

## ORIGINAL ARTICLE

# Incidence of Orthopedic Implant Removal, its Indications, and the Effect of the Covid-19 Pandemic

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## ABSTRACT

**Aims & Objective.** To assess the incidence and rate of implant removal among orthopedic patients, its indications, and the effect of COVID-19 pandemic.

**Material & Method:** A retrospective study was done during the period from October 2017 to October 2020 included all patients admitted for removal of orthopedic implants.

**Results:** One-hundred eleven patients with a mean age of  $28 \pm 10.9$  years were included in this study. Most (83.8%) were males. The incidence rate of removal was 20.2%. The mean period between implant fixation and removal was  $26 \pm 20$  months. Lower limb fractures constituted 85.6% of cases with about half of them as foot and ankle fractures. The most frequently presented fractures were femur and tibia (33.3% and 21.6%, respectively), while the most frequently removed implants were plate and screws (43.2%). Only 8.9% of surgeries were indicated for removal, and only 4.5% of all patients suffered post-removal complications.

**Conclusion:** Non indicated implant removal occurs at a significantly high rate in Saudi Arabia. No real indications for such a procedure were found in the majority of patients. COVID-19 control strategies caused a significant decrease in this high rate.

**Keywords:** COVID19; Orthopedics; Incidence Rate; Kingdom of Saudi Arabia; Bone Pins

## INTRODUCTION

The procedure for stabilizing bone and fractures among orthopedic trauma patients has been developed and improved surgically over recent decades<sup>1</sup>. Involvement of different metallic implants in internal fixation (intramedullary nail, plate, and screws) has been a cornerstone in the stabilization process and considered as a definitive management for many types of upper and lower limbs fractures<sup>1,2</sup>. However, the trend among the population, the rate of removal of these implants also has been encountered with an increased prevalence to be one of the frequently performed elective orthopedic surgeries<sup>3,5</sup>. The incidence of these procedures varies worldwide and constitute a significant portion of orthopedic procedures<sup>1,6</sup>. This rate is increasing without clear indications or established guidelines and is time-consuming and costly for surgeons and hospital facilities in addition to predisposing patients to significant and unnecessary operative related complications (bleeding, neurovascular injury, refracture) ranging from 3% up to 42%, which cost even more<sup>1-3,7-9</sup>. Literature supports the findings that absolute indications, such as infection, pain, surrounding soft tissue infection, and prominence of implants and hypersensitivity, mandate removal<sup>1,2</sup>. However, regarding other relative indications which are the most frequently reasons for removal of implants (patient request, occasional implant discomfort, military recruitment), no clear established guidelines can be found, and even most of authors do not recommend its removal<sup>1-3</sup>. Even among patients with painful implants, debates about the reason of pain with respect to whether the pain is caused by the implants or the fracture itself are ongoing since even after removal, a chance that the pain will not improve is still present<sup>3,10-11</sup>. This situation mandates careful evaluation of risks and potential complications in which benefits should outweigh potential damage and not to perform it as a routine surgery<sup>1,2,10,11</sup>. However, some studies report improvement in function and an increase in patient satisfaction after removal of their

implants<sup>2,8,12</sup>. Although most orthopedic surgeons do not advise elective removal of implants as there is lack of established guidelines and the high risk of complications to the patients<sup>1,2</sup>, the rate of elective removal is increasing but this finding needs further study and evaluation. On December 31, 2019, a novel coronavirus (COVID-19) was identified and has spread worldwide to become one of the largest pandemics, affecting more than 70,829,855 people with 1,605,091 deaths worldwide and 359,888 case with 6048 deaths in Saudi Arabia<sup>13</sup>. On March 1, 2020 the Saudi Ministry of Health reported the first confirmed case of COVID-19 and started the strategies and plans for COVID control, one of which was to stop all elective surgeries<sup>14</sup>. This study assessed the rate of elective orthopedic implant removal, its indications, and the effects of Covid-19 pandemic on the rate of this procedure.

## MATERIAL & METHOD

**Study Design:** A retrospective study designed to assess the incidence and rate of implants removal among orthopedic patients, as well to detect its indications, and the effects of COVID-19 pandemic, during the period from October 2017 to October 2020. Our hospital is a trauma center and one of two main public hospitals in the region with a 500-bed capacity. During the COVID-19 pandemic, it was the only hospital receiving patients, while the other hospital was locked and reserved for quarantining COVID-19 patients as mandated by the Saudi Ministry of Health. Inclusion criteria included several parameters: (1) Age 12–65 years, (2) both male and female, (3) patients admitted to the operating room during the period from October 2017 to October 2020 for implant removal, and (4) patients with all types of implants.

Exclusion criteria included several parameters: (1) Age < 12 years, (2) arthroplasty patients, (3) fixators that planned to be removed once healing achieved (K-wires, external fixators, syndesmotomic screw, elastic nail), and (4) files missing > 50% of the data.

**Data collection methods and procedure:** A total of 111 patients underwent elective implant removal during the period from October 2017 to October 2020. We accessed the patients' stored data in their files and hospital system. History, location of fracture, duration since fixation, type of implant removed, reason for removal, and any history of complications occurred were collected. Socio-demographic data (age, gender, nationality, marital status, chronic disease, occupation, and body mass index [BMI]) were also collected.

**Data Analysis:** Statistical analysis was done by using Statistical Package for the Social Sciences Program (SPSS 21). Descriptive analysis was done to detect the central tendency and dispersion of data (mean, mode, and standard deviation). Frequency and percentages were also calculated.

**RESULTS**

This study included 111 patients with a majority of male participants (83.8%), Saudi (82.9%), single (79.3%), students (48.6%), and no significant medical history (90.1%). The incidence of removal rate was 20.2%. The incidence per year was 20%, 52%, 28%, and 1% from 2017 to 2020, respectively, as shown in the chart. The incidence rate for intramedullary nail removal was 21% and for plate and screw removal, 14%. The mean age was 28 ± 10.9 years, and the mean period between fixation and implant removal was 26 ± 20 months as shown in Tables 1 and 2. Lower limb fractures formed most of cases (85.6%) with about half of the cases due to foot and ankle fractures. The most frequently presented fractures were femur and tibia (33.3% and 21.6%, respectively), while the most frequently removed implants were plate and screws (43.2%). Only 8.9% of surgeries were indicated for removal, and only 4.5% of all patients suffered post-removal complication as shown in Table 3. Figure 1 shows the frequency of cases went through fixation and removal for each year.

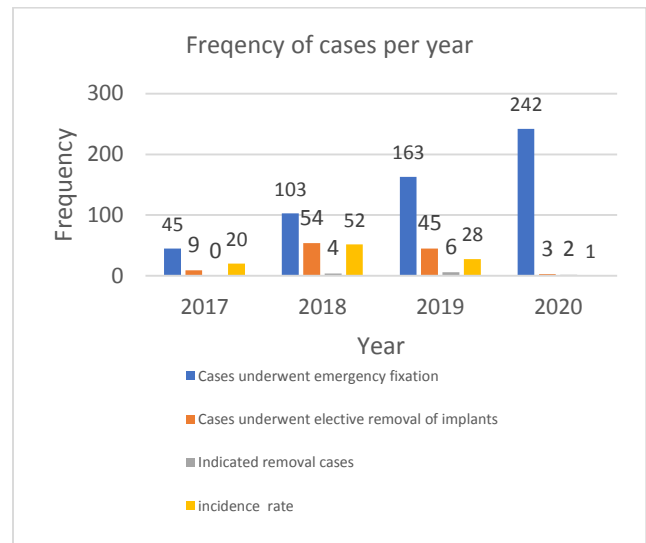
Table 1. Continues variables analysis.

	Mean ± Standard Deviation	Mode	Minimum–Maximum
Age	28.0 ± 10.9	28	13–65
Body mass index (BMI)	25.9 ± 6.4	24	17.3–62
Period of fixation (in months)	26 ± 20	11	1–90

Table 2. Sociodemographic data.

Variable	N (%)
Gender	Male 93 (83.8%)
	Female 18 (16.2%)
Nationality	Saudi 92 (82.9%)
	Non-Saudi 19 (17.1%)
Marital status	Single 88 (79.3%)
	Married 21 (18.9%)
	Divorced/widow 2 (1.8%)
Occupation	Student 54 (48.6%)
	Jobless 21 (18.9%)
	Military 4 (3.6%)
	Health employee 4 (3.6%)
	Others 28 (25.2%)
Chronic Disease	Yes 11 (9.9%)
	No 100 (90.1%)
(BMI) category	Under 1 (1.2%)
	Normal 43 (51.8%)
	Overweight 30 (36.1%)
	Obese 9 (10.8%)
Smoking	Yes 8 (7.2%)
	No 103 (92.8%)
Residency	City 108 (97.3%)
	Village 3 (2.7%)

Variable	Count	%	
Type of fracture	Humerus	6	5.4%
	Radius	2	1.8%
	Ulna	2	1.8%
	Femur	37	33.3%
	Tibia	24	21.6%
	Distal Radius	2	1.8%
	Medial malleolus	6	5.4%
	Lateral malleolus	14	12.6%
	Bimalleolar	2	1.8%
	Ulna & radius	1	0.9%
	Calcaneus	4	3.6%
	Talus	2	1.8%
	Metatarsals	3	2.7%
	Hand phalanges	2	1.8%
	Hip	3	2.7%
Fracture site	Acromioclavicular	1	0.9%
	Upper limbs	16	14.4%
Type of implant	Lower limbs	64	57.7%
	Foot & ankle	31	27.9%
	Plate & screws	48	43.2%
Interval in months	Intramedullary nail	44	39.6%
	Screws	19	17.1%
	<6 months	8	7.7%
	6–12 months	22	21.2%
Reason for removal	13–18 months	19	18.3%
	19–24 months	18	17.3%
	> 25 months	37	35.6%
	Pain	3	2.7%
	Infection	5	4.5%
Post-removal complications	Stiffness	2	1.8%
	Malunion	1	0.9%
	Patient request	100	90.1%
	Yes	5	4.5%
	No	106	95.5%



**DISCUSSION**

Elective removal of orthopedic implants is defined as removal of symptomatic implants which has fulfilled its function (healed fracture), while routine removal is for asymptomatic implants<sup>1</sup>. No evidence or guidelines for removal of asymptomatic orthopedic implants can be found<sup>1,2</sup>. The overall incidence in our study was 20%, which is similar to other studies<sup>5</sup>; however, after considering that each year's incidence shows diversity ranging from 1% during 2020 (which can be explained by COVID-19

pandemic and strict prevention of all elective surgeries except indicated ones) to 52% in 2018 (regular rate). We owe this variation to the lack of clear indications and weak hospital policy for implant removal, and we assumed that lack of patient awareness also plays a role. We found that the period between fixation and removal varied significantly, ranging from two months up to seven years with an even shorter period of one month but with a clear indication as an infected implant. However, most patients submitted for removal after more than 25 months (35.6%) or from 6 to 12 months (21.2%), which is consistent with some studies<sup>4</sup>, and disagrees with others [8], which might reflect randomness and subjectivity. Patients' requests constituted the majority (90%) as found in many studies<sup>3,4,16,17</sup>; however, the rate in our study was the highest found in all reports. Patients' requests is a relative indication for removal together with military requirement, and we assume that most of the patient requested the procedure for military recruitment, but surprisingly, the majority of patients were students (48.6%), and only four patients (3.6%) were actually undergoing recruitment. Pain as the most common reason was also found in many studies [4,5,8,11,18,19] in addition to infection<sup>15</sup>, which is reasonable as pain is a common outcome after many orthopedic implantations, especially intramedullary nailing of long bones<sup>11</sup>; however, this finding was not the reason in our study even with majority of femur and tibia fracture (33.3%, and 21.6%, respectively), which is also consistent with previously mentioned studies<sup>3-5</sup>. Some patients (4.5%) suffered complications, such as failure of implant removal, broken implant, meniscal injury, and iatrogenic fracture, which is the lowest rate compared to similar studies<sup>4,8,15,16</sup>; however, this rate represents both intra-operative and immediate post-operative complications. Most of removed implants were plate and screws (43%) for upper and lower limbs, and foot and ankle fractures, a finding that is consistent with some studies and in conflict with others<sup>3-5,19</sup>. The COVID-19 pandemic had significantly reduced the rate of all surgeries worldwide, including orthopedic and elective procedures<sup>20,21</sup>. Our study showed a marked decrease in elective removal of implants from 45 to 54 cases per year to only three cases. Although this procedure is not urgent, this decrease was accompanied by a significant increase in the removal rate of indicated implants of 9% to 13% up to 67%, which confirms the unnecessary and waste of man-hours, increase in complication-related patient risks<sup>1,3,11,15,16</sup> in addition to the need to control this high rate by raising awareness and restricting the system.

**Limitations:** Our study lacks an assessment of the subjective factor to detect and explore this high rate of unnecessary removal in addition to post-operative follow-up data and improvement or complication information.

**Recommendations:** For future studies, we recommend covering the subjective aspect by formatting questionnaire design in addition to using prospective design studies to detect future improvements or complications. We recommend a well-organized and defined guideline for our institution before submitting the patient to unnecessary elective removal to control this high rate. By raising awareness and educating patients, we expect to see a reduction in this high rate.

## CONCLUSION

The rate of unindicated implant removal has been increasing. COVID-19 positively influenced this rate by causing a decrease in its incidence.

**Source of funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not for-profit sectors".

**Conflict of Interest:** The authors declare that there is no conflict of interest.

**Ethical Approval:** This research was approved by the Research Ethics Committee and Institutional Review Board of directorate of health affairs, Taif, numbered: 302, date 22/12/2019.

**Acknowledgment:** The author would like to Acknowledge the following names for their participation and data collection in this research: Adnan Ali Alghamdi, Danah Kamal Kabrah, Mohammed Modif Alqorashy, Khalid Ahmed Alghamdi.

**Authors contributions:** OMH conceived and designed the study, conducted research, and provided research materials, RAA collected and organized data. OMH and RAA analyzed and interpreted data. OMH and AAM wrote initial and final draft of article, and provided logistic support. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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