

Evaluation of Implant Failure in Long Bones Fractures – A Retrospective Study

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Abstract

Background: Variety of implant design and quality are available and being used by orthopaedic surgeon to restore anatomy and enhance healing process of fractured bone. At times implants fail to achieve desired outcome in few cases and a repeat surgery is required. This study evaluates causes of implant failure in fracture long bones.

Methods: Retrospective study analyzing 53 patients with 66 long bone fractures with failed implants dividing them into plate, unlocked nails and locked nails group was performed at level – I trauma centre of tertiary level medical college in North India, during January 2011 to March 2014. After thorough clinico-radiological evaluation, results were analyzed.

Results: Maximum implant failure occurred in 20-50 yrs of age. Lower limb long bone implant failure 48 (72.7%) was more common than upper limb long bones 18 (27.3%). In all three groups fatigue failure (39%) was most common followed by bending (27.2%), loosening (18.8%) and infection 15.5% was observed. Implants differ in design and quality from manufacturer to manufacturer. Surgeons had chosen implants according to their technical knowledge and surgical skills. Re-trauma and patient non-compliance with instructions was also important cause of implant failure.

Conclusion: Cause of implant failure is multi-factorial hence we recommend use of suitable design and quality implant to match fracture configuration with proper surgical techniques. Patient should be educated and followed up according to rehabilitation protocol to avoid disappointments.

Keywords; Implant failures, Fatigue failure, Long bone fractures, Implant corrosion, Implant loosening

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Introduction

Fractures of long bones are common fractures encountered in Orthopaedic surgery. They are result of significant trauma and are often associated with considerable soft tissue damage. Trauma may vary from low to high to very high velocity changing the radiological and clinical picture in every case. Incidence of trauma related surgeries has increased in order to provide early rehabilitation and good quality of life.

The implants are used to provide stability to fractured bone and maintain reduction and thus help in reducing fracture disease. Orthopaedic surgeons have been using variety of implants since past. Some implants have not shown good patient compatibility resulting in non union and infection in few cases. They are manufactured using different types of materials such as cobalt-chromium alloys, stainless steels, titanium and alloys that are in optimum combinations of biocompatibility, corrosion resistance, mechanical strength and cost effectiveness^(1,2). 316 L austenitic type stainless steel is used in vast majority of implant but use of titanium and its alloys is on the rise. Implant failure

is a complication associated with fracture management, screws and plates pull out, nails and plate loosen, bend and break and rods and pins migration.

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.

The aim of this study was to evaluate the cause of implant failure in fractures of long bones with intent to reduce the likely hood of reoccurrence.

Material & Method

The patients attending the orthopaedic OPD and level – I trauma centre at tertiary level medical college in North India, with fractures of long bones treated in past, where primary implant had failed to achieve the desired outcome and repeat surgery was required were included in study. The failure in achieving the desired outcome would be due to implant based factors; e.g. breakages, bending, corrosion/ metal reaction, patient based factors like early ambulation, excessive weight, poor hygiene care, non compliance to instructions or surgeon based factors or a combination of these or due to re-trauma. 53 patients with 66 long bones with implant failure were included and analyzed retrospectively for the evaluation of implant failure during Jan 2011 to March 2014.

After selection patients were subjected to thorough history taking including mode of trauma, associated injury and illness, post operative activities including beginning of range of motion, ambulation and weight bearing on operated limb before bone healing. History of re-trauma and infection was also taken.

All the necessary pre-operative, post operative data was collected and patients were divided into 3 groups of plate, unlocked intra-medullary nail and locked intra-medullary nail and then further necessary investigations were carried out to evaluate the cause behind the implant failure in these cases.

Result & Observations

Out of 53 patients there were 47 (80.3%) males and 6 (19.7%) female cases with age ranging from 7 yrs to more than 60 yrs. Maximum failure occurred in age group of 20 - 50 yrs. Out of total 66 long bones, implant failure was observed in 28 (42.7%) bones managed with plates, 22 (33.3%) bones managed with unlocked intra-medullary nails and 16 (24.2%) bones managed with locked intra-medullary nails. (**Table 1**)

Implant failure was observed more commonly in lower limb 48 (72.7%) long bone fractures (femur & tibia) as compared to upper limb 18 (27.3%) long bones (humerus, radius, ulna).

As per history and record analysis, out of 66 long bone fractures, 20 (30%) cases had open wounds at the time of initial injury 46 (69.7%) cases had close injury. Retrospective radiological analysis showed 40 (60.6%) long bones had unstable fracture configuration as

compared to 26 (39.3%) having stable fracture pattern at the time of initial trauma. (**Table 2**)

57 (86%) long bone fractures were managed by open reduction techniques (28 with plates, 18 with unlocked nails & 11 with locked nails) as compared to only 09 (13%) long bones managed by closed reduction technique (4 with unlocked nail & 5 with locked nail) by surgeons at the time of initial surgery (**Table 2**).

With in 28 plate failure group we found infection in 3, loosening in 5, bending in 7 and fatigue failure in 13 cases. Where as in 22 unlocked nail group bending of implant in 11, loosening in 4, fatigue failure in 4 cases and infection in 3 cases was observed. In 16 locked intra-medullary nail failure group, fatigue failure in 9 cases, loosening in 3 and infection in 3 cases were observed as the cause of implant failure (**Table 3**). Improper selection of implant and poor surgical techniques, skills were found to be more responsible for implant failure in study. Surgeons preferred open reduction techniques in most of the cases for fracture fixation. Improper selection of implant resulted in instability, non-union and subsequently fatigue failure, bending, loosening occurred with loading or re-trauma in few cases. Patient's non compliance during rehabilitation and early ambulation was also found to be responsible for implant failure.

In our study fatigue failure 26 (39%) was more common among the failed implants, followed by bending 18 (27.2), loosening 12 (18.8%) and infection 10 (15.5%).

Table 1: Numbers of failed implants and groups

Number of failed implant in groups		
Group	Frequency (n=66)	
Plates	28	42.4%
Unlocked Nails	22	33.3%
Locked Nails	16	24.2%

Table 2: Nature of injury, fracture pattern and surgical procedure adopted by surgeons according to implant groups

Group	Nature of Injury		Fracture Pattern		Surgical Procedure	
	Close	Open	Stable	Unstable	ORIF	CRIF
Plates (28)	19	9	17	11	28	---
Unlocked Nails (12)	14	8	6	16	18	4
Locked Nails (16)	13	3	3	13	11	5
Total	46 (69.69%)	20 (30.30%)	26 (39.39%)	40 (60.60%)	57 (86.36%)	9 (13.63%)

Table 3: Reasons of Implant Failure

Implant group	Infection	Bending	Loosening	Fatigue Failure	Total
Plates (28)	3	7	5	13	28
Unlocked Nails (22)	3	11	4	4	22
Locked Nails (16)	4	--	3	9	16
Total (66)	10 (15.15%)	18 (27.27%)	12 (18.18%)	26 (39.39%)	66



Fig. 1: X-ray showing poor fixation and improper selection of implant for ulna fracture with broken and corroded plate in radius



Fig. 3: Radiograph showing fracture at distal tibia with broken plate



Fig. 2: Broken and corroded plate with screw after removal



Fig. 4: X-ray showing broken locked intra-medullary nail



Fig. 5: X-ray showing loosening of locked intra-medullary nail

Discussion

With every surgical procedure and implantation in orthopaedic there starts a race between implant failure and healing process of fracture⁽³⁾. Implant failure can be in form of plastic deformation, corrosion or fatigue failure. Mechanical failure of implant can result due to repetitive loading and stress. In absence of union even the toughest metallic device and best designed implants are known to fail⁽⁴⁾.

Technical aspects of implant failure have been studied in various studies^(2,5,6,7,8). According to laboratory results from two studies Azevedo in Brazil and Amel Farad H in Iran, manufacturers did not follow the standards in their cases of failed implant analysis. It is possible that implants differ in terms of purity and alloy inclusion from manufacturer to manufacturer⁽⁸⁾. In another study by Barbosa on three cases of implant failure, surgical technique and implant design, selection of implant have been reported to be important cause of implant failure⁽⁶⁾. Studies on implant quality control, designing errors are out of scope of this research and are limiting factors.

In study by Sharma et al 2.4% implant failure was associated with deep infection⁽⁵⁾. In our study infection was found in 10 cases (15%). This infection was superficial to deep and associated with loosening of implant. Infection could have occurred during the surgery due to faulty surgical technique of open reduction and fixation of implant. Re-trauma is also major factor of implant failure during consolidation

phase of fracture healing. Sharma et al have also found re-trauma as significant cause for implant failure in their study.

Excessive body weight of the patient and early weight bearing on affected lower limb imparts more stress on implant during the healing stage of fracture. During the stance phase of gait cycle, load on lower limb is more than three times the body weight. Alfred O. Ogbemudia et al in their study found patient non compliance and excessive body weight as significant reason for failure of implant and suggested cautious ambulation and graduated weight bearing⁽⁹⁾.

Plastic deformation, brittle and fatigue failure are known to occur with minor loads and re-trauma. 39% Fatigue failure was observed in all cases in our study. Fatigue failure is associated with poor design, workmanship, handling and implant breaks from cyclical loading⁽³⁾. Surface notches or holes severely affect fatigue strength. Scratches or corrosion can also reduce the strength and predispose to implant failure. Fatigue failure of plates is more common than nails as intra-medullary location of nails in shaft prevents some bending forces responsible for fatigue failure⁽¹⁰⁾. Plate ends act as stress riser leading to fresh fractures at ends. Plate fixation requires perfect reduction and anatomical reconstruction and may interfere with periosteal blood supply⁽¹¹⁾. Poorly fixed implant with excessive soft tissue handling leads to failure of union and implant.

Intra-medullary implant are load sharing and provide good stability to fractures of long bone, allowing early rehabilitation and functional recovery of patient. Locked intra-medullary nail provide excellent axial and rotational stability as compared to unlocked intra-medullary nail. Intra-medullary implant failures occur with small diameter nail, improper selection of implant which is not suitable for unstable fracture configurations. Failure to provide rotational stability at fracture site leads to loosening of implant and failure⁽¹²⁾.

At times inability to select a suitable implant to match the fracture configuration or a improper surgical technique to restore fracture anatomy, inadequate fixations, pre/ post-operative complications like infections, patient non-compliance with implant instructions and degree of union lead to failure of implant⁽¹³⁾.

Conclusion

Considering the above reasons we have reached to conclusion that cause of implant failure is multi-factorial in long bone fractures. We recommend selection of proper design and quality implant to match fracture configuration. Also thoroughly guide the patient regarding the rehabilitation protocol to avoid implant failure and prevent patient's suffering and cost associated with implant failure.

Abbreviations:

n = Number of fractured long bones with failed implants

ORIF = Open reduction and internal fixation technique.

CRIF = Close reduction and internal fixation technique.

Conflict of Interest: None**Source of Support: Nil****References**

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