Reduction of Abnormal Foot Pressures in Diabetic Neuropathy Using a New Polymer Insole Material

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The precise pressures and loads under 69 neuropathic feet have been measured during walking using a modified microprocessor-controlled optical system. Abnormally high pressures were demonstrated in 94% of feet with a history of foot ulceration, with pressures as high as 20–30 $kg \cdot cm^{-2}$ under the forefoot. All subjects were also studied using a new visco-elastic polymer material recently used for insole manufacture. A reduction in pressure was demonstrated that was proportional to peak pressure (linear regression line correlation coefficient of 0.91; $P < 0.001$). We conclude that this material causes a significant reduction in the abnormally high pressures recorded under neuropathic feet, and should provide a useful insole for the management of patients at risk of neuropathic foot ulceration. DIABETES CARE 7: 42–46, JANUARY–FEBRUARY 1984.

We have recently shown that neuropathic diabetic subjects with a history of foot ulceration have abnormally high pressures under the feet during walking.[1] Such patients are at risk of recurrent ulceration because of impaired pain and joint-position sensation[2,3] and increased pressures under the metatarsal heads persisting after the healing of forefoot ulcers.[1] However, in our earlier study, we were unable to document the peak pressures reached in neuropathic subjects, as such extreme levels were not within the reach of the calibration of the system. The use of molded insoles or specialist footwear for subjects with insensitive feet has been emphasized by Reed[4] who also advised that careful measurement of foot-pressure distribution be made in such patients. Studies of the new visco-elastic polymer material, sorbothane (BTR Industries Ltd., Burton-on-Trent, United Kingdom; IEM Orthopaedics Inc., Aurora, Ohio), have shown that the transient acceleration on heel strike during walking is markedly reduced when a sorbothane insert is worn in the shoe[5] as an integral part of the heel. Further studies in Achilles tendonitis and other painful conditions affecting the heel have confirmed that sorbothane inserts abolish symptoms in active patients.[6] We have, therefore, chosen to study the effect of sorbothane using the foot-pressure measurement system in neuropathic diabetic subjects both with and without a history of foot ulceration. Furthermore, we have also been able to document the precise peak pressures under neuropathic feet after a modification of the optical method and its calibration, used for analysis of pressures.

PATIENTS

Thirty-five diabetic subjects took part in the study, which was approved by the hospital ethical committee. All subjects had peripheral neuropathy and satisfied the following previously defined strict criteria for selection, as assessed independently by two investigators: (1) painful symptoms in both legs (paresthesia, burning pains, and/or cramps, with symptoms more pronounced nocturnally) for at least 1 yr before study, or a past history of such symptoms together with a history of neuropathic foot ulcers; (2) absent ankle reflexes; (3) no history of intermittent claudication, i.e., foot pulses palpable bilaterally; and (4) motor conduction velocity in the peroneal nerve less than 42 m/s.[1] Full clinical details of the subjects are provided in Table 1.

METHODS

The foot-pressure measurement apparatus has been previously described[1] with the exception of one major improvement. The system has now been modified[7] by mounting the pressure-sensitive plate on force transducers to determine the accurate instantaneous load during each frame of the dynamic video sequence obtained from the video camera monitoring

TABLE 1
Clinical details of the subjects studied

Group	N (male : female)	Mean age (yr)	Mean duration of diabetes (yr)	Mean duration of neuropathy (yr)	Mean wt (kg)
A (diabetic neuropathy)	35	52.9	13.1	5.2	74.3
	(25:10)	(28–69)*	(1–36)	(1–14)	(47–101)
A_1 (neuropathy + ulcers)	11†	55.8	14.6	7.0	79.0
	(9:2)	(31–68)	(2–36)	(2–14)	(69–101)
A_2 (neuropathy, no ulcers)	24	51.5	12.4	4.4	72.2
	(16:8)	(28–69)	(1–26)	(1–9)	(47–91)

*Range.
†Four of the group A_1 patients had a history of ulceration on one foot only; a further patient had amputation of one foot.

the pressure image. This enables a frame-by-frame calibration check to be carried out by comparison of the sum of the force transducer outputs with the integrated pressure output. This procedure makes possible more accurate measurement of pressure values. The full details of the total system have been described by Franks et al.[7]

Dynamic foot pressure recordings were made on all 69 feet within group A. The first analysis was performed with the patient walking in bare or stockinged feet over the pressure-sensitive area, and this was followed by a recording of the patient walking over the area covered with a 5-mm-thick sheet of the visco-elastic polymer.

STATISTICAL METHODS

Linear regression and Mann-Whitney U tests were used in the statistical analysis of the data. The results in the tables are given as means together with ranges as indicated. Whereas pressure is generally measured in kilopascals (kPa), the results are presented in $kg\cdot cm^{-2}$ at the request of the clinical staff for whom kg (the units of body weight) and square centimeters have a meaning not present in kPa ($1\ kg\cdot cm^{-2} = 98.1\ kPa = 14.2\ lb\cdot in^{-2}$).

RESULTS

The results of the foot-pressure analyses are shown in Table 2 and Figures 1 and 2. There was a significant difference ($P < 0.001$) in peak pressures under the foot between those neuropathic diabetic patients with a history of ulceration (group A_1) and those with no such history (group A_2). The peak pressures under the feet of group A_1 patients were, with one exception, well above the normal limit[8] of approximately 10 $kg\cdot cm^{-2}$ (i.e., 94% of feet). The peak pressures under the feet of the most severely affected patients were very high, some reaching levels in the range 20–30 $kg\cdot cm^{-2}$. The peak pressures under the feet of group A_2 patients were abnormally high in 33% of cases. Combining groups A_1 and A_2 shows 48% of feet having abnormally high peak pressures. These figures are in good agreement with those given by Boulton et al.[1]

The results in Table 2 and Figure 2 show a significant reduction in peak pressure under the foot with the visco-elastic polymer material in both groups of patients ($P < 0.001$ in both cases). When using the polymer, the percentage of feet with abnormal pressures reduced from 94% to 47% with group A_1 patients, and from 33% to 6% with group A_2 patients. The reduction in peak pressure was greater in the group A_1 patients than in the group A_2 patients ($P < 0.001$). This is also shown in the graph of Figure 1, in which the reduction in pressure with the polymer material is plotted against the peak pressure without the polymer material. The reduction in pressure is clearly greater when the initial peak pressure is higher. The linear regression line shown in Figure 1 has a correlation coefficient of 0.91 ($P < 0.001$). This graph also illustrates the markedly higher peak pressures encountered in some of the patients with a history of neuropathic foot ulceration (group A_1, the open circles).

Figures 3 and 4 show typical plotter outputs for dynamic studies. On the left are 10 sample frames from the total number recorded, in which the footprint is shown with isopressure contour lines for each of the frames. On the right is shown the composite image (i.e., overlay of all recorded frames enabling selection of areas of interest), the areas of interest (i.e., the heel, five metatarsal heads, great toe, and other toes), and the peak pressure/time curves for the selected areas of interest. The isopressure contour lines, the areas of interest, and the peak pressure/time graphs are normally produced in color-coded form, but for the purposes of

TABLE 2
Results of the dynamic foot pressure studies, without and with the visco-elastic polymer, showing the mean peak pressure values for the groups studied

Group	Mean peak pressure without the visco-elastic polymer ($kg\cdot cm^{-2}$)	Mean reduction of pressure with the visco-elastic polymer ($kg\cdot cm^{-2}$)
A_1	19.9	10.3
(neuropathy + ulcers)	(9.2–37.2)*	(2.7–20.7)
A_2	8.95	3.9
(neuropathy, no ulcers)	(2.7–22.1)	(0.2–12.6)

*Range.

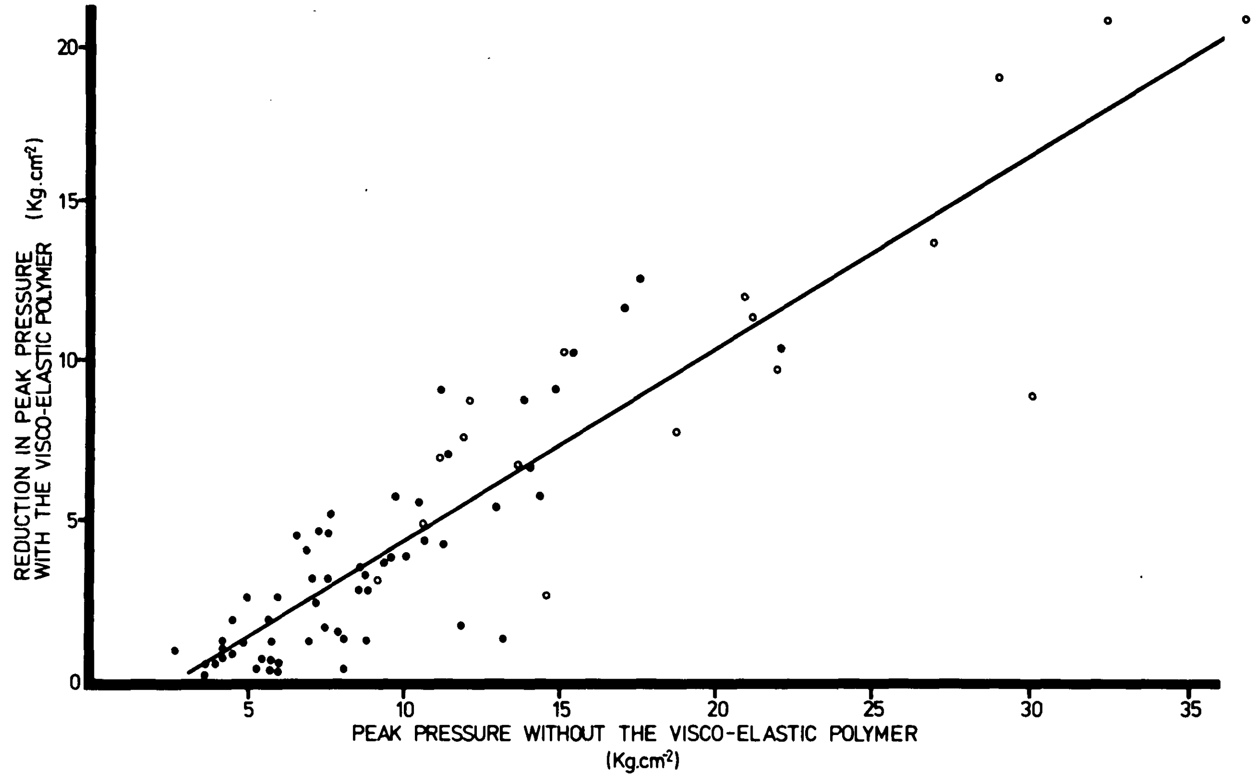


FIG. 1. *Graph showing the reduction of peak pressures with the visco-elastic polymer relative to the initial peak pressures without the polymer. The linear regression line has a correlation coefficient of 0.91. All points are for patients with peripheral neuropathy, the open circles representing those with a history of foot ulceration. 1 kg·cm^{-2} = 98.1 kPa.*

photographic illustration, Figures 3 and 4 are shown in black only and the graphs have been numbered by hand. Although eight areas of interest are shown, the results used in this article are for the pressures under the forefoot only. For convenience, the upper limit of the ordinate axis scale on the peak pressure/time graphs is set at about 11.5 kg·cm^{-2}; however, all the pressure values below and above this level are tabulated against time on the microprocessor system printer output.

Figure 3 shows the foot-pressure distributions for a neuropathic subject with a past history of an ulcer under the first metatarsal head. This clearly demonstrates a high-pressure area at this ulcer site, which was reduced to within normal limits with the use of the polymer. Similarly, the foot-pressure distributions of a neuropathic subject with no history of ulceration are shown in Figure 4. The abnormal peak pressures under the metatarsal heads were returned to normal limits with the use of the polymer (Figure 4B).

DISCUSSION

We have previously reported that diabetic neuropathic subjects with a history of foot ulceration have abnormally high pressures at the ulcer site during walking,[1] and in the present study, we have been able to quantitate actual pressures under the metatarsal heads by the addition of force transducers to the optical system. In an earlier study using the same system, Duckworth et al.[8] demonstrated that pressures in excess of 10 kg·cm^{-2} do not normally occur under feet during walking. However, we have now shown that pressures under neuro-

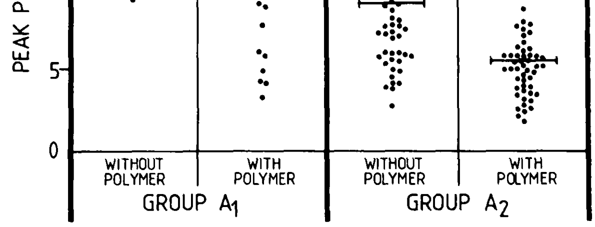
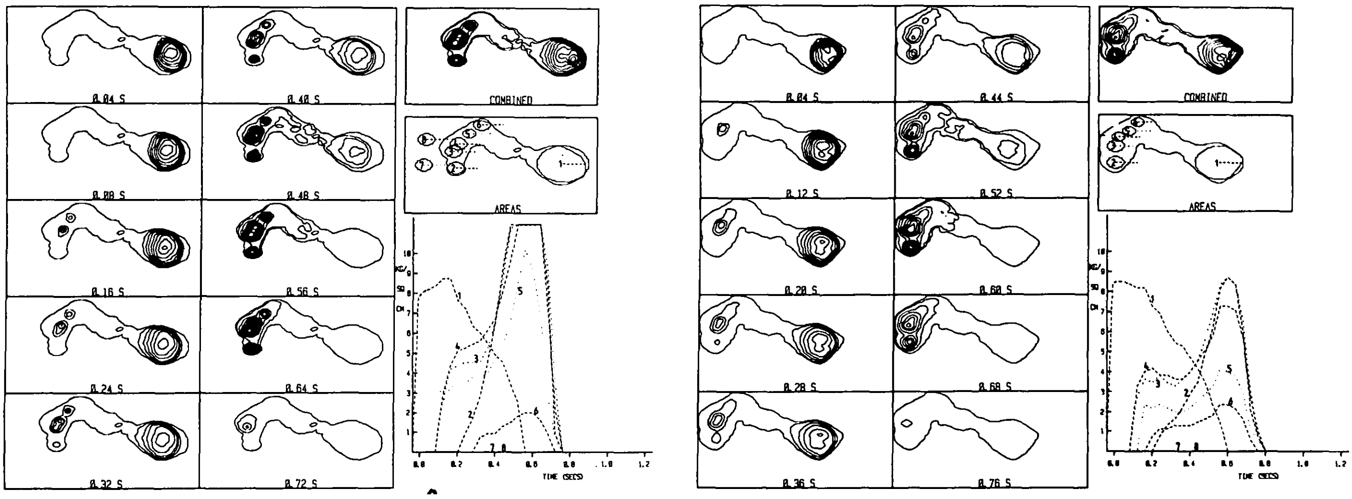


FIG. 2. *Scatter diagram showing the peak pressures under the feet of group A_1 and group A_2 subjects without and with the visco-elastic polymer. Points off the scale of the graph are represented by ⇣. The mean values of the groups are shown as bars.*

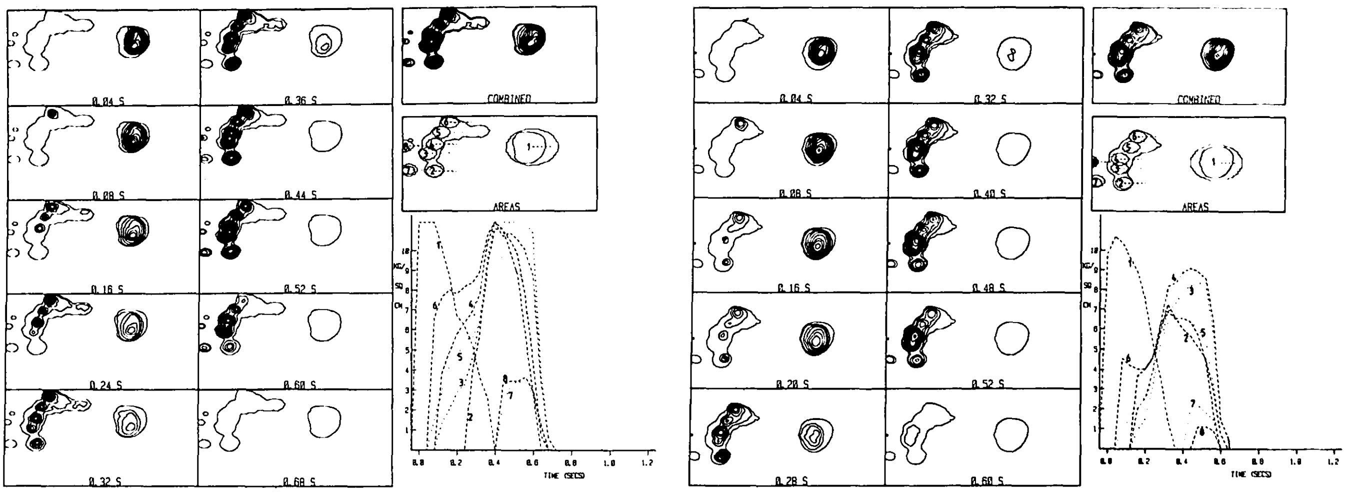


A B

FIG. 3. The color plotter output (in black only) for the right foot of a subject from group A_1 (diabetic patient with previous foot ulcer) showing the dynamic foot pressures without (A) and with (B) the visco-elastic polymer. Pressures under the first to fourth metatarsal heads have exceeded the normal range, the first metatarsal head having a peak pressure of 21 kg·cm^{-2}, double the maximum upper limit of normality. All abnormal pressures were reduced to normal levels with the use of the visco-elastic polymer.

pathic feet may reach as high as 20–30 kg·cm^{-2}. It is appropriate to comment on the high levels of peak pressures being measured. Much of the literature on the measurement of the distribution of load under the foot has come from workers using "small" transducers of the piezo-electric crystal or strain gauge form. These transducers, although very accurate, integrate the force over their measurement area, and any pressure values are therefore average pressure values derived from the measurement of load over the transducer's sensitive area.

In the system currently described, the foot-pressure image is made up from the scanning of TV lines (by a television camera) across a continuous-pressure image produced by an optical system. This has therefore enabled spot pressures to be measured and recorded from any point in the image field. In the measurements described in this article, the pressures quoted are spot peak pressures recorded from within the specified areas of interest. The typical size of a piezo-electric transducer might be 1 cm^2, which is in the region of the total area covered by a single metatarsal head, and the pressure values derived will thus be an average value over this area. With the system described here, the pressure value



A B

FIG. 4. The color plotter ouput (in black only) for the right foot of a subject from group A_2 (neuropathy, no history of foot ulcers) showing dynamic foot pressures without (A) and with (B) the visco-elastic polymer. Abnormal pressures under the metatarsal heads were reduced to normal levels with the use of the visco-elastic polymer.

measured is the peak value detected within the area covered by any single metatarsal head. The extreme values of pressure measured (up to 30 kg·cm^{-2}) were for patients with feet so badly affected that they walked in such a way as to bear their body weight only on the heel and the metatarsal heads, thus producing a very marked gradient of pressure over the area covered by any single metatarsal head. Some indication of the steep gradients of pressure that can occur under metatarsal head areas is shown in Figures 3A and 4A.

The long-term effects of peripheral neuropathy frequently lead to small muscle wasting and the development of "claw-toes." This, in turn, results in prolongation of the load on the metatarsal heads during the footstep so that patients "lift off" from the metatarsal heads rather than from the toes. Thus, reduced toe-loading was commonly seen in the neuropathic subjects that we studied.

These findings confirm the assumption made by earlier workers in this field,[2,3] and there has therefore been much interest in the use of insoles and specialist footwear to attempt to reduce the load under the neuropathic foot.[4,9–12] We chose to measure the pressure-relieving properties of the new visco-elastic polymer, sorbothane. Earlier studies with this material have shown that, because of its energy-absorbing properties, it is superior to other insole materials such as soft-rubber crepe. Furthermore, smaller volumes of this material are needed as it is able to dissipate much of the energy of deformation.[5,6] Our results have confirmed that sorbothane leads to a redistribution and reduction in high pressures under the diabetic neuropathic foot, and, more importantly, that the more abnormal is the pressure, the greater is the pressure reduction. Thus, whereas feet with a normal load distribution had only minor redistribution of pressures, those with extremely high pressure areas under the metatarsal heads experienced a dramatic redistribution of pressures. Many subjects with very high metatarsal head pressures showed a reduction of up to 50% with sorbothane, and in many of these patients, the pressure was reduced to <10 kg·cm^{-2}. The reduction in the percentage of feet subjected to abnormally high peak pressures from 33% to only 6% in those patients without a history of foot ulceration (group A_2) suggests that suitable pressure-relieving insoles may be useful in the management of patients at risk of developing foot ulcers. However, a number of subjects with very abnormal results who were virtually walking on their metatarsal heads showed a reduction in pressure insufficient to bring them back into the normal range of values. Such subjects would still be at risk of developing foot ulcers. It is probable that, because of the anatomical abnormalities in such patients, a thicker insole would be required to demonstrate a greater reduction in pressure. However, the weight of such an insole, if constructed of the visco-elastic polymer, might be a limiting factor. An alternative solution for the grossly abnormal foot might be a combination of visco-elastic polymer insole with a rocker shoe,[4] or a combination insole of visco-elastic polymer and another material such as plastazote.

We are, at present, unable to measure the pressure at the foot-insole interface, but the development of small-pressure transducers will enable such studies to be undertaken in the future.[12] We therefore conclude that pressures up to the region of 20–30 kg·cm^{-2} have been recorded under the metatarsal heads of neuropathic diabetic subjects with a history of foot ulceration. Reduction of these very abnormal pressures has been demonstrated using a 5-mm, visco-elastic polymer insole, which could be of practical use in the management of those diabetic patients with a history of, or at risk of developing, foot ulceration.

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REFERENCES

1 Boulton, A. J. M., Hardisty, C. A., Betts, R. P., Franks, C. I., Worth, R. C., Ward, J. D., and Duckworth, T.: Dynamic foot pressure and other studies as diagnostic and management aids in diabetic neuropathy. Diabetes Care 1983; 6:26–33.

2 Oakley, W., Catterall, R. C. F., and Martin, M. M.: Aetiology and management of lesions of the feet in diabetes. Br. Med. J. 1956; 2:953–57.

3 Ellenberg, M.: Diabetic neuropathic ulcer. J. Mt. Sinai Hosp. 1968; 35:585–94.

4 Reed, J. K., Jr.: Footwear for the diabetic. *In* The Diabetic Foot. Levin, M. E., and O'Neall, W., Eds. St. Louis, C. V. Mosby Co., 1983:360–77.

5 Light, L. H., MacLellan, G. E., and Klenerman, L.: Skeletal transients on heel strike in normal walking with different footwear. J. Biomechanics 1980; 13:477–80.

6 MacLellan, G. E., and Vyvyan, B.: Management of pain beneath the heel and achilles tendonitis with visco-elastic heel inserts. Br. J. Sports Med. 1981; 15:117–21.

7 Franks, C. I., Betts, R. P., and Duckworth, T.: A microprocessor based image processing system for dynamic foot pressure studies. J. Med. Biol. Eng. Comp. 1983; 21:566–72.

8 Duckworth, T., Betts, R. P., Franks, C. I., and Burke, J.: The measurements of pressures under the foot. Foot and Ankle 1982; 3:130–41.

9 Block, P.: The diabetic foot ulcer: a complex problem with a simple treatment approach. Milit. Med. 1981; 146:644–46.

10 Reed, J. K., Jr.: Plastazote insoles, sandals and shoes for insensitive feet. *In* Surgical Rehabilitation in Leprosy. McDowell, F., and Ema, C. D., Eds. Baltimore, Williams and Wilkins, 1974:323–30.

11 Cracchiolo, A.: Office practice: footwear and orthotic therapy. Foot and Ankle 1982; 2:242–48.

12 Pollard, J. P., LeQuesne, L. P., and Tappin, J. W.: Forces under the foot. J. Biomed. Eng. 1983; 5:37–40.