



## Biomechanical comparison of three 2.7-mm screws and two 3.5-mm screws for fixation of simple oblique fractures in human distal fibulae

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### ABSTRACT

**Background:** Fixation of simple oblique fractures of short tubular bones with only inter-fragmentary screws is simple and clinically useful. This study compared the biomechanical properties of fixation using three 2.7-mm mini-screw and two conventional 3.5-mm lag screw constructs for simple oblique fractures of the distal fibula in human osteoporotic bone.

**Methods:** Simple oblique fractures of the distal fibula at the level of the syndesmosis were simulated in 15 paired fresh frozen ankles, and the calcaneal bone mineral density was measured in each. Fixation with either three 2.7-mm mini-screws (new system) or two 3.5-mm cortical screws (conventional system) was performed in each pair of ankles. The sample size for each type of stress (cantilever bending stress, five pairs; external rotational load to failure, 10 pairs) was calculated before the test. The biomechanical variables (maximal failure load and construct stiffness) of the two fixation groups were compared using a non-inferiority test method with a pre-specified non-inferiority margin.

**Findings:** The bone mineral density of the calcaneus was assessed as osteoporotic based on reference values for 20- to 29-year-old healthy Koreans. The new system was not inferior to the conventional system in terms of the tested biomechanical properties. The construct failure was initiated from the distal-most screw hole in the anterior cortex.

**Interpretation:** Fixation with only three 2.7-mm mini-screws provided biomechanical stability comparable to two 3.5-mm cortical screws for simple oblique osteoporotic fractures in the distal fibula under one-shot stress. Mini-screw application for this common fracture might extend the scope of surgical indications for the screws-only fixation method.

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### 1. Introduction

The management of displaced distal fibular fractures requires anatomical reduction and secure fixation (Hughes et al., 1979; Phillips et al., 1985). There are several methods for fixing distal fibular fractures. Traditionally, displaced oblique fractures of the fibula at the level of the syndesmosis have been treated with lateral neutralising plating and an independent lag screw (Hahn and Colton, 2000; Muller et al., 1991). Recently, the lag-screw-only fixation technique using a 3.5-mm lag screw fixation system (LSFS) to treat simple oblique or spiral distal fibular fractures without plating has shown satisfactory clinical outcomes for select patients (Hammacher et al., 1986; Kim and Oh, 1999; McKenna et al., 2007; Tornetta and Creevy, 2001). The merits of this method are shorter incision and fixation times and reduced patient complaints compared with an implant (e.g., lateral ankle skin pain, restricted shoe wearing, and request for implant removal).

However, this method is difficult to use because a 3.5-mm cortical screw can result in breakage of poor-quality bone, especially in elderly patients with a small fibula (McKenna et al., 2007; Tornetta and Creevy, 2001). Moreover, the lag screw technique is inconvenient and presents the possibility of iatrogenic bone breakage because the screw holes must be bored with drill bits of different diameters (Nicklin et al., 2008; Roth and Auerbach, 2005).

We introduced a novel bicortical mini-screw fixation system (BMFS) that uses more than three 2.7-mm mini-screws for simple oblique fractures of the distal fibula. The 2.7-mm mini-screws penetrate less bone than do the 3.5-mm cortical screws and thus reduce the risk for iatrogenic bone breakage. The strength of fixation can be increased because more screws can be inserted per unit area. Moreover, bicortical fixation has well-known clinical and biomechanical effects on metacarpal bone because the threads of the screw achieve purchase in both cortices, conferring comparable stiffness to the fracture site, while being simpler and more straightforward than lag screw fixation (Nicklin et al., 2008; Roth and Auerbach, 2005). Although the use of one or two 3.5-mm lag screws for oblique fractures has been investigated (Kim and Oh, 1999), at least two screws

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are required to prevent a rotational deformity with only one screw (Muller et al., 1991). We hypothesised that to obtain the effect of fixation with two 3.5-mm lag screws, three bicortical 2.7-mm mini-screws would be needed. This biomechanical experiment compared the stabilities of the BMFS and the LSFS in human cadavers.

## 2. Methods

### 2.1. Sample size estimation (Table 1)

Significant differences in torsional stability (torque-to-failure and construct stiffness) between lateral locking plating and anti-glide posterolateral plating have been reported (Minihane et al., 2006). From the previous biomechanical results, the non-inferiority margin ( $\delta$ ) and standard deviation for biomechanical variables (the torque-to-failure and construct stiffness) could be determined as the primary variables. The hypothesis of this study for torque-to-failure was as follows:

**H<sub>0</sub>**. torque-to-failure of new method – torque-to-failure of conventional method  $\leq -|\delta|$

**H<sub>1</sub>**. torque-to-failure of new method – torque-to-failure of conventional method  $> -|\delta|$ .

In the same way, the hypothesis for construct stiffness could be inferred.

Assuming paired groups and using the statistical programme PASS (Dupont and Plummer, 2009), we calculated required sample sizes of six and 10 for torque-to-failure and construct stiffness, respectively, with a power of 80% and level of significance of 0.05 for the torsional stress test (TST).

Using the same statistical method, we calculated required sample sizes of five and four for the load-to-failure and construct stiffness, respectively, from the previously reported biomechanical study comparing locking and non-locking plates for metacarpal fractures under the cantilever bending stress test (CBST) (Ochman et al., 2010). Ten pairs of lower legs (for the TST) and five pairs of distal fibulae (for the cantilever bending test) were prepared for this biomechanical comparison test.

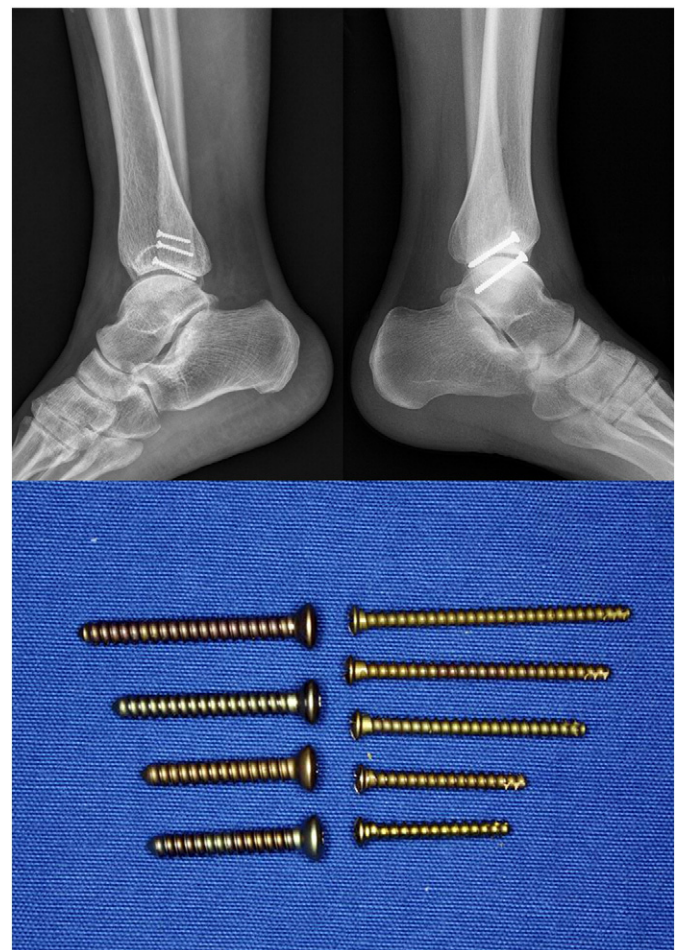
### 2.2. Sample preparation

Fifteen paired fresh-frozen cadaveric lower legs (from the tibial plateau to the foot) were acquired and stored at  $-20\text{ }^{\circ}\text{C}$ . The donors (10 females and five males) had a mean age of 76 (range, 55–98) years. After thawing the specimens at room temperature for 24 h, the soft tissues were removed to allow attachment of the tibia and fibula to the testing apparatus and to expose the superficial ligaments and bony structures. The proximal part was disarticulated at the knee joint level, preserving the proximal tibiofibular joint. The specimens had no gross deformities or previous ankle surgery. Dual-energy X-ray absorptiometry (DXA) scanning (Hologic Explorer, Bedford, MA, USA) of the calcaneus was performed, and the bone mineral density (BMD) was

documented for each specimen. Specimen assignment to the stress tests was randomised with a statistical software package (SPSS ver. 18, Chicago, IL, USA). For each specimen pair, the different constructs (three 2.7-mm mini-screw fixation system [BMFS] or two 3.5-mm lag screw fixation system [LSFS]) were also randomised as to side using the same software. The BMFS consisted of three bicortical, anterior-to-posterior, 2.7-mm mini-screws (Leibinger, Freiburg, Germany) that maintain compression reduction in the distal fibula (Fig. 1, left). The bicortical screw technique, which is straightforward and provides adequate fracture stability and healing for small bones, was used as Roth's method (Roth and Auerbach, 2005) without the lag screw technique. The LSFS consisted of two 3.5-mm cortical screws (Synthes, Paoli, PA, USA) with the lag screw method according to the recommended AO (Arbeitsgemeinschaft für Osteosynthesefragen) technique (Fig. 1, right). All cadaver work was performed by one orthopaedic surgeon.

### 2.3. TST setup

For the TST specimens, the anterior and posterior tibiofibular ligaments and the superficial and deep deltoid ligaments were identified and sectioned sharply, simulating a Lauge–Hansen supination–external rotation injury (type IV) with deltoid disruption ankle injury. The syndesmosis and interosseous membrane was left intact. Each repaired specimen was loaded into a universal testing machine (Instron E10000, Norwood, GA, USA) that produces compression bending and rotational torsion at a controlled velocity and measures



**Fig. 1.** Radiographic lateral images of the two constructs used for biomechanical testing. Left, three 2.7-mm mini-screw bicortical fixation. Right, conventional system with two 3.5-mm lag screws. Lower photo compares the mini screws and conventional screws.

**Table 1**  
Sample size calculation for biomechanical stress tests.<sup>a</sup>

		Non-inferiority margin ( $\delta$ )	Presumed standard deviation	Calculated sample size
Torsional stress test	Torque-to-failure	2.4	3.88	6
	Construct stiffness	0.08	0.08	10
Cantilever bending stress test	Load-to-failure	109	56	5
	Construct stiffness	37	12	4

<sup>a</sup> Power of test: 80%, and level of significance: 0.025.

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