

Multicenter Analysis of Implant Breakage of the TFNA Cephalomedullary Nailing System

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Purpose: Intertrochanteric (IT) fractures are most commonly treated with cephalomedullary nails (CMNs). A 2019 retrieval study of the TFNA nailing system raised concerns about a unique failure mechanism resulting in increased rates of implant breakage. The purpose of this study is to compare breakage rates of the TFNA nailing system to other popular CMNs in IT fractures.

Methods: This was a multicenter, retrospective study of adult patients with IT fractures who underwent surgical fixation with 1 of the 3 cephalomedullary nailing systems: Synthes TFNA, Stryker Gamma3, or Smith & Nephew Trigen InterTan. Patients with less than 3-month follow-up or for whom polymethylmethacrylate bone cement was used were excluded. Primary outcome was implant breakage. Radiographs were reviewed by orthopaedic surgeons at each institution to determine fracture pattern (standard obliquity [AO/OTA 31A1, A2] vs reverse obliquity / transverse [AO/OTA 31A3]) and postoperative femoral neck-shaft angle (NSA). Patient age, sex, mechanism of injury, and implant type were also collected. For the purposes of analysis, the TFNA nailing system was compared to a composite group of the Gamma3 and InterTan nailing systems.

Results: 2132 patients were included including 769 patients (36.1%) treated with the TFNA nailing system and 1363 patients (63.9%) with either the Gamma3 or InterTan system. There were 17 cases (0.8%) of implant breakage across all nailing systems. In univariate analysis, patients with the TFNA were more likely to have implant breakage than patients with other CMNs (1.3% vs 0.5%, $P = 0.050$). Of note, groups were imbalanced; patients with the TFNA had more unstable fracture patterns (17.2% vs 12.7%, $P = 0.005$) and fewer varus reductions (defined as $NSA < 128.5^\circ$, 34.3% vs 40.8%, $P = 0.003$). After controlling for age, sex, fracture pattern, high-energy mechanisms, and varus reduction, there was no statistically significant association between implant type and implant breakage (odds ratio [OR] 2.54, 95% confidence interval [CI] 0.95-6.78).

Conclusion: The TFNA nailing system did not have significantly higher rates of implant breakage than a control group of other popular CMNs after adjusting for demographic and radiographic characteristics, despite a significant association in univariate analysis. Additional studies with more patients are needed to confirm or refute these findings.

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