Validity of clinical plantar pressure assessment in the diabetic foot

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1 Severely elevated plantar pressure is a significant risk factor for ulceration and failed healing.

2 Clinical assessment techniques were compared to computer pressure readings of plantar pressure and percentage agreement on sites of severe elevation were analysed.

3 Differences between the three clinicians' opinions of severely elevated pressure sites were compared.

4 There was a significant discrepancy between clinical and computer assessment results and also between the clinicians' judgements.

5 More research is needed into the validity of clinical plantar pressure assessment.

KEY WORDS

- **Plantar pressure**
- **Diabetic foot**
- **Clinical assessment**
- **Validity**
- **Inter-tester agreement**

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Introduction

Elevated plantar pressures are a key risk factor in the development and failed healing of neuropathic foot ulcers. Three clinicians with varying levels of experience conducted clinical evaluations to identify sites of highly elevated plantar pressure. Ten participants with diabetes, both with and without a history of neuropathic foot ulceration, were assessed and then underwent computerised plantar pressure measurement. The results of the study suggested that current approaches to clinical pressure assessment are only moderately valid. Furthermore, there was variance in the agreement of pressure evaluations from clinician to clinician and therefore disparity existed between the level of inter-tester agreement between clinicians.

Trauma caused by elevated pressure areas under the foot, when in combination with sensory neuropathy, is a key risk factor for both the development and failed healing of chronic neuropathic foot ulceration in diabetes. The role of high plantar pressures as a significant aetiological factor in this has been identified throughout the research literature (Veves et al, 1992; Frykberg et al, 1998; Lavery et al, 1998). In addition, several studies have demonstrated that plantar pressures are elevated in people who have peripheral neuropathy due to diabetes, highlighting the increased risk of this group (Ctercteko et al, 1981; Veves et al, 1992).

More recent research has investigated various structural, functional and behavioural factors as potential causes for elevated plantar pressures in populations with and without diabetes (Cavanagh et al, 1997; Morag and Cavanagh, 1999; Ahroni et al, 1999; Mueller et al, 2003). As no one unique set of features has been identified, it has been suggested that the overall cause is likely to be due to a combination of several factors, which vary from individual to individual. Given that at this stage it is usually not feasible to directly treat the primary cause of elevated plantar pressures, management is focused primarily on pressure offloading, using devices such as footwear and orthoses.

Although different levels of pressure have been suggested as ulcerogenic, research suggests that, due to the multi-factorial nature of this condition, some ulcers will form where lower pressures exist, and some where higher pressures are. This apparent discrepancy is most likely due to the influence of other co-existing factors, such as activity levels, skin integrity and the degree of sensory loss, the mix of which will vary from case to case.

In addition, there are differences in measuring equipment and study methodology utilised in research to date. This creates difficulties in allowing accurate comparison of data and specific pressure values across studies. It is, however, generally accepted that the higher the pressure the greater the ulcer risk (Armstrong et al, 1998). For this reason the inclusion of a pressure assessment in a clinical diabetes foot evaluation is fundamental to inform accurate risk assessment through examining for features such as callus and foot deformity (Cavanagh et al, 2000).

Currently, elevated pressures can be measured with computerised systems or evaluated clinically. Computerised measurement has resulted in significant developments in our understanding of this area; however computerised systems are expensive and not widely available. Clinical assessment involves observation and routine examination, based intuitively around features which are thought likely to indicate elevated pressure areas. Evidence on certain factors

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1 Appropriate and timely assessment and management of risk factors is important in reduction of lower extremity complications.

2 Three experienced clinicians performed clinical assessments of underfoot pressures in 10 patients, using both static and dynamic techniques.

3 Clinicians were asked to identify areas where they thought elevated pressures existed, with particular attention to severely elevated pressure sites.

4 F-Scan computerised readings of plantar pressures in these patients were then taken.

which may cause elevated plantar pressures, such as biomechanical foot alterations, foot deformity and plantar callus, has come to light recently, increasing the information on which evidence-based medicine can be practiced (Ahroni et al, 1999; Mueller et al, 2003). There are still gaps, however, in our understanding of the validity of clinical assessments.

Appropriate and timely assessment and management aimed at identification of risk factors for ulceration or amputation has been identified as the most likely means of preventing end-point lower extremity complications (Reiber et al, 1999; Pham et al, 2000). It is crucial, therefore, that high underfoot pressures can be accurately detected in the clinical setting.

A primary strategy to reduce ulcers is through breaking a significant link in the causal pathway but key risk factors must firstly be adequately detectable. To date, however, the validity of routine clinical techniques remains relatively unexplored. Good assessment is pivotal to inform sound clinical practice as we strive to improve patient outcomes. Therefore clinicians require information on the validity of clinical approaches of plantar pressure assessment currently in use.

Aims

Overall, this study aimed to investigate the validity of the clinical assessment for very high underfoot pressures. Furthermore, the study investigated the level of inter-tester agreement between clinicians for the clinical assessment of significantly elevated plantar pressure. These aims were investigated through posing the following questions:

- What percentage of the time is a site of severely elevated plantar pressure able to be detected utilising the current clinical assessment approach?
- What percentage of the time is a site of severely elevated plantar pressure missed utilising the current clinical assessment approach?
- What percentage of the time do clinicians agree on the site of severely elevated plantar pressures?

Table 1. Inclusion/exclusion criteria for study participants

Inclusion criteria	Exclusion criteria
● Diabetes mellitus	● Active foot ulceration
● Positive or negative history of peripheral neuropathy	● Diminished peripheral blood flow as determined by an ankle brachial pressure index of less than 0.7
● Positive or negative history of past neuropathic foot ulcers	● Acute lower limb or foot injury
	● Current lower limb or foot pain
	● Systemic musculoskeletal conditions which may result in altered plantar pressures

Research methods

Institutional ethics approval was granted prior to the study commencing. Three clinicians with three, 10 and 12 years respectively of related clinical podiatric experience volunteered to perform clinical assessments of underfoot pressures. Participants who matched the inclusion criteria (see *Table 1*) were recruited from the patient body at the Caulfield General Medical Centre, Podiatry Department (Melbourne, Australia). This unit's focus is on the provision of podiatric care to people who have diabetes mellitus. Ten participants, i.e. 20 feet (see *Table 2*), with a variety of diabetes-related foot complications volunteered to participate.

The 10 participants were initially assessed clinically for elevated plantar pressures by each of the three clinicians. All clinical assessments were conducted independently in separate rooms. A computerised measurement of plantar pressures was then conducted on all participants utilising the F-Scan system, in order to obtain measurements to which the clinical assessments could be compared.

Clinical assessment protocol

Clinicians were instructed to question and examine the patient as they would in a routine podiatric consultation, in order to form a clinical judgement on what was thought to be the location and magnitude of elevated plantar pressures. This included the use of both static assessment techniques, such as observing for callus, restricted joint motion or foot deformity, and dynamic assessment techniques, such as gait analysis (see *Figure 1* for an example of a participant's foot).

Clinicians were asked to identify any anatomical location on the plantar surface of the foot over which elevated pressure was

thought to exist. Once identified, clinicians were asked to rate the degree of elevation (mild, moderate or severe) with particular attention to highlighting those sites where the pressure was judged to be severely elevated. The definition of this was given as a site that is markedly elevated and is at significantly greater risk of ulcer formation if other risk factors were to present. This definition was offered in an attempt to link what clinicians were being asked to evaluate to a tangible outcome and to set a consistent benchmark against which all clinicians were making a judgement.

Computerised measurement protocol

All participants then underwent a computerised assessment of plantar pressures with the F-Scan (Tekscan USA) in-shoe pressure measurement system. This consists of paper-thin computerised insoles that have an embedded matrix of pressure sensors. The insoles are placed in the shoes of the patient and pressure data is transported back to a computer through the attached transducer boxes and cords. Measurements are conducted in a dynamic situation as a patient walks. Three standard walking trials, including both the right and left feet, were taken for each participant. Walking speed was at a self-selected 'comfortable' pace. All measurements were conducted according to the manufacturer's guidelines and there was minimal usage of each new pair of computerised insoles to avoid sensor fatigue. The F-Scan was calibrated prior to each participant undergoing measurement and all protocols strictly adhered to throughout the study.

Analysis

The 'severely elevated' pressure sites were focused on as these are most likely to be linked with the most severe clinical outcome. The cut-off point used to define a severely elevated plantar pressure utilising computerised measurement in this study was any site which measured at 350 kilopascals (KPa) or above. The range of pressures obtained through the computerised measurements was collated and the highest 10% of pressures were observed to measure at 350 KPa and above. This figure was then cross-checked against those participants who had a past history of plantar neuropathic ulceration. Seven of the 12 past ulcer sites had a corresponding peak plantar pressure above this range.

The validity of the clinical assessment was evaluated by comparing the results obtained in the study to the results of the 'gold standard' computerised plantar pressure assessment. For the F-Scan measurements, plantar pressure data available from all mid-trial footsteps of each of the three walking trials collected, were averaged. Therefore one average pressure (of approximately 12 steps) was calculated for each specified site under the foot, for each participant. The specified sites or masks under the feet (the foot was divided into 13 sites for the purposes of analysis) were the same for the left and right feet and were as follows; the hallux, the second, third, fourth and fifth toe, the first, second, third, fourth and fifth metatarsophalangeal joint, medial longitudinal arch, lateral longitudinal arch, and the heel. The number of sites under the feet for each participant that recorded as <350 KPa were documented and the number of times they were correctly identified during the clinical assessments was evaluated. In addition, the number of times in which severely elevated pressure sites were measured using the F-Scan but not detected during the clinical evaluations was calculated.

The analysis then involved an assessment of inter-tester agreement by observing the number of occasions in which the clinicians agreed with each other on the location of severely elevated plantar pressures.

Results

Clinical assessment vs computerised measurement

Of a possible 26 plantar foot sites per patient (i.e. 13 on each foot), with 10

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1 Computerised insoles placed in participants' shoes were used to assess plantar pressures as participants were walking.

2 Readings from mid-trial footsteps were recorded and averaged for each of 13 sites on both feet of the 10 participants.

3 Computer-measured severely elevated pressure sites (<350 KPa) were noted and compared to the number of times they were correctly identified and number of times undetected during clinical assessments.

4 Clinician agreement on where they judged severe pressure sites to be was analysed.

Table 2. Characteristics of the 10 study participants (20 feet)

Age (years)	Mean: 56 (range: 52–83)	
Gender	Male: 8	Female:2
Diabetes type	All type 2	
History of sensory neuropathy	Yes: 8	No: 2
History of foot ulceration	Yes: 7	No: 3
History of foot amputation (minor)	Yes: 3	No: 7

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1 From 256 measured sites, 28 were identified as being severely elevated.

2 Clinical assessments agreed with computer assessments in 30–68 % of cases.

3 Thirty-two to 61 % of cases measured as severely elevated by the computer were not identified during clinical evaluation.

4 Of the 28 severely elevated sites found, seven of the past 12 neuropathic ulcers participants had occurred on these.

5 Clinicians used previous ulcer sites as an indicator of high pressure, but had poor ability to discriminate which measured high versus low.

6 Clinicians who were more accurate in selecting past ulcer sites associated with severely elevated pressures selected more sites in general, so the false positive rate was higher.

7 There was significant disparity in the clinical assessment of elevated plantar pressures between clinicians.

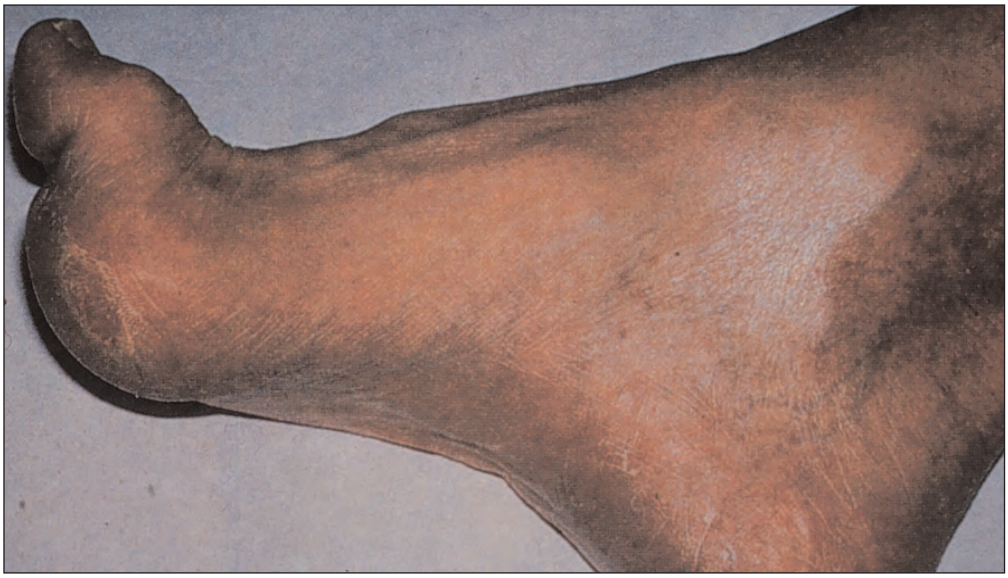

Figure 1. An example of the type of foot assessed in the study. Note the metatarsophalangeal joints are prominent on the plantar surface of the foot which corresponded to measurable sites of elevated plantar pressure.

patients overall (minus four amputation sites) there were 256 sites in total where plantar pressure judgements were made. Of these, 28 were measured by the F-Scan as being severely elevated at <350 KPa. The accuracy with which they were identified during the clinical evaluations as being severely elevated was then determined (see *Table 3*). As demonstrated in *Table 3,* the clinical assessments were consistent with the computer assessments between 39 % and 68 % of the time. This equates to 32 % to 61 % of the time in which sites measured as severely elevated during computerised assessment were not identified. This is of concern given the potential risk associated with these areas; however, they must be interpreted with care in light of the sample size reported.

From the 10 participants, a total of 12 past neuropathic ulcer sites existed. Of these it was identified from computerised measurement that seven had formed on <350 KPa areas and five on sites <350 KPa (three lower by a modest amount, two were significantly lower). *Table 4* presents data on the clinical accuracy of detecting significantly elevated pressure sites over areas of past ulceration. While previous ulceration was a strong indicator used by clinicians to elect a site as highly elevated, there was a poor ability to differentiate between those sites that were actually associated with high pressure as compared to those which were not, i.e. past ulcer sites were often picked but were not necessarily those sites that were associated with high pressures.

Clinicians who were more accurate in detecting past ulcer sites associated with severely elevated plantar pressures were not necessarily more accurate in discriminating against those past ulcer sites associated with lower pressures. Overall, the trend for those clinicians was that more sites were selected in total; therefore, while there was higher true positive identification of severely elevated sites, there was a corresponding increase in false positive error rate.

Inter-tester agreement

The level of agreement between clinicians on the location of severely elevated plantar pressures in the participants evaluated was assessed. For the 28 severely elevated plantar pressure sites: nine sites were identified by all three clinicians as elevated; six were identified by two clinicians; and five by one clinician. Eight of the 28 sites measured as severely elevated using the F-Scan were not selected by any of the clinicians during the clinical evaluations conducted.

In addition, for those nine sites which were identified by all three clinicians, the magnitude by which they were judged to be elevated differed. Two of the nine sites were rated as severely elevated by all clinicians,

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1 Discrepancy between computerised and clinical results may be due to clinical evaluation being only moderately valid due to pressures presenting more subtly than thought.

2 Some of this discrepancy may be explained by errors present in the computerised measurements and the use of a single pressure value.

3 There was no obvious explanation for the difference in agreement between clinicians on severe plantar pressure sites.

4 Mixed inter-tester agreement on which sites of past ulcers were severely elevated was not surprising given the questionable validity of clinical pressure assessments.

5 The range in pressure values of previous neuropathic ulcers re-enforces the multifactorial aetiology of foot ulceration.

two others by two clinicians and the remaining five sites by only one clinician. These results suggest that there is significant disparity in the clinical assessment of elevated plantar pressures.

Conclusions

This study shows a clear discrepancy between the results obtained during computerised pressure evaluation for very high plantar pressures and those reported clinically. There may be several possible explanations for this result. Firstly, it may be that the clinical evaluation of elevated plantar pressures is only moderately valid. Results of this study suggest that severely elevated plantar pressures may be going undetected and low pressures are potentially being judged as very high, in some cases over 50% of the time. While sites of elevated pressure have traditionally been associated with the location of callus or foot deformity, and therefore have anecdotally been thought to be easily detectable clinically, it is possible in light of the findings of this study that they may present more subtly and may be more difficult to observe then previously thought.

However, other issues require consideration. While computerised pressure measurement is the 'gold standard', every measure is associated with a margin of error. It may be that there was some error in the computerised measurements conducted, which could reflect poorly on the analysis of the clinical data. However, the pressure readings utilised were an average of a number of steps over three trials so a component of the potential random error would be cancelled out. It is deemed unlikely, therefore, that system error would explain the majority of the differences noted.

An alternative explanation is the <350 KPa cut-off point. It was necessary to identify such a point and it has some degree of internal validity. The use of a single pressure value and above however may be clinically somewhat arbitrary given the range of pressures at which neuropathic ulceration can occur. It was deemed that this was a relatively high cut-off point to utilise, given it fell within the top 10% of all pressure values and based on its strong association with past ulceration. As clinicians were instructed to evaluate for sites which were 'markedly elevated', which is a strong risk factor for ulceration, it can be argued that scores above the <350 KPa range meet this criteria. These methodological issues, however, hold importance in the accurate interpretation of the study data and must be considered in light of the results reported.

It was found that clinicians who had a greater ability to correctly detect highly elevated pressure areas, overall selected a higher number of sites and so created a higher number of false positive results. There was no obvious explanation for this difference. Clinicians One and Three were more accurate in detecting severely elevated pressures over past ulcer sites, but had a higher rate of error in discriminating between those associated with lower pressure areas. This was in contrast to Clinician Two. The mixed agreement between clinicians on which sites were severely elevated was not a surprising result given the two measurement parameters are inter-related. Again this may be a true result but it must be considered that there may be an alternative explanation, such as an artefact from a difference in levels of understanding the study methods.

The range in pressure values of previous neuropathic ulcers reported re-enforces the multifactorial aetiology of foot ulceration and the role of mixed variables on individual outcomes.

Table 3. Validity of the clinical assessment of severely elevated plantar pressures when compared to computerised measurement as the 'gold standard'

	Clinician One	Clinician Two	Clinician Three
Number of severely elevated sites detected clinically (of 28 sites detected from computer measurement)	19	11	15
Percentage detected clinically	68%	39%	54%
Percentage missed clinically	32%	61%	46%

Table 4. The ability of clinicians to identify which past ulcer sites were associated with severely elevated plantar pressures as compared to those which were associated with low plantar pressures

	Clinician One	Clinician Two	Clinician Three
Number of past ulcer sites identified clinically as associated with severely elevated pressures (of 7 sites detected from computer measurement at <350 KPa)	6	4	6
Number of past ulcer sites *incorrectly* identified clinically as associated with severely elevated pressures	5	5	5

This research has relevance to clinical practice as the data suggest that there may be significant error associated with the clinical assessment of high plantar pressure in people who have diabetes. Clearly this finding is of concern as it may mean that this risk factor is unknowingly going undetected and therefore perhaps is not being modified according to current best practice standards. Ultimately, if the causative pathways to foot ulceration are not appropriately detected and modified, reducing the incidence of foot ulceration in this population is likely to be challenging. Also, if there is a poor ability to differentiate between high and low plantar pressures clinically, it is difficult to identify who is in greater need of pressure-relieving therapy. This may create a dilemma in ensuring treatment is introduced where needed but resources are not directed where not required.

While future research is required to confirm these results and explore the issues further, it may be that greater access to computerised measurement is indicated in the future – particularly if clinical approaches cannot be improved upon. Pham et al (2000) reported that measuring foot pressures offered good specificity in detecting patients at risk of foot ulceration, but due to low sensitivity this technique was not suitable as an approach to screening. A primary indication for the use of computerised measurement may, therefore, be after an initial assessment where other risk factors, such as neuropathy, are found to be present.

The accurate assessment of risk factors is pivotal in detecting and preventing long-term foot complications. In order to construct a sound, evidence-based approach, it is necessary to establish the degree to which our assessments accurately inform us about the parameter under evaluation. Given the significant clinical implications of this finding, further research is recommended to verify results as a subsequent review of clinical assessment guidelines may be indicated. ■

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1 The research data suggest there may be significant error associated with clinical assessment of high plantar pressure in people who have diabetes.

2 This may make it difficult to determine those in greater need of pressure-relieving therapy and to reduce foot ulceration incidence.

3 A primary use for computerised measurement may be after initial assessment where other risk factors are present.

4 Due to the significant implications suggested by the results, more research is needed to verify them.

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