Introduction
Ankle fractures involving the distal fibula belong to the most common fractures. Operative treatment is indicated in unstable ankle fractures by open reduction and internal fixation with plate and screws. Especially in the elderly, the osteoporotic bone provides reduced stabilization of this fixation. Therefore, an implant providing improved mechanical stabilization could allow a more functional treatment and avoid complications as cut out of the implant.

We designed an anatomic preshaped locking plate for fixation of distal fibula fractures, focussing the osteoporotic bone (Fig. 1). Biomechanical comparison was performed between the new contoured locking plate and an existing regular contoured plate. The regular contoured plate showed in a previous study a four fold increased stiffness and torsional strength in comparison to the third tube plate.

Material and Methods
Biomechanical experiments by applying axial load and torsional moment were performed with a Zwick / Roell (2020, Zwick / Roell, Ulm, Germany) testing machine. An osteoporotic bone model (0800 generic bone, osteoporotic, Synbone AG, Malans, Switzerland) was used in this study. As implants, we used the regular six hole contoured plate (Malleolarplate, 3716-08, Argomedical, Cham, Switzerland) and prototypes of locking contoured plates (Figs. 1, 2; Argomedical, Cham, Switzerland).

To isolate test the distal part of the implant and evaluate the angular stable system, the proximal part of the plate was directly fixed with a custom made holder. Screws were inserted in the contoured part of the plate and placed into a 67 mm long artificial bone. To identify a possible correlation between screw - length and biomechanical properties, screws were inserted with different lengths of 14, 16 and 20 mm. The regular plate was placed with three monocortical cancellous bone screws (lengths 14 16, and 20 mm, diameter 4.0 mm, Synthes, Oberdorf, Switzerland) and 4 prototypes of locking screws (length 14, 16, and 20 mm, diameter 2.7 mm, Argomedical, Cham, Switzerland) were inserted with a constant configuration in the locking plate (Fig. 2).

Different testing modes were employed. As rotational forces interact to the distal fibula more than axial compression, we applied a torsional moment with a constant load of 1 N. In the moment to failure testing, the proximal holder rotated with 5° per second. Stiffness, angle as moment of failure, and energy to failure were identified. In additional tests, proximal and distal screws were placed into the osteoporotic bone to evaluate the complete construct. Three proximal cortical screws were inserted bicortical with a length of 20 mm (Synthes, Oberdorf, Switzerland); distal screws (length 20 mm) were placed monocortical as it is described above. Five constructs of each implant were evaluated.

Cyclic testing consisted of 4000 cycles with 20% of the mean moment to failure at 10° per second with a constant load of 1 N. The holder fixed the proximal part of the plate in cyclic testing. Torque to failure, angular rotation, construct stiffness and displacement were determined. After 4000 cycles the moment to failure testing was performed. Ten constructs of each implant and each screw length (16 mm and 20 mm) were evaluated.

Statistical analysis was performed after Mann and Whitney, and Spearman’s correlation test).

Results
Torque to failure testing
In a first series, the proximal plate was directly fixed with the holder, to evaluate the distal contoured part between the regular plate and the locking system (n = 10 for each implant). Comparing screws at different lengths, the locking system had a higher torque of failure with 20 mm long screws (Fig. 3; + 16.5%; p < 0.01).

Remarkably, stiffness was lower for the angular stable system at 20 mm screw length (-14.4% ; p < 0.01). A trend to a higher energy to failure was visible in the angular stable system. Within one group, a positive correlation was found between screw length and torque to failure. In additional experiments, proximal and distal screws with a length of 20 mm were inserted to stabilize a resection osteotomy. The place of failure of the regular contoured plate (n = 5) occurred always at the distal screw – bone – construct as cancellous screws cut out of the bone. In the locking system (n = 5), proximal bicortical regular cortical screws failed in all cases and distal locking screws remained in situ.

Cyclic testing
In cyclic experiments consisting of 4000 cycles at 20% of the torque of failure, the proximal part of the plate was directly fixed (n = 10 for each implant). In the moment to failure - respecting the amplitude of movement and the singular angles - was not different between the groups. After 4000 cycles, the angular – stable system showed a higher torque to failure (+ 23.2%; p < 0.01 at 20 mm long screws). The energy to failure and angle of failure did not differ significantly between the groups.

Discussion
In this study, we demonstrated improved biomechanical properties of a locking contoured plate for fixation of distal fibula fractures. In the present study, the locking system showed a higher torque to failure. Analogous, a trend of a higher energy to failure could be demonstrated. A positive correlation exists between the lengths of screws and the torque to failure. The clinical impact of this correlation would be the use of screws, reaching to the contralateral corticalis to guarantee the most possible stabilization.

The place of implant failure occurred always at the distal fragment, when the regular implant stabilized the osteotomy. If the locking system stabilized the osteotomy, the place of failure was in all cases the proximal fragment. This clearly demonstrated the improved stabilization of the new locking plate with the new configuration of screws.

In the torque to failure mode after cyclic testing, parameters of the single load to failure could be confirmed. We showed a higher torque to failure of the angular stable system, before and after cyclic testing. Remarkably, the stiffness and moment of failure, were not decreased within one group after cyclic testing. These results indicate, that there was no implant failure or dislocation of the screw – bone – construct in the locking system. A cut out or ease could not be noted visual. These findings indicate, that the locking system with improved biomechanical features could permit a more functional postoperative treatment.

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Figures
Fig. 1 shows the new contoured locking plate with complete placement of screws at the contoured part

Fig. 2 shows the setting of the torque to failure testing with the regular contoured plate (left) and the new locking contoured plate (right).

Fig. 3. Shows the higher torque of failure of the locking contoured plate compared to the regular contoured plate at 20 mm long screws.