Custom Therapeutic Insoles Based on Both Foot Shape and Plantar Pressure Measurement Provide Enhanced Pressure Relief

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OBJECTIVE — The purpose of this study was to determine whether custom insoles tailored to contours of the barefoot pressure distribution and shape of a patient's foot can reduce plantar pressures in the metatarsal head (MTH) region to a greater extent than conventional custom insoles.

RESEARCH DESIGN AND METHODS — Seventy regions of elevated barefoot pressures (mean peak 834 kPa under MTHs) were identified in 20 subjects with diabetes. Foam box impressions of their feet were sent to three different orthotic supply companies for fabrication of custom insoles. One company was also given plantar pressure data, which were incorporated into the insole design. Measurements of in-shoe plantar pressures were recorded during gait for the three custom insoles in a flexible and a rocker-bottom shoe. Peak pressure and force-time integral were extracted for analysis.

RESULTS — In 64 of 70 regions, the shape-plus-pressure–based insole in the flexible shoe achieved superior unloading compared with the two shape-based insoles. On average, peak pressure was reduced by 32 and 21% (both $P \leq 0.0001$) and force-time integral by 40 and 34% (both $P < 0.0001$) compared with the shape-based insoles. At the midfoot, force-time integral was increased by 51 and 33% (both $P < 0.01$). Similar trends were found using the rocker-bottom shoe.

CONCLUSIONS — Compared with insoles based only on shape, the use of foot shape with barefoot plantar pressure measurements in designing custom insoles results in enhanced offloading of high-pressure areas under the forefoot. This offloading was achieved by a greater transfer of load to the midfoot without additional loading of other forefoot structures.

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Custom insoles are frequently prescribed for individuals with diabetic neuropathy to offload high pressures from the metatarsal heads (MTHs) and other areas, which reduces the risk of plantar ulceration (1–3). Insoles provide the important interface between the foot and the shoe and, together with outsole modifications (4,5), offer the most direct approach to the reduction of potentially damaging tissue stresses on the plantar aspect of the foot. The Medicare Therapeutic Shoe Bill recognized the importance of this intervention for primary and secondary ulcer prevention (6). The current reimbursement schedule allows for three pairs of insoles per year and one pair of shoes with sufficient additional depth to accommodate the insoles.

Because of concern over the heterogeneity of insoles supplied under Medicare coverage and their varied efficacies, the required methods of manufacturing to qualify for reimbursement have been clarified in the following extract from the most commonly used Medicare claims code, A5513: "For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore A 35 durometer or higher, includes arch filler and other shaping material, custom fabricated" (7). These requirements stress the shape-based component of insole design because a long-standing tenet of therapeutic shoemaking states that "total contact" insoles provide optimal offloading (3,8,9). The other main focus of insole design attention has been on features such as metatarsal pads and bars that are designed to offload pressures from bony prominences in specific regions. The design and placement of such devices are traditionally part of the pedorthist's "art," although a number of studies using pressure distribution measurement have shown that variations in placement of such features by as little as 5 mm can have a dramatic effect on their offloading efficacy (10,11).

This study was designed to test the hypothesis that the combination of foot shape measurement with the placement of offloading features on the basis of quantitative measurement can lead to an insole design that achieves better offloading than the current shape-based approach.

RESEARCH DESIGN AND METHODS

— Twenty-two subjects with diabetes (11 men and 11 women aged 63.7 ± 10.7 [mean ± SD] years with height 1.73 ± 0.07 m, weight 93.6 ± 20.6 kg, and BMI 31.6 ± 7.6 kg/m^2; 15

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P.R.C. has received honoraria for serving as a speaker and consultant for and owns stock in DIApedia LLC and is a named inventor on U.S. patents 6,610,897, 6,720,470, and 7,206,718, the last of which elucidates the method of insole manufacture described in this article. His participation in this study was regulated by a Conflict of Interest Management Plan approved by Cleveland Clinic's Conflict of Interest Committee.

Abbreviations: MTH, metatarsal head; ROI, region of interest.

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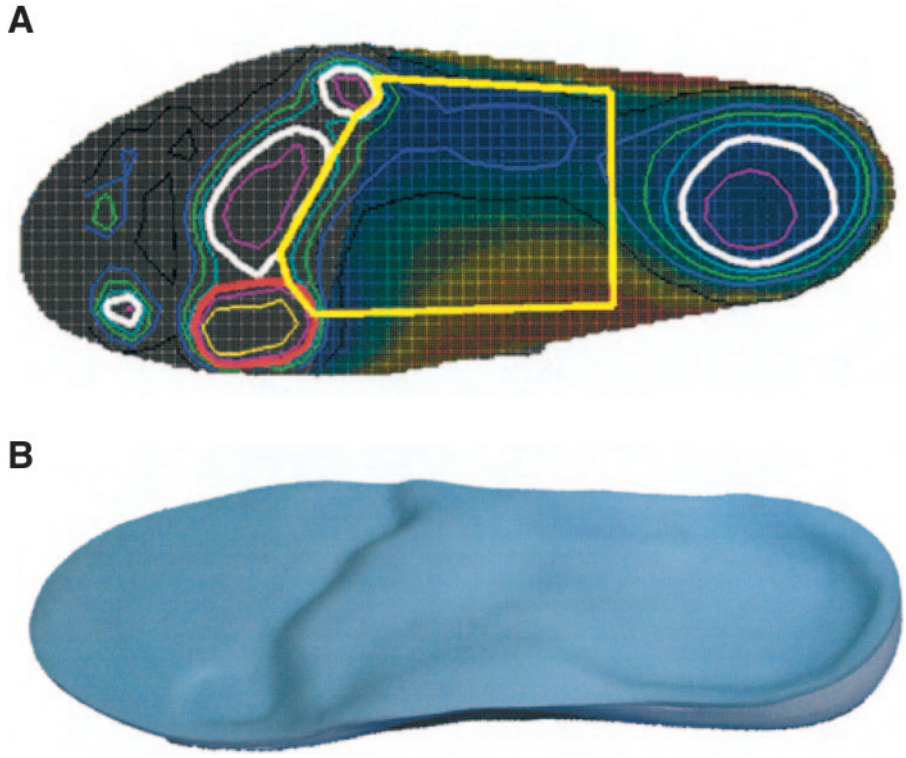

Figure 1—A*: Screen shot of the insole design program used for the shape-plus-pressure–based insole Z. Shape variation is represented by continuous color change; contours represent plantar pressure. The design algorithm identified a pressure contour along which a metatarsal bar was created (anterior border of the yellow line). A 3-mm-deep area of the insole underneath a MTH was removed in regions of excessive local pressure (>1,000 kPa).* B*: The final CAD_CAM insole with custom metatarsal bar.*

subjects had loss of sensation to 10 g touch at one or more sites tested) were recruited from the institutional review board–approved registry of the Diabetic Foot Care Program at the Cleveland Clinic, Cleveland, Ohio. Subjects were selected on the basis of high plantar pressures (>750 kPa) in the MTH region during barefoot walking as measured by an emed pressure platform (Novel, Munich, Germany) using a first-step collection method. Among the exclusion criteria were a current foot ulcer, the inability to walk unassisted for 10 m, or a shoe size outside the range of our instrumented insoles (women's size smaller than 5.5 or men's size greater than 12.5). The study protocol was approved by the institutional review board of Cleveland Clinic. Participants provided written informed consent and received compensation for participating.

Protocol

The initial experimental session consisted of recording a health history, measuring plantar pressures during barefoot walking, and taking foam impressions of the feet. The health history included recording any lower-extremity amputations, prior ulcers, deformities, current calluses/preulcers, skin conditions, a 10-g monofilament test for sensitivity to touch (at hallux, MTH1, MTH5, lateral arch, and heel), and self-reported activity level.

Plantar pressures during barefoot walking were measured using an emed-D pressure platform with 4 sensors/cm^2 (Novel). Barefoot subjects began walking by stepping directly onto the center of the pressure platform with a specific foot and continued walking for an additional few steps. Only the first step of each trial was recorded. A trial was considered successful only if the entire foot made contact with the pressure platform. Five successful trials were collected for each foot.

Three sets of foam impressions were made for each subject. Seated subjects were positioned with their knee at 90° and ankle in neutral position while the impressions were obtained. The same examiner pressed the foot deeply into the foam box by stabilizing a subject's ankle and applying downward pressure from above the knee. Additional pressure was applied to the dorsum of the foot and toes. The foot was then removed from the foam, and the process was repeated with the opposite foot.

After the initial visit, the foam impressions were sent to three different orthotic supply companies (companies X, Y, and Z) for fabrication of custom insoles. The prescription forms required by the companies were completed by the same podiatric physician. The companies were also supplied with the following information: patient with diabetes, location of prior ulcers, location of preulcers or calluses in the MTH region, foot deformities, and loss of protective sensation (if any). Company Z was also supplied with the plantar pressure data, which were integrated into its algorithms for fabrication of the custom insoles.

Insoles from company X were shape based and made of a molded thin polypropylene shell with Korex, sponge, or Plastazote cover. Insoles from company Y were shape based and consisted of a 45 shore A durometer ethylene vinyl acetate base with Procell or Plastazote top cover. Company Z provided insoles based on both shape and pressure, with a 35 shore A hardness Microcel Puff ethylene vinyl acetate base and a Poron or P-cell top cover.

To combine shape and pressure data, company Z generated a computer display on which the shape and pressure contours were superimposed onto an outline of the intended insole perimeter (Fig. 1*A*) (1). An automated design algorithm identified a pressure contour along which a metatarsal bar was created (anterior border of the yellow line). A 3-mm-deep area of the insole underneath a MTH was removed in regions of excessive local pressure (>1,000 kPa). After appropriate smoothing of the metatarsal bar into the shape contours, a stereolithography file suitable for computer-assisted manufacture was generated, and the resulting insole was manufactured on a computer numerical control milling machine and hand finished by the application of a top cover (Fig. 1*B*).

After receipt of the three pairs of custom insoles per subject at the research laboratory, subjects returned for the second experimental session involving the measurement of in-shoe plantar pressures with each type of custom insole. Each subject was supplied with shoes (Xtra Depth Erika or Canfield Leisure Time; P.W. Minor, Batavia, NY) to wear during testing. In addition to the standard flexi-

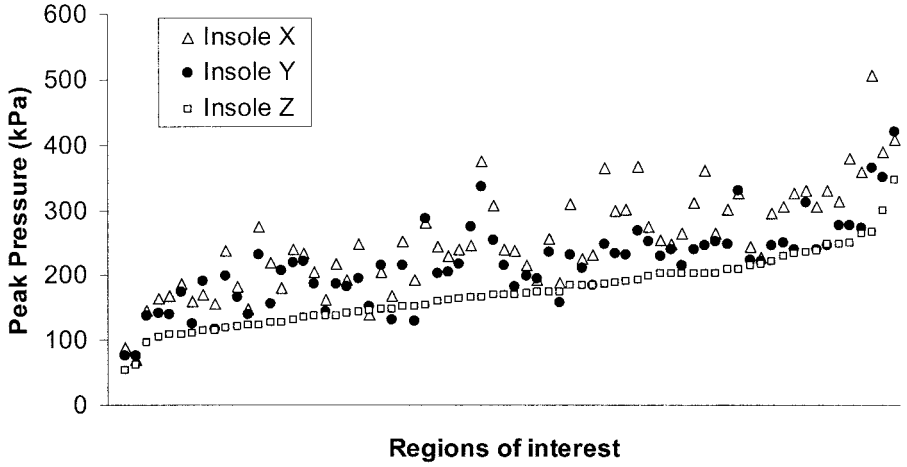

Figure 2—*Individual peak pressures (ranked by peak pressure of insole Z) at 70 ROIs for insoles in flexible shoes. △, insole X; ●, insole Y; □, insole Z.*

ble shoe, subjects were also tested in a rigid, rocker version of the same shoe. The rigidity was provided by a 1/16 × 1-inch spring steel shank that was embedded into the shoe under the outsole. The take-off point of the 20° rocker angle was located at 65% of the sole length as measured from the heel (12). During the experimental session, seven testing conditions were randomly presented, as follows: the flexible shoe with the three custom insoles, the rocker shoe with the three custom insoles, and the flexible shoe with its stock insole as supplied by the shoe manufacturer (the latter, called the standard condition, is not reported here).

Before data collection, subjects established their average walking speeds by walking in their own shoes along a 20-m walkway three times. All subsequent trials were required to be within 10% of this established speed; otherwise, the trial was discarded. In-shoe plantar pressures were measured using pressure-sensitive arrays from the Pedar-X system (Novel). Pedar insoles corresponding to the subjects' shoe sizes were taped to the bottom of each bare foot, and the foot was covered with a nylon sock. Subjects then donned the particular insole-shoe condition corresponding to their first testing condition. Subjects performed multiple passes along the 20-m walkway to collect data from ~30–40 foot contacts for each foot for each condition. Once data for an appropriate number of steps had been collected, the current insole-shoe condition was removed and replaced with the next until data from all seven conditions were collected.

Data analysis

The five trials of barefoot walking collected during the initial experimental session were averaged for each foot, and regions representing MTH1, MTH2, and lateral MTH (MTH3–5) were identified using masked analysis. Any region that had a peak pressure ≥450 kPa was considered a region of interest (ROI), whereas any remaining MTH region (peak pressure <450 kPa) was considered a non-ROI.

In-shoe pressure data were analyzed using Novel software. For each condition, all collected steps were averaged for each foot. Using the flexible shoe with its standard insole condition as baseline, a mask was created that represented four regions of each foot: first MTH, second MTH, lateral MTH (MTH3–5), and midfoot. For each region, peak pressure and force-time integral were extracted.

Statistical analysis

A separate repeated-measures ANOVA was performed to explore the significance of insole type for the ROI, non-ROI, and midfoot of each shoe. The grand means of all of the variables were computed, and the pairwise comparison of differences for those variables that were significant was run using the methods of Tukey-Kramer. Because of multiple comparisons, this method adjusted the associated *P* values of the individual comparisons to ensure that they were being tested at the specified level of significance. A comparison with a level of $P < 0.05$ was considered statistically significant.

RESULTS — A total of 70 ROIs (mean ± SD pressure of 834 ± 264 kPa) were identified from both feet of 20 subjects in the masked analysis of the barefoot pressures. These included 25 ROIs at MTH1, 29 ROIs at MTH2, and 16 ROIs at the lateral MTH. Because of medical reasons unrelated to the study, 2 of the 22 subjects originally enrolled were unable to return for the second experimental session (pressure of 941 ± 315 kPa from 7 ROIs). During the second experimental session, 1 subject was unable to ambulate comfortably in the rigid rocker shoe. Thus, the reported data are from 20 subjects for the flexible shoe and 19 subjects for the rocker shoe, respectively.

In 64 of the 70 ROIs, the shape-plus-pressure–based insole Z in the flexible shoe achieved superior unloading compared with insoles X and Y, both of which were based only on shape (Fig. 2). Insole Z significantly reduced the peak pressure at the ROIs by 32% that of insole X and 21% that of insole Y (both $P \leq 0.0001$) (Fig. 3*A*), whereas insole Y significantly reduced the peak pressure by 14% that of insole X ($P = 0.003$) (Fig. 3*A*). Insole Z significantly reduced the force-time integral at the ROIs by 40% that of insole X and 34% that of insole Y (both $P < 0.0001$) (Fig. 3*B*). Insoles X and Y were not significantly different from each other ($P = 0.47$) (Fig. 3*B*).

Peak pressures in the rocker shoe conditions were significantly lower than those in the flexible shoe ($P < 0.0001$) (Fig. 3*A* and *C*), whereas force-time integrals did not differ significantly ($P = 0.104$) (Fig. 3*B* and *D*). In the rocker shoe, insole Z significantly reduced the peak pressure at the ROIs by 37% that of insole X and by 29% that of insole Y (both $P < 0.0001$) (Fig. 3*C*), whereas insole Y significantly reduced the peak pressure by 11% that of insole X ($P = 0.022$) (Fig. 3*C*). Insole Z significantly reduced the force-time integral at the ROIs by 42% compared with insole X and by 40% compared with insole Y (both $P < 0.0001$) (Fig. 3*D*). Insoles X and Y were not significantly different from each other ($P = 0.81$) (Fig. 3*D*).

The adjusted mean ± SD peak in-shoe pressures in the flexible shoes were 246 ± 63, 211 ± 79, and 168 ± 53 kPa for insoles X, Y, and Z, respectively. The corresponding values for the rigid shoes were 200 ± 46, 178 ± 59, and 127 ± 38 kPa for insoles X, Y, and Z, respectively.

Monitoring areas in the forefoot identified as non-ROIs is important because

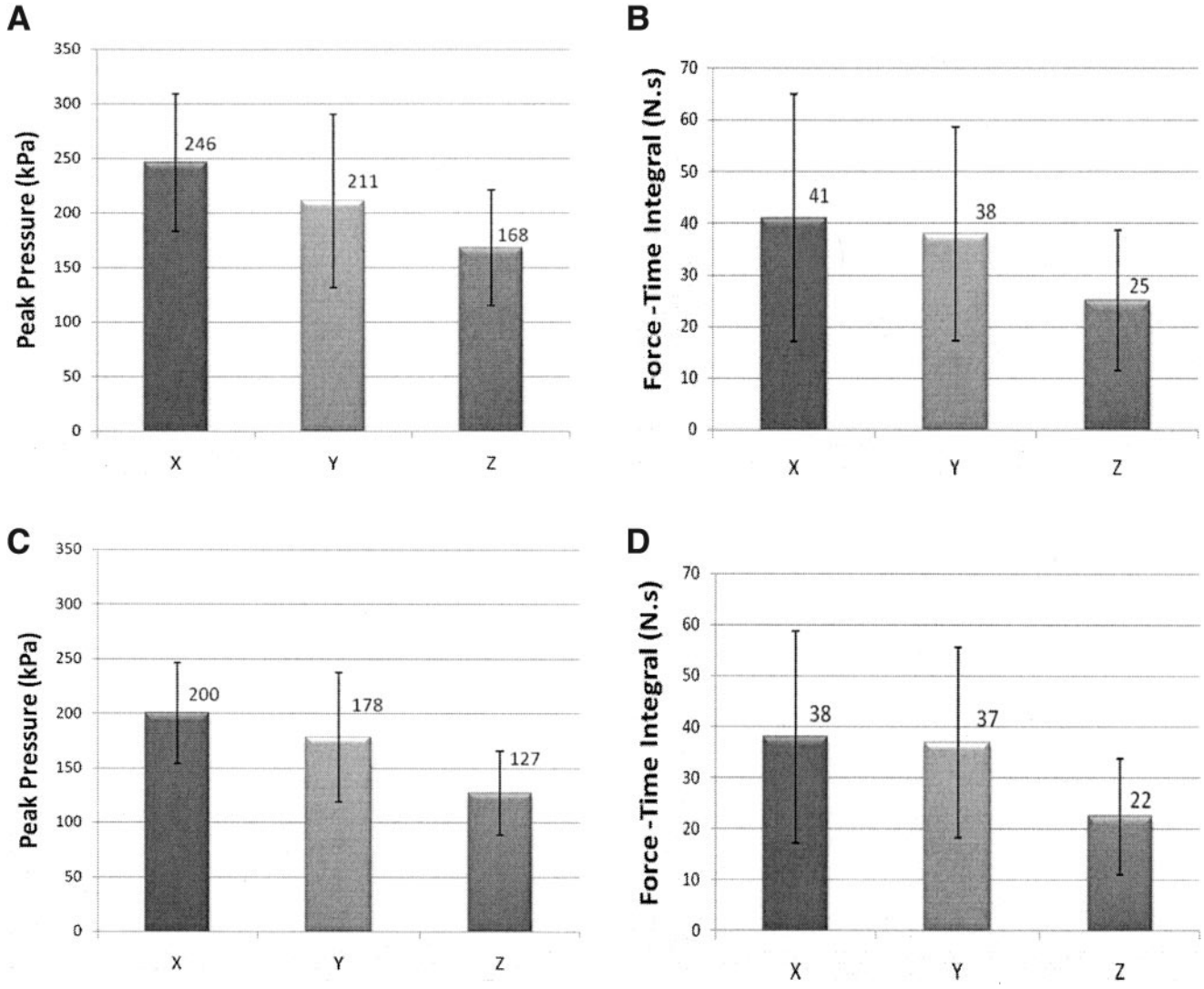

Figure 3—A*: Peak pressure at the ROIs for insoles in flexible shoe* (n = *70 ROIs from 40 feet)*. B*: Force-time integral at the ROIs for insoles in flexible shoe* (n = *70 ROIs from 40 feet)*. C*: Peak pressure at the ROIs for insoles in rocker shoe* (n = *66 ROIs from 38 feet)*. D*: Force-time integral at the ROIs for insoles in rocker shoe* (n = *66 ROIs from 38 feet)*.

unloading one forefoot region at the expense of increasing the loading on another region is theoretically possible but would usually be undesirable. The analysis indicated that peak pressure at the non-ROI was not significantly different between insoles in the flexible shoes, although a trend did exist (insole X [185 kPa] > insole Y [171 kPa] > insole Z [152 kPa]; $P = 0.051$). Insole Z significantly reduced the force-time integral by 24% that of insole X ($P = 0.018$), but no other significant differences in force-time integral were observed ($P > 0.05$). In the rocker shoe, insole Z significantly reduced peak pressure by 22% that of insole X ($P = 0.002$), but no other significant differences in peak pressure occurred (all $P > 0.05$). The force-time integral for insole Z was reduced by 23% that of insole X and 19% that of insole Y ($P = 0.0001$ and 0.009, respectively). There was no significant difference in the force-time integral between insoles X and Y ($P = 0.46$).

The midfoot, particularly the medial longitudinal arch, is invariably a target for load transfer from the forefoot in insole design (3) because this region can often bear load safely and effectively. In the flexible shoe condition, insole Z significantly increased peak pressure by 15% compared with insole Y ($P = 0.035$), but no other significant differences in the peak pressure at the midfoot were observed ($P > 0.05$). Insole Z also significantly increased the force-time integral in the midfoot by 51 and 33% compared with insoles X and Y, respectively ($P < 0.0001$ and $P = 0.003$, respectively). Insoles X and Y did not differ significantly from each other ($P = 0.44$). In the rocker shoe, no significant differences for peak pressure (all $P > 0.05$) were observed, whereas insole Z increased the force-time integral by 51% that of insole X and 33% that of insole Y ($P < 0.0001$ and $P = 0.003$, respectively).

CONCLUSIONS — This study demonstrates the considerable differences in offloading efficacy of insoles that a health care provider may order from different vendors, even though all products may qualify for the same reimbursement under the Medicare Therapeutic Shoe Bill. The approach to manufacturing custom insoles based on shape alone has remained relatively unchanged for decades. A number of publications have shown shape-based insoles to be both successful

(3,9,13,14) and unsuccessful (3,15,16) in offloading areas of plantar prominence. Further, the offloading efficacies of additional features such as metatarsal pads and bars to insoles have recently been demonstrated to be highly sensitive to small variations in placement (10,11). Presumably, the success in both of the above approaches depends heavily on the skill, intuition, and experience of the practitioner.

New technology for the measurement of foot shape and plantar pressure has provided opportunities for a quantitative custom prescription, and the present study indicates that an approach taking advantage of such technology can result in enhanced offloading. This pressure reduction was achieved by a greater transfer of load to the midfoot without additional loading of other forefoot structures, which is demonstrated by increased peak pressure and force-time integral in the midfoot and the lack of additional loading in the non-ROIs.

Increasing the thickness and changing the mechanical properties of material under bony prominences is an effective approach to the reduction of plantar pressure, although there is a lack of systematic studies that could help predict the optimal design and placement of pressure relief features of various sizes, shapes, and material properties (11). Medicare guidelines require a "base layer minimum of 3/16 inch (4.76 mm) material of shore A 35 durometer or higher. . . ."

It is not clear whether the "minimum reimbursable thickness" was chosen arbitrarily or whether some unpublished data were used to specify this value. We are not aware of an experimental study with systematically varied thickness and reports of pressure relief (although our group has previously published model results of this nature in the heel [17]). Furthermore, different manufacturers arbitrarily choose hardness values at or above the lower limit specified by Medicare, and the effects of such variation on plantar pressure have not been examined. The maximum thickness of material that can be used under the MTHs is limited by footwear depth because excessive depth can, depending on the shoe, put the patient at risk for dorsal ulceration. The shape-plus-pressure–based insoles (insole Z) used in the present study were ~2 and 4 mm thicker under the forefoot than shape-based insoles X and Y, respectively. Our previous studies have suggested that a reduction in plantar pressure of ~2–6 kPa/mm may be expected as insole thickness is increased (18), and thus thickness alone probably would not have accounted for the 43- and 78-kPa differences between shape-plus-pressure–based insole Z and shape-based insoles X and Y, respectively, seen in the flexible shoe condition. We believe many insole manufacturers do not fully exploit the available volume in the shoe under the midfoot and arch to use as a transfer area for MTH loads, and the shape-plus-pressure–based insoles in the current study have emphasized use of this space (Fig. 1*B*). Also, the customized design of the metatarsal bar in the midfoot in the shape-plus-pressure–based insoles is likely to have resulted in more consistent unloading than the shape-based designs.

Plantar pressure measurement has been proposed as an indicator of risk in patients with diabetes (19,20), although barefoot peak pressure has been reported to be only moderately sensitive and specific as a predictor of ulcer location. Elevated barefoot plantar pressure has, however, been shown in one prospective study to be predictive of ulceration (21). In-shoe pressure is probably a much more important predictor of tissue damage than barefoot plantar pressure, assuming the patient wears his or her prescription footwear for the majority of weight-bearing activity. The use of a variable such as the force-time integral has also been proposed as more representative of cumulative tissue stress than peak pressure alone (22) because it includes a time component in the assessment of loading. An additional advantage of the approach described is that the time between prescription and dispensing can be greatly reduced compared with present standards because of the automation of the design and manufacturing process.

Although the superior offloading capacity of shape-plus-pressure–based insoles compared with shape-based insoles has been demonstrated by this study, this finding cannot be interpreted to mean that ulceration or reulceration rates in patients with diabetes will necessarily be reduced by wearing such insoles. The etiology of plantar ulceration is complex and multifactorial (23,24), and a randomized controlled prospective study with ulceration rate as the outcome will be required to determine efficacy. To prescribe the insoles described in this article, the practitioner would need equipment for measurement of both shape and pressure. It is likely that this will require greater reimbursement than the current Medicare rate of $73 per pair. This could be justified if greater efficacy in primary or secondary ulcer prevention is demonstrated because the treatment costs for a single ulcer have been estimated to be $17,500–$27,987 (25,26).

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