Autologous Fat Grafting for Pedal Fat Pad Atrophy: A Prospective Randomized Clinical Trial

Jeffrey A. Gusenoff, M.D.
Ryan T. Mitchell, M.D.
Kwonho Jeong, M.S.
Dane K. Wukich, M.D.
Beth R. Gusenoff, D.P.M.

Pittsburgh, Pa.

Background: Pedal fat pad atrophy is associated with pain, decreased tissue thickness, and increased foot pressures. To date, no objective studies investigating the use of fat grafting to the forefoot have been performed. The authors hypothesize that pedal fat grafting can reduce pain, increase tissue thickness, and decrease pedal pressures.

Methods: A prospective randomized study was performed to assess tissue thickness, pain, and foot pressures. Group 1 underwent fat grafting immediately with 1-year follow-up, and group 2 underwent conservative management for 1 year.

Results: Thirteen patients (two men and 11 women) constituted group 1 and 12 patients (four men and eight women) constituted group 2. Ten patients in group 1 underwent bilateral injections with a mean volume of 4.8 cc per foot. Mean follow-up time was 11.1 ± 5.4 months for group 1 and 13.8 ± 4.2 months for group 2. At 1 year, group 1 demonstrated improved foot function ($p = 0.022$), pain ($p = 0.022$), and work/leisure activities ($p = 0.021$). Group 1 had no change in tissue thickness, whereas in group 2, the right third metatarsal tissue thickness decreased significantly ($p = 0.036$). Foot pressures in group 1 did not improve; however, group 2 had a significant increase in left foot pressure ($p = 0.011$). When comparing the groups at 1 year, group 2 had significantly higher foot pressures and forces than group 1 ($p < 0.05$).

Conclusions: Pedal fat grafting significantly improves pain and disability outcomes, and prevents against worsening foot pressures. Future analysis will reveal whether fat grafting has lasting efficacy. (*Plast. Reconstr. Surg.* 138: 1099, 2016.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Plantar fat pad atrophy may be caused by age, obesity, steroid injections, use of high-heeled shoes, iatrogenic surgical consequences, or abnormal foot mechanics. Disease states such as diabetes and collagen vascular disease may result in loss of soft-tissue integrity. Displacement or atrophy of the fat located in specialized compartments of the forefoot can lead to increased torque, shear, and osseous prominences that result in patients presenting with the sensation that they are walking on bone. In sensate patients, the pain can lead to emotional and physical pain, leading to productivity and financial losses.[1–5] Currently, fat pad atrophy is a diagnosis of exclusion, and there are no tissue thickness parameters to define the condition.

Augmentation of the plantar fat pad has been demonstrated with various external devices (i.e., shoe orthosis and pads) that are prone to breakdown and patient compliance issues.[6] A higher prevalence of foot fat pad atrophy is seen in patients with a cavus, or high-arched foot. Often, the cavus foot does not have enough room in a shoe to accommodate bulky external devices. Augmentation with fillers has been described to aid in

From the Department of Plastic Surgery, Division of General Internal Medicine, Department of Medicine, and Division of Foot and Ankle Surgery, Department of Orthopaedics, University of Pittsburgh Medical Center.
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adding volume and reducing plantar pressures, but there is a large gap in knowledge because of the lack of evidence-based medicine. Most reports are anecdotal and subjective.[7–9] By minimizing high peak plantar pressures through autologous fat transfer, pain and skin lesions have the potential to be minimized.

To date, no prospective objective clinical trials with standardized fat grafting techniques have been performed to assess fat grafting for pedal fat pad atrophy. We hypothesize that pedal fat grafting can reduce pain, increase tissue thickness, and decrease pedal pressures.

PATIENTS AND METHODS

Thirty adult patients who experienced pain from fat pad atrophy were recruited for an institutional review board–approved, prospective, randomized, clinical trial. Patients were included in the study if they had foot pain under the head of the metatarsals, diagnosed with fat pad atrophy by a foot and ankle specialist, and were 6 months after any surgical intervention or injection into the foot (Fig. 1). Exclusion criteria included patients with open ulcerations or osteomyelitis, diabetes, active infection anywhere in the body, diagnosis of cancer within the last 12 months and/or presently receiving chemotherapy or radiation treatment, known coagulopathy, systemic disease that would render the fat harvest and injection procedure unsafe to the patient, pregnancy, and tobacco use within the past year.

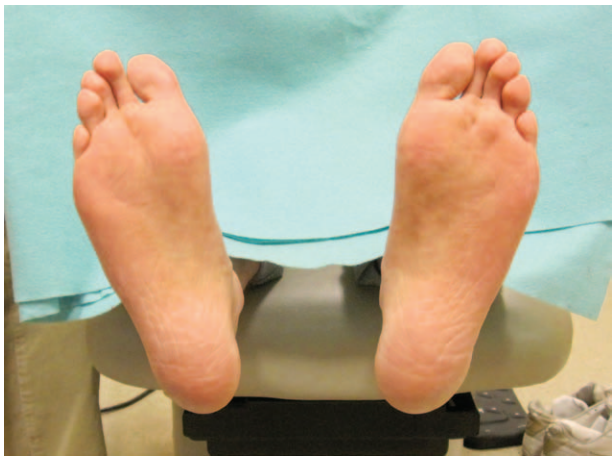

Fig. 1. A 45-year-old male avid cyclist with pedal fat pad atrophy secondary to resection of neuromas of the feet. He ambulates with crutches and bears weight only on the heel to avoid pressure on the forefoot. Plantar view demonstrates loss of fat pad at the sites of the neuroma resections between the second and third rays and third and fourth rays of the left foot and second and third rays of the right foot.

Screening visits included informed consent, medical, social, and activity history. Vital signs including height, weight, and body mass index were obtained. Any prior foot injuries or previous foot ulcerations were noted. A physical examination and complete foot examination including a vascular, neurologic, dermatologic, and orthopedic baseline assessment were documented. For the vascular baseline assessment, if pedal pulses were nonpalpable, a noninvasive arterial study was completed. Protective sensation was assessed with a 5.07 Semmes-Weinstein monofilament test. The Tekscan HR Mat pressure measurement system and Research Foot Module (Tekscan, Inc., South Boston, Mass.) were used to collect pedobarographic data to assess and document baseline plantar foot forces and pressures.[10] Ultrasound (Terason Ultrasound Imaging System, Version 4.7.6; Terason, Burlington, Mass.) was used to document plantar tissue thickness under each metatarsal head. A gait and shoe gear evaluation was completed. After completion of the screening visit, phlebotomy was performed to assess serum complete blood count with differential, comprehensive chemistry panel, coagulation studies, erythrocyte sedimentation rate, albumin, and hemoglobin A1C. Standardized photographs of the foot, callus, and lesion pattern were taken. If the patient was deemed eligible and signed the consent form, the patient was randomized.

The subjects were randomized to either the autologous fat transfer group (group 1) or the standard of care group (group 2) for 1 year. Randomization into the groups was determined using the GraphSoft random number generator function (GraphPad Software, Inc., La Jolla, Calif.) and was provided to us by an independent research coordinator not involved in the trial. For group 1, patients followed up at 2 weeks, 4 weeks, 2 months, 6 months, and 12 months. For group 2, patients were evaluated at 6 months and 12 months. No patients were allowed to have a second round of fat grafting during the clinical trial.

Operative Procedure

Surgical procedures were performed at the University of Pittsburgh Medical Center Aesthetic Plastic Surgery Center. Subjects received local anesthesia (lidocaine 1% with epinephrine 1:100,000) at the site of aspiration of the fat grafts and often received 5 to 10 mg of oral valium before the procedure. A tumescent solution (500 ml of normal saline, 10 ml of 2% lidocaine, and 1 ml

of 1:1000 epinephrine) was injected into the harvest site, which was usually abdominal or flank subcutaneous tissue. A posterior tibial nerve and Mayo block of the foot was performed using ethyl chloride spray and a 50:50 mixture of 2% lidocaine and 0.5% bupivacaine without epinephrine. A blunt-tip hollow cannula was used to aspirate approximately 50 to 100 cc of fat tissue through a less than 2-mm incision made with a no. 11 blade. The most common sites used were the abdomen, followed by the flanks, which are easily accessed with the patient in the supine position. Liposuction was performed under a low consistent negative pressure using 10-cc syringes to limit trauma to the adipocytes. Incisions for the donor sites were typically closed with benzoin and Steri-Strips (3M, St. Paul, Minn.).

Fat was processed using the Coleman technique where the harvested fat graft was placed in centrifugation at 3000 rpm for 3 minutes.[11] The resultant adipose aspirate was decanted, oil was wicked using absorbent gauze, and the high-density fraction (bottommost 1 ml of each 10-cc syringe) was transplanted to the recipient areas of the foot using 1-cc syringes. An 18-gauge needle was used to make an entry site between the first and second toes and the fourth and fifth toes on the plantar aspect of the foot. A 0.9-mm blunt cannula was used to inject the 1-cc syringes of fat into the foot in a cross-hatched pattern. For patients that had prior dorsal scars from neuroma resection, 1 cc of fat was injected dorsally at the prior incision site toward the plantar surface to fill in any potential soft-tissue defect between the metatarsals. Filling was performed until a soft cushion was created, being careful not to overfill and cause tenseness or blanching of the skin. On average, 4 to 6 cc of fat was placed under the primary areas of concern and fanned to the other metatarsals to create an even layer of padding. Entry sites were dressed with benzoin and Steri-Strips. Ultrasound was performed postoperatively to measure the increased tissue thickness immediately after injection.

Postoperatively, the insoles of a comfortable sneaker were padded to allow for offloading of the fat grafting region, and patients were allowed to walk out of the office. Patients were encouraged to limit strenuous activity for 4 to 6 weeks after the procedure and wear a cushioned, supportive sneaker. No barefoot walking was permitted during this period. Patients used shower pads or placed towels on the shower floor for the short periods during which they were without shoe gear.

Measurement of Foot Force and Pressure

The Tekscan HR Mat pedobarograph was performed without shoe gear to get an accurate foot pressure reading. Patients were first calibrated by weight for standing forces and pressures, and then recalibrated for walking forces and pressures. Standing measurements were taken from an average of 150 seconds, and walking

Table 1. Baseline Demographics and Clinical Characteristics of the Groups

Variable	Group 1 (Early Intervention) (%)	Group 2 (Crossover Later) (%)	*p*
No. of patients	13	12	
Female patients	11 (85)	8 (67)	0.378*
Mean age at screening ± SD, yr	59.9 ± 5.3	65.3 ± 8.5	0.053†
Caucasian	13 (100)	11 (92)	>0.480*
Smoking history			
Never	11 (92)	6 (50)	0.069*
Quit	1 (8)	6 (50)	
Mean BMI ± SD, kg/m^2	27.2 ± 5.4	25.6 ± 6.1	0.430†
Bilateral injection	10 (77)	0 (0)	N/A
Right injection volume (n = 12)	4.8 ± 0.8		
Left injection volume (n = 11)	4.7 ± 0.7		
Mean follow-up period ± SD, mo	11.1 ± 5.4	13.8 ± 4.2	0.009†
No. of participants who had any follow-up	13 (100)	12 (100)	N/A
Cause‡			0.766*
Age-related	7	4	
Postsurgery§	3	4	
Neuroma excision	2	2	
Steroid injection	2	4	

BMI, body mass index; N/A, not applicable.
*Fisher's exact test.
†Wilcoxon rank sum test.
‡Some patients had multiple causes.
§Bunionectomy, metatarsal lift procedure, tendon procedure.

measurements were taken from an average of a minimum of three individual passes for each foot at a self-selected speed. Pedobarography was performed at the screening visit, and at the 1-month, 2-month, 6-month, and 12-month follow-up visits.

Measurement of Tissue Thickness

Ultrasound was performed at the screening visit; immediately postoperatively; and at the 1-month, 2-month, 6-month, and 12-month follow-up visits.

Measurement of Foot Pain and Disability

Foot pain was measured with the Manchester Foot and Disability Index, a validated assessment of the foot that includes components of function, personal appearance, pain, and work/leisure activities.[12] The questionnaire was performed at the screening visit and at the 1-month, 2-month, 6-month, and 12-month follow-up visits.

Statistical Analysis

Using standard conventions of alpha = 0.05 and beta = 0.8, an a priori power analysis indicates that enrollment of at least five patients should provide sufficient power to detect clinically meaningful differences in the tissue thickness under the metatarsal as assessed by ultrasound between groups.[9] Only data for injected feet were used, to avoid diluting the results with unaffected foot measurements. Background characteristics were summarized for each intervention group and compared using nonparametric methods of Fisher's exact test and Wilcoxon rank-sum test because we have a relatively small number of subjects in each arm. The Wilcoxon rank sum test was used to evaluate how outcomes at baseline and at 6 and 12 months between two groups are different separately. Because our primary question was whether there was any difference in our endpoints between two groups at each follow-up period, this analytic approach was chosen. The difference of outcomes between time points within a group was examined using the Wilcoxon signed rank test. All statistical analysis was performed using Stata/SE version 12.0 (StataCorp, Inc., College Station, Texas). All statistical tests were two-sided and significance was set to the level of $p < 0.05$.

RESULTS

Thirteen patients (11 women and two men) constituted group 1, and 12 patients (eight women and four men) constituted group 2 (Table 1).

Table 2. Differences in Manchester Foot Pain and Disability Index between the Groups at Baseline, 6 Months, and 12 Months

	Baseline					6 Mo					12 Mo				
	Group 1		Group 2			Group 1		Group 2			Group 1		Group 2		
	No.	Mean ± SD	No.	Mean ± SD	*p**	No.	Mean ± SD	No.	Mean ± SD	*p**	No.	Mean ± SD	No.	Mean ± SD	*p**
Functional	12	10.3 ± 6.4	12	9.6 ± 7.0	0.862	13	6.1 ± 5.1	12	14.0 ± 16.4	0.102	8	4.0 ± 3.2	11	10.7 ± 6.9	0.039
Personal appearance	12	2.2 ± 1.5	12	1.8 ± 1.4	0.511	13	1.0 ± 1.2	11	1.4 ± 1.1	0.332	8	1.0 ± 1.2	11	1.5 ± 1.8	0.568
Pain	12	6.7 ± 1.0	12	5.7 ± 2.8	0.363	13	2.8 ± 2.4	12	5.5 ± 2.6	0.02	8	2.8 ± 2.9	11	5.9 ± 2.5	0.019
Work/leisure	12	26.5 ± 33.3	12	14.7 ± 30.2	0.792	13	8.6 ± 18.4	12	22.5 ± 38.7	0.101	8	7.0 ± 17.4	11	46.8 ± 34.0	0.002

*Wilcoxon rank sum test.

Table 3. Manchester Foot Pain and Disability Index Differences between Time Points

	Group 1 (p*)			Group 2 (p*)		
	0 vs. 6 Mo	0 vs. 12 Mo	6 vs. 12 Mo	0 vs. 6 Mo	0 vs. 12 Mo	6 vs. 12 Mo
Functional	0.013	0.022	0.466	0.407	0.141	0.305
Personal appearance	0.075	0.05	0.303	0.834	0.925	0.927
Pain	0.005	0.022	0.434	0.423	0.963	0.389
Work/leisure	0.014	0.021	0.622	0.899	0.052	0.136

*Wilcoxon signed rank test.

Mean age at baseline was 59 ± 5.3 years in group 1 and 65.3 ± 8.5 years in group 2 ($p = 0.053$). Mean body mass index at baseline was 27.2 ± 5.4 kg/m^2 in group 1 and 25.6 ± 6.1 kg/m^2 in group 2 ($p = 0.430$). Causes of fat pad atrophy included failed neuroma surgery, prior foot surgery, steroid injections, and overuse. Ten patients in group 1 underwent bilateral injections with a mean volume of 4.8 ± 0.8 cc in the right foot and 4.7 ± 0.7 cc in the left foot. Mean follow-up time was 11.1 ± 5.4 months for group 1 and 13.8 ± 4.2 months for group 2 ($p = 0.009$).

At baseline, there was no significant difference between the groups regarding Manchester Foot and Ankle Disability Index scores (Table 2). One patient in the intervention group did not complete the Index at the screening visit, but all subsequent scores were recorded and included in the combined analysis. At 6 months after injection, group 1 had statistically significant improvement in pain compared with the control group (2.8 ± 2.4 versus 5.5 ± 2.6; $p = 0.02$). By 12 months, group 1 had statistically significant improvements in function ($p = 0.039$), pain ($p = 0.019$), and work/leisure activities ($p = 0.002$) compared with the control group. When comparing scores at baseline and 6 months after injection, patients in group 1 had statistically significant improvements in function ($p = 0.013$), pain ($p = 0.005$), and work/leisure activities ($p = 0.014$) at 6 months. These relationships were still present at 12 months, with no significant change between 6 months and 12 months (Table 3). The control group demonstrated no significant changes from baseline to 6 months or 12 months, or between 6 months and 12 months.

Fat injections were routinely performed, with most of the fat volume being placed under the second to fourth metatarsal heads. Some patients had more significant loss in specific areas. To generalize our data, we looked at the tissue thickness under each metatarsal and averaged the five metatarsals for each foot. There was no significant difference between the groups at baseline (Table 4). At 6 months, group 1 had significantly greater tissue thickness of the second metatarsal of both feet and the fifth metatarsal of the left foot ($p < 0.04$). The mean of the five left metatarsals in group 1 was significantly greater than in group 2 at 6 months ($p = 0.005$). By 12 months, only the right second metatarsal maintained a statistically significant difference in tissue thickness ($p = 0.033$). When comparing baseline to 6 months after injection, group 1 had a significant increase in tissue thickness for the mean of the five right metatarsals and the second and third metatarsals ($p < 0.04$), which failed to reach significance by 12 months (Table 5). Group 2, however, experienced a significant decrease in tissue thickness in the mean of the left fifth metatarsals over the first 6 months ($p < 0.05$) that was no longer significant at 1 year, and a decrease in the third metatarsal thickness of the right foot from baseline to 12 months ($p = 0.036$), with most of the worsening occurring between the 6-month and 12-month time points ($p = 0.023$).

Mean foot pressures and forces were assessed for walking and standing using the pedobarograph. There were no significant differences between the groups at baseline (Table 6). Walking left foot pressures were lower at 6 months ($p = 0.041$) compared to the control group, and at 12 months, left foot standing foot force ($p = 0.017$) and pressure ($p = 0.013$) were significantly lower, as was walking right foot force ($p = 0.042$). The differences between the groups were largely attributable to a significant increase in the control group's forces and pressures over the first 6-month and 12-month intervals, whereas there were no significant changes in foot pressures or forces in group 1 at 6 months or 12 months (Table 7).

Most patients experienced postoperative bruising of the donor site and feet. No patients experienced infection, hematoma, seroma, or oil cysts. No perioperative antibiotics or narcotics were used.

DISCUSSION

The foot is composed of specialized fat pads to provide shock absorption and protection against

Table 4. Mean Tissue Thickness Differences between Groups at Baseline, 6 Months, and 12 Months

	Baseline					6 Mo				12 Mo			
	Group 1		Group 2			Group 1		Group 2		Group 1		Group 2	
Metatarsals	No.	Mean ± SD (cm)	No.	Mean ± SD (cm)	*p**	No	Mean ± SD (cm)	No.	Mean ± SD (cm)	*p**	No.	Mean ± SD (cm)	No.	Mean ± SD (cm)	*p**
Right															
Mean of five	12	0.7 ± 0.1	12	0.7 ± 0.1	0.931	12	0.8 ± 0.1	12	0.7 ± 0.1	0.126	7	0.8 ± 0.1	11	0.7 ± 0.1	0.07
First	12	1.0 ± 0.2	12	1.0 ± 0.1	0.885	12	1.0 ± 0.1	12	1.0 ± 0.1	0.885	7	1.1 ± 0.2	11	1.0 ± 0.2	0.276
Second	12	0.8 ± 0.1	12	0.8 ± 0.2	0.885	12	0.9 ± 0.2	12	0.8 ± 0.1	0.035	7	0.9 ± 0.1	11	0.8 ± 0.1	0.033
Third	12	0.7 ± 0.1	12	0.8 ± 0.2	0.544	12	0.8 ± 0.1	12	0.7 ± 0.1	0.386	7	0.7 ± 0.1	11	0.7 ± 0.1	0.238
Fourth	12	0.7 ± 0.1	12	0.6 ± 0.1	0.583	12	0.7 ± 0.1	12	0.6 ± 0.1	0.148	7	0.7 ± 0.1	11	0.6 ± 0.1	0.468
Fifth	12	0.5 ± 0.1	12	0.5 ± 0.1	0.817	12	0.6 ± 0.1	12	0.5 ± 0.1	0.563	7	0.6 ± 0.1	11	0.5 ± 0.1	0.112
Left															
Mean of five	11	0.8 ± 0.1	10	0.8 ± 0.1	0.778	11	0.8 ± 0.1	10	0.7 ± 0.1	0.005	7	0.8 ± 0.1	9	0.7 ± 0.1	0.266
First	11	1.0 ± 0.1	10	1.0 ± 0.1	0.275	11	1.0 ± 0.1	9	1.0 ± 0.1	0.47	7	1.1 ± 0.1	9	1.0 ± 0.1	0.595
Second	11	0.9 ± 0.2	10	0.9 ± 0.2	0.724	11	1.0 ± 0.1	10	0.8 ± 0.2	0.005	7	1.0 ± 0.2	9	0.8 ± 0.1	0.266
Third	11	0.8 ± 0.2	10	0.7 ± 0.1	0.724	11	0.8 ± 0.1	10	0.7 ± 0.2	0.204	7	0.8 ± 0.2	9	0.7 ± 0.2	0.204
Fourth	11	0.7 ± 0.1	10	0.7 ± 0.2	0.805	11	0.7 ± 0.1	10	0.6 ± 0.1	0.112	7	0.7 ± 0.1	9	0.6 ± 0.1	0.525
Fifth	11	0.6 ± 0.1	10	0.5 ± 0.1	0.647	11	0.6 ± 0.1	10	0.5 ± 0.1	0.026	7	0.6 ± 0.1	9	0.5 ± 0.1	0.244

*Wilcoxon rank sum test.

shearing, compressive, and pivoting forces during the gait cycle. Fat pad degradation and displacement in the foot are common and can cause callus formation, pain, and ulceration. There are multiple causes of pad breakdown. Soft-tissue integrity deteriorates with age, leading to increased foot pain and injury in the elderly.[13,14] Plantar fat pad destruction is associated with traumatic events, including repetitive steroid injections, fractures, burns, iatrogenic surgical causes, and prolonged activity on an orthopedically compromised foot.[15] Several patients in our trial had Morton neuromas, which are enlargement of the medial and lateral plantar nerve in the third interspace of the foot. Treatment includes steroid injections or surgical excision. Repeated steroid injections may destroy the fat pads or aggressive surgical excision may remove excess fat around the neuroma, leading to symptoms of fat pad atrophy. Diabetic patients are at high risk for foot complications because of their higher incidence of elevated pedal pressures, neuropathy, deformity (i.e., hammertoes), and soft-tissue glycosylation. This potentially leads to ulcer formation and ultimately to amputation, with devastating consequences.[4] We have a separate clinical trial ongoing for fat grafting in well-controlled diabetic patients.

Currently, plantar fat pad destruction is addressed through the use of extrinsic foot padding or orthotic management. By providing extra padding or pocketing out for a prominent pedal area, there will be a reduction of both pressure and tissue breakdown (Fig. 2). However, the patient may not be compliant with the extrinsic device or may experience increased friction, irritation, and breakdown at a different location on the foot, because of thickness of the device in the shoe. The patient may fail to replace the device as soon as it breaks down.

There are minimal data describing the use of augmentation of the fat pad with internal techniques. In 1994, a subjective study was performed by Chairman.[7] Fifty patients were subjectively interviewed over 9 to 28 months postoperatively after fat grafting in combination with bone surgery. All but two patients had subjective improvement in pain, but no objective data were recorded. Fat was harvested from the calf, with no explanation of how the fat was processed.

Rocchio published a case series of 25 patients treated with acellular dermal graft to treat fat pad atrophy.[8] GRAFTJACKET matrix (Wright Medical, Memphis, Tenn.) was surgically inserted using a "parachute technique" and a tie-over bolster. Patients were non–weight-bearing for 2 weeks and

Table 5. Mean Tissue Thickness Differences between Time Points

	Group 1 (*p**)			Group 2 (*p**)		
Metatarsal	0 vs. 6 Mo (a vs. c)	0 vs. 12 Mo (a vs. e)	6 vs. 12 Mo (c vs. e)	0 vs. 6 Mo (b vs. d)	0 vs. 12 Mo (b vs. f)	6 vs. 12 Mo (d vs. f)
Right						
Mean of five	0.015	0.09	0.204	0.754	0.374	0.12
First	0.844	0.444	0.149	0.723	0.789	0.965
Second	0.034	0.075	0.237	0.326	0.533	0.789
Third	0.009	0.051	0.236	0.346	0.036	0.023
Fourth	0.195	0.352	0.444	0.694	0.964	0.654
Fifth	0.059	0.499	0.931	0.724	0.689	0.026
Left	0.11	0.091	0.866	0.047	0.407	0.374
First	0.689	0.236	0.612	0.314	0.953	0.233
Second	0.248	>0.999	>0.999	0.114	0.26	0.374
Third	0.109	0.499	0.866	0.721	>0.999	0.594
Fourth	0.068	>0.999	0.799	0.445	0.11	0.255
Fifth	0.656	0.612	0.398	0.083	0.477	0.766

*Wilcoxon rank sum test.

half underwent concomitant bony or soft-tissue operations. Most patients were satisfied with the treatments. Ultrasound thickness demonstrated significant increases over the course of the study, but only nine patients made it to the 6-month ultrasound and only two made it to 12 months, reducing the significance of the long-term conclusions of the study. Objective pain assessments and foot pressure/forces were not measured. A disadvantage of this technique is that incision and dissection of the plantar surface of the foot requires disruption of the natural fibrous septa, potentially leading to neurovascular damage or aberrant scar formation. There remains scant evidence-based research to date on acellular dermis for fat pad augmentation in the foot.

More data have been published about injectable materials, such as silicone.[9,16,17] Injected liquid silicone increases plantar tissue thickness, decreases plantar pressure, and stimulates proliferation of surrounding collagen fibers. However, after 2 years, the cushioning ability of silicone diminished, resulting in increased plantar pressure.[9] Another adverse event of silicone is the potential to migrate and not remain in the allocated fat pad position.[16] Although migration appears to be asymptomatic, microscopic droplets can be identified in the groin lymph nodes. In diabetic patients, silicone may be at risk for infection as a foreign body. Other fillers commonly used for facial augmentation have been used off-label by podiatrists and foot and ankle specialists as an off-the-shelf solution to this problem, with no evidence in the literature. The use of 1 to 2 cc of filler per metatarsal head may result in a very expensive temporary solution. Some fillers that require reconstitution with saline may have a dispersion of the product with ambulation that can lead to unpredictable results and likely require multiple treatments with no guarantee of success.

We initially hypothesized that fat grafting to the foot would decrease pain, increase tissue thickness, and decrease foot pressure and pain. Our results demonstrate that foot function, pain, and work/leisure activities improved significantly when compared to the control group over 12 months. This was an interesting finding considering that the improvements in pain were more significant at the 12-month time point than the 6-month time point. We suspect that this may be attributable to the cushioning effect of the fat on the bone. Because of this internal offloading, healing of bone contusions and/or edema ultimately results in decreased pain.

Although we thought the fat would increase the tissue thickness under the metatarsal for a prolonged period, our data demonstrate that by 6 months, and even more at 12 months, the fat had resorbed under the metatarsal or shifted in position. One pitfall of our current study design is that the ultrasound assesses only a single point under the metatarsal head. It is possible that the fat may be redistributing around the metatarsal head to offload it. This may account for the long-term offloading effect that explains the improved pain over 12 months despite the loss of fat directly under the metatarsal head. Although we did not directly measure fat graft survival in this study, we are currently using magnetic resonance imaging before and after fat grafting to assess volumetric changes in the fat.

An optical pedobarograph can objectively measure the pressures under the foot.[10] Our initial hypothesis that fat grafting would reduce pedal forces and pressures was based on the 1- and 2-year clinical trials using silicone to augment

Table 6. Mean Force and Pressure Differences between the Groups at Baseline, 6 Months, and 12 Months

	Baseline					6 Mo				12 Mo			
	Group 1		Group 2			Group 1		Group 2		Group 1		Group 2	
	No.	Mean ± SD	No.	Mean ± SD	*p**	No.	Mean ± SD	No.	Mean ± SD	*p**	No.	Mean ± SD	No.	Mean ± SD	*p**
Standing															
Left force, N	11	9.9 ± 8.5	10	9.9 ± 5.3	0.36	11	8.6 ± 4.0	10	15.4 ± 9.3	0.078	7	9.6 ± 8.0	9	15.4 ± 6.9	0.017
Right force, N	12	7.9 ± 6.4	12	8.2 ± 5.6	0.544	12	7.8 ± 4.7	12	10.1 ± 7.5	0.356	7	7.0 ± 2.1	11	9.6 ± 4.5	0.342
Left pressure, kPa	11	98.9 ± 82.7	10	102.6 ± 61.9	0.398	11	86.1 ± 39.8	10	159.2 ± 100.1	0.091	7	95.7 ± 78.5	9	154.8 ± 73.2	0.013
Right pressure, kPa	12	82.4 ± 64.0	12	85.8 ± 63.1	0.817	12	81.4 ± 53.0	12	103.3 ± 77.4	0.356	7	69.0 ± 20.3	11	98.9 ± 46.8	0.297
Walking															
Left force, N	11	48.5 ± 21.1	10	56.1 ± 19.7	0.481	11	46.4 ± 12.6	10	64.7 ± 22.9	0.067	7	52.2 ± 17.1	9	50.9 ± 16.4	0.711
Right force, N	12	40.3 ± 15.7	12	47.6 ± 22.7	0.603	12	41.3 ± 13.1	12	55.3 ± 20.3	0.094	7	39.1 ± 9.8	11	48.7 ± 15.5	0.042
Left pressure, kPa	11	500.8 ± 233.9	10	578.7 ± 217.9	0.481	11	463.1 ± 124.6	10	653.6 ± 233.9	0.041	7	531.3 ± 172.4	9	514.0 ± 162.2	0.634
Right pressure, kPa	12	408.4 ± 155.6	12	488.0 ± 242.0	0.525	12	415.4 ± 135.0	12	548.8 ± 197.0	0.094	7	393.1 ± 100.7	11	489.8 ± 152.5	0.063

*Wilcoxon rank sum test.

patients with pedal fat pad atrophy.[9,17] These studies demonstrated significant reduction in pedal pressures after augmentation, with some increase in pressure as the 2-year mark was reached, suggesting that retreatment may be required. However, we noted that patients with significant pain in the forefoot compensate their standing and gait to accommodate for the pain. Thus, patients with forefoot pain were hesitant to put pressure on the ball of the foot during screening pedobarography, but actually increased the amount of pressure over time. This may explain the lack of a robust difference noted in the foot forces and pressures over the 1-year period. The fat augmentation likely increased the cushion of the foot, reduced pain, and allowed for more pressure to be applied over time, whereas the control group continued to have increased foot pressures and forces over the 1-year period. This suggests that at the very least, fat grafting to the foot may provide a protective function against worsening foot pressures and pain over time. Our control group patients will cross over into the fat grafting group and be followed for 1 year as part of a larger 2-year randomized crossover trial.

A major caveat to our study is using averaged data for the metatarsals, given that different volumes of fat were used in different areas of the foot for different anatomical variations. Several patients had an abnormal gait, which compromises the pedobarographic data. We plan to include surface area assessments in the future. Patients with pes cavus feet bear greater weight on the forefoot and heel throughout the entire gait cycle and are prone to fat pad atrophy. Muscle imbalance seen with rigid cavus feet may cause hammertoes, which further magnify metatarsal head pressure and pain. The muscle imbalance commonly seen in pronated feet may cause osseous deformities such as bunions or hammertoes, aggravating plantar forefoot pressures. In addition, some patients who undergo neuroma surgery may have inadvertent lumbrical damage leading to hammertoe formation. Hammertoes cause a retrograde force leading to greater plantar flexion and prominence of the metatarsal heads with fat pad displacement. The ideal situation may be to address the osseous deformities at the same time as fat grafting; however, this may not be feasible for patients with significant medical comorbidities who are unable to comply with 6 to 8 weeks of nonambulatory status. Fat grafting alone as a minimally invasive approach may not be a long-term cure for patients with osseous deformities, but it may involve a less debilitating recovery.

Table 7. Mean Force and Pressure Differences between Time Points

	Group 1 (p*)			Group 2 (p*)		
	0 vs. 6 Mo	0 vs. 12 Mo	6 vs. 12 Mo	0 vs. 6 Mo	0 vs. 12 Mo	6 vs. 12 Mo
Standing						
Left force, N	0.722	0.31	0.398	0.013	0.011	0.441
Right force, N	0.875	0.176	0.237	0.05	0.374	>0.999
Left pressure, kPa	0.79	0.31	0.499	0.013	0.011	0.678
Right pressure, kPa	0.814	0.176	0.31	0.041	0.328	>0.999
Walking						
Left force, N	0.859	0.176	0.091	0.093	0.441	0.11
Right force, N	0.695	0.612	0.31	0.05	0.929	0.248
Left pressure, kPa	0.657	0.398	0.063	0.139	0.374	0.11
Right pressure, kPa	0.695	0.612	0.398	0.05	0.859	0.286

*Wilcoxon signed rank test.

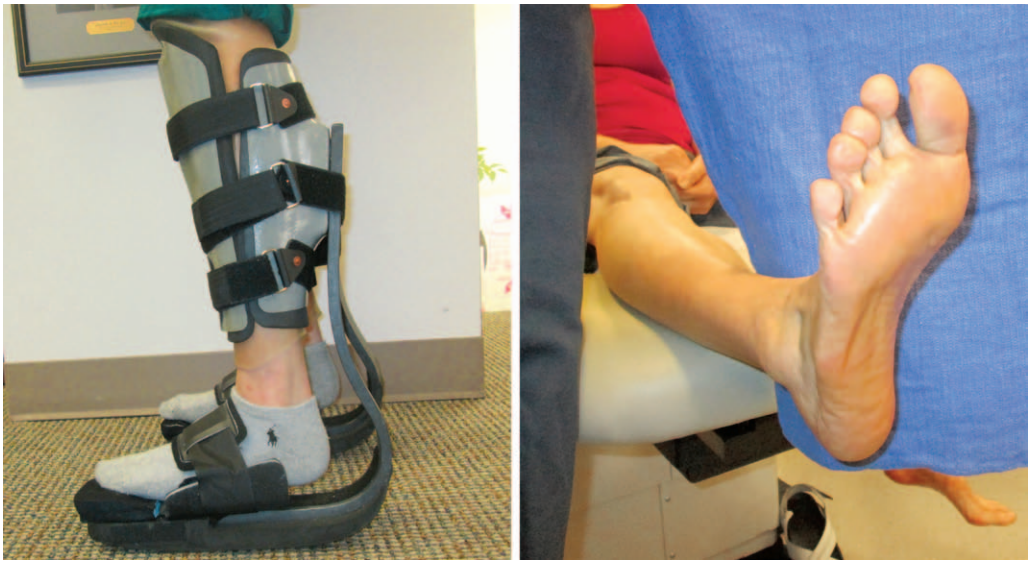

Fig. 2. The patient is a 63-year-old woman with a 10-year history of fat pad atrophy of the plantar surface of the foot managed with orthotics. (*Left*) She has obtained custom orthotic devices to completely offload the forefoot and heel. (*Right*) Her foot demonstrates the common cavus deformity with a high arch and displacement of the fat pads distally from the metatarsal heads.

Additional limitations of our trial include the small sample size, patient compliance with keeping off their feet after surgery, and the fact that we do not make patients non–weight-bearing for an extended period, which may compromise graft survival. Unilateral injections and complete offloading may improve outcomes.

CONCLUSIONS

Despite decreasing tissue thickness over time, fat grafting for forefoot fat pad atrophy significantly improves pain and disability outcomes, decreases foot pressures and forces, and prevents against worsening foot pressures and forces. Pedal fat grafting is a safe, minimally invasive approach to treat fat pad atrophy. Future analysis will reveal whether fat grafting has lasting efficacy.

Jeffrey A. Gusenoff, M.D.
Department of Plastic Surgery
University of Pittsburgh Medical Center
3380 Boulevard of the Allies, Suite 180
Pittsburgh, Pa. 15213
gusenoffja@upmc.edu

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CODING PERSPECTIVE

The information in this coding perspective provided by Dr. Raymond Janevicius is intended to provide coding guidance.

20926 Tissue grafts, other (eg, paratenon, fat, dermis)

- Code 20926 is used to report fat grafting.
- The code is not anatomic-site specific. Report code 20926 for any area of fat grafting, whether it is the face, the breast, or the foot.
- The code is not volume specific. Code 20926 is reported whether 5 cc of fat is grafted or 250 cc of fat is grafted. Extensive fat grafting involving large volumes may require use of modifier 22. This should be determined preoperatively during the preauthorization process.
- The fat grafting code is reported once per anatomic site. Thus report code 20926 once for the foot, even if several areas are grafted.
- Fat grafting of both feet is reported as follows:

20926	Fat grafting, right foot
20926-59	Fat grafting, left foot

- This is not considered a "bilateral code" per Current Procedural Terminology and Centers for Medicare & Medicaid Services guidelines, so the bilateral modifier, 50, would not be used.
- Fat grafting procedures should all be preauthorized *in writing* by the insurance company, as many payers consider fat grafting to be cosmetic.

CODING PRINCIPLE: As with other grafting Current Procedural Terminology codes (e.g., skin, bone), the fat grafting code, 20926, includes harvest, preparation, and placement of the graft. To code separately for harvest and placement is unbundling. It is not appropriate to report a liposuction code (1587X) for harvest of fat, and injection of the fat is not reported with code 1195X ("Subcutaneous injection of filling material"). The 1195X series of codes is used for "off-the-shelf" products such as collagen and is not appropriate to report for fat injections. Code 20926 is global and includes harvest by liposuction, appropriate preparation of fat for grafting, and injection of fat into the recipient site.

Disclosure: Dr. Janevicius is the president of JCC, a firm specializing in coding consulting services for surgeons, government agencies, attorneys, and other entities.

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