

**Prospective, Multicenter, Observational Study Evaluating the Augmentation with Calcium Phosphate Cement (chronOS Inject) for Bone Defect After Internal Fixation of Proximal Tibial Fractures**

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**Purpose:** The primary objective of this study was to observe the safety and the radiologic and clinical outcomes of chronOS Inject after having been used as bone void filler in internal fixation of proximal tibial fractures. Secondary objectives were to assess the surgeon's satisfaction in using chronOS Inject and patient satisfaction post surgery.

**Methods:** 36 proximal tibial fractures (Schatzker I-VI) with bone defect in 36 patients were prospectively enrolled. All fractures were treated with this bone void filler during internal fixation of proximal tibial fractures. All patients were evaluated preoperatively, at 6 weeks, and at 6 and 12 months postoperatively. The average age of patients was 55 years. Radiographic union and amount of articular subsidence were assessed by the investigator using plain films supplemented with CT scans. Pain, function, and adverse events were collected at all visits.

**Results:** 34 of 36 assessed patients achieved fusion at the site of chronOS Inject implantation. Mean time to union was calculated to be 7.5 months (standard deviation = 0.441), based on the Kaplan-Meier estimator of the survivorship function. No evidence of articular subsidence of >2 mm could be found at 6 weeks, while one patient showed evidence at 6 months that lasted throughout to the 12-month visit. Absorption rates were calculated from radiographs with the INFINITT program. After 6 weeks, 14% of the calcium phosphate cement was absorbed, at 6 months 37%, and at 12 months 64%. A statistically significant mean percent improvement from baseline was observed in physical composite score at month 12 ( $P = 0.0166$ ) in the Short Form (SF)-12 health survey.

**Conclusion:** Augmentation with calcium phosphate cement prevented subsidence of articular fragment as the fracture healed, including elimination of morbidity related with bone graft harvesting.