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Original Research Article

A COMPREHENSIVE STUDY ON IMPLANT BREAKAGE IN INTRAME- DULLARY INTERLOCKING NAILS OF LONG BONES

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ABSTRACT

Background: Traditionally long bone diaphyseal fractures are being treated with inter- locking nails. Being minimally invasive, excellent functional outcome. However, some- times these implants fail in form of nail breakage before union. Our study aims at studying cases of nail breakage in long bones, pattern of breakage and their possible causes.

Materials and Methods: This is retrospective study carried out at Tertiary hospital between 2009 to 2016. 45 Patients with broken nails in femur, tibia and humerus were included in this study. Broken nails were removed and refixation done. The broken nails were studied to understand the pattern of breakage. Detailed history and x-rays were studied to under- stand the possible causes of the implant failure.

Results: Majority of the cases were in the age group 20-40 years with male predominance. There were 25 cases of femur,20 of tibial and 2 cases of humerus IMIL nail breakage respectively. Most of the nail breakage had occurred in cases with fracture of dist al 1/3 shaft of bone (46.67%). most cases of breakage occurred at distal 1/3 nail region (68%). Among the causes of nail breakage, surgeon related causes were found in 14 cases (31.11%), patient related in 7 (15.56%), multifactorial causes in 14 (31.11%) and un- known cause in 10 (22.22%).

Conclusion: The IMIL Nail is good treatment option but its breakage is related to mul- tiple factors. The surgeon related factors are most common cause of nail failure. Accurate technique, correct size and choice of implant, good patient compliance are all important to avoid implant failure and achieve good fracture union.

Keywords: Long bone fracture; Intramedullary interlocking nail; IMIL nail; Implant failure; Nail breakage.

INTRODUCTION

Diaphyseal fractures in long bones is a common occurrence and the cases are on a rise with increase in cases of road traffic accident. Conventionally these fractures have been treated with intramedullary interlocking nails.[1] In all designs of nail, the nail initially holds a considerable portion of external loads which is increasingly shared with the bone as the fracture consolidates. Due to the evident dimensional restraints of the intramedul- lary canal, even after the consolidation a nail can sustain close to 50% of the initial ex- ternal loads.[2,3] These nails provide minimally invasive treatment method that allows early mobilization and early weight bearing of the patients, hence improving functional out- come4. However due to the design shortcomings of the interlocking nail, nail breakage may sometimes

occur. There is an increasing incidence of nail failure reported in the literature.[3,5-8] Although articles have also appeared reporting nail breakage after bony union,[9,10] it usually occurs before bone healing is complete. In other words, in cases of nail breakage, a secondary surgical intervention must usually be performed to promote fracture healing. Above all, the revision procedure becomes more complex: open reduc- tion, removal of the failed implant, insertion of a new implant and cancellous bone grafting are all part of the routine procedure. Sometimes a lengthening procedure must be added. The surgical risk is markedly higher in the late operation than in the early one. For this reason, prevention of implant failure should be more important than treatment.[11] There can be several reasons for the breakage and failure of these nails, including patient factors, surgeon factors, metallurgical causes or multifactorial. Our study aims at study- ing these cases of nail breakage, its pattern of breakage and finding out possible causes of these implant failure.

MATERIAL AND METHODS

This was a retrospective (2009-2014) study carried out between August 2009 to August 2014, at Tejasvini Hospital & SSIOT, Mangalore. In this study patients treated with in- tramedullary interlocking nails for diaphyseal fractures in femur, tibia and humerus who had broken implants were enrolled. A total of 45 such patients were studied 42 were done elsewhere and 3 were done at our institute. All these patients had Clinical & radiological evidence of non-union at fracture site. Cases with nail breakage in united fractures were excluded. On enrolling, thorough history was taken and all previous radiographs were collected and studied and the probable cause for each failure was analyzed. The causes of implant failure were in terms of: (1) Surgeon-related factors where the technique used by the surgeon was not the most ideal / recommended or there was an improper selection of implant. (2) Patient-related factors: where there was non-compliance of patient in terms of early weight bearing, bad fracture pattern, comorbidities known to delay healing and re-trauma in consolidation phase. (3) Multifactorial where there was no single distinct cause known. (4) Unknown factors: when no particular cause of failure could be outlined. All the patients underwent revision surgery in the form of Exchange nailing ± bone graft- ing for Femur or tibia or open reduction & plate osteosynthesis ± bone grafting for Hu- merus depending on whether the cause of failure was mechanical, biological or both. The broken distal parts of nail were removed by following methods: (a) Nail extractor hook
(b) Opening the fracture site in cases where bone grafting was done. (3) “Rail- Road” Technique for Femur nails in which hook did not fit. The extracted broken nails were analyzed visually for presence of any metallic abrasions at screw hole site which showed that the Surgeon had inadvertently drilled eccentrically during screw insertion which could have led to mechanical weakness of the nail. A Statistical software SPSS vers. 17.0 (SPSS Inc. Chicago) and MS Excel vers. 2010 was used to do the analysis.

RESULTS

T Of the 45 patients, most of the patients in our study (73%) were in the age group of 20 - 40 years, with male predominating (80%). Right side Intramedullary Interlocking nail failure was more common than left side in our study with right: left ratio being 5: 4. there were 12 cases of open fractures (7 cases of type II and 5 cases of type III open fracture as per Gustilo-Anderson classification). Out of 45 cases there were 2 cases of segmental femur and tibia nail breakage. So, there were in all 47 nail breakage cases comprising of 25 femur IMIL nail breakage, 20 tibial nail breakage and 2 cases of humerus nail break- age. In this study we found that most of implants failed during 7-12 months post-operative period (71.1%) with mean implantation age of 9.5 months. Out of all the cases, 34 cases had Indian interlocking nails and 11 cases had imported interlocking nails. Most of the nail breakage had occurred in cases with fracture of distal 1/3 shaft of bone 21 cases (46.67%). [Table 1]
The nails were divided into proximal 1/3, middle 1/3 and distal 1/3 regions. Nine nails were broken at proximal 1/3 region (19.14%), six nails broken at mid-1/3 (12.76%) and thirtytwo nails broke at distal 1/3 region (68%).
Among the causes of nail breakage, surgeon related causes were found in 14 cases (31.11%), patient related causes in 7 (15.56%), multifactorial causes in 14 (31.11%) and unknown cause in 10 cases (22.22%).
Femoral nail failures: The mean time from initial IM Nailing to nail failure was 9.5 months (range from 4-19 months). Of the 24 femoral nail failures, 16 broke at the distal third level (12 at the proximal hole of the distal interlocking holes and 4 at the distal hole) (Picture:1), whereas 4 nails broke at the middle third and 3 at the proximal third of the femur.

Figure 1: shows broken femur nail at proximal screw slot of distal locking screws

Tibial nail failures: The mean time from intramedullary interlocking nailing to tibial nail failure was 9.42 months (range 4–18 months). Of the 19 failures, 1 broke at the middle 3rd of the nail, 12 broke at proximal hole of the distal third, 4 broke at the proximal third (Picture:2), 2 broke at distal most screw hole site.

Figure 2: Shows Tibia nail broke at distal slot of proximal locking screws

Humeral Nail Failures: The mean time from humeral nailing to failure was 6.5 months (range 4-9 months). Of the two humeral nail failure, 1 broke at middle 3 rd and other at distal 3rd at proximal of distal locking screw (Picture:3).

Figure 3: shows broken humerus nail at proximal screw slot of distal locking screws

Table 1: Showing number of cases with location of fracture of femur, tibia and humerus re- spectively

SITE OF BONE FRACTURE	FEMUR	TIBIA	HUMERUS
PROXIMAL 1/3	4	3	0
MIDDLE 1/3	10	6	1
DISTAL 1/3	10	10	1

DISCUSSION

In our study we found that the incidence of implant failure was predominantly in males (4:1) and in the age group of 20-40. This indirectly points to the fact that shaft fractures are very common in this age group as against elderly population. We found that 12 of the cases were of open type. most of open fractures have devitalised bone and no matter how well the fixation is done, the healing will be impaired considering the abnormal biology. Also, in most of these cases there was significant comminution / bone loss which adds on to the impaired healing similar finding were report by Gardner et al reported open and comminuted distal femur fracture often associated with nonunion.[12] So, a Surgeon must be extra cautious in dealing with open injuries, bone loss. Most of the nail failures occurred in distal shaft fractures and most nails broke in distal 1/3 part, suggesting in distal fracture healing is delayed leading to fatigue nail breakage.[13] The 2 distal holes are the most common site of nail failure because of stress concentration caused by the hole effect and slot effect. Nicking the area by drilling around the distal holes during distal locking further weakens the strength of the nail holes and increases stress.[13] In distal fractures, there is a greater bending load at the middle hole because it is closer to the fracture site than the distal hole and causes more nail failure. The choice of implant depending on fracture type can avoid fatigue implant failure as IMIl and Locking plate both give similar results 14. To compare the findings of our study with other studies as reported in literature, we analyzed breakage of nail at three levels. [Table 2]

In this study, we analysed the different causes of nail failure. We found the following causes of nail failure overall:

1. Surgeon-related factors:- a) Small diameter nail in eleven cases of femur and six cases of tibia fracture. b) Improper reduction in four, two, one cases of femur, tibia, and humerus cases respectively. c) Fixation in distraction in four cases of femur, four of tibia, one of humerus fracture case. d) Eccentric drilling for screws in 5 cases (picture:4). e) Plastic deformity of nail during insertion in three femur and one case of tibia. F) Improper implant for the fracture patter-three cases of femur.

Figure 4: Shows nail broke at site of nicking

2. Patient-related factors. a) Noncompliance (early weight bearing) in 3 cases of femur b) Fracture pattern – open / comminuted / bone loss. - 4 cases of femur, 8 cases of tibia c) Comorbidities / addiction- 5 cases of femur and 4 cases of tibia d) Re-trauma- 2 cases of tibia, 1 case of humerus
3. Combined –cases with surgeon and patient related factors. 7 cases in femur, 6 cases in tibia and 1 case of humerus
4. Unknown causes – the cases in which a clear cause was not apparent, were labelled as due to "unknown causes"- 5 cases of femur and 5 cases of tibia.

A case of implant failure needs surgical intervention. It has to be borne in mind that each successive surgery is more difficult than the index surgery.[10] So, for any fracture pattern proper pre-operative planning is mandatory and the surgeon must anticipate any difficul- ties in surgery and be well-equipped to handle it. The surgeon must have all sizes (diam- eter and length) of nails available intra-operatively. In few scenarios, where the fracture pattern is bad, the Surgeon must take a decision to intervene. In case of a large, far -lying wedge fragment especially if it is reversed, a mini-open reduction & encirclage wiring will be more beneficial. In case of bone loss, the surgeon must not hesitate to do bone grafting either as primary procedure or as an adjunct during initial period after about 2 -3 months if there are no signs of healing. The surgeon must review the immediate post-operative radiograph to check for any signs of plastic deformity of the nail, malreduction, fixation in distraction and in such scenario, it has to be redone as early as possible. Dy- namization if required needs to be done early (2-3 months) to reduce fracture gap and promote healing. After the surgery, the patient must be properly counselled about the protocols for exercises and weight bearing and must strictly adhere to it to prevent fail- ures. Treatable / controllable comorbidities if any like cigarette smoking, diabetes must be taken care of to prevent delay in healing. It must be borne in mind that even when all the factors have been properly taken care of, there can still be failures due to inherent defect in nail manufacturing process and hence using standard company nails would be better.

CONCLUSION

To conclude, intramedullary interlocking nail is an excellent treatment option in case of diaphyseal fractures of long bones. However, if the surgeon doesn't take proper care in the technique of nailing, choose wrong sized implant, wrong choice of implant, the implant can fail. Some patient factors like bad fracture personality, early weight bearing, comorbidities/ addiction or re-trauma also contribute to implant failure. Nail breakage occurs most commonly in distal 1/3 fractures and in the distal 1/3 of the nails. Ultimately it is a race between fracture union and implant fatigue and the surgeon, the patient must ensure that all necessary steps to aid the fracture union must be taken care of so that the fractured bone goes on to heal uneventfully.

Limitation of Study

5. This study doesn't include cases of implant failure, where fracture are united. So, causes of nail breakage in such cases needs to be studied
6. Metallurgical and biomechanical studies are excluded from this study which can also aid in understanding the nature, pattern and cause of particular nail breakage.

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