

Treatment of Tibial Plateau Fractures with a Novel Fenestrated Screw System for Delivery of Bone Graft Substitute

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Purpose: Our objective was to describe the rate of articular subsidence, complications, reoperation, and patient-reported outcomes following surgical fixation of tibial plateau fractures using a novel fenestrated screw for the delivery of calcium phosphate bone graft substitute.

Methods: 34 patients with unicondylar and bicondylar tibial plateau fractures were treated according to the usual technique of 2 surgeons. After fixation, the N-Force Fixation System was placed and used for injection of the proprietary calcium phosphate bone graft substitute into the subchondral void. For all included patients, demographic information, operative data, radiographs, and clinic notes were reviewed. Patients were considered to have articular subsidence if 1 or more of 3 observations were made when comparing postoperative to their most recent clinic radiographs: >2 mm change in the distance between the screw and the lowest point of the tibial plateau, >2 mm change in the distance between the screw and the most superior aspect of the plate, or a decrease in the quality of reduction (excellent, adequate, poor) as determined by an orthopaedic trauma surgeon who was not involved in the surgical care of the patient. Patients were contacted by telephone to complete a 10 question PROMIS (Patient-Reported Outcomes Measurement Information System) Physical Function Assessment. Data were analyzed to determine if there were any identifiable risk factors for complication or subsidence using a Fisher exact test, Mann-Whitney U test, and binary logistic regression.

Statistical significance was set at $P < 0.05$.

Results: The fractures were classified according to the OTA / AO system as follows: 1 41B1, 1 41B2, 15 41B3, 7 41C1, 4 41C2, and 6 41C3. The mean time from injury to surgery was 15.4 days. One screw was used in 19 cases (55.9%) while 2 screws were used in 15 cases (42.9%). The screws were placed above the raft screws in 5 (14.7%) of cases and below the raft screws in 29 (85.3%) of cases. Patients followed up for a mean of 32.0 weeks (range, 2.1-103.9) and were allowed to weight-bear at 11.8 ± 2.7 weeks. There were a total of 6 complications (17.6%; 5 infections requiring reoperation, 1 other unplanned reoperation) and 4 (11.8%) cases of subsidence. The average PROMIS Physical Function T-Score was 43.67 ± 11.8 among 5 patients. On univariate analysis, concomitant soft-tissue injury was associated with a decreased risk of subsidence ($P = 0.039$). There were no significant findings on multivariate analysis.

Conclusion: The rate of articular subsidence after fixation of tibial plateau fractures with a novel fenestrated screw for delivery of calcium phosphate bone graft substitute is within the range of subsidence reported in the current literature. An appropriately powered prospective study is warranted to better identify the true rate of subsidence as well as identify risk factors for complication and reoperation.

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.