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Mechanical properties of regionally (India) manufactured versus internationally manufactured intramedullary tibial nails - A pilot study

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ABSTRACT

Purpose: Despite the advances in fixation methods for tibial shaft fractures using intramedullary nails (IM), implant failure continues to be a major cause for reoperation. The failure of an implant depends on its physical, chemical and biomechanical properties. Biomechanical properties of tibial nails from international manufacturers have been exhaustively studied and reported. Regionally manufactured nails lack such specific biomechanical data from independent researches and surgeons. In this pilot study, we analyzed the biomechanical properties of three commonly used regionally manufactured nails in comparison to three internationally manufactured nails available in the market.

Methodology: A total of six titanium IM nails from six manufacturers (three regional manufacturers (India); R1, R2, R3 and three international; G1 G2, G3) were procured and subjected to static four-point bending tests and static axial loading test according to the American society for testing materials (ASTM) F1264 guidelines. The bending structural stiffness and fatigue strength were then calculated.

Results: The load required for plastic deformation for regional nails were 2520 Newtons (N) for R1, 2760 N for R2, 2760 N for R3 and for international nails, it was 3070 N for G1, 2220 N for G2, 2930 N for G3. The comparative data suggests that the internationally manufactured nails were much stiffer than the regional nails.

Conclusion: This pilot study provides a reference to the Orthopaedic community about the standards of existing intramedullary nails. This data is a value addition in expanding the research and to direct towards reforms in the standardization of manufacturing and usage of the intramedullary nails.

1. Introduction

Tibial shaft fractures are one of the most common long bone fractures, majority of them from a high energy motor vehicular accident with a bimodal age distribution.[1,2] Intramedullary fixation is one of the most common methods of surgical treatments of tibia shaft fractures. In spite of many advancements with intramedullary nails over the years, implant failure continues to be a major cause for re-operation.[3] The failure of an implant depends on its physical, chemical and biomechanical properties. Biomechanical studies on tibial nails from global manufacturers has been exhaustively studied previously.[4–11] However, in India apart from isolated clinical studies which have observed that regionally made nails have a higher incidence of implant failure,[12] there is a paucity of research data regarding the biomechanical properties of indigenously manufactured nails. A large number of patients undergo surgical fixation of the tibial fractures with regionally manufactured nails due to cost constraints, so

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knowledge about the biomechanical strength of the available nails would help the Orthopaedic surgeon in selecting the right implant. The objective of this pilot biomechanical study was to compare the mechanical properties of commonly available intramedullary tibial nails in India, from both international and regional manufacturers. The data generated from this study would help guide further research and provide useful information to the Orthopaedic community, the regulatory authorities as well as the manufacturers.

2. Materials and Methods

This pilot biomechanical study was conducted on six tibial IM nails, each from different manufacturers. All six nails were of same length and diameter (10mm X 340mm). The characteristics and manufacturers of the nails are shown in theTable 1.

2.1. Static four-point bending test

Static four point bending test was performed according to the ASTM F1264-16 standards.[13] The setup is shown in Figure 1.[8]

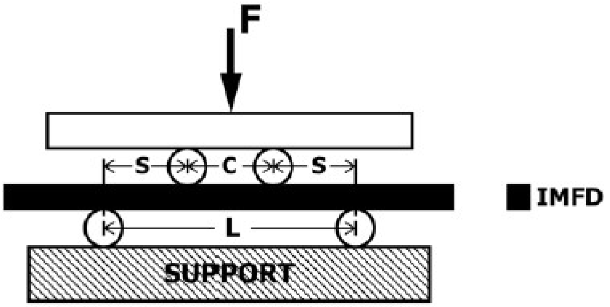

Fig. 1: Static four-point bending test set up

Figure 1 shows the set up for the static four point bending test. Testing method as per ASTM F1264-16.where, 'F' is the force on the system.L is total span of working length (2s+c), the distance between support rollers.

'c' is the center span, the distance between loading rollers

's' is the distance between the support and the loading rollers.'IMFD' is diameter of intramedullary fixation device.

The bending structural stiffness was then calculated using the equation,

$$(El)e = \frac{s^2(L+2C)F/Y)}{12}$$

Here F/Y represents the slope of elastic portion of the load vs displacement curve.

2.2. Static axial loading

Single cycle tests were performed on each of the implants to evaluate the fatigue strength and to simulate the static failures most commonly seen in the clinical setting. Each nail was placed in a custom-made jig made of high carbon steel without interlocking screws (Figure 2). The test was conducted with a displacement force of 40mm/min. The jig was designed to cover the proximal and distal locking sites, so as to isolate the working length of the nail. The stress versus strain graph was then plotted and the load required for plastic deformation was calculated (Figure 3). The tests were conducted on a Universal testing machine (UTM-"ZWICK" model) according to ASTM F1264-16 standards[13] (Figure 2). Failure was defined as the breakage or the visible deformation of the implant.

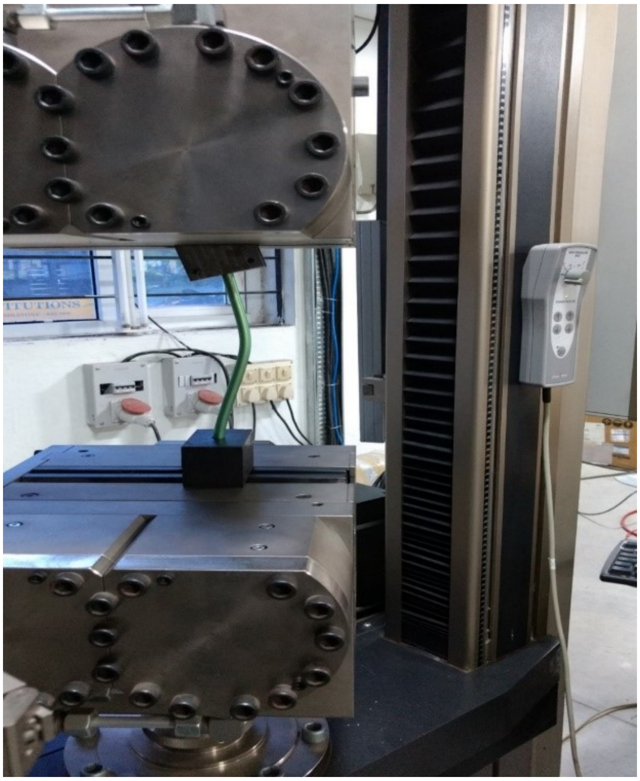

Fig. 2: Static axial loading on IM nail placed in a custom-made jig

3. Results

The bending structural stiffness calculated by the static four-point bending test and fatigue strength calculated by static axial loading are tabulated in Table 2 and Table 3 respectively. The load versus displacement curves are depicted in Figure 3. The mean fatigue strength of regional titanium nails was 2680 (N) and that of global titanium nails was 2740 (N).

Table 1: Characteristics of Tibial intramedullary nail

Product	Material	Dimension	Cross section
Regional 1 (R1) Yogeshwar surgical implants	Titanium	10mmx340mm	Cannulated
Regional 2 (R2) Kaushik surgical implants	Titanium	10mmx340mm	Cannulated
Regional 3 (R3) Hardik surgical implants	Titanium	10mmx340mm	Cannulated
Global 1 (G1)Medtronics	Titanium	10mmx340mm	Cannulated
Global 2 (G2) Synthes	Titanium	10mmx340mm	Cannulated
Global 3 (G3) Smith and Nephew	Titanium	10mmx340mm	Cannulated

Table 2: Static four point bending test results

S.No.	Product	Material	Bending structural stiffness (Nm2)
1.	Global (G1)	Titanium	255
2.	Global (G2)	Titanium	140
3.	Global (G3)	Titanium	244
4.	Regional R (1)	Titanium	158
5.	Regional R (2)	Titanium	191
6.	Regional R (3)	Titanium	211

Table 3: Static axial loading test results

S. No.	Product	Material	Fatigue strength of nails (N)
1.	Global (G1)	Titanium	3070
2.	Global (G2)	Titanium	2220
3.	Global (G3)	Titanium	2930
4.	Regional R (1)	Titanium	2520
5.	Regional R (2)	Titanium	2760
6.	Regional R (3)	Titanium	2760

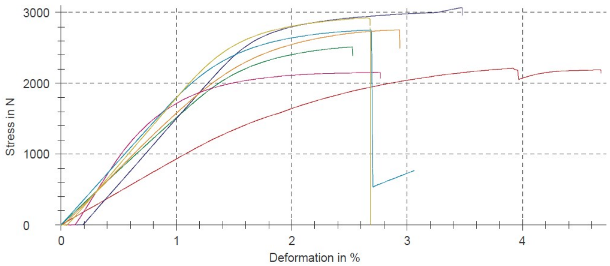

Fig. 3: Load versus displacement curve of the test

4. Discussion

Structural bending stiffness is a characteristic of the elastic behavior of intramedullary nails and it allows to compare the nails made of different materials. Studies have shown that the magnitude of the stiffness is strongly dependent on the diameter of the intramedullary nail, and within the same diameter the stiffness varies with differences in material of the intramedullary nail.[8] Our study demonstrates that the bending structural stiffness of the regional nails were found to be lower than that of the internationally manufactured nails. The bending structural stiffness of the titanium is lower than that of the stainless steel implants because the modulus of elasticity of titanium is lower than the stainless steel.[8] In our pilot study we included the nails made of titanium. The mean bending stiffness of the titanium international nails was 213 Nm2 as compared to 186 Nm2 for the regionally manufactured titanium nails. When we compared our findings with the reported values for the clinically accepted equivalent products they were found to be within the range.[11]

The fatigue strength of several intramedullary tibial nails in an axial compression device has been studied by many authors.[4,5,10] Wagner et al.[10] did a biomechanical study to evaluate the fatigue strength of several different statically locked tibial nail constructs in an axial compression device that would approximate the normal physiological stress placed on a nail over 16 weeks with full weight bearing. They tested for five different nail designs with 2 proximal and 2 distal locking bolts. All the constructs failed with the breakage or bending off one of the locking bolts. In their study they determined that the constructs had a fatigue strength ranging between 800 and 1600 N.

In our study we found that the fatigue strength varied from 2220 N for the G3 nail to 3070 for the G1 nail.

In Wagner et al.[10] study when 2 interlocking bolts were placed proximally and distally, the fatigue strength was between 900 and 1100 N for the Stryker nail, 1100 and 1300 N for the Zimmer nail, 1200 and 1400 N for the Synthes nail, and 1400 and 1600 N for the Smith & Nephew nail. This difference we think is because Wagner et al[10] tested the constructs using the cyclic loading with each construct tested for 500,000 cycles, there by approximating the normal physiological stress placed on a nail over 16 weeks with full weight bearing. Where as in our study the nails were subjected to single cycle tests with failure defined as the breakage or the visible deformation of the implant. Also we subjected the nails to direct axial compression rather than a tibial nail construct with cadaveric bone or some type of synthetic material. This explains why the fatigue strengths of the nails in our study appear higher. We also found that G2 (Global titanium nail) had a significantly lower load to plastic deformation in comparison to that of regional nails. We think that this might be explained by the variation in the material properties utilized by the different manufacturers.

This study has several limitations. Being a pilot study our sample size is small, we included nails with one diameter only, and the data was not suitable for any statistical analysis because of the small sample size. We also didn't address the torsional and shear stresses to which a tibial nail construct would be subjected to. We tested the fatigue strength of the nails themselves rather than a nail construct with cadaveric bone. Many studies show that the most common place of failure of a nail construct is through the interlocking screws. Our jig tested the fatigue strength of the nail by isolating the working length which was achieved by covering the proximal and distal locking sites.

5. Conclusions

Although our study has several limitations, it is a pilot study and it gives an insight in to the existing quality of the products available in the market for use by orthopedic surgeons and also the lack of standardization in the manufacturing process. This pilot study provides a reference to the Orthopaedic community about the standards of existing intramedullary nails. This data is a value addition in expanding the research and to direct towards reforms in the standardization of manufacturing and usage of the intramedullary nails.

6. Source of Funding

None.

7. Conflict of Interest

None.

References

1. Mcgrath LRS. Fractures of the tibial shaft (including acute compartment syndrome). *Surg*. 2007;25:439–44.
2. Weiss RJ, Montgomery SM, Ehlin A, Dabbagh ZA, Stark1 A, Jansson KÅ. Decreasing incidence of tibial shaft fractures between 1998 and 2004: Information based on 10,627 Swedish inpatients. *Acta Orthop*. 2008;79(4):526–33.
3. Bhandari M, Guyatt G, Walter SD, Tornetta P, Schemitsch EH, Swiontkowski M, et al. Randomized Trial of Reamed and Unreamed Intramedullary Nailing of Tibial Shaft Fractures. *J Bone Joint Surg Am*. 2008;90(12):2567–78.
4. Calafi LA, Antkowiak T, Curtiss S, Neu CP, Moehring D. A biomechanical comparison of the Surgical Implant Generation Network (SIGN) tibial nail with the standard hollow nail. *Injury*. 2010;41(7):753–7.
5. Eveleigh RJ. A review of biomechanical studies of intramedullary nails. *Med Eng Phys*. 1995;17(5):323–31.
6. Gaebler C, Stanzl-Tschegg S, Laube W, Vécsei V. The fatigue strength of small diameter tibial nails. *Inj*. 2001;32(5):401–5.
7. Letechipia J, Alessi A, Rodriguez G. Design and preliminary testing of an active intramedullary nail. *Rev Invest Clin*. 2014;66(1):70–8.
8. Pisano MBM, Carrizo N, Pazos L. Mechanical Behaviour of Argentinian-Made Intramedullary Nails. In: Braidot A, Hadad A, editors. VI Latin American Congress on Biomedical Engineering CLAIB. Springer; 2014.
9. Schandelmaier P, Krettek C, Tscherne H. Biomechanical Study of Nine Different Tibia Locking Nails. *J Orthop Trauma*. 1996;10(1):37–44.
10. Wagner M, Liu Q, Ellis TJ. Fatigue Load of Current Tibial Intramedullary Nail Designs: A Simulated Study. *Orthop*. 2011;34:195.
11. Ahmady SSHA, Othman NAA. Bending Stiffness of IM Nails for Orthopedic Applicatins: A Comparative Study between 12 Specimen Group from 9 Established Manufacturers. In: Toi V, Toan N, Khoa TD, Phuong TL, editors. 4th International Conference on Biomedical Engineering. Springer;.
12. Bhat AK, Rao S, Bhaskaranand K. Mechanical Failure in Intramedullary Interlocking Nails. *J Orthop Surg*. 2006;14(2):138–41.
13. Standard Specification and Test Methods for Intramedullary Fixation Devices ASTM F1264-16. Sweden: Swedish Institute for Standards; 2016.

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