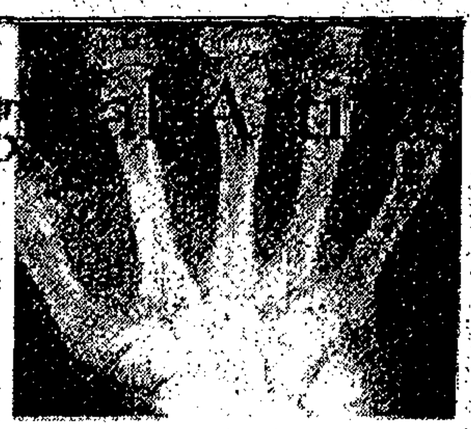

Can Foot Orthoses Prevent Hallux Valgus Deformity in Rheumatoid Arthritis?
A Randomized Clinical Trial*

Elly Budiman-Mak, Kendon J. Conrad, Kathryn E. Roach, James W. Moore, Yongsuk Lertratanakul, Alisa E. Koch, John L. Skosey, Christopher Froelich, Nicholas Joyce-Clark

Hallux valgus deformity is the most commonly observed forefoot deformity in patients with rheumatoid arthritis. This 5-year, double-blind, randomized clinical trial compared treatment orthoses with placebo orthoses for the prevention of hallux valgus deformity in the rheumatoid arthritic foot.

One hundred and two subjects with active rheumatoid arthritis and with foot pain and minimal radiographic changes of the feet participated in the study. They were recruited from five arthritis clinics in the Chicago metropolitan area that are affiliated with or are teaching clinics of area medical schools. Patients were followed for 3 years.

Eighty-one subjects completed the study. In a logistic regression analysis, the treatment group was 73% less likely to develop hallux valgus deformity compared with the control group (adjusted odds ratio 0.27, 95% confidence interval 0.078, 0.916 $p = .04$). These findings suggest that foot orthoses can prevent or slow the progression of hallux valgus deformity. **(J Clin Rheumatol 1995;1:313–321)**

Key words: Orthoses, Rheumatoid foot, Hallux valgus

Hallux valgus deformity is the most commonly observed forefoot deformity in patients with rheumatoid arthritis (1–4). Other abnormal forefoot findings include hammer toe and splayed foot; subtalar joints are frequently involved in arthritis leading to progressive calcaneal valgus and flattening of the longitudinal arch. Varus deformity of calcaneus is rare in rheumatoid arthritis (5). Deformity involving the foot significantly affects ambulation, decreases employment potential, increases the risk of falling and causes difficulty with activities of daily living (6–8). When treated with analgesics and anti-inflammatory nonsteroidal drugs (NSAIDS), disease processes are not stabilized. Stabilization and/or improvement of biomechanical foot function may be achieved by surgery or external braces and/or foot orthoses (9).

Although foot orthoses are frequently prescribed to stabilize the alignment of forefoot and hindfoot, relatively little is known about the effect of foot orthoses in the prevention of forefoot deformity in rheumatoid arthritis patients. No previous randomized clinical trials using foot orthoses in the prevention of hallux valgus deformity were found. Therefore, we conducted a study to determine whether foot orthoses could retard or even prevent the progression of hallux valgus deformity in patients who had active rheumatoid arthritis involving multiple joints, including foot joints. Specifically, we hypothesized that foot orthoses could prevent or slow the progression of hallux valgus

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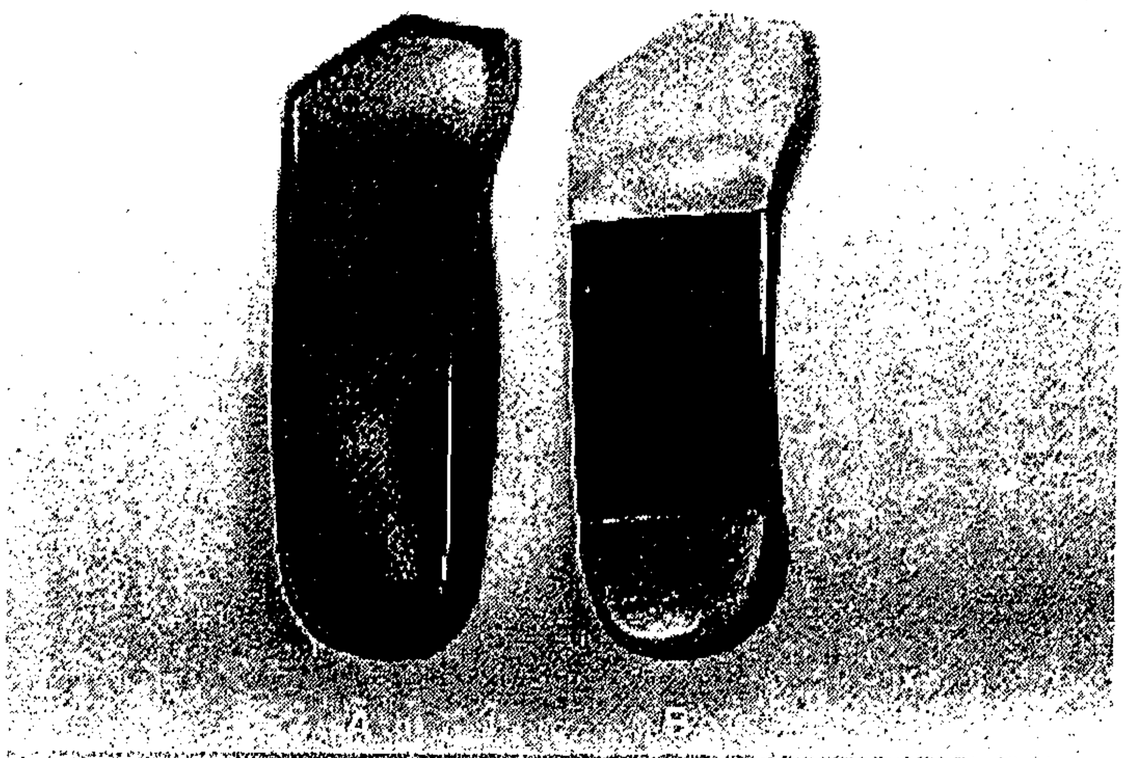

FIGURE 1. *Rheumatoid foot, hallux valgus, orthoses: (A) A superior view of the functional foot orthosis; (B) An inferior view of the functional foot orthosis with posting of the heel and forefoot. This picture depicts the fit of foot orthoses in size 9 shoes.*

deformity in patients with active rheumatoid arthritis.

METHODS

Setting and Subjects

The study was conducted from 1986 to 1991 under the guidelines of the Human Studies Sub-Committee of the Veterans Administration (VA) Hines Hospital in Illinois and was coordinated by the Hines Veterans Hospital, Midwest Center for Health Services and Policy Research. Six hundred thirty-six consecutive rheumatoid arthritis subjects of one university hospital and four university-affiliated Veterans hospitals in the metropolitan Chicago area were screened from the arthritis clinics from 1986 to 1987. Of the 636, 102 subjects with rheumatoid arthritis were enrolled in the study. They were from the arthritis clinic of the VA hospitals: Hines (n = 62), West Side (n = 13), Lakeside (n = 9), North Chicago (n = 7) and the University of Illinois Hospital (n = 11). Subjects included in the study had all of the following characteristics: a) met the American Rheumatism Association (ARA) 1958 criteria for classical or definite rheumatoid arthritis and were in ARA functional class I or II (10); b) were between 18 and 75 years of age; c) had foot pain; d) had radiologic changes of stage I or II in one or both feet (11); e) had active disease defined either as six or more joints that were painful on palpation and tender on motion or had three or more swollen joints with ≥ 45 minutes of joint stiffness in the morning or Westergren sedimentation rate of ≥ 28 mm/h. Subjects were excluded if they had a) forefoot deformities such as hallux valgus, rigid hammer digit syndrome, plantar displacement of a metatarsal, or hallux rigidus; b) rigid or fused first metatarsal-phalangeal joint; c) any rigid deformities of lower extremities including foot or comorbid conditions altering either their gait or ambulation; d) rigid or deformed hindfoot that could not be controlled by a functional foot orthosis; e) inability to read, give written responses on the questionnaire, follow instructions or comply with the study protocols.

Each participant had to be willing to wear shoes of a style and fit that neither constricted the foot nor impaired foot function, with heels no higher than $^{3}/_{4}$ inch. Shoes with boxed toes or athletic shoes of proper fit and shape were preferred. A special shoe was not required. The determination as to whether their footwear fulfilled these requirements was made by the team's research podiatric physician.

Randomization and Intervention

Participants were randomized to placebo or foot orthoses using a computer-derived random number and were stratified by facility. The numbers were sealed in an envelope and assigned to subjects at pretest after baseline evaluation. The assigned number became the identification number for the orthotic prescription as well as for the plaster impression of the feet. Foot orthoses were prescribed based on the research podiatrist's examination of the lower extremities and feet. All prescriptions were sent to Burns Orthotic Laboratory in McCook, Nebraska, which fabricated the orthoses for the study.

Foot Orthosis

The treatment orthosis (Fig. 1) consisted of a functional posted foot orthosis fabricated of Rohadur (12), which is a thermoplastic material distributed by Durr-Fillauer of Chattanooga, Tennessee. The purpose of this type of orthosis is to maintain during ambulation an angular anatomic relationship between the forefoot and hindfoot and between the leg and walking surface. If the forefoot and hindfoot are not parallel to each other when the subtalar joint is in neutral position (neither pronated nor supinated) on static examination, an ideal functional alignment is not likely to be maintained in the foot during ambulation (13). Abnormal compensation for an abnormal forefoot/hindfoot relationship or alignment is accomplished by pronation or supination of the midtarsal joint (14). Proper maintenance of this functional alignment and control of the abnormal compensation for abnormal structure and/or function is accomplished by use of forefoot and/or hindfoot wedges (posts) on the orthosis. Criteria for prescribing the foot orthosis were based on the method described by Root (13) so that the orthosis allows the foot to function in neutral position, with proper alignment, and the foot and leg were able to move in a more ef-

ficient transmission of forces through the kinetic foot while inhibiting abnormal ranges of the motion or position (14). The wedges were made and tailored to the measurement obtained from each subject's forefoot and hindfoot relationship; measurements involved the angles of the calcaneus, forefoot and subtalar joints. This method was also described by Root (13). These specific measurements obtained from the subjects enabled us to determine the angle and degree of the forefoot and hindfoot posts. These measurements were open kinetic chain and the reliabilities of the measures during the study were not proven by any statistical method.

The placebo orthosis was fabricated as a thin flexible leather shell molded over a plaster impression of the patient's foot (Fig. 2). The shell was covered with thin naugahyde of the same color and design as the thermoplastic functional posted foot orthosis. This molded shell was of uniform consistency and thickness, had no rigid or firm reinforcement and had no wedges or inclined planes. Furthermore, there was no added material to accommodate for structural prominence or to reduce abnormal shearing forces. Thus, the placebo orthosis did not control foot function nor reduce stresses in the foot. Either the treatment orthosis or thin placebo orthosis was to be inserted into the subjects' shoe gear during daily activity for the entire study period.

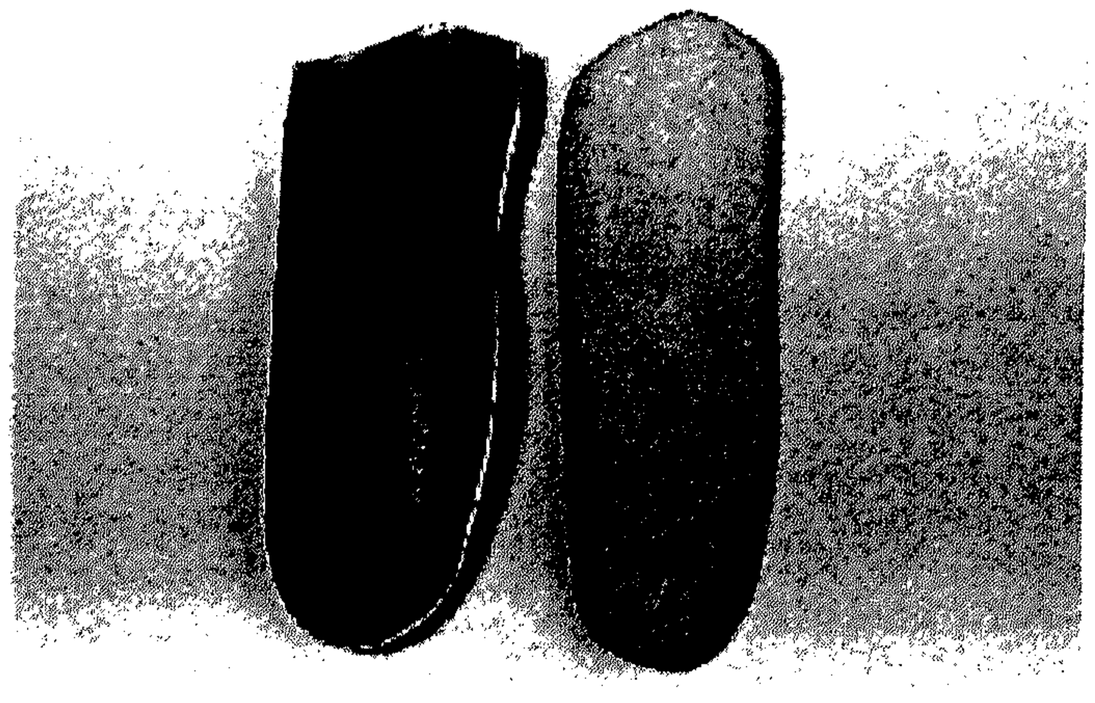

FIGURE 2. *Rheumatoid foot, hallux valgus, orthoses: (A) a superior view of the placebo orthosis; (B) an inferior view of the placebo orthosis without posting of the heel or forefoot.*

Double-Blind Procedure

Both the subjects and physicians were blinded to the treatment status. To test the success of the blinding, at the termination of the study or upon early withdrawal by the patient, the patients were asked to state whether they believed that the assigned orthosis was the treatment orthosis or the placebo orthosis. At each study visit, the onsite investigators were prevented by the research assistants from seeing the patients' shoes or orthoses.

Assessment and Data Collection

Assessment of rheumatoid arthritis activity was based on measures of grip strength, walking time and the number of joints with pain and swelling. Pain and swelling were recorded as present or absent. The metatarsal phalangeal joints were counted as one unit and the proximal interphalangeal joints as another unit; a total of 52 joints were counted. Because the intervention was aimed at stabilizing the joints rather than reducing inflammation, joint pain rather than joint swelling was selected as one of the outcome variables of interest. Information on medications used in the management of rheumatoid arthritis was also recorded. All data were collected at baseline and every 6 months thereafter. The joint examination was performed as described by McCarty (15), and grip strength was measured using a Vigormeter (Ehmed Inc., Addison, IL). Three readings were averaged for each hand. Walking time was measured by instructing the subject to walk a marked 50-foot distance as fast as possible. Performance was timed using a stopwatch and recorded to the nearest 0.1 second. The podiatrist assessed the range of motion of the primary joints of the foot and ankle joints to determine the static calcaneal stance position, the subtalar joint neutral position (13, 14) and the size of the wedges for the treatment orthosis. Weight-bearing radiographs of the feet in anterior-posterior and lateral positions were taken according to a standard technique to measure the hallux abductus angle (16). Patients' self-assessment of foot pain at rest and during ambulation and performance of daily living activities were recorded. Foot pain was assessed through self-report on seven aspects of pain specific to the foot. Three items were adapted from the McGill Pain Questionnaire (17), which described the location, quality and intensity of the pain as well as four items related to the severity of foot pain when wearing or not wearing shoes. Each item had a five-point response scale with five being the highest score, where a higher score indicated more pain. Disability was assessed using adapted Arthritic Impact Measurement Scales (AIMS) (18) to measure lower extremity and foot functioning. There were 12 questions, with each question having a five-point response scale with five being the poorest functioning. These instruments were used in measuring the baseline subjects' characteristics; later in the study, we developed the Foot Function Index (19), which measured foot pain, function and disability. (Another paper related to this outcome measured is in press.) Eight separate evaluations were

conducted during the 3-year study period. Evaluations were performed every 6 months, with the exception of the second visit, which occurred 2 months after baseline in order to re-evaluate the patients' general status and disease activity, and to dispense the orthoses.

During the study, participants continued to receive customary treatment, including medications, joint injections, physical therapy, hospitalization and surgical treatment of joints. The on-site clinical investigators were assisted by a research assistant and a research podiatrist to assure high quality data collection. All patients were monitored at each visit to ensure that the functional foot orthosis properly fit the contour of the foot. The forefoot and hindfoot posts of the orthosis were inspected to insure that the prescribed angle of the post had not been altered because of wear. Patients were also questioned for any possible sources of pain that might be associated with changes in foot contour, such as nodules, etc. Orthoses were adjusted to accommodate these changes. Placebo orthoses were checked to rule out any possible changes in the leather such as wrinkled or worn areas that might cause discomfort or irritation to the patient's feet. At each visit, patients were re-instructed to wear specified footgear, follow a recommended wearing schedule, and provide appropriate foot care and care of the foot orthoses. (Appendix)

Hallux Abductus Angle

Hallux valgus was defined as a hallux abductus angle that was ≥ 21 degrees (20). The hallux abductus angle was defined as the intersection of the longitudinal bisection of the first metatarsal and the proximal phalanx as visualized on an anterior-posterior weight-bearing foot radiograph. This measurement was developed for this study, because, during the study, there was no acceptable measure available to document hallux valgus deformity from foot radiographs. The inter-rater and intrarater reliability and validity of the measure have been published (21).

Wearing Orthosis and Posttest Evaluation

The intervention began after the distribution of the orthosis at the second visit. The foot orthosis wearing time was estimated as the total hours that the orthosis had been worn during the week preceding the study visit. The hours were averaged to yield the average wearing time per week. A total of six data points were collected. Theoretically, the expected treatment effect in the group with the treatment orthoses would be greater compared with that of the group with placebo. The adverse effects were evaluated by the number of injuries/ulcerations and surgeries to the foot after the insertion of the foot orthoses.

To conduct unbiased posttest clinical measures and measurement of hallux abductus angle on the radiographs of the foot, we recruited and trained a podiatrist who had never participated in this study and who remained blinded to the patient treatment status.

Withdrawal Criteria and Adverse Event

Subjects were withdrawn from the study if they were not wearing or were unable to wear the orthoses for more than 30 days continuously, e.g., if subject became very ill or nonambulatory, or if the patient died. They were also withdrawn if they were relocated where clinical monitoring would be impossible. Reasons for withdrawal were recorded for each subject who left the study before the final visit.

At the final visit, each patient answered an orthosis-related questionnaire regarding wearing time, benefits, adverse events and special care related to the foot problem received since the previous visit.

Statistical Analysis

The statistical package SAS, version 6.07 (22), was used for data analysis. The effect size and power calculations were based on the clinical estimates of the investigators on the progression of hallux abductus angle during the 3-year study. Based on the literature and clinical judgment, an effect size of a 5-degree increase or greater in hallux abductus angle in the control group indicated a progression of hallux valgus deformity (21). A sample size of 50 subjects provided the power to detect a medium effect size of a 5-degree angle, with 90% power, $p < 0.05$, on a one-tailed t test (23). The one-tailed directional test provided sufficient power to determine the key question of whether the treatment orthosis had a positive effect.

Data were analyzed based on intention to treat, in which all subjects were maintained in the analysis once they were randomized and assigned to the study group. Additionally, we did a secondary analysis on subjects who completed the study. Means, standard deviations (SDs), skewness estimates, histograms and normal probability plots were obtained to detect outliers and examine distributional properties of the variables. On pretest, Student's t test was used to test the null hypothesis of no difference at baseline between groups ($p < 0.05$) for continuous data, whereas the chi-square test was used for categorical data on the variables of interest (Table 1).

A chi-square statistic was used to determine the odds ratio of progression of hallux valgus deformity comparing prescription foot orthoses with control. Multiple logistic regression was used to estimate the association of progression of hallux valgus deformity with the following independent variables at baseline: duration in years of rheumatoid arthritis, weight and also treatment status. The first and second independent variables were selected because the groups differed in these factors at baseline. This model estimates the probability of the progression of hallux valgus de-

TABLE 1. Baseline characteristics for all participants

CHARACTERISTIC	TREATMENT n = 52 MEAN	SD	CONTROL n = 50 MEAN	SD	*p*-VALUE
Age (years)	60.2	10.6	58.8	11.9	0.52
Duration of rheumatoid arthritis (years)	9.8	8.0	6.1	6.0	0.0105*
Height (cm)	68.6	3.3	68.0	3.7	0.37
Weight (lb)	183.9	29.4	171.6	31.7	0.0446*
Total number of painful joints	16.8	11.4	14.8	10.7	0.36
Number of painful foot joints	2.3	2.6	2.7	2.5	0.41
Angle measurements (degrees):					
Hallux abductus angle (left)	17.3	5.2	15.8	6.9	0.54
Hallux abductus angle (right)	17.3	6.6	15.4	5.4	0.56
Subtalar neutral (left)	2.5	0.9	2.2	1.0	0.64
Subtalar neutral (right)	2.4	1.1	2.2	1.2	0.63
Calcaneal stance valgus (left)	3.3	1.1	3.1	1.0	0.65
Calcaneal stance valgus (right)	3.1	1.2	2.9	0.9	0.66
Foot pain**	5.6	5.7	4.5	5.3	0.33
Foot disability**	8.3	3.3	8.2	2.9	0.96
50-foot walk time (seconds)	12.8	4.7	11.9	3.4	0.26
Total disability score**	29.9	15.3	30.1	12.8	0.96
	(n = 46)		(n = 43)		
Male	88.5%		86.0%		0.72
ARA functional class	(n = 47)		(n = 49)		
ARA class I	78.7%		87.8%		0.13
ARA class II	21.3%		12.2%		

*p value is significant at <0.05.

**higher score means poor result.

formity in terms of an odds ratio adjusting for duration of rheumatoid arthritis and weight. A test-based confidence interval (CI) of the odds ratio was also obtained from the regression analysis.

RESULTS

Screening and Selection of Subjects

Of 636 subjects screened for inclusion in this study, only 102 (16%) were recruited, whereas the remaining 534 (84%) were excluded. Reasons for exclusions were: a) 266 (41.8%) did not have active disease and/or criteria for definite or classical rheumatoid arthritis, b) 180 (28.3%) had severe foot deformity or previous foot surgery, c) 38 (6%) had problems with ambulation, d) 18 (2.8%) refused to participate, e) 17 (2.7%) did not have rheumatoid arthritis, f) 9 (1.4%) did not meet age criteria, and g) 6 (1%) had a fused ankle joint or very limited range of motion of the ankle joint.

Fifty patients were randomized to treatment and 52 to control. They all had active disease and a mean total count of 16 painful joints, SD 11.4. Sixty-three (62%) had classical and 39 (38%) had definite rheumatoid arthritis, 76 (75%) were in stage I and 26 (25%) in stage II anatomic radiologic stage (10). Fifteen patients (15%) were receiving treatment with NSAIDs only, 62 (61%) were on NSAIDs and prednisone, and 25 (25%) were on NSAIDs, prednisone and disease-modifying antirheumatic drugs.

Withdrawal

Four (4%) patients, two from each group, had baseline data collected but refused to continue with the study: one because of the illness of his wife, two because of work commitments; the other gave no reason. They were recruited from three clinics and displayed no specific patterns in their baseline characteristics. Therefore, 98 patients or 96% of the 102 patients were included in the intent-to-treat analysis up to their last visit.

Fourteen (14%) patients, eight from treatment and six from control, left the study; the mean total days of participation in the study for the treatment group was 517.2 with an SD of 313.8 and for the control group was 504 with an SD of 308.9

TABLE 2. Progression of hallux abductus angle by treatment status

		HAA				
GROUP	n	PROGRESSION n (%)	NO PROGRESSION n (%)	OR	95% CI*	*p*-VALUE
Intent-to-treat analysis: n = 98.						
Treatment	50	5 (10.0)	45 (90.0)	0.3	0.1, 1.0	0.05
Control	48	12 (25.0)	36 (75.0)			
Total	98	17 (17.4)	81 (82.6)			
Secondary Analysis: n = 81						
Treatment	41	5 (12.2)	36 (87.8)	0.3	0.1, 1.0	0.05
Control	40	12 (30.0)	28 (70.0)			
Total	81	17 (21.0)	64 (79.0)			

* Test based 95% confidence interval.
HAA, hallux abductus angle; OR, odds ratio.

($p = 0.62$). The reasons patients left the study were as follows: six patients died, four developed lung cancer, and one each because of breast cancer, pneumonia, and liver cirrhosis. Another eight patients left the study: five patients left because of illness unrelated to rheumatoid arthritis, one left because of a diabetic ulcer of the foot; another left because of a debilitating condition from colon cancer. Two patients were lost to follow-up, and one moved out-of-state. These patients were from four clinics and displayed no specific pattern related to the a) origin of the clinics, b) baseline characteristics (except that three of eight in the treatment group were female), c) treatment status, d) frequencies of deaths, or e) comorbidities ($p = 0.79$).

Missing Data

Three patients (3%), one from control and two from treatment, did not have foot radiographs on their final visits. They were recruited from two clinics, and the mean duration in the study was 937.25 days (range 569–963). In total, 21 patients (21% of the 102) did not complete the study or did not have complete data: 9 from control and 12 from treatment. Overall, 81 (79%) patients completed the study, and secondary analysis was performed based on these data.

Blinding Procedure

Patients' responses on the questionnaire during their final visits, indicated that 31% had not worn their orthotic/placebo in the last 30 days before their visits. These subjects were divided equally between the treatment and control groups. Therefore, the blinding procedure seems to have been successful.

Baseline Equivalence

At baseline, there were 52 treatment and 50 control subjects (Table 1). Both groups were similar in age, height, total painful joint count, painful foot joint count, 50-foot walking time, hallux abductus angle of right and left foot, subtalar neutral and calcaneal stance positions of right and left foot, and ARA functional class. Also, there were no significant differences in foot pain, foot disability and total disability scores (17, 18). Statistically significant differences were present between the two groups in the duration of rheumatoid arthritis and in weight at the time of enrollment in the study. The mean duration of rheumatoid arthritis was 3.7 years longer and the body weight was 12.3 pounds greater in the treatment than in the control group (Table 1).

Outcomes

The outcome was defined as hallux valgus deformity as a result of progression of hallux abductus angle (21). Ninety-eight patients (96%), 50 treatment subjects and 48 control subjects, were included in the intent-to-treat analysis. Their mean duration in the study was 983.2 days (SD 38.89) for treatment and 987.39 days (SD 37.69) for control ($p = 0.93$). No significant between-group differences were found in the demographics and clinical characteristics except for duration of rheumatoid arthritis and body weight (Table 1). Ten percent of the 50 treatment patients (as compared with 25% of the 48 control patients) experienced progression in hallux valgus deformity (Table 2). To confirm this finding, a secondary analysis was performed on 81 patients who completed the study. This group consisted of 41 treatment and 40 control subjects. The mean duration of group participation was 1075 days (SD 98.91) for the treatment group and 1083 days (SD 94.61) for the control group, $p = 0.67$. Differences between baseline mean duration of rheumatoid ar-

thritis and weight were maintained. Of the 40 subjects belonging to the control group, 30% had progression of hallux valgus deformity as compared with 12.2% of the 41 subjects in the treatment group (Table 2).

Because the treatment group had a longer duration of rheumatoid arthritis and heavier body weight, logistic regression analysis was used to estimate the effect of treatment on the odds ratio of hallux valgus deformity progression, controlling for duration of rheumatoid arthritis and weight at baseline. The 95% test-based CI was also obtained. The adjusted odds ratio for the treatment group compared with the control group was 0.27, with a 95% CI of 0.078, 0.916, $p = 0.04$ (Table 3). Thus, treatment group subjects were 73% less likely to demonstrate progression of deformity.

Therefore, both analyses showed significant differences between groups in progression to hallux valgus deformity. Furthermore, we performed a cross-validation of the secondary outcome and examined the relationship of deformity with the length of wearing time of the orthoses. Subjects in the treatment group who experienced progression of hallux valgus deformity wore their orthosis an average of only 19.0 hours per week versus 46.1 hours per week for those who did not have progression of deformity. In the control group, the mean wearing time was similar for subjects who did and did not have progression of hallux valgus deformity (40.2 vs. 44.2 hours per week). Measures of pain, disability and function of the foot showed little or no benefit from the orthosis (24).

Adverse Events

There were no injuries or ulcerations from wearing the orthoses, nor was there any breakage of the orthosis caused by wear and tear during the study. Seven (7%) patients, five from the treatment group and two from the control group, complained of having foot discomfort during the 2 weeks after the initiation of the intervention. Those orthoses were reexamined, adjusted and fitted to their comfort. Four (4%) patients underwent foot surgeries: one from the treatment group who underwent removal of the nail bed and three from the control group—of which one patient underwent metatarsal resection, another had resection of a rheumatoid nodule, and the third underwent removal of the plantar neuroma. All surgeries were healed without complications.

DISCUSSION

Our study showed that subjects wearing the orthosis were protected from deformity and were 73% less likely to demonstrate progression of hallux valgus deformity than were subjects in the control group. Thus, when properly fitted and worn, the orthosis has the potential to prevent or slow hallux valgus deformity, the most common forefoot pathology. Hallux valgus deformity is seen frequently in primary and tertiary care settings. Categorical classification of hallux valgus deformity is customarily practiced among podiatrists and orthopedists. Our analysis was based on a categorical measure, which is in

TABLE 3. The association between progression of hallux abductus angle controlling for confounding variables using logistic regression

MODEL	*p*-VALUE	ADJUSTED OR***	95% (L), CI** (U)
INTENT-TO-TREAT ANALYSIS: n = 98			
Treatment	0.05	0.33	0.1, 1.0
Treatment, duration	0.04	0.29	0.09, 0.98
Treatment, weight	0.04	0.29	0.09, 0.93
Treatment, duration, weight	0.04	0.26	0.08, 0.9
SECONDARY ANALYSIS: n = 81			
Treatment	0.05	0.32	0.102, 1.028
Treatment, duration	0.04	0.29	0.085, 0.967
Treatment, weight	0.04	0.30	0.091, 0.966
Treatment, duration, weight	0.04	0.27	0.078, 0.916

L, lower limit; U, upper limit.
** Test base 95% CI.
*** OR, odds ratio.

concurrence with the customary practice of the clinicians (25, 26).

Rigorous analyses paired with cross-validation on factors such as length of wearing time and double blindness seemed to assure that the intervention could have an effect. Furthermore, most of the subjects wore the foot orthosis up until the end of the 3-year study. The wearing time of the foot orthosis far exceeded that of the surgical shoes reported by Harold (27), suggesting that subjects were satisfied with the foot orthosis. Additionally, the orthosis was conveniently removable and could be inserted into a variety of shoe gear for indoor and outdoor activities. A preventive intervention, as described, could have a significant economic impact on patients and the health care system, inasmuch as this intervention could potentially obviate the need for some foot surgery.

. . . subjects wearing the orthosis were protected from deformity and were 73% less likely to demonstrate progression of hallux valgus deformity . . . .

Advantages of Measuring Hallux Valgus Deformity

Radiologically observed deformity reflects joint pathology (28). This finding can be scored and can become a permanent record for sequential studies. It reflects prognosis and can be used to select the type of intervention. This objective outcome measure is relatively independent of personal and social forces. However, transient deformity caused by an inflammatory process or injury that produces swelling and limited motion are not measurable by this method.

Limitation of The Study

The study had several limitations. First, rheumatoid arthritis is more common in females (29). Because the research subjects were predominantly male (Table 1), our findings may not generalize to female rheumatoid arthritis sufferers, especially with regard to biologic and aesthetic differences, i.e., the rate of rheumatoid arthritis progression and type of foot gear worn. Second, the timing and duration of the intervention might not be ideal, because participants had a mean duration of rheumatoid arthritis of longer than 2 years. Others have reported that the rate of joint damage peaks at 2 years after the onset and slows down thereafter (30–32), and the duration of intervention in this study might be too short to have observed the full impact on the clinical outcome of rheumatoid arthritis. Third, we were unable to measure the midfoot joints, although we realized their function was important in aligning the fore and hindfoot while the subject was wearing the orthosis. Fourth, the measurement of forefoot to rearfoot relationship was an open kinetic chain, and the reliability during the study was not proven by any statistical method, unlike the study done by Picciano et al. (33). However, this measurement had been used widely and successfully for many years to assess the biomechanical status of the foot and ankle and to determine the desired prescription for posting or not posting functional foot orthosis. Fifth, during the study, great care was given to the fit and accommodations of the shoe insert, within the shoes. The soles of the shoes could vary in their mechanical properties and hence could influence the development of foot pathology. However, because this is a double-blind randomized clinical trial, randomization theoretically would equalize the dilution effects in both the treatment and control groups. Sixth, regression analysis was performed on data transformed from continuous to categorical. This transformation results in some loss of detail (34). However, this analysis was necessary to adjust for age and duration of rheumatoid arthritis. Seventh, although results indicated that treatment orthotics were effective in preventing progression of hallux abductus angle, a wide CI was found; this was because a small number of subjects were classified as having progression of hallux valgus deformity.

Future research should target both male and female subjects with an onset of rheumatoid arthritis of less than 2 years. In addition, study of a larger population would increase generalizibility and the precision of the estimate of the intervention effects.

CONCLUSION

This was a 5-year, multiclinic, double-blind, randomized clinical trial, in which 79% of 102 recruited patients completed the study. Despite some limitations, results from this study suggest that the treatment foot orthosis was easy to wear, practical, durable, safe and may well benefit subjects with rheumatoid arthritis.

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Appendix. Orthotic prescription information

YOUR FOOT ORTHOSES WERE FABRICATED SPECIFICALLY FOR YOU BY A PROFESSIONAL ORTHOTIC LABORATORY.

1. FOR BEST RESULTS, YOUR FOOT ORTHOSIS MUST BE WORN 7 DAYS A WEEK, AT LEAST 12 HOURS PER DAY WHENEVER YOU BEAR WEIGHT ON YOUR FEET, in shoes that do not interfere with normal foot function.
2. LACE OXFORDS or athletic shoes with firm but flexible soles, heel height more than 1 inch, soft leather or canvas uppers and round toes (such as navy or service shoes) will be to your best advantage.
3. DO NOT WALK WITHOUT SHOES. This can be damaging to your foot condition and may bring about the early development of painful structural changes.
4. NEW SHOES should be fitted with your foot orthoses in them. Most patients have no difficulty wearing their foot orthoses and find them comfortable from the beginning. There is a possibility that you might experience some tiredness and/or mild discomfort in the feet and legs caused by restored function to parts that before did not function properly. Should you have such an experience:
   a. Remove your foot orthoses from your shoes.
   b. After 1 hour, replace them in your shoes.
   c. Keep your orthoses in your shoes, but remove them if they become uncomfortable.
   d. Follow this routine until your orthoses can be worn in comfort the whole day.
   e. NEVER FORCE YOURSELF to wear your orthoses.
   f. Minor adjustments may be necessary before desired comfort is obtained.

   IF YOUR FOOT ORTHOSES "SQUEAK" in your shoes when you walk, dust the undersurface of your orthoses and the insole of your shoes (under your orthoses) with foot powder. If your foot orthoses give you more problems than have been mentioned, contact the research podiatrists at (708) 343-7200, extension 2414.
5. Anytime your foot develops an open sore (ulceration) or you are advised by your physician to have foot surgery or another procedure, you should inform the research podiatrists.

COMMENTARY

The authors have conducted an excellent, high quality study in an important area. The concept of using custom molded in-shoe orthoses for prevention of hallux valgus deformity is not new. The novel contribution made by Budimann-Mak et al. is the objective proof of this concept.

In general, the efficacy and effectiveness of custom molded in-shoe orthoses has been controversial (1–6). The literature contains studies that report positive or beneficial findings as well as studies that do not. Most studies are cross-sectional (i.e., examining a 'slice' in time) or a repeated measure type design whereby the period of follow-up ranges from 4 weeks to 3 months. In the Budimann-Mak et. al. paper, the design was prospective. Patients without hallux valgus were randomly assigned into one of two groups: (a) those receiving custom-molded orthoses and (b) those who received a placebo. The 81 rheumatoid arthritis (RA) patients were blind to the treatment and were followed for a 3-year period. In addition, the on-site investigators were blind to whether patients had the candidate treatment orthotic or placebo. These are solid principles by which to design such a study.

No study is perfect, and as an investigator who has conducted several studies of orthotic efficacy, I wish to share some thoughts that support the notion that 'the devil is in the details.' The authors state that "shoes with boxed toes or athletic shoes of proper fit and shape were preferred. A special shoe was not required." It should be noted that a rigid type of hard sole shoe will exhibit very different mechanical properties than a Nike Air Jordan™ (Nike, Beaverton, OR) sneaker and that the overall foot/insole/shoe gear complex dictates the mechanical shock (acceleration) or, more appropriately, deceleration, that the lower extremity experiences at every heel strike. These factors might influence development of pathology; for that reason, allowing different shoes in the study could be considered a confounding variable. The details of the effect that shoe designs and materials have upon humans during standing, walking and running has recently caused the International Society of Biomechanics (ISB) to develop the Subcommittee on Footwear, which has its own scientific meetings in conjunction with ISB meetings.

So that other clinical investigators may benefit from these findings, it is imperative that the specific prescription measurement criterion, casting techniques, and type of in-shoe orthoses be explicitly stated in this type of research. Several clinical biomechanical measurements as popularized by Root, Orien, and Weed (6) have been used in documenting the foot malalignment or deformity such as resting calcaneal stance position (RCSP), neutral calcaneal stance position (NCSP), forefoot-to-rearfoot relationship (FF/RF), and subtalar joint neutral position (STJN). Of these goniometric techniques, only one (i.e., RCSP) has withstood the rigors of inter-rater reliability. The take-home message is that it's important for investigators to state how they measured a given patient's foot deformity and to document its correction, or realignment, via in-shoe orthoses. The unfortunate caveat is that the measurement technique used might be reliable or might require reliability testing. The onus of parameter reliability verification rests upon the investigator who has selected that parameter for his/her study. Note that the authors of the aforementioned paper did establish intra-rater and inter-rater reliability of their hallux abductus angle measurement.

Budiman-Mak et. al. made a fine contribution by establishing efficacy of in-shoe orthoses for prevention or minimization of hallux abducto-valgus deformity in the RA patient. The cost effectiveness of such a treatment as compared with the economic consequences of requiring surgery for the correction of that deformity are significant benefits to this approach.

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