Comparison of Orthotic Materials on Foot Pain, Comfort, and Plantar Pressure in the Neuroischemic Diabetic Foot

A Case Report

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Foot pain and lower-limb neuroischemia in diabetes mellitus is common and can be debilitating and difficult to treat. We report a comparison of orthotic materials to manage foot pain in a 59-year-old man with type 1 diabetes mellitus, peripheral neuropathy, peripheral arterial disease, and a history of foot ulceration. We investigated a range of in-shoe foot orthoses for comfort and plantar pressure reduction in a cross-sectional study. The most comfortable and most effective pressure-reducing orthoses were subsequently evaluated for pain relief in a single system alternating-treatment design. After 9 weeks, foot pain was completely resolved with customized multidensity foot orthoses. The outcome of this case study suggests that customized multidensity foot orthoses may be a useful intervention to reduce foot pain and maintain function in the neuroischemic diabetic foot. (J Am Podiatr Med Assoc 98(2): 143-148, 2008)

In Australia, 7.4% of adults have diabetes mellitus, a figure that has doubled in the past 20 years.[1] Foot problems such as nonhealing ulceration, infection, and amputation are a major concern for the diabetes community. Pain is a very common clinical sequela of these problems, particularly in diabetic patients with lower-limb peripheral arterial disease.[2]

Peripheral arterial disease is common and associated with considerable morbidity and mortality. The prevalence of peripheral arterial disease in diabetes is reported to be as high as 30%.[3] Peripheral arterial disease is a progressive condition characterized by arterial stenosis and occlusions in the peripheral arterial bed and is associated with an elevated risk of cardiovascular and cerebrovascular events, such as myocardial infarction, stroke, and death. Peripheral arterial disease affects health-related quality of life because of chronic pain and loss of mobility and function.[2] In the lower limb, peripheral arterial disease may manifest as mild or moderate intermittent claudication, critical limb ischemia with nonhealing foot ulceration, rest pain, and gangrene that requires amputation.[4]

As part of long-term management of peripheral arterial disease, patients are routinely advised to exercise by walking 30 to 60 min daily to develop collateral circulation.[3] This management plan can be difficult to adhere to because of the presence of foot pain. Although claudication is present in 10% to 20% of patients, 50% of patients report aching, tiredness, and foot pain as the limiting factor to exercise.[5] Interestingly, it is assumed that for a patient with diabetes mellitus, peripheral arterial disease, and peripheral neuropathy (neuroischemia), pain would be less of a consideration because of the presence of neuropathy. However, 70% of insensate patients and 36% of ischemic patients with diabetes report pain most or all the time.[2] Research that evaluates treatment of foot pain in this most-at-risk group of patients is therefore a priority.

Foot pain and diabetic foot ulceration are thought to be the result of abnormal pressure distribution on the plantar surface of the foot.[6, 7] Plantar pressure is defined as the force applied over the distributed area of ground contact and can be measured at the foot-

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to-ground interface with a platform (eg, EMED System, Novel GmbH, Munich, Germany; Musgrave Footprint system, Musgrave Systems Ltd, Llangollen, North Wales) or at the foot-to-shoe interface with an in-shoe system (eg, Pedar system, NovelGmbH, Munich, Germany; F-Scan, Tekscan, Boston, Massachusetts). Plantar pressures have been shown to be higher in patients with diabetes and lower-limb neuroischemia than in neuropathic patients and healthy controls, perhaps because of the reduced plantar soft tissue thickness in peripheral arterial disease, which is considered a contributing factor to high plantar pressures in diabetes.[8] Foot ulceration in these patients can result in infection, the need for minor or major lower limb amputation, and even death.[9]

Conservative foot care such as off-loading casts, therapeutic footwear, and foot orthoses customized to an individual have been shown to reduce pressure loading, foot ulceration, and major amputations in patients with neuroischemic ulceration.[10-12] However, there is limited evidence of treatment for foot pain in the neuroischemic diabetic patient at risk of foot ulceration and amputation. In particular, evidence for foot orthoses commonly prescribed for this clinical condition is lacking, and there is a need to evaluate their effect on foot pain, comfort, and plantar pressure distribution. Indeed, if the patient determines that foot orthoses provide an improved level of foot comfort, the patient is more likely to adhere to prescribed daily levels of walking for exercise, thereby improving mobility, function, and long-term peripheral arterial flow, which is critical for patient survival.

As more than 80% of amputations follow a foot ulcer or injury, early recognition of at-risk individuals and appropriate foot care may result in a reduced incidence of foot pain, ulceration, and, consequently, amputation.[13] In this article, we evaluate a range of foot orthoses on plantar pressure, foot pain, and comfort in a patient with diabetes mellitus and lower-limb neuroischemia.

Case Report

A 59-year-old male patient (height, 1.75 m; weight, 55 kg) with type 1 diabetes mellitus of 40 years' duration attended the Foot Wound Clinic (Westmead Hospital, Sydney, Australia). The patient complained of bilateral foot pain of 5 years' duration, described as a "bruising" pain beneath the forefoot metatarsal region when walking. He had a history of foot ulceration on the margins of the foot (fourth and fifth digits) as well as the presence of intermittent claudication after 20 minutes of walking.

On examination, the patient exhibited peripheral neuropathy (vibration perception threshold [Neurothesiometer; Bailey Instruments, Manchester, United Kingdom]: left hallux 32.5 V, right hallux 35.5 V) and severe peripheral arterial disease (toe-brachial index: left 0.41, right 0.53). Lower-limb peripheral arterial disease was confirmed with peripheral arterial scans. The patient had no foot deformity (eg, Charcot's foot, forefoot amputation, calcaneus resection, hallux valgus), and his foot structure was considered to be normal as defined by a Foot Posture Index of +2 for the left foot and +1 for the right foot.[14] His foot pain was subsequently diagnosed as bilateral metatarsalgia with forefoot plantar fat pad atrophy (left foot worse than right). Other relevant medical history included hypertension, retinopathy, hypercholesterolemia, and glomerulonephropathy.

There were three parts to this study: a cross-sectional comparison of a range of foot orthoses, an 8-week single system alternating-treatment design, and a 1-week follow-up of the preferred orthotic device after customization. The study was conducted with informed consent of the patient in accordance with the Declaration of Helsinki.

Part 1

Eight common orthotic materials were evaluated for patient comfort and plantar pressure distribution (Table 1). For the initial evaluation, the orthotic materials were not molded to the morphology of the patient's foot. For each pair of foot orthoses, overall comfort was assessed with a visual analog scale: 0 mm (not comfortable at all) to 150 mm (most comfortable condition imaginable) during two walking laps of a 20-m walkway. This method has been shown to provide a reliable measure of overall footwear comfort.[15]

Plantar pressure was recorded using the Pedar-X system (Novel GmbH), which is an accurate, reliable, and valid measure of in-shoe pressure.[16, 17] Plantar pressure was measured before (baseline) and after each orthotic condition, while the patient wore a standardized shoe and sock (Brooks Addiction, Texas Peak Pty Ltd, Melbourne, Australia). Following a familiarization period, data were collected at 100 Hz for approximately 40 steps on a 20-m walkway. To prevent a disturbance in gait pattern and to ensure a natural gait, cadence and walking speed were monitored but not controlled. Nine straight-line walking steps from the left foot were selected and processed in the Novel Multimask Software Version 13.3.23 (Novel GmbH). The foot was then divided into three anatomically and clinically relevant regions (rearfoot, midfoot, and forefoot), as described previously.[7] For the forefoot region, the peak pressure (kPa) and pressure-time integral

Table 1. Comparison of Orthotic Materials and Their Effect on Forefoot Plantar Pressures and Comfort

Condition	Peak Pressure (kPa)	Peak Pressure Change (%)	Pressure-Time Integral ([kPa] × s)	Pressure-Time Integral Change (%)	Comfort Score (0 mm to 150 mm)[a]
Sock and shoe only (Brooks Addiction, Texas Peak Pty Ltd, Melbourne, Australia)	213	NA	41	NA	42
Extra soft cellular urethane (6 mm Poron Microcellular, Rogers Corp, Woodstock, Connecticut)	211	–1	47	+15	88
Soft cellular urethane (6 mm Poron Medical, Rogers Corp, Woodstock, Connecticut)	198	–7	37	–10	118
Neoprene (3 mm Spenco, Spenco Medical Corp, Waco, Texas)	198	–7	37	–10	99
Trilaminate (6 mm Microcel Puff/Poron/Microcel Puff, Acor Orthopedic, Inc, Cleveland, Ohio)	193	–9	40	–2	18
Slow-rebound cellular urethane (6 mm Poron Performance, Rogers Corp, Woodstock, Connecticut)	186	–13	39	–5	89
Slow-rebound cellular urethane and soft cellular urethane (6 mm Poron Performance/6 mm Poron Medical, Rogers Corp, Woodstock, Connecticut)	163	–23	30	–27	144
Neoprene/soft cellular urethane (3 mm Spenco; Spenco Medical Corp, Waco, Texas/6 mm Poron Medical, Rogers Corp, Woodstock, Connecticut)	158	–26	34	–17	136
Contoured multidensity orthoses (Step 2 Evolution, Thanner GmbH, Hochstadt, Germany)	95	–55	18	–56	131

Abbreviation: NA, not applicable.
[a]Visual analogue comfort scale: 0 mm (not comfortable at all) to 150 mm (most comfortable condition imaginable).

([kPa] × sec) were analyzed. Peak pressure is the highest pressure experienced by any one sensor during foot contact, and the pressure-time integral is the sum of peak pressure in each frame of foot contact multiplied by the duration of foot contact. To examine the relationship between orthoses comfort and plantar pressure, a series of correlational analyses were calculated in SPSS Version 13.0 (SPSS Inc, Chicago, Illinois). Statistical tests were considered significant at $P < .05$.

Part 2

In the second part of the study, the longer-term effect of foot orthoses on foot pain was evaluated. On the basis of the orthoses comparison, the patient was prescribed the most effective pressure-reducing foot orthoses and the most comfortable foot orthoses in an ABAC single system alternating-treatment design over an 8-week period,[18] where A = no foot orthoses (2 weeks each time); B = most effective pressure-reducing foot orthoses (2 weeks); and C = most comfortable foot orthoses (2 weeks). Intensity, presence, and nature of foot pain was measured with the 100-point Foot Health Status Questionnaire (FHSQ) at baseline and at weekly intervals for 8 weeks (0 = worst, 100 = best). The FHSQ was selected because it is an accurate, valid, and reliable means of measuring patient-based, foot-health–specific quality of life before and after treatment.[19]

Part 3

The patient was asked to nominate his preferred orthotic device on the basis of comfort and foot pain relief during the 8-week test period. The chosen device

was then customized to the exact morphology of the patient's foot for long-term therapeutic management. A final foot pain questionnaire (FHSQ) was conducted 1 week later to conclude the study.

Results

Part 1

The contoured multidensity foot orthoses (Step 2 Evolution, Thanner GmbH, Hochstadt, Germany) were most effective at reducing peak pressure and pressure-time integral than the shoe alone. The patient reported the slow-rebound cellular urethane and soft cellular urethane combination (6 mm Poron Performance and 6 mm Poron Medical, Rogers Corp, Rogers, Connecticut) as the most comfortable (Table 1).

There was a strong correlation between peak pressure and comfort ($r = -0.838$, $P = .005$), which indicates that 70% (r^2) of the variability in patient comfort can be attributed to differences in peak pressure. A similarly strong correlation between pressure-time integral and comfort was also evident ($r = -0.756$, $P = .019$).

Part 2

During the 8-week longitudinal study, foot pain improved more with the contoured multidensity foot orthoses after 2 weeks' wearing time (FHSQ score, 93.8) than it did with the slow-rebound cellular urethane and soft cellular urethane combination after 2 weeks' wearing time (FHSQ score, 87.5) (Fig. 1).

Part 3

The patient nominated the contoured multidensity foot orthoses (Fig. 2) as his preferred treatment. This device was then molded to neutral-suspension plaster casts of the feet according to a reliable technique[20] by an experienced podiatric physician (J.B.). One week later, the final foot pain questionnaire (FHSQ) revealed complete resolution of foot pain (FHSQ score, 100; Fig. 1), and the patient commented that his feet were the "best they have felt in years."

Discussion

The ultimate goal of treatment for the patient with diabetes mellitus and lower-limb neuroischemia is to maintain functional status, reduce or eliminate ischemic symptoms, and prevent progression of the disease. This study has shown that various types of foot orthoses can have a positive effect on footwear comfort, plantar pressure distribution, and foot pain in the neuroischemic diabetic foot. In particular, the contoured multidensity foot orthoses (Step 2 Evolution) customized to the patient's foot morphology was most effective in this case report. Specifically, the contoured multidensity foot orthoses reduced forefoot peak pressure and pressure-time integral by approximately 55%; considerably improved footwear comfort (from 42 mm to 131 mm on a 150-mm visual analog scale); and completely resolved the patient's previously chronic forefoot pain status (from an FHSQ score of 84.38 to a score of 100).

Interestingly, the patient commented that, despite being the most comfortable initially, the slow-rebound cellular urethane and soft cellular urethane combination orthoses caused his feet to ache by the end of the day. Although they were the most comfortable in part 1 of the study, the contoured multidensity orthoses were the most effective at reducing foot pain, perhaps because of the superior plantar-pressure–reducing and redistributing qualities of the device. However, the efficacy and the mechanism of orthotic therapy for patients with diabetes mellitus and lower-limb neuroischemia cannot be determined in this single case report. Further studies of cushioned and contoured foot orthoses in larger samples of neuroischemic patients are warranted.

Conclusion

The ultimate goal of managing diabetic neuroischemia is to maintain function, reduce ischemic symptoms, and prevent progression of disease. This case report suggests that customized multi-density foot orthoses may be a useful intervention to reduce foot pain in the neuroischemic diabetic foot. Reducing foot pain will encourage patient adherence to prescribed daily levels of walking for exercise to improve mobility, function, and long-term peripheral arterial flow, which are critical for patient survival.

Financial Disclosures: None reported.
Conflict of Interest: None reported.

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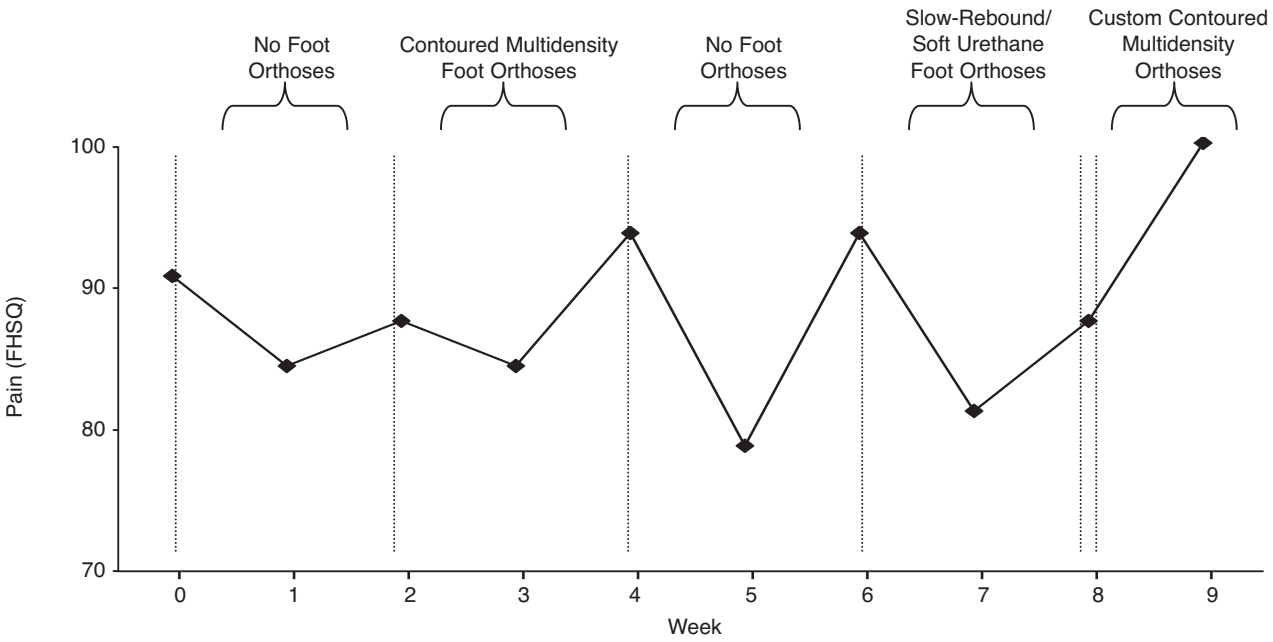

Figure 1. Foot pain as measured by the 100-point Foot Health Status Questionnaire (FHSQ) (0 = worst, 100 = best) for no orthoses, contoured multidensity foot orthoses, and slow-rebound cellular urethane and soft cellular urethane combination orthoses over the 8-week longitudinal study and after wearing the customized contoured multidensity foot orthoses at 1-week follow-up.

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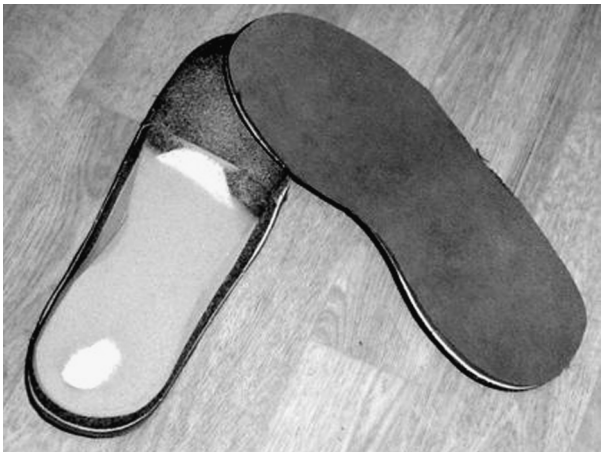

Figure 2. The contoured multi-density foot orthoses (Step 2 Evolution, Thanner GmbH, Hochstadt, Germany) that the patient preferred.

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