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Impacts of Foot Orthoses on Pain and Disability in Rheumatoid Arthritics

Kendon J. Conrad,[1,2,*] *Elly Budiman-Mak,*[3,4] *Kathryn E. Roach,*[5] *and Donald Hedeker*[6]

[1]MIDWEST CENTER FOR HEALTH SERVICES AND POLICY RESEARCH, VA HOSPITAL, HINES, ILLINOIS, [2]HEALTH POLICY AND ADMINISTRATION, UNIVERSITY OF ILLINOIS AT CHICAGO, SCHOOL OF PUBLIC HEALTH, CHICAGO, ILLINOIS, [3]MEDICAL SERVICE, VA HOSPITAL, HINES, ILLINOIS, [4]LOYOLA UNIVERSITY OF CHICAGO, STRITCH SCHOOL OF MEDICINE, MAYWOOD, ILLINOIS, [5]DEPARTMENT OF ORTHOPEDICS AND REHABILITATION, DIVISION OF PHYSICAL THERAPY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE, CORAL GABLES, FLORIDA, AND [6]DEPARTMENT OF BIOSTATISTICS, UNIVERSITY OF ILLINOIS AT CHICAGO, SCHOOL OF PUBLIC HEALTH, CHICAGO, ILLINOIS

ABSTRACT. Rheumatoid arthritis (RA) frequently causes foot pain and swelling that affect ambulation. Pharmaceutical management of pain and disability is standard in clinical practice. The use of functional posted foot orthoses, as an adjunct to pharmaceutical treatment, is a promising treatment for managing foot pain and disability in RA. Its effectiveness, however, has not been rigorously evaluated. We performed a double-blind clinical trial using foot orthoses vs. placebo orthoses in the management of the rheumatoid arthritic foot, while subjects continued customary treatment. On the basis of findings of no effect on disability and pain measures, this study indicates no benefit of functional posted foot orthoses over placebos. J CLIN EPIDEMIOL 49;1:1–10, 1996

KEY WORDS. Foot, orthoses, pain, disability

INTRODUCTION

Rheumatoid arthritis (RA) frequently causes foot joint synovitis in early stages, and eventually foot abnormalities occur with a frequency of 20–90%, depending on the duration of the disease process [1–3]. Foot pain in RA could result from active inflammation, a combination of inflammation and structural or biomechanical changes, or other coexisting medical conditions [4, 5]. Subjects with RA frequently experience increasing forefoot pain due to depressed or prominent metatarsal heads and displaced or absent fat pads and impaired ambulatory ability and gait [6–8]. It is also known that RA increases work disability [9, 10].

Pain and abnormal foot functions can be controlled by initiating nonsteroidal antiinflammatory drugs (NSAIDS) and analgesics. Stabilization and improvement of biomechanical functioning of the joints can be achieved through internal bracing or by wearing a foot orthosis [11]. Although pain is commonly known as a primary cause of morbidity in RA [12], foot pain has not been well studied as a longitudinal outcome. While systematic longitudinal measurement of pain is very difficult, Wolfe *et al.* [13, 14] were able to study a group of RA subjects with various illness duration and followed them for at least 5 and up to 15 years. Findings from this study demonstrated that pain scores slightly increased with time while functional disability increased more sharply. Pharmaceutical clinical trials have frequently been conducted to test the effectiveness of pain control in RA [15] and were found to be effective during the short-term studies. No clinical trial measuring the effects of wearing foot orthoses on pain and disability has previously been performed. However, in nonrandomized clinical trials, utilization of foot orthoses caused significant symptomatic relief of pain in 30 to 74% of patients [16, 17].

Objective

The purpose of this study was to test the hypothesis that at the end of 3 years of intervention, the group of patients who received a functional posted foot orthosis would have significantly less foot pain and disability [18] when compared to those wearing placebo orthoses.

Method

This was a randomized clinical trial, double-blinded at pretest and final posttest, with the treatment group assigned to wear functional foot orthoses and the control group to wear placebo orthoses for a 3-year period.

Study Sample

The patients were recruited from the arthritis clinics of VA Hospital (Hines, IL) ($n = 62$), West Side VA Medical Center (Chicago, IL) ($n = 13$), Lakeside VA Medical Center (Chicago, IL) ($n = 9$), North Chicago VA Medical Center (North Chicago, IL) ($n = 7$), and the University of Illinois Hospital (Chicago, IL) ($n = 11$). Of the 636 patients who were screened, 102 fulfilled the eligibility criteria (Table 1). Subjects were eligible for inclusion in the study if they were (1) between 18 and 75 years of age; (2) having foot pain; (3) met American Rheumatism Association (ARA) criteria for classic or definite RA and were in an ARA functional class I or II [19]; (4) had radiological changes of stage I or stage II in one or both feet [20]; (5) had active disease defined as having six or more painful joints or being tender on motion and/or three or more swollen joints with 45 minutes or longer of joint stiffness in the morning or a Westergreen

*Address correspondence to: Kendon J. Conrad, Ph.D., Associate Director, Midwest Center for Health Services and Policy Research, VA Hospital, Hines, IL 60141.

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sedimentation rate of 28 mm or more per hour; (6) had flexible functional discrepancies in their feet, measured as calcaneal valgus stance positions that could be controlled by a functional foot orthosis; and (7) had a minimum range of motion in feet and ankles making ambulation possible.

In general, subjects were chosen on the basis of their likelihood of benefitting from orthoses. Because this project also studied the effects of orthoses on foot deformity [21], subjects were chosen who had active RA diagnoses, but had not yet developed severe clinical foot deformities such as hallux valgus, rigid hammer digit syndrome, plantar displacement of metatarsal bone, hallux rigidus, or surgical fusion of the hallux or if they had any rigidity or deformity of the midfoot, hindfoot, including ankle joints, or any comorbid conditions that could cause an apropulsive gait. Subjects were also excluded if they were unable to read and give responses on the questionnaire or follow instructions and comply with the study protocols.

All eligible subjects who agreed to participate in the study and signed an informed consent were measured for foot orthoses. The measurements along with a plaster mold of each subject's feet were given to the research assistant for random assignment either to a control group or treatment group. Both the subject and the physician were blinded to the treatment status of the subject.

Foot Orthoses

Theoretically, plantar forefoot pain can be managed by providing a compliant stress-absorbing surface for weight bearing and by redistributing weight-bearing forces. Materials such as microcellular rubber, closed-cell neoprene, closed-cell foamed polyethylenes, felt, cork, rubber, or leather can be used. Molded orthoses made of these materials are capable of absorbing impact under the metatarsal heads and allowing the entire plantar surface to bear weight [22]. The treatment group wore custom-molded orthoses fabricated from Rohadur and posted at the rear and forefront, that is, functional posted orthoses. In a previous paper we found that this type of foot orthosis prevents or slows progression of hallux valgus deformity [21]. A placebo orthosis fabricated from a thin naugahyde shoe insert was designed to fit the feet of patients but had no posting or inclined planes that could hold the foot or control its motion in any way.

Random Assignment, Blinding Procedure, and Observation Schedule

The study employed a pretest/multiple posttest design [23] with random assignment of subjects to experimental and placebo control groups. Random assignment was conducted after the pretest assessment to assure an unbiased double-blind pretest. As a condition of participation in the study, subjects were blinded to their group status by the use of a placebo orthosis. Thus, each patient was given either a true functional posted foot orthosis or a placebo, but subjects were not informed as to which they were wearing. Furthermore, at each study visit, the on-site investigators were prevented by the research assistants from seeing patient orthoses.

All patients were seen at 6-month intervals following baseline, and clinical assessments were recorded in the data collection forms. Therefore, there was a maximum of eight data points. Investigators at each participating clinic evaluated patient joints for pain, swelling, and foot functioning. They were assisted by a research assistant and a research podiatrist to assure high-quality data collection.

At the final visit each patient was asked to complete a questionnaire regarding their wearing time, benefits, adverse effects, if any, from wearing the orthoses, and care received since the last visit. For those who refused to continue the study or withdrew early from other causes, demographic data and the reason for attrition were obtained. Any orthosis-related adverse effects for subjects who withdrew from the study were also recorded.

To test the success of the blinding, at the termination of the study or early withdrawal by the patient, the patients were asked to state whether they believed that the assigned orthoses were functional posted foot orthoses or placebo foot orthoses. To ensure further the double blind, a podiatrist, who was blinded to the patient treatment status, was recruited to perform the final posttest evaluation of each patient. This procedure was designed to ensure a completely unbiased final evaluation.

Customary Treatment Regimen

Patients continued receiving the customary treatment regimen for their arthritis at the clinics. This orthotic treatment was not intended to substitute for the customary treatment regimen, which included medications, joint injections, physical therapy, hospitalization or surgical treatment. Patients did not require special shoes, but were instructed to wear comfortable dress shoes with boxed toes or gym shoes. They were also instructed how to care for their foot orthoses. Therefore, the only observed difference between groups was the prescription of the orthoses in the treatment group versus the placebo in the control group. Following a baseline assessment at visit 1, they were asked to return in 2 months for visit 2. At this visit they were reevaluated, the orthoses were dispensed, and the intervention started.

Demographic and Clinical Variables

The pretest variables included age, duration of RA, height, weight, total number of painful joints, foot pain, total disability, 50-foot walking time, foot-specific total disability score, male (yes = 1, no = 0). Forefoot measurement (i.e., hallux abductus angle), mid- and hindfoot measurement (subtalar neutral and calcaneus valgus stance positions, expressed in degrees), and medications commonly added to the treatment regimen of RA in controlling pain, such as analgesics (i.e., acetaminophen), narcotics (i.e., propoxyphene, codeine) and antidepressants (i.e., amitriptyline) were examined as well.

Wearing Time

Wearing time is the self-reported estimated time of wearing orthoses during the week prior to each visit. Theoretically, a greater impact would be expected for those who were wearing the orthoses for a longer duration of time. Hypothetically, the effect should be observed only in the experimental group because the control group received only a placebo. Therefore, low wearing time in the experimental group would indicate a lack of intended treatment implementation, which could result in a dilution of intended treatment effects.

Physician Assessment of Painful Joints and Walking

To assess objectively the number of painful joints in the feet and ankles and hands and wrists, the physician applied pressure to each joint and attempted to move it through full range of motion [24]. Pain produced on either maneuver was considered a positive test. The ankle, tarsal, metatarsal–phalangeal (MP), and phalangeal (PIP) joints were assessed for the foot joint count. Because the MP and PIP joints were assessed as a unit, a total score of 8 was possible for the foot joint count (JNTCNT). Fifty-foot walking time was measured

by instructing the subject to walk a marked 50-foot distance as fast as possible. Performance was timed using a stop watch and was recorded to the nearest tenth of a second. Similarly, all other joints were also assessed and their sum was termed total painful joint count (PANTOT).

Measurement of Foot Pain and Disability

Pain and function were measured concurrently using two different instruments: (1) foot pain, adapted from Melzack [25], and disability, which was adapted from the Arthritis Impact Measurement Scale (AIMS) [26] to measure general disability; and (2) the foot function index, which was developed to measure foot-specific pain and disability [18].

Foot Function Index, Self-Report of Foot Pain and Disability

Because all of the instruments available to measure the pain and disability associated with arthritis were global rather than foot specific, the Foot Function Index (FFI) was developed [18] and was implemented from study visit 6 and every 6 months until the end of the study. A total duration of one and a half years, and a maximum of three data points, were collected. The FFI was designed to measure both current state, defined as the past week, and change in status. The FFI consisted of 23 items grouped into 3 subscales. These items were chosen to reflect the precise impact of foot problems on function, activity limitation, and pain. A total foot function score is derived by calculating the average of the three subscale scores.

Foot pain (PAIN) was assessed through self-report on seven aspects of pain specific to the foot. The first three items described foot pain: (1) at its worst, (2) at its least, and (3) at the present time [25]. Items 4 through 7 had three-point response scales describing the severity of foot pain: (4) standing with shoes on, (5) walking with shoes on, (6) standing with shoes off, and (7) walking with shoes off.

A subjective assessment of disability was performed using a 12-item general assessment of disability due to arthritis adapted from the AIMS [26]. Subjects reported having trouble performing the following activities: (1) vigorous activities, such as running; (2) bending, lifting, and stooping; (3) walking several blocks or climbing a few flights of stairs; and (4) walking one block or climbing one flight of stairs. Subjects further described themselves as needing (5) assistance to walk or (6) travel around the community; (7) having to stay indoors most or all of the day; (8) being in bed or a chair most of the day; (9) having general trouble in moving around; (10) using the toilet; (11) bathing or showering; (12) having severe pain. From the AIMS questionnaire, the general disability assessment (TOTDIS) was derived.

Given the evidence that foot pain is likely to be intermittent, we monitored foot pain and disability at 6-month intervals for 3 years. For each patient, we collected at least two and as many as eight pain and disability assessments.

Statistical Analysis

The original sample size and power calculations were based on the clinical estimates obtained in the previously cited literature. The final sample of 88 subjects available for most analyses provided the power to detect an effect size (d) of 0.3, 90% power, $p < 0.05$, on a one-tailed t-test; for longitudinal data, the effect size would be even greater [27]. To improve power, pretest covariates were entered into the multiple regression equations. Therefore, it is reasonable to estimate that this study had the power to detect effects conventionally considered to be small, e.g., $d = 0.2$ [28]. Except where noted, data were analyzed using SAS version 6.07 [29] and the Statistical Package for the Social Sciences (SPSS) [30].

Pretest Analysis

Data were analyzed on the basis of intention to treat, which means that the subjects randomized to treatment or control were analyzed as assigned, whether or not they actually wore the orthoses. Means, standard deviations, skewness estimates, histograms, and normal probability plots were obtained to examine outliers and distributional properties of the variables. On pretest, Student's t-tests were performed to test the null hypothesis of no difference at baseline between groups ($p < 0.05$).

Posttest Analysis

Because this was a randomized controlled trial, the posttest data could be validly analyzed using t-tests (Table 2). However, to provide a more thorough assessment of changes across the follow-up period, random effects models for longitudinal data [31–33] were used to examine the follow-up assessment data. For longitudinal data, an advantage of the random effects model (also termed multilevel model, hierarchical linear model, and variance component model) over traditional analysis of variance models for repeated measures is that it allows subjects to be measured at a different number of time points, thereby allowing subjects with incomplete data to be included in, rather than removed from, the analysis. Essentially, the model assumes that the data that are present for a given subject reasonably reflect that subject's deviation from the estimated model. The missing data can be either missing at random or explainable given the variables that are present in the statistical model [34].

Where appropriate, log or square root transformation was used to better approximate the normality assumption inherent in the statistical model. For those outcome variables for which, even after transformation, the assumption of normally distributed interval-level measurement could not be justified, a generalization of the random effects model for ordinal outcome data was used [35, 36]. To estimate the terms of the random effects model, the software programs MIXOR [37] and ML3 [38] were used for continuous and ordinal outcome variables, respectively.

For all analyses, to improve the precision of effect estimates, variables were included as covariates that were significantly correlated with the outcomes at baseline; these were weight and average wearing time. Duration of RA, the only baseline measure on which the groups significantly differed at baseline, was included as a covariate in all analyses in order to control for differences in initial level. The baseline level of each outcome measure was included to improve precision (see Table 3). These were calculated on the basis of the first two time points of the study (visits 1 and 2), which was prior to the intervention implementation. Following these two baseline time points, subjects were assessed at a maximum of six follow-up time points (visits 3 through 8). Analysis based on these six follow-up time points was performed for the variables foot pain (PAIN), painful foot joint count (JNTCNT), painful total joint count (PANTOT), and total disability (TOTDIS); while the remaining variables obtained from the FFI were assessed only at the last three follow-up time points (visits 6 through 8): data were obtained by using the FFI instrument, which included total foot function index score (FFI), FFI pain score (PTOT), FFI activity limitation score (FTOT), and FFI difficulty score (DTOT). For these latter four variables, the baseline level of PAIN was included as a covariate in order to improve power and adjust for possible differ-

Table 1. Subjects screened for participation in clinical trial

Status	Criteria	Number of subjects	Percentage
Included	Met inclusion criteria	102	16.0
Excluded	Did not have active and definite or classic RA	266	41.8
Excluded	Had severe foot deformity or previous foot surgery	180	28.3
Excluded	Had ambulation problem	38	6.0
Excluded	Refused to participate	18	2.8
Excluded	Had other medical problem	17	2.7
Excluded	Too old	9	1.4
Excluded	Ankle ROM too limited to fit for orthosis	6	1.0
Total:		636	100.0

Abbreviation: ROM, range of motion.

ences in initial level. In all, longitudinal data from 99 subjects were analyzed for the variables measured across all 6 time points (PAIN, JNTCNT, PANTOT, TOTDIS), while data from 87 subjects were analyzed for the variables assessed only at the last 3 time points (FFI, PTOT, FTOT, DTOT). Finally, because results were in the hypothesized direction and because we were attempting to maximize power in testing for benefits due to the orthosis group condition, one-tailed tests of significance were applied to the tests of group.

RESULTS

Screening and Selection of Subjects

A total of 636 subjects was screened for inclusion in this study. Only 16% of the subjects screened were actually recruited. Approximately 42% of the possible subjects were excluded because they did not have active and definite or classic RA. Another 28.3% of the possible subjects were excluded because they had severe foot deformity or previous foot surgery (Table 1).

Of the patients who entered the study, 63 had classic RA, 39 had definite RA, with 76 in stage I and 26 in stage II anatomical radiological stage [19]. They all had active diseases as defined earlier. Fifteen patients were receiving treatment of NSAID only, 62 were on NSAID in combination with prednisone, 25 were on NSAID with prednisone and gold/D-penicillamine/antimalarial, and 10 were taking NSAID with prednisone and methotrexate/azathioprine.

Baseline Equivalence

At baseline, analysis was done with $n = 102$ (52 treatment and 50 control) (Table 2). The baseline equivalence of the treatment and control groups was examined using a two-tailed Student's t-test and chi-square statistics. No significant differences were found at $p < 0.05$ between the groups in age, height, total painful joint count, painful foot joint count, foot pain, foot disability, 50-foot walking time, total disability score, and proportion of male subjects. Furthermore, there were no statistically significant differences between these two groups when considering the hallux abductus angles (HAA), subtalar neutral and calcaneal stance valgus positions, and the use of analgesics, narcotics, and antidepressant medications. There were, however, statistically significant differences between the two groups in the duration of RA and in weight at the time of enrollment in the study. The mean duration of RA was 3.7 years longer and the weight was 12.3 pounds heavier in the treatment than in the control group.

Attrition

A total of 14 subjects withdrew before completing the trial: 8 subjects withdrew from the treatment group and 6 from the control group. Of these 14 subjects, 6 died, 5 withdrew due to illness, 1 had relocated out of state, and we were unable to locate 2. There was no difference between groups in reason for attrition due to death, comorbidity, inability to locate, or having moved away. There were no adverse effects from wearing foot orthoses during the entire study period.

Eighty-eight subjects (86%) completed the trial, which included 44 treatment and 44 control subjects who were used in the analysis performed at the final visit. Mean duration of enrollment in study was 1075 days for the treatment group and 1083 days for the control group. This difference was not statistically significant. Analysis of the baseline characteristics of these subjects revealed that one significant difference at the 0.05 level between the treatment and control groups in duration of RA was maintained. The mean baseline weight for treatment group subjects was 11.7 pounds heavier than for control group subjects.

Effectiveness of Blinding Procedure

To test the success of blinding, at the time of termination of the study or at patient early withdrawal, both the treating rheumatologists and patients were asked to state the treatment or control status; that is, whether they believed that the assigned orthoses were functional posted orthoses or placebo orthoses. All five rheumatologists stated that they had no knowledge of the type of orthoses their patients were wearing, were never informed of the treatment status of any patient, and had never asked patients or research staff about treatment status.

Wearing Time

To examine further the success of the blinding procedure for patients, we compared the two groups on the percentage of subjects who had not worn either the orthotic or the placebo in the 30 days prior to the last visit. Of those who finished the entire 3 years of the clinical trial, at the time of the last visit, 31% had not worn their orthotic/placebo in the last 30 days. These subjects were divided equally between the treatment and control groups with no statistically significant difference. Wearing time was not influenced by whether or not a subject had a treatment or placebo orthotic. This was interpreted as evidence of the effectiveness of the blinding procedure. There were no differential effects of wearing time between the groups.

t-Test Results: Pain, Functioning, Disability

None of the t-tests comparing unadjusted group means were significant on measures of painful foot joint count, total painful joint count, foot pain, all of the FFI scales, and total disability (Table 2). And no differences were found in their use of analgesics, narcotics, and antidepressants between baseline and the final visit.

Table 2. *t* Tests of foot pain and disability at final visit by treatment status

Outcome measure	Treatment ($N = 44$) mean[a]	SD	Control ($N = 44$) mean	SD	*p* Value
Painful foot joint count (JNTCNT8)	1.5	1.9	1.3	1.7	0.642
Total painful joint count (PANTOT8)	9.3	9.0	8.2	7.4	0.529
Foot pain (PAIN8)	5.4	5.5	5.2	5.9	0.872
FFI					
Pain Scale (PTOT1)	28.2	29.1	29.1	27.7	0.784
Disability Scale (DTOT1)	34.1	28.6	38.3	28.0	0.491
Activity Limitation Scale (FTOT1)	16.5	19.3	14.9	22.7	0.717
Total score (FFI1)	26.5	20.3	27.9	22.2	0.759
Total disability (AIMS) (TOTDIS8)	29.2	16.1	30.3	17.5	0.908

[a]Higher mean = poorer result.

Random Effects Model Results

Table 3 lists the results from the random effects analyses of the longitudinal data. Baseline levels were significantly related to subsequent levels for all variables; in all cases, higher baseline levels were associated with higher follow-up levels. The treatment effect was observed to be nonsignificant for the foot pain (PAIN) and FFI pain score (PTOT) measures.

Average wearing time was significantly related to foot pain (PAIN) regardless of group. Specifically, longer wearing time was associated with less pain and less total disability (TOTDIS) scores, and also it was marginally significantly related to painful foot joint count (JNTCNT) and total activity limitation (FTOT) scores; in all cases, increased wearing time was associated with decreased levels of pain and disability for both groups. This association could be due to the equal effect of treatment and placebo or it could be an artifact such as compliance-mediated bias [39]. Weight was observed to be significantly related to painful foot joint count (JNTCNT), where lower weight was associated with increased painful foot joint count.

Although not presented in Tables 1–3, we examined whether significant trends across the follow-up period were present in the outcome measures (time effect), and whether any potential trends across time in the outcome variables differed by treatment group (time by treatment group interaction). In all cases, no significant time or group by time effects were observed.

DISCUSSION

Pain and disability are major issues in RA and can lead to serious consequences such as surgery. In this study, the only existing randomized controlled trial of the effects of functional posted foot orthoses on foot pain and functioning, the effect of orthotics was assessed over time while patients continued their customary treatment regimens. *t*-Test comparisons of the two groups at the final, 3-year posttest revealed no differences in pain and disability. The more powerful random effects analyses of the longitudinal data with covariates did not suggest that the foot orthosis group experienced less pain ($p < 0.05$, one-tailed) in six follow-ups over two and a half years and in a concurrent data collection using another pain measure (FFI pain score) over three follow-ups during the last year and one half. No main group effects were observed on painful joint count or disability measures. Additionally, the use of analgesics, narcotics, and antidepressants was unchanged, which supports the finding of no significant effect on pain. The finding that lower weight was associated with increased painful joint count was not surprising because RA is indeed a systemic disease where an increase in disease activity is usually accompanied by weight loss. It is interesting to us that average wearing time influenced foot pain, painful foot joint count, total disability, and FFI activity limitation. This implies that subjects who tended to wear either foot orthoses or placebo orthoses for a longer period of time experienced less pain and disability. The fact that no group by wearing time interactions were observed indicates that the influence of wearing was basically the same in both groups regardless of whether foot orthoses or placebo orthoses were worn.

Additionally, the effective use of placebo orthoses controlled for a differential reporting bias such as that caused by resentful demoralization in the control group [23]. In other words, because there was an equal perception of receiving treatment in both groups, the hypothesis of a difference due to knowledge of participation in one treatment or the other could be ruled out. These findings differed from the observational nonrandomized studies of Miller [16], Craxford *et al.* [17], and Dimonte and Light [40], where pain was significantly relieved and functioning was improved. Given the fact that subjects were carefully targeted to achieve maximum benefit, we were surprised at the lack of observable effects.

Limitations and Advantages

The following limitations of the study design could dilute the effects of treatment on pain. The fact that our subjects were older males with a long duration of illness might mean that they have adapted to the pain because they had the disease for so long, or because they may not like to admit that they had pain [41, 42]. This limits the generalizability of the results to the current study population. Studies of younger males, females, and people with earlier onset RA studied for a longer time could reveal significant effects. It would have been useful to have a third control group, who wore neither treatment nor placebo orthoses. This would make it possible to test whether the placebo itself had an effect and thereby served to dilute the observed effect of the treatment orthoses. Finally, it would have been additionally informative to have a true "no treatment" control group. However, because this would mean withdrawing customary drug treatments, this would be unethical.

The findings of the study were in the expected direction but nonsignificant, even when statistical controls were used and power was maximized by analyzing multiple time points using random regression models with one-tailed tests. As we know, a study with a small *n* will find nonsignificant results, but if that *n* is doubled the results can become significant. However, we believe that this study had the power to observe small effects, and we used statistical techniques to increase

Table 3. Random effects analyses of longitudinal data

Dependent variable	Independent variables	Estimate[a]	Z[b]	p Value
Foot pain (self-report)	Baseline level	0.586	7.67	0.001***
	RA duration	0.003	0.38	0.70
	Weight	0.001	0.25	0.80
	Average wearing	−0.006	−3.32	0.001***
	Treatment status (control = 0, exp. = 1)	−0.167	−1.52	0.13
Painful foot joint count (JNTCNT) (analyzed as an ordinal outcome)	Baseline level	1.022	3.71	0.001***
	RA duration	−0.020	−1.19	0.23
	Weight	−0.008	−2.15	0.032*
	Average wearing	−0.008	−1.90	0.058
	Treatment status	−0.255	−1.09	0.28
Total painful joint count (all joints) (sqrt)	Baseline level	0.387	3.97	0.001***
	RA duration	0.002	0.10	0.92
	Weight	−0.003	−0.74	0.46
	Average wearing	−0.005	−1.22	0.22
	Treatment status	−0.068	−0.27	0.79
Total disability (AIMS)	Baseline level	0.757	11.42	0.001***
	RA duration	0.039	0.30	0.76
	Weight	0.040	1.24	0.22
	Average wearing	−0.113	−3.51	0.001***
	Treatment status	−1.502	−0.77	0.44
Total foot function index (sqrt)[c]	Baseline level	1.350	3.96	0.001***
	RA duration	0.008	0.27	0.79
	Weight	0.004	0.57	0.57
	Average wearing	0.008	−1.08	0.28
	Treatment status	−0.500	−1.06	0.29

[a]Because higher scores indicate poorer results, negative values for estimates indicate favorable outcomes, e.g., both increased average wearing time and treatment status (control = 0, exp. = 1) were associated with less foot pain.
[b]All tests are two-tailed.
[c]Total foot function index was assessed only at the last three time points. Baseline level refers to baseline foot pain scores.
*$p < 0.05$.
***$p < 0.001$. (Used to make results easier to read.)

power as much as possible. A larger trial, which was able to target more clearly those subjects with recent onset RA, would have more power to observe smaller effects if present.

CONCLUSION

On the basis of findings of no effect on disability measures and marginal or equivocal effects on pain measures, this randomized clinical trial indicates that functional posted foot orthoses provide little, if any, benefit over placebos. This no-effect finding is important because it is contrary to the findings of previous studies and to the prevailing beliefs about good clinical practice.

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References

1. Vanio S. The rheumatoid foot: A clinical study with pathological and roentgenological comments. **Ann Chir Gynaec Finniae** 1956; 45(Suppl.): 1–107.
2. Flemming A, Crown JM, Corbert M. Incidence of joint involvement in early rheumatoid arthritis. **Rheum Rehab** 1976; 15: 92–96.
3. Speigel TM, Spiegel JS. Rheumatoid arthritis in the foot and ankle—diagnosis, pathology and treatment: The relationship between foot and ankle deformity and disease duration in 50 patients. **Foot Ankle** 1982; 2: 318–324.
4. Wood B. Foot pain. In: **Text Book of Rheumatology** (Kelly W, ed.). W.B. Saunders, Philadelphia, Pennsylvania, 1985, Chapter 31.
5. Bouysset M, Bonvoisin B, Lejeune E, Bouvier M. Flattening of the rheumatoid foot in tarsal arthritis on x-ray. **Scand J Rheumatol** 1987; 16: 127–133.
6. Inman VT, Mann RA. Biomechanics of the foot and ankle. In: De Vries **Surgery of the Foot** (Mann RA, eds.). C.V. Mosby, St. Louis, Missouri, 1978, pp. 3–21.
7. Jahss MH. **Disorder of the Foot,** Vol. 2. W.B. Saunders, Philadelphia, Pennsylvania, 1982, pp. 1032–1033.
8. Regan-Smith MG, O'Connor GT, Kwoh CK, Brown LA, Olmstead EM, Burnett JB. Lack of correlation between the Steinbrocker staging of hand radiographs and the functional health status of individuals with rheumatoid arthritis. **Arthr Rheum** 1989; 32: 128–133.
9. Makisara GL, Makisara P. Prognoses of functional capacity and work capacity in rheumatoid arthritis. **Clin Rheum** 1982; 2: 117–125.
10. Yelin EH, Katz PP. Transitions in health status among community dwelling elderly people with arthritis. **Arthr Rheum** 1990; 33: 1205–1215.
11. Donatelli R, Hurbert C, Conway D, Pierre RS. Biomechanical foot orthotics: A retrospective study. **J Orthoped Sport Phys Ther** 1988; 10: 205–212.

12. Kazis LE, Meenan RF, Anderson JJ. Pain in the rheumatoid diseases. **Arthr Rheum** 1983; 26: 1017–1022.
13. Wolfe F, Hawley DJ, Cathey MA. Clinical and health status measures over time: Progress and outcome assessment in rheumatoid arthritis. **J Rheum** 1991; 18: 1290–1297.
14. Wolfe F, Cathey MA. The assessment and prediction of functional disability in rheumatoid arthritis. **J Rheum** 1991; 18: 1298–1306.
15. Bellamy N, Buchanan WW. Clinical evaluation in rheumatic diseases. In: **Arthritis and Allied Health Condition,** 12 Ed. (McCarthy DJ, Koopman WJ, eds.). Lea & Febiger, London, 1993, pp. 151–178.
16. Miller WE. The anterior heel for metatarsalgia in the adult foot. **Clin Orthoped** 1977; 123: 55.
17. Craxford AD, Stevens J, Park C. Management of the deformed rheumatoid forefoot. **Clin Orthoped Related Res** 1982; 166: 121–125.
18. Budiman-Mak E, Conrad KJ, Roach KE. The foot function index: A measure of foot pain and disability. **J Clin Epidemiol** 1991; 44: 561–570.
19. Roper MW, Bennett GA, Cobb J *et al.* 1958 Revision of diagnostic criteria for rheumatoid arthritis. **Arthr Rheum** 1959; 2: 16–20.
20. Steinbrocker O, Traeger CN, Botterman RC. Therapeutic criteria in rheumatoid arthritis. **JAMA** 1949; 140: 659–662.
21. Budiman-Mak E, Conrad KJ, Roach KE *et al.* Can foot orthoses prevent deformity in rheumatoid arthritis? **J Clin Rheum**, in press.
22. Olson WR. Orthoses, an analysis of their component materials. **JAPMA** 1988; 78: 203–206.
23. Cook TD, Campbell DT. **Quasiexperimentation: Design and Analysis Issues for Field Settings.** Rand-McNally, Skokie, Illinois, 1979.
24. McCarty DJ. Differential diagnosis of arthritis, analysis of signs and symptoms. In: **Arthritis and Allied Conditions** (McCarty DJ, ed.). Lea & Febiger, Philadelphia, Pennsylvania, 1985.
25. Melzack R. The McGill pain questionnaire: Major properties and scoring methods. **Pain** 1975; 1: 277–298.
26. Meenan RF, Gertman PM, Mason JM. Measuring health status in arthritis: The Arthritis Impact Measurement Scales. **Arthr Rheum** 1980; 23: 146–152.
27. Kraemer HC, Thiemann S. **How Many Subjects? Statistical Analysis in Research.** Sage, Beverly Hills, California, 1987.
28. Cohen J. **Statistical Power Analysis for the Behavioral Sciences.** Academic Press, New York, 1977.
29. SAS Institute, Inc. **SAS User's Guide,** Release 6.07 1990 edition. SAS Institute, Inc., Cary, North Carolina.
30. SPSS, Inc. **Statistical Package for Social Sciences,** 1988 edition, SPSS, Inc., Chicago, IL.
31. Laird NM, Ware JH. Random effects models for longitudinal data. **Biometrics** 1982; 38: 963–974.
32. Goldstein H. **Multilevel Models in Educational and Social Research.** Oxford University Press, New York, 1987.
33. Bock RD. Measurement of human variation: A two-stage model. In: **Multi-Level Analysis of Educational Data** (Bock RD, ed.). Academic Press, New York, 1989.
34. Laird NM. Missing data in longitudinal studies. **Stat Med** 1988; 7: 305–315.
35. Jansen J. On the statistical analysis of ordinal data when extravariation is present. **Appl Stat** 1990; 39: 75–84.
36. Hedeker D, Gibbons RD. A random-effects ordinal regression model for multilevel analysis. **Biometrics** 1994; 50: 933–944.
37. Hedeker D. MIXOR: A Fortran program for mixed-effects ordinal probit and logistic regression. In: **Technical Report.** Prevention Research Center, School of Public Health, University of Illinois, Chicago, Illinois.
38. Prosser R, Rasbash J, Goldstein H. **ML3 Software for Three-Level Analysis,** users' guide for v.2. Institute of Education, University of London, London, 1991.
39. Horwitz RI, Horwitz SM. Adherence to treatment and health outcomes. **Arch Intern Med** 1993; 153: 1863–1868.
40. Dimonte P, Light H. Pathomechanics, gait deviations and treatment of the rheumatoid foot. **Phys Ther** 1982; 62: 1148–1156.
41. Ross CK, Siwacore JM, Stiers W, Budiman-Mak E. The role of expectation and preferences in health care satisfaction of patients with arthritis. **Arthr Care Res** 1990; 3: 92–98.
42. Deyo RA, Inui TS, Leininger J *et al.* Physical and psychological function in rheumatoid arthritis: Clinical use of a self-administered health status instrument. **Arch Intern Med** 1982; 142: 879–882.