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A New Minimally Invasive Procedure for Treating Plantar Heel Pain

Stromal Vascular Fraction Gel Grafting

Bihua Wu, MD,[a] Shune Xiao, MD, PhD,[a,b] Sanhong Yang, MD,[a] Zairong Wei, MD,[a,b] and Chengliang Deg, MD, PhD[a,b]

Atrophy of the fat pad is considered to be one of the main causes of plantar heel pain. Recent studies showed fat grafting increased fat pad volume and was beneficial for treating pedal fat pad atrophy. However, traditional fat grafting has a high absorption rate because of lower concentration of adipose-derived stem cells. Stromal vascular fraction gel (SVF-gel), as a novel fat grafting and rich in adipose-derived stem cells, is prepared by a simple mechanical process. This study aimed to assess the efficacy of SVF-gel in the treatment of plantar heel pain.

Methods: Fourteen patients who experienced plantar heel pain and underwent plantar heel SVF-gel grafting between January 2019 and June 2020 were included in this retrospective study. Foot pain and disability were measured at the screening visit and at the 3-, 6-, and 12-month follow-up visits. The volume of the heel fat pad was measured by magnetic resonance imaging.

Results: Four of the patients had bilateral plantar heel pain, and 10 patients had unilateral plantar heel pain. All patients showed significant improvements in pain and foot function at 3 months after SVF-gel grafting compared with the baseline, with the greatest improvement at 6 months and the effect lasting 1 year or more. In addition, the thickness of the heel fat pad was significantly greater than at baseline at 3 months, and the effect lasted for 1 year or more.

Conclusion: Stromal vascular fraction gel grafting is a safe, minimally invasive, and effective approach to treat plantar heel pain.

Key Words: fat grafting, stromal vascular fraction gel, plantar heel pain

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Plantar heel pain is a common problem of the foot in adulthood and can be caused by age, abnormal bone mechanics, plantar fasciitis, fat pad atrophy, or neuropathic pain.[1,2] Because of its unique anatomical structure, the fat pad under the calcaneus plays an important role in the shock absorption of the heel and provides protection from sheer and compression forces.[3] A previous study revealed that people with heel pain show a significantly decreased thickness of the subcalcaneal fat pad, regardless of sex.[4] In addition, the heel pad was thinner in the painful heels of patients with plantar fasciitis.[5] Atrophy of the fat pad leads to bony prominence and may cause obvious pain or compensatory gait, leading to callus formation and even ulceration.[6] Chronic pain can also cause depression and other mental health problems, which combined with physical pain significantly reduce patients' life quality. Augmentation of the heel fat pad has been shown to minimize the risk of heel pain, and beneficial effects have been demonstrated with various external devices (ie, shoe orthoses and pads).[7] However, external devices are prone to breakdown, and are inconvenient and cause patient compliance issues. In recent years, studies have demonstrated that pedal fat grafting significantly increases metatarsal fat pad volume and is beneficial for the treatment of pedal fat pad atrophy.[8,9] However, there is only 1 report of a pilot study of fat transplantation to treat chronic heel pain in adults after surgery for flat foot deformity.[10] In addition, traditional fat transplantation has a high absorption rate. In order to improve the retention rate, it is necessary to increase the volume of transplanted fat, which leads to severe swelling and inflammatory reaction in the recipient area after injection and prolongs the recovery time.

Stromal vascular fraction gel (SVF-gel), which is rich in extracellular matrix and functional cells, is prepared by simple mechanical processes of centrifugation and intersyringe shuffling.[11] Stromal vascular fraction gel acts as a natural filler, has shown excellent cosmetic results in facial rejuvenation, and has shown improvement of horizontal neck wrinkles, and patients can enjoy a remarkably quick recovery period without significant swelling after injection.[12,13]

In this study, we aimed to investigate the efficacy of SVF-gel grafting in the treatment of plantar heel pain. To date, there have not been any studies concerning SVF-gel transplantation for plantar heel pain.

METHODS

Retrospective Analysis

Patients who experienced plantar heel pain and underwent plantar heel SVF-gel grafting between January 2019 and June 2020 at the Department of Plastic Surgery of our hospital were analyzed retrospectively. Patients with plantar heel pain diagnosed with plantar fasciitis or fat pad atrophy by a foot and ankle specialist were included, and the follow-up time was longer than 1 year. Patients with diabetes or incomplete follow-up data were excluded. The study was approved by the Ethics Committee of the Affiliated Hospital of Zunyi Medical University. All the participants provided written informed consent before enrolling in the study, and the authors were allowed to use their photographs for scientific purposes.

Selection of Donor Sites and Fat Acquisition

The surgery was performed under local anesthesia combined with intensive intravenous anesthesia. In clinical practice, the lower abdomen and inner thigh are considered as the best donor sites for fat graft harvest. These are considered to be the optimal donor sites because of

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From the [a]Department of Plastic Surgery, Affiliated Hospital of Zunyi Medical University; and [b]The Collaborative Innovation Center of Tissue Damage Repair and Regeneration Medicine of Zunyi Medical University, Zunyi, Guizhou, China.

Ethical approval: This study was approved by the Clinical Research Ethics Committee of the Affiliated Hospital of Zunyi Medical University.

Data Availability: The data used to support the finding of this study are included within the article.

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Informed consent: All patients provided preoperative informed consent and allowed the authors to use their photographs for scientific research reports.

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Reprints: Chengliang Deng, MD, PhD, Department of Plastic Surgery, Affiliated Hospital of Zunyi Medical University, 149 Dalian Rd, Zunyi, Guizhou 563000, China. E-mail: cheliadeng@sina.com; Zairong Wei, MD, The Collaborative Innovation Center of Tissue Damage Repair and Regeneration Medicine of Zunyi Medical University, 6 Xuefu West Road, Zunyi, Guizhou 563000, China. E-mail: zairongwei@163.com.

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their high subcutaneous fat content and hidden location, as well as their good contour remodeling effect after fat suction. Consequently, we also chose the lower abdomen and the inner thigh as donor sites.

Through a small incision, a tumescent solution consisting of 500-mL 0.9% NaCl, 150-mg lidocaine (0.03%), 50-mg ropivacaine (0.01%), and 0.5-mg adrenaline (1:100,000) was infiltrated into the subcutaneous fat layer. Blunt-tipped cannulas with sharp side holes 3 mm in diameter were attached to 20-mL Luer-Lok syringes for liposuction. The lipoaspirate was allowed to settle in the syringes under gravity for 15 minutes, then the swelling liquid at the bottom was removed and the upper layer of adipose tissue was retained. A total of 50 mL of adipose tissue was harvested from patients with unilateral heel pain and 100 mL from patients with bilateral heel pain.

Stromal vascular fraction gel Preparation and Grafting

The harvested adipose tissue was centrifuged at 1200 × *g* for 3 minutes. After centrifugation, the middle layer of adipose tissue was collected, and the upper layer of oil and the lower layer of swelling fluid were discarded. Stromal vascular fraction gel was prepared as previously described. Briefly, two 20-mL syringes were connected via a female-to-female Luer-Lok connector (2.4-mm inner diameter), and the collected fat was then transferred between the 2 syringes for mechanical emulsification at 10 mL/s for 1 minute. The emulsified fat was then centrifuged at 2000 × *g* for 3 minutes, and the material below the oil layer was defined as the SVF-gel (Fig. 1).

An 18-gauge needle was used to make an entry site at the inside of the heel. The injection method was as shown in Figure 2 and Supplementary Video 1 (http://links.lww.com/SAP/A883). First, 1–1.5 mL of SVF-gel was injected with a 27-gauge cannula under the most painful point of the heel, then another 3.5–4 mL of SVF-gel was diffusely distributed with a 0.9-mm blunt cannula into the plantar heel in a cross-hatched pattern. The total injection volume was 5 mL. After the filling was completed, a soft cushion was created under the skin and the plantar heel appeared plump (Fig. 3). The entire foot was covered with cotton pads and bandages, and activities on the ground were restricted for 1 week. Patients were encouraged to limit strenuous exercise and wear cushioned and supportive sneakers for 4 to 6 weeks after the operation. Barefoot walking was not allowed during this period.

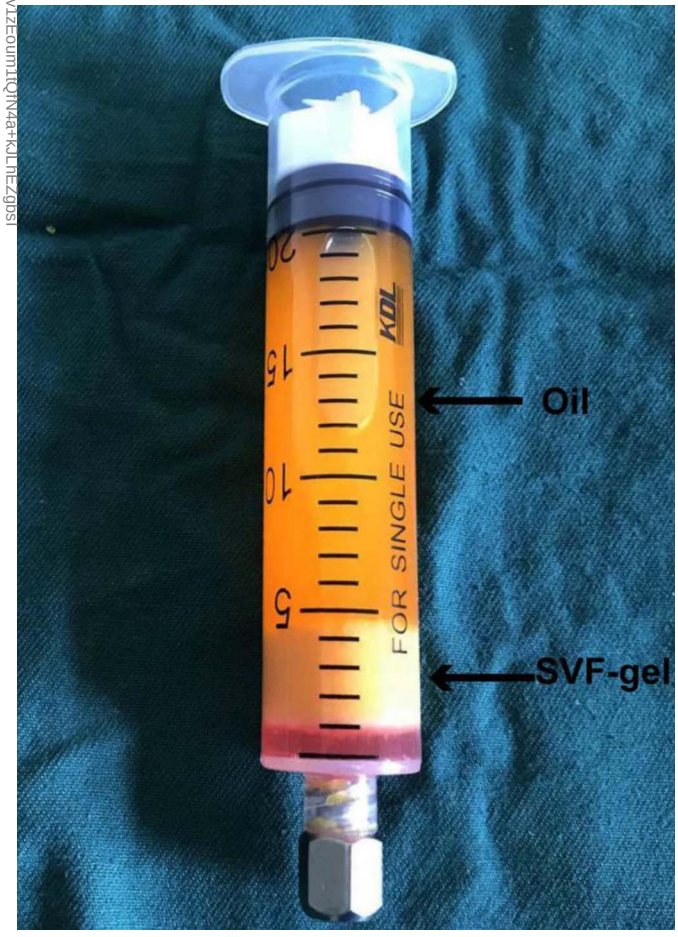

FIGURE 1. Appearance of the SVF-gel. full color online

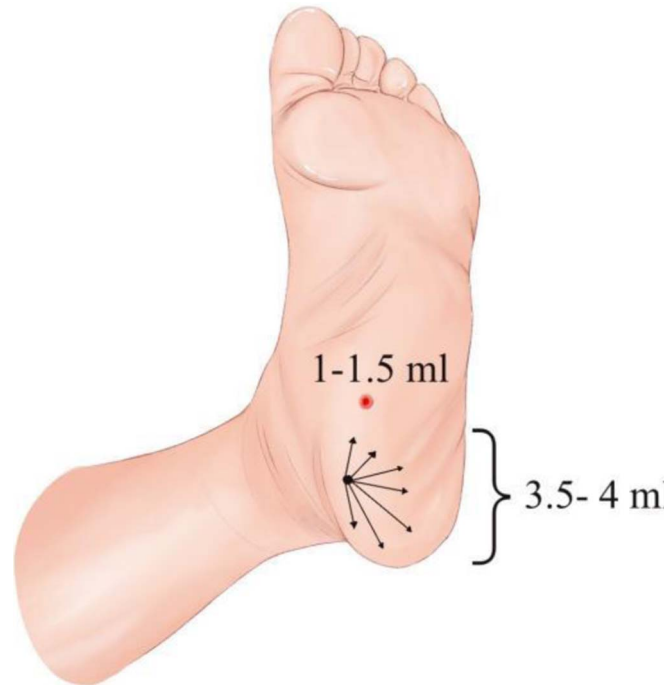

FIGURE 2. Stromal vascular fraction gel was transplanted into the plantar heel. full color online

Measurement of Pain and Disability

The Chinese Manchester Foot Pain and Disability Index (C-MFPDI) was used to measure foot pain and related function in

FIGURE 3. Appearance of the plantar heel before (A) and immediately after SVF-gel injection (B). full color online

TABLE 1. The Baseline Parameters of Patients

	Age/Sex	BMI	Heel Pain Location	Diagnosis	SVF-Gel Volume, mL	Follow-up	Complication
1	49/F	26.4	Bilateral heel	Heel fat pad atrophy	10	13	No
2	49/F	21.9	Left heel	Heel fat pad atrophy	5	15	No
3	57/F	34.6	Bilateral heel	Heel fat pad atrophy	10	12	No
4	42/M	21.4	Bilateral heel	Heel fat pad atrophy	10	16	No
5	59/M	25.5	Left heel	Heel fat pad atrophy	5	21	No
6	57/F	27.1	Bilateral heel	Heel fat pad atrophy	10	18	No
7	43/F	23.0	Left heel	Heel fat pad atrophy	5	13	No
8	70/M	23.7	Right heel	Heel fat pad atrophy	5	16	No
9	33/M	25.4	Left heel	Heel fat pad atrophy	5	12	No
10	57/F	25.1	Right heel	Heel fat pad atrophy	5	17	No
11	46/F	29.5	Right heel	Heel fat pad atrophy	5	16	No
12	59/F	26.0	Right heel	Plantar fasciitis	5	14	No
13	70/F	24.9	Left heel	Plantar fasciitis	5	19	No
14	49/M	22.0	Right heel	Plantar fasciitis	5	13	No

patients.[14] The 17-item MFPDI[15,16] was divided into 3 components: pain (5 items), functional limitation (10 items), and personal appearance (2 items). The C-MFPDI subscale scores were calculated to none of the time (score = 0), some days (score = 1), and on most days/every day (score = 2).[14] The questionnaire was conducted at the screening visit and at the 3-, 6-, and 12-month follow-up visits.

Measurement of Tissue Thickness

Magnetic resonance imaging (MRI) was used to assess the 3D volume of fat under the plantar heel after SVF-gel grafting. Magnetic resonance imaging examination was performed at the preoperative screening visit and at the postoperative follow-up visits at 3 and 12 months.

Statistical Analysis

Statistical analyses were performed using SPSS (Version 17.0.; SPSS Inc, Chicago, IL) statistical software. The difference in outcomes between time points was examined using the Wilcoxon signed-rank test. A P value of less than 0.05 was considered statistically significant.

RESULTS

Participant Characteristics

Fourteen patients, comprising 9 women and 5 men, were enrolled. Mean age at baseline was 53 years, ranging from 33 to 70 years. Mean body mass index at baseline was 25.3 kg/m^2, ranging from 21.4 to 34.6. Causes of plantar heel pain were 3 cases of plantar fasciitis and 11 cases of heel fat pad atrophy. Four patients experienced bilateral plantar heel pain and underwent bilateral injections with a volume of 10 mL (5 mL on each side). The other 10 patients experienced unilateral heel pain and received unilateral injections of 5 mL. Mean follow-up time was 15.5 months, ranging from 12 to 21 months. The baseline parameters of patients are listed in Table 1.

Most patients developed donor site bruising and heel swelling postoperatively, which disappeared within 1–2 weeks after surgery. None of the patients developed infection, hematoma, seroma, or oil cysts. No perioperative antibiotics or pain relievers were used. No serious adverse events or unanticipated events occurred.

Pain and Disability Outcomes

Chinese Manchester Foot Pain and Disability Index scores were surveyed at each time point, with lower scores indicating improvements in function, pain, and appearance. Three months after treatment, all patients showed statistically significant improvements in pain and functional limitation compared with the baseline. In addition, the appearance of the plantar heel appeared plump after treatment compared with the baseline (Fig. 4). These relationships were still present at 6 months and demonstrated significant changes from baseline to 3 or 6 months, or between 3 and 6 months (Fig. 5). However, there was no significant difference in MFPDI scores between the 6- and 12-month follow-up. Supplementary Video 2 (http://links.lww.com/SAP/A884) showed a representative case, a patient with left plantar heel pain due to heel fat pad atrophy. Significant preoperative pain and function limitation were observed, and 6 month after SVF-gel injection, the pain and function limitation were significantly relieved.

Tissue Thickness Outcomes

Figure 6 shows the heel fat pad MRI volume measurements at baseline and 3 and 12 months postoperatively. Heel fat pad thickness was lower at baseline and significantly thicker at 3 months after grafting. There was no significant difference in the measurements between 3 and 12 months.

DISCUSSION

Plantar fasciitis and heel pad atrophy are the most common causes of heel pain, although the exact mechanism is unknown.[1,2] However, it is believed that the thickness of the heel fat pad is an important indicator of the stress in the tissue, and that reduction of the thickness of the heel fat pad will reduce shock absorption, leading to heel pain.[17,18]

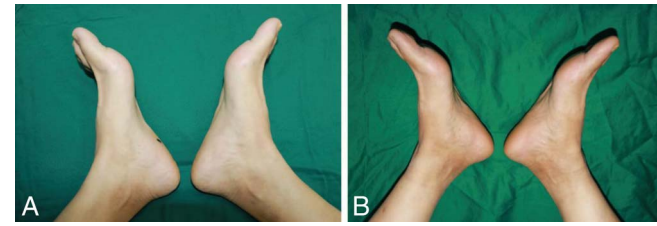

FIGURE 4. Appearance of the plantar heel (left heel) before (A) and 1 year after SVF-gel injection (B). full color online

Heel pain leads to emotional stress, decreased productivity, and economic loss. Treatments for heel pain include steroid injections, physical therapy, or surgical resection.[19–21] However, the effects are generally unsatisfactory. Repeated steroid injections may destroy the fat pads, whereas aggressive surgical procedures may cause scar adhesion, leading to symptoms of atrophy of the heel fat pad. Jeffrey A. Gusenoff and colleagues confirmed that pedal fat grafting could provide long-lasting improvements in pain and function.[22] However, the mentioned study was performed in patients with plantar pain caused by fat pad atrophy in the forefoot, and there are few data describing the use of fat grafting on patients with planter heel pain.

Stromal vascular fraction gel is a product derived from adipose tissue produced by a simple and purely mechanical process.[11] Unlike the fat used in traditional fat transplantation, SVF-gel contains condensed adipose tissue extracellular matrix fibers and a number of functional cells, such as adipose-derived stem cells (ADSCs), which have a low inflammatory effect and a high retention rate after transplantation.[23] Therefore, it has the potential to not only function as a filler but also regulate inflammation, promote vascularization, and promote extracellular matrix generation through the paracrine effects of ADSCs and other SVF cells. Previously, SVF-gel transplantation was demonstrated to promote wound healing and increase the survival rate of ischemic flaps because of its inflammation-regulating and proangiogenic effects.[24,25] In addition, SVF-gel has been proven to have excellent efficacy in improving horizontal neck lines and achieving facial rejuvenation.[13,26] It has been reported that the mechanism of fat grafting for improvement of various causes of neuropathic pain is attributable to the anti-inflammatory effects of ADSCs combined with the mechanical cushioning by adipose tissue.[27] Therefore, SVF-gel transplantation has the potential to provide an effective strategy for the treatment of planter heel pain and overcome the shortcomings of traditional fat transplantation.

Our results showed significant improvements in pain and foot function after SVF-gel transplantation compared with baseline, with the greatest improvement at 6 months and lasting 1 year or more. In addition, our data demonstrated that the thickness of the heel fat pad was significantly greater than baseline at 3 months, and lasted for 1 year or more. We speculate that this may be due to the buffering effect of fat on bone and the paracrine role of adipose stem cells in regulating inflammation and promoting angiogenesis. Of course, the specific mechanism needs to be further studied, and the long-term effect needs to be further verified.

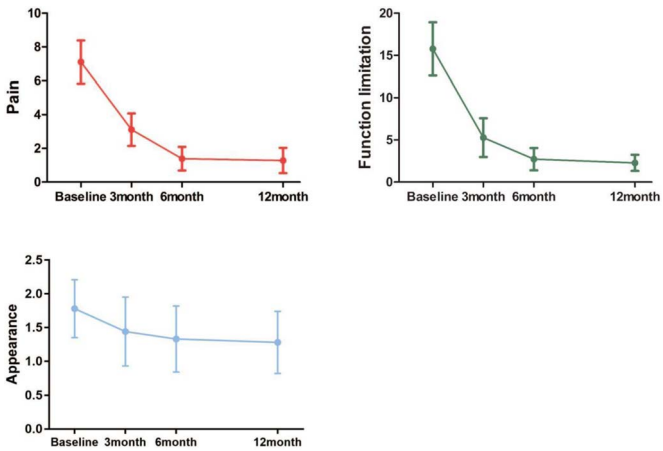

FIGURE 5. Chinese Manchester Foot Pain and Disability Index scores at different time points, which comprise values for pain, functional limitation, and appearance. All patients showed significant improvements in pain, functional limitation, and appearance from baseline to 3 or 6 months, or between 3 and 6 months ($P < 0.05$), and no significant difference between the 6- and 12-month follow-up ($P > 0.05$). full color online

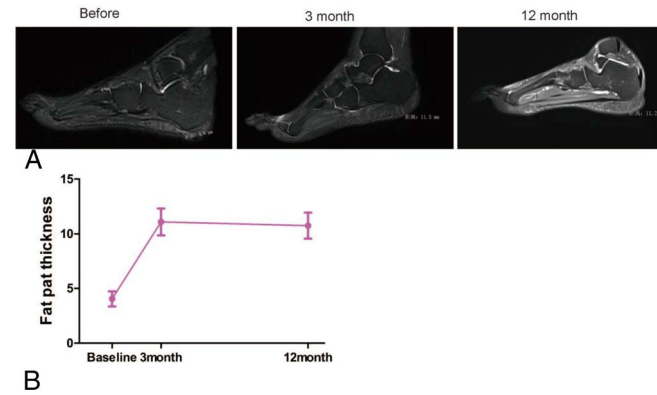

FIGURE 6. Magnetic resonance imaging measurements of the plantar heel fat pad volume before and after SVF-gel transplantation. A, Representative MRI images. B, Quantification results of fat pad thickness evaluated by MRI before transplantation and at 3 and 12 months after transplantation. Heel fat pad thickness showed significant thickness at 3 months compared with the baseline ($P < 0.05$) and no significant difference in the measurements between 3 and 12 months ($P > 0.05$). full color online

Limitations of the present study included lack of control subjects; however, we had a separate clinical controlled study ongoing to compare traditional fat grafting and SVF-gel grafting for plantar heel pain. Previously, we confirmed that the biological function of adipose stem cells derived from diabetic patients was impaired.[28] For patients with plantar heel pain and diabetes, whether SVF-gel transplantation is effective and the duration of any effect remains to be confirmed by further studies. Additional limitations of our study include the small sample size. Whether the volume of the heel fat pad can be maintained for a long period also needs further follow-up confirmation.

CONCLUSION

Stromal vascular fraction gel grafting was a safe, minimally invasive approach to treat plantar heel pain, which significantly improved pain and disability outcomes and increased the thickness of the heel fat pad. Further studies will show whether this increased fat pad volume is maintained over the longer term.

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