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Risk factors and prognosis of humeral head inferior subluxation in proximal humeral fractures after osteosynthesis

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Background: Humeral head inferior subluxation often occurs immediately after osteosynthesis for proximal humeral fracture; however, the underlying cause remains largely unknown. In addition, the prognosis of postoperative inferior subluxation has not been fully investigated. This study aimed to clarify the predictive factors that affected the onset of postoperative inferior subluxation using multivariate analysis and examine the postoperative course of inferior subluxation and its influence on postoperative outcomes.

Methods: We retrospectively reviewed 212 patients who underwent osteosynthesis for Neer 2- or 3-part proximal humeral fractures. In the multivariate analysis, the dependent variable was set as the inferior subluxation observed 1 week after the surgery. The explanatory variables included age, sex, affected side, body mass index, smoking, local osteoporosis, preoperative axillary nerve injury, time from injury to surgery, fracture dislocation, fracture pattern, preoperative inferior subluxation, surgical procedure, surgical approaches, blood loss, operative time, and postoperative drainage. Baseline variables, which were observed to be significant in the univariate analysis, were included in multivariate models. Furthermore, based on the presence of inferior subluxation at 1 week after the surgery, we divided the patients into two groups: with inferior subluxation (+IS group) and without inferior subluxation (–IS group). We compared the postoperative outcomes (incidence of postoperative complications and range of motion) between these two groups.

Results: Of 212 patients, 64 (30.7%) experienced inferior subluxation at 1 week after the surgery. On multivariate analyses, preoperative inferior subluxation (odds ratio = 4.69; 95% confidence interval = 2.45–9.76; $P < .001$) and longer operative time (odds ratio = 1.01; 95% confidence interval = 1.00–1.02; $P = .049$) were the risk factors for postoperative inferior subluxation. In the +IS group, inferior subluxation resolved at 1 year after the surgery in 89.5% of patients. There was no significant difference in the postoperative outcome between the +IS and –IS groups. However, four of six patients with persistent inferior subluxation, more than 6 months after the surgery, experienced complications, such as varus angulation of the humeral head or screw joint perforation.

Conclusions: This study provides new information on the risk factors for and prognosis of post-osteosynthesis inferior subluxation in patients with proximal humeral fracture. Longer operative time and presence of preoperative inferior subluxation was associated with an increased risk of postoperative inferior subluxation, although it was temporary in most cases, and had no significant influence on the postoperative outcomes. However, in patients with persistent inferior subluxation of more than 6 months duration, inferior subluxation may be related to postoperative complications.

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This study was approved by the Saiseikai Utsunomiya Hospital Independent Ethics Committee (No. 2020-55) and National Hospital Organization Tokyo Medical Center Independent Ethics Committee (No. R20-141).

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Inferior subluxation of the humeral head can occur after acute shoulder trauma, such as proximal humeral fracture, glenoid fracture, anterior glenohumeral dislocation, and rotator cuff tear.^{2-4,9,11,13-15} It is also thought to be caused by muscle fatigue, such as of the deltoid,³ hypotonic deltoid or rotator cuff muscles,^{2,4,9} capsular injury,¹⁴ peripheral nerve injury,¹⁵ and loss of negative intra-articular pressure.⁹ In addition, inferior subluxation is frequently experienced immediately after open reduction and internal fixation of proximal humeral fracture; the incidence of which is reported to reach 42% at 2 weeks after the surgery.⁹ However, the underlying cause and risk factors for postoperative inferior subluxation remain largely unknown.

Furthermore, the prognosis of humeral head inferior subluxation, occurring immediately after osteosynthesis, has not been fully elucidated. As per the previous literature, all patients with early postoperative inferior subluxation of the humeral head recovered within 2 years of the surgery,⁹ whereas inferior subluxation of the humeral head persisted in 4.6% of cases at 1 year after the surgery.² None of the studies, by far, have examined in detail the postoperative shift of inferior subluxation along with the postoperative progress. In addition, little has been reported on the influence of postoperative inferior subluxation on clinical outcomes.

The purpose of this study was to clarify the factors that affected the onset of humeral head inferior subluxation, immediately after the surgery, in patients with proximal humeral fracture using multivariate analysis. Second, we examined shifts in humeral head inferior subluxation that occurred during the postoperative follow-up and analyzed the influence of inferior subluxation on postoperative outcomes.

Materials and methods

This study was approved by the independent ethics committee of our hospitals.

Patients

This was a retrospective study that consisted of patients who underwent open reduction and internal fixation for proximal humeral fracture at two general hospitals between January 2008 and December 2019. We included the adult patients (with closed epiphysis), who underwent open reduction and internal fixation for 2-part or 3-part (Neer classification⁸) proximal humeral fracture. We excluded patients with pathologic fractures, open fractures, multiple injuries, isolated fractures of the greater tuberosity, isolated fractures of the lesser tuberosity, head-split fractures, previous surgery for upper limb involvement, and upper limb paralysis, such as those caused by cerebral infarction, and patients who underwent arthroplasty.

In this study, we identified 212 patients (women, 141; men, 71), who met the inclusion criteria. The mean age was 66.6 ± 15.8 years (range, 22-95 years). The injured side was the right side in 107 patients and the left side in 105 patients. Preoperatively, axillary nerve paralysis was found in 10 cases (4.7%), fracture dislocation in 14 cases (6.6%), and inferior subluxation in 52 cases (24.5%). Axillary nerve injury was evaluated based on descriptions of hypesthesia in the axillary nerve area region or paralysis of the deltoid muscle in clinical notes. Isolated surgical neck fractures occurred in 107 patients (50.5%) and Neer 3-part fracture (humeral neck + greater tuberosity fracture or lesser tuberosity fracture) in 105 patients (49.5%). For these fractures, we performed open reduction and internal fixation using a locking plate in 126 patients (59.4%) and an intramedullary nail (IMN) in 86 patients (40.6%).

Surgical procedure

The surgery was performed by 14 orthopedic surgeons; all procedures were performed in the beach-chair position under general anesthesia. Osteosynthesis, using a locking plate or IMN, was performed via the deltopectoral approach or deltoid-split approach, the decision of which was left at the discretion of the surgeon. The plate fixation was performed using a PHILOS plate (DePuy Synthes, Oberdorf, Switzerland), NCB proximal humerus plate (Zimmer Biomet, Warsaw, IN, USA), AxSOS proximal humerus plate (Stryker, Kalamazoo, MI, USA), or MODE proximal humeral plate (MDM, Tokyo, Japan). The IMN fixation was performed using a MultiLoc proximal humeral nail (DePuy Synthes, Oberdorf, Switzerland), expert proximal humeral nail (DePuy Synthes, Oberdorf, Switzerland), T2 proximal humeral nail (Stryker, Kalamazoo, MI, USA), Polarus proximal humeral nail (Acumed, Hillsboro, OR, USA), Targos proximal humeral nail (B. Braun Aesculap, Tuttlingen, Germany), or ARISTO proximal humeral nail (MDM, Tokyo, Japan). In 23 cases, drainage was performed by inserting an SB VAC (Sumitomo Bakelite, Tokyo, Japan) into the fracture site for 1-2 days after the surgery. Afterward, the patients wore a sling for 1-2 weeks, during which passive range-of-motion training was started; active motion training was started at 4-6 weeks postoperatively. Even when humeral head inferior subluxation was observed after the surgery, the immobilization period was not prolonged.

Radiological evaluation of humeral head inferior subluxation

There are various methods for evaluating humeral head inferior subluxation.^{1,2,6} Carbone et al² proposed a radiographic method of evaluation, where they defined humeral head inferior subluxation as “when the distance between the glenoid inferior edge level and the anatomic neck of the humerus level was 1 cm or greater.” This procedure has been reported to obtain high intraobserver and excellent interobserver reliability²; therefore, we selected this method of radiographic evaluation for this study (Fig. 1). On the basis of past reports,^{1,2} we used plain radiographic images, in the anteroposterior view, with the patient in the upright position. For the patients with fracture dislocation, inferior subluxation was evaluated using the radiographic images after reduction of dislocation. A single examiner evaluated the distance before the surgery

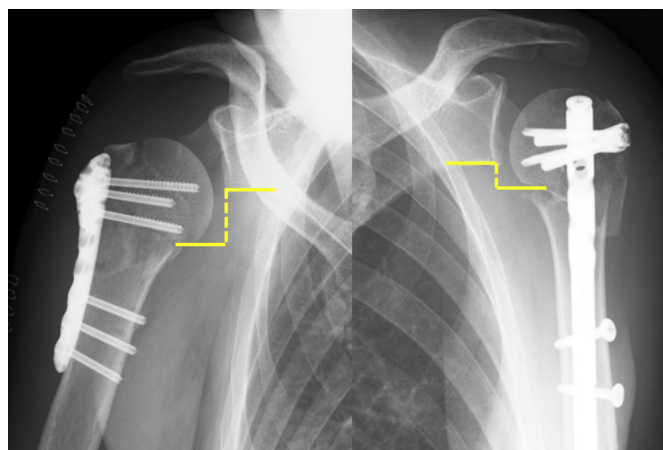


Figure 1 Radiological measurement of humeral head inferior subluxation. The humeral head inferior subluxation was evaluated by measuring the distance between the glenoid inferior edge level and the humeral anatomic neck level on plain radiographic images.

Table 1
Univariate and multivariate predictors of inferior subluxation at 1 year after surgery.

Variables	Univariate predictors			Multivariate predictors	
	+IS group (N = 64)	–IS group (N = 148)	P value	Odds ratio (95% CI)	P value
Age (yr)	69.5 ± 13.9	65.3 ± 16.4	.056	-	-
Sex (female/male)	45/19	96/52	.678	-	-
Affected side (right/left)	42/21	65/83	.004*	1.64 (0.88-3.04)	.119
BMI	23.4 ± 4.9	22.7 ± 4.3	.362	-	-
Smoking	7	22	.519	-	-
Local osteoporosis	35	66	.182	-	-
Preoperative axillary nerve injury	4	6	.494	-	-
Time from injury to surgery (d)	9.0 ± 5.0	8.9 ± 5.0	.848	-	-
Dislocation fracture	1	13	.069	-	-
Fracture pattern (Neer 2-/3-part)	36/28	69/79	.232	-	-
Inferior subluxation before surgery	30	22	<.001*	4.69 (2.45-9.76)	<.001*
Surgical procedure (plate/IMN)	41/23	86/62	.648	-	-
Surgical approach (deltopectoral/Deltoid split)	27/37	40/108	.037*	1.57 (0.77-3.21)	.216
Blood loss (g)	135 ± 113	115 ± 162	.296	-	-
Operative time (min)	133 ± 36	118 ± 41	.011*	1.01 (1.00-1.02)	.049*
Drainage after surgery	7	17	1	-	-

BMI, body mass index; CI, confidence interval; IMN, intramedullary nail; +IS, with inferior subluxation; –IS, without inferior subluxation.

* P < .05.

and at 1 week, 1 month, 3 months, 6 months, and 1 year after the surgery. In this study, we defined humeral head inferior subluxation observed on plain radiographs at 1 week after the surgery as inferior subluxation immediately after the surgery. Based on the presence of inferior subluxation at 1 week after the surgery, we divided the patients into two groups: with inferior subluxation (+IS group) and without any inferior subluxation (–IS group). In this study, 64 of 212 patients (30.2%) showed humeral head inferior subluxation immediately after the surgery; therefore, the +IS group included 64 patients and the –IS group included 148 patients (Table 1).

Outcome measures

In multivariate analysis, to examine for the factors that affect the postoperative inferior subluxation, dependent variable was set as inferior subluxation, observed on anteroposterior plain radiographs 1 week after the surgery. The explanatory variables included age, sex, affected side of the shoulder, body mass index, history of smoking, local osteoporosis, preoperative axillary nerve injury, time period from injury to surgery, fracture dislocation, fracture pattern (Neer 2- or 3-part fracture), humeral head inferior subluxation before surgery, surgical procedure (locking plate or IMN), surgical approach (deltopectoral or deltoid-split approach), amount of blood loss, operative time, and postoperative drainage. With regard to local osteoporosis, we measured the average cortical bone thickness at two sites of the humerus, based on a previous report, and defined an average proximal humerus cortical thickness of 6 mm as the potential threshold value for predicting local osteoporosis.^{2,7} We evaluated fracture dislocation and fracture type using plain radiographs and computed tomography scans, obtained preoperatively.

In the analysis to examine the effect of postoperative inferior subluxation (at 1 week after the surgery) on postoperative outcomes, we identified 175 patients who were on follow-up for 1 year after the surgery. Seven patients in the +IS group and 30 patients in the –IS group were excluded owing to inadequate follow-up. Postoperative outcomes included the frequency of postoperative complications (delayed bone union, nonunion, screw cut out, fixation failure, reduction loss >10°, avascular necrosis, and infection) and range of motion at 1 year after the surgery (elevation and external rotation [ER] at the side). A single examiner, who was

blinded to the results of inferior subluxation, evaluated postoperative complications as per past clinical notes and plain radiographic images. We defined delayed bone union as a lack of bone bridging at 1 year after the surgery. We evaluated the quality of reduction using the head-shaft angle, based on previous reports.^{5,10} An angle of 130 ± 10° was considered an adequate reduction¹⁰; therefore, in this study, an increased varus angulation of ≥10° was defined as significant displacement. Postoperative range of motion was evaluated either by the physician who performed the surgery or an occupational therapist. The data on range of motion were missing for elevation in 29 patients and ER in 83 patients.

Statistical analysis

All statistical analyses were conducted using the SPSS software program (version 26.0; IBM Corp., Armonk, NY, USA). In univariate analyses, we used the Student's *t*-test to compare the average of continuous values (age, body mass index, time from injury to surgery, blood loss and operative time), whereas Fischer's exact test was used to compare the proportion of discrete variables (sex, side of injury, smoking, local osteoporosis, preoperative axillary nerve injury, fracture dislocation, type of fracture, inferior subluxation before surgery, surgical procedure, surgical approach, and drainage after surgery). The baseline variables with *P* < .05 on the univariate analyses were included in the multivariable models. Multivariate analyses were performed using logistic regression analysis to identify the independent predictors of inferior subluxation after the surgery. The regression model fit was estimated using the Hosmer-Lemeshow goodness-of-fit test. For the analysis to examine the effect of postoperative inferior subluxation on clinical outcomes, we used the Student's *t*-test to compare the average of range of motion and Fischer's exact test to compare the proportion of postoperative complications. The threshold for significance was set at *P* < .05.

Results

The univariate analysis results revealed that the affected side (right) (*P* = .004), inferior subluxation before the surgery (*P* < .001), surgical approach (deltopectoral approach) (*P* = .037), and longer operative duration (*P* = .011) were significantly associated with the onset of humeral head inferior subluxation immediately after the

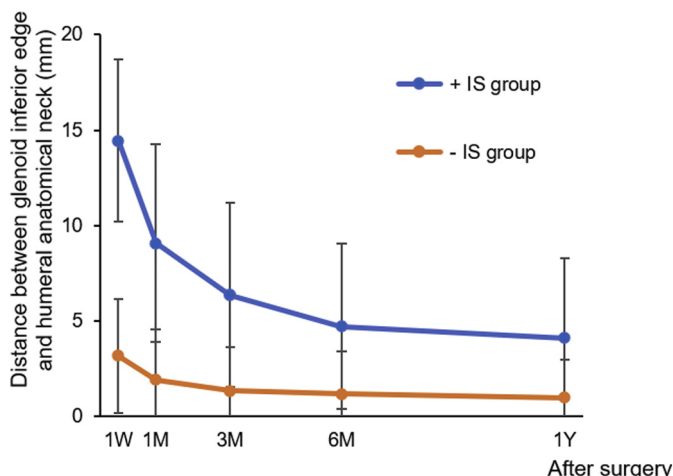


Figure 2 The postoperative shift of humeral head inferior subluxation. The graph shows the distance between the glenoid inferior edge and humeral anatomic neck of the +IS group and the -IS group at 1 week, 1 month, 3 months, 6 months, and 1 year after osteosynthesis of proximal humeral fracture. W, M, and Y on the horizontal axis represent week, month, and year, respectively.

surgery. Multivariate analyses showed that inferior subluxation at the time of injury (odds ratio = 4.69; 95% confidence interval = 2.45-9.76; $P < .001$) and longer operative duration (odds ratio = 1.01; 95% confidence interval = 1.00-1.02; $P = .049$) were the risk factors for humeral head inferior subluxation after the surgery (Table 1). The Hosmer-Lemeshow goodness-of-fit test showed no significant departure from good model fit ($P = .523$).

The postoperative shift of humeral head inferior subluxation for the +IS and -IS groups is presented in Figure 2. This graph indicates a decrease in the distance between the glenoid inferior edge level and the anatomic neck of the humerus level over time, in the both groups. In the +IS group, inferior subluxation resolved at 1 month after surgery in 59.7%, at 3 months after surgery in 77.2%, and at 6 months after surgery in 89.5%. The patients ($n = 6$, 10.5%) who had persistent humeral head inferior subluxation at 6 months after the surgery also had it at 1 year after the surgery. In the -IS group, there were no patients with newly developed humeral head inferior subluxation within 1 year of the surgery (Supplementary Table S1).

There was no significant difference in the incidence of postoperative complications between the +IS and -IS groups (Table II). Two patients showed asymptomatic nonunion, and five patients had asymptomatic avascular necrosis. Among 11 patients with screw cutout, four underwent implant removal, and the screw was retained in seven asymptomatic cases. Among two patients with infection, debridement was performed in one and the implant was removed in the other. None of the asymptomatic patients underwent an additional surgery. In addition, there was no significant difference observed between the +IS group and -IS group in the

range of motion of elevation ($120 \pm 37^\circ$ vs. $124 \pm 36^\circ$, respectively; $P = .491$) and ER ($41 \pm 18^\circ$ vs. $45 \pm 17^\circ$, respectively; $P = .292$) at 1 year after the surgery.

Among the six patients with persistent humeral head inferior subluxation at 1 year after the surgery, varus angulation of the humeral head progressed in four patients. Owing to screw joint perforation, one patient experienced implant removal (Table III) (Fig. 3). An elevation of $122 \pm 23^\circ$ and ER of $50 \pm 22^\circ$ was observed among the six patients; no significant difference in the mean range of motion was observed, when compared with the group without inferior subluxation at 1 year after the surgery. The mean age was significantly higher in the group with persistent inferior subluxation at 1 year after the surgery than in the group without inferior subluxation ($P = .040$) (Supplementary Table S2).

Discussion

In this study, we conducted a multivariate analysis to identify factors that affect the onset of postoperative humeral head inferior subluxation in patients with proximal humeral fracture and examined the postoperative course of the inferior subluxation. As a result, we made two important clinical observations.

First, the results of this study showed that the preoperative presence of humeral head inferior subluxation and longer operative time were significant factors contributing to inferior subluxation at 1 week of the surgery in patients with proximal humeral fracture. In the only previous study investigating the risk factor for inferior subluxation that occurred in early postoperative months in proximal humeral fractures, the female sex, older age, obesity, and pin or screw articular surface perforation were significantly associated with humeral head inferior subluxation at 3 months after the surgery.² However, in this study, although the results of univariate analysis showed that the female sex, older age, and high body mass index tended to be more common in the group with inferior subluxation, there was no significant difference, which was in contrast to the past results. This discrepancy may be attributed to the fact that, in the present study, we analyzed patients earlier after the surgery (at 1 week after the surgery), and thus, the effect of surgery and the extent of preoperative damage to soft tissue by injury could have had a greater impact on inferior subluxation than factors pertaining to patient background, such as sex, age, and obesity. In this study, we identified the preoperative presence of inferior subluxation as a factor that had a significant impact on inferior subluxation occurring immediately after the surgery. Given that inferior subluxation occurring after proximal humeral fracture injury is thought to be caused by muscle fatigue of deltoid,³ loss of muscle tone such as deltoid and rotator cuff,^{2,4,9} capsular injury,¹⁴ peripheral nerve injury,¹⁵ or loss of negative intra-articular pressure,⁹ the present study raised the possibility that the state of damage to soft tissue sustained at injury, such as in the deltoid, rotator cuff muscle, or joint capsule, may have affected the onset of postoperative inferior subluxation. In addition, we observed a significant relationship between operative time and the onset of

Table II Postoperative complication (+IS group vs -IS group).

Complication N (%)	+IS group (N = 57) (%)	-IS group (N = 118) (%)	P value
Delayed union	3 (5.2)	9 (7.6)	.753
Nonunion	1 (1.7)	1 (0.8)	1
Screw cut out	5 (8.8)	6 (5.1)	.340
Fixation failure	7 (12.3)	10 (8.5)	.425
Reduction loss >10°	15 (26.3)	20 (16.9)	.162
Avascular necrosis	1 (1.7)	4 (2.9)	1
Infection	1 (1.7)	1 (0.7)	1

+IS, with inferior subluxation; -IS, without inferior subluxation.

Table III
Details of patients with inferior subluxation at 1 year after surgery.

Age/Sex	Type (Neer)	Preoperative inferior subluxation	Surgical approach	Surgical procedure	Complication
63/male	3-part	-	Deltoid split	Plate	Varus progression from 2 mo after surgery
76/female	3-part	+	Deltoid split	Plate	Varus progression from 3 mo after surgery
70/male	3-part	+	Deltopectoral	Plate	Owing to screw joint perforation, implant was removed at 6 mo after surgery. Varus progression and nonunion at 1 yr after surgery
87/female	2-part	-	Deltoid split	Plate	-
78/female	3-part	+	Deltopectoral	Plate	Varus progression from 1 mo after surgery
74/female	2-part	-	Deltopectoral	IMN	-

IMN, intramedullary nail.

inferior subluxation; however, the underlying mechanism remains unclear. Hypothetically, retraction of the muscle attached to the humerus, such as the deltoid or rotator cuff for a long period during surgery could have caused muscle fatigue or atony, or long-term surgical operation could have affected peripheral nerve traction and compression, which may have led to postoperative inferior subluxation.

Second, in this study, most cases showed an improvement in humeral head inferior subluxation that occurred immediately after proximal humeral fracture, during the postoperative follow-up, and the presence of postoperative inferior subluxation had no significant effect on the incidence of postoperative complications and shoulder range of motion at 1 year after the surgery. To date, no studies have examined the detailed postoperative shift in inferior subluxation, occurring immediately after the surgery, in patients with proximal humeral fracture. Here, a gradual improvement was noted in the inferior subluxation during the postoperative period. Inferior subluxation disappeared at 1 month after the surgery in approximately 60% of cases and at 6 months after the surgery in approximately 90% of cases, suggesting that most cases of inferior

subluxation, occurring immediately after the surgery, are temporal. Furthermore, although a significantly higher proportion of patients who experienced longer operative duration was included in the +IS group, no significant difference was observed in the incidence of postoperative complications and range of motion at 1 year after the surgery between the +IS and -IS groups. Our findings are consistent with the previously reported studies, which suggested that the inferior subluxation immediately after proximal humeral fracture was temporary and had an excellent prognosis.⁹ However, in this study, inferior subluxation persisted for more than 6 months after the surgery in approximately 10% of patients; in whom, four out six patients developed complications, such as varus progression of the humeral head and screw joint perforation. This finding was in line with a report indicating that persistent humeral head inferior subluxation at 1 year after the surgery was significantly correlated with screw joint perforation.² Because varus angulation of the humeral head and screw joint perforation after the surgery were the most common reasons for revision surgery,¹² the results of this study suggest follow-up with close examination and careful attention in patients with persistent inferior subluxation more than

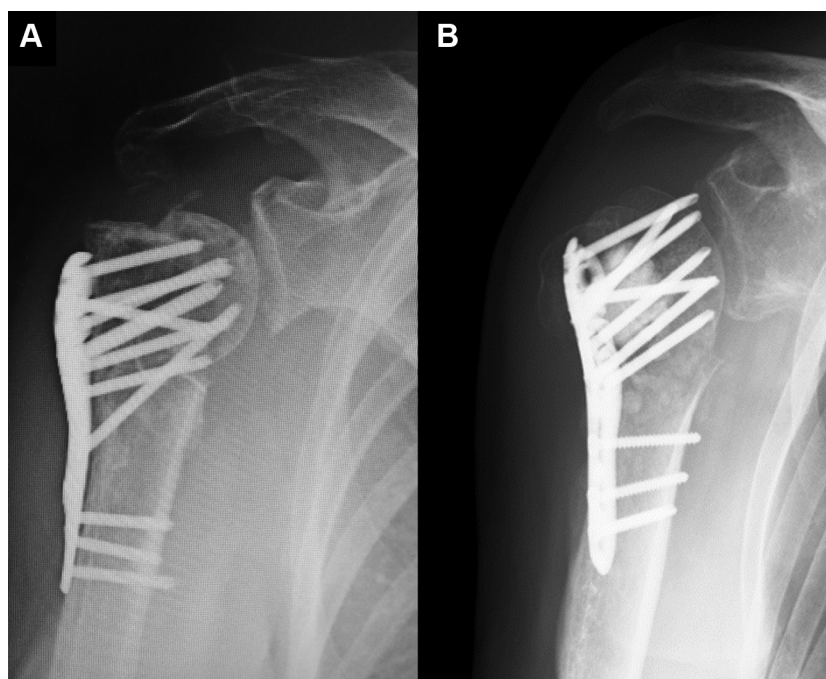


Figure 3 Plain radiographs of the patients with persistent humeral head inferior subluxation 1 year after surgery. A 78-year-old woman underwent plate fixation for Neer 3-part proximal humeral fracture: however, varus angulation of humeral head progressed from 3 months after surgery and inferior subluxation remained at 1 year after surgery (A). A 70-year-old man underwent plate fixation for Neer 3-part proximal humeral fracture: however, plate was removed at 6 months after surgery owing to the screw joint perforation (B).

6 months after the surgery. Univariate analysis of our study suggested that older patients were at a significant risk of inferior subluxation at 1 year after the surgery. Similarly, a previous report indicated a significant correlation in older patients (patients aged ≥ 70 years) and inferior subluxation at 1 year after the surgery²; therefore, due care would be needed for older patients in particular.

This study had four major limitations. First, this was an observational study, and therefore, the results could be affected by residual confounding bias owing to differences in factors that were not measured between the groups. For example, surgery in the present study was performed by 14 orthopedic surgeons; however, we neither evaluated the impact as per the competency of the practitioner and assistants nor as per the implant used. In addition, because none of the patients underwent magnetic resonance imaging before the surgery, we could not evaluate the injury to soft tissue, such as the deltoid, rotator cuff muscles, or joint capsule. The delayed time for surgery may have affected postoperative complications because about half of the patients underwent the surgery at least 1 week after injury. Second, because a questionnaire survey was not included, it was not possible to determine additional objective functional outcomes. Moreover, in this study, there are numerous missing values for the range of motion 1 year after the surgery, which may result in insufficient evaluation of the range of motion. Third, in the +IS group, there were significantly more patients with preoperative inferior subluxation and patients who underwent surgery using the deltopectoral approach, and the mean operation time was significantly longer. Thus, these factors may have affected the postoperative outcomes. Fourth, as the two institutions where this study was performed were emergency hospitals, the target patients were often transported to the emergency department; consequently, this led to fewer walk-in patients; this may have caused a selection bias, thereby lowering the generalizability of the study findings.

Conclusions

This study provides new information on the risk factors for and prognosis of inferior subluxation immediately after osteosynthesis for proximal humeral fracture. In patients who experience a long operative time and those with preoperative inferior subluxation, postoperative inferior subluxation could occur; however, it is temporary in most cases and has no significant influence on the postoperative outcomes. However, in patients with persistent inferior subluxation more than 6 months after the surgery, inferior subluxation may persist and be related to postoperative complications.

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Supplementary data

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