Is Total Ankle Arthroplasty the New Gold Standard for End-Stage Ankle Arthritis?
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Welcome

Hodges Davis, MD
OrthoCarolina
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Almost thirty years ago, Bob Anderson and I performed our first total ankle replacement surgery together. The experience was hopeful at best, but stressful and difficult to reproduce. Some called us crazy or stupid—or both—but we believed that total ankle replacement could be better, and would be better, with the right technology. It was that belief that allowed us to move past that first ankle and ultimately lead us to collaborate with Wright Medical when they acquired the INBONE™ total ankle system in 2008. Nearly 1,000 ankle replacements later, we have made significant progress in ankle arthroplasty, completely changing the way we treat end stage ankle arthritis (ESAA). The “gold standard” in our practice changed from fusion to TAR when we began to see the advancements in technology provide patients with not merely “satisfactory” results, but with increasingly better long-term outcomes than we had seen in our ankle fusion patients.

Wright Medical has remained at the forefront of foot and ankle technology, and I, along with Bob Anderson, Greg Berlet, Murray Penner, Steven Haddad, and Bill McGarvey, have partnered with Wright as their surgeon design team. Together, we have paved the way to challenge the standard of fusion for the treatment of ankle arthritis, and introduced many firsts: the first modular, stemmed ankle replacement (INBONE™ TAR), the first low-profile ankle replacement system with preoperative navigation and patient specific instruments (PROPHECY™ INFINITY™ TAR), and the first system specifically designed for revision ankle replacement (INVISION™ TAR). As a design team, we have collectively undergone a transformative change in the way we approach ESAA based on our experiences with the Wright Medical total ankle systems. Individually, we each bring a different perspective, with very different journeys towards making total ankle replacement the gold standard in our practices.

Having now performed nearly 1,000 ankle replacement surgeries, I know very well what implant and instrument designs will work in my hands. However, the average young foot and ankle surgeon has not yet seen a thousand ESAA patients. But this new generation of surgeons has the advantage of fourth-generation technology and educational resources necessary to offer their patients the “TAR gold standard” for the treatment of end-stage ankle arthritis without a learning curve of hundreds of surgeries over decades of time.

I am extremely excited to continue my collaborative journey with Wright Medical at the forefront of total ankle replacement innovation.

Hodges Davis, MD
How Do We Define a “Gold Standard” Procedure?

Hodges Davis, MD
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In medical practice, “gold standard” refers to a benchmark treatment that is considered the most reliably available under reasonable conditions. In the field of orthopedics, we expect to see gold standard treatments challenged and superseded, but this will never happen with a “novel” treatment. Substantial clinical data with extensive follow-up is required to demonstrate that a new treatment has become safer, more reliable, and better for the patient. Total knee replacement has supplanted the now-unconscionable knee fusion. Are we now entering a new era in which ankle fusion should be considered a last resort?

TAR Utilization is on the Rise

Total ankle replacement has been growing at a much faster rate than ankle fusion. Over two decades, TAR surgeries increased ten-fold, while the number of ankle arthrodesis procedures remained relatively constant. Trends indicate that ankle replacement will likely supersede ankle fusion in the next decade.

Patient Selection is Expanding

The increase in total ankle procedures over the past five years is the result of growing clinical success in the new generation of implant designs. Building on lessons learned from previous ankle designs, the newer designs aim to more closely replicate human anatomy and gait, and utilize predictable, reliable instrumentation and improved surgical techniques. These improvements have resulted in increasingly longer-term survivorship in an expanding patient population. Coronal deformity, high BMI, and physical activity were once considered too high-risk for ankle replacement, and these patients would not have been considered a candidate for ankle replacement.

However, several recent studies have provided evidence that preoperative deformity, high BMI, and recreational activity level do not negatively affect clinical outcomes if a stable, neutrally aligned ankle is obtained.

Pedowitz et al. (2016) conducted radiographic assessment of talonavicular movement and reviewed SF-12, VAS, and FAAM scores in 41 TAA patients and 27 arthrodesis patients. They concluded that “TAA preserves more anatomic sagittal plane motion and provides greater pain relief and better patient-perceived outcomes compared with ankle arthrodesis.”

Seo et al. (2017) performed a gait analysis on TAR ankle fusion and healthy patients (control group). The results included four key characteristics of biomechanical function in which TAR compared favorably to fusion:

1. Faster walking speed
2. Increased ROM in forefoot sagittal motion, especially dorsiflexion
3. Increased hindfoot sagittal motion, especially dorsiflexion
4. Stronger ankle plantarflexion power

These results indicate that TAR would be a more effective treatment for severe ankle arthritis. Seo 2017.

Dekker et al. (2017) evaluated TAR patients with range of motion radiographs and PROMS. The authors found a positive correlation between PROMS and radiographic sagittal plane ankle motion. TAR is a powerful procedure for alleviation of pain from ESAA, and the motion these implants afford is something patients value.

TAR is a powerful procedure for alleviation of pain from ESAA and represents a technological advance as compared with arthrodesis. Dekker 2018.

Odum et al. (2017) analyzed a statistically matched cohort of patients who underwent either an ankle fusion or a TAR. The authors concluded that “ankle arthrodesis was associated with a 1.8 times higher risk of a major complication but a 29% lower risk of a minor complication.”

Younger et al. (2017) analyzed patient expectation and satisfaction pre- and postoperatively. The authors concluded that the TAR patients had higher expectation scores prior to surgery than arthrodesis patients and that patient expectations “may be more likely to be met by ankle replacement compared with ankle fusion.”
Preoperative Navigation: A Game Changer for TAR

Prophecy™ Preoperative Navigation has been a game changer in my practice by allowing for deliberate consideration of the patient’s anatomic details and accurate implant placement to be planned in my office, prior to surgery. Preoperative navigation allows ankle arthroplasty to fit into my choreographed operative schedule with little stress and full confidence in the technical excellence of my TAR surgeries. In my early years of practice, my balance of ankle fusion to TAR was 20:80, but with the inclusion of Prophecy™ planning and guides, I am now using TAR as my gold standard with a current ratio of 80:20 in favor of TAR.

Accuracy Matters

Final implant position and successful soft tissue balancing are key components to the longevity of total ankle implants. Malrotation and malalignment of a total ankle implant increase peak pressures, decrease contact area, and increase rotational torque, thereby contributing to polyethylene wear and a means for implant failure.¹ Neutral coronal ankle alignment has been defined as less than 5° of valgus to less than 5° of varus.² Studies have now demonstrated that the Prophecy™ system is reliable for obtaining coronal balance of the implanted components.

- Daigre et al. showed Prophecy™ helped reproduce a post-op neutral alignment in 93% of patients. The only 3 outliers were exactly 5° varus.¹
- Saito et al. were able to obtain neutral alignment in 96% of their 99 patient cohort.³
- Hsu et al. showed Prophecy™ preoperative navigation guides aided in obtaining neutral alignment in 100% of their 42 patients.⁴

The etiology of ankle arthritis is post-traumatic in a majority of ankles. Therefore, significant deformity related to trauma may be present in many ESAA patients. Prophecy™ preoperative navigation guides aid the surgeon in dealing with deformity by taking into account the mechanical vs anatomic axis alignment, rotational deformities, and sagittal plane deformities.

Images courtesy of Greg Berlet, MD
Time Matters

Minimizing OR is a shared goal with many benefits: less time under anesthesia for the patient, less radiation exposure for OR personnel, and controlling costs for all involved. Efficiency in the OR is a priority for every orthopedic surgeon. By utilizing the preoperative planning capabilities of the PROPHECY™ system, time-consuming steps such as determining alignment, choosing implant size, and reliance on fluoroscopic guidance are all reduced.

Hamid and colleagues studied their PROPHECY™ experience and reported a four minute decrease in hardware setup time and a 34 minute reduction in operating time, for a total time savings of 38 minutes per TAR surgery through use of the technology.

Cost Effectiveness

Reduction in operating room and anesthesia times could provide cost savings for the health care facility. In a 2005 survey of 100 private for-profit and nonprofit U.S. hospitals, the average operating room cost, including anesthesiologist fee, was $66.24 (range: $24.00 to $139.22) per minute.

An Engineer’s Perspective

Paul Stemniski, Director PROPHECY™ R&D

The technical goal of any arthroplasty procedure is to put the right implant in the right place. But imagine if you had a partner for total ankle cases who could help you understand the biggest challenges prior to walking into the OR. PROPHECY™ is the only* pre-op navigation system with patient specific instrumentation for total ankle arthroplasty in the world, backed by over 20,000 total ankle replacement cases. This patient-specific system is also surgeon-specific. Your surgical preferences are the instructions that the engineers follow when digitally planning a case.

20,000 scans and counting…

The PROPHECY™ Process


*As of August 2019
CASE STUDY: Total Ankle Arthroplasty in a Patient with ESAA with Proximal Deformity and Substantial Difference in Mechanical and Anatomical Axes

Contributed by: Andy Goldberg, OBE MD FRCSI FRCS (TR&Orth)
Orthopaedic Foot & Ankle Specialist

Patient History
This 63-year-old female patient presented with severe right ankle pain that had a profoundly negative effect on her quality of life. She required a cane for walking and had failed conservative treatment. At the age of 21, she suffered fractures of the right femur, tibia, and fibula in a traffic accident. She was treated with a femoral nail and ORIF of the tibial plateau, and she eventually returned to an active lifestyle. About five years prior to presentation, her symptoms began to progressively deteriorate.

Physical Examination
At presentation, the patient walked with a severe antalgic and short-legged gait. The stance phase was shortened on the painful right side. Her walking tolerance was less than one block. She had a leg length discrepancy with shortening on the right side of one inch.

Her ankle pain was circumferential around the front and sides of the ankle joint. The soft tissue envelope was intact with good perfusion. The ankle joint was stiff with dorsiflexion to neutral only and plantar flexion to 20 degrees. She had very little motion at the subtalar joint, although motion at the talonavicular and calcaneocuboid joints was supple, with no pain or tenderness in that area.

Radiographic Examination
AP and lateral standing ankle x-rays showed end-stage arthritis with neutral intra-articular alignment and severe subtalar arthritis. (FIGURES 1A and 1B) Long leg films showed a major tibial malunion with translation and varus malalignment. (FIGURE 2) The difference between her anatomical and mechanical axis of the tibia was 7.1 degrees in the coronal plane. An MRI and CT scan of her ankle were arranged, and these confirmed severe subtalar arthritis.

Diagnosis and Case Assessment
The patient had end stage ankle osteoarthritis with failure of all nonoperative modalities, therefore surgery was indicated. The options of arthrodesis and ankle replacement were discussed with her. Her concern with fusion was that the subtalar joint was already worn, and a fusion of the ankle

FIGURES 1A and 1B. Preoperative AP and lateral x-ray
would undoubtedly risk this worsening. Extensive discussion took place in relation to the mechanical malalignment and in particular surgery to her knee. Her knee was asymptomatic, and she was not prepared to consider revision of the proximal malalignment or total knee arthroplasty. The patient elected to undergo total ankle arthroplasty with the INFINITY™ Total Ankle Replacement System using PROPHECY™ Preoperative Navigation Guides.

Preoperative Planning

With the patient’s history of prior trauma, long leg films were taken to make a complete assessment of alignment. Careful consideration was given as to whether to balance the implant on the mechanical or anatomic axis, or to split the difference between the two so as to avoid the appearance of excessive correction on the postoperative images. Using the PROPHECY™ preoperative planning process, the decision was taken to implant the tibial component along the mechanical axis to improve her overall function. The PROPHECY™ guides were designed and produced according to this plan. (FIGURES 3A and 3B)

Surgery

A standard anterior surgical approach was used. The patient-specific PROPHECY™ Guides were used to set the locations of the pins needed to make the tibial and talar cuts. After the pins were set, the guides were removed, and the standard resection guides were placed over the pins to guide the cuts.

The procedure was completed with the INFINITY™ Total Ankle instrumentation following the standard surgical technique. Fluoroscopy was used to confirm that implant positioning and seating were consistent with the preoperative plan. (FIGURES 4A, 4B, and 4C)

As a result of the mechanical axis alignment, the implant appeared to be in an overly varus position. However, we were confident with the preoperative planning process, and intraoperative fluoroscopy confirmed that the PROPHECY™ alignment was correct.

The patient was placed in a well-padded plaster backslab before leaving the operating room.

Postoperative Care*

At two weeks postoperative, the splint and sutures were removed, and the patient was placed into a full below-knee cast. She was advised that she could bear weight as much as was comfortable. At six weeks postoperative, the patient was transitioned to an ankle brace, and a physiotherapy program was initiated. At 12 weeks postoperative, the patient was cleared for return to daily function, but she advised to wear the ankle brace for any strenuous activity. She was instructed to avoid activities that risked falling, vigorous twisting, or repetitive impact of the ankle.

One Year Postoperative

At 18 months postop, ankle range of motion is 5° dorsiflexion and 30° plantarflexion. The patient reports that her symptoms are much improved, and her back pain has resolved. Her exercise tolerance is far improved, and she can perform most of her activities without limitation. She no longer uses a cane. She had hoped for better dorsiflexion; due to her stiff subtalar joint walking on uneven surfaces was difficult but far better than prior to her ankle replacement. A posterior decompression with Achilles lengthening was discussed, but she reported that she was satisfied with her current range of motion and declined further surgery. She will be followed annually.

*Postoperative care is the responsibility of the individual surgeon. Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery. Consult your doctor to find out if surgery is right for you.
The revolution in the treatment of end-stage ankle arthritis that has occurred over the past two decades has been truly remarkable. It was only just over 20 years ago, during the time of my training, that ankle arthrodesis was the only option. But in the relatively short time following this, a monumental shift has occurred. Over the past 20 years, through the hard work of many innovative surgeons, investigators and developers, a large body of data has emerged to demonstrate the reliability, durability, and superior outcomes for total ankle replacement compared to arthrodesis. I have now reached the point in my practice where, for age- and indication-appropriate patients, total ankle replacement is now the new “gold standard”.

Murray J. Penner, MD, FRCSC
Vancouver, British Columbia Canada

In my own practice, early total ankle replacement designs had major limitations, with instrumentation and techniques that often led to unpredictable implantation, limiting results. The launch of the INFINITY™ ankle represented the results of just such further development and signified a huge step forward for ankle replacement. With the INFINITY™ ankle, particularly when coupled with PROPHECY™ instrumentation, highly reproducible implantation became possible, with excellent primary stability at the bone-implant interface and stable articular mechanics that replicated ankle motion very well, all while minimizing bone resection with a low-profile design. In over six years of experience with INFINITY™, in my practice, it has proven to be an extremely reliable prosthesis, with none of the major problems associated with the designs I used previously. Over this time, the INFINITY™ ankle, has clearly become the “gold standard” for the treatment of end-stage ankle arthritis in my practice.

Early Clinical Results

Early-to mid-term outcomes with the INFINITY™ ankle have been excellent. In 2018, we published the outcomes of our first 67 cases done at two centers with minimum 2-year follow-up. In this series, we found excellent patient-reported prospective clinical outcomes, with revision of only two components. Surgeons outside of the INFINITY™ design team have also published very good early results. King et al. reported a series out of the UK with minimum 2-year follow-up in 20 cases with very positive results. Radiographic analysis demonstrated excellent alignment with no evidence of loosening in any cases, and no cases underwent or were pending revision. Saito et al. also reported similarly low revision rates with early usage, with only three of 64 cases undergoing revision.

97% SURVIVORSHIP at 2 YEAR FOLLOW-UP

Growing Utilization Outside the US

Not only has the INFINITY™ ankle become the number one choice of surgeons in the US, it has also changed the way TAR is performed in another large TAR market, the UK. Prior to release of the INFINITY™, usage was dominated primarily by mobile bearing designs. In the latest report from the National Joint Registry (NJR) for the UK, this trend is documented by showing the INFINITY™ ankle to be the most frequently used prosthesis for the last reported year (2017).

*PearlDiver Technologies, Inc. | April, 2017
One of the Largest Total Ankle Studies Now Underway

Enrollment has now been completed for a UK-based post-market INFINITY™ Total Ankle System follow-up study. With 500 patients enrolled across 12 sites in the UK, this marks one of the largest total ankle replacement studies conducted. The multicenter, non-randomized, prospective study of 500 total ankle replacement patients will evaluate 10 year implant survivorship and outcomes associated with the INFINITY™ Total Ankle System. Study investigators include 20 surgeons led by David Townshend, MBBS FRCS (Orth), Consultant Orthopedic Surgeon, Northumbria NHS Healthcare Trust, UK.

“Understanding the experiences of more than 500 patients will give us valuable insights to help us better serve patients suffering from end-stage ankle arthritis,” expressed lead investigator Mr. David Townshend. “Early results have been highly encouraging, and we, along with Wright Medical, are committed to collecting and assessing robust clinical data that substantiates the value of these new systems.”

The Importance of Options

As the total ankle replacement procedure becomes increasingly prevalent and surgeons gain more experience, the need for implant options designed to address patient-specific needs is greater than ever. Patients are likely to present with variations in bone quality, deformity, pre-existing hardware and a number of other unique, patient-specific surgical challenges. The PROPHECY™ system allows for a preoperative game plan to address these challenges. However, having the tools and implant options needed to successfully build that game plan is equally important. This process begins with prosthesis selection.

Is the INFINITY™ or INBONE™ system more appropriate for this patient? If the answer is INFINITY™, assessment of the quantity and quality of talar bone stock should be done to determine the most appropriate construct configuration. In cases of quality bone in younger patients, a chamfered talus should be considered to ensure that options for revision are available years down the road. If a patient presents with questionable talar bone stock, which can be assessed via the PROPHECY™ report, or with a flat top talus, implantation of an INBONE™ talar component is a viable solution.

Images courtesy of Murray J. Penner, MD, FRCSC

CASE STUDY: Total Ankle Arthroplasty in a Patient with Post-traumatic Ankle Arthritis

The patient had severe pain and dysfunction of the left ankle with failed nonoperative treatment, making surgical treatment of his left ankle arthritis well-warranted. The patient’s age, BMI, activity goals, and ankle alignment make him a candidate for either ankle arthrodesis or arthroplasty. Despite requiring three reoperations over the past 10 years to replace broken polyethylene inserts on his right STAR ankle replacement, the patient strongly favored total ankle replacement over fusion for his left ankle. He felt the preserved motion in his right ankle was extremely beneficial and wished to maintain his range of motion on the left as a result. In view of his experience with TAR, his well-preserved left ankle range of motion, and good bone stock, the patient elected to undergo total ankle arthroplasty with the INFINITY™ Total Ankle Replacement System.

Patient History
The patient presented as a healthy, physically fit 64-year-old female with a BMI of 25. She reported that she enjoys skiing and horseback riding, but was no longer able to do these activities due to severe left ankle pain. At age 16, she had a left distal tibia fracture that was treated with casting (FIGURES 1A and 1B). The fracture healed, and she did not have a problem with the ankle for many years. Over the past five years, the patient began to experience gradual onset of left ankle pain, which she described as “severe” at the time of presentation. Previous treatment for the pain included NSAIDs, an ankle brace, and a cushioned, rocker-sole shoe. Corticosteroid injection provided good pain relief, but only lasted for about six weeks.

Examination
At presentation, the patient walked with a mild limp favoring her left side and had a walking tolerance of about one block. Her left ankle pain was localized to the anterior portion of her ankle, with pain also present medially and laterally. Her pain was worse with dorsiflexion and when walking on uneven surfaces. The left foot was neutral in appearance and alignment. The ankle had a range of motion of 0° degrees dorsiflexion and 30° plantarflexion. She had full range of motion at the subtalar joint, with no pain or tenderness in that area.

Imaging and Diagnosis
AP and lateral standing ankle x-rays (FIGURES 2A and 2B) show end-stage arthritis with neutral intra-articular alignment and no adjacent hindfoot arthritis (COFAS Type 1). A left ankle CT scan (FIGURE 3) shows advanced ankle arthritis with no subtalar arthritis.
Case Assessment
The patient had significant ankle pain and dysfunction. She failed nonoperative treatment, therefore surgical treatment was warranted. The patient’s age, activity goals, low BMI, and neutral foot alignment made her a candidate for either ankle arthrodesis or arthroplasty. After extensive discussion, and in view of her activity goals and reasonably preserved ankle range of motion, the patient elected to undergo total ankle arthroplasty with the INFINITY™ Total Ankle Replacement System.

Preoperative Planning
PROPHECY™ Preoperative Planning Guides were used to optimize implant position and ensure that any deformities resulting from the previously fractured tibia would be accounted for by aligning the tibial component to the mechanical axis (blue line shown in FIGURE 4). A 3° correction of the talar varus angle was incorporated into the patient-specific plan (FIGURE 5).

Due to the surgeon’s preclinical evaluation, which showed good ankle range of motion and excessive wear of articular cartilage, the PROPHECY™ Preoperative Plan incorporates smaller bone resections (per the surgeon’s recommendation) in order to restore joint height.

Surgery
A standard anterior surgical approach was used. The patient-specific PROPHECY™ Guides were used for both the tibial and talar cuts. The procedure was completed with INFINITY™ Total Ankle instrumentation following the standard surgical technique. Excellent implant positioning and seating were confirmed with intraoperative fluoroscopy (FIGURES 6A and 6B).

Postoperative Care*
The patient was placed in a well-padded plaster splint before leaving the operating room. She remained splinted and non-weightbearing for two weeks, after which the splint and sutures were removed, and the patient was placed in a below-knee walker boot. The patient was allowed to begin gentle range-of-motion ankle exercises and weightbearing in the walker boot as tolerated. At six weeks postop, the walker boot was discontinued, and a vigorous physiotherapy program was initiated. At 12 weeks postop, the patient was allowed full return to function. The patient was instructed to return annually for reassessment with x-rays.

The patient is currently at one year postop (FIGURES 7A and 7B). Ankle range of motion is 15° dorsiflexion and 30° plantarflexion. She reports no ankle pain at all and has an unlimited tolerance for walking and standing. She can walk on uneven surfaces, including sand, with no problems. She has returned to horseback riding and moderate level skiing.

*Postoperative care is the responsibility of the individual surgeon.
Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery. Consult your doctor to find out if surgery is right for you.
A Decade of Experience with a Modular Implant System

I have been fortunate to have a career that has spanned the evolution of modern total ankle arthroplasty. I feel privileged to have been both an observer and participant in what began as a frontier experience, attempting to solve challenges in component survivability in situations that we now consider commonplace with predictable solutions. Though we continue to develop the next generation in the evolution of the total ankle prosthesis, the toolbox of today cannot be overlooked, as it contains many powerful implants. Switching my implant choice to INBONE™ I in 2008 was not without pause, as that system was decidedly different in many ways from its predecessors. Still, I appreciated the potential durability of that implant and the control and predictability of implantation via the secure jig mechanism. When I implanted the first INBONE™ II in September 2010, I knew that I was using a prosthesis that I could trust to give my patients the best possible sustainable outcomes. Having implanted 452 INBONE™ II prostheses to date, my trust in both the design and implantation of this prosthesis has not waned, and I consider it my workhorse for biologically compromised mild deformity to severely deformed reconstruction patients.

No Two Arthritic Ankles are the Same

In 2014, Tennant et al. published their results of a cadaver study investigating the potential iatrogenic damage to the talar blood supply during implantation of four ankle prosthesis designs. The authors’ methodology was meticulous, however, as a highly experienced practitioner, I had practical concerns about the in vitro reproducibility of their data. Placing an implant in a cadaver without ankle pathology has limitations in extrapolation to most arthritic ankles. Over one third of TAR candidates present with at least 10 degrees of coronal plane deformity, and even those without ankle deformity often have mal-alignment of the foot beneath. I appreciate the authors’ concern that a 6mm drill hole placed through the calcaneus as part of the INBONE™ II surgical procedure could violate the sinus tarsi blood supply. Because I had not observed this issue with my INBONE™ II patients, I conducted my own mini-investigation to determine the clinical likelihood of blood supply violation.

I asked my then-resident, Andy Hsu, MD, to pull 40 random INBONE™ II cases (out of a pool of 200) performed by me that had a minimum 2-year follow-up and review the post-op CT scans. I routinely order a CT scan at 3 months post-op to confirm ongrowth at the bone/implant interface. The axial and sagittal cuts provided precise information regarding the location of the intramedullary drill hole and guide placement. Dr. Hsu independently reviewed the scans for drill hole placement. He measured the distance between drill hole and the portion of the sinus tarsi where critical vascular anatomy traverses.

Dr. Hsu found that the intramedullary drill bit violated the critical location of the sinus tarsi in only 3/40 (7.5%) patients (Figure 1A). This finding was substantially lower than the 75% (3/4 cadavers) reported by Tennant et al. The 2-year post-op radiographs for these three patients showed no evidence of AVN, avascular changes, or difficulty of ongrowth at the bone/implant interface. We hypothesize that extraosseous and intraosseous anastomoses prevented excessive blood supply disruption. In the remaining 37 cases, we found that a margin of bone averaging 2.5 mm +/- 1.6 mm (Figures 1B and 1C) separated the landmarks.

Images courtesy of Steven L. Haddad, MD
The intent of my case review was not to refute the research reported by the University of Iowa group, but to investigate its clinical validity and determine whether I was potentially creating additional pathology to compromised patients through this method of implantation. Upon review of my patient data, my concerns were allayed. We sent our findings in a letter to the editor of JBJS AM. However, we cannot find reference to the letter on the journal’s digital archive.

Early to Midterm Results

Early to midterm results of the INBONE™ prosthesis demonstrate significant improvements in radiographic, functional, and patient reported outcomes in those suffering from end stage ankle arthritis. The INBONE™ “high profile” design raises concern among some surgeons about bone sacrifice and the capability of revising a stemmed implant. These surgeons may exclusively utilize TAR designs that in theory are “resurfacing” or “low profile” designs in order to have the capability to revise them in the future. I initially subscribed to this theory, but clinical experience has shown me that the patient’s biology and pathophysiology surrounding the implant warrant as much consideration or more—than the implant design. From this, I have learned that no single TAR design works for all patients with end stage ankle arthritis. It is the obligation of the surgeon to select the appropriate implant design or configuration for each patient.

There are many circumstances in which a higher-profile, stemmed implant is the correct choice, even for patients below the age of 50. Post-traumatic avascular changes, osteopenia/osteoporosis, or systemic arthropathy can result in poor bone quality at the bone-to-implant surface, requiring an implant that will accommodate or replace the diseased segments to provide a sustainable outcome. Significant pre-existing deformity or eccentric postoperative loading due to imbalanced gait or proximal limb disease require an implant that maximizes surface area for ongrowth in order to prevent micromotion and resultant loosening. Obese patients can have a more predictable outcome with a durable implant that allows better load sharing. I frequently use the INBONE™ II TAR due to the prevalence of these conditions in my cohort of end-stage ankle arthritis patients, making ability to revise less of a worry.

Routine follow-up procedures, e.g., bone grafting osteolytic cysts in compromised areas or polyethylene exchange for wear, are relatively small compared to revision of a lower-profile metal component. In contrast to the popular dogma of using low profile implants to limit bone resection, the talus does not discriminate in bone loss due to implant failure, and revision becomes equally challenging with subsided metal components.

Finally, should it become necessary, we now have excellent instrumentation to assist with revising stemmed implants and avoid anterior tibial corticotomy, thus providing security to the surgeon utilizing INBONE™ II in primary TAR. There is a role for both high-profile and low-profile TAR designs, and careful study of the preoperative data should steer the surgeon towards the correct design to provide long-term patient satisfaction.

CASE STUDY: Total Ankle Replacement in a Patient with Painful Varus Hindfoot Deformity

Contributed by:
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Patient History and Prior Surgery
This 63-year-old gentleman presented with a painfully deformed left ankle and hindfoot. His history included four separate incidents of fracture about his foot and ankle. He had an arthroscopy of his ankle one year prior (performed elsewhere), and he noted that the deformity progressed after that procedure, as did his pain. He had failed brace management.

Discussion of Pathology
The patient had pathology on multiple levels: an anterior extruded talus with significant varus deformity of 25 degrees; (FIGURES 1A, 1B, and 1C) motion restricted to -5 degrees dorsiflexion and 25 degrees plantarflexion, though both of these measurements are artificial given the ankle was not articulating; grossly unstable ankle with respect to deformity, but rigid in the sense that the deformity was not correctable. The significant ligament pathology would mandate a non-anatomic repair should he choose total ankle replacement (TAR).

CT scan showed his bone quality to be sufficient (FIGURE 2A), and this was critical in determining his ability to heal following either fusion or TAR. However, he had significant adjacent joint arthritis at the subtalar joint. Coronal plane CT imaging revealed additional pathology, including the erosion of the medial distal tibia and the medial translation of the calcaneus upon the talus, accentuating the varus deformity (FIGURES 2B and 2C).

Treatment Plan
The patient understood the technical difficulty in his ankle reconstruction and further understood that the treatment plan would require two surgical stages: a subtalar fusion in the first surgery, and total ankle arthroplasty in the second surgery. There were two primary reasons for this staging. First, performing a subtalar fusion at the same time as a total ankle arthroplasty is believed to compromise the talar blood supply, resulting in avascular necrosis of the talus. There is also a higher likelihood of subtalar nonunion if the two procedures are combined because of differing postoperative protocols: subtalar fusion requires immobilization postoperatively, while arthroplasty requires early motion.

Second, the dislocated ankle joint would require a strong lateral ligament reconstruction to keep the corrected varus from recurring and to maintain the prosthesis within the ankle joint. The patient also understood that if the correction were not successful in the first stage, he might require an ankle arthrodesis in the second stage instead of an ankle arthroplasty.

Stage 1: Subtalar Fusion

Deformity Reduction and Fixation
In the first surgical procedure, the deformity was reduced and pinned in a neutral position. The deformity was very rigid, so a smooth wire was inserted and used as a “joystick” to manipulate the ankle to a neutral position (FIGURE 3A). Cement in liquid form was then added to the medial ankle joint and allowed to harden in order to maintain the deformity reduction (FIGURE 3B).
Flat cuts were made at the subtalar joint, removing bone at all three facets (posterior, middle, anterior) to allow maximal bone contact at the subtalar joint while allowing lateral translation of the calcaneus, further reducing varus. The flat cuts incorporated a closing wedge to ensure the heel was reduced. Screws were placed to maintain the correction (FIGURE 3C).

**Ligament Reconstruction**

The ligament reconstruction was fixed with spiked ligament washers to prevent ligament “creep” at the insertion site. This type of ligament reconstruction must be tight to prevent anterior translation of the talus and varus deformity recurrence. Note the drill hole in the fibula, which required a significant bone bridge at the apex (anterior distal fibula) to prevent bone breakage and tendon graft pullout.

The anatomic insertion points for the washers can be seen in (FIGURE 3D). It is critical to create an anatomic ligament reconstruction with the allograft to maintain alignment.

**Stage 2: Total ankle replacement surgery**

Three and a half months after stage 1 surgery, the total ankle replacement procedure was performed.

The previous hardware was removed, and the INBONE™ II footholder was applied, holding the deformity corrected via a lamina spreader. The cement block was removed, although this step is not always required, as the cutting block will cut “around” the cement, allowing joint reduction during preparation.

The INBONE™ II components were placed according to the standard surgical technique. Simulated weight bearing confirmed stability and a balanced ankle joint (FIGURES 4A, 4B, and 4C).

Secondary calcaneal assessment via an intraoperative fluoroscopic view (FIGURE 4D) revealed a mild residual heel varus, which required correction (FIGURE 4E). A secondary closing wedge calcaneal osteotomy was performed to align the calcaneus to neutral.

No deforming force can be allowed to occur following an ankle replacement of this complexity.

**Postoperative Care***

Following the second surgery (total ankle replacement), physical therapy commenced two weeks postoperative, working on passive range of motion. Weightbearing stretch was begun at four weeks postoperative because patient had a well-fixed prosthesis without significant supplementary procedures, e.g. osteotomies.

Standing in a CAM boot was implemented at six weeks postop with gradual increase in walking from a few steps to return to shoe at 10 weeks.

Physical activities were avoided until four months postoperative in order for the bone mass to increase to prevent stress fractures or subsidence at the prosthesis.

**Patient Outcome**

At 1.5 years postoperative, patient was capable of walking in a shoe without pain. Radiographically, no component subsidence was noted, confirming good resting bone strength to support the prosthesis (FIGURE 5A). True ankle range of motion is shown in the flexion/extension radiographs (FIGURES 5B and 5C).

*Postoperative care is the responsibility of the individual surgeon.

Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery. Consult your doctor to find out if surgery is right for you.
The Unique Challenges of Revision Arthroplasty

In my practice, the number of arthrodesis procedures versus arthroplasties have essentially inverted over the course of the last two decades, from approximately 90% fusion and 10% arthroplasty to the converse. Ankle replacement has become preferable for many surgeons --myself included --as the treatment option of choice in the management of end-stage ankle arthritis due to its favorable performance in comparison to arthrodesis. With respect to pain and functional outcome scores, arthroplasty performs favorably by providing equal, if not better, pain relief, improved gait patterns, and better stride length. While longer term follow-up data is needed, survivorship is so far promising. It is this last point that stirs the greatest debate as to the value of arthroplasty over arthrodesis.

Traditional considerations for failed arthroplasty were focused on highly complex fusion techniques often involving large bulk allograft or metallic space fillers. In extreme situations, amputation was also a consideration. While these are still standard treatment within the domain of revision ankle replacement surgery, there is a burgeoning area of growth within this discipline as the concept of revision arthroplasty emerges as a primary consideration for these difficult scenarios.

The Need for a Robust Modular System

The INBONE™ II system has long been the logical choice for revision of failed ankle implants due to the system’s key design features.

In a study of 35 Agility to INBONE™ II revisions, Williams et al. concluded that revision TAR is a viable treatment for failed primary TAR and that the design of the INBONE™ II makes it suitable for revision cases, attributable to three features of the system:

1. The tibial component is modular and relies more on the intramedullary canal for stability, which is crucial in revision cases with substantial bone loss where the tibial plafond cannot be relied upon for stable fixation.
2. The instrumentation serves as a reliable guide for alignment of the prosthesis with the anatomic axis of the tibia shaft.
3. The wide talar base and the modular design of the talus maximizes talar support.

STAR implant presenting mechanical loosening at five years. Revised with INBONE™ II

Images courtesy of Michael Brage, MD
An Implant Designed Specifically for Revision Arthroplasty

Studies have shown that patient-reported outcome scores improved after revision surgery but never reached the same degree of improvement seen after primary TAA. The reason for the differences is unclear, but two influencing factors were bone loss and raising or lowering the joint line. These two unique challenges were taken into consideration during the design of the INVISION™ Total Ankle Revision System.

The INVISION™ talar plate provides a platform with which the surgeon can build a solid stable construct over potentially large cavitory talar defects to more equally and effectively dissipate forces and absorb stresses.

Steven Haddad, MD and Brian Steginsky, DO illustrated the potential of the INVISION™ talar plate in a 2019 study looking at 16 patients who underwent revision total ankle arthroplasty using the INVISION™ talar plate. There was a significant improvement in talar height of 4.7mm after revision total ankle replacement and talar height was maintained at most recent follow-up. The authors concluded “early outcomes demonstrate a predictable method to salvage catastrophic prosthesis failure associated with severe talar subsidence and deformity.”

Pre-Op Navigation for Revision Arthroplasty Opens New Possibilities

The addition of PROPHECY™ Pre-Op Navigation for revision applications adds yet another valuable tool to the total ankle surgeon’s armamentarium to tackle revision arthroplasty of increasing complexity. The ability to preoperatively plan out these cases and determine appropriate alignment based on the individual patient’s CT data will provide surgeons with an extra level of confidence that the implants will be positioned in the optimal alignment.

Images courtesy of Steven L. Haddad, MD.

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Images courtesy of Dr. William McGarvey

3. Steginsky B, Haddad SL. Restoration of Talar Height using a Modular Revision Prosthesis after Failed Total Ankle Arthroplasty. AOSSM Specialty Day, 2019
CASE STUDY: Total Ankle Revision of a Failed Agility Total Ankle Replacement

Contributed by:
William C. McGarvey, MD
Chief of Foot and Ankle Surgery at the McGovern Medical School at the University of Texas Health Science Center Houston, TX

For more detailed Case Study Information visit totalankleinstitute.com

Patient History
The patient was a 65-year-old female who was referred to me in 2005 for right ankle post-traumatic arthritis. In 2006, the patient underwent an Agility total ankle arthroplasty (Depuy Synthes) performed by me. The patient did well in the immediate postoperative period with reported relief of ankle joint pain, however her recovery was compromised by an early fall. She did reasonably well for several years but never had complete relief of her pain. In 2012, she underwent a subtalar fusion in an attempt to alleviate the pain, which was marginally successful.

Examination and Radiography
Twelve years after her ankle replacement surgery, the patient returned for re-evaluation due to increasing pain. Clinical examination at that time demonstrated tenderness throughout the ankle articulation. She had reasonable alignment but exhibited increased external rotation with gait and static stance. Radiographic studies demonstrated some subsidence of the Agility talar component and lucency around the malleolar borders of the tibial component, particularly the lateral side. (FIGURES 1A and 1B).

CT confirmed the radiographic findings and showed solid subtalar fusion (FIGURES 2A and 2B).

Treatment Plan
We elected to use INVISION™ Total Ankle Revision with PROPHECY™ Preoperative Navigation to aid in the preoperative planning and orientation of the new implant. Using CT scans of the ankle, a PROPHECY™ alignment plan was created, reviewed, and adjusted (FIGURES 3A, 3B, and 3C). Alignment guides were then manufactured (FIGURE 3D). The perceived advantage of the system was the opportunity to determine appropriate alignment with respect to the mechanical axis of the native tibia despite the malunion of the original fracture. Additionally, rotational control could be evaluated based on real anatomic landmarks such as malleolar axis in reference to the tibial tubercle, which could only be “eyeballed” without three-dimensional information provided by the PROPHECY™ CT data. Using this planning system, an INBONE™ tibial tray was identified to restore joint height and compensate for the bone loss related to the original implant. The 3mm thick INVISION™ talar plate would not only provide excellent perimeter coverage but also cover the talar fin defect left by the Agility implant.

Surgery
The patient underwent explantation of the existing Agility replacement and installation of a new INBONE™ tibia and INVISION™ talus implant.

First, the PROPHECY™ Tibial Alignment Guide was used to place pins to align the cut block in order to make the predetermined tibial cut after implant removal (FIGURES 4A and 4B). Additional pins were placed prophylactically in each malleolus to aid in fracture prevention, as the malleoli were thin due to resection at the time of implanting the Agility and vulnerable upon its removal.
Once the Agility was explanted, the sequence was the same as that for a primary PROPHECY™ INBONE™ except that the talar resection was referenced from the tibial cut (FIGURES 5A and 5B). Ankle deformity correction was accomplished by a combination of manual positioning of the foot plus the use of assistive, intra-articular, patient-specific spacer blocks to facilitate re-alignment of the talus bone based on the predetermined corrected state from the alignment plan. The final talus resection depth was adjusted manually and determined using lateral fluoroscopy.

The remainder of the case followed the steps of a routine PROPHECY™ case, but using an INVISION™ talar construct instead of INBONE™.

Intraoperative fluoroscopy shows excellent position of the implant with restoration of ankle height and good talar coverage and outstanding range of motion, which was better than preoperative (FIGURES 6A and 6B). To reduce the risk of postoperative malleolar fracture, cannulated screws were inserted into both malleoli over the existing K-wires.

Postoperative Care* and Follow-up
Immediately postoperative, the patient was placed in a splint and immobilized for the first few days after surgery.

At one week postoperative, the patient began early ROM exercises. Progressive weightbearing was introduced at three weeks postoperative.

At three months postoperative, the implant continues to show good alignment radiographically (FIGURES 7A and 7B). The patient reports that her pain has improved substantially. She reports that her ankle pain is now less than at any time during the history of the previous implant. Her range of motion has improved to 40° plantarflexion (35° preop) and 10° dorsiflexion (5° preop). She walks without a limp and reports that her life has regained normalcy from pain relief and substantially improved function. To date, her postoperative recovery course has been uneventful.

*Postoperative care is the responsibility of the individual surgeon. Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery. Consult your doctor to find out if surgery is right for you.
Growing numbers of patients use the Internet to self-educate and self-diagnose—with mixed results. Some of my patients are surprised that they are a candidate for surgical intervention, and as many are disappointed that they are not. It is more important than ever to discuss and understand the patient’s goals and expectations for surgery. Just as arthrodesis is a suboptimal solution for many patients, not every patient is a good candidate for TAR. As more data becomes available for the long-term survivability of TAR, we as clinicians can help manage patient expectations and make better-informed recommendations. Three such studies are now underway, with early results to be reported in 2020 and a plan to report up to 10-year results as they become available:

**ITAR Study: INFINITY™ Total Ankle Replacement**

Launched in 2017, the ITAR Study is a prospective, post-market, clinical follow-up study of patients implanted with primary unilateral or bilateral INFINITY™ Total Ankle Replacement for the treatment of ankle arthritis (rheumatoid, post-traumatic, and degenerative disease). The study is led by co-principal investigators Drew Murphy, MD (Campbell Clinic, Memphis, TN) and Jesse Doty, MD (Erlanger Foot and Ankle Institute, Chattanooga, TN). The investigators are non-inventor surgeons experienced in foot and ankle surgery, including TAR. Target enrollment is 200 patients at 10 sites in the United States. The primary outcome is long-term implant survivorship of 10+ years. Secondary outcomes will include PROMIS, AOS, FAOS, and TAR Satisfaction collected preoperatively (where applicable) and at follow-up intervals of 6 months, and 1, 2, 5, 7, and 10 years. The study is sponsored and funded by Wright Medical.

**UK INFINITY™ Ankle Study**

The UK study was launched in 2016 as a prospective, post-market clinical follow-up study of patients implanted with primary unilateral or bilateral INFINITY™ Total Ankle Replacement for the treatment of ankle arthritis (rheumatoid, post-traumatic, and degenerative disease). The study comprises 20 non-inventor foot and ankle specialist surgeons in the United Kingdom, with Mr. David Townshend, MBBS FRCS (Orth) as Chief Investigator. Enrollment is complete with 500 patients from 12 sites. The primary outcome is long-term implant survivorship of 10+ years, and secondary outcomes include EQ5DL, AOS, MOXFQ, and radiographic studies collected preoperatively and at follow-up intervals of 6 months, and at 1, 2, 5, 7, and 10 years. The study is sponsored and funded by Wright Medical.

**TARVA Study: Total Ankle Replacement**

Goldberg et al. have completed recruitment to the TARVA (total ankle replacement versus arthrodesis) study in the UK. The study is a multicentre, prospective, randomised, controlled trial involving 17 sites across the UK comparing TAR (164 patients) with arthrodesis (164 patients). The trial aims to investigate the clinical outcomes, complications, and cost-effectiveness of TAR against ankle arthrodesis in the treatment of end stage ankle arthritis in patients aged 50–85 years. The study will include data collected preoperatively and at 2, 6, 12, 26, and 52 weeks postoperatively. Longer term follow-up of patients is planned at 2, 5, and 10 years, although the paper, to be published in mid-2020, will only include short-term findings. This trial is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme.

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A 2019 survey showed that only 28% of adults have heard of a total ankle replacement (TAR). Many individuals with end-stage ankle arthritis who are unwilling to undergo ankle fusion mistakenly assume they have no other options—and continue to suffer needlessly.

What is MOVEWRIGHT™?

The MOVEWRIGHT™ brand is an umbrella name chosen to represent the Wright Medical total ankle replacement portfolio. It includes:

- PROPHECY™ Preoperative Navigation System
- INBONE® Total Ankle System
- INFINITY™ Total Ankle System
- INVISION™ Total Ankle Revision System

As the leader in total ankle replacement, Wright Medical is committed to increasing awareness. The MOVEWRIGHT™ direct-to-patient (DTP) campaign educates potential TAR patients and connects them with MOVEWRIGHT™ trained specialists. To learn more, visit movewright.com and see how Wright is providing patients with renewed hope for pain relief and improved mobility, giving them the tools for taking the next step.

*Survey by MQD Consulting, February 2019
**PearlDiver Technologies, Inc. | April, 2017