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Fixed-Angle Versus Polyaxial Locking Plate Fixation Systems for Periprosthetic and/or Osteoporotic Distal Femoral Fractures

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Background/Purpose: Contemporary fixation of distal femoral fractures, especially in the presence of poor bone stock and/or of an ipsilateral knee arthroplasty, refers to the use of precontoured locking plating systems. They have evolved to include stainless steel or titanium alloy plates, with different thickness, shapes, external targeting jigs, and reduction tools for minimal invasive surgery, multidirectional or fixed-angle locking options. We hypothesized that the use of a plating system of newer design, adopting the concept of polyaxial technology and having options of insertion of different screw designs at the metaphyseal part, is equally effective in comparison to the first generation of periarticular distal femoral locking plates.

Methods: A prospective, concealed randomized clinical trial was conducted from 2010 between 4 UK centers, with selection criteria on osteoporotic and/or periprosthetic distal femoral fractures, excluding patients with dementia, loose femoral components, preinjury impaired mobility, or associated trauma influencing ambulation. The primary objective of the study was to test the hypothesis that the Polyax-BIOMET achieves similar union rates at comparable time frames with the LISS-DePuy/SYNTHES. The secondary objectives of this study included the comparison of intraoperative details (ie, closed vs open reduction, length of incisions, duration of surgery), the comparison of radiological characteristics of the plate/bone constructs (stiffness score, plate/screw density, plate span width, working length), the comparison to the incidence of nonunion, malunion, hardware failure, complications, secondary surgery, and the functional outcome according to the Oxford knee score, and the EuroQol (EQ)-5D. All fractures were classified according to the AO/OTA system, as well as the Rorabeck system, and bone density using the Singh score. The analysis of the accumulated data was a logistic regression of union on covariates that included use of either system with variables including: age, sex, smoking, mechanism, fracture type, Singh index, timing of ambulation progress, complication rates, quality-of-life score, and knee function. Statistical significance was set to the P value < 0.05.

Results: In a 1:1 ratio, 40 patients were recruited following informed consent, and completed a 12-month follow-up. The overall union rate at 6 months was 73%, at 9 months was 90%. The 4 overall nonunions led all to revision surgeries, 2 exchanging to a retrograde femoral nail, 2 by using bone grafting without revision of osteosynthesis. Malunion was evident in 2 cases, one with 17° of recurvatum and 10° valgus, and one with 10° of recurvatum. The mortality rate at 1 year was 10%. Between the 2 plating systems statistical analysis verified

See pages 47 - 108 for financial disclosure information.

no significant differences in regards to the demographics (mean age, 78 years (range, 58-99); gender 87.5% females), the mechanism of injury (falls from standing height 87.5%), the impact of comorbidities (Charlson score mean 5 (Range, 2-9), Singh score mean 2 (range, 1-4), the ratio of periprosthetic fractures (32%), the duration of surgery (mean 86 min; range, 55-192), the surrogate length of incisions (mean 15 cm; range, 7-33 cm), the stiffness score (mean 1; range, 0-3), the percentage of filled holes (mean 50.7%; range, 33.6-88.3%), the plate span width (mean 2.35; range, 1.3-4.3), the working length (mean 135 cm; range, 46-227 cm), the ratio of working length / fracture length (mean 1.56; range, 0.75-3.27), the hospital stay (21 days; range, 10-43), and the ambulatory progress, as well as functional, quality of life and pain scoring at 6, 9, and 12 months. The number of open reductions (29% vs 19%) were more in the LISS group, although more complex fractures according to the AO/OTA system were managed in the later group (22.5% LISS 33.A1 vs 77.5% LISS 33.A2/3/B/C instead of 15% vs 85% POLYAX). Another significant difference favoring the POLYAX group was the minimal medial prominence of metaphyseal screws, which occurred in just 1 case versus in 6 cases of the LISS group, and led to secondary surgery in 3 of them.

Conclusion: The primary hypothesis was verified, with very good union rates for both systems, and limited implant-related complications. Good reduction, mechanically sound construct, and respect of the local fracture biology appears to be more important than the particular plate characteristics. The new generation of locking plates offer versatility, better use of locking corridors in poor bone stock, less screw-related soft-tissue impingement, and a short learning curve.

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.