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# Diabetic 'Functional' Orthotics

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## Background

Foot ulceration in diabetic patients is still a major problem and a source of concern in health services Worldwide. Prevention is a high priority, both in prevention of initial ulceration and in recurrence of ulceration.

In the case of an abnormal plantar pressure distribution and/or inappropriate footwear, the areas of peak pressure do not always correspond to those where the patient senses the pain, either because the subject has changed the pattern of his/her walking to protect the area of pain or because it is related to a functional problem.

Bevans (1), in his study, quantified foot function as related to subtalar joint position. As a result, he found that ulceration was related to the subtalar joint position – lateral ulcers were associated with Supination and medial ulcers with pronation. Masson(2) confirmed this clinical finding and related them to joint alterations in mobility, which he found to be as important as high pressure in causing ulceration under the plantar surface of the diabetic foot.

Bolton (3), Schie, et al studied this and found that when there was increased pressure patients did not always ulcerate, and later showed that loading time of the forefoot was more important than absolute peak plantar pressures, again confirmed by Barnett.

Abboud (4) showed in studies at Ninewells in Dundee that patients with Diabetic Neuropathy had earlier and prolonged foot ground contact (statistically significant compared to control population). This showed that pressure time contact was longer in the diabetic population.

## Treatment

Standard treatment for patients with Diabetes and Neuropathy would be to give cushioning insoles, to attempt to reduce peak plantar pressures, however with this regimen many patients continue to ulcerate, which may be indicative of the fact that peak pressure is not the only cause. We need to consider the loading time. Standard cushioning or total contact insoles (TCI) do not change loading times or patterns, but reduce peak pressure by increasing surface area contact.

Barnett in 2005/6 stated that the loading time in flexible Neuropathic feet can be reduced by using functional (antipronatory) foot Orthoses; this has since been shown in studies. Barnett et al(5), Bolton et al(6), Paton.(7)

Traditionally from this treatment would consist of using custom made functional insoles, made of Ethyl Vinyl Acetate (EVA) in combination with cushioning materials such as Poron™.

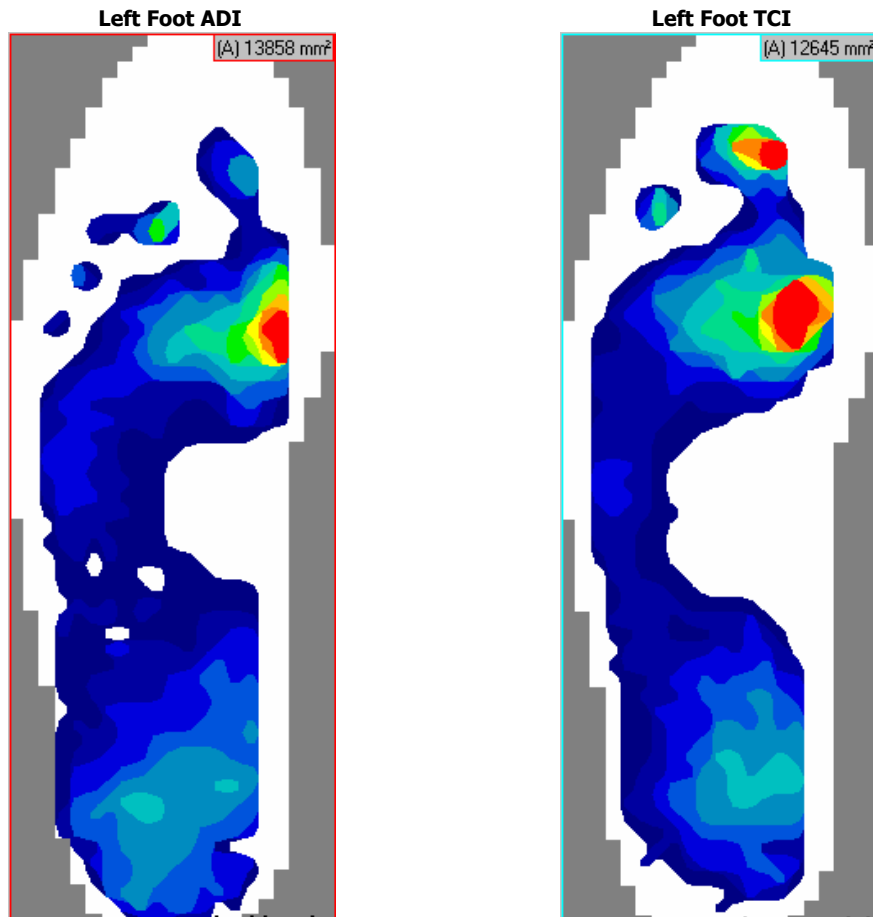
What we have attempted to do is to reduce the costs and time delay by developing a prefabricated antipronatory foot Orthoses.

**The Orthoses that we have developed The Algeos Diabetic Insole in a standard antipronatory insole which has functional and cushioning properties. Following development we have now completed early pilot studies comparing custom made Orthoses with the Algeos Insole.**

## Results

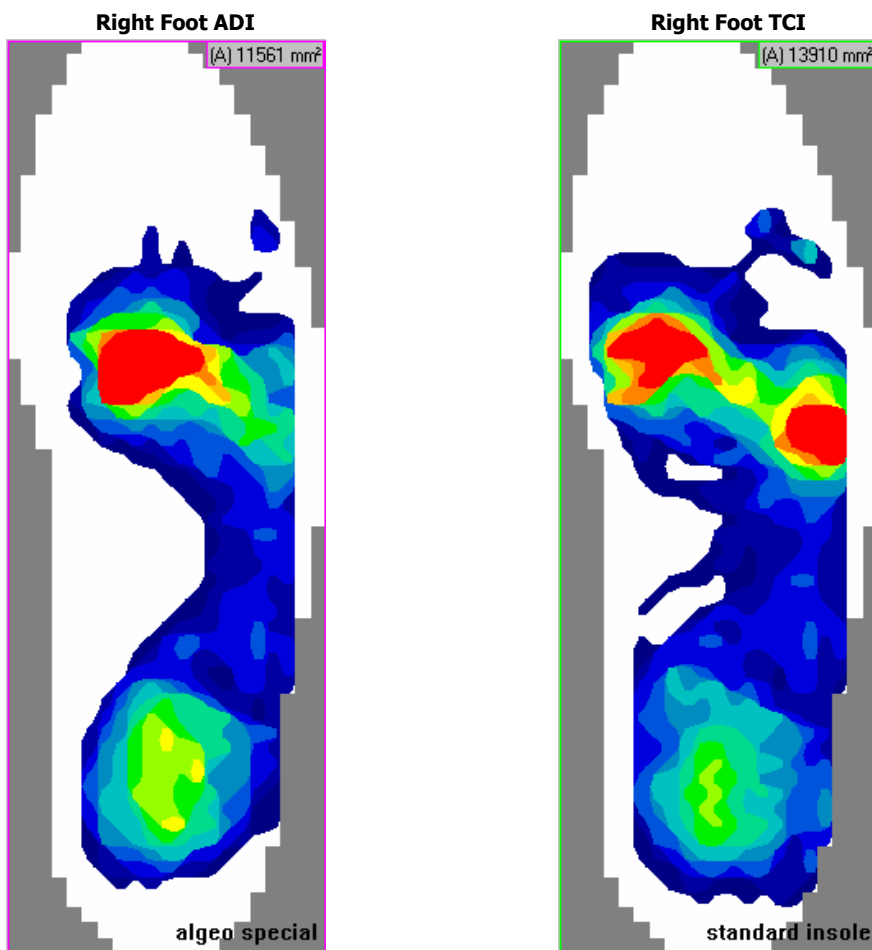
We chose Barnett (UWE Bristol UK ) and Paton (Plymouth University UK) to undertake pilot studies as they are both well known in the area of Diabetic Biomechanics and have both presented and published papers relating to this topic.

We looked at Diabetic patients who currently had standard (TCI) Orthoses and functional custom made Orthoses to compare peak pressures and forefoot loading time (force/time integral) to Algeos Diabetic Insole.



We can see from the peak pressure results above that there has been a reduction in pressure at the 1<sup>st</sup> Interphalangeal joint, and a move of a high pressure point more medially over the 1<sup>st</sup> Metatarso-phalangeal joint with the ADI compared to TCI.

This has resulted in the ulcer over the second MTPJ healing and remaining healed with continued use of the ADI. There had been previous ulceration and recurrent ulceration with TCI treatment.

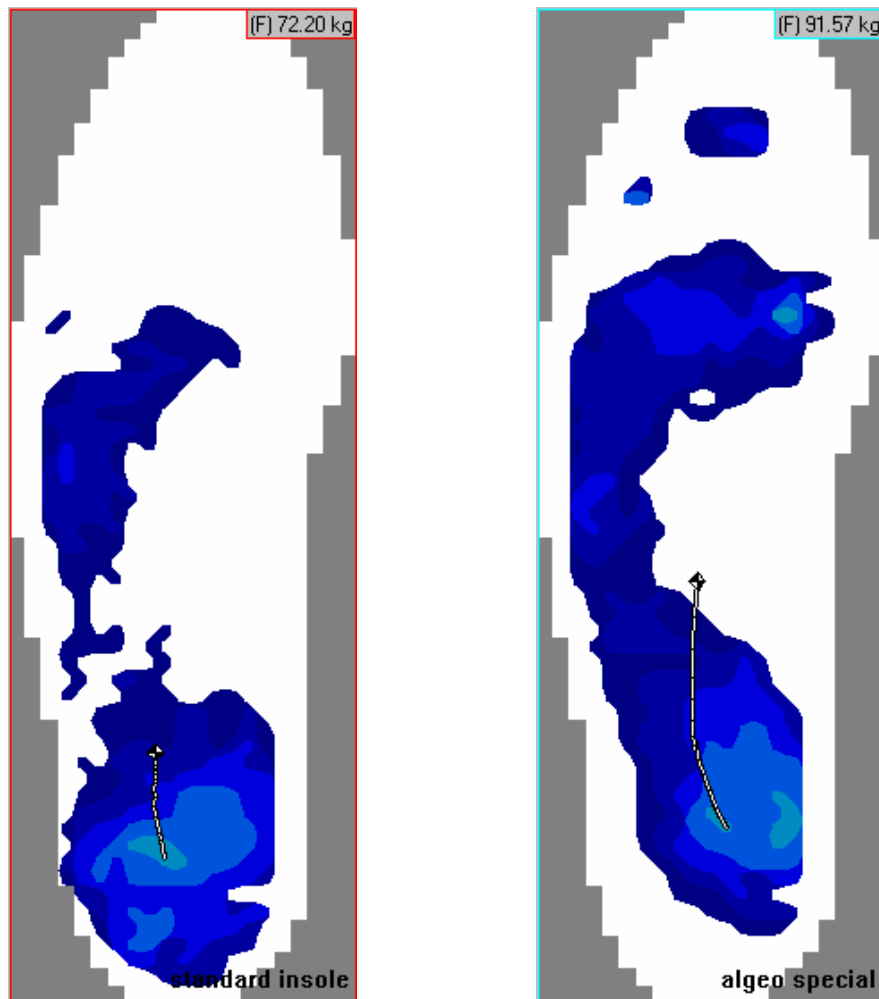


This foot had previous ulceration which had resulted in amputation of toes. Again as can be seen from the peak pressure results show that there has been a reduction in peak pressure in the forefoot especially over the lateral border. The foot again has remained healed with the use of the ADI.

Further studies have shown that the loading time at the fore foot has been reduced by approximately 40%, due to improved foot gait function.

Test Condition	Pressure Time Integral Under the 1 <sup>st</sup> MTP
Algeos Insole	172.95 Kpa*Sec
Custom Made Insole	205.08 Kpa*Sec

This shows that there has been an increase in speed of progression and therefore a reduction in the loading time over the forefoot, which studies have shown reduces the risk of ulceration in these areas.



We can also see that there has been an increase in the velocity of the centre of trajectory with ADI compared to TCI. This shows a more efficient gait and therefore increased progression over the ground and so reduced loading time.

These results show that with the ADI we have established that there is improvement in gait and reduction in loading times when compared to a standard custom made TCI. In the patients studies this has resulted in no recurrence of previous ulceration and no new ulcer formation.

### **Comparison with Custom Made Functional Insole**

Looking at the results of this comparison showed that there were no statistically significant differences in the peak pressure or in the force /time integral between the two types of insole, and we can therefore conclude that ADI is as effective in use as a custom made functionally corrective insole.

## References

- 1) **Bevans JS** (1992) *The Foot* 2: 166-172
- 2) **Masson E** (1989) *Diabetic Medicine* 6: 426-428
- 3) **Bolton et al** (1996) *Diabetic Medicine* 13: 979-982
- 4) **Abboud R** (1999) *The Clinical Biomechanics Journal* 15: 37-45
- 5) **Barnett** (2005) University of Wales in Cardiff Paper Presentation
- 6) **Barnett** (2006) The Diabetic Foot Journal Conference Paper Presentation
- 7) **Bolton et al** (1992) *Diabetologia* 335: 660-664
- 8) **Paton** (2006) PhD Thesis Plymouth University