Comparison of three personalised 3D-printed foot orthoses designs for targeted plantar pressure offloading in people with diabetes

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Introduction

Personalised foot orthoses (FOs) are shown to reduce high pressure in people with diabetes. Minimum of 30% reduction of plantar pressure is necessary for clinical effectiveness (Bus et al. 2016). Recent advances in additive manufacturing, material composition and computer aided design have allowed for the development of lattice structures within custom FOs whose mechanical properties can be tuned through design and manufacturing.

Objective

The aim of this study is to develop and compare three modular personalised 3D-printed FOs that are designed to offload plantar pressure from high-risk areas of the foot in people with diabetes.

Methods

15 controls and 15 participants with diabetes, all with elevated forefoot peak pressure (PP) were recruited. Three sets of personalised FOs were designed using 3D-scanning and barefoot pressure data and manufactured through 3D-printing.

All FOs used a common 3¼-length total-contact base and incorporated targeted modifications at the highest-pressure site: (1) U-shaped cut-out, (2) circular cut-out, or (3) multi-density structure with reduced infill and no cut-out.

A repeated-measures randomized crossover design was employed, with participants testing all three designs alongside a control flat insole with a standardized footwear. In-shoe pressure was used to measure offloading at metatarsal heads with barefoot PP ≥ 450 kPa, and pressure redistribution at non-target metatarsal heads. Clinical success was defined as ≥30% PP reduction compared to control insole.

Findings

- Both cohorts showed a significant difference in pressure reduction between designs.
- U design achieved the highest offloading of 36% (controls) and 34% (diabetes), while resulting in highest redistribution in non-target forefoot regions.
- Multi-density resulted in more moderate offloading, but less pressure increase in non-target regions.
- Clinically successful pressure offloading was achieved in 61% (control) and 55% (diabetes) of the regions of interest using U design while the success was only 19.5% (control) and 26.5% (diabetes) using the multi-density design.

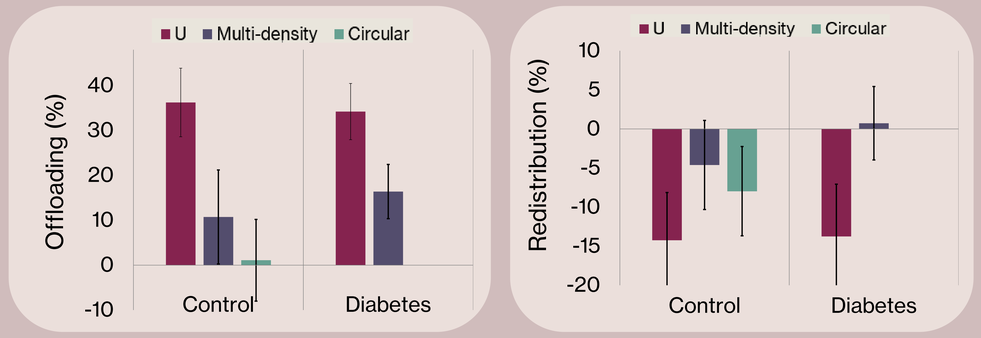

Fig 1. Offloading and redistribution of FOs

Table 1. Clinical success

Cohort	Design	Successful ROIs (n)	Success (%)	Statistical test
Control	Multi-density	8/41	19.5	Cochran's Q = 27.63, p < 0.001
	U	25/41	61.0	
	Circular	4/41	9.8	
Diabetes	Multi-density	13/49	26.5	McNemar's p = 0.003
	U	27/49	55.1	

Conclusions

The present modular personalised FOs with forefoot offloading modifications showed promising results in offloading high-risk feet in both cohorts. U-shaped design provided the most effective targeted pressure offloading and greater redistribution compared to the other designs. These modular concepts are adaptable to the changes in clinical needs over time. This represents the first evidence of an innovative design that improves offloading compared with state-of-the-art insoles.

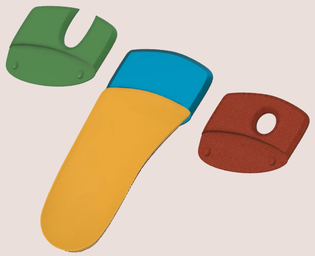

Fig 2. Modular FOs with offloading modifications

References

Bus, S. A., J. J. van Netten, L. A. Lavery, M. Monteiro-Soares, A. Rasmussen, Y. Jubiz, and P. E. Price. 2016. 'IWGDF Guidance on the Prevention of Foot Ulcers in At-Risk Patients with Diabetes'. *Diabetes/Metabolism Research and Reviews* 32:16–24. doi:10.1002/DMRR.2696.

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