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Vanisaben Patel
Bethesda Hospital East, VanisabenP@baptisthealth.net

Jason Gold
Bethesda Hospital East, drjasongold@comcast.net

Jodi Schoenhaus
Bethesda Hospital East

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Retrospective analysis of the use of an injectable allograft for bone marrow lesions of the foot and ankle

Jodi Schoenhaus, DPM, RPhS, FACFAS[1], Vanisaben Patel, DPM[2], Jason Gold, DPM, FACFAS[3]

1 - Research Coordinator and Attending Foot and Ankle Surgeon, Bethesda Hospital East Foot and Ankle Surgical Residency, Baptist Health of South Florida, Boynton Beach, FL, Private Practice Boca Raton, FL
2 - Third Year Resident Physician, Bethesda Hospital East Foot and Ankle Surgical Residency, Baptist Health of South Florida, Boynton Beach, FL
3 - Bethesda Hospital East Foot and Ankle Surgical Residency, Baptist Health of South Florida, Boynton Beach, FL, Private Practice Boynton Beach, FL

Background: Stress fractures occur to the musculoskeletal system on a frequent basis. This injury in the foot and ankle is relatively benign and treated conservatively with a walking boot or postoperative shoe. The use of an injectable bone graft has shown success with bone marrow edema and osteoarthritis in the knee, thus the same effects would be seen worthy of stress fractures relating to other parts of the body such as the foot and ankle. The foot and ankle sustains a high level of stress and is prone to stress fractures. This retrospective analysis documents several cases of stress fractures treated with an injectable allograft.

Methodology/Procedures: A retrospective analysis was conducted on twenty-eight individuals, ages 20-75, who underwent bone repair with an injectable calcium phosphate graft by one of the study investigators. Diagnosis was made with MRI imaging studies prior to surgical intervention. Intraoperatively, fluoroscopy was used to identify the surgical site to be injected. After appropriate targeted position of a cannula, the graft was injected into the site of injury. Retrospective analysis was performed by chart review and phone contact to each participant with a minimum follow-up of twelve months post-procedure. A prewritten questionnaire was used to acquire patient and procedure feedback after verbal consent was obtained.

Results: A total of twenty-seven patients were evaluated. Thirteen underwent injection of bone graft for calcaneal stress fractures, six for talus stress fractures, three for metatarsal fractures, and one for a fibula fracture. One individual presented with both a calcaneus and a talus stress fracture, one with a cuboid and a metatarsal fracture and two patients with both metatarsal and cuneiform fractures. Of those represented in this trial, 24 out of the 27 patients felt no pain and were back to their normal lifestyle and routines four weeks post-procedure. At their 12-month follow-up questionnaire conducted verbally, patients continued to report no pain and actively had resumed their lifestyles.

Discussion: The analysis showed that 80% of participants had a minimum of 75% relief twelve-months post-procedure. Only 3/25 patients reported a level 5 or higher on a pain scale of 10, after the use of this treatment. Most participants returned to lifestyle activities quickly and were pain-free after a short postoperative period of treating their bone marrow lesion.

Keywords: subchondroplasty, heel pain, stress fractures, bone marrow lesions, osteoarthritis, calcaneal fractures, talus fracture, fracture, plantar fasciitis, foot pain, pain relief, bone marrow edema, lower extremity fractures, calcium phosphate, bone graft

Subchondroplasty (SCP) is a minimally-invasive procedure used in various bone lesions to enhance the strength and integrity of cancellous trabeculation. The fluoroscopically-assisted procedure targets and fills defects of subchondral and cancellous bone with the delivery of a synthetic biomaterial, bone substitute material (BSM). This BSM is a nanocrystalline that contains highly porous injectable calcium phosphate (CaP). The technique of subchondroplasty has most notably been used in the knee, but gained traction for use of foot and ankle pathology due to its ease of use, low-risk procedure with positive outcomes [1]. SCP is considered to be a minimally invasive surgical procedure that targets areas of bone defects also known as bone marrow lesions (BML). These BML's are often painful to patients and occur in the area of the spongy cancellous bone derived from trauma or chronic stress. Although most subchondroplasty

procedures are commonly used to treat lesions in the talus, the authors have found that patients who present with chronic symptoms related to traditional heel pain have been misdiagnosed with plantar fasciitis [1]. MRI's have been used to show bone marrow lesions located at the inferior calcaneus due to the "pulling" forces of the plantar fascia where it originates at the inferior calcaneus.

The purpose of this retrospective analysis was to determine whether the subchondroplasty procedure can benefit patients suffering from chronic pain associated with bone marrow defects in the foot and ankle. Specific attention was directed to patients who presented with symptoms of plantar fasciitis with MRI findings of BML and their outcomes with the SCP procedures.

Background

Patients with bone marrow lesions presented with pain that was chronic in nature. Pathology was often misdiagnosed as bone marrow lesions were not routinely seen on plain radiographs. Clinical assessment with the patient's historical presentation, physical examination and no concrete radiographic findings support the necessity of obtaining an MRI. An MRI was the most sensitive and specific diagnostic tool for identification of bone marrow lesions [2]. Most easily identified on T2 images, bone marrow lesions appear with a light signal within the dark black background of bone. This made for a confirmative diagnosis and an easy visual contrast for patient education [2].

In the clinic of the investigator, bone stress fractures and osteochondral lesions were some common pathologies treated with subchondroplasty [3]. Other bone marrow lesions identified on MRI that were not traditionally treated with injectable bone graft included Freiberg's infarction, subchondral stress reactions seen in osteoarthritis, and calcaneal stress reactions. The investigators have found that patients who presented with chronic symptoms of plantar fasciitis were being overlooked. All of the patients included in this analysis had recalcitrant pain in the plantar heel and had calcaneal bone stress changes due reactive forces from the plantar fascia.

Historically, treatment options for bone marrow lesions have included immobilization for four to six weeks or surgical drilling with arthroscopy [4]. For the past two years, the authors treated bone marrow lesions with subchondroplasty as a primary treatment option. The purpose of this study was to analyze the short- and long-term effects of the treatment of bone marrow lesions with orthobiologic material of calcium phosphate bone substitute.

Methodology

This retrospective analysis was conducted on twenty-eight individuals that underwent injection of bone graft with calcium phosphate by the investigators. To meet the inclusion criteria, all participants were between the ages of 20-75 and underwent the procedure by one of the research investigators for a diagnosis of a bone marrow lesion of the foot or ankle. The procedure provided was injection of the bone marrow lesion with an injectable calcium phosphate. All patients had failed traditional conservative measures such as stretching, oral anti-inflammatory medication, and orthotic management and control. These individuals were candidates for the procedure as diagnosed by MRI.

Treated individuals were between the ages of 22-74 with the mean age of all patients being 52.33. Of the 27 individuals, 23 were female and 4 were male. Attempts were made to contact the twenty-seven subjects for feedback at a minimum of 12 months post-procedure. The average length of time from the date of procedure to date of retrospective questionnaire was 31.33 months. Consent was obtained verbally. In consideration of a retrospective analysis, an internal review board submission was obtained and approved by Western IRB, approval number 20222703.

The 27 patients in this study were asked a series of six questions regarding the procedure, the before and after thoughts of the procedure and overall pain and relief from the procedure. All 27 participants were called and contacted via email to answer the series of six questions. Of the 27 contacted, 25/27 were able to be reached via phone call or email to provide their responses. Multiple attempts were made to contact all individuals over the course of two months. Once contacted, all patients were asked for consent for their responses and their responses were recorded by the authors of this research. The questions asked to all patients were as followed:

1) On a pain scale of 0-10 what level has your pain returned since surgery?
2) What other treatments for your condition have you needed to have since you had surgery?
3) Would you recommend this procedure to others in the future?
4) Is there anything you wish you were informed about the procedure that you did not know prior to surgery?
5) What limitations to activity are you currently experiencing? If any?
6) If you were able to give a percentage of relief of your presurgical symptoms what would it be? 0 to 25%, 26 to 50%, 51 to 75%, 76 to 100% relief?

Procedure Overview

Procedures were performed at an outpatient surgical center with general anesthetic or monitored anesthetic care. The average operating time was thirty minutes. The patient was kept in a supine position while on the operative room table. A tourniquet was not required for the procedure but should be utilized based on physician preference.

Once the patient was prepped in a normal, sterile fashion, the area of concern was evaluated and all bony landmarks identified and marked. Fluoroscopy imaging was used to target the surgical site to be injected. Next, a stab incision was made in the skin and an 11-gauge drill with attached cannula was driven into the bone. After placement was confirmed, ensuring that all open slits in the distal cannula were beyond the cortex of the treated bone, the drill was removed from the sleeve leaving the cannula in place. This step is critical on the first attempt as creating a second cortical drill hole would result in the injected graft extracting out of the second hole and into soft tissue.

While the surgeon obtained bone access, the surgical nurse prepped the calcium phosphate graft utilizing standard packaging instructions. The graft was placed into 1.0 mL syringes. Next, the subchondroplasty calcium phosphate material in the syringe was attached and locked into the cannula delivery system. Upon initial injection, approximately 0.7mL of graft filled the cannula. Continued injection allowed the material to fill into the bone defect. Minimal pressure was placed on the syringe allowing for a slow-fill of graft material into the bone. Confirmation of the graft in bone was made with the appearance of a radiodense image under fluoroscopy. The graft was inserted into the bone until mild resistance was met, indicating that the bone void was appropriately filled. When the surgeon felt that enough graft had filled the bone defect, the syringe was removed and the drill was placed back into the cannula. This propelled the remaining 0.7mL of graft into the bone and must be accounted for. The amount of graft used depended on the location and size of the bone defect. The drill and cannula were left in the bone allowing the graft to harden for approximately eight minutes. Care must be taken to avoid removing the cannula too soon as this can cause leakage of calcium phosphate into the soft tissue. Finally, the drill was reversed and the entire delivery system was removed from bone. A simple nylon stitch or steristrip was used for skin closure. Adjunctive procedures and post-procedure protocols are based on surgeon preference. Table 1 shows the amount of bone graft used in each case.

Bone	Volume
Talus	1.0-1.5 cc
Distal Aspect of Tibia	1.0-2.0 cc
Calcaneus	1.0-2.0 cc
Midfoot	0.5cc-1.5cc
Forefoot Metatarsals	0.25- 0.5 cc

Table 1 Subchondroplasty locations and amount of graft injected. Cannula size may vary depending on location of subchondroplasty and type of system being used. The amount may also vary depending on size and region of defect.

Below a full-description of the use of the injectable bone graft material into the affected regions of the foot are described. This general concept of application can be used in any area showing increased bone marrow edema or stress fracture related injuries.

Calcaneus

Careful approach to bone marrow lesions of the calcaneus requires identification of pertinent neurovascular structures. It is the author's preference to use a stab-incision on the medial aspect of the heel between the medial calcaneal nerve and lateral plantar nerve.

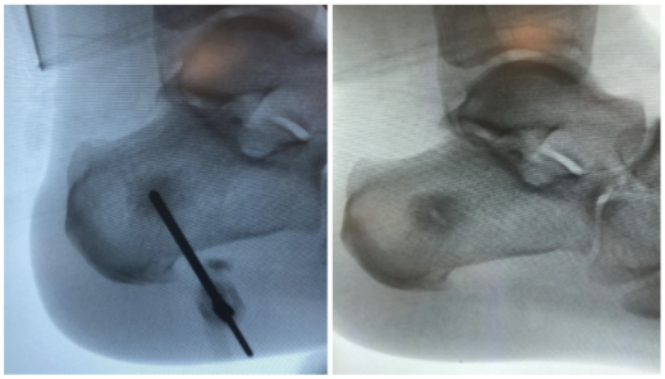

Figure 1 Calcaneal drilling and placement of calcium phosphate graft in calcaneal stress fracture.

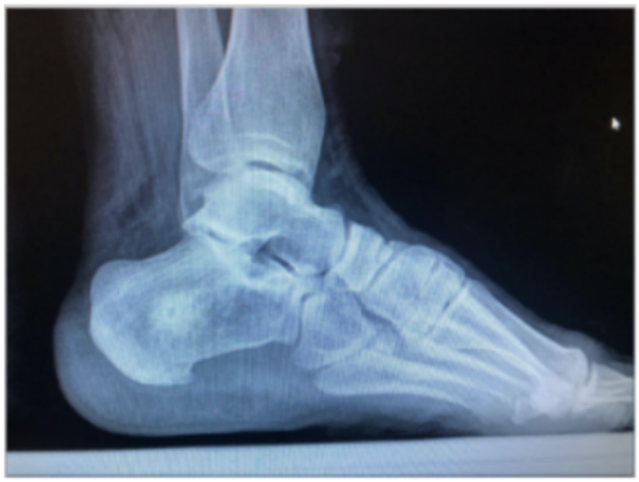

Figure 2 Postoperative appearance of calcium phosphate graft placed into calcaneal stress fracture.

This provides a direct access to the calcaneus without injury to neurovascular structures. Under live intraoperative fluoroscopy, the drill and cannula for the subchondroplasty system was inserted to the level of bone targeting the area of the bone marrow lesion. The drill and cannula were then advanced through the cortex of the calcaneus, into the medullary canal. After preparation of the bone graft, injection was performed and the graft allowed to harden prior to removal of the system from the bone (Figures 1 and 2).

Talus

Bone marrow lesions of the talus are targeted through an anterior medial approach. Identification of the tibialis anterior tendon and posterior tibial tendon are marked at the level of the talus.

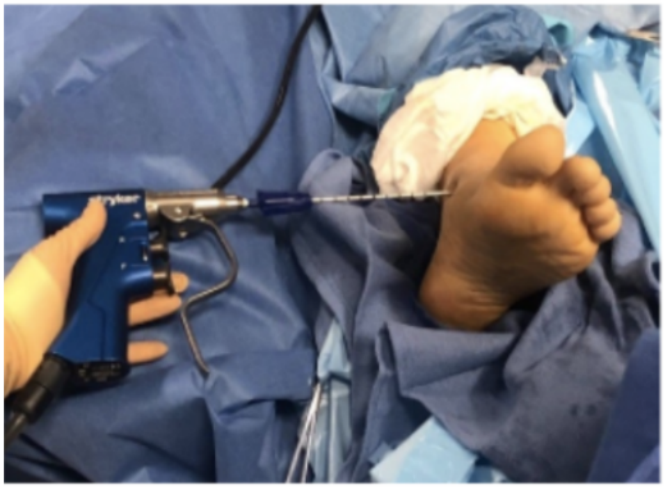

Figure 3 Drilling and placement of calcium phosphate graft into the talus.

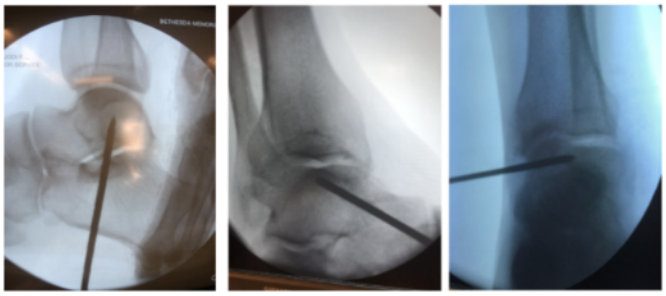

Figure 4 Placement of guidewire and injection of calcium phosphate graft into the talus stress fracture.

The mid of the tendon structures overlies the talar neck without encountering any neurovascular structures.. Under live intraoperative fluoroscopy, a stab incision was then created, and the drill and cannula for the subchondroplasty system was then inserted down to the level of bone (Figure 3). The direction of the drill and cannula were advanced targeting the bone marrow lesion. Position into the medullary canal was confirmed. After preparation of the bone graft, injection was performed and the graft allowed to harden prior to removal of the system from the bone (Figure 4).

Patients were found to have less cortical density to the affected area with softer bone structure. Evaluation of patients has shown that chronic long-term plantar fasciitis and underlying stress fractures to the region of the calcaneus is often missed on radiological review or misdiagnosed.

Postoperative Protocol and Follow-Up

All patients received a soft, dry, sterile dressing consisting of Betadine soaked Adaptic dressing, sterile dry 4x4 gauze, Kling and a compression bandage along with a postoperative shoe or walking boot to the affected lower extremity. Patients were encouraged to be weight bearing as tolerated after the procedure, as well and ice and elevation of the operated extremity for 72 hours. Pain medication was prescribed and taken as needed. The majority of patients only required acetaminophen for the pain with some needing stronger pain medications for a brief postoperative period.

Patients were scheduled to follow-up one week postoperatively. Incision sites were all evaluated for post-surgical changes, signs of infection and dehiscence. No patients from this study displayed any post-surgical complications regarding infection, DVT or dehiscences to incision sites. Immediate post-procedure pain was minimal. Patients were then scheduled for postoperative follow-up appointments at week 2, week 4 and then every few months to follow. Patients were able to return to lifestyle activities immediately with the chief complaint of pain having resolved.

Results

A total of twenty-seven patients were evaluated all consisting of various stress fractures to the foot and ankle. Of the twenty-seven patients, thirteen underwent SCP use for calcaneal stress fractures, six for a talus stress fracture, three for a metatarsal fracture, and one for a fibula fracture. One individual presented with both a calcaneus and talus stress fracture, one with a cuboid and metatarsal fracture and two patients with both metatarsal and cuneiform fractures. Of those represented in this trial, 24 out of the 27 patients felt no pain and were back to their normal lifestyle and routines four weeks post-procedure. Three patients reported continued pain after the 4-week mark stating 75% percent relief of pain with only mild discomfort. The mean follow-up for these patients was 31.33 months. Table 2 outlines the individual demographics and their procedure details.

Based on the retrospective questionnaire, 14/25 patients had complete relief of symptoms after surgery with 20/25 recommending the procedure to others. In some instances, patients did have a return in pain and were able to supplement the procedure with conservative treatment options such as steroid injections and the use of supportive orthotics in the daily shoe gear. In regards to pain relief, 3/25 individuals had 0-25% relief, 1/25 of patients had 26-50% relief, 1/25 of patients had 51-75% relief and 20/25 of patients had relief of 75-100%.

Fifty-six percent of patients had complete relief of symptoms from this procedure at the various locations of the foot and ankle. Sixty-eight percent of participants stated they had no limitations after their procedure and were able to carry on to their normal lifestyle activities with twenty-eight percent of patients stating they had some limitations with exercise or range-of-motion with their affected areas. Sixty-eight percent of patients stated they needed no further support after their procedures. The results of the questionnaire are noted in Figure 5.

Subject Number	*Patient Age*	*Gender*	*Bone Marrow Lesion Location*	*Amount of SCP Used*	*Length of Conservative Care Attempted*	*Postoperative Time Period until Relief*	*Length of time from date of surgery to retrospective questionnaire*
1	22	Female	Calcaneus	1.7cc	7 months	2 weeks	31 months
2	23	Female	Cuboid and Metatarsal	0.3 cc to Metatarsal, 0.4cc to Cuboid	3 months	2 weeks	22 months
3	24	Female	Talus	2.5cc	3 months	2 weeks	54 months
4	34	Female	Calcaneus	1.6 cc	6 months	3 weeks	16 months
5	37	Female	Calcaneus and Talus	1.7 cc into Talus and 2.6cc in Calc = Total 4.3cc	9 months	2 weeks	40 months
6	38	Female	Metatarsal	2.5 cc	6 months	3 weeks	15 months
7	41	Female	Calcaneus	1.7 cc	5 months	2 weeks	16 months
8	42	Female	Calcaneus	1.3 cc	1.2 years	4 weeks	17 months
9	44	Female	Calcaneus	1.3 cc	2 months	2 weeks	55 months
10	46	Female	Talus	1.5 cc	3 months	1 week	24 months
11	50	Female	Talus	1.5 cc	3 months	2 weeks	14 months
12	54	Female	Calcaneus	1.3cc	2 months	2 weeks	17 months
13	54	Female	Fibula	1.7 cc	2 months	1 week	16 months
14	55	Male	Talus	1.5 cc	2 months	3 weeks	60 months
15	55	Female	Calcaneus	0.4cc	11 months	1.5 weeks	34 months
16	56	Female	Calcaneus	1.5cc	1 year	8 weeks	19 months
17	61	Female	Metatarsal	0.6 cc	3 months	2 weeks	34 months
18	62	Female	Metatarsal, Cuneiform	0.3 cc in each location	2.5 months	4 weeks	16 months
19	62	Male	Talus	0.5cc	9 months	1 week	21 months
20	63	Female	Calcaneus	2.0 cc	2.5 month	1 week	16 months
21	65	Female	Calcaneus	1.6 cc	6 months	1.5 weeks	16 months
22	68	Male	Metatarsal	0.4 cc	6 months	6 weeks	16 months
23	69	Female	Calcaneus	1.5cc	3 years	1.5 weeks	22 months
24	69	Female	Cuneiform, Metatarsal	0.4 in each location	8 months	3 weeks	17 months
25	72	Female	Talus	3.0 cc	2.5 years	2 weeks	52 months
26	73	Male	Calcaneus	1.7cc	4 years	3 weeks	22 months
27	74	Female	Calcaneus	0.6 cc	1.5 months	16 weeks	51 months

Table 2 Demographic and perioperative details of reviewed patients.

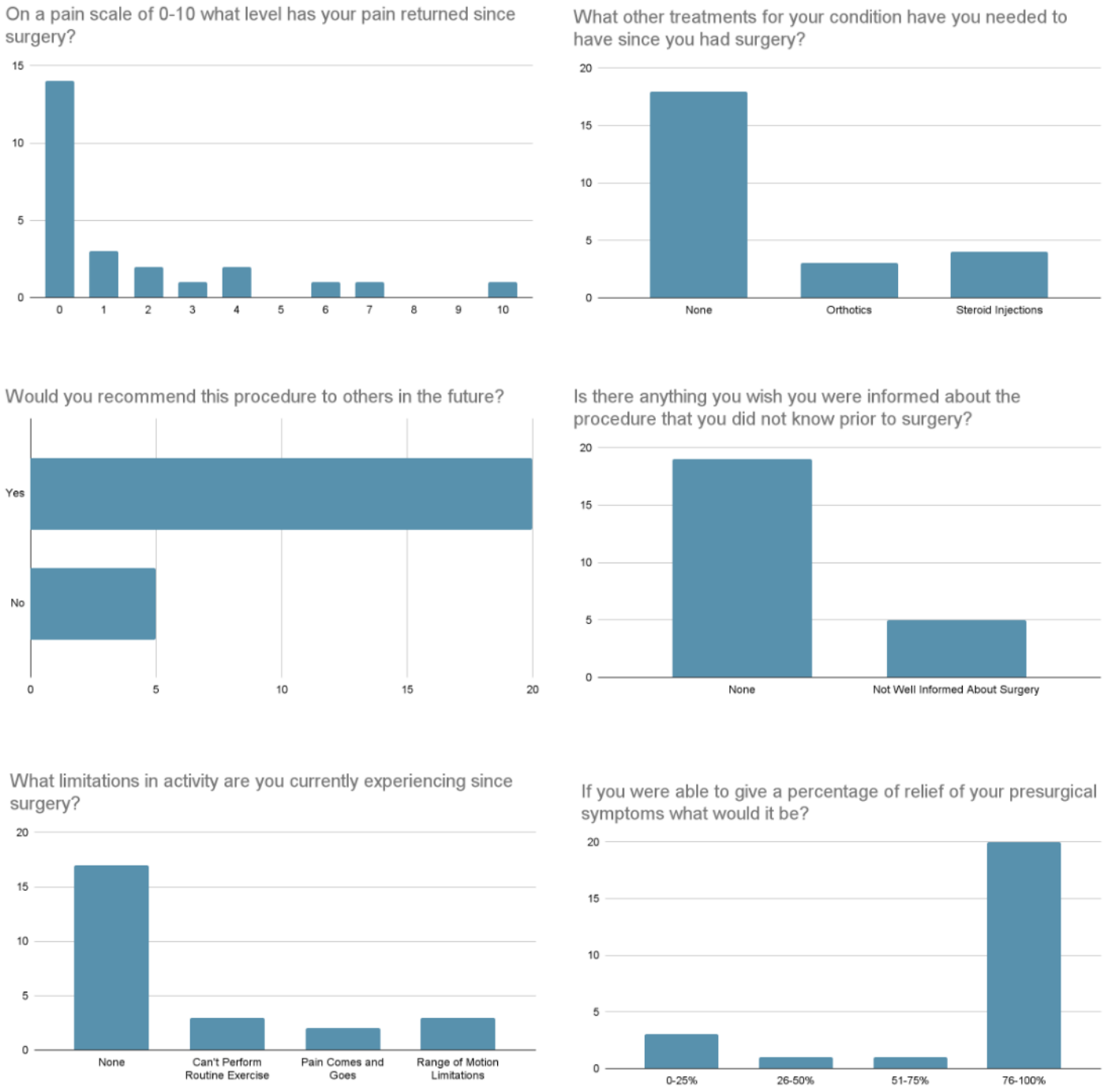

Figure 5 Survey questions and responses.

Discussion

Bone marrow lesions typically present in the foot and ankle due to increased subchondral stress and mechanical imbalance that occur in the hip, knee and ankle [5]. LaPorta, et. al., in 2018, conducted an overview regarding the use of SCP in the treatment of bone marrow lesions specifically in the foot and ankle with patients experiencing pain, cartilage loss of various boney structures and limitation of function in day to day activities [5]. In order to favor positive outcomes with the use of subchondroplasty, an accurate diagnosis was seen to be a critical element in patient success. Clinical identifiers of possible bone marrow lesions of the calcaneus with or without the presence of associated plantar fasciosis included a positive calcaneal squeeze and pain on palpation of the central or lateral process of the calcaneal tuberosity. Most patients with acute central and lateral pain to the calcaneus were automatically sent for advanced imaging with an MRI. In patients who presented with chronic heel pain, with or without a history of conservative care treatment for "plantar fasciitis", the investigators obtained an MRI. Pain in the talus, tarsal bones or metatarsals who had failed conservative management and had negative x-ray findings supported the medical necessity for an MRI.

Historically, conservative management of bone marrow lesions included immobilization of the affected area [6,7]. Patients presenting with bone marrow lesions in our clinic were offered different conservative care options prior to surgical intervention including immobilization and orthotic management [8].

The authors found that the use of an injectable bone graft was the most effective treatment for bone marrow lesions. This retrospective analysis showed that 80% of participants had a minimum of 75% relief twelve months post-procedure. Overall, when reviewing the results of the patients, it can be noted that only 3/25 patients reported a level 5 or higher on a pain scale of 10 after the use of this treatment. Of these three patients that reported a higher pain level after the procedure, it was noted that this increase in pain was attributed to overuse injuries soon after the procedure, and other lower extremity issues that were separate from the procedure site.

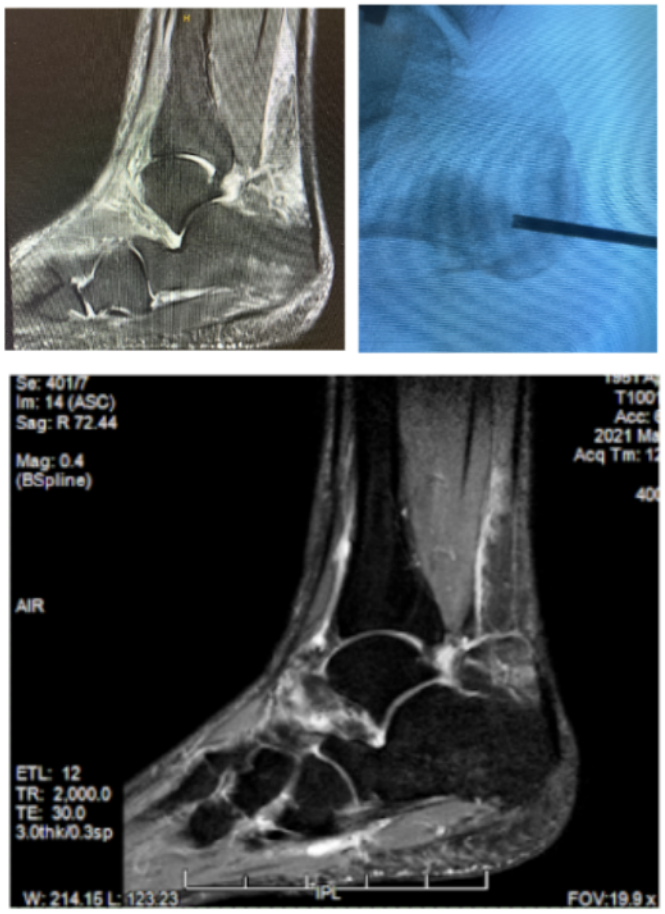

Figure 6 Preoperative MRI, intraoperative fluoroscopic view, and postoperative MRI of calcium phosphate treatment of calcaneal stress fracture.

Of these three patients, two of the patients had other attributed traumas that associated with their increased pain and a minimally invasive attempt was made to alleviate these pains in a short time period.

Further evaluation of participants in this study revealed that 13/27 patients were seen to have pain at the infracalcaneal aspect of the foot. These patients had been dealing with chronic heel pain and had been symptomatic for years. Investigation based on the questionnaire results identify that the participants suffering from chronic plantar fasciitis or heel spur syndrome had 100% pain relief from the calcium phosphate injection. Figure 6 identifies a 69 year-old female patient who was treated for calcaneal stress reactions. The pre-procedure MRI was performed in July of 2020. The intraoperative fluoroscopy was obtained in August 2020 and the final MRI was obtained seven months postoperatively in March 2021. 1.5cc of calcium phosphate was used to address the calcaneal stress changes with relief of symptoms identified two weeks post-procedure.

The participant was contacted twenty-two months post-procedure and related that she remained 100% pain-free without any limitations of activity. Our results suggest that calcium phosphate used for chronic plantar fasciitis is more effective than a plantar fasciotomy as the injectable graft addresses the main etiology of the heel pain.

Review of present literature revealed the use of subchondroplasty in patients with bone marrow edema specifically in the knees has positive effects on patients [4]. In a study published by Byrd, et al., patients were evaluated using a follow-up questionnaire in short term and midterm (>2 year) follow-ups before and after their SCP procedure. These patients had all failed conservative measures and were candidates for TKA at the time. 133 of 143 SCP patients with the average age of 57 yrs-old (38-84) responded to the questionnaire. Short-term groups with average follow-up of 14.6 months showed a satisfaction rating of 8.3/10 with 82% willing to do SCP again and 89% recommending the treatment to others. The midterm group with average follow-up of 32.1 months showed a satisfaction rating of 8.5/10 with 95% willing to do SCP again and 96% recommending. SCP was seen as an effective and well received treatment for patients with knee Osteoarthritis and BME.

More than 50% of stress fractures occur to the lower extremity [9]. Most literature regarding SCP is in regards to use in the knees with osteoarthritis with emphasis noted to movement towards lower extremity use with imaging playing a strong role in the factors that allow SCP to show outcomes. In a recent piece of literature published by McWilliams et. al goes further into the discussion of the use of subchondroplasty of the ankle and hindfoot region regarding the treatment of osteochondral lesions (OCD) and stress fractures [10,11,12]. Eighteen patients (ten males and eight females) with an average age of 43.1 year old underwent procedures to the ankle/hindfoot region with the use of SCP over a total of 14 months. Patients received a variety of imaging studies, CT, MRI preoperatively and postoperatively to verify reasoning for treatment and success or failure of treatment during the postoperative period. Patients in this study all suffered from either symptomatic bone marrow lesions secondary to osteochondral lesions or stress fractures. Sixteen of the eighteen subjects in the study had a BML secondary to an OCD. During the postoperative period, MRI imaging showed a decrease in size of BML and extra-osseous extrusion of CaP was not seen on postoperative imaging. The treatment of the BML's secondary to OCD or stress fractures were not able to be identified after a certain period of time on these patients showing full healing of these lesions and fracture sites. This study's ultimate goals were to describe the pre and postoperative findings of SCP on imaging of the foot and ankle and the lack of lesion noticed after a postoperative period demonstrating the effects SCP has on these lesions and how quickly it produces results. While many stress fractures can be treated conservatively, certain areas of fractures are harder to treat such as avascular structures of the talus and areas of the calcaneus. With the addition of calcium phosphate to the area of stress fractures, bone is allowed to heal as it is assisted in the callus forming processing needed for primary and secondary healing.

Conclusion

Stress fractures commonly occur in individuals who suffer from mild traumatic events, repetitive force, and overuse injuries resulting in bone quality degradation. Although these injuries usually are amenable to conservative treatment, the authors have found that early intervention with an injectable allograft allows for faster healing with good long term functional outcomes.

This retrospective analysis presented positive outcomes for the treatment of bone marrow lesions with calcium phosphate injections. One limitation of this study was the small sample sized participant group with various foot and ankle pathologies. A larger sample size focused on one specific pathology would yield more accurate results on the efficacy of the procedure.

Injectable bone grafting has a profound effect on the ability for a patient to return to an active lifestyle with minimal downtime and pain. After conducting the postoperative questionnaire, the majority of participants presented after their first postoperative visit with no pain to the injured area and returned to full activity. This study presented significant and relevant evidence for the improvement in pain, lifestyle and positive clinical outcomes in the use of calcium phosphate for stress fractures of the calcaneus and talus. This less invasive procedure allows for minimal surgical intervention and time

under anesthesia to reduce fracture sites and improve healing to the defective bone site. Imaging modalities such as that of x-ray demonstrate a good incorporation of the bone graft in the areas of the stress fractures showing evidence of bone remodeling. The investigators of this study feel that due to the favorable outcomes the participants showed in this study, a larger study would be warranted for the exploration in a prospective controlled trial aimed specifically at certain regions of the foot and ankle with an associated diagnoses such as plantar fasciitis and infracalcaneal bone marrow lesions.

Financial Disclosure

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Competing Interest Statement

None

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