

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

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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 (Algeos Ltd) 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 lady 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 absent of 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;

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 (Interpod Diabetic Algeo Ltd) as a successful alternative to total contact insoles, benefiting the low-arched pronated neuropathic diabetic foot.

Key words

- Neuropathic foot ulceration
- New prefabricated insole
- Foot type
- Plantar load reduction

Page points

1. Expensive and time consuming to produce, total contact insoles may be inadequate to address all foot types.
2. Insole provision for low-arched, pronated neuropathic feet should consider the already high total plantar contact area and medial forefoot pressure distribution.
3. Determining best insole design and fabrication for individual need is currently dependent upon clinical experience and anecdotal evidence.
4. This report compares the custom total contact insole with the prefabricated functional insole in the case of a 54-year-old lady with type 2 diabetes and peripheral neuropathy, presenting with an ulceration overlying the third metatarsal region.

Spencer, 2004). Traditionally used, the custom total contact insole reduces peak pressure by maximising total plantar contact area (Bus et al, 2004). Expensive and time consuming to produce, total contact insoles may be inadequate to address all foot types with diabetes-related biomechanical dysfunction, influential to plantar load distribution and 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 (Algeos Ltd) is one such functional device incorporating biomechanical features believed to benefit the low-arched foot.

Determining 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 after wear 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 lady 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.

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 osteomyelitis 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 dehissed (*Figure 1*). Despite total contact insoles and therapeutic footwear, the wound remained.

Displaying a low-arch profile and pronated foot type, Mrs X seemed suitable to benefit from the newly available prefabricated functional insole (Interpod Diabetic insole, Algeos Ltd). To inform best practice, the option of substituting insoles was objectively evaluated using the F-scan in-shoe pressure measurement system (TEKSCAN).

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 EVA

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



shell shaped to mirror the contours of the foot, covered with 6 mm poron (Figure 2).

Functional prefabricated insole

Fitted to foot size, the Interpod Diabetic insole (Algeos Ltd) consisted of a prefabricated full-length polyurethane contoured shell covered in 3 mm poron 96. The device incorporated a six-degree bi-planar medial rearfoot skive and plantar fascia groove (Figure 2).



Figure 2. Left: prefabricated functional insole (Interpod Diabetic insole; Algeo Ltd). Right: Custom-made total-contact insole.

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 sensels (four cells 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 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 (Figure 3)
- Forefoot pressure time integral
- Duration of metatarsal region load as a percentage of stance (Figure 4).

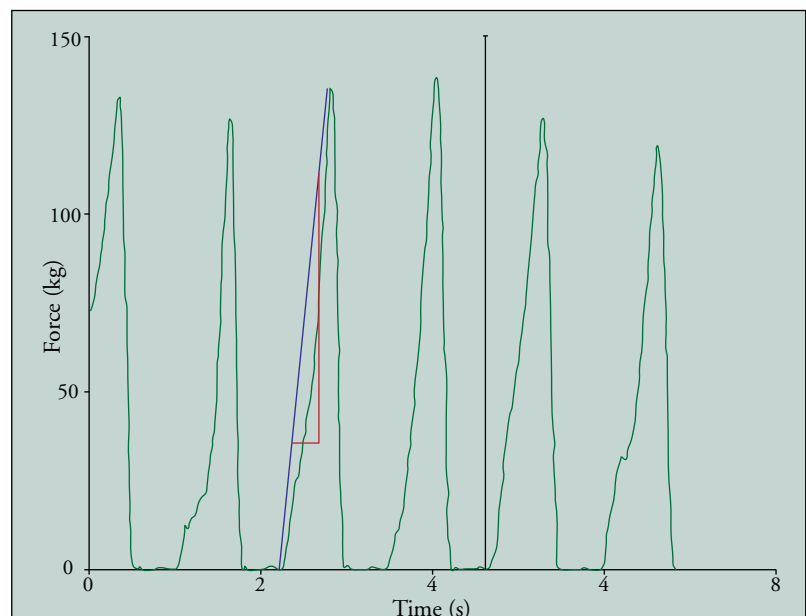
Results

The F-scan in-shoe pressure measurement system (TEKSCAN) showed similar changes in mean peak pressure and rate of forefoot load (Table 1); the proposed prefabricated (Algeos Ltd) insole appeared comparable in effect to the current total contact insole (TCI).

Duration of load as a percentage of stance for the total contact insole condition showed greater percent load duration for the first metatarsophalangeal joint (MTP) relative to the fifth MTP. 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 (Algeos Ltd) was 20% more efficient in reducing forefoot pressure time integral (Table 1). This information endorsed the treatment decision to prescribe the prefabricated functional insole. Four weeks following the

Figure 3. 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.



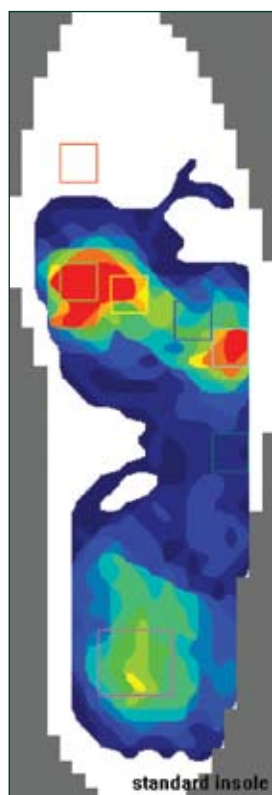


Figure 4. F-scan display showing position of TAM boxes. F-scan TAM analysis software computes the mean duration and range of each box's load as a percentage of stance.

issue of the prefabricated insole, the ulcer healed, although Mrs X's general health and mobility had declined (Figure 5).

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 not essential in this case.

The total contact insole increased total plantar contact area 18% more than 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 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 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). The pressure–time integral, that 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.

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. The new prefabricated functional insole (Algeos Ltd) now offers an instant option designed to address poor mechanics in individuals with diabetes and neuropathy presenting with low-arched, pronated feet. 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 (Algeos Ltd) 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.

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



Figure 5. Resolution of ulcer with use of the prefabricated functional insole.

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

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