Effectiveness of Different Types of Footwear Insoles for the Diabetic Neuropathic Foot

A follow-up study

VIJAY VISWANATHAN, MD, PHD[1]
SIVAGAMI MADHAVAN, BSC[1]
SARASWATHY GNANASUNDARAM, ME[2]
GAUTHAM GOPALAKRISHNA, ME[2]
BHABENDRA NATH DAS, MTECH[2]
SEENA RAJASEKAR, BA[1]
AMBADY RAMACHANDRAN, MD, PHD, FRCP[1]

OBJECTIVE — To compare the effectiveness of different types of footwear insoles in the diabetic neuropathic foot.

RESEARCH DESIGN AND METHODS — A sample of 241 consecutive diabetic patients (158 men and 83 women, age 57.5 ± 9.6 years [mean ± SD], and mean duration of diabetes 12.3 ± 7.2 years) attending the foot clinic with previous foot ulceration and those considered at high risk of foot ulceration were included in the study. The study groups consisted of group 1, patients provided with sandals with insoles made with microcellular rubber (n = 100); group 2, with sandals with polyurethane foam (n = 59); group 3, with molded insoles (n = 32); and group 4, with their own footwear containing leather board insoles (n = 50). Neuropathy status was assessed using a biothesiometer. Plantar pressure was measured using the RS Scan inshoe pressure measurement system. Data obtained from the metatarsal heads were used as the peak pressure. The state of the sandals was assessed after 9 months. The patients were considered to have had an ulcer relapse when either a new ulcer appeared at the site of a previous one or a new foot ulcer appeared in a different area.

RESULTS — Patients who were using therapeutic footwear showed lower foot pressure (group 1, 6.9 ± 3.6; group 2, 6.2 ± 3.9; and group 3, 6.8 ± 6.1 kPa; P = 0.0001), while those who used the nontherapeutic footwear showed an increased foot pressure (group 4, 40.7 ± 20.5 kPa; P = 0.008). The occurrence of new lesions was significantly higher in patients in group 4 (33%) when compared with that of all other groups (4%).

CONCLUSION — Therapeutic footwear is useful to reduce new ulceration and consequently the amputation rate in the diabetic population.

Diabetes Care 27:474–477, 2004

Diabetic foot infection is a common cause for hospital admission among diabetic patients in India. This could be attributed to several sociocultural practices, such as walking barefoot, inadequate facilities for diabetes care, poor education, and poor socioeconomic conditions (1). It was reported earlier (2) that recurrence of foot infection was common among South Indian type 2 diabetic subjects and was related to the presence of peripheral vascular disease and neuropathy. A diabetic patient with a history of previous ulceration or amputation is at an increased risk for further ulceration, infection, and subsequent amputation. Alterations in foot dynamics due to ulceration, joint deformity, or amputation can cause abnormal distribution of plantar pressures and result in the formation of a new ulcer (3). In our earlier study (4), we reported that limited joint mobility and increased plantar pressure appear to be important determinants of foot ulceration irrespective of the duration of diabetes.

The reduction of pressure peaks by providing special shoes turns out to be an effective tool for managing the neuropathic foot. Data from randomized trials on the usefulness of therapeutic footwear in preventing foot ulcers varies, with some studies showing benefits (5–7) and a few others not showing any beneficial effects (8,9). The aim of this study was to determine the efficacy of therapeutic footwear in preventing foot ulcers and reducing plantar pressures in diabetic patients.

RESEARCH DESIGN AND METHODS

— In the present study, therapeutic footwear for diabetic patients was developed using commercially available cushioning materials. Three different kinds of insoles were developed and used to construct footwear for diabetic patients with neuropathy. The materials selected were polyurethane, ethylene vinyl acetate (EVA), microcellular rubber (MCR), and cork. A full-length foam inner sole was included in the footwear to cradle and support the foot. Polyurethane, EVA, and MCR are relatively lightweight, shock absorbent, flexible, and highly durable materials. Customized footwear was developed for the patients with foot ulcers or deformity. It was constructed over the positive model of the patient's foot, using leather and other materials of equal quality with some form of shoe closure.

The plantar pressure was measured in 241 consecutive patients (158 men and

From the [1]M.V. Hospital for Diabetes and Diabetes Research Centre, Royapuram, Chennai, India; and the [2]Central Leather Research Institute, Adyar, Chennai, India.

Address correspondence and reprint requests to Dr. Vijay Viswanathan, MD, PhD, Diabetes Research Centre, WHO Collaborating Centre for Research, Education & Training in Diabetes, No. 4 Main Rd., Royapuram, Madras, 600 013, India. E-mail: dr_vijay@vsnl.com.

Received for publication 28 June 2003 and accepted in revised form 4 November 2003.

Abbreviations: EVA, ethylene vinyl acetate; MCR, microcellular rubber.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

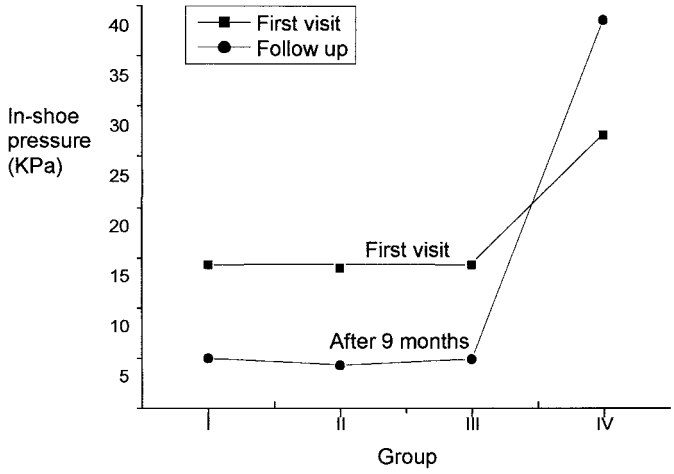

Figure 1—*Comparison of inshoe pressure in kilopascals for the four groups of diabetic patients during the first visit (■) and after 9 months (●).*

83 women, mean age 57.5 ± 9.6 years [mean ± SD], and mean duration of diabetes 12.3 ± 7.2 years). Subjects were enrolled in the study within a time frame of 2 months (January to February 2002). Only patients with previous foot ulceration, who had a high risk of foot ulceration (10), were included in the study. The selected patients were allowed to choose the type of footwear. An overwhelming majority of the patients (group 1 [n = 100]) chose to wear the MCR insoles, while a smaller group (group 2 [n = 59]) chose to wear the polyurethane foam–insoled footwear. Patients with foot deformity (group 3 [n = 32]) were prescribed to wear molded footwear. Patients assigned to group 4 (n = 50) were those who declined to have the prescribed sandals due to economic reasons. They wore their usual footwear with an insole containing hard leather board. The footwear materials used for group 1 were 10 mm MCR as insole and 8 mm rubber sole as the outer sole; for group 2 were 5 mm polyurethane foam as insole, 5 mm MCR as midsole, and 10 mm EVA as the outer sole; and for group 3 were 10 mm EVA as the outer sole, 6 mm cork as midsole, and 6 mm polyurethane foam as insole.

Age, body weight, HbA_{1c}, and duration of diabetes were recorded. All patients gave informed consent for the study. Patients with active ulcers were excluded from the study.

The patients in groups 1, 2, and 3 were provided with customized footwear with different types of insoles. The footwear was prepared at the footwear unit of the foot clinic after taking foot measurements of the patients in groups 1, 2, and 3. All patients received the same educational guidelines on foot care. Neuropathy was diagnosed by biothesiometer (11). Peripheral vascular disease was diagnosed as an ankle brachial index <0.8. Dynamic plantar foot pressure was evaluated using the RS Scan inshoe pressure measurement (RS Scan, Olen, Belgium). Data were collected at 250 Hz, using a 0.7-mm thick capacitance insole with 356 sensors and a spatial sensor resolution dependent on insole size.

For each patient, four gait trials were performed with the RS Scan insole placed in direct contact with the sole of the foot. Subjects were allowed to practice walking until they felt comfortable so that their gait pattern would be as consistent as possible during each trial. Data obtained from the metatarsal heads were used as the peak pressure. Along with peak plantar pressure, percentage of load and contact period were also recorded and analyzed. At the follow-up examination conducted 9 months later, the same parameters were measured and recorded for all patients. Furthermore, the patients were asked about foot problems, such as ulceration, infection, gangrene, and amputation. Patients were asked whether they had used the footwear daily. If they said that they had not, this answer was taken as reliable. If they confirmed having worn the footwear regularly every day, this was checked by inspection of the footwear. The patients were considered to have had an ulcer relapse when either a new ulcer appeared at the site of previous one or a new foot ulcer appeared in a different area.

Statistical comparisons

Data are means ± SD. Group comparisons were done by χ^2 or Student's t test as relevant. P values of <0.05 were considered significant.

RESULTS — The characteristics of patients in the study groups are shown in Table 1. Intergroup differences were absent in body weight, duration of diabetes, and HbA_{1c}. The mean age for group 1 was higher when compared with that of groups 2 and 3 (P = 0.03 and 0.001, respectively).

Table 2 demonstrates the mean peak pressures under metatarsal heads in kilopascals and the percentage change from baseline measurements. The high-risk patients in the first three groups showed a relatively decreased foot pressure (group 1, 6.9 ± 3.6; group 2, 6.2 ± 3.9; and group 3, 6.8 ± 6.1 kPa; P = 0.0001) after 9 months through usage of the therapeutic footwear, whereas those who used the

Table 1—*Baseline characteristics of the study groups*

	Group			
	1	2	3	4
n	100	59	32	50
Sex (M/F)	61/39	40/19	22/10	33/17
Age (years)	59.1 ± 8.2	54.5 ± 9.1*	53.9 ± 9.3†	59.1 ± 11.7
Duration of diabetes (years)	13.5 ± 7.2	11.8 ± 7.5	11.4 ± 6.2	12.9 ± 6.8
Weight (kg)	67.9 ± 8.1	67.9 ± 8.8	64.8 ± 8.1	66.8 ± 7.6
HbA_{1c} (%)	9.2 ± 2.3	8.8 ± 2.2	8.9 ± 1.9	9.1 ± 2.1
Peripheral vascular disease	14 (14)	5 (8)	2 (6)	7 (14)
Previous foot ulceration	68 (68)	34 (58)	23 (72)	32 (64)

Data are means ± SD or n (%). *P = 0.001 vs. group 1; †P = 0.003 vs. group 1.

Table 2—*Comparison of inshoe pressure*

Group	*n*	Inshoe pressure: First visit (kPa)	Inshoe pressure: Follow-up (kPa)	Inshoe pressure: Change in pressure (%)	*P*	New lesions [*n* (%)]	Time worn (h)
1	100	16.2 ± 6.1	6.9 ± 3.6	−57.4	0.00001	4 (4)	8
2	59	16.3 ± 8.2	6.2 ± 3.9	−61.96	0.00001	2 (4)	8
3	32	16.2 ± 1.3	6.8 ± 6.1	−58.02	0.00001	1 (3)	9
4	50	29.2 ± 22.1	40.7 ± 20.5	39.38	0.008	16 (33)	8

Data are means ± SD unless noted otherwise.

nontherapeutic footwear showed an increase in foot pressure (group 4, 40.7 ± 20.5 kPa; $P = 0.008$). Group 4 patients had a higher number of new lesions (33%) compared with 4% new lesions in groups 1 and 2 and 3% in group 3 ($\chi^2 = 36.854$; $P \leq 0.001$) (Table 2).

Figure 1 shows a comparison of plantar pressure in patients in the therapeutic and nontherapeutic footwear groups during the initial and follow-up visit. Tables 3 and 4 highlight the percentage load and percentage contact time, respectively, for all of the groups. Patients in groups 1, 2, and 3 showed a reduction in percentage load (10, 19, and 19%, respectively), whereas those in group 4 showed an increase in percentage load (13%). On an identical parallel, the percentage contact times of the therapeutic footwear groups were reduced by 10, 8, and 8%, respectively, whereas in the case of the nontherapeutic footwear group, it was increased by 9%

CONCLUSIONS — Nontherapeutic footwear does not reduce foot pressures significantly, and thus foot ulcers are still subject to load, which hampers the healing process. The higher recurrence rate of ulceration in the nontherapeutic footwear group underscores the need to use specially designed footwear and include it as part of the overall diabetes care regimen for these patients.

A reduction of plantar pressures with the therapeutic footwear in a 9-month period clearly highlights the benefit of using soft, shock-absorbing insole materials and correctly designed footwear in diabetic patients, particularly those with high-risk feet. The materials and styling of footwear are clearly able to reduce the pressure on high-pressure regions.

The present study suggests that effective load distribution is absent in nontherapeutic footwear and consequently leads to regions of stress concentration. This would in turn produce pressure on the ulcerated regions and cause delayed healing. The higher contact time observed in group 4 patients can be attributed to the use of nontherapeutic footwear. High contact time may cause ulcer relapse. Such complications can be prevented by using therapeutic footwear, which provides effective load distribution and thereby reduces healing time.

In a study by Uccioli et al. (5), it was shown that customized footwear was beneficial for patients with previous foot ulceration and for those considered at high risk of foot ulceration. Reulceration occurred in 58% of patients who resumed wearing their own footwear, compared with 28% of those who wore therapeutic footwear. However, patients with foot deformity, such as charcot joint, were not included in this study.

In our study, we found that patients with prior foot ulceration without deformity could benefit from noncustomized footwear itself and did not require costly customized insoles, which is contrary to the findings of Uccioli et al (5). However, for patients with deformity, customized footwear was found to be essential.

The prevalence and severity of foot deformities and ulceration in diabetic subjects who had had a great toe amputation was studied by Quebedeaux et al. (12). They found that because of altered pressure distribution, the foot with great toe amputation developed more frequent and more severe deformities of the lesser toes and metatarsophalangeal joints compared with the other intact foot. Because these patients were at high risk for subsequent ulceration, the use of special footwear to protect the feet was highly recommended. In a recent clinical trial, Reiber et al. (9) found that therapeutic footwear did not prevent foot ulceration in patients with diabetes. Reduction in risk for foot ulcers was not seen in the patients who used therapeutic footwear. However, that study had its own limitations, namely the definition of the ulcers, low ulcer event rate, and selection of the study subjects. In our study, only subjects who had no protective sensation were included and standard therapeutic shoes were used for treatment. This most likely explains the difference in the findings of both of these studies. The effect of therapeutic footwear in ischemic or neuropathic ulcers was studied in 239 patients by Edmonds et al. (13). The reulceration rates were 26% among the therapeutic footwear group and 83% among those who wore their own footwear.

The benefits of therapeutic footwear are well known. In a study by LeMaster et al. (14), it was shown that education by mailed motivation brochures improved the awareness and increased the number of people making therapeutic footwear claims. This study underscores the benefits of footwear education regarding therapeutic footwear use.

A few limitations of our study are: *1*) The higher reulceration in group 4 patients could not be wholly attributed to the nontherapeutic footwear used. It could be due to other psychological and physical parameters, which had not been analyzed. *2*) The numbers of subjects in the study groups differed because the subjects were not randomly assigned. *3*) We could not get sufficient details regard-

Table 3—*Comparison of percentage load*

Group	*n*	Percentage load: First visit	Percentage load: Follow-up	Percentage load: Change (%)	*P*
1	100	30 ± 4.5	27 ± 10.1	−10	0.008
2	59	28 ± 6.3	23 ± 8.8	−19	0.00001
3	32	25 ± 5.4	21 ± 7.6	−19	0.02
4	50	38 ± 8.8	43 ± 10.9	13	0.02

Data are means ± SD.

Table 4—*Comparison of percentage contact time*

Group	*n*	Percentage contact time			*P*
		First visit	Follow-up	Change (%)	
1	100	82 ± 8.7	74 ± 6.7	−10	0.00001
2	59	80 ± 4.8	73 ± 5.7	−8	0.00001
3	32	75 ± 10.6	69 ± 9.2	−8	0.02
4	50	90 ± 6.5	99 ± 4.8	9	0.001

Data are means ± SD.

ing the history of previous foot ulceration to make detailed analyses regarding the characteristics of the ulcers. Despite these limitations, we have been able to demonstrate that the use of therapeutic footwear, which is scientifically designed to redistribute load and pressures effectively, prevent pressures from acting on the affected ulcerated regions. Attention to the limited joint mobility must form part of the treatment procedure. Use of this footwear is recommended to reduce ulceration and, consequently, the amputation rate in the diabetic population.

References

1. Vijay V, Snehalatha C, Ramachandran A: Sociocultural practices that may affect the development of the diabetic foot. *IDF Bulletin* 42:10–12, 1997
2. Vijay V, Narasimham DVL, Seena R, Snehalatha C, Ramachandran A: Clinical profile of diabetic foot infections in South India: a retrospective study. *Diabet Med* 17:215–218, 2000
3. Bid DE, Selby JV, Sinnock P, Browner WS: Lower-extremity amputation in people with diabetes: epidemiology and prevention. *Diabetes Care* 12:24–31, 1989
4. Vijay V, Snehalatha C, Sivagami M, Seena R, Ramachandran A: Association of limited joint mobility and high plantar pressure in diabetic foot ulceration in Asian Indians. *Diabetes Res Clin Prac* 60:57–61, 2003
5. Uccioli L, Fagila E, Monticone G, Favales F: Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care* 18: 1376–1378, 1995
6. Mueller MJ: Therapeutic footwear helps protect the diabetic foot. *J Am Podiatr Med Assoc* 87:360–364, 1997
7. Chantelau E, Kushner T, Spraul M: How effective is cushioned therpeutic footwear in protecting diabetic foot? A clinical study. *Diabet Med* 7:355–359, 1990
8. Reiber GE, Smith DG, Wallace C, Sullivan K, Hayes S, Vath C, Maciejewski ML, Yu O, Heagerty PJ, Le Master J: Two types of therapeutic shoes were no better than usual footwear for preventing foot reulceration (Abstract). *J Bone Joint Surg Am* 84A:2107, 2002
9. Reiber GE, Smith DG, Wallace C: Effect of therapeutic footwear on foot reulceration in patients with diabetes. *JAMA* 287: 2552–2558, 2002
10. Birke JA, Sims DS: Plantar sensory threshold in the ulcerative foot. *Lep Rev* 57:261–264, 1986
11. Young MJ, Veves A, Breddy JL, Boulton AJM: The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds: prospective study. *Diabetes Care* 17:557–560, 1994
12. Quebedeaux TL, Lavery DC, Lavery LA: The development of foot deformities and ulcers after great toe amputation in diabetes. *Diabetes Care* 19:165–167, 1996
13. Edmonds M, Blundell M, Morris M: Improved survival of the diabetic foot: the role of a specialized foot clinic. *Q J Med* 60:763–771, 1986
14. LeMaster JW, Sugarman JR, Baumgardner G, Reiber GE: Motivational brouchers increase the number of Medicare-eligible persons with diabetes making therapeutic footwear claims. *Diabetes Care* 26:1679–1684, 2003