

# Running Shoes for Relief of Plantar Pressure in Diabetic Patients

T. Kastenbauer<sup>\*1</sup>, G. Sokol<sup>2</sup>, M. Auinger<sup>2</sup>, K. Irsigler<sup>1,2</sup>

<sup>1</sup>L. Boltzmann Research Institute for Metabolic Diseases and Nutrition, Vienna-Lainz Hospital, Vienna, Austria

<sup>2</sup>Third Medical Department for Metabolic Diseases and Nephrology, Vienna-Lainz Hospital, Wolkersbergenstraße 1, A-1130 Vienna, Austria

There is a causal relationship between diabetic foot ulceration, elevated plantar pressure, and severe sensory neuropathy. Cushioned footwear intended to relieve plantar pressure is well established for prevention and healing of plantar ulcers. The aim of the present study was to investigate whether pressure relief by means of a running shoe with optimized forefoot pressure damping is comparable to that of a custom-made soft insole placed into an in-depth shoe. The in-shoe pressures were compared to an in-depth shoe with the original cork insole and with a leather-soled Oxford shoe. The maximum reduction of plantar pressure in the running shoe was 47 % under the 2nd and 3rd metatarsal heads, 29 % at the first metatarsal head, and 32 % at the great toe in comparison to the Oxford shoe. This was surpassed only by the custom-made insole, which reduced pressures at the metatarsal heads by 50 %. The specially designed running shoe yielded the same pressure relief at the central metatarsal heads as the custom-made insole. Such shoes are likely to be very useful in preventing diabetic foot ulceration in high-risk patients as a comparatively affordable and immediately available device. © 1998 John Wiley & Sons, Ltd.

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## Introduction

Neuropathic ulceration contributes to increased morbidity and mortality of diabetic patients.<sup>1</sup> A major risk factor for diabetic foot ulceration is the loss of protective sensation in patients suffering from high plantar load. Veves *et al.* prospectively demonstrated the close causal relationship between foot ulcers and elevated plantar pressures in neuropathic patients.<sup>2</sup>

Because of the lack of effective treatments for diabetic peripheral neuropathy, the primary target for prevention and healing of neuropathic plantar ulcers is pressure relief. Ulcers commonly occur under the first, second, or third metatarsal heads and beneath the great toe,<sup>2,3</sup> so pressure-reducing strategies are targeted mainly at the forefoot region. Cushioned footwear is widely used for prevention of (re)-ulceration.<sup>4–6</sup> Chantelau and Haage<sup>7</sup> showed that protective footwear, which relieves forefoot plantar pressure up to 50 % compared to normal shoes, was highly effective in preventing ulcer recurrence in patients with history of diabetic foot ulceration, when worn for more than 60 % of the day.

The aim of the present study was to investigate the pressure-reducing ability of a running shoe, which was designed for maximal forefoot pressure relief, in

comparison to leather-soled Oxford-style shoes, and to soft custom-made insoles. For the purposes of this study, a decrease of in-shoe pressure by nearly 50 % compared to an Oxford-style shoe was considered to be clinically significant.

## Patients and Methods

### Subjects

Thirteen patients with long-standing diabetes were enrolled into the study (for patient characteristics see Table 1). One subject had a minor active ulcer at the

Table 1. Patient characteristics and diagnosis of peripheral neuropathy

<i>n</i>	13
Age (a)	56 ± 8
Female/male	8/5
Diabetes duration (a)	20 ± 9
Type 1/Type 2	5/8
BMI (kg·m <sup>-2</sup> )	28.6 ± 4.9
HbA <sub>1c</sub> (%)	8.5 ± 1.5
NCV (m·s <sup>-1</sup> )	41.3 ± 6.1
VPT (V)	27 ± 18

BMI, body mass index; NCV, peroneal nerve conduction velocity; VPT, vibration perception threshold at the hallux.

\*Correspondence to: Thomas Kastenbauer, 3rd Medical Department, Vienna-Lainz Hospital, Wolkersbergenstraße 1, A-1130 Vienna

tip of the third toe, three had a history of forefoot ulceration. The others had risk factors for plantar ulceration, with loss of protective sensation, intrinsic muscle atrophy, and plantar hyperkeratosis. None had severe foot deformities. All subjects were instructed in proper foot care prior to the study, especially in the removal of hyperkeratosis. Subjects who already suffered from foot ulceration were supplied with cushioned footwear (custom-made soft insoles placed into orthopaedic shoes); the others received comparable soft insoles placed into an in-depth shoe. We included only those patients who regularly wore their prescription footwear and those having insoles in a time period between 2 and 6 months before beginning the study in order to avoid falsifications of pressure measurements caused by different degrees of wear in the shoes.

All patients were informed about the goal of the study in detail and gave their consent to participate. The study was approved by the Chairman of the IRB of Vienna-Lainz City Hospital in November 1994.

### *Instrumentation and Collection of Data*

We measured barefoot plantar pressure during walking across an Emed SF platform device (Novel, Germany) wearing 100 % cotton jogging socks. In-shoe pressures were measured with flexible pressure sensitive insoles (Mikro EMED, Novel). To control walking speed we used a treadmill set at  $3 \text{ km} \cdot \text{h}^{-1}$ ; every subject was given a time period of about 5 to 10 minutes to become accustomed with it.

The sampling frequency of the Mikro Emed was set at 80 Hz to balance the loss of short-lasting peak pressures (lowering the frequency) with a decrease in step count (a high sampling rate results in less steps recorded). The drawback of the Mikro Emed insole is the relatively large area of the pressure sensors, each one square centimetre compared to the Emed platform sensors. The results of pressure measurements may differ between the platform and the insoles because of the different sensor size. Due to these differences of sampling frequency and sensor size, the crude data of in-shoe and barefoot (platform) measurements were not comparable.

We took two runs for measuring in-shoe pressures in each foot in every subject with different footwear, always wearing the jogging socks. Five single steps of each run were analysed, avoiding the first and last two steps of each run, resulting in 10 single steps for each footwear of every subject. Four plantar regions were analysed for mean peak plantar pressure (MPP) by means of the Multimask software package (Novel): beneath the great toe, under the first metatarsal head (MTH), under the second and third MTH and also beneath the heel. The intraindividual coefficient of variation was 3.8 % for the Oxford shoe and 7.9 % for the running shoe, the interindividual CV ranged from 31 % to 41 %.

### *Footwear*

Patients were asked to bring along their leather-soled Oxford-style shoe. Four commercial sports shoe manufacturers (Adidas, Nike, Puma, Reebok) were asked if they could supply running shoes built for maximal pressure relief at the forefoot region (as opposed to under the heel, as in conventional shock-absorbing running shoes). Furthermore, the soles should have long-lasting damping properties. The only company who responded was Adidas, suggesting their model 'Adidas Torsion Equipment Cushion' with a Dynaprene layer (Neoprene based, Dupont) built into the shoesole. This is now effectively available as Adidas Equipment Support and the Dynaprene layer is called Adiprene. Finally, a generally available in-depth shoe (Finn Comfort, Waldi, Germany) was obtained. Pressure measures were taken from two insoles, placed into this in-depth shoe; the original cork insole and a custom-made orthopaedic insole for each diabetic patient. This orthopaedic insole is a modular multilayer of up to 10 different layers, mainly PPT (Professional Protective Technology, manufactured by Schein Orthopadie Service, Reinscheid, Germany) and Birkozell, which was constructed for supporting the foot distally beneath the metatarsal bones, sloping down forwards to relieve the metatarsal heads.

### *Statistical Analyses*

The results of pressure measurements were transformed by  $x' = 1/\text{square root}(x + 1.5)$  to achieve near normal distribution. We considered the repeated character of the in-shoe measurements in order to compare the different footwear, and therefore ran a nested-designed two-way MANOVA-Analysis with a 'Tukey honest significant difference test for unequal N (Spjotvoll/Stoline Test)'. Dependent variables were the MPP under the great toe, under the MTH 1, under the MTH 2 + 3, and beneath the heel.

There was or is no dependent relation of the study authors to the manufacturers of shoes and insoles. We were supplied with footwear by Adidas Austria and Geier Orthopadie Technik without other sponsorship. Neither have access to detailed data until final publication.

### *Results*

In-shoe pressure in the in-depth shoe provided with the custom-made insole was the lowest in all footwear tested; the pressures under the great toe, under the first MTH, and beneath the heel were significantly different ( $p < 0.01$ ) from those measured in the Oxford shoe (Figure 1). The absolute values of plantar pressure under the central MTH was slightly higher compared to that of the medial one, but the difference still reached significance ( $p < 0.05$ ), compared to the Oxford shoe.

The running shoe yielded a highly significant ( $p < 0.01$ )

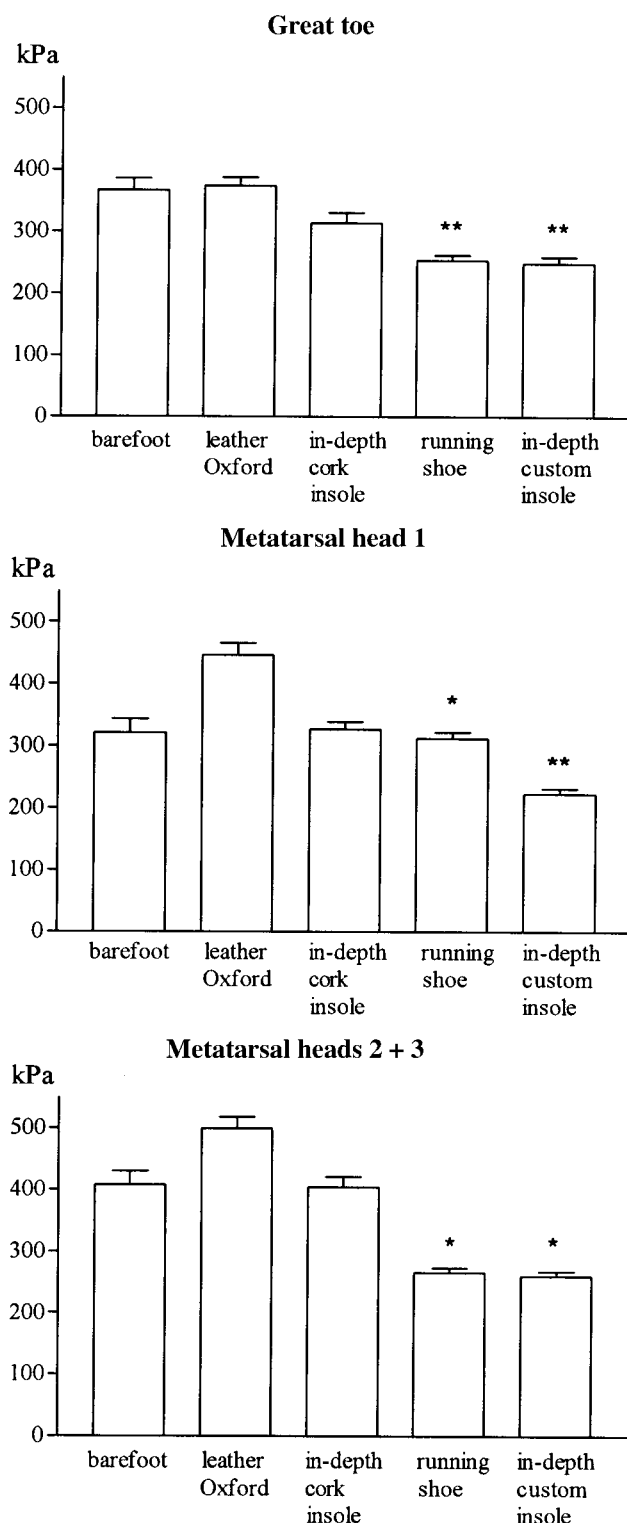


Figure 1. Plantar pressures during barefoot walking wearing jogging socks and in-shoe pressures of a leather-soled Oxford shoe, of an in-depth shoe with a cork or a custom-made insole and of a running shoe with optimised forefoot damping. Values are mean  $\pm$  SEM; \* $p < 0.05$ , \*\* $p < 0.01$  in comparison to the Oxford shoe

pressure decrease under the great toe and under the heel. Beneath the metatarsal heads pressures were evenly distributed showing a mean of 316 kPa under the first and with 267 kPa under the second and third MTH ( $p < 0.05$  vs Oxford shoe).

Relief of pressure by the in-depth shoe supplied with the cork insole was small in the great toe area and also under the central metatarsal heads. In-shoe pressures at the first metatarsal head and under the heel were reduced by one-third, but this did not achieve statistical significance.

In comparison to barefoot walking, plantar load inside an Oxford shoe was increased in the metatarsal head region, and to some smaller degree under the heel too although the differences in measurement technique make this comparison speculative. However the platform measurements would be expected to be higher than the in-shoe measurements, so we should not have overestimated the effect of the Oxford shoe.

For calculating the percentile pressure relief out of the mean values, the leather-soled Oxford shoe was used as a reference (= 100 %). The custom-made insole yielded a 50 % reduction of MPP under the metatarsal heads and under the heel, whereas it was minimized only for one-third under the great toe (Table 2). The running shoe reduced MPP by 32 % in the great toe area, 29 % at the MTH 1 and for 47 % at the MTH 2 and 3. The cork insole did not significantly affect in-shoe pressures but did show a minor pressure relief under the entire surface.

## Discussion

Cushioned footwear significantly reduces plantar pressure<sup>8,9</sup> and relief of plantar pressure significantly lowers the prevalence of plantar tissue breakdown.<sup>6</sup> The disadvantage of such custom-made orthopaedic footwear lies in its non-availability during the first days or weeks after ulcer development as well as in its price. Even the manufacturing and fitting of orthopaedic insoles takes a few weeks, a time period prolonged in need of custom-made orthopaedic shoes for patients with foot deformities.

The aim of our study was to look for effective, immediately available footwear (a running shoe) which might provide patients at risk of plantar ulceration as early as possible with appropriate protective shoes, cheaper than in-depth shoes combined with an orthopaedic insole. We also wanted to compare such footwear with the pressure reducing ability of custom-made insole, put into an in-depth shoe.

The pressure relief potential of running shoes was shown recently by Perry *et al.*<sup>10</sup> The authors found an inexpensive running shoe (Nike Air Craft) was as effective in decreasing plantar pressures under the forefoot and heel, in an average range of  $31 \pm 9$  % in comparison to an Oxford shoe. They found a percentile decrease of in-shoe pressure in the Nike with 27 % to 38 %, a little lower than that demonstrated here in the Adidas shoe (29 % to 47 %). This difference in pressure reduction

Table 2. Percentile reduction of in-shoe plantar pressure in comparison to the Oxford shoe

	Great toe	Metatarsal head 1	Metatarsal heads 2 and 3	Heel
Oxford shoe (reference)	100%	100%	100%	100%
Barefoot with socks <sup>a</sup>	-4 %	-26 %	-13 %	-14 %
In-depth shoe with cork insole	-16 %	-27 %	-19 %	-34 %
Running shoe	-32 %	-29 %	-47 %	-39 %
In-depth shoe with custom insole	-33 %	-50 %	-48 %	-49 %

Data are per cent change from measurements in Oxford shoes, calculated out of the mean values.

<sup>a</sup>This used a different measurement system.

might be of minor importance for ulcer prevention at first, but the long-lasting damping properties of the Neoprene layer built into the sole of the Adidas shoe may be an advantage. It must however, be remembered that the benefit of running shoes in preventing foot ulcers remains unproven.

To our knowledge, there have been no studies of pressure reduction by commonly used therapeutic footwear such as in-depth shoe equipped with a custom-made insole. In our department, the custom insoles are constructed using printouts of plantar pressure measurements (pedography), projected on the crude insoles. They are made of a modular multilayer (mainly of Birkozell for support and different layers of PPT (Professional Protective Technology, manufactured by Schein Orthopaedic Service, Reinscheid, Germany) for cushioning, primarily designed for pressure relief at regions of maximal plantar load and also for an equal distribution of foot-insole forces over the entire surface. The present study revealed a marked decrease of in-shoe pressure by the custom-made insoles, culminating in a 50 % reduction beneath the metatarsal heads and the heel, surpassing the high-end running shoe. This reduction meets the criteria for halving the plantar pressure, demanded by Chantelau *et al.* as sufficient for prevention of ulcer recurrence.<sup>7</sup>

The Oxford shoes increased plantar pressure under the metatarsal heads. This might be due to the stiff character of the Oxford shoe with the metatarsal head-region being pressed against the leather sole of the shoe during roll-off in walking. These bending forces might increase pressure especially beneath the metatarsal heads, as our results indicate. Diabetic patients with loss of peripheral sensation tend to buy and wear overly tight shoes, as Litzelman *et al.*<sup>11</sup> demonstrated. At least 25 % of investigated Type 2 diabetic patients wore improperly sized footwear. Individuals who have insensate feet should be discouraged from wearing leather-soled Oxford shoes because of the risk of plantar ulceration due to increased pressure and of lateral ulceration due to ill-fitting shoes.

Although the pressure relief of the running shoe came close to meeting the goal of halving plantar load, we would not suggest it is appropriate as a primarily healing-

aid for active plantar ulceration; only a complete non-weight bearing regimen, like a total-contact cast, is likely to be effective.<sup>12</sup>

The present study established a certain running shoe designed for maximal forefoot pressure relief to be effective in decreasing plantar pressure, although the pressure relief obtained was not as great as that of the custom-made soft insole in an in-depth shoe. The running shoe was associated with a reduction of pressure in the range of one-third to one-half in comparison to the Oxford shoe. However, we suggest that the 'Adidas Torsion Equipment Cushion' running shoe might be a good compromise between pressure relief, durability, availability and costs in at-risk diabetic patients without foot deformities. Its clinical effectiveness in reducing the incidence of foot ulcers needs to be further evaluated.

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