

Mg OSTEOCRETE™

Case Studies

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Mg OSTEOCRETE™

Case Study: Osseous Remodeling in Void Backfill with Mg OSTEOCRETE After Hardware Removal

Thomas L. Hand, MD- UT Health San Antonio

20YO F.

Recalcitrant nonunion right distal femoral diaphysis.

Hardware removed. Retrograde motorized compression nail at nonunion.

15cc Mg OSTEOCRETE injected to protect neck bone void.

Progressive resorption of Mg OSTEOCRETE from 6 weeks to 3 months post-op.











Bone trabeculae visualized extending across regions where Mg OSTEOCRETE was injected.

Sclerotic rim from previous screw is less evident.

Minimal Mg OSTEOCRETE is radiographically visible.





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These results are specific to this individual only. Individual results and activity levels after surgery vary and depend on many factors including age, weight, and prior activity levels. There are risks and recovery times associated with surgery, and there are certain individuals who should not undergo surgery. Mg OSTEOCRETE is not intrinsic to the stability of the bone.

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CASE STUDY

Calcaneal Fracture with Mg OSTEOCRETE Bone Substitute

CLINICAL SCENARIO/ PRE-OPERATIVE IMAGING

Twenty-five year old male presented with an acute comminuted pathologic calcaneal fracture with subtalar joint extension. The patient was sliding down a hill and sustained this low energy mechanism fracture.

CT imaging confirmed the pathologic nature of the fracture given a large underlying calcaneal bone cyst.



Pre-Op: Acute calcaneal pathologic fracture

SURGICAL INTERVENTION WITH HARDWARE FIXATION AND MG OSTEOCRETE

Treatment:

After surgical approach to the fracture site, the fracture fragments were mobilized and reassembled with lateral plate and screw fixation. In order to promote stabilization, the highly comminuted fracture superimposed on the large cystic void, the void was filled with a resorbable bone cement. The Mg OSTEOCRETE Bone Void Filler was prepared until it reached a liquid/pasty viscosity and then 10cc was injected into the void. Final fixation yielded near anatomic alignment of the calcaneus.



Immediate Post-Op: Demonstrates reduced calcaneal fracture with plate and screw fixation + Mg OSTEOCRETE augmentation

6-Week Follow Up:

At the 6-week follow up, some initial resorption of the Mg OSTEOCRETE was observed on the x-ray along the periphery of the filled void area. Additionally, the density of the Mg OSTEOCRETE was decreased overall when compared to the immediate post-op x-ray.



6-Week Follow Up: Demonstrates some early remodeling

10-Month Follow Up:

When the patient returned for a 10-month follow up, the x-rays demonstrated progressive remodeling of the graft and complete fracture healing. The cyst area was filled with normal trabecular bone and minimal residual bone void filler. The patient did not suffer any postoperative complications.



10-Month Follow Up: Demonstrates fracture healing with almost complete resorption of Mg OSTEOCRETE and resolution of underlying bone cyst



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Mg OSTEOCRETE™

Case Study: Calcaneal Fracture Repair with Mg OSTEOCRETE

Thomas L. Hand, MD- UT Health San Antonio



Lateral surgical approach. Elevation of impacted posterior facet followed by plate and screw fixation.

36 YO M, fall from roof. Comminuted calcaneal fracture with impaction of the

posterior facet.

10cc **Mg OSTEOCRETE** was used to fill the residual bone void.

Mg OSTEOCRETE resorption visualized within 4 months as demonstrated by decreased opacity of the bone graft and blurring of the peripheral margins.









Resorption After 7 Months



Marked decreased opacity of bone graft posteriorly with bone trabeculae formation noted throughout the graft area.

Residual **Mg OSTEOCRETE** remains anteriorly, but opacity of bone graft area with trabeculae formation is decreased.

Lateral cortex is well-healed.



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CASE STUDY

Femoral Large Void filled with Mg OSTEOCRETE Bone Substitute

CLINICAL SCENARIO/ PRE-OPERATIVE IMAGING

Patient presented pain with ambulation due to a proximal femoral unicameral bone cyst (UBC). Concern for femoral neck fracture with continued ambulation.



Pre-Op: Proximal Femoral Unicameral Bone Cyst

SURGICAL INTERVENTION

First Surgical Intervention: Demineralized Bone Matrix

Patient was treated with prophylactic ORIF and synthetic grafting with DBM. Post-op six months, there was no graft incorporation and the patient continued to experience ongoing pain, ultimately requiring further treatment.



First Surgical Intervention: 6 Month Post-Op

Second Surgical Intervention: Calcium Phosphate/Sulfate Bone Void Filler

Cyst area was treated with aggressive curettage and filled. At 10-months post-op, filler was resorbing but cortical bone was thin with no presence of structural bone and cyst continued to expand.



Second Surgical Intervention: 10 Month Post-Op

Third Surgical Intervention: Mg OSTEOCRETE

Cyst area was treated with additional curettage and hardware was replaced. The area was injected with 80cc of Mg OSTEOCRETE.



Third Surgical Intervention: Immediate Post-Op



Third Surgical Intervention: 1 Year Post-Op

RESULTS

At one year post-op, the Mg OSTEOCRETE continued to remodel into trabecular bone. Cortical bone was formed and the femoral neck thickness increased. Patient was pain-free and returned to normal activity within six months of treatment.

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CASE STUDY

Distal Humerus Fracture with Mg OSTEOCRETE Bone Substitute

CLINICAL SCENARIO/ PRE-OPERATIVE PLANNING

Patient is a 75 y/o female that fell from standing directly onto her left elbow and presented with a Grade I open left distal humerus fracture. Initial radiographs revealed a comminuted supracondylar, with intercondylar extension, fracture of the distal humerus. Due to medical co-morbidities, surgical clearance was delayed for 48 hours. Due to the complexity of the injury, the initial surgery was limited to I&D and subsequently referred to the trauma attending for definitive fixation.



Pre-Op: AP and Lateral Radiographs of Humeral Fracture

TREATMENT

Posterior approach to the distal humerus was performed, the fracture was reduced and internal fixation applied to the medial and lateral columns utilizing 180-degree plating. Due to the comminuted nature of the open fracture and the debridement of loose bone fragments, a void was present centrally. This void was felt to be best managed with a resorbable bone cement and thus 5cc of Mg OSTEOCRETE Bone Void Filler was prepared and packed into the defect. Final fixation showed anatomic restoration of the distal humerus.



Intraoperative Clinical Photo with Mg OSTEOCRETE in the Osseous Defect



Intraoperative Fluoroscopic Image Demonstrating Osseous Void



Intraoperative Fluoroscopic Image After Mg OSTEOCRETE Implantation

RESULTS

6-Week Follow Up:

At the 6-week follow up, the incision had healed without signs of infection. The Mg OSTEOCRETE was still visible and hardware was intact. There was no loss of alignment or failure of fixation.

At the 3-month follow up, the patient's pain was 1/10. Elbow range of motion extended from 30-110 degrees and she had full supination/ pronation. Radiographs show continued fracture consolidation and



6-Week AP and Lateral Radiographs



6-Week AP and Lateral Radiographs



3-Month Follow Up:

incorporation of the Mg OSTEOCRETE.

At the 5-month follow up, the patient's exam remained unchanged. Radiographs show further incorporation of the Mg OSTEOCRETE (an average of 60% resorption) and fracture healing, especially along the anterior cortex.



5-Month AP and Lateral Radiographs



1-Year AP and Lateral Radiographs

1-Year Follow Up:

At the 1-year follow up, the patient had no pain and gained additional motion. Her elbow range of motion now extended from 10 to 130 degrees and she maintained full pronation/supination. Radiographs show complete incorporate of the Mg OSTEOCRETE.



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Mg BONE SOLUTIONS

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10212 Rev C

Mg OSTEOCRETE[™]

Case Study: Bicondylar Tibial Plateau Fracture Repair with **Mg OSTEOCRETE**

Thomas L. Hand, MD- UT Health San Antonio



54 YO F, fall from skateboard.

Left bidondylar tibial plateau fracture with significant lateral impaction.

Medial and lateral surgical approach. Initial fixation of the medial condyle, followed by reconstruction and fixation of the lateral condyle to the medial plateau.

15cc **Mg OSTEOCRETE** was used to fill the lateral condyle metaphyseal bone void.

Mg OSTEOCRETE resorption visualized within 3 months as demonstrated by decreased opacity of the bone graft and increased irregularity and blurring of the peripheral margins.





Resorption After 7 Months



Bone trabeculae formation noted around the periphery of the bone graft.

Mg OSTEOCRE

Residual Mg OSTEOCRETE noted centrally.

Decreased distinction of peripheral rim of new bone formation/graft resorption area. Well-healed lateral cortex.



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CASE STUDY

Unicameral Cyst Distal Femur filled with Mg OSTEOCRETE Bone Substitute

PRE-OPERATIVE IMAGING

A unicameral bone cyst (UBC) was identified and the patient underwent surgical intervention.



Pre-Op: Distal Femoral Unicameral Bone Cyst

SURGICAL INTERVENTION

Surgical Intervention: Mg OSTEOCRETE

The cyst area was debrided, treated with curettage and the area was filled with Mg OSTEOCRETE. At 5 months post-op, x-rays showed remodeling and incorporation of new bone. The bone continued to remodel over time as shown in the x-rays taken 29 months post-op.



Post-Op: Filled Distal Femoral Cyst Site



5 Months Post-Op: No Subsidence of Product



10 Month Post-Op



15 Month Post-Op



29 Month Post-Op: Evidence of Bone Remodeling



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CASE STUDY

Posterior Lumbar Interbody Fusion Cage packed with/surrounded by Mg OSTEOCRETE Bone Substitute

PRE-OPERATIVE IMAGING

Posterior lumbar interbody fusion procedure with cage and fixation hardware.



Pre-Op: Vertebral Fusion Surgery Stabilized with Screws and Rods

SURGICAL INTERVENTION

Surgical Intervention: Mg OSTEOCRETE

L4-L5 secured with pedicle screws and rods. Cage implanted in interverterbal area and packed and surrounded by Mg OSTEOCRETE.



Intraoperative: Cage Packed/Surrounded by Mg OSTEOCRETE



6 Weeks Post-Op



6 Month Post-Op



1 Year Post-Op: Successful fusion at L4-L5 utilizing Mg OSTEOCRETE



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Case Study:

Lateral Malleolus Fracture: Delayed Fixation with Mg OSTEOCRETE Bone Void Filler



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A 48-year-old female presented with a lateral malleolus fracture after tripping. Patient initially did not want to have surgery and chose to attempt conservative management. After 10 weeks of non-weight bearing and immobilization, no signs of fracture consolidation were visualized radiographically. An MRI was ordered and images showed incomplete osseous bridging across the lateral malleolar fracture site and incomplete healing of the syndesmosis.



Fig 1A Radiographic image at initial presentation



Fig 1B Radiographic image after 10 weeks of conservative management



Fig 1C MRI delayed healing of the lateral malleolus fracture

Standard lateral malleolar open reduction approach was performed. The fracture line was recreated using an osteotome and mallet. Once the fracture line had been completed and the capital fragment was freed, a large defect remained once reduction had been achieved. With this free space between the fragments being too wide to heal, 5cc of Mg OSTEOCRETE Bone Void Filler was utilized to fill the gap. Mg OSTEOCRETE Bone Void Filler was prepared until it reached a paste-like consistency and was applied within the fracture fragment site that had been created. Fixation was then implemented, and anatomic reduction of the ankle joint was achieved.

The patient fell and twisted the operative extremity during the post-operative period. This resulted in the patient being non-weight bearing for 10 weeks.

Due to the patient experiencing a fall and having some ankle discomfort, an MRI was ordered 12 weeks post-operatively to ensure there was healing across the fracture site.



Fig 2 Immediate post-op radiographs demonstrating presence of Mg OSTEORETE Bone Void Filler with lateral malleolar fracture fixation and syndesmotic screw fixation



Fig 3 Radiographic image 10 weeks post-op



Fig 4 MRI was limited due to metal artifact, but ongoing healing was confirmed given lack of fracture gap formation and remodeling at site of bone graft placement

At the patient's 9-month follow-up, the patient had no pain and radiographic images showed Mg OSTEOCRETE resorption and complete osseous remodeling across the fracture site. The patient was now able to perform daily acts of life painfree.









Case Study:

Tibial Plateau Fracture with Mg OSTEOCRETE Bone Void Filler



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Case Study: Tibia Plateau Fracture filled with **Mg OSTEOCRETE**

Robert J Wetzel, MD Assistant Professor Case Western Reserve School of Medicine Fellowship Director, Orthopaedic Trauma University Hospitals Cleveland Medical Center



56YO F, Fall Down Flight of Stairs

Proximal Tibia Fracture

10 cc Mg OSTEOCRETE was used to fill the void in the tibia plateau along with internal fixation hardware.

At 12 and 20 weeks, x-rays showed signs of remodeling of the bone graft material and new bone formation.

Conclusion

At 12 weeks, the patient was weight-bearing and had full range of motion. The average resorption rate of the Mg OSTEOCRETE was 60%.

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Case Study:

Calcaneal Intraosseous Lipoma Excision with **Mg OSTEOCRETE**



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A 56-year-old female presented to the clinic with left heel pain that had been persistent for several months. Upon initial radiographic imaging, a well-circumscribed osteolytic lesion was seen in the calcaneus. Clinically, pain could be elicited upon calcaneal squeeze test. Magnetic resonance imaging (MRI) was then obtained demonstrating characteristic findings of a calcaneal intraosseous lipoma. Given risk of a pathologic fracture, it was elected to proceed with surgical intervention.



Fig 1 Radiographic image at initial presentation demonstrating a well-circumscribed osteolytic lesion.



Fig 2 MRI demonstrates a well-defined calcaneal lesion with internal fat signal measuring 2.0 x 1.7 x 1.8 cm. Findings reflective of intraosseous lipoma.

A curvilinear incision was made extending from the lateral aspect of the posterosuperior calcaneus to the lateral aspect of the calcaneocuboid joint under tourniquet. The bone tumor location was identified using intraoperative fluoroscopy. Power instrumentation was used to remove the lateral calcaneal cortex to gain access to the medullary canal with identification of the bone tumor. The bone tumor was removed in total and sent to pathology, which later confirmed the diagnosis of intraosseous lipoma. The defect at the site of the prior tumor was then filled with approximately 8 cc of a combination of Mg OSTEOCRETE and cancellous bone chips. The lateral calcaneal wall was reapproximated and closure was then performed in surgical layers. The patient was instructed to be non-weight bearing to the surgical foot for 6 weeks.



Fig 3 Intraoperative picture of calcaneal intraosseous lipoma contents.



Fig 4 Postoperative radiograph immediately after surgery demonstrating Mg OSTEOCRETE in previous intraosseous lipoma location.

At the 3-month follow-up appointment, radiographic imaging demonstrated residual Mg OSTEOCRETE centrally, with the peripheral border undergoing resorption and bone remodeling. Healing of the calcaneal osteotomy bone window was also present.



Fig 5 3-Month postoperative radiograph showing incomplete incorporation of Mg OSTEOCRETE

At the 6-month follow-up appointment, radiographic imaging showed complete healing of the osteotomy, and progression of Mg OSTEOCRETE incorporation (with an average of 60% resorption) with an increased degree of remodeling peripherally and decreased residual bone graft centrally. The patient was pain-free without complications.



 Fig 6
 6-Month postoperative radiograph revealed continued Mg OSTEOCRETE incorporation



