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RESEARCH ARTICLE
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IMPLANT FAILURE IN ORTHOPAEDICS IN A TERTIARY CARE HOSPITAL OF NORTH INDIA

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Abstract
Introduction: Orthopedic implants are medical devices designed to support bones, joints, or cartilage affected by damage or deformity. These implants assist in bone fixation. Implant failure occurs when the implant does not perform its intended function, often due to complications arising from the implantation procedure. This study aims to assess the causes of implant breakage and loosening in orthopedics. Understanding these causes will help in guiding preventive measures, improve the success of future orthopedic implantations, and reduce the stress associated with patient rehabilitation and medical care.
Aim: Evaluating the causes of orthopaedic implant failure was the aim of this research.
Methods: A total of 50 patients, fulfilling the inclusion criteria, were selected
from the orthopaedic outpatient department and emergency department of Government Medical College, Jammu. Research type: Cross sectional study. Study time frame: One year (12 months) (1st January 2023 to 31st December 2023). The study was done to evaluate the causes of implant failure in orthopaedics.
Results: The most common cause of implant failure was non-union, which accounted for 20 patients. Infection was the second-most common reason for implant failure in our analysis. Infection led to bone lysis at the fracture site and around the implant, implant loosening, and non-union, which eventually lead to implant failure since it affected bone healing. Aseptic loosening may be the consequence of insufficient initial fixation, progressive mechanical fixation loss, or biologic fixation loss brought on by particle-induced osteolysis surrounding the implant.

INTRODUCTION:

In orthopaedic surgery worldwide, surgical implant devices have been used for over hundred years [1]. Implants like plates and screws used in rigid fixation have been advocated in study of internal fixation. Nowadays, in fracture fixation, arthroplasties, spine fixation, reconstruction of tissues modern implants play an important role. [2] To perform active exercises of muscles and joints immediately after an operation it is necessary to have stable fixation. Usage of implants that are stronger, more acceptable to body and durable are currently the main focus in modern orthopaedics. It is important

to note biomechanical properties of corrosion/erosion resistance and adaptation to biological environment before insertion of the implant. Metals such as cobalt–chrome alloy, stainless steel (SS), titanium, and their alloys are used for implants as they have good biological adaptation, corrosion/erosion resistance, and mechanical hardness. [3]. Inherent problems that are associated with implants are pain, local irritation and stress-shielding phenomenon. [4,5] Implant failure is defined as the total failure of the implant to fulfil its purpose (functional, aesthetic, or phonetic) because of mechanical or biological reasons, which therefore requires revision surgeries which are mostly time consuming, demanding and difficult [6]. In these revision surgeries failed implant is removed which causes great expense and hardship to the patient.[7] Implant survival is the time from the date of implant placement to the date of its failure.[8] Implants are made of different types of biomaterials like Titanium, stainless steel, polymers and composite materials. A good biomaterial should have good mechanical and biological compatibility and enhanced corrosion resistance.[9] An implant is said to have failed when there is a need to remove the implant prematurely.[10] The main aim in modern orthopaedics is to obtain anatomical union of fracture and give maximum return of functions to the patient by fixation with appropriate implant but success or failure of implant is determined by multiple factors like insertion technique, patient's cooperation, fracture healing rate and inherent properties of implant.[11] Implant failures arise from loosening or breakage of the internal fixation device. Because bones are more flexible than metal plates, screwing a metallic plate to bone stiffens it and produces 'stress riser' at each end of the plate. In the absence of union, even the strongest metal plates and screws will eventually break or pull out of bone. Fatigue arising from cyclic loading can cause fracture of an implant which effectively leads to failure of the fixation device. Implant failure from fatigue fracture is more common with plates than intramedullary nails (IMNs) because the location of an intramedullary nail in the centre of the shaft tends to spare the IMN of some of the bending forces responsible for fatigue failure. An earlier retrospective study showed that implant failure occurred more often with plate and screws than intramedullary nails. [12]

Implant failure increases patient's morbidity, lengthens the healing process and increases the cost of treatment. An implant failure often leads to re-fracture, complicating the healing process and a more complicated repeat surgery. In vast majority of these cases mechanics of fracture, implant design and surgical procedure are to be blamed. [13] Patients with implant failure usually present with pain and deformity of the operated limb which may or may not be related with a recent trauma. Patients admitted with failed implant face psychological stress and financial burden because they have already lost many working days and spent more on the primary surgery. For orthopaedic surgeon these revision surgeries become challenging because the tissue planes are scarred and retrieval of broken implant is always a difficult job. Chances of neurovascular injury, infection and fixation failure are more in revision surgeries. [14]

METHODS AND MATERIALS

Location of Study: Department of Orthopaedics, Government Medical College, Jammu.

Research type: Cross sectional study

Time frame: One year (12 months) (1st January, 2023 to 31st December 2023).

Research subjects: From the orthopaedics outpatient department and emergency department, 50 patients who matched the inclusion criteria were chosen and added to the study.

Inclusion Criteria: 1) Age: All age groups 2) Normal neurological and vascular condition of the limbs.3) Capable of adhering to follow-up criteria.

Exclusion Criteria: Patients who had refused to take part in extended rehabilitation following surgery.

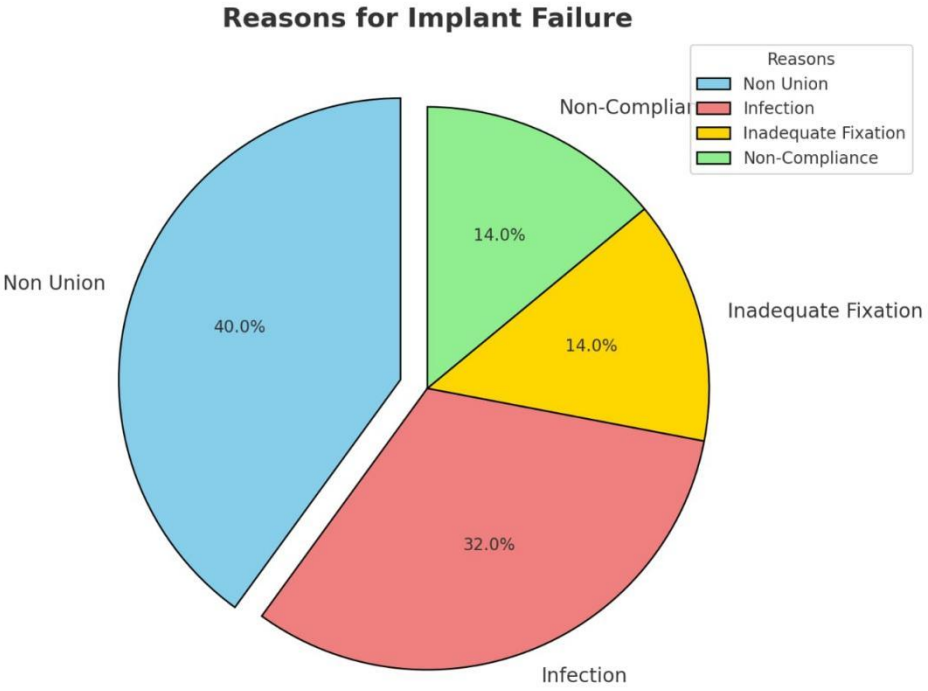
Preoperative evaluation of the patients was done in patients diagnosed with implant failure. The evaluation included routine blood investigations Complete blood count, Coagulation profile, HIV, HBSAg, HCV, Renal function test, Liver function test, Serum electrolytes, FBS/RBS, C-reactive protein, Erythrocyte sedimentation rate, Standard radiographs, Culture and sensitivity in cases of infection.

RESULTS

Evaluating the causes of orthopedic implant failure was the aim of this research. Outcomes were observed by means of failure of union by various causes of implant failure. The age group with the highest frequency of failure was 20– 50 years old, with a mean age of 44.9 years. 35 (70%) of the 50 cases were male, and 15 (30%) were female. It takes 4.5 months on average for an implant to fail. Two to three was the ratio of the upper to lower limbs. Twenty of the fifty cases were closed injuries at presentation, while thirty were open injuries. While 28 individuals exhibited a complex pattern of injuries, 22 patients had a basic pattern. After looking into the cases, it was found that 36 patients were immunocompromised because they had comorbidities such as type 2 diabetes and hypertension, were persistent tobacco users, were chronic smokers, and were on medicine for HIV and HCV.

TABLE 1: REASONS FOR IMPLANT FAILURE

REASONS	FREQUENCY
• **Non union**	• **20(40%)**
• **Infection**	• **16(32%)**
• **Inadequate Fixation**	• **7(14%)**
• **Non-Compliance**	• **7(14%)**



Based on the mode of implant failure, all failed implants were typically divided into four groups. Of the 50 cases in our analysis, 20 cases (40%) had non-union status as their primary cause.16 cases (32%) had infectious causes. Other prevalent causes included insufficient implant fixation (7 cases,14%) and patient noncompliance with postoperative recommendations (7 cases, 14%)

TABLE 2: TYPES OF IMPLANTS INVOLVED

Type of Implant	Number of Cases	Percentage
DCP	16	**32%**
LCP	5	**10%**
Anatomical plates	9	**18%**
IMN	1	**2%**
ILN	14	**28%**

PFN	5	**10%**
TOTAL	**50**	**100%**

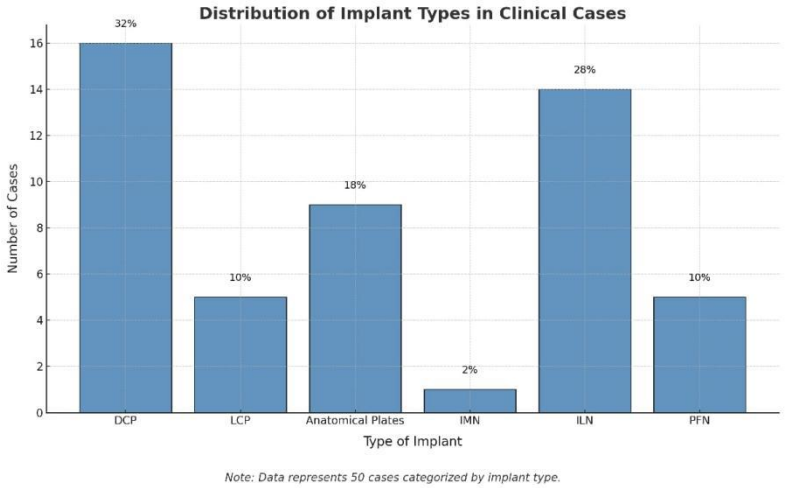


Figure 1: An example of a broken ILN femur: The absence of union was the reason for failure.

Figure 2: ILN Humerus: A case of hypertrophic non-union

Figure 3: Non-union with Varus collapse resulting in broken proximal tibia plate

Figure 4: Noncompliance with postoperative instructions: The patient began lifting heavy weights and doing strenuous workouts in the gym.

TABLE 3: TYPES OF IMPLANT FAILURE

IMPLANT	FAILED AS
• **DCP (16)**	• Broken (Fatigue Failure) **(6)** • Bending **(1)** • Aseptic Loosening **(3)** • Infection **(6)**
• **LCP (5)**	• Broken (Fatigue Failure) **(4)** • Bending **(0)** • Aseptic Loosening **(0)** • Infection **(1)**
• **Anatomical Plate (9)**	• Broken (Fatigue Failure) **(3)** • Bending **(3)** • Aseptic Loosening **(0)** • Infection **(3)**
• **Intramedullary Nail (1)**	• Broken (Fatigue Failure) **(0)** • Bending **(1)** • Aseptic Loosening **(0)** • Infection **(0)**
• **PFN (5)**	• Broken (Fatigue Failure) **(2)** • Bending **(1)** • Aseptic Loosening **(0)** • Infection **(2)**
• **Interlocking Nail (14)**	• Broken (Fatigue Failure) **(9)**

	• Bending **(0)** • Aseptic Loosening **(2)** • Infection **(3)**

TABLE 4: IMPLANT FAILURE WITH PERCENTAGE DISTRIBUTION

FAILURE TYPE	CASES	PERCENTAGE
Broken plate	13	26%
Broken nail	11	22%
Infective loosening of plate	10	20%
Infective loosening of nail	5	10%
Bent plate	4	8%
Bent nail	2	4%
Aseptic loosening of plate	3	6%
Aseptic loosening of nail	2	4%
Total	**50**	**100%**

DISCUSSION

The age group in our study ranged from 17 to 81 years. With increasing age, there was a decrease in bone mineral density, progressive cognitive decline, and delayed healing of fractures as compared to a young age, so a trivial fall and non-compliance during the post-op period can cause implant failure. After analysing our study results, we discovered that the most common cause of implant failure was non-union, which accounted for 20 instances (40%). The primary patient factor in non-union was the blood supply. When the blood flow to the bone decreases, it is unable to repair the fracture. There were systemic causes like smoking, which decreases blood supply. Chronic alcohol users had an increase incidence of osteopenia.

There were 4 cases (20%) of hypertrophic non-union with radiographically abundant callus formation, but there was no bridging bone, and the ends were not united which indicated that there was adequate blood supply and biology (with the formation of callus) but inadequate stability; 12 cases of atrophic non-union with radiographically absent callus, which indicated poor biology and a lack of blood supply; 3 cases of oligotrophic non-union with incomplete callus formation due to inadequate reduction; and 1 case of septic non-union with infection leading to reduced blood flow and deficient nutrient supply to the healthy bone, Because of the non-union, all load and stress were passed exclusively to the implants, resulting in failure.

Infection was the second-most common reason for implant failure in our analysis. Infection led to bone lysis at the fracture site and around the implant, implant loosening, and non-union, which eventually lead to implant failure since it affected bone healing. Open fractures could have been the source of infection. Other causes of infection included failure to administer intravenous antibiotics in the first 60 minutes after the injury, improper debridement of the infected, dead and necrotic tissues, improper wound irrigation and deficient post-operative wound care.

Inadequate fixation was responsible for 7 instances of implant failure (14%). Inadequate fixation was attributed to the incorrect and in adequate choice of implants. 5 cases (10%) of noncompliance with post- operative recommendations, such as early weight bearing by the patient, and 2 cases (4%) of lifting excessive weights attributed to implant failure.

Patients' lack of physiotherapy, poor diet, smoking, alcohol consumption, failure to follow up on dressings, resuming their work early, particularly in plate fixation cases caused implant breakage and bending since the fracture was in the healing stage, and all of the stress and strain transmitted to the implant resulted in deformation and fatigue failure of their implant.

CONCLUSSION

There are innumerable reasons for implant failure. Accurate and precise assessments of reasons have been tried in this study. The most common type of failure, according to our data, was broken implants (48%), which was followed by infective loosening (30%). Non- union (40%) was the largest single risk factor, followed by infection (32%). Comorbidities like diabetes, smoking, and tobacco use were also important contributors to non-union and infection, and their presence increases the risk of these outcomes even after revision surgery. The fracture pattern and the existing weak bones, such as osteoporotic bone. Bone grafting and proper fixation could lower implant failure rates. Sterilization of OT equipment and surroundings and implant autoclaves done correctly are important to prevent and control hospital-acquired infections and to give correct irrigation, debridement, and dressings for open fractures. At last, various measures to consider are implant choice, better rehabilitation and compliance with physiotherapeutic measures, better control of nutrition, timely antibiotics, and weight bearing as advised, diabetic status control, healthy diet and proper follow-up for dressings, medications and compliance to other advises of the index surgeon.

BIBLIOGRAPHY

1. Tezuka A. Total joint replacement in rheumatoid hip and knee. Orthop Traumatol. 1980;29(4):787–90.
2. Okazaki Y. Development trends of custom-made orthopaedic implants. J Artif Organs. 2012;15(1):20–5.
3. Peivandi MT, Sani Y, Farzad A. Exploring the reasons for orthopaedics implant failure in traumatic fractures of the lower limb. Arch Iran Med. 2013;16:478–82.
4. Hughes TB. Bioabsorbable implants in the treatment of hand fractures: an update. Clin Orthop Relat Res. 2006;445:169–74.
5. Waris E, Konttinen YT, Ashammakhi N, Suuronen R, Santavirta S. Bioabsorbable fixation devices in trauma and bone surgery: current clinical standing. Expert Rev Med Devices. 2004;1(2):229–40.
6. El Askary AS, Meffert RM, Griffin T. Why do dental implants fail? (part I). Implant Dent. 1999;8:173–85.
7. Hak DJ, McElvany M. Removal of broken hardware. J Am Acad Orthop Surg. 2008;16(2):113–20.
8. Sivakumar M, Kumar Dhanadurai KS, Rajeswari S, Thulasiraman V. Failures in stainless steel orthopaedic implant devices: A survey. J Mater Sci Lett. 1995;14(5):351–4.
9. Woo SK V, Chuang S, Muftu A. Dentoalveolar reconstructive procedures as a risk factor for implant failure. Journal of Oral and Maxillofacial Surgery. 2004;62(7):773–80.
10. Geetha M, Singh AK, Asokamani R, Gogia AK. Ti based biomaterials, the ultimate choice for orthopaedic implants — A review. Prog Mater Sci. 2009;54(3):397–425.
11. Peter M, Diana M, Vivek S. Dental Implant Failure Rates and Associated Risk Factors. International Journal of Oral and Maxillofacial Implants. 2005;20(4):569–77.
12. Akeson WH, Woo SLY, Rutherford L, Coutts RD, Gonsalves M, Amiel D. The effects of rigidity of internal fixation plates on long bone remodeling:A bio mechanical and quantitative histological study. Acta Orthop Scand. 1976;47(3):241–9.
13. Ogbemudia AO, Umebese PFA. Implant failure in osteosynthesis of fractures of long bones. J Med Biomed Res. 2009;5(2).
14. Sharma AK, Kumar A, Joshi GR, John JT. Retrospective study of implant failure in orthopaedic surgery. Med J Armed Forces India. 2006;62(1):70–2.