

# CRITICAL REVIEW

## Podiatry interventions in the rheumatoid foot

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### ABSTRACT

**Introduction:** Podiatry interventions for the rheumatoid foot are frequently recommended yet the evidence is often disparate. The development of effective care pathways for the treatment of foot and ankle pain associated with rheumatoid arthritis is dependent on robust research.

**Aims:** The aim of this review is to identify and evaluate the current evidence base for the effectiveness of treatments utilised in the management of foot problems associated with rheumatoid arthritis.

**Methods:** The databases were searched from 1984 to June 2004 and for inclusion, studies were randomised controlled trials and controlled clinical trials, case controlled studies, cohort studies and single case studies or qualitative questionnaires/surveys of interventions designed to treat foot problems associated with rheumatoid arthritis. One reviewer selected the studies and extracted the data, and the methodological quality of the papers was assessed using a validated scale.

**Results:** Sixteen papers met the inclusion criteria. Seven studies dealt with foot orthoses, three studies dealt with footwear, two studies dealt with foot orthoses, footwear and physical therapy combined, one study dealt with padded hosiery and one study dealt with callus debridement.

**Conclusions:** There is insufficient evidence to make firm conclusions about the effectiveness of podiatry interventions for people with rheumatoid arthritis. This review, however, suggests that podiatry interventions such as foot orthoses, hosiery adaptations and attention to footwear design all have a positive effect on foot pain associated with RA and that, when these therapies are used in combination with other physical therapies, the treatment effect may be greater. Opinions regarding callus debridement, on the other hand, remain inconclusive with treatment effects reported to last for up to seven days only and plantar forefoot pressures were reportedly increased.

**Recommendations:** Extensive recommendations are made for future work in this area.

### BACKGROUND

To be effective in improving clinical outcomes, investigation and treatment of patients should be evidence based. Implicit in this is the need for an awareness of the presence, nature and extent of disease. Rheumatoid arthritis (RA) commonly affects the foot<sup>1-3</sup> and prevalence has been related to the duration of systemic illness.<sup>1</sup> The general goals of management of foot problems associated with RA are to reduce pain and joint inflammation, with the aim of altering the course of the disease by slowing the rate of progression of joint damage.<sup>5</sup>

Lack of robust evidence in the literature to support fundamental practices in the management of foot problems associated with

RA such as the removal of skin callosities, the use of foot orthoses and prescribed footwear<sup>6</sup> has been identified as a barrier to effective management. The development of dedicated podiatry services for these patients is thus hampered as the implementation of effective care pathways for the treatment of foot and ankle pain and prevention of complications associated with RA are dependent on robust research evidence. Furthermore, the use of interventions is not controlled by strict legislation in the way that pharmacological agents are. Consequently these interventions are employed without prior robust clinical trials and this gives rise to their weakened credibility.<sup>6</sup>

### OBJECTIVES

The objective of this review is to identify and evaluate the evidence for effectiveness of treatment in managing foot problems associated with RA.

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**METHODS****Electronic Search Strategy**

The following databases were electronically searched for all articles related to podiatry interventions in the RA foot (1984 up to June 2004):

- PubMed
- Embase
- Cinahl
- The Cochrane Database of Systematic Reviews
- The Cochrane Database of Abstracts of Reviews of effects
- The Cochrane Central Register of Controlled Trials
- The Cochrane Database of methodology reviews
- The Cochrane Methodology Register, the Health Technology assessment database
- The NHS Economic evaluation Database (1984-June 2004)

**Hand Search Strategy**

The following Journals were hand searched:

- *The British Journal of Podiatry* (1998-2004).
- *The Foot* (1992-2004)
- *The Journal of British Podiatric Medicine* (1991-1997)

Only English Language studies and studies that were less than twenty years old were considered. Date limitations from 1984-June 2004 were applied in order to obtain currency from the evidence. Non-human studies were not considered as applicable for inclusion in this review. Unpublished work, such as conference presentations, both aural and poster and consultations with 'expert' colleagues in the field, were not included in this review. Although the consequence of this is that very recent and ongoing work is not reviewed, to include all relevant conference presentations (essential to avoid bias) would have resulted in a very large database. Furthermore, the peer review process is an effective gateway for screening research and selecting only high quality work. The authors have therefore taken advantage of this process by reviewing any work published in peer reviewed journals.

**Search Terms**

Keywords relating to podiatry interventions, rheumatoid arthritis and the foot and ankle were combined using Boolean logic to make the search more effective. Keywords used to search the current literature for this review were as follows:

- Rheumatoid Arthritis AND Podiatry
- Rheumatoid Arthritis AND Chiropody
- Rheumatoid Arthritis AND Orthoses
- Rheumatoid Arthritis AND footwear
- Rheumatoid Arthritis AND insoles
- Rheumatoid Arthritis AND padding
- Rheumatoid Arthritis AND splinting AND foot
- Rheumatoid Arthritis AND physical therapy AND foot
- Rheumatoid Arthritis AND steroid injection AND foot
- Rheumatoid Arthritis AND callus
- Rheumatoid Arthritis AND corns
- Rheumatoid Arthritis AND foot AND ulceration
- Rheumatoid Arthritis AND bursae AND foot
- Rheumatoid Arthritis AND bursitis AND foot
- Rheumatoid Arthritis AND nodules AND foot

**TYPES OF STUDIES****Inclusion criteria**

For inclusion, studies were thus randomised controlled trials (RCTs) and controlled clinical trials (CCTs), case controlled studies, cohort studies and single case studies or qualitative questionnaires/surveys of interventions designed to treat foot problems associated with rheumatoid arthritis.

**Exclusion criteria**

The review objectives are focused on podiatric interventions and implicit in this is that studies were limited to 'mainstream' podiatric interventions. The main exclusion criteria were studies involving surgical interventions, corticosteroid injection therapy and studies involving patients aged below 18 years.

Surgical interventions were excluded as most podiatrists have not undertaken the extra qualifications that entitle them to practice forefoot reconstructive surgery<sup>8</sup> and thus it was not considered a 'mainstream' intervention. Surgical interventions by other professionals were also excluded for the same reason. Intra-articular and peri-articular injection of corticosteroid within the foot and ankle is said to be beneficial,<sup>9</sup> however, only a few podiatrists are currently trained in injection therapy and therefore injection therapy was not deemed a 'mainstream' intervention either. Studies involving patients aged below 18 years of age would skew any results comparisons due to epiphyseal growth plate factors and joint derangements.<sup>9</sup>

**Aetiology**

In the quest for a broad view of interventions for foot and ankle problems associated with rheumatoid arthritis, any type of patient with a classical or definitive diagnosis of RA and any 'mainstream' podiatric intervention for the treatment of foot and ankle problems associated with rheumatoid arthritis, excluding surgery, were included in this review.

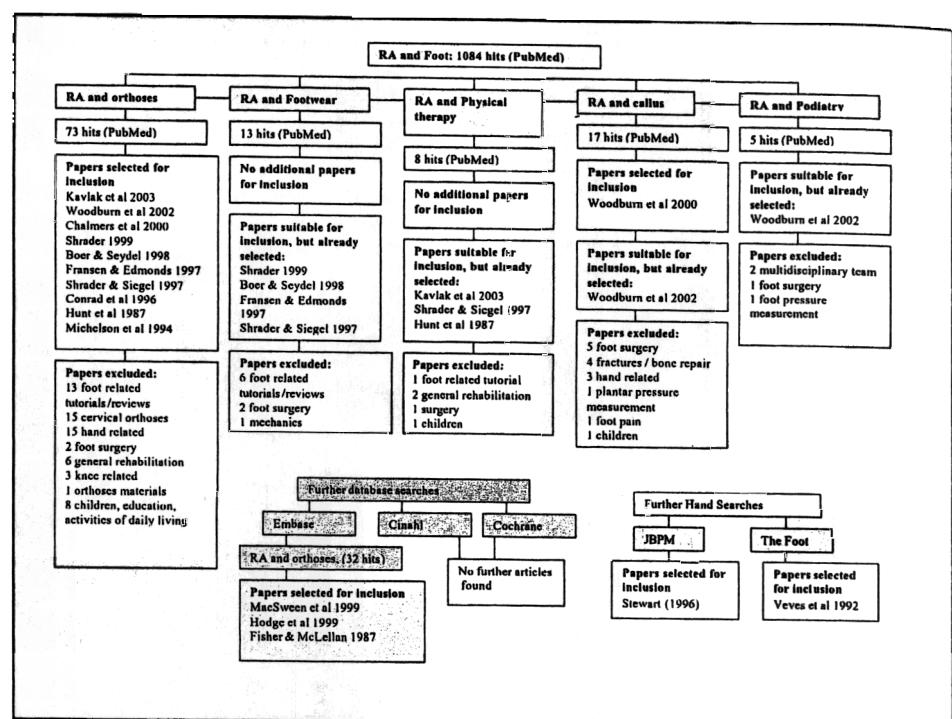
**Data analysis**

Reported studies that fulfilled the inclusion criteria were reviewed and summarised by a single reviewer. Evidence statements were drafted for each type of intervention. A predefined data extraction form with study characteristics, patient characteristics and interventions and outcomes was used.

Methodological quality of the studies was assessed according to the SCP (Society of Chiropodists and Podiatrists) classification system<sup>10</sup> that grades evidence from A to D depending on the quality of the literature reviewed and focussing on the inclusion of randomised controlled trial (A), well conducted clinical studies (B), non-experimental descriptive studies (C) or evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities (D).

**RESULTS**

The results of the search strategy can be seen in the flow chart (figure 1). The flow chart illustrates how references were selected from the initial hits of the search terms on the main PubMed



**Figure 1.** Search term, the number of hits and the corresponding articles that were selected for this review.

## Description of Studies

Sixteen papers that reported on interventions for the foot affected by rheumatoid arthritis are included in this review. The characteristics of the studies selected for inclusion in this review can be seen in Table 1. In applying the proposed SCP classification system four of the sixteen studies could be categorised by grade A,<sup>11-14</sup> seven were placed in grade B,<sup>15-20</sup> two placed in grade C<sup>21,22</sup> and three categorised in grade D.<sup>23-25</sup>

## Participants

Analysis of demographic variables could be completed on fifteen of the sixteen studies. The numbers of patients included in the trials ranged from 1 to 102 (mean 40.60) and the total number of participants was 609. Most of the studies were small, however, with fewer than forty participants in total and only five using more than eighty participants.

The mean age collated from the review studies, when reported was 59.15 years (range 49.70-73) and 58.83 years (range 49.70-65) if single subject studies are excluded. The mean disease duration from all the included studies that involved patient participation, when reported, was 14.17 years (range 3-30) and 12.62 years (range 3-22), if single subject studies are excluded. On average, therefore,

participants disease onset was at 44.98 years and 46.21 years if single subject studies are excluded. These findings are consistent with global epidemiological data that report patients as being most commonly first affected in the third to sixth decades and that prevalence increases with age, approaching 5% in women over age 55.<sup>27,28</sup>

Both incidence and prevalence of rheumatoid arthritis are two to three times greater in women than in men.<sup>27,28</sup> Overall, this is reflected by the data in the reviewed studies. Twelve studies included data for both male and female participant numbers.

Authors	MC	Methods	Intervention	Outcome measure
Conrad et al (1996) <sup>11</sup>	A	RCT	Foot Orthoses	Wearing time, Physical assessment of painful joints of feet, ankles, hands & wrists, Walking time (50 ft). Foot pain and disability (Foot Function Index plus foot pain adapted from Melzack & disability adapted from Arthritis Impact Medical Score (AIMS).
Woodburn, Barker & Helliwell (2002) <sup>12</sup>	A	RCT	Foot orthoses	Foot pain & disability: Foot Function Index (FFI), Disease Activity Score (DAS), Health Assessment Questionnaire (HAQ). Larsen Index joint erosion scores in hands and feet. Treatment tolerance. Daily and weekly use patterns. Self reported adverse reactions.
Bodumian-Mak et al (1995) <sup>13</sup>	A	RCT / Double blind	Foot orthoses	Grip strength (Vigometer). Walking time (50 foot). Number of joints with pain and swelling. Foot pain: FFI. Hallux abducto valgus angle measured with weightbearing radio-graphs. Patients' self-assessment of foot pain at rest and during ambulation. Patients' self-assessment of performance of activities of daily living and disability.
Kavlik et al (2003) <sup>14</sup>	B	Clinical trial	Foot orthoses	Pain intensity: FFI subscale of pain; Temporal distance values (stride length, step width, step length, foot angle). Cadence: number of steps in 1 min. Velocity: Physiologic Cost Index.
MacSween et al (1999) <sup>15</sup>	B	Repeated measures	Foot orthoses	Velocity, Average stride, Cadence: prototype contact sensitive walkway system (5 walks with orthoses & 5 walks without orthoses at self selected speed). Foot length. Comfort assessment.
Hodge et al (1999) <sup>16</sup>	B	Repeated measures	Foot orthoses	Plantar pressures (stance phase duration, calculation of cadence): Emed pedal in-shoe system. Pain: Visual Analogue Score (VAS) based on FFI subscale.
Hunt et al (1987) <sup>17</sup>	D	Case Report	Leg/hindfoot orthoses	Pain: verbal report. Gait (velocity, cadence, stride, single limb stance): Footswitch stride analyser
Fransen & Edmonds (1997) <sup>18</sup>	B	Small RCT & repeated measures	Footwear	Gait (mean velocity, cadence, mean stride length): 8m footswitch walkway. Pain: VAS: during level walking, ascending and descending stairs, non-weightbearing periods, general well being. Physical function: Stanford HAQ.
Boer & Seydel (1998) <sup>19</sup>	C	Questionnaire	Footwear	Perceived advantages and disadvantages of orthopaedic footwear. Attitude to prescribing orthopaedic footwear. Need for education. Satisfaction with co-operation with podorthists.
Stewart (1996) <sup>20</sup>	C	Questionnaire	Footwear	Satisfied: yes/no; Dissatisfaction: fit and comfort, style, colour, weight, other.
Chalmers et al (2000) <sup>21</sup>	A	Randomised single blind, sequential trial	Foot orthoses & footwear	Pain: VAS. Lower extremity synovitis: American Rheumatism Association joint count. Lower extremity function: standing, walking and stair climbing. Subjects' impression of treatment effectiveness: VAS. Material compression: Teclcock® dial gauge.
Michelson et al (1994) <sup>22</sup>	B	Prevalence study	Footwear & Orthoses	Functional capacity and functional status; Steinboker classification and global VAS. Detail of overall joint involvement. Physical examination: range of motion and motor strength of the ankle and foot. Unassisted gait assessment. Ability to perform heel rise test.
Shrader & Siegel (1997) <sup>23</sup>	D	Case Report	Foot orthoses & footwear	Visual observation: complete lower extremity evaluation, stance and gait. Range of motion: tibiotaral, subtalar, midtarsal, hip and knee joints. Strength of selected lower extremity muscles. Sensation: both feet: Semmes-Weinstein monofilaments. Weightbearing plantar pressure distribution: Podoscope. Pain in foot and ankle: VAS.
Shrader & Siegel (2003) <sup>24</sup>	D	Case report	Foot orthoses, Footwear, Phys therapy	Walking distance/time. Peak pressures
Woodburn, Stableford & Helliwell (2000) <sup>18</sup>	B	Clinical trial	Callus	Forefoot pain: VAS (Left and right separately) after 8m walking exercise; Global arthritis pain. Forefoot plantar pressures (peak pressure, peak force, contact time): Emed Pedar.
Veves et al (1992) <sup>25</sup>	B	Repeated measures study & RCT	Hosiery	Highest pressure area under each foot recorded: optical pedobarograph. Pain relief: VAS. Patients asked their overall opinion regarding the hosiery.

**Table 1.** Summary of results analysis of included studies.

Authors	Trial orthoses design	Control / placebo orthoses
Conrad et al (1996) <sup>11</sup>	Rohadur posted at rear and fore foot	Thin naugahyde shoe insert
Woodburn, Barker & Hellwell (2002) <sup>12</sup>	Super-Lyte® carbon graphite composite with deep heel cup and contoured medial arch. Inbuilt correction customised for each patient according to degree of valgus hindfoot deformity. Covered with 1.6mm PPT.	These patients were permitted other orthoses, if prescribed, during the 30 month trial period. The type of intervention was noted.
Budiman-Mak et al (1995) <sup>13</sup>	Rohadur (thermoplastic) functional posted foot orthoses. Forefoot / hindfoot posts were tailored to the measurement of each subject.	Thin flexible leather shell moulded over a plaster impression of the patient's foot.
Kavlak et al (2003) <sup>15</sup>	Custom made orthoses - medial longitudinal arch support / medial forefoot & heel wedges / metatarsal pads / metatarsal bar.	none
MacSween et al (1999) <sup>16</sup>	Custom moulded EVA orthoses "based on the UC-BL model"	Shoe only
Hodge et al (1999) <sup>17</sup>	Prefabricated foot orthoses (AOL soft density) Standard custom moulded foot orthosis (10mm, 220kg/m <sup>3</sup> density EVA) Custom moulded foot orthosis with metatarsal dome (latex rubber) Custom moulded foot orthoses with metatarsal bar	Shoe only
Hunt et al (1987) <sup>25</sup>	Low temperature thermoplastic material formed the rigid shell. 0.25 inch thick polyethylene liner to provide softness. Custom formed leg-hindfoot	Shoe only

**Table 2. Outline of the different methods for the design and manufactures of the foot orthoses utilised within the review papers.**

From an amalgamated participant number of 307, 86 were male and 221 were female (giving a ratio of 1 male to 2.5 females). However, one study reporting on orthoses interventions was male dominated.

Most studies reported participants as being diagnosed with rheumatoid arthritis, although only seven cited the diagnosis according to the 1987 baseline criteria of The American College of Rheumatology<sup>29</sup> (formerly the American Rheumatism Association).<sup>11-14,16,19,20</sup> From these seven, only two used the original reference source,<sup>12,16</sup> whilst one cited the diagnosis as ACR 1987 although it was unreferenced.<sup>19</sup> Two studies utilised the old ARA 1958 criteria,<sup>11,13</sup> one utilised a secondary text book source<sup>14</sup> and one was unrecognisable as a reference source.<sup>20</sup> In the remaining studies, only one cited the RA diagnosis according to the 1987 baseline criteria of The American College of Rheumatology, although the citation was not completely accurate.<sup>4</sup>

Unfortunately none of the studies were similar enough to allow any pooling of results other than the basic demographics detailed above. The interventions, including the studies on orthoses, were all different, as were the timescales for the studies, data collection points and the methods of outcome measurement.

## Duration of studies

Timescales for the duration of the studies ranged from three years to one day, and data collection ranged from eight data collection points on separate occasions following baseline assessment to data being taken only once.

## Outcome measures

The main themes of outcome measurement emerged as gait assessment, pain measurement, assessment of physical function, measurement of plantar foot pressures and treatment tolerance. Other themes that authors recorded as outcomes for their studies were structural assessment, range of motion, physical examination, visual observation, assessment of foot sensation, and material compression (Table 1).

## Interventions

The interventions can be separated into foot orthoses (n=7), footwear (n=3), foot orthoses in combination with footwear (n=2), foot orthoses, footwear and physical therapy (n=2), padded hosiery (n=1) and callus debridement (n=1).

### 1. Foot Orthoses

Three of the studies that investigated foot orthoses were randomised controlled trials<sup>11-13</sup> and therefore classified as grade A, two repeated measures trials<sup>16,17</sup> and one clinical trial<sup>15</sup> classified as grade B and one case report<sup>25</sup> classified as grade D. All studies utilised different methods for the design and manufacture of the foot orthoses (Table 2).

Three studies examined the effects of wearing rigid custom-designed foot orthoses against placebo foot orthoses.<sup>11-13</sup> One study<sup>12</sup> reported significant improvement for orthoses group over control group in Foot Function Index (FFI)<sup>30</sup> measurement (p=0.026), although there was no significant difference for global pain (p=0.587), Disease Activity Score (DAS)<sup>31</sup> (p=0.409), Health Assessment Questionnaire (HAQ)<sup>32</sup> (p=0.811) and Larsen radiological scores<sup>33</sup> for the hands (p=0.442) and feet (p=0.820); 30% patients reported difficulty of fit related to inadequate room between 0-6 months, which reduced to 12% by 30 months. Mean disease duration of these participants was three years. A second study<sup>13</sup> reported that subjects wearing the orthoses were 73% less likely to demonstrate progression of hallux valgus when orthoses were properly fitted and worn (p=0.04) but little or no benefit from the orthosis for measures of pain, disability and function. The mean disease duration for the second study<sup>13</sup> was reported as 9.8 years. The third study<sup>11</sup> reported no significant differences in painful foot joint count (p=0.642), total painful joint count (p=0.529), foot pain on all FFI scales (p=0.759) and total disability (p=0.908). The mean disease duration in this study was not reported.

When four styles of foot orthoses were compared (prefabricated, standard custom-moulded, custom with metatarsal bar, custom with metatarsal dome)<sup>17</sup> no significant difference was found in the cadence of participants using foot orthoses (p=0.980). The preferred foot orthoses were reported by the participants as being the custom-moulded foot orthoses with metatarsal domes (latex rubber) and these also significantly reduced standing pain and foot pressures (1st, 2nd, 3rd 4th & 5th MPJs) (p<0.05). Standard custom-moulded foot orthoses (10mm, 220kg/m<sup>3</sup> density EVA) significantly reduced walking pain and foot pressures (1st & 2nd MPJs) (p<0.05). Custom-moulded foot orthoses with metatarsal bar and prefabricated foot orthoses (AOL soft density) significantly reduced foot pressures (1st, 2nd, 3rd 4th & 5th MPJs) (p<0.05). The mean disease duration was reported as 22 years.<sup>17</sup>

Other reported effects were that custom-made orthoses (medial longitudinal arch support/medial forefoot and heel wedges/metatarsal pads/metatarsal bar) improved pain, step length, stride length and physiological cost index significantly (p<0.05).<sup>15</sup> Mean disease duration was reported as eight years.<sup>15</sup>

For custom-moulded EVA orthoses, velocity, cadence and stride were measured with changes in all three parameters noted although only the level of change reported for stride was significantly increased (p<0.05) with the use of foot orthoses.<sup>16</sup> Participants comments however, related to comfort and 62.5% stated that walking with orthoses was more comfortable and 37.5% stated that walking with orthoses was much more comfortable and that subjects who experienced hindfoot and lower limb joint pain responded more favourably to the orthoses.<sup>16</sup> Mean disease duration was reported as 11.9 years.<sup>16</sup>

One study<sup>25</sup> reported on a case experience of a custom-formed leg/hindfoot orthosis consisting of a low temperature thermoplas-

tic material forming a rigid shell with a 6.5mm thick polyethylene liner to provide softness and two straps attached around front of orthosis to secure it on the leg and heel. The case study patient, with a disease duration of 18 years, reported substantial relief of pain both immediately and 22 months on: with orthoses, she was able to walk "two blocks" at an even pace without ambulatory aid. Other parameters included an increase in velocity, cadence, stride length and single limb stance although these were not tested for significance. The authors reported that their decision to use a more extensive orthotic approach was based upon roentgenograms indicating severe degenerative changes at both ankles, and the alternative therapy being a surgical fusion of the ankle and subtalar joints.

## 2. Footwear

Three studies investigated footwear alone.<sup>18,21,22</sup> Fransen and Edmonds (1997) conducted a small randomised controlled trial (n=15 control, n=15 footwear group) followed by a further repeated measures analysis utilising the control participants (n=15) and was therefore classified as grade B. Stewart (1996) conducted a postal survey investigating patient satisfaction with bespoke footwear with a response rate of 83 participants (86% response).<sup>22</sup> Boer and Seydel (1998) conducted a survey investigating medical opinions about the use of orthopaedic footwear (n=181).<sup>21</sup> Both of these surveys were classified as grade C.

Participants who wore extra-depth shoes for two months demonstrated significant improvements in physical function ( $p=0.0001$ ), walk pain ( $p=0.0002$ ), stair pain ( $p=0.0001$ ) and pain-free walk time ( $p=0.0007$ ) without increase in use of arthritis medications or walking aids compared with those who wore regular footwear.<sup>18</sup>

When questioned on satisfaction with their orthopaedic footwear, 78.8% of patients were overall satisfied, 10.8% were dissatisfied with fit and comfort, 7.2% were dissatisfied with weight and 6.0% were dissatisfied with colour.<sup>22</sup> In addition, participants reported difficulty experienced with weight (28%), difficulty with calefaction (heat) (49%) and difficulty with comfort (42%).<sup>22</sup> Women were significantly more dissatisfied than men with the style of their footwear ( $p=0.0004$ ).<sup>22</sup>

## 3. Foot orthoses in combination with footwear

Two studies investigated the combination of use of footwear and foot orthoses. One an RCT, categorised grade A,<sup>14</sup> one prevalence study that investigated patients' satisfaction and use of foot orthoses and prescribed footwear categorised as grade B.<sup>4</sup>

From 99 patients who were interviewed to assess their functional status, functional capacity and to detail overall joint involvement, 95 patients had no special shoes/inserts, one patient had an orthotic insert and three patients had custom-made shoes.<sup>4</sup>

With regard to studies of the combined effects of special shoes and foot orthoses, participants who wore semi-rigid insoles in extra depth shoes over 12 weeks reported better pain scores than when they wore extra depth shoes alone.<sup>14</sup> When soft insoles in extra depth shoes were compared to extra depth shoes alone there was no reported difference in pain scores.<sup>14</sup> Neither of the interventions had a significant effect on synovitis or function and both types of orthoses had significant material compression ( $p<0.002$ ). When asked for a preference, however, nearly half the participants chose soft foot orthoses and the other half chose the semi-rigid orthoses.<sup>14</sup>

## 4. Foot orthoses, footwear & physical therapy

Two studies reporting on the combination of therapies were both single case reports and categorised as grade C.<sup>23,24</sup>

In the two individual case reports patients were given physical therapy, foot orthoses and footwear interventions. The first involved six sessions of physical therapy, a right foot orthosis (semi-rigid) plastazote, cushioned rubber filler, and 3mm thick high density polyethylene, thermo cork 25° varus wedge, PPT forefoot extension and footwear (extra depth Oxford shoes featuring deerskin uppers, roomy toebox, supportive heel counter, and cushioned neoprene sole).<sup>24</sup> The second involved four sessions of physical therapy, semi-rigid foot orthoses, footwear modifications and patient education.<sup>23</sup> Both studies reported complete relief of pain for the patient with improvements in gait parameters, although the latter were not tested for significance.

## 5. Padded Hosiery

One study reported on the effectiveness of padded hosiery via use of a repeated measures design and was categorised as grade B.<sup>20</sup>

A study on two types of commercially available hosiery, one with medium and one with high density padding (padding is increased under forefoot and heel) resulted in significant pressure relief when compared to barefoot ( $p<0.001$ ). Painful symptoms were reduced by both types of hosiery, 51% in experimental hosiery ( $p<0.01$ ) and 45% in walking socks ( $p<0.02$ ) when compared with patients own socks and all patients were satisfied with the socks and would have liked to continue wearing them.<sup>20</sup>

## 6. Callus Debridement

One study reported on the effectiveness of callus debridement as tested via a clinical trial and was categorised as grade B.<sup>19</sup>

One of the fundamental practices of podiatry is callus debridement, yet this was not reflected in the literature with only one study identified relating to RA and callus debridement.<sup>19</sup> The study itself was a preliminary investigation that found the debridement of hyperkeratotic lesions significantly reduced forefoot pain immediately at the post-treatment time point ( $p=0.01$ ). Contact times on the painful forefoot were reduced, and peak pressures and peak forces were elevated immediately following scalpel debridement, although none reached statistical significance. No significant change in global arthritis pain was achieved over the duration of the study and the treatment effect of callus debridement was reported to have been lost within seven days.

At the time of the review data analysis, one further study was published regarding the debridement of plantar callosities,<sup>26</sup> although it was too late to be included. Results from this study support the immediate positive treatment effect of callus debridement in RA patients although the observed improvements in pain and function were no different from the group of patients who had sham (no) debridement.

## 7. Referral to Podiatrists as the source of footwear interventions

When professionals in a Dutch study were questioned on their views of orthopaedic footwear, the orthopaedists and rehabilitation practitioners strongly agreed that prescription of orthopaedic footwear should be considered in the case of RA.<sup>21</sup> The reported rate of prescription however, was not related to desirability of prescription, but was related to beliefs such as perceived advantages, perceived disadvantages and satisfaction with co-operation with the podorthist.<sup>21</sup>

## DISCUSSION

This review has identified, graded and synthesised the available

literature regarding the evidence for effectiveness of treatment in managing foot problems associated with RA. Many tutorial and review articles on the topic of foot and ankle problems associated with RA cite foot orthoses, supportive, orthopaedic footwear and general podiatry practice as being beneficial yet, from this review, there appears to be very few quantitative controlled trials on these interventions and no true qualitative studies.

Study of the effectiveness of interventions in individuals with RA however is more complicated, due to the fluctuating nature of the disease. Most people with RA may not be in a steady state and disease variations may differ greatly from one individual to another.<sup>34</sup> Fortin, Stucki & Katz (1995) challenged researchers to address the threats to "relevance of change" within their study designs.<sup>34</sup>

Some studies in this review attempted to overcome disease state variations by the use of the participant as their own control (randomised sequential trials)<sup>15-17,25</sup> and others by use of an age and sex matched control group of participants with RA.<sup>11-13</sup> Sample sizes, however, could have been larger to reflect the fluctuating nature of RA, or studies could have stratified patients prior to analysis by disease activity.

Those studies that included the use of measures of relevant change in disease state were more informative with regard to the analysis of the effectiveness of the interventions under investigation. In the four A-rated studies<sup>11-14</sup> the outcomes of local pain, global pain, foot function and general physical function or activities of daily living had all been used in an attempt to gain both a local and holistic view of the variables that might affect the trial results. In an attempt to standardise disease assessment, EULAR (The European League against Rheumatism) developed a statistically-derived index based on decisions in daily practice that is now well validated and allows for continuous variability.<sup>35</sup>

The core set of criteria includes the following:

Disease activity score:

- 28 joints (contains tender & swollen joint count)
- ESR (erythrocyte sedimentation rate)
- Patients' global disease activity score

Gait assessment and foot pressure measurement also emerged as useful outcome measures for interventions associated with foot and ankle pain. However, all of the outcome measurements were based on assessment of external influences on the data that relied on the integrity of the joint complexes. No study reported on assessment of soft tissue problems such as bursitis or rheumatoid nodules and none utilised imaging techniques to assess severity and activity of synovitis in the foot joints, although one study did use radiographic evaluation of foot joint erosion.<sup>12</sup>

Given the fluctuating course of the disease, it is difficult to standardise materials and composition of foot orthoses as participants' foot health status will undoubtedly differ. This was illustrated with foot orthoses where each study identified used different materials and design of the splints. Largely, results indicated that custom-moulded rigid orthoses (Rohadur™)<sup>11</sup> and soft orthoses (low density plastazote with metatarsal lifts)<sup>14</sup> gave no treatment effect, whereas composite rigid orthoses (Super-Lyte® carbon graphite with deep heel cup and 1.6mm PPT™ foam as covering) reported problems with fit up to six months with significant treatment effect thereafter.<sup>12</sup> Similarly, custom-made semi rigid orthoses (Subortholene® with PPT™ foam under the forefoot) gave a significant treatment effect<sup>14</sup> and patients reported preferences for a custom-moulded foot orthosis (latex rubber) with metatarsal dome.<sup>17</sup>

Disease duration can be considered as a further complication that creates difficulties in the comparison of study results. In view of the studies on foot orthoses, better treatment effects and patient preferences were reported as semi-rigid design with low density materials for patients with reported mean disease duration of eight

years and greater. Only one study investigated early diagnosis patients (mean disease duration of three years) and reported a significant treatment effect with composite rigid orthoses.<sup>12</sup>

Discourse from this study<sup>12</sup> suggests that the earlier the disease duration, the more rigid the orthoses material design should be. It follows that as the disease state progresses, orthoses materials and design should evolve to semi-rigid composite designs and then to soft accommodative materials for chronic disease.

The question of who should be prescribing foot orthoses and footwear requires further clarification and a systematic approach to selection of foot orthoses/footwear would be useful. It is clear that other professionals are unsure of the scope of practice of a podiatrist, especially in the field of rheumatology.<sup>21</sup> Gorter *et al* (2001)<sup>36</sup> also reported similar findings when they questioned general practitioners on seven case scenarios of foot and ankle problems that asked for their diagnosis and proposed management. The most frequently suggested management was referral to a podiatrist, although for patients with RA, 79% suggested referral to a medical specialist.<sup>36</sup>

## REVIEWERS' CONCLUSIONS

### Implications for Practice

The quality of the studies in this review differed, with only four (all based on foot orthoses) out of the sixteen studies attempting to increase internal validity via the blinding of outcome assessors, attention to control groups or concealed randomisation. Therefore caution is required when drawing conclusions from the data presented in this review.

In general, though, this review suggests that podiatry interventions such as foot orthoses and hosiery adaptations all have a positive effect on foot pain associated with RA and that, when these therapies are used in combination with other physical therapies, the treatment effect may be greater. Callus debridement, however, may not be as effective as experience suggests with unproven treatment effects in terms of pain and function, and studies suggesting that further investigations regarding the cause of forefoot pain is necessary.

This review has further highlighted that referral to a podiatrist for treatment of a foot problem associated with RA is largely due to interprofessional relationships rather than knowledge of scope of practice. To develop dedicated podiatry services for these patients, more widespread dissemination of information regarding the qualifications and scope of the podiatric practitioner is essential.

### Implications for Research

Podiatry-related research is still in its infancy and more so for evidence of fundamental podiatric interventions for foot and ankle problems associated with RA. Much of the research concerning podiatric interventions is lacking in rigor and quality. In those studies reviewed, most sample sizes were small and in the majority, details regarding participant selection were either not documented, not documented correctly or did not acknowledge the ACR (American College of Rheumatology) criteria. None of the studies were similar enough to make any valid comparisons, with differing timescales, data collection points and outcome measures. The link between research and practice needs to also be emphasised further, in that good quality research and 'grade A' evidence provides other practitioners (particularly consultants) with the confidence to refer patients for podiatric intervention. For future work, recommendations are as follows:

- The study of baseline data that would indicate the range of inter-

ventions, including materials and design of orthoses that are currently in use by podiatrists in their management of foot and ankle problems associated with RA.

- The development of a systematic approach to the selection of appropriate foot orthoses or footwear
- Studies involving direct comparison between podiatric interventions
- Trials with larger sample sizes are required, perhaps via collaboration of podiatry research teams through the UK. Sample sizes must be large enough to ensure adequate power. This would also ensure more rigorous methodologies as tighter controls over internal validity would be necessary.
- Participant recruitment should be in line with the 1987 baseline criteria of The American College of Rheumatology and this should be documented in the presented paper alongside basic demographics of the population that states the male to female ratios, age and disease duration of the sample.
- Disease status in RA undoubtedly has an effect on treatment outcomes and should be taken into account and recorded in any investigations that involve patients with RA. Use of the 1996 EULAR core set criteria is recommended.
- Standardisation of outcome measures so that papers may be compared more easily. It is recommended that, as a minimum for data collection, researchers capture the variables of local pain, global pain, foot function and general function (activities of daily living). Further, that diagnostic imaging – in particular dynamic ultrasound imaging of internal structures – may be a useful adjunct to this palette.
- To measure change in chronic fluctuating diseases, such as RA, there is a need for longitudinal observations made over several time points. Studies conducted on this patient group would, therefore, be more informative if they followed a prospective design.
- Consideration needs to be made for qualitative research in respect of the influences on the patient's engagement with health interventions and the effect of the patient/practitioner relationship.

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