

Validation of Plantar Pressure Measurements for a Novel In-Shoe Plantar Sensory Replacement Unit

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Abstract

Background:

Research concerning prevention of diabetic foot complications is critical. A novel in-shoe plantar sensory replacement unit (PSRU) has been developed that provides alert-based feedback derived from analyzing plantar pressure threshold measurements in real time. The purpose of this study was to compare the PSRU device to a gold standard pressure-sensing device (GS-PSD) to determine the correlation between concurrent measures of plantar pressure during walking.

Methods:

The PSRU had an array of eight sensors with a range of 10–75 mmHg and collected data at 4 Hz, whereas the GS-PSD had 99 sensors with a range of 1–112 mmHg and collected data at 100 Hz. Based on an *a priori* power analysis, data were collected from 10 participants (3 female, 7 male) while walking over ground in both devices. The primary variable of interest was the number of data points recorded that were greater than 32 mmHg (capillary arterial pressure—the minimum pressure reported to cause pressure ulcers) for each of the eight PSRU sensors and corresponding average recordings from the GS-PSD sensor clusters. Intraclass correlation coefficient (2,1) was used to compare data between the two devices.

Results:

Compared with the GS-PSD, we found good-to-very-good correlations (*r*-value range 0.67–0.86; *p*-value range 0.01–0.05) for six of the PSRU's eight sensors and poor correlation for only two sensors (*r* = 0.41, *p* = .15; *r* = 0.38, *p* = .18) when measuring the number of data points recorded that were greater than 32 mmHg.

Conclusions:

Based on the results of the present study, we conclude the PSRU provides analogous data when compared with a GS-PSD.

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Abbreviations: (CoP) center of pressure, (ICC) intraclass correlation coefficient, (GS-PSD) gold standard pressure-sensing device, (PMD) pressure measurement device, (PSRU) plantar sensory replacement unit

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