DIABETES TECHNOLOGY & THERAPEUTICS
Volume 7, Number 4, 2005


# Wear and Biomechanical Characteristics of a Novel Shear-Reducing Insole with Implications for High-Risk Persons with Diabetes

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## ABSTRACT

**Objective:** This study was designed to measure pressure and shear reduction of a novel insole design.

**Methods:** We compared three multilayer viscoelastic insoles to a novel insole design (GlideSoft®, Xilas Medical, Inc., San Antonio, TX). The bottom pad of each insole was fabricated from firm-density Plastazote® [Apex Foot Products (now Aetrex), South Hackensack, NJ] with an upper of Plastazote, ethyl vinyl acetate, or PORON® (Langer Biomechanics Group, Inc., Deer Park, NY). The GlideSoft design used the same materials with two intervening thin sheets of a low friction material. We measured foot pressures, shear, and material stiffness prospectively as the insoles aged during daily usage in 30 healthy adults. We used the *F-Scan*® (Tekscan, Inc., Boston, MA) to determine in-shoe foot pressures and the Automated Stress-relaxation Creep Indenter System (Xilas Medical) to measure material stiffness. To evaluate shear force, the insole was placed on the slide assembly of a custom-designed shear tester equipped with a reciprocating mechanism and force transducers.

**Results:** The GlideSoft exhibited 57% less peak shear force than the standard insole ($P < 0.05$) in laboratory testing under simulated conditions. Ethyl vinyl acetate had higher compressive stiffness values than Plastazote and PORON at all test intervals ($P < 0.05$). There were no statistical differences between any of the insoles for peak in-shoe pressure measurements ($P > 0.05$).

**Conclusions:** The GlideSoft design demonstrated a significant reduction in shear while maintaining equivalent pressure reduction compared with standard insole designs with three different material combinations for up to 320,000 steps.

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## INTRODUCTION

THE ETIOLOGY OF FOOT ULCERATIONS in diabetes is commonly associated with peripheral neuropathy and unrecognized repetitive injury at high-pressure sites on the sole of the foot.[1] Many studies have linked plantar pressures to the sites of ulceration in neuropathic patients.[2] Duckworth et al.[3] evaluated neuropathic and non-neuropathic patients with diabetes and demonstrated that all neuropathic patients who ulcerated had pressures greater than 112 N/cm$^2$. However, data from other research suggest that "threshold pressures" may be substantially less than previously reported. In fact, the average peak pressure at the site of ulceration in three separate studies was 82 N/cm$^2$, 87.5 N/cm$^2$, and 92 N/cm$^2$.[1,4,5] In addition, many patients with low or moderate foot pressures developed ulcerations.

This suggests that factors other than vertical compressive forces may play a significant role in ulceration. Zhang et al.[6] concluded that the effects of shear are additive to vertical pressures causing damage to the deeper soft tissues, as well as causing superficial damage. They noted that the internal compression stress in underlying soft tissues is a resultant of both pressure and shear components, which have been shown to have equal effects in the reduction of blood flow in tissues.[6] However, at this time very little has been published regarding the contribution of shear to the development of foot ulcers in patients with diabetes, although empirically it seems that any frictional force, such as shear, imparted on neuropathic skin in a repetitive fashion should have a detrimental effect on the viability of the integument.

Special insoles are one of the standard mechanisms to decrease pathologic forces on the sole of the foot in high-risk patients with diabetes. Currently there are no commercially available insoles that have been shown to reduce or modulate shear in a controlled fashion. The study's first objective was to measure the efficacy of a novel insole design, termed GlideSoft® (Xilas Medical, Inc., San Antonio, TX), and standard accommodative insole designs in reducing both pressure and shear. The study's second objective was to evaluate the durability of the GlideSoft and standard viscoelastic insoles in reducing pressure and shear over time. Our hypotheses were that the GlideSoft would significantly reduce shear forces as compared with current insole designs and that the vertical pressure reduction by the GlideSoft design would be comparable to that of traditional insole designs.

## RESEARCH DESIGN AND METHODS

We compared three traditional multilayer viscoelastic insoles with GlideSoft insoles, a novel shear-reducing insole design. We used a combination of insole materials to form three types of multi-laminar insoles, which is the industrial standard. The bottom layer or pad (in contact with the shoe) was fabricated from a 3.2-mm-thick Plastazote® [PLZ; Apex Foot Products (now Aetrex), South Hackensack, NJ] to provide a stable foundation. The material in this layer was a closed-cell dense polyethylene foam with a durometer of 30. A 1.5-mm top cover (in contact with the foot) of medium-density PLZ (durometer 20) was used. The middle pad consisted of a 3.2-mm-thick layer of one of three different materials: (a) firm-density PLZ; (b) PORON® (PPT), an open-cell, polyurethane foam with a durometer of 20 (Langer Biomechanics Group, Inc., Deer Park, NY); or (c) ethyl vinyl acetate (EVA) with a durometer of 45 (Durr-Fillauer Medical, Inc., Chattanooga, TN).

The GlideSoft insole design used the same material combinations as standard insoles. The GlideSoft design did not alter the shape, surface area, contour, or thickness of the insole. The GlideSoft insole had two thin intervening layers of low friction materials, which slide on each other (Fig. 1A). Thin woven fiberglass sheets coated with Teflon® (Dupont, Wilmington, DE) were placed in between the upper and lower pads of the GlideSoft insole and held together with elastic bindings (Fig. 1A and B). When a shear force is applied to the multilayered GlideSoft, the upper pad moves incrementally (along with the foot) relative to the lower portion (Fig. 1C). As the binders are stretched because of the movement between the upper and lower pads, they exert a retraction force, and correspondingly the shear force increases linearly at the skin–insole interface.

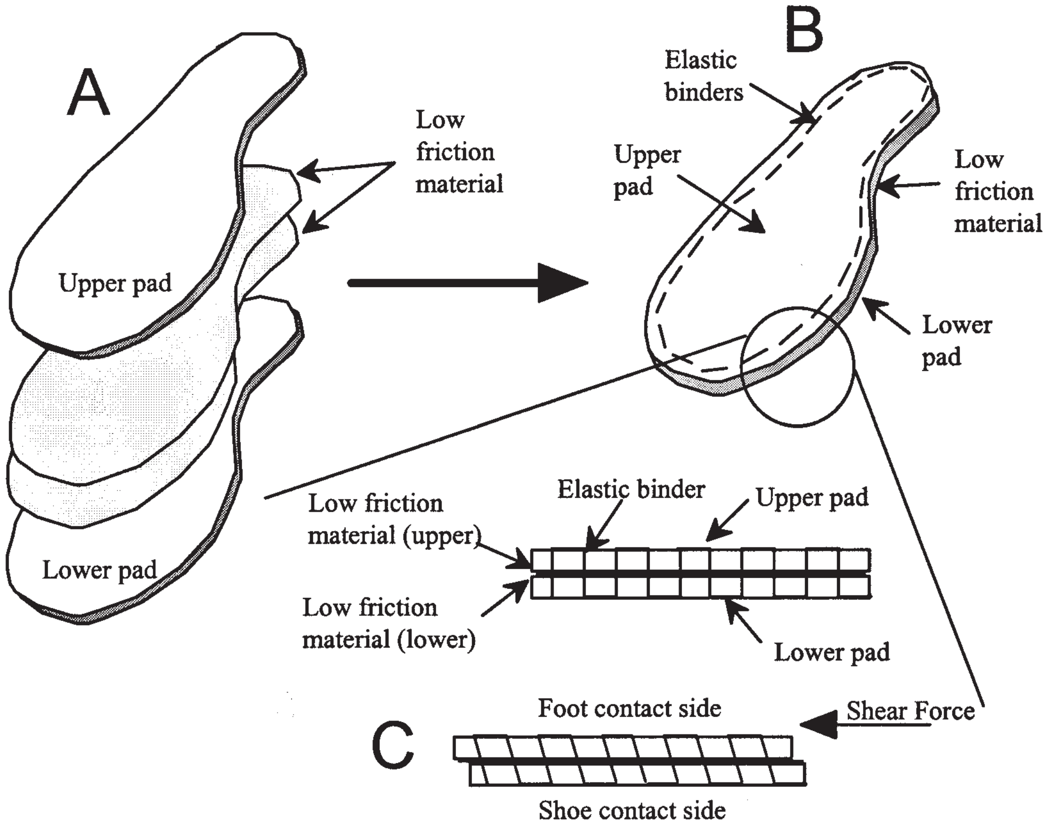


**FIG. 1.** The various layers of the GlideSoft insole are shown separately (**A**) and assembled with elastic bands (**B**). **C:** The schematic shows a cross-section of the insole with no shear force (**upper panel**) and with an applied shear force (**bottom panel**). As a result of shear, the upper pad of the insole displaces relative to the lower portion. The elastic bindings stretch and eventually stop the relative motion within the GlideSoft.

However, this increase is gradual and only up to a point where just enough friction is provided for toe-off. Thus the system is designed to reduce shear forces on the surface of the skin while retaining the vertical pressure reduction characteristics of traditional insoles.

*Gait analysis and in vivo pressure measurements*

We used three groups of 10 healthy volunteers (14 men, 16 women). Each walked four segments of 80,000 steps each for a total of 320,000 walking steps. The average time required to walk 80,000 steps was 16.4 ± 5.6 days (mean ± SD). The average age of the subjects was 44 ± 15 years. Subjects used the insoles during daily activity and recorded their activity using a commercially available electronic pedometer (Model 350, SportLine, Yonkers, NY). Each volunteer maintained a daily activity log with pedometer recordings.

Subjects were provided standardized walking shoes (models *Freetime* for women and *Timeout* for men, San Antonio Shoe Makers, San Antonio). Each volunteer used a GlideSoft insole in the right shoe and the same material combination without the GlideSoft design in the left shoe, in order to expose each insole to the same number of steps during each evaluation period. Five activity intervals were evaluated: 0, 80,000, 160,000, 240,000, and 320,000 steps. These subjects were randomized to three groups, each with different mid-pad types (PLZ, EVA, or PPT). This scenario was followed with three groups of volunteers concurrently. At intervals of 80,000 steps subjects returned for in-shoe (in vivo) pressure evaluation and in vitro mechanical testing. The insoles were returned to the volunteers the following day for continued use.

Dynamic, in-shoe plantar pressures were evaluated with the *F-Scan*® (Tekscan, Inc., Boston, MA), a high-resolution computerized insole sensor system. Each subject was evaluated on the same walking surface with the same style and brand of shoe using established procedures.[7–11] The *F-Scan* sensors were placed between the foot and the insole. Both feet were assessed at the same time. To minimize abnormal readings from starting and stopping forces, five mid-gait steps were evaluated for the right and left feet. Peak plantar pressures were evaluated under the metatarsal heads in both feet.

### *Evaluation of stiffness*

The Automated Stress-relaxation Creep Indenter (ASCI) system[12–14] (Xilas Medical) was used to measure the stiffness of the multi-laminar insoles. The ASCI is a closed-loop computer-controlled device that allows for the precise application of a load and then accurately measures the corresponding deformation. The insole specimen was mounted onto a six degrees of freedom positioning assembly and held fixed in such a way that the point of interest on the surface of the material was perpendicular to the testing tip. Each specimen was loaded with a solid, flat indenter tip measuring 2.92 mm in diameter. The indentation displacement, indenter tip radius, and equilibrium load were used as variables in the Boussinesq–Papkovitch equation. This equation was used to calculate the Young's modulus of the insole: $E = P(1 - v^2)/2aw_o$, where $E$ is the Young's modulus (in MPa), $P$ is the load applied (in N), $v$ is the Poisson's ratio (in this case, a constant, assumed to be 0.3),[15] $a$ is the radius of the loading tip (in mm), and $w_o$ is the maximum indentation (in mm). Each insole was marked where the first metatarsal contacted the insole and was tested at the same location for all test intervals.

### *Evaluation of shear*

It is generally not possible to directly and accurately measure shear forces between an insole and the foot because of two primary reasons: (1) there are no commercially available force sensors that can measure such shear in situ, plus (2) the very act of introducing sensors between the insole and skin alters the mechanics of the interface and hence, the shear force. Thus, alternate simulated conditions have been used to assess an insole's shear-reducing ability. In this study a custom-designed shear force tester was used for this purpose. After the other tests had been performed, insoles were placed on the slide assembly of the shear force tester. A 6.0-kg load was applied via a 27-mm-diameter cylinder, which created a 103 kPa vertical pressure on the insole. Then the slide assembly was translated in a reciprocating pattern with a displacement magnitude of 2.3 mm. A 4.6-mm displacement cycle (over and back) was completed every 1.44 s. The reactive force and the displacement were measured with electronic transducers and a computerized data acquisition system (LabView, National Instruments, Austin, TX). The computer collected force, displacement, and time data at 50 points per second. Maximum shear force was determined by measuring the shear force range (peak to peak) for one displacement cycle.

### *Data analysis*

We used StatView software (Abacus Concepts, Inc., Berkeley, CA) to perform the statistical analysis of these data. A paired $t$ test analysis was performed at each test interval for each material comparing the left insole to the right (GlideSoft insole vs. standard insole). Comparing left with right allowed us to use each subject as his or her own control. In addition, we looked for changes in insole performance by comparing each individual insole group to itself over the 320,000-step study. An analysis of variance with post hoc analysis for correlated samples was employed to compare the differences between baseline and follow-up foot pressure, insole shear, and stiffness measurements. As part of the post hoc analysis we did pairwise comparisons using a Bonferroni adjustment.

## RESULTS

### *Evaluation of shear*

Two typical shear force versus displacement profiles from the shear force tester experiments are shown in Fig. 2, which includes examples of both a standard insole and a GlideSoft ex-

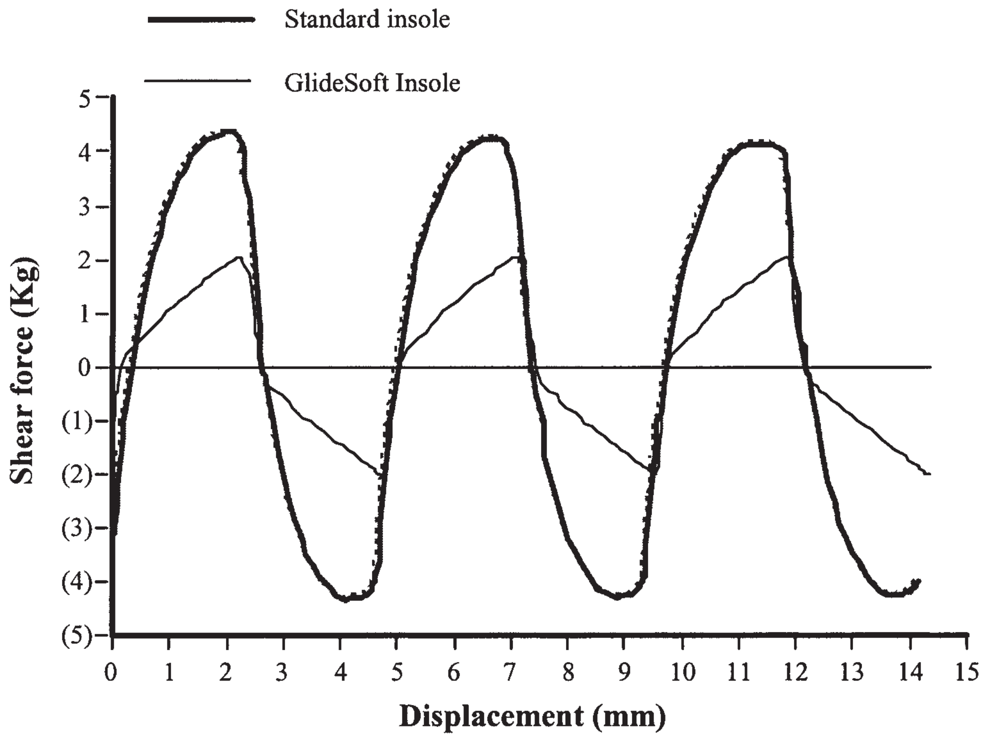


**FIG. 2.** Representative shear force versus displacement profile from an in vitro shear experiment. The GlideSoft exhibited a peak shear force that was less than half shown by the standard insole.

periment. The results of the shear force measurements taken at 80,000-step intervals are listed in Table 1. In all material groups and at all test intervals, the GlideSoft had significantly less shear force as compared with the standard insole ($P < 0.05$). The average shear reduction due to the GlideSoft design was 43.5% (range 40–50%) at a 1.15-mm insole displacement.

When within-group values in the standard insole design groups were evaluated, PPT insoles had significantly less shear force than both the EVA and PLZ insoles throughout the study ($P <$ 0.05). Similar results were found when evaluating within-group comparisons of the GlideSoft insoles. GlideSoft PPT insoles had significantly less shear, except at 320,000 steps. At the last measurement interval, there were no differences between any of the material groups. This was the probable result of the elastic binders stretching or loosening after several weeks of usage in the EVA and PLZ GlideSoft insoles.

*Evaluation of stiffness*

The equilibrium force and displacement values were used in the Boussinesq–Papkovitch equation to calculate the Young's modulus (stiffness) of each insole. Measurements were taken at 80,000-step intervals, and the stiffness results are listed in Table 1. Insoles with EVA middle pads had higher stiffness values than both the PLZ and PPT insoles at all time intervals ($P < 0.05$). This was because the EVA had an initial stiffness durometer of 45 as compared with the lower durometer of 20 and 30 for PPT and PLZ, respectively. No significant stiffness differences were measured between the PLZ and PPT insoles ($P > 0.05$) except between the GlideSoft insoles at 0 steps, where the PPT was softer than the PLZ standard insole design ($P < 0.05$). These results demonstrate the shear-reducing technology does not adversely affect the compressive stiffness of the insole materials for at least up to 320,000 steps of usage.

There was a trend of increasing stiffness in all three insole material types with increasing number of steps. However, this increase was statistically significant only in the EVA material where insoles at baseline (0 steps) were softer compared with the other time intervals.

TABLE 1. SHEAR FORCE, YOUNG'S MODULUS, AND PEAK IN-SHOE PRESSURE AS A FUNCTION OF WALKING STEPS FOR TWO TYPES OF INSOLE DESIGNS, GLIDESOFT OR A STANDARD DESIGN, WITH EACH INSOLE CONTAINING ONE OF THREE TYPES OF MULTILAMINAR MATERIALS, EVA, PPT, OR PLZ

| | *0 steps* | *80,000 steps* | *160,000 steps* | *240,000 steps* | *320,000 steps* |
|---|---|---|---|---|---|
| Shear force (N) | | | | | |
| PPT | | | | | |
| GlideSoft | 36.1 ± 5.9 | 37.6 ± 2.6 | 36.0 ± 2.1 | 34.2 ± 2.0 | 37.0 ± 2.4 |
| Standard insole | 75.3 ± 4.2 | 79.3 ± 4.7 | 77.7 ± 6.2 | 79.3 ± 6.5 | 79.4 ± 5.9 |
| PLZ | | | | | |
| GlideSoft | 42.1 ± 4.7 | 41.5 ± 1.7 | 40.8 ± 2.2 | 41.9 ± 3.2 | 37.7 ± 5.0 |
| Standard insole | 104.4 ± 5.6 | 97.7 ± 2.6 | 94.3 ± 5.2 | 89.6 ± 5.6 | 89.4 ± 6.4 |
| EVA | | | | | |
| GlideSoft | 43.8 ± 3.2 | 40.0 ± 3.1 | 40.5 ± 3.0 | 39.5 ± 1.1 | 40.1 ± 1.2 |
| Standard insole | 101.1 ± 6.1 | 95.9 ± 3.4 | 95.2 ± 3.7 | 93.2 ± 4.9 | 89.5 ± 4.3 |
| Young's modulus (MPa) | | | | | |
| PPT | | | | | |
| GlideSoft | 0.31 ± 0.02 | 0.37 ± 0.07 | 0.37 ± 0.09 | 0.39 ± 0.05 | 0.37 ± 0.10 |
| Standard insole | 0.34 ± 0.01 | 0.38 ± 0.06 | 0.40 ± 0.06 | 0.40 ± 0.05 | 0.40 ± 0.05 |
| PLZ | | | | | |
| GlideSoft | 0.40 ± 0.02 | 0.42 ± 0.13 | 0.45 ± 0.18 | 0.47 ± 0.23 | 0.46 ± 0.13 |
| Standard insole | 0.39 ± 0.05 | 0.47 ± 0.11 | 0.48 ± 0.10 | 0.49 ± 0.13 | 0.49 ± 0.11 |
| EVA | | | | | |
| GlideSoft | 0.52 ± 0.09 | 0.91 ± 0.12 | 0.93 ± 0.12 | 0.96 ± 0.09 | 0.99 ± 0.07 |
| Standard insole | 0.56 ± 0.10 | 0.92 ± 0.17 | 0.97 ± 0.16 | 1.03 ± 0.13 | 1.05 ± 0.12 |
| Peak in-shoe pressure (kPa) | | | | | |
| PPT | | | | | |
| GlideSoft | 231.6 ± 118.2 | 199.0 ± 70.9 | 188.2 ± 57.8 | 205.0 ± 68.2 | 295.4 ± 69.4 |
| Standard insole | 195.0 ± 56.1 | 200.2 ± 58.1 | 204.4 ± 69.2 | 192.4 ± 70.2 | 228.1 ± 69.4 |
| PLZ | | | | | |
| GlideSoft | 191.8 ± 57.8 | 169.0 ± 45.0 | 177.7 ± 72.7 | 185.8 ± 79.0 | 177.6 ± 72.7 |
| Standard insole | 176.8 ± 45.4 | 171.1 ± 43.3 | 160.6 ± 40.3 | 156.8 ± 47.5 | 162.2 ± 54.7 |
| EVA | | | | | |
| GlideSoft | 221.2 ± 82.4 | 166.1 ± 40.8 | 198.2 ± 29.8 | 186.8 ± 23.8 | 211.4 ± 96.2 |
| Standard insole | 205.6 ± 62.7 | 184.0 ± 19.5 | 197.1 ± 42.9 | 187.4 ± 28.0 | 212.6 ± 39.0 |

Results are mean ± standard deviation values.

*Gait analysis/in vivo pressure measurements*

Peak in-shoe pressure measurements were taken at the foot–insole interface. Both the left and right foot pressure profiles were measured for each subject at 80,000-step intervals. The results are listed in Table 1. When within-group comparisons of standard insoles and GlideSoft insoles were evaluated, the latter exhibited slightly higher peak pressures at 0 steps, although there were no statistically significant differences between the insoles at all test intervals ($P > 0.05$). This was despite the fact the EVA was much stiffer than both the PPT and PLZ materials. The marginally higher peak pressures measured for the GlideSoft insoles at 0 steps were temporary and were perhaps due to a manifestation of the stiffness of the underlying fiberglass sheets prior to the compression and stiffening of the top cover PLZ due to the test subject's weight. These results demonstrate that the shear-reducing technology did not affect in-shoe pressure-reducing abilities of the insole materials for up to 320,000 steps.

## CONCLUSIONS

Viscoelastic inserts are commonly used as an artificial shock absorber in athletes and in high-risk patients with diabetes to prevent the development of injuries as the result of repetitive injury.[16–20] Gait laboratory studies have demonstrated significant reduction in peak foot pressures in high-risk patients with diabetes using single and layered insole designs.[15,21] Clinical studies by Uccioli et al.[16] and Chantelau et al.[17] suggest that the development of ulcerations in high-risk patients with diabetes can be significantly decreased with therapeutic footwear and insoles. However, even in patients who received therapeutic footwear and insoles, the rate of ulceration can still be as high as 28%[16] and 50%,[17] respectively. Two factors related to insoles may contribute to such reinjuries: (1) Most insoles lack a design with superior shear-reducing capabilities; and (2) while it is already known that the ability of viscoelastic materials to absorb shock and alter foot pressures may decrease over time as materials age or wear out, the durability and pressure distribution properties of these materials as a function of time have not been well defined. Both these issues were addressed in this study.

Laboratory material evaluations of insole material are traditionally divided into studies that measure either force or deformation following a drop test.[22–27] Campbell et al.[22] examined the separate effects of heat, static loading, and dynamic loading on the compressive stiffness of insole material. They showed that, in most materials, the repetitive loading had the greatest effect on the declining compressive stiffness. In some cases, repetitive loading was the only condition that resulted in a stiffness change. The main drawback of these laboratory studies has been the lack of correlation of their findings to a well-defined, clinical conclusion that can be used as a "take home message" by clinicians and the inability to evaluate shear.

Several investigators have attempted to study the ability of commercially available materials to reduce plantar pressure in clinical subjects.[28–31] For example, Boulton et al.[28] used a pressure-sensitive platform to measure peak plantar pressures in 35 neuropathic patients with diabetes. Pressures were measured with patients walking barefoot and then over an area covered with a 5-mm-thick sheet of a viscoelastic polymer (Sorbothane®, Sorbothane, Inc., Kent, OH). The results demonstrated a significant reduction in plantar peak pressures. More recently, McPoil et al.[9] also used a pressure platform system to test three insole materials: PPT, Spenco® (Spenco Medical Corp., Waco, TX), and Viscolas® (Viscolas Inc., Soddy Daisy, TN). Their study suggested that there were no differences among the three materials in reducing plantar pressures in the forefoot. However, there was a significant reduction in pressures in the rear foot with PPT and Spenco compared with Viscolas. Limitations in these studies may be found in three important areas: (1) Pressures were measured on the bottom of the insole and not on the bottom of the foot. It is well known that dynamic changes in pressure must be measured directly on the site of the ulceration or pathology, i.e., the bottom of the foot. Thus, it is imperative that the foot–insole interface be studied. (2) Neither the effects of patient activity level nor the effects of temporal changes in the insole material on the pressure field were evaluated. (3) None of these studies evaluated shear. To eliminate many of the potential confounding factors encountered in clinical research, in vitro approaches are frequently preferred, since they entail faster, simpler, and less expensive experimental protocols. Our study used both an in vivo and in vitro approach in order to gain further insight into material, pressure, and shear changes over a 320,000-step test period. The results show that the GlideSoft technology has the highly desirable benefit of reducing shear in insoles, which constitute a major component in our armamentarium to help patients with diabetes at high risk for ulceration.

The GlideSoft system encompasses an invention that can reduce shear forces on the surface of the skin while retaining the vertical pressure reduction characteristics of traditional insoles. The system reduces shear by significantly decreasing the peak shear force, which would be applied to the surface of the skin during gait. As described earlier, when a shear force is applied to the GlideSoft, the upper pad of the insole moves relative to the lower portion. The elastic binders, which, by gradually stretching, retard and eventually stop the movement between the upper and lower pads of the insole, play a very important role in this design. They not only provide enough friction for ambulation, but, by controlling the relative movement of the insole layers to less than approximately 1.5 mm, they minimize the potential for injury to the foot. No subjects in this study exhibited any adverse effects due to wearing the GlideSoft, and none complained of any discomfort.

By virtue of the work performed in this study, we have demonstrated that the GlideSoft technology reduces shear forces significantly as compared with standard insoles without affecting the material characteristics of the insole materials. In addition, the GlideSoft maintained an equal amount of in-shoe pressure reduction as compared with the standard insole. We also demonstrated that the amount of shear reduction in the GlideSoft varied as a function of insole displacement. At small insole displacements, which occur at the start of each step, the GlideSoft shear force was as little as one-sixth of the corresponding value for the standard insole design. At larger displacements, the shear force was reduced to approximately half of that for a standard insole. This is due to the stretching of the elastic binders, which increase the insole's resistance to the movement between the upper and lower pads. Thus, the GlideSoft technology significantly reduced shear forces while maintaining vertical pressures equal to that of standard insoles.

## ACKNOWLEDGMENTS

This project was funded by grant 1 R44 DK 55909-0 from the National Institutes of Health.

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