Rheumatology 2007;46:302–307
Advance Access publication 28 July 2006
doi:10.1093/rheumatology/kel234

A clinical trial of specialist footwear for patients with rheumatoid arthritis

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Objectives. **The structural and functional changes in the RA foot often affect the patient's gait and mobility, impacting on the patient's quality of life. Successful management of these foot pathologies and resultant problems can involve the provision of specialist therapeutic footwear. The aim of the study was to evaluate the value of a new footwear design based on patients' opinions compared with a traditional footwear design.**

Method. **A total of 80 patients with RA of 5 yrs or more duration, foot deformity, difficulty in being able to obtain suitable retail footwear and self-reported foot pain were recruited. Patients were randomly assigned to either an intervention group (new design) or the control group (traditional design). Patients completed two specific health-related quality of life scales (Foot Health Status Questionnaire and the Foot Function Index) at baseline and after 12 weeks.**

Results. **Only 36 patients completed the trial. Ten refused the footwear outright and 34 withdrew from the study after the footwear was supplied, due to either non-footwear related problems or reasons related to the footwear. Both the specific health-related quality of life scales demonstrated significant improvement from baseline to week 12 with the intervention group ($P < 0.05$). There was no significant difference in both specific health-related quality of life scales after week 12 with the traditional group ($P > 0.05$).**

Conclusions. **Improvement in pain and patient satisfaction with the new design of footwear for patients with RA over the traditional design indicates the importance of patient involvement in the design process and throughout the process of supplying and monitoring the footwear. The fact that the new-design shoe was based on patients' involvement in the design process in a previous study may be the most important factor in its success. In order to meet the clinical goals of this footwear the patients need to wear them, and to achieve this the patients' requirements need to be acknowledged.**

KEY WORDS: Foot health, Foot pain, Footwear.

Background

A number of studies have described the common structural and functional changes in the foot affected by rheumatoid arthritis (RA) [1, 2], and there are reports of up to 89% of RA patients having some form of foot pathology [3]. O'Connell [4] and Michelson *et al*. [5] identified forefoot pain as being the most frequent and severe foot problem affecting the gait and mobility of people with RA.

The management goals for RA foot are pain management and the preservation of foot function and patient mobility [6]. Two therapeutic components that are generally accepted as achieving these goals are insoles [7, 8] and footwear [9]. Clinical provision for both is included in national guidelines for the management of RA [10, 11]. Evidence for the value of various types of insoles is now emerging from clinical trials [12–14]. In contrast, whilst the importance of bespoke (patient specific) and 'off-the-shelf' footwear appears to be well-recognized in clinical practice, there is little research evidence to support their use. Fransen and Edmonds [9] carried out a randomized study of 30 patients with RA who had foot pain >1 yr. Over a 2-month period, the specialist 'off-the-shelf' footwear reduced pain during walking and stair climbing more than retail footwear. Despite the potential clinical benefits of specialist footwear, reports of patient experiences consistently identify dissatisfaction with this footwear resulting in low compliance or non-usage [15–18]. This dissatisfaction tends to be in the areas of poor fit, poor cosmetic acceptability, weight of the shoe and perception of comfort [15, 16].

Achieving the potential clinical benefits from therapeutic footwear, for example, pain relief, ulcer prevention and improved mobility, is not just about the footwear being designed and fitted to meet the clinical needs of the patient. It requires that the patient wears the footwear once they leave the clinic. The issues related to why patients do or do not wear the footwear we provide is a complex, ill-understood and neglected area. The issues beyond the traditional perspective on footwear. For example, footwear is the external view of the foot, it therefore has the potential to hide or to emphasize foot deformity and the presence of disease. This means that footwear is intimately linked to body image, and therefore the way others perceive us and in turn to self-esteem, all of which are most likely linked to mood, depression, well-being and quality of life, and these are known to be affected by RA [18–20]. The potential for footwear to identify someone as having deformity, disease and disability should not be trivialized, nor should the importance which a patient may place on this. The importance of footwear in personal perception and subsequently self-esteem and well-being should not be underestimated, particularly if it results in patients not wearing the footwear sufficiently to achieve the maximum potential foot health benefits. Footwear needs to be designed to meet both clinical needs of the patient and

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Submitted 14 March 2006; revised version accepted 12 May 2006.

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personal needs related to body image, and reflect the fact that footwear can be a public marker for disability and produce considerable stigma. If we meet both clinical and personal needs of the patient, clinically excellent footwear might get onto and stay on the patient's feet.

The current footwear has been developed by clinicians to meet the clinician's perceptions of patients' needs. At best, patients have only indirect influence on the evolution of therapeutic footwear through feedback to clinicians. To address this problem, our previous work sought to identify patients' requirements and perceptions of existing footwear through focus groups, structured interviews and questionnaires [21]. The results were used in consultation with clinicians to develop a new design of specialist therapeutic footwear based on both the patient and clinician contributions. The new shoe incorporated several features that were identified by the patients as being their preferred features of footwear. These included the shape of the front of the shoe, design of the heel and sole unit, the quality of leather and linings, ease of donning and doffing, height of the heel and thickness of the sole unit. This new shoe was intended to replace an existing one that was used throughout the UK and had been designed by shoe manufacturers and their clinical staff several years previously. The new shoe incorporated a firm contoured insole, whereas the pre-existing shoe incorporated a flat insole of 6 mm Plastazote (low-density polyethylene foam) and 3 mm Poron (open cellular polyurethane 'memory' foam).

To our knowledge, no previous study has investigated the benefits of the footwear designed in consultation with patients compared with that designed by clinicians. The aim of this study was to evaluate the clinical effectiveness of the new therapeutic shoe compared with the pre-existing one.

Method

The study was a randomized controlled clinical trial.

Patients

After the local Ethics Committee's approval, consenting patients were recruited from four local rheumatology clinics. The patients attended the University of Salford Podiatry Department for all assessments and provision of the footwear. The inclusion criteria were that the patients had RA of 5 yrs or more duration according to the American Rheumatism Association criteria for RA [22], foot deformity such as hallux abducto valgus, as defined by the Manchester Grading system [23] for hallux abducto valgus as moderate (grade 3) or severe (grade 4), difficulty in being able to obtain suitable retail footwear defined by the Footwear Suitability Scale [24] and self-reported foot pain. Whilst the Footwear Suitability Scale was developed in relation to patients with diabetes, its criteria are applicable to those with and without foot pathology or systemic disease affecting the foot. In the absence of an equivalent tool specific to RA, it was deemed sensitive to the foot and footwear problems experienced by people with RA. Patients were excluded if they had peripheral neuropathy as they would not be able to report foot pain (a primary outcome).

Based on previous work using the Foot Function Index (FFI) [25] to evaluate the impact of foot orthoses on RA patients [14], a sample of 70 patients gave 90% power to detect an effect size of 0.3 at $P < 0.05$. To take into account a 10% drop-out, we recruited 80 patients with RA (45 females and 35 males).

The patients were randomly assigned by an independent observer to be in one of two groups using a computer random number generator. The intervention group (group 1) was allocated to the new design of footwear and the control group (group 2) was allocated to the pre-existing (traditional) footwear design group. The patients were blind to the group allocation, but because of the distinct features of the footwear and the assessments required, i.e. examination of the feet and footwear, the researcher was not blind as to which group the patients were allocated.

Outcomes

The primary outcomes of the study were foot pain, activity limitation and disability and foot health status. These were assessed using the FFI [25] and the Foot Health Status Questionnaire [26], both self-administered questionnaires. The Foot Health Status Questionnaire (FHSQ) is a validated tool that measures the level of foot health status in relation to factors regarding the quality of life and lifestyle [27]. It has been used to investigate the outcome of foot surgery and foot orthotic interventions for plantar fasciitis [28, 29], and has three sections. Section 1 has four domains

- *Foot pain*: evaluates foot pain in terms of severity and duration.
- *Foot function*: evaluates feet in terms of impact on physical function.
- *Footwear*: examines lifestyle issues related to footwear and feet.
- *General foot health*: looks at the individual's self-perception of body image related to their feet.

Section 2 measures aspects of the patient's quality of life using questions from the validated short form 36 (SF36) [30] in relation to social capacity, general health and vigour. Section 3 collects the standard demographic data.

The FHSQ is self-administered but was checked by the researcher for completeness. After completing the questionnaire, the scores were translated into a scale of 0 (indicating the poorest health) to 100 (indicating the best possible health). As the patients were wearing specialist footwear, the questions relating to footwear suitability were deemed not appropriate. Both designs of the shoe fulfilled the clinical requirements for being good and the patients did not purchase the footwear. This domain was omitted from data analysis.

The FFI is a measure of foot pain and its impact on mobility and activity limitation that has been validated for patients with RA [25] and used to evaluate the effectiveness of foot orthoses [14]. The FFI is a self-administered questionnaire consisting of 23 items grouped in three domains: foot pain (nine items), disability (nine items) and functional limitation (five items). All items are rated using 100 mm visual analogue scales, and higher scores indicate greater pain, disability and limitation of activity and thus poorer foot health. To obtain a domain score, the item scores are totalled and then divided by the maximum total possible for all of the domain items that the patient indicated as applicable. If a subject indicates that they did not perform an activity such as wearing an orthotic, then that item is marked as not applicable. Any item marked as not applicable is excluded from the total possible. To eliminate the decimal point, the score for each domain is multiplied by 100. Therefore domain scores range from 0 to 100 with the higher scores indicating a greater impact of foot pain. Calculating the average of the three domain scores derives a total foot function score. The score for each domain is converted into a percentage, and then the average of the three percentages is calculated [25].

All assessments were carried out at baseline and 12 weeks post footwear fitting, unless the patients withdrew from the study or failed to attend for an assessment. Patients were seen twice during this 12-week period to adjust the fitting and routine foot health checks. Any adverse incidents experienced by the patients such as excessive wear of the upper or sole components of the footwear were recorded.

Statistical analysis of Foot Function Index & Foot Health Status Questionnaire

Paired-samples *t*-tests with 95% confidence intervals were performed to evaluate the impact of the shoes for

within-group comparison. Independent-samples *t*-tests with 95% confidence intervals were performed to compare the baseline and after week 12 to evaluate between-group comparison. All analyses were undertaken using SPSS for Windows Version 11.5.

For the purposes of randomization and analysis the males and females were not separated into groups. The male and female shoes in both groups had the same features with different dimensions to accommodate foot size and shape, and only minor cosmetic differences.

Results

Eighty patients were recruited following full explanation of the study (45 females and 35 males). Following randomization, 40 (29 females, 11 males) were randomized to group 1 (new design) and 40 (21 females, 19 males) to group 2 (traditional design). The mean disease duration (yrs) for all patients was 17.07 ± 14.41. Their mean weight (kg) 76.22 ± 19.15, mean height (cm): 164 ± 0.09 and mean BMI: 24.26 ± 5.08.

Between the fitting of the footwear and week 12, 34 patients withdrew from the study after wearing it for a certain period (Fig. 1). Of these, four patients died during the study, and one before the footwear was fitted. Five patients withdrew at various stages due to unrelated health problems, three due to work or travel problems, and ten, before fitting, as they disliked the style of the footwear (shape of the shoe and the sole unit), i.e. five from the women's traditional style, four from the men's traditional style and one from the ladies new style. Four patients were excluded because they required major external adaptations to the footwear as a consequence of either surgery to the lower limb or because the shoes showed excessive and rapid wear (Fig. 1). Three patients did not attend for the 12-week follow-up assessment. Therefore, of the 80 patients recruited, only 36 completed the 12-week period. The baseline and week-12 assessments were completed by 27 patients from group 1 (new design) and nine patients from group 2 (traditional design).

Adverse incidents

Two patients in group 2 (traditional design) complained that the shoe made their feet hotter than the previous footwear. One pair of the traditional design was deemed unfit for purpose after 3 weeks of wear and one patient complained of excessive slippage at the heel which lead to the formation of a blister. Three patients in group 1 (new design) stated that their heels slipped out of the footwear. However, they continued to use the footwear without any problems.

Foot Health Status Questionnaire

The within-group comparison of FHS scores demonstrated a significant improvement ($P < 0.05$) in foot function, general foot health and physical activity from baseline to week 12 in group 1 (new design) (Table 1). There was no significant improvement in the social capacity, general health and vigour after 12 weeks in group 1 (new design) ($P > 0.05$). In comparison, there

TABLE 1. Within-group comparison of FHSQ scores at baseline and week 12 (mean ± S.D. and 95% CIs)

Domain	Group 1: new design	Group 2: traditional design
Foot pain		
Baseline	39.13 ± 28.44	44.04 ± 26.27
Week 12	65.04 ± 16.36	39.45 ± 23.63
P-value and 95% CI	0.00 (CI: 32.95 to 18.88)	0.37 (CI: 15.10 to −5.98)
Foot function		
Baseline	38.66 (23.65)	34.01 (26.85)
Week 12	59.72 (22.17)	32.99 (20.32)
P-value and 95% CI	0.00 (CI: 25.60 to 16.52)	0.87 (CI: 13.62 to −11.59)
General foot health		
Baseline	16.12 ± 15.72	20.14 ± 18.44
Week 12	37.29 ± 22.58	19.44 ± 21.17
P-value and 95% CI	0.00 (CI: 27.77 to 14.58)	0.85 (CI: 8.14 to −6.75)
General health		
Baseline	39.01 ± 20.01	39.44 ± 23.88
Week 12	40.40 ± 21.13	41.64 ± 26.08
P-value and 95% CI	0.66 (CI: 4.97 to −7.73)	0.70 (CI: 9.42 to −13.80)
Physical activity		
Baseline	30.99 ± 22.58	27.44 ± 27.41
Week 12	36.98 ± 27.02	26.84 ± 30.70
P-value and 95%CI	0.02 (CI: 11.07 to 0.90)	0.83 (CI: 6.46 to −5.22)
Social capacity		
Baseline	54.99 ± 27.31	55.56 ± 27.53
Week 12	60.33 ± 28.33	56.53 ± 29.06
P-value and 95% CI	0.17 (CI: 13.10 to −2.41)	0.83 (CI: 8.59 to −10.54)
Vigour		
Baseline	37.15 ± 16.4)	44.11 ± 18.86
Week 12	40.82 ± 19.71	44.11 ± 19.24
P-value and 95% CI	0.24 (CI: 9.91 to −2.58)	0.99 (CI: 12.49 to −12.47)

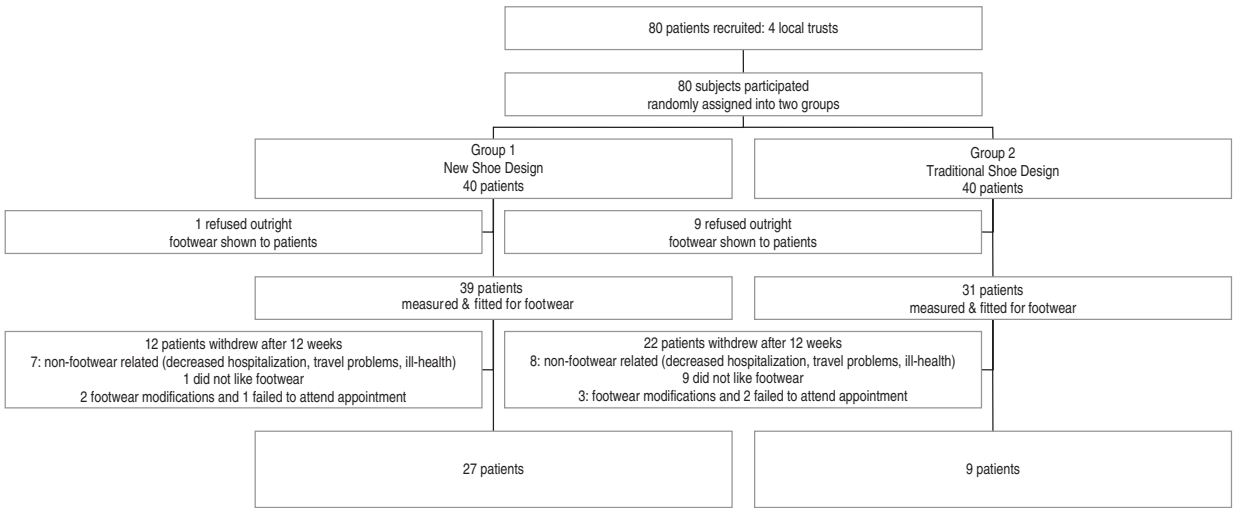

FIG. 1. Patient pathway through the study.

TABLE 2. Between-group comparison of FHSQ scores for baseline and week 12 (mean ± S.D.)

Domain	Group 1: new design	Group 2: traditional design	*P*-value and 95% CIs
Foot Pain			
Baseline	39.13 ± 28.44	44.04 ± 26.27	0.71 (CI: 17.36 to −11.87)
Week 12	65.04 ± 16.36	39.45 ± 23.63	0.00 (CI: 36.69 to 15.15)
Foot function			
Baseline	38.66 ± 23.65	34.01 ± 26.85	0.32 (CI: 19.20 to −6.32)
Week 12	59.72 ± 22.17	32.99 ± 20.32	0.00 (CI: 39.40 to 14.84)
General foot health			
Baseline	16.12 ± 15.72	20.14 ± 18.44	0.49 (CI: 11.60 to −4.30)
Week 12	37.29 ± 22.58	19.44 ± 21.17	0.01 (CI: 31.08 to 5.78)
General health			
Baseline	39.01 ± 20.01	39.44 ± 23.88	0.91 (CI: 11.78 to −10.46)
Week 12	40.40 ± 21.13	41.64 ± 26.08	0.82 (CI: 14.61 to −11.60)
Physical activity			
Baseline	30.99 ± 22.58	27.44 ± 27.41	0.78 (CI: 14.53 to −10.92)
Week 12	36.98 ± 27.02	26.84 ± 30.70	0.24 (CI: 25.9 to −6.50)
Social capacity			
Baseline	54.99 ± 27.31	55.56 ± 27.53	0.73 (CI: 15.95 to −11.25)
Week 12	60.33 ± 28.33	56.53 ± 29.06	0.70 (CI: 19.27 to −12.98)
Vigour			
Baseline	37.15 ± 16.48	44.11 ± 18.86	0.31 (CI: 14.13 to −4.27)
Week 12	40.82 ± 19.71	44.11 ± 19.24	0.50 (CI: 14.94 to −7.37)

was no significant improvement ($P > 0.05$) in any of the foot health status domains associated with group 2 (traditional design) after 12 weeks. Indeed, there was deterioration in scores with the traditional design in foot pain, foot function, general foot health, physical activity and vigour, although the results were non-significant.

The between-group comparison of FHS scores (Table 2) demonstrated no significant difference in any of the domains' scores at baseline between groups 1 and 2 ($P > 0.05$). However, at week 12, there was a significant difference (improvement) in foot pain, foot function and general foot health in group 1 (new design) compared with group 2 (traditional design) ($P < 0.05$). All other domains demonstrated no significant differences between the two groups ($P > 0.05$).

Foot Function Index

The within-group comparison (Table 3) demonstrated that group 1 displayed a significant decrease in the FFI scores between baseline and week-12 assessments ($P < 0.05$), indicating that the shoes were effective in reducing the patient's pain, disability and physical limitation scores. In group 2, there was no significant difference in scores between baseline assessment and week-12 assessments ($P = 0.41$).

The between-group comparison of FFI scores (Table 4) demonstrated no significant difference between group 1 and group 2 at baseline ($P = 0.52$). However, at week 12, the FFI scores were significantly different between both the groups ($P = 0.01$).

TABLE 3. Within-group comparison of FFI scores at baseline and week 12 (mean ± S.D. and 95% CIs)

	Group 1: new design	Group 2: traditional design
Pain		
Baseline	62.96 ± 26.54	63.22 ± 23.18
Week 12	36.15 ± 23.14	58.56 ± 25.44
P-value and 95% CI	0.00 (CI: 33.74 to 19.89)	0.13 (CI: 11.02 to −1.68)
Disability		
Baseline	44.74 ± 25.20	44.00 ± 18.74
Week 12	24.59 ± 20.31	45.67 ± 22.08
P-value and 95% CI	0.00 (CI: 26.28 to 14.01)	0.51 (CI: 3.93 to −7.26)
Limitation		
Baseline	7.52 ± 4.23	6.67 ± 2.83
Week 12	2.56 ± 2.19	8.56 ± 5.86
P-value and 95% CI	0.00 (CI: 6.35 to 3.58)	0.15 (CI: 0.84 to −4.62)
Total		
Baseline	38.52 ± 17.79	42.89 ± 15.48
Week 12	21.26 ± 13.76	37.56 ± 16.54
P-value and 95% CI	0.00 (CI: 21.56 to 12.96)	0.41 (CI: 19.43 to −8.76)

Discussion

The current study found significant differences for both the specific foot outcome measures between the new footwear design and the traditional footwear design over the 12 weeks (FFI and FHSQ). Furthermore, the results demonstrated significant differences from baseline to 12 weeks with the new footwear design. Improved clinical results with the new design of stock footwear for patients with RA over the traditional design are clearly demonstrated in this trial. It is known from previous work that there is a link between levels of usage and patient satisfaction with footwear [15–17], and therefore we can assume that the higher levels of use of the new design were associated with greater satisfaction. These data indicate that clinical needs of patients were addressed more by the new design of footwear compared with the traditional design. The lower levels of refusal to use the footwear and lower drop-out during the trial suggests that the new design also met the more personal needs of patients in relation to their footwear. We assume that, this reflects the use of patient's as well as clinician's opinions in the development of the footwear [21].

Chalmers *et al.* [31] recognized the importance of considering the footwear and insole as a single therapeutic intervention. In this study, the new design of footwear had a contoured insole, which is in keeping with current evidence basis for insole use in RA [8–10]. The traditional shoe had a flat cushioning insole, perhaps reflecting the lack of evidence basis to insole provision at the time of its design. The contoured insole used in the new-design shoe may have contributed to the success of this shoe over the

TABLE 4. Between-group comparison of FFI scores for baseline and week 12 (mean ± S.D.)

	Group 1: new design	Group 2: traditional design	*P*-value and 95% CIs
Pain			
Baseline	62.96 ± 26.54	63.22 ± 23.18	0.98 (CI: 20.43 to −19.91)
Week 12	36.15 ± 23.14	58.56 ± 25.44	0.02 (CI: 40.95 to 3.87)
Disability			
Baseline	44.74 ± 25.20	44.00 ± 18.74	0.94 (CI: 17.91 to −19.39)
Week 12	24.59 ± 20.31	45.67 ± 22.08	0.01 (CI: 37.30 to 4.85)
Limitation			
Baseline	7.52 ± 4.23	6.67 ± 2.83	0.58 (CI: 2.23 to −3.94)
Week 12	2.56 ± 2.19	8.56 ± 5.86	0.02 (CI: 8.68 to 3.32)
Total			
Baseline	38.52 ± 17.79	42.89 ± 15.48	0.52 (CI: 17.88 to −9.14)
Week 12	21.26 ± 13.76	37.56 ± 16.54	0.01 (CI: 27.61 to 4.99)

traditional design. The separate contributions of the insole and the footwear in the outcomes of this study are in fact inseparable. Insoles will always be used inside footwear, never in isolation, and footwear will always create an interface with the foot, so the effects of insoles and footwear cannot be independent of each other.

Although we perceive that the improvements in foot health contribute to the improvement of the patient's general health, we found no evidence of this over 12 weeks. This might be because the improvement in foot health may take longer to impact on the patient's perception of their general health. However, it might be that health status tools such as the FFI and FHSQ do not cover the general health issues upon which footwear might have an impact. They were both designed to measure the health outcome from a clinical perspective. Because footwear is the external view of the foot and is intimately linked to body image, the way others perceive us and our self-esteem, it might be that general health outcomes are more personal and patient-based than those assumed by the existing definitions of general health. Other methods are required to identify whether there are 'person' level outcomes from footwear which the existing measures do not address. To this end, qualitative research is currently underway (A. E. Williams) exploring the patient's experiences and behaviour associated with specialist footwear.

Whilst the high drop-out rate from group 2 may be seen as a limitation in the effect on the statistical power of the study, it reflects the clinical reality that many patients choose not to wear the footwear they are provided with [15, 16]. Deciding not to wear the footwear at the time of provision is an important result. We believe that the drop-out and refusal to wear the footwear (for reasons relating to the footwear) reflect outcomes in the context of more personal issues for patients, such as cosmesis, perception of others regarding their footwear and the stigma of foot deformity and disability. In the clinical setting, patients do not generally have the opportunity to refuse the footwear before it is provided [17], even if they fail to wear them afterwards. Patients in this study were aware of their involvement in research and therefore they may have felt more empowered in refusing the footwear. In contrast to the equivalent retail footwear experience, choice of specialist therapeutic footwear is often very limited, and patients become passive recipients of the footwear rather than the active consumers they would otherwise be. This shift in roles is likely to increase the likelihood of disengagement of patients in the decision-making process, which would contribute to low levels of usage.

Clinicians who refer patients for specialist therapeutic footwear should be aware that there are a wide range of footwear designs and any recommendation should seek to address the clinical and personal needs of the patient. Furthermore, we recommend that footwear manufacturers include patient opinions and user feedback in the development of future designs in order to meet both clinical and patient goals. Since we know that much of the footwear supplied clinical practice ends up as 'shoes in the cupboard' [17], it may be more cost effective to spend more time evaluating the patient's needs from their perspective, than dispensing footwear for it not to be worn. This might result in some cost-benefit analysis to explore the complex cost/health-benefit dynamics. As a minimum standard of practice, patients must be effectively engaged and empowered in the choice of footwear as an acceptable intervention for their foot problems.

Conclusion

This randomized clinical trial clearly demonstrates that it is possible to improve the foot health status in patients with RA with specialist therapeutic footwear which meets the patient's criteria. Long-term studies are required to look at the impact on the patient's general health and the cost effectiveness of such footwear.

This study indicates the importance for considering specialist footwear requirements from a patient-centred view at the design stage, at the initial consultation with the individual and at some point following the supply of the footwear to maintain patient involvement. The influence of the prescribing practitioner may be the most important factor in defining the focus of the patient's footwear assessment and monitoring. Patients will be more likely to wear shoes with which they are satisfied with the comfort, fit, appearance and long-term function and only then will long-term foot health benefits be achieved.

This research was sponsored by the manufacturers of both types of footwear evaluated. Research sponsorship was made to the University of Salford; no personal payments were made to the researchers. The researchers (A.E.W. and C.J.N.) were awarded patent status on the new footwear design after the work in this study was completed, but prior to submission of the paper to the journal. The researchers acted independent of the sponsor in all respects, including trial organization, patient recruitment, randomization, data collection, analysis and this journal publication. The researchers have and will not receive any personal benefits from sales of either type of the footwear evaluated in this study.

Rheumatology	Key messages
	• Specialist footwear can impact on foot health. • Patient acceptance of footwear is necessary to achieve clinical benefits. • Patient involvement in footwear design improves usage and foot health.

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