

Clinical and Imaging Outcomes of Plantar Fasciotomy Using Microdebrider Coblation Wand

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Abstract

Background: A plantar fasciotomy using a microdebrider coblation wand may be an effective treatment for treating chronic plantar fasciitis. The objective of this prospective study was to determine the success rate of performing a plantar fasciotomy using a microdebrider coblation wand to treat plantar fasciitis and determine utility of ultrasonographic imaging to evaluate for recovery after treatment.

Methods: Patients with plantar fasciitis treated with a plantar fasciotomy using a microdebrider coblation wand were prospectively followed for 1 year. Outcome measures included numeric rating scale (NRS) for pain, Foot and Ankle Disability Index (FADI), the Foot and Ankle Ability Measure for activities of daily living (FAAMA) and for sports (FAAMS), and plantar fascia thickness evaluated with ultrasonographic imaging.

Results: Forty patients were included. Average patient age was 53.4 ± 9.9 years. Average symptom duration prior to the procedure was 20 ± 26 months. Five patients dropped out of the study at various points, most due to the COVID quarantine. The mean preoperative NRS score was 4.7 and at 3 and 6 months postprocedure was ≤ 2 . At 1 year, the outcomes were all improved compared to the preoperative status: NRS 0.7 ± 1.3 ($P < .001$), FADI 107 ± 16 ($P < .001$), FAAMA $95\% \pm 10\%$ ($P < .001$), FAAMS $84\% \pm 19\%$ ($P < .001$), and plantar fascia thickness 6.8 ± 1.2 mm ($P = .014$). Furthermore, 86% of patients had clinically successful outcome in pain, defined as NRS score ≤ 2 (95% CI 0, 2), and 91% of patients had a clinically successful outcome in their function, defined as having an FAAMA score $\geq 75\%$. There were no complications at the operative site either during or after the procedure.

Conclusion: In this study of 40 patients followed prospectively, we found percutaneous plantar fasciotomy using a microdebrider coblation wand to be an effective treatment for plantar fasciitis, with a low incidence of complications. Ultrasonographic imaging may help evaluate for interval healing.

Level of Evidence: Level IV, prospective case series.

Keywords: plantar fasciitis, fasciotomy, microdebrider coblation wand, ultrasound

Introduction

Plantar fasciitis is defined as an inflammation of the plantar fascia and surrounding perifascial structures. It is one of the most common causes of heel pain in adults, accounting for approximately 1 million patient visits per year in the United States.⁶ The lifetime incidence is 10%.²⁰ In 2018, Nahin¹⁵ analyzed data from the 2013 US National Health and

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Wellness Survey and calculated a 0.85% overall prevalence of symptomatic plantar fasciitis. Among those, 62% of patients reported daily pain and 54% reported that their pain interfered with their work. Women were 2.5 times more likely than men to report plantar fasciitis and patients with a body mass index ≥ 30 were 5 times more likely than those with a body mass index less than 25.¹⁵

Conservative treatments for plantar fasciitis typically include nonsteroidal antiinflammatory drugs, night splints, cortisone injections, and physical therapy.^{6,16,19,20} Unfortunately 10% to 20% of patients with these treatments do not obtain significant clinical improvement within 12 months.^{16,19,20} For many years, the only other option for recalcitrant cases was performing an operative release of the plantar fascia, with the endoscopic technique being preferred over the open release,^{19,20} unless a nerve compression is involved.¹⁶

Outcomes of the operative release are variable and there is poor evidence (level C) to support this procedure.¹² A plantar fasciotomy using a microdebrider coblation wand (Topaz EZ coblation wand; Smith & Nephew, London, United Kingdom) has been studied as an effective treatment for recalcitrant cases.^{2-4,22-24} This minimally invasive procedure can achieve similar outcomes to the operative release without requiring an operative incision.²²⁻²⁴ However, existing studies of the microdebrider technique have small sample size or are retrospective studies.

In addition, no prior study has evaluated the interval healing of the plantar fascia after a fasciotomy using ultrasonographic imaging. Normal plantar fascia observed under sonography shows a heterogenous fibrillar pattern because of the hyperechoic appearance of type 1 collagen fibers and hypoechoic extracellular matrix, and a mean thickness of 4 mm. In plantar fasciitis, there is a loss of fibrillar structure noted as a decrease in the echogenicity of the collagen fibers, increased thickness over 4.5 mm, and perifascial collections and/or calcifications within the fascia.^{5,9} Johannsen et al⁸ observed the plantar fascia of 11 patients under ultrasonography after endoscopic partial plantar fasciotomy. Eight of 11 patients were observed pre- and 1-year postprocedure, and average thickness decreased from 6.0 to 3.5 mm. In the other 3 cases, scar tissue made it impossible to clearly outline the fascia.

This study prospectively evaluated patients who received a plantar fasciotomy using the microdebrider coblation wand to determine if there is a statistically significant improvement in pain and functional outcomes up to 1 year after the procedure. The primary objective of this study was improvement of pain. The secondary objectives of this study included the evaluation of functional improvement for activities of daily living and sports, and evaluation of interval healing of the plantar fascia after the procedure using ultrasonographic imaging.

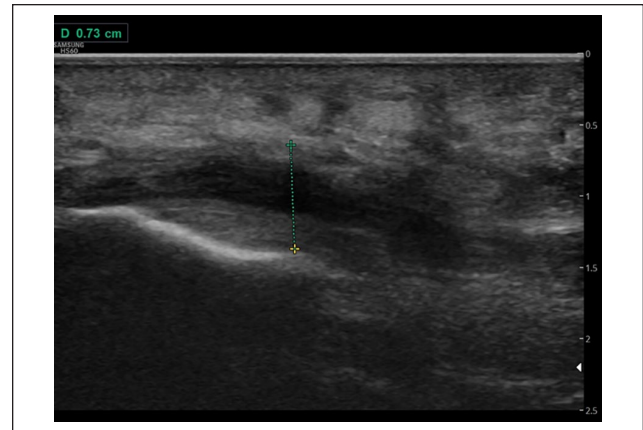


Figure 1. Ultrasonographic imaging of the plantar fascia origin at the calcaneus before the plantar fasciotomy showing the hypoechoic swelling in the fascia and a plantar fascia thickness of 7.3 mm.

Methods

The study design was a prospective case series. Ultrasonographic images were assessed for evidence of healing postprocedure and compared with preprocedure images. All patients were evaluated and treated by a single sports medicine physiatrist with added certification in musculoskeletal ultrasonography. Patients completed a questionnaire at the preprocedure visit, on the day of the procedure, and at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postprocedure. All patients were evaluated with ultrasonographic imaging at the preprocedure visit, as well as 3 months, 6 months, and 1 year after the procedure.

Patients of all sex, race, and ethnicity between the ages of 19 and 65 years with the primary diagnosis of plantar fasciitis that were evaluated between June 2019 and July 2020 were invited to participate in the study. Inclusion criteria were a diagnosis of plantar fasciitis based on (1) tenderness to palpation over the plantar fascia origin at the calcaneus, (2) heel pain that was worse with walking or weightbearing activities, and (3) ultrasonographic image showing abnormal thickening of the plantar fascia, defined as thickness greater than 4.5 mm.²² As normal plantar fascia thickness ranges from 2.7 to 4.5 mm, it is considered pathologic when the thickness is greater than 4.5 mm.²¹ Figure 1 provides an example of a pathologic plantar fascia thickness. Additionally, patients must have had symptoms for more than 3 months and tried and failed at least 4 weeks of conservative treatment, including at least 2 of the following treatments: antiinflammatory medication (ie, nonsteroidal antiinflammatory drug), cortisone injection, or physical therapy program. Exclusion criteria were (1) prior calcaneal fracture, infection, or operative treatment for plantar fasciitis; (2) active ankle or foot tendonitis; (3) diagnosed

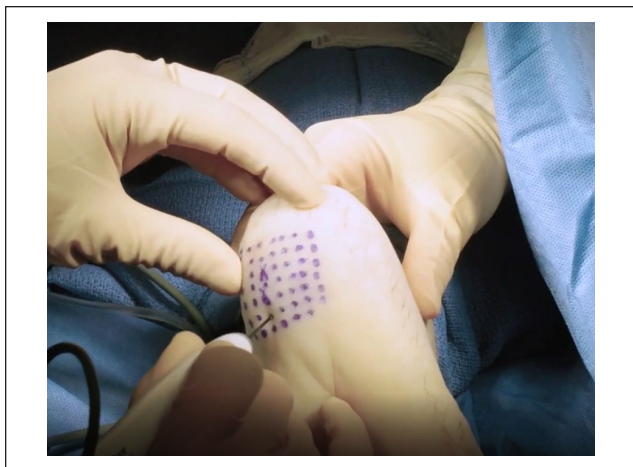


Figure 2. Plantar fasciotomy using the microdebrider coblation wand in the operating room.

insulin-dependent diabetes mellitus; (4) pregnancy; (5) diagnosed peripheral neuropathy, peripheral vascular disease, rheumatoid arthritis, and systemic inflammatory or other immunosuppressive conditions; (6) diagnosed plantar fibroma, tarsal tunnel syndrome, or ankle osteoarthritis; (7) current use of opioid medication, fluoroquinolone medication, or blood thinner medication; or (8) any imaging findings suggesting the presence of additional pathology in the ankle or hindfoot such as subtalar joint osteoarthritis, calcaneal stress fracture, cellulitis, etc.

Prior to the procedure, patients completed a survey that included the numeric rating scale (NRS) for pain, Foot and Ankle Disability Index (FADI) assessment, and Foot and Ankle Ability Measure (FAAM) questionnaire.^{7,13,14} For the NRS score, patients stated their current pain on a scale from 0 (no pain) to 10 (unbearable pain).⁷ The FADI assessment graded activity level from 0 (unable to do) to 4 (no difficulty) and pain related to the foot and ankle from 0 (unbearable) to 4 (no pain).¹³ The FAAM questionnaire evaluated the patient's current function as a percentage from 0% (inability to perform any daily activities) to 100% (function prior to foot and ankle problems).¹⁴ This questionnaire had 2 subscales: one for activities of daily living (FAAMA) and one for sport (FAAMS). All patients completed the FAAMA questionnaire. In addition, those patients who indicated that they played sports completed the FAAMS questionnaire. The plantar fascia thickness was calculated with ultrasonographic imaging by scanning the fascia at the calcaneal origin in the sagittal and coronal planes and measuring the thickest part using a Samsung HS60 ultrasound machine with an LA4-18BD linear probe (Samsung / Neuro Logica Corporation, Danvers, MA).

All procedures were performed at an outpatient surgery center following the same standard outpatient surgery protocols with conscious sedation described by Colberg et al⁴ (Figure 2):

The plantar fascia origin and the point of maximal tenderness were identified by palpation, and a grid of 40 dots was marked with a permanent marker on the skin over the whole plantar fascia origin. A local tibial nerve block was performed under ultrasound guidance proximal to the tarsal tunnel by injecting 3 mL lidocaine 1% and 2 mL Marcaine 0.25%. Another 5 mL lidocaine 1% was injected on the plantar side of the heel to cover areas innervated by the lateral calcaneal nerve that the tibial nerve block did not anesthetize. Skin punctures were then performed using an 18-gauge needle with a blade at the tip (Nokor Admix, Becton, Dickinson and Company, Franklin Lakes, N.J.) at the 40 marked sites over the plantar fascia origin (the [blade] did not penetrate the plantar fascia). The microdebrider coblation wand was then introduced at each of the 40 puncture sites, advanced into the plantar fascia origin, and activated in order to coblate the plantar fascia tissue at each site. Another 5 mL lidocaine 1% with epinephrine was injected into the treated area to minimize postoperative bleeding and pain. The wound was covered with dressing and the foot was placed in a short CAM [controlled ankle motion] boot.

The patient was instructed to remove the dressing in 3 days. Weight Bearing restrictions were as follows: touchdown weight bearing for 3 days, partial weight bearing for 4 days, then weightbearing as tolerated for 1 week. The boot was used at all times, including sleeping, for 2 weeks. Then, a 7-day boot wean protocol was initiated together with physical therapy for 4 weeks.

Although the operative procedure was identical to that described by Colberg et al, the patients in this prospective study were a new cohort.⁴ The patients were seen for regular follow-up visits postprocedure at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year.

In order to determine whether the outcome metrics changed postprocedure, statistical analyses were performed using SPSS 27.0 (IBM Corporation, Armonk, NY). Descriptive statistics (ie, means and SDs and/or CIs) were calculated for any outcome variables (ie, 4 survey scores and the measured plantar fascia thickness), measured at each visit. The percentage of patients who obtained a clinically relevant successful outcome in their pain and function at the 1-year postprocedure follow-up was calculated, defined by an NRS score of 2 or below and an FAAM score of greater than 75%. In addition, the most recent value before the procedure for each outcome variable (ie, day of procedure values for the surveys and preprocedure visit values for plantar fascia thickness) was compared to the 1-year postprocedure visit value using paired *t* tests. To illustrate trends across all available time points, mean survey score values were calculated and plotted across 7 time points (preprocedure visit; day-of-procedure; and follow-ups at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postprocedure), whereas plantar fascia thickness values were plotted across all 4 available time points (preprocedure visit; and at 3 months, 6 months, and 1 year postprocedure). To evaluate

Table 1. Mean \pm SD Values for the Outcome Variables Prior to the Procedure and at Final Follow-up Visits (With *P* Value for the Paired *t* Test Comparison).^a

Measurement	Before Procedure	1 y Postprocedure	<i>P</i> Value
NRS score	4.1 \pm 1.8	0.7 \pm 1.3	<.001 ^b
FADI score	70.0 \pm 17.0	107.3 \pm 15.9	<.001 ^b
FAAMA score %	58.5 \pm 15.7	94.7 \pm 10.5	<.001 ^b
FAAMS score %	31.2 \pm 17.5	84.6 \pm 19.6	<.001 ^b
Plantar fascia thickness (mm)	7.5 \pm 1.2	6.8 \pm 1.2	.014 ^b

Abbreviations: FADI, Foot and Ankle Disability Index; FAAMA, Foot and Ankle Ability Measure (FAAM) for activities of daily living; FAAMS, FAAM for sports; NRS, numeric rating scale.

^aThe “before” plantar fascia thickness measurement was taken at the preprocedure visit, whereas the “before” survey scores were from the day of the procedure.

^bDenotes a statistically significant difference ($P < .05$).

possible sex-related differences in outcomes, the change in each of the 5 variables was compared between male and female groups using unpaired *t* tests. To determine possible age-related differences in outcomes, the change in each of the 5 variables was related to age using a Pearson correlation analysis. Finally, Pearson correlations were also performed to evaluate the relationship between the duration of symptoms prior to the procedure and the plantar fascia thickness at both the preprocedure and 1-year postprocedure visits. The threshold for statistical significance for all tests was set at $\alpha = 0.05$.

Results

During the recruitment period, 195 patients were seen in the clinic and treated for plantar fasciitis. A total of 40 patients (9 males and 31 females) met inclusion/exclusion criteria and consented to participate. The average age was 53.4 ± 9.9 years. The average duration of symptoms prior to the procedure was 20 ± 26 months, with a range between 4 months and 11 years. All 40 patients received the procedure. Thirty-five patients (88%) completed the study through the 1-year follow-up point (7 males and 28 females). Five patients dropped out of the study at various points. One patient was doing 80% better at 6 weeks and was lost to follow-up afterward. One patient did not obtain significant subjective relief after 6 months in the study despite the outcome measures showing interval improvement of symptoms and sought a second opinion. Three other patients were lost to follow-up during the COVID-19 pandemic (2 at the 6-month visit and 1 at the 1-year visit).

Table 1 provides the mean (and SD) values for the 5 measurements at the preprocedure and 1-year postprocedure visits. All 5 measures showed statistically significant improvement. There were no statistically significant relationships between age or sex within these improvements.

Figure 3 shows the improvement in NRS scores over time. Compared with the day of procedure, patients reported

on average a 10% improvement in the pain NRS score at 2 weeks ($n = 40$), 35% improvement at 6 weeks ($n = 40$), 50% improvement at 3 months ($n = 39$), 64% improvement at 6 months ($n = 37$), and 82% improvement in NRS scores at 1 year ($n = 35$). At the 1-year follow-up, 86% of patients (30 of 35) had obtained a clinically successful outcome in their pain, defined as an NRS score of 2 or below, 25 patients (71%) reported an NRS score of 0 of 10 at the 1-year follow-up, 5 patients (14%) reported pain between NRS scores 1 and 2, and the other 5 patients (14%) reported an NRS score of 3 or 4. No patient reported pain higher than an NRS score 4 of 10. Of the patients who did not complete the study, 80% (4 of 5) had an NRS score of 2 or below at their last completed time point.

Evaluating functional outcomes, Figure 4 shows the FADI, FAAMA, and FAAMS scores across various time points. Functional scores decreased for the first 2 weeks after the procedure while the patients used the boot, but then continuously increased for the remainder of the year postprocedure. At the 1-year follow-up, 91% of patients (32 of 35) had obtained a clinically successful outcome in their function, defined by a FAAMA score greater than 75%. All 5 patients who did not complete the study had a FAAMA score greater than 75% at their last completed time point.

Figure 5 shows the change in plantar fascia thickness over time. The average plantar fascia thickness significantly decreased from 7.5 ± 1.2 mm preprocedure to 6.8 ± 1.2 mm 1 year postprocedure ($P = .014$). Follow-up ultrasonographic imaging of the plantar fascia at 1 year demonstrated an increase of hyperechoic signal within the fascia, correlating with remodeling of the collagen fibers (Figure 6). No statistically significant correlations were found between plantar fascia thickness and patients' severity or duration of symptoms prior to the procedure.

There were no significant complications that were directly related to the microdebridement procedure. One patient developed posterior tibialis tendonitis approximately

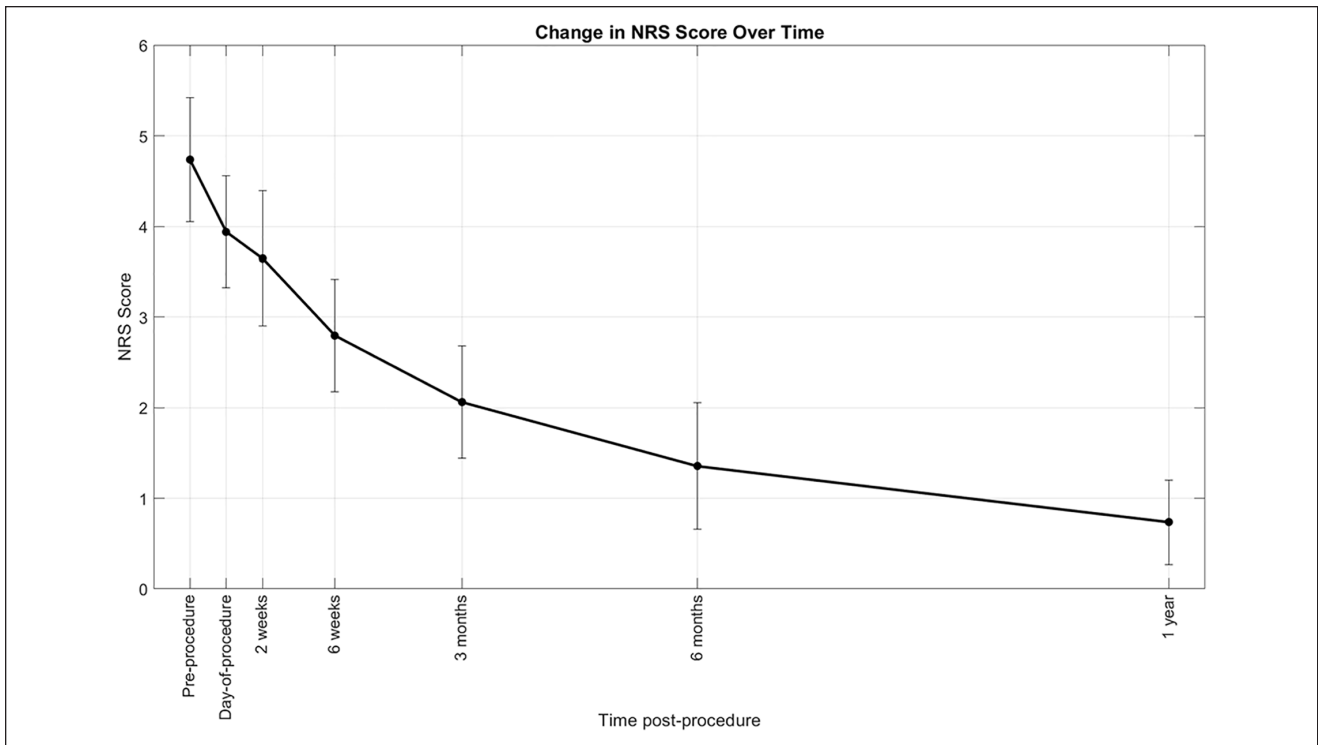


Figure 3. Mean values of numeric rating scale (NRS) scores of all patients with data for all 7 time points. Error bars correspond to 95% CIs.

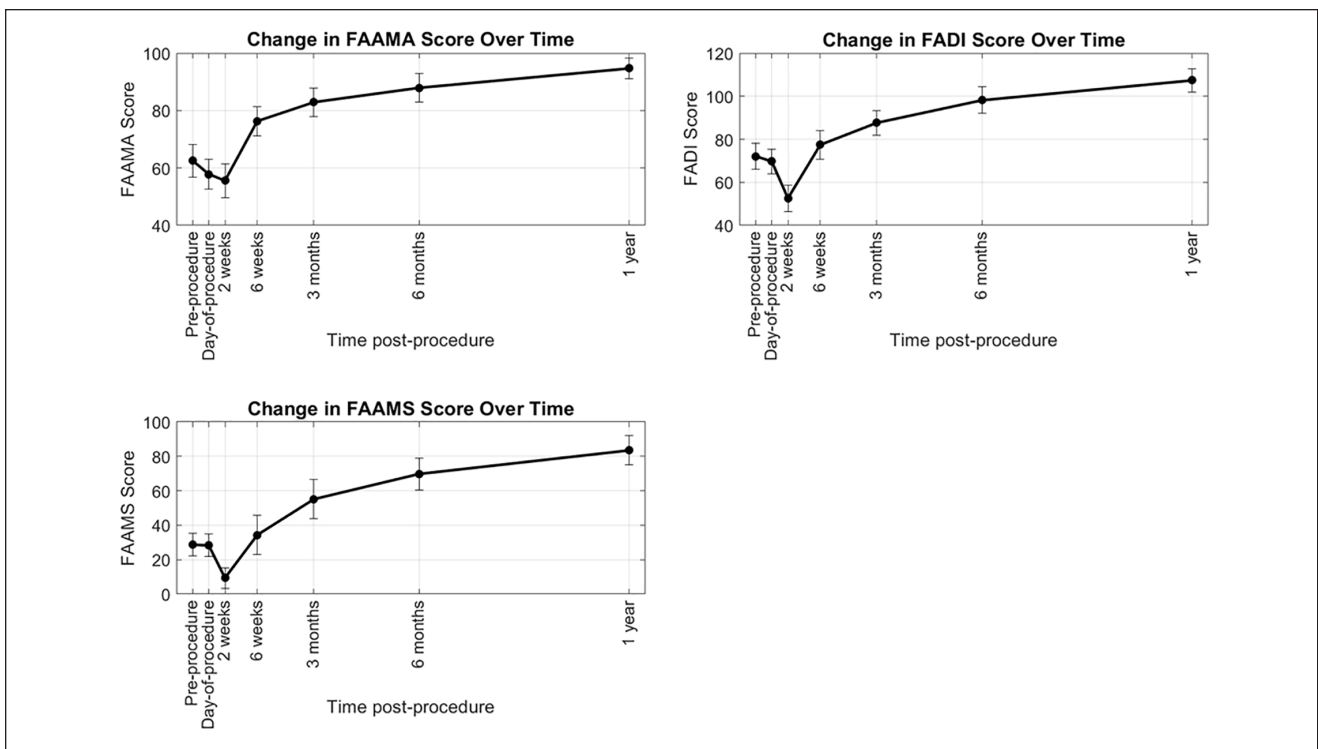


Figure 4. Mean values of FAAMA (top left), FADI (top right), and FAAMS (bottom left) scores of patients with data for all 7 time points. FAAMA and FAAMS are reported as a percentage. Error bars correspond to 95% CIs. FADI, Foot and Ankle Disability Index; FAAMA, Foot and Ankle Ability Measure (FAAM) for activities of daily living; FAAMS, FAAM for sports.

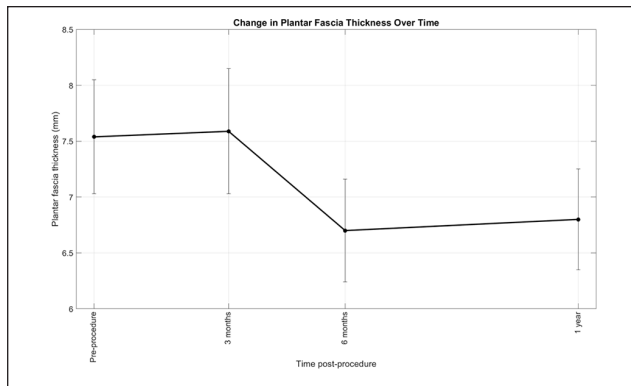


Figure 5. Mean values of plantar fascia thickness of all patients with data for all 4 time points. Error bars correspond to 95% CIs.

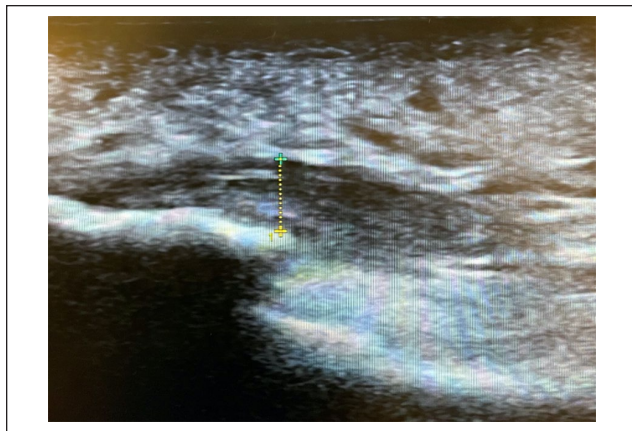


Figure 6. Ultrasonographic imaging of the plantar fascia origin at the calcaneus 1 year after the plantar fasciotomy showing improvement in the hypoechoic swelling in the fascia and a plantar fascia thickness of 4.7 mm.

1 month postprocedure and another patient developed peroneal tendonitis during physical therapy; both were treated successfully. Another patient sustained a gastrocnemius strain during physical therapy that was treated with meloxicam and a compression sleeve. Three patients sustained injuries on the opposite foot during at-home activity. Another patient stepped on a pitchfork with the treated foot and sustained a puncture wound at 9 months postprocedure that was well-treated.

Discussion

Overall, patients undergoing percutaneous plantar fasciotomy using the microdebrider had successful results in this study. Patients had a statistically significant improvement in pain (NRS score). The literature suggests that patients report similar outcomes with the percutaneous procedure compared with both open and endoscopic releases^{22,24,25}

apart from 1 study.¹⁸ Wang et al²² compared 12 patients who underwent endoscopic plantar fasciotomy and 22 patients who underwent open radiofrequency microtenotomy. Although patients in the endoscopy group fared better at 3 months, both patient groups reported similar improvements at 6 and 12 months postprocedure. That being said, Wang et al completed an open radiofrequency microtenotomy, whereas this study used a percutaneous technique.

Yassin et al performed percutaneous radiofrequency microtenotomy on 24 patients and compared results to 39 patients who underwent endoscopic plantar fasciotomy.²⁴ At an average of 30 months postprocedure, both groups reported similar increases in the American Orthopaedic Foot & Ankle Society (AOFAS) questionnaire scores and similar decreases in NRS scores. Furthermore, the percutaneous group reported no complications with the procedure whereas 3 patients in the endoscopy group reported residual numbness in the operative site and 2 patients reported pain in the lateral side of the foot, potentially related to Baxter nerve injury. Similarly, there were no complications with the procedure in this study.

Yuan et al compared 16 patients (19 feet) who received open plantar fascia release to 15 patients (20 feet) who received percutaneous radiofrequency ablation.²⁵ Although both groups had similar improvements postprocedure in NRS and AOFAS ankle hindfoot scores at an average of 59 months, the radiofrequency group had a shorter mean operative time ($P = .012$) and a shorter recovery time ($P = .008$) than the open release group. Tay et al²⁰ compared 32 feet treated with an open microtenotomy procedure and 27 feet treated with a percutaneous microtenotomy approach. They reported similar outcomes in both groups at 3 and 6 months in NRS, AOFAS, and the 36-Item Short Form Health Survey (SF-36) scores, with some exceptions in SF-36 subscales. At 12 months, the open group had a lower NRS score compared to the percutaneous group, but similar AOFAS and SF-36 scores. Tay et al reported that the open and percutaneous groups had a final NRS score of 0.8 and 3.0 ($P = .035$), respectively.²⁰ In this study, the average NRS score at 1 year was 0.7 ± 1.3 , which is similar to the open group and lower than the percutaneous group in Tay et al. Their nonrandomized trial used a similar microdebrider coblation wand to the one used in this study. However, looking at their percutaneous approach, Tay et al had fewer puncture sites and did not provide weightbearing restrictions to either group.²⁰ Hence, performing 40 puncture sites may provide more pain relief by treating a greater part of the plantar fascia origin, and a gradual weightbearing protocol may also be needed to obtain outcomes similar to the ones in this study.

When looking at clinically meaningful improvement in function, 91% of patients (32 of 35) in this study had a minimum 8-point improvement in the FAAMA scale, with 97% of patients who played sports (28 of 29) meeting

improvement in the FAAMS subscale. For the FADI score, 86% of patients (30 of 35) had a minimum 8-point improvement. Only 2 patients did not meet clinically meaningful improvement in any of the metrics in this study, and, thus, 94% of patients saw successful improvement of their plantar fasciitis.

Reviewing the final FAAM scores in this study, the FAAMA and FAAMS scores at 1 year postprocedure were 95% and 84%, respectively. These outcomes are comparable to or better than outcomes cited in recent studies that reviewed results from both open and endoscopic release.^{11,20,24} Furthermore, in this study, 89% (31 of 35) patients scored greater than 90% at 1 year postprocedure. The retrospective study by Colberg et al⁴ reported that 94% of patients (34 of 36) reached FAAM scores of 97% to 100% at 1.5 years postprocedure. Figure 4 shows a continuous trend in improvement in the FAAM scores that had not plateaued. This suggests that the patient's function may continue improving after 1 year postprocedure and the FAAM scores could reach higher values.

Klein et al¹⁰ compared patients with acute and chronic conditions using the FAAM scores for activities of daily living (FAAMA) and sports (FAAMS). They reported an average FAAMA score of 62% and 65%, respectively, and average FAAMS scores of 47% and 45%. In our study, the baseline FAAMA and FAAMS scores the day of procedure were 59% and 31%, respectively.

Interestingly, all the functional scores (FADI, FAAMA, and FAAMS) decreased at 2 weeks postprocedure in this study (Figure 4). All patients were required to be immobilized with a tall walking boot for 2 weeks after the procedure and use crutches for the first week. Therefore, the reported decrease in functional scores is related to the patient's inactivity and limited mobility during this period. In addition, patients received a procedure that involved incising the plantar aspect of their heel with a no. 18 blade at 40 sites; therefore, patients are expected to have pain at the operative site for the first 2 weeks after the procedure as the wounds heal.

There are no longitudinal studies reporting improvement in the plantar fascia thickness over time, regardless of treatment or symptoms. The ultrasonographic evaluation in this study suggests that there are chronic, permanent changes to the plantar fascia after a percutaneous fasciotomy. There was normal fibrillar structure and echogenicity observed in the plantar fascia at 1 year, suggesting interval healing of the collagen fibers. In addition, there was a statistically significant decrease in the plantar fascia thickness when comparing before procedure to 1 year after the procedure; however, the plantar fascia thickness remained above the normal parameter of 4.0 mm. This finding could indicate that the plantar fascia heals with a hyperplastic change in response to the microdébridement, causing the plantar fascia to remain thickened. Histologic evaluation of plantar

fasciitis demonstrates angiofibroblastic hyperplasia.¹⁷ Therefore, measuring the plantar fascia thickness would be an appropriate tool to evaluate for interval healing only if prior images and measurements are available for that patient to compare with. In patients who do not get ultrasonographic measurements before the procedure and require sonographic evaluation after a percutaneous fasciotomy, analyzing the echogenicity of the plantar fascia seems to be the most reliable tool.

There were limitations to this study. Five patients did not complete the study. Although most of these patients did not complete the study because of a valid reason, they did not want to return to the clinic because of the COVID pandemic, they had actually reported significant improvement in symptoms at their last follow-up visit. Nonetheless, their successful outcome is not accounted for in the final 1-year follow-up data analysis. There was 1 patient who withdrew from the study after 6 months to seek a second opinion because of persistent heel pain. This patient's plantar fascia at the last visit showed interval improvement in the collagen fibrillar pattern and the thickness measured 5.4 mm, which is less than the average plantar fascia thickness for the study. A reason this patient may not have seen resolution of the symptoms after this procedure is that the heel pain could have had a neural component. This would involve a differential diagnosis that includes complex regional pain syndrome, tarsal tunnel syndrome, and Baxter neuritis.¹ Patients who fail to respond to the percutaneous fasciotomy may benefit from an ankle magnetic resonance imaging and/or electromyography. Additionally, we did not include a prospective control arm for comparison. A randomized, case-control study comparing a percutaneous plantar fasciotomy to endoscopic plantar fascia release and to a conservative treatment protocol is warranted.

Conclusion

We found percutaneous plantar fasciotomy using a microdebrider coblation wand to be an effective treatment for plantar fasciitis that carried a low risk of complications. Most patients had successful outcomes based on the NRS, FADI, FAAMA, and FAAMS scores, and there was interval improvement in the plantar fascia thickness. This procedure may be considered as a viable alternative treatment option for recalcitrant plantar fasciitis. Ultrasonographic imaging can be used to monitor plantar fascial remodeling after treatment.

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Ethical Approval

Ethical approval for this study was obtained from Sterling Institutional Review Board (7084-REColberg).

Declaration of Conflicting Interests

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