Evaluation of plantar pressure measurements obtained using PressureStat™ during diabetic foot screening in a community cohort

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Patients with diabetes may develop motor and sensory peripheral neuropathy, rendering them vulnerable to foot ulceration. Motor neuropathy contributes to deformities, e.g. pes-cavus foot, pes-planus foot, digital retraction and hallux-valgus deformity, affecting pressure distribution in the foot. A carbon footprint tool (PressureStat™) may identify areas of elevated plantar pressure (EPP). This study investigated the utility of these footprints in predicting diabetic foot ulceration. PressureStat measurements were obtained from 524 participants in the West of Ireland Diabetes Foot Study and interpreted. Participants were followed for 18 months to identify ulceration. Seventy-six per cent of patients had evidence of EPP at one site or more. EPP was associated with evidence of sensory neuropathy. The risk of future ulceration was greater in participants who had multiple sites of EPP. This data suggests that EPP detected on carbon footprints is associated with evidence of sensory neuropathy and is weakly associated with future ulceration risk.
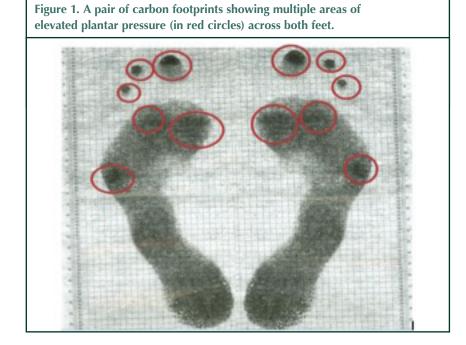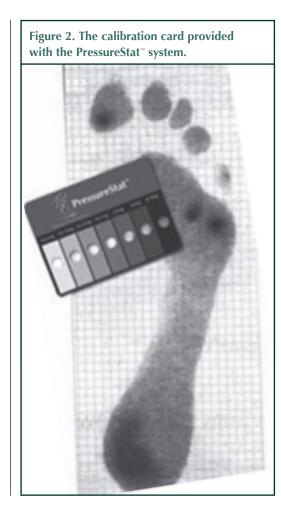
Article points

1. This study assessed the use of carbon footprint measurements to detect elevated plantar pressure.

2. The association between elevated plantar pressure and other evidence of neuropathy and risk of future ulceration is evaluated.

3. This work was undertaken as part of the West of Ireland Diabetes Foot Study.

Key words

- Diabetic neuropathy
- Elevated Plantar Pressure
- PressureStat
- Ulceration

I n the diabetic foot, peripheral neuropathy affecting motor nerves leads to deformity and areas of elevated plantar pressure (EPP) (Veves et al, 1991; Murray et al, 1996). People with diabetes may develop a number of deformities, such as hallux valgus or hammer/claw toe deformity; a pes-cavus foot type is also more common (Ledoux et al, 2005). In combination with reduced sensation, this increases the risk of ulceration due to altered pressure distribution and friction from improperly fitted footwear (Reiber et al, 1999). Risk stratification identifies people with diabetes who are most in need of podiatric input to prevent ulceration (Monteiro-Soares et al, 2011). Assessment of deformity is an important component of risk stratification (DiPreta, 2014). Objective assessment of sensory impairment can be easily performed using tools such as a 10-g monofilament; however, detection of deformity can be more challenging.

It has been established that elevated plantar pressure (often associated with deformity) is a risk factor for foot ulceration in patients with diabetes (Mueller et al, 2003; Bus et al, 2005). This has been established with digital analysis of gait, however this is a resource-intense modality used almost exclusively in a research setting (Lavery et al, 2003). An alternative — and more feasible — method is the use of carbon footprint tools to assess areas of elevated plantar pressure (Van Schie et al, 1999; Cuaderes et al, 2009). The reliability of these tools in rheumatoid arthritis has also been investigated (Firth et al, 2007).

Aims

The authors sought to assess whether elevated plantar pressure detected on a carbon footprint tool was associated with evidence of sensory neuropathy, and whether it predicted future ulceration. This project was undertaken as part of the larger West of Ireland Diabetes Foot Study (WoIDFS; Hurley et al, 2013).

Methods

The methods of recruitment and criteria for eligibility in the larger WoIDFS have been

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Figure 1. A pair of carbon footprints showing multiple areas of elevated plantar pressure (in red circles) across both feet.

Figure 2. The calibration card provided with the PressureStat™ system.

described previously (Hurley et al, 2013). Briefly, a prospective cohort study involving 17 general practices in both rural and urban areas in the West of Ireland was undertaken. All patients registered with diabetes were invited for foot screening at baseline (the investigations performed as part of the screen process are listed in *Table 1*) and were followed for the development of foot ulceration by or before an 18 month follow-up appointment. Demographic and clinical characteristics was collected at baseline.

PressureStat™ (Visual Footcare Technologies) — a carbon footprint tool used to assess EPP (*Figure 1*) — measurements were obtained for some WoIDFS participants. Participants were asked to walk barefoot on a carbon footprint mat from heel-strike to toe-off while maintaining as natural a gait as possible. Carbon foot-printing was performed at baseline only.

A researcher trained in PressureStat assessment reviewed the footprints collected. A calibration card was provided with the PressureStat system (*Figure 2*). Plantar pressures of $>6\,kg/m^2$ (588 kPa) is the standard definition of EPP. Based on comparison with this card, areas with pressures $>6\,kg/m^2$ were determined. Virtually all participants had an area of $>6\,kg/m^2$ on the heel that appeared to be related to heel-strike being increased when 'targeting' the mat. Therefore, the heel was excluded from our analysis.

Pairs of footprints were assessed as being positive or not for the following: (a) ≥1 area of EPP on either foot; (b) a total of >5 areas of EPP across both feet; (c) a total of >10 areas of EPP across

Table 1. Foot screening investigations performed at baseline as part of the West of Ireland Diabetes Foot Study (Hurley et al, 2013).

- Pedal pulse palpation
- Pedal pulse doppler assessment
- Ankle-brachial pressure index
- Insensitivity to 10-g monofilament
- Neurothesiometry
- PressureStat™ (Medical Gait Technology BV) assessment of elevated plantar pressure
- Modified Neuropathy Disability Score (Forouzandeh et al, 2005).

Table 2. Odds ratios for risk of ulceration.

Test	Odds ratio	95% CI
EPP at ≥1 site	2.1	0.3-16.7
EPP at >5 sites	6.3*	1.4-28.5
EPP at >10 sites	11.5*	3.7-35.7
Insensitivity to 10-g monofilament	20.2*	4.4-92.5
Significant NDS	12.2*	3.3-45.3
Abnormal vibration perception threshold	5.4*	1.5-19.6
History of previous ulcer	71.1*	20.0-252.5
History of previous amputation	103.5*	21.1-509.1

CI = confidence interval; EPP = elevated plantar pressure; NDS = neuropathy disability score.

Table 3. Causes of ulceration.

Ulcer cause	Participants (n)	EPP
Ischaemic	2	2/2
Neuroischaemic	2	2/2
Neuropathy/pressure	7	7/7
Neuropathy/Skin fissure	1	1/1
Neuropathy/burn injury	1	0/1
Total	**13**	**12/13**

EPP = elevated plantar pressure.

both feet. Potential sites of EPP were: beneath the tips of each digit, beneath each metatarsal head and beneath the mid-foot.

Statistical analysis was performed using SPSS (version 19; IBM, Armonk, NY). Chi-square tests or Mann–Whitney U-tests were used to analyse the relationship between plantar pressure and other variables collected. Odds ratios (ORs) were generated to determine if plantar pressure abnormalities at baseline were associated with foot ulceration at 18-month follow-up. ORs for other established risk factors were generated for comparison.

Results
Data collection
Paired carbon footprints were obtained in 524 of 563 WoIDFS participants (93%) who attended for foot screening. Mean age was 64 years (standard deviation [SD], 13.4 years), 61% were male, 90% had type 2 diabetes and the mean HbA_{1c} was 56 mmol/mol. The mean BMI was 31.2 kg/m² (SD, 6.1 kg/m²). Of the 39 participants who did not undergo plantar pressure measurement the most common reasons were limited mobility or unsteadiness of gait.

EPP on ≥1 site on either foot was shown in 398 (76%), >5 sites in 235 (45%) and >10 sites 57 (11%). The mean number of sites of EPP was 3.3, with an average total area of EEP of 3.7 cm² for the right foot and 3.6 sites with an average total area of 4.2 cm² for the left foot. The most common sites for EPP were the first metatarsal head (50%), the hallux (44%) and the fifth metatarsal head (28%).

Association with evidence of neuropathy
An association was seen between EPP and insensitivity to 10-g monofilament. Insensitivity to the monofilament was more common among individuals with versus without EPP ≥1 site (25% versus 15%; P=0.043), in those with versus without EPP at >5 sites (27% versus 19%; P=0.048) and also in those with versus without EPP >10 sites (48% versus 21%; P<0.001).

A significant modified Neuropathy Disability Score (NDS) (Forouzandeh et al, 2005) score was also more common among individuals with EPP at >10 sites (50.0% versus 20.0%; P<0.001) but not at ≥1 or >5 sites. This relationship between sensory impairment and EPP was not significant for vibration perception testing (VPT) using the neurothesiometer (P=0.086); VPT measurements were only available in 316 participants.

Risk of future ulceration
ORs for risk of future ulceration were generated. This analysis was limited by the number of ulcers that developed during the 18-month follow-up period. Of the 524 participants for who PressureStat™ readings were available, 13 developed an ulcer (2.4%); three of the 39 who did not complete PressureStat™ measurements developed an ulcer (7.6%). The ORs and confidence intervals for the 13 participants with PressureStat™ measurements who developed an ulcer are shown in *Table 2*. While the OR was not significant for participants with a single site of EPP, those with multiple areas of EPP showed

a significant association with future risk of ulceration.

Of the 13 participants with foot ulceration for whom EPP data were available, the causes of ulceration are shown in *Table 3*. It is interesting to note that EPP was not detected at baseline in only one participant and that this patient's ulcer was partly attributed to a burn injury. Correlation between site of EPP and site of ulceration was not possible.

Discussion

This research demonstrates an association between excessive plantar pressures assessed using a carbon footprint tool and sensory neuropathy. Our data also suggest that EPP, especially when present at multiple sites, may be predictive of future ulceration. It is interesting to note that the sites where EPP was most frequent have previously been identified as those most likely to ulcerate (Cuaderes et al, 2009). There are a number of limitations to this study which we acknowledge.

Limitations

Plantar pressures of >6 kg/m² (588 kPa) is the standard definition of EPP. This was semi-quantitatively assessed using a calibration card provided with the PressureStat tool. Using this definition and measurement tool, EPP was common, with 76% of participants having evidence of EPP. The ORs generated were not statistically significant when looking at participants with a single site of EPP. The authors agree with those who suggest that a lack of specificity limits the value of pressure assessment for risk stratification purposes (Pham et al, 2000).

In order to improve the specificity of EPP for foot deformity we restricted our analysis to participants with multiple sites of EPP. This reduced the number of participants selected and ORs generated were positive in participants with >5 and >10 sites of EPP across both feet. However this is an artificial threshold and would risk missing people at risk of ulceration with fewer, but potentially vulnerable, sites of excess pressure. Furthermore, the association between EPP (reflected by the size of the OR)

was less than the association with other known risk factors for foot ulceration (e.g. impaired monofilament, neurothesiometry, NDS or history of ulceration or amputation).

An additional limitation of our study would be the necessity to exclude the heel area from analysis, as ulcers do develop in this area.

The number of ulcers that developed in the period of follow-up limited our ability to establish the risk attributable to different factors. Although the number of ulcerations was representative of the population, sufficient power for multivariate analysis was not possible.

Comparison with previous work

Few studies have investigated the utility of carbon footprints to predict foot ulceration. Use of the PressureStat to detect areas of high pressure was investigated by Cuaderes et al (2009). They found acceptable agreement between different interpreters and suggested that PressureStat might be a useful screening tool to identify participants at risk of ulceration.

Van Schie et al (1999) compared carbon footprint devices with digital methods of assessing areas of EPP. Areas of EPP detected on another carbon footprint tool, the Podotrack™ (Medical Gait Technology BV) were similar to those detected on an optical pedobarograph but inter-observer variability was noted.

Firth et al (2007) investigated the use of a PressureStat mat to identify areas of EPP in people with rheumatoid arthritis. However, they did not conclude it could be clinically useful in the setting of rheumatoid arthritis as results were imprecise. A recent large study did not find that EPP was a useful predictor of ulceration in those with rheumatoid arthritis (Firth et al, 2014).

Lavery et al (2003) found that pressure assessment was a poor independent predictor of ulceration, even when assessed with more sophisticated measurement tools.

Clinical implications

The authors do not recommend that PressureStat be used as a routine part of diabetic foot ulcer risk assessment. While EPP as shown by PressureStat is correlated to some extent with risk of future

ulceration, the sensitivity and specificity of other tests — in particular the 10-g monofilament — are superior. This was demonstrated by the Hurley et al (2013) as part of the WoIDFS, from which this study originated.

Neuropathic diabetic foot ulceration is treated through pressure-offloading. Use of total-contact casting (TCC) is considered the gold standard of care (Snyder et al, 2014). It may be of interest to assess whether plantar pressure assessment can serve as a useful guide for offloading therapies in the future. As related but less cumbersome devices such as TCC-EZ (Derma Sciences) become available (Sambrook et al, 2015) it may be possible to explore this area further.

It has been suggested that carbon footprints can be used as a patient education tool (DiGironimo, 2003). However, they are expensive at £1.30 per sheet (at the time of research) and hence the authors question this application without further evidence of educational efficacy.

Conclusion

Despite a number of limitations, the data presented here indicate that EPP assessed with a carbon footprint (as a surrogate for deformity) is associated with evidence of sensory neuropathy in a large cohort of people with diabetes. However, there is only a weak associated between EPP and risk of future ulceration. Our ability to draw conclusions with regard to risk prediction was limited by a small number of ulcers during the study period in this cohort. The authors conclude that EPP detected by the PressureStat device is not useful as an independent predictor of diabetic foot ulceration. ■

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