A Randomized Controlled Trial of Foot Orthoses in Rheumatoid Arthritis

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ABSTRACT. **Objective.** To investigate the clinical effectiveness of early foot orthosis intervention for painful correctable valgus deformity of the rearfoot in rheumatoid arthritis (RA).

Methods. Patients with RA were randomized to receive custom manufactured rigid foot orthoses under podiatry supervision (n = 50) or enter a control group (n = 48). The control group received foot orthoses only when prescribed under normal medical care. Foot pain and disability, using the Foot Function Index (FFI), along with disease activity, tolerance, and adverse reactions, were serially measured over 30 mo continuous treatment.

Results. The group assigned foot orthoses demonstrated an immediate clinical improvement, the effect peaking at 12 mo. At 30 mo the FFI total score was reduced by 23.1% from baseline in the intervention group. Area under the curve analysis showed a statistically significant reduction in FFI scores for total score (p = 0.026), foot pain (p = 0.014), and foot disability (p = 0.016) when intervention was compared to control scores. There were no confounding effects from differences between groups for disease activity or pharmacological or other management strategies. Most patients (96%) used their orthoses and most found them comfortable (97%), although minor adverse reactions, such as tender spots, blisters, and callus, were reported in 30% of patients in the early stages of treatment and persisted in 12% for 30 mo.

Conclusion. Custom designed foot orthoses used continuously over a 30 mo treatment period resulted in a reduction in foot pain by 19.1%, foot disability by 30.8%, and functional limitation by 13.5%. Clinical effectiveness might be enhanced by their use in the early stages of rearfoot pain and deformity. (J Rheumatol 2002;29:1377–83)

Key Indexing Terms:
RHEUMATOID ARTHRITIS   FOOT ORTHOSES   VALGUS DEFORMITY

In rheumatoid arthritis (RA), valgus deformity of the subtalar joint is associated with localized pain and joint stiffness, and with progressive impairment of gait and disability[1-7]. Measures to prevent or delay the progression of this condition must combine management of both the joint and soft tissue synovitis and any underlying mechanical dysfunction. A number of uncontrolled studies in RA have shown short term clinical benefits from mechanical foot therapy in the form of insoles, splints, and orthoses[8-12]. Moreover, it has been suggested that orthoses used in early rearfoot disease in RA might help avoid or delay late stage orthopedic surgery and, through linked mechanics, protect the knee joint[3,5,6,13,14]. Orthotic intervention for metatarsalgia in RA is studied more frequently than ankle/rearfoot disease[8,11,14,15].

Foot orthotic therapy is becoming more widely accepted, but these devices vary considerably in terms of design, material components, and therapeutic function. Realignment of the rearfoot joint complex and stabilization of mobile joint deformity may be achievable by rigid orthoses with inbuilt customized correction[15]. By definition, these devices should only be used in patients with RA when the tarsal joints are well preserved. A fairly open window of opportunity may exist to exploit this approach as radiological studies have shown that tarsal joint erosions occur later and with less frequency than more distal foot joints[16]. This hypothesis is partly supported by the findings from one randomized controlled trial, restricted to male patients with long-standing disease, where no clinical benefit of active orthosis over a so-called placebo device was reported[13].

This study was initiated to evaluate the effects (clinical and mechanical) of custom designed foot orthoses in RA patients with early and correctable rearfoot deformity under controlled conditions. We focus specifically on the clinical outcomes (foot pain and related disability) with reference to treatment tolerance and adverse reactions.

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Submitted July 20, 2001; revision accepted January 16, 2002.

MATERIALS AND METHODS

Patients. Local research ethics committee approval was granted for this project and written informed consent was obtained from each patient. Patients with RA (satisfying the 1987 American College of Rheumatology revised criteria for RA) were enrolled from hospital outpatient clinics[17]. History of bilateral subtalar and/or ankle and/or talonavicular pain and valgus heel deformity were the inclusion criteria. Normal range of motions was required at the ankle, subtalar, and midtarsal joints. Passive range of motion testing was used to ensure the valgus heel deformity was correctable with ≥ 10° of subtalar joint inversion past neutral. Concomitant musculoskeletal disease, central or peripheral nervous system disease, and endocrine disorders, especially diabetes mellitus, were all exclusion criteria. Patients with a history of orthopedic foot surgery, those currently using foot orthoses, and those with inappropriate footwear were not eligible. Normal daily walking aids were permitted.

Interventions. The orthoses were custom designed and manufactured to a standardized protocol from impression casts taken of the feet using the subtalar neutral suspension technique[18]. The orthoses were constructed of Super-Lyte® carbon graphite composite with deep heel cup and contoured medial arch (Langers Biomechanics Group, Cheadle, UK). The inbuilt correction was customized for each patient, according to the degree of valgus heel deformity present, and used intrinsic posting in the rearfoot and maximum forefoot balancing techniques[19]. All devices were covered with 1.6 mm cushioning material (PPT) extended to the toe sulcus region.

Patients randomized to the control group received no prescribed foot orthoses at baseline. Over 30 months these patients were permitted orthoses if prescribed at any subsequent outpatient medical consultation. The attending physicians were blinded to the patients' inclusion in the study. The hospital appliance department provided orthoses prescribed in this manner and a record of the intervention was made at followup.

Randomization. Patients were randomly assigned to study groups in balanced blocks of 4, each block transferred from the central office to the rheumatologist authorized to allocate the treatment schedules. The assignments were placed in sequentially numbered, opaque, and sealed envelopes. Allocation was performed for outpatients from the next record sheet and the attached envelope. Masking of the treatment allocation was not possible.

Clinical assessment. The Foot Function Index (FFI) for RA was used to measure foot pain and disability[20]. This validated self-administered questionnaire consists of 23 items grouped into 3 domains: foot pain (FFI_{pain}) (9 items), disability (FFI_{dis}) (9 items), and functional limitation (FFI_{fl}) (5 items). All items are rated using 100 mm visual analog scales (VAS). To obtain a subscale score, the item scores are totalled and divided by the total number of items the patient indicated were applicable. Calculating the average of the 3 subscale scores derived a total FFI score (FFI_{total}).

Clinical variables included Disease Activity Score (DAS), Health Assessment Questionnaire (HAQ), and Larsen index joint erosion scores in the hands and feet[21-23]. The DAS employed the modified 28 tender and swollen joint count, erythrocyte sedimentation rate (ESR; derived from C-reactive protein and plasma viscosity using conversion formulae when ESR not available), and patient global assessment[24]. Radiographs were read by the same experienced observer blinded to assignment group and time point of the radiograph. Over the duration of the study records were maintained for drug management, inpatient care, physiotherapy, and orthopedic surgery interventions on the feet.

Treatment tolerance and adverse reactions. Semistructured telephone interviews were conducted between 0 and 3, 3 and 6, 6 and 9 months and at study exit (30 mo). Information was collected on daily and weekly use patterns, and self-reported adverse reactions. Spontaneous adverse reactions could be reported using a 24 h telephone support line. Followup appointments were offered where adverse reactions required orthotic device modification.

Statistical analyses. The FFI was chosen as the primary outcome measure because it was judged to be a clinically appropriate measure of foot pain and disability. Sample size estimates and effect size were based on clinical estimates obtained in other studies[13,15]. For the trial to have 80% power of detecting a 30% decrease in foot pain and disability over 30 months of continuous foot orthotic treatment, at α = 0.05, 55 patients in each treatment arm were needed. The statistical software package SPSS for Windows, Version 9.0, was used for analyses. The distribution of data was tested for normality using the Shapiro-Wilks test before analysis. Between-group comparisons for numerical data were done by either Student t test or the Mann-Whitney U test. The significance level p was set at 5% (2 tailed tests).

Clinical assessments were conducted at baseline, 3, 6, 12, 18, 24, and 30 months and analyzed using the technique of summary measures[25]. Changes from baseline FFI score were derived and plotted for each time point. Improvement in status was assigned a negative change and deterioration a positive change. Intention-to-treat principles were applied: all subjects were analyzed according to group assignment. Missing data were replaced by last value carried forward. Using the trapezium rule the area under the curve (AUC) was calculated for each subject. FFI_{total} and subscale AUC data were normally distributed and between-group comparisons were by Student t test. Further analyses were conducted on FFI_{total} peak response and time to peak response using the Mann-Whitney U test and chi-square analysis. The summary measure AUC technique was also employed for clinical variables, while comparison of nominal measures was by chi-square test. Treatment tolerance and adverse reaction data were summarized descriptively.

RESULTS

Trial profile. Two hundred fifty-four patients were identified as potential participants in the study. Fifty patients were excluded because they felt unable to complete the trial protocol. One hundred three patients were ineligible; 29 had significant co-morbidity, 27 patients had severe and uncorrectable rearfoot deformity, 26 had unsuitable footwear, and 21 patients were currently using foot orthoses. One hundred one subjects were randomized but 3 patients immediately withdrew consent following allocation to the control group. At baseline 50 patients received custom designed orthoses and 48 patients were allocated to the control group. At 30 months, 38/48 (79%) patients in the control group and 43/50 (86%) patients in the intervention group completed the study. Reasons for withdrawal are presented in Figure 1.

Baseline results are given in Table 1. Patient groups were similar in sex distribution, ethnic origin, age, body mass, disease duration, and HAQ score. The global pain score and DAS were higher in the intervention group. The control group had higher joint erosion scores in the hands and feet compared to the intervention group. None of these differences was statistically significant. More patients in the control group received nonsteroidal antiinflammatory drugs (NSAID), the trend reversed for disease modifying antirheumatic drugs (DMARD), but the proportions were not significantly different. Oral glucocorticosteroid therapy was comparable between groups. A small number of patients had received outpatient physiotherapy and inpatient care in the previous month, but there was no case of orthopedic intervention for foot disease.

FFI data. As shown in Table 1, the baseline FFI_{pain}, FFI_{dis}, FFI_{fl} subscale, and FFI_{total} scores were higher in the inter-
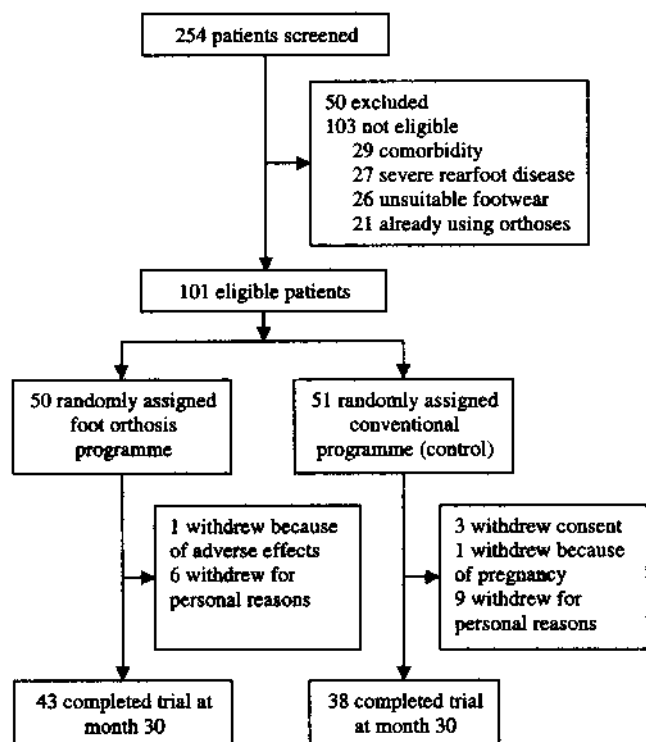
Figure 1. Trial profile.

vention group. AUC analysis showed a large improvement for the orthosis group compared to a slight improvement in foot status for the control group over 30 months, and this difference was statistically significant (p = 0.026). For FFI subscales, the foot orthosis group showed a large reduction in foot pain in comparison to the control group, and this difference was statistically significant (p = 0.014). Foot disability was reduced in both groups, but the change over time was significantly greater in the intervention group as reflected by the AUC scores (p = 0.016). FFI_{fl} scores decreased over 30 months in the intervention group and increased over time in the control group, but the difference was not statistically significant (p = 0.344).

A one in 5 random sample of individual FFI_{total} scores plotted as change in score from baseline against time for patients in both groups is presented in Figure 2. In the foot orthosis group the median (interquartile range) peak response was –17 (–34, 0) and time to peak response 12 months (3, 24). In the control group the median (IQR) peak response was –3 (–22, 23) and time to peak response 12 months (6, 24). There was no statistically significant difference in the time to peak response between the groups (p = 0.207), but the intervention group had a statistically significant higher peak response (p = 0.044).

Clinical data. There were no statistically significant group differences for change in global pain (p = 0.587), disease

Table 1. Baseline characteristics of the study participants.

Characteristic	Foot Orthosis, n = 50	Control Group, n = 48
Demographics		
Age (yrs)*	54.0 (11.8)	53.1 (11.1)
Male/female (n)	16/34	17/31
Ethnic origin (Caucasian) (n)	45	45
Body mass (kg)*	73.7 (15.1)	73.2 (12.6)
Foot Function Index*		
Total	41.1 (20.3)	33.6 (21.5)
Pain	53.3 (27.2)	40.8 (24.3)
Disability	48.3 (27.7)	39.8 (26.8)
Functional limitation	21.5 (17.9)	19.9 (22.2)
Condition		
Disease duration (yrs)**	3 (1,7)	3 (2,6)
Global pain (0–100 mm VAS)*	45.0 (27.7)	36.8 (28.8)
Disease activity score*	3.4 (1.2)	3.2 (1.6)
Health Assessment Questionnaire(0–3)**	1.00 (0.47, 1.75)	1.00 (0.38, 1.75)
Larsen Index-Hands (0–150)**	12.5 (1.5, 29.3)	18 (6, 41.8)
Larsen Index-Feet (0–50)**	5.5 (0, 13.8)	9 (4, 18.8)
Interventions (n)		
NSAID	29	35
DMARD	40	33
Glucocorticosteroids	5	4
Outpatient physiotherapy	8	2
Inpatient care	4	2
Orthopedic surgery	0	0

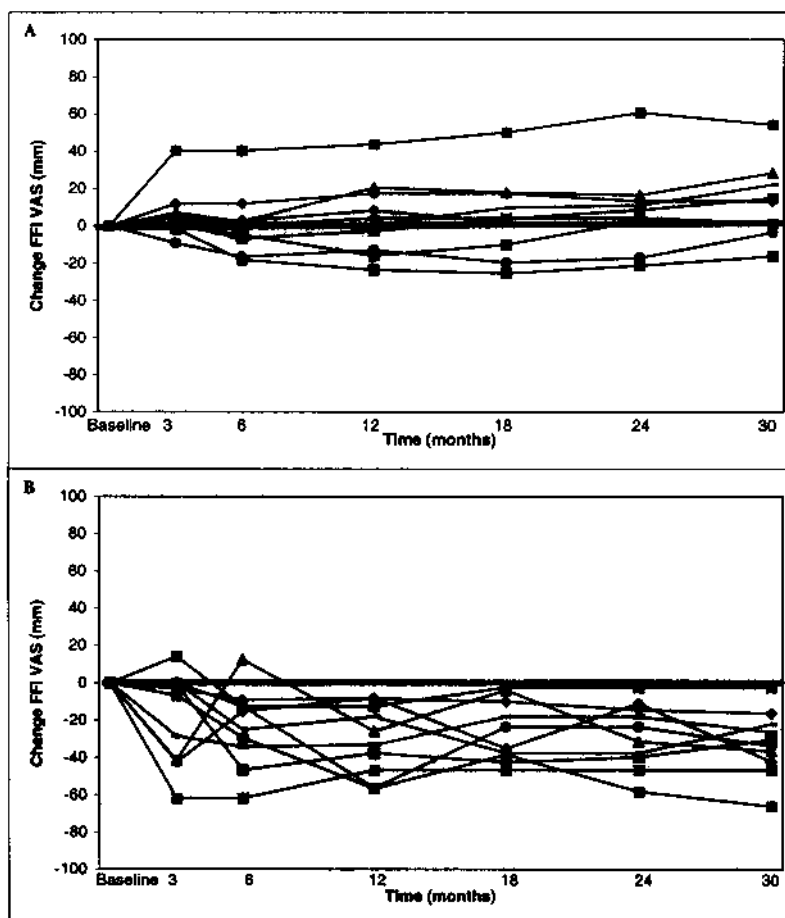*Mean (SD);** Median (IQR): VAS: visual analog scale.

Figure 2. Change in FFI total scores from baseline to 30 months in a random sample of 20% of study subjects. A: control group; B: foot orthosis group.

Table 2. Effect of foot orthoses on Foot Function Index scores and clinical variables.

Variable	Foot Orthosis, n = 50	Control, n = 48	Difference (95% CI)	p
Foot Function Index*				
Total	–241.3 (458.3)	–22.8 (498.3)	218.5 (26.3 to 410.7)	0.026
Pain	–333.4 (632.8)	–25.6 (581.3)	307.8 (63.8 to 551.7)	0.014
Disability	–334.1 (634.0)	–25.0 (618.3)	309.1 (57.9 to 560.4)	0.016
Functional limitation	–63.9 (416.1)	17.5 (430.5)	81.4 (88.4 to 251.1)	0.344
Condition				
Global pain *	17.0 (681.4)	94.3 (719.5)	77.3 (204.0 to 358.6)	0.587
Disease Activity Score*	16.6 (37.7)	10.0 (40.8)	–6.6 (–22.4 to 9.2)	0.409
HAQ **	0 (–7.5, 0.8)	0 (–6.5, 0.7)	0 (–2.6 to 1.5)	0.811
Larsen hands**	54 (0, 99)	57 (31, 169)	18 (–18 to 48)	0.422
Larsen feet**	60 (7, 155)	62 (28, 149)	3 (30 to 33)	0.820

*Mean (SD) of the change in outcome score from baseline as area under the curve with analysis by Student t test; ** median (IQR) change in outcome score from baseline area under the curve with analysis by Mann-Whitney U test.

activity score (p = 0.409), Stanford Health Assessment Questionnaire scores (p = 0.811), or Larsen radiological scores for the hands (p = 0.442) and feet (p = 0.820) over the 30 month duration of the study.

In both arms of the trial the trend was for the number of patients receiving DMARD therapy to increase. However, the use of NSAID, DMARD, and oral glucocorticosteroid therapy was comparable between groups as was utilization

of inpatient, physiotherapy, and orthopedic surgical services, with no statistically significant differences in proportions between the groups at each time point.

Treatment tolerance and adverse reactions. Averaged across the duration of the study, 96% of patients were wearing the orthoses during the week prior to each interview, and 97% found them comfortable. Orthoses were worn on average for 6.3 h per day (SD 3.5 h) and 6.1 days per week (SD 1.9 days). Three patients reported initial fit problems related to irritation to the plantar skin, and these orthoses were modified. Difficulty in fit, related to inadequate room inside the shoe or heel slipping out of shoe, was reported by 30% of patients between baseline and 6 months and by 12% of patients by 30 months. Specific problems such as tender areas on the foot (12%), skin blisters (8%), and thickening of the plantar skin (10%) were reported at 3 months. At 30 months, many of these minor complaints persisted (5% tender areas, 5% skin blisters, and 10% skin thickening). One patient withdrew with a toe infection (resolved with antibiotics), the suspicion being that the portal of entry was caused by skin irritation from footwear made tight by the addition of the foot orthosis.

From outpatient consultations, only 3 patients from the control groups over 30 months were referred for foot orthoses. One received semi-rigid custom manufactured orthoses and 2 received standard valgus insole devices.

DISCUSSION

In RA patients with early correctable valgus deformity of the rearfoot, the administration of custom designed rigid foot orthoses, used continuously, resulted in a significant reduction in foot pain and disability. Short term clinical effectiveness has been described in a number of uncontrolled studies and our data support these findings, but more importantly and for the first time, a mid to longterm sustainable treatment effect has been observed[8-12]. After 30 months, the intervention had the greatest clinical effect on foot disability, reducing this by 30.8% from the baseline value. Foot pain was reduced by 19.1%, functional limitation by 13.5%, and the composite FFI score by 23.1%. By 30 months, the devices were well worn and ready for replacement so the treatment effect was sustainable within the physical life of the orthosis.

The study groups were heterogeneous in terms of underlying disease activity, initial levels of foot pain and disability, and pharmacological management, so it was no surprise to see variable responses to the orthotic intervention. Choosing statistical techniques that analyzed change from baseline results removed any differences between the groups with respect to the pretreatment levels of foot pain, disability, and functional limitation (the subscale components of the FFI). Further, close monitoring of disease activity and pharmacological and other interventions over the duration of the study led us to believe that clinical effec-tiveness was not confounded by these variables. The FFI can detect improvement related to the control of inflammation as much as any mechanical response. Despite an increase in the numbers of subjects prescribed DMARD, the global pain, DAS, and radiological pathology scores increased over the duration of the study in both groups. Therefore, the overall improvement in foot pain and disability in the control group could be either a true response or more likely a response attributed to the Hawthorne effect.

The improved FFI_{dis} scores for the intervention group were not carried forward or were masked by deteriorating upper limb subitem scores in the final HAQ. However, foot orthoses in RA do improve gait function and for future studies, analysis of gait and/or mobility measures may help discriminate lower limb and foot function between treatment arms more precisely[8,10-12]. Weight-bearing load patterns in the forefoot can be shifted medially by valgus heel deformity[5]. By changing the function of the rearfoot and by adding forefoot cushioning, we speculated that the orthoses might beneficially influence forefoot pathology by altering the loading pattern and reducing tissue stresses. However, there was no statistically significant difference between groups in the rate of development of radiological pathology over 30 months as measured by the Larsen scores for the metatarsophalangeal joints. Joint inflammation at these sites appears therefore to be unresponsive to modulation of the mechanical loading. This finding has been reported in a study of semi-rigid orthoses[15].

The rigidity of the carbon graphite orthotic material produced a hard surface at the interface between the foot and the orthosis and this can cause discomfort in the short term. Indeed, 11/50 patients reported deterioration of FFI measured foot pain and disability in the 3 months following start of treatment. By 6 months, 8 of these subjects reported a net improvement in symptoms from baseline scores. There was no apparent relationship between this poor initial response and other clinical or disease management variables or with adverse reactions. There was no difference in the daily wear time between first and final reviews, and although a gradual wear-in period was recommended, most patients persisted with the devices for the full period of daily shoe wear. This may partly explain why one-third of patients reported minor adverse reactions in the early stages. These amounted to pressure induced skin lesions or tender points in the forefoot, medial arch, and heel region. We suspect that these adverse reactions were not perceived as troublesome, since 97% of patients continued to describe the devices as comfortable and there was no apparent effect on the clinical outcomes. However, these problems persisted in 12% of patients and included the withdrawal of one patient, where a toe abrasion became infected. These findings indicate a need for careful early monitoring with a need to consider extra-depth footwear in individual cases. In 4 previous foot

orthosis studies in RA, no adverse reaction data were provided[8,10,11,13].

Studies of foot orthoses in RA have focused on the use of soft inserts and semi-rigid orthoses for the relief of forefoot pain, a clinical entity altogether more easy to identify and manage in the rheumatoid foot[8,11,15]. Some of these studies were not adequately controlled or longitudinal, contained few patients, or failed to account for the effects of the disease process on clinical outcomes. Soft cushioning orthoses serve to increase the weight-bearing contact area and reduce plantar stresses at painful joint sites. The mechanisms by which the foot orthoses induced the observed clinical change in our study are not apparent. The orthoses were intended to control rearfoot motion and correct deformity, thus reducing intraarticular and soft tissue stresses. The contoured shape of the orthosis and the use of an extended cushioning material may have also served to protect the midfoot and forefoot. Although potentially confounding on the measurement of the foot pain and disability as undertaken here, this additional treatment effect would nonetheless be beneficial clinically. Indeed, semi-rigid orthoses have been shown to have a greater effect on forefoot pain, in combination with extra-depth shoes, than soft orthoses[15].

Although there were significant improvements in foot pain and disability, these findings should be viewed with caution, since the design was in effect an open-label study and these changes may reflect spontaneous changes in foot health status or a placebo effect. Furthermore, the study failed to recruit the desired number of patients and was therefore slightly underpowered. In contrast, Conrad and co-workers found no clinical benefit of orthoses over placebo devices, the active orthosis closely resembling those used in this study[13]. However, the study was limited to older male patients and there was no evidence to support the claim that, by definition, the placebo was therapeutically inert. A mechanically inert placebo orthosis needs to be developed to establish efficacy in a larger placebo controlled trial.

According to our data for the control group, underrecognition and treatment of this condition clearly exists, as only 3 patients in the control group received orthoses during the 30 month followup period. This is not surprising, as the rearfoot is difficult to examine and deformity in early disease is often subtle and difficult to detect, especially if no weight-bearing or gait observations are made. Based on our observation of average wear, it is recommended that devices be replaced every 24 months, and at a unit cost of £60, the annual treatment costs are relatively low. In the future we aim to compare custom orthoses against a variety of other devices, some inexpensive premanufactured devices, and to undertake more robust health economic analysis.

Custom manufactured rigid foot orthoses are a clinically effective treatment for RA patients with early correctable deformity of the rearfoot. If it were possible to determine some quantifiable changes in rearfoot joint function in association with the clinical effectiveness demonstrated here, then the indication for custom designed orthosis use in this patient group may have a stronger evidence base.

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