A comparative study of PressureStat, a simple semiquantitative plantar pressure measuring device, and the optical pedobarograph in the assessment of pressures under the diabetic foot

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Abstract

Aims To test PressureStat, a simple inexpensive semi-quantitative footprint mat, for potential use as a screening tool for high plantar pressures, against the optical Pedobarograph (a computerized device).

Methods PressureStat was superimposed on the pedobarograph for simultaneous measurement of pressures from both systems. Three independent observers quantified the pressures of PressureStat footprints from healthy controls and diabetic patients, both before (n=164) and after (n=183) training. The sensitivity of PressureStat to identify high pressure areas measured by the pedobarograph (> 12.3 kg/cm2) was 78.7%, 45.8% and 44.3% (observer A, B and C) before training, but improved to 96.2%, 92.4% and 91.1% after training ($P < 0.01$). Specificity for all three observers was more than 90% before and after training. Inter-observer agreement improved significantly after training ($P < 0.001$).

Conclusion After a simple training of the observers, PressureStat identified approximately all high-pressure areas, suggesting that [he PressureStat could be a useful screening tool to identify areas at risk of ulceration in diabetic patients. We recommend a standard training package for new PressureStat users, to optimize identification of diabetic patients at risk of foot ulceration.

Diabet. Med.16, 154-159 (1999)

Keywords diabetic foot, plantar pressure, pressure measurement device, risk for ulceration, screening device

Abbreviations C, controls; O, diabetic controls; ON, diabetic neuropathic patients; PBG, optical pedobarograph; VPT, vibration perception threshold

Introduction

Early identification of feet 'at risk' for ulceration is important in preventing plantar lesions in diabetic patients with insensitive feet. Plantar pressures are higher in diabetic neuropathic patients than in their nondiabetic and non-neuropathic Counterparts (1-3). As high plantar pressure is a proven risk factor for foot ulceration (4), effective screening for high plantar pressures in diabetic patients could have a major influence on the incidence of diabetic foot ulceration. Plantar pressure measurement can be used to identify specific areas under the foot which are prone to ulceration (5,6). Several pressure measurement devices have been developed, but most are too expensive for routine clinical use as screening tools. In order to identify high-risk patients in a clinical setting, a simple system for screening is needed which is easy to use, reliable and gives results which are easy to interpret and can be immediately available to both the patient and staff. Several simple foot print techniques do exist but these cannot usually quantify pressure and only provide a crude indication of plantar pressure distribution [71. PressureStat footprint mat has recently been developed as a simple, inexpensive and practical foot pressure measurement device intended for routing clinical use. It is a semiquantitative footprint mat which quantifies plantar pressure by visual comparison between the greyness of the footprint and a calibration card.

The object of this study was to compare PressureStat with the optical pedobarograph. The first aim was to test the efficacy of PressureStat and its sensitivity and specificity to identify high pressure areas predictive for foot ulceration. The second aim was to test the need for and effect of training the observers on the quantification of pressure from PressureStat footprint.

Patients and methods

Patients

Twenty-four subjects including five nondiabetic controls (C), nine controls with diabetes but no neuropathy (D) and 10 diabetic neuropathic patients (DN) were used to make footprints which were analysed before observer training. Thirty-seven subjects (four C, eight D, 25 DN) were used to make a second set of footprints which were analysed after observer training. Diabetic neuropathy was diagnosed clinically using vibration perception threshold (VPT) at the great to<; of 25 Volts, calculated from a mean of three readings. There were no significant differences in age and VPT between subjects of the two groups.

Equipment

PressureStat (Medical Gait Technology BY, Emmen, The Netherlands) is a semiquantitative footprint mat which measures peak pressures by comparing the greyness of the footprint with a specially designed calibration card containing seven different gradings of grey, each characteristic of a specific range of pressure measurements (Fig. 1). The Podo-track consists of three layers: a top transparent foil; a DLA colorant carrier (which cannot now be further defined because it is patent pending) and a bottom sheer with a grid marked on it. The DLA colorant has a standard black colour and is made of graphite, oil, soot and paraffin. These substances are combined in such a way that a reaction occurs between [he adhesive layer of the plastic foil and the colorant substances when pressure is applied. The intensity of the load on the top sheet determines the greyness of the print. PressureStat can be fixed to the floor with adhesive strips, so that patients do not slip when stepping on the mat.

The optical pedobarograph is a well-established computerized pressure measurement device which has been used in many studies [1-4,8-14]. The basic system consists of a glass plate illuminated at its edges by strip lights and covered with a thin sheet of opaque reflective plastic on which the subject walks. Recordings depend on the breakdown of total internal reflections at the surface of the glass sheet caused by contact with the plastic [3,15,16]. Both the optical pedobarograph and PressureStat use the same unit for pressure measurement (kg/cm2).

Figure 1 Examples of PressureStat footprints and the calibration card which is used to quantify the pressures. The plantar pressure in the left footprint does nor exceed 6 kg/cm2, while in the right footprint the pressure under the midfoot, the first metatarsal head and hallux are in the highest range of the calibration card (> 9 kg/cm2). The calibration card contains the following pressure ranges: 0-0.5, 0.5-1.5, 1.5-2.5, 2.5-4, 4-6, 6-9 and > 9 kg/cm2

Methods

The study was approved by the local ethics committee. Informed consent was obtained form each patient.

For each subject, barefoot dynamic plantar foot pressures were measured simultaneously by placing PressureStat on the recording platform of the optical pedobarograph. PressureStat is very thin (0.38 mm) with no added cushioning. The effect of superimposing a PressureStat was tested in our laboratory and no significant differences between pedobarographic measurements with and without PressureStat were found (data not shown).

Between one and 10 steps were assessed for each foot, with a median (range) of five (1-20) steps per subject. Prior to pressure measurements, subjects familiarized themselves with the testing procedure. All subjects walked at their own pace, using a fixed starting point. Pressure measurement was done during the second step after subject started to walk. The subjects were asked to look straight ahead while walking over the foot pressure systems, to avoid aiming for PressureStat footprint mat. Any footstep regarded by the investigator as atypical or out of balance was not used for analysis.

Two series of quantification were performed, first without any form of observer training or agreement about how to quantify pressures of a PressureStat footprint mat. The second quantification was repeated after a simple form of training by the same observers. The training included two sessions during which 10 PressureStat prints, one by one, were quantified and compared with the pressure values measured with the optical pedobarograph. Any differences between PressureStat and Pedobarograph measurements were discussed between the observers. The optimal position for quantification (background light and position of the calibration card) was standardized between the observers.

Three independent observers, inexperienced with the Podo-track, quantified the peak plantar pressure in seven different areas of all footprints (heel, all five metatarsal heads, hallux and occasionally the midfoot when high pressure was present). The observers were blind to the subjects' status when quantifying the pressures and all footprints were analysed in a random order. The pedobarograph pressures were analysed in identical areas and peak pressure values categorized in the same ranges of pressure as PressureStat calibration card.

A comparison was performed to determine whether high plantar pressures measured with the optical pedobarograph were also identified as high pressure by PressureStat. A cut- off level of pedobarograph pressure of 12.3 kg/cm2 was used because plantar pressures above this level have been proven to predict foot ulceration (4). For PressureStat a cut-off of > 9 kg/cm2 was used, as this is the highest pressure range of the calibration card.

As quantification of the peak pressures using PressureStat calibration card is subjective, it was necessary to obtain inter-observer agreement values. Inter-observer agreement is given as percentage of all the scoring done identically and within one range of PressureStat calibration card. Another measurement of agreement, adjusted for chance agreement, is the kappa coefficient. The weighted kappa coefficient has been proposed to adjust for the seriousness of different levels of disagreement (17). In this case, scoring identically was given a weight of I, scoring in a neighbouring pressure range was given a weight of 0.5 and a disagreement of more than one range was given a weight of zero.

The within-subject coefficient of variation was derived from 10 pressure readings in each of two controls and two diabetic patients. The inter-observer coefficient of variation for quantification of PressureStat footprints \vas derived from 20 different footprints. of which the highest pressure area was quantified by six independent observers (chiropodists). Before quantification the ob- servers practiced and standardized their method of pressure quantification using five different example footprints of which the pedobarograph pressures were known.

Statistical analysis

Statistical evaluation of sensitivity and specificity and calculations of agreement were done using SPSS and Excel software. A chi-squared test was used to test for significant changes after training. Weighted kappa coefficients were used to measure the level of inter-observer agreement. The weighted kappa coefficients were calculated using a method recommended for comparing level of agreement with categorical data [181.

Results

Before training, the percentage of regions scored identically on PressureStat and pedobarograph was low for all three observers, as well as scoring within one range of the calibration card . After training the scoring agreement of PressureStat observers with the pedobarograph improved substantially both for scoring identically and within one range ($P<0.0001$) and the inter-observer agreement was significantly improved for two of the three observer pairs ($P < 0.001$).

The weighted kappa coefficients before training indicated fair agreement for observer pairs A-B and A-C and moderate for B-C . These levels of agreement improved for all three observer pairs to good agreement for observer pairs A-B and B-C and to moderate agreement for observer pair A-C after training.

Sensitivities and specificities of PressureStat to identify high pressure areas as measured by the pedobarograph (> 12.3 kyjcm2) are shown in Table 2. Sensitivity improved substantially after training ($P < 0.01$). Specificity values were more than 90% for all three observers both before and after training.

The within-subject coefficient of variation was 20.6% for the optical pedobarograph and 12.7%,12.8% and 11.0% for PressureStat, respectively, for observers A, B and C, respectively, at the fifth metatarsal head. At the first metatarsal head the coefficients were 8.0% for the optical pedobarograph and 6.0%, 10.1% and 6.9% for observers A, B and C, respectively. The coefficients of variation at the fifth meta-tarsal were the highest of all areas, whereas at the first metatarsal head these were the lowest. The inter-observer coefficient of variation of the quantification of the highest pressure area by six independent observers was 5.9%, confirming a high level of agreement.

Discussion

Most pressure measurement devices are not routinely used as screening tools in daily clinical practice in the diabetic foot because of their expense (e.g. the Pedobarograph costs in the region of £12-15000) and sophistication. An inexpensive alternative method to measure plantar pressures might make this type of screening more widely available. PressureStat is potentially a welcome alternative and in this study we have tested its performance against the optical pedobarograph, the only pressure measurement device with an established threshold for ulceration.

The overall agreement of PressureStat assessment with pedobarographically measured pressures improved substantially after simple observer training, when the percentage of scoring the former within one range of the latter approached 90%. After training, scoring between PressureStat and pedobarograph was, if not identical, usually in a neighbouring range, with very small differences between the two devices, which were not clinically significant at high pressures, making the Podo- track a useful screening tool for detecting these.

Since the principal use of PressureStat would be as a screening tool for high plantar pressures, we did not consider accurate measurement of low pressures as clinically important as correct identification of high pressure areas. The highest pressure range on the calibration card will identify almost all patients at risk of foot ulceration, i.e. those patients with pedobarographically measured pressure > 12.3 kg/cm2 [4). There will also be a small number of false positives but these patients still have high plantar pressures (> 9 kg/cm2), and carry a certain degree of risk. Before any form of observer training, PressureStat was not sensitive enough to identify all high pressure areas, however, after training, more than 90% of all high pressure areas were identified correctly. Thus, these results suggest that a simple form of training is required before PressureStat can be used effectively as a screening tool for high plantar pressures.

The level of inter-observer agreement calculated as a kappa coefficient was increased substantially after training. Before training, levels of agreement were not acceptable (18).

Training of the observers in this study was done using the pressure readings of the optical pedobarograph, which will not be an option for the majority of future PressureStat users. A suggested training method is to use a sample set of PressureStat footprints, accompanied with their known pressures, to teach new users how to quantify pressures and to show examples of typical pressure distribution patterns. As a result of our study the manufacturer of PressureStat is developing a new information booklet, which will provide PressureStat sample footprints and information on how to quantify the pressure of a footprint.

With experience, the observers developed an optimal way for quantification: sufficient background light, PressureStat held at arm's length (to give the footprint a more equally graded grey print) with the calibration card a few centimetres from PressureStat print, so that the greyness of the print appears to merge with one of the pressure ranges of the calibration card. High pressure may exist in a very small spot, thus it is important to check dark grey-coloured areas for small darker spots, where pressure could be in the highest pressure range.

Using PressureStat takes about a minute, once patients have removed their shoes for routine examination. The short barefoot walk is unavoidable to make the footprint. It has previously been suggested that simple screening tests such as measurement of VPT can be used to identify patients at high risk of fool ulceration, who could then be further assessed by foot pressure measurement. We suggest that PressureStat could be used for this purpose.

In addition to its use in screening, PressureStat could also be useful as an educational tool for patients (19). Showing a print of their own foot with high pressure areas could improve high-risk patients' awareness of their need to take good care of their feet.

In conclusion, PressureStat is an inexpensive, highly sensitive and simple alternate device for measuring foot pressures. Our results show that a simple training of operators is required before it can be used effectively. Such training is recommended, before the device is used to screen diabetic patients at risk of foot ulceration in the clinic and the manufacturer is currently developing guidelines which may suffice.

Acknowledgements

This study was funded by a grant from the NHS R & D programme for people with physical and complex disabilities: PressureStat footprint mats were kindly provided by Medical Gait Technology BV.

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SOURCE: 1999 British Diabetic Association. Diabetic Medicine (pages 154-159)