Clinical Research on Foot & Ankle

Santos, Clin Res Foot Ankle 2015, 3:1
DOI: 10.4172/2329-910X.1000165

Research Article Open Access

The Effects of off-the-Shelf Foot Orthoses on the Quality of Life of Patients Diagnosed with Early Rheumatoid Arthritis

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Received date: January 29, 2015; **Accepted date:** February 23, 2015; **Published date:** February 27, 2015

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Abstract

Background: Rheumatoid Arthritis (RA) is a chronic and progressive disease that is reported to affect the foot in about 90% of cases. Off-the-shelf foot orthoses are widely used to treat patients with early RA because they are cost-effective but more evidence on their clinical effectiveness is required. This study aims to strengthen the current evidence for off-the-shelf foot orthoses.

Methods: Thirty-five patients participated in the study (mean age (SD) was 52.4 (13.3) years). None of the participants had received foot orthoses or had contra-indications to their use. Participants were excluded if they suffered from concomitant musculoskeletal disease, endocrine disorders, and neurological disease. For the within subject controlled study design, data was collected at baseline, three months and six months. A biomechanical assessment was carried out at baseline and the chair-side customized off-the-shelf foot orthoses supplied. Every patient completed the Leeds Foot Impact Scale (LFIS) questionnaire at each visit.

Results: For $LFIS_{if}$ subscale there was statistical significance between baseline and three months (p=0.000) and baseline and six months (p=0.000). Similar results were also found for $LFIS_{ap}$ between baseline and three months (p=0.001) and baseline and six months (p=0.000).

Conclusion: This study suggests that cost-effective off-the-shelf foot orthoses are effective in the management of early RA patients. Patients may expect to see an improvement in QOL by three months with a further improvement by 6 months. This positive effect on QOL is also clinically significant provided patients wear their orthoses for at least six months.

Keywords: Foot; Orthoses; Orthotics; Insoles; Quality of life; Leeds foot impact scale; Quality of life; Rheumatoid arthritis; Podiatry; Management

Introduction

Rheumatoid Arthritis (RA) is a chronic, autoimmune-mediated, systemic, inflammatory disease affecting 0.5-1.5% of the population [1-3]. During the course of the disease, the foot is commonly affected in 90% or more of cases and it has been shown that the incidence of foot problems associated with RA increases with disease duration [2,4]. This suggests that there is a relatively small window of opportunity for early Podiatry intervention to manage the foot in RA [5].

Structural foot insufficiencies as a result of the effects of RA mean that the foot will have to find various ways to compensate for these problems, so that the body can still progress over the supporting limb. The result of this is a foot that has to work particularly hard to achieve what the healthy foot can, and perhaps take longer to achieve it. Additionally, the compensations that the foot employs, coupled with the effects of active small joint synovitis, will inevitably give rise to deformities over time, such as hallux valgus and claw toes [6]. Due to the many functions of the foot required for efficient gait, foot involvement in RA can have a negative effect on gait, and subsequently inhibit the patient's movement, physical activity levels, and general activities of daily living, resulting in a poor quality of life [6,7]. Foot orthotics, commonly known as insoles, are prescribed by podiatrists with the aim of improving joint and bone alignment thus, improving gait mechanics and indirectly influencing positively pain levels and quality of life. The precise mechanism with regards to how foot orthotics may affect pain is unknown. A number of potential theories have been proposed, with foot orthoses leading to a more re-aligned foot improving foot posture thus, allowing more normalized motion at joints; reduction and redistribution of plantar foot pressure; reduction in pressure time integral; altering muscle activity; and altering proprioceptive feedback [8-12]. However, it is more likely that a combination of more than one theory is more likely and that different theories may affect pain through more than one pathway.

At present in RA, the primary intervention and best evidence base is pharmacological with its associated side-effects however, any new evidence for conservative non-invasive cost-effective treatments with no side effects that complements the pharmacological intervention and helps reduce pain and improve the quality of life should be considered. Foot orthoses has been prescribed to patients with RA for a number of years however the evidence base is only now starting to emerge suggesting that they can have a positive effect in reducing pain however few studies have investigated their effect in quality of life. The evidence base is also focused on custom-made foot orthoses which are

not cost-effective and there is a delay in supply thus does not conform to current rheumatology guidelines of early treatment [13,14]. Off-the-shelf orthoses have also been shown to have positive effects on clinical outcomes [12,15]. Studies comparing custom-made to off-the-shelf devices have suggested that there is no difference between the types of foot orthoses with regards to clinical outcomes [12,16].

Prescribed foot orthoses can be divided into two main types: custom-made or off-the-shelf. Off-the-shelf foot orthoses are pre-fabricated to different foot sizes and provide patients with an intervention that can be dispensed at the chair side on the day of diagnosis and so the patient can start to wear the device in their shoes immediately, compared to having to wait weeks or perhaps even months for custom molded devices. However, while custom-made foot orthoses are considered to be the gold standard, anecdotal evidence suggests that less expensive prefabricated off-the-shelf foot orthoses are often prescribed for the management of foot and ankle problems associated with RA [17]. While it appears that many podiatrists are prescribing off-the shelf foot orthoses in the management of foot problems in patients with RA, no study has investigated the effectiveness of off-the-shelf foot orthoses in patients with early RA. In spite of the anecdotal evidence surrounding the use of off-the-shelf foot orthoses in patients with RA, little scientific scrutiny has been applied to determining the effectiveness of off-the-shelf foot orthoses in discrete conditions. Without the support of well controlled research studies, the effectiveness of these devices remains equivocal, and so scientific evidence to confirm these observations is now needed. The aim of this study is to investigate the effects of off the shelf foot orthoses on quality of life in patients with early rheumatoid arthritis.

Methods

Ethics

Ethical approval was obtained from Queen Margaret University Ethics Committee, Edinburgh and Forth Valley and Tayside Research Ethics Committee, NHS Fife. Written consent was obtained from all subjects according to the Declaration of Helsinki.

Subjects

All participants were recruited from NHS Fife Rheumatic Diseases Unit. A total of 35 patients (6 males and 29 females) participated in the study. Age ranged from 26 to 80 years (mean age 52.4 years; Standard Deviation (SD) 13.3 years). The duration of disease ranged from one month, to one year and nine months (mean disease duration 0.7 years; SD 0.6 years). None of the participants had previously been managed with foot orthoses or had contra-indications to the use of foot orthoses. Participants were excluded from the study if they suffered from concomitant musculoskeletal disease, endocrine disorders, especially diabetes mellitus, and neurological disease.

Procedure

A within subject controlled study design was used. Data was collected at baseline, three months and six months. The Slim flex Plastic® (Algeos Ltd. UK) foot orthoses was selected following a survey of podiatrists in Scotland and insole prescription trends [17]. At baseline a biomechanical assessment was carried out and the diagnosis informed the orthoses prescription. Prior to supply of orthoses the patient's footwear was checked for suitability and orthoses were only prescribed where shoes were suitable for supply. Each off-the-shelf foot orthoses was customized for each patient reflecting current chair-side modifications made to these devices by podiatrists in rheumatology practice. The following combinations of chair-side modifications were used: plantar metatarsal pad (standard Poron), valgus dome pad (standard Poron) and/or 3.5˚ or 5˚ rear foot and/or forefoot wedge.

Patient's medical notes were examined, at each visit, to determine when any pharmacological treatment had initially commenced and any changes to current medication. Every patient was then asked to complete the Leeds Foot Impact Scale (LFIS) questionnaire and patient's demographics details were also taken.

Statistical Methods

SPSS version 16.0 was used for all data analysis. Appropriate descriptive statistics were presented for parametric and non-parametric data. Significance level was set at p=0.05. For parametric data a repeated measures analysis of variance (ANOVA) test was used. Pairwise comparisons determined where the significant changes were occurring. For non-parametric data a Friedman's test was used. An exact Wilcoxon rank test with Bonferroni multiple corrections was carried out to determine where the significant changes were occurring. With Bonferroni multiple comparisons, the significance level was adjusted accordingly by dividing the p value by the number of comparisons being tested, so significance was set at p=0.02.

Results

Demographics

Details of changes of medication and/or new joint injections were recorded during the study thus; any effect could be attributed to the foot orthoses where the only change over the period of the study was the introduction of the foot orthoses. Stable medication referred to no changes, and unstable indicated that changes to medication or new steroid injections were administered during the 6 months study period. Thirty-five participants were recruited, of these 34% (n=12) were on stable medication. In the stable medication group the age ranged from 37 to 75 years (mean age 52.3 years; SD 11.3 years). Duration of disease ranged from two months, to one year and eight months (median disease duration 0.8 years; IQR 1.6 years). A comparison of the demographics between the total patient group and the stable medication group is shown in Table 1.

	Total patient group (n=35)	Stable medication group (n=12)
Gender	6 males/29 females	1 male/11 females
Age (years)	Mean 52.4; SD 13.3	Mean 52.3; SD 11.3
Disease Duration (years)	Median 0.5; IQR 1.8	Median 0.8; IQR 1.6

Table 1: Demographics of the total patient group and the stable medication group.

LFIS

All patients: The $LFIS_{if}$ subscale and the $LFIS_{ap}$ subscale were examined individually. Normality was confirmed for the $LFIS_{if}$ subscale at baseline, three months and six months and non-normality

for the $LFIS_{ap}$ subscale at six months. A parametric repeated measures ANOVA was used to analyse the $LFIS_{if}$ data. Mauchly's test was non-significant (p=0.426) hence assumptions of sphericity was not violated. Table 2 and Figure 1 shows the descriptive statistics and p values for the $LFIS_{if}$ subscale over the six months. For the mean value of the $LFIS_{if}$ score over the six months there appears to be a trend towards a reduction on the $LFIS_{if}$ subscale over the study period. A repeated measures ANOVA test for the $LFIS_{if}$ showed a significant effect with the use of the foot orthoses over the six months (p=0.000). Pair wise comparisons showed that this significance was lying between baseline and three months (p=0.000) and baseline and six months (p=0.000). There was no significant change in $LFIS_{if}$ between three months and six months (p=0.467).

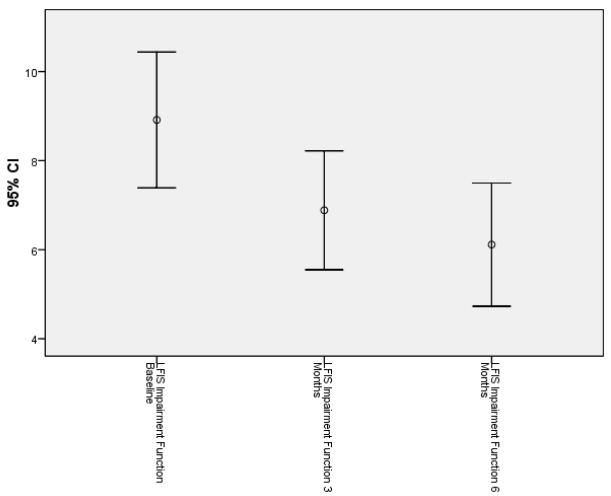

Figure 1: $LFIS_{if}$ score results for all patients. Shows an error bar chart for the $LFIS_{if}$ score (0-21) at baseline, three months, and six months.

	Mean	SD	Baseline-3 months	3-6 months	Baseline-6 months
$LFIS_{if}$ baseline	9	4	P=0.000	-	P=0.000
$LFIS_{if}$ 3 months	7	4		P=0.467	
$LFIS_{if}$ 6 months	6	4	-		

Table 2: The mean, SD and p values for the LFIS Impairment Function ($LFIS_{if}$) at baseline, three months and six months.

Table 3 and Figure 2 shows the descriptive statistics for the $LFIS_{ap}$. For the $LFIS_{ap}$ data over the six months there appears to be a trend towards a reduction in $LFIS_{ap}$ scores. A non-parametric Friedman's test showed this trend to be statistically significant with the use of foot orthoses over the six months period (p=0.000). In order to determine where the significant effect was occurring over the six months, a Wilcoxon test with Bonferroni multiple comparisons was used with significance level adjusted to p=0.02. The significant effect with the foot orthoses was found to be between baseline and three months (p=0.001) and baseline and six months (p=0.000). There was no significant change in $LFIS_{ap}$ between three months and six months (p=0.169).

	Median	IRQ	Baseline-3 months	3-6 months	Baseline-6 months
$LFIS_{ap}$ baseline	14	29	P=0.001	-	P=0.000
$LFIS_{ap}$ 3 months	10	27		P=0.169	
$LFIS_{ap}$ 6 months	8	26	-		

Table 3: The descriptive statistics and p values for the $LFIS_{ap}$ over the six months with the use of the foot orthoses.

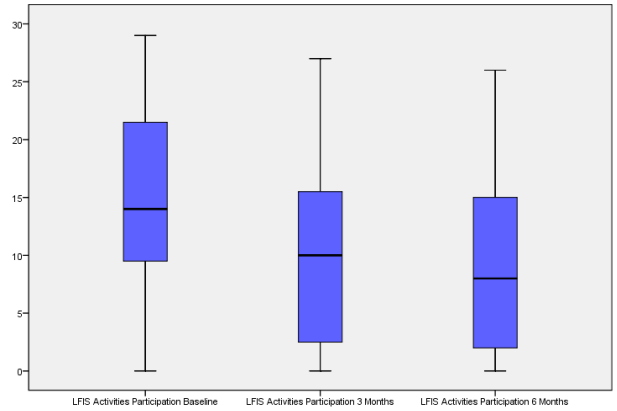

Figure 2: $LFIS_{if}$ score results for all patients. The box plots to demonstrate the distribution of the $LFIS_{ap}$ data at baseline, three months, and six months. The LFIS score (0-30) is shown on the y axis.

Stable medication group only

The data from the stable medication group was assumed to be non-parametric as the number of patients included was less than 30 [18]. A non-parametric Friedman's test suggested a significant change in $LFIS_{if}$ score over the six months (p=0.001). Using a Wilcoxon test with Bonferroni multiple comparisons, a significance result was found between baseline and six months (p=0.001). There was no significant change in $LFIS_{if}$ scores between baseline and three months (p=0.065) and three months and six months (p=0.065) (Table 4 and Figure 3).

	Median	IRQ	baseline-3 months	3-6 months	baseline-6 months
$LFIS_{if}$ baseline	10	14	P=0.065	-	P=0.001
$LFIS_{if}$ 3 months	8	10		P=0.065	
$LFIS_{if}$ 6 months	6	11	-		

Table 4: The median, IQR and p values for the $LFIS_{if}$ at baseline, three months, and six months-stable medication.

The distribution of the $LFIS_{ap}$ subscale data shows a decreasing trend (Figure 2). The Friedman's test showed that there was a statistically significant difference in the $LFIS_{ap}$ subscale score over the six months (p=0.027). Post hoc analysis showed that the significance was occurring between baseline and three months (p=0.009) and baseline and six months (p=0.005). There was no significant change

between three months and six months (p=0.373) (Table 5 and Figure 4).

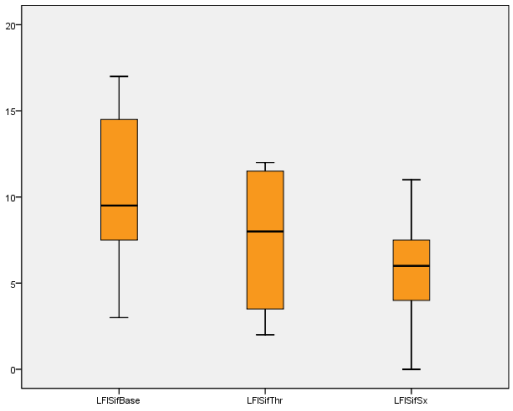

Figure 3: $LFIS_{if}$ score results for all patients. Box plots to illustrate the distribution of the $LFIS_{if}$ data in the stable medication group at baseline (Base), three months (Thr) and six months (Sx). The $LFIS_{if}$ score (0-21) is shown on the y axis.

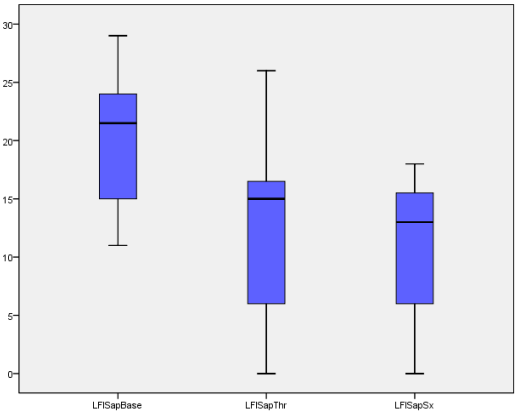

Figure 4: $LFIS_{if}$ score results for all patients. Box plots for the $LFIS_{ap}$ score in the stable medication group at baseline (Base), three months (Thr) and six months (Sx). The $LFIS_{ap}$ score (0-30) is shown on the y axis.

	Median	IRQ	Baseline-3 months	3-6 months	Baseline-6 months
$LFIS_{ap}$ baseline	22	18	P=0.009	-	P=0.005
$LFIS_{ap}$ 3 months	15	26		P=0.373	
$LFIS_{ap}$ 6 months	13	18	-		

Table 5: Median and IQR for $LFIS_{ap}$ activities participation at baseline, three months and six months-stable medication.

Discussion

This study provides positive new evidence for the effectiveness of off-the-shelf foot orthoses on quality of life in patients with early RA. The primary management strategy for these patients is pharmacological management with painkillers, NSAIDs, DMARDs, corticosteroids and others, such as folic acid. DMARDs are the most commonly prescribed drugs for the long term management of RA and take up to four weeks to have an effect on their symptoms with a further improvement up to six months after commencing DMARD therapy [19]. Turner et al. (2007) identified stable drug management as a main challenge in recruiting patients for their study to investigate the effectiveness of podiatry care in early RA [20]. They included patients who had been on the same drug therapy for the three months prior to recruitment. They reflected that this eligibility was too stringent and concluded that it is important to gauge the level of drug monitoring and intervention in other secondary and primary care settings to help set more pragmatic exclusion rules. How the problem of stable drug management in RA is handled in other non-pharmacological trials is not well documented. In this study, to attribute any effects to the off-the-shelf foot orthoses, patients were not included in the study unless they had been on DMARDs for at least six months. In addition, since it's common for medication to change frequently in this patient group, any changes in medication during the study was recorded. This allowed for the group to be sub-divided further for post-hoc analysis into stable medication (no change in pharmacological management during the study) and unstable medication (changes in pharmacological management during the study). By studying the stable medication group this allowed for any findings to be solely attributed to the use of off-the-shelf foot orthoses. However, the numbers on the stable medication group was low (n=12) and thus any findings for this sub-group should be interpreted with caution. Future studies are required to verify any trends shown by this sub-group.

The LFIS is a QOL measure that is specific to the foot in RA [21]. The LFIS contains items where the sense of frustration, annoyance and fear associated with foot pain in RA can be assessed, such as "I cry with pain" and "I feel isolated because I can't go very far" and "I dread finishing up in a wheelchair". The findings suggest that the Slim flex™ Plastic off-the-shelf foot orthoses is effective in improving foot health related QOL in patients with early RA. The four domains investigated by the LFIS include impairment, activities, participation and footwear, and so the foot orthoses may affect one or more of these to result in the patient feeling that they have an improved foot health related QOL. The LFIS scores for the group of patients used in this study are comparable to the LFIS scores reported in other studies to determine the impact of disease localized to the feet in RA. In one study the LFIS was used to investigate the impact of RA on foot function in the early stages of the disease [22]. Another study used the LFIS to characterize the clinical features of severely deformed feet in RA however, the higher scores in this study would be expected as these patients had more established disease [6].

Overall, the findings from the LFIS show that with the use of the Slim flex™ Plastic off-the-shelf foot orthoses over the six months period, patients reported that they were significantly less impaired, and able to participate in more activities. Post hoc analyses showed that the significant effect was occurring between baseline and three months, and baseline and six months, which suggest that patients may experience an improvement in foot health related quality of life by three months. With regards to the stable medication group, there was a statistically significant improvement in the $LFIS_{if}$ and $LFIS_{ap}$ subscale

scores with the foot orthoses over the six months. Post hoc analyses showed that this significance was occurring between baseline and six months in the $LFIS_{if}$ subscale, and between baseline and three months, and baseline and six months in the $LFIS_{ap}$ subscale. This suggests that patients may experience an improvement in impairment and function by six months, and an improvement in activities and participation by three months. The results from the stable medication group imply that the effects on foot health related quality of life may be due to the foot orthoses alone, and not as a result of any effects of medication. However, further research with larger sample size is required to confirm this finding.

While the results show that there was a statistically significant decrease in LFIS scores over the six months with the foot orthoses, Helliwell et al (2005) state that the $LFIS_{if}$ subscale requires a change of three points for a minimally important clinical difference, and the $LFIS_{ap}$ subscale needs a change of eight points [21]. It is common for clinicians and researchers to view statistical significance as clinical significance; however statistical significance does not always mean that the result is clinically worthwhile [23]. The most effective method of examining a study's results for clinical significance is comparing the results against an already established minimal important difference [23]. A minimal important difference is the smallest difference in score in the domain of interest which patients perceive as beneficial and which would result in a change in management or treatment [23]. Turner et al (2007) state that based on previously unpublished data a minimally clinically difference of three points for the $LFIS_{if}$ subscale is required [20]. There was a difference of two between the $LFIS_{if}$ scores at baseline and three months, and a difference of three between baseline and six months. The difference in $LFIS_{ap}$ scores between baseline and three months was four, and between baseline and six months was six. So according to Helliwell et al (2005) a clinically important difference was seen in the $LFIS_{if}$ score between baseline and six months, but not in the $LFIS_{ap}$ as the difference in scores was less than eight [21]. According to the clinically important differences found, Slim flex™ Plastic off the-shelf foot orthoses did improve foot health related QOL in patients with early RA, in terms of impairment and function, and activities and participation. However, for a clinically important change in $LFIS_{if}$ scores patients are required to wear the orthoses in their shoes for at least six months.

In the group of patients with stable medication there was a statistically significant reduction in $LFIS_{if}$ scores over the six months, with the significance occurring between baseline and six months ($p=0.001$). At baseline the score was 10, at three months it was eight, and at six months it was six. The difference in scores between baseline and six months was four, and so according to Helliwell et al (2005) a clinically important difference was reached [21]. The $LFIS_{ap}$ scores in the group of patients on stable medication were 22 at baseline, 15 at three months, and 13 at six months. There was a statistically significant difference in $LFIS_{ap}$ scores in the group of patients on stable medication, the difference in scores between baseline and six months was nine, suggesting that there was a clinically important change. From the study findings in the group of patients with stable medication it can be concluded that Slim flex™ Plastic off-the-shelf foot orthoses do positively affect foot health related QOL in terms of impairment and function, and activities and participation by six months.

Foot orthoses can be used optimally early on in the disease process to control any abnormal movement of the foot during walking when the joints are inflamed and susceptible to damage, leading to deformity [7]. Early assessment in recently diagnosed patients would provide podiatrists with the opportunity to identify any structural and functional abnormalities that can be managed through interventions such as foot orthoses. This could prevent or slow down the occurrence of foot problems, and subsequently limit the time and resources required in later stages of the disease, such as corrective foot surgery which is accounted to occur in about 20% to 30% of patients with RA [4]. There are two main approaches to supplying foot orthoses; custom moulded foot orthoses and off-the-shelf foot orthoses [16] Although most of the evidence supports the use of custom foot orthoses in RA, custom foot orthoses requires specialised facilities to manufacture, are labour intensive and result in a delay in supply of weeks or months [16,24] In contrast, off-the-shelf foot orthoses are mass produced to fit a generic foot shape, and can include a variety of flat insoles, arch supports, and single plane wedges; as well as contoured devices that imitate many of the physical characteristics of customised devices [25]. Custom foot orthoses have been estimated to cost three and a half times more than off-the-shelf foot orthoses [25]. When it is estimated that in 2004 the annual National Health Service (NHS) budget for orthoses was about £38 million, of which 30% was spent on foot orthoses and footwear, any savings on foot orthoses whilst providing evidenced based health benefits to patients would be welcomed [26]. Thus, off-the-shelf foot orthoses offer the advantage that they can be customised chair-side without the need for specialised machinery, are cost-effective and are supplied immediately to the patients complying with current guidelines for the management of early RA patients. Anecdotal evidence suggests that these type of devices as currently the preferred choice of foot orthoses for the podiatric management of patients with early RA in Scotland despite poor research evidence to support their use [17].

Conclusion

This study provides some evidence to support the use of off-the-shelf cost-effective foot orthoses to patients with early RA. Patients using chair-side customized off-the-shelf foot orthoses may expect to see an improvement in their QOL by three months with a further improvement by 6 months. According to the LFIS QOL tool used, off-the-shelf foot orthoses had a positive effect on foot health related QOL in patients with early RA, both in terms of impairment and function, and activities and participation. This positive effect on QOL was not only statistically significant but also a clinically important change provided patients wear their orthoses in their shoes for at least six months.

Key Messages

- Off-the-shelf foot orthoses supplied to patients with early RA has a positive effect on their quality of life.
- Patients using chair-side customized off-the-shelf foot orthoses may expect to see an improvement in their quality of life by three months with a further improvement by 6 months.
- According to the quality of life (QOL) tool used, off-the-shelf foot orthoses had a positive effect on foot health related QOL, both in terms of impairment and function, and activities and participation.

Acknowledgements

The authors would like to thank the Fife Rheumatic Diseases Unit (FRDU) for their help and support with this study. This study was funded by a PhD grant from Queen Margaret University.

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