

Perforating Fat Injections for Chronic Plantar Fasciitis: A Randomized, Crossover Clinical Trial

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Summary: Plantar fasciitis affects 2 million patients per year. Ten percent of cases are chronic, with thickened plantar fascia. Treatment may lead to prolonged recovery, foot instability, and scar. The authors hypothesized that perforating fat injections would decrease plantar fascia thickness, reduce pain, and improve quality of life. Adults with plantar fascia greater than 4 mm for whom standard treatment had failed were included in a prospective, randomized, crossover pilot study. Group 1 (intervention) was followed for 12 months. Group 2 was observed for 6 months, injected, and then followed for 6 months. Validated patient reported outcome measures, ultrasound, and complications were assessed. Group 1 had nine female patients and group 2 had five patients. A total of 2.6 ± 1.6 ml of fat was injected per foot at one to two sites. In group 1, plantar fascia thickness decreased from screening at 6 and 12 months ($p < 0.05$). Group 2 had decreased plantar fascia thickness from screening to 6 months after injection ($p < 0.05$). Group 1 had pain improvements at 6 and 12 months compared with screening ($p < 0.01$). Group 2 reported no pain difference after injections ($p > 0.05$). Group 1 had improved activities of daily living and sports activity at 6 and 12 months compared with screening ($p < 0.003$). Group 2 noted increased sports activity 6 months after injection compared with screening ($p < 0.03$). In conclusion, perforating fat injections for chronic plantar fasciitis demonstrate significant improvement in pain, function, and plantar fascia thickness. (*Plast. Reconstr. Surg.* 149: 297e, 2022.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

The plantar fascia becomes thickened and fibrosed in chronic plantar fasciitis.¹⁻³ Plantar fasciitis is the most common cause of heel pain and accounts for 11 percent to 15 percent of all medical foot complaints, and 10 percent of patients with plantar fasciitis progress to the chronic form, plantar fasciosis.⁴⁻⁹ Surgical release of plantar fascia may involve prolonged immobilization and recovery, risk of venous thromboembolism, nerve damage, wound infection, calcaneal cuboid syndrome, arch instability, scar formation, and recurrent plantar fasciitis.¹⁰⁻²³ The overall

complication rate is 11 percent.²⁴ Satisfaction with fasciotomy procedures ranges between 50 percent and 95 percent.²⁰ Percutaneous scar release allows expansion of tissues, and filling with fat allows for a more beneficial scar-healing process.²⁵⁻²⁸ We hypothesized that percutaneous perforations with injections of fat into chronically thickened plantar

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fascia can reduce plantar fascia thickness, reduce pain, and improve quality of life.

PATIENTS AND METHODS

Adults with heel pain secondary to plantar fasciosis were recruited for an institutional review board–approved, prospective, randomized, unblinded crossover pilot study (ClinicalTrials.gov identification no. NCT02855983) from 2016 to 2020. Patients were included in the single-center study if they had heel pain, failure of at least 6 months of conservative treatment, no evidence of heel fat pad atrophy, plantar fascia ultrasound measurement of 4 mm or greater, and 6 months without any surgical intervention or injection into the foot. Patients with uncontrolled diabetes and those who were active smokers were excluded. Ultrasound (Terason Ultrasound Imaging System, version 4.7.6; Terason, Burlington, Mass.) was used to assess plantar fascia thickness. For standardization, measurements were taken at the plantar fascia insertion of the calcaneus along the second metatarsal ray, then the probe was transposed 90 degrees for a transverse measurement in the same location. The two measures were averaged.^{29–32} Foot questionnaires included the Foot and Ankle Ability Measure, the Manchester Foot Pain and Disability Index, and the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale.^{33–35}

One-to-one randomization into the two groups was performed using the GraphSoft random number generator function (GraphPad Software, Inc., La Jolla, Calif.). Subjects were randomized to either the perforating fat group (group 1) or the standard-of-care group using night splints and arch supports (group 2) for 6 months. Group 1 patients were followed up at 1, 2, 6, and 12 months after the procedure. Group 2 patients were followed up at 2 and 6 months, at which time they crossed over to the intervention group. After the procedure, they were followed up at 1, 2, and 6 months. Adverse events and complications (i.e., bleeding, infection, and nodules) were recorded at all visits.

Operative Procedure

All procedures were performed with the patient under local anesthesia with a standard tumescent mix of lidocaine, epinephrine, and saline. Fat was hand-harvested from a donor site with 10-cc syringes and processed using the Coleman technique. A small stab was made in

the skin with an 18-gauge needle at the medial band of the plantar fascia. The plantar fascia was perforated with a blunt tip cannula and the fat was injected on withdrawal. Perforations were made in a grid-type fashion (Fig. 1) until no resistance was noted. Subjects limited their weight-bearing activity to 10 minutes per hour and stretched their Achilles and plantar fascia with a night splint for at least 1 hour per day. Subjects were advised to use a supportive shoe with the insole but without any accessory orthotic device or arch support.

Statistical Analysis

To determine subject sample size, we assumed a power of 0.8 with a type I error of 0.05. We calculated the minimal detectable standardized difference for the foot pain analyses to be 0.8, from which the power analysis revealed that a minimum of 15 subjects should be entered into each arm of the pilot study. Student *t* tests were used to compare change over time (paired) in foot pain and tissue thickness between group 1 and group 2 (unpaired). Significance was determined at *p* values less than 0.05, 0.01, and 0.001, as noted. Only data for the injected feet were used to avoid



Fig. 1. Plantar fascia is marked at the insertion on the calcaneus, and perforations are made from a single site. In a 1 cm × 1 cm grid, a skin perforation is made with an 18-gauge needle at the center of the box. A blunt cannula enters the skin and is angled to perforate the plantar fascia in several locations. After the “pop” of penetrating the plantar fascia is felt, the fat is injected upon withdrawal of the cannula, with 0.1 ml injected with each perforation. Depending on the thickness of the plantar fascia, a second injection site is made 1 cm more distal on the plantar fascia. Injections are terminated when no more resistance is felt.

diluting the results from untreated feet. Statistical analyses were performed with Microsoft Excel (Microsoft, Redmond, Wash.) and SPSS version 24.0 software (IBM Corp., Armonk, N.Y.), and data are expressed as mean \pm standard deviation and percent change.

RESULTS

Group 1 had nine subjects and group 2 had five subjects. Patient characteristics are presented in Table 1. As measured using the Manchester Foot Pain and Disability Index score, group 1 function improved significantly at 6 (5 ± 3 , $p = 0.013$) and 12 (3 ± 2 ; $p = 0.01$) months postoperatively compared with screening (7 ± 2) (Fig. 2). Pain improved significantly at 6 (7 ± 6 , $p = 0.015$) and 12 (5 ± 5 , $p = 0.0001$) months postoperatively compared with screening (12 ± 4). (See Table, Supplemental Digital Content 1, which shows statistically significant data; SOC, standard of care; MFPDI, Manchester Foot Pain and Disability Index; FAAM, Foot and Ankle Ability Measure; POV, postoperative visit; PRF, plantar fascia; L, left; R, right, <http://links.lww.com/PRS/E862>.) There was a significant improvement in pain between 6 months and 12 months postoperatively ($p = 0.08$). Group 2 had no significant change in function or pain between any time point. Group 1 activities of daily living improved significantly at 6 (Foot and Ankle Ability Measure score, 88.2 ± 23.3 , $p = 0.004$) and 12 (85.2 ± 21.8 , $p = 0.002$) months postoperatively compared with screening (52.0 ± 19.5) (Fig. 3). Sport-related outcomes improved significantly at 6 (Foot and Ankle Ability Measure score, 62.5 ± 32.4 , $p = 0.030$) and 12 (61.1 ± 28.4 , $p = 0.028$) months postoperatively compared with screening (34.2 ± 13.6). For group 2, there was no significant change in activities of daily living at any time point. Sport-related outcomes improved significantly at 6 months postoperatively (71.9 ± 9.1) compared with the preoperative 6-month standard-of-care visit (49.1 ± 14.8 , $p = 0.028$) and screening (43.1 ± 18.8 , $p = 0.025$). Groups 1 and 2 had no significant change in American Orthopaedic Foot and Ankle Society at any time point. Group

1 right foot plantar fascia thickness was significantly less at 6 (0.37 ± 0.05 mm, $p = 0.034$) and 12 (0.32 ± 0.05 mm, $p = 0.001$) months postoperatively than at screening (0.51 ± 0.11 mm) (Fig. 4). [See Figure, Supplemental Digital Content 2, which shows plantar fascia (PF) thickness (0.50 cm) in a 41-year-old woman with chronic plantar fasciitis; a reduction in plantar fascia thickness to 0.32 cm was noted after 12 months, <http://links.lww.com/PRS/E863>.] Left foot plantar fascia thickness was significantly less at 6 (0.42 ± 0.1 mm, $p = 0.003$) and 12 (0.34 ± 0.03 , $p = 0.004$) months postoperatively than that at screening (0.60 ± 0.15 mm). In group 2, left foot plantar fascia thickness was significantly less at 6 months postoperatively (0.3 ± 0.1 mm) than at the 6-month standard-of-care visit (0.5 ± 0.1 mm, $p = 0.012$). Right foot plantar fascia thickness decreased significantly from the 6-month standard-of-care visit (0.43 ± 0.15 mm) to 6 months postoperatively (0.39 ± 0.10 mm, $p = 0.038$). There was no significant difference in plantar fascia thickness at baseline screening between groups 1 and 2. There were no adverse events or complications.

DISCUSSION

Chronic plantar fasciitis cases are addressed with surgical procedures, including open fasciotomy and endoscopic plantar fasciotomy.¹⁰⁻²³ However, recently there has been a plea to stop plantar fascial excision, which has a risk of foot destabilization, increased scar tissue, and other mechanical compensatory issues.³⁶ Our procedure of fat injections into the plantar fascia decreases plantar fascia thickness and improves pain and quality of life with a minimally invasive procedure that avoids the complications of fasciotomy procedures.

Limitations include small sample size, varying numbers of sites and amounts of fat injected due to the differing foot mechanics, and difficulty in quantifying compliance with walking restrictions and night splint usage. Due to the time constraints of our funding, we could not reach recruitment targets. To reduce user bias,

Table 1. Patient Characteristics

	Intervention	Standard of Care	<i>p</i>
No. of patients	9	5	n/a
Gender, male	0	1	n/a
Age at screening, years	54.2 ± 11.5	43.6 ± 14.0	0.26
Body mass index at screening, kg/m ²	27.7 ± 5.8	31.0 ± 2.3	0.16
Average plantar fascia thickness at screening, mm	0.55 ± 0.13	0.48 ± 0.13	0.21
Fat volume injected, ml	3.2 ± 0.8	3.4 ± 0.9	0.58

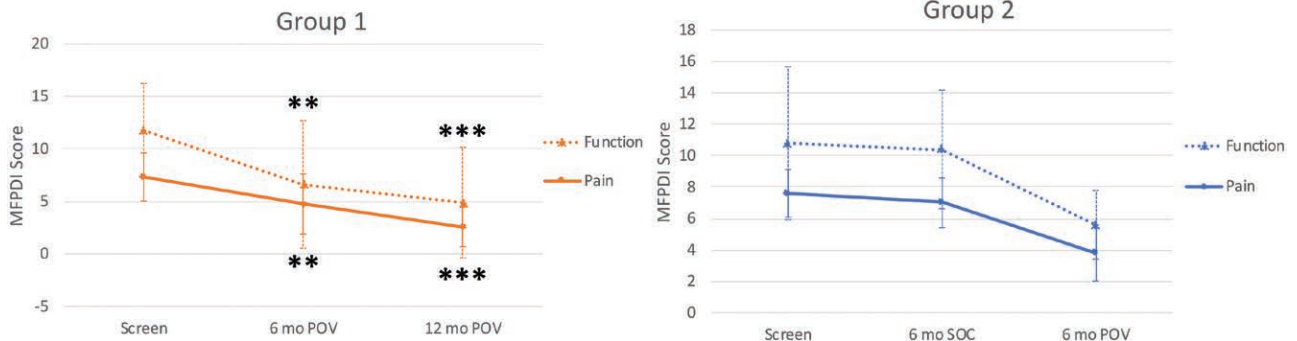


Fig. 2. Manchester Foot Pain and Disability Index (MFPDI) score indicated a significant improvement in function at 6 ($p = 0.01$) and 12 months ($p = 0.001$) and in pain at 6 ($p = 0.01$) and 12 months ($p = 0.0001$) for those in group 1 compared with screening. Although scores trended toward improvement, no statistically significant change in function or pain was detected in group 2 ($p > 0.05$). A decrease in score was associated with improved outcomes. * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$. POV, postoperative visit; SOC, standard of care visit.

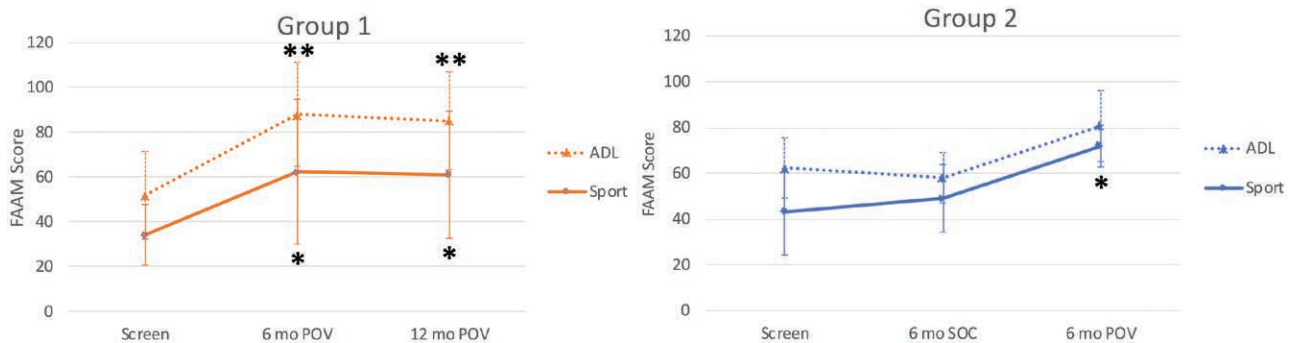


Fig. 3. The Foot and Ankle Ability Measure (FAAM) reported a significant improvement in activities of daily living outcomes at 6 ($p = 0.004$) and 12 ($p = 0.002$) months for those in group 1 as well as sport-related outcomes at 6 ($p = 0.03$) and 12 ($p = 0.03$) months for those in group 2 compared with screening. Although there was no change in activities of daily living for those in group 2 ($p > 0.05$), there was a significant improvement in sport-related outcomes at 6 months postoperatively compared with both the 6-month group 2 ($p = 0.03$) and screening ($p = 0.02$). An increase in score was associated with improved outcomes. * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$. ADL, activities of daily living; POV, postoperative visit; SOC, standard of care visit.

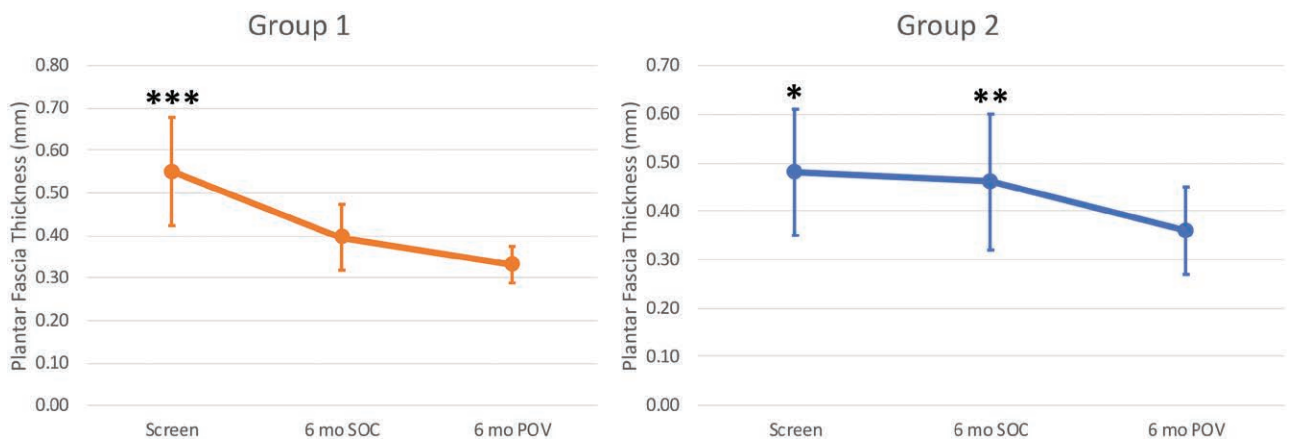


Fig. 4. Plantar fascia thickness significantly lessened over time for those in the group 1 at 6 ($p = 0.0002$) and 12 months postoperatively ($p = 6.58 \times 10^{-6}$) compared with screening, as well as for those in the group 2 compared with 6 months postoperatively from both the 6-month standard-of-care preoperative visit ($p = 0.007$) and screening ($p = 0.02$). There was no significant difference in plantar fascia thickness between the groups at screening ($p = 0.21$). * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$. POV, postoperative visit; SOC, standard of care visit.

all ultrasounds were performed by the same physician. Although the plantar fascia thickness decreased significantly, only histological examination of the plantar fascia may confirm regeneration of the tissue. A larger study comparing perforating fat injections to perforations alone is warranted.

CONCLUSION

Perforating fat injections for chronic plantar fasciitis demonstrate significant improvement in pain, function, and plantar fascia thickness.

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