Review Article

A critical review of foot orthoses in the rheumatoid arthritic foot

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Foot orthoses are commonly prescribed by health professionals as a form of intervention for the symptomatic foot in rheumatoid arthritis. However, there is a limited evidence base to support the use of foot orthoses in this patient group. This article provides a critical review of the use of foot orthoses in the management of rheumatoid arthritic foot pathologies. A search was conducted in the Cochrane Controlled Trials Register (current issue of the Cochrane Library), Physiotherapy evidence database (PEDro), Medline, The Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Allied and Complementary Medicine (AMED) and from reference lists in journal articles. The language was restricted to English. Searching of the databases was undertaken between December 2004 and March 2005. The results indicated there is no consensus of opinion on the choice of foot orthoses used for the management of pathology in the rheumatoid foot, although there is strong evidence that foot orthoses do reduce pain and improve functional ability. The type of foot orthoses used ranged from simple cushioned insoles to custom-made rigid cast devices. Methodological issues raised included small sample size and poor use of valid and reliable outcome measures. There is limited evidence pertaining to cost-effectiveness. The results indicated a need for further investigation into the most clinically and cost-effective foot orthoses to prescribe in the management of the rheumatoid arthritic foot. This review highlights the need to identify the various types of foot orthoses that are most effective in the management of the established rheumatoid arthritic foot.

KEY WORDS: Rheumatoid arthritis, Foot orthoses, Pain, Gait.

At diagnosis, 16% of rheumatoid arthritis (RA) patients may have foot joint involvement [1], increasing to 90% as disease duration increases [2, 3]. This can lead to joint instability, difficulties in walking and limitation in functional ability that restricts activities of daily living [4]. The talonavicular joint is the most commonly affected [5]; subtalar joint involvement shows a similar pattern, with an increase of 25% between 5 and 10 yr of duration [5]. Deformity of the tarsal joints and forefoot also occurs with disease progression.

Foot orthoses (FO) are prescribed by clinicians to relieve forefoot, midfoot and rearfoot pain and normalize gait pattern [6]. Unfortunately there are few well-controlled studies published supporting the use of FO in RA patients, and those that are available are often conflicting. Most reasoning for the use of FO is anecdotal; there is a lack of scientific evidence supporting practitioners' claims [7]. The aim of this article is to critically review the use of the FO as a clinical intervention in patients with RA.

Search strategy for identification of studies

A search was conducted in the Cochrane Controlled Trials Register (current issue of The Cochrane Library), PEDro, Medline (1980 to January 2005), CINAHL (1980 to January 2005) and AMED (1980 to January 2005) and from reference lists in journal articles. The language was restricted to English.

Searching of the databases was undertaken between 28 December 2004 and 15 January 2005. The search strategy used the following words: rheumatoid arthritis; foot orthoses; pain; gait; orthotics.

Description of studies

Twenty-one papers were identified from literature relating to the use of FO in the rheumatoid foot. Six were randomized clinical trials [2, 3, 8–11] and five were non-randomized case–control or comparison studies [1, 12–15]. One study included both adult and juvenile-onset patients [15]. All participants had a diagnosis of RA as defined by the American College of Rheumatology Criteria for classical or definite RA [16]. Other articles, including audits, case studies and reviews, were excluded [17–25]. The randomized and non-randomized clinical trials that were considered for this review, as in the paper by Landorf *et al.* [7], were only well-controlled studies. Themes emerging from the papers were used to cluster the information, as follows: (i) types of FO; (ii) pressure studies; (iii) joint deformity; (iv) FO wearing time; (v) pain and disability; (vi) comfort/preference/satisfaction; (vii) gait parameters; (viii) footwear; (ix) cost-effectiveness; and (x) clinical relevance. Participants in the trials were adults with RA meeting the inclusion criteria for the trial type.

A review from the Cochrane Controlled Trials Register was identified [26] that reported on the effectiveness of splints/

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orthoses in relieving pain, decreasing swelling, and/or preventing deformity, and determined the impact of these on strength, mobility and function in RA [26]. The review concluded that there was potential for FO to provide pain relief for varying periods of time in certain patients and at a relatively low cost, although this conclusion appeared to be in relation to hand and wrist splints rather than FO, and supported the current practice of trying out various types of splints/orthoses to determine whether they are helpful.

Methodological quality of included studies

Six trials were randomized [2, 3, 8–11]. Budiman-Mak *et al.* [8] and Woodburn *et al.* [11] reported their methods of randomization, but the remaining studies do not state the randomization procedure used [2, 3, 9, 10]. Five studies were not randomized [1, 9, 12, 14, 15].

Three studies reported power calculations to determine sample size [3, 8, 11]. Woodburn *et al.* [11] failed to recruit sufficient numbers. Budiman-Mak *et al.* [8] and Conrad *et al.* [3] recruited the necessary number of subjects to ensure the power of their studies.

Budiman-Mak *et al.* [8] and Conrad *et al.* [3] used double-blind methods administered at pre/post-test, evaluated at the end of each study to ensure an unbiased result. Chalmers *et al.* [2] used a single blind methodology with the assessor blinded to the intervention type. Woodburn *et al.* [11] blinded attending physicians as to the inclusion of subjects, but acknowledge that masking of the treatment allocation was impossible to achieve. Assessor blinding and patient numbers lost to follow-up were reported in four randomized controlled trials [2, 3, 8, 11]. Intention-to-treat-analysis was applied in three studies [3, 8, 11], which also reported on adverse effects [3, 8, 11]. Control groups were used in three studies [3, 8, 9]. Woodburn *et al.* [11] used no FO as a control, Hodge *et al.* [12] and Jackson *et al.* [9] used a shoe-only control. Three studies compared FO data with values obtained from healthy subjects [10, 14, 15].

Methodological issues

Landorf and Keenan [7] commented that evaluation of FO can be undertaken using different types of method, usually dependent on the philosophies of the investigators. As there were disparities in the data collected and types of FO intervention, data comparison was difficult.

Types of FO

Types of FO used varied greatly (Table 1). Custom-moulded, hard FO, with posting, made from rigid materials were used in

TABLE 1. Description of foot orthoses

Author	Orthosis type	Orthosis construction	Part of foot related to	No. of patients sampled
Woodburn *et al.* [11]	Custom-made rigid FO using a subtalar neutral technique for casting	Rigid shell with soft covering material	History of bilateral ankle and/or subtalar and/or talonavicular pain and valgus heel deformity	101 recruited but 3 withdrew, 98 at baseline
MacSween *et al.* [1]	Custom-made using a subtalar neutral technique for casting	Semirigid shell	Bilateral forefoot pain with/without swelling of metatarsal heads	8
Li *et al.* [14]	Metatarsal pad incorporated proximal to metatarsal heads	Mouldable materials. Metatarsal pad made from materials with extra density	Foot pain in walking	12 female RA patients and 8 healthy females
Chalmers *et al.* [2]	Custom-made using a subtalar non-weight bearing position	Rigid shell with intrinsic posting covered in leather	Metatarsal phalangeal joint pain	28 patients started trial, 24 completed
	Custom-made using a weight-bearing position	Soft FO		
Conrad *et al.* [3]	Custom-moulded rigid FO using a subtalar neutral technique for casting	Rigid shell with intrinsic posting	Foot pain and minimal radiographic changes in the feet	102 males
	Placebo	Rigid shell with no posting		
Budiman-Mak *et al.* [8]	Custom-made rigid FO using a subtalar neutral technique for casting	Rigid shell with intrinsic posting	Foot pain and minimal radiographic changes in the feet	102
	Placebo moulded over positive cast	Flexible thin leather covered with soft material		
	Uniform thickness and density	No posting		
Hodge *et al.* [12]	Prefabricated FO	Soft material	Pain on shod weight-bearing	12
	Custom made subtalar neutral and metatarsal bar or dome	Semirigid material. Metatarsal domes/bar made from latex rubber		
Mejjad *et al.* [10]	Prefabricated FO	Semirigid shell	Only forefoot pain	16
Kavlak *et al.* [13]	Custom-made arch support, metatarsal bar	Rigid material with medial rearfoot wedging. Metatarsal bar made from rigid material incorporated into shoe vamp	Not specified	18
Locke *et al.* [15]	Custom-made FO	Material not described	Not specified, ability to walk 15 m	25 RA patients and 20 healthy patients
Jackson *et al.* [9]	(1) Prefabricated insole	Expanded urethane foam, hardness 25 on Shore A scale	Pain with shod weight-bearing in the forefoot region	10
	(2) Metatarsal bar/dome, different sizes	Dome/bar, latex foam		

four studies [2, 3, 8, 11]. MacSween et al. [1] used custom-moulded FO based on a model described by Locke et al. [15], who did not record the materials used. Two studies [2, 12] used soft FO made from mouldable materials. Kavlak et al. [13] used unspecified soft FO that were palliative, combined with foot-wear modifications. Mejjad et al. [10] used varied types of FO depending on the subjects' symptoms. Li et al. [14] used FO with a transverse arch, medial longitudinal arch and metatarsal pads made from different mouldable materials. Jackson et al. [9] used flat prefabricated expanded foam insoles with latex metatarsal bars and domes.

Throughout the papers reviewed [1–3, 8–15], there was no apparent standardization of FO. Choice of construction materials and design were not reported, making it difficult for clinicians to translate the data into effective clinical practice and make informed choices for patients regarding the most appropriate type of FO to use.

Pressure studies

Three clinical trials [9, 12, 14] studied the effect of foot pressure distribution and loading forces during gait using two different computerized in-shoe pressure systems. Hodge et al. [12] measured plantar pressure, stance-phase duration and cadence in RA patients with forefoot pain. No significant difference in cadence was found between the study groups, suggesting cadence did not vary with the use of FO. There were highly significant differences between various types of FO for walking and standing pain, suggesting that pain experienced during standing appeared to be similar to that experienced during walking—therefore a static clinical test could be used to assess pain levels. Standard custom-moulded FO and FO with a metatarsal dome had lower walking pain ratings than the shoe-only control. The other types of FO did not result in significant pain reduction compared with the shoe-only control. There was a significant correlation between average pressure and walking pain, and standing and walking pain. More uniform pressure distribution was obtained in all the FO compared with shoes that were worn alone, which demonstrated that FO can be effective in the management of pain in the rheumatoid foot.

Li et al. [14] studied the biomechanical effect of foot pressure measurements and loading distribution during gait, with and without FO, in both the rheumatoid foot and healthy patients. The authors demonstrated that foot pressures with FO were significantly lower than those without in both study groups. The FO of RA patients provided greater pressure reduction and redistribution than those of the control group. In contrast with respective body weight, loading force under the rearfoot and forefoot in both groups lessened, but increased under the midfoot in RA patients, suggesting that FO provided a partial loading redistribution. RA patients had greater loading changes during the stance phase of gait. The study showed that FO provided a significant increase in pressure and loading force relief and redistribution in rheumatoid subjects over that seen in healthy subjects.

Jackson et al. [9] measured average reductions in peak pressures over the metatarsal heads and calculated a cadence score for each test state. Both insole designs reduced mean peak pressures with significant reductions at the central metatarsal heads compared with the shoe-only control. No significant changes in mean cadence were noted. The insole plus metatarsal bar pad significantly reduced greater mean peak plantar pressures than the insole plus metatarsal dome pad, suggesting that a prefabricated insole incorporating a metatarsal bar is to be recommended in the management of high plantar forefoot pressures in patients with RA.

All three studies found FO useful in reducing pressure over the forefoot and rearfoot. Hodge et al. [12] concluded that metatarsal domes and bars were equally effective at reducing plantar forefoot pressures, contrasting with Jackson et al. [9], who found the metatarsal bar performed better that the metatarsal dome. Hodge et al. [12] used the relationship between pressure and pain as an outcome measure, finding a significant correlation. The study suggested that average pressure is the more important variable in the RA foot when using an in-shoe measurement system, and the significant relationship between standing and walking pain could be used clinically when fitting FO for RA patients. This contrasts with Li et al. [14] and Jackson et al. [9], who both used an in-shoe system and recorded peak pressure but did not consider pain as an outcome. Hodge et al. [12] also noted that the metatarsal pads used needed to be appropriately sized and placed. Only two studies described the method used to achieve this [9, 12].

Joint deformity

Budiman-Mak et al. [8] was the only paper to evaluate the effects of FO on hallux valgus progression. Ninety-eight patients, predominantly male, with disease duration of more than 2 yr were included. Over a 3-yr period, 10% of the treatment group compared with 25% of the control group experienced progression in hallux valgus deformity. Secondary analysis was performed on 81 patients who completed the study. Thirty per cent of the patients in the control group had progression of hallux valgus deformity compared with 12% of patients in the treatment group. As the treatment group had longer duration of RA and heavier body weight, logistic regression analysis was used to estimate the effect of treatment on the odds ratio of hallux valgus deformity progression. The results demonstrated that the treatment group was 73% less likely to demonstrate progression of hallux valgus deformity.

The findings of Budiman-Mak et al. [8] suggest that FO can prevent or slow the progression of hallux valgus deformity in RA. However, it should be noted that this study had limitations. The research patients were predominantly male and the results were therefore not generalizable to female RA sufferers. Subjects also had a mean duration of RA of more than 2 yr. Van Der Heijde et al. [27] reported that the rate of joint damage peaks 2 yr after onset; therefore, the duration of intervention may have been too short to observe its full impact.

FO wearing time

FO wearing time as an outcome was recorded in four studies [2, 3, 8, 11]. Chalmers et al. [2] recorded mean daily wearing time for FO and shoes alone. Regression analysis showed no significant correlation between pain suffered and the amount of time FO were worn. However, Chalmers et al. [2] found a significant correlation between treatment effectiveness using a visual analogue scale (VAS) and wearing time and analysed pain scores over time, finding that the mean pain scores for hard FO showed a highly significant effect from baseline to final visit. This was achieved during the first 6 weeks of the trial and was then maintained with patients wearing their FO for 6.15 h each day. Two studies [3, 8] recorded wearing time as a self-reported estimate of the amount of time FO were worn in the week prior to an evaluation visit. Budiman-Mak et al. [8] estimated the mean wearing time per week. Patients in the treatment group, who experienced progression of deformity, wore their FO for an average of 19 h per week, as opposed to 46 h per week for those who did not. In the control group the mean wearing time was very similar (40 vs 44 h per week) [8]. Conrad et al. [3] reported that increased wearing time related to significantly decreased pain and disability for both groups, regardless of the type FO worn. Woodburn et al. [11] demonstrated that 96% of subjects wore

their FO in the week prior to interview. FO were worn on average for 6 h per day and 6 days per week. There was no difference in daily wearing time between first and final reviews, showing that most subjects persisted with wearing their FO.

Wearing time appears to be a crucial factor in the effectiveness of FO as in all four studies [2, 3, 8, 11] increased wearing time appears to relate to a decrease in pain, disability and deformity, with a treatment effect achieved during the first 6 weeks and maintained whilst wearing the FO [2]. Although there is no consensus on the method used to calculate wearing time [2, 3, 8, 11], two studies appear to suggest FO are worn for an average of 6 h per day [2, 11].

Pain and disability

Foot pain and disability were outcomes measured in three trials [2, 12, 13]. Measures of function and disability were used in three studies [3, 8, 11]. Patient perception of pain was measured using a 10-cm visual analogue pain scale in four trials [2, 10, 12, 13]. Two studies [3, 8] initially used an adapted Arthritis Impact Measurement Scale [3], a subjective measure to assess foot pain, function and activity limitation. Budiman-Mak *et al.* [8] then developed the Foot Function Index [8], a subjective measure to assess foot pain, function and activity limitation. Unfortunately this was implemented during the second half of two studies [3, 8], and may not discriminate disability related to the foot from that related to the lower extremities [21]. Hodge *et al.* [12], Woodburn *et al.* [11] and Kavlak *et al.* [13] used the pain subscale of the Foot Function Index [8] to measure pain, disability and activity restriction. Two studies measured pain using seven items adapted from the McGill pain questionnaire [3, 8], which describes the self-reported location, quality and intensity of pain, plus four items referring to pain severity when wearing or not wearing shoes, using a five-point response scale.

Budiman-Mak *et al.* [8] demonstrated that the measurement of pain, disability and function using a subscale of the Foot Function Index showed little or no benefit from wearing hard FO, possibly because the FO was used to stabilize joints rather than to reduce swelling.

Locke *et al.* [15] asked patients to self-grade their degree of pain on a scale in which 1 represented no pain in the joint and 4 represented severe pain preventing ambulation.

Chalmers *et al.* [2] compared the effects of FO on metatarsal pain, metatarsal synovitis and function using a VAS (Table 1). When adjusted from baseline, mean pain scores at the final visit showed significant differences between hard and soft FO, and hard FO and shoes. There was no significant difference between soft FO and shoes. Over time the mean pain scores for hard FO showed a highly significant improvement from baseline to final visit, achieved during the first 6 weeks of the trial. None of the interventions showed any effect on metatarsal joint synovitis or lower extremity function from baseline to final visit. Soft and hard FO had significant material compression, but there was no correlation between the former, pain and body weight. A reduction in mean pain scores from baseline to final visit showed that hard FO had a highly significant effect on metatarsal phalangeal joint pain.

Conrad *et al.* [3] compared a control with a treatment group over a 3-yr period (Table 1). At baseline there was no difference between the two in outcome variables, apart from disease duration, which was significant, and weight, which was not. Both were greater in the treatment group. Low weight was significantly related to painful foot joint count, possibly due to greater disease activity. No significant differences were found in disability or foot function using the Arthritis Impact Measurement Scale [3] or the Foot Function Index [8]. No significant differences in pain or disability were found, as supported by the patients' use of analgesia, narcotics and antidepressants, which had not changed over the 3-yr study period. Subjects who wore placebo or FO for longer periods experienced decreased foot pain and disability scores, regardless of FO type. Based on these findings, the study indicated no benefit of hard FO over placebo FO. However, it should be noted that the sample population consisted predominantly of older males with a long disease history. Subjects were chosen on the likelihood of FO benefit, and were more likely to have 'burnt out' disease states and less pain initially. Treatment effects were not accounted for.

Woodburn *et al.* [11] evaluated the effects of custom-made hard FO (Table 1) in RA subjects with early and correctable rearfoot deformity, focusing on clinical outcomes. Global pain scores and disease activity scores were higher in the intervention group. At baseline the Foot Function Index scores were higher in the treatment group, showing greater improvement compared with less improvement in the control group. After 30 months of wear the treatment group showed significant foot pain improvement; foot disability was reduced in both groups, with greater change in the intervention group. The intervention group had a significantly higher peak response time, but there was no significant change in the erosion index disease activity score or Health Assessment Questionnaire. Medical intervention or medication use remained the same. The study found that a custom-designed FO worn continuously over a 30 month period resulted in a 19% reduction in foot pain, 31% reduction in foot disability and 14% reduction in functional limitation. Therefore the clinical effectiveness of FO may be enhanced by use in the early stages of rearfoot pain and deformity. The Foot Function Index was also used in three further studies to measure functional ability and pain [11, 12, 13].

Mejjad *et al.* [10] evaluated improvement in gait parameters and pain with the use of FO (Table 1). With and without FO, comparison with healthy subjects showed rheumatoid subjects had no significant difference in walking speed and cadence, stride and step lengths, swing and late swing duration, early swing speed, support and cycle duration and late swing speed. The only significant difference seen was step length on the left side, although no reasons for this were discussed. Pain scores were lower for the FO group. Therefore, wearing the FO decreased pain but not sufficiently to improve gait in rheumatoid patients with metatarsalgia.

Conrad *et al.* [3] noted that pain is commonly recognized as a primary cause of morbidity in RA, but foot pain has not been well studied as an outcome. No consistent tools were used to quantify different types of pain or disability, although the Foot Function Index was the most commonly used tool to measure pain, disability and limitation of function [3, 8, 11–13], followed by the VAS [2, 10, 12, 13] to measure pain.

One paper found a significant improvement in early rearfoot pain [11] and one paper found a significant improvement in forefoot pain [2] with the use of hard FO. In contrast to this, Conrad *et al.* [3] reported no effect on disability measures and a marginal effect on foot pain measures, indicating that hard FO provided little or any benefit over placebo FO; and Budiman-Mak *et al.* [8] found no improvement in foot pain using hard FO, but did find slowed progression of joint deformity. Two studies [1, 15] did not provide sufficient information regarding the type of FO used; one reported a decrease in rearfoot pain [15] and the other improved comfort levels [1]. Three studies reported significant reductions in pain using soft FO, two regarding forefoot pain [10, 12] and one regarding general foot pain [13]. Two studies did not measure pain at all [9, 14]. These studies do suggest that FO improve foot pain and disability. For clinical application, soft and hard FO improve forefoot pain, and hard FO improve rearfoot pain in early onset RA but the picture is less clear regarding patients with foot pain and established RA.

Comfort/preference/satisfaction

Perception of comfort, preference or patient satisfaction with FO was explored in five papers [1, 2, 9, 11, 12]. Jackson *et al.* [9] demonstrated that patient preference contradicted the study findings, as patients chose to wear the FO with a metatarsal dome, although the FO with a metatarsal bar was found to significantly reduce greater mean peak plantar pressures. Hodge *et al.* [12] demonstrated that 50% of subjects preferred FO with a metatarsal dome. Chalmers *et al.* [2] used a ranked treatment preference questionnaire, finding that patients equally preferred hard and soft FO, two patients preferring no treatment, contradicting the authors' conclusion that hard FO were significantly more clinically effective than shoes alone. MacSween *et al.* [1] used a five-point Likert scale, finding that comfort levels improved with the use of FO. Woodburn *et al.* [11] used semistructured telephone interviews; 97% of patients reported comfort. These papers [1, 2, 9, 11, 12] suggest that the majority of patients find wearing FO comfortable, whether they be hard or soft, and in those with forefoot pain a metatarsal dome is preferable to a metatarsal bar.

Gait parameters

Lower extremity function was measured using various methods. Chalmers *et al.* [2] used the ambulation section of the Robinson Bashall Functional Assessment [28] to measure lower extremity function, which consists of standing, walking and stair-climbing scales, and the walking and stair climbing components of the Toronto Activities of Daily Living Measure [29]. Clinicians have reported the Robinson Bashall Functional Assessment as more useful for identifying patient problems than in assessing functional improvement over time [28].

Gait parameters were measured by a number of studies [1, 2, 10, 13, 15]. MacSween *et al.* [1] conducted a small study looking at the effect of custom-moulded FO using a pressure-sensitive walkway mat, finding that average stride length was the only gait parameter that showed a significant improvement.

Kavlak *et al.* [13] conducted a trial to determine the effects of pain, gait and energy expenditure. The study used footprints collected when subjects walked 15 m at a self-selected speed, measuring stride length, step width, right and left step lengths and foot angle, and estimating cadence. Velocity was calculated using the subject's physiological cost index, calculated as the time taken to walk 100 m, expressed as net number of heartbeats per minute. Using custom-made FO and following 3 months of use, the study found significant reduction in pain intensity, significant differences in right and left step lengths and stride length and an improvement in physiological cost index, suggesting energy demands are reduced during gait when wearing FO.

Locke *et al.* [15] documented ankle and subtalar joint motion during gait using an electrogoniometer; assessed non-weight-bearing passive range of motion via an examiner, and determined stride characteristics using an insole foot-switch system. Rheumatoid subjects demonstrated a reduced range of ankle and subtalar motion compared with healthy subjects, except for the range of rearfoot valgus. The results also demonstrated a slower gait velocity and less single-limb support time. Non-randomized cohorts were stratified into small groups; new FO wearers and current FO wearers found that a significant increase in velocity and single-limb support time occurred with shoes, and a further significant increase with FO. Ninety per cent of subjects also reported a decrease in ankle and rearfoot pain when using the FO. The study demonstrated the positive effect of FO in the treatment of rheumatoid subjects with rearfoot and ankle pain and deformity.

In summary, four papers suggest that gait parameters improve with the use of FO: average stride and step length increased [1, 2, 13], as did velocity and single-limb support time, with reduced energy demands [15]. In contrast, no significant difference in cadence was found by two studies [10, 12], Mejjad *et al.* [10] reporting that the difference seen in left step length was not enough to improve gait in RA patients with metatarsalgia.

Footwear

In general the papers did not consider footwear. Jackson *et al.* [9] reported that subjects wore their own low-heeled lace shoes, with thin 100% nylon ankle-high socks. Budiman-Mak *et al.* [8] and Conrad *et al.* [3] described taking care with footwear fit and commented that varied shoe soles could influence the development of foot pathology. Woodburn *et al.* [11] highlighted a need to monitor footwear depth as using FO could result in a higher number of adverse effects.

Cost-effectiveness

In 1999 it was estimated that 6 000 000–10 000 000 people required FO and the annual National Health Service (NHS) budget was approximately £38 million, of which 30% was spent on FO and footwear [30]. The Audit Commission report in 2000 stated that acute trusts spent £400 000 per year on average on orthotics, with approximately half of this spent on footwear [31]. Only two papers considered FO cost [2, 11]. Chalmers *et al.* [2] noted only that price was not a factor. Cost information was recorded using a treatment effectiveness questionnaire that ranked interventions, including price. Woodburn *et al.* [11] noted that, based on observations of average wear, FO should be replaced every 24 months, incurring low annual treatment costs as the FO unit used in the study cost £60 per pair.

Clinical relevance

The types of FO reviewed were varied and sometimes unspecified [10, 13], making it difficult to draw conclusions regarding the most appropriate type of FO for the RA foot. Hodge *et al.* [12], however, found significant differences between types of FO for walking and standing pain, suggesting that pain experienced whilst static and when walking were similar, and therefore that a static assessment of foot pain could predict dynamic pain levels. FO with metatarsal domes and bars reduced average pressures under the plantar surface of the forefoot, although Jackson *et al.* [9] found metatarsal bars performed better as long as they were correctly placed [12]. Patient preference appears to be important in this issue, with patients preferring FO with metatarsal domes [9], possibly because of decreased bulk in footwear. Patients also preferred wearing FO compared with footwear alone, finding improved comfort levels [1, 2, 11]. Foot pressures were also significantly lower in those RA patients wearing FO than those without [14]. Hard FO prevented or slowed the progression of hallux valgus [8], and FO wearing time appeared to influence the outcome of wearing FO. Chalmers *et al.* [2] found that mean pain scores from baseline to final visit showed a significant effect when wearing FO, which occurred in the first 6 weeks. A treatment effect therefore appears to occur in the first 6 weeks and is maintained with an average wearing time of 6 h per day [2, 11]. Hard FO had a highly significant effect on metatarsal joint pain [2], and on rearfoot pain in early RA [11]. Soft FO improved both forefoot and general foot pain [10, 12, 13]. Gait parameters such as step and stride length, velocity and single support phase significantly improved with the use of FO [1, 2, 13], as did energy expenditure [15], although no significant

difference in cadence was found [10, 12]. Woodburn *et al.* [11] recommended replacing hard FO every 24 months, based on observations of average wear.

Conclusion

From the review there is limited and conflicting evidence upon which to base clinical practice. The suggestion is that FO may reduce foot pain and improve functional ability, but these outcomes were not achieved by all studies. The studies did not relate specific types of FO to specific joints of the foot in general. Both hard and soft FO decreased forefoot pain, and hard FO decreased rearfoot pain in the patient with early-onset RA [11]. Hard FO also decreased levels of foot deformity in RA patients with hallux valgus, but did not improve pain levels [8]. Types of FO used are varied, providing no consensus regarding the optimum type to use for specific painful joints in the established RA foot. Reliable and valid rheumatoid foot-specific tools for measuring pain and disability have been developed, although these may not be sensitive enough to distinguish between deformity caused by inflammation and synovitis and other factors, such as footwear pressure or heredity. The Foot Function Index was the most common tool used to measure foot pain, disability and function [3, 8, 11–13]. Methodological rigour is not present in all studies, which detracts from the validity of results. Sample sizes used within the studies varied greatly. MacSween *et al.* [1] sampled eight consecutive patients walking five times each over a contact-sensitive walkmat, but acknowledged this as a study limitation. Seven studies [2, 9–15] used sample sizes between 10 and 28 patients, with no reference to the use of sample size calculations. Three studies reported on power calculations to determine sample size [3, 8, 11]. Woodburn *et al.* [11] recruited 98 patients the study but acknowledged it was still underpowered. Conrad *et al.* [3] and Budiman-Mak *et al.* [8] used power calculations and both recruited 102 patients. However, Conrad's [3] sample was atypical of RA patients as it consisted of men without foot deformity with long disease duration and is therefore not transferable to the predominantly female RA population. Li *et al.* [14] recruited all female patients and their study findings are therefore also not transferable.

There is also limited evidence pertaining to the cost-effectiveness of FO. To ensure consistency throughout the NHS, the Department of Health (1998) called for quality to be placed at the top of the agenda [32]. This led to the establishment of the National Institute for Clinical Excellence (NICE) in 1999 'to provide guidance to the NHS on the use of new and established technologies' [33]. The government called for clinical decisions to be effective and efficient. Consequently, NICE synthesizes evidence on effectiveness and cost of treatments, and reaches a 'judgement as to whether on balance the intervention can be recommended as a cost effective use of NHS resources' [34]. Therefore, the need for evidence-based information on the cost-effectiveness of FO cannot be underestimated.

The authors have declared no conflicts of interest.

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