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Reliability of peak foot pressure in patients with previous diabetic foot ulceration

Pei-Yueng Lee[a], Pui-Wah Kong[b], Yong-Hao Pua[c,*]

[a] Department of Podiatry, Singapore General Hospital, Singapore
[b] National Institute of Education, Nanyang Technological University, Singapore
[c] Department of Physiotherapy, Singapore General Hospital, Singapore

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ABSTRACT

Background: Previous reliability studies on peak plantar pressure measurements in patients with previous diabetic foot ulceration (DFU) did not stratify their analyses according to whether the foot had a previous ulcer.
Research question: Does test-retest reliability of peak foot pressure measurements from the various foot regions differ between the ulcerated and non-ulcerated feet?
Methods: Data from 23 participants with peripheral neuropathy and healed plantar DFU were analysed in this test-retest reliability comparison study. Plantar pressure was evaluated on two sessions using Pedar®-X in-shoe system, with a mean of 7.2 days (SD = 1.6) between sessions.
Results: The intraclass correlation coefficient (ICC) and coefficient of variation (CV) were calculated for 10 foot regions. Overall, test-retest reliability was excellent (ICCs, 0.82 to 0.95) for all peak pressure variables. CV ranged between 6.3% and 18.3%, and exceeded 15% over the hallux and medial forefoot regions in the ulcer foot (18.3% and 16.4%, respectively). Hallux peak pressure CV was significantly higher over the ulcer foot than over the non-ulcer foot (5.7%, 95% CI, 1.7%–10.2%). Peak pressure CV over the forefoot also tended to be higher over the ulcer foot (medial forefoot: 6.1%, 95% CI, -0.5%–14.5%; lateral forefoot: 4.1%, 95%CI, -0.7%–11.1%).
Significance: Peak plantar foot pressure may be useful to distinguish between groups of patients with peripheral neuropathy and healed plantar DFU. However, clinical decisions based on ulcer foot hallux and forefoot peak pressure measurements should be interpreted with caution.

1. Introduction

Diabetic foot ulceration (DFU) is a common complication of diabetes mellitus and has been associated with significantly higher morbidity and mortality [1,2]. The lifetime risk of DFU development can be as high as 25% [1], while foot re-ulceration rates can reach up to 65% within five years [2]. A history of foot ulceration or amputation is the strongest predictor of subsequent DFU [2,3]. To reduce the risk of foot re-ulceration, plantar pressure-guided footwear interventions are advocated in patients with previous foot ulceration [2,4–7].

However, the reliability of plantar pressure in this specific group of patients with previous DFU has yet to be established. Previous plantar pressure reliability studies in patients with diabetes either excluded participants with a history of previous foot ulceration [8], had a low percentage of participants with previous foot ulceration [9], did not report a history of previous foot ulceration [10], or were limited by a small sample size [11]. These studies [8–10] cannot be generalised to this clinically distinct group of patients with previous DFU as there are differences in foot ulceration risk, plantar pressure profiles and gait biomechanics as compared to patients without a history of DFU [2,3,12,13].

More importantly, none of the previous reliability studies on plantar pressure stratified their analyses according to whether the foot had a previous ulcer [8–11]. This is clinically important as the recently healed ulcer area would be weaker and more likely to re-ulcerate when combined with behavioural factors such as non-compliance to prescribed footwear [2]. Furthermore, the association between foot ulceration risk and plantar pressure also varies with different foot regions [14].

Thus, to overcome the limitations of previous studies, we aimed to compare, in patients with previous diabetic foot ulceration, the test-retest reliability of plantar pressure measurements from the various foot regions between the ulcerated and non-ulcerated feet.

* Corresponding author at: Singapore General Hospital Rehabilitation Centre, National Heart Centre Building Level 7, 5 Hospital Drive, 169609, Singapore.
E-mail address: pua.yong.hao@sgh.com.sg (Y.-H. Pua).

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2. Methods

2.1. Setting

The study was conducted in the largest tertiary hospital in Singapore, a country with a high diabetes national prevalence of 13.7% of the population [15]. Data collection was done in a gait laboratory located within the hospital campus.

2.2. Participants

Ethics approval was granted from the Singhealth Centralised Institutional Review Board (2014/471/F and 2015/2578) prior to the commencement of the study. All patients with healed plantar neuropathic foot ulcer(s) at a hospital-based outpatient Podiatry clinic were contacted by study investigators to determine if they were keen to join the study. Written informed consent was obtained from all participants.

Participants were included if they had diagnosed diabetes mellitus (Type 1 or Type 2), peripheral neuropathy, and a history of healed plantar foot ulceration. Peripheral neuropathy was indicated by participant's (i) Vibration Perception Threshold (VPT) being more than 25 V using a Neurothesiometer, or (ii) insensitivity to a 5.07 Semmes-Weinstein Monofilament at one or more sites out of four sites on the plantar forefoot [16].

Participants were excluded if they had any of the following: hallux blood pressure less than 35 mmHg, Charcot neuroarthropathy, rigid foot deformities, inability to ambulate 100 m unaided, previous stroke or other neurological conditions affecting gait, current foot ulceration or gangrene and previous major foot or lower limb amputation in either limb, including foot amputations proximal to the tarsometatarsal joints. Participants with partial foot amputations distal to the tarsometatarsal joints were included. Rigid deformities were defined by no available motion present in the any of the (i) first metatarsophalangeal, (ii) subtalar, or (iii) ankle joints.

Thirty-one participants were recruited but two withdrew after the first session for reasons unrelated to the study. One participant met one of the exclusion criteria. Technical equipment problems rendered the data of two participants completely unusable. Three participants re-ulcerated between the sessions. Therefore, only data from 23 participants were used in the analyses (Table 1).

2.3. Equipment

Plantar pressure was evaluated using the Pedar®-X in-shoe measurement system (Novel GmbH, Munich, Germany). This in-shoe plantar pressure system comprised 99 capacitive sensors embedded within a thin flexible insole, sampled at 50 Hz. The insoles were calibrated prior to data collection. This system has previously been shown to be valid and reliable in healthy adults [17,18].

2.4. Procedures

Participants presented to the laboratory for two sessions with a mean of 7.2 days (SD = 1.6, range = 6–14 days) between sessions. Plantar pressure was evaluated during both sessions. The Pedar®-X sensor insoles were placed within participants' own shoes without any existing insoles. The same pair of shoes was worn for both sessions. After an initial familiarisation period, the participants completed four walking trials. Participants were timed using a multi-beam timing light system as described by Clark and colleagues [19] as they walked at a comfortable self-selected speed along an 8 m walkway. To ensure consistency of walking speed, any trial was eliminated and repeated if the time differed by more than 5% of the original trial time during the session.

Table 1
Participant characteristics (N = 23).

	Mean (SD), [range] / N (%)	
Age (years)	56.7 (11.3), [30 – 72]	
Sex	6 females (26%), 17 males (74%)	
Ethnicity	Chinese = 15 (65%), Indian = 4 (17%), Malay = 3 (13%), Eurasian = 1 (4%)	
Height (m)	1.68 (0.07), [1.57 – 1.87]	
Body mass (kg)	77.0 (13.4), [55.9 – 101.3]	
BMI (kg/m^2)	27.5 (4.6), [19.9 – 35.7]	
Medical history		
Diabetes type	Type 1 = 2 (9%), Type 2 = 21 (91%)	
Diabetes duration (years)	14.2 (9.4), [0.3 - 33]	
Most recent HbA1c (%) / (mmol/mol)	7.9 (1.6), [5.3 - 11.4] / 63 (17.5), [34 – 101]	
Peripheral Vascular Disease (N)	4 (17%)	
Chronic Kidney Disease (N)	4 (17%)	
Previous partial foot amputation (N)	13 (57%)	
- Toe(s) amputation	3 (23%)	
- Ray(s) amputation	8 (62%)	
- Distal transmetatarsal amputation*	2 (15%)	
Foot ulcer history		
Primary foot ulcer site	10 left foot (43%), 13 right foot (57%)	
- Located on same foot as previous partial foot amputation	9 (39%)	
- Plantar hallux ulcers (N)	9 (39%)	
- Plantar metatarsophalangeal joint ulcers (N)	12 (52%)	
- Plantar forefoot amputation stump ulcer (N)**	2 (9%)	
Healing time of primary foot ulcer (days)	43 (65) [6 - 309]	
History of recurrent ulcers over any foot (N)	15 (65%)	
History of recurrent ulcer over the same site as the current primary foot ulcer site (N)	8 (35%)	
- Number of times of ulcer recurrence over the same site	3.1 (1.0), [2,3,4,5]	
History of bilateral foot ulcers (N)	8 (35%)	
Foot characteristics	Ulcer foot	Non-ulcer foot
Passive 1st MTPJ ROM (^{0})	69 (16), [41 – 95]	70 (15), [48 – 97]
Weight-bearing lunge maximum ankle dorsiflexion ROM (^{0})	68 (11), [34 – 83]	66 (9), [38 – 83]
Presence of lesser toe claw toes/ hammertoes/ subluxed toes (N)	8 (38%)	3 (13%)

* 1 participant had previous 1st-4th ray amputation and was classified as distal transmetatarsal amputation instead due to the extent of amputation. ** the participant who had 1st-4th ray amputation had ulceration over the ray amputation stump, hence was classified as plantar forefoot amputation stump ulcer. HbA1c = glycated haemoglobin (A1c), BMI = Body Mass Index, Ulcer foot = foot with the primary foot ulcer, non-ulcer foot = foot opposite to the foot with the primary foot ulcer, Passive 1 st MTPJ ROM = range of motion of the first metatarsophalangeal joint recorded using a handheld goniometer in a non-weight-bearing setting, Weight-bearing lunge maximum ankle dorsiflexion ROM = range of motion of the ankle joint recorded using a handheld goniometer while performing a weight-bearing lunge.

2.5. Data processing

Only peak pressure was analysed in this study. Pressure-time integral was not reported due to its limited additional value in characterising the plantar loading in the diabetic foot [20]. Data from 16 steps (middle four steps of each trial, four walking trials) per participant were averaged for each session and analysed using the Novel-win program.

Peak pressure data were masked based on percentage length and width of the foot to allow for analysis according to the different foot regions as specified: hallux, medial forefoot, lateral forefoot, midfoot and heel. Data of the lesser toes (digits 2–5) were excluded due to poor repeatability [18]. For participants with previous ray amputations, the medial and lateral forefoot masks were not excluded in the analyses as they provided valuable information on plantar pressure over the

remaining metatarsal shaft stump. For first ray amputation, only the hallux mask was excluded from analysis due to the absence of pressure over the entire hallux mask. For transmetatarsal amputations, the corresponding hallux, medial and lateral forefoot masks were excluded from analysis.

Instead of analysing according to the right or left foot, as was done in previous studies, we believe it is more clinically meaningful to analyse both feet according to the previous foot ulceration. This was due to the high risk of foot re-ulceration [2,3,5]. The most recently healed foot ulcer was termed the primary foot ulcer, and the foot was labelled as the 'Ulcer foot'; the contralateral or opposite foot was labelled as the 'Non-ulcer foot'. Foot ulcer history was determined based on the participant's self-report of previous foot ulcer location and corroborated with the corresponding clinical records. In the event of a history of concurrent bilateral foot ulceration, the foot with any current pre-ulcerative lesion was used as the 'Ulcer foot'. A pre-ulcerative lesion was defined as a site at risk of ulceration, indicated by the formation of callus or areas of non-blanchable erythema [2,5].

2.6. Statistical analysis

Data are expressed as means with SDs and medians with quartiles for continuous variables and as counts with percentage for categorical variables. To assess relative reliability, we computed intraclass correlation coefficient model 3,1 (ICC [3,1]) and corresponding confidence intervals (CI) [21]. Point estimates of the ICC were then interpreted as follows: excellent (0.75–1), modest (0.4-0.74), or poor (0-0.39). The Wilcoxon signed rank test was used to evaluate for any systematic bias in the test-retest scores, with median of differences used as an estimate of the test-retest differences.

The peak pressure data were explored for heteroscedasticity using Bland-Altman plots. To formally evaluate the extent of heteroscedasticity, we computed Spearman correlation between the absolute test-retest difference scores against the mean test-retest scores [21]. For peak pressure variables that did not show evidence of heteroscedasticity, the standard error of measurement (SEM) was obtained by dividing the standard deviation of the difference scores by square root two [22]. To facilitate results comparison between variables that are measured on different scales, the coefficient of variation (CV) for homoscedastic variables were obtained by dividing the SEM by the total mean, multiplied by 100% [21]. If the variables showed heteroscedasticity, the data were log transformed and the CV was the antilog of the square root of the mean square error (MSE) term from the respective repeated analysis of variance of the transformed data [21].

A bootstrapping procedure was then used to formally compare the difference in CV between the ulcer foot and non-ulcer foot [23]. For each foot region, 1000 bootstrap samples of the difference in CV of the ulcer foot and non-ulcer foot were generated. The 95% CI of the differences was then computed using the bias corrected and accelerated (BCa) percentile method [23]. If the 95% CI contained zero, the CV between the ulcer foot and non-ulcer foot was not considered to be different. All analyses were done using *R* statistical software (version 3.5.0, http://www.r-project.org).

3. Results

The test-retest relative reliability was excellent (ICC 0.82 - 0.95) for all peak pressure variables (Tables 2–3). Retest-session peak pressures were significantly higher for 4 variables: medial forefoot of the non-ulcer foot, lateral forefoot of both feet and heel region of the non-ulcer foot. Bland-Altman analyses showed that data heteroscedasticity varied with foot regions (Fig. 1). Data were heteroscedastic for the hallux and forefoot regions of the ulcer foot. In contrast, there was no evidence of heteroscedasticity over all regions of the non-ulcer foot, as well as over the midfoot and heel regions of the ulcer foot.

In terms of absolute reliability, plantar pressure CV values ranged between 6.3% and 18.3%, and exceeded 15% over the hallux and medial forefoot regions in the ulcer foot (18.3% and 16.4%, respectively). Hallux peak pressure CV was significantly higher over the ulcer foot than over the non-ulcer foot (5.7%, 95% CI, 1.7%–10.2%). Peak pressure CV over the forefoot also tended to be higher over the ulcer foot (medial forefoot: 6.1%, 95% CI, -0.5%–14.5%; lateral forefoot: 4.1%, 95%CI, -0.7%–11.1%). For the midfoot and heel regions, the bootstrap 95% CI crossed zero, indicating no statistically significant differences in CV between the two feet (Table 3).

4. Discussion

This study aimed to evaluate the test-retest reliability of plantar pressure in patients with previous diabetic foot ulceration by distinguishing the analyses between the ulcer foot and non-ulcer foot. The results showed that the CV of peak pressure over the hallux region for the ulcer foot was higher than the non-ulcer foot. The relative test-retest reliability of peak pressure over the different foot regions was also excellent in this group, albeit with a reasonably high degree of absolute test-retest error over the hallux region of both feet and forefoot regions of the ulcer foot.

The large CV over the hallux and forefoot regions was expected in this group; patients with diabetes have greater gait variability [24], while those with previous diabetic foot ulceration [13] and partial foot amputation [25] display altered gait biomechanics. These factors could account for the varying test-retest heterogeneity of peak pressure over the different foot regions, which could in turn contribute towards the test-retest measurement error, as quantified by the CV [21].

Comparing our results with those reported by Ramanathan and colleagues on healthy adults using the same type of equipment [18], the results from our and Ramanathan's group were surprisingly similar. This is unexpected, as the clinical characteristics of diabetes, peripheral neuropathy and previous DFU have been shown to increase gait variability [13,24]. Nevertheless, protocol differences between the 2 studies preclude a direct comparison of results. Firstly, we ensured consistency of participants' self-selected walking speed by eliminating walking trials that differed by more than 5% of the original trial time during the session. Ramanathan et al [18] did not evaluate walking speed - a known confounder of plantar pressure [26]. Secondly, we grouped the forefoot masks into two main regions (medial and lateral forefoot) to reduce variability associated with the use of small masks [27]. In contrast, Ramanathan and colleagues [18] utilised a smaller masking protocol in which each individual metatarsal region was analysed during the data processing stage.

To our knowledge, ours is the first reliability study to stratify the analysis of plantar pressure according to a history of foot ulceration. Indeed, previous reliability studies in patients with diabetes [8–11] have performed their analyses on the right or left foot and disregarded foot ulceration history. Reviewing the literature, we identified 2 cross-sectional comparative studies that stratified the plantar pressure analysis according to the affected limb [28,29]. In one study, Kanade and colleagues [28] reported on patients with active diabetic foot ulceration and healed partial foot amputation, and they found that standard deviation of peak pressure over the forefoot and hallux regions of the affected limb were considerably greater than that over the opposite (unaffected) foot. These findings are also consistent with those reported by Fernando and colleagues [29]. Thus, our findings that the variability of the ulcer foot was higher than that of the non-ulcer foot over the hallux and forefoot regions agree with these previous findings.

Two possibilities may explain why hallux peak pressure CV for the ulcer foot is higher than that for the non-ulcer foot. First, our results could be due to potential gait compensation. This is plausible as all study participants had adequate range-of-motion in their ankle, subtalar, and first metatarsophalangeal joints which potentially allowed for gait pattern adjustments. Although we do not have three-dimensional kinematic and temporo-spatial data to confirm this conjecture,

Table 2
Descriptive and reliability measures for peak pressure over the forefoot regions of (previously) ulcerated and non-ulcerated feet.

Foot region	Measures	Ulcer foot	Non-ulcer foot	CV Difference (95% CI)
Hallux	Sample size	19	22	–
	Baseline PP (kPa)	175.0 (120.0 – 315.0)	181.2 (137.5 – 242.5)	–
	Retest PP (kPa)	167.5 (136.2 – 308.8)	211.2 (153.1 – 256.2)	–
	Median of differences (kPa)	7.5	10.0	–
	CV (%)	18.3	12.6	5.7 (1.68, 10.17)
	ICC [3,1] (95% CI)	0.89 (0.73 – 0.95)	0.91 (0.80 – 0.96)	
Medial forefoot	Sample size	21	22	–
	Baseline PP (kPa)	252.5 (185.0 – 317.5)	196.2 (152.5 – 280.6)	–
	Retest PP (kPa)	260.0 (210.0 – 325.0)	211.2 (183.1 – 280.0)	–
	Median of differences (kPa)	10.0	17.5*	
	CV (%)	16.4	10.3	6.1 (-0.47, 14.46)
	ICC [3,1] (95% CI)	0.86 (0.69 – 0.94)	0.91 (0.80 – 0.96)	
Lateral forefoot	Sample size	21	22	–
	Baseline PP (kPa)	220.0 (192.5 – 287.5)	225.0 (188.8 – 286.2)	–
	Retest PP (kPa)	247.5 (220.0 – 325.0)	248.8 (192.5 – 293.8)	–
	Median of differences (kPa)	25.0*	13.8*	–
	CV (%)	12.7	8.6	4.1 (-0.70, 11.05)
	ICC [3,1] (95% CI)	0.87 (0.70 – 0.94)	0.92 (0.81 – 0.96)	

Data are expressed in median (25%–75% quartiles). The sample size for the various foot regions are different due to technical error over the heel region for two participants.
PP = Peak Pressure (kPa), Median of differences = median of the differences between retest PP and baseline PP, CV = coefficient of variation, ICC [3,1] = intraclass correlation coefficient, model 3,1 with 95% confidence interval expressed in parenthesis, BCa = bias corrected and accelerated percentile method.
* $p < 0.05$ obtained from Wilcoxon signed rank test for between-session peak pressure comparison.

Fernando et al [30] suggest that patients with diabetic peripheral neuropathy may adopt a 'guarded gait strategy' to prevent excessive loading of the ulcerated limb. Second, it is also plausible that the difference in CV could have been contributed by previous partial foot amputation. As a sensitivity analysis suggested by the reviewer, we stratified our analysis by amputation status and found that the CV differences were more pronounced in participants with previous amputation ($n = 13$, CV difference, 7.4%; 95% CI, 0.3–18.7). Ostensibly, a foot amputation could lower gait stability and alter foot biomechanics [25,31], leading to greater variability in peak pressure CV in the ulcerated foot. Given this interesting but preliminary finding, future studies should explore this possibility.

Our study findings have implications given that international working groups on the diabetic foot have advocated the use of plantar pressure assessment of offloading devices in clinical and research settings [6,7]. The excellent relative reliability of peak pressure, as indicated by the ICC values, indicate that plantar pressure assessment may be a useful tool for distinguishing between individuals or groups [21]. Indeed, the ICC values were ≥ 0.82 across all regions, indicating that ≥82% of the variability in peak plantar pressure measurements was due to genuine differences in peak pressure measurements between participants, with the remaining 18% being due to errors in the measurement process and the observer involved [32]. However, the difference in peak pressure CV between the ulcer and non-ulcer foot over the hallux region indicate that peak pressure analyses in this group would have to consider the most recent foot ulceration side and be specific to the foot region. Furthermore, the random measurement error associated with peak pressure, as quantified by the CV, is large over certain foot regions. This indicates that studies using peak pressure as an outcome variable across a period of time could inadvertently be underpowered [21]. Additionally, these large measurement errors could also result in regression dilution bias or over-estimation when peak pressure – in particular, over the hallux and medial forefoot regions of the ulcer foot – is used as a predictor of foot ulceration [33,34].

In terms of clinical implications, peak pressure measurements can still be useful given that (i) there are no better alternatives in a clinical setting and (ii) the lack of protective sensation in these patients [2] makes it a clinical challenge to ascertain the effectiveness of any interventions placed in their footwear. However, clinicians should be aware of the large random measurement errors over the hallux and

Table 3
Descriptive and reliability measures for peak pressure over the midfoot and heel regions of (previously) ulcerated and non-ulcerated feet.

Foot region	Measures	Ulcer foot	Non-ulcer foot	CV Difference (95% CI)
Midfoot	Sample size	23	23	–
	Baseline PP (kPa)	130.0 (108.8 – 138.8)	120.0 (108.8 – 138.8)	–
	Retest PP (kPa)	130.0 (108.8 – 142.5)	127.5 (110.0 – 148.8)	–
	Median of differences (kPa)	−2.5	5.0	–
	CV (%)	9.6	9.4	0.2 (-4.51, 3.47)
	ICC [3,1] (95% CI)	0.91 (0.79 – 0.96)	0.82 (0.62 – 0.92)	
Heel	Sample size	21	21	–
	Baseline PP (kPa)	200.0 (180.0 – 252.5)	197.5 (182.5 – 247.5)	–
	Retest PP (kPa)	210.0 (182.5 – 257.5)	210.0 (202.5 – 262.5)	–
	Median of differences (kPa)	7.5	20.0*	–
	CV (%)	6.3	8.0	−1.7 (-6.58, 1.42)
	ICC [3,1] (95% CI)	0.95 (0.88 – 0.98)	0.87 (0.70 – 0.94)	

Data are expressed in median (25%–75% quartiles). The sample sizes for the various foot regions are different due to technical error over the heel region for two participants.
PP = Peak Pressure (kPa), Median of differences = median of the differences between retest PP and baseline PP, CV = coefficient of variation, ICC [3,1] = intraclass correlation coefficient, model 3,1 with 95% confidence interval expressed in parenthesis, BCa = bias corrected and accelerated percentile method.
* $p < 0.05$ obtained from Wilcoxon signed rank test for between-session peak pressure comparison.

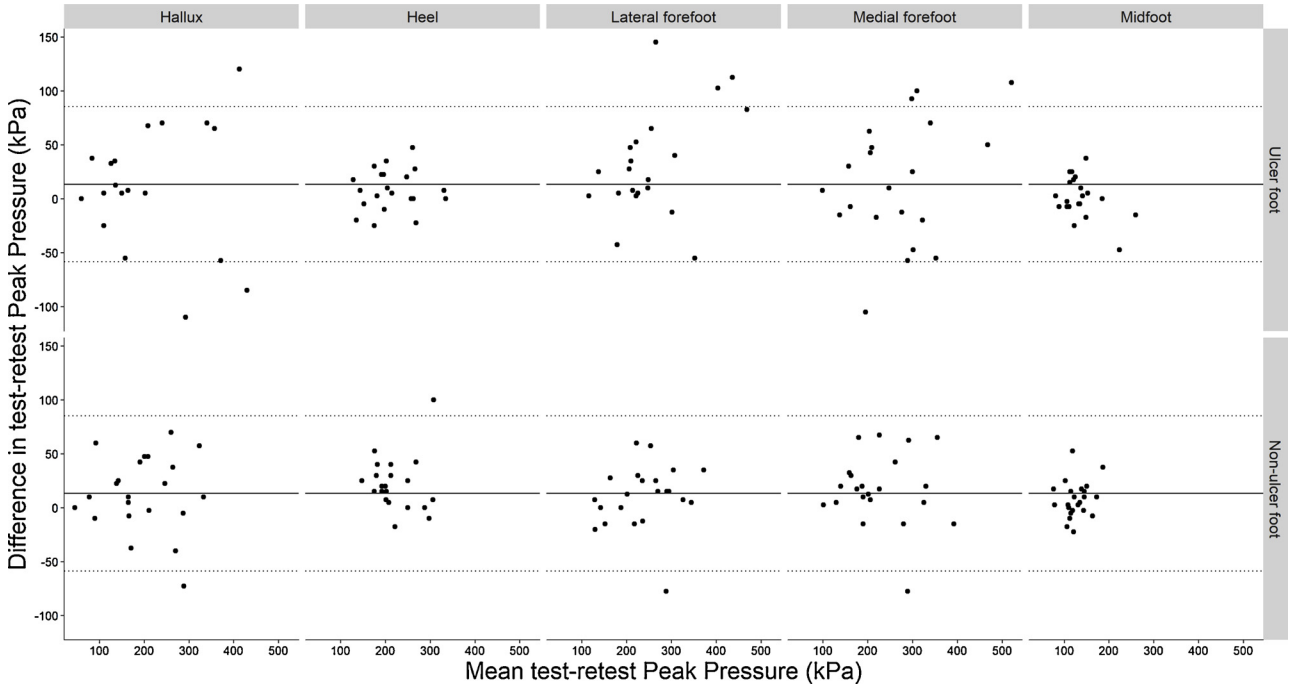

Fig. 1. Bland-Altman plot of the difference in test-retest peak pressure (kPa) against the mean of the test-retest peak pressure (kPa) for the different foot regions, grouped by the foot with the primary foot ulcer (Ulcer foot) and the opposite foot (Non-ulcer foot).

forefoot regions when using peak pressure to evaluate offloading interventions within the same individual or over different time points; offloading devices may still need to be adjusted between consultation sessions despite demonstrated pressure-relief in the clinical setting. More weight should be given to other clinical indicators of excessive loading over the foot region, such as excessive callus or pre-ulcerative lesions [2,5], and the patient would still require close clinical monitoring.

Our study has limitations. First, given our modest sample size, we acknowledge that our study results are preliminary and that they would need to be confirmed in a larger study. Second, we did not control for the test-retest walking speed of our participants which may result in the mean bias observed in some of the re-test measurements. That said, controlling the walking speed between sessions could introduce other unintended confounders to foot pressures, such as a change in stride length and joint moments [35]. Therefore, the results from this study are likely reflective of this heterogeneous group. Third, we studied a heterogeneous sample group in which 57% of the participants had a history of various partial foot amputations. Nonetheless, this sample group is a clinically representative sample of patients with previous DFU for two main reasons: firstly, a history of foot amputation or ulceration is the strongest predictor for subsequent DFU [2,3]. Hence, it is common that patients with a history of DFU to also have previous foot amputation – which is similar in other studies [4,5]. Secondly, all the primary DFU sites for the participants in this study were located over either the hallux or plantar forefoot regions. These foot regions are the most common foot locations for ulcer recurrence in clinical practice [2,3,5,14].

5. Conclusion

In conclusion, our findings indicate that while excellent relative test-retest reliability was found in patients with previous DFU for peak foot pressure measurements from the various foot regions of the ulcer and non-ulcer feet, absolute reliability of peak pressure measurements over the hallux and the forefoot regions of the ulcer foot was poorer than that over the non-ulcer foot. Peak pressure would be useful for distinguishing between groups in this specific group, but caution is advised when using peak pressure as a measurement tool over different time points or when comparing between interventions for an individual.

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Conflict of interest

None.

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References

[1] N. Singh, D.G. Armstrong, B.A. Lipsky, Preventing foot ulcers in patients with diabetes, JAMA 293 (2005) 217–228.
[2] D.G. Armstrong, A.J.M. Boulton, S.A. Bus, Diabetic foot ulcers and their recurrence, N. Engl. J. Med. 376 (2017) 2367–2375.
[3] F. Crawford, G. Cezard, F.M. Chappell, G.D. Murray, J.F. Price, A. Sheikh, et al., A systematic review and individual patient data meta-analysis of prognostic factors for foot ulceration in people with diabetes: the international research collaboration for the prediction of diabetic foot ulcerations (PODUS), Health Technol. Assess. 19 (2015) 1–210, https://doi.org/10.3310/hta19570.
[4] J.S. Ulbrecht, T. Hurley, D.T. Mauger, P.R. Cavanagh, Prevention of recurrent foot ulcers with plantar pressure-based in-shoe orthoses: the Careful prevention multicenter randomized controlled trial, Diabetes Care 37 (2014) 1982–1989, https://doi.org/10.2337/dc13-956 Epub 014 Apr 23.
[5] R. Waaijman, M. de Haart, M.L. Arts, D. Wever, A.J. Verlouw, F. Nollet, et al., Risk

factors for plantar foot ulcer recurrence in neuropathic diabetic patients, Diabetes Care 37 (2014) 1697–1705, https://doi.org/10.2337/dc13-470 Epub 014 Apr 4.
[6] S.A. Bus, D.G. Armstrong, R.W. van Deursen, J.E. Lewis, C.F. Caravaggi, P.R. Cavanagh, IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes, Diabetes Metab. Res. Rev. 32 (2016) 25–36, https://doi.org/10.1002/dmrr.2697.
[7] W.J. Jeffcoate, S.A. Bus, F.L. Game, R.J. Hinchliffe, P.E. Price, N.C. Schaper, Reporting standards of studies and papers on the prevention and management of foot ulcers in diabetes: required details and markers of good quality, Lancet Diabetes Endocrinol. 4 (2016) 781–788, https://doi.org/10.1016/S2213-8587(16)30012-2 Epub 2016 May 10.
[8] J.K. Gurney, P.W. Marshall, D. Rosenbaum, U.G. Kersting, Test-retest reliability of dynamic plantar loading and foot geometry measures in diabetics with peripheral neuropathy, Gait Posture 37 (2013) 135–137.
[9] J.H. Ahroni, E.J. Boyko, R. Forsberg, Reliability of F-scan in-shoe measurements of plantar pressure, Foot Ankle Int. 19 (1998) 668–673.
[10] M.L. Arts, S.A. Bus, Twelve steps per foot are recommended for valid and reliable in-shoe plantar pressure data in neuropathic diabetic patients wearing custom made footwear, Clin. Biomech (Bristol, Avon) 26 (2011) 880–884, https://doi.org/10.1016/j.clinbiomech.2011.05.001.
[11] M. Fernando, R.G. Crowther, M. Cunningham, P.A. Lazzarini, K.S. Sangla, P. Buttner, et al., The reproducibility of acquiring three dimensional gait and plantar pressure data using established protocols in participants with and without type 2 diabetes and foot ulcers, J. Foot Ankle Res. 9 (2016) 4, https://doi.org/10.1186/s13047-016-0135-8 eCollection 2016.
[12] M.E. Fernando, R.G. Crowther, E. Pappas, P.A. Lazzarini, M. Cunningham, K.S. Sangla, et al., Plantar pressure in diabetic peripheral neuropathy patients with active foot ulceration, previous ulceration and no history of ulceration: a meta-analysis of observational studies, PLoS One 9 (2014) e99050, , https://doi.org/10.1371/journal.pone.0099050 eCollection 2014.
[13] A. Raspovic, Gait characteristics of people with diabetes-related peripheral neuropathy, with and without a history of ulceration, Gait Posture 38 (2013) 723–728.
[14] W.R. Ledoux, J.B. Shofer, M.S. Cowley, J.H. Ahroni, V. Cohen, E.J. Boyko, Diabetic foot ulcer incidence in relation to plantar pressure magnitude and measurement location, J. Diabetes Compl. 27 (2013) 621–626, https://doi.org/10.1016/j.jdiacomp.2013.07.004 Epub Sep 4.
[15] I.D. Federation, IDF Diabetes Atlas, 8th ed., International Diabetes Federation, Brussels, Belgium, 2017.
[16] A.J.M. Boulton, D.G. Armstrong, S.F. Albert, R.G. Frykberg, R. Hellman, M.S. Kirkman, et al., Comprehensive foot examination and risk assessment: a report of the task force of the foot care interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists, Diabetes Care 31 (2008) 1679–1685.
[17] A.B. Putti, G.P. Arnold, L. Cochrane, R.J. Abboud, The Pedar in-shoe system: Repeatability and normal pressure values, Gait Posture 25 (2007) 401–405.
[18] A.K. Ramanathan, P. Kiran, G.P. Arnold, W. Wang, R.J. Abboud, Repeatability of the Pedar-X in-shoe pressure measuring system, Foot Ankle Surg. 16 (2010) 70–73.
[19] R.A. Clark, K. Paterson, C. Ritchie, S. Blundell, A.L. Bryant, Design and validation of a portable, inexpensive and multi-beam timing light system using the Nintendo Wii hand controllers, J. Sci. Med. Sport 14 (2011) 177–182, https://doi.org/10.1016/j.jsams.2010.12.001 Epub 1 Jan 17.
[20] S.A. Bus, R. Waaijman, The value of reporting pressure-time integral data in addition to peak pressure data in studies on the diabetic foot: a systematic review, Clin. Biomech. (Bristol, Avon) 28 (2013) 117–121, https://doi.org/10.1016/j.clinbiomech.2012.12.002 Epub Dec 27.
[21] G. Atkinson, A.M. Nevill, Statistical methods for assessing measurement error (reliability) in variables relevant to sports medicine, Sports Med. 26 (1998) 217–238.
[22] W.G. Hopkins, Measures of reliability in sports medicine and science, Sports Med. 30 (2000) 1–15.
[23] J. Carpenter, J. Bithell, Bootstrap confidence intervals: when, which, what? A practical guide for medical statisticians, Stat. Med. 19 (2000) 1141–1164.
[24] L. Allet, S. Armand, A. Golay, D. Monnin, R.A. de Bie, E.D. de Bruin, Gait characteristics of diabetic patients: a systematic review, Diabetes Metab. Res. Rev. 24 (2008) 173–191, https://doi.org/10.1002/dmrr.809.
[25] M.P. Dillon, S. Fatone, M.C. Hodge, Biomechanics of ambulation after partial foot amputation: a systematic literature review, J. Prosthet. Orthot. 19 (2007) 2–61.
[26] J.M. Burnfield, C.D. Few, O.S. Mohamed, J. Perry, The influence of walking speed and footwear on plantar pressures in older adults, Clin. Biomech. (Bristol, Avon) 19 (2004) 78–84.
[27] K. Deschamps, I. Birch, J. Mc Innes, K. Desloovere, G.A. Matricali, Inter- and intra-observer reliability of masking in plantar pressure measurement analysis, Gait Posture 30 (2009) 379–382.
[28] R.V. Kanade, R.W. van Deursen, K. Harding, P. Price, Walking performance in people with diabetic neuropathy: benefits and threats, Diabetologia 49 (2006) 1747–1754 doi: 10.007/s00125-006-0309-1. Epub 2006 Jun 7.
[29] M.E. Fernando, R.G. Crowther, P.A. Lazzarini, K.S. Sangla, S. Wearing, P. Buttner, et al., Plantar pressures are higher in cases with diabetic foot ulcers compared to controls despite a longer stance phase duration, BMC Endocr. Disord. 16 (2016) 51, https://doi.org/10.1186/s12902-016-0131-9.
[30] M.E. Fernando, R.G. Crowther, P.A. Lazzarini, K.S. Sangla, P. Buttner, J. Golledge, Gait parameters of people with diabetes-related neuropathic plantar foot ulcers, Clin. Biomech. (Bristol, Avon) 37 (2016) 98–107, https://doi.org/10.1016/j.clinbiomech.2016.06.006 Epub Jun 29.
[31] P.J. Kim, Biomechanics of the diabetic foot: consideration in limb salvage, Adv. Wound Care (New Rochelle) 2 (2013) 107–111, https://doi.org/10.1089/wound.2011.0315.
[32] P. Stratford, Reliability: consistency or differentiating among subjects? Phys. Ther. 69 (1989) 299–300.
[33] J.A. Hutcheon, A. Chiolero, J.A. Hanley, Random measurement error and regression dilution bias, BMJ 340 (2010) c2289, https://doi.org/10.1136/bmj.c2289.
[34] T.B. Brakenhoff, M. Mitroiu, R.H. Keogh, K.G.M. Moons, R.H.H. Groenwold, M. van Smeden, Measurement error is often neglected in medical literature: a systematic review, J. Clin. Epidemiol. 98 (2018) 89–97, https://doi.org/10.1016/j.jclinepi.2018.02.023 Epub Mar 6.
[35] L. Allet, H. Ijzerman, K. Meijer, P. Willems, H. Savelberg, The influence of stride-length on plantar foot-pressures and joint moments, Gait Posture 34 (2011) 300–306.