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Biomechanical comparison of stability of tibiotalocalcaneal arthrodesis with two different intramedullary retrograde nails

Martinus Richter MD, PhD[a,*], Julia Evers[b], Dirk Waehnert[b], Jim K. DeOrio[c], Michael Pinzur[d], Martin Schulze[b], Stefan Zech[a], Sabine Ochman[b]

[a] Department for Foot and Ankle Surgery Rummelsberg and Nuremberg, Hospital Rummelsberg, Schwarzenbruck, Germany
[b] Department of Trauma, Hand and Reconstructive Surgery, University of Muenster, Muenster, Germany
[c] Department for Orthopaedics, Duke University, Durham, NC, USA
[d] Department for Orthopaedics, Loyola University Chicago, IL, USA

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ABSTRACT

Background: The aim of the study was to compare the initial construct stability of two retrograde intramedullary nail systems for tibiotalocalcaneal arthrodesis (TTCF) (A3, Small Bone Innovations; HAN, Synthes) in a biomechanical cadaver study.
Methods: Nine pairs of human cadaver bones were instrumented with two different retrograde nail systems. One tibia from each pair was randomized to either rod. The bone mineral density was determined via tomography to ensure the characteristics in each pair of tibiae were similar. All tests were performed in load-control. Displacements and forces were acquired by the sensors of the machine at a rate of 64 Hz. Specimens were tested in a stepwise progression starting with six times ±125N with a frequency of 1 Hz for 250 cycles each step was performed (1500 cycles). The maximum load was then increased to ±250N for another 14 steps or until specimen failure occurred (up to 3500 cycles).
Results: Average bone mineral density was 67.4 mgHA/ccm and did not differ significantly between groups (*t*-test, $p = .28$). Under cyclic loading, the range of motion (dorsiflexion/plantarflexion) at 250N was significantly lower for the HAN-group with 7.2 ± 2.3 mm compared to the A3-group with 11.8 ± 2.9 mm (*t*-test, $p < 0.01$). Failure was registered for the HAN after 4571 ± 1134 cycles and after 2344 ± 1195 cycles for the A3 (*t*-test, $p = .031$). Bone mineral density significantly correlated with the number of cycles to failure in both groups (Spearman-Rho, $r > .69$, $p < 0.01$).
Conclusions: The high specimen age and low bone density simulates an osteoporotic bone situation. The HAN with only lateral distal bend but two calcaneal locking screws showed higher stability (higher number of cycles to failure and lower motion such as dorsiflexion/plantarflexion during cyclic loading) than the A3 with additional distal dorsal bend but only one calcaneal locking screw. Both constructs showed sufficient stability compared with earlier data from a similar test model.
Clinical relevance: The data suggest that both implants allow for sufficient primary stability for TTCF in osteoporotic and consequently also in non-osteoporotic bone.
Level of evidence: Not applicable, experimental basic science study.

1. Introduction

Tibiotalocalcaneal arthrodesis may be performed with different techniques. Screws, plates, external fixators, and intramedullary nails have been described [1–4]. Tibiotalocalcaneal arthrodesis with intramedullary implants can be performed with retrograde femoral nails or retrograde ankle arthrodesis nails [1–4]. The first biomechanical studies in the literature investigated first-generation retrograde (femoral) nails without foot and ankle specific locking options [5–8]. Second-generation nails with foot and ankle specific locking options such as anteroposterior locking within the calcaneus and/or optional compression were designed to increase stability [9,10]. Mann et al. found increased stability with a retrograde nail with posterior-to-anterior interlocking screw passed through the calcaneus in comparison with the same nail construct with a conventional transverse calcaneal screw [9]. Berson et al. found increased stability with an (external) compression mechanism [9,11]. Muckley et al. registered a positive effect of compression on the initial stability of a tibiotalocalcaneal

* Corresponding author at: Department for Foot and Ankle Surgery Rummelsberg and Nuremberg, Location Hospital Rummelsberg, Rummelsberg 71, 90592 Schwarzenbruck, Germany. Tel.: +49 9128 50 43450; fax: +49 9128 50 43260.
E-mail address: martinus.richter@sana.de (M. Richter).
URL: http://www.foot-surgery.eu

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arthrodesis done with an intramedullary nail in a synthetic bone model [10]. The same group analyzed later the effects of angle-stable locking or compressed angle-stable locking on the initial stability and found that angle-stable locking of retrograde nails increased the stability [12]. Different systems with angular stable locking and optional compression have been introduced since then. As far as we know, these modern systems have not been compared with each other regarding construct stability. The goal of this study was to compare the initial construct stability of two actual systems (A3, Small Bone Innovations, Morrisville, PA, USA; HAN, Synthes, West Chester, PA, USA) in a biomechanical study (cyclic loading and load to failure, paired fresh-frozen human specimens). The null hypothesis was that the investigated parameters would not differ significantly in relation to the two systems compared.

2. Methods

Tibiotalocalcaneal arthrodesis was performed in fresh frozen paired human cadaver bones with use of two different intramedullary retrograde nail systems (A3 and HAN) Both implants were made of the same alloy (Ti6–Al4–V).

2.1. A3 (Small Bone Innovations, Morrisville, PA, USA, Fig. 1)

The A3 – Anatomic Arthrodesis System is designed for simultaneous arthrodesis of the ankle and subtalar joints (Fig. 1). The implant consists of a retrograde intramedullary non-cannulated nail, locking screws, a compression bolt, and endcap. The specific shape of the A3 nail includes a distal "double" bend; one posterior (15°) and one lateral (10°), and a proximal bend which is a slight recurvatum. The direction of the distal locking screws is adapted to the axes of the talus (15° plantiflexion in relation to tibial axis/middle nail portion, and 15° internal rotation) and calcaneus (15° dorsiflexion in relation to tibial axis/middle nail portion and neutral rotation). A compression bolt provides mechanical compression between the calcaneus and talus, and between the talus and tibia, and angular locking of the calcaneal locking screw with the nail. Static locking without compression is optional. An endcap with 5, 10, 15 mm length is optional. An aiming device for the preparation of the canal for the nail includes a guide for two wires which allows for exact placement of the drill while respecting the distal bend of the nail. The aiming arm is attached to the nail during and after nail insertion and allows precise locking screw placement with different options for static, dynamic of compressive locking.

2.2. HAN (Synthes, West Chester, PA, USA, Fig 2)

The HAN – Expert Hindfoot Arthrodesis Nail is designed for simultaneous arthrodesis of the ankle and subtalar joints (Fig. 2). The system comprises specific implants and instruments. The implants consist of a retrograde intramedullary cannulated nail, locking screws, spiral blades, and endcap. The instruments include aiming devices for locking screw insertion. The specific shape of the HAN nail includes a distal lateral bend (12°). The direction of the distal locking screws/spiral blades is perpendicular to the nail. A spiral blade is optional instead the calcaneal locking screw. An endcap provides angular locking of the distal locking screw or blade with the nail. An aiming arm is attached to the nail during and after nail insertion allows for precise locking screw/spiral blade placement.

2.3. Specimens

Eighteen (nine pairs) fresh-frozen below-the-knee specimens were used. All donors agreed to the use of their body or parts of them for education and research. The mean age at death of the donors (five females, four males) was 85.3 (range, 77–95) years. Radiographs in two planes of all specimen excluded prior bone pathology. The number of tested specimens was determined by a statistician by prior evaluation of the study design before the study by a power analysis. The power of all used statistical tests of the cyclic loading testing sequence for the determined sample size was >8. The specimens were stored at −18 °C and thawed to room temperature prior mechanical testing. The bone mineral density of

Fig. 1. A3 (Anatomic Arthrodesis System, Small Bone Innovations, Morrisville, PA, USA).

Fig. 2. HAN (Expert Hindfoot Arthrodesis Nail, Synthes, West Chester, PA, USA).

the cancellous bone in the calcaneus was determined with quantitative computed tomography (Somatom Definition, Siemens, Erlangen, Germany). The tibia and fibula were transected 30 cm proximal to the ankle joint, and the midfoot and forefoot were dissected through the transverse tarsal (Chopart) joint. Soft tissues were removed except the distal syndesmotic complex, the membrana interossea, the deltoid ligaments, the lateral ligaments, and the intraosseous ligament. The joint surfaces were left in place.

2.4. Instrumentation

Both implants, A3 and HAN, were inserted by experienced orthopaedic foot and ankle surgeons (XXX, AAA) following the manual of the manufacturer. All implants were used for one single specimen. The nail length was 300 mm for the A3 and 240 mm for the HAN. The proximal diameter was 10 mm for both, A3 and HAN. The intramedullary tibial canal was reamed to a diameter of 11 mm with use of a SynReam™ system (Synthes, West Chester, PA, USA,). The tibial locking included two standard locking screws in *static* position. The talar locking included the standard locking screw in *standard* position. The calcaneal locking included the standard two locking screws in *standard* position for the HAN, and the standard locking screw in *compression* position for the A3. The HAN endcap was used for angular locking of the calcaneal locking screw for the HAN. The A3 compression screw was used for compression between calcaneus and talus and between talus and tibia, and for angular locking of the calcaneal locking screw. The A3 endcap was used for lengthening of the distal end of the nail if this was not flush with the caudal surface of the calcaneus (constructs No. 3, 4, 7, 8). The position of all implants, and the lengths of all locking screws and A3 endcaps were fluoroscopically checked. The lengths of the tibial locking screws were adjusted for bicortical fixation. The lengths of the tibial and calcaneal locking screws were adjusted for maximal possible subcortical length. The lengths of the endcaps for the A3 were adjusted to be flush with the caudal surface of the calcaneus.

2.5. Setting (Fig. 3a and b)

The test setting was previously described (Fig. 3a) [12,13]. We used a modified setup with an additional sledge at the lever arm to exclude shear stress to the specimen (Fig. 3b). The sledge provided a constant lever arm for load application. The calcaneus and the proximal 150 mm of the remaining tibia were each potted with the use of bone cement (Technovit 4000, Heraeus Kulzer GmbH, Wernheim, Germany) in an aluminium casing, after all protruding implant portions and the gap of the subtalar joint had been covered with a modelling compound to prevent bridging of the potting medium affecting the biomechanical properties [13]. The positioning and adjustment of the calcaneus in the aluminium casing was verified by laser measurement. Adjustment of the testing machine and standardized distance between the actuator and tibial axis was verified using a cross table. Testing was commenced as soon as the resin had cured [13]. Measurements were performed on a biaxial test machine (Instron 8874; Instron, Darmstadt, Germany) equipped with a 10 kN/100 Nm load cell for compression, extension and torsion. All tests were performed in load-control. Displacements and forces were acquired by the sensors of the machine at a rate of 64 Hz. Specimens were tested in a stepwise progression starting with six times ±125N with a frequency of 1 Hz for 250 cycles (compression and tension force) each step was performed (1500 cycles). Afterwards each step an X-ray control followed (Fluoroscan Insight, Hologic, Bedford, MA, USA). The maximum load was then increased to ±250N for another 14 steps or until specimen failure occurred (up to 3500 cycles). X-ray controls were done before and after testing to exclude fractures or loosening of the fixation devices.

2.6. Data evaluation

Range of Motion (ROM) was calculated following Wilke et al. from the load displacement curves [14]. Construct failure was defined as a change of 10 mm in axial displacement.

2.7. Statistical analysis

The data was analyzed with SPSS software (IBM SPSS Statistics 21, IBM, Armonk, NY, USA). A paired *t*-test (homoscedatic) was used for comparison of bone mineral density values and displacement during cyclic loading. These parameters were equally normally distributed. The number of cycles to failure was not normally distributed and compared with a Wilcoxon-rank test, Pearson's correlation coefficient *r* was determined for the correlation between the bone mineral density and the number of

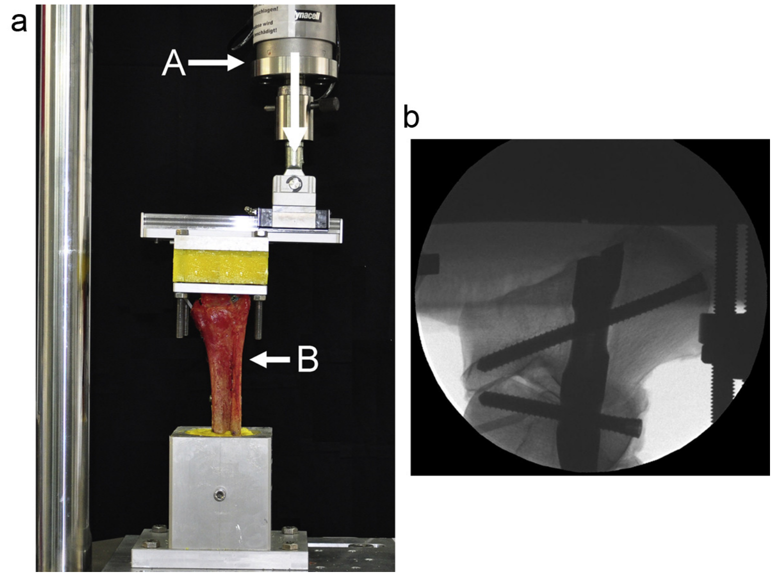

Fig. 3. (a and b) Test setting: (a) shows the test setting (A, testing machine; B, load cell; C, specimen (distal part up)) and (b) shows a fluoroscopic image.

cycles to failure. Our null hypothesis was that the different constructs, A3 or HA, would produce the same stability.

3. Results

3.1. Bone mineral density

Average bone mineral density was 67.4 mgHA/ccm and did not differ significantly between groups (t-test, $p = .28$).

3.2. Cyclic tests

Under cyclic loading with 125N the axial range of motion was significantly lower for the HAN group with 2.3 ± 0.7 mm compared to the A3 group with 5 ± 2.1 mm (t-test $p < 0.01$). At 250N axial loading the range of motion was also significantly lower for the HAN-group with 7.2 ± 2.3 mm compared to the A3-group with 11.8 ± 2.9 mm (t-test, $p < 0.01$) (Figs. 4 and 5, Table 1).

3.3. Load to failure

Failure was registered for the HAN after 4571 ± 1134 cycles and after 2344 ± 1195 cycles for the A3 (t-test, $p = .031$). Bone mineral density significantly correlated with the number of cycles to failure in both groups (Spearman-Rho, $r > .69$, $p < 0.01$). (Fig. 6 and Table 1).

The null-hypothesis was rejected for motion during cyclic loading, and number of cycles and maximum force during load to failure.

4. Discussion

Intramedullary devices for tibiotalocalcaneal arthrodesis have increased the surgeon's possibilities for hindfoot stabilization [13]. Many of the patients considered for tibiotalocalcaneal arthrodesis have multiple comorbidities affecting bony stability [13]. Intracalcaneal fixation has been shown to be an important factor affecting stability [9,12,13]. Mann et al. concluded that the posterior-to-anterior routing of a calcaneal locking screw

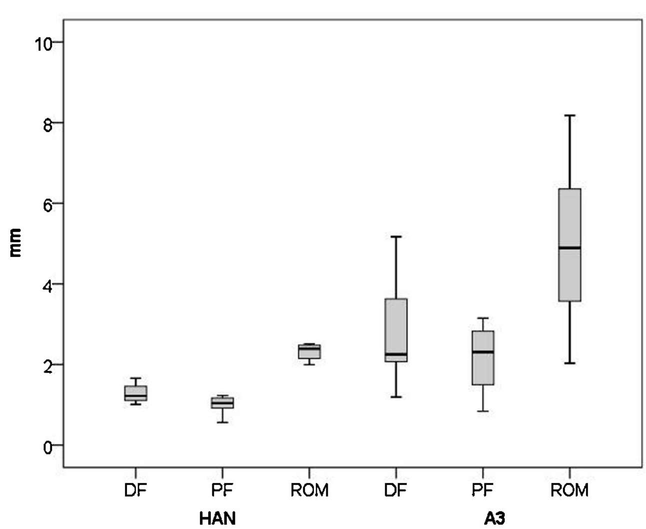

Fig. 4. Cyclic loading with 125N. Boxplots of displacement in mm. DF, dorsiflexion; PF plantiflexion; ROM, range of motion dorsiflexion–plantiflexion.

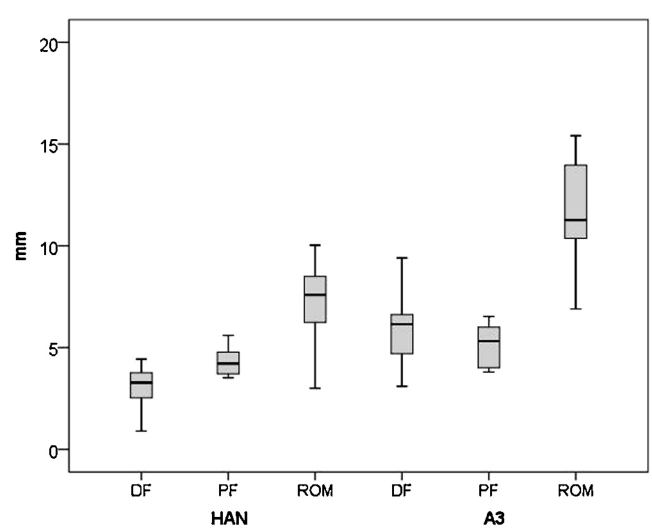

Fig. 5. Cyclic loading with 250N. Boxplots of displacement in mm. DF, dorsiflexion; PF plantiflexion; ROM, range of motion dorsiflexion–plantiflexion.

Table 1
Data cyclic loading and load to failure.

Parameter		A3	HAN	Statistics
Cyclic loading	DF125	2.86 ± 1.37	1.32 ± 0.57	*t*-test, $p = 0.01$
	PF125	2.14 ± 0.88	1.0 ± 0.23	*t*-test, $p = 0.006$
	ROM125	4.99 ± 2.11	2.32 ± 0.72	*t*-test, $p = 0.006$
	DF250	5.9 ± 2.1	3.03 ± 1.2	*t*-test, $p = 0.008$
	PF250	5.85 ± 2.81	4.13 ± 1.15	*t*-test, $p = 0.112$
	ROM250	11.75 ± 2.95	7.16 ± 2.27	*t*-test, $p = 0.003$
Load to failure	Cycles (n)	2344 ± 1195	4571 ± 1134	Wilcoxon rank test, $p = 0.031$

DF, dorsiflexion; PF plantiflexion; ROM, range of motion (dorsiflexion–plantiflexion); 125, 125N; 250, 250N; all values in degree except cycles (n).

significantly enhances stability [9]. Mückley et al. demonstrated the superiority of angle-stable over non-anglestable intracalcaneal locking [12]. Klos et al. found increased stability of cement augmented locking screws [15]. However, only the locking screws themselves and not the nail position, was considered for all investigations. Most nails, including the HAN have a distal lateral bend but only the A3 has an additional posterior distal bend. This feature was designed to increase the distance of the nail within the calcaneus with the intention to increase stability. The present study was performed to analyze this special nail shape to assess construct stability. In common with other studies, the joint surfaces were left intact [7,8,12,15,16]. The test set-up and the load levels used were similar to those employed in other biomechanical studies of tibiotalocalcaneal arthrodesis [7,8,12,15,16]. Testing with increasing cyclic loading has been found useful in earlier studies and includes cyclic loading and load to failure [15,17]. As seen from earlier studies, cyclic testing at a constant load level would not necessarily have allowed testing to failure, even over 250,000 cycles [7,8,12,15,16]. This would have made it difficult to compare the two different construct groups. Dorsiflexion was chosen which represents the predominant loading mode of the arthrodesis site during weight bearing in the postoperative period [16]. Fresh frozen paired cadavers were used to diminish the effect of the cadavers on the outcome parameters [8,16]. Consequently, the bone mineral density was similar on both groups. The HAN with only lateral distal bend but two calcaneal locking screws showed higher stability (lower motion during cyclic loading and higher number of cycles to failure) than the A3 (Figs. 4–6 and Table 1). To date, cyclic loading is considered to be the most biocompatible test modus for clinically relevant construct stability [17]. Consequently, the HAN might provide more clinically relevant stability than the A3. Still,

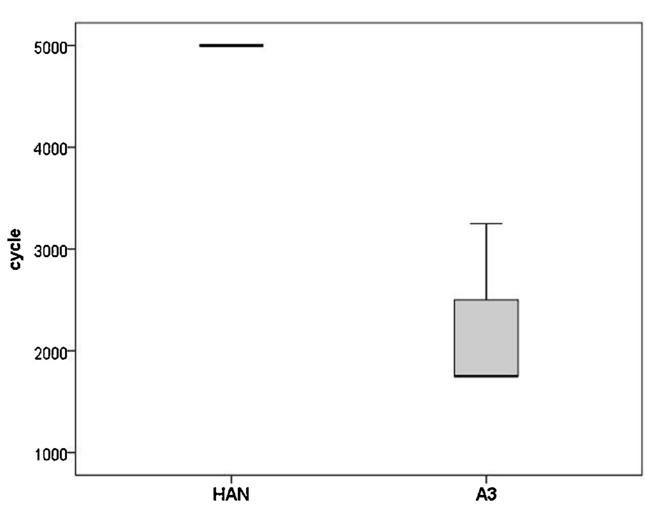

Fig. 6. Load to failure (number of cycles).

higher initial stability does not necessarily signify a better clinical outcome. However, less movement at the tibiotalocalcaneal arthrodesis site could result in faster arthrodesis, and the greater load tolerance would increase the safety especially for (older) patients with less reliability for limited weight bearing in the postoperative situation. Both implants showed higher stability than other implants in similar studies before (data from other studies not shown) [12,15]. This allows the conclusion that both, HAN and A3, have sufficient construct stability.

This study has the limitations similar to all biomechanical studies, which can reflect the actual in vivo conditions only to a limited extent [18,19]. As well as the increasing bony union and the stabilizing action of the surrounding soft tissues that would be expected to occur in vivo and could not be taken into account [12,13,16]. Regarding the implant construction, we tried to utilize the systems from both companies in a most similar fashion. Both nails had different lengths and distal locking modes but similar diameters and proximal locking modes. The HAN construct included five locking screws in total with two calcaneal locking screws, and the A3 included four locking screws in total with one calcaneal locking screw. The spiral blade as calcaneal locking option which is only available for the HAN was not used. The HAN nail with distal spiral blade locking may alter the stability of the nail construct but was not tested in this experiment. Additionally, the nail length was different, 300 mm for the A3 and 240 mm for the HAN. There is no longer nail available for the HAN. The A3 is available with 200 and 300 mm, and the 300 mm nail is recommend for standard cases. It would be optimal to compare nails with equal length and one could suspect that a 300 mm HAN would be more stable, or vice versa, a 240 mm A3 would be less stable. From a mechanical standpoint, a cannulated nail is weaker than a solid nail. In contrast, bending a nail does not make it weaker. This is applied physics. Both nails have just one single distal bend which is directed towards lateral for the HAN and towards lateral and posterior but still one single bend for the A3. In conclusion the HAN nail as such should be weaker than the A3 because of the cannulation. Still, this potential weakness did not lead to lower construct stability in the test setting. One could argue that the both systems are quite similar. Of course both are retrograde intramedullary interlocking nails, and both are made of the same titanium alloy, but the following features are different: cannulation (HAN, yes; A3, none), number and direction of locking screws (HAN, 5 screws, all perpendicular to nail; A3, 4 screws, tibial screws perpendicular to nail, talar 15° dorsiflexed, calcaneal 15° plantiflexed), locking/compression mode (HAN, angular locking of distal calcaneal locking screw; A3 compression and angular locking of calcaneal screw and compression talar screw), distal lateral bend (HAN, 12°; A3, 10°), distal posterior bend (HAN, none; A3, 15°), proximal bend (HAN, none; A3, recurvation), length (HAN, 240 mm; A3, 300 mm). Other minor differences are the shape or locking screws, and the instruments. All in all this sums up to more than ten differences. The stilll present cartilage might also influence the construct stability. This was done in order to eliminate an additional variable, and to create a worst-case scenario of minimal intraarticular friction [7,8,12,15,16]. All these issues are hypothetical and have not been tested. A biomechanical study demonstrated higher stability using a "long" retrograde locked intramedullary nail (>150 mm) for tibiocalcaneal arthrodesis in patients with systemic or localized osteopenia like we used in our study [20]. The typical failure was nevertheless not at the proximal nail but at the distal portion which implies that the proximal nail length is by far not as important for the construct stability as the distal system design. The definition of failure at 10 mm seems to be a bit excessive. We followed here the definition by the earlier descriptions of the setting, and we could not find any literature showing that 10 mm would not be adequate.

The high specimen age (85 years on average) and consequently low bone density simulates an extremely osteoporotic bone situation. This calls into question the biocompatibility of the study. The mean age of patients in clinical studies is 50–60 years for this kind of procedure [1,3,21]. Consequently, the mean age of the specimens is much higher than the patient age in the typical clinical situation as in most other cadaver studies [12,13,16]. Nevertheless, the real-life situation with increasing patient age will secondly make the tested situation even more realistic. Furthermore, one could conclude that implants which provide sufficient stability in osteoporotic bone would also do so in non-osteoporitic bone, i.e., in all kind of bone situations.

In conclusion, the HAN with only a single lateral distal bend but two calcaneal locking screws showed higher stability (higher number of cycles to failure and lower motion such as dorsiflexion/plantarflexion during cyclic loading) than the A3 with additional distal dorsal bend but only one calcaneal locking screw. Both constructs showed sufficient stability compared with earlier data from a similar test model. The data suggest that both implants allow for sufficient primary stability for TTCF in osteoporotic and consequently also in non-osteoporotic bone.

Conflict of interest statement

Martinus Richter is consultant for Small Bone Innovations and Synthes, James K. DeOrio and Michael Pinzur are consultants for Small Bone Innovations, and the institution of Julia Evers, Dirk Waehnert, and Sabine Ochman received funding in relation to this study.

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