Original Article

Clinical outcomes and prognostic factors depending on implant design in the treatment of proximal humeral fractures: A retrospective study

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ABSTRACT

Purpose: We aimed to examine the clinical outcomes of proximal humeral fractures treated with different intramedullary nail shapes.

Methods: Thirty-seven patients were divided into two groups depending on the implant shape. We also defined F group as a subgroup of fracture classification.

Results: In the F group, the flexion of the shoulder joint was significantly greater in S (mean, 134.6°) than in C groups (mean, 109°) ($p = 0.04$). The complication rate was significantly larger in the C group ($p = 0.04$).

Conclusions: Patients with one kind of fracture and who were treated with straight nails had better outcomes.

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1. Introduction

Proximal humeral fractures frequently occur in elderly people, and the number of patients is increasing exponentially with the rate of the aging elderly population.^{1,2} Treatment for this trauma includes conservative or surgical management. Surgical procedures are performed with pins, intramedullary nails, plates, and arthroplasty.³ Damage to the soft tissue is considered less severe with intramedullary nailing, and improvement in the nail design has enabled surgeons to use intramedullary nails for severe fractures in osteoporotic cases.^{3,4} Curved nail designs were commonly used in the beginning. However, since curved nail designs are associated with several complications (e.g., iatrogenic greater tuberosity fracture, varus malalignment related to a lateral entry point or a violation of supraspinatus on a greater tuberosity), a straight intramedullary nail design was developed to minimize these complications and catch the densest part of the humeral head.^{5,6} Currently, different designs of nails are used, but there are few reports on outcome in comparative studies on the intramedullary nail design.⁵

The aim of this study was to examine the clinical outcome of proximal humeral fractures treated surgically with two different

shapes of intramedullary nails, and to determine the prognostic factors that affect these outcomes, with a focus on the specific fracture location.

2. Materials and methods

We conducted a retrospective study on 44 patients (4 male, 40 female) who had undergone operation at our institution and one cooperate hospital with intramedullary nailing for a proximal humeral fracture from March 2011 to July 2013. The exclusion criteria is defined as Neer four-part fracture or nonparticipation of this study.⁷ Seven patients were excluded; three patients with four-part fracture and four nonparticipations. The remaining 37 patients (4 male, 33 female) were included. They were followed at least 16 months postoperatively, and they had Neer two- or three-part fractures.

This study was approved by the research and ethics committee of the Author's institution (Seikeikai Hospital). Informed consent was obtained. All study procedures were performed in accordance with the Declaration of Helsinki.

The age, side of the injury, sex, fracture classification, operation time, bleeding, and follow-up period were reviewed as the patients' characteristics.

Patients were divided into two groups according to the shape of the intramedullary nail: straight nail (S) group (15 patients; Aesculap Targon PH-P nail[®]; Aesculap Targon, Tuttlingen,

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Germany) and the curved nail (C) group (22 patients: 20 received the Stryker T2 nail[®] [Stryker Orthopedics, Mahwah, New Jersey, USA]; 2 received the Acumed Polarus2[®] nail [Acumed, Beaverton, OR, USA]). Each surgeon selected the implants. Classification of the fractures on radiographs and computed tomography (CT) scans was used for diagnosis. The type of fractures that were reviewed were classified by Neer classification.⁷ In addition to the Neer classification, we divided the humeral head into three equal parts along the major horizontal plane. We defined the F group as those with a fracture line that extended to the outer 1/3 of the humeral head above the glenoid center line (Fig. 1). In addition to examining the F group, we examined the insertion points of the straight and curved nails. First, we determined whether the nail most proximal to the humeral fracture site had been inserted within 5 mm from the fracture line on the postoperative frontal plain radiographs.⁸ Furthermore, the sites of nail insertion were divided into the middle and lateral parts of the trisected humeral head, as shown in Fig. 1, for assessment.

In summary, we analyzed outcomes of S and C groups in each these subgroups additionally (Fig. 2).

2.1. Surgical procedure and postoperative therapy

In all cases, the operations were performed through the deltoid splitting or delto-pectoral approach under general anesthesia.⁹ After performing reduction using the joy-stick method, we inserted an intramedullary nail through the optimal position in accordance with each manufacturer's implant instructions. Nails in the S group were inserted through the central tip of the humeral head, while nails in the C group were inserted through the central or slightly lateral position of the humeral head.

Fig. 1. The schema of the trisected humeral head. The hatched area is defined above the half line in the glenoid and lateral third part of the humeral head. Line A shows the half line of the glenoid. We classified the fracture groups using this procedure on A–P view of plain radiographs. We defined the cases that have fracture line in the hatched area as F group.

Postoperative therapy usually began with mild pendulum exercises. The surgeons decided the contents of the exercise, which depended on the intraoperative stability of each case.

2.2. Clinical outcomes

We evaluated the functional and radiological outcomes as clinical outcomes at the final follow-up. The range of motion

Fig. 2. The schema of this study. We recruited 44 patients who underwent nailing for proximal humeral fracture at our hospital including one corporate hospital. Seven patients were excluded following exclusion criteria. The patients for evaluations are subdivide to subgroup as F group, the group depended on the place of nail insertion or the group within 5 mm from fracture line. We evaluated outcomes of S and C group in each these subgroups. The abbreviations mean that S is S group and C is C group.

(ROM) was evaluated as an objective functional outcome, and it was measured using a standard goniometer. The Quick Disability of Arm, Shoulder, and Hand (Quick DASH) score and 12-item Short-Form Health Survey (SF-12) were used as a subjective patient-based outcome.^{10,11} The Quick DASH and SF-12 were measured using the corresponding questionnaire, which were sent to patients by mail. The SF-12 score for quality of life is broken down into the physical component summary scales, mental component summary scales, and role component summary scales.¹⁰

Three radiographic views (anteroposterior [A–P], axillary, and scapula Y) of the shoulders were taken during follow-up. When there was cortical bone continuity in three directions on radiographs, the condition was defined as bone union. A lack of cortical bone continuity at follow-up was defined as non-union. We defined radiographic outcomes as bone union and complications, and evaluated these based on three directions radiographs except for neck-shaft angle. Complications included screw back-out, postoperative displacement at the fracture site, loss of neck-shaft angle and non-union. We calculated the neck-shaft angle on A–P view of postoperative radiograph.¹² When there was a difference of $>15^\circ$ between the postoperative and last observation, this condition was defined as displacement.

2.3. Statistical analysis

Quantitative variables are presented with their frequency distribution and percentage. Quantitative variables were summarized using a mean and standard deviation. We evaluated the association between qualitative variables using the Mann–Whitney *U* or Fisher exact tests. A statistically significant difference was defined as $p < 0.05$. All statistical analyses were performed with EZR, which is a graphic user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).¹³

3. Results

3.1. Patients' characteristics

There were no significant differences in the age, side of injury, sex, fracture classification, operation time, bleeding, or the follow-up period between the S and C groups. The details were shown in Table 1. The number of F-group patients in whom the fracture line extended to the upper lateral part was not different between the S and C groups, exactly S group had 7 patients and C group had 14 patients ($p = 0.25$). The number of patients with a nail inserted within 5 mm from the fracture line was not significantly different between the S and C groups. In the S group, significantly more

patients had straight nails inserted into the middle part of the trisected humeral head. Namely, nail insertions from lateral side in humeral head were more frequent in the C group (68.2%, $p = 0.02$) (Table 1).

3.2. Outcomes

Twenty-nine patients completed the Quick DASH and SF-12 (78.4%: S group, 13 patients and C group, 16). Follow-up rate was 78.4%. Forward elevation of the shoulder joint was significantly greater in the S group (mean, 134.6° ; range, 90° – 170°) than in the C groups (mean, 109° ; range, 60° – 170°) ($p = 0.04$). The mean abductions were not significantly different between the S and C groups. The Quick DASH and SF-12 scores were also not significantly different between the two groups, too (Table 2).

Radiographic analysis was performed in all patients (Fig. 3). The bone union, and complication rate were not significantly different between the two groups. Regarding complications, postoperative displacement was found in 1 case of the S group (6.7%) and in 4 cases of the C group (18.1%), and screw back-out was found in 3 cases of the C group (13.6%). One case in the S group (6.7%) and two cases in the C group (9.1%) were shown non-union. One case with non-union postoperatively in the C group had to undergo reoperation because of pain. The other cases were not reoperated because the patients' activities were poor and the general conditions were bad. At final observation, there were no cases of humeral head necrosis or infection (Fig. 4, Table 2).

Next, further analyses of the F group showed that ROM of the forward elevation in the S group was significantly better than that in the C group (mean, 128.5° [range, 100° – 160°] and mean, 99.6° [range, 60° – 175°], respectively) ($p = 0.04$). Additionally, the loss of neck-shaft angle in the C group was significantly larger than that in the S group ($p = 0.04$). The rate of bone union did not show a significant difference (Table 3). Furthermore, Table 3 shows the results of the distance between the point of nail insertion and a fracture line <5 mm (4 of 15 cases in the S group and 10 of 22 cases in the C group). The distribution of these cases was not significantly different between the two groups ($p = 0.31$). The functional and radiographic outcomes revealed no significant differences (Table 3).

Next subgroup was depended on the place of nail insertion: the central or lateral parts of the trisected humeral head following Fig. 1. The S group had 4 cases in central and 11 cases in lateral, the C group had 7 and 15 cases respectively. In the S and C groups, the treatment outcomes were not significantly different between patients with nails inserted in the middle part of the humeral head and those with nails inserted in the lateral part of the humeral head. However, the treatment outcomes tended to be poorer in

Table 1
Patients characteristics.

	S group (n = 15)	C group (n = 22)	p value
Age	75.8 (SD 10.4; range 58–92)	74.2 (SD 8.8; range 59–90)	0.82
Injury side (right)	8 (53.3%)	12 (54.4%)	0.60
Female	15 (100%)	18 (81.8%)	0.13
Neer classification ⁷			
2-Part	8 (53.3%)	10 (45.5%)	0.45
3-Part	7 (46.7%)	12 (54.5%)	0.45
Operation time (min)	74.6 (SD 26.4; range 41–124)	71.7 (SD 29.1; range 33–105)	0.69
Bleeding intraoperation (g)	26.6 (SD 23.3; range 10–80)	30.9 (SD 38.2; range 10–150)	0.46
Follow-up period (months)	21.8 (SD 15.7; range 16.7–33.1)	20.1 (SD 14.8; range 16.6–30.4)	0.71
Subgroups			
F group	7 (46.7%)	14 (63.6%)	0.25
Within 5 mm nail insertion	4 (26.7%)	10 (45.5%)	0.31
Lateral nail insertion	4 (26.7%)	15 (68.2%)	0.02 ^a

SD, standard deviation.

^a Fisher exact test.

Table 2
Functional and radiographic outcomes.

	S group	C group	p value
Functional outcomes	n = 13	n = 16	
Forward elevation (°)	134.6 (SD 26.1; range 90–170)	109 (SD 30.2; range 60–170)	0.04 ^a
Abduction (°)	115.3 (SD 24.3; range 90–140)	98.4 (SD 32.9; range 45–175)	0.19
Quick DASH score	24.8 (SD 22.5; range 2.3–77.3)	28.3 (SD 26.1; range 0–79.7)	0.66
SF-12			
PCS	39.9 (SD 12.6; range 13.9–53.6)	40.7 (SD 19.4; range 7.5–74.2)	0.91
MCS	53.9 (SD 8.1; range 44.4–73.1)	58.5 (SD 8.6; range 44.4–77.6)	0.17
RCS	35.9 (SD 12.6; range 11.4–61)	34.4 (SD 14; range 5.6–53.4)	0.77
Radiographic outcomes	n = 15	n = 22	
Bone union	14 (93%)	18 (81.8%)	0.31
Loss of neck shaft angle (°)	4.6 (SD 11.0; range 0–45)	6.3 (SD 6.3; range 0–20)	0.91
Complication	1 (6.7%)	7 (31.8%)	0.11
Screw back out	0	3 (13.6%)	0.26
Postoperative displacement	1 (6.7%)	4 (18.1%)	0.63
Non-union	1 (6.7%)	2 (9.1%)	0.64

Quick DASH, quick disability of the arm, shoulder and hand; SF-12, 12-items short-form health survey; PCS, physical component summary scales; MCS, mental component summary scales; RCS, role component.

^a Mann–Whitney *U* test.

Fig. 3. A case without complications in F group. (a) A 68-year-old woman with a Neer two-part fracture. This case is excluded from the F group. (b) Postoperative picture. The straight nail is used (S group), and the nail is inserted centrally. (c) One and a half years postoperatively. Bone union is identified. There are no complications.

patients with nails inserted in the lateral part in terms of loss of reduction in the S group and ROM in the C group (Table 4).

4. Discussion

Our study showed that the superiority of straight nails compared to curved nails in terms of greater forward flexion and complication rate. To the best of our knowledge, few studies have been previously published that compare outcomes according to the shape of the implants.⁵ In that study, Lopez et al. compared straight and curved nails and showed a significantly lower incidence of complications associated with straight nails. However, their study did not examine the impact of different fracture types, as it only compared the shape of the implants, and it did not show any treatment outcome in association with the fracture types. Thus, our study can be regarded as the first attempt to compare treatment outcomes in patients with a specific type of fracture according to the shape of the implant. Our study findings may help operating surgeons select appropriate implants during clinical practice.

Surgical treatment using intramedullary nails for proximal humeral fractures has advantages, including a small skin incision and a low incidence of soft tissue injury. However, loss of reduction, limited ROM, shoulder-related complaints like pain, and complications such as pseudarthrosis have been reported.^{4,5,14,15}

Herein, we discuss the reasons why the complication rates were significantly higher in patients with a fracture line extending to the upper lateral part of the humeral head (F group), among those with a two- or three-part fracture (according to the Neer classification). One of the reasons is instability at the fracture sites. The lateral insertion of nails has also been indicated to cause postoperative displacement due to poor fixation resulting from the fragmentation of bone fragments.^{5,16} In our study, the C group included more patients with curved nails inserted into the lateral part of the trisected humeral head. Thus, it is assumed that in patients with curved nails, poor fixation or instability of the fracture site may have been triggered, causing aggravation and presented as screw back-out or postoperative displacement on radiography.

Furthermore, we separately examined the S and C groups according to the sites of nail insertion. In the S and C groups, our findings showed that the outcomes regarding ROM and loss of

Fig. 4. A case with complications in F group. (a) A 76-year-old woman with a Neer three-part fracture. This case has a fracture line at the lateral side and is included in the F group (arrow). (b) Postoperative radiograph. A curved nail is used (C group). The nail is inserted in the lateral area. (c) Approximately 14 months postoperatively. Bone union is identified on the radiograph; however, there is screw back-out (arrow). Additionally, the loss of neck-shaft angle is 20°.

Table 3
Functional and radiographic outcomes in subgroups.

F group	S group	C group	p value
Functional outcomes	n = 6	n = 10	
Forward elevation (°)	128.5 (SD 22.9; range 100–160)	99.6 (SD 34.6; range 60–175)	0.046 ^a
Abduction (°)	110 (SD 21.3; range 90–140)	87.5 (SD 36.3; range 45–175)	0.11
Quick DASH score	30.2 (SD 25.7; range 2.3–77.2)	29.6 (SD 26.4; range 4.6–79.7)	0.67
SF-12			
PCS	38.5 (SD 12.3; range 13.4–47.9)	41.5 (SD 20.6; range 7.4–74.1)	0.74
MCS	54.3 (SD 9.1; range 44.4–73)	55.2 (SD 7.6; range 44.4–68.1)	0.85
RCS	40.5 (SD 13.2; range 27–61)	37.7 (SD 11.3; range 13.9–53.4)	0.7
Radiographic outcomes	n = 7	n = 14	
Bone union	7 (100%)	10 (71.4%)	0.17
Loss of neck shaft angle (°)	1.4 (SD 2.2; range 0–5)	6.4 (SD 7.4; range 0–20)	0.04 ^a
Complication	0	7 (50%)	0.047 ^b
Screw back out	0	3 (21.4%)	0.27
Postoperative displacement	0	4 (28.6%)	0.17
Non-union	0	2 (14.3%)	0.53
Within 5 mm from fracture line	S group	C group	p value
Functional outcomes	n = 4	n = 10	
Forward elevation (°)	132 (range 100–160)	108 (range 60–175)	0.16
Abduction (°)	112 (range 90–140)	90 (range 45–175)	0.29
Quick DASH score	21.9 (range 2.3–50)	34.4 (range 4.6–79.7)	0.53
SF-12			
PCS	41.8 (range 32.5–46.9)	38.9 (range 7.4–74.1)	0.84
MCS	57.5 (range 44.4–73)	54.1 (range 46.5–65.8)	0.61
RCS	42.3 (range 35.3–60)	34.5 (range 13.9–50.7)	0.34
Radiographic outcomes	n = 4	n = 10	
Bone union	4 (100%)	6 (60%)	0.25
Loss of neck shaft angle (°)	2.5 (range 0–5)	8.5 (range 0–20)	0.18
Complication	0	5 (50%)	0.22
Screw back out	0	2 (20%)	1
Postoperative displacement	0	3 (30%)	0.51
Non-union	0	2 (20%)	1

Quick DASH, quick disability of the arm, shoulder and hand; SF-12, 12-items short-form health survey; PCS, physical component summary scales; MCS, mental component summary scales; RCS, role component.

^a Mann–Whitney *U* test.

^b Fisher exact test.

Table 4
Results of nail insertion place.

Place of nail insertion	S group		p value	C group		p value
	Central	Lateral		Central	Lateral	
Functional outcomes	n = 4	n = 11		n = 7	n = 15	
Forward elevation (°)	139 (range 100–160)	117 (range 90–170)	0.21	117 (range 60–175)	93.3 (range 60–140)	0.09
Abduction (°)	117 (range 90–140)	110 (range 90–160)	0.64	107 (range 60–175)	83.3 (range 45–120)	0.09
Quick DASH score	23.1 (range 4.5–50)	30.1 (range 2.3–77.2)	0.66	18.4 (range 0–79.7)	34.1 (range 2.3–79.7)	0.27
SF-12						
PCS	40.5 (range 32.5–47.9)	37.9 (range 13.3–53.5)	0.78	51 (range 10.5–74.1)	34.5 (range 10.8–54.1)	0.11
MCS	55.6 (range 44.4–66.7)	48.1 (range 41.1–73.0)	0.18	58.8 (range 44.4–77.6)	34.2 (range 13.9–51.3)	0.9
RCS	35.5 (range 11.4–61.0)	37.4 (range 25.5–56.0)	0.84	34.2 (range 13.9–51.3)	34.5 (range 5.5–53.4)	0.97
Radiographic outcomes	n = 4	n = 11		n = 7	n = 15	
Bone union	4 (100%)	10 (91%)	1	7 (100%)	11 (73.3%)	0.26
Loss of neck shaft angle (°)	1.3 (range 0–5)	13.8 (range 0–45)	0.06	2.1 (range 0–5)	6.3 (range 0–20)	0.16
Complication	0	1 (9.1%)	1	2 (28.6%)	5 (33.3%)	1
Screw back out	0	0 (0%)	1	2 (28.6%)	2 (28.6%)	0.56
Postoperative displacement	0	1 (9.1%)	1	0	3 (20%)	0.52
Non-union	0	1 (9.1%)	1	0	2 (14.3%)	0.53

Quick DASH, quick disability of the arm, shoulder and hand; SF-12, 12-items short-form health survey; PCS, physical component summary scales; MCS, mental component summary scales; RCS, role component.

reduction tended to be poorer when the nails were inserted in the lateral part. Young et al. reported that the sites of nail insertion contribute most to postoperative stability and that insertion in the middle part of the humeral head is important.¹⁷ Since bone density in the lateral part of the humeral head is lower in terms of the anatomy, lateral insertion should be avoided.³ Furthermore, in a study that used fresh cadavers, Frich et al. showed that bone mass in the middle part of the humeral head is favorable for trabecular and subchondral bones, which are indicated as optimal sites for screw insertion.¹⁸ Our present findings support these previous reports. Regarding whether the insertion of implants from a point proximal to the fracture line leads to poor fixation, Liew et al. previously indicated in a cadaver study that screw insertion within 5 mm from the fracture line causes poor fixation of implants.⁸ However, the present clinical study did not show any significant difference in the treatment outcomes of nail insertion within 5 mm from the fracture line between the S and C groups, as shown in Table 3, and such insertion did not cause poor fixation. According to our study findings, it seems especially important to select straight nails in order to avoid the lateral part of the humeral head, which is associated with poor bone mass, according to previous clinical and anatomical studies.^{8,17,18} In addition, nails should be inserted from the middle part of humeral head to prevent loss of reduction in patients with a fracture line extending to the upper lateral part of the humeral head.

Shoulder joint-related complaints of limited ROM and cuff tears have been sporadically reported after using antegrade intramedullary nails through an approach that damages the cuff.¹⁹ While such complaints were not addressed in our study, Lopiz et al. reported that the use of straight nails is associated with significantly fewer complaints.⁵ In our study, no significant difference was observed in the subjective patient-based outcomes of the Quick DASH or in other assessments of upper limb function. Generally, with regard to the reasons for cuff-related complaints in cases with curved nails, the complaints may be affected by a property of the hypovascular area within the critical zone of the cuff footprint that has difficulty in healing.^{20,21} Similarly, ROM may be reduced postoperatively depending on the severity of the cuff tear or displacement, and there is also a report on limited ROM due to the insertion of a proximal screw for fixation of a nodule into the long head of the biceps brachii tendon.²² In many cases, longitudinal split of the cuff is necessary in order to approach the humeral head. In all of our study patients, the cuff was split in order to approach the target site, and dissection may have affected the limited ROM and shoulder joint-related complaints. Thus,

various techniques such as the Neviaser approach have been developed in previous reports to prevent cuff tears.^{23,24} In the future, comparative studies on postoperative shoulder-related complaints after using a single implant are needed.

Most previous clinical studies on the complications of nail insertion or treatment outcomes are based on the implantation of a single implant.^{4,25–28} The functional outcomes and clinical outcomes regarding bone union in our study are largely comparable to those described in previous reports.^{25,29} As for complications, although our study compared the proportions of patients with screw back-out and postoperative displacement, there was no clear difference observed between our study and previous reports.^{15,26} For example, Rajasekhar et al. reported that bone union rate was 96% and complication rate was 16%.¹⁵ Similar to that, the mean of our study's bone union and complication rate were 86.5% and 8.1% respectively.⁹

The limitations to our study are the period of follow-up and the number of patients. This is a retrospective study, and multivariate analysis could not be performed because of the small sample size. The follow-up period was short, and the follow-up rate was not 100%. The fracture lines and sites of nail insertion were assessed only on plain radiographs, not in CT image. The postoperative treatment strategy was left to the discretion of the operator, and thus, there is no standard treatment strategy. Lastly, the screw location was not confirmed by postoperative CT, and it was not assessed by detailed imaging such as three-dimensional imaging.

5. Conclusions

Better clinical outcomes and lower complication rates were demonstrated in patients with a specific type of fracture (i.e., a fracture line extending to the lateral part of the humeral head) who were treated with straight nails.

Conflicts of interest

The authors have none to declare.

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