Biomechanical Benefits of the VariAx Distal Lateral Fibula Plate

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Abstract

Distal fibula fractures are the most common injury of weight bearing bones. Several studies have shown the benefit of locking plates especially in osteoporotic bone. The aim of this biomechanical study was to test the anatomically shaped VariAx Distal Lateral Fibula Plate in comparison to a commonly used 1/3 Tubular Plate. The implants were assembled to bone surrogates simulating a comminuted fracture. For determination of the implant strength a strong bone surrogate was chosen, while for determination of the cut-out behavior a weak surrogate simulated poor quality bone. The VariAx plate showed higher bending fatigue strength and also higher cut-out strength than the 1/3 Tubular Plate. Therefore, the VariAx plate provides potential biomechanical benefits.

1 Introduction

Fractures of the distal fibula are the most common injuries of weight bearing bones with an occurrence in adults of more than one per 1'000 [1]. Various study groups have confirmed a better outcome after anatomical reconstruction by internal fixation in comparison to non-operative treatment [2][3]. A dislocation of more than 2mm ad latum, a shortening of more than 2mm or a malrotation of more than 5 degrees have been identified as factors causing arthritis even if different stabilization techniques are described [4]. Standard treatment for these fractures is compression screws in combination with a neutralization plate. A recent biomechanical study illustrated the benefit of locking plates especially in osteoporotic human fibulae. Kim et al. tested two locking screws in the distal fragment in comparison to three non-locking screws whereas the locking plate fixation was independent of bone mineral density [5].

The VariAx Distal Lateral Fibula Plate offers the possibility to insert four locking screws in the distal fragment in variable axes. The aim of this study was to test this four-screw locking configuration in comparison to the commonly used two-screw locking configuration.

2 Material

The VariAx Distal Lateral Fibula Plate was designed to anatomically fit a maximum percentage of the target population (Caucasian and Asian). Advanced implant fitting software was used to determine best match between the bone shapes and implant design. Then the plate shape was optimized to fit the bone anatomy for the final design. In Figure 1 the results of the fitting errors are illustrated [6][1]:

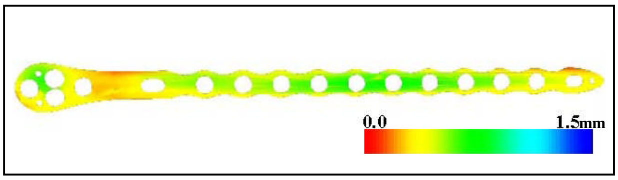

Figure 1: Mean fitting error distribution for Caucasian and Asian bone set (0mm represents perfect fit).

The prospective Early Product Surveillance of 57 cases showed that the newly developed anatomical plate has very good anatomical fit [7] with minimal or no bending.

Two implants with locking screws (Table 1) were compared in terms of fatigue strength and cut-out strength (the latter in a poor quality bone model). Cut-out was defined as failure of the screw/bone interface by screws pulling out and damaging the bone.

Implant	Locking Screw	Material Anodization
VariAx Distal Lateral Fibula Plate (Stryker)	3.5x16mm PolyAxial	Titanium Anodization Type II
LCP 1/3 Tubular Plate (Synthes)	3.5x16mm MonoAxial	Titanium Anodization Type III

Table 1: Implants tested.

The design of the VariAx Distal Lateral Fibula Plate offers the option for four distal screws. In the

[1] A white paper concerning the bone fitting study is in preparation.

model of the present study the LCP 1/3 Tubular Plate allowed for two distal screws [5].

3 Method

3.1 Sample preparation

To simulate a comminuted fracture at the level of the tibial-calcaneal joint, an 11mm gap was created (Figure 2). All screw holes were filled with locking screws.

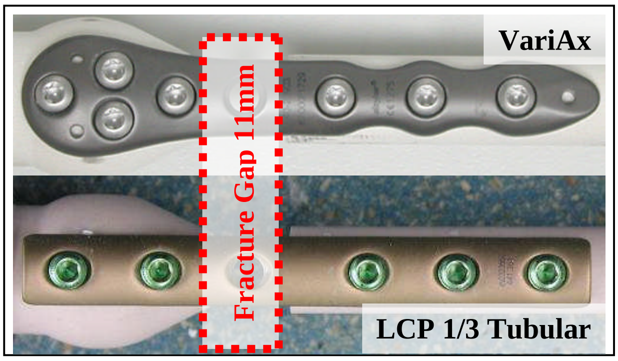

Figure 2: Construct assembly with three proximal screws and two/four distal screws.

The bone surrogates were manufactured in a simplified anatomical shape. Neither plate had a perfect anatomic fit. The LCP 1/3 Tubular Plate was contoured to fit the bone surrogate while the anatomically shaped VariAx Fibula Plate did not require contouring (Figure 3).

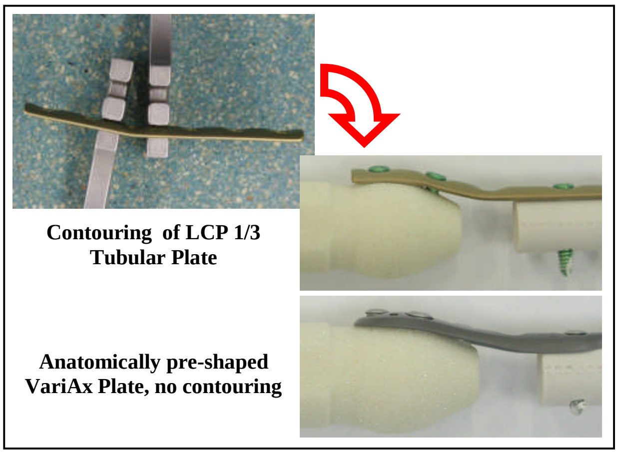

Figure 3: Plates' fit on the bone surrogate.

The contouring of the LCP 1/3 Tubular Plate led to a convergent trajectory of the two distal screws. The four distal VariAx screws were inserted with the maximum diverging angulation of 15 degrees orthogonal to the plate surface.

3.2 Biomechanical loading

According to Wülker et al., the body weight on the talus causes bending and shear forces in the malleoli. These forces can lead to different bending moments on the malleoli, and therefore, to different fracture types of the upper ankle joint [8].

Lambert K. L. describes the contact forces at the tibio-fibular joint that may result in bending moments in the distal part of the fibula [9].

3.3 Test fixture

A cyclic bending load was applied to the construct until failure occurred. A four-point bending fixture applied a uniform bending moment over the entire plate length (Figure 4).

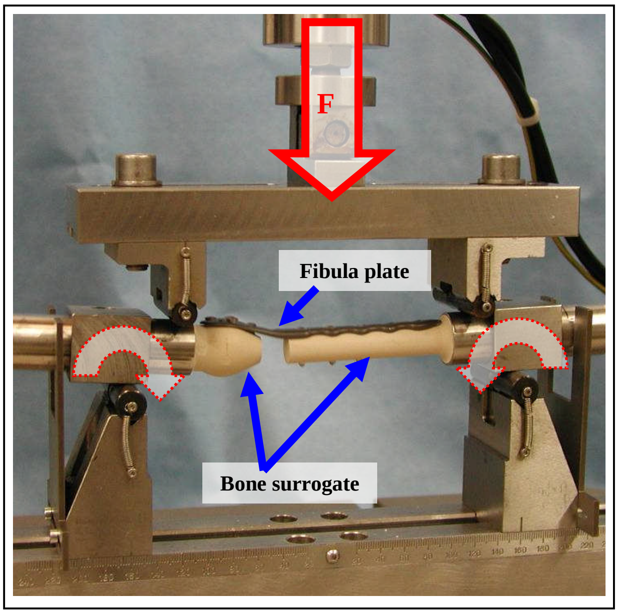

Figure 4: Setup for four-point bending test with uniform bending moment across the plate.

3.3.1 Fatigue strength

The aim of the fatigue test was to determine the plate strength. A strong bone surrogate was chosen to achieve plate failure [10].

Clinical significance: Creating a construct with higher fatigue strength may provide benefits in vivo.

The fatigue strength was determined for half a million load cycles using a stair case method as described in R.E. Little [11]. This corresponds to approximately six months in vivo accounting for normal and delayed fracture union [12].

The fatigue strength was calculated with six samples per group [11].

3.3.2 Cut-out strength

The cut-out test focused on the interface between screws and bone. To simulate the worst case interface, a poor quality bone model was chosen for the distal fragment. The proximal fragment was fixed to a strong bone model to encourage a cut-out failure mode in the distal fragment.

A bone surrogate, made out of polyurethane foam, density 80kg/m^3, was used to simulate poor quality bone [13][14].

Clinical significance: Creating a construct with higher cut-out strength may provide benefits in vivo.

Cyclic loading was applied in a staircase procedure, starting at 10N. If no failure occurred, the load was increased by 10N after every 1'000 load cycles. Three samples of each group were tested. Failure was defined as a construct collapse by 10 degrees. At 10 degrees loss of reduction serious surgical actions (e.g. revision surgery) may be considered.

4 Results

4.1 Fatigue strength

The results presented in Figure 5 show a higher fatigue strength for the VariAx Distal Lateral Fibula Plate than for the LCP 1/3 Tubular Plate [15][16].

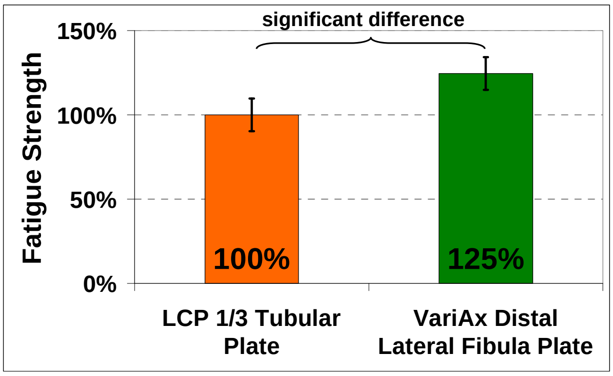

Figure 5: Fatigue strength with a 95% confidence interval. (100% represents 2.8Nm).

4.2 Cut-out strength

The results presented in Figure 6 show higher cut-out strength for VariAx Distal Lateral Fibula Plate constructs than for LCP 1/3 Tubular Plate constructs [17].

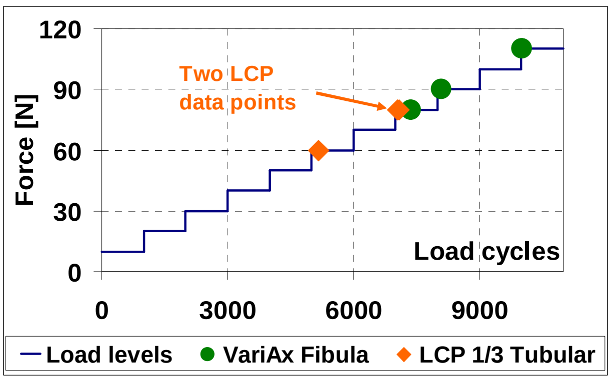

Figure 6: All VariAx constructs sustained a higher number of load cycles than the LCP constructs. The later the construct fails, the better the cut-out resistance.

5 Discussion

5.1 Fatigue strength

The fatigue strength is influenced by implant material and design. Furthermore, a proper bone fit has a positive influence on the construct strength. It enhances the load distribution and decreases stress peaks.

The **clinical significance** of these results is that the VariAx Distal Lateral Fibula Plate showed a higher fatigue strength than the clinically proven LCP 1/3 Tubular Plate.

5.2 Cut-out strength

Main factors for higher cut-out strength are the number of screws and the screw orientation in the distal fragment.

Again, the anatomical fit of the VariAx plate potentially leads to an increased cut-out strength, as the bone segment is well-supported by the plate.

The **clinical significance** of these results is that the VariAx Distal Lateral Fibula Plate showed a higher cut-out strength than the clinically proven LCP 1/3 Tubular Plate.

This study only investigated bending loads. However, the allocation of the four VariAx screws also suggests higher cut-out strengths in other load cases such as torsion and compression.

6 Conclusion

The VariAx Distal Lateral Fibula has higher fatigue strength in bending compared to a Synthes LCP 1/3 Tubular plate.

The VariAx Distal Lateral Fibula Plate provides potential biomechanical benefits with its four distal screws and plate design. Additionally, the VariAx plate has superior cut-out behavior compared to a Synthes LCP 1/3 Tubular plate when loaded in bending.

7 Limitations

The results of this study may be limited for clinical use as a simplified load case was applied to the constructs (lateral bending only) and a bone surrogate model instead of real fibulae were used to remove the natural variation of bone. This study did not consider any soft tissue interactions.

Screw configurations, fracture types and potential joint rehabilitation may differ in clinical use.

Rotational forces may also be induced to the fibula as reported by Michelson J. D. but, in the present investigation, they were considered minor during bone healing and rehabilitation phase [18].

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