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# Utilization of the foot load monitor for evaluating deep plantar tissue stresses in patients with diabetes: Proof-of-concept studies

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ABSTRACT

The purposes of the present study were to (1) determine the internal plantar mechanical stresses in diabetic and healthy subjects during everyday activities, and (2) identify stress parameters potentially capable of distinguishing between diabetic and healthy subjects. A self-designed, portable, real-time and subject-specific *foot load monitor* which employs the Hertz contact theory was utilized to determine the internal dynamic plantar tissue stresses in 10 diabetic patients and 6 healthy subjects during free walking and outdoors stair climbing. Internal stress parameters and average stress-doses were evaluated, and the results obtained from the two groups were compared. Internal plantar stresses and averaged stress-doses during free walking and outdoors stairs climbing in the diabetic group were 2.5–5.5-fold higher than in the healthy group ($p < 0.001$; stair climbing comparisons incorporated data from five diabetic patients). The interfacial pressures measured during free walking were slightly higher (~1.5-fold) in the diabetic group ($p < 0.05$), but there was no significant difference between the two groups during stairs climbing. We conclude that during walking and stair climbing, internal plantar tissue stresses are considerably higher than foot–shoe interface pressures, and in diabetic patients, internal stresses substantially exceed the levels in healthy. The proposed method can be used for rating performances or design of footwear for protecting sub-dermal plantar tissues in patients who are at risk for developing foot ulcers. It may also be helpful in providing biofeedback to neuropathic diabetic patients.



## 1. Introduction

Foot ulcers are a well-recognized complication of diabetes, with cumulative lifetime incidence reaching as high as 25% [1]. Between 15% and 27% of all ulcers result in bone removal [2]. World Health Organizations define peripheral neuropathy, foot skeletal deformities, elevated plantar pressures, peripheral vascular disease and history of previous ulcers or amputation as being high-risk conditions for foot ulceration [1,3,4]. Singh et al. [3] and Lavery et al. [5] concluded that the risk of foot ulceration may be reduced by patient screening for early identification and close monitoring of those at high risk. Such pinpointed screening also led to fewer hospitalizations and shorter hospital stays [5]. Professional organizations specifically recommend fitting high-risk patients with proper footwear to reduce elevated plantar pressures and to deal with foot deformities [3].

Since there is currently no acceptable injury threshold that can reliably predict ulcer formation [6], researchers are looking into other injury predictors, such as stress distributions at deep layers of the plantar tissue. Delbridge et al. [7] and Gefen [8] hypothesized that stiffening of plantar tissue due to hyperglycemia-induced collagen changes causes pronounced internal stresses under bony prominences. Thus, it is very likely that severe ulcers do not begin on the skin surface, but rather in deeper, sub-dermal tissue layers. As such, it is essential to develop a real-time patient-specific monitoring method which enables quantification of internal plantar tissue stresses in addition to the concomitant interfacial pressures.

The hypothesis of initial ulcer onset in deep tissue layers was supported by two studies using commercial software for finite element (FE) modeling of normal and diabetic feet [8,9]. The issue is attracting growing attention, manifested, e.g. in two presentations at the recent Orthopaedic Research Society meeting (2008) where FE models of the foot were utilized to investigate the complexity of the relationship between plantar loading and internal soft tissue stresses in the foot [10,11]. The hypothesis

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was not addressed in clinical trials though, because dynamic patient-specific modeling by means of commercial FE codes is not clinically applicable due to the complexity of depicting the human foot geometry and tissue mechanical properties. A real-time patient-specific FE code which calculates internal plantar tissue strains/stresses was previously developed in our lab [12], but it requires the computer power of a PC laptop, which precludes its use during everyday activities. The alternative is to use analytical methods (i.e. closed mathematical solutions) to evaluate internal mechanical stress distributions in the plantar foot. Zou et al. [13] recently developed an analytical method to assess three-dimensional mechanical stress components as well as principal and shear stresses in the subsurface of the plantar tissue; however, their method is not suitable for a portable device, i.e. for monitoring everyday activities, because it requires a pressure plate. Moreover, the method of Zou et al. [13] does not include any specific measures related to the patient's individual foot geometry or to patient-specific plantar pad mechanical properties. Finally, neither Zou et al. [13], nor others compared internal stresses in the plantar pad between patients with diabetes and healthy subjects.

Another potential analytical method for determining internal mechanical conditions in the plantar foot is based on the Hertz contact theory. The relative simplicity of calculations with this theory allows to employ a pocket PC for evaluating internal plantar stress in real-time. The Hertz contact theory was previously applied to evaluate pressures between the foot and a midsole [14]. In this proof-of-concept study, we now applied it to determine and compare internal plantar stresses in diabetic and healthy subjects during everyday activities, and to identify stress parameters that could be potentially used for distinguishing between these groups.

## 2. Methods

### 2.1. Foot load monitor

We recently developed a foot load monitor device to evaluate dynamic deep plantar tissue stresses occurring at the regions of contact between the plantar tissue and the foot's bony prominences, i.e. the calcaneus and metatarsal heads. Detailed descriptions of the biomechanical theory implemented in this monitor, its hardware and software components, calibration, validation studies against a physical foot phantom, and inter-/intra-subject variability studies are provided elsewhere [15]. The present paper is focused on human studies with this monitor in the clinical setting, as follows.

For conducting clinical studies, it was important that this monitor would be subject-specific and that it could estimate dynamic deep plantar stresses in real-time, for possibly providing biofeedback to the patient or immediate feedback to interventions made by the clinician. In addition, the monitor should be cost-effective, suitable for patient screening in large populations, and be able to perform stress evaluations both indoors and outdoors. Accordingly, we selected the Hertz contact theory [16] for our biomechanical model, as it provides *analytical* solutions to stress distributions in tissues, that is, it needs relatively low computer power.

To review the biomechanical model implemented in the foot load monitor briefly, the Hertz theory represents tissues as interfacing elastic bodies. It assumes that one of the interfacing bodies has a spherical surface ("bone") and the other is a semi-infinite elastic bulk ("plantar tissue") [16–19]. Several other assumptions are made regarding the mechanical loading state between the two bodies and their mechanical properties, as detailed in [15]. These assumptions do not, however, adequately accommodate real-life conditions relevant to the contact problem between plantar tissue and foot bones, and thus, the biomechanical model of the bone/plantar tissue interaction requires some adjustments [15]. Plantar tissue is idealized as elastic incompressible semi-infinite bulk (with mechanical properties measured by means of indentation), which is penetrated by a sphere with the bone's radius of curvature (measured from X-ray) and its mechanical properties [15]. Additionally, the reaction force under the bony prominence is assumed to be equal to the compression force that the bone loads onto the plantar tissue [16]. Stress analyses are made over a small region of interest (ROI) defined around the lowest contact surface within the plantar pad. Moreover, based on previous studies, the theory is extended to include large deformations within the ROI [15]. The theoretical geometric limitation and simplification of the real mechanical properties cause some errors in the stress evaluations and it was therefore essential to find correction factors for minimizing these errors, as reported in detail in [15].

For clinical application, our foot load monitor requires three input parameters (Fig. 1): the bony prominence's radius of curvature of the individual (measured from a medio-lateral X-ray), the thickness of the plantar pad underneath the bony prominence (measured from the same X-ray), and an effective elastic modulus of the plantar pad (measured by indentation *in vivo*). A set of three sensors (FlexiForce, Tekscan Co., Boston, USA) is attached at the foot–shoe interface under the bony prominence to measure real-time reaction forces during standing or walking. For each reaction force measurement, the foot load monitor provides, in real-time, the internal stress distribution maps and peak values of compression, tension, shear and von Mises stresses. Furthermore, the foot load monitor computes the mean von Mises stresses and principal stresses over the ROI, as well as the average stress-doses (i.e., stress integrals over the stance phase time) of the principal and von Mises stresses over the contact axis (between the bone and soft tissue) and the symmetry axis of the ROI.

For assessing the stress states in deep plantar tissue of individuals during ordinary activities of daily living (i.e., climbing stairs and walking outdoors), we built a portable real-time subject-specific foot load monitor prototype as described in [15]. Briefly, the monitor operates on a portable digital assistant platform (Dell, Axim x51v) using a LabView 8 PDA module (National Instruments Co.). The monitor's quantitative output data are peak compression, peak tension and peak von Mises plantar tissue stresses which are all saved in the device. The foot load monitor was tested in comprehensive validation studies described in detail in [15]. For example, an experimental apparatus that included a large elastic bulk and rigid half-sphere, with conditions close to the geometrical, mechanical and loading theoretical limitations of the Hertz theory, was built, and tested against the monitor predictions for that case. The relative error between the measured (by sensors) and predicted (by our foot load monitor) averaged compression stress at the contact region was $<13\%$ [15]. In addition, we derived calibration factors that better fit the monitor to real-life conditions, using foot phantom studies designed to find correction factors for errors resulting from geometric limitations of the Hertz theory [15]. Another correction factor was needed for errors in estimating the effective planar pad elastic modulus using tissue indentation [15].

### 2.2. Experimental protocol

This study was designed as a proof-of-concept, prospective two-cohort trial, with a group of healthy subjects and a group of patients with diabetes (Table 1). Group ages, body masses and body mass index (BMI) values were not matched, as we decided not to expose healthy individuals to ionizing radiation for determining the bone's radius of curvature and plantar tissue thickness. Hence, in order to obtain these data from healthy we recruited a convenience sample of subjects who held X-rays of their foot a-priori (to rule out ankle ligament tears or foot fractures following an ankle sprain or fall within less than 2 years prior to the present study). This healthy group included six subjects (four males and two females) between 25 and 37 years of age, with body mass of $71 \pm 18$ kg (mean $\pm$ standard deviation) and BMI ranging between 17 and 32 kg/m$^2$. The patient group included 10 subjects (five males and five females) between 58 and 79 years of age, with body mass of $83 \pm 13$ kg and BMI ranging between 25.6 and 39.5 kg/m$^2$. The study, conducted at the Dana Gait Laboratory of Tel-Aviv Sourasky Medical Center, was approved by the institutional ethics committee, and all subjects signed an informed consent form. Inclusion criteria for the patient group were type-1 or type-2 diabetes for a period of at least 5 years, with or without peripheral neuropathy. Patients with any foot deformities, a previous foot surgery or an active foot ulcer were excluded.

Our present studies focused on the interaction between the calcaneus and the plantar pad around it. The diabetic subjects were first tested for loss of "protective sensation" using the 5.07/10g Semmes–Weinstein monofilament (Stoelting, Co., IL, USA). The protective sensation is a threshold of insensitivity that puts patients with diabetes at risk for developing plantar ulcers [20,21]. The 5.07/10g Semmes–Weinstein device was found to be a good tool for identifying loss of protective sensation [20,21]. We followed Mueller's method of using the monofilament (detailed in [20]). Due to technological limitations, only one foot was tested with our foot load monitor for each subject. The tested foot was chosen according to the result of the sensation test as follows: first priority was given to the foot with higher insensitivity. When both feet had the same sensation result, the studied foot was chosen randomly. Next, medio-lateral X-ray image of the tested foot was taken (for the diabetic group) and the effective elastic modulus was evaluated using indentation using the protocol of Yarnitzky et al. [12]. A set of three sensors was attached under the subject's calcaneus to measure the reaction force during activity. Each subject walked freely, at his/her own customary walking speed, on a flat surface for 2 min, and was then asked to climb up and down an ordinary 10-stair staircase (stair height, depth, and width were approximately 17, 28, and 120 cm, respectively). Subjects from both groups used their own customary walking shoes during all trials.

In order to validate the plantar pressures measured by our device, we also measured plantar pressures during free walking using the Pedar system (Novel Co., Munich, Germany) in separate experiments involving the same subjects. We compared the mean plantar pressure under the calcaneus measured by Pedar to the mean plantar pressure measured by the sensors of the foot load monitor per each subject in order to detect potential significant differences using a two-tailed paired *t*-test. Statistical significance was set at the 0.05 level.

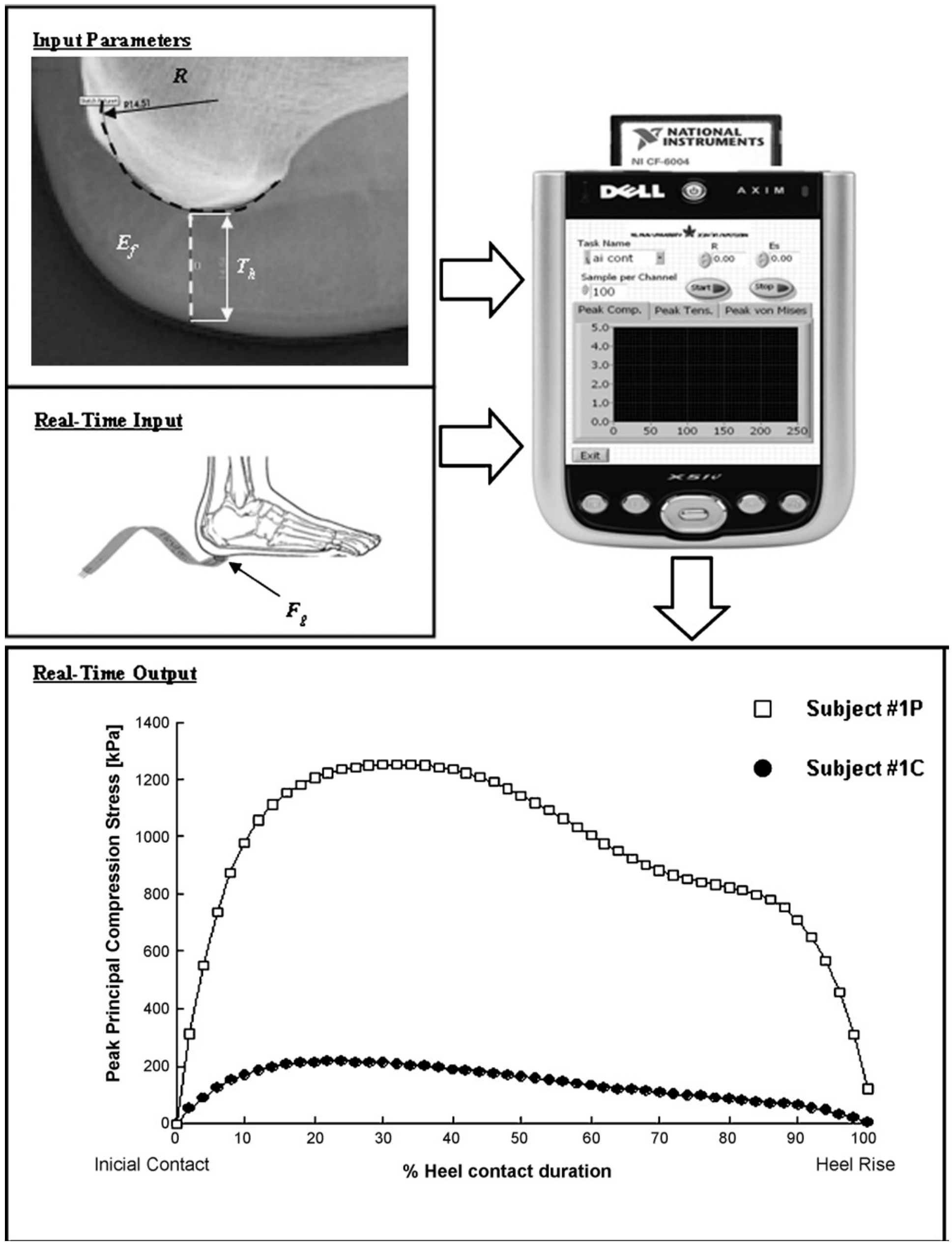


**Fig. 1.** Technical operation of the *foot load monitor*. For each new patient we enter the following input parameters: (i) the bony prominence's radius of curvature ($R$), (ii) plantar pad maximal thickness under the prominence ($T_h$), and (iii) an effective elastic modulus of the plantar pad ($E_f$). A set of force sensors measures the foot-ground reaction force ($F_g$) and sends the data to the monitor, which processes it in real-time. The monitor presents online: (i) stress distribution maps of compression, tension, shear and von Mises stresses, (ii) peak value of each stress component, and (iii) average stress-doses of the principal and von Mises stresses over the contact and symmetry axes. The bottom graph is an example of results obtained for peak internal plantar tissue compression stresses under the calcaneus during free walking of a healthy subject (black circle) and of a diabetic subject (white square).

*2.3. Data analysis*

First, we located the peak plantar pressure for each gait cycle in the dataset of each participant. We then calculated the prevalence of these maximal values and chose ten representative cycles for each subject accordingly. The group comparisons focused on six stress parameters: peak plantar pressure, peak internal principal compression stress, peak internal principal tension stress, peak internal cylindrical shear stress, peak internal von Mises stress and mean internal von Mises stress (over the area of the ROI). In addition, we conducted a secondary comparison based on two stress-dose (stress integral over time) parameters [12]: mean von Mises stress-dose over the contact axis and mean von Mises stress-dose over the symmetry axis. We used a two-tailed unpaired *t*-test to determine significant differences for each parameter between the groups.

Use of the foot load monitor outdoors during stair climbing yielded internal plantar stress data of sufficient quality for analysis from five diabetic subjects (subjects #1P, #2P, #4P, #5P and #8P, Table 1); the five datasets that were excluded were treated so because of high noise in the foot-ground force signal, associated with a very slow or insecure stair climbing. Analyses of measured plantar pressures and calculated internal stresses during stair-climbing included all the measured cycles. Although no single repeatable pattern of loading during stairs climbing was found across subjects/patients, it is possible to compare the maximal value of each stress parameter since it is an indicator of full loading. Therefore, we used the same statistical method to compare between the healthy and diabetic groups for each assessed parameter.

We also conducted intra-group comparisons of the stress parameters detailed above between diabetic subjects with and without loss of "protective sensation", using a two-tailed unpaired *t*-test.

**Table 1**
Physical characteristics of the study participants.

| | Gender (M/F) | Age [years] | BMI [kg/m$^2$] | Calcaneus radius of curvature [mm] | Thickness of plantar pad under the heel [mm] | Measured elastic modulus of the plantar pad [kPa] | Plantar pad effective elastic modulus* [kPa] | Loss of protective sensation (Y/N)** |
|---|---|---|---|---|---|---|---|---|
| Control group | | | | | | | | |
| Subject #1C | M | 26 | 24.7 | 11 | 20 | 162 | 1,677 | – |
| Subject #2C | M | 37 | 22.5 | 15 | 18 | 150 | 3,081 | – |
| Subject #3C | M | 36 | 32 | 15 | 15 | 107 | 3,113 | – |
| Subject #4C | F | 25 | 17 | 6.5 | 16 | 161 | 1,062 | – |
| Subject #5C | M | 36 | 22.4 | 10.2 | 16 | 191 | 2,300 | – |
| Subject #6C | F | 25 | 22.6 | 13.2 | 14 | 176 | 4,929 | – |
| Group mean (standard deviation) | | 31 (6) | 23.5 (4.5) | 11.8 (3) | 16.5 (2) | 158 (26) | 2,694 (1237) | |
| Patient group | | | | | | | | |
| Subject #1P | M | 58 | 39.5 | 15.6 | 18.5 | 1140 | 23,858 | Y |
| Subject #2P | M | 69 | 25.6 | 16 | 18 | 439 | 9,196 | N |
| Subject #3P | M | 76 | 37 | 8.3 | 18.7 | 378 | 2,924 | Y |
| Subject #4P | M | 78 | 26.2 | 12.3 | 14.3 | 415 | 9,004 | Y |
| Subject #5P | M | 59 | 26.3 | 22.7 | 14.7 | 402 | 29,162 | N |
| Subject #6P | F | 66 | 30.4 | 9.1 | 13.4 | 711 | 10,306 | N |
| Subject #7P | F | 74 | 31.2 | 15.4 | 15.3 | 434 | 12,740 | N |
| Subject #8P | F | 79 | 30.3 | 13 | 14 | 374 | 9,492 | N |
| Subject #9P | F | 72 | 28.4 | 14.5 | 14.5 | 189 | 5,467 | N |
| Subject #10P | F | 62 | 34.5 | 14 | 15.5 | 291 | 6,953 | Y |
| Group mean (standard deviation) | | 69 (8)§§ | 30.9 (4.7)§ | 14.1 (4) N.S. | 15.7 (2) N.S. | 477 (268)§§ | 11,910 (8,247)§§ | |

N.S.: not significantly different from controls ($p \geq 0.05$).
* After correction of the indentation test to consider large deformations, friction, layered tissue structure and finite thickness as detailed in [15].
** According to a physician's examination using the Semmes–Weinstein 5.07/10g monofilament [20,21].
§ Significantly different with respect to controls: $p < 0.05$.
§§ Significantly different with respect to controls: $p < 0.01$.

## 3. Results

The age, BMI, geometric and mechanical parameters for all subjects are specified in Table 1. The radii of curvature of the calcaneus bone and thicknesses of the plantar pad were statistically indistinguishable between the diabetic and control groups ($p = 0.24$ and $p = 0.47$, respectively, in two-tailed unpaired *t*-tests). Four diabetic patients demonstrated loss of protective sensation (Table 1). The mean effective plantar pad elastic modulus of the diabetic group was ~4-fold higher than of the healthy ($p < 0.01$). The plantar pressures under the heel during free walking measured by our foot load monitor sensors and the Pedar system were similar (differences within a ±10% range).

During free walking, predicted internal stresses in the diabetic group were significantly higher ($p < 0.001$) than those of the healthy (Table 2). In addition, plantar pressures under the calcaneus of the diabetic patients were slightly higher than those of the healthy ($p < 0.05$), but not as much as for the internal stresses. When we defined the contact region between the calcaneus bone and the plantar pad as a circle (according to Hertz contact theory [16]), the contact radius in the healthy was 43% (average) larger than that of the diabetic patients ($p < 0.05$). The stress-doses that were estimated in the diabetic group were >5.5-fold than those in the healthy ($p < 0.05$).

Internal plantar stresses evaluated in the diabetic group during stair climbing were again significantly higher than in the healthy ($p < 0.05$) (Table 2), although no significant difference was found between plantar pressures of the two groups during this activity ($p > 0.1$) (Table 2). The stress-dose results for stairs climbing showed a similar pattern.

We found no statistically significant differences in any of the stress parameters between subjects from the diabetic group tested positive for loss of protective sensation, and those tested negative.

**Table 2**
Results of stress parameters during free walking and stairs climbing averaged over 10 gait cycles for healthy and diabetic subjects.

| Parameters mean (standard deviation) | Free walking | | Down stairs | | Up stairs | |
|---|---|---|---|---|---|---|
| | Healthy subjects | Diabetic subjects | Healthy subjects | Diabetic subjects | Healthy subjects | Diabetic subjects |
| Peak heel-shoe pressure [kPa] | 80 (31) | 127 (44)§ | 45 (40) | 33 (14) N.S. | 33 (22) | 34 (15) N.S. |
| Peak principal compression stress [kPa] | 225 (63) | 687 (293)§§ | 164 (40) | 495 (196)§ | 149 (24) | 505 (216)§ |
| Peak principal tension stress [kPa] | 3 (0.85) | 9 (4)§§ | 2.2 (0.5) | 7 (3)§ | 2 (0.3) | 7 (3)§ |
| Peak cylindrical shear stress [kPa] | 26 (11) | 139 (66)§§ | 23 (9) | 106 (42)§ | 22 (8) | 108 (46)§ |
| Peak von Mises stress [kPa] | 223 (63) | 681 (290)§§ | 163 (40) | 490 (195)§ | 148 (24) | 500 (214)§ |
| Mean von Mises stress across area of ROI [kPa] | 180 (54) | 475 (190)§§ | 122 (36) | 273 (107)§ | 109 (23) | 281 (120)§ |
| Mean von Mises stress-dose contact axis [kPa s] | 40 (15) | 224 (115)§§ | 34 (19) | 213 (135)§ | 46 (22) | 258 (115)§ |
| Mean von Mises stress-dose symmetry axis [kPa s] | 34 (12) | 192 (97)§§ | 30 (16) | 167 (103)§ | 41(19) | 202 (86)§ |

N.S.: not significantly different from controls ($p \geq 0.05$).
§ Significantly different with respect to controls: $p < 0.05$.
§§ Significantly different with respect to controls: $p < 0.01$.

## 4. Discussion

The aim of our present proof-of-concept study was to determine and compare internal plantar pad stresses occurring during daily-life activities in diabetic and healthy subjects, using an analytical-model-based real-time subject-specific foot load monitor. After previously developing and validating the monitor with a laboratory apparatus, analyzing its sensitivity to the input parameters and determining calibration factors as described in an earlier publication [15], we now conducted comparisons of plantar stress parameters between groups of diabetic and healthy subjects, for free walking and stair climbing tests. Internal plantar stresses and averaged stress-doses evaluated during free walking and stair climbing in the diabetic group were between 250% and 550% higher than in the healthy ($p < 0.001$). The interfacial pressures measured during free walking were slightly higher (~50%) in the diabetic group ($p < 0.05$), and there was no significant difference between the two groups during stair climbing.

There are scarce data on subsurface stresses in plantar tissue, particularly during dynamic activities, and in diabetic patients. The method of testing closest to ours is that of Zuo et al. [13], but while we employed the Hertz contact theory, they based theirs on the potential theory and did not consider any effect of bone shape on the developed internal stress state, nor any other specific parameters of the patient. Nevertheless, their results on the rearfoot peak maximal shear stress during walking in diabetic patients lie within the range of our evaluations. In Gefen and Linder-Ganz's work [9], internal plantar tissue stresses occurring under the second metatarsal during the midstance phase of gait in diabetic and healthy subjects were simulated using a two-dimensional FE model. The averaged internal compression stress and averaged von Mises stress in fat tissue under the metatarsal head of their diabetic foot model were 1.95-fold and 2.58-fold greater than the respective stresses in a healthy foot model. Although the study area was different from the present work, their results are similar to ours. Our results on the mild increase in plantar pressure during walking in diabetic patients compared to healthy subjects agree with other studies as well [8,22,23].

Factors other than diabetes might have contributed to the stress differences between the two groups. First, they were not age-matched, and plantar pad stiffness generally increases with age [24,25]. Hsu et al. loaded the plantar pad of young adults and elderly at different impact velocities, and reported that its elastic modulus under the metatarsals is 27–70% stiffer in the elderly [24]. According to our sensitivity analysis, this would cause a change of 41% and 78% in peak internal principal compression stress at high and low impact velocities, respectively [15]. Hence, the larger plantar stress differences found herein between healthy and diabetics relate mostly to the disease, not to the age factor. Second, each subject walked at his/her own customary speed, but walking speed was shown to influence foot loads by ~47% [26,27]. Third, groups were also not matched by body mass or BMI, and so, diabetic subjects were on average 12 kg-heavier and with about 7-BMI-points more (Table 2). However, diabetes and obesity are closely related morbidities, and the most recent research shows that they very likely have common key mechanisms [28], and so, isolating the "diabetes" factor from the "overweight" factor appears artificial.

Simplicity of the Hertz contact theory and its relatively low demand for computer resources facilitates real-time operation and portability of the foot load monitor on a handheld device. Reliance on this theory has its drawbacks though, especially when applied to soft tissues. The plantar pad tissue overlying the calcaneus, specifically, is known to be nonlinear viscoelastic, and to undergo large deformations under physiological loading [29,30]. Accordingly, some of the basic assumptions of the Hertz model, e.g. the elasticity of the two contacting bodies, the relatively small contact zone in comparison to the size of the bodies themselves, the absolute smoothness of the contacting surfaces and frictionless contact conditions, and the elasticity of the deformations are, to put it mildly, inaccurate when describing the foot (quantitative analysis of inaccuracies in applying the Hertz theory to a bone-soft tissue contact problem is provided elsewhere [31]). It is therefore almost surprising that the overall results of the model are very plausible, in comparison to other state-of-the-art investigations [8–10,12]. For example, peak internal compression stresses and von Mises stresses in plantar tissue overlying the calcaneus during level walking were both found to be on the order of 200 kPa for healthy, and on the order of 700 kPa for subjects with diabetes (Table 2). Using a different, more complex real-time FE method [12], we previously found that healthy exert peak heel pad compression and von Mises stresses of 200–400 kPa during heel-strikes while walking freely, which is in good agreement with the present data. The explanation for the nice performances of the Hertz model despite its relative simplicity may lie in the fundamental nature of the theory, and the ease with which it accepts the corrections for some of the above limitations, as specified in [15]. In this regard, we observed that accuracy is needed in measuring the bone radius of curvature and plantar pad elastic modulus, since errors in these parameters might substantially affect the stress readings [15]. Additionally, our model considers only compression loading, which may cause some underestimation of the evaluated internal stresses [15].

In conclusion, our present proof-of-concept study shows that (i) it is possible to evaluate internal plantar pad stresses in healthy and non-healthy individuals in real-time using low computer power and a portable device. (ii) Such evaluations can be carried out both indoors (e.g. in a clinical setting) and outdoors (e.g. in the subject's own natural environment). (iii) During walking and stair climbing, internal plantar stresses are considerably higher than foot–shoe interface pressures, and in diabetic patients, the internal stresses substantially exceed the levels in healthy. Future studies are needed to characterize how internal plantar stresses are affected by the severity of neuropathy, by previous (healed) ulcers which might affect plantar pad stiffness, and ultimately, to find damage thresholds for sub-dermal plantar tissue in terms of deep tissue stress. These studies are straight-forward using the new foot load monitor device. Afterwards, we believe that the present model and device could be used in order to develop a method to create custom-made footwear that will protect feet of diabetic patients at high risk for ulceration. The method and device may also be useful as means for biofeedback to compensate for loss of protective sensation in neuropathy.

## Conflict of interest

None.

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