

## Original Article

# Asymptomatic Implant Removal After Fracture Union Based on Request to Remove. Is It Worth Considering, an Indian Perspective?

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## ABSTRACT

**Objectives:** Hardware removals are among the commonly performed surgical procedures in orthopedics, but they sometimes prove quite difficult. The purpose of our study was to evaluate the risk, benefit and drawbacks of asymptomatic implant removal based on patients' desire.

**Material and Methods:** A total of 105 patients who had been previously treated for a fracture and voluntarily wanted its removal and who did not report clinical indications or occasional regional pain were included in the study cohort.

**Results:** For the 105 patients surveyed, implant removals were performed in the leg (41 patients; 39%), the ankle joint (32 patients; 30%), the thigh (19 patients; 18%) and the forearm and the wrist (15 patients; 14%). The most common indication for removal was patients' request in 66 (62.8%) cases. Altogether, 98 (93%) patients were satisfied because of the fulfillment of their desire, despite the instances of complication being frequent (32.8%).

**Conclusion:** In our study, we reported a surprisingly high rate of satisfied patients after surgical hardware removal once their requests for hardware removal were taken into consideration. However, it was closely associated with multiple risks. Therefore, judicious selection of actually eligible patients is highly recommended instead of the unqualified fulfilment of their requests for removal.

**Keywords:** asymptomatic implant; implant removal; patient desire; patient safety

## INTRODUCTION

The surgical removal of orthopedic hardware or implants used for the fracture fixation of bones is considered as one of the most commonly performed orthopedic surgeries.<sup>[1]</sup> In a study conducted in Germany in 2010, a total of 1,80,000 hardware removals were performed, making this type of surgery the fourth-most common surgical procedure in the orthopedic field.<sup>[2]</sup>

However, there is still a debate in the literature regarding the justification of elective surgical implant removal.<sup>[3,4]</sup> The common indications for removal are surgical site infection, loosening of implant, metal allergy, implant failure, soft tissue compromise and union failure; the minor indications include intended improvement of function, regional pain, foreign body sensation, implant irritation and MRI compatible issues. However, the above mentioned literature does not offer any instances of implant removal based on patients' desire because "implants are simply not required once fracture has fully united".

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In a 2008 study by Hanson, which included 730 patients in Davos, Switzerland, 380 of 655 surgeons (58%) disagreed that routine implant removal was unnecessary while 48% felt that removal was riskier than leaving an implant *in situ*. These findings were probably influenced by various unwanted complications that could occur during and after implant removal.<sup>[5-9]</sup> The socioeconomic impact of implant removal must therefore also be taken into consideration, especially in a developing country like India, where less than 20% of the total population has access to medical insurance. In fact, hardware removal is cost- and time-consuming for both patients and hospitals, and any complication would further increase the financial burden on patients, leading to emotional breakdown and feelings of disheartenment.

Our study aimed to evaluate the risk, benefit and drawbacks of asymptomatic implant removal based solely on patients' request, using a simple, easily comprehensible and self-explanatory questionnaire. We hypothesized that our patients' satisfaction after implant removal would be high when their requests for removal had been taken into consideration since patients tend to avoid keeping a metal throughout life if doing so is not required, despite the possibility of associated post-surgery complications.

## MATERIAL AND METHODS

Our study was conducted in two hospitals by the same team of surgeons between February 2018 and August 2022. Overall, 105 consecutive patients aged between 10 and 65 years (mean age of 37 years) were included in the study. Patients with occasional pain at the site of implant, especially in winter due to unknown reasons, were also included. In summary, this study included 39 women, 56 men and 10 children (aged between 10 and 15 years). All of the patients' fractures were united radiographically and were deemed clinically asymptomatic. Notably, the study was conducted only after the approval of a relevant institutional review board, and all patients signed an informed consent form agreeing to participate in the same.

First, all patients were carefully examined to rule out any clinical indications for removal. Accordingly, patients who had previously undergone hardware removal for a known cause – such as infection, implant irritation, implant failure, painful implant and fracture non-union – were excluded from the study. The study aimed to evaluate the patients' satisfaction levels after asymptomatic implant removal on patients' request, that is, the request for implant removal by asymptomatic patients.

At 6 months after removal, a patient satisfaction questionnaire was prepared for all the patients of our cohort. It consisted of two questions: (1) Are you happy and satisfied that

the hardware was removed and (2) What are your overall experiences after surgery?

Moreover, the Short Musculoskeletal Function Assessment Questionnaire (SMFA) and the Medical Outcomes Study (MOS) Short Form-36 (SF-36), two standardized surveys assessing functional outcomes, were recorded as a baseline at 3, 6 and 12 months after removal (to obtain post-operative data). In addition, SF-36 health survey score questionnaires were used both preoperatively and post-operatively, and as per the scores recorded, many patients were deemed satisfied and asymptomatic. Furthermore, information was obtained from each patient (interview, pain score, SF-36, SMFA) from their respective hospital chart (injury and treatment information) and their post-operative radiographs (healing of the fracture, type of plate and screws, and prominence of the hardware) for our study. To determine each patient's satisfaction level, she or he was interviewed by one of the authors.

### Inclusion criteria

- (a) Age between 10 and 65 years
- (b) Previous surgical fixation with metallic implant
- (c) Fracture union had occurred
- (d) Patients who were asymptomatic but requested implant removal
- (e) No previous attempt had been made to remove the implant

### Exclusion criteria

- (a) Fracture was not yet fully united
- (b) Failed attempt at implant removal in the past
- (c) Symptomatic implant, for example, infection, implant irritation, implant failure, fracture non-union, loosening and migration of implant

## RESULTS

For the 105 patients surveyed, implant removals were performed in the leg (41 patients; 39%), ankle joint (32 patients; 30%), thigh (19 patients; 18%) and forearm and the wrist (15 patients; 14%). Out of the total number of patients, 10 were children in the 10- to 15-year age group. Among them, six had fractured shaft femur and were treated by plating, while the remaining four were treated for fractured radius and ulna. The hardware of all 10 children (9% of the entire cohort) were removed within 1 year since index surgery, as desired by their parents. Notably, the most common indication for hardware removal was patients' request (66 patients; 62.8%), while surgeon recommendation – in cases of previous surgery – was the indication for 23 patients (21.9%). Moreover, MRI compatibility issues served as the indication for 5 patients (4%), while 11 patients (10.4%) thought that their pain occurred due to their implant.

The demographic characteristics of the entire study population are shown in Table 1. Out of the entire cohort, 98 (93%) patients were satisfied irrespective of the nature of the specific implant removed. All of the 10 children (9.5%) in the cohort underwent removal operations within one year since their index surgery [Table 2]. In addition, the types of implants and the different anatomical sites are shown in Table 3. Interestingly, we noted various peri- and post-operative complications in 35 (32.8%) patients.

**Table 1: Demographic characteristic of the study population.**

Age of patients	No. of patient - n (%)
10-15	10 (9.5%)
16-25	25 (23.8%)
26-35	11 (10.4%)
36-45	33 (31.4%)
46-55	14 (13.3%)
56-65	12 (11.4%)
Male	49 (46.6%)
Female	56 (53.3%)
Upper limb	13 (12.3%)
Lower limb	92 (87.6%)
<b>Mechanism of injury</b>	
Road accident	42 (40%)
Sports related	29 (27.6%)
Fall from height	12 (11.4%)
Hit while walking on road	13 (12.3%)
Assault	9 (8.5%)
<b>Type of fracture</b>	
Closed	69 (65.7%)
Open	
Grade I	25 (23.8%)
Grade II	7 (6.6%)
Grade IIIA	2 (1.9%)
Grade IIIB	2 (1.9%)

**Table 2: Period from initial operation to implant removal.**

Time of removal after the initial operation	No. of patients
<6 months	04 (3.8 %) – all 04 children
7-12 months	06 (5.7%) – all 06 children
13-18 months	11 (10.4%)
19-24 months	29 (27.6%)
24-36 months	47 (44.7%)
>36 months	7 (6%)

Furthermore, the localisations of surgical hardware removal from body parts are shown in Figure 1. As per Figure 2, delayed wound healing was the most common complication in 31% of the cohort, followed by infections. To reiterate, patients' request was the most common reason for surgical removal of implant [Figure 3].

As mentioned above, the most common indication for hardware removal in our study was patients' desire – in 66 (62.8%) cases – while surgeon recommendation (in cases of previous surgery) was the indication in 23 (21.9%) cases. MRI compatibility issues served as the indication in five (04%) cases, while 11 patients (10.4%) thought that their occasional pain was due to their implants.

Of the cohort, 69% exhibited high satisfaction levels upon the fulfilment of their desire, reporting significant subjective improvements in overall function after implant removal. In this vein, the scores of the SF-36 are shown in Figure 4, with higher scores indicating higher functional levels. Notably, the mean SF-36 scores for patients with implant-related pain (n = 11) were significantly lower in all the sub-score areas. The greatest of such difference was observed regarding pain where a given implant was located; in this regard, patients who thought that their hardware induced pain had a mean

**Table 3: Body Location and type of hardware removed.**

Implant	Femur	Tibia	Malleolus	Radius	Ulna	Clavicle	Humerus
<b>Total Nails</b>	12 (11.4%)	10 (9.5%)					
Solid nails	2						
Cannulated	10	3					
<b>Material</b>		-					
Titanium	3	10					
Steel nail	9						
<b>Total Plates</b>	6 (5%)	11 (10.4%)		19 (18%)	9 (8%)	12 (11.4%)	14 (13.3%)
DCP	2	5		13	5	9	11
LCDCP	4	6		6	4	3	3
<b>Material</b>							
Titanium	2	2		7	-	3	5
Steel	4	9		12	9	9	9
Screws			12 (11.4%)				

DCP: Dynamic compression plate, LCDCP: Low contact dynamic compression plate

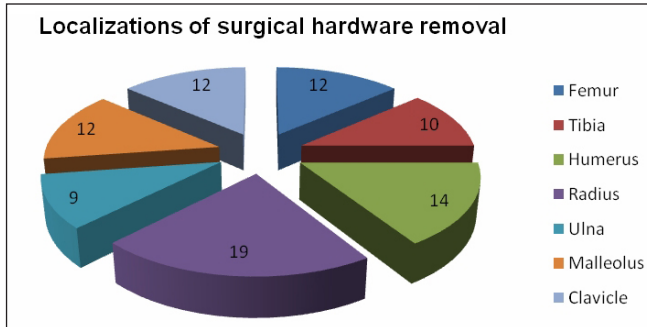


Figure 1: Localisations of surgical hardware removal.

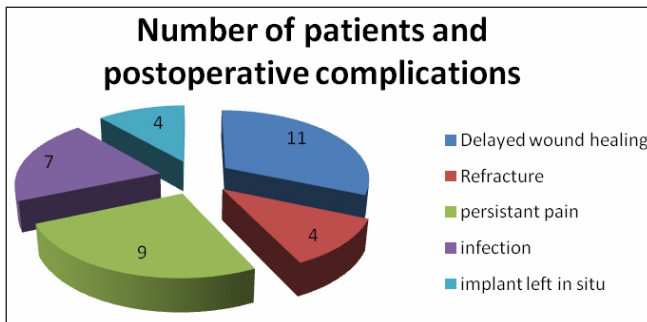


Figure 2: Post-operative complications following removal of asymptomatic orthopedic implants.

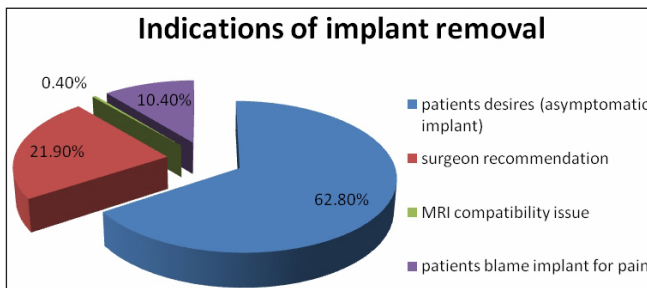


Figure 3: Indications of implant removal.

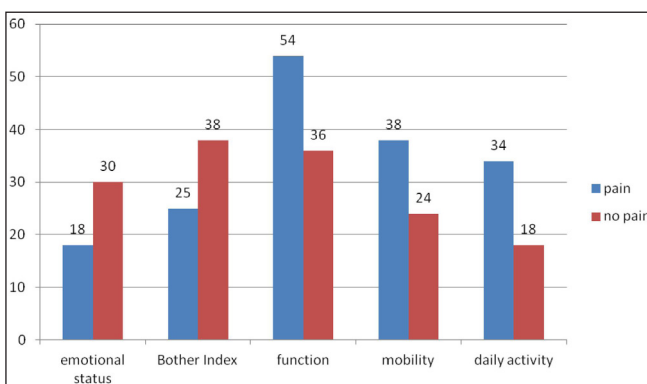


Figure 4: Selected SMFA sub-scores for patients with and without a hardware-related problem. Lower the scores better the function. Statistical significance was reached for each sub-score presented ( $p < 0.006$  for all).

Table 4: SMFA scores for the dysfunction and bother indices at pre-surgery (baseline) and after implant removal.

Variable	n	Pre-surgery		Post-surgery	
		Dysfunction mean	bother mean (SD)	Dysfunction mean	bother mean (SD)
Upper limb with implant	13	37.5 (21)	30.7 (13)	31.5 (21)	21.6 (11)
Lower limb with implant	92	39.2 (22)	33.8 (14)	25.6 (13)	22.2 (11)
Child with implant	10	35.7 (19)	42.7 (31)	22.6 (13)	23.7 (12)

score of  $42.6 \pm 31.4$ , whereas pain-free patients who still desired hardware removal had a mean score of  $71.3 \pm 28.5$  ( $p = 0.0006$ ). The average scores regarding emotional status were  $31.82 \pm 19.20$  for patients with pain and  $26.76 \pm 16.3$  for patients without pain ( $p = 0.001$ ). Table 4 contains the SMFA scores for the dysfunction and bother indices at pre-surgery (baseline) and after implant removal.

## DISCUSSION

In our study, the patients had a positive experience insofar as their requests for orthopedic implant removal were considered. Of the total cohort who underwent orthopedic implant removal, 65% reported high satisfaction levels, despite minor complications being reported, for example, impaired wound healing occurring during or after the procedure. The patients clearly articulated that they were happy and satisfied, especially because many surgeons had previously refused to consider their request for implant removal in the absence of clinical indications.

### Patient experiences and function after implant removal

Our study data revealed a high percentage of patient satisfaction and the subjective improvement of function after implant removal. Indeed, 98 (93%) patients out of the total cohort were satisfied with their implant removal. This finding speaks to many previous studies that have reported variable improvements in pain after implant removal. For example, Brown *et al.*, in their study of ankle plate removal, have shown a 50% concomitant improvement in pain.<sup>[10]</sup> Gustilo<sup>[11]</sup> has also reported an improvement in knee pain, from 64% to 96%, after removal of the nail.

In our study, the desired satisfaction levels were achieved as 93% of the cohort desired to remove their implants. This finding aligns with those of many related studies that have shown that the removal of implants improves function.<sup>[12,13]</sup>

### **Patient satisfaction after orthopedic implant removal**

Surprisingly, 93% of our cohort, and additionally 65% of those patients who subjectively perceived some complications regarding wound healing (although minor) after hardware removal, reported that they would opt for implant removal again, if required. This finding adds to the gap in the literature regarding the relations between implant removal and patients' desire and their satisfaction after removal. Indeed, our study indicates that patient satisfaction can be surprisingly high even with complications subsequent to implant removal, if the reason for hardware removal is their own personal request.

Crucially, in our study, the patients were seemingly more satisfied after foreign material was removed from their own body, even with the potential disadvantages such as post-operative complications being associated with this kind of surgery. This was a refreshing finding in the locational context of India, where many orthopedic surgeons remain very reluctant to remove asymptomatic implants only based on patient requests, leading to emotional torment and adverse psychological impacts on patients' health.

However, metallosis is an alarming complication that may arise where the quality of implant is not always reliable, especially within a developing country. Ideally, clinically asymptomatic implants should not be removed because of the risk of complications. This view has been supported by Gosling *et al.*, who have noted increases in pain in 20% of asymptomatic individuals (under study) after nail removal from femur; Gosling *et al.* have concluded that only patients suffering from pain after femoral nailing would improve after or benefit from implant removal.<sup>[14]</sup> Unno *et al.* have also shown that implant removal should not be considered a routine procedure and should be decidedly undertaken after detailed clinical examination.<sup>[15]</sup> Plus, Sidky *et al.*, in their study of 130 patients, have revealed a tibial intramedullary (IM) nail removal rate of 23.9%, additionally reporting an improvement in 72.2% of their patients' symptoms after nail removal.<sup>[16]</sup> Williams *et al.*,<sup>[17]</sup> in a prospective study of 69 patients, have recorded notable pain relief upon the removal of painful implants. Kovar *et al.*<sup>[18]</sup> who performed 424 hardware removals in 371 consecutive patients following a proximal femur fracture, and divided their patients into two groups – with the clinically indicated group consisting of 299 patients (80.59%) and with 72 patients (19.41%) being grouped as the non-clinically indicated group – have noted that non-clinically indicated implant removal should be avoided due to the higher complication rates (as high as 28%). Again, Onche *et al.*, in their study cohort of 47 patients, have recorded patient requests as the main indication for removal in 34 patients (72.3%), symptomatic implants as the indication for four patients (8.5%), surgeon's request without

any symptoms as the indication for seven patients (14.9%) and six patients (10.7%) were symptomatic, where four (8.5%) due to postoperative chronic osteomyelitis and two patients (4.3%) in intractable pain. Onche *et al.* have concluded that plates should be removed from the lower limb because of the stress-shielding effect of the plates. Furthermore, IM nails are stress-sharing devices and can be left *in situ*.<sup>[19]</sup> Jamil *et al.* have claimed that generally metallic implants should be removed once their purpose is served.<sup>[20]</sup> Even Mølster *et al.*, in their questionnaire-based study, have concluded that although implant removal is desirable after fracture healing, it is also associated with a certain morbidity and with the incidence of complications.<sup>[21]</sup>

A related study by Reith *et al.* has asserted that implants should be removed by default, being associated with post-operative complications at a rate of 10%.<sup>[22]</sup> In contrast, a study by Raney *et al.*, within the pediatric age group, has not found any conclusive evidence in the literature to support or refute the practice of routine implant removal in children.<sup>[23]</sup>

### **LIMITATIONS**

This study focused on patient experience and satisfaction with respect to a particular surgical intervention based on their desires. Data collection was also limited to verbal focus-group interviews with a small cohort of patients. Thus, it inherently offers limited transferability. Therefore, future research should investigate patients' experiences in a variety of contributory roles across different surgical fields in order to draw stronger conclusions. Clearly, the establishment of definite correlations between psychological factors, patient satisfaction and clinical improvement warrants further investigations.

### **CONCLUSION**

In our study, we noted a high rate of satisfied patients after surgical hardware removal despite the explained and noticed complications. Hence, we suggest that implants should only be removed in light of clinical indications and not merely be based on patient requests. Although the concomitant complication risk is considered to be only as high as 32.8%, keeping in mind patients' safety and quality of life, any indication for asymptomatic implant removal still has to be assessed and scrutinized judiciously.

In summary, patient requests cannot be considered as the absolute indication for implant removal. Nevertheless, the removal of implant gives patients a high level of satisfaction. In our study, the majority of patients considered the futility of keeping a metal in their bodies throughout their lives even when it was not required, despite the surgeon's opinion that it would not be necessary to remove their implants even after the fracture union.

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## Ethical approval

The research/study complied with the Helsinki Declaration of 1964.

## Declaration of patients consent

Patient's consent not required as there are no patients in this study.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

## Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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