The Use of a Calcium Phosphate Cement in Open Reduction and Internal Fixation (ORIF) for Tibial Plateau Fractures: A Comparison with Traditional ORIF

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Purpose: Tibial plateau fractures are reported to account for approximately 1% of all fractures. The treatment of choice is ORIF, with or without bone grafting. Several biocompatible calcium-based phosphate bone fillers have been developed, providing suitable alternatives to traditionally employed bone grafts. The goal of this study was to determine if a drillable calcium based cement indicated for filling defects in cancellous bones, combined with ORIF, is a successful treatment for tibial plateau fractures when compared against traditional, nonsupplemented ORIF.

Methods: Following IRB approval, all tibial plateau fractures treated operatively at our Level I trauma center between November 2009 and November 2014 were recruited retrospectively. Patients were eligible if they presented with a tibial plateau fracture and they were 20 years of age or older. Potential subjects were excluded if: the 3-month follow-up radiograph was missing, or the tibial plateau fracture was open, pathologically related, or periprosthetic. 118 patients were enrolled, and divided in two treatment groups: Traditional (nonsupplemented ORIF) and Filler (ORIF + filler), depending if a drillable calcium cement was used during surgery. Of the initial 118 patients, 51 belonged to the Filler group, and 67 to the Traditional group. Data were collected retrospectively from medical records, and radiographs were analyzed at 3, 6 and 12 months postoperatively. Radiographic measurements of interest included depression (mm), intercondylar widening (mm), and varus/valgus angulation (degrees). Comparisons between the two treatment groups were done using Student's t tests. Pearson X^2 tests were used to evaluate comparisons between groups with regards to gender, race, smoking habits, Schatzker's and AO classification, mechanism of injury, and diabetes status. Fracture subsidence (mm) was calculated for each patient with available radiographs by computing differences in plateau depression between 3 and 6 months, and 3 and 12 months. To further evaluate whether use of a filler yielded different results than traditional ORIF in fractures characterized by severe depression, measures extracted from preoperative radiographs were categorized using a scoring system similar to the anatomical radiographic Rasmussen score. Specifically, fractures were classified as Not Depressed if presented with 0 mm of depression, Slightly Depressed if depression was<5 mm, Depressed if depression was between 5 and 10 mm, and Very Depressed if depression was >10 mm.

Results: No difference was detected between the two treatment groups with regard to age, body mass index (BMI), gender, mechanism of injury, race, and diabetes at any point in the study's timeline. Of the 118 total patients, only 7.36% developed infections during recovery, all belonging to the Traditional group (P = 0.004). There were no differences in mean preoperative joint depression (P = 0.28), widening (P = 0.11), or angulation (P = 0.54) between the two treatment groups. All measures were significantly reduced at the 3, 6, and 12-month follow-up time points when compared to the preoperative values (P < 0.0001). Fracture

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

subsidence (mm) was calculated with available radiographs by computing differences in residual depression between 3 and 6 months, and 3 and 12 months. There was a significant difference in subsidence with fractures treated in the Traditional group showing a greater increase in plateau depression between 3 and 6 months (P = 0.0268) and 3 and 12 months (P = 0.0005). There were no differences in variations in angulation and widening between the two groups.

Conclusion: This comparative retrospective study suggests that the calcium phosphate drillable cement filler may be a helpful, less risky solution to preserve the level of reduction attained during surgical fixation of tibial plateau fractures, preventing postoperative subsidence while avoiding the multiple comorbidities involved in bone grafting. In addition, it may be a better treatment solution when compared to traditional bone grafts due to its increased malleability that allows for better filling of the fractured defects.

See pages 49 - 106 for financial disclosure information.