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An indentation apparatus for evaluating discomfort and pain thresholds in conjunction with mechanical properties of foot tissue in vivo

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Abstract—The mechanical properties of human foot tissue in vivo as well as discomfort and pain thresholds are important for various applications. In this study, an apparatus for measuring the discomfort and pain thresholds and the mechanical properties of human tissues is presented. The apparatus employs a stepper motor that controls the indentation speed, as well as a load cell and potentiometer that determine the corresponding reaction force and tissue deformation (displacement), respectively. A LabVIEW program (LabVIEW 8, National Instruments Corporation; Austin, Texas) was developed to control the indentation via a data acquisition card. The apparatus can accommodate indentor displacements up to 35 mm and can impart forces up to 150 N at a controlled indentation speed in the range of 0 to 10 mm/s. Tests showed that the displacement measurement error is <0.17 mm in the nominal range (0.5% in the full scale) and the measurement error of force is <1.6 N in the nominal range (1.1% in the full scale). Experimental results indicate that the apparatus is reliable and flexible for measuring the mechanical properties of foot tissue in vivo in conjunction with pain and discomfort thresholds.

Key words: algometer, diabetic foot, discomfort, discomfort threshold, foot, heel compression, indentation, pain, pain threshold, repeatability, tissue, tissue indentor, tissue mechanical properties, tissue stiffness.

INTRODUCTION

The mechanical properties of foot tissue are useful to the design of differing types of footwear [1–2] and in the detection and diagnosis of foot tissue abnormalities [3–4]. These properties are also the basis for the development of finite element models of feet [5–10]. In clinical settings, tissue assessments are predominantly performed through palpation [11], even though such evaluations are inherently subjective and rely on observer experiences [12]. Thus, not surprisingly, differing instruments have been developed for objectively characterizing the mechanical properties of foot tissue [3,11,13].

Most instruments used in the past have an indentor that compresses the tissue while both force and tissue deformation are recorded simultaneously. Indentation tests, widely used, resemble hand palpation in a controlled manner [14]. Units with pen-sized handheld indentors composed of an ultrasound transducer and a load cell have been developed that improve portability [4,6,8,11]. Even though portability is a prime consideration, concerns have been reported about the reliability and accuracy of such instruments [15], primarily because of the lack of control of the indentor alignment and the

Abbreviations: ATT = automatic tissue tester, CV = coefficient of variation, F-D = force-deformation, ICC = intraclass correlation, PDT = pressure discomfort threshold, PPT = pressure pain threshold, SD = standard deviation.

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indentation speed [11]. Foot tissue—for that matter, any living tissue—is anisotropic; in other words, the mechanical properties are direction-dependent and also viscoelastic, meaning they depend on the speed of deformation [8,16–19]. Thus, controlling both the direction of indentation and the speed of indentation is of utmost importance if reliable data are to be obtained [8].

Rome and Webb developed an instrument to reduce the problem of alignment by encompassing the actuator with a persplex plate [11]. They claimed a high reproducibility of coefficient of variation (CV) = 6.2 percent based on repeated measurements at the same point. A similar apparatus was reported by Vannah and Childress [20]. Even though the indentation direction is controlled, these instruments offer little or no control of the indentation speed. Dohi et al. used an apparatus, developed by Axiom Ltd (http://www.axiom-j.co.jp/), in which the indentor was driven by a stepper motor and controlled by a computer [21–22]. A similar rate-controlled indentation instrument with a large indentor displacement (up to 30 mm) is reported by Pathak et al. [23]. One shortcoming of these two systems is related to the alignment of the person or the body tissue that is tested so that it is always perpendicular to the indentor. Using such an apparatus for testing various foot sites would be difficult if the apparatus were not designed to accommodate angular positioning [4]. The system developed by Torres-Moreno also has similar limitations [24].

Tenderness is a major, and sometimes the only, indicator of musculoskeletal dysfunction, and assessing tenderness by palpation is subjective. Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" [25]. Discomfort is a precursor to pain. In short, both pain and discomfort are psychological experiences and should be assessed so that pain and discomfort thresholds can be used when products such as footwear are designed. Even though many different types of indentation instruments exist, discomfort and pain thresholds of mechanical forces have been studied extensively with the use of the pressure algometer [26–27]. Unfortunately, pressure algometers are, in general, handheld devices that cannot maintain a constant indentation speed [28] and are not designed to measure tissue deformation [29]. In other words, recording the corresponding indentation depths, in addition to force-related pain thresholds, is also important.

Even though indentation instruments and pressure algometers exist, these have not been connected so that tissue properties as well as discomfort and pain thresholds can be assessed at the same time. Both are important; thus, our aim with this study was to develop a flexible and cost-effective apparatus for measuring mechanical properties of foot tissue, in vivo, in conjunction with discomfort and pain thresholds at different locations on the foot. Our main specifications for the apparatus were—

1. Force can be applied to any area of the foot, perpendicular to the skin surface, while the subject assumes a natural standing posture with load on both feet.
2. Subject can indicate discomfort as well as pain thresholds during testing in a "noninvasive" manner so that tissue properties as well as the psychological experience can be recorded simultaneously without affecting each other.
3. Direction and indentation speed can be computer-controlled with quick replacements of indentors.
4. System is safe and affordable and comprises a computer data acquisition unit.

METHODS

Apparatus Design and Fabrication

Based on the literature [23,30] and the preliminary results from a pilot test, the technical specifications of the apparatus were set as follows: (1) precise indentation speed control with a maximum speed of 10 mm/s, (2) compressive force up to 150 N, (3) indentations of up to 35 mm, (4) manufacturing cost (<$5,000), (5) adjustable indentation direction from 0° to 360°, (6) quick replacement of indentation probes, and (7) negligible delay between loading and unloading of tissue so that hysteresis can be observed and measured.

The automatic tissue tester (ATT), fabricated at a cost of about $4,000, consists of three main parts: a mechanical unit, a control unit, and two remote operation panels. Each of these parts is described in the following paragraphs.

Mechanical Unit

The mechanical unit comprises a 200 step/revolution stepper motor (model KH42KM2-901; Japan Servo Co., Ltd; Japan) and a linear motor guide to transfer the motor rotation to the linear movement of the indentor (**Figure 1**). The force is measured with a tension-compression load cell (model 8435-5500: measuring range of 0–500 N) from Burster Praezisionsmesstechnik GmbH and Co.

(Gernsbach, Germany; www.burster.com/) and the displacement measured with a three-turn potentiometer (model 533-1-1) from Vishay Intertechnology, Inc. (Malvern, Pennsylvania); www.vishay.com/). A lightweight aluminum chamber houses the load cell and guides the indentation probe. The chamber is fixed to a high-stiffness aluminum stand, allowing the unit to rotate if needed (**Figure 1(b)**). This design allows the indentor to be aligned in any direction when the foot is evaluated. The indentor slides through an insert that is pressed onto the Plexiglas platform. Different inserts are used for the differing probe sizes. The difference between the inner diameter of the inserts and outer diameter of the indentor probe is around 2 mm. This will prevent any friction affecting the measurements and any effects related to tissue squeezing.

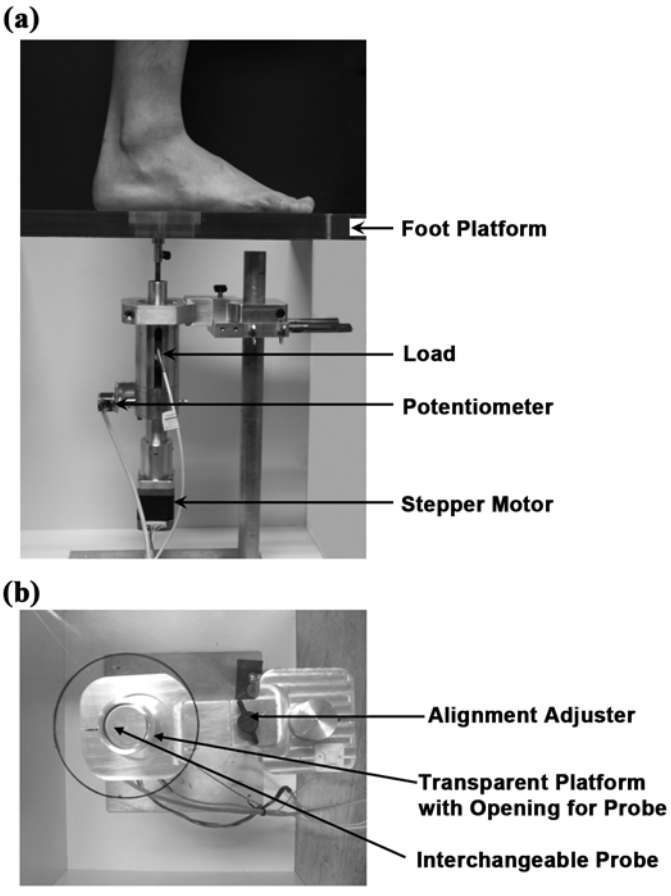

Figure 1.
Mechanical configuration of automatic tissue tester: **(a)** front view and **(b)** top view.

Control Unit

The control unit consists of a power supply, circuit box, and custom LabVIEW program (LabVIEW 8, National Instruments Corporation; Austin, Texas) running on a host personal computer. The LabVIEW program issues commands to the stepper motor driver to control the indentation speed. The differential signals from the potentiometer and load cell are acquired by the data acquisition card (model NI PCI-6025E, National Instruments Corporation) at an acquisition frequency of 1,000 Hz. The system was also programmed to acquire the digital signals from the push buttons on the remote operation panels (described in the next paragraph).

Remote Operation Panels

Two remote operation panels are built into the system. The subject panel has two switches labeled “discomfort” and “pain,” and the experimenter panel has two switches labeled “pain” and “emergency stop.” The subject panel is used for recording the subject’s pressure perceptions related to discomfort and pain [29,31] and as a safety device: when the pain switch is pressed, the indentor is released automatically. The emergency stop on the experimenter panel gives a second level of protection by instantaneously powering off the complete system and thereby stopping the indentor’s movement. An additional safety precaution is the test platform design, which enables the subject to move his/her limb away from the indentor at any time to prevent injury. The subject can stand on the platform so the thresholds can be measured, even when the foot bears weight. This aspect is very important because it allows the pain thresholds to be evaluated with differing magnitudes of superimposed loading.

Apparatus Calibration

Calibration allows the voltage signals from the measurement transducers to be transformed into their corresponding physical units. A dial gauge (model U60A, Sony Corporation; New York) with an accuracy of 0.0015 mm set at an operating range of 0 to 35 mm was used as the calibrator. The tip of the dial gauge rested on a rigid flat piece of Plexiglas firmly fixed to the indentation probe, so the dial gauge movement was the same as the indentation probe. The dial gauge (millimeter) versus potentiometer (volt) plot was highly linear and the least squares line was used for the conversion of the voltage signal to the amount of displacement.

We used a precalibrated load cell with an accuracy of ±0.03 percent (model GM, Sensotec; Columbus, Ohio; www.sensotec.com/) to calibrate the force in the range of 0 to 150 N. The identical force was made to act on the precalibrated load cell and the indentation probe. We added a cylindrical silicone sample (area = 2.0 cm^2; height = 1.7 cm) (Shin-Etsu Silicone; Tokyo, Japan; Shin-Etsu CAT-RM = 10:1) between the precalibrated load cell and the indentation probe to (1) provide distributed loading during the test and (2) simulate soft tissue. The readings from the two load cells were acquired and recorded simultaneously at a sampling rate of 1,000 Hz. The raw signal from the ATT load cell was amplified 250 times with a universal in-line transducer amplifier (model UV-10, Sensotec), and the amplified signal was filtered with a second-order Butterworth low-pass filter. A linear regression was used thereafter.

To assess the calibration accuracy of displacement and force measurements, we performed 24 test runs (2 trials × 6 indentation speeds × 2 modes) and calculated the errors from the deviations of the corresponding regression lines. The test speeds were 0.5, 1.0, 2.0, 3.0, 4.0, and 5.0 mm/s, and the two modes were compressive loading and unloading the test sample. Only two trials were tested for each condition because the results were highly repeatable.

Calibration repeatability was assessed at the same six speeds (0.5, 1.0, 2.0, 3.0, 4.0, and 5.0 mm/s) under both loading and unloading modes over five trials. In other words, 60 test runs (5 trials × 6 indentation speeds × 2 modes) occurred in the repeatability test.

Test on Foot

To validate the system and assess its reproducibility and repeatability, we conducted an experimental study with five Chinese university students (mean age of 25.6 years, age range 20–35 years). We determined the force-deformation (F-D) characteristics at two locations (**Figure 2**), heel pad under calcaneus [32] and plantar foot center—defined as the intersection point between the line through the first metatarsal head point (P1) and lateral plantar arch point (P4) and the line through the fifth metatarsal head point (P2) and medial plantar arch point (P3) [21,29], respectively. We chose these two locations to represent a bony region that bears high load and a soft tissue region, which generally has low load; the extremes of tissue type and loading are captured by testing these two locations. The two locations were indented three times on each of 3 days.

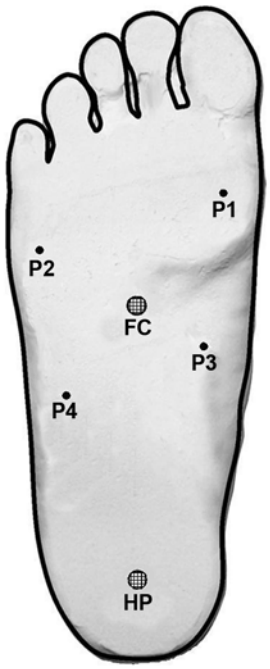

Figure 2.
Two locations (foot center [FC] and heel pad [HP]) on right plantar foot for indentation test. P1 = first metatarsal head point, P2 = fifth metatarsal head point, P3 = medial plantar arch point, P4 = lateral plantar arch point.

The two locations were determined through palpation and foot geometry [29] and marked with permanent ink. The test conditions were as follows: (1) indentation speed fixed at 1.0 mm/s, with an indentor area of 1.0 cm^2 with chamfered edges to minimize any edge effects; (2) loading followed by unloading when the subject pressed the pain button (this process helped ensure subject safety); (3) to minimize foot skeletal motion and the corresponding effects changes of the test locations (such as the metatarsal bones) during the indentation procedure [4], subject constrained to a natural, standing posture with half the body weight on each foot; (4) similar to many previous studies [33–34], test was conducted with no preconditioning trials, because this represents the state of tissue at clinical intervention [35]. Lack of preconditioning also helps to minimize subject fatigue and sensitization or adaptation due to repeated pressure stimuli [36–37]. Prior to the indentation test, the indentor probe was moved up through the insert until its top surface was flush with the top surface of the transparent foot platform. Thereafter the subject's foot was aligned for the indentation test. In

this way, the tissue did not bulge into the hole because the difference in diameter was only 2 mm. The effects of any change in tissue characteristics were assumed to be negligible.

RESULTS

Calibration Accuracy and Repeatability

Accuracy

The statistics (mean ± standard deviation [SD]) of the prediction errors (equal to predicted displacement – actual displacement, as measured by the dial gauge) from different test conditions (24 test runs) are summarized in **Table 1**. The data show that for the six indentation speeds, the overall mean absolute calibration error was <0.05 mm for both loading and unloading modes. As to the maximum absolute calibration error, the loading mode has a mean of 0.144 mm with a range from 0.128 to 0.166 mm and the unloading mode has a mean of 0.146 mm with a range from 0.128 to 0.167 mm. Overall, the maximum absolute calibration error on displacement measurements is within 0.17 mm for all test conditions in the operating range 0 to 35 mm.

The statistics (mean ± SD) of the prediction errors related to force are also summarized in **Table 1**, which shows that, for the six test speeds, the mean ± SD absolute calibration error is 0.408 ± 0.124 N during loading and 0.407 ± 0.131 N during unloading. As to the maximum absolute calibration error, the loading mode has a mean of 1.193 N with a range from 0.512 to 1.553 N, while the unloading mode has a mean of 1.153 N with a range from 0.485 to 1.499 N. Overall, the maximum absolute calibration error is within 1.6 N for all test conditions in the operating range 0 to 150 N.

Repeatability

For both displacement and force measurements, all 60 tests (5 trials × 6 speeds × 2 modes) had R^2 >0.9999, indicating a very high linearity between the transducer output and the calibrator. All CVs on the slope of the regression lines (which correspond to the number of units of change of actual displacement or force to one unit of voltage change from the transducer) from the five test trials, at different indentation speeds, are <0.2 percent for displacement and <0.6 percent for force measurement. These low values indicate good calibration repeatability during loading and unloading. Additionally, even though the two sample *t*-tests showed that the loading mode does not have significantly different (p = 0.207) calibration slopes (23.333 ± 0.007 mm/V) from the unloading mode

Table 1.
Absolute errors of displacement and force calibration from linear regressions of 24 test runs.

Speed (mm/s)	Trial	Absolute Error from Calibration (mean ± SD)			
		Displacement (mm)		Force (N)	
		Loading	Unloading	Loading	Unloading
0.5	1	0.042 ± 0.028	0.046 ± 0.032	0.612 ± 0.293	0.654 ± 0.296
0.5	2	0.040 ± 0.025	0.041 ± 0.029	0.608 ± 0.310	0.577 ± 0.286
1	1	0.033 ± 0.024	0.037 ± 0.027	0.402 ± 0.330	0.411 ± 0.336
1	2	0.031 ± 0.022	0.032 ± 0.026	0.337 ± 0.234	0.315 ± 0.231
2	1	0.038 ± 0.021	0.040 ± 0.022	0.453 ± 0.372	0.467 ± 0.398
2	2	0.035 ± 0.022	0.039 ± 0.027	0.471 ± 0.311	0.469 ± 0.307
3	1	0.052 ± 0.031	0.054 ± 0.034	0.448 ± 0.227	0.458 ± 0.238
3	2	0.049 ± 0.029	0.051 ± 0.032	0.436 ± 0.223	0.433 ± 0.219
4	1	0.054 ± 0.032	0.057 ± 0.036	0.340 ± 0.189	0.342 ± 0.197
4	2	0.052 ± 0.033	0.055 ± 0.033	0.321 ± 0.176	0.298 ± 0.167
5	1	0.056 ± 0.034	0.059 ± 0.038	0.236 ± 0.149	0.244 ± 0.152
5	2	0.062 ± 0.035	0.063 ± 0.037	0.226 ± 0.129	0.215 ± 0.119
Mean ± SD	—	0.045 ± 0.010	0.048 ± 0.010	0.408 ± 0.124	0.407 ± 0.131
Maximum	—	0.062 ± 0.035	0.063 ± 0.038	0.612 ± 0.372	0.654 ± 0.398
Minimum	—	0.031 ± 0.021	0.032 ± 0.022	0.226 ± 0.129	0.215 ± 0.119

SD = standard deviation.

(23.327 ± 0.0163 mm/V) on the displacement measurement, the calibration slope of the loading mode is significantly lower on the force measurement than the unloading mode by about 1.0 N/V (about 2.0%).

Foot Tissue Test

Indentation Response

Representative F-D curves on plantar tissue at heel pad and plantar foot center of one subject are shown in **Figure 3**. Loading and unloading can be clearly differentiated, demonstrating the typical hysteresis phenomenon related to the viscoelastic behavior of living tissues. The F-D curves from the two sites are different as well: the same force on heel pad produced smaller deformations than at plantar foot center. This result indicates that the heel pad tissue is stiffer than the tissue at plantar foot center, consistent with the feeling of palpation of an experienced clinician. Additionally, the heel pad can bear higher forces and thus more pressure than the plantar foot center before any pain is experienced (**Figure 3**).

The F-D curve has important implications in terms of tissue behavior. The slope of the curve represents the stiffness of tissue. One can clearly see that the curve is somewhat piecewise linear. At the heel, up to around 3 mm, the curve can be modeled with a regression line as

$$F = 3.45 \times D + 0.23; R^2 = 0.9987 \quad . \qquad \textbf{(1)}$$

Beyond 3 mm, the deformation up to the point of pain corresponding to a deformation of approximately 10 mm, can be modeled as

$$F = 12.42 \times D - 37.64; R^2 = 0.9943 \quad . \qquad \textbf{(2)}$$

Similarly, at the foot center ,

$$F = 0.32 \times D - 0.70; R^2 = 0.7597 \text{ for } 0 < D < 8 \text{ mm}, \qquad \textbf{(3)}$$

and

$$F = 5.68 \times D - 55.14; R^2 = 0.9793 \text{ for } 10 < D < 18 \text{ mm} . \qquad \textbf{(4)}$$

These models illustrate that the initial stiffness (gradient of these lines) of tissue is low (3.45 N/mm and 0.32 N/mm at the heel pad and foot center, respectively), and thereafter the tissue stiffness increases drastically to 12.42 N/mm and 5.68 N/mm, respectively. These values are for one representative subject. The mean values of day 3 and trial 3 of all subjects are 3.9 N/mm and 24.9 N/mm at the heel pad and 0.4 N/mm and 6.7 N/mm at the foot center, respectively. Interestingly, the first region ends about 30 to 52 percent of the maximum deflection for all subjects, with a mean of 41 and 47 percent at foot center and heel, respectively.

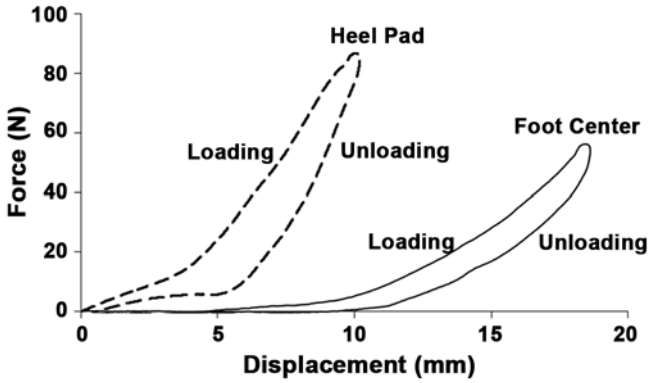

Figure 3.
Force-deformation indentation curves at two sites (heel pad and foot center) of subject 1.

The loading portion of the curve can also be used to characterize the psychological experience of discomfort represented by the pressure discomfort threshold (PDT) and pain threshold (PPT, defined as the pressure at which subjects judge pressure as painful) [37].

Reliability of Measurements

Pressure thresholds (PDT and PPT) for the three repetitions and the 3 days of the five healthy subjects are summarized in **Table 2**. We checked the within-day and between-day repeatability using the intraclass correlation (ICC) type (2, 1) [38]. ICC values for the two pressure thresholds are shown in **Table 3**. For both PPT and PDT, all ICC values for within-day and between-day are >0.88 with one exception (**Table 3**), indicating high repeatability [39]. Even the exception has acceptable or moderate measurement reliability because it is >0.6 [39].

The PDT and PPT values of the five healthy subjects are shown in **Figure 4**. The consistency of the values over the 3 days is clear. In general, PDT tends to be about 40 to 50 percent of PPT very similar to the maximum deflection in the first region of the F-D curve. The variations among the three trials over the 3 days for one subject are shown in **Figure 5**.

Table 2.
Mean ± standard error of pressure discomfort threshold and pressure pain threshold of five subjects for three repetitions on 3 days.

Location/Day	Pressure Discomfort Threshold (kPa)			Pressure Pain Threshold (kPa)		
	Repetition 1	Repetition 2	Repetition 3	Repetition 1	Repetition 2	Repetition 3
Foot Center						
Day 1	169.6 ± 44.8	209.7 ± 71.5	203.1 ± 58.9	522.0 ± 91.9	539.5 ± 117.0	517.9 ± 110.8
Day 2	180.5 ± 57.2	240.4 ± 81.3	262.8 ± 100.5	517.0 ± 106.8	532.6 ± 115.3	558.5 ± 127.6
Day 3	191.6 ± 66.1	225.6 ± 81.6	248.1 ± 71.6	477.5 ± 92.6	507.0 ± 123.0	538.0 ± 122.5
Heel Pad						
Day 1	462.9 ± 198.9	465.7 ± 167.1	667.1 ± 228.5	1,073.6 ± 224.1	1,087.3 ± 198.1	1,136.6 ± 261.4
Day 2	498.1 ± 159.5	535.6 ± 191.9	482.9 ± 187.3	1,039.2 ± 194.7	1,113.7 ± 185.2	1,116.4 ± 190.1
Day 3	555.1 ± 288.8	508.1 ± 194.9	546.8 ± 214.2	1,013.8 ± 260.8	1,048.5 ± 278.2	1,094.8 ± 218.1

Table 3.
Intraclass correlation (2,1) of pressure thresholds of five subjects for three repetitions on 3 days.

Location/Day	Pressure Discomfort Threshold		Pressure Pain Threshold	
	Within-Day	Between-Day*	Within-Day	Between-Day*
Foot Center				
Day 1	0.644	—	0.888	—
Day 2	0.881	0.912	0.937	0.965
Day 3	0.936	—	0.916	—
Heel Pad				
Day 1	0.888	—	0.969	—
Day 2	0.909	0.976	0.900	0.970
Day 3	0.953	—	0.963	—

*Mean of three repetitions of each day is used to calculate between-day reliability.

DISCUSSION

Design Considerations

Since human tissue is viscoelastic and anisotropic, any instrument designed and developed to assess tissue characteristics should be capable of controlling the indentation rate and maintaining the required alignment during operation. To support rate-controlled indentation, we used a cylindrical indentor with a load cell driven by a stepper motor, allowing indentation rate variations from 0 to 10 mm/s, which is appropriate for tissue [13,23]. To control the alignment during the operation, we had a lightweight aluminum chamber that housed the indentor and was fixed to a high-stiffness aluminum stand for portability. To ensure that the indentor was perpendicular to the skin without orienting the person or the limb, we designed a simple mechanism (**Figure 1(b)**). This feature is important, especially to improve on repeatability, because the subject has to be in a comfortable posture during testing [29]. In addition, two-level protection was added to prevent any injury to the subjects in both software (the remote operation panel with push buttons for both the subject and the operator as well as "maximum force for loading" set in the LabVIEW program) and hardware (a specialized foot platform).

The apparatus had an operating range of 0 to 35 mm for indentor displacement and 0 to 150 N for force. These are acceptable levels for testing mechanical properties of foot tissue [4,23,29]. The calibration accuracy and repeatability of the apparatus were assessed at six different indentation speeds on loading and unloading.

Calibration Accuracy and Repeatability Test

The accuracy test on the displacement measurement showed that the apparatus had an average error of <0.05 mm (**Table 1**) and a maximum error of <0.17 mm in the operating range of 0 to 35 mm when compared with a dial gauge. Results for the force measurement showed an average error <0.41 N (**Table 1**) and a maximum error <1.6 N in the operating range of 0 to 150 N when compared with a precalibrated load cell. Overall, the accuracy of the system is sufficient to measure the F-D data of foot tissue in

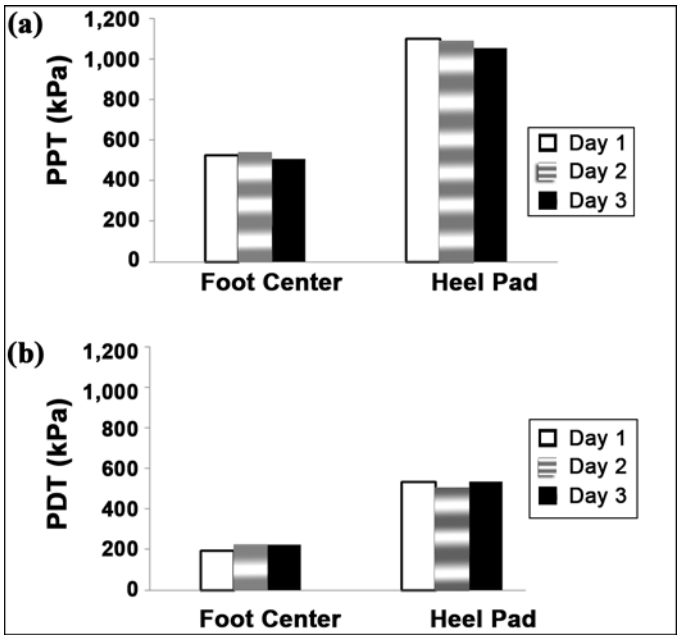

Figure 4.
Mean (n = 5) of **(a)** pressure pain threshold (PPT) and **(b)** pressure discomfort threshold (PDT) for five subjects for 3 different days at two locations, foot center and heel pad.

vivo, even though it is slightly lower than the reported accuracy of the indentation systems developed by Zheng et al. [8] and Vacalebri et al. [13].

The repeatability tests showed that the variations in the calibration slopes among the trials are very small (CV <0.2% in the displacement measurement and CV <0.6% in the force measurement), thereby demonstrating that the apparatus is capable of producing nearly identical data from differing test trials under the same test conditions. Even though the loading and unloading calibration slopes are not significantly different in the displacement measurements, the tests showed that the slope for the force during unloading is significantly higher than during loading by a value of about 1.0 N/V at each indentation speed. The higher force calibration slope during unloading may be due to the frictional force or a phase difference between indentor unloading and material decompression. The use of two different calibration equations for loading and unloading can minimize this effect.

Indentation of Foot Tissue

Indentation tests at two sites on the plantar surface indicated differences in mechanical properties as well as discomfort and pain thresholds, as shown in **Figure 3**. For the particular subject shown in **Figure 3**, the maximum force at pain was 87 N. This value compares well with the 6 percent of sample that reported pain at a load of 88 N obtained by Robbins et al. [40] with a 10 mm spherical end on a penetrometer. The mean value for all subjects over the 3 days and three trials was 108 N when pain set in. Even though the indentation rate is relatively small, the forces and indentations induced by the device (**Figure 3**) are adequate to simulate those in shod walking, found to be about 79 N and 9 mm, respectively [41–42]. The typical hysteresis and nonlinear phenomenon can be clearly observed from the F-D curve, which is consistent with other studies [4–5,12,21].

Because of the nonlinear nature of the F-D curve, characterizing the F-D curve is challenging, and researchers have proposed the use of an effective Young's modulus [4,8]. However, this requires additional information such as tissue thickness and Poisson's ratio, both of which are difficult to measure without error. In any case, Klaesner et al. have shown that Young's modulus is not appropriate for plantar tissue because it is not a linear elastic material [4]. Instead, the slope of the piecewise linear F-D curve, which represents tissue stiffness, can be used to classify the various classes of tissue. Plantar tissue stiffness can be used to identify the pathological stiffening of plantar tissue of the diabetic foot [43] or conditions related to plantar heel pain [44]. Thus, the F-D curves are useful to the clinician to assess bone and soft tissue changes or damage in patients. The stiffness of the epidermal layer is different than the "secondary phase" of indentation, and palpating the deeper tissue is difficult (**Figure 3**). One can use the stiffness of the secondary layer to identify tissue variations of a person. In the range of forces <12 N, Klaesner et al. found that the heel stiffness is about 2.5 N/mm with a manually controlled indentor [4].

In this experiment, we see that the heel stiffness of a subject is about 3.9 N/mm in the low deformation region and is comparable with the maximum stiffness value of 3.22 N/mm obtained by Rome et al. on subjects without any plantar heel pain [44]. The softer tissue, such as those in the center of the plantar surface of the foot, has a larger deformation and lower stiffness in the first phase. Interestingly, the analyses show that the stiffness changes around the point when discomfort sets in, which has a mean of about 40 to 50 percent of the maximum permissible deformation for the two sites tested. Thus, knowing the discomfort deformation allows the maximum pain deformation to

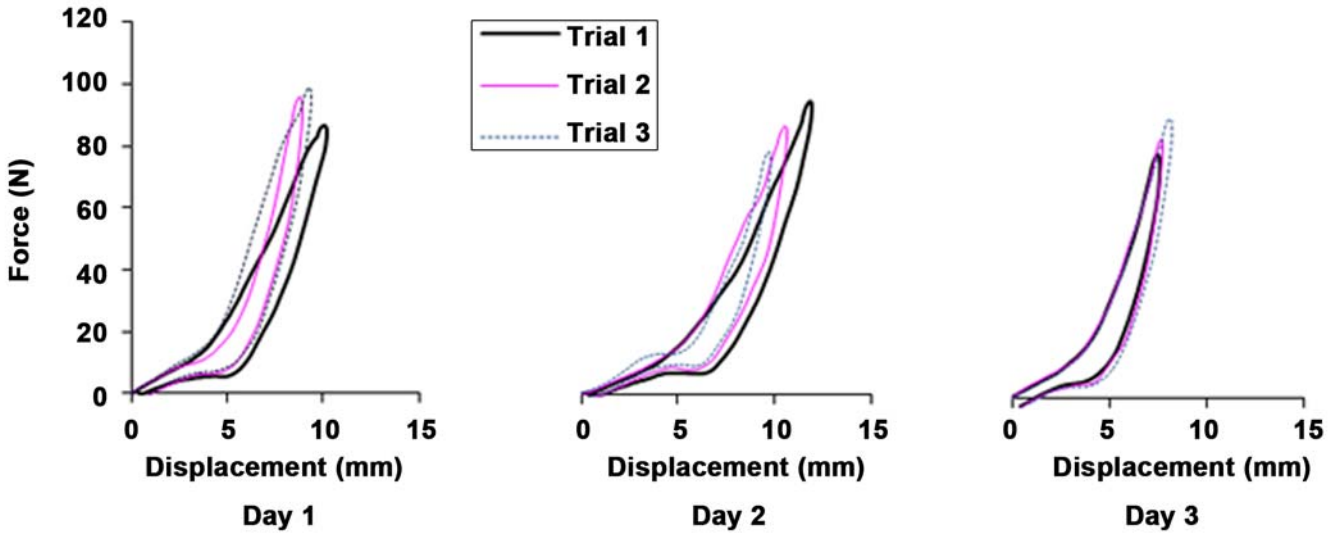

Figure 5.
Force-deformation curves of heel pad for three trials on 3 different days of one subject.

be predicted. Even though more locations should be tested, such information can be useful to the clinician.

Previous studies have shown that simple devices for assessing tissue characteristics result in statistically different values for the slope of the F-D curve [3–4,45]. **Figure 5** shows a similar pattern. A closer look reveals that on the first and second days, the F-D responses among the three trials are varied. However, on the third day, the response characteristics among the three trials are similar. In this experiment, the subject's foot was not constrained and the subject could move freely at any time. The variations on the first two days could possibly be due to the lack of subject familiarity with the equipment or possibly a slight variation in the location when indenting or positioning or even related to tissue conditioning [20]. The differences cannot be due to stress relaxation, because this is generally completed about 1 s after the indentation [20]. The variations do not seem to exist on the third day. The variations of PPT and PDT among the 3 days are also acceptable (**Figure 4**). The subjective thresholds vary between the two sites (**Figure 4**). The softer tissue tends to have lower thresholds compared with the harder tissue, such as the heel pad.

Others have developed portable instruments for tissue investigations. For example, Fischer developed a portable handheld tissue compliance meter [3] and later Kawchuk and Herzog examined its reliability and reported low ICC values (all <0.22) for interrater reliability [45]. Klaesner et al. also developed a handheld portable indention system but with very high interrater and intrarater reliability (ICC values = 0.99) [4]. The ICC values on PPT (**Table 3**) were, in general, higher than the values reported by Cathcart and Pritchard [46] (mean of 0.77, range of 0.69–0.88) and the values reported by Persson et al. (range of 0.70–0.94) [47], when a pressure algometer was used. Precise control of the indentation speed and indentation direction may have contributed to the high measurement reliability of PPT.

The device allows the comparison of different types of tissue as well. Goonetilleke and Luximon showed that if a measure such as pressure × displacement to pain is used, this particular measure appears to be somewhat consistent across differing pain threshold studies and differing locations on the body [37,48–49]. For the limited number of Chinese male subjects we tested, the mean values of PPT × deformation to pain at the heel and foot center are 9.5 N/mm and 8.2 N/mm, respectively. This measure was about 5 N/mm on the dorsal side of the foot of U.S. male subjects as reported by Goonetilleke and Luximon [48]. The higher values in this study may be due to the thicker epidermal layers on the plantar surface of the foot or possibly the difference in the populations tested. The rationale for such a measure is a coupling between the work metric force × displacement related to a membrane, like the skin, that undergoes deformation. Again, such a measure, if proven, will have great value in characterizing healthy and pathological tissue.

In general, the determination of the differing mechanical properties of tissue in vivo, coupled with the subjective responses of discomfort or pain thresholds, has significant use in the understanding of pathologies and related therapeutic interventions.

Limitations and Future Work

This study is not without limitations. The tests were performed on nondisabled subjects and more characterizations are necessary to generate data for the nondisabled and pathological populations [32]. A more serious issue exists with patients who are insensate, because the apparatus can increase risk of ulceration because they may not be able to sense and deactivate the probe like a healthy subject would. Some form of hybrid control that incorporates an automatic withdrawal at a preset threshold, in addition to close monitoring by the clinician and being in charge of operating the indentor release button, may help overcome this issue. The subject's foot is placed on the test platform so that indentation can be performed with load on the whole foot. For a subject unable to ground the foot, issues related to unbalanced loading between the two feet, body sway, and center of pressure shifts can cause inaccuracies in the F-D curves. The weight difference between feet may be overcome with the use of weighing scales or force platforms. The data reported in this article are tissue properties without any preconditioning, which generally results in a shift of the F-D curve to the right due to multiple loading cycles [18], even though a consistent preconditioning protocol does not appear to exist [35]. Nevertheless, the lack of preconditioning in this experiment may have reduced the indentation reliability and may have overestimated the tissue stiffness. More research is needed to determine an appropriate and reliable preconditioning protocol that can allow the F-D curves to be better determined and modeled with more complex formulations such as second-order polynomials. This will allow an accurate determination of stiffness at various deformations. Finally, the maximum allowable indentation speed of 10 mm/s may be too slow for an understanding of deformations during normal gait [4].

CONCLUSIONS

A computer-controllable indentation apparatus has been developed. The apparatus can (1) measure the mechanical properties of foot tissue in vivo, in addition to the subjective measures of pressure-related discomfort and pain; (2) control indentation from 0 to 5 mm/s in increments of 0.1 mm/s with a theoretical maximum rate of 10 mm/s; (3) measure the force in the range of 0 to 150 N with maximum error <1.6 N (1.1% in full scale) and the displacement in the range of 0 to 35 mm with maximum error less than 0.17 mm (0.5% in full scale); (4) have sufficient flexibility to check the characteristics of both the plantar and dorsal surfaces of the foot; and (5) interchange the probe size quickly without much effort. Although the main purpose of this device is to test foot tissue, it can be used on other parts of the human body related to clinical assessments of pressure pain thresholds to detect sensory loss or hypersensitivity in patients or in the evaluation of the effects of different treatment plans on tissue tenderness [26,29].

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