

Randomized Controlled Trial Comparing the Outcome of Titanium Elastic Nailing versus Stainless Steel Nailing in the Management of Pediatric Diaphyseal Femur Fractures

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Purpose: Pediatric femoral fracture mostly occurs in the middle shaft. The treatment method is basically guided by the age/weight of the child, fracture personality, and level of fracture as well as surgeons preferences. Flexible intramedullary nailing is a reliable method of diaphyseal fracture fixation in children between 6-11 years old, fracture fixation being done either with titanium or stainless steel intramedullary nail. Systematic review and biomechanical analysis provides little evidence to support one over another. Thus this prospective randomized controlled trial aims to compare the functional outcome between titanium and stainless steel nail as a fixation device for pediatric femoral shaft fractures and to study the fracture and surgery/technique-related complications.

Methods: Children between 6 and 11 years with recent closed traumatic isolated femoral shaft fracture were treated randomly either by titanium or stainless steel nail fixation under C-arm control. 30 children were included in each group. Children with abnormal bowing or deformed femur, pathological fractures, and polytrauma were excluded. Study included 22 transverse, 17 short oblique, 12 spiral, and 9 comminuted fractures. Similar group, type, strength, and duration of perioperative antibiotics were given. 8 cases required open reduction. Clinicoradiological evaluation was done for fracture healing at 2 weeks, 6 weeks, 12 weeks, 24 weeks, and 52 weeks.

Results: Mean age (years), duration of surgery (min), hospital stay (days), and blood loss (mL) were 9.727 ± 2.2 , 54.55 ± 14.3 , 6.14 ± 2.66 , and 59.55 ± 37.09 for titanium and 9.22 ± 1.8 , 55.0 ± 13.39 , 5.18 ± 5.83 , and 55.28 ± 22.19 for stainless steel nailing (all with $P > 0.01$). Overall, all fractures united in 16 to 22 weeks, 12 cases had limb-length discrepancy (< 1.5 cm), maximum angulation seen was 8° varus and 14° anterior angulation, 5 skin irritation/bursitis at entry point, opposite cortex penetration and trochanter/neck perforation 1 patient each, with results being comparable between the two groups ($P > 0.01$). The treatment cost in titanium nailing group was significantly different than the stainless steel group ($P < 0.05$) owing to the much higher cost of the titanium implants.

Conclusion: There is no statistically significant difference between the functional outcome of titanium elastic nailing and stainless steel nailing for fixation of pediatric diaphyseal femur fracture. However, the stainless steel nailing is cost-effective, and equally good results can be obtained at much lower cost by using stainless steel nails instead of titanium ones.