Analysis of a generic talar prosthetic with a biological talus: A cadaver study

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ARTICLE INFO

Keywords:

Talus
Generic prosthesis
Cadaveric assessment
Avascular necrosis

ABSTRACT

Treatment for talar avascular necrosis is challenging. This study evaluates the feasibility of a generic talar implant by cadaveric assessment. Ten cadaveric ankles were CT-scanned to determine talar implant size. The opposite ankles were CT-scanned with the biological talus and then with the implant. 3D ankle geometry was reconstructed and implant position was compared to the biological talus position. The averages among specimens' positive and negative average-deviations were 0.91 mm and 0.70 mm. Seventy percent of talar dome deviations between the biological talus and implant were within an acceptable range. This study yields promising results to support a generic talus bone prosthetic.

1. Introduction

After calcaneus fractures, talus fractures are the most frequent of all tarsal bone fractures and account for 0.1–0.85% of all fractures.^{1–3} They are most common in a young, active patient population and are more likely to occur in men than in women by a ratio of three to one.^{1,4} Fractures of the talar neck, which account for approximately 50% of significant injuries to the talus, can result in avascular necrosis (AVN) in 20–100% of patients with displaced fractures.⁴ The avascular bone can be unsuitable to hold the required load and collapse can occur resulting in severe incongruity of the ankle joint with subsequent pain, swelling, and restricted range of motion.

The most common surgical treatment option for this injury is ankle arthrodesis (fusion), wherein talus is fused to the tibia or to the tibia and calcaneus. Although arthrodesis often enables the patient to walk with decreased pain, it results in loss of motion and function of the joint.^{5,6} Additionally, this procedure can be difficult because of a lack of healthy bone due to AVN.

Ankle arthroplasties have become a more desirable alternative to fusion as they have the potential to offer increased mobility of the ankle joint. More recently, they have been designed and implanted with increasing success⁷; however, ankle arthroplasties are not suitable when

the talus fracture results in AVN because the talus is often lacking in healthy bone stock that is required for support of the talar portion of the prosthesis.

One possible solution to the issues associated with arthrodesis and arthroplasties is a talar body implant that replaces the avascular portion of the talus or the entire talus to maintain ankle joint motion and function.⁸ At this time, there have been some reports of talar body replacements. These implants have been custom made from various materials – stainless steel,⁹ alumina ceramic,^{10–12} titanium alloy,¹³ and cobalt-chrome.¹⁴ The prostheses developed by Harnroongroj and Vanadurongwan used custom measurements of volume and dimensions (including curvatures) of the contralateral talus; they were implanted in 16 patients.⁹ Tanaka et al. developed a prosthesis similar to Harnroongroj and Vanadurongwan and implanted it in three patients initially¹⁰ and then in 52 patients with good results.¹² Both Magnan et al.¹³ and Stevens et al.¹⁴ replaced a talus utilizing CT scans to develop a prosthesis based on the real geometry of the bone. All of these implants were custom-made and as such, add a level of complexity and can be expensive compared to a generic, off-the-shelf implant if it was available.

Development of a generic talus bone prosthetic in different sizes could simplify the complexity of design and decrease the costs to

Abbreviations: ANOVA, analysis of variance; AVN, avascular necrosis; CT, computed tomography; DCM, deviation colour map; DICOM, Digital Imaging and Communications in Medicine; MRI, magnetic resonance imaging; TTF, Talus-Tibia and Fibula

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<https://doi.org/10.1016/j.jor.2018.01.015>

Received 20 October 2017; Accepted 12 January 2018

Available online 03 February 2018

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provide this treatment alternative. This requires a generalization of the geometry of the talus. Islam et al.¹⁵ proposed an implant in five sizes; however, that study had limitations including a small sample size ($n = 27$), lack of a diverse sample selection such that the female population was severely underrepresented, a randomly selected reference implant, and an incremental jump in size of volume (which will be more significant in the smaller sizes as volume is a cubic function). Trovato et al.⁸ improved upon this study by increasing the sample size ($n = 91$) with 45% of the subjects being female, selectively choosing the reference implant, and using incremental jump in the cube root of the volume between sizes. From this analysis, ten unisex implant sizes for the talus bone were created to maintain geometric compatibility of the ankle joint.

This study evaluates the feasibility of using 10 implant sizes by verifying the joint compatibility of the talar implants using cadaveric assessment; and attempts to link the contact area differences between the biological and generic implant to deviations in geometry between the two implants when situated in the cadaveric ankle. To achieve this, we explored how a generic talar implant fits into the ankle joint as compared to the biological talus using cadaveric assessment.

2. Materials and methods

2.1. Ankle joint imaging

After obtaining ethical approval from the University of Alberta research ethics board, 10 embalmed cadavers (4 male, 6 female; age at death 84.5 ± 12.0 years) were obtained from the University of Alberta Anatomy department. The feet were isolated from the cadavers approximately 100 mm above the ankle joint and a CT scan was performed on the left ankle.

Each ankle was placed in the CT scanner approximating the clinical position. The CT scan was performed using a high-resolution Somatom definition flash scanner with the following specifications: pitch 0.8 mm, gantry tilt 0° , effective mAs 300, voltage 80 kV, rotation time 1.0 s, and a constant slice thickness of 0.6 mm and increment of 0.1 mm. The Digital Imaging and Communications in Medicine (DICOM) images were provided with a resolution of 512×512 pixels/slide.

2.2. Geometric analysis

From these scans, the DICOM images were imported into the 3D image processing software, MIMICS (Materialize NV, Belgium), and a 3D model was created (Fig. 1). Following this, the computer software Geomagic (Geomagic®, Morrisville, North Carolina; USA) was used to obtain the volume of the talus and from this volume, the implant size for the right talus was selected by comparing the volume of the talus to the implant sizes defined in a previous study.⁸ The talus was then scaled

Fig. 1. 3D model of the right biological talus and surrounding bones.

Fig. 2. Cadaveric foot with elastics.

up by 0.5 mm over the entire surface area to account for articular cartilage on the talar dome that is approximately 1 mm thick,¹⁶ and then 3D printed.

The right ankle of each cadaveric specimen was dissected in a consistent fashion (Fig. 2). Skin, subcutaneous tissue, muscle and tendons were excised from the anterior and posterior aspect of the talus, ankle joint and subtalar joint. To maintain connectivity of the leg (tibia and fibula) to the foot, the tibiocalcaneal ligament and surrounding soft tissues were left intact on the medial side, and the calcaneofibular and surrounding soft tissues were left intact on the lateral side. All ligamentous attachments to the talus were then excised and the biologic talus was removed from each specimen. Elastic bands were placed around the ankle to improve connectivity and apply a small load when the biologic talus was reinserted for imaging (Fig. 2).

The biologic talus was inserted back into the right ankle and was scanned perpendicular to the length of the tibia from just above the talus to the bottom of the foot three times with only the elastic band load: (1) in a neutral position, (2) 20° dorsiflexion, and (3) 20° plantarflexion. A custom holder, (Fig. 3), held foot in the pre-determined position. Subsequently, the biologic talus was removed from the ankle and replaced by the prosthetic implant and scanned in the same manner. Three-dimensional models of the scans were reconstructed in the same manner as stated above.

2.3. Implant vs. biological talus: geometric comparison

For each angle and each specimen, the position of the talus-tibia and fibula (TTF) articulating surfaces was compared between the biologic and the implant tali. The articulating surface was isolated and the change of position of the implant was appraised by comparing the talar

Fig. 3. Cadaver foot holder.

Fig. 4. Neutral biological tibia, fibula and talus cropped anterior and lateral view.

dome surface of the biological talus and the implant using the following five steps.

1. All bones, except for the talus, tibia, and fibula were deleted.
2. The tibia and fibula from the model with the biological talus and talar implant were aligned to each other.
3. The model was cropped to facilitate viewing of the articulating surfaces. The tibia and fibula were cropped approximately 20 mm above the highest point on the talus. The tali in both models were cropped off to focus on the articulating talar dome (Fig. 4).
4. The tibia and fibula were re-aligned after cropping.
5. The deviation in the talar dome of the biological talus and the implant was examined.

This alignment and the deviation analysis were carried out using Geomagic. The alignment of the tibia and fibula was achieved using the Geomagic software built-in best-fit approach. This aligned the tibia and fibula from the scan with the biological talus to the scan with the implant. Because the tibia and fibula are the same in both scans, this procedure should result in perfect alignment. During the alignment process, the positions of the biological talus and implant relative to the tibia and fibula from the biological and implant scans were kept fixed. Once the models were aligned, the tibia and fibula on each model were deleted leaving only the biologic talus and the implant for examination of their relative positions to each other. Deviation contour maps (DCMs) between the biological talus and implant were generated using the Geomagic 3D Compare Analysis. This resulted in finding the relative difference between the surfaces of the biological talus and the implant in the three defined positions.

For each specimen, and each position, the three variables average positive deviation, average negative deviation, and percentage of talar dome within an acceptable range (-0.5 mm to 1.5 mm deviation)¹³ were extracted from the map of relative difference between the biological talus and implant. Statistical analysis was performed using SPSS Statistics 23 (IBM, Armonk, USA) and significance was concluded when $p < 0.05$. All data were subjected to Levene's test to assess for homogeneity of variance and Shapiro-Wilk test to assess for normality of distribution. Neutral position, dorsiflexion and plantar flexion were compared in the analysis for the three dependent variables. In the event that data were found to be homogeneous and normally distributed, a one-way analysis of variance (ANOVA) was used with Tukey post-hoc testing when the ANOVA was significant ($p < 0.05$). For data that were not homogeneous or normally distributed, a Kruskal-Wallis ANOVA was used with Dunn-Bonferroni post-hoc testing when the Kruskal-Wallis ANOVA was significant ($p < 0.05$).

3. Results

The size distribution was as follows: four size 4, two size 5, two size 6, one size 7, and one size 9. When looking at the volumes of the right tali as determined by CT scans, it was found that 6 of the 10 tali were on the cusp of two of the sizes found by Trovato et al.⁸ The sizes of implants corresponding to the volumes of each subject are illustrated in

Table 1

Measured volumes of tali and corresponding sizes of implants (Left size was used in all subjects).

Subject	Size		Volume (mm ³)		Percent Difference
	Left	Right	Left	Right	
1	7	7	43988	45679	−3.84
4	4	4	30600	30034	1.85
5	4	4	31539	31412	0.40
9	6	5	38055	36596	3.83
11	6	6	37558	37504	0.14
16	5	6	36130	37685	−4.30
17	9	9	54568	53367	2.20
18	4	4	29689	29309	1.28
22	4	4	30612	29072	5.03
24	5	6	36218	39331	−8.60

Table 1.

A typical DCM of the talar dome (in which the biological talus and the generic implant are overlaid after tibia and fibula are aligned) is illustrated in Fig. 5. The darker blue colours indicate increasing negative deviation of the implant compared to the biologic talus while progressively red colours indicate increasing positive deviation of the implant compared to the biologic talus.

The positive and negative average-deviations (indicating that the implant surface is sitting outside/above or inside/below the biological talus surface respectively) on the talar dome are illustrated in Table 2 by subject and in Table 3 by position. The average among specimens (D_{avg}) positive and negative average-deviations for all subjects in all positions was 0.91 mm and 0.70 mm respectively.

The average positive deviation in mm in dorsiflexion ($P = 0.05$) and plantarflexion ($P = 0.046$) were significantly greater when compared to the neutral position. The average negative deviation in mm between all three groups was not significantly different ($P = 0.77$).

The percentage of the talar dome within the acceptable range of -0.5 mm and 1.5 mm are illustrated in Table 4 by subject and in Table 5 by position. There was no significant difference between the three groups in percentage of talar dome deviation ($P > .56$).

4. Discussion

The implant size for the talus was selected from the scan of the contralateral talus (in this case, the left talus) because in clinical practice, the talus being replaced is deformed and as such, is not reliable to determine the original size of the talus. All 10 left ankles were scanned in the cadaver foot holder and modelled to obtain the sizes for the implants. The generic implant sizes were printed (for the right talus) based on these size determinations. Using the volume of the left talus is valid for determining the right generic talus implant because the left and right talus bones of humans have been found to be mirror images of one another.¹⁷ The articulating surfaces on the talus are critical in considering a total talus bone replacement; however, the talar dome, which articulates with the tibia and fibula in the ankle joint, is of most

Fig. 5. Deviation map of Subject 1 – biological talar dome vs implant talar dome in the neutral position (units in mm).

Table 2

Average deviations of the implant from the biological talus on the talar dome for each subject.

Subject	Average Deviation (mm)		
	Positive	Negative	Standard Deviation (mm)
1	0.94	0.99	1.18
4	1.06	0.45	0.86
5	0.83	0.77	1.03
9	1.19	1.24	1.63
11	0.87	0.72	1.07
16	0.97	0.64	1.06
17	0.74	0.62	1.10
18	0.89	0.66	1.05
22	0.88	0.40	0.92
24	0.74	0.52	0.78

Table 3

Average deviations (of the 10 subjects) of the implant from the biological talus on the talar dome for each position.

Position	Average Deviation (mm)		
	Positive	Negative	Standard Deviation (mm)
Dorsiflexion	0.99	0.72	1.05
Plantarflexion	0.99	0.69	1.15
Neutral	0.75	0.70	0.95

Table 4

Deviations of the biological talus and implant on the talar dome for each position.

Position	Percentage of Talar Dome between –0.5 mm and 1.5 mm deviation
Dorsiflexion	67.96
Plantarflexion	71.57
Neutral	73.45

Table 5

Deviations of implant from the biological talus on the talar dome for each subject.

Subject	Percentage of Talar Dome between –0.5 mm and 1.5 mm deviation
1	61.76
4	77.39
5	64.28
9	53.97
11	72.35
16	71.33
17	76.81
18	69.65
22	81.37
24	81.04

importance because the ankle joint controls plantarflexion and dorsiflexion enabling the ability to walk.¹⁸ Therefore, the focus of implant validation was on the talar dome. By assuming that the biological talus is a perfect fit for the ankle, if the implant sits in the same position as the biological talus, the implant will be an acceptable fit. In order to investigate the position of the generic implant relative to the biological talus, the tibia and fibula from the biological talus scan were aligned with the tibia and fibula from the generic implant scan. Although small movement of the surrounding bone might occur while replacing the biological talus with the generic implant talus we assumed that the location of the tibia and fibula remains unchanged and as such can be aligned. This enabled examining where the implant was positioned compared to the biological talus when the surrounding bones were aligned.

Typically the cartilage is about 1 mm thick on the talar dome; however, considering that at this point we were not accounting for the surface on the opposite side of the talus (in the plan for implantation); the decision was made to add 0.5 mm globally around the talus. In the clinical situation, reduction of an injured talus to within 1 mm is considered satisfactory.¹⁹ Therefore, the implant could be considered to be in the same position as the biological talus if deviations were in the range of –0.5 mm to 1.5 mm. These percentages of the talar dome that lie within this acceptable range are illustrated by subject (Table 4) and

position (Table 5). The results from average deviations indicate that the implant may be compatible. The positive D_{avg} of 0.91 mm is well within the acceptable range (−0.5 mm to 1.5 mm). The 0.70 mm negative D_{avg} is just outside the range indicating there may be issues with the implant sitting slightly too far inside from where the biological talus was. The implant sitting inside of the biological talus indicates that the articulating surfaces in the case of the implant is recessed relative to the biological talus at that particular location. This might be less of a concern than the reverse as it will not result in increased pressure on the opposing articular surface at that location. Furthermore, if it is a small area, its effect will likely be minimal. In the three scenarios here, the percentage area that had a negative deviation greater than 2.0 mm was less than 3.2% in all groups. On the positive deviation, less than 4% of the surface area had positive deviations greater than 2.5 mm. On average, 70% of the deviations on the talar dome between the biological talus and implant were within the acceptable range. This indicates that the geometric compatibility of the implant when in the ankle joint may be tolerable. It is important to note that the cartilage on the biological talus was dehydrated and thinner than expected. This is a limitation of the study because the biological talus may not have been situated in a completely normal position within the ankle mortise. It was difficult to compensate for this fact considering that the joint had to be dissected and the generic implant inserted for comparison purposes therefore cadavers were required.

Dorsiflexion and plantarflexion take place between the talus and the tibia/fibula within the ankle mortise; therefore, this type of motion is of great importance to the study. The passive range of motion of the ankle is 20° dorsiflexion and 50° plantarflexion.²⁰ The range of motion for the ankle joint that corresponds to normal walking is 10° dorsiflexion to 20° plantarflexion.²¹ Since the clinical objective of a talar body replacement is to restore the normal walking range of motion, it is important that our study encompasses that complete range. The dorsiflexion range was increased from 10° to 20° as 10° dorsiflexion is very near neutral and that small variation in range may not be as informative. As such, the range of 20° dorsiflexion to 20° plantarflexion was chosen for this study. From Tables 3 and 5, the implant matches the biological talus best in the neutral position as there are the lowest deviations between the biological talus and generic implants in this position noted in the positive deviations. There is no difference noted in negative deviations in any position. The difference in positive deviation is less than an average of 0.25 mm which indicates that the implant maintains similar congruity as the biological talus does throughout functional range of motion.

Size discrepancies may be the cause of some of the increased deviations as six of the tali were on the cusp of two different sizes (e.g. subject 9, size 5 for left foot and size 6 for right foot). These discrepancies may be because there is a small margin of error in the modelling process especially due to the fact that many of the scans showed osteopenic bones that are more difficult to model (likely due to the age of the cadavers). Results may be improved upon by either sizing up or down an implant accordingly. In a clinical setting, it would be ideal to have two or three trial sizes of the implant available. The surgeon would then be able to place each implant into the joint and determine which implant fits the joint best using direct vision and fluoroscopic guidance. That said, given the differences are in fractions of millimeters in some measurements, it may be difficult to visualize the actual effect and the corresponding articulating cartilage on the opposing surface may be able to mask some minor irregularities.

From this study it appears that a generic implant chosen based on our earlier study revealed good functional and geometric compatibility of the ankle joint as compared to biological talus. The majority of the articular surface of the dome of the generic implant talus was within 1 mm deviation (positive and negative) compared to the biological talus over a 10 sample range. This study mimicked the clinical scenario where an uninjured left talus would be CT scanned and used to determine the size of a generic right sided talus implant. The ability to range the generic implant 40° without much change in conformity is

promising for actual clinical outcomes. Future work should entail use of magnetic resonance imaging (MRI) data to determine cartilage thickness in surrounding cartilage and finite element analysis to determine contact pressures throughout the joint surface comparing a custom talus implant modeled exactly to the biological talus versus a generic implant as described in this study.

Ethical approval

Ethical approval was obtained from the University of Alberta Human Research Ethics Board Biomedical – Determination of talar dimensions Pro00026057.

Conflict of interest

None.

Funding

Funding for this research was provided by Alberta Innovates Technology Futures, Natural Sciences and Engineering Research Council of Canada, University (of Alberta) Hospital Foundation and Edmonton Orthopaedic Research Committee. None of the funders had any input into any aspect of the research.

Authors contributions

ANT – study design, study performance, preparation and review of manuscript; TDB – study performance, preparation and review of manuscript; ME – study design, data analysis, and manuscript review; SSD – CT consultation and performance and manuscript review; SA – study design, data analysis, manuscript preparation and review; NMJ – study design, study performance, data analysis, manuscript preparation and review.

Acknowledgments

We would like to acknowledge Shannon Stefaniuk, Carmen Thompson, and Heidi Corrigan at Medical Imaging Consultants, Century Park for assisting with the CT scanning process; Hugh Barrett and Jason Papirny with the Anatomical Gifts Program at the University of Alberta for their assistance with the cadavers; and Craig Michael Goplen for assistance with cadaver dissection.

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