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Shoe Inserts Alter Plantar Loading and Function in Patients With Midfoot Arthritis

Arthritis has emerged as the nation's leading cause of disability.¹¹ In recent years, the incidence of arthritis of the tarsometatarsal joints (midfoot) has increased at an alarming rate. Injuries to the midfoot (Lisfranc) joint complex affect approximately 55 000 people per year.¹⁸ Lisfranc injuries are particularly concerning because as many as 20% are missed or misdiagnosed.^{15,16} While midfoot injuries are frequently reported in the athletic population,^{12,29,30}

these injuries have increased in frequency as well as severity, secondary to motor vehicle trauma.^{28,39,42,55} Irrespective of the mechanism of trauma, midfoot arthritis has been reported to be inevitable sequelae of significant tarsometatarsal joint injuries.^{34,43,50}

Patients with midfoot arthritis experience moderate to severe foot pain, which may limit their participation in walking and recreational physical activity. Pain is most commonly localized to the dorsum of the foot in the vicinity of the first and/or second tarsometatarsal joints, and is aggravated by weight bearing. Pain and activity limitation are accompanied by radiographic evidence of degenerative arthritis at the first and/or second tarsometatarsal joints, including joint space narrowing, osteophyte formation, and exuberant dorsal bossing.³⁶ In addition to degenerative changes, poor foot alignment has been reported. Preoperative radiographs of patients with midfoot arthritis have demonstrated low-arch foot alignment, evidenced as an increase in the lateral talar-first metatarsal angle.²³

Midfoot arthritis is characterized by a high potential for chronic secondary disability. The primary aim of treatment of patients with midfoot arthritis is to provide pain relief, and conservative in-

- **STUDY DESIGN:** Experimental laboratory study supplemented by a case series.
- **OBJECTIVES:** (1) To assess the effect of a 4-week intervention with a full-length insert on functional outcomes in patients with midfoot arthritis; (2) to examine the effect of the custom-molded three-quarter-length (3Q) and full-length (FL) carbon graphite insert on plantar loading in patients with midfoot arthritis.
- **BACKGROUND:** Given the coexistence of pain and lower-arched foot alignment in patients with midfoot arthritis, arch-restoring orthotic devices such as the 3Q insert are frequently recommended. However, patients continue to report foot pain despite using the 3Q insert. The FL insert has been proposed as an alternative, but objective data examining its efficacy are lacking.
- **METHODS:** Twenty female patients with midfoot arthritis participated in the study. Functional outcomes were assessed using the Foot Function Index-Revised (FFI-R). Plantar loading during walking was measured in the following conditions: shoe only, shoe with 3Q insert, and shoe with FL insert. Repeated-measures analyses of variance with post hoc analyses were used for statistical analysis.

- **RESULTS:** FL insert use for 4 weeks resulted in a 12% improvement in total FFI-R score (mean \pm SD before, 35.6 ± 10.9 ; after, 31.1 ± 9.8 [$P = .03$]). FL insert use resulted in a 20% reduction in medial midfoot average pressure loading (mean \pm SD, 64.8 ± 20.4 and 51.0 ± 15.4 kPa, with 3Q and FL insert respectively [$P = .015$]) and an 8.5% reduction in medial midfoot contact time (mean \pm SD, $84.9\% \pm 6.4\%$ and $76.4\% \pm 7.1\%$ of stance, with 3Q and FL insert respectively [$P < .01$]), compared to the 3Q insert. No differences in plantar loading were discerned between the shoe-only and FL conditions.
- **CONCLUSION:** Symptomatic improvement in patients with midfoot arthritis treated with a FL insert was accompanied by reduced magnitude and duration of loading under the medial midfoot. These preliminary outcomes suggest that the FL insert may be a viable alternative in the conservative management of patients with midfoot arthritis.
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- **KEY WORDS:** Lisfranc, orthoses, tarsometatarsal

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terventions serve as the first line of treatment. Operative intervention in the form of arthrodesis is challenging due to the complex anatomy of the midfoot region. While surgical intervention has been accompanied by decreased pain, there have been surprisingly modest improvements in function.^{1,2,25,27,43,50}

Given the coexistence of pain and lower-arch foot alignment, arch-restoring orthotic devices, such as the custom molded three-quarter-length (3Q) shoe insert, are frequently recommended. The biomechanical rationale underlying prescription is that the design features of the 3Q insert, which include an arch build-up, will potentially restore foot alignment and thus afford pain relief. In addition to altering foot alignment, 3Q inserts also alter regional plantar loading.^{7,9,26} Custom-molded inserts have been shown to decrease plantar loading at the forefoot and heel, and to increase plantar loading at the midfoot.^{7,9,26} Bus et al⁹ have used the term “load transfer” to describe the changes in regional loading accompanying use of the 3Q inserts.

Load transfer mechanisms have been accompanied by favorable functional outcomes in patients with forefoot pathology such as rheumatoid arthritis, diabetes, and painful pes cavus.^{7,52} However, functional outcomes following the use of 3Q inserts in patients with midfoot arthritis have not been as positive. While the design features of the 3Q insert facilitate pain relief in patients with forefoot pathology, the load transfer accompanying their use may be detrimental to patients with midfoot pathology. Recent clinical experience suggests that patients with midfoot arthritis continue to report foot pain during walking, despite use of the 3Q insert.⁴⁰ To date, the majority of assessments of foot function in clinical populations have predominantly focused on rheumatoid and diabetic disease.^{14,19,20,32,41,47,52,53,56,57} Studies of degenerative disorders of the foot, particularly midfoot arthritis, remain underrepresented in the literature.⁵¹

Full-length carbon graphite (FL) shoe

inserts, over-the-counter orthotic devices, have been proposed as an alternative to 3Q inserts in patients with midfoot arthritis. In a retrospective review of 56 patients with midfoot arthritis, promising results have been reported following intervention with the FL insert.⁴⁰ The rationale guiding selection of the FL shoe insert is to modify characteristics of plantar loading, including location, magnitude, and duration of loading on the painful regions of the foot. However, limited objective evidence exists to support this contention. Studies examining the effect of the FL insert have been limited to patients with hallux rigidus,^{37,45} or samples of convenience.¹⁷ To our knowledge, no data are available regarding the effects of the FL insert on plantar loading in patients with midfoot arthritis.

The purpose of this study was 2-fold: (1) to assess the effect of a 4-week intervention with a FL insert on functional outcomes and pain in individuals with midfoot arthritis, and (2) to examine the effect of shoe inserts (3Q and FL insert) on plantar loading in patients with midfoot arthritis. We hypothesized that 4-week intervention with a FL insert would provide pain relief and improve functional outcomes in patients with midfoot arthritis. We also anticipated lower medial midfoot plantar loading during walking using the FL insert compared to the 3Q insert in patients with midfoot arthritis. The findings of this study will help elucidate the mechanisms by which different types of shoe inserts may be effective in altering midfoot loading. These results have immediate application for enhancing patient care through effective orthotic recommendations.

METHODS

Subjects

PATIENTS WERE RECRUITED FROM the outpatient orthopaedic foot and ankle clinic at the University of Rochester Medical Center. All patients were seen by a fellowship-trained foot and ankle specialist orthopaedic surgeon.

Inclusion and Exclusion Criteria Inclusion criteria were presence of pain on the dorsum of the foot, localized to the tarsometatarsal region and aggravated by weight bearing. The diagnosis of midfoot arthritis was confirmed by radiographic evidence of degenerative changes at 1 or more tarsometatarsal joints. Radiographs were also used to rule out fractures and/or subluxation of the base of the metatarsals. All patients with midfoot arthritis were invited to participate in this study, with the following exclusion criteria: (1) injury or surgery of the lower extremity within the past 6 months, (2) other conditions, such as stroke, that may affect walking, or (3) use of assistive devices such as a cane or walker. In accordance with the Institutional Review Board at the University of Rochester Medical Center and Ithaca College and Health Insurance Portability and Accountability Act guidelines, informed consent was sought prior to initiating study procedures.

Demographic Data Twenty-two patients met the inclusion criteria, of whom 2 patients refused participation for logistical reasons (lived more than 2 hours away). Twenty patients with midfoot arthritis seen consecutively at the foot and ankle clinic participated in this study. The patients' mean \pm SD (range) age was 63 ± 6 (55-78) years and their body mass index was 29.7 ± 5.1 (19.9-38.1) kg/m². All patients were women. Sixteen of the 20 (80%) patients were previous users of 3Q inserts and continued to report persistent midfoot complaints. Based on clinical history and radiographic findings confirming midfoot arthritis, a FL insert (Wrymark Inc, St Louis, MO) was recommended by the orthopaedic foot and ankle specialist for all patients.

Radiographic Data Foot alignment was characterized using the following parameters from lateral radiographs. Calcaneal inclination was defined as the angle between the horizon and the inferior surface of the calcaneus¹⁰ (FIGURE 1). Calcaneal-first metatarsal angle was defined as the angle subtended by the tangent to the inferior surface of the calcaneus and a line



FIGURE 1. Radiograph of a patient with midfoot arthritis showing measures of foot alignment.



FIGURE 2. Full-length carbon foot plate (bottom left) and 2 custom-molded three-quarter-length shoe inserts.

RADIOGRAPHIC MEASURES OF FOOT ALIGNMENT IN PATIENTS WITH MIDFOOT ARTHRITIS*		
TABLE 1	Midfoot Arthritis Group (Current Study)	Normative Values (From the Literature)
Calcaneal inclination	15 ± 4 (10-23)	22 ± 6 ⁴¹
Calcaneal-first metatarsal angle	147 ± 8 (134-163)	132 ± 10 ⁴⁶

* Data are mean ± SD (range) in degrees. Lower values in calcaneal inclination and higher values in calcaneal-first metatarsal angle are reflective of lower arch alignment.

drawn along the dorsum of the midshaft of the first metatarsal⁴⁴ (FIGURE 1).

Reliability and normative values for these parameters have been established in previous studies.^{10,44} Compared to normative values obtained from the literature, patients with midfoot arthritis in the current study demonstrated lower calcaneal inclination and greater calcaneal-first metatarsal angle, which is indicative of low-arch foot alignment (TABLE 1).

Data Acquisition

Patients with midfoot arthritis participated in 2 testing sessions, 4 weeks apart, before and after intervention with the FL insert. Similar testing has found adequate accommodation to orthoses in 4 weeks.³⁸

Orthoses All patients were given 1 pair of FL inserts at initial evaluation. The FL inserts are over-the-counter inserts made of carbon graphite. At initial evaluation, if the patient was using 3Q inserts, she

was tested in the 3Q insert that she was using when she sought treatment and presented with midfoot pain. Because patients presented with their individual 3Q insert, the orthoses were not all fabricated alike. However they were consistent in terms of the following design characteristics: (1) ending at, or just proximal to, the metatarsal heads, (2) semirigid, with an average thickness of 3.79 mm, and (3) included arch buildup and contour heel. In contrast, the FL insert featured the following design characteristics: (1) full length, in that the orthosis extended from the heel to the tip of the toes, (2) semirigid (according to manufacturer’s specifications), with an average thickness of 1.59 mm, and (3) no arch buildup or contour heel (FIGURE 2). In addition, all subjects were assessed in shoe condition without inserts at initial evaluation.

Functional Outcomes The Foot Function Index-Revised (FFI-R), a region-specific outcome instrument, was used

to assess foot function in the following subscales: pain, disability, activity limitation, and psychosocial issues. Each item in the FFI-R assesses foot function over the past week. To obtain a subscale score, the item scores for a subscale are totaled and divided by the maximum total possible for the subscale items which the patient indicated were applicable. The total FFI-R score is then computed as the mean of the 4 subscale scores. The reliability, validity, and responsiveness of the original Foot Function Index has been established in patients with chronic foot disorders.^{5,48,49} In 2006, the Foot Function Index was revised to include a more rigorous theoretical model that incorporated International Classification of Function elements, biopsychosocial aspects of health, as well as quality of life. The construct validity, internal consistency, and reliability of the FFI-R were established in field testing on a sample of 92 patients, of whom 63 (69%) reported having degenerative arthritis.⁴ Given its psychometric properties and wide applicability, the FFI-R was selected to assess patients with midfoot arthritis. Data were collected and analyzed by 2 different individuals involved in the conduct of the study. The person responsible for analysis was therefore blinded to the testing session because all data were coded to remove personal identifiers.

The clinical significance of the change in FFI-R scores following intervention was examined using the minimal detectable change score with 90% confidence bounds (MDC₉₀). The MDC₉₀ was computed as follows: $MDC_{90} = SEM \times 1.64 \times \sqrt{2}$, where SEM

refers to standard error of measurement, calculated as $SD \times \sqrt{2 - ICC}$.

Intraclass correlation coefficients (ICCs) were obtained for the FFI-R total scores and component subscales from the literature.⁴

Assessment of Plantar Loading Plantar loading was assessed using flexible instrumented insoles placed inside the subjects' shoes (Pedar-X; Novel Inc, St Paul, MN). Each insole consists of a matrix of 99 capacitive sensors, encased in a protective covering. The insoles are 2 mm thick, flexible, and conform to the plantar surface of the foot. Prior to data collection, all insoles were calibrated using the TruBlu calibration device to read pressures in the 20- to 600-kPa range. Patients' shoe sizes ranged from US sizes 6 to 10 (women). Accordingly, patients were fitted with the appropriate pressure insole size prior to its placement inside the shoe. In an attempt to recreate subjects' habitual walking performance and improve external validity, testing was performed with the subjects' own footwear.

Plantar loading data were acquired with a sampling rate of 90 Hz, using a telemetry-based system. Data for a minimum of 10 steps were collected in each condition using the midgait protocol^{8,31} to eliminate the effects of acceleration and deceleration accompanying gait initiation and termination, respectively. The order in which the conditions were presented was randomized. Plantar-loading data were collected as patients walked at self-selected speed, monitored using an infrared timing system (Brower Timing Systems, Draper, UT). As plantar loading is influenced by walking speed,^{6,46,54} within- as well as between-session walking speeds were maintained within $\pm 5\%$ for all walking trials and did not differ between shoe inserts (mean \pm SD walking speeds were 0.94 ± 0.24 , 0.94 ± 0.16 , and 0.91 ± 0.20 m/s for the 3Q shoe insert, FL shoe insert, and shoe conditions, respectively [$P = .73$])

The following regions of interest were characterized: heel, medial midfoot, lateral midfoot, and forefoot, and defined

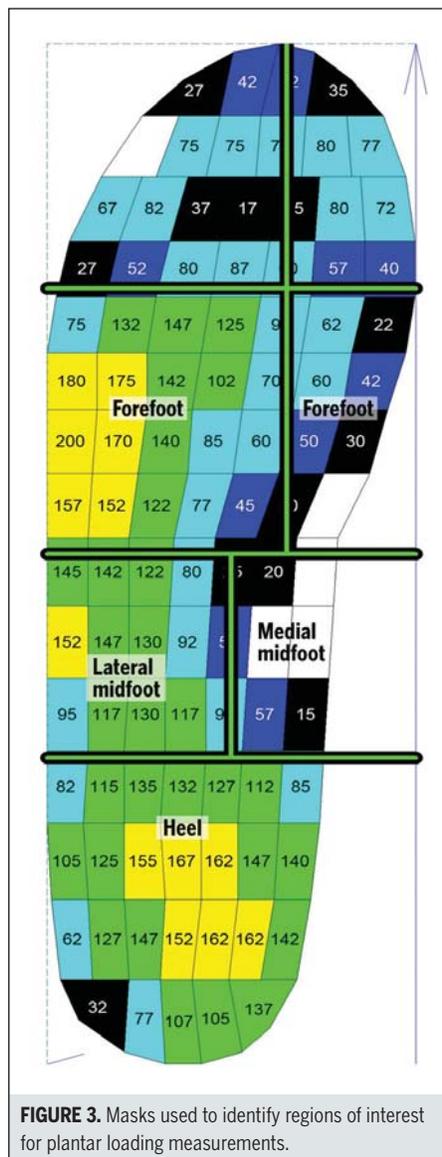


FIGURE 3. Masks used to identify regions of interest for plantar loading measurements.

as a percentage of foot length and width (FIGURE 3). Given the location of pain in patients with midfoot arthritis, loading characteristics at the medial midfoot were the primary focus of analysis. In addition, the medial and lateral midfoot masks were combined to define a midfoot region for secondary evaluation of comparative regional loading, or load transfer between the heel, midfoot, and forefoot.

Plantar loading was characterized using the dependent variables of average pressure, contact time, and contact area, and computed using Novel-win software (Novel GmbH, Munich, Germany). Average pressure was defined as the mean of

the highest pressures sustained in each sensor within each mask and expressed in kilopascals (kPa). This definition is referred to within Novel software as "maximum mean peak pressure." Our definition is consistent with previous studies that have used average pressure to examine the relationship between plantar loading and patient-reported outcomes,²⁰ as well as to assess the effect of orthoses on plantar loading.⁹ Duration of loading or contact time was defined as the duration of loading for each mask and expressed in percent of stance duration. Contact area was defined as the sum of the areas of all the loaded sensors in each mask and expressed in square centimeters (cm²). The reliability of measurements of these 3 parameters has been established in previous studies for the heel, midfoot, and forefoot regions using the Pedar in-shoe system. Using similar methodology, the intraclass correlation coefficient for average pressure ranged between 0.88 and 0.96, 0.81 to 0.94 for contact time, and 0.78 to 0.90 for contact area.^{24,35}

Statistical Analysis

Assumptions related to normality and variance homogeneity were first examined. A paired *t* test was used to assess the changes in the FFI-R scores assessed at baseline and following a 4-week intervention with the FL insert. In addition, MDC₉₀ scores were computed for each subscale, as well as the total FFI-R score.

Given that patients present with pain localized to the medial midfoot, loading characteristics of the medial midfoot were the primary focus of analysis. Therefore, the effect of shoe insert (shoes, shoes with 3Q insert, shoes with FL insert) on the medial midfoot was tested using a repeated-measures analysis of variance (ANOVA), with Bonferroni post hoc corrections. To assess load transfer mechanisms, a secondary analysis was undertaken. In terms of load transfer mechanisms, 2 possibilities were considered: load transfer in the medial-lateral direction and load transfer in the anterior-posterior direction, using

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separate repeated-measures ANOVAs. Load transfer mechanisms were assessed using 2-factor repeated-measures ANOVA (alpha, .05) using SPSS, Version 13.0 (SPSS Inc, Chicago, IL). The factors of shoe insert (shoes, shoes with 3Q shoe insert, shoes with FL insert) and foot region (medial and lateral midfoot) were included as fixed effects to assess load transfer in the medial-lateral direction. A 2-factor repeated-measures ANOVA with shoe insert (shoes, shoes with 3Q insert, shoes with FL insert) and foot region (heel, midfoot, and forefoot) was used to assess load transfer in the antero-posterior direction. Separate 2-factor ANOVAs were performed for each dependent variable of interest (average pressure, contact time, and contact area). Post hoc tests were used to examine the effect of shoe inserts on each foot region. Bonferroni post hoc tests were used to control for type 1 error with multiple pairwise comparisons and maintain overall alpha equal to .05.

RESULTS

Function

USE OF THE FL INSERT FOR 4 WEEKS was accompanied by symptomatic relief, discerned using the FFI-R. Significant reduction in total FFI-R score, reflecting improvement, was noted following use of the FL insert ($P = .03$). Greatest improvement was noted in pain (17% decrease) and activity limitation (14% decrease) subscales (TABLE 2). The clinical relevance of these findings was interpreted using the MDC_{90} , which was computed as a 5-, 5-, and 7-point change for total FFI-R score, and the pain and activity limitation subscales, respectively. Using the MDC_{90} as a cut-off, 75% of the patients showed improvement in total score and 65% showed improvement in pain and activity limitation subscales.

Plantar Loading

The 1-way ANOVA comparing average pressure at the medial midfoot across the 3 shoe inserts was significant ($F = 5.4$, $P = .03$). Post hoc pairwise comparisons re-

vealed that, compared to the 3Q insert, use of the FL insert was accompanied by a significant decrease in average pressure under the medial midfoot ($P = .016$, TABLE 3).

The 1-way ANOVA comparing contact time at the medial midfoot across the 3 shoe inserts was significant ($F = 6.2$, $P = .02$). Post hoc testing revealed that the

TABLE 2		FOOT FUNCTION INDEX-REVISED SCORES BEFORE AND AFTER A 4-WEEK INTERVENTION WITH THE FL CARBON GRAPHITE INSERT*					
	Before Intervention [†]	After Intervention [†]	P Value	Percent Change	Effect Size	MDC ₉₀	95% CI Change Score
Pain	37.1 ± 9.5	30.6 ± 10.1	.050	17%	0.66	5	2.4 to 12.0
Disability	37.3 ± 10.7	35.0 ± 11.6	.270	6%	0.20	6	-1.7 to 7.1
Activity limitation	38.3 ± 12.7	32.3 ± 12.3	.019	16%	0.36	7	2.1 to 13.0
Psychosocial issues	29.7 ± 10.0	26.6 ± 9.8	.068	10%	0.28	7	-2.0 to 9.0
Total score	35.6 ± 10.9	31.1 ± 9.8	.032	12%	0.43	5	1.0 to 9.0

Abbreviations: CI, confidence interval; FL, full-length.
 * A score of 100 indicates worst possible pain and function, while lower scores are indicative of higher levels of function.
[†] Data are mean ± SD.

TABLE 3		PLANTAR LOADING IN THE MEDIAL MIDFOOT DURING WALKING IN THE 3 SHOE INSERT CONDITIONS*		
	Custom-Molded 3Q Insert	FL Carbon Graphite Insert	Shoe	
Average pressure (kPa)	64.8 ± 20.4	51.0 ± 15.4 [†]	52.4 ± 13.8	
Contact time (% stance)	84.9 ± 6.4	76.4 ± 7.1 [†]	79.1 ± 6.1	
Contact area (cm ²)	14.2 ± 4.3	11.3 ± 4.6 [†]	13.1 ± 4.6	

Abbreviations: 3Q, three-quarter-length; FL, full-length.
 * 1-way analysis of variance examining the effect of shoe insert was significant for average pressure ($F = 5.4$, $P = .03$), contact time ($F = 6.2$, $P = .02$), and contact duration ($F = 4.5$, $P = .04$). Data are mean ± SD.
[†] Indicates statistically significant difference, based on post hoc pairwise comparisons between FL carbon graphite shoe insert and 3Q shoe insert, respectively ($P < .016$).

TABLE 4		PLANTAR LOADING IN THE MIDFOOT DURING WALKING IN THE 3 SHOE INSERT CONDITIONS*		
	Custom-Molded 3Q Insert	FL Carbon Graphite Insert	Shoe	
Medial midfoot				
Average pressure (kPa)	64.8 ± 20.4	51.0 ± 15.4	52.4 ± 13.8	
Contact time (% stance)	84.9 ± 6.4	76.4 ± 7.1	79.1 ± 6.1	
Contact area (cm ²)	14.2 ± 4.3	11.3 ± 4.6	13.1 ± 4.6	
Lateral midfoot				
Average pressure (kPa)	70.6 ± 20.3	66.1 ± 18.6	63.1 ± 18.7	
Contact time (% stance)	91.0 ± 6.8	89.8 ± 6.3	92.5 ± 6.8	
Contact area (cm ²)	19.5 ± 2.0	18.9 ± 2.2	19.3 ± 2.2	

Abbreviations: 3Q, three-quarter-length; FL, full-length.
 * The secondary analysis examining medial-lateral load transfer did not indicate a significant foot region by shoe insert interaction effect for average pressure ($F = 1.79$, $P = .30$), contact time ($F = 2.3$, $P = .19$), or contact area ($F = 1.9$, $P = .23$). No significant main effect of shoe insert was found for average pressure ($F = 3.3$, $P = .08$), contact time ($F = 3.5$, $P = .10$), or contact area ($F = 3.1$, $P = .09$). Data are mean ± SD.

medial midfoot was loaded for a shorter percentage of stance duration when using the FL insert compared to the 3Q insert ($P = .018$, **TABLE 3**). The 1-way ANOVA com-

paring contact area at the medial midfoot across the 3 shoe inserts was significant ($F = 4.5$, $P = .04$). Post hoc pairwise comparisons showed greater contact area

during use of the 3Q insert compared to use of the FL insert ($P = .019$, **TABLE 3**). At the medial midfoot, neither average pressure, contact time, nor contact area were different between the shoe and FL conditions ($P = .22$, **TABLE 3**).

The secondary analysis examining medial-lateral load transfer did not indicate a significant foot-region-by-shoe-insert interaction effect for average pressure ($F = 1.79$, $P = .30$), contact time ($F = 2.3$, $P = .19$), or contact area ($F = 1.9$, $P = .23$). No significant main effect, which effectively collapses the data for the medial and lateral midfoot, of shoe insert was found for average pressure ($F = 3.3$, $P = .08$), contact time ($F = 3.5$, $P = .10$), or contact area ($F = 3.1$, $P = .09$, **TABLE 4**).

The assessment of anterior-posterior load transfer, using a 2-way ANOVA, revealed significant foot-region-by-shoe-insert interaction for average pressure ($F = 6.5$, $P = .02$). Therefore, data were “sliced” by factor of interest and simple effects (ie, the effects of shoe insert at each foot region were assessed). These analyses demonstrated that the FL insert resulted in a significant reduction in midfoot average pressure ($P = .03$, **FIGURE 4**), along with increased forefoot ($P = .04$) and heel ($P = .04$) average pressure, compared to the 3Q insert. A significant foot-region-by-shoe-insert interaction was found for contact time ($F = 6.2$, $P = .04$). Subsequent analysis of the effects of shoe insert at each foot region revealed that use of the FL insert was accompanied by decreased contact time in the midfoot ($P = .02$, **FIGURE 5**), while equivocal changes were noted in duration of loading at the heel and forefoot, compared to the 3Q insert. No significant foot-region-by-shoe-insert interaction ($P = .48$) or main effect ($P = .68$) was found for contact area (**TABLE 5**).

DISCUSSION

THE KEY FINDINGS OF OUR STUDY reveal that a 4-week intervention with the FL carbon graphite shoe insert affords symptomatic relief in patients with midfoot arthritis. In terms

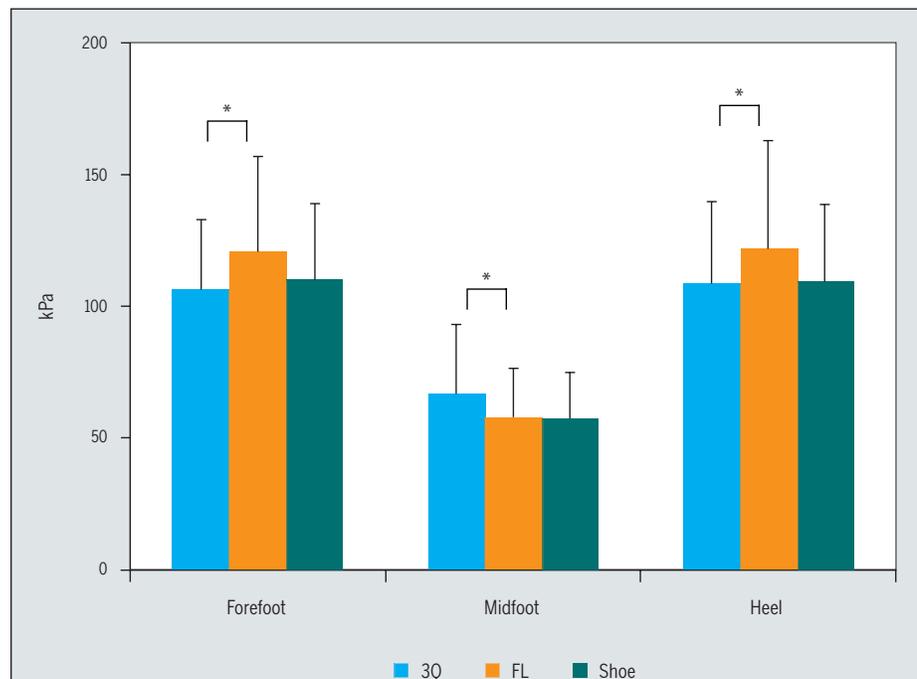


FIGURE 4. Reduction in midfoot average pressure resulting from the use of the full-length (FL) insert was accompanied by concomitant increase in heel and forefoot average pressure compared to the three-quarter-length (3Q) shoe insert condition. *Indicates statistically significant difference between FL and 3Q inserts ($P < .016$). Error bars indicate standard deviation.

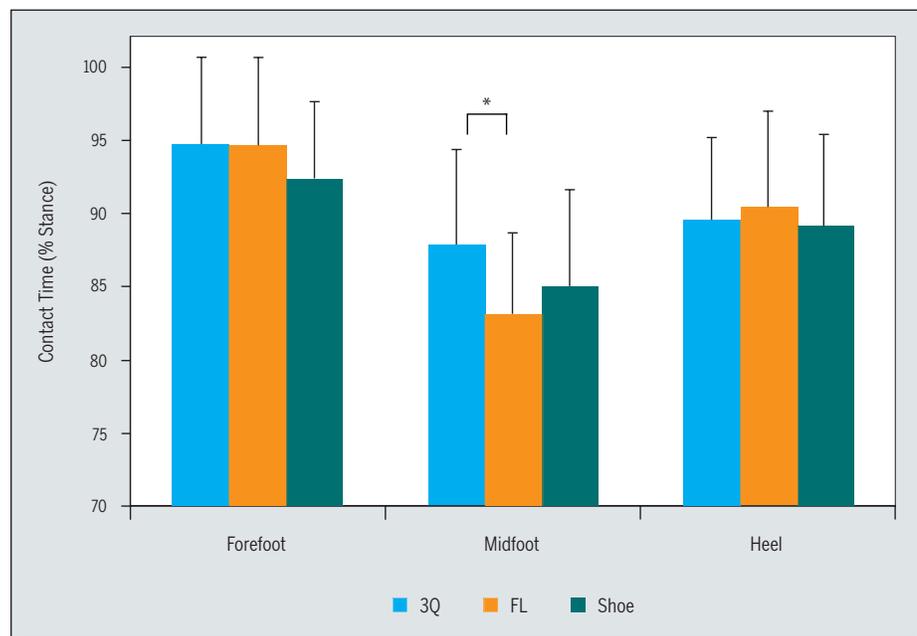


FIGURE 5. Use of the full-length (FL) insert was accompanied by decreased duration of loading in the midfoot ($P < .05$) and equivocal changes in duration of loading at the heel and forefoot. Error bars indicate standard deviation.

TABLE 5

CONTACT AREA IN THE FOREFOOT, MIDFOOT, AND HEEL MASKS IN THE 3 SHOE INSERT CONDITIONS*

Contact Area	Custom-Molded 3Q Insert	FL Carbon Graphite Insert	Shoe
Forefoot	36.1 ± 5.4	35.0 ± 3.2	36.1 ± 3.7
Midfoot	31.6 ± 4.9	30.1 ± 4.9	32.4 ± 5.1
Heel	41.7 ± 4.6	40.1 ± 5.5	41.2 ± 4.7

Abbreviations: 3Q, three-quarter-length; FL, full-length.

**Data are mean ± SD in cm². No statistically significant difference across conditions (P>.05).*

of plantar loading, use of the FL insert resulted in reduced magnitude and duration of loading on the medial midfoot compared to the 3Q insert. To our knowledge, this was the first study to examine the mechanisms underlying the efficacy of orthoses in midfoot arthritis, as demonstrated through changes in plantar loading. These findings suggest that the FL insert may be a viable alternative in the conservative management of patients with midfoot arthritis.

Use of the FL insert provided symptomatic relief as discerned by the FFI-R. The overall 12% (effect size, 0.43) improvement in total FFI-R score was driven largely by decreases in pain (17%; effect size, 0.66) and activity limitation (16%; effect size, 0.36). Improvements in self-reported functional outcomes are important because reduced physical function is a strong predictor of restrictions in daily activity, future disability, and loss of independence.²² Effective early intervention may play an important role in influencing modifiable mechanical risk factors and prevent progression of symptoms.

Sixteen of the 20 subjects were previous users of the 3Q insert, but this fact did not appear to influence the change in FFI-R scores, as both groups showed similar improvement in the activity limitation subscale (8 points) and total FFI-R score (5 points).

The mean magnitude of improvement following intervention with the FL insert is slightly lower than symptomatic relief reported by patients with chronic foot and ankle conditions treated with shoe inserts.^{14,56} In a previous investigation by Woodburn et al,⁵⁷ patients with rheumatoid arthritis treated with custom-mold-

ed inserts showed 23% improvement in composite FFI score at 30-month follow-up. Similarly, de P. Magalhães et al¹⁴ reported a 26% improvement in FFI score at 4-week follow-up in patients with rheumatoid arthritis treated with foot orthoses. In addition, they noted that the initial improvement in symptoms, occurring in the first month of treatment, was sustained over 6-month follow-up. Our results warrant longer-duration follow-up to confirm continued therapeutic benefit over 6 to 12 months.

An additional consideration in the interpretation of differences in magnitude of outcomes between our study and previous reports is patients' baseline severity. Patients in our study reported lower pain scores (mean baseline FFI-R pain score, 37.1), compared to other reports of patients with rheumatoid arthritis (mean baseline FFI pain score, 66.7)¹⁴ and patients with midfoot arthritis (mean preoperative FFI pain score, 52.1).²³ Due to differences in severity at initial evaluation, the magnitude of improvement demonstrated by patients in the current study may be attenuated. In light of these findings, the clinical relevance of the change in functional outcomes was examined using the MDC₉₀. Using the MDC₉₀ as a cut-off, 75% patients showed improvement in total score, 65% showed improvement in pain and activity limitation subscales. The positive outcomes accompanying intervention are encouraging and indicate that the FL insert was effective in the majority of patients.

In terms of plantar loading, use of the FL insert was accompanied by a 20% decrease in magnitude and an 8.5% decrease

in duration of medial midfoot loading compared to the 3Q insert. These findings are consistent with recent reports indicating that regional loading is a key mediator of pain relief in patients with chronic foot pain and pathology. Burns et al⁷ reported a significant relationship between total foot pressure time integral and foot pain in patients with pes cavus. In patients with rheumatoid arthritis, Hodge et al²⁰ found a significant relationship between average pressure sustained under the head of the second metatarsal and pain during walking. Similar results were reported by Jannink et al²¹ in patients with degenerative disorders of the foot.

Degenerative disorders of the foot, such as arthritis, may render the foot more susceptible to pain either through mechanical overloading of plantar regions that are not usually loaded, or because the foot has a lower tolerance to normal plantar loading.²¹ When considering the possibility of mechanical overloading in the shoe condition, our patients demonstrated magnitudes of regional plantar loading comparable to those measured in previous studies (ie, plantar loading was not excessive).^{3,6,19,54} However, they continued to experience foot pain, supporting the latter contention that patients with midfoot arthritis may be less tolerant of medial midfoot loading. The favorable outcomes accompanying reduction in both magnitude, as well as duration, of midfoot loading highlight the importance of addressing plantar-loading characteristics in mediating pain relief in patients with midfoot arthritis.

Regional plantar loading may contribute to the development of symptoms by directly stimulating mechanoreceptors and nociceptors in the plantar aspect of the foot. Additionally, they may also have indirect consequences on the reaction forces and moments reflective of articular loading sustained at the tarsometatarsal joints. While subtle changes in plantar pressure have been postulated to alter articular contact area and forces, the direct relationship between plantar pressure

changes observed with foot orthoses and their subsequent effects on joint loading remain unknown. Investigations are underway to examine the consequences of regional plantar loading on articular loads sustained at the tarsometatarsal joints.

In agreement with Bus et al,⁹ our findings support the contention that the design features of the 3Q insert, including an arch build-up and a contoured heel, result in load transfer from the metatarsal head and heel regions to the midfoot. While this transfer may have a favorable therapeutic effect in patients with forefoot pathology, such as patients with forefoot pain⁷ or diabetes and neuropathy,^{26,33} it may exacerbate symptoms in patients with midfoot arthritis. The latter contention may have been the case for 16 (80%) of the 20 patients in the current study who were previous users of 3Q inserts and continued to report persistent midfoot complaints.

Load transfer analyses revealed that the FL insert favors load transfer away from the midfoot to the forefoot and heel regions. These load transfer patterns suggest that the FL insert must be used with caution in patients with forefoot pathology such as metatarsalgia. While no adverse effects were reported in the current group of patients in this short-term follow-up study, longer-term follow-up studies are underway to rule out any negative effects associated with load transfer to the heel and forefoot regions. Further, while the FL insert reduced the duration of loading on the midfoot, duration of loading at the heel and forefoot remained unchanged between the shoe insert conditions.

The current study did not compare the 3Q insert to the FL insert using a randomized clinical trial; therefore, direct comparisons between functional outcomes following the use of the 2 inserts is beyond the scope of our study. In addition to providing objective data regarding the mechanisms underlying effectiveness of shoe inserts in patients with midfoot arthritis, these data have

significant implications in terms of costs. The 3Q insert is custom molded, while the FL insert is available over the counter. There are wide discrepancies in the direct costs of custom-molded (approximately \$300) versus over-the-counter shoe inserts (approximately \$80), as well as in the indirect costs associated with orthoses fabrication and fitting time. Orthosis that do not optimally target mechanisms mediating symptoms may fail to offer satisfactory pain relief. In the absence of objective data to guide orthoses prescription in patients with midfoot arthritis, selection of the orthoses is often a matter of trial and error until the patient reports pain relief. Not only is this approach inefficient in terms of costs and effort, but may also prolong the patients' pain and disability when unsuccessful. Preliminary evidence from the current cohort study suggests that the FL insert may be a viable and cost-effective alternative in the conservative management of foot pain in patients with midfoot arthritis.

The chief limitations of this study include the small sample size and relatively short intervention period. The lack of representation of both genders in the study sample may appear to be a limitation. However, a review of the gender distribution of patients with rheumatoid arthritis¹⁴ and patients with midfoot arthritis^{13,23} revealed that women constitute 65% to 85% of the study sample in previous reports. Further, the gender distribution of patients in the current study is representative of the patient population with chronic foot and ankle problems (general and midfoot arthritis, in particular) who seek treatment at the orthopaedic foot and ankle clinic. Longer-term follow-up studies are underway to confirm the continued therapeutic benefit of the FL insert, as well as to rule out any negative effects associated with load transfer to the heel and forefoot regions.

An additional consideration in the clinical interpretation of this study is that loading characteristics did not differ between the shoe and FL insert conditions.

This finding may suggest that discontinuing use of the 3Q insert will provide adequate symptomatic relief. To address this potential limitation, future studies should be designed with a "washout" period. In addition to altering plantar-loading characteristics, shoe inserts may also influence foot motion and thus afford symptomatic relief. Additional studies are underway to examine alternative mechanisms by which conservative intervention may be effective.

CONCLUSION

THE RESULTS OF OUR STUDY PROVIDE preliminary evidence that foot pain in patients with midfoot arthritis may be amenable to a simple and cost-effective intervention. In patients with midfoot arthritis, 4-week intervention with the FL carbon graphite shoe insert was accompanied by symptomatic relief and concomitant reductions in both the magnitude and duration of medial midfoot loading. Based on the preliminary findings presented in this study, larger-scale randomized clinical trials are indicated to establish optimal intervention strategies that are both scientifically based and cost-effective for patients with midfoot arthritis. ●

KEY POINTS

FINDINGS: A 4-week intervention with the full-length (FL) carbon graphite shoe insert affords symptomatic relief in patients with midfoot arthritis. Use of the FL insert was accompanied by reduced magnitude and duration of loading on the medial midfoot.

IMPLICATIONS: These positive outcomes suggest that the FL insert may be a viable alternative in the conservative management of patients with midfoot arthritis.

CAUTION: This study assessed a relatively small sample over short-term (4-week) follow-up. Additional analyses examining longer-term outcomes, as well as alternative mechanisms of pain relief, are indicated.

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