Formthotics™
Foot Science

Can Foot Orthoses Prevent Diabetic Foot Complications?

“The Rule of 15”

Years ago, two respected podiatrists proposed a now widely cited clinical adage:

- 15% of people with diabetes will develop a foot ulcer
- 15% of those will progress to bone infection (osteomyelitis)
- 15% of those will require amputation

The cascade is devastating – and tragically, often avoidable. Today in the United States, more than 150,000 lower extremity amputations occur annually. Globally, the projected number of people with diabetes by 2030 is 643 million. In New Zealand, roughly 1,200 diabetes-related amputations are performed each year.

But it gets worse. Among patients who heal from a foot ulcer:

- 65% experience recurrence within 5 years
- The 5-year mortality rate following diabetic foot ulcer (DFU) is comparable to all cancers

Despite these sobering outcomes, true preventive care – before ulceration begins – remains underutilised worldwide.

Understanding Risk: Why the Foot Becomes Vulnerable

Key risk factors for DFU include:

- Peripheral neuropathy (most common after 5+ years with diabetes)
- Peripheral arterial disease (PAD)
- Structural foot deformity (e.g. hallux valgus, hammer toes)
- Minor trauma or pressure
- Poor footwear fit or design

While neuropathy and PAD are difficult to modify directly – and surgical correction of deformity is not always accessible – podiatrists or other clinicians may offer surgical correction of many structural foot deformities, and this is recommended when patients can be medically cleared for the procedure. Podiatrists are also in a uniquely strong position to intervene using conservative strategies, including footwear management and foot orthoses.

Why Orthoses Matter in Diabetes Care

More than 80% of DFUs occur on the plantar surface of the foot, where pressure and shear stress exceed tissue tolerance. In these patients, foot orthoses offer an evidence-based, cost-effective strategy to reduce risk and preserve function.

When orthotic therapy is introduced early – especially in those at moderate or high risk – the chance of ulcer formation or recurrence drops significantly.

Foot orthoses can:

- Redistribute plantar pressure
- Accommodate deformity or bony prominences
- Reduce shear forces that cause skin breakdown
- Offload previously ulcerated or at-risk sites

Evidence from Clinical Trials

Several studies show meaningful reductions in ulcer rates with the use of well-designed orthoses:

- A 12-month trial using instant-optimised insoles reported ulceration in 22.5% of the intervention group vs 33.3% in controls
- A long-term study found ulceration rates of:
  - 12.8% vs 38.6% at 1 year
  - 17.6% vs 61% at 3 years
  - 23.5% vs 72% at 5 years

Formthotics®: A Practical, Adaptable Solution

Formthotics are particularly well-suited to diabetic care due to:

- Modifiable design: Adjust pressure zones, add offloading pads, contour reliefs – all within a single clinic visit
- Multiple density and profile options: Match patient needs from mild to complex presentations
- Affordability and scalability: Enables fitting of multiple pairs, increasing adherence and reducing reliance on single “protected” shoes

Importantly, follow-up adjustments are straightforward, meaning real-time pressure redistribution can be part of the treatment process – not a delayed external fabrication step.

From Prevention to Remission: Rethinking Our Role

There is growing consensus that post-ulcer care should now be referred to as “remission,” not “healed” — a recognition that risk remains high, and ongoing offloading is essential. Preventing the first wound, however, is even more impactful.

In high-risk patients, the first contact with a podiatrist may be the best opportunity to change their long-term outcome.

As clinicians:

- We can’t reverse neuropathy.
- We can’t promise perfect vascular supply.
- But we can offload, cushion, and prevent mechanical trauma – often the trigger that starts the ulceration spiral.

Conclusion

Foot orthoses are more than just supportive devices – they are critical components of preventive medicine for people living with diabetes.

When delivered with clinical precision and tailored to the individual, orthoses can:

- Prevent wounds
- Reduce re-ulceration
- Lower amputation rates
- Improve survival and mobility

Formthotics offer a practical, adaptable tool to make this possible – helping clinicians translate intention into action, and risk into resilience

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