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

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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

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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).