



Percutaneous Skeletal Fixation of Painful Subchondral Bone Marrow Edema Utilizing an Injectable, Synthetic, Biocompatible Hyaluronic Acid–Based Bone Graft Substitute

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Abstract: Subchondral bone marrow edema (SBME) represents a pathologic alteration of subchondral bone. A strong correlation exists between its presence and the progression of osteoarthritis. Very few treatment options exist between the spectrum of conservative management and the definitive treatment of total knee arthroplasty (TKA). Tactoset® is an injectable synthetic, biocompatible hyaluronic acid–based bone graft substitute that allows for a minimally invasive treatment for painful SBME via percutaneous skeletal fixation (PSF). We present the technique of PSF using Tactoset.

Early osteoarthritis of the knee is a well-recognized cause of pain and disability among men and women in the United States, ultimately creating a significant burden on our health care system. Millions of patients will be affected at some point in their lifetimes, resulting in decreased quality of life and significant economic impact in terms of health care costs and lost productivity.¹ Osteoarthritis is defined as a loss of articular cartilage and joint space narrowing; however, significant evidence has shown that subchondral bone marrow edema (SBME) resulting from subchondral insufficiency fractures is both indicative and predictive of worsening osteoarthritis.^{2,3} SBME represents a pathologic alteration of subchondral bone, with histological analysis demonstrating bone

marrow necrosis and fibrosis, abnormal trabeculae, increased vascularization, and microfractures.^{4,5} Multiple studies have proven that once a focus of SBME is detected in patients with early knee osteoarthritis, the need for total knee arthroplasty (TKA) becomes highly predictable, with 1 study demonstrating that patients were 9 times more likely to progress to TKA over a 3-year period than patients with no identifiable SBME.⁶ Interestingly, SBME often appears before established joint degeneration occurs, and thus is a possible candidate for the long-sought indicator of early osteoarthritis that can be detected before irreversible cartilage degeneration.⁷

TK) has been recognized as a proven treatment option for osteoarthritis and the pain associated with insufficiency fractures related to SBME. However, the management of younger patients with early degenerative changes or SBME who have failed conservative management remains a perplexing and often trying dilemma for the patient and treating surgeon. TKA in these patients is certainly not guaranteed to last their lifetime, with the literature demonstrating that younger patients have a substantial risk of aseptic loosening requiring early revision surgery.^{8,9} For these reasons, less-invasive, joint-preserving treatment options are desirable, particularly in younger patients or those seeking to delay TKA.

Tactoset® (Anika Therapeutics, Bedford, MA) is an injectable synthetic, biocompatible hyaluronic acid–based bone graft substitute material intended for filling bone voids or defects of the skeletal system that are

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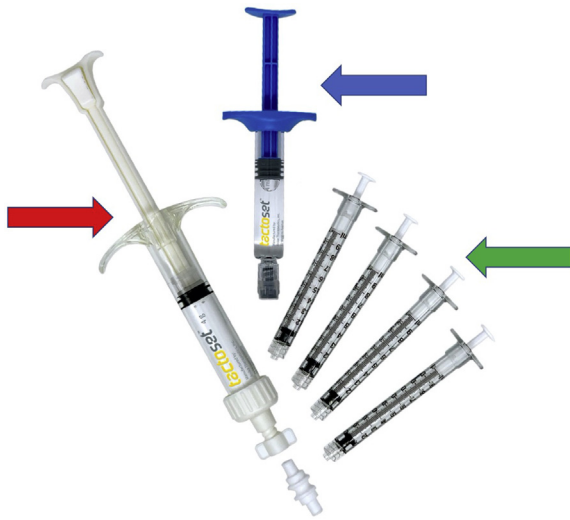


Fig 1. The Tactoset® system provides a prefilled syringe of calcium phosphate powder (red arrow) with a syringe of hyaluronic acid (blue arrow). They are combined in a sterile, closed system that allows for the injectable to be transferred to four 1-cc syringes (green arrow) for use.

not intrinsic to the stability of bony structure (Fig 1). The Tactoset system provides an injectable, self-setting, osteoconductive bone graft substitute that hardens, is resorbed, and is replaced by the growth of new bone during the healing process. The combined hyaluronic acid and calcium phosphate injection remodels to hydroxyapatite, the mineral component of bone.

Tactoset allows for a minimally invasive treatment option for painful SBME via percutaneous skeletal fixation (PSF) (Fig 2). The goal of the procedure is to improve the structural quality of the affected subchondral bone and promote local bone remodeling while preventing subchondral bone collapse and subsequent progression of osteoarthritis.^{2,3,10} To date, PSF has yielded acceptable results with predictable pain relief through a minimally invasive approach, allowing patients to resume activity quickly, with few known complications. A recent study followed patients for a 2-year period after PSF treatment of painful SBME and noted significant improvements in pain and function, with only a 6.8% conversion rate to TKA at 2 years postoperatively.¹¹

Surgical Technique

Indications

The indications for percutaneous skeletal fixation of painful SBME are based on history, physical examination, and magnetic resonance imaging (MRI) findings. A patient can be considered for PSF who has failed conservative management (physical therapy and injections) as well as has MRI findings of SBME that correlate with symptoms. It is also required that the patient not have any concomitant intra-articular pathology or moderate

to severe osteoarthritis that could also explain the symptoms, as PSF is a treatment for isolated SBME rather than diffuse degenerative changes.

Patient Evaluation and Imaging

Upon evaluation of a patient, a thorough history and physical examination should be performed. Patients typically describe the pain of SBME as a deep, aching pain that can be aggravated by physical activity. On physical examination, pain and tenderness can often be reproduced through percussion or placement of a tuning fork over the area of involvement. It is recommended that weightbearing radiographs be obtained to rule out any fracture or degenerative changes (Fig 3A, B). MRI, however, is the gold standard in terms of diagnosis of SBME. On MRI, SBME is identified by a region of hyperintense signal on T2-weighted or short tau inversion recovery sequences, as well as a region of hypointense signal on T1-weighted sequences (Fig 4A, B).

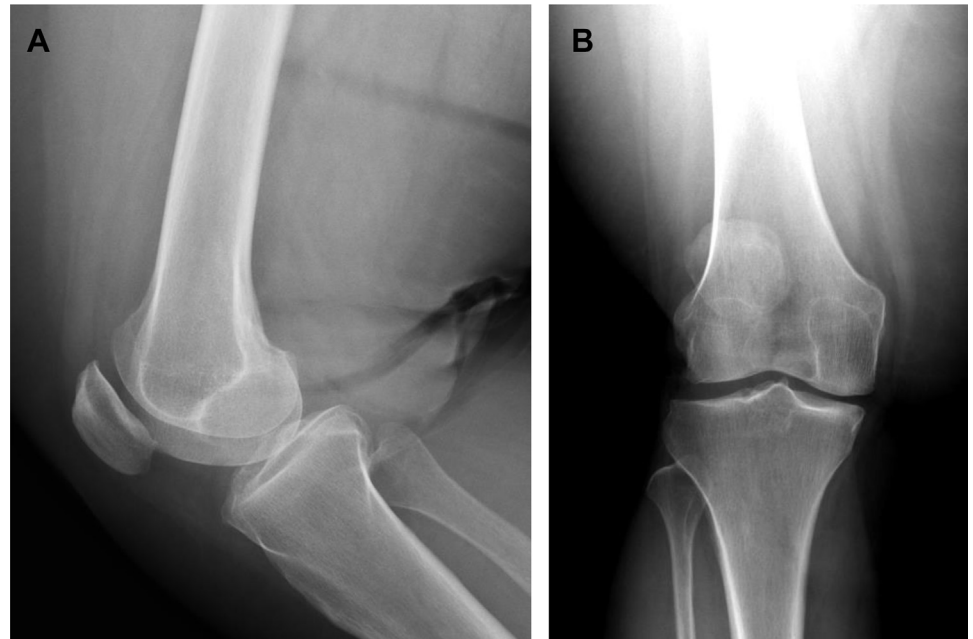
Technique

The patient is taken to the operating room and placed on a radiolucent table in the supine position. After general anesthesia is administered, the patient is prepped and draped in a sterile fashion. The operating room setup (Fig 5) allows for the surgical arthroscopy tower



Fig 2. The Tactoset® system contains an 11-gauge, black-handled, drillable outer pin. The blue arrow indicates the cannula lock, which always faces the direction of the side-delivery holes at the end of the cannula. Once in the appropriate location, the inner sleeve of the pin can be removed to allow for either a single end delivery (blue) or 3-hole side delivery (green) of the injectable. A metal push rod is available to remove the excess calcium phosphate from the chamber of the delivery pin.

Fig 3. Weightbearing lateral (A) and anteroposterior (B) x-rays revealing mild signs of osteoarthritis.



to be positioned toward the head of the bed on the contralateral side of the affected limb. The C-arm is positioned on the contralateral side as well, with clearance to be able to enter the sterile field for direct anteroposterior (AP) and lateral imaging in relationship to the knee. A Mayo stand is positioned on the ipsilateral side of the affected limb toward the head of the bed to allow for the MRI images identifying the SBME location to be readily available by the treating surgeon on a laptop. See [Video 1](#) for demonstration.

At the commencement of the surgical arthroscopy, the scrub nurse begins mixing the Tactoset. Using the closed mixing system, the hyaluronic acid and calcium phosphate are mixed for 60 seconds, and the four 1-cc syringes are filled. It is recommended that the syringes be placed on the table rather than held in a hand until needed: this will prevent premature setting of the calcium phosphate. The working time from mixing until hardening within the bone is typically 15 to 20 minutes. During the arthroscopy portion of the case, identification

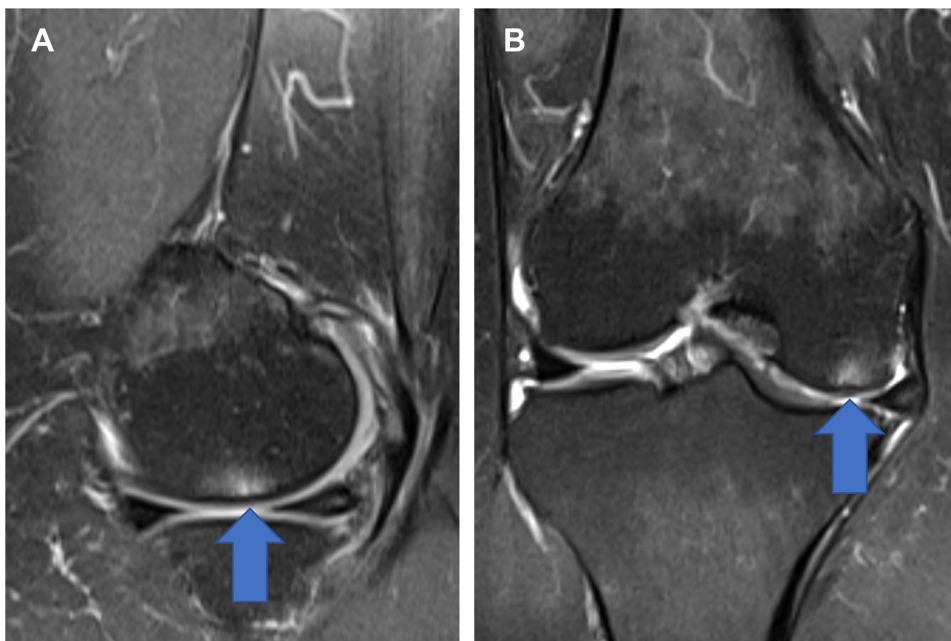


Fig 4. T2-weighted magnetic resonance coronal (A) and sagittal (B) images demonstrating subchondral bone marrow edema (SBME) (arrows) within the weightbearing surface of the medial femoral condyle.

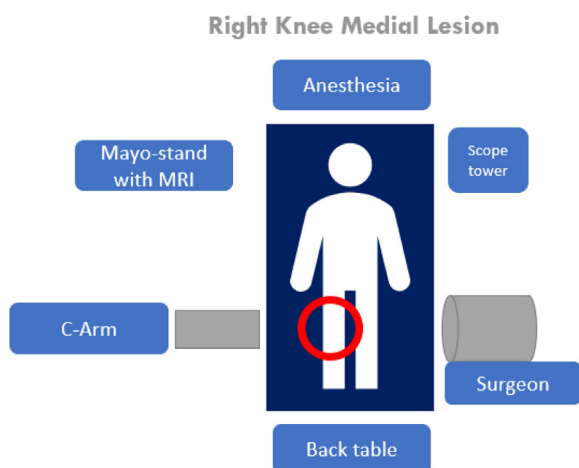


Fig 5. The operating room is positioned to allow for the C-arm to enter from the contralateral side of the affected limb. A Mayo stand with a laptop open displaying the magnetic resonance images should be available to make intraoperative triangulation of the subchondral bone marrow edema (SBME) even simpler and more precise for the operating surgeon.

of the cartilage defect on the femoral condyle is noted to correlate with the location of the SBME, as noted on the bedside MRI images. A spinal needle is used in an outside-in technique at the level of the joint line to provide reference for the SBME and corresponding cartilage damage (Fig 6). This pearl can be a useful landmark for the surgeon in patients with a larger body habitus during targeting of the SBME with the 11-gauge pin (Table 1).

After completion of the surgical arthroscopy, attention is turned to the percutaneous skeletal fixation. The lead author prefers to stand on the side of the lesion to allow for ease of pin drilling. As such, to best treat a

medial femoral condyle lesion, the surgeon moves to the contralateral side of the bed. With the pin against the skin at the area of the previously marked spinal needle location, a true AP fluoroscopic image is taken and compared with the coronal T2 MRI image on the monitor. After location confirmation, the pin is percutaneously pierced and placed against the cortex of the medial femoral condyle. A radiolucent triangle is next positioned beneath the operative knee to allow for a true lateral fluoroscopic image. Fluoroscopy is again used to confirm the pin position against the condyle in relationship to the SBME on the T2 sagittal MRI (Fig 7A, B).

After AP and lateral fluoroscopy confirmation, the pin is driven into the medial femoral condyle under power with care taken to not drill past the lesion. Next, the inner sleeve of the drill pin is removed, and the green, 3-hole side-delivery pin sleeve is inserted. The lead author prefers the side-delivery pin for femoral lesions and the end-delivery pin for tibial and patellar lesions. Identification of the location of the side-delivery holes can be recognized, as once the inner guide is snapped into the outer sheath, the holes face the direction of the cannula lock (Fig 2). The calcium phosphate is then delivered with thumb pressure into the lesion (Fig 8). It is important to not overpressurize the lesion. When resistance or tactile “pushback” is met, the lead author recommends rotating the pin 90° and then continuing the injections. Once the pin has been rotated 360°, the inner cannula is removed and replaced by the push rod for 5 to 7 minutes while the calcium phosphate sets. During this time, the lead author recommends reinserting the arthroscope into the joint to ensure that none of the calcium phosphate has extruded into the joint. A shaver can be used to easily remove any calcium phosphate if found.

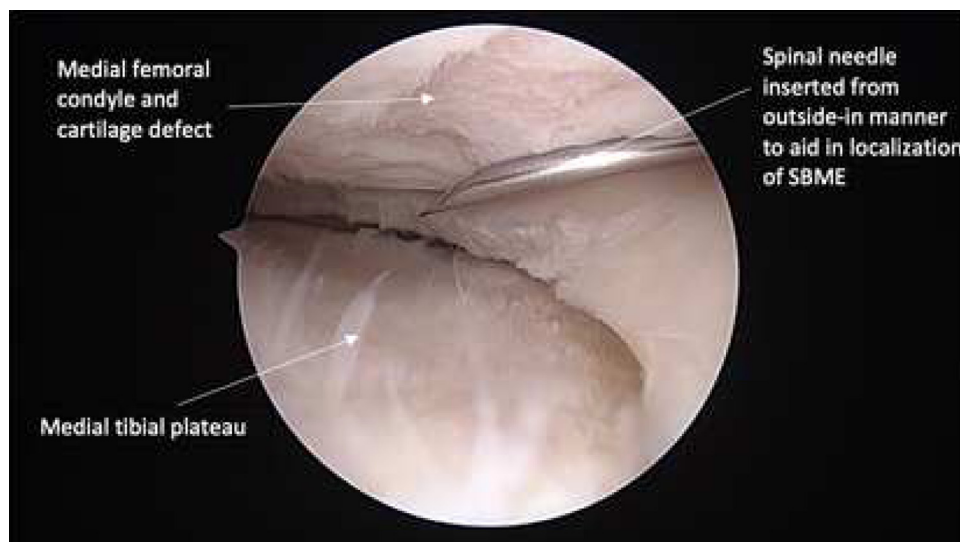


Fig 6. Arthroscopic view of the medial compartment of the knee, demonstrating a cartilage defect on the medial femoral condyle. A spinal needle can be used in an outside-in manner at the location of cartilage damage to aid in triangulation of the subchondral bone marrow edema (SBME) while comparing with the magnetic resonance images. This extra confirmation can aid in reducing misfiring of the drill pin, particularly in patients with high body mass index.

Table 1. Pearls and pitfalls**Pearls**

A preoperative evaluation to thoroughly assess for any concomitant pathology is necessary to achieve a positive postoperative outcome. Laptop with sagittal and coronal magnetic resonance images of bone marrow lesion (BML) can be placed on a Mayo stand at the head of the bed for surgeon reference.

A spinal needle can be used in an outside-in technique at the level of the joint line to provide reference for the BML and corresponding cartilage damage.

If a pin is misdirected into the incorrect location, leave it in place, both to serve as a guide for the second pin placement and to avoid cement extravasation from this pin tract.

When resistance or tactile “pushback” is met during injection, rotating the pin 90° allows for further flow of calcium phosphate, completely filling the void.

While the cement is setting, reinsert the arthroscope to examine the joint for any calcium phosphate extravasation. Any free calcium phosphate can be easily removed with a shaver.

Pitfalls

Must obtain perfect anteroposterior and lateral fluoroscopic images to adequately locate and triangulate the area of bone marrow edema.

Drilling too close to subchondral bone can lead to cement extravasation into the joint once the defect is filled.

Care should be taken to avoid overcompression of calcium phosphate cement into the subchondral bone. Overfilling the defect may be associated with increased immediate postoperative pain and extravasation into the joint.

Once the calcium phosphate has completed hardening, it is recommended to inject local anesthetic to the periosteum at the location of the pin for analgesia before removing the pin from the condyle via hand or power. A final fluoroscopic image can be taken once the pin is removed for confirmatory purposes.

Postoperative Protocol

Postoperatively, the patient is weightbearing as tolerated (WBAT) on crutches for 2 to 3 days for comfort. A 5-day course of opioid and anti-inflammatory

medications is provided, as well as instructions to ice the area. Physical therapy is typically begun 7 to 10 days after the procedure, with a focus on quadriceps and core strengthening. Routine radiographs are taken in the office at the initial follow-up visit.

Complications

Overall, PSF for SBME is a very safe procedure. A literature review was conducted by Astur et al.,¹² who found that the most common complaint following these procedures is disproportionate knee pain. The pain was noted to improve by 72 hours postoperatively. The only other 2 complications noted were calcium phosphate extravasation into the joint, which is easily removed with an arthroscopic shaver, and 1 patient who suffered deep vein thrombosis.¹²

Coding

When treating these patients, the lead author prefers to use ICD-10 code M84.453A, recognizing that SBME is a result of an insufficiency fracture in the subchondral bone. When treating these areas of edema, the lead author uses CPT code 27509 or percutaneous skeletal fixation of femoral fracture, distal end, medial, or lateral condyle. When treating SBME in the tibia, the lead author uses M84.469A and CPT code 29855.

Discussion

Insufficiency fractures related to SBME are an often-underrecognized source of knee pain in patients. They have been shown to have a high predictive level of need for TKA.⁶ Through interceding with the treatment of percutaneous skeletal fixation for these insufficiency fractures, a plausible alternative to TKA exists for younger patients or those unable or unwilling to have a TKA. Understanding the presentation of the symptoms with a thorough history and physical examination will lead to ordering the appropriate imaging to identify

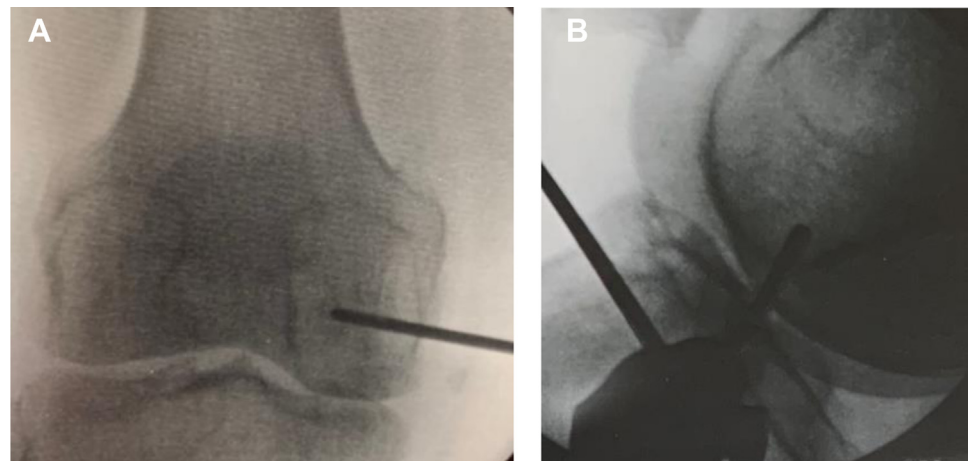


Fig 7. (A) Anteroposterior and (B) lateral fluoroscopy of pin placement correlating to the location of the subchondral bone marrow edema (SBME) on magnetic resonance images.



Fig 8. Through the 3-hole side-delivery cannula, the calcium phosphate injectable is delivered using thumb pressure to allow for tactile feedback when the lesion is filled. The pin has been placed within the circle drawn on the skin where the spinal needle had localized the intra-articular cartilage defect and correlating to the subchondral bone marrow edema (SBME) on the magnetic resonance images.

these lesions. Anecdotally, the lead author will often use a tuning fork during the physical examination and place it over the area of complaint. If the patient reports reproduction of the pain generated by the tuning fork, this further supports ordering an MRI to identify the SBME. A thorough discussion with the patient as to the expectations and literature-based outcomes on the procedure is paramount to ensure outcomes meet expectations.

The treatment of insufficiency fractures has become significantly more common over the past decade, with a variety of modalities currently available on the market. Despite the relative success of some of these modalities, gaps in the treatment of these lesions still exist. The Tactoset system offers the ability to percutaneously treat painful insufficiency fractures related to SBME through enhanced techniques of delivery of a hyaluronic acid–infused calcium phosphate injectable. The

addition of the hyaluronic acid increases the flow of the calcium phosphate in comparison to other available injectables. This ability allows for it to interdigitate with the remaining bony trabeculae rather than crush it. As such, the potential to remodel and heal the lesion is predictable. Through appropriate patient identification, proper techniques, and the management of patient expectations, the Tactoset system can allow for the reduction of pain in patients with painful SBME in a minimally invasive way.

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