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Elastosonographic evaluation after extracorporeal shockwave treatment in plantar fasciopathy

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Abstract

Aim: To assess the ultrasound features in patients with plantar fasciopathy before and after extracorporeal shock waves therapy (ESWT), using conventional grey-scale imaging and both strain (SE) and shear wave (SWE) elastosonographic evaluation. **Material and method:** Consecutive patients of both sexes attending our outpatient's clinic, with diagnosis of unilateral plantar fasciopathy, were enrolled. Patients were treated with 3 sessions of ESWT once a week, and underwent clinical and ultrasound evaluation at baseline and at one and three months after treatment. Roles and Maudsley score (RM), visual analog scale (VAS) and 17-Italian Foot Function Index (FFI), were used to assess pain and functional improvement. **Results:** Twenty patients (11 female and 9 male) were enrolled in the study. Contralateral asymptomatic healthy plantar fascia was used as a control. At baseline, SWE velocity (SWEv) showed statistically significant difference between affected 3.8 (1.5; 5.1) m/s and healthy side 4.7 (4.07; 7.04) m/s, (p=0.006); no significant difference was found for strain ratio values (p=0.656). SWEv post hoc test results showed a significant difference from baseline 3.8 (1.5-5.1) m/s and three month 5.23 (4.55-6.74) m/s follow up visit (p=0.003). Significant statistical negative correlation was found between the SWEv and VAS (p=0.001) and between SWEv and FFI (p=0.012). **Conclusion:** SWE was effective in assessing plantar fascia elasticity and its alteration in fasciopathy. Furthermore, on the basis of the correlation with pain and functional scales, this technique appears to be a useful additional technique to conventional ultrasound for monitoring the efficacy of treatment

Keywords: shear wave elastography; strain elastography; strain ratio; plantar fasciitis; extracorporeal shock waves therapy

Introduction

Plantar fasciopathy is a common cause of inferior heel pain [1]. It is known from histological research that plantar fasciopathy is not an acute inflammatory change but rather a process of chronic degeneration [2], with thickening and degenerative tissue findings, so the term 'plantar fasciopathy' should better defined the disorder known as 'plantar fasciitis' [3].

The typical symptoms, including pain when getting out of bed and during initial weight bearing in the morning, are generally exacerbated with increased sporting activity [4]. Even if the diagnosis of plantar fasciopathy is usually based on clinical presentation and physical examination, magnetic resonance imaging (MRI) and ultrasonographic evaluation are often used to aid the diagnosis [5,6]. Conventional ultrasound (US) findings of

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plantar fasciopathy include loss of normal architecture, hypoechoic areas within the fascia, peri-fascial fluid and thickening of the plantar fascia [7]. Some authors consider thickness values >4 mm diagnostic of plantar fasciopathy [5,8-10]. These morphological changes, however, are not always observed with a conventional US in patients with plantar fasciopathy [7,8].

Elastography is a recently developed, non-invasive ultrasonographic imaging technique that provides information on tissue elasticity and stiffness [11-15]. There are two main elastographic techniques widely used: strain elastography (SE) and shear wave elastography (SWE) [12].

To date, studies on healthy and degenerative Achilles tendons [16-18], lateral epicondylitis [19], plantar fascia [20] and several rheumatologic conditions [21,22] have been published. Wu et al [23] reported that plantar fascia is softened in subjects with the characteristic symptoms of plantar fasciitis and Lee et al [24] found that the loss of elasticity of the affected plantar fascia may anticipate morphologic changes visible on B-mode imaging using semi-quantitative methods.

The treatment of plantar fasciopathy is primarily non-operative and includes stretching exercises, non-steroidal anti-inflammatory drugs, low laser therapy, local injection and extracorporeal shock wave therapy (ESWT) [25-27]. Recent systematic reviews with meta-analysis showed that ESWT seems to be particularly effective in relieving pain associated with chronic plantar fasciopathy compared with other conservative treatment. ESWT should be considered when traditional treatments have failed [28-31].

The purpose of this study was to assess the US characteristics of the plantar fascia in patients with plantar fasciopathy before and after ESWT treatment, using clinical parameters, conventional grey-scale imaging and US elastography with both SE and two-dimensional SWE (2D-SWE) techniques.

Material and methods

Study design and population

Consecutive patients of both sexes attending our outpatient's clinic between October 2017 and December 2018 with unilateral plantar fasciopathy diagnosis, were enrolled in the study. The study protocol was approved by the hospital's Ethical Review Board and was conducted in accordance with the principles of the Declaration of Helsinki and its amendments. Patients were fully informed of the characteristics of the study before providing consent and written informed consent was obtained from all subjects.

To be included, a diagnosis of plantar fasciopathy should have been confirmed by: thickening of plantar fascia at US evaluation > 4 mm, pain assessed through visual analog scale (VAS) > 4 out of 10, more than 3 months history of heel pain at the plantar fascial insertion at the medial tubercle of the calcaneus, pain non responsive to previous noninvasive conservative treatment with non-steroidal anti-inflammatory medication, night splints and stretching exercises for at least 3 months.

The exclusion criteria were the diagnosis of inflammatory rheumatologic disease, nerve compression syndrome or previous local trauma. Furthermore, patients who had received steroids, hyaluronic acid or PRP injections within the 3 months before, or had received oral cortisone therapy in the previous month were excluded. Contraindications to ESWT treatment include coagulopathy, cancer, cardiac pacemaker presence and pregnancy.

Study intervention

Patients were treated with 3 sessions of ESWT, once per week. Clinical and US evaluation were performed at the baseline (T0) when patients underwent the first ESWT treatment, at 1-month (T1) and 3 months (T2) after the end of ESWT treatment. Roles and Maudsley (RM) score [32], VAS and 17-Italian Foot Function Index (17-FFI) [33] were used to assess improvement of pain and function. The RM scores were grouped in four categories (excellent, good, average and poor), based on pain and activity ranges in daily life. Visual Analog score (VAS) used as symptoms severity and disease control scale, is a horizontal 100 mm line with verbal descriptors at each end to describe the extremes of level of pain: with "no pain" on the left side (score of 0) and "worst pain imaginable" on the right side of the line (score of 10). Patients were asked to mark the point on the line that corresponded to their current level of pain. 17-Italian Foot Function Index (17-FFI) is a specific outcome measure of the impact of pathologies on foot and ankle function. It consists of 17 items divided into three subscales: pain (5 items), disability (9 items), and activity limitation (3 items).

Ultrasound evaluation

US evaluation of each plantar fascia included grey-scale scanning and elastography, all performed using Toshiba Aplio i800 machine (Canon Medical System Europe BV) equipped with a multi-frequency 5-18 MHz linear probe. All the examinations were performed by a musculoskeletal physician with 10 years of experience in imaging and more than 12 months of experience in US elastography. The patients were placed in a prone position, with the feet hanging over the edge of the examination table.

Longitudinal and short-axis B-mode imaging and longitudinal elastography imaging of both feet were performed. The plantar fascial thickness and the presence of fascial hypoechogenicities and peri-fascial oedema were evaluated.

Fascial thickness and echogenicity were recorded in longitudinal and transverse views. The thickness of the plantar fascia was measured vertically from the anterior edge of the medial inferior calcaneal border to the inferior border of the plantar fascia [32]

SE was performed by applying gentle compression to the heel with hand-held transducer. The force applied to the region was adjusted according to the quality factor bar and the curve displayed on the screen. During the examination, the grey-scale image and the US elastography were displayed concurrently, side by side, on the screen. The elastogram appeared as a colour coded image superimposed over the grey-scale image. The colours represented the relative stiffness of the tissues within the ROI and conventionally ranged from blue (hard) to red (soft) in a continuous spectrum. Yellow/green indicated medium stiffness. Three images of each plantar fascia were recorded.

The qualitative representations of the different colour were examined and used to put the ROI. Strain ratio was calculated by choosing two ROIs: the calcaneus and the plantar fascia according to Kim et al [33]. The dimension of the ROI was intentionally chosen to be 3 mm-diameter and standardized (fig 1). We did not use subcutaneous fat as a reference area, as frequently used in literature, because ESWT influences not only the plantar fascia but also the surrounding fat layer [34].

2D-SWE was performed with the heel and probe in the same position and three evaluations were recorded for each plantar fascia. The SWE measurement was taken 1 cm distally from the calcaneal insertion of the plantar fascia with a 3 mm diameter ROI, trying to avoid the artefact induced by calcifications (fig 2). SWE results were recorded in m/s (SWEv).

ESWT protocol

ESWT was performed in 3 sessions, once a week. Focused shock waves were generated electromagnetically with a MODULITH SLK shock wave device (Storz Medical, Tagerwilen, Switzerland) equipped with an in-line ultrasound positioning system. Ultrasound gel was used as a conductive medium between the skin and the treatment head. All treatments were performed without local anesthesia. According to Schmitz et al [35], 2400 consecutive impulses were applied in each treatment session with a frequency of 4Hz, and an energy flux density of 0.2 mm J/mm^2.

Before the treatment, the clinician located the point of maximal tenderness. Patients lay in a prone position and the affected foot was positioned on the treatment head to allow for perpendicular application of shock waves under ultrasound guidance.

Statistical analysis

Statistical analysis was performed using SPSS software, version 10 (IBM, Armonk, NY). The results are presented as the median and interval (minimum and maximum values). For all variables, the normality of data was ascertained using the Kolmogorov-Smirnov test. Because all the parameters were not normally distributed, the nonparametric Wilcoxon signed-rank test was used to compare the plantar fascia characteristics of the asymptomatic healthy side with the symptomatic affected side. A Friedman test was run to determine if there were differences in thickness, strain ratio (SR) and share wave velocities (SWEv) at baseline and subsequently at one month and three months after the last session of ESWT. A Spearman's rank-order correlation was run to assess the relationship between the two elastographic techniques and the functional and pain scales. A p value <0.05 was chosen for statistical significance.

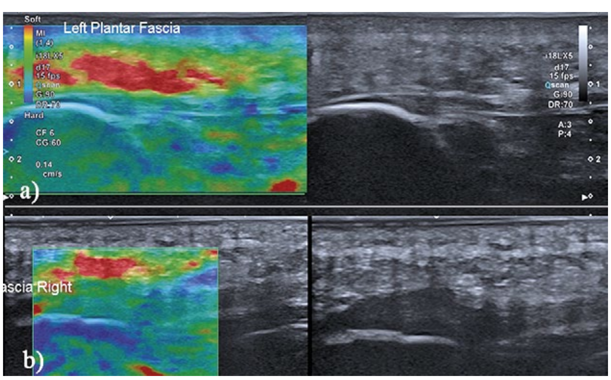

Fig 1. Long-axis Strain Elastography images of a) healthy plantar fascia and b) in a patient with plantar fasciopathy.

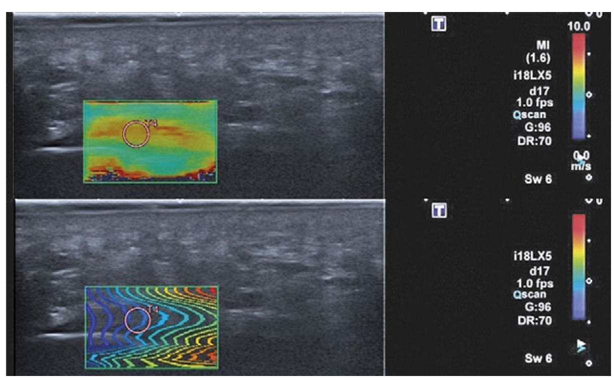

Fig 2. Long-axis Shear Wave Elastography images of plantar fascia in a patient with plantar fasciopathy.

Results

Twenty patients satisfied the inclusion criteria (9 male: 11 female, 50±4.4 and 45±6 years, mean body mass index 24±3.3 and 22.8±2.3 kg/m^2, respectively); the contralateral asymptomatic plantar fascia was used as a control. No side effects were observed or reported by the patients themselves during or after treatment.

Ultrasound findings

At baseline, the affected side showed a thickened plantar fascia comparing with healthy side (<4 mm), (p=0.005). Table I shows the B-mode and elastographic results, at baseline and after ESWT treatment.

At baseline, according to SE, the elastogram color mapshowed on the affected sidepredominantly soft and edematous (54% of cases) features, whereas higher elasticity was found in the asymptomatic contralateral healthy side with homogeneous blue elastogram color map. No significant difference was found for SR values between healthy and affected plantar fascia (p=0.656).

A statistically significant difference was found in SWEv between the affected and healthy sides with a higher value on the healthy side (p=0.006).

One month after ESWT, SWEv increased from the baseline (p<0.05), while no statistically significant differences were found with regards to SR values (p=0.4) and plantar fascia thickness (p= 0.73).

At three months follow up a significant increase in SWEv values (p=0.04) was found (p=0.003). Furthermore, the affected side showed higher stiffness with increased of the blue areas on the color map. Plantar fascia thickness, showed higher values than contralateral healthy side over time (p<0.05). Regard SR values, no statistically significant differences were found from baseline and follow up (p>0.05).

In order to assess whether the two elastographic techniques display different results when compared with functional outcome measures, the Spearman rank test was applied. Significant statistical negative correlation was found between SWEv and VAS score (r=-0.41;p=0.001) and between SWEv and FFI score (r=-0.67; p=0.012); no statistically significant correlation with RM score was found. No statistically significant correlations were found between the SE and both functional and pain scales (p>0.05).

Outcome measures results

Results of outcome measures are shown in table II. According to the VAS score, a significant change in test performance over time was observed in the group patients (p=0.003). A significant decrease in pain was found between the baseline and the three-month follow-up visit (p=0.003). According to the FFI index, significant change over time was observed in the patients' group (p<0.0001) and significant functional improvement was found between baseline and the three-month follow-up visit (p<0.0001).

According to the RM score, significant improvement over time was observed in the group patients (p<0.00001), with a significant difference between the baseline and three-month follow-up visit (p<0.0001).

Discussions

In our study symptomatic plantar fascia have significant lower Young's Moduli values than asymptomatic ones; this means that they are "softer" or "less elastic." This finding is also supported by the elastogram color map, that showed predominantly soft and edematous appearance plantar fasciopathy, whereas in the asymptomatic contralateral healthy side showed higher elasticity color-coding map. These findings are indicative of the presence of less rigid, edematous tissue in patients with plantar fasciopathy in accordance with data in the literature [15,34,36]. SWEv well describes the plantar fascia structural alteration due to fasciopathy, indeed showing lower values in plantar fasciopathy than the healthy asymptomatic plantar fascia [37]. This result could be interpreted as a lack of elasticity on the affected side due to degenerative processes resulting in collagen breakdown, fibroblastic hypertrophy, matrix degradation and

Table I. B-mode and elastographic evaluation at baseline and after ESWT treatment.

	Symptomatic plantar fascia T0	**Symptomatic plantar fascia T1**	**Symptomatic plantar fascia T2**	**Healthy plantar fascia**	**P-value**
Plantar fascia thickness	5 (4;6.9)	5.1 (4.2;7.2)	5.9 (3.6;7)	**3.8 (3.2; 4)**	0.73
SE	*Blue*: 38% Yellow: 54% *Red*: 8%	*Blue*: 32% Yellow: 54% *Red*: 14%	*Blue*: 66% Yellow: 34% *Re*: 0/10	Blue: 19/16 (99%) Yellow: 1 (1%) Red: 0	
Strain Ratio	0.86 (0.3;1.5)	1.3 (0.3;1.6)	0.86 (0.38;1.12)	0.91 (0.63; 1.6)	0.4
SWE (m/s)	3.34 (1.5;5.7)	4.9 (2.5;6.6)	5.45 (4.5;6.7)	4.7 (4.07;7.04)	**< 0.003***

Data presented as median (range). T0: baseline, T1: 1 month after treatment; T2: three months after treatment. SE: strain elastography, SWE: shear wave elastography. * Statistically significant differences between T0 and T2.

Table II. Functional and pain scale at baseline and after ESWT treatment

	T0	T1	T2	P-value
VAS	7 (4;10)	6 (1;10)	4 (1;8)	< 0.003*
RM	4 (2;4)	3 (2;4)	2 (2;3)	< 0.00001*
FFI INDEX	113 (55;144)	60 (16;131)	42 (9;88)	< 0.00001*

Data presented as median (minimum and maximum values). VAS= visual analog scale; RM: Roles and Maudsley score, FFI INDEX: Italian Foot Function Index; T0: baseline, T1: 1 month after treatment; T2: three months after treatment; *Statistically significant differences between T0 and T2

vascular ingrowth observed from cadaver surgical biopsy [4,38,39].

Our findings at one month follow up showed an increase in plantar fascia thickness and the softest areas at the elastogram color map; this finding can be attributed to the ESWT effects on tissue, activating a neovascularization process [40], amplifying growth factor and protein synthesis to stimulate collagen synthesis and tissue remodeling [41]. Hammer et al [42], reported a reduction of the plantar fascia thickness gradually at 6 months after ESWT together with clinical symptom improvement. Instead SWEv increased from the baseline, underlying its usefulness to detect plantar fascia improvement earlier than conventional US.

In our study, three months after the treatment had ended, we found an improvement in pain assessed by VAS and RM scale and function assessed through the FFI index, which correlated with the improvement in both SWEv and the number of blue color areas in the elastography color map.These findings can be correlated with the synthesis of new collagen and therefore with the restoration of plantar fascia characteristics after ESWT treatment according to Vetrano et al [43].

Limits of this preliminary study are the use of contralateral healthy side plantar fascia as a control, the small sample size and the fact that despite the long-term effects of ESWT, we did not follow these patients long enough to evaluate the recurrence rate, possible complications and possible reduction of plantar fascia thickness. Further long-term follow up studies are mandatory. Another issue is represented by the fact we used bone and plantar fascia ROI measurement to assess strain ratio which is not yet universally accepted but still under debate [34,38,44].

In **conclusion,** SWE seems to be a useful elastographic technique to assess plantar fascia elasticity and its alteration in fasciopathy. Furthermore, on the basis of the correlation with pain and functional scales, this technique appears useful in addition to conventional US for monitoring the efficacy of treatment, providing quantitative data. However, further prospective evaluations on a larger population are warranted to confirm these promising results.

Conflict of interest: none

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