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The Use of Foot Orthoses in the Management of the Rheumatoid Arthritis Patient

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ABSTRACT

Rheumatoid arthritis is a systemic inflammatory autoimmune condition of unclear aetiology. Foot problems, including pain, deformity and functional limitation, are common amongst patients. Despite orthotic intervention being common in rheumatoid arthritis, there is reportedly limited and conflicting evidence for its effectiveness. The aim of this review is to identify and evaluate the evidence for the effectiveness of foot orthoses in the management of adult patients with rheumatoid arthritis. A systematic literature review was conducted to identify relevant literature pertaining to the use of orthoses in the management of the rheumatic foot. Fifteen articles, comprising both primary and secondary evidence, were identified that met the inclusion criteria. Their methodological quality varied, but was generally good. Most interventions described reported beneficial effects on pain and function, using pre- and post-intervention measures or through comparisons with placebos. There were few studies that directly compared the effectiveness of different foot orthoses interventions (such as hard, soft, semi-rigid) in the management of rheumatoid arthritis of the foot. Clinical recommendations are difficult to make without this comparative data. The most appropriate foot orthoses may also be dependent on the type and level of foot deformity present from rheumatoid arthritis. Further research is recommended to identify appropriate orthotic interventions for different clinical scenarios.

INTRODUCTION

Rheumatoid arthritis (RA), a systemic inflammatory autoimmune condition of unclear aetiology, is the most common form of inflammatory arthritis.^{1,2} Furthermore, the extent of the problem is expected to rise dramatically with the ageing population.³ Foot problems, including deformity and functional limitation, are common amongst patients with RA.⁴⁻⁶ Research indicates that the foot is the initial site of involvement in up to one-third of RA cases, with over 85% developing significant foot involvement and symptoms as the disease progresses.^{4,6} Foot pain is common, affecting up to three-quarters of patients with RA, which substantially limits both ambulation and activities of daily living.⁵⁻⁷

The pattern of joint involvement in the rheumatoid foot is a matter of contention. Farrow et al. states that forefoot involvement is more prevalent; however, other authors claim that the talonavicular joint is most commonly affected, with similar involvement of the subtalar joint.^{4,6} Despite this, the purpose for the use of foot orthoses (FO) remains constant. The aims of orthotic usage for foot problems associated with RA are to relieve and redistribute plantar pressure during weight bearing, reduce pain, and prevent the progression of joint deformity, with such outcomes leading to improvements in gait and functional ability.^{2,4,6-8}

Despite orthotic intervention being common in RA, there is reportedly limited and conflicting evidence for its effectiveness.⁶ This is in part due to the variety of different orthoses reported, both in terms of design and material, along with the frequency and duration of wear.^{2,6} Moreover, the issue of whether the effects of orthoses are limited to specific regions of the rheumatic foot remains.⁶ Methodological limitations also cloud much of the available literature.⁶ Thus, the aims of the current study are to identify and evaluate the evidence for the effectiveness of FO in the management of adult patients with RA.

METHODS

A systematic literature review was conducted to identify relevant literature pertaining to the use of orthoses in the management of the rheumatic foot. The search strategy is detailed in Table 1. Titles and abstracts were reviewed for relevance and satisfaction of inclusion criteria, whilst the primary author [AO] undertook hand-searching of reference lists to identify additional articles.

Table 1. Search strategy

Databases searched	Academic Search Elite, CINAHL, Cochrane Library, Google Scholar, MEDLINE, PEDro
Key terms	1. rheumatoid OR rheumatic 2. orthoses OR orthotic OR foot pad OR insole

Inclusion/Exclusion Criteria

Only articles that were able to be accessed in full-text and published in the English language between 1997 and 2010 were included. Clinical guidelines, systematic reviews, meta-analyses, randomised controlled trials, controlled clinical trials, and case-control studies were eligible for inclusion. For the purpose of this review, foot pain was defined as any pain in the forefoot, midfoot, hindfoot, or ankle. An orthoses was defined as any device worn by the patient with RA to relieve symptoms and/or improve foot function.

Articles describing subjects under 18 years of age were excluded because of the differing pathological features and prognosis of juvenile rheumatoid arthritis. Studies reporting subjects with notable co-morbidities (e.g. fracture, neurological conditions) were also excluded. Surgical and other interventions for the management of the rheumatic foot were not considered. Lower levels of evidence, including case-studies and opinion articles, were excluded. To avoid duplication of data, primary research articles identified during the literature search were not obtained if they were already reported in an included systematic review. No limit was placed on the type of outcome reported.

Critical Appraisal and Data Extraction

Identified systematic reviews were appraised using the AMSTAR instrument.⁹ The AMSTAR is a recently-developed 11 item instrument with demonstrated evidence of validity.⁹ Primary studies were appraised using the PEDro Scale, also an 11 item assessment of methodological quality.¹⁰ However, Item 1 is not used to calculate the total score as it relates to external validity, thus the total score is out of 10 (item 2-item 11). Identified clinical guidelines were appraised using the iCAHE Guideline Appraisal Checklist.¹¹ This is a simple tool to assess the believability of the guideline, across six domains. Articles were critically appraised by the authorship team and any disagreement was resolved through discussion. Relevant data, including key statistics and summary conclusions, was independently extracted into a purpose-built MS Excel spreadsheet by the primary author.

Heterogeneity

Opportunities for pooling the data were sought in terms of identifying comparable outcome measures between studies.

RESULTS

Search Results

The initial database search netted 592 hits, of which 15 were relevant and satisfied the inclusion criteria (Figure 1). Because of the exclusion criteria of primary literature if included within identified systematic reviews, the majority of the retrieved studies were systematic reviews. Table 2 contains a description of all retrieved studies. To avoid duplication of data, only primary studies not already reported in the systematic reviews were included.

Figure 1. Consort diagram

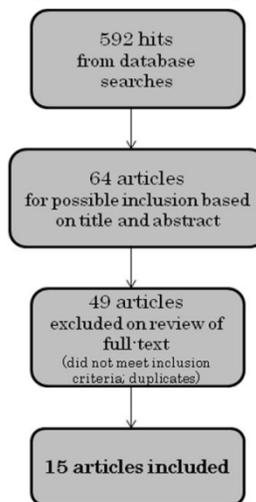


Table 2. Description of studies

Author	Date	Design	Articles reviewed	Location	Population	Reported Interventions
Forestier et al ¹²	2009	Clinical guideline	N/A	France	Adult patients diagnosed with RA	Orthoses, footwear
Clark et al ⁶	2006	SR	11	-	Not specified	Hard FO, soft FO, semi-rigid FO, custom orthoses
Gossec et al ¹³	2006	Clinical guideline	N/A	-	Not specified	Insole
Farrow et al ⁴	2005	SR	33	-	Any with diagnosed RA	Hard FO, semi-rigid FO, extra-depth shoes, custom orthoses, orthopaedic/surgical footwear, Cherwell splint, experimental sandal, UCBL extended orthosis
Egan et al ³	2001	SR	3 specific to FO	-	People aged 18 years or over with diagnosed RA	Extra-depth shoes, insoles, combination therapies
Bowen et al ¹⁴	2005	SR	16	-	People aged 18 years or over with diagnosed RA	Hard FO, soft FO, semi-rigid FO, custom orthoses, orthopaedic/surgical footwear, combination therapies, padded hosiery
Hawke et al ¹⁵	2008	SR	11 (3 specific to RA)	-	Participants of any age who reported foot pain of any type, aetiology and duration.	Custom orthoses
Oldfield et al ¹⁶	2008	SR	13 (4 specific to FO)	-	Not specified	Custom manufactured rigid FO; newly designed specialist orthotic shoe; soft FO, semi-rigid FO; orthopaedic shoes
Christie et al ¹⁷	2007	SR	28 (2 specific to FO)	-	Patients with RA (aged >18 years)	Orthoses and special shoes
Mejjad et al ⁹	2004	Randomised cross over trial	N/A	France	Sufferers of RA aged 18 to 80 with forefoot pain (n=16)	Semi-rigid FO
Magalhaes et al ¹⁸	2006	Prospective cohort	N/A	Brazil	Patients with RA aged 20 to 75 with foot pain and no major comorbidities (n=36)	Hard FO, soft FO
Woodburn et al ¹⁹	2003	RCT	N/A	UK	Patients with RA with bilateral involvement of peritalar joint complex and valgus heel deformity (n=98)	Hard FO
Novak et al ²⁰	2009	RCT	N/A	Slovenia	(n=40)	Custom FO
Cho et al ²¹	2009	RCT	N/A	Korea	(n=42)	ExtradePTH forefoot-rockered shoes, + Semi-rigid FO
Matsumoto et al ²²	2010	Single group pre-post study	N/A	Japan	Patients with RA (n=20)	Fuß-sole stocking

SR = systematic review; RCT = randomised control trial; N/A = not applicable; RA = rheumatoid arthritis; FO = foot orthoses; UCBL = University of California at Berkeley.

Methodological Quality and Critical Appraisal

The methodological quality of the included systematic reviews using AMSTAR raw scores ranged from 6 – 10 out of 11 (Mean 7.85) (Table 3). The most common criterion that the identified reviews did not fulfil was a list of both included and excluded studies. The methodological quality of the primary studies using the PEDro instrument ranged from 3 – 9 out of 10 (Mean 5.67). The main drawback to nearly all primary studies was a lack of blinding amongst participants and researchers (Table 4). The methodological quality of the two included clinical guidelines was 10 and 11 out of the 14 stated elements of a believable guideline (Table 5).

Table 3. Critical appraisal scores for secondary evidence

Author	AMSTAR Criteria											Total (Yes)
	1	2	3	4	5	6	7	8	9	10	11	
Clark et al. ⁶	Y	C	Y	Y	N	Y	Y	Y	N/A	N/A	Y	7
Farrow et al. ⁴	Y	C	Y	Y	N	Y	Y	Y	N/A	N/A	Y	7
Egan et al. ³	Y	C	Y	Y	Y	Y	Y	Y	N/A	N/A	Y	8
Bowen et al. ¹⁴	Y	C	Y	Y	Y	Y	Y	Y	N/A	N/A	Y	8
Hawke et al. ¹⁵	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	10
Oldfield et al. ¹⁶	Y	Y	Y	Y	Y	Y	Y	Y	N/A	N	Y	9
Christie et al. ¹⁷	Y	N	Y	Y	N	Y	Y	Y	N/A	N	N	6

Key: Y = Yes N = No C = Can't Answer N/A = Not Applicable

Table 4. Critical appraisal scores for primary studies

Author	PEDro Score											Total (Yes)
	1*	2	3	4	5	6	7	8	9	10	11	
Mejjad et al. ⁸	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	7
Magalhaes et al. ¹⁸	Y	N	N	Y	N	N	N	Y	Y	N	Y	4
Woodburn et al. ¹⁹	Y	Y	Y	Y	N	N	N	N	Y	Y	Y	6
Novak et al. ²⁰	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9
Cho et al. ²¹	Y	Y	N	Y	N	N	N	N	Y	Y	Y	5
Matsumoto et al. ²²	N	N	N	N	N	N	N	Y	Y	N	Y	3

Key: Y = Yes N = No

* Item 1 is not used to calculate the total score as it relates to external validity, thus the total score is out of 10 (item 2-item 11).

Table 5. Score for the clinical guideline

	Rule 1 Information			Rule 2 Currency			Rule 3 Finding the evidence, and determining the evidence base				Rule 4 Developers		Rule 5 Purpose and target users	Rule 6 Easy to read
	Full text	Full ref list	Summary of recommendations	Date of completion	Review date	Date lit inclusion	Search strategy	Evidence hierarchy	Evidence quality systems	Body of evidence	Guideline developers	Relevant developers linked to purpose and users	Stated purpose and target	Easy to read and to navigate
Forestier et al. ¹²	√	√	√	x	x	√	√	√	x	√	√	x	x	√
Gossec et al. ¹³	√	√	√	x	x	√	√	√	x	√	√	√	√	√

Reported Interventions

A variety of interventions and outcomes were reported. The most commonly reported interventions were hard FO, soft FO, semi-rigid FO, custom orthoses, extra-depth shoes, orthopaedic/surgical footwear, and combination interventions (e.g. orthopaedic footwear coupled with semi-rigid FO). Whilst the specific measures varied, foot pain, function, plantar pressure, gait, and patient satisfaction were commonly reported outcomes. The Foot Function Index (FFI) and the Visual Analogue Scale (VAS) were the most commonly reported measures; however, they were reported under a variety of conditions. Other measures were the Bessou's locometer, electromagnetic tracking (EMT) system, Japanese Orthopaedic Association's foot-scoring system, and the Brazilian version of the FFI. The outcome measures were heterogenous and there was no opportunity to pool the data from even two studies. This information is reported in Table 7.

Effects of Interventions

Hard FO

Hard FOs were consistently reported to significantly reduce foot pain, most frequently measured by the Visual Analog Scale.^{3,4,6,13,14,18,19} Reductions in pain were reported for standing and during gait, at both the hindfoot and forefoot.⁶ Hard FOs were also consistently reported to limit the progression of hallux valgus deformity in patients with RA in several systematic reviews.^{3,4,6,14} Bowen et al. report that hard FO treatment groups were 73% less likely to demonstrate a progression of the deformity.¹⁴ However, the effects of hard FO on foot deformity should be viewed cautiously, with Gossec et al concluding no effect of hard FO on joint deformity, whilst Clark et al. prefaced their results by noting that substantial methodological limitations existed in the reviewed literature.^{6,13} The effects of hard FOs on foot function are contentious. There is a lack of consensus within the reviewed literature, with most systematic reviews reporting inconclusive or conflicting findings.^{4,6,14} Similarly, whilst Magalhaes et al. reported significant improvements as measured by the Foot Function Index ($p=0.018$), no corresponding reduction in activity limitation was noted ($p=0.188$).¹⁸ However, improvements in gait biomechanics are described by Woodburn et al.¹⁹

Soft FO

Like hard FO, significant reductions in foot pain are reported with the use of soft FO.^{6,14} This is believed to be due, at least in part, to a load redistribution in weight-bearing, with significant reductions in foot pressure consistently reported by Clark et al.⁶ Varying findings were identified with respect to gait parameters; however, there is evidence to suggest that both step and stride length can increase, along with single-leg support time, with the wearing of soft FOs.^{6,14} When soft FO incorporated a metatarsal bar or dome, significant ($p<0.05$) increases in step and stride length were reported.¹⁴ Possible benefits to energy consumption may also result from these gait effects; however, cadence appears not to be significantly influenced by the use of soft FO.^{6,14} Significant functional improvements ($p<0.001$) were also reported in a recent prospective cohort investigated by Magalhaes et al.¹⁸ In a review by Egan et al., they found that soft FO provided no change in the level of pain or function.³

Semi-rigid FO

Pain reduction was consistently reported with the use of semi-rigid FO.^{3,4,6,8} Significant reductions in both forefoot and rearfoot pressure in weight-bearing were reported in the review of Clark et al; however, it should be noted that this was identified from few studies.⁶ Similarly, gait parameters were infrequently reported, however Bowen et al. identified one primary study describing significant increases in stride length.¹⁴ However, other gait parameters were unaltered, a finding supported by Mejjad et al.⁸

Custom orthoses

'Custom orthoses' have been grouped in a separate category as their designs were often not explicitly defined so as to be grouped within other classifications, such as hard FO or soft FO. Varying pain outcomes were reported and where benefits are stated the significance is unclear.^{4,6,14} Indeed, of the three studies reviewed by Farrow et al, two described conflicting findings as to the significance of any benefit.⁴ A third study reportedly increased patient comfort, but no statistical information was presented.⁴ Increased stride length of between 4.36 to 26 cm, appear to be a more commonly reported outcome of the use of custom orthoses.^{4,14} The review by Hawke et al. included only three studies that considered custom orthoses in adults with RA.¹⁵ There were no significant differences in pain outcomes or function outcomes from wearing a custom orthoses.¹⁵ Two studies considered disability as an outcome and reported varying results.¹⁵ Novak et al. found a significant reduction in foot pain and gait parameters for users of custom orthoses, however the improvement was only slightly better than the control group.²⁰

Insoles

The two reviews that investigated insoles reported varying results on pain, progression of deformity and foot function.^{3,13} Although the same group of interventions were reported on by both Gossec et al. and Clark et al., Gossec et al. classified the intervention as 'insoles' whereas Clark et al. classified them as hard FO.^{6,13} This differing classification may confound the interpretation of results.⁶ The review by Egan et al.³ although they classified the interventions as insoles, the description of the insoles was more aligned with differing types of FO. Thus we have presented the results from this review under the appropriate FO category, based on their description.

Extra-depth shoes and orthopaedic/surgical footwear

Extra-depth shoes were consistently reported to have significant benefits on foot pain.^{3,4} Compared to patients wearing regular footwear, patients with RA had significantly less pain with gait (Mean difference -18.70 [95% CI -28.46 - -8.94]) and with stair-climbing (Mean difference -27.00 [95% CI -37.83 - -16.17]).³ Other forms of orthopaedic/surgical footwear reportedly had similar outcomes, with significant reductions in pain during both gait and stair-climbing.⁶ Significant functional improvements compared to regular footwear, including increases in pain-free walking time (Mean difference 18.20 [95% CI 8.22 - 28.18]) were also identified in the literature.^{3,14} Experimental sandals reviewed by Farrow et al. reportedly resulted in improved pain, foot function and plantar pressure outcomes though no statistical information was presented.⁴

Combination interventions

Three types of combination interventions were identified in the literature; notably the combination of extra-depth or orthopaedic footwear with either insoles or semi-rigid orthoses.^{3,14} With the exception of soft insoles in extra-depth shoes, combination interventions typically recorded significantly better pain outcomes than interventions in isolation.^{3,14,16} A combination of semi-rigid FOs and extra-depth shoes reportedly resulted in significantly less pain than extra-depth shoes alone (Mean difference -1.90 [95% CI -3.27 - -0.51]).³ Significant benefits for a combination intervention of orthopaedic shoes and hard FOs in comparison to regular footwear ($p < 0.05$) have also been reported.¹⁶ However, no additional functional benefits were reported with the use of any combination intervention compared to extra-depth or orthopaedic shoes in isolation.^{3,14} Compared to either soft FOs or semi-rigid FOs in isolation, significantly less metatarsal pressure was recorded with the use of a combined orthopaedic shoe and semi-rigid FO intervention ($p < 0.002$).¹⁴

Other Interventions

Other orthotic interventions were also described in the identified literature that did not easily fit into the aforementioned classifications. Padded hosiery is one such intervention, which reportedly resulted in significantly less pain ($p < 0.02$) and significantly less plantar pressure ($p < 0.001$) when compared to barefoot gait.¹⁴ The Fuß-sole stocking found significant improvements in foot sole pain ($p < 0.001$) and undertaking activities of daily living ($p = 0.002$). All patients reported a favourable impression of the Fuß-sole because it was breathable and reduced foot sole pain.²² The extended orthoses developed by the University of California at Berkeley, a vaguely reported intervention, was deemed to decrease pain and improve gait in the review of Farrow et al.⁴ One study identified by the reviewers reported significant increases in stride velocity by up to 50 m/min ($p < 0.01$), along with significant increases in single leg support time ($p < 0.01$).⁴ Cherwell splints, which aim to support valgus deformities in existing footwear were concluded to be a beneficial intervention for patients with valgus deformities in one study identified by Farrow et al., although no detailed statistical information was presented.⁴ Patient satisfaction with all such interventions was reportedly good.

Table 6. Summary of secondary evidence results for foot orthoses in RA

Intervention	Outcome	Key Findings
Hard FO	Pain	2 SRs (6/8 primary studies) concluded significant ($p < 0.05$) reductions in pain as measured by Visual Analog Scale
	Function	Varying findings with respect to foot function
	Deformity	3 SRs concluded significant ($p < 0.05$) reductions in progression of hallux valgus deformity
	Gait parameters	Varying findings with respect to step and stride length
Soft FO	Pain	2 SRs concluded significant reduction in pain
	Foot pressure	2 SRs (4/4 primary studies) concluded consistent significant reductions in foot pressure (forefoot & rearfoot)
	Gait parameters	Varying findings with respect to step and stride length
Semi-rigid FO	Pain	4 SRs concluded significant reductions in foot pain; Farrow et al. ⁴ concluded semi-rigid FO more effective than soft FO or supportive shoes in pain reduction
	Foot pressure	1 SR concluded significant reductions in forefoot and rearfoot pressure; however this was based on few primary studies
	Gait parameters	Stride length may be increased, however identified from few studies
Custom orthoses	Pain	Varying pain outcomes; where decreases are reported the significance is unclear 1 SR reported no significant difference in pain outcomes
	Function	1SR reported significant functional increases in function, however this was from few primary studies 1 SR reported no significant difference in function outcomes
	Gait parameters	2 SRs described significant increases in stride length (4.36 – 26cm); varying effects on gait velocity or cadence
	Energy	1 SR described significant decreases in energy expenditure reported, but this was based on few studies
	Disability	1 SR reported varying results. 1 primary study reported no significant differences in disability at 3 months, but were statistically significant for scores summarising changes over 30 months; whereas another reported no statistically significant differences at 36 months.
Extra-depth shoes	Pain	2 SRs concluded consistent significant reductions in pain in standing, gait and with stair-climbing
Orthopaedic/surgical footwear	Pain	2 SRs reported significant reduction in pain with gait and stair-climbing
	Function	2 SRs reported significant improvement in physical function and increases in pain-free walking time
Combination therapies	Pain	2 SRs concluded significantly better pain outcomes than single interventions
	Function	No additional effects compared to single interventions reported
	Foot pressure	Orthopaedic shoes with semi-rigid FO displayed significantly less metatarsal compression with soft or semi-rigid FO

Key: FO = Foot Orthoses SR = Systematic Review

Table 7. Summary of additional primary evidence results for foot orthoses in RA

Author	Intervention	Outcome	Specific measure and conditions	Key Findings
Mejjad et al ⁸	Semi-rigid FO	Pain	VAS pain – during gait	Significantly less pain vs. controls (no orthosis) ($p=0.008$)
		Gait parameters	Bessou's locometer – during gait	No significant difference in gait speed/cadence vs. controls ($p>0.05$)
Magalhaes et al ¹⁸	Soft FO	Pain	Brazilian version of the FFI – conditions not stated	Significant reduction in pain ($p<0.001$)
		Function	Brazilian version of the FFI - conditions not stated	Significant increase as measured by Foot Function Index ($p<0.001$)
	Hard FO	Pain	Brazilian version of the FFI - conditions not stated	Significant reduction in pain ($p=0.028$)
		Function	Brazilian version of the FFI - conditions not stated	Significant increase as measured by Foot Function Index ($p=0.018$)
Woodburn et al ¹⁹	Hard FO	Joint motion	Electromagnetic tracking (EMT) system - under walking conditions	Significant reduction in internal leg rotation during gait for RA sufferers wearing hard FO vs. not wearing hard FO ($p=0.007$)
Novak et al ²⁰	Custom FO	Pain	FFI – conditions not stated	No significant difference in levels of pain reduction between custom FO users v controls, as measured by pain subscale Foot Function Index.
		Gait parameters	6 minute walking test – pain whilst walking	Custom FO showed greater improvement in the walking test than controls ($p=0.076$), though only marginally significant
Cho et al ²¹	Extra deep forefoot-rockered shoe with a custom-made semi-rigid FO	Pain	VAS – conditions not stated	Significant reduction in pre-post foot pain measured by VAS ($p<0.05$)
		Function	FFI – conditions not stated	No significant reduction in pain as measured by the Foot Function Index
		Severity of rheumatic disease	VAS – conditions not stated Erythrocyte sedimentary rate Active joint counts C-reactive protein Medication usage	Significant reduction in pre-post subjective severity measured by VAS ($p<0.05$) No significant reduction in pre-post subjective severity measured by erythrocyte sedimentary rate, active joint counts, C-reactive protein, or amount of medication
	Extra deep forefoot-rockered shoe with a ready-made simple soft FO	Pain	VAS – conditions not stated	Significant reduction in pre-post foot pain measured by VAS ($p<0.05$)
		Function	FFI – conditions not stated	No significant reduction in pain as measured by the Foot Function Index
		Severity of rheumatic disease	VAS conditions not stated Erythrocyte sedimentary rate Active joint counts C-reactive protein Medication usage	Significant reduction in pre-post subjective severity measured by VAS and erythrocyte sedimentary rate ($p<0.05$) No significant reduction in pre-post subjective severity measured by active joint counts, C-reactive protein, or amount of medication
Matsuno et al ²²	Fuß-sole stocking which incorporates a plantar insole made of breathable fabric	Pain	Japanese Orthopaedic Association's foot-scoring system – conditions not stated	Significant improvement in foot sole pain ($p<0.001$) measured by an eight-item scoring system endorsed by the Japanese Orthopaedic Association
		Disability	Japanese Orthopaedic Association's foot-scoring system – conditions not stated	Significant improvement in activities of daily living ($p=0.002$) measured by an eight-item scoring system endorsed by the Japanese Orthopaedic Association

Key: FO = Foot Orthoses

Table 8. Summary of evidence for outcome measures for each intervention synthesised from primary studies and systematic reviews

Intervention	Comparator	Pain	Function	Severity of disease	Joint Motion	Gait	Disability
Hard FO	pre-post	sig ↓	sig ↑				
	control group (no orthotic intervention)				sig ↓ internal leg rotation		
	N/a (SR)	sig ↓ (2SRs)	varying Δ	sig ↓ in progression of deformity (3SRs)		varying Δ	
Soft FO	pre-post	sig ↓	sig ↑				
	pre-post	sig ↓	no sig Δ	sig ↓ AND no sig Δ			
	N/a (SR)	sig ↓ (2SRs)				varying Δ	
Semi-rigid FO	control group (no orthoses)	sig ↓				no sig diff in gait speed/cadence	
	pre-post	sig ↓	no sig Δ	sig ↓ AND no sig Δ			
	N/a (SR)	sig ↓ (4SRs)					
Custom FO	control group	no sig Δ				↑ improvements	
	N/a (SR)	varying Δ	sig ↑ (1SR) AND no sig Δ (1SR)			sig ↑ in stride length (2SRs)	varying Δ
Fuß sole stocking	pre-post	sig ↓					↑ improvements

DISCUSSION

This review was conducted in the context of foot problems associated with RA, and the increase in associated foot symptoms that would reasonably be expected to occur as the population ages.³ Foot orthoses are commonly prescribed for the management of the rheumatoid foot in order to optimise its function.⁶ Unaddressed foot problems are likely to have a significant effect on functional status and activity participation of RA sufferers, a situation highlighted by Magalhaes et al who state that "...the feet are one of the most important means of contact between human and environment, and maintenance of their function results in liberty and independence of locomotion" (p.449).¹⁸

The aim of this review was to identify and evaluate the evidence for the effectiveness of FO in the management of adult patients with RA manifesting as symptoms in the foot. This review identified a variety of FO interventions that had been identified in both the primary and secondary body of literature. The literature included in this review did not report any direct comparisons between different FO interventions; rather the included literature compared pre- and post-intervention measures within subjects, or different FO were compared against controls (which did not use any FO intervention).

There is consistent evidence to support claims that FO reduce pain and improve functional ability in patients with RA; however, there are notable limitations in that evidence.⁶ There is no evidence regarding the differential effectiveness of different types of orthoses, as no studies were found which presented results comparing two orthotic types. Moreover, there is a lack of consensus regarding the optimal choice to achieve patient outcomes.⁶ Indeed, definition and description of FO interventions are often poor, which limits a clinician's ability to draw clear conclusions.⁶

Overall it was found that all FO reduced pain levels (irrespective of how these were measured), except for customised FO where there were mixed results.^{4,6,14,15,20} All of the FO reported different effects in terms of functional outcome. Hard FO and soft FO had varying effects; semi-rigid FO provided no benefit, whilst surgical footwear improved function.^{3,4,6,14,15,18,21} There were no additional benefits in terms of function from using a combination of FO therapies. Soft FO and semi-rigid FO had mixed findings for severity of disease, depending on which outcome measure was used.²¹ Hard FO significantly decreased the internal leg rotation as reported for joint motion.¹⁹ Customised FO, hard FO, soft FO and semi-rigid FO all reported mixed findings in terms of improvements in gait.^{4,6,8,14,19,20} The Fuß sole stocking improved disability outcome, as did hard FO, whereas customised FO had varied findings.^{3,4,6,14,15,22}

Significant associations have been reported between plantar pressure and foot pain; thus, it is not surprising that significant benefits were identified for both foot pressure and pain in the included studies.⁶ Pain was a common outcome of interest in the included studies and is a serious problem in patients with RA. Pain also has a link with functional outcomes, with Hodge et al contending that during weight-bearing, the painful rheumatic foot will limit a person's ability to perform basic tasks of daily living.⁷

Whilst the secondary evidence identified in this review was typically of good quality, the systematic reviews themselves noted numerous methodological limitations within the primary literature.⁶ Most often this pertained to sample limitations, but definitions and intervention descriptions also varied. Notably, the studies of Gossec et al and Clark et al classified the interventions of the same primary studies differently, which confounds any conclusions that can be drawn.^{6,13} It should be noted that by including relevant primary studies that had not been included in the systematic reviews, a more comprehensive and current body of literature was sourced.

Based on the review's findings, all types of FO are useful in managing symptoms and function of the RA foot. However, by not having direct comparisons in a 'like' environment, recommendations on which FO are most effective cannot be made.

On the basis of the current literature, more specific clinical recommendations are difficult to make. Whilst the body of literature was not as scarce as anticipated, it failed to provide information about direct comparisons of different FO interventions in their effectiveness for managing RA foot. Therefore, this body of literature does not provide the information on which to make clinical recommendations regarding the most effective FO. However, it can be argued that the majority of FO, particularly combination interventions, significantly reduce pain in the RA foot. Varying results for pain with customised FO probably reflect the varying designs due to the customised nature.^{4,14} Similarly, whilst the evidence suggests that both soft and semi-rigid FO can reduce foot pressure in weight-bearing, greater benefits are achieved via combination interventions.^{3,14,16} The evidence also suggests that hard FO can significantly reduce the progression of hallux valgus deformity.^{4,6,14} Functional improvements are also reported with a range of FO, however effects on gait parameters are inconsistent.

Whilst clinical recommendations are limited, implications for further research are apparent. Future research is required in order to determine the effects of different types of FO on the RA foot and to consider the sensitivity of different foot-specific outcome measures so that the most appropriate measures can be applied.

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KEY TERMS

Rheumatoid arthritis, orthosis, orthoses, foot