J Shoulder Elbow Surg (2014) 23, 369-376

ELSEVIER

Journal of Shoulder and Elbow Surgery

www.elsevier.com/locate/ymse

SHOULDER

Proximal humerus nailing: a randomized clinical trial between curvilinear and straight nails

Yaiza Lopiz, PhD, MD*, Javier Garcia-Coiradas, MD, Carlos Garcia-Fernandez, MD, Fernando Marco, PhD, MD

Shoulder and Elbow Unit, Department of Orthopaedic Surgery, Clínico San Carlos Hospital. Complutense University of Madrid, Madrid, Spain

Background: Intramedullary nailing of displaced proximal humerus fractures is an attractive option in the elderly patient. However, in recent reports, some existing intramedullary nails have shown high rate of complications, so new designs are being developed. The objective of the present study is to report on outcomes and complications when comparing a straight to a curvilinear nail design.

Methods: We prospectively include 54 patients with Neer's 2- or 3-part proximal humerus fractures. Two were lost to follow-up, 26 were surgically treated with a new straight humeral nail (MultiLoc, Synthes) mean age 69 (range, 47-87 years), and 26 with a curvilinear nail (Polarus, Acumed) mean age 71 (range, 38-89 years). At final follow-up (average 14 months), patients underwent a clinical and radiographic evaluation. Clinical outcome was assessed with the adjusted Constant score.

Results: All but 1 fracture went on to radiographic union. Mean Constant score in the Polarus nail was 72.7 ± 16.0 and 83.3 ± 16.7 in the MultiLoc ($P = .246$). Symptoms related with rotator cuff disease were present in 19/26 patients (73%) and in 9/26 (34.6%), respectively ($P = .001$). The mean neck-shaft angle at final follow-up was 135° in the MultiLoc group and 130° in the Polarus group ($P > .05$). Reoperation rate was 42% for Polarus and 11.5% for MultiLoc.

Conclusion: Straight intramedullary nails had a comparable union rate to an accepted curvilinear design, with a much lower incidence of complications. Rotator cuff pain and dysfunction can be minimized with the use of newer generation straight nails.

Level of evidence: Level II, Randomized Controlled Trial, Treatment Study.

Keywords: Proximal humeral nail; MultiLoc; Polarus

Fractures of the proximal humerus are common, and significantly associated with osteoporosis. Their incidence is therefore rising, due to an increased life expectancy.[3,7]

The optimal treatment method for displaced fractures continues to be under debate. There are a variety of fixation techniques but none of them have been proved to be more effective.[28] Traditionally, antegrade nailing has been associated with problems related to a difficult indirect reduction of the fracture, and the morbidity of the rotator cuff.[20] Other complications and problems observed with existing intramedullary nails have been iatrogenic greater tuberosity fractures caused by a lateral entry point, varus malalignment and failure of proximal fixation associated with a poor

Institutional Review Board or Ethical Committee Approval: Confirmed by Comité Ethico de Investigación Clinica, (13/315-P), September 6, 2013.

*Reprint requests: Yaiza Lopiz, PhD, MD, Department of Shoulder and Elbow, Complutense University, Cl Azafran, 1. 3°D., 28222 Majadahonda, Madrid, Spain.

E-mail address: yaizalopiz@gmail.com (Y. Lopiz).

1058-2746/$ - see front matter © 2014 Journal of Shoulder and Elbow Surgery Board of Trustees.
http://dx.doi.org/10.1016/j.jse.2013.08.023

bone quality, improper orientation, and the absence of a safe locking mechanism of the proximal screws that can occasionally cause its migration.[10] New intramedullary devices have been developed to improve fixation and minimize the complications encountered when a nail is used to treat a displaced proximal humerus fracture.

The Polarus intramedullary nail (Acumed LLC, Hillsboro, OR, USA) is a curvilinear implant specifically designed for proximal humeral fixation widely employed in our department for several years. Previous studies have reported good clinical and radiographic outcomes[1,2,13,24,27]; however, some papers have reported higher percentage of unsatisfactory results and reoperation rate with this nail.[14,22]

MultiLoc Proximal Humeral Nail (MPHN) (MultiLoc PHN; Synthes GmbH, Solothurn, Switzerland) is a new straight nail with multiple locking options. The straight design theoretically increases stability of proximal nail end, leaving a safe zone between the nail insertion hole in the head segment and the lateral head fracture line to avoid an uncontrolled crack in this area. ''Screw in screw'' technique is available for additional proximal fixation in the posteromedial area of the humeral head and it has an ascending calcar screw that provides additional support to the medial hinge, which could benefit the treatment of unstable proximal humerus fractures limiting the risk of secondary loss of reduction.[29] We began to use this nail in our department in March 2011.

The objective of the present study is to analyze the clinical and radiographic results, and register early postoperative complications, obtained with antegrade nailing of proximal humerus fractures by comparing a new generation implant and a well-established implant.

Material and methods

Study group

This study was performed at the Shoulder and Elbow Unit of the Orthopaedics Department of the Clínico San Carlos Hospital, Madrid. All surgeries were performed by 1 of the 3 senior trauma surgeons in the unit.

Between March 2011 and September 2012, 54 patients with displaced Neer 2- or 3-part proximal humerus fractures were randomized to be treated with 1 of two antegrade intramedullary nails: 28 were treated with MultiLoc proximal humeral nail (MPHN) ®(Synthes-DePuy, Solothurn, Switzerland) and 26 with the Polarus® humeral nail (Acumed LLC, Hillsboro, OR, USA). Pathological or open fractures, 4-part fractures, concomitant fractures in the same upper limb, or the opposite and previous surgery on that shoulder were excluded from the study.

A power calculation was performed prior to the study to determine the sample size that would be needed to detect differences between the 2 groups. All patients were randomized by a research coordinator who was not involved subsequently in the study. This assistant generated the random allocation sequence, which was concealed from the authors. Patients were randomly assigned to 2 parallel groups, initially at a 1:1 ratio, to receive either MPHN or Polarus nail. Randomization was carried out with use of sequentially numbered, opaque, sealed envelopes. In the emergency room, the attending orthopaedic resident identified patients who met the inclusion criteria and gave them introductory information on the study procedure. A member of the research group then gave each patient a thorough explanation, obtained informed consent, and enrolled the patient in the study. The health care providers involved with subsequent patient care were not blinded to the treatment.

Two patients in the MPHN were excluded from the study (one expired and one was lost to follow-up). The rest of patients were successfully prospectively followed for an average of 14 months (min 6 months; max 22 months) to obtain clinical and radiographic outcome.

Clinical and radiographic assessment

Clinical and radiographic evaluation was performed at 1, 3, 6, and 12 months postoperatively.

Radiographic assessment with a standard 3-view (anteroposterior, axillary and lateral scapular ''Y'') include: the presence of nonunion, protrusion of the osteosynthesis material (subacromial impingement or articular surface intrusion of the screws) and final alignment of the healed fracture. For the latter, the neck-shaft angle was measured in the anteroposterior view in the immediate postoperative x-ray and in the final follow-up x-ray. Less than 120° of valgus neck/shaft angle was defined as Malunion. Nonunion was defined as fixation failure or nonunited fracture at last follow-up.[2]

Patients' shoulder function was assessed with the Constant score[8,9] the results were graded as excellent (>90 points), good (90-80), satisfied (79-70), fair (69-60), and poor (<59 points). Strength in the shoulder was measured with an isometric dynamometer (Basic-BFG Dynamometer, Mecmesin Corp., Sterling, VA, USA). We also used the adjusted Constant scale,[17] depending on age and sex of each patient, for a more accurate estimate of the final result.

All patients were also assessed for evidence of rotator cuff disease[22] (Neer's sign, Hawkin's sign, arc of pain, supraspinatus/greater tuberosity tenderness, abduction strength, external rotation strength, subacromial crepitus, drop arm sign, external rotation lag sign, and the lift-off sign) in order to establish entry point morbidity.

Operative technique

Every patient of the study was operated under general anesthesia and interscalene block placed in a beach-chair position. Fluoroscopic imaging allowed biplanar views of the shoulder and arm.

The short Polarus nail is a standard titanium 150-mm cannulated and tapered device with 4 proximal and 2 distal interlocking holes. The nail is available in an 8 mm diameter. After closed fracture reduction, a small deltoid-splitting and rotator cuff incision is made (Fig. 1). Under image-intensifier control, the medullary canal is opened with an awl just medial to the greater tuberosity (Fig. 2). After introduction of the guide wire the humeral canal is reamed with a hand reamer. The nail connected to a targeting device is inserted over the guide wire into the medullary cavity. Proximal locking was performed via drill sleeves with 5-mm cancellous