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Robotic Cadaver Testing of a New Total Ankle Prosthesis Model (German Ankle System)

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ABSTRACT

Background: **An investigation was carried out into possible increased forces, torques, and altered motions during load-bearing ankle motion after implantation of two different total ankle prostheses. We hypothesized that the parameters investigated would not differ in relation to the two implants compared.** ***Methods:*** **We included two different ankle prostheses (Hintegra, Newdeal, Vienne, France; German Ankle System, R-Innovation, Coburg, Germany). The prostheses were implanted in seven paired cadaver specimens. The specimens were mounted on an industrial robot that enables complex motion under predefined conditions (RX 90, Stäubli, Bayreuth, Germany). The robot detected the load-bearing (30 kg) motion of the 100th cycle of the specimens without prostheses as the baseline for the later testing, and mimicked that exact motion during 100 cycles after the prostheses were implanted. The resulting forces, torques, and bone motions were recorded and the differences between the prostheses compared.** ***Results:*** **The Hintegra and German Ankle System, significantly increased the forces and torques in relation to the specimen without a prosthesis with one exception (one-sample-t-test, each $p \leq 0.01$; exception, parameter lateral force measured with the German Ankle System, $p = 0.34$). The force, torque, and motion differences between the specimens before and after implantation of the prostheses were lower with the German Ankle System than with the Hintegra (unpaired t-test, each $p \leq 0.05$).** ***Conclusions:*** **The German Ankle System prosthesis had less of an effect on resulting forces and torques during partial weightbearing passive ankle motion than the Hintegra prosthesis. This might improve function and minimize loosening during the clinical use.**

Key Words: Ankle Prosthesis; Biomechanics; Robotic Testing; Total Ankle Replacement

INTRODUCTION

Since the early 1970s, total ankle arthroplasty has been considered for the treatment of severe osteoarthritis of the ankle.[13] During the following decade, disappointing clinical results in relation to earlier designs meant ankle arthrodesis was designated the surgical "gold-standard" treatment for patients suffering from this condition.[20,23,26,46] The marked high incidence of nonunion, secondary degenerative changes of adjacent joints, infection, and loss of motion resulting from this surgery have contributed to the high degree of interest in total ankle arthroplasty in recent years.[8,12,14,47] Although subsequent clinical reports were slightly more satisfactory, total ankle arthroplasty is still not as successful as total hip and total knee arthroplasties.[1,17,25,55] For total ankle arthroplasty to be considered a viable alternative to arthrodesis, an effective range of ankle motion needs to be recovered.[33,43] The disappointing clinical results of the latest generation of total ankle arthroplasty can be subscribed to a poor understanding of the structures guiding joint motion.[33,43] When designing implants, most attention is given to the geometry of the prosthetic components in relation to the morphologic features of the intact articular surfaces.[33,39,43,45] Little attention has been given to the restoration of ligament function.[16,33,43] When it comes to the ankle, the replication of natural anatomic shapes seems to be the only guideline used in prosthesis design resulting

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The prostheses and surgical instruments were manufactured and donated by Newdeal SA, Vienne, France and ARGE Medizintechnik Inc., Hannover, Germany. The corresponding author was involved in the development of the German Ankle System prosthesis by ARGE Medizintechnik, Hannover Germany with whom a preliminary agreement for the payment of royalties to the corresponding author or their institutions has been reached. The project was later purchased by R-Innovation, Coburg, Germany at a stage of development including this study.

in the disputed solution of replacing only one of the two articulating surfaces with natural shapes.[5,22,24,33,43]

Investigations have shown how the passive structures of the ankle control and limit joint mobility.[33,34,43] Experiments have described movements at ankle and subtalar levels in virtually unloaded conditions.[28,34,52–54] Two-dimensional mathematical models of the intact ankle have shown that a preferred path of complex motion is guided by the articular surfaces and the ligaments interacting in a complementary manner.[31,33,43] These findings on the motion of the intact ankle in the sagittal plane have been supported by a study on joint stability with a three-dimensional arrangement of the ligaments.[9] These models have contributed to the design of a new total ankle implant.[29,30] An additional problem associated with total ankle replacement is loosening.[4,50] Loosening is caused by overloading of the bone-component interface.[33,43] This means that minimization of the forces during ankle motion under weight is crucial to avoid loosening. Based on these considerations, we have developed a new total ankle prosthesis that should minimize the forces and torques during ankle motion under weightbearing. The purpose of this study was to compare the newly developed prosthesis with an actual design that demonstrated favorable functions in vitro and in vivo.[17,52–54] A robot-based cadaver test was developed for the study. This new method was developed to improve the biocompatibility of previously described settings.[17,30,43,48,52–54] The use of a navigation-guided robot should especially improve the complexity and accuracy of the predefined motion applied to the cadaver. The increased forces after implantation of the prostheses during weightbearing ankle motion, in particular, should be investigated. We hypothesized that the investigated parameters would not differ in relation to the two implants compared.

MATERIALS AND METHODS

Specimens

Seven pairs of embalmed cadaver specimens were used for the test (age, 87.6 ± 9.6; gender, two male, five female; weight, 66.7 ± 12.2 kg; height, 166.9 ± 11.2 cm; bone density, 253.2 ± 73.5 g/cm^2). The bone density was measured at the distal metaphysis of the tibia by peripheral quantitative computed tomography (pQCT) as previously described.[6,18,35] None of the specimens had evidence of previous ankle or foot surgery, and radiographic assessment ensured that no joint degeneration or deformity was present. All ligaments and tissues crossing the knee joint were removed after disarticulation at the knee joint. The proximal tibiofibular joint was left intact. The number of tested specimens was determined by a statistician by prior evaluation of the study design using power analysis. The power of all used statistical tests of the cyclic loading testing sequence for the determined sample size was >0.8.

Prostheses

Two ankle prostheses were tested: Hintegra (Newdeal SA, Vienne, France) and the German Ankle System (R-Innovation, Coburg, Germany). The Hintegra is a three-component prosthesis with a flat tibial component, a polyethylene inlay, and convex conic talar component with a smaller medial radius (Figure 1, A).[52] The tibial and talar components both have ventral shields for possible screw fixation.[52] Side borders on the talar component keep the inlay in position and should prevent inlay dislocation.[52] A porous hydroxyapatite coating was used on the undersurfaces to facilitate fixation of both of these components to the bone.

The German Ankle System is a three-component prosthesis (Figure 1, B and C). The interface between the tibial and meniscal components is a spherical shape, allowing rotation around each of the three possible axes. The articular surface of the tibial component is the convex segment of a sphere. The selected radius of curvature for the arc in the sagittal plane is similar to that of the arc in the frontal plane. The upper surface of the talar component is conical with a smaller medial radius to be compatible with the physiological screw-like ankle motion.[19,49,58] Side borders on the talar component keep the inlay in position and should prevent inlay dislocation. The articulating surfaces of the tibial and talar components are made of CrMo with a ceramic coating. A porous coating with Bonit® (DOT Inc., Rostock, Germany) is used on the under-surfaces to facilitate fixation of both these components to the bone. All components can be used for either side. The system includes computer-assisted surgery (CAS) guided implantation as an option.

The prostheses were implanted through a ventral approach to the ankle, using the sets of instruments provided by the respective manufacturers. The German Ankle System was not implanted with CAS guidance. No cement fixation was used. Surgeries were performed by two surgeons (MR and SZ). The surgeons were randomized. The implantation was controlled by radiographic assessment to ensure placement accuracy. We did qualitatively assess the correct implantation, but we did not measure quantitative parameters regarding the implant position and did not correlate implant position with other parameters. We increased the height at the implanted ankles comparable to the situation in vivo, but we also did not measure this lengthening. A randomized paired-testing was performed regarding prosthesis implantation, i.e. each cadaver specimen was randomized to one prosthesis type and the sequence of the tested prostheses randomized.

Robot

A robot (RX 90, Stäubli Tec-Systems, Bayreuth, Germany) was used for testing. The robot arm has 6 degrees of freedom. The technical features of the robot arm are as follows: nominal load capacity, 6 kg; maximal load capacity, 11 kg; reach, 985 mm; maximal speed, 11 m/s; maximal torque, 100 Nm, repeatability, 0.02 mm, angular resolution, 0.00087 degrees (producer's information). The robot was

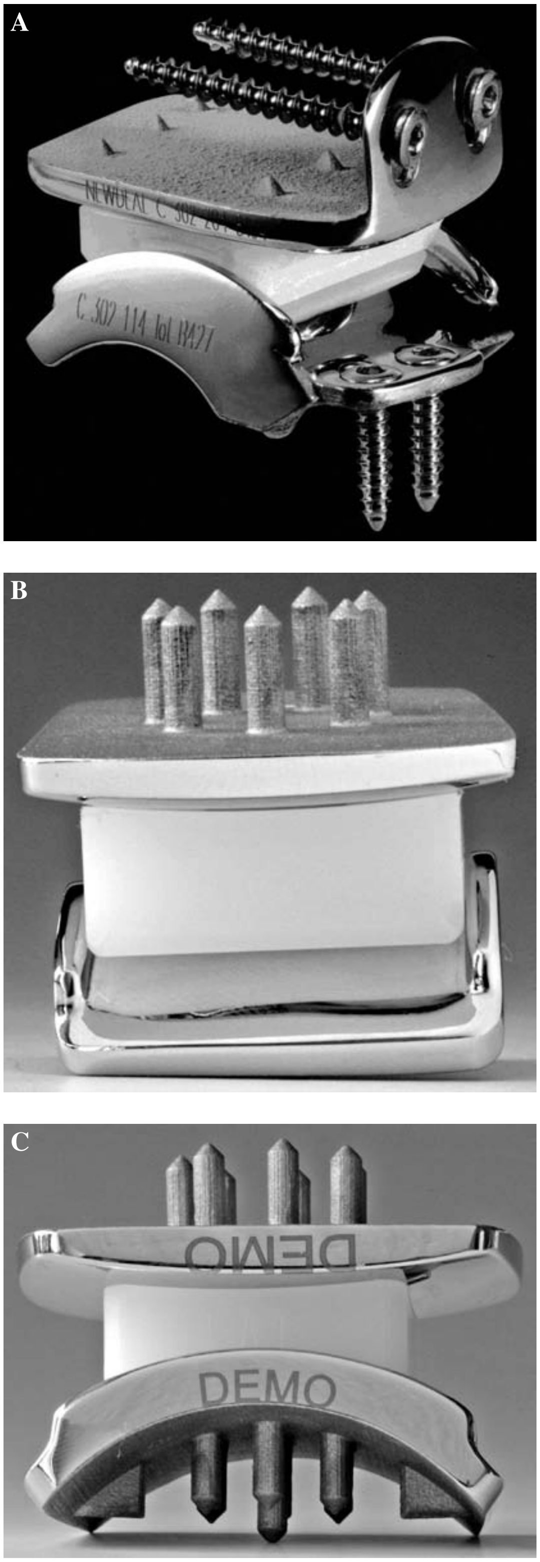

Fig. 1: **A,** Hintegra (Newdeal SA, Vienne, France). **B and C,** German Ankle System (R-Innovation, Coburg, Germany).

guided by a navigation system (VectorVision™, BrainLAB Inc., Kirchheim-Heimstetten, Germany), and by the real-time measurements of the included load cell (see below). The Dynamic Reference Bases (DRB) of the navigation system were fixed to the tibia and footplate (Figure 2). The robot has advantages over a dynamic material testing machine regarding the possible extent and velocity of motions. The most important advantage is that the robot is able to perform complex motions under defined conditions (predefined force or motion). A standard material testing machine is not able to perform complex motions as requested in our special setting. The advantage of guidance of the robot through a navigation system is that the changed coordinative system after implantation of a prosthesis does not alter the applied motion because the navigation system is totally independent from the position of the specimen. Therefore, the navigation system guides the robot under permanent consideration of the specimen's position.

Force Measurement

A load cell (model FT Delta SI-660-60; Schunk, Lauffen, Germany) was used to transmit three-dimensional force and torque values to a computer. Its inaccuracy was less than 1% up to a maximal force of 1,980 N along the shaft axis, and 660 N along the two other axes, and less than 1% up to a maximal torque of 60 Nm in all three degrees of freedom (manufacturer's information)(see Figure 2).

The collected data were transmitted to a commercial personal computer and saved. The recording frequency was 10 s^{-1}. The resulting total force ($F_{res} = \sqrt{F_x^2 + F_y^2 + F_z^2}$) and torque ($M_{res} = \sqrt{M_x^2 + M_y^2 + M_z^2}$) were calculated for each record.

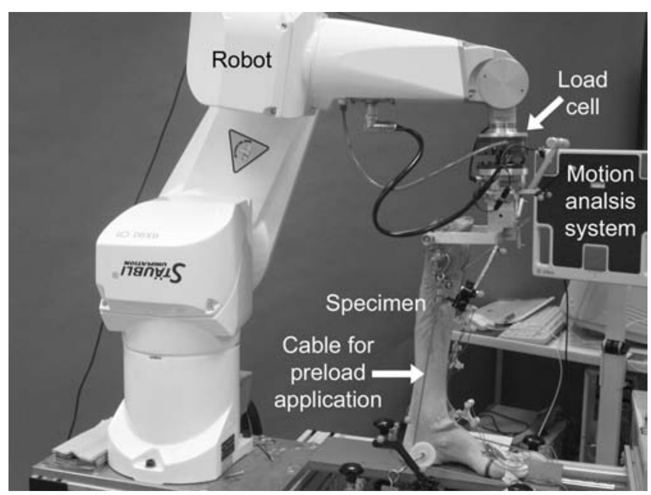

Fig. 2: Setting with robot, specimen, and motion analysis system. Specimen mounted is to the robot and footplate. Triaxial transducers of the motion analysis system were fixed to the footplate (black color and in the front) and to the specimen (transparent and at the back of the image or rather the lateral side of the specimen).

Motion Measurement

The spatial orientation of the specimen and plate was recorded by an ultrasound measurement system (model CMS HS; Zebris Inc., Tuebingen, Germany). The sound transducers were included in the measurement system (cylindrical shape, height 10 mm, diameter: 5 mm, weight: 1 g). The absolute spatial accuracy of the system was rated as 0.1 mm, resolution as 50 μm and the angular accuracy for the triaxial sensors as less than 1 degree in all 6 degrees of freedom. This was reported by the manufacturer and independently in literature.[44,56] Two different measurements were performed.

1. The tibia and fibula were equipped with triaxial transducers at the distal third of the shaft. The transducers were situated at the edges of an equilateral star-shaped adapter (model Plexiglasstern; Workshop, Hannover Medical School, Hannover, Germany, made of Plexiglas™, Rohm and Haas, Philadelphia, PA, USA) with a side length of 50 mm. The adaptors were fixed to the bone with Kirschner wires (model 2.0 mm Titan-K-Draht, Synthes Osteosynthese Inc., Bochum, Germany) (see Figure 2). In several pretests, the neck of the talus also was equipped with a triaxial transducer as planned when designing the study. Stable fixation of this transducer failed despite extensive efforts. Therefore, the talus was not equipped with a transducer during the definitive test. The ankle motion was calculated indirectly by defining the axis of rotation of the tibia as proposed before.[43] The motion data from the motion analysis system was used for this calculation.
2. The footplate was equipped with one triaxial transducer (see Figure 2).

Testing sequence

The load cell was fixed to the robot arm. An adaptor was fixed on the other side of the load cell, which was fixed to the specimen tibias (see Figure 2). The fixation adaptor included two 5-mm Schantz screws that were inserted 5 cm deep into the tibia 1 cm below the knee joint level from the medial and lateral side. A third 5-mm Schantz screw was inserted from anterior to posterior direction in the tibial shaft 10 cm below the knee joint level and was fixed to the above described adaptor. Before the leg was fixed to the robot, the approach for the implantation of the prosthesis was performed. The skin was sutured with staples before each test. The dorsal retinaculum was not sutured. The foot was mounted on the footplate and this footplate was affixed to the base of the robot. The fixation of the foot to the footplate was established in a pre-test. One hole with a 6-mm diameter was drilled into the calcaneus from lateral to medial through stab incisions located at the standard position for calcaneal extension (2 cm distal and dorsal the distal tip of the fibula). A standard climbing robe with a 5-mm diameter was pulled through this hole and through two 6-mm holes in the footplate that were positioned close to the calcaneal hole. A similar rope was inserted through the forefoot around the heads of the second through fourth metatarsals. The rope was pulled through a stab incision in the web space between the first and second and fourth and fifth metatarsal heads. Furthermore, a standard 4.5-mm five-hole plate (4.5 mm Dynamic Compression Plate, Synthes, Bochum, Germany) was placed dorsally on the forefoot and fixed with two 4.5-mm fully-threaded screws though the first and fifth plate hole and the above described stab incisions into the foot plate. The rope was pulled through two 6-mm holes in the footplate which were located close to the stab incisions in the foot sole. The rope end at the bottom side of the footplate was pulled manually as much as possible and fixed with clamps. The specimen fixation included an axial preload of 30 kg which was realized with a cable and pulleys. The pulleys were mounted to the footplate at the exact height of the ankle joint axis. This was intended to minimize the influence of the preload forces to the measured forces. In a pretest, the influence of that system for partial weightbearing introduction was analyzed. This pretest was performed with three different specimens that were not included in the definite test. All specimens were first moved 100 cycles as described below without partial weightbearing and then another 100 cycles with partial weightbearing. Forces, torques and motions as described were compared between the cycles with and without partial weightbearing. No significant differences occurred leading to the conclusion that the system for partial weightbearing did not alter the measured parameters (data not shown). Furthermore, since all later testings included the same method for partial weightbearing introduction, a significant influence on the principle results (differences between specimens with and without prosthesis) was not suspected.

The range of motion of the ankle was defined by the robot by applying 100 Nm for dorsiflexion and plantarflexion in the ankle. The angles were measured with the ultrasound based motion analysis system as described before.[44,56]

The robot then performed 100 cycles of the predefined full range of motion with a velocity of 0.25 m/s. The robot's control system guided the motions based on the load cell data in such a manner that the course of the motion followed the course of normal ankle motion including possible rotation with the lowest resulting forces and torques and torques in an unconstrained manner regarding rotation, abduction, adduction, and anteroposterior or medial-lateral translation. This course has been considered to be as close as possible to the physiologic ankle motion during gait.[19] During the 100th cycle, the course of the motion was recorded by the robot control system as the baseline for the later testing. A prosthesis was then implanted as described previously. The specimen remained fixed to the footplate and robot during the prosthesis implantation. The cables for the introduction of partial weightbearing were removed during prosthesis implantation. One hundred cycles were performed with the prosthesis exactly as the last (100th) cycle which was performed without the prosthesis. During all cycles the forces, torques, and motions were recorded as described above. After the testing, each specimen was examined for reduced fixation of the prosthesis or specimen itself. The position of the prosthetic components also was assessed radiographically by an independent investigator (radiologist) in a blinded manner.

Statistical Analysis and Hypothesis Testing

The data were evaluated by a professional statistician using SPSS 11.5 (SPSS Inc, Chicago, IL). A one-sample-t-test was used for the analysis of the differences between the measurements with prosthesis (100 cycles) and the measurements of the last (100^{th}) cycle without prosthesis (test-value). These differences also were considered as relative values. A paired-t-test was used to compare the cycles 6 to 10 with the cycles 96 to 100 with prosthesis. An unpaired-t-test (homoscedastic) was used for comparison of absolute and relative measurements of both prostheses. The null hypothesis at the $p < 0.05$ level means there is no difference between the Hintegra and the German Ankle System.

Ethical Approval

The study was approved by the Ethical Commission of the Hannover Medical School, Hannover, Germany.

RESULTS

All implants were considered to be correctly positioned. No shifting or dislocation of the tibial or talar components in relation to the specimen was observed after the testing by radiographic assessment. No shifting or dislocation of the specimen in relation to the robot arm or the footplate was observed after the testing. No significant differences of forces, torques, and motions (parameters as described below) occurred between the cycles 6 to 10 and the cycles 96 to 100 with a prosthesis (paired-t-test for all parameters, $p > 0.05$).

Table 1 shows the results of the force and torque measurements and Table 2 the results of the motion measurements.

Forces (see Table 1, Figure 3)

The Hintegra and German Ankle System significantly increased the forces and torques in relation to the specimen without a prosthesis with one exception (one-sample-t-test of the differences between the measurements with prosthesis [100 cycle] and the measurements of the last 100^{th} cycle without a prosthesis [test-value], each $p < 0.001$ without the exception). The exception was the parameter lateral force measured with the German Ankle System that did not significantly differ from the lateral force measured without a prosthesis (one-sample-t-test as described above, $p = 0.34$).

The force differences between the specimens before and after implantation of the prostheses were lower with the German Ankle System than with the Hintegra except for the lateral forces (unpaired t-test, each $p < 0.05$ except lateral force, $p = 0.65$; see Table 1).

Torques (see Table 1, see Figure 3)

The Hintegra and German Ankle System significantly changed the torques in relation to the specimen without a prosthesis (one-sample-t-test of the differences between the measurements with prosthesis [100 cycles] and the measurements of the last 100^{th} cycle without a prosthesis [test-value], each $p < 0.001$). The dorsoventral torques were significantly decreased by both prostheses and the lateral

Table 1: Results of force measurement

	Hintegra		German Ankle System		unpaired-t-test (p-values)	
	absolute values	relative values	absolute values	relative values	absolute values	relative values
Forces (N)						
Dorsoventral	−11.98 ± 14.00	4.10 ± 16.98	−6.69 ± 8.84	2.16 ± 6.67	0.05	0.01
Lateral	3.46 ± 7.34	2.86 ± 11.44	−3.54 ± 4.17	−0.31 ± 7.85	0.65	<0.001
Axial	55.96 ± 41.93	37.51 ± 41.38	43.09 ± 45.77	30.01 ± 48.95	0.01	0.003
Resulting total	64.50 ± 32.80	32.49 ± 33.28	45.07 ± 45.97	23.63 ± 29.19	<0.001	<0.001
Torques (Nm)						
Dorsoventral	−0.88 ± 1.40	−1.71 ± 5.87	−0.14 ± 1.12	−0.42 ± 3.08	<0.001	<0.001
Lateral	2.81 ± 4.36	3.84 ± 7.12	1.04 ± 6.17	2.20 ± 5.69	<0.001	<0.001
Axial	−0.42 ± 0.62	−0.31 ± 1.48	0.21 ± 1.57	0.20 ± 0.39	0.02	<0.001
Resulting total	4.48 ± 3.06	−2.67 ± 5.44	5.35 ± 3.51	1.47 ± 3.52	0.05	<0.001

The absolute values are the measured values with a prosthesis. The relative values are the difference between the measurements with a prosthesis (100 cycles) and the measurements of the last (100^{th}) cycle without a prosthesis (mean values and standard deviations for both are given). An unpaired-t-test (homoscedastic) was used for comparison of absolute and relative values of both prostheses.

Table 2: Results of motion measurement

		Hintegra		German Ankle System		unpaired-t-test (p-values)	
		absolute values	relative values	absolute values	relative values	absolute values	relative values
Ankle	Dorsiflexion (°)	12.1 ± 2.6	-2.9 ± 2.7	12.1 ± 3.9	-2.1 ± 3.9	1.0	1.0
	Plantiflexion (°)	35.7 ± 7.3	-2.9 ± 3.9	37.1 ± 7.0	-0.7 ± 1.9	0.72	0.41
Tibia	X (mm)	20.2 ± 5.6	4.5 ± 1.8	18.9 ± 4.1	2.4 ± 1.9	0.54	0.05
	Y (mm)	3.2 ± 1.6	0.9 ± 1.6	1.9 ± 0.9	0.5 ± 1.7	0.04	0.04
	Z (mm)	5.1 ± 3.6	2.3 ± 2.7	3.1 ± 1.9	1.4 ± 0.9	0.05	0.01
	Plantar/dorsiflexion (°)	47.8 ± 5.6	-5.8 ± 3.7	49.2 ± 4.9	-2.8 ± 1.9	0.82	0.05
	Adduction/abduction (°)	0.6 ± 1.6	-5.1 ± 4.6	5.5 ± 4.5	-0.6 ± 1.6	<0.001	<0.001
	Internal/external rotation (°)	5.4 ± 3.6	-1.9 ± 2.5	6.2 ± 4.2	-0.6 ± 1.1	0.56	0.03
Fibula	X (mm)	25.4 ± 10.6	3.9 ± 4.1	26.9 ± 12.9	2.0 ± 3.5	0.78	0.05
	Y (mm)	3.4 ± 2.6	2.7 ± 2.7	1.8 ± 1.6	1.3 ± 1.9	0.05	0.01
	Z (mm)	6.3 ± 4.6	2.9 ± 3.5	4.3 ± 2.9	1.5 ± 2.0	0.04	0.001
	Plantar/dorsiflexion (°)	43.5 ± 10.5	-6.7 ± 6.2	46.1 ± 9.9	-3.5 ± 2.8	0.82	0.05
	Adduction/abduction (°)	2.3 ± 2.1	-2.0 ± 2.5	5.9 ± 4.9	-0.5 ± 2.1	0.01	0.01
	Internal/external rotation (°)	4.5 ± 2.7	-1.6 ± 1.7	7.6 ± 7.1	-0.1 ± 2.9	0.12	0.05

The absolute values are the measured values with a prosthesis. The relative values are the difference between the measurements with a prosthesis (100 cycles) and the measurements of the last (100^{th}) cycle without a prosthesis. The motion of the bones is specified as the range of translation at the ankle joint level in X direction (anterior-posterior), Y direction (medial-lateral) and Z direction (proximal-distal), and as range of rotation plantar/dorsiflexion, adduction/abduction and internal/external rotation Table 2.

torques were significantly increased by both prostheses. The axial torques and resulting total torques were significantly decreased by the Hintegra and significantly increased by the German Ankle System. The torque differences between the specimens before and after implantation of the prostheses were lower with the German Ankle System than with the Hintegra (unpaired t-test, each $p < 0.001$; see Table 1).

Motion (see Table 2, Figure 4)

Ankle range of motion

The Hintegra significantly decreased the ankle dorsiflexion but did not significantly change the ankle plantarflexion in comparison with the specimen without a prosthesis (one-sample-t-test of the differences between the measurements with prosthesis [100 cycles] and the measurements of the last [100^{th}] cycle without prosthesis [test-value]; ankle dorsiflexion, $p = 0.03$; ankle plantarflexion, $p = 0.20$). The German Ankle System did not siginificantly change the range of ankle dorsiflexion or plantarflexion (one-sample-t-test as described above; ankle dorsiflexion, $p = 0.10$; ankle plantarflexion, $p = 0.36$). The absolute or relative ankle range of motion did not significantly differ between the Hintegra and German Ankle System (unpaired t-test, $p > 0.05$; see Table 2).

Bone Motion

The Hintegra significantly increased the translation in a proximal-to-distal direction (Z) of the tibia and fibula, and the translation in a medial-to-lateral direction (Y) of the fibula (one-sample-t-test of the differences between the measurements with prosthesis [100 cycles] and the measurements of the last [100^{th}] cycle without prosthesis [test-value]; tibia Z, $p = 0.05$; fibula Z, $p = 0.04$; fibula Y, $p = 0.03$). The Hintegra significantly decreased the range of adduction and abduction and internal and external rotation of tibia and fibula (one-sample-t-test as described above; each $p \leq 0.05$). The Hintegra did not significantly change the translation in an anterior-to-posterior direction (X), the range of plantarflexion and dorsiflexion of the tibia or fibula, and the translation in a medial-to-lateral direction (Y) of the tibia (one-sample-t-test as described above; each $p>0.05$).

The German Ankle System did not significantly change any translation or rotation of the tibia or fibula (one-sample-t-test as described above; each $p > 0.05$).

The absolute translation in anteroposterior direction (X) and the absolute translation of range of plantarflexion and dorsiflexion of the tibia and fibula did not significantly differ between the Hintegra and German Ankle System (unpaired t-test, each $p > 0.05$; see Table 2). The remaining absolute values and all relative values significantly differed between the Hintegra and German Ankle System (unpaired t-test, each $p \leq 0.05$; see Table 2).

Null Hypothesis

The null hypothesis was rejected for all forces and torques except the lateral forces, and for all force and torque

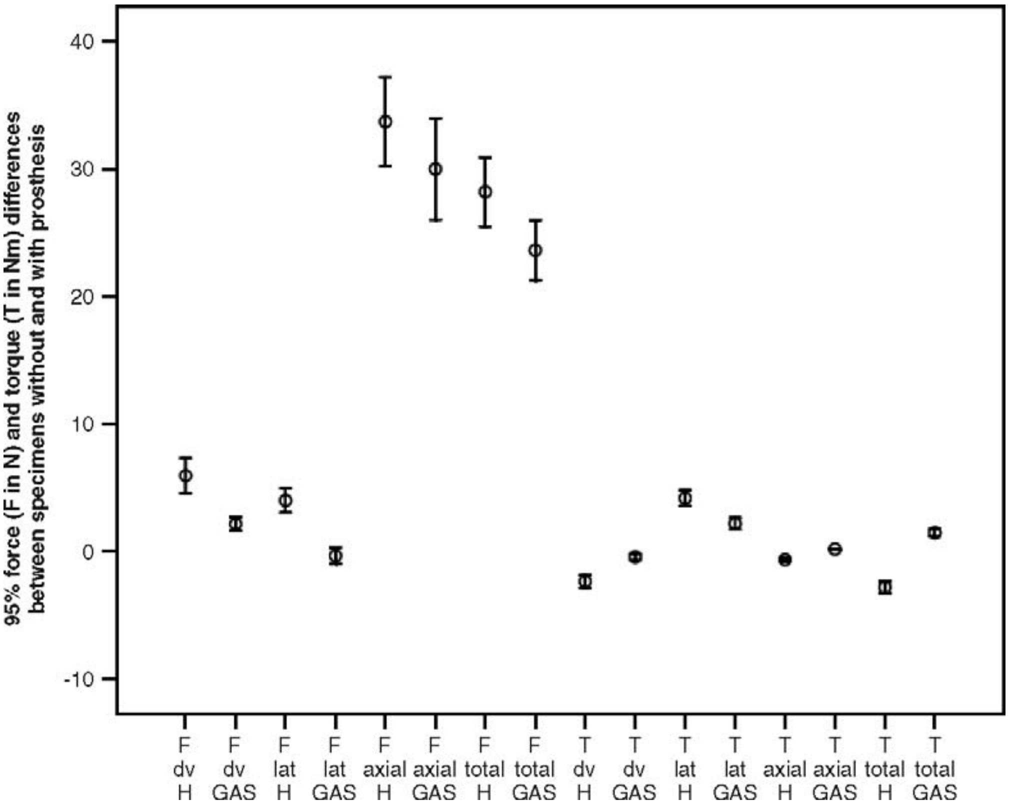

Fig. 3: Error bars with 95% confidence interval of force differences between the measurements with a prosthesis (100 cycles) and the measurements of the last (100^{th}) cycle without a prosthesis. (F, force; T, torque; H, Hintegra; GAS, German Ankle System; dv, dorsoventral; lat, lateral; total, total resulting).

differences between the measurements with a prosthesis (100 cycles) and the measurements of the last (100^{th}) cycle without a prosthesis. The null hypothesis was rejected for all bone translations and rotations except translation in anteroposterior direction (X) and range of plantarflexion and dorsiflexion of the tibia and fibula, and for all bone translation and rotation differences between the measurements with a prosthesis (100 cycles) and the measurements of the last (100^{th}) cycle without a prosthesis.

DISCUSSION

Construction of a new ankle prosthesis

The design of a total ankle prosthesis involves striking a delicate balance between several contrasting criteria.[33] A new total ankle prosthesis, as proposed here, will have articular surface shapes compatible with the isometric rotation of certain ligament fibers, and screw-like motion as observed in the natural joint. The congruent mobile-bearing prosthesis permits three-dimensional unresisted relative motion of the replaced ankle while maintaining full contact at the tibial-meniscal and meniscal-talar articulations in all joint positions. Furthermore, the anatomic shape of the talus with a smaller medial radius was taken into consideration in the design of the talar component to mimic the physiologic screw-like ankle motion.[19,49,58] The new design is not without limitations. Similar to the mobile-bearing ankle implants currently available, our design is subject to instability in ligament-deficient joints.[32,38] Although the risk of double-sided wear has been disproved in retrieval studies of meniscal knee replacements, the risk of dislocation in relation to the meniscal bearing is a potential problem.[40,42] In this respect, fully congruent and ligament-compatible articular surfaces may confer an advantage over some prostheses currently available.[33] The present convex tibial component may experience transmission of shear forces between the tibial and meniscal components, with an associated higher risk of the tibial component becoming loose.[33] However, in current implants with a corresponding flat-to-flat interface, the resulting shear forces alone are resisted by the ligaments, which must be well balanced.[33] The appropriate ligament tensioning ensures that the ligaments play their full role in transmitting the shear forces, which may help reduce the shear forces at the bone-component interface. The fundamental difference between this design and its predecessors is that no constraints were imposed here to exactly reproduce the anatomical shapes of either natural articular surface. Three-component prostheses currently available aim to reproduce the shape of the tibial plafond but use a flat tibial surface to articulate with the meniscus.[5,17,24] It has been shown that these designs are unlikely to restore the characteristic original pattern of ligament tensioning.[30] In contrast to previous

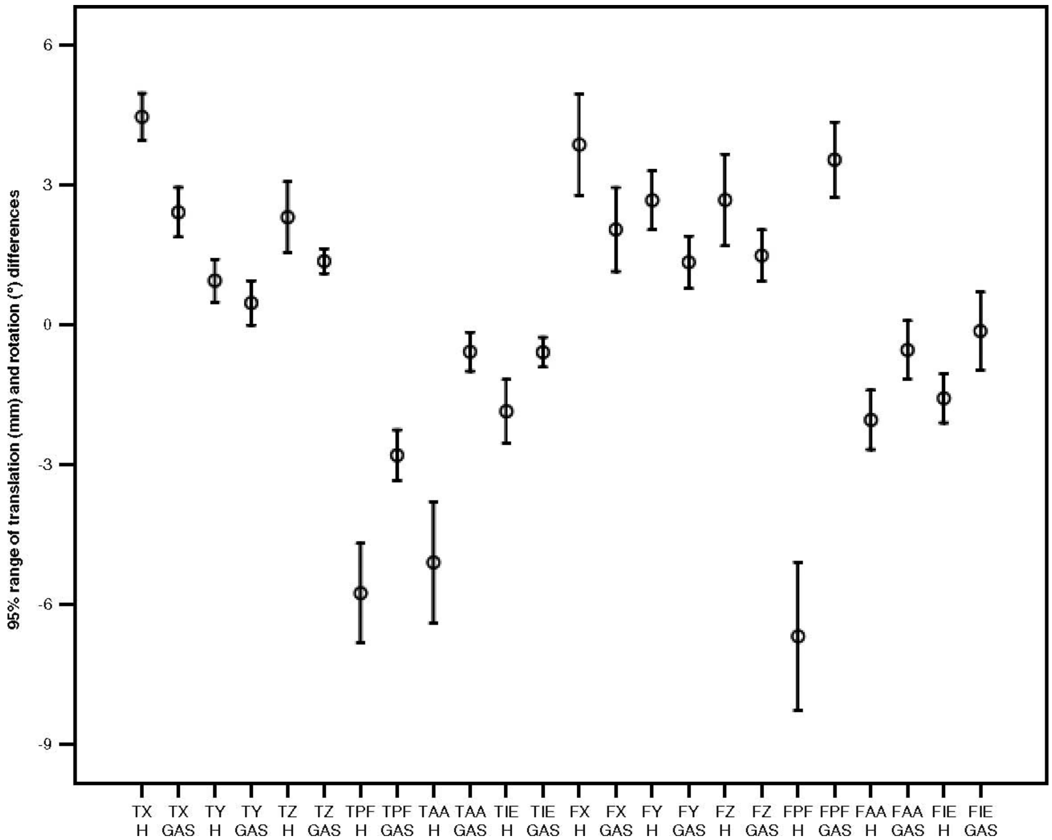

Fig. 4: Error bars with 95% confidence interval of the motion differences between the measurements with a prosthesis (100 cycles) and the measurements of the last (100th) cycle without a prosthesis. The motion of the bones is specified as the range of translation at the ankle joint level in X direction (anterior-posterior), Y direction (medial-lateral) and Z direction (proximal-distal), and as range of rotation plantarflexion/dorsiflexion, adduction/abduction and internal/external rotation TX, tibia X (mm); TY, tibia Y (mm); TZ, tibia Z (mm); TPF, tibia plantarflexion-dorsiflexion (°); TAA, tibia adduction/abduction (°); TIE, tibia internal/external rotation (°); FX, fibula X (mm); FY, fibula Y (mm); FZ, fibula Z (mm); FPF, fibula plantarflexion-dorsiflexion (°); FAA, fibula adduction/abduction (°); FIE, fibula internal/external rotation (°); H, Hintegra; GAS, German Ankle System.

three-component designs, our design allows for inversion and eversion in addition to internal and external rotation at the tibial-meniscal interface. This is particularly important when considering that the device should restore the characteristic motion of the entire ankle complex, comprising the ankle joint and subtalar joint. Inversion and eversion do not require lift-off.

Navigation

An instrument system based on CAS might improve the accuracy of ankle prosthesis implantation as previously demonstrated in total knee replacement.[7,11,15,21,27] This higher degree of accuracy may be a basis for lower loosening rates and improved clinical outcome.[36] The logical consequence was to include CAS in the development of the new prosthesis.

Experimental Testing

The main goal for developing our new prosthesis was to imitate the physiological ankle function more closely than was achieved with previous designs. The possible increased forces that may occur after implantation of a prosthesis during weightbearing ankle motion, in particular, should be minimized. We considered those forces as one of the most important factors for restricted function and increased loosening.[33,36,48,50] We, therefore, intended to measure and compare those forces on ankles with and without a prosthesis. A robot-based cadaver test was developed for this purpose. This test comprised matched pairs of cadaver legs, with partial weightbearing and exact simulation of physiological ankle motion, which might be better than all previous tests.

We used matched pairs of cadaver extremities for optimal comparison of the two prostheses. Valderrabano et al.[52] used unpaired single cadavers for testing three different prostheses, i.e. all three prostheses were tested sequentially. When testing sequentially, weakening of bony and soft-tissue structures throughout the test might influence the measured parameters because the different implants are inserted after a different number of test cycles. This effect is compensated during matched pairs testing, since both prosthesis types are implanted after the same number of earlier cycles. The use of matched-pairs specimens ensures equal mechanical properties for sides and prosthesis.[2,10,37,41,51] The sides also were randomized to compensate for the effect of the potentially higher mechanical strength of the dominant side.

Embalmed cadavers were used in our tests. In an earlier study, we were unable to demonstrate a difference in mechanical bone strength between freshly frozen and embalmed specimens.[57] The use of both specimen types, therefore, seems to be just as adequate for mechanical testing regarding bone stability.[3,57] Another concern against the embalmed specimen is the questionable biocompatibility regarding the ligament function. It is unknown if ligament function is different in embalmed specimens in comparison with fresh specimens or fresh frozen and thawed specimens. However, the more important question is how cadaver specimens differ from the in vivo situation. We also were not able to find the answer to this question. We believe that we minimized the possible effect on different ligament functions in our specimens by testing the same specimens without and with a prosthesis. We, furthermore, compared the parameters of the cycles 6 to 10 with the cycles 96 to 100 with the prosthesis to analyze the effect of possible alterations of the biomechanical behavior of the specimens during the testing sequence, and did not observe significant differences in our main outcome parameters (paired-t-test, $p > 0.05$).

The prostheses were not cemented as previously proposed.[48,52–54] The most important difference between previous tests of different prostheses is that we implanted only one prosthesis in one specimen and not three after an arthrodesis as previously described.[52–54] We are aware that prosthetic ingrowth is not possible during cadaver testing. However, we achieved stable press-fit fixation without cement since we did not observe any shifting or dislocation of the tibial or talar components after the testing sequence in our pretests and the definitive test. In one of the extensive pretests, a continuous image intensifier registration comparable to a lateral standard view was performed during 10 cycles. A qualitative assessment of these recorded images was performed by an independent investigator (radiologist) who did not detect any motion between bone and implant at the interfaces. We consequently considered the implant fixation to be sufficient. Since we considered all the implantations as correctly placed, we did not think that a correlation of the same correct position with other measured parameters (force, torque, motion) was useful.

We achieved only partial weightbearing with 30 kg during the experimental test. The intention was to perform the test under full weightbearing, i.e. the measured body weight of the entire cadaver. We failed to achieve this goal during extensive pretests because we were not able fix the entire body weight to the cadaver. Valderrabano et al.[52–54] used a preload of only 100 N in their test. Saltzman et al.[48] also achieved only near full weightbearing (600 N) during their tests of ligament tension after total ankle arthroplasty. Another very important and critical point for all experimental in vitro testings is the axial type of loading that is not representative of actual loading that occurs during gait. The off-tibial-axis loading that occurs during normal gait imparts forces to the ankle joint (and prosthesis) that might alter the pattern of motion.[19] As far as we know, not a single in vitro test and especially not an in vitro test for ankle prosthesis could mimic physiological weightbearing.[19] Therefore, the effect of a nonphysiological axial loading in comparison with the physiological off-tibial-axis loading also is unknown. We were not able to mimic physiological loading, but we think that we achieved more physiological loading than previous studies. Since the loading was the same for the specimen with and without a prosthesis, our main outcome parameter, i.e. differences between specimens with and without a prosthesis, might have been less affected.

A general concern for all in vitro settings is the passive motion that might be different from active motion.[19] Since active motion during in vitro testing with cadavers with a prosthesis is extremely unrealistic, we think that this possible criticism is not specific for our study. The distance of the load cell to the ankle also is a critical point. We have measured forces in the ankle joint in an earlier testing.[44] However, we found this method not applicable in this setting, because the intraarticular sensor could only measure forces in a perpendicular direction to its surface and could not measure shearing forces or torque. In pretests, we tried to fix the load cell in a bone gap in the tibia 5 cm above the ankle level to achieve a measurement that is located closer to the ankle, though we were not able to fix the load cell properly, and we were not able to achieve constant and plausible measurements. Using shorter specimens would be another possibility for closer load cell positioning. We deliberately did not use shorter specimens because we considered intact articular function of the distal and proximal tibiofibular joints as an important factor for near physiological testing conditions. Finally, we could not find any better testing setup in the literature for achieving a more appropriate measurement. The used system is not infinitely rigid. Based on the guidance of the robot not by its own software that would not consider bone position (or altered bone position by increased height) but by the navigation system that makes guidance dependent on the specimen's position, we were able to mimic the ankle motion accurately despite the changed coordinate system. The preload was applied through a cable system that is not affected by increased length. Both prosthesis types had the same height. Taking these aspects into consideration, our setting appears to be more appropriate than those previously described.[30,48,52–54]

Findings

Both prostheses increased the forces in relation to the specimen without a prosthesis with one exception (parameter lateral force measured with the German Ankle System). The torques were changed by both prostheses but not all increased. In our understanding, the massive increase of the axial forces, and, as a consequence, the total resulting increased forces were caused by an increased height respective to the length of the entire specimen after implantation of the prosthesis, which resulted in an increased load of the load cell in axial direction. The increased height might influence all other measured parameters. However, we were able to measure the isolated forces and torques in all 6 degrees of freedom. Therefore, we could analyze forces and torques for rotation, and dorsoventral and mediolateral directions independently from the increased axial forces because of the increased specimen length. The dorsoventral torques were decreased by both prostheses, and the axial torques and resulting total torques were decreased by the Hintegra. The Hintegra decreased ankle dorsiflexion but did not change ankle plantarflexion, whereas the German Ankle System did not change the range of ankle dorsiflexion or plantarflexion. The Hintegra increased the translation in a proximal-to-distal direction of the tibia and fibula, and the medial-to-lateral translation of the fibula, and decreased the range of adduction and abduction and internal and external rotation of tibia and fibula, whereas the German Ankle System did not change any translation or rotation of the tibia or fibula. Particularly, the German Ankle System allowed similar abduction and adduction as the specimen without a prosthesis, whereas this was decreased by the Hintegra.

Our principle parameter was the difference in force and torque during ankle motion under partial weightbearing with and without a prosthesis. That difference in force and torque was significantly lower for the German Ankle System than for Hintegra. In addition, we observed that the motion of bones in the German Ankle System was less altered than in Hintegra. We did not only measure the ankle range of motion but also the angular and translational motions of the tibia and fibula in all 6 degrees of freedom. These motions comprise also the so-called coupled motions. Assuming that increased forces and torque or altered motion will effect ankle function and loosening of the prosthesis, the German Ankle System might, at least, be similar to the Hintegra in this regard.

In conclusion, the German Ankle System prosthesis had less of an affect on resulting forces, torques, and motions during partial weightbearing passive ankle motion than the Hintegra prosthesis. This might improve function and minimize loosening during the clinical use.

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