

## STUDY OF EVALUATION OF VARIOUS CAUSES FOR IMPLANT FAILURE IN ORTHOPAEDIC TRAUMA PATIENTS

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**Abstract: Introduction:** The success of an implant depends on various factors and it is vital to assess whether implant failure was inherent to the device or occurred due to external factors like lack of patient cooperation in post-operative care, improper application, or rate of fracture healing. The removal of failed implants is expensive and imposes significant mental hardship on the patient. Also, these revision surgeries are demanding, and time consuming. Studies on implant failures in developing countries like India are less. Hence, we conducted this study with an aim of knowing various factors responsible for the failure of implants used in fracture fixation.

**Materials and methods:** The current study was conducted in the Department of Orthopaedics, in a tertiary care hospital from October 2020 – September 2022 after getting approval from Institutional Ethics Committee. Patients coming to an outpatient unit with implant failure were taken as a study sample based on inclusion and exclusion criteria after obtaining informed consent. Data collected in case record form analysed for causes of implant failure.

**Results:** We studied 20 patients with implant failure, majority of the patients were males (65%) and belonged to the age group 21 to 30 years. More common in obese and daily labours. Most often seen in lower limb. Fatigue failure of implants is most common cause.

**Conclusion:** Proper education and adequate immobilisation in post-operative period, proper use of implant with correct size, placement and adequate number of screws and early aggressive use of bone grafting may avoid implant failure.

**Key words:** Implant failure, Orthopaedic surgery, Etiological factors

### Introduction:

An orthopaedic implant is a device that is produced to replace a missing joint or bone. It also helps support the damaged bone. The implant is commonly fabricated with stainless steel and titanium for strength and plastic coating on it acts like artificial cartilage. [1] Surgical implants have been used globally for more than 100 years. [2] The goal of modern orthopaedics is to provide anatomical reduction of fractures compatible with the achievement of functional return of the patient. Implants are used joint replacement, tissue reconstruction, spine fixation and for fracture fixation.[3] During internal fixation, the bone fragments are reduced to normal alignment and then held together using internal fixators like plates, screws, pins, wires, and nails. Materials that are commonly used in prosthetics include metals, polymers, and ceramics. Metals that are commonly used include stainless steel, titanium and cobalt-based alloys. Stainless steel (SS) is the most commonly used material, especially for osteoporosis bones. It is resistant to corrosion, and it does not pose more risk of infection. The success of an implant depends on various factors and it is vital to assess whether implant failure was inherent to the device or occurred due to external factors like lack of patient

cooperation in post-operative care, improper application, or rate of fracture healing. [4] There are many instances of implant failure that require surgery revision. Implant failure is defined as a total failure of an implant that is required to fulfil its functional or aesthetic purpose. This occurs due to mechanical or biological reasons. [5] Failed implants should be revised. The removal of failed implants is expensive and imposes significant mental hardship on the patient. Also, these revision surgeries are demanding, and time consuming. [6] Studies on implant failures in developing countries like India are less. Hence, we conducted this study with an aim of knowing various factors responsible for the failure of implants used in fracture fixation.

### Materials and Methods:

The current study was conducted in the Department of Orthopaedics, in a tertiary care hospital from October 2020 – September 2022 after getting approval from Institutional Ethics Committee. Patients coming to an outpatient unit of the Orthopaedics department with implant failure were taken as a study sample based on inclusion and exclusion criteria after obtaining informed consent.

**Inclusion criteria:** All Implant failure patients attended to orthopaedics outpatient department in our hospital

**Exclusion criteria:** Patients with incomplete data, those who lost to follow up patients, Pregnant and lactating women and patients with acute serious illnesses like cardiac disorders, lung, renal and hepatic disorders, cancers and unfit for further procedures.

After selection of patients demographics like age, gender, occupation were recorded, thorough history from every patient was taken which includes history of trauma, and associated injuries was taken details on comorbidities were noted. History of comorbidities and addictions if any noted. BMI of each patient assessed and noted. Necessary radiological and haematological examinations were done. Radiographs assessed, post-operative activities including range of motion (ROM), ambulation, and any history of repeated trauma, time from index surgery to implant failure weight bearing on an operated limb before bone healing and infections around the implant were noted. After confirmation of diagnosis, implant/prosthesis removal was done. Fracture site was freshened, revision fixation done by a proper implant. During revision surgery cause of implant failure assessed with intra operative findings like corrosion, bending, union status and infection. Data was entered in a case record form designed for the study and it was subjected to statistical analysis.

Statistical analysis: The data collected was entered in MS Excel 2019 and analysis was carried out using Microsoft excel and statistical software called Epi info version 7.2.5 free version. Frequencies and percentages were also used. Mean and SD was used.

### Results:

We studied 20 patients with implant failure who came to the department of orthopaedics at our hospital. The majority of the patients belonged to the age group 21 to 30 years, followed by 31 to 40 years in the current study. Patient's ages ranged from 5 years to 60 years. The median age was 31 and mean age was  $32.2 \pm 15.1$  years. Age wise distribution of patients is shown in table 1

Table 1: age wise distribution of patients

AGE GROUP	Frequency	Percent	Cum. Percent
11 to 20	2	10.00%	10.00%
21-30	6	30.00%	40.00%
31-40	4	20.00%	60.00%
41-50	3	15.00%	75.00%

51-60	3	15.00%	90.00%
Below 10	2	10.00%	100.00%

Majority of patients were males (65%) in the current study. This indicates that implant failure is commonly seen among males. 70% of patients had normal BMI.

Table 2: BMI among patients

BMI	Frequency	Percent	Cum. Percent
Normal	14	70.00%	70.00%
OBESE	3	15.00%	85.00%
Overweight	2	10.00%	95.00%
Underweight	1	5.00%	100.00%

Majority of patients (55%) were daily labourers.

Table 3: occupation of patients

OCCUPATION	Frequency	Percent	Cum. Percent
Daily labourers	11	55.00%	55.00%
Farmer	1	5.00%	60.00%
Housewife	2	10.00%	70.00%
Unemployed-males	6	30.00%	100.00%

10% of patients were alcoholics and 10% were smokers in the current study.

Table 4: Habits among patients

Habits	Frequency	Percent	Cum. Percent
Alcohol	2	10.00%	10.00%
Nil	16	80.00%	90.00%
Smoking	2	10.00%	100.00%

Majority (55%) of patients came with a complaint of pain. 10% of patients reported discomfort. 35% of patients had mobility problem. Diabetes and hypertension are the most common comorbidities. Diabetes was seen in 15% of patients. Hypertension was seen in 20% of patients overall.

Table 5 comorbidities among patients

COMORBIDITIES	Frequency	Percent	Cum. Percent
DM	2	10.00%	10.00%
DM, HTN	1	5.00%	15.00%
Hepatitis B	1	5.00%	20.00%
HTN	3	15.00%	35.00%
Nil	13	65.00%	100.00%

In majority (40%) of cases, implant failure seen at the femur, in 30% of cases, implant failure occurred in the tibia. In 70% of patients, implant failure was seen in lower limb.

Table 6: Site of implant

IMPLANT LOCATION	Frequency	Percent	Cumulative Percentage
Clavicle	1	5.00%	5.00%
Femur	8	40.00%	45.00%
Humerus	3	15.00%	60.00%
Tibia	6	30.00%	90.00%
Radius and Ulna	2	10.00%	100.00%

Plates are commonest type of implants that were failed in the current study.

Table 7: Type of implant

TYPE OF IMPLANT	Frequency	Percent
Bipolar prosthesis	4	20.00%
Plate	8	40.00%
Screws	3	15.00%
Nailing	4	20.00%
TENS nail or ENDERS Nail	1	5%

Infection was seen in 15% of patients with implant failure. Implant failure occurred within one year in 90% of patients after previous surgery. In 10% of patients, it occurred after one year. In majority (40%) of patients, the reason for implant failure was fatigue fracture.

Table 8: Reasons for implant failure

REASONS FOR IMPLANT FAILURE	Frequency	Percent	Cumulative Percent
Bending	4	20.00%	20.00%
Fatigue fracture	8	40.00%	60.00%
Infection/metallosis	4	20.00%	80.00%
Varus	4	20.00%	100.00%

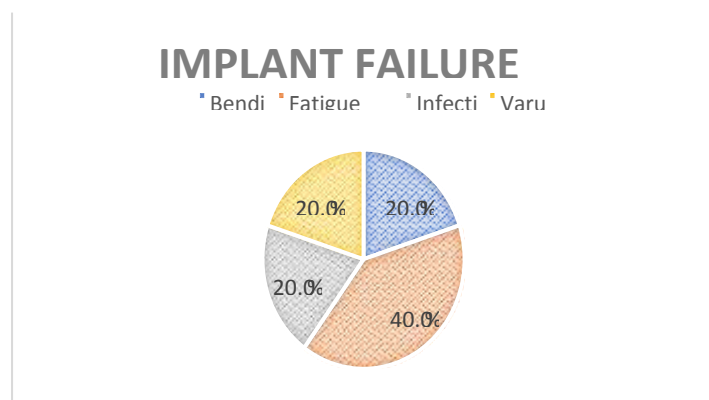


Figure 1: showing various reasons for implant failure

Figures two to seven showing various implant failures seen in our cases



Figure 2: showing failed clavicle plate



Figure 3: broken clavicle plate after removal



Figure 4: showing broken austin moores prosthesis



Figure 5: broken austin moores prosthesis after removal



Figure 6: showing broken nailing tibia



Figure 7: showing broken humerus plate

**Discussion:**

Most of the patients in reproductive age group had implant failures in our study. 65% of patients were males and 35% were females in the current study. This indicates that implant failure is commonly seen among males.

In the study done by Prashanth, 217 patients who underwent removal of implant were included.[7] These surgeries constituted 11.1% of total surgeries done in orthopaedics department during the study period. This study was done at Mandhya Institute of Medical sciences from 2019 to 2021 for two years. Among 217 patients, 161 patients were males and 56 patients were females. Male preponderance was similar to the current study. The mean age was 36.2 years. Age of patients ranged from 4 years to 96 years. There were more patients during reproductive age. In majority of the cases, implant failure occurs in the age group of 16–45 years.

In the studies done by Haseeb [8], Kadir [9], Onche [10], Kuubiere [11] also, implant failures were commonly observed in patients in the reproductive age group, similar to the current study, as patients in the reproductive age group were more active.

In the study done by Shresta, implant failures were found to be more common among males.[12] It was seen in 189 patients out of 275 implant failure cases. In the study done by Abidi<sup>23</sup>, 85% of patients with implant failure were males.[13] The reason for this male preponderance could be due to the fact that males are more involved in outdoor activities and hence fractures resulting in more implant removal.

**Site of the implant in implant failure patients:**

In 40% of cases, implant failure happened at the femur, and in 30% of cases, implant failure occurred in the tibia. In 70% of patients, implant failure was seen in the lower limb in the current study. In the study done by AK Sharma, among 41 patients included, 23 had femoral implant failure, four patients had tibia implant failure, 12 patients had humeral implant failure and 2 patients had failure of radial implant, most common site is femur, similar to the current study. [14]

**Reason for implant failure:** In 40% of patients, the reason for implant failure was fatigue fracture. In 20% of patients, the reason was an infection, in 20% of patients the reason for implant failure was bending and in 20% of patients, the reason was varus collapse in the current study. Fatigue failure occurs due to repetitive loading on the device. So, when a surgeon inserts an implant, he should know that is entering a race between fatigue of the implant and fracture healing.

**Type of implant failure:** Plates are the commonest type of implant that failed in our study. In the study done by AK Sharma, authors reported 30 plate and eleven Nail failures. [14] Extreme care must be taken in the usage of plates, as they exhibit good and bad characteristics of implants. Plates allow for reconstruction of the bone, providing early mobilization. Brittle and plastic failure happens due to minimal load in small plates and trauma in large plates. Plate ends act as stress riser causing a fresh fracture proximal or distal to original one. In the current study, among 20 patients, 4 patients had nail. An IM Nail gives good stability for a fractured bone along with better biomechanical environment for healing. It allows good rehabilitation and early recovery. It fails due to fatigue that occurs due to cyclical loading.

In the study of Prashanth, Distal tibia is the most common site for implant removal. Plates and screws were the most common implant to be removed. [7] This finding was similar to the current study. Titanium elastic nail was the next most common implant that was removed. While in the current study, 4 patients had intramedullary nail implant failure. 20% bipolar prosthesis that was failed and removed. In this study plates are the most common implants to fail similar to our study.

Among reasons for implant remove, it was found that Patient request is the most common indication followed by surgeon request. In the current study, all implant removal cases were not included. Only implant failure cases were included. Prominent hardware is the common indication followed by infection and implant failure for implant removal. In 37.7% of patients, implant removal happened within one year after surgery. History of post-operative mobilization: There is inadequate mobilization in the past history in the postoperative period in 55% of patients in the current study. In the study of AK Sharma, 16 among 41 patients gave a history of insufficient immobilization during the PO period along with re-trauma and 16 had insufficient fixation followed by more loading at the fracture site. [14]

Comparison of various parameters with Yusuf Ali's study [15]

Parameters	Current study	Yusuf Ali's
Sample size	20	50
Gender	Males more than females	Males more than females
Failed plates prevalence	40%	42%

In the study done by Barbosa amongst three patients with implant failure it was found that surgical technique and design of implant and selection of implant were main reasons for implant failure. [16] In the study done by Sharma et al, 2.4% failures were found to be related to deep infection.[14]

Excess body weight of patients and early load bearing on fractured lower limb causes more stress on the implant during the time of healing of fracture.

Fatigue failure of plates may occur commonly due to the location of nails at the shaft which prevents certain bending forces that cause fatigue failure. [17] Plate fixation needs reduction with anatomical reconstruction that may affect the periosteal blood supply. [18, 19]

BMI role in implant failure: 70% of patients had normal BMI. 15% were obese. 10% were overweight and 5% were underweight in the current study. Ogbemudia et al identified that more body weight is a major reason for implant failure and suggests cautious ambulation and gradual weight bearing. [20]

In the research done by Rohan R Patil, 37 patients were included, it was identified that the commonest site of implant breakage was femur in 40.5% of cases.[21] This finding was similar to the current study. The most commonly involved implant was intramedullary nails. This finding was in contrast to the current study finding.

In the research done by Zimmerman and Klasen, authors found that IM nails failed more due to fatigue of the implant.[22] Early fatigue of the nail can occur due to unstable fracture and location of the fracture.[23]

## CONCLUSION

The current study shows that screw failure was common compared to plate failure. Implant failures occurred most commonly in lower limbs compared to upper limbs. Being male, presence of the addictions, obesity, presence of hepatitis B, diabetes and hypertension, and inadequate post-operative immobilization were few risk factors for implant failure. Fatigue fracture is the most common cause of implant failure. In most of the patients with implant failure, there was significant re-trauma that happened during consolidation stage of healing. In many patients, there was insufficient post-operative immobilization.

Information on tension band principle is vital so that a plate will be placed on the bone subject to tension and not bending.

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