Section: Cellular Therapy

Original Research Article

EFFICACY OF AUTOLOGOUS GROWTH FACTOR CONCENTRATE (GFC) INFILTRATE VS CONVENTIONAL TREATMENT IN PLANTER FASCIITIS: A RANDOMIZED CONTROLLED TRIAL

***Aakriti Baijal*[1], *Aman Baijal* [2]**

[1]*Associate Professor in Department of Immmunohematolgy and Blood Transfusion, Sriram Murti Smarak Institute of Medical Sciences Bareilly. India*
[2]*Senior resident in Department of Orthopaedics, Uttar Pradesh, University of Medical Sciences, Saifai, Etawah, India*

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Corresponding Author:
Dr.Aakriti Baijal
Associate Professor in Department of Immmunohematolgy and Blood Transfusion, Sriram Murti Smarak Institute of Medical Sciences Bareilly. India.
Email: aakritibaijal111@gmail.com

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ABSTRACT

Background: Plantar fasciitis (PF) is a common cause of heel pain resulting from degenerative changes in the plantar fascia, often linked to obesity, faulty biomechanics, and repetitive stress. Recently, biologic options such as Platelet-Rich Plasma (PRP) and Autologous Growth Factor Concentrate (GFC) have emerged as alternatives to standard care. This study evaluates the efficacy and safety of GFC versus conservative management in improving pain and function in PF patients.

This randomized controlled trial was conducted at tertiary care teaching hospital in rural North India, over 18 months. A total of 72 patients with a confirmed diagnosis of plantar fasciitis were randomly allocated into two equal groups (n = 36). Participants in Group A underwent standard conservative management only, whereas those in Group B received GFC therapy in addition to standard conservative care. Pain and functional outcomes were assessed using the Visual Analog Scale (VAS) and the American Orthopaedic Foot and Ankle Society (AOFAS) score at baseline and subsequently at 1, 3, and 6 months.

Both groups showed significant improvements in VAS and AOFAS scores. However, Group B showed superior pain relief and functional outcomes at 3 and 6 months ($p<0.05$). No major complications were reported, and adverse effects such as persistent pain and limited motion were slightly lower in Group B. GFC therapy, when combined with conservative treatment, offers greater improvement in pain and function than conservative management alone. It is safe, well-tolerated, and holds promise as an adjunctive therapy for PF.

Keywords: Plantar fasciitis, Growth Factor Concentrate, heel pain, biological therapy, VAS score, AOFAS score

INTRODUCTION

Plantar fasciitis (PF) is among the leading causes of heel pain. In India, estimates suggest a prevalence of about 4–7% in the general population for plantar heel pain. It impacts both active and sedentary individuals and is usually linked to chronic strain caused by physical activity or lifestyle factors.[1] Although the suffix '-itis' implies inflammation, plantar fasciitis is largely a degenerative disorder of the fascia at its calcaneal attachment. The plantar fascia plays a vital role in maintaining arch stability and absorbing impact during normal foot function. The classic symptom is sharp, localized heel pain.[2] reported prevalence varies worldwide; for example, an Indian study among pharmacists aged 46–60 noted a prevalence of 54%, while another study found morning heel pain in 45.8% of middle-aged people.[2] Roughly 15% of heel pain is attributed to PF.[2,3] PF is frequently associated with repetitive overuse, microscopic tears, direct trauma, or biomechanical abnormalities such as pes planus, pes cavus, and restricted ankle dorsiflexion[3]. The disorder is most common in adults between 40 and

60 years of age, with a greater occurrence among females, individuals with a BMI exceeding 25 kg/m², and those in the 45–64 year age bracket[4,5]. In runners, the prevalence has been reported to be as high as 22%[5]. Platelet-rich plasma (PRP) has emerged as a promising biological therapy for tendon and ligament pathologies, including PF. PRP is prepared from autologous blood and contains bioactive molecules such as PDGF-BB, TGF-β1, VEGF, EGF, and IGF-1, which facilitate tissue regeneration and repair[6,7]. Despite substantial research from Western populations, Indian-specific data are still limited.[8] Autologous Growth Factor Concentrate (GFC) therapy has been introduced as a promising option for PF. GFC is rich in cytokines and hormones that support wound repair, tissue regeneration, and cell proliferation.[9,10] Its components include EGF, FGF, IGFs, HGF, VEGF, and TGF-β, which together aid fibroblast activity, angiogenesis, collagen synthesis, and immune modulation.[9] This autologous nature reduces immunological risks and increases therapeutic safety. Activated platelets are separated before centrifugation, minimizing pain, inflammation, and enabling faster recovery compared to PRP. This research seeks to assess the effectiveness and safety of GFC compared to standard options such as NSAIDs, physiotherapy, corticosteroid injections, and orthotics in reducing pain and improving function in PF.

MATERIALS AND METHODS

This prospective randomized clinical study was carried out in the Department of Orthopaedics, at tertiary care hospital in rural north India over a period of eighteen months (June 2023 – December 2024). The study involved patients reporting with heel pain who were clinically diagnosed as PF. Ethical clearance (Ethical Approval letter no 74/Cert. /IEC/UPUMS/2023-24) was obtained from the Institutional Ethics Committee before initiating the research. Participants aged 18–65 years, of either gender, with a confirmed diagnosis of unilateral or bilateral PF, were included. Patients were excluded if they had acute lower limb trauma, neuromuscular disorders, systemic rheumatologic diseases (e.g., rheumatoid arthritis, gout), were pregnant/lactating, had metastatic disease, local infections, were on antiplatelet therapy, had prior steroid/PRP/GFC injections. Informed consent was obtained from every participant. Out of 90 individuals screened for eligibility, 18 were excluded (5 did not meet the criteria, 9 refused participation, and 4 were excluded for other reasons). Acomputer-generated randomization sequence was used to allocate the remaining 72 participants equally into two groups (n =36 per group). Group A: received only conservative management. Group B: received conservative management plus GFC.

Sample size calculation:-

$$n=\frac{(Z(1-\alpha/2)+Z)^2\times 2\sigma 2}{(\mu_1-\mu_2)^2}$$

Where

n=sample size required in each group(36)

$Z(1-\alpha/2)$is the critical value for the chosen level of significance .In this case it is (1.96)

Z is the critical value for the desired power of the test,which is (.84)

σ is the common standard deviation of the two groups(2.64)

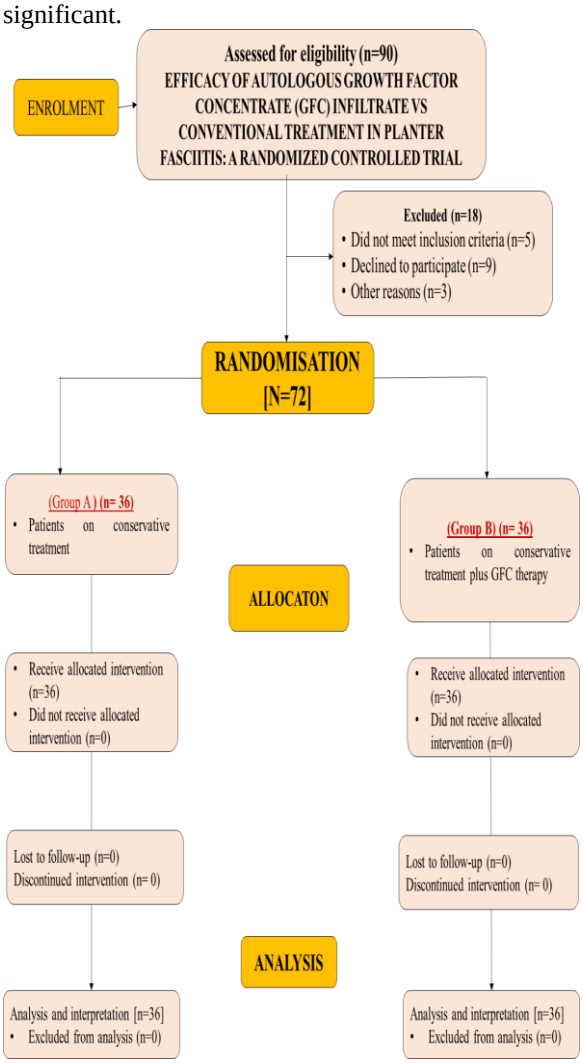
$(\mu_1-\mu_2)$ is clinically significance difference that investigator wishes to detect which is 3 in this case

Total sample size is 72(36 in each group)

The preparation of Growth Factor Concentrate (GFC) involves a series of precise steps to ensure optimal platelet activation and separation. Initially, 4 ml of blood is collected in each vacutainer provided in the kit. To activate the platelets, the vacutainer is gently inverted 6 to 10 times before being kept upright for 30 minutes, allowing the commercial proprietary chemical activator to initiate platelet activation. Following this, the vacutainers are counter-balanced and centrifuged at 3400 rpm for 10 minutes to facilitate the separation of GFC. Once centrifugation is complete, the vacutainer is inverted, and GFC is collected through the cap using a needle. For maximum recovery, the needle's tip is carefully inserted beneath the cap to extract the concentrate effectively. The resulting pure, acellular, autologous growth factors are then ready for injection. The plantar fasciitis injection is performed with the patient positioned either supine with the knee flexed and ankle dorsiflexed, or prone with the foot hanging free. After sterile preparation of the heel, the point of maximal tenderness is identified, most commonly at the medial calcaneal tuberosity. Using a 22–25 gauge needle, the preferred medial approach is chosen to avoid injury to the heel fat pad. The needle is advanced until resistance from the fascia or calcaneal bone is felt, after which aspiration is performed to exclude intravascular placement [Figure 1-2]. The needle is withdrawn, pressure applied, and the site covered with a sterile dressing. The procedure was conducted in a minor operating room or injection room. After the injection, Group B participants were advised rest for at least 48 hours, followed by ice packs, compression bandaging, oral NSAIDs for pain/inflammation, and foot and calf stretching exercises. Baseline pain and function were measured using VAS and AOFAS Ankle-Hindfoot scores, with follow-up assessments at 1, 3, and 6 months to evaluate clinical improvement.

Statistical Analysis: Data were analyzed using SPSS version 26. Continuous variables (age, VAS, AOFAS) were expressed as mean ± SD and compared using Student's *t*-test. Categorical variables (gender, side, calcaneal spur,

complications) were presented as frequency/percentage and compared with Chi-square/Fisher's exact test. A *p*-value <0.05 was considered significant, and <0.001 highly significant.



RESULTS

Demographic and baseline clinical parameters were similar in both groups. No significant differences were observed in age distribution (p=0.2370), mean age (44.50 ± 11.20 vs. 43.17 ± 9.83 years; p=0.5940), or gender (p=0.4578). The side of heel involvement and presence of calcaneal spurs were also similar (p=0.8136). [Table-1] General examination parameters showed no significant intergroup differences, with only minor variations in pallor, edema, and a single case of clubbing in Group B. [Table-1] X-ray findings of calcaneal spur were observed in 47.22% of participants in Group A and 50.00% in Group B, showing no significant difference. [Figure-3] VAS scores improved in both groups over 6 months, with significantly greater pain reduction in Group B. At baseline, the mean VAS was 4.75 ± 1.02 (Group A) and 5.18 ± 1.32 (Group B; p=0.1265). At 1 month, Group B showed lower scores (3.85 ± 0.90 vs. 4.80 ± 1.05; p=0.0001), with the difference widening at 3 months (3.05 ± 0.80 vs. 4.15 ± 1.10; p<0.0001) and 6 months (1.94 ± 1.10 vs. 2.66 ± 0.94; p=0.0039). AOFAS scores also improved significantly in both groups. At baseline, scores were comparable (57.90 ± 11.20 in Group A vs. 53.20 ± 14.50 in Group B; p=0.1283). At 1 month, Group A had higher scores (63.20 ± 8.10 vs. 58.30 ± 12.00; p=0.0461), but Group B showed superior gains at 3 months (74.30 ± 7.00 vs. 62.50 ± 12.10; p<0.0001) and 6 months (85.70 ± 7.30 vs. 80.40 ± 9.20; p=0.0085). [Table-2] No infections or nerve palsy occurred in either group (p=0.7112). Persistent pain was noted in 19.44% of Group A and 13.89% of Group B, while decreased range of motion was seen in 13.89% and 8.33%, respectively. Although these differences were not statistically significant, Group B showed slightly fewer complications. [Figure-4] Both groups showed significant improvements in VAS and AOFAS scores from 1 to 6 months. Between 1 and 3 months, Group A showed greater pain relief and functional gain, while from 1 to 6 months, Group B showed a more pronounced overall improvement. [Table-3-4]

Table-1: Demographical parameters of the enrolled patients.

Demographical Parameter	GROUP-A	GROUP-B	P-VALUE
Age Categories			
18–40 years	14 (38.89%)	19 (52.78%)	X=1.399 p=0.2370
41–60 years	22 (61.11%)	17 (47.22%)	
Mean Age (± SD)	44.50 ± 11.20	43.17 ± 9.83	t=0.5355 p=0.5940
Gender			
Female	27 (75.00%)	29 (80.56%)	X=0.7845 p=0.4578
Male	9 (25.00%)	7 (19.44%)	
Side of Affected Foot			
Left	17 (47.22%)	18 (50.00%)	X=0.05560 p=0.8136
Right	19 (52.78%)	18 (50.00%)	
Presence of Calcaneum Spurs			
Yes	17 (47.22%)	18 (50.00%)	X=0.05560

No	19 (52.78%)	18 (50.00%)	p=0.8136
General Physical Examination			
General Condition (Un-Stable)	2 (5.55%)	0(0.00%)	X=6.853 p=0.0767
Pallor (Present)	6 (16.67%)	4 (11.11%)	
Pulse Rate (Abnormal)	0 (0.00%)	0 (0.00%)	
Blood Pressure (Abnormal)	2 (5.55%)	1 (2.77%)	
Respiratory Rate (Abnormal)	0 (0.00%)	0 (0.00%)	
Temperature (Abnormal)	0 (0.00%)	0 (0.00%)	
Icterus (Present)	0 (0.00%)	0 (0.00%)	
Cyanosis (Present)	0 (0.00%)	0 (0.00%)	
Clubbing (Present)	0 (0.00%)	1 (2.77%)	
Edema (Present)	4 (11.11%)	3 (8.33%)	
Lymphadenopathy (Present)	0 (0.00%)	0 (0.00%)	

Table-2: VAS and AOFAS score of the enrolled patients.

OUTCOMES	GROUP-A	GROUP-B	P-VALUE
VAS Score (Mean ± SD)			
Baseline	4.75 ± 1.02	5.18 ± 1.32	t=1.547 p=0.1265
1 Month	3.85 ± 0.90	4.80 ± 1.05	t=4.122 **p=0.0001***
3 Months	3.05 ± 0.80	4.15 ± 1.10	t=4.852 **p<0.0001***
6 Months	2.66 ± 0.94	1.94 ± 1.10	t=2.986 **p=0.0039***
AOFAS Score			
Baseline	57.90 ± 11.20	53.20 ± 14.50	t=1.539 p=0.1283
1 Month	63.20 ± 8.10	58.30 ± 12.00	t=2.031 p=0.0461
3 Months	74.30 ± 7.00	62.50 ± 12.10	t=5.065 **p<0.0001***
6 Months	80.40 ± 9.20	85.70 ± 7.30	t=2.708 **p=0.0085***

Table-3: Comparison of VAS and AOFAS Scores Between 1 Month and 3 Months (Within Groups, n = 36).

Outcome	Group	1 Month (Mean ± SD)	3 Months (Mean ± SD)	Mean Difference	t-value	p-value
VAS Score	Group A(Conservative)	3.85 ± 0.90	3.05 ± 0.80	0.80	6.112	<0.0001
	Group B(GFC)	4.80 ± 1.05	4.15 ± 1.10	0.65	4.015	0.0003
AOFAS Score	Group A(Conservative)	63.20 ± 8.10	74.30 ± 7.00	11.10	8.265	<0.0001
	Group B(GFC)	58.30 ± 12.00	62.50 ± 12.10	4.20	2.581	0.0139

Table-4: Comparison of VAS and AOFAS Scores Between 1 Month and 6 Months (Within Groups, n = 36).

Outcome	Group	1 Month (Mean ± SD)	6 Months (Mean ± SD)	Mean Difference	t-value	p-value
VAS Score	Group A(Conservative)	3.85 ± 0.90	2.66 ± 0.94	1.19	7.104	<0.0001
	Group B(GFC)	4.80 ± 1.05	1.94 ± 1.10	2.86	12.021	<0.0001
AOFAS Score	Group A(Conservative)	63.20 ± 8.10	80.40 ± 9.20	17.20	10.345	<0.0001
	Group B(GFC)	58.30 ± 12.00	85.70 ± 7.30	27.40	13.872	<0.0001

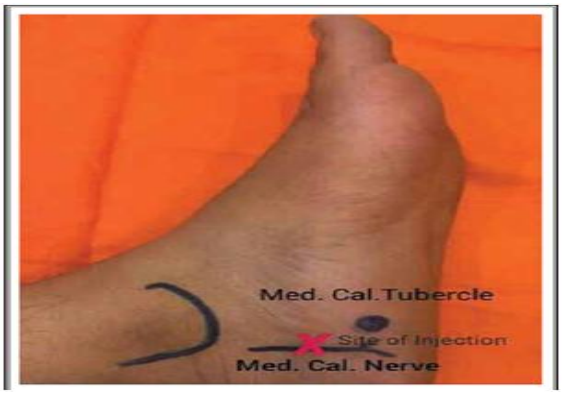


Figure-1: Injection site

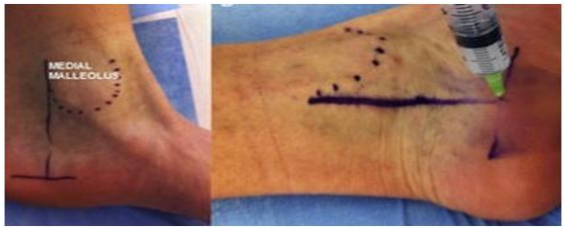


Figure-2: Injection technique

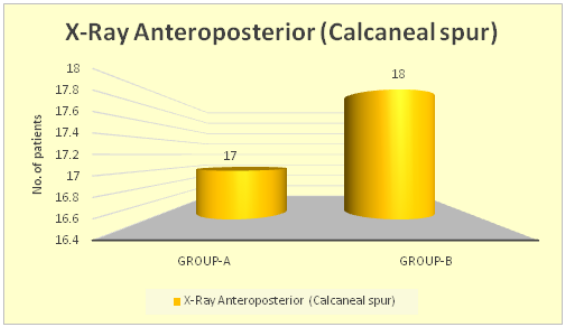


Figure-3: Investigation of the enrolled patients.

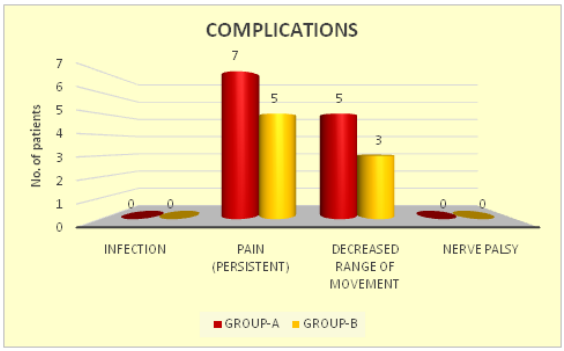


Figure-4: Complication of the enrolled patients.

DISCUSSION

PF, an overuse injury marked by recurrent microtears at the fascia-calcaneus junction, presents commonly with heel pain during initial morning steps or after prolonged activity. Risk factors include obesity, systemic diseases, foot arch abnormalities, and overpronation. Histologically, it is a chronic degenerative rather than inflammatory condition, characterized by fibrosis, immature vascularization, and immune cell infiltration, leading to tissue degeneration and replacement by angiofibroblastic hyperplastic tissue.[11] Traditional anti-inflammatory therapies offer only temporary relief and do not address underlying degeneration. PRP therapy, leveraging growth factors such as PDGF, TGF-β, IGF1, and VEGF from platelet α granules, promotes tissue repair and regeneration.[12] Autologous GFC, derived from the patient's blood, may accelerate healing, reduce inflammation, and provide long-term relief. This study, through a randomized controlled trial, aims to compare GFC with conventional treatments, potentially establishing a more effective, individualized therapy that improves outcomes and reduces reliance on pharmaceuticals. The present study showed no significant difference in age (p=0.2370) or gender distribution (p=0.4578) between Group A (mean age 44.50 ± 11.20 years; 75% females) and Group B (mean age 43.17 ± 9.83 years; 80.56% females), ensuring well-matched groups. Sevilla G et al.[13] reported a younger average age in Group I (34.95 ± 5.8 years; 85% females) and an older average in Group II (49.2 ± 4.8 years; 91.7% females), with clear gender predominance. In contrast, the current study had a more balanced gender ratio. Kothari S et al.[14] found a majority of patients aged 25–45 years, with 57% being housewives, again suggesting a female preponderance. Compared to these studies, the current research offers a demographically consistent sample, strengthening the validity and generalizability of its outcomes. Both groups had comparable baseline characteristics, including affected foot side and presence of calcaneal spurs (p=0.8136), with no significant differences in vital signs or general physical findings. Minor symptoms like edema, pallor, and a single case of clubbing in Group B were not statistically significant, supporting baseline uniformity for reliable outcome assessment. Both groups showed improvement in VAS scores, but Group B had significantly better pain reduction. The baseline VAS scores were similar (Group A: 4.75 ± 1.02 vs. Group B: 5.18 ± 1.32; p=0.1265). However, at 1 month, Group B showed a greater decrease (3.85 ± 0.90 vs. 4.80 ± 1.05; p=0.0001), with the difference increasing at 3 months (3.05 ± 0.80 vs. 4.15 ± 1.10; p<0.0001) and 6 months (2.66 ± 0.94 vs. 1.94 ± 1.10; p=0.0039). Kothari et al. [13,14] found significant improvement in VAS scores at 3 weeks for ultrasound therapy, but this was not sustained. Ahmad W et al.[15] and Ragab E et al.[16] reported sustained improvement with PRP therapy, showing consistent pain reduction, which aligns with our findings for Group B. Group A's improvements were less sustained, similar to the results in Kothari et al.'s study. Both groups in our study showed improvement in AOFAS scores, with Group B demonstrating superior functional outcomes. At one month, Group B had a lower score (58.30 ± 12.00 vs. 63.20 ± 8.10; p=0.0461), but their improvement was more

noticeable by three months (62.50 ± 12.10 vs. 74.30 ± 7.00; p<0.0001), and at six months, Group B had a higher score (85.70 ± 7.30 vs. 80.40 ± 9.20; p=0.0085). Jindal and Jindal[17] reported steady progress in AOFAS scores, with the best results at later follow-ups. In their study, AOFAS scores at six weeks (72.96 ± 12.84), 12 weeks (80.83 ± 12.93), 18 weeks (84.43 ± 12.75), and 24 weeks (84.94 ± 13.70) improved significantly. While both studies show consistent improvement, Group B in our study showed more gradual and prolonged recovery, with superior outcomes, especially at six months. Both therapies in our study showed similar safety profiles, with no incidents of infection or nerve palsy (p=0.7112). Group A had 19.44% experiencing chronic pain and 13.89% reduced range of motion, while Group B had 13.89% with chronic pain and 8.33% with reduced mobility, but these differences were not statistically significant. GFC therapy showed a slight advantage in reducing chronic pain and mobility issues. Sandrey MA[18] reported significant improvements in pain and function across intervention groups, but no clear benefit over control groups at the final follow-up. Vahdatpour B et al.[19] found no significant differences between PRP and WB groups. Our study showed that Group B (GFC treatment) had a significant and lasting reduction in pain, especially at 6 months. This aligns with Jindal and Jindal[17], who found no major complications in their study. While both therapies led to pain reduction, GFC therapy may offer better outcomes for certain patients. Our research highlights the benefits of autologous growth factor concentrate (GFC) therapy for PF, particularly in providing long-term pain relief and improved function. While both GFC and traditional therapies showed positive results, GFC offered a slight advantage in reducing chronic pain and limited mobility without significant side effects. These findings align with previous studies, suggesting GFC as a more reliable option for long-term pain management and functional recovery. The study underscores the importance of personalized treatment for effective PF management.

CONCLUSION

This study confirms that conservative management, whether used independently or in combination with GFC, results in meaningful improvement in pain and function among plantar fasciitis patients. While both groups showed positive outcomes, the addition of GFC therapy in Group B resulted in superior pain relief and functional recovery, as evidenced by significantly better VAS and AOFAS scores at 6 months. Both treatments were equally safe, with no cases of infection or nerve palsy and only minor differences in complications such as persistent pain and decreased range of movement. These findings suggest that GFC therapy may offer additional benefits in enhancing treatment outcomes for PF, though both approaches are effective and well-tolerated.

However, the study has several limitations. The 6-month follow-up period may not capture the long-term effectiveness or potential side effects of GFC therapy. The presence of single blinding may have introduced bias in the outcome assessments, and the study's focus was limited to comparing conservative treatment with GFC therapy, excluding other potential treatment options. Future research should include a larger sample size, extended follow-up periods, and blinding to minimize bias. Additionally, comparing GFC therapy with other treatments, such as corticosteroid injections or shockwave therapy, would provide valuable insights into its relative efficacy.

CONFLICT OF INTEREST: The authors declare no potential conflicts of interest.

FUNDING: No external funding was received for this study.

CONSENT: Written informed consent was obtained from all participants, in accordance with international and institutional guidelines, and has been retained by the authors.

ETHICAL APPROVAL: The study was conducted in accordance with international and institutional ethical standards, with written approval obtained and maintained by the authors.

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