Original article

Does a polyaxial-locking system confer benefits for osteosynthesis of the distal fibula: A cadaver study

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ARTICLE INFO

Article history:
Received 13 October 2015
Accepted 15 March 2016

Keywords:
Ankle
Fibula fracture
Antiglide plating
Locking plate
Polyaxial
Biomechanical tests

ABSTRACT

Background: In plate osteosynthesis involving the distal fibula, antiglide plating is superior to lateral plating in terms of the biomechanical properties. The goal of this study was to examine whether polyaxial-locking implants confer additional benefits in terms of biomechanical stability.

Methods: Seven pairs of human cadaveric fibulae were subjected to osteotomy in a standardized manner to simulate an uncomplicated Weber B fracture. The generated fractures were managed with a dorsolateral antiglide plate. To this end, one fibula of the pair was subjected to non-locking plating and the other to polyaxial-locking plating. Biomechanical tests included quantification of the primary bending and torsional stiffness. In addition, the number of cycles to failure in cyclic bending loading were determined and compared. Bone mineral density was measured in all specimens.

Results: Bone mineral density was comparable in both groups. Primary stability was higher in the polyaxial-locking group under torsional loading, and higher in the non-locking group under bending loading. The differences, however, were not statistically significant. All specimens except for one fixed-angle construct failed the cyclic loading test. The number of cycles to failure did not differ significantly between polyaxial-locking and non-locking fixation.

Conclusion: In a cadaveric Weber B fracture model, we observed no differences in biomechanical properties between polyaxial-locking and non-locking fixation using an antiglide plate. Based on the biomechanical considerations, no recommendation can be made regarding the choice of the implant. Further biomechanical and clinical studies are required.

Clinical relevance: Information on the behavior of polyaxial-locking plates is relevant to surgeons performing internal fixation of distal fibula fractures.

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1. Introduction

Ankle fractures pose a common challenge to trauma surgeons. Although fractures of the ankle and foot are not considered typical osteoporotic fractures [1] the incidence of ankle fracture is likely to increase due to the aging population [2–5]. This fact is associated to the growing size of the older population and its increasing activity level [2]. Several studies have conclusively established that open reduction and internal fixation of displaced fractures is superior to conservative therapy [6–9].

Many methods for internally fixing the ankle joint are commonly used, ranging from lag screw only fixation [10,11] to plate osteosynthesis with variable-angle, fixed-angle, or biodegradable [12–17] systems, including wire-augmented or cement-augmented constructs [3,18,19]. A gold standard, however, has not been defined. Open reduction and internal fixation with plate osteosynthesis is the most widely applied treatment. When non-locking implants are used, antiglide plating is superior to neutralization plating in terms of biomechanical soundness [16,17]. This may be due to the direct support provided to the distal fragment on the plate, as well as the potential for direct interfragmentary compression with the plate serving as an abutment. In addition, bicortical screw anchorage in the distal fragment is possible in certain cases, conferring additional pullout resistance [20]. On the other hand, antiglide plating is associated with an increased rate of peroneal tendon complications [21].

Fixed-angle implants have increasingly been successfully used in complex fractures and fractures associated with poor bone
quality [22]. Numerous studies have been published on this topic in relation to distal fibular fracture, some of them yielding contradictory results, making it impossible to conclusively establish an overall superiority of the fixed-angle approach. To the best of our knowledge, there are no published reports of a direct comparison between a conventional variable-angle or in other words a non-locking osteosynthesis (e.g. a one-third-tubular plate) and fixed-angle or locking plating in an antiglide position.

The present study was an in-depth examination of the antiglide plate in relation to the type of plate used. We aimed to determine how the use of an antiglide plate alters the biomechanical parameters, such as the stiffness and laxity, depending on the type of plate osteosynthesis used to manage distal fibular fractures.

2. Material and methods

2.1. Specimens

Seven fresh frozen human fibula pairs (3 female and 4 male pairs with a median age of 82.8 years [range, 79 through 89 years]) were used. First, bone mineral density (BMD) was determined in the associated calcanei (QDR 4500 Elite Densitometer, Hologic, Bedford, MA, USA). The fibula specimens were thawed at room temperature. Soft tissue was dissected off the bone.

2.2. Fracture model

After cutting the distal fibula to a length of 13 cm, a Weber B fracture (AO-Classification: 44-B1) was simulated with a standardized osteotomy using a handsaw. Osteotomy was initiated on the ventral aspect, 30-mm proximal to the fibular tip, and extended in the dorsal proximal direction at a 35-degree angle (see Fig. 1). Every osteotomy was performed by the same person. The location and the angle of the fracture were chosen due to the clinical experience, what also corresponds with the fracture-models used in the literature [15,16]. Although genuine fractures mostly appear curved and irregular we used a plain saw-cut to ensure reproducibility.

2.3. Osteosynthesis

Next, the fracture was subjected to dorsolateral antiglide plating with an interfragmentary lag screw applied through the plate. One fibula of each pair was treated with a non-locking 6-hole one-third tubular plate with 3.5 mm small fragment screws (plate and screws made of titanium alloy, De-Puy-Synthes, Umkirchen, Germany). Each contralateral fibula was treated with a polyaxial-locking 6-hole plate from the VariAx Locking Plate System (Stryker Leibinger GmbH & Co. KG, Freiburg, Germany) (Fig. 2).

In both fixation techniques, two screws were positioned proximally and distally, respectively, to the interfragmentary lag screw. The plate hole positioned proximally to the lag screw was left unoccupied. Bicortical screw placement was used in each case. Selection of the relevant treatment method was performed in a randomized manner.

Prior to embedding, the osteosynthesis gap and all segments of the osteosynthesis material that could come in contact with the embedded specimens were capped with modeling clay to eliminate contact with the liquid methylmethacrylate used in the next step. Next, both ends of the specimen were embedded in liquid methylmethacrylate (Technovit 3040, Heraeus Kulzer GmbH, Wehrheim, Germany) in a cylindrical form, approximately matching the size of the mounting device of the test machine. To prevent slippage of the cylinder in the mounting device it is fixed with a knurled-head screw. Once hardening was complete, the biomechanical testing commenced (Figs. 3 and 4).

2.4. Test design and procedure

Biomechanical testing was performed using a universal testing machine with a 100-N force sensor (tabletop testing system type TC-FR10TH.D09, Zwick Z1.0; Zwick/Roell, Ulm, Germany). First, the torsional stiffness was determined in the specimens, followed by bending stiffness. The final step involved cyclic bending loading with 5000 cycles of loading and unloading, each with an applied force of 30 N.

To determine torsional stiffness, a maximum force of 30 N was applied at the proximal embedding cylinder over a 60-mm long lever arm with a speed of 1 mm/s in both directions of rotation.

Torsional stiffness was calculated with this equation:

\[
\text{Torsional stiffness} = \frac{F \cdot h}{2 \cdot \tan^{-1} \left( \frac{1}{2} \right)}
\]
2.5. Statistical analysis

Statistical analysis of the bending and torsional stiffness, and the associated ROM was performed using the Mann–Whitney U test for comparison of medians and rank sums of the two study groups. BMD values were statistically analyzed using the Wilcoxon signed-rank test. A Monte Carlo simulation with 10,000 samples served as an additional, more accurate approximation method. A Kaplan–Meier survival analysis was performed to evaluate the nominally scaled failures. Statistical comparison of the two groups was performed according to Breslow. A $P<.05$ was considered statistically significant for all tests. The IBM SPSS Statistics (version 20) software was used for all calculations.

3. Results

3.1. Bone mineral density measurement

Bone density did not differ significantly between the respective members of the specimen pairs (median: BMDfixed-angle $0.442$ g/cm$^3$ (0.26–0.64 g/cm$^3$); BMDvariable-angle $0.419$ g/cm$^3$ (0.3–0.6 g/cm$^3$); $P=.292$).

3.2. Initial torsional and bending stiffness

The initial values of torsional and bending stiffness, as well as the corresponding ROM, are shown in Table 1. Initial torsional and bending stiffness were not significantly different between the treatment groups.

3.3. Cyclic bending test

Because macroscopically visible failure of one fibula of the pair was established as early as during the initial testing, only five specimen pairs could be subjected to cyclic loading test. In the cyclic test, all specimens except for one with fixed-angle fixation met the failure criterion after 5000 cycles (Fig. 5). No statistically significant difference was detected between groups $(P=.170)$.

4. Discussion

Unstable fractures involving the distal fibula are usually managed by lateral plate fixation and an interfragmentary lag screw, or by a dorsolateral antiglide plate and an interfragmentary lag screw inserted through the plate [14,16,17]. From a biomechanical point of view, non-locking dorsolateral antiglide plating should be superior to lateral plating [16,17]; yet this method does not provide superior clinical results [17,23]. The use of fixed-angle implants in the distal fibula segment could be very promising, particularly in the management of osteoporotic ankle fractures. Nevertheless, a separate study failed to demonstrate differences between these two fixation techniques in terms of the biomechanical properties associated with the use of fixed-angle implants [24].

In the present study, the biomechanical properties of dorsolateral plating in the antiglide position were studied in detail. Based on seven fresh frozen human cadaveric fibular pairs, non-locking
plate osteosynthesis was compared and contrasted with polyaxial-locking plating. No statistically significant differences were found. Therefore, the findings of this study did not establish superiority of polyaxial-locking plating. The results of the present study are consistent with several preliminary studies [12,14,19].

A similar set-up was used in the study by Eckel et al. [12]. Forty fresh frozen human cadaveric fibulae were used to compare four types of plate osteosynthesis applied from the lateral aspect, with 3 groups also receiving an interfragmentary lag screw. Both locking and non-locking implants were used. None of the plate osteosynthesis types was superior to any of the other types in terms of biomechanical properties [12], consistent with the findings of the present study.

The use of locking plate systems is not universally advantageous, and each clinical case should be examined individually prior to deciding on a particular fracture treatment. In osteoporotic bone, the goal is to maximize biomechanical stability, at least in terms of achieving the highest possible primary stability facilitating, for example, a primary load-bearing osteosynthesis where the full functional load is borne by the fixation. Under cyclic loading, however, a very rigid implant is often associated with an equally high degree of laxity of the screw-bone connection, which could result in osteosynthesis failure, as reported by Lill et al. [25] who compared different types of osteosynthesis for the treatment of proximal humeral fractures in osteoporotic bone. Based on 35 cadaveric humeri, Lill et al. [25] demonstrated that very rigid implants display a high stiffness under static loading. By contrast, under cyclic loading, the particularly rigid osteosyntheses showed a significantly greater degree of reduction in stiffness and an earlier failure. Elastic implants were significantly superior in these circumstances. This phenomenon is explained by a local overloading of the weak bone at the bone-implant interface.

A similar effect is possible at the distal fibula, because here the bone is similarly soft as in the proximal humerus. The theoretical increase in stability conferred by locking screw-plate constructs according to the theory described above may not fully translate to practical applicability because the transmission of force at the screw-bone junction, especially under cyclic loading, may lead to osteosynthesis failure secondary to construct pull-out. To this end, extension of the osteosynthesis material is theoretically an option toward achieving a more homogeneous force transmission from the plate to the bone [26]. From a practical perspective, however, this is hardly possible in a Weber B fracture involving the distal fibula fracture with a very small distal fragment; hence, in antiglide plating used in daily trauma surgery practice, a maximum of two screws can be placed into the distal fragment.

There are some limitations to the present study, including the small number of sample pairs (n = 7). While the preceding bone mineral density measurement allows for comparison between the members of each pair, there was a wide spread in values (BMD: bending and torsional stiffness) between specimen pairs. Prior studies established a direct relation with the biomechanical properties [14]. Taken together, these findings inevitably result in a similar wide spread of the torsional and bending stiffness values. Thus, a statistically significant difference would occur, if at all, only with a much larger number of samples. Additionally hidden micro fractures or micro displacements of the fragments during creation of the specimens or the testing procedure cannot be excluded totally. There was no randomization what tested first (bending or torsion) prior cyclic bending testing and there was no cyclic torsional test.

In contrast to many other studies using more or less intact lower leg specimens [3,16,27], we used only human fibulae. In our opinion, this is the most accurate method for assessing the biomechanical properties of fixation, as it allows for the exclusion of a variety of additional, non-measurable stabilizers. The biomechanical testing included only the torsional and bending tests, and bending was tested in a single plane only. This is a gross oversimplification of the complex motion exercised at the upper ankle joint and of the resulting forces acting on the fibula. Previous studies from this laboratory and others established that when isolated fibulae are used, specimens withstand comparatively smaller loads. For example, Eckel et al. [12] applied only 10 N in the bending test. To be able to perform the cyclic loading test, we reduced the force of the loading and unloading to 30 N in the present study, although the physiologic stresses on the entire ankle joint during walking are potentially significantly higher. Using a cadaveric bone model the effect of bone healing on the biomechanical properties could not be taken into account.

For these reasons, the results cannot be directly extrapolated to the actual conditions of an immediate full weight-bearing osteosynthesis for a Weber B fracture, which is particularly desirable in elderly patients [22].

5. Conclusion

The findings of the present study revealed no difference between the polyaxial-locking and non-locking plating of an uncomplicated Weber B fracture using an antiglide plate, based on the biomechanics. Further clinical studies are thus required before a conclusive recommendation can be made, especially because the biomechanical properties of fixation are only one aspect to consider in the selection of an osteosynthesis technique. Numerous other factors, such as anatomic condition, soft tissue complications, and the patient’s ability to comply adequately with weight-bearing limitations must also be considered.

Disclosure of interest

This study was partially financed by Stryker Trauma AG company.

Acknowledgment

We are grateful to Prof. Dr. A. Roth for the determination of bone mineral density.

Many thanks to Felix Wipf and Claudia Beimel (Stryker Trauma AG) supporting design, realization an statistical analysis of this study.
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