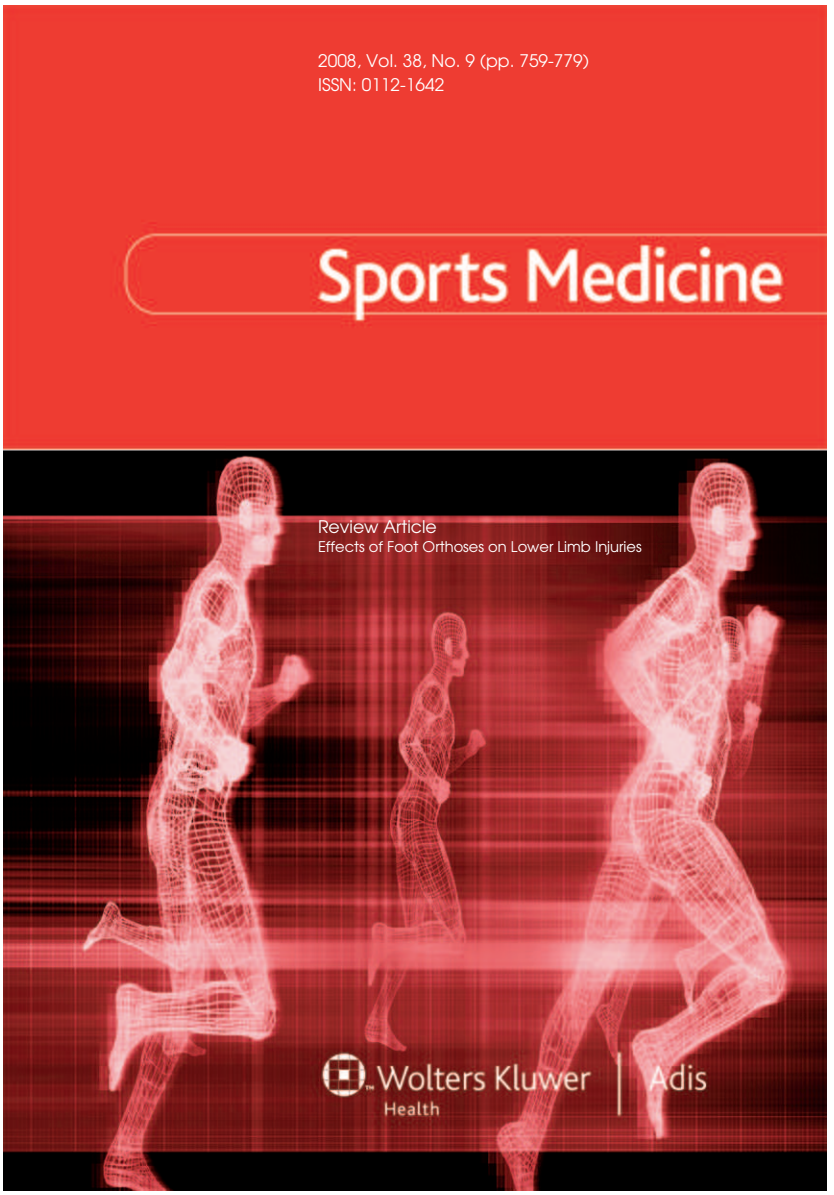

REVIEW ARTICLE

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Effectiveness of Foot Orthoses for Treatment and Prevention of Lower Limb Injuries

A Review

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Contents

Abstract

Healthcare professionals prescribe foot orthoses (FOs) for treatment and prevention of lower limb injuries, but previous reviews of the effectiveness of FOs

have been inconclusive. We have therefore performed a review emphasizing the magnitude of treatment effects to evaluate the clinical effectiveness of FOs in the treatment and prevention of lower limb injuries.

Qualifying studies were mainly controlled trials, but some uncontrolled clinical trials of patients with chronic injuries were analysed separately. Injuries included plantar fasciitis, tibial stress fractures and patellofemoral pain syndrome; these were included because of the large treatment costs for these frequent injuries in New Zealand. Outcomes were pain, comfort, function and injury status. Continuous measures were expressed as standardized differences using baseline between-subject standard deviations, and magnitudes were inferred from the intersection of 90% confidence intervals with thresholds of a modified Cohen scale. Effects based on frequencies were expressed as hazard ratios and their magnitudes were inferred from intersection of confidence intervals with a novel scale of thresholds.

The effects of FOs for treatment of pain or injury prevention were mostly trivial. FOs were not effective in treating or preventing patellofemoral pain syndrome. Some studies showed moderate effects for treatment of plantar fasciitis. Only a few studies showed moderate or large beneficial effects of FOs in preventing injuries.

Customized semi-rigid FOs have moderate to large beneficial effects in treating and preventing plantar fasciitis and posterior tibial stress fractures, and small to moderate effects in treating patellofemoral pain syndrome. Given the limited randomized controlled trials or clinical controlled trials available for the injuries of interest, it may be that more or less benefit can be derived from the use of FOs, but many studies did not provide enough information for the standardized effect sizes to be calculated. Further research with randomized controlled trials is needed to establish the clinical utility of a variety of FOs for the treatment and prevention of various lower limb injuries.

Movement of the foot and ankle influences the transfer of forces through the lower limb during locomotion. It is important for the lower extremity to distribute and dissipate compressive, tensile, shearing and rotatory forces during the stance phase of gait, as inadequate distribution of these forces could lead to abnormal stress and eventual breakdown of connective tissue and muscle.[1] Pathologies such as plantar fasciitis, shin splints and nonspecific knee pain may result from abnormal mechanics of the foot and ankle, and are commonly treated with foot orthoses (FOs).

Plantar fasciitis is an overuse syndrome of the heel characterized by localized inflammation of the plantar fascia at its anatomical insertion on the calcaneus. Plantar fasciitis causes heel pain in active as well as sedentary adults of all ages and is a common condition estimated to affect 10% of runners.[2] The aetiology of plantar fasciitis is somewhat controversial, but many risk factors may contribute to its development.[3-6]

Tibial stress fractures are an overuse syndrome of the lower limbs characterized by localized inflammation around bones, in particular the medial border of the tibia, but can also present in the lateral aspect of the tibia, along the lower third of the fibular, and in the calcaneus. The aetiology of stress fractures includes poor foot mechanics and high repetitive loads. Disturbances in bone remodelling can lead to the occurrence of stress reactions and bone stress fractures.[7] Stress fractures are considered to result from repetitive loading of bone, during which high strains or high strain rates occur.[8] When the repetitive strain environment in the bone is above the level that it is used to, exceeding its local strength, microdamage is thought to result.[9] Stress fractures are a problem frequently seen by healthcare professionals among people who participate in recreational sports

and physical fitness training.[9] Stress fractures particularly in the region of the tibia, are a significant problem in military recruits[9-11] and in athletes, particularly long distance runners,[7,12] and are seen more commonly in people between the ages of 18 and 28 years.[13] The ideal strategy for stress fracture prevention is to decrease the magnitude and intensity of bone stress without affecting the quality of training.[8] Measures carried out by healthcare professionals to prevent stress fractures include modifications to footwear and FOs.[7] This review focuses on tibial stress fractures.[7]

Patellofemoral pain syndrome is characterized by pain and swelling at the front of the knee and weakness of the vastus medialis obliqus muscle.[14] The knee pain experienced appears to worsen after activities involving heavy knee loads, such as walking up stairs, running or cycling.[15] The aetiology of patellofemoral pain syndrome is still unclear.[16-18] Some authors have suggested that the pain and discomfort is likely to be the result of abnormal muscular and biomechanical factors that alter the distribution of shearing and compressive forces on the patellofemoral joint during normal activity.[19,20] The most common reasons proposed for the development of anterior knee pain are overuse, malalignment and trauma.[17] A deviant tracking pattern of the patella with respect to the femoral groove could cause an abnormal distribution of the joint's reaction stress on the subchondral bone of the patella and impingement of surrounding soft tissues.[19] Malalignment of the patellofemoral mechanism is not only caused by local patellofemoral mechanics, but also reflects anatomical variations throughout the entire lower extremities; indeed, patellofemoral pain syndrome is in some studies highly correlated with excessive pronation.[20]

FOs are considered a biomechanical treatment modality for prevention and/or rehabilitation of foot and ankle injuries to re-establish the normal biomechanics of the foot and ankle.[13] However, there is limited knowledge about the specific function that FOs perform.[21] The same type of FO is often used to solve several different problems.[22] FOs are often prescribed to improve lower extremity alignment. However, studies have shown that FOs have no effect on knee alignment and, while they may or may not alter subtalar joint alignment, the clinical benefit of such a possible change remains unclear.[23] Individual responses in kinematics and kinetics due to systematic interventions are not consistent.[24] Therefore, one should not expect systematic results in the functioning of such FOs, but rather a wide variety of effects produced by FOs. Additionally, the reaction of subjects to FO interventions is influenced by many factors, including mechanical, neurophysiological, anatomical and maybe even psychological,[24] which makes the prediction of an FO intervention outcome even more difficult. From a biomechanical point of view, FO comfort may be related to fit, additional stabilizing muscle work, fatigue and damping of soft tissue vibrations. Nigg et al.[22] proposed that an optimal FO should reduce muscle activity, feel comfortable and should increase athletic performance. The insert or FO filters the ground reaction force information, which is then transferred to the CNS to provide a subject-specific dynamic response. It has been proposed[22] that for any given movement task, the skeleton has a preferred path, and an intervention can support or counteract the preferred movement path by reducing or increasing the corresponding muscle activity. Some authors have suggested that the shock-absorbing effects of FOs, and not their ability to correct alignment and control motion, may be their most useful asset.[22,25]

The aim of this article is to review the clinical (not biomechanical) effects of FOs in the treatment and prevention of plantar fasciitis, tibial stress fractures and patellofemoral pain syndrome.

1. Research Methods

The review methodology broadly followed that outlined by the Cochrane Collaboration[26] to evaluate the effectiveness of FOs in the treatment and prevention of lower limb injuries. The methodology included the following: a literature search; assessment of study quality (e.g. whether it was a randomized controlled trial, or a controlled or uncontrolled clinical study); data collection of study characteristics including methods, participants, interventions, outcome measures and results; analysis and interpretation of results; recommendations for clinical practice and further research. We have outlined study characteristics and have attended to the issue of magnitude of effects.

1.1 Study Selection

Searches of AMED, CINAHL, OVID MEDLINE, and SPORTDISCUS databases were performed for studies published in English up to and including March 2008. The computer databases provided access to sports-oriented and biomedical journals, serial publications, books, theses, conference papers and related research published since 1948. The search terms used for relevant research studies included randomised controlled trials (RCT), orthoses (also orthotic devices and insoles), patellofemoral pain syndrome (also anterior knee pain, patella tendinopathy, chondromalacia patella), plantar fasciitis (also plantar heel pain, heel pain, heel spur, plantar fasciopathy), and tibial stress fractures (also shin splints, anterior compartment syndrome).

The heel pain search strategy came from Crawford and Thompson's[2] Cochrane Review on interventions for treating plantar heel pain. The patellofemoral pain syndrome strategy came from the Cochrane Review by D'Hondt et al.[19] on orthotic devices for treating patellofemoral pain syndrome. The stress fractures strategy came from the Cochrane review by Rome et al.[7] on interventions for preventing and treating stress fractures and stress reactions of bone of the lower limbs in young adults. Articles that were not published in English and/or in scientific journals were excluded. The reference lists of review articles and all included articles identified by the search were examined for other eligible studies.

Papers were gained and initially reviewed by one researcher, and then each paper and the summary of the first review were evaluated by two researchers to confirm inclusion in the analysis. At the end of the first analysis, a fourth researcher conducted another independent full search using an expanded keyword list of terms and found only one additional paper than had been published since the first search. The results of the analyses were then independently reviewed by a fifth researcher.

1.2 Types of Studies Included

This paper reviews randomized controlled trials, controlled clinical studies, and uncontrolled clinical studies, as well as Cochrane reviews and systematic reviews.

1.2.1 Randomized Controlled Trials

Initially only controlled trials of FOs on injured subjects were eligible for the effect size calculations. Numerous studies were excluded on the grounds of no control group, a non-injured control group, inappropriate comparisons or poor reporting of statistics.

A limited number of randomized controlled studies were reported in the Cochrane reviews that investigated the use of FOs. For example, the patellofemoral pain syndrome[19] and Achilles tendonosis[27] reviews unfortunately provided no information on randomized controlled studies that had used FO interventions as a means of treatment or prevention. If a review did identify a randomized controlled trial, generally between one and three studies were reported. A more recent Cochrane review conducted on stress fractures[7] identified six possible randomized controlled trials that had used or compared the use of FOs. These trials tended to be poorly designed or did not provide enough vital information required for effect size calculation, such as specific p-values. This was indicated in the identified Cochrane reviews where the so-called randomized controlled trials were generally classified with a poor to moderate quality score. No additional randomized controlled trials were located from any of the remaining search strategies.

1.2.2 Controlled Clinical Studies

A number of controlled clinical studies that were conducted in a time series manner were also identified, several of which used healthy individuals to investigate mechanical alterations due to the use of FOs. For a study to be included in the clinical trials tables (see section 2), there needed to be a chronic condition with a relatively short treatment duration compared with the prior duration of the injury in order to reduce the risk of bias from natural recovery. Some studies with co-interventions were excluded if the effect of the co-intervention was not clear.

1.2.3 Uncontrolled Clinical Studies

We analysed uncontrolled clinical trials (time series) that assessed the effectiveness of FOs in treating chronic lower limb pain, in descending order of strength of evidence. For a study to be included, there needed to be a chronic condition with a

relatively short treatment duration compared with the prior duration of the injury in order to reduce the risk of bias from natural recovery. It is noted that phenomena such as the 'placebo effect', the 'Hawthorn effect' and 'natural resolution of the condition' are not addressed in studies without a control group. Therefore, there is potential for overestimation of the effect of the interventions.

1.2.4 Cochrane and Systematic Reviews

A number of systematic reviews on FOs in general or treatments for the injuries of interest were retrieved. Seven Cochrane reviews that met the criteria of the search strategy were found.[2,7,19,27-30]. Each injury area of interest generally had a meta-analytical review conducted on the interventions for treating or preventing the respective injury. However, the scope of these reviews was such that multiple interventions were reviewed (i.e. surgery, exercise, stretching, NSAIDs). Data were extracted from these reviews where possible.

1.3 Types of Injuries Included

There were limited randomized controlled trials, controlled clinical studies or uncontrolled clinical studies for the injuries of interest: plantar fasciitis; tibial stress fracture; and patellofemoral pain syndrome.

1.4 Types of Foot Orthoses

There is no universal definition of FOs.[31] Terminology used in the clinical setting and the evidence base includes accommodative, functional, off-the-shelf, pre-fabricated, prescription and functional FOs. Rome and Brown[32] have noted that the rationale by authors for the choice of specific FOs used in studies is often unclear, and there is variation and imprecision in the terms used to describe FOs. Wu[33] described FOs as a medical device employed to support and align the foot, to prevent or correct foot deformities, or to improve the functions of the foot. FOs can either be prefabricated or customized. Hawke et al.[34] defined customized FOs as contoured, removable, in-shoe devices that are moulded or milled from an impression of the foot (for example, a plaster cast or 3-dimensional laser scan), and fabricated according to practitioner-prescribed specifications.

Many of the customized FOs are either placed in a subtalar neutral position or weight-bearing position. It is generally accepted that subtalar neutral position is attained when the subtalar joint is neither pronated nor supinated.[35] Although this position is widely used as the reference point to clinically measure and diagnose the relationship between the forefoot and the rearfoot, previous studies have questioned the value of using this position.[36] The reliability of this method varies according to experience of the clinician and position of the patient.[37]

In summary, to overcome the problems of terminology and definitions, this review categorizes FOs into customized or prefabricated rigid, semi-rigid and soft.[38-40] The difference between the three types is based upon the physical properties (such as density, thickness and shore durometer readings) of the construction materials for FOs. Materials can range from foam rubber to complex thermoplastic polymers such as polypropylene and carbon-graphite. Future work should focus on descriptions and definitions of FOs.

1.5 Analyses

1.5.1 Outcome Measures for the Effectiveness of Orthoses in Treatment or Prevention of Injury

The effectiveness of different treatment protocols can be evaluated using outcome measures of patient satisfaction, improved quality of life, cost,[41] and movement pattern changes in the alignment of the lower extremity. This paper discusses the evidence for FOs being effective in the treatment of injuries and deformities of the leg and foot in terms of patient pain and comfort. The paper also discusses the evidence for FOs being effective in the prevention of lower limb injury in terms of reduced incidence of injury.

Differences, changes or differences between changes in the means of continuous measures were expressed as standardized[42] effects using the baseline between-subject standard deviation of the measure as the denominator. Magnitudes of the standardized effects were interpreted using the following version of Cohen's[42] scale, as modified by Hopkins:[43] <0.20 = trivial; 0.20–0.59 = small; 0.60–1.19 = moderate; ≥1.20 = large. For outcomes representing counts or proportions of injuries, we

Table I. Summary of the strength of the evidence for treating and preventing injuries and the number of studies in each category that met the criteria for paper selection

Injury (estimates)[a]	Type of foot orthosis			Type of study		
	rigid	semi-rigid	soft	treatment controlled	treatment uncontrolled	prevention controlled
Plantar fasciitis (33)	++/−	++	+/0	3	3	−
Patellofemoral pain (5)			+	0	2	1
Tibial stress fractures (10)	0	+	+	0	0	6

a Number of estimates used to determine the overall effect.

0 indicates a trivial or unclear effect; **+** indicates a small beneficial effect; **++** indicates a moderate beneficial effect; **−** indicates a small harmful effect.

used the following unpublished approach. First, we assumed a constant rate of injury in each group to allow calculation of an instantaneous rate ratio (hazard ratio [HR]). Next, we calculated relative risk and odds ratios and their confidence limits, and then derived confidence limits for the HR by assuming these were approximately equal to the square root of the product of the corresponding confidence limits for the relative risk and odds ratio. Finally, we interpreted the magnitude of the HR using the following scale, which is based on a Cohenization of the time to injury (or time to recovery from injury) when the HR is constant: <1.28 = trivial; 1.28–1.99 = small; 2.0–4.4 = moderate; ≥4.5 = large (and corresponding inverses of these values: >0.78 = trivial; 0.78–0.51 = small; 0.50–0.23 = moderate; ≤0.22 = large).

1.5.2 Inferences about Magnitude of Effects

In keeping with recent trends in inferential statistics,[44] we made magnitude-based inferences about true (population) values of effects by expressing the uncertainty in the effects as 90% confidence limits. An effect was deemed unclear if its confidence interval overlapped the thresholds for substantiveness (that is, if the likelihood of the effect being either substantially positive or negative was >5%); otherwise, the magnitude of the effect was reported as the magnitude of its observed value.[44,45]

1.6 Summary of Criteria for Paper Selection and Outcome Measures

Papers fulfilled selection criteria if they were studies on one of the three injury types, human studies and published in English. Randomized controlled trials and controlled clinical studies were termed 'controlled studies'. Uncontrolled clinical studies using prospective methods were termed 'uncontrolled studies'. Studies were divided into those that used FOs for treatment and those that used FOs prospectively for prevention of injuries. The data presented in table I show that there were few studies that satisfied the inclusion criteria, and several did not provide enough detail to allow magnitudes of effects to be calculated. For example, several papers showed no pre-data so pre-post values could not be calculated,[15,46-49] the focus was on biomechanical variables instead of function or pain,[18,20] or subjects did not have a chronic injury to start with.[50,51] One study focused on an injury that was not of interest to this review (flat feet)[52] and another addressed overuse conditions by pooling data and generalizing results rather than reporting for specific conditions.[3] Of the papers that met the inclusion criteria, there were several outcome measures, and these were classified as continuous or count measures, such as pain on a scale of 0–100, percentage injured and HRs.

2. Results

Table I shows that the three categories of FOs had varying effects (e.g. trivial or unclear, small beneficial, etc.) for treating or preventing injuries.

Table II shows that two studies provided enough information for the standardized effect sizes to be calculated for continuous outcome measures (i.e. there were pre-means and standard deviations). One study showed positive effects of FOs and one showed moderate harmful effects for treating injuries (table II). Table III shows that four studies provided enough information for assessment of magnitude for hazard ratios to be calculated. Two studies showed moderate positive benefits, one study showed mod-

Table II. Controlled clinical trials of effectiveness of foot orthoses in the treatment of chronic lower limb pain for continuous outcome measures of pain and foot function, where the control group did or did not have a mechanical intervention. Studies are sorted in descending order of benefit

Pre-existing condition	Prior duration of injury (mo)	Orthotic group (O) treatment	no. of subjects	D/L	Control group (C) treatment	no. of subjects	D/L	Follow-up time (wk)	Outcome measure	Change[a] scores	Effect[b] (%); ±90% CL	ES; ±90% CL	Assessment of magnitude
Landorf et al.[54]													
Plantar fasciitis	≥1	Prefabricated semi-rigid	44	0/0	Customized soft sham	46	0/2	12	Foot pain 0–100 at 3 mo	O: 29.3 C: 18.3	11; ±8	0.54; ±0.39	Moderate benefit
									Foot function 0–100 at 3 mo	O: 25.7 C: 11.5	14; ±8	0.52; ±0.30	Moderate benefit
		Prefabricated semi-rigid	44	0/1	Customized soft sham	46	0/3	52	Foot pain 0–100 at 12 mo	O: 41.7 C: 37.2	5; ±6	0.22; ±0.31	Small benefit
									Foot function 0–100 at 12 mo	O: 33.4 C: 14.1	19; ±7	0.71; ±0.24	Moderate benefit
		Customized semi-rigid	46	0/1	Customized soft sham	46	0/2	12	Foot function 0–100 at 3 mo	O: 21.9 C: 11.5	10; ±7	042; ±0.30	Moderate benefit
									Foot pain 0–100 at 3 mo	O: 23.4 C: 18.3	5; ±7	0.25; ±0.36	Small benefit
		Customized semi-rigid	46	0/1	Customized soft sham	46	0/3	52	Foot pain 0–100 at 12 mo	O: 34.7 C: 42.7	8; ±7	0.39; ±0.36	Small benefit
									Foot function 0–100 at 12 mo	O: 28.0 C: 19.6	8; ±7	0.34; ±0.28	Moderate benefit
Pfeffer et al.[55] [c]													
Proximal plantar fasciitis	≥1	Prefabricated soft	50	7/0	Stretch	46	7/0	8	Pain 0–100	O: 28, C: 16	12; ±12	NA	[d]
Proximal plantar fasciitis	≥1	Prefabricated soft (silicone)	51	9/0	Stretch	46	7/0	8	Pain, 0 –100	O: 23 C: 16	7; ±11	NA	[d]
		Customized semi-rigid	42	8/0	Stretch	46	7/0	8	Pain, 0–100	O: 19 C: 16	3; ±12	NA	[d]
		Prefabricated soft (felt)	47	5/0	Stretch	46	7/0	8	Pain, 0–100	O: 19 C: 16	3; ±11	NA	[d]
Lynch et al.[56]													
Plantar fasciitis	?	Customized rigid	35	7/1	Anti-inflamm-atories	35	4/7	12	Pain 0–10	O: 4.4 C: 3.4	10; ±14	NA	[d]

Continued next page

Table II. Contd

Pre-existing condition	Prior duration of injury (mo)	Orthotic group (O) treatment	no. of subjects	D/L	Control group (C) treatment	no. of subjects	D/L	Follow-up time (wk)	Outcome measure	Change[a] scores	Effect[b] (%); ±90% CL	ES; ±90% CL	Assessment of magnitude
Rome and Brown[32]													
Plantar heel pain	≥2	Prefabricated semi-rigid	26	?/?[a]	Prefabricated soft	22	?/?	4, 8	FHSQ footwear 0–100	O: 3 C: −6	9; ±14	0.38; ±0.61	Unclear
									FHSQ foot pain 0–100	O: 35 C: 32	3; ±13	0.14; ±0.59	Unclear
									FHSQ foot function 0–100	O: 20 C: 16	4; ±14	0.15; ±0.50	Unclear
									FHSQ GFH 0–100	O: 9 C: 18	−9; ±10	-0.38; ±0.41	Small harm
Lynch et al.[56]													
Plantar fasciitis	?	Prefabricated soft	35	9/11	Anti-inflamm-atories	35	4/7	12	Pain, 0–10	O: 2.2 C: 3.4	−12; ±17	NA	[d]
Martin et al.[57]													
Plantar fasciitis	≥5	Customized semi-rigid	61 F, 24 M	6/8	Tension night splint	69 F, 16 M	22/3	12	Pain during day, 0–10	O: 3.4 C: 2.8	6; ?	NA	[d]
									Pain 1st step, 0–10	O: 5.3 C: 6.1	−8; ?	NA	[d]
		Prefabricated semi-rigid	65 F, 20 M	18/5	Tension night splint	69 F, 16 M	22/3	12	Pain during day, 0–10	O: 3.2 C: 2.8	4; ?	NA	[d]
									Pain 1st step, 0–10	O: 5.3 C: 6.1	−8; ?	NA	[d]

a Positive scores indicate improvement, i.e. less pain or more comfort.

b All scores have been converted to 0–100 scale to allow comparison.

c Proportion of females in final subjects 60% and 72%.

d Not enough information was provided to make this assessment.

CL = confidence limit; **D/L** = drop-outs/lost to follow-up; **ES** = standardized effect; **F** = female; **FHSQ** = foot health status questionnaire; **GFH** = general foot health; **M** = male; **NA** = not available; **?** indicates unknown/not reported.

Table III. Controlled clinical trials of effectiveness of foot orthoses in treatment of chronic lower-limb pain for count outcomes, where the control group did not have a mechanical intervention. Studies are sorted in descending order of benefit

Pre-existing condition	Prior duration of injury (mo)	Orthotic group (O)			Control group (C)			Follow-up time (wk)	Outcome measure	Proportion with outcome (%)	Outcome	
		treatment	no. of subjects	D/L	treatment	no. of subjects	D/L				HR; ± HR 90% CI	assessment of magnitude
Lynch et al.[56]												
Plantar fasciitis	?	Customized semi-rigid	35	7/1	Anti-inflammatories	35	4/7	12	Final assessment positive	O: 70 C: 33	3.0; ±1.4, 6.2	Moderate benefit
									Treatment success	O: 96 C: 77	2.2; ±0.83, 6.1	Moderate benefit
									Low pain	O: 64 C: 45	1.7; ±0.90, 3.3	Small benefit
Pfeffer et al.[55] a												
Proximal plantar fasciitis	≥1	Pre-fabricated soft (silicone)	51	9/0	Stretch	46	7/0	8	Perceived better	O: 4.8 C: 28	2.4; ±1.1, 5.1	Moderate benefit
Proximal plantar fasciitis	≥1	Pre-fabricated soft (rubber)	50	7/0	Stretch	46	7/0	8	Perceived better	O: 12 C: 28	1.7; ±0.95, 3.1	Small benefit
Lynch et al.[56]												
Plantar fasciitis	?	Pre-fabricated soft	35	9/11	Anti-inflammatories	35	4/7	12	Treatment success	O: 58 C: 77	0.58; ±0.30, 1.1	Small harm
									Low pain	O: 23 C: 45	0.44; ±0.19, 0.99	Moderate harm
									Final assessment positive	O: 30 C: 33	0.90; ±0.38, 2.1	Unclear
Pfeffer et al.[55] a												
Proximal plantar fasciitis	≥1	Customized semi-rigid	42	8/0	Stretch	46	7/0	8	Perceived better	O: 32 C: 28	0.90; ±0.51, 1.5	Unclear
Proximal plantar fasciitis	≥1	Pre-fabricated soft (felt)	47	5/0	Stretch	46	7/0	8	Perceived better	O: 19 C: 28	1.3; ±0.76, 2.3	Unclear

a Proportion of females in final subjects 60–72%.

D/L = drop-outs/lost to follow-up; **HR** = hazard ratio; **?** indicates unknown/not reported.

erate harm and one study was unclear. In the uncontrolled clinical trials, there was a bias towards studies showing a positive effect (table IV). All FOs showed at least a moderate benefit on all but one outcome measure (100-m walk time).[53] Effect sizes were considered large if greater than 90%, or moderate if between 75% and 90%. Three controlled clinical studies reported benefits of FOs in reducing the prevalence of an injury (table V). Unfortunately, no controlled clinical trials of FOs were effective in preventing chronic lower limb pain as assessed by a reduction in the proportions of injuries where the control group was a mechanical (table VI).

2.1 Effectiveness of Foot Orthoses in Treating or Preventing Injuries

2.1.1 Plantar Fasciitis

A number of studies showed that FOs could help to reduce the pain associated with plantar fasciitis. Lynch et al.[56] randomly assigned 103 patients (average age 49 years, range 19–81 years) with plantar fasciitis to one of three treatment categories: group 1 (n = 35) received anti-inflammatory therapy; group 2 (n = 33) received soft prefabricated FOs via a viscoelastic heel cup; and group 3 (n = 35) received prefabricated rigid FOs. Patients were treated for 3 months, with follow-up visits at 2, 4, 6 and 12 weeks. There were no statistically significant differences between treatment groups with respect to the effect of heel pain on leisure, work, exercise activities or first-step pain in the morning. However, of the 85 patients who successfully completed the study, there was a statistically significant difference in visual analogue scale pain score change between the two groups. Decreased visual analogue scale pain scores ranging from 0 to 2 post-12 weeks' treatment were reported for 45% (14 of 31) of the patients in group 1, 23% (6 of 26) of patients in group 2, and 64% (18 of 28) of patients in group 3. Lynch et al.[56] concluded that mechanical control of the foot with FOs was more effective than either anti-inflammatory therapy with NSAIDs in combination with injections or soft prefabricated FOs with heel cups in the conservative treatment of plantar fasciitis. Our analyses of Lynch's data (see table III) showed that the magnitude of the effect of the prefabricated rigid FOs was moderately beneficial for the positive final assessment and for treatment success outcomes.

Pfeffer et al.[55] randomized 236 patients (160 women and 76 men, ≥16 years of age) with plantar fasciitis into five different treatment groups for a prospective trial of 8 weeks: (1) stretching only; (2) prefabricated soft FOs (silicone heel pad) plus stretching; (3) prefabricated rigid FOs (rubber heel cup) plus stretching; (4) prefabricated soft FOs (felt pad) insert plus stretching; and (5) customized semi-rigid FOs (polypropylene) plus stretching.[1] All groups performed Achilles tendon and plantar fascia stretching in a similar manner; 200 patients returned for follow-up examination. The percentages improved in each group were as follows: prefabricated soft FOs (silicone) = 95%; prefabricated soft FOs (rubber) = 88%; prefabricated soft FOs (felt pad) = 81%; stretching only = 72%; customized semi-rigid FOs = 68%. Combining all the patients who used soft prefabricated FOs, the improvement rates were significantly higher than those assigned to stretching only and for those who stretched and used customized semi-rigid FOs. Pain scores (0 = best, 100 = worst) from the Foot Function Index improved by 22.9 points for all the soft prefabricated FO groups combined versus 16.9 points for the customized semi-rigid FOs and 17.2 points for the stretching-only group. Pfeffer et al.[55] concluded that prefabricated FOs, when used in conjunction with a stretching programme, were more likely to produce improvement in symptoms of plantar fasciitis than customized semi-rigid FOs as part of the initial treatment. Our analyses of Pfeffer's data (see table III) showed a moderately beneficial effect for perceived better outcome for plantar fasciitis for the soft prefabricated silicone FOs.

Seligman and Dawson[60] investigated the effects of a customized soft FO heel pad worn in conjunction with a soft prefabricated FO for plantar fasciitis. Ten subjects (71 ± 9.1 years; range 58–87 years) wore the FOs for 6 weeks. Pain levels were recorded with verbal and Likert-type scales with pre-FO scores being 5.70 ± 1.95 out of 10 (range 2.0–9.0).

1 It should be noted that the thickness of the FOs was unclear from the description provided in the paper; therefore, it was classified as semi-rigid.

Table IV. Uncontrolled clinical trials of effectiveness of foot orthoses (FOs) in treatment of chronic lower limb pain, stiffness and foot disability. Studies are sorted in descending order of strength of evidence

Pre-existing condition	Subjects	Prior duration of injury (mo)	FO	Recruitment method	Agreed to participate (%)	Co-intervention	Follow-up time (mo)	Lost to follow-up	Outcome measure	Magnitude of effect[a]	Assessment of magnitude
Johnston and Gross[58]											
Patello-femoral pain	13 F, 3 M	>2[b]	Customized semi-rigid	Prospective	?	?	0.5, 3	1	Pain, standardized[c]	−0.5, −0.7	Strong evidence for moderate benefit
									Stiffness, standardized[c]	−0.5, −0.7	Strong evidence for moderate benefit
									Function, standardized[c]	0.3, 0.7	Strong evidence for small-moderate benefit
Martin et al.[57]											
Plantar fasciitis	61 F, 24 M	≥5	Customized rigid	Clinical database, prospective	?	Probably none	3	14	Pain on 1st step, 0–10	7.8 pre; 2.5 post (ES = 2.2)	Good evidence of large benefit
									Pain during day, 0–10	5.7 pre; 2.3 post (ES = 1.5)	Good evidence of large benefit
			Prefabricated rigid						Pain on 1st step, 0–10	7.8 pre; 2.5 post (ES = 2.2)	Good evidence of large benefit
									Pain during day, 0–10	5.8 pre; 2.6 post (ES = 1.5)	Good evidence of large benefit
Stell and Buckley[59]											
Various[d]	30	3 (88%), 6 (66%)	Customized rigid	Clinical database, prospective	?	?	1, 3	?	Proportion with perceived improvement	97%, 97%	Fair evidence of large benefit
			Customized semi-rigid	Clinical database, prospective	?	?	1, 3	?	Proportion with perceived improvement	87%, 87%	Fair evidence of moderate benefit

Continued next page

Table IV. Contd

Pre-existing condition	Subjects	Prior duration of injury (mo)	FO	Recruitment method	Agreed to participate (%)	Co-intervention	Follow-up time (mo)	Lost to follow-up	Outcome measure	Magnitude of effect[a]	Assessment of magnitude
Gross et al.[53]											
Plantar fasciitis	7 F, 8 M	2–96	Customized semi-rigid	Prospective	100	Probably none	0.5	0	FDI, 0–100	37 pre; 9 post	Good evidence of moderate benefit
									Walking pain, 0–100	53 pre; 18 post	Good evidence of moderate benefit
									100-m walk time (sec)	81 pre; 81 post	Good evidence of no benefit or harm
									Proportion still using FO	100%	Good evidence of large benefit
Seligman and Dawson[60]											
Heel pain, plantar fasciitis	10	≥6	Customized soft	Clinical database, retrospective	NA	?	1–2.5	?	Pain, 1–10	5.7 pre; 1.9 post (ES >2)	Fair evidence of large benefit
Saxena and Haddad[61]											
Patello-femoral pain	46 F, 54 M	21	Customized semi-rigid	Clinical database, retrospective	NA	?	1	?	Proportion with perceived improvement	78%	Failure to report important data; poor evidence of moderate benefit

a Pre-measurements without FO; post-measurements assumed to be with FO. The two values are for the two follow-up times unless pre or post is shown.

b Mean 35 mo; stability of pre-existing condition also established with two pre-intervention measurements 2 wk apart.

c Approximate change in WOMAC subscale score divided by pre-test standard deviation.

d Anterior knee pain 43%; plantar fasciitis 12%; shin splints 10%, Achilles tendonitis 9%; low-back pain 8%.

ES = standardized effect size;[42] **F** = female; **FDI** = foot disability index; **M** = male; **NA** = not applicable; **WOMAC** = Western Ontario and McMaster Universities Index of Osteoarthritis; **?** indicates unknown/not reported.

Table V. Controlled clinical trials of effectiveness of foot orthoses in preventing chronic lower limb pain, where the control group did not have a mechanical intervention. Studies are sorted in descending order of benefit

Orthotic group (O)			Control group (C)			Follow-up time (wk)	Outcome measure (prevalence)	Proportion with outcome (%)	Outcome HR; ± HR 90% CI	Outcome assessment of magnitude
prevention treatment	subjects	D/L	prevention treatment	subjects	D/L					
Larsen et al.[62] (infantry recruits)[a]										
Customized semi-rigid	58	14/5	None	63	3/3	12	Shin splints	O: 6, C: 24	0.23; ±0.07, 0.73	Large benefit
							Back or lower limb injury	O: 40, C: 56	0.62; ±0.36, 1.1	Small benefit
							No. of days off duty	O: 1, C: 1	2.6; ±0.17, 40	Unclear
Finestone et al.[9] (army recruits)[a]										
Customized soft	128 M	53/?	Insoles	126 M	73/?	14	Tibial stress fractures	O: 11, C: 25	0.40; ±0.19, 0.84	Moderate benefit
Customized semi-rigid	132 M	81/?	Insoles	126 M	73/?	14	Tibial stress fractures	O: 16, C: 25	0.61; ±0.29, 1.3	Small benefit
Milgrom et al.[10] (army recruits)[a]										
Customized semi-rigid	143	?/? (30)	None	169	0/0	14	Metatarsal stress fractures	O: 2, C: 5	0.33; ±0.09, 1.2	Moderate benefit
							Femoral stress fractures	O: 10, C: 18	0.52; ±0.29, 0.95	Small-moderate benefit
							Tibial stress fractures	O: 18, C: 23	0.74; ±0.47, 1.2	Small benefit
Sherman et al.[63] (infantry recruits)[a]										
Prefabricated soft	517	5%	None	397	5%	?	Stress fractures	O: 1, C: 1	1.8; ±0.58, 5.61	Small benefit
							Patellofemoral pain	O: 4, C: 3	1.6; ±0.86, 3.07	Small benefit
							Lower limb pain clinic visits	O: 40, C: 31	1.4; ±1.13, 1.68	Small benefit
Withnall et al.[64] (RAF recruits)[a]										
Prefabricated soft	421	?/?	Non-shock insoles	401	?/?	24	Withdrawal from training due to injury	O: 17, C: 18	1.0; ±0.73, 1.3	Trivial
Prefabricated soft	383	?/?	Non-shock insoles	401	?/?	24	Withdrawal from training due to injury	O: 20, C: 18	1.1; ±0.85, 1.5	Trivial

a No prior duration of injury reported.

D/L = drop-outs/lost to follow-up; **HR** = hazard ratio; **?** indicates unknown/not reported.

Table VI. Controlled clinical trials of effectiveness of foot orthoses in preventing chronic lower limb pain for proportions of injuries, where the control group had a mechanical intervention

Orthotic group (O)			Control group (C)			Follow-up time (wk)	Outcome measure	Proportion with outcome (%)	Outcome	
treatment	subjects	D/L	treatment	subjects	D/L				HR; ± HR 90% CI	assessment of magnitude
Finestone et al.[11] **(infantry recruits)**[a]										
Customized semi-rigid	215	?/35	Customized soft	227	?/23	14	Proportion of foot problems	O: 14, C: 17	0.79; ±0.51, 1.2	Trivial
							Proportion of ankle sprains	O: 9.3, C: 9.9	0.94; ±0.54, 1.6	Unclear
							Proportion of tibial stress fractures	O: 9.7, C: 9.1	1.1; ±0.62, 1.9	Unclear
Prefabricated semi-rigid	208	?/36	Customized soft	227	?/23	14	Proportion of ankle sprains	O: 8.0, C: 9.9	0.80; ±0.45, 1.4	Unclear
							Proportion of tibial stress fractures	O: 9.1, C: 9.1	1.0; ±0.57, 1.8	Unclear
							Proportion of foot problems	O: 20, C: 17	1.2; ±0.79, 1.7	Trivial
Prefabricated semi-rigid	224	?/11	Customized soft	227	?/23	14	Proportion of tibial stress fractures	O: 8.9, C: 9.1	1.0; ±0.57, 1.7	Unclear
							Proportion of foot problems	O: 20, C: 17	1.1; ±0.78, 1.7	Trivial
							Proportion of ankle sprains	O: 11, C: 9.9	1.1; ±0.66, 1.8	Unclear

a No prior duration of injury reported.

D/L = drop-outs/lost to follow-up; **HR** = hazard ratio; **?** indicates unknown/not reported.

Scores recorded post-FO were 1.85 ± 1.13 (range 1.0–4.5). A significant difference in pre-post scores (95% CI 2.45, 5.25) was reported in all patients ranking their pain as being reduced after using the soft prefabricated FOs. Seligman and Dawson[60] concluded that customized soft FOs and soft prefabricated FOs are an effective first-line treatment for heel pain and loss of function associated with plantar fasciitis. Our analysis showed fair evidence of a large benefit (see table IV) of both types of FOs.

A recent study by Landorf et al.[54] demonstrated that a prefabricated semi-rigid FO (firm foam) or a customized semi-rigid FO (semi-rigid plastic) produces small short-term benefits in function and may also produce small reductions in pain for people with plantar fasciitis, but does not have long-term beneficial effects compared with a sham customized soft FO (soft, thin foam). A pragmatic, participant-blinded, randomized trial was conducted with a 12-month follow-up for each of the 125 participants. After 3 months of treatment, compared with the sham FOs, the mean pain score (0–100 scale) was significantly better for the prefabricated semi-rigid FOs (8.7 points; 95% CI −0.1, 17.6) and for the customized semi-rigid FOs (7.4 points; 95% CI −1.4, 16.2). The mean function score (0–100 scale) was also significantly better for the prefabricated semi-rigid FOs (8.4 points; 95% CI 1.0, 15.8) and significantly better for the customized semi-rigid FOs (7.5 points; 95% CI 0.3, 14.7). There were no significant effects on primary outcomes at the 12-month review.

In a randomized prospective study, Martin et al.[57] randomly assigned 255 patients with plantar fasciitis to one of three treatment groups: customized semi-rigid FOs (n = 85); prefabricated rigid FOs (n = 85); and posterior tension night splint [a prefabricated semi-rigid FO set at 5° of ankle dorsiflexion] (n = 85). Patients ranged in age from 21 to 70 years, with an average age of 47 years; 65% of the patients were women. Patients were treated for 3 months, with follow-up visits at 2, 6 and 12 weeks. All treatments reduced pain over the 3-month period; however, no statistically significant differences were identified among treatment groups with respect to the initial visual analogue scale score of pain felt during the day or first-step pain in the morning. The customized rigid FO group showed

the greatest improvement over time. Martin et al.[57] concluded that mechanical control of the foot is a successful method of treating plantar fasciitis, with customized rigid FOs, prefabricated rigid FOs and tension night splints all being effective as initial treatments. Our analysis of Martin et al.[57] (see table IV) showed good evidence of large benefits of customized rigid FOs and over-the-counter rigid FOs for decreasing pain on first step and also in decreasing pain during the day.

Gross et al.[53] examined eight men and seven women (mean age 44.7 ± 9.0 years) with plantar fasciitis symptoms for pain experienced during a timed 100-m walk at a self-selected speed pre- and post-treatment (12–17 days) with customized semi-rigid FOs. The pain experienced during the walk was rated using a 10-cm visual analogue scale in conjunction with the completion of the pain and disability subsections of a Foot Function Index questionnaire. Pre-FO 100-m walk times (81.2 ± 15.3 sec) were not significantly different to post-FO walk times (80.6 ± 13.8 sec). Pre-FO pain ratings for the 100-m walk (3.0 ± 1.7) were significantly greater than post-FOs pain ratings (0.7 ± 0.7). Maximum pain and maximum disability pain subsection scores of the Foot Function Index following FO intervention were significantly reduced (by 66% and 75%, respectively). Gross et al.[53] suggested that customized semi rigid FOs may significantly reduce pain experienced during walking, and may reduce more global measures of pain and disability for patients with chronic plantar fasciitis. Our analysis of Gross et al.[53] (see table IV) showed good evidence that the semi-rigid FOs had a moderate beneficial effect for improving foot disability and decreasing walking pain, a large beneficial effect for increasing the proportion still using the FOs at the end of the study, and no benefit for improvement in 100-m walk time.

Given the results of Lynch et al.,[56] Landorf et al.[54] and Pfeffer et al.,[55] there is some evidence that FOs can effectively treat pain associated with plantar fasciitis.

2.1.2 Tibial Stress Fractures

The rate of tibial stress fracture occurrence using different types of FOs was examined by Finestone et al.[9] A total of 386 infantry recruits (mean age 18.77 ± 0.734 years; range 17.7–27.3 years) training on the same base at the same time were randomly assigned to one of three treatment groups: customized semi-rigid FOs (n = 132); customized soft FOs (n = 128); and prefabricated soft FOs without supportive or shock-absorbing qualities (n = 126). All recruits wore infantry boots with prefabricated soft FOs (similar to those designed for basketball shoes) and their assigned insoles during 14 weeks of basic training, with examinations occurring every 2 weeks. For the semi-rigid FOs, prefabricated soft FOs and control groups, respectively, the completion rates of recruits within the study were 39%, 59% and 42%, and the incidence of stress fractures was 15.7%, 10.7% and 27%. Although no significant differences were identified between FO treatment groups, there was a significant difference in the incidence of tibial stress fractures between recruits who trained with customized semi-rigid FOs and those who trained without such FOs. Our analysis of the data (see table V) showed that there was a moderate beneficial effect of the semi-rigid FOs compared with the prefabricated soft FOs (HR = 0.61; 90% CI 0.29, 1.3) and a moderate beneficial effect of the customized soft FOs compared with the prefabricated soft FOs without supportive or shock-absorbing qualities (HR = 0.4; 90% CI 0.19, 0.84).

A more recent study by Finestone et al.[11] examined the incidence of tibial stress fractures, ankle sprains and foot problems in male infantry recruits randomly assigned to one of four groups: soft customized FOs (n = 227); soft prefabricated FOs (n = 224); semi-rigid FOs (n = 215); and semi-rigid prefabricated FOs (n = 208). The recruits wore the assigned FOs during 14 weeks of training. A significantly lower number of recruits in the soft prefabricated FO group (53%) finished basic training than in the soft customized FO group (72%), semi-rigid FO group (75%) or semi-rigid prefabricated FO group (82%). There were no significant differences in the incidence of tibial stress fractures, ankle sprains or foot problems between recruits using the different types of FOs. Significantly higher comfort scores were reported for the soft customized (3.54) and soft prefabricated (3.43) FO groups than for the semi-rigid (3.23) and prefabricated (3.17) FO groups. Our effect size analysis of Finestone et al.'s[11] data showed that there were only trivial or unclear effects for any of the comparisons of FOs in the proportion

of tibial stress fractures, foot problems and ankle sprains (see table VI).

Milgrom et al.[10] investigated the effects of wearing semi-rigid FOs on the rate of tibial stress fracture occurrence. Military male recruits were randomly assigned standard infantry boots (n = 152) or semi-rigid FOs in conjunction with standard infantry boots (n = 113) during 14 weeks of training. No significant differences were identified between the groups for the rate of tibial stress fractures experienced by the participants. Our effect size analysis of the data from this study (see table V) showed a small benefit in reducing tibial stress fractures (HR = 0.74; 90% CI 0.47, 1.2).

Larsen et al.[62] investigated the use of customized semi-rigid FOs in preventing problems in the back and lower extremities in military conscripts over a 3-month period. Participants were randomly assigned to either a FO group (n = 58) or a control group (n = 63). The number of subjects with problems in the back or lower extremities was significantly lower in the FO group than in the control group (36% vs 56%). The same applied for specific problems with shin splints (13% vs 24%), and for the number of off-duty days (<1% [23 days] vs 1% [43 days]). Our effect size analysis of the data from this study (see table V) showed that there was a large benefit of the customized semi-rigid FOs in reducing shin splints (HR = 0.23; 90% CI 0.07, 0.73), a small benefit in reducing back and lower limb injury (HR = 0.62; 90% CI 0.36, 1.06), and an unclear benefit in reducing the amount of days off-duty (HR = 2.6; 90% CI 0.17, 39.97).

Sherman et al.[63] investigated the use of soft prefabricated FOs in preventing injuries in 1132 male military trainees. Trainees were randomized to having an insert or no insert; however, some trainees purchased their own inserts, resulting in 517 in the orthotics group and 397 in the control group. The number of trainees visiting the injury clinic for lower limb pain was recorded. Of those in the FO group, 38% were seen for lower limb pain problems, as opposed to 29% of those in the control group and 38% of those who bought their own inserts. Our effect size analysis of the stress fracture prevalence data from this study (see table V) showed that there was a small benefit of the soft-prefabricated FOs in reducing prevalence of stress fractures (HR = 1.8; 90% CI 0.58, 5.61) and a small benefit in reducing the number of trainees visiting the injury clinic for lower limb pain (HR = 1.4; 90% CI 1.13, 1.68).

It should be noted that Milgrom et al.[10] also investigated the effect of orthotics on prevention of metatarsal fractures and femoral fractures, and showed that prefabricated semi-rigid FOs had a moderate benefit in reducing the prevalence of metatarsal stress fractures in army recruits (HR = 0.33; 90% CI 0.09, 1.2).[10] Future work on the effectiveness of FOs in reducing stress fractures other than tibial stress fractures should be conducted. For example, Simkin et al.[51] reported that orthotics prevented femoral stress fractures only in recruits with high arches, but low-arched recruits had >3-fold more femoral stress fractures.

Given the results of Larsen et al.[62] and Finestone et al.,[9] there seems to be initial support for the benefit of FOs in reducing the risk of posterior tibial stress fractures. However, it should be noted that the outcomes from military studies[9-11,62,63] cannot represent the general sports population and that further work on sporting groups is required, particularly in long distance runners.

2.1.3 Patellofemoral Pain Syndrome

There were a limited number of quality trials on the effects of FOs in treating or preventing patellofemoral pain syndrome. Saxena and Haddad[61] conducted a retrospective review of 100 patients (46 women and 54 men, mean age 37.9 ± 15.9 years, range 12–87 years) who were treated for patellofemoral pain syndrome with a customized semi-rigid FO. The patients had exhibited excessive forefoot or rearfoot varus and had been prescribed the FOs for 4 weeks. Post-FO intervention, 2% of the patients were asymptomatic, 76.5% were improved, 16.7% experienced no change and one patient was worse. Saxena and Haddad[61] concluded that semi-rigid FOs are an effective means of relieving clinical symptoms of patellofemoral pain syndrome. Our effect size analysis of the data from this study (see table IV) showed that there was poor evidence of a moderate benefit (78%) of the semi-rigid FOs in improving perceived improvement. Saxena and Haddad[61] failed to report important data to enable us to determine a better rating for the strength of the evidence. Our effect size analysis of the patel-

lofemoral pain prevalence data of Sherman et al.[63] (see table V) showed that there was a small benefit of the soft-prefabricated FOs in reducing prevalence of patellofemoral pain (HR = 1.6; 90% CI 0.86, 3.07). Our evaluation of the study by Johnston and Gross[58] on the effects of a customized semi-rigid FO on quality of life for 16 individuals with patellofemoral pain syndrome showed strong evidence for a moderate benefit in reducing pain, reducing stiffness and improving function.

2.1.4 Summary of the Effectiveness of Foot Orthoses in Treating or Preventing Injuries

Only a few studies showed moderate or large beneficial effects of FOs in treating injuries, and these were generally for inflammation conditions using a variety of FOs:

- Prefabricated semi-rigid FOs showed a moderate beneficial effect compared with customized soft sham FOs for the treatment of foot pain and foot function at 3 months and 12 months for plantar fasciitis.[54]
- Customized rigid FOs showed a moderate beneficial effect compared with anti-inflammatories for a positive final assessment, and for treatment success outcomes for plantar fasciitis.[56]
- Customized semi-rigid FOs showed a moderate beneficial effect compared with stretching for a perceived better outcome for plantar fasciitis.[55]
- Customized semi-rigid FOs showed a moderate beneficial effect for reducing pain, reducing stiffness and improving function for patellofemoral pain.[58]

One study showed a moderate harmful effect of FOs when trying to treat injuries, again for an inflammation condition:

- Rigid FOs showed a moderate harmful effect of FOs compared with anti-inflammatories for a low pain outcome for plantar fasciitis.[56]

There were only two studies that showed moderate or large beneficial effects of FOs in preventing injuries, and these were for posterior tibial stress fractures using a variety of FOs.

- Customized rigid FOs showed a large benefit in reducing the incidence of posterior tibial stress syndrome (shin splints) in infantry recruits (HR = 0.23; 90% CI 0.07, 0.73).[62]
- Prefabricated soft FOs showed a moderate benefit compared with insoles in reducing the incidence of posterior tibial stress fractures in army recruits (HR = 0.40; 90% CI 0.19, 0.84).[9]

In addition, Finestone et al.[9] reported that customized semi-rigid and customized soft FOs compared with insoles had a moderate beneficial effect in increasing comfort for army recruits (see table VII).

3. Discussion

3.1 The Quality of the Studies

There were limited randomized control trials or controlled clinical studies for the injuries of interest (plantar fasciitis, tibial stress fractures, patellofemoral pain syndrome). Many studies did not provide enough information for the standardized effect sizes to be calculated (i.e. there were no pre-means or standard deviations). Our assessment of magnitudes of the meta-analysed effects is based on a generic statistical approach using mean effects standardized with the between-subject standard deviation of patients at baseline. Our assessment of magnitude directly related to health outcomes used a meta-analysis of controlled trials of the effects of FOs on morbidity for lower limb injuries (tables VI and VII). Uncontrolled clinical trials (time series) may have overestimated the effect of the interventions as a result of phenomena such as the 'placebo effect', the 'Hawthorn effect', and 'natural resolution of the condition'.

3.2 Effectiveness of Foot Orthoses in Treating or Preventing Injuries

Given the results of Lynch et al.,[56] Landorf et al.,[54] Pfeffer et al.,[55] Martin et al.,[57] and Gross et al.,[53] there is some evidence that FOs can effectively treat pain associated with plantar fasciitis. The results of Johnston and Gross[58] provide initial support for the benefit of FOs in reducing pain and stiffness and improving function for patellofemoral pain syndrome The results of Larsen et al.,[62] Milgrom et al.,[10] and Finestone et al.[9] provided initial support for the benefit of FOs in reducing the risk of tibial stress fractures. It should, however, be noted that the outcomes from military studies[9-11,62] cannot

Table VII. Controlled clinical trial of effectiveness of foot orthoses in preventing chronic lower limb pain for continuous outcome measure of comfort, where the control group had a mechanical intervention. Outcomes are sorted in descending order of benefit

Orthotic group (O)			Control group (C)			Follow-up	Outcome	Change[a] scores	Effect[b] (%); ± 90% CL	Standardized effect	Assessment of magnitude
prevention treatment	subjects	D/L	prevention treatment	subjects	D/L	time (wk)	measure				
Finestone et al.[9] **(army recruits)**[c]											
Customized soft	128 M	53/?	Simple shoe insole	126 M	73/?	14	Comfort, 1–4	O-C: 1.2[d]	39; ±11	1.15; ±0.32	Moderate benefit
Customized semi-rigid	132 M	81/?	Simple shoe insole	126 M	73/?	14	Comfort, 1–4	O-C: 0.7[d]	23; ±14	0.67; ±0.40	Moderate benefit
Finestone et al.[11]											
Customized semi-rigid	215	?/35	Customized soft	227	?/23	14	Comfort 0–5	O-C: −0.2[d]	−3; ±4	−0.13; ±0.16	Trivial
Prefabricated semi-rigid	208	?/36	Customized soft	227	?/23	14	Comfort 0–5	O-C: −0.1[d]	−2; ±4	−0.08; ±0.16	Trivial
Prefabricated soft	224	?/11	Customized soft	227	?/23	14	Comfort 0–5	O-C: −0.5[d]	−9; ±4	−0.38; ±0.17	Small harm

a Positive values indicate improvement, i.e. less pain or more comfort.
b All scores have been converted to 0–100 scale to allow comparison.
c No pre-existing condition.
d Post-test means and standard deviations only.
CL = confidence limit; **D/L** = drop-outs/lost to follow-up; **?** indicates unknown/not reported.

represent the general sports population and that further work on sporting groups is required, particularly in long distance runners. Our effect size analysis of Saxena and Haddad's[61] data showed that there was poor evidence of a moderate benefit of the semi-rigid FOs in improving perceived improvement. In summary, a variety of FOs have shown moderate to large effects in reducing pain for inflammatory conditions such as plantar fasciitis, and moderate effects in preventing injuries such as posterior tibial stress fractures. However, there are a number of confounders to take into account such as foot type, arch type, type of activity and footwear. Further research on specific types of FOs for specific injuries and individual anatomical characteristics should be conducted. Given the paucity of good studies on the effects of FOs on treatment and prevention of patellofemoral pain syndrome, more research should focus on these lower limb injuries.

One limitation of the literature available is a detailed description of the FOs examined. Since FOs come in many types with different intended functions, it is important that healthcare professionals understand the basic definition of FOs. A future recommendation is an international consensus pertaining to FO definition.

3.3 Future Research

This paper did not review the effectiveness of FOs in changing lower limb biomechanics. High knee joint moments with respect to tibial abduction-adduction and tibial rotation have been shown to be associated with the development of patellofemoral pain syndrome.[65] Therefore, FOs should help to reduce knee joint moments and corresponding internal forces and stresses if they are to be effective. Since it has been shown that systematic changes in FOs do not produce systematic kinematic, kinetic and muscle activity outcomes,[24] it seems important that the these effects of FO interventions are assessed individually for a prescribed intervention. It would be important to know whether FO interventions that produce the same kinematic, kinetic and muscle activity results produce the same outcomes in a homogeneous group of subjects.[24] The weak conclusions about the use of FOs shown in this study for most injury groups may be primarily due to the fact that the mechanical characteristics of

the orthotics, and not the functional kinematics, kinetics and EMG produced by these interventions, were used as a criterion in these studies. Future studies should include functional outcome analysis. Further epidemiological, biomechanical and clinical studies should be conducted to examine the evidence for FOs re-establishing normal lower extremity biomechanics, improving lower extremity alignment, controlling subtalar joint movement and excessive pronation, changing lower extremity kinematics and kinetics, attenuating the forces of weight bearing and reducing lower extremity shock.

4. Conclusions

There has been a recent plethora of reviews relating to the use of FOs for lower limb injuries over the last decade, but the current review has evaluated the beneficial effects of FOs for specific conditions.[49-53,60] We have demonstrated that customized semi-rigid FOs have moderate to large beneficial effects in treating plantar fasciitis, moderate effects in preventing posterior tibial stress fractures, and small to moderate effects in treating or preventing patellofemoral pain syndrome. Prefabricated semi-rigid FOs have moderate beneficial effects in treatment of foot pain and foot function. Given the limited randomized controlled trials or clinical controlled trials available for the injuries of interest, it may be that more or less benefit can be derived from the use of FOs, but many studies did not provide enough information for the standardized effect sizes to be calculated. Further research with randomized controlled trials is needed to establish the clinical use of particular types of FOs (i.e. rigid, semi-rigid, soft) for treatment and prevention of various lower limb injuries.

5. Practical Implications

Plantar fasciitis and posterior tibial stress fractures can be both treated and prevented using semi-rigid FOs. Healthcare professionals should administer FOs with a specific functional kinematic, kinetic and/or muscle activity goal in mind (for example, reduction of resultant knee joint moments, reduction of tibial rotation). Based on recent evidence, a healthcare professional or a biomechanist is not able to predict the kinematics, kinetics and/or EMG outcomes produced through FO intervention. Consequently, biomechanists and healthcare professionals should work together to verify that the functional goal (kinematics, kinetics and/or muscle activity) of the intervention is achieved with a prescribed FO, given the variation in reaction to FO intervention by individual patients.

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