

Δ Radiologic and Clinical Outcomes of Augmentation in Fragility Intertrochanteric Hip Fracture Treatment: A Randomized Multicenter Clinical Trial

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Purpose: Osteoporotic bone is mechanically weak which, after reduction of the fracture, varus collapse and screw migration within the femoral head are associated with the implants cutting-out and cutting-through the proximal femur—2 catastrophic complications that lead to reoperation, increased mortality, and morbidity in this already fragile population. Augmentation is considered to improve the bone-implant construct stability and biomechanical studies show that it improves the pull-out strength and increased resistance to failure. Thus far, the advantage of this technique used in a clinical scenario is yet to be determined.

Methods: A randomized, multicenter, single-blinded clinical trial was conducted in patients aged 65 years or older who were admitted to 2 Level I trauma centers with a fragility intertrochanteric hip fracture (OTA/AO 31A1, 31A2, 31A3, 32A2) during September 2015 and December 2017. Once included, patients were stratified in 2 groups: patients between 65 and 84 years old and patients 85 years or older. Within each group, a balanced block randomization was performed using blocks of 6 patients: 3 patients assigned to the control group (no augmentation) and 3 patients to the intervention group. Follow-up appointments were done at 1, 3, 6, and 12 postoperative months documenting the tip-apex distance (TAD). A total of 90 eligible patients were included but only 53 patients completed a 1-year follow-up.

Results: The mean immediate postoperative and the 1-year follow-up TAD measurement from the whole cohort (20.99 mm vs 21.3mm, respectively) showed no statistical significance ($P=0.18$). For patients included in the control group, the difference of TAD measurement from the immediate postoperative and 1-year follow-up was -0.25 mm ($P=0.441$). Meanwhile, for patients included in the intervention group, the difference of the TAD measurement from the immediate postoperative and 1-year follow-up was -0.48 mm ($P=0.383$). No statistical significance was found between both groups stratified by age (95% confidence interval [CI] 0.24-2.21, $P=0.78$). One patient from the control group had an implant failure caused by cutting-through 1 month after the surgical procedure. Readmission 30 days after the surgery showed no statistically significant difference between the control and the intervention group (7 vs 7 patients, respectively) (95% CI 0.42-4.9, $P=0.754$).

Conclusion: The use of augmentation can be considered a safe procedure for the fixation of fragility hip fractures. Additional studies should be done to determine any additional advantages of this technique in the clinical scenario.