

## Original Research Article

# Indications for implant removal: a prospective study

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**Received:** 08 January 2019

**Revised:** 22 January 2019

**Accepted:** 25 January 2019

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## ABSTRACT

**Background:** The implants removal after fracture healing has always been an issue of controversy. After union, the implant ceases to be important and can be removed. Nevertheless, some patients require metallic implant removal due to various implant-related difficulties. Our study was aimed to identify the most common causes for removal of implant.

**Methods:** The patients admitted for implant removal in our department were consented and included in the study. Pre-operative radiological images collected and evaluated. Post-operatively, images were taken and followed for resolution of symptoms or appearance of new problems.

**Results:** A total of 60 patients were studied. Of these, 47 were males and 13 were females. Mean age was 33.7 years (range 4-70 years). Patient request (35% of patients) was the main indication for removal of implants. Reasons were found to be discomfort due to implant, infection, failure of implants and others.

**Conclusions:** Belief regarding hardware removal has been set and most of them are agreed that routine removal should not be performed unless obviously indicated. In our attempt to fill this gap, we trust that routine removal should not be performed in 'asymptomatic' patients. The procedure should not need a big procedure than the implant fixation surgery. Procedure should be sought also as a risk like refracture, bleeding, infection, neurovascular injury and prior to surgery, proper consent to be taken and patient should be well explained. Sometimes indicated results expected after surgery can't be fulfilled, and instead, complication can results.

**Keywords:** Implants removal, Failure of implants

## INTRODUCTION

Treatment of fracture with internal fixation has been arrived as boon. Fractures, in recent advances in medical era, almost of all bones can be fixed with internal fixation devices. The devices used in fixations are of various configurations and provides harmless behavior to our internal milieu. Though, our society still follows the concept of natural healing by bone fixer without experimenting the well-known scientifically proven implantation hardware. Maximum patients wish traditional management except when all other means have unsuccessful. Worldwide metal implants (e.g. plates, screws and nails) are used which are generally

made of stainless steel or titanium alloys. After fracture healing has taken place an implant no longer has any function and the question rises whether the implant should be removed and if so, why and when? Though there are several presumed benefits of implant removal, like functional improvement and pain relief, the surgical procedure can be very challenging and may lead to complications such as neurovascular injury and refractures, whereas the expected outcome is not well determined yet. The (medical) indications for surgical removal of these metal implants are not well defined and a variety of view points with large differences in opinions and practices between surgeons, countries, patients, anatomical locations and implant materials exist.<sup>1-7</sup> In

children, though, routine implant removal after fracture union is still standard procedure.<sup>8</sup> This study is aimed at determining the indications and other variables of orthopedics hardware removal, performed at the Sri Aurobindo Medical College and Postgraduate Institute, Indore.

## METHODS

The study was conducted prospectively on patients admitted for removal of implants in the orthopedics department at SAMC and PGI, Indore from duration of September 2016 to May 2018. Patients who presented in the outpatient department (OPD) with hardware related problems and those demanded removal were admitted. Patients excluded from our study were those who needed removal of fixation devices proposed to be taken out after a certain interval to start with, like percutaneous K-wires, external fixators and joint prosthesis.

During the time of admission, the possible risks of the operation and the possibility of non-favorable concerns were described to all patients. After admission, routine investigations were done on all patients to evaluate their fitness for surgery. Implant removal was then done according to their name in OT list. All patients received prophylactic antibiotics 0.5 hours prior to surgery and tourniquet was used wherever likely. Postoperatively, the patients were remained in the hospital for variable times subjecting on the indication of implant removal and the state of the wound. Longer duration of antibiotic were given in patients with infected hardware. All the patients were strictly advised, at the time of discharge, to protect the limb for a flexible length of period as required by the bone and the implant removed. They were followed in the OPD whenever advised in their discharge sheet and assessed for relief of symptoms, persistence of old complaints and development of new problems, and the data were composed.

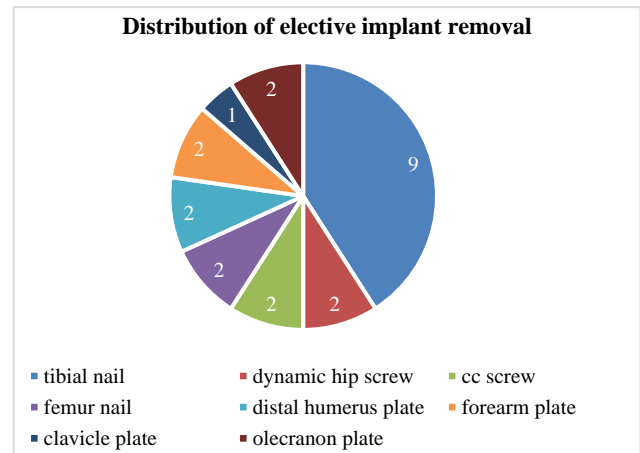
## RESULTS

Over the period of our designed study, all the 60 patients fulfilling the criteria of selection were evaluated. All implants removed in our series were Indian made and were made of stainless steel.

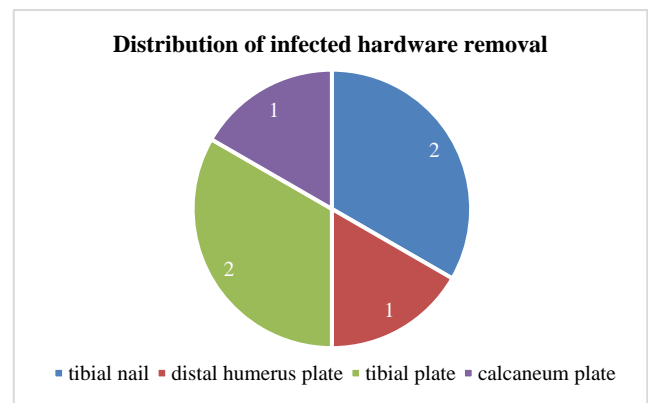
47 were male (78.3%) and 13 were female (22.7%). Their ages ranged from 4 years to 70 years, and the mean age was 33.7 years. The reasons for removal of implants were found to lie in following categories: infected hardware, implant failure, elective (patient's claim), change in treatment plan and pediatrics conditions.

Twenty two patients out of sixty had demands for implant removal (35%). They ranged in age from 20 to 56 years (mean age 37.7 years). The implants most commonly responsible in order of frequency were tibial intramedullary nail (n=9), DHS (n=2), cortico-cancellous screw (n=2), femoral IM nails (n=2) and distal humerus

plate (n=2). The mean duration of hospital stay in these patients was 5 days. No patient developed infection in their follow ups (Figure 1 and 5).



**Figure 1: Distribution of elective hardware.**



**Figure 2: Distribution of infected hardware.**

Six patients out of 60 (10%) needed implant removal due to development of infection at the implant site inconstant period after osteosynthesis. Their ages ranged from 40 to 65 years (mean 51.83 years). Union was present in all patients at the time of implant removal. In this group, the implants most commonly removed included proximal/distal tibia plates (n=2), tibial intramedullary nail (n=2) and calcaneum plate (n=1) and distal humerus plate (n=1). After the removal, infection subsided in all the patients except for 1 with fracture calcaneum fixed with plate, developed chronic osteomyelitis with persistent discharge in follow up duration (Figure 2 and 6).

15 (25%) patients required implant removal and revision osteosynthesis for implant failure. Their average age was 44.9 years (22-70 years). These included 4 both bone forearm plating, 2 DHS, 2 distal tibial locked plates, 2 distal humeral plate, 2 proximal femoral nail, 1 femoral intramedullary nail and 1 clavicle plate and 1 patient with broken ender nail in shaft humerus fracture required plating with bone graft (Figure 3 and 7-9).

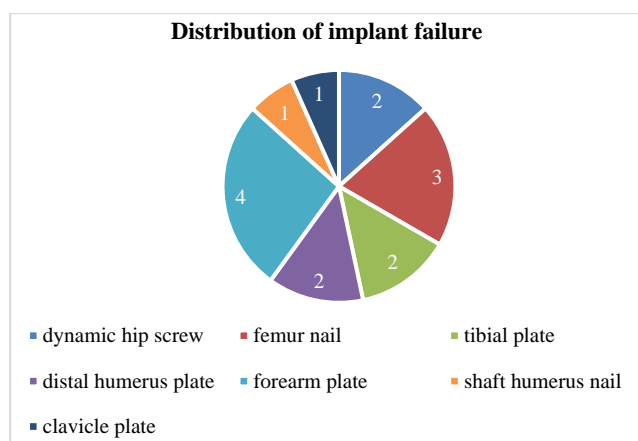


Figure 3: Distribution of failed hardware.

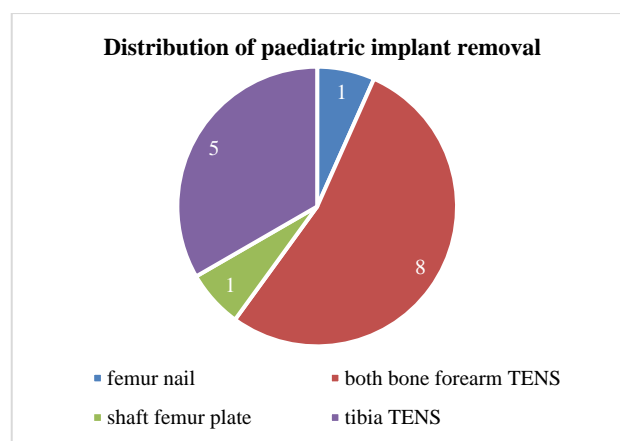


Figure 4: Distribution of paediatric hardware.

Table 1: Distribution of cases.

S.no	Type of implant	Patient's demand/ elective removal	Infected hardware	Implant failure	Change in orthopaedic plan	Pediatrics
1.	Tibia nail	9	2		3	
2.	Dynamic hip screw	2		2		
3.	Cortico-cancellous screw in tibia	2				
4.	Femur nail	2		3		1 (enders nail)
5.	Distal humerus plate	2	1	2		
6.	Tibial plate		2	2		
7.	Calcaneum plate		1			
8.	Both bone forearm plate	2		4		
9.	Shaft humerus			1		
10.	Clavicle plate	1		1		
11.	Olecranon plate	2				
12.	Both bone forearm TENS/rush nail					8
13.	Shaft femur plate					1
14.	Tibia TENS					5

TENS- Titanium elastic nailing system.



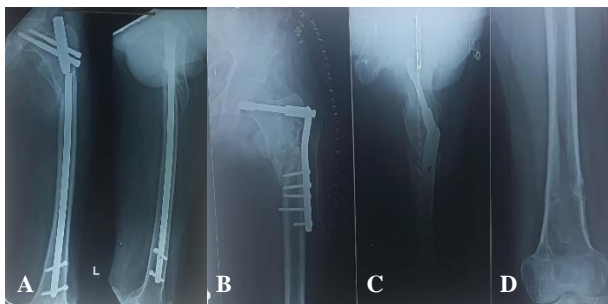
Figure 5 (A-D): Prominent implant with distal humerus plate removal.



**Figure 6 (A-E): Infected plate in proximal tibia.**



**Figure 7 (A-D): Implant failure with fracture distal tibia/fibula.**



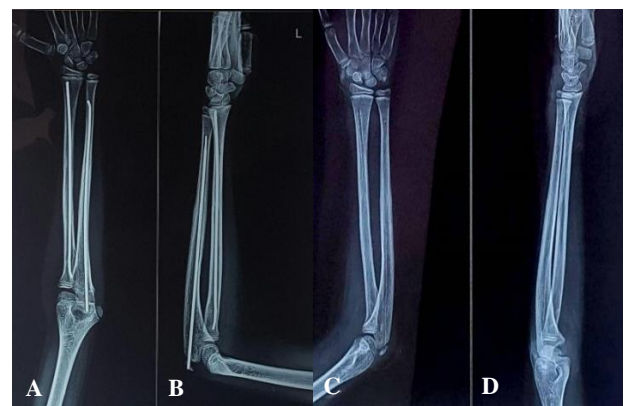
**Figure 8 (A-D): Failed long proximal femoral nail.**



**Figure 9 (A-D): Failed distal radius plate with implant removal and replating.**

Three (5%) population of our study required revision for temporary fixation to definitive procedure. External

fixators were removed in such cases and definitive plating done. One of these three cases required further plate removal due to persistence of pus discharge from the site of fixation (Figure 4 and 10).



**Figure 10 (A-D): Both bone forearm TENS removal.**

In pediatrics population, 15 (25%) cases were included in our study group. The mean age at the time of implant removal was 8.9 years (range 4-16 years). These included 7 both bone forearm TENS, 5 tibia TENS, 1 femur shaft plate, 1 both bone forearm rush nail, 1 ender nail for shaft femur fracture. No patients have developed infection post implant removal in pediatrics age group.

Implant removal did not come without any hindrance and it sometimes become too tedious while operating. This was seen especially in locked plates at various sites, with ingrowth of bone everywhere the plate/screws and slippage of screw driver due to distortion of screw head.

In one patient who had presented for implant failure of an interlocked proximal femoral nail, we failed to extract the nail despite best efforts. We were lucky enough that did not encounter major vascular injury during the implant removal surgery.

## DISCUSSION

Metallic hardware inserted for fracture stabilization may at some time or the other be removed for a variety of reasons. However there is still little consensus on if such hardware be removed routinely in the setting of a healed



fracture.<sup>9</sup> Opinions and habits not only vary between surgeon-related factors (e.g., differences between countries), but also patient-related factors (e.g., differences between children and adults, anatomical locations) and implant-related factors (e.g., stainless steel versus titanium alloys).<sup>7</sup> pediatric group have different indications to be considered during clinical evaluation on follow up. Pediatric patients who have had internal fixation may have it removed if it causes pain, however it is advocated that such hardware especially the in hip be left alone.<sup>3</sup>

Distribution of aspects related to implant removal surely vary from cases to cases, and implications for doing surgeries should be weighted first, that how much benefit patient will get after operation. Many a times, patient's request becomes 'absolute demand' to get implant removed despite any 'absolute indication'. Patient's request may be phobia due metal inside body or fear related to future problems or advice from relatives/doctor.

Currently, most indications for removal are 'relative', meaning that they are not really necessary and are often driven by patient's complaints and symptoms. Pain, functional impairment, prominent material, possible future problems, and the patient's request are the main examples of 'relative' indications for removal.<sup>7</sup> These following indications can be considered as 'absolute' for hardware removal that includes Broken material, Infection, Avascular necrosis, Cut out of material, Intra-articular material, Tenosynovitis and Tendon rupture.

Improvement of complaints after removal is debatable and disadvantages, such as surgery-related complications or even worsening of the complaints, can appear and are important reasons for the antagonists of removal to leave the implant in.<sup>10-13</sup> In general, the complication rate differs significantly between studies and estimated risks for adverse events vary from 0 to 1% for postoperative hematoma, up to 14% for wound infection, 1–29% for nerve injury, 1–30% for a refracture, and up to 9% for obtaining a cosmetically disturbing scar.<sup>10,11,13-19</sup> However, in symptomatic patients, the disadvantages are accepted to give these patients the benefit of the doubt, as one of the potential advantages of implant removal might be the improvement of complaints. On the other hand, in asymptomatic patients, it is accepted to leave the implant in.<sup>7</sup>

78.3% constituted male population came for their hardware removal. Our study, however, also included children with sum of 25%. Abidi et al reviewed 40 patients with implant-related pain who required removal. 30 of these (75%) were males.<sup>20</sup> Shrestha et al in their retrospective series also found a male preponderance (189 out of 275 patients) to the tune of 68.72%.<sup>21</sup> There categorically looks to be a strong male majority in implant removal surgeries.

In our study, patient demand was the most common reason dictating removal (35%). Although we did not primarily aim to evaluate the outcome after removal, all our patients had at least some relief in their hardware pain at follow-up. About There was a statistically significant improvement in the mean pain VAS after implant removal.<sup>22</sup> Brown et al found that 31% patient under going open reduction and internal fixation of ankle fractures had persistent lateral pain.<sup>23</sup> They also found that only 11 of 22 patients who got their hardware removed had improvement in the pain. Minkowitz et al prospectively studied 60 patients who had implant removal for hardware pain, and at 1 year follow-up all their patients were satisfied.<sup>24</sup>

Implant failure (25%) was the next most common indication in our series. Patient noncompliance, defective implants used, shortage of instrumentations, fault in technique, surgeons skill are the important consideration to be seen while performing surgeries. Akhtar et al cited the most common cause of failure as poor quality of the implant.<sup>25</sup> Peivandi et al also concluded that the most common reason for implant failure was poor manufacturing. They recommended that credible and trusted implant brands should be used in fracture fixation.<sup>26</sup> Sharma et al in a retrospective study of 41 failed upper and lower limb implants found that plate failure was more common than nail failure in the lower limb.<sup>27</sup>

Hardware removal surgeries are mainly performed by registrars and post graduates use to assist them followed by consultants in our institute as this is looked as straight forward or there is less struggle due to incision is taken over the old surgical scar and no obvious fear of likelihood of complication. Surgeons believe on his skills of performing the skilled operation and this do not significantly contribute to operation duration ( $p > 0.05$ ). Hospital stay also vary person to person for same kind of procedure and not significant ( $p > 0.05$ ). Khan et al corroborates our finding when they reported a hospital stay between 2-4 weeks as a result of infection.<sup>28</sup> Matthew et al reported an overall average of 11 days of sick leave for IM nail removal in the lower limbs.<sup>9</sup>

Refracture following removal of hardware was seen in 2 (3.33%) patient with congenital pseudoarthroses. Refracture is most common in the forearm.<sup>10,14,16,17,29</sup> Refracture could result either before or after hardware removal. Refracture usually occurs from stress risers commonly associated with plates and screws, more especially with large fragment DCP system.<sup>29</sup>

## CONCLUSION

Here, we are addressing the gap in concrete indication guidelines in the implant removal procedures, as it creates a noteworthy portion of elective orthopedic surgeries. Many publications have been made to direct the surgeons about selection of patients on basis of their

indications and non-indications. Belief regarding hardware removal has been set and most of them are agreed that routine removal should not be performed unless obviously indicated. In our attempt to fill this gap, we trust that routine removal should not be performed in asymptomatic patients. The procedure should not need a big procedure than the implant fixation surgery. Procedure should be sought also as a risk like refracture, bleeding, infection, neurovascular injury and prior to surgery, proper consent to be taken and patient should be well explained. Sometimes indicated results expected after surgery can't be fulfilled, and instead, complication can results.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the institutional ethics committee*

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**Cite this article as:** Jain RK, Patel Y, Jayaswal A, Verma A. Indications for implant removal: a prospective study. Int J Res Orthop 2019;5:253-9.