


# Comparison of Calcaneal Subchondral Injection of Calcium Phosphate and Plantar Fasciotomy vs Plantar Fasciotomy Alone for Refractory Infracalcaneal Heel Pain

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## Abstract

**Background:** Treatment of chronic refractory heel pain has evolved to consider calcaneal structural fatigue as a component of the symptom profile. While concomitant calcium phosphate injection has become a method of addressing the accompanying calcaneal bone marrow edema (BME) frequently seen in this population, there is no literature supporting its use compared to traditional fasciotomy.

**Methods:** Consecutive patients with symptoms of refractory infracalcaneal heel pain and calcaneal BME were treated in our practice by either surgical fasciotomy (n = 33) or fasciotomy plus calcium phosphate injection (n = 31) between 2014 and 2019. Outcomes were retrospectively assessed via Foot and Ankle Outcome Scores (FAOS), return to activity, and complication rate.

**Results:** Sixty-four patients (64 feet) were included with a mean age of  $50.3 \pm 12.9$  years and mean follow-up of  $23.2 \pm 22.3$  months. No differences were observed between groups preoperatively. Significant improvements in 4 of 5 FAOS subscales were observed postoperatively in both groups ( $P < .05$  for all, paired *t* test). However, patients undergoing concomitant calcium phosphate injection reported significantly better scores for both activities of daily living (ADL; mean difference +10.2; 95% confidence interval [CI] 0.07-20.2) and foot-specific QOL (mean difference +21.9, 95% CI 7.0-36.6) at final follow-up compared with those undergoing plantar fasciotomy alone. All patients returned to their desired level of activity, and the frequency of complications did not differ between groups ( $P > .05$ , Fisher exact test).

**Conclusion:** In patients presenting with recalcitrant infracalcaneal heel pain accompanied by calcaneal BME, calcium phosphate injection into the calcaneus, when combined with plantar fasciotomy, was safe and more effective than traditional plantar fasciotomy alone.

**Level of Evidence:** Level III, retrospective comparative study.

**Keywords:** plantar fasciitis, bone marrow edema, bone marrow lesion, PROM, FAOS

## Introduction

Patients with chronic heel pain present a unique challenge to the physician. They often have been symptomatic for years, and have proven recalcitrant to a myriad of conservative treatments.<sup>6</sup> In some regions of the US and abroad, clinical thinking has started to expand around chronic heel pain, and many surgeons have begun targeting not only the tight and contracted plantar fascia, but also the frequently accompanying chronic stress fatigue seen within the calcaneus

itself.<sup>19</sup> Part of the evolution of this thinking has its basis in the questionable long-term results with regard to isolated plantar fasciotomy.<sup>9</sup> Studies demonstrating continued

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symptoms post fasciotomy alone suggests the potential for a deeper, underlying etiology that has, to this point, possibly remained largely unaddressed in our chronic heel pain patients.<sup>9</sup>

Bone marrow edema (BME), also commonly frequent to as bone marrow lesions, is a frequent finding on magnetic resonance imaging (MRI) in this population. They are osseous lesions not recognized on plain radiographs, but appear as diffuse water-intense signals on fat-suppressed MRI sequences.<sup>3,7,11</sup> They often appear in a periarticular fashion, and may also present in areas of increased focal stress or reduced healing capacity such as in the body of the calcaneus or talus.<sup>8,16</sup> Histopathologic evaluation of BME is that of a chronic nonhealing stress fracture, thereby providing the basis for a more interventional approach to treatment.<sup>20</sup>

Operative management of bone marrow lesions was first developed and popularized in the knee area, with literature supporting and, at times, refuting its use.<sup>2,3,8,18</sup> Operative so-called stabilization of BME lesions involves percutaneous injections of calcium phosphate (with or without marrow or biologic augmentation) under fluoroscopic guidance.<sup>3,8,18</sup> Some studies have shown that the synthetic injected calcium phosphate is resorbed and replaced with endogenous healthy trabecular bone on an average of 6-22 months post-operatively.<sup>5,21</sup> The purported success with regard to knee lesions allowed for expanded applications then to foot and ankle lesions, but with little to no high evidence literature to support or guide its use.

The purpose of this study, therefore, was to compare patient reported outcomes achieved in our practice with plantar fasciotomy combined with calcium phosphate injection to those of traditional plantar fasciotomy alone in the treatment of recalcitrant infracalcaneal heel pain accompanied by calcaneal BME.

## Patients and Methods

We retrospectively evaluated patients who underwent surgical management of chronic, recalcitrant heel pain in our practice.<sup>4</sup> Data from 3 attending surgeons were obtained from January 2014 to June 2019 by searching *International Classification of Diseases, Ninth and Tenth Revisions*, and *Current Procedural Terminology* codes. Exempt determination and Health Insurance Portability and Accountability Act waiver was obtained from our local institutional review board. Patients were stratified into one of 2 groups, either the study (calcium phosphate injection plus plantar fasciotomy) arm or the comparison (plantar fasciotomy) arm.

The treatment group consisted of patients with BME appreciated on MRI who underwent operative calcium phosphate injection in addition to a plantar fasciotomy for the management of chronic, recalcitrant heel pain. The decision to proceed with operative intervention was typically based on a combination of the chronicity of symptoms,

severity of the BME appreciated on MRI, and the patient's magnitude of symptoms. Operative bone marrow edema was defined as BME extending superiorly into the calcaneal body or tuber that corresponded to patient symptoms on examination. Patients with infracalcaneal spur BME were excluded as this is a common finding and the anatomic area is not amenable to subchondral stabilization. Similarly, our comparison group consisted of patients who also exhibited calcaneal BME on MRI preoperatively, but underwent only isolated plantar fasciotomy for the surgical management of chronic heel pain. These patients tended to be those who were treated in our practice prior to 2016, when concomitant use of calcium phosphate injection became more routine in our practice. All patients had exhausted a standardized plantar fasciitis protocol and had had pain for >6 months prior to surgical intervention. The standardized heel pain protocol included strapping, splinting, stretching, orthotics, a short course of nonsteroidal antiinflammatory drugs (provided no contraindications existed), and footwear changes. Physical therapy and cortisone injections were considered as well if initial recalcitrance was appreciated.

Eligible subjects had to have Foot and Ankle Outcome Scores (FAOS) completed preoperatively with respect to their operative foot and at final follow up. In our practice, FAOS data are typically obtained on many of our operative patients to help with clinical decision making and to monitor postoperative progress, and maintained in a repository. The FAOS is a validated patient-based tool for evaluating surgical outcomes that has demonstrated internal consistency, convergent validity, and structural validity for a variety of foot/ankle disorders.<sup>12,13,17</sup> The survey consists of 42 items and 5 subscales: pain, symptoms, function/activities of daily living (ADL), function/sport and recreation, and foot and ankle-related quality of life. Subscale scores are reported on a scale that ranges from 0 to 100, with higher values indicating better scores (eg, less pain, fewer symptoms, higher functioning).

Exclusion criteria included lack of complete FAOS data, less than 10 months of patient follow-up, and/or lack of available preoperative MR imaging. We also excluded patients who had any concomitant surgery/procedure other than calcium phosphate injection or plantar fasciotomy intraoperatively (eg, concomitant gastrocnemius recession, high-energy extracorporeal shockwave, and tarsal tunnel or other nerve release) and during follow-up (eg, platelet-rich plasma, amniotic injection), and patients who had undergone subchondral injections of osseous structures other than the calcaneus.

## Surgical Technique

All surgeries were performed by one of 3 board-certified foot/ankle surgeons. The surgical calcium phosphate injection was standardized among surgeons (Figures 1-3).



**Figure 1.** Given the chronicity of the patient's symptoms and recalcitrance to appropriate conservative means, a magnetic resonance image (MRI) was obtained that appreciated a significant amount of bone marrow edema (BME) in the calcaneal tuber in fat-suppressed images, in addition to chronic plantar fascial changes. Given the extent of the lesion, operative subchondral stabilization was discussed and agreed on at this time in addition to a plantar fasciotomy. This MRI with marrow edema extending superiorly into the calcaneus (as opposed to localized to plantar fascial insertion) is representative of the patients contained within this dataset.

Preoperatively, MRI was used to appreciate and localize bone marrow edema lesions in the calcaneus. Intraoperatively, the BME lesions were identified using intraoperative fluoroscopy and correlated with available MRI images. A specialized trocar and cannula were carefully triangulated and guided by power into the area of BME under intraoperative fluoroscopy. Once the area was ascertained to be the correct location, approximately 2 mL of calcium phosphate were injected through the cannula into the BME lesion to act as a reinforcing scaffold to enhance the healing potential and structural stability of the calcaneus. The injected calcium phosphate was mixed with unconcentrated bone marrow aspirate prior to injection at the discretion of the attending surgeon. The trocar was then left in place for 12 minutes to allow for hardening of the calcium phosphate, so as to prevent extravasation into the surrounding soft tissues. Postoperatively, patients were

made weightbearing as tolerated in a pneumatic boot for 2 weeks, followed by transition to athletic shoe gear and resumption of activity as tolerated.

Figures 1-3 are a clinical series from a 68-year-old woman presenting with a 1-year history of infracalcaneal heel pain recalcitrant to conservative care.

Plantar fasciotomies were performed on all patients in both groups. Three techniques were used: either an open, endoscopic, or topaz micro fasciotomy. Each technique was used at the discretion of the attending surgeon.

### Statistical Analysis

Descriptive statistics were generated for the study population. Between-group differences were examined using independent *t* test for continuous variables, and chi-square or Fisher exact test for categorical variables. Within-group differences were assessed with a paired *t* test. All analyses were conducted with SAS software, version 9.4 (SAS Institute, Cary, NC; Microsoft Corporation, Redmond, WA). Test results with  $P < .05$  were considered significant. All tests were 2-tailed.

### Results

Preoperative FAOS data were available for 78 consecutive patients that met our inclusion criteria during the study time frame. Our final sample consisted of 64 patients and 64 feet (31 subchondral stabilization, 33 plantar fasciotomy alone) with a mean age of  $50.3 \pm 12.9$  years and mean follow-up of  $23.2 \pm 22.3$  months (82% of the original sample). There were no differences observed between groups preoperatively (Table 1). Surgeon was not associated ( $P > .05$ ) with procedure (exposure) nor any of the FAOS subscales at final follow-up (outcome). Furthermore, type of fasciotomy (ie, open, endoscopic, or micro fasciotomy) was not associated ( $P > .05$ ) with outcome. Significant improvements in 4 of the 5 FAOS subscales were observed postoperatively in both groups ( $P < .05$  for all, paired *t* test). Changes were noted in all subscales except Symptoms. Patients undergoing concomitant calcium phosphate injection reported significantly better scores for both ADL (mean difference +10.2, 95% CI 0.07-20.2) and foot-specific QoL (mean difference +21.9, 95% CI 7.0-36.6) at final follow-up compared with those undergoing plantar fasciotomy alone (Table 2). Follow-up time was significantly longer in the plantar fasciotomy alone group (mean difference +18.2  $\pm$  20.5 months). All patients returned to their desired level of activity by final follow-up, and the frequency of complications did not differ between the groups ( $P > .05$ , Fisher exact test). There was 1 instance of increased stress response and pain post calcium phosphate injection in the treatment arm that resolved uneventfully

**Table 1.** Preoperative Demographic Data on the Patients in the 2 Groups.<sup>a</sup>

	Subchondral Stabilization (n = 31)	Plantar Fasciotomy Alone (n = 33)
Male-female, n	4:26	6:27
Age, y, mean (range)	52.6 (26-79)	48.0 (20-69)
Preop FAOS		
Symptoms	80.2 (10.1)	77.2 (10.3)
Pain	47.8 (15.3)	46.8 (12.6)
ADL	67.2 (15.7)	63.8 (16.4)
Sports/Rec	60.2 (22.7)	53.8 (20.2)
QoL	31.4 (19.1)	27.0 (13.5)

Abbreviation: FAOS, Foot and Ankle Outcome Score; ADL, Activities of Daily Living; QoL, Quality of Life.

<sup>a</sup>There was no difference between the groups with regard to any parameter. The maximum score is 100 points for each subscale. Higher scores indicate improved function and less pain/symptoms. Data in table are presented as mean (SD) or count unless otherwise indicated.

**Table 2.** Final Postoperative Results Between the 2 Groups.

	Subchondral Stabilization (n = 31)	Plantar Fasciotomy Alone (n = 33)	P Value
Follow-up, mo	13.8 (3.6)	32.0 (24.4)	.001 <sup>a</sup>
Postoperative FAOS			
Symptoms	81.9 (12.8)	76.5 (18.4)	.176
Pain	75.5 (20.1)	68.9 (24.3)	.243
ADL	85.2 (15.3)	75.1 (24.1)	.048 <sup>a</sup>
Sports/Rec	78.2 (23.5)	67.8 (33.1)	.153
QoL	67.7 (23.8)	45.8 (34.2)	.004 <sup>a</sup>

Abbreviation: FAOS, Foot and Ankle Outcome Score; ADL, Activities of Daily Living; QoL, Quality of Life.

<sup>a</sup>Statistically significant test result. The maximum score is 100 points for each subscale. Higher scores indicate improved function, and less pain/symptoms. Data in table are presented as mean (SD).

after 4 weeks of immobilization, and the patient eventually returned to fully pain-free activity.

## Discussion

This study is the first of its kind to critically evaluate calcium phosphate injection for use in infracalcaneal heel pain. Our results suggest that calcium phosphate injection of bone marrow lesions in the calcaneus, when combined with plantar fasciotomy, is safe and possibly even more effective than traditional plantar fasciotomy alone.

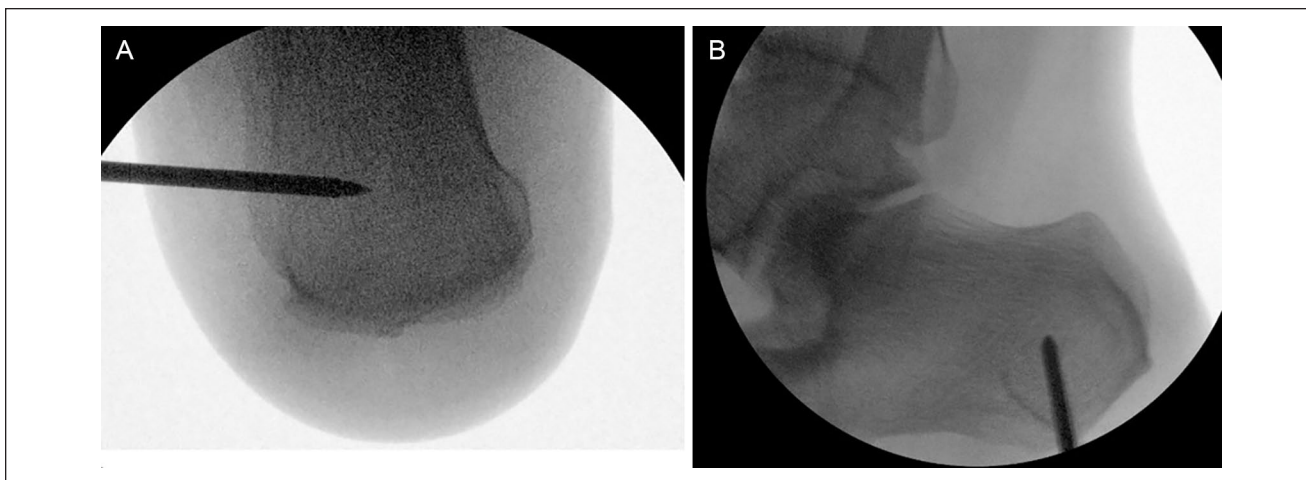
To this point, previous literature on calcium phosphate injection in the foot and ankle has been limited to lower evidence case reports and technique papers. Miller and Dunn published on a case series of 2 patients who underwent calcium phosphate injection in the talus, both of which endorsed improvement at final follow up.<sup>14</sup> Pelucacci and LaPorta published a technique paper expanding the use of the technique to other osseous structures, such as the first metatarsal.<sup>15</sup> The significance of their work is in the expanded use of subchondral stabilization, though they offered no clinical data or follow up. An additional single case report by Bernhard et al. specifically looking at the

use of calcium phosphate injection in the calcaneus, but was limited to only a single patient.<sup>1</sup>

Though our study presents positive results with regard to calcium phosphate injection in the realm of recalcitrant heel pain, caution should be taken with regard to widespread adoption of this novel surgical technique. Each pathology and anatomic region of the lower extremity has unique indications for the use of calcium phosphate injection, with complications and risk profiles varying across different osseous structures. An excellent example of this is recent work published by Hanselman and colleagues, who appreciated a concerning rate of avascular necrosis in the talus following calcium phosphate injection.<sup>10</sup> Their findings suggest that the rate of complications with regard to calcium phosphate injection is not only injection volume dependent, but also dependent on the type of bone as the talus has a more tenuous blood supply than other structures (such as the calcaneus).

Although our study has several strengths, including having a closely matched comparison group and use of a validated patient-reported outcome measure, it should be interpreted also within the context of its limitations. For example, our study was likely underpowered to detect small





**Figure 2.** Intraoperative fluoroscopic images showing triangulation of the (A) trocar and (B) cannula to correspond to available preoperative magnetic resonance images.



**Figure 3.** Two-week postoperative weightbearing radiograph appreciating well-seeded calcium phosphate injection. Patient successfully returned to full pain-free baseline activity at this time.

and medium size between-group differences. Although postoperative scores were generally higher across all FAOS domains in patients undergoing concomitant subchondral stabilization, only 2 of these comparisons (ADL and QoL) reached statistical significance. It is likely that with larger patient numbers, we might have seen statistically significant differences emerge in 1 or more of the other FAOS subscales. Furthermore, treatment assignment was not randomized, so there is a possibility that our results might be hampered by residual confounding and unequal distribution of unmeasured, but important, covariates. We took steps to mitigate this by excluding patients with concomitant (additional) procedures outside of what we were interested and including only patients who had BME lesions on their preoperative MRIs; however, only a randomized prospective study design could ensure equal distribution of all potentially important covariates. Also, as treatment of BME lesions within the calcaneus has become relatively

commonplace in our practice in recent years, most of the isolated plantar fasciotomy procedures were performed prior to this and therefore followed for a longer period of time, leading to the unequal follow-up. This might also help to explain the group differences we observed; however, we would argue that the natural history for patients following plantar fascial surgery is more likely to continue to improve with time, and not necessarily the other way around. Finally, some would argue that 3 surgeons having performed the procedures would impact the internal validity of the study; however, we did not find that the surgeon was associated with either the operative technique or outcome, so we do not feel it is a viable confounder. In fact, if anything, having multiple surgeons and less control of the exact techniques used would increase the external validity of the findings and should have biased the results toward the null hypothesis of concluding there was no difference between the treatment groups, and we found the opposite.

In conclusion, in our patients presenting with recalcitrant, infra calcaneal heel pain accompanied by calcaneal BME, calcium phosphate injection of the calcaneus, when combined with plantar fasciotomy, was safe and more effective than traditional plantar fasciotomy alone. We feel these initially favorable results would warrant further exploration in a larger, prospectively designed and controlled trial.

#### **Declaration of Conflicting Interests**

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## Ethical Approval

Ethical approval for this study was waived by the Rosalind Franklin University of Medicine and Science IRB because the project involved the use of existing, deidentified data only.

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