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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 $\leq$10 mm with the help of the distraction device and can be bent $\leq 25^\circ$ to both sides to correct the deformity with the help of the proximal swivel

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Conflict of Interest: The funding was used to produce 10 mini-external fixators and buy plastic bone models and cannulated screws. Production of these mini-external fixators was performed by Tasarim Med, Eyup, Istanbul, Turkey, by contract, and the authors have no financial interest in or financial conflict with this company as it relates to the present report.

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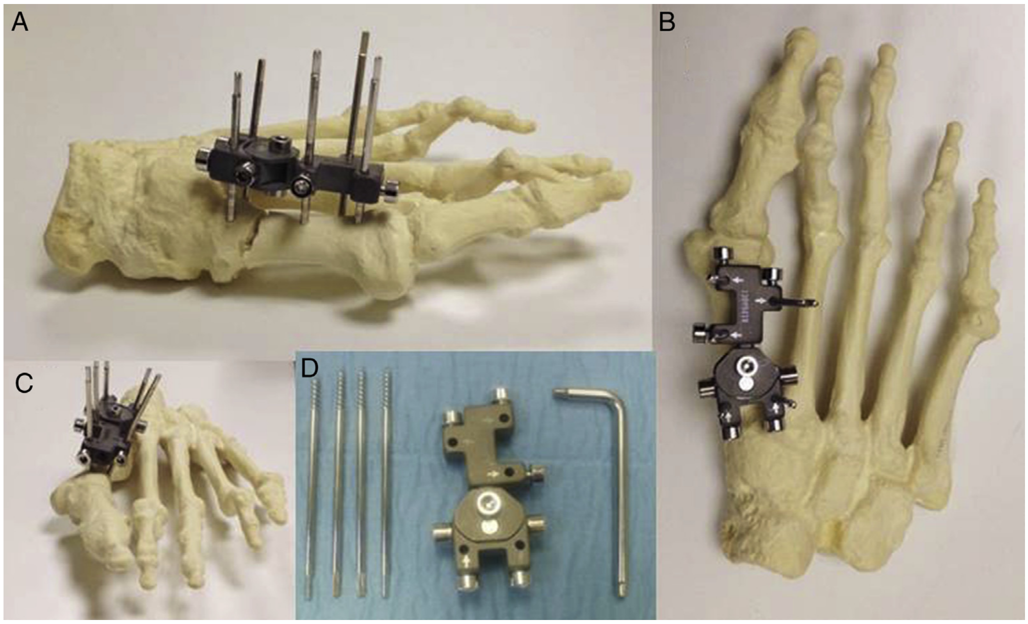

Fig. 1. (*A* and *B*) The new titanium mini-external fixator. It weighs 37.2 g and is 31.5 mm wide, 57.5 mm high, and 17 mm thick. (*C*) It can be applied to a metatarsal bone with 2 proximal and 3 distal 2.5-mm Schanz pins oriented to converge on the axis of the metatarsal with the (*D*) angled pinholes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

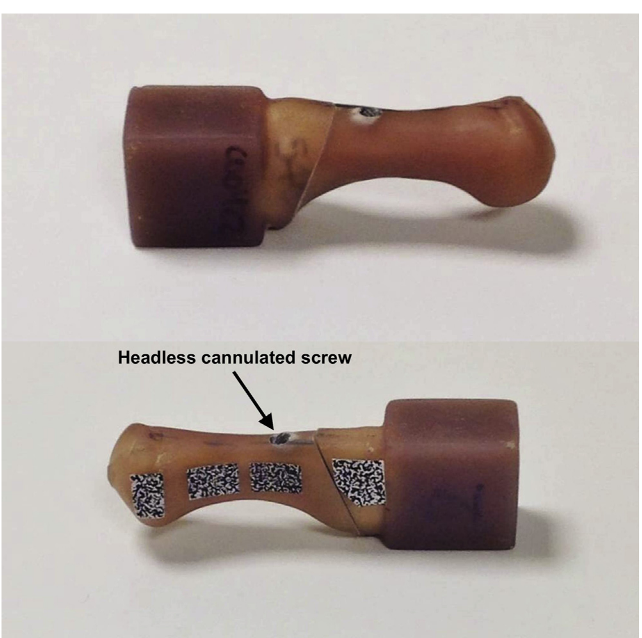

Fig. 2. Fixation of a composite bone model of the first metatarsal with a headless cannulated screw 18 mm long and 3.0 mm in diameter (Acutrak, Acumed).

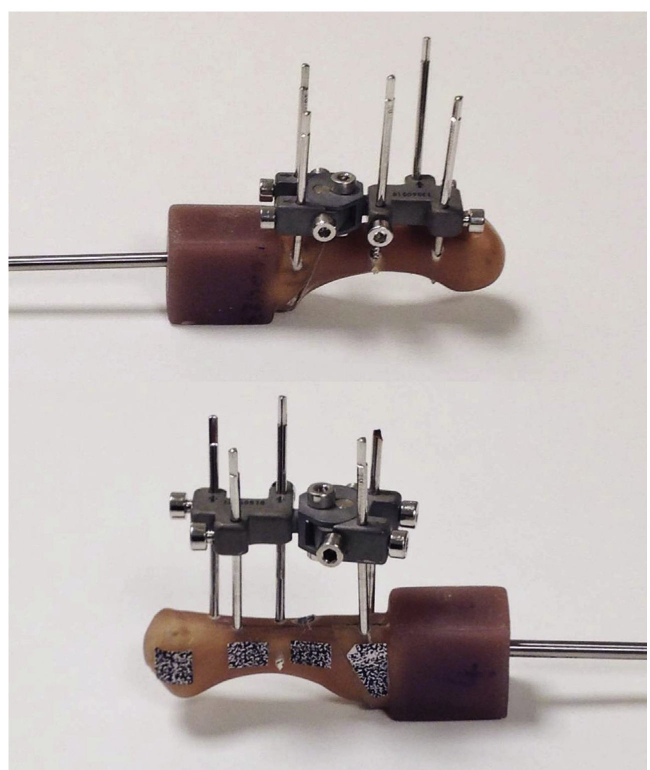

Fig. 3. The bone model stabilized using the mini external fixator. External fixators were applied with 2 obliquely directed (to the transverse plane) mini-Schanz screws proximal to the osteotomy site and 3 obliquely directed (to the transverse plane) mini-Schanz screws distal to the osteotomy site.