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ORIGINAL ARTICLE

A Novel Plate for Vertical Shear Fractures of Medial Malleolus: A Biomechanical Study

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Background: This study aims to evaluate and compare stiffness and the load to failure values of our novel medial malleolus compression plate (MP) and 3,5mm 1/3 tubular plate (TP) in the treatment of vertical shear fractures of medial malleolar fractures.

Methods: Fourteen identical synthetic third generation composite polyurethane bone models of right distal tibia were randomly separated into two groups. Fracture models were created with a custom-made osteotomy guide to provide the same fracture characteristics in every sample (AO OTA type 44A2). Fractures were reduced and novel medial malleolus compression plate was applied to bone models in MP group and tubular plate was applied to TP group. All samples were evaluated biomechanically, force/displacement and the load to failure values were recorded.

Results: The force required to create displacement in MP group was twice of that of the TP group. There was a significant difference between two groups in all amounts of displacement ($p = .006$, $p = .005$, $p = .007$ and .015 for 0.5, 1.0, 1.5, and 2.0 mm, respectively).

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Conclusions: In the treatment of vertical shear fractures of the medial malleolus, the strength of fixation with the novel medial malleolar compression plate is biomechanically higher than the one-third semi-tubular plate.

Fractures of the ankle are common injuries that represent 17% of all hospitalized fractures (1). Medial malleolus is a key element in ankle stability. However, the optimal fixation method for these injuries still remain controversial, ranging from K-wire, tension band or screw-only methods to various plate applications (2). The controversy becomes even more prominent in vertical shear fractures, which occur due to a supination adduction force over medial malleolus articular surface (3). Neutralization plate fixation of these vertical fractures have been found biomechanically superior to screw fixations (2). On the other hand, compression achieved by screws passing the fracture line perpendicularly creates an important benefit in screw fixation methods (4) (5). To combine these advantages of both methods we have developed a novel medial malleolus plate, which comprises two holes for cannulated compression screws and a sliding compression mechanism.

In this biomechanical study we aimed to compare the stiffness and load to failure values of our novel medial malleolus compression plate (MP) and 3,5mm 1/3 tubular plate (TP) (Fig.

1). Our hypothesis was MP would achieve higher load to failure values and a stiffer fixation construct compared to TP.

Materials and Methods

This study was conducted at İzmir Katip Çelebi University University Biomechanics Laboratory between June and August 2021. Approval was obtained from the Biomechanics Department before the start of the study.

Fourteen identical synthetic third generation composite polyurethane bone models of right distal tibia were randomly separated into two groups. Fracture models were created with a custom-made osteotomy guide to provide the same fracture characteristics in every sample (AO OTA type 44A2). Fractures were reduced and novel medial malleolus 3.5 mm compression plate (Patent app. no: TR 2019/17934) was applied to bone models in MP group and tubular plate was applied to TP group. All 5 holes of both constructs were filled with one 3.5 mm non-locking cortical, two 3.5 mm locking cortical, and two 4.0 mm partially threaded cancellous screws.

Fixation Technique

For MP group, the medial malleolus was reduced anatomically using a bone clamp. After that, the novel medial malleolus compression plate was placed. The distal two holes allow to use K-wires; over the K-wires the bone was drilled utilizing a sleeve. Also, a K-wire was placed in the middle part of the plate. After the placing of distal two 4.0 mm partially threaded cancellous screws, the plate was ~~slided~~ slid proximally and compression was maintained by a 3.5 mm non-locking cortical screw. Two proximal 3.5 mm locking cortical screws were placed to complete the fixation.

In TP group, after reduction and using a K-wire as a guide, the medial malleolus was drilled and two screws were placed. To obtain the buttress effect, 3.5 mm 1/3 tubular plate was used and fixation was completed (Fig. 2).

Biomechanical Testing

The biomechanical testing was performed using Shimadzu AG-IC static tester (Shimadzu Corp., Kyoto, Japan). A fixing gripper compatible with the tester was designed to apply force to specimens at angulation of 17-degree using SolidWorks (v.2016, SolidWorks Corp., MA, US). This apparatus consists of fixing points, cementing, and slider mechanism, as shown in Figure 3. Bone specimens are placed in the gripper, horizontal movement is provided so that the load with the slider mechanism is precisely on the head of the bone. Parts of the gripper were transferred to Simplify3D (v.4.0, Cincinnati, OH, US) as an STL file. They were formed with polylactic acid (PLA) material at 80% infill using the Mass Portal 3D printer (Grand Pharaoh XD 40, Mass Portal SIA, Riga, LV). The prepared specimens were fixed in a rigid way using the tile adhesive (C1TE) with approximately 36 hours of waiting time. A specimen of the tibia bone placed in the tester is shown in Figure 4. Force/displacement and the load to failure values were recorded. The load value at the failure point is known as the load-to-failure. It may be described as the location where there is a sudden decrease in load following the deformation. In this study, we accepted the failure point as a 2mm displacement from the starting point of the test. Because during the experiments, sudden decreases in force values were observed after 2mm.

Pretesting was carried out in order to prevent potential changes between anatomical bone models. The pretest was applied as a 10N preload for calculating the elastic modulus of bones. Testing was performed at a 1 mm/min speed until 2 mm displacement in the fracture line.

Statistical Analysis

Test results were analyzed to investigate whether there is a significant difference between groups with SPSS (v.25, IBM, NY, US) software for forces at four different displacements. The p-value (95%) was calculated using the Independent t-test. If a p-value is less than 0.05, it can be deduced that there is a significant difference between these two groups for loading.

Results

Force-displacement values at 0.5, 1, 1.5 and 2 mm were analyzed separately. In the analysis, it was found as $p < 0.006$ at 0.5mm, $p < 0.005$ at 1mm, $p < 0.007$ at 1.5mm and finally $p < 0.015$ at 2mm. According to the results, a significant difference was observed between the two plates. The load-to-failure of the two plates is shown in Figure 5.

The force required to create displacement in MP group was twice of that of the TP group. There was a significant difference between two groups in all amounts of displacement ($p = .006$, $p = .005$, $p = .007$ and .015 for 0.5, 1.0, 1.5, and 2.0 mm, respectively) (Table 1).

Discussion

The main finding of our study is that novel medial malleolus plate provided higher load to failure values compared to the tubular plate on osteotomized synthetic bone models to create AO OTA type 44A2 fractures.

Medial malleolus has a key role in providing the ankle stability. In treatment of medial malleolar fractures, various type of implants has been tried. The optimal fixation method is still remains controversial. K-wire, tension band or screw are the methods that are mostly preferred by orthopedic surgeons (2). Parallel screw fixation is the most popular method, owing to excellent compression achieved with this implants (5,6).

The controversy becomes even more prominent in vertical shear fractures, which occur due to a supination adduction force over medial malleolus articular surface (3). Neutralization plate fixation of these vertical fractures have been found biomechanically superior to screw fixations (2). Some authors suggest hook plate technique in fixation of medial malleolar fracture (7,8).

Jones et al. (8) compared three different constructs for fixation of medial malleolar fracture. The results of their study showed that antiglide plating technique is biomechanically superior to hook plate. In this study, only 3.5 mm non-locking cortical screws were used in all models. Considering that the fracture site is the metaphyseal region and that these fractures can develop in osteoporotic bone, the use of locking screws becomes essential. Our novel medial malleolus model has a design that allows the use of both locking and non-locking cortical screws. Vajapey et al. (7) also stated that the hook plate they used in their studies allowed cortical, cancellous and locking screw options as an advantage. Unlike the hook plate's design, in our plate design there are two holes in the distal that allow the fixation of the medial malleolus.

A study in a cadaveric model by Pollard et al. (9) demonstrated that 3.5-mm bicortical screws have greater pullout strength compared with 4.0-mm partially threaded cancellous screws. In our study we used 4.0-mm partially threaded cancellous screws in both groups. Our novel plate allows to use both bicortical and cancellous screws.

Anatomic reduction and ~~ridged~~ rigid fixation are essential for a better outcome and satisfactory results. However, the anatomical reduction is difficult in medial malleolar fractures with small fragments and bone loss. Therefore, instead of screw only fixation the hook plate is recommended by some authors (7,8). Also for a vertical shear fracture of medial malleolus, the tubular plates are used for a buttress effect (10). The novel plate provides a buttress effect and allows placing two screws for medial malleolus. This study presented a ~~safe and~~ rigid fixation with the novel medial malleolus compression plate.

Toolan et al. (11) concluded that an antiglide plate, with or without a distal lag screw, does not offer any advantage over lag screw fixation for the clinical treatment of vertical shear fractures of the medial malleolus. On the contrary, this study showed that the load to failure value of the novel plate was higher than that of the one third semitubular plate with distal lag screws.

Although various fixation methods have been described, two 3.5-mm, partially threaded cancellous screws or tension band wire is recommended for fixation of medial malleolar fractures (12). While these methods are sufficient in transverse fractures of the medial

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malleolar tip, plate seems to be superior in terms of union and stability in AO OTA type 44A2 fractures (7).

The morphology of medial malleolus fractures varies in a wide range of fracture types and accurate determination requires a 3D CT evaluation (13). As different treatment strategies are essential for different fracture morphologies, a recent classification proposed by Liu et al, also emphasized the unique characteristics of vertical fractures under a specific fracture type. Our findings may help develop a surgical strategy for these vertical fractures, and novel medial malleolus plate may constitute an important intervention modality. Different techniques and implants have been tried in the fixation of vertical shear fractures of medial malleolus by some authors (14,15). Zheng et al. (14) concluded that distal radius T-plates have advantages in the treatment of vertical shear fractures of medial malleolus. They thought that this plate has less soft tissue stimulation and could achieve early function exercise. Blake et al. (15) reported a case with a vertical shear medial malleolus fracture. They preferred to use a locked fibular plate for fixation. Good fracture healing was obtained and the study has demonstrated the potential for an alternative implant to use as a neutralization plate in the fixation of this type of fractures.

The advantages of the novel medial malleolar compression plate include 1) the ability to provide compression at the vertical fracture site due to its unique slider mechanism; 2) early ankle movements and weight bearing due to strong fixation; and 3) multiple screw options.

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Limitations of the study

This novel plate is not compared with hook plate. Jones et al. compared the hook plate with one-third tubular plate and one-third tubular plate showed superior results. We preferred to compare the stronger fixation method with our novel plate.

It has been evaluated only biomechanically, and it would be appropriate to evaluate the effect of clinical applications on radiological outcomes and ankle scores.

Conclusions

Regarding load to failure and stiffness of our novel medial malleolar compression plate has superiority to the traditional one-third semitubular plate with lag screws in AO OTA type 44A2 malleolar fractures. Clinical trials are essential to support the findings and determine the superiority regarding bone healing and outcomes.

Financial Disclosure: None reported.

Conflict of Interest: None reported.

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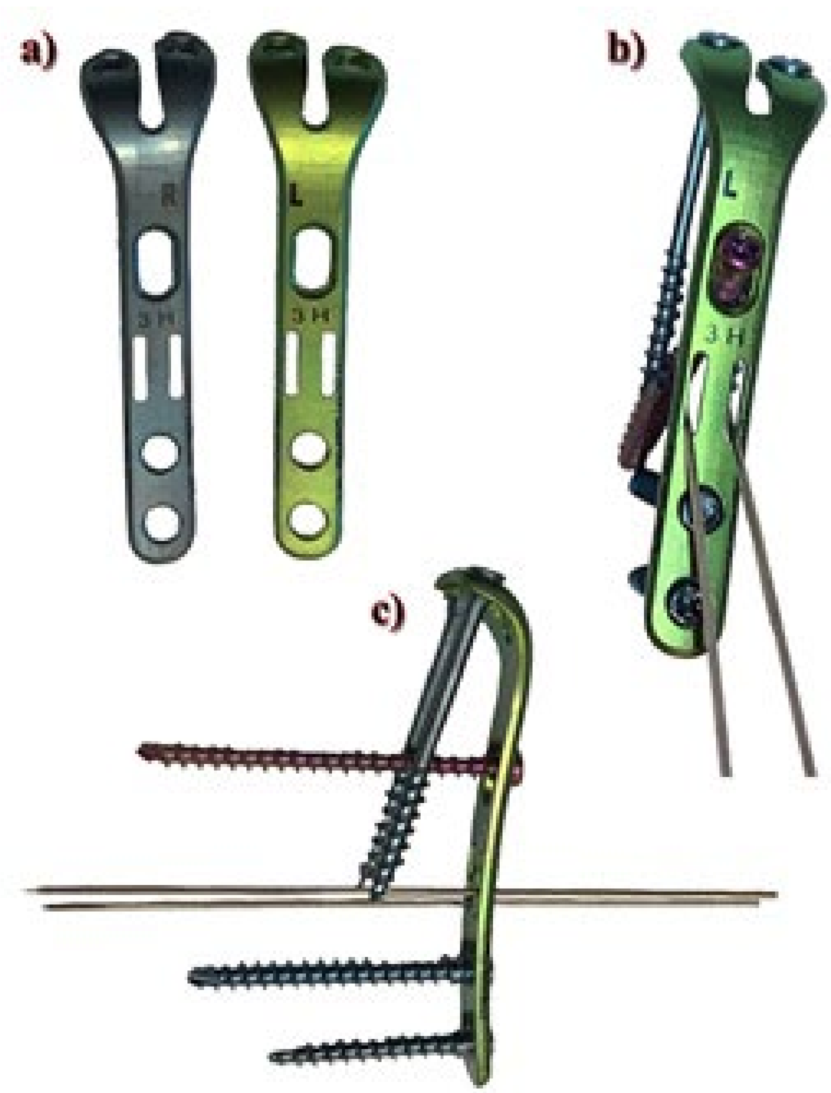

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Figure 1. The anteroposterior (a, b) and lateral (c) view of the novel medial malleolus compression plate. This plate can be used anatomically to the left and right sides.

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Figure 2. 3.5 mm 1/3 tubular plate and fixation on a synthetic bone model with two 4.0 mm partially threaded cancellous screws.

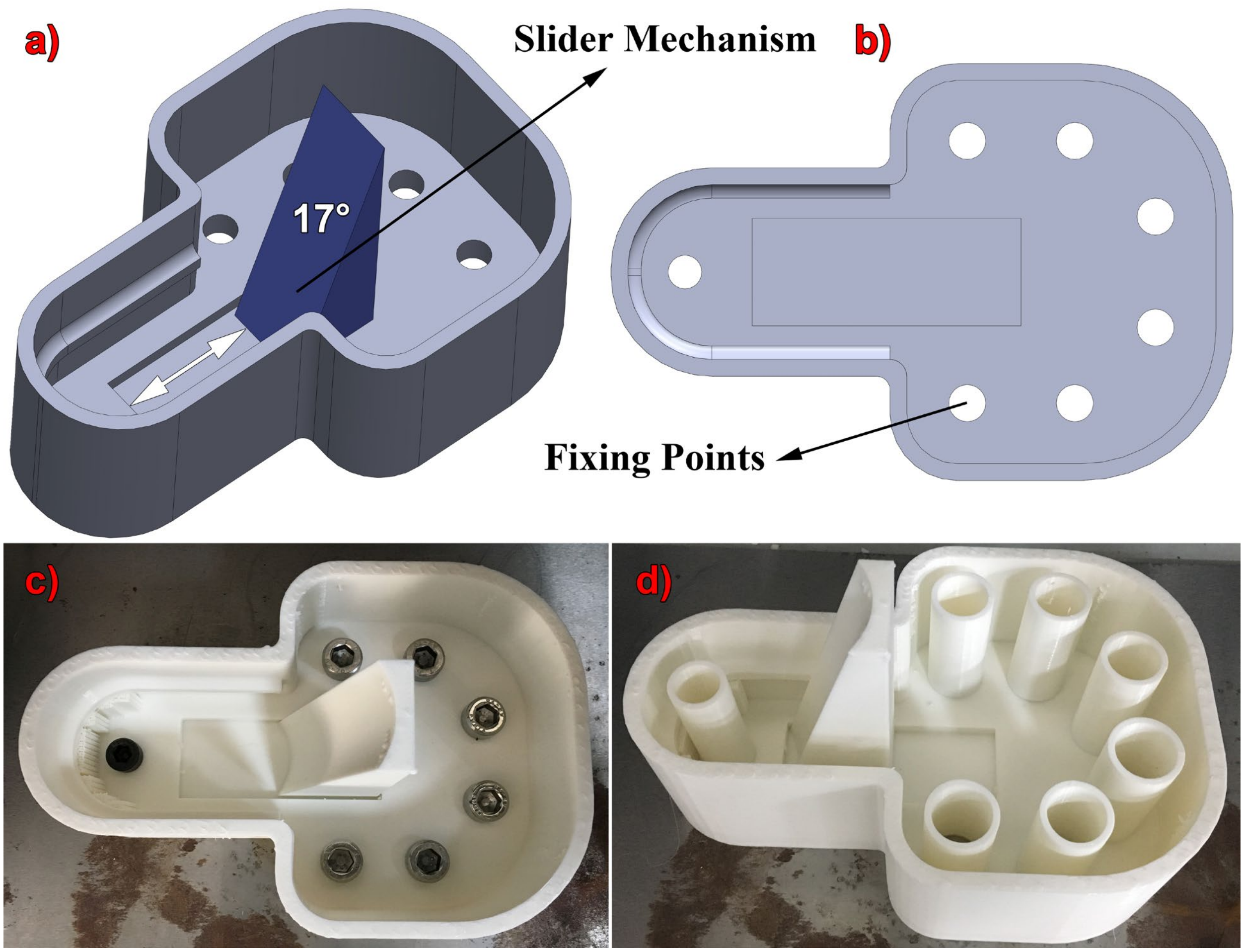

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Figure 3. a) The 3D drawing of the sample holder that provides an angle of 17 degrees b) The top view of the fixing points of the apparatus to the static tester c) 3D printing of the holder and its placement on the testing device d) Adjusting the slider mechanism for aligning the head of the bone precisely with the clamping mechanism.

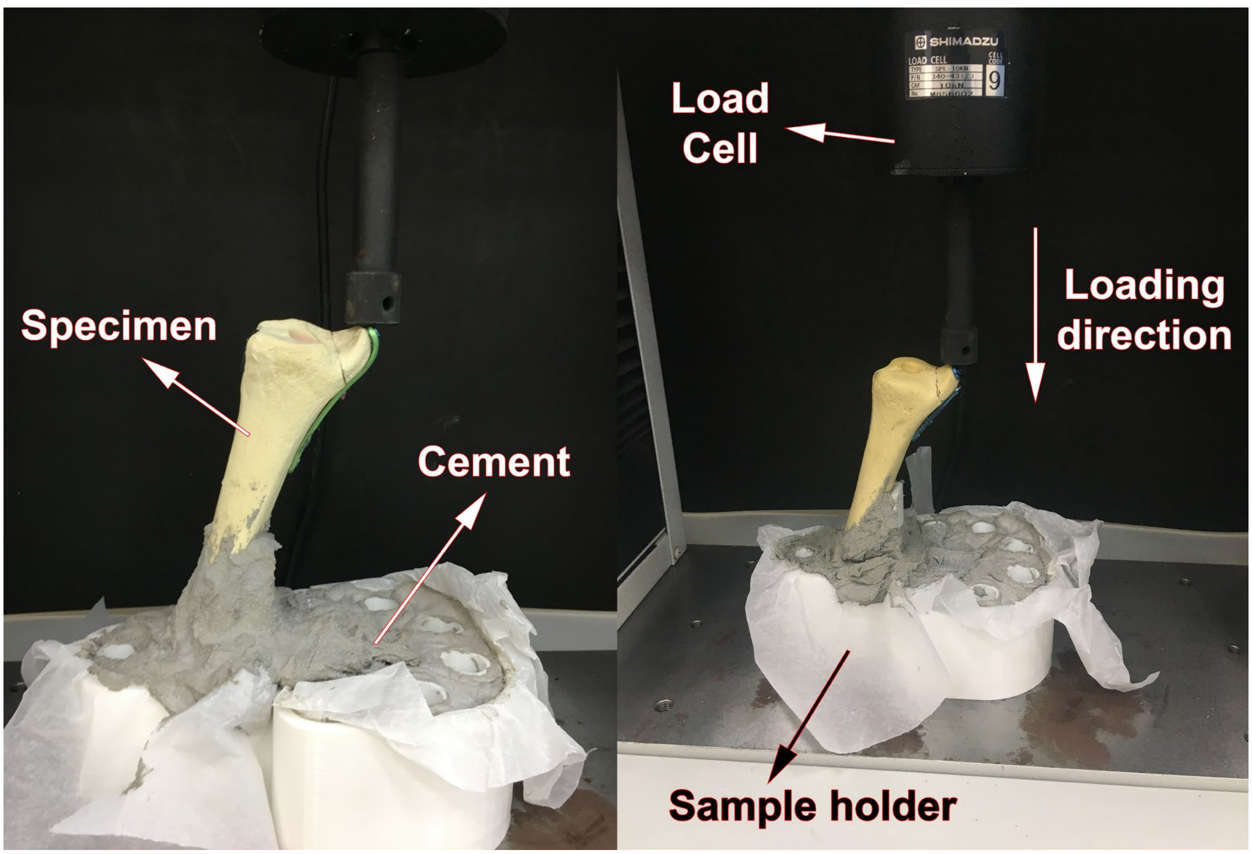

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Figure 4. Fixing the tibia bone specimens firmly with cement and aligning them to the compression apparatus for testing.

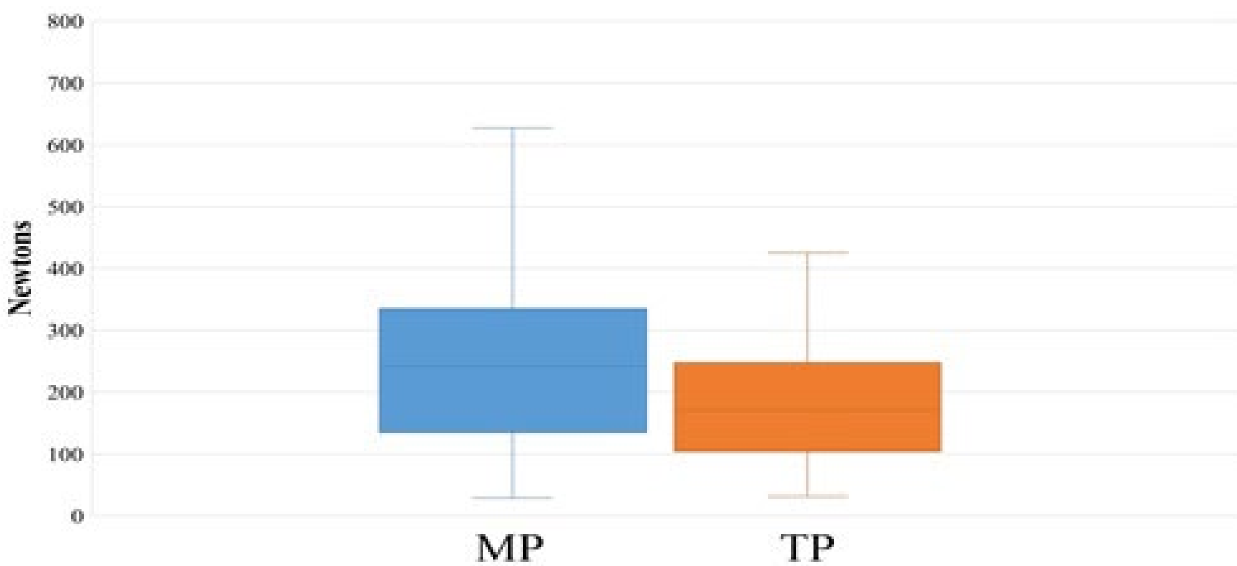

Figure 5. Load-to-failure of two plates.

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Table 1. The biomechanical comparison of medial malleolar anatomic plate (MP) and tubular plate (TP)

Groups	**Mean Axial Load (N) Mean ± SD**			
	0.5mm	**1mm**	**1.5mm**	**2mm**
MP	55,54 ± 13,22	100,89 ± 33,64	148,97 ± 54,68	192,14 ± 76,89
TP	30,53 ± 14,78	49,42 ± 21,95	69,38 ± 22,84	95,04 ± 27,97
Mean Difference	25,01	51,47	79,59	97,10
P-value	0.006*	0.005*	0.007*	0.015*

**p<.05*