

**Foot Orthoses in the Management  
of Chronic Subtalar and Talo Crural Joint pain  
in Rheumatoid Arthritis**

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**Abstract**

**Background:** This **pilot** study investigated whether semi-rigid and soft orthoses had an effect on pain, disability and functional limitation in participants with chronic Rheumatoid hindfoot involvement.

**Methods:** Participants with chronic hindfoot pain were randomly assigned to 2 groups, commencing either with semi-rigid Subortholene orthoses or soft EVA orthoses. The Foot Function Index and the Ritchie Articular Index were administered pre- and post-intervention, which lasted for 3 months. Following a 2 week washout period, each group was switched over to the other type of orthoses.

**Results:** Nine female participants (Mean age 52.2yrs (SD 9.1); mean weight 71kg (SD 12.64); mean height 160cm (SD 5.18)) with a mean RA duration of 11.7years (SD 7.83), and a mean ankle/subtalar joint pain duration of 5.7years (SD 2.62), completed the programme. Mean improvement in FFI score for both orthoses resulted in the same statistical significance ( $p=0.001$ ). Statistically significant reduction in pain, disability and functional limitation was observed for both interventions, together with improvement in the Ritchie Articular Index score.

**Conclusion:** Both Subortholene and EVA orthoses significantly reduced pain, disability and functional limitations in participants with chronic ankle/subtalar joint pain in rheumatoid arthritis.

**Keywords:** foot orthoses; hindfoot rheumatoid disease; chronic ankle arthritis; foot function index

## Introduction

Rheumatoid Arthritis (RA) is a chronic systemic disease affecting predominantly synovial joints, often resulting in their progressive destruction through joint erosion and subsequent deformity [1]. RA affects around 90% of afflicted sufferers' feet, which have been found to be the most common reason for incapacity in patients with this disease [2], leaving a severe negative impact on mobility and functional capacity when this disease process begins to affect their feet [3]. Synovitis, with ingrowth of pannus and cytokines, causes destruction of joint cartilage that can lead to erosions [4] and resultant pain, which has a strong influence on functional ability [5].

In RA, involvement of the hindfoot has been quoted as being between 17% in a Swedish study [6] to 40% [7]. The resultant pain, functional loss and disability are difficult to manage [8], becoming in many instances significant sources of morbidity [9]. It appears likely that the subtalar and ankle joints are affected in the most severe form of the disease, with the subtalar joint being involved approximately 5 to 7 years prior to the talocrural joint [10]. The talus, a component common to both joints, is the single bone through which the whole body weight is channelled during walking (Laude, 2001). Abnormal alignment of the subtalar joint and mechanical stress have been attributed for many of the changes in the ankle in arthritis [11].

Patients living with RA need to be managed with drugs that carry potential risks of significant side effects in order to reduce joint destruction and consequent pain. However, in spite of the best medical management, significant foot problems persist, even when treated with biological therapies [12]. Unfortunately, besides drug therapy,

there are not many options for the management of painful ankles in RA except for surgical intervention. While arthrodesis reduces pain, it does not improve function since the addressed joint is surgically locked. Furthermore, results can often be disappointing [9], besides possible complications such as infection and non-union [13].

In arthritis, orthoses are indicated for a variety of reasons such as resting and stabilization of joints, reduction of pain and inflammation, to improve function and prevent deformity [14], being nowadays more widely accepted [15]. However, even though orthoses are used quite extensively in the management of the rheumatoid foot, there are few trials which investigate directly their effect on the RA hindfoot. In fact, studies have concentrated more on forefoot-related conditions [16]. This could possibly be due to the inherent problems in studying the hindfoot. It is quite difficult to identify subjects purely with hindfoot disease, because the forefoot is normally affected first. In a critical review of foot orthoses in the rheumatoid arthritic foot, Clark et al [17] argued that, although there is strong evidence that foot orthoses do reduce pain and improve functional ability, there is no consensus on the choice of foot orthoses used for the management of rheumatoid foot pathology, with types of orthoses ranging from rigid devices to simple cushioned insoles. Hennessy et al [18] report weak evidence for custom orthoses reducing pain and forefoot plantar pressures, while evidence was inconclusive for foot function and other gait parameters. They concluded that although custom orthoses may be beneficial, more definitive research is required in this area.

Foot orthoses can be assessed utilizing several methodologies, including patient satisfaction, pain and deformity, plantar pressure, position and motion, muscle activity and oxygen consumption [19]. Pain is used as a primary outcome measure in many such studies because it is the reason most patients seek treatment and for which practitioners prescribe orthoses [20]. The Foot Function Index (FFI) is indicated for the assessment of treatment outcomes in rheumatology [21] and has been used in a number of trials involving the assessment of orthoses in rheumatoid feet. SooHoo et al [22] performed a study which demonstrated increased responsiveness of foot and ankle specific outcomes tools compared to the SF-36. De P Magalhaes et al [23] utilized the FFI to evaluate the effectiveness of foot orthoses in a group of patients with RA over a period of 6 months, concluding that foot orthoses were effective as an adjuvant in the management of the rheumatoid foot.

Woodburn, Barker and Helliwell [24] utilized the Foot Function Index and 3D kinematics, kinetics and plantar pressure distribution to establish that custom-manufactured foot orthoses are indicated in *early* hindfoot deformity in RA. The orthoses lessened foot-related pain, disability and functional limitation. Cameron-Fiddes concluded that patients diagnosed with early RA may benefit from using off-the-shelf foot orthoses with the majority of their pain reduction occurring within the first 3 months of use [25]. However, following an extensive literature search, there is a clear paucity of information regarding trials aimed at investigating advanced hindfoot disease.

Subtalar and ankle joint alignment and stress are determinant factors in hindfoot disease. It is possible that the reduction of stress and possibly the realignment of these

joints, whenever possible, through the use of orthoses, would be beneficial in reducing pain, disability and functional limitation for the afflicted patients. Hence the aim of this study was to determine whether two types of orthoses - semi-rigid Subortholene and soft ethylene vinyl acetate (EVA) orthoses - are effective in reducing pain, disability and functional limitation in patients with chronic ankle joint complex involvement in RA. This study would additionally provide information about two types of orthoses that may be used for the management of the painful hindfoot in RA.

### **Method**

Ethical approval was sought and obtained from the University Ethics Committee. A prospective, experimental crossover design was employed for this study, in which two interventions (semi-rigid and soft Orthoses) were applied sequentially to the same participants in random order. This had the advantage that each participant acted as his own control, thus a smaller sample size would be required [26].

Adult participants (aged 18years and over) living with chronic Rheumatoid Arthritis diagnosed by a consultant rheumatologist were included. The chronicity factor was a common feature amongst participants since hindfoot involvement is known to occur in advanced disease. As inclusion criteria, all participants exhibited subtalar and/or ankle joint pain of at least 6 months' duration and required orthoses for biomechanical mal-alignment of the feet as per clinical practice. Participants were also required to have the ability to read unhindered in order to be able to independently complete the presented questionnaire.

Participants were excluded if they had foot pain other than subtalar/ankle pain, were in a flare, had a change of treatment during the trial period, were unable to read, had a history of foot surgery or had trauma to the foot during the trial period.

Twenty-one patients attending a Rheumatology Outpatient clinic at a General Hospital, medically confirmed to be suffering with RA and who presented with subtalar and/or ankle joint pain were identified as potential participants for the trial. These were reduced to 10 because of the exclusion criteria adopted, the main criteria of which was that they only had to suffer from hindfoot pain without coexisting forefoot involvement. Thus eleven patients were excluded mainly because they presented with such concurrent foot pain.

Out of the remaining ten who started the trial, another participant had to be excluded half way through the trial because she developed a rheumatoid flare, for which she was prescribed steroid and Disease Modifying Anti-Rheumatic Drug Therapy, thus invalidating her as a participant.

### **Casting**

In order to ensure consistency, all the casts were taken and then modified by the same investigator (AG), who had fifteen years' experience in this method of casting and orthotic manufacture.

A standard plaster of Paris suspension cast was taken with the patient prone and the feet over the edge of the couch. Where necessary, a towel was placed under the hip on

the side of the foot which was being casted to ensure that the foot was maintained in a straight position by rotating it internally. **The manufacture of the orthoses followed normal procedures as would be employed in the clinic. These were constructed following a detailed biomechanical examination in which the range of motion of the joints of the foot, most notably that of the subtalar joint, were assessed and measurements at Neutral Calcaneal Stance Position and Resting Calcaneal Stance Position determined the amount of rearfoot posting that was incorporated into the orthoses.**

Since the majority of participants were in an advanced state of RA, with limited range of motion of the joints, a pronated cast was taken [27, 28]. This has often been quoted as being the best method for managing the arthritides since, if the foot is rigid, it is inappropriate to attempt to position it in any particular orientation [28].

### **Orthoses**

All the orthoses were manufactured by the same person in order to ensure a standard device. The positive casts were modified as outlined by Philips [29]. Following the necessary positive model modifications, two different types of orthoses were manufactured simultaneously over the same cast for each participant. The materials utilized were 3mm Subortolene (Tuefel GmbH, Frankfurt, Germany) and low-density (Shore A25) Etylene Vinyl Acetate (EVA) (Algeos Ltd, Liverpool, UK). For descriptive purposes, these interventions were termed Condition 1<sub>Subortolen</sub> and Condition 2<sub>EVA</sub>.

It had been determined beforehand to start five subjects with Condition 1<sub>Subortolen</sub> and the other five with Condition 2<sub>EVA</sub> to offset any carryover effect that might occur

during the trial. The condition was assigned randomly to each subject using the *raffle method* [30].

The orthoses were dispensed as per normal clinical practice. Each participant was advised to start using the orthoses in appropriate footwear, initially just for two hours, and then to gradually increase wearing time each day until they could be worn comfortably for most of the day [29]. If for any reason there was a problem with fitting, the participant had to contact the investigator for any necessary minor adjustments.

Each intervention lasted for 3 months, with a two week period for washout in between [20]. Thus, if a participant started with Condition 2<sub>EVA</sub>, she then continued with Condition 1<sub>Subortolen</sub>, and vice versa for the other participants (AB/BA).

At the start and end of each intervention, the Foot Function Index [31] and Ritchie Articular Index (RAI) [32], were applied to each participant. Although the FFI is foot specific, it does not differentiate from pain in different areas of the foot - eg. forefoot from rearfoot pain. Thus if a subject had pain located in any areas of the foot other than those under observation, the FFI would not be able to make allowances for this and the results would not reflect the actual pain condition specifically for the hindfoot. Hence, particular attention was given to subject selection, ensuring that only subjects with hindfoot pain were included, so as not to invalidate the study.

The RAI is used solely or in conjunction with other indexes to measure efficacy of treatments in RA by recording joint tenderness [32, 33]. When assessing the RAI for the ankle, the finger of the examining hand was placed between the extensor hallucis

longus and extensor digitorum longus tendons at the level of the malleoli, followed by the application of pressure until blanching underneath the nail of the investigator was observed (in order to apply a consistent amount of pressure as required by the RAI). For assessment of the subtalar joint, the ankle joint was fixed anteriorly with the supporting hand, then the index and middle fingers and thumb of the examining hand were placed on either side of the subtalar joint. This was then moved through inversion and eversion of the calcaneum by 5° to 10°, depending on the range of movement available at the joint [32].

The participants' responses were then tabulated accordingly; with 0 for no pain, +1 for *Tender*, +2 for *Tender and Winced* and +3 for *Tender, Winced and Withdrew* [33].

An important aspect of the whole study design was the determination that no *carryover effect* was present, which would invalidate the results since one would not be able to determine which part of the second result would be due to the second intervention itself and which part to attribute to the first intervention. To eliminate this possibility, a 2 week *washout* period was implemented, as is normal practice in crossover designs.

## **Results**

Nine female participants (mean age 52.2yrs (SD 9.1); mean weight 71 kg (SD 12.64); mean height 160cm (SD 5.18)) completed the whole programme. Participants had a mean RA duration of 11.7 years (SD 7.83), with a mean ankle/subtalar joint pain duration of 5.7years (SD 2.62).

Testing for *carryover effect* (defined as the possible effect from the first intervention on to the second intervention) was achieved by grouping the first pre-intervention scores together (i.e. 5 subortholen and 4 EVA) and the second pre-intervention scores together (i.e. 4 subortholen and 5 EVA), then testing with the One-Sample Kolmogrov-Smirnov Test, which revealed a normal distribution. Consequently a paired t-test was performed, which showed that there were no statistically significant differences between the two groups ( $p=0.726$ ).

Statistical analysis was performed on the pre-intervention and post-intervention results. Pre- and post-intervention pain results for each participant for Subortholene and EVA are presented in figures 1 and 2 respectively. Mean pre- and post-intervention FFI results for pain, disability and functional limitation, together with Mean FFI Scores for Subortholene and EVA are presented in Tables 1 and 2. Paired t-test analysis scores for Subortholene Orthoses resulted in a statistically significant difference ( $p=0.002$ ). EVA Orthoses were similarly tested, also yielding statistically significant results ( $p=0.009$ ).

Mean FFI score (the mean of all 3 variables added together) for Subortholene and EVA Orthoses resulted in the same statistical significance of  $p=0.001$ . There was a reduction of pain in both instances – with a pain reduction of 40.4% and 39.2% for Subortholene and EVA respectively.

The other two criteria of the FFI – Disability and Functional Limitation – also exhibited significant improvement, with disability reduced by 24.7% and 33%, while

Functional Limitation scores were also reduced by 41.5% and 48.5% for Subortholene and EVA respectively.

An improvement in the RAI score for Subortholene Orthoses of 54% was recorded, with the paired t-test analysing these scores before and after intervention yielding  $p=0.001$ . Likewise, same statistical test for EVA Orthoses, RAI score improvement resulted in  $p=0.004$ . Pre- and post-intervention RAI scores are presented in Table 3.

### **Discussion**

Although advanced hindfoot disease in RA is a difficult condition to manage, there have been no significant recent studies on the effectiveness of orthoses on chronic talocrural and subtalar joint pain, disability and functional limitation in this condition. Most studies in fact concentrated on forefoot pain and kinematics. The lack of such trials has been specifically attributed to a difficulty arising from subjects' inability to differentiate between subtalar and ankle joint pain [16]. In order to circumvent this problem, and since the subtalar and ankle joints are interdependent, with the talus being a common component, this study was devised to include both joints (often termed the 'ankle joint complex') so that participants did not have to differentiate between pain in either of the two joints which comprise the hindfoot.

This study explores the possibility of providing an adjunct, non-pharmacological treatment modality for the painful ankle joint complex, which is most often affected in advanced disease. All participants had been on powerful immunosuppressants, steroids and non-steroidal anti-inflammatory drugs for the management of their condition. Notwithstanding this, however, they were still under considerable pain, as

evidenced by their FFI scores, for a mean duration of 5.7 years as determined by their medical history and interview. Certainly, this condition had become chronic, with these patients requiring another modality of treatment besides pharmacological management which, undeniably, carries potentially severe side effects. Since such prolonged drug therapy is likely to affect quality of life, a supplementary management modality such as orthoses would become necessary.

A reduction in pain might mean a reduction in intake of drugs and hence reduced side-effects, with consequent improvement in patients' quality of life. Furthermore, if drastic surgery, such as arthrodesis, can be prevented or at least delayed or the problem accommodated during long surgical waiting lists, orthoses would become an attractive option in the management of painful rheumatoid ankles.

For each intervention, pain was assessed before and after wearing the orthotic for 3 months. There was a clear reduction of pain in both instances – with a pain reduction of 40.4% and 39.2% for Subortholene and EVA respectively. It can be deduced, however, that the pain had not disappeared completely after 3 months' use of the orthoses. Their longer term effect, unfortunately, has not been assessed in this trial.

**Possibly 3mm subortholene and low-density EVA offered the same amount of control on the talo-crural joint. This was further ensured as both orthoses were manufactured simultaneously over the same cast, thus ensuring the same amount of posting applied.**

The non-coincidental effect of orthoses on pain can be further demonstrated by the fact that, when the first set of devices was stopped, the participants reverted back to their previous pain levels, which was again reduced upon the introduction of the second type of orthoses.

The small sample size is a limitation of this study. However, with the strict inclusion/exclusion criteria, it became quite difficult to recruit the right participants and indeed 11 prospective participants had to be excluded for various reasons. Nonetheless, the highly statistically significant results attained throughout the study clearly demonstrate that in this case the sample size was sufficient. **Nonetheless, this pilot study should inform the design of a larger study given the optimal results obtained.**

Summation of the scientific data arising out of this trial indicates that orthotic intervention in hindfoot pain in RA produced a significant improvement in participants' pain scores, lessened disability, reduced functional limitation, reduced the overall FFI score and the RAI score. Notwithstanding this, however, participants' pain reduction was not complete.

These findings indicate that orthoses could be a management option that should be taken in consideration when RA patients present with ankle/subtalar joint pain that often may produce significant disability and functional limitation.

## **Conclusion**

Both Subortholene and EVA orthoses significantly reduced pain, disability and functional limitations in participants with chronic ankle/subtalar joint pain in rheumatoid arthritis. Either type of orthoses should be considered as an adjunct to pharmacological treatment of patients with painful chronic ankle joint complex in RA.

### **Figures legends**

**Figure 1:** Mean pre- and post- intervention FFI Subortholene Scores

**Figure 2:** Mean pre- and post-intervention FFI EVA Scores

### **Tables:**

**Table 1:** FFI Scores Subortholen Orthoses

**Table 2:** FFI Scores EVA Orthoses

**Table 3:** Ritchie Articular Index Scores for both types of Orthoses Pre and Post Intervention

### **Conflict of Interest declaration**

The authors declare that they have no competing interests

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	Pre-Intervention		Post-Intervention		p-value
	Mean	ST Dev	Mean	St Dev	
<b>Pain</b>	44.33	15.24	25.42	11.08	0.002
<b>Disability</b>	51.697	18.21	33.761	10.59	0.003
<b>Activity Limitation</b>	15.98	12.15	9.35	7.46	0.024
<b>FFI Score</b>	37.34	11.79	22.84	8.04	0.001

**Table 1: FFI Scores Subortholen Orthoses**

	Pre-Intervention		Post-Intervention		p-value
	Mean	ST Dev	Mean	St Dev	
<b>Pain</b>	44.36	19.94	26.94	12.08	0.009
<b>Disability</b>	54.10	15.19	36.06	10.72	0.001
<b>Activity Limitation</b>	19.31	12.47	9.95	6.32	0.007
<b>FFI Score</b>	39.27	12.47	24.19	7.89	0.001

**Table 2: FFI Scores EVA Orthoses**

<b>Condition 1<sub>subortholen</sub></b>			
	<b>Pre intervention</b>	<b>Post intervention</b>	<b>Difference (improvement)</b>
<b>MEAN</b>	6.78	3.11	3.67
<b>SD</b>	3.46	1.90	
<b>Condition 2<sub>EVA</sub></b>			
<b>MEAN</b>	6.22	4.00	2.22
<b>SD</b>	2.99	2.55	

**Table 3: Ritchie Articular Index Scores for both types of Orthoses Pre and Post Intervention**

## Brief Summary

### What is known:

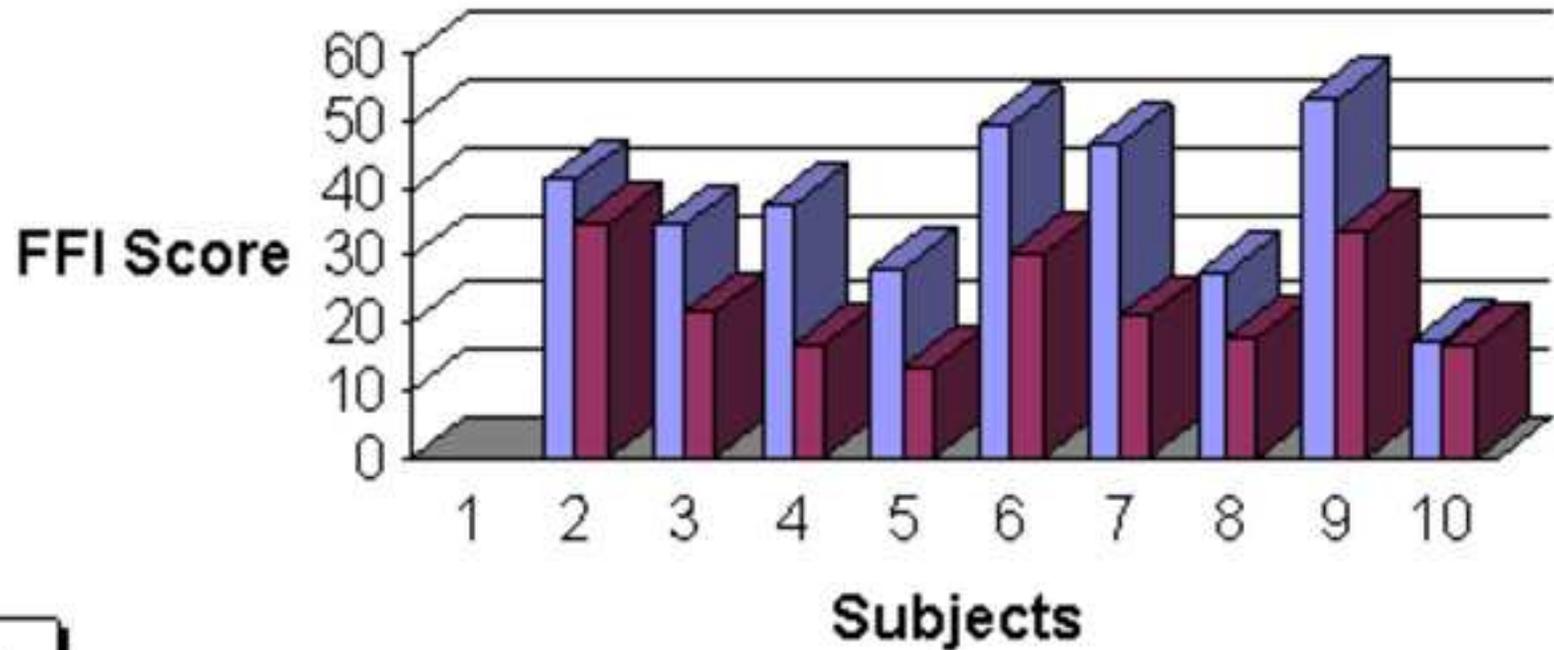
- In Rheumatoid Arthritis, involvement of the hindfoot may be up to 40%
- Chronic ankle joint complex disease causes significant pain, functional limitation and disability
- subtalar and ankle joints are affected in the most severe form of the disease, with the subtalar joint being involved approximately 5 to 7 years prior to the talocrural joint

### What this study adds:

- Both Subortholene and EVA orthoses significantly reduced pain, disability and functional limitations in participants with chronic ankle/subtalar joint pain in rheumatoid arthritis.
- Either type of orthoses should be considered as an adjunct to pharmacological treatment of patients with painful chronic ankle joint complex in RA.
- A reduction in pain might mean a reduction in intake of drugs and hence reduced side-effects, with consequent improvement in patients' quality of life.

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### Mean FFI Scores Pre & Post Intervention



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