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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 x 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 seconds in the Novel TruBlue™ device. The regional protocol utilised cylinders with contact surfaces of 3.14 and 15.9cm² 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 protocol 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 200-300 kPa; Pedar performed well across all pressures. Contact area was less precise, but relatively repeatable for all systems.

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 second 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 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).

Method

Three commercially available in-shoe pressure measurement systems were compared (Table 1, Figure 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 were not used between the protocols, tests or days.

****Table 1 near here****

****Figure 1 near here****

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 20-600 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.

Regional Protocol

Two cylinders with contact surface areas 3.1cm^2 and 15.9cm^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). 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 $\approx 12\%$ of the insole length.

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 seconds and data extracted from different times within this period.

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 second 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 seconds) 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 calculated for the four durations of load application using intra-class correlation coefficients (ICC). For the regional protocol contact area was calculated as the cumulative area of the active sensors. Validity was established by comparison to the known area of the contact surface and repeatability within and between day was calculated using intra-correlation coefficients (ICC). . All statistical analysis was undertaken in SPSS 20 (IBM, USA).

Table 2 near here

Results

Regional Protocol

The CA error ranged from a 92% underestimation to a 249% overestimation of area of the regional loading device (Figure 2). Both Medilogic and Pedar provided more accurate area measures in the largest area and lower pressure condition (15.9 cm² at 50 kPa). Tekscan error was relatively systematic across the insole sizes and conditions (-50 to -92%), with these pressures being below the reported operating range. The between-day repeatability of the CA demonstrated medium to high values for all systems and sizes (ICC \geq 0.797). Pedar and Medilogic systems exceeded 0.925, whereas the two Tekscan insoles recorded lower repeatability for the size 4 insole (ICC = 0.797).

Figure 2 near here

Whole Insole Protocol

MPE of the systems was low for Pedar (mean 4.5%, maximum 16.2%) and higher for Tekscan (60.5%, 135.7%) and Medilogic (10.7%, 20.77%). Pedar underestimated mean pressures at T0 and became progressively more accurate. The resistive systems consistently overestimated MP (Figure 2). The MP increased in all systems from T0 to T30 (Medilogic: +8.1%, Pedar: +6.6%, Tekscan: +14.7%) due to drift. PPE was low for Pedar (mean 4.8%, max 25%) and higher for Medilogic (46.2%, 89.1%) and Tekscan (195.3%, 677.3%). PPE did not vary from T0 to T30. At T0 above 50 kPa the NOS5% for Pedar was 100%. With Tekscan (30-52%) and Medilogic (27-42%) NOS5% was lower.

RMSE for all pressure values at T0 varied across systems: Medilogic (mean 28.5, max 45.7 kPa), Pedar (2.5, 4.7 kPa) and Tekscan (25.5, 41.8 kPa). The Medilogic RMSE reduced to 25.6 kPa at T30, Pedar remained consistent, while Tekscan displayed increased RMSE (28.6 kPa at T30).

The between-day repeatability of the MP demonstrated high values for all systems and sizes (ICC \geq 0.993). Repeatability of PP was equally high for Medilogic (\geq 0.996) and Pedar (\geq 0.999), while Tekscan values were lower (0.859-0.965).

****Figure 3 near here****

Discussion

The comparison of the reliability and validity of three measurement systems acts to inform the application of in-shoe pressure systems in clinical and research settings. The utilisation of both a whole insole and regional protocol in combination infers information for the measurement of pressures and contact areas across the whole foot in addition to at specific locations on the sole.

For the loading of the entire insole; the largest error in peak pressures recorded with Pedar (25.0%) was recorded at 50 kPa in the size 4 insole, consistent with findings from McPoil at the same pressure (16%) [1] and below pressure ranges that may be required for clinical screening [12]. However, the corresponding values for the resistive systems exhibited high errors (mean error in peak pressure from 200-600 kPa Medilogic = $40.0\pm 21.8\%$ and Tekscan $\approx 143.3\pm 133.5\%$), which reduces their validity for peak pressure calculations compared to Pedar. A mean peak pressure of 207 kPa has been proposed as a potential threshold to reduce risk in the previously ulcerated foot affected by diabetes [12]. The mean pressure error was within the ranges previously reported of 1.9-12.1% for the Pedar system and 1.3-33.9% for Tekscan when applying pressures of 30-500 kPa over two seconds [5]. Further demonstrating high error from the systems in a clinically relevant pressure range. Additionally, mean pressure errors were higher in all systems at lower pressures, which

would influence contact area variables, such as utilised in comfort testing and insole validation [13]. Grouping and summing sensors and utilising regional values will reduce error due to imprecise single-sensor response, particularly for users who do not require peak pressure values and is a recommendation of this study. If peak pressure is required and resistive systems are used, a systematic adjustment to the data should be undertaken, based on the strong linear relationship with force plate data previously identified [14].

The findings from the regional protocol showed high variability in contact area measures where only three of the 18 values were within 10% of the area applied for all three systems. The resolution (i.e. the number of sensors for a given absolute insole area) varied between insole sizes for Pedar, but was consistent for both Medilogic and Tekscan (Table 1). Despite this, within-system the insole size had limited influence on measured contact area. The Medilogic system provided the most accurate measures of contact area. The Tekscan system had higher average errors and lower repeatability for contact area, particularly at lower pressures (50-200 kPa). This is potentially due to an interaction between the inherent noise in the resistive system and the larger number of sensors. The methodology we implemented ensured that all sensors which recorded over 10 kPa at any point during the trial were included. Some sensors which had been identified as active became inactive during the 30 second trial in the Tekscan insoles and therefore the measured contact area was not stable over the trial. The insole top surface differed between systems with Medilogic and Pedar using a soft foam and Tekscan a thin plastic film. The contact area was greater in the systems which used soft foam. This may be a result of a more even load distribution causing more sensors (even those which were only partially loaded) to be activated. This contrasts the Tekscan system in which only directly loaded sensors became active. The sensor area is a consideration for isolating specific anatomical points on the foot and Tekscan may offer advantages due to its higher resolution, however the limitations highlighted above should be

considered. We suggest that care should be taken if contact area variables are required from specific time points such as mid-foot contact area at mid-stance.

For the assessment of differences between treatments, the variability across the sensors within the insole must be low while the repeatability of the sensors between measurements must be high. The two resistive systems displayed high root mean square error across the sensors in the whole insole (RMSE 27 kPa) and low number of sensors within 5% of the insole mean (NOS5% 13-77%). This error was substantially lower (RMSE 3kPa), and the consistency of the sensor readings substantially higher (NOS5% 100%) with the Pedar system. The reduced accuracy and precision of the resistive systems demonstrates higher variability between sensors, which may question their appropriateness for quantifying pressure redistribution following a treatment. This error may be a function of the inherent sensor noise and as such is a random error, which although normally distributed cannot easily be removed and may also influence measurement repeatability.

The repeatability across the whole insole (ICC) is consistent with those previously reported for Tekscan within-day (0.94) [12] and between-day for force magnitude using Pedar (0.84) and Tekscan (0.76) [1]. Tekscan displayed lower repeatability for peak pressure values across the whole insole (PP), suggesting caution when the efficacy of treatments is being evaluated. The repeatability is higher for pressures over 100 kPa, consistent with pressure ranges more commonly reported in literature [13]. Despite providing more local repeatability, the nature of the analysis did not isolate the individual repeatability of sensors, so further work should establish this, particularly when peak pressure (PP) is the determinant of treatment efficacy.

Limitations

The applied pressure varied slightly between insoles but was always within 2% of the desired load. The effect of this on the ICC cannot be isolated. The range of pressures utilised in both the regional loading and full insole protocol included some below the reported operating range of Tekscan (Table 1) although within ranges reported in plantar pressure literature [9]. The contact surfaces used to produce the regional loading responses were flat and solid and as such did not fully represent the loading applied by the soft tissues of the foot or the interaction with footwear materials that would be evident in-shoe. The influence of in-shoe factors such as temperature and bending were not considered and may affect the systems differently.

Conclusions

In-shoe pressure measurement systems vary in their response to loading and these characteristics should be considered when selecting a system. The less costly (most clinically accessible) resistive systems appear less valid and repeatable. The Pedar system demonstrated greatest accuracy and repeatability suggesting it is valid for use in clinical and research settings.

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Figures:

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



Figure 2. Contact area data for each insole and applicator size for day two across the 30 second trials. Where error bars denote the standard deviation across the three trials. Note: this is below the Tekscan operating range.

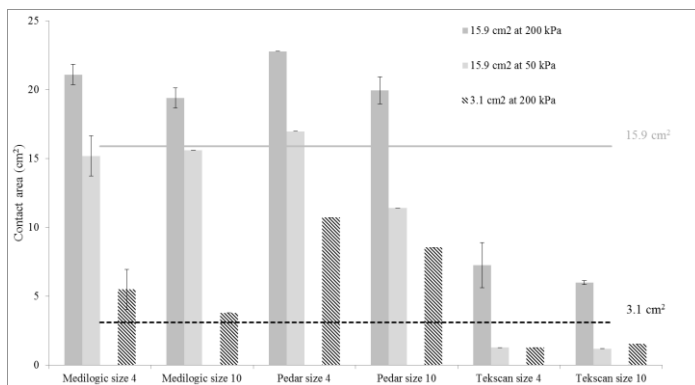
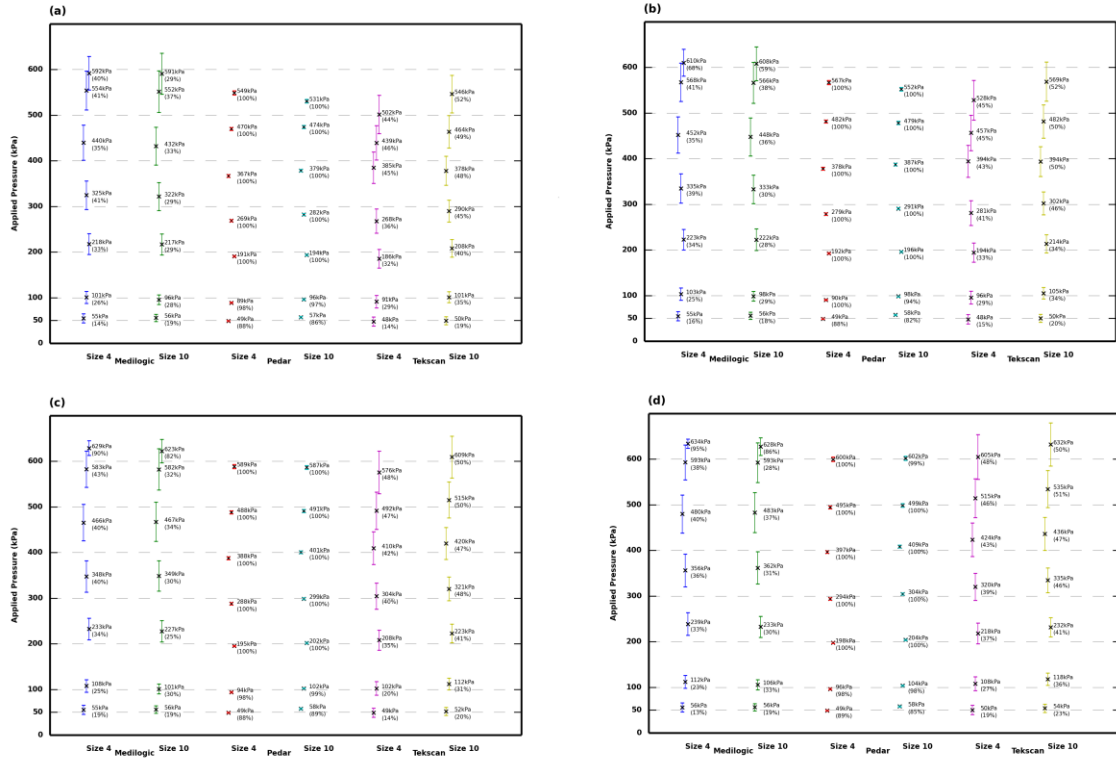


Figure 3. Mean pressure values recorded over 0 (a), 2 (b), 10 (c) and 30 (d) seconds of applied load for day two.



Footnote: Data for 7 applied loads (50, 100, 200, 300, 400, 500 and 600 kPa), 3 systems (Medilotic, Pedar and Tekscan) and 2 size insoles (UK 4 and UK 10). Where x marker and data label denotes the recorded load value in kPa, error bars denote the Root Mean Square Error (RMSE) for the individual sensors about the mean recorded value and data label in brackets denotes the percentage of sensors from the insole recording pressure values within 5% of the mean recorded value.

Tables:

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

Table 2. Definition of variables quantified for in-shoe pressure measurement comparison

Variable	Definition	Abbreviation	Unit
Peak Pressure	Single sensor with the highest reading.	PP	kPa
Mean Pressure	Mean value across all sensors.	MP	kPa
Peak Pressure Error	Absolute value of peak pressure versus target pressure as the percentage of the target pressure	PPE	%
Mean Pressure Error	Absolute value of mean pressure versus target pressure as the percentage of the target pressure	MPE	%
Root Mean Square Error	RMSE across sensors.	RMSE	kPa
Number of sensors within 5% of insole mean	Number of sensors within 5% of the insole mean.	NOS5%	#
Contact Area	Computed for the regional protocol, quantifying the cumulative area of active sensors.	CA	cm ²