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American Society of Biomechanics Clinical Biomechanics Award 2012: Plantar shear stress distributions in diabetic patients with and without neuropathy

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ABSTRACT

Background: The exact pathology of diabetic foot ulcers remains to be resolved. Evidence suggests that plantar shear forces play a major role in diabetic ulceration. Unfortunately, only a few manuscripts exist on the clinical implications of plantar shear. The purpose of this study was to compare global and regional peak plantar stress values in three groups; diabetic patients with neuropathy, diabetic patients without neuropathy and healthy control subjects.
Methods: Fourteen diabetic neuropathic patients, 14 non-neuropathic diabetic control and 11 non-diabetic control subjects were recruited. Subjects walked on a custom-built stress plate that quantified plantar pressures and shear. Four stress variables were analyzed; peak pressure, peak shear, peak pressure-time and shear-time integral.
Findings: Global peak values of peak shear ($p = 0.039$), shear-time integral ($p = 0.002$) and pressure-time integral ($p = 0.003$) were significantly higher in the diabetic neuropathic group. The local peak shear stress and shear-time integral were also significantly higher in diabetic neuropathic patients compared to both control groups, in particular, at the hallux and central forefoot. The local peak pressure and pressure-time integral were significantly different between the three groups at the medial and lateral forefoot.
Interpretation: Plantar shear and shear-time integral magnitudes were elevated in diabetic patients with peripheral neuropathy, which indicates the potential clinical significance of these factors in ulceration. It is thought that further investigation of plantar shear would lead to a better understanding of ulceration pathomechanics, which in turn will assist researchers in developing more effective preventive devices and strategies.

1. Introduction

The estimated annual cost of diabetic foot ulcers and related amputations to the US healthcare system is over $30 billion (Rogers et al., 2008). Each year about 100,000 lower extremity amputations are performed on Americans with diabetes (Bloomgarden, 2008). Diabetic foot complications place a major burden not only on the US healthcare system but also on amputees' quality of life.

The lifetime risk of developing a foot ulcer for diabetic patients is between 15 and 25% (Lavery et al., 2003a; Reiber, 1996). Diabetic patients with peripheral neuropathy are four times as likely to develop foot ulcers as those without neuropathy (Frykberg et al., 1998). In a cohort of 469 diabetic patients, the cumulative incidence of ulceration was 20% and 3%, for individuals with and without peripheral neuropathy, respectively (Young et al., 1994). The exact pathology of diabetic foot ulcers is still not known. It is believed however that repetitive moderate mechanical stresses, in the presence of peripheral neuropathy, are the primary etiologic factors in plantar ulceration (Brand, 1978; Delbridge et al., 1985; Hall and Brand, 1979). Among these mechanical factors, horizontal component of the ground reaction forces (GRFs), namely shear forces, and their relevance to diabetic ulcers have not been adequately studied. This is related to the technical challenges in the measurement of frictional shear force distribution under the foot (Perry et al., 2002). On the other hand, preliminary studies on plantar shear stresses have demonstrated the potential clinical significance of frictional shear in the pathology of diabetic foot lesions (Pollard and Le Quesne, 1983; Yavuz et al., 2007a, 2008). Furthermore, in an animal model application of frictional shear forces accelerated tissue breakdown (Goldstein and Sanders, 1998). Excessive frictional shear forces that act on soft tissue lead to hyperkeratosis (i.e. callosities), which have been previously associated with ulceration (Goldblum and Piper, 1954; MacKenzie, 1974; Murray et al., 1996).

In order to design better preventive devices and care, it is essential to understand the actual pathway to diabetic ulceration. Investigators deemed elevated plantar pressures responsible for diabetic foot lesions. However, efforts towards identifying a threshold pressure value for ulceration have failed. As a result pressure has been labeled as a "poor tool" in ulcer prediction (Armstrong et al., 1998a; Lavery et al., 2003b). Murray et al. (1996) reported that out of other risk factors,

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such as the presence of calluses, high plantar pressures were the least predictive of ulcer formation. Therapeutic footwear, designed to redistribute pressures on the sole of the foot have been found only "meagerly" effective in preventing ulcer occurrences in a systematic review (Bus et al., 2008).

Therefore, revisiting the complicated pathology with a more extensive approach is crucial in order to minimize ulceration rates. Thus, the purpose of this study was to explore the clinical significance of plantar shear as well as pressure in ulceration by comparing global and regional stress data in diabetic neuropathic, diabetic non-neuropathic and a healthy control group. To our knowledge, this is also the first study that quantified plantar shear stresses in a diabetic non-neuropathic cohort that served as a control group.

2. Methods

Informed consent was obtained from 28 diabetic patients and 11 healthy volunteers who wanted to participate in the study, which was approved by the Institutional Review Board of the Kent State University College of Podiatric Medicine. The diabetic patients consisted of fourteen individuals with peripheral neuropathy and fourteen individuals without neuropathy. Exclusion criteria were having foot pain, prior surgeries in both feet and gross foot deformities. Inclusion criterion was the ability to walk along a 3.6 m walkway multiple times without assistance.

The patients were recruited from endocrinology and/or podiatry departments of various hospitals and clinics in the Greater Cleveland area (Ohio, USA). Peripheral neuropathy was assessed with a Biothesiometer (Biomedical Instrument Company, OH, USA) according to the task force report of the American Diabetes Association (Boulton et al., 2008). A vibration perception threshold of 25 V was used to identify neuropathy. Based on neuropathy testing, diabetic patients were categorized as either neuropathic or non-neuropathic. The first cohort comprised the diabetic neuropathic group (DN) whereas the second cohort comprised the diabetic control group (DC). Group healthy control (HC) comprised healthy control individuals who were free of foot pain, prior surgeries and major foot deformities (Table 1).

The subjects were asked to walk at self-selected speeds multiple times on a custom-built pressure-shear plate, which was set flush on the 3.6 meter walkway. The device measures 11.4 cm × 14.2 cm with 1.5 mm space in between each of the 80 sensors that complement the plate. Each sensor measured 1.25 cm × 1.25 cm generating an effective surface area of 1.56 cm^2. Eighty transducers were arranged in an 8 × 10 array, which looked like a checker-board in appearance. Further specifications of the plate have been explained elsewhere (Yavuz et al., 2007b).

Data from three trials were averaged and used in the statistical analysis. Data was collected implementing the two-step method, which has been shown to produce similar pressure values to that of the mid-gait method (Bryant et al., 1999). The subjects were first asked to walk on the walkway a few times at self-selected gait speeds and their average step length was visually determined. Then the subjects were asked to position themselves about two steps before the stress plate. The volunteers then took a step with the non-dominant foot so that their dominant foot (in the case of a previous dominant foot surgery, vice versa) was on the stress plate. Subjects practiced this routine multiple times while the starting distance from the plate was adjusted as necessary until the subjects had their second step (forefoot) on the stress plate.

Table 1
Characteristics of subjects enrolled in the study. Values are mean (standard deviation), where applicable.

	DN	DC	HC
N of subjects	14	14	11
Gender	2 f. 12 m	9 f. 5 m	7 f. 4 m
Age (years)	64.8 (6.8)	52.4 (12.9)	65.5 (6.0)
BMI	32.0 (5.1)	28.9 (7.4)	27.8 (5.9)
Duration of diabetes (years)	13.1 (11.4)	14.2 (11.5)	n/a
Type 1/Type 2 diabetes	2/12	5/9	n/a
Vibration perception (V)	35.6 (9.1)	11.7 (4.9)	n/a
Average gait speed (m/s)	0.81 (0.24)	0.88 (0.15)	1.17 (0.15)

Four major stress variables were identified in each subject; peak pressure (PP), peak shear (PS), peak pressure-time integral (PTI) and peak shear-time integral (STI). Time-integral values were calculated by implementation of the trapezoidal rule over the stress-time curves using 99 subdivisions for each sensor. Then, spatial and temporal maximum values were identified as PTI or STI. Data analyses were based on global peak and regional peak values. For the regional stress analysis, pressure and shear profiles of the enrollees were masked into five forefoot regions by a custom-written Matlab (Mathworks, MA, USA) script; hallux, lesser toes, medial forefoot (first metatarsal head), central forefoot (second and third metatarsal heads) and lateral forefoot (fourth and fifth metatarsal heads). The forefoot was selected as the region of interest since most plantar ulcers develop in this area (Caselli et al., 2002; Oyibo et al., 2001).

Group characteristics were analyzed using analysis of variance (ANOVA). Plantar stress values were analyzed using ANOVA (global stress values) or analysis of covariance (ANCOVA) (global and regional stress values). While analyzing regional stress values, gait speed was used as the covariate. Significant group effects identified by ANOVA were further examined using Bonferroni post-hoc comparisons. For significant group effects identified by ANCOVA, simple linear contrasts (DN vs. DC, and DN vs. HC) were carried out. For all analyses, alpha was set to ≤0.05. IBM SPSS statistical software (v20, SPSS, Inc., Chicago, IL, USA) was used to analyze data.

3. Results

The groups differed significantly on gait speed ($P < .001$) and age ($P = .004$), but not body-mass index (BMI, $p = .214$). HC subjects walked about 25% faster than DC subjects at 1.17 m/s ($P < .001$), and about 30% faster than DN subjects ($P = .001$). The mean age of diabetic neuropathic patients was significantly higher than the mean age of diabetic control patients ($P = .003$); the mean age of DN and HC subjects was not significantly different. As expected, vibration perception threshold was significantly higher in DN subjects compared to DC subjects ($P < .001$).

3.1. Global analyses

ANOVAs performed on the global data showed significant differences (Table 2) on PS, PTI, and STI ($P < 0.05$), but not PP ($P > 0.05$). For PS, STI, and PTI, differences between the DN and HC groups were significant ($P = .035$, .006, and .003, respectively), as assessed by Bonferroni post-hoc comparisons. For PTI, the difference between DN and DC groups was also significant ($P = .010$). When age and BMI were added separately as covariates to the analyses, neither accounted for a significant proportion of the variance, and the group differences for PS, STI, and PTI remained significant. When gait speed was added to the analyses as a covariate, it predicted a significant amount of the variance in PS and STI (14.6% and 17.6%, respectively), but not PP and

Table 2
Global peak results for three subject groups. Values are means (standard deviation).

Variable	DN	DC	HC	P	Partial eta squared
PP (kPa)	591.7 (113.1)	506.2 (141.7)	481.1 (109.8)	0.069	0.138
PS (kPa)	91.3 (29.0)	82.0 (26.4)	64.6 (15.7)	0.039*	0.165
STI (kPa·s)	34.4 (19.2)	20.3 (5.1)	18.2 (2.8)	0.002*	0.282
PTI (kPa·s)	234.7 (72.3)	167.4 (53.3)	154.0 (32.7)	0.003*	0.299

* Denotes statistically significant difference.