

A study to investigate the effectiveness of a commonly prescribed off-the-shelf foot orthosis on foot health related quality of life (QOL) in patients with early diagnosed Rheumatoid Arthritis (RA).

Dr Vicki Cameron-Fiddes
April 2011

Title

A study to investigate the effectiveness of a commonly prescribed off-the-shelf foot orthosis on foot health related quality of life (QOL) in patients with early diagnosed Rheumatoid Arthritis (RA)

Abstract

Off-the-shelf foot orthoses are not evidence based for patients with RA. The aim was to investigate any effects of the Slimflex™ Plastic orthosis on foot health related QOL in patients with early RA, using the LFIS. Thirty-five patients with mean age of 52.4 years and median disease duration of 0.5 years were included. Sub-analyses on patients with stable medication (n=12) and unstable medication (n=23) were also undertaken. Ethical approval was obtained. The study used a repeated measures design. Data was analysed with SPSS version 16.0. In the total group the Slimflex™ Plastic reduced the LFIS_{if} (p<0.05) and LFIS_{ap} (p<0.02). In the stable medication group the orthosis reduced the LFIS_{if} and LFIS_{ap} (p<0.02). In the unstable medication group the orthosis reduced the LFIS_{if} (p<0.02) but did not significantly affect the LFIS_{ap} (p>0.02). This study suggests that the Slimflex™ Plastic off-the-shelf foot orthosis positively affects foot health related QOL, in early RA.

1.0 Introduction

Rheumatoid Arthritis (RA) frequently affects the foot, and it has been shown that the incidence of foot problems associated with RA increases with disease duration (Bouysset et al. 2006). This suggests that there is a relatively small window of opportunity for early Podiatry intervention to manage the foot in RA (Woodburn et al. 2010). Off-the-shelf foot orthoses can be dispensed at the chairside on the day of diagnosis, so the patient receives treatment immediately. This is particularly

crucial in RA, as early intervention is thought to improve patient outcomes in the long term (Luqmani et al. 2006). This is compared to custom moulded devices where a delay in treatment may exist due to the lengthy process of manufacture.

Foot orthoses provision is reported to be a relatively expensive intervention (Branthwaite et al. 2004). A recent study reported that customised devices were three and a half times more costly than off-the-shelf devices in terms of labour, materials and laboratory costs (Redmond et al. 2009). An audit comparing the cost and therapeutic value of off-the-shelf foot orthoses to custom moulded foot orthoses, also found a significant cost advantage with the off-the-shelf devices in terms of reduction of time in manufacture (Brocklesby 2009).

While custom moulded foot orthoses are considered to be the gold standard, anecdotal evidence suggests that less expensive off-the-shelf foot orthoses are often prescribed for the management of foot and ankle problems associated with RA (Cameron et al. 2009). However, no clinical studies exist to support this practice. The aim of this study was to investigate the effects on foot health related QOL of one commonly prescribed off-the-shelf foot orthosis in patients with early RA.

2.0 Methods

A total of 35 patients (six male and 29 female) participated in the study between September 2006 and November 2007. A sample size of 30 was for a minimum

power of 80% and significance of 0.05, two sided, and also takes into account attrition. The age of patients ranged between 26 to 80 years (mean age 52.4 years; SD 13.3 years). Disease duration ranged from one month to one year and nine months (median disease duration 0.5 years; interquartile range [IQR] 1.8 years). No patient presented on Biologic therapy.

The inclusion and exclusion criteria are illustrated in table 2.1.

Table 2.1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Diagnosed with RA within the past two years according to the 1987 American Rheumatism Association Revised Criteria for RA	Musculoskeletal disease other than RA
	Central or peripheral nervous system disease
	Endocrine disorders (especially Diabetes)
	Wearing foot orthoses, or had worn previously
	History of orthopaedic surgery or fracture
	STJ ROM <12°
	Ankle Equinus (Osseous)
	Unable to walk barefoot for 15 minutes

Patients presented for data collection at baseline, three months, and six months. The Slimflex™ Plastic device was used based on the results of a cross-sectional survey undertaken as a preliminary study to this research study (Cameron et al. 2009). The foot orthoses were individually customised for each patient to reflect

current chairside modifications made to off-the-shelf devices by Podiatrists in Rheumatology practice today.

Data was analysed with SPSS version 16.0. The descriptive statistics presented for parametric data are the mean and the SD. For non-parametric data the median and the IQR are displayed. A repeated measures design was used. The 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 found at $p=0.02$.

3.0 Results

Due to the known effects of medication, data is presented for the total patient cohort ($n=35$) followed by the findings from the sub-analyses on the group of patients who presented with stable medication ($n=12$) and the group of patients who presented with unstable medication ($n=23$). Stable medication was defined as DMARD therapy for at least six months prior to entry into the study, with no change in medication or change in dose of medication, and no steroid injection, throughout the study.

In the total patient cohort (n=35) a repeated measures ANOVA for the LFIS_{if} showed a significant effect with the use of the foot orthosis 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). This is illustrated in table 3.1.

Table 3.1 shows the mean, SD and p values for the LFIS Impairment Function (LFIS_{if}) at baseline, three months (3) and six months (6).

	Mean	SD	P Value (Baseline-3)	P Value (Baseline-6)	P Value (3 -6)
LFIS _{if} Baseline	9	4	0.000	0.000	
LFIS _{if} 3 Months	7	4			0.467
LFIS _{if} 6 Months	6	4			

There was a significant change in LFIS_{ap} score with the use of foot orthoses over the six months (p=0.000). In order to determine where the significant effect was occurring, a Wilcoxon test with Bonferroni multiple comparisons was used. Correspondingly, the significance level was 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). This is shown in table 3.2.

Table 3.2 shows the median, IQR and p values for the LFIS Activities Participation (LFIS_{ap}) at baseline, three months (3), and six months (6).

	Median	IQR	P Value (Baseline-3)	P Value (Baseline-6)	P Value (3-6)
LFIS _{ap} Baseline	14.00	29.00	0.001	0.000	
LFIS _{ap} 3 Months	10.00	27.00			0.169
LFIS _{ap} 6 Months	8.00	26.00			

These findings indicate that the null hypothesis can be rejected, that there is no statistically significant difference in foot health related QOL, when patients with early RA walk with a Slimflex™ Plastic off-the-shelf foot orthosis compared to walking barefoot, and with shoes only over six months.

In the stable medication group (n=12) there was a significant change in LFIS_{if} score over the six months as p=0.001. A Wilcoxon test with Bonferroni multiple comparisons showed that the significance was lying between baseline and six months (p=0.001). There was no significant change in LFIS_{if} score between baseline and three months (p=0.065) and three months and six months (p=0.065). This is shown in table 3.3.

Table 3.3 shows the median, IQR and p value for the LFIS_{if} at baseline, three months (3), and six months (6) – *stable medication*.

	Median	IQR	P Value (Baseline-3)	P Value (Baseline-6)	P Value (3-6)
LFIS _{if} Baseline	10	14	0.065	0.001	
LFIS _{if} 3 Months	8	10			0.065
LFIS _{if} 6 Months	6	11			

The Friedman's test showed that there was a statistically significant difference in the LFIS_{ap} subscale score over the six months as $p=0.027$. 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 as $p=0.373$, as illustrated in table 3.4.

Table 3.4 shows the median and IQR for LFIS_{ap} Activities Participation at baseline, three months (3) and six months (6) – *stable medication*.

	Median	IQR	P Value (Baseline-3)	P Value (Baseline-6)	P Value (3-6)
LFIS _{ap} Baseline	22	18	0.009	0.005	
LFIS _{ap} 3 Months	15	26			0.373
LFIS _{ap} 6 Months	13	18			

In the patient group with unstable medication (n=23) there was a significant change in LFIS_{if} over the six months as p=0.001. A Wilcoxon test with Bonferroni multiple comparisons showed that the significance was lying between baseline and six months (p=0.001) and between baseline and three months (p=0.001). There was no significant difference between three months and six months (p=0.678). This is illustrated in table 3.5.

Table 3.5 shows the mean, SD and p values for the LFIS Impairment Function (LFIS_{if}) at baseline, three months (3) and six months (6) – *unstable medication*.

	Median	IQR	P Value (Baseline-3)	P Value (Baseline-6)	P Value (3 -6)
LFIS _{if} Baseline	9	17	0.001	0.001	
LFIS _{if} 3 Months	10	29			0.678
LFIS _{if} 6 Months	6	16			

The Friedman's test showed that there was no statistically significant difference in the LFIS_{ap} subscale score over the six months as p=0.03. This is illustrated in table 3.6.

Table 3.6 shows the median and IQR for LFIS Activities Participation (ap) at baseline, three months (3) and six months (6) – *unstable medication*.

	Median	IQR	P Value (Baseline-3)	P Value (Baseline-6)	P Value (3-6)
LFIS _{ap} Baseline	9	27	0.026	0.031	
LFIS _{ap} 3 Months	6	17			0.359
LFIS _{ap} 6 Months	6	26			

4.0 Discussion

The mean LFIS_{if} score at baseline was nine, which decreased to seven at three months, and further decreased to six at six months. The decrease in LFIS_{if} score was statistically significantly between baseline and three months ($p=0.000$) and between baseline and six months ($p=0.000$). A similar trend was seen with the LFIS_{ap} score which reduced from 14 at baseline, to 10 at three months, and to eight at six months. The decrease in score was statistically significantly between baseline and three months ($p=0.001$) and baseline and six months ($p=0.000$).

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. 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.

In the group of patients with stable medication (n=12) 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. 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 no statistically significant difference in LFIS_{ap} scores in the group of patients on stable medication, however the difference in scores between baseline and six months was nine, suggesting that there was a clinically important change.

In the group of patients with unstable medication (n=23) there was a statistically significant reduction in LFIS_{if} score over the six months, with the significance occurring between baseline and three months and baseline and six months. The median LFIS_{if} scores were nine at baseline, ten at three months and six at six months. So, according to Helliwell et al (2005) there was a clinically important difference between baseline and six months, and three months and six months. There was no statistically significant reduction in LFIS_{ap} score over the six months.

The median LFIS_{ap} score was nine at baseline, six at three months, and six at six months, so no clinically important differences were seen.

The findings suggest that the Slimflex™ Plastic off-the-shelf foot orthosis may positively affect foot health related QOL in patients with early RA, and that these changes may be evident by three months. However, it is unknown if these effects are due to the foot orthosis alone, or as a result of the devices in combination with any effects of medication. To investigate this, sub-analyses on the group of patients with stable medication throughout the study were undertaken. The results suggest that in patients with stable medication the Slimflex™ Plastic foot orthosis may positively affect impairment and function by six months, and activities and participation by three months. However, it is acknowledged that the numbers used in the stable medication group were small, and so further research is needed to substantiate these findings. In order to determine if the scores from the stable medication group influenced the total patient group results, sub analyses on the patients with unstable medication throughout the study (n=23) were also carried out. The results showed that the foot orthosis had a positive affect on impairment and function, which may be evident by three months, but showed no significant effect on activities and participation. It can therefore be concluded that the Slimflex™ Plastic off-the-shelf foot orthosis may positively affect foot health related QOL in terms of impairment and function, in patients with early RA who present with either stable or unstable medication. It may be more likely for activities and participation to be positively affected in patients with stable medication.

A number of studies have used the LFIS to measure disease impact in the foot (Turner et al. 2006; Turner and Woodburn 2008; Rome et al. 2009), but only one study was identified that has used the LFIS to investigate the effectiveness of an intervention. An exploratory randomised controlled parallel arm clinical trial was undertaken to investigate Podiatry care, and the primary outcome measure was a change in foot health status using the LFIS (Turner et al. 2007). Patients with a history of foot problems with an LFIS_{if} score of more than four were recruited into the study. The primary outcome was the LFIS_{if} subscale which was measured at eight, four and zero weeks prior to treatment to establish a precise baseline measure. This was then repeated at three, six, nine and 12 months following the start of podiatry care. The LFIS_{ap} subscale was used as a secondary outcome measure. The effectiveness of the podiatry intervention was determined by comparing the change in LFIS_{if} score between baseline and 12 months. There was a statistically significant between groups differences in the primary outcome, however there was no change from the baseline score in the podiatry intervention group. There was a small deterioration in the no Podiatry group. Overall the effect size was small and reported to be clinically unimportant.

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 localised to the feet in RA. The LFIS was used to investigate the impact of RA on foot function in the early stages of the disease (Turner et al. 2006). Twelve patients with less than two years disease duration (from symptom onset) were recruited. Six patients had an LFIS_{if} score of more than 11, and four patients had an LFIS_{ap} score of more than 15, indicating moderate-high disease impact. Five patients had an LFIS_{if} score of

less than 10 indicating moderate disease impacts on the feet, and seven patients had an LFIS_{ap} score of less than 14, indicating moderate disease impact. One patient had an LFIS_{ap} score of less than four indicating low disease impact.

5.0 Conclusions

Early intervention in patients with RA is crucial, to prevent or limit joint damage in established disease, and to maintain functionality for the patient. Off-the-shelf foot orthoses can be dispensed at the chairside on the day of diagnosis, which means that the patient receives treatment immediately. This is compared to custom moulded foot orthoses where a delay of treatment may exist. The findings suggest that the Slimflex™ Plastic off-the-shelf foot orthosis is effective in the management of the foot in RA, in terms of foot health related QOL. However it remains unknown if off-the-shelf foot orthoses are as effective, or more effective as a custom moulded device. A double blind and adequately powered RCT directly comparing the effects of an off-the-shelf foot orthosis to a custom moulded foot orthosis would be a logical extension to this study, and the findings from this study provide information for the development of a gold standard RCT.

6.0 Clinical Implications

By investigating the possibility of introducing an off-the-shelf foot orthosis in the management of patients with early RA, it was anticipated that clinicians would be provided with an up to date rigorous evidence base that would support their clinical practice. It follows that this would result in patients receiving an effective and timely intervention, and so would improve pain in the short term and patient foot health

related outcomes in the long term. The findings suggest that that the Slimflex™ Plastic off-the-shelf foot orthosis is effective in the management of the foot in early RA, and that an improvement in foot health related QOL may be seen by three months.

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