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Reduction of Hypoechoic Lesions in Ultrasound Imaging of Plantar Fasciitis Patients: A Proposed Tool for Indication of Treatment Effectiveness

Michael H. Slayton[1*], Richard C. Amodei[2], Keegan B. Compton[3]

[1*]Guided Therapy Systems, Inc. CEO. Guided Therapy Systems, LLC,33 South Sycamore Street Mesa, AZ 85202 USA
[2]Guided Therapy Systems, Inc. Director, Clinical Support, Guided Therapy Systems, LLC,33 South Sycamore Street Mesa, AZ 85202 USA
[3]Guided Therapy Systems, Inc. Biomedical Engineer, Guided Therapy Systems, LLC,33 South Sycamore Street Mesa, AZ 85202 USA

***Corresponding author:** Michael H. Slayton, Guided Therapy Systems, Inc. CEO. Guided Therapy Systems, LLC, 33 South Sycamore Street Mesa, AZ 85202 USA. Tel: +4806494399; Email: m.slayton@guidedtherapy.com

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Abstract

*Ultrasound is the diagnostic tool most used in podiatric practice to evaluate Plantar Fasciopathy **[1]**. It is also the most widely reported imaging modality utilized for this condition **[1]**. Plantar fascia thickness is currently the primary ultrasound imaging criterion confirming a plantar fasciitis diagnosis and for tracking patients after treatment. The thickness measurement has a strong correlation with patients' pain scores **[1-2]**. A plantar fascia thickness up to 4mm is considered normal **[1]**. Yet studies focusing on post-treatment tracking of chronic patients have shown a reduction in pain without a corresponding thinning of the plantar fascia below the ultrasound imaging threshold. Another ultrasound criterion, shown to have significant presence in both acute and chronic symptomatic patients **[2-10]**, is the appearance of perifascial hypoechoic lesions. A retrospective study analyzing the depth and thickness of symptomatic and contralateral plantar fasciae via ultrasound imaging revealed the presence of perifascial hypoechoic lesions in 93% of symptomatic patients. Following these results, a combined study was conducted analyzing the volumes of hypoechoic lesions as well as the correlation of plantar fascia thicknesses and pain scores. Results of the combined study showed over 90% of patients had a hypoechoic lesion prior to treatment. Furthermore, an average 42% reduction in VAS pain score, an average of 15% reduction in thickness and an average 68% reduction in hypoechoic lesion volume was observed at 12 weeks post-treatment when compared to baseline. The average plantar fascia thickness for the treatment group was 5.1mm at 12 weeks, exceeding the 4mm diagnostic ultrasound threshold. A Pearson correlation coefficient of r= 0.982 was found after linear regression analysis of average lesion size reduction from baseline to VAS pain score reduction from baseline. We propose that tracking the presence and volume changes of these lesions may be as important a collaborating indicator for successful PF treatment as is the change of plantar fascia thickness. This gives clinicians another quantitative tool to compare against changes in pain scores and a better understanding of a treatment's efficacy, especially for chronic patients.*

1. Keywords: Echogenicity; Hypoechoic lesions; Intense therapeutic ultrasound; Pain reduction; Plantar fasciitis; Plantar fascia thickness; Plantar fasciitis treatment; Ultrasound imaging

2. Introduction

Plantar fasciitis (PF) is one of the most common causes of heel pain, often caused from repetitive excessive load on the local tissue in acute cases and degeneration in chronic cases. The most common diagnostic imaging indicator of PF is an increased thickness of the central and medial bands of the plantar fascia. Ultrasound imaging is often employed to confirm the diagnosis of PF and the extent of thickening as well as to localize the area for invasive treatments. A systematic review performed by Mahowald et al. showed that the average thickness of asymptomatic plantar fascia across several studies was 3.4mm, whereas thicknesses over 4mm are generally considered symptomatic. Furthermore, the study showed that plantar fascia thickness correlated well with patient pain **[1]**. Some studies have shown that the opposite correlation to be true as well: as treatment of PF takes effect and patient pain is reduced, the thickness of the plantar fascia reduces as well **[1,2]**. Since a standard practice for diagnosing a patient with plantar fasciitis involves observing a thickness above a certain threshold (usually > 4.0mm), measuring the thickness after administering treatment that results in the thinning of the plantar fascia is used to indicate the treatment's efficacy **[11-15].**

However, one detail not discussed in these studies is the length of time patients experienced the symptoms of heel pain, thus no distinction is made between acute and chronic conditions. Although thickening of the plantar fascia is a good indicator for PF diagnosis, even for chronic patients **[16]**, acute and chronic patients may differ in the extent of degeneration of the fascia tissue. This degeneration is seen as another main characteristic of PF: presence of hypoechoic lesions during ultrasound imaging **[2]**. Hypoechoic lesions in ultrasound imaging of the plantar fascia indicate fluid buildup at the site of tissue regeneration, an example of which can be seen in **(Figure 1)**. As the condition becomes chronic, persistent lesions indicate a malformation in tissue healing and a weakness at the site that may contribute to the patient's pain level. A study by Lemont et al. suggests that the condition should be called 'fasciosis' due to these non-inflammatory changes to the structure of the plantar fascia in PF patients **[17]**.

A retrospective study of patients diagnosed with unilateral PF, analyzing the ultrasound images from 126 PF patients for plantar fascia thickness, depth, and presence of hypoechoic lesions in both the symptomatic and contralateral asymptomatic feet, was conducted **[18]**. Patients who experienced symptoms for ≤ 3 months were considered acute and > 3 months were considered chronic. This time-point was chosen based on the time needed for the formation of collagen during the wound healing process and reaching the remodeling phase, especially in fascial tissue with poor blood supply **[19]**. Results from the study show significant differences in plantar fascia thickness between acute and chronic patients' symptomatic feet. Moreover, significant differences were found between the symptomatic and contralateral asymptomatic feet of the acute patients, while the chronic patients did not demonstrate a significant difference in PF thickness **(Figure 2)**. In addition, 93% of symptomatic feet showed the presence of hypoechoic lesions, while only 15% of the asymptomatic contralateral feet demonstrated any hypoechogenicity in the perifascial region **[18].**

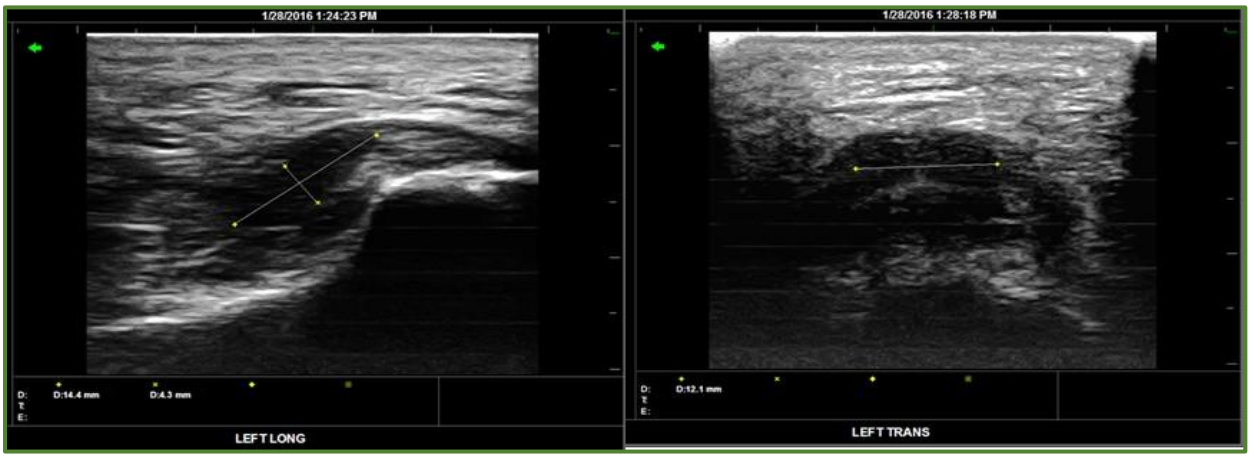

Figure 1: Example of Hypoechoic Lesion in Ultrasound Imaging.Symptomatic feet often show reduced echogenicity during diagnostic ultrasound imaging. The volume of the hypoechoic lesions was measured from finding the maximum radii of the anterior/posterior (left image, left to right), superior/inferior (left image, top to bottom), and medial/lateral (right image, left to right) axes.

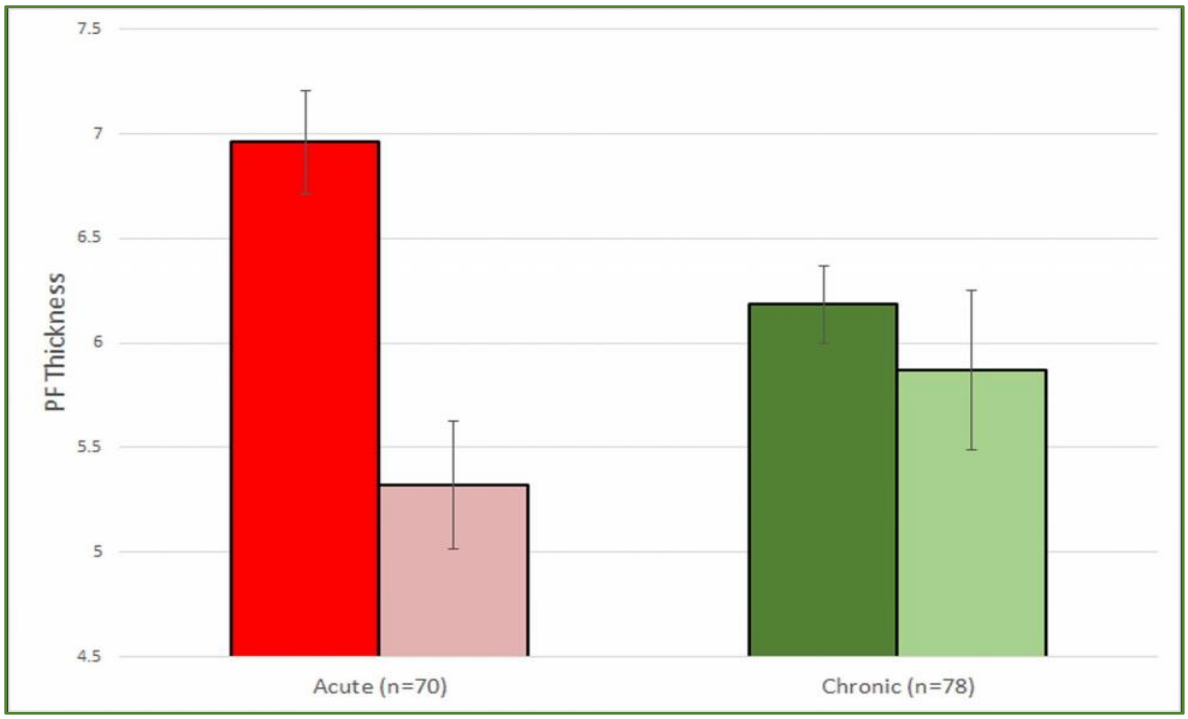

Figure 2: Retrospective Study PF Thickness Averages for Acute & Chronic Groups for Symptomatic and Asymptomatic Feet. Symptomatic acute (deep red, 6.96 ± 1.77mm) was significantly different from both symptomatic chronic (deep green, 6.18 ± 1.48mm, $p = .01$) and asymptomatic acute (light red, 5.32 ± 1.29mm, $p < .001$). When the condition was chronic, no significant difference was found between symptomatic and asymptomatic (light green, $p = .48$). Differences between asymptomatic categories were insignificant as well ($p = .25$). The average PF thickness for all groups was above 5mm, higher than the generally accepted diagnostic threshold of 4mm.

The retrospective study results led to the development of a combined study (double-blinded, sham controlled feasibility study &a single-blinded pivotal study) **[18, 20]** analyzing the presence and change in hypoechoic lesion volumes as well as the correlation of that change to changes in patient pain scores. An objective of this combined study was to determine if hypoechoic lesion volume or size, just like plantar fascia thickness, could be directly correlated to treatment effectiveness in PF patients.

3. Materials and Methods

3.1. Inclusion/Exclusion Criteria

Subjects between 18 and 85 years of age, previously diagnosed with chronic plantar fasciitis and were experiencing unilateral pain (>90 days) after conservative "standard of care" regimens, and in some cases more aggressive minimally invasive therapies, failed to relieve pain in the plantar fascia were included in the study. Subjects provided both written and verbal consent as well as willingness to complete treatment and post-treatment regimen as prescribed.

Subjects were excluded from the studies if they experienced bilateral plantar fascia pain, local infections, previous foot surgery or other foot/ankle pathologies, were pregnant or planning to become pregnant, or were unwilling or unable to complete the post-treatment "Standard-of-Care" regimen as prescribed by the PIs. Patients currently enrolled in any other non-conservative, device, or IND clinical

trial, or who have participated in a clinical study involving the Plantar Fascia, thirty days prior to study initiation; patients who have participated in any other clinical study involving an investigational product 30 days prior to enrollment that, in the opinion of the Principal Investigators, could affect the outcome of the studies were also excluded. Patients who had received previous treatment, within the last 90 days, in the symptomatic foot (not including conservative treatment) were excluded from the study.

3.2. Treatment Regimen

Subjects underwent 2 treatments 2-4 weeks apart at time 0 and 2-4 weeks from the start of each study. A series of ultrasound pulses, up to 1000 per treatment, with an energy level up to 5 Joules were administered to the plantar fascia, approximately 13-15 mm below the skin line. All subjects were instructed to complete both stretching and strength building exercises as prescribed by the Principal Investigators (PI). The PI for the pivotal study also included the use of a walking boot for 2 – 4 weeks after each treatment, depending on the subject's progress.

3.3. Outcome Measures

Lesion volume was tracked at baseline and at weeks 4, 8, and 12 after initial treatment. Volume was calculated via ultrasound images of the long and transverse planes by measuring the inferior-to-superior and posterior-to-anterior radii in the long axis and the medial-to-lateral radius of the transverse axis and applying the following formula for the volume of an ellipse: Volume = (4/3) π*r1*r2*r3:

Patients reported an overall pain score relating to plantar fascia pain using the visual analog scale (VAS) pain score of 0-10, with 0 indicating no pain and 10 indicating worst imaginable pain. Patients self-reported this pain score at baseline and at each follow-up visit and phone calls at 4, 8, 12, and 26 weeks after initial treatment. In addition to comparing patient's pain scores and lesion sizes to baseline, correlation of corresponding average pain scores and average lesion size changes for weeks 4, 8, and 12 following treatment was performed to determine the strength of relationship between these two calculations.

3.4. Statistical Analysis

Lesion sizes and pain scores reported at follow-up time points were compared to baseline measurements for each subject. Student paired T-tests were utilized to determine statistically significant differences between baseline and subsequent follow-up measurements. Error displayed in the text (as "(±X.X%)") are standard error. The level of significance (α) was set to 0.05.

4. Results

4.1. Patient Information

74 Patients were included in this study; 50 females and 24 males. The age range of the study group was 31-73 years old, with a median age of 56. The number of patients declined over the course of the study due to attrition, with 69 patients at week 4, 65 patients at week 8, 59 patients at week 12, and 48 patients at week 26.

4.2. Lesion Size

More than 90% of patients showed a presence of hypoechoic lesions in ultrasound imaging of the symptomatic foot prior to treatment. After treatment, the average volume change of the hypoechoic lesions was significant at each follow-up time point, starting at -33% (±6.8%) at week 4 and further to -68% (±9.8%) at week 12. An example of lesion volume reduction can be seen in **(Figure 3)**.

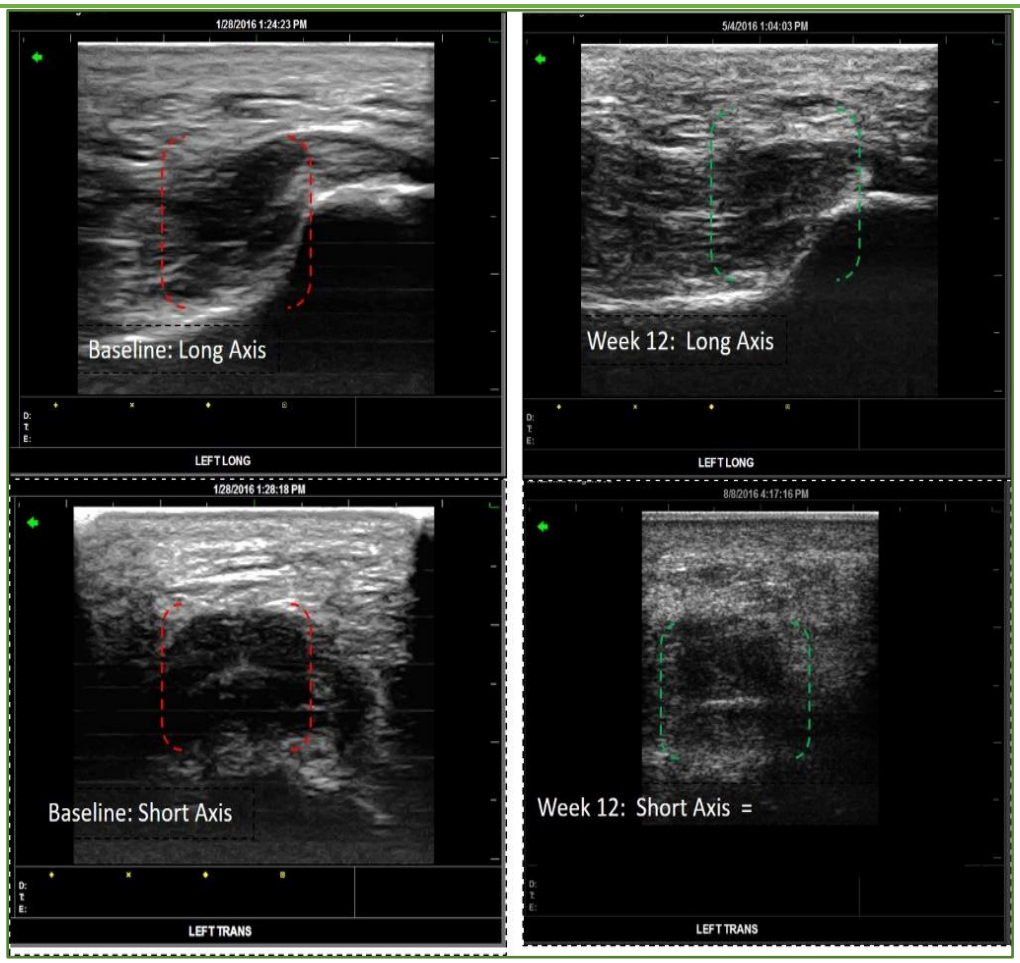

Figure 3: Hypoechoic Lesion Presence in PF Symptomatic Foot, Baseline & 12-Week Follow-Up. Ultrasound images taken at baseline (left top & left bottom) and 12 weeks (right top and right bottom). Hypoechoic lesions at baseline (red brackets) were prevalent in over 90% of patients. After 12 weeks (green brackets), there is a return of echogenicity and a reduction of hypoechoic lesion volume, indicating fascial tissue repair.

4.3. Pain Score

Patients showed significant reduction in pain at all follow-up visits. The treatment group had an average pain reduction of -26% (±5.6%) at week 4, and that reduction improves to -43% (±4.7%) and -40% (±6.2%) at weeks 12 and 26, respectively.

4.4. Lesion Size/Pain Score Correlation

Correlation of those reductions gave a correlation coefficient value of r=0.982, indicating a very strong positive correlation between these two measures, seen in **(Figure 4)**.

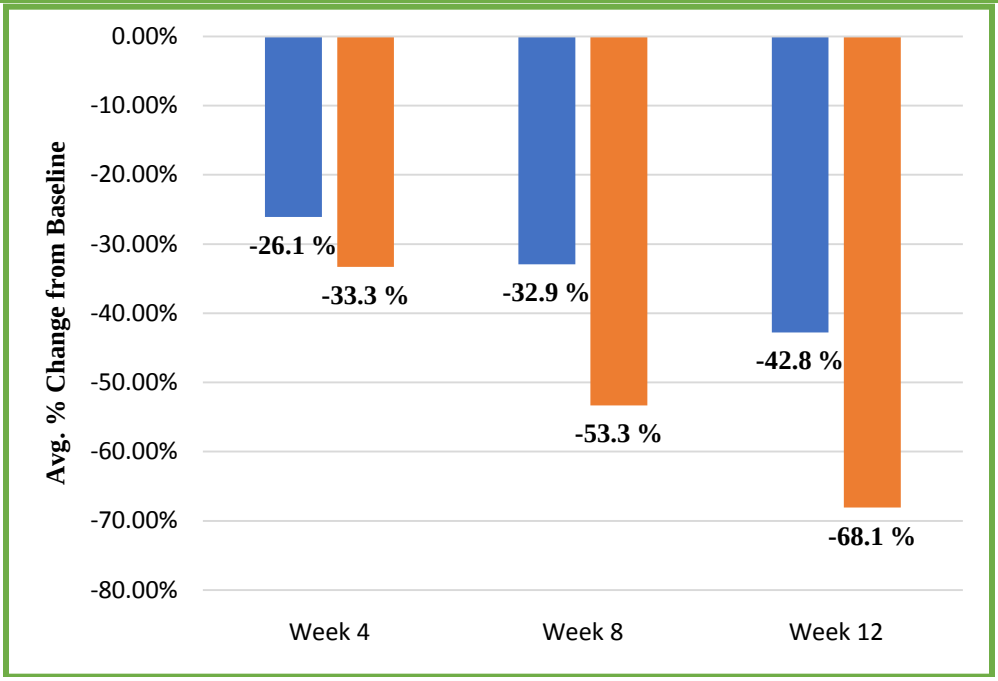

Figure 4: Average % Change: Pain and Lesion Size Compared to Base line. Average reductions of VAS score (blue) and lesion volume (orange) from baseline measurement correlated well along the 3 follow-up time points. Linear regression analysis of these average measurements for the 3 follow-ups showed a Pearson correlation coefficient of r=0.982, indicating a strong direct correlation.

4.5. Plantar Fascia Thickness

At 12 weeks after treatment, the average plantar fascia thickness was 5.1mm, exceeding the 4mm threshold by 25%.

5. Discussion

(Table 1) shows several studies that use PF thickness as an outcome measure for treatment efficacy **[3-5, 21-25]**. Both pain scores and plantar fascia thicknesses see significant drops in 7 of the 8 studies, yet the latest post-treatment follow-ups still have average plantar fascia thicknesses above the diagnostic ultrasound imaging threshold of 4mm. Results of the retrospective study **[18]** showed the average plantar fascia thickness above 4mm in both the chronic symptomatic and the contralateral asymptomatic feet. The methodology by which the thickness measurement is performed is dependent on both the technician and the equipment used, possibly creating some result variation.

The chronic, recalcitrant nature of the injury for these patients means that the plantar fascia has undergone degeneration in addition to thickening. Several studies have stated that ultrasound imaging of symptomatic plantar fasciae often demonstrates the presence of hypoechoic lesions compared to images of healthy feet **[2-10]**. A study performed by Moustafa et al. utilized ultrasound to track PF patients experiencing 2+ months of heel pain and receiving a subsequent corticosteroid treatment. Both plantar fascia thickness and hypoechogenicity were assessed by diagnostic ultrasound. The results showed significant post-treatment reductions of both. Furthermore, along with an increase in PF thickness, a significant percentage of symptomatic feet demonstrated the presence of hypoechoic lesions when compared to the contralateral asymptomatic feet **[10].**

This current combined study took the hypoechoic lesion tracking another step further and quantified the volume change in order to correlate the data with pain reduction, and the results show a strong direct correlation. This suggests that tracking hypoechoic lesion volume may be an additional diagnostic ultrasound tool for quantifying treatment success for PF alongside plantar fascia thickness.

Author	Treatment	Follow-up	PF Thickness Pre-Treatment (mm)	PF Thickness Follow-up (mm)	Number of Patients	Patients' Duration of Symptoms
Kayhan et al.[12]	Sonography-guided corticosteroid injection	6 weeks	5.44 ± 1.014	4.07 ± 0.86	31	Avg.: 9.6 months (2-24 months)
Hammer et al.[13]	ESWT	6, 12, 24 weeks	5.2 ± 1.5	6 weeks: 4.5 ± 1.4 12 weeks: 4.7 ± 1.4 24 weeks: 4.4 ± 1.0	22	At least 6 months (inclusion criteria)
Yucel et al.[14]	Sonography-guided corticosteroid injection Silicone insoles	1 month	5.61 ± 1.22 5.77 ± 0.69	4.43 ± 0.85 5.15 ± 0.89	67	At least 3 months (inclusion criteria)
Kane et al.[15]	Sonography-guided corticosteroid injection	6, 24 months	Avg.: 6.16 (symptomatic) Avg.: 4.10 (asymptomatic)	N/A	4 (5 symptomatic feet)	Not specified; all patients previously underwent conservative treatment that failed.
McMillan et al.[16]	Sonography-guided corticosteroid injection	4, 8, 12 weeks	6.67 ± 1.53 (injection) 6.29 ± 1.20 (placebo)	5.74 ± 1.14 (injection @ 12w) 5.94 ± 1.34 (placebo @ 12w)	82	At least 8 weeks (inclusion criteria)
Chew et al.[17]	Autologous Plasma Injection (ACP) ESWT Conventional treatment	6 months	Avg.: 6.4 Avg.: 5.4 Avg.: 5.55	Avg.: 4.8 (@ 6 mo) Avg.: 4.9 (@ 6 mo) Avg.: 4.8 (@ 6 mo)	54	At least 4 months (inclusion criteria)
Gordon et al.[18]	low energy extracorporeal pulse activated therapy (EPAT)	12-54 months	7.3 ± 2.0	6.0 ± 1.3	25 (35 feet)	At least 1 year (inclusion criteria)
Liang et al.[19]	ESWT (low) ESWT(High) (high)	6 months	4.6 ± 1.2 4.7 ± 1.3	4.2 ± 1.3 4.5 ± 1.1	53 (78 feet)	At least 6 months (inclusion criteria)

Table 1: Literature on Pre- and Post-Treatment Measurements of PF Thickness, Chronic Patients.

6. Conclusion

Plantar fascia thickness by diagnostic ultrasound has been established as the standard for quantifying PF diagnosis prior to treatment. Although it is hypothesized that a reduction of a plantar fascia thickness correlates with a reduction in pain, several studies have shown that a thickness above the threshold of 4mm can still see significant drops in pain level especially in chronic cases. Ultrasound images analyzed in the combined study found the presence of hypoechoic lesions in ultrasound imaging prevalent in over 90% of symptomatic feet. When assessing chronic PF patients, post-treatment, the corresponding volume change of those lesions correlated well with pain reduction. Plantar fascia thickness was also reduced but the average thickness for the treatment group exceeded the 4mm threshold, averaging 5.1mm at 12 weeks. For future studies concerning the treatment of heel pain associated with PF, tracking the presence and volume change of hypoechoic lesions by ultrasound imaging should hold the same consideration as plantar fascia thickness in determining successful treatment. This approach may give clinicians another quantitative tool to compare against changes in pain scores and a better understanding of a treatment's efficacy, especially for chronic patients.

7. Acknowledgements

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