MUSCULOSKELETAL SECTION

Original Research Article

A Comparative Efficacy Evaluation of Ultrasound-Guided Pulsed Radiofrequency Treatment in the Gastrocnemius in Managing Plantar Heel Pain: A Randomized and Controlled Trial

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Abstract

Objective. The treatment of plantar heel pain is highly challenging. We report ultrasound-guided pulsed radiofrequency treatment (UG-PRF) in the gastrocnemius to treat plantar heel pain and minimize the safety issues.

Design. This study compared UG-PRF with sham treatment in 100 patients with plantar heel pain. Primary outcome measures include the pain subscale of the Foot Health Status Questionnaire (FHSQ-pain) and "first step" pain as measured on a visual analogue scale (VAS-"first-step" pain). The secondary outcome measures include the FHSQ-foot function and general foot health, and health related quality of life (assessed using the Short Form-36 questionnaire [SF-36]). All outcomes were measured at 3 and 6 months post-treatment.

Results. The results showed the efficacy of UG-PRF in terms of pain management, as reflected by higher FHSQ-pain score (increased by 20.0 ($P < 0.0001$) and 17.9 ($P = 0.001$) compared with the sham treatment at 3 or 6 months, respectively) and lower VAS-"first-step" pain (reduced by 26.1 ($P < 0.0001$) and 14.3 ($P = 0.01$) compared with the sham group at 3 or 6 months, respectively). The FHSQ-foot function and FHSQ-general foot health were increased by the UG-PRF ($P < 0.05$, vs sham treatment at 3 or 6 months). The SF-36 physical component score in the sham group was 10.8 ($P = 0.042$) and 10.4 ($P =

0.044) lower than the UG-PRF group at 3 or 6 months, respectively. No severe complications were observed.

Conclusions. We conclude that the UG-PRF is both safe and efficacious in managing plantar heel pain.

Key Words. Plantar Heel Pain; Trigger Points; Pulsed Radiofrequency; Ultrasound-Guided; Randomized Trial

Introduction

Plantar heel pain is a common source of pain and disability with prevalence rates ranging between 3.6% and 7.5% [1–4]. Although many strategies including heel pads and orthoses have been used to treat this disease, there is limited evidence for the effectiveness of local corticosteroid therapy, and the effectiveness of other frequently used treatments in altering the clinical course of plantar heel pain had not been established [5,6].

It is reported that limited ankle dorsiflexion may be commonly associated with plantar heel pain, and gastrocnemius contracture may be associated plantar heel pain [3,7]. Furthermore, gastrocnemius recession was found to be effective when used to relieve recalcitrant foot pain in those patients with an isolated gastrocnemius contracture without deformity [8]. A recent systematic review examined the effect of gastrocnemius stretching on ankle range of motion and found that stretching produces a small but statistically significant increase in ankle range of motion [9]. However, it is unclear whether a change in ankle range of motion translates to a clinically relevant outcome for patients. Radford et al. indicated that when used for the short-term treatment of plantar heel pain, a 2-week gastrocnemius stretching program provides no statistically significant benefit in "first-step" pain, foot pain, foot function, or general foot health compared with not stretching [10]. Thus, whether relieving gastrocnemius contracture could relieve plantar heel pain still remains unclear.

Trigger points are discrete, focal, and hyperirritable spots located in a taut band of skeletal muscle [11,12]. It is noteworthy that Travell et al. revealed an association between trigger points and plantar fasciitis [13]. Inactivation of trigger points may contribute to relieve the muscle tightness and spasm and to improve the local circulation, and subsequently, to interrupt the vicious cycle phenomenon of trigger points [11]. Elimination of latent myofascial trigger points and inactivation of active myofascial trigger points may also effectively reduce accelerated muscle fatigue and prevent overload spreading within a muscle [14]. It is reported that gastrocnemius contracture could alter the biomechanics of the foot causing an overload of the plantar heel pain [8,15,16], and stretching in the gastrocnemius could increase the ankle range of motion and may reduce the symptoms of plantar heal pain [17,18]. Thus, we hypothesize that inactivation of trigger points in the gastrocnemius could relieve gastrocnemius contracture and treat plantar heel pain.

Pulsed radiofrequency (PRF) treatment is a minimally neurodestructive alternative to radiofrequency heat lesions [19]. PRF has been reported in the treatment of trigger points [20,21]. The precise mechanism of the action of PRF remains unclear, although there is some evidence for a neuromodulatory effect [22]. To increase the accuracy of PRF, ultrasound imaging could be used to avoid unexpected damage to these important structures, with no irradiation to the patients [23,24].

In this study, we used ultrasound-guided pulsed radiofrequency treatment (short for UG-PRF) to treat plantar heel pain with minimal safe problems. Herein, we compared the efficacy and safety of UG-PRF and sham treatment in patients with plantar heel pain.

Materials and Methods

Setting and Sample

This study was performed in China, in compliance with the Consolidated Standards of Reporting Trials guidelines [25]. The study was approved by the Institutional Review Board of the Renji Hospital (Shanghai, China), and registered in the Chinese Clinical Trial Register (ChiCTR, ChiCTR-TRC-3003410).

This study was a prospective, randomized, and controlled clinical trial. Patients were recruited from the Department of Pain Management at Reni Hospital from August 2013 to December 2013. Eligibility was determined at the preliminary interview. For inclusion in this study, patients had to meet the following criteria (Table 1): age ≥18 years; clinical diagnosis of plantar heel pain in accordance with the Clinical Guidelines linked to the International Classification of Function, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association [26]; history of plantar heel pain for more than 1 month; first step pain during the previous week rated at least 2 cm on a 10 cm visual analogue scale (VAS); with palpable trigger points in the gastrocnemius. The exclusion criteria included: pregnancy; the presence of coagulopathy, or the use of anti-coagulants(except for acetylsalicylic acid at dosages up to 325 mg/day); an inability to understand instructions or complete a questionnaire; plantar heel pain caused by inflammatory, malignant, or autoimmune disease; the presence of a chronic medical condition that might preclude participation in the study such as: malignancy, systemic inflammatory disorders, neurological abnormalities, sciatica, and/or chronic pain; a history of surgery to the plantar fascia; a known hypersensitivity to metals. Informed consent was obtained from all participants. The baseline demographic details, duration of disease, previous treatments, body mass index, and outcome measures are shown in Table 1. The flow chart of this study was presented in Figure 1.
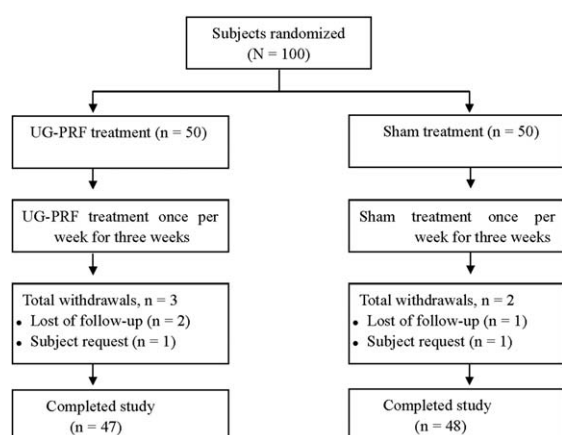
Figure 1 Schematic presentation of the study flow.

Randomization and Sequence Generation

Using a computer-generated random allocations sequence, 100 patients with plantar heel pain were randomized and assigned into two equal groups by a nurse: a UG-PRF group and a sham treatment group. UG-PRF was applied to the UG-PRF group (n = 50). In the sham treatment group (n = 50), the method was followed as in the PRF group except that radiofrequency energy was not applied. Allocation was concealed using cards in numbered opaque envelopes. The next envelope in the sequence was opened when the participant had given informed consent. The treatment was carried out once a week for 3 weeks among all patients.

Pain Management

The pulsed radiofrequency (PRF) treatment was performed as described below (Figure 2). Briefly, after the patient was placed in the prone position, the trigger point was established by physical signs (hypersensitive bundle or nodule of muscle fiber that were harder than normal upon palpitation) and ultrasound imaging (hyper-echoic skin, hyperechoic marbled appearance of the muscle, and mixed echogenicity) [27–29]. Then, the skin over the tender area was marked. The skin was sterilized by povidone iodine, and a sterile surgical towel was placed on the patient. A high resolution (7–12 MHz) linear array transducer probe (S Nerve, Sonosite, Bothell, WA, USA) was used to scan the marked area in the sagittal and coronal plane. Initially, the probe was used to identify the medial gastrocnemius (Figure 3A), and then to identify any visible changes in the muscle corresponding to the marked area on the skin. The popliteal artery was identified as to avoid undesirable damage to it (Figure 3B). Local anesthetics (1% lidocaine) were performed, in the form of the skin infiltration. After then, under the ultrasound (S-nerve, Sonosite?, Bothell, WA) guidance, a 20-G 10 cm needle with a 5-mm tip (RF SimJect Cannula, NeuroTherm, Wilmington, MA) was inserted into the muscle (Figure 3C). Once the needle entered the visualized area, patient response was noted (needle sign: reproduction of the patient's pain but at a great intensity). After an electrode was connected with the PRF needle, the altered area was treated by the PRF (PMG230, Baylis medical company Inc, Montreal, Quebec, Canada) at 42 °C for 5 minutes and 3 mL of 0.5% levobupivacanie was injected into the trigger points. This procedure was repeated, if the patient had more than one trigger point. Patients did not receive any medication afterward and was discharged on the same day. In the sham group, the method was followed as in the PRF group except that radiofrequency energy was not applied. The PRF treatment was performed by the same investigator (Dr. Yongjun Zheng). The assessment and follow-up was performed by other investigators (Dr. Dongping Shi and

Table 1 The baseline characteristics of the patients before treatment

Variables	UG-PRF (n = 50)	Sham Treatment (n = 50)
Demographic		
Age (yr)	49.0 ± 13.8	51.8 ± 11.3
Sex, male (%)	62%	62%
Duration of disease (yr)	4.5 ± 3.1	5.7 ± 3.5
Previous analgesic medication (%)	46%	50%
BMI in kg/m^2	31.3 ± 4.8	30.1 ± 5.2
VAS-"first-step" pain	70.5 ± 27.2	73.6 ± 21.4
FHSQ-pain	37.9 ± 18.7	34.5 ± 15.5
FHSQ-foot function	57.3 ± 27.5	58.6 ± 23.3
FHSQ-general foot health	32.8 ± 17.9	31.3 ± 24.4
SF-36 PCS	43.8 ± 13.7	45.1 ± 19.5
SF-36 MCS	47.2 ± 15.1	48.4 ± 13.2

The data are expressed as mean ± SD

BMI = body mass index; FHSQ = the Foot Health Status Questionnaire; VAS = visual analogue scale; SF-36 = Short-form-36; PCS = physical component score; MCS = mental component score.
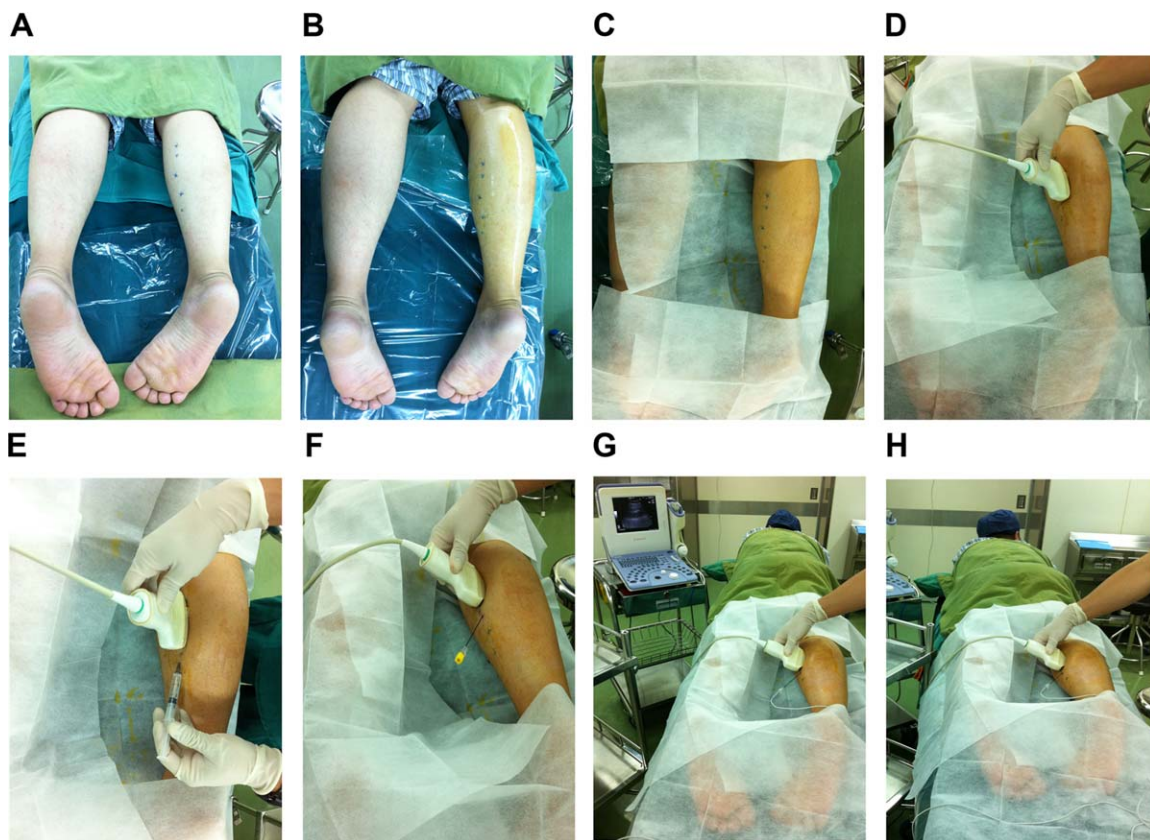
Figure 2 The procedure of UG-PRF treatment. A. Trigger points were identified by palpation and marked. B. The skin was sterilized by povidone iodine. C. A sterile surgical towel was placed on the patient. D. The trigger points were determined by ultrasound. E. Intradermal anesthesia was performed on the trigger points. F. The PRF needle was inserted into the muscle. G. An electrode was connected with the PRF needle. H. The PRF treatment was carried out by at 42°C for 5 minutes. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Figure 3 The ultrasound imaging of UG-PRF. A. The ultrasound imaging of the medial gastrocnemius. B. The ultrasound imaging of the popliteal artery (indicated by a square frame). C. The PRF needle (indicated by white arrows) was inserted into the muscle. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Dr. Le Ye). The investigators participating in the PRF treatment, assessment and follow-up were not aware of the groupings or the mode of the PRF used for each patient. The instrument was operated by a nurse of our department of pain management. The standard PRF program was applied to the PRF group, with the same procedure applied to the sham group without an energy output. The nurse did not participate in any other treatment, assessment, and follow-up or trial discussions. A statistician not involved with the treatment analyzed the data of this study. UG-PR For sham treatment was performed on the patients once a week for 3 weeks.

Outcomes Measures

Primary outcomes measures included the pain domain of the Foot Health Status Questionnaire (FHSQ) and "first-step" pain as measured on VAS [30]. The "first step" pain was evaluated as the severity of pain at the heel when getting out of bed in the morning over the past week. Higher FHSQ pain score indicates less pain, whereas higher VAS pain score indicates more pain. The secondary outcome measures include the FHSQ-foot function and general foot health, and health related quality of life (assessed using the Short Form-36 questionnaire-Version Two). Higher FHSQ-foot function, general foot health, and health related quality of life scores indicate better conditions.

The assessments were made blind by a medical specialist in pain management at the time of the visit of patients to the clinic and at 3 and 6 months post-treatment. All outcome data were reported by the study patients. They completed printed questionnaires at the time of their visit to the clinic and at 3 and 6 months post-treatment. A recording of possible adverse events was made by the medical specialist on days 1, 3, 7, 14, and 28 after treatment.

Sample Size

The study aimed to recruit approximately 100 participants (50 for each group) based on sample size calculations. An initial prospective sample size calculation estimated that 76 participants will provide 80% power to detect a minimally important difference of 13 points in the pain domain of the FHSQ [31] with a standard deviation of 20 points and an alpha set at 0.05, and the number of participants (76) was increased by approximately 20.0% to account for probable subject dropouts.

Statistical Analysis

All data were analyzed with SPSS 13.0 (SPSS Inc., Chicago, IL). For continuous variables, means and standard deviations (SD) of the mean were calculated upon normal distribution. Independent Student's t-tests were used for continuous variables, and chi-square tests or Fisher's exact tests were used for categorical variables. Data that were not normally distributed were analyzed by Mann-Whitney tests. Analysis of covariance was used to test a difference in the outcome measure between the UG-PRF and sham groups, after adjusting for an outcome measure at baseline: analyses of covariance were performed with the FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function and general foot health, and Short Form-36 [SF-36] at 3 months and 6 months as outcomes, while the treatment was as an explanatory variable and adjusted for difference in the FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function and general foot health, and SF-36 at baseline. The significance level for all the tests was set at 0.05.

Efficacy analyses were conducted on the intent-to-treat population, defined as all randomized patients who received at least 1 dose of the intervention. All randomized patients who received at least 1 dose of study medication were included in the safety population.

Results

From August 2013 to December 2013, a total of 100 patients entered the randomization. The overall dropout rate was 5% (5/100). The dropout rate did not differ between the UG-PRF and sham treatment groups (6% vs 4%, $P = 1.00$, Fisher's exact tests).

At 3 months, an adjusted FHSQ-pain in the UG-PRF group was 20.0 points higher than the sham treatment group [$\beta = 20.0$ (SD = 4.4, 95% confidence interval [CI] = 11.179–28.841), $P < 0.0001$]; at 6 months, the adjusted FHSQ-pain in the UG-PRF group was 17.9 points higher than the sham treatment group ($\beta = 17.9$ [SD = 5.0, 95%CI = 7.886–27.978], $P = 0.001$; see Table 2). The increase in the FHSQ-pain from baseline to 3 months was 87.0% in the UG-PRF group compared with 46.7% in the sham treatment group. The increase in the FHSQ-pain from baseline to 6 months was 71.2% in the UG-PRF group compared with 34.5% in the sham treatment group.

For analysis of VAS-"first-step" pain, at 3 months, an adjusted VAS-"first-step" pain in the sham treatment group was 26.1 mm higher than the UG-PRF group ($\beta = 26.1$ [SD = 5.5, 95%CI = 15.133–37.058], $P < 0.0001$); at 6 months, the adjusted VAS-"first-step" in the sham treatment group was 14.3 mm higher than the UG-PRF group ($\beta = 14.3$ [SD = 5.4, 95%CI = 3.526–25.097], $P = 0.01$; see Table 2). The reduction in VAS-"first-step" pain from baseline to 3 months was 48.4% in the UG-PRF group compared with 14.9% in the sham treatment group. The reduction in VAS-"first-step" pain from baseline to 6 months was 39.9% in the UG-PRF group compared with 23.1% in the sham treatment group.

Similarly, improvements in FHSQ-foot function and FHSQ-general foot health were significantly greater in the UG-PRF group than in the sham treatment group at 3 months or 6 months ($P < 0.05$). For example, the improvement in FHSQ-foot function from baseline to 3 months was 41.9% in the UG-PRF group compared with 6.0% in the sham treatment group ($P < 0.0001$).The

Table 2 Comparison of primary outcomes between the UG-PRF (n = 50) and sham treatment (n = 50) groups at 3 months

Outcomes	UG-PRF	Sham Treatment	Adjusted Between Group Difference (95% CI)*	P-Values
FHSQ-pain				
Baseline	37.9 ± 18.7	34.5 ± 15.5	20.0 (11.179 to 28.841)	
3-month follow-up	70.9 ± 23.5	50.6 ± 24.5		<0.0001
VAS-"first-step" pain				
Baseline	70.5 ± 27.2	73.6 ± 21.4	−26.1 (−37.058 to −15.133)	
3-month follow-up	36.4 ± 27.4	62.6 ± 27.5		<0.0001
FHSQ-foot function				
Baseline	57.3 ± 27.5	58.6 ± 23.3	19.291 (10.628 to 27.955)	
3-month follow-up	81.3 ± 19.9	62.1 ± 23.5		<0.0001
FHSQ-general foot health				
Baseline	32.8 ± 17.9	31.3 ± 24.4	10.181 (0.637 to 19.726)	
3-month follow-up	49.5 ± 23.1	39.4 ± 24.6		0.037
SF-36 PCS				
Baseline	43.8 ± 13.7	45.1 ± 19.5	10.8 (0.379 to 21.234)	
3-month follow-up	64.9 ± 28.8	54.6 ± 24.8		0.042
SF-36 MCS				
Baseline	47.2 ± 15.1	48.4 ± 13.2	3.506 (−6.896 to 13.909)	
3-month follow-up	56.8 ± 26.4	53.5 ± 25.7		0.51

The data are expressed as mean ± SD.

*Between-group differences were determined using analyses of covariance which were performed with FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function, FHSQ-general foot health, SF-36 at 3 months as outcomes, while the treatment was as an explanatory variable and adjusted for difference in FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function, FHSQ-general foot health, SF-36 at baseline.

improvement in FHSQ-general foot health from baseline to 3 months was 50.9% in the UG-PRF group compared with 25.9% in the sham treatment group (P = 0.037).

For analysis of SF-36 physical component score (PCS) at 3 months, an adjusted SF-36 PCS in the sham treatment group was 10.8 lower than the UG-PRF group (β = 10.8 [SD = 5.3, 95%CI = 0.379–21.234], P = 0.042); at 6 months, the adjusted SF-36 PCS in the sham treatment group was 10.4 lower than the UG-PRF group (β = 10.4, [SD = 5.1, 95%CI = 0.298–20.586], P = 0.044; see Table 2). The improvement in SF-36 PCS from baseline to 3 months was 48.2% in the UG-PRF group compared with 21.1% in the sham treatment group. The improvement in SF-36 PCS from baseline to 6 months was 40.0% in the UG-PRF group compared with 13.1% in the sham treatment group. However, there was no significant difference in SF-36 mental component score between the UG-PRF and sham treatment groups.

Adherence with treatment did not differ significantly between the UG-PRF and sham treatment groups. Forty-seven of 50 subjects (94%) in the UG-PRF group and 48 of 50 (96%) in the sham treatment group completed the study protocol (P = 1.00, Fisher's exact tests).

Three (6%) participants in the UG-PRF group reported mild reactions during the UG-PRF treatment, mainly slight pain and somatic reactions such as sweating. However, all these participants agreed to continue the treatment. Two participants (4%) in the sham treatment group experienced mild reactions similar to those reported in the UG-PRF group. No serious adverse complications (e.g., nerve injury) that lead to serious disability or hospital admission or death were observed in the treatment.

Discussion

The results from this randomized trial showed that the UG-PRF treatment in the gastrocnemius is efficacious for plantar heel pain in the FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function and general foot health, and health-related quality of life in comparison with sham treatment. In terms of safety issues, we did not observe severe side effects in both UG-PRF treatment and sham treatment.

Although relieving gastrocnemius contracture would be effective for the treatment of plantar heel pain, the choice of the methods of relieving gastrocnemius contracture is critical. The common methods reported previously are not satisfactory. For example, gastrocnemius stretching is convenient in relieving gastrocnemius contracture, and could produce a small but statistically significant increase in ankle range of motion and may

Table 3 Comparison of primary outcomes between the UG-PRF (n = 50) and sham treatment (n = 50) groups at 6 months

Outcomes	UG-PRF	Sham Treatment	Adjusted Between Group Difference (95% CI)*	P-Values
FHSQ-pain				
Baseline	37.9 ± 18.7	34.5 ± 15.5	17.9 (7.886 to 27.978)	
6-month follow-up	64.9 ± 27.9	46.4 ± 21.9		0.001
VAS-"first-step" pain				
Baseline	70.5 ± 27.2	73.6 ± 21.4	−14.3 (−25.097 to −3.526)	
6-month follow-up	42.4 ± 28.8	56.6 ± 25.0		0.01
FHSQ-foot function				
Baseline	57.3 ± 27.5	58.6 ± 23.3	13.941 (4.01 to 23.873)	
6-month follow-up	75.7 ± 23.0	61.7 ± 26.5		0.006
FHSQ-general foot health				
Baseline	32.8 ± 17.9	31.3 ± 24.4	9.54 (1.876 to 17.205)	
6-month follow-up	46.2 ± 18.0	36.6 ± 20.8		0.016
SF-36 PCS				
Baseline	43.8 ± 13.7	45.1 ± 19.5	10.4 (0.298 to 20.586)	
6-month follow-up	61.3 ± 27.1	51.0 ± 23.7		0.044
SF-36 MCS				
Baseline	47.2 ± 15.1	48.4 ± 13.2	−3.388 (−13.553 to 6.778)	
6-month follow-up	55.4 ± 25.0	58.6 ± 26.2		0.52

The data are expressed as mean ± SD.

*Between-group differences were determined using analyses of covariance which were performed with FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function, FHSQ-general foot health, SF-36 at 6 months as outcomes, while the treatment was as an explanatory variable and adjusted for difference in FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function, FHSQ-general foot health, SF-36 at baseline.

reduce the symptoms of plantar heal pain [17,18]. However, a 2-week gastrocnemius stretching program provides no statistically significant benefit in "first-step" pain, foot pain, foot function, or general foot health compared with not stretching [10]. Gastrocnemius recession, although effective in relieving gastrocnemius contracture and recalcitrant foot pain in those patients with an isolated gastrocnemius contracture, possesses traumatic property and is not very acceptable for many patients with plantar heel pain [11]. Thus, it is urgent to develop an effective and no traumatic strategy to relieve gastrocnemius contracture. Significantly, our UG-PRF is both safe and efficacious in managing plantar heel pain.

In our study, inactivation of trigger points would be expected to relieve gastrocnemius contracture. Trigger points can produce muscle twitch, tightness and spasm, and inactivation of trigger points may help to relieve the muscle tightness and spasm [11]. It is reported that, according to the direct evidence of intramuscular electromyographic recordings, a latent myofascial trigger point is associated with an accelerated development of muscle fatigue and simultaneously overloading active motor units close to a myofascial trigger point [14]. Elimination of latent myofascial trigger points and inactivation of active myofascial trigger points may effectively reduce accelerated muscle fatigue and prevent overload spreading within a muscle [14]. Thus,

inactivation of trigger points would be expected to relieve gastrocnemius contracture. The use of ultrasound in the PRF treatment is very critical for inactivation of trigger points in enhancing both accuracy and safety profile. Because the needle used in the PRF treatment has a larger gauge and there is, potentially, an increased risk of nerve injury. Ultrasound scanning definitely allows the accurate placement of the needle tip in the underlying muscle, which, in turn could enhance the success of this technique. This study provided evidence that the UG-PRF treatment is a safe approach in managing plantar heel pain.

In contrast to limited effectiveness of current approaches in the treatment of plantar heel pain [6,32], UG-PRF treatment in the gastrocnemius showed much enhanced efficacy in managing plantar heel pain than sham treatment. At 3-month and 6-month follow-up, the reduction in the VAS-"first-step" pain was significantly greater in the UG-PRF group than the sham treatment group. The improvement in the FHSQ-pain, FHSQ-foot function and general foot health, and SF-36 PCS was significantly greater in UG-PRF group than in the sham treatment group. It is noteworthy that all the outcome measures (including FHSQ-pain, VAS-"first-step" pain, FHSQ-foot function, and general foot health), except VAS-"first-step" pain at 6 months, exceed the Minimal Important Difference of the VAS and the FHSQ

which was defined by Landorf [31]. We conclude that the PRF would inactivate the trigger point in gastrocnemius, relieve gastrocnemius contracture and reduce the pain, increase the foot function and general foot health. The results revealed similarly low dropout rate (6% vs 4%) adding support to the efficacy of the treatment. Another strength of this study is that the outcome measures used were well known and well validated. Self report may cause concern in some investigators, but patient experience is much more important than physician evaluation in this type of study, in our opinion.

There are several limitations in this study. The first limitation is that all treatments were provided by only one practitioner. This could be also regarded as strength because the treatment provided is consistent. However, the results could be more readily generalized if there were several practitioners providing treatment. The second limitation is that the precise mechanism of the action of the PRF treatment on the trigger points remains unclear. The third limitation is that the direct evidence that inactivation of trigger points could relieve gastrocnemius contracture was not investigated in this study.

In summary, the results of this study demonstrated that the UG-PRF treatment could significantly reduce pain intensity, foot health and function, and significantly improve health-related quality of life in comparison with sham treatment in patients with plantar heel pain, without risk for severe complications.

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