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Foot Orthoses in Lower Limb Overuse Conditions: A Systematic Review and Meta-Analysis

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INTRODUCTION

Foot orthoses have long been advocated in the management of musculoskeletal overuse conditions of the lower limb.[43] As early as 1972, abnormal foot pronation and subsequent overstress on lower limb soft-tissue structures were implicated in running injuries such as chondromalacia of the patella, shin splints, Achilles tendinopathy, heel spurs, and lower-limb stress fractures.[18,43,46] Anecdotal reports of successful clinical treatment with foot orthoses often were construed to support the theory that foot orthoses control excessive or prolonged foot pronation during the stance phase of gait, minimizing overstress on soft tissues and alleviating associated symptoms.[46] Current definitions of foot orthoses in the clinical guidelines of the American College of Foot and Ankle Orthopedics and Medicine (ACFAOM)[3] and the Australian Podiatry Council (APC)[4] reflect this concept, making reference to the goal of controlling abnormal foot motion with orthoses. However, debate in recent years on the mechanism underlying the therapeutic effect of foot orthoses[28,33] questions the role of motion control as a primary mechanism of action. Nevertheless, orthoses currently are defined as in-shoe devices that are either custom fabricated (i.e. based on a three-dimensional representation of the individual's foot) or prefabricated (generically shaped). Prefabricated kits for orthoses may allow some degree of customization to the individual patient through heat molding or add-on posts.

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In parallel with this is the evolution of health care towards an evidence-based model in which high quality research evidence is promoted in clinical decision making.[41] Randomized controlled trials (RCT), widely deemed as the gold standard in providing high-quality evidence, are only surpassed by the pooling of several RCT findings in a systematic review and meta-analysis, which represents the highest level in Sackett's hierarchy.[2,41] The current literature on the clinical efficacy of foot orthoses is reflective of their anecdotal origins, with a predominance of clinical viewpoint and review papers and a lack of experimentally based publications. The lack of higher order synthesis of clinical trials to date makes it difficult for a practitioner who wishes to use evidence-based practice in the prescription of foot orthoses. It is, therefore, timely to conduct a systematic review of the current RCT literature, with the aim to evaluate the clinical efficacy and cost effectiveness of foot orthoses in the management of individuals with, or at risk for, lower limb musculoskeletal overuse conditions.

METHODOLOGY

Literature Search Strategy

A comprehensive search strategy devised using guidelines provided by the Cochrane Reviewer's Handbook,[1] was used by a single reviewer (NC) to search the following databases: MEDLINE, EMBASE, CINAHL and Pre-CINAHL, Physiotherapy Evidence Database (PEDro), PubMed, Sportdiscus, Biological Abstracts, Web of Science, Allied Health and Complimentary Medicine Database, and the full Cochrane Library. All publications listed up until the September 28, 2005, were considered for inclusion, and no restrictions were placed on year of publication, status of publication, or language. Abstracts, then full-text versions of papers were retrieved at successive stages for further evaluation. The same reviewer hand searched reference lists of papers that met the inclusion criteria, as well as systematic reviews on related topics that were identified by the search strategy.

Selection Criteria

To be deemed suitable for inclusion in this systematic review, studies identified by the search strategy had to fulfill key criteria. Clinical trials were selected that randomly allocated participants into intervention groups. Foot orthoses, as defined above, were required to constitute at least one of the interventions used in the management of lower-limb overuse injuries. Overuse conditions were included on the basis of the ACFAOM guidelines,[3] according to which foot orthoses were rated as being medically indicated or essential, useful, or beneficial as an adjunct to other interventions. Finally, at least one clinically relevant outcome measure was required to measure the effect of the intervention over a minimum period of 1 week.

Quality Assessment

Papers identified by the comprehensive search strategy that fulfilled the selection criteria were retrieved for evaluation of their methodological quality. Two independent reviewers (NC and LB), who were blinded to authors, affiliations, and the publishing journal, rated each paper using a modified version of the PEDro rating scale[36] (Appendix A). The original PEDro scale was based largely on the Delphi list of Verhagen et al.[49] Three items that were deemed important in other rating scales were added to the 11 existing PEDro criteria: justification of sample size, use of outcome measures with known validity and reliability, and reporting of adverse or side effects.[31] Specific standardized guidelines were provided for each criterion to minimize rater error. A point was only awarded for a specific criterion when it was clearly satisfied. Points scored by an article across all 14 criteria were then summed to give a final quality rating score. A similar version of this scale has been used recently, with good inter-rater agreement (κ 0.824).[6]

Final study ratings for each reviewer were collated and examined for discrepancies. Any disagreement between raters was discussed in a consensus meeting (NC and LB), and unresolved items taken to a third reviewer (BV) for resolution.

Data Management and Statistical Analysis

Inter-rater reliability of the modified PEDro scores was evaluated with the kappa (κ) statistic.

Synthesis of quantitative data was conducted using Review Manager (Version 4.2)[38] Data was extracted directly from papers where available, using data provided by intention-to-treat analysis when supplied. A formal written request was made to authors when studies reported insufficient data.

Relative risk (RR) and standardized mean difference (SMD) with 95% confidence intervals (CI) were used to represent the effect size of dichotomous and continuous variables, respectively, for interventions on a random effects model. Based on previous reports,[6,45] a RR of greater than 1.5 or less than 0.7 was set to represent a clinically beneficial effect in favor of either foot orthoses or the comparison group, respectively; with a RR of 1 signifying a null effect. The SMD was calculated from the mean change score and population standard deviation, using methods of Herbert[17] to extract population standard deviations from pre-standard to post-standard deviations or 95% CI where available. A SMD of greater than or equal to 0.8 was considered to represent a large clinical effect, 0.5 a moderate effect, and 0.2 a weak effect,[8] with a positive value favoring foot orthoses over the comparison intervention. An SMD of 0 represented a null effect. Data pooling was conducted for studies where there was similarity of factors such as the type of foot orthoses, comparator intervention, and timing of outcome measures.

A sensitivity analysis was conducted to determine if the score on the modified PEDro scale would influence the findings of this study, as would be anticipated after the work of Moher et al.[30] who showed that studies with improved quality scores returned findings of reduced efficacy of treatment.

RESULTS

Search Strategy

The comprehensive search strategy identified 3192 publications for further evaluation (Figure 1). Of these, 22 papers met the criteria for inclusion in the systematic review, one of which reported two separate studies. Included studies fell into two categories: those that investigated prevention of onset of a lower limb overuse injury (eight studies reported in seven publications) and those that looked at treatment of injuries (15 studies) (Tables 1 and 2). Within these categories, divisions were made based on the comparison group, that is: foot orthoses versus control or other interventions; or custom versus prefabricated foot orthoses. Of the 23 studies, 14 measured up to 3 months followup, seven up to 6 months followup, and two investigated outcomes up to 12 months.

Methodological Quality

Modified PEDro scores ranged from two to 11 out of 14 (mean score 5.77). As demonstrated in Table 3, a number of criteria were poorly represented. Those reported by less than half of the papers were specification of eligibility criteria (criteria one), allocation concealment (criteria three), blinding (criteria five, six, and seven), intention to treat analysis (criteria nine), justification of sample size (criteria 12), and reporting of adverse or side effects (criteria 14).

Of the modified PEDro ratings given independently by the two reviewers, initial disagreement occurred in 41 out of 308 items (κ0.73). Consensus was reached on all but five items on initial discussion between the two reviewers, which were all resolved in discussions with the third reviewer (BV). Inter-rater reliability for individual criteria ranged from weak (κ0.25) for criterion one to 100% agreement for criteria two and 10.

There was no significant correlation between the quality rating score and effect sizes of RR ($p = 0.60$) and SMD

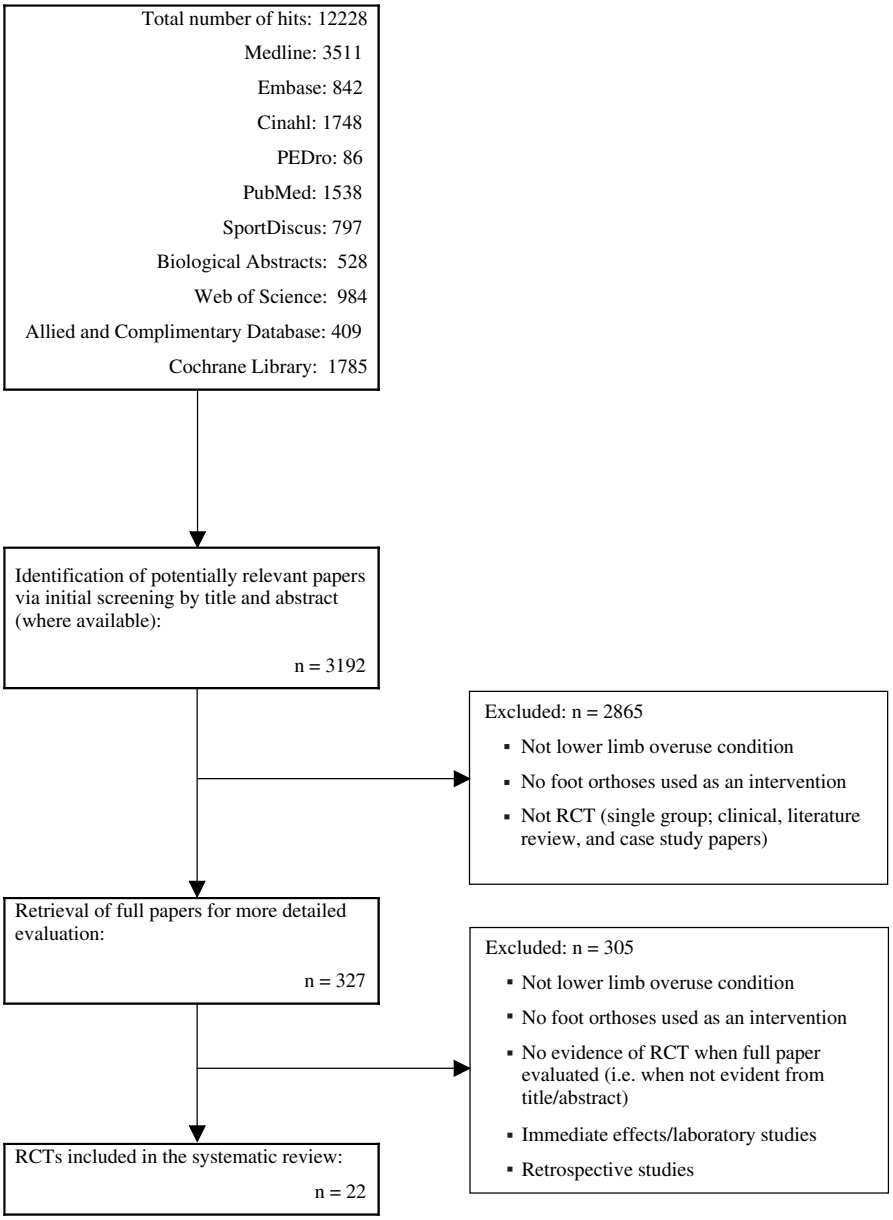

Fig. 1: Flow chart of the process and rationale used in selecting papers for inclusion in the review, using a highly sensitive search strategy. RCT, randomized controlled trial.

($p = 0.10$). Thus, all studies were included in the systematic review.

Prevention Studies

All eight studies that investigated the preventative role of foot orthoses used military populations of similar ages that were undergoing basic or regular military training (Table 1). Reasonable sample sizes were available for individual studies, with cohorts ranging from 47 to 451. Intervention periods and timing of final outcome measures were similar for all studies (8 to 16 weeks), reflecting the standard military basic training period. Although other outcome measures were used (Table 4), incidence of injury (number of participants injured compared to noninjured) was consistently used as a primary outcome measure.

Foot orthoses compared to controls

Pooled data from four studies[13,24,29,32] that compared foot orthoses to a control group provided evidence of a significant and reasonably sized effect in favor of foot orthoses (RR 1.49; CI 1.07 to 2.08) (Figure 2). A fifth study by Simkin et al.[44] for which effect sizes could not be calculated also reported significant results in favor of foot orthoses.

Table 1: Prevention studies: summary of rated studies

	Condition	Orthoses vs. Comparison	Sample: total randomized (total analyzed) per group	Mean (SD) age of participants (years)	Intervention & followup (weeks)	Effect size: incidence of injury RR (95% CI)	Notes regarding study. Study conclusions (where effect size = ID)
Foot orthoses vs. Control							
Esterman, 2005	Lower limb pain or injury	Prefabricated customised[1] **vs** Control	25 (25) **vs** 22 (22)	ID∼	8	0.23 (0.03 to 1.80)	
Larsen, 2002	Lower limb problems	Custom (casted) **vs** Control	77 (58) **vs** 69 (63)	ID	12	1.43 (0.99 to 2.08)	
Milgrom, 1985	Lower limb stress fractures (metatarsal, tibial, femoral)	Prefabricated[2] **vs** Control	143 (113) **vs** 152 (152)	ID	14	1.58 (1.13 to 2.20)	
Mundermann, 2001	Lower limb or back pain/injury	Prefabricated[3] **vs** Control	103 (34) **vs** 103 (45)	28.5 (6.6)∼	16	2.52 (0.75 to 8.45)	Participants randomized to orthoses group were assigned to 1 of 6 prefabricated orthoses that they rated highest on a comfort scale.
Simkin, 1989	Lower limb stress fractures	Prefabricated[2] **vs** Control	143 (113) **vs** 152 (152)	ID	14	ID	Study conclusions: foot orthoses significantly decreased the incidence of femoral stress fractures in participants with high arches, and metatarsal stress fractures in participants with low arches.

(*Continued*)

Table 1: (*Continued*)

	Condition	Orthoses vs. Comparison	Sample: total randomized (total analyzed) per group	Mean (SD) age of participants (years)	Intervention & followup (weeks)	Effect size: incidence of injury RR (95% CI)	Notes regarding study. Study conclusions (where effect size = ID)
Foot orthoses vs. Other intervention							
Finestone, 1999	Lower limb stress fractures	Custom (semirigid + soft) **vs** Simple flat insoles	260 (126) **vs** 126 (53)	18.77 (0.734)	14	1.95 (1.14 to 3.32)	2 custom orthoses groups were pooled for this review (reported no significant difference in incidence of injury).
Custom foot orthoses vs. Prefabricated foot orthoses							
Finestone, 2004a	Lower limb problems (stress fractures, ankle sprains and foot problems)	Custom (casted, soft) **vs** Prefabricated (soft)	227 (204) **vs** 224 (213)	18.74 (0.72)	14	1.06 (0.78 to 1.46)	Finestone 2004a and Finestone 2004b were two separate studies reported in a single publication
Finestone, 2004b	Lower limb problems (stress fractures, ankle sprains and foot problems)	Custom (casted, semirigid) **vs** Prefabricated (semirigid)	215 (180) **vs** 208 (172)	18.91 (1.1)	14	1.25 (0.88 to 1.77)	

ID, inadequate data provided by authors; ~, no significant difference between groups ($p = 0.05$); ID ~, authors have only reported statistical significance; SD, standard deviation; RR, relative risk; CI, confidence interval.

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Table 2: Treatment studies: summary of rated studies

	Condition	Orthoses vs. Comparison	Sample: total randomized (total analyzed) per group	Mean (SD)/ median[#] age of participants (years)	Mean (SD)/ median[#] symptom duration (months)	Intervention & followup (weeks)	Patient perceived effect RR (95% CI)	Effect size: Visual analogue scale SMD (95% CI)	Effect size: Foot health status questionnaire SMD (95% CI)	Notes regarding study. Study conclusions (where effect size = ID)
Foot orthoses vs. Control										
Pfeffer, 1999	Plantar fasciitis	Custom (casted) + stretches **vs** no orthoses + stretches	42 (34) **vs** 46 (39)	48.5[#] **vs** 47[#]	ID~	8	0.87 (0.43 to 1.75)	0.15 (−0.31 to 0.61)	—	Achilles & plantar facscia stretches.
Wiener-Ogilvie, 2004	Anteromedial knee pain	Prefabricated customised[1] + lower limb exercises **vs** No orthoses + lower limb exercises	11 (9) **vs** 10 (9)	61.8 (10.3) **vs** 51 (22.5)	29.8 (38) **vs** 10.6 (8.2)	8	1.20 (0.57 to 2.53)	0.87 (−0.11 to 1.85)	—	Lower limb strengthening and stretches.
Foot orthoses vs. Other intervention										
Dimou, 2004	Plantar fasciitis	Custom **vs** Chiropractic adjustments + stretches	10 (10) **vs** 10 (10)	42.3 (10.3)	21.8 (24.1)	8	—	ID	—	Achilles stretches. Study conclusions: sample too small to draw firm conclusions; both groups showed significant improvements on final outcome measures.
Eng, 1993	Anterior knee pain	Soft customised[2] + exercises **vs** flat insoles[2] + exercises	10 (10) **vs** 10 (10)	14.8 (1.2)~	9.85 (9.85)	8	—	ID	—	Study conclusions: significantly greater decrease in VAS with running, squatting & stairs in orthoses group ($p < 0.05$).
Kelly, 1999	Lesser metatarsalgia	Prefabricated custom[3] **vs** silicone insole[4]	15 (15) **vs** 18 (18)	51.25	67 **vs** 51	8	3.33 (1.15 to 9.66)	0.09 (−0.60 to 0.77)	—	

(*Continued*)

Table 2: (*Continued*)

	Condition	Orthoses vs. Comparison	Sample: total randomized (total analyzed) per group	Mean (SD)/ median# age of participants (years)	Mean (SD)/ median# symptom duration (months)	Intervention & followup (weeks)	Patient perceived effect RR (95% CI)	Effect size		
								Visual analogue scale SMD (95% CI)	Foot health status questionnaire SMD (95% CI)	Notes regarding study. Study conclusions (where effect size = ID)
Kilmartin, 1994	Morton's neuroma	Supination orthoses **vs** pronation orthoses	10 (10) **vs** 11 (11)	43 (12)	30 (61.4) **vs** 13 (7.6)	52	1.09 (0.48 to 2.48)	−0.19 (−1.05 to 0.67)	—	
Kriss, 2003	Heel pain	Soft antipronatory pad **vs** local steroid injection	26 (26) **vs** 22 (22)	59.33	7.56	12	—	−0.77 (−1.36 to −0.18)	—	
						24	—	−0.43 (−1.01 to 0.14)	—	
Lynch, 1998	Plantar fasciitis	Custom **vs** viscoelastic heel cups	35 (28) **vs** 33 (26)	49 ~	(L) 46 (R) 26.5	12	—	0.70 (0.15 to 1.25)	—	
		Custom **vs** local steroid injection + NSAIDs	35 (28) **vs** 35 (31)	49 ~	(L) 46 (R) 26.5	12	—	0.32 (−0.19 to 0.84)	—	
Martin, 2001	Plantar fasciitis	Custom **vs** tension night splints	85 (71) **vs** 85 (60)	47 (12)~	20# **vs** 24#	12	—	ID	—	Study conclusions: no significant differences between groups at final outcome on pain measures; reported slight differences between groups in VAS (no p value).
Pfeffer, 1999	Plantar fasciitis	Custom + stretches **vs** silicone heel pad[5] + stretches	42 (34) **vs** 51 (42)	48.5# **vs** 49.5#	ID~	8	0.15 (0.03 to 0.62)	−0.22 (−0.67 to 0.23)	—	
		Custom + stretches **vs** rubber heel cup[6]	42 (34) **vs** 50 (43)	48.5# **vs** 44#	ID~	8	0.36 (0.14 to 0.94)	−0.42 (−0.87 to 0.04)	—	
Postema, 1998	Primary metatarsalgia	Custom moulded **vs** ready-made insole	41 (41) **vs** 41 (41)	58.6 (20.4)	ID	2	—	—	—	'Ready made insole' poorly defined in paper, but appeared to be a flat insole. Participants served as own comparison. Study conclusions: significantly lower pain scores with custom orthoses ($p < 0.00$).

(*Continued*)

Table 2: (*Continued*)

	Condition	Orthoses vs. Comparison	Sample: total randomized (total analyzed) per group	Mean (SD)/ median# age of participants (years)	Mean (SD)/ median# symptom duration (months)	Intervention & followup (weeks)	Patient perceived effect RR (95% CI)	Effect size: Visual analogue scale SMD (95% CI)	Effect size: Foot health status questionnaire SMD (95% CI)	Notes regarding study. Study conclusions (where effect size = ID)
Rome, 2004	Plantar heel pain	Functional foot orthoses **vs** accommodative (cushioning)	26 (22) **vs** 22 (13)	59.9 (13.5)	12.4 (19.6) **vs** 21.6 (40.5)	8	—	—	−0.13 (−0.81 to 0.56)[a] −0.14 (−0.83 to 0.54)[b] −0.33 (−1.02 to 0.36)[c] 0.39 (−0.30 to 1.09)[d]	Reported significant decrease in foot pain & increase in foot function ($p = 0.01$)
Russell, 2000	Plantar fasciitis	Custom **vs** night resting splint	26 (14) **vs** 21 (13)	34.4 (7.6)	8.2 (11.4)	12	ID	ID	—	Pain measured as component of Foot Function Index ($p = 0.9312$). PPE only reported as a correlation with splint wearing time. Study conclusions: no significant difference between groups at final outcome.
Saggini, 1996	Myofascial pain syndrome of peroneus longus	Custom **vs** heel lift	6 (6) **vs** 6 (6)	29.85 (6.9)	ID^	4	—	ID	—	Study conclusions: VAS significantly lower in foot orthoses group at 2, 4 & 8 weeks ($p < 0.001$). Nonresponders crossed over at end of 4 weeks (Group C); not considered in this review.
Turlik, 1999	Heel spur syndrome	Functional foot orthoses **vs** heel pads (generic)	26 (25) **vs** 34 (30)	45 ~	12.5 ~	12	ID	ID	—	Study conclusions: significantly greater improvement in morning heel pain and overall symptom relief with custom foot orthoses ($p \leqslant 0.042$).
Wiener-Ogilvie, 2004	Anteromedial knee pain	Prefabricated customised[1] **vs** lower limb exercises	11 (9) **vs** 10 (9)	38.7 (17.2) **vs** 51 (22.5)	17.9 (17.8) **vs** 10.6 (8.2)	8	0.75 (0.45 to 1.26)	0.80 (−0.17 to 1.77)	—	Lower limb strengthening and stretches.

(*Continued*)

Table 2: (*Continued*)

	Condition	Orthoses vs. Comparison	Sample: total randomized (total analyzed) per group	Mean (SD)/ median# age of participants (years)	Mean (SD)/ median# symptom duration (months)	Intervention & followup (weeks)	Patient perceived effect RR (95% CI)	Effect size: Visual analogue scale SMD (95% CI)	Effect size: Foot health status questionnaire SMD (95% CI)	Notes regarding study. Study conclusions (where effect size = ID)
Custom foot orthoses vs. Prefabricated foot orthoses										
Landorf, 2004	Plantar fasciitis	Custom **vs** formthotic[7]	46 (45) **vs** 44 (43)	48.25 (11.8)	11.5#	12	1.24 (0.62 to 2.46)	—	0.28 (−0.14 to 0.69)[a] 0.16 (−0.25 to 0.58)[b] 0.17 (−0.25 to 0.58)[c] −0.03 (−0.45 to 0.38)[d]	
						26	1.05 (0.64 to 1.70)	—	0.05 (−0.37 to 0.46)[a] 0.14 (−0.27 to 0.56)[b] 0.08 (−0.34 to 0.49)[c] −0.06 (−0.47 to 0.36)[d]	
						52	0.98 (0.55 to 1.73)	—	0.34 (−0.08 to 0.77)[a] 0.25 (−0.17 to 0.67)[b] 0.18 (−0.24 to 0.60)[c] −0.03 (−0.45 to 0.39)[d]	
Martin 2001	Plantar fasciitis	Custom **vs** prefabricated arch supports	85 (71) **vs** 85 (62)	47.5 (12)∼	20# **vs** 16# ∼	12	—	ID	—	Study conclusions: no significant differences between groups at final outcome on pain measures; reported greater improvement in VAS with custom orthoses of 0.2/10 (no *p* value).
Pfeffer, 1999	Plantar fasciitis	Custom + stretches **vs** felt insert[8]	42 (34) **vs** 47 (42)	48.5# **vs** 48#	ID∼	8	0.59 (0.27 to 1.30)	0.01 (−0.44 to 0.46)	—	

ID, inadequate data provided by authors; ∼, no significant difference between groups ($p = 0.05$); ID∼, authors have only reported statistical significance; PPE, patient perceived effect; VAS, visual analog scale; NSAIDS, nonsteroidal anti-inflammatory drug; SMD, standard deviation difference; RR, relative risk; CI, confidence intervals.
Components of FHSQ: [a] Foot pain; [b] Foot function; [c] Footwear; [d] General foot health; ^ Participants only included in study if symptom duration ⩾ 6 months; [1] AOL; [2] Spenco Sports Medicine Products, Toronto, Ontario, Canada; [3] Langer Blueline, Langer Biomechanic Group, Inc.; [4] Viscoped, Bauerfiend Gmbh, Hampshire, UK; [5] Bauerfiend, Kennesaw, GA, USA; [6] Tuli International Comfort Products, San Marcos, CA, USA; [7] Footscience International, Christchurch, New Zealand; [8] Hapad, Bethel Park, PA, USA.

Foot orthoses compared to other interventions

Finestone et al.[14] demonstrated a significant and clinically beneficial effect of foot orthoses over simple insoles (Table 1).

Custom compared to prefabricated foot orthoses

Pooled data from two studies within one publication[15] comparing custom casted foot orthoses to prefabricated foot orthoses showed no significant effect favoring one type over the other (RR 1.14; CI 0.90 to 1.44) (Table 1; Figure 2).

Treatment Studies

In contrast to the prevention studies, the 15 studies that evaluated the treatment of lower limb overuse conditions with foot orthoses had greater heterogeneity in comparator interventions and the type and timing of outcome measures (Table 2). Consequently, pooling of data was only conducted where similar comparison groups were used, and analysis was divided into three time periods: up to and including 3 months; from 3 months up to and including 6 months; and greater than 6 months. The consistent use of three outcome measures, patient perceived treatment effect (PPE), pain visual analogue scale (VAS) and Foot Health Status Questionnaire (FHS), enabled calculation and comparison of effect sizes and pooling of data for some studies. Table 4 lists other outcome measures used. Studies evaluated the use of foot orthoses predominantly in plantar heel pain or fasciitis (eight studies), but also in anterior knee pain, primary and lesser metatarsalgia, Morton's neuroma and peroneus longus myofascial pain syndrome.

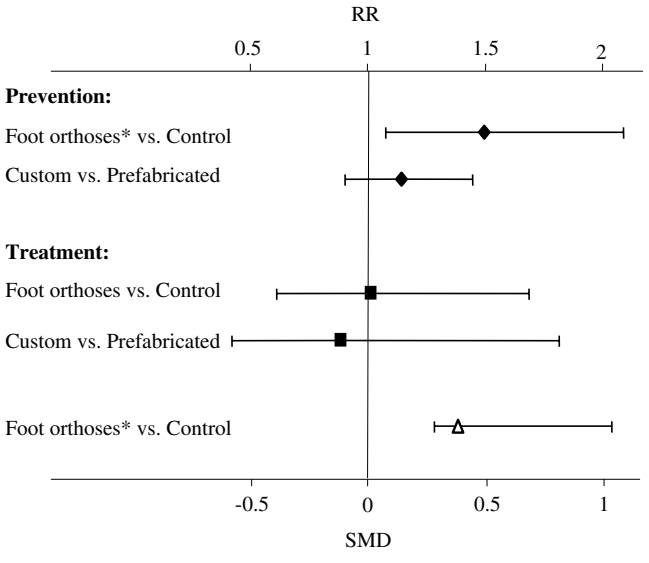

Fig. 2: Pooled results from prevention and treatment studies comparing foot orthoses to control, and custom to prefabricated foot orthoses. Solid shapes indicate relative risks (RR); hollow shapes indicate standardized mean differences (SMD). Timing of outcome measures all 0–3 months. * favors orthoses.

Foot orthoses compared to controls

Pooling of data from two studies[35,50] that compared foot orthoses to no orthoses, with all subjects performing exercises, showed no significant effect in favor of either group for PPE (RR 1.01; CI 0.61 to 1.68) or VAS (SMD 0.38; CI −0.28 to 1.03) (Table 2; Figure 2).

Foot orthoses compared to other interventions

In the intervention period of up to 3 months, data pooling was not conducted because of violation of the assumption of homogeneity of the data (Table 2). Two studies compared foot orthoses to a local steroid injection, with Kriss[22] finding a significant moderate effect in favor of the injection on VAS, but Lynch et al.[25] showing no significant difference in VAS between groups (Table 2). Heel inserts were more frequently used as a comparison intervention, with studies reporting conflicting findings. Lynch et al.[25] showed a significant moderate effect in favor of foot orthoses, whereas Pfeffer et al.[35] found significant small effects in favor of two different heel inserts on PPE measures, but no significant differences on VAS. Two other studies[42,48] reported significantly greater improvements in pain measures for foot orthoses than heel inserts, but insufficient data were provided to calculate effect sizes. Different outcomes also arose for studies that compared foot orthoses to a cushioning or flat insole. Kelly and Winson[20] showed a significant effect in favor of foot orthoses on PPE but not VAS, whereas Rome et al.[39] showed no significant effect of one group over the other on FHS. Both Eng and Pierrynowski[11] and Postema et al.[37] found foot orthoses to be significantly better than flat or ready made insoles on pain measures ($p < 0.05$) but did not provide sufficient data for effect size calculation. Of the two studies that compared foot orthoses to night splints for plantar fasciitis, Martin et al.[26] reported slight differences between groups on VAS but did not report statistical significance levels, while Russell[40] measured pain as a component of the Foot Function Index (which overall showed no significant difference between groups ($p > 0.05$)) but did not report separate pain data. A single study comparing foot orthoses directly to a lower limb exercise program showed no effect in favor of either intervention on VAS or PPE,[50] while another study that used chiropractic foot and ankle manipulations as a comparison provided insufficient data for effect size calculation but reported no significant difference on final measures.[10]

One study that evaluated treatment effects at 6 months found no significant effect of foot orthoses or local steroid injection on VAS[22] (Table 2). Similarly, PPE and VAS measures from a single study looking at treatment effects beyond 6 months showed no significant effect between pronation and supination foot orthoses.[21]

Custom compared to prefabricated foot orthoses

Three studies compared custom to prefabricated foot orthoses up to a 3-month period.[23,26,35] Pooling of data for

Table 3: Quality ratings using Modified PEDro Scale of reviewed papers (n = 22). Listed in descending order of quality rating (see Appendix A for details of Criteria 1–14)

Study	Criteria														Score	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	(/14)	(%)
Landorf, 2004	■	■	■	■		■		■	■	■	■	■	■		11	(79)
Dimou, 2004		■		■			■	■	■	■		■	■	■	9	(64)
Wiener-Ogilvie, 2004	■	■	■					■		■	■	■	■	■	9	(64)
Esterman, 2005	■	■		■				■	■	■	■		■	■	9	(64)
Larsen, 2002	■	■		■				■	■	■	■	■			8	(57)
Kelly, 1998	■	■		■				■		■	■		■	■	8	(57)
Kilmartin, 1994	■	■		■				■		■	■			■	7	(50)
Rome, 2004	■	■		■						■	■		■	■	7	(50)
Postema, 1998	■	■			■		■	■		■	■				7	(50)
Turlik, 1999	■	■		■				■		■	■				6	(43)
Finestone, 2004*		■			■			■		■				■	5	(36)
Pfeffer, 1999		■							■	■	■		■		5	(36)
Saggini, 1996		■		■				■		■	■				5	(36)
Eng, 1993		■		■						■			■		4	(29)
Lynch, 1998		■								■	■		■		4	(29)
Martin, 2001		■		■						■			■		4	(29)
Milgrom, 1985		■						■		■				■	4	(29)
Kriss, 2003		■						■		■	■				4	(29)
Mundermann, 2001	■	■								■			■		4	(29)
Russell, 2000		■								■			■		3	(21)
Finestone, 1999		■								■					2	(14)
Simkin, 1989		■								■					2	(14)

* Single publication that used consistent methodologies to report results from two separate populations

PPE from two studies showed no significant effect favoring either custom or prefabricated foot orthoses (RR 0.88; CI 0.42 to 1.81) (Figure 2), which also reflected effect sizes calculated for the two individual studies.[23,35] Martin et al.[26] did not report statistical analysis to support their findings of greater improvement in VAS in the group receiving custom orthoses, nor did they provide sufficient data for effect size calculation.

Landorf[23] was the only study to measure effect beyond 3 months, with PPE and all subsets of the FHS showing no significant effect for either type of orthoses at both 6 and 12 months.

Cost Effectiveness of Foot Orthoses Intervention

Only two studies evaluated cost effectiveness of interventions.[24,39] As well as representing both prevention and treatment studies, they used different comparison interventions and inconsistent outcome measures, therefore pooling of data was not possible.

Based on intention-to-treat analysis, Larsen et al.[24] reported that the number of people to be fitted with foot orthoses that are needed to prevent one case of injury was six (95% CI 3–59) at a cost of US $122 (95% CI 58 to 1103). Effect sizes were unable to be calculated; however, the authors did report a nonsignificant relative risk of 0.7 (CI 0.5 to 1.1).

A more extensive cost-effectiveness analysis conducted by Rome et al.[39] provided some data for effect size calculation. The total mean cost per patient for using prefabricated foot orthoses in the treatment of plantar heel pain was significantly greater than using a cushioning insole (SMD −3.31; CI −4.38 to −2.24), as was the total mean cost to the hospital podiatry department (SMD −3.89; CI −5.07 to

Table 4: Summary of measures of outcome used in 23 randomized controlled trials of foot orthoses in lower limb overuse conditions. Includes studies that used components of scales

Outcome measures		Number of studies
Occurrence of injury	Presence of lower limb injury (self-report, P/E, radiograph, scintigraphy)	8
	Development of other symptoms	1
	Lower limb pain in the previous 24 hours	1
Patient percieved treatment effect	Global/final outcome score; perceived improvement; response rate*	6
	Progression of pain*	1
	Relief with intervention*	1
	Symptom relief VAS	1
	Patient satisfaction questionnaire*	1
	Time to start of improvement	1
Pain	Pain VAS (daily; during activities; first-step pain)	7
	Pain*	1
	Numeric Pain Rating Scale 101	1
	First-step pain*	3
	Frequency/severity of morning heel pain*	1
	Change in pain under various specific circumstances	1
	Feelings about life with pain*	1
	Worry about current pain*	1
Pain and function	Foot Health Status Questionnaire	3
	Foot Function Index	2
	MACTAR patient specific measure of maximal function	1
	Knee Pain Scale	1
	Effect of heel pain on leisure/work/exercise*	3
General health	Short Form 36	2
	EuroQol (EQ5D)Questionnaire	1
	World Health Organization Quality of Life Questionnaire (WHOQOL) Short Form	1
Activity	Hours of activity per week	1
	Change in activity	1
	Type & amount of exercise per week; walking distance	2
	Hours on feet per day	1
Physical measures	Gait analysis	3
	Surface electromyography (sEMG)	1
	Nerve conduction studies	1
	Pressure pain threshold	2
Orthoses comfort	Orthoses comfort*	2
Compliance	Compliance with treatment (% wear, daily splint wearing time)	3
Cost effectiveness	Cost of treatment	1
	Total off-duty days; subjects with $\geq$ 1 off-duty days due to lower limb problem	1

P/E, physical examination; VAS, visual analogue scale (100mm); *, Likert rating scale; MACTAR, McMaster Toronto Arthritis Patient Preference Questionnaire.

−2.70). There was no significant difference in total mean cost to other National Health Service (NHS) services per patient between the two groups. Rome et al.[39] also reported that, based on mean scores from the EuroQol health status questionnaire,[12] use of the foot orthoses resulted in a quality-adjusted life year gain of 0.0109 compared to the cushioning insert, and an incremental cost per quality-adjusted life year of $3210.

Two studies mentioned costs of materials for different shoe inserts in their discussion of study findings[35,40] but did not relate these to improvements in outcome measures or consider the total cost of intervention.

Adverse effects of foot orthoses intervention

Only eight of the 22 papers that were included in the systematic review analyzed or mentioned the occurrence of adverse events arising from interventions provided. Kilmartin and Wallace[21] was the only study to report an actual incidence of adverse events, with no significant difference between groups receiving pronation or supination orthoses. Both Dimou et al.[10] and Wiener-Ogilvie and Jones[50] reported no adverse events with any of the interventions.

Overall, the main adverse effect reported was discomfort. This was the primary reason for discontinuing use in reports by Finestone et al.[15] and Esterman and Pilotto[13] and was also reported by participants in the study conducted by Rome et al.[39] Twenty-one percent of participants (30 of 143 recruits) allocated to receive foot orthoses in a preventative role discontinued their use in the first 14 days because of discomfort.[29] Other reported adverse effects of foot orthoses included arch or metatarsal pain,[15] shin splints, and slipping of the orthoses in the boots.[13] Comments about adverse effects of cushioning inserts were slightly different in nature. The silicone insole used in the study by Kelly and Winson[20] was described as being too hot and slippery, while the insole used by Rome et al.[39] tended to go hard and flat and lose its cushioning ability after 4 weeks of wear.

DISCUSSION

Two distinct bodies of literature were identified by the comprehensive search strategy: studies that evaluated foot orthoses in a prevention role, and studies investigating foot orthoses in the treatment of lower limb overuse conditions. The systematic review and pooling of data support the use of foot orthoses in preventing lower limb overuse conditions in military populations. However, caution should be exercised in making inferences to populations other than military personnel undergoing basic or standard training. In comparison, there was insufficient evidence to support or refute the use of foot orthoses, either custom or prefabricated, in the treatment of lower limb overuse injuries.

Custom foot orthoses, defined in the ACFAOM guidelines[3] as being derived from a three-dimensional model of the foot, often are regarded to be superior to prefabricated (off-the-shelf) foot orthoses. A particularly interesting finding from this review was the lack of any differential efficacy between custom and prefabricated foot orthoses, both from pooled data and individual study data that could not be pooled. This finding requires followup evaluation. Importantly, this appears to have clinical implications in the management of lower limb overuse conditions, suggesting that the more readily available prefabricated foot orthoses are similar in clinical effect to custom fabricated orthoses. While the cost effectiveness was not directly investigated by the included studies, the custom fabricated orthoses tend to be more resource-intensive (e.g. equipment, material, technical expertise). Another consideration is the wearing-in period often associated with custom foot orthoses and the delay between fitting and supply particularly when prescriptions need to be sent off site. In addition, the lack of differences between custom and prefabricated foot orthoses supports our decision to consider both types of foot orthoses as one group in comparisons with control or other interventions.

Using the best current evidence, it would seem appropriate that clinical guidelines should de-emphasize the difference between custom and prefabricated foot orthoses in the management of overuse conditions. However, this statement should be tempered with consideration of deficits in the studies reviewed and the recognition of the need for further research in this area.

A potential deficiency of this review was that specific overuse conditions being studied in individual papers were generalized, that is, studies were evaluated and pooled across a range of overuse conditions. We considered this to be a legitimate approach, because the findings from previous prevention studies have shown that foot orthoses were effective in preventing a range of overuse conditions, regardless of lower limb site. In addition, the overuse conditions included have a putative association with abnormal foot function, usually ascribed to excessive pronation,[5,9,19,27,47] and it is frequently recommended that foot orthoses be included in their management.[7,16,34] Importantly, the ACFAOM guidelines[3] indicate custom foot orthoses to be either 'medically indicated and essential' or 'useful' in all of the conditions studied in the reviewed papers, with the exception of Morton's neuroma and peroneus longus myofascial pain syndrome. When Morton's neuroma has been diagnosed, ACFAOM[3] have recommended foot orthoses as an adjunct to treatment. Peroneus longus myofascial pain syndrome as described by Saggini et al.[42] was not discussed in the ACFAOM guidelines.[3]

As highlighted in the results, there were a number of criteria from the modified PEDro scale that were reported by less than half of the included studies. Although this has implications for the internal and external validity as well as overall power of the studies, correlation analyses between the modified PEDro score and effect size showed that the deficits in methodological quality did not appear to affect

the overall outcome of the meta-analysis. This differs from previous studies that have reported that the inclusion of low methodological quality studies in a meta-analysis can bias the interpretation of the intervention's benefit.[30]

One of the strengths of this systematic review was the minimization of bias through the use of independent reviewers who were blinded to authors, affiliations, and publishing journals. In addition, publication bias was reduced through using a comprehensive search strategy that encompassed all publication forms, including conference presentations and placed emphasis on hand searching of reference lists.

This systematic review has attempted to fill a gap in the literature with respect to Level I evidence but also has identified a number of issues for future research. Not only is more research into the role of foot orthoses in the treatment of lower limb overuse conditions required but it needs to be of higher quality. Overall, greater consensus is necessary in the literature as to what constitutes foot orthoses, perhaps with one consistent set of guidelines that is based on current evidence. Based on evidenced published to date, we would propose the following definition for foot orthoses: in-shoe devices shaped to match the plantar surface of the foot and used in the prevention and treatment of injury, pain, and disability through the optimization of lower extremity function. In addition, the methodology of future RCT research requires more meticulous planning, using the CONSORT statement[31] as a guideline to direct high-quality study. Future research should also investigate the long-term efficacy of foot orthoses.

SUMMARY

There is evidence from the meta-analysis to support the use of foot orthoses in the prevention of the first incidence of lower-limb overuse conditions. The inclusion of orthoses in a treatment program for individuals who already have an overuse condition is difficult to support or refute because of the generally poor research base, which has been highlighted by this systematic review.

There is evidence from pooled data that there is no difference between the use of custom and prefabricated foot orthoses, inferring that practitioners may use either in the prevention and treatment of lower-limb overuse injuries.

Focal points for future research conducted in this area include longer intervention durations, greater consistency with reliable measures, and better consensus in definitions of foot orthoses.

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Appendix A: Modified PEDro rating scale

All criteria: points are only awarded when a criterion is clearly satisfied. If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.

1. **Eligibility criteria were specified.** This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

2. **Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated in order in which treatments were received).** A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomization need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomization allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.

3. **Allocation was concealed.** *Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware when the decision was made of to which group the subject would be allocated. A point is awarded for this criteria, even if it is not stated that allocation was concealed when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site."

4. **The groups were similar at baseline regarding the most important prognostic indicators.** At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated **and** at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ on the basis of baseline differences in prognostic variables alone by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.

4, 7–11. *Key outcomes* are those outcomes which provide the primary measure of effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.

5–7. *Blinding* means that the person in question (subject, therapist, or assessor) did not know to which group the subject had been allocated. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (e.g. visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.

5. **There was blinding of all subjects.**

6. **There was blinding of all therapists who administered the therapy.**

7. **There was blinding of all assessors who measured at least one key outcome.**

8. **Measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.** This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes were measured at several points in time, a key outcome must have been measured in more than 85% of subjects at the time of *primary interest*.

(*Continued*)

Appendix A: (*Continued*)

9. **All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analyzed by "intention to treat."** An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and when measures of outcome were available, the analysis was performed as if subjects received the treatment (or control condition) to which they were allocated. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
10. **The results of between-group statistical comparisons are reported for at least one key outcome.** A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyze the data, the latter often is reported as a group x time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
11. **The study provides both point measures and measures of variability for at least one key outcome.** A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcome, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quartile ranges), and ranges. Point measures or measures of variability may be provided graphically (for example, standard deviations may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent standard deviations or standard error). When outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.
12. **The sample size is justified.** In calculating the sample size, statistical evidence was provided regarding the power of the study and its effect size.
13. **The study uses outcome measures that have known validity and reliability.** Outcome measures used in the study were referenced for their validity and reliability. If more than one assessor was used for the outcome measures, inter-tester reliability studies were performed, and results of these stated.
14. **Adverse or side effects were reported.** All adverse events were described and correctly attributed to allocated treatment. If no adverse events occurred, the report explicitly states "no adverse events." A comparison was made between the beneficial effect of the intervention and the adverse events (i.e. did the benefits of the intervention outweigh the adverse events?).