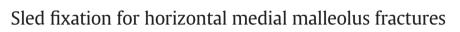
Contents lists available at ScienceDirect

Clinical Biomechanics

journal homepage: www.elsevier.com/locate/clinbiomech



Adam M. Wegner^a, Philip R. Wolinsky^a, Robin Z. Cheng^b, Michael A. Robbins^a, Tanya C. Garcia^c, Derek F. Amanatullah^{b,*}

^a University of California Davis Medical Center, Sacramento, CA, USA

^b Stanford University School of Medicine, Stanford, CA, USA

^c University of California Davis, Davis, CA, USA

ARTICLE INFO

Article history: Received 16 June 2016 Accepted 15 January 2017

Keywords: Horizontal fracture Supination-external rotation Pronation-external rotation Pronation-abduction Medial malleolus Medial malleolar sled Internal fixation Biomechanical study

ABSTRACT

Background: Horizontal fractures of the medial malleolus occur through exertion of various rotational forces on the ankle, including supination--external rotation, pronation--external rotation, and pronation-abduction. Many methods of fixation are employed for these fractures, but the optimal fixation construct remains unclear. *Methods:* Horizontal medial malleolus osteotomies were performed in synthetic distal tibiae and randomized into two fixation groups: 1) two parallel unicortical cancellous screws or 2) medial malleolar sled fixation. Specimens were subjected to offset axial tension loading and tracked using high-resolution video. Clinical failure was defined as 2 mm of articular displacement.

Findings: There were statistically significant increases in mean stiffness (127% higher, P = 0.0007) and mean force to clinical failure (52% higher, P = 0.0002) with the medial malleolar sled. The mean stiffness in offset tension loading was 232 (SD 83) N/mm for medial malleolar sled and 102 (SD 20) N/mm for parallel unicortical cancellous screws. The mean force to clinical failure was 595 (SD 112) N for medial malleolar sled and 392 (SD 34) N for unicortical screws. In addition, the medial malleolar sled demonstrated elastic recoil to pre-testing alignment while the unicortical screws did not.

Interpretation: Medial malleolar sled fixation was significantly stiffer and required more force to clinical failure than parallel unicortical cancellous screws. A medial malleolar sled requires more dissection to apply surgically, but provides significantly more initial fixation strength. Additionally, a medial malleolar sled acts like a tension band in its ability to capture comminuted fragments while being low profile enough to minimize soft tissue irritation.

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1. Background

Horizontal fractures of the medial malleolus can result from the application of rotational force through the tibiotalar joint oriented in various positions, including supination-external rotation, pronationexternal rotation, and pronation-abduction. The medial malleolus is vital for providing stability and normal biomechanical function of the ankle joint. Displaced fractures of the medial malleolus require anatomic reduction followed by internal fixation in order to promote early recovery of range of motion, restore articular congruency, and decrease risk of post-traumatic arthritis to optimize post-surgical ankle function (Griend et al., 1996; Patel et al., 2013). Multiple techniques have been described for internal fixation of the medial malleolus, including the application of unicortical or bicortical screws, tension band constructs, or a mini-fragment T-plate (Amanatullah et al., 2012; Rovinsky et al., 2000;

E-mail address: dfa@stanford.edu (D.F. Amanatullah).

Toolan et al., 1994). However, the optimal method and configuration for fixation is still unclear. The AO Foundation currently advocates for two parallel 4.0 mm partially threaded cancellous lag screws oriented perpendicular to the fracture to provide compression as the gold standard for medial malleolus fixation (Fowler et al., 2011; Patel et al., 2013). Tension band fixation is a less commonly used technique that converts tensile forces into compressive forces on the articular side of the medial malleolus, but complications that require operative implant removal often result from this method of fixation (Brown et al., 2001; Jacobsen et al., 1994; Johnson and Fallat, 1997; Patel et al., 2013).

Sled fixation is a relatively novel method of fixing fractures. In addition to the medial malleolus, sled fixation has been studied for olecranon fixation. An olecranon sled was shown to be simple-to-use, and exhibited excellent rates of olecranon union and few complications requiring implant removal in the fixation of olecranon osteotomies (lorio et al., 2013).

The medial malleolar sled fixation system (TriMed, Santa Clarita, CA, USA) is a one-piece tension band that utilizes two prongs inserted into the medial malleolus that are connected by a U-loop. The U-loop is





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^{*} Corresponding author at: Department of Orthopaedic Surgery, Stanford University, 450 Broadway Street, Redwood City, CA 94063-6342, USA.

inverted in relation to the inserted prongs and lies on the periosteal surface of the medial malleolus. A specialized washer and two screws are applied on the periosteal surface within the U-loop and fixed into the tibia to provide additional stabilization to the sled construct. Sled fixation has recently been shown to be a promising new technique for repairing fractures of the medial malleolus. In a study that compared sled fixation with fixation using two cancellous lag screws in a cadaveric model, sled fixation was able to withstand a higher load at 2 mm gap in tibial distraction and demonstrated lower gapping when torsion was assessed using internal rotation (Patel et al., 2013). These results indicate that sled fixation withstands greater tension and is just as effective as lag screws in torsion. Previous studies have suggested that using a mini-fragment T-plate is superior to two fixation techniques: parallel cancellous screw fixation and tension band wiring (Amanatullah et al., 2012). Sled fixation functions in a similar manner to the mini-fragment T-plate, but placement of the sled requires less soft tissue stripping, and the lower profile of the sled may reduce soft tissue irritation compared to the mini-fragment T-plate.

Additionally, the prongs of the sled are thicker than traditional Kwires, thus allowing the sled to maintain a higher resistance to bending forces (Patel et al., 2013). Also, a sled fixation construct can provide additional stiffness and strength against shear forces via the two additional points of fixation provided by the two screws and the specialized washer (Patel et al., 2013).

The average stiffness in tension, average force at 2 mm of joint line displacement, mode of catastrophic failure, and capacity for elastic recoil of medial malleolar sled fixation versus parallel unicortical cancellous screws were assessed in an offset tension model in Sawbones. This model was chosen to eliminate the variability of cadaver bone, and stiffness and elastic recoil after displacement were assessed, as those were not evaluated in the previous cadaver study. It was hypothesized that there would be significantly greater stiffness and load at 2 mm of joint line displacement with medial malleolar sled fixation.

2. Methods

Identical horizontal osteotomies were made by a band saw in 20 left fourth generation composite synthetic distal tibiae (Sawbones, Pacific Research Labs, Vashon, WA, USA; Model#: 3401) to simulate an OTA type 44-A2.3 fracture. Cuts were made with a custom jig set at a 15-degree angle from the tibial plafond, 10 mm from the distal tip of the medial malleolus, and directed toward the articular surface. A pre-hoc power analysis (1- β : 0.8, α : 0.05) suggested that 7 samples would be necessary to detect a difference between fixation methods. After osteotomy, tibiae were randomized to two fixation groups (n = 10 specimens for each group): 1) two parallel partially threaded unicortical 4.0 mm diameter 40 mm cancellous screws and 2) medial malleolar sled (TriMed, Santa Clarita, CA, USA) fixation (Fig. 1). Custom poly(methyl-methacrylate) jigs were used to reproducibly drill identical holes with a 2.5 mm drill for the parallel unicortical screw constructs. The medial malleolar sled constructs were assembled per manufacturer protocol (TriMed, Santa Clarita, CA, USA). Screws for the unicortical fixation construct were provided by Depuy-Synthes (West Chester, PA, USA), and medial malleolar sleds were provided by TriMed (Santa Clarita, CA, USA).

Specimens were fixed to the base of a servohydraulic testing machine (Model 809, MTS Systems Corporation, Eden Prairie, MN, USA) with an axial-torsional load transducer (Model no. 662.20-01; Axial capacity of 250 kg, torsional capacity 2.88 kg-m; MTS Systems Corporation, Eden Prairie, MN, USA). They were set in a vice with the distal tip of the medial malleolus offset 2 cm from the axis of the MTS crosshead and at a vertical distance of 7 cm from the plafond. Two 1.5 mm solid steel wires were placed 8 mm from the tip and 10 mm apart in the distal medial malleolus fragment, placed over the crosshead of the MTS testing machine, and held in place with U-bolt cable clamps to apply an offset axial tension load simulating the pull of the deltoid ligament in rotation ankle injuries that has been described previously (Fig. 2) (Amanatullah et al., 2012). Tension was applied to the medial malleolus

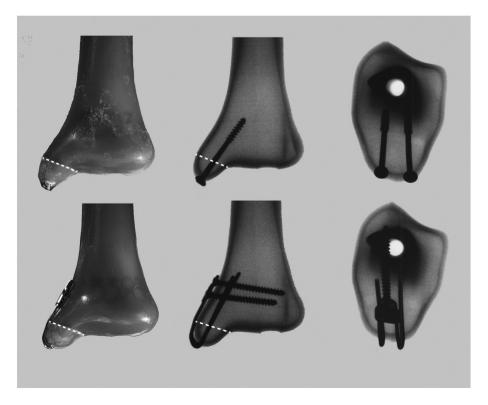


Fig. 1. Pre-testing images of the parallel unicortical cancellous screw construct (top left) and medial malleolar sled construct (bottom left). Anterior-to-posterior X-rays of the parallel unicortical cancellous screw construct (top middle) and medial malleolar sled construct (bottom middle). Axial X-rays of the parallel unicortical cancellous screw construct (top right) and medial malleolar sled construct (bottom right). Dashed lines indicate osteotomy cuts.

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