Original Research Article

Prospective Study of Indications and Outcomes of Implant Removal in Orthopaedic Surgeries

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Abstract

Background: Fracture fixation has become improved with the advancements and usage of new and custom metal implants for each type of fracture. Once the union has occured, implant may or may not be removed depending on the implant. Implant removal are among the most commonly performed surgical techniques worldwide. Routine removal is suggested by some surgeons and opposed by others. Nevertheless, some patients require removal of the implants because of various implant related problems. The removal of implants after fracture healing has always been a controversial issue and are associated with complications. Aims of this study was to identify the most common causes for implant removal and complications associated with that.**Methods:**The present study was carried out from November 2018 to October 2020 at Rajarajeshwari medical college and Hospital. During this period 66 patients underwent implant removal. All patients were operated before for the upper and lower limb fractures. Regular follow up was done periodically for 4 months to evaluate x-rays and functional outcome with questionarie which were developed by Department of Trauma and Orthopaedic Surgery, Cologne Merheim Medical Center, Witten/Herdecke University, Cologne, Germany. Helios Medical Center Wuppertal, ZBAF, Center for Biomedical Education and Research, Witten/Herdecke University, Witten, Germany.**Results:**A total of 60 patients were studied. 38 of them were male and 22 were females. The mean age was 38 years. The reasons for removal of implants were found to lie in following categories: Pain, doctor recommendation, prominent hardware, infected hardware, elective (patient's insistence), and other reasons (implant failure). Overall, the most frequently removed implants in our series were tibialnail (19.69% of implants removed), forearm plate (16.66%). 60 out of 66 patients that is 90.90 % were responding patients and 16.66 % of the patients who suffered from subsequent complications. After implant removal because of pain or impaired function (77.55 %) of the patient reported decreased pain, (69.23 %) of patients reported improvement in function as well as. **Conclusion:**The clinical indications for the implant removal are not well defined, and few definitive data exist to guide whether the routine implant removal is appropriate. Symptomatic implant frequently needs removal. We have found that pain and implant prominence (mechanical symptoms) are the most common indications. Infection is the next most common, followed by hardware failure. Removal of the implant is also challenging and frequently troublesome nature of surgical hardware removal and wear of the implant may make its removal difficult.

Keywords: Implant removal, implant, infected, symptomatic,Hardware removal, Complication, Patient satisfaction

Introduction

Surgical removal of hardware for internal fixation of fractured bones is one of the most frequently performed orthopaedic surgeries in the western world[1]. The removal of orthopaedic implants after fracture has healed has always been a topical issue, firstly because the science of biomechanics of internal fixation is highly dynamic with development of newer and better fixation devices[2] and secondly because the criteria for removal has never been clearly documented[3-5]. There is an ongoing debate concerning the justification of elective surgical implant removal[6-8].Certainly, the indication for hardware removal is unquestioned in patients with surgical site infection, metal allergy, soft tissue compromise or failure of the osteosynthesis . However, the benefits of relative indications such as intended improvement of function, foreign body or pain sensation, spatial limitation for future surgical procedures or plainly the patient's desire for hardware removal have not yet sufficiently been proven. In a study by Hanson in 2008 which surveyed 730 attendees of the AO Principles and Masters Courses of

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Operative Fracture Treatment in Davos, Switzerland,380 of 655 surgeons (58 %) did not agree that routine implant removal is necessary and 48 % felt that removal is riskier than leaving the implant in situ[9].This probably was mainly influenced by numerous complications which can occur during and after operative implant removal.Commonly observed complications after hardware removal are infections, impaired wound healing, refractures, tissue and nerve damage and post-operative bleeding or an incomplete removal. There is some evidence indicating that the postoperative complication rate depends on the specific localization of the implanted material. However, inter-individual differences are significant and published data still lacks consistency[10-15]. Therefore general recommendations cannot yet be established. Besides the above mentioned medical issues, the socioeconomic impact must be taken into consideration.Hardware removal is cost consuming for both hospitals and health care resources . Add to this the patients' demands owing to their own perceptions and fears about the "foreign device" inside their body. In children, though, routine implant removal after fracture union is still standard procedure. Implants may disturb function, and some theoretical long-term risks such as growth disturbance, foreign body reaction, chronic infection, and corrosion are used as arguments for removal. However, benefits should outweigh risks and removal should not require a more extensive operation than insertion[16]

Aims and Objectives

The aim of this study was to identify the most common causes for implant removal and complications associated and the functional outcome after the implant removal with that in Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India.

Study Duration

November 2018 to October 2020 in Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India.

Materials & Methods

The present study was carried in out from November 2018 to October 2020 in Rajarajeswari Medical College and Hospital, Bengaluru, Karnataka, India. During this period 66 patients underwent implant removal. Prior ethical approval from the institutional committee was sought. Adult patients aged 18 years or more who presented in the outpatient department (OPD) with hardware related problems that necessitated removal was admitted. Patients admitted over a period of 7-month starting November 2018 were included in the study. Patients who had fixation devices intended to be removed after a definite interval to begin with, like percutaneous K-wires, external fixators and tarsal screws, were not included in the study. Patients requiring removal of joint prostheses were also excluded from the study. At the time of admission, the potential risks of the operation and the possibility of non-favorable outcomes were explained to all patients. After admission, routine inpatient investigations were performed on all patients to evaluate their fitness for surgery. Implant removal was then done in the next OT list. All patients received prophylactic antibiotics and tourniquet was used wherever possible. Postoperatively, the patients were retained in the hospital for variable periods depending on the indication of removal and the condition of the wound. Antibiotics were continued for longer duration in patients with infected hardware. At discharge, all the patients were strictly advised to protect the extremity for a variable length of time as demanded by the bone and the implant removed. They were followed in the OPD for another 4 months and evaluated for symptom relief/ persistence/ new problems, and the data were collected. The data were analyzed by the authors and also by statistician using SPSS software and applying *t*-test, and results were compiled.

Inclusion criteria:

1. Age >18years
2. No medical contradictions to Anaesthesia

Exclusion criteria:

1. Age < 18 years
2. Patients who had fixation devices intended to be removed after a definite interval to begin with, like percutaneous K-wires, external fixators and tarsal screws.
3. Patients requiring removal of joint prostheses were also excluded from the study.

General information like name, age, sex, occupation and address were noted. Past medical illness and family history were also recorded. General condition of the patients was examined for pallor, pulse rate and blood pressure. Respiratory and cardio vascular system were examined for any abnormalities.

The distal neurovascular status of the affected upper limb was examined Routine investigation like Hb%, Total count, Differential count, ESR, Blood urea, Sugar, Serum creatinine and ECG were done. HBsAg and HIV test were done before surgery on all patients

Statistical Analysis

Data was entered into Microsoft excel data sheet and was analysed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions.

Continuous data was represented as mean and standard deviation.

Results

Sixty six patients fulfilled the inclusion criteria, but six patients did not return for follow-up. That left us with sixty patients on whom to conduct the study (n = 60).

Thirty eight patients were males (63.33%) and twenty two were females (36.66%). Their ages ranged from 20 years to 65 years, and the mean age was 38 years. The reasons for removal of implants were found to lie in five categories: Pain, prominent hardware, infected hardware, Doctor recommendation, patient's insistence, and other reasons.

Twenty two patients out of sixty had hardware pain or discomfort (36.66%).The time since fracture fixation ranged from 4 months to 96 months (average 38 months). The implants most commonly responsible in order of frequency were femur nail (n=5), tibial nail(n=4), clavicle plate (n=2). Eleven patient had hardware prominence (18.33) patella tension band wiring (TBW) (n = 4), olecranon TBW/plates (n = 3), and clavicle (n = 3). The mean duration of hospital stay in these patients was 5 days. At 4 months follow-up, 38 patients out of 49 reported relief of pain compared to before (77.55%). 38 patients out of 49 reported relief of pain compared to before (77.55%). 69.23% had pain relief compared to before surgery. No patient developed infection. One had an radial nerve palsy postoperatively, which recovered after 2months and another patient had common peronial nerve palsy recovered after 3 months.

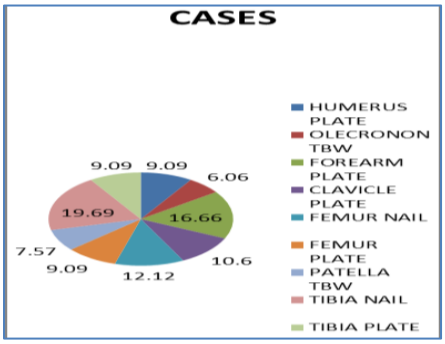

Fig 1:Distribution of cases

Two patients out of 66 (3.33%) needed hardware removal because they had developed infection at the implant site a variable duration after osteosynthesis. Their mean age was 38.5 years, and the duration since first surgery varied from 16 months and 18 months. Union was present in 1 patient at the time of implant removal. One ununited fracture was managed with external fixator;. In this group, the implants removed were proximal tibial plate (n = 1), and distal tibial/ankle plates (n = 1) . After the removal, infection subsided in one patient. One patients developed chronic osteomyelitis with persistent discharge.

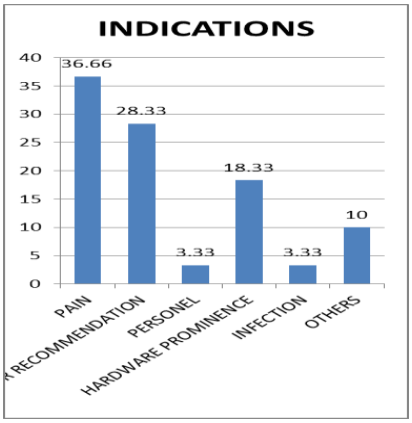

Fig 2:Indications for hardware removal

Six (10%) patients required implant removal and revision osteosynthesis for implant failure. Their average age was 35 years (18-50 years), and the average time since the primary procedure was 7.6 months (2-12 months). These included 3 femoral IM nails, 2 distal tibial nails, 1 ulna plate.

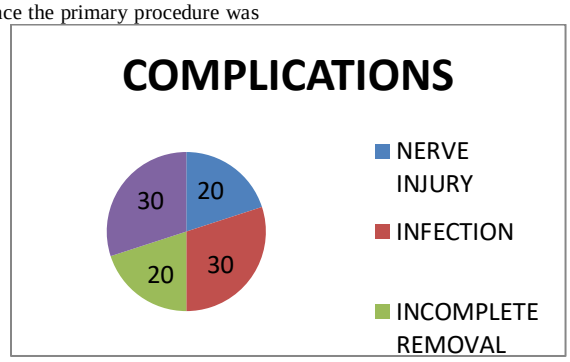

Fig 3:Complications after implant removal

Personnel (3.33%) patients had their implants removed on demand, despite being asymptomatic. During the course of their follow-up,that did not have any complications.

Altogether 77.55% of the patients reported a subjective improvement of pain compared to before surgey. The patients described an improved function after the operation that is 69.23 % compared to before.An overview on pain and functional status before and after the removal is given in **Figs.**

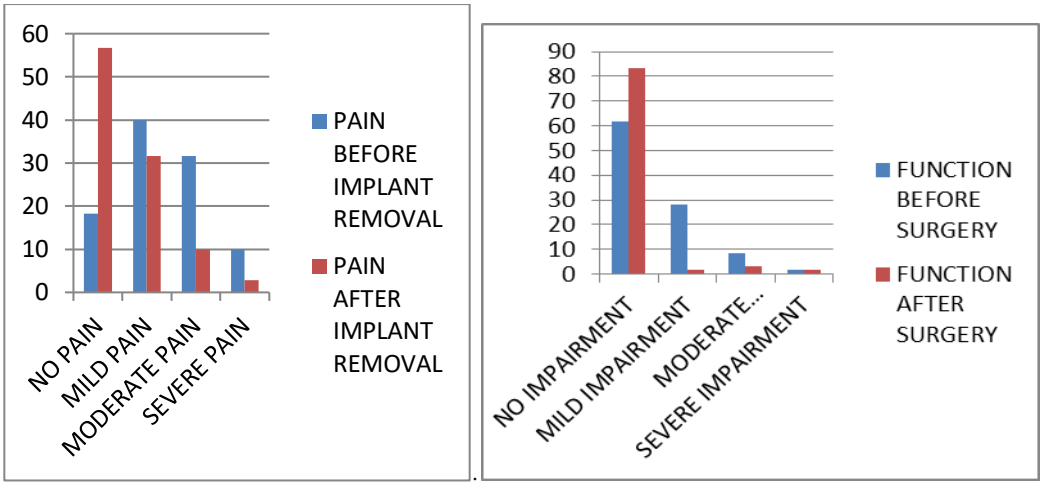

Fig 4:overview on pain and functional status before and after the removal

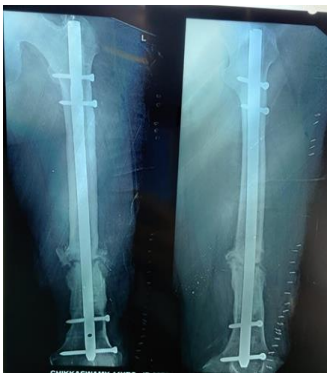

Fig 5:Non union of femur with implant insitu

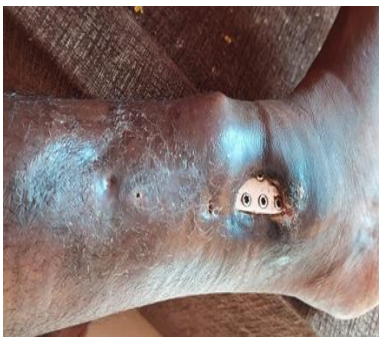

Fig 6: Exposed distal tibia implant with infection

Fig 7:Superficial infection of proximal and anterior aspect of leg with implant insitu

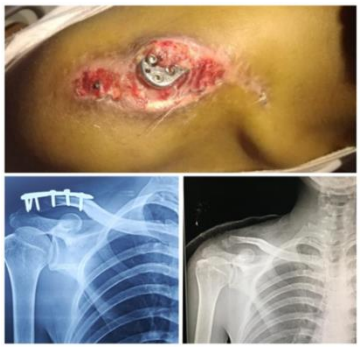

Fig 8:Exposed clavicular plate

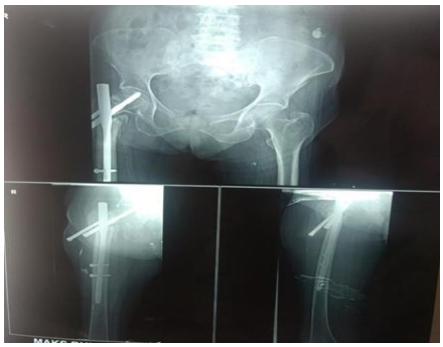

Fig 9:Infected non union with implant failure

Discussion

The issue of removing metallic implants used in fracture fixation has been often discussed, and at length. Popular opinion probably still is that implant removal should not be considered a routine procedure[7,9,17]Although the AO-Association for the Study of Internal Fixation has published recommendations on the timing of hardware removal in recent fractures with uncomplicated healing , the clinical indications for implant removal are not well established, and few definitive data exist to guide whether routine implant removal is appropriate. Furthermore, the surgical procedures for implant removal are fraught with risks of fracture, neurovascular injury, and infection. Various arguments have been made from time to time to justify removal of hardware after fracture union, e.g., metal allergy, corrosion, carcinogenesis and metal ion toxicity, but for none has concrete proof been produced. Large studies on implant removal in symptomatic patients are lacking, though many patients get their implants removed for one reason or another. Our aim was to document the common indications for removal of internal fixation devices and associated complications, even as most specialists are already well versed with them.To our knowledge this is the first survey assessing the patients' individual experiences regarding surgical implant removal. Principle findings of this study were, firstly, that 10 % of the 332 responding patients who underwent orthopedic implant removal perceived complications occurred during or after the procedure with the most common complication being impaired wound healing. Secondly, when the indication for hardware removals was pain or limited function, patients reported a subjective improvement in 95 % and 72 % respectively. Thirdly, overall 96 % of all patients and even 66 % of the patients with peri- or postoperative complications would opt for the operation again. All of the patients who personally wished to have the implant removed would come to the same decision all over again even if they perceived having suffered complications. These results seem to contradict our initial hypothesis. Several limitations must be considered regarding this study. The retrospective, open nature of the selection of the patients might result in bias, mainly, because not all of the patients who had surgical hardware removed in the observed time period were accessible for inclusion into this study. Concerning the response rate, similarly designed studies reached similar response rates. [18,19] Particularly, results on reasons for the operation and the subjective satisfaction after the operation could be biased. This also holds true for "doctor's recommendation". This questionnaire item was not specified further; in our personal clinical experience as a specification of the German medical system, many patients present for implant removal because their general practitioner or orthopaedic out-patient specialist without surgical capacity recommended to get the implants removed without further elaboration. Furthermore, the contribution of a placebo effect cannot ultimately be excluded, because of the lack of a control group. Finally, our observations are based on pure subjective patient information, even for type and severity of complications, for pain and function in a non-validated questionnaire. Therefore our results may only carefully be compared to more objective studies based on physical examination and standardized outcome measures or specific scientific scores. However, we deliberately chose this study design as the principle goal of this study was to assess the individual and subjective impression of the affected patients themselves. Due to their design and make orthopaedic implants may permanently remain inside the body. Out of this reason and the often elective nature of the intervention,patients' consent and request for the implant removal is central to the entire procedure. In order to analyzethis,the personal impressions of the included patients themselves is what first and foremost can contribute to the assessment of the patients' quality of life and level of satisfaction after undergoing surgery. And thereby, from our point of view, patient satisfaction and patients' perception of the success of the treatment are among the most important goals for a successful surgical practice.In our study, implant associated pain or discomfort was the most common reason necessitating removal (36.66%). Brown *et al.* found that 31% patient sunder going open reduction and internal fixation of ankle fractures had persistent lateral pain[20].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[21]The next most common indication in our series was doctor recommendation (about 28.33%), followed by that the indication was the hardware prominence (18.33%), 2 patients had infection(3.33%). Trampuz and Widmer estimated that overall about 5% of all internal fixation devices become infected[22]. They also impressed the role of biofilms in the resistance of pathogens to systemically administered antibiotics. None of the infections in our study requiring removal was "early," i.e., within 2 weeks of index procedure. Only one was a delayed infection (after 6 months), a with an tibial plate who developed skin necrosis and the plate had to be removed 3 years after surgery. All the others were "late" infections, caused by constant hematogenous seeding of the implant from skin, respiratory, dental and urogenital infections. Infection after internal fixation is associated with greatly increased morbidity and cost. The incidence of infections is likely to rise as more operations are performed by the day, and longevity increases translating into greater periods of possible bacterial implant seeding in the body. Trampuz and Widmer recommended stoppage of any antibiotics 2 weeks before the removal surgery, if possible, to get an accurate intraoperative tissue culture. They also suggested that the removed implant be sonicated in saline to dislodge microorganisms from its surface and the resultant sonicated fluid be sent for microbiologic examination. Kukla *et al*. in a study of implants removed from the proximal femur (dynamic hip screw and Gamma Nails) found that the most common indications were avascular necrosis of the femoral head, deep chronic infections, shaft fractures, and screw cut-out[23]

Implant removal operations constitute a significant portion of elective orthopedic surgeries. Several studies have been carried out

on the indications of removal of metalwork in asymptomatic patients. Although most authors agree that routine removal should not be practiced, they also agree that there is a need for the development of concrete indication guidelines for implant removal. At the same time, there is a paucity of literature assessing the relative frequency of the "usual" indications of implant removal, *viz*., in symptomatic patients. Our study was an attempt at filling this gap. We believe that routine removal in asymptomatic patients should not be practiced, and if at all necessary, the removal should not require a larger procedure than the index operation. We also agree that implant removal surgeries are fraught with risks, including fractures, bleeding, nerve injuries and infection, and should be done only after explaining to the patient the possibility of all these complications. In addition to the possible new problems, the removal surgery may not entirely fulfill the intended purpose, e.g., the pain may not completely go away, infection may not resolve, and additional surgeries may be required. All these factors must be borne in mind before embarking on such a process with high hopes of success.

Our study is limited by a small sample size and a short follow-up period. Furthermore, almost all implants removed in our series were local made stainless steel. This may falsely favor titanium implants, although the probable reason for this is the low affordability of patients catered to by our center. More studies with greater number of cases and wider study dimensions are needed to produce concrete literature on the patterns of removal surgeries in symptomatic implants.

Conclusion

The symptomatic implant or the hardware frequently needs removal. We found that pain and doctor recommendation are the most common indications. Hardware prominence is the next most common, followed by other indications are implant failure, infection and patient's will. Males are more likely to develop symptoms requiring removal of hardware. Others include heavy implants over the olecranon and femoral IM nails. Carefully done, the removal should be a safe procedure, and there is a low but definite possibility of complications. Several factors like bone ingrowth and wear of the implant and long time from the primary surgery may make its removal difficult. Operative complications like nerve and vessel injury and fracture may occur. The symptoms too may not completely disappear the following removal. In this study, we report a surprisingly high rate of satisfied patients after surgical hardware removal. This may lead to the conclusion that implants should be removed by default. However, postoperative complications occurred at a rate of 17 %. Hence, for the sake of both patients' safety and quality of life, the indication for hardware removal still has to be assessed with scrutiny. Nevertheless, removal of implants might relief pain, increase range of motion and function and thus enhance the patient's satisfaction. The definite causality between psychological factors, satisfaction and physiological improvement needs further investigations.

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