Custom-made total contact insoles and prefabricated functional diabetic insoles: A case report

Joanne Paton, Elizabeth Stenhouse, Ray Jones, Graham Bruce

Article points

1. Assessment of foot structure and biomechanical dysfunction is crucial to prescribing load-reducing insoles for diabetic individuals.
2. In-shoe pressure measurement systems can instantly compare and optimise offloading interventions with limited patient risk.
3. This case study showed the prefabricated functional insole as a successful alternative to total contact insoles, benefiting the low-arched pronated neuropathic diabetic foot.

Key words

- Neuropathic foot ulceration
- Prefabricated insole
- Plantar load reduction

Author details are given at the end of this article.

Insoles are commonly prescribed to offload the mechanical stress transmitted to the plantar tissues of the foot. Traditionally, the custom-made total-contact insole (TCI) is favoured over its prefabricated counterpart. The introduction of a new prefabricated diabetic insole (A Algeo Ltd, Liverpool) designed to modify foot biomechanics may offer an instant, low-cost, clinically-effective alternative. We report on a comparison of the two insoles in the case of a 54-year-old woman with type 2 diabetes and peripheral neuropathy, presenting with ulceration overlying the third metatarsal region. The F-scan in-shoe pressure measurement system (TEKSCAN) provided an objective measure of effect.

Ulceration is a devastating complication of the foot affecting 15% of all individuals with diabetes at some time (Palumbo and Melton, 1985). The complex etiology of diabetic foot ulceration is reflected by the multifaceted management approach necessary for successful wound resolution (Muha, 1999; Millington and Norris, 2000; Dang and Boulton, 2003). Reducing plantar mechanical stress is one crucial aspect of optimising healing potential, particularly in neuropathic feet withour protective sensation, where plantar loads and tissue stress are increased (Pitei et al, 1999; Lavery et al, 2003; Grimm et al, 2004; Spencer, 2004).

Research has established links between peak plantar pressure and the formation of neuropathic foot ulcers (Armstrong et al, 1998; Frykberg et al, 1998). Thus, insoles designed to reduce elevated plantar pressure are prescribed to prevent and manage diabetic foot ulceration (Kato et al, 1996; Bus et al, 2004; Spencer, 2004). Custom total-contact insoles are traditionally used to reduce peak pressure by maximising total plantar contact area (Bus et al, 2004). However, as they can be expensive and time consuming to produce, total

Page points

1. Insole provision for low-arched, pronated neuropathic feet should consider the already high total plantar contact area and medial forefoot pressure distribution.
2. Determining the best insole design and fabrication for individual need is currently dependent upon clinical experience and anecdotal evidence.

Figure 1. Ulceration with use of custom-made total-contact insole.

contact insoles may be inadequate to address all types of diabetes-related biomechanical dysfunction in the foot and can contribute to mechanical tissue stress (Mueller et al, 2003; Morag and Cavanagh, 1999).

Insole provision for low-arched, pronated neuropathic feet should consider the already high total plantar contact area and medial forefoot pressure distribution (Mueller et al, 1990). In this foot type, the potential increase in plantar contact area generated by the total contact insole is relatively small; therefore, a functional insole design modifying the timing and direction of load transfer through the foot may be indicated. The prefabricated interpod diabetic insole is one such functional device incorporating biomechanical features believed to benefit the low-arched foot.

Determining the best insole design and fabrication for individual need is currently dependent upon clinical experience and anecdotal evidence. The ability of an insole to achieve its treatment objective is evaluated only by clinical outcome at follow up; a perilous strategy for neuropathic individuals unable to detect the adverse affects of tissue damage by protective sensory feedback. The advancement of in-shoe pressure measurement systems offering immediate objective measures of mechanical plantar load affords healthcare professionals the capacity to instantly compare and optimise offloading interventions with limited risk to the individual.

This report compares the custom total-contact insole with the prefabricated functional insole in the case of a 54-year-old woman with type 2 diabetes and peripheral neuropathy, presenting with an ulceration overlying the third metatarsal region. The F-scan in-shoe pressure measurement system (TEKSCAN) informs treatment choice.

Box 1. Treatment timeline for Mrs X.

- At initial presentation, the ulcer underlying the third metatarsophalangeal joint was deep: probing approximately 20mm into the foot with rough eroded bone felt at base. The foot was red, hot and swollen.
- Mrs X was demonstrating high blood glucose levels and was admitted for surgical intervention on day of presentation.
- The post-surgical wound was elliptical in shape and measured approximately 60mm wide by 40mm in length, with a maximum depth of 20mm
- The wound was initially packed with absorbent dressings (such as Sorbsan) and offloaded with a pneumatic diabetic aircast walker incorporating an adapted insole to suspend the wound site.
- Wound slowly progressed to almost healing, but then deteriorated to a non-healing ulcer that probed to about 10mm.
- Offloading by Mrs X's own bespoke sandals and custom insoles could not bring wound to complete closure.
- The prefabricated insole was introduced approximately 12 months after initial surgery admission.
- The time lapse between issue of the prefabricated insole and *Figure 4* was 4 weeks.
- Following use of insole the wound progressed to healing, the area remained heavily scarred, but skin integrity was achieved.

Case study details

Mrs X is a 54-year-old female presenting with a 4-year history of ulceration underlying the right third metatarsal head. Following the onset of osteomylitis and subsequent systemic illness, she underwent emergency surgery to remove metatarsal heads two, three and four, leaving the toes intact. After 7 months, the wound cavity healed but following complications dehisced (*Figure 1*). Despite total contact insoles and therapeutic footwear, the wound remained.

Displaying a low-arch profile and pronated foot type, Mrs X appeared suitable to benefit from the newly available prefabricated functional insole. To inform best practice, the option of substituting insoles was objectively evaluated using the F-scan in-shoe pressure measurement system. A timeline of Mrs X's treatment and recovery is shown in *Box 1.*

Intervention

Custom-made total-contact insole

Produced from a semi-weight bearing foam box foot impression, the custom total contact insole comprised a full-length medium ethylene vinyl acetate shell shaped to mirror the contours of the foot, covered with 6mm poron.

Functional prefabricated insole

Fitted to foot size, the Interpod diabetic insole consisted of a prefabricated full-length polyurethane contoured shell covered in 3mm poron. The device incorporated a six-degree bi-planar medial rearfoot skive and plantar fascia groove. The bi-planar rearfoot skive intrinsic to the device is designed to offer both frontal and sagittal plane rearfoot control. The medial skive transmits a frontal plane supination moment about the subtalar joint generating rearfoot inversion, while the anterior skive applies a dorsiflexion moment anterior to the calcaneum to maintain the sagittal plane inclination angle of the calcaneum. The plantar fascia groove is designed to reduce arch irritation and facilitate the windlass mechanism and first ray function.

Instrumentation

The F-scan in-shoe pressure analysis system collected dynamic data from beneath the ulcerated foot. The high spatial resolution of the F-scan detects discrete areas of high pressure under individual metatarsal heads – clinically useful information for at-risk foot management (Lord, 1997). The F-scan in-shoe sensor consists of 960 sensing elements (four per cm²) integrated into a 0.15 mm-thick flexible polymer insole. Once cut to size, the sensors were calibrated in accordance with manufacturer recommendations. Six to seven consecutive steps were recorded per trial – for relative decisions, the F-Scan is capable of achieving acceptable reliability using a mean of at least three steps recorded in a single day (Mueller and Strube, 1996) – at a sampling frequency of 50 Hz, disregarding the first and last step to exclude the effects of gait acceleration and deceleration.

Outcome measures

Five preselected outcome measures compared effectiveness of the two insoles in terms of plantar load distribution and mechanical control:

- peak plantar pressure
- total plantar contact area
- rate of forefoot load
- forefoot pressure time integral
- duration of metatarsal region load as a percentage of stance.

Results

The rate of forefoot load is shown in *Figure 2* and the duration of metatarsal region load as a percentage of stance in *Figure 3*. The F-scan in-shoe pressure measurement system showed similar changes in mean peak pressure and rate of forefoot load (*Table 1*); the proposed prefabricated insole appeared comparable in effect to the current total contact

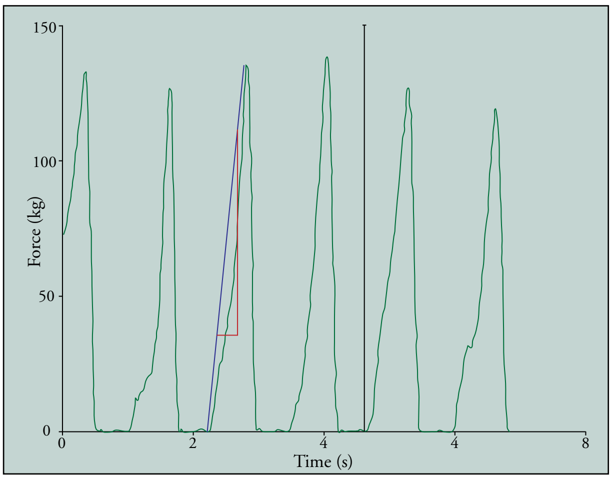

Figure 2. F-scan display of forefoot force–time curve. Rate of forefoot load is calculated by the time taken to reach peak force; the steepness of the slope.

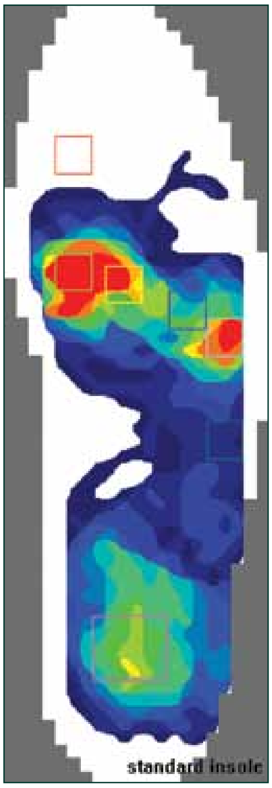

Figure 3. F-scan display showing position of TAM boxes. F-scan TAM analysis softwear computes the mean duration and range of each box's load as a percentage of stance.

Figure 4. Resolving ulcer with use of a prefabricated functional insole for 4 weeks.

insole.

Duration of load as a percentage of stance for the total contact insole condition showed greater percent load duration for the first metatarsophalangeal joint relative to the fifth. By contrast, the reverse effect was recorded using the prefabricated insole (*Table 2*). When compared, the total contact insole increased total contact area by a further 18% (*Table 1*).

The prefabricated insole was 20% more efficient in reducing the forefoot pressure–time integral (*Table 1*). The pressure–time integral is the product of magnitude of pressure and duration of load, reflects areas exposed to short periods of very high pressure and also areas of lower pressure but longer duration. This information endorsed the treatment decision to prescribe the prefabricated functional insole. Four weeks following the issue of the prefabricated insole, the ulcer healed (*Figure 4*), although Mrs X's general health and mobility had declined.

Discussion

Comparison of F-scan data suggested both insoles had a similar effect on peak pressure. No data were collected without insoles; therefore, the actual reduction in peak pressure with insoles in shoe was unknown. Collecting in-shoe pressure data without offloading the foot would have placed the individual at unnecessary risk of further tissue damage. Moreover, although studies indicate insoles reduce peak pressure (Viswanathan et al, 2004), the magnitude of reduction deemed clinically significant is undetermined and, in the authors' opinion, not essential in this case.

The total-contact insole increased total plantar contact area by 18% over the prefabricated insole and yet mean peak pressure was similar for both. Simply increasing total plantar contact area during gait may not therefore be the only mechanism of reducing peak pressure.

Duration of load (calculated as a percentage of stance with the total contact insole) recorded initial and longer medial forefoot ground contact. This forefoot load pattern is undesirable in the presence of medial forefoot lesions but typical of excessively pronated feet (Bevans, 1992; Perry, 1992). By contrast, the prefabricated function insole reversed the trend; the lateral forefoot loaded first and for longer.

The prefabricated functional insole reduced the forefoot pressure–time integral by 20% more than the custom-made insole. The pressure–time integral has been associated with ulceration in the neuropathic foot and may be more sensitive than peak pressure in detecting areas of increased ulceration risk (Stacpoole-Shea et al, 1999).

Although objective evaluation of kinetic data supported the clinical decision to prescribe the prefabricated functional insole, we are unable to confirm that its use led to wound healing, particularly given the decline in Mrs X's health and activity levels over the following weeks.

Foot structure and biomechanical dysfunction are clearly relevant to plantar load distribution, neuropathic diabetic ulceration and ulcer site (Mueller et al, 1990; Bevans, 1992; Cavanagh et al, 2000). The provision of total-contact insoles without attention to foot type and function may not achieve optimal reduction in plantar load in all cases. This case illustrates how the prefabricated functional insole may provide a successful alternative to the total contact insole. Further evidence is required to support the use of prefabricated functional insoles in the management of diabetic neuropathic feet.

Conclusion

The prefabricated functional insole offered a successful alternative to the total contact insole, emphasising the importance of considering foot biomechanics to prescribe load-reducing insoles in ulcer prevention and management.

Two important issues need investigation to improve load-reducing methods and better treat the neuropathic diabetic foot:

- The role of prefabricated insoles.
- The application of biomechanics principles. ■

Acknowledgements

The authors would like to thank Tania Woodrow, Diabetic Specialist Podiatrist, for her help with this study. The prefabricated insoles used in this project were supplied by A Algeo Ltd, Liverpool.

Author details

Joanne Paton is a Podiatry Lecturer; Elizabeth Stenhouse is a Senior Lecturer; and Ray Jones is a Professor of Health Informatics. All work in the Faculty of Health and Social Work, University of Plymouth. Graham Bruce is a Diabetic Specialist Podiatrist at Plymouth Teaching PCT.

There is no conflict of interest to declare. There was no sponsorship forthcoming from A Algeo Ltd to conduct the study.

Table 1. Comparison of insoles: Magnitude and distribution of load.

Outcome measure	Total contact insole	Prefabricated insole
Mean peak pressure	1346 kPa	1353 kPa
Total contact area	14348 mm^2	11742 mm^2
Rate of forefoot load	259.5 kg/sec	282.7 kg/sec
Forefoot pressure–time integral	61.8 kPa*sec	49.5 kPa*sec

Table 2. Comparison of insoles: Timing of forefoot load.

	Duration of load as percentage of stance			
	Total contact insole (%)		Prefabricated insole (%)	
Metatarsal head	**Mean**	**Range**	**Mean**	**Range**
1st	79	73–82	75	41–89
2nd	77	70–82	72	43–87
3rd–4th	78	70–81	80	70–85
5th	65	31–83	81	70–88

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