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Indications, outcomes, and complications of orthopaedic implant removal: a prospective observational study

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ABSTRACT

Background: Orthopaedic implant removal is a common procedure, but its indications and outcomes remain debated. This study aimed to examine the indications, outcomes, and complications of implant removal in a tertiary care center.
Methods: A prospective observational study was conducted on 66 patients undergoing implant removal between February 2022 and February 2024. Patient demographics, indications for removal, time to removal, and complications were recorded. Follow-ups were conducted at 6 weeks, 3 months, and 6 months post-removal.
Results: The study included 47 males and 19 females, with 74% adults and 26% paediatric patients. Pain was the most common indication for removal (42%), followed by elective removal (36%). Most implants (33%) were removed after 2 years. Complications were minimal, with 4.5% incomplete removals and 1.5% failure to remove. No intraoperative fractures or postoperative infections were observed. Patients generally reported improvement in symptoms or psychological well-being following implant removal.
Conclusion: Implant removal should be approached selectively, with careful consideration of indications and potential complications. Pain relief and improved function were common outcomes, but risks such as incomplete removal should be considered. The study supports individualized decision-making in implant management, emphasizing the need for thorough preoperative planning and skilled surgical execution.

Keywords: Fracture management, Hardware removal, Orthopaedic implants, Postoperative complications, Patient outcomes, Surgical indications

INTRODUCTION

Orthopaedic implants have revolutionized the management of fractures and skeletal deformities, provided stability and facilitated bone healing. These medical devices, including screws, plates, nails and prostheses, are designed to stabilize or splint damaged or deformed bones, allowing for secure bone positioning and restoration of articulating surfaces in various joints.[1] However, the question of whether to remove these implants after fracture healing remains a topic of considerable debate in orthopaedic practice. The removal of orthopaedic implants is a common procedure, constituting a significant portion of orthopaedic surgeries performed in many institutions.[2] Despite its frequency, the decision to remove an implant is complex and multifaceted, involving considerations of potential benefits, risks and patient preferences. The clinical justifications for implant removal often lack clear criteria and remain poorly defined, leading to variations in practice among surgeons and institutions.[3] Several factors drive the decision to remove orthopaedic implants. The most prevalent reasons include mechanical symptoms such as implant prominence and discomfort.[1] Pain, often localized to the implant site, is a primary motivator for patients seeking removal. Other indications include hardware

failure, infections, patient desire and concerns about long-term effects such as stress shielding leading to bone resorption.[4] In pediatric patients, additional considerations come into play, including the potential for growth disturbance, foreign body response, and the risk of implant migration as the child grows.[5]

While implant removal can potentially improve functionality and alleviate discomfort, the procedure itself is not without risks. Complications such as refracture, hemorrhage, nerve damage and infection have been reported following implant removal surgeries.[4] These potential adverse outcomes underscore the need for careful patient selection and thorough preoperative planning. The timing of implant removal is another critical factor that influences outcomes. Premature removal may compromise fracture stability, while delayed removal can lead to difficulties due to bony overgrowth or implant deterioration.[6] Furthermore, the decision to remove implants varies significantly between pediatric and adult populations, with growth-related concerns often necessitating earlier removal in children.[5]

Despite the frequency of implant removal procedures, there is a paucity of high-quality evidence to guide clinical decision-making. Many surgeons rely on personal experience and institutional protocols rather than evidence-based guidelines.[7] This lack of standardization highlights the need for more comprehensive studies examining the indications, outcomes, and complications associated with implant removal. In developing countries, where surgical fracture management is increasingly common, implant removal has become a frequent elective orthopaedic procedure.[8] However, the economic implications of these surgeries, both in terms of healthcare resources and patient costs, are significant and often overlooked in clinical decision-making.[9] Given these complexities and the lack of clear consensus, there is a pressing need for more prospective studies to evaluate the indications, outcomes, and complications of implant removal. Such research can help refine clinical guidelines, improve patient selection and ultimately enhance the quality of care provided to orthopaedic patients.

The primary aim of this study is to evaluate the indications, outcomes, and complications associated with orthopaedic implant removal in a tertiary care setting.

Primary objective

To identify and analyze the various indications for orthopaedic implant removal.

Secondary objectives

To assess the outcomes of implant removal through clinical and radiological follow-up at 6 weeks, 3 months and 6 months post-operatively, to document and evaluate the complications associated with implant removal procedures, to examine the relationship between the timing of implant removal and patient outcomes, to analyze the frequency and types of implants removed across different anatomical sites. These objectives are designed to provide a comprehensive understanding of the practice of implant removal, its clinical implications and potential risks. By addressing these specific aspects, the study aims to contribute valuable insights to guide clinical decision-making in orthopaedic practice regarding implant management and removal.

METHODS

Study type

This prospective observational study.

Study place

The study was conducted in the Department of Orthopaedics at Bharati Vidyapeeth Deemed University Medical College, Pune, India.

Study duration

The study period spanned 24 months, from February 2022 to February 2024.[10]

Ethical considerations

The study protocol was approved by the Institutional Ethics Committee of Bharati Vidyapeeth Deemed University Medical College. Informed consent was obtained from all participants or their legal guardians before enrollment in the study.[11]

Inclusion criteria

All patients reporting for implant removal to the outpatient department or admitted to the orthopaedic ward, patients willing to undergo the implant removal procedure, patients able to provide informed consent

Exclusion criteria

Spinal implants, pelvic implants, patients unwilling to participate in the study, patients unable to follow up as per the study protocol. A total of 66 patients meeting the inclusion criteria were enrolled in the study.[12]

Data collection

A detailed history was obtained from each patient, including, demographic information (age, gender), clinical presentation and symptoms, date of the index operation (initial implant placement), indication for implant removal. Physical examination findings were recorded and pre-operative radiographs were obtained to assess, type of implant, position of implant, status of bone union, presence of any screw cut-out or back-out, signs of infection in the bone.[13]

Surgical procedure

All implant removal surgeries were performed by experienced orthopaedic surgeons following standard protocols. Intraoperative difficulties during implant removal were documented.[14]

Post-operative assessment

Immediate post-operative radiographs were taken to check for, Complete removal of the implant, Any iatrogenic fractures, Status of bone union.[15]

Follow-up protocol

Patients were followed up at intervals of, 6 weeks, 3 months, 6 months. At each follow-up, clinical and radiological assessments were performed to evaluate, Wound healing, Pain relief, Functional outcomes, Complications, Radiological evidence of bone healing or any new pathology.[16]

Data analysis

Patient data were compiled and analyzed using appropriate statistical methods. Descriptive statistics were used to summarize patient demographics, indications for removal, types of implants and complications. The relationship between timing of implant removal and outcomes was examined.[17]

Outcome measures

Primary outcome measures included, indications for implant removal, complications associated with the removal procedure. Secondary outcome measures included, functional outcomes at follow-up visits patient satisfaction, time to return to normal activities.[18]

This methodology was designed to provide a comprehensive assessment of the practice of implant removal, its indications, outcomes and associated complications in a tertiary care setting. The prospective nature of the study allowed for real-time documentation of patient experiences and surgical outcomes, contributing valuable data to the field of orthopaedic implant management.

RESULTS

Patient demographics

A total of 66 patients underwent implant removal during the study period. The gender distribution and age group classification are presented in Table 1.

Anatomical distribution of implants

The distribution of implant removals between upper and lower limbs was nearly equal, as shown in Table 2.

Table 1: Demographic characteristics of patients undergoing implant removal.

Characteristic	Number (%)
Gender	
Male	47 (71)
Female	19 (28)
Age group	
Paediatric	17 (26)
Adult	49 (74)

Table 2: Anatomical distribution of implants.

Site	No. of cases	%
Upper limb	31	48
Lower limb	34	52

Table 3: Indications for hardware removal.

Indication	Number	%
Pain	28	42
Elective	24	36
Surgical site infection	7	11
Palpable hardware	6	9
Broken implant	1	2

Table 4: Distribution of patients according to time period of removal of hardware.

Time period (years)	Number	%
<1	5	7.5
>1	13	19.69
>2	22	33.33
3-5	13	19.69
>5	9	13.6
>10	3	4.54
>15	1	1.51

Table 5: The frequency of each implant type removed.

Implant	Number
Proximal humerus implants	3
Distal humerus plates	4
Lateral condyle of humerus screws	3
Proximal ulna TENS nail	2
Radius and ulna plates	6
Radius ulna TENS nail	3
Distal radius plate	8
Hip bipolar prosthesis	1
DHS plate	2
Distal femur plate	1
Proximal femur nail	6
IMIL or TENS nail of femur	7
Tibial IMIL nail	8
Proximal tibia plate	6
Ankle fracture plates	6

Table 6: The complications of removal.

Complication	Number	%
Incomplete implant removal	3	4.5
Failure to remove implant	1	1.5
Intraoperative fractures	0	0
Postoperative infections	0	0

Indications for implant removal

The primary indications for implant removal are summarized in Table 3.

Clinical outcomes

All patients except the 4 with incomplete or failed removals reported improvement in symptoms or psychological well-being following implant removal. Detailed functional outcome scores were not provided in the thesis. In summary, the results demonstrate that pain was the most common indication for implant removal, with the majority of removals occurring after 2 years from initial implantation. Complications were rare and patient satisfaction was generally high post-removal.

Timing of implant removal

The time interval between initial implant placement and removal varied widely, as shown in Table 4.

Figure 1: Preoperative clinical photo of an infected proximal tibial implant.

Figure 2: Preoperative X-ray of infected implant of proximal tibia.

Figure 3: Intraoperative clinical photo with draining pus.

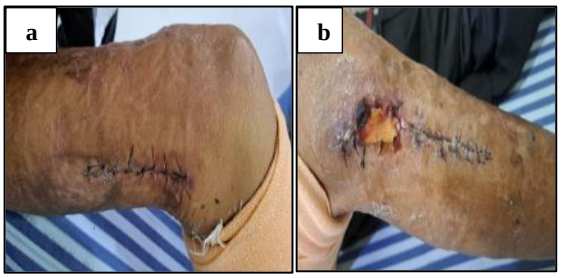

Figure 4: (a, b) After closure and skin grafting clinical image.

Figure 5: After complete healing of the infected site.

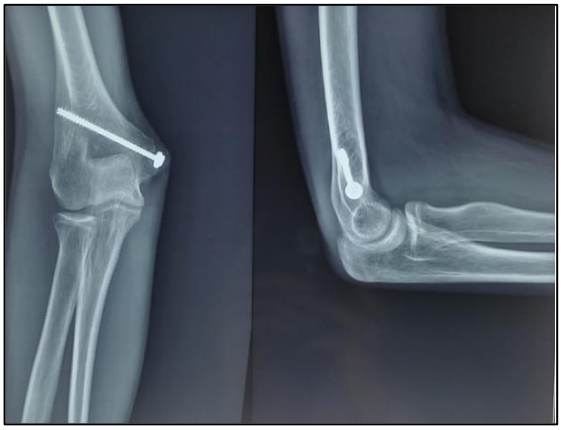

Figure 6: Before removing the implant due to impinging hardware of medial condyle fracture.

Frequency of implant removed

There were variety of implants removed in this study in both upper and lower limbs, as shown in Table 5.

Complications

Complications associated with implant removal were minimal, as listed in Table 6.

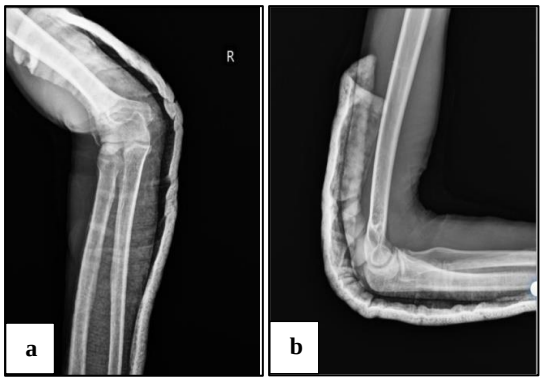

Figure 7 (a and b): After removing the implant from medial condyle.

Figure 8: Picture of the bent screw.

DISCUSSION

This prospective observational study provides valuable insights into the practice of orthopaedic implant removal in a tertiary care setting. Our findings highlight several key aspects of implant removal, including indications, timing and associated complications.

Indications for implant removal

Pain emerged as the primary indication for implant removal in our study, accounting for 42% of cases. This finding aligns with previous research by Haseeb et al and Mue et al, who reported pain and discomfort as leading reasons for hardware removal.[19,20]

Haseeb et al, found that pain was the indication in 15% of cases, while our study shows a higher percentage, possibly due to differences in patient population or clinical practices.

The high proportion of elective removals (36%) in our study suggests a proactive approach to implant management. This practice may be influenced by factors such as patient preference, surgeon experience, and institutional protocols. However, the necessity of routine implant removal remains a topic of debate in the orthopaedic community.[21]

Timing of implant removal

Our findings indicate that the majority of implants (33.33%) were removed after 2 years from the initial surgery. This timing aligns with recommendations in current literature, which suggest waiting for complete bone healing and remodeling before implant removal.[22] Vos and Verhofstad in their review emphasized the importance of timing in implant removal, particularly in relation to bone healing and potential complications.[22] The variation in removal timing, ranging from less than a year to over 15 years post-implantation, reflects the complex decision-making process involved in implant management. This wide range is consistent with observations by Reith et al, who noted significant variability in the timing of implant removal across different orthopaedic practices.[23]

Complications

The low complication rate observed in our study (4.5% incomplete removals and 1.5% failure to remove) is encouraging and compares favorably with rates reported in the literature. Sanderson et al, reported a complication rate of up to 20% in their series, significantly higher than our findings.[24] The absence of intraoperative fractures and postoperative infections in our cohort may be attributed to meticulous surgical technique and appropriate patient selection.

However, the challenges encountered in complete implant removal, particularly in cases of excessive bone overgrowth or implant integration, underscore the technical difficulties that can arise during these procedures. This emphasizes the need for careful preoperative planning and the potential benefit of advanced imaging techniques in complex cases, as suggested by Georgiadis et al.[25]

Patient demographics and implant types

The predominance of male patients (71%) in our study population likely reflects the higher incidence of traumatic injuries requiring internal fixation in this demographic, consistent with epidemiological data reported by Court-Brown and Caesar.[26] The nearly equal distribution between upper and lower limb implant removals suggests a balanced approach to hardware management across different anatomical sites.

The variety of implant types removed in our study, ranging from small screws to larger constructs like proximal femur nails, highlights the diverse challenges faced in implant

removal surgeries. The higher frequency of certain implants (e.g., proximal femur nails and tibial IMIL nails) may reflect regional patterns of fracture occurrence and treatment preferences.[27]

Clinical implications

The generally positive outcomes reported by patients following implant removal support the potential benefits of this procedure when appropriately indicated. However, the decision to remove asymptomatic implants should be approached cautiously, weighing the potential benefits against the risks of surgery, as emphasized by Busam et al.[28] The low complication rate observed in our study suggests that implant removal can be a safe procedure when performed by experienced surgeons in a well-equipped setting. Nevertheless, the technical challenges encountered in some cases highlight the importance of proper surgical planning and technique.

This study has several limitations. The single-center design may limit the generalizability of our findings to other settings. The relatively short follow-up period (6 months) may not capture long-term outcomes or complications. Additionally, the lack of a control group of patients with retained implants limits our ability to compare outcomes between removal and retention strategies. Future research should focus on long-term follow-up studies, randomized controlled trials comparing implant removal to retention, and the development of standardized protocols for decision-making in implant management. Investigation into patient-reported outcome measures, as suggested by Black, would provide valuable insights for clinical practice and healthcare policy.[29]

CONCLUSION

This prospective observational study provides valuable insights into the practice of orthopaedic implant removal in a tertiary care setting. Our findings highlight pain as the primary indication for removal (42% of cases), followed by elective removal (36%), with most implants removed after 2 years post-implantation. The low complication rate, with only 4.5% incomplete removals and 1.5% failure to remove, suggests that implant removal can be a safe procedure when performed by experienced surgeons.

These results support a selective approach to implant removal, based on careful consideration of patient symptoms, implant characteristics, and potential risks and benefits. While generally safe and effective, implant removal should be approached as a significant surgical intervention, requiring thorough preoperative planning and skilled execution.

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