Distal Locking Screws for Intramedullary Nailing of Tibial Fractures

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abstract

Recently introduced tibial intramedullary nails allow a number of distal screws to be used to reduce the incidence of malalignment and loss of fixation of distal metaphyseal fractures. However, the number of screws and the type of screw configuration to be used remains obscure. This biomechanical study was performed to address this question. Thirty-six Expert tibial nails (Synthes, Oberdorf, Switzerland) were introduced in composite bone models. The models were divided into 4 groups with different distal locking configurations ranging from 2 to 4 screws. A 7-mm gap osteotomy was performed 72 mm from the tibial plafond to simulate a 42-C3 unstable distal tibial fracture. Each group was divided in 3 subgroups and underwent nondestructive biomechanical testing in axial compression, coronal bending, and axial torsion. The passive construct stiffness was measured and statistically analyzed with one-way analysis of variance. Although some differences were noted between the stiffness of each group, these were not statistically significant in compression (P=.105), bending (P=.801), external rotation (P=.246), and internal rotation (P=.370). This in vitro study showed that, when using the Expert tibial nail for unstable distal tibial fractures, the classic configuration of 2 parallel distal screws could provide the necessary stability under partial weight-bearing conditions. [*Orthopedics.*]

Intramedullary (IM) nailing continues to be the gold standard of treatment for long bone fractures. For the tibia in particular, excellent healing rates have been reported with minimal procedure-related complications.[1] Lately, IM nailing has been used for the stabilization of more proximal and more distal fracture patterns.[1] However, the ability to maintain a stable reduction is compromised by the expansion of the tibial canal diameter distally, predisposing the fixation to an increased risk of malalignment and failure. Hahn et al[2] described 5 cases of fractures within 7 cm from the ankle joint treated with a nail and 1 distal locking screw. However, at a mean of 7 months postoperatively, all nails failed. A solution to this problem was the use of a shortened nail, which allowed 2 distal screws and thus a stronger fixation. This concept was then tested by both clinical and biomechanical studies,[3-5] and the positive results obtained led to the introduction of newly designed nails with multiple locking options both distally and proximally, such as the Expert tibial nail (Synthes, Oberdorf, Switzerland), which allows for 4 distal locking screws.

Despite this evolution in nail design, currently there are no evidence-based guidelines regarding the optimal number and configuration of distal screws that should be used.

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Table 1

Four Groups With Differing Numbers and Configurations of Distal Screws

Group	Screw Configuration	Total No. of Screws Used
A	2 parallel mediolateral screws	2
B	1 distal mediolateral, 1 anteroposterior	2
C	2 parallel mediolateral, 1 anteroposterior	3
D	2 parallel mediolateral, 1 anteroposterior, 1 oblique	4

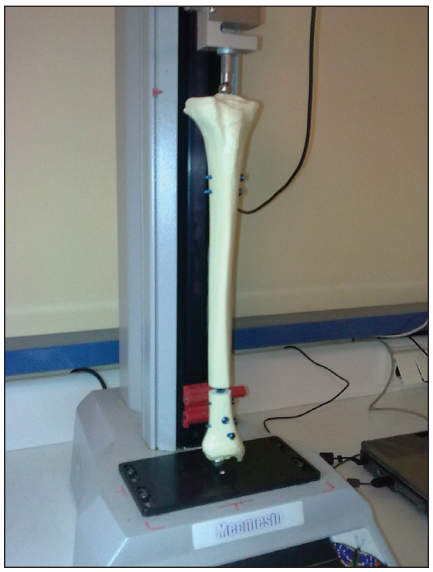

Figure 2: Axial compression test.

The classic AO/ASIF manual suggested the use of all the available locking options that the fracture configuration allows.[6] However, distal locking is technically demanding, and the use of more screws can lead to longer radiation exposure to both the surgical team and the patient. Furthermore, neurovascular and tendinous injuries are more likely to occur, and operative time

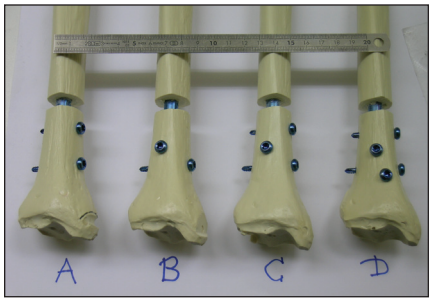

Figure 1: Photograph of the distal half of 4 prepared models, 1 from each locking mode group.

is prolonged significantly.[7,8] Consequently, there is a need to ascertain the minimum number of screws required to be inserted distally to maintain a stable reduction. The current biomechanical study was performed in an effort to answer this question.

Materials and Methods

Thirty-six composite bone models of the tibia (model number 1149; Synbone, Malans, Switzerland) were used. This bone model has been previously used for several biomechanical studies.[9-11] The IM nail chosen for the tests was the Expert tibial nail, which has a variety of locking options both proximally and distally. There are 4 holes distally, allowing the use of screws at a distance of 5, 13, 22, and 37 mm from the tip of the nail. Two of them are mediolateral, 1 is anteroposterior, and the most distal one is oblique.

Specimen Preparation

The bone model was stabilized using a custom-made clamp, and the entry point was determined in a reproducible manner using identical landmarks on the models. The medullary canal was entered using a 3.2-mm drill bit, and a guidewire of the same size was advanced into the tibial model. Starting with the 8.5-mm reaming head, the canal was reamed in 0.5-mm increments to a diameter of 10.5 mm. The proximal 10 cm of the model were reamed up to 12 mm for the metaphysis to accommodate the wide proximal segment of the nail without the risk of breaking. A 9-mm cannulated Expert tibial nail was advanced over the guidewire using the insertion handle. The markings on the handle helped to insert the nail to the same depth in each model. With the help of the aiming device, 2 mediolateral static screws were used for locking the proximal part of the nail. Again, using landmarks on the model, it was ensured that the screw entry point and the rotation of the nail were identical on every specimen.

The specimens were subsequently divided into 4 groups depending on the adopted locking strategy (**Table 1**). The distal screws were inserted to each group by the same surgeon (F.A.) under image intensifier using the freehand technique.[7] A 7-mm osteotomy gap was then performed 10 mm cranially to the most proximal distal interlocking screw hole, simulating the conditions of an unstable distal third 42-C3 fracture according to the AO classification of long bone fractures,[6] as in the technique used by Horn et al.[12] The osteotomy was done with a handsaw and not a power tool to avoid any damage of the implants. The distance of the fracture from the tibial plafond was 72 mm (**Figure 1**).

Mechanical Testing

Each of the 4 groups of specimens was then divided in 3 subgroups and underwent biomechanical loading in 3 modes respectively: axial compression, coronal bending, and axial torsion in internal and external rotation. This resulted in 3 specimens per combination of group and loading mode. More specifically, in the axial compression mode, the bone model was held and loaded on the compression testing machine (Materials Testing Machine Imperial 2500; Mecmesin, Slinfold, United Kingdom) by means of steel balls fitted at the proximal and distal ends of the anatomical axis of the tibia. Loading was conducted at a loading speed of 10 mm per minute between 50 and 700 N, with simultaneous load and displacement data acquisition at a sampling frequency of 10 Hz (**Figure 2**). In the coronal bending mode, the specimens were loaded on the

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compression testing machine by means of steel cylindrical supports, which were adjusted equidistant to the vertical machine axis, and the 3-point loading was conducted at a speed of 10 mm per minute between 25 and 250 N, with load and displacement data acquisition at a frequency of 10 Hz (**Figure 3**). Finally, during axial torsion, the proximal end of the model was fixed on the torsional load cell of the torsion testing machine (Torsion Testing Machine with DTD-F-50 Nm Torque Sensor; Applied Measurements Ltd, Aldermaston, United Kingdom) via a static custom-made chuck, and the distal end was connected via another similar chuck to the rotating apparatus. Torsion was conducted in increments of 1.5° until 8 Nm in both directions (**Figure 4**). For all loading modes, preconditioning cycles were executed, followed by 3 final loading cycles for data acquisition. The quantitative outcome of all tests was the calculated value of passive construct stiffness, representing the specimen's rigidity. The loading and data acquisition protocol was previously described by Goett et al.[13] The loading forces represent partial weight bearing for a subject weighing 65 to 85 kg and were adapted from previous studies.[4,14,15]

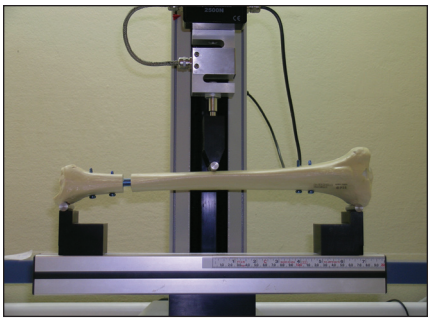

Figure 3: Three-point loading in the coronal plane.

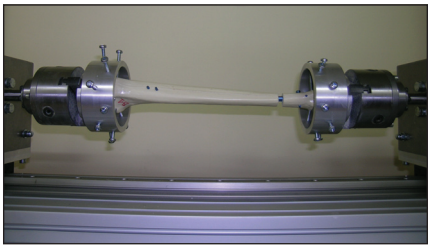

Figure 4: Internal and external rotation test.

Statistical Analysis

Statistical analysis was performed with SPSS statistical software version 17.0 (IBM, Armonk, New York). Data retrieved from each loading mode were analyzed with one-way analysis of variance. A *P* value less than .05 was considered statistically significant.

Table 2

Stiffness Values

	Group											
Variable	**A**			**B**			**C**			**D**		
Stiffness values (N/mm) for compression 200-700 N												
Specimen	AC1	AC2	AC3	BC1	BC2	BC3	CC1	CC2	CC3	DC1	DC2	DC3
Specimen average	257.4	266.6	232.6	302.6	277.5	314.2	291.8	280.0	273.8	293.9	252.0	307.3
Group average		252.2			298.1			281.9			284.4	
Group SD		17.6			18.8			9.1			28.8	
Stiffness values (N/mm) for bending 100-250 N												
Specimen	AB1	AB2	AB3	BB1	BB2	BB3	CB1	CB2	CB3	DB1	DB2	DB3
Specimen average	42.0	44.2	38.3	49.5	41.5	36.3	43.3	36.0	36.4	47.6	38.4	38.3
Group average		41.5			42.4			38.6			41.4	
Group SD		3.0			6.7			4.1			5.3	
Stiffness values (Nm/degree) for external rotation 4-8 Nm												
Specimen	AT1	AT2	AT3	BT1	BT2	BT3	CT1	CT2	CT3	DT1	DT2	DT3
Specimen average	0.590	0.694	0.600	0.672	0.592	0.643	0.726	0.676	0.673	0.648	0.627	0.647
Group average		0.63			0.64			0.69			0.64	
Group SD		0.06			0.04			0.03			0.01	
Stiffness values (Nm/degree) for internal rotation 4-8 Nm												
Specimen	AT1	AT2	AT3	BT1	BT2	BT3	CT1	CT2	CT3	DT1	DT2	DT3
Specimen average	0.686	0.671	0.597	0.687	0.615	0.607	0.739	0.676	0.630	0.720	0.680	0.690
Group average		0.65			0.64			0.68			0.70	
Group SD		0.05			0.04			0.05			0.02	

Table 3

Statistical Analysis for Each Testing Mode

	P			
Statistical Test	**Compression**	**Bending**	**External Rotation**	**Internal Rotation**
Normality test	.385	.353	.407	.668
Equal variance test	.582	.823	.700	.757
One-way ANOVA	.105	.801	.246	.370
Power of performed test (alpha=0.05)	0.311	0.050	0.137	0.073

Abbreviation: ANOVA, analysis of variance.

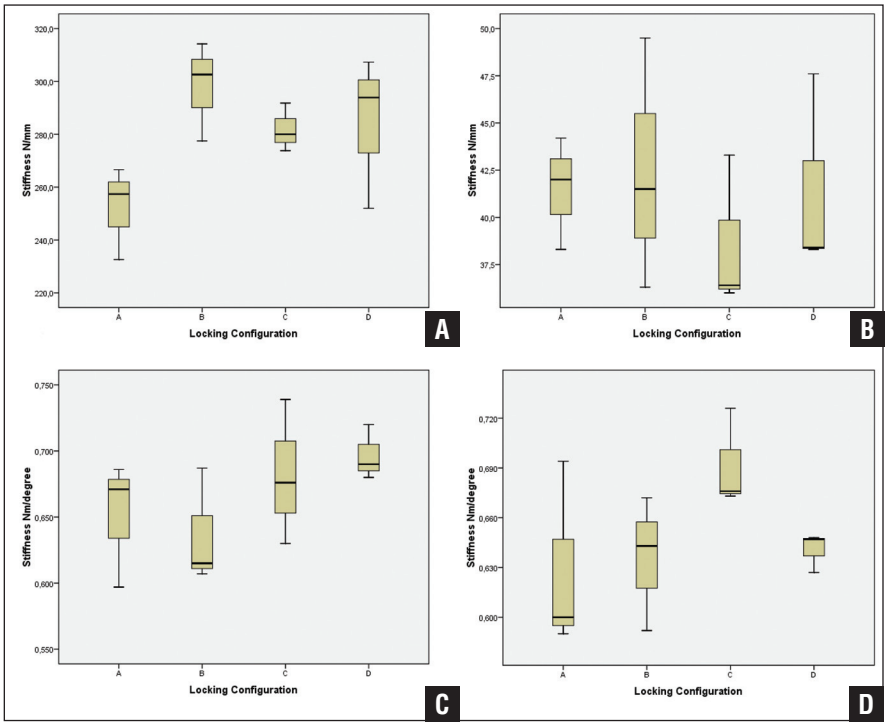

Figure 5: Box plots comparing the stiffness during axial compression (A), 3-point bending (B), internal rotation (C), and external rotation (D).

Results

There were no implant or bone model failures during the biomechanical testing. The results are summarized in **Table 2**. Average stiffness was calculated from the data acquired during the 3 loading cycles for each specimen. Average stiffness and SD for each group of specimens were statistically analyzed (**Table 3**). In all cases, tests for normality and equal variance passed ($P>.05$), showing that each group sample is drawn from a normally distributed population and that there is a common variance. Average compression stiffness was 252.2±17.6 N/mm for group A, 298.1±18.8 N/mm for group B, 281.9±9.1 N/mm for group C, and 284.4±28.8 N/mm for group D. Although group B showed higher stiffness, there was no statistically significant difference ($P=.105$). During coronal bending, average stiffness was 41.5±3 N/mm in group A, 42.4±6.7 N/mm in group B, 38.6±4.1 N/mm in group C, and 41.4±5.3 N/mm in group D. Group B again showed a marginally higher stiffness, but it was not significant ($P=.801$). Average stiffness for external and internal rotation was 0.63±0.06 and 0.65±0.05 Nm/degree, respectively, in group A; 0.64±0.04 and 0.64±0.04 Nm/degree, respectively, in group B; 0.69±0.03 and 0.68±0.05 Nm/degree, respectively, in group C; and 0.64±0.01 and 0.70±0.02 Nm/degree, respectively, in group D. Separate statistical analysis showed no statistically significant differences for external ($P=.246$) and internal ($P=.370$) rotation (**Figure 5**).

Discussion

Recently introduced IM nails include more than 2 proximal and distal locking options. This design change has extended the indications of IM nailing to more proximal and more distal metaphyseal fractures. However, the number of screws to be used and what type of configuration remains obscure. Regarding diaphyseal tibial fractures, a clinical study showed that the use of a third distal screw offered no advantages. On the contrary, it increased radiation exposure and proved to be less cost-effective.[16] In a prospective, randomized study, Kneifel and Buckley[17] compared 1 distal locking screw to 2 distal locking screws in 44 tibial fractures treated with an unreamed IM nail. The single distal screw failed more frequently (59.1%) compared with the 2 distal screws (5%), but time to fracture union was not affected.[17] During pilot testing, the current authors anecdotally measured the stiffness of bone models with 1 distal screw, which proved to be significantly less than configurations with more than 1 screw.

Mohammed et al[18] studied 65 patients with distal tibial fractures and reported that 15 developed nonunion. The majority of those patients (12/15) had only 1 distal screw. The authors concluded that distal locking with a single screw should be avoided. In a recent cadaveric study,

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Attal et al[19] used 2 groups of lower-limb specimens with a distal tibial and fibular fracture to test whether fibular plating would improve stability. The first group was treated with an Expert tibia nail and 4 distal screws, and the second group with a solid conventional distal locking nail (unreamed tibial nail; Synthes). The authors concluded that adding a fibular plate did not improve stability and the group with the 4 distal screws was more stable. The difference in stability was attributed to the fourth screw, which was in a third plane. However, other mechanical factors, such as screw diameter, different nail design, or screw distance from the tip of the nail, were not taken into account.[19]

In a biomechanical study, Chen et al[20] showed that despite initial enthusiasm for the use of biplanar interlocking, fixation stability is not superior to parallel screws. The current study's results are in accordance with this conclusion because the stiffness of the construct did not change between groups A and B, where 2 parallel and 2 perpendicular screws were used. In a comparison of 4 small diameter nails for the treatment of distal tibial fractures, Schüller et al[21] found that the number of distal locking screws (3 or 4) did not substantially influence the axial movements at the fracture gap. The current study's findings are in agreement with this conclusion.

For their experiments, the current authors selected composite tibial bone models, whose use has been validated in previous biomechanical studies.[9-11] These models provide a number of advantages as compared with cadaveric bone, including assurance of uniformity, availability in large numbers, consistent geometry and material composition, and predictable mechanical properties.[11] The type of the composite model corresponded to a tibia with normal bone density. It is beyond the scope of this study to examine how an osteoporotic model would perform. The transverse osteotomy was wide enough to recreate the worst-case scenario in terms of fracture instability.[12] The same osteotomy is used in other studies of distal tibial fractures; however, it would be interesting to study how different fracture patterns behave under the same loading conditions. Due to the complexity of the setup, a finite element analysis would be a more appropriate approach to the problem.[14,22] Apart from axial loading, the current authors also tested coronal bending and axial torsion to check for varus-valgus and rotational instability, which are clinically important.[23] They chose to compare all possible combinations of distal locking, from 2 to 4 screws. To the best of their knowledge, the current study is the first to compare this combination of distal locking in 3 loading modes.

The study's results showed that 2 parallel mediolateral screws provide comparable stability to more complicated locking options. In the clinical setting, this may suggest that it is not necessary to lock a nail with 3 or 4 screws, thus avoiding radiation exposure, extra cost, and prolonged operative time. Furthermore, tibial IM nails tend to break at the level of an unused screw hole due to stress concentration, whereas unused holes promote bone ingrowth that can make implant removal difficult or even impossible.[24,25] As a result, the presence of a fourth or even a fifth screw hole in the distal part of the nail may pose an unnecessary risk.

There are certain limitations to this study. Only one type of IM nail was tested; another type of nail with different mechanical properties may have behaved in a different fashion under the same conditions. Distal locking was performed by the same surgeon in a reproducible manner under optimal conditions. This is often not the case in the clinical setting, where multiple efforts to introduce a distal screw can widen the cortical window and result in poor purchase of the screw on the bone.

Conclusion

This biomechanical study showed that, when using the Expert tibial nail for unstable distal tibial fractures, 2 parallel distal screws could provide the necessary stability under partial weight-bearing conditions. The use of 2 screws in a biplanar fashion, and even 3 or 4 screws in a bi- or triplanar fashion, does not appear to be justified unless technical difficulties are encountered during the implantation of the initial 2 screws. Controlled trials comparing the use of multiple locking strategies are necessary to confirm these results in the clinical setting.

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