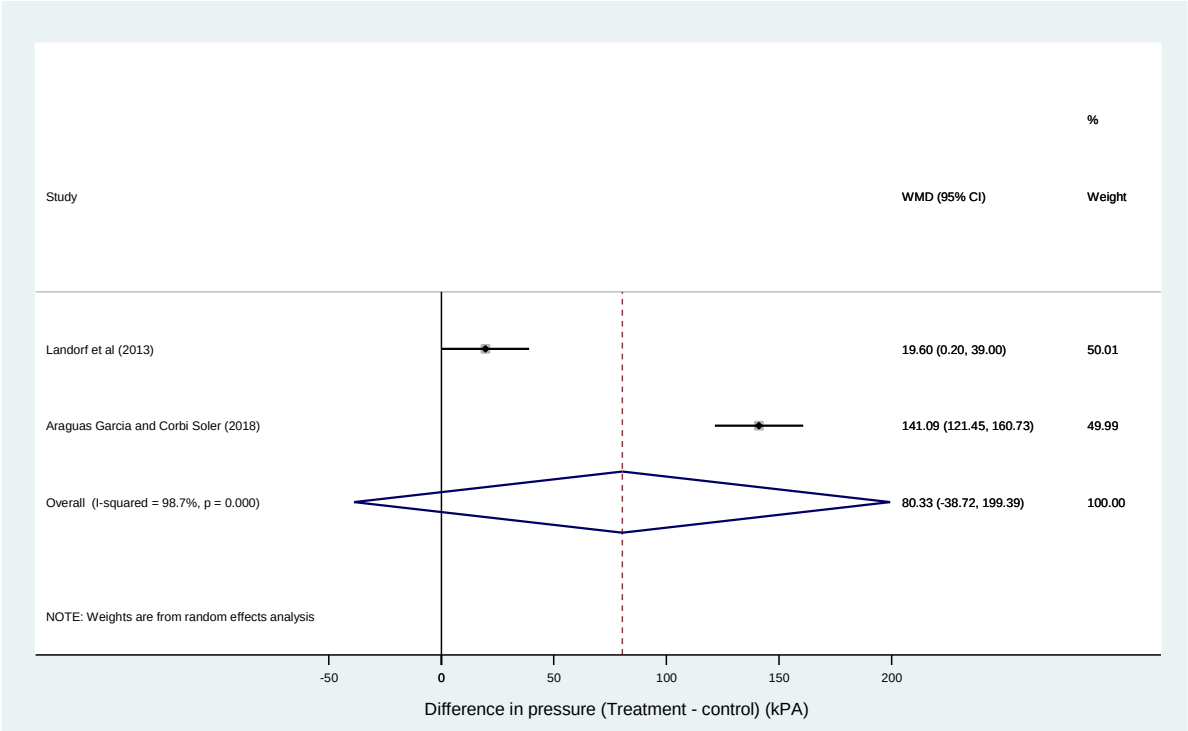


3.2.7 Peak plantar pressure (kPa) immediately following treatment

Two studies (Landorf et al., 2013; Araguas Garcia and Corbi Soler, 2018) considered the effect of an intervention to assess peak plantar pressure (kPa) immediately after treatment in randomised controlled trials. A random effects meta-analysis conducted on study data revealed that the synthesized estimate for the unstandardised difference in means between treatment and control groups (treatment – control) was 80.3 points (95% confidence interval -38.7 to 199.4). A Z-test for overall effect revealed no evidence that this difference was statistically significant at the 5% significance level (Z = 1.32, p = 0.186). Cochran's Q test revealed evidence for statistical heterogeneity ($\chi 2$ (1)=74.39; p<0.001). The I^2 statistic was

98.7%, indicating high statistical heterogeneity. The τ^2 statistic (between-study variance) was 7.3e+03. Results are summarized in a forest plot (Figure 3-6).

Figure 3-6 Forest plot for meta analysis of peak plantar pressure immediately following treatment



3.3 Discussion

This is the first meta-analysis that has evaluated the efficacy of the usual treatment of SSD for the management of painful hyperkeratosis. The meta-analysis revealed that SSD has a beneficial effect in reducing self-reported pain immediately following treatment when compared to any comparator, however, by six weeks these effects are diminished. Peak plantar pressures are reduced immediately following SSD when compared to sham debridement treatment. Three and six months following treatment, complete resolution of

the corn was two times more likely to occur in those that received any comparator when compared to SSD. Debridement and enucleation is a quick and simple treatment to perform, which could – alongside patient reported feedback – provide an explanation for its continued use in routine practice. In addition, the treatment does not rely on patient compliance like other treatment alternatives, such as orthotics, dressings, and therapeutic regimens, which could influence their success. Whilst other treatment comparators, such as salicylic acid plasters and electrosurgery, appear to provide greater benefits over the standard SSD treatment, these other treatments are limited for use in patients who are considered 'low risk', which excludes a large proportion of the population with painful hyperkeratosis (Farndon et al., 2013; Bevans & Bosson, 2010).

A drawback of the meta-analysis is that the limited number of studies included impacted on the ability to analyse the influence of other clinical factors, such as: type of corn and severity of pain and size at baseline. It has attempted to pool the data of similar studies by having strict pre-determined criteria, such as study population and follow-up periods, to help reduce heterogeneity.

3.4 Summary of literature review and meta-analysis

The literature review and subsequent meta-analysis has highlighted the need for further research into the field to help identify the optimum treatment for patients with painful plantar corns. The evidence indicates that the removal of painful hyperkeratosis should coincide with other strategies to offload and reduce plantar pressures under the metatarsal area. The purpose of this is to help prevent the recurrence of the plantar corn through the

use of insoles and/or footwear modifications. This could prolong the time before the recurrence of pain, the re-formation of the corn, and the need for a repeat treatment. It is important that these outcomes are achieved, since the majority of NHS podiatry services in the UK offer a standard three-month minimum wait for an appointment (Farndon et al., 2009). The short-term clinical effects of SSD alone are insufficient in meeting patients' requirements (Landorf et al., 2013; Woodburn et al., 2000). The delay in treatment could consequently lead to further complications, such as severe pain and risk of ulceration, especially in high-risk patients.

Only three small-scale studies have investigated the efficacy of various flat cushioned insoles and custom-moulded orthotics in the management of plantar hyperkeratosis (Caselli et al., 1997; Colagiuri et al., 1995; Duffin et al., 2003). Due to lack of quantitative measures of hyperkeratosis, there are flaws in the methodology, with no statistical comparison of the differences in improvements seen between groups. This raises the question of whether those wearing the insoles in conjunction with debridement experienced significantly greater benefits than those receiving debridement only, which would help to justify the additional cost incurred for the provision of the insole therapy. In spite of the limitations, the studies have helped to provide an insight into the potential effectiveness of insole therapy in the management of plantar hyperkeratosis.

A plantar metatarsal adhesive felt pad, with a cut-out aperture at the site of the corn, is frequently applied to the skin following SSD and enucleation of the painful corn. Since this is only a short-term device lasting no longer than one week, metatarsal pads with cut-out apertures are incorporated into an insole in an attempt to offload the pressure in the long

term. There is currently no evidence available to justify the use of metatarsal padded insoles in clinical practice. This is problematic for core podiatric medicine, since decisions on funding are increasingly being driven by evidence-based research (Hashmi et al., 2016). If metatarsal padded insoles were found to provide improved benefits for patients, including corn prevention or delayed recurrence, it would both reduce the need for repeated debridement treatments, and be more financially appealing for commissioners. The project will aim to conduct a preliminary investigation into the use of plantar metatarsal padded insoles with an aperture, which are designed for managing painful plantar corns to help improve patient outcomes.

3.5 Research aims and objectives

The purpose of this project was to conduct a preliminary investigation into the use of metatarsal padded insoles in the management of painful plantar corns. This was to be achieved through a pilot study to determine the practicality of evaluating the metatarsal padded insoles in a larger-scale study.

It was clear from the review of the literature that, prior to conducting a pilot study to evaluate the insoles, the following objectives needed to be accomplished to help determine the insole for investigation:

1) To identify what plantar metatarsal pads are currently being prescribed in practice for managing plantar corns.
2) To establish the compressional stiffness of various orthotic materials available for use in managing plantar corns.

3) To determine patients' perspectives of the materials available for use in managing plantar corns.
4) To investigate whether the chosen plantar metatarsal pad reduces the plantar pressure from the forefoot.

Chapter 4 - Insole selection

The literature review and meta-analysis chapters highlighted that further research into effectiveness of insoles is important, to establish if there is any additive value in the management of hyperkeratosis. The formulation of an evidence base is essential to help practitioners justify using insole therapy routinely in practice, when managing corns, rather than relying primarily on anecdotal evidence, particularly since the management of this common and often debilitating skin pathology constitutes the foundations of a podiatrist's workload (Farndon et al., 2009).

Researchers have implied, based on their experience that corns unresponsive to treatment with insoles are unresponsive due to inadequate prescription, fabrication, and fitting within the footwear (Bevans & Bosson, 2010). It is important, when evaluating the use of insoles in this project, to recognise these possible suggestions for treatment failure, to attempt to improve potential outcomes.

Prior to carrying out the pilot study, it was necessary to gain a greater understanding of insoles that are currently used to offload pressure from the forefoot, to assist in establishing the appropriate insole for investigation. This chapter begins with a review of the literature into pressure-relieving insoles, including their design, manufacture, and materials used to construct the device. Significant gaps in the literature were identified, a factor which influenced the selection of the insole for testing. Four small-scale investigations were conducted as a result, the findings of which are presented and discussed in this chapter. The chapter concludes with a justification of the insole selected for analysis in the pilot study.

4.1 Review of the literature

4.1.1 Insoles used to manage excessive forefoot pressures

Podiatrists frequently prescribe insoles to relieve pressure from the forefoot, beneath the metatarsal heads, as this is the most common area of foot pathology (Forghany, Bonanno, Menz, & Landorf, 2018). These pathologies are metatarsalgia (a generalised term for pain in the metatarsal region), foot ulcerations, and pathological hyperkeratosis. Research into orthotic insoles typically focuses on the management and prevention of diabetic foot ulceration, and reducing patients' pain by relieving pressure in those with degenerative changes (Arias-Martín, Reina-Bueno, & Munuera-Martínez, 2018; Paton, Bruce, Jones, & Stenhouse, 2011). A vast range of insoles have been evaluated in the literature, which have demonstrated a benefit in reducing pressure by up to 28% in participants with diabetes mellitus (DM) and rheumatoid arthritis (RA) (Paton et al., 2011). There is no optimum insole type and specification identified for patients with DM, or patients with forefoot arthropathy (Arias-Martín et al., 2018).

There are currently no studies investigating the use of insoles in the management of corns, instead research focuses on calluses alone (Caselli et al., 1997; Colagiuri et al., 1995; Duffin et al., 2003; Timson & Spooner, 2005). These four papers were identified and critically evaluated in Chapter 2. Whilst the research has helped gain a greater insight into the insoles' potential value, the findings are restricted in their scope and cannot be applied to clinical practice due to the limited outcome measures used. None of the studies quantitatively measured the size of the calluses, commented on their characteristics, or measured patient comfort and compliance with the insoles. Only one of the studies analysed the insoles' effect on patients' reported pain associated with the calluses, and

their effects on pressure. This project will attempt to address the flaws of these studies by including more pertinent outcome measures, which focus on patient-related outcomes.

There are three main types of orthotic insoles: simple (flat insoles with or without padding to address painful sites), prefabricated (off-the-shelf insoles that can be modified by the clinician), and customised (custom-moulded bespoke insoles based on a 3D computerised image or foot impression) (Chapman et al., 2018). The papers that investigate insole use for callus management evaluate different devices, including: rigid, prefabricated Viscoped insoles (Caselli et al., 1997); rigid, custom-moulded Rohadur insoles (Colagiuri et al., 1995); simple cushioned insoles (Duffin et al., 2003); and ethylene vinyl acetate (EVA) insoles (Timson & Spooner, 2005).

A recent survey by Chapman et al. (2018) evaluated habits around the prescription of foot orthoses, and found that podiatrists in the UK were more likely to prescribe prefabricated or simple insoles when employed by the NHS, in comparison to those in private practice, who prescribed more customised insoles. In 2017, an exploratory trial found that custom-moulded devices incur a significantly greater cost (3.5 times more) than prefabricated insoles (Rome et al., 2017). This vast difference in cost could help explain the reported disparity of insole habits between the NHS and private sector, particularly with the ongoing funding issues within the NHS (Chapman et al., 2018). In addition, evidence is available to suggest that there is no significant difference between the effectiveness of customised and prefabricated insoles (McCormick, Bonanno, & Landorf, 2013; Redmond et al., 2009; Salles & Gyi, 2013). Redmond et al. (2009) measured the effects of prefabricated and custom-moulded insoles for reducing pressure in participants with pes planus. Both insoles

significantly reduced peak pressure at the forefoot, compared to the footwear only condition ($p < 0.05$). Non-significant differences in peak plantar pressure (PPP) were found when the prefabricated and custom-moulded devices were compared ($p = 0.105$). This provides a rationale for the habits of the participants in the study by Chapman et al. (2018), as comparable clinical outcomes could potentially be achieved, with considerable cost savings.

It was decided that this project would not evaluate custom-moulded insoles, similar to those evaluated by Colagiuri et al. (1995), in the management of calluses, due to their high cost (approximately £75 per pair). It would have been financially challenging for both the project and the NHS to implement these devices into routine practice, should any additive benefit(s) have been found. The pressures NHS podiatrists face with limited budgets make it necessary to primarily evaluate devices that are simple and more economically viable (Siddle et al., 2013). Custom-moulded insoles also take more time to manufacture, requiring further resources.

Simple insoles have a greater cost saving than both prefabricated and custom-moulded insoles, and are quick to dispense. The survey by Chapman et al. (2018) highlighted that simple insoles were the most frequently prescribed treatment for patients with forefoot pain, which includes hyperkeratotic lesions. Duffin et al. (2003) and Timson and Spooner (2005) have demonstrated some positive preliminary findings for the use of simple insoles in callus management. Simple insoles were selected for investigation in this project. Metatarsal pads are affordable and can be manufactured quickly in clinical practice. Most podiatry educational textbooks describe the use of metatarsal pads with an aperture to

manage corns, yet there is no research evidence to support this practice (Dawber et al., 2001; Frowen & Brewster, 2010).

4.1.2 Effectiveness of metatarsal pads in reducing pressure and pain

The choices of forefoot pads available to clinicians are extensive, with variations in the type of pad, positioning, material used, and whether the device is prefabricated or custom-made. Within the literature there is a general consensus concerning terminology for the types of forefoot pads; however, it is apparent that occasionally these are used interchangeably, causing confusion for practitioners. Figure 4-1 illustrates the shapes of different types of forefoot pads.

Figure 4-1: Different types of forefoot pads available in practice.

A) Metatarsal pad

B) Metatarsal pad with cut-out aperture

C) Metatarsal bar

D) Metatarsal cushion

E) Metatarsal dome

Whilst there is no research available which evaluates the efficacy of any of these forefoot pads in the management of corns, there is a wealth of evidence that has demonstrated their ability to reduce pressure at the forefoot, shown in Table 4-1.

Table 4-1: Changes in forefoot peak pressures after implementing a forefoot padded insole in comparison to no insole.

Study	Type of forefoot pad	Mean PPP (kPa)	p – value
Poon and Love (1997)	Dome	-46.0 (-16%)	0.05
Hodge, Bach, and Carter (1999)	Dome	-40.5 (-16%)	0.05
	Boomerang pad	-50.3 (-20%)	0.05
Jackson et al. (2004)	Dome	-32.5 (-12%)	0.02
	Metatarsal cover/pad	-58.4 (-21%)	0.02
Kang, Chen, Chen, and Hsi (2006)	Dome	-27 (-12%)	0.028
Lott et al. (2006)	Dome	-33 (-19%)	0.001
P. Lee et al. (2014)	Dome (10 mm proximal to metatarsals)	-34.3 (-9%)	0.004
	Dome (5 mm distal to metatarsals)	-67.1 (-17%)	0.001
	Metatarsal bar	-40.8 (-10%)	0.001
	Metatarsal cover/pad	-77 (-19%)	0.001
Hähni et al. (2016)	Dome	+2.0 (+0.6%)	0.858
	Metatarsal cover/pad	-32.0 (-10%)	0.003

The studies, highlighted in Table 3-1, evaluate different populations, including: participants with metatarsalgia (Kang et al., 2006; Poon & Love, 1997), DM (Lott et al., 2006), RA (Hodge et al., 1999; Jackson et al., 2004), runners (Hähni et al., 2016), and those aged 65 years and above who are otherwise healthy (P. Lee et al., 2014). Significant reductions in pressure were found for all types of forefoot pads in the populations when compared to no insole, except the dome pad in the study by Hani et al. (2016). The metatarsal pad has been shown to offer reductions of up to 21%, a significantly greater reduction compared to other forefoot pads (Jackson et al., 2004).

There appears to be substantial variation in the peak pressures found amongst the studies evaluating metatarsal domes, ranging between a decrease of 19% and an increase of 1% (Hähni et al., 2016; Lott et al., 2006). This has led to researchers further investigating the longitudinal positioning and height of metatarsal domes on insoles, and the subsequent effect on pressure (Brodtkorb et al., 2007; Hsi, Kang, & Lee, 2005; Koenraadt, Stolwijk, Wildenberg, Duysens, & Keijsers, 2012; P. Lee et al., 2014). The research evidence is contradictory. Hsi et al. (2005) measured peak pressures with the dome positioned in various locations from the metatarsal heads. Optimum pressure reduction was found when the dome was placed 4.4 mm proximal to the metatarsal head (678 kPa without dome pad; 427 kPa with, $p = 0.05$). Similarly, Hastings et al. (2007) observed the greatest reduction in PPP when the metatarsal dome was positioned 10.6 mm proximal to the metatarsal head. Variable reduced pressures were noted when the dome was located between 1.8 mm distal and 6.1 mm proximal to the metatarsal heads. Importantly, pressure was found to increase when the dome was placed more than 16.8 mm proximal and more than 1.8 mm distal to the metatarsal heads. In contrast, Brodtkorb et al. (2007) observed non-significant

decreases in force when the dome was positioned at 5-mm increments between 0-25 mm proximal to the metatarsal heads.

Whilst both Hsi et al (2005) and Hastings et al. (2007) found a significant reduction in peak pressure when the dome was located proximal to the metatarsal heads, their findings contradict the research by P. Lee et al. (2014), who found that metatarsal domes positioned 5 mm distal to the metatarsal heads demonstrated a greater reduction in peak pressure of 17%, in comparison to 9% when the dome was positioned 10 mm proximal. The contrasting findings could be due to the different equipment used to measure pressure in the studies, which could impact on the accuracy of the data. Importantly, Hastings et al. emphasised the difficulties in consistently placing the dome in the intended location. In addition, the studies used different materials to construct the domes, which included: foam rubber (Hsi et al., 2005), cork (Hastings et al., 2007), EVA (Brodtkorb et al., 2007), and PPT (P. Lee et al., 2014). The properties of these materials vary, typically their compressive ability, which impacts on their pressure-relieving action (Campbell, Newell, & McLure, 1982). The variation in findings among the studies raises awareness of the difficulties clinicians face when finding the optimum location of the metatarsal dome for pressure relief.

Brodtkorb et al. (2007) is the only study available to investigate the effects of metatarsal dome height on forefoot loading. Two different thicknesses (5 mm and 10 mm) were compared to participants' mean forces when wearing no metatarsal dome. Both the 5-mm and 10-mm dome insoles significantly decreased the mean plantar force, when compared to the control ($p < 0.05$). The 10-mm dome was significantly more effective at reducing force when compared to the 5-mm dome ($p < 0.05$). Whilst these are important findings for

clinical practice it is important to recognise the implications the height of the dome can have on patient comfort. In the study by Caselli et al. (1997), although there were significant improvements in foot function seen when wearing the Viscoped insoles, participants found the height and also positioning of the dome uncomfortable. Patient comfort is essential for adherence, which subsequently affects the success of the insole treatment.

Few studies have analysed the effects of forefoot pads on the reported pain across the metatarsals. This is an essential area for clinical practice, due to the high prevalence of forefoot pain amongst the general population (Menz, 2008). Poon and Love (1997) and Kang et al. (2006) are the only studies to have evaluated the effects on participants' reported pain levels using the 100 mm VAS, focusing in particular on metatarsal domes. Both studies found considerable reductions in pain, with a 20% reduction at two weeks (Kang et al., 2006) and a 71% reduction at 15 weeks (Poon & Love, 1997). In addition to the participants being evaluated at different points, Poon and Love reported greater pain at baseline, with a mean of 7.0 cm in comparison to Kang et al.'s 4.9 cm. There is greater scope for pain relief with a higher baseline pain score, and this therefore could help explain the disparity between the pain reductions seen. Furthermore, the dome insoles could have been different: Poon and Love do not outline the specifics of the insole, such as where the dome was positioned, its construction, and materials used.

Although fewer studies have investigated metatarsal pads, plantar pressures have been shown to reduce by up to 21% with their use (Jackson et al., 2004). Similarly, P. Lee et al. (2014) observed significantly greater reductions in peak pressure with the metatarsal pad, in comparison to the metatarsal bar ($p = 0.027$) and metatarsal dome (positioned 10 mm

proximal to the metatarsal heads) ($p = 0.007$). Whilst the metatarsal pad showed slightly improved peak pressures (-19%) in comparison to the metatarsal dome (located 5 mm distal to the metatarsal heads) (-17%), this difference was non-significant ($p = 1.000$). It could be argued that metatarsal pads are easier to construct than domes, as there is no dispute within the literature regarding the pads' location and subsequent effects on pressure relief (Jackson et al., 2004; P. Lee et al., 2014).

There is a lack of guidance within the evidence as to the preferred device for reducing pressure and pain, and managing specific foot pathologies, such as painful corns. Clinical decisions on the insole choice are challenging for practitioners, and often result in trialling insoles, which is a burden on limited resources and can prolong patients' pain. The type of forefoot pad currently being prescribed to patients with corns is unknown. It can be assumed that this would be a metatarsal pad with an aperture, since this is the type outlined in podiatry educational books as a short-term measure (Dawber et al., 2001; Frowen & Brewster, 2010). This project aimed to evaluate the use of metatarsal pads for managing corns. Whilst both metatarsal pads and domes have been shown to be effective in offloading pressure from the metatarsal heads, there is great variability in the findings of the studies evaluating metatarsal domes (Hähni et al., 2016; Hastings et al., 2007; P. Lee et al., 2014). The lack of consensus regarding the optimal longitudinal positioning of the dome for achieving the best pressure relief would pose a challenge for clinicians in practice (Lee et al., 2014). Research by Curran, Ratcliffe, and Campbell (2015) has emphasised the potential benefits of a metatarsal pad with an aperture at the second metatarsal, to assist in further reducing pressure over the prominent metatarsal head. An investigation into the use of

metatarsal pads, with an aperture at the site of the corn to assist in its healing, has not previously been conducted, which helps to justify the necessity of conducting this project.

4.1.3 Cavities in insoles to accommodate a painful site or lesion

The use of cavities in insoles has also been explored, predominantly to help prevent tissue breakdown, or to assist in the healing of ulceration in patients with diabetic peripheral neuropathy (Actis et al., 2008; Lin et al., 2013; Nubé et al., 2006). Similarly, Actis et al. (2008) and Lin et al. (2013) evaluated the use of insoles with removable plugs at sites of high pressure in participants with diabetic neuropathy. Both studies demonstrated greater improvements in pressure when wearing insoles with cavities, in comparison to wearing those without. Lin et al. (2013) found peak pressures to be significantly reduced by 33%, after the cavities were implemented ($p < 0.001$).

In addition to reducing pressure, research has shown cavities in metatarsal padding are effective at healing diabetic foot ulceration (Nubé et al., 2006; Zimny, Schatz, & Pfohl, 2003). Nubé et al. (2006) evaluated the use of semi-compressed felt forefoot pads, which included an aperture (cavity) at the site of the ulcer, to assist in the healing of diabetic foot ulceration. The 32 participants included in the study were randomised to receive the forefoot pad either directly onto the skin, or within the footwear. At the four week evaluation, both applications of the metatarsal aperture pad were successful, showing a 73% and 74% reduction in wound size in the skin application group and footwear group, respectively ($p = 0.9$). This indicates that the method of application of the pad, either directly onto the skin or within the footwear, had no effect on the clinical outcome. Timson and Spooner (2005) evaluated the use of a simple EVA insole with an aperture at the site of

the painful callus. After six weeks, the 12 participants reported significantly less pain with the callus ($p = 0.002$). These papers demonstrate that, when localised high peak pressures exist, such as in the case of a painful lesion or bony prominence, cavities within the treatment device may be a viable option to offer further pressure relief.

4.1.4 Insole material

It is essential the material of the insole, alongside its thickness, is carefully considered to achieve optimum pressure relief for the patient (Chatzistergos, Naemi, Healy, Gerth, & Chockalingam, 2017). Foam rubber materials have been evaluated within the literature to assess their ability to reduce pressure. These include: open cell foams, known as polyurethanes (Poron, Professional Protective Technology (PPT) and Cleron) and polyethylene foams (Plastazote, Nickelplast); and closed cell materials, such as, neoprene foams (Spenco) and Ethylene Vinyl Acetate (EVA) of different densities (Nicolopoulos, Black, & Anderson, 2000).

The stiffness of a material is considered to be a pertinent feature in its ability to reduce pressure, although the optimum degree of softness has not yet been identified. Few studies have investigated the compressive ability of insole materials (Campbell et al., 1982; Lo, Yick, Ng, & Yip, 2014; Paton, Jones, Stenhouse, & Bruce, 2007). Campbell et al. (1982) assessed the compression characteristics of 31 foam rubber materials, using the Instron Universal Testing Machine. Disc-shaped samples, measuring 2.9 cm in diameter, were compressed at a constant rate of 10 mm/min to a maximum load of 23 kg. This generated load and deformation data, which were used to obtain the stress-strain relationship of each material. The materials appeared to fall within three distinct categories, from very stiff to highly

deformable. Campbell et al. (1982) concluded that those in the moderately deformable category, including Poron, Bonfoam, and Pelite, were considered preferable in reducing pressure. These materials were shown in the stress-strain curves to progressively deform throughout the loading process. It is thought that the moderate compressibility of the material will accommodate the bony prominences of the metatarsals during gait, and allow the transfer of load to other areas (Healy, Dunning, & Chockalingam, 2010).

Whilst other research uses similar categorisations of materials according to their properties, the specific materials that fall within these categories will differ. For instance, some researchers have reported that foam rubbers are highly deformable, while others have categorised them as moderately deformable (Paton et al., 2007). This creates confusion for clinicians, increasing the uncertainty in making decisions about insole choice in practice. The tested materials' thickness, density, and hardness (Shore values) are often not reported within the research, which could help explain the contradictory findings. Curran et al. (2015) argue that the greater the material thickness, the more pressure is relieved. It is assumed that pressure relief reaches a maximum when materials are approximately 10 mm thick (Birke, Foto, & Pfiefer, 1999). The differences in methods used to measure compressive stress could also impact upon findings.

Paton et al. (2007) focused on assessing the most common materials used in the prevention of neuropathic diabetic foot ulceration, examining various qualities including stiffness. In contrast to Campbell et al. (1982) and Sanders, Greve, Mitchell, and Zachariah (1998), stiffness was measured by dropping an 800-g mass from a height onto the test material and the F-scan pressure analysis system. Stiffness was determined by measuring the time taken

for the weight to be unloaded from the material. Paton et al. (2007) found great variation in offloading time on repeat testing of each sample, demonstrating that this is an unreliable and inaccurate method for analysing stiffness of a material. Minimal differences in the time to offload were observed between the materials (0.008 seconds), providing further difficulties for any meaningful analysis. A more recent study returned to the previously described method for analysing compressional stiffness, using Instron bench equipment to analyse materials frequently used in insoles for patients with diabetes (Lo et al., 2014). The study measured the force required to compress the material to 40% of its initial thickness. Plastazote was found to require the least compressive stress of 98 kPa, demonstrating that it has a high ability to conform to the shape of the foot, but possesses poor pressure-relieving properties. The Nora Lunalastike (Shore 25) exhibited a moderate compressive resistance of 233 kPa, and was therefore assumed to be able to conform adequately to the foot to relieve plantar pressure. Although bench and simulated in-shoe testing help improve the knowledge of the properties of materials, it is not clear whether the effect will be replicated when placed in the shoe (Healy et al., 2010).

An abundance of research has been conducted to evaluate the effectiveness of different insole materials in reducing pressure during walking (Healy et al., 2010; Leber & Evanski, 1986; Rogers, Otter, & Birch, 2006; Tong & Ng, 2009). The literature demonstrates that PPT and Spenco (Leber & Evanski, 1986); Poron (Birke et al., 1999); Neoprene (Hinz et al., 2007); Poron combined with high density Plastazote (Tong & Ng, 2009); and polyurethane (PU, Shore A) (Healy et al., 2010) are significantly more effective at reducing pressure from the foot, in comparison to other foam rubber materials and control groups with no material. Three studies have investigated whether the pressure-relieving benefit of the materials

lasted after continuous wear (Barrow, Hughes, Clark, & Klenerman, 1992; Rogers et al., 2006). Barrow et al. (1992) measured the plantar pressures in seven participants before and after wearing both PPT and Spenco insoles for one month each. The significant differences reported in the reduction of pressure when wearing PPT and Spenco insoles, in comparison to the no-material control group ($p < 0.0001$), remained the same after one month's wear. Similarly, Rogers et al. (2006) observed significant reductions in pressure when wearing Poron and Poron with Plastazote insoles, in comparison to no insole ($p < 0.05$), and noted no change in these reductions of peak pressure following 50,000 steps with the insoles.

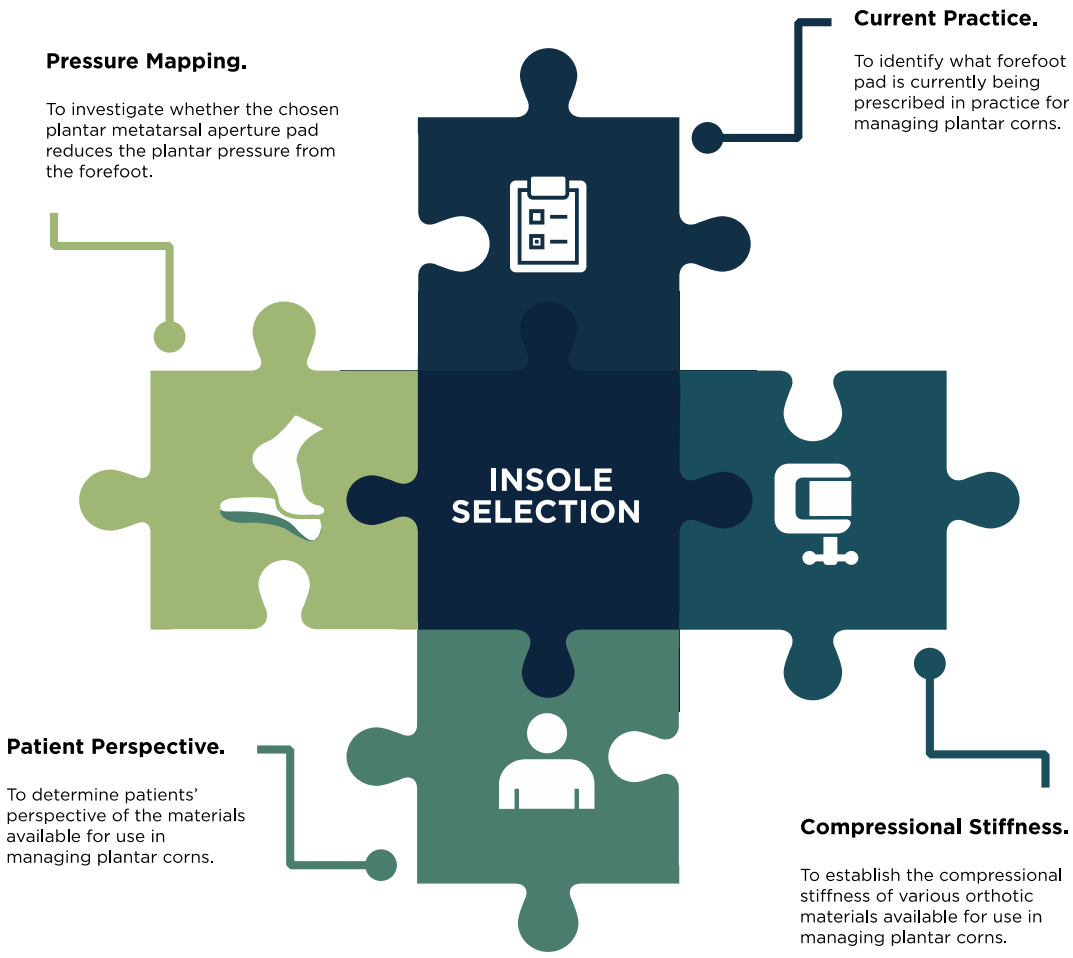
Whilst there is a wealth of research evaluating the properties of various materials, a standardised classification system identifying their qualities to help inform practitioners is still lacking (Healy et al., 2010; Paton et al., 2007). This is not currently possible due to the vast variations amongst the studies' methodologies, including the outcome measures used, equipment, and materials tested (types, densities, and thicknesses). The review of the literature highlights the importance of cushioning materials for pressure relief, typically polyurethane materials. Newer polyurethane materials are on the market, such as PodoPro Urethane, which are of a different density to those previously evaluated. Since it is not clear what materials are currently being prescribed to manage painful plantar corns, further compressional stiffness and pressure analysis may be necessary to ensure appropriate selection of the insole for investigation.

4.1.5 Gaps in the research into insoles for corn management

The literature review has accentuated the vast variations of forefoot pads and materials available to practitioners. Before conducting the pilot study, it was necessary to carry out

further investigations to ensure the most appropriate insole was selected for testing, to optimise treatment effectiveness (Lo et al., 2014). Four key elements were conducted to help address gaps in the knowledge within the evidence, to help formulate a logical rationale for the design and material to be used for the simple insole. Ethical approval to carry out these four elements was applied for and granted by the University of Huddersfield's School Research Ethics Panel (SREP) (Appendix 9.1). These elements are highlighted in Figure 4-2, below, and will be discussed in this chapter.

Figure 4-2: Elements investigated to assist in the selection of the appropriate insole for testing.



4.2 Current practice

4.2.1 Aim

The following element was conducted to gain a greater insight into which forefoot pads are currently being prescribed in podiatric practice for managing plantar corns.

4.2.2 Method

A quantitative approach using a survey design was implemented instead, of gathering qualitative data through interviews. Information could then be gained from a larger proportion of the target population in a shorter time-scale, requiring fewer resources (Bowling, 2014). A total of 62 practitioners participated in the survey. The survey was conducted at the College of Podiatry Annual Conference in Harrogate, 2015, which was considered the ideal event for targeting the population of practising podiatrists. It attracts over 1,300 qualified podiatrists and students, enabling access to those working in and outside the UK from both the private sector and NHS. Permission to distribute the survey at the conference was sought for and granted by the College Conference Chair Committee and Director of Education and Development (Appendix 9.2).

For practicality, convenience sampling was used to enable the quick collection of data (Hicks, 2009). Only qualified podiatrists who were currently in practice were invited to participate, thereby allowing the generation of data from practitioners who had current experience treating patients. Students were excluded as they were deemed likely to follow the practice of their instructors, which could have potentially influenced the results if more students from a particular institution participated than from another (Bellamy, 2007). Those

who met this criterion and were willing to participate were asked to complete a short paper questionnaire, taking no longer than five minutes (Appendix 9.3).

The questionnaire was paper based and administered face-to-face in the Specialised Advisory Group area in the exhibition hall at the conference. Although online surveys have their advantages, including a reduction in missing data for given questions and fewer data entry errors, further resources would have been required to enable participants to complete the survey at the conference (McDonald & Adam, 2003). Yetter and Capaccioli (2010) argue that questionnaires completed on paper, particularly face-to-face, achieve greater response rates than those online.

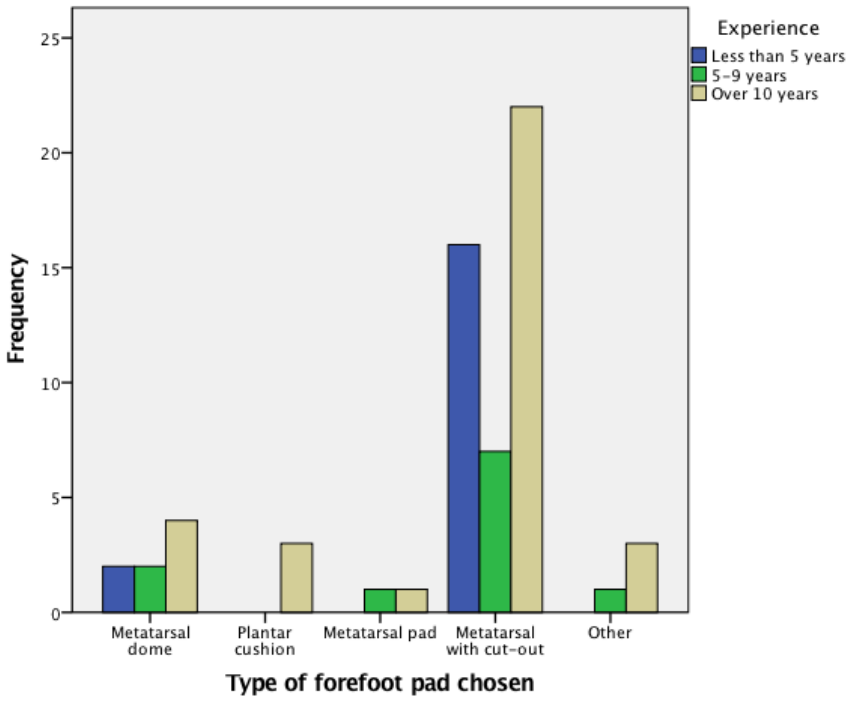
Both open and closed questions were designed for the questionnaire to allow the podiatrists to elaborate on key areas. The questionnaire was piloted to highlight any issues with the clarity of the questions, and these issues were subsequently addressed prior to conducting the survey. Questions focused on determining which forefoot pad the podiatrist would prescribe for a patient with a painful plantar corn, and whether the podiatrist incorporated metatarsal padded insoles in their practice. It was also necessary to collect demographic data, such as age, gender, qualifications, number of years' experience, and sector of employment. These variables could have influenced the participants' responses, due to their previous experiences and resources available to them in practice. Completed questionnaires were placed in an enclosed submission box and stored in a secure cabinet in a locked office. All participants were given a written information sheet (Appendix 9.4), and it was assumed that by completing the questionnaire the practitioner was providing their consent for involvement in the study.

All raw data was inputted into SPSS statistical software (Version 22) and analysed descriptively.

4.2.3 Results

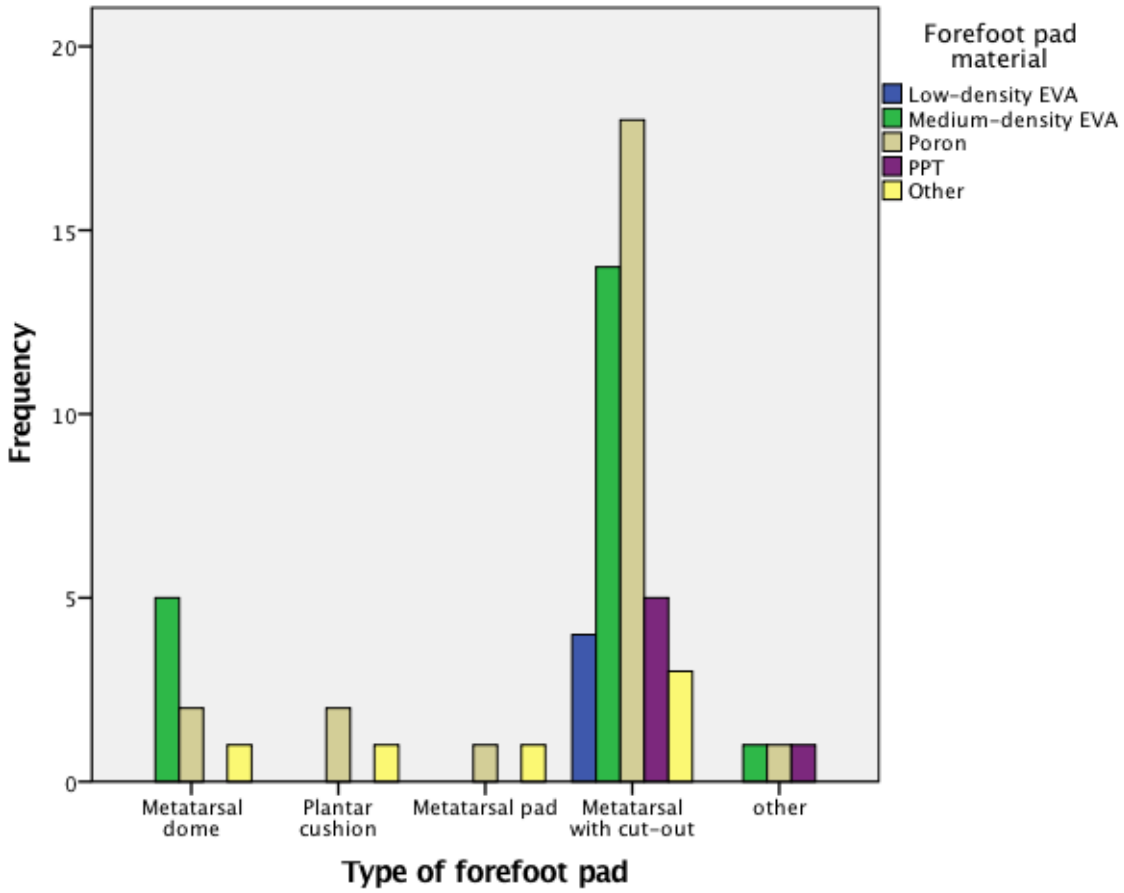
The 62 participants who completed the survey were primarily female, totalling 41 (66%), compared to 21 (34%) males. The number of years' experience ranged between 1 to 36 years, with a mean of 13 years (SD 10.59). Most participants, 45 (73%), indicated that they would prescribe a plantar metatarsal pad with a cut-out for a patient with a plantar corn located on the second metatarsal head. A further 2 (3%) participants reported that they would prescribe a metatarsal pad but without a cut-out. The 3 participants (4.8%) who selected "other" provided drawings similar to the metatarsal pad with a cut-out. Metatarsal dome-shaped pads were selected by the remaining 13% of the participants. The number of years' experience did not influence the types of forefoot pads chosen, shown in Figure 4-3.

Figure 4-3: Chosen type of forefoot pad and participants' experience.



The most selected material choice for the forefoot pad was Poron (n = 24, 39%). This was closely followed by medium density EVA (n = 20, 32%). The 6 participants who selected "other" reported that they would either prescribe a polyurethane material or semi-compressed felt. Two participants did not respond to this question. Figure 4-4 illustrates the frequency of materials selected in relation to the preferred forefoot pad.

Figure 4-4: Chosen forefoot pad and material



The thickness of the pad participants would prescribe ranged between 2 mm and 10 mm (mean 4.57 mm; SD 1.62 mm). Participants were asked to specify whether the insoles they would prescribe to manage plantar corns would have a base and/or top cover material, and if so, what that would be. The responses demonstrate great variability for both the base material and top cover, as shown in Tables 4-2 and 4-3.

Table 4-2: Frequency of materials selected for the base of the insole.

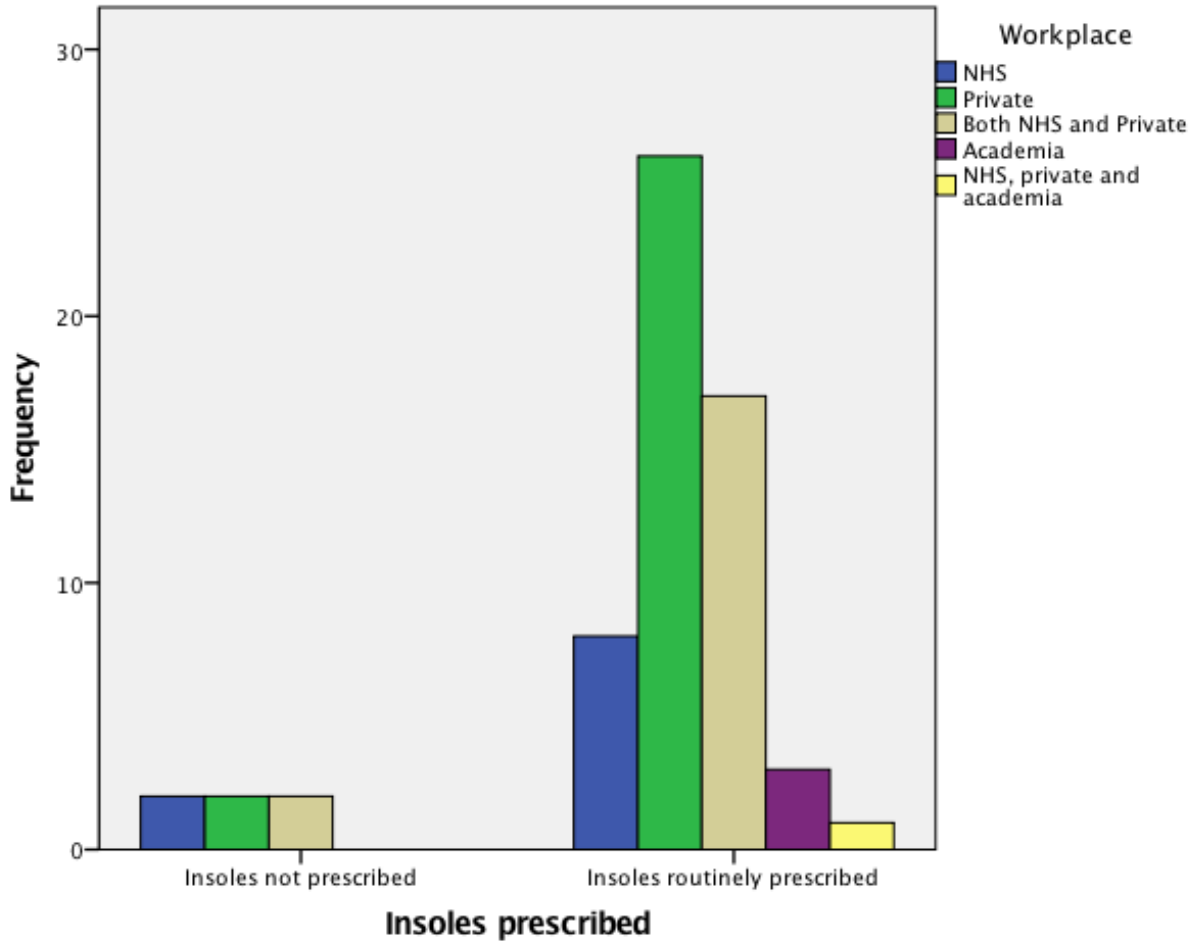
Base materials	***Frequency***
Texon	13 (21%)
EVA	13 (21%)
Leather board	8 (13%)
Poron	6 (10%)
Prefabricated insole (slim-flex)	12 (19%)
None	6 (10%)
Other	1 (2%)

Table 4-3: Frequency of materials selected for the top cover of the insole.

Top cover materials	***Frequency***
Poron	18 (29%)
Yampi	14 (23%)
Synthetic leather	8 (13%)
EVA	5 (8%)
None	10 (16%)
Other	5 (8%)

A total of 55 participants (90%) stated that they currently prescribe insoles in practice to manage painful plantar corns. There appears to be no correlation between employment sector and whether or not the practitioners prescribe insoles, illustrated in Figure 4-5.

Figure 4-5: Relationship between whether practitioners prescribe insoles for managing corns and their sector of work.



A mean of 7 insoles per month (SD, 8) were found to be prescribed in practice to manage corns, with one anomaly stating they prescribe 40. The 10% of participants who do not prescribe insoles in practice explained this was due to the lack of facilities, time constraints and an obligation within their employment policy to refer patients on to the biomechanics department.

4.2.4 Discussion

4.2.4.1 Interpretation of results

This survey has helped to develop an understanding of current practice in insole provision in for the management of painful plantar corns. It has demonstrated the lack of consensus amongst practitioners concerning the design of the devices. The results have further emphasised the necessity for conducting the pilot study, evidenced by the vast majority of participants (90%) who prescribe insoles to manage corns in clinical practice, alongside sharp scalpel debridement (SSD) and enucleation. The demographic evaluation of UK podiatry services by Farndon (2016) reveals that corns and calluses were the most common conditions presenting to podiatrists for management. It is essential this routine practice is based upon validated research evidence, as practitioners must be able to justify their clinical decision-making, not only to their patient but also their governing body.

The majority of participants (73%) in this survey of current practice stated that they would prescribe a metatarsal pad with a cut-out at the site of the corn, with only 3% reporting that they would prescribe it without the cut-out. Although metatarsal pads have been shown to significantly reduce pressure at the forefoot by up to 21%, research investigating these pads with cut-outs is not available, neither is the research available which determines whether the pads are effective at preventing or delaying the recurrence of corns (Jackson et al., 2004; P. Lee et al., 2014). This raises the question of whether the inclusion of the cut-out in the metatarsal pad at the site of the corn further reduces pressure from the lesion.

It is apparent that podiatrists, in their treatment of painful corns, are applying knowledge gained from the evidence that has demonstrated the effectiveness of metatarsal pads with

cut-outs in the healing of diabetic foot ulcerations (Nubé et al., 2006; Zimny et al., 2003). The rationale for this could be the assumption that the inclusion of the cut-out will raise the corn off the ground, which will reduce, if not eliminate, the mechanical stresses and irritation at the site, thereby allowing healing. Armstrong, Liswood, and Todd (1995) raised concerns about the effects of deflective adhesive padding when used for the healing of ulcers due to the potential elevation of pressure created around the wound as a result of the cut-out. Deflective padding is still widely used in practice due to the wealth of evidence emphasising its successful healing rates. Raspovic and Landorf (2014) highlighted that 94% (n = 36) of clinicians use this type of deflective padding in routine practice for healing diabetic forefoot plantar ulcerations.

In this survey of current practice, considerable disparity amongst clinicians was found regarding their choice of materials for the forefoot pad, the top and base of the insole for patients with a painful plantar corn. Whilst Poron was the most commonly selected material (n = 24, 39%) used to construct the metatarsal pad, 20 participants (32%) would have used medium-density EVA. Since the properties of Poron and medium-density EVA, the two most popular materials cited in the survey, differ significantly, this raises questions about why these materials are interchangeably prescribed for the same purpose. Bellamy (2007) suggests that the subjective feedback from patients could explain the discrepancy amongst clinicians, for instance, if patient feedback differs from the published evidence-based research. Further variation was demonstrated in participants' responses for the thickness of material they would prescribe for the metatarsal pad. This is also evident in the research that evaluates the efficacy of metatarsal pads in reducing pressure (P. Lee et al., 2014; Tong & Ng, 2009). The vast variation of forefoot pads available, alongside the lack of research

evidence, could provide a rationale for the differences reported in insole prescription for corn management seen in this survey.

4.2.4.2 Strengths and limitations

One key strength of this survey was that it was conducted at the largest podiatry event in Europe, enabling the survey to capture data from practicing podiatrists across a broad geographical area, working within different sectors, including both private practice and the NHS. The number of participants (n = 62) was sufficient to meet the aims of the investigation: to gain a greater appreciation of the types of insoles that are being prescribed in current practice. Although a large sample size was not necessary for this preliminary investigation, response rates to the survey were relatively low, given the large number of attendees at the event. This could be due to the poor positioning of the stand in the exhibition hall, and the fact that the survey was not well publicised. Additionally, many of those attending the conference could have been non-practising podiatrists or students, who were excluded from this survey, reducing the number of potential participants. In future, for surveys that require a large sample, it may be beneficial to seek permission for copies of the questionnaire to be located in the main lecture suite to increase awareness.

4.2.4.3 Implications for further investigation

This survey has highlighted that practitioners routinely prescribe metatarsal padded insoles with a cavity to manage plantar corns. Since there is currently no research evidence available investigating their use, there is a need for the proposed pilot study to evaluate their efficacy to justify this practice. The survey indicated that the materials practitioners use to manufacture insoles differs considerably. Prior to an evaluation, further research is

required into these materials for the metatarsal pad. Material stiffness and patient comfort are two key elements for reducing pressure and increasing patient compliance when wearing the metatarsal padded insoles (Paton et al., 2007). This led to the investigations described below.

4.3 Compressional stiffness of materials

4.3.1 Aim

To attain a deeper understanding of the compressional stiffness property of the various materials available for use in managing plantar corns, including: Poron, PPT, PodoPro Urethane, medium-density EVA, and low-density EVA.

4.3.2 Method

This element involved working inter-professionally with the Department of Engineering. The Instron 3369 Compressional Testing equipment in the laboratory was selected to measure the stiffness of the selected materials. Previous studies have used this equipment due to its accuracy and reliability (Campbell et al., 1982; Chatzistergos et al., 2017; Lo et al., 2014).

Poron, PPT, medium-density EVA and low-density EVA were selected for compressional testing. In the survey of current practice, discussed previously, participants reported these materials would be used in the prescription of a metatarsal pad. Another polyurethane material, PodoPro Urethane, which has been newly launched by DLT, was also selected for compressional testing. A total of 50% of the participants in the current practice survey stated that they would prescribe a polyurethane material. The majority of the research

evidence highlights that polyurethane materials are effective at reducing pressure from the forefoot (P. Lee et al., 2014; Lo et al., 2014).

Fifteen standard disc-shaped samples were cut from each of the five materials, namely: low- and medium-density EVA, Poron, PodoPro Urethane, and PPT. The samples were cut to a diameter of 22.5 mm to match the diameter of the formers. Only small samples were required, since painful plantar corns typically occur on the high-pressure points overlying the metatarsal heads (Freeman, 2002). Limited evidence is available determining the average size of the metatarsal head. Van Deventer, Strydom, Saragas, and Ferrao (2018) observed the median radius of the arc of the first (largest) metatarsal to be 13 mm. Other studies that have investigated the compressional stiffness of materials have used similarly sized samples (Campbell et al., 1982).

The thickness of each material was standardised to 6 mm. The previous investigation of current practice demonstrated that there was no standard thickness of forefoot pad that practitioners prescribed, as participants' responses ranged between 2 mm and 10 mm. Previous research has suggested that the greater the thickness, the more pressure reduced (Birke et al., 1999). The patients' footwear and foot function limits the amount of material placed under the metatarsal heads. Excessive forefoot padding could impact on normal forefoot mechanics during gait and exceed the depth available within the footwear leading to increased pain and tissue breakdown for patients. A 6-mm thick metatarsal pad is considered appropriate, as previous studies investigating forefoot pads have used 6-mm thick devices (P. Lee et al., 2014).

Three differently shaped formers (the instrument that compresses the sample) were manufactured for the testing process: a flat, semi-domed, and domed former (Figure 4-6).

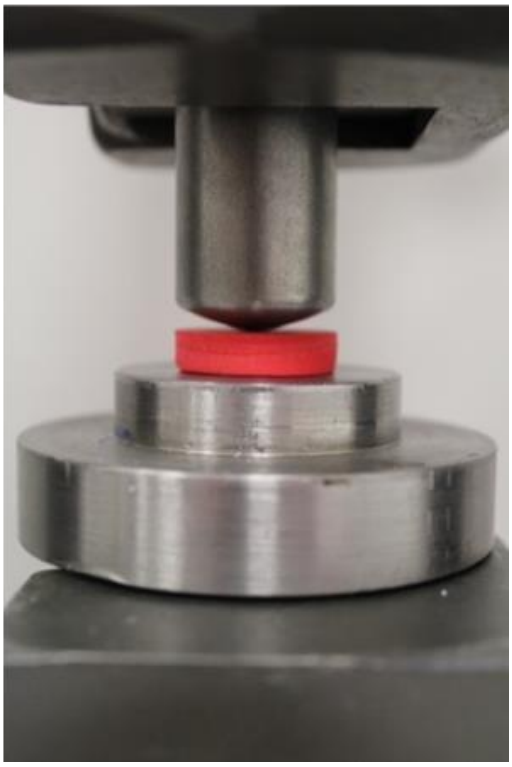
Figure 4-6: Three differently shaped formers used to compress the materials.

a) *Domed* *b) Semi-domed* *c) Flat*

These were produced to assess whether the profile of downward force influences the degree of compression of the material. Although previous studies have used flat formers to compress the material, the metatarsal heads are shaped differently, which could influence the data gathered pertaining to the materials' stiffness (Campbell et al., 1982). A recent morphology study reported that the majority of the 87 first metatarsal heads reviewed were round (61%), in comparison to flat (32%) and chevron-shaped (7%) (Van Deventer et al., 2018).

The sample was placed on the lower platen for testing, and the former was brought down to meet the top of the sample, illustrated in Figure 4-7.

Figure 4-7: Low-density EVA before being compressed by the domed former.



To standardise conditions for every material, the equipment was then set to measure the amount of force required to compress the material from 6 mm to 1.5 mm. The material was compressed to 25% of its original thickness, as any further stress would be past the capability of the material, a limit beyond which the effectiveness of the material would be greatly diminished in practice (Campbell et al., 1982). The sample was then compressed as illustrated in Figure 4-8.

Figure 4-8: Medium-density EVA compressed by the flat former.

Every test was repeated five times for each of the three formers to ensure reliability of the data (Hicks, 2009). This included a total of 75 tests for the five materials.

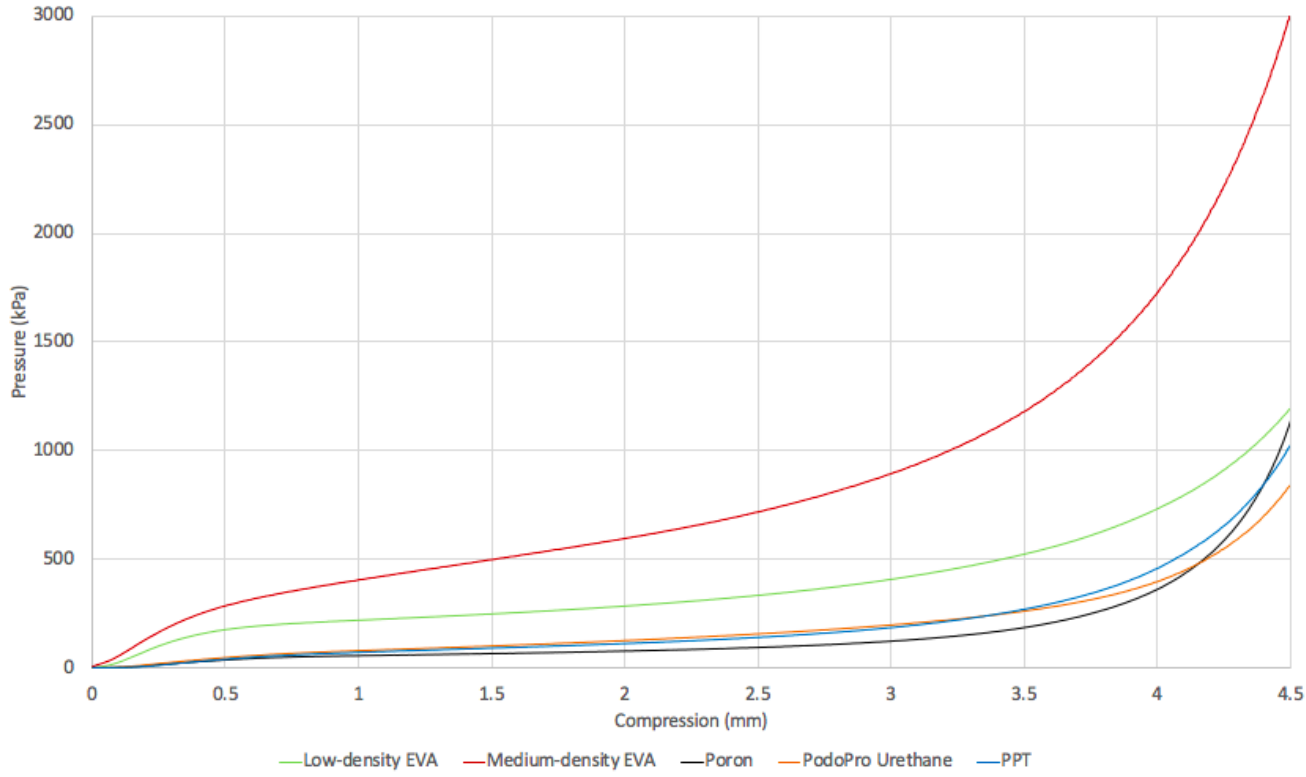
In addition to this, testing was also completed with base and top covers on the metatarsal pad materials, to investigate whether the base and top cover materials with glue changed the compressional properties of the metatarsal pad materials.

Stress-strain curves were constructed from the extracted data for all materials. Output from the test (measured in kilograms, kg) was first converted to load (Newtons, N) by multiplying by *g* (9.80665 m/s^2). Pressure (Pascals, Pa) was calculated by dividing load by the surface area of each former (0.000398 m^2), and then divided by 1,000 to express the pressure in kilopascals (kPa).

4.3.3 Results

Analysis of the stress-strain curves showed that medium-density EVA required a greater stress than the other materials to compress the material from 6 mm to 1.5 mm using the flat former. Figure 4-9 illustrates the average stress-strain curves for the materials using the flat former.

Figure 4-9: Stress-strain curves for materials using the flat former.

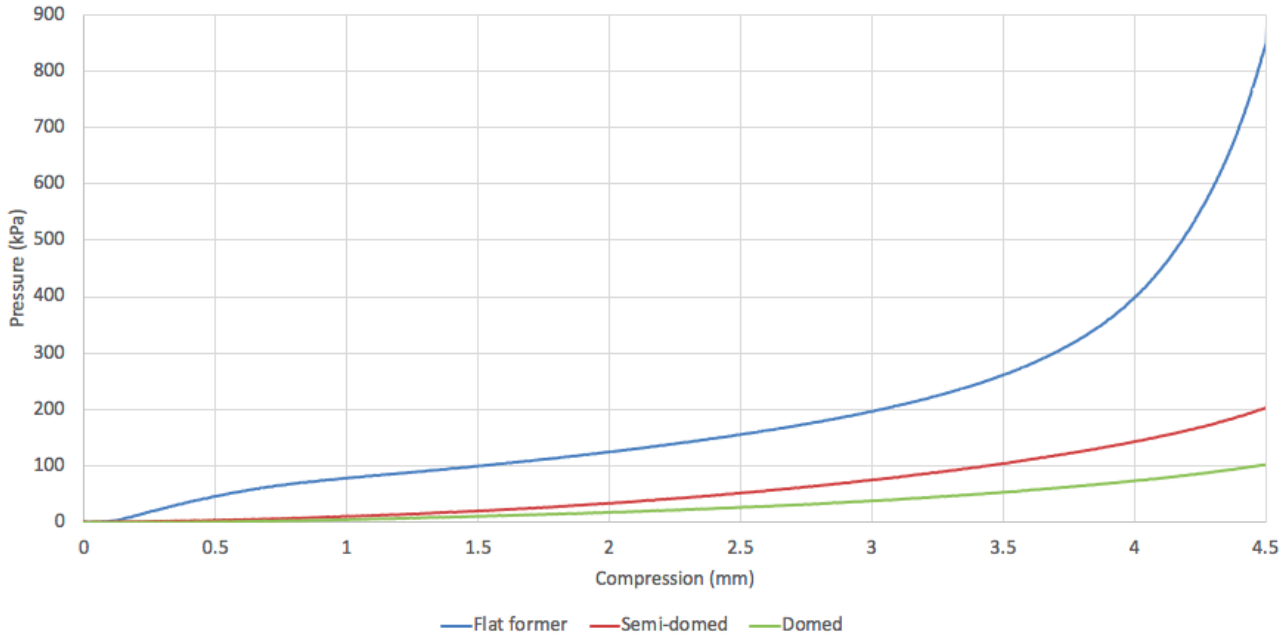


The stress-strain curve for medium-density EVA illustrates an initial increase in pressure to compress the material by 0.5 mm. Stress is continued to enable the material to compress. A rapid increase in pressure is required during the final phase to compress the material beyond 3.5 mm of its original thickness to 4.5 mm. This sudden elevation in pressure at the final proportion of the curve is demonstrated by all the materials tested.

The polyurethane materials are more deformable than low- and medium-density EVA, requiring less pressure to compress the material to a thickness of 1.5 mm. The polyurethane materials required approximately 1,000 kPa of force to compress the material. Importantly, following removal of the compressional load, it was visibly clear that the polyurethane materials visually returned to their original thickness, in comparison to the low- and medium-density EVA, which showed some signs of damage and degradation.

The differences in average stiffness of the PodoPro Urethane material, when compressed by the differently shaped formers is illustrated in Figure 4-10.

Figure 4-10: Stress-strain curves highlighting the differences in compressional stiffness of PodoPro Urethane when compressed by the different formers.



The stress-strain curves emphasise the decreased amount of force required when using the dome-shaped formers to compress the material to 25% of its width, due to the decreased

surface area towards the leading point of contact with the former. The flat former required 880 kPa to compress the material to 1.5 mm; the semi-domed shaped former required 206 kPa, and dome-shaped former 104 kPa. Analysis of the stress-strain curves for each of the other materials when comparing the three different formers showed similar results. The ranking of the stiffness of the materials was consistent across the three types of former, the rankings being the same as those seen using the flat former. Samples tested with the base and top cover did not appear to have affected the compressional stiffness of the metatarsal pad materials. The results are considered reliable due to the fact each test was repeated five times, all of which produced similar results.

4.3.4 Discussion

4.3.4.1 Interpretation of results

Compressional stiffness should be taken into account when selecting materials for reducing pressure from the forefoot, since the greater level of stress within the material directly correlate to the added stress within the soft tissue covering the bony prominences (Paton et al, 2007). If this increased load is not reduced, the excessive pressure could lead to tissue breakdown or hyperkeratosis (Lo et al., 2014). To successfully reduce pressure over the forefoot the material should continuously deform. The stress-strain curves demonstrate that all the materials progressively deform; however, low- and medium-density EVA are considerably stiffer, as the pressures required to compress the materials were greater (approximately 2,000 kPa). Research evaluating peak pressure in participants with hyperkeratosis at the forefoot has found mean pressures of 387 kPa in older participants who are otherwise healthy, 375 kPa in those with DM and 254 kPa in those with RA (Araguas Garcia & Corbi Soler, 2018b; Davys et al., 2005; Pitei et al., 1999; Woodburn et al.,

2000). Fawzy, Arafa, Mervat, and Shaimaa (2014) measured the forefoot PPP in diabetics with and without ulceration: pressures of 335 kPa were found to be the cut-off point for ulceration risk. The stress-strain curves using the flat former demonstrate the polyurethane materials (PPT, Poron and PodoPro Urethane) appear to be more appropriate to reduce pressures across the forefoot, as the materials will continuously deform to absorb pressures of up to 880 kPa. This is adequate to lessen the PPPs occurring at the forefoot in patients with hyperkeratosis. Medium-density EVA may be too stiff to reduce and accommodate the pressures experienced by the soft tissue. This material may be best suited to improving foot function foot where greater material stiffness is required (Healy et al., 2010).

A rapid increase in pressure was observed in all the materials during the final portion of the stress-strain curve. This was more prominent in the medium-density EVA curve than the polyurethane materials. Visible signs of damage to the EVA materials were observed, particularly in the medium-density sample, where the material did not return back to its original thickness. This demonstrates its inability to recover its original potential following application of pressures of up to 3,000 kPa. Research evaluating pressures at the forefoot have indicated that the material would not be placed under stresses this high under the foot during normal walking, and therefore normal use would not cause permanent deformation (Davys et al., 2005; Landorf et al., 2013). Importantly, the polyurethane materials returned to their original form following compression, and showed no signs of alteration in structure, which is in line with previous research that has evaluated durability (Paton et al., 2007).

Prominent metatarsal heads are commonly observed in practice and are often round in shape (Van Deventer et al., 2018). The resultant reduction in surface area increases the

pressure within the soft tissue during walking in these patients, which can increase the risk of hyperkeratosis and ulceration. This investigation emphasised that the resistance of the materials to compression was substantially decreased when compressed by the domed-shaped formers, in comparison to the flat former. It was demonstrated that the polyurethane materials have the ability to relieve pressure by up to 880 kPa when compressed by the flat former, which would accommodate the typical pressures occurring across the forefoot (Davys et al., 2005; Landorf et al., 2013). When compressed by the domed-shaped former, analysis suggests that the materials would be incapable of absorbing pressures greater than approximately 200 kPa, which would not be of benefit in practice. This raises the importance of incorporating cut-outs (apertures and cavities) within the design of insoles to accommodate bony prominences. The surface area will be increased, improving the material's resistance to compression, and its ability to reduce the pressure experienced by the area, thereby helping to prevent the formation of hyperkeratosis and tissue breakdown.

4.3.4.2 Strengths and limitations

Currently there is no other research available within the literature that has used different formers to replicate the various shapes and contours of the bony prominences of the foot. Since this variation in bony prominences has been demonstrated by morphology studies (Van Deventer et al., 2018), it is therefore important to assess the compressional stiffness of materials using different formers other than flat ones. One limitation is the size of the equipment used. The Instron 3360 machinery is manufactured to typically load forces of up to 50 kN, and therefore may not be sensitive enough to accurately measure the small variations in load between the materials.

4.3.4.3 Implications for further investigation

The polyurethane materials tested may be more suitable for pressure relief than the low- and medium-density EVA, as they have a greater ability to deform to accommodate the forces typically occurring across the forefoot. A cut-out within the insole at the site of a bony prominence or lesion will increase the surface area over which these forces are dissipated, improve the material's resistance to compression, and be conducive to pressure reduction.

It was observed during the testing that the EVA materials did not return to their original shape. Compression fatigue testing was attempted; however, the machinery load capacity was too large to accommodate the small loads required to compress the materials. Paton et al. (2007) conducted durability testing on various orthotic materials, but this did not include the materials used in this investigation. Further research could be completed to assess the durability of these materials; however, this was considered unnecessary at this stage of the project. Once the insole was selected for the pilot study, the durability would then be evaluated. This approach enabled the study to be more practically based on participants' day-to-day activities, rather than based in a laboratory environment.

4.4 Patient perspective

The suitability of a material for a metatarsal padded insole should not be solely based on the material's physical properties; the patients' perspective should also be considered when assessing the applicability of these commonly used materials in clinical practice.

4.4.1 Aim

To investigate the patients' perspective of the materials, including: medium-density EVA, Poron and PodoPro Urethane, which are available for use in managing painful plantar corns.

4.4.2 Method

A quantitative approach was implemented using a questionnaire with a scale comprising five Likert items, enabling a more objective measure of the comfort of each insole. Conducting interviews would have further prolonged the time participants were required to dedicate to the study. Open-ended questions were also included in the questionnaire to enable participants to expand on areas of importance to them.

A total of five to 10 participants was considered to be an adequate number to gain an insight into patients' perspectives of insoles for this preliminary investigation. Similarly to the current practice survey, convenience sampling was selected due to the associated time constraints (Bowling, 2014). Healthy volunteers, including both staff and students from the University of Huddersfield were invited to participate via email and information sheets (see Appendices 9.5 and 9.6). Participants were excluded for ethical reasons: those with current ulceration and loss of sensation were excluded to prevent any unnecessary harm, and those who were unwilling to participate effectively self-excluded (Bowling, 2014). Furthermore, those who wore unsuitable regular-use footwear were excluded. This was defined as: high heels, narrow fashion shoes, sandals, or flip-flops. Appropriate footwear is essential when prescribing insoles. There should be enough space to accommodate the insole comfortably to optimise comfort and function (Edelstein & Bruckner, 2002). Prior to involvement, all

participants were aware of what the investigation entailed, and provided their informed consent (see Appendix 9.7).

Templates were taken from each participant to allow appropriate construction of the plantar metatarsal pads using the three different materials. The protocol for producing the template was standardised to the same process that is incorporated into routine practice, as outlined clearly by Menz (2008), which is discussed in Chapter 5.

Three materials were selected for testing, namely medium-density EVA, Poron and PodoPro Urethane. These materials were highlighted as requiring further investigation, based on the research evidence available and the supplementary investigations conducted (illustrated above), in order to help develop a greater understanding of the patients' perspective. Testing more than three insoles was considered too onerous for the participants, and too time consuming and costly for the researcher to produce and test so many devices. Poron and medium-density EVA were selected for this element, as the current practice survey highlighted that over 70% of the podiatrists surveyed would prescribe either Poron or medium-density EVA. Additionally, it has been established by the compressional stiffness testing that these two materials differ greatly in their properties. Therefore it was considered to be of value to investigate them further in terms of patient feedback. Research investigating the use of metatarsal padded insoles for reducing pressure at the forefoot has focused on the efficacy of polyurethane materials, such as Poron and PPT, rather than medium-density EVA (Healy et al., 2010; P. Lee et al., 2014). Evidence is available to demonstrate that EVA is effective at pressure redistribution in the healing of diabetic ulcerations, when used for total contact insoles (TCIs) (Elraiyah et al., 2016). Although EVA

has not been investigated for use in metatarsal pads, podiatrists may be transferring this knowledge of the evidence regarding diabetic ulcerations, and/or their clinical experience, and applying it to the management painful plantar corns (Bellamy, 2007). It is therefore important to establish the patients' perspective of medium-density EVA as a forefoot pad. There is no research evidence available that has evaluated low-density EVA for offloading forefoot plantar pressures and few podiatrists in the survey conducted (4 participants; 6.5%) reported they would prescribe this. Therefore this material was not chosen.

The third material chosen to be evaluated was the newly launched polyurethane material, PodoPro Urethane. The evidence base highlights that polyurethane materials, including Poron and PPT, are effective at reducing pressure from the forefoot when used for the metatarsal pad (P. Lee et al., 2014; Tong & Ng, 2009). This was reflected in the survey, as 50% of the participants reported they would prescribe a polyurethane material, including Poron, PPT, and when specified in 'other'. Research has demonstrated that medium-density polyurethanes, including PPT and PodoPro Urethane, are the most effective at reducing pressure and increasing average contact area (Healy et al., 2010). Evidence has suggested that PPT has poor thermoregulatory properties, further increasing moisture content in the shoe microclimate (P. Lee et al., 2014; Lo et al., 2014). Furthermore, few podiatrists surveyed stated that they would prescribe PPT. Therefore this material was not chosen for investigation. PodoPro Urethane was chosen as it is a new material that costs considerably less (up to -30% less) than Poron and PPT.

The three insoles were produced by the same clinician, the researcher, for each patient, and fitted to their typical footwear. Participants were then instructed to walk up and down the

gait analysis room for as long as they felt necessary to be able to appropriately rate the comfort of each insole on the questionnaire. The scale consisted of scores from 1 to 5, from 'very uncomfortable' to 'very comfortable', as shown in Appendix 9.8. Previous research by Mills, Blanch, and Vicenzino (2011b) used this scale to measure the comfort of various therapeutic orthoses in healthy participants. Demographic information was also collected in the questionnaire, such as age, gender, height, and weight. Participants were also asked to state which insole they preferred, their reasons why, and any improvements that could be made. The data from the questionnaires was transferred to SPSS statistical software for descriptive analysis.

4.4.3 Results

A total of 8 participants (3 male and 5 female) were recruited, with ages between 21 and 53 years old. All the participants rated the medium-density EVA material as either 2 (uncomfortable) or 3 (acceptable). In comparison, none of the participants rated either the Poron or PodoPro Urethane material as less than 3 (uncomfortable to very uncomfortable). The majority of participants rated the PodoPro Urethane and Poron insoles as 4 (comfortable) to 5 (very comfortable) (88% and 63%, respectively); see Table 4-4, below.

Table 4-4: Rated comfort levels for each of the three materials tested.

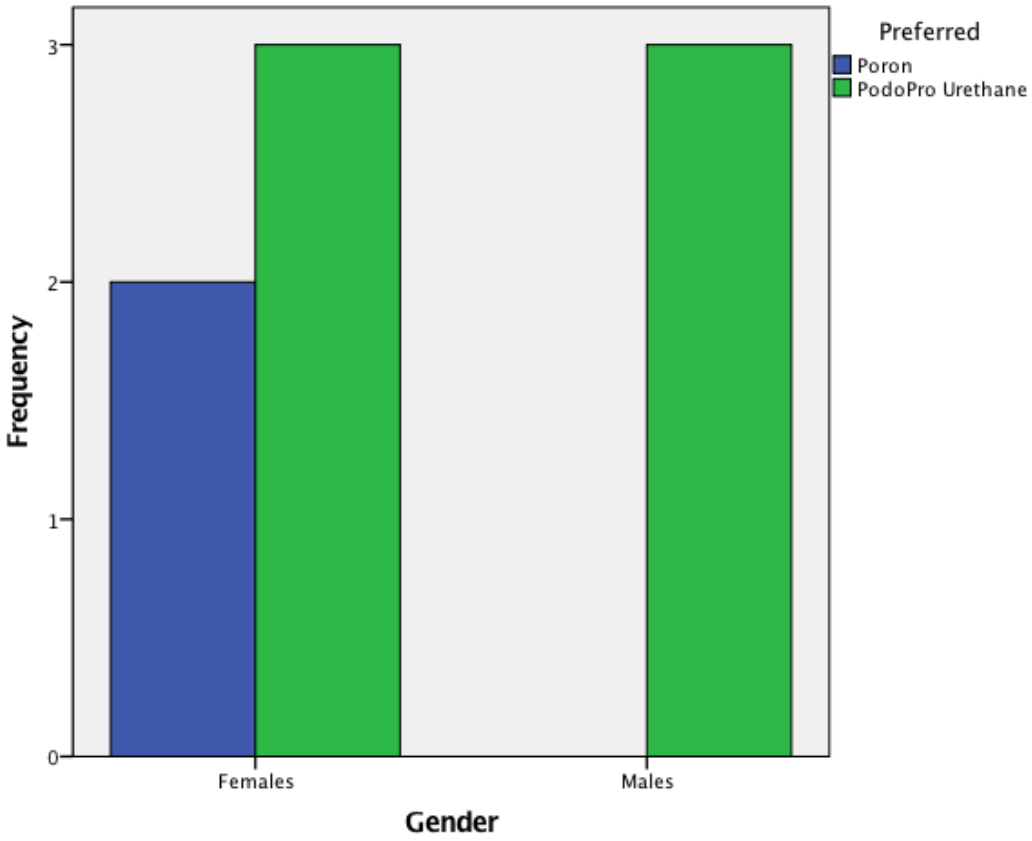
	Material tested (frequency)		
Rating 1-5	**Poron**	**Medium-density EVA**	**PodoPro Urethane**
1 Very uncomfortable	0	0	0
2 Uncomfortable	0	4	0
3 Acceptable	3	4	1
4 Comfortable	4	0	6
5 Very comfortable	1	0	1
	Total = 8	Total = 8	Total = 8

There were no disparities amongst the findings when isolating demographic variables, such as height, weight, and gender. Participants stated the insoles could be improved by reducing the width of the plantar metatarsal pad to fit better in the footwear. Participants reported that the medium-density EVA material was too hard and thick.

PodoPro Urethane was the preferred insole choice for 75% of the participants, and the remaining 25% favoured Poron. None of the participants chose medium-density EVA. Similarly, insole preferences were not found to be influenced by demographic variables. Foot shape, stature, and length have been found to differ considerably between genders in previous research, with males having broader and longer feet than females (Wunderlich & Cavanagh, 2001). Putti, Arnold, and Abboud (2010) reported a significantly greater contact area and force-time integral in males, in comparison to females ($p < 0.05$), implying that there are differences in load distributions between genders during walking. Whilst research has suggested the design of the shoe affects comfort ratings between genders, it is not understood if material choice differs between genders in relation to comfort (Hawes et al.,

1994). Gender differences were considered but were not found to influence insole material preference. Figure 4-11, demonstrates the distribution of preferred insole choice between genders.

Figure 4-11: Participants' preferred insole material, by gender.



4.4.4 Discussion

4.4.4.1 Interpretation of results

When prescribing insoles, patient comfort is an essential factor to consider, as patients will not adopt uncomfortable insoles into their everyday activities (Lo et al., 2014). Patient compliance is fundamental to successfully evaluate metatarsal cut-out padded insoles in the management of plantar corns. This small investigation has provided further understanding

of patients' perspectives with regards to insole materials used in practice, which supports the current evidence available (Hähni et al., 2016; Mills, Blanch, & Vicenzino, 2011a; Mills et al., 2011b; Mündermann, Stefanyshyn, & Nigg, 2001). The findings from this element demonstrate that all the participants preferred the more deformable polyurethane materials, in comparison to the medium-density EVA. Mills et al. (2011b) found that soft, flat orthoses were rated as significantly more comfortable than the hard ($p < 0.001$), medium ($p < 0.001$), and soft, contoured orthoses ($p < 0.001$). Hähni et al. (2016) compared the comfort ratings between metatarsal pads and domes made from polyurethane. Participants rated the metatarsal pads as more comfortable by 15 mm, on a 100-mm scale, which is clinically significant. The hardness and shape of the material placed at the forefoot are clearly influential factors for comfort perception in patients.

In this current investigation of perceived comfort, participants commented on reducing the width of the metatarsal pad to improve overall comfort and fit within the footwear. This is essential to recognise when manufacturing the insoles in the pilot study to maximise adherence rates.

4.4.4.2 Strengths and limitations

The participants recruited in this small-scale investigation were healthy individuals with no forefoot pain. Future investigations should target patients with painful hyperkeratosis, as this could influence the comfort ratings of the materials. The time participants are expected to spare should also be considered in future investigations, as this study involved participants dedicating approximately one hour, which could have discouraged involvement.

4.4.4.3 Implications for further investigation

The ongoing use of insole therapy is imperative to continue to reduce pressure from the forefoot in an attempt to promote prolonged treatment effects. It was found in the investigation that the more deformable the material, the greater the reported comfort. The findings support previous research in this area, and have helped inform the decision on the insole to be evaluated in the pilot study. It would be beneficial for future investigations to explore perceived comfort levels over longer periods of wear. This would allow participants to more extensively incorporate the insoles' into their daily routines, which would involve a variety of footwear and activities. Participants would then be able to more thoroughly assess each insoles' adaptability, suitability, and comfort.

Future research investigating foot orthoses should include reporting on the perceived comfort of the insoles therapy, rather than solely on outcome measures. The comfort of the insoles and associated compliance, or lack thereof, could be the reason for treatment success or failure.

Using an interview design may be beneficial for future evaluation of perceived comfort. This would provide the opportunity to explore the issues of orthoses pertinent to patients in more depth. For instance, this would allow researchers to gain a greater breadth of information about the patients' preferred qualities regarding orthotic designs, the process of implementing them in their daily lives, and how past experiences might influence future use.

4.5 Simple insole selected for investigation

After reviewing the literature and findings of the supplementary investigations, an informed decision was made on the simple insole for the pilot study. Figure 4-12 illustrates the simple insole used for the evaluation.

Figure 4-12: Simple insole selected for evaluation in the pilot study.

Metatarsal pads with a cut-out at the site of the lesion were chosen for investigation, as this type of pad is described in the literature for managing corns (Frowen & Brewster, 2010; Mooney & West, 2009). The research evidence indicates that metatarsal pads are effective in reducing pressure across the forefoot by up to 21% (Jackson et al., 2004; P. Lee et al., 2014). Furthermore the first preliminary investigation, which involved conducting a survey

of podiatrists, found that the majority (73%) of participants prescribe metatarsal pads with a cut-out in routine practice to manage corns. The compressional stiffness element of the investigations found that the materials' resistance to compression was substantially less when the profile of downward force was more protrusive, due to a reduction in surface area at the point of contact. Incorporating cut-outs within the design of insoles, to accommodate the prominent painful lesions, will improve the materials capacity to reduce pressure from the site, and increase the potential for treatment success.

PodoPro Urethane was selected to make the metatarsal pad. Substantial evidence is available illustrating its effectiveness in reducing PPP (Healy et al., 2010; P. Lee et al., 2014; Rogers et al., 2006). The survey of current practice revealed that the majority of podiatrists surveyed would prescribe polyurethane materials in clinical practice for corn management. Healy et al. (2010) concluded that medium-density polyurethanes, similar to PodoPro Urethane, increased the average contact area when compared to low-density urethanes, such as Poron. This increased contact area improves the material's ability to further reduce peak pressure across the forefoot. In comparison to PPT and Poron, PodoPro Urethane is the least expensive, saving approximately £15 per sheet (100 cm x 46 cm). Podiatrists face continued pressure to manage conditions in the most economically viable way. For similar cost-saving reasons, as well as the fact that no prior research has been completed in this area, a simple insole was chosen for the metatarsal pad, which was composed of a Texon base and 1.2 mm Poron top cover.

4.5.1 Plantar pressure mapping

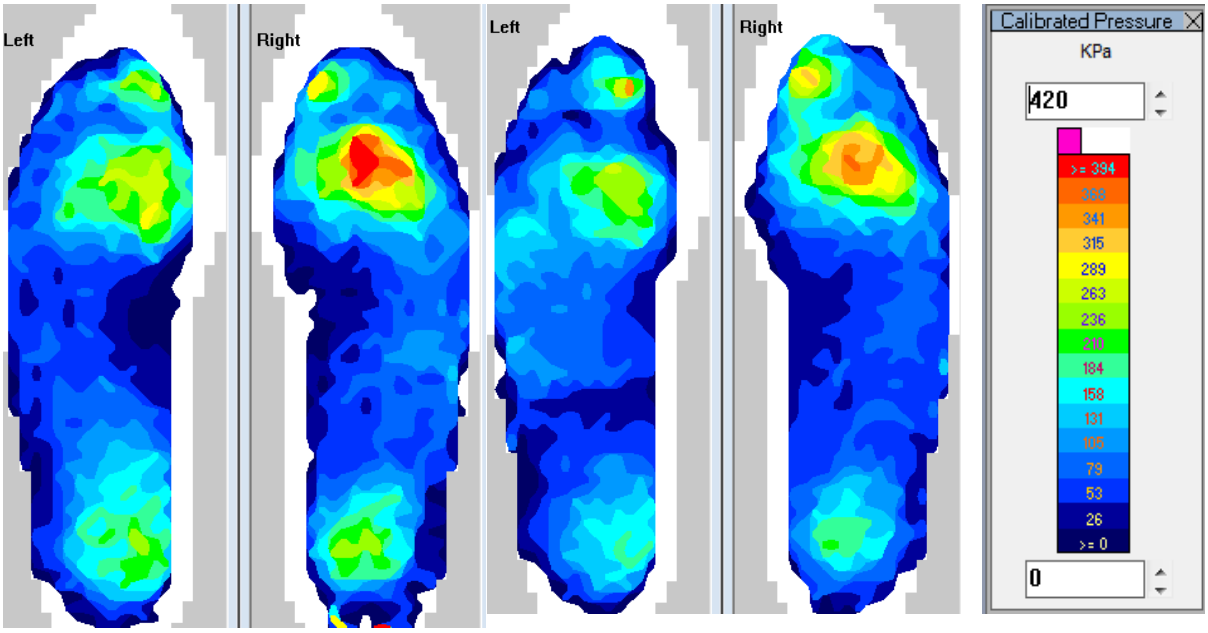
This fourth element was performed to verify that the selected insole for testing did indeed reduce pressure from the forefoot. Similarly to the other investigations, ethical approval was applied for and granted by the University of Huddersfield (see Appendix 9.1).

A total of six participants with existing painful plantar corns were recruited using convenience sampling. Participants were excluded if their typical footwear was deemed inappropriate to accommodate the insoles. Information sheets were provided to the participants prior to involvement, and consent forms were completed.

Templates were taken from each participant in accordance with the standardised procedure outlined in the literature review, and described in Chapter 5 (Menz, 2008). One researcher manufactured all of the insoles using the chosen material, and fitted them to the participants' footwear. The F-scan in-shoe pressure analysis system (Tekscan) was utilised to observe the changes in peak pressures across the forefoot, with and without the insoles. F-scan is widely used and supported for assessing pressure (Healy et al., 2010; Tong & Ng, 2009). The system was calibrated for each participant before testing with and without the insole. Participants were initially asked to walk up and down the gait analysis room in the laboratory at their own pace without the insoles. To allow enough time for the participants to adjust into their normal walking rhythm data was not recorded for the first 10 steps (P. Lee et al., 2014). A minimum of eight steps was recorded, of which was repeated three times to capture an average stance. This process was then repeated with the participant wearing the metatarsal padded insole with an aperture.

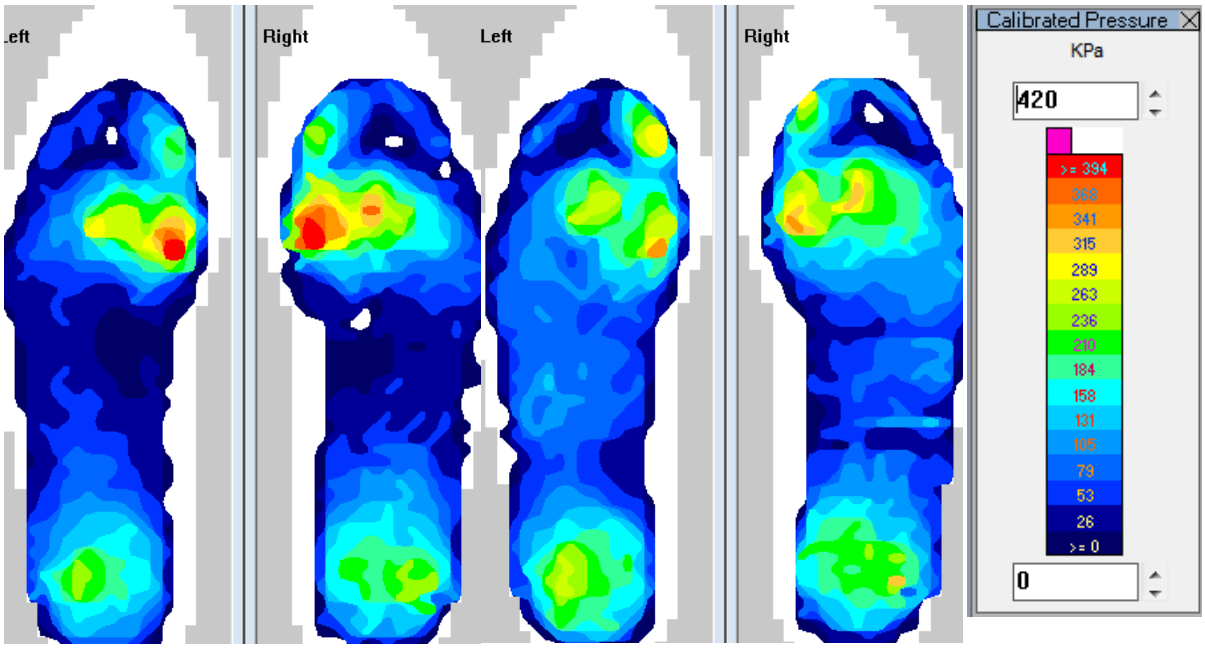
The results were reviewed qualitatively, as the aim of the element was to help support the decision of the selected insole, by providing confirmation that the chosen material did in fact reduce pressure from the forefoot. An in-depth quantitative analysis was considered unnecessary at this stage. The legend provided to assist in the analysis of the coloured pressure maps indicates areas of high pressures, i.e. those over 396 kPa, in red, with light green indicating average pressures of approximately 210 kPa, and dark blue showing no pressures. All six participants demonstrated a reduction in the red areas of high peak pressure at the forefoot when walking with the insole. Figures 4-13 and 4-14 illustrate the pressure maps of two participants.

Figure 4-13: Pressure map of the average stance of participant 3, (a) without, and (b) with the insoles.



a) Without insoles b) With insoles

Figure 4-14: Pressure map of the average stance of participant 4, (a) without, and (b) with the insoles.



Without insoles a) With insoles

Studies that have evaluated peak pressure in participants with corns and calluses have reported similar pressure values of 250 kPa and above (Davys et al., 2005; Landorf et al., 2013). Pressure can vary greatly due to factors such as walking speed and footwear type (P. Lee et al., 2014). Previous research investigating polyurethane materials for metatarsal pads have found significant reductions in pressure (Deshaies et al., 2011; Jackson et al., 2004; P. Lee et al., 2014). The insole selected for evaluation in the pilot study appears to be effective in reducing pressure from the forefoot. The element investigating perceived comfort utilised this insole with a base and top cover, and participants found it to be comfortable.

4.6 Summary

These four key elements have formed an integral part of the study, which – alongside the current research evidence base – has helped to formulate an informed rationale for the choice of insole to be tested in the proof of concept pilot study. This chapter has further reiterated the necessity for conducting the study: to investigate whether this routine practice for managing corns is beneficial. The findings from this chapter have been presented at the Materials Forum at the University of Huddersfield (Parfitt, 2016b). Various professionals attended the event including biologists and engineers. Furthermore, dissemination of the findings via poster presentation has been undertaken at the University of Huddersfield Postgraduate Research Conference (see Appendix 8.09) (Parfitt, 2016a). The design methodology of the pilot study is discussed in the next chapter.

Chapter 5 – Proof of concept pilot study methods

The purpose of this project was to examine a currently ambiguous issue in routine podiatric practice: do metatarsal aperture padded insoles, in conjunction with debridement, improve patient outcomes significantly more than sharp debridement alone in the management of corns?

This chapter presents the methods implemented in conducting the study to achieve the aims and objectives of this research. A rationale is outlined for the selected methods, including: research methodology, design, sample used, outcome measures, data collection, and subsequent analysis.

5.1 Research methodology

A quantitative approach was adopted, as this was the most applicable to test and validate the research question. It enabled data to be gathered from a larger sample size, which improves the generalisability of the findings that tests the feasibility and applicability of incorporating plantar metatarsal padded insoles into practice (Hicks, 2009). Qualitative methods were considered, such as interviews, which would have enabled a greater insight into participants' perspectives of the insoles by generating rich, in-depth, subjective data. To analyse the aims of the study objectivity was required, to quantify the measurement of whether combining the two treatments led to corn resolution and improvements in other patient reported outcome measures (PROMs). Quantitative methods allow the researcher have greater control in respects to how the data is collected. Previous studies that have investigated the effects of either sharp scalpel debridement (SSD) or insole therapy on

hyperkeratotic lesions have also focused on quantitative methods (Colagiuri et al., 1995; Davys et al., 2005; Farndon et al., 2013; Landorf et al., 2013; Tollafield, 2017).

5.2 Research design

The study design was a pragmatic, parallel-group, randomised controlled proof of concept pilot trial to investigate the use of metatarsal padded insoles in the management of painful plantar corns.

Following the selection of the plantar metatarsal padded insole, it was necessary to conduct a proof of concept study, to investigate its feasibility and verify the insoles potential for use in clinical practice (Kendig & Kendig, 2016). A pilot RCT was appropriate to ensure recruitment, randomisation, treatment, and follow-up assessments run effectively, prior to conducting a large-scale randomised controlled trial (RCT) (National Institute for Health Research (NIHR), 2015). The literature review, discussed in Chapter 2, emphasised the lack of research evidence available investigating the effectiveness of metatarsal padded insoles in the management of painful corns. Pilot studies are considered an important subset of feasibility studies (Eldridge et al., 2016; Lancaster, Dodd, & Williamson, 2004). Prior to 2015, there was a lack of guidance and consensus on the definitions of pilot and feasibility studies, which led to inconsistencies within the literature (Lancaster et al., 2004). The framework developed by Eldridge et al. (2016) emphasises that whilst pilot studies aim to address similar questions to those of feasibility studies, (i.e., “can this study be done?”), pilot studies have specific design features that mimic the protocols of their corresponding larger-scale studies. Since the literature review has identified previous studies that have evaluated the

use of alternative insole therapies for callus management, and other RCTs that have evaluated different treatments for corn management, a research protocol could be designed, and therefore a pilot study was undertaken (Caselli et al., 1997; Duffin et al., 2003; Timson & Spooner, 2005).

A pragmatic approach to the pilot was deemed appropriate to enable the results to be generalised and applied clinically, in comparison to an explanatory approach (Sedgwick, 2014). Evaluation of the intervention will be as near as possible to that seen in routine practice, using patient-centred outcomes.

A parallel design was necessary to successfully investigate whether any additional effects exist when SSD is combined with metatarsal padded insoles (Koshy et al., 2011). The control group consisted of participants receiving treatment used in routine practice, which include SSD and enucleation and patient education (e.g., maintaining good foot health and using emollients). The only difference between the intervention and control groups was the inclusion of insole therapy.

A cross-over design method was considered as an alternative, whereby participants act as their own control. Although this would reduce the sample size required for statistical power in a large-scale study, a substantial sample size was not required for this pilot study. Additionally, a cross-over design would prolong the already-restricted timeframe for data collection, since treatments would be separated by a "washout" period to prevent "carry-over" effects of the initial treatment (Knapp, 1998). Importantly, the effects of SSD are not all reversible. Farndon et al. (2013) demonstrated that, at 12 months following SSD, 31%

(16/51) of corns had remained resolved, highlighting that it would be unfeasible to undertake a cross-over study.

Participants were assigned to treatment groups through simple random allocation, using the sealed envelope technique with a 1:1 allocation ratio. Block randomisation (block size 2) was undertaken to ensure comparable group sizes in case of termination of recruitment before the required sample had been collected. Equalising the chance that participants would be selected to either group reduces selection bias, as samples gathered tend to contain heterogeneous characteristics (Bowling, 2014). Random allocation facilitates comparisons increasing the likelihood that any difference found between groups is attributable to the metatarsal padded insole. Temporal threats affecting the internal validity are also minimised through random allocation (Hicks, 2009). For instance, events unrelated to the study, such as increased activity levels, could occur between baseline and final measurements. Random allocation allows such events to be equalised across groups, hence minimising the potential impact on results. Grouios (2004) identifies high activity levels as a risk factor for developing corns, as the mechanical stress at the site is escalated.

5.3 Hypotheses generated for pilot and future RCT

The following hypotheses were generated to provide a framework for testing the research proposition in a future large-scale study, rather than for use in this pilot trial (Rudestam & Newton, 2007):

Null hypothesis:

There is no difference in patient-reported outcomes between SSD alone and the combination of SSD with a metatarsal padded insole in the management of corns.

Alternative hypothesis:

There are differences in patient-reported outcomes between SSD alone and the combination of SSD with a metatarsal padded insole in the management of corns.

A two-tailed hypothesis was selected since research in this area is lacking it was important to consider all possibilities (Ruxton & Neuhauser, 2010).

5.4 Ethical and research approvals

Before the pilot trial commenced, ethical approval was sought from, and granted by the University of Huddersfield, School Research Ethics Panel (shown in Appendix 8.1). Permission to advertise in a local GP family practice was granted by the practice manager who was approached by the researcher. Participants self-referred to the University's private clinic to be assessed for eligibility for the pilot trial.

5.5 Sample

5.5.1 Recruitment method

Convenience sampling was necessary to access eligible participants efficiently, due to the associated time constraints and lack of funding for the pilot (Bowling, 2014). The purpose of this pilot trial was to provide a valuable insight and identify potential practical issues for conducting a larger-scale study, rather than to attempt to accept or reject the null

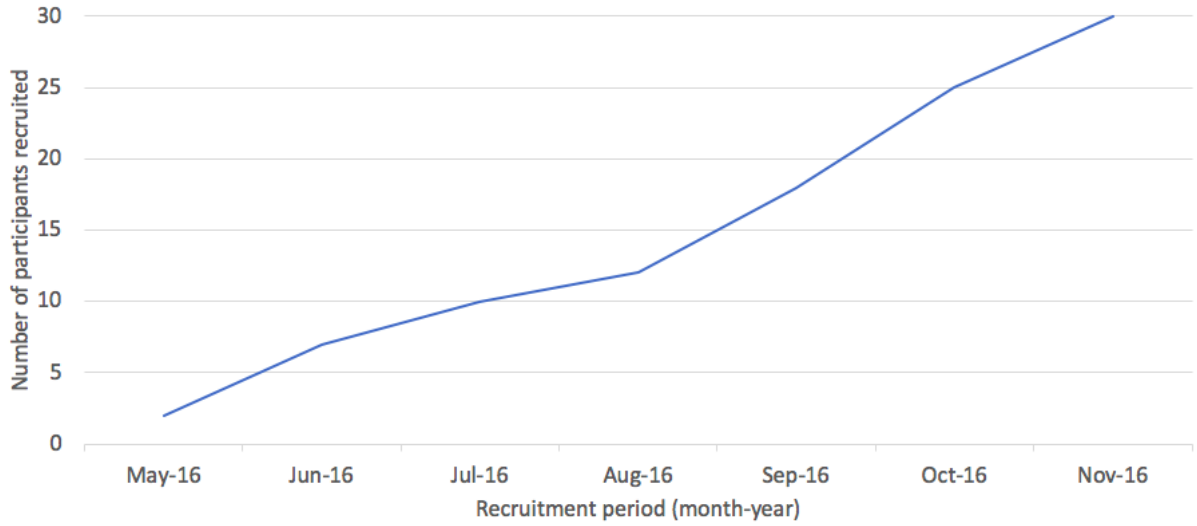
hypothesis. As a pilot study, it was not intended to achieve sufficient power to assess the effectiveness of the treatment, and therefore gaining a sufficient sample size for the study was not necessary, making a sample size calculation inappropriate in this case (Whitehead, Julious, Cooper, & Campbell, 2016). In the pilot study by Woodburn et al. (2000), which evaluated the effects of debridement in patients with painful hyperkeratosis and rheumatoid arthritis (RA), a total of eight participants were recruited. For pilot studies with two treatment arms, Julious (2005) suggests a minimum of 12 within each group. The number of participants recruited in all other RCTs not classified as pilot studies that evaluate the treatments for corns and calluses varies, ranging between 20 and 202 participants (Colagiuri et al., 1995; Farndon et al., 2013). This pilot study aimed to recruit a minimum of 10 participants in each treatment arm, as this was deemed appropriate to assess the practicality of performing a larger-scale study.

Students, members of staff, and patients at the University of Huddersfield clinic were targeted. Various advertisement strategies were implemented. A generic email was circulated to staff and students throughout the University (shown in Appendix 9.10). Posters were displayed on notice boards, and flyers were distributed in the cafeterias and in the podiatry clinic reception, highlighted in Appendix 9.11. Podiatry students and lecturing staff were made aware of the study informing potential patients in the University clinic. In addition to this, letters and posters were sent to local health practices, informing GPs of the trial in order to generate referrals to the clinic and further recruitment onto the trial.

Recruitment commenced at the beginning of May 2016 and finished at the end of November 2016. A six-month recruitment period was considered to be an appropriate

timeframe to enable a sufficient number of participants to be involved, without further restricting the time constraints of the study. Extending the recruitment period would not have been feasible, since total data collection occurred over a 12-month period, and participants were evaluated for six months of the total 12. Thirty participants were enrolled onto the study, with a total of 31 corns evaluated. Figure 5-1 illustrates the rate of recruitment during the six months. The majority of participants (n = 18) were recruited in the last three months of the study period, i.e., September to November. Few participants were enrolled in May (n = 2) and August (n = 2).

Figure 5-1: Participant recruitment during the six-month period.



5.5.2 Inclusion and exclusion criteria

Eligibility criteria were clearly outlined during the recruitment process. Criteria were carefully considered both to increase the accuracy of the results by attempting to reduce participant bias, and to protect participants from harm. In addition, careful criteria selection

was intended to enhance the external validity of the conclusions, by avoiding unnecessary exclusion of populations, which could restrict findings
(Patino & Ferreira, 2018).

Eligibility for the study included the presence of a corn located across the plantar metatarsal area. Participants were excluded if they met any of the following criteria:

- **Participants who were unprepared to implement an insole into daily activity.** Participants randomised to the intervention group were required to wear insoles routinely to enable the effects of treatment to be observed (Torgerson & Torgerson, 2008)
- **Participants whose regular-use footwear was unsuitable**. Sandals, high heels, plimsolls, and other narrow, depthless shoes were defined as inappropriate for inclusion. Prescribing insoles for use in inadequate footwear could cause harm to the patient due to the restriction of spacing in the shoe leading to discomfort and blistering (Frowen, O'Donnell, Lorimer, & Burrow, 2010).
- **Participants with current foot ulceration.** Ulceration treatment requires advanced management pathways to effectively provide quality of care to the patient. Involvement in the pilot trial could interfere with this and potentially prolong healing time.
- **Participants with pre-existing prescribed functional foot orthoses.** The insole used in this study aimed to reduce pressure at the site of the corn, rather than altering any malfunctions at the mid- or rear-foot (Frowen & Brewster, 2010). Removing the participants' functional device would have been inappropriate and unethical, as this would have reversed any benefit the patient had experienced.

- **Participants with sensory neuropathy.** Accurately reporting pain requires responses from the nervous system. Participants with neurological issues could have altered pain scores, thereby skewing any potential differences between groups, which could affect the internal validity of the results (Mueller et al., 2003).
- **Participants whose corn was infected.**
- **Participants with heloma millare (seed corns).** Heloma millare, the causes of which are still unknown, can occur on the plantar aspect of the foot. Since these lesions can occur on non-weightbearing borders of the feet suggesting excessive pressure is not the primary cause – including this type of corn in the analysis could influence the internal validity of the findings and conclusions (Freeman, 2002; Grouios, 2004).
- **Participants whose mental capacity prevented them from providing informed consent.**
- **Children**. Patients under 18 years were excluded from the study.
- **Patients who refused to participate in the study**.

5.6 Study measures

Previous research evaluating painful hyperkeratosis influenced the selection of outcome measures used in this pilot study (Bevans & Bosson, 2010; Farndon et al., 2013; Landorf et al., 2013; Siddle et al., 2013). Inclusion of an outcome measure was also dependent on whether this was deemed pertinent to patients, and if substantial evidence existed to support the validity and reliability of the outcome's measurement tool. The primary outcomes of this pilot study were: the presence of an improved plantar corn at six months following treatment, and time-to-resolution. Improvements were defined as either full

resolution (corn no longer being present), partial resolution (a greater than 50% reduction in baseline area measurement), or no change (a less than 50% reduction in baseline area measurement). Secondary outcome measures included: patient-reported pain associated with the corns; foot disability; health-related quality of life; and participant feedback on the insoles, including compliance rates. Previous studies have evaluated the effects on pressure and various gait parameters in the management of hyperkeratosis. These outcomes were not considered directly relevant to patients, therefore they were not included in this study.

Hunt and Hurwit (2013) conducted a review of patient-reported outcome measures used in foot and ankle research during a 10-year period. It was found that 139 outcome tools specific to the foot and ankle were implemented amongst the 878 studies included. This accentuates the vast variation in outcomes used to evaluate the efficacy of treatments, which could have an impact on podiatrists when making clinical decisions on evidence-based practice. Both Hasenstein, Greene, and Meyr (2017) argue that a methodological change towards consistent use of valid and reliable tools is essential to improve evidence and practice. The chosen tools to measure each outcome are identified and discussed below.

5.6.1 Demographics and corn parameters

It was essential to collect participant demographics and corn parameters, since a secondary aim of the study was to determine whether these characteristics were associated with differences in treatment effectiveness. Furthermore, by recording this data, subsequent analysis could identify whether these confounding variables were equally distributed during randomisation, and therefore allow an assessment of whether any differences seen

between groups were due to the treatment. The participants' general demographics that were documented included: age, gender, weight, height, typical footwear, and medical and social history. The information recorded relating to the corn included: number of years present, location, type, and any current and/or previous treatment.

5.6.2 Assessing corn resolution and time-to-resolution

To assess the presence of an improved corn in terms of resolution, measurements of the corn were taken at baseline. Disposable paper rulers were used to measure the width and length of the corn in millimetres to calculate the area – a commonly used method in clinical practice described within the literature (Bien, Anda, & Prokocimer, 2014). At follow-up and six-month evaluation, the area was assessed to determine if the corn was still present, and measurements were recorded onto an acetate lesion chart to capture progress. Previous studies evaluating the efficacy of treatments for hyperkeratosis have utilised this method (Bevans & Bosson, 2010; Farndon et al., 2013).

Whilst measuring lesions is an essential aspect of clinical practice to monitor and evaluate treatment progress to enhance quality of care, the majority of the research that evaluates techniques focuses on the measurement of wounds (Foltynski et al., 2015; Mirzaalian Dastjerdi, Töpfer, Rupitsch, & Maier, 2019; Wannous, Lucas, & Treuillet, 2011). Despite the wealth of research evidence, there is no gold-standard method outlined in the literature for measuring wounds or other skin lesions (Khoo & Jansen, 2016; Mirzaalian Dastjerdi et al., 2019). The ruler technique is the simplest, quickest, and least expensive method for measuring skin lesions, in comparison to digital planimetry methods (Wannous et al., 2011). Ahn and Salcido (2008) argue that digital methods are more favourable, as the precision and

inter-rater reliability can vary when using the ruler technique. This may only be applicable in the assessment of wounds, where the edges and borders are typically not well defined, making measurements more subjective. Although corns have a clearly demarcated border making measurements more objective – the same researcher assessed all corns to assist in improving reliability (Grouios, 2004).

Various methods of measuring the width and length of lesions to calculate the area have been described in the literature, including: measuring the greatest length and greatest perpendicular width, and measuring the greatest length and greatest width at any angle (Bien et al., 2014; Langemo, Anderson, Hanson, Hunter, & Thompson, 2008). Langemo et al. (2008) found that the most accurate measurements in assessing the area were the greatest length and greatest perpendicular width of the lesion for the different wound shapes evaluated (symmetrical, L-shaped, and pear-shaped). This method was implemented in the pilot study.

In addition to evaluating corn resolution rates between treatment groups, it was important to analyse any differences in time-to-resolution to help justify implementing the insoles in practice for managing corns. Participants were asked to return for follow-up appointments at two and four months.

5.6.3 Assessment of patient-reported pain

Pain on weight-bearing areas of the foot is commonly experienced by patients with plantar corns (Farndon et al., 2015; Grouios, 2004). This can lead to functional deterioration and altered gait patterns, particularly in the older population, which subsequently increases the

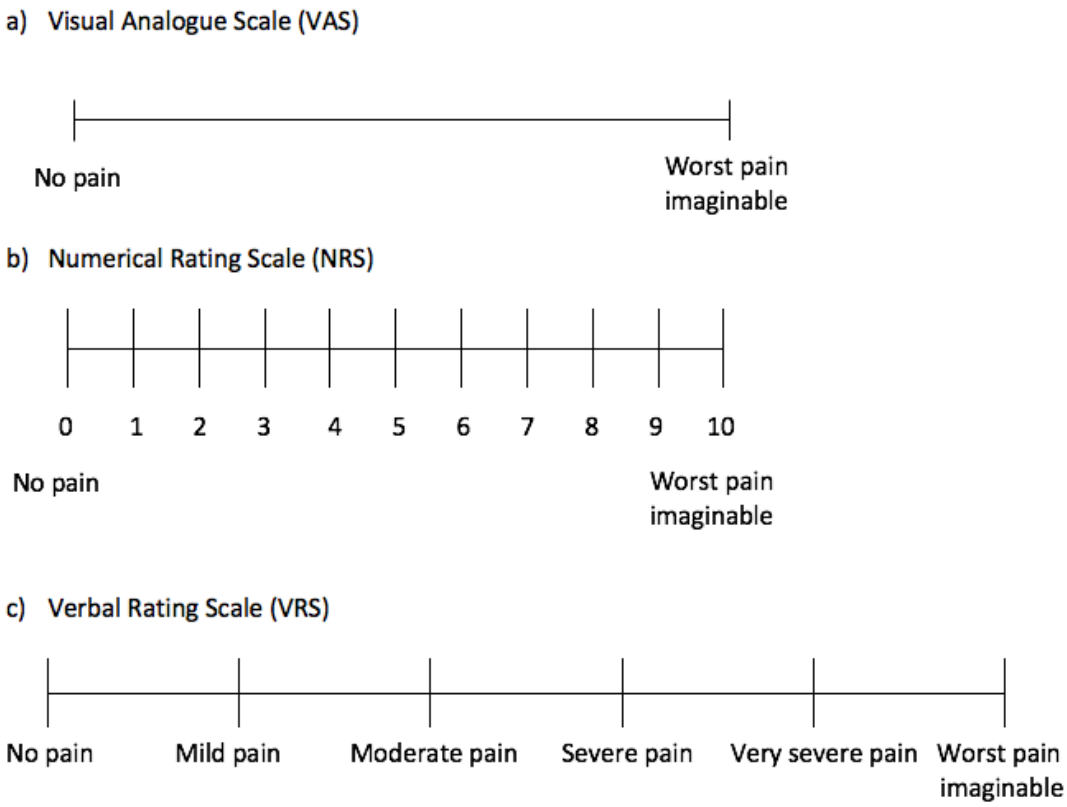
risk of falls and decreases health-related quality of life (Menz & Lord, 2001). Assessment of pain intensity associated with the lesion is essential to evaluate treatment success.

The most frequently used measure of pain intensity in clinical practice is a visual analogue scale (VAS) using a 100-mm vertical or horizontal line (Hasenstein et al., 2017; Hijji, Schneider, Pyper, & Laughlin, 2019). First described by Woodforde and Merskey (1972), the scale is designed to be self-completed by participants by asking them to mark on the line from 0 mm (indicating no pain) to 100 mm (worst pain imaginable) their perceived pain intensity. Alternative measures of pain intensity include: the numerical rating scale (NRS), the verbal rating scale (VRS), the McGill Pain Questionnaire, and pain dairies (Williamson & Hoggart, 2005). The McGill Pain Questionnaire is more complex than the aforementioned rating scales, and involves 78 descriptors that are used by respondents to specify their pain (Melzack, 1975). Pain diaries are another method used to interpret patients' self-reported pain (Scholz, 1995). One of the main benefits of this method is that as well as capturing pain intensity scores, information gathered would also include details of the activities the participant was carrying out at the time, etc (Gaertner, Elsner, Pollmann-Dahmen, Radbruch, & Sabatowski, 2004). It was decided that this additional data to assess the efficacy of the interventions for managing painful plantar corns was not necessary. The literature has identified causative factors for pain, which were discussed in Chapter 1 (Farndon et al., 2015). Furthermore a major limitation is the greater burden on participants' and researchers' time with respects to the large quantities of data collected (Scholz, 1995). Participants would be required to complete a daily diary of their pain symptoms This increased onus on the participant could increase the likelihood of missing data. Incomplete

data could impact on the accuracy of the study's findings, as estimates would have to be made of what the missing pain scores might have been.

The three commonly used rating scales to assess pain are shown in Figure 5-2.

Figure 5-2: Three pain assessment scales used in clinical practice.



The pilot study utilised a 100-mm VAS to measure participants' pain levels over the six months to examine their responses to treatment. A greater amount of evidence exists in support of the VAS to evaluate treatments in clinical practice, in comparison to other methods to measure pain. Whilst evidence is available to support the NRS, the VAS is more widely implemented and has been previously used in research evaluating treatments for

hyperkeratosis. Hijji et al. (2019) found in their review of 541 studies that the VAS was considerably more favoured in foot and ankle research than the NRS, with 42% (n = 227) implementing the VAS as an outcome measure, in comparison to 1.5% (n = 8) for the NRS. An abundance of research is available emphasising that the VAS has a high test-retest reliability, a high construct validity, and a good ability to detect changes in pain for a range of lower-limb conditions (Alghadir, Anwer, Iqbal, & Iqbal, 2018; Bird et al., 2016; Chiarotto et al., 2019; Ferraz et al., 1990; Gur et al., 2017; Jenson, Karoly, & Braver, 1986; Phan et al., 2012; Sindhu, Shechtman, & Tuckey, 2011). Importantly, Ferraz et al. (1990) highlight that test-retest reliability is slightly lower in illiterate participants (n = 65, r = 0.71) when compared to those who are literate (n = 25, r = 0.94).

The sensitivity of the outcome tool used to detect changes in pain over the duration of the six-month pilot trial is important. Jenson et al. (1986) found the VAS to have greater sensitivity in measuring participants' pain levels when compared to other scales, particularly the VRS. For a change to be apparent in the VRS, a larger response to the treatment modality is required due to the reduced number of options with which participants can give feedback (Williamson & Hoggart, 2005). Scrimshaw and Maher (2001) evaluated the sensitivity of the VAS to specify pain over a 24-hour period, in comparison to the McGill Pain Questionnaire, in 76 participants. Results demonstrated that the VAS was significantly more responsive to change (p = 0.004).

Recent research has evaluated the use of a digitally administered VAS, in comparison to the paper-based version (Bird et al., 2016; Delgado et al., 2018; Sindhu et al., 2011). Studies demonstrate good concurrent validity between tools with high correlation coefficients

reported by both Sindhu et al. (2011) (n = 33, r= 0.97) and Bird et al. (2016) (n = 22, r = 0.99). Similarly, results in the studies demonstrate high test-retest reliability scores. The paper-based VAS requires manual measurement of the marked value with a ruler, in comparison to the digital VAS, which automatically calculates the pain rating (Delgado et al., 2018). Whilst the digital VAS could be more efficient in measuring pain, the paper-based VAS was implemented in the pilot study for ease, as these scales were more readily available.

A horizontal scale was selected rather than a to vertical orientation. Previous research has found data to be more normally distributed around the mean when the VAS was presented horizontally, in comparison to vertically, particularly in participants who were English (Ogon, Krismer, Sollner, Kantner-Rumplmair, & Lampe, 1996). Aun, Lam, and Collett (1986) assessed the horizontal and vertical VAS on Chinese-speaking participants, who traditionally read vertically, and found the vertical scale to be more preferable. This implies that the reading method of the population influences the outcome of the VAS. Whilst Scott and Huskinsson (1979) found a high correlation between the two scales ($r = 0.99$, $p = 0.001$), scores were found to be slightly lower on the horizontal scales. This highlights the importance of remaining consistent with the orientation of the VAS during the pilot study.

Pain was assessed at three stages: prior to any debridement at baseline, at follow-up and at the final six-month evaluation.

5.6.4 Evaluating health-related quality of life (HRQol)

Whilst corn resolution is a key primary outcome for participants, foot pain caused by conditions such as corns can have a significant impact on patients' quality of life (Menz &

Lord, 2001). It was necessary, therefore, to measure the HRQol of participants both before treatment and at the six-month evaluation following intervention. HRQol is most frequently measured using the Medical Outcomes Study Short-Form 36 (SF-36) or EuroQol 5 Domain (EQ-5D) questionnaire tools (EuroQol Group, 2019; RAND Health Care, 2019; Selivanova, Buskens, & Krabbe, 2018). Data collected from either questionnaire is numerical, enabling statistical analysis of changes pre- and post-treatment, as well as differences between intervention groups. These tools are effective at measuring HRQol, as they enable an adequate assessment of multiple dimensions of health, which are pertinent to patients (Ravens-Sieberer et al., 2010). There is currently no recommended instrument with which to measure quality of life in patients with skin complaints, such as corns (Wukich & Raspovic, 2018). Brazier, Deverill, and Green (1999) argue that whilst the EQ-5D questionnaire is easy to administer and for respondents to understand, the sensitivity of the tool may not be sufficient to detect small changes in scores, particularly in minor health conditions. Despite this criticism, Farndon et al. (2013) utilised the EQ-5D questionnaire to evaluate HRQol in participants with painful corns, and reported significant changes amongst intervention groups at the 12-month evaluation ($p = 0.005$). Since no other studies are available that investigated HRQol in participants with corns, the EQ-5D-3L questionnaire was selected for use in the pilot study for consistency, and to enable comparisons.

Five health domains are assessed in the EQ-5D-3L instrument (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), in addition to a 20-cm VAS (shown in Appendix 9.12). Participants are asked to rate each domain on three levels (severe, moderate, none). In 1995, the Measurement Valuation of Health Group conducted a large survey on 2997 recruits to outline the possible values of health from the EQ-5D

questionnaire in the general population, to help verify its interpretation. Full health is scored as 1; should participants report problems in their health within any of the domains, their score is reduced, with the minimum possible score being -0.59. Prior to conducting the study, a licence for approval to use the questionnaire and scoring system was obtained, shown in Appendix 9.13.

Despite the wide validated support for the EQ-5D-3L questionnaire, the EQ-5D-5L was developed in 2009 to help address concerns within the literature regarding the former's sensitivity (Brazier, Roberts, Tsuchiya, & Busschbach, 2004; Macran, Weatherly, & Kind, 2003; Ravens-Sieberer et al., 2010). The number of levels participants can respond to within each domain has increased from three to five in the EQ-5D-5L questionnaire. The difference in the terminology of these additional levels are subtle, for instance, Level 4 corresponds to 'severe' problems; Level 5 corresponds to 'extreme'. Several research studies have demonstrated that this has caused difficulties for respondents when distinguishing their preferred perceived health status, which could impact on the findings' consistency (Craig, Pickard, & Rand-Hendriksen, 2015; Xie, Pullenayegum, Gaebel, Oppe, & Paul, 2014). Selivanova et al. (2018) conducted a large-scale study involving 3,698 participants to investigate the spread and weighting attributed to each of the levels and domains. The anxiety and depression domain was found to be the greatest contributor to overall health status in the EQ-5D-5L questionnaire, in comparison to EQ-5D-3L, where the highest weighting was found to be mobility. EQ-5D-3L questionnaire was considered more appropriate for the pilot study, as corns are deemed to have a greater impact on mobility than anxiety and depression (Menz & Lord, 2001).

5.6.5 Foot disability

Since foot problems have been strongly associated with deterioration in functional ability – typically in those aged 65 years and above – foot disability was also measured as a secondary outcome (Menz, 2008; Menz & Lord, 2001; Mickle, Munro, Lord, Menz, & Steele, 2011a; Roddy, Muller, & Thomas, 2009). The Manchester Foot Pain and Disability Index (MFPDI) questionnaire tool was utilised to measure participants' foot disability at baseline prior to commencing treatment, and at the six-month evaluation. It was considered inappropriate to measure both foot disability and HRQol at the two-, three- and four-month follow-up appointments, as it was assumed that changes within this period would be minimal.

The MFPDI was developed and validated by Garrow et al. (2000). Prior to this, no questionnaire tool was available to measure foot-specific disability in the general population. Other questionnaires, including: the Functional Limitations Profile questionnaire and the Foot Health Status Questionnaire, are useful in evaluating participants' walking function and overall foot health, but are unable to determine disability and its impact associated with a condition specifically related to the foot (Brudiman-Mak, Conrad, & Roach, 1991). Garrow et al. (2000) evaluated the questionnaire on 1,000 participants, and demonstrated high internal consistency in reliability testing (Cronbach's alpha analysis = 0.99). High reliability has been found in other subsequent research, reporting similar Cronbach's alpha analysis of 0.86 and above (Dawson et al., 2006; Roddy et al., 2009). High degrees of content, construct, and criterion validity have been demonstrated through interviews and subsequent investigations comparing differences between participants' foot health profiles and their responses to the questionnaire (Garrow et al., 2000).

The MFPDI is a simple and widely used questionnaire employed in other similar clinical trials (Farndon et al., 2013; Spink et al., 2011; Waxman et al., 2003). It consists of 19 items relating to functional limitation, pain intensity, personal appearance, and the ability to perform work and leisure activities (see Appendix 9.14). Participants are required to respond using one of three categories: “none of the time” (score = 0), “on some days” (score = 1), “one most/every day(s)” (score = 2) (Riskowski, Hagedorn, & Hannan, 2011). A licence to use the questionnaire and associated scoring system was obtained prior to commencing the pilot trial, shown in Appendix 9.15.

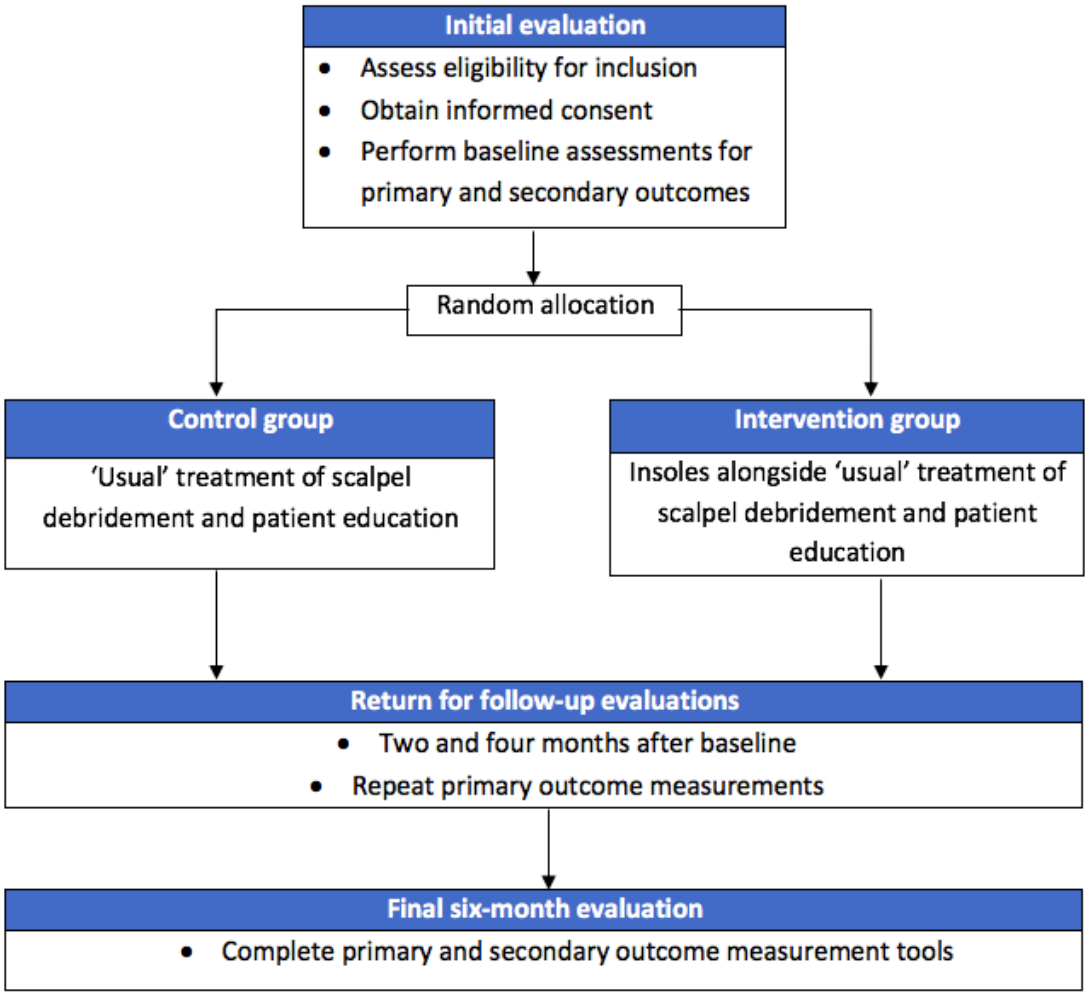
5.6.6 Participant feedback and compliance with insoles

Participants’ perceptions of the insoles were important to inform future insole use in clinical practice and any further investigation that might be undertaken. A short questionnaire was developed, shown in Appendix 9.16. Participants randomised to the insole group were asked to self-complete the questionnaire at the six-month evaluation. It involved rating the comfort of the insoles and ease of use on a scale of 1 (being very uncomfortable and very difficult) to 5 (very comfortable and very easy). Participants were asked if they believed that the insoles had benefited the management of their corn, and to explain why. In addition, to assist in measuring compliance rates a question on how often participants wore the insoles during the study was included. Regular wear of the insoles was vital to maximise the treatment’s full potential and its effect on the research outcomes. Insoles were also reviewed at each follow-up appointment to examine wear and durability.

5.7 Data collection

An overview of the data collection process is shown in Figure 5-3.

Figure 5-3: Overview of the data collection process.



All data collection occurred at the University of Huddersfield's podiatry clinic. Each participant had a separate paper-based file, which was kept on the University site, and stored in a locked cupboard in a locked room.

At the initial appointment, diagnosis of the suspected corn was achieved through clinical observations by the principal investigator. This involved ruling out differential diagnoses, such as callus and verruca pedis. Once a corn diagnosis was confirmed, participants were assessed against the exclusion criteria outlined in Section 4.5.2. Prior to participants giving their informed consent for inclusion in the study and for the associated treatments, an outline of the study including expectations was reiterate, and any questions raised were answered.

Treatment allocation was randomly selected. Participants received either: the 'usual' treatment of debridement and patient education, alongside a metatarsal padded insole; or the 'usual' treatment alone. If a participant presented with more than one corn, these were individually analysed and included in the final analysis. Whilst Timson and Spooner (2005) included only a principal callosity in their evaluation of insole therapy, this does not reflect outcomes in real-life clinical practice. Clinicians would treat and to aim to resolve all corns that a patient presents with, and in the case of multiple corns, a cut-out would be placed at the site of each corn present. Conducting this pilot prior to a large-scale RCT gave the opportunity to evaluate the feasibility of this method, that is, including participants with more than one corn in the analysis, with respects to any data clustering effects. Only one participant recruited had more than one corn, and they were randomised to the intervention group. There did not appear to be any effect on data clustering. Although the demographic characteristics for the two data sets associated with this participant were the same, the characteristics of the corns differed, including their sizes and associated pain.

In addition to recording the participants' general medical and social history, a thorough history of the corn(s) was established, including: duration, previous treatment, location, and type. Participants were asked to complete a questionnaire to gain further demographic data (see in Appendix 9.16). Measurements of the participants' weight (kg) and height (cm) were recorded on the questionnaire. Participants were asked how many hours they typically spent a week undertaking various activities, if any. Physical activity is considered an important factor in corn formation, with Benvenuti et al. (1995) and Springett et al. (2003) reporting a higher prevalence in those who are more physically active. It was important, therefore, to collect this information to determine if this variable had been equally distributed between groups during randomisation. Similarly, participants were required to provide details of their occupation, since this would also influence the intensity and duration of activity that a participant would spend on their feet. In addition, whilst the participants were required to wear suitable footwear during the six-month evaluation, they were also asked to define the type of footwear that they wore most often prior to enrolling onto the pilot study.

Baseline assessments were completed and recorded in each participant's file, which included:

- Measurements of the corn (mm), recorded on an acetate lesion chart.
- Photographs of the corn before and after debridement.
- Pain associated with the corn on the 100-mm VAS.
- EQ-5D-3L questionnaire.
- MFPDI questionnaire.

After the initial assessment, participants were required to return for follow-up assessment every two months, with the final evaluation at six months. The EQ-5D-3L and MFPDI questionnaires were only completed at baseline and at the six-month evaluation.

5.7.1 Sharp debridement

Both treatment groups received the 'usual' treatment of SSD and enucleation of the corn with standard patient education on foot health. Plantar corns were debrided using a scalpel with a number 15 blade, which is routinely used for the debridement of callosities and corns (Freeman, 2002; Frowen & Brewster, 2010). A standardised protocol for debridement was followed to ensure patient safety and to optimise consistency (see Appendix 9.17) (Frowen et al., 2010). Debridement and enucleation of corns and callosities is associated with low inter-rater reliability, due to the subjectivity of the treatment. This was one of the main limitations of the study by Landorf et al. (2013), who used multiple student practitioners to debride lesions. Several other studies addressed this issue by restricting debridement to one qualified and experienced podiatrist (Davys et al., 2005; Gijon-Nogueron et al., 2015; Gijón-Noguerón et al., 2017). This method was used by this pilot study. Since the optimal degree to which a lesion is debrided is subjective, it was essential to optimise intra-rater reliability of the study. To verify intra-rater reliability, an independent podiatrist external to the study examined photographs of the corns post-debridement from five randomly selected participant files. These were then judged by the external podiatrist as to whether they had been debrided to a consistent and satisfactory standard. Should there have been any discrepancy, the participant's data relating to that corn would have been excluded. Constructive feedback would then have been discussed and acted on appropriately.

5.7.2 Patient education

Foot health promotion is an area that is becoming increasingly researched. This is likely due to the ever increasing demand on podiatry services (Farndon, Vernon, & Moore, 2007). A review of activity across 37 NHS services identified an average of 1,952 referrals per 100,000 of the population (NHS Benchmarking Network, 2015). In addition podiatrists have recognised their ability to further improve patient-related outcomes by utilising the facing contact time with patients more effectively. Podiatrists average face to face contact time with patients is 19 minutes, which is considerably higher than other Allied Health Professionals (AHPs) (NHS Benchmarking Network, 2015).

Research has been conducted to evaluate the efficacy of self-foot care programmes amongst the elderly with diabetes (Donohoe et al., 2000; Nguyen, Edwards, Do, & Finlayson, 2019), rheumatoid arthritis (Graham & Williams, 2016; Stolt et al., 2017), and those who were otherwise healthy (Farndon et al., 2007; Waxman et al., 2003). Waxman et al. (2003) randomised 153 participants aged 60 years and over to receive either a self-management programme or usual foot care by a professional. At six months lower disability scores were found in the group that received the self-management programme, with a median difference of -1 ($p = 0.019$). Participants who received self-management education returned for fewer appointments during the six month evaluation, 32 in comparison to 92. This demonstrates that by encouraging patients to self-manage could enable priority groups to access care they require more efficiently, which would otherwise be frequently used by non-urgent cases. Despite this positive finding it is important to recognise that 63% (n = 259) of the 529 participants invited to participate refused, with over half reporting a lack of

interest and preference for usual care. Donohoe et al. (2000) found attitudes towards footcare were significantly improved in participants with diabetes that received an integrated educational initiative, in comparison to those that received standard delivery of care ($p < 0.001$, 95% CI 1.29 to 5.07). A limitation of the study's findings was the large number of incomplete questionnaires, which influences the internal validity (40%, n = 1,163). Whilst there was no difference in the number of incomplete questionnaires between groups, this impacts on the statistical power of the study's findings. Research has shown that health promotion interventions have positive effects for patients, although further research is required to investigate the long term impact on these population groups.

In addition to SSD, standard treatment of corns and callus typically involves patient education and promotion of the frequent application of topical emollients, typically urea based (Locke, Baird, Hendry, 2012). Observational studies have revealed that decreased moisture content of the stratum corneum, outermost layer of the skin, degrades the desmosome links and intercellular lipids of keratinocytes (Bouwstra et al., 2003; Wu et al., 2006). This leads to decreased cohesion of the keratinocytes and impacts the skins' ability to withstand mechanical stress, accelerating the stiffness of the skin. Several small scale studies have found that urea based emollients are effective at rehydrating the skin (Baird, Skinner, Trail, & Frankie, 2003; Scholermann, Paschen, Filbry, & Rippke, 2007; Tausch, Bohnsack, Scholermann, Rippke, & Gassmuller, 1997). It is not clear how a urea based cream compares to other types of emollients, as the studies either compare an alternative urea based product or the use of no emollient. The sample sizes of the studies are insufficient to permit adequate statistical power of the findings. Alongside analysing the effects on skin hydration, other outcomes need to be evaluated that are pertinent to the patient, including

the subsequent effects on pain experienced by the hyperkeratosis. Despite the limitations of the studies, urea based emollients continue to be promoted within clinical practice due to continued anecdotal evidence to support their use (Locke et al., 2012). Further research is required using larger sample sizes to measure short- and long-term effects of regular emollient use.

There is an abundance of evidence in support of motivational interviewing as the most effective method to promoting behaviour change (Burke, Arkowitz, & Menchola, 2003; Lundahl, Kunz, Brownell, Tollefson, & Burke, 2010). When promoting health it is essential to advocate and mediate the education to enable the patient to adopt change more effectively, rather than dictating advice. The key principles of motivational interviewing were considered when delivering health promotion education in the project.

Alongside debridement, to follow routine practice standardised education was provided to all participants (Hashmi et al., 2016). This involved discussing the importance and benefits of daily emollient use with the participant at baseline assessment. Participants were advised to apply a 10% urea based emollient to both feet, focusing on areas of hyperkeratosis and avoiding interdigital areas. Examples of 10 % urea based creams and where to source these were highlighted to the participant, such as: Flexitol, CCS, Dermatonics, and Calmurid. Carers or family were provided with the education, should participants have been unable to reach their feet to apply the emollient effectively. This advice was provided both verbally and written at baseline, and discussed verbally at subsequent visits.

5.7.3 Construction of the insoles

Participants randomised to the insole group were provided with one pair of insoles, which could be used interchangeably between footwear. A pair was provided to participants, rather than a single insole just for the affected foot, to assist in improving comfort and balance during walking. Just one pair was initially supplied to participants, in order to assess the durability and wear of the devices. The life-span of insoles also depends on activity level, and the frequency worn. Subsequent insoles were provided to participants, should they have required replacing. A standardised approach (outlined in Appendix 9.18) was utilised to manufacture and fit the insoles for participants, which was developed in line with the guidance in podiatric textbooks and from previous research (Dawber et al., 2001; Frowen et al., 2010; P. Lee et al., 2014; Yates & Merriman, 2009).

5.8 Data analysis

The IBM Statistical Package for the Social Sciences (SPSS) version 24 was used to analyse the data. Data was primarily analysed descriptively by presenting the means and standard deviations for numerical variables, such as corn size and associated pain, and frequencies for categorical variables including, resolution rates. Independent Samples t-tests were conducted to compare means for corn size and pain experienced at baseline and at six months, between the intervention and control groups. To determine the time-to-resolution of the corn from baseline to six months between groups survival analysis was performed using non-parametric methods was performed to determine the corns time-to-resolution from baseline to six months. Kaplan-Meier graphs were then used to interpret the data, and

subsequent log-rank hypothesis testing was undertaken to compare the difference in time taken for corn resolution in both groups.

5.9 Funding

DLT Podiatry Supplies funded the cost of the insole materials, which included: Texon, PodoPro Urethane, and Poron – for the base material, metatarsal pad, and top cover, respectively. There were no conflicting interests. The appointment fee of £12 for each participant to attend the clinic for treatment was kindly subsidised by the University of Huddersfield; it was thought that recruitment onto the pilot trial would generate future learning resources for the undergraduate students by increasing the patient caseload. In addition, disposable scalpel blades were also funded by the University.

5.10 Summary

In summary, this chapter has outlined the methods used to investigate the use of metatarsal padded insoles in the management of plantar corns. The results of the investigation are described in the following chapter.

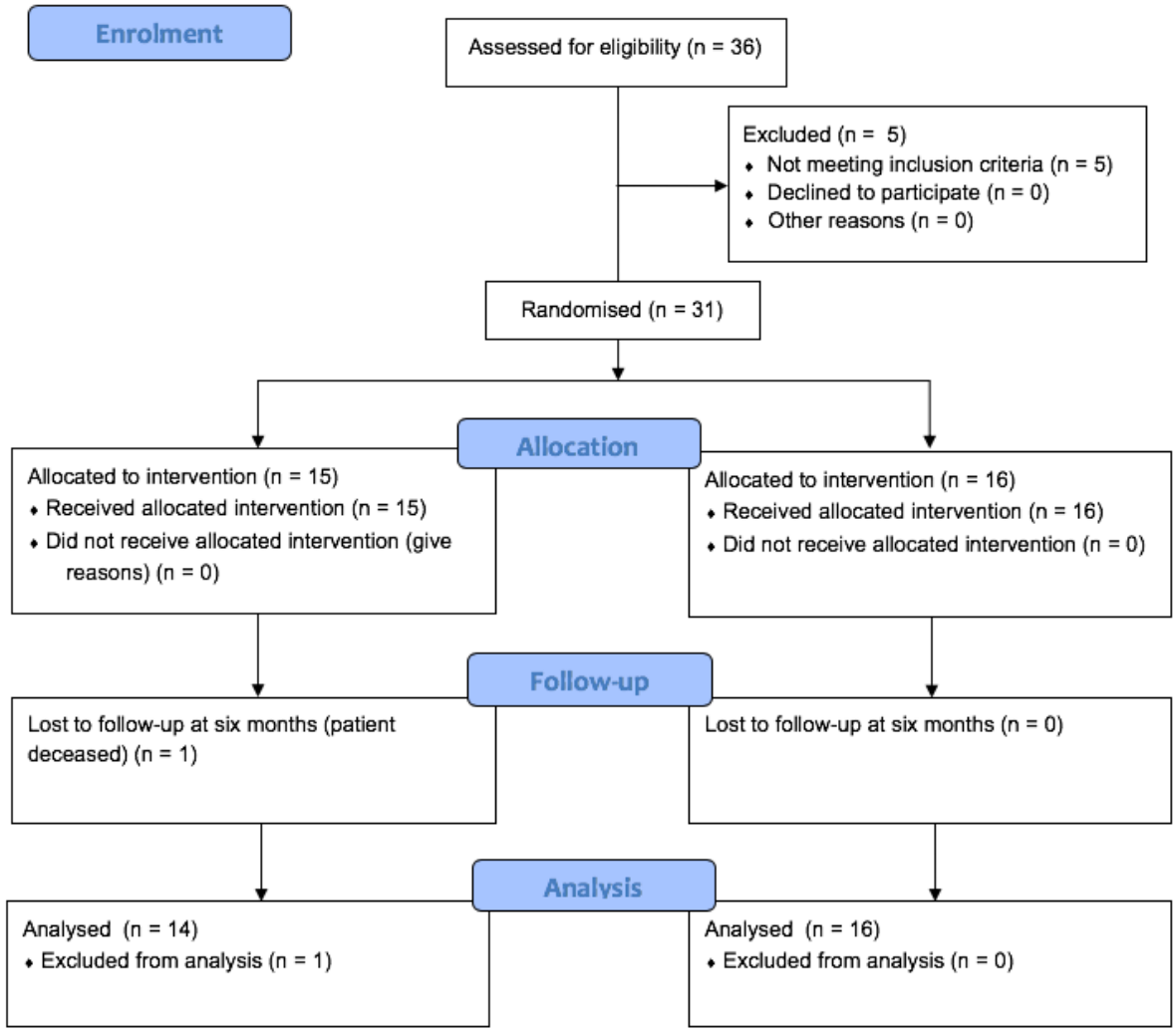
Chapter 6 - Results of the proof of concept pilot trial

The general overall function and nature of the pilot study was to determine if a large randomised controlled trial (RCT) would be viable. This chapter presents the data, which was mainly explored descriptively, in addition to some inferential statistical analysis for the proposed primary outcomes (resolution rate and time) and secondary outcomes (pain, foot disability, health-related quality of life, compliance, and durability of the insoles). The proof of concept pilot was neither designed nor powered to seek statistical significance. The aim of performing the analysis was to expose any potential problems for future investigation, whilst beginning to evaluate whether the inclusion of a metatarsal padded insole, alongside sharp scalpel debridement (SSD) and enucleation, provides any additional benefit in the management of plantar corns (Leon, Davis, & Kraemer, 2010).

6.1 Recruitment and follow-up rates

A total of 30 participants were recruited to the study for the six-month period. Data is presented as a CONSORT flow diagram to highlight the recruitment and follow-up rates of the pilot study (see Figure 6-1).

Figure 6-1: Recruitment and follow-up data.



Enrolment: From the 35 patients who expressed interest and attended for an initial assessment, most were recruited through the university clinic via posters and invitation letters (n = 18, 51.4%). Fourteen (40%) patients self-referred to the clinic after becoming aware of the pilot through posters displayed in their local GP practice. Finally, three (8.6%) were recruited via the university staff intranet. Of the 35 who attended for an initial appointment, five patients did not meet the inclusion criteria: three were diagnosed with a verruca rather than a corn, and the remaining two did not meet the inclusion criteria for involvement in the study. These two patients, due to the time of year, wore flat open

sandals and were not prepared to wear suitable footwear to accommodate the insoles, should they be potentially randomised to the intervention group.

Allocation: Overall, 31 corns were investigated from 30 subjects, with 15 randomised to the control and 15 to the intervention groups. Only one participant had more than one painful corn, one of which was located on the right second metatarsophalangeal joint (MTPJ); and the other was located on the left. This participant was randomised to the intervention group. Outcome measures were recorded for both lesions and received the same intervention.

Follow-up: Attrition loss during the six-month evaluation was minimal. Only one participant in the control group did not attend the four-month follow-up or final evaluation, due to unforeseen circumstances. Another participant in the control group did not attend their four-month follow-up appointment, as the participant was too busy with work-related commitments. It is unlikely the participants lost to follow-up will have had an impact on the characteristics observed between the two groups, as the numbers lost were too low, thereby reducing attrition-related bias of the results (Dumville, Torgerson, & Hewitt, 2006).

Analysis: Intention-to-treat (ITT) analysis was applied to avoid any potential bias in overestimating the efficacy of the metatarsal padded insoles (Elkins & Moseley, 2015). The design of the pilot is pragmatic, and therefore it is necessary to include in the analysis patients who may have deviated from the treatment protocols (such as non-compliance with the insoles) and withdrawals, as this is likely to reflect events that occur in clinical practice. In total, 31 corns were included in the inferential analysis.

6.2 Characteristics of the sample

Participants recruited included a greater number of females (n = 18, 58%) compared to males (n = 13, 42%). These ratios were approximately seen within each group after randomisation, as demonstrated in Table 6-1. The frequencies of other pertinent variables are also presented in Table 6-1.

Table 6-1: Demographics of participants.

Characteristic		*Control*	*Intervention*	*All Participants*
Gender	Males	6 (19%)	7 (23%)	13 (42%)
	Females	9 (29%)	9 (29%)	18 (58%)
Mean age in years (SD)		66.9 (12.3)	58.7 (12)	62.7 (12.6)
Mean BMI in kg/m^2 (SD)		27.6 (4.51)	27.2 (3.45)	27.4 (3.91)
Occupation	*Unemployed*	0 (0%)	2 (100%)	2 (6%)
	Physically demanding	1 (17%)	5 (83%)	6 (19%)
	Mentally demanding	5 (50%)	5 (50%)	10 (32%)
	Retired	9 (69%)	4 (31%)	13 (42%)
Vigorous activity level	*Less than recommended*	9 (47%)	10 (53%)	19 (61%)
	Recommended	3 (50%)	3 (50%)	6 (19%)
	More than recommended	3 (50%)	3 (50%)	6 (19%)
Moderate activity level	*Less than recommended*	1 (14%)	6 (85%)	7 (23%)
	Recommended	2 (33%)	4 (66%)	6 (19%)
	More than recommended	12 (67%)	6 (33%)	18 (58%)
Footwear	*Inappropriate*	8 (53%)	9 (56%)	17 (55%)
	Appropriate	7 (47%)	7 (44%)	14 (45%)

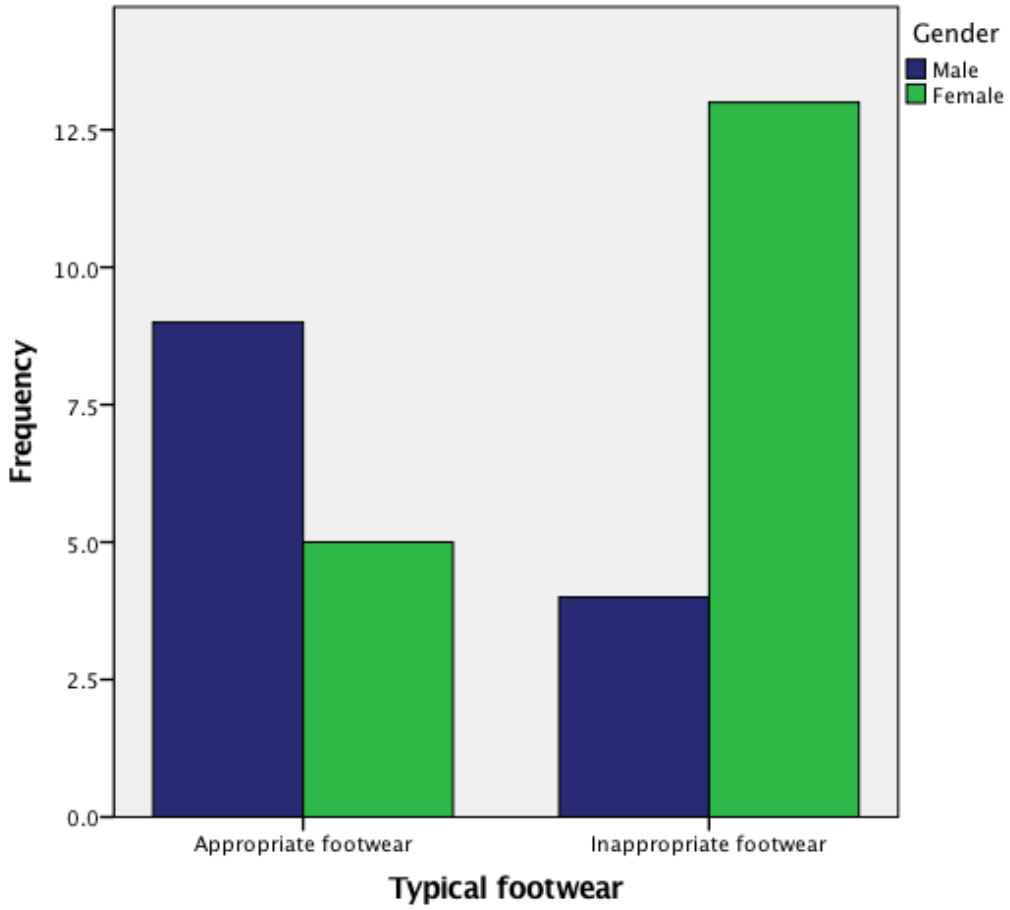
The mean age of all the participants included was 62.7 years (SD 12.6), and ages ranged between 42.0 and 85.0 years. Participants in the intervention group were slightly younger, with a mean age of 58.7 years (SD 12.0, range 42.0-81.0 years) compared to 66.9 years (SD 12.3, range 47.0-85.0 years) in the control group. This slight imbalance noted in age is reflected in the differences of occupations of participants amongst the control and intervention groups. Whilst the majority (n = 13, 42%) of participants were retired, nine (69%) of these were in the control group. Five (83%) of the six (19%) that had physically demanding jobs, such as a gardener or warehouse worker, were randomised to the intervention group and were younger in age. Ill-health was the reason for two participants being unemployed, and they were randomised to the intervention group. These imbalances could have implications on the effectiveness of the treatments reported. Research evidence suggests that the development of hyperkeratotic lesions, such as corns, is exacerbated by the amount of physical activity and time spent in weight-bearing activities (Grouios, 2004; Spink et al., 2009).

It could be proposed that the retired participants, more of whom fall into the control group, may be less physically active and as a result experience reduced pressures at the sites of the corns. This could lead to an overestimated improvement in resolution rates and time-to-resolution in the control group, although it was found that both control and intervention groups partake in less than the recommended amount of vigorous activity (n = 19, 61%).

The BMIs of the participants were balanced evenly between control and intervention groups, with means of 27.6 and 27.2 kg/m^2, respectively. In addition, groups were approximately evenly matched in terms of their typical footwear prior to commencing the

trial. Most participants (54.8%) described footwear that was defined as ‘inappropriate’. When analysing gender differences in footwear, males (n = 9, 69%) were found to wear more ‘appropriate’ footwear than females (n = 5, 28%), demonstrated in Figure 6-2.

Figure 6-2: Gender differences in participants' typical footwear.



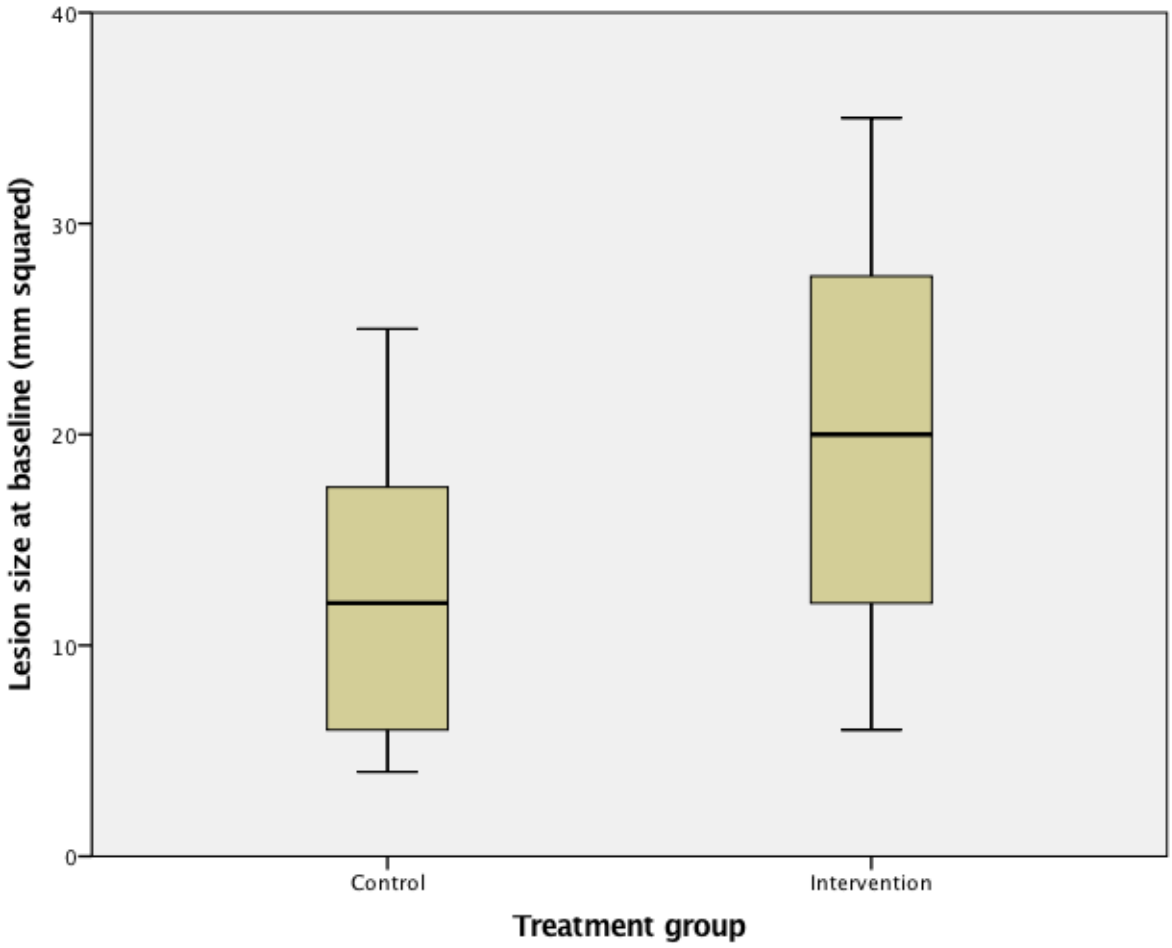
Inappropriate footwear, such as court shoes, are a precurser for corn development, and exacerbate the symptoms experienced (Menz & Morris, 2005). Females may therefore respond poorly to either treatment, should the recommended advice not be followed, due to the negative impact of their footwear (McRitchie, Branthwaite, & Chockalingam, 2018).

This should not influence the internal validity of findings, as females were evenly matched between groups.

6.3 Characteristics of the corns at baseline

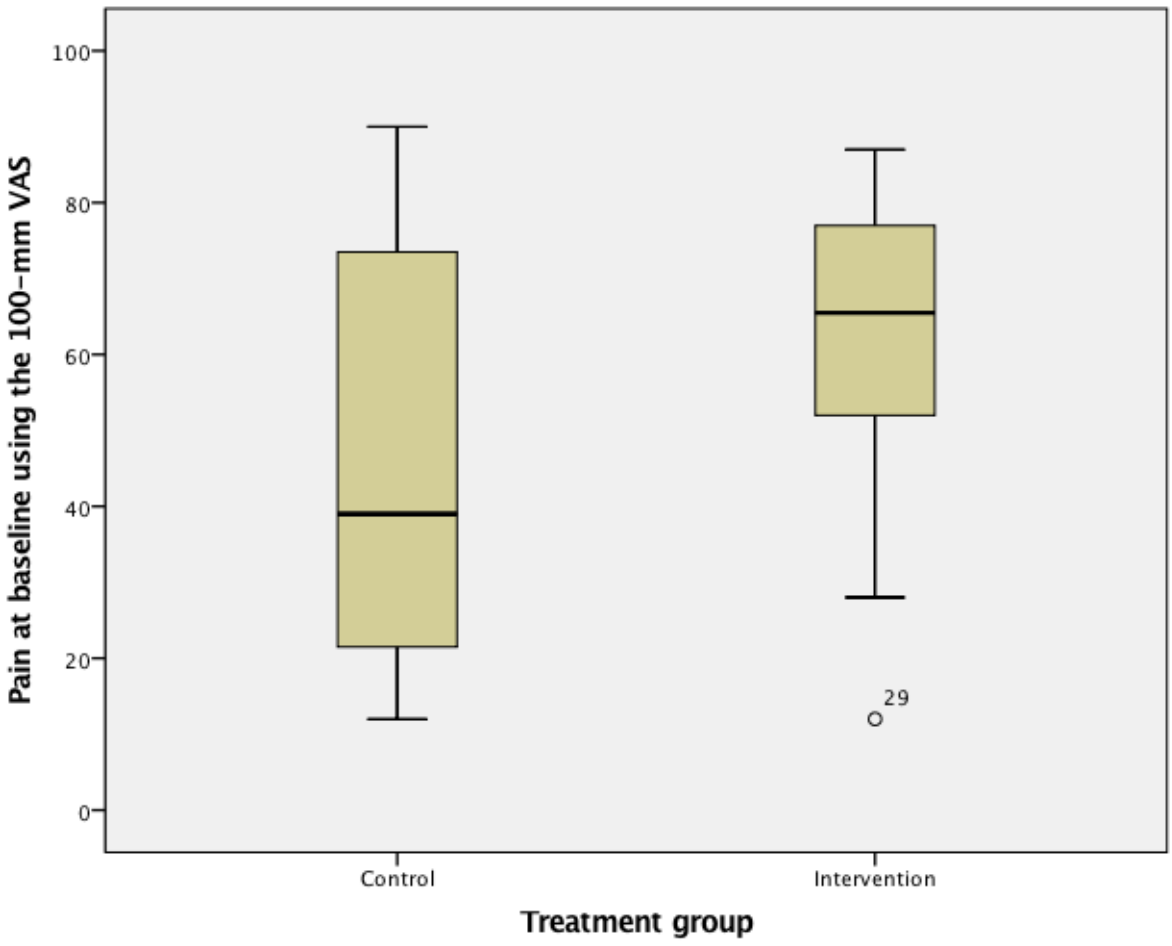
All participants involved in the study presented at baseline with great differences in the size of their corn(s) (4-35 mm^2) and associated pain on the 100-mm Visual Analogue Scale (VAS) (12-90 mm). Figure 6-3 presents the spread and distribution of corn size between treatment groups.

Figure 6-3: Distribution of corn size at baseline between treatment groups.



The distribution in corn size was greater in the intervention group, presenting with a minimum size of 6.0 mm^2 and maximum size of 35.0 mm^2, in comparison to 4.0 mm^2 and 25.0 mm^2 in the control group. The intervention group had a higher mean size of 20.8 mm^2 (SD 9.2 mm^2) in contrast to the control group with 12.7 mm^2 (SD 7.0 mm^2). In addition, there was variation in pain scores at baseline for the treatment groups, presented in Figure 6-4.

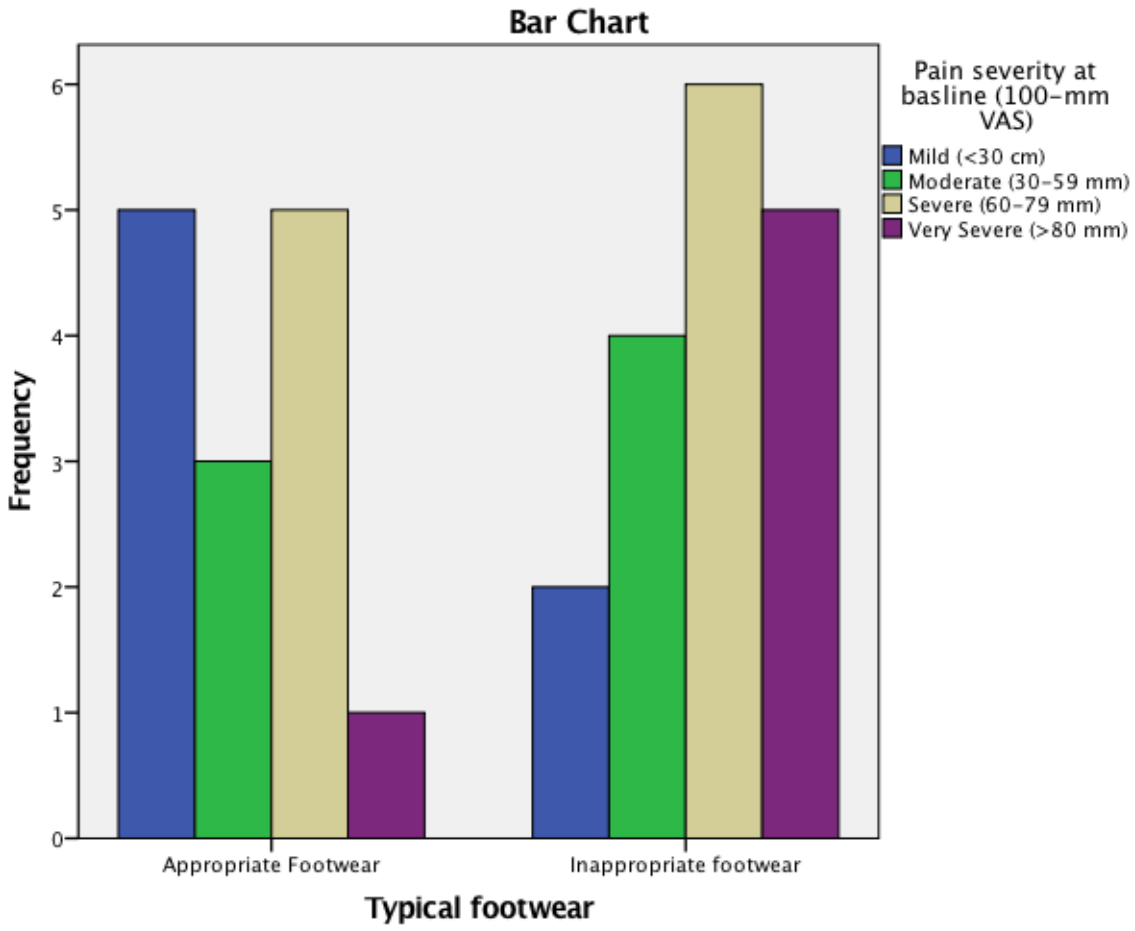
Figure 6-4: Distribution of pain scores at baseline between treatments.



The control group had a large range of reported pain levels at baseline, from 12 mm to 90 mm, with a large interquartile range of 60 mm. An outlier is present in the plot for the intervention group. Only two participants reported pain levels below 42 mm in the intervention group, which could skew the data, although it was decided to leave the outlier in place. A greater mean pain score of 62 mm (SD 21 mm) was still found in the intervention group, in comparison to 47 mm (SD 30 mm) in the control. Despite randomisation, the intervention group presented with a greater mean corn size (8.1 mm^2) and increased level of pain (15 mm) at baseline, and these differences could impact on the effective interpretation of the treatment outcomes. The intervention group had larger scope for improvement, and therefore the 'usual' treatment of debridement would have had to provide advanced benefit to demonstrate its efficacy. These differences at baseline, however, were adjusted for in the statistical analysis (Dumville et al., 2006).

Participants who wore footwear considered to be inappropriate prior to commencing the trial, presented with greater levels of pain at baseline on the 100-mm VAS of 30 mm and above, which is classified as moderate to very severe pain, illustrated in Figure 6-5.

Figure 6-5: Differences in footwear worn by participants and pain experienced at baseline.



Additionally, it was found that participants who presented with pain levels of 60 mm and above on the 100-mm VAS (categorised as severe to very severe) were not as active as those who reported less pain. Figures 6-6 and 6-7 highlight that a greater number of participants who experienced severe to very severe pain with their corns undertake less than the recommended amount of moderate and vigorous exercise.

Figure 6-6: Distribution of involvement in moderate exercise in relation to baseline pain levels.

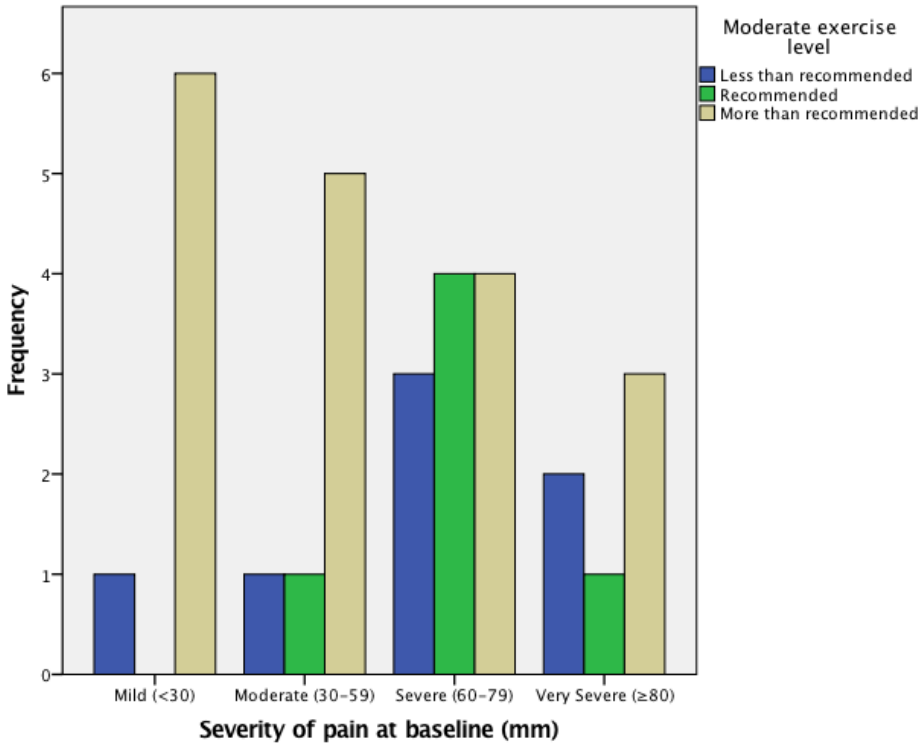
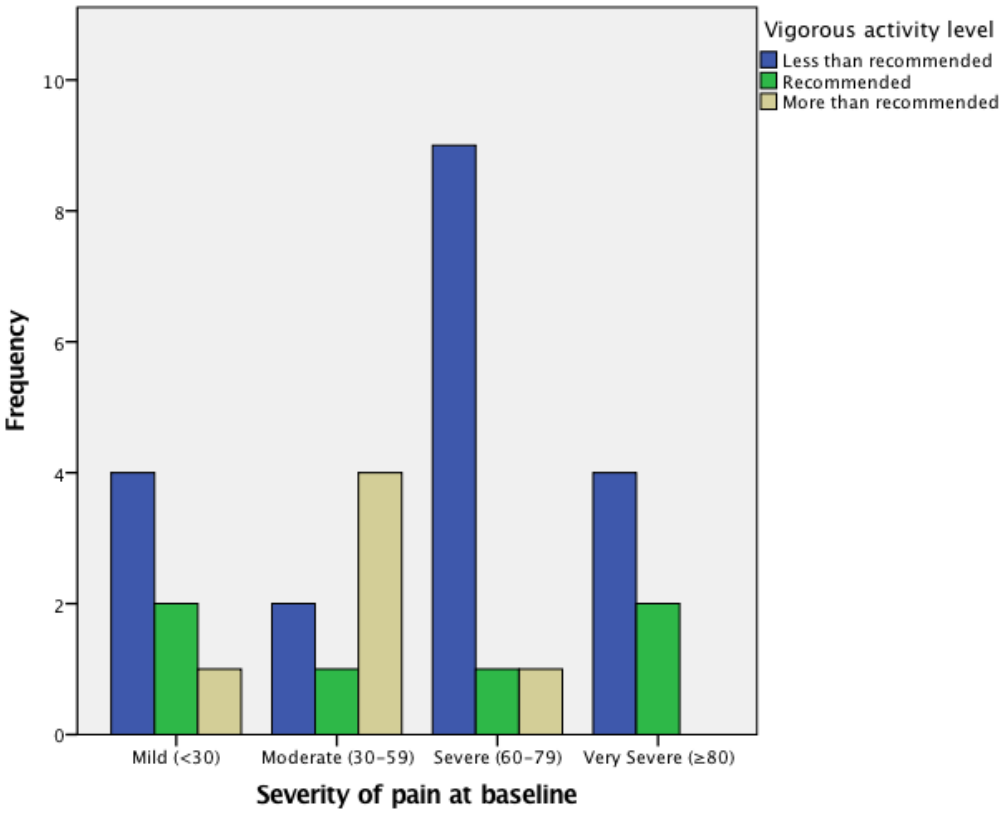


Figure 6-7: Distribution of involvement in vigorous exercise in relation to baseline pain levels.



A comparison of the characteristics of participants' corns between groups, including the corn type and location, are presented in Table 6-2.

Table 6-2: Characteristics of the participants' corns.

Characteristic		Control	Intervention	All participants
Type	*Heloma Durum*	14 (56%)	11 (44%)	25 (81%)
	Fibrous/neurovascular	1 (17%)	5 (83%)	6 (19%)
Location	*1st MTPJ*	3 (100%)	0 (0%)	3 (10%)
	2nd MTPJ	6 (55%)	5 (45%)	11 (35%)
	3rd MTPJ	0 (0%)	3 (100%)	3 (10%)
	4th MTPJ	0 (0%)	2 (100%)	2 (6%)
	5th MTPJ	6 (50%)	6 (50%)	12 (39%)

Importantly the type of plantar corn was also recorded, as fibrous and neurovascular corns are renowned within the literature for their lack of response to treatment due to their chronic complex nature, as discussed in Chapters 1 and 2 (Bevans & Bosson, 2010). Whilst most of the corns (n = 25, 81%) were defined as a heloma durum and were evenly distributed amongst the groups, five of the six (83%) fibrous and neurovascular corns included in the pilot were randomised to the intervention group. Seven of the participants with a heloma durum reported pain less than 30 mm on the VAS at baseline, in comparison to participants with fibrous and neurovascular corns, who all had pain levels greater than 30 mm.

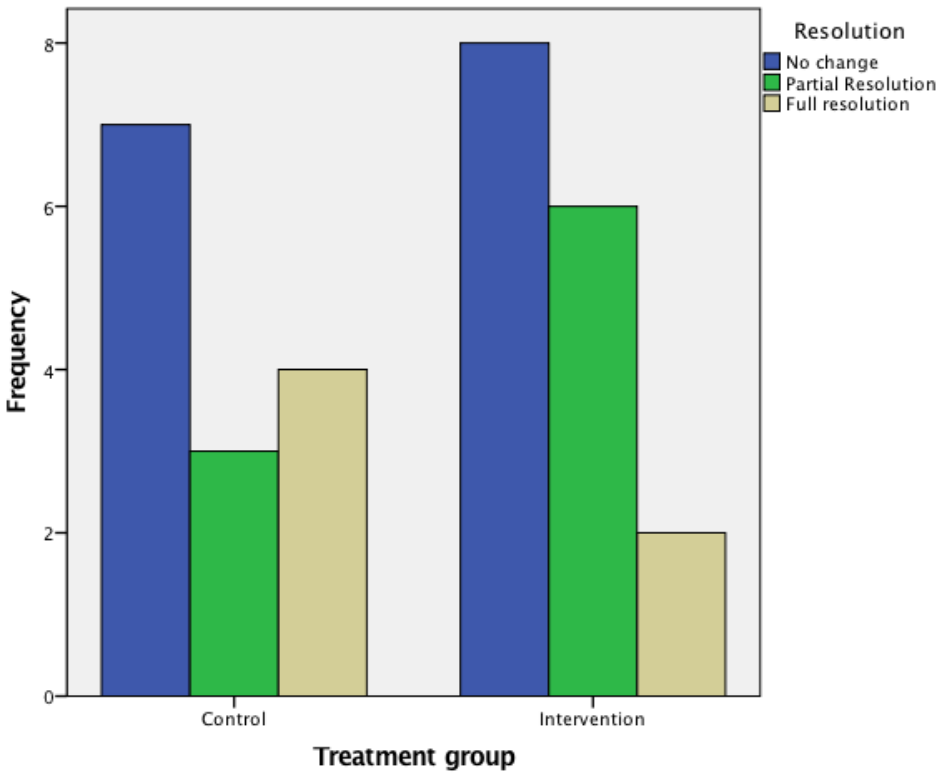
In summary, the randomisation process evenly distributed many variables, however there were imbalances amongst some important characteristics that may influence the outcomes

and subsequently bias the statistical analysis (Dumville et al., 2006). The substantial differences found were that participants in the intervention group had larger, more painful corns, and a higher proportion of these included fibrous and neurovascular corns in comparison to the control group. This imbalance occurred by chance; for a large RCT it is likely that the greater sample size would assist in distributing these influential characteristics more evenly. The imbalances amongst the groups will be taken into consideration and accounted for in the analysis.

6.4 Resolution rates and time

The primary outcomes of the pilot were the presence of an improved plantar corn at six months following treatment and time-to-resolution. Improvements were defined as either full resolution (corn no longer being present), partial resolution (a greater than 50% reduction in baseline area measurement), or no change (a less than 50% reduction in baseline area measurement). Figure 6-8 highlights the differences in corn resolution rates between groups.

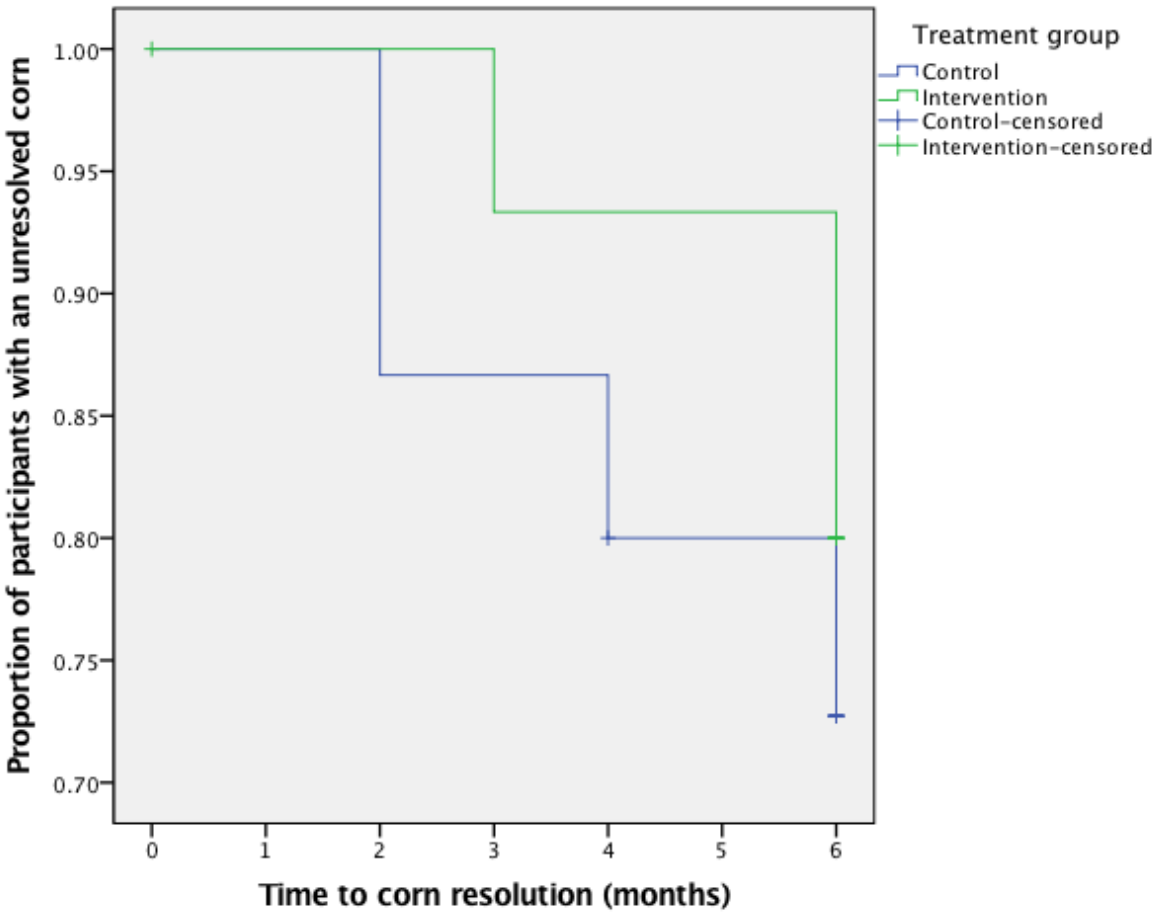
Figure 6-8: Resolution rates between treatment groups at the six-month evaluation.



A total of 50% of participants presented with a resolved or partially resolved corn at the six-month evaluation: seven (50%) in the SSD (control) group and eight (50%) in the insole (intervention) group. Of the 30 corns included in the evaluation, six (20%) had resolved, of which four (66.7%) had been randomised to the control group. A further 30% (n = 9) of corns – six (66.7%) in the intervention group and three (33.3%) in the control group – were partially resolved (reduced in size by more than 50%) when measured at the final evaluation. Statistical analysis (two-sided Fisher's exact test) confirmed that these small differences in resolution rates between groups were non-significant (p = 0.793).

To compare the difference in time-to-resolution of the corn from baseline to six months Kaplan-Meier analysis was conducted, as shown in Figure 6-9.

Figure 6-9: Comparison of time-to-resolution of the corn between treatment groups.

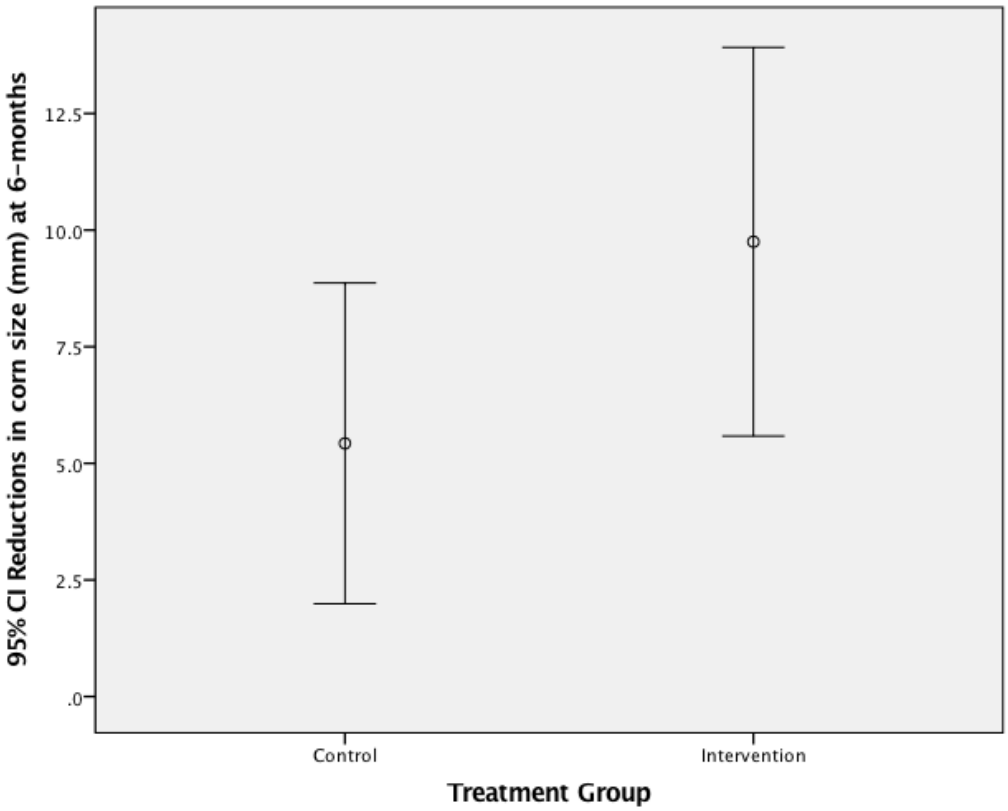


The curve illustrates that participants in the control group (SSD and enucleation only) had a slightly higher probability of corn resolution than the intervention group at two, four, and six months. Log rank testing revealed that this small difference in probability was non-significant ($\chi^2_{(1)} = 0.325$; $p = 0.569$). The curve demonstrates that the time taken for the corn to resolve in the intervention group was greater than those in the control.

6.5 Improvements in corn size

Since there were no significant differences seen in resolution rates, improvements in corn size were further analysed. The differences in reduction of corn size (mm^2) between groups at six months is presented in Figure 6-10.

Figure 6-10: Reductions in corn size between groups at the six-month evaluation.



Reductions in corn size varied greatly following control and intervention treatments, which is emphasised in Figure 5-10 (95% CI 1.99 to 8.87 and 5.58 to 13.92, respectively). Those in the intervention group had a greater mean reduction in corn size of 9.75 mm^2 (SD 7.82 mm^2) from baseline to six-month follow-up, in comparison to 5.43 mm^2 (SD 5.96 mm^2) in the control group. An independent samples t-test (two-tailed) found the mean difference in reduction of 4.32 mm^2 to be non-significant at the 5% significance level (p = 0.163, 95% CI -

9.58 to 0.92). Table 6-3 highlights the differences in mean reductions in corn size at all follow-up appointments.

Table 6-3: The mean reduction in corn size at follow-up appointments.

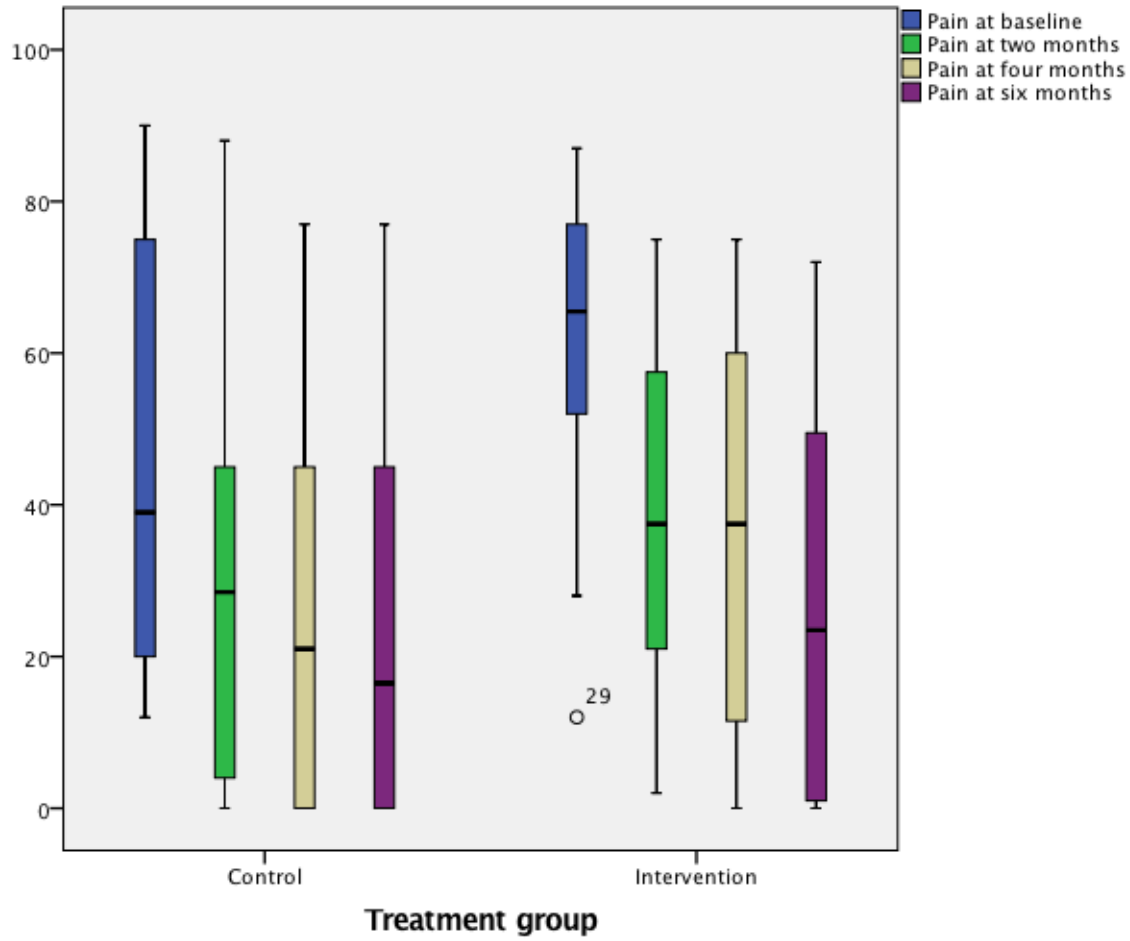
	Mean reduction in corn size in mm^2 (SD)		
	Two-month	***Four-month***	***Six-month***
Control	2.14 (4.04)	4.73 (5.71)	5.43 (5.96)
Intervention	7.00 (9.52)	7.81 (6.72)	9.75 (7.82)

Whilst greater mean reductions were found in the intervention group at follow-up evaluations, differences observed between groups were found to be non-significant ($p < 0.05$).

6.6 Evaluation of pain experienced

Comparisons in reported pain scores experienced with the corn on the 100-mm VAS at baseline, and at two-, four-, and six-month follow-up periods are presented in Figure 6-11.

Figure 6-11: Distribution of pain scores using the 100 mm VAS between treatment groups at various intervals.

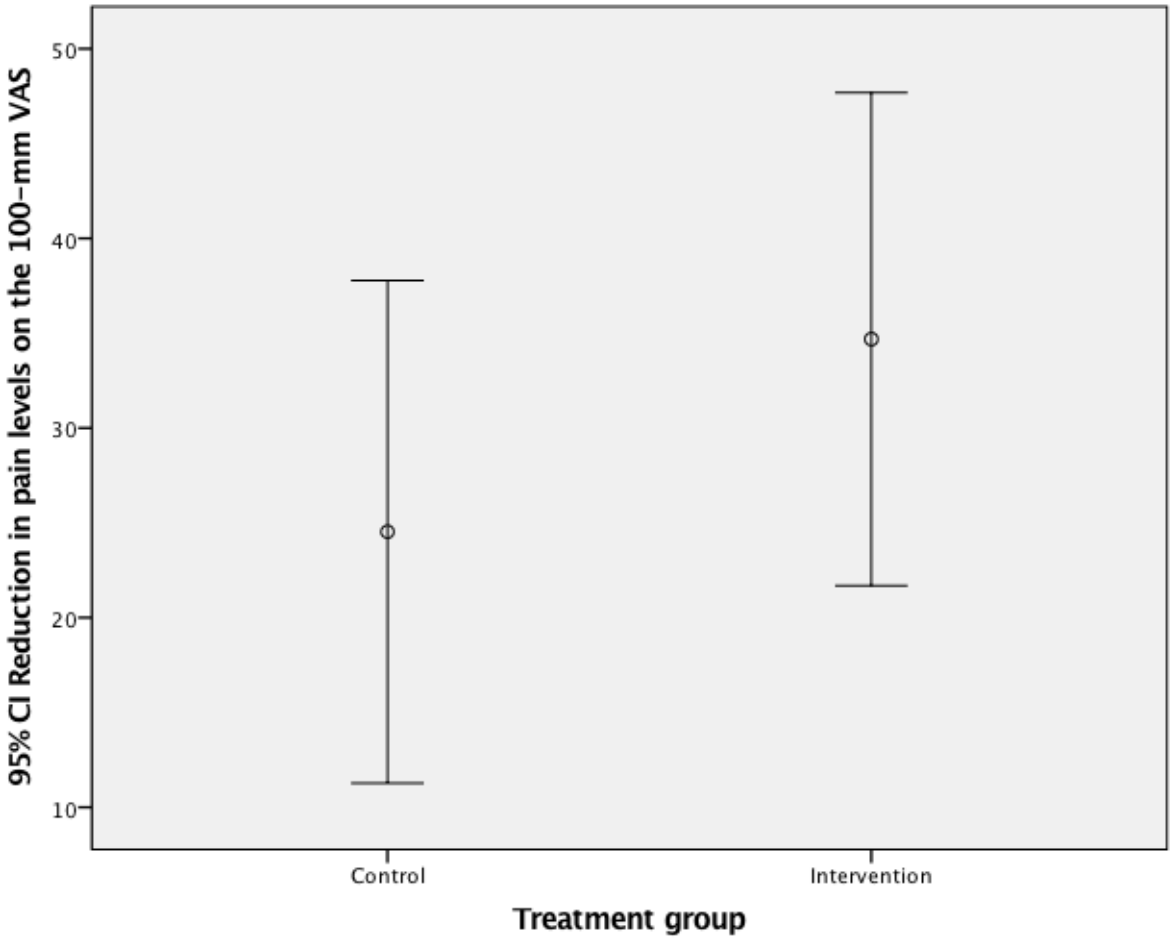


The box-plots highlight a reduction in pain scores reported at the two-, four-, and six-month follow-up evaluations, when compared to baseline measurements. Mean pain scores reported on the 100-mm VAS at the two-month follow-up were 39 mm (SD 24 mm) in the intervention and 31 mm (SD 25 mm) in the control group. The intervention group showed a greater reduction in mean pain of 23 mm, in comparison to 17 mm in the control, when compared to baseline mean scores (62 mm (SD 21 mm), 47 mm (SD 30 mm), respectively). At four months, both groups continued to show improvements in average mean pain levels compared to baseline: the intervention group by 26 mm, and the control by 21 mm. Mean

pain values at six months were 28 mm (SD 24 mm) in the intervention group and 23 mm (SD 26 mm) in the control.

Both groups showed a decrease in pain levels experienced with the corn at six months when compared to baseline measurements (shown in Figure 6-12).

Figure 6-12: The reduction in mean pain levels at six months between groups.



The intervention group showed a greater decrease of 10 mm more than the control group on the 100-mm VAS. An independent samples t-test found these differences in mean pain scores between treatment groups at six-month evaluation to be non-significant (95% CI -11.9 to 0.3, p = 0.154).

Large ranges were reported for both the pain associated with the corn and size. Epker (2013) criticised the use of pain as an outcome measure, due to its subjectivity, and emphasised the need to implement objective methods. It was appropriate to investigate whether a relationship existed between the size of the corn and reported pain, to support the validity of the assumption that as a lesion reduces in size pain also reduces. It would be expected that at baseline the greater the size of the corn, the greater the level of pain experienced with the corn. Scatterplots were used to investigate if there was a relationship between the variables both at baseline and six months, as illustrated in Figures 6-13 and 6-14.

Figure 6-13: Correlation between the size of the corn and level of pain at baseline.

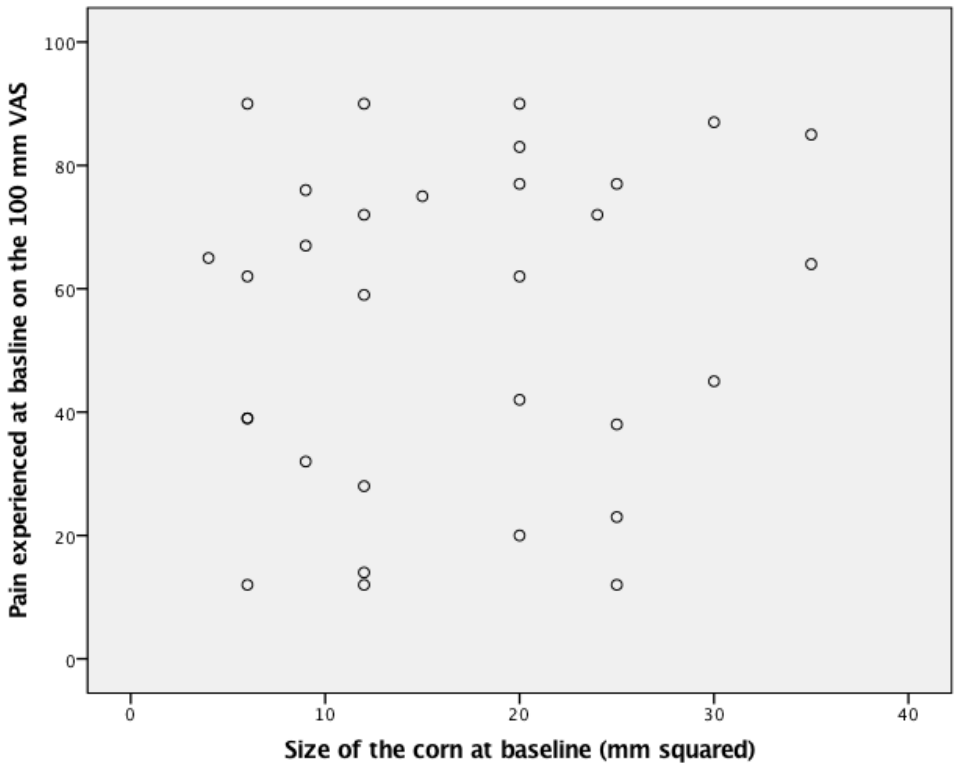
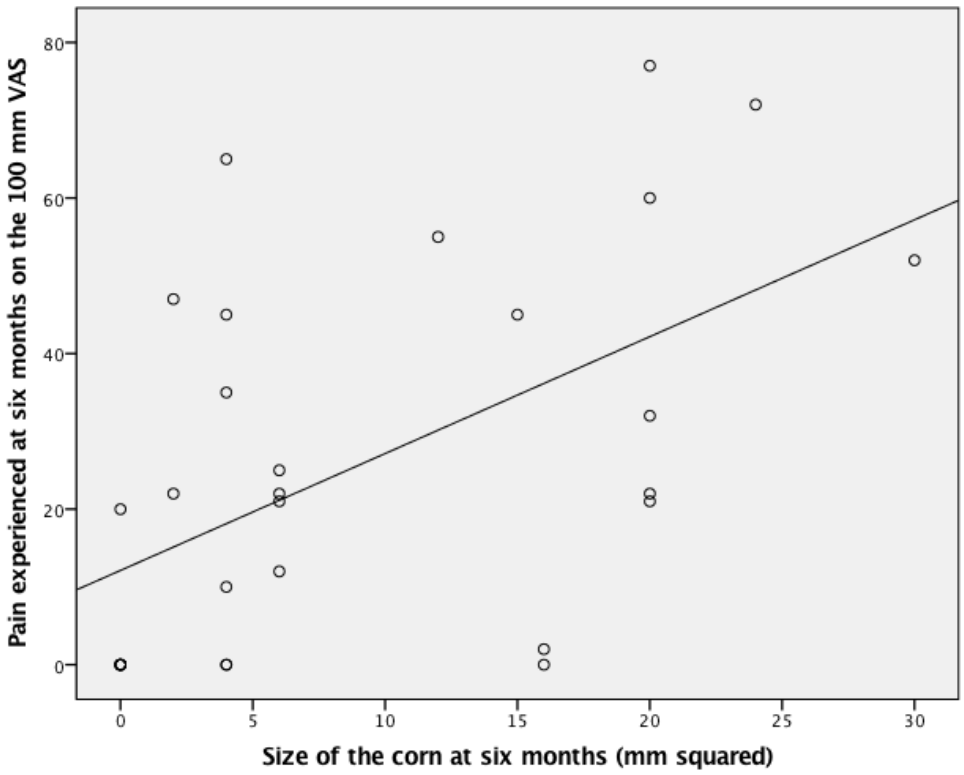


Figure 6-14: Correlation between the size of the corn and level of pain at six months.



At six months a positive linear relationship between the size of the corn and pain experienced was found, in contrast to the lack of correlation seen at baseline. The greater the size of corn, the more pain reported by the participant at six months. Pearson's product moment analysis was performed to explore the correlation coefficients and significance found between variables. The relationship between baseline lesion size and pain is weak ($r = 0.148$, $p = 0.213$), however, at six months there was a positive correlation ($r = 0.538$) which was of significance ($p = 0.002$).

6.7 Foot disability

The simple scoring system was incorporated to analyse the results from the Manchester Foot Pain and Disability Index (MFPDI) questionnaire (Garrow et al., 2000). Garrow et al. grouped the 19 questions into sub-scales: functional limitation, personal appearance, pain intensity, and work/leisure. Since most of the participants in this pilot study did not complete one of the two questions in the work/leisure category – mainly due to the fact that the question did not apply to them, as many were retired – this sub-scale was not analysed. A high score indicates that the participant experiences greater foot pain and disability than someone with a lower score. Each question within the sub-scales was scored as one of: 0, for those that responded 'none of the time'; 1, for 'on some days'; and 2, for 'on most/everyday(s)'. Table 6-4 presents the mean and standard deviation values from the questionnaire completed at baseline and six months for each group.

Table 6-4 Mean and standard deviation scores for the MFPDI questionnaire.

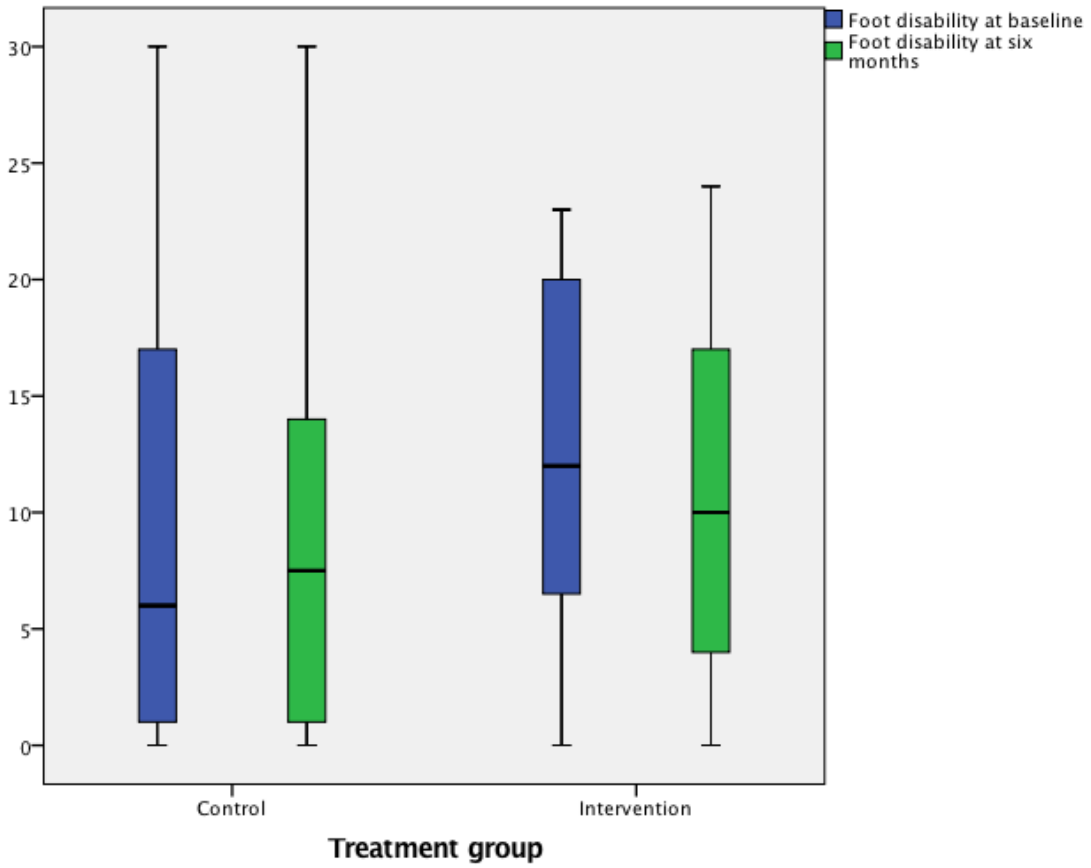
MFPDI sub-scales with score range	**Control**		**Intervention**		**All participants**	
	Baseline	***6 months***	***Baseline***	***6 months***	***Baseline***	***6 months***
1.Functional limitation (0-20)	5.93 (6.54)	5.50 (6.61)	7.25 (4.93)	6.81 (5.33)	6.61 (5.71)	6.20 (5.90)
2.Personal appearance (0-4)	1.00 (1.25)	0.79 (1.31)	1.56 (1.41)	1.19 (1.38)	1.29 (1.35)	1.00 (1.34)
3.Pain intensity (0-10)	3.40 (3.10)	2.64 (3.08)	3.75 (2.46)	2.63 (2.85)	3.58 (2.74)	2.83 (2.91)
Overall score of sub-scales 1-3 (0-34)	9.86 (10.08)	8.93 (9.89)	12.63 (7.73)	10.88 (8.10)	11.52 (8.77)	9.97 (8.87)

The differences between groups across all sub-scales at baseline were non-substantial. In all three sub-scales, participants' mean scores had reduced from baseline to the six-month evaluation. The average functional limitation scores for the treatment arms had reduced equally at the six-month evaluation: by 0.43 in the control, and 0.44 in the intervention group. Baseline scores were similar for personal appearance and pain intensity, and reduced by a similar amount in the control and intervention groups.

A strong significant correlation was observed between the scores for pain intensity in the MFPDI questionnaire and pain reported on the 100-mm VAS, both at baseline ($r = 0.58$, $p = 0.001$) and six months ($r = 0.68$, $p = 0.001$), indicating that pain levels on the 100-mm VAS increased with MFPDI questionnaire pain intensity scores.

Overall foot disability scores were analysed between groups from baseline to final evaluation, shown in Figure 6-15.

Figure 6-15: Overall foot disability scores of participants at baseline and six months.

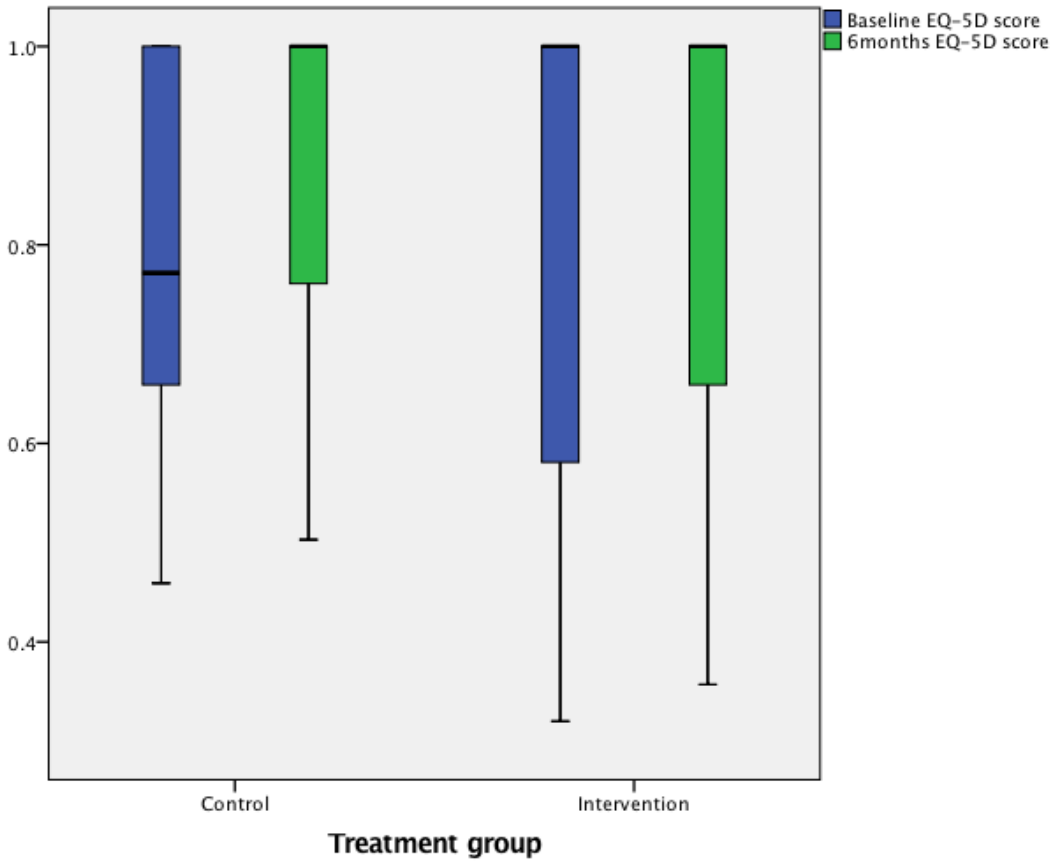


There is great variability amongst the foot disability scores in both groups, which is more prevalent in the control group. At six months the median score in the control is greater than at baseline by 1.5, whereas the intervention group demonstrates a decrease in the median score by 2.0. At six months the overall mean foot disability scores improved in both treatment arms: by 0.93 in the control and by 1.75 in the intervention group, demonstrating a greater improvement in the intervention group of 0.82 compared to the control. These differences between groups were non-significant (p = 0.596, 95% CI -8.67 to 4.78).

6.8 Health-related quality of life (HRQol)

HRQol was measured using the EQ-5D-3L scores generated from the results of the questionnaire completed by participants at baseline and at six months. A participant who is of full health is rated as 1, and the minimum health score is 0. The scoring criteria were provided by the EuroQol Group. The distribution of health scores from baseline to six months between groups is shown in Figure 6-16.

Figure 6-16: Distribution of HRQol scores at baseline and six months between groups, using the EQ-5D-3L questionnaire.



At baseline, mean HRQol scores were relatively equal between the control (0.79, SD 0.20) and intervention groups (0.77, SD 0.27). Participants in the intervention group had a greater range of HRQol scores at baseline (0.32-1.00) than the control group (0.46-1.00). The median HRQol score at baseline and six months in the intervention group was 1.00, indicating that many of those participants had full health. At baseline the control group had a median score of 0.77; following treatment for six months the median score increased to 1.00. At six months, improvements in HRQol scores were found in both the control and intervention groups, demonstrating mean scores closer to 1.00 (0.88, SD 0.18 and 0.82, SD 0.22, respectively).

Analysis of each dimension of the questionnaire, indicated minimal differences at baseline and six months. Table 6-5 highlights the number of responses to each dimension of the questionnaire at baseline and six months between groups.

Table 6-5 Frequency of responses at each HRQol dimension at baseline and six months between groups.

HRQol Dimension		**Baseline (%)**			**Six months (%)**		
		Control	Intervention	Total	Control	Intervention	Total
Mobility	No problems	10 (56)	8 (44)	18 (60)	12 (57)	9 (43)	21 (72)
	Some problems	5 (42)	7 (58)	12 (40)	2 (25)	6 (75)	8 (28)
	Confined to bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Self-care	No problems	13 (48)	14 (52)	27 (90)	12 (44)	15 (56)	27 (93)
	Some problems	2 (67)	1 (33)	3 (10)	2 (100)	0 (0)	2 (7)
	Unable to manage	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Usual activities	No problems	11 (52)	10 (48)	21 (70)	12 (55)	10 (45)	22 (76)

	Some problems	4 (44)	5 (56)	9 (30)	2 (29)	5 (71)	7 (24)
	Unable to perform	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Pain	None	7 (47)	8 (53)	15 (50)	9 (50)	9 (50)	18 (62)
	Moderate	7 (58)	5 (42)	12 (40)	5 (50)	5 (50)	10 (35)
	Extreme	1 (33)	2 (67)	3 (10)	0 (0)	1 (100)	1 (3)
Anxiety/ depression	None	13 (52)	12 (48)	25 (83)	13 (57)	10 (43)	23 (79)
	Moderate	2 (50)	2 (50)	4 (13)	1 (17)	5 (83)	6 (21)
	Extreme	0 (0)	1 (100)	1 (3)	0 (0)	0 (0)	0 (0)

Table 6-5 illustrates that the majority of the participants experienced no problems at baseline in each of the dimensions for mobility (60%), self-care (90%), usual activities (70%), pain (50%), and anxiety/depression (83%). This ceiling effect impacts on the ability to detect if the interventions have had any improvements on the HRQol dimensions at six months. Minimal differences were subsequently found when compared to responses at baseline, which provided difficulties when analysing the implications of treatments on HRQol dimensions. Of the participants who experienced some problems in walking at baseline, mobility was improved at six months in two (14%) of the participants in the control group and one (7%) participant in the intervention group. One (7%) participant in the intervention group no longer experienced issues with self-care in comparison to baseline. Of the 9 (30%) participants who experienced some problems in performing usual activities at baseline, only one participant randomised to the control group improved following treatment at six months to reporting no problems. One (7%) participant in the intervention group stated that they are in extreme pain at baseline, which improved at six month follow-up to experiencing moderate pain. The participant who presented with extreme pain in the control group at baseline was lost at the six month follow up. Whilst one (7%) participant

demonstrated an improvement in anxiety/depression in the intervention group, two (13%) participants who expressed no anxiety or depression at baseline reported moderate anxiety/depression at six months.

In addition the EQ-5D-3L questionnaire included a 100-mm VAS requiring participants to mark their health state on that day, with 100 mm being the optimum. At baseline mean scores were 82.4 mm (SD 11.2) in the control and 83.2 mm (SD 12.8) in the intervention group. Following six months of treatment reported health states on the 100-mm VAS improved in both control and intervention groups (84.8 (SD 10.6) and 84.1 (SD 12.9), respectively).

6.9 Participant feedback on the insoles

Participants in the intervention group were asked to complete a questionnaire at the end of the six-month evaluation to provide valuable feedback on the insoles. The response rate of the questionnaire was high at 87% (n = 13). Only two participants did not complete the questionnaire, for reasons which are unknown.

6.9.1 Perceived effectiveness

Participants were asked whether they felt the insoles were of benefit in the management of the corn, and why. Of the 13 respondents, 85% (n = 11) reported that the insoles were advantageous in the management of the corn. Three key themes were identified during the analysis of participants' explanations: (1) perceived reduction in pressure, (2) pain-relief and (3) fit of the insole. Participants emphasised that the insoles provided cushioning across the

forefoot, which improved mobility and decreased the frequency of podiatry appointments they felt they needed to attend. The explanations of the two participants who felt the insoles were not of benefit were focused on the third theme, namely (3) the fit of the insole. The two participants explained that the insoles did not fit well in every pair of shoes they had, making it difficult to incorporate into everyday activities.

6.9.2 Comfort

The comfort levels of the insoles experienced by the participants is important, as this can affect compliance rate. The insoles were rated as comfortable to very comfortable in 69% (n = 9) of the respondents. The comfort of the insoles was rated as acceptable by 31.8% (n = 4) of the respondents. Importantly, none of the participants found the insoles to be uncomfortable.

6.9.3 Acceptability into everyday life

In addition to comfort, participants rated their ability to incorporate the insoles into their everyday life during the six-month evaluation period. Of the 13 respondents, 54% (n = 8) stated the insoles were easy or very easy to incorporate into their everyday routine, as they were found to be comfortable (shown in Table 6-6).

Table 6-6: Ability of the participants to implement insoles into everyday life.

Rating	***Frequency***
Very difficult	0 (0%)
Difficult	2 (13%)
Acceptable	3 (20%)
Easy	4 (27%)
Very easy	4 (27%)

In contrast, 13% (n = 2) found the insoles difficult to implement into their lifestyle. These participants found transferring the insoles between shoes inconvenient, and the fitting of the insoles differed between shoes, making some feel tighter. It is important to recognise these findings, as this could have negatively impacted how often these participants wore the insoles.

6.9.4 Compliance

Participants were asked to rate how often they wore the insoles during the six-month evaluation period, on a scale of 1 ('never') to 5 ('all of the time'). The majority of participants (n = 7, 54%) who completed the questionnaire, stated that the insoles were worn all of the time. This reflects the number of participants who rated the insoles as comfortable and easy to adapt into their everyday routine. A considerable proportion of participants (n = 6, 46%) stated that they only wore the insoles half of the time, or never, during the six-month evaluation period. This is important to recognise, as this could have influenced the effectiveness of the insoles.

The majority of participants (n = 8) attended follow-up appointments wearing the insoles in their footwear, which on examination appeared to have been worn. Reasons participants gave for not wearing the insoles to their appointment were that they were in different footwear and they had little time to transfer them.

Importantly, 85% (n = 11) of the 13 participants who completed the questionnaire in the intervention group stated they would continue to wear the insoles. The reasons the respondents gave were that the insoles reduced their pain and improved walking. Two participants went as far as saying that the insoles are a “necessity”, as they have considerably reduced their pain and their need to attend, and subsequently reduced the frequency of, repeat debridement treatments. The remaining 15% (n = 2) would choose not to continue to wear the insoles. This was primarily due to the insoles not fitting adequately in all footwear, causing an inconvenience with being able to wear them for certain activities including work.

6.9.5 Durability of the insoles

During the six-month evaluation period, only one participant required a replacement for their insoles, which was required at nine weeks. On examination, the Texon base of the insole had become damaged due to the wet/damp conditions in the participant’s footwear, due to the nature of their occupation (gardener). At follow-up it was difficult to fully assess the durability of the insoles as more than one pair of insoles had been provided to three of the participants, who complained the fit was not suitable in some of their footwear.

6.10 Influence of participant demographics and corn characteristics on treatment effectiveness

Following randomisation, some variables were not equally distributed amongst the control and intervention groups, such as type of corn, location, size, and pain experienced. It would be expected that in a larger-scale study these variables would be equally distributed between groups. Further descriptive analysis was conducted to investigate whether any of these variables were found to have impacted on the primary outcome measures. This may help identify any potential problem variables in advance of a subsequent large-scale RCT.

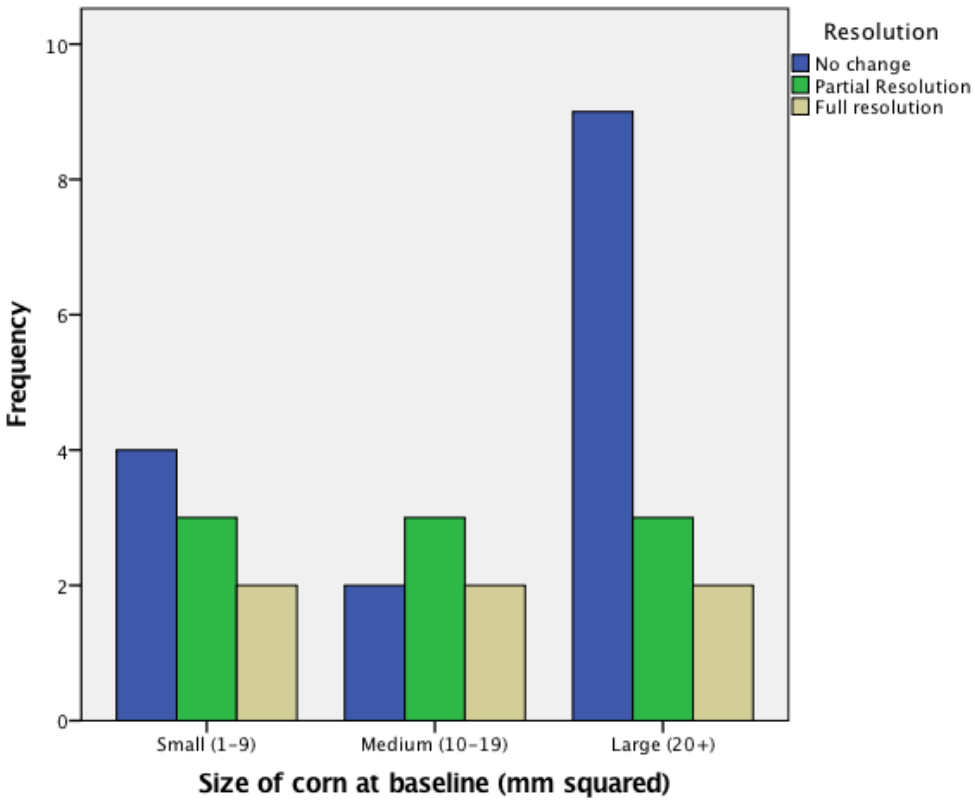
At baseline the intervention group presented with a greater mean difference in corn size of 8.1 mm^2. The sizes of corns were categorised into three groups, to help investigate whether the size of the corn influenced the resolution rate. Corns measuring less than 9 mm^2 were defined as 'small', those measuring 10-19 mm^2 were defined as 'medium-sized', and those 20 mm^2 and over were defined as 'large'. The majority of participants with corns categorised as large were randomised to the intervention group (n = 11, 73%), in comparison to the control group (n = 4, 27%), demonstrated in the cross-tabulation below (Table 6-7).

Table 6-7: Size of the corns and group allocation.

	Control	Intervention	All participants
Small (<9 mm^2)	6 (67%)	3 (33%)	9 (29%)
Medium (10-19 mm^2)	5 (71%)	2 (29%)	7 (23%)
Large (≥20 mm^2)	4 (27%)	11 (73%)	15 (48%)
Total	15	16	31

Participants with corns measuring 20 mm^2 or more were less likely to present with a completely or partially resolved corn, in comparison to the resolution rates of corns that were small or medium sized (demonstrated in Figure 6-17).

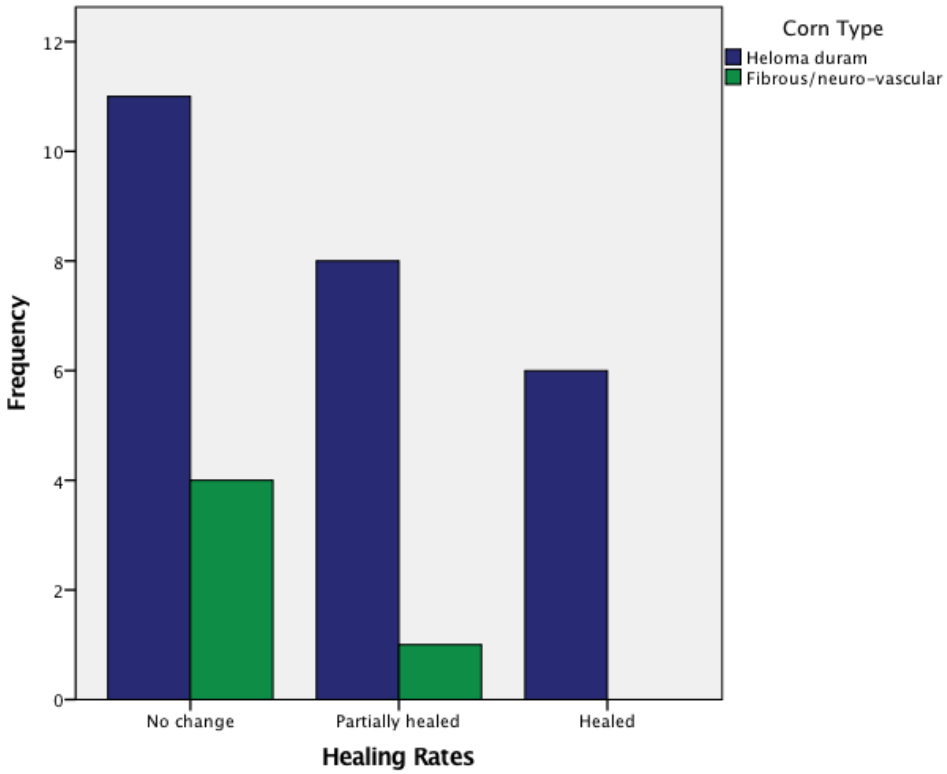
Figure 6-17: Resolution rates at six-month evaluation in relation to the size of the corn at baseline.



Over half (56%, n = 5) of the of nine participants with small-sized corns had resolved or partially resolved corns at the six-month evaluation, more of whom were randomly allocated to the control group. In those with large corns, only 35% of participants (n = 5) responded to the treatment, achieving either full or partial resolution.

During randomisation, five (83%) out of the six participants with fibrous and neurovascular corns were allocated to the intervention group, in comparison to the control, which was allocated just one (17%). At the six-month evaluation, none of the participants with fibrous or neurovascular corns had fully resolved, as highlighted in Figure 6-18.

Figure 6-18: Resolution rates of the different types of corns.



Of the 30 participants, 10 (33%) stated that they were a smoker. At the six-month evaluation, none of these 10 presented with a resolved corn. Future studies should investigate whether a link exists between smoking and corn formation, and/or resistance to treatment.

The location of participants' corns were distributed evenly between groups, with participants most commonly presenting with corns on the fifth MTPJ (n = 12, 39%) and second MTPJ (n = 11, 35%). It may be interesting to investigate the rate of treatment success in relation to the location of corns in larger sample sizes, particularly with the use of insole therapy. Of the six corns that had resolved, five (83%) were located on the second MTPJ. Of the 15 that had shown no change, eight (53%) were located on the fifth MTPJ.

6.11 Summary of results

A total of 30 participants were evaluated in the pilot study, presenting with a total of 31 corns. Attrition loss during the six-month study was low: one participant did not complete the final evaluation due to unforeseen circumstances. Although participants were randomly allocated, due to the nature of pilot studies having low numbers of participants, disparity between treatment groups was observed for some variables, including baseline pain and lesion size. The corns were mainly characterised as a heloma durum, and were mostly located on the second and fifth MTPJ. The majority of the complex corns (n = 5, 83%), i.e., those that were fibrous and/or neuro-vascular, were allocated to the intervention group.

At the final six-month evaluation, 50% of the corns had resolved or partially resolved. The differences in time-to-resolution were found to be non-significant between groups ($\chi^2_{(1)}$ = 0.325; p = 0.569). A large majority of the participants in the intervention group (73%; n = 11), stated that they would continue to wear the insoles due to the benefits they had experienced in relation to their corn. Importantly, 40% (n = 6) of the participants in the intervention group wore the insoles for only approximately half the duration of the study, or in some cases never. These key findings will be interpreted in the following chapter, with reference to other relevant literature highlighted in Chapter 2. Furthermore, the following chapter will encompass an in-depth appraisal of the pilot process, including recruitment strategy, data collection, appropriateness of the various outcome measures, and data analysis, in order to establish the feasibility and recommendations for a future large-scale study.

Chapter 7 - Discussion

The primary aim of the pilot was to investigate the use of metatarsal padded insoles alongside sharp scalpel debridement (SSD) in improving patient-related outcomes, when compared to SSD alone, in the management of plantar corns. This chapter discusses the process of the pilot study following data collection and analysis, identifying any challenges that occurred and issues that could potentially arise when replicating this pilot trial on a larger scale. Although this investigation was not powered to achieve statistically significant outcomes, this chapter synthesises key findings in relation to previous research illustrating the strengths and limitations of the research. It discusses the implications of the study for patients, clinical practice, and future research.

7.1 Pilot trial design and methods

7.1.1 Recruitment and retention

Initial recruitment onto the trial was slower than expected, with only two participants recruited within the first three weeks. The pool of available staff, students, and patients at the university who met the inclusion criteria could have been overestimated, which is typical of investigators conducting research (Thoma, Farrokhyar, McKnight, & Bhandari, 2010). In addition, advertisement strategies used may not have reached the target population in a timely manner. Approval from the practice manager of a local GP family practice to advertise the university clinic and pilot study was delayed due to miscommunication. A large proportion of participants (40%, n = 14) were recruited onto the trial using this advertisement method once permission was granted in June. It is important to recognise that recruitment onto the trial was greatest following the summer months

(September to November). Only 17% (n = 5) of the 30 participants involved in the pilot were recruited in July and August. Many patients attending the university clinic expressed interest but would not have been eligible to participate, as during these summer months their choice of footwear was sandals, which could not accommodate an insole. One of the main recruitment strategies was advertisement of the trial to patients attending the clinic via students and staff, signposting those suitable, and by posters displayed in the waiting area. During June to October, the university clinic reduces its opening hours from four days per week to one, thereby decreasing the potential population for recruitment over this period.

In order to successfully replicate the pilot on a larger scale, it may be beneficial to gain approval from the NHS Research Ethics Committee, to enable access to a greater patient population with corns. Since a large percentage (40%, n = 14) were recruited through self-referral to the clinic after becoming aware of the trial through advertisement in a local GP practice, a larger population could be reached by further communication with other GP practices in the area to gain approval for advertisement. A letter of invitation sent to patients on the university clinical database who have been identified by the researchers as having a corn may be useful in identifying a larger sample; however, this would have an additional cost implication for conducting the study. Increasing the duration of recruitment from 6 to 12 months may be necessary, should funding also allow for this.

Participant dropouts in randomised controlled trials (RCTs) are common, a factor which compromises the statistical power and internal validity of the findings (Wood, White, & Thompson, 2004). Selection bias is increased if treatment effects differ between those remaining in the study and those lost at follow-up, particularly if there are altered levels of

attrition between groups (Abshire et al., 2017). Wood et al. (2004) reviewed the dropout rates of 71 RCTs published in principal medical journals, including: The Lancet, The British Medical Journal (BMJ), The Journal of the American Medical Association, and The New England Journal of Medicine. Over 80% (n = 63) were found to have missing data, with reported dropout rates of 20% or more in 18% of trials (n = 13). This pilot trial had high retention rates during the six-month evaluation period, with only one participant being lost at final follow-up (Bell, Kenward, Fairclough, & Horton, 2013). The number of follow-up appointments participants were expected to attend was kept to a minimum, and each appointment required a time commitment of only 20 minutes. Furthermore, appointments were scheduled at the participants' convenience. All of these factors helped to reduce the burden on those involved in the pilot, thereby increasing engagement. Participants may have also recognised that their involvement was making a meaningful contribution to the knowledge in this area of podiatry. In addition, participants may have experienced benefits from the treatment, which could also explain their continued involvement in the pilot study. Further studies would benefit from exploring patient perceptions.

Whilst this pilot study had low attrition, a larger-scale study should consider implementing strategies to ensure retention rates remain high. A larger RCT may not have the flexibility of this pilot study when scheduling follow-up appointments, which may subsequently increase the level of inconvenience imposed on participants by the study. Appointment availability should be made clear to participants during the recruitment process, to ensure participant expectations are recognised early, thereby allowing forward planning of commitments.

7.1.2 Data collection and analysis

The data collection process was a success; participants understood what was expected from them, data was managed appropriately, retention rates were high (97%), and the data gathered served its purpose. This pilot was a single-centred trial with one researcher collecting the data; a larger-scale study will require a multi-centred approach with multiple researchers, which could introduce potential barriers that this study did not experience. Management of data, including its organisation and preservation, is essential to ensure the data can be used in the future (Eaker, 2016). Doucette and Fyfe (2013) conducted a survey of 360 research graduates, demonstrating that 17% (n = 61) had lost a data file when conducting group research which could not be retrieved, and 14% (n = 50) of respondents reported that the data collection process had to be duplicated. These data-handling errors impact on the time and expense of the research. In advance of an RCT, a thorough plan is necessary to improve the co-ordination, quality control, and management of the data to be collected. To reduce the possibility of any variation in evaluations conducted across the various research sites, standardised protocols should be followed, and regular, effective communication between site investigators should be maintained (Eaker, 2016). As this research was a single site with only one researcher there was no requirement for inter site communication.

The study outcomes were evaluated over a six-month period. Time-to-resolution analysis showed that participants in the intervention group took a longer time to resolve than those in the control group, with the majority in the intervention group resolving five months following treatment, instead of two months in the control. It would be advantageous for a larger-scale study to assess the long-term benefits of the insoles beyond six months, as

possible benefits of the insoles may be missed. A longer study duration was not feasible in this pilot due to the associated time constraints. The large-scale RCT by Farndon et al. (2013) found that 54 (68%) of the 80 participants who received SSD presented with an improved corn, measuring a greater than 50% reduction in size, with 24 (30%) having completely resolved. Despite these positive findings, at the 12-month evaluation it was revealed that approximately 50% of the participants had a recurring corn that had reverted to its size at baseline. This emphasises the importance of increasing the duration of future evaluations, if feasible.

7.1.3 Intervention protocols

Inter-rater reliability was eliminated in this pilot trial since the same investigator performed the treatments for both the control and intervention groups. Although this was possible for the pilot study, a larger-scale study would require involvement from multiple practitioners, which has the potential to impact on the inter-rater reliability of the study. In order to qualify as a registered podiatrist, one of the requirements is that the practitioner is competent in SSD of corns and calluses. Whilst the level of debridement of corns and calluses can be regarded as subjective, the practitioners involved in a larger-scale study would be certified to practice to a minimum standard, that is, complete removal of the central parakeratotic core. Should there be any discrepancies in the level of debridement between practitioners, the randomised nature of the study should allow for these discrepancies to be equalised across the groups (as through randomisation, no single practitioner would be responsible for treating every participant in a single group).

Introducing multiple researchers would not affect the inter-rater reliability of the insole construction, as this should not carry any subjectivity. Researchers should follow the standardised protocols for both treatments shown in Appendix 9.17 and 9.18.

The simple insole selected for investigation was a metatarsal pad with an aperture at the site of the corn made from PodoPro Urethane with a Poron top cover and Texon base. Following the pilot study, an adjustment to the construction of the insole would be beneficial. Using a prefabricated Frelon device, such as Slimflex, instead of Texon and Poron as base and top covers would make the insoles more durable and easier for participants to transfer the devices between shoes, which subsequently may increase compliance rates. One participant required a replacement during the course of the pilot. Three other participants requested a number of pairs, as the fit of the insoles was not suitable for the variation in their footwear. A prefabricated Frelon device would address this, as it is more ergonomically designed for use in the shoe. For example, the raised lip of the heel cup allows purchase when inserting into and removing from the shoe. This would improve the ease of use for participants and, as a result, compliance rates.

7.1.4 Outcome measure instruments

Completion rates of the questionnaire tools used to measure the outcomes were high, with only one participant missing data at four and six months due to unforeseen circumstances. This implies that participants did not find the questionnaires challenging or onerous to complete, which are often reasons for missing data on questionnaires (Hicks, 2009).

Correlation analysis found a strong positive association (statistically significant at the 5% significance level) between the scores for pain intensity in the MFPDI questionnaire and pain reported on the 100-mm VAS, both at baseline ($r = 0.58$, $p = 0.001$) and six months ($r = 0.68$, $p = 0.001$). This indicates that pain levels on the 100-mm VAS increased with MFPDI questionnaire pain intensity scores. In a future large-scale RCT, it could be recommended that only one of the tools is employed, since these two tools are measuring outcomes that are strongly related to one another. Pain intensity constitutes only one of the three domains included in the MFPDI questionnaire, therefore, should future investigations wish to assess more than just pain in foot-related disability the questionnaire should be considered for use (Garrow et al., 2000).

7.1.5 Research timeline

Reviewing the length of time it took to complete pertinent milestones of this research is key to assist in the planning and estimation of funding required to conduct a subsequent larger-scale RCT. Following enrolment onto the PhD programme in October 2014, planning of the pilot occurred over a 19-month period. This involved a thorough review of the literature, application for ethical approval, and subsequently the conducting of preliminary investigations. Once the research design and protocols were defined, recruitment for the pilot commenced in May 2016, and lasted until November 2016. In May 2017 all participants had completed the six-month evaluation. Data from the pilot study was then analysed, and the remaining time was spent writing the thesis. Figure 7-1 outlines the key milestones of this research process.

Figure 7-1: Timeline of the research project milestones

Date	***Research Process***
1st October 2014	Registered onto PhD.
October 2014 to April 2015	Review of the literature/background reading to develop research question.
April to September 2015	Methodology development for both parts of the study.
September 2015	Applications to SREP for ethical approval for both parts of the study. Permissions to conduct survey at College of Podiatry conference granted.
October 2015	Study granted ethical approval.
November 2015	Conducted survey of current practice at the College of Podiatry conference.
December 2015	Conducted laboratory tests to investigate compressional properties of insole materials.
January 2016	Evaluated patients' comfort levels of the insole materials
November 2015 to February 2016	Findings from preliminary investigations analysed and insole for pilot study was selected.
March 2016	Presented findings of preliminary investigations at Post-Graduate Research (PGR) Conference at the University of Huddersfield.
April 2016	An investigation to ensure selected insole relieved pressure from the forefoot.
May 2016	Pilot study recruitment commenced.
November 2016	Recruitment finished.
May 2017	Pilot study data collection completed following participants' six-month review.
July 2017	Presented preliminary findings at the Materials Forum at the University of Huddersfield.
July to November 2017	Data inputted into SPSS and analysed.
November 2017 to September 2019	Write-up of the study.
September 2019	Thesis submitted.

7.1.6 Sample size calculation for a future clinical trial

To establish the number of participants required to detect a difference between treatment effects, data from the pilot study was used to calculate the sample size required for future RCTs. Two sample size calculations were performed based on the primary outcome of the pilot study. A sample size calculation conducted using complete corn resolution data (4/14 in the control group and 2/15 in the intervention group) from the pilot study revealed that a study of 114 intervention cases and 107 controls (i.e. 221 in total) would be required to reject the null hypothesis that proportions of patients with completely resolved corns were equal in both the treatment and control groups at standard levels of significance (0.05) and power (0.8). To allow for 10% attrition loss in both groups, a follow-up study would aim to recruit 127 treatment patients and 119 control patients; i.e. 246 in total.

A sample size calculation conducted using partial corn resolution data (3/14 in the control group and 6/15 in the intervention group) from the pilot study revealed that a study of 99 intervention cases and 92 controls (i.e. 191 in total) would be required to reject the null hypothesis that proportions of patients with partially resolved corns were equal in both the treatment and control groups at standard levels of significance (0.05) and power (0.8). To allow for 10% attrition loss in both groups, a follow-up study would aim to recruit 110 treatment patients and 103 control patients; i.e. 213 in total.

7.2 Interpretation of the results

7.2.1 Participant demographics

Participants' demographics were evenly distributed among groups with respect to gender. The pilot study comprised more females (n = 18, 58%) than males (n = 13, 42%), which

reflects the prevalence of corns in the general population as emphasised in epidemiological studies (Dunn et al., 2004; Garrow et al., 2004; Spink et al., 2009; White & Mulley, 1989). Similarly in the RCT evaluating corn plasters and SSD by Farndon et al. (2013), fewer males (n = 84, 42%) were recruited than females (n = 118, 58%), which is comparable to other research evaluating treatments for corns (Araguas Garcia & Corbi Soler, 2018b; Gijón-Noguerón et al., 2017; Landorf et al., 2013).

The prevalence of foot problems, including corns, in females is an important public health issue, particularly in those over the age of 65 years, due to its impact on disability (Dawson et al., 2002; Leveille, Guralnik, et al., 1998). Anatomical and physiological variations between genders could contribute to the increased likelihood of developing foot problems. Studies have revealed that variations in foot shape and size exist between genders, particularly the angle formed by the axis of the metatarsal heads and arch dimensions (Hawes & Sovak, 1994; Wunderlich & Cavanagh, 2001). Women have an increased laxity within the ligaments at the joints (Wilkerson & Mason, 2000). Beynnon et al. (2005) argue this is due to the increased serum oestradiol and progesterone levels in females. In addition, Zifchock, Davis, Hillstrom, and Song (2006) found that women demonstrated significantly greater flexibility in the medial longitudinal arch of the foot compared to men ($p < 0.001$). A flexible, low-arched foot has considerable implications for gait, particularly during toe-off, as the foot is less able to create a rigid lever for stability, thus stretching and altering the forces through the soft tissues of the forefoot (Wilkerson & Mason, 2000; Zifchock et al., 2006). Research studies investigating the alignment of knees between genders have found that females have a greater tendency for valgus (knees caving inward) when compared to males, which increases the tendency for pronation and feet with lowered arches (Russell, Palmieri,

Zinder, & Ingersoll, 2006). These intrinsic variations could be important in the pathogenesis of skin lesions, such as corns.

Extrinsically, the differences in footwear habits between genders could be responsible for the disparity in the prevalence of corns (López López et al., 2015; Menz & Morris, 2005; Vernon et al., 2007). Menz and Morris (2005) demonstrated that women were more likely to wear inappropriate footwear that was significantly smaller in terms of length, width, and area in relation to their foot size compared to men ($p < 0.01$). Although this pilot study excluded participants who were not prepared to wear appropriate footwear during the study period, participants were asked to comment on their typical footwear prior to involvement in the study. This pilot study found that of the 17 participants who wore inappropriate footwear, 76% (n = 13) were female, whilst 24% (n = 4) were male – similar to the proportions found in the research by Menz and Morris. It is clear that inappropriate footwear characteristics play a key role in the development of corns and calluses, since the majority of participants (55%, n = 17) wore inappropriate footwear prior to induction into the pilot study. Other studies with larger sample sizes found greater differences (Menz & Morris, 2005; Palomo-López et al., 2017). Palomo-López et al. (2017) demonstrated that 61% (n = 37) of the 61 participants with hyperkeratosis wore inappropriate footwear, while only 15% (n = 6) of the 39 participants without hyperkeratosis wore inappropriate footwear. Although participants in this pilot study were expected to wear suitable footwear for the duration of the six-month evaluation period, there was limited control over this variable. Following randomisation participants appeared to be evenly matched between intervention and control groups, in terms of the appropriateness of their footwear prior to induction, therefore it is expected that results should not be influenced by this variable.

The greater prevalence of corns in females than males is linked to both anatomical and physiological variations and footwear. This pilot study showed no differences in resolution rates between males and females.

Demographic data showed that participants in the control group had a slightly greater mean age (66.9 years, SD 12.3) than in the intervention group (58.7 years, SD 12.0). There is no evidence to suggest that this small difference in age had any effect on the participants' response to treatment. Previous research studies evaluating treatments for hyperkeratosis have recruited participants of a similar age (Colagiuri et al., 1995; Farndon et al., 2013).

Of the participants who were enrolled onto the study with a fibrous or neurovascular corn, the majority (n = 5, 83%) were randomised to the intervention group, with only one participant (17%) being allocated to the control group. This imbalance between groups is likely to have influenced the findings of the pilot study, as these types of corns are widely known to be notoriously more difficult to treat (Grouios, 2004; Yates & Merriman, 2009). Bevans and Bosson (2010) emphasise that these lesions are typically unresponsive to treatment, meaning that patients attend appointments more frequently due to the severity in pain experienced. The findings of the pilot study at the six-month evaluation showed that none of the fibrous or neurovascular corns belonging to the six participants had resolved. In a subsequent study with a larger number of recruits, it would be expected that there would be a more even distribution of types of corns between groups (Hicks, 2009). Nonetheless, this variable should be closely monitored during the recruitment process. Future research should include these complex corns, as due to the small sample size associated with pilot

studies, it cannot be concluded that the intervention is not effective in managing these complex corns.

The mean baseline size of the corns in this pilot study (20.8 mm^2 in the intervention group and 12.7 mm^2 in the control) is similar to the size of corns studied by other research evaluating the treatments for corn management (Farndon et al., 2013; Khan & Evans, 1996; Petersen et al., 1991). Khan and Evans (1996) evaluated chronic corns that measured a mean of 22.05 mm^2.

Participants' pain at baseline, measured using the 100-mm VAS, had a range of 12-90 mm, with a mean score of 62 mm in the intervention group and 47 mm in the control group. In comparison to this pilot, previous RCTs evaluating the treatments for painful corns report similar levels of mean pain on the 100-mm VAS: between 47 mm and 75 mm (Bevans & Bosson, 2010; Farndon et al., 2013; Gijón-Noguerón et al., 2017; Landorf et al., 2013).

Baseline data demonstrated that the size of the corns included in this pilot study and their associated pain were unevenly distributed between groups. Participants in the intervention group typically presented with a corn greater in size than those in the control, with a mean difference of 8.1 mm^2, and with an increased level of pain, with a mean difference of 15 mm on the VAS. These differences could have influenced the pilot study, as participants in the intervention group presented with larger and more painful corns, meaning there was greater scope for improving parameters for this group. However, there is no evidence available to indicate whether larger and more painful corns respond better to treatment than corns that are smaller and less painful, or vice versa. This pilot study, however, analysis

of covariance adjusted for these unequal variations between groups at baseline. A future RCT involving a greater number of participants should, with group allocation being randomised on a larger scale, increase the likelihood of these variables being equally distributed between groups, which would negate the need for such adjustments in the analysis.

7.2.2 Primary outcomes

One of the primary outcome measures of the pilot study was the presence of an improved plantar corn at six months following treatment. Full resolution occurred in 20% (n = 6) of the total number of participants: 29% (n = 4) of those randomised to the SSD (control) group and 13% (n = 2) of those in the insole (intervention) group had a resolved corn. Findings in the large RCT by Farndon et al (2013) found comparable resolution rates of 30% (n = 24) in the 80 participants that received SSD. No comparisons can be made to the findings of those that received the insoles as no previous investigations have been conducted.

In this pilot study both treatment arms received the usual treatment of SSD and patient education – the only difference between the groups being that the participants in the intervention group also received the metatarsal padded insole. If both groups were evenly matched at baseline in terms of corn type, size, and associated pain, and should the insole have been found to have no additive effect, resolution rates of the intervention group would be expected to be similar to those control group. This highlights that the skewed data at baseline may have had a substantial impact on the participants' response to treatment. In the evaluation of electrosurgery by Bevans and Bosson (2010), only chronic complex corns that were difficult to manage within routine practice were included. Bevans and Bosson

revealed that nine (26%) of the 34 participants randomised to the electrosurgery group, and only one (4%) of the 25 subjects that received SSD, had resolved at six months. Substantially higher resolution rates have been reported in studies that investigate the effectiveness of these treatments in less complex corns, such as a heloma durum (Farndon et al., 2013; Smith & Morrison, 1990). Smith and Morrison (1990) reported resolution rates of 79% (n = 52) in the 66 randomly selected participants who received electrosurgery treatment. Similarly, this pilot study demonstrated that neurovascular and fibrous corns are challenging to treat, since complete resolution only occurred in participants with a heloma durum. This emphasises the importance of this variable in relation to the corns' response to treatment. The majority (83%, n = 5) of the neurovascular and fibrous corns were randomised to the intervention group. Participants with these corns constituted a total of 33% of the intervention group (comprising 31% of the corns in that group, as one participant had more than one corn). Given this uneven spread between the control and intervention groups, it is likely that this will have influenced the study's overall findings.

Partial improvement (a greater than 50% reduction in baseline area measurement, but without complete corn resolution) was seen in 38% (n = 6) of the 16 corns in the intervention group. In the control group 20% (n = 3) presented with partial improvement. A total of 50% of participants in both control and intervention groups presented at six months with complete or partial resolution. Farndon et al. (2013) found greater improvements in resolution rates (complete and partial) at six months in the 80 participants who received SSD (n = 54, 68%) and in the 74 participants who were treated with corn plasters (n = 62, 84%). The corns located on non-weight-bearing areas of the foot included in the study by Farndon et al. could explain the increased number of participants with an improved corn at

six months in comparison to this pilot study. Complete resolution has been found to be significantly greater in those with corns on the dorsum of the digits and interdigitally (Hazard ratio (HR) 1.189, 95% CI 1.06 to 2.63, p = 0.027) (Stephenson et al., 2016). Pressure is thought to be one of the key causative factors in the development of corns (Grouios, 2004). It is easier to identify and address the cause of the increased pressure at the site of the corn in patients with dorsal and interdigital corns, by implementing simple adjustments, such as wearing shoes with a deeper toe box. In comparison, plantar corns are more challenging to treat as they are subject to repetitive mechanical stresses through large ground reaction forces during the gait cycle (Hamatani et al., 2016).

Time-to-resolution was another key primary outcome of this pilot study. The time taken for the corn to resolve in the intervention group was greater than the control group. At the two-month review, the probability of an unresolved corn in the intervention group was 100%, in comparison to 86% in the control. This is likely due to the fact that participants in the intervention group had larger corns at baseline than those in the control, with a greater mean difference in corn size of 8.1 mm^2, thereby taking longer to heal. Since the time-to-resolution was greater in the intervention group than in the control and that a substantial number of participants in the intervention group presented at six months with partial improvement (36%, n = 6) this emphasises that a 12-month follow-up evaluation may have revealed greater resolution rates in the intervention group. Similarly, improvements in resolution rates may have also been seen in the control group. A future large-scale RCT study should aim to review the effectiveness of the treatments over a longer timescale, if feasible. This is particularly relevant since the analysis by Stephenson et al. (2016) found

that the median resolution time of plantar corns was 14.9 months, in comparison to 5.9 months for dorsal and interdigital corns.

7.2.3 Secondary outcomes

7.2.3.1 Pain

One of the secondary outcomes was pain, measured using the 100-mm VAS at baseline, and at two, four, and six months. Both groups demonstrated substantial reductions in mean pain levels at the six-month evaluation. A greater difference in mean pain from baseline to six months was seen in the intervention group (35 mm) when compared to the control (25 mm). Bevans and Bosson (2010) reported a similar difference from baseline to six months in their intervention group that received electrosurgery (38 mm). Comparable to this pilot study, the control group in the evaluation by Bevans and Bosson involved SSD. The differences in improvements in pain levels from baseline to six months were substantially less in the control group (14 mm) in the study by Bevans and Bosson. This could be due to the fact it is difficult to enucleate the entirety of a neurovascular and/or fibrous corn with SSD alone, therefore any parakeratotic tissue remaining would continue to cause pain. There was only one neurovascular or fibrous corn included in the control group of this pilot study, whereas the majority of the corns in the study by Bevans and Bosson were of this type.

Although the pilot study demonstrated statistically non-significant differences in improvements in pain levels between groups (95% CI -11.9 to 0.3, p = 0.154), the differences may be clinically important. There is disparity within the literature regarding the position of the lower threshold for a clinically important difference between pain scores on the 100-

mm VAS (Gallagher, Liebman, & Bijur, 2001; Kelly, 1998; Todd, Funk, & Bonaci, 1996). According to Gallagher et al. (2001) and Todd et al. (1996), research that records less than 13 mm on the 100-mm VAS is not of clinical importance. In contrast, Kelly (1998) analysed the pain scores of 152 participants who presented to Accident and Emergency (A&E) with acute pain, but evaluated a range of conditions and found the minimum clinically important difference in VAS pain scores was 9 mm. Although the purpose of this pilot was to determine whether a larger-scale study is feasible, rather than with the intention of testing for significant differences, it is difficult to determine whether the differences found in pain levels between the intervention and control groups were clinically significant. There is no evidence available that has evaluated the clinical importance of pain levels on chronic skin lesions, such as corns. Furthermore, the current research evidence that analyses participants with acute pain is ambiguous.

7.2.3.2 Foot disability

The majority of the participants enrolled onto the study presented with disabling foot pain (90%), reporting overall scores between 1 (mild) and 30 (severe) on the Manchester Foot Pain and Disability Index (MFPDI) questionnaire. Studies that have investigated the prevalence of disabling foot pain, but in community-dwelling cohorts, report that between 26% and 54% are affected (Dunn et al., 2004; Hill et al., 2008; Menz et al., 2006; Mickle, Munro, Lord, Menz, & Steele, 2010). Whilst this pilot study also included participants aged less than 65 years, the high prevalence of disabling foot pain in the cohort highlights the implications of plantar corns on foot disability. Garrow et al. (2004) demonstrated in their survey of a general population that participants with disabling foot pain, who self-reported on their conditions, were significantly more likely to have corns and callosities (HR 1.5, 95%

CI 1.2 to 1.9, $p < 0.05$). This further supports the necessity of conducting research in the area of plantar corns: to assist in improving treatment outcomes for this disabling condition.

When comparing overall foot disability scores from baseline to six months, in this pilot study only minimal improvements were found. Participants in the intervention group reported greater score improvements compared to the control group (1.75 vs 0.93, respectively) ($p = 0.596$, 95% CI -8.67 to 4.78). Farndon et al. (2013) is the only large-scale RCT (n = 202) to have used the MFPDI questionnaire to evaluate the effectiveness of corn treatments on foot disability. Analysis of this trial by Stephenson et al. (2016) also found only slight improvements at six-months in foot disability scores: an improvement of 4.33 in those that received SSD (control group), and 0.38 in the corn plaster (intervention) group.

7.2.3.3 Health related quality of life (HRQol)

Participants involved in this pilot study were considered relatively healthy, as baseline HRQol scores were relatively close to 1 (0.79 (SD 0.20) and 0.77 (SD 0.27) for the control and intervention groups, respectively). The EQ-5D scores in the trial by Farndon et al. (2013) were slightly lower compared to this pilot at baseline, with an overall mean of 0.66 (SD 0.29) for the aggregated intervention and control groups. Participants in the large-scale RCT were predominantly recruited from among those accessing treatment from the National Health Service (NHS). Those accessing this service tend to have greater co-morbidities than those accessing treatment privately (Farndon, 2016). A larger-scale study evaluating the use of metatarsal padded insoles may consider recruiting from multiple healthcare sectors.

An in-depth analysis of each dimension of the HRQol questionnaire was not possible as minimal improvements were found between baseline and six months across each of the five dimensions for HRQol. A high proportion of the participants scored the maximum at baseline. This ceiling effect could impact on the accuracy of the reported findings as the range of responses of the questionnaire is limited, reducing the variability, and sensitivity of the data collected. The small sample size, associated with pilot studies, could also explain the minimal improvements in HRQol.

Similar to Farndon et al's. (2013) study, non-significant differences were found between EQ-5D scores at baseline and six months between groups (Stephenson et al., 2016). This suggests that the treatments for corns, such as SSD and corn plasters, may not have a noticeable impact on the HRQol questionnaire tool. Since there are no other studies that use this tool or outcome measure to evaluate the effectiveness of corn treatments, it is unclear whether the treatment of corns can significantly improve patients' HRQol, or whether this tool is effective at demonstrating a difference. It may be beneficial for future RCTs to utilise other methods of measuring HRQol, which could be more sensitive to detecting differences. The EQ-5D-5L questionnaire rather than the EQ-5D-3L tool could be implemented (Brazier et al., 2004). The additional two levels to which participants can respond within each domain may improve the sensitivity of the findings (EuroQol Group, 2019; Xie et al., 2014). Alternatively the medical outcomes short-form 36 questionnaire tool could be more suitable, although, this has not been used to measure the effects of hyperkeratosis treatments on HRQol previously (Palomo-López et al., 2019). The tool is generic and consists of 36 questions covering 8 domains of health. A scoring scale from 0 (worst quality of life) to 100 (best quality of life) is used to measure each domain. This

scoring system could enable greater variability of responses and ability to detect subtle changes in health.

7.2.3.4 Participant feedback on the insoles

The metatarsal padded insole evaluated in the pilot study was found to be comfortable and easy to implement in everyday activities by the majority of participants. Further feedback given by participants regarding their perception of the insoles revealed that the devices had helped to improve mobility and reduce pain, with 85% stating they would continue to wear the insoles. The majority of patients followed the recommended advice and wore the insoles on a daily basis throughout the study period. Although the data from this questionnaire has reduced validity, participant feedback is essential, particularly, since in circumstances where patients are involved in the decisions regarding their treatment, there is a shift from compliance to concordance (Department of Health, 2012). These findings are important as it implies that the metatarsal padded insole will be readily accepted by participants in subsequent research. It is important to continue to measure compliance in future studies, as some participants wore the insoles less frequently than recommended, which could impact on the findings.

7.3 Strengths and limitations of the study

This pilot study has several possible strengths and limitations. The cohort recruited for the pilot study was considered large enough to adequately assess the practicalities of the proposed research design and protocol. Previous evaluations of the use of insole therapy in the management of calluses have been based on smaller samples; for example Colagiuri et

al. (1995) recruited 20 participants, and Timson and Spooner (2005) included 25 participants. These examples were not outlined as being pilot studies. Following the six-month evaluation, this pilot study retained all the recruits except for one, which strengthens the internal validity of the research. Retention rates are a recurrent issue in many RCTs, and patient attrition is prevalent in this research field (Caselli et al., 1997; Farndon et al., 2013). Caselli et al. (1997) initially recruited 60 participants, and at the four-week review 25 had dropped out, which impacts on the internal validity of the study's findings.

Some research within this field has used non-experimental methods to evaluate the treatments used for hyperkeratosis management (Balanowski & Flynn, 2005; Redmond et al., 1999). One key strength of this pilot design is the inclusion of a control group for comparison, and the randomised method of allocation, which is important for any future large-scale study that might be conducted to test the efficacy of the metatarsal padded insole. Randomisation attempts to reduce selection and allocation bias by balancing both known and unknown prognostic variables (Hicks, 2009). Many factors have been identified in the literature as contributors to the formation of corns, as discussed in Chapter 1. It was therefore it was essential to measure these variables. Although randomised methods were used to allocate participants, the variables were not evenly distributed amongst the intervention and control groups. Whilst the aim of the pilot study was not to seek statistical significance, this imbalance in variables could have impacted on the results of the pilot study. It is expected that, in a large-scale RCT, these potential confounding variables would be evenly spread between treatment groups.

The sample of participants involved in this pilot study varied on a wide range of demographics, including age, gender, activity level, occupation, and typical footwear. In addition, the participants' corn characteristics differed with respects to the type, size, location, and associated pain. This demonstrates that the sample studied was representative of the general population with corns, thereby improving the external validity of the research findings.

The level of SSD and enucleation can vary between practitioners. There is no evidence to suggest how this subjectivity affects patient outcomes, if there is any effect at all. It is assumed that maximising debridement has a positive impact on the treatment outcome. Evaluations of debridement in RCTs have revealed the use of different methods to perform the treatment, either by one researcher (Araguas Garcia & Corbi Soler, 2018b; Davys et al., 2005; Gijon-Nogueron et al., 2015) or by multiple researchers (Landorf et al., 2013; Siddle et al., 2013). It is not clear whether the findings of these studies are influenced by the differences in the methods of debridement or populations studied. Both Davys et al. (2005) and Landorf et al. (2013) found that the benefits of SSD are not significantly greater when compared to sham debridement in participants with rheumatoid arthritis (RA) and in those aged over 65 years. Araguas Garcia and Corbi Soler (2018b) found significant improvements in pain in the real debridement group compared to the sham debridement group in those aged over 65 years. Intra-rater reliability was improved by having a podiatrist, independent to the study, examine randomly selected participants' photographs, before and after SSD and enucleation, to judge the consistency of tissue removal. In addition, the insoles were all produced by the same researcher to reduce any potential inconsistencies during the

process. A standardised protocol was followed to enable consistent replication of the devices.

The instruments and tools used to measure the outcomes of the pilot study, including: the 100-mm VAS, MFPDI, and EQ-5D-3L questionnaire, are widely used in the measurement of common podiatric conditions (Davys et al., 2005; Farndon et al., 2013; Landorf et al., 2013). Importantly, sufficient evidence is available to support their validity and reliability in measuring the associated outcome (Garrow et al., 2000; Hawker, Mian, Kendzerka, & French, 2011; Riskowski et al., 2011). This is important as it ensures that the results drawn from the study are accurate and can be confidently applied in clinical practice.

7.4 Implications for the patient and clinical practice

A large proportion of the patients seen by podiatrists present with corns and calluses, with studies reporting a prevalence of between 26% and 46% in podiatry clinics (Bennett, 2012; Bennett, Patterson, Wearing, & Baglioni, 1998; Farndon, 2016). Corns are renowned to cause pain and subsequent disability for the patient due to the parakeratotic central core (Singh et al., 1996). This can have a detrimental effect on patients, particularly those over the age of 65 years, due to the influence that pain has on mobility (Menz, 2008; Menz & Morris, 2005).

The most effective treatment for corn management is yet to be identified within the literature. SSD and enucleation of the corn is the usual treatment. However, evidence emphasises that the beneficial effects of this treatment, including resolution and improvements in pain, are short lived (Farndon et al., 2013; Landorf et al., 2013). Further

research evaluating other treatments for corns has been conducted in an attempt to improve outcomes for patients, including the use of corn plasters and electrosurgery (Bevans & Bosson, 2010; Farndon et al., 2013). The research evidence demonstrates that these treatments are an effective alternative to the usual treatment of SSD and enucleation. The samples selected for evaluation, however, excluded participants that are commonly affected by corns; those with diabetes, peripheral arterial disease, and RA were excluded (Bevans & Bosson, 2010; Farndon et al., 2013). The inability to apply these interventions to all patient groups results in those patients not suitable for these treatments experiencing continued poor treatment outcomes. Strategies to relieve pressure are routinely implemented in practice, with such strategies currently based on anecdotal evidence (Caselli et al., 1997; Duffin et al., 2003; Potter & Potter, 2000). This study aims to address the large gap in evidence-based knowledge regarding the use of metatarsal padded insoles, and whether these insoles provide any additive effects when compared to the usual SSD treatment alone.

The findings of the pilot study imply that there is no superior effect of the metatarsal padded insole when compared to SSD and enucleation alone. This suggests that the additional cost implications of the insole therapy to the patient or healthcare provider may not be economically viable. It is important, however, that these preliminary findings are not drawn upon, as the aim of the pilot trial was merely to assess the feasibility of conducting a larger-scale study, rather than determining any significance from the data. The sample size of the study is reflective of that typically seen in a pilot, and would be deemed too small to seek any significance. In addition to the reasons concerning the small sample size, it would be inappropriate to apply these findings in clinical practice, due to the large disparity

between control and intervention groups in relation to corn size, type, and associated pain. The findings of the pilot study in relation to the feasibility of conducting a larger-scale study, however, are pertinent as further analysis will benefit the patient and healthcare provider in clinical practice.

7.5 Implications for further research

A larger-scale RCT is feasible and warranted; however, a number of recommendations have been identified in the pilot study which would optimise the efficiency and robustness of a larger trial. These recommendations have been discussed within this chapter, including: recruitment and retention rate strategies, efficacy of expanding the study over multiple sites using multiple researchers, and feasibility of increasing the follow-up period from six to 12 months.

Importantly, feedback from the participants regarding the insoles was positive with respect to comfort, ease of use, and perceived benefits (improvements in pain and mobility). This is imperative for the success of an intervention as patients are more likely to comply with the treatment. Patient compliance is often a challenge in clinical practice for healthcare professionals. The preliminary results of this pilot suggest that the metatarsal padded insole evaluated could be readily adopted by participants in a larger-scale study. Whilst the majority of participants in the intervention followed the recommended advice on wearing the insoles on a daily basis, there were still a number of participants who wore the insoles less frequently, which could impact on the effectiveness of the treatment. In a future large-scale trial it is, therefore, important to continue to measure compliance rates through questionnaires and observations.

7.6 Summary

This chapter presents the process of conducting this pilot study, highlighting any problems that could potentially arise in advance of a larger-scale study. The purpose of this pilot was not aimed at testing statistical significance, but instead to determine if a large-scale trial would be feasible. Results revealed improvements in resolution rates and pain for both the control and intervention groups. This pilot study has helped contribute to improving the knowledge of the use of metatarsal padded insoles in the management of corns. It has highlighted that a large-scale study is warranted, and is feasible with the recommendations discussed. The next chapter concludes the project, outlining a summary of the findings from both the preliminary investigations and the pilot study.

Chapter 8 – Conclusion

This chapter provides a summary of the research, including both preliminary investigations and subsequent pilot study. It provides an overview of key findings discussed within the thesis, and concludes by highlighting implications for clinical practice and recommendations for future research.

Critical appraisal of the evidence available identified gaps in the current knowledge base regarding the efficacy of treatments to manage corns, followed by a subsequent meta-analysis (presented in Chapters 2 and 3 of the thesis). Research demonstrated that effects of the usual treatment of sharp scalpel debridement (SSD) are short lived; as a result, patients require frequent treatment to help manage the recurring corn and associated pain (Farndon et al., 2013; Landorf et al., 2013). Other research has focused on the efficacy of alternative methods to remove corns, such as electrosurgery and salicylic acid plasters. Whilst these treatments have been found to provide improved outcomes, the long-term effects remain poor. To improve treatment success, the management of corns should primarily focus on addressing the cause. The literature highlights that it is necessary to combine pressure-relieving strategies, such as metatarsal padded insoles, with the usual treatment of SSD to optimise patient outcomes. Appearing in most podiatry textbooks, forefoot metatarsal pads are a common method used in the management of corns, yet this practice is currently based on anecdotal evidence. The purpose of this research was to conduct a preliminary investigation into the use of metatarsal padded insoles in the management of painful plantar corns, to help address the large gap in evidence-based knowledge.

Critical analysis of the theoretical and research base regarding forefoot pads was necessary to determine the type of metatarsal pad to investigate, prior to conducting a pilot study to evaluate its use. Metatarsal pads were found to be the most effective in reducing pressure across the forefoot, in comparison to other forefoot pads (Jackson et al., 2004; Lee et al., 2014). The analysis highlighted gaps in current knowledge, including knowledge of: the type of insole currently being prescribed in practice, the stiffness of the materials commonly prescribed, and patients' perspectives. Filling in these gaps would help formulate a logical rationale for the design and material to be used for the simple insole. Further preliminary investigations were subsequently conducted to address this gap in knowledge.

A survey conducted with practising podiatrists revealed the majority of participants prescribe metatarsal pads with an aperture in routine practice for the management of corns. It demonstrated that there is considerable disparity amongst clinicians regarding their choice of materials for the metatarsal padded insole. The lack of research investigating the efficacy of insoles for corns could have resulted in this variation of insole prescriptions, as the materials chosen (medium-density EVA and Poron) differ considerably in their properties. The results from the survey emphasise the necessity of conducting research in this field, that is, to help improve practitioners' knowledge of this clinical practice that is currently being implemented without validated research evidence.

Compressional stiffness testing was performed on common materials identified in the survey and research base for the management of corns, these included: medium-density EVA, low-density EVA, PPT, PodoPro Urethane, and Poron. Paton et al. (2007) emphasises

that materials that continuously deform are ideal for reducing pressure. The findings support the assumption that apertures within the design of the insoles assist in accommodating painful prominent lesions. It was identified that the materials' resistance to compression was substantially reduced when the profile of downward force was more protrusive (simulating the profile of a prominent lesion). The inclusion of an aperture in a metatarsal padded insole at the site of a prominent corn will improve the materials' compressional capacity, due to the increase in surface area at the point of contact, which could help to reduce pressure from the site and improve patient outcomes.

A simple insole was chosen for the metatarsal pad, as previous studies have demonstrated some positive preliminary findings for their use in callus management (Duffin et al., 2003; Timson and Spooner, 2005). This type of insole has also been found to be the most commonly prescribed for patients with forefoot pain, including pain caused by corns and calluses (Chapman et al., 2018). Furthermore, simple insoles are the least expensive in comparison to prefabricated and custom-moulded ones.

The review of the research base alongside findings from the preliminary investigations highlighted that polyurethane materials are more favoured over polyethylene materials, such as medium-density EVA, in the design of the metatarsal pad for the management of corns. Appraisal of the evidence reviewing the effectiveness of insole materials in reducing pressure indicated that polyurethanes, particularly those of medium density, have a greater ability to reduce peak plantar pressures (PPPs) (Healy et al., 2010; Lee et al., 2014; Rogers et al., 2006). The preliminary investigation, which evaluated patients' perspectives of the insoles, found that patients preferred those made from the polyurethane materials, rather

than medium-density EVA. Since minimal differences in the level of pressure relief, stiffness, and patient comfort have been reported between medium-density polyurethanes, PodoPro Urethane was selected as the material for the evaluation of the metatarsal pad, due to its low cost. This is currently the least expensive polyurethane material, when compared to the widely used materials PPT and Poron, saving approximately £15 per sheet (100 cm x 46 cm). Cost implications are important to consider, as there is continued pressure for clinicians in practice, particularly those working in the NHS, to manage conditions in the most economically viable way without compromising quality of care and patient safety.

The second part of the research involved conducting a proof of concept pilot study to determine the feasibility and acceptability of evaluating the selected metatarsal padded insole in a larger-scale study. The major finding of the pilot study was that a larger-scale randomised controlled trial (RCT), evaluating the use of metatarsal padded insoles alongside SSD and enucleation, is feasible with recommendations – which were discussed in Chapter 7. This new contribution to podiatric knowledge is essential for the success of future research, which will assist in improving treatment outcomes for patients with plantar corns and enhance their quality of life.

Patient concordance is an essential component in the success of insole therapy for the management of painful plantar corns; this concordance contributes to prolonged treatment effects. Importantly, this pilot study demonstrated that participants could readily adopt the metatarsal padded insole into their everyday activities. Future research should continue to explore patients' perceived comfort and compliance levels in their use of the insoles.

The findings of the pilot study suggest that there is no additive effect of the use of metatarsal padded insoles in the management of plantar corns, when compared to SSD alone. Should the findings of a large-scale RCT be congruent to those of this pilot study, this implies that time and resources could be better utilised in clinical practice, with focus redirected to other pressure-relieving strategies. Although the research base strongly supports the theory that excessive pressure is a major contributory factor in the development of corns, further research investigating the causes of corn development is required to help establish the optimum treatment.

These preliminary investigations evaluating the use of metatarsal pads have provided the foundations of new knowledge upon which future research can build. This will continue to improve outcomes for patients with painful plantar corns. Future research should continue to investigate treatments that address the cause of corn development, rather than simply the removal of the lesion.

Chapter 9 - Appendices

9.1 School of Human and Health Research and Ethics Committee approval letter

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2 November 2015

TO WHOM IT MAY CONCERN

School Research Ethics Panel (SREP) Submission

Applicant Name:	**Grace Parfitt – PhD Student School of Human and Health Sciences University of Huddersfield**
Research Project:	**"The current use of plantar metatarsal pads in podiatric practice"**
Reference:	**SREP/2015/93**

I confirm that the above titled research project received ethical approval from the School of Human and Health Sciences Research Ethics Panel (SREP), University of Huddersfield on 30 October 2015.

I also confirm that indemnity for this project is covered by the insurance policy held by the University of Huddersfield, as it falls within the normal range of research activity.

Prof Rachel Armitage
Chair, School Research Ethics Panel (SREP)
School of Human and Health Sciences
Direct Tel: +44 (0)1484 473854
Email: R.A.Armitage@hud.ac.uk

Queensgate, Huddersfield, HD1 3DH, UK
+44 (0) 1484 422288 +44 (0) 1484 516151
Patron: HRH The Duke of York, KG
Vice-Chancellor: Professor Bob Cryan CBE DL MBA DSc CEng FIET FHEA

INVESTORS IN PEOPLE

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9.2 Permission from the College of Podiatry and Director of Education and Development

WF

Wilfred Foxe <wf@scpod.org>

Thu 05/11/2015, 12:50

Dear Grace,

I have heard back from the Conference Chair and he has given the green light to go ahead.

If you have a preferred way of moving forward it would be good to learn of that pretty soon.

Well done and good wishes

Wilfred

9.3 Questionnaire form used to investigate current practice of insole use

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The current use of plantar metatarsal pads in podiatric practice

I would like to invite you to take part in my research study being undertaken as a part of my PhD studies. The purpose of the research is to establish what is common practice for podiatrists prescribing plantar metatarsal pads.

Before you decide to complete the questionnaire I would like you to understand why the research is being done and what it will involve for you. You are being invited to complete this questionnaire that should take no longer 5 minutes about the current use of plantar metatarsal pads in podiatric practice. By completing the questionnaire you are consenting to taking part and you understand that once submitted the information will be used for my PhD. The data collected will be written-up as part of my PhD thesis. All data will be anonymised and stored securely on a password-protected computer and encrypted memory stick. Only my supervisors and myself will have access to the raw data.

Results may be presented at conferences and will be published in an academic journal. The information will be retained for 5 years and will then be disposed of securely. Only qualified podiatrists currently in practice can be involved in the study.

If you wish to be entered into the prize draw enter your mobile number or email on the bottom of the questionnaire. This will be drawn on Friday at 4.00pm.

PARTICIPANT QUESTIONNAIRE FORM

NO:

1) Please state your gender?

Male ☐ Female ☐ Other ☐

2) What is your age?

18-30years ☐ 31-40years ☐ 41-50years ☐ 51-60years ☐ 60+years ☐

3) What is your chiropody/podiatry qualification(s)?
(Please tick those that apply)

- ☐ Diploma in Foot Health (SMAE – grand parented)
- ☐ Diploma in Podiatric Medicine (DPodM)
- ☐ Podiatry BSc (Hons) Degree
- ☐ Masters (MSc)
- ☐ Doctorate (PhD)
- ☐ Other (Please Specify) _____

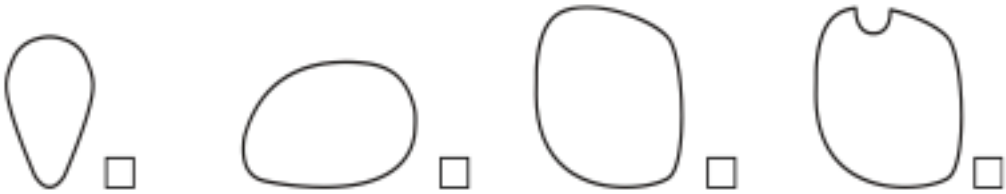
4) How many years experience do you have?

_____

5) In which of the following do you practice? (Please tick one of the following)

- ☐ NHS
- ☐ Private Sector
- ☐ Both NHS and Private sector
- ☐ Other (Please specify) _____

6) Please indicate which metatarsal pad you would make for a patient with a painful plantar corn located on the second? (Please tick one of the following)



Other (Please specify) ☐

7)

A. Which material would you use to construct this pad on an insole?
(Please tick one of the following)

- ☐ Low Density Ethyl Vinyl Acetate (EVA)
- ☐ Medium Density EVA
- ☐ High Density EVA
- ☐ Poron
- ☐ PPT (Professional Protective Technology)
- ☐ Other (Please specify) _____

B. What thickness (millimetres)?

_____

C. Please explain what you are hoping to achieve with this material and thickness?

_____

_____

D. What material would you use for the base, if any?
(Please tick one of the following)

- ☐ No Base
- ☐ Texon
- ☐ EVA
- ☐ Leather board
- ☐ Other (Please Specify) _____

E. What material would you use for the top cover, if any?
(Please tick one of the following)

- ☐ No top cover
- ☐ Poron
- ☐ Yampi
- ☐ Synthetic Leather
- ☐ EVA
- ☐ Other (please specify) _____

8)

A) Do you use insoles to manage painful plantar corns in your practice?
(Please tick one of the following)

- ☐ Yes (Go to question 6C)
- ☐ No (Go to question 6B)

B) If no, could you please let us know why you don't use them?

_____

_____

C) If yes, how many do you prescribe per month approximately?

_____

D) What outcome measure(s) do you use to assess the effectiveness of the plantar metatarsal pad insole?

_____

_____

Thank you for your time and cooperation it is greatly appreciated.

9.4 Participant information sheet for current practice survey

The current use of plantar metatarsal pads in podiatric practice

INFORMATION SHEET

You are invited to take part in this study.

Before you decide to take part it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Do not hesitate to ask if anything you read is unclear or would like further information.

What is the study about?

Currently there is no research evidence available that identifies what is common practice for podiatrists prescribing plantar metatarsal pads. A survey will be conducted to address this gaining insight into routine practice. Additionally the surveys' findings will provide a basis for further research in this field and ultimately to evidence based practice.

Why have I been approached?

You have been invited to participate because you are aged 18 years and above and are a qualified podiatrist. The study hopes to recruit a minimum of 100 participants.

You will not be able to take part if you tick any of the following:

- You are not currently practicing podiatry

Do I have to take part?

It is entirely your decision whether or not you take part. If you decide to be involved in the study you will be asked to complete a consent form. You will be free to withdraw at any time and without giving a reason.

What will I need to do?

You will be required to complete a short questionnaire this will take no longer than 5 minutes of your time.

Will my identity be disclosed?

All information collected will be kept confidential and anonymous, except where legal obligations would necessitate disclosure by the researcher to appropriate personnel. Paper data will be stored in a locked cabinet, within a locked office accessed only by the researcher. Similarly electronic data will be stored on an encrypted computer and password protected.

What are the advantages of taking part?

I cannot promise the study will help you but the information we get from the study will advance the knowledge in the area and will lead to further research to possibly improve the treatment of people with pain at the ball of their foot.

What will happen to the information?

The information collected from you during this research will be kept secure and any identifying material such as names will be removed in order to ensure anonymity. The study

will be written-up as part of my thesis. Results may be presented at conferences and will be published in an academic journal. Should this happen your anonymity will be ensured, although it maybe necessary to use your words in the presentation of the findings. Permission for this is included in the consent form. All information will be retained for 5 years and will be disposed of securely.

Further information and contact details:

Researcher: Grace Parfitt Grace.parfitt@hud.ac.uk / 07517 219403
Main Supervisor: John Stephenson, j.stephenson@hud.ac.uk /014844 471513

9.5 Email advertisement for patient comfort element

Good morning,

You are invited to participate in a research study aimed at evaluating materials used for plantar metatarsal pads. The purpose of the study is to establish which material provides the most comfort under the ball of the foot.

What does it involve?
If you decide to participate in this study it will take between 45 minutes to an hour. The researcher will take measurements of your foot to make 3 padded insoles using different materials. You will be asked to wear each of the pads for just a few minutes in your shoe then complete a short questionnaire rating the insoles comfort.

The study is completely voluntary. You will be free to withdraw at any point prior to write up of the data (November 2015). However once write up has commenced the information collected will be used for the research.

If you are interested in taking part please read the information sheet carefully. Contact myself on Grace.Parfitt@hud.ac.uk to arrange an appointment at your convenience or for any further information.

Thank you in advance.

Kind regards,
Grace Parfitt
PhD Student

9.6 Participant information sheet for patient comfort element

An evaluation of insole materials routinely used for plantar metatarsal pads

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INFORMATION SHEET

You are invited to take part in this study.
Before you decide to take part it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully. Do not hesitate to ask if anything you read is unclear or would like further information.

What is the study about?
Various materials are prescribed for plantar metatarsal pads in routine practice. The purpose of this study is to establish which material used for these pads the general population prefers. This will help podiatrists decide upon possibly more successful treatment plans for patients. It will also lead to a randomised controlled trial evaluating the effectiveness of the plantar metatarsal pad for the treatment of corns a common and often painful skin complaint.

Why have I been approached?
You have been invited to participate because you are aged 18 years or above and are either a student at the university or a member of staff. This pre-study hopes to recruit 10 participants.

You will not be able to take part if you tick any of the following:

- Unsuitable regular-use footwear. This includes, high heeled and narrow fashion shoes, sandals, and flip-flops.
- Current ulceration
- Loss of sensation (neuropathy)
- You refuse to participate in the study

Do I have to take part?
It is entirely your decision whether or not you take part. If you decide to be involved in the study you will be asked to complete a consent form. You will be free to withdraw at any time and without giving a reason.

What will I need to do?
The study will take between 45 minutes to an hour. The researcher will take measurements of your foot to make 3 padded insoles using different materials. You will be asked to wear each of the pads in your shoe completing a short questionnaire rating the insoles comfort.

Will my identity be disclosed?
All information collected will be kept confidential and anonymous, except where legal obligations would necessitate disclosure by the researcher to appropriate personnel. Paper data will be stored in a locked cabinet, within a locked office accessed only by the

researcher. Similarly electronic data will be stored on an encrypted computer and memory stick and password protected.

What are the advantages of taking part?
I cannot promise the study will help you personally but the information we get from the study will advance the knowledge in the area and possibly improve the treatment of people with pain at the ball of their foot.

What will happen to the information?
The information collected from you during this research will be kept secure and any identifying material such as names will be removed in order to ensure anonymity. The study will be written-up as part of my thesis. Results may be presented at conferences and will be published in an academic journal. Should this happen your anonymity will be ensured, although it maybe necessary to use your words in the presentation of the findings. Permission for this is included in the consent form. All information will be retained for 5 years and will be disposed of securely.

Further information and contact details:

Researcher: Grace Parfitt Grace.parfitt@hud.ac.uk / 07517 219403
Main Supervisor: John Stephenson, j.stephenson@hud.ac.uk /014844 471513

9.7 Participant consent form for patient comfort element

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An evaluation of insole materials routinely used for plantar metatarsal pads

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CONSENT FORM

It is important that you read, understand and sign the consent form. Your contribution to this research is entirely voluntary and you are not obliged in any way to participate. If you require any further details please contact the researcher.

Participant ID Number ☐

I have been fully informed of the nature and aims of this research ☐

I consent to taking part in it ☐

I understand that I have the right to withdraw from the research without giving reason at any point prior to write up of the data (before December 2015). Once write up has commenced the information collected will be used. ☐

I give permission for my words to be quoted (by use of pseudonym) ☐

I understand that the information collected will be kept in secure conditions for a period of 5 years at the University of Huddersfield ☐

I understand that no person other than the researcher/s and facilitator/s will have access to the information provided. ☐

I understand that my identity will be protected by the use of pseudonym in the report and that no written information that could lead to my being identified will be included in any report. ☐

If you are satisfied that you understand the information and are happy to take part in this project please put a tick in the box aligned to each sentence and print and sign below.

Signature of Participant:	Signature of Researcher:
_____	_____
Print:	Print:
_____	_____
Date:	Date:
_____	_____

One copy to be retained by Participant /one copy to be retained by Researcher

9.8 Questionnaire form for patient comfort element

Participant Questionnaire Form

Please take the time to answer the questions below. All the information will be kept confidential and anonymous by allocating you a number. If you feel uncomfortable disclosing any sensitive information please leave this blank.

Participant Number: - _____

1) What is your gender?

   _____

2) What is your age?

   _____

3) Weight, measured in pounds and kilograms?

   _____

4) Height, in feet and inches?

   _____

5) Please rate the comfort of each insole on the scales of 1-5 (5 being the most comfortable and 1 being the least).

   a. **Insole 1**

   Least Comfortable 1 2 3 4 5 Most comfortable

   b. **Insole 2**

   Least Comfortable 1 2 3 4 5 Most comfortable

   c. **Insole 3**

   Least Comfortable 1 2 3 4 5 Most comfortable

6) a. Do you think the comfort of the insoles can be improved? (Please circle)

No (Move to question 8)

Yes

b. If yes which insole(s) can be improved?

_____

7) How can the insole(s) be improved?

_____

_____

8) From the three insoles, what would be your preferred choice of insole?

_____

9) Why would this be your preferred choice?

_____

_____

10) Any further comments about the insoles?

_____

_____

Thank you for your time and co-operation.

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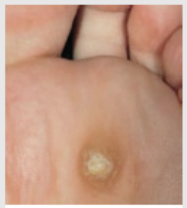
Material selection for plantar metatarsal pad insole therapy in the management of corns

Parfitt, G., Stephenson, J., Ousey, K., & Fleming, L.

INTRODUCTION

Sharp scalpel debridement and enucleation is the standard routine treatment for the management of corns. Since the effects of this treatment are short lived plantar metatarsal pads (PMPs) are widely prescribed alongside debridement. It is assumed that offloading the excessive pressure will subsequently decrease the mechanical stress and irritation at the site providing further relief for patients. Although this strategy is widespread there is no research evidence available to justify this clinical practice. A randomised controlled trial is proposed to establish whether the inclusion of a plantar metatarsal aperture pad alongside debridement provides any additional benefit in the management of corns.

The lack of clarity within the literature and the vast variety of materials available to podiatrists makes it a challenging process when prescribing the insoles. This preliminary research is essential to provide podiatrists with further knowledge and clarity during this process. Similarly, to assist in the development of the pilot protocol and the decision of the material to take forward within this clinical trial.



Plantar corn

PMP with aperture cut out at site of corn

Location of corn

METHODOLOGY

4 OBJECTIVES TO MEET THE AIM

To determine the preferred material for PMPs' in the management of corns.

1 To investigate what is currently being prescribed for plantar corns

Qualified podiatrists attending an annual conference were invited to complete a short questionnaire.

2 To conduct compression testing on the materials

Compression testing on various materials involved inter-disciplinary collaboration with the engineering department using the Instron 3369.

3 To evaluate the materials on healthy individuals

Participants were asked to wear 3 different PMP insoles:
Insole 1 – Poron
Insole 2 – Medium density EVA
Insole 3 – Podopro urethane

A questionnaire was then completed rating each insole for comfort.

4 To analyse the data

Microsoft Excel was used to analyse the data and decide upon the most appropriate material

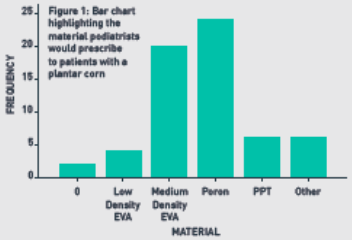


Figure 1: Bar chart highlighting the material podiatrists would prescribe to patients with a plantar corn

RESULTS

1 Survey

Of the 62 participants 55 (88%) of the participants emphasised they use PMPs to manage corns in routine practice. See figure 1 for material.

2 Compression Tests

Medium density EVA is the stiffest, 300kPa is required to compress the material 0.5mm. Poron is the most deformable (50kPa).

Figure 2: Pie chart illustrating the preferred choice of PMP material

3 Comfort study

Figure 2 illustrates that 75% of the 8 participants preferred podopro urethane PMP.

DISCUSSION POINTS

The survey demonstrates further investigation is required to evaluate the effectiveness and design of PMPs' as podiatrists are continuously prescribing them in routine practice without validated research evidence.

Although compression testing highlighted that medium density EVA has the greatest compressional strength, participants found this the least comfortable when asked to wear the insole. Patient compliance is essential when prescribing insoles this could explain why in the survey the majority of podiatrists prescribed poron.

One limitation of the comfort study is the sample size and population as the results may not be generalizable to patients with forefoot pain.

One strength of the compressional testing is the consistent results when testing each material specimen three times demonstrating high reliability and repeatability.

CONCLUSION

The podopro urethane material will be selected for investigation. This material is stiffer than poron and participants found the insole the most comfortable.

9.10 Email advertisement of pilot study

Good morning,

ATTENTION: Have you got a corn on the ball of your foot?

If eligible you can receive free treatment of your diagnosed plantar corn for the duration of the study.

A clinical trial is being conducted at the university in the podiatry department.

The study is aimed at establishing whether scalpel debridement and the use of metatarsal padded insoles have a beneficial role in preventing recurrence of corns, enhancing mobility and reducing pain. The overall intentions of the research are to advance knowledge and improve the management of this common and often painful skin compliant.

If you are interested in taking part please read the information sheet carefully. Contact myself on Grace.Parfitt@hud.ac.uk to arrange an appointment at your convenience or for any further information.

Thank you in advance.

Kind regards,
Grace Parfitt
Full time PhD Student

9.11 Poster advertisement pilot study

Patients Needed
For PHD Research

Have you got a corn on the ball of your foot?

Patients who meet the criteria will receive **free treatment**. The research will investigate the effectiveness of scalpel debridement and the use of padded insoles.

Contact Grace Parfitt for more information:-
Grace.Parfitt@hud.ac.uk - 07517219403

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9.12 EQ-5D-3L questionnaire form

Health Questionnaire

English version for the UK

(Validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain / Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety / Depression

I am not anxious or depressed ❑

I am moderately anxious or depressed ❑

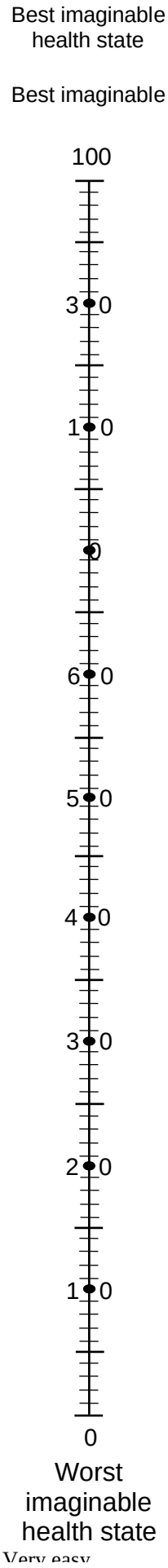
I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today

YVery uncomfortable



9.13 License approval to use EQ-5D-3L questionnaire

Date: Monday, 3 August 2015 08:53
To: Grace Parfitt <parfittgrace@outlook.com>
Subject: RE: EQ-5D registration

Dear Ms. Parfitt,

Thank you for registering your research at the EuroQol Reseach Foundation's website.

As the "The effectiveness of sharp scalpel debridement and plantar metatarsal pads for the management of corns" study you registered involves low patient numbers (100) you may use the EQ-5D-3L instrument (Paper version) free of charge. Please note that separate permission is required if any of the following is applicable:

- Funded by a pharmaceutical company, medical device manufacturer or other profit-making stakeholder;
- Number of respondents over 5000
- Routine Outcome Measurement;
- Developing or maintaining a Registry;
- Digital representations (e.g. PDA, Tablet or Web)

Please find attached the English (United Kingdom) EQ-5D-3L version (word format). A brief user guide is downloadable from the EuroQol website (www.euroqol.org)

Kind regards,

9.14 Manchester Foot Pain and Disability Index (MFPDI) questionnaire form

The Manchester Foot Pain and Disability Index

Below are some statements about problems people have **because of pain in their feet.**

For each statement indicate if this has applied to you **during the past month.** If so, was this only on some days or on most or every day in the past month?

PLEASE TICK A BOX FOR EACH STATEMENT.

	During the past month this has applied to me			
Because of pain in my feet:	**None of the time**	**On some days**	**On most/ every day(s)**	
I avoid walking outside at all	☐	☐	☐	
I avoid walking long distances	☐	☐	☐	
I don't walk in a normal way	☐	☐	☐	
I walk slowly	☐	☐	☐	
I have to stop and rest my feet	☐	☐	☐	
I avoid hard or rough surfaces when possible	☐	☐	☐	
I avoid standing for a long time	☐	☐	☐	
I catch the bus or use the car more often	☐	☐	☐	
I need help with housework/shopping	☐	☐	☐	
I get irritable when my feet hurt	☐	☐	☐	
Because of pain in my feet:				
I feel self-conscious about my feet	☐	☐	☐	
I feel self-conscious about the shoes I have to wear	☐	☐	☐	
I still do everything but with more pain and discomfort	☐	☐	☐	
I have constant pain in my feet	☐	☐	☐	
My feet are worse in the morning	☐	☐	☐	
My feet are more painful in the evening	☐	☐	☐	
I get shooting pains in my feet	☐	☐	☐	
Because of pain in my feet:				**Not applicable**
I am unable to carry out my previous work	☐	☐	☐	☐
I no longer do all my previous activities (sport, dancing, hill walking etc)	☐	☐	☐	☐

TICK HERE WHEN YOU HAVE READ ALL THE STATEMENTS ON THIS PAGE ☐

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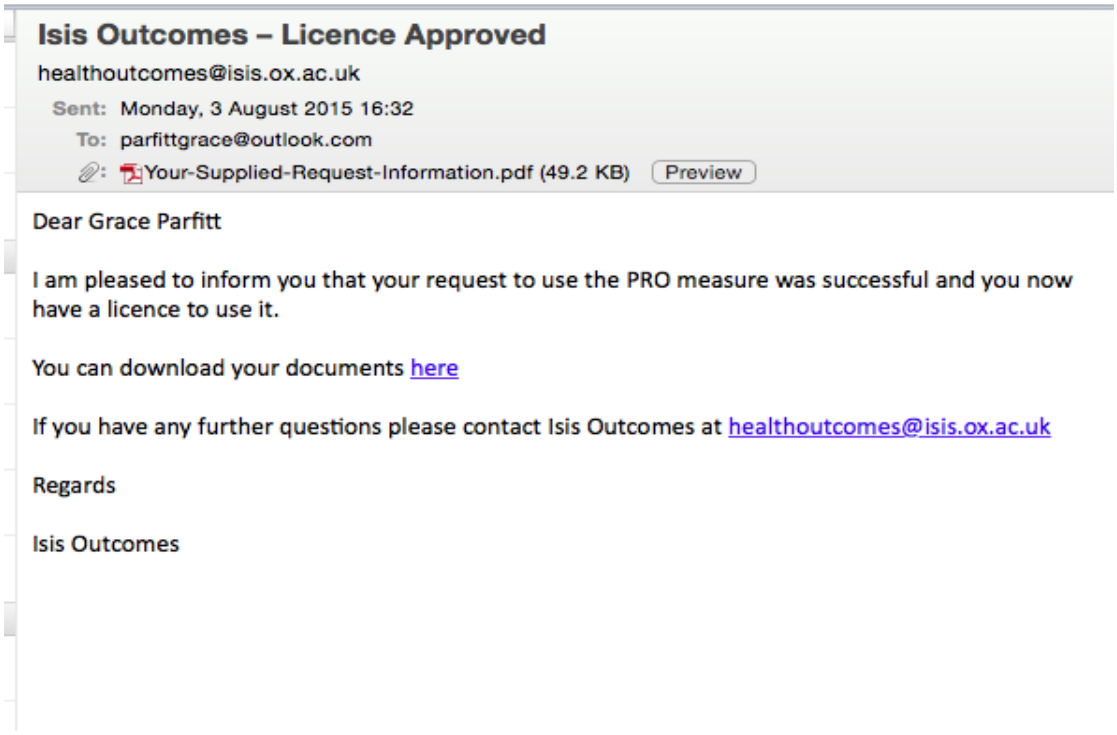
9.15 License approval to use MFPDI questionnaire



Isis Outcomes – Licence Approved

healthoutcomes@isis.ox.ac.uk

Sent: Monday, 3 August 2015 16:32

To: parfittgrace@outlook.com

Your-Supplied-Request-Information.pdf (49.2 KB) Preview

Dear Grace Parfitt

I am pleased to inform you that your request to use the PRO measure was successful and you now have a licence to use it.

You can download your documents here

If you have any further questions please contact Isis Outcomes at healthoutcomes@isis.ox.ac.uk

Regards

Isis Outcomes

9.16 Participant feedback questionnaire form for the pilot study

Participant Feedback Questionnaire Form- Insole Group

Please take the time to answer the questions below. All the information will be kept confidential and anonymous by allocating you a number. If you feel uncomfortable disclosing any sensitive information, please leave this blank.

Participant No:

1) A) Do you think the insoles provided benefit in the treatment of your corn?

Yes
No

B) Please state why?

_____

_____

2) Please rate the comfort of the insole on the scale 1-5 below (5 being the most comfortable and 1 being the least).

Very uncomfortable 1 2 3 4 5 Very comfortable

3) Please rate how often you wore the insoles over the course of the study on the scale 1-5 below (5 being all the time and 1 being rarely).

Rarely 1 2 3 4 5 All the time

4) A) Please rate how easy the insoles were to incorporate into your daily routine on the scale 1-5 below (5 being very easy and 1 being very difficult).

Very Difficult 1 2 3 4 5 Very easy

B) Please give your reason(s) for the above answer (4A).

_____

_____

5) A) Will you continue to wear the insoles after the study?

Yes
No

B) Please state your reason(s) for this?

_____

_____

6) Any additional comments

_____

_____

Thank you for your time and co-operation.

9.17 Debridement protocol for pilot study

Protocol for debridement

Preparation

To reduce the risk of cross-contamination ensure the clinical area is decontaminated. Follow the necessary hand hygiene steps and apply personal protective equipment (PPE)

SSD and enucleation

Ensure effective skin tension is applied adjacent to the corn and overlying callus to control depth of debridement and stabilise the underlying soft tissue.

Firstly debride the callus by starting at the most distal border. Continue to reduce the thickness of the devitalised tissue until the area has returned to a pink appearance similar to the adjacent healthy tissue and papillary ridges are no longer visible.
The nucleus of the corn should now be exposed. Scalpel handling should now be changed to a pen grip technique.
With the point of the blade, to minimise risk of injury to surrounding healthy tissue, circumscribe the peripheral edge of the nucleus.

Remove the nucleus by angling the blade approximately 90° undercutting the devilized, and hard translucent tissue minimalising injury.

Ensure the corn is completely removed by assessing the appearance and applying direct pressure to gain patient feedback.

Haemorrhage caused

No

Following SSD and enucleation

Provide patient with standardised verbal/written patient advice regarding the daily use of a urea based emollient.

Ensure sharps are disposed of appropriately according to university policy.

For infection control purposes decontaminate clinical area and wash hands post-treatment.

Provide patient with an appointment for a follow-up evaluation.

Yes

Management of haemorrhage

Apply pressure to the site to stem the haemorrhage. Use of a haemostatic dressing to control haemorrhage if necessary.

Apply a dry, low-adherent dressing to the area using the aseptic-no-touch technique

9.18 Protocol for insole construction

Template

Match and fit two pieces of card to the patients inlay of their typical shoe.

Locate the metatarsal heads, styloid process, and corn then mark with lipstick.

The patient should now carefully place their feet inside their shoes and stand up.

Remove cards from the shoe and review the templates, ensuring it matches the markings on the patient's foot.

Draw the shape of the metatarsal pads. The metatarsal pad should follow the shape of the metatarsal heads covering them by 5 mm. Its sides should be parallel to the width of the card inlay. The pad should finish distal to the styloid process (Frowen et al., 2010; P. Lee et al., 2014; Yates & Merriman, 2009).

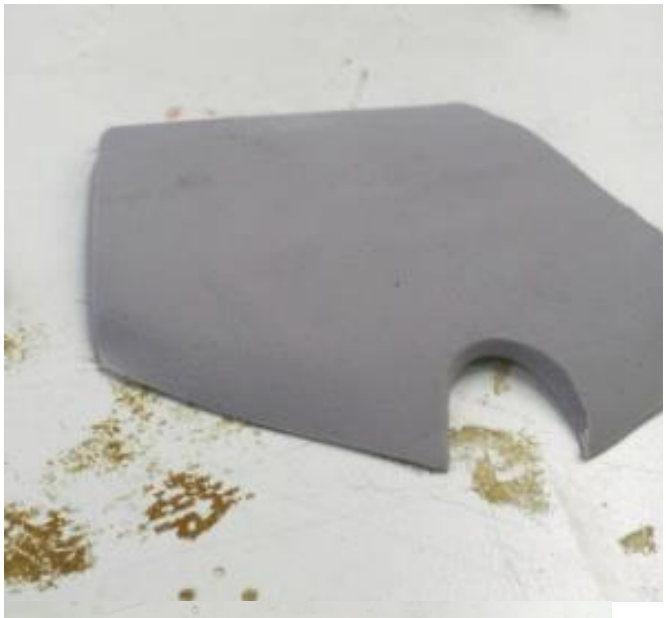
An aperture should be drawn onto the metatarsal pad template at the site of the corn on the affected foot. The aperture should border the corn by 5 mm (Nubé et al., 2006). A ‘U’ or ‘winged’ shaped cut-out, dependent on the location of the corn, should be placed when the corn lies close to the distal border of the pad. ‘U’ shaped when the corn is located on the second to forth metatarsal heads. ‘Wing’ shaped when located on either first or fifth (Frowen et al., 2010; Yates & Merriman, 2009).

Manufacture

Draw the shape of the insole card template onto Texton to create the base for the device.

Carefully cut-out the metatarsal pad from the card template.
Draw around the metatarsal pad template on to the 6 mm PodoPro urethane material.

Cut-out the 6 mm PodoPro urethane material around the shape. Using the grinder, smooth off the edges and bevel the borders at a 45° angle.



Place the card template over the top of the Texon base to line up the location of the metatarsal pad accurately.

Glue the metatarsal pad onto the Texon base and cover with Poron (1.2 mm)

Fitting

Line insole up against the plantar aspect of the patient's foot to check positioning is accurate.

Place insole inside patient's typical footwear and ask the patient to walk up and down the clinic to assess for comfort.

Should the patient report any discomfort insoles were reviewed and addressed accordingly.

Give appropriate verbal and written advice to patient:

1) To wear devices during everyday activities during weight-bearing.
2) Devices can be transferred to other suitable footwear
3) To remove should patient develop any pain or discomfort and contact the researcher.

Patient to return for follow-up evaluation.

Chapter 10 - References

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