Initial Experience with Subchondral Stabilization for Bone Marrow Lesions of the Midfoot and Forefoot

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Research

Keywords: pain, months, patients, mean, bone, evidence

Posted Date: October 12th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-951394/v1

Abstract

Disabling foot pain is often accompanied by MRI evidence of bone marrow edema which may represent early structural fatigue. Emerging evidence suggests subchondral stabilization with injectable calcium phosphate can alleviate pain associated with bone marrow edema in the hindfoot, ankle and knee; however, there is no data supporting its use or safety for midfoot or forefoot lesions.

We identified 54 patients who underwent SS of various midfoot/forefoot osseous structures in our practice over a four-year period. All patients proved recalcitrant to standard conservative measures, and all had advanced imaging appreciating BME. VAS for pain at 1, 3, 6, and 12 months postoperatively served as the primary outcome measure.

41 patients were included with a mean age of 54.3 ± 14.9 years and mean follow up of 14.1 ± 6.9 months. Patients saw a significant decrease in VAS pain as early as 1 month postoperatively ($p<0.05$). Mean postoperative VAS at 12 months was 2.11 ± 2.50, and the mean reduction in VAS pain from preop to 12 months postop was -5.00 (95% CI -3.44 to -6.56, $p<0.05$). Fourteen patients (34%, 14/41) were pain free at 12 months. Treatment of more than one bone (unadjusted OR 6.23 [95% CI 1.39 to 27.8], P=0.017) was associated with a greater likelihood of not achieving a pain free status at 12 months.

Initial experience suggests that SS was both safe and effective in our patient population. Simultaneous treatment of multiple bones should be entered into with caution, and further research on the subject is necessary.

Level of Evidence: IV (Retrospective Case Series)

Introduction

The surgical management of bone marrow edema of osseous structures of the foot and ankle has become increasingly more in vogue over the past couple of years. Such pathology most commonly occurs in patients with chronic, recalcitrant foot pain unresponsive to standard conservative means. Bone marrow edema (BME), also referred to as bone marrow lesions, are a common finding that appear as diffuse water intense signals on fat suppressed magnetic resonance imaging (MRI) sequences, and are commonly found in this patient population.[1,2,3] Bone marrow lesions often appear around joints, but also may present in other areas of increased focal stress and/or reduced healing capacity such as the bones of the midfoot and forefoot.[4,5] Histopathologic evaluation of BME has previously been likened to that of a chronic nonhealing stress fracture, thereby suggesting a basis for a more interventional approach to treatment.[6]

Operative management of BME lesions was developed and popularized in the knee arena, with early ample literature supporting its use.[2,5,7,8] Operative subchondral stabilization of BME lesions involves percutaneous injections of calcium phosphate (with our without marrow or biologic augmentation) under fluoroscopic guidance.[2,5,8] Studies show that the synthetic injected calcium phosphate is resorbed and

replaced with endogenous healthy trabecular bone on an average of 6-22 months postoperatively.[8] The success with regards to knee lesions allowed for expanded applications then into foot and ankle lesions, but with little to no high evidence literature to support or guide its use.

In addition to reporting outcomes from this new minimally invasive novel approach, we wanted to present outcomes in a way that focused on resource optimization and value based care. As value based care becomes a more important metric in healthcare, Maximal Medical Improvement (MMI) has become a more refined way to evaluate patient progress.[9,10] The rationale behind MMI utilization as a primary outcome is that it helps focus on the difference between statistically and clinically significant outcomes.[11] MMI has come to be defined as time point at which a patient can no longer detect further improvement following surgery, data which can help inform both outcomes and resource utilization with regards to this new novel surgical procedure.

The purpose of this study therefore was to describe our initial experience with using subchondral stabilization for the treatment of osseous lesions of the forefoot and midfoot. We report on the clinical outcomes of consecutive patients who were seen in large foot/ankle specialty practice for disabling foot pain. We were interested in better understanding whether patients do better after this procedure, and if so, when can maximum medical improvement be expected? We were also interested in determining whether there are any factors predictive of non-response or unfavorable outcomes with this novel technique.

Patients And Methods

Patients who underwent operative subchondral stabilization of osseous foot structures excluding the talus and calcaneus were retrospectively evaluated from January 2015 to December of 2019. Data from three attending surgeons within our single center foot and ankle specialty practice were identified by searching available ICD-9/10 codes. Inclusion criteria included patients with preoperative MRI imaging appreciating bone marrow edema of the forefoot/midfoot who underwent subchondral stabilization, and who had available VAS data at one, three, six, and twelve months post operatively. Patients who underwent any kind of concomitant procedure or who had incomplete data were excluded from the study (n=32). Initial record search yielded a study population of 54 patients, with a remaining 41 patients after exclusion criteria were applied. Exempt determination and HIPAA waiver was obtained from out local Institutional Review Board prior to initiating this work.

Surgical Technique:

All surgeries were performed by one of three board certified foot/ankle surgeons. Technique and post operative protocol were standardized amongst surgeons (Figures 1-6), as was the calcium phosphate injection product (Subchondroplasty, Zimmer Biomet). Preoperatively, MRI was utilized to appreciate and localize bone marrow edema lesions of various midfoot/forefoot bones. Intraoperatively, the BME lesions were identified using intra-operative 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 intra-

operative fluoroscopy. Once the area was ascertained to be the correct location, calcium phosphate was injected through the cannula into the BME lesion to act as a reinforcing scaffold to enhance the healing potential and structural stability of the operative bone in question. The injected calcium phosphate was mixed with bone marrow aspirate or other biologic augmentation 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 allowed to weight bear as tolerated in a pneumatic boot for two weeks, followed by transition to athletic shoe gear and resumption of activity as tolerated.

Statistical Analysis:

Descriptive statistics were generated for the study population and are given as mean ± standard deviation. Repeated measures ANOVA was used to detect changes in mean VAS pain scores over time (baseline, 1 month, 3 months, 6 months and 12 months). Simple logistic regression was used to determine independent variables associated with achieving a 'pain free' rating postoperatively, and to determine independent variables associated with non-response after surgery. Pain free was defined as a VAS pain score of '0' at 12 months. Non-response was defined as less than 50% reduction in VAS pain from baseline to 12 months. All analyses were conducted with SAS software version 9.4 (SAS Institute, Cary, NC; Microsoft Corporation, Redmond, WA). Test results with $p<0.05$ were considered significant. All tests were two-tailed.

Results

Forty-one patients (4 men, 37 female) were included with a mean age of 54.3 ± 14.9 years, mean BMI 30.4 ± 5.43 kg/m^2, and mean follow up of 14.1 ± 6.9 months. Patients saw a significant decrease in VAS pain from preop to 1 month postop that continued at all follow up time points ($p<0.05$ for all, see figure 2, and Table 1). The greatest reduction in VAS pain was seen at 1 month postoperatively, and there were no statistically significant differences found for mean VAS pain during the various postoperative time points. Mean postoperative VAS at 12 months was 2.11 ± 2.50, and the mean reduction in VAS pain from preop to 12 months postop was -5.00 (95% CI -3.44 to -6.56, $p<0.05$).

Table 1
Change In VAS Pain Over Time (n=41)

	Preop VAS	1 month Postop VAS	3 month Postop VAS	6 month Postop VAS	12 month Postop VAS
Mean	7.12 ± 1.66	3.48 ± 2.46	2.35 ± 2.53	2.61 ± 2.90	2.11 ± 2.50
Mean change from Preop	–	-3.64 (-2.13 to -5.14)	-4.76 (-3.25 to -6.26)	-4.50 (-3.00 to -6.01)	-5.00 (-3.44 to -6.56)
P value	–	<0.05	<0.05	<0.05	<0.05
Mean values are given as mean ± sd, mean change is given as estimate (95% CI).					

Twelve patients (29%, 12/41) failed to respond to surgery using our definition of a successful treatment response. No independent variables (i.e., age, BMI, gender, VAS pain preoperatively, or treatment of greater than one bone) were associated with non-response (all, p>0.05).

Fourteen patients (34%, 14/41) were pain free at 12 months. Higher preoperative VAS pain scores (unadjusted OR 2.13 [95% CI 1.20 to 3.77], P=0.010) and treatment of more than one bone (unadjusted OR 6.23 [95% CI 1.39 to 27.8], P=0.017) were associated with a greater likelihood of not achieving a pain free status at 12 months.

There were 2 postoperative complications: one patient developed CRPS, and another developed a mild postoperative cellulitis that resolved with oral antibiotics.

Discussion

This paper describes our initial experience using subchondral stabilization of osseous lesions outside of the talus or calcaneus. Our results suggest that subchondral stabilization of bone marrow lesions within the mid- and forefoot is a relatively safe and effective procedure, with a mean decrease in VAS pain of 5 cm (on a 10 cm scale) and one third of patients achieving a pain free status at 12 months. Our study also and identified variables that complicated achieving a ‘pain free’ response at 12 months (i.e., treatment of more than one bone, and higher VAS pain score at baseline). This information can help providers while educating their patients and hospital administrators, and suggests that subchondral stabilization offers promise in the treatment of osseous lesions outside of the rearfoot/ankle.

Another important observation in our study was the expected timeframe for achieving MMI with these procedures. There were no statistically significant changes in VAS pain after 1 month postoperatively in our cohort, which suggests the most improvement is seen as early as the 1st postoperative month. That said, patients did continue to see modest *clinical* improvements (slightly greater than 1.0 cm on 10.0 cm scale) from postoperative months 1 to 3 which then plateaued thereafter. This suggests then that MMI is likely achieved with this procedure within the 1st through 3rd postoperative months. Given this rather rapid response to treatment with subchondral stabilization, we feel this procedure offers a promising new

alternative to the treatment of foot pain accompanied by underlying structural osseous fatigue. To this point, treatment of these lesions has centered around immobilization of the foot with walking boots, braces and/or orthoses, activity restrictions, and addressing any metabolic deficiencies (e.g., calcium, vitamin D deficiencies). However, in our experience, this approach is often met with limited success and many times only partial relief of symptoms and typically requires prolonged periods of immobilization.

While our work is the first to evaluate subchondral stabilization of the foot in a critical manner, it is not the first work on the subject. Miller and Dunn published a case series of two patients who underwent subchondral stabilization in the talus, both of which endorsed improvement at final follow up.[12] Pellucci and LaPorta published a technique paper expanding the use of the technique to other osseous structures, such as the first metatarsal and others.[13] The significance of their work is in the expanded use of subchondral stabilization, although they offered no clinical data or follow up. Finally, Bernhard and colleagues previously described the use of subchondral stabilization of the calcaneus in a patient with concomitant refractory plantar fasciitis.[14] Although the authors' experience was positive, this report was limited to only a single patient's experience.[14]

Our findings should be interpreted within the context of the study. First, we do not have a comparison group with which to compare/contrast our findings. Second, our results are limited by a relatively small sample size, so several comparisons may have failed to achieve statistical significance. Also, because of the smaller sample size, we were unable to perform a multivariable analysis, and instead reported only the unadjusted (crude) odds ratios for the independent predictors. Finally, outcomes data reported at 12 months postoperatively represents a relatively short follow up for orthopedic procedures.

In conclusion, our initial experience suggests subchondral stabilization is a relatively safe and effective treatment option for patients presenting with disabling foot pain associated with presumed structural fatigue and underling bone marrow edema. While our results are favorable, the topic warrants further exploration in a larger prospective trial. Simultaneous subchondral stabilization of multiple bones of the mid- and forefoot should be entered into with caution, and further research on the subject is necessary.

Declarations

Acknowledgements:

None.

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Figures

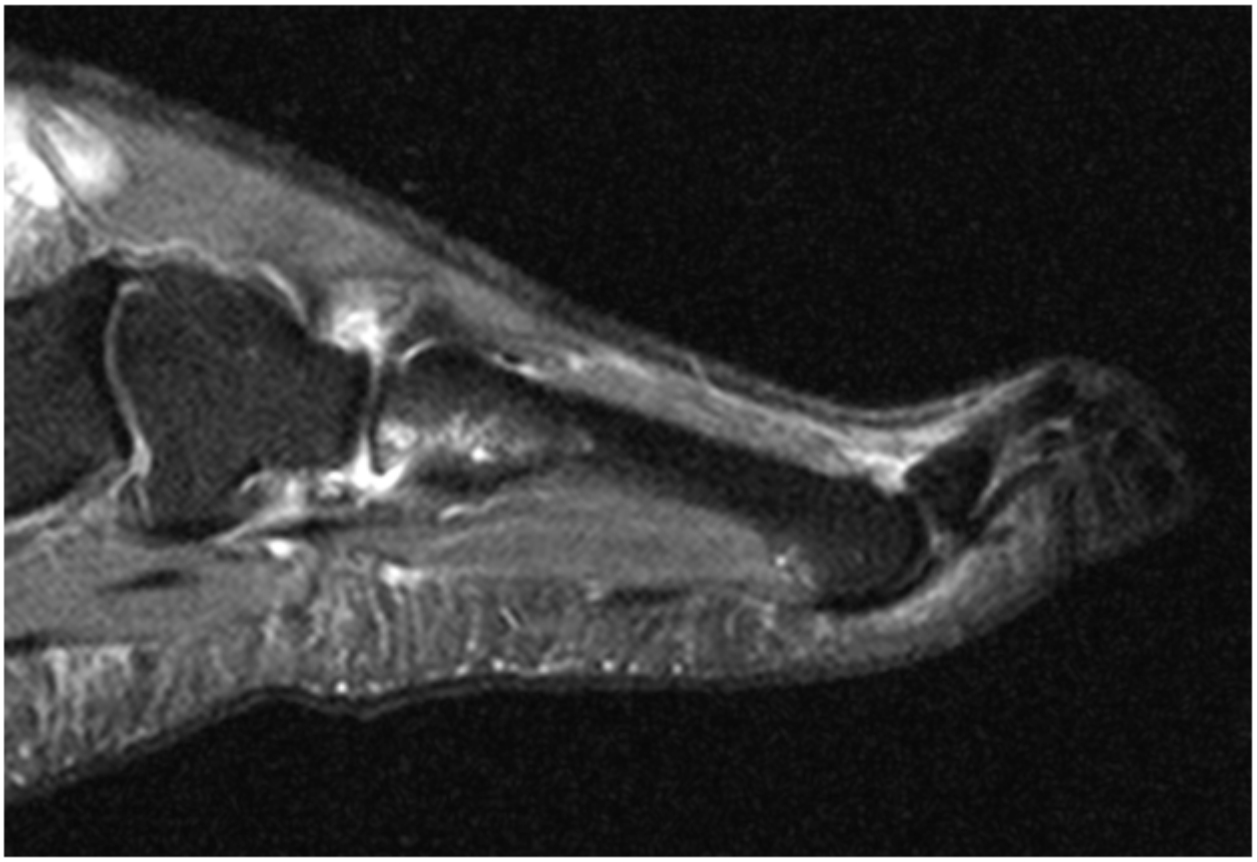

Figure 1

Given the patient’s recalcitrance to conservative means following clinical diagnosis of left fourth metatarsal stress fracture an MRI was obtained appreciating bone marrow edema localized to left fourth metatarsal proximal metadiaphysis corresponding precisely to patient’s symptoms. Given her recalcitrance to months of immobilization and other conservative measures, and her continued symptoms post immobilization, patient elected to proceed with subchondral stabilization of the left fourth metatarsal.

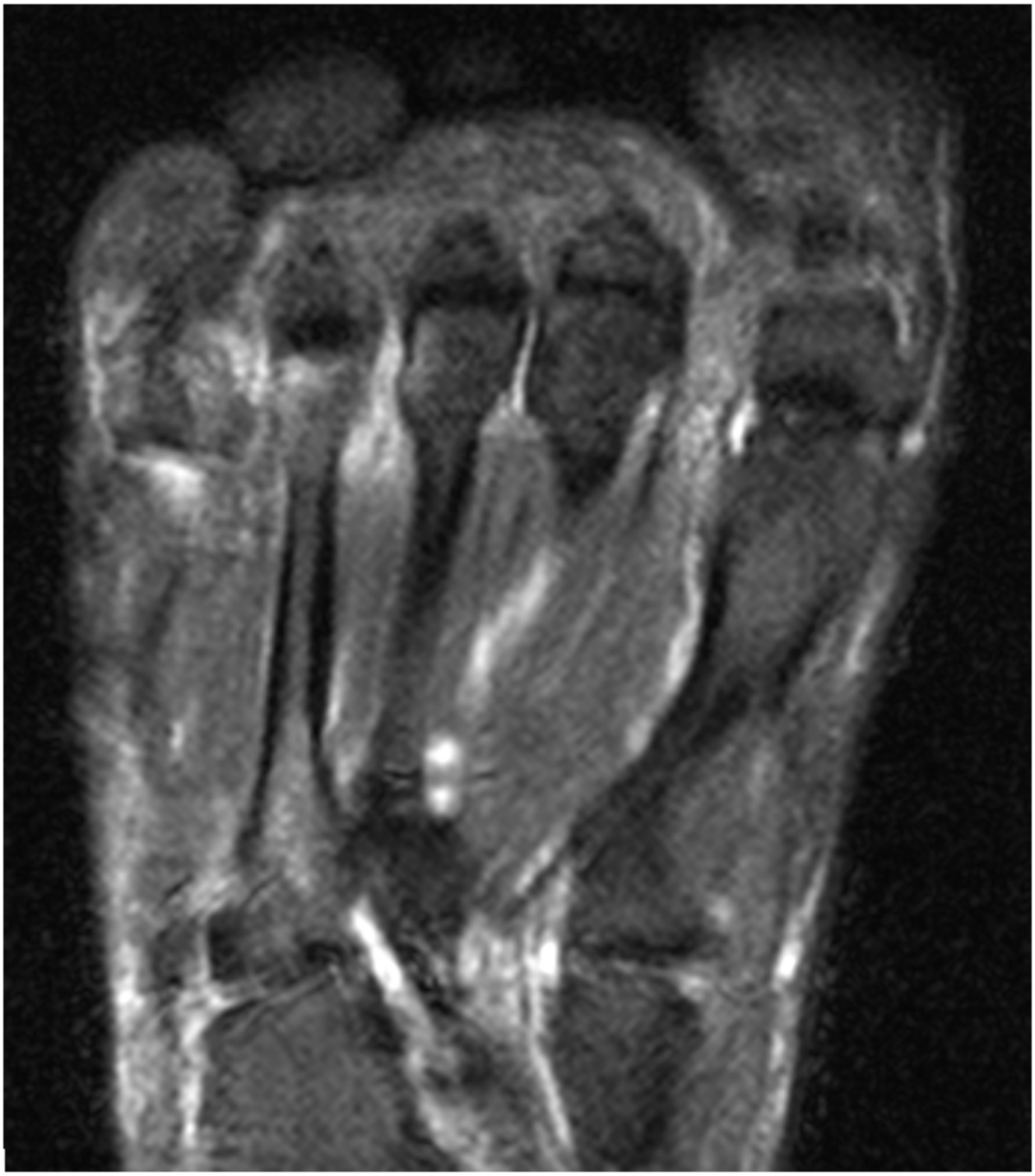

Figure 2

Given the patient’s recalcitrance to conservative means following clinical diagnosis of left fourth metatarsal stress fracture an MRI was obtained appreciating bone marrow edema localized to left fourth metatarsal proximal metadiaphysis corresponding precisely to patient’s symptoms. Given her recalcitrance to months of immobilization and other conservative measures, and her continued symptoms post immobilization, patient elected to proceed with subchondral stabilization of the left fourth metatarsal.

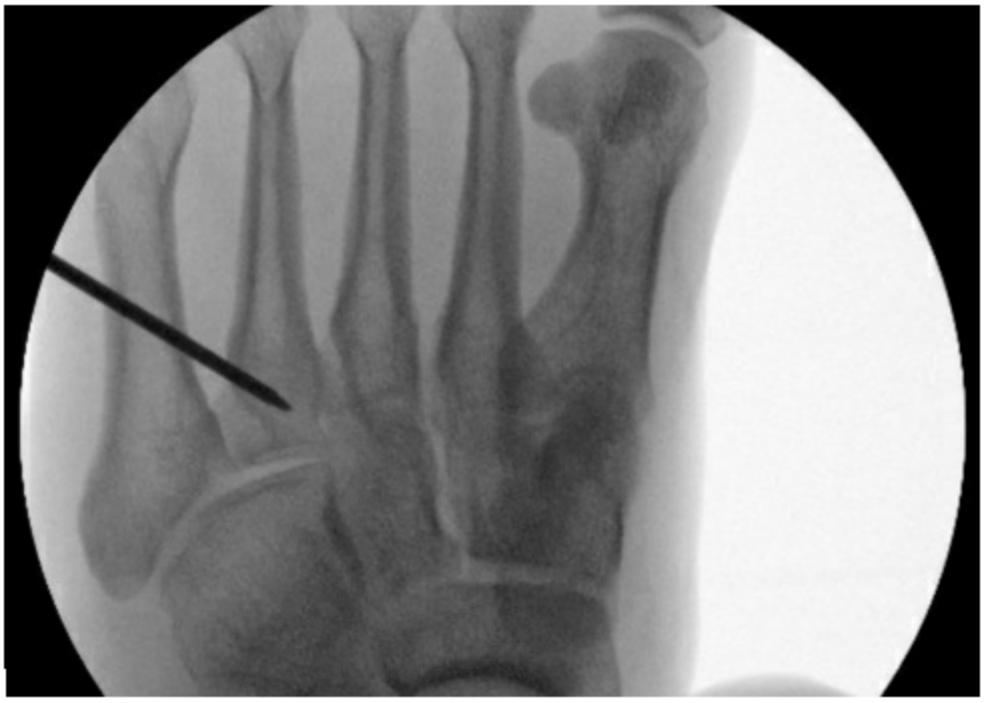

Figure 3

Figure 3 demonstrates intraoperative fluoroscopic localization and insertion of the trocar/cannula into the left fourth metatarsal metadiaphysis based on preoperative imaging findings.

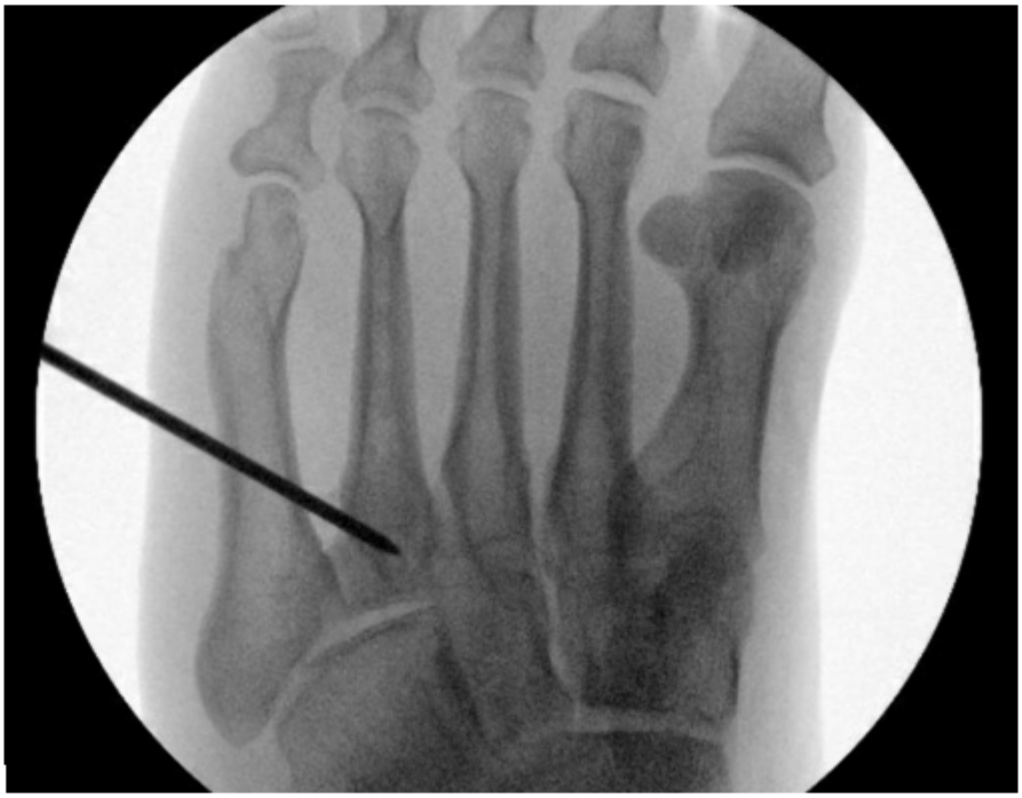

Figure 4

Figure 4 demonstrates intraoperative fluoroscopic imaging post injection of the calcium phosphate allograft. Note the opacity of the allograft is slightly diminished due to the fact that it was mixed with calcaneal bone marrow aspirate prior to injection.

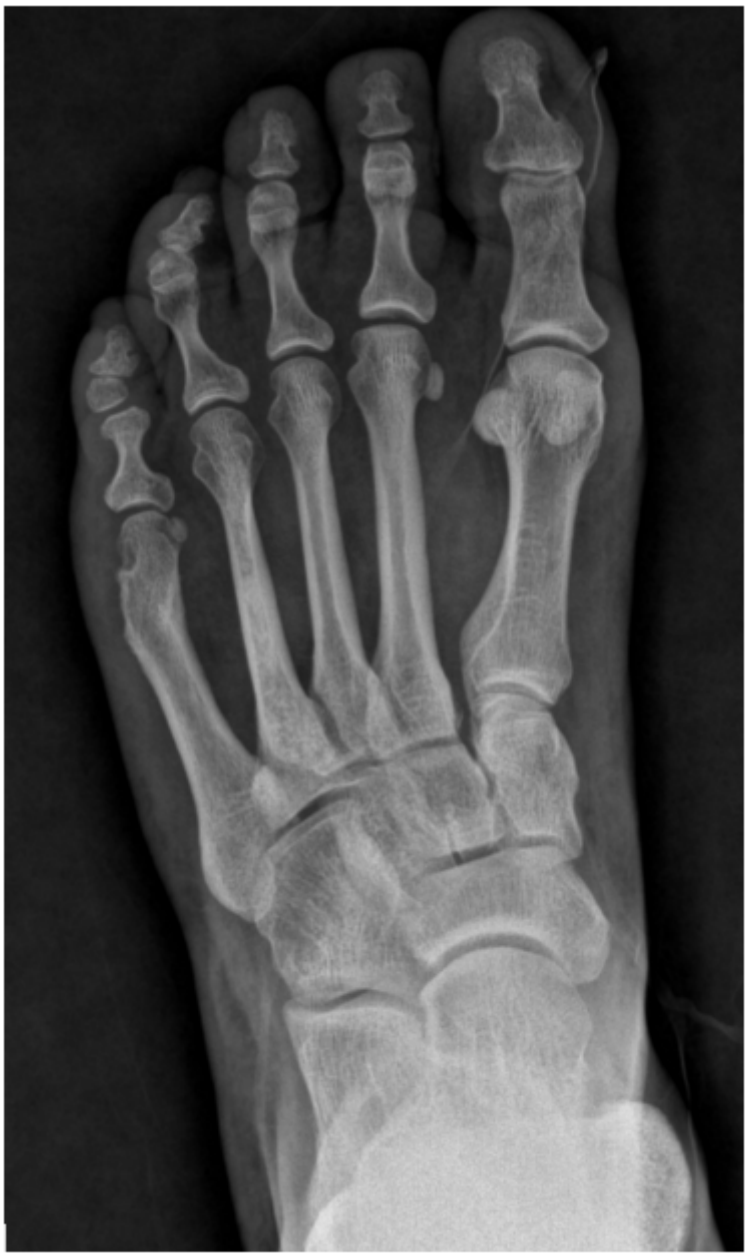

Figure 5

AP and MO images of the left foot one year status post subchondral stabilization of the proximal left fourth metatarsal. Patient returned to pain free ambulation two weeks post operatively, and recorded VAS scores of 0 for each of the 1, 3, 6, and 12 month endpoints.

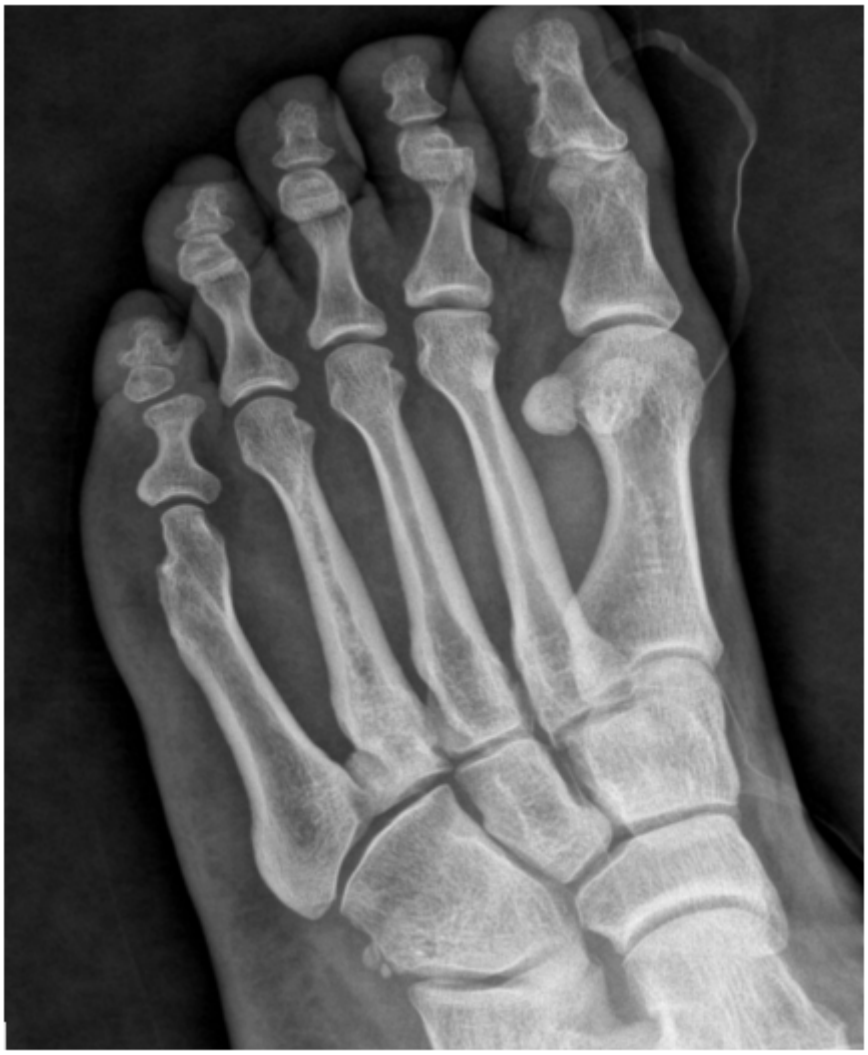

Figure 6

AP and MO images of the left foot one year status post subchondral stabilization of the proximal left fourth metatarsal. Patient returned to pain free ambulation two weeks post operatively, and recorded VAS scores of 0 for each of the 1, 3, 6, and 12 month endpoints.

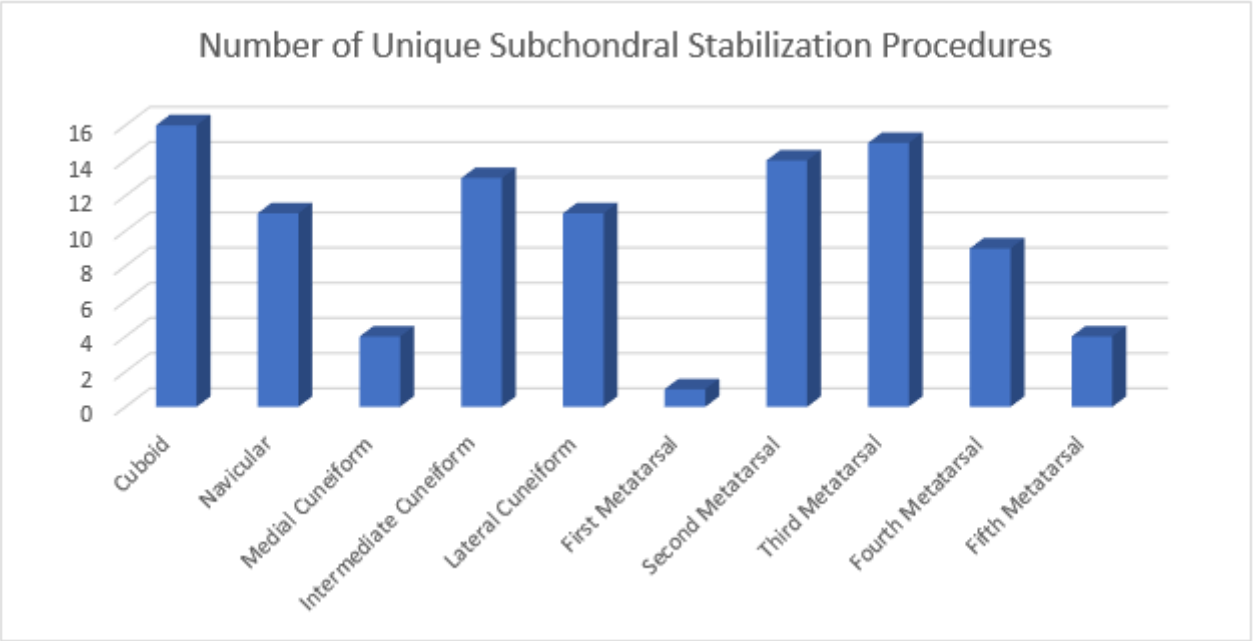

Figure 7

Distribution of bones undergoing unique subchondral stabilization procedures. The median number of bones treated per operative session was 1.0 (range: 1.0 to 7.0). The mean number of bones for the cohort was 2.29 ± 1.69. Fifty one percent of patients had only one bone treated (21/41).

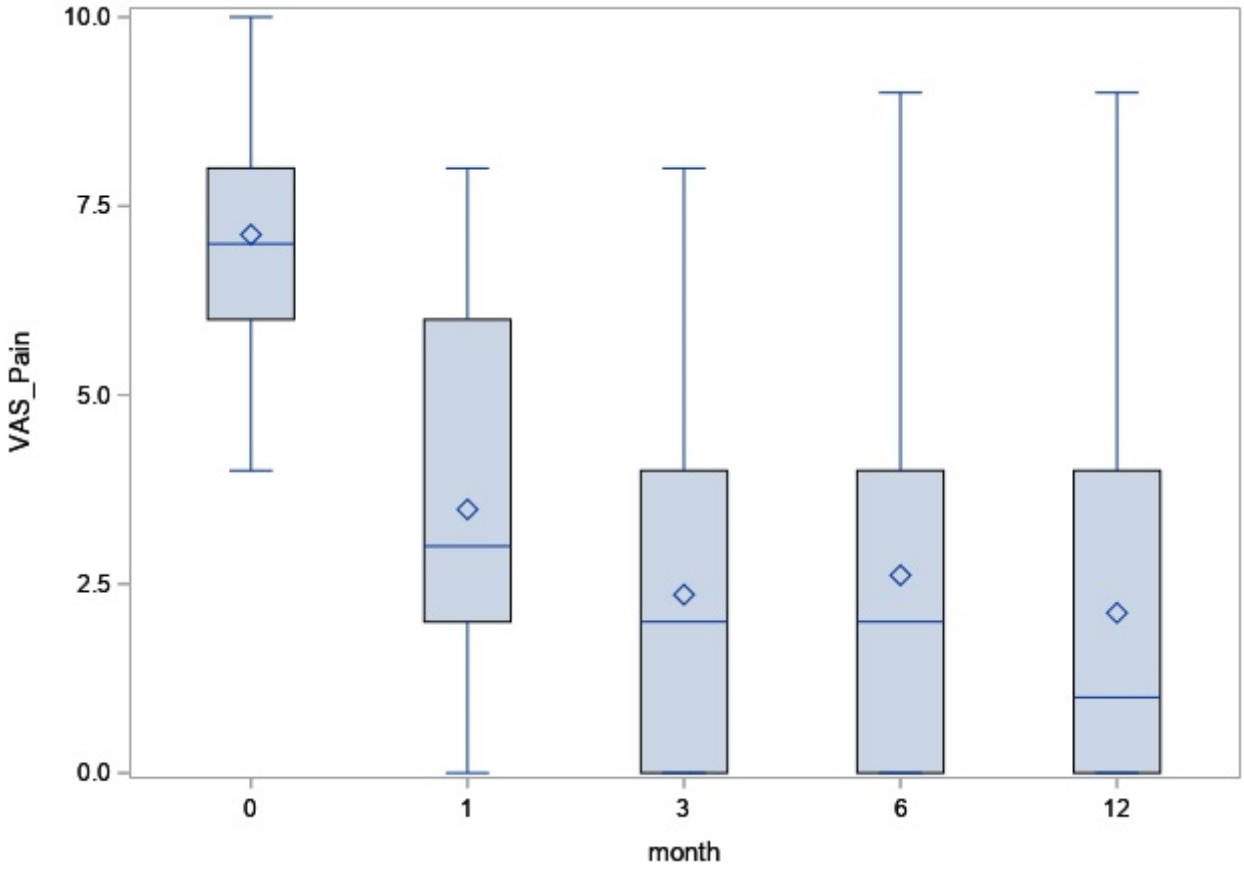

Figure 8

Boxplots showing the observed decrease in VAS pain from preop (month 0) to 1 month postop ($p<0.05$). There were otherwise no statistically significant differences for mean VAS pain among the other postoperative time points (months 1-12, all $p>0.05$).