



## SEQUENTIAL USE OF NON BIODEGRADABLE AND BIODEGRADABLE LOCAL ANTIBIOTIC CARRIERS IN MANAGEMENT OF CHRONIC OSTEOMYELITIS

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### Abstract

**Purpose:** To report our experience with two-stage treatment of chronic osteomyelitis using a prospective protocol involving the use of the antibiotic loaded PMMA beads followed by antibiotic-loaded calcium sulphate pellets after bony debridement. **Patients and methods:** A single patient of age 58 years was treated according to a protocol that included surgical debridement of bone and infected tissues, local antibiotic therapy including vancomycin loaded on PMMA gentamycin loaded on calcium sulphate space filling biodegradable pellets along with intravenous antibiotics according to culture and sensitivity results. **Results:** After a minimum of one-year follow-up, infection was eradicated in the patient, the average rate of filling of the bony defect was 70.47%. **Conclusion:** The technique proved safety and efficacy in eradicating the infection and bony healing of the defects after debridement.

**Keywords:** Chronic Osteomyelitis; PMMA, calcium sulphate pellets, vancomycin and gentamycin



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### INTRODUCTION

Chronic osteomyelitis (chronic OM) is one of the oldest known diseases. Despite of the recent technologies and advances in microbiology and surgery, there is no general agreement on a single treatment strategy in the present time (1). This may be explained by the great variability of the offending organisms, clinical presentation, patients' health status and the extent of bone/soft tissue involvement (2). However, the role of surgical debridement is not a matter of debate (3). The major concern is the reliable safe antibiotic eradication method of the residual germs. The desired minimal inhibitory concentrations (MIC) when intravenous antibiotics are used may reach out toxic levels putting the hosts' health at risk (4). The principle of using locally acting antibiotics was developed as a solution that keeps desirable tissue antibiotic levels without threatening the hosts (5). Those antibiotics need a local carrier that is needed to maintain early and lengthy elution levels enough for bacterial elimination and prevention of biofilm formation (6).

Different kinds of carriers were tested both in vitro and in vivo. A widely used example is the polymethylmethacrylate (PMMA) that was used in different forms of eluting antibiotics (7). The major disadvantages were the late start of antibiotic release, low local concentrations of eluted antibiotics, the need for at least one additional surgery for its removal and bone grafting and the absence of any osteo-conductive potentials (8).

More recently, biodegradable ceramic carriers were used to fill the bony voids and provide an osteo-conductive potential for subsequent healing of the osseous defect as they dissolve away (9). Currently, many manufacturers provide these bio-composites commercially with encouraging results published in the literatures (10). However, there is still a risk of postoperative fractures ranging from 5 to 14% specially when larger bone voids remained after debridement (11).

The incidence of these fractures could be partly explained by the initial instability as a result of the radical excision of infected bony segments, but the absence of any osteo-inductive or osteogenic properties of these bio composites is another issue that may have an impact (12).

#### **CASE REPORT:**

**Patient Presentation and History:** A 58-year-old male presented with a history of discharging sinuses over right leg. There was previous history of RTA 7 years back which led to compound fracture at middle 3<sup>rd</sup> of Right Tibia and Fibula. Fracture fixation was done 2 days after said injury via Intramedullary interlocking nailing of Tibia with debridement of wound. Patient started to have discharge from the area of open wound 3 months followed by fixation. Wound debridement was done immediately after the complaints. Implant removal was done 18 months post fixation along with another round of debridement. 2 years post removal, patient sustained another RTA which led to degloving injury and depression fracture at lateral condyle of Right Proximal Tibia. Fixation was done using single CC screw with washer and skin graft is applied over the site of degloving injury.

Patient came to MGH 3 years later with chief complaints of 2 discharging sinuses over anteromedial aspect of middle 3<sup>rd</sup> of right leg since a year with non-healing ulcer over posterior aspect of middle 3<sup>rd</sup> of right leg. Swab was sent for culture and sensitivity which came out as MRSA positive.

**Clinical Evaluation:** There is 6x2cms defect over anteromedial aspect of middle 3<sup>rd</sup> of right tibia with 2 discharging sinuses in it. Skin surrounding the sinus and defect is puckered and has hyperpigmentation. Non healing ulcer of 9x3cms is present over middle 3<sup>rd</sup> of posterior aspect of right leg with irregular borders with pale, unhealthy granulation tissue on the floor of ulcer. Indurated edges are noted and base of ulcer is on anteromedial aspect of tibia. Hyperpigmentation is noticed surrounding the ulcer.

**Radiological evaluation:** Plain radiographs of the right leg in Anteroposterior and Lateral Views were taken showing Osteomyelitis changes

**Figure 1: Clinical pictures of Right leg (a) anterior view showing defect over anteromedial aspect of middle 3<sup>rd</sup> of right leg with 2 discharging sinuses (b) posterior view with Non healing ulcer**



**Figure 2: Radiographs of Right tibia and fibula in anteroposterior and lateral view**



**Surgical Procedure:** Under Spinal anesthesia, the affected right lower limb was thoroughly scrubbed, painted and draped under strict aseptic precautions.

**Stage -1:** Single CC screw with washer was removed from lateral condyle of proximal Tibia through 1.5cm stab incision under C arm fluoroscopic guidance. A 7cms incision is given over the defect with discharging sinuses on anteromedial aspect followed by soft tissue dissection and debridement was done by removing fibrous unhealthy tissue. After exposing the anteromedial aspect of Tibia, a single bony sinus is noted. A 3mm Kirschner wire is taken to make fenestrations around the bony sinus to create a window. An Osteotome with mallet are used to create an oval cortical window. Complete bony debridement is done by removing pus and infected tissue using bone scoop till paprika sign is seen. Edges of the cortical window were made smooth and even using bone nibbler. Thorough wash is given initially with betadine mixed normal saline of 1liter, followed by 3L normal saline wash is given using pulse vac. Operating area and the cortical window were dried out. In the meantime, PMMA was prepared along with addition of 2 ampules of Vancomycin. PMMA is molded over 16gauge SS wire into 10 to 12 beads of each 1cm and inserted into the space created via cortical window. Soft tissue flap coverage was planned after 6 weeks along with STIMULAN.

**Stage -2:** 6weeks after initial procedure, the bead of chain made with PMMA is carefully removed and all beads are recovered. There was no evidence of induced membrane formation. Another round of debridement is done. Meanwhile, Calcium Sulphate powder (STIMULAN) was prepared along with addition of 3 ampules of Gentamicin. A wait period of 15 to 20mins was given for the pellets to set in the provided silicone mould. Pellets were added and packed into the cavity via the cortical window. To cover large defect, a Transpositional flap of 13x6cms is taken from Anterolateral aspect of Right leg and positioned over the operated area on anteromedial aspect. The donor area is covered with Split skin graft taken from anterior aspect of Right Thigh. Non healing ulcer is debrided and covered with Split skin graft. Flap and graft are secured with staples. Operated area is covered with sterile dressing. An above knee POP slab is applied over Right lower limb.

STIMULAN was preferred over PMMA in stage 2 instead of retainment, as PMMA beads needs another surgery for removal which will damage soft tissue coverage(flap) planned for the case.

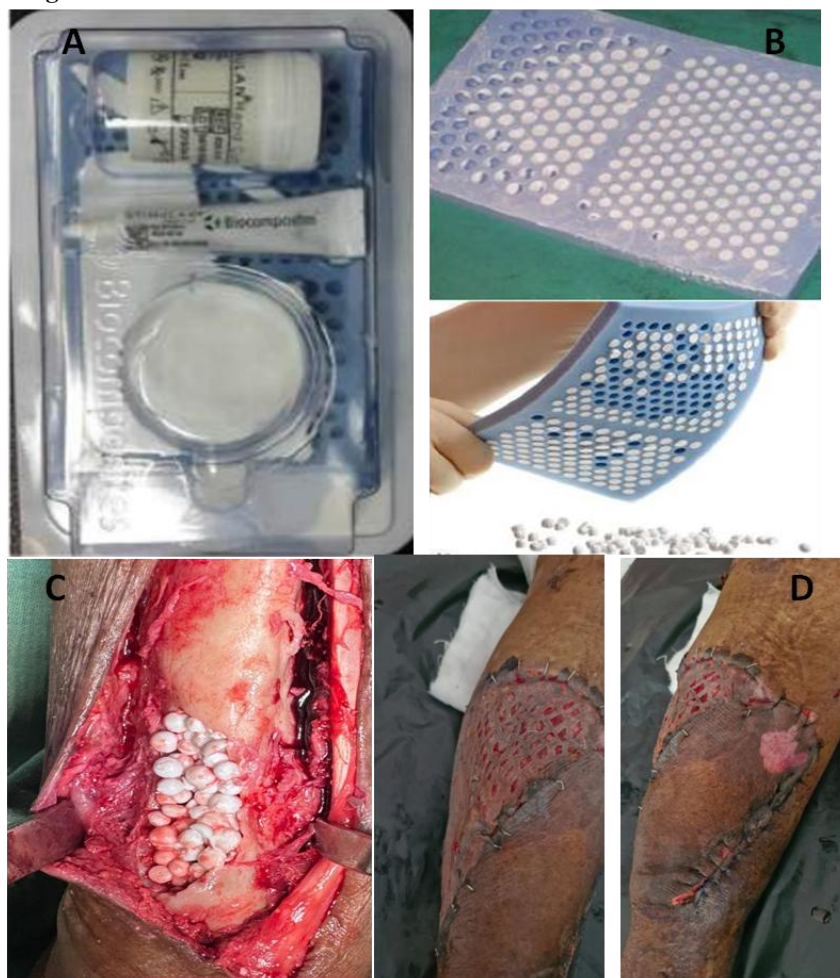
**Figure 3: Intraoperative images showing cortical window followed by bony debridement with paprika sign**



**Figure 4: Radiographs of Right tibia and fibula in anteroposterior and lateral view showing PMMA cement beads insitu**



**Figure 5:** Intraoperative picture showing, (A) Stimulan Rapid Cure kit. (B) Preparation of the pellets. (C) Pellets inside the osseous defect STIMULAN filled into bony window. (D) Transpositional flap of 13x6cms is taken from Anterolateral aspect of Right leg and positioned over the operated area on anteromedial aspect. The donor area is covered with Split skin graft.



**Figure 6:** Radiographs of Right tibia and fibula in anteroposterior and lateral view showing antibiotic impregnated calcium sulphate beads insitu

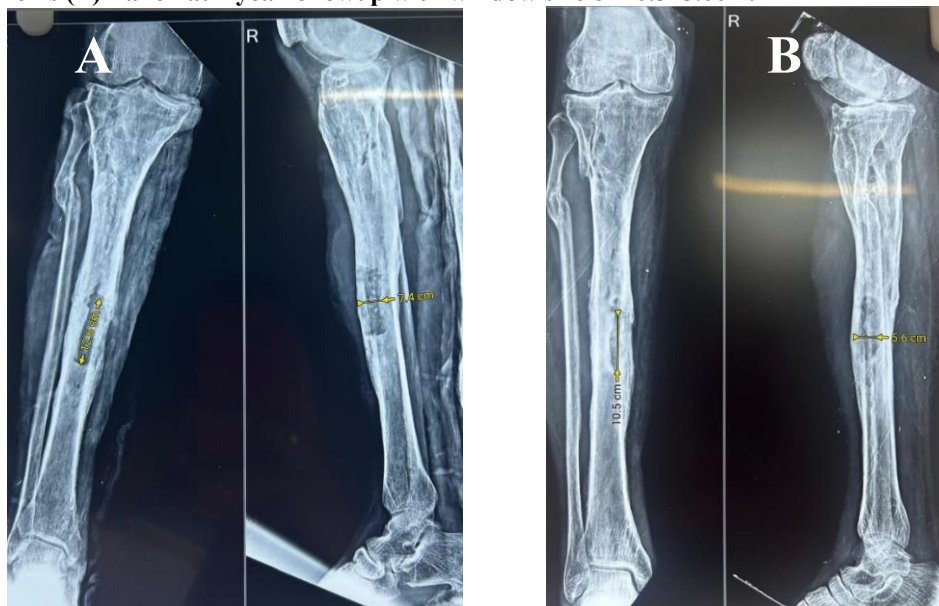


**Post-Operative Care and Follow Up:** Patient was discharged after 5 days with instructions of immobilization and maintenance of Above knee slab. Follow up evaluations were performed at POD 11, 3weeks, 2months, 6months and 1 year post-operatively

**Figure 7 A-E: Follow-up Radiographs of Right tibia and fibula in anteroposterior and lateral view at (A) POD -11, (B) 3weeks, (C) 2months, (D) 6months and (E) 1year**



**FIGURE 8: Radiographs of Right Leg in anterior posterior and lateral view. (A) Taken at 1<sup>st</sup> week showing cortical window of 12.6x7.4cms (B) Taken at 1 year followup with window size of 10.5x5.6cm.**



## DISCUSSION

Chronic osteomyelitis remains a difficult clinical problem because of the persistence of microorganisms within biofilms and the presence of necrotic bone, which acts as a nidus for infection (14). Surgical debridement combined with appropriate antibiotic therapy remains the cornerstone of treatment (3).

Local antibiotic delivery systems have been widely used to achieve high antibiotic concentrations at the site of infection while avoiding systemic toxicity (5). Polymethylmethacrylate (PMMA) antibiotic beads have been used extensively for this purpose since they provide high local antibiotic concentrations and help fill dead space following debridement (7). However, PMMA beads are non-biodegradable and require a second surgical procedure for removal (8).

Biodegradable carriers such as calcium sulphate have gained popularity in recent years (9). Calcium sulphate acts as a local antibiotic carrier while also functioning as a bone void filler with osteoconductive properties (10). Additionally, it gradually resorbs, eliminating the need for secondary removal surgery (15).

In our case, a staged approach was adopted in which PMMA beads were initially used to control infection and deliver high local concentrations of vancomycin (16). After adequate infection control, the beads were removed and the defect was filled with gentamicin-loaded calcium sulphate pellets. This approach allowed sustained antibiotic delivery while simultaneously addressing the bone defect (17).

Previous studies have demonstrated promising results with calcium sulphate antibiotic carriers in the

management of chronic osteomyelitis (18). The combination of surgical debridement, local antibiotic therapy, and appropriate soft tissue coverage remains critical for successful outcomes (19). Our case demonstrates that sequential use of PMMA antibiotic beads followed by biodegradable calcium sulphate pellets can be an effective strategy for infection eradication and defect management in chronic osteomyelitis (20).

## CONCLUSION

The use of the antibiotic-loaded  $\text{CaSO}_4$  pellets allows fast and prolonged delivery of antibiotic into bone voids after debriding chronic osteomyelitis. It provided both safety and efficacy in infection eradication.

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