J Shoulder Elbow Surg (2016) 25, 695–703

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

Locking intramedullary nails compared with locking plates for two- and three-part proximal humeral surgical neck fractures: a randomized controlled trial

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Background: Previous studies have shown good clinical results in patients with proximal humeral fractures (PHFs) treated with locking intramedullary nails or locking plates. Our study compared the clinical and radiographic outcomes in patients with 2- and 3-part surgical neck fractures.

Methods: In this prospective, randomized controlled trial, 72 patients with 2- or 3-part surgical neck PHFs were randomly assigned to receive fixation with locking intramedullary nails (nail group) or locking plates (plate group). The primary outcome was the 12-month Constant-Murley score. The secondary outcomes included the Disabilities of the Arm, Shoulder and Hand score, the visual analog scale pain score, the shoulder passive range of motion, the neck-shaft angle, and complication rates.

Results: There was no significant mean treatment group difference in the Constant-Murley score at 12 months (70.3 points for the nail group vs. 71.5 points for the plate group; $P = .750$) or at individual follow-up assessments. There were no differences in the 3-, 6- and 12-month Disabilities of the Arm, Shoulder and Hand scores, visual analog scale scores, and range of motion, except for the medial rotation at 6 months. The neck-shaft angle was equivalent between the groups at 12 months. There were significant differences over 12 months in total complication rates ($P = .002$) and reoperation rates ($P = .041$). There were no significant differences for the rotator cuff tear rate ($P = .672$).

Conclusion: Fixation of PHFs with locking plates or locking intramedullary nails produces similar clinical and radiologic results. Nevertheless, the complication and reoperation rates were higher in the nail group.

Level of evidence: Level I; Randomized controlled trial; Treatment study

Keywords: Randomized controlled trial; recovery of function; bone nails; bone plates; comparative study; shoulder fractures; postoperative complications

This study was approved by the Department of Orthopedics and Traumatology/ University of São Paulo Ethics Committee for Review of Research Projects (No. 0232/11).

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1058-2746/$ - see front matter © 2016 Journal of Shoulder and Elbow Surgery Board of Trustees.
http://dx.doi.org/10.1016/j.jse.2016.02.003

Proximal humeral fractures (PHFs) are the third-most common type of fractures among older adults.[36] Their incidence, currently 105 per 100,000 individuals, is increasing, similar to other osteoporosis-related fractures.[36] Displaced fractures are commonly treated surgically despite the controversy regarding its advantages compared with conservative treatment.[2,9,16,28,34,38]

Locking plate osteosynthesis is considered the gold standard treatment for these fractures.[8] However, its use is associated with a high rate of complications.[4,41-43] Fixation with locking intramedullary nails exhibits some biomechanical advantages, including higher stiffness for varus, valgus, and torsional loading,[12,19,49] but its disadvantages include the risk of rotator cuff tears[15] and that it does not contribute to fracture reduction.[32,50]

Different studies have compared these 2 approaches to fixation.[3,15,17,21,22,24,44,45,50] The clinical results of cohort studies are similar,[3,15,17,21,22,24,44,45] whereas the complication rate associated with nailing was inferior or similar. The only randomized study performed to date, which assessed 2-part PHFs of the surgical neck only, reported similar Constant-Murley scores and a lower complication rate in the locking intramedullary nail group.[50] No randomized studies have compared locking plates and locking intramedullary nails for treatment of PHFs affecting the surgical neck and the greater tuberosity of the humerus. Despite a recent meta-analysis,[47] the controversy between these techniques remains, indicating the need for more randomized controlled trials.

The primary aim of the present study was to compare 2 methods of osteosynthesis of 2- and 3-part PHFs: locking plates and locking intramedullary nails. The primary outcome was the Constant-Murley score at 12 months after surgery. Our hypothesis was that no difference would be observed between the groups regarding the primary outcome.

Methods

Study design and participants

This study was a single-center, prospective, randomized controlled trial. All patients provided written informed consent to participate. The study was registered at https://clinicaltrials.gov/ct2/show/NCT01984112 (NCT01984112).

The inclusion criteria were an age between 50 and 85 years and a PHF with displacement ≥1 cm or ≥45° of angulation between the head and diaphysis of the humerus, with or without involvement of the greater tuberosity, and treated surgically ≤21 days after the injury. The exclusion criteria were isolated tuberosity fractures, articular split, fracture dislocation, open fractures, neurologic injury, previous surgery on the affected shoulder, associated fractures in the ipsilateral limb, pathologic fractures, psychiatric diseases, inability to understand the questionnaires, active or previous infection in the shoulder, irreparable tendon tears of the rotator cuff, and loss to follow-up before the first clinical assessment at 3 months.

Preoperative evaluation

Radiographs were obtained with 3 views: anteroposterior in the scapular plane, a lateral view of the scapula, and a supine axillary view. We assessed the Neer[30] and Arbeitsgemeinschaft für Osteosynthesefragen (AO)[29] classifications, parameters described by Majed et al[27] and Resch et al,[39] and presence of medial metaphyseal comminution.

Interventions

All surgical procedures were done by the principal investigator (M.E.C.G.). Surgery was performed with the patient under general anesthesia combined with an interscalene brachial plexus block and in dorsal decubitus with 30° of elevation.

Nail group

We used the Centronail (Orthofix, Verona, Italy) intramedullary nail with 3 proximal locking screws, which was introduced via a longitudinal anterolateral transdeltoid approach. The supraspinatus and infraspinatus tendons were identified and sutured with nonabsorbable sutures. When present, greater tuberosity fractures were reduced before the intramedullary nail was inserted. The humeral head was reduced and provisionally fixed with Kirschner wires. For the entry point, a guidewire was placed 1 cm posterior to the intertubercular groove and 1 cm medial to the transition between the head and the greater tuberosity. A longitudinal 1.5-cm incision was made in the supraspinatus tendon. The nail was placed 5 mm below the cartilage and proximally fixed with 3 screws and distally fixed with 2 screws. An end cap was screwed in to lock the 2 most proximal screws, and tension-band sutures were placed around the proximal screws, with nonabsorbable sutures passed through the rotator cuff tendons. The supraspinatus tendon was repaired with nonabsorbable suture (see Supplementary Fig. 1, available on the journal's website at www.jshoulderelbow.org).

Plate group

We used the PHILOS (DePuy-Synthes, Solothurn, Switzerland) stainless steel plate, with 3 holes for the diaphysis, which was introduced via the deltopectoral approach. The plate was placed 1 cm inferior to the upper portion of the greater tuberosity and 1 cm lateral to the long head of the biceps tendon. Three guidewires were inserted through the plate proximal holes, followed by distal fixation with a cortical or locking screw under radioscopic imaging. At least 5 locking screws were inserted proximally, followed by 2 more distal locking screws, with a minimum of 3 distal screws. Tension-band sutures were placed in the proximal plate holes, with nonabsorbable sutures passed through the rotator cuff tendons.