Designing and Manufacturing of Solid Intramedullary Interlocking Tibial Nail

Kumar J.,[1] Syed Muhammad Awais[2]
Address for Correspondence: *Assistant Professor, Department of Orthopaedic Surgery, Chanka Medical College, Larkana*

Introduction: The closed intramedullary nailing is only practiced in prestigious few institutions in our country, although it is the norm in developed for closed or open fractures. The reason why it is not practiced in our domestic setup is financial.

Aims and Objectives: due to high price of imported undreamed tibial nail (UTN) and difference in topographic measurement of the European and Asian Skeleton it was deemed necessary to develop an unreamed tibial nail.

Material and Method: This study was carried out in the Department of Orthopaedic Surgery, Jinnah Hospital and Mayo Hospital, Lahore between the, June 1995 to June 1997. 50 normal healthy males were included. The present study was carried out in two phases: phase I – collection of data regarding measurements of tibia in 20-40 years old male population by CT scan and phase II – designing and manufacturing of solid tibia nail alongwith inserting and interlocking instruments.

Results: The collected data values were analyzed statistically. The two sizes obtained 330 mm and 350 mm in length and 9 mm in diameter. Solid nail developed from 316 L stainless steel. The inserting and interlocking instruments were made from stainless steel, used in surgical instruments. Inserting and interlocking as insertion handle, connecting screw, drill sleeve, inserter – extractor and slide hammer.

Conclusion: An intramedullary nail is a load sharing device and allows the bone to transmit the compressive force while maintaining axial alignment. An ideal nail should have a cross – sectioned geometry consistent with the anatomic shape of the bone combined with a design that allows for the maximum bending and polar moments in inertia. On keeping the above mentioned biomechanics properties, we made a solid nail of 316L stainless steel and inserting as well as interlocking instruments of stainless steel.

Introduction

A tibial shaft fracture is a common injury largely owing to its superficial location and the subcutaneous characteristics of its anteromedial aspect easily cause open fractures.[1,2] In recent year, intramedullary nailing has become an increasing attractive treatment method for tibial fractures.[3,4] Unreamed tibial nails (UTNs) have been shown to be a reasonable treatment option to external fixator in tibial shaft fracture with severe soft tissue damage.[5] Intramedullary nailing is often the treatment of choice in the management of fractures in the tibial diaphysis.[6] More recently, unreamed nailing of open tibial fracture has become popular.[5]

Singer and Kellam[7] suggested that unreamed locked intramedullary nailing is the treatment of choice in the management of open tibial diaphyseal fractures because locked unreamed nails have improved rate of union in open tibial diaphyseal fractures. In contrast, reamed intramedullary nailing of open tibial fractures has been associated with a much higher rate of complications. These include linear propagation of the fracture from the insertion of ankle joint, neurologic injury, malunion, nonunion and deep infection.[8]

The closed intramedullary nailing on the other hand is only practised in prestigious few institutions in our country, although it is the norm in developed for closed or open fractures. The reason why it is not practised in our domestic setup is financial. The cost of implant and instrumentation is too high. The purpose of this study is to obtain measurement of tibia in our population and then to develop a solid nail or set of nails which could fit in most of the tibias and also develop jigs for insertion and interlocking of these nails.

Material and Methods

This study was carried out in the Department of Orthopaedic Surgery, Jinnah Hospital and Mayo Hospital, Lahore between the, June 1995 to June 1997, 50 normal healthy males were included. The present study was carried out in two phases : phase I – collection of data regarding measurements of tibia in 20 – 40 years old male population by CT scan and phase II – designing and manufacturing of solid tibia nail alongwith inserting and interlocking instruments. A Siemen's Tomoscan 60 / TX scanner, which is a third generation high resolution whole body scanner, was used. A slice thickness of 5 mm and a pixel size of 0.55 x 0.55 mm were chosen and the exposure factors were 125 kv 300 mA and 45 AS. During CT examination the person was lying in the supine position with parallel legs. After an scout view (topogram), scanning was performed in cross – sections as tibial plateau level, tibial tuberosity level, mid diaphyseal level and at the junction of upper 3/4th and lower 1/4th. The measurements were recorded according to the predetermined reference points with CT scan. **L1** – length of the tibia from proximal articular surface to distal articular surface. $\mathbf{L_2}$ – Tibial tuberosity to distal articular surface. $\mathbf{ID_1}$ – Antero-posterior distance at the level of the tibial plateau. $\mathbf{ID_2}$ – Medio – lateral distance at the tibial plateau. $\mathbf{ID_3}$ – Size of the medullary cavity antero-posterior at the tibial tuberosity.

ID$_4$ – Size of the medullary cavity medio – lateral at the tibial tuberosity. **ID$_5$** – Size of the medullary cavity antero-posterior at mid shaft of the tibia. **ID$_6$** – Size of the medullary cavity medio – lateral at mid shaft of the tibia. **ID$_7$** – Size of the medullary cavity antero-posterior at the junction of upper 3/4th and lower 1/4th of the tibia. **ID$_8$** – Size of the medullary cavity medio – lateral at the junction of upper 3/4th and lower 1/4th of the tibia. The instruments were manufactured at orthopaedic workshop, Mayo Hospital, Lahore. The inserting and interlocking instruments were made from stainless steel, used in surgical instruments. Inserting and interlocking as insertion handle, connecting screw, drill sleeve, inserter-extractor and slide hammer.

Solid nail developed from 316 L stainless steel. Initially the nail was made from metallic steel in a clover leaf cross-section and solid core. The size was 33 cm in length and 9 mm in diameter (predetermined). The bend in the nail, taken into account the anatomic angle of about 11, formed for the access canal and the medullary canal. The metallic nail has two holes for medio-lateral access at its proximal end, these two holes of 4 mm in diameter for proximal locking. At the distal end, there were three holes, two for medio-lateral access and middle one for anterior-posterior access. Manufacturing of solid nail : Step 1 – turning 316$_L$ rod of 14 mm diameter and 40 cm in length fixed on lathe machine. Turning of rod done to make the proximal end 10 mm in diameter for 5 cm length and below that of 9 mm. Step 2 – milling (tapering) then the rod was fixed on milling machine for tapering both the sides to make the rod in triangular shape. Step 3 – tapping the hole of 5 mm diameter was made on proximal end of rod with lathe machine and threaded M6 with depth of 20 mm for fixing the rod with inserter / extractor or connector. Step 4 – slotting on the milling machine, the 2 mm slot made on proximal end of rod for fixing the proximal interlocking jig. Step 5 – hole formation on the drilling machine rod fixed and two holes of 4 mm in diameter made with the gap of 2.5 cm from each other at proximal 1/4th of rod 6 cm away from proximal end for proximal interlocking. The two holes of 4 mm in diameter made from mediolaterally on distal part of rod, 1 cm away from distal end and with a gap of 2 cm between each other and one hole of same diameter made anteroposteriorly in between two holes. Step 6 – bending nail was finally bended 11° at 10 cm below the proximal end with apex facing superiorly.

Results

The collected data values were analyzed statistically. The two sizes obtained 330 mm and 350 mm in length and 9 mm in diameter.

L$_1$ = The average length of the tibia was obtained 350.4 ± 31.3 mm range 310 to 390 mm.

L$_2$ = The average length was 300.44 ± 27.02 mm, range 230 to 370 mm.

ID$_1$ = The average distance was 48.1 ± 4.8 mm range 36 – 57 mm.

ID$_2$ = The average distance was 82.7 ± 5.4 mm range 65 – 92 mm.

ID$_3$ = The average diameter was 21.6 ± 4.2 mm with range of 10 – 30 mm.

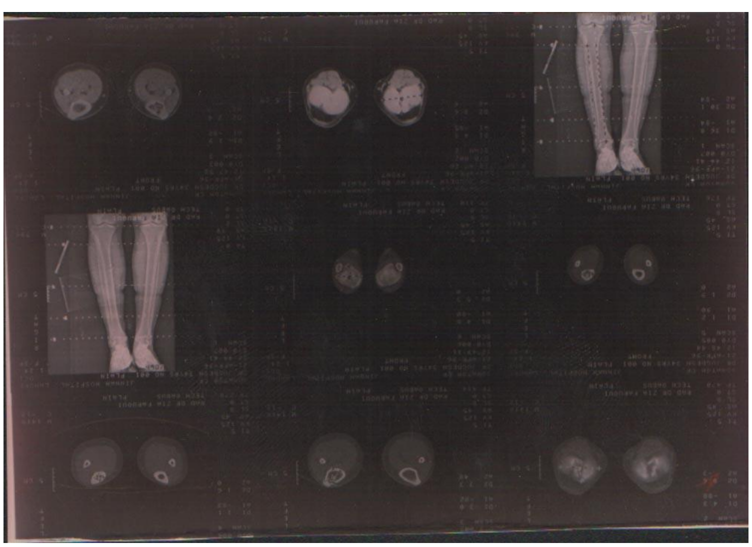
ID$_4$ = The average diameter was 27.8±5.8 mm range of 16 – 38 mm.

ID$_5$ = The average diameter was 11.0 ± 4.9 mm range of 6 – 14 mm.

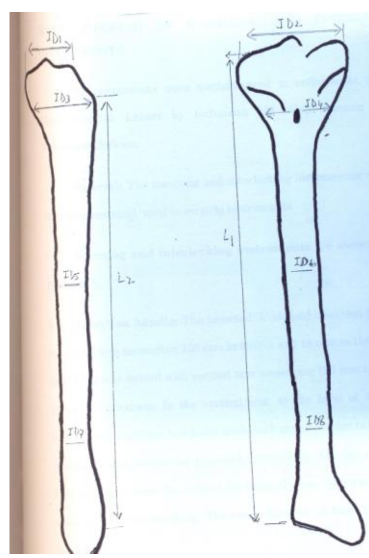
ID$_6$ = The average diameter was 11.3 ± 2.9 mm range of 6 – 16 mm.

ID$_7$ = The average diameter was 11.1 ± 2.2 mm range of 6 – 17 mm.

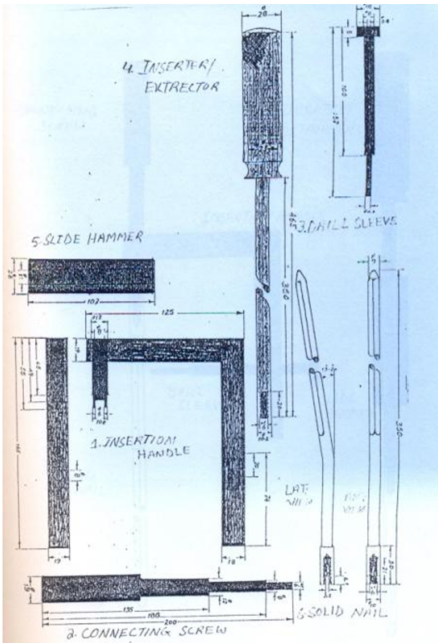
ID$_8$ = The average diameter was 11.8 ± 3.3 mm range of 5 – 20 mm.



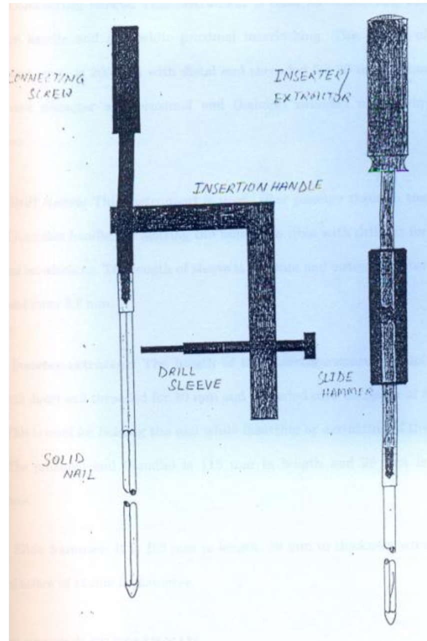
CT Scan film showing scout view and cross Section at various levels of Tibia



Predetermined anatomical reference points.

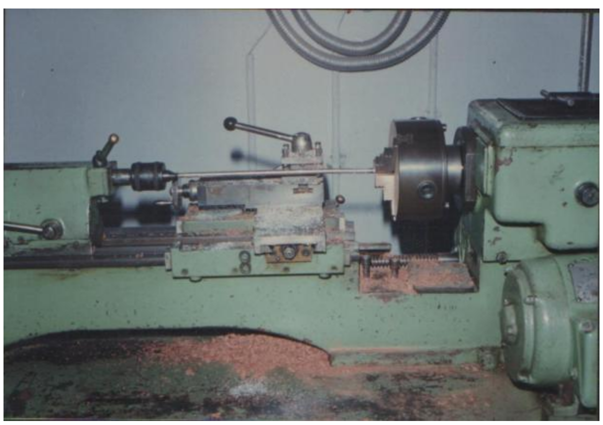


Diagrammatic view of nail and interlocking instruments.

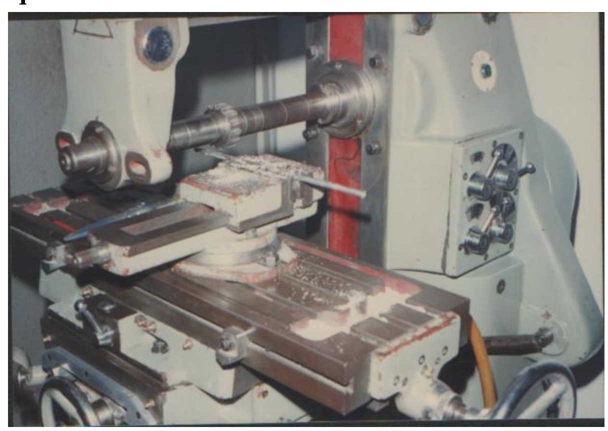


Diagrammatic view of solid nail after assembly.

Manufacturing Techniques of Solid Nail

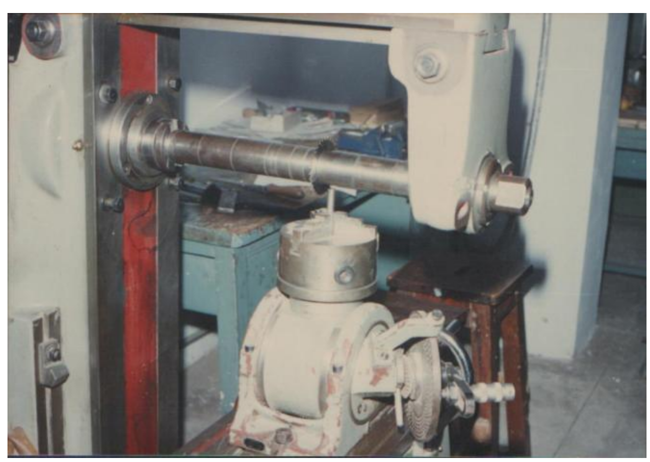


Step# 01 Turning



Step# 02 Milling (tapering)

Step# 03 Tapping



Step# 04 Slotting

Step# 05 Holes formation

Step# 05 Holes formation

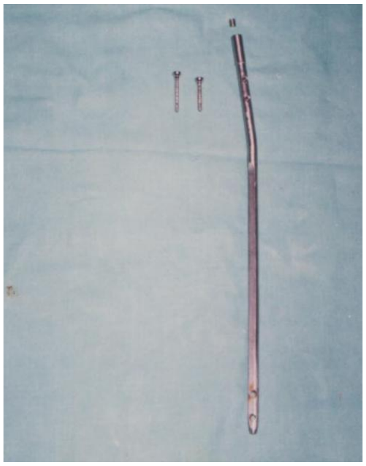
Techniques of Inserting Manufactured Nail in Cadaveric Tibia

Portal of entry in cadaveric tibia with power drill

Nail inserted

Proximal interlocking

X-ray of cadaveric tibia which solid intra medulary nail



Solid nail with locking bolts and nail cap

Implant and instruments for undreamed interlocking in tibial nailing.

Discussion

The closed intramedullary nailing with solid nail with undreamed technique for management of open tibial fracture is the routine in developed countries. The reason why it is not widely practiced in our country is cost factor and technology (an AO solid nail for tibia without inserting instruments costs more than Rs. 11,000,00).

In our study, the attempt was made to obtain measurements of tibia in our local population. The aim was to select minimum number of sizes of nails which could fit in if not all, 97.6% of the tibia. We achieved the aim by finding the two sizes of nail 9 x 330 mm and 9 × 350 mm, by analyzing the data statistically. In the present study only two patients, we had inserted nail of size 9 × 350 mm and in remaining 18 patients nail of size 9 × 330 mm.

Kuntscher[9] reported principles of intramedullary surgical technique and its place in orthopaedic surgery. Bone in their role as structural members are subjected to a administration of compressive, torsional and bending loads. Both bending and torsional loading of bones produce tensile, compressive and shear stresses and strains in the bone.[10] A study of any osteosynthesis must take into account the loads expected to act on the limb during healing, the strength and rigidity of the appliance and the ability to transmit stresses from the bone to the metallic implant.[11]

Kyle[12] reported in his series regarding strength, rigidity or stiffness and stability in torsion, by examining the various devices inserted into cadaveric bone. A 25% increase in diameter of the nail will double its bending strength. This is because of the most effective material to resist bending forces on an intramedullary rod is the material distributed the furthest away from its bending axis. Clinically, bending strength and stiffness can be optimized by using as large diameter a rod as possible. The relative bending stability of the locked nails was slightly greater than that of a standard AO nail. Torsional testing demonstrates that a rod with an open section on one side (Kuntscher) is markedly weaker in torsion than a rod without an open section. It can be optimized by using static interlocking systems, the locked AO rod by far the best in resisting torsional stress. An unlocked intramedullary device cannot resist compressive forces. An intramedullary rod is a load sharing device and allows the bone to transmit the compressive force while maintaining axial alignment.

Allen *et al*[10] suggested, an ideal nail should have a cross – sectioned geometry consistent with the anatomic shape of the bone combined with a design that allows for the maximum bending and polar moments in inertia. An open section structure should be avoided. The nail should be designed so that an intimate gripping surface can be introduced against the cortical bone. The insertion of the nail can be aided by proper design of the cutting edge.

Conclusion

On keeping the above mentioned biomechanics properties, we achieved the aim by finding the two sizes of nail 9 × 330 mm and 9 × 350 mm by analyzing the data statically and made a solid nail of 316_L stainless steel and inserting as well as interlocking instruments of stainless steel.

References

1. Clifford RP, Beanchamp CG, Kellam JF, et al. Plate fixation of open fractures of tibia. JBJS 1988; 70B: 644.
2. Henley MB. IM devices for tibial fracture stabilization. Clin Orthop 1989; 240: 87.
3. Bone LB, Johnson KD. Treatment of tibial fractures by remaining and intramedullary nailing. J Bone Joint Surg 1994; 68A: 877-87.
4. Alho A, Benterud JG, Erkhogevold H, Ekeland A, Stromosoe K. Comparison of functional bracing and locked intramedullary nailing in the treatment of displacement tibial shaft fractures. Clin Orthop Related Res 1992; 277: 243-50.

5. Schandelmaier D, Krettek C, Rudolf J, Tschern H. Outcome of tibial shaft fractures with severe soft tissue injury treated by unreamed nailing versus external fixation. J Trauma Inj Infect Critical Care 1995; 39: 707-11.
6. Freedman EL, Johnson EE. Radiographic analysis of tibial fracture malalignment following intramedullary nailing. Clin Orthop Related Res 1995; 315: 25-33.
7. Singer RW, Kellam JF. Open tibial diaphyseal fractures : results of undreamed locked intramedullary nailing. Clin Orthop Related Res 1995; 315: 114-8.
8. Duwelius PJ, Schmidt AH, Rubinstein Ra, Green JM. Nonreamed interlocked intramedullary tibial nailing: one community's experience. Clin Orthop Related Res 1995; 315: 104-13.
9. Kuntscher G. Intramedullary surgical technique and its place in orthopaedic surgery. Clin Orthop 1965; 47: 800-18.
10. Allen WC, Piotrowski G, Burstein AH, Frankel VH. Biomechanical principles of intramedullary fixation. Clin Orthop 1968; 60: 13-20.
11. Kuntscher G. Intramedullary nailing of fractures. Clin Orthop 1968; 6: 5-12.
12. Kyle RF. Biomechanics of intramedullary fracture fixation. Orthopaedics 1985; 8: 1356-9.