Efficacy of Multilayered Hosiery in Reducing In-Shoe Plantar Foot Pressure in High-Risk Patients With Diabetes

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OBJECTIVE — High plantar pressure is an acknowledged risk factor in the development of plantar ulcers in the diabetic neuropathic foot. This study examines the ability of preventive foot care (PFC) socks to reduce plantar foot pressures in a sample of high-risk patients with diabetes.

RESEARCH DESIGN AND METHODS — Nineteen patients with established peripheral neuropathy attending a complications clinic of the Manchester Diabetes Centre were recruited to the study. Fifteen (78%) of the patients were male, 40–80 years of age, and ulcer-free at the time of recruitment. In-shoe plantar pressure measurements were recorded using the F-Scan and compared PFC socks with ordinary supermarket socks. The analysis measured differences in maximum foot contact area and plantar pressure for the whole foot, forefoot, and peak plantar pressure areas.

RESULTS — The results showed a significant increase in maximum foot contact area of 11 cm^2 (95% CI 7–11) when subjects wore the PFC socks ($P < 0.01$). This was accompanied by 5.4 kPa (3.5–7.3) or 9% reduction in total foot pressure ($P < 0.01$). Similar results were observed at the forefoot, which showed a 14.2% increase in contact area and a 10.2% reduction in peak forefoot pressure.

CONCLUSIONS — These results suggest that the wearing of PFC socks increases the underfoot contact area and hence decreases plantar foot pressures. Further studies are required to determine whether the pressure and friction reductions achieved by this simple intervention would be effective in reducing the incidence of foot ulcers in high-risk patients.

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The personal and health care costs associated with diabetic foot ulcers are well recognized. It has been estimated that ~2% of the diabetic population will have an active foot ulcer (1) and a similar proportion will develop a new lesion each year (1,2). Many factors are associated with the development of foot ulcers including neuropathy, deformity, and trauma (3,4). It is also recognized that although neuropathy is a major contributory factor in the development of ulcers, the ulcer is usually preceded by unrecognized minor tissue damage, commonly from footwear (5). It is not surprising, therefore, that footwear is considered to be an important and modifiable risk factor for foot ulceration.

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Abbreviation: PFC, preventive foot care.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

The main stresses that act upon the feet are step shock, pressure, friction, and shear. These stresses often occur together to damage insensitive and delicate foot structures. Step shock is the impact force generated by the body, particularly as the foot makes initial contact with the ground. This impact force is thought to be associated with a variety of bone and soft tissue disorders affecting the foot as well as other structures in the body (6). Not only have high plantar pressures been implicated in the development of foot ulcers (7,8) but also the offloading of diabetic foot ulcers is now also considered to be an essential component of foot wound management (9–11). Friction is the static or active force that acts on the skin and resists sliding (12). This force acts parallel to the contact area and also offers resistance before the foot begins to move along the floor or inside a shoe. Localized friction on the skin surface will induce skin exfoliation but, if persistent, the heat generated may result in erythema and possible blistering (13). Unlike friction which may be said to occur only on the external surface of the foot, the term shear is restricted to the static situation, and it can act on both the contact surface and deeper within the tissues (14). To illustrate, as the foot (usually the heel) makes initial contact with the ground, friction between the foot and the ground generates a horizontal force that acts backwards against the foot (shear) which, when repeated, may cause either direct damage to the skin and deeper tissues such as blistering or indirect damage due to callus formation and restriction of blood flow (15).

Much of the work aimed to reduce stresses acting on the feet has concentrated on shoes. Outer sole materials with good shock-absorbing properties are frequently used in the manufacture of sports shoes, high-comfort street footwear, and prescribed shoes to reduce the effects of step shock. Indeed, for many years standardized bench tests have been performed on a variety of soling materials for the shoe industry (16). The primary aim

Table 1—*Mean area and pressure differences with PFC socks versus supermarket socks*

Test conditions	Mean (95% CI)	*P* value
Total contact area (cm^2)		
Supermarket socks	138 (128–149)	
PFC socks	149 (138–160)	<0.01
Difference (PFC − supermarket)	11 (7–11)	
Total contact pressure (kPa)		
Supermarket socks	57.9 (53.2–62.6)	
PFC socks	52.5 (48.6–56.4)	<0.01
Difference (PFC − supermarket)	−5.4 (3.5–7.3)	
Forefoot contact area (cm^2)		
Supermarket socks	85.6 (75.5–95.8)	
PFC socks	97.1 (86.5–107.7)	<0.01
Difference (PFC − supermarket)	11.4 (58.1–171.1)	
Forefoot contact pressure (kPa)		
Supermarket socks	461.9 (396.7–527.2)	
PFC socks	414.9 (355.1–474.5)	<0.01
Difference (PFC − supermarket)	−47.0 (−77.0 to −17.1)	

of many therapeutic in-shoe devices is to redistribute pressure to other regions of the foot by allowing other parts of the foot to bear weight during standing and walking (17,18). Because socks may offer the first line of defense to the at-risk foot, several studies have provided some direct evidence that padded hosiery can reduce peak plantar pressures (19,20) and indirect evidence that they can reduce friction and shear by the reduction in occurrence in blisters (21).

In this study, we have examined the pressure-relieving properties of a new kind of hosiery (preventive foot care [PFC)]) socks compared with standard supermarket socks using the F-scan (Tekscan, Boston, MA). The main aim of the study was to examine whether PFC socks can reduce total plantar foot pressure by increasing the total foot contact area.

RESEARCH DESIGN AND METHODS

— A total of 19 subjects attending a complications clinic of the Manchester Diabetes Centre were recruited to the study, 15 of whom were male with a mean age of 65.5 (range 39–80). All participants showed moderate to severe signs of peripheral neuropathy evidenced by a modified Neuropathy Disability Score >5 (1) or a vibration perception threshold ≥25 (22). The majority (63%) had long-standing type 2 diabetes (median duration 20 years, interquartile range 11–32), were overweight or obese (BMI 29, 24–36) (23) but ulcer-free at the time of recruitment. Measurements were recorded by a single observer who noted that all subjects had at least one area on the sole of the foot with a pressure ≥6 kg/cm^2 (∼588 kPa) using the PressureStat system at the time of recruitment. This threshold has previously been used as a cutoff value for peak plantar pressure in people with diabetes (8). Participants provided written consent, and ethics approval for the study was granted by the local ethics board.

The socks used in this study were provided by Legend Care (Mullingar, County Westmeath, Ireland). These socks have an innovative double-layer construction consisting of a padded outer layer to cushion the feet combined with a low-friction fiber inner layer to help reduce friction at the sock/foot interface (24).

Participants were asked to attend a single gait laboratory session and underwent a standardized clinical examination including foot length and girth measurements and assessments of foot deformity. In addition, a dynamic image of the foot during normal stride was taken using the PressureStat. This is a simple and semi-quantitative method of recording a permanent footprint image from which areas of high pressure can be quantified using a calibrated scaling card. A previous study using this technique demonstrated that the system had good sensitivity in identifying areas of high pressure highlighted by the optical pedobarograph and also good interobserver repeatability (25).

The order in which participants wore the PFC socks or standard supermarket hosiery was randomized before data collection. F-scan in-shoe pressure measurements were taken in the participants' own footwear along a flat 5-m walkway. Participants took a number of trial walks to familiarize themselves with the equipment and procedure before three sets of readings were taken for each subject wearing the PFC socks and standard hosiery.

In-shoe pressure

F-scan in-shoe pressure measurements were taken in the patient's own footwear, and a total of three representative steps for each person wearing both the PFC and standard hosiery (total of six representative steps) were selected for analysis. These steps occurred approximately halfway through each set of readings to avoid acceleration at the start of the recording and deceleration at the end (15,26). Two graphs, the first plotting total contact area versus time and the second total contact pressure versus time, were generated using the standard software package supplied with the F-scan. The position during the step where the foot was in maximum contact with the ground was identified, and the total contact area for each of the three steps was recorded. An average of these three steps was used in the analysis. Shifting to the pressure/time graph, the total contact pressure in this position was also recorded and, once again, an average of the three steps was taken. The same procedure was used to calculate an average peak forefoot pressure.

Statistical methods

Because pressure and area measurements with the patient wearing the two different types of hosiery were taken on the same individuals with both following normal distributions, the differences observed in the test conditions were assessed using paired *t* tests. Using the mass of the participants and total in-shoe contact area derived from the F-scan, it was possible to calculate the overall footprint contact pressure using the standard formulae for force [force (Newtons) = mass (kilograms) × acceleration (9.81 ms^{-2})] and pressure [pressure (kilopascals) = force (Newtons)/area (meters squared)]. An estimate of the increase in contact area that would be required to achieve a total foot contact pressure reduction was also cal-

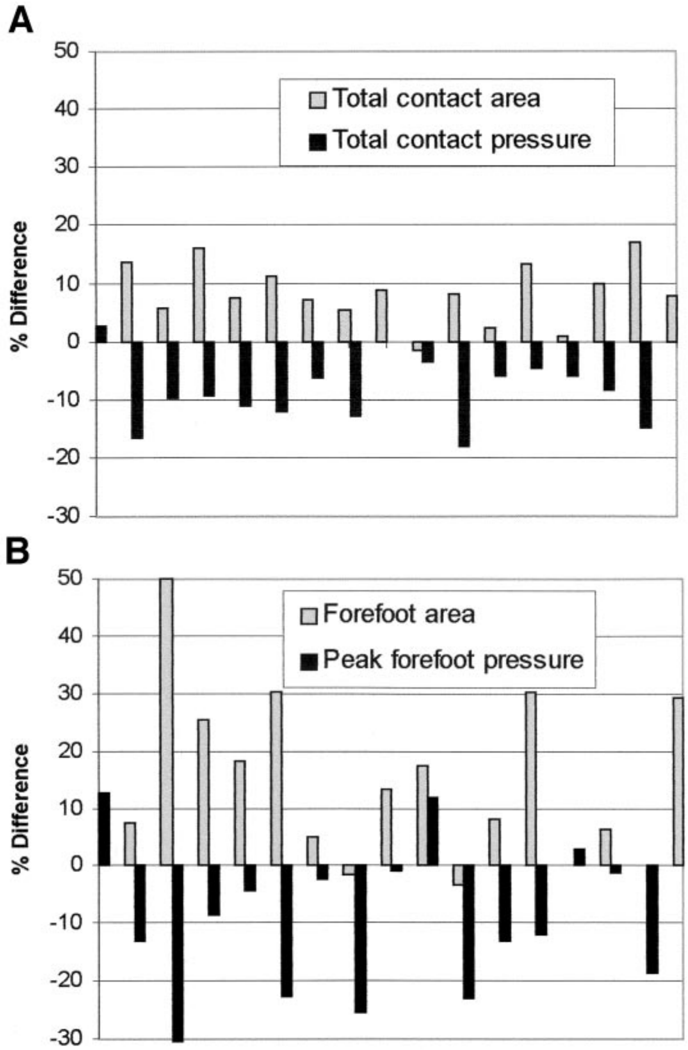

Figure 1—*Individual percentage differences in total* (A) *and forefoot* (B) *contact area and total and peak pressure.*

culated and compared with the F-scan output. A Bland and Altman plot (the mean of the F-scan output and the calculated contact pressure values plotted against the absolute difference between the two methods) was used to assess the agreement between F-scan derived and calculated pressure values (27).

Areas of high pressure identified by the PressureStat were also compared with the peak forefoot pressures recorded by the F-scan to provide an indication of the level of agreement between the two systems. Because no significant foot differences were observed, only left foot results are presented. Descriptive statistics and *t* tests were carried out using STATA version 7 (College Station, TX), and the Bland and Altman analysis was produced using Analyze-It Software (Leeds, U.K.).

RESULTS— As mentioned previously, the patients recruited to the study were mainly male patients with type 2 diabetes presenting with a number of risk factors for foot ulceration. Foot deformities were quite common in this series with 52.6% having a recognizable hallux valgus (28), 63.2% with a lesser toe deformity, and 21.1% with a high arch. These clinical features would be compatible with the presence of an "intrinsic minus foot deformity" (29). Two of the male participants had previous fifth ray amputations, which were accommodated in made-to-measure extra-depth shoes with custom molded insoles. With regard to foot pressure, data from two male participants were corrupted so the results are based on the remaining 17 (89%).

The average total foot contact area increased from 138 cm^2 in standard supermarket socks to 149 cm^2 (7.9%) in the PFC socks, which was accompanied by an 8.9% reduction in total contact pressure from 57.9 to 52.5 kPa (Table 1).

Slightly larger changes were seen in the forefoot where the area increased by 14.2% accompanied by a 10.2% reduction in peak pressure with the peak pressure reductions showing greater variability than total foot contact pressure values. Mean area and pressure differences for the sample are shown in Table 1 with individual percentage differences graphically represented in Fig. 1.

Using the calculated force for each person (force = mass × 9.81) and the total foot contact area generated by the F-scan, the total contact pressure (force/area) was calculated for each participant while wearing the supermarket socks. From these values, it was then possible to calculate that a 9.7% increase in total contact area would be required to achieve the observed 8.9% reduction in total contact pressure, a figure very close to the 7.9% produced by the F-scan.

Total contact pressure values derived from the F-scan correlated well with those calculated using the formula ($r^2 = 0.81$). Furthermore, the Bland Altman plot showed the magnitude of bias in the F-scan measures to be small (−2.4 kPa [95% CI −4.8 to 0.17]), normally distributed and unlikely to be clinically important (Fig. 2).

On the PressureStat footprint, the observer classified 14 of 17 (82%) individuals as having whole-foot peak plantar pressures that were highlighted on the F-scan image. In addition, nine areas marked as being of a high pressure on the PressureStat were not recorded as such by the F-scan. Peak pressure areas were most commonly observed beneath the second and third metatarsophalangeal joints (6/17 [35%]), first metatarsophalangeal joint (4/17 [24%]), fifth metatarsophalangeal joint (2/17 [12%]), and first interphalangeal joint (2/17 [12%]).

CONCLUSIONS— The results demonstrated that a significant 9% reduction of in-shoe total foot and a 14% reduction of peak forefoot pressure can be achieved by wearing the PFC socks, resulting from an 8% increase in foot contact area.

A novel observation in this study was the strong correlation between total contact pressure values and those calculated

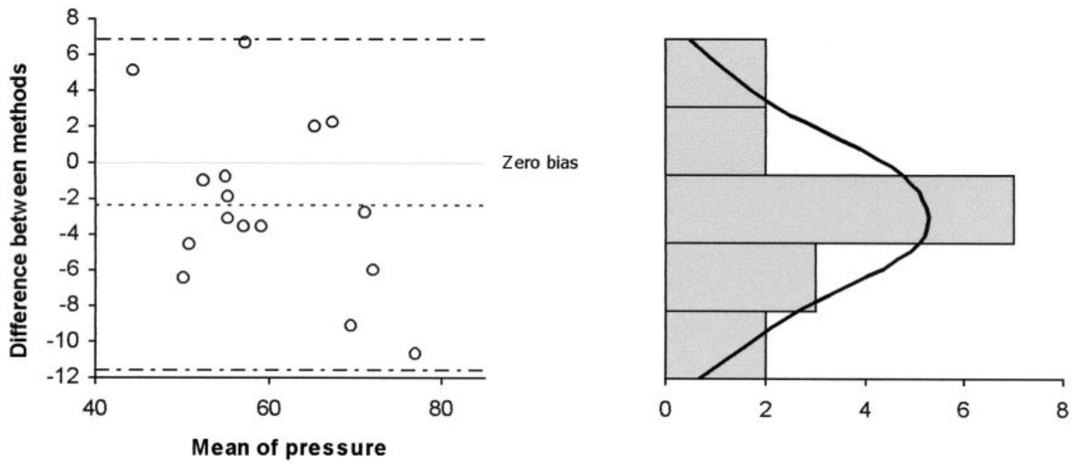

Figure 2—*Bland and Altman plot showing the agreement between F-scan–generated and calculated total foot contact pressures.*

using the simple formula for force and pressure. Although in this series the total foot contact area was derived directly from the F-scan output, the close agreement between the two measures suggests that it may be possible to estimate contact foot pressures using the PressureStat footprint image. Ongoing work will assess the level of agreement between PressureStat and F-scan generated values and determine whether this could provide an additional simple way of screening for patients with high foot pressures.

Both strengths and weaknesses of this study can be found in the study design. The use of only one observer eliminated the possibility of interobserver variability. Another of the strengths was that the randomization process reduced the likelihood that the results would be affected by temporal variations in the F-scan system or other possible order effects. No attempt was made to standardize the shoes worn by the participants. The wearing of optimal experimental shoes would possibly have resulted in even greater differences between the PFC and supermarket hosiery. Our study design, however, was thought to be more representative of a clinical situation where hosiery was being supplied either to supply immediate protection or enhance the pressure relieving properties of existing shoes and orthoses.

All experiments in this small study were carried out at a single gait laboratory session. Although the characteristics of the participants were typical for male patients with diabetic complications, further work is required to confirm the generalizability of these findings and the long-term performance of the PFC socks. This would be needed to establish how often the socks should be replaced to achieve optimal benefit for the patients. Dorsal pressures were not measured in this study. It is important to remember that hosiery offering any additional padding will reduce the volume within the shoe. Compared with the supermarket socks which were ~0.7 mm thick, the maximum thickness of the PFC hosiery was 2.7 mm around the toes, metatarsal phalangeal area, and the heel. Although 2 mm may represent only a moderate increase in bulk inside the shoe, additional care in the fitting of shoes is nonetheless required when considering the use of such hosiery to avoid any localized increases in foot pressures.

At 462 kPa, the maximum in-shoe peak plantar pressure values of the study sample were broadly similar to that of other high-risk patients (18,30,31). Because of differences in study design, it is difficult to make direct comparisons with previous studies of in-shoe devices which have shown considerable variability of in-shoe peak pressure reduction.

Up to a 50% reduction has been reported when peak barefoot pressures taken on a hard surface were compared with in-shoe values while participants were wearing molded orthoses (30). In their follow-up study comparing the performance of a composite molded insole with "neutral" shoes with no cushioning, Lobmann et al. (31) observed an immediate 33% reduction in peak pressure that reduced with natural wear-and-tear to 13% after 1 year. The smallest effects (16–26%) were seen when molded orthoses were compared with standard inserts and ones made of open-cell urethane foam (18,26).

Previous work has also shown padded hosiery to be effective in reducing barefoot peak plantar pressure using the optical pedobarograph (20,32). Very few studies, however, have looked at the ability of hosiery to reduce in-shoe plantar foot pressures. Donaghue et al. (33) issued padded hosiery and therapeutic footwear to 50 subjects at high risk of foot ulceration. The authors found a significant 10.7% reduction of peak in-shoe pressure when the supplied shoes and socks were compared with existing footwear and a 6.3% reduction in peak pressure between padded socks and ordinary socks outside the shoe. Because in-shoe data for the two different sock types were not presented, a direct comparison between the Donaghue study and this study is not possible. More recently, Blackwell et al. (34) achieved a nonsignificant 6.7% reduction in average plantar pressure below the metatarsal heads between barefoot in slippers and slippers with padded hosiery but found no difference between barefoot and padded hosiery inside the patient's own shoes.

Some of the differences between this study and previously published work will be due to a lack of standardization of study method and data analysis as well as differences in the thickness of padding provided by the socks used in the studies. Nevertheless, this study provides evidence that the wearing of multilayered hosiery may be effective in reducing some of the potentially damaging pressures underneath the feet. Unlike foot pressure where a variety of computerized systems are available, there are currently only a few experimental devices that can measure foot shear in vivo. Early published work reported a 15% reduction in shear beneath the first metatarsal head when thin nylon hosiery was compared with barefoot values (15). Recent laboratory tests of the PFC sock showed that the material had, on average, a 30% significantly lower coefficient of friction than other sock fabrics such as acrylic, polyester, and cotton, a value which was sustained over 1,400 repetitive cycles (35).

The etiology of foot ulcers is undoubtedly very complex. Mechanical stresses such as step shock, pressure, friction, shear and individual activity will all impact on the skin and subcutaneous tissues often affected by diabetes. Altering the kind of socks for our patients is a simple, cosmetically acceptable, and potentially cost-effective method of protecting the at-risk foot in diabetes. Further longitudinal studies are required to determine whether the combination of padding and friction reduction offered by the PFC socks would be useful in the primary or secondary prevention of diabetic foot ulcers.

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