A Multicenter RCT Comparing the InterTAN Device Versus the Sliding Hip Screw in the Treatment of Geriatric Hip Fractures: Results Depend on Preinjury Functional Level

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Background/Purpose: The benefit of intramedullary devices for the treatment of intertrochanteric hip fractures in the elderly is unknown. This may be related to the functional capacity of patients who sustain hip fractures, as incremental improvements in function may be difficult to appreciate. The InterTAN (IT) device was designed to allow earlier mobilization for patients with intertrochanteric fractures. Our objective was to determine whether the mechanical benefits of this device would translate into improved function for elderly patients with hip fractures, compared to a conventional sliding hip screw (SHS).

Methods: 249 patients aged 55 years or older were prospectively enrolled in an REB-approved multicenter study, and computer randomized to either IT (n = 123) or SHS (n = 126). Patients were followed for 12 months. The validated primary outcome measures were the Functional Independence Measure (FIM), to measure function, and the Timed Up and Go test (TUG), to measure motor performance. Secondary outcome measures included femoral shortening, complication,s and mortality. A preinjury FIM was measured by retrospective recall, and all outcomes assessed at discharge, 6 weeks, 3 and 6 months, and 1 year postoperative. 100 patients per group with complete data were required to have 80% power to detect differences in the FIM score of 7.8 points or greater using a two-sided ANOVA (analysis of variance) with a type I error rate of 5%.

Results: Fractures included 43 31A-1, and 199 31A-2 fractures. Age, sex, body mass index (BMI), living status, and comorbidities were similar between groups. The recalled preinjury FIM scores were similar between the SHS and IT groups and followed a similar pattern of recovery after discharge. The average FIM motor subscale at 12 months was 4.5 ± 1.1 points lower than preinjury. The proportion of patients able to complete the TUG, as well as the time, was similar between the SHS and IT groups at each time interval. Fewer patients who received an IT (17.2%) had limb shortening greater than 2.5 cm compared to those who received a SHS (42.9%) (P <0.001). There were no differences in secondary outcomes. To determine

the role of preinjury function, we analyzed the subgroup of patients with the ability to walk 150 feet independently preinjury (FIM walk score of 7) and a 31A-2 fracture. 70 patients met these criteria (36 SHS, 34 IT). Patients treated with SHS followed a bimodal distribution of outcomes, associated with radiographic shortening. In this subgroup, patients treated with SHS with greater than 2.5 cm of shortening demonstrated poorer FIM and TUG scores compared to patients treated with SHS without shortening, or patients treated with an IT.

Conclusion: Patients with intertrochanteric proximal femur fractures can expect similar results whether treated with an intramedullary or extramedullary device. However, our study demonstrates an advantage to the IT device in patients with superior functional capacity prior to their unstable intertrochanteric hip fracture. In these patients, treatment with a SHS complicated by shortening resulted in worse outcome. These results may help orthopaedic surgeons decide which surgical implant is most appropriate for individual patients in the treatment of intertrochanteric hip fractures.

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.