Fat Grafting for Pedal Fat Pad Atrophy in a 2-Year, Prospective, Randomized, Crossover, Single-Center Clinical Trial

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Background: By age 60, 30 percent of Americans suffer from fat pad atrophy of the foot. Forefoot fat pad atrophy results from long-term aggressive activity, genetically dictated foot type, multiple forefoot steroid injections, surgery, and foot trauma.
Methods: The authors present data from a 2-year, prospective, randomized crossover study performed to assess pain and disability indexes, fat pad thickness, forces, and pressures of stance and gait. Group 1 underwent fat grafting with 2 years of follow-up, and group 2 underwent conservative management for 1 year, then underwent fat grafting with 1 year of follow-up.
Results: Eighteen subjects (14 women and four men) constituted group 1. Thirteen subjects (nine women and four men) constituted group 2. Group 1 reported the worst pain at baseline and group 2 experienced the worst pain at 6- and 12-month standard-of-care visits; pain for both groups improved immediately following fat grafting and lasted through study follow-up ($p < 0.05$). Group 1 demonstrated functional improvements at 12, 18, and 24 months postoperatively ($p < 0.05$), whereas group 2 demonstrated the highest function at 12 months postoperatively ($p < 0.05$). Pedal fat pad thickness of subjects in group 1 increased postoperatively and returned to baseline thickness at 2 months postoperatively; subjects in group 2 experienced return to baseline thickness at 6 months postoperatively ($p < 0.01$). Forces and pressures of stance and gait increased over the 2 years of follow-up for group 1 ($p < 0.05$).
Conclusion: Pedal fat grafting provides long-lasting improvements in pain and function, and prevents against worsening from conservative management. (*Plast. Reconstr. Surg.* 142: 862e, 2018.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, I.

Forefoot fat pad atrophy is seen with advancing age, obesity, abnormal foot mechanics, corticosteroid injections, prior surgery, and overuse resulting from athletic training or careers demanding prolonged standing.[1–3] Loss or displacement of fat pad under metatarsal heads leads to bony prominence. The pain resulting from pedal fat pad atrophy debilitates patients and

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prevents them from performing routine activities of daily living. Pain of the forefoot may result in disability, loss of productivity, and depression.[4–8]

Approximately one-third of adults older than 60 years and one-half of adults older than 70 years have pedal fat pad atrophy.[9] Although current treatment options include external devices such as orthotics or shoe inserts, these solutions break down with use, are expensive, and often result in poor patient compliance.[10] Fillers, such as hyaluronic acid and silicone, have been used to address pedal fat pad atrophy; however, very few objective data are available for such use.[11–13]

The fat padding under metatarsal heads provides shock absorption and protection from sheer, compression, and pivoting forces during gait. Fat pad loss may encourage callus formation and even ulceration, especially in neuropathic patients. There is an unmet need for a cushioning under the metatarsal heads to prevent further tissue breakdown and reduce patient pain.

To date, our team has published the only objective data reporting autologous fat grafting to the feet.[14] Our previous report demonstrated that pedal fat injections improved quality of life compared with a control group, which worsened over 1 year under standard-of-care management. In this article, we present data collected from a 2-year, prospective, randomized, crossover, clinical trial describing the benefits of autologous fat grafting for pedal fat pad atrophy with the objectives of improving pain and disability indexes, fat pad thickness, forces, and pressures of stance and gait.

PATIENTS AND METHODS

Trial Design

Thirty-one adults who experienced pain from fat pad atrophy were recruited into an institutional review board–approved, prospective, randomized, crossover clinical trial. The overall purpose of this outcomes study was to assess whether fat grafting to the forefoot in patients with fat pad atrophy will reduce foot pressure during gait, increase the soft-tissue thickness of the foot pad, and ultimately reduce pain. Inclusion criteria consisted foot pain under the head of the metatarsals, a diagnosis of fat pad atrophy by a foot and ankle specialist, and a period of 6 months after any surgical intervention or steroid injection to the foot. Exclusion criteria included uncontrolled diabetes mellitus (hemoglobin A1c level >7.0 percent), open ulcerations, infection (including osteomyelitis), systemic disease that would render the fat harvest and injection procedure unsafe to the patient, pregnancy, known coagulopathy, and tobacco use within the past 12 months.

Medical, surgical, social, and activity histories were performed. Vital signs including temperature, blood pressure, height, weight, and body mass index were obtained. Any prior foot injury, surgery, or previous foot ulcerations were noted. A physical examination and complete foot examination were documented. Complete vascular and neurologic evaluations were performed.

On 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 level. Standardized two-dimensional photographs of the foot, including any callus and/or lesion pattern, were captured.

Once the patient provided informed consent, eligibility was determined, followed by randomization. Randomization was determined using the GraphSoft random number generator function (GraphPad Software, Inc., La Jolla, Calif.) and was provided by an independent research coordinator not involved in the trial. Subjects were randomized to either the autologous fat grafting pathway (group 1) or to the standard-of-care pathway (group 2).

Subjects in group 1 received pedal fat grafting treatment immediately and returned for follow-up visits at 2 weeks and 1, 2, 6, 12, 18, and 24 months. Subjects in group 2 followed standard-of-care treatments for 1 year with visits at 6 months and 12 months; received pedal fat grafting treatment; then returned for follow-up visits at 2 weeks and 1, 2, 6, and 12 months. (**See Figure, Supplemental Digital Content 1**, which outlines the study schema , along with a description of research visits conducted. *SOC*, standard of care; *POV*, postoperative visit, ***http://links.lww.com/PRS/D99***.)

Intervention

Surgical consent was provided and surgical procedures were performed in the University of Pittsburgh Medical Center Aesthetic Plastic Surgery Center in Pittsburgh, Pennsylvania. Subjects received local anesthesia (lidocaine 1% with epinephrine 1:100,000) at the site of aspiration of the fat grafts (abdomen, thighs, or flanks, according to principal investigator discretion) and 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. A tibial nerve block and forefoot Mayo block was performed with a 50:50 mixture of 2% lidocaine and 0.5% bupivacaine without epinephrine. A blunt-tip multihole hollow cannula was used to aspirate approximately 50 to 100 ml of fat tissue through a stab incision made with a no. 11 blade. Liposuction was performed under a low, consistent negative pressure using 10-ml syringes to limit trauma to the adipocytes. Incisions for donor sites were closed with benzoin and Steri-Strips (3M, St. Paul, Minn.).

A standard Coleman technique was used to process the fat, where the harvested fat graft was placed in centrifugation at 3000 rpm for 3 minutes.[15] The resultant fat was decanted, oil was wicked using absorbant gauze, and the high-density fraction (bottom-most 1 ml of each 10-ml syringe) was transferred to 1-ml syringes for injection into the foot. 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, allowing for a cross-hatch injection pattern. Occasionally, injections were performed from the dorsal aspect. A 0.9-mm blunt cannula was used to inject the 1-ml syringes of fat into the foot.

Postoperatively, subjects walked out of the clinic in comfortable sneakers with padded insoles, allowing for offloading of the fat-grafted region. Subjects were instructed to limit strenuous activity for 4 to 6 weeks, including barefoot walking. No subjects received additional treatment of fat grafting or underwent any other surgical intervention to the foot during the clinical trial.

Measurement of Pain and Disability

Foot pain and subject disability was measured by the Manchester Foot and Disability Index, a validated assessment of the foot that includes components of pain, function, appearance, and work/leisure activities.[16] The questionnaire was administered to both groups 1 and 2 at every visit, excluding the operative visit and the 2-week postoperative visit.

Measurement of Tissue Thickness

Ultrasound (Terason Ultrasound Imaging System, Version 4.7.6; Terason, Burlington, Mass.) was used to measure plantar tissue thickness under each metatarsal head. Ultrasound of both groups 1 and 2 was performed by the clinicians at every visit, excluding the 2-week postoperative visit.

Measurement of Stance and Gait Force and Pressure

The Tekscan HR Mat pressure measurement system and Research Foot Module (Tekscan, Inc., South Boston, Mass.) was used to obtain pedobarographic data to determine baseline plantar foot forces and pressures. Subjects were weight-calibrated to measure forces and pressures applied while standing, then recalibrated for walking. Standing measurements were captured from an average of 150 seconds. Walking measurements were captured from an average of a minimum of three passes for each foot at a self-selected speed. The pedobarograph was performed with both groups 1 and 2 at every visit, excluding the operative visit and the 2-week postoperative visit.

Statistical Analyses

The a priori power analysis indicated that enrollment of at least five subjects would provide sufficient power to detect clinically meaningful differences with standard conventions of $\alpha = 0.05$ and $\beta = 0.80$. Data for injected feet only were evaluated, to avoid diluting the results with unaffected foot measurements.

Statistical analyses were performed with IBM SPSS Version 24.0 (IBM Corp., Armonk, N.Y.). Wilcoxon rank sum tests were used to evaluate differences in means between group 1 and group 2 and how outcomes vary between time points. Tests were two-sided and significance was set to the level of $p < 0.05$, $p < 0.01$, or $p < 0.001$, as indicated. All outlier data (2σ) were removed before analyses.

Correlations were determined by the Pearson coefficient at a confidence level of $p < 0.05$. Normality tests of Kolmogorov-Smirnov and Shapiro-Wilk were conducted and are listed in Supplemental Digital Content 2. [**See Figure, Supplemental Digital Content 2**, which shows tests of normality obtained for (*above, left*) pain, (*second row, left*) function, (*third row, left*) appearance, (*fourth row, left*) work/leisure, (*below, left*) fat pad thickness, (*above, right*) standing forces, (*second row, right*) standing pressures, (*third row, right*) walking forces, and (*fourth row, right*) walking pressures at baseline, 1-month postoperative visit (*POV*), 2-month postoperative visit, 6-month postoperative visit, and 12-month postoperative visit. [a]Lilliefors significance correction; *lower-bound of the true significance, ***http://links.lww.com/PRS/D100***. **See Figure, Supplemental Digital Content 3**, which shows all descriptive statistics, including number; mean; standard deviation; minimum and maximum; and 25th, 50th (median), and 75th percentiles of (*above, left*) pain, (*second row, left*) function, (*third row, left*) appearance, (*fourth row, left*) work/leisure, (*below, left*) fat pad thickness, (*above, right*) standing forces, (*above, second*

Table 1. Subject Demographics

	Group 1 (Intervention)	Group 2 (Standard-of-Care)	*p*
Sex			
Female	14	9	0.09
Male	4	4	0.09
Average age at screening, yr	61.3 ± 7.5	66.5 ± 7.1	0.06
Average BMI at screening, kg/m^2	26.8 ± 4.2	26.0 ± 3.4	0.35

BMI, body mass index.

row) standing pressures, (*above, third row*) walking forces, and (*fourth row, right*) walking pressures at baseline, 1-month postoperative visit (*POV*), 2-month postoperative visit, 6-month postoperative visit, and 12-month postoperative visit. [a]Lilliefors significance correction; *lower bound of the true significance, ***http://links.lww.com/PRS/D101***.]

RESULTS

Participant Characteristics

Eighteen fat pad atrophy patients (14 women and four men) constituted group 1 and 13 (nine women and four men) constituted group 2. Subject demographics are listed in Table 1. Figure 1 represents preoperative and postoperative

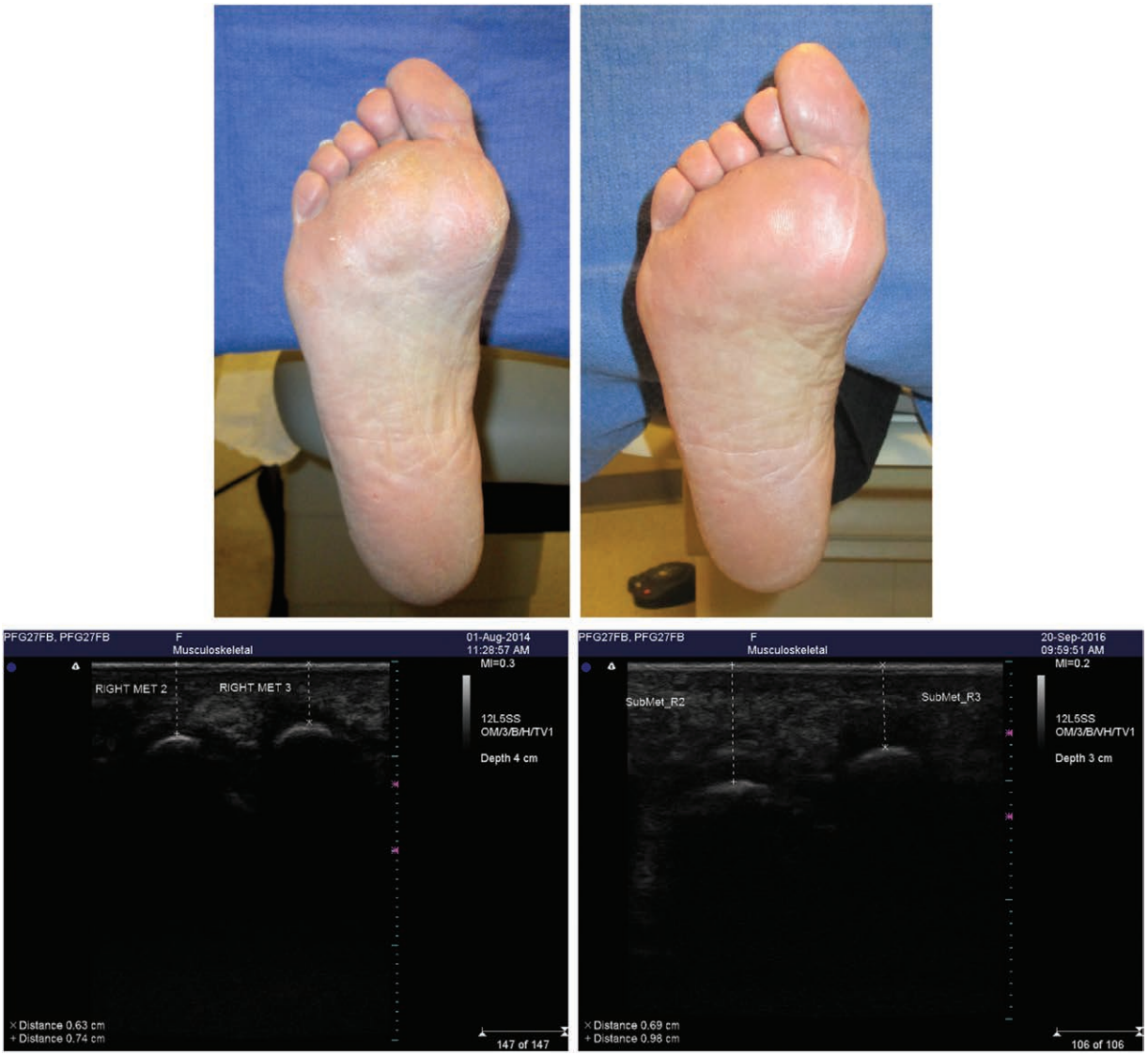

Fig. 1. Photographs of a 66-year-old female patient with fat pad atrophy before (*left*) and 2 years after 5 ml of fat injection into the forefoot (*right*). Preoperative photograph demonstrates significant hyperkeratosis under the metatarsal heads. Two-year postoperative photograph demonstrates significantly improved quality of the skin with less hyperkeratosis. Comparison of preoperative and postoperative ultrasound images confirms improvement in the thickness under the metatarsal heads.

Table 2. Fat Graft Injections

	Group 1 (Intervention)	Group 2 (Standard-of-Care)	*p*
No. of feet injected	30	23	—
Average volume injected, cc			
Right foot	3.9 ± 2.1	4.7 ± 1.5	0.42
Left foot	4.0 ± 2.0	4.5 ± 2.1	0.56

photographs and ultrasound results. No significant differences in age or body mass index were found between groups 1 and 2. Age was found to have no correlation to any outcome in any group. Body mass index was strongly correlated to standing pressure ($p = 0.01$, $r = 0.62$). Causes for fat pad atrophy include failed neuroma surgery, prior foot surgery, steroid injections, and overuse.

Fat injection volumes are listed in Table 2. In group 1, fat pad atrophy was diagnosed in 30 feet where 12 subjects underwent bilateral fat grafting injections and six subjects underwent fat grafting in only the one injured foot. In group 2, fat pad atrophy was diagnosed in 23 feet, with 10 subjects undergoing bilateral fat grafting and three subjects receiving fat grafting in only the one injured foot.

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

No serious adverse events or unanticipated events occurred. Three subjects desired a second round of fat grafting after completion of the study and have enrolled in a subsequent pedal fat grafting clinical trial.

Pain and Disability Outcomes

No significant difference was observed between group 1 and group 2 regarding all four categories of Manchester Foot and Disability Index scores at any time—pain, functionality, appearance, and work/leisure activities ($p > 0.05$). When comparing pain scores within groups, group 1 reported highest pain at screening, then less pain at every visit through 2 years postoperatively: 1, 2, 6, 12, 18, and 24 months postoperatively ($p = 0.006$, $p = 0.017$, $p = 0.012$, $p = 0.023$, $p = 0.027$, and $p = 0.05$, respectively) (Fig. 2, *above*, *left*). Group 2 reported the lowest pain at 2 months postoperatively, and significantly lower pain than at 6- and 12-month standard-of-care visits ($p = 0.005$ and $p = 0.025$, respectively) (Fig. 2, *above*, *right*).

Pearson correlations indicated that lower reported pain by means of the Manchester Foot and Disability Index was directly correlated to increased standing and walking pressures and forces in both groups ($p < 0.05$), and higher reported pain scores were directly correlated to lower fat pad thickness in both groups ($p < 0.05$). Increase in pain scores directly correlated to worsened reported work/leisure and function outcomes in both groups ($p < 0.05$).

Functionality in group 1 improved at 12, 18, and 24 months postoperatively ($p = 0.025$, $p = 0.027$, and $p = 0.012$, respectively) (Fig. 2, *second row*, *left*). Similarly, functionality in group 2 improved at 12 months postoperatively from baseline and 1 month postoperatively ($p = 0.017$ and $p = 0.049$, respectively) (Fig. 2, *second row*, *right*). Functionality directly correlated (by means of Pearson correlation) with fat pad thickness in both groups ($p < 0.05$) (i.e., subjects with thicker fat padding reported improved functionality). Similarly, functionality was directly correlated to increased standing and walking pressures and forces in both groups ($p < 0.05$).

No change in appearance over time was observed in group 1 (Fig. 2, *third row*, *left*), whereas subjects in group 2 reported significant improvements in appearance at 6 and 12 months postoperatively ($p = 0.033$ and $p = 0.047$, respectively) (Fig. 2, *third row*, *right*).

No change in work/leisure activities over time was observed in group 1 (Fig. 2, *below*, *left*). Although subjects in group 2 reported significant improvements in work/leisure activities at 1 and 2 months postoperatively ($p = 0.039$ and $p = 0.016$, respectively), improvements were not sustained through the 1-year of follow-up (Fig. 2, *below*, *right*).

Tissue Thickness Outcomes

As the fat pad thicknesses in each group changed over time, group 1 experienced the same fat pad thicknesses as group 2 postoperatively and at all follow-up visits through 1 year. Figure 3 displays fat pad thickness measured over time for group 1 (Fig. 3, *left*) and group 2 (Fig. 3, *right*). In group 1, fat pad thickness is lower at screening than immediately postoperatively and at 1 month postoperatively ($p = 0.000$); then, at 2 months postoperatively, fat pad thickness returns to baseline ($p = 0.083$).

In group 2, fat pad thickness increases after the procedure and remains through the first 2

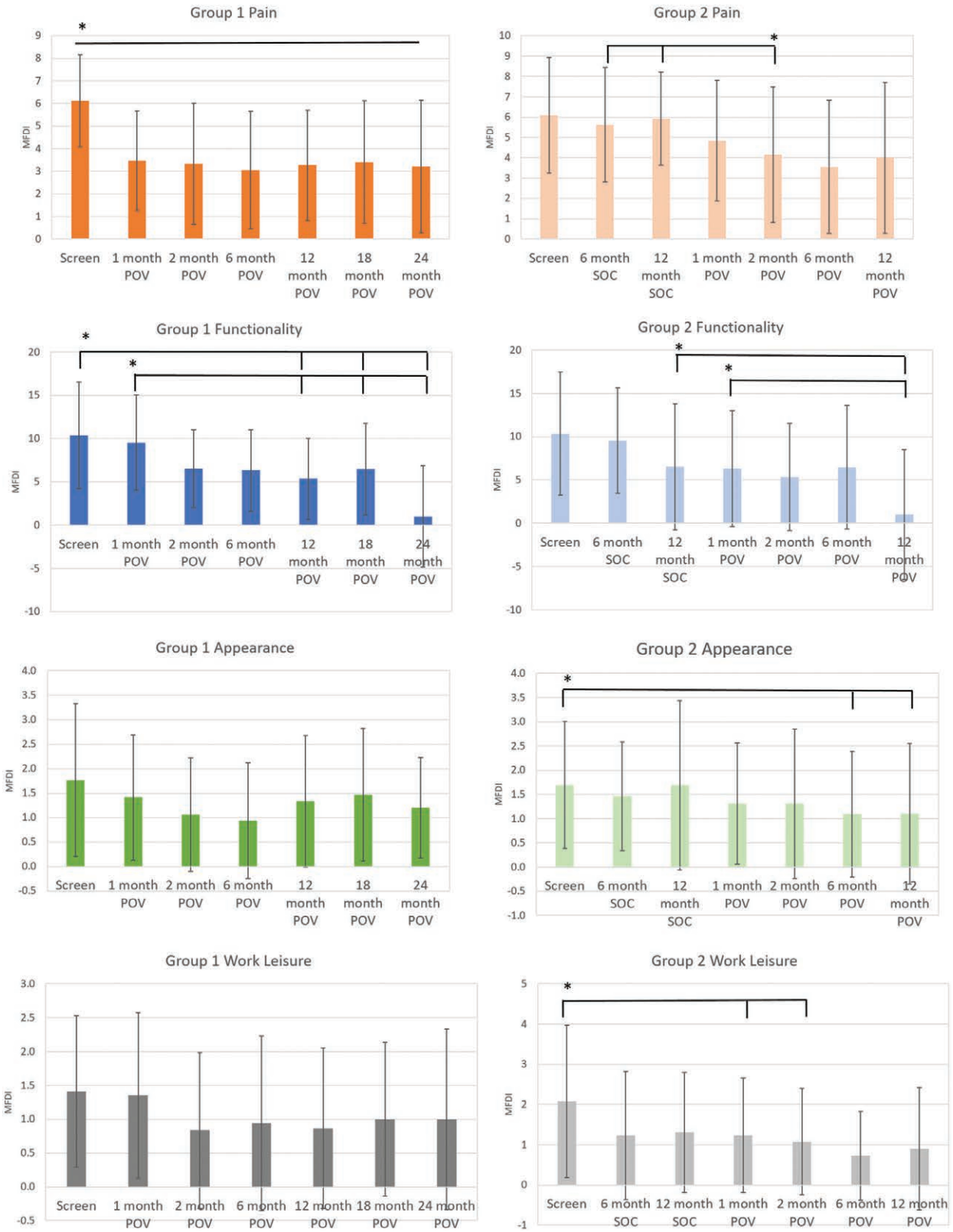

Fig. 2. Average Manchester Foot and Disability Index results collected from group 1 (*left*) and group 2 (*right*) at all time points for (*above*) pain, (*second row*) functionality, (*third row*) appearance, and (*below*) work and leisure activities. *Asterisk* (*$p < 0.05$) placed above time point indicates significant difference from the time points under the bar.

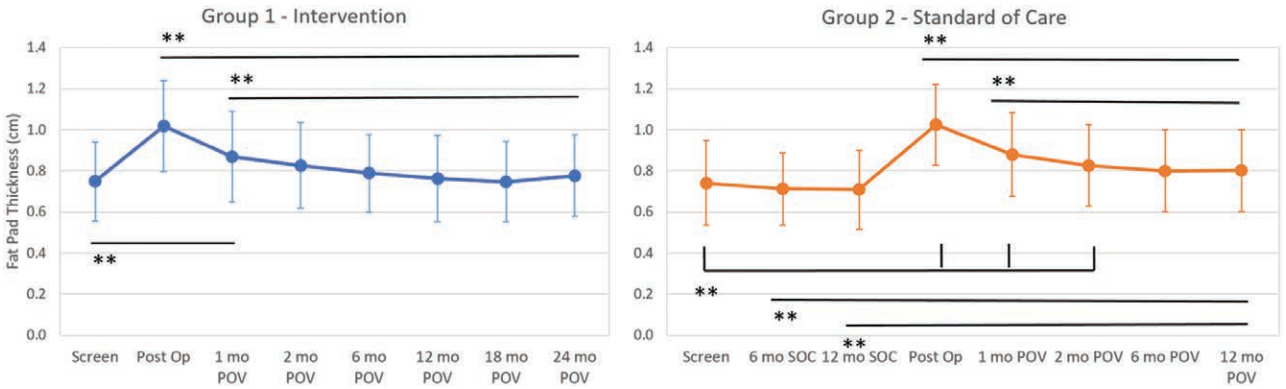

Fig. 3. Fat pad thickness results. Average fat pad thickness over time as measured in (*left*) group 1 and (*right*) group 2. *Asterisks* (*$p < 0.05$; **$p < 0.01$) placed above time point indicate significant difference from the time points under the bar.

months ($p = 0.000$); then, at 6 months postoperatively, fat pad thickness returns to baseline ($p = 0.140$) but is still thicker than at 6- and 12-month standard-of-care visits ($p = 0.000$).

Stance and Gait Force and Pressure Outcomes

Groups 1 and 2 experienced differences in standing forces only at the 2-month postoperative visit ($p = 0.04$). There was no difference between the two groups' standing pressure or walking force at any time point. Group 2 experienced higher walking pressures than group 1 at 1-, 2-, and 6-month postoperative visits ($p = 0.000$, $p = 0.014$, and $p = 0.041$, respectively) and the same walking pressures at screening and at 12-month postoperative visits. Standing forces in group 1 begin to increase at 12 months postoperatively ($p = 0.004$) and are highest at 18 months postoperatively ($p = 0.001$) (Fig. 4, *above*, *left*). Standing forces in group 2 are lowest at baseline and at 1 month postoperatively ($p < 0.05$) (Fig. 4, *above*, *right*).

In group 1, standing pressures increase at 12 months postoperatively ($p = 0.013$) (Fig. 4, *second row*, *left*). In group 2, standing pressures are lowest at the 1-month postoperative visit ($p < 0.05$) and then rise at 6 months postoperatively ($p < 0.05$) (Fig. 4, *second row*, *right*).

Walking forces in group 1 increase at 12, 18, and 24 months postoperatively compared to screening and 1, 2, and 6 months postoperatively ($p < 0.05$) (Fig. 4, *third row*, *left*). No difference in walking forces exists between time points in group 2 (Fig. 4, *third row*, *right*).

In group 1, walking pressures are highest at 18 and 24 months postoperatively ($p < 0.01$) (Fig. 4, *below*, *left*). No differences in walking pressures exists between time points in group 2 (Fig. 4, *below*, *right*).

DISCUSSION

Pedal fat pad atrophy is a progressive disorder, debilitating the lifestyles of 30 percent of adults older than 60 years. Younger patients, especially athletes, may be prone to this condition. Until now, no current invasive treatment has proven effective. External options, such as orthotics or shoe pads, sometimes provide temporary relief but are not a cure. Most patients presenting for fat grafting to the forefoot have visited a multitude of specialists, undergone multiple tests, and have had no successful treatments. Fat pad atrophy is a diagnosis of exclusion.

Fat injections increased tissue thickness directly under the metatarsal head for less than 6 months, despite ongoing improvement in pain and function scores. This suggests that fat may be redistributing around the metatarsal heads, providing cushion long-term, rather than completely resorbing. We are currently conducting a separate clinical trial to assess three-dimensional volume of the foot using magnetic resonance imaging. This study will provide insight to bone integrity before and after fat grafting. In addition, intrinsic factors in the fat may influence the bone or soft tissues. To assess this, investigation of stem cell characteristics obtained from study subjects' leftover adipose tissue is currently underway.

Thinner fat pads directly correlated with increased reported pain in both groups, and thicker fat pads directly correlated with less reported pain in both groups, validating the effect of pedal fat pad thickness on pain. Similarly, thinner fat pads directly correlated with lessened functionality in both groups, whereas thicker fat pads directly correlated with increased functionality in both groups.

In addition, in both groups, lower reported pain was directly correlated to higher

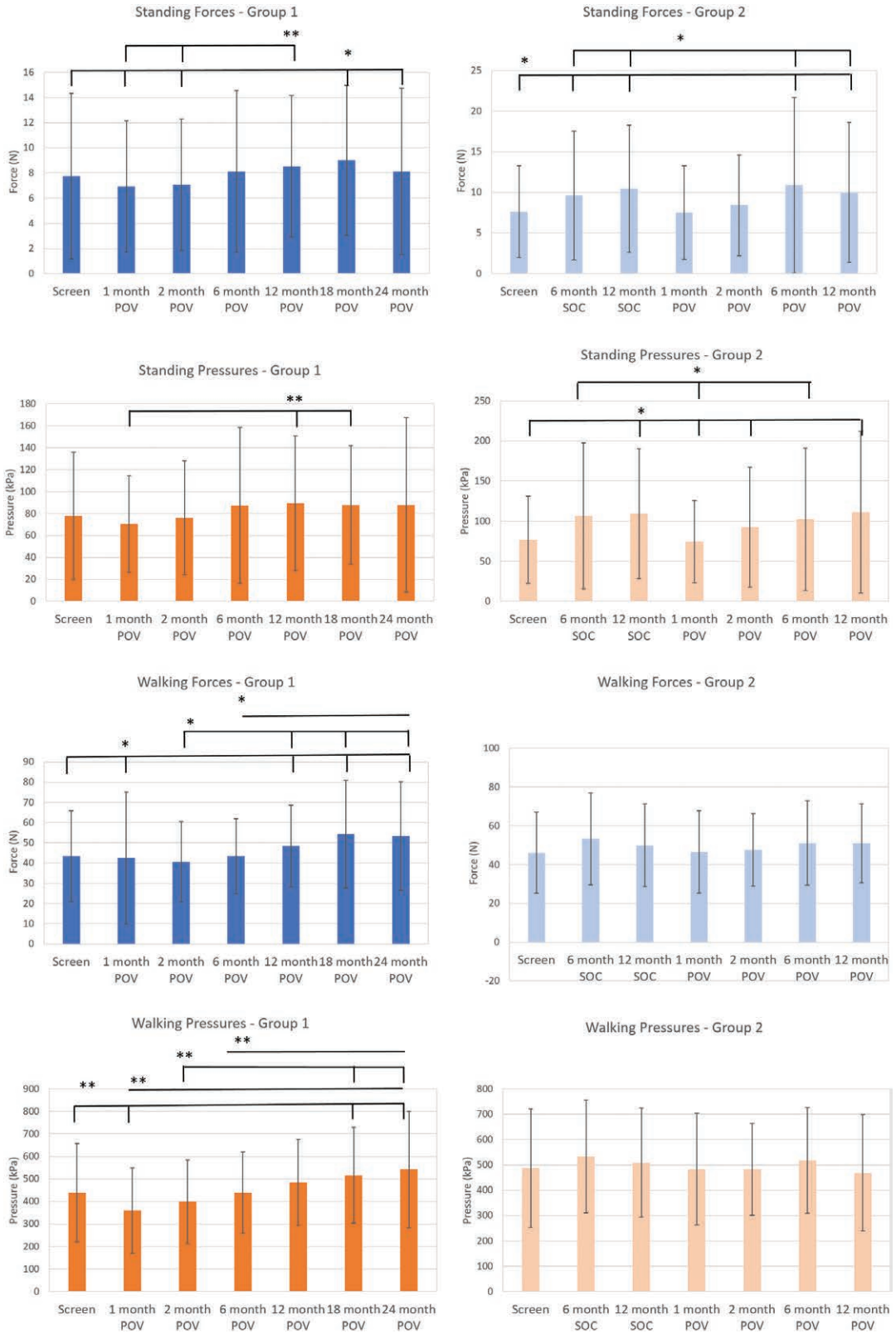

Fig. 4. Average pedobarograph data obtained at each research visit from group 1 (*left*) and group 2 (*right*) while standing (*above* and *second row*) and walking (*third row* and *below*). *Asterisks* (*$p < 0.05$; **$p < 0.01$) placed above time point indicate significant difference from the time points under the bar.

pedobarograph force and pressure, indicating that as subjects heal, their gait becomes more normal. This is contrary to literature of prior studies involving silicone that demonstrated decreased foot pressure and forces with injection. We noted during our screening visits that patients were hesitant to apply pressure to the painful forefoot, which likely altered our pedobarographic data. Barefoot walking is extremely painful for patients with pedal fat pad atrophy, and they compensate weight bearing on the pedobarograph. More reliable pressure devices, such as pressure-sensing insoles, may have provided more accurate data. We plan to use this technology in future studies.

Higher walking pressures captured in group 2 at 1-, 2-, and 6-month postoperative visits compared to those at screening and at 12-month postoperative visits may be attributable to the two additional visits the subjects in group 2 were exposed to with the pedobarograph, allowing more familiarity with the tool. Because the two groups have no difference in walking pressures at screening or at 12 months postoperatively, we can conclude that the two groups recovered equally at 1 year.

Pain and function reports were directly correlated in both groups as well. Lower functionality at 1-month postoperative visits (in both group 1 and 2) was attributable to required recovery time after the procedure with prescribed limited activity.

Limitations of the presented study include the treatment of various causes and foot types with varying injection-site needs. For instance, some fat pad atrophy patients have need under specific metatarsals because of neuroma excisions, whereas others have a generalized loss of fat pad and require treatment under all metatarsals. To simplify our analyses, we averaged data from the metatarsals together in an attempt to have a generalized understanding of the benefits of fat grafting, but this may have altered some of our findings. Although cause of pedal fat pad atrophy was neither an exclusion criterion for our study or analyzed here, further investigation in correlation to fat graft performance would provide insight for future pedal fat graft patients. Furthermore, because Manchester Foot and Disability Index data were collected by means of survey, pain, functionality, work/leisure, and appearance results are from the perspective of the subjects.

Additional limitations to our trial include the nonparametric nature of the data and subject compliance with limiting activity following the procedure. To possibly improve outcomes, unilateral injections (as opposed to the injection of different volumes of fat used in this study) and complete offloading following the procedure may be tested.

CONCLUSIONS

Pedal fat grafting is a safe, minimally invasive approach to treat pedal fat pad atrophy. Although the fat directly under the metatarsal does not seem to last more than 6 months, it may be redistributing to offer lasting improvements in pain and functional outcomes. Fat grafting can help prevent prolonged pain and disability compared with conservative therapy.

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