Predictive Value of Foot Pressure Assessment as Part of a Population-Based Diabetes Disease Management Program

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OBJECTIVE — To evaluate the effectiveness of dynamic plantar pressure assessment to determine patients at high risk for neuropathic ulceration. In choosing the cut point, we looked for an optimum combination of sensitivity and specificity of plantar pressure to screen for neuropathic ulceration.

RESEARCH DESIGN AND METHODS — A total of 1,666 consecutive individuals with diabetes (50.3% male) presenting to a large urban managed care–based outpatient clinic were enrolled in this longitudinal 2-year outcome study. Patients received a standardized medical and musculoskeletal assessment at the time of enrollment, including evaluation in an onsite gait laboratory.

RESULTS — Of the entire population, 263 patients (15.8%) either presented with or developed an ulcer during the 24-month follow-up period. As expected, baseline peak plantar pressure was significantly higher in the ulcerated group than in the group who did not ulcerate (95.5 ± 26.4 vs. 85.1 ± 27.3 N/cm^2, $P < 0.001$). There was also a trend toward increased pressure with increasing numbers of foot deformities, as well as with increasing foot risk classification ($P = 0.0001$). Peak pressure was not a suitable diagnostic tool by itself to identify high-risk patients. After eliminating patients without loss of protective sensation, using receiver operating characteristic (ROC) analysis, the optimal cut point, as determined by a balance of sensitivity and specificity, was 87.5 N/cm^2, yielding a sensitivity of 63.5% and a specificity of 46.3%.

CONCLUSIONS — The data from this evaluation continue to support the notion that elevated foot pressure is an important risk factor for foot complications. However, the ROC analysis suggests that foot pressure is a poor tool by itself to predict foot ulcers.

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Neuropathic foot ulcers in individuals with diabetes are precipitated by a combination of pressure and cycles of repetitive stress (1,2). Identification, quantification, and mitigation of pressure and cycles of stress (activity) are thought to be important components in risk assessment and management of patients both before and after ulceration (3–8).

Several investigators have evaluated populations of high-risk patients to identify strata of foot pressures that might assist in assessment. Boulton et al. (9) reported that pressures were >110 N/cm^2 for every subject with a foot ulcer, suggesting a threshold pressure below which individuals would not ulcerate. Only 31% of individuals with diabetes without a history of ulceration demonstrated abnormal peak foot pressures based on the criteria of Boulton et al. However, it is not clear if a threshold pressure level exists because other reports have identified lower peak foot pressures at sites of neuropathic ulceration than those identified by Boulton et al. (8–10). For instance, diabetic subjects with peak plantar pressures >65 N/cm^2 have been shown to be at a six times greater risk for ulceration than subjects with pressures below this value (3). In a previous case-control study, our group was unable to identify a clear-cut threshold pressure that could be used to identify risk (11). Clearly, identification of an optimal peak plantar pressure cut point to help physicians stratify diabetic subjects by risk would be a valuable tool. Therefore, the purpose of this study was to determine, in a large patient sample, a practical combination of sensitivity and specificity of plantar pressure to screen for neuropathic ulceration.

RESEARCH DESIGN AND METHODS

— We implemented a diabetes disease management lower-extremity screening and treatment program in San Antonio, Texas, in collaboration with two large physician groups. Patients with diabetes were identified from inpatient and outpatient administrative databases to identify patients with any 250 ICD-9-CM (*International Classification of Diseases, Ninth Revision, Clinical Modification*) code. The diagnosis of diabetes was confirmed by review of medical records, review of laboratory data, or communication with the primary care physician. This report includes data from the first 1,666 patients screened and followed for a mean of 24 months (range 20–29).

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Abbreviations: OR, odds ratio; ROC, receiver operating characteristic.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Lower-extremity screening involved a review of the patient's past medical history and a comprehensive lower-extremity physical examination. Patients were screened to identify risk factors such as history of lower-extremity pathology (previous foot ulceration, amputation, Charcot arthropathy, lower-extremity arterial bypass, or lower-extremity angioplasty), peripheral sensory neuropathy, peripheral vascular disease, foot deformities, or abnormal foot pressures. A lower-extremity sensory examination was conducted using a 10-g Semmes-Weinstein monofilament (Touch-Test Sensory Evaluator; North Coast Medical, Morgan Hill, CA) and vibration perception threshold testing (VPT Tester; Salix Medical, San Antonio, TX) using the methods previously described by Armstrong et al. (12). A diagnosis of peripheral sensory neuropathy with loss of protective sensation was based on either the inability to accurately detect the 10 sites evaluated with the Semmes-Weinstein monofilament on each foot or a vibration perception threshold level of >25 V. Lower-extremity vascular status was assessed by palpating the dorsalis pedis and posterior tibial pulses. If any foot pulse was not palpable or if the patient had a history of intermittent claudication or rest pain, arterial Doppler studies were performed. A diagnosis of peripheral vascular disease was defined as a nonpalpable foot pulse and an ankle-brachial index in either foot of <0.80.

A musculoskeletal examination was performed by a staff podiatrist to identify the presence of hallux valgus, hammer or claw toes, tailor's bunions, hallux rigidus (dorsiflexion of the first metatarsophalangeal joint <50°), and ankle equinus (dorsiflexion <0°) (3,13). The presence of callus was identified on the sole and dorsum of the foot. In addition, peak foot pressures were assessed using Novel's EMED force-plate gait analysis system (Novell, Minneapolis, MN). Peak foot pressure was identified for each foot with a two-step method using previously described criteria (14,15). The system measures pressures at a resolution of ~4 pixels per square centimeter over the entire surface of contact. The location and value of the largest (peak) focal pressure was recorded. For selecting the optimal diagnostic cutoff points on the scale of measurement, receiver operating characteristic (ROC) curves were used (16).

Based on screening results, patients were then categorized by their risk of diabetic foot complications, and either preventative or acute care was provided based on specific risk-based protocols. Low-risk (foot risk category 0) patients were rescreened annually. Patients were considered high risk if they fell into categories 1 or higher. Risk category 1 included patients with neuropathy and no deformity. Category 2 included patients with neuropathy and deformity. Patients with a history of ulcer or amputation fell into risk category 3. This risk classification system is based on previously published systems by Armstrong et al., the International Working Group on the Diabetic Foot, and Peters and Lavery (17–19). Patients in the high-risk groups were scheduled for group diabetes education, evaluation by a pedorthist, and regular foot care by staff podiatrists. High-risk patients were scheduled for regular podiatry evaluation and treatment at least every 12 weeks. In addition, they were evaluated and fitted with therapeutic shoes and insoles by a certified pedorthist at the conclusion of their initial evaluation by the podiatrist. Insoles were replaced three times a year or as needed, and therapeutic shoes were replaced at least on a yearly basis.

We used a *t* test for independent samples to evaluate the difference between continuous variables between groups and a χ^2 test with 95% CIs and odds ratios (ORs) to evaluate dichotomous variables. To compare differences between race and peak plantar pressures, risk level and plantar pressures, and increasing plantar pressures based on numbers of deformity, we used an ANOVA with a post hoc Tukey Studentized Range Test for multiple comparisons. We also used a χ^2 test for trend (χ^2 trend) to assess the proportion of patients with increased plantar pressures who presented with one, two, and three forefoot deformities. For selecting the optimal diagnostic cutoff points on the scale of pressure measurement, ROC curves were used (16,20). This is a graphical method of representing sensitivity and specificity for a given test. For all analyses, we used an α of 0.05. All values are expressed as means ± SD (21).

RESULTS — Of the entire population, 263 patients (15.8%) developed an ulcer during the 24-month follow-up period. Characteristics of the study population are provided in Table 1. The distributions of pressure for patients with and without neuropathy show a bimodal distribution (Fig. 1). Individuals with neuropathy have a distribution that is significantly skewed to the right compared with the group without neuropathy (neuropathic group: skewness coefficient = 4, nonneuropathic group: coefficient = 0.1). We also evaluated differences in individuals with and without ulceration. As expected, peak plantar pressure was significantly higher in patients who developed ulcers during the follow-up period than in patients who did not develop ulcers (95.5 ± 26.4 vs. 85.1 ± 27.3 N/cm^2, $P < 0.001$).

We assessed peak plantar pressures based on level of foot risk using the International Diabetic Foot Risk Classification Scheme (18,19) (Fig. 2). Patients with neuropathy and deformity and patients with a history of ulceration or amputation had significantly higher peak plantar

Table 1—*Population descriptive characteristics*

N	1,666
Age (years)	69.1 ± 11.1
% male	50.4
Weight (kg)	83.8 ± 19.7
Duration of diabetes (years)	11.1 ± 9.5
Peak plantar pressure (N/cm^2)	86.6 ± 27.4
Vibration perception threshold (V)	22.5 ± 11.7

Data are means ± SD unless otherwise indicated.

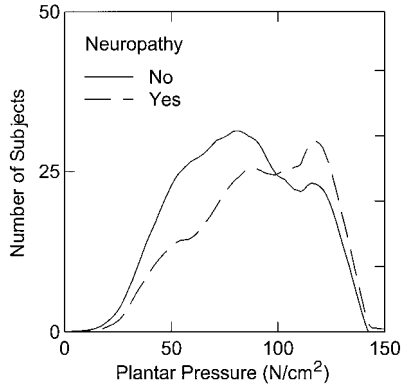

Figure 1—*Distribution of foot pressures in neuropathic and nonneuropathic patients. The neuropathic group was significantly skewed toward higher plantar pressures (skewness coefficient = 4.0, skewness = −0.4, SE of skewness = 0.1). The nonneuropathic group was not significantly skewed (coefficient = 0.1).*

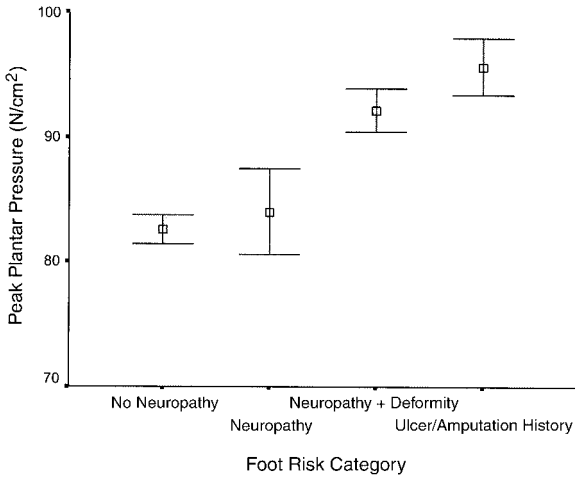

Figure 2—*Peak pressure by foot risk category. There was a trend toward higher foot pressures as the foot risk group classification increased in severity.*

pressures than patients without neuropathy ($P = 0.0001$ for both associations). However, we could not detect a significant difference in peak plantar pressure between patients with a history of ulceration or amputation (risk group 3) and patients who had neuropathy and deformity without an ulcer or amputation history (risk group 2) ($P = 0.64$). Patients with a history of ulceration or amputation had higher mean peak plantar pressures than patients with neuropathy alone ($P = 0.01$). These data are illustrated in Fig. 2.

The presence of structural forefoot deformity among patients with neuropathy had a strong correlation with elevated foot pressures. For instance, individuals with hallux valgus (bunion) deformity were 1.5 times more likely to have elevated foot pressures than individuals without deformity (41.2 vs. 32.6%, $P = 0.007$, OR 1.5, 95% CI 1.1–1.9). Patients with hallux limitus (limited motion at the metatarsophalangeal joint) (59.6 vs. 49.6%, $P = 0.005$, OR 1.5, 95% CI 1.1–2.0) and hammer or claw toe deformity (45.0 vs. 35.7%, $P = 0.002$, OR 1.5, 95% CI 1.1–1.9) were also more likely to have elevated pressures than individuals without these deformities.

It appears that multiple deformities may lead to increased pressures. There was a significant trend toward higher plantar foot pressures as the number of forefoot deformities increased (χ^2 trend = 18.6, $P = 0.0001$). Furthermore, the magnitude of plantar pressure increased with increasing numbers of deformities (Fig. 3).

The presence or absence of callus was also a factor associated with elevated pressure. In this population, individuals with callus had elevated foot pressures 2.4 times more frequently than individuals without callus (65.9 vs. 44.2%, $P = 0.0001$, OR 2.4, 95% CI 1.9–3.2). Individuals with callus had 18.2% higher plantar forefoot pressure than individuals presenting without callus (92.7 ± 26.4 vs. 78.4 ± 26.4 N/cm^2, $P = 0.0001$).

After eliminating patients without a loss of protective sensation, using ROC analysis, the optimal cut point, as determined by a balance of sensitivity and specificity, was 87.5 N/cm^2, yielding a sensitivity of 63.5% and a specificity of 46.3% (Fig. 4). At peak pressures >87.5 N/cm^2, the positive predictive value was 17.4% and the negative predictive value was 90.4% (Fig. 5). Patients with pressures >87.5 N/cm^2 were twice as likely to develop an ulcer in the follow-up period (17.4 vs. 9.6%, $P = 0.0001$, OR 2.0, 95% CI 1.4–2.9). A useful ROC curve should look like a hump up toward the upper left corner of the curve, and the area under the ROC curve should be significantly larger than 50%. The ROC curve from this study (Fig. 4) looks like a 45° line, and the area under the ROC curve is only 57%.

CONCLUSIONS — The data from this evaluation continue to support the notion that elevated foot pressure is an important risk factor for foot complications. In our study, individuals with diabetes and elevated foot pressures were two times more likely to develop a foot ulcer than subjects with lower foot pressures. As expected, foot pressures were higher in individuals with neuropathy, deformity, callus, and previous foot ulceration or amputation (22–25). However, the ROC curve suggests that foot pressure is a poor tool by itself to predict foot ulcers.

As stated above, data in this article indicate that among individuals with diabetes and sensory neuropathy, peak plantar pressures alone are not an especially valuable tool for predicting foot ulceration. Sensitivities and specificities approaching 64 and 40% (Fig. 5) for peak pressures in the range described by our group and other authors as pathological suggest strongly that pressure cannot be the sole factor associated with development of skin breakdown. Clearly, there are other factors at play that increase predictive potential when combined with plantar foot pressure assessment. We think that issues such as pressure time integral (the time that the patient spends at a point of high pressure) or activity level (the number of repetitions at the point of high pressure per unit time) may

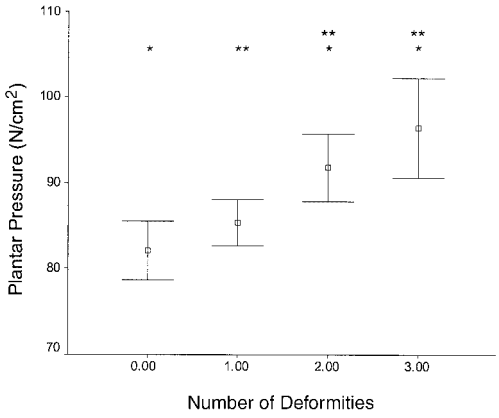

Figure 3—*The influence of forefoot deformity on plantar pressure. *Pressure with 0 deformities < pressure with 2 deformities,* P = *0.001; 0 deformities < 3 deformities,* P = *0.0001. **Pressure with 1 deformity < pressure with 2 deformities:* P = *0.04; 1 deformity < 3 deformities:* P = *0.005.*

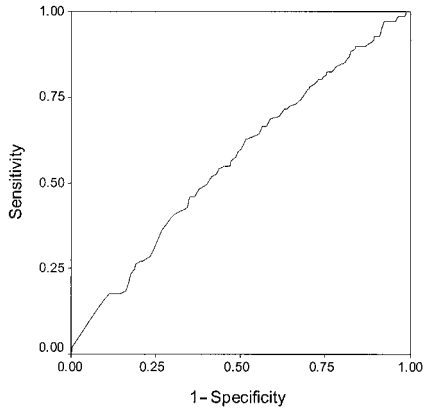

Figure 4—*ROC curve for neuropathic subjects with diabetes. Area under the curve = 0.57, P = 0.03 (95% CI 0.51–0.62).*

be candidates for increasing predictive potential when combined with plantar pressure.

There are a number of factors that contribute to the development of foot ulceration that we were unable to capture. The combination of neuropathy, repetitive injury, and elevated pressure and shear forces on the sole of the foot often results in unrecognized injury, inflammation, and damage to sequential tissue layers (26). Unfortunately, there are very few data to describe the effect of shear forces on the sole of the foot or to quantify the number of repetitive cycles of injury (foot steps per day) that put a patient at risk for ulceration. Without these additional factors (as mentioned before), the independent role of foot pressures remains incomplete.

Most prevention treatments have logically focused on reduction of pressure because this has been the easiest factor to evaluate (2,7,13). Evaluating and modifying activity (steps per unit time) has generally not been addressed in any widespread fashion. The number of cycles of stress may be a more important factor than absolute pressure or sheer. Perhaps a metric combining pressure, shear and activity volume in the high-risk neuropathic foot will prove to be a more useful instrument. With the advent of computerized activity monitors, this information can be readily available to most consumers. This type of dynamic data would also allow patients to monitor their activity just as they might check their blood glucose on a home monitoring device. We believe that future studies evaluating large samples of patients using plantar pressure assessment and activity monitoring might yield a more clinically meaningful prognostic instrument as well as an additional tool for prevention.

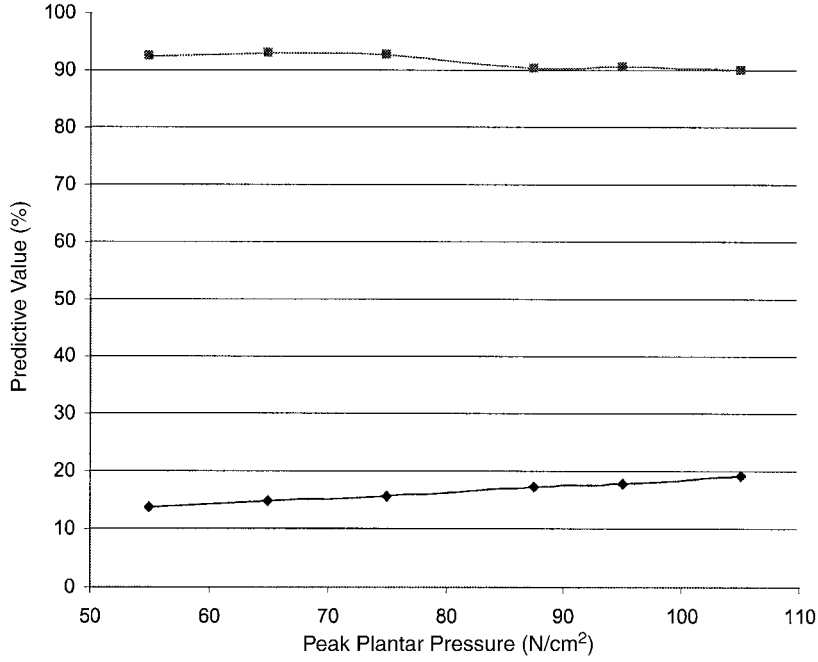

Figure 5—*Plantar foot pressures and neuropathic foot ulceration: positive and negative predictive values. ◆, Positive predictive value (%); ■, negative predictive value (%). Predictive value of a positive test is the proportion of patients with a positive diagnosis who develop the outcome (ulcer). This measures how well the diagnostic tool predicts the outcome. It appears that positive predictive value is poor. Predictive value of a negative test is the proportion of patients with a negative diagnosis who do not develop the outcome. The negative predictive value is good. This supports the conclusion that high peak pressure alone is not useful for screening high-risk patients.*

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