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Pressure redistribution by molded inserts in diabetic footwear: A pilot study

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Abstract—A small-scale trial is described to demonstrate and evaluate the redistribution of plantar pressure resulting from the use of custom-molded inserts in the orthopedic shoes of diabetic patients at risk of plantar ulceration. A pressure-measuring insole based on force-sensitive resistor technology enabled the load distribution to be compared using molded inserts and flat inserts fitted into the same shoes. An analysis of the 12 peaks of pressure that could be identified under a discrete metatarsal head of six subjects in the trial showed that the pressure was significantly reduced with the use of molded inserts (flat inserts: 305 ± 79 kPa; molded inserts: 216 ± 70 kPa; $n = 6$ $p < 0.005$). Technical limitations of the equipment and the difficult choice of match of flat insert to molded for comparison suggest that further studies are required for a definitive result.

Key words: *diabetes, foot, gait, insole sensors, molded inserts, neuropathy, plantar pressure, pressure sores.*

INTRODUCTION

It has been demonstrated that diabetic patients with a history of neuropathic plantar ulceration have abnormally high pressures under the foot in walking (1–3). Peaks of pressure occur most frequently under the metatarsal heads and correlate frequently with the sites of ulceration. Reduction of the pressure peaks can be achieved by providing special shoes (4), which form an important part of an effective management program for the neuropathic foot. The deep inserts normally provided in these shoes may be either flat or molded to the contours of the patient's foot.

Flat inserts are made of a soft material that provides local cushioning in the metatarsal region to replace the natural fat pad that has been lost or displaced distally. The action of this cushioning is to spread the loading of each head out over a larger local area. Lower-density grades of Plastazote®, a closed-cell polyethylene foam, are commonly used and described for this purpose by Tuck (5). Other materials used include PPT®, an open-cell foam; Sorbothane®, a viscoelastic polymer; and Spenco®, a closed-cell neoprene sponge. Although flat inserts have been demonstrated to reduce abnormally high pressure peaks, an insert of practicable thickness may not be able to reduce the pressure in the most severe cases to within a normal range (6). The alternative, molded inserts, are contoured usually against a cast or impression of the foot. These are often described as providing a redistribution of the load away from the metatarsal region, primarily due to increased support under the midfoot. Molded inserts are often made of a sandwich construction, with a firm base such as high-density Plastazote (e.g., hard black grade HD115[1]) and cushioning upper.

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[1] BXL Plastics Ltd, 675 Mitcham Road, Croydon, Surrey, CR9 3AL, UK.

The pressure-relieving effect of molded vs. flat inserts has not been compared scientifically, primarily due to the previous lack of measurement techniques. Methods of measurement and clinical applications of foot pressure have been extensively reviewed by the authors (7, 8) and others (9, 10). Most of the early techniques were limited to barefoot measurements, often in a static situation, or else severely restricted by bulky transducers. A resurgence of interest has been stimulated recently by new technology that can now provide a flexible insole to measure in-shoe pressures during walking. Several commercial systems are available, including the F-Scan Gait Analysis System[2] used in this study.

This study evaluates the reduction in peak pressure obtained by patients attending the Diabetic Foot Centre at King's College Hospital London through the use of their routine custom-molded inserts. Comparison is made with a soft flat insert placed in the same shoes to minimize effects due to shoe design. The study was undertaken as a pilot, because of the developmental nature of the F-Scan equipment at that time.

METHODS

Patients and their Footwear

The patients were identified from those routinely attending the diabetic foot clinic. After the start of the trial, the first patients who were selected had the following criteria:

- wore custom-made orthopedic shoes with molded inserts
- had inserts that were still serviceable
- had one foot at least free of gross deformity (e.g., Charcot joints, ray amputations)
- had no recent foot surgery
- had no major skin lesions (i.e., open plantar ulcers) requiring padded dressings
- were able to walk unaided
- were able to stand on one foot for 4 seconds (necessary for calibration routine). A loss of digits and thin sterile dressings on healing plantar ulcers were acceptable.

Due to technical reasons that will be explained below, only six patients' results were analyzed. These were two females and four males, ages ranging from 43 to 68 years (mean 59.6, SD 9 years), weight from 58 to 102 kg (mean 77.4, SD 15.7 kg). Five of the patients had diabetic neuropathy, and the sixth had a neuropathy of unknown origin. Sites of previous plantar ulceration and complications were noted from each patient's chiropody case notes: four had had plantar metatarsal ulcers. Only one patient had a healing ulcer of very small size, which required no padded dressing.

Custom-molded inserts were all provided by the same orthotics company (**Figure 1**). Some are of a "rocker design," that is, with a bottom shape similar to the sole of a clog so that roll-off of the forefoot occurs behind the metatarsophalangeal joint of the foot. This alters the biomechanics of gait and is said to reduce the load that can be borne under the forefoot area at push-off (11). The inserts are manufactured from a plaster cast of the patient's feet and adjusted to add length onto the forefoot. Usually low-density Plastazote is molded against the model, bringing this well up into the arch; this

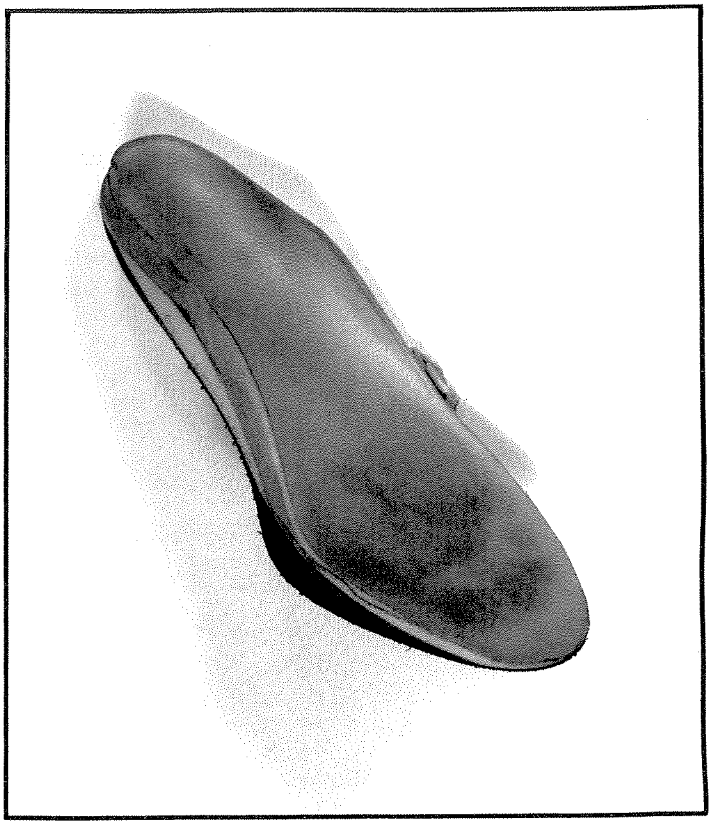

Figure 1.
A custom-molded insert with rockered design.

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[2] Tekscan Inc, 4th Floor, 451 D Street, Boston, MA, USA

material will further mold to the foot in use. A middle layer of resilient PPT is sometimes provided if very high pressures are anticipated. Finally, the base of the insert is constructed of high-density Plastazote, which is shaped into a rocker sole in the forefoot, providing a break just posterior to the metatarsal heads; the thickness reduces to nil at the toe end. All molded inserts are covered routinely with thin leather. Descriptions of materials and their thicknesses used in the construction of the patients' molded inserts were given by the orthotist (**Table 1**). The ages of the inserts are also shown.

Pressure Recording

In-shoe plantar pressure was recorded under the chosen foot using the F-Scan Gait Analysis System, version 1.2. This system provides a 0.2-mm thick, flexible pressure-sensitive insole. Each full-size insole (U.S. men's size 14) consists of 960 square cells spaced 5 mm apart (**Figure 2**). The cells are constructed by sandwiching a printed circuit of force-sensitive resistive material (FSR) in mylar film. The insole can be cut to size for adult ranges. A handle extending from the side of the insole couples directly into a cuff unit worn above the patient's ankle. The cuff unit provides preamplification and signal conditioning. A coaxial cable interfaces the cuff unit to a personal computer. Data collection is enabled from each cell at 50 Hz over 4 seconds.

The pressure measuring insoles are flexible in that they will easily wrap around a cylinder, but being inextensible, they are not capable of following a doubly curved surface such as a sphere. Some problems were experienced when the insoles were laid against the curved surfaces of the molded inserts. Creases formed around the heel cup which, although not resulting in much loss of data, could be uncomfortable. This was alleviated in some cases by cutting one or two small notches around the edge of the heel. Although the cutting resulted in the loss of the most posterior line of cells, this was not thought to be seriously detrimental. Creasing also occurred occasionally in the forefoot area, caused as the shoe was put on and the foot dragged on the insole. This problem is more acute with insensitive neuropathic patients than for asymptomatic subjects, who can feel and avoid this problem. Such creasing usually causes a break in the printed circuit tracks, resulting in the drop-out of a whole column in the matrix of cells, which may appear intermittently during recordings.

The F-Scan system used was an early prototype that was found to be more temperature sensitive than the production model now available (temperature sensitivity is a known factor in FSR technology). Errors due to temperature sensitivity were minimized by allowing for equilibration and assessed by a calibration procedure. The variability between insole sensors has not been established conclusively. Other authors (12) working with this system suggest that researchers need to use one insole sensor for each subject, which will allow for relative comparisons irrespective of absolute accuracy.

Trial Procedure

The patient's molded insert was removed from the shoe and replaced by a flat, 6-mm-thick PPT insert. This is less deep than the molded inserts in some areas, notably the forefoot, although this was the maximum depth that could be sensibly accom-

Table 1.
Molded insert construction in the metatarsal region: materials are quoted in stock thicknesses (1/4″ ∫ 6.4 mm, 3/8″ ∫ 9.5 mm, 1/2″ ∫ 12.7 mm): overall thickness generally 3/4″ or 19 mm.

Patient	Construction of Insert (in inches)			Insert
	Top	Middle	Bottom	Age (mos)
1	1/4 LD Plastazote	1/4 PPT	1/4 HD Plastazote	14.5
2	1/4 LD Plastazote	—	3/8 PPT	18
3	1/4 LD Plastazote	1/4 PPT	1/4 HD Plastazote	59
4	1/4 LD Plastazote	—	1/4 PPT	15
5	1/4 LD Plastazote	—	1/2 PPT	11
6	1/8 LD Plastazote	1/4 PPT	3/8 HD Plastazote	15

modated along the entire length of the shoe, particularly in the heel area. An F-Scan insert was cut for the same shoe and placed on top of the flat insert. The patient, wearing normal hosiery, then put on the shoe. For calibration purposes, a 4-second recording was then made with the patient bearing weight through one foot. A second similar recording was made after the patient had been wearing the shoe for 3 minutes.

Each patient then walked three times along a 10-m corridor at normal speed and plantar pressure was recorded for 4 seconds in the central walk. The first walk was conducted with the PPT insert in the shoe. This was followed by recordings with the PPT insert substituted by the molded insert. Since there was a tendency for the F-Scan insole to crease when placed on top of the curved surface of the molded inserts, leading to defective lines of sensing cells, the authors made two recordings to maximize the chance of a good record.

Although it would have been desirable to take at least three recordings and average results in order to improve reliability (13), this was not feasible both because of limitations of insole life and because the walking speed during the recordings was uncontrollable, as pacing by artificial means may lead to a more erratic gait (13) (repeated walks are not tolerated by these patients). Comparison of the cadence, however, can be made from the timing information.

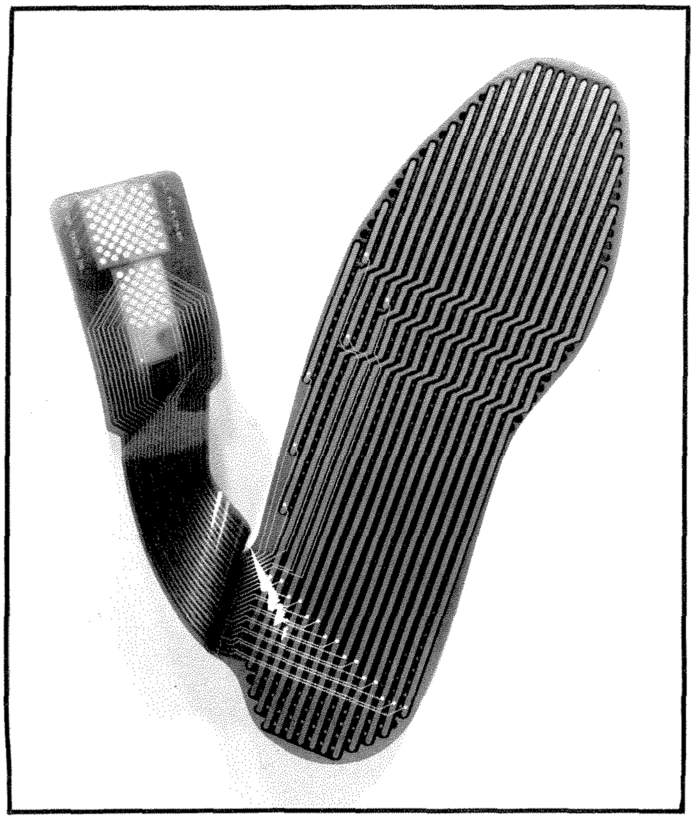

Figure 2.
The F-Scan pressure measuring insole.

The calibration procedure was repeated again at the end of the walking session. The entire procedure added no more than 25 minutes to the patient's regular chiropodist appointment.

RESULTS

Instrumentation

Although patients exercised care in putting on their shoes, on inspection of the records from the molded insert walk, the authors found that insert creasing had caused whole lines of cells to become defective for four patients. These four patients were then excluded from the analysis, as mentioned earlier, leaving six patient records for analysis.

Even for records that were good for analysis of forefoot pressures, some cell drop-outs occurred in other areas, particularly the heel area on the curved molded inserts. These drop-outs sometimes recovered when the insole was placed back onto a flat insert. However, not all did, which calls into question the value of the final calibration against body weight.

Calibration

There was found to be no significant difference between the vertical force obtained from the two recordings for all patients taken with 3 minutes separation at the start of the trial ($0.05<p<0.1$; $n=6$)[3]. This demonstrated that a temperature stability had been gained. The vertical force given from both trials was compared separately against the patient's body weight. Again there was no significant difference at the same confidence level. However, there was found to be a significant difference between the vertical force readings at the end of the trial with the earlier calibration (mean 764 N, falling to 631 N; $0.02<p<0.05$; $n=5$; one final calibration record was unavailable due to major creasing).

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[3] All significances quoted appertain to paired *t*-tests.

Because the observed cell drop-out would have the effect of reducing the apparent vertical force, this does not necessarily imply that the instrumentation was subject to a downward drift in sensitivity. This loss of data occurred mainly due to cutting tracks in the heel area, as mentioned above, and it would therefore be a better test to consider the loads under the forefoot separately in the calibration test.

In a more detailed analysis, each pressure map was therefore divided into forefoot and hindfoot areas at an arbitrary but constant position in the midfoot, and the load under each area was measured independently. Because of body sway, the load balance between forefoot and hindfoot would be predicted to vary over the 4-second period, sometimes quite dramatically for these relatively unstable patients (**Figure 3**). The load was therefore determined as an average of three readings taken at 1, 2, and 3 seconds for each calibration recording. The mean of these averages was then determined for the group. It was found that the mean load in the heel also fell significantly from 446 N to 308 N ($0.02<p<0.05$; $n=5$), whereas the mean load in the forefoot was not significantly changed from 317 N to 323 N ($0.5<p<1$; $n=5$). Since there is no apparent reason to suggest that all patients would stand with their balance consistently offset in the anteroposterior direction at the end of the trial, these results are consistent with no significant instrumentation drift.

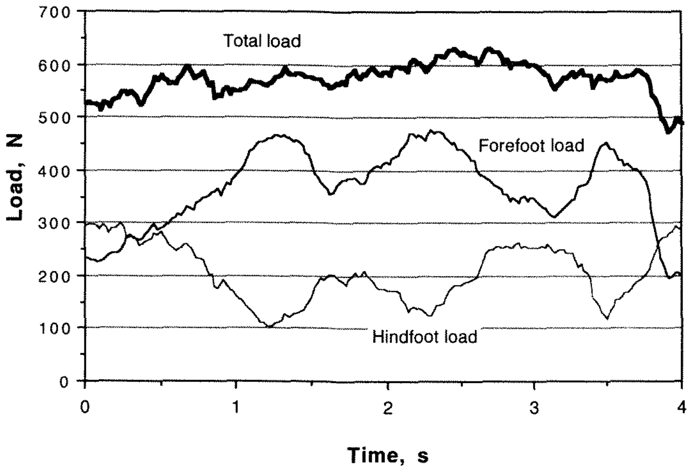

Figure 3.
An example of the foot loading taken during a standing calibration recording, with load shown under the total plantar area, forefoot only, and hindfoot only.

Comparison of Flat and Molded Inserts

The cadence of the first walk with each treatment was analyzed from the timing over two whole strides. The cadences in steps per minute were as follows: flat inserts, mean 97.3, SD 13.1, range from 77 to 114; molded inserts, mean 100.5, SD 10.5, range from 85 to 117. The worst difference between cadences was 8 steps per minute, presenting a 10 percent change; the average change was 5 percent, with two cases of slightly reduced cadence and 4 of increased cadence.

The authors decided to make this comparison on the basis of the relief provided only under metatarsal heads that displayed discrete peaks of pressure. The F-Scan recordings were first inspected to identify sites where a peak could clearly be distinguished (i.e., where a localized area of high pressure could be seen in the region of one metatarsal head, such as those identified in **Figure 4**). Because these recordings were all taken with a high degree of cushioning present that would tend to smooth peaks, only 13 such peaks could be safely identified in the six patients' records. Every patient showed at least two peaks: always a peak under the

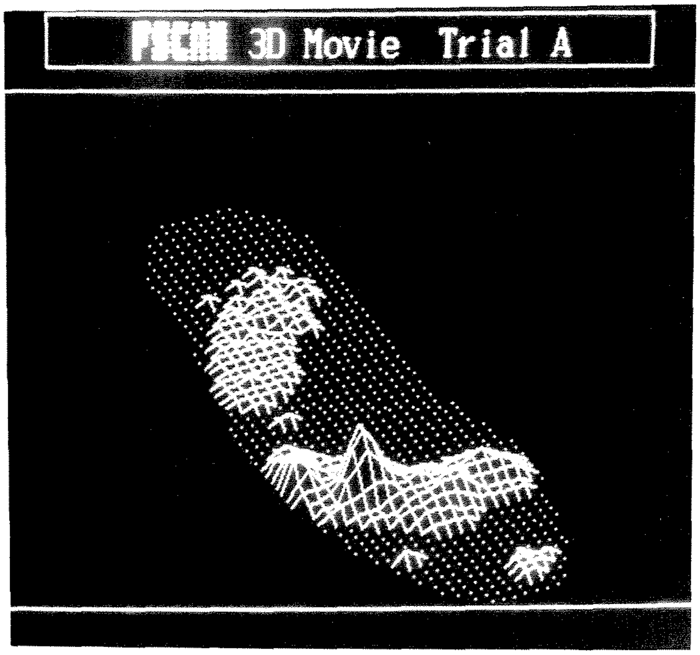

Figure 4.
The pressure distribution recorded at an instant around heel lift, when a pressure peak can clearly be identified under the fourth metatarsal head; a clear peak develops in the first metatarsal head region a little later in the stance phase (patient 2).

first metatarsal head, and the other peak under either the second or third head. The remaining additional peak was identified on one patient under the fourth head, which for reasons of performing a valid statistical analysis, was excluded.

There existed considerable variability in pressure level at one site between successive steps of each walk (**Table 2**). To be consistent, the authors followed a fixed protocol for analysis. From the (single) recording with the flat insert and the first recording with the molded insert, three complete steps were used for analysis in every case. The sequence of foot pressure maps representing the footstep was inspected visually to determine the spatial location of any metatarsal pressure peak, most evident at the push-off phase of gait. Peak pressures are read as an average over nine adjacent cells (i.e., over a square area of 15 mm × 15 mm). This spatial averaging is used to minimize the variability from cell-to-cell calibration inaccuracies, although it is recognized that this also has the effect of reducing the true value of peak pressure due to spatial smoothing. However, this is not so deleterious when recording foot loading onto deep cushioning, where the pressure profiles are considerably smoother than on a harder surface. The maximum value with respect to time under each identified peak was then recorded for each step.

Table 2.
Maximum pressures recorded under the peaks at the first and second/third metatarsal heads (mh) during the three steps of walks, for flat inserts compared to molded inserts.

Patient	Insert Type	Location of Peak (mh)	Maximum Peak Pressure, kPa Step number 1	2	3	Average Pressure kPa
1	Flat	1	107	161	121	130
		3	299	205	269	258
	Molded	1	168	163	142	158
		3	178	227	195	200
2	Flat	1	332	311	479	374
		2	378	383	325	362
	Molded	1	183	194	248	208
		2	310	279	275	288
3	Flat	1	311	394	361	355
		2	372	351	345	356
	Molded	1	269	290	167	242
		2	290	285	346	307
4	Flat	1	199	269	226	231
		3	269	280	221	257
	Molded	1	165	165	196	175
		3	107	130	167	135
5	Flat	1	336	362	301	333
		3	368	427	457	417
	Molded	1	216	178	216	203
		3	368	399	311	359
6	Flat	1	157	279	388	275
		3	415	342	185	314
	Molded	1	143	116	136	132
		3	196	211	152	186

On this basis, a mean maximum peak pressure of 305 ± 79 kPa was obtained for the flat PPT inserts. This was significantly higher than the mean maximum peak pressure for the same areas taken for the molded inserts, 216 ± 70 kPa ($p<0.005$; $n=6$). In the significance tests, note that $n=6$ and not 12 because the two peaks under each foot for each condition were not independent and were therefore averaged for analysis. By inspecting the maximum pressures recorded during each footstep, the authors observed that the reduction of maximum pressures under the forefoot peaks was often associated with pressure redistribution into the midfoot.

DISCUSSION

To obtain a conclusive result from any plantar pressure trials with orthopedic footwear has in the past proved difficult, due to the number of variables to be controlled, instrumentation constraints, and the problem of comparing like with like. This trial is no exception. For reasons of cost, patients were tested with their supplied molded inserts, which were of varying constructions and ages. The details of the footwear were not recorded, and although these were all of a similar lace-up type supplied by the same company, there were no doubt some differences. The instrumentation was observed to be drifting during the course of the experiment, with calibrations against weight varying from the beginning to the end of each trial. It cannot be determined to what extent this was due to cell drop-outs rather than a general drift in all cells. The numbers of subjects were reduced by loss of data from the pressure-measuring insole due to creasing. Finally, there must be compromises in the design of a flat insert to "match" the molded insert.

Nevertheless, the trial was designed to test a single hypothesis (i.e., that molded inserts as provided in this clinic are more effective in reducing local peaks of pressure than alternative simple flat cushioning inserts), and it is suggested that the results support this claim. Visual inspection also supported the view that this reduction under the metatarsals was at least partly achieved by redistribution of load into the midfoot area. However, the molded inserts of rocker design were sometimes considerably deeper in the metatarsal region than the flat inserts (up to 19 mm when new although compressed by use, compared with 6 mm), so the effect could also be attributed to more cushioning. There is considerable step-to-step variability of maximum pressures under the peaks (**Table 2**). In general, the variability may be larger in these patients than in asymptomatic persons due to their plantar sensory deficit.

The FSR technology employed in the measurement of pressures provides a vast jump forward in in-shoe techniques. However, some experimentation is required to optimize the reliability of the results. The initial calibration procedure adopted, where the integration of pressures was compared statically to body weight, indicated no significant change in sensor sensitivity over a short period of inactivity before the walks, but that variation was occurring during the walks. There are several reasons that have been postulated for drift in transducers employing FSR technology, including increased temperature due to the activity and gradual change in sensitivity of the FSR material during use. The latter may be due to an initial flattening of surface peaks on the layers of photoresistive material that are laid down in a printing process onto the substrate, and that therefore bed in to give a more constant result after a period of use. Indeed, the manufacturers have suggested this possibility informally, with a recommendation to embed the insole during several minutes of activity before making recordings. This was not considered a reasonable request to make to our particular patient group, but preconditioning of the insoles by a loading device would have been advantageous. However, a more detailed analysis of the loads under the forefoot and hindfoot was conducted separately for the calibration recordings, and this supported the conclusion that the apparent drift was attributable to loss of tracks under the heel rather than a general loss of sensitivity.

CONCLUSION

It has been demonstrated that where high peaks of pressure existed under metatarsal heads, a molded insert has proved more effective at reducing the pressure level than a simple flat insert. This result, however, must be qualified by the details of construction of the two types of insert compared.

Also, further experience in the measurement techniques is indicated to provide a more reliable measurement. Nevertheless, the new in-shoe measurement systems show an exciting potential to yield clinically significant results to support the prescription of appropriate orthotic devices for plantar stress reduction.

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REFERENCES

1. Stokes IAF, Faris IB, Hutton WC. The neuropathic ulcer and loads on the foot in diabetic patients. Acta Orthop Scand 1975:46:839-47.
2. Ctercteko GC, Dhanendran M, Hutton WC, Le Quesne LP. Vertical forces acting on the feet of diabetic patients with neuropathic ulceration. Br J Surg 1981:68:609-14.
3. Boulton AJM, Hardisty CA, Betts RP, et al. Dynamic foot pressure and other studies as diagnostic and management aids in diabetic neuropathy. Diabetes Care 1983:6:26-33.
4. Cavanagh PR, Sanders LJ, Sims Jr, DS. The role of pressure distribution measurement in diabetic foot care. Rehabil Res Dev Progr Rep 1987:25:54.
5. Tuck WH. Surgical footwear and foot orthoses. In: Klenerman L, ed. The foot and its disorders. London: Blackwell Scientific Publications, 1991.
6. Boulton AJM, Franks CI, Betts RP, Duckworth T, Ward JD. Reduction of abnormal foot pressures in diabetic neuropathy using a new polymer insole material. Diabetes Care 1984:7:42-6.
7. Lord M. Foot pressure measurement: a review of methodology. J Biomed Eng 1981:3:91-9.
8. Lord M, Reynolds DP, Hughes J. Foot pressure measurement: a review of clinical findings. J Biomed Eng 1986:8:283-94.
9. Alexander IJ, Chao EYS, Johnson KA. The assessment of dynamic foot-to-ground contact forces and plantar pressure distribution: a review of the evolution of current techniques and clinical applications. Foot Ankle 1990:11:152-67.
10. Cavanagh PR, Hewitt FG, Perry JE. In-shoe pressure measurement: a review. Foot 1992:2:185-94.
11. Geary NPJ, Klenerman L. The rockered soled shoe: a method to reduce peak forefoot pressure in the management of diabetic foot ulceration. In: Pratt DJ, Johnston GR, eds. The biomechanics and orthotic management of the foot. Proceedings of the Conference at Nene College, Northants, UK, 1986:161-73.
12. Rose NE, Feiwell LA, Cracchiolo III A. A method for measuring foot pressures using a high resolution, computerized insole sensor: the effect of heel wedges on plantar pressure distribution and centre of force. Foot Ankle 1992:13:263-70.
13. Hughes J, Pratt L, Linge K, Clark P, Klenerman L. Reliability of pressure measurement: the EMED F system. Clin Biomech 1991:6:14-8.