Shoulder and Elbow Unit, Department of Orthopaedic Surgery, Clínic 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.

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**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.

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. Traditionally, antegrade nailing has been associated with problems related to a difficult indirect reduction of the fracture, and the morbidity of the rotator cuff. 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...
Bone quality, improper orientation, and the absence of a safe locking mechanism of the proximal screws that can occasionally cause its migration. 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, however, some papers have reported higher percentage of unsatisfactory results and reoperation rate with this nail.

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 postero-medial 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. 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 2 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, and 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 (antero-posterior, 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.

Patients’ shoulder function was assessed with the Constant score. 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, 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 (Neer’s sign, Hawkins’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 binplanar 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
screws into the humeral head. Cortical screws for distal locking were inserted into the upper shaft via targeting sleeves using cortical screws. Finally, the rotator cuff incision is carefully closed with absorbable suture.

MultiLoc proximal humeral nail is a titanium 160 mm cannulated nail with multiple proximal 4.5 and 3.5 mm (screw-in-screw), locking screw options and polyethylene inlay for angular stability that works against screw back-out, and 2 distal multi-planar locking options. It has also an ascending screw that provides calcar support. It is available in 2 diameters: 8 and 9.5 mm. The nail insertion was made under fluoroscopic control percutaneously in those cases where closed reduction was possible (Fig. 1). The entry point is situated at the apex of the humeral head (Fig. 2), in line with the medullary canal in both anterior-posterior and lateral views. A guide rod wire is employed to decide the exact entry point, 1 cm incision is made over the wire, and the hollow drill is passed through the protection sleeve and over the guide rod. The nail insertion is then made using the insertion handle, with the aiming arm oriented laterally. The nail is advanced under direct visualization until its proximal end is below proximal cortex. A K-wire marked the exact height of nail insertion, ensuring to be below the humeral head surface. As in the Polarus nail, cortical screws for distal locking were inserted into the upper shaft via targeting sleeves using cortical screws. Finally, if a percutaneous technique was employed, only the subcutaneous tissue was closed with an absorbable suture.

When needed, regardless of the nail used, K-wires were used as a joystick to reduce the fracture into a more valgus position (Fig. 3). If the reduction was not achieved with closed maneuvers, an open reduction with extended superior incision was performed in order to reduce tuberosities with traction sutures.

Postoperatively, patients are immobilized with a sling. Passive range-of-motion exercises are allowed 24-48 hours after surgery, followed as soon as possible by active assisted motion.

**Statistical analysis**

Qualitative variables are presented with their frequency distribution and percentage. Quantitative variables were summarized with mean and standard deviation (±SD). Quantitative variables showing a skewed distribution were summarized with median and interquartile range (IQR).

We evaluated the association between qualitative variables with chi-square test or Fisher exact test, in the event that more than 25% of the expected were fewer than 5. A comparison of continuous variables that show a normal distribution was performed by analysis of variance (ANOVA). For variables with skewed distribution, a Kruskal-Wallis nonparametric test was used.

Linear relationship was studied between continuous variables by calculating the Pearson correlation coefficient. For the comparison between mean scores of subjective and objective Constant between groups, multiple analyses of variance adjusting for
follow-up time were used. We used the Student t test for related data to compare scores between objective and subjective Constant within each subject. For all tests, a value of significance of 5% was accepted. Processing and data analysis was performed using SPSS 15.0 (SPSS Inc, Chicago, IL).

Results

Demographics

Mean age in years of the Polarus group patients was 71 (range, 38-89) and in the MPHN group 69 (range, 47-87) (P > .05). The gender distribution in groups was 18% male/82% female in the Polarus group and 24% male/76% female in the MPHN group (P > .05). The most frequently affected side in both groups was the right side (P > .05). Therefore, no significant differences regarding demographic characteristics of the 2 groups were found. Demographics data are summarized in Table I.

Perioperative characteristics

Preoperative radiographs were used to classify the fractures according to the Neer classification of proximal humeral fractures. Of the complete group of 26 patients treated with Polarus nail, 20 were 2-part surgical neck fractures and 6 were 3-part greater tuberosity fractures. Of the 26 treated with the MPHN, 17 were 2-part surgical neck and 9 were 3-part fracture.

The distribution of patients regarding their anesthetic risk (American Society of Anesthesiologist: ASA) was 8% ASA I, 72% ASA II, 10% ASA III in the Polarus nail and 13% ASA I, 80% ASA II, 7% ASA III in the MPHN. No statistically significant differences were found between the 2 groups.

Surgical data

Mean operative time including patient positioning, closed reduction, and x-ray control before actual nailing was 104 ± 30 minutes in the Polarus group and 98 ± 17 minutes in the MPHN (P > .05). Open reduction with an extended superior incision rather than a small deltid-splitting incision was necessary in 2 cases treated with the Polarus nail and 3 cases instead of a percutaneous technique in the MultiLoc group, all being 3-part fractures. No intraoperative complications were found.

Postoperative data

The mean hospital stay was 4 ± 3 days in the Polarus nail and 3 ± 2 in the MPHN (P > .05). Two patients required transfusion due to postoperative anemia. There were no more postoperative incidences.

Clinical and radiological results

Radiographic analysis

All but 1 fracture healed. The fracture that did not heal was 1 case of osteosynthesis material migration in the Polarus group that finally needed a reverse shoulder replacement.

The mean neck-shaft angle at final follow-up was 135° ± 17° in the MPHN group and 130° ± 18° (excluding the case that required an arthroplasty) in the Polarus group.
Proximal humerus nailing: randomized trial

Table II  Functional outcome at final follow-up as measured by Constant score related to nail type

<table>
<thead>
<tr>
<th>Constant score</th>
<th>POLARUS (n)</th>
<th>MPHN (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;90 (excellent)</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>89-80 (good)</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>79-70 (satisfactory)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>69-60 (fair)</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>&lt;59 (poor)</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

with no statistically significant differences between groups found in the final results ($P > .05$). Five (20%) of 25 patients in the Polarus group (leaving the arthroplasty case out) had final neck/shaft angles $<120^\circ$ and were considered radiographic malunions, while 3 cases (11.5%) in the MultiLoc group had final neck/shaft angles $<120^\circ$.

Five cases in the Polarus group (19%) and 2 cases (7.7%) in the MPHN had postoperative impingement. Four cases (2 Polarus and 2 MPHN) were immediate, caused by inadequate positioning of the nail (the nail was higher than recommended), while 3 cases (Polarus nail) were detected during the healing process. Those nails were inserted through the greater tuberosity fracture and lateral to the sulcus, healing with a varus collapse of the head. We only found 1 case of articular surface intrusion of the screw (MultiLoc group). The high percentage of proximal screw back-out found in the Polarus group compared to the MPHN group must be addressed. Seven patients in the Polarus group (26%) had one or more screws loosened versus none in the MPHN ($P = .02$).

Clinical outcomes
The total mean Constant shoulder score in the operated shoulder was $51.4 \pm 11.5$ (74% compared to the non-operated shoulder) in the Polarus nail group, and $61.2 \pm 9.3$ (83% compared to the nonoperated shoulder) in the MPHN group. Given the high mean age of our patients, we decided to refer to the adjusted Constant score by age and sex. The results after adjustment were $72.72 \pm 15.96$ in the group of patients treated with Polarus nail and $83.3 \pm 16.7$ in the group of patients treated with MPHN. Table II presents the number of patients with excellent, satisfactory, or poor results based on the type of nail employed. Although we found no differences between the 2 nails regarding total Constant score ($P = .246$), there were discovered differences in the presence of symptoms related with rotator cuff disease ($P = .001$), resulting in a better outcome in those parameters in the MPHN group compared with the Polarus (Table III). Neer and Hawkin’s signs were positive in 19 of 26 patients (73%) in the Polarus group and in 9 of 26 patients (34.6%) in the MPHN group. Tenderness in the supraspinatus/greater tuberosity were present in 20 patients (76.92%) treated with Polarus and in 16 patients (61.5%) treated with the MPHN.

The mean range of motion for lateral elevation in the Polarus group was $115^\circ \pm 33^\circ$ and $124^\circ \pm 53^\circ$ in the MultiLoc group. Regarding forward flexion, the mean range of motion in the Polarus group was $127^\circ \pm 42^\circ$ and $132^\circ \pm 46^\circ$ for the MultiLoc group. The mean external rotation measured in Polarus nails was $31^\circ \pm 15^\circ$ and $29^\circ \pm 12^\circ$ in MultiLoc humeral nails. The ranges of motion are summarized in Table III.

Complications
In the Polarus nail group, 11 patients (42%) required an additional surgery for hardware removal due to loss of fixation and/or prominent hardware (subacromial impingement). Seven cases (26%) were minor surgeries (only proximal screw removal due to back-out), while the others required complete hardware removal, with one patient ending up in a revision to a reverse arthroplasty at 3 weeks after surgery (Fig. 4). In the MPHN group, there were 3 cases of hardware removal (11.5%), 2 cases due to subacromial impingment that required nail removal once the fracture was healed, and 1 case required only proximal screw removal because of articular surface intrusion.

Discussion
Proximal humeral fractures are considered problem fractures in the elderly and are a cause of significant morbidity. Previous studies have reported good clinical and radiographic outcomes with the use of the Polarus nail. However, some recent studies have reported higher percentage of unsatisfactory results and reoperation rates with this device. Nolan et al, with the employment of the Polarus nail, reports a 94% union rate, but also 50% malunion rate because of a loss of reduction during the healing process. They conclude that this nail violates the rotator cuff and is unable to resist the deforming forces that can lead to loss of fixation and varus collapse. Additionally, Hirose et al reported unsatisfactory results with high complication rate of up to 32%, while Sosef et al recorded 32% complication rate and 14% (4 cases of 28) of proximal screw migration. A possible reason for this failure could be that the implant design is not optimized for bone characteristics of osteopenic and osteoporotic patients. Iatrogenic greater
tuberosity fracture related to a lateral entry point, varus malalignment linked to the orientation of the proximal screws, and lack of proximal fixation associated with the absence of a practical locking proximal screw mechanism are some of the failure mechanisms. New intramedullary devices have been developed in an effort to minimize some of these complications. The purpose of the MPHN design features is to improve the anchoring of the implant to the bone and to support the head fragment, thereby increasing construct stability.

Both types of nails achieved fracture union in our series. Although no statistical differences between the 2 nails in the mean neck-shaft angle at final follow-up were found, the incidence of malunion (neck-shaft angle <120°) with the employment of the Polarus nail was higher (20%) than with the MPHN (11.5%). Although significantly lower than described by Nolan et al (50%) with the Polarus nail, it is still very high. This discrepancy between both nails with a minor incidence of varus collapse in the MPHN could be explained by different characteristics, such as the presence in this device of the ascending screw that could prevent the loss of reduction especially in elderly patients. These older patients, prevalent in our group, show osteoporotic fractures with metaphyseal comminution and suboptimal primary stability. This screw targets bone areas with statistically significant higher quality in the posteromedial part of the humerus, thus reducing varus deformation.26 For appropriate positioning of the calcar screw, the nail height must be optimal staying just below the subchondral bone for support.

The other factor that, in our opinion, influences the final reduction achieved with each nail is the entry point. Nails with more lateral starting points (as happened commonly with the Polarus nail), and also with associated metaphyseal comminution, were likely to displace into less than 120° neck/shaft angle. Agel et al2 described bending moments associated with this relative varus create an environment for fixation failure with accompanying screw loosening and subsequent fracture displacement, thereby leading to loss of fixation and failure. Our radiographic measurements, showing a high incidence of varus collapse (20%), support this assertion. The authors believe that the MPHN is particularly useful for the stabilization of 3-part fractures with greater tuberosity involvement, because this more medial entry point avoids an uncontrolled iatrogenic bone split in this area.

Failure of proximal fixation represents one of the most frequent complications after intramedullary nailing of humeral fractures. Two factors contribute to this failure: absence or poor locking mechanism and poor proximal screw orientation to areas of the humeral head with lower bone density. Our incidence of loosening of the proximal cancellous screws (26%) in the Polarus nail was higher than published in other series that range from 4% to 20%.2,14,15,24 We think this is related to the poor locking mechanism for proximal screws in this nail type (nail-based fixation), which leaves proximal fixation depending only on the ability of the screw to hold in osteopenic bone (bone-base fixation) in a series of patients with a prevalence of females and geriatric age were osteoporosis is common (71 years average and 82% of females).

To prevent the loosening of the proximal screws, Inoue et al recommended that the second and third proximal cancellous screws should be anchored by penetration into the far cortex.15 In the MPHN, no proximal screw back-out was found. This fact must be related to the finding of the study performed by Schiuma et al which shows how directing the proximal screws at regions with higher bone densities, as is intended in this nail type, can improve stability.26

Agel et al recently reported on 20 patients with acute proximal humerus fractures who were treated with the Polarus nail.2 Only 11 healed without complication. Three patients had proximal screw loosening and 2 required revision surgery for proximal fixation failure (25%).

Adedapo and Ikpeme reported on 23 fractures treated with a Polarus nail, all of which healed. A large percentage
of patients had complete pain relief. Of the patients, 3 (13%) had painful proximal screw loosening and required screw removal.1

In our clinical results, although there were no statistical differences in the final functional results between the 2 nails (mean adjusted Constant score: 83 in the MPHN and 73 in the Polarus nail), patients treated with MPHN have better functional outcomes mainly in terms of pain. Although the cause of residual shoulder pain after intramedullary nail fixation can be multifactorial (violation of the rotator cuff tendon footprint, prominent hardware, shoulder impingement, stiffness, varus collapse, and positive greater tuberosity to humeral head distances), the authors think that the difference in pain between the 2 nails is based on the low rates of symptoms related with the rotator cuff after the treatment, with a MPHN (34%) over the Polarus nail (73%). Nolan et al 22 identified their paper as the first study to correlate the use of the Polarus nail with the presence of rotator cuff morbidity, showing a high incidence of symptoms and rotator cuff weakness after its employment. Our study is the first one that compares the presence of these symptoms in the MPHN (a straight nail) with the Polarus nail (a curvilinear nail). We believe that the low incidence of them with the employment of the MPHN correlates with the more medial entry point in this nail that avoids the critical hypovascular zone of the rotator cuff. In a cadaveric study performed by our group in four shoulders from three preserved human specimens employing this nail we confirmed this hypothesis.12 The entry point was always medial to the myotendinous junction in an area of rich blood supply being the myotendinous junction located an average of 4.5 mm (range, 2.21-7.30) lateral to the entry point. This entry point has no clinical consequences as proved by our experience and the literature, as humeral cartilage at that level has not contact with the glenoid.

To address cuff tendon insertion violation, several technical adjustments have been developed to perform a more medial entry point (Nevisier portal, rotator cuff interval, anterior acromial approach).18,23,25 However, prospective comparative studies between the employment of curvilinear (more lateral entry point and theoretically more rotator cuff damage) and straight nails (more medial entry point and consequently more articular cartilage damage) have not been published. Studies of healing rates after rotator cuff repair have demonstrated nonhealing rates up to 80%.4,11,16

It is possible that some of the patients with the Polarus nail with an entry point more lateral requiring a tenotomy of the rotator cuff had nonhealing of the tendon insertion as suggested by Nolan et al and therefore they have increased shoulder pain.22

Limitations of the current study are the absence of information regarding rotator cuff pathology previous to fracture. It is possible that the age of our patient population (average 69 in the MPHN and 71 in the Polarus nail) predisposes to rotator cuff pathology prevalence. However, this is true for both groups; therefore, the Polarus higher incidence should be taken into account.

**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.


