Sonoelastography on diabetic heel pads: a feasibility study

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Authors: S. Matteoli, L. Forzoni, F. Vannetti, A. Virga, A. Corvi, R. Molino-Lova; Firenze/IT
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Aims and objectives

The aim of this study is to investigate whether it is possible to differentiate between diabetic and healthy heel pads by means of real-time sonoelastography (ElaXto). To date, sonoelastography has not been used for clinical investigations of the heel pad elasticity. Eight diabetic (4M-4F, 55-80 years) and 8 healthy subjects (5F-3M, 60-76 years) underwent B-Mode ultrasound (for heel pad thickness measurement) and sonoelastography (for soft tissue investigation) on both heel pads. Findings showed that there was no statistically significant difference in UHPT between diabetics and healthy subjects (P-value=0.70). However, diabetics tended to have lower UHPT than healthy subjects. Moreover, no statistically significant difference was found between the two groups in the soft layer (P-value=0.76), but diabetics tended to have higher soft tissue than healthy subjects.

The interest in quantifying the mechanical properties of human soft tissues is an important aspect in diagnosing diseased tissues. Knowledge of the mechanical properties of heel pad tissue could be used in tools for screening patients for the purpose of preventing further complications in the foot (e.g. ulcerations in diabetics [1]) as well as of obtaining validated examination methods for medico-legal purposes (e.g. falanga torture [1]).

Sonoelastography is a non-invasive method to support the physician in assessing tissue elasticity. This technology provides additional information to standard B-Mode, a better definition of the lesion area, and it is suitable for diagnosis and follow-up. Moreover, it gives information on tissue elasticity by associating different chromatic patterns. Real-time Esaote (Esaote S.p.A., IT) sonoelastography (ElaXto) is based on the concept of elastic strain: an object, subject to stress, distorts proportionally to the intensity of the applied stress and depending on the material. It is known that tissue elasticity, in different districts, is correlated to pathologies [2]. Palpation, which is routinely used in clinical exams, is based on this assumption. In order to perform the sonoelastographic exam, the user has to apply a perpendicular pressure through rhythmic movements on the tissue under exam. Thanks to the pressure given by that action, it is possible to evaluate the modification of the echo signal and thus to compute how the different tissues distort (if they are soft) or move (if they are hard) compared to the probe position. The result of this calculation, computed in real-time, is shown by a color image overlapped to the B-Mode image. The deformability degree is given by a chromatic scale [2]. ElaXto is a qualitative analysis where the estimation of strain information is computed in relation to the surrounding tissue. The computed strain information is dependent on the tissue of the Region of Interest (ROI) [2]. To date, sonoelastography has not been applied on in vivo heel pad for tissue elasticity investigations. The human heel pad is a portion of the plantar foot tissue located between the heel skin and the tuberosity of the calcaneus bone. Anatomically it consists of a very complex structure made of neuronal, vascular, fibrous and elastic components which are intertwined with fat cells [3]. It acts as an efficient
shock absorber, smoothing the effects of impact forces during gait. The heel pad exhibits non-linear visco-elastic behavior as characteristic of soft biological tissues. Due to the visco-elastic nature, when a loading/unloading cycle is applied, a load-deformation curve is obtained showing a hysteretic behavior.

In some pathological conditions (e.g. diabetic foot) the damage of the intricate septation may imply the loss of its shock absorbing, causing great pain for the subject, when trying to stand and walk. Specifically, collagen septa in diabetic heel fat pads are found to be thicker and adipose cells smaller than in normal heel fat pads [3, 4]. It is also known that diabetes is associated with an increase of fragmentation [5]. These changes indicate that diabetes may affect the microscopic and macroscopic composition of the plantar soft tissues, making them more vulnerable to mechanical stresses which would lead to ulcerations [4]. Indeed, the diabetic fat pad is reported to be less elastic and less able to distribute pressure, leading to an impaired cushioning effect [4].

The aim of this study is to investigate whether it is possible to differentiate between diabetic and healthy heel pads in terms of elasticity by means of ElaXto.
Methods and materials

A. Subjects

Eight subjects affected with Type II diabetes (4M-4F, 55-80 years) and 8 controls (5F-3M, 60-76 years) were enrolled in this study. The subjects’ characteristics are reported in Table 1. Both feet of each subject were considered so that 32 heels were investigated. All subjects declared to have never had injuries/trauma to any of the feet. All participants were volunteers and were informed about the conditions of the test that involved no harmful procedures or physical pain.

Before starting the experimental procedure (which included B-Mode ultrasound - US - and sonoelastography - ElaXto), each volunteer was asked to give information about age, weight, height, nature of physical activity and hours per week, shoe size and, in case of diabetes, the number of years of disease as well as the therapy used, the presence or absence of neuropathy and history of foot ulcer.

B. Ultrasonography investigations

The same expert operator performed ultrasonography examinations using a portable US system (MyLabAlpha, Esaote S.p.A., IT), always applying the same protocol. Specifically, the right foot was always the first to be scanned and the ultrasound images were performed with the probe in both longitudinal and transversal positions (Figure 1). B-Mode US acquisitions (performed to measure the heel pad thickness) were followed by ElaXto scans.

Table 1 Subjects’ characteristics

<table>
<thead>
<tr>
<th></th>
<th>Controls</th>
<th>Diabetic subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of subjects</strong></td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td>68±7</td>
<td>72±9</td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
<td>72.8±16.6</td>
<td>75.0±10.3</td>
</tr>
<tr>
<td><strong>Height (m)</strong></td>
<td>166±11</td>
<td>166±10</td>
</tr>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td>26±5</td>
<td>27±6</td>
</tr>
<tr>
<td><strong>Shoe size</strong></td>
<td>40±3</td>
<td>41±3</td>
</tr>
<tr>
<td><strong>Sport (h/week)</strong></td>
<td>3±1</td>
<td>2±3</td>
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</table>
A large amount of ultrasound gel (Parker Aquasonic 100, Parker Laboratories, USA) was used in order to avoid compression of the probe coupling with the heel skin. Indeed, it is known that even a small compression changes the shape and dimension of the heel tissues. The technique adopted consisted in starting to couple the probe (SL1543, 3-13 MHz, Esaote S.p.A., IT) with the heel tissue up to complete coupling of the probe on the center part of the echographic image sector. The probe movement towards the tuberosity of the heel stopped at the moment the first tissue compression was noticed.

The heel pad thickness (UHPT), defined as the shortest distance between the calcaneus tuberosity and the heel skin, was calculated for each heel as the mean value between the longitudinal and transversal measurements.

During the activation of sonoelastography modality, the ROI was positioned over the heel tissues between the tuberosity and the skin coupled with the ultrasound probe (in average 3 mm over the tuberosity of the heel and up to 3 mm before the skin coupled with the ultrasound transducer). The height of the soft layer (colored red in ElaXto) was measured from each sonoelastography acquisition.

Statistical analyses (paired and unpaired t test) were carried out in order to differentiate between healthy and diabetic heel pads. A P-value<0.05 was chosen to indicate a significant difference.
Images for this section:

Fig. 1: US probe on the heel during ultrasonography examinations

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Results

A. B-Mode ultrasound

An example of heel pad scanned by US is shown in Figure 2, where the yellow dashed line indicates the UHPT. Table 2 shows UHPT values of both feet grouped by gender and expressed as mean ± one standard deviation.

Table 2: Average heel pad thickness of right and left heels for controls and diabetic patients

<table>
<thead>
<tr>
<th></th>
<th>Controls</th>
<th>Diabetic subjects</th>
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<tbody>
<tr>
<td>UHPT (mm) right heel</td>
<td>16.9±4.1</td>
<td>15.7±2.1</td>
</tr>
<tr>
<td>UHPT (mm) left heel</td>
<td>16.9±4.1</td>
<td>16.0±2.1</td>
</tr>
</tbody>
</table>

Paired t-test showed no significant difference between right and left heel pads in UHPT within the same group (P-value=0.61); unpaired t-test showed no significant difference in UHPT between diabetic and healthy heel pads (P-value=0.49).

B. Sonoelastography

Sonoelastography images showed two characteristic layers: a soft one (red color) close to the bone, and a hard/medium one (blue/green colors) close to the heel skin. This finding confirms the anatomy of the heel pad which consists of layers of macrochambers (near the bone) and microchambers (near the heel skin) [6].

Due to the difference between images (Figure 3), it was necessary to divide them into three classes depending on the homogeneity of the soft tissue, considering the soft (red) and medium hardness (blue/green) area. The homogeneity was evaluated depending on the visual control of the density of the central area of the heel tissue: 1) high homogeneity - red area more present than the blue/green one (Figure 3a); 2) medium homogenity (Figure 3b) - red area comparable to the blue/green one; 3) scarce or absent homogeneity (Figure 3c) - more blue/green area than the red one.

Table 3 reports the percentage of soft tissue measured for controls and diabetic subjects. Paired t-test showed no significant difference between right and left heel pads (P-value=0.64) in case of healthy subjects, whereas there was a significant difference (P-value=0.007) in case of diabetic subjects.
Unpaired t-test showed no significant difference between healthy and diabetic heel pads (P-value=0.25) when comparing the right heels, whereas a significant difference (P-value=0.02) in case of the left heels.

**Table 3** Percentage of soft tissue measured from ElaXto images of right and left heels for controls and diabetic subjects

<table>
<thead>
<tr>
<th></th>
<th>Controls</th>
<th>Diabetic subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Soft tissue right heel (%)</strong></td>
<td>33.6±4.0</td>
<td>36.5±3.5</td>
</tr>
<tr>
<td><strong>Soft tissue left heel (%)</strong></td>
<td>34.6±5.0</td>
<td>40.7±3.6</td>
</tr>
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</table>

One important finding was the evident difference between ElaXto images belonging to healthy and diabetic subjects: the latter had often a larger hard layer close to the bone, as shown in Figure 4.
**Fig. 2:** Typical US scan with UHPT marked with a yellow dotted line

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Fig. 3: Three typical ElaXto images belonging to the subjects investigated: a) high homogeneity, b) medium homogeneity, c) scarce or absent homogeneity

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Fig. 4: ElaXto image belonging to typical a) control and b) diabetic subject

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Conclusion

The aim of this study was to investigate whether it is possible to differentiate between diabetic and healthy heel pads in terms of elasticity by means of ElaXto sonoelastography.

To date, sonoelastography has not been used for clinical correlation of heel pad elasticity. Over the past decades, ultrasound technology has been one of the most popular techniques for the evaluation of the morphology and properties tissues [7], but reported controversial results in diabetic patients. Huntley and Walter (1990) [8] and Hashmi et al. (2006) [9] showed that the plantar tissue thickness was significantly higher in diabetic patients without neuropathy compared to healthy subjects; Klaesner et al. (2002) [10] reported that the plantar tissue for people with diabetic neuropathy was significantly more rigid than in healthy subjects of the same age; Gooding G. et al (1986) [11] the heel pad thickness in controls was greater than that of the diabetics without foot ulcers; Robertson et al. (2002) [12] showed, instead, no significant difference in the soft tissue thickness between diabetic patients and controls. Further investigations are thus needed to clarify the effects of diabetes on the heel pad on the basis of the characteristics of inhomogeneous soft tissue.

Our findings suggests that sonoelastography could be used as a predictor of clinical evidence that such a body area leads to diabetes.

A portable US system, with the capability of sonoelastography modality and high level of image quality, was used due to its transportability. Indeed, many of the subjects with heel pain or heel injuries often have limited mobility. Moreover, sonoelastography is a non-invasive method to support the physician in assessing tissue elasticity. US diagnostic technology is in general cost effective, widely available, real-time, not-ionizing (therefore enabling also repetitive follow ups) and suitable, in case of portable systems, also for home diagnosis (being the US system used for those tests, able to be transported, it can avoid to move the patient which is an interesting plus in case of reduced motility subjects). Sonoelastography enables the clear differentiation of soft and hard structures with the desired Region of Interest (ROI) [13]. Moreover, it is a relatively-quantified technology: tissues are shown as harder or softer in a relative and not absolute manner, therefore, tissues soft are softer than the average value of the tissues within the ROI, while they can be hard if compared to other tissues.
Personal information

Sara Matteoli,

Department of Industrial Engineering, University of Florence, Florence, Italy, sara.matteoli@unifi.it
References


