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Study of Causes of Implant Failure in Orthopaedics

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ABSTRACT

An implant fails if it is unable to live up to the expectations of its manufacturer or the healthcare professional installing it. Depending on the patient's age, the type of implant and the location of fractures, some implants have a higher failure rate than others. Additional risk factors include infection, trauma, non-compliance to post operative instructions, smoking, tobacco use and pathological fractures. The aim of this study is to ascertain the orthopaedic implant failure pattern and potential risk factors in a north Indian tertiary hospital. To determine the potential reason of implant failure, 50 patients who were hospitalized from emergency rooms and outpatient departments were followed up for a period of 12 months in an observational study. After data collection, analysis took place. The mean age was 44.9 years and 70% of the participants were men. The majority of procedures (60%) involved the lower limbs and the most prevalent type of failure is the broken implant (48%), followed by infective loosening (30%) and non-union (40%), is the biggest single risk factor. Our research has led us to the conclusion that comorbid conditions like as diabetes, smoking and tobacco use are significant contributors to non-union and infection. These conditions also increase the likelihood of non-union even following revision procedures involving bone grafting, which can result in implant failure. Adequate fixation and bone grafting minimize implant failure along with compliance to post operative instructions.

INTRODUCTION

Implant devices have been utilized for more than a century in orthopaedic surgery globally[1]. In the study of internal fixation, implants such as plates and screws that are utilized in rigid fixation have been considered. These days, new implants are crucial in tissue reconstruction, arthroplasties and fracture fixing[2]. Stable fixation is required to do vigorous workouts of the muscles and joints right after surgery. The current focus in modern orthopaedics is on the use of implants that are stronger, more aesthetically pleasing to the body, and long-lasting. Prior to implant insertion, it is crucial to consider the bio-mechanical characteristics of implant corrosion, erosion resistance and biological environment adaptation. Materials with strong biological adaptability, resistance to corrosion and erosion, and mechanical hardness, such as titanium, stainless steel, cobalt chrome alloys and their alloys, are utilized in implants[3].

Pain, localized discomfort and the stress-shielding phenomenon are inherent issues with implants[4,5]. Implant failure is described as the complete inability of the implant to achieve its intended function, aesthetics, or phonetics due to mechanical or biological factors. This necessitates revision operations, which are difficult, time-consuming and demanding[6]. These revision procedures remove failing implants, which come at a significant financial and personal cost to the patient[7]. Orthopaedic implants are man-made mechanical devices that are affixed to the human skeleton for a variety of functions, including bone support, joint replacement and tendon or ligament reattachment[8]. The period from the date of implant insertion to the date of failure is known as implant survival[9]. Various bio-materials, including composite materials, stainless steel, polymers and titanium, are used to make implants. Stronger corrosion resistance and improved mechanical and biological compatibility are essential qualities of an ideal biomaterial[10]. The primary goals of modern orthopaedics are to achieve anatomical union of fractures and maximize functional return for the patient through fixation with the appropriate implant., however, the success or failure of an implant is contingent upon several factors, including insertion technique, patient cooperation, fracture healing rate and intrinsic implant properties[11].

One of the biggest developments in orthopaedics history is the production of orthopaedic implants, which are used to replace or support bones. The adoption of high-standard implants is required due to an increase in traffic accidents and an increase in human life expectancy[12]. The goal of treating fractures is to promote union and prompt functional recovery. An early restoration to normal function is facilitated by early ambulation, which is the aim of internal fixation. Non-union or delayed union, however, could result from an internal fixation device's inability to hold the reduced fracture until union. The internal fixation device breaking or becoming loose is the cause of implant failures. Screwing a metallic plate to a bone stiffens it and creates a stress riser at each end of the plate because bones are more malleable than metal plates. Even the hardest metal screws and plates will eventually break or come out of the bone if there is no union[13].

Cyclic loading-induced fatigue can result in implant fractures, which ultimately cause the fixation device to fail. The occurrence of fatigue fractures in implants is more common in plates than in intramedullary nails (IMNs). This is because the IMN is shielded from part of the bending stresses that cause fatigue failure by its placement in the centre of the shaft. An earlier retrospective analysis revealed that intramedullary nails failed significantly fewer than plates and screws when it came to implant failure[13]. The management of fractures, pulling out screws and plates, loosening of nails and plates, bending and breaking and migration of rods and pins are all connected with implant failure. Failure of an implant prolongs the healing period, raises treatment costs and increases patient morbidity as regards his physical and mental well-being. Refractures resulting from implant failure can impede the healing process and necessitate more involved follow-up surgery. The great majority of these occurrences can be attributed to implant design, surgical technique, improper planning and fracture mechanics[14].

Patients who have implant failure typically arrive with discomfort and limb deformity, which may or may not be connected to a recent trauma. Since they have already lost numerous workdays and incurred higher costs for the initial operation, patients who are admitted with a failing implant experience both financial and psychological hardship. The damaged tissue planes and the difficulty of retrieving shattered implants make these revision operations tough for orthopaedic surgeons. Revision operations carry a higher risk of neurovascular damage, infection and fixation failure[15].

MATERIALS AND METHODS

This is a hospital-based observational study with a cross-sectional study design conducted in a tertiary care centre in north India with a total of 50 implant failure patients presented to emergency and OPD who were followed for 12 months from 2021-2024 after consenting and receiving approval from the institute ethical committee and research committee with the following inclusion criteria: 1. Age: Every age range. 2. Normal neurological and vascular conditions of the limbs. 3. Capable of adhering to follow-up criteria and with the following. exclusion criteria: 1. Pregnancy, 2. A patient who had refused to take part in extended rehabilitation following surgery and he was physically unfit for surgery. At the time of admission, the patients and attendants were informed of all probable surgical risks and post-operative problems as documented in the literature. Patient transferred to the ward, A basic examination was performed following all baseline investigations and preoperative evaluation of the patients. The assessment will comprise 1) routine blood investigation, 2. C-reactive protein 3. The erythrocyte sedimentation rate, 4. HBA1C, 5. Standard radiograph.6. Culture and sensitivity in the event of an infection, 7. Implant radiographs, 8. Previous surgical records, 9. Specifics of implant used, 10. Personal history of addictions such as diabetes, smoking, tobacco and alcohol., fitness checked., patient placed on OT list. Consent forms were signed and non-infected patients received prophylactic antibiotics 30 minutes before the first skin incision. A tourniquet was applied wherever necessary and intraoperative samples for culture sensitivity were collected. Patients were given intravenous antibiotics following surgery, and infective cases were given antibiotics for a longer period of time based on culture results. All patients were discharged and follow-up was done on an outpatient basis. Patients are evaluated clinically and radiologically every six, twelve, twenty-four and forty-eight weeks for indicators of implant failure.

RESULTS AND DISCUSSIONS

From the orthopaedics outpatient department and emergency department, patients who matched the inclusion criteria were chosen and added to the study during our study period. The patients underwent radiological and clinical examinations. A thorough physical examination was done and a clinical history was taken. Evaluating the causes of orthopaedic implant failure was the aim of this research. This observational study was conducted at Rajindra Hospital, Patiala between April 2023 and April 2024. 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 (or 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 at presentation, while thirty were open(compound). 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 of the patients were immunocompromised because they had comorbidities such as diabetes and hypertension, were persistent tobacco users, were chronic smokers and were on medicine for HIV and HCV.

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 (or 40%) had non-union status as their primary cause. Of the 50 cases, 16 had infectious causes (32%). Other prevalent causes included insufficient implant fixation (7 cases., 14%) and patient noncompliance with postoperative recommendations (7 cases., 14%).

50 implant failure cases were categorized into four groups according to the type of failure. According to our analysis, implant breakage accounted for 24 cases (48%) of all implant failures, followed by infective loosening (15cases, 30%), bent implants (6 cases, 12%), and aseptic loosening (5 cases, 10%). According to our analysis, lower limb instances (60%) outweigh upper limb cases (40%) and plate failure (60%) is more common than nail failure (40%). In 20 instances of non-union, when revision surgeries including autologous bone grafting were scheduled, it was found that 17 cases of implant failure due to non-union (85%) result in favourable outcomes., the three non-union cases (15%) were associated with co-morbidities such as diabetes, smoking and tobacco use.

At the time of initial presentation, 16 cases (32%) of infective implant failure with infective non-union and loosening were found to be associated with open fractures. Of these 16, 14 cases had immunocompromised status due to diabetes, chronic smoking, or chronic tobacco use, while 3 cases were HCV+and 2 cases had HIV. After the implants were taken out, bone cement with intravenous antibiotics was used for six to eight weeks, depending on the culture and sensitivity of the patient. Blood culture, CRP and ESR measurements were performed on the cases that were followed up on. Infection was decreased with appropriate glycaemic control, appropriate irrigation of infected wounds, debridement and wound care., all aseptic procedures were followed during revision procedures, including bone grafting. 14 (88%) of the 16 patients had successful outcomes, with no implant failures.

Table 1: Reasons for Implant Failure

Study	Reasons	Frequency
Present Study	Non union	20(40%)
	Infection	16(32%)
	Inadequate Fixation	7(14%)
	Non-Compliance	7(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%

Table 3: Bone and Site Involved in Implant Failure

Study	Bone Involved		Level of Fracture		
			Proximal	Shaft	Distal
Present Study					
	Femur	40%	6 (12%)	8 (16%)	6 (12%)
	Tibia	20%	3 (6%)	3 (6%)	4 (8%)
	Humerus	28%	-	14 (28%)	-
	Radius ulna	12%	-	4 (8%)	2 (4%)

Table 4: 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)
IM 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)
IL NAIL (14)	Broken (Fatigue Failure) (9) Bending (0) Aseptic Loosening (2) Infection (3)

Table 5: 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%

We conducted a hospital-based observational study from April 2023 to April 2024 to identify the causes of orthopaedic implant failure. 50 cases of implant failure presented to OPD and Emergency who met the inclusion criteria were followed up prospectively and retrospectively for reasons for implant failure. The age group in our study ranged from 17-81 years old. There

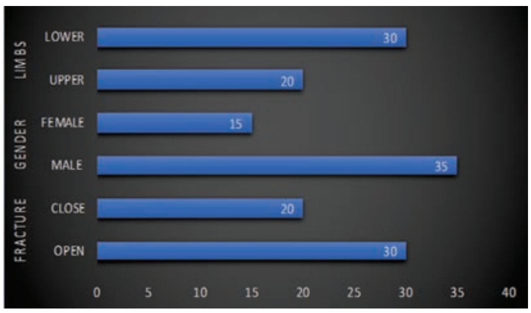

Fig. 1: Displaying the number of instances according to the affected limbs, the gender predisposing to the condition and the fracture type at the time of presentation to the treating surgeon

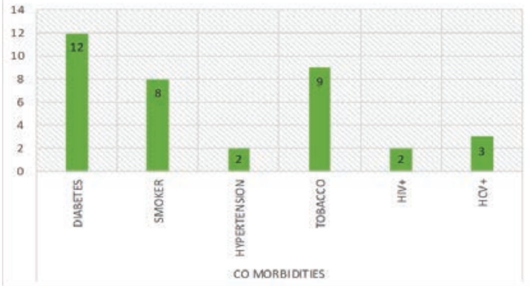

Fig. 2: 36 cases have comorbidities

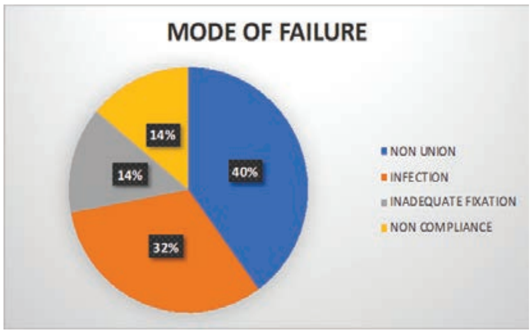

Fig. 3: Modes Of Implant Failure

Fig. 4: Inadequate fixation using a short PFN rather than a long PFN for a sub-trochanteric femur fracture results in implant failure

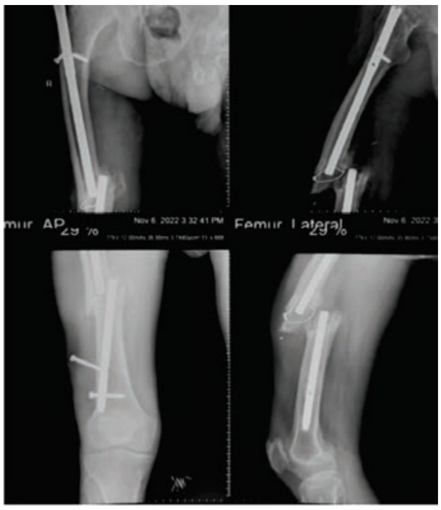

Fig. 5: An example of a broken ILN femur (right): The absence of union was the reason for failure

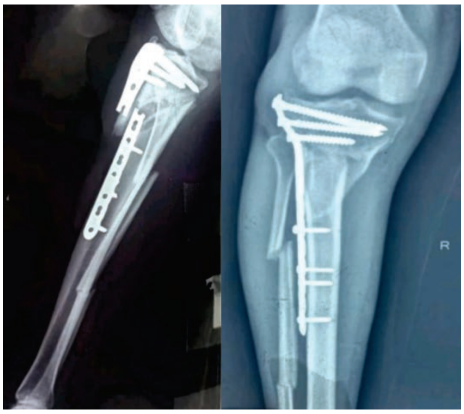

Fig. 6:In the case of a distal femur fracture treated with DFLP (L), the patient started bearing weight early, which caused the implant to bend and resulted in varus collapse

Fig. 7:Non-union with Varus collapse resulting in broken proximal tibia plating

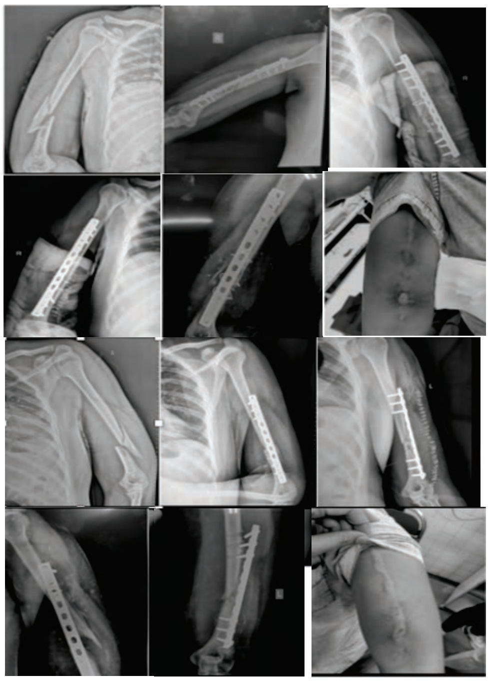

Fig. 8:An example of infectious loosening of bilateral shaft humerus plating with discharging sinuses: the patient smokes and has diabetes

Fig. 9:Situation: hypertrophic non-union in a broken interlock nail tibia., implant extraction., exchange nailing with bone grafting

Fig. 10: Reverse Z-effect Lateral migration of the superior screw is followed by medial migration of the inferior screw

were different factors associated with young and old age groups, such as a higher incidence of non-compliance with post-op protocols and a higher repeat trauma rate at a young age in road traffic accidents and sports injuries, which was found in 30% of cases in our study as compared with 32.4% in Patil[21] and 45.45% in Talib[18] 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. This was comparable to previous studies of age group 17-95 years in Patil[21] 23-98 years in Onuoha[20] 17-65 years in Sharma[13] and 19-76 years in Talib[18] The mean age of failure in our study was 44.9 years, which was similar to 42.5 years in Deoda[17] The male-to-female ratio of 7:3 suggested a male predominance in the current investigation. This could be because men were more likely than women to engage in outdoor activities and sustain injuries in traffic accidents, which was consistent with previous findings of 33:4 in Patil[21], 8:1 in Sanaullah[15], 47:6 in Kumar[16] and 9:2 in Talib[18] Furthermore, the lower limb experiences implant failure more frequently than the upper., in our analysis, the reason for this could be that at the stance phase of the gait cycle, each lower limb bears an average of three times the body weight, resulting in more strain on lower limb implants than the upper limb, which led to more failure in lower limb implants. The upper-to-lower limb ratio of implant failure was 2:3, compared to 3:8 in the Sunil Kumar[16] study, 1:5 in Patil[21], 1:6 in Sivakumar[8], 1:2 in Sharma[13], 1:3.6 in Talib[18] and 1:2 in Abidi[23] In our study, significant factors that contributed more to lower limb implant failure were patient noncompliance and high body weight, which were similar to the Ogbemudia[12] study.

The patient's increased body weight and early weight bearing on the affected lower limbs put additional strain on the implant during the fracture healing phase. Early weight bearing before union result in implant loosening or fatigue failure. Patients having implant fixation surgery, particularly in the lower limbs, were encouraged to walk cautiously and gradually increase their weight-bearing. After analysing our study results, we discovered that the most common cause of implant failure was non-union, which accounted for 20 instances (40%) in our study group. The FDA's most widely accepted standard definition of non-union was a fracture that lasted at least nine months and showed no indications of healing for three months radiologically[30].

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. Fracture union was considered to be attained in patients who had healed four cortices on two tangential radiographs more than nine months after the initial injury[23]. Our analysis classified the reasons for non-union into two categories: Local factors included infection (2 instances., 10%), which resulted in a loss of blood supply, inadequate fracture fixation or stabilization (2 cases., 10%) and poor mechanical stability at the fracture site, all of which might reduce the fracture's healing potential. Clinical factors at the time of presentation could severely restrict blood supply, such as high-energy fractures with soft tissue compromise and open fractures (7 cases., 35%). Fracture patterns contributing to non-union include bone loss with fracture gaps greater than 3 mm, lack of cortical continuity, highly comminuted and butterfly fragments (4 cases., 20%)[30]. There were systemic causes like smoking causes vasoconstriction, which decreases blood supply[24]. Chronic alcohol users had an increased incidence of osteopenia, accompanied by decreased serum bone GLA protein (osteocalcin), a biomarker for active bone formation secreted solely by osteoblasts[25], increased advanced glycation end-product formation, reactive oxygen species generation and inflammation, which caused osteoblast differentiation to decrease and osteoclast activity to increase. Long-term oxidative stress in diabetic patients lowers bone mass and quality[26], peripheral vascular disease leading to decreased blood supply, NSAID, steroids, vitamin D insufficiency, low haemoglobin and endocrine causes (5 instances., 25%). All of these factors resulted in a decrease in osteogenic cells, damage to the osteoconductive scaffold, reduced new bone production and a decrease in the biologic growth factors required to repair the fracture.

In our data, non-union accounts for 40%, compared to 13.5% of implant failure cases in Patil[21] In our study, out of 20 cases of non-union, 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 indicates that there was adequate blood supply and biology (with the formation of callus) but inadequate stability[30] 12 cases of atrophic non-union with radiographically absent callus, which indicates 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 and thereby, reducing the new bone formation[30]. 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. In infected implant failure cases we discovered sinuses, wound dehiscence, purulent discharge from the site, and the presence of pus during revision surgery of these cases. Pathogenic organisms were detected through the culture of deep tissue or implant specimens obtained after the surgical intervention.

The laboratory study revealed a raised in WBC count, ESR and CRP. Clinically, the patient exhibited new-onset pain that was typically without weight bearing, which intensified with time, as well as local redness, swelling and an increase in local temperature. Infection affects callus development, causing fibrous tissue to form instead, impairing woven bone deposition and reducing mechanical stability and total osseous healing[27].

In our study, we discovered that open fractures could had been the source of infection. Bacteria can easily move down to the fractured bone where the protective skin barrier had been damaged, which was found in 30 cases (60%). The open: close injury ratio in our study was 3:2, while it was 3:7 in Sunil Kumar *et al*.'s study[16]. Because there were more open cases in our study, the infection case percentage was higher at 32%, compared-15.5% in Sunil Kumar *et al*.'s study[16]. Other causes of infection included failure to administer intravenous antibiotics in the first 60 minutes after the injury, no proper debridement of the infected, dead and necrotic tissues, improper wound irrigation and deficient wound care. To treat open fractures, patients should receive IV antibiotics within 60 minutes of arriving at the hospital. They should also be evaluated for tetanus vaccination requirements and taken to the operating room for irrigation (with normal saline low pressure- high volume) and debridement within 24 hours. Soft tissue coverage should be completed within 7 days of the injury[31]. Failure to complete these processes can lead to infection and definitive fixation before completing these vital steps would result in infection within the bone and eventually, implant failure.

Inability to maintain proper OT (operation theatre) atmosphere could be another reason for infection., in a standard OT environment, the minimum total air changes should be 20[32]. The fresh air component of the air change should be at least 4 air changes out of the total of 20 air changes[32]. The airflow should be unidirectional and downward on the OT table. The air face velocity of 25-35 FPM (feet per minute) from a non-aspirating unidirectional laminar flow diffuser or ceiling array is recommended[32]. The minimum positive pressure recommended is 2.5 Pascal[32]. There is a requirement to maintain a positive pressure differential between OT and adjoining areas to prevent outside air from entering OT. Positive pressure should be maintained in OT at all times (operational and non-operational hours)[32]. There is a requirement to maintain a temperature of 21 degrees Celsius (±3 degrees Celsius) and a relative humidity of 20-60%[32]. In our OT, there were frequent openings of OT doors, even after the commencement of surgery, which led to the upset of the positive pressure within the OT. Failure to maintain the above-mentioned OT standards can become the additional reason for the intraoperative infections[32].

Using an implant that had not been properly autoclaved, OT staff's lack of care for sterility, such as movement within the OT without masks and caps, not properly scrubbing, not wearing gloves in a sterile way, and not adequately painting and draping the operating site. Improper fumigation of the operating theatre following surgeries could be a source of infection.

Comorbidities such as diabetes, smoking and patients on HCV or HIV medication make patients immunocompromised and more susceptible to infections. Infections account for 32% (n=16) of the causes, according to our research, compared to 40% in the Onuoha K M study[20], 5.4% in the Patil *et al.* study[21], 2.4% in a study by Sharma[13] had implant failure linked to infection, 15.5% of cases in a study by Kumar[16] and 14% of cases in a study by Yusuf Ali Deoda[17] had infection. In our study 16 cases (32%) had shown signs of infections out of which 1 case (2%) developed septic non-union and 15 cases (30%) had septic implant loosening which is 18% in Yusuf Ali Deoda[17] and 18.8% in Sunil Kumar[16] Implant-related infections were caused by bacterial adherence to the implant surface and biofilm formation at the implantation site[19].

Inadequate fixation was responsible for 7 instances (14%) in our analysis, compared to 10.8% in Patil[21] 21% in Sanaullah study[15] and 39% in Sharma[13]. Inadequate fixation was attributed to the incorrect selection of implants. For example, we found two cases of subtrochanteric femur fractures that were treated with short PFN rather than long PFN, resulting in implant breakage. One example of proximal tibia fracture occurred when an LCDCP plate was put instead of a proximal tibia anatomical plate, resulting in varus collapse. One example of a shaft femur fracture was fixed using a small diameter and small length ILN femur as torsional rigidity and bending rigidity were proportional to the radius to the fourth power, this led to decreased stiffness of the construct and bending of the implant. One case of distal femur fracture with medial comminution in which only a lateral plate was placed, which eventually showed implant bending and one case of K nail fixation instead of ILN in shaft femur fracture due to the inability of an unlocked nail to provide rotational support at the fracture site, resulting in fracture fragment rotation[22]. Excessive or insufficient construct stiffness, mal-reduction, insufficient plate length, the inability to purchase both cortices can lead to implant failure. One case of failure occurred as a result of using 6-hole DCP for a shaft humerus fracture, which was treated with two cortical screws proximal to the fracture and three screws distal to the fracture, resulting in failure because a minimum of six cortices should be purchased in every bone: three proximal to the fracture and three distal to the fracture, but in this case only five cortices were purchased, leading to implant failure. Optimal number of cortices per bone are necessary for adequate plate fixation. In our study, we found 5 cases (10%) of noncompliance with postoperative recommendations, such as early weight bearing by the patient and 2 cases (4%) of lifting excessive weights. Patients' lack of physiotherapy, poor diet, smoking, alcohol consumption, failure to follow up on dressings, neglect of calcium and vitamin D3 supplementation after surgery, 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. In our study, 7 (14%) of 50 patients failed due to non-compliance, compared to 24.3% in Patil[21], 39% in Sharma[13] and 36.36% in Talib[18].

There are four principles of fracture fixation that were integral to optimal fracture fixation and healing. The first of which was fracture reduction to restore anatomical relationships. The second principle was fracture fixation to provide absolute or relative stability. The third principle was the preservation of blood supply to soft tissue and bone. The final principle was early and safe mobilization. These principles allowed for optimal bone healing and the prevention of delayed healing and non-union[28].

As observed in our study, plate failure (60%) was higher than nail failure (40%) as plate is a load-bearing device, thus all of the load is carried by the plate alone until the union of the fracture and if the patient starts bearing full weight at this point, failure would occur, as was the case in our study. Intra-medullary implants are load-sharing devices and provide good stability to fractures of long bones, allowing early rehabilitation and functional recovery in patients.

In comparison to unlocked intramedullary nail, locked intramedullary nails provide good axial and rotational stability. Plate fatigue failure was more common than nail fatigue failure because the intra-medullary position of nails in the shaft limits some bending stresses that cause fatigue failure. Plate fixation necessitates proper reduction and anatomical restoration and may interfere with periosteal blood flow. A poorly fastened implant combined with excessive soft tissue manipulation results in implant failure[16]. Plates and screws rigidly fix fractures, which in turn slows down the rate of callus formation. In our study callus formation in cases following internal fixation by plates was so minimal that the extent of ongoing union was more difficult to judge than in intramedullary nailing. The inherently slow rate of callus formation after plate fixation allows fatigue failure of the plate if subjected to cyclical loading, as would occur in early weight bearing[12]. Plate bending rigidity was proportional to thickness to the third power, but nail bending rigidity was proportional to radius to the fourth power, explaining why plates fail more easily than nails do. Hence, the inherent properties of rigidity of implants were the cause of failure.

Placing a concave bend on a plate is advantageous in transverse fractures because it ensures compressive forces occur on both the fracture's far and near cortices. In previous studies, similar results of plate failure were found: 73.2% in Sharma[13], 75% in Ogbemudia[12], 78.5% in Abidi[23] and 86.3% in Talib[18]. DCP was the most common implant failure in our study, accounting for 16 cases (32%), which was similar to other previous studies by Deoda[17](42%), Kumar[16] (42.7%), Sharma[13] (73.2%) and Talib[18] (86.4%). The possible reason for DCP to be the most common implant to fail was not giving a prebend to DCP plate before fixing them.

Subsequent data analysis showed that, in our study, the femur bone had the most cases of implant failure (40%) which was similar to other studies that found that this bone had the greatest number of implant failure cases in 47.62% of cases in Abidi[23], 52.1% in Ogbemudia[12], 54.6% in Talib[18], 56% in Sharma[13] and 67.5% in Patil[21] This can be due to the fact that the femur is the most significant bone for bearing body weight and a variety of loads and stresses act on the femur, particularly the proximal region, such that straight leg lift puts two times the body weight, typical walking puts three times the body weight, sitting on a chair puts four times, fast walking puts seven and sprinting puts 10 times the body weight stress on the femur.

During regular activities, the femur was susceptible to different types of loads and different parts of femur process different mechanical loads. Because of its composition, mechanical properties such as hardness, impact and bending characteristics differ from one region to another. The femur shaft hardens from proximal to distal. Hardness of femur was highest at the distal region and lowest at the proximal region, and as a result of the variable hardness, impact strength was higher at the proximal region and lower at the distal region. Between the ages of three and ninety years femoral cortical bone's impact energy absorption decreases by a factor of three[29]. As a result of this, the mid shaft of the femur was the most frequently failed site in our investigation (8 out of 20 femur instances; 40% at the mid shaft, equal to 40.5% in the Patil[21] study.

Similar to other research, the most frequent type of failure in our study (48%., n=24 instances) was broken implants. A study by Kumar[16], Deoda[17], Sharma[13] and Talib[18] found 39%, 42%, 63% and 68% of the total respectively. In our investigation, early weight bearing, cyclical loading in the absence of union and subsequent trauma postsurgery during the consolidation phase of fracture healing were the causes of breakage of implants.

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. Aseptic loosening was seen in 10 instances (20%) in our investigation, which was in coherence with 18.1% of aseptic loosening cases reported by Kumar[16] and Deoda[17].

CONCLUSION

There are innumerable reasons for implant failure. Accurate and precise assessments of reasons have been tried. Various reasons as per our study assessment are enlisted and discussed according to their occurrence, from the majority to the least common factors in order. The most common type of failure, according to our data, was broken implants (48%), which was followed by infective loosening (30%) and non-union (40%), which 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. Other elements that contributed to this were 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 were important to prevent and control hospital-acquired infections and to give correct irrigation, debridement and dressings for open fractures. Re-trauma, fall, disobedience to ambulation standards, non-union at the fracture site, and ongoing infection were found to be the causes of implant breakage. Orthopaedic doctors cannot be held liable for implant failure or breakage due to negligence in the part of the patients in post operative time. Various ways to assess and control implant failure have been studied and discussed in our study. So, appropriate measures can be taken to lessen the causes of failure and improve the outcome of the surgery, thereby reducing the factors for non-union and ultimately reducing hospital visits and revision surgery rates.

At last, various measures to consider are implant choice, better rehabilitation and compliance with physiotherapeutic measures, better control of nutrition, timely antibiotics, weight bearing as advised, diabetic status control, a healthy diet and proper follow-up for dressings, medications and compliance to other advises of the index surgeon.

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