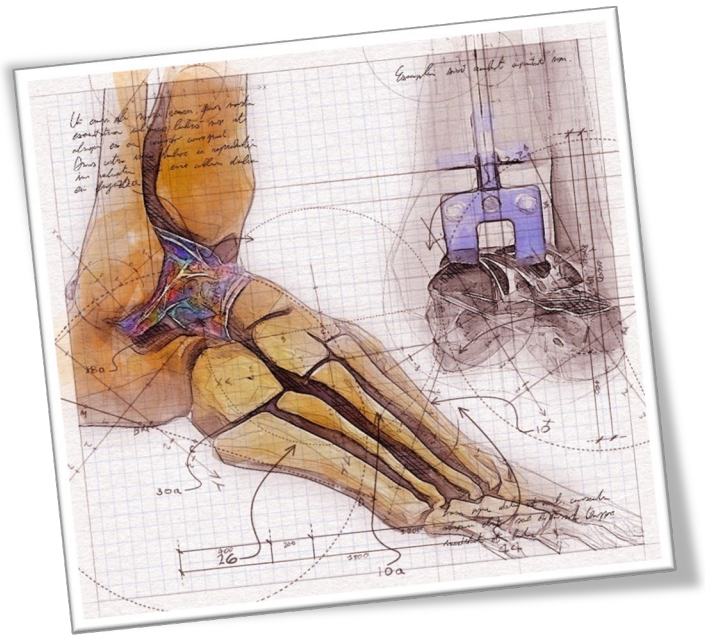
ALEXANDER ORTHOPAEDIC ASSOCIATES

Adam D. Perler

DPM, FACFAS

A Patient's Guide to 3D Printing and Customized Foot & Ankle Surgery

> **"So many things are possible just as long as you don't know they're impossible."**
>
> **- Norton Juster, The Phantom Tollbooth**



Get ready… the future is here. As technology has advanced at a light-speed velocity over the last several years, new opportunities have arisen for significant advancements in orthopedic surgery. We are now standing at the ground level of a revolutionary expanse of medical technology focused on personalized solutions that is set to unlock unlimited potential in the field of medicine. Additive Manufacturing (AM) or 3D printing is the next big thing and the impact will be huge.

In the past, a skilled surgeon's approach to a complex deformity was somewhat limited to their own personal/professional training, outcomes data from the literature in dealing with similar pathology, and the use of mass produced and generic hardware provided by a multitude of orthopedic device companies who must go through an extensive amount of work to get their product line approved for use. To create something new is both challenging and expensive with lots of hurdles in place to prove the technology is safe and effective. Even so, it is not personalized to address the needs of an individual patient or their specific deformity, but to a much broader group of patients. It can be compared to eating at a buffet versus hiring a 5-star personalized chef who can create something different each time based on your

cravings at the moment. In other words, with a conventional approach the surgeon's solution or operative plan is often limited and shaped by what type of generic solutions are already available on the market.

Customizing surgery that is patient specific is an all new approach that is used at Alexander Orthopaedic Associates, where options are no longer limited by what is already out there regarding a more generic approach that surgeons have taken in the past. Instead, a customized surgical focus is aimed at helping us create a unique and problem specific solution that is geared towards the type of deformity that we are presented with, especially in dealing with complex deformities or revisions of previously failed surgical procedures. Surgical customization allows each patient to have personalized care that was never possible in the past and marks the starting point of a whole new generation of surgical principals aimed solely at producing far better and more predictable outcomes… and the surgeons at Alexander Orthopaedic Associates are leading the way.

What is Additive Manufacturing (AM) or 3D Printing?

Medical three-dimensional (3D) printing, which is based on Additive Manufacturing (AM), is an emerging area of technology that explores how 3D printing can be used to replace or support an existing biological structure, create Patient Specific Implants/Instruments (PSI), replicate the unique and often complex topography of each individual patient's deformity, and allow for the surgeon to "rehearse" a correction on a computer before they execute the plan on a patient during surgery. 3D printing based technologies represent a shift in the medical manufacturing industry that is a direct result of recent advancements in the Additive Manufacturing industry which has led to improvements in both the size and affordability of 3D printers. This has set the stage to make this customized technology widely accessible, allowing doctors and researchers to create personalized devices and solutions for patients. A related area of 3D printing called bioprinting, involves combining structural printing and the biological printing of human tissue and organs by layering living cells instead of pure plastic or titanium. While bioprinting remains in the experimental phase, the ability to print human tissue will likely have a huge impact on such things as the design of personalized medications, organ or tissue transplants, surgical operations, and complex reconstructive surgery. In Europe, for example, scientists have figured out how to print a "living skin" to transfer directly onto patients who have suffered full thickness skin loss or extensive burns.

The Rise of Medical 3D "Makerspaces"

While 3D printing was first invented by Charles Hull in the late 1980's, it didn't start to become mainstream until last several years. At first, it was typically utilized by hobbyists who sought to print out novel items such as a toy, a miniaturized copy of their dog, or a plastic replacement part for their car. These hobbyists would then share their concept or solution online with each other. This was called a "makerspace" and served as an open forum to new and exciting creations. We then saw a few medical device solutions, such as finger splints, customized shoe insoles, and braces make their way into these makerspaces. More recently we have begun to see several medical device companies create their own "medical makerspace" and are now becoming the key drivers of the 3D printed medical market. Three such examples are Materialize, 4Web, and Additive Orthopaedics.

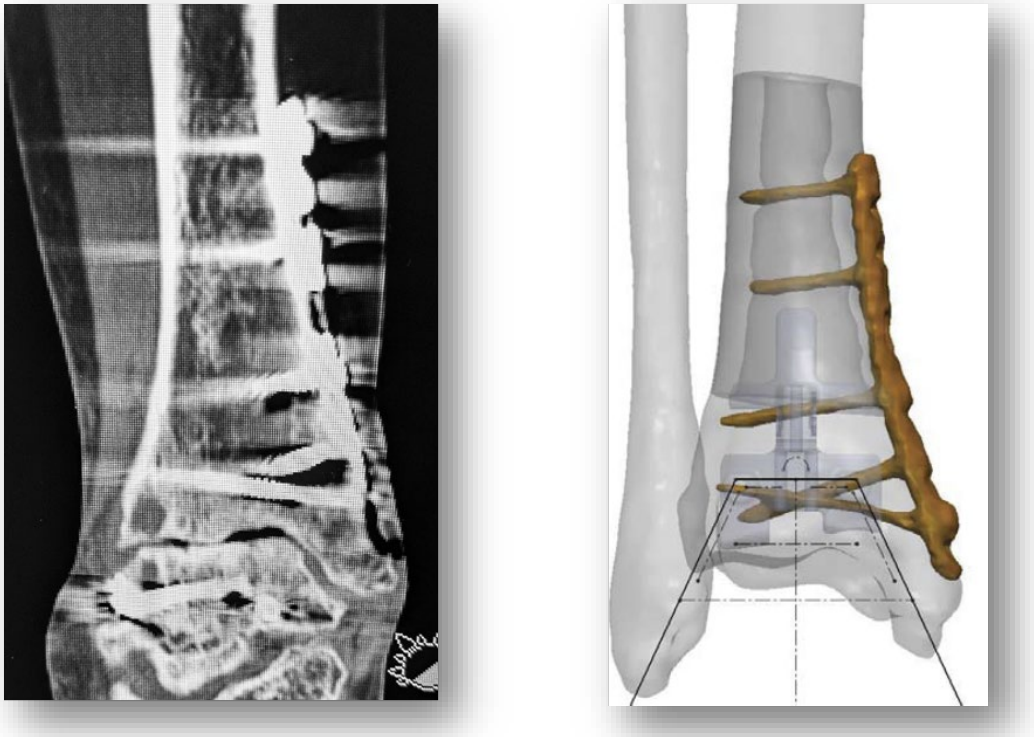
Furthermore, some medical practitioners have now begun using on-site 3D printers to produce medical devices right in their offices. The dental field has paved the way for this with temporary caps, crowns, and Invisalign. Current examples of medical 3D printing successes include the creation of specialized customized orthotics, custom casts and limb prosthetics, as well as custom implant solutions in the dental industry that are 3D printed on-site.

Dr. Adam Perler works closely with several of the existing 3D printing makerspaces and has been recognized as one of the leading centers in the country when it comes to incorporating customized patient specific surgery, PSI and 3D printing. Dr. Adam Perler and Alexander Orthopaedic Associates are also currently laying down the groundwork to create our very own medical 3D printing makerspace and be one of the first offices in the country to do so.

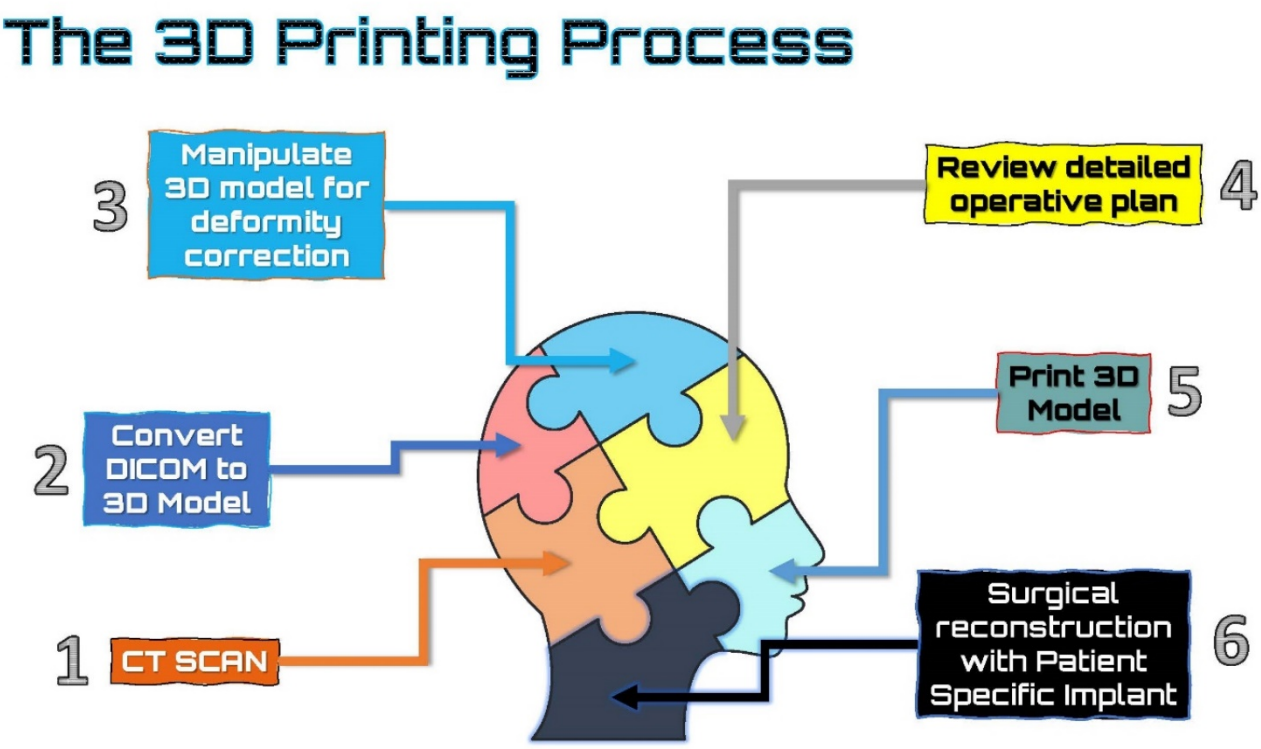
Data generation (CT, MRI, 3D scan)

Prior to 3D printing, the ability to manufacture patient-specific parts directly from a scan was not cost-effective with conventional manufacturing techniques where parts had to be milled from a solid block of material such as stainless steel or titanium. This has changed with the emergence of Additive Manufacturing that makes 3D printing possible. These tailored parts are made possible through special software that converts the patient's own data derived from images a CT scan of their foot or ankle into three dimensional (3D) files. These files essentially encode each patient's specific anatomic or pathologic features, which is then converted to a 3D model which is then utilized to plan a surgery and fabricate customized implants or instrumentation with the use of advanced 3D medical printers.

CT Scan - CT scans use multiple x-ray projections through a subject to computationally reconstruct cross-sectional images that can be complied into a 3D model. CT is considered the imaging method of choice for bone imaging due to its ability to capture surface detail of bone and for the collection of data that is then used to produce medical models of hard tissue structures like bone. CT scans are widely used in emergency rooms because the scan takes fewer than 5 minutes. **Depending on the type of problem, sometimes it is even useful to get a CT scan image of both feet or ankle so that a deformity can be compared to the "normal" side, especially in the case where an entire bone segment needs to be 3D printed.**



The Image on the left is the CT scan while the image on the right is the 3D rending of the same ankle



The 3D printing process starts with the identification of the right patient and application. The patient is then sent for a CT scan **(step 1).** CT scan data is then converted to a virtual digital model **(step 2).** This model can then be manipulated and reconstructed with never before seen precision to assess and correct the deformity **(step 3).** Once this is accomplished, a customized surgery is planned by a team of individuals including the surgeon and a design engineer from the partnering additive manufacturing company who adjust the model to mimic the type of correction the surgeon is wanting to achieve **(step 4).** Once the plan is reviewed and approved by the surgeon, the patient specific plan then sent for additive manufacturing or 3D printing **(step 5).** Upon completion, the 3D printed part is sent to the surgical facility and prepared for surgery. Prior to surgery, the surgeon reviews the detailed pre-operative plan… and then performs the surgery according to the plan **(step 6).** Click here for a video that reviews the 3D printing process for a total talus replacement surgery.

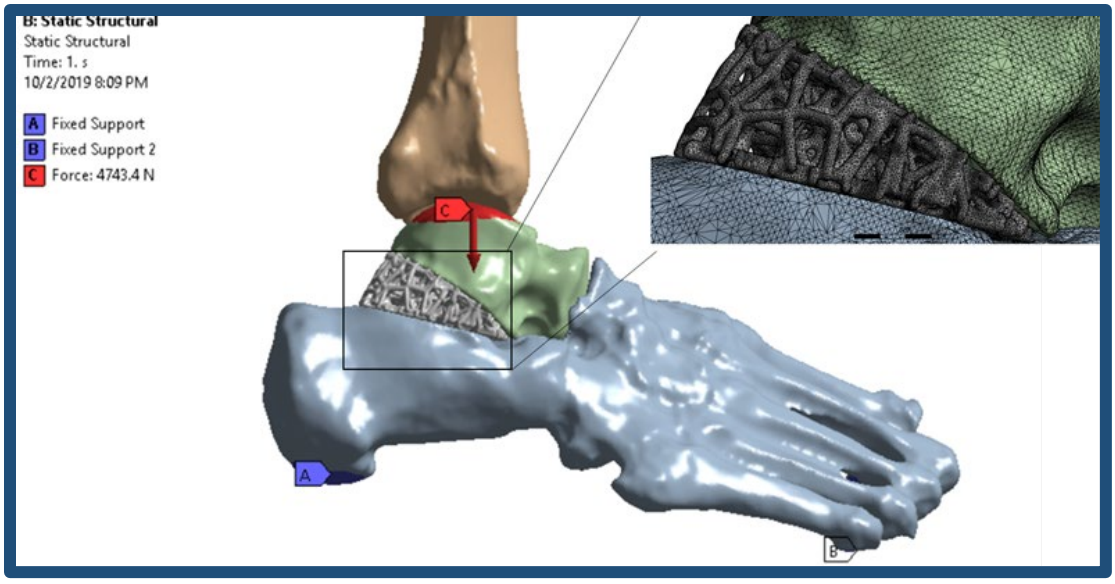
3D Printed total talus pre and intra-operative views

Current Applications of Customize Patient Specific Surgery and 3D Printing at Alexander Orthopaedic Associates

- ### Surgical learning tools and Complex Surgical Planning:

While much of the focus for 3D printing in the medical industry has been around implants and medical devices used by patients, one of the largest areas of application has concentrated on the ability to create anatomical replicas. Historically, clinical training, education, and device testing have relied on the use of animal models, human cadavers, and mannequins for hands-on experience in a clinical simulation. These options have several deficiencies including limited supply, expense of handling and storage, the lack of pathology within the models, inconsistencies with human anatomy, and the inability to accurately represent tissue characteristics of living humans. The advantage of 3D printing is that actual pathology or deformity can be 3D printed. This combined with the detailed pre-operative planning process allows the surgeon to perform a trail run of the surgery before the actual operation which greatly reduces the potential for intra-operative errors.

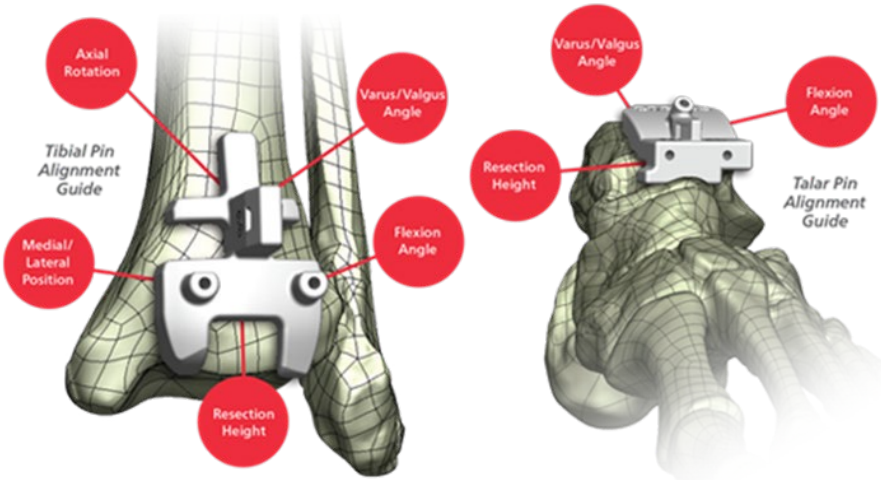
At Alexander Orthopaedic Associates, we often use the planning phase of 3D technology derived from patient scan data to improve treatment decisions, enhance surgical planning, and in some cases, even practice selected surgical interventions in advance of the actual treatments. This is the AOA Customized Patient Specific Surgical approach. These models/plans are used to model a patient's anatomy pre-operatively that is typically difficult to visualize and helps to eliminate possible "surprises" that can happen intraoperatively. Models also assist in accurately sizing medical devices and implants. At AOA, we often use the models or surgical plans to explain an upcoming surgery to patients and their families and to communicate the surgical steps to the surgical team to optimize and facilitate the surgery.



Actual surgical plan prepared by Additive Orthpaedics engineering team and Dr. Perler

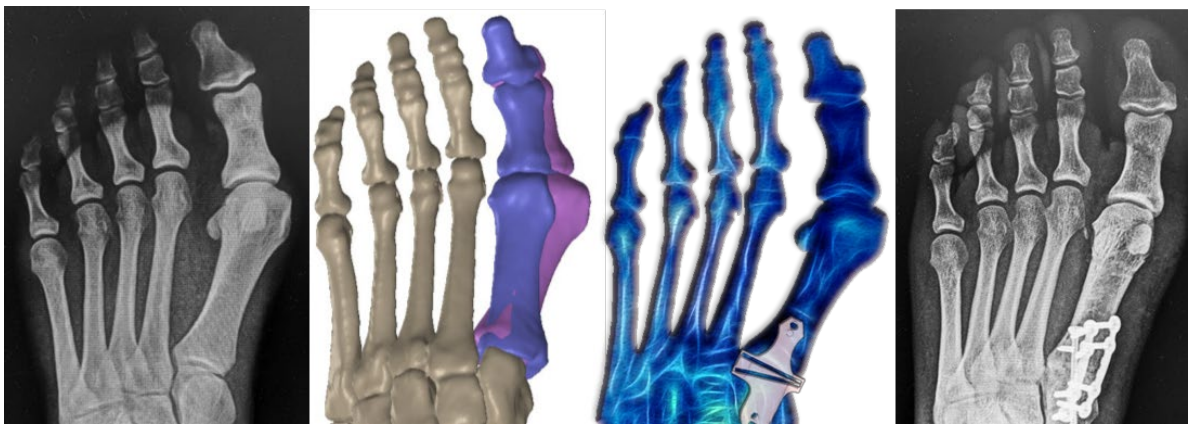
- ## Surgical Guides and Instruments:

Much like a carpenter who uses a drill jig to ensure a hole is placed in the exact right location, physicians also implement guides and tools to assist in surgery. Historically, surgical guides and tools were generic devices made of titanium or aluminum which could not be easily adapted to individual anatomic variations.



Example of Patient Specific Instrumentation (PSI) used for a Wright Medical Prophecy Total Ankle Implant

By implementing 3D Printing principles, Dr. Perler helped to co-found RedPoint Medical, a company that aims to assist physicians in the creation of patient specific guides that precisely contour a patient's unique anatomy, accurately locating drills, saws, or other instruments used during surgery. RedPoint Medical is currently focused on the correction of complex bunion deformities by producing a 3D printed patient specific and customized cut guides that enables surgeons to flawlessly execute a complex bunion reconstruction through the delivery of a detailed pre-operative plan, customized cut guides and tools that aid the on-the-table correction with the highest level of precision available on the market resulting in reduced complications, shorter operations, reduced exposure to anesthesia and x ray, and significantly improved postoperative results.



Before and after xays of a bunion deformity that was corrected with a RedPoint Medical 3D printed patient specific cut guide

- ## 3D Printed Implants:

The ability to 3D print fine mesh or lattice structures on the surface of surgical implants can promote better bone integration and reduce rejection rates. Biocompatible materials such as titanium and cobalt-chrome alloys are now available for applications in orthopedics implantation. The superior surface geometry produced by 3D printing has been shown to improve implant survival rate by a factor of 2 when compared to traditional grafting products. The controlled porosity that mimics the patient's actual bone coupled with the high level of customization and ability to manufacture 3D customized implants from traditional medical materials has led to the expansion of 3D printing applications which is quickly becoming one of the fastest growing segments of the medical industry.

Sample porosity of tibial bone segment replacement utilized in a complex reconstruction following a bone tumor removal

- ## Prosthetics and Casts

3D printing is perhaps currently most utilized in the world of prosthetics. With over 200,000 amputations each year in the US alone, getting access to a highly functioning and well-made prosthetic is both time consuming and expensive by traditional methods. 3D printing is now being regularly implemented to speed up the time it takes to create a prosthetic and can produce complex geometries needed to help the prosthesis fit to the patient. Mixed with nanotechnology, we are even starting to see electronic/mechanical limbs that not only help with ambulation or grasping, but that are starting to enable the patient to feel and control their limb by their own brain power. In addition to this, prosthetics can be printed with skin like substitutes that look and feel like the real thing all the way down to hair follicles, birthmarks and skin pores. 3D printing is also providing a much cheaper alternative

3D printed casts are just now starting to become available and have a lot of advantages such as comfort, style and weight. Perhaps the biggest advantage is the fact that the leg or arm can get wet without compromising the cast. AOA is currently working on bringing this technology into our practice.

Example of a custom 3D printed cast

3D Printing and Customized Surgery Challenges

While the time it takes to 3D print a part is usually much more efficient than traditional manufacturing methods, it does not take into account the other vital steps of the design process including obtaining the CT scan of the patient, converting the data to 3D images and for a team of engineers, software experts and physicians get together and create a unique surgical approach using either customized instruments and/or implants. In addition to the extra time and effort needed in planning stages, there is elevated costs involved preparing for these patient specific cases. Because of this, for more urgent cases like trauma surgery, the use of generic implants or medical devices are certainly viewed as a more desirable and timely solution. At this point, 3D printing applications are typically preserved for complex surgical reconstructive cases. Fortunately, Alexander Orthopaedics Associates and Dr. Adam Perler have extensive experience in the evolving science of 3D printing and in many way are leading the charge nationally as one of the six Centers of Excellence for 3D printing as designated by the American Orthopaedic Society of 3D Printing.

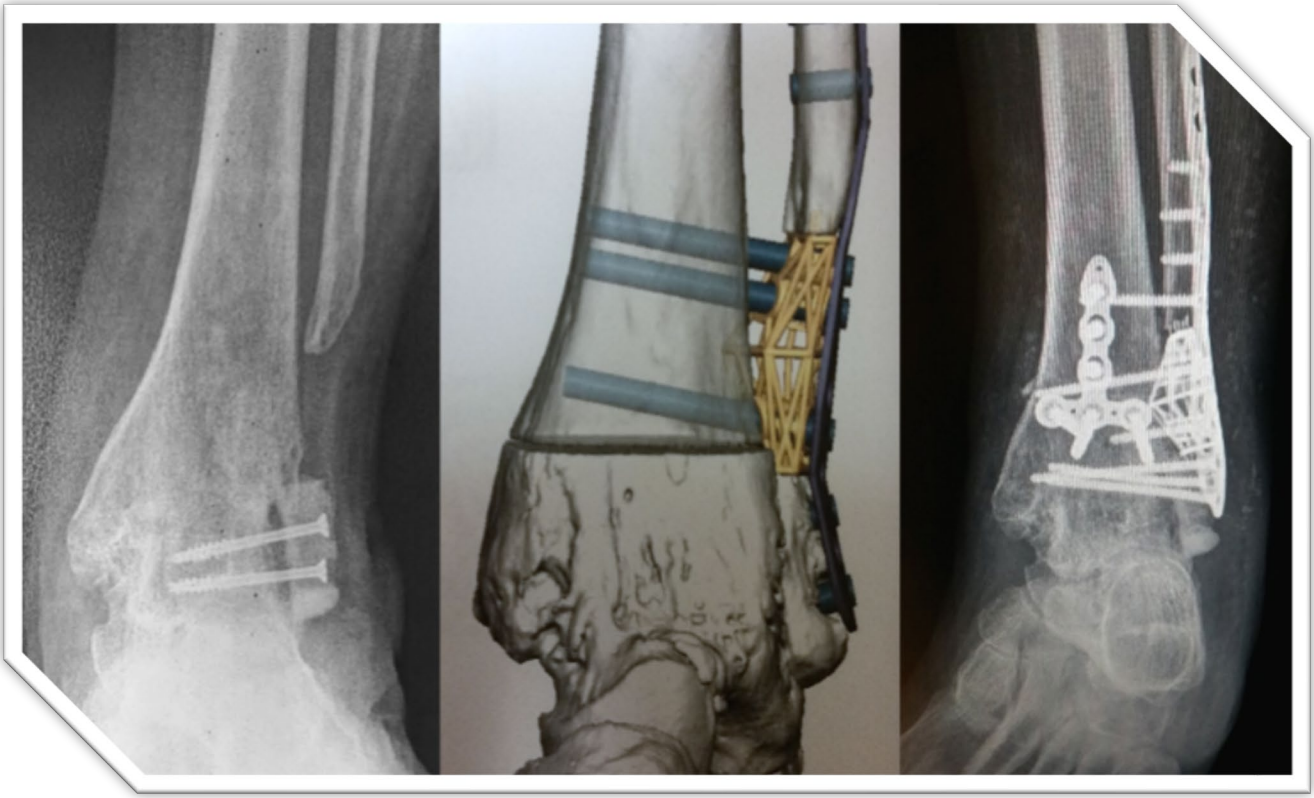
AOA 3D Printing and Customized Patient Specific Surgical Expertise:

Dr. Perler has been using 3D printing applications in his practice since it was first introduced and is one of the original members of the American Orthopaedic 3D printing society. He is the sixth surgeon in the country to be designated as a 3D Printing Center of Excellence. He currently has a patent pending status on a new technique based on 3D printing and PSI and is active in product development involving new PSI techniques.

- (2014) First 3D printed fibular reconstruction in the US using 4Web Medical **(Sample Case 1)**
- (2014) Started using PSI with Wright Medical Prophecy InBone and Infinity **(Sample Case 2)**
- (2016) PSI Total Ankle Replacement – On development team for a new ankle replacement (Zimmer/Biomet) device will utilize PSI/3D printing
- (2018) First 3D printed titanium implant/prosthesis (partial ankle replacement) utilizing Additive Orthopaedics in the state of Florida
- (2019) First 3D printed partial ankle replacement and instrumentation in the US to be designed and performed from a frontal approach (Additive Orthopaedics) **(Sample Case 3)**
- (2019) First 3D subtalar joint fusion block in the country (Additive Orthopaedics). **(Sample Case 4)**
- (October 2019) Using CAD/CAM computer modeling, was the first surgeon in the world to implant an Exactech Vantage Total Ankle Replacement using at FlatTop talar component **(Sample Case 5)**
- (November 2019) Performed first advanced bunion reconstruction (Lapidus) using a 3D printed patient specific cut guide (RedPoint Medical).
- (December 2019) Performed the first 3D printed total talus in conjunction with a total ankle replacement including a fusion interface of the subtalar joint in Florida and one of the few in the country. **(Sample Case 6)**

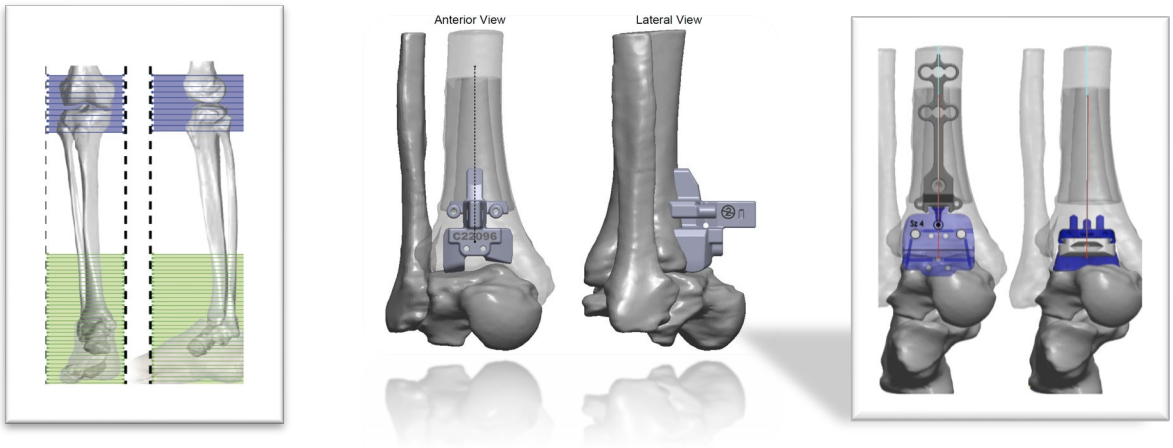
- (January 2020) Performed 2nd 3D printed total case in Florida that was performed in conjunction with an ankle replacement and resurfacing of the subtalar joint on a patient from Canada (Sample Case 7)
- Clinical Consultant for 3D printed biopolymer models made of based on individualized patient pathology – FiberTuff
- (2019) Co-Founder and Chief Medical Officer of Red Point Medical, a start-up company that focuses on the utilization of 3D printing to create Patient Specific Instrumentation and customized cutting guides for complex deformity correction. Dr. Perler is leading a team of talented foot and ankle surgeons from across the country and working with a specialized software company to advance this technology and help surgeons improve their outcomes through more precise and reproducible techniques.
- (2019 – Present) Member and designated a 3d Printing Center of Excellence of the American Orthopaedic Society of 3D Printing.

Case 1: 3D Printed Fibular Bone Defect Case (2014)



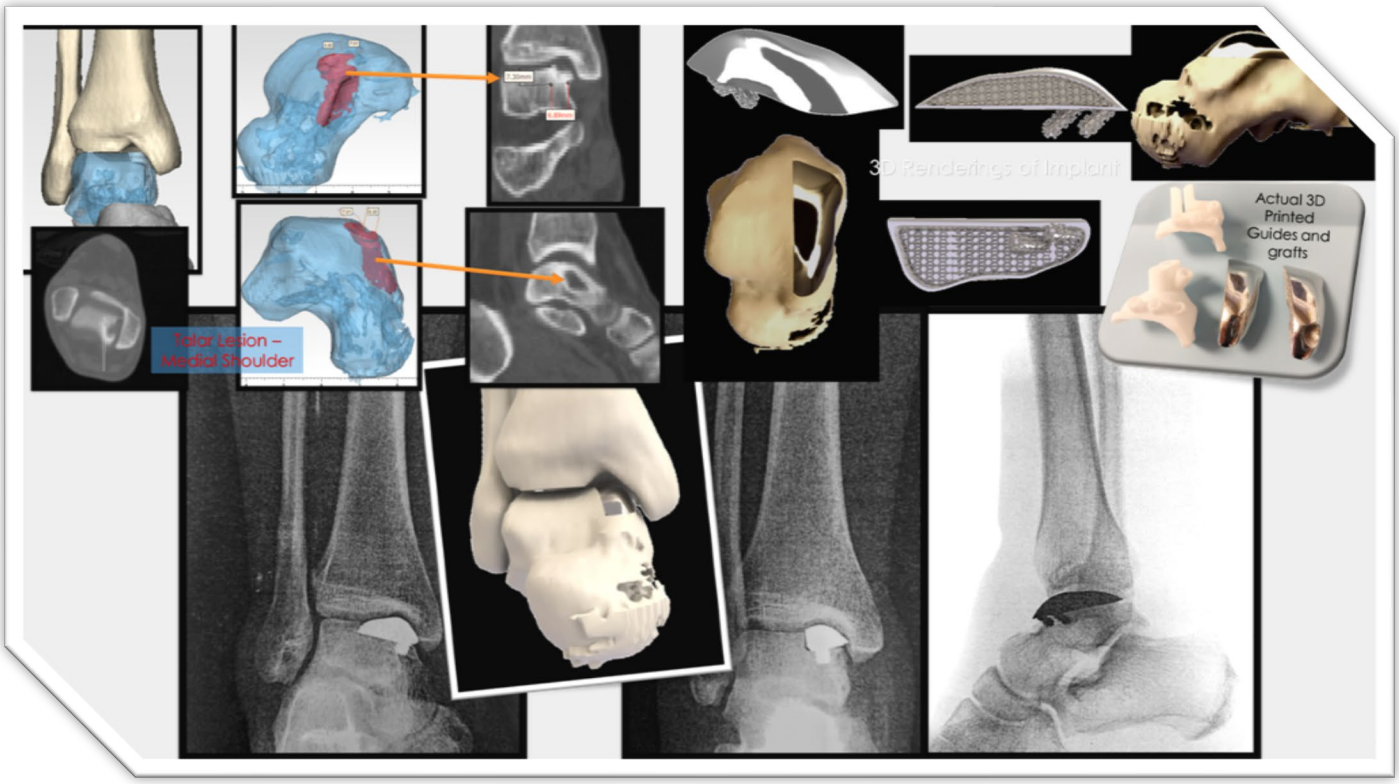
Performed by Dr. Adam Perler in October 2014 in Indianapolis, Indiana. At the time this was the first 3D printed fibular replacement in the US. This was performed on a patient that had presented with a previous ankle fusion which had healed in a flexed position and who had a significant defect in her fibula. The patient desired to have the fusion taken down and converted to an ankle replacement which was not possible due to the fibular defect. Using 4Web technology, the surgery was planned on the computer, the fibula was custom designed to work with the hardware of choice, 3D printed, and the plan was executed as demonstrated above. Now that she is fully healed, the patient plans to travel St. Petersburg, FL from Indianapolis, IN to have her ankle converted from a fusion to a replacement which is now possible thanks to this unique approach.

Case 2: Wright Medical Prophecy Total Ankle (Prophecy PSI)

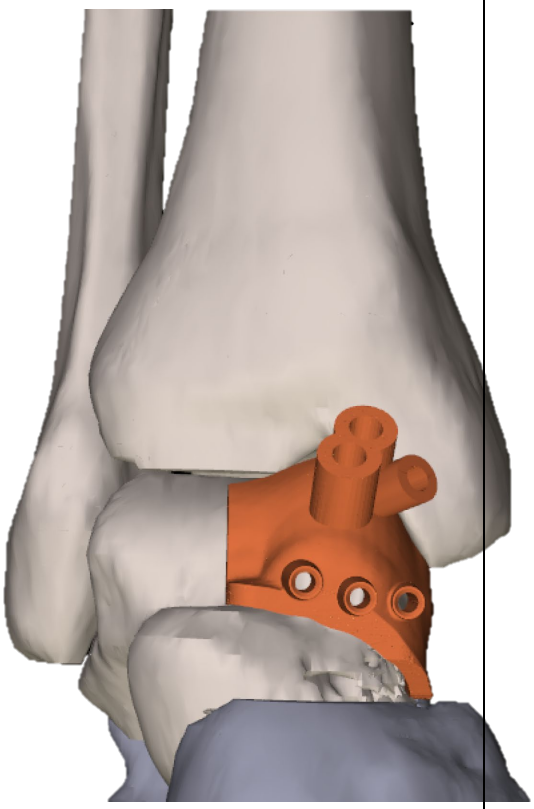


This was a patient of Dr. Perler's who works as a dentist and had suffered severe trauma to his right ankle in 1991 which required surgical reduction. He had developed post-traumatic arthritis with significant cystic changes to both the tibia and talus. In order to avoid a fusion and to delay an ankle replacement, in 2014 he underwent a partial ankle resurfacing using a fresh cadaveric specimen. This was unique as it replaced both sides of the joint. While, the bone took and the cysts were "filled" in, the cartilage portion of the graft continued to degrade. This patient's insurance denied a request for an ankle replacement stating that they did not feel it was medically necessary. The patient, who was a former patient of Dr. Perler's from Indiana, opted to fly down to St. Petersburg to continue his care. After several appeals and peer to peer reviews, the patient was finally approved for a total ankle replacement. This was life altering for this patient since a more traditional ankle fusion would have likely ended his career as a dentist. This was performed in 2017 using the Wright Medical Prophecy Infinity Total Ankle (Patient Specific Instrumentation) to ensure that all cystic bone was resected and that all the planned components were a perfect fit.

Case 3: 3D Partial Ankle Replacement (2018)



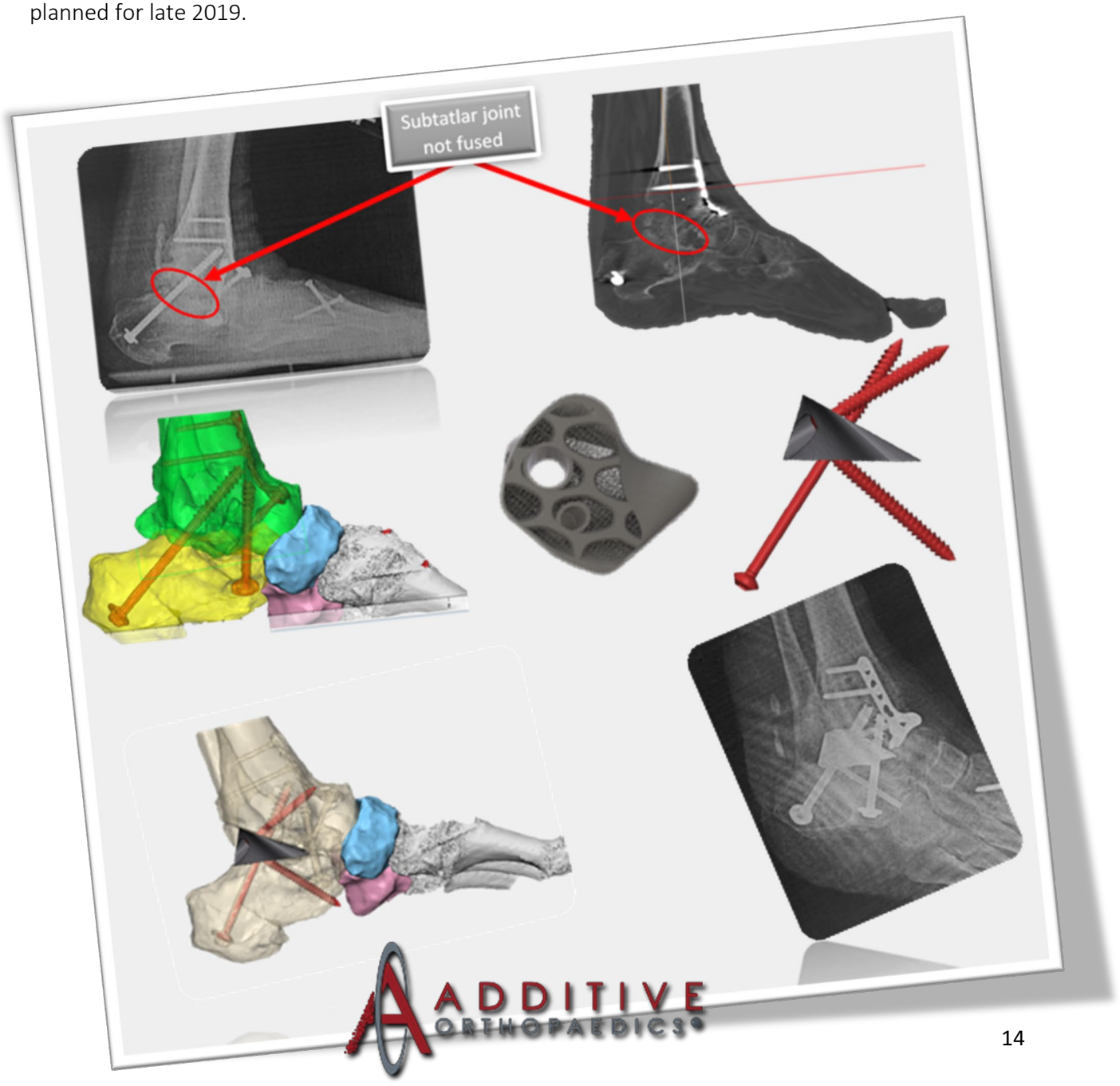
Performed by Dr. Adam Perler in 2018. This was a young patient who presented with a large defect inside her ankle joint involving part of her talus. Traditionally this would have been treated by cutting her inner ankle bone, flipping it down and a placing a replacement cadaver bone segment. This is a very technically demanding surgery and it is very difficult to get proper joint contours. Although these can be successful, the failure rate is about 50% leaving a total ankle replacement or joint fusion as her only option. This pathway would require two additional surgeries (hardware removal and then either a fusion or replacement). Dr. Perler teamed up with Additive Orthopaedics to design the first partial ankle joint replacement that is placed from a frontal approach without needing to cut inner ankle bone away. This was complete with specialty PSI (patient specific instrumentation) that allowed for accurate placement of the device. This will keep all future reconstruction options open and allow for a single staged reconstruction in the future if ever needed.



ADDITIVE ORTHOPAEDICS®

Sample Case 4: 3D Printed Revision Fusion Subtalar Joint w/Fixation:

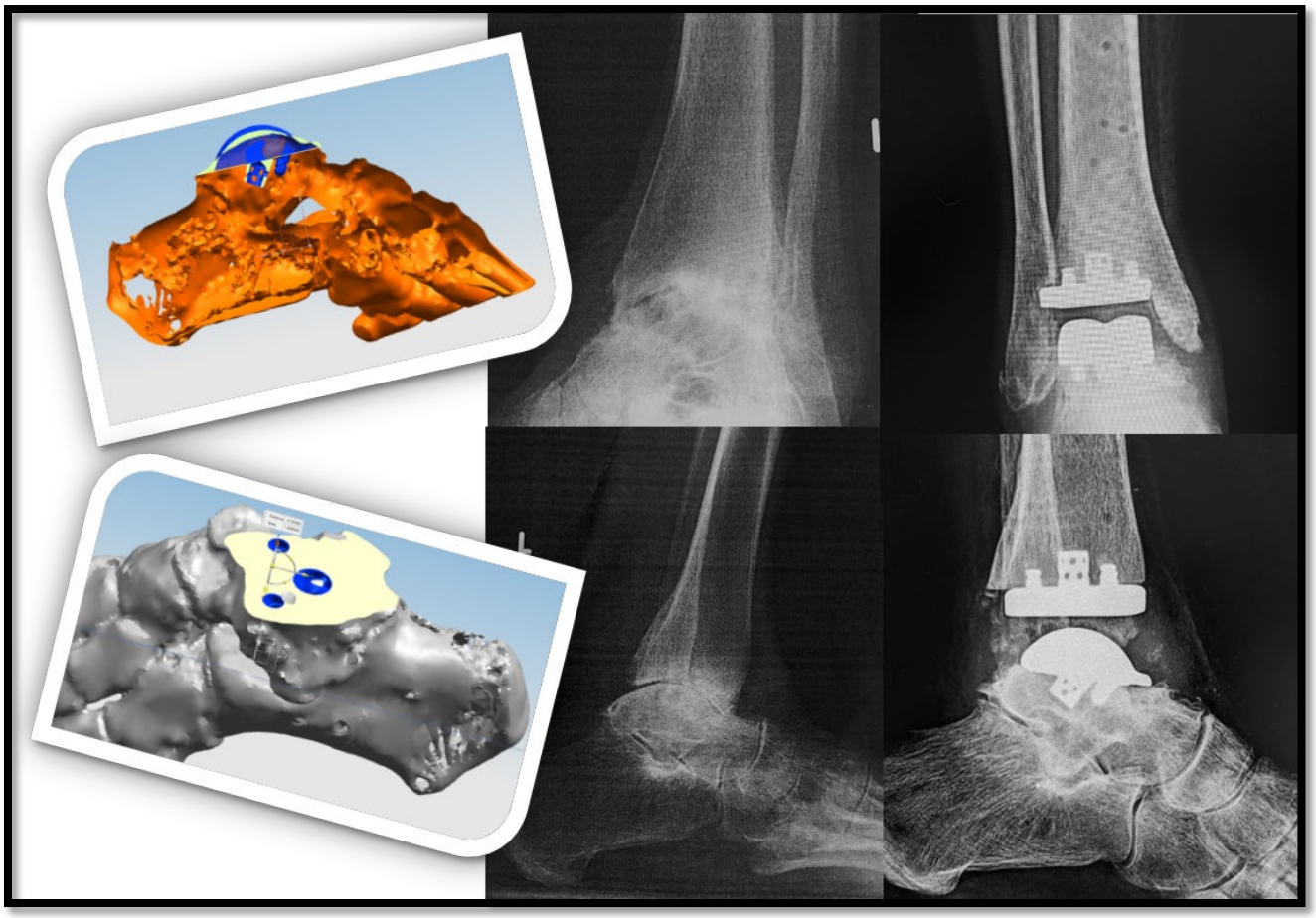
Performed in 2018. This was a patient who had an ankle fusion performed by another doctor in the St. Petersburg area. The original surgery failed to alleviate the patient's pain, so a second operation was done to revise the ankle fusion and add in a hindfoot (subtalar joint) fusion. This ultimately failed. This was then revised a third time without success. He then presented to Dr. Perler who tried bracing and minimally invasive techniques to avoid another open surgery. Due to the multiple failures of the subtalar joint fusion, Dr. Perler utilized Additive Orthopaedics to 3D print a subtalar graft with a built-in metal to bone interface and fixation hardware. This was the first graft of its kind and was successfully placed in 2018. Since that case, there are two other similar procedures being planned for late 2019.



Sample 5: Exactech Vantage Total Ankle with a FlatTop Talar Design

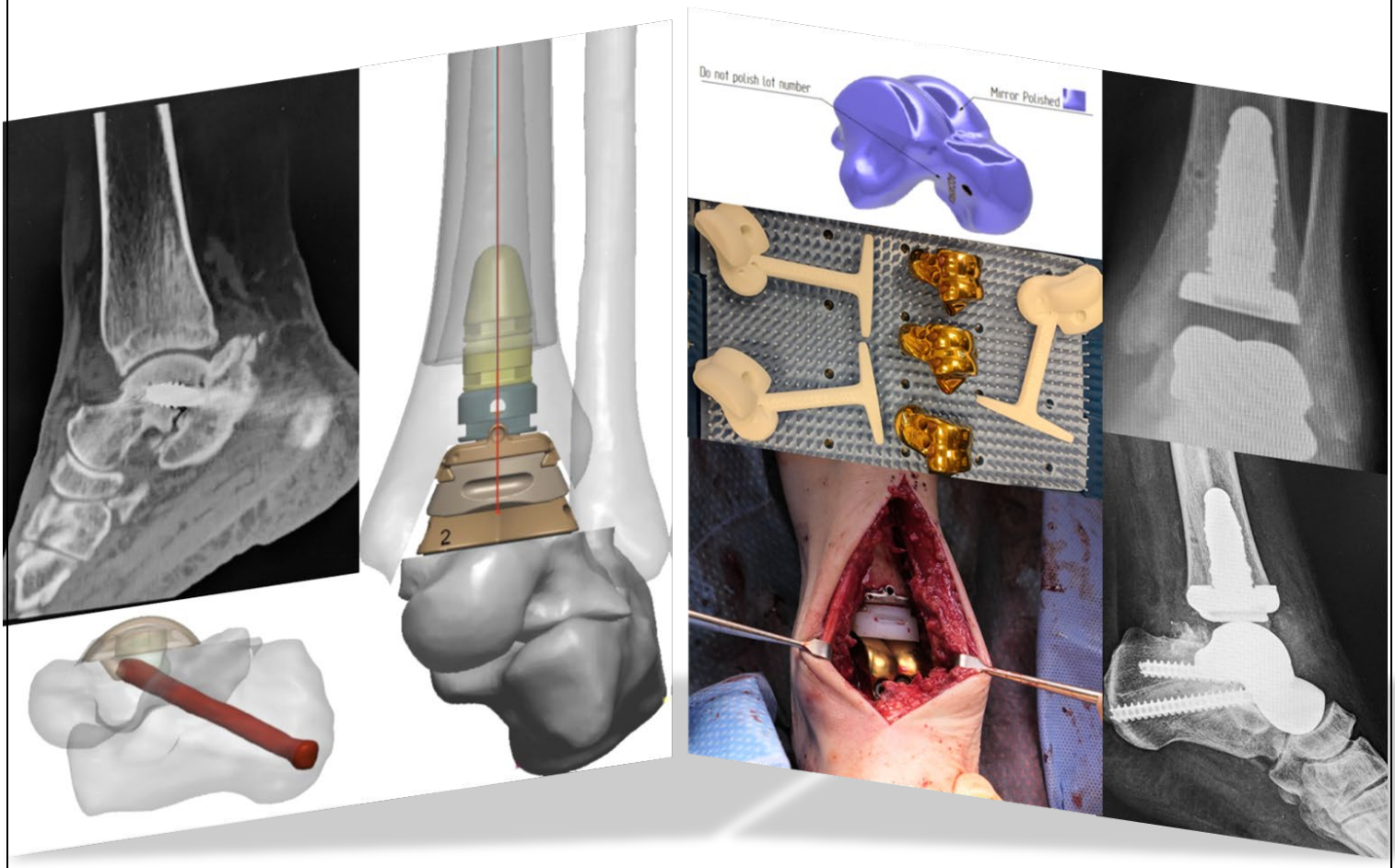
Performed by Dr. Adam Perler in September, 2019 at St. Anthony's Hospital. This was a new modification of the Exactech Vantage Ankle Replacement specifically designed for patients who have had significant injury to the talar side of their ankle joint where the bone has flattened out or become cystic in the upper portion making the use of a standard talar component more challenging. Dr. Perler along with the help of a team of designers at Exactech utilized 3D renderings from the patient's CT scan to determine the best size and placement of the new component prior to the surgery. This was the first Exactech Vantage Flattop case performed in the world.

Exactech®
Surgeon focused. Patient driven.™



Sample 6: Total Ankle Replacement w/3D Printed Talus (STJ Fusion)

Performed by Dr. Adam Perler in November, 2019 at SurgCenter Pinellas. Patient had a previous attempt at a subtalar joint fusion several years that ultimately failed, leading to debilitating arthritis of both her ankle and subtalar joints. Patient didn't want fusion and a traditional ankle replacement was not feasible due to the loss of bone integrity of the talus. The patient elected to have a total ankle replacement with a simultaneous subtalar joint fusion using a special 3D printed total talus. She was the first patient to have this performed in Florida. The surgery was done using Wright Medical Prophecy patient specific instrumentation for the tibia and bearing and Additive Orthopaedics for the 3D printed total talus.



Sample 7: Total Ankle Replacement w/3D Printed Talus (STJ Resurface)

Performed by Dr. Adam Perler in January, 2020 at SurgCenter Pinellas. Patient presented from Canada where she had suffered a car accident which shattered both her tibia and her talus. She underwent surgery to plate both bones, but over the years developed debilitating traumatic arthritis. Patient didn't want to have her ankle fused and an ankle replacement would have been very challenging given the poor status of her talus, which showed signs of avascular necrosis, where the bone starts to lose its blood supply. Considering this and the fact that 3D printing is not currently available in Canada, she elected to have her ankle surgery performed at Alexander Orthopaedic Associates. In her case, we were able to perform an ankle replacement with a 3D printed talus which also resurfaced her subtalar and talonavicular joints successfully.

References

Murphy, S.V. & Atala, A. 3D bioprinting of tissues and organs. *Nat. Biotechnol.* 32, 773–785 (2014)

Elnakib A, Gimel'farb G, Suri J, El-Baz A. Medical image segmentation: a brief survey in multi modality state-of-the-art medical image segmentation and registration methodologies. New York: Springer, 2011. [Google Scholar]

Yushkevich PA, Piven J, Cody Hazlett H, et al. User-guided 3D active contour segmentation of anatomical structures: Significantly improved efficiency and reliability. Neuroimage 2006; 31:1116-28. [PubMed] [Google Scholar]

Sheth U, Theodoropoulos J, Abouali J. Use of 3-dimensional printing for preoperative planning in the treatment of recurrent anterior shoulder instability. Arthrosc Tech 2015;4:e311-e316. PMID:26759768. [PMC free article] [PubMed] [Google Scholar]

Ogden K, Ordway N, Diallo D, Tillapaugh-Fay G, Aslan C. Dimensional accuracy of 3D printed vertebra progress in biomedical optics and imaging. Proceedings of SPIE 2014; 9036:903629. [Google Scholar]

Imanishi J, Choong PF. Three-dimensional printed calcaneal prosthesis following total calcanectomy. Int J Surg Case Rep 2015;10:83-7. [PMC free article] [PubMed] [Google Scholar]

Mazzarese B, Nicotera N, Theriault H. Modeling bone fixation implants with absorbable polymers using 3-D printing Biomedical Engineering Conference (NEBEC), 2015 41st Annual Northeast 2015; 7117129. [Google Scholar]

Pati F, Song TH, Rijal G, Jang J, Kim SW, Cho DW. Ornamenting 3D printed scaffolds with cell-laid extracellular matrix for bone tissue regeneration. Biomaterials 2015;37:230-41. PMID:25453953. [PubMed] [Google Scholar]

Zhang YZ, Lu S, Chen B, Zhao JM, Liu R, Pei GX. Application of computer-aided design osteotomy template for treatment of cubitus varus deformity in teenagers: a pilot study. J Shoulder Elbow Surg2011;20:51-6. [PubMed] [Google Scholar]

Oliker, Aaron. Medical 3D Printing. Americas Quarterly. https://www.americasquarterly.org/content/medical-3d-printing

Redwood, Ben. Medical 3D Printing Applications