Reducing Plantar Pressure in the Neuropathic Foot

A comparison of footwear

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OBJECTIVE - To compare the effectiveness of therapeutic, comfort, and athletic shoes with and without viscoelastic insoles.

RESEARCH DESIGN AND METHODS - We compared pressure reduction at ulcer sites under the hallux (II = 10), first metatarsal (*n* = 10), and lesser metatarsals (*n* = 12), using extra-depth, athletic, and comfort shoes with and without viscoelastic insoles. A rubber-soled canvas oxford was used to establish baseline pressure values.

RESULTS - When used in conjunction with a viscoelastic insole, all shoe types reduced mean peak plantar pressure better than their non-insoled counterparts ($P < 0.05$). Consistently comfort shoes reduced pressure significantly better than both the cross trainers and extra-depth shoes for ulcers under the first and lesser metatarsals ($P < 0.05$). For each shoe type, the addition of the viscoelastic insole provided a significant reduction in mean peak pressure ($P < 0.05$). Compared with stock insoles, viscoelastic insoles reduced pressures an additional 5.4-20.1% at ulcer sites. The same trend was also observed at regions of the foot not associated with ulceration.

CONCLUSIONS - When used in conjunction with a viscoelastic insole, both the comfort and athletic cross-trainer shoes studied were as, if not more, effective than commonly pre- scribed therapeutic shoes in reducing mean peak first and lesser metatarsal pressures. Furthermore, comfort shoes were as effective as therapeutic shoes in reducing pressure under the great toe. Both of these shoe types may be viable options to prevent the development or recurrence of foot ulcers.

Foot ulceration is the most common component in the causal pathway leading to lower-extremity amputation among individuals with diabetes (I). Therefore, practical intervention strategies implemented to prevent the development of foot ulcers could interrupt this pathway and thus prevent a large number of amputations in high-risk individuals. Neuropathic ulcers on the sole of the foot normally develop at sites exposed to mod- erate-to-high repetitive pressures during the course of normal walking (2-4). In the presence of normal sensation, this type of exposure would result in pain or discomfort long before any tissue destruction would occur. In an effort to relieve this discomfort, gait modification, such as limping, or cessation of activity would follow (5) Unfortunately; patients who suffer peripheral sensory deficits lack the protective pain perception normally responsible for causing alterations in gait and are therefore apt to develop foot ulcers (6).

Therapeutic shoes and insoles have been widely accepted as a front-line defense to cushion the foot, decrease foot pressures, and reduce tissue destruction associated with repetitive high pressures in the insensate foot. Although therapeutic shoes are strongly advocated by diabetic foot specialists, little scientific information is available concerning their effectiveness in high-risk individuals with diabetes. Furthermore, because the definition of what has been considered therapeutic is quite broad, most health care providers have a poor understanding of what defines a therapeutic shoe. Typically, the spectrum of what has been considered therapeutic ranges from off-the-shelf athletic shoes to custom-moulded footwear and insoles (7-10). Because of the lack of scientific information in this area, much guesswork is required regarding the relative effective- ness of specific footwear options.

Previous studies have suggested that running shoes could significantly reduce foot pressures and the incidence of calluses on the sole of the foot in individuals without diabetic foot pathology (7). With recent advances in both the materials and craftsmanship of athletic and comfort shoes we hypothesized that certain off-the-shelf footwear may be as effective as more traditional therapeutic footwear often prescribed for high-risk diabetic individuals to reduce peak plantar foot pressures. The aim of this study was to compare the effectiveness of comfort shoes, athletic shoes, and commonly prescribed extra-depth therapeutic shoes to off-load pressures at sites of Neuropathic ulceration with and without viscoelastic insoles.

RESEARCH DESIGN AND METHODS - Thirty-two consecutive patients with diabetes mellitus and an existing or recently healed plantar Neuropathic forefoot ulcer from c1inics at University Hospital, San Antonio, TX, were enrolled in the study: Descriptive data for this population is summarized in Table 1. Each subject was then tested with three different types of shoes: Sir Super Depth and Duchess (P.W. Minor & Son, Batavia, NY; retail price, S125) for men and women, respectively: New Balance MX750WB cross trainers (New Balance,

Boston. MA; retail price $65): and SAS Timeout and Freetime comfort shoes (SAS Shoemakers, San Antonio, TX; retail price, $65) for men and women, respectively (Figs. 1-3). These shoe types were chosen because the manufacturer's inserts could be removed and an accommodative insole could be inserted in their place and because they are often used as an alternative to traditional therapeutic extra-depth shoes (7,11). In addition to being tested with the manufacturer's insole, each shoe was evaluated with an unmodified 4mm plastazote/urethane insole (AliMed, Dedham, MA) (Fig. 4). We also used a thin rubber-soled canvas oxford sneaker to establish baseline pressures that might be observed in individuals without therapeutic footwear (Fig, 5).

D}i1amic plantar foot pressures were evaluated using the Novel Pedar in-shoe pressure measurement system (Novel. Minneapolis, MN). Data were collected at 50 Hz using 2mm thick capacitance insoles with 99 sensors per insole and a spatial sensor resolution dependent on insole size (average, I sensor/cm2). The thin pressure-measuring insole has a linear response to applied loads ranging from 0 to 50 N/cm² with minimal error and has not been shown to interfere with normal gait characteristics (12). A description of the Novel Pedar system and components have been previously reported (12,13).

Four gait trials were performed for each of the six treatment methods with the Novel Pedar insole placed in direct contact with the sole of each patient's foot, Treatments were evaluated in a random order. For each treatment, subjects were allowed to practice walking until they felt comfortable, so their gait pattern would be as consistent as possible during each trial. After this "break-in" period, subjects were instructed to walk at a self-selected pace. To eliminate the highly variable steps associated with termination and initiation of gait, only mid-gait steps were evaluated from each trial. From these trials, we measured pressure distribution from a total of 32 steps for each patient for each treatment.

Table 1 Patient Characteristics

Age (years)	50.5 ± 9.5 (29-6j)
Duration of diabetes (years)	13.6 ± 9.9 (1-37)
Biothesiometer (V)	41.2 ± 13.0 (8-50)
BMI (kg/m2)	31.2 ± 5.0 (22-41)
Diabetes (type 1/2)	2/30
Sex (M/F)	21/11
Ulcer site	
First metatarsal	10
Second through fifth metatarsals	12
Great toe	10

We used SPSS version 7.5 to perform the statistical analysis of this data (SPSS, Chicago, IL). For the purposes of analysis, pressures for ulcers located under the first metatarsal head (n = 10), second through fifth metatarsal heads (n = 12), and great toe (n = 10) were evaluated separately. We focused comparisons of treatments on the site of ulceration because this was thought to be the most important site clinically; the site of the highest pressure (l1,14), and the most likely site of re-ulceration (6,15). Therefore, to compare the effect of different shoe types with and without plastazote/urethane insoles, we used a repeated measures design in which 32 replications were nested within each treatment for each patient analysis of the data was carried out using univariate and multivariate analysis of variance procedures. Tukey's multiple range test was used to compare mean differences simultaneously between shoe types both with and without viscoelastic insoles. We then used a paired t test to perform a within-group comparison of peak foot pressures with the manufacturers stock insoles and viscoelastic insoles for each shoe type. For all analyses, we used an α of 0.05.

RESULTS -Table 2 demonstrates mean peak pressures and the percentage change from baseline measurements with canvas oxford shoes for each of the shoe types, evaluated with and without a viscoelastic (plastazote/urethane) insole. When initially comparing peak pressure reduction between shoe types, we used the manufacturers stock insole provided with each pair of shoes. When this treatment group was evaluated, there was a consistent pattern of performance for ulcers located under the first and lesser metatarsals. Comfort shoes provided significantly lower pressures than both the cross trainers and extra-depth shoes ($P < 0.05$).

For great-toe ulcers, extra-depth shoes and comfort shoes functioned equally well, and both reduced pressures significantly more than cross trainers ($P < 0.05$). In fact, the only instance where foot pressures were actually increased (compared with baseline values) was in patients with great-toe ulcers treated with off-the-shelf cross trainers. Peak foot pressure was increased 12.2% using this treatment. For all other sites, there was a significant reduction in peak foot pressures.

Then we substituted the manufacturers stock insole with an unmodified plastazote/urethane insole. When this combination was evaluated, the comfort shoes, cross trainers, and extra-depth shoes were equivalent in their ability to reduce plantar foot pressures for ulcers under the first and lesser metatarsals ($P < 0.05$). For great-toe ulcers, comfort shoes and extra-depth shoes provided similar pressure reduction, and both reduced pressure significantly more than cross trainers ($P < 0.05$). At regions of the foot not associated with ulceration, there was a significant decrease in pressure, compared with baseline measurements with rubber-soled canvas oxfords ($P < 0.05$).

In the third pan of the analysis, we compared pressure measurements with manufacturer stock insoles and viscoelastic insoles. For each shoe type, the addition of the viscoelastic insole provided a significant reduction in mean peak pressure ($P < 0.05$). Compared with stock insoles.

Therapeutic insoles reduced pressures an additional 5.4-20.1% at ulcer sites. The same trend was also observed at regions of the foot not associated with an ulceration (Table 2).

CONCLUSIONS - Many studies have linked high plantar pressures to sites of ulceration in diabetic individuals with neuropathy (14,16). Brand (3) identified neuropathy; abnormal pressures, and repetitive trauma as important causative factors in the development of foot ulcers. He theorized that repetitive moderate pressures applied over an extended period of time caused a local inflammatory response, followed by focal tissue ischemia, tissue destruction, and finally ulceration. A logical treatment approach based on these observations is that interrupting this pathway would decrease the likelihood that an insensate individual would develop an ulcer. Since efforts to improve peripheral sensation and decrease patient activity have been typically unsuccessful (6), using shoes and insoles to reduce foot pressures seems to be one of the least expensive and most practical means to prevent the development or recurrence of Neuropathic foot wounds (11,17).

Table 2 – Effectiveness of shoes with and without insoles to reduce pressures at ulcer sites

		Patients with first success Metatarsal ulcers			**Patients with second Metatarsal ulcers**			**Patients with great-toe ulcers**		
Shoe type	Insole	Ulcer site	Second through fifth metatarsals	Great toe	Ulcer site	First metatarsal	Great toe	Ulcer site	First metatarsal	Second through fifth metatarsal
Canvas oxfords (baseline)	No	49.7±16.9	39.6±10.9	22.1±13.7	45.2±11.8	38.5±13.8	20.5±10.7	21.1±11.0	25.2±8.7	36.1±11.4
P.W. Minor therapeutic shoes	Yes	28.4±10.2 42.9	22.3±6.1 43.7	15.7±7.3 29.0	23.8±4.5 47.3	22.2±5.4 42.3	16.4±7.3 20.0	17.2±6.5 18.5	22.7±7.0 9.9	21.8±5.2 39.6
	No	35.5±16.2 28.6	27.6±9.2 30.3	19.0±9.1 14.2	27.7±7.1 38.9	25.5±7.9 33.8	18.1±8.4 11.7	19.2±8.2 9.0	23.8±6.3 5.6	24.3±5.4 32.7
New Balance cross trainers	Yes	28.5±10.5 42.7	23.4±6.3 40.9	16.9±6.8 23.7	24.6±4.9 45.6	20.8±4.7 46.0	17.9±8.8 12.7	20.4±8.2 3.3	20.3±6.3 19.4	22.6±4.7 37.4
	No	32.4±12.5 34.8	26.0±6.5 34.3	18.0±6.7 18.6	26.5±5.1 41.4	23.0±4.9 40.3	18.2±8.4 11.2	23.7±10.9 -12.3	21.5±5.4 14.7	24.5±5.6 32.1
SAS comfort shoes	Yes	27.4±10.3 44.9	24.0±7.6 39.4	17.8±6.9 19.5	23.3±4.0 48.5	22.1±4.6 42.6	14.8±7.1 27.8	17.6±9.0 16.6	22.7±7.8 9.9	20.1±4.8 44.3
	No	29.2±12.9 41.2	24.6±6.6 37.9	18.5±9.2 16.3	24.7±5.3 45.4	21.6±4.1 43.9	16.1±7.1 21.5	19.8±11.0 6.2	24.8±6.6 13.5	22.2±5.4 38.5

On of the goals of shoe therapy for high-risk individuals with diabetes is to reduce potentially dangerous pressures to safe levels (8), Boulton et al. (18) evaluated barefoot pressures in Neuropathic and non- Neuropathic diabetic patients and found that pressures were >110 Ncm^2 for every subject with a foot ulcer, suggesting a threshold pressure below which individuals would not ulcerate, Only 31% of diabetic subjects without a history of ulceration demonstrated abnormal peak foot pressures based on criteria of Boulton et al. (18) It is not clear if a threshold pressure level exists since other reports have Identified lower foot peak pressures at sites of Neuropathic ulceration (14) than those identified by Boulton et al (14.18) In fact, pressure values for the patient population in this study were substantially lower than those previously reported. Ulceration m the insensate foot is probably a function of both the magnitude of pressure and the frequency of exposure (i.e., the number of steps an individual takes every day) (2). Therefore, a reduction of plantar pressures below an individual's pathological level may help to prevent the development of Neuropathic foot ulcers, even when patients maintain their normal level of activity:

The results of this study suggest that there were significant differences in pressure reduction based on shoe type, anatomic location of ulcer, and use of therapeutic insoles. Both the comfort and athletic shoes evaluated in this study appear to be viable options to traditional unmodified extra-depth shoes. The comfort and athletic shoes were often equivalent to traditional extra-depth therapeutic shoes in reducing peak plantar pressures. This proved to be the case for ulcers located under the metatarsal heads. However, for great-toe ulcers, athletic shoes failed to decrease pressures, as well as the other shoes evaluated. Furthermore, when the manufacturers stock Insoles were substituted with off-the-shelf plastazote/urethane insoles, a further reduction in peak plantar pressure was realized. Although, not the focus of the study it is interesting to note that pressures were systematically decreased for ulcer and non-ulcer areas with and without insoles, except when cross trainers were used by patients with ulcers under the great toe.

Unfortunately, there are only a handful of clinical studies that describe or compare the effectiveness of therapeutic shoes and insoles. One of the principal drawbacks of the current literature is that specifications regarding the composition of therapeutic shoes and insoles are ill defined. Clinical studies suggest that the development of new ulcers in high-risk diabetic individuals can be significantly decreased with therapeutic footwear (9.19). In our study conventional shoes, both with and without special insoles, were as effective as traditional extra-depth therapeutic shoes in decreasing foot pressures. However, it is still unclear if alternative footwear, such as comfort and athletic shoes, can be as effective as traditional therapeutic shoes in a clinical setting.

Although there was a significant reduction in pressures at all ulcer sites, there was considerable variation in both baseline values and the reduction in pressures for great-toe ulcers, compared with ulcers under the metatarsal heads. In-shoe base-line peak pressures for ulcers under the metatarsal heads were more than twice as high as those Identified in patients with great-toe ulcers. In addition, pressure reduction was 3.2-18.5% for great toe ulcers treated with insoles and shoes, compared with a pressure reduction of 42.6 - 48.4% for ulcers under the first metatarsal and lesser metatarsals (Table 2). These results are similar to the observations reported by Perry et al. (11), which indicate that the greatest reduction in foot pressures was consistently at the site of the highest barefoot pressure (11). We have been unable to identify previous studies reporting that pressures for great-toe ulcers are significantly lower than those under the ball of the foot. This may be because of the fact that few studies have stratified outcomes by ulcer location, and many pressure studies performed in the laboratory use healthy volunteers or diabetic patients without ulcers.

The differences we observed are probably due to the unique biomechanical pathologies affecting each site (20,21). It can be inferred from the results of this study that the location of the ulcer may dictate the style and type of shoe that physicians prescribe. Certainly, common modifications to shoes such as rigid shanks and rocker soles need to be evaluated in laboratory and clinical settings to evaluate the impact of ulcer location on shoe and insole selection.

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