

Indications and complications in relation to removal of clavicle implants

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ABSTRACT

INTRODUCTION: Implant-related discomfort (soft-tissue irritation, pain and cosmetics) is often seen in patients with surgically treated clavicle fracture. The aim of this study was to investigate indications, complications, functionality and patient satisfaction following implant removal of surgically treated clavicle fractures.

METHODS: A total of 97 patients (73 males, mean age 43 years) had a clavicle plate removed at our department between 2007 and 2014. A purpose-made questionnaire was used to assess self-perception of cause of implant removal, remission, complications and overall satisfaction. Functionality was assessed using the Quick DASH score.

RESULTS: Two patients died before follow-up and were excluded. Five different indications for implant removal were found. A total of 65/95 of the patients answered the purpose-made questionnaire; 50/65 reported satisfaction and 14/65 had a complication following the removal of their implant. The mean QuickDASH score was 7 (range: 0-91). Only 18/36 of those with pain and soft tissue irritation due to a clavicle plate had complete remission after implant removal.

CONCLUSIONS: The indications for clavicle plate removal are many and mainly subjective. Implant removal in patients following surgically treated clavicle fractures generally causes very few complications, and most patients seem to experience a positive effect. However, it is important to inform the patient of the risk of no remission or even a worsening, which is not an uncommon occurrence.

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Clavicle fractures are common representing close to 4% of all fractures [1]. Overall results following surgical treatment of clavicle fractures seems satisfying as the union rate is reported to be as high as 98.8%, and functionality at one year after surgery is close to normal, measured by the DASH and the Constant score [2, 3].

Implant removal following fracture healing is controversial [4]. Overall this procedure does not guarantee relief of symptoms, and patients are exposed to a risk of complications [5]. Whether it is meaningful to perform elective implant removal following surgically treated clavicle fractures remains unknown.

The aim of this study was to investigate the indica-

tions, complications, functionality and patient satisfaction following implant removal of surgically treated clavicle fractures.

METHODS

This study was a retrospective review of all adult patients undergoing elective implant removal following surgically treated clavicle fractures. The patients were identified in our regional surgical database system by the procedure code used for removal of implants in the shoulder region (SKS code: KNBU49). All extracted cases were then radiologically reviewed to identify the procedures only involving removal of implants following clavicle fracture surgery. Patients undergoing implant removal between 24 October 2007 and 31 December 2014 were included.

We did not include patients from other hospitals, but we expect that this bias would be so small that it would not affect our results, as patients are usually affiliated with a single public hospital.

Basic demographic patient data and fracture type (according to the Robinson Classification) [6] were recorded for all patients through a survey of the electronic patient files and preoperative radiographs. The type of implant and radiological bony healing (formation of callus with a bony bridge or invisible fracture lines) were recorded on the latest post-operative radiographs prior to implant removal.

By studying the patient files, we identified the surgical indications for removal of implants.

A purpose-made questionnaire (**Table 1**) was used to assess patient self-perception for cause of implant removal, patient-perceived complications related to implant removal, patient-perceived positive effect related to symptoms and satisfaction following implant removal. The Danish version of the Disabilities of the Arm, Shoulder and Hand Score (QuickDASH) was used to assess patient functionality. The QuickDASH is a scoring system that assesses functionality of the upper limb; a score of 0 indicates a normal function and a score of 100 indicates a severely disabled limb.

Primarily answers to the questionnaire and QuickDASH were retrieved via phone by a single interviewer between April and May 2015. Those who were not available by phone had both the purpose-made

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 TABLE 1

Purpose-made questionnaire.

Question	Answer
Satisfaction after implant removal?	Yes No
Indication for removal?	Symptoms of pain or soft tissue irritation Patient request due to cosmetics Decreased range of motion Infection Other indications
Complications?	Infection Refracture Bigger scar Increased numbness Other complications

questionnaire and the QuickDASH sent by mail in the course of May and June of 2015. Patients who still failed to respond were considered dropouts.

Trial registration: not relevant.

RESULTS

Throughout the study period, a total of 313 patients at our department had undergone surgical fixation of their acute clavicle fracture. Implant removal was performed in 97 of these patients. Two patients died before follow-up, and were therefore excluded. Implants were removed after a median of 12 months (range: 0-86 months) following the initial treatment. The male-to-female-ratio was 3:1 and the median age was 42 years (range: 19-71 years).

According to the Robinson Classification, 25 fractures were 2B1 (simple, one bone width dislocated midshaft fracture), 46 were 2B2 (comminuted, one bone width dislocated midshaft fracture), 11 were 3B1 (extra-articular, one bone width dislocated lateral fracture) and 13 were 3B2 (intra-articular, one bone width dislocated lateral fracture). The implants were radiologically identified as either a midshaft locking plate (n = 70), a lateral locking plate (n = 14), a Hook-plate (n = 9), an anterior locking plate (n = 1) or an intramedullary nail (n = 1).

The elective indications for implant removal were: symptoms of pain or soft tissue irritation related to the implant (n = 60), patient request due to cosmetics (n = 12), decreased range of motion (n = 5), surgeon's recommendation/advice of removal without patient having symptoms (n = 7), implant failure (n = 8), infection (n = 1) and unknown indication (n = 2).

A total of 65/95 patients completed the purpose-made questionnaire and QuickDASH. In all, 50 of the patient assessments were completed by a phone interview. The remaining group was assessed by question-

naires sent out by ordinary mail. We found no statistical difference between the results assessed by phone and those that were assessed by mail. The median time for assessment after plate removal was 42 months (range: 8-86 months).

Table 2 presents the relation between the indication for implant removal and the complications, remission and satisfaction reported by the patients. Fourteen patients reported complications related to implant removal; refracture (n = 3), bigger scar (n = 9) and increased numbness (n = 2). Of the three refractures, one had a relevant trauma two months after implant removal, whereas the other two refractured through the "old" fracture line without relevant trauma and were probably not healed at time of implant removal. All three patients reported a worsening of symptoms following their implant removal.

A total of 39/65 reported complete remission of symptoms, 12/65 reported some remission and 14 reported a worsening of symptoms following implant removal. A total of 50/65 reported satisfaction with the results following the procedure.

A total of 65/95 patients completed the QuickDASH with a median score of 7 (range: 0-91). In all, 49 of the patients had a score below 10, which is considered normal function of the arm [7].

DISCUSSION

This study indicates that the implant removal rate following surgical treatment of clavicle fractures is approximately 31% (97/313). The indications for removal are many, but the single-most common indication is a sensation of pain or irritation related to the implant. Based on patient feedback, the complication rate in our study was 14/65. However, most patients experience complete or some remission of symptoms, and more than three fourths (50/65) of all patients were satisfied with the procedure.

Indication for plate removal

A survey of surgeon's preferences towards elective implant removal revealed that surgeons generally do not recommend this operation and that they do not believe in post-operative improvement of symptoms after removal of the implant [8]. It seems then that there is no consensus about what type of indications is relevant for implant removal in general. In this study, we found five different indications for implant removal after osteosynthesis of patients with clavicle fractures. Most of the plates that were removed in this study were anatomically shaped and had a low profile. However, this seems not to cause fewer complaints than other shapes. This is not surprising, as the clavicle plate mounted on the superior side of the clavicle will be prominent due to the

thin layer of soft tissue under the skin.

Implant removal due to pain or discomfort seems to yield improvement and satisfaction in most patients (Table 2). However, 7/36 reported worsening due to complication after implant removal. Results following implant removal due to pain or discomfort has not previously been investigated in patients with clavicle fractures. However, a larger patient survey following implant removal in general reported results similar to ours, as 72% of all of those sensing pain or discomfort reported improvement [9]. The second-most common indication of implant removal in this study was patients experiencing cosmetic deficits due to the plate or the scar. Almost all of these patients reported complete remission and satisfaction following implant removal and only one had a complication after surgery (bigger scar). Though based on few cases, it seems that implant removal caused by cosmetic deficits may be justified. Implant removal due to implant failure is probably unavoidable, as failure may be related to a lack of healing and a failed implant would be expected to hover a lot and thereby result in soft-tissue irritation and cosmetic deficits. Analysis of the last two indications (decreased range of motion of shoulder related to implant and surgeon's recommendation/advice of removal without any symptoms) is difficult to conduct due to the limited number of cases.

However, we believe that implant removal based on the surgeon's recommendation with patients who have no symptoms should be avoided as the patients are exposed to unnecessary risks and potential complications. In our seven cases, a minimum of two experienced impairment following plate removal. In general, it seemed that our department did not have a clear in-

struction for implant removal during the investigated time period and the indications were primarily based on the surgeon's own assessment or belief.

Complications

The 65 patients responding to our questionnaire reported a total of 14 complications. The patient files of the remaining 30 patients who did not return the questionnaire were reviewed in order to identify any registered complications. None were found. In the literature, complications and the rate following elective implant removal seem to differ depending on the type of implant and the anatomical site of removal [10, 11]. Most of the reported complications in this study seem to be subjective (bigger scar or increased numbness) and would not necessarily be categorized as a complication by a surgeon. However, most of the patients reporting a complication due to bigger scar or numbness also reported worsening of symptoms related to implant removal. This means that the patient's expectation is key to the final result and should be carefully considered and regarded prior this type of surgery.

Refracture was found in three cases. In one case, the patient had a relevant new trauma of the affected shoulder and the refracture cannot be directly related to implant removal, whereas the other two probably did not have a healed fracture at the time of implant removal. Wang et al reported refracture in three of 27 patients undergoing implant removal following a clavicle fracture [12]. Only in one of our cases could the refracture be related to the implant removal as the fracture passed through a screw hole, whereas the other two cases had a relevant trauma to the shoulder.

Based on our results and those of Wang et al, it



TABLE 2

Relation between the elective indications for implants removal, the numbers of non-responders, remissions and complications, the satisfaction rates, and the QuickDASH scores reported by the patients.

Indication for removal of plate	Total, N	Non-responders, N _n	Remission, n			Satisfaction, n/N _n	Type of complication, n			QuickDASH score, median (range)
			complete	some	worsening		refracture	bigger scar	increased numbness	
Pain and soft tissue irritation	60	24	18	11	7	28/36	1	5	1	3.4 (0-90.9)
Implant failure	8	2	3	1	2	3/6	1	1	0	0 (0-79.6)
Patient request due to cosmetics	12	1	10	0	1	10/11	0	1	0	2.3 (0-13.6)
Decreased range of motion	5	1	2	0	2	2/4	0	1	1	1.1 (0-15.9)
Surgeon's recommendation	7	0	5	0	2	6/7	1	1	0	6.8 (0-13.6)
Infection	1	0	1	0	0	1/1	0	0	0	4.5 (-)

DASH = disabilities of the arm, shoulder and hand; n = non-responders; r = responders.



This patient's indication for removal of clavicle plate was cosmetic complaints and the removal was post-operatively reported with no complications and a normal QuickDASH-score.

seems that the risk of refracture following implant removal is very low.

Limitations

This study has some limitations, mainly due to the retrospective case series design that makes comparison to a control group impossible. Furthermore, most of our results are based on a patient survey, which is associated with a risk of recall bias. Furthermore, telephone interviews are prone to bias as the interviewer may mislead the interviewee thereby affecting the final answer. However, the interviewer was aware of this and tried to be as neutral as possible. The 68% response rate may be considered a concern, but we believe it is difficult to achieve a much higher response in this type of study. Polk et al found that the effort needed to achieve a higher response rate does not affect the overall results and therefore we assume that our low response rate did not become a major bias [13]. Lastly, we might have underestimated both the overall risk of implant removal (due to risk of patients having the implant removed at another hospital) and the complication rate (as our response rate was not complete). However, an underestimation in this case only enhances the relevance of the discussed topic.

CONCLUSIONS

Implant removal in patients following surgically treated clavicle fractures generally results in very few complications and most patients seem to experience a positive effect. This study neither justifies nor discards elective implant removal in patients with osteosynthesis of clavicle fracture. However, good results may be expected in patients sensing pain or discomfort due to the implant. It is though important in this particular indication for removal to inform the patients that only 50% may expect complete remission, 19% may expect a worsening and

the final 31% will continue to experience some discomfort.

This study cannot be used to advise the surgeon on the optimal indication decision, but should be used to assist the surgeon and the patient in counseling whether implant should be removed or not.

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