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Validity and repeatability of three in-shoe pressure measurement systems

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ABSTRACT

In-shoe pressure measurement devices are used in research and clinic to quantify plantar foot pressures. Various devices are available, differing in size, sensor number and type; therefore accuracy and repeatability. Three devices (Medilogic, Tekscan and Pedar) were examined in a 2 day × 3 trial design, quantifying insole response to regional and whole insole loading. The whole insole protocol applied an even pressure (50–600 kPa) to the insole surface for 0–30 s in the Novel TruBlue™ device. The regional protocol utilised cylinders with contact surfaces of 3.14 and 15.9 cm^2 to apply pressures of 50 and 200 kPa. The validity (% difference and Root Mean Square Error: RMSE) and repeatability (Intra-Class Correlation Coefficient: ICC) of the applied pressures (whole insole) and contact area (regional) were outcome variables. Validity of the Pedar system was highest (RMSE 2.6 kPa; difference 3.9%), with the Medilogic (RMSE 27.0 kPa; difference 13.4%) and Tekscan (RMSE 27.0 kPa; difference 5.9%) systems displaying reduced validity. The average and peak pressures demonstrated high between-day repeatability for all three systems and each insole size (ICC ≥ 0.859). The regional contact area % difference ranged from −97 to +249%, but the ICC demonstrated medium to high between-day repeatability (ICC ≥ 0.797). Due to the varying responses of the systems, the choice of an appropriate pressure measurement device must be based on the loading characteristics and the outcome variables sought. Medilogic and Tekscan were most effective between 200 and 300 kPa; Pedar performed well across all pressures. Contact area was less precise, but relatively repeatable for all systems.

1. Introduction

In-shoe pressure measurement devices are commonly used in both research and clinical settings to quantify contact area and pressure on the plantar surface of the foot when wearing a shoe. The devices enable the measurement and comparison of pressure in cases of diseases such as diabetes, and the evaluation of footwear or orthotics designed to modify plantar pressures [1,2]. Various devices are available, which differ in size, sensor number, sensor type and therefore their response to loading and their accuracy. The strengths and weaknesses of each system in terms of validity and repeatability influence the appropriateness of each device for specific tasks in both clinical and research settings.

The task undertaken by the patient or participant in the clinical assessment or research study defines the duration, rate and range of the load application, in addition to the insole area which the load is applied over. Prolonged static loading (e.g. 60 s balance tasks) and cyclic dynamic loading (e.g. walking) differ in loading conditions and demand different characteristics from the insole systems. The range and duration of these applied loads influences the dynamic response of the sensors and thus outcome variables. Error in the measurement of high plantar pressures poses a clinical problem where in-shoe devices are utilised to screen at risk patients, or to assess research interventions to reduce peak pressures [1,3]. Error in the measurement of low plantar pressure values will influence pressure redistribution and contact area measures. Midfoot contact areas for example are utilised for the estimation of foot type and therefore require systems which can capture reliable contact area measures [4].

The validity and repeatability of some in-shoe measurement devices have been investigated utilising both bench-top [1,5] and in-situ methods [6] through protocols with varying methodologies. High repeatability with the Pedar in-shoe system has been demonstrated between days [6,7] and the measurement of midfoot pressure and contact area variables also demonstrate high intra class correlations between trials [4]. The loading characteristics of

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the Medilogic in-shoe system have not been considered in publications. The Tekscan system has been reported to have low durability and to demonstrate significant creep and hysteresis, high variability between and within sensors and low overall repeatability [8]. However, findings from research are hard to compare due to different loading conditions being employed in studies. Additionally, the external validity of some protocols is low due to a consideration of whole insole variables, which may not reflect their practical application as variables are generally computed regionally [2,9]. These studies highlight that consideration of appropriate technical specification of the in-shoe pressure system is required prior to selecting a system for use in clinic and for research purposes.

A thorough analysis of the repeatability and validity of commercially available plantar pressure measurement plates has been undertaken by Giacomozzi [10,11], however no similar work exists for in-shoe pressure devices. The aim of the current research therefore was to quantify the validity and repeatability of three in-shoe pressure measurement systems across a range of applied pressure magnitudes and durations (Medilogic, Pedar and Tekscan).

2. Method

Three commercially available in-shoe pressure measurement systems were compared (Table 1, Fig. 1) for two sizes representing small and larger adult feet (UK 4 and 10). All three systems had been in use in our facility for in excess of 3 years and had been purchased through normal procurement channels. Insoles tested were new (Medilogic and Tekscan) or recently refurbished (Pedar) and calibrated prior to testing (described below). Both a regional and whole insole protocol were undertaken (described below) and repeated on two days, one day apart. Insoles operated at 50 Hz were not used between the protocols, tests or days.

2.1. Calibration

The Pedar and Tekscan insoles were calibrated utilising the protocols recommended in the instruction manuals. Pedar calibration used multiple measurements taken across a loading range from 20 to 600 kPa, while Tekscan calibration used a two point loading method at 300 and 500 kPa to calculate sensor output. Additionally, the Tekscan insoles were "Equilibrated" at 50, 100, 200, 300, 400, 500 and 600 kPa. The TruBlue calibration device (Novel, Munich, Germany) was utilised to calibrate (and "equilibrate") the insoles. This includes an inflatable bladder to apply an even, known pressure across the insole surface. As recommended, the Medilogic insoles were calibrated by the company prior to testing.

Fig. 1. Test insoles from the three systems: Pedar, Medilogic and Tekscan (left to right).

2.2. Regional protocol

Two cylinders with contact surface areas 3.1 cm^2 and 15.9 cm^2 were loaded through their centres to generate pressures of 110 kPa (3.1 cm^2) and 50 and 200 kPa (15.9 cm^2) for 30 s. These aimed to provide realistic pressures and contact areas for anatomical features of the plantar foot surface (metatarsal head and calcaneus). The contact surface was applied to sensors in the heel region along a central line from the insole heel to toe with the apex at ≈12% of the insole length.

2.3. Whole insole protocol

The TruBlue device was used to apply an even load over the insole surface at a range of pressures (50, 100, 200, 300, 400, 500 and 600 kPa), monitored with a pressure gauge (VDO Instruments, Germany) and ensured to be within 2% of the target pressure. Each pressure was applied as quickly as possible. Data was collected for 30 s and data extracted from different times within this period.

2.4. Variables

Variables were calculated for the regional and whole-insoles protocol using custom-written scripts in Python (Enthought Canopy, Version 1.4.1) (Table 2). Active sensors were defined as sensors which registered above 10 kPa during the 30 s trial and these were included in data analysis. Within the whole insole protocol the repeatability and validity of the held load (at 0, 2, 10 and 30 s) were outcome variables (T0, T2, T10 and T30). Validity was established by comparison to the known loads applied in the TruBlue device for the whole-insole protocol. Repeatability was

Table 1
Characteristics of the insole conditions tested.

Feature	Medilogic	Pedar	Tekscan
Sensor model	SohleFlex Sport	Pedar-X	F Scan 3000E Sport
System cost (current quote)	£10,500 (inc. insoles)	£12,600 (not inc. software + insoles)	£14,000 (inc. insoles)
Sensor technology	Resistive	Capacitive	Resistive
Number of sensors	Variable based on insole size (upto 240)	99	Variable based on insole size (upto 960)
Sensor density	0.79 per cm^2	0.57–0.78 per cm^2	3.9 per cm^2
Insole thickness (at sensor region)	1.6 mm	2.2 mm	0.2 mm
Maximum sampling rate	300 Hz	100 Hz	169 Hz
Measurement range	6–640 kPa	20–600 kPa	345–862 kPa
Calibration method	By Manufacturer – polybaric characteristics	Insole: Tru-Blu – Pneumatic Calibration	Device: Factory Insole: Human Standing or calibration device.
Recommended time between calibrations	1 year or 5000 steps	Variable	Disposable insoles – calibrate at each use