Journal of Diabetes Science and Technology
Volume 7, Issue 5, September 2013

SYMPOSIUM

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

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Abstract

An article by Ferber and coauthors in *Journal of Diabetes Science and Technology* reported on the ability of a novel in-shoe plantar sensory replacement unit (PSRU) to provide alert-based feedback derived from analyzing plantar pressure (PP) threshold measurements in real time. The study aimed at comparing the PSRU device to a gold standard pressure-sensing device (GS-PSD) to determine the correlation between concurrent measures of PP during walking. Data were collected simultaneously from 10 participants who walked overground with both devices. The variable of interest was the number of recorded data points greater than 32 mm Hg for each of the PSRU sensors and corresponding average recordings from the GS-PSD. Authors concluded that the PSRU provides analogous data to the GS-PSD.

However, several aspects of the study should be considered when interpreting their clinical relevance.

J Diabetes Sci Technol 2013;7(5):1176–1178

Diabetic peripheral neuropathy either reduces or even abolishes protective sensation; it also induces changes in foot structure and function.[1–5] These conditions predispose patients to high foot plantar pressure (PP), an important predictive risk factor for the development of diabetic foot ulceration.[1,6–8] Thus the need of measurement systems that can evaluate the effect of abnormal PP on diabetes subjects' feet during gait. It should be further considered that the majority of prevention programs, aiming at avoiding plantar ulcer formation on diabetic neuropathic foot, include orthotic-device prescription; and that these function to transfer weight away from a painful area and place increased PP where the foot can guarantee a better ambulation.[1–8] Reported in this issue of *Journal of Diabetes Science and Technology* are the findings of a study conducted by Ferber and coauthors[9] that assesses the performance of a plantar sensory replacement unit (PSRU) device by comparing it to a gold standard pressure-sensing device (GS-PSD). Hence the correlation between concurrent measures of PP during walking was determined. The PSRU had an array of eight sensors with a range of 10–75 mm Hg and collected data at 4 Hz, whereas the GS-PSD had 99 sensors with a range of 1–112 mm Hg and collected data at 100 Hz. Data were collected from 10 participants while walking overground in both devices. The primary variable of interest was the number of data points recorded that were greater than 32 mm Hg (capillary arterial pressure—the minimum pressure reported to cause pressure ulcers) for each of

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Abbreviations: (CoP) center of pressure, (GS-PSD) gold standard pressure-sensing device, (PP) plantar pressure, (PSRU) plantar sensory replacement unit

Keywords: correlation, diabetes, insole, neuropathy, orthotic, pressure

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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. The PSRU was the SurroSense Rx™ Insole (Orpyx Medical Technologies Inc., Calgary, Canada) and the GS-PSD was the Pedar X® (Novel, St. Paul, MN) pressure system. The PSRU pressure threshold was *a priori* designed to detect and provide real-time feedback for any PP measure greater than 32 mm Hg. Specifically, the PSRU measures PP over time and alerts the wearer when the specified PP threshold is exceeded. Each insole contains eight flexible, resistive pressure sensors located at critical, discrete points along the plantar surface of the foot (the heel, the lateral foot, the first metatarsal head, the lateral metatarsal heads, the great toe, and the lateral toes). Pressure measurements from these key locations are continuously recorded at a rate of 4 Hz, and these values are analyzed and catalogued by the device as being either "above" or "below" the aforementioned capillary pressure threshold. The insole takes the information over the past 15 min and calculates whether each area on the foot has seen "high," "medium," or "low" integrated pressure over that 15 min period. Pressure stratifications are based on the percentage of measurements taken over 15 min that exceed capillary pressure ("high" pressure corresponds to >95%; "medium" pressure corresponds to 50–89%; and "low" pressure corresponds to <50%). The PSRU device collects and relays integrated time-pressure data from the sole of the foot via wireless protocol, and the collected data are sent to a display device (mobile application or wristwatch) to provide alerts when "high" pressure has been reached, as well as offloading guidance to the wearer.

Good-to-very-good correlations (r value range 0.67–0.86; p value range 0.01–0.05) was found for six out of eight PSRU 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 showed a PP greater than 32 mm Hg.

Accurate PP measurements are necessary in both clinical and research applications,[10,11] therefore anytime a new device is introduced on the market, it becomes mandatory to assess the appropriateness of its PP measurement. In this context, Ferber and coauthors[9] provided a methodology that enabled comparative assessment of the reliability of the PSRU's PP measurement with respect to a gold standard. Furthermore, a well-established technology for PP measurement was chosen for comparison, which strengthens the importance of their results.

Through simultaneous PP measurements with both PSRU and GS-PSD devices, Ferber and coauthors[9] were able to demonstrate the PSRU's ability to accurately measure PP greater than 32 mm Hg. Their results also suggest that the ability of the PSRU to detect pressure is related to the location, line of travel, and velocity of movement in the center of pressure (CoP) during a gait cycle. Further studies are necessary in order to evaluate the validity of the PSRU device in determining CoP position during walking. This is essential for prevention, treatment, and real-time monitoring of PP for neuropathic and non-neuropathic diabetes subjects. Indeed several works reported important CoP path alterations in diabetes subjects with respect to healthy ones[1,5–8] and demonstrated their relationship with sites of plantar ulcers.

However, some limitations of the present study should not be neglected. According to Giacomozzi and coauthors,[10] the major difficulties to cope with when discussing the technical performance of PP measurement devices are related to significant differences in sensor technology, matrix spatial resolution, pressure range, sampling rate, calibration procedures, and raw data preprocessing.[10,11] With respect to this, the two devices compared by Ferber and coauthors[9] differed from one another in most of the above-mentioned characteristics, and this should be taken into account when interpreting the results of the present study. A dedicated consensus activity (i.e., agreement on PP measurements device hardware performance), which has been conducted by the Pedobarographic Group (i-FAB-PG) of the International Foot and Ankle Biomechanics Community,[10] reported definition and standardization of tools and protocols for the technical assessment of PP measurement device hardware performance that should be taken into account when performing studies that aim at assessing validity of PP measurement devices.

In this context, suitability of the testing equipment adopted in the study of Ferber and coauthors[9] should be further supported with respect to the consensus requirements,[10] e.g., in terms of capability to apply a well-controlled, uniform force or pressure over local areas or over the entire PP measurement device active area and ability to have higher precision and accuracy than those expected for the PP measurement device. Also, technical characteristics of the

sensors of the PSRU device should be further investigated in terms of: response variability and absolute value of pressure and sensor hysteresis and sensor response in terms of creep, accuracy, and repeatability of the estimation of CoP coordinates. These characteristics should be assessed over the entire active area.

This study takes one of several steps needed to demonstrate that the PSRU can make a significant impact on diabetes self-management in terms of an efficient PP monitoring system. In this context, Orpyx Medical Technologies will succeed in creating a novel and timely method to actively monitor foot health in order to reduce and prevent ulcer formation on the feet of diabetic foot subjects. This would positively impact the social and economic burden of diabetic foot disease.

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