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ORIGINAL RESEARCH

Biomechanical Properties of Conventional Versus Angular Stabilized-Intramedullary Nail Distal Interlocking Screw Configurations in a Distal Tibia Fracture Model

Raj H. Shani, MD; Randal P. Morris, BS; Zbigniew Gugala, MD, PhD; Ronald W. Lindsey, MD

Department of Orthopaedic Surgery and Rehabilitation
University of Texas Medical Branch, Galveston, TX

ABSTRACT

Introduction: A new intramedullary nail (IMN) (Expert Nail) has recently been introduced with a design including an angular stable locking system (ASLS), which provides a fixed-angle interlocking construct. The study objective is to provide biomechanical assessment of IMN fixation of a distal tibia fracture using conventional versus ASLS interlocking screw options, and the effects of number of screws and/or their orientation on fracture stability.
Methods: A distal segmental defect in large composite tibia models was stabilized with an Expert IMN. Distal fixation consisted of five distinct single versus double distal interlocking and ASLS versus conventional screw configurations. The IMN constructs were tested using cyclic axial and torsional loading.
Results: There were no significant differences between distal interlocking screw configurations for axial loading stiffness. In torsion, a single medial-to-lateral conventional interlocking screw was significantly less stiff than the other configurations.
Discussion: A single ASLS screw provides biomechanically comparable fixation to two conventional screw configurations in the fixation of distal tibia fractures with IMN. The screw orientation does not appear to affect stability of the construct.
Keywords: Distal tibia fracture; Intramedullary nailing; Distal interlocking.

INTRODUCTION

Intramedullary nailing (IMN) has become a common and effective fixation option in definitive management of tibia fractures (1-7). Although typically indicated for tibia shaft fractures, IMN fixation of the very proximal or distal tibia fractures is challenged by the limited cortical bone contact with the nail and the risk for loss of fracture alignment, implant failure, or nonunion (8-14). In such cases, IMN frequently requires supplemental fixation (eg, blocking screws), cast/brace support, and/or protective weight bearing. Recent modifications in tibia IMN designs aim to enhance the proximal and distal IMN

Corresponding Author:
Zbigniew Gugala, MD, PhD
Department of Orthopaedic Surgery & Rehabilitation
University of Texas Medical Branch
301 University Blvd.
Galveston, TX 77555-0165, USA
e-mail: zgugala@utmb.edu

interlocking screw fixation to effectively treat these demanding juxta-metaphyseal tibia fractures (8-17).

A novel tibia IMN (Expert Nail; DePuy Synthes; Paoli, USA) has recently been introduced to specifically address the challenges associated with juxta-metaphyseal tibia fracture fixation. It includes multiplanar interlocking screw placement options (anterior-posterior, oblique, medial-lateral) for both proximal and distal nail ends. Furthermore, a polymer sleeve is applied to encase the screw within the nail interlocking hole as an angle-stabilized locking system(ASLS) fixation option (18-20). The sleeve locks the interlocking screw within the nail establishing a fixed-angle screw-nail construct (Figure 1).

Although the ASLS has hypothetically improved juxta-metaphyseal tibia fracture IMN fixation, its biomechanical merits compared to traditional interlocking designs have not been fully explored. Previous studies have demonstrated that ASLS may provide a stiffer construct than conventional screws in proximal tibia fractures, but these studies did not assess the efficacy of ASLS in distal tibia fractures (17-20). Furthermore, the optimal distal interlocking screw placement configuration and the minimum number of interlocking screws required for optimal construct fixation stability have not been determined. We hypothesize in the study that the application of an ASLS polymeric sleeve augments interlocking screw stability to the extent that a single interlocking screw with a sleeve is biomechanically equivalent to two screws without the sleeve. Validating this hypothesis can potentially expand the application of tibia IM nail fixation to include very distal tibia fractures that do not permit placement of two interlocking screws with the application of a single interlocking ASLS screw with a polymeric sleeve without significantly compromising fracture stability.

The objective of this study was to establish the biomechanical merits of using the polymer sleeves and the optimal number and orientation of screws to compare ASLS versus conventional distal interlocking screws in an unstable distal tibia fracture.

MATERIALS & METHODS

Tibia Fracture Model

Twenty fourth-generation large left composite tibia models (Sawbones™, model #3402; Pacific Research Laboratories, Vashon, WA) were used in the study. These composite tibia models are validated to represent a cadaveric adult male tibia (21). A superior entry portal was used to ream the medullary canal sequentially up to 12 mm to accommodate a tibia nail with a diameter of 10 mm and length of 375 mm (Titanium Cannulated Tibial Expert Nail; Synthes, Inc., West Chester, PA). A distal metaphyseal osteotomy was created 6 cm from the tibia articular surface using an oscillating saw. The nail was then inserted into the intramedullary canal of the proximal and distal tibia fragments creating a 5-mm gap, and locked proximally with 4 interlocking screws and distally in one of the five screw configurations (Figure 2).

Experimental Groups

Group 1 consisted of two conventional medial-lateral interlocking screws in a parallel configuration; this group represents the most often clinically used configuration. Group 2 consisted of two conventional screws, one anterior-posterior, and one medial-lateral in an orthogonal configuration. Group 3 consisted of a single conventional,

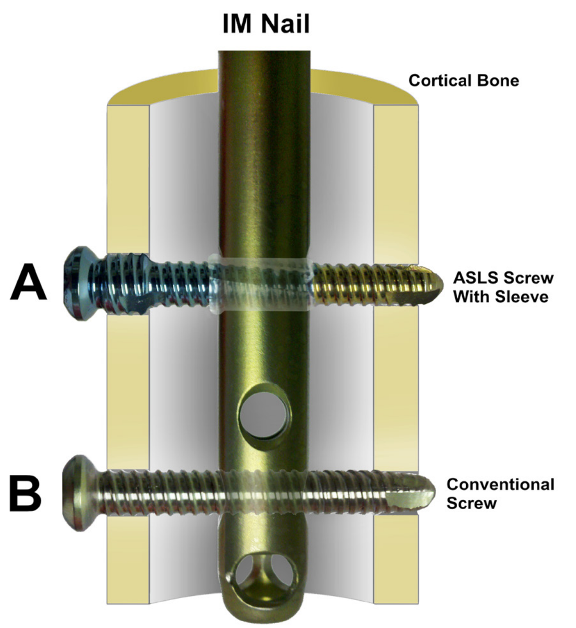

Figure 1. The two-screw systems used in the study: the angular stable locking system (ASLS) with a polymeric sleeve (**A**), and the conventional IMN interlocking screw (**B**).

interlocking screw placement. Group 4 consisted of two ASLSs placed medial-lateral to represent the ASLS version of Group 1. Group 5 consisted of one ASLS placed medial-lateral to represent the ASLS version of Group 3.

Biomechanical Testing

All specimens were positioned vertically on a material testing system (MTS 858 Mini-Bionix, MTS, Eden Prarie, MN) and tested in cyclic axial compression and torsion. For axial compression, the tibiae were positioned between two poly(methyl methacrylate) (PMMA) molds (Figure 3A), and load was applied eccentrically through a bearing at a point 10 mm medial and 10 mm lateral to

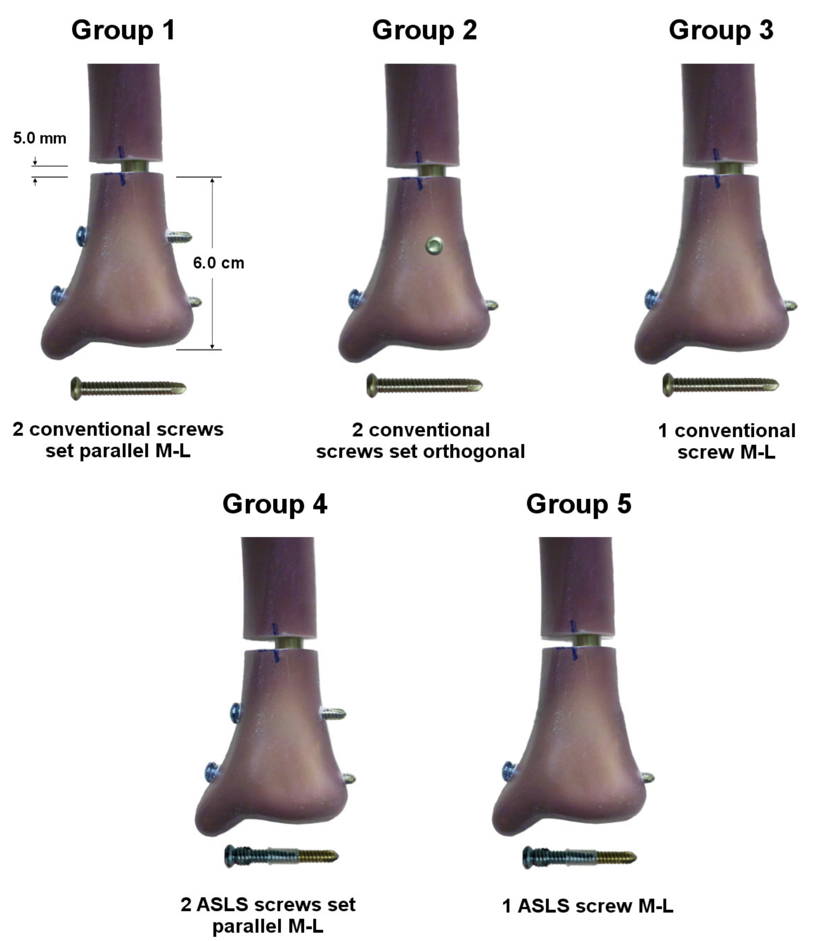

Figure 2. The five distinct distal locking configurations tested in this study with the type of screw employed for each.

the intercondylar tubercle (18,19). Each specimen was preloaded to 100 N, and then a sinusoidal loading cycle of median 700 N and 600 N amplitude was applied for 20 cycles at 1 Hz, providing a total compressive load range of 100-1300 N (22). For torsion testing, the tibiae were vertically clamped using a custom jig and PMMA molds (Figure 3B) and loaded to 7 Nm in both internal and external rotation at 1 Hz for 20 cycles. The loading conditions were chosen to simulate immediate postoperative full weight-bearing forces.

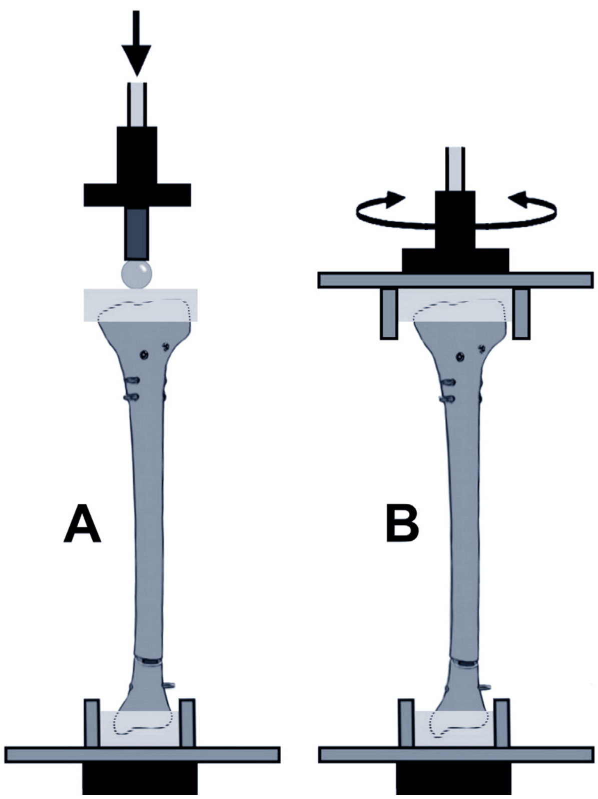

Figure 3. Mechanical testing setup for axial compression (**A**) and torsional (**B**) testing.

Stiffness was determined from load versus displacement curves for each loading test. Average displacement and stiffness were recorded and compared between the experimental groups. Statistical analysis included analysis of variance (ANOVA) with Tukey adjustment for multiple comparisons and alpha of 0.05. A priori power analysis from a pilot run revealed that 4 specimens in each of five experimental groups would be sufficient for detecting statistically significant differences.

RESULTS

The axial load testing results for all groups are depicted in Figure 4. The average R2 value for axial stiffness was 1.00. The mean axial stiffness of each group was 1628.10±142.07 N/mm for Group 1; 1554.58±115.06 N/mm for Group 2; 1632.95±171.61 N/mm for Group 3; 1801.88±133.31 N/mm for Group 4; and 1610.75±133.00 N/mm for Group 5. The greatest axial stiffness was demonstrated in Group 4 (ASLS parallel) specimens. The mean axial displacement of each group was 0.71±0.05 mm for Group 1; 0.73±0.04 mm for Group 2; 0.72±0.07 mm for Group 3; 0.64±0.05 mm for Group 4; and 0.71±0.05 mm for Group 5. There were no statistically significant differences between any of the groups for axial stiffness or displacement.

The torsion loading mean stiffness and total displacement test results for all groups are depicted in Figure 5. The total torsion stiffness of each group was 1.15±0.20 N/mm-deg for Group 1; 1.25±0.13 N/mm-deg for Group 2; 0.75±0.15 N/mm-deg for Group 3; 1.25±0.11 N/mm-deg for Group 4; and 1.12±0.22 N/mm-deg for Group 5. The greatest construct torsion stiffness was demonstrated in Groups 2 and 4, and the average R2 value was >0.94. Group 3 (single ML conventional) specimens demonstrated significantly lower values for torsion stiffness compared to all other testing groups ($p<0.048$). The total torsional displacement of each group was 9.61±1.27 deg for Group 1; 8.91±0.47 deg for Group 2; 13.22±2.56 deg for Group 3; 8.55±0.28 deg for Group 4; and 10.20±2.33 deg for Group 5.

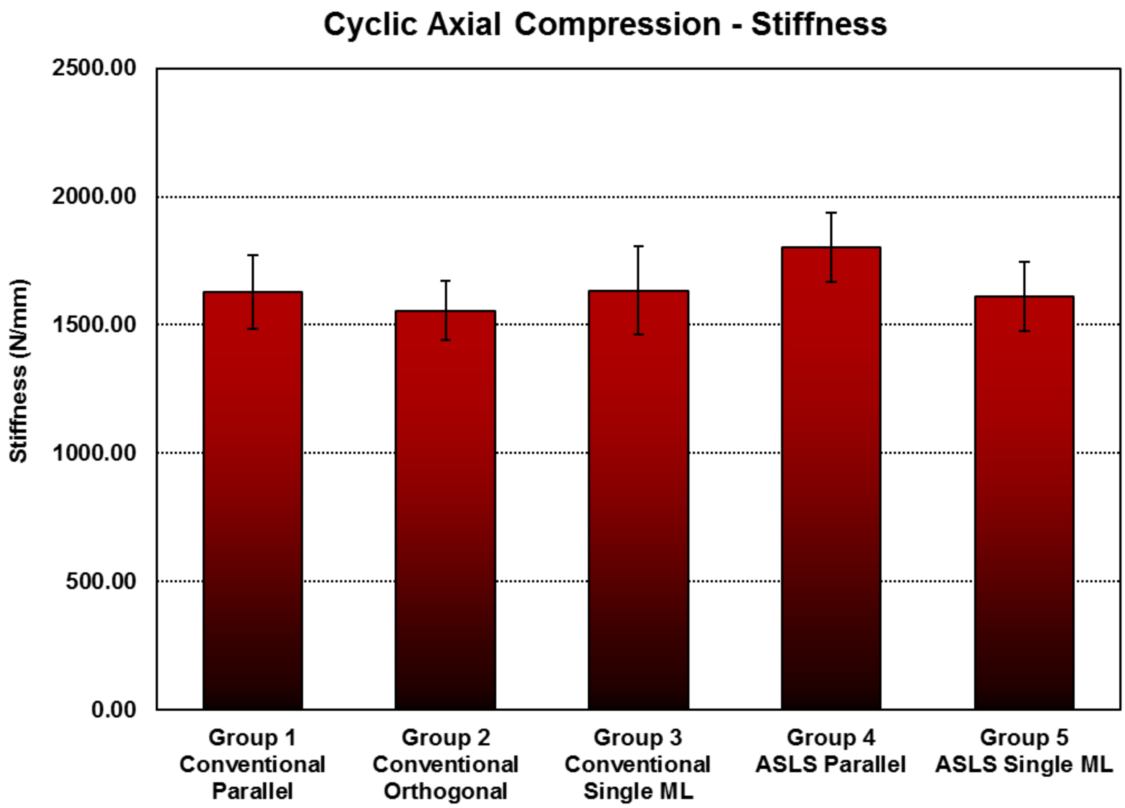

Figure 4. Average axial compressive stiffness for each of the five groups. No difference in the axial stiffness was observed between tested configurations.

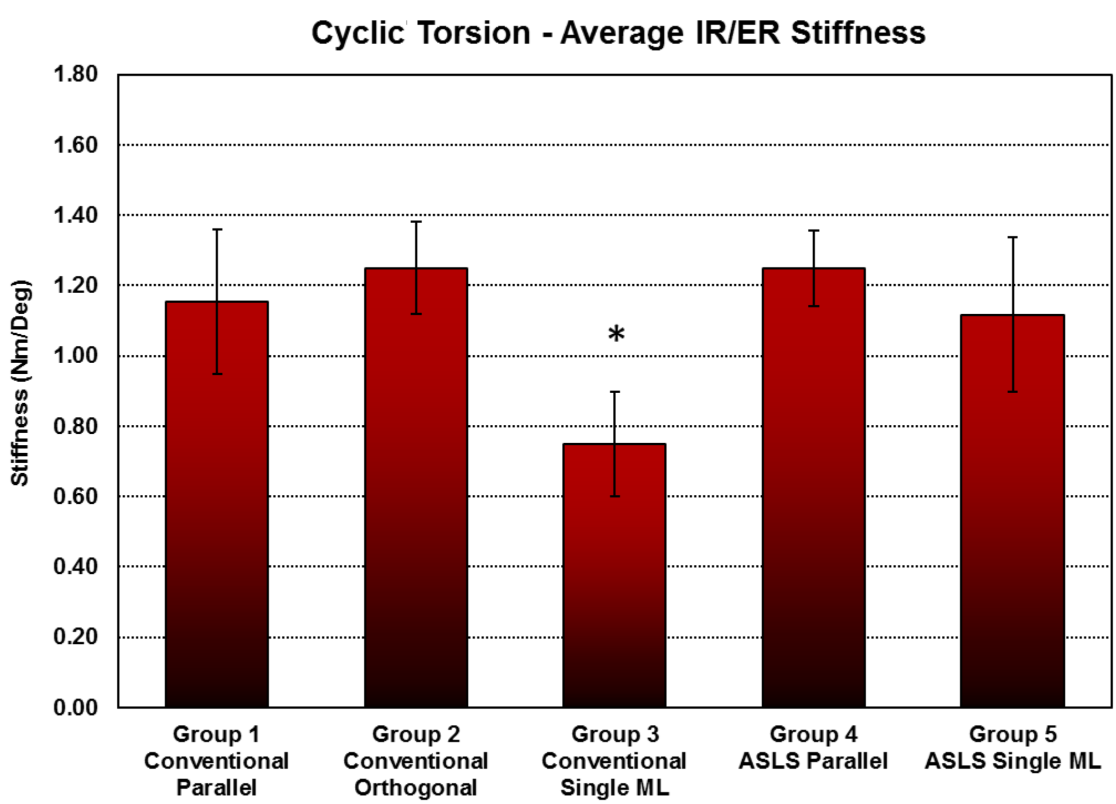

Figure 5. Average of internal and external torsional stiffness for each tested group. Significanly lower torsional stiffness was observed for Group 3 compared to the other groups.

There were no statistically significant differences in mean torsional displacement between internal and external rotation among any of the testing groups. Total torsional displacement was significantly greater for Group 3 (single ML conventional screw) compared to Group 2 (two conventional orthogonal) (p=0.017) and Group 4 (ASLS parallel) (p=0.01), respectively.

DISCUSSION

The management of unstable distal tibia fractures remains challenging (23,24). Although IMN fixation of tibia shaft fractures is considered the “gold standard”, there is considerable concern about the use of IMN for distal metaphyseal tibia fractures. This apprehension is due to the problems associated with the limited availability of bone for distal fragment fixation, maintaining fracture reduction, and the risk of nail penetration into the ankle joint. These issues can frequently result in distal tibia fracture malunions, delayed unions, or nonunions (8,25). Although IMN surgical technique modifications (blocking screws, larger nails, oblique distal interlocking screws orientation, supplemental plate augmentation) were developed to address some of these concerns, very distal tibia fracture fixation problems continue (8).

The Expert tibia nail with ASLS capability is a novel concept that can convert the standard nail-interlocking screw to a fixed-angle construct for enhanced distal fragment fixation. Previous biomechanical studies using ASLS (18,20,26,27) have demonstrated an increase in both axial and/or torsional stability. Horn et al. (18) reported a twofold increase in axial stiffness between ASLS versus conventional screws (620 N/mm vs 1420 N, respectively). However, the mean age of the human cadaver specimens used in that study was 77 years. In addition, 10 mm diameter nails were utilized in each specimen regardless of the size of the cadaver tibia diameter. Although the ASLS axial stiffness values in the present study of composite bone tibiae were similar to those previously reported (18), axial stiffness in the conventional screw group were found to be higher and more comparable to the ASLS group. This suggests that ASLS, similar to conventional locking plate designs, may have its most substantial effect in the older and/or more osteoporotic patient. The Horn at al. study (18), however, did not assess the torsional merits of ASLS.

Gueorgueiv et al. (20), in a cadaver tibia model, similarly demonstrated that the torsional stability of three conventional distal interlocking screws was comparable to two ASLS screws. Wähnert et al. (27), compared a three-screw configuration with ASLS versus conventional screws in porcine bone and found that the ASLS group exhibited only a 10% increase in axial stiffness, but a 70% increase in torsional stiffness.

Our study suggests that there is no statistical difference (p>0.05) between any of the groups when two distal interlocking screws are employed regardless of screw orientation or the presence of ASLS. While the two-screw ASLS stiffness had trend to higher values in both axial and torsion loading, this was not statistically significant compared to other two-screw fixation. These results, similar to those of Wähnert et al. (27), demonstrated an approximate 10% increase in axial stiffness for ASLS versus conventional two-screw configuration; however, no difference in stiffness with respect to torsion was observed. In addition, the orthogonal conventional screws (Group 2) were also higher in torsional stiffness compared to the medial-lateral conventional screws (Group 1). In fact, the orthogonal screw model torsional stiffness was comparable to that of all of ASLS groups.

Our study also demonstrated that the axial and torsional stability of one-screw ASLS (Group 5) is not statistically different (p=0.99) from that of either of the two conventional screw constructs (Groups 1 and 2). The weakest group was the single conventional screw (Group 3), which showed similar axial loading stiffness but significantly (p<0.048) less torsion compared to the other groups. This suggests that a single conventional screw, while providing sufficient axial stiffness to the construct, may not provide sufficient torsional resistance, and therefore two conventional screws would be recommended for optimal IMN fixation. The single-screw ASLS group (Group 5) was statistically stiffer in torsion than the single conventional screw (Group 3), and had comparable axial stiffness and displacement to the two screw configurations in Groups 1, 2, and 4. This suggests that one ASLS may offer the same biomechanical characteristics as two conventional screw configurations, and may avoid the placement of multiple distal screws. Previous studies have documented that the placement of distal interlocking screws is not entirely benign, and in addition to the surgical time, radiation exposure, and costs, there is always the possibility of soft tissue injury during the procedure (28,29). The surgeon's ability to maintain optimal construct stability while eliminating the risks associated with multiple screws constitutes a clear design advantage of the ASLS over more conventional locking screw designs in intramedullary nailing of the distal metaphyseal tibia fractures.

There are several study limitations. The tibia fixation and loading characteristics of synthetic bone utilized may not reflect the variations in bone quality and conformation encountered in vivo. However, because the composites are manufactured to achieve consistency in composition and configuration, direct comparisons across study groups involving different fixations are more feasible. Another limitation is the limited number of specimens tested per group; however, consistent and important relationships and differences in the groups tested were demonstrated. Finally, without repetitive cyclic loading, this study could not assess the effects of short- and long-term degradation of the biodegradable sleeve and/or conventional interlocking construct stability.

CONCLUSIONS

This is the first study to compare the biomechanical effects of IMN interlocking screw number and orientation between ASLS versus conventional interlocking screw constructs in a distal tibia fracture model. The study concludes that in this composite tibia model, one ASLS provides adequate axial and torsional stiffness and displacement compared to other two-screw configurations (both ASLS or conventional). Although two ASLS screws provide increased axial and torsional stiffness and less displacement compared to all of the IMN interlocking constructs, this difference was not statistically significant when compared to other two-screw conventional configurations. Finally, this biomechanical study demonstrated no statistically significant difference in the orthogonal versus parallel conventional interlocking screw placement in distal tibia fracture IMN fixation.

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