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**Article Title:** A Locking Contoured Plate for Distal Fibular Fractures: Mechanical Evaluation in an Osteoporotic Bone Model Using Screws of Different Length

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A locking contoured plate for distal fibular fractures: Mechanical evaluation in an osteoporotic bone model using screws of different length

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Abstract

Osteoporotic bone with poor mechanical capacity provides limited stability after fixation of ankle fractures. Stabilization with an implant providing increased fixation strength in osteoporotic bone could reduce failure rates of fixation and allow a more functional treatment. The purpose of this study was to evaluate a locking contoured plate for fixation of distal fibular fractures in comparison to a conventional contoured plate in an osteoporotic bone model. Eighty cylinders of osteoporotic bone surrogates were fixed with the two plates. We performed torque to failure and cyclic testing experiments using screws of different length with a Zwick/Roell testing machine. The locking system showed higher torque to failure and maximum torque levels as compared to the conventional plate in torque to failure experiments and torsional cyclic testing. The locking contoured plate provides improved fixation strength in the osteoporotic bone model. The locking system may be appropriate for fixation of distal fibular fractures, especially in osteoporotic bone with poor mechanical capacity.

Keywords: locking plate, ankle fractures, osteoporotic bone model
Introduction

Ankle injuries including distal fibular fractures represent the most common injuries of the lower extremity. An increasing number of ankle fractures in the elderly has been observed in recent years. Stabilization of these ankle fractures is a current topic in musculoskeletal science. The recommended operative treatment of oblique transsyndesmoidal fibular fractures includes fixation with lateral neutralization or posterolateral antiglide plates. Especially in elderly female patients the osteoporotic bone provides poor mechanical capacity, reflected in reduced holding power and increased fragility. Therefore, conventional plating systems are predisposed to higher failure rates including screw or plate loosening compared to locking fixation. The distal cancellous fibular fragment can only be fixed unicortically to prevent joint penetration. When bone quality is reduced, this area is predisposed to failure.

An implant providing improved fixation strength in osteoporotic bone could reduce failure rates of fixation and allow a more functional treatment resulting in earlier return to daily living. Locking plates provide improved biomechanical stability and are thus often indicated in osteoporotic fractures. In contrast to other regions, few biomechanical studies investigating locked plating of the distal fibula exist. Fixation of experimentally induced distal fibular fractures of human elderly cadavers with a contoured locking plate has shown improved stability as compared to conventional plating in an earlier study.

In the current study, we used an osteoporotic bone model with a constant structural quality to enable a higher number of experiments including cyclic testing. Increased fixation strength of the locking system would justify its use for stabilization of distal fibular fractures in osteoporosis. Therefore, the primary question of the study was to test whether the locking plate had improved fixation strength in comparison to the conventional plate (Figs. 1
and 2). Furthermore, mechanical parameters were evaluated in regard to screws of different length.

**Methods**

80 cylinders with a length of 67 mm of osteoporotic surrogate bone (0080 generic bone, osteoporotic, Synbone AG, Switzerland; diameter 25 mm) were adapted to the distal part of the plates without destroying the corticalis along the distal 30 mm with a maximum of 1 mm modulation of the surface (Fig. 2). Experiments (total n = 80) by applying axial load and torque were performed with a Zwick / Roell testing machine (Z020, Zwick / Roell, Ulm, Germany).

We compared the conventional six hole contoured plate (Malleolar plate, classic, 3716-08, Argomedical, Cham, Switzerland; Figs. 1 and 2) with the locking contoured plate (Malleolar plate, locking, 3726-08, Argomedical, Cham, Switzerland; Figs. 1 and 2). Both implants have the same design with a profile of 2.8 mm and differ at the distal fixation system. Plates and locking screws are made of titanium (Ti6Al4V, ISO 5832 - 3).

In order to evaluate the locking distal part of the implant, the proximal part of the plate was directly fixed between two clamps of a custom made holder (Fig. 2). Screws were inserted in the distal part of the plates and unicortically placed into the surrogate bone. Distal screws were inserted in lengths of 16 and 20 mm with only one length per experiment. The conventional plate was placed with all 3 distal cancellous screws (diameter 4.0 mm, Synthes, Oberdorf, Switzerland) and 4 of 7 possible locking screws (diameter 2.7 mm, Argomedical, Cham, Switzerland) were inserted in the locking plate with one constant configuration (Fig. 2).

Two clamps of the second custom made holder fixed the surrogate bone below the distal end of the plate over a length of 30 mm (Fig. 2). The two holders allowed an alignment
of the plate and bone surrogate with the axis of rotation of the testing apparatus and prevented any movement of the plates and bone surrogates; position of bone substitute was marked to visualize any movement. A torque with a constant axial load of 1 N was applied and maintained during the experiments, as torsion is one of the main components of forces in ankle fractures.\textsuperscript{15,17} Torque to failure and cyclic testing were performed with this experimental setting. The proximal holder rotated with 10° per second.

In torque to failure testing, stiffness, angle as torque to failure, and energy to failure - identified by measuring the area below the curve - were calculated. Torque to failure was determined by a decrease of the graph - the first turning point / inflection of the curve - of the torque versus angle of rotation under visual control (Fig. 3). Further, the maximum torque was analyzed. Ten constructs of each group were evaluated (n = 10 per implant for each screw length, Fig. 1).

Cyclic testing consisted of 4000 cycles with 20% of the average torque to failure.\textsuperscript{24,25} Angular rotation, construct stiffness and displacement by measuring the angle of ten testing times at 1, 500, 2000, 3000, and 4000 cycles were determined. After 4000 cycles a torque to failure test was performed (n = 10 per implant for each screw length, Fig. 1).

The specific mode of failure was documented. Data was filtered at 50 Hz (torque to failure testing) respectively at 16 Hz (cyclic testing) and continuously stored using TestXpert II software (Zwick / Roell, Ulm, Germany). Statistical analysis was performed with Mann-Whitney U tests to compare independent variables between the groups and with the Wilcoxon test for dependent variables within one group before and after cyclic testing.

**Results**

The locking system provided higher torque to failure levels in 16 and 20 mm long screws compared to the conventional plate (locked versus conventional plating: + 17%, p =
.005 respectively + 17%, p = .0002; Fig. 4, table 1). The maximum torque in both lengths of locked screws was higher compared to the conventional plating (locked versus conventional plating: + 24% at 16 mm, p = .003; and + 17% at 20 mm, p = .002; Fig. 5, table 1).

Energy to failure did not differ significantly between the two systems, but a trend to a higher energy to failure of the locking plate was visible (Table 1 A).

Within one fixation system, plating with longer screws displayed higher fixation strength compared to shorter screws. Conventional screws of 20 mm length showed higher torque to failure (p = .0003), maximum torque (p = .0002), angle at failure (p = .0005), energy to failure (p = .008), and stiffness (p = .007) compared to conventional screws of 16 mm length. Long locking screws (20 mm) showed higher torque to failure (p = .004), maximum torque (p = .0006), angle at failure (p = .003), and energy to failure (p = .0008) compared to shorter screws (16 mm).

The displacement - respecting the angle at the end of cyclic testing and the difference between the angle at the beginning and end of cyclic testing - was not different between the groups (n = 10 per implant for each screw length; Table 2). A non-significant trend to a relative lower displacement of the locking system was observed as the conventional plate showed an increase of the angle of 0.41° (+ 25%) at 16 mm long screws and of 0.32° (+ 17%) at 20 mm long screws. The angle of the locking system increased of 0.39° (+ 17%) at 16 mm long screws and of 0.33° (+ 15%) at 20 mm long screws.

After 4000 cycles, the locking system displayed in both cases a higher torque to failure (+ 15%, p = .034 respectively + 23%, p = .002) and a higher maximum torque compared to the conventional plate (+ 14%, p = .041 respectively + 28%, p = .002; Table 1 B). Interestingly, the stiffness was lower in the locking system at 16 mm long screws (~ 24%; p = .0005).
Different failure modes were registered (Fig 6). Failure of the conventional implant consisted of screws cutting out or fragmentation of the surrogate bone depending on the used screw length. Conventional screws of 16 mm cut out in half of the experiments (Fig. 6 A). This failure mode was characterized by multiple inflections of the curve (Fig. 3 A). In the remaining samples, partial fragmentation of the surrogate bone was induced (Fig. 6 B). Long (20 mm) conventional screws always induced a fracture of the bone substitute. Induction of a fracture was registered in 38 of 40 samples with locking screws (Fig. 6 C); a sharp decrease characterized the torque versus angle of rotation curve of this failure manner (Fig. 3 B). Fractures did not occur at the modulated areas of bone substitutes (Fig. 6).

Discussion

Osteoporotic bone with poor mechanical capacity provides limited stability for fixation of ankle fractures. Therefore, some authors prefer posterior antiglide plates to stabilize distal oblique fibular fractures, especially in cases of reduced bone quality.20,26 Beside biomechanical differences of posterior placed antiglide plates and lateral plates,20,27 there exist varieties of specific complications.3,28 Even if the risk of intraarticular screw penetration is avoided or reduced with dorsally placed antiglide plates, we prefer lateral fixation with neutralization plates. Both contoured plates are designed for lateral application.

Wound healing complications and superficial wound infections can be reduced by choosing the adequate time frame for surgical treatment after subsidence of soft tissue edema combined with atraumatic operative technique.3,28 Both anatomical contoured plates with a low profile of 2.8 mm contribute to this fracture management. Indicating the importance of implant design, a previous study has shown increased rates of wound healing complications with locking plates without low profile in distal fibular fractures.29
Kim et al. confirmed the hypothesis, that fewer locking screws are can achieve similar biomechanical stability compared to conventional screws. They demonstrated that in the setting of elderly ankle fractures a locking plate with two distal unicortical screws was mechanically equivalent to a conventional plate with three distal screws. Like in our study, no statistical significant differences of stiffness existed between the groups. In contrast to the conventional plates fixation with locking plates was independent of bone mineral density. Kim et al. concluded that locking plates may be advantageous in patients with the most severe osteoporosis. Which patients may benefit of expensive locking implants remained unclear.

Only one configuration of screws for each implant was used in our study. One may argue, that four locking screw are superior to three conventional cancellous screws. With respect to the specific configuration and the different diameters of these screws with 2.7 mm for locking screws and 4.0 mm for cancellous screws, we consider our configuration comparable. Furthermore, locking screws up to a maximum of seven may be placed in the contoured locking plate to allow an ideal configuration depending on the individual fracture. However, this study gives no information of the particular screw configuration that would be clinically ideal. As expected, longer screws showed higher fixation strength compared to shorter screws. Distal screws can only be fixed unicortically to prevent joint penetration and intraarticular screw positioning. When bone quality is reduced, this area is the predisposed place of failure, which was the background for the distal locking system. Therefore, the clinical impact of our results would be the use of screws reaching to the contralateral corticalis to guarantee maximum stability, as it is usually practised.

Failure of fixation is commonly displayed as screw loosening at the distal fibular fragment with subsequent loss of achieved reduction. Two different types of failure modes, which were independent of the modulated areas of the surrogate bones, were
identified in our study. Induction of a fracture of the bone substitute in the majority of samples with the locking system is specific for the experimental model, as a fracture above the implant is not typically seen in patients. This artificial failure mode is due to the high degree of rotation. The use of torsion alone limits this investigation, as axial or bending loads were not used in this study, however, torsion is one of the main forces on the distal fibula in ankle injuries.

In cyclic testing, the two implants showed similar dislocations. There was no implant cut out and no displacement after 4000 cycles, which could be due to the low cyclic load in the actual study.

As in any current test with surrogate bones, this study has the limitation of a simplified artificial model with only distally placed screws. The load scenario with rigid fixation of the plate and the surrogate bone between the two clamps induces constraining forces and does not represent the pure physiological loading of the distal fibula. The low failure torque indicates that there are probably other forces which have not been controlled and may have influenced the failure level. The use of the specific bone substitute, with no extent proof of its similarity to osteoporotic bone, limits the actual investigation even if surrogate bones and the synbone model are used in orthopaedic trauma research.

We employed bone substitutes to reduce uncontrollable parameters and perform tests at a constant quality. Studies in human cadavers to validate the use of bone analogues are still needed to support the outcomes of this study: the material’s similarity to osteoporotic bone in stiffness, in failure behaviour and in fatigue have been assumed.

However, we demonstrated superior biomechanical properties of the locking contoured plate stabilizing experimental induced transsyndesmoidal fibular fractures of human cadavers in an earlier study. Locked plating did show higher torque to failure, maximum torque, and angle at failure compared to the conventional plate. In contrast to
conventional plating, fixation with the locking plate was independent of bone mineral density.\textsuperscript{17}

The actual study investigated mechanical properties of a locking contoured plate in comparison to a conventional contoured plate in an osteoporotic bone model. Stabilization with the locking contoured plate showed improved fixation strength. Therefore, fixation of distal fibular fractures with the contoured locking plate in osteoporotic bone may reduce complications such as implant related failure, consequences of immobilization and allow a more functional treatment.\textsuperscript{17,28}

Acknowledgements

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Funding:

Argomedical provided the implants of this study.

Conflict of Interest Disclosure:

There are no conflicts of interest.
References


34. Marintschev I, Gras F, Schwarz CE, Pohlemann T, Hofmann GO, Culemann U. Biomechanical comparison of different acetabular plate systems and constructs-the role

Figure 1

<table>
<thead>
<tr>
<th>Screw length (mm)</th>
<th>16</th>
<th>20</th>
<th>16</th>
<th>20</th>
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<td>Mode of testing</td>
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<td></td>
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<tr>
<td>Torque to failure (n = 10)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Cyclic testing (n = 10)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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</tbody>
</table>

Figure 1 Testing modalities with the two anatomically preshaped plates. The locking system includes threads inside the plate and the screw head.
Figure 2 Experimental setting of torque to failure and cyclic testing with proximal fixed plate. A: conventional contoured plate B: locking contoured plate.
Figure 3 Torque-rotation relationship. A: Torque to failure of the conventional contoured plate. The first inflection of the curve represents the first screw loosening defined as torque to failure (indicated by *). Following local peaks display individual loosening and finally cutting out of all conventional screws. Maximum torque is indicated by **. B: Torque to failure of the locking contoured plate. Failure of fixation occurred by fracturing the surrogate bone indicated by a sharp decrease of the curve.
**Figure 4** The locking system had higher torque to failure levels compared to the conventional plate (p = .005 at 16 mm long screws respectively p = .0002 at 20 mm long screws).
Figure 5 Maximum torque of the locking plate was higher compared to conventional plating (p = .003 at 16 mm long screws respectively p = .002 at 20 mm long screws).

Figure 6 Failure modes. A: Cutting out of 16 mm long conventional screws occurred in 50% of the experiments. B: In the other 50%, fragmentation of surrogate bones was induced. C: Induction of a fracture was registered in 38 of 40 samples with locking screws.
Table 1: Tabulated summary (mean ± standard deviation) of mechanical parameters of the conventional and locking plate. A: torque to failure experiments B: cyclic testing

### A

**Screw length: 16 mm**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Conventional plate</th>
<th>Locking plate</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torque to failure (Nm)</td>
<td>1.84 ± 0.16</td>
<td>2.15 ± 0.23</td>
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<tr>
<td>Maximum torque (Nm)</td>
<td>2.10 ± 0.28</td>
<td>2.61 ± 0.41</td>
<td>.03</td>
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<tr>
<td>Angle at failure (°)</td>
<td>19.5 ± 2.87</td>
<td>22.8 ± 4.9</td>
<td>.198</td>
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<tr>
<td>Energy to failure (Nm°)</td>
<td>24.9 ± 5.22</td>
<td>30.7 ± 7.81</td>
<td>.082</td>
</tr>
<tr>
<td>Stiffness (Nm°)</td>
<td>213.3 ± 22.9</td>
<td>211.5 ± 42.7</td>
<td>.762</td>
</tr>
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**Screw length: 20 mm**

<table>
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<tr>
<td>Torque to failure (Nm)</td>
<td>2.73 ± 0.1</td>
<td>3.18 ± 0.22</td>
<td>.0002</td>
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<tr>
<td>Maximum torque (Nm)</td>
<td>3.22 ± 0.38</td>
<td>3.78 ± 0.31</td>
<td>.002</td>
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<tr>
<td>Angle at failure (°)</td>
<td>26.0 ± 3.88</td>
<td>27.8 ± 3.64</td>
<td>.405</td>
</tr>
<tr>
<td>Energy to failure (Nm°)</td>
<td>46.1 ± 7.32</td>
<td>54.1 ± 11.7</td>
<td>.112</td>
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<tr>
<td>Stiffness (Nm°)</td>
<td>298.7 ± 39.8</td>
<td>255.7 ± 52.4</td>
<td>.069</td>
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### B

**Screw length: 16 mm**

<table>
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<tr>
<td>Torque to failure (Nm)</td>
<td>1.86 ± 0.15</td>
<td>2.13 ± 0.28</td>
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<tr>
<td>Maximum torque (Nm)</td>
<td>2.42 ± 0.28</td>
<td>2.75 ± 0.41</td>
<td>.041</td>
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<td>Angle at failure (°)</td>
<td>18.4 ± 2.87</td>
<td>21.2 ± 8.38</td>
<td>.65</td>
</tr>
<tr>
<td>Energy to failure (Nm°)</td>
<td>22.9 ± 4.89</td>
<td>29.7 ± 17.0</td>
<td>.545</td>
</tr>
<tr>
<td>Stiffness (Nm°)</td>
<td>293.1 ± 29.7</td>
<td>223.1 ± 31.0</td>
<td>.0005</td>
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**Screw length: 20 mm**

<table>
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<tbody>
<tr>
<td>Torque to failure (Nm)</td>
<td>2.76 ± 0.26</td>
<td>3.4 ± 0.39</td>
<td>.002</td>
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<tr>
<td>Maximum torque (Nm)</td>
<td>3.31 ± 0.49</td>
<td>4.25 ± 0.51</td>
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<tr>
<td>Angle at failure (°)</td>
<td>26.9 ± 5.34</td>
<td>26.8 ± 4.72</td>
<td>.879</td>
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<tr>
<td>Energy to failure (Nm°)</td>
<td>50.4 ± 13.36</td>
<td>61.9 ± 14.76</td>
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<tr>
<td>Stiffness (Nm°)</td>
<td>332.1 ± 38.1</td>
<td>315.8 ± 25</td>
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Table 2 Displacement in cycling testing

<table>
<thead>
<tr>
<th></th>
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<th>angle at end (°)</th>
<th>SD</th>
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<tbody>
<tr>
<td>Conventional plate</td>
<td>16 mm long screws</td>
<td>1.68 ± 0.28</td>
<td>2.09 ± 0.35</td>
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<tr>
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<td>20 mm long screws</td>
<td>1.94 ± 0.25</td>
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<tr>
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<td>20 mm long screws</td>
<td>2.19 ± 0.23</td>
<td>2.52 ± 0.43</td>
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