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ORIGINAL PAPER

The primary stability of angle-stable versus conventional locked intramedullary nails

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Abstract

Purpose The aim of this study was to compare the initial biomechanical characteristics of the angle-stable locking system for intramedullary nails using the new biodegradable sleeve with conventional locking in the treatment of unstable distal tibial fractures.

Methods Eight pairs of fresh, frozen porcine tibiae were used for this study. The expert tibial nail (Synthes) was equipped with either conventional locking screws (CL) or the angle-stable locking system (AS). This system consists of a special ASLS screw with a biodegradable sleeve. For this investigation distal tibias (5.5 cm) were used and the nails were locked with three screws in both groups. Biomechanical testing included non-destructive torsional and axial loading.

Results The AS group showed a significantly higher torsional stiffness (70%) compared to the CL group. The range of motion was 0.5 times smaller for the AS constructs. The neutral zone was eight times higher in the CL group ($p<0.001$). In axial loading the AS group also showed a 10% higher axial stiffness and a 12% lower range of motion ($p<0.001$).

Conclusion The angle-stable locking system (ASLS) using a special screw and sleeve locking for intramedullary nails provides a significantly higher primary stability. The differences determined in this study may have clinical relevance particularly for torsional loads. For the new biodegradable angle-stable sleeve we found a comparable stability to the PEEK-based sleeve system. This system has the potential to decrease complications such as secondary loss of reduction and mal-/non-union.

Introduction

In modern trauma care the treatment of unstable and osteoporotic distal tibia fractures is still challenging. There is one area of agreement among trauma surgeons: these fractures need to be treated operatively [1–4]. The standard treatment option includes open reduction and internal fixation using angular stable plate osteosynthesis. One major disadvantage of this procedure is the considerable soft tissue damage with the increased risk of wound healing problems and infection [2, 5, 6]. Intramedullary nailing of distal tibia fractures can decrease these risks but is attended by other problems such as decreased biomechanical stability due to the anatomical conditions of the distal tibia [1, 7]. Nevertheless the indications of intramedullary nailing have been extended to include even more distal fractures [7, 8]. To increase mechanical stability a new implant system, the angle-stable locking system (ASLS, Synthes GmbH, Solothurn, Switzerland) was developed.

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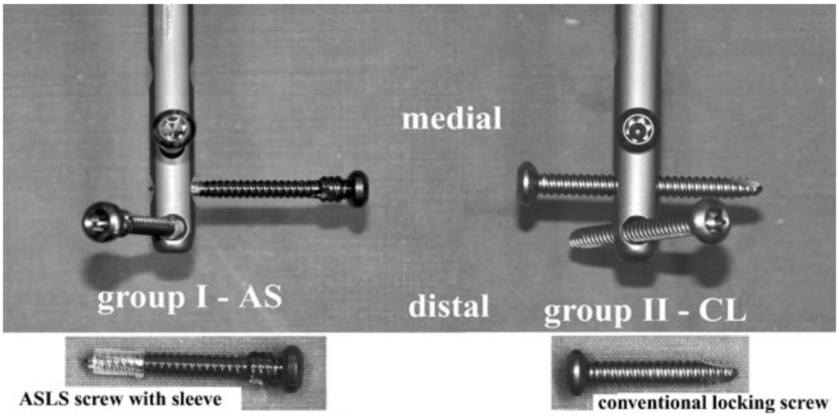

Fig. 1 Screw configuration used for this study with three screws for distal locking. AS (*left*) using 4-mm ASLS screws with corresponding sleeves. CL (*right*) using conventional 4-mm locking screws

Whereby a sleeve is applied over the locking screw. During locking the sleeve is twisted and thus angle-stable locked screws are created. The ASLS was introduced using a PEEK (polyetheretherketone) sleeve, then the manufacturer completely changed the sleeve material to biodegradable 70:30 poly(L-lactide-co-D,L-lactide). There are only three studies investigating this system, all of them using the PEEK sleeve. These studies found a significant reduction in medio-lateral neutral zone and fracture gap movement for the angle-stable system. Additionally, the angle-stable fixation reduced the influence of BMD [9–11].

The purpose of this study was first to investigate the primary mechanical characteristics of the angle-stable locking system using the new biodegradable sleeve and second to compare the results with former studies to show the consistency of both systems.

Material and methods

Specimens

Eight pairs of fresh frozen porcine tibiae (all female, all same age) were used for this study. Specimens were frozen, stored at −20°C, and thawed at room temperature 24 hours before potting and mechanical testing. Within each pair of tibiae, one was randomized to receive angle-stable locking (group I, AS), whereas the contralateral received conventional locking (group II, CL). Before testing, specimens were completely stripped of soft tissues and a transverse osteotomy was performed 5.5 cm proximal to the tibiotalar joint line.

Implants

The 8-mm cannulated expert tibial nail (Synthes GmbH, Solothurn, Switzerland) was used; it is made of titanium aluminium niobium alloy (TiAl6Nb7). All nails were cut 20 cm above the distal end. Proximally they were embedded over a length of 5 cm in two component cast resin (RenCast FC 52; Huntsman Advanced Materials, Monthey, Switzerland). An additional hole in the antero-posterior direction was drilled 13 cm proximal to the nail tip to connect the nail to a custom-made drill guide jig.

For locking in both groups the three most distal screw holes were used as follows: distal screw from antero-lateral to postero-medial, middle screw from medial to lateral and proximal screw from anterior to posterior (Fig. 1). In group I (AS), 4-mm ASLS screws were used with the corresponding ASLS sleeve. In group II (CL), 4-mm standard locking screws were used. All screws were chosen with the appropriate length for a bicortical purchase.

Instrumentation

The nail was tapped into the unreamed distal tibia section to a distance of 15 mm from the distal articular surface. The position of the nail was checked using an image intensifier. Afterwards the distal locking was performed using a

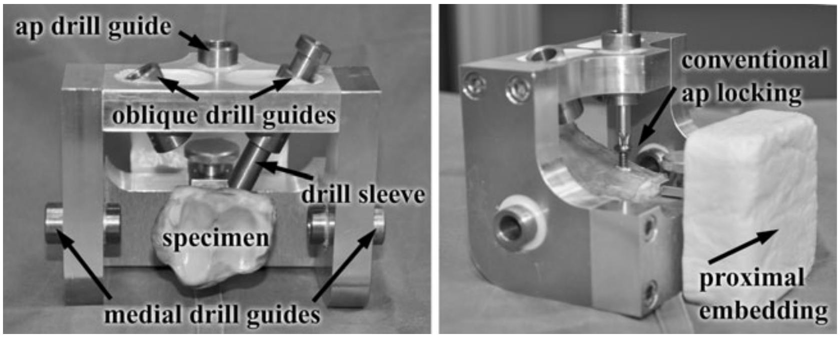

Fig. 2 Distal locking using the custom-made locking jig. Following nail insertion the construct was fixed to the jig and standardized drilling and locking could be performed (for left and right tibiae)

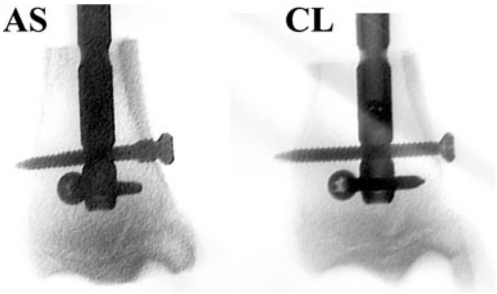

Fig. 3 X-ray control after nail locking showing an angle-stable locked construct (*left*) and a conventional one (*right*)

custom-made drill guide to ensure standardized distal locking (Fig. 2). The locking procedure followed the manufacturer's surgical technique and all steps were checked with the image intensifier (Fig. 3).

Before distal embedding all exposed implant surfaces were covered with modeling compound to prevent direct contact with the two component cast resin. A custom made jig was used for both distal and proximal embedding to ensure a central nail position. Thus torsional loading without any bending was assured.

Mechanical testing

Quasi-static mechanical testing was performed on a servo-hydraulic testing machine (Instron 8874, Instron, High Wycombe, Bucks, United Kingdom; Fig. 4).

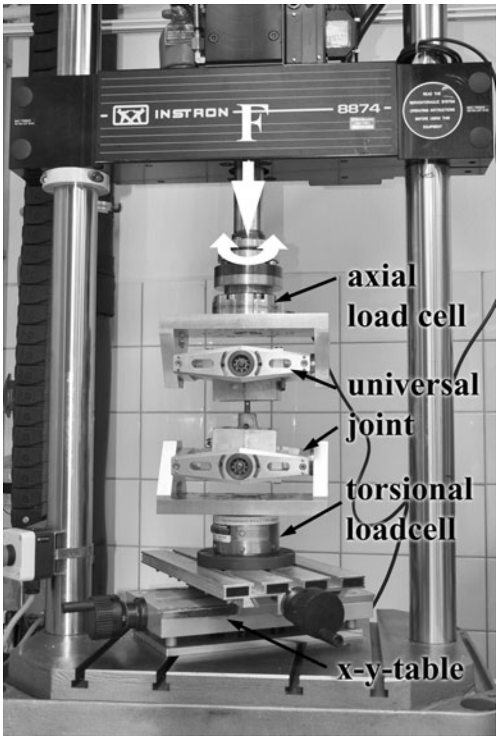

Fig. 4 Test setup for torsional and axial testing showing the two universal joints and the x-y-table for exact placement of the specimen

Axial and torsional testing was performed subsequently, starting with torsional loading. The specimens were loaded with 5 Nm in external and internal rotation for ten cycles with a crosshead speed of 1 Nm/s. Afterwards axial testing was performed with a crosshead speed of 1 mm/min for ten cycles. Maximum load was set to 50 N (tension and compression). Using these loads we ensured non-destructive biomechanical testing to allow subsequent long-term biomechanical investigation of the biodegradation.

Data acquisition and evaluation

Time, load, displacement, torsional moment, angle and cycle number were acquired and plotted with use of MAX software (version 9.2; Instron, Canton, Massachusetts). Using Microsoft Excel (Excel 2010, Microsoft Cooperation, Munich, Germany) and the load displacement curves axial and tosional stiffness, range of motion (ROM) and the neutral zone (NZ) were determined following Wilke et al. [12]. These parameters were calculated for all ten cycles, for further statistical analyses the mean of these ten cycles was used for each specimen. Statistical analyses were performed using SPSS for Windows (Version 16, SPSS Inc., Chicago). After testing for normal distribution (Shapiro-Wilks test) the Mann–Whitney test was used to determine significant differences between the groups. Significance was set to a level of 0.05.

Results

All results are summarized in Table 1. In torsional testing the mean range of motion was 0.5 times smaller for the angle-stable locked group compared to the conventional locked group ($p<0.01$, Fig. 5). The angle-stable constructs showed a 70% higher mean torsional stiffness compared to the conventional constructs ($p<0.01$, Fig. 6). Furthermore the mean neutral zone was eight times larger in the conventional constructs ($p<0.01$, Fig. 7).

Table 1 Results of biomechanical testing shown as mean (standard deviation) and significance determined with Mann–Whitney test

Parameter	Group I AS	Group II CL	Significance (*p*)
Torsion			
ROM [°]	2.7 (0.3)	5.0 (1.6)	<0.01
Stiffness [Nm/°]	3.7 (0.4)	2.2 (0.6)	<0.01
NZ [°]	0.2 (0.03)	1.3 (0.9)	<0.01
Axial			
ROM [mm]	0.23 (0.02)	0.26 (0.05)	<0.01
Stiffness [N/mm]	445 (41)	403 (58)	<0.01

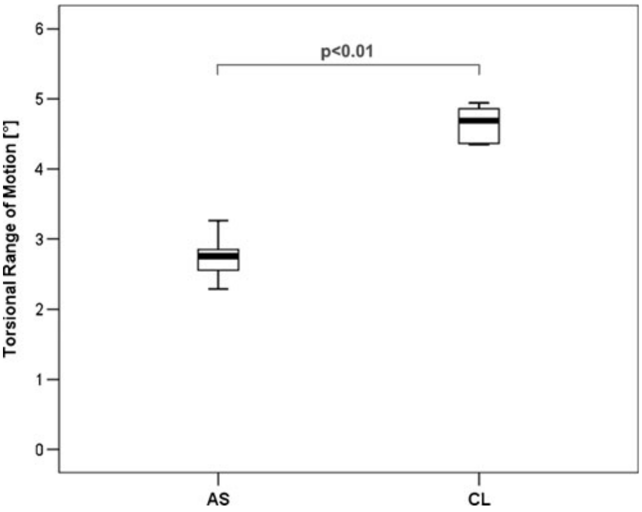

Fig. 5 Box plot of the torsional range of motion [°] showing the median, the 25% and 75% quartiles and the minimum and maximum, and p-value of the Mann–Whitney test

The mean axial range of motion was 12% lower, and mean axial stiffness was 10% higher in the angle-stable locked group ($p<0.01$, Fig. 8).

Discussion

In this investigation the angle-stable locked constructs showed significantly higher torsional stiffness values and less neutral zone and range of motion under torsional loading. Thus, angle-stable locking provides higher construct stability and reduces fragmentary movement compared to conventional locking.

The treatment of tibia fractures using intramedullary nails has been increasingly performed to address even more distal fractures in the past few years. Following this change in the spectrum of indications, the numbers of complications such as secondary loss of reduction, mal/non-union and delayed union increased [2, 4, 6, 7, 13, 14]. Various modifications and implant developments have been investigated to exploit the benefits of intramedullary nailing [6, 15]. With respect to the local anatomic characteristics of the distal tibia (wide intramedullary canal, thin cortex), the distal locking options (number and sites) have been adapted.

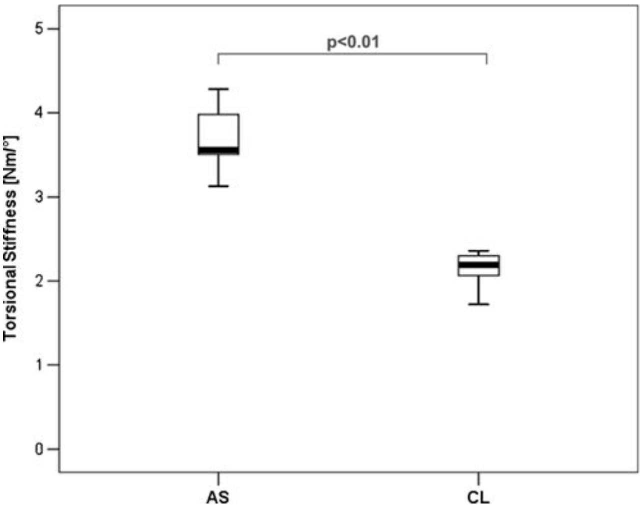

Fig. 6 Box plot of the torsional stiffness [Nm/°] with p-value

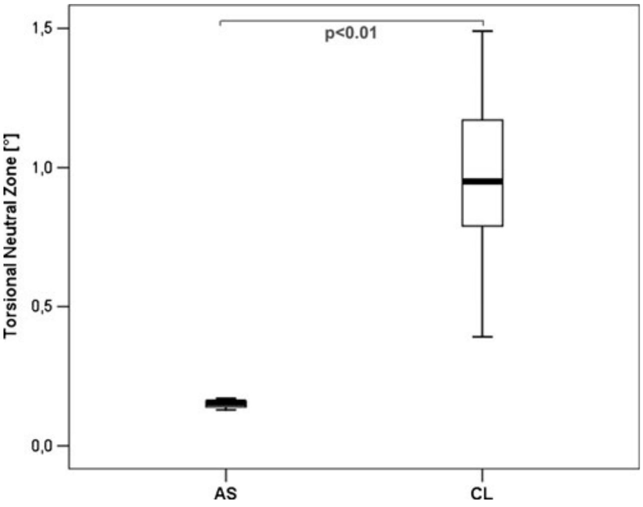

Fig. 7 Box plot of the torsional neutral zone [°] with p-value

Modern tibia nails enable the insertion of up to four distal screws for the management of distal tibia fractures. A novel approach to manage the problems of distal tibia fractures is the angle-stable locking system (ASLS, Synthes, Solothurn, Switzerland) for intramedullary nails. Three previous biomechanical studies have already shown the biomechanical benefit. The angle-stable locked constructs had a significantly higher axial stiffness and significantly less fracture gap movement [10]. Horn et al.

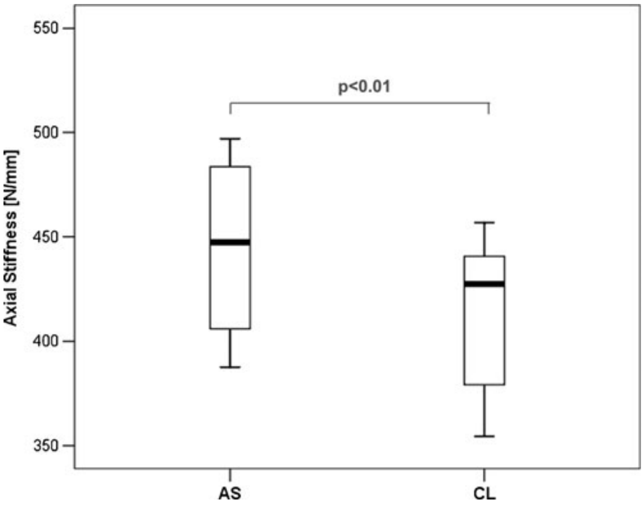

Fig. 8 Box plot of the axial stiffness [N/mm] with p-value

reached an axial stiffness of 1420 N/mm for the angle-stable and 620 N/mm for the conventional constructs. The differences from our investigation (445 N/mm versus 403 N/mm) are based on the differences in the test setup: Horn et al. used complete human tibiae with long nails whereas we used only the distal part, and the reaming procedure also differed.

The second study described a significant reduction of the neutral zone in medio-lateral bending and a significant reduction of fracture gap angle under cyclic axial loading [9]. In another study Gueorguiev et al. showed equal mechanical stability when comparing two angle-stable with three conventional distal locking screws. In this study Gueorguiev et al. also showed the significantly smaller torsional NZ (AS 0.08 versus 0.46 CL); our study showed higher values for the NZ (AS 0.2 versus CL 1.3) due to a different test setup and measurement with a machine actuator compared to 3D motion tracking [11]. Comparing the differences, the CL constructs had a 6 and 5.8 times higher NZ in our investigation, respectively, compared to the study of Gueorguiev et al. The same applies for the torsional stiffness which was 1.68 and 1.69 times higher, respectively, for the AS group in our study compared to the study of Gueorguiev et al.

The major disadvantage of all studies is the use of the old PEEK (polyetheretherketone) sleeve. These sleeves were completely replaced by biodegradable sleeves, which retain their stability for four weeks. Afterwards, they gradually break down to lactide acid.

In an in vivo study Epari et al. found torsional and sheer stresses to have negative influence on fracture healing [16]. Therefore angle-stable locking is an option to reduce risk of delayed union and, because of the increased stability, of secondary loss of reduction. Thus, it provides an option to use intramedullary nailing in even distal tibia fractures and osteoporotic fractures. Kaspar et al. found angle-stable locking of intramedullary nails in tibia fractures to result in less fracture gap movement and better radiologic, histomorphometric, biomechanical and clinical fracture healing in sheep [17].

Although this biomechanical study has limitations (using porcine bones, small sample size, biomechanical in vitro study) our results suggest that angle-stable locking of intramedullary nails in distal tibia fractures could improve the clinical outcome. Porcine bone is widely used for biomechanical testing due to its availability [18–22]. From these investigations we know that the bone mineral density of the porcine tibia is higher than human [23, 24]. For the interpretation of the results we have to take into account that we do not have an osteoporotic bone model, but the advantage of increased stability of the angle-stable locking is due to decreased screw-nail movement and will also be present in osteoporotic bone. Nevertheless, the first step to be taken is a long-term study to investigate the degradation of the sleeve and its influence on the biomechanical characteristics. Second, clinical studies will be required to investigate the utility of the technique in the management of these difficult to treat distal tibia fractures.

Conclusion

With our study we could clearly show the biomechanical benefit of the new angle-stable locking sleeve for the expert tibial nail in the treatment of distal tibia fractures. We can conclude that the new system provides a comparable stability to the PEEK based sleeve system. Using this system even distal or osteoporotic tibia fractures with a poor implant purchase may be treated sufficiently with an intramedullary nail. This system has the potential to decrease complications like secondary loss of reduction and mal/non-union.

Acknowledgement All implant materials (nails, screws and sleeves) were supplied by the manufacturer Synthes (Solothurn, Switzerland).

Conflict of interest statement All authors disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) this work.

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