Effectiveness of Diabetic Insoles to Reduce Foot Pressures

The F-Scan system was used to measure peak plantar pressures in 11 diabetics each with a unilateral great toe amputation and an intact contralateral extremity (nonamputated), to evaluate the effectiveness of five footwear-insole strategies: 1) extra-depth shoes without an insole, 2) extra-depth shoes with a Plastizote™[1] insole, 3) extra-depth shoes with a Plastizote™ insole and a metatarsal pad, 4) extra-depth shoes with a Plastizote™ insole and a medial longitudinal arch pad, and 5) extra-depth shoes with a Plastizote™ insole and a combination of metatarsal pad and arch pad. When we compared extra-depth shoes with and without insoles, peak pressures were significantly reduced with insoles under the first metatarsal, the lesser metatarsals, and the heel ($p < 0.001$) in feet with and without an amputation, as well as under the great toe on the contralateral foot (nonamputated, $p < 0.001$), but not under the lesser toes (giant toe, $p = 0.088$; nonamputated, $p = 0.763$). There was no significant difference between the different insole modifications. (The Journal of Foot & Ankle Surgery 36(4):268–271, 1997)

Key words: amputation, pressure, foot, insole, ulceration, diabetes mellitus

Hisham R. Ashry, DPM, AACFAS[2]
Lawrence A. Lavery, DPM, AACFAS[2,3,4]
Douglas P. Murdoch, DPM, AACFAS[2]
Monica Frolich, DPM[2]
David C. Lavery, MS[5]

A high rate of reamputation in people with diabetes mellitus after a primary amputation has been well documented in the medical literature (1–7). We have observed frequent reamputation in diabetics with a partial foot amputation involving the hallux. Greteman and Dale (8) showed that 65% of the feet developed new ulcerations following a great toe amputation, with 53% requiring further amputation.

Foot ulcerations have been identified as an important component in the causal pathway of diabetic peripheral neuropathy predispose the diabetic foot to abnormal weightbearing and areas of concentrated pressure that have been associated with the development of these ulcerations (10–12). Ulceration in the insensitive foot has been attributed to moderated areas of pressure that are exposed to repetitive stress (12). In diabetic patients, accommodative insoles are a widely recognized tool for preventing plantar ulcers. The purpose of the insoles is to cushion the sole and reduce weightbearing forces. Although footwear modifications are regarded as an important component in the multidisciplinary approach to the diabetic foot, there is little scientific evidence to support specific treatment recommendations.

We felt that many reamputations in patients with an amputation of the great toe (GT) and first metatarsal head were needed because of neuropathic ulcers that developed as a result of high-pressure areas on the sole of the foot and that reducing these pressures with insoles would be an effective treatment strategy. Insight into insole design could improve prevention strategies in high-risk diabetics and reduce the need for additional ablative surgery. The purpose of this study was to evaluate the effectiveness of insole modifications to reduce peak plantar foot pressures in diabetics with peripheral neuropathy and GT amputations.

Methods

We evaluated seven males and four females with noninsulin-dependent diabetes mellitus (NIDDM) and a unilateral amputation of the GT and first metatarsal of at least 6-months duration. Eleven consecutive patients from the Podiatry and Orthopaedic Clinics at The University of Texas Health Science Center at San Antonio who fit the study criteria were invited, and agreed to participate in the project. The average age of participants was 65.1 years with a range of 39 to 78 years. All 11 patients had NIDDM for an average of 9.9 years with a range of 3 to 37 years. The average body mass index

[1] Acor Orthopaedics, Cleveland, OH.

From the Department of Orthopaedics, The University of Texas Health Science Center, San Antonio,[2] and the Mexican American Medical Treatment Effectiveness Research Center, San Antonio, Texas.[3]

[4] Address correspondence to: Lawrence A. Lavery, Department of Orthopaedics/Podiatry Service, The University of Texas Health Science Center, San Antonio, TX 78284-7776

[5] Department of Mathematical Sciences, The United States Military Academy, West Point, New York.

The Journal of Foot & Ankle Surgery 1067-2516/97/3604-0268$4.00/0

(BMI) was 28.1 kg./m.^{2} with a range of 23.6 to 38.5 kg./m.^{2}. Patients with a previous amputation of the contralateral foot were excluded. All patients showed evidence of peripheral sensory neuropathy. Semmes-Weinstein monofilaments were used to test sensory perception, using the method and criteria described by Birke and Holewski (13, 14).

Foot pressures under five conditions were evaluated for each participant. Participants were evaluated in extra-depth shoes (EDS; P. W. Minor Super extra-depth for men and Dutchess for women[6], without an insole and in EDS with four different heat-molded insole designs: 1) a 6-mm. medium Plastizote™, insole with a metatarsal pad placed proximal to the metatarsal heads, 2) a 6-mm. Plastizote™ insole with a medial longitudinal arch pad, 3) a 6-mm. Plastizote™ insole with a combination of a medial longitudinal arch pad and a metatarsal pad (Fig. 1), and 4) a 6-mm. Plastizote™ insole without any modifications. The EDS had a Blucher-style upper with a deep back quarter and heel, orthoflare, wide shank, and Vibram™ sole.[7] A new, custom-molded, medium-density Plastizote™ insole was used for each design. To construct a heat-molded insole, a positive cast was made from each patient's foot impression. This cast was then used to fabricate the heat-molded Plastizote™ insole. The metatarsal pad and the medial longitudinal arch pad were of high-density polyurethane material. The appropriate sizing and placement of pads (Fig. 1), selection of footwear, and construction of insoles were performed by a certified pedorthist. Hallux fillers were not used on the affected foot.

The F-Scan[8] insole pressure assessment system was used to measure plantar foot pressures. The application of this equipment and software has been described previously (15, 16). The F-Scan pressure insoles were calibrated for each patient according to the manufacturer's specifications. Before testing, patients walked for several minutes with each insole design, in order to become comfortable with the insole and shoe. The same insole design was worn bilaterally. Data collection began after the second step and continued for at least six consecutive steps on the same walkway. Patients were asked to walk at their normal cadence and stride length. There were three repeat trials for each study group. The average of the peak plantar pressures was determined under the great toe [on the nonamputated contralateral (NA) foot only], the first metatarsal head, the lesser

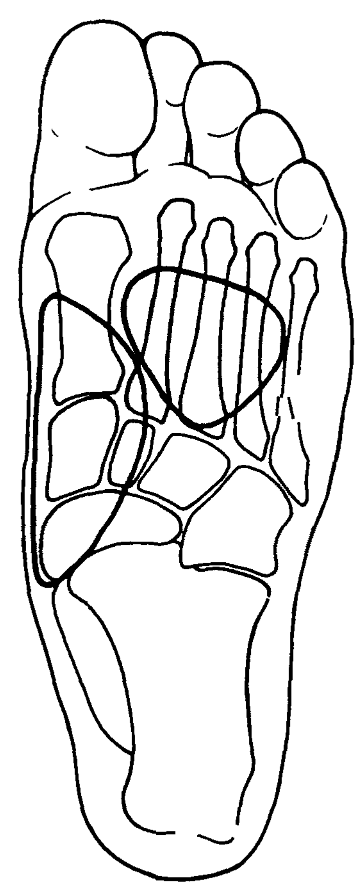

FIGURE 1 Placement of metatarsal and longitudinal arch pads on the insole in relationship to anatomic landmarks.

metatarsal heads, the lesser toes, and the heel. The amputations in this study group were resections of the distal portion of the first metatarsal head. Generally, compared to the contralateral foot, the peak pressures were several centimeters proximal. In these cases, interpretation of in-shoe sensors was adjusted to measure the highest pressure at the distal portion of the first metatarsal.

We used Kruskal-Wallis analysis of variance (17) to compare treatments, and Minitab statistical software[9] to perform the statistical analysis. Data are presented as means ± standard deviations.

Results

The average of the peak plantar pressures of all 11 subjects is described in Table 1. At all sites evaluated, the mean peak plantar pressure was higher when EDS were worn without an insole, compared to any of the groups with insole modifications, with the exception of the area under the lesser toes of the contralateral foot. Foot pressures were significantly higher when no insole

[6] P. W. Minor & Son, Batavia, NY.

[7] Blucher is a shoe style that laces in the front; the tongue is part of the forepart of the shoe and the quarters remain open. Orthoflare indicates that the sole is wider at the bottom than the top. The P. W. Minor Superdepth shoe has a 7 degree orthoflare. Vibram is a trademarked cushion crepe sole made of EVA (ethyl vinyl acetate).

[8] Tekscan, Boston, MA.

[9] Minitab, Boston, MA.

TABLE 1 **Mean peak plantar pressure ± SD (g/cm^2) in great toe amputations**

Location	Extra Depth Shoes	Plastizote	Metatarsal Pad	Arch Pad	Metatarsal-Arch Pad
1st Metatarsal head	6797 ± 469	3576 ± 469	3081 ± 469	3528 ± 477	3329 ± 477
Lesser metatarsal heads	6317 ± 358	3443 ± 358	3277 ± 358	3755 ± 364	3403 ± 364
Lesser toes	3712 ± 394	3288 ± 394	3317 ± 394	3530 ± 401	3163 ± 401
Heel	3331 ± 136	2481 ± 136	2500 ± 136	2434 ± 138	2517 ± 138

TABLE 2 **Mean peak plantar pressure ± SD (g/cm^2) in nonamputated feet**

Location	Extra Depth Shoes	Plastizote	Metatarsal Pad	Arch Pad	Metatarsal-Arch Pad
Great toe	5242 ± 2357	3057 ± 965	2914 ± 994	2969 ± 1081	2942 ± 836
1st Metatarsal head	4582 ± 2290	2866 ± 1145	2579 ± 1191	2681 ± 1125	2568 ± 694
Lesser metatarsal heads	3360 ± 1145	2200 ± 519	2193 ± 387	2136 ± 344	2166 ± 391
Lesser toes	1561 ± 662	1586 ± 653	1578 ± 743	1682 ± 535	1465 ± 654
Heel	4400 ± 2007	2670 ± 527	2821 ± 548	2740 ± 536	2797 ± 617

was used, compared to the four insole designs in GT amputations and nonamputated (NA) feet under the first metatarsal (GT, $p < 0.001$; NA, $p < 0.001$), the lesser metatarsals (GT, $p < 0.001$; NA, $p < 0.001$); the heel (GT, $p < 0.001$; NA, $p < 0.001$), and the great toe (NA, $p < 0.001$) but not under the lesser toes (GT, $p = 0.88$; NA, $p = 0.763$).

There was a 47 to 55% reduction of pressure under the first metatarsal head, a 41 to 48% reduction under the lesser metatarsal heads, and a 24 to 27% reduction under the heel in feet with great toe amputations (Fig. 1). Similar results were observed on the contralateral limb. There was a 42 to 44% reduction of pressure under the hallux, a 37 to 44% reduction under the first metatarsal head, a 35 to 36% reduction under the lesser metatarsal heads, and a 36 to 39% reduction under the heel. Conversely, the mean peak plantar pressure under the lesser toes was reduced by 5 to 15% in feet with great toe amputations and 0 to 7% on NA feet with the different insole modifications, compared to pressures in EDS without an insole.

Discussion

In order to prevent ulcerations, insoles that reduce high-pressure areas on the sole of the foot have been advocated (18, 19). However, despite the fact that physicians who treat high-risk patients with diabetes often use special accommodative insoles as a mainstay of therapy, there is little quantitative data that supports effectiveness of these devices. Studies in this area have largely addressed in-shoe pressure changes with various shoe modifications and mechanical testing of insole materials. We have been unable to identify any data in the English-language literature that describes or quantifies the effectiveness of insole modifications in patients with diabetes and GT amputations.

Our findings show that the mean peak plantar pressures were significantly reduced under the first metatarsal head, the lesser metatarsal heads, and the heel with all insole designs, compared to pressure measurements in EDS without an insole. However, no difference was found among the different insoles designed to reduce peak plantar pressure. Chang *et al.* (20), have demonstrated similar results in their evaluation of the effectiveness of metatarsal pads in persons without diabetes. Chang placed the metatarsal pad 5 mm. proximal to the metatarsal heads and found no statistical significance in the reduction of plantar pressures. In both our study and Chang's, the metatarsal pads were placed proximal to the metatarsal head. The metatarsal pads may be more effective if placed more distal or if a larger pad is used. However, metatarsal pads may not be an effective component to reduce plantar foot pressures even though they have been widely touted as a vital component of accommodative insoles. Our findings would suggest that the extra time, effort, and expense that is required to fabricate an insole with additional accommodative modifications is unwarranted. This contradicts the accepted "oral tradition" that is the foundation of insole therapy for diabetics.

Conclusion

In this study, we measured foot pressures, with and without insoles, of high risk diabetics. We also modified the insoles to see if this further decreased peak pressure measurements on the sole of the foot. Our results show that in-shoe foot pressures are significantly lower when insoles are used, compared to measurements without insoles. There was no significant reduction in plantar pressure when the insoles were modified with metatarsal pads, medial longitudinal arch pads, or a combination of both modifications. Future work in this area should evaluate the redistribution of plantar foot pressures over time, as insole materials compress. Specific foot types, deformities, and ulcer locations should be independently evaluated to aid in choosing the most effective materials and designs to solve each problem.

References

1. Couch, N. P., David, J. K., Tilney, N. I., Crane, C. Natural history of the leg amputee. Am. J. Surg. 133:469–473, 1977.
2. Fylling, C. P., Knighton, D. R. Amputation in the diabetic population: incidence, causes, cost, treatment, and prevention. Enterostomal Ther. 16:247–255, 1989.
3. Hodge, M. J., Peters, T. G., Efird, W. G. Amputation of the distal portion of the foot. South. Med. J. 82:1138–1142, 1989.
4. Light, J. T., Rice, J. C., Kerstein, M. D. Sequelae of limited amputation. Surg. 103:294–298, 1988.
5. Sizer, J. S., Wheelock, F. C. Digital amputations in diabetic patients. Surg 72:980–989, 1972.
6. Turnbull, A. R., Chester, J. F. Partial amputations of the foot for diabetic gangrene. Ann. R. Coll. Surg. Engl. 70:329–331, 1988.
7. Effeney, D. J., Lim, R. C., Schecter, W. P. Transmetatarsal amputation. Arch. Surg. 112:1366–1370, 1977.
8. Greteman, B., Dale, S. Digital amputations in neuropathic feet. J. Am. Podiatr. Med. Assoc. 80:121–126, 1990.
9. Pecoraro, R. E., Reiber, G. E., Burgess, E. M. Pathways to diabetic limb amputation basis for prevention. Diabetes Care 13:513–521, 1990.
10. Bauman, J. H., Girling, J. P., Brand, P. W. Plantar pressures and trophic ulceration. J. Bone Joint Surg. Am. 458:652–673, 1963.
11. Boulton, A. J., Betts, R. P., Franks, C. I., Ward, J. D., Duckworth, T. The natural history of foot pressure abnormalities in neuropathic diabetic subjects. Diabetes Res. 5:73–77, 1987.
12. Brand, P. W. The insensitive foot, ch 22,. In *Disorders of the Foot and Ankle*, 1st ed. vol. 1, pp. 2170–2186, edited by M. H. Jahss, W. B. Saunders Company, Philadelphia, 1982.
13. Birke, J. A., Sims, D. S. Plantar sensory threshold in the ulcerated foot. Lepr. Rev. 57:261–267, 1986.
14. Holewski, J. J., Stess, R. M., Graf, P. M., Grunfeld, C. Aesthesiometry quantification of cutaneous pressure sensation in diabetic peripheral neuropathy. J. Rehabil. Res. Dev. 25:1–10, 1988.
15. Young, C. R.: The F-Scan system of foot pressure analysis. Clin. Podiatr. Med. Surg. 10:455–461, 1993.
16. Sarnow, M. R., Veves, A., Giurini, J. M., Rosenblum, B. I., Chrzan, J. S., Habershaw, G. M. In-shoe foot pressure measurements in diabetic patients with at-risk feet in healthy subjects. Diabetes Care 17:1002–1006, 1994.
17. Siegel, S., Castellan, J. N. The case of k independent samples, ch 8. In *Nonparametric Statistics for the Behavioral Sciences,* 2nd ed., pp. 206–211 McGraw-Hill, NY, 1988.
18. Albert, S., Rinoie, C. Effect of custom orthotics on plantar pressure distribution in the pronated diabetic foot. J. Foot Ankle. Surg. 33:598–604, 1994.
19. Wu, K. J. Diagnosis and Treatment of foot ulcers ch. 11 In *Foot Orthoses: Principles and Clinical Applications,* pp 279–291, Williams & Wilkins, Baltimore, 1990.
20. Chang, A. H., Abu-Faraj, Z. U., Harris, G. F., Nery, J., Shereff, M. J. Multistep measurement of plantar pressure alterations using metatarsal pads. Foot Ankle 15:654–660, 1994.