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The effect of foot orthoses in rheumatoid arthritis

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***Objective*. To evaluate the effectiveness of foot orthoses using the foot function index (FFI) in a group of patients with rheumatoid arthritis (RA) during a period of 6 months.**

***Methods*. Thirty-six rheumatoid subjects with foot pain were examined and appropriate foot orthoses were prescribed according to each patient's needs. All the patients were evaluated 30, 90 and 180 days after the baseline visit. FFI values, daily time of wearing the orthoses and adverse effects were noted at each appointment. The Stanford Health Assessment Questionnaire (HAQ) was used at the initial visit to evaluate the influence of physical condition on FFI response.**

***Results*. With the use of foot orthoses, FFI values decreased in all subscales (pain, disability and activity limitation). This reduction was noted in the first month and was maintained throughout the trial. Those using EVA (ethyl-vinyl acetate; $n = 28$) orthoses presented results similar to those for the total group. Patients wearing made-to-measure orthoses ($n = 8$) exhibited higher initial FFI values and worse evolution during the trial, significant for pain and disability but not for activity limitation. Minor adverse reactions were noted; none required interruption of treatment. There was no relation between HAQ and FFI evolution.**

***Conclusions*. Foot orthoses were effective as an adjuvant in the management of rheumatoid foot. They significantly reduced pain, disability and activity limitation, as measured by the FFI, with minor adverse effects.**

KEY WORDS: Orthoses, Rheumatoid foot, Foot function index, Rheumatoid arthritis.

The feet are one of the most important means of contact between man and his environment, and the maintenance of their function results in liberty and independence of locomotion. In rheumatoid arthritis (RA), there is a high prevalence of foot damage (more than 90% of cases) [1].

The forefoot, especially the metatarsal phalangeal (MTF) joints, is involved in the early stages of the disease, and pain at this site is one of the most common complaint of patients. Instability of these joints can also result in hammer toe deformity. Valgus deformity is common in the first MTF joint, which forces the lesser toes into lateral deviation. Changes in subtalar and talonavicular joints can result in loss of support for the talar head, forcing it to move in a plantar–medial direction, leading to an abducted forefoot position, valgus calcaneus deviation and flat-foot deformity. Involvement of the ankle joint and the tibial posterior muscle may contribute even more to these alterations [2, 3].

As a result of this damage, pain and foot deformity are serious problems in patients with RA. In the treatment of rheumatoid foot, orthoses have been used widely in order to improve joint support, relieve specific pressure points and provide wide distribution of weight with good stability and minimal pain [4]. Although this is a well-established practice among physicians, its efficiency has not been well evaluated in longitudinal studies [5].

The aim of this study was to evaluate a group of rheumatoid patients using foot orthoses, by using the foot function index (FFI) during a 6-month period.

Materials and methods

Subjects

Thirty-six rheumatoid patients from the arthritis clinics of the State University of Campinas (UNICAMP), satisfying the 1987 American Rheumatism Association revised criteria for RA, were eligible for this study [6]. The project was explained and subjects signed an informed consent form approved by the local ethics committee. The inclusion criteria were foot pain, age between 20 and 75 yr, and 1 month without the use of other foot orthoses. Patients were excluded if they had been diagnosed with a neurological or muscle disease or diabetes mellitus, if they had skin lesions (ulcers, dermatitis) or previous joint surgery in the lower limbs, and if they were unable to read and give the responses required by the FFI questionnaire.

At the first visit, all patients were examined, foot deformities and skin callosities were noted, and the main pain sites were located. Foot orthoses were then prescribed in accordance with each patient's needs. The orthoses were made of microrubber [ethyl-vinyl acetate (EVA)] in the Orthotics Prosthetics Unit of the State University of Campinas, and their purpose was supportive but not corrective. The following modifications were applied to each insole: for patients with flat foot, a medial arch support; for those with metatarsalgia or callosities under the metatarsal heads, a pad supporting the diaphysis of the second, third and fourth metatarsal bones; for those with pain in the plantar area of the heel, a soft local pad; for those with callosities on specific plantar surfaces or under bone pre-eminences, soft supports under these

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areas were used to reduce local overload. For very deformed feet, made-to-measure (MM) insoles were preferred. These were made from a plaster cast mould and, if necessary, with the modifications described above. The subjects were then instructed to use the insoles for brief periods of the day at the beginning of the study; when they felt more comfortable, with pain relief, they could use them for most of the day.

After the first evaluation, other visits were scheduled at 30, 90 and 180 days. At each appointment the patients reported the daily wearing time (h/day) and adverse effects. They were also asked to answer the FFI questionnaire.

The FFI consists of 23 items about the impact of foot impairments in three subscales: foot pain (FFI pain) (nine items), foot disability (nine items) and activity limitation (five items) [7]. In the Brazilian version of FFI, the original 100 mm visual analogue scale was changed to an analogue scale (0–10) to make it more comprehensive to the local population [8]. Each patient was asked to mark the number who best reflected his or her condition on each situation. To obtain a subscale score, the values of each item were totalled and divided by the number of items considered applicable by the patient. Calculating the average of the three subscale scores produced a total FFI score (FFI total).

The Stanford Health Assessment Questionnaire (HAQ) was administered at the first visit and it was used to evaluate the influence of physical condition on the patient's FFI response [9].

Statistical analysis

To analyse the impact of insole use on the FFI values during the study, analysis of variance for repeated measures was used. For comparisons between different times, profile analysis was used. Because of the absence of a normal distribution, the variables were transformed into ranks.

To investigate the influence of HAQ on the FFI results, we calculated Spearman correlation coefficients for HAQ and FFI differences between the initial visit and subsequent appointments.

For statistical analysis, we used the SAS System for Windows (Statistical Analysis System), version 6.12 (SAS Institute, Cary, NC, USA).

A significance level of $P<0.05$ was considered to indicate significance.

Results

Thirty-six patients fulfilled the criteria for entry into the study: 31 women and 5 men. Their age ranged from 32 to 68 yr (mean, 46.08 yr) with a mean disease duration of 11 yr (range, 1–34 yr).

Insoles were prescribed according to each patient's needs. For 28 patients, EVA-based insoles were indicated: in 21 cases, where metatarsalgia was the main problem, a metatarsal pad was used, with medial arch support when there was a flat foot (11 patients); in the other seven cases, hindfoot pain was the major complaint and medial arch support was used, in three cases with a heel pad because there was calcaneodinia.

For the remaining eight patients, with very deformed feet, we preferred to use MM orthoses with a plaster cast mould and medial arch support (five patients) and soft support under tender points (five patients).

Minor adverse effects were noted in the first month: heat foot (seven patients), tight shoes (three patients) and pain (one patient). None of them required interruption of the treatment. The patient with pain was using inappropriate shoes and felt more comfortable after using larger sized shoes.

Orthoses were worn on average for 7.14 h in the first month, without significant differences from other visits (6.53 and 6.94 h at 3 and 6 months, respectively; $P=0.228$).

Table 1. Values of the FFI index in patients with rheumatoid foot for the total group, patients using EVA orthoses and patients using made-to-measure (MM) orthoses

Variable	Mean (range)	s.d.	Median
Total group ($n=36$)			
FFI pain			
Initial visit	66.75 (20–94)	20.77	73.00
30 days	44.56 (4–81)	20.56	42.50
90 days	41.08 (4–84)	20.45	39.00
180 days	38.86 (0–81)	23.58	36.50
FFI disability			
Initial visit	66.91 (7.77–100)	24.44	74.50
30 days	51.81 (8–87)	25.44	50.00
90 days	45.75 (0–91)	26.95	40.00
180 days	41.00 (0–97)	26.51	35.50
FFI activity limitation			
Initial visit	53.33 (0–100)	31.97	60.00
30 days	41.64 (0–90)	29.72	41.50
90 days	30.92 (0–96)	30.35	24.50
180 days	31.06 (0–90)	30.70	21.50
FFI total			
Initial visit	62.33 (9–97)	23.75	67.83
30 days	46 (4–85)	23.59	44.00
90 days	39.25 (1–90)	23.59	37.00
180 days	36.97 (1–88)	25.31	24.33
EVA ($n=28$)			
FFI pain			
Initial visit	63.39 (20–92)	20.62	70.50
30 days	41.25 (4–81)	21.07	39.00
90 days	37.46 (4–80)	18.75	36.50
180 days	33.61 (0–78)	20.75	32.00
FFI disability			
Initial visit	62.56 (7–100)	24.61	71.50
30 days	46.54 (8–87)	25.05	43.00
90 days	38.14 (0–87)	24.31	33.50
180 days	34.75 (0–97)	24.41	30.50
FFI activity limitation			
Initial visit	48.21 (0–100)	32.83	51.50
30 days	35.21 (0–90)	28.46	29.50
90 days	24.43 (0–86)	28.46	15.00
180 days	23.14 (0–90)	28.96	11.50
FFI total			
Initial visit	58.06 (9–97)	23.95	66.17
30 days	41.00 (4–85)	22.95	38.83
90 days	33.35 (1–83)	21.68	27.50
180 days	30.50 (1–88)	23.25	22.17
MM ($n=8$)			
FFI pain			
Initial visit	78.50 (38–94)	17.70	84.50
30 days	56.13 (37–78)	14.25	55.50
90 days	53.75 (12–84)	22.31	52.50
180 days	57.25 (4–81)	24.94	67.00
FFI disability			
Initial visit	82.13 (45–96)	17.63	89.50
30 days	70.25 (37–85)	17.78	78.00
90 days	72.38 (42–91)	17.60	74.00
180 days	62.88 (20–85)	22.61	71.50
FFI activity limitation			
Initial visit	71.25 (36–96)	21.93	73.00
30 days	64.13 (22–86)	23.44	73.00
90 days	53.63 (14–96)	26.90	55.00
180 days	58.75 (33–80)	18.78	62.00
FFI total			
Initial visit	77.29 (44–95)	17.39	84.00
30 days	63.50 (33–82)	17.37	69.17
90 days	59.92 (36–90)	18.47	59.17
180 days	59.63 (22–77)	19.08	66.33

Table 1 shows the mean values of FFI pain, FFI disability, FFI activity limitation and FFI total scores for all the patients studied (total group) and for the patients using EVA or MM orthoses. When evaluating the results of the total group, it was noted that these values showed an early decline, in the first month

TABLE 2. Results of analysis of variance (ANOVA) for repeated measures for FFI indexes, for the total group and for patients using EVA or made-to-measure (MM) orthoses

Variable[a]	F statistic	*P*-value	Difference[b]
Total group ($n=36$)			
FFI pain	$F(3,105)=31.90$	**<0.001**	**T0 *vs* T30 ($P<0.001$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
FFI disability	$F(3,105)=23.66$	**<0.001**	**T0 *vs* T30 ($P<0.001$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
FFI activity limitation	$F(3,105)=16.48$	**<0.001**	**T0 *vs* T30 ($P=0.002$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
FFI total	$F(3,105)=30.85$	**<0.001**	**T0 *vs* T30 ($P<0.001$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
EVA ($n=28$)			
FFI pain	$F(3,81)=28.62$	**<0.001**	**T0 *vs* T30 ($P<0.001$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
FFI disability	$F(3,81)=19.90$	**<0.001**	**T0 *vs* T30 ($P<0.001$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
FFI activity limitation	$F(3,81)=15.01$	**<0.001**	**T0 *vs* T30 ($P=0.003$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
FFI total	$F(3,81)=27.02$	**<0.001**	**T0 *vs* T30 ($P<0.001$)**
			T0 *vs* T90 ($P<0.001$)
			T0 *vs* T180 ($P<0.001$)
MM ($n=8$)			
FFI pain	$F(3,21)=4.38$	**0.028**	**T0 *vs* T30 ($P=0.006$)**
			T0 *vs* T90 ($P=0.047$)
			T0 *vs* T180 ($P=0.07$)
FFI disability	$F(3,21)=4.67$	**0.021**	**T0 *vs* T30 ($P=0.104$)**
			T0 *vs* T90 ($P=0.206$)
			T0 *vs* T180 ($P=0.027$)
FFI activity limitation	$F(3,21)=1.87$	**0.188**	–
FFI total	$F(3,21)=4.18$	**0.018**	**T0 *vs* T30 ($P=0.052$)**
			T0 *vs* T90 ($P=0.055$)
			T0 *vs* T180 ($P=0.017$)

[a]Variables changed to ranks; [b]profile test; significant *P* values are in bold type.

after using orthoses, and that this improvement was maintained in the follow-up period. A similar outcome was seen in patients using EVA, whether the patients had metatarsalgia or hindfoot pain as their major complaint. For the group of patients treated with MM orthoses the results were worse, with an improvement in FFI pain, FFI disability and FFI total, but not FFI activity limitation (Table 2). Figure 1 shows the evolution of patients during the study. The EVA group (with metatarsalgia or hindfoot problems) presented almost an overlapping evolution, very similar to the total group. Unlike these patients, those using MM orthoses, with higher initial FFI values, had lesser reduction of the indexes.

The mean HAQ score was 1.29, ranging from 0.25 to 2.63, and there was no significant correlation between this score and the evolution of FFI in the group of patients studied (Table 3).

Discussion

Foot orthoses are commonly used in the management of patients with RA, with the intention of giving better joint support and preventing deformity, providing pain relief and reducing disability. Many strategies have been proposed, such as metatarsal pads or bars to relieve pressure and pain in the forefoot, and medial arch support to limit pronation by holding the subtalar joint in a neutral position [10, 11]. Nevertheless, a limited number of studies have been published regarding the efficacy of foot orthoses [5].

In this study, foot orthoses were effective in the management of rheumatoid foot. The evolution of FFI revealed significant reduction in pain, disability, activity limitation and total indexes for the patients using foot orthoses. This improvement was sustained during the whole trial. When studying only patients using EVA, we noted a similar evolution of FFI values for metatarsalgia and hindfoot complaints. Patients with MM orthoses presented worse results, with less improvement in FFI values, which were significant for pain and disability but not for activity limitation. In the small number of patients using this kind of orthosis, the presence of a more deformed foot and higher initial FFI values may explain the poorer results. Further study with a larger number of patients, including both mild and severe conditions, may confirm our findings.

In a randomized study of rheumatoid foot with correctable valgus deformity, Woodburn *et al.* [12] also found good results. During 30 months of follow-up, they observed reductions in FFI pain, FFI disability and FFI total indexes. However, when they considered FFI activity limitation, despite a tendency for the index to improve in the intervention group, there was no significant difference compared with the control group, without orthoses. As was the case in our study, this improvement was seen early in the follow-up and was sustained during all the trial, with minor adverse reactions. On the contrary, in a study comparing similar foot orthoses *vs* placebo, Conrad *et al.* [13] found no clinical benefit for the former. However, their subjects were atypical older male rheumatoid patients and the placebo orthoses used could have interfered in the final results.

When treating metatarsalgia, Chalmers *et al.* [14], in a blinded study with rheumatoid patients using supportive shoes alone *vs* supportive shoes with soft (Subortholen) or semirigid (Plastazote) orthoses, found significant MTP joint pain relief in a group using semirigid orthoses but not in others. This effect occurred in the first 6 weeks of treatment and was maintained throughout the trial. No functional improvement was found. Similar results were observed by Mejjad *et al.* [15], who verified pain relief without improvement in gait parameters in a group of rheumatoid patients with metatarsalgia using foot orthoses.

Craxford *et al.* [16], comparing surgery with conservative treatment, found significant pain relief with surgical shoes with total-contact Plastazote. In other studies, improvement of pain and function in rheumatoid patients has been obtained with footwear modifications [17, 18].

The good results obtained with the foot orthoses can be explained by a better distribution of pressure under the foot. Investigating the effectiveness of foot orthoses with metatarsal support, Hodge *et al.* [19] concluded that they could reduce pressure beneath the metatarsal heads and alleviate the patients' pain ratings. Li *et al.* [20] and Magalhães *et al.* [21] also found better redistribution of plantar pressure in rheumatoid feet using insoles.

In this trial we used foot orthoses according to each patient's needs. Kavlak *et al.* [22] used the same proceeding during a 3-month trial and also found significant differences in foot pain and function in their patients.

This was not a controlled study and we cannot rule out a placebo effect of the insoles. However, the long daily wearing time (about 7 h/day) and the maintenance of FFI improvement throughout the study (6 months) support a specific effect of the foot orthoses. It is also difficult to evaluate control groups in trials with foot orthoses. As suggested by Conrad *et al.* [13], the placebo orthosis may itself have an effect like that of a treatment orthosis. The use of a control group without treatment could also increase the number of patients withdrawing, or may be unethical.

The results of this trial and others published previously strongly suggest that foot orthoses are effective as an adjuvant treatment for rheumatoid foot. Also, they are readily available, adverse reactions

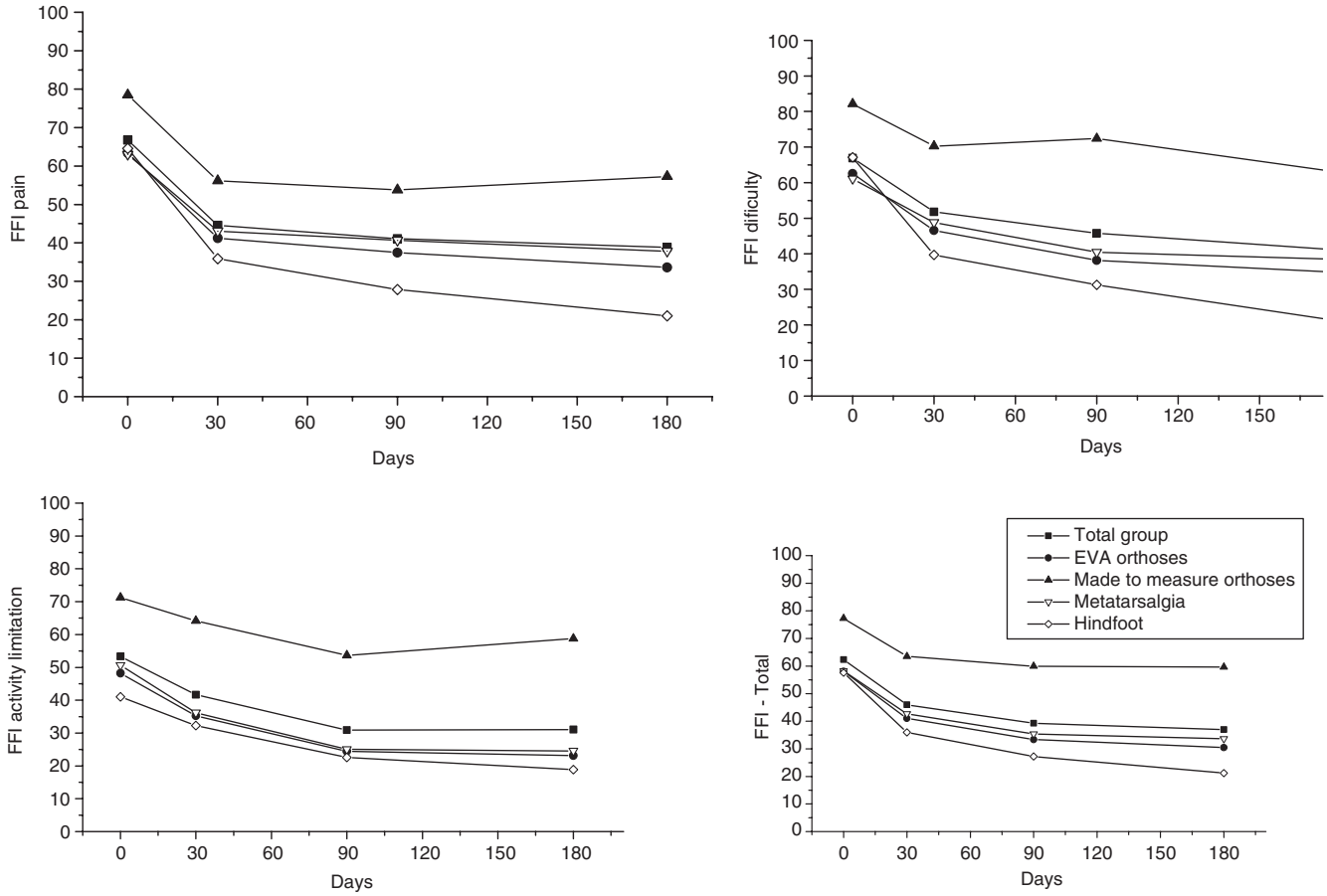

FIG. 1. Evolution of FFI scores after the use of insoles in the total group and in patients using EVA (with metatarsalgia or hindfoot problems) and made-to-measure (MM) orthoses. Note the early reduction in indexes in the first month and the maintenance of the reduction during 60 and 180 days for the total group and for those using EVA orthoses. The patients with MM orthoses had the poorer results.

TABLE 3. Correlation between HAQ and FFI

	30 days	90 days	180 days
HAQ *vs* FFI pain	$r = -0.17939$	−0.03197	0.10643
	$P = 0.2951$	0.8532	0.5367
HAQ *vs* FFI disability	$r = -0.04493$	0.10598	0.03170
	$P = 0.7947$	0.5384	0.8544
HAQ *vs* FFI activity limitation	$r = -0.22015$	−0.12730	−0.15450
	$P = 0.1970$	0.4594	0.3683
HAQ *vs* FFI total	$r = -0.14211$	0.00110	0.05582
	$P = 0.4084$	0.9949	0.7464

are minor, and they are well accepted by rheumatoid patients independently of their health status. Relief of pain may be their primary benefit, but they can also have an effect on disability. Studies regarding plantar pressure distribution and comparisons among different materials will provide more evidence of the benefits of foot orthoses and will improve their efficiency.

Physicians should always be able to identify causes of pain in rheumatoid foot and to prescribe foot orthoses with appropriate modifications in situations in which they could be helpful.

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