EXACTECH | **EXTREMITIES**

Design Rationale

VANTAGE® TOTAL ANKLE

Fixed Bearing Design Rationale

VANTAGE®
TOTAL ANKLE

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Design Team

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Victor Valderrabano, MD, PhD, is an internationally-renowned foot, ankle and traumatology specialist in Basel, Switzerland. Dr. Valderrabano received his medical degree from the University of Zurich and a doctorate in biomechanics from the University of Calgary. Dr. Valderrabano is an accomplished author and presenter.

James DeOrio, MD, is a foot and ankle specialist and professor of orthopaedic surgery at Duke University. Dr. DeOrio completed his fellowship at the AO Foundation in Switzerland, and is a world-renowned foot and ankle surgeon, passionate about research and development. He has performed more than 1,300 total ankle surgeries and is co-editor of "Total Ankle Replacement: An Operative Manual."

Mark Easley, MD, is an associate professor of orthopaedic surgery and co-director of the foot and ankle fellowship at Duke University Medical Center. Dr. Easley completed a foot and ankle fellowship at Union Memorial Hospital and a knee fellowship at the Insall Scott Kelly® Institute. He is the immediate past-president of AOFAS and continues to be involved in national and international educational opportunities and foot and ankle research.

Introduction

The Exactech Vantage® Total Ankle System was designed through a collaborative effort of engineering research and the global thought leader expertise of Victor Valderrabano, MD, PhD; Mark Easley, MD; James DeOrio, MD; and James Nunley, MD. Their goal was to design an anatomic and bone conserving total ankle system that addresses the current clinical challenges and the biomechanics of the native ankle.

The tibial component is an anatomic design that is right- and left-specific to respect the native anatomy of the tibia as well as provide articulation of the fibula. It utilizes a press-fit central cage and plasma pegs to achieve initial fixation.[1] Meanwhile, the talar component is designed with a bicondylar articulating surface that replicates the native anatomy with the goal of reproducing the natural biomechanics during the gait cycle.[1] It preserves bone through an arc-shaped talar interface that follows the diseased anatomy, which was based on the results of a CT reconstruction study that focused on the differences between healthy and diseased talus morphologies.[1-2]

The Vantage Ankle is designed to address clinical challenges, such as cyst formations and subsidence around the implant. The tibial design does not violate the anterior cortex, and the talar implant allows for a uniform load transfer from the implant to the prepared talar bone. To further address the risk of talar subsidence, the anterior talar shield supports the implant on the talar neck.

Design History and Evolution of Designs

Total ankles have been implanted since the 1970s. These first generation ankle replacements were formed by two components: a concave polyethylene tibial component and a convex metal talar component. Constrained and non-constrained designs were used, but poor results and high failure rates were recorded.[3]

Overall, first generation designs required large bone resections and cement fixation, and after their poor results, there was a quiet period for ankle designs until the second generation designs in the 1980s.[4] The first U.S.-designed total ankle, DePuy Synthes' Agility™ LP Total Ankle Replacement System, was launched in 1992 and designed by Frank Alvine, MD. By this time, second generation ankles were semi-constrained, cementless and used porous coatings to encourage bone in-growth.[3]

Third generation implants were introduced globally with the launches of the Salto (Tornier), Hintegra® (Allegra), Mobility™ (DePuy), Takakura Nara Kyocera (TNK) and the BOX® (MatOrtho). Almost all of these designs were three-part, mobile bearing implants. The third and fourth generation implant systems incorporated one or more of these design features: anatomic biomechanics and unique implantation techniques. Some examples of third and fourth generations designs include the INBONE™ (Wright), Salto Talaris® and the Zimmer Biomet Trabecular Metal™ Total Ankle.[5]

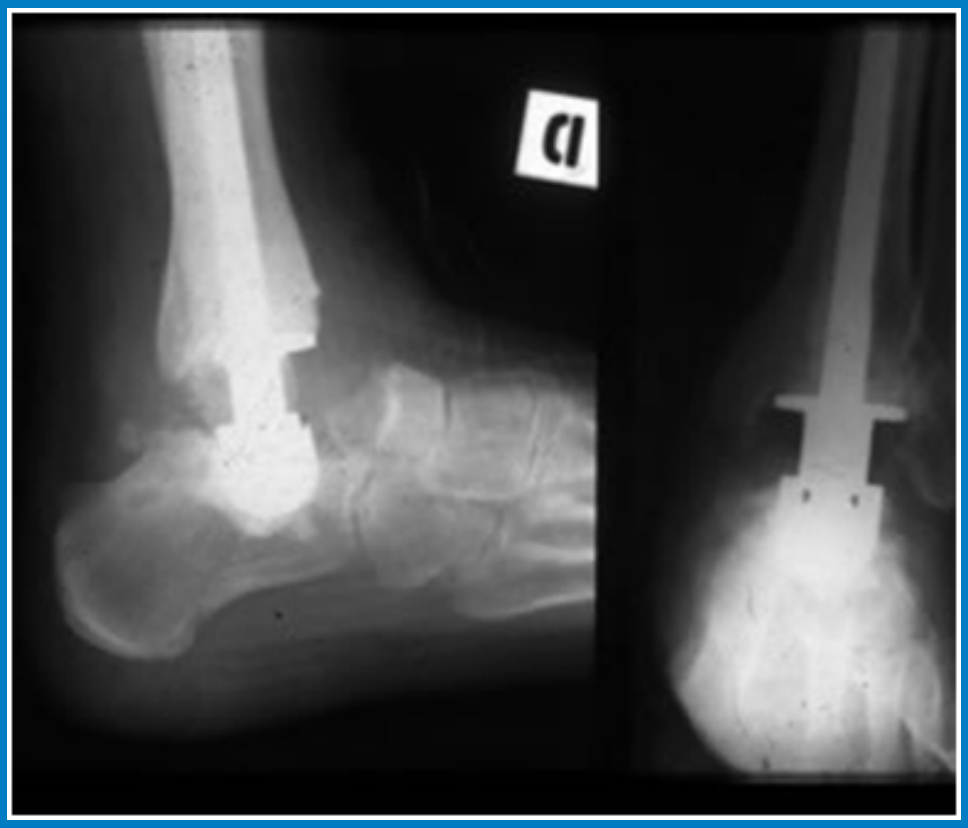


Figure 1: Lord and Marrotte implant 1970

Table 1[3,5-6]

Name	Year	Designer	Design
First Generation			
Lord and Marrotte	1970	Lord and Marrotte	Inverted hip
St. Georg Prosthesis	1973	Swedish surgeon	Semi-constrained
Imperial College of London Hospital TAR	1972	Bolton-Maggs	Two-component, constrained total ankle with polyethylene tibial component[7]
Irvine Total Ankle	1970s	Waugh, Evanski, Freeman	Non-constrained, tried to recreate the talar anatomy
CONAXIAL Beck-Steffe Prosthesis	1975	Beck-Steffe	Constrained implant
Mayo Total Ankle Replacement	1974	Stauffer	Constrained design
Newton Ankle Implant	1970s	Newton	Incongruent surface, two components
Richard Smith Ankle Arthroplasty	late 1970s		Non-constrained, incongruent surface
Thompson-Richard Prosthesis (TPR)	1976		Hinge only, allowed plantar and dorsiflexion
Bath-Wessex Total Ankle Implant	1980s		Two-component, non-constrained
Second Generation			
New Jersey LCS Implant/Buechel-Pappas	1981	Pappas and Buechel	First mobile bearing design
DePuy Agility	1984	Alvine	Longest design used in U.S., fixed bearing, semi-constrained, sintered bead surface
Scandinavian Total Ankle Replacement (STAR™)	1981/1984	Koefed	Fixed bearing, unconstrained, changed to mobile bearing 1984
Third Generation			
STAR (Third Generation)	1990	Koefed	Mobile bearing, unconstrained, talar facet covered by implant, added double HA coating to improve fixation in 1999
ESKA Ankle Prosthesis	1990	Rudigier	Lateral approach, fibula takedown
Salto	1997	Bonnin	Non-constrained, more anatomic of talus, cementless
Hintegra	2000	Hintermann	Screw fixation for tibia extended flange on talus
Mobility	2002	Rippstein, Wood, Coetzee	Mobile bearing, BP-type prosthesis, tibial stem
BOX	2003	Rizzoli Institute-Oxford, UK	Normal ankle kinematics
INBONE	2005	Riley	Semi-constrained, modular, long tibial stem, convex talar component, cemented
Salto Talaris	2006	Bonnin	Semi-constrained, fixed bearing design, cemented
Zimmer Biomet Trabecular Metal Total Ankle	2012		Lateral approach, resurfacing of talus requires fibula takedown and plating
Vantage Total Ankle	2017	Valderrabano, Easley, Nunley, DeOrio	Semi-constrained, cemented fixation on tibial side, curved talus, anatomically-shaped talus and tibia

Summary of Clinical Experience

Clinical results have led to much debate on the efficacy of total ankles. Many studies have looked at implant-specific results, registries, hospital volumes and the learning curve of the surgeons.[8] Direct comparisons among specific implant designs are difficult to make due to the learning curve, implant changes over time, and other variables that cannot be accounted for through function and outcome scores.

PAIN AND FUNCTION SCORES

However, one consistent result is that pain and function scores have improved. Gougoulias et al., reported improved outcome scores in 13 studies reviewed for meta-analysis; and Haddad et al., reported AOFAS score improvements in both total ankle and arthrodesis patients.[5,9] These positive function and pain results have been reported even when considering varying patient ages, obesity and preoperative deformities.

Likewise, Demetracopoulos et al., reported all patient groups (younger than 55, 55-70 and older than 70) in his 395-patient study had significant improvements in function and outcome scores.[10] Gross et al., also published a prospective study of 455 primary total ankles with a minimum follow-up of two years and showed significant improvement in post-operative function scores at their one year follow-up.[11] The patients were divided into three BMI groups: under 30 (266 patients), 30-35 (116 patients) and over 35 (73 patients). There was no difference of complication, infection or failure rates between the three groups.

INCONSISTENT DEFINITIONS

A big concern with total ankle results is the inconsistency in defining a failure/complication. Many studies consider an outcome a failure only if one or more of the metal implants have been removed. Surgeries that do not require metal implant revision, such as polyethylene removal or bone grafting for cyst formations, are not considered a failure or complication. Therefore, it is important to consider discrepancies in interpretation of failures/complications in reviewing any clinical outcomes results.

With those parameters in mind, there is value in reviewing compiled research from multiple sources in the area of ankle arthroplasty.

Gougoulias completed a meta analysis that examined total ankle studies and concluded an average overall failure rate of 10 percent at five years with a wide range of 0 to 32 percent was found.[12] Haddad et al., also reviewed publications from 1990 to 2005, including conference presentations for 2003-2004, and found implant survivorship 78 percent at five years.[9] Similarily, Zhao et al., performed a systematic review on available literature for the STAR™ Ankle, consisting of 16 studies with 2,088 implants. An average survivorship of 85.9 percent at five years and 71.1 percent at 10 years were reported.[13] All of these systematic meta-analysis results are much lower than the reported greater than 90 percent, 10-year hip survivorship and 15-year knee survivorship.[14]

INTERNATIONAL RESULTS

In addition to the meta-analyses, outcome data of international joint registries can be beneficial to review, but with the knowledge that some international sources, such as from New Zealand, Sweden and Norway, have lower volume of total ankles. For example, a 2007 New Zealand study reported results of 86 percent at five-year survivorship for 18 surgeons and 18 hospitals.[15] In this study, only two surgeons had performed more than 25 total ankle replacements. Henricson et al., reported on 780 total ankles implanted between 1993 and 2010 and showed a similar high failure rate with a five-year survivorship of 81 percent and a 10-year survivorship of 69 percent.[16]

Additionally, a study from the UK database examined reoperation rates within 12 months of a procedure and found positive results. The revision rate was 6.6 percent, which is lower than both hip and knee reports; however, they did not consider polyethylene removal a revision. Another concern is that the database itself mentions its low revision rates being inconsistent with other studies.[17] The British Orthopaedic Foot and Ankle Society stated of the 2016 UK registry, "BOFAS believes that

the small number of revisions above may indicate under-reporting of the revision procedures as these figures are lower than published data in the literature."[18] Another weakness is that ankle failure modes may have a longer timeline for presentation, and that study only looked at the 30 days and 12 month revision procedures.

IMPLANT LOOSENING

One of the reasons suggested by the literature for the high percentage of TAR failures is due to implant loosening, which can present itself after 12 months. Gadd et al., performed a retrospective review of the Sheffield Foot and Ankle Unit TAR database from 1995 to 2010. They concluded a 23 percent complication rate and a 17 percent revision rate of the 217 implants. Three percent of the complications were due to aseptic loosening, which the authors regarded as a high grade complication *(Table 2)*. Complications that were classified as aseptic loosening required revisions 80 percent of the time. In addition, five revisions were excluded from the data due to "unclassifiable poor outcomes." If included, these five patients would result in a revision rate of 19 percent.[19]

IMPLANT SPECIFIC RESULTS

Over the years, ankle implant designs have evolved and different design elements have resulted in different outcomes. There are multiple studies that look at only one implant. Criswell et al., showed good pain relief, represented by VAS score in the Agility TAA, but still saw high failure rates (39 percent revision rate within an average of four years).[20] Meanwhile, Giannini et al., reported the BOX Ankle Replacement had a short-term follow-up with promising AOFAS score improvements, reoperation at only 6 percent and two cases for full implant removal.[21]

Adams et al., reported that Wright Medical's INBONE implant showed significant improvements in VAS pain scores and AOFAS scores as well as patient self-assessments.[22] Revisions occurred in 6 percent of patients, with revisions defined as removal of the metallic prosthesis, and 11 percent (21 patients) had "non-revision-" related operations directly related to TARs. "Non-revision" procedures include debridement for impingement and bone grafting for osteolytic cysts.[22]

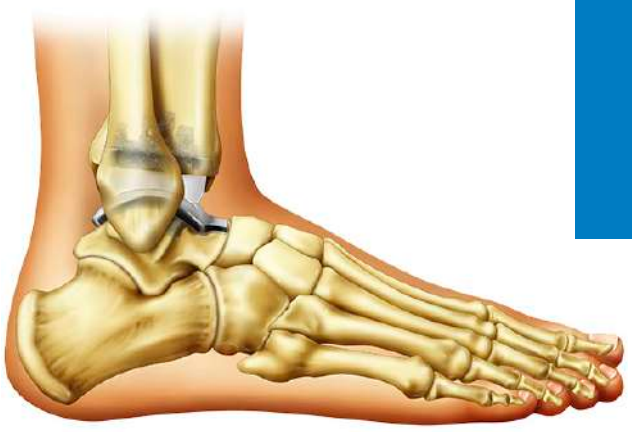


Table 2: FIG Grades[19]

Grade	Complication
High	Deep Infection
	Aseptic Loosening
	Implant Failure
Medium	Technical Error
	Subsidence
Low	Postoperative Fracture
	Intraoperative Fracture
	Wound Healing Issues

This table showcases the complication grades of Gadd's study. Aseptic loosening is a high grade complication.

There are three recent studies that describe the use of the Salto Talaris. Gaudot et al., studied the difference between the fixed and mobile bearing versions for a short-term study with an average of two year follow-up, ranging from one to five years. The study concluded that both mobile and fixed bearing designs showed significant improvements in AOFAS scores. The mobile bearing prosthesis reported 18 percent subluxation between the tibial component and the polyethylene insert and only one case of talar necrosis in the fixed bearing design. There were, however, significantly more radiolucent lines around the tibial implant in the mobile bearing cohort than the fixed bearing (39 percent vs.12 percent).[23]

Chao et al., also reported on the high radiolucent lines at rates of 30.4 percent in the fixed bearing version of the Salto Talaris.[24] Oliver reported positive results of 3 percent reoperation for gutter debridement and 2.3 percent revision to fusion or another total ankle.[25]

The Stryker's STAR is the only mobile bearing system in the U.S. market. Three studies reported its medium to long-term outcomes. Mann et al., showed a 25 percent complication rate and 14 percent revision rate when a revision is defined by any type of revision.[26] Karantana et al., also reported similar results with survivorship at 84 percent at eight years and a 17 percent revision rate.[27] Brunner et al., however did not replicate those results and reported a 38 percent revision rate and 70 percent survivorship at 10 years.[28] A possible explanation to the variance of results in the studies is that Brunner's average follow-up was longer.[28]

Table 3: Implant Comparison[20-28]

Clinical Results						
Authors	**Implants**	**Mean F/U**	**Survivorship**	**AOFAS Scores Pre-Op**	**AOFAS Post-Op**	**VAS Score**
Criswell 2009	Agility	8 years	62 percent at 9 years			4
Giannini 2011	BOX	1.4 years		36.3	79	
Adams 2014	Inbone	3.7 years	89 percent at 3.7 years	39.7	78	14.1
Gaudot 2014	Salto	2 years		34	85	
Gaudot 2014	Salto Talaris	2 years		35	90	
Oliver 2016	Salto Talaris	3.3 years		41.1	84.9	17.9
Chao 2015	Salto Talaris	3 years	82.6 percent at 3 years	42.7	88	1.3
Mann 2016	STAR	9.1 years	86 percent at 11 years	42.7	81.9	1.7
Brunner 2013	STAR	12.4 years	70.7 percent at 10 years	25	73	2.4
Karantana 2009	STAR	6.7 years	84 percent at 8 years	n/a	78	

TECHNICAL ADVANCEMENTS

The goal of arthroplasty is to recreate the patient's normal alignment and provide the best opportunity for long-term outcomes. Malrotation and malalignment in a total ankle implant can increase stresses and decrease contact pressures, which can contribute to polyethylene wear and increase the mode of failure.[29] Patient-specific instruments (PSI) have been studied extensively in total knee arthroplasty (TKA) and reported mixed results. Some studies support PSI, some are agnostic, and others have been against the use.[29]

A key difference between TAR and TKA is that their respected methods of guidance are very different.[29] A TAR requires a significant amount of fluoroscopy, which adds time, cost and radiation exposure to both patients and staff. Regardless, the very epidemiology of ankle arthritis is reason enough not to extrapolate the inconsistent results found in TKA literature.[30] Saltzman et al., showed that 70 percent of patients with ankle arthritis were post-traumatic, which can lead to the need for treatment of malaligned ankle joints.[31]

Exactech Design Philosophy

Exactech combined some of the best minds in total ankle arthroplasty with a committed team of engineers to answer the question: can we do better? The previous clinical studies have shown that the complications and revision and survivorship rates are not equivalent to other joint replacement procedures.[14,32] Many of the papers attribute this to the procedural difficulty of TARs.[5] Most of the studies previously discussed "hedge" their complication and revision rates by classifying them as categories, such as insert fracture or exchanges, and unexplained pain or impingement.

The challenge Exactech embarked on was to create an ankle that addresses these clinical challenges. **James Nunley, MD; Mark Easley, MD; James DeOrio, MD**; and **Victor Valderrabano, MD, PhD**, worked with Exactech to identify six unmet clinical needs:

- Implant subsidence
- Implant loosening
- Bone cysts around implants
- Instability
- Impingement leading to pain during movement/activity
- Polyethylene revision

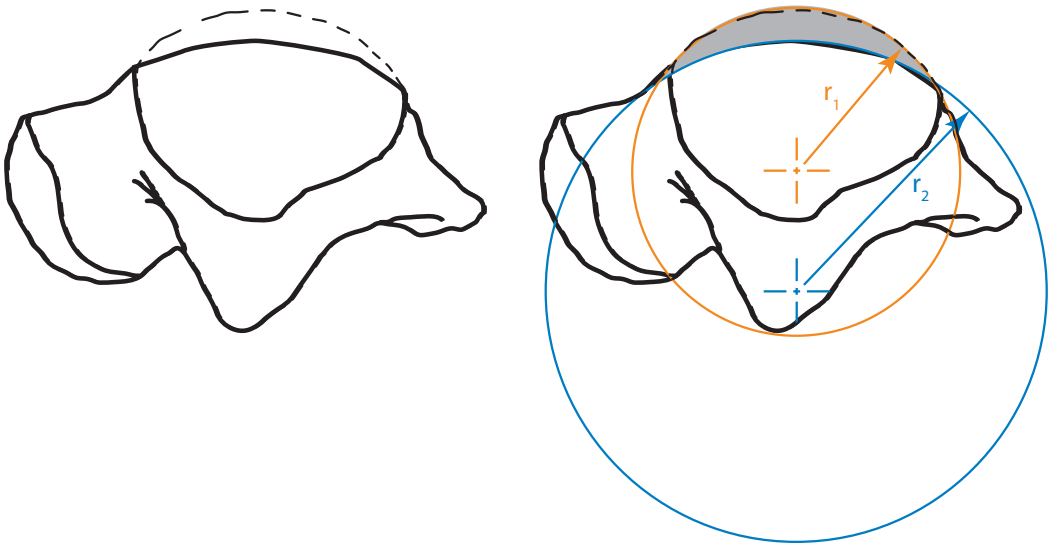
Implant Subsidence

During the design of the Vantage Ankle, we examined several studies that focused on bone strength and the concern that subsidence presents a high risk of potential failure in total ankles.[32-34] Many world-renowned foot and ankle surgeons have described their concern using non-anatomic implants that do not make use of the whole resection surface.[35] The knowledge gained from these studies helped us focus on learning the anatomical changes that occur in the arthritic ankle, and, in effect, led to an implant design with the goal of reducing that risk.

A study on 10 amputated specimens, by means of multiple penetration tests, showed that the tibial bone is weaker than the talus by about 40 percent.[33] Lee et al., reported on a radiographic study of 262 ankle replacements and determined that 62.2 percent had some form of radiographic abnormality with a lucency rate of 34 percent and a hardware subsidence rate of 24.4 percent.[36] Penner, Almousa and Kolla also described the leading cause of total ankle failure as aseptic loosening with or without implant subsidence.[35]

Another study that helped us was by Wiewiorski. Wiewiorski et al., in 2016 performed a computed tomographic evaluation of patients with end-stage ankle arthritis.[37] This study looked at patients with primary osteoarthritis (OA) and compared it to a patient-matched control group with patients of the same age, gender, height, weight and BMI. The results showed primary OA patients with an increase in the radii of curvature in the talus' sagittal plane, which suggests an overall flattening of the talus. The flattening of the talus was further eluded to by the change in talus height of 1-2mm compared to the control group. The primary OA patients also had an increase in A/P width on the tibia as well as a sagittal curvature of 1-2mm change that matched the morphology on the talus.[37]

Figure 2: Representation of Collapsed Talus[37]



CT RECONSTRUCTION AND SIZING STUDIES

Using Wiewiorski's study as a foundation, Exactech created a library of healthy and diseased patients from U.S. and Europe with collaboration from our design team surgeons. A cohort of 22 OA patients and 19 healthy patient matches were used. We modified the measurements from Wiewiorski's study in order to provide reference points with the goal of creating an implant to address the diseased anatomy. The resulting implant geometry is an anatomic tibia that provides articulating space for the fibula as well as respecting the size and shape of the posterior and anterior portion of the tibia.[1]

In addition, we also completed a sizing study using the population of 73 CT scans to determine the size offerings of the Vantage Ankle.[1]

ANATOMIC STUDY

Likewise, our anatomic study used a similar method in order to design the talus component. Exactech recognized that there was a collapse of the talar height as osteoarthritis progresses.[1] This is an important design input as it allows for the surgeon to prep and address the diseased talus while providing an articulating surface that recreates the normal anatomy.

Although the subsidence of the implant is normally found in the tibia[32], migration of the talar component can also be detrimental to the prosthesis. A study from Granata et al., presented at the AOFAS 2013 annual meeting, reported talar subsidence in the AP and lateral radiographs.[34] The Vantage Ankle design team recognized the risk of this complication, and in addition to the anatomic considerations, designed the talar component with an anterior flange that provides support to the talar neck to increase the load sharing of the implant.[1]

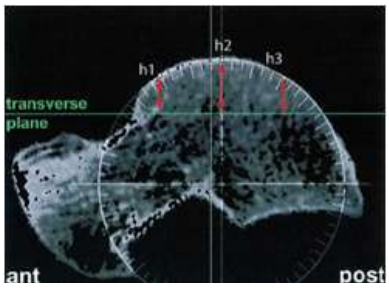


Figure 4: A CT scan of a healthy talus with measurement markers that was used in the CT study.

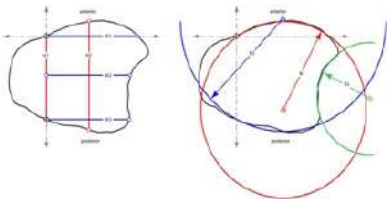


Figure 5: Engineers compiled data from the CT studies to design the tibia component.

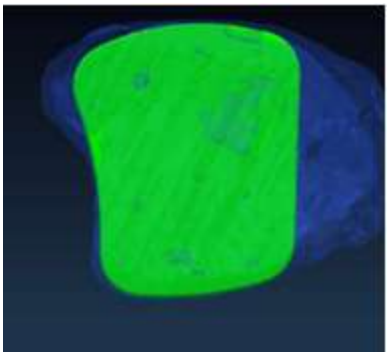


Figure 6: This is a CT scan of a virtual template of the tibia component in place.

Figure 7: Vantage Ankle Fixed Bearing System

Implant Loosening

Infection and implant loosening have been identified as the major failure modes that lead to TAR failure.[5] Early designs that relied on cemented all-polyethylene tibia components resulted in catastrophic failure. Since then, many different designs have attempted to develop fixation methods for total ankle implants.

All designs to date have used different materials and shapes of fixation, such as pegs, stems, modular stems, rails, cylinders and rectangular bars.

All ankles within the U.S., except STAR, are indicated for use with cement. The Vantage Ankle uses its press-fit central cage and plasma pegs on the tibia to achieve initial fixation, and it uses cement on the tibia and talar for the primary mean of fixation. Meanwhile, the talar component's curve-on-curve shape is designed to create inherent stability in the A/P direction, and its pegs provide stability in the medial/lateral.[1]

The Vantage Ankle has full coverage on the tibia component while also providing a curved talar design that reduces the amount of talar preparation and provides a stable interface throughout the gait cycle.[1] When the talar is prepared using a flat or a chamfer cut, then the loading profile and shear force changes during the gait cycle *(Figures 8 and 9)*.

In a flat cut during plantar flexion, there is an increased shear force on the bone implant interface. Likewise, a chamfer cut design yields high contact stresses on the chamfer interface throughout the gait cycle.

In comparison, the curved talus provides constant loading to the prepped surface and strengthens the talus' bone support *(Figure 10)*.[38] The ability for a curved talus preparation to provide stability was tested internally at 1 million cycles with a maximum load of 890 pounds and 99 pounds of shear force.

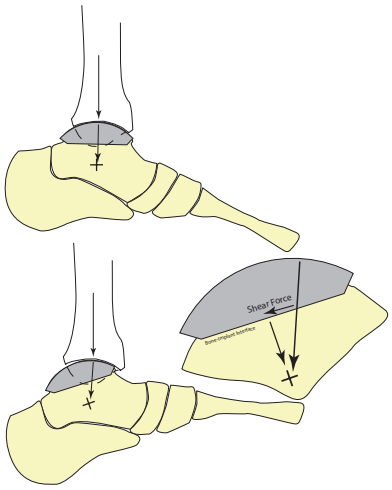


Figure 8: Flat Cut Talar Preparation

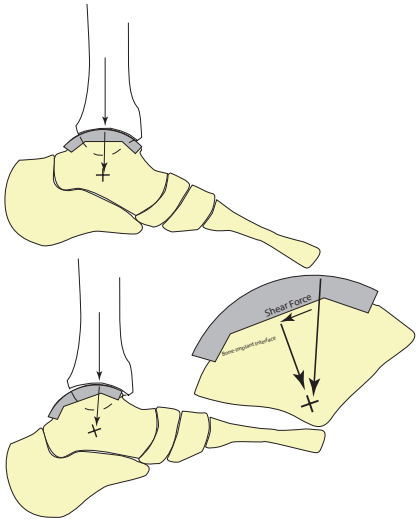


Figure 9: Chamfer Cut Talar Preparation

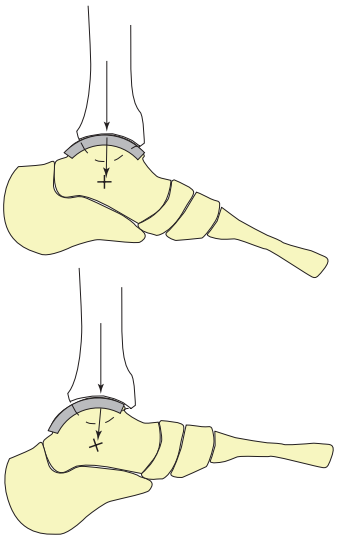


Figure 10: Curved Cut Talar Preparation

Bone Cyst Around the Implant

A high incidence of osteolysis has been described in TAR. Literature has reported 0 to 94.7 percent incidence of osteolysis.[39] There have been many thoughts on the causes of cyst formations, but no definitive agreement on its origin. Jan Willem K. Louwerens, past president of the European Foot and Ankle Society, commented to *Orthopedics Today Europe*, "Sometimes we think it is polyethylene wear or it might be a form of stress shielding, or a combination, or it is joint fluid getting into these cysts."[40]

The most common thought on osteolysis is that polyethylene particles react with the bone and cause osteolysis. This has been a common mode of failure in total hip arthroplasty, and it has been theorized that ankle cysts are formed by a similar mechanism.[39,41] Atkins reviewed the role of polyethylene articles in periprosthetic osteolysis and found convincing evidence that particles produced by the wear of the prostheses are causal in the loss of bone around the implant. The review of hip literature showed that the size of the particles and access can increase the bioactivity of the polyethylene and bone reaction.[41]

Besides Atkins' study, few other studies have been conducted for this and all contain small sample sizes. An internet search of "ankle osteolytic cyst" resulted in six studies, with the largest sample size at 50, which used the Ankle Evolutive System (AES) implant. Four of the six studies used histologic results to determine the cause. Besse found polyethylene particles in all samples and metal particles in 16 cysts; however, there was no correlation with the samples, polyethylene particles and time of reoperation.[42] This led to the conclusion that polyethylene particles were not the primary cause of the cyst formations, but most likely a secondary factor.[42] Meanwhile Dalat et al., concluded the opposite and showed that 95 percent of 22 AES ankles had polyethylene particles and that implant debris seems to be implicated.[43]

The current method for treating bone cysts is to re-operate and graft the lesions. Gross et al., showed a 60.6 percent success rate after 48 months following a bone grafting cyst without need for removal of the implant.[39]

While this showed that there is a treatment option that can extend the survivorship of TARs, we wanted to design an implant aimed to address the complication of cyst formation.

VANTAGE ANKLE DESIGN

The Vantage Ankle took a five-stage approach to cyst formations:

- Address micromotion
- Minimize bone resection
- Do not violate the anterior cortex
- Address stress shielding
- Use a polyethylene that has a high fracture toughness and low wear

The anatomic left and right tibia and talar components allow for the ankle implant to be placed in a position that offers better coverage and support.[1] This is a design feature that provides a better fit than non-anatomic designs.

By minimizing the amount of bone removed on the talar side and providing a curved surface for the implant to sit, the Vantage Ankle is designed to provide a good fit without removing excess subchondral bone.[1] By removing less bone, the pathway for polyethylene debris to enter the talus and tibia is minimized. In comparison, many early ankle designs used barrels or cylinders to aid in rotational control of the implant. The Vantage Ankle was designed to avoid violating the anterior tibia in order to minimize the pathway for polyethylene debris.[45]

FINITE ELEMENT ANALYSIS

The Vantage Ankle team conducted a study to review the effect of stress shielding based on implant design. Wolf's law states that bone that is not stimulated will atrophy, meaning there is reason to believe that stress shielding can cause bone cyst formations.[38]

Specifically, Exactech conducted a Finite Element Analysis (FEA) of the STAR, Salto Talaris and Vantage

Ankle designs to see if the load applied to the implant would load on the fixation points of the implant and create stress shielding below the fixation points. The study applied 300 pounds of force perpendicular to the tibial implant of all three designs to determine the risk of stress shielding.

The FEA analysis of the STAR showed a substantial decrease in stress from the top part of the barrels to the tibial surface, an increase in stress at the top of the barrel, and significant stress at the edges of the tibial component. In the Salto Talaris, the area from the center of the keel to the outer edge of the tibial component received less stress than the surrounding areas *(Figure 11)*. There was no clear evidence of stress shielding where the bone stress field was blocked by a protrusion on the implant; there was a disproportionate load transfer under the keel of the Salto Talaris and between the barrels of the STAR.

In comparison, the Vantage Ankle's cage and peg design showed elevated stress at the top of these fixation points, though in a very low amount (.5 MPa to 3.0 MPa), indicating that the implant does not transfer excessive load in any one region *(Figure 11)*. It did demonstrate regions of higher stress at the superior surfaces of the pegs and cage; however, these stress fields, along the tibial bone interface, were more uniformly distributed than the other devices in the study.[1]

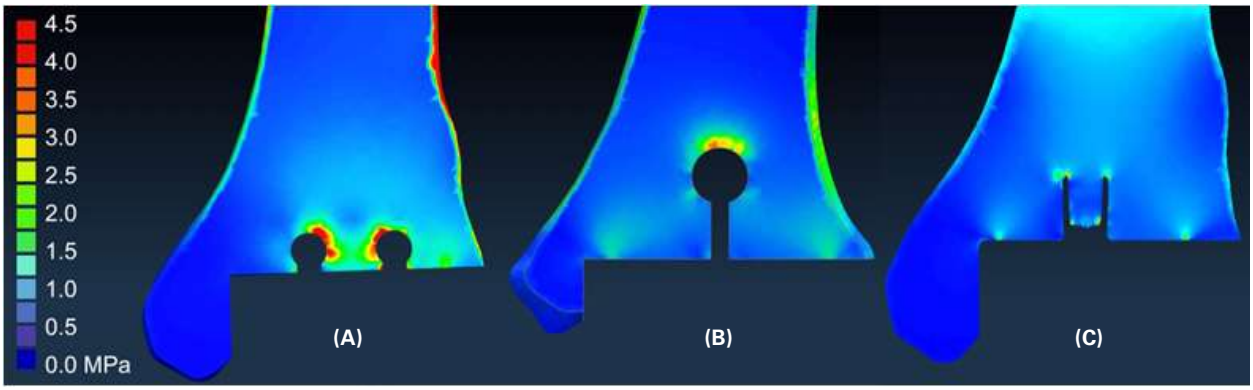


Figure 11: FEA Analysis[1]

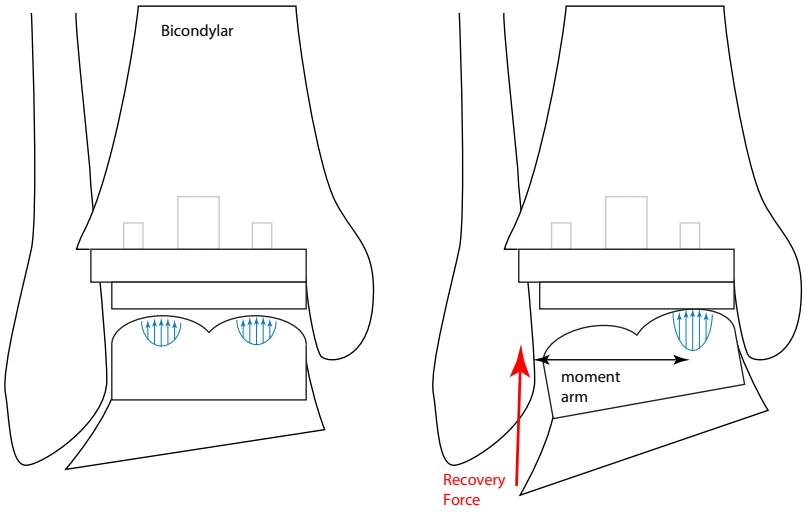


Figure 12: Bicondylar Stability

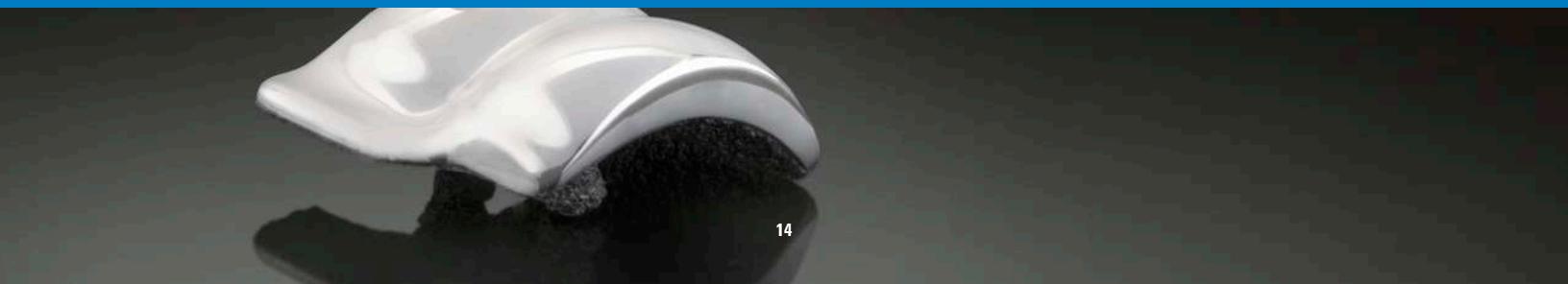
A semi-constrained bicondylar design allows for the implant to continue to have broad contact when the ankle goes into varus/valgus tilt.

Instability

The Vantage Ankle utilizes a bicondylar-shaped talus and polyethylene insert with the goal of increasing stability and reducing contact forces. The anterior/posterior congruency between the metal talar component and the polyethylene insert provides resistance in the anterior/posterior direction. The sulcus between the two condyles in the coronal plane is designed to resist movement in the medial-lateral direction. The A/P translation of the talus relative to the tibia is between 2 and 6mm depending on the study reported.[45-46] The Vantage Ankle maintains peak constraint in the A/P direction +-2mm and continues constraint to 10mm of translation.[1]

The degree of constraint needed to resist dislocation was based on the ratio of shear force applied to general motion to the normal load across the joint. The bench study, which Exactech conducted, showed that the shear force ratio needed to dislocate the ankle prosthesis in +-15-degrees of flexion is 2.3 times the reported ratio in the anatomy during that point in the gait cycle.[1] In the medial lateral direction, the ankle is aided by the medial malleolus, the lateral fibula, and soft tissue. The Vantage Ankle has peak constraint in +-1mm of medial-lateral translation and follows closely with cadaveric ankles in rotation until beyond 5 degrees of rotation. At this point, it is expected that soft tissue will play a roll.

Another benefit of a bicondylar shape is in varus/valgus tilt. A semi-constrained bicondylar design allows for the implant to continue to have broad contact when the ankle goes into varus/valgus tilt *(Figure 12)*. We believe this is an important design aspect because of the hyper-mobility of the ankle joint.



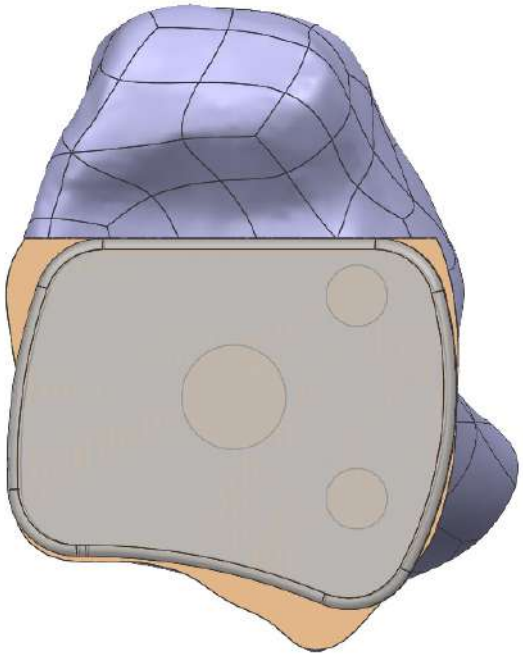


Figure 13a: Vantage Ankle Tibia Design[1]

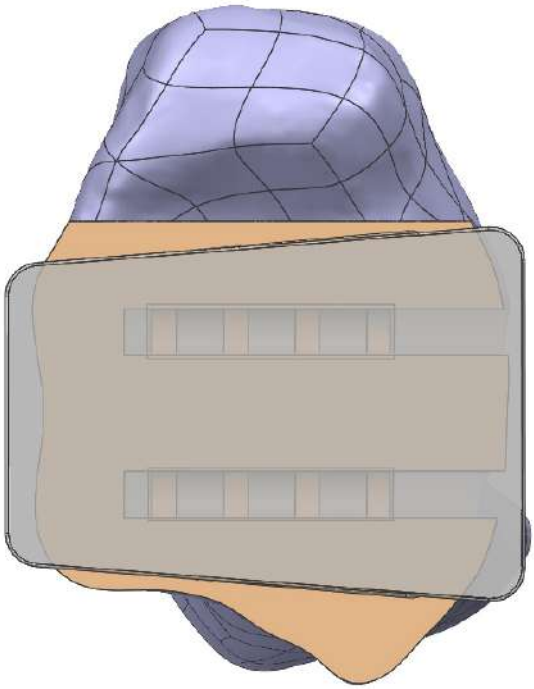


Figure 13b: Historical Tibia Designs[1]

Pain During Activity

IMPINGEMENT

When designing an ankle replacement that has a complex geometry, it is necessary to make an implant that respects the left and right orientation of the anatomy. The investigation of a painful TAR is difficult and can end without a definitive cause of pain; however, the most common explanation is impingement with gutter clean-up as the most commonly recommended solution.[47]

Residual pain has been reported as high as 60 percent and malleolar-specific pain as high as 23.5 percent.[5,48] Although the literature does not classify this as a revision, the Vantage Ankle team took a different view. If patients are required to have reoperation due to pain, then it's not an ideal situation for patient or surgeon. The Vantage Ankle utilizes left- and right-specific tibial implant components that are designed to create a best-fit implant *(Figure 13a and 13b)*.

BIOMECHANICS

Another theory on the cause of residual pain is painful collateral ligaments. Hintermann reported that the use of non-anatomic talar components (symmetrical radius of curvature) caused overstretching of the medial collateral ligaments.[49] Based on Hintermann's learning and other studies, we completed a review of the market's implant designs and their biomechanic philosophies.

One issue with the market's current understanding of ankle biomechanics is the available research that lacks modern technology. In 1952 and 1956, Close and Inman published their work on ankle biomechanics.[50] They classified the ankle joint as a one degree of freedom joint with a fixed axis. This axis was defined as running from the distal tip of the medial malleolus to the distal tip of the lateral malleolus. The lateral fibula is lower than the distal tibia, which means the axis is not parallel to the articulating surface of the talus. The subsequent anatomic measurements of the talus were based on the single axis assumption. The best-fit circle measurements used by Inman and others concluded that the medial side radius of curvature is smaller than the lateral side. However, Inman himself questioned the conical shape and observed that it is incongruent with the pronation and supination of the ankle joint.[50]

Leardini, O'Connor, Catani and Giannini have published an alternate theory. They studied the motion of seven intact ankles and concluded that there was a general agreement to previous reports, but with one major difference: the ankle was multiaxial.[51] This means the talus acts as a hinge as well as rotates and slides on the articulating surface. While the ankle multiaxial theory was a new concept in TAA, similar motion had been found in the knee joint by Townsend, Izak and & Jackson who described the knee joint as a combination of sliding and rolling between the contacting tibia and femoral condyle surfaces.[52]

Siegler, Toy, Seale and Pedowitz further confirmed this through the anatomic measurements of the talus using the multiaxial theory. Their study revealed that the lateral talus has a smaller radius of curvature than the medial, going against many commercially-available ankle replacements.[50] Exactech's CT study of 73 patient scans compared healthy and diseased ankle joints and confirmed that the medial radius of curvature for the talus was smaller than the lateral radius.[1]

Many total ankle systems have been designed using these biomechanic philosophies to recreate the motion of the ankle. Both the single axis theory and the multiaxial theory have been used to design implants. In designs that use the conical shape/medial apex, the joint is forced into internal rotation. A study from Baxter, Sturnick, Demetracopoulos, Ellis and Deland showed that the use of this conical shape/medial apex design had significant changes in transverse plane movement.[53] The Salto Talaris forced the ankle joint into significant internal rotation compared to the control group.[53]

Leardini's research shaped the BOX Total Ankle, which mimics the ankle's motion path.[49] Both the STAR and BOX Total Ankle dictated the motion of the ankle; however, Baxter showed that normal ankle motion had a variation of kinematics *(Figure 14)*.[53]

With these understandings, our design team felt it was important to create an ankle that allowed soft tissue to dictate the motion of the ankle.

TALAR COMPONENT

Additionally, the Vantage Ankle also addresses the biomechanical challenges of bone loading and anterior/posterior resistance of the talus.

In an anatomic ankle, the force on the talus is distributed to different areas throughout the gait cycle in an arc shape. The ankle can receive over 3,500N in ground reaction forces[54] and carry as much as 5.2 times the patient's body weight,[55-56] in addition to potentially changing throughout the gait cycle *(Figure 15)*.

Today's implant designs either use a chamfer, flat or curved talar preparation cut. However, when the ankle is prepped in a chamfer or flat cut, there can be a risk that forces will load the bone/implant interface in a non-anatomic, biomechanic profile. This is explained by the axial load being applied as the talus is moving through plantar and dorsiflexion *(Figure 14)*.[53]

Some implants have metal shields that block the X-ray evaluation of the implant-bone interface.[57,58] Exactech designed the Vantage Ankle to use X-ray views to determine if the implant is seated properly and allow for the bone to be loaded. The curve preparation is designed to respect the native talus anatomy.[59]

TIBIA COMPONENT

Wolff's law was also used when designing the Vantage Ankle's tibial component.[38] The philosophy used in our design was to create a tibial component that offers fixation without increasing the risk of stress shielding.

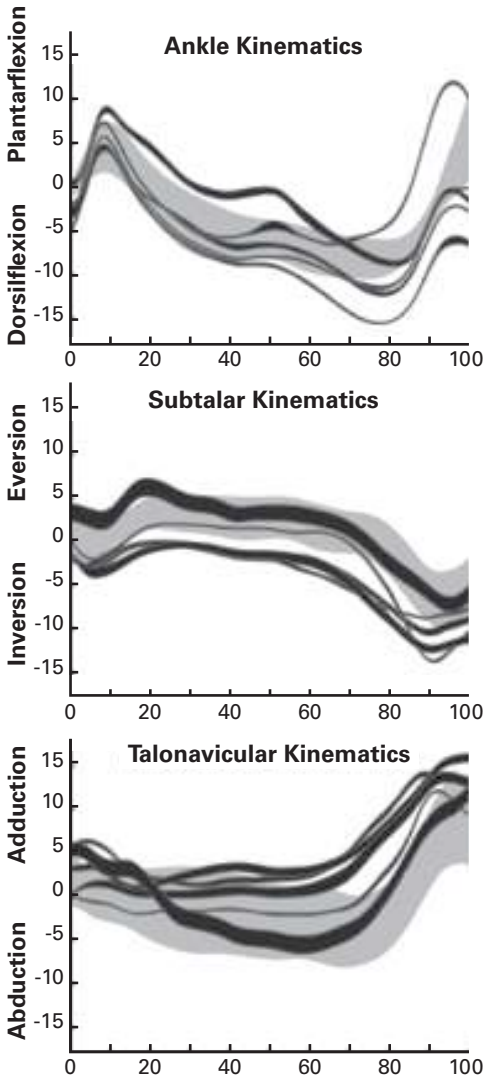


Figure 14: Gait Cycle

Figure 15: GRF Ankle Joint

The results of ground reaction forces (GRF) helped shape the design of the Vantage ankle.

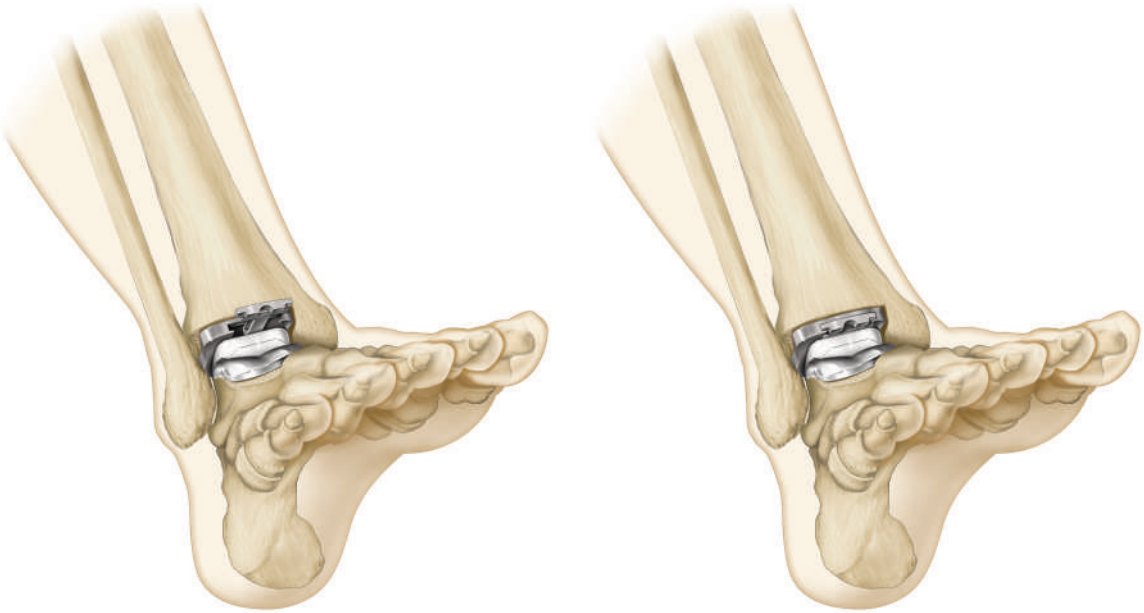


Figure 16: Vantage Ankle's Unique Locking Mechanism

Revision-Friendly Polyethylene

Since polyethylene failure is a common cause for revision,[12] Exactech wanted to create an implant with a locking mechanism that would create both stability and easy revisability (if needed). Historically, fixed bearing designs had interference-fit polyethylene where the polyethylene was deformed into the locking mechanism.[1] This provided a stable locking mechanism, but created difficulties implanting and revising.

Instead, the Vantage Ankle fixed bearing utilizes a unique locking mechanism that allows for the polyethylene to be inserted with finger pressure and removed with a simple unlocking tool *(Figure 16)*. This benefit allows for the polyethylene to be inserted without increasing stress on the implant bone interface during impaction and removed easily if needed.[1]

Conclusion

Our team of world-renowned surgeons and engineering experts created an ankle implant founded on both biomechanics and ankle anatomy with the goal of addressing the most common clinical challenges: subsidence, implant loosening, bone cysts, impingement leading to pain, and revisability. The result of our collaboration was a new perspective in total ankle– the Vantage Ankle.

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