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Original Research Article

TO STUDY THE INDICATIONS AND OUTCOMES ASSOCIATED WITH THE REMOVAL OF IMPLANTS IN ORTHOPAEDIC SURGERIES

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Abstract

Background: The field of fracture fixation has witnessed significant advancements and improvements due to the utilization of novel and tailored metal implants specifically designed for different types of fractures. Following the occurrence of the union, the removal of an implant may or may not be necessary, contingent upon the specific characteristics of the implant in question. The removal of implants is a widely practiced surgical procedure that is performed frequently on a global scale. There is a divergence of opinions among surgeons regarding the recommendation for routine removal. However, certain patients may necessitate the extraction of implants due to a range of complications associated with the implants. The topic of removing implants following the healing of fractures has long been a subject of debate and is often linked to the occurrence of complications. This study aims to prospectively examine the indications and outcomes associated with the removal of implants in orthopaedic surgeries. **Materials and Methods:** A total of 50 patients who underwent implant removal were included during this period. During the admission process, patients were provided with a comprehensive explanation regarding the potential risks associated with the surgical procedure, as well as the likelihood of unfavorable outcomes. Following admission, a series of routine inpatient investigations were conducted on all patients in order to assess their suitability for surgical procedures. The removal of the implant was subsequently performed during the subsequent operating theater session. **Result:** The indications for implant removals, including Pain (36%), Recommendation (28%), Personal (4%), Hardware Prominence (18%), Infection (4%), and Others (10%). Prior to the removal of implants, it was observed that 30% of patients reported no pain, 40% experienced mild pain, 20% reported moderate pain, and 10% reported severe pain. Following the removal of implants, it was observed that 60% of patients reported the absence of pain, while 26% experienced mild pain, 10% reported moderate pain, and 4% reported severe pain. **Conclusion:** The study revealed that pain and doctor recommendation emerged as the prevailing indications. The subsequent most prevalent factor is the prominence of hardware, followed by additional indicators such as implant failure, infection, and the patient's volition.

INTRODUCTION

The surgical extraction of hardware used for internal fixation of fractured bones is a commonly conducted orthopaedic procedure in Western societies. The topic of removing orthopaedic implants following the healing of a fracture has consistently been a subject of interest. This is primarily due to the continuous advancements in the field of biomechanics of internal fixation, which have led to the development of more advanced and effective fixation devices. Additionally, the criteria for determining when to remove these implants has not been adequately documented. There exists a continuous discourse surrounding the rationale behind the elective removal of surgical implants. The necessity for hardware removal is widely accepted in patients who exhibit surgical site infection, metal allergy, compromised soft tissue, or failure of the osteosynthesis.[1-3] Nevertheless, the efficacy of relative indications, such as the intended enhancement of functionality, alleviation of foreign body or pain sensation, spatial constraints for future surgical interventions, or simply the patient's preference for hardware removal, has not been adequately substantiated. A survey conducted by Hanson in 2008 examined the

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perspectives of 730 participants who attended the AO Principles and Masters Courses of Operative Fracture Treatment in Davos, Switzerland. Out of the 655 surgeons surveyed, 380 (58%) expressed disagreement with the notion that routine implant removal is essential, while 48% believed that leaving the implant in place posed fewer risks compared to removal. This phenomenon is likely to have been primarily influenced by a multitude of complications that may arise during and following the removal of a surgical implant. Frequently encountered complications subsequent to the removal of hardware include the occurrence of infections, compromised wound healing, instances of refractures, as well as tissue and nerve damage, along with post-operative bleeding or incomplete removal. There exists evidence suggesting a correlation between the localization of the implanted material and the rate of postoperative complications. Nevertheless, it is important to note that there are substantial inter-individual variations, and it is worth mentioning that the existing published literature exhibits a lack of uniformity.[4-7] As a result, it is currently not possible to establish overarching recommendations. In addition to the aforementioned medical concerns, it is imperative to consider the socioeconomic ramifications. The process of hardware removal incurs significant costs for both healthcare institutions and healthcare resources. In addition to this, it is important to consider the patients' demands, which stem from their individual perceptions and fears regarding the presence of the "foreign device" within their body. However, it is important to note that routine implant removal following fracture union remains a common practice in pediatric patients. Implants have the potential to disrupt normal bodily function, and certain theoretical long-term risks, such as growth disturbance, foreign body reaction, chronic infection, and corrosion, are often cited as reasons for their removal. Nevertheless, it is imperative that the advantages of a certain procedure surpass any potential drawbacks, and the act of extracting should not necessitate a more complex surgical procedure than the act of implanting.[8]

MATERIALS AND METHODS

The current investigation was conducted within the orthopedic department. A total of 50 patients who underwent implant removal were included during this period. The researchers obtained ethical approval from the institutional committee prior to conducting the study. The study included adult patients aged 18 years or older who sought medical care in the outpatient department (OPD) due to hardware-related issues that required removal. The study did not include patients who were initially treated with fixation devices, such as percutaneous K-wires, external fixators, and tarsal screws, that were intended to be removed after a specific period of time. The study excluded patients who necessitated the removal of joint prostheses. During the admission process, patients were provided with a comprehensive explanation regarding the potential risks associated with the surgical procedure, as well as the likelihood of unfavorable outcomes. Following admission, a series of routine inpatient investigations were conducted on all patients in order to assess their suitability for surgical procedures. The removal of the implant was subsequently performed during the subsequent operating theater session. Prophylactic antibiotics were administered to all patients, and tourniquets were utilized whenever feasible. Following the surgical procedure, the patients were kept in the hospital for varying durations, which were determined based on the criteria for removal and the state of the wound. In patients with infected hardware, the administration of antibiotics was extended for a prolonged period. Upon discharge, patients were provided with explicit instructions to exercise caution and protect the affected limb for a duration determined by the specific characteristics of the bone and implant that were removed. The participants were monitored in the outpatient department (OPD) for an additional four-month period, during which their symptoms were assessed for relief, persistence, and the emergence of any new issues. Data pertaining to these evaluations were subsequently gathered.

The researcher recorded basic demographic details such as the individual's name, age, gender, occupation, and residential address. The medical history of the patient, including past illnesses and family medical history, was also documented. The overall health status of the patients was assessed by evaluating indicators such as pallor, pulse rate, and blood pressure. The respiratory and cardiovascular systems were assessed for the presence of any abnormalities.

The examination of the distal neurovascular status of the upper limb in question was conducted. A standard investigation was conducted, encompassing various parameters such as hemoglobin levels, total blood cell count, differential blood cell count, erythrocyte sedimentation rate, blood urea levels, blood sugar levels, serum creatinine levels, and electrocardiogram analysis. Prior to the surgical procedure, all patients underwent testing for HBsAg and HIV.

Statistical Analysis

We conducted data analysis, using SPSS 25.0 software. They employed t-test methodology and compiled the resulting outcomes.

RESULTS

A total of 50 participants were enrolled in the present study. Out of the total sample size of 50 patients, 30 individuals were identified as males, accounting for 60% of the population, while the remaining 20 individuals were identified as females, constituting 40% of the population. The average age of the

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patients was 37.58±3.69 years. The rationales behind the removal of implants were identified as falling within five distinct categories: pain, conspicuous hardware, infected hardware, recommendations from medical professionals, patient's insistence, and miscellaneous factors.

The implants that exhibited the highest frequency of responsibility were Nail 10 (20%), with Forearm Plate 8 (16%) following closely behind. Other notable contributors included Humerus Plate 6 (12%), Femur Nail 6 (12%), Clavicle Plate 5 (10%), Femur Plate 5 (10%), Tibia and Tibia Plate 4 (8%), Olecronon TBW 3 (6%), and Patella TBW 3 (6%). [Table 1]

[Table 2] presents the indications for implant removals, including Pain (36%), Recommendation (28%), Personal (4%), Hardware Prominence (18%), Infection (4%), and Others (10%).

[Table 3] presents the occurrence of complications subsequent to implant removal, including nerve injury observed in 12 cases (24%), infection in 16 cases (32%), incomplete removal in 16 cases (32%), and other complications in 6 cases (12%).

Prior to the removal of implants, it was observed that 30% of patients reported no pain, 40% experienced mild pain, 20% reported moderate pain, and 10% reported severe pain. Following the removal of implants, it was observed that 60% of patients reported the absence of pain, while 26% experienced mild pain, 10% reported moderate pain, and 4% reported severe pain. [Table 4]

Prior to the surgical procedure, a lack of impairment was observed in 60% of cases, while following the surgery, this figure decreased to 42%. Before and after surgery, there were respective percentages of 28% and 6% for mild impairment, 8% and 6% for moderate impairment, and 4% and 4% for severe impairment. [Table 5]

Table 1: Distribution of Patients

	Number	**Percentage**
Humerus Plate	6	12
Olecronon TBW	3	6
Forearm Plate	8	16
Clavicle Plate	5	10
Femur Nail	6	12
Femur Plate	5	10
Patella TBW	3	6
Tibia Nail	10	20
Tibia Plate	4	8

Table 2: Indications for hardware removal

Indication	**Number**	**Percentage**
Pain	18	36
Recommendation	14	28
Personal	2	4
Hardware Prominence	9	18
Infection	2	4
Others	5	10

Table 3: Complication after implant removal

Complication	**Number**	**Percentage**
Nerve Injury	12	24
Infection	16	32
Incomplete removal	16	32
Others	6	12

Table 4: Pain status before and after the removal

	Pain	
	Before implant removal	**After implant removal**
No Pain	15	30
Mild Pain	20	13
Moderate Pain	10	5
Severe Pain	5	2

Table 5: Functional status before and after the removal

	Function	
	Before Surgery	**After Surgery**
No Impairment	30	42
Mild Impairment	14	3
Moderate Impairment	4	3
Severe Impairment	2	2

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DISCUSSION

The topic of removing metallic implants utilized in fracture fixation has been extensively debated and thoroughly examined. The prevailing viewpoint likely remains that the routine removal of implants should not be deemed necessary.[9] While the AO-Association for the Study of Internal Fixation has provided recommendations regarding the optimal timing for hardware removal in recent fractures that have healed without complications, there is a lack of well-established clinical indications for the removal of implants. Furthermore, there is a scarcity of definitive data to inform the appropriateness of routine implant removal. In addition, it is important to note that surgical procedures involving implant removal carry inherent risks such as the potential for fracture, neurovascular damage, and infection. Over the course of time, several arguments have been put forth to support the removal of hardware following fracture union. These arguments include concerns related to metal allergy, corrosion, carcinogenesis, and metal ion toxicity. However, it is important to note that no definitive evidence has been presented to substantiate these claims. There is a dearth of comprehensive studies examining the removal of implants in symptomatic patients, despite a substantial number of patients undergoing implant removal for various reasons. The objective of our study was to systematically document the prevalent indications for the removal of internal fixation devices and the associated complications. It is important to note that while these indications and complications are already familiar to most specialists, our aim was to provide a comprehensive academic analysis. To the best of our knowledge, this survey represents the initial attempt to evaluate the individual experiences of patients with respect to the removal of surgical implants. All patients who expressed a personal desire to have the implant removed would consistently reaffirm their decision, even in cases where they experienced perceived complications. The obtained results appear to be in opposition to our initial hypothesis. There are several limitations that need to be taken into account with respect to this study. The retrospective and non-randomized approach used to select patients for this study may introduce bias, as it was not possible to include all patients who underwent surgical hardware removal during the specified time frame. With regards to the response rate, studies that were designed similarly achieved comparable response rates.[10,11] Specifically, the findings pertaining to the motivations behind the surgical procedure and the subsequent levels of subjective satisfaction may exhibit inherent biases. This assertion is applicable to the concept of a "doctor's recommendation" as well. The specific details of this questionnaire item were not provided. Based on our personal clinical experience within the German medical system, it is observed that a significant number of patients seek implant removal due to recommendations from their general practitioners or orthopaedic out-patient specialists who lack surgical capabilities. However, these recommendations are often provided without additional explanation or elaboration. Moreover, the potential influence of a placebo effect cannot definitively be ruled out due to the absence of a control group. Ultimately, our observations rely solely on subjective patient information, including the type and severity of complications, as well as pain and function, as assessed through a non-validated questionnaire. Hence, it is imperative to exercise caution when comparing our findings, as they can only be effectively juxtaposed with more objective investigations that rely on physical examinations, standardized outcome measures, or specific scientific scoring systems. However, the study design was intentionally selected in order to primarily evaluate the individual and subjective perception of the patients who were affected. Orthopaedic implants have the potential to remain permanently within the body due to their specific design and composition. The significance of patients' consent and request for implant removal is paramount due to the aforementioned rationale and the frequent discretionary nature of the intervention. To conduct a comprehensive analysis, it is imperative to consider the subjective perspectives of the patients included in the study. Their personal impressions play a crucial role in evaluating their quality of life and level of satisfaction following surgical intervention. From our perspective, it can be argued that patient satisfaction and patients' perception of treatment success are crucial objectives for achieving success in a surgical practice. The most prevalent cause for removal of implants in our study was implant-associated pain or discomfort, accounting for 36% of cases. According to the study conducted by Brown et al., it was observed that 31% of patients who underwent open reduction and internal fixation for ankle fractures experienced persistent lateral pain.[12] Additionally, it was discovered that a mere 50% of the patients (11 out of 22) who underwent hardware removal experienced a reduction in pain. In a prospective study conducted by Minkowitz et al., a cohort of 60 patients who underwent implant removal due to hardware pain were examined. Upon a one-year follow-up, it was observed that all patients expressed satisfaction with the outcome.[13] The subsequent most prevalent indication observed in our series was a recommendation from a medical professional, accounting for 28% of cases. This was followed by the indication of hardware prominence, which accounted for 18% of cases. Additionally, two patients presented with infection, representing 4% of the total cases. Trampuz and Widmer (year) estimated that approximately 5% of internal fixation devices experience infection. The authors also emphasized the significance of biofilms in the development of resistance among pathogens against antibiotics administered systemically. All of the infections observed in our study that necessitated

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removal did not occur during the "early" period, defined as within 2 weeks of the index procedure. There was only one instance of a delayed infection, occurring after a period of 6 months. This particular case involved an individual with a tibial plate, who experienced skin necrosis and subsequently required the removal of the plate 2 years post-surgery. The remaining infections were classified as "late" infections, resulting from the continuous dissemination of microorganisms through the bloodstream to the implant site, originating from various sources such as skin, respiratory, dental, and urogenital infections. The occurrence of infection subsequent to internal fixation is correlated with a significant rise in both morbidity and cost. The frequency of infections is expected to increase due to the escalating number of surgical procedures being conducted and the subsequent rise in life expectancy, resulting in extended periods during which bacterial implantation in the body can occur. Trampuz and Widmer (year) have recommended that, when feasible, it is advisable to discontinue the administration of antibiotics at least two weeks prior to the surgical removal procedure. This practice aims to ensure the acquisition of a precise intraoperative tissue culture.[14] Additionally, they proposed the utilization of sonication in saline solution to dislodge microorganisms from the surface of the extracted implant. The resulting sonicated fluid would then be subjected to microbiologic examination. In a study conducted by Kukla et al., an analysis of implants extracted from the proximal femur, specifically dynamic hip screws and Gamma Nails, revealed that the prevailing indications for removal were avascular necrosis of the femoral head, deep chronic infections, shaft fractures, and screw cut-out.[15] The extraction of implants is a substantial component of elective orthopedic surgical procedures. Numerous studies have been conducted to investigate the indications for the removal of metalwork in patients who do not exhibit any symptoms. While the majority of authors concur that routine removal should be avoided, there is a consensus regarding the necessity for the establishment of explicit indication guidelines pertaining to implant removal. Simultaneously, there is a scarcity of scholarly literature that evaluates the comparative prevalence of the conventional indications for implant removal, specifically in patients experiencing symptoms. The present study aimed to address this research gap. It is our contention that the practice of routine removal in asymptomatic patients should be avoided, and if deemed necessary, the removal procedure should not exceed the complexity of the initial operation. It is also concurred that the surgical procedure of implant removal carries inherent risks, such as fractures, bleeding, nerve impairments, and infection. Consequently, it is imperative to thoroughly apprise the patient of the potential occurrence of these complications prior to undertaking the surgery. In addition to potential novel complications, the surgical procedure for removal may not fully achieve its intended objectives, such as complete alleviation of pain, resolution of infection, and potential necessity for subsequent surgical interventions. It is imperative to consider all of these factors prior to initiating such a process with optimistic expectations of achieving success.

The present study is constrained by a limited sample size and a relatively brief duration of follow-up. Additionally, the vast majority of implants that were extracted in our study were domestically manufactured stainless steel implants. There is a potential for bias towards titanium implants in our study, which may be attributed to the financial constraints faced by the patients served by our institution. Further research is required to generate comprehensive literature on the patterns of removal surgeries in symptomatic implants, necessitating studies with larger sample sizes and broader study parameters.

CONCLUSION

The study revealed that pain and doctor recommendation emerged as the prevailing indications. The subsequent most prevalent factor is the prominence of hardware, followed by additional indicators such as implant failure, infection, and the patient's volition. There is a higher likelihood of males experiencing symptoms that necessitate the removal of hardware. Additional options for treatment include the utilization of substantial implants placed over the olecranon and intramedullary nails inserted into the femur. The removal procedure should be executed with caution to ensure safety, as there exists a small yet distinct likelihood of complications. The removal of an implant can be challenging due to various factors, such as bone ingrowth, implant wear, and the extended duration since the initial surgery. Potential complications such as nerve and vascular damage as well as fractures may arise during operative procedures. The extraction of implants has the potential to alleviate pain, improve range of motion and functionality, ultimately leading to an enhanced level of patient satisfaction.

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