Locking Intramedullary Nails and Locking Plates in the Treatment of Two-Part Proximal Humeral Surgical Neck Fractures

A Prospective Randomized Trial with a Minimum of Three Years of Follow-up

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Background: Locking intramedullary nails and locking plates specially designed for proximal humeral fractures are widely used. The purpose of our study was to compare the outcomes between these two types of implants in patients with a two-part surgical neck fracture. The advantages and shortcomings of each method were analyzed.

Methods: A prospective randomized study was performed. Fifty-one consecutive patients with a fresh two-part surgical neck fracture were randomized to be treated with a locking intramedullary nail (n = 25) or a locking plate (n = 26). Clinical and radiographic assessments were conducted at one year and three years after the surgery. A visual analog scale (VAS) was used to assess shoulder pain. The American Shoulder and Elbow Surgeons (ASES) scores and Constant-Murley scores were recorded to evaluate shoulder function.

Results: Fracture union was achieved in all patients within three months after the surgery. At one year postoperatively, a significant difference (p = 0.024) was found with regard to the complication rate between the locking plate group (31%) and the locking nail group (4%). The average ASES score, median VAS score, and average strength of the supraspinatus were significantly better in the locking plate group (90.8 compared with 83.6 points [p = 0.021], 1.0 compared with 0.5 point [p = 0.042], and 77.4% compared with 64.3% [p = 0.032]). At three years postoperatively, no significant difference could be found in terms of any parameter between the two groups. Significant improvement in the VAS pain scores, ASES scores, and Constant-Murley scores were found between the one-year and three-year follow-up examinations in each group.

Conclusions: Satisfactory results can be achieved with either implant in the treatment of two-part proximal humeral surgical neck fractures. There was no difference regarding the ASES scores between these two implants at the time of the final, three-year follow-up. The complication rate was lower in the locking intramedullary nail group, while fixation with a locking plate had the advantage of a better one-year outcome.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Fractures of the proximal part of the humerus are common in elderly patients with osteoporosis[1,2]. Open reduction and internal fixation may be necessary for a fracture with prominent displacement, but poor bone quality may not allow secure fixation. Conventional plate-and-screw fixation has a very high failure rate when used to treat this fracture[3-6]. Locking plates and locking intramedullary nails have been specially designed for proximal humeral fractures to overcome problems with achieving adequate fixation. Although several clinical studies in which these two implants were used have been reported, very few comparative studies were found in the literature[7]. The purposes of our study were to compare the outcomes of two groups of patients with similar injuries who had been treated with either a locking plate or a locking nail, and to investigate the advantages and limitations of each method.

We hypothesized that, with proper surgical techniques, (1) satisfactory results can be achieved with the treatment of two-part surgical neck fractures with either implant and (2)

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there is no difference between these two implants with regard to final outcomes.

Materials and Methods

Study Design

This study was approved by the local institutional review board.

The inclusion criteria for this study were a skeletally mature patient who agreed to participate in the study, a two-part surgical neck fracture of the proximal part of the humerus as classified with the Neer system[8], and an acute fracture treated surgically within twenty-one days after the injury. The exclusion criteria were open physes, fracture and displacement involving the greater or lesser tuberosity or extension of the fracture line distally beyond the deltoid tubercle, associated musculoskeletal injuries to the ipsilateral upper extremity, an open fracture, and prior surgery on the affected shoulder.

Between November 2004 and December 2006, 243 patients with a proximal humeral fracture were treated surgically in our clinic and were evaluated for eligibility for the present study. One hundred and twelve patients did not meet the inclusion criteria, and seventy-four patients refused to participate in any clinical trial. With these 186 patients excluded, fifty-seven patients who met the inclusion criteria and agreed to participate were included in the study.

Randomization was accomplished with use of a random-numbers list generated by software and kept by the operating room nurse. Before the surgery, the circulating nurse reviewed the random-numbers list. Patients who had been assigned an odd number were subsequently treated with a locking nail, and those who had been assigned an even number were managed with a locking plate.

At one year after the surgery, all but two patients, both from the locking nail group, were available for follow-up. At three years after the surgery, one patient in the locking nail group had died of a cause unrelated to the surgery and three patients in the locking plate group had been lost to follow-up, leaving fifty-one patients (89%) available for final evaluation. Among them, twenty-five (nine males and sixteen females) were treated with the intramedullary locking nail and twenty-six (eight males and eighteen females), with the locking plate. The flow diagram for this trial is shown in Figure 1.

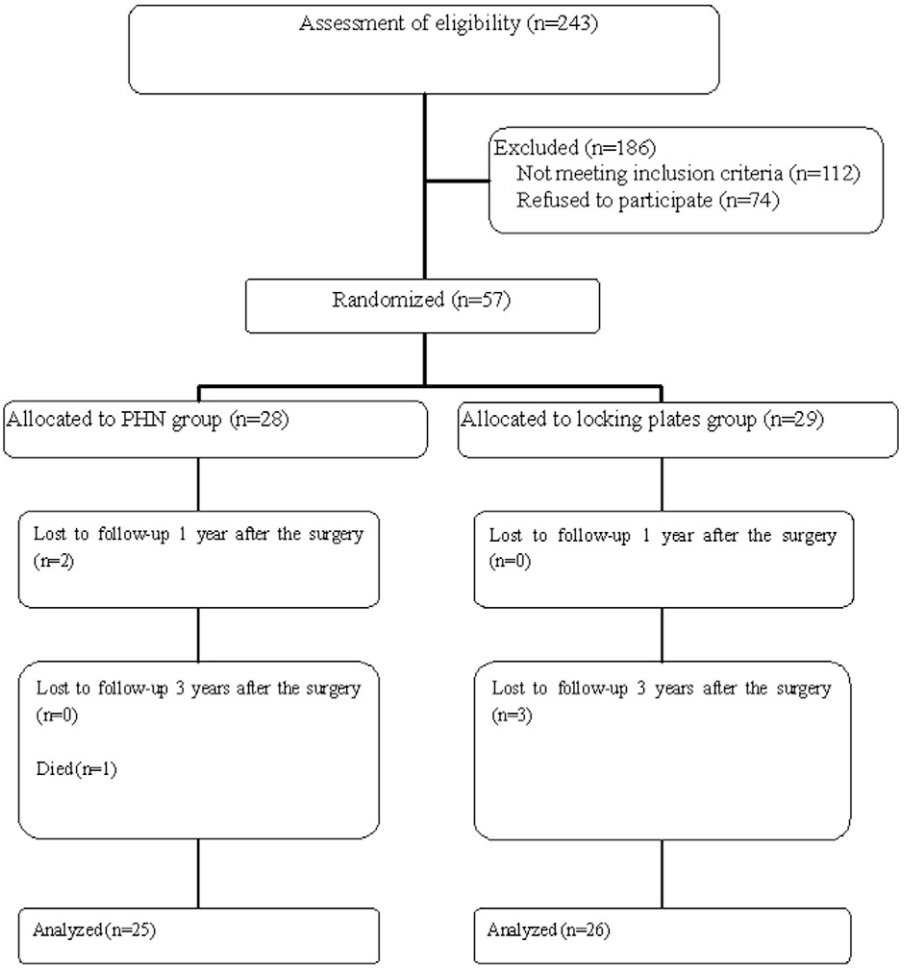

Fig. 1

Flow diagram for enrollment and analysis. PHN = locking nail.

Implants

The locking nail used in this study was the Proximal Humeral Nail (PHN; Synthes, Oberdorf, Switzerland). Two types of locking plates—the Locking Proximal Humeral Plate (LPHP; Synthes) and the Proximal Humeral Internal Locking System (PHILOS; Synthes)—were used.

Preoperative Evaluation

A detailed history was obtained preoperatively. Radiographs included an anteroposterior view with the shoulder in neutral rotation, a lateral view in the scapular plane, and a Velpeau axillary view. All fractures were classified as two-part surgical neck fractures according to the Neer system[8].

Surgical Indication

If the displaced fracture could not be adequately reduced by closed reduction or the reduction could not be maintained, open reduction and internal fixation was recommended.

Surgical Procedure

All surgical procedures were done by the senior surgeon (C.J.), with the patient in the supine position and the arm draped to move freely intraoperatively. For the patients in the locking nail group, the surgery was done with use of an interscalene brachial plexus block. A 4-cm-long incision was made lateral to the acromion parallel to the Langer line. The deltoid was split, separating its anterior and middle thirds, from the acromion to a point approximately 4 cm distally. A 1-cm incision was made on the supraspinatus tendon in line with its muscle fiber orientation. The medullary canal was opened with an awl. Under image control, the entry point was made just lateral to the articular margin in the sulcus between the greater tuberosity and the articular margin. A Proximal Humeral Nail was inserted without reaming after the fracture was fully reduced. After insertion of the spiral blade and the distal locking screws, an end cap was screwed in to lock the spiral blade. The rotator cuff tendon and the deltoid were carefully repaired during wound closure.

General anesthesia combined with an interscalene block was used for the patients in the locking plate group. A standard deltopectoral approach was employed to expose the fracture. Indirect reduction with use of an elevator under the guidance of an image intensifier was achieved, and the fracture was reduced and temporarily fixed by a Kirschner wire. A locking plate was placed on the proximal part of the humerus along the lateral border of the bicipital groove. The plate was placed about 5 to 8 mm inferior to the tip of the greater tuberosity, to avoid subacromial impingement, and 2 to 4 mm lateral to the bicipital groove. The position of the plate was checked with the image intensifier intraoperatively, and the plate was fixed with locking screws. Finally, a thorough fluoroscopic screening was done to ensure that no screw was penetrating the articular surface of the humeral head (Fig. 2).

The surgery time, blood loss during surgery, and need for blood transfusion were recorded.

Postoperative Rehabilitation

Postoperative rehabilitation was the same for both groups. The affected extremity was protected by a sling for six weeks postoperatively. Passive range-of-motion exercises, supervised by a physical therapist, were initiated on the first postoperative day. Active and active-assisted exercises began after six weeks, when early callus formation could be seen on radiographs. Strengthening exercises were started three months after the surgery.

Postoperative Evaluation

All of the follow-up physical examinations and radiographic evaluations were done by the same independent observer. The fracture was considered to be clinically healed when no tenderness was present at the fracture site.

Radiographic Evaluation

Proximal humeral radiographs were obtained on the second day and at six weeks, three months, one year, and three years

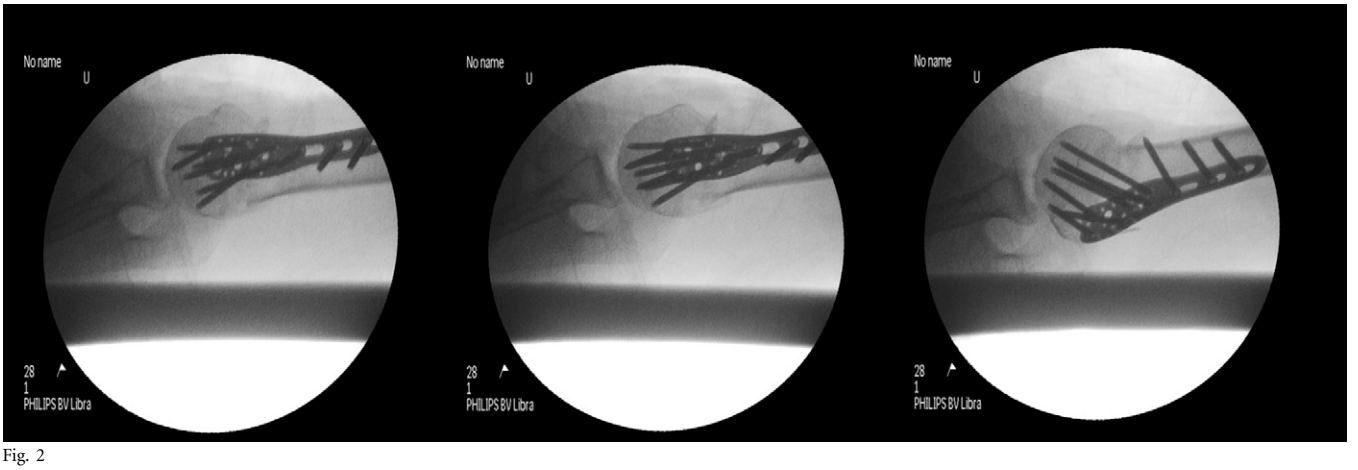

Fig. 2

Intraoperative fluoroscopic images used to check for screw-tip penetration from the axillary view with the shoulder in internal rotation (left image), neutral (middle), and external rotation (right).

after the surgery. The fracture was deemed healed when bridging callus was seen at the fracture site.

The neck-shaft angle was measured on anteroposterior radiographs with the shoulder in neutral rotation. A line was drawn from the superior to the inferior border of the articular surface (the A-B line in Fig. 3). Then a perpendicular line (the C-D line) was drawn, through the center of the humeral head, through the A-B line. The angle between the C-D line and the line bisecting the humeral shaft (the E-F line) was measured as the neck-shaft angle (Fig. 3). A secondary varus collapse was diagnosed if the neck-shaft angle decreased >10° during the follow-up period[9].

The radiographs were evaluated for osteonecrosis of the humeral head[10], nonunion or malunion of the fracture, failure of fixation, or penetration of screws through the articular surface after the surgery. Signs of posttraumatic glenohumeral arthritis were also noted[11].

Evaluation of Shoulder Function

A physical examination was done at one year and three years postoperatively. In addition, a validated electronic isometric strength dynamometer (HFG-45; Transducer Techniques, Temecula, California) was used to evaluate the strength of the supraspinatus muscle of both shoulders with the patient's arm pronated and elevated 90° in the plane of scapula. The ratio of the supraspinatus strength of the affected side to that on the healthy side was used to determine recovery of supraspinatus function. The range of shoulder motion was measured with a standard goniometer. American Shoulder and Elbow Surgeons (ASES) scores[12] and Constant-Murley scores[13] were recorded to evaluate shoulder function. The severity of pain was graded on a 10-cm visual analog scale (VAS) anchored by two extremes of pain—no pain and extreme pain—with the patients indicating a point between these extremes.

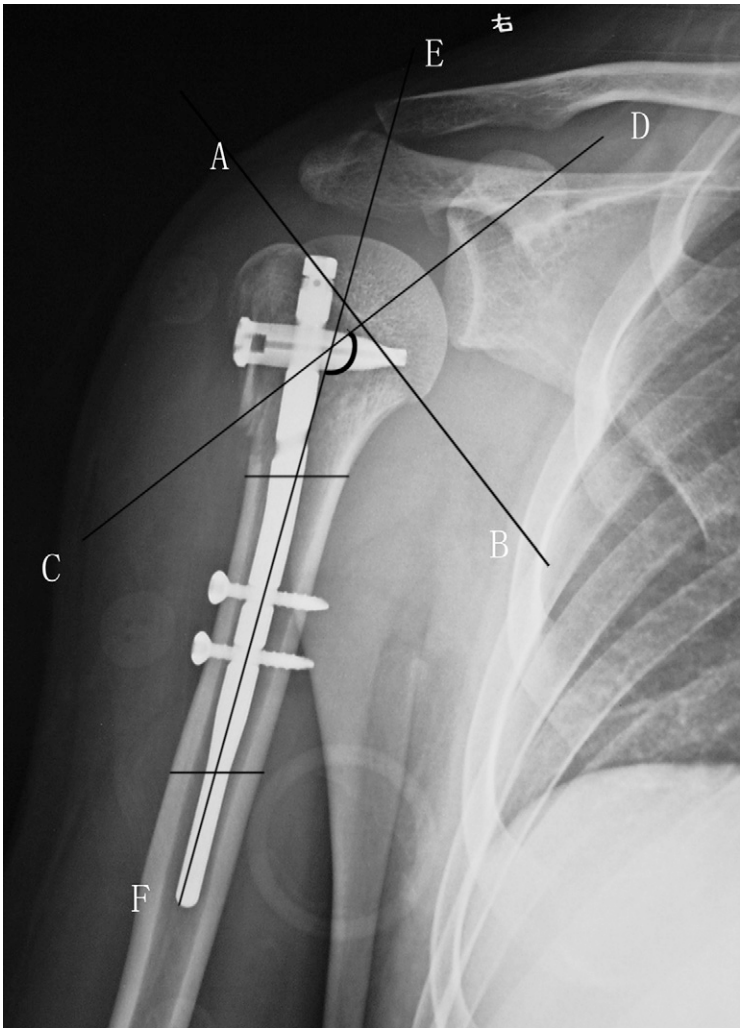

Fig. 3

Measurement of the neck-shaft angle on a postoperative anteroposterior radiograph with the shoulder in neutral rotation. See text for an explanation of the lines.

Statistical Analysis

A difference of 6.4 points in the ASES score between the two groups was considered to be the minimal clinically important difference[14]. On the basis of a preliminary study of the first eight cases in this series, the standard deviation was calculated. A power analysis, with a power of 90% and an alpha of 0.05, demonstrated that a sample size of twenty-four patients per group was needed.

Continuous variables were reported as the mean and one standard deviation. Differences between groups of continuous data were analyzed with the Student t test. If the data were non-normal, the median and interquartile range were reported and a Mann-Whitney U test was used to perform the analysis. For all analyses, $p < 0.05$ was considered to be significant.

Source of Funding

No external funding was received for this study.

Results

Demographic Characteristics

The average patient age was 54.8 ± 17.1 years in the locking nail group compared with 50.5 ± 19.9 years in the locking plate group. The dominant extremity was involved in nine patients in the locking nail group and ten patients in the locking plate group. The interval between the injury and the surgery was 9.4 ± 5.7 days in the locking nail group compared with 9.2 ± 5.7 days in the locking plate group. Medial cortical comminution (defined as one or more butterfly fragments adjacent to the medial cortex on the anteroposterior view with the shoulder in neutral rotation) was found in four patients in the locking nail group and two in the locking plate group. The demographic characteristics of each group are summarized in Table I. A matched-pair analysis was performed on these two groups to ensure that the patients had similar demographic characteristics. No difference was detected between the two groups with regard to age ($p = 0.41$), sex ($p = 0.69$), involvement of the dominant side ($p = 0.86$), medial cortical comminution ($p = 0.627$), or interval between the injury and the surgery ($p = 0.91$).

TABLE I Demographic Characteristics

	Locking Nail Group	Locking Plate Group
No. of patients	25	26
Male	9	8
Female	16	18
Age* *(yr)*	54.8 ± 17.1	50.5 ± 19.9
Dominant side involved†	9	10
Medial cortical comminution†	4	2
Interval between surgery and injury* *(days)*	9.4 ± 5.7	9.2 ± 5.7

*The values are given as the mean and standard deviation. †The values are given as the number of patients.

Intraoperative Parameters

The average duration of the surgery was 84.4 ± 36.9 minutes in the locking nail group compared with 109.3 ± 36.0 minutes in the locking plate group ($p = 0.013$). The average blood loss was 214.1 ± 140.2 mL in the locking nail group and 382.1 ± 200.6 mL in the locking plate group ($p < 0.01$). Blood transfusion was needed in one patient in the locking nail group and five patients in the locking plate group ($p = 0.229$).

Radiographic Outcomes

Bridging callus was seen on radiographs within three months after the surgery in all patients. No osteonecrosis of the humeral head, degenerative change of the glenohumeral joint, or secondary varus collapse was found during the three years of follow-up.

Clinical Outcomes

Active Range of Motion

At one year postoperatively, the active forward flexion, external rotation, and internal rotation of the shoulder were 151.6° ± 20.4°, 44.0° ± 4.5°, and T9 (range, T2 to the buttock), respectively, in the locking nail group compared with 155.4° ± 13.6°, 38.5° ± 3.2°, and T8 (range, T4 to L2) in the locking plate group (Table II). No significant difference between the two groups was found regarding active forward elevation ($p = 0.441$), active external rotation ($p = 0.321$), or active internal rotation of the shoulder ($p = 0.433$).

At three years, the active forward flexion, external rotation, and internal rotation of the shoulder were 160.8° ± 11.9°, 47.8° ± 17.3°, and T8 (range, T2 to the buttock), respectively, in the locking nail group compared with 157.3° ± 15.1°, 40.4° ± 17.4°, and T8 (range, T2 to the buttock) in the locking plate group. No significant difference between the two groups was found regarding active forward elevation ($p = 0.365$), active external rotation ($p = 0.133$), or active internal rotation of the shoulder ($p = 0.636$).

Strength of Supraspinatus Muscle

At one year, the strength of the supraspinatus muscle on the affected side in the locking nail group (64.3% ± 18.3%) was significantly less ($p = 0.032$) than that in the locking plate group (77.4% ± 20.8%). However, no significant difference was found in the strength of the supraspinatus muscle between the locking nail group (70.2% ± 16.0%) and the locking plate group (79.3% ± 20.4%) at three years ($p = 0.106$) (Fig. 4).

Pain

At one year, the median VAS score in the locking nail group was 1.0 with an interquartile range of 1.0 and that in the locking plate group was 0.5 with an interquartile range of 1.8. A significant difference was found between the two groups ($p = 0.042$).

TABLE II Clinical Outcomes

	Locking Nail Group	Locking Plate Group	P Value
1-year follow-up			
Forward elevation* *(deg)*	151.6 ± 20.4	155.4 ± 13.6	0.441
External rotation* *(deg)*	44.0 ± 4.5	38.5 ± 3.2	0.321
Internal rotation†	T9 (T2-buttock)	T8 (T4-L2)	0.433
Strength of supraspinatus (affected side/healthy side)* *(%)*	64.3 ± 18.3	77.4 ± 20.8	0.032
VAS score† *(points)*	1.0 (1.0)	0.5 (1.8)	0.042
ASES score* *(points)*	83.6 ± 11.7	90.8 ± 9.7	0.021
Constant-Murley score* *(points)*	88.0 ± 10.4	92.0 ± 6.3	0.096
3-year follow-up			
Forward elevation* *(deg)*	160.8 ± 11.9	157.3 ± 15.1	0.365
External rotation* *(deg)*	47.8 ± 17.3	40.4 ± 17.4	0.133
Internal rotation†	T8 (T2-buttock)	T8 (T2-buttock)	0.636
Strength of supraspinatus (affected side/healthy side)* *(%)*	70.2 ± 16.0	79.3 ± 20.4	0.106
VAS score† *(points)*	0 (1.0)	0 (0.8)	0.624
ASES score* *(points)*	90.0 ± 8.1	94.0 ± 6.3	0.059
Constant-Murley score* *(points)*	93.3 ± 6.7	94.5 ± 5.8	0.489

*The values are given as the mean and standard deviation. †The values are given as the mean with the range in parentheses. ‡The values are given as the median with the interquartile range in parentheses.

At three years, the median VAS score in the locking nail group was 0 with an interquartile range of 1.0 and that in the locking plate group was 0 with an interquartile range of 0.8. No significant difference was found between the two groups at three years ($p = 0.624$).

When the VAS score was compared between the first and second follow-up examinations in each group, a significant improvement in the pain score at the second follow-up interval was noted not only in the locking nail group ($p = 0.010$) but also in the locking plate group ($p = 0.012$).

Functional Scores

After one year of follow-up, the patients in the locking nail group showed a significantly lower ASES score ($p = 0.021$),

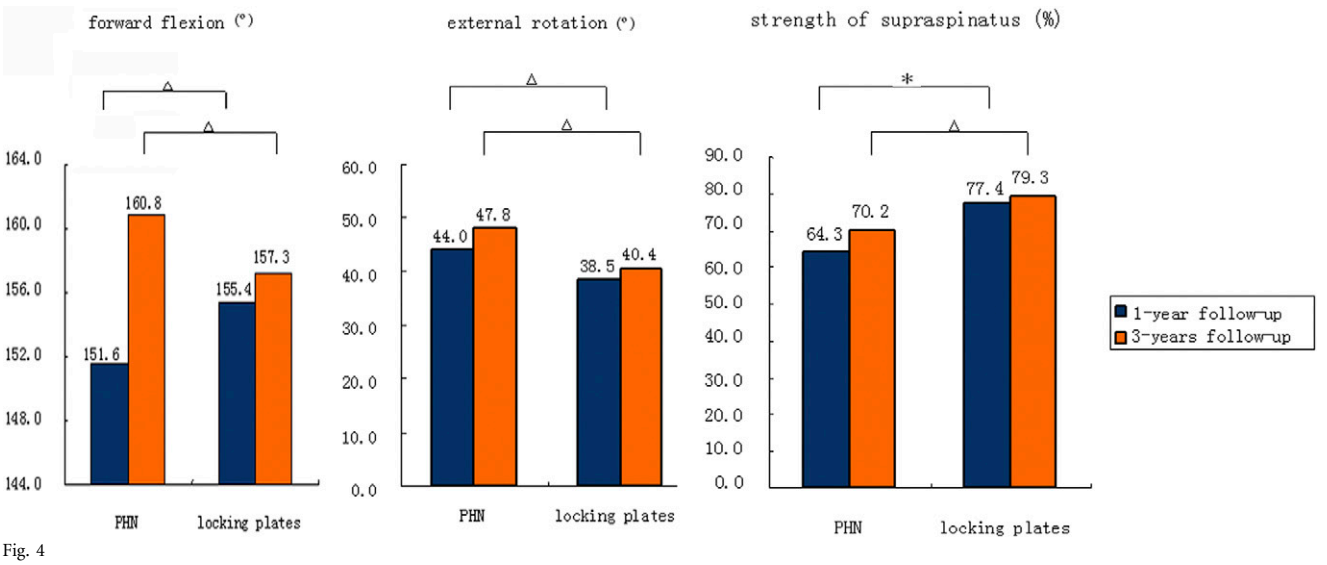

Fig. 4

Forward flexion, external rotation, and supraspinatus strength in the locking nail (PHN) and locking plate groups at one year and three years postoperatively. A significant difference is indicated by an asterisk, whereas a triangle indicates that the difference is not significant.

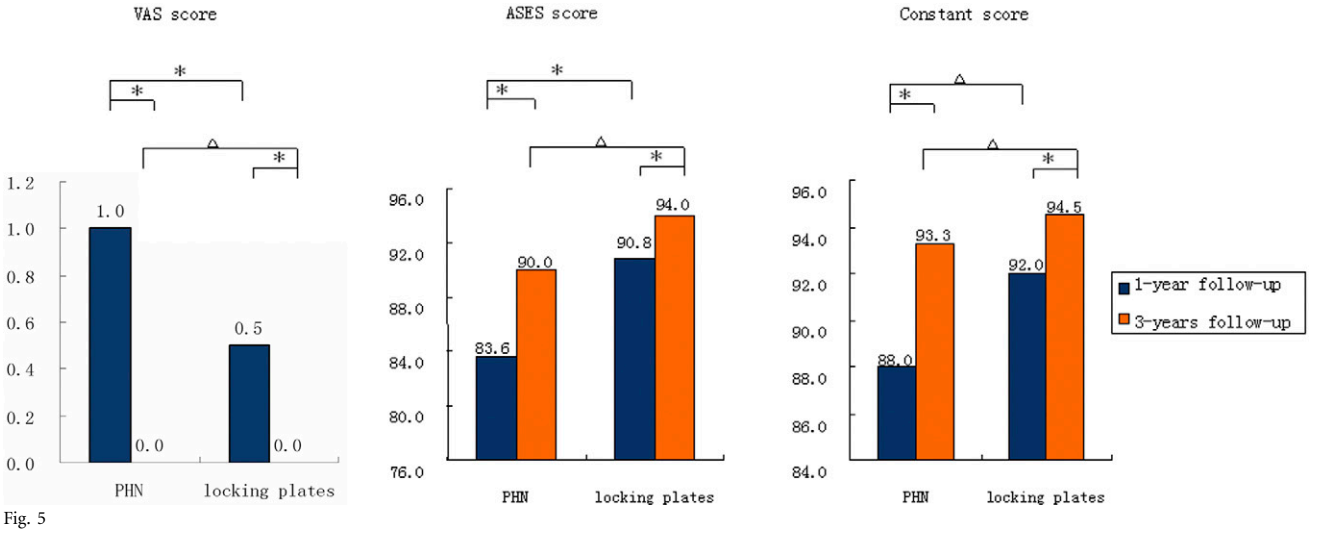

Fig. 5

The median VAS score, mean ASES score, and mean Constant-Murley score in the locking nail (PHN) and locking plate groups at one year and three years postoperatively. A significant difference is indicated by an asterisk, whereas a triangle indicates that the difference is not significant.

with a mean of 83.6 ± 11.7 points compared with 90.8 ± 9.7 points in the locking plate group. No significant difference was found in the Constant-Murley score ($p = 0.096$), with 88.0 ± 10.4 points in the locking nail group and 92.0 ± 6.3 points in the locking plate group.

After three years of follow-up, no significant difference was found between the locking nail and locking plate groups with regard to either the ASES score (90.0 ± 8.1 and 94.0 ± 6.3 points, respectively; $p = 0.059$) or the Constant-Murley score (93.3 ± 6.7 and 94.5 ± 5.8 points, respectively; $p = 0.489$).

When the ASES scores at the first and second follow-up examinations were compared within each group, a significant improvement in the score at the time of the second follow-up was found in both the locking nail group ($p = 0.004$) and the locking plate group ($p = 0.007$). Likewise, improvements in the Constant-Murley scores were found in the locking nail group ($p = 0.002$) and in the locking plate group ($p = 0.015$) (Fig. 5).

Complications

No infection was seen in either group. Heterotopic ossification was found in one patient in the locking nail group and two patients in the locking plate group. Screw penetration into the articular surface of the humeral head was noted in five patients in the locking plate group within three months after the surgery. The screw tips penetrated beyond the subchondral bone, and all patients underwent screw revision or removal after this was noted on the radiographs. No degenerative change of the glenohumeral joint was observed at the time of final follow-up in these five patients, and there was no apparent functional impact. The difference in the final ASES score between the five patients with screw penetration (97.1 ± 3.7 points) and the twenty-one patients without penetration (93.4 ± 6.6 points) was not significant ($p = 0.294$). A pneumothorax occurred during interscalene anesthesia in one patient in the locking plate group. The overall complication rate was 4% in the locking nail group and 31% in the locking plate group. The locking nail group had a significantly lower complication rate compared with the locking plate group ($p = 0.024$).

Discussion

The use of intramedullary nailing to treat complex proximal humeral fractures remains controversial. We do not recommend nailing for such fractures. Our indication for the use of a proximal humeral nail is limited to two-part surgical neck fractures with an intact proximal osseous ring.

There have been several clinical studies on the use of intramedullary fixation for proximal humeral fractures[6,15-18]. Many studies have demonstrated good results with the use of locking plates for this fracture[14,19-22], but high complication rates have also been reported[9,19]. The mean postoperative Constant-Murley scores were usually between 70 and 80 points in these previous studies. In our series, patients in both groups recovered good shoulder function, with a mean Constant-Murley score of 93.3 points in the locking nail group and 94.5 points in the locking plate group at three years after the surgery. No difference was found between the two groups regarding fracture-healing, pain, the active shoulder range of motion, the ASES score, or the Constant-Murley score at three years. There was no secondary varus collapse in either group, which proved that both methods can provide biomechanical stability in patients with a two-part surgical neck fracture. Our results supported our two hypotheses: (1) treatment of a two-part surgical neck fracture with either implant can achieve satisfactory results, and (2) there is no difference in the final outcomes between these two implants. The better results achieved in our study as compared with those in other reported studies may be partly due to the inclusion in our study of only patients with a two-part surgical neck fracture (Figs. 6 and 7).

Although good results were obtained in both groups, each method has its own characteristics.

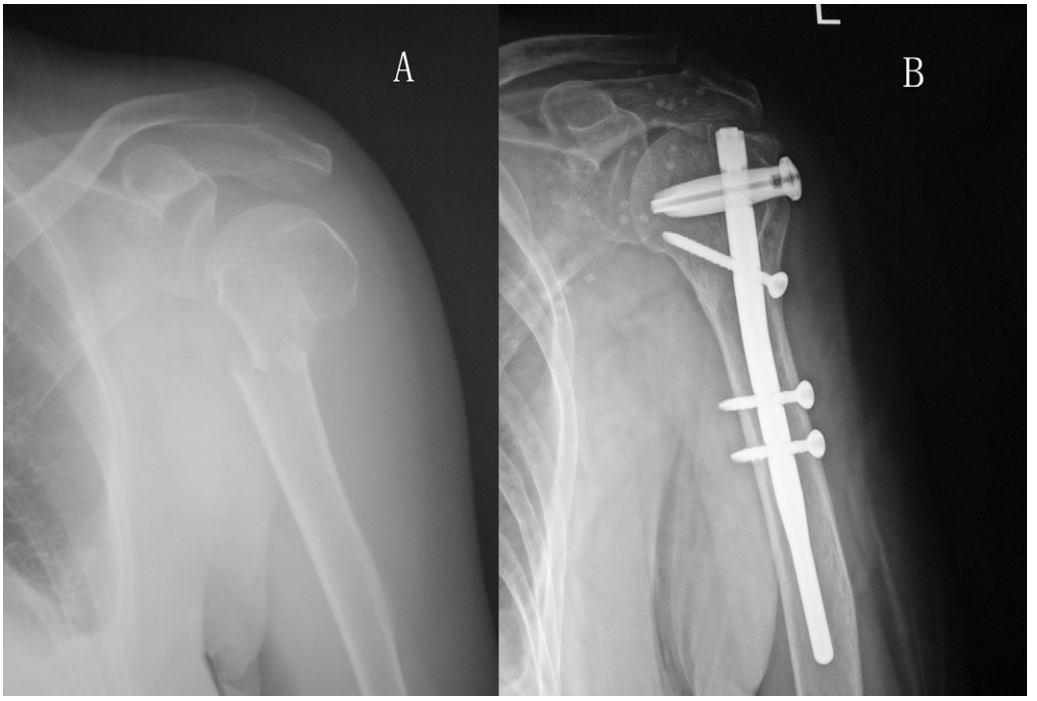

Fig. 6

A: Anteroposterior radiograph demonstrating a two-part surgical neck fracture in a sixty-nine-year-old woman. *B:* Anteroposterior radiograph after fracture fixation with a proximal humeral nail.

The surgical techniques for application of locking nails and locking plates are very different. When the locking plates were applied, indirect reduction techniques could be used to aid in fracture reduction. The first screw was a standard cortical screw, which was placed in the long combi-hole. By tightening the screw, we could use the compression generated from this screw to help during fracture reduction to match the contour of the plate. The locking screws were inserted after this temporary reduction. Medial cortical support may be critical for the stability of the fixation with a locking plate. Good medial support will be achieved by anatomical reduction of the medial cortex and placement of locking screws in the most inferomedial region of the humeral head. With regard to the locking nails, only after the reduction had been fully achieved could the nail be inserted into the medullary canal. We were not able to use the nail to aid or adjust reduction after the entry point was opened because of concern about fracture propagation into the greater tuberosity. A correct entry point is crucial to the success of nail

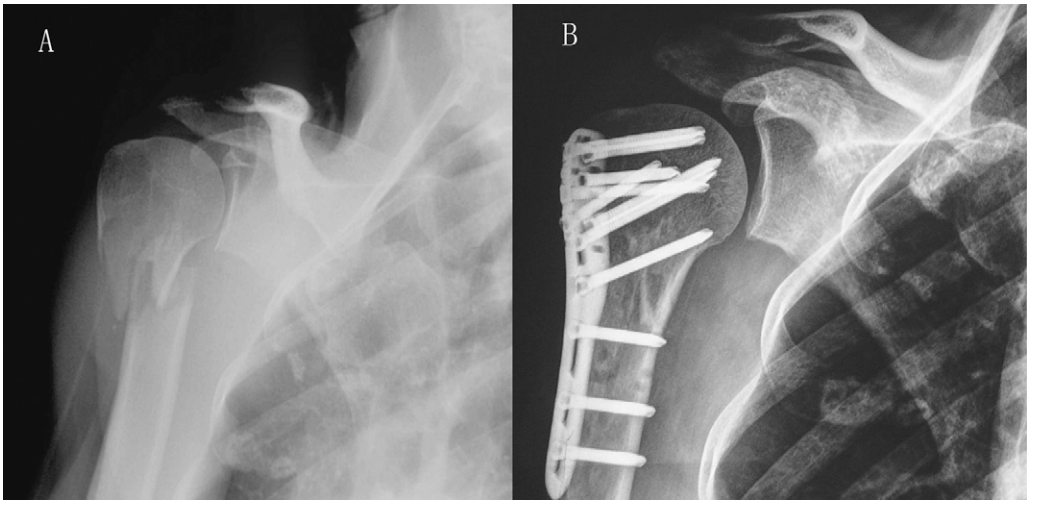

Fig. 7

A: Anteroposterior radiograph demonstrating a two-part surgical neck fracture in a fifty-three-year-old man. *B:* Anteroposterior radiograph after fracture fixation with a locking plate.

fixation. Agel et al. demonstrated that a fracture fixed with a nail placed through an entry point that was too lateral was more likely to become secondarily displaced, leading to a varus deformity[23].

Intramedullary fixation can be executed with a minimally invasive approach, which may facilitate fracture-healing, whereas a long incision is needed for the locking plate. Conversely, morbidity related to the entry point is a major concern with antegrade nailing in shoulders.

Many authors have reported limitations of shoulder function after antegrade nailing[20,21,24,25]. The entry point for the nail is on the articular margin medial to the edge of the supraspinatus tendon, which is incised when a nail is introduced into the intramedullary canal. This may explain why the locking nail group had a significantly lower ASES score, VAS score, and recovery of supraspinatus strength compared with the locking plate group at one year postoperatively.

The patients in our study were informed preoperatively that the implant would not be removed, so the nails were inserted flush with the articular margin. We never use a limited approach with a stab incision to open the entry point. Direct visualization of the supraspinatus tendon is mandatory before the entry point is opened. The supraspinatus tendon was incised along its muscle fiber orientation and repaired carefully afterward. The similarity of the supraspinatus strength between the two groups at the three-year follow-up examination may be a result of improved healing of the supraspinatus tendon, the limited number of patients enrolled in our study, or compensation by the other rotator cuff muscles. Although substantial precautions were taken to protect the supraspinatus during the insertion technique, entry point morbidity is still the primary concern when using a proximal humeral nail in an antegrade fashion.

The complication rate was significantly higher with the locking plates in our series, with the most frequent complication being screw penetration after locking plate fixation (a prevalence of 19%)[19,22,26,27]. Possible reasons for screw penetration include the screw cutting out after secondary varus collapse or improper operative technique. Because no obvious secondary varus displacement was found in our series during the follow-up examinations, we believe that the latter was the main reason for the penetration. Most of our patients were elderly, with very osteoporotic bones, so we put the locking screws close to the dense subchondral area to achieve better stability. Although we routinely rotate the shoulder to check the anteroposterior and the axillary lateral view under fluoroscopy during the operation, the tips of screws were found to be protruding over the subchondral bone on follow-up radiographs of five patients. Only the very tips of the screws penetrated beyond the subchondral bone in these five patients, and they had screw revision when this diagnosis was made. No obvious degenerative change of the shoulder joint or negative impact on shoulder function was found at the final, three-year follow-up examination. To further decrease the prevalence of screw penetration, we now place screws farther from the articular surface and leave a 2 to 3-mm distance between the tips of the screws and the border of the articular surface as seen on both anteroposterior and axillary views.

The VAS pain score, ASES score, and Constant-Murley score at the three-year follow-up examination were all improved compared with those at the one-year examination in both groups. Patients with shoulder functional impairment one year after surgery should be encouraged to pursue a rehabilitation program for further improvement.

Our study had several weaknesses. The number of patients involved was small, and the duration of follow-up was short. Although the follow-up physical examinations were done by an independent observer, that observer was not blinded with regard to the type of surgery that the patient had had, which may have caused a bias. Furthermore, we did not perform follow-up imaging studies to verify the integrity of the supraspinatus after the locking nail fixation.

In conclusion, satisfactory results can be achieved by treating two-part proximal humeral surgical neck fractures with either a locking plate or a locking nail. There is no significant difference regarding the final ASES scores between these two implants at three years postoperatively. At one year, the pain scores and functional outcomes are better in patients treated with a locking plate, which implies faster functional recovery compared with that after treatment with a locking nail. The complication rate associated with locking intramedullary nails is significantly lower than that with locking plates, but the entry point morbidity associated with the locking nail requires a longer time to achieve functional recovery of the shoulder. ■

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