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TITLE Evaluation of personalised 3D printed functionally graded metamaterial foot orthoses with an offloading boot

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ABSTRACT (maximum 450 words. Please use the following or similar headings: Background/Methods/Results/Conclusions)

Background

3D printing enables rapid and low-cost manufacture of personalised foot orthoses and opens new opportunities to enhance their mechanical function. One opportunity is the use of metamaterials, which are a class of structure with complex internal architectures that enables precise control of mechanical properties, including stiffness. Functionally graded metamaterials (FGMs) have an internal architecture that varies through the structure, leading to mechanical properties that vary smoothly and continuously. FGMs could be leveraged to improve pressure redistribution and may be particularly beneficial in designing orthoses for offloading treatment of diabetes-related foot ulceration (DFU) when used with guideline-recommended boots. By varying stiffness across an orthosis, softer support can be placed under higher pressure areas, and stiffer support under lower pressure areas, potentially improving offloading effectiveness. While FGMs allow for tailorable orthosis stiffness to potentially improve offloading, there is little known about how stiffness should be distributed to maximise offloading effectiveness. To address this need, we developed a novel workflow to produce personalised FGM orthoses using fused filament 3D printing and compared three algorithms that design orthosis stiffness based on plantar pressure data.

Methods

Fourteen healthy participants were recruited for a within-subjects immediate-effects crossover trial. For each participant, one contoured and three flat FGM orthoses were 3D printed, with stiffness personalised using automated algorithms informed by plantar pressure. Comparators included a personalised contoured ethylene-vinyl acetate (EVA) orthosis and a flat prefabricated orthosis. Each orthosis was worn in an offloading boot, and changes in peak plantar pressure and force time integral were measured using Novel Pedar. This study was prospectively registered with Australian New Zealand Clinical Trials Register (ACTRN12624001175561).

Results

A novel automated workflow was developed to design and 3D print personalised FGM offloading orthoses based on plantar pressures. Peak plantar pressures and force time integrals at the forefoot in contoured 3D printed FGM orthoses were similar to those observed in contoured EVA orthoses. Reductions in force-time integral were observed at the forefoot in contoured orthoses compared to the flat prefabricated orthosis. Differences in peak plantar pressure and force time integrals were observed between flat orthoses designed using different stiffness algorithms, with stiffer metamaterial designs associated with increased load.

Conclusions

Contoured 3D printed FGM orthoses, when used within an offloading boot, achieved forefoot plantar load reduction comparable to contoured EVA orthoses. This finding suggests that effective offloading can be achieved through rapid point-of-care manufacturing using low-cost materials and equipment. This study also provides initial guidance on automated design algorithms for plantar pressure redistribution, highlighting how mechanical tuning influences offloading performance. The findings of this study with healthy participants will inform future studies aimed at optimising design algorithms and evaluating their efficacy in individuals with peripheral neuropathy or DFU.