

Interlocking nails: Indian or imported? A study of 131 patients

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Abstract

Background: Currently, intramedullary nails used for displaced mid-shaft fractures of tibia and femur are either made locally or imported. For a majority of Indian patients, cost of imported implants could be a constraint. In spite of their extensive use, there is no published data comparing their performance with respect to bony union and complication rates.

Objective: To compare bony union and post-operative complication rates when Indian and imported nails are used for mid-shaft fractures of tibia and femur.

Methods: Retrospective analysis of patients having undergone reamed antegrade interlocking nailing for mid-shaft (AO Type A1 for femur and OTA type A for tibia) closed femoral or tibial fractures between January 2005 and December 2014. Adult patients with a minimum follow-up of 1 year after the index surgery were included.

Results: Records of 131 patients (137 surgeries) were analyzed. There were 103 males and 28 females with mean age 36.9 ± 15.6 years (range 18-76 years). High velocity injuries had contributed to 105 (76.6%) fractures. There were 92 (67.2%) tibial mid-shaft fractures and 45 (32.8%) femoral mid-shaft fractures. Indian nails were used in 64 (46.7%) and imported nails in 73 (53.2%) surgeries. Significantly more femoral fractures were treated using imported nails as compared to tibial fractures (68.9% Vs 45.7%; $p < 0.005$). Bony union was slightly, but not significantly delayed in the imported nails group for both fractures. No rod breakage, breakage of locking bolt or revision surgery was found in either group. No statistically significant association found between type of implant and radiological non-union.

Conclusion: Both, Indian and imported interlocking nails yield similar radiological outcome.

Keywords: interlocking nails, femur, tibia, Indian implants, complications

Introduction

Tibial and femoral mid-shaft fractures are among the most common long bone fractures. Interlocking nailing is the treatment of choice for mid-shaft fractures of tibia and femur [1,2]. Current practice is to use intramedullary nails that are locally made or imported from abroad. A majority of Indian surgeons are inclined to use imported implants because of better company support and presumed quality of implants and instruments. In India, there is lack of information about the source and type of metal used, and details about the manufacturing processes and quality control standards of manufacturers of Indian implants. There is a huge difference in the cost of the two: imported nails being almost four times as expensive as Indian nails. Choice of implant make is important from the patient's viewpoint due to financial implications and its effect on outcomes. For a majority of Indian patients, cost could be a constraint while choosing imported implants. Patients very often ask the treating surgeon whether the make of the nail used (Indian/imported) affects the bony union and complication rates. In spite of being extensively used

all over the country, there is no published data evaluating performance of Indian interlocking nails in these aspects. We report findings of our retrospective study specifically looking at whether there is a difference in the bony union achieved and postoperative complication rate when Indian and imported nails are used.

Subjects and Methods

This study was approved by the Ethics Committee of our Institute. We carried out a retrospective analysis of patients who had undergone reamed interlocking nailing for mid-shaft (AO Type A1 for femur and OTA type A for tibia) closed femoral or tibial fractures. We included data of patients operated between January 2005 and December 2014 at our hospital (a teaching charitable trust hospital in urban setting). Patients more than 18 years of age and a minimum follow-up of 1 year after the index surgery were included. All cases where reamed antegrade nailing was performed were included. Patients with incomplete data were excluded from the study. All data was retrieved from the electronic hospital information system. Patients were divided into two groups for analysis: Group A: Indian interlocking nails and Group B: Imported interlocking nails. Demographic data, associated systemic comorbidities and mechanism of injury (high or low velocity) were noted in each case. Implant details such as diameter and length and number of locking bolts used were noted for both, groups A and B. Also, details of post-operative events such as infection, duration (in weeks) to

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achieve radiological bony union (defined as presence of bone trabeculae crossing the fracture site on at least three cortices at the fracture site), non-union or delayed union, implant failure (breakage of the interlocking bolt, rod breakage, bent nail, backing out of the implant), requirement of revision surgery and implant removal were noted. Data was analyzed using SPSS 20.0 for Windows by applying chi square test, two-tailed Fisher's exact test and Student's T test for independent samples.

Results

Indian nails manufactured by two CE certified Indian companies were used. Similarly, imported nails that were used were also made by two companies. Implant selection was done based on a joint decision by surgeon and patient. All procedures were done in the antegrade manner under image intensifier control by 6 orthopedic surgeons of similar number of years in practice and similar expertise in trauma surgery. Piriformis entry point was used in all femora and the patellar tendon splitting approach was used for tibial procedures. All femoral surgeries were performed in supine position with patient on fracture table. All tibial surgeries were performed in supine position on standard radioluscent table with a bump underneath the knee to maintain flexion. We found complete data of 131 patients. There were 103 males and 28 females with mean age 36.9 ± 15.6 years (range 18-76 years). High velocity injuries were

fractures. All patients with tibial fractures had fibular fractures and 3 patients also had femoral fractures. Out of the 137 surgeries, 64 (46.7%) were performed using Indian nails, while imported nails were used in 73 (53.2%) of them. Significantly more femoral mid-shaft fractures were treated using imported nails as compared to tibial fractures (68.9% Vs 45.7%; $p < 0.005$). Not a single case of implant failure in terms of rod breakage, breakage of locking bolt or revision surgery was found in either group. Characteristics of patients with tibial and femoral mid-shaft fractures are shown in tables 1 and 2 respectively. None of the differences in the characteristics between the two groups (Indian and imported nails) were significant. No statistically significant association was found between type of implant used and occurrence of radiological non-union. Also, no significant association was found between presence of comorbidities such as diabetes and hypertension and post-operative complications in both groups of nails in either type of fractures (data not shown). Imported nails were used in a significantly greater proportion of older patients with femoral mid-shaft fractures ($p=0.01$). The diameters as well as lengths of interlocking nails used for both, tibial and femoral mid-shaft fractures were similar in the Indian and imported groups. Time required for bony union was slightly more in the imported nails group for both fracture types; however, this difference was not significant (Table 3).

found to have contributed to 105 (76.6%) fractures. Among the 131 patients, there were 92 (67.2%) tibial mid-shaft fractures in 74 males and 15 females (male to female ratio 5:1). The mean age was 38.2 ± 15 years. There were 45 (32.8%) femoral mid-shaft fractures in 29 males and 13 females (male to female ratio 2:1) with mean age of patients being 34.3 ± 16.4 years. None of the patients had isolated tibial

Table 1: Characteristics of patients with tibial mid-shaft fractures (N= 92)

Characteristics	Indian implant n = 50	Imported implant n = 42	P value
Sex (n = 89)			
Male	40 (85.1%)	34 (81%)	0.6
Female	07 (14.9%)	08 (19.0%)	
Mode of Injury			
Low velocity	14 (28.0%)	11 (26.2%)	0.84
High velocity	36 (72.0%)	31 (73.8%)	
Co-morbidities			
Yes	10 (20.0%)	06 (14.3%)	0.47
No	40 (80.0%)	36 (85.7%)	
Type of intramedullary nailing			
Open reduction	01 (2.0%)	01 (2.4%)	0.7
Closed reduction	49 (98%)	41 (97.6%)	
Non-union			
Yes	02 (04.0%)	03 (07.1%)	0.5
No	48 (96.0%)	39 (92.9%)	

Table 2: Characteristics of patients with femoral mid-shaft fractures (n= 45)

Characteristics	Indian implant N = 14	Imported implant N = 31	P value
Sex (n = 42)			
Male	12 (85.7%)	17 (60.7%)	0.09
Female	02 (14.3%)	11 (39.3%)	
Mode of Injury			
Low velocity	01 (7.1%)	06 (19.4%)	0.29
High velocity	13 (92.9%)	25 (80.6%)	
Co-morbidities			
Yes	02 (14.3%)	07 (22.6%)	0.52
No	12 (85.7%)	24 (77.4%)	
Type of intramedullary nailing			
Open reduction	1 (7.1%)	0	0.13
Closed reduction	13 (92.9%)	31 (100%)	
Non-union			
Yes	0	02 (06.5%)	0.33
No	14 (100)	29 (93.5%)	

Table 3: Difference in Indian and imported implants

Characteristics	Indian implant Mean \pm SD	Imported implant Mean \pm SD	P value
Tibial mid-shaft fractures (n=92)			
Age of patient (yrs)	37.6 \pm 15.4	38.8 \pm 14.7	0.69
Length of nail (cm)	332.1 \pm 24.0	336.5 \pm 27.5	0.41
Diameter of nail (mm)	9.55 \pm 0.6	9.29 \pm 0.68	0.06
Hospital stay (days)	6.8 \pm 3.0	6.9 \pm 4.0	0.83
Time for radiological bony union (days)	134.4 \pm 55.4	140.4 \pm 58.8	0.61
Femoral mid-shaft fractures (n=45)			
Age of patient (yrs)	27.2 \pm 9.5	37.5 \pm 17.9	0.01
Length of nail (cm)	365 \pm 40.9	358.5 \pm 55.4	0.69
Diameter of nail (mm)	9.64 \pm 0.63	9.87 \pm 0.76	0.33
Hospital stay (days)	13.2 \pm 10.6	10.1 \pm 5.3	0.18
Time for radiological bony union (days)	163.9 \pm 67.3	185.3 \pm 115.5	0.52

Discussion

This study highlights non-inferiority of Indian nails when compared to imported ones for treating mid-shaft femoral and tibial fractures as both were found to have similar complication rates and time to union. Femoral and tibial mid-shaft fractures are common and majority are treated with reamed intramedullary nailing. Implant selection forms an important part of treatment plan of any fracture undergoing surgical treatment. Choice of implant is based on fracture geometry, surgeon's preference, instrumentation and patient's preference. There is a significant difference in the cost of the two: imported nails being generally four times as expensive as Indian ones. Common questions asked by patients are whether use of any one particular type affects risk of complications and outcome of fracture treatment. To the best of our knowledge, this is the first study that provides information regarding how Indian-made interlocking nails perform as compared to imported interlocking nails. The only other study has compared Indian and imported pedicle screws and has shown that the complication rate is similar in both groups [3]. In this study, Rawall and co-authors have shown that there was no statistically significant difference in failure rates of Indian pedicle screws and foreign pedicle screws

(0.56% Vs 0.15%). The functional outcome was the same in both groups (87% excellent or good functional outcome). In our study, the rate of non-union was almost the same in both groups. Among tibial fractures, 4% in the Indian group and 7% in the imported group had non-union. Among femoral fractures, the rate was 0% and 6.5% respectively. These rates are consistent with the non-union rates described in literature [4–6]. There were no implant related complications observed in our study. Implant related complications such as broken nails, broken interlocking screws and bent nails may happen because of numerous reasons. Size of the implant, fracture pattern, weight of the patient, design of the nail, quality of implant/metal and patient's activity level play an important role in implant related complications [7–10]. However, in our study, there was no significant difference in the diameters and lengths of

interlocking nails between Indian and imported groups. Our study has several limitations such as lack of objective functional outcome measure and lack of comparison of mechanical properties of two implants. From the available data, it was not possible to comment on the quality of the instruments and surgeon's comfort. We do accept that apart from familiarity with the instrument and individual experience, "good" quality implants increase the surgeon's comfort levels and may lead to preference for that particular make of implant. Further studies are necessary to address these questions.

Conclusion

Our findings suggest that Indian interlocking nails are as good as imported interlocking nails and both yield similar complication rates and radiological outcomes.

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