



Does intramedullary elastic nail augmentation increase resistance to bending stress in plate fixation of long bones? A biomechanical study on lamb cadaveric femurs

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Long bone fractures are one of the common problems in orthopedics and traumatology practice. These fractures, previously treated with conservative methods, tend to be treated surgically currently, thanks to advancing orthopedic surgical procedures and fixation implants.^[1,2] Developing implant technology offers many fixation options such as plate-screw, intramedullary nail (IMN) and external fixator.^[3,4] The main goal of all these devices is to provide stable fixation of the fracture. Although these methods have some biomechanical advantages or disadvantages over each other, it is still controversial which fixation method should be preferred.^[5]

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ABSTRACT

Objectives: The aim of this study was to evaluate the bending strength of plate-screw fixation augmented with titanium elastic nails (TENs) in a simple long bone fracture model using lamb cadaver femurs.

Materials and methods: A total of 24 lamb cadaveric femurs that were osteotomized transversely from the mid-diaphysis with a bone saw were used to obtain a simple fracture model. The femurs were divided randomly into three groups. In Group 1, only plate-screw was used for fixation. In Group 2, plate-screw fixation was augmented with a 2.5-mm TEN. In Group 3, plate-screw fixation was augmented with two 2.5-mm TENs. Each bone model was positioned on a mechanical testing machine. Subsequently, three-point bending loads were applied to each bone to measure the force required for failure at the osteotomy site. The data were recorded on a computer connected to the test device and the bending strengths of all samples were calculated.

Results: There was no statistically significant difference in the bending strength (megapascals) between Groups 1 and 2 or between Groups 2 and 3 ($p>0.05$). However, the bending strength in Group 3 was significantly higher than in Group 1 ($p<0.05$).

Conclusion: The application of intramedullary TEN during surgery in long bone fractures, combined with a bridge plate, may be helpful to strengthen the fixation stability.

Keywords: Biomechanics, diaphyseal fractures, elastic nail augmentation, plate fixation, three-point bending.

Fixation implants stabilize the fracture site by transferring deforming forces to intact bone fragments. Thus, a suitable environment for fracture healing is provided.^[6] In particular, weight-bearing long bone fractures are subjected to axial, torsional and bending

forces.^[3,5] Therefore, these deforming forces should be considered while deciding on the most optimal fixation method. In clinical practice, plate-screw or elastic IMNs (EIMN) can be preferred in the treatment of pediatric femur fractures.^[7,8] The plate-screw is more stable for torsional forces, but weaker against bending forces by the longer moment arm; therefore, the plate failure risk with weight-bearing is higher than with intramedullary methods.^[9,10] This situation is a handicap for plate-screw fixation to achieve early weight-bearing during fracture healing.^[11,12]

In the present study, we hypothesized that EIMN augmentation could increase resistance to bending force in long bone fractures fixed with plate-screw. We, therefore, aimed to evaluate the bending strength of plate-screw fixation augmented with titanium elastic nails (TENs) in a simple long bone fracture model using lamb cadaver femurs.

MATERIALS AND METHODS

Bone harvesting and sample preparation

Lamb femurs were used in this study due to the high cost and low availability of obtaining human cadaveric femurs and sawbones. Lamb cadaver femurs

were obtained from a slaughterhouse inspected by the Republic of Türkiye, Ministry of Agriculture and Forestry. Twenty-four femur bones were selected from healthy lambs, four to six-month-old, and 35 to 45 kg in weight, which were regularly checked by the veterinarian and included in the study. The femurs of fresh lamb cadavers were dissected and scraped from their soft tissues (Figure 1). Significant bone deformity or slaughter damage was evaluated visually and excluded. The narrowest width (mm) of the mid-part of the bone diaphysis, the length (cm) between the proximal-distal bony ends and the bone weight (g) were measured for each sample. The samples were, then, placed in numbered packages and their measurements were recorded. Bone quality was considered similar, as the femurs were obtained from healthy lambs of similar age groups and had similar measurements. Therefore, no additional bone density measurements were made. The prepared samples were stored at 4°C until the surgical procedure.

Study design and groups

Three groups were formed by randomly selecting the femurs, with eight samples in each group. After the fracture model was created, it was planned to



FIGURE 1. Preparation stages of fracture models. (a) Scrubbed lamb femur sample from soft tissues. (b) A simple transverse osteotomy with a motored handsaw. (c) Long bone fracture model from the mid-diaphysis.

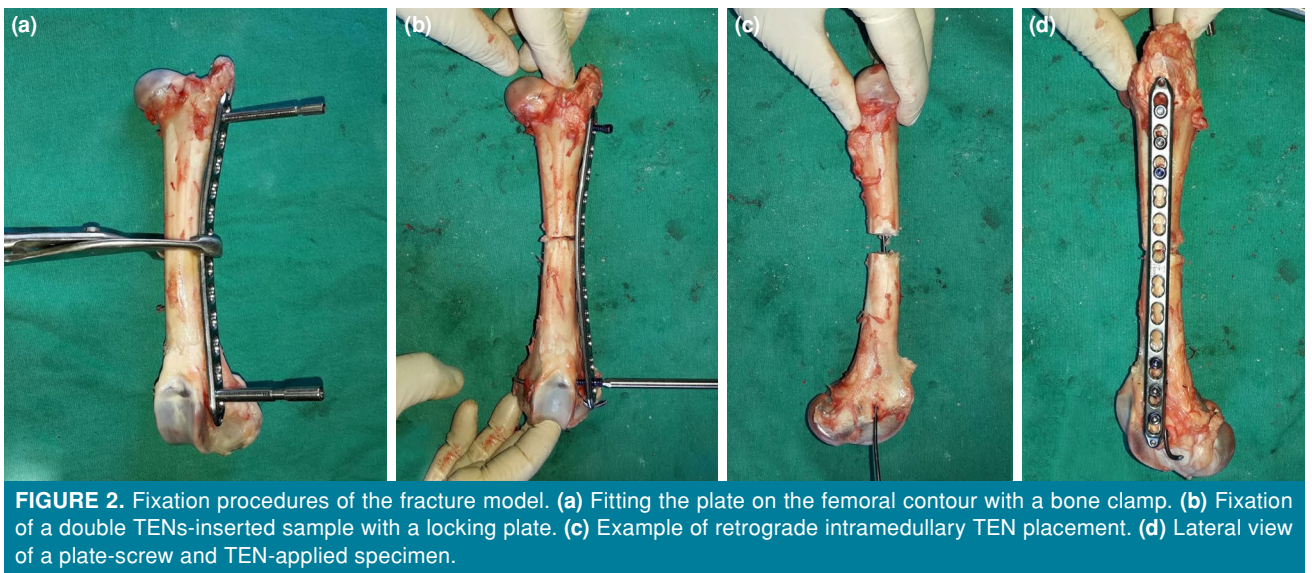


FIGURE 2. Fixation procedures of the fracture model. (a) Fitting the plate on the femoral contour with a bone clamp. (b) Fixation of a double TENs-inserted sample with a locking plate. (c) Example of retrograde intramedullary TEN placement. (d) Lateral view of a plate-screw and TEN-applied specimen.

apply plate-screw fixation to Group 1, plate-screw and single EIMN fixation to Group 2, and plate-screw and double EIMNs fixation to Group 3.

Fracture model and fixation technique

A standard simple fracture model was created by cutting all femurs transversely with a motored handheld saw in the mid-diaphysis (Figure 1). The implants for fixing the fractures are 3.5-mm-thick, 12-hole titanium limited contact dynamic compression plates, 3.5-mm in diameter cortical locking screws and 2.5-mm in diameter (TENs) (TST Tibbi Aletler San., Istanbul, Türkiye). In Group 1, the fracture was fixed with a lateral plate while in the anatomically reduced position. The plate was placed with a bone clamp to fit the lateral cortex curvature of the femur and fixed with six locking screws of appropriate size, which were inserted through the double cortex into three consecutive holes in the most proximal and distal (Holes 1, 2, 3 - 10, 11, 12) (Figure 2). In Group 2, the fracture was fixed anatomically with a lateral plate following the placement of a single EIMN. The distal lateral metaphysis of the femur was pierced with an awl at the level of the inter-epicondylar axis and in the midline in the sagittal plane. The EIMN was placed retrogradely through the awl hole. Then, a plate was applied to the lateral femur using the same technique in Group 1. In Group 3, the fracture was fixed anatomically with a lateral plate, after double EIMNs placement. The distal metaphysis of the femur was pierced medially and laterally with an awl at the level of the inter-epicondylar axis and in the midline in the sagittal plane. Double EIMNs were placed retrogradely through the awl holes. Then, a plate was

applied with the same technique as others (Figure 2). In Group 2 and Group 3, EIMNs were placed first, then plate-screw. Thus, the screws did not interfere with nail placement.

The fixation procedures were completed and, then, radiographic images of each femur were taken. These radiographs were examined to confirm that the implants were placed with proper technique and the screws did not affect the TEN orientation, and there were no iatrogenic fractures (Figure 3).

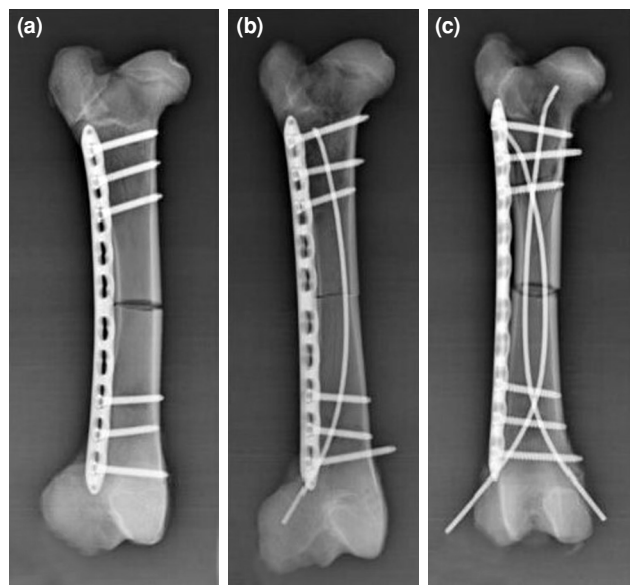


FIGURE 3. Radiographic images of the groups. (a) Group 1 sample. (b) Group 2 sample. (c) Group 3 sample.

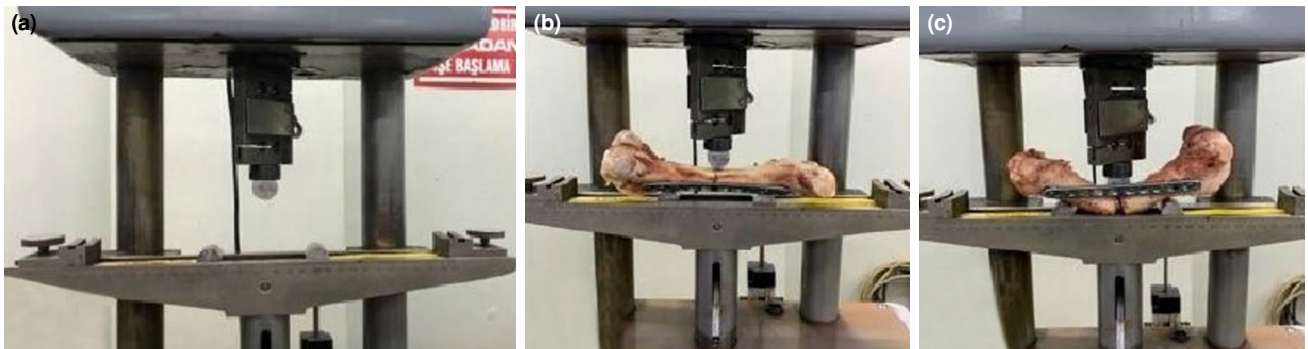


FIGURE 4. Positioning of bone models and application of mechanical tests. (a) Appearance of the testing machine. (b) Positioning of bone models at the testing machine. (c) Application of three-point bending load to the samples and deformation.

Subsequently, all samples were frozen at -20°C and stored until the day of biomechanical testing.

Biomechanical test

Frozen lamb femurs were transferred to the Yıldız Technical University, Metallurgical and Materials Engineering Laboratory under suitable conditions. Samples were defrosted at room temperature before the biomechanical test and were evaluated for any missed inappropriate situation before insertion into the test device. Bone fissure developing at the screw edge was noticed in one sample in Group 1 and was excluded from the study. The three-point bending test was performed with a hydraulic loading device (Serial number 7079, Mohr-Federhaff, Germany). Specially designed 20 mm-height steel fulcrums and a loading head were developed for the test (Figure 4). The samples were placed on the

fulcrums at equal distances from the mid-diaphyseal fracture line. A load of 0.75 mm/min was applied, with the loading head to the fracture. The force applied during the loading test was recorded by a computer in Newtons (N). The point at which force began to decrease was described as the deformation force.^[13] The bending strengths were calculated using morphometric measurements and biomechanics test data in Megapascals ($\text{MPa}=\text{N}/\text{mm}^2$).

Statistical analysis

Statistical analysis was performed using the IBM SPSS for Windows version 20.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were presented in mean \pm standard deviation (SD), median (min-max) or number and frequency, where applicable. The distribution of the data was evaluated with the Shapiro-Wilk test. The Kruskal-Wallis test

TABLE I
Results of bone dimensions and weights measured

Sample no	Measurement data of lamb femurs								
	Group 1			Group 2			Group 3		
	Length (cm)	Width (mm)	Weight (g)	Length (cm)	Width (mm)	Weight (g)	Length (cm)	Width (mm)	Weight (g)
1	21	19	77	17	16	69	18	18	78
2	19	17	75	16	17	67	20	19	79
3	22	20	86	17	17	73	18	16	75
4	16	12	66	17	20	77	16	15	70
5	17	18	71	19	18	75	18	17	73
6	19	18	74	15	16	72	16	17	71
7	17	19	72	16	17	74	18	17	75
8				19	21	81	19	18	77
Mean \pm SD	18.7 \pm 2.2	17.6 \pm 2.6	74.4 \pm 6.2	17 \pm 1.4	17.7 \pm 1.8	73.5 \pm 4.4	17.9 \pm 1.4	17.1 \pm 1.2	74.7 \pm 3.2

SD: Standard deviation.

TABLE II			
Bending strengths of samples according to groups			
Sample no	Bending strength results (MPa)		
	Group 1	Group 2	Group 3
1	38.21	43.91	56.06
2	37.39	52.73	48.67
3	35.14	43.96	53.90
4	45.70	43.91	42.18
5	48.89	39.18	58.82
6	39.68	54.22	58.50
7	46.51	38.34	47.54
8		40.88	43.37
Mean±SD	41.65±5.30	44.64±5.88	51.13±6.59

MPa: Megapascal; SD: Standard deviation.

was used to compare the quantitative data among the three groups. The Mann-Whitney U test was used to evaluate the paired groups that made a significant difference. A *p* value of <0.05 was considered statistically significant.

RESULTS

The mean height of the lamb femurs was 18.7±2.2 (range, 16 to 22) cm in Group 1, 17±1.4 (range, 15 to 19) cm in Group 2, and 17.9±1.4 (range, 16 to 20) cm in Group 3. The mean mid-diaphyseal width was 17.6±2.6 (range, 12 to 20) mm in Group 1, 17.7±1.8 (range, 16 to 21) mm in Group 2, and 17.1±1.2 (range, 15 to 19) mm in Group 3. The mean weight was 74.4±6.2 (range, 66 to 86) g in Group 1, 73.5±4.4 (range, 67 to 81) g in Group 2, and 74.7±3.2 (range, 70 to 79) g in Group 3 (Table I). There was no

significant difference among the groups in terms of the femur length, width and weight (*p*>0.05 for all).

According to the three-point bending test results of the samples, the mean bending strength was 41.65±5.30 (range, 35.14 to 48.89) MPa in Group 1, 44.64±5.88 (range, 38.34 to 54.22) MPa in Group 2, and 51.13±6.59 (range, 42.18 to 58.82) MPa in Group 3 (Table II) (Figure 5). There was no significant difference between Group 1 and Group 2 (*p*=0.354). In addition, no significant difference was found between Group 2 and Group 3 (*p*=0.074). However, the bending strength of Group 3 was significantly higher than Group 1 (*p*=0.021) (Table III).

DISCUSSION

Conservative treatment of long bone fractures, particularly load-bearing, has been replaced by surgical treatment methods due to prolonged hospitalization and complications secondary to immobilization.^[2,14] Surgical treatment has some complications such as devascularization of the fracture, nonunion and infection.^[1,2] To minimize these complications, biological fixation methods such as IMN and submuscular bridge plating that preserve the blood supply of the fracture area are preferred.^[3] The bridge plating method preserves biology, but is less stable than rigid fixations. Preservation of soft tissues and blood supply is essential for fracture healing, but an unstable fixation is likely to result in nonunion and failure.^[1,2,15] Therefore, the main goal of fracture fixation is to increase the stability while preserving the biology.^[5]

In our study, the placement of intramedullary double TENs significantly strengthened plate

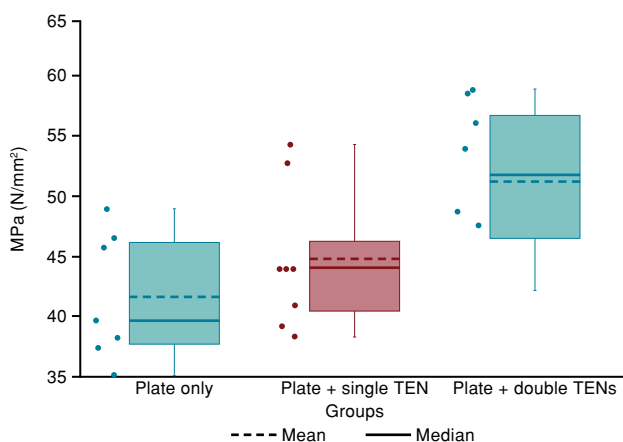


FIGURE 5. The bending strength scatterplot of the samples by groups.

TABLE III
Statistical comparison of biomechanical test results among three groups

Comparison of groups	Bending strength statistics			p
	Mean±SD (MPa)	Min-Max (MPa)	Median (MPa)	
Group-1	41.65±5.30	35.14-48.89	39.68	0.354
Group-2	44.64±5.88	38.34-54.22	43.91	
Group-1	41.65±5.30	35.14-48.89	39.68	0.021*
Group-3	51.13±6.59	42.18-58.82	51.28	
Group-2	44.64±5.88	38.34-54.22	43.91	0.074
Group-3	51.13±6.59	42.18-58.82	51.28	

MPa: Megapascal; SD: Standard deviation; * p<0.05.

fixation against bending loading. Intramedullary augmentation of plate fixation can prevent plate failure by reducing the deforming forces on the structure. Başıcı et al.^[16] in the sawbones distal femur fracture model, found that the combination of IMN and plate had the highest strength compared to the plate or IMN only, and that combining fixation methods eliminated each other's weaknesses. Based on principles similar to our study, Koval et al.^[17] observed that plate fixation with intramedullary Kirschner wires was beneficial in fibular fractures in elderly patients. Similarly, Anderson et al.^[7] reported that adding EIMN to the treatment of femoral shaft fractures that could not be adequately stabilized by external fixation alone could be used as a simple method to obtain adequate stability and predictable results. Ertürk et al.^[18] observed that this combination shortened external fixation times and improved clinical and radiological outcomes in their prospective clinical study in which they used EIMN and an external fixator together in the definitive treatment of open tibial fractures. All the aforementioned studies indicate that the locking plate and the external fixator, which performs the same function, can be supported by an intramedullary fixation to form a solid structure resistant to all deforming forces including rotational. Our study results also support this.

Ertürk et al.^[18] provided faster union than expected in their studies. As reaming is not required for EIMN placement, the effect on intramedullary blood supply is minimal. When three-point fixation is applied in diaphyseal fractures, it provides internal fixation without disturbing the blood flow. Katı et al.^[19] compared IMN and bridge plate technique in tibial fractures and found the union times to be similar. They reported that the bridge plate provided fixation in the periosteum without iatrogenic damage.

Considering these studies, augmentation of bridge plating with EIMN may shorten the union time, as it increases stability without impairing fracture blood supply. *In vivo* animal studies and clinical studies are needed to confirm this.

In our study, single EIMN augmentation did not provide any significant benefit. This may be due to the diameter of the material covering the medullary canal. Hulse et al.^[20] in a biomechanical study investigating the effect of intramedullary pin size on reduction in bone plate strain, an intramedullary fixation of 30% of the medullary canal diameter did not provide significant support to the plate (resistance increase of 6%) and IMN covering 50% of the medullary canal diameter increased plate tension 13 times (resistance increase 78%). Mahar et al.^[21] observed the greatest increase in stability in fixation of the femur sawbones fracture model with a canal diameter of 9 mm, when they increased the TEN diameter from 3 mm to 3.5 mm and 80% of the canal was filled. The highest strength was found in the fixation made with TENs with a diameter of 4 mm. We used a 2.5-mm TEN in our study. A single EIMN application may have also made a significant contribution to stability, if a thicker diameter TEN was used. Double TEN may have added significant strength to the system, both by filling the medullary canal and by what we call the "double-sided three-point principle".^[22] According to the biomechanical data of our groups, the average bending strengths increased with a single EIMN. Also, no significant difference in resistance was found between single and double EIMNs augmentation. Another reason why single EIMN was not found to be statistically significant may be the insufficient number of samples. This can be clarified with further studies using a higher TEN diameter and a larger sample size.

Bone-like materials are limited for *in vitro* studies. Although sawbones are standard products with anatomical and mechanical properties similar to human bone, no synthetic material is the same as bone tissue with a collagen network and mineral matrix.^[23] However, obtaining the human cadaver femur is difficult and expensive. Sawbones or various animal bones were used in previous similar studies.^[16,20] In this study, we preferred cheap and easily accessible fresh lamb cadaveric femurs, with an organic and mineral matrix of bone tissue. Nevertheless, there are differences between human and lamb femurs. The loading dynamics of bipedal humans and quadrupedal animals are of course different.^[24] There are many differences in the organic collagen network and inorganic mineral matrix density, trabecular and cortical architecture, anatomical structure and dimensions.^[25] Under these conditions, the vectorial magnitude and direction of the bending forces we examined in our study cannot be expected to correspond exactly to human femoral biomechanics. However, this is a preclinical *in vitro* study, and it could provide an idea for the comparison of fixation methods in a long bone fracture model due to the similarity of its organic matrix, rough anatomy, and cortical and medullary structure.

Although the gold standard treatment of long bone fractures is rigid reaming IMN, plate-screw fixation can still be preferred as an alternative method in some cases.^[26,27] Pediatric or adolescent patients with femur fractures with active physis are an example of this situation. The EIMN or plate-screw are two effective methods for internal fixation of pediatric femur fractures.^[27] While EIMN is preferred in children under 40 to 50 kg, plate-screw is firstly preferred in overweight patients with open physis.^[27,28] The disadvantage of plate fixation compared to intramedullary methods is that it is weaker against bending forces acting on the bone.^[5,16,19] The reason for this is that the moment arm is longer due to the laws of physics. This may cause fractures and failure in the plate-screw system during the postoperative weight-bearing and mobilization process.^[29] As in our study, the bending stresses on the plate could be reduced by combining plate-screw and intramedullary TEN in selected patients. In this way, early weight-bearing and mobilization of the patient could be beneficial in terms of fracture healing and reducing morbidity. Additionally, during the fixation of displaced and unstable long bone fractures with plating, the placement of an intramedullary TEN first helps to

provide and maintain the alignment of the fracture more easily and malalignment could be prevented.

Limitations

First, in our study, fresh lamb cadaver femurs were evaluated instead of human femurs. The lamb femur does not have the same features as the human femur in terms of structure and biomechanics. Second, the bone qualities were considered similar, since the examined healthy lamb femurs were of similar age groups, sizes, and weights. However, evaluating bone quality with bone mineral density or indentation measurement would provide more objective results. Third, three-point bending test was applied until deformation occurred in the biomechanical test device. Instead, repeated cyclic bending and four-point bending tests would have been more appropriate to examine the physiological loading. In addition, other deforming forces of physiological loading such as torsion, axial loading and shear were unable to be evaluated due to lacking technical facilities. In the current study, we examined lamb cadaver femurs in a biomechanical laboratory and could not predict outcomes *in vivo*. Therefore, an animal study investigating the effect of our method would provide more valid results.

In conclusion, augmentation of the long bone plate-screw fixation with intramedullary double TENs significantly increased the three-point bending strength in the fresh lamb cadaveric femur fracture model. Based on these findings, adding intramedullary TEN on the plate-screw fixation may increase stability, particularly in the lower extremity long bone fractures, and benefit early weight-bearing and fracture healing in clinical practice. Further well-designed, more comprehensive biomechanical and *in vivo* animal studies are needed to evaluate their effects.

Ethics Committee Approval: Ethics committee decision is not required as the study was performed on sheep cadaver femurs.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept: C.E., E.E.; Design: E.E., C.E.; Control/supervision, critical review: C.E., H.B.; Data collection and/or processing, materials: E.E., J.H.T., E.K.; Analysis and/or interpretation: E.E., H.B., J.H.T.; Literature review, writing the article: E.E., H.B.

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