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3D Optical Investigation of 2 Nail Systems Used in Tibiotalocalcaneal Arthrodesis: A Biomechanical Study

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Abstract

Background: Although retrograde intramedullary nails for tibiotalocalcaneal arthrodesis (TTCA) are an established fixation method, few studies have evaluated the stability of the available nail systems. The purpose of this study was to compare biomechanically the primary stability of 2 nail-systems, A3 (Small Bone Innovations) and HAN (Synthes), in human cadavers and analyze the exact point of instability in TTCA by means of optical measurement.

Methods: In 6 pairs of lower legs (n = 12) of fresh-frozen human cadavers with osteoporotic bone structure, bone mineral density (BMD) was determined. Pairwise randomized implantation of either an HAN or A3 nail was executed. Performance and stability were measured by quasi-static tests using 3D motion tracking (NDI Optotrak-Certus) followed by cyclic loading tests during dorsi- and plantarflexion.

Results: 3D optical analysis in quasi-static tests showed a significantly lower degree of movement for the HAN nail in rotational and dorsi-/plantarflexion, especially in the subtalar joint. Cyclic loading tests were consistent with quasi-static tests.

Conclusion: The A3 nail offered lower stability during axial torsion in the ankle and subtalar joints and during plantar- and dorsiflexion in the subtalar joint in osteoporotic bones. This study was the first to examine the primary stability of different arthrodesis nails in TTCA and their bony parts with a 3D motion analysis.

Clinical Relevance: The better stability of the locking-only HAN nail in this osteoporotic test setup could lead to more favorable results in comparison to the A3 nail in clinical use.

Keywords: tibiotalocalcaneal arthrodesis, intramedullary nail, nonunion, 3D motion tracking, retrograde nail

Introduction

Tibiotalocalcaneal arthrodesis (TTCA) using retrograde intramedullary nails is an established operative method for treating combined pathology of the ankle and subtalar joints. Implant anchorage is of particular importance in multimorbid patients with osteoporotic bone and unfavorable soft-tissue situation. Since the first osteosynthesis with femur nails,[13] new generations of intramedullary nails have been designed with specific features, especially considering the anatomy of the ankle. New developments in nail design for TTCA have contributed to lower complication rates in the clinical setting.[8,14-17,19,27] Nonunion rates of up to 24% occur in recent studies.[2,4,6,18,24]

A3 is a newly developed intramedullary nail. It has several structural differences from other standard arthrodesis nails. First, it has 2 additional bends, one of which is located proximally and simulates the physiologic bend of the medullary cavity of the tibia. The other bend is distally located, with a posterior bend of 15 degrees. This feature is to increase the anchorage in the calcaneus. Second, the lateral bend of 10 degrees should mirror the physiologic valgus bend in the human ankle.[23] Third, the direction of the distal locking screw of the calcaneus is angled at 15 degrees dorsiflexion in relation to the tibial axis, the middle portion of the nail, and the neutral rotation. Fourth, the nail has a compression bolt that provides mechanical compression between the calcaneus and the talus and between the talus and the tibia as well as angular locking of the calcaneal

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locking screw. Moreover, the distal part of the A3 nail is oblique with reference to the plane of the calcaneus.[23]

The HAN nail is a standard nail in arthrodesis and was therefore used as a control in this study. It has only 1 valgus bend of 12 degrees distally. For calcaneal locking, we used the available 2 screw bolts instead of the blade for better comparison to the A3 nail, which uses 1 screw bolt in the calcaneus.

The purposes of this study were to compare the performance of 2 retrograde intramedullary nail systems, A3 (Small Bone Innovations, Morrisville, PA) and HAN (Synthes, West Chester, PA), and analyze by means of optical tests the exact point of instability in TTCA.

We hypothesized that the A3 retrograde intramedullary nail system would provide better primary stability in osteoporotic bone than the HAN retrograde intramedullary nail system as a result of its improved design that mirrors anatomic structuring. Also, we report of the effectiveness of this enhanced test setup with 3D optical analysis for tibiotalocalcaneal arthrodesis.[5]

Materials and Methods

Informed consent for the current study was given by the institutional review board. All cadaveric specimens used in the current study were provided by the Institute of Anatomy.

The study was conducted on 6 pairs of fresh-frozen below-knee cadaver specimens (stored at −18°C). The mean age of the specimens at death (3 males, 3 females) was 83.5 years (range, 77-95). The specimens were thawed 24 hours at room temperature prior to preparation and testing. Screening for preexisting bone pathologies was performed by conventional radiography in anteroposterior and lateral views. Additionally, the bone mineral density (BMD) of the cancellous bone in the calcaneus was measured by quantitative computed tomography (qCT, Somatom Definition; Siemens, Erlangen, Germany) at the local Department of Radiology.

The leg specimens were prepared by carefully removing all soft tissues. Care was taken to leave all stabilizing ligaments at the ankle intact, such as the distal syndesmotic complex, the interosseous membrane, the collateral ligaments, and the capsules of the ankle and subtalar joints. The surfaces of the ankle and subtalar joints were also left intact, and the foot was amputated at the Chopart joint. In contrast to the study of Klos et al, [11,12] the fibula was not resected but was instead transected with the tibia 30 cm above the ankle joint.

Either an A3 or a HAN nail was implanted on the left or right side (6 in each group) of paired legs at random so that always a pair of legs was tested against each other with equal biomechanical properties. Two trained orthopedic surgeons with long-term experience in TTCA conducted the procedures according to the manufacturer's instructions. One implanted all HAN nails and the other implanted all A3 nails. The A3 nail was implanted in locking-compression mode, according to the manufacturer's recommendations, the HAN nail was implanted in pure locking mode, because it was found to not provide a sufficient compression mode. Resection of cartilage was not performed because of possible difficulties to perform this step in a standardized manner.[11]

First, the calcaneus was embedded in bone cement (Technovit 4000; Heraeus Kulzer GmbH, Wernheim, Germany) ensuring that the subtalar joint was unaffected. To ensure the biomechanical properties of the bone were not affected by the potting medium, the screw holes of the nails were covered with an elastic rubber mass. Next, 150 mm of the proximal part of the shafts of the tibia and fibula were embedded. Adjustments and positioning were verified by vertical and horizontal laser alignment.

The specimens for the imaging setup had 3 rigid bodies, which consisted of infra-red marker triplets (iLED) fixed at the calcaneus, talus, and tibia. A fourth rigid body was fixed at the bottom of the setup and served as a general positioning reference (Figure 1A, B). For the tibia, talus, and calcaneus, typical anatomic landmarks were chosen as reference for optical measurement. Software was used to calculate the local coordinate system for every rigid body. A setup originally described by Mückley et al and Klos et al[11,16] was used after some modifications, which was published recently.[5]

A biaxial testing machine (Instron 8874; Instron, Darmstadt, Germany), equipped with a 10-kN/100 Nm load cell for compression, extension, and torsion, was used. Fine-tuning of the testing machine and standardization of the distance between the actuator and tibial axis were established using a cross-table. Additional shear stresses could be excluded by these means. All tests were performed under controlled loading. 3D motion tracking (Optotrak Certus, NDI Europe GmbH, Radolfzell, Deutschland) was used to measure the relative movements between the groups of bone constructs. The accuracy of measurement of translational motions was ±0.03 mm with a resolution of 0.01 mm, and the rotational accuracy was 0.0757 ± 0.121 degrees (Figures 1 and 2).[25] Measurements were recorded at a frequency of 25 Hz. Measurements between the tibia and talus, between the talus and calcaneus, and of the overall movement of the construct (between the tibia and calcaneus) were referred to as TIBTAL, TALCAL, and TIBCAL, respectively.

In quasi-static tests the initial stability of the constructs was measured in dorsi-/plantarflexion, varus-valgus directions, and axial torsion. A biaxial torque of ±5 Nm was applied to the specimens in all modalities of testing during quasi-static testing. Additionally, for axial torsion an axial preload of 10 N was applied. This value was used as suggested in other studies.[11,16,17] Torque was achieved with an 80-mm-long lever arm attached to the load entry point (Figure 1A, B). This lever with a slide for minor friction was connected to the actuator of the testing machine with a suspension with 3 rotational degrees of freedom, allowing

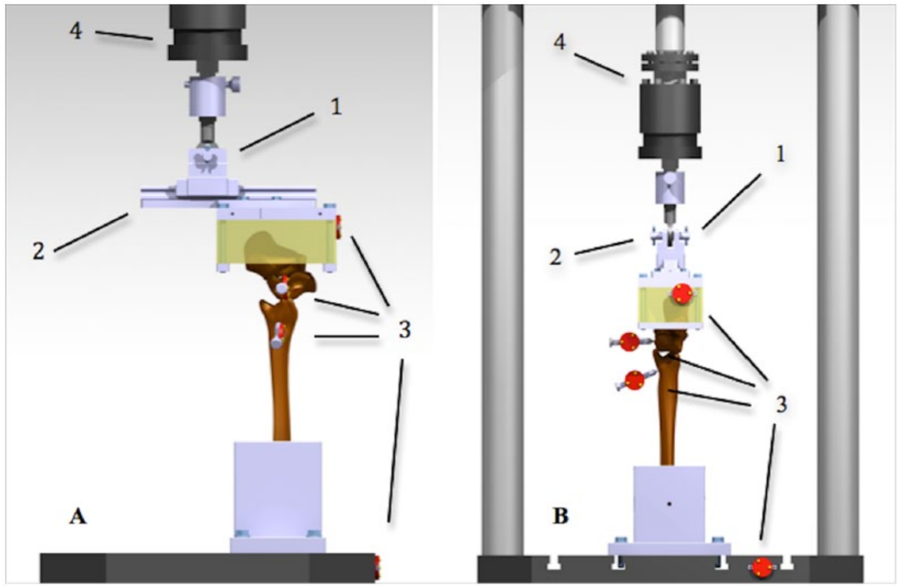

Figure 1. (A) Lateral view on the test setup during tests in dorsi-/plantarflexion directions, showing the embedded calcaneus linked to a slide (1) with a lever arm (2) for applying load, and the i-LEDs (3) attached to the embedded calcaneus, the talus, tibia, and the biaxial testing machine (4). (B) Anteroposterior view on the test setup.

compensations of small movements. For dorsi/-plantarflexion, the load was applied 80 mm behind the ankle, with the construct placed in the front of the load cell (Figure 1). For varus-valgus tests, the load was applied 80 mm lateral to the ankle via the lever arm. For axial torsion, the construct was placed in line with the load cell and the load was applied by the rotational actuator of the testing machine. All adjustments and positioning were verified by laser.

After each loading, the construct was checked both visually and radiologically for signs of loosening or breakage. A radiologic C-arm (Fluoroscan Insight, Hologic, Bedford, MA) was used for this purpose. For consecutive analysis during the cyclic loading tests, the C-arm was left in place.

A cyclic loading test was performed to measure the change in rotational movements during dorsi-/plantarflexion for a total of 5000 cycles (divided into 20 groups of 250 cycles).

To start, a load of ±125 N was applied for a total of 1500 cycles and was then increased to ±250 N for the next 3500 cycles or until failure of the construct. None of the specimens reached the failure criteria. Measurements were finished after 5000 cycles. This number of cycles was chosen to mimic the first days after an operation, when mobilization is still limited in elderly patients.[28] Failure was defined as displacement of the actuator of >18 mm in the dorsal or >15 mm in the plantarflexion direction, with an overall displacement of more than 33 mm or ROM of the construct of 22.4 degrees.[20,21] Another failure mode was breakage of a nail implant or the bone model, which was radiologically checked after each group of 250 cycles. Range of motion (ROM) was determined by motion tracking.

Data were analyzed using the SPSS software (IBM SPSS Statistics 21, IBM, Armonk, NY). All data were tested for normal distribution and homoscedasticity. A paired t test was used to detect significant differences in BMD and the amount of displacement during cyclic loading. Because of a nonnormal distribution, the numbers of cycles to failure were compared using a Wilcoxon rank test. The level of significance was $P \leq .05$.

Results

Bone Mineral Density

The means obtained for BMD were 83.2 mgHA/cm^3 for the HAN group and 87.2 mgHA/cm^3 for the A3 group and were not significantly different ($P = .432$).

Quasi-static Tests

The varus-valgus test showed no difference between the groups for TIBTAL ($P = .833$), TALCAL ($P = .833$), and TIBCAL ($P = .753$) (Figure 2). However, the overall range of motion represented by the movement between the tibia and the calcaneus (TIBCAL) was 1.6 degrees (range: 0.6 degrees-1.9 degrees) in the HAN group and 0.9 degrees (range, 0.5 degrees-2.9 degrees) in the A3 group.

Figure 2. Anteroposterior view on the testing machine with an embedded specimen for quasi-static testing in dorsi-/plantarflexion directions. The i-LEDs are attached to the embedded calcaneus, the talus, tibia, and the biaxial testing machine.

The overall movements (TIBCAL) in the torsional direction were significantly different between the groups (P = .028) (Figure 3). The ROM of TIBCAL was 4.0 degrees in the HAN group and 11.2 degrees in the A3 group, which represents a 283% increased motion in the A3 group. This difference can also be observed in the examination of isolated movements between the tibia and the talus (TIBTAL) (P = .028) and between the talus and the calcaneus (TALCAL) (P = .028) (see Figure 3).

3D motion tracking during quasi-static tests and dorsi-/plantarflexions gave varied results (Figure 4). Although TIBTAL analysis showed a nonsignificantly higher stability in the A3 group (A3 = 0.6 degrees) (HAN = 0.8 degrees) (P = .249), the movement between the talus and the calcaneus (HAN = 0.2 degrees) (A3 = 0.9 degrees) (P = .028) and the overall movement of the construct were significantly lower in the HAN group (HAN = 1.2 degrees) (A3 = 1.7 degrees) (P = .028) (Figure 5). Following table displays, all median values for quasi-static tests in the different ankles and overall construct (Table 1).

Cyclic Testing

The results obtained following cyclic testing were similar to those of the quasi-static tests in dorsi-/plantarflexion. Figure 5 shows that there was no difference in movement during the first load level (AD1 to AD6) and only a slight increase during the second load level. Movement in the ankle joint (TIBTAL) did not increase significantly. A comparison of the first and last load steps showed lower stability in the HAN group (HAN = 1.4 degrees) (A3 = 1.0 degrees). However, this difference was not significant (P = .116) (Figure 6). Figure 6 shows a more evident change in movement in the subtalar joint (TALCAL). Although the movement between the talus and the calcaneus in the HAN group did not change during the first load level, the movement in the A3 group changed by 0.5 degrees (P = .027). In the second load level, no strong changes were observed for both groups. However, the overall change in movement between the first and last load steps was high in both groups. The movement in the HAN group was 1.0 degrees, whereas in the A3 group, it increased to 3.8 degrees (P = .028). Figure 7 shows that overall movement (between the tibia and the calcaneus: TIBCAL) did not differ during the first or second load levels in either group. However, the change in ROM between the first and last steps of loading was significantly less in the HAN group (HAN = 2.6 degrees) than in the A3 group (A3 = 4.7 degrees, P = .046) (Figure 8).

Discussion

TTCA is a salvage procedure for combined pathology in the ankle and subtalar joints. Possible major complications include non-union, infection or implant failure.[3,8,17,18,22]

Intramedullary nails have become a preferred tool because they combine stability with the least amount of soft tissue morbidity. In addition to soft tissue protection, anchorage of the osteosynthesis material components plays a prominent role.[6,7] Many different fixation options for the intramedullary nail, especially in the osteoporotic bone, have been developed. Compression is generally accepted in the literature to lead to higher stability and a higher osseous union rate.[1,10,16] Many authors have noted the importance of calcaneal locking by intramedullary nails for TTCA.[11,14,15]

Mückley et al showed that a locking-only mode in osteoporotic bone results in higher stability compared with a locking-compression mode, although these findings were not significant in a human bone model.[17] These findings were confirmed by our study.

In the A3 nail, talar and calcaneal fixation can be performed with locking screws, and compression can be applied via a compression bolt, which was used in our test

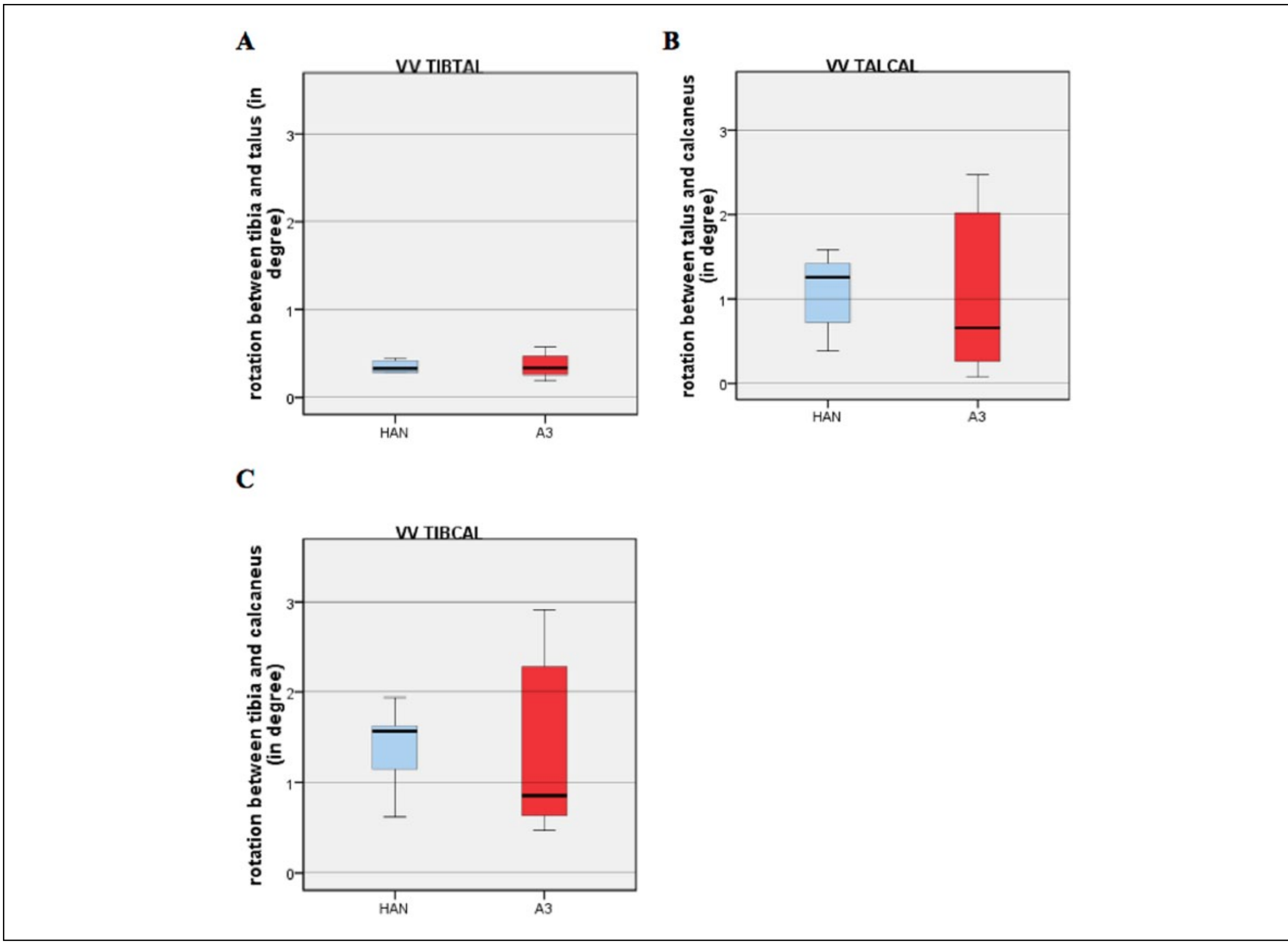

Figure 3. (A) Boxplot shows the range of motion (ROM) between the tibia and the talus (TIBTAL) in the varus/valgus (VV) direction. (B) Boxplot shows the ROM between the talus and the calcaneus (TALCAL) in VV direction. (C) Boxplot shows the ROM between the tibia and the calcaneus (TIBCAL) in VV direction.

setup with the A3 nails. The HAN nail was found not to have an effective compression mode.[1] For this reason, a pure locking technique was applied with this nail design. In our study, the locking-only nail type (HAN) provided the highest stability in the subtalar joint.

The valgus bend in the distal part of the nail is present in both in the HAN nail and the A3 nail and is thought to lead to higher stability and soft tissue protection.[19] A major change in nail-design for the A3 nail is the dorsal bending in the most distal part of the nail, which is intended to yield better anchorage of the nail in the calcaneus but does not seem to lead to higher stability in this setting. In quasi-static tests, the varus-valgus motion showed no differences between the groups, whereas during torsion we found significantly higher stability for the HAN group in the ankle (TIBTAL) and subtalar joints (TALCAL) and in the overall motion of the construct (TIBCAL). The dorsi-/plantarflexion movement observed in both the quasi-static tests and the cyclic testing showed a trend toward higher stability in the A3 group for the ankle joint (TIBTAL). For the subtalar joint (TALCAL) and the whole construct (TIBCAL), the stability was significantly higher in the HAN group. The subtalar joint in TTCAs is prone to the development of nonunions in clinical studies.[6,4,18]

The literature provides validation for the successful use of motion tracking systems and reports a high accuracy for biomechanical measurements.[9,26] We used 3D motion tracking in addition to the machine data. The analysis of machine data can only provide evidence for an overall loss of stability within the whole construct. Motion tracking identifies the exact region and is therefore crucial for the analysis of data.[5] During testing in dorsi-/plantarflexion, both quasi-static and load-to-failure tests, only by 3D motion tracking the loss of stability could be localized in the subtalar joint (TALCAL) for the A3 nail, while the nail showed a trend toward higher stability in the ankle joint.

Different limitations must be recognized in this study. One is the small sample size of 12 specimens. For ethical

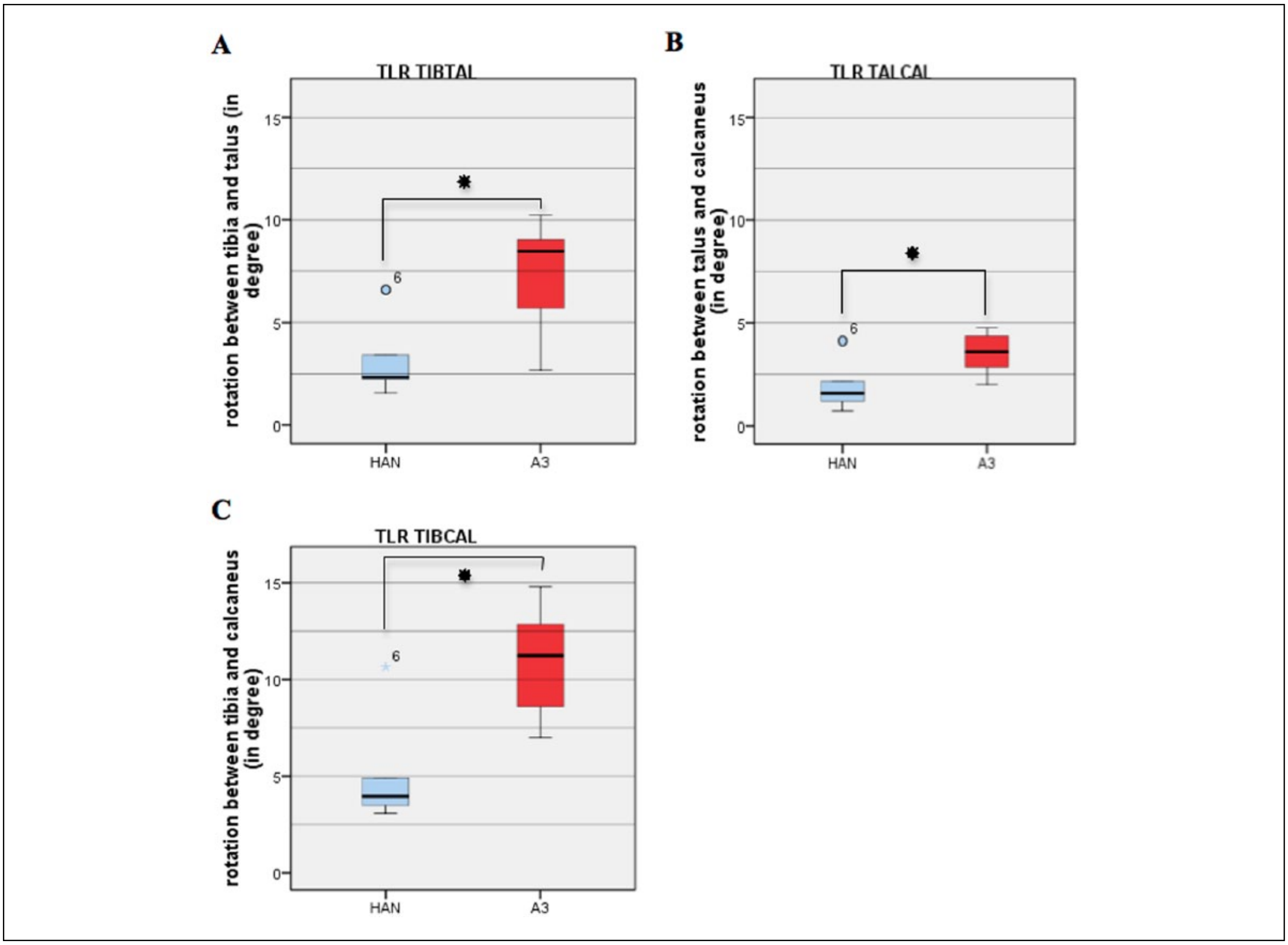

Figure 4. (A) Boxplot shows the ROM for TIBTAL during axial torsion (TLR). (B) Boxplot shows ROM for TALCA during TLR. (C) Boxplot shows ROM for TIBCAL during TLR. Asterisks show significant differences.

reasons, testing with human material should be kept to a minimum. With the available and significant data, the number was considered sufficient. Furthermore, soft tissue was resected, muscle strengths were not simulated, and the joint surfaces were not resected, as would have occurred during a regular TTCA. The bony fusion of the subtalar and ankle joints also could not be simulated. The applied number of cycles to failure in our setting was rather low. However, in accordance with pedometer studies, this number represents a possible number of steps of an older person during the first postoperative week after TTCA during early weight bearing.[28] Other studies have shown that dorsi-/plantarflexion is the main loading motion postoperatively after TTCA.[20,21]

The results of this biomechanical testing cannot be transferred to the clinical setting.[16,21] A recent clinical study with a 2-year follow-up for TTCAs with A3 nails showed sufficient union rates after 2 years.[24] The authors included 60 patients with a mean age of 58.5 years (range 22-80 years). Control of bony fusion of an arthrodesis was performed by clinical checkups and standard radiographs of the ankle. Nonunion after 1 year was not considered a complication. Authors documented delayed union in the ankle joint after 1 year in 7% of patients. The subtalar joint showed union in all 60 patients after 1 year. No CTs were performed in any of the patients, which was one of the limitations of their study. This study demonstrated noticeable differences in the results for the subtalar joint. A main factor could be the difference in mean age of patients in the clinical study (58.5 years) and ours (83.5 years), and the possible higher bone density of patients in the study by Richter and Zech.[24] Locking-only nail types show favorable results in osteoporotic bone, which might have led to higher stability of the HAN in our specimens with low BMD.

Conclusion

The more anatomical design of the A3 nail in the setting of our osteoporotic bone model only partly met our expectations. Our analysis showed that the primary stability in the

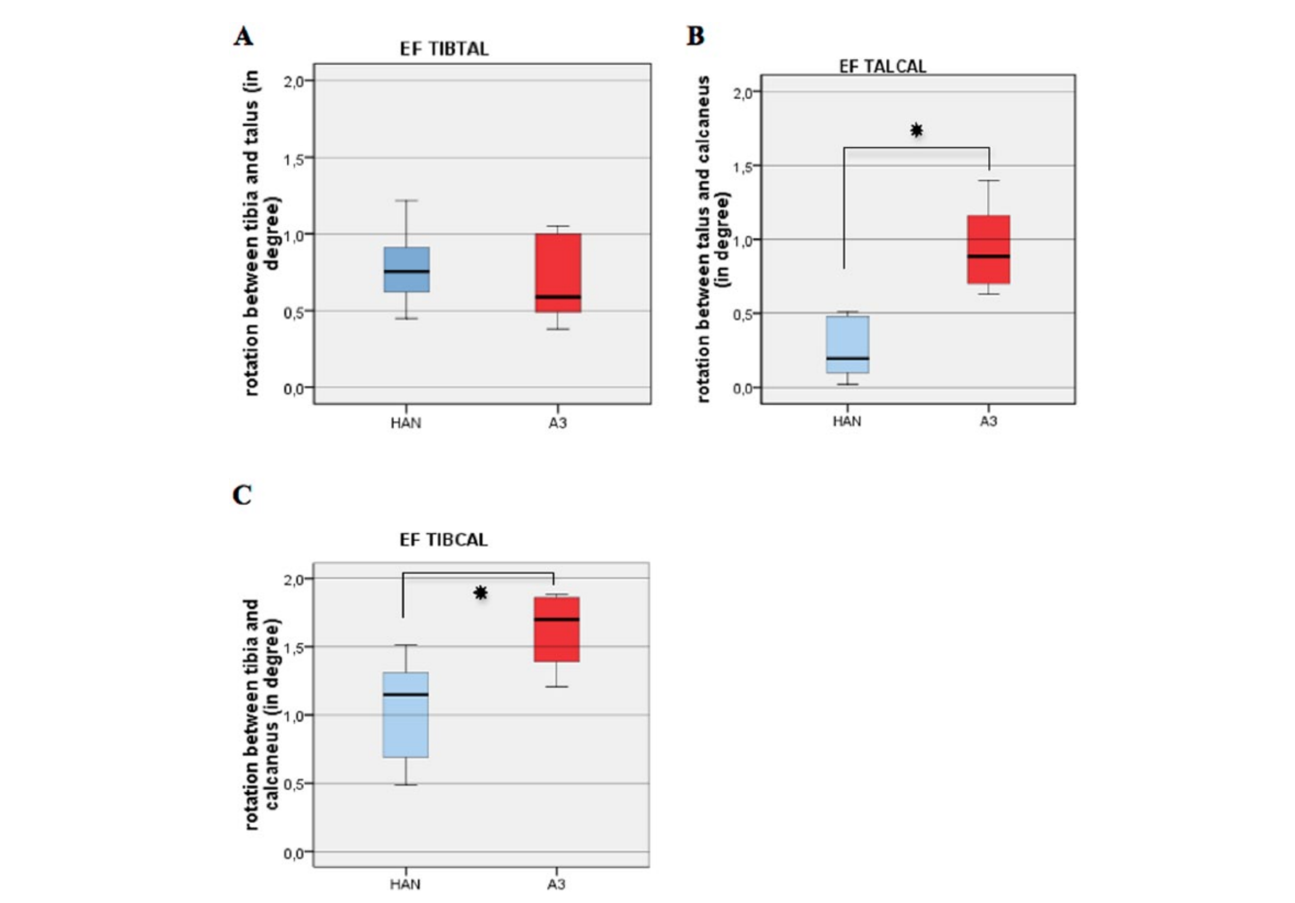

Figure 5. (A) Boxplot shows ROM for TIBTAL during dorsi-/plantarflexion movement (EF). (B) Boxplot shows ROM for TALCAL during EF. (C) Boxplot shows ROM for TIBCAL during EF. Asterisks show significant differences.

Table 1. Median values during quasi-static tests for different arthrodesis nails (HAN and A3) in different load modi (dorsi-/plantarflexion, torsion, varus/valgus) for different joints (TIBTAL and TALCAL) and overall construct (TIBCAL), with *P* values.[a]

	Dorsal-/Plantarflexion (degrees)	Torsion (degrees)	Varus/Valgus (degrees)
TIBCAL	**HAN = 1.15**	**HAN = 3.97**	HAN = 1.57
	A3 = 1.7	A3 = 11.24	**A3 = 0.86**
	(*P* = .028)*	(*P* = .025)*	(*P* = .753)
TIBTAL	HAN = 0.76	**HAN = 2.35**	HAN = 0.33
	A3 = 0.59	A3 = 8.48	A3 = 0.33
	(*P* = .249)	(*P* = .028)*	(*P* = .833)
TALCAL	**HAN = 0.2**	**HAN = 1.58**	HAN = 1.26
	A3 = 0.88	A3 = 3.6	**A3 = 0.66**
	(*P* = .028)*	(*P* = .028)*	(*P* = .833)

[a]Bold type labels more stable values and the corresponding nail. Asterisks label significant findings.

HAN group was higher than that in the A3 group which was not consistent with our hypothesis.

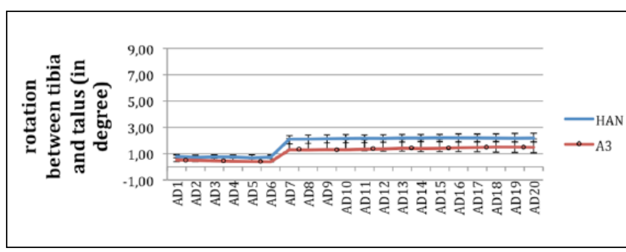

Figure 6. Movement in TIBTAL during the different load steps in load-to-failure testing for the HAN nail construct (plain line) and the A3 nail construct (dotted line).

In this first biomechanical comparison of 2 intramedullary nails for TTCA via 3D motion tracking, an exact localization of the loss of stability could be verified. Comparing the 2 different nail designs demonstrated that the HAN nail, which contains 2 calcaneal locking screws and a locking mechanism, showed higher stability than the A3, with a distal dorsal bend, 1 calcaneal locking screw, and a locking

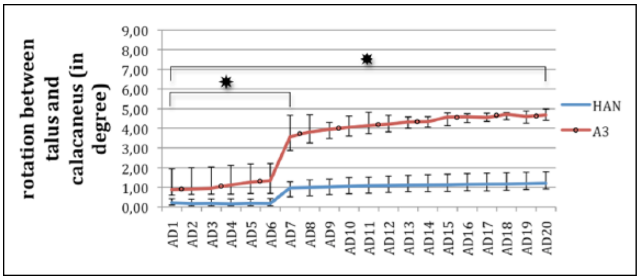

Figure 7. Movement in TALCAL during the different load steps in load-to-failure testing for the HAN nail construct (plain line) and the A3 nail construct (dotted line). Asterisks mark significant differences.

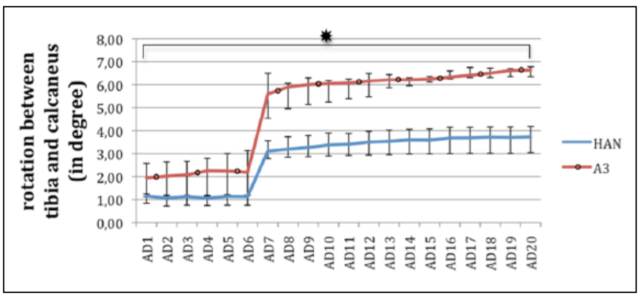

Figure 8. Movement in TIBCAL during different load steps in load-to-failure testing for the HAN nail construct (plain line) and the A3 nail construct (dotted line). Asterisks mark significant differences.

compression mechanism. The movement at the subtalar joint with the HAN nail was notably lower. Our results were consistent with Mückley et al[17] that locking-only nail types provide better stability in osteoporotic bone than the locking-compression mode provided by the A3 nail.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Julia Evers, MD, Dirk Wähnert, MD, Martin Schulze, MSc, Martinus Richter, MD, Michael J. Raschke, MD, and Sabine Ochman, MD, report grants and non-financial support from Small Bone Innovations, during the conduct of study.

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