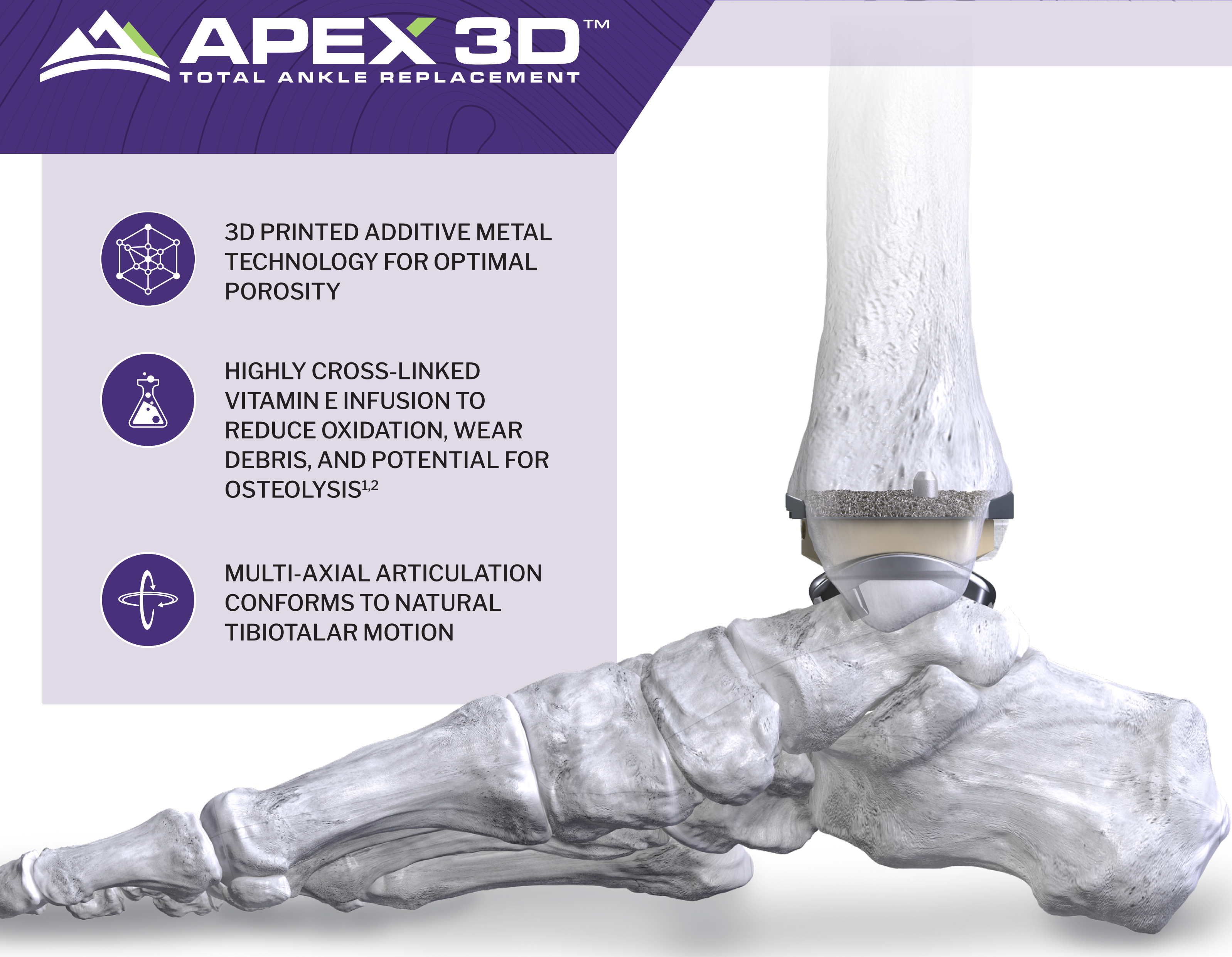
APEX 3D™

TOTAL ANKLE REPLACEMENT



3D PRINTED ADDITIVE METAL TECHNOLOGY FOR OPTIMAL POROSITY

HIGHLY CROSS-LINKED VITAMIN E INFUSION TO REDUCE OXIDATION, WEAR DEBRIS, AND POTENTIAL FOR OSTEOLYSIS[1,2]

MULTI-AXIAL ARTICULATION CONFORMS TO NATURAL TIBIOTALAR MOTION

DESIGN RATIONALE

RESEARCH DRIVEN. | **SOLUTION** FOCUSED.

Exclusively foot & ankle

Paragon 28®

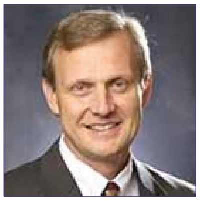
CONTENTS

DESIGN SURGEONS

Mark Dalton, MD
Austin, TX

Mark Myerson, MD
Denver, CO

Jeffery Christensen, DPM
Everett, WA



Michael Houghton, MD
Fort Collins, CO

THE PARAGON 28® APEX 3D™ TOTAL ANKLE REPLACEMENT SYSTEM MARKS THE NEXT GENERATION... in total ankle arthroplasty, with advanced technologies and a keen eye towards optionality. The APEX 3D™ System is the newest addition to the Paragon 28® Precision Ankle Solutions portfolio of products and complements the Gorilla® Ankle Fracture Plating System, Silverback® Fusion Plating System, Phantom™ Hindfoot TTC and ActivCore™ Nail Systems.

BASED ON OVER A CENTURY OF COMBINED CLINICAL EXPERIENCE... and cutting-edge biomechanical research, the APEX 3D™ System was designed to address end-stage ankle arthritis and current challenges within the total ankle market including, but not limited to: implant loosening, pathological wear, instability and persistent pain.

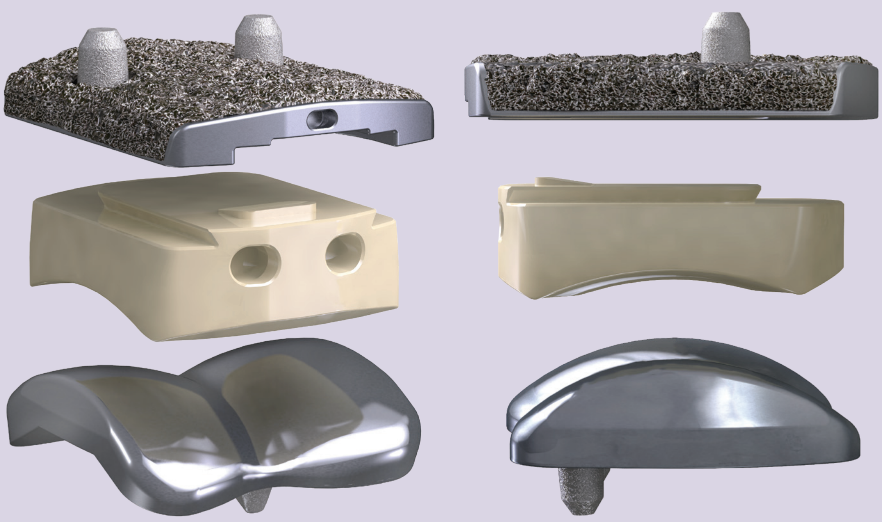
THE P28® DESIGN TEAM HAS A GREAT DEAL OF EXPERIENCE... addressing both historic reasons why ankle replacements fail as well as current insufficiencies such as tibial tray radiolucency and talar dome subsidence. It was important for the Design Team and Paragon 28® to investigate clinically reported modes of ankle replacement failure, conduct research to better understand tibiotalar morphology and joint kinematics in order to introduce clinically relevant solutions.

IMPLANT DESIGNS WERE GUIDED BY...

- Newer clinical evidence
- Advanced technologies
- Implant sizing & anatomic footprint based on pre-clinical arthritic tibiotalar morphology studies
- Healthy ankle kinematic weight-bearing CT research
- Extensive R&D testing

MECHANICAL IMPROVEMENTS WERE DESIGNED TO ADDRESS...

- Inadequate initial fixation
- Mechanical loss of fixation
- Biologic loss of fixation



CLINICAL INVESTIGATION

TOTAL ANKLE REPLACEMENT HAS INCREASINGLY BECOME A VIABLE OPTION... for patients who experience end-stage ankle arthritis. However, limitations still exist and based on literature findings, survivorship rates range from 82.6% to 95.8% at 3 to 5 years[3-7] to 84% - 94% at 5 - 12 years respectively. [55, 56, 57, 58] *(Registry data has shown 73% survivorship at 10 years)*

END-STAGE ANKLE ARTHRITIS IS A DISABLING CONDITION... that causes severe pain, substantial functional impairment and decreased quality of life. The most common etiologies found in applicable literate were:

- Post-traumatic arthritis [3,7-34]
- Primary osteoarthritis [3,8-10,13,15-18,20,22-24,26-29,31-40]

TAR SURGICAL COMPLICATIONS... *in the literature were identified as:*

- Component Loosening [3,6,7,12,19,20,27,30-33,44-46]
- Implant Subsidence [3,5,6,12,19,20,24,27,28,31-34,39,41]
- Persistent Pain [3,6,12,14,17,19,20,27,30,32,34,38]
- Intraoperative Malleolar Fracture [3,5,17,18,30,32,38,46]
- Post-operative Malleolar Fracture [17,19,25,30,32,34,38,39]

HIGH OCCURRENCE COMPLICATIONS... *relative to their study populations included:*

- Heterotopic ossification (95.6%) [47]
- Impingement (7.5% to 29%) [6,7,23,25,30,32,39]

MOST COMMON REASONS FOR REVISIONS...

- Talar subsidence, osteolysis, aseptic loosening [27,28,34,45,46]

DEVICE REVISION COMPLICATIONS LED TO...

- Patient harm such as pain, reoperations, revision to arthrodesis, or below-the-knee amputations. [6,25-28,31,33,45,48]

CAUSES OF TAR FAILURES[54]...*included:*

Cause of failure	Total ankle replacement
Aseptic loosening	38 (#1)
Luxation Instability	8.5
Septic loosening	9.8
Perioprosthetic fracture	2
Pathological wear	8
Persistent pain	12 (#2)
Implant failure	5.3
Technical error	4.6

Table adapted from Barg et al. Total Ankle Replacement, Deutsches Arzteblatt International (2015) 112,177-84.

POTENTIAL LIMITATIONS OF JOINT REPLACEMENT... *identified in the literature included:*

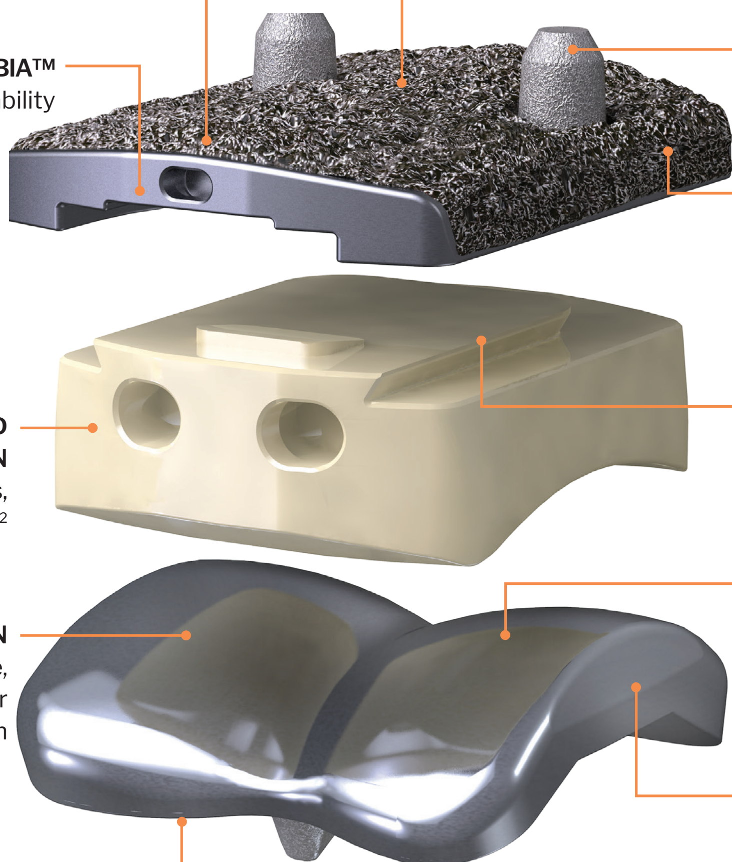
BONE RESORPTION... is currently considered a natural consequence of total joint arthroplasty due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure.

OSTEOLYSIS... is the result of localized foreign-body reaction to particulate debris generated by cement, metal, and Ultra-High Molecular Weight Polyethylene (UHMWPE). Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The phagocytic action results in the release of cytokines and intercellular mediators (IL-1, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and the potential ways to reduce its occurrence.

AS A RESULT OF THIS CLINICAL INVESTIGATION, PARAGON 28® SOUGHT TO INTRODUCE... implant design features, precision bone preparation instrumentation and advanced technologies to help mitigate the occurrence of surgical complications.

PRINCIPLES OF DESIGN

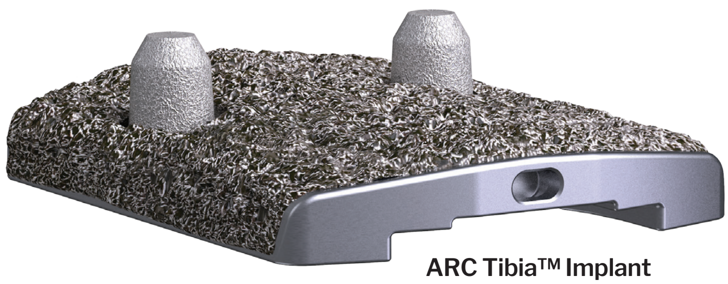
PARAGON 28® APEX 3D™ TOTAL ANKLE SYSTEM... has been efficiently streamlined to adapt to surgeon preference, accommodate patient needs and is equipped to address a wide range of arthritic ankle conditions. Implant designs are based on pre-clinical arthritic tibiotalar morphology studies, guided by healthy ankle weight-bearing CT research and extensive clinical investigation findings. The APEX 3D™ System consists of cemented, fixed-bearing anatomically contoured implant components, intuitive instrumentation and precision bone resection guides intended for use in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery is also indicated when sufficient bone stock is present. Components are intended for cemented use only*.



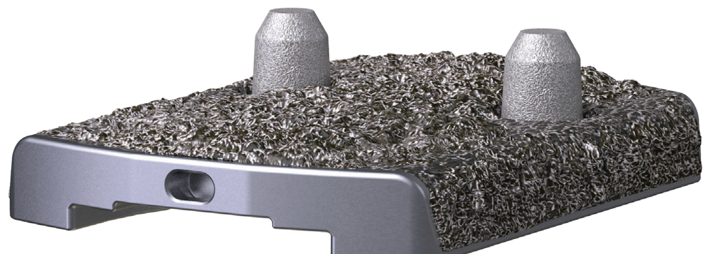
*For additional information regarding Indications for Use, Contraindications, Warnings, Precautions, etc. please visit: https://www.paragon28.com/ifus/

PRINCIPLES OF DESIGN

3D PRINTED BONE FACING GEOMETRY



ARC Tibia™ Implant



FLAT Tibia Implant

APEX 3D™ PRINTED TIBIAL COMPONENTS...

- 3D Printed *(Titanium Alloy)*
  - Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial)
- 52 Anatomically contoured low-profile sizing options available in sizes 1 - 6 (Lengths: Short*, Standard & Long)
- Left & right specific components offered in:
  - 2 distinct ARC Tibia™ & FLAT Tibia geometric configurations
- Anterior/posterior lengths, curvatures and medial/lateral widths based on arthritic ankle pre-clinical morphology studies

DESIGNED TO PROVIDE...

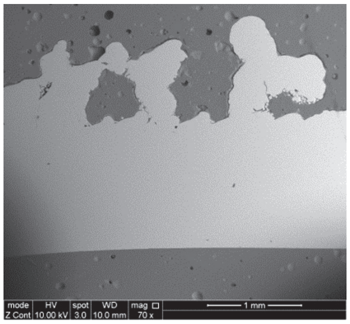
- Optimal porosity and rotational stability
- Broad anterior contact surface interface
- Distal tibia bone coverage with off-set posterior curvature to reduce potential for component loosening
- Medial/lateral side-wall surface area for added fixation and rotational stability
- Initial fixation and stabilization with two non-coated vertical pegs positioned slightly posterior to midline where peak bone density is located [49]

TIBIAL TRAY IMPLANT DESIGN BASED ON... pre-clinical arthritic tibiotalar morphology studies and healthy ankle weight-bearing CT research. 3D printed additive metal manufacturing process was introduced to allow for a low-profile, singular construct with integrated gradient zones of porosity.

Anatomically contoured implants include: 3D printed low-profile style options (ARC Tibia™ & Flat Tibia, 5 mm in thickness) with porous architecture and gradient zones down to solid titanium substrate. The ARC Tibia™ geometric architecture was designed to provide rotational stability and decrease rotational forces reducing potential for component loosening as seen in existing tibial implants. [19,20] The basis of the two posterior-biased vertical peg design was introduced to mitigate findings from clinical publications citing posterior lucency and subsidence of existing tibial components. [19,20,39] Vertical pegs were also designed to reduce posterior translation during implantation and mitigate potential for posterior gapping compared to designs with anterior peg placement.

Enhanced bone preparation techniques were introduced, featuring corners created from a drill rather than two intersecting saw cuts, resulting in rounded edges intended to help mitigate the risk of tibial stress fracture [38,39] and malleolar fracture seen in existing tibial implant designs, [19,39] as well as post-operative malleolar fracture seen in other total ankle replacement designs. [17,25,30,32,34]

Cross Section of Porous Titanium Architecture

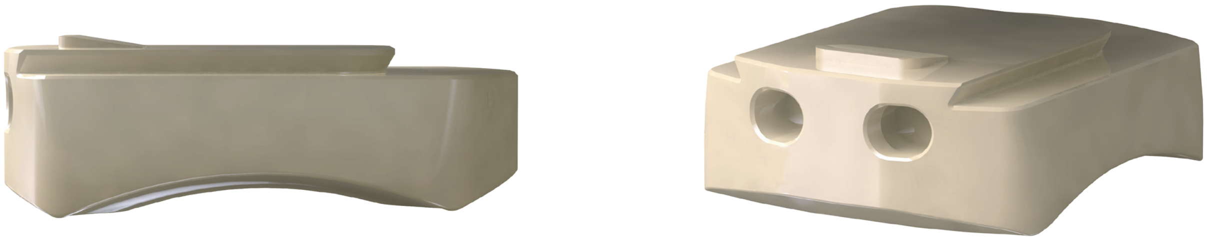


Substrate Interface = 0µm

Zone 1 (0-200µm) Zone 2 (200-400µm) Zone 3 (400-600µm)

PRINCIPLES OF DESIGN

HIGHLY CROSS-LINKED VITAMIN E INFUSION



Neutral Poly Insert

VITAMIN E TIBIAL INSERT - HIGHLY CROSS-LINKED POLYETHYLENE

- Ultra-high-molecular-weight polyethylene (UHMWPE) + Medical Grade Vitamin E Formula
- 35 Sizing options with universal locking mechanism available in sizes 1 - 5
- 7 primary and revision thicknesses options including 6 - 12mm offered in 1mm increments
- 5 semi-constrained sizing options with bicondylar bearing surface that allow for anatomic conformity

IMPLANT OPTIONALITY & WEAR CHARACTERISTICS...

- Vitamin E infusion introduced to help reduce oxidation, long-term wear and potential for osteolysis that can lead to implant failure.
- Equipped with a universal locking mechanism for additional implant optionality
  - Provides the ability to: upsize by one & downsize without restriction*

**Largest size tibia component, size 6 can be paired with smallest size 1 poly insert.*
**Polyethylene size will always follow the selected talar dome*

RECENT RESEARCH ON... *In vivo* oxidation has shown that UHMWPE may oxidize, through not only radiation induced free radicals, but also free radicals generated in vivo by cyclic loading and by the reaction of lipids absorbed from the synovial fluid.[1] Vitamin E infusion was introduced to help reduce oxidation, wear debris and potential for osteolysis that can lead to implant failure.[1,2]

Researchers have suggested that it may be useful to have sufficient Vitamin E activity in UHMWPE to prevent oxidation by thermal degradation during radiation cross-linking and compression molding. In a series of experiments, researchers from Kyoto University demonstrated that UHMWPE sterilized components blended with Vitamin E exhibited resistance to oxidation and fatigue wear, when compared with unstabilized controls.[1]

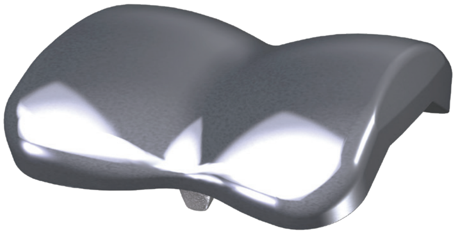
CONTACT AREA ANALYSIS... A 3D CAD model finite element analysis (FEA) was conducted to evaluate and determine contact area.[TR-19021119]

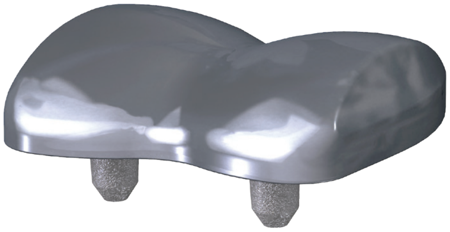
Dorsiflexion Contact Area | Neutral Flexion Contact Area | Plantar Flexion Contact Area

Reflects right-sided limb and joint articulation

PRINCIPLES OF DESIGN

ANATOMICALLY CONTOURED TALAR DOME


Chamfer Talar Implant


Flat-Cut Talar Implant

ANATOMICALLY CONTOURED TALAR DOMES...

- Cobalt-chromium-molybdenum alloy (CoCr)
- Titanium Plasma Spray undercoating (TPS)
- 12 Anatomically contoured sizing options available in sizes 1 narrow (1N) & 1 – 5.
- Left & right specific components offered in two distinct style configurations: Chamfer & Flat
- Anterior/posterior lengths, curvatures, and medial/lateral widths based on - Tibia & Talar Sizing & Morphology Study- Sizes 1N - 5

DESIGNED TO PROVIDE...

- Anatomic fit and optimize talar bone coverage
- Initial fixation and rotational stability
- Intercondylar spacing for coronal plane stability to resist varus/valgus motion
- Multi-axial smooth articulation that mimics natural tibiotalar motion reducing the potential for bony and component impingement
- Tapered medial/lateral shoulders to reduce potential for painful gutter impingement

ANATOMIC RELEVANT LOADING... in healthy patients is critical to understanding interactions of joint articulations. The APEX 3D talar dome implant design considers tibiotalar motion during simulated gait using modern weight-bearing CT technology. The design and enhanced bone preparation techniques allow the implants to be properly impacted, overcoming issues of posterior gapping and potential for component loosening, as noted in current designs. [12,19,20,31] The chamfer option includes an anterior biased non-coated central fin for ease of insertion and initial stability. The Flat-cut option is equipped with dual non-coated anterior pegs designed for rotational stability, and both options provide posterior medial coverage to help to avoid FHL impingement.

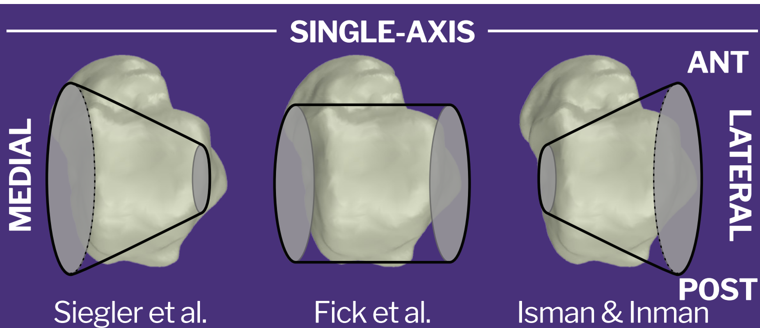
WEIGHT-BEARING CT BASED TALAR MORPHOLOGY RESEARCH [59]

Paragon 28® sought to better understand if the curvature of the medial and lateral aspects of the talus could be more accurately described by dividing the condyles into anterior and posterior regions, creating bi-radial curves.

Paragon 28® found that the healthy ankle joint experiences varying, tri-axial rotation demonstrating that Inman,[50] Seigler,[51] Barnett and Napier, [52] were all correct in part with their assessments of ankle joint line axes.

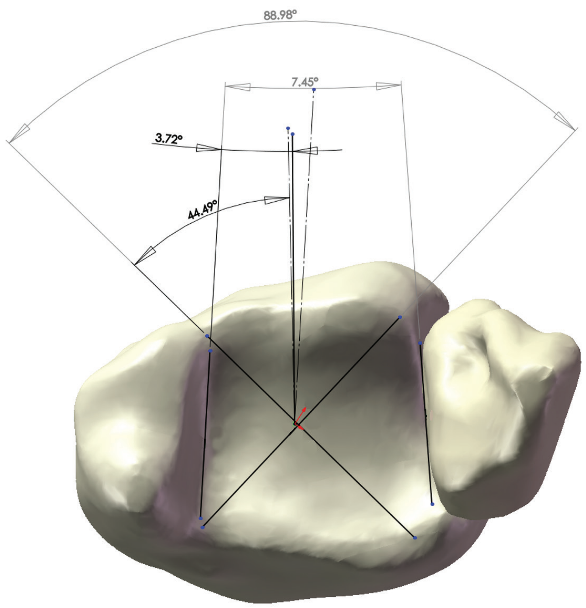
FINDINGS: *Lateral Anterior Radius > Medial Anterior Radius. Medial Posterior Radius > Lateral Posterior Radius*[59]

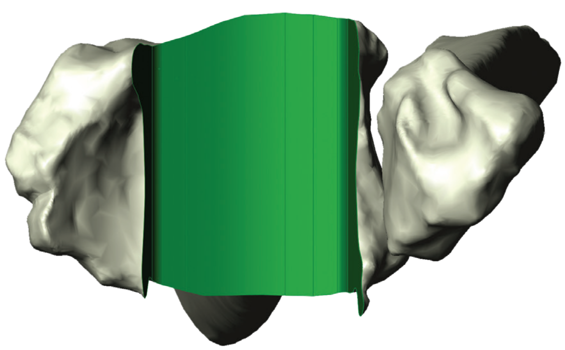
BIOMECHANICAL IMPLICATIONS: Confirms the ankle does not have a single joint line axis.

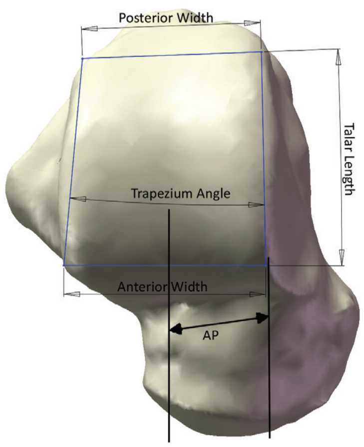


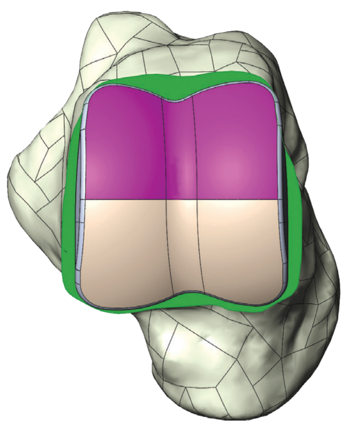
IMPLANT SIZING RESEARCH

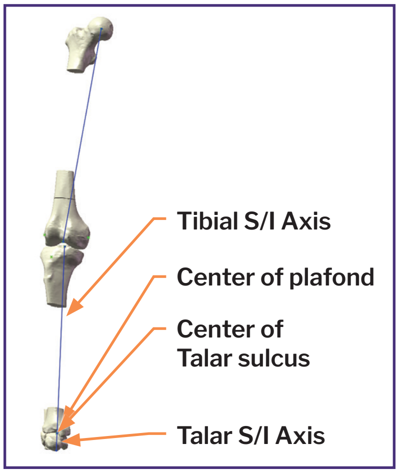
RESEARCH OVERVIEW Implants were developed based on arthritic ankle morphology scans then compared for fit and coverage to a second subset of subjects to confirm coverage rate. CT scans of arthritic patients for total ankle replacement were segmented and landmarks identified on each bone in the ankle joint: tibia, fibula, and talus. Measurements were taken to determine size and morphology data for the subject population. Statistical analyses were conducted on the measurement data to identify means, outliers, correlations, and measurements that best corresponded with input dimensions for the development of a new total ankle replacement (TAR) implant system. Once identified, the sizing dimension data were used to drive the critical dimensions for a system of TAR tibial trays and talar dome components based on a desired coverage rate of 95%. Implants were developed based on these inputs and compared for fit and coverage to a second subset of subjects to confirm coverage rate. [TR-19021117]







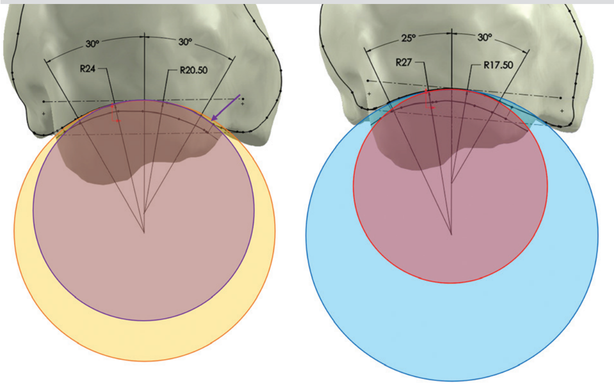




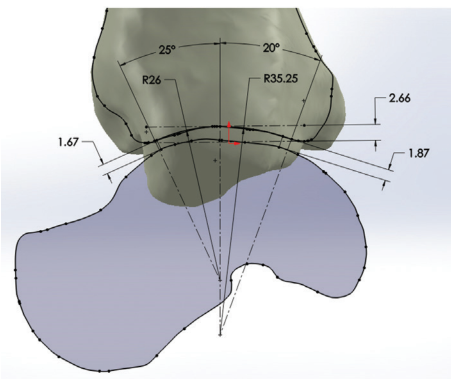
THE PURPOSE OF THIS STUDY... was to depict the most appropriate fitting ankle prosthesis on to a range of sizes of subject bones to ensure the design input requirements of this implant system were fulfilled.

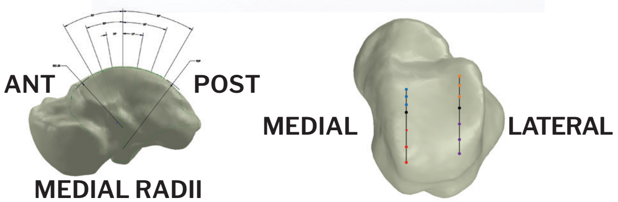
RESULTS... at the resection levels, tibia anterior/posterior lengths were taken at the medial, lateral and center to establish optimal bone coverage and size offerings. Similarly, the talar medial-lateral widths at the anterior & posterior aspects were taken.

MORPHOLOGY & KINEMATICS



MEDIAL RADII LATERAL RADII





BI-RADIAL CURVATURE MORPHOLOGY OF THE HEALTHY TIBIOTALAR JOINT [59]

Study Goals:

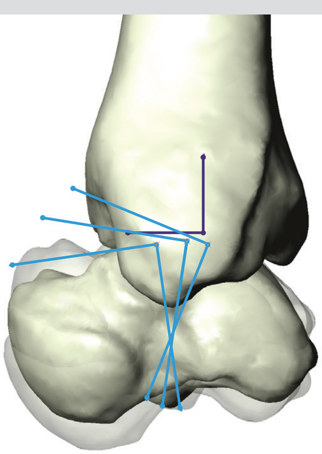
- More accurately describe the curvature of the distal tibia as well as the medial and lateral talar condyles
- Create bi-radial curves for both the medial and lateral sides of the distal tibia and proximal talus
- Compare the regional congruency between the distal tibia and proximal talus

Distal Tibia Findings:

- Anterior Tibial Radii > Anterior Talar Radii
- Lateral Posterior Tibial Radii < Lateral Posterior Talar

Proximal Talus Findings:

- Radius increases from anterior to posterior of both the medial and lateral sides of the talus
- Lateral Anterior Radius > Medial Anterior Radius
- Lateral Posterior Radius < Medial Posterior Radius



Early Mid-Stance Mid-Stance Late Mid-Stance

IN VIVO KINEMATICS OF THE HEALTHY ANKLE USING WEIGHT-BEARING CT [TR-19021110]

Study Goals:

- Measure talar rotation with respect to tibia through three different stages of mid-stance *(early mid-stance, mid-stance, late mid-stance).*

Findings:

- The healthy ankle joint experiences varying, tri-axial rotation

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