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TITLE Validity and reliability of the PressureGuardian® to measure pressure underneath the feet of people with diabetes

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

Effective prevention of diabetes-related foot ulcerations relies on the prescription of appropriately fitting insoles and footwear. Historically, clinicians have assessed the effectiveness of insoles and footwear using experience and knowledge. However, guidelines from the International Working Group for the Diabetic Foot recommend plantar pressure measurement to quantify pressure under the foot to optimise insoles and footwear. There are two validated plantar pressure measurement systems (Emed® and Pedar®) to measure plantar pressure, however, they are expensive and require specialist knowledge to operate and interpret. In contrast, the Pressure Guardian® is substantially less expensive, easier to use, and more versatile in clinical settings. This project aimed to assess the validity and reliability of the PressureGuardian® compared to the established Emed® and Pedar® systems.

Methods

This study included patients referred to The Royal Melbourne Hospital Diabetic Foot Unit with diabetes, peripheral neuropathy and a current, or previous diabetes-related foot ulcer. Ethical approval was obtained from Royal Melbourne Hospital and La Trobe University, and all participants provided informed consent.

Three sub-studies were conducted:

- (i) PressureGuardian® concurrent validity compared to the platform-based Emed® system;
- (ii) PressureGuardian® concurrent validity compared to the in-shoe Pedar® system;
- (iii) PressureGuardian® within- and between-session reliability assessed via same-day (10-minute interval) and day-to-day (two-week interval) test-retest protocols, respectively.

The PressureGuardian® was worn concurrently during Emed® platform testing and Pedar® in-shoe testing. Statistical testing included Pearson's correlation coefficients and paired t-tests.

Results

Twenty-five participants were recruited. Participants' mean (SD) age was 66.4 years (11.0), 80% were men, their mean (SD) BMI was 29.7 kg/m2 (6.0). Their mean (SD) duration of diabetes was 16.8 (7.3) years, and 4% had Type 1 diabetes, 8% had Type 2 managed by diet, 44% had Type 2 managed by oral hypoglycaemics, and 44% had Type 2 managed by insulin.

The Pressure Guardian® was strongly correlated with the Emed® (0.802, 95% Cl 0.584, 0.906) but weakly correlated with the Pedar® (0.289, 95% Cl - 0.135, 0.616). The absolute peak pressure values were significantly different between the Pressure Guardian® and both the Emed® and the Pedar®. The PressureGuardian® detected a mean of 287.1 (95% Cl 185.8, 388.5) kPa less than the Emed® (p < 0.001) and a mean of 55.1 (95% Cl 27.2, 83.1) kPa less than the pedar (p < 0.001).

Conclusion

The PressureGuardian® is reliable for measuring plantar pressure in people with diabetes. While it demonstrated strong correlation with the platform-based Emed®, its correlation with the in-shoe Pedar® was weaker. Absolute pressure values differed significantly from the Emed® and Pedar®. Therefore, while the Pressure Guardian® is not suitable to replace the Emed® and Pedar® systems for precise measurement, it offers a somewhat valid and reliable, cost-effective alternative for plantar pressure assessment in clinical settings.