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Early locking plate removal following open reduction and internal fixation of proximal humeral fractures could prevent secondary implant-related complications

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ABSTRACT

Introduction: Proximal humeral fracture is a common cause of morbidity in the elderly and poses a challenge for the orthopedic surgeon. Open reduction and internal fixation (ORIF) with a locking plate is associated with high rate of secondary implant-related complications (IRC). Early implant removal could potentially reduce the risk of IRC and further improve the outcome in relatively asymptomatic patients. The purpose of this study was to evaluate the clinical and radiologic outcomes following implant removal.

Methods: A total of 56 patients with an average age of 63 ± 13 years and a mean follow-up of 29 months were evaluated retrospectively following removal of a locking plate in the proximal humerus. Postoperative functional outcomes were evaluated with the Constant-Score, Subjective shoulder value and *Quick*-DASH score.

Results: Early implant removal resulted in high functional outcomes with 96% of the patients reporting an improvement of their shoulder function following implant removal. No intraoperative complications were reported. Avascular necrosis (AVN) of the humeral head occurred in 12.5% of the patients, but no secondary screw cut-out was reported.

Conclusion: Early implant removal might be a safe option to avoid secondary IRC with significant subjective functional improvement also in asymptomatic patients. Although early implant removal cannot reverse the process of AVN, it could potentially prevent secondary IRC and subsequent glenohumeral cartilage destruction.

1. Introduction

Proximal humerus fracture is a leading cause of mortality and morbidity among the elderly, associated with persistent pain and limited function.[1] It is the third most frequent fracture in the patients older than 65 years of age with an annual incidence of 82 per 100,000.[2] Although the majority of proximal humeral fractures can be treated nonoperatively.[3] About 20% require surgical intervention.[4] Open reduction and internal fixation (ORIF) with locking plate is gaining popularity over arthroplasty in the treatment of displaced proximal humerus fractures due to the joint-preserving nature of the technique, the optimal tensioning of the glenohumeral joint capsule, rotator cuff, and deltoid permitting an early active mobilization.[5,6]

Despite the significant advances in plate osteosynthesis of proximal humerus fractures, ORIF is associated with significant complication (15%) and re-operation (12.7%) rate,[7,8] mostly due to screw cut-out, avascular necrosis (AVN), malunion.[9] persistent pain and functional impairment secondary to symptomatic hardware.[10] As a result, several studies suggested long-term follow-up or early implant removal to early detect or avoid glenohumeral joint cartilage destruction due to the migration of the screws, respectively.[10,11]

Regarding hardware removal, the primary indications are mostly relative, and patient-driven such as pain, dysfunction, prominent implant[12] or request for implant removal in relatively asymptomatic patients.[13] Although a limited number of studies reported a significant clinical improvement after implant removal in symptomatic patients that were previously treated with ORIF for a proximal humerus fracture,[14,15] there are no data in the literature regarding the clinical outcomes following implant removal in relatively asymptomatic patients.

We hypothesized that early plate removal might reduce the risk of secondary implant-related complications (IRC) and further improve function in asymptomatic patients treated with ORIF for proximal humerus fractures. Therefore, the purpose of this study was to evaluate the clinical and radiologic outcomes following implant removal in

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Table 1
Patient and fracture characteristics. The values were given in mean value and standard deviation.

Patient group	Follow-up group	Patients with no avascular necrosis	Patients with delayed avascular necrosis
Number of patients	56	49	7
Age	63 (12)	62 (12)	67 (9)
Gender			
Female	39 (70%)	34 (69%)	5 (71%)
Male	17 (30%)	23 (31%)	2 (29%)
Affected side			
Right	26 (46%)	19 (39%)	7 (100%)
Left	30 (54%)	38 (61%)	0 (0%)
Affected side			
Dominant	28 (50%)	22 (45%)	6 (85%)
Non-dominant	28 (50%)	35 (55%)	1 (15%)
Follow-up (months)	29 (5)	30 (6)	32 (5)
Time to ORIF (Days)	3 (2)	3 (2)	1 (1)
Duration of ORIF (Minutes)	88 (21)	87 (22)	100 (15)
Time to Implant removal (Months)	7 (2)	7 (1)	9 (3)
Duration of Implant removal (Minutes)	39 (8)	39 (7)	41 (13)
Fracture Dislocation	8 (14%)	6 (12%)	1 (14%)
Fracture Classification (Neer)			
2-part	10 (18%)	10 (20%)	0 (0%)
3-part	38 (68%)	34 (70%)	4 (57%)
4-part	8 (14%)	5 (10%)	3 (43%)

asymptomatic patients treated with an ORIF with a locking plate for a proximal humerus.

2. Methods

2.1. Study design and participants

All the patients gave informed consent before participation, and the study was approved by the institutional review board and the ethical committee (Ethikkommission Nordwest-und Zentralschweiz: 2014-169). The current retrospective study was conducted entirely in the authors' institution.

2.2. Participants

A total of 56 patients (Male: 17 Female: 39) with an average age of 62.7 (range: 28 to 86) years were included in the current study. The average follow-up was 29 (range: 24 to 37) months (Table 1). The average time to implant removal was 9 (range: 7 to 17) months (see Table 2).

2.3. Surgical technique

All the ORIF and implant removal were performed under general anesthesia supervised by the senior author (U.R) in a beach-chair position using the standard deltopectoral approach. Every patient received preoperative antibiotics before skin incision and for 24 h postoperatively. The surgery was performed in an outpatient or inpatient setting according to patient preference. In the inpatient setting, the wound was closed over a suction drain, which was removed after 48 h.

In the ORIF the rotator-cuff tendons were identified and fixed by a suture (FiberWire®, Arthrex®, Naples, USA) to the locking plate. The fracture fragments were reduced directly, and the reduction was temporarily maintained using two or more K-wires. Consequently, the locking plate was fixed distally to the shaft with a cortical screw maintaining the reduction. The proximal locking screws were inserted in the predetermined divergence angle under fluoroscopic control with approximately 10–14 mm from the articular margin of the humeral head to decrease the risk of screw cut-out while maintaining an adequate screw purchase. The implants used in the current study was the five-hole Philos®-Plate (Synthes®, Switzerland).

The initial deltopectoral approach was used for the implant removal with minimal soft-tissue dissection. The plate was exposed completely, and the suture was removed. Following the removal of all screws, the plate was detached. Complete hardware removal was confirmed by fluoroscopy. Debridement around the former plate bed an open arthrolysis was performed.

Table 2
Pre- and postoperative functional outcomes. The values were given in mean value and standard deviation. *Indicates statistically significant difference ($P < 0.05$).

Patient group	Preoperative	Postoperative	Significance (p-value)
Constant Score	–	85.6 (12)	-
Subjective shoulder value	–	92.8 (24)	-
Quick-DASH score	–	11.1 (2.2)	-
External rotation (°)	38 (0–65)	41 (8.3)	.07
Abduction (°)	125 (29)	140 (25)	**.001***
Flexion (°)	130 (27)	150 (20)	**.001***

2.4. Postoperative management

After ORIF, an immobilization was performed using an arm bandage fixing the shoulder in internal rotation and adduction with a 90° angle of the elbow. No active mobilization in the first six weeks was advised. A physiotherapy prescription was given to every patient with an advised limitation of passive range of motion of a flexion up to 90°, an external rotation up to 20° and internal rotation to the belly. The full active motion was allowed after the first radiologic follow-up six weeks. Permission to increase force transmission was given three months postoperatively by clinical and radiological evidence of fracture healing and an early plate removal (after 6 months following the ORIF) was recommended to all patients.

After plate removal, no fixation or bandages were used, and no limitation concerning a range of motion and weight bearing was advised.

2.5. Clinical evaluation

Postoperatively, the patients were followed-up clinically and radiographically at six weeks and three months postoperatively. Furthermore, there was a clinical and radiological assessment, six weeks at one year following implant removal. Medical records were reviewed and patient demographics, fracture characteristics, time to ORIF, duration of ORIF, time to implant removal, duration of implant removal were recorded. Interviews with patients were contacted personally in the clinic. The clinical examination and radiologic evaluation were performed by an independent to the study orthopedic surgeon of our clinic in a standardized matter. The shoulder range of motion (ROM) was measured using a goniometer with scapular immobilization using the global coordinate system. The Constant Score (CS),[16] Subjective Shoulder Value (SSV)[17] and *Quick*-DASH Score[18] were assessed as well. The subjective shoulder function was assessed using a 3-point Likert Scale for responses: "improved significantly," "did not improve significantly," "worsened."

2.6. Radiologic measurements

An anterior-posterior, axial and Neer-view radiograph was performed to evaluate fracture healing, potential implant-related complications, osteoarthritis, and avascular necrosis.

2.7. Statistical analysis

Descriptive statistics used frequencies and percentages to present the data. All parameters were tested with the Kolmogorov-Smirnov test for normality. When the criteria for normality were met, a two-tailed *t*-test was used. The level of significance level was set at a = 0.05. All the statistical analyses were performed using SPSS version 23 software (SPSS Inc., Chicago, Illinois).

3. Results

3.1. Intraoperative complications and perioperative parameters

The average implant removal operation duration was 40 (range: 30 to 60) minutes. The average hospital stay was two days (range: 0 to 3). No perioperative complications were recorded.

3.2. Complication rate and revision

At a mean follow-up of 29 months after implant removal, seven patients (12.5%) presented signs of AVN of the humerus head (Table 1). No other complications were reported. All the patients presented with a delayed avascular necrosis reported no or limited pain, were satisfied with the function of the shoulder, could manage their daily activities without significant limitations (Fig. 1) and did not required further operative treatment.

3.3. Functional scores and range of motion

The average Constant-score and subjective shoulder value were 83.8 and 92.8 at the one-year follow-up after implant removal, respectively (Table 2). The average *Quick*-DASH Score was 11.1. The majority of the patients (96%) reported a subjective increase in their shoulder function, whereas 4% of the patients reported a not significant increase in their shoulder function. No patient reported worsening of their symptoms following implant removal.

4. Discussion

Proximal humeral fracture is a common cause of morbidity in the elderly and poses a challenge for the orthopedic surgeon. A common complication of ORIF with a locking plate is a secondary screw cut-out and destruction to glenohumeral cartilage due the AVN of the humeral head. Therefore, a long-term follow-up is recommended,[19] which is associated however with high costs, x-ray exposition of the patient over the years and requires high patient compliance. Early implant removal could potentially reduce the risk of secondary IRC and even improve the function in asymptomatic patients treated with ORIF for proximal humerus fractures. The purpose of this study was to evaluate the clinical and radiologic outcomes following locking plate removal. The results of the current study showed that early implant removal resulted in high Constant-score and subjective shoulder value. The majority of the patients (96%) reported a subjective increase in their shoulder function. No intraoperative or postoperative complications were reported due to the implant removal. Although AVN of the humeral head occurred in 12,5% of the patients, due to the early implant removal, no glenohumeral cartilage destruction was reported, and no revision surgery was required.

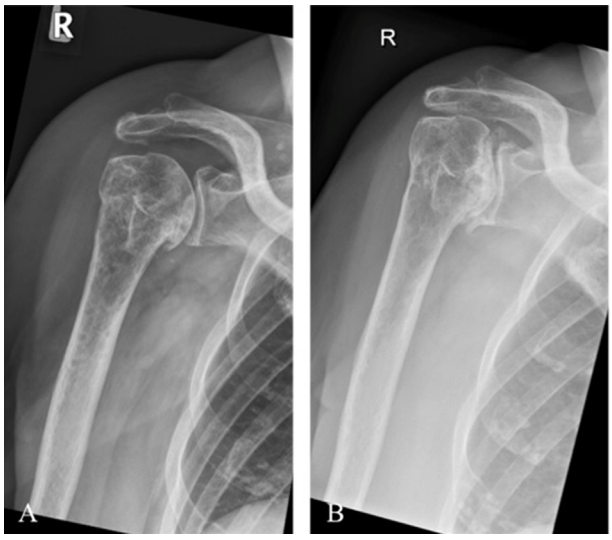

Fig. 1. An example of delayed avascular necrosis of humeral head in the same patient following open reduction and internal fixation (ORIF) and subsequent implant removal.
A: Six weeks following implant removal (Ten months from ORIF). B: Five years following implant removal.

The primary concern with ORIF using a locking plate for a displaced humeral head fracture is the AVN of the humeral head and the secondary screw cut-out with an incidence rate of 16–23%,[11,20] which can result in glenohumeral joint cartilage destruction associated with poor outcomes and need for glenoid resurfacing if arthroplasty is subsequently required.[10,11] In accordance with the literature, the incidence rate of AVN in the current study was 12.5% (7 out of 56 patients). Our patients received, however, an early implant removal before radiologic evidence of AVN, and therefore, glenohumeral joint cartilage destruction was not observed in any of our patients. All the patients presented with a delayed avascular necrosis reported that they have only limited pain, were satisfied with the function of the shoulder and could manage their daily activities without significant limitations. Furthermore, due to early implant removal, glenohumeral joint cartilage was not damaged by secondary screw cut-out.

Recently, patient satisfaction and subjective functional improvement received increased attention as essential aspects of medical care and fundamentals factor influencing the quality of life following surgery.[21] Even though implant removal represents the 30% of elective orthopedic procedures[22] only a relatively few numbers of studies reported the clinical outcomes following implant removal following an ORIF for proximal humeral fracture. Specifically, Kirchhoff et al.[15] in a prospective study of 59 patients (25 with implant-related impingement, 13 with persistent ROM deficit and 21 asymptomatic) found an average increase in Constant-score from 66.2 preoperative to 84.3, six months following implant removal and no surgical-related complications were reported. The implant was removed at an earliest 12 months, and patients with AVN of the humeral head and secondary screw perforation were excluded from the study. Similarly, Acklin et al.[14] reported a significant improvement of Constant-score following hardware removal from 71 to 76, in 20 patients who underwent implant removal for subjective restriction (55%), persistent pain (20%) and due patient wish without symptoms (15%), without any complications. However, patients with AVN of the humeral head and screw perforation were also excluded from the study and the time to implant removal was not reported. In the current study, the average Constant-score and subjective shoulder value were 83.8 and 92.8 at the one-year follow-up following implant removal, respectively, in 59 asymptomatic patients. No patient reported worsening of their symptoms following implant removal, whereas the majority of the patients (96%) reported a subjective increase in their shoulder function. This data imply that even asymptomatic patients, without any subjective functional limitation or pain, could experience an improvement following an early implant removal after ORIF for a displaced humeral head fracture.

The current study should be interpreted in light of its potential limitations. The main drawback was the lack of a control group. Although, the majority of the patients reported a significant improvement following implant removal, it is possible that some patients would

have shown an improvement irrespective of hardware removal and the implant was simply removed before the patients achieved their plateau of recovering. According to the literature, the shoulder function reaches a plateau at about 6–12 months following ORIF of a proximal humerus fracture.[23,24] However, because AVN and secondary screw cut-out could appear earlier than 12 months,[10] an early implant removal at minimum 6 months following ORIF in radiographically consolidated fractures was performed in all of our patients, without any complications.

5. Conclusion

The current study is the only available in the literature reporting both clinical and radiologic outcomes, as well as perioperative complications in asymptomatic patients undergoing early implant removal following ORIF for proximal humeral fracture. The results of this study suggest that early implant removal might be a safe option to avoid secondary IRC, with significant subjective functional improvement in asymptomatic patients. Although early implant removal cannot reverse the process of AVN, it could potentially prevent the secondary screw cut-out and subsequent glenohumeral cartilage destruction.

Conflict of interest disclosure

The authors of this manuscript have nothing to disclose that would bias our work.

IRB approval

Ethikkommission Nordwest-und Zentralschweiz: 2014-169.

Level of evidence

II.

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