The Influence of Shoe Design on Plantar Pressures in Neuropathic Feet

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OBJECTIVE — The aim of this study was to investigate the effect of shoe design on the plantar pressure dynamics of patients with diabetic neuropathy during walking.

RESEARCH DESIGN AND METHODS — Three shoe design categories were tested. Total contact area and biomechanical variables in multiple areas under the foot were measured.

RESULTS — Shoes with a rocker bottom principle reduced pressure 35–65% underneath the heel and the central metatarsal heads. Increased contact area did not result in significant pressure reductions underneath the forefoot. Pressure dynamics underneath the heel and medial forefoot (first metatarsal head and hallux) on average showed no significant differences among the different shoes with a cushioning insole.

CONCLUSIONS — The most effective way to offload the forefoot of patients with neuropathic feet is through the use of the rocker sole principle. In general, the effect of an insole depends on the design characteristics of a shoe. Predicting the effect of therapeutic footwear on an individual scale, however, remains difficult. Therefore, in-shoe pressure measurements seem to be necessary to evaluate a therapeutic shoe prescription in certain individual cases.

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Bauman et al. (1) were among the first researchers who published their study on the relationship between high-pressure areas and plantar ulceration in the insensitive foot. They appreciated the effect of both a total contact cast and certain orthopedic shoes on the healing process of neuropathic ulcers. They investigated the effect of shoe sole design on plantar pressure reduction using small pressure sensors taped to specific areas underneath the sole of the foot.

Using similar equipment 25 years later, Nawoczenski et al. (2) showed that certain pivotal and curved rocker bottom shoes were able to effectively reduce forefoot pressure in normal subjects. Many studies have followed since then (rev. in 3). However, despite all the pioneering work, different disciplines dealing with the neuropathic foot often still disagree about which therapeutic shoe modalities to prescribe. In the Netherlands, also, this is a continuing topic of dispute. Although some strongly propagate the use of custom made (orthopedic) shoes with a stiff sole and rocker bar to prevent recurrence of a neuropathic ulcer, others recommend the use of an extra depth shoe. It has been argued that these less heavy, more cosmetically attractive shoes would be at least as effective in preventing recurrence of neuropathic ulcers.

According to Spencer, "There is a need to measure the effectiveness of the range of pressure relieving interventions for the prevention and treatment of diabetic foot ulcers as there is a small amount of poor quality research in this area" (3). The present study was performed to investigate the relation between shoe design and pressure reduction in the context of the above discussion. Three shoe design categories were tested. Total contact area and biomechanical variables in multiple areas under the foot were measured using a repeated measures design in a series of 10 subjects with known peripheral sensory neuropathy.

RESEARCH DESIGN AND METHODS

Subjects

For this study, 10 female patients (mean age 63 years, range 44–78 years) known to have long-standing diabetes (mean duration 10.2 ± 8.6 years) were asked to participate. Inclusion criteria included the following: *1*) presence of peripheral sensory neuropathy (objectified using Semmes-Weinstein monofilaments as described by Frykberg et al. [4]), *2*) absence of important foot deformity (i.e., able to wear manufactured shoes), *3*) having no present foot ulceration, *4*) having sufficient walking capacity, and *5*) having no other diseases of the lower extremity. All patients were informed about the goal of the study in detail and gave their written consent to participate.

Footwear

The subjects wore thin (1 mm), cotton-based, seamless Falke Run socks (Falke, Schmallenberg, Germany). On the test day, each subject received a new pair of socks. Three shoe design categories, involving six pairs of shoes per subject and differing mainly in heel height, insole design, and longitudinal outsole curvature (determined by bending/rocker point and rocker angle; for details see technical description, below, and Fig. 1) were selected. These models roughly cover the wide range of shoes often worn by female diabetic patients in Western Europe. The "rocker point" defines the effective bending point of the shoe given as a percentage of the total shoe length as measured from the heel. The "rocker angle" is determined

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Abbreviations: EVA, ethyl vinyl acetate; VAS, visual analog scale.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

by the angle of the shoe sole with the horizontal plane as measured from the rocker point of the shoe toward the nose. Each shoe modality was preconditioned by having it worn at home by each subject for about half an hour. The rubber outer soles were slightly patterned.

Shoe categories

Category A shoes were "over-the-counter" leather shoes, chosen because these are typical shoes that female patients might buy in Western Europe. Shoe modality one (sm 1) was a rubber-soled Oxford-style leather shoe without any insole (model 7143-A; effective heel height +22 mm, rocking angle 5°, rocking point at 61.5%; Van der Hammen B.V., Waalwijk, the Netherlands) as a reference model. Shoe modality two (sm 2) was a rubber-soled Xtra Depth Oxford-style leather shoe (model 3116; effective heel height +30 mm, rocking angle 10°, rocking point at 67.5%; Bimakon Nederland BV, Drunen, NL) with a three-quarter custom-molded ethyl vinyl acetate (EVA)-based insole (Supronorm; Schrijver Orthopaedics, Utrecht, the Netherlands) covered with a full-length PPT layer (3 mm thick; Langer Biomechanics Group, Stoke-on-Trent, UK). For each subject, this insole was customized by an experienced shoe technician using a static blueprint of the foot. This insole was basically aimed at increasing total contact area underneath the foot without inducing any major change in foot mechanics. The same insole was also worn in both category B shoes.

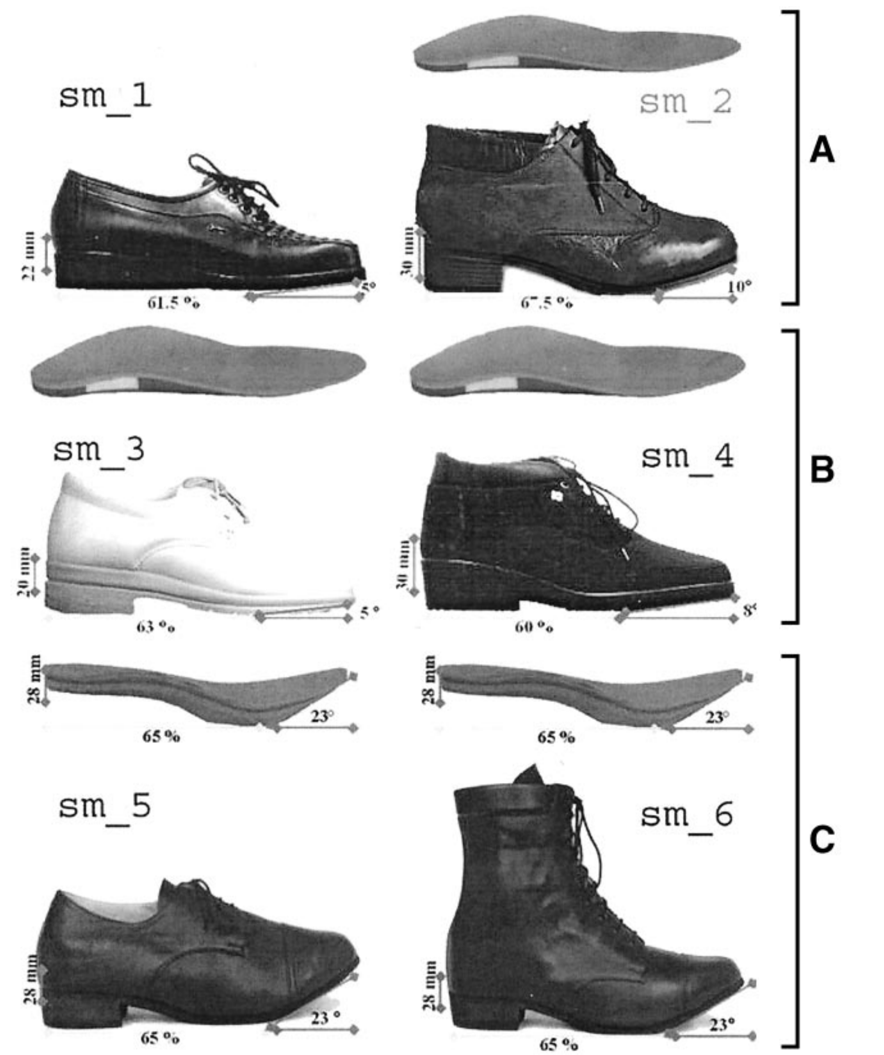

Figure 1—*Pictures of the six shoe modalities, categorized into groups A, B, and C. The insole used for a specific shoe modality is shown above each picture. The arrows indicate relative rocking axis position, rocking angle, and relative heel height.*

Category B shoes included semi-orthopedic Xtra Depth shoes, often recommended and prescribed by diabetic foot teams in the Netherlands for their width, elastic, thermoplastic, and fashionable properties of the upper material. Shoe modality three (sm 3) comprised a PU-soled Xsensible Xflex shoe (2700 series, with laces; effective heel height +20 mm, rocking angle 5°, rocking point at 63%; Nimco Orthopaedics, Berg en Dal, the Netherlands) with the above-mentioned custom-molded insole. Shoe modality four (sm 4) was a polyurethane-soled Xsensible Xstretch shoe (model 28074; effective heel height +30 mm, rocking angle 8°, rocking point at 60%; Nimco Orthopaedics, Berg en Dal, the Netherlands) with the above-mentioned custom-molded insole.

Category C included two fully individualized, plaster cast–based, soft leather rocker-bottom shoes for each subject. Shoe modality five (sm 5) was a low-shafted (below the malleoli) shoe (effective heel height 28 mm, rocking angle 23°, rocking point at 65%). This rocker sole design was based on unpublished observations (C. van Schie and P. R. Cavanagh). Shoe modality six (sm 6) was basically a copy of sm 5, except that it was a high-shafted rocker bottom shoe with a shaft length twice the lateral malleolar height. This shoe modality was added as it is generally believed that, according to the total contact cast principle, relative immobilization of the ankle joint will improve the pressure reducing effects (5). All category C shoes were fabricated by a single orthopedic shoe technician, highly experienced with the diabetic foot. The insole was made from EVA, both for its low weight and shock absorption properties, and covered with a full-length 3-mm thick PPT layer. In both shoes, the rocking principle was implemented inside the insole through rockering the bottom surface and using a 3-mm thick layer of stiff, thermoplastic, "m.o." material that was glued in between the 3-mm PPT layer and the 10-mm thick EVA layer (Fig. 1). Because the lasts (i.e., the solid form around which a shoe is molded) of both rocker-bottom shoes were identical, each subject could use the same insole for both these category C shoes.

Instrumentation

A footscan insole system (RSscan International, Olen, Belgium) with a sample frequency of 500 Hz was used to measure in-shoe pressures. The polymer sensors measure 5–7 mm with a resolution of three sensors per square centimeter. The flexible insole is 0.7 mm thick, and the different sizes enable a good fit inside the different shoe modalities. Both insoles were connected to a data logger (114 × 90 × 32 mm, weight 264 g) attached to the waist of the subject. Data were stored on a 4-Mb memory card, which enabled free gait dynamic in-shoe pressure measurements during 8 s (10–16 steps) for both the left and right foot. Before the experiment, each insole was calibrated using a strain gauge−based force plate, according to the manufacturer's instructions. The basic pressure inside the shoe, present during unloading and mainly depending on lacing technique and shoe fit, was softwarematically subtracted from the pressure measurements obtained during the stance phase. With a cordless remote control system, data collection could be started after the subject had reached a comfortable constant walking speed. After each trial, the measurements were immediately checked for artifacts or large deviations in step-to-step variability using the subject's body weight. If the step-to-step variability was too high, the trial was repeated.

Data collection

After the preconditioning phase, shoe aesthetics and comfort were rated with the visual analog scale (VAS), as these aspects of shoes might determine whether a patient will actually wear the most appropriate shoe (6,7). Patients were asked to rate consecutively the fit, appearance, and walking comfort on a scale of 0–10 and were also asked how often they would like to wear a specific shoe in daily life. The average of these rating was called the mean VAS score.

On the test day, before the measurements were taken, the left and right feet were inspected for any signs of ulceration. Both the purpose of the study and protocol were again explained to each subject. The six shoe modalities were measured in a random sequence to anticipate any order effects. Subjects walked along a 20-m flat walkway at a self-chosen constant walking speed. To avoid any speed effects, walking speed was monitored with a stopwatch and marker points on the floor. In case the walking speed deviated >±5% from the average, data were excluded from analysis and the specific trial was repeated once more. Each shoe modality was measured twice to obtain representative data. Because all shoe modalities were measured on the same day, subjects were given sufficient time to rest between trials.

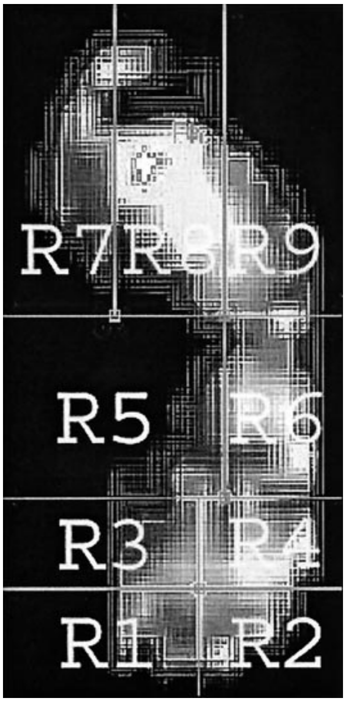

Figure 2—*The standard mask areas (R1–R9) that were used to divide the foot pressure readings into nine different anatomical regions.*

Data analysis and statistics

Total contact area and a number of biomechanical variables were measured for nine standardized mask regions underneath the foot (Fig. 2).

A power analysis with a power of 0.90 and an α of 0.05, which was based on pilot data underneath the forefoot (mean peak pressure, 30.2 ± 7.4 N/cm^2 [mean ± SD]) showed that 10 patients would be sufficient to show a significant pressure reduction of 30%, assuming that this difference has clinical meaning for the treatment of diabetic foot ulcers (8).

Using the SPSS 9.0 statistical package, ANOVA for repeated measures was performed for all biomechanical variables, followed by a post hoc Bonferroni correction for multiple comparisons. Student's *t* test for repeated measures was used to compare the contact area and VAS scores for the different shoe modalities. A significance level of $\alpha = 0.05$ was used throughout.

RESULTS

Effect of shoes

The Oxford-type shoe without an insole was used as a baseline measurement. As can be seen in Table 1, peak pressures underneath the central forefoot were relatively high with large standard errors (average 28.8 ± 13.8 N/cm^2). In all three Xtra depth shoes with EVA insoles, the mean peak pressures underneath the forefoot were very similar (31.3 ± 6.8, 27.3 ± 7.8, and 30.0 ± 5.9 N/cm^2, respectively). The lower standard errors show there was less variation among subjects in the shoes with the insole than in the reference shoe without an insole. Among the different shoe categories there was no significant difference in pressure parameters underneath the heel (R1–R4) and lateral midfoot (R6).

Compared with shoes from categories A and B, both rocker-bottom shoes showed peak pressure reductions of ~50% in the central forefoot.

A closer look at the data showed that individuals with high pressures showed large pressure reductions. Because this might have clinical meaning, we calculated the correlation coefficients between the initial peak pressure and the absolute and relative pressure reduction in the central forefoot (R8), according to the method described earlier by Perry et al. (9). For shoe modalities 2–6, we found significant negative correlation coefficients (range −0.87 to −0.96) for the absolute differences. For the relative difference, Pearson's *r* varied between −0.75 and −0.90. These results correspond with the results described by Perry et al. (9) for running shoes.

Effect of insole

Adding an EVA insole in shoe category A did not result in an overall reduction of pressure underneath the forefoot, despite the increase in contact area. In a few individual cases, the insole reduced the pressure underneath the forefoot, but the large variance revealed that the effect of this insole depended to a large extent on

Table 1—*Peak pressures and total contact area for the specific mask areas and whole foot*

	Category A		Category B		Category C	
Foot region	sm 1	sm 2	sm 3	sm 4	sm 5	sm 6
Posterolateral heel R1	31 ± 6	20 ± 2	24 ± 2	22 ± 2	24 ± 2	26 ± 2
Posteromedial heel R2	29 ± 3	20 ± 2	23 ± 3¶	19 ± 2*‡¶	21 ± 2	24 ± 2
Anterolateral heel R3	21 ± 3	24 ± 2	24 ± 2	25 ± 2	21 ± 3	21 ± 1
Anteromedial heel R4	18 ± 2	22 ± 3	21 ± 2	23 ± 3	21 ± 2	19 ± 2
Medial midfoot R5	6 ± 1	8 ± 1	8 ± 1¶	8 ± 1¶	9 ± 1¶	10 ± 1¶
Lateral midfoot R6	16 ± 2	14 ± 1	10 ± 1†¶**	10 ± 1¶**	12 ± 1	12 ± 1
Medial forefoot R7	26 ± 5	26 ± 3	24 ± 3	24 ± 2	23 ± 3	21 ± 2
Central forefoot R8	29 ± 4	31 ± 2	27 ± 3	30 ± 2	16 ± 2¶#	18 ± 2¶#
Lateral forefoot R9	17 ± 6	12 ± 1	14 ± 2	14 ± 1	10 ± 1	9 ± 1
Total contact surface (cm^2)	104 ± 3	108 ± 3*	107 ± 2*	108 ± 2*	108 ± 3*	111 ± 3*†‡§‖

Data are means ± SEM. Pressure is recorded as N/cm^2. *$P < 0.05$ vs. sm 1; †$P < 0.05$ vs. sm 2; ‡$P < 0.05$ vs. sm 3; §$P < 0.05$ vs. sm 4; ‖$P < 0.05$ vs. sm 5; ¶$P < 0.05$ vs. category A shoes; #$P < 0.05$ vs. category B shoes; **$P < 0.05$ vs. category C shoes.

the individual. Pressures underneath the posteromedial heel area (area R2) tended to decrease when an EVA insole was used.

Effect of contact area

As can be seen in Table 1, total contact surface increases significantly (on average 3.4–7.3 cm^2) when an insole is used. Depending on the shoe modality, this increase in contact area correlates weakly with an increase in total pressure time integral underneath the medial aspect of the midfoot (area R5; Pearson's r, 0.13–0.63) and a decrease in total pressure time integral underneath the central forefoot (area R8; Pearson's r, 0.01 to −0.53). This difference in average pressure appeared significant only in the high rocker shoe ($P < 0.05$).

Effect of shaft height

A decrease in the range of motion of the ankle joint through the use of a high shaft in a rocker bottom shoe led to a significant increase of effective contact area (average 2.6 cm^2). However, this did not result in significant pressure changes in these areas. Even a more detailed analysis of individual pressure readings could not reveal any consistent pattern.

VAS scores

The mean total VAS score of shoe modalities 1–6 (mean ± SEM) were 5.7 ± 2.2, 5.7 ± 2.3, 6.8 ± 2.3, 6.7 ± 1.7, 6.9 ± 2.0, and 6.4 ± 2.2, respectively, on a scale of 1–10. As indicated by the high standard errors of the mean, there was a widespread difference in individual preference for certain shoe modalities. However, on average, no statistically significant differences in mean VAS scores could be distinguished ($P > 0.05$).

CONCLUSIONS — There is a consensus in the literature that pressure relief underneath a diabetic foot is the most effective way to treat and prevent neuropathic (re)ulceration (3,10). However, among physicians and shoe technicians dealing with the diabetic foot, there is often disagreement about which shoe modalities are the most effective in establishing biomechanical stress relief. It is often reasoned that lightweight, soft, well-cushioned shoes (comparable with the category A and B shoes in the present study) serve just as well as heavy, ugly, custom-made rocker bottom shoes (the category C shoes of this study). The primary goal of the present study was to establish the effect of shoe design on plantar pressure dynamics, but not to investigate the risk for certain patients or foot types of acquiring a neuropathic ulcer nor to establish which patients are to be treated with specific shoe modalities.

In the present study, only category C shoes showed significant pressure reductions underneath the central forefoot, reducing the forefoot pressures to clinicaly acceptable levels in every subject. Our results once more confirmed former studies that rocker bottom shoes are the most effective method for reducing the pressure underneath a neuropathic forefoot. The value of a rocker bottom principle inside a surgical boot, as was the case in the category C shoes, has recently been examined in a pilot study and shown to be very effective (11). Our results also indicated that especially patients with high baseline pressures benefit in absolute pressure reduction with these rocker bottom shoes/insoles, which confirms earlier findings by Perry et al. (9) in running shoes.

It might be of clinical importance that the use of rocker bottom shoes does not result in decreased pressure under the first and fifth ray, which are the locations where ulceration most often occurs in patients with cavovarus deformity (12).

Several studies have found that increased contact area reduces plantar pressure in the forefoot by 35–44% (3,4,13–17). Although in our study the use of an individualized EVA insole inside an Xtra depth shoe increased the effective contact area between foot and insole, this did not result in significant pressure reductions underneath the forefoot. An explanation for our findings might be that our Oxford leather shoe (sm 1) had a full-length curved sole and our Xtra depth shoes were all shoes in combination with a separate heel with different sole curvatures and heel height (sm 2–4). This seems to indicate that for an average patient, the pressure-reducing effect of a cushioning insole may be counteracted by putting such an insole in a shoe with a different last, heel height, or outer sole curvature. In fact, this might explain why certain types of running shoes, which are designed to optimize the "roll-off" propulsion phase, work so well in reducing plantar pressures underneath the forefoot without the use of any special insole or orthotic (9,17).

Although it is often recommended that adding a high shaft to a rocker bottom shoe improves pressure reduction underneath the forefoot, we could not measure a difference in forefoot pressure dynamics between the low- and high-shafted rocker bottom design. Indeed, the contact area and impulse underneath the midfoot were increased with a high shaft, meaning that the high shaft itself did have some effect on foot mechanics, possibly explained by a decrease in range of motion of the subtalar and ankle joint (18). Despite this change in mechanics underneath the midfoot, this did not result in an effective reduction in vertical stress underneath the forefoot. However, because only vertical stress was measured, it is still possible that the shear stresses are lower in a high-shafted shoe, which would explain the clinical experience that high-shafted rocker shoes are sometimes more effective in ulcer prevention.

In our patient group, the average shoe ratings could not confirm significant differences in VAS scores concerning the appearance of the different shoe modalities. The statistical power of our VAS score measurements was probably too small to exclude any group preference for certain shoe models. Nevertheless, based on patient feedback, it is clear that shoe cosmetics do play an important role. This aspect should be taken into consideration to increase therapy compliance and success of the intervention.

In essence, our study confirmed the results of earlier studies that a shoe with a rocker sole principle reduces forefoot pressure more than an extra depth shoe. Outsole curvature and design of footwear have an important influence on the effect insoles have on plantar pressure dynamics under the forefoot. Predicting the effect of therapeutic footwear on an individual scale remains difficult. Therefore, for certain individual patients, in-shoe pressure measurements seem to be necessary for evaluating an individual therapeutic shoe prescription.

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