Integra®
Addressing Deformity with Cadence®
Total Ankle System in patients presenting with Anterior and Posterior Subluxations of the Talus
Indications

The Integra® Cadence® Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint.

The Integra® Cadence® Total Ankle System is indicated for use to treat:

• systemic arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
• primary arthritis (e.g. degenerative disease)
• secondary arthritis (e.g. post-traumatic, avascular necrosis, if minimally 2/3 of the talus is preserved)

Integra® Cadence® Total Ankle System is also indicated for revision surgeries following failed total ankle replacement and non-union/mal-union of ankle arthrodesis, provided sufficient bone stock is present.

NOTE: In the United States, this device is intended for cemented use only.

NOTE: Outside the United States, this device is intended for cemented or cementless use.
Addressing Deformity with Cadence® Total Ankle System in patients presenting with Anterior and Posterior Subluxations of the Talus

About the Author:

Dr. Tim R. Daniels is an orthopaedic surgeon and the Chief of the Division of Orthopaedic Surgery of St. Michael's Hospital, Professor at the University of Toronto in the Department of Surgery, the Head of the University of Toronto Foot and Ankle program, and the Term Chair in Foot and Ankle Research. He has served on numerous national and international academic, research committees and organizations, most notably on the Board of Directors for the American Orthopaedic Foot and Ankle Society (AOFAS) as Member-At-Large.

He is the recipient of the University of Toronto’s Orthopaedic Chair’s Teaching Award for contributions to orthopaedical education. He is the recipient of the Award of Merit from Canadian Orthopaedic Association (COA). Nationally and Internationally, he is recognized as Canada’s Top Orthopaedic Foot and Ankle surgeon and is the physician to whom other orthopaedists send their most complex and challenging foot and ankle cases. He trains fellows from all over Canada, US, Europe, Middle East, South Africa, Asia, Australia, New Zealand and South America. He is the co-founder and inaugural president of COFAS: Canadian Orthopaedic Foot and Ankle Society – the Canadian counterpart to the American, AOFAS – and the co-founder of the bicoastal Biennial Foot and Ankle Symposium.

Dr. Daniels’s research interests are broad with over 100 publications in peer-reviewed journals, books and review articles covering a variety of topics in foot and ankle pathology. His current research focuses on hindfoot arthritis and deformity and Dr. Daniels is considered a world expert on total ankle replacements. He has one of the largest prospective ankle arthritis databases with data gathered since 2002. He is the four-time recipient of the Roger Mann Award which, to date, is unprecedented: in 2007, 2012, 2014, and 2015. This prestigious award is named in honor of the AOFAS Past President Roger A. Mann, MD – the AOFAS is the largest and most prestigious Foot and Ankle Society in the world. Dr. Daniels is also the two-time recipient of the Takakura Award at International Federation of Foot and Ankle Societies (IFFAS) in 2005, 2014. The IFFAS Takakura Prize is awarded at the Triennial Meeting of the IFFAS and is named in honor of the IFFAS founder, Dr. Yoshinori Takakura.
Addressing Intra-Articular Malalignment due to Subluxed Tali using Bias HXL UHMWPE Inserts provided within the Cadence® Total Ankle System

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate techniques in each patient.

Case 1: Anterior Subluxed Talus

Patient Profile:

A 76-year-old female patient with a history of an ankle fracture 20 years prior and treated with ORIF, (the hardware subsequently removed several years later), presented with increasing pain and swelling to her right ankle. The radiographs demonstrate end stage arthritis of the ankle and anterior subluxation of the talus with equinus contracture and extensive anterior osteophytes (Figure 1).

After the patient was provided with all her potential treatment options, she elected for Total Ankle Replacement. The patient was advised that a functional range of motion of approximately 20° dorsiflexion* / plantarflexion (with correction of the stiff ankle pathology), along with alignment restoration would be possible via the use of the Anterior Biased Polyethylene Insert and the Cadence® Total Ankle Replacement System. The Cadence system was selected due to the ability and ease to address any anterior / posterior translation of the talus with one of the 35 Bias HXL UHMWPE (Highly Cross Linked Ultra High Molecular Weight Polyethylene) insert options provided within the Cadence system which also features anatomic and bone sparing properties.

*Design verification data indicates 15 degrees of dorsiflexion is achievable, however, this is dependent upon anatomy such that 20 degrees may be achievable. Values stated are approximations as stated by the surgeon.
Procedure:

Following administration of general and regional anesthesia (popliteal block), the patient was placed in a supine lazy lateral position. A pneumatic tourniquet at thigh level was placed and the Cadence Surgical Technique utilized. A standard anterior approach to the ankle was performed with the incision starting just lateral to the anterior tibial crest. The dissection was taken to the extensor retinaculum, and the level of superficial peroneal nerve was identified and protected. The extensor retinaculum was opened and the interval between the tibialis anterior and extensor hallucis tendon was developed, reflecting the deep neurovascular structures in a lateral direction. Next, a midline ankle joint capsulotomy was performed and of all osteophytes removed. Once the joint was exposed an intra-articular release of the lateral and medial ligaments were performed. Special attention was paid to the osteophytes and new bone formation at the talar neck (talar bossing), the excess bone was removed to recreate a normal sulcus. Following a ligament release and normalization of the bony anatomy, an intra-operative Silfverskiold test was performed and found to be negative. This indicated that both the Soleus and Gastrocnemius portions of the tenodachilles complex were contracted. Consequently, percutaneous tendo-achilles lengthening (Hoke procedure) was performed prior to performing bony cuts in order to decrease risk of potential malleolar fracture. The external tibial alignment guide was positioned. The slope was estimated and the gap sizer was placed. The tibial cutting guide was attached to the distal alignment block. Alignment was checked for varus/valgus rotation, medial/lateral translation, and slope. (Figure 2). After appropriate placement of the guide was confirmed, and pinned, a saw blade was used to cut the tibia, and the box cut osteotome was used to perform the medial cut. The tibial bone was then removed with rongeur and curettes.

Once the superior talar cut was performed with the appropriate cut guide, the tibial alignment guide was removed. The appropriate posterior and then anterior chamfer cutting guides were attached in sequence and the talar chamfer cuts performed (Figures 3a and 3b).

Figure 2. The tibial cutting guide is attached proximally with clamp at the level of the Proximal Tibial Tuberosity and distal aspect is checked for varus/valgus, rotation and medial/lateral translation.

Figure 3a. The posterior chamfer talar cutting guide is applied to the flat surface of the talus, rotation is checked and the back of the guide lines up with the back side of the talus. Care is taken to place the cutting guide in the middle of the talus, lateral fluoroscopy is used to assess accuracy of position.

Figure 3b. The anterior chamfer cutting guide is depicted. It is positioned based on the pre-determined location of the Posterior Chamfer cutting guide after appropriate pin exchange.
Next the talar peg holes were drilled with the appropriate guide (Figure 4a).

The ankle joint is now ready for trialing implants before opening the final tibial, talar and polyethylene components. A posterior or anterior biased insert can be added to the polyethylene trials during trialing to help determine if a biased polyethylene component is required (Figure 4b).

Figure 4a. The prepared talus with peg holes drilled.

Figure 4b. A biased insert trial extension may be added to the poly insert trial.
The sizing guide was utilized to determine the appropriate tibial trial, and then confirmed via fluoroscopic guidance. Once the tibial and talar trials were inserted; the anterior biased 6mm polyethylene insert trial was added, and anterior drawer test was performed on the talus to confirm adequate stability. Lateral and anterior fluoroscopy images were conducted to confirm the appropriate depth of the tibial component was achieved. The tibial peg holes were then drilled, the ankle was ranged from approximately 20° of dorsiflexion* to approximately 20° of plantarflexion with the trial components in place. The trial components were then removed and the wound was thoroughly irrigated. The final implants placed and impacted [i.e., tibia size 2X, talus size 2, and an anterior biased 6mm HXL Ultra High Molecular Weight Polyethylene (UHMWPE) insert]. (Figure 5)

Intraoperative radiographs of the ankle were obtained showing good position of the Cadence on AP and lateral views, and intraoperative lateral fluoroscopy after implant insertion (Figure 6) demonstrated reduction of the talus beneath the tibia with the patient having approximately 20° of dorsiflexion* with the knee extended, and good stability to sagittal stressing (anterior drawer test).

Routine closure was performed with staples to skin and soft dressing applied. After postop radiographs were taken in recovery, a fiberglass cast with metal stirrup was applied so that the patient could start partial weight-bearing immediately.

*Design verification data indicates 15 degrees of dorsiflexion is achievable, however, this is dependent upon anatomy such that 20 degrees may be achievable. Values stated are approximations as stated by the surgeon.
Post-Operative Course:

Ten to fourteen days post-operatively the patient’s sutures were removed and another metal stirrup cast applied. The patient was instructed to fully weight bear in the metal stirrup fiber glass cast and returned at four weeks post-operatively for application of a removable air boot. Physical therapy was started and continued until 3 months post-operatively. The patient graduated out of the air boot between 6 – 8 weeks following the operation.

The anterior biased polyethylene insert demonstrates that the talus is now reduced below the tibia. The patient was pain free with a functional range of ankle motion and went on to high level functioning at 6 months following the Cadence TAR and deformity correction. The talus remains reduced below the tibia on lateral radiographs and the ankle is stable (Figure 7).

Discussion:

The additional material on the biased poly option is designed to further resist dislocation posteriorly or anteriorly, as required, to achieve better alignment and prevent mal-alignment for patients with a subluxed talus. This is important because sagittal mal-alignment has been linked to increased complications and poorer TAA outcomes. From a mechanical standpoint, mal-alignment 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.

The Cadence ankle replacement has many strengths. First, with 5 talar dome sizes, side-specific polyethylene inserts that come in 7 heights (6-12mm), each with additional anterior and posterior biased options. The modularity of the system allows for over 600+ combinations and helps to select the best fit for the patient. Second, the design is anatomic, and allows for three cortices of coverage on the tibia, without lateral fibular impingement. The incisura on the tibia allows the fibula to nestle into the groove, hopefully minimizing posterolateral ankle pain. Fourth, during the procedure, the talar pins are not placed into the talar neck or anterior body thus preserving talar blood flow. Finally, the highly cross linked UHMWPE (ultra-high molecular weight polyethylene) bias poly implants allow for correction in the sagittal plane, which is unique to the Cadence system.
Case 2: Posterior Subluxed Talus

Patient Profile:

A 69-year-old female patient presented with a pes planus deformity and end-stage arthritis of the ankle joint. She has had ankle pain for approximately 15 years with significant pain and disability over the past 2.5 years. She recalls a severe ankle sprain when she was in her early 20’s that required approximately one year of recovery. She has bilateral total knee replacements, and has tried a short AFO with foot orthotic with no relief.

Standing Anteroposterior (AP) and Lateral radiographs demonstrated end stage arthritis of the ankle, with posterior subluxation of the talus within the ankle mortise (Figure 1, 2). The posterior subluxation of the talus was due to multi-directional ligament instability of the ankle, including insufficiency of the deltoid ligament and the posterolateral ligament complex of the ankle. Widening of the syndesmosis can also occur with this presentation. On the lateral view note the dorsal subluxation of the Navicular due to instability through the midfoot. On the AP view of the right foot, note the lack of forefoot abduction that indicates the ligament instability involves more the ankle then the midfoot (Figure 3). This is also the pattern of collapse commonly seen in patients who start with a flexible forefoot driven Cavovarus deformity, and then develop multi-directional instability of the ankle. The hindfoot alignment view did not demonstrate as much lateral translation of the calcaneus as one would expect given the pes planus deformity (Figure 4). Pes planus deformity is another characteristic of Forefoot Driven Cavus deformities that develop multi-directional instability of the hindfoot with posterior subluxation and/or valgus of the talus.

Figure 1. Lateral of Right hindfoot
Figure 2. AP of Right Ankle
Figure 3. AP of Right Foot
Figure 4. Hindfoot alignment
Surgical Procedure:

A lateral exposure over the calcaneus was completed, and a 45° transverse cut was made through the calcaneus with medial translation osteotomy of approximately 10mm performed. The osteotomy was secured with two 4.5mm cannulated screws. After closure of the lateral wound a standard anterior approach was utilized to perform total ankle reconstruction with the Cadence Total Ankle System. Once the joint was exposed the ankle was distracted with laminar spreaders, and the deltoid ligament was seen to be intact with a good end-point but attenuated. Though anterior and posterior drawer stressing indicated that there was substantial sagittal instability, it was decided to proceed with a total ankle replacement as ligament support was sufficient with tension on the joint. The procedure was performed as per protocol measuring the talus to a size 3 and the tibia to a size 3X. A 7mm polyethylene insert resulted in adequate tensioning of the soft tissues, and a posterior bias trial created sagittal stability. After inserting the final components, the anterior incision was closed. During the implant preparation the syndesmosis was stressed and found to be unstable. The distal syndesmosis was cleaned and after insertion of the implant a 4.5mm fully threaded cannulated screw with washer was inserted into the fibula with the fibular hole over-drilled with the 4.5mm drill to allow for compression of the syndesmosis. Next, a medial incision was made and the deltoid ligament was imbricated with #2 fiberwire suture. Lastly, a Silfverskiold test revealed a 10° equinus contracture with the knee extended, and a posteromedial incision was made at the juncture of the middle / distal third of the calf and a Strayer slide of the Gastrocsoleus complex performed.

Post-Operative Course:

Immediate post-operative repair was performed as per the previous patient protocol. The patient was functioning at a high level 6 months following deformity correction and total ankle reconstruction with the Cadence Total Ankle System. The talus remains reduced below the tibia on lateral radiographs and the ankle remains stable (Figure 5, 6).

Figure 5.
*Other devices pictured are not Integra® product

Figure 6.
*Other devices pictured are not Integra® product
Discussion:

Cadence total ankle prosthesis features biased poly insert options to further accommodate patients with anterior and posterior subluxated talus. While standard neutral profile inserts are relatively symmetric in the sagittal plane, biased poly insert have an additional 2mm's of material on one front or back of the insert (either anterior or posterior).

For patients with an anterior or posterior subluxated talus, following proper ligament release and/or reconstruction, this additional support by the biased polyethylene inserts helps to reduce and maintain the talus beneath the tibial in the sagittal plane. For tali that are extruded anteriorly on pre-op lateral radiographs an anterior biased poly may be required and for tali that are extruded posteriorly on pre-op lateral radiographs a posterior biased poly may be required. This is important because midline talar sagittal alignment has been associated with better outcomes (The effect of the Three-Component Total Ankle Replacement Malalignment on Clinical Outcome: Pain Relief and Functional Outcome in 317 Consecutive Patient, A Barg et al JBJS-A. 2011;93:1969-78). The author finds the posterior biased polyethylene insert extremely helpful in the posteriorly subluxed talus with multidirectional ankle instability.

NOTE: The Cadence prosthesis is designed to address 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.
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