

Effect of Orthosis Material Hardness on Walking Pressure in High-Risk Diabetes Patients

James A. Birke, PhD, PT, Cped
James G. Foto, BSME, Cped
Larry A. Pfeifer, MApSt, RPh

ABSTRACT

This study evaluated the effect of levels of hardness of a commonly used orthosis material in reducing plantar pressure in patients at high-risk for foot ulcers. The mean peak pressure was measured, by using the Pedar System, on 19 patients with diabetes mellitus and a history of plantar foot ulceration. Patients walked in standard extra-depth shoes with no orthoses, standard extra-depth shoes with 1/4-inch Poron® orthoses in seven different levels of hardness (14, 17, 22, 27, 32, 40, and 55 Shore "O" durometer), and their own nonstandardized footwear with molded orthoses. Mean peak walking pressures were lower in the standard shoes with the 22, 27, and 32 durometer Poron orthoses compared with those in the standard shoes with the 14, 17, and 55 durometer Poron orthoses. Walking pressures were lowest in the patients' nonstandardized footwear fitted with molded orthoses. Results support the use of medium-hardness Poron materials, which includes the current standard formulation (22 Shore "O" durometer), in orthosis fabrication in patients with diabetes at high risk for foot ulceration.

Introduction

Plantar ulcerations, commonly seen in diabetes mellitus, develop in insensate feet over areas of high pressure.¹⁻³ In these high-risk feet, high pressure is associated with motor neuropathy, foot deformity, limited joint mobility, and callus formation.⁴⁻⁷ Protective footwear may lower pressure and prevent plantar ulceration.⁸⁻¹¹ Demonstrating the effectiveness of footwear materials and designs is a critical issue for foot-care providers in ulcer treatment and prevention programs.

Footwear and orthoses designed with soft and molded surfaces can lower plantar pressure by increasing the foot-contact area, where pressure equals force over area. The effectiveness of soft and molded orthoses in reducing plantar pressure has received limited study. Footwear designed with soft insoles and outer soles have been shown to reduce walking pressure compared to hard leather soled shoes.¹² Shoes and sandals fit with soft, nonmolded inserts have been shown to reduce pressure in the neuropathic feet of patients with Hansen's disease.¹³ Soft and molded orthoses have been shown to reduce walking pressures in normal subjects and patients with diabetes.¹⁴⁻¹⁶ In studies of barefoot subjects, soft materials including Poron® (Rogers Corp, Rogers, CT), Spenco®, and medium Plastazote® (Zotefoam Inc., Hackettstown, NY) have been shown to increase contact area, reduce foot pressure, but do not reduce total force in normal subjects.¹⁷⁻¹⁸ Pressure has also been shown to be a function of the soft-tissue padding in the foot¹⁹⁻²⁰ and the thickness of the orthosis material.²⁰ Poron, and to a lesser extent, Spenco, have been shown to resist permanent deformation from repeated shear and compression,²¹ and thereby continue to lower pressure after long-term use. Depth shoes fit with soft orthoses have been shown to reduce the recurrence of plantar ulcerations in patients with diabetes.²²

The issue of what degree of orthosis-material hardness is best for lowering walking pressure has not been investigated. Comparisons of reported material hardness data might not be valid, because measurements used to determine material hardness are dependent on the technique and the durometer gauge used.

This study evaluates the effect of levels of hardness of a commonly used orthosis material in reducing pressure in patients with diabetes at high risk for plantar ulcerations. In a recent survey of foot-care providers, Poron was found to be the most popular nonmolded orthosis material.²³

Methods

Nineteen male and female patients with diabetes mellitus and a history of plantar foot ulceration participated in the study (Table 1). All patients were volunteers free of ulceration at the time of testing, and provided informed consent. Data were collected on 35 feet. Patients with amputation or severe deformity were excluded. Weight and height were measured to determine their influence on the treatment effect. Seven formulations of commercially available Poron, a nonmoldable polyurethane foam material, were studied. Sheets of 1/4-inch thickness (2 x 1/8", stacked) of each of the seven Poron formulation conditions were cut into orthoses for testing. Measurements of their hardness were made by using a Shore "O" durometer gauge and constant load adapter (Rex Gauge Co., Buffalo Grove, IL) (Table 2).

Subject No.	Sex	Age	Height (y)	Weight (cm)	Ponderal Index (kg)	Left Recording Sites*	Right Recording Sites*
1	F	57	152.4	80	35.4	Central MTH	Central MTH
2	M	78	171.5	97	37.3	Great Toe	Central MTH
3	F	69	157.5	87	35.5	Medial MTH	Medial MTH
4	M	62	188.0	89	42.1	Central MTH	Central MTH
5	F	56	172.7	93	38.2	Medial MTH	Central MTH
6	F	57	170.2	97	37.1	Central MTH	Central MTH
7	F	42	165.1	107	34.8	Medial MTH	Central MTH
6	M	63	182.9	86	41.4	Medial MTH	Central MTH
9	M	61	185.4	120	37.6	Medial MTH	Central MTH
10	M	74	181.6	76	42.9	Medial MTH	Medial MTH
11	M	63	180.3	122	36.4	Medial MTH	Central MTH
12	F	48	160.0	86	36.2	Central MTH	Great Toe
13	F	71	162.6	90	36.3	Medial MTH	Medial MTH
14	F	48	177.8	115	36.5	Central MTH	Medial 1MTH
15	M	63	193.0	61	48.9	Great Toe	Central MTH
16	M	45	190.5	75	45.1	Central MTH	Central MTH
17	M	72	170.2	115	35.0	—	Central MTH
18	M	52	177.8	116	36.5	—	Central MTH
19	M	63	185.4	100	40.0	—	Medial MTH

* n (recording sites) = 35 MTH = metatarsal heads

Table 1. Description of the subjects.

Conditions	Poron Formulations	Durometer (Shore "O")	Density (lbs/ft ³)
1	4000-59-20125-1648	14	20
2	4000-01-15125-1604	17	15
3	4000-01-20125-1604*	22	20
4	4000-05-17125-1605	27	17
5	4000-05-20125-1637	32	20
6	4000-12-20125-1604	40	20
7	4000-12-30125-1604	55	30

Poron® is a registered trademark of the Rogers Corporation, Rogers, CT.
*Standard formulation used in orthosis fabrication.

Table 2. Poron® conditions with durometer and density.

Pressure measurements were made during walking by using the EMED Pedar System (Novel USA, Minneapolis, MN), shown in figure 1 , and Pedar Clean Up and Step Analysis (v. 4.1) data-reduction software. The Pedar sensors were calibrated by the manufacturer prior to the start of the study. Sensors were held against the plantar surface of the foot with a nylon stocking and were fit over the

orthoses in the shoe. Each patient performed nine walking trials at a self-selected pace for a distance of 40 feet. Recordings were made on five steps during the middle of the walking trials for each of the following nine treatment conditions: no orthosis in a standard shoe, Poron conditions 1 to 7 in a standard shoe, and the patient's own custom molded orthosis and shoe. Treatments were randomly assigned to prevent a systematic error. Subjects were blinded from knowledge about the specific orthoses used in trials.



Figure 1. The EMED Pedar System (Novel USA, Minneapolis, MN) used for in-shoe pressure measurements.

The standard shoe consisted of an extra-depth shoe (Thermomold, contour last, PW Minor, Batavia, NY). Patients' molded orthoses were not used with standard footwear to eliminate problems associated with orthoses/ footwear incompatibility.

The area of highest pressure was determined from recordings made during the no-orthosis treatment condition. Comparisons were made of mean peak pressure (MPP), at the area of highest pressure, for five steps for nine walking trials. Comparisons of MPP were analyzed by using an analysis of variance for repeated measures. A Tukey's studentized range test was used to establish which treatments differed, using an alpha level of 0.05. The effect of weight or ponderal index (a measure of body stoutness) on treatment was analyzed by using a general linear model (SAS Institute Inc., Cary, NC). Ponderal index was defined as $PI = 10^3 \times \text{cube-root}(W) / H$.²⁴ Weight and ponderal index were studied to determine their influence on the effect of material hardness on pressure.

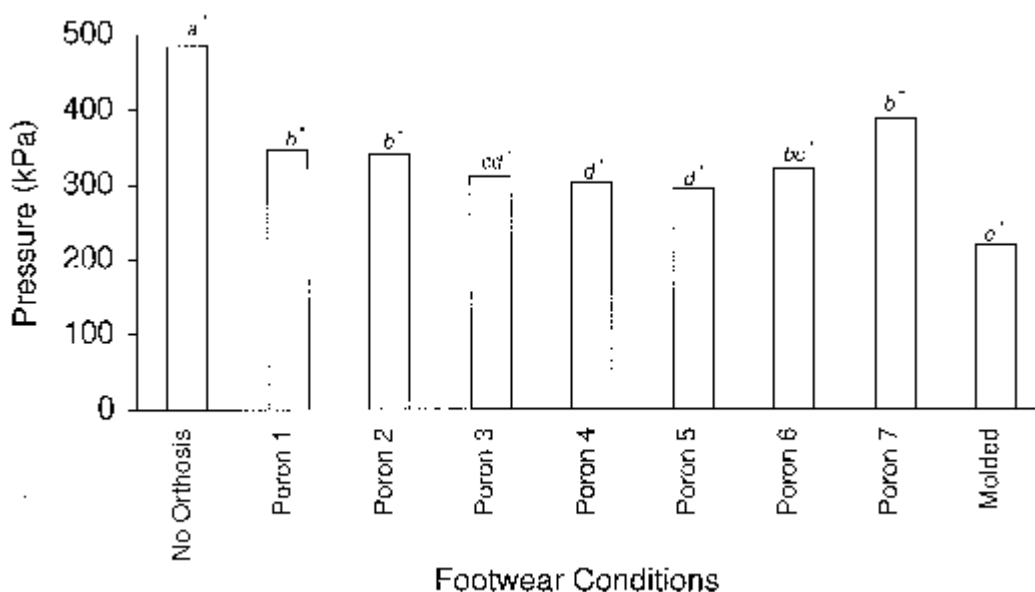
Results

There was a significant difference in MPP between treatment conditions ($p < 0.0001$). Mean peak pressure (Table 3 and Figure 2) was lower when patients were walking in standard footwear with Poron condition 3, 4, or 5, as compared to Poron conditions 1, 2, or 7, or footwear without orthoses. Pressure was also lower in Poron conditions 4 and 5 compared to Poron condition 6. Pressure was lowest when the patient was walking in his or her own custom molded orthoses and footwear, compared to all other treatment conditions.

Footwear Treatment Condition	Mean Walking Pressure (kPa ± SD)
No Orthoses	484 ± 131 ^a
Poron 1	346 ± 102 ^b
Poron 2	339 ± 98 ^b
Poron 3	310 ± 87 ^{cd}
Poron 4	301 ± 83 ^d
Poron 5	293 ± 90 ^d
Poron 6	321 ± 69 ^{bc}
Poron 7	387 ± 86 ^b
Molded Orthoses	218 ± 83 ^c

* a>b>c>d>e (p < 0.05)

Table 3. Mean peak walking pressure at the location of highest pressure in 35 feet of 19 patients with diabetes.



* a>b>c>d>e, p < 0.05

Figure 2. Mean peak walking pressure in standard shoes with no orthoses, standard shoes with seven different Poron orthoses conditions, and nonstandardized footwear with molded orthoses.

Both weight and ponderal index were mildly related to MPP ($p < 0.001$, $R^2 = .19$ and $p < 0.001$, $R^2 = .06$, respectively). Adjusted means based on weight or ponderal index did not affect the relationship between Poron conditions and MPP.

Discussion

In this study the mean peak walking pressure at the area of highest foot pressure was reduced by 36%-39% in the standard shoe fitted with 1/4 inch of a medium hardness Poron (Poron conditions 3-5) compared to the standard shoe without orthoses. Softer and firmer formulations of Poron were less effective in reducing pressure, but were still better than no orthosis material at all. Orthoses thinner than 1/4 inch may not relieve pressure because of a bottoming-out affect, which reduces the material's ability to distribute force.²⁰ While extra-depth shoes with nonmolded orthoses made of Poron reduced foot pressure, they were not as effective as the patients' custom molded orthoses and footwear which reduced pressure 55%. Previous studies have shown molded orthoses are more effective than nonmolded orthoses in reducing pressure.¹⁵

This study supports the use of medium-hardness Poron material (Shore "O" durometers 22-32),

which includes the current standard formulation (Shore "O" durometers 22), for fabricating orthoses in high-risk diabetic patients. This study does not support the use of harder materials for heavy or stout subjects for the purpose of pressure reduction. This practice, however, may extend material durability and lower pressure over time. In this study, the footwear with molded orthoses were not standardized. Further studies are needed to evaluate which methods and materials used in molded orthoses fabrication are best for lowering pressure in individuals with high-risk feet.

Acknowledgements

This study was supported in part by a grant from the Pedorthic Footwear Association, Columbia, MD.

References:

1. Ctercteko GC, Dhanendran M, Hutton WC, et al. Vertical forces acting on the feet of diabetic patients with neuropathic ulceration. *Br J Surg*. 1981;68:608-614.
2. Stokes IAF, Faris IB, Hutton WC. The neuropathic ulcer and loads on the foot in diabetic patients. *Acta Orthop Scand*. 1975;46:836-847.
3. Veves A, Murray HJ, Young MJ, Boulton AJM. Do high foot pressures lead to ulceration: a prospective study. *Diabetologia*. 1992; 35:660-663.
4. Boulton AJM. Peripheral neuropathy and the diabetic foot. *Foot* 1992;2:6772.
5. Young MJ, Cavanagh PR, Thomas B, Johnson MM, Murray H, Boulton AJM. The effect of callus removal on dynamic plantar foot pressures in diabetic patients. *Diabet Med*. 1991;9:55-57.
6. Boulton AJM, Betts RP, Franks CI, et al. Abnormalities of foot pressure in early diabetic neuropathy. *Diabet Med*. 1987; 4:225-228.
7. Fernando DJS, Masson EA, Veves A, Boulton AJM. Relationship of limited joint mobility to abnormal foot pressures and diabetic foot ulceration. *Diabetes Care* 1991;14:8-11.
8. Brand PW. Repetitive stress in the development of diabetic foot ulcers. In: Levin ME, O'Neal LW (eds). *The Diabetic Foot*. 4th ed. St. Louis: CV Mosby; 1988: 83-90.
9. Birke JA, Sims DS. The insensitive foot. In: Hunt GC, McPoil TG (eds). *Physical Therapy of the Foot and Ankle*. 2nd ed. New York: Churchill Livingstone; 1995:159-206.
10. Janisse DJ. A scientific approach to insole design for the diabetic foot. *Foot* 1993;3:105-108.
11. Albert S, Rinoie C. Effect of custom orthotics on plantar pressure distribution in the pronated diabetic foot. *J Foot Ankle Surg*. 1994;33:598-604.
12. Perry JE, Ulbrecht JS, Derr JA, Cavanagh PR. The use of running shoes to reduce planar pressures in patients who have diabetes. *J Bone Jt Surg*. 1995;77A:1819-1828.
13. Birke JA, Foto JG, Deepak S, Watson J. Measurement of pressure walking in footwear used in leprosy. *Lepr Rev*. 1994;65:262-271.
14. Corbett ML, Abramowitz AJ, Fowble CD, Rask B, Whielaw GP. In-shoe plantar pressure measurement of the first metatarsophalangeal joint in asymptomatic patients. *Foot Ankle* 1993;14:520-524.
15. Lord M, Hosein R. Pressure redistribution by molded inserts in diabetic footwear: a pilot study. *J Rehabil Res Dev*. 1994;31:214-221.
16. Ashry HR, Lavery LA, Muldoch DP, Frolich M, Lavery DC. Effectiveness of diabetic insoles to reduce foot pressures. *J Foot Ankle Surg*. 197;36:268-272.
17. McPoil TG, Cornwall MW. Effect of insole material on force and plantar pressures during walking. *J Am Pod Med Assoc*. 1992;82:412-416.
18. Sanfilippo PB, Stess RM, Moss KM. Dynamic plantar pressure analysis. *JAMA*. 1992;82:507-513.
19. Smith L, Plehwe M, McGill M, Genev N, Yur DK, Turtle JR. Foot bearing pressure in patients with unilateral diabetic foot ulcers. *Diabet Med*. 1989;6:573-575.
20. Lemmon D, Shiang TY, Hashmi A, Ulbrecht JS, Cavanagh PR. The effect of insoles in therapeutic footwear: a finite element approach. *J Biomechan*. 1997;30:615-620.

21. Brodsky JW, Kourosch S, Stills M, Mooney V. Objective evaluation of insert material for diabetic and athletic footwear. *Foot Ankle* 1988;9:111-116.
22. Chantelau E, Jushner T, Spraul M. How effective is cushioned therapeutic footwear in protecting diabetic feet: a clinical study. *Diabet Med.* 1990;7:355-359.
23. Foto J, Birke JA. Who's using what: an orthotic materials survey. *Biomechanics* 1996;3:63-68.
24. Kreighbaum E. *Biomechanics: A Qualitative Approach For Studying Human Movement.* Minneapolis, MN: Burgess Publishing Co; 1985:54-56.

Source: Journal of Prosthetics and Orthotics 1999; Vol 11, Num 2, p 43

URL: http://www.oandp.org/jpo/library/1999_02_043.asp