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# A New Mini-External Fixator for Treating Hallux Valgus: A Preclinical, Biomechanical Study

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A R T I C L E I N F O

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A B S T R A C T

Proximal metatarsal osteotomy is the most effective technique for correcting hallux valgus deformities, especially in metatarsus primus varus. However, these surgeries are technically demanding and prone to complications, such as nonunion, implant failure, and unexpected extension of the osteotomy to the tarsometatarsal joint. In a preclinical study, we evaluated the biomechanical properties of the fixator and compared it with compression screws for treating hallux valgus with a proximal metatarsal osteotomy. Of 18 metatarsal composite bone models proximally osteotomized, 9 were fixed with a headless compression screw and 9 with the mini-external fixator. A dorsal angulation of 10° and displacement of 10 mm were defined as the failure threshold values. Construct stiffness and the amount of interfragmentary angulation were calculated at various load cycles. All screw models failed before completing 1000 load cycles. In the fixator group, only 2 of 9 models (22.2%) failed before 1000 cycles, both between the 600th and 700th load cycles. The stability of fixation differed significantly between the groups ($p < .001$). The stability provided by the mini-external fixator was superior to that of compression screw fixation. Additional testing of the fixator is indicated.



More than 100 surgical techniques have been created for treating hallux valgus (HV) (1,2). Proximal metatarsal osteotomies are the most effective in correcting angular HV deformities, especially in metatarsus primus varus (3–5). These surgeries are technically demanding, however, and surgeons are often reluctant to use them (1–5). Additionally, complications, such as nonunion, implant failure, and unexpected extension of the osteotomy to the tarsometatarsal joint, makes these procedures challenging (3–5).

First described by Mann and Coughlin (6) in 1981, proximal crescentic osteotomy of the first metatarsal has become more popular in the past 20 years (7,8). The most difficult step in this operation is fixing the osteotomy. We hypothesized that external fixation would provide more stable fixation than would cannulated compression screws in proximal metatarsal osteotomy. Although several studies have reported external fixator procedures for treating HV, we found no biomechanical studies on these fixators (9–13). Accordingly, we designed and tested a mini-external fixator (MEF). The MEF has proximal swivel clamps and a lengthening device that allow metatarsal lengthening and bending to both sides in the transverse plane to provide better biomechanical control and better bone healing after percutaneous crescentic osteotomy. We compared the MEF with cannulated compression screws in proximal osteotomized metatarsal bone models to determine the durability of each device under cyclic loading and end-failure load.

## Materials and Methods

### *Design of MEF*

The MEF is a prototype produced by Tasarim Med (Eyup, Istanbul; Fig. 1). Made of titanium (Ti6Al4V), it weighs 37.2 g and is 31.5 mm wide, 57.5 mm high, and 17 mm thick. It can be lengthened ≤10 mm with the help of the distraction device and can be bent ≤25° to both sides to correct the deformity with the help of the proximal swivel

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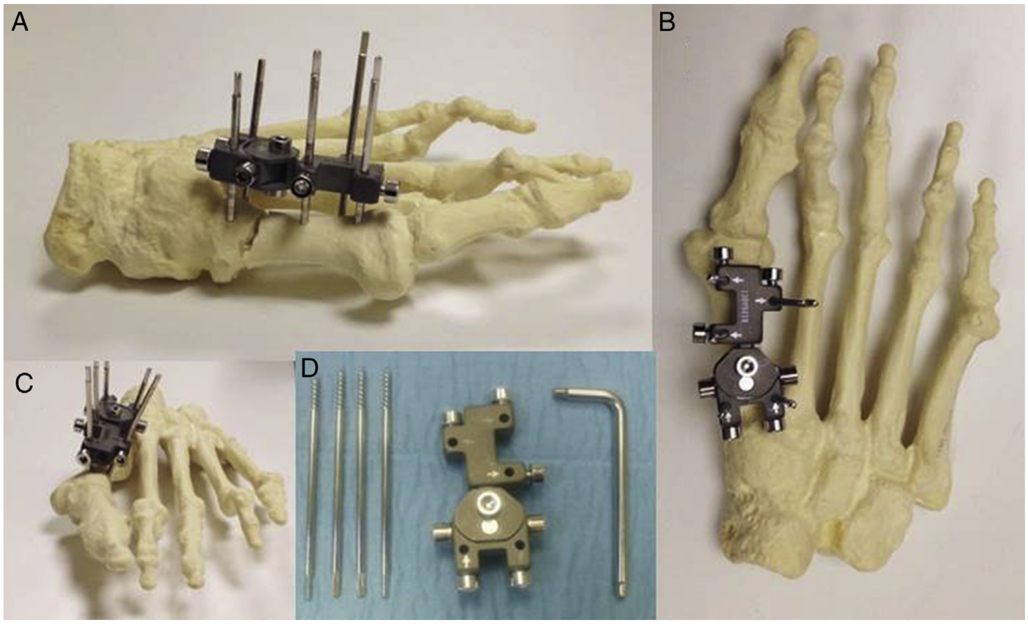


**Fig. 1.** (*A* and *B*) The new titanium mini-external fixator. It weighs 37.2 g and is 31.5 mm wide, 57.5 mm high, and 17 mm thick. (*C*) It can be applied to a metatarsal bone with 2 proximal and 3 distal 2.5-mm Schanz pins oriented to converge on the axis of the metatarsal with the (*D*) angled pinholes of the fixator.

clamps. The 5 Schanz pins converged on the axis of the metatarsal through the angled pinholes of the fixator (Fig. 1).

*Composite Metatarsal Bone Model*

Eighteen composite cortical bone models of fourth-generation metatarsals (Sawbones™, Pacific Research Laboratories, Vashon, WA) were prepared for biomechanical study. We performed a crescentic proximal osteotomy from 10 mm distally to the proximal end of the bone using a power crescentic oscillating saw with a thickness of 1 mm and radius of 10 mm (Aesculap GC 554 Inox 16™; Aesculap-Werke AG, Tuttlingen, Germany). After the osteotomy, a distal bone fragment was shifted laterally 10 mm. In the screw fixation group, the fragments were stabilized with an 18-mm-long, 3.0-mm-diameter headless cannulated screw (Acutrak™, Acumed, Beaverton, OR) directed at an oblique inferior angle of 45° into the center of the base of the bone model (Fig. 2). In the fixator group, the models were stabilized using the MEF. All external fixators were applied using mini-Schanz screws, 2 directed obliquely to the transverse plane,

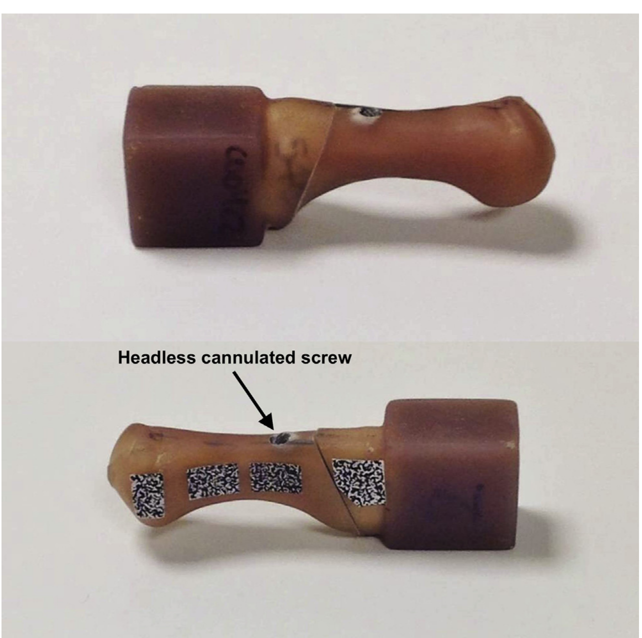


**Fig. 2.** Fixation of a composite bone model of the first metatarsal with a headless cannulated screw 18 mm long and 3.0 mm in diameter (Acutrak, Acumed).

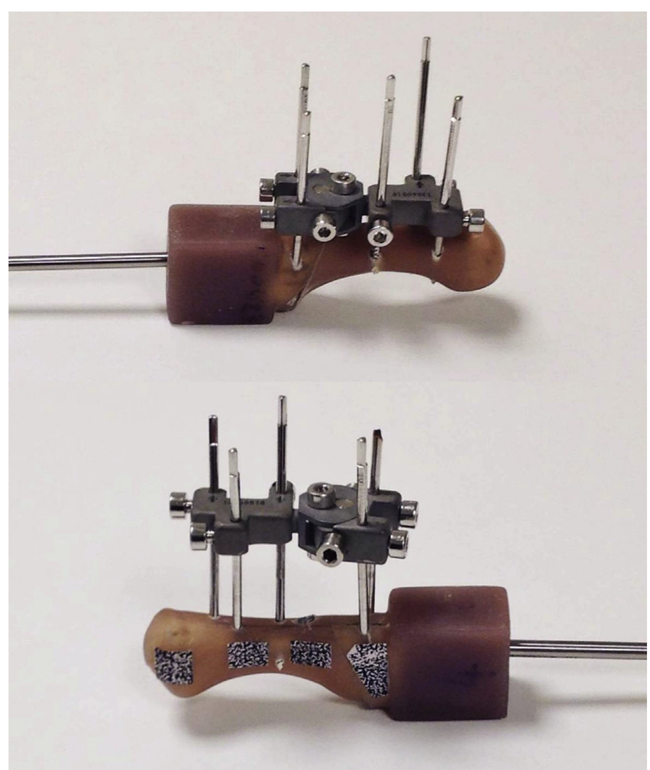

**Fig. 3.** The bone model stabilized using the mini external fixator. External fixators were applied with 2 obliquely directed (to the transverse plane) mini-Schanz screws proximal to the osteotomy site and 3 obliquely directed (to the transverse plane) mini-Schanz screws distal to the osteotomy site.


**Fig. 4.** The MTS 858 Mini Bionix 2-in. universal dynamic test system for measuring load, displacement, and angulation.

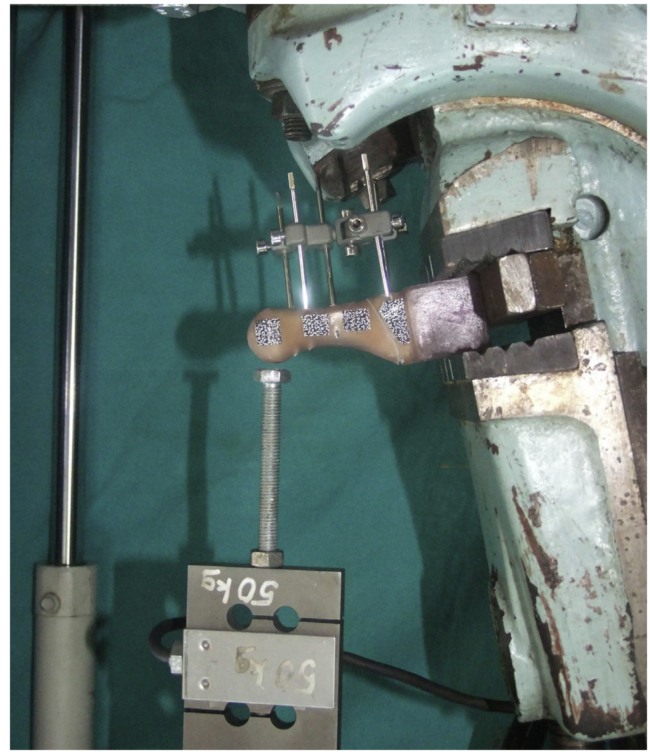

**Fig. 5.** To simulate the forces of standing, the base of each bone model was clamped, with the metatarsal inclined 15° from the horizontal during testing.

proximal to the osteotomy site, and 3 directed obliquely to the transverse plane distal to the osteotomy site (Fig. 3).

*Mechanical Testing*

Testing was performed using a universal dynamic test system (MTS 858 Mini Bionix II™; MTS Corp., Minneapolis, MN; Fig. 4). The base of the each bone model was clamped with the metatarsal inclined 15° from the horizontal to simulate the anatomic standing position (Fig. 5). To simulate the daily cyclic loading of the leg (approximately 5000 cycles daily), postoperative limb loading was estimated as 1000 cycles. Therefore, we applied linear ramp loads at 7.75 N/s at cycles of 1, 10, 50, 100, 200, 300, 400, 500, 600, 700, 800, 900, and 1000. All other load cycles were sinusoidal at 0.5 Hz. We applied cyclic loading in the plantar and dorsal directions. The effective load was varied from 5 to 31 N at the center of the metatarsal head. After reaching the peak (31 N), the load was reduced to 5 N within 10 seconds.

Failure of the model was defined as >10° of angulation and 10 mm of translation (2,14,15). At the end of each cycle, the angulations and translations were photographed using optic cameras (Vic-Snap 2010 Image Acquisition™; Correlated Solutions, Columbia, SC). After failure of the models with cyclic loading, a preload pressure of 5 N was applied with a 0.1 mm/s velocity until the model had failed with continuous loading. Photographs and the load-displacement values were also obtained at this stage.

Time, loading, dorsal angulation, cycle number, and camera signals were concurrently monitored and recorded. We used 50-kg load cells in the loading measurement (STCS 50 C3™; Esit Electronics, Istanbul, Turkey). Data from the optic camera in the measurement system were analyzed using digital image correlation software (Vic-3D 2010™; Correlated Solutions).

All models were tested for axial compression, distraction, torsion, and bending. These measurements were recorded and controlled using the MultiPurpose TestWare™ software (MTS Corp.). A static optical camera and a 3-dimensional correlation system were used to measure the displacement of the osteotomy site. The dynamic, axial, and torsional loading capacity of the system was 100 Hz, 25 kN, and 200 Nm, respectively.

The number of load cycles before failure with dorsal angulation >10° at each cyclic load interval was compared between groups using paired, Mann-Whitney *U* tests. The $\alpha$ value was set at $p \leq .5$, and all tests were 2-tailed.

## Results

The mean number of failure cycles was 556 (range 456 to 823) in the compression screw group and 997 (range 621 to 1204) in the fixator group (Table 1). According to the mean number of failure cycles, the fixator group was statistically more stable ($p < .001$). All the models in the compression screw group failed before 1000 load cycles; however, only 2 (22.2%) failed before 1000 cycles in the fixator group (Table 1).

The construct stiffness of the fixator group was significantly greater statistically than that in the compression screw group at the 10th ($p < .05$), 400th ($p = .003$), 500th ($p = .014$), 700th ($p = .05$), 800th ($p = .001$), 900th ($p = .004$), and 1000th ($p = .011$) cycle. The results of the comparison of the MEF and compression screw groups are listed in Table 2.

## Discussion

Osteotomy stability and end-load failure results were better with the MEF than with lag screw fixation. The MEF also allowed the first metatarsal to be lengthened or shortened to correct HV. These results indicate that additional testing in cadaver bones is justified and, eventually, clinical evaluation will be useful to better understand the practical characteristics of the MEF for first metatarsal fixation.

Several fixation devices have been used to stabilize the osteotomy, and many studies have evaluated screw and plate-and-screw fixation (14–17). Despite the superior biomechanical results of plate fixation over screw fixation, however, technical difficulties, soft tissue problems, and possible nonunion because of periosteal stripping have reduced the efficacy of plate fixation (14). Geometric analytic studies showed that crescentic osteotomies of the first proximal metatarsal

**Table 1**
Comparison of failure loads and cycles

| Sample No. | Cycle | Rotation (°) | Loading Force (N) |
|---|---|---|---|
| Compression screw group | | | |
| 1 | 483 | 10.10044903 | −43.882555 |
| 2 | 467 | 10.00219535 | −25.193509 |
| 3 | 504 | 10.13468748 | −25.675737 |
| 4 | 823 | 10.0650151 | −48.511898 |
| 5 | 521 | 10.01460297 | −69.702598 |
| 6 | 456 | 10.00904273 | −49.02869 |
| 7 | 732 | 10.09952415 | −40.653568 |
| 8 | 521 | 10.01506781 | −27.158024 |
| 9 | 504 | 10.01460297 | −69.702598 |
| Mean (range) | 556 (456 to 823) | 10.0505764 | −44.38990856 |
| Fixator group | | | |
| 1 | 689 | 10.09952415 | −40.653568 |
| 2 | 621 | 10.01506781 | −27.158024 |
| 3 | 1052 | 10.07248936 | −55.175339 |
| 4 | 1092 | 10.0650151 | −48.511898 |
| 5 | 1108 | 10.02157487 | −45.314831 |
| 6 | 1062 | 10.01460297 | −69.702598 |
| 7 | 1138 | 10.00904273 | −49.02869 |
| 8 | 1204 | 10.01921627 | −62.884133 |
| 9 | 1007 | 10.00490772 | −56.641602 |
| Mean (range) | 997 (621 to 1204) | 10.03571566 | −50.56340922 |

**Table 2**
Comparison of results of 2 fixation methods for failure cycles and failure loads

| Variable | Outcome | Screw Fixation | MEF | $p$ Value |
|---|---|---|---|---|
| Cycles to failure | Failure before 1000 cycles | 556 (456 to 823) | 997 (621 to 1204) | $< .001$ |
| Failure load | $>10^\circ$ angulation, 10 mm translation | −44.38 N | −50.56 N | $< .05$ |

Abbreviation: MEF, mini-external fixator.

provide a wide range of angular correction potential (18,19). Additionally, the crescentic shape provides a wider contact area at the osteotomy site, allowing for better bone healing (18,20).

Several studies have compared different proximal osteotomy types with different fixation methods (2,21,22). The different biomechanical properties of these osteotomy types produced inconsistent results in the biomechanical stability of the fixation methods (2,22). To accurately compare 2 fixation methods, we chose the first proximal metatarsal crescentic osteotomy, which is suitable for both MEF and cannulated screw fixation.

Some biomechanical studies have compared the fixation methods for a first proximal metatarsal crescentic osteotomy (14–16). One study with bone models showed that plate-and-screw fixation had twice the resistance to disruption of the osteotomy under cyclic loading conditions than did screw fixation (14). Furthermore, in another study using bone models, plate-and-screw fixation had biomechanical properties superior to those of a combination of Kirschner wire and screw fixation (15). In a study of proximal crescentic osteotomy with fresh-frozen cadaver first metatarsals, cannulated screw fixation provided better stiffness than did Kirschner wire fixation. However, these 2 techniques did not differ significantly when assessed for forced to failure load (16). In our study, the MEF provided significantly better construct stiffness and significantly greater cyclical failure loads than did screw fixation and had nearly 1.8 times the resistance to disruption of the osteotomy than did screw fixation in the cyclical loading analysis.

The present preclinical pilot test of the MEF has limited clinical value because we used bone models, not cadaver bones. We also did not compare the MEF with plate fixation. However, plate fixation is not commonly used because of rapid bone union, wound complications, and longer operative times when proximal osteotomy of the first metatarsal is undertaken. Additionally, we tested only proximal crescentic osteotomy with 1 screw, rather than with 2 or with Kirschner wire osteotomy fixation models. Finally, we used failure values of $>10^\circ$ of angulation and $>10$ mm of translation, just as did similar biomechanical studies (2,14,15). However, surgeons might have different definitions of failure in different situations.

In conclusion, depending on the results of additional developmental testing, the MEF could prove to be a good alternative for treating metatarsus primus varus deformities by providing satisfactory stability and by allowing the bone to be lengthened or shortened to correct other deformities.

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