Integra®

Cadence® Total Ankle System

INTEGRA®
LIMIT UNCERTAINTY



DESIGN RATIONALE

The Next Step in the Advancement of Ankle Arthroplasty



Timothy R Daniels, MD, FRCSC

Professor, Department of Surgery
University of Toronto
Toronto, Canada



Christopher F. Hyer, DPM , MS

Co-Director Foot and Ankle Surgery Fellowship
Orthopedic Foot and Ankle Center
Columbus, OH



Selene G Parekh, MD, MBA

Professor, Department of Orthopaedic Surgery
Duke University
Durham, NC



David I Pedowitz, MD , MS

Associate Professor of Orthopaedic Surgery
Rothman Institute
Philadelphia, PA

Introduction

The Cadence® Total Ankle System by Integra Lifesciences Corporation is designed to treat ankle arthritis through replacement of the ankle joint with a metal and polyethylene prosthesis, thereby reducing pain, restoring alignment, and allowing more natural movement at the replaced joint.
Cadence is designed to refine and improve upon proven successful concepts and features of today's total ankle arthroplasty systems. At the same time, Cadence is also designed to address challenges, inefficiencies, and unmet clinical needs inherent with these legacy systems.

Common challenges experienced by surgeons performing total ankle arthroplasty procedures became considerations for the Cadence design. These include:

(1) suboptimal ankle alignment,
(2) excessive talar bone removal/resection,
(3) violation of talar vascular supply,
(4) fibular impingement, and
(5) inefficient, difficult to reproduce bone preparation techniques.



Advancements featured in the Cadence Total Ankle System include:

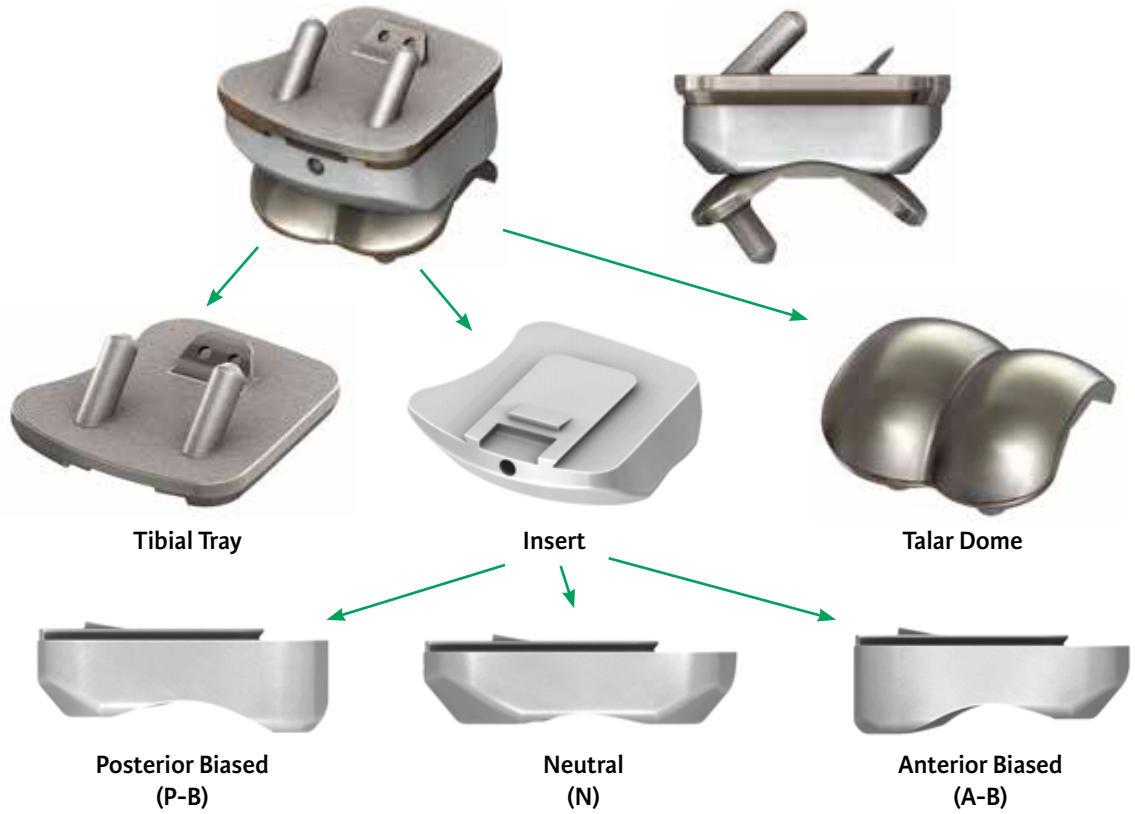
(1) anatomic, side specific (left/right), *tibial component* with a fibular cutout to maximize coverage along three corticies, while reducing fibular impingement
(2) anatomic, side specific (left/right), *talar component* designed to minimize talar bone resection, preserve talar bone, and replicate natural kinematics of the ankle
(3) proprietary HXL Ultra High Molecular Weight Polyethylene (UHMWPE) bearing material for improved wear characteristics for increased survivorship, and
(4) Biased polyethylene insert options for maintaining proper alignment to those patients presenting with anterior or posterior subluxated ankles.



The Cadence Total Ankle system is designed to support surgical technique efficiencies through instrumentation advancements. From the initial adjustable extra-medullary alignment guide to final implant inserter, each step is coupled to previous steps, reducing instances of freehand technique. Reducing required freehand technique steps translates into easier, quicker, and a more reproducible procedure for foot and ankle surgeons. Location of temporary pins used in the technique was chosen to be directed away from important vascular supply at the talar neck area. While Cadence offers a huge assortment of implant options (672 possible prosthesis combinations can be created), instrumentation is efficiently packaged in two color-coded instrumentation trays to facilitate procedure flow by operating room staff. The goals of instrumentation and surgical technique improvements are to reduce learning curve and facilitate improved outcomes, through potential reduction of intraoperative errors.

Cadence shares basic similarities with other fixed bearing, three component prosthetic designs: a tibial tray, talar dome and a polyethylene insert (Figure 1). When all components are implanted, with the insert rigidly locked to the tibial tray, the polyethylene insert acts as a single bearing along the talar dome, enabling flexion/extension and rotation movement at the replaced ankle joint. In the US, Cadence is indicated for cement-use only. Outside the US, Cadence is indicated for both cement use and without cement use. Cadence is indicated for use in patients with ankle joint affected by post-traumatic, rheumatoid, or degenerative arthritis through a primary or revision total ankle arthroplasty procedure.

Figure 1: Cadence Total Ankle Prosthesis Components



Currently, Cadence is commercially available in the US, Canada, and several European countries. Cadence was first implanted clinically in March of 2016; within the first year of commercial introduction, over 200 prostheses have been implanted.*

* Data on file

History of Total Ankle Prosthetics

Patients in the 1970s with degenerative joint disease, and/or deformity with significant debilitating clinical symptoms were hopeful that the first-generation total ankle prosthetic designs would restore their quality of life. Implants of this era consisted mostly of highly constrained polyethylene tibial components used with cement for implant stabilization, and a metallic talar piece. Though these were remarkably stable, the implants experienced numerous complications. The two design types available (i.e., congruent and incongruent designs according to the shape of the two articular surfaces) created a large amount of shear, compression, and rotary forces through the bone prosthetic interface which led to osteolysis, bone loss, component loosening, and instability.[2,4,10,14,15,16,19,26] Spherical designs resulted in early instability, and cylindrical semiconstrained implants exhibited high rates of mechanical failure.[7]

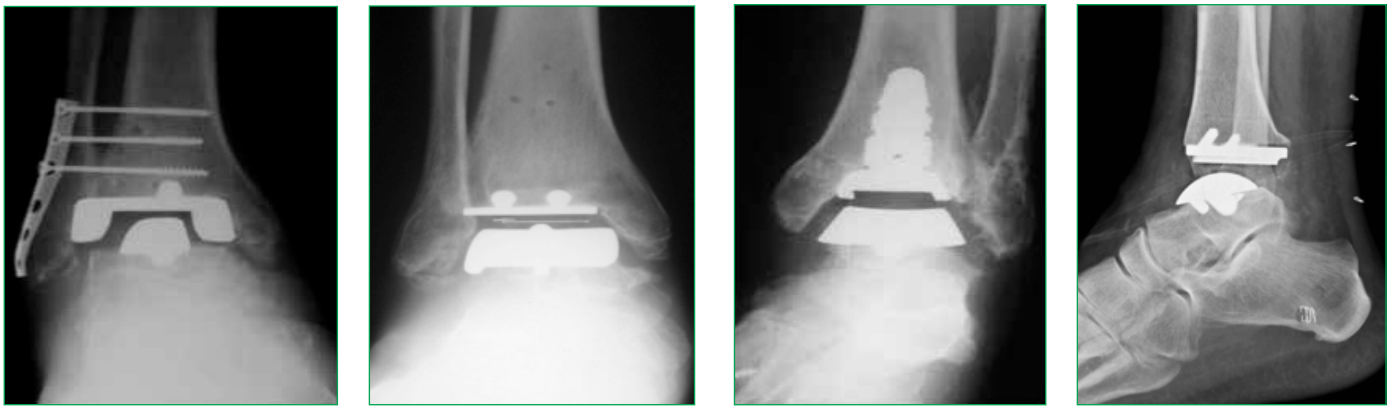
History of Total Ankle Prosthetics

- Significant improvements been made over the last 40 years in the field of total ankle arthroplasty, leading to better clinical and functional outcomes
- Cadence was designed to address common clinical concerns that surgeons experienced using other available implant systems: mal-positioning, loose/subsidence, compromised talar blood supply, and fibular impingement.



With two-component designs resulting in unsatisfactory outcomes, the 1980's ushered in a second generation of new three-component, mobile bearing implant designs. These were developed by incorporating a polyethylene bearing interposed between the two metal bone-affixed components. Again, these systems included congruent and incongruent designs that incorporated polyethelene bearings at the articular surfaces, designed to minimize wear and component deformation.[22] The Depuy Mobility™ Total Ankle Replacement System, Endotec Buechel-Pappas™ Total Ankle System, and the Stryker Scandinavian Total Ankle Replacement (STAR™) were the principal implants of this generation, and were characterized by their symmetric, nonanatomic design of the talar components. Incomplete understanding of the functions of these structures guiding ankle motion in the natural joint (ligaments and articular surfaces), resulted in poor restoration of these functions in the replaced joint, and were responsible for further complications and revisions.[8,24]

Modern ankle replacement implants consist of two or three components, fixed or mobile-bearing designs with metallic tibial and talar components, stabilized with or without cement. They improved the accuracy of placement, immediate stable fixation to bone, and were a better anatomic match. A 'meniscus-like' component, which the majority incorporate a UHMWPE polyethylene material, is either fixed to the tibial component or is mobile, articulating with both components.[10] The addition of the polyethylene 'meniscus' artificial joint, allows congruent motion, and a more normal ankle kinematic with decreased load stresses and wear rates.[10] In a systematic review and meta-analysis of 58 studies and 7,942 total ankle replacements, an overall survivorship was 89% at 10 years was reported with an annual failure rate of 1.2%.[30]



Though the vast majority of study publications from 2004 through 2015 demonstrate improvements in clinical and functional outcomes such as ROM, strength, pain VAS, disability scores, survivorship, and patient satisfaction following total ankle arthroplasty[29] there exists opportunities for improvement over the currently available systems.

The principal goals driving the design of the Cadence prosthesis are (a) minimizing resected bone, particularly in the talus to preserve blood supply, (b) maximizing endplate coverage, (c) utilizing anatomic designs, and (d) ensuring proper sagittal plane alignment, addressing anterior/posterior subluxation.

Initially, the surgeon design team focused on the genesis of complications and poor outcomes reported in literature (i.e., revisions/reoperations with most studies reporting between 8% and 12%, loosening/subsidence reported to occur generally in less than 10% of patients, wound complications, and others related to fracture, mal-positioning, non-union, lysis, device breakage, fracture and wear rates between 2-4%).[29]

Specifically, true anatomic coverage of both the tibia and talus has been a challenge. Only a few systems have a standard and 'long' tibial implant to provide adequate posterior tibial coverage. Even in these, however, there is a lack of adequate medial and especially lateral tibial coverage with frequent impingement into the fibula, which can be a source of pain. In addition, most of the current generation implants use a generic talar implant, not specific right and left geometry. This has a deleterious effect of limiting natural ankle kinematics and range of motion since the ankle joint is not a neutral hinge joint.

Additionally, many of the systems are inefficient in their instrument and procedural design requiring multiple steps of pinning in and out, cutting pins, multiple guide and template exchanges and even cumbersome external fixation devices. These inefficiencies potentially lengthen operative time, which is a known risk for complications such as infection and wound healing difficulties.

Designing An Anatomic Ankle

A key hypothesis in the design of the Cadence® Total Ankle System, is that by designing anatomic shaped components, a prosthesis that better replicates natural kinematics can be achieved.

Designing an Anatomic Ankle

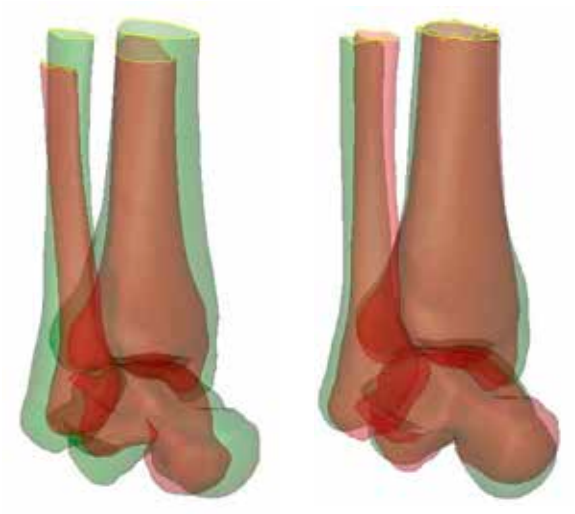
- Cadence tibial and talar component designs are based on a database of ankle joint CT scans
- Statistical composites were created, resulting in the final shapes and sizes

In 2013, Integra procured the services of Materialise and their Anatomical Data Mining (ADaM) technology to gain an accurate understanding of total ankle morphology and function. This consisted of statistical analysis of the individual bones of the tibia, fibula, and talus separately, as well as the full ankle joint. The Materialise input dataset consisted of 86 CT ankle scans [i.e., 54 male, 32 female, with varied ages between 29 and 96 (average of 67)].[5] The final yield was a set of statistical bone models which represented the foremost statistical variations of each bone. The models were then used to design standard devices that fit onto the ankle joint, thus optimizing the fit for each of the variations within the population.

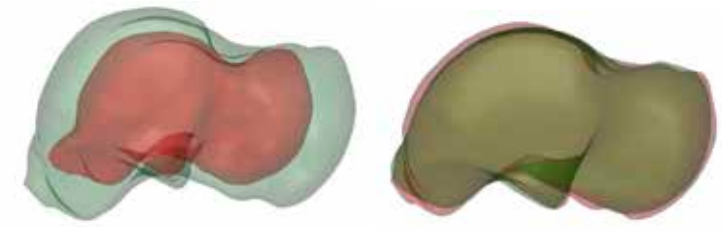
Sizing for each Cadence component's middle size (size 3) was based on the average statistical composites (Figure 2). One size smaller (Size 2) and one size larger (Size 4) correspond to statistical composites +/-1 standard deviation of the data set; the system's smallest (Size 1) and largest (Size 5) components correspond to +/- 2 standard deviations. The dimensions in the medial-lateral direction varied slightly more than in the anterior-posterior direction.[5]

Surgeons are able to mix and match component sizes as needed, resulting in a more patient specific anatomic implant, which by design helps to more successfully restore the normal kinematics of the ankle. Cadence is the first ankle arthroplasty system to offer all side specific components (i.e., tibial, talar, and polyethylene inserts); a total of 672 possible implant combinations to treat a variety of patient anatomy.

Figure 2: ADaM: Using Statistical composites to develop an anatomic ankle



Ankle in the dataset (red) with the corresponding shape from the ADaM model (green).



Talus in the dataset (red) with the corresponding shape from the ADaM model (green).

Designed to Replicate Natural Ankle Kinematics

The first implant design goal was to replicate the original joint function, restoring appropriate kinematics to the replaced joint. Patient perception of a natural gait in which the prosthesis matches and mirrors the natural kinematics of the opposing ankle requires an anatomic, conical, side-specific implant for the highest patient satisfaction.

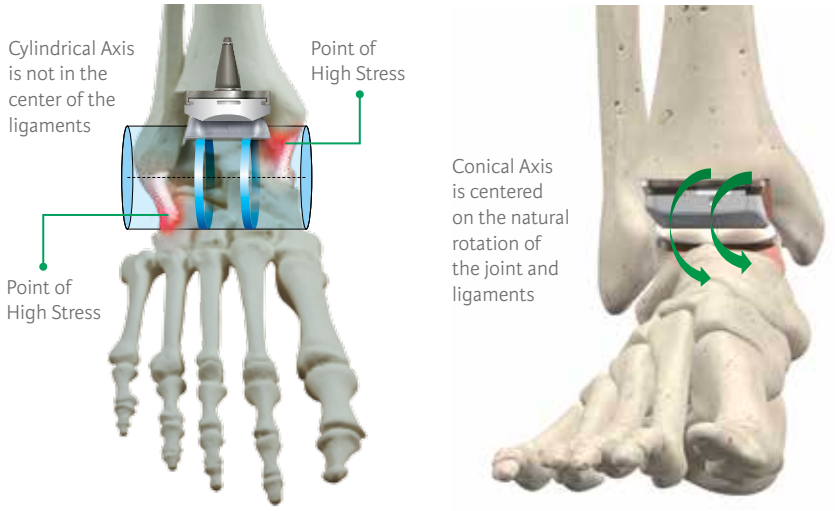
Non-anatomic implants primarily permitted flexion-extension movement (i.e., minimal inversion-eversion or rotation), which potentially resulted in elevated constraint at the bone implant interfaces, which in turn would increase the stresses across the ligamentous structures. Symmetric designs, with cylindrical talar components, did not replicate natural ankle kinematics, and resulted in abnormal horizontal flexion-extension axis and potential for Deltoid Ligament Complex (Figure 3). Additionally, though these implants were designed to reduce the stresses on the fixation components, provide for cementless fixation and permit boney ingrowth, as well as reduce bone resection and preserve bone to support a more reliable anchoring of the prostheses in denser subchondral bone, failures of primary fixation and secondary fixation resulted in subsidence of the components.[13]

The rotational axis of the talocrural joint is obliquely oriented in the three spatial planes: axial, coronal, and sagittal.

Designed to Replicate Natural Kinematics

- Rotation axis of prosthesis is oblique, designed to better simulate natural gait as compared to cylindrical/hinge designs
- Enables internal rotation while in plantarflexion and potentially reduces points of high stress on the deltoid and lateral ligaments
- Accomodates approximately 50° Range of Motion

Figure 3

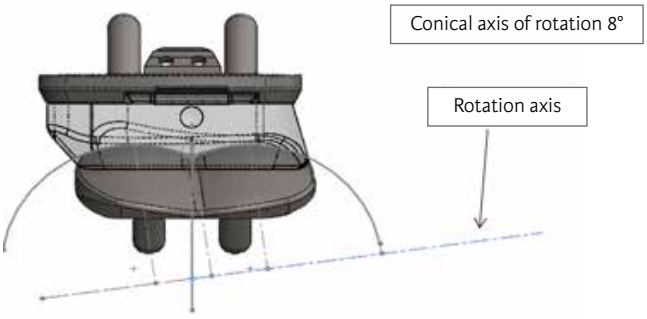


Traditional (Hinge) Ankle
Cylindrical Articulating Geometry

Cadence Ankle
Anatomical Articulating Surface

The Cadence talar dome and the corresponding bearing surface of the Cadence poly insert are designed accordingly, with the goal of replicating natural kinematics of the ankle. The Cadence talar dome component features a smaller medial condyle and larger lateral condyle and the bearing surface of the poly insert is similarly shaped, with a congruent fit between the two components. As a result, the flexion-extension axis of the talar component is aligned with the physiologic axis of the ankle (obliquely directed medially, anteriorly, and upward 8° to the horizontal; Figure 4). Because the rotational axis is oblique, dorsiflexion is always associated with a valgus inclination and a few degrees of external rotation. Conversely, plantar flexion is associated with varus and internal rotation.[3,18]

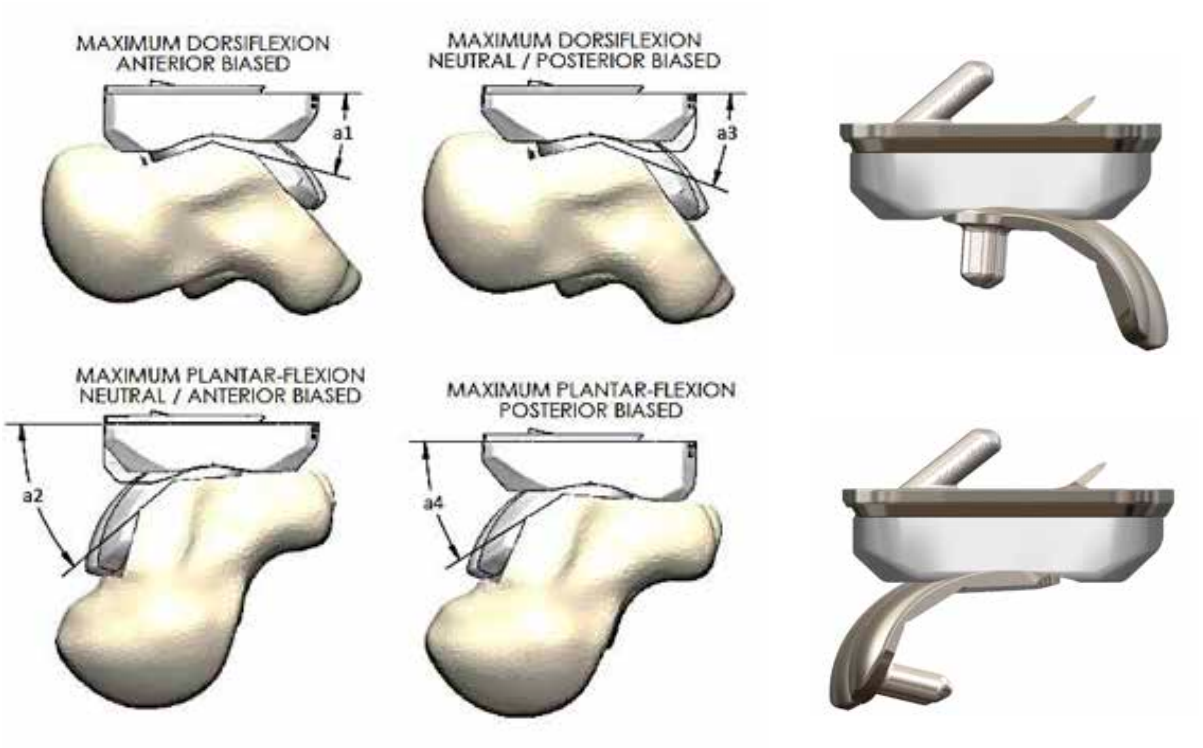
Figure 4



Cadence: The axis of rotation is oblique and the shape of the talar dome fits into a truncated cone with conical axis of 8 degrees

Based on literature and design standards, the requirement for range of motion is a minimum of 15 degrees in both dorsiflexion and plantar-flexion.* Modern implants try to retain the radius of the curvature of the talus, resulting in improved and a more natural ROM (range of motion).[26] In the design of Cadence ankle prosthesis, ROM analysis was performed to determine the maximum range of motion for each size in relation to the surrounding bony anatomy (Figure 5). Computed Tomography (CT) models of talus were cut in CAD environment to simulate a surgically prepared talus in a manner consistent with surgical technique. The five CT models correlated to the five talar dome sizes, Sizes 1-5. Talar dome models appropriate to each talus size were assembled to the talus and a tibial insert was constrained to the talar dome using axis of the articular surface. The insert was rotated in both dorsiflexion and plantar-flexion until bony contact reached and the resultant angle was measured (Figure 5).

Figure 5



Maximum dorsiflexion and plantar-flexion limits of the total ankle design

Poly	Dorsiflexion	Plantar-flexion
N	21-26 deg	37-40 deg
A-B	15-18 deg	37-40 deg
P-B	21-26 deg	27-32 deg

* Data on file

Advancements with Cadence Anatomic Talar Dome Design

Preservation of talar bone stock was a top design consideration for the Cadence® Total Ankle system talar component. Talar resection depths of 4.3mm are kept to a minimum and confined to the trochlear articular surfaces; the low-profile design supports a more reliable anchoring of the prostheses in denser subchondral bone (Figure 6)[13,27]. The talar component for ankle arthroplasty prosthesis sustains the weight of the body and transmits the weight in different directions via the calcaneus and navicular bones.[21] Trabeculae of the cancellous bone are formed along the direction of the lines of stresses to which a bone is subjected.[21]

Anatomic Talar Dome Design

- Minimal Talar Bone resection ; 4.3mm
- Temporary pins used in surgical technique are placed in the body of talus aimed posteriorly to avoid bicortical penetration into the sinus tarsi and subtalar joint; designed to preserve talar blood supply
- Unobstructed radiographic view, sagittal plane



Good quality underlying talar bone is an essential requirement for long term survival of total ankle implants.[17,27] Poor quality underlying talar bone results in direct mechanical insufficiency, periprosthetic osteolysis, and ultimately talar subsidence and implant failure.[17] Clinical studies have demonstrated failures of talar components caused by aseptic loosening and implant subsidence. Glazebrook et al.[9] systematically evaluated twenty studies on total ankle arthroplasty complications and found subsidence (10.7%) and aseptic loosening (8.7%) to be the most commonly reported.

Figure 6



Accurate conforming talar design of the Cadence ankle prosthesis allows for excellent primary fixation of the talar component via two anterior pegs to minimize risk of loosening, while providing for appropriate load transfer to the bone and improving longevity of the implant.

Secondary fixation is achieved via coating composed of plasma sprayed titanium applied onto the inferior surface of the implant, designed to improve bone ongrowth at the bone-implant interface. (Figure 7) The talar dome itself is manufactured using a cobalt chrome alloy (CoCrMo), a widely adopted material in joint replacement applications typically selected for its properties to reduce wear of the poly bearing. The plasma spray is applied because titanium is a bioinert, osteoconductive material that enhances bone on growth, as opposed to cobalt chrome alloy, which remains separated from the bone by a thin layer of collagen.[20]

Figure 7



Because the Cadence talar dome component conforms to the natural curvature of the talus, without medial or lateral flanges, it also allows for unobstructed radiographic sagittal views (Figure 8).

Figure 8

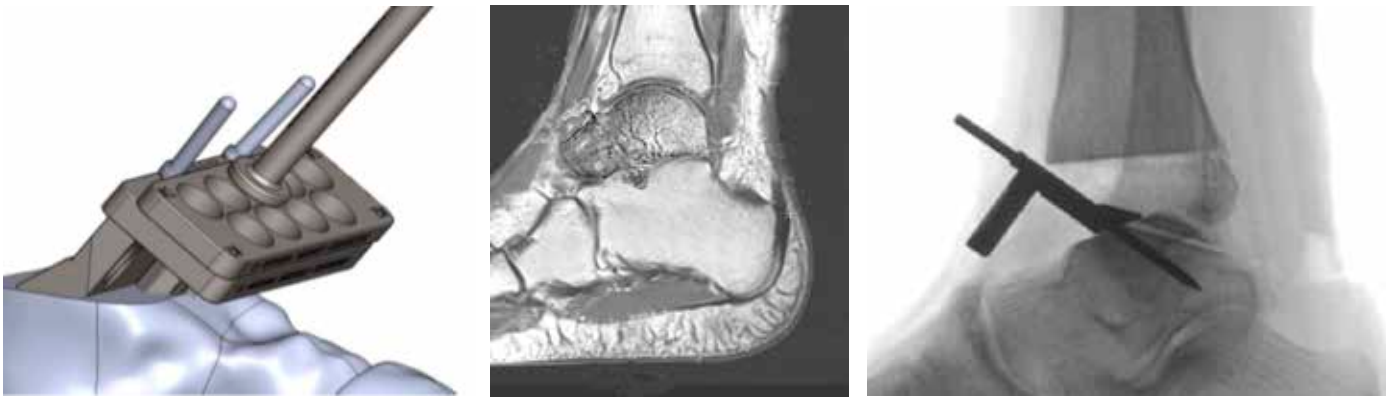




Previous TAA designs have had a negative impact on the talar blood supply, associated with vascular compromise through anterior or lateral approaches.[25] All currently marketed implant designs have vascular risks that are unavoidable. In addition to removal of talar bone, a surgical technique requiring placement of fixation pins/ drills that either violate the subtalar joint or the sinus tarsi can also potentially compromise blood supply. The magnitude of vascular disruption and the subsequent osteonecrosis (AVN) is commensurate with the damage of the three extraosseous arterial branches that supply the bone: the posterior tibial artery, the dorsalis pedis artery, and the perforating peroneal artery. The talar head is supplied by branches of the dorsalis pedis artery entering from the superior surface, and the artery of the sinus tarsi entering the inferolateral aspect of the talar neck. Protection of the extraosseous blood supply of the talus is also amplified when considering that the network of intraosseous anastasmoses in the talus decreases with increased age.[25]

Cadence is designed to avoid extraosseous vascular damage via bone sparing design and a surgical technique utilizing temporary pins placed away from vascular structures, such as the talar neck and anterior talar body (Figure 9). Pin placements are confined within the exposed cancellous bone aimed posteriorly to avoid bicortical penetration into the sinus tarsi and subtalar joint. Talar bone resections via the three chamfer cuts (anterior, superior, and posterior which are prepared using an oscillating saw for the posterior talar and dome cuts, and a specialized reamer for the anterior chamfer cuts) allow for reproducible positioning of the implant to ensure preservation of the talar blood supply.

Figure 9



Temporary pins used in surgical technique are placed in the body of talus aimed posteriorly to avoid bicortical penetration into the sinus tarsi and subtalar joint; designed to preserve talar blood supply

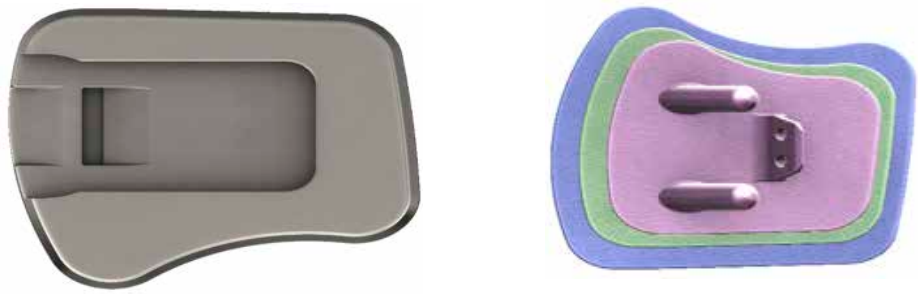
Advancements with Cadence Anatomic Tibial Tray Design

The Cadence® Total Ankle System tibial tray is designed to provide endplate coverage of the epiphysis on three cortical walls in both the anterior-posterior and medial-lateral directions (Figure 10). Standard as well as extra-long sizing options are available. Side-specific configurations of the implant include lateral cutouts to preserve the lateral gutter and reduce fibular impingement. Oversized tibial components usually lead to painful impingement with the fibula which may require consideration of bone resection procedure of the impingement area.[23]

Anatomic Tibial Tray Design

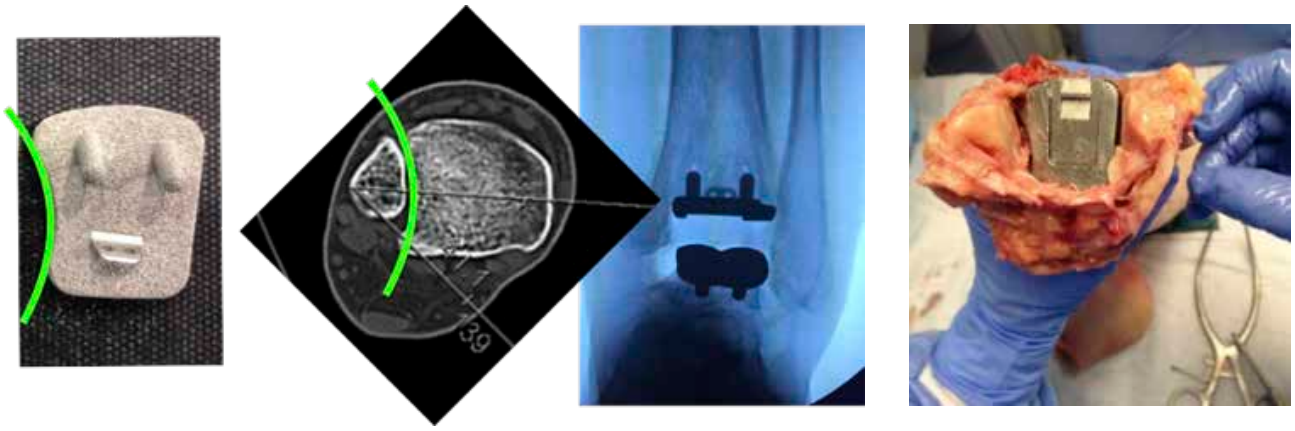
- Anatomic shape; designed to optimize tibial coverage, minimize fibular impingement
- Posterior Fin designed for added stability, prevent posterior lift-off
- Multiple options for AP coverage (i.e. standard and long), given same ML width
- Ti material, Ti Plasma spray coating

Figure 10



The anterior border is larger than the posterior border, and a cut along the posteromedial angle avoids any impingement with the tibialis posterior tendon. The medial rim protects the medial malleolus from impingement by limiting the medial excursion of the polyethylene component (Figure 11).

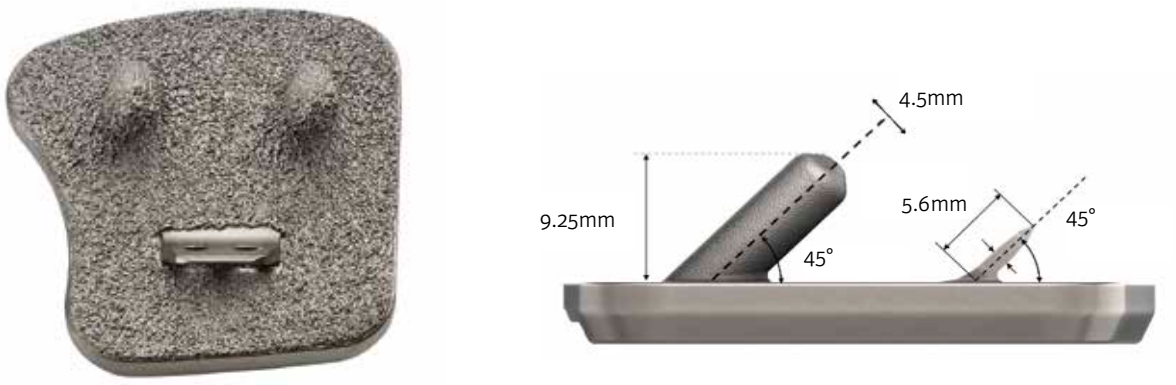
Figure 11



The Cadence prosthesis is a fixed bearing design; a highly congruent polyethylene insert is secured to the tibial tray. For each size, in the transverse plane, the perimeter of the polyethylene bearing matches the perimeter of its corresponding tibial tray size, which decreases the amount of stress within the poly. Theoretical advantages of the fixed-bearing designs reduce the risk of bearing dislocation and overhang of the polyethylene component with respect to the baseplate which decreases the risk of malleolar impingement.

Primary fixation of the tibial component is achieved via two press-fit 45 degree anterior posts and a press-fit posterior fin. The posterior fin, with its wedged shape geometry, is designed to serve two purposes: (1) prevent posterior migration of the tibial tray once the fin is fully engaged into bone and (2) prevent intraoperative and postoperative lift off of the tray, until bone ingrowth may take place.

Figure 12



A secondary fixation is achieved via plasma spray titanium applied onto the superior surface of the implant and on the pegs, designed to improve bone on-growth at the bone-implant interface (Figure 12) .

The tibial tray components are manufactured from titanium alloy (Ti6Al4V), a gold standard orthopaedic implant material selected for its strength, corrosion resistance, and biocompatibility.

Cadence Poly: Advancements with HXL UHMWPE and Biased Inserts

Cadence features several advancements in regards to the design of the poly insert bearing including use of a proprietary HXL (highly cross linked) UHMWPE (ultra-high molecular weight polyethylene) material and biased profiles. These advancements also translate into a high degree of customization (210 total poly options) for individual patients; for each of the 5 talar dome sizes, side-specific inserts that come in 7 heights (6-12mm), each with additional anterior and posterior options.

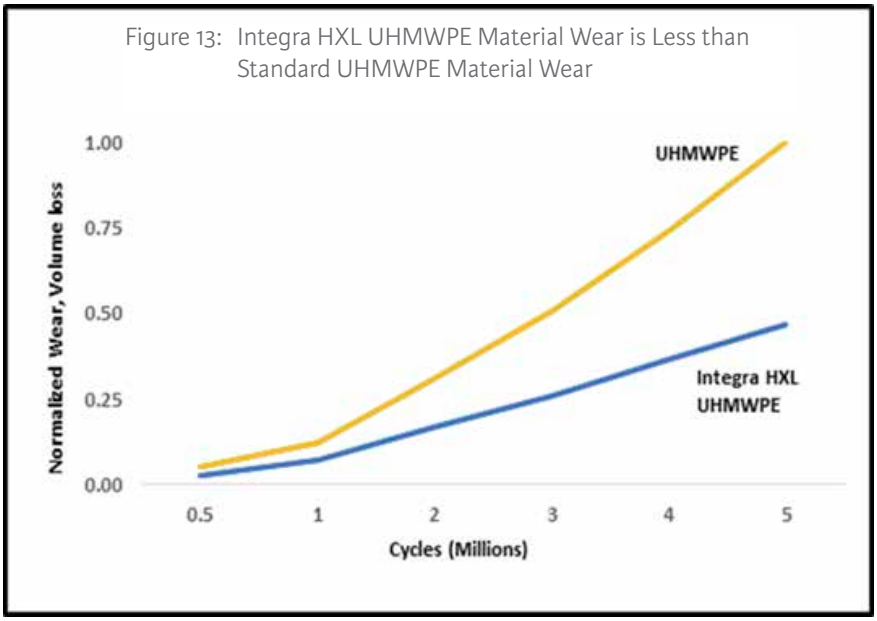
Cadence Poly Advancements

- Biased inserts designed to to accommodate anterior/posterior subluxated ankle
- Proprietary Integra HXL UHMWPE Material with improved wear resistance; designed for increased prosthesis life
- Comprehensive selection of 210 poly options allows for customization to individual patients

Integra's highly cross-linked UHMWPE is manufactured from compression molded UHMWPE that is cross-linked through gamma irradiation and subsequent annealing prior to machining of the implants. Integra's proprietary manufacturing process decreases the wear rate while retaining adequate strength and toughness.*

Figure 13 shows the results of a cross-shear multidirectional pin-on-disk wear test. The wear rate, based on volumetric net loss, of Integra's highly cross-linked UHMWPE is less than half the wear rate of standard UHMWPE. For this test, the amount of wear (volume loss) observed at 2.5M cycles for standard UHMWPE was similar to the amount of wear following 5M cycles for Integra's HXL UHMWPE.

Figure 13: Integra HXL UHMWPE Material Wear is Less than Standard UHMWPE Material Wear



Values normalized to the amount of wear recorded with standard poly at 5 million cycles

It has been shown that the contact stress increases as the thickness of polyethylene decreases, and that these stresses increase almost exponentially for thicknesses less than 6 mm.[1] Five distinct design variables may have contributed to accelerate wear. These are: 1) thin polyethylene, 2) screw holes, 3) high contact stresses due to reduced congruency, 4) heat-pressed polyethylene, and 5) third body wear debris. Polyethylene wear will increase with time and with the weight and activity level of the patient. Engh et al. recommends: 1) a minimum thickness of 6 mm of actual polyethylene in metal-backed total and unicompartmental knee replacements; 2) a minimum of 8 mm of polyethylene over any screw holes; 3) no overhang of polyethylene and 4) avoidance of heat-pressing for minimally congruent designs.[6]

* Data on file

Cadence total ankle prosthesis features biased poly insert options to further accommodate patients with anterior and posterior subluxated talus. (Figure 14). While standard neutral profile inserts are relatively symmetric in the sagittal plane, biased poly insert options have more material on one side (either anterior or posterior) than the other.

For patients with a subluxated talus, following proper reduction of the joint, this additional material on the biased poly option is designed to assist in maintaining functional sagittal alignment. This is important because sagittal malalignment has been linked to poorer TAA outcomes; recent literature suggests ideally the joint should be returned to neutral alignment in the sagittal plane[28]. From a mechanical standpoint, malalignment in the sagittal plane leads to edge loading and contact stresses of the poly. By design, biased poly helps maintain the talus in the correct position and provides a larger articular surface for the talus to bear load against compared to neutral sagittal profile poly, thereby reducing contact stresses that potentially contribute to accelerated wear of the prosthesis.

NOTE: The Cadence prosthesis is designed to correct intra-articular malalignment resulting from wear or intra-articular malunion; it is not designed to correct extra-articular deformities. Therefore, any extra-articular deformity must be corrected before TAA with the Cadence device. Malalignment due to ligament laxity can also be corrected as long as good ligament balance is restored, which sometimes requires ligament reconstruction.

Figure 14



Subluxation: Anterior



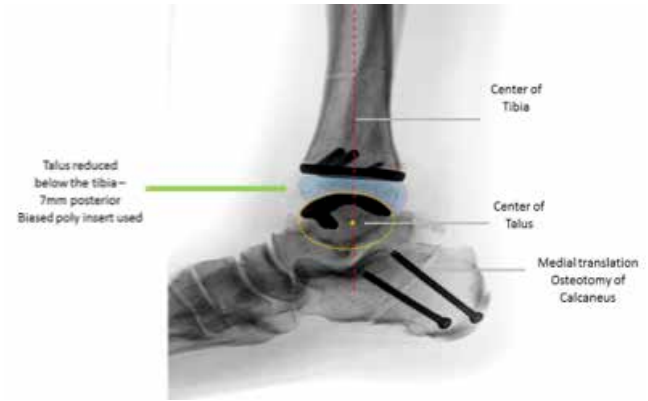
Subluxation: Posterior





The multitude of poly options available in Cadence complement the anatomic design considerations of the tibial and talar components to achieve a higher level of customization to individual patient anatomy, which in turn are designed to improve pain, quality of life, and standard functional measures in patients with end-stage ankle arthritis.





Streamlined Instrumentation and Surgical Technique Designed for Efficiency and Repeatability

In designing the Cadence® Total Ankle System, much consideration was given to optimizing instruments and making advancements to the surgical technique.

Streamlined Instrumentation and Surgical Technique

- Incorporates successful concepts from widely adopted total ankle arthroplasty systems to reduce learning curve
- Many instruments are multi-purpose, used for multiple technique steps
- Consideration for temporary pin placement to avoid vasular structures in talus
- Designed to improve operative experience for talar chamfer resection and implant insertion
- Two color-coded instrumentation trays

Total ankle arthroplasty is regarded by many foot and ankle specialists and orthopaedic surgeons to be technically challenging with an associated learning curve. Several published studies correlate higher surgeon expertise (both in terms of overall TAA procedures performed and expertise with a specific system) to significantly better patient outcomes and reduced complications resulting from surgical errors.[11,12] The importance of the learning curve has been underscored by the Swedish registry, reporting a survival rate of 70% at 5 years for the typical surgeon for the first 30 implantations and 86% as the surgeon performs more procedures.[11,12]

As such, the following were design goals for the Cadence instrumentation design: (1) achieve repeatability between procedures and reproducibility among surgeons, by minimizing instances of required freehand technique; (2) use the best concepts from widely adopted TAA systems to reduce learning curve; (3) innovate new concepts to address existing challenges associated with widely adopted TAA systems; (4) streamline instrumentation and optimize sterilization tray presentation to facilitate efficiency among OR staff.

The Cadence total ankle system technique begins with a standard anterior approach. A single extramedullary tibial alignment guide is secured using one or more pins in the distal tibia. Much inspiration for the alignment guide comes from Integra's previous design experience. A similar guide for an earlier ankle prosthesis system marketed by Integra for over fifteen years received praise its for simplicity and versatility. A spring loaded clamp fits around the proximal tibia, negating the need for a pin through the proximal tibia. Shouldered bone pins provide extra stability by pinning the alignment guide, as well as subsequent cutting guides, to the bone. A single pin in the distal tibia secures the alignment guide while allowing for subtle adjustments to sagittal and coronal orientation; a second pin can be added for further fixation of the guide. This all-in-one alignment guide enables the surgeon to adjust the following: (a) cutting slope in the sagittal plane, (b) global resection level, (c) precision tuning for resection level, (d) rotational alignment, (e) global medial-lateral translation to accommodate varus/valgus deformity, (f) precision tuning for medial-lateral positioning. (Figure 15)

Figure 15



Several instrumentation concepts for tibial bone resection and creating the superior talar bone cut in Cadence were inspired by other widely adopted ankle systems. Preparation of the tibial resection and superior talar resection is performed using cutting guides secured over the single alignment guide. Several templates and alignment tools are included to fine tune the positioning of these cuts, both visually and radiographically. A corner osteotome and a 5mm diameter bone pin are included to facilitate removal of resected bone, complementing standard resection technique of using a sagittal saw and reciprocating saw. (Figure 16, 17)

Figure 16



Figure 17



Two technique advancements developed in Cadence for these steps: (a) use of laminar spreaders in conjunction with the alignment guide to tension the collateral ligaments, thereby ensuring the superior talar cut is made on a horizontal plane and (b) a 2mm tibial cut guide to efficiently resect more tibial bone after removal of the alignment guide if necessary. (Figure 18, 19)

New instrumentation concepts and techniques were developed for preparing chamfered surfaces on the talus; for these steps, benchmarking existing commercially available options revealed opportunities for improvement. Here, efficiencies in the Cadence technique result from having sizing trials double as bone preparation/cut guides and use of common placed pins for multiple bone preparation steps. Temporary pin locations were selected to be in the posterior portion of the talus, intended to preserve talar blood supply. Another key improvement in Cadence involves preparation of the anterior chamfer through a reaming technique successively removing small amounts of bone until a smooth surface is achieved, with minimal preparation afterwards. Overall, preparation of the talus for the Cadence prosthesis is designed to be both reliable and efficient. (Figure 20, 21)

While offering implant options for 672 prosthesis combinations, the Cadence modular trialing system fits in half an instrumentation tray, including trials for various sagittal profile poly designs, (anterior-biased, neutral, posterior-biased). A full trial prosthesis may be constructed in the joint, then moved through the patient's range of motion, prior to preparing bone for securing final implants. Anterior pegs used to secure the tibial tray and the talar dome components are in the same location relative to the anterior edge for all sizes of each implant, allowing for a degree of interchangeability following preparation steps. (Figure 22)

Final insertion of the Cadence prosthesis is performed through three direct inserter/impactor instruments, one for each component. (Figure 23)

Finally, several design improvements were made to the presentation and layout of the sterilization trays, with goal of facilitating efficiency among OR staff. All instrumentation is compactly packaged in two single layer trays, with instrumentation presented in sequential order and colored zones based on specific surgical technique steps. (Figure 24)

Figure 18



Figure 19

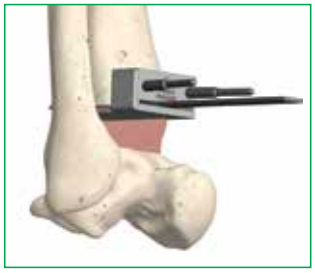


Figure 20



Figure 21



Figure 22



Figure 23



Figure 24





Cadence: Next Step in Ankle Arthroplasty

The Cadence® Total Ankle System is designed to advance TAA procedure through improvements to prosthesis, instrumentation, and surgical technique. Inspiration for and execution of the design comes from collective history of the TAA procedure; our goal is to incorporate and refine proven successful concepts while innovating new solutions to address common areas of concern.

For the Cadence prosthesis, much emphasis was given to anatomic considerations and attempting to recreate natural kinematics of the ankle joint. A multitude of side-specific implant options, including biased poly inserts for subluxated talus anatomy, offers the surgeon an ability to customize the Cadence prosthesis to each individual patient. In doing so, we are striving to reduce potential postoperative complications encountered with current TAA systems, such as fibular impingement, sagittal malalignment, and implant loosening.

For the Cadence surgical technique and instrumentation, there are two key design goals: (1) minimizing bone resection of the talus and (2) streamlining procedural flow. By achieving the first goal, we are seeking to maintain vascularity in the talus, thus reducing potential avascular necrosis. Regarding the second goal, Cadence synthesizes the best instrumentation and technique concepts from preceding ankle systems while addressing areas of opportunity, which is designed to reduce learning curve and increase repeatability and efficiency.

While more clinical use will be needed to fully establish the efficacy of Cadence relative to preceding TAA systems, the advancements in the Cadence Total Ankle System design are intended for us all to take the next step in ankle arthroplasty.

References

1. Bartel DL, Bicknell VL, Wright TM. The effect of conformity, thickness, and material on stress in ultra-high molecular weight components for total joint replacement. J Bone Joint Surg (Am) 1986; 68-A; 1041-51.
2. Bolton-Maggs BG, Sudlow RA, Freeman MA: To tal ankle arthroplasty: A long-term review of the London Hospital experience.J Bone Joint Surg Br 1985;67(5):785-790.
3. Brockett CL, Chapman GJ. Biomechanics of the ankle. Orthopaedics and Trauma. 2016;30(3):232-238. doi:10.1016/j.mporth.2016.04.015.
4. Demottaz JD, Mazur JM, Thomas WH, Sledge CB, Si mon SR: Clinical study of total ankle replacement with gait analysis: A preliminary report. J Bone Joint Surg Am 1979;61(7):976-988.
5. Dexkx, J. Anatomical Data Mining (ADaM) report. 2013
6. Engh GA, Dwyer KA, Hanes CK.Polyethylene wear of metal-backed tibial components in total and unicompartmental knee prostheses.J Bone Joint Surg Br. 1992 Jan;74(1):9-17.
7. Feldman MH, Blake WJ, Perler AD, Paradoa AC, Rockwood JW. The Buechel-Pappas Total Ankle Joint Replacement: Report on Fifty-Seven Cases. In: Update 2002 Proceedings of the Annual Meeting of the Podiatry Institute, Update '02 pp. 310–319, edited by NS Vickers, The Podiatry Institute, Tucker, GA.
8. Giannini, S; Romagnoli, M; O'connor, J.; Malerba, F; Leardini, Alberto (2010). "Total Ankle Replacement Compatible with Ligament Function Produces Mobility, Good Clinical Scores, and Low Complication Rates: An Early Clinical Assessment". Clinical Orthopaedics and Related Research. 468 (10): 2746–53.
9. Glazebrook MA, Arsenault K, Dunbar M. Evidence-based classification of complications in total ankle arthroplasty. Foot Ankle Int. 2009 Oct;30(10):945-9.
10. Gougoulias NE; Khanna A; Maffulli N. History and evolution in total ankle arthroplasty. Br Med Bull. 2009;89:111-51. doi: 10.1093/bmb/ldn039.
11. Henricson A, Skoog A, Carlsson A: The Swedish Ankle Arthroplasty Register: An analysis of 531 arthroplasties between 1993 and 2005. Ada Orthop 2007;78(5):569-574.
12. Henricson A, Nilsson JA, Carlsson A: 10-year survival of total ankle arthroplasties: A report on 780 cases from the Swedish Ankle Register. Acta Orthop 2011;82(6):655-659.
13. Hintermann, B. Ruiz, R. Ankle arthritis and the treatment with ankle replacement. Revista Médica Clínica Las Condes. Volume 25, Issue 5, September 2014, Pages 812–823. DOI: 10.1016/S0716-8640(14)70112-9
14. Kirkup J: Richard Smith ankle arthroplasty.J R Soc Med1985;78(4):301-304.
15. Kitaoka HB, Patzer GL, Ilstrup DM, Wallrichs SL: Survivorship analysis of the Mayo total ankle arthroplasty. J Bone Joint Surg Am 1994;76(7):974-979.
16. Kitaoka HB, Patzer GL: Clinical results of the Mayo total ankle arthroplasty .J Bone Joint Surg Am 1996;78(11):1658-1664.
17. Krause M, Rupprecht M, Mumme M, Püschel K, Amling M, Barvencik F. Bone microarchitecture of the talus changes with aging. Clin Orthop Relat Res. 2013 Nov;471(11):3663-71. doi: 10.1007/s11999-013-3195-0. Epub 2013 Jul 27.
18. Neumann, DA; Kinesiology of the Musculoskeletal System: Foundations of Rehabilitation. iKnowledge: Your Knowledge Base System. Published 2015-03-18, last modified 2015-03-18. Retrieved 2017-04-17, from http://clinicalgate.com/ankle-and-foot/
19. Newton SE III: Total ankle arthroplasty: Clinical study of fifty cases. J Bone Joint Surg Am 1982;64(1):104-111.
20. Ochsner PE. Osteointegration of orthopaedic devices. Semin Immunopathol. 2011 May;33(3):245-56. doi: 10.1007/s00281-011-0241-4. Epub 2011 Jan 21. Review.
21. Pal, GP; Routal RV. Architecture of the cancellous bone of the human talus. Anat Rec. 1998 Oct;252(2):185-93.
22. Prusinowska A, Krogulec Z, Turski P, Przepiórski E, Małdyk P, Księżopolska-Orłowska K. Total ankle replacement – surgical treatment and rehabilitation. Reumatologia. 2015;53(1):34-39. doi:10.5114/reum.2015.50555.
23. Roukus, T et al. Secondary Procedures in Total Ankle Replacement, An Issue of Clinics in Podiatric Medicine and Surgery, Clinics Review Articles: Clinics in Podiatric Medicine and Surgery page 498
24. Saltzman, CL; McIff, TE; Buckwalter, JA; Brown, TD (2000). "Total ankle replacement revisited". Journal of Orthopaedic & Sports Physical Therapy. 30 (2): 56–67. doi:10.2519/jospt.2000.30.2.56. PMID 10693083.
25. Tennant JN1, Rungprai C2, Pizzimenti MA3, Goetz J4, Phisitkul P2, Femino J2, Amendola A2. Risks to the blood supply of the talus with four methods of total ankle arthroplasty: a cadaveric injection study. J Bone Joint Surg Am. 2014 Mar 5;96(5):395-402. doi: 10.2106/JBJS.M.01008.
26. Total ankle replacement (TAR). OrthopaedicsOne Articles. In: OrthopaedicsOne - The Orthopaedic Knowledge Network. Created Nov 09, 2009 11:25. Last modified Jul 09, 2012 11:11 ver.51. Retrieved 2017-04-19, from http://www.orthopaedicsone.com/x/30KdAQ.
27. Van Bergen CJ, de Leeuw PA, van Dijk CN. Treatment of osteochondral defects of the talus.Rev Chir Orthop Reparatrice Appar Mot. 2008 Dec;94(8 Suppl):398-408. doi: 10.1016/j.rco.2008.09.003. Epub 2008 Nov 11.
28. Veljkovic, A et al. Sagittal Distal Tibial Articular Angle and the Relationship to Talar Subluxation in Total Ankle Arthroplasty. FAI 2016 V37(9) 929-937.
29. Weiser, A Integra Data used for Internal documention (available upon request)
30. Zaidi R1, Cro S, Gurusamy K, Siva N, Macgregor A, Henricson A, Goldberg A. The outcome of total ankle replacement: a systematic review and meta-analysis. Bone Joint J. 2013 Nov;95-B(11):1500-7. doi: 10.1302/0301-620X.95B11.31633. total ankle arthroplasty systems today

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

For more information or to place an order, please contact:

United States, Canada, Asia, Pacific, Latin America
USA 800-654-2873 ▪ 888-980-7742 fax
International +1 609-936-5400 ▪ +1 609-750-4259 fax
integralife.com/contact

INTEGRA®
LIMIT UNCERTAINTY

Cadence, Integra and the Integra logo are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries.
STAR is a trademark of Stryker European Holdings I, LLC. INBONE, INFINITY and PROPHECY are registered trademarks of Wright Medical Technology, Inc.
MOBILITY is a trademark of DePuy International Limited. Buechel-Pappas, B-P are trademarks of Endotec, Inc.
©2017 Integra LifeSciences Corporation. All rights reserved. Printed in USA. 0650680-1-EN