Metatarsalgia and Rheumatoid Arthritis — A Randomized, Single Blind, Sequential Trial Comparing 2 Types of Foot Orthoses and Supportive Shoes

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ABSTRACT. ***Objective.*** To compare the effects of semi-rigid and soft orthoses worn in supportive shoes, and supportive shoes worn alone, on metatarsal phalangeal (MTP) joint pain, MTP joint synovitis, and lower extremity function in patients with rheumatoid arthritis.

Methods. Twenty-eight subjects referred to occupational therapy received in random order 3 interventions for 12 week trials, separated by 2 week washouts. A crossover design compared effectiveness of interventions.

Results. Twenty-four subjects completed the study. A reduction in mean pain scores from baseline to final visits showed that semi-rigid orthoses had a highly significant effect on pain. Soft orthoses did not show a significant effect on pain from baseline to final visit, nor did shoes worn alone. None of the interventions had a significant effect on synovitis or function.

Conclusion. Semi-rigid orthoses worn in supportive shoes were an effective treatment for metatarsalgia. Supportive shoes worn alone or worn with soft orthoses did not provide pain relief for metatarsalgia. (J Rheumatol 2000;27:1643–7)

Key Indexing Terms:
FOOT ORTHOSES
RHEUMATOID ARTHRITIS
METATARSALGIA
SUPPORTIVE SHOES

Rheumatoid arthritis (RA) has a reported prevalence of foot problems as high as 90%[1,2]. In a review of 200 patients with chronic RA, 67% had subluxation of the metatarsal phalangeal (MTP) joints[3]. Chronic inflammation of the MTP joints causes capsular distension, laxity of supporting structures, cartilage destruction, and eventual subluxation. Resultant migration of the distal fat pad leads to loss of cushioning and development of plantar callouses[4,5]. Instability of the hindfoot and midfoot may contribute to pain and deformity in the forefoot, by allowing increased medial motion[4,6], which prevents the foot from locking into a rigid lever necessary for push off.

In the Occupational Therapy Department of the Mary Pack Arthritis Centre, metatarsalgia secondary to RA was initially treated using soft orthoses. Since the 1970s, supportive shoes worn with firmer orthoses have been routinely prescribed to support and control the subtalar, midtarsal, and MTP joints. Various semi-rigid materials have been used such as sterane®, polyethylene, subortholen®, and polypropylene. In 1986, we surveyed 39 arthritis treatment programs in North America to ascertain the type of orthosis used most often to treat metatarsalgia. Of the 13 respondents, two-thirds used soft orthoses most frequently.

We compared the effect of semi-rigid and soft orthoses worn in supportive shoes, and supportive shoes worn alone, on MTP joint pain, MTP joint synovitis, and lower extremity function.

MATERIALS AND METHODS

The dependent variables, MTP joint pain, MTP joint synovitis, and lower extremity function, were identified by staff occupational therapists using the Delphi technique[7] to reach a consensus. Pain was identified as the primary outcome because it is the reason most clients seek treatment and the symptom for which therapists most often prescribe orthoses.

In a 1989 pilot study to evaluate methodology, sample size, and outcome measures, 11 subjects were randomly assigned one intervention for a 12 week trial. Due to the magnitude of change in pain, the primary outcome, the sample size calculation indicated that 25 subjects would be sufficient to identify a change of 33% on the pain scale at a 2 sided significance level of 5% and with a power of 80% in a crossover design.

Subjects. Subjects recruited from occupational therapy (OT) referrals had a diagnosis of RA using American College of Rheumatology criteria[8], were more than 18 years of age, had a minimum of 2 subluxed MTP joints bilaterally, and had MTP joint pain as their most significant foot problem.

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Supported by grants from B.C. Health Research Foundation and Vancouver Foundation.

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Submitted June 28, 1999; revision accepted December 24, 1999.

Exclusion criteria were midtarsal pain with passive motion and on weight bearing; prior foot surgery, except hallux valgus correction; an unstable medication regimen; impaired mental status and/or poor English comprehension. Concurrent foot treatment was not permitted except regularly scheduled podiatric skin and nail care. Subjects using foot orthoses or shoe adaptations were required to stop their use and participate in a 2 week washout.

Approval to conduct the study was received from the Ethics Committee of the University of British Columbia and the Research Committee of The Arthritis Society. Subjects were screened by a rheumatologist and an OT, and then signed consent forms. Data collection occurred over 6 years. Slow recruitment was attributed to stringent exclusion criteria requiring stability of medications and the need for discontinuation of previously worn orthoses.

Design. Each subject was randomized to a sequence of three 12 week trials, separated by 2 week washouts. Assessments were done at the beginning, midterm, and final visit of each trial by designated OT who were blinded to the interventions. All assessments occurred at about the same time of day. Entry baseline data were collected twice over 2 weeks, and then averaged.

There were 3 interventions: supportive shoes worn alone, supportive shoes worn with soft orthoses, and supportive shoes worn with semi-rigid orthoses. All interventions were provided at no cost. Participating OT had at least 2 years' experience in arthritis care. They supervised the shoe fitting and fabricated the orthoses according to clinical protocols.

Extra-depth shoes, made by the P.W. Minor or Drew Co., priced at roughly $220.00 Cdn, were provided. They were selected because of their high, firm heel counter; heel height of 1.5 to 2.0 cm; instep lacing, wide, deep toe box; and thick, composite sole. This type of footwear accommodates an orthosis and helps to maintain the neutral alignment of the foot.

The semi-rigid orthoses were made from 3 mm subortholen® (Sub), on casts taken in a non-weight bearing position. The distal end of the subortholen followed the line of the metatarsal heads and ended just proximal to them. Underlying forefoot and hindfoot nickleplast posts were attached. A full length leather liner, cushioned under the forefoot with 1/8 PPT® foam®, was added. This type of orthosis costs $115.00 Cdn per pair.

The soft orthoses were formed by the subject standing on preheated 1/4" low density plastazote® (Plas) and extended the full length of the foot. Medium density 1/4" plastazote metatarsal lifts were added to the underside. These orthoses were priced at $35.00 Cdn per pair.

Adjustments to the orthoses were completed within 2 weeks. Subjects were asked to record their daily wearing time and use of other footwear in a log book.

Outcome measures. Pain was measured using a 10 cm horizontal visual analog scale (VAS), anchored by "no pain" and "pain as bad as it can be"[10,15].

The joint count method of the Cooperating Clinics of the ARA was used to assess lower extremity joint synovitis[16]. It was administered by the rheumatologist during screening and by an OT assessor at each trial sequence.

Lower extremity function was measured using the ambulation section of the Robinson Bashall Functional Assessment (RB), consisting of standing, walking, and stair climbing scales[17,18] and the walking and stair climbing components of the Toronto Activities of Daily Living Measure (TADL)[19]. Fifty foot walking time was also recorded[20].

A 10 cm VAS was used to record subjects' impression of treatment effectiveness at the midterm and end of each intervention. At their last visit subjects completed a treatment preference questionnaire ranking the interventions including "no treatment." They repeated this ranking considering the price of each intervention.

To detect material compression over time, the thickness of the forefoot portion of the orthoses was measured using a Teclock® dial gauge that measures to 0.01 mm. At each assessment 2 specific points were measured, directly under the 3rd metatarsal head and 2 cm proximal to it.

Statistical methods. The 3 treatments were compared by means of a crossover design. Patients were assigned at random to one of 6 possible sequences, using a Latin square balanced for carryover effects[21]. Potential carryover effects were further minimized by introducing a 2 week washout period between successive treatments. Analysis of variance (ANOVA) was carried out to compare treatment effects, testing as well for carryover and period effects[21]. Analysis of covariance was used to adjust for entry baseline levels and again for baseline levels at the start of each intervention, and results were compared with those of the ANOVA unadjusted for baselines. Duncan's method was used to adjust for multiple comparisons[22].

To investigate the effects of duration of treatment on the various outcomes measured, repeated measures ANOVA were employed, using data at the start, midterm, and completion of each 12 week intervention.

Regression analysis was employed to relate the amount of log book wearing time to final visit pain scores and subjective assessment of the effectiveness of each intervention. Multiple regression related pain scores to change in orthosis thickness, adjusted for body weight.

Subjects' impressions of treatment effectiveness were compared by means of ANOVA. Similar analyses were carried out on mean pain scores in comparison with corresponding treatment preference and on the comparison of treatment preference with age, lower extremity functional level, and ankle or subtalar joint involvement.

RESULTS

Twenty-eight subjects started the study. Four withdrew before its completion: one moved away, 2 had medical complications, and one died. Of the 24 that completed the study, 2 subjects stopped the shoe trial early and one stopped the plastazote trial early, at which point assessments were done and scores carried forward. Twenty-one subjects were women with a mean age of 60 ± 10 (SD) years and 3 were men with a mean age of 63 ± 2 years. The average duration of their disease was 15 ± 9 years. Their mean body weight was 154 ± 46 lb. On entry, they had a mean of 7 MTP joints with synovitis and 8 with subluxation.

The mean pain scores at final visits, not adjusted for baseline, showed subjects had significantly less pain when using subortholen (mean 3.02) than when using shoes alone (mean 4.92) ($p = 0.013$). Scores for plastazote (mean 4.0) were indistinguishable from both. When adjusted for differences in baselines at the start of each intervention, the mean pain scores at final visits showed a significant difference in the 3 treatments ($p = 0.006$), with the difference lying between subortholen and plastazote, and subortholen and shoes. There was no significant difference between plastazote and shoes (Table 1).

Table 1. Mean pain scores.

	Subortholen (SD)	Plastazote (SD)	Shoes (SD)
Baseline	4.89 (2.37)	4.00 (2.15)	4.86 (2.58)
Midterm	2.99 (2.23)	3.66 (2.43)	4.32 (2.92)
Final (unadjusted)*	3.02 (2.00)	4.00 (2.37)	4.92 (2.82)
Baseline–final difference**	1.87 (2.20)	0.01 (2.49)	–0.05 (2.7
Final adjusted for baseline***†	2.88 (SE 0.44)	4.27 (SE 0.45)	4.79 (SE 0.

*$p = 0.013$ comparison across treatments, subortholen (Sub) significantly different from shoes. **$p = 0.027$ comparison across treatments, Sub significantly different from plastazote (Plas) and shoes. ***$p = 0.006$ comparison across treatments, Sub significantly different from Plas and shoes. †Adjusted for baseline value by analysis of covariance[21].

When pain scores were analyzed over time, the mean pain scores for suborthotlen showed a highly significant effect from baseline (mean 4.89) to final visit (mean 3.02) ($p = 0.0004$). This effect was achieved during the first 6 weeks of the trial. Over time, the mean pain scores for plastazote orthoses and supportive shoes worn alone did not show significant change. When compared across treatments, the change in pain for suborthotlen was significantly different from the change that occurred with both plastazote and shoes alone ($p = 0.027$) (Table 1).

None of the interventions showed a significant effect on MTP joint synovitis or lower extremity function, from baseline to final visit (Table 2).

The treatment effectiveness VAS rated suborthotlen (mean 6.87) as significantly more effective than shoes alone (mean 4.86) ($p = 0.035$). Plastazote ranked in the middle (mean 6.00) and was not statistically distinguishable from either.

Mean "daily wearing time" for suborthotlen was 6.15 h (SD 2.32), for plastazote 5.89 h (SD 2.36), and for shoes alone 5.79 h (SD 2.53). Regression analysis showed no significant correlation between the amount of pain and the amount of time subjects wore the intervention. However, there was a significant correlation between treatment effectiveness VAS and wearing time for suborthotlen orthoses ($r = 0.52$, $p = 0.01$). No corresponding correlation was found for shoes or plastazote orthoses.

Repeated measures analysis showed that both types of orthoses had statistically significant material compression ($p < 0.002$). From baseline to final visit, the mean compression of suborthotlen was 0.04 cm under the 3rd MT head and 0.07 cm at the point 2 cm proximal to it. During the same period, plastazote compressed 0.28 cm and 0.27 cm, respectively. For both types of orthoses, no correlations were seen in pain, body weight, and material compression.

On the treatment preference questionnaire, 11 subjects chose suborthotlen, 11 chose plastazote, 2 chose no treatment, and no one chose shoes alone. The group who chose "no treatment" was not analyzed due to small sample size. The subjects who chose plastazote had similar mean pain scores during both their suborthotlen (mean 3.13) and plastazote trials (mean 2.95). However, the subjects who chose suborthotlen had significantly more pain when wearing plastazote (mean 4.79) than when wearing suborthotlen (mean 3.11) ($p = 0.002$) (Table 3). The price of the orthoses was not a factor in treatment preference. Patient preference did not correlate with age, lower extremity functional level, or ankle/subtalar joint involvement.

Table 3. Mean pain scores for treatment preference groups.

	Prefer Suborthotlen (SD), n = 11	Prefer Plastazote (SD), n = 11
Mean pain wearing suborthotlen	3.11 (1.62)	3.13 (2.34)
Mean pain wearing plastazote	4.79* (1.71)	2.95 (2.08)

*p = 0.002 vs mean pain wearing suborthotlen.

DISCUSSION

An early literature review found several descriptive articles and a retrospective survey on the conservative management of metatarsalgia, but no randomized controlled studies. Various authors recommended external metatarsal (MT) bars, internal MT pads, orthoses, and extra depth or molded shoes[5,23,37]. These measures are designed to relieve pain by transferring weight bearing from the metatarsal heads, absorbing shock, reducing shearing forces, and accommodating deformity[29,32,36]. A survey in 1982 compared surgical and conservative treatment for metatarsalgia secondary to RA. Of the 27 subjects in the conservative group, 74% reported relief from shoes modified with foam orthoses[38].

A more recent review found 3 studies that examined the effect of shoes or orthoses on lower extremity pain and func-

Table 2. Mean lower extremity function and joint synovitis scores at baseline and final visits.

	Suborthotlen (SD)		Plastazote (SD)		Shoes (SD)	
	Baseline	Final	Baseline	Final	Baseline	Final
RB walking, s	88.2 (17.5)	86.9 (21.4)	83.5 (21.0)	88.9 (19.6)	86.1 (21.0)	86.3 (19.9)
RB stairs, s	92.8 (8.2)	92.4 (11.3)	92.0 (10.7)	91.6 (11.0)	90.9 (15.6)	90.9 (11.9)
RB stand, s	576.3 (77.1)	561.1 (100.5)	538.7 (146.7)	570.4 (86.5)	556.6 (113.3)	556.8 (131.1)
TADL walking	7.1 (0.90)	7.0 (1.08)	7.0 (0.98)	7.0 (1.11)	6.9 (1.15)	6.9 (1.15)
TADL stairs	5.0 (0.20)	5.0 (0.20)	5.0 (0.00)	5.0 (0.21)	5.0 (0.20)	5.0 (0.21)
TADL sub walk	*	3.7 (1.01)	*	3.4 (1.12)	*	2.8 (1.30)
50' walking, s	14.1 (3.84)	14.1 (4.3)	14.4 (3.88)	13.9 (4.0)	14.6 (4.87)	13.9 (4.1)
Lower extremity joint count	17.5 (7.66)	14.9 (7.90)	14.7 (8.71)	15.1 (8.66)	17.3 (7.94)	17.5 (8.7)
MTP joint count	7.7 (2.66)	7.0 (2.9)	6.1 (3.43)	7.0 (3.0)	7.3 (2.80)	7.2 (3.0)

No significant difference in scores at final visits.
RB: Robinson Bashall Functional Assessment. TADL: Toronto Activities of Daily Living Measure.

tion in subjects with RA. In 1990, Moncur and Ward[24] provided heat moldable shoes to 25 subjects. All subjects reported increased comfort and 80% reported improved walking. There was no control group and outcome measures were based on self-report. In 1996, Conrad, *et al*[39] studied the effect of rigid and placebo orthoses on foot pain and disability. Their sample was atypical of RA, as it consisted of men without foot deformity despite long disease duration. No treatment effect was found, perhaps due to lack of control of footwear and medical regimen, and a possible treatment effect from the placebo. In addition, the Foot Function Index[40], one of the measures used to record foot-specific pain and disability, was not introduced until the 2nd year, by which time a treatment effect may have occurred. In a 1997 controlled trial studying the effect of extra depth shoes on chronic foot pain in RA, Fransen and Edmonds[41] reported improvement in pain, function, gait velocity, and stride length. However, investigators were not blinded and concurrent use of orthoses was not controlled. Their design was unconventional, as the control group became an experimental group in the latter part of the study. In contrast, our study used blinded assessors and a sample typical of most described RA populations. We also controlled for change in medical regimen and other concurrent foot therapy.

We found subortholen orthoses had a highly significant effect on MTP joint pain, the primary outcome, with a 38% reduction in pain exceeding our expectation of 33%. This effect, which we believe is clinically significant, occurred in the first 6 weeks and was maintained throughout the trial. Neither plastazote orthoses nor supportive shoes showed a statistically or clinically significant effect on pain. Moreover, 2 subjects, while wearing shoes alone, had a dramatic increase in MTP pain causing them to stop this trial within 2 weeks. Our results with supportive shoes are in contrast to the Fransen and the Moncur studies.

Both orthoses showed statistically significant material compression, due in part to the precision of the dial gauge. With subortholen orthoses, the 3% loss was probably due to thinning of the leather lining and is unlikely to be clinically significant. The plastazote orthoses compressed roughly 25%. Although no correlation was found between material compression and pain, a longer trial with further compression may have resulted in increased pain. This could have clinical importance, since frequent replacement of the orthoses may be required to maintain pain relief.

The 11 subjects who preferred subortholen had significantly more pain when using plastazote than when using subortholen, suggesting more effective pain relief guided their choice. The 11 subjects who chose plastazote had similar levels of pain with both plastazote and subortholen, suggesting factors other than pain relief, perhaps softness or ease of wear, guided their choice.

None of the interventions showed an effect on MTP synovitis. This may be because the joint assessment scoring procedure recorded only the presence or absence of synovitis, not its varying degrees.

Lower extremity function as measured was unchanged by the interventions. Laboratory gait analysis may have detected change in gait variables, but this was not available. Our results on lower extremity function are in contrast to the Moncur[24] and the Fransen[41] studies. Moncur showed improvement in walking on a self-report scale, and the Fransen study showed improved gait velocity and stride length. Our results concur with the Conrad[39] study, where no functional improvement was found.

In this study, semi-rigid foot orthoses worn in supportive shoes were shown to be an effective treatment for metatarsalgia secondary to RA. While it was not a controlled trial, it is the only reported sequential trial studying conservative treatment of metatarsalgia in a standard RA population. Although the supportive shoes used in our study were ineffective, jogging shoes with a more shock absorbing sole may reduce MTP joint pain, and should be investigated. Soft orthoses did not provide significant pain relief and have limited durability. However, they may be clinically useful for clients who cannot tolerate more rigid materials.

Controlled clinical trials using objective measures such as laboratory gait analysis are needed to determine specific indicators for orthotic prescription and to investigate the effectiveness of orthoses on pain in other joints of the foot and lower extremity.

ACKNOWLEDGMENT

We acknowledge the support of The Arthritis Society, BC and Yukon Division; the clinical cooperation of the Occupational Therapy staff of the Mary Pack Arthritis Program; and the clerical assistance of Susan Keith, Helen Langford, and Adele Aquino.

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