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Identify Key Parameters for Offloading Footwear and Orthoses Prescription Toward a Clinical Decision Support System: A Retrospective Data-Driven Insight from a Single-Centre Study TITLE

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

The financial burden of managing plantar foot ulceration (PFU) exceeds over AUD 300 million per year. Beyond cost, inadequate management can result in serious complications including infection, hospitalisation and amputation. This risk is further elevated in patient with less common foot pathologies including hallux rigidus, limitus and claw/hammer digits. Currently, there are no established guidelines or evidence-based recommendations to manage this issue through the use of offloading devices including footwear and orthoses. Clinicians must therefore rely on experience and expert consensus leading to prolonged trial and error interventions, that increase complication rates and treatment costs. An evidence-based clinical decision support system (CDSS) represents a promising solution, enabling personalised prescription of footwear and orthoses based on individual patient parameters. The objective of this study is to identify key footwear and orthoses prescription parameters and patient predictor parameters to develop a CDSS for the prevention of plantar hallux rigidus, hallux limitus, and claw and hammer digital related

Methods:

We retrospectively curated data from a single-centre between August 1, 2024, and April 30, 2025. Patients who met the selection oriteria which included history of PFU to the hallux and digits and had no re-ulceration to those sites whilst using the footwear and orthoses prescribed. Data curation of patient predictor parameters included sociodemographic and clinical foot assessments. Prescriptive offloading parameters included footwear and orthoses modifications. Ethical approval was obtained from the Charles Sturt University Research Ethics Committee (Protocol Number H24197). Descriptive analysis and inferential statistics, including Cramer's V, were employed to understand insights and identify key relationships among parameters.

Ninety-seven patients were selected from a pool of over 2000 patients. Initial parameter lists included 18 patient predictors, and 15 offloading device parameters based on existing forefoot offloading literature. Data analysis confirmed 16 patient predictors, and 13 offloading device parameters as important. The most prevalent hallux pathology in this study was hallux limitus 54%. There was significant presence of claw/hammer digits, accounting for 67%. Notably, a novel value was observed under the parameter orthoses modification which involved the combination of reverse Morton's extension, hallux bar and metatarsal bar. Key parameters include hallux and digital pathology, footwear type, footwear rocker profile and insole modification. Cramer's V indicated a moderate association between foot structure and footwear type (V=0.43), and a low-to-moderate association between hallux pathology and insole modification (V=0.32).

This study refined and identified critical patient predictor and offloading device parameters, along with key associations between them, to inform the development of an evidence-based CDSS for optimised, personalised offloading in patients at risk of plantar re-ulceration due to hallux rigidus, limitus and digital deformities. By defining essential parameters and quantifying their relationships, these findings provide a robust foundation for designing CDSS algorithms that can deliver tailored prescription recommendations and improve clinical decision-making. However, further multicentre studies are necessary to validate these parameters across diverse populations.