

Management of Traumatic Bone Defects in Tibial Plateau Fractures with Antibiotic-Impregnated Biodegradable Calcium Sulfate Beads: A Prospective Clinical Trial

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Purpose: There has been widespread interest in utilizing local antibiotics in fractures involving significant soft-tissue trauma where postoperative infections are a major concern. STIMULAN Rapid Cure (Biocomposites) is a resorbable calcium sulfate that can be mixed with a variety of antibiotics and formed into beads to create a nonstructural void filler. The primary goals of this study were to assess resorption of the device (STIMULAN Rapid Cure with antibiotics) and identify device-related adverse events in tibial plateau fractures.

Methods: This was a multicenter, prospective study of 30 patients with a tibial plateau fracture (AO-OTA type 41B and 41C), recruited from 5 trauma centers. The articular surface was reduced, the fracture was fixed with plates and screws, and the subchondral void was filled with the device. We assessed the local wound reaction to the device by recording redness, swelling, and serous drainage. We also measured the resorption rate of the calcium sulfate on serial radiographs. Follow-up was done at 6 weeks, 12 weeks, 6 months, and 1 year. Secondary outcomes were time to union and postoperative depression of the subchondral surface. Descriptive statistics were used for analysis.

Results: 13 male and 17 female patients were included. Patients had a mean age of 53 years (range, 29 to 78) and a mean body mass index of 29 (standard deviation [SD] = 8.7). Postoperative swelling and redness were within normal limits. Two patients reported serous drainage: 1 resolved without treatment, the other required oral antibiotics for superficial infection of a stitch abscess. There were no other infections at the operative site and no local or systemic allergic reactions. There was 1 report of intra-articular heterotopic ossification requiring debridement. Three patients experienced hardware irritation: 1 was revised to a smaller plate and 2 required implant removal. One patient was revised to a total knee replacement after loss of fixation. None of these were deemed related to the study device. 76.7% of fractures were healed by 3 months with 100% healed at 1 year with no significant subchondral collapse. Resorption of the material averaged 70% by 12 weeks and 87% had no visible calcium sulfate beads on radiographs at 6 months.

Conclusion: This device appears to perform well when mixed with antibiotics for fractures with a high risk of infection. An additional advantage is being able to choose from a range of antibiotics. Surgical site drainage was very low, and 100% union rate was achieved. There were no remaining beads visible at 1 year. This should be a safe surgical augment for local release of a chosen antibiotic into the subchondral void of a tibial plateau fracture.