

TAMPA FOOT AND ANKLE FELLOWSHIP MEETING – OCTOBER 2018

# 3D PRINTED IMPLANTS

From Custom Implants to "Off-the-Shelf" Evans / Cotton

Keith A. Heier, MD  
Fellowship 1998-99  
Dallas, Texas



---

---

---

---

---

---

---

---

## Disclosures

- Stock
- The owner is my neighbor!



---

---

---

---

---

---

---

---

## Tampa, FL

- Fellowship 1998-99
- A True Religious Experience



---

---

---

---

---

---

---

---

What is the difference between Art, Roy and Heidi Stephens?

---

---

---

---

---

---

---

---

Heidi is the only one that is Fellowship trained in Foot and Ankle surgery.

---

---

---

---

---

---

---

---

Ankle fusion with fibula strut autograft to make up lateral defect



---

---

---

---

---

---

---

---

### Failed Ankle Fusion with Severe Valgus Collapse



---

---

---

---

---

---

---

---

### Bone Resection

### Cage Placement



---

---

---

---

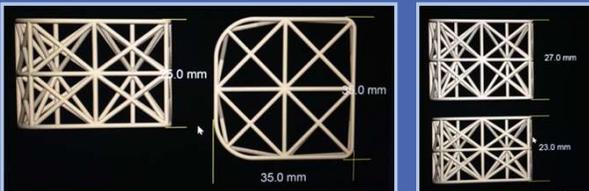
---

---

---

---

### Cage Design



---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---



---

---

---

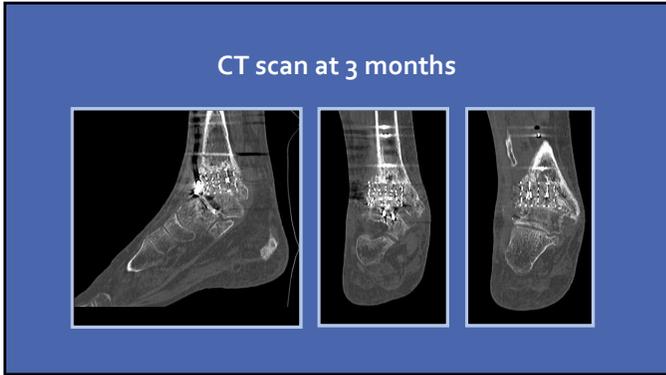
---

---

---

---

---



---

---

---

---

---

---

---

---

Why use a titanium cage for this complex ankle fusion?

What are my other reasonable options?

- Ilizarov/spatial frame
- Femoral Head allograft or other bulk allograft
- Bulk iliac crest autograft
- **4WEB Titanium cage (custom implant)**

---

---

---

---

---

---

---

---

Triangles in Engineering

• Engineers rely on triangular trusses to make strong structures. This concept has been used in many industries for centuries.



---

---

---

---

---

---

---

---

### Trusses Facilitate Forces

Trusses Provide

- 1 Uniform distribution of all stresses (tension & compression) throughout the structure
- 2 Force distribution that can be fine-tuned by arrangement and size of the truss members
- 3 6x strength compared to straight bar of same material and weight

Trusses can do **MORE** with **LESS**.

---

---

---

---

---

---

---

---

---

---

### Implant Design and Manufacturing

- 3D Printed
- Titanium
- Truss/lattice technology: stability and bone inducing

---

---

---

---

---

---

---

---

---

---

### 3D Additive Manufacturing – Disruptive Technology

- Truss Technology is only possible with 3D printing capabilities

High power electron beam at high temperature in a vacuum

Layers of trusses being applied through electron beam melting

Adds layer upon layer of material to specific design parameters

Sandblasting printed truss implants

Allows complex, intricate designs that are not possible with casting or forging

---

---

---

---

---

---

---

---

---

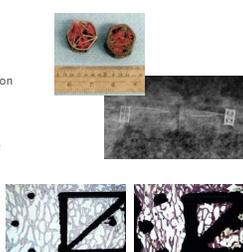
---

### Bone Through-Growth: Fusion

**Protocol**

- Ovine model – 18 mature sheep
- Implants with 0.75mm or 1.5mm truss diameters
- Both devices implanted into each sheep with equal distribution per level (L2-3 and L4-5)
- All implants packed with autograft
- Sacrifice 6 sheep at 3, 6 and 12 months
- Radiographic and histology fusion scores were calculated for each tissue slide at all time points

Results show that the 4WEB implants can be designed to distribute strain in the range that promotes mechanobiological dynamic responses for stimulating bone on-growth, through-growth and implant fusion.




---

---

---

---

---

---

---

---

### Finishing Touch – Bioactive Topography

**3D Surface Topography**  
Present in 360° on every cylindrical surface of every truss ..... throughout the entire implant.



All other manufacturer's surface coatings are on flat surfaces, available only on a small percentage of the implant.

**4WEB implants provide 5X surface area for bony attachment.**

---

---

---

---

---

---

---

---

### What are the other options for 3D printed implants?




---

---

---

---

---

---

---

---

### What are my other NonCage options?

- Texas Total Ankle



---

---

---

---

---

---

---

---

### Off-the-shelf Titanium Cages for the Foot and Ankle



---

---

---

---

---

---

---

---

### Availability and Predictability of the Implant

- Unlimited supply of the implant unlike autograft or bulk pieces of allograft
- All cages have the same stability, unlike the variability seen with autograft or allograft



---

---

---

---

---

---

---

---

### We need a Stable Implant to Maintain Correction in Lateral Column Lengthenings (LCL)

- Loss of correction of the lengthening without plates
- Average of 2.45mm loss of correction and 23% have distal calcaneal migration

Dayton P et al. *J Foot Ankle Surg.* 2013 Nov-Dec; 52(6):710-3.



---

---

---

---

---

---

---

---

### LCL with cage and 2.5mm plate



---

---

---

---

---

---

---

---

### Severe Flatfoot Deformity



---

---

---

---

---

---

---

---

### LCL and 1<sup>st</sup> TMT fusion



---

---

---

---

---

---

---

---

### Patient Specific Implants

- Failed MTP fusions
- Nonunions with bone loss
- Subtalar fusions
- Failed Total Ankles
- Anywhere you can imagine



---

---

---

---

---

---

---

---

### Use of Patient Specific 3D Printed Titanium Implants for Complex Foot and Ankle Limb Salvage, Deformity Correction, and Arthrodesis Procedures

- Dekker TJ et al (Sam Adams –Duke), Foot Ankle Int 2018 Aug;39(8):916-921.
- 15 pts with custom implants and >1 year f/u
- CT scan fusion in 13-15 patients
- 2 failures (1 infection, 1 nonunion)
- Significant improvement in pain and function

---

---

---

---

---

---

---

---

**Large Osseous Defect Reconstruction using a Custom 3D Printed Titanium Truss Implant**

- So E et al, J Foot Ankle Surg, 2018 Jan-Feb;57(1): 196-204
- 3 patients with custom implant for large bone defect
- 3/3 CT scan fusion by 12 month

**Patient Specific 3D Printed Titanium Truss Cage with TTC Arthrodesis for Salvage of Persistent Distal Tibia Nonunion**

- Hsu AR, Ellington JK. Foot Ankle Spec 2015 Dec;8(6):483-9.
- Single case of a healed TTC nail with a cage

---

---

---

---

---

---

---

---

**Revision 1<sup>st</sup> MTP Fusion**



---

---

---

---

---

---

---

---

**Failed Agilty Ankle at 12 years**



---

---

---

---

---

---

---

---

## Anterior plate-allows ST preservation




---

---

---

---

---

---

---

---

---

---

[Foot Ankle Int.](#) 2006 Oct;12(10):759-63.

Tibiototal calcaneal arthrodesis using a dynamically locked retrograde intramedullary nail.

[Pelton K](#), [Hofer JB](#), [Thornlanen CB](#).

**Abstract**

**BACKGROUND:**

Tibiototal calcaneal arthrodesis is an important salvage method for patients with complex hindfoot problems, including Charcot arthropathy, osteonecrosis of the talus, combined arthritis of the ankle and subtalar joint, and failed total ankle arthroplasty. This study evaluated the results of a dynamic retrograde intramedullary nail for fixation with posterior to anterior distal interlocking screws placed through the calcaneus for tibiototal calcaneal fusion.

**METHODS:**

Thirty-three consecutive tibiototal calcaneal fusions were done by a single surgeon (DBT) and were stabilized with a dynamic retrograde intramedullary nail. Time to fusion, impaction of the nail relative to the intramedullary canal, nail-tibial angle, and complications were noted. Average followup was 14 months.

**RESULTS:**

Twenty-nine of 33 feet (88%) fused at an average of 3.7 months after surgery. Average impaction of the nail was 2.3 (0.5 to 5.0) mm. Cortical hypertrophy at the tip of the rod or at the proximal interlocking screw was noted in 13 of 27 patients. A trend toward a higher nonunion rate was noted in patients with an increased nail-tibial angle.

**CONCLUSION:**

Dynamic retrograde intramedullary nailing for fixation of the tibiototal calcaneal fusions is a good method of stabilizing this complex fusion construct.

---

---

---

---

---

---

---

---

---

---

[Foot Ankle Int.](#) 2013 Sep;13(9):1266-66. doi: 10.1177/1071100713488765. Epub 2013 May 6.

Tibiototal calcaneal arthrodesis with bulk femoral head allograft for salvage of large defects in the ankle.

[Jeng CL](#), [Campbell JT](#), [Tang EV](#), [Cerrato RA](#), [Myerson MS](#)

**Abstract**

**BACKGROUND:**

Tibiototal calcaneal arthrodesis in patients with large segmental bony defects presents a substantial challenge to successful reconstruction. These defects typically occur following failed total ankle replacement, avascular necrosis of the talus, trauma, osteomyelitis, Charcot, or failed reconstructive surgery. This study examined the outcomes of tibiototal calcaneal (TTC) arthrodesis using bulk femoral head allograft to fill this defect.

**METHODS:**

Thirty-two patients underwent TTC arthrodesis with bulk femoral head allograft. Patients who demonstrated radiographic union were contacted for SF-12 clinical scoring and repeat radiographs. Patients with asymptomatic nonunions were also contacted for SF-12 scoring alone. Preoperative, intraoperative, and postoperative factors were analyzed to determine positive predictors for successful fusion.

**RESULTS:**

Sixteen patients healed their fusion (50% fusion rate). Diabetes mellitus was found to be the only predictive factor of outcome; all 9 patients with diabetes developed a nonunion. In this series, 19% of the patients went on to require a below-knee amputation.

**CONCLUSIONS:**

Although the radiographic fusion rate was low, when the 7 patients who had an asymptomatic nonunion were combined with the radiographic union group, the overall rate of functional limb salvage rose to 73%. TTC arthrodesis using femoral head allograft should be considered a salvage procedure that is technically difficult and carries a high risk for complications. Patients with diabetes mellitus are at an especially high risk for nonunion.

---

---

---

---

---

---

---

---

---

---

60 yo female, 6 weeks post op



---

---

---

---

---

---

---

---

Implant removal, I&D, cement spacer placement



---

---

---

---

---

---

---

---

FF femoral head, Dynanail



---

---

---

---

---

---

---

---

CT: healed ankle, ST nonunion



---

---

---

---

---

---

---

---

ST revision fusion



---

---

---

---

---

---

---

---

Fall 6 weeks after IM nail removal



---

---

---

---

---

---

---

---

Time to consider another career  
in medicine?



---

---

---

---

---

---

---

---

Revision Cage fusion



---

---

---

---

---

---

---

---

Star TAR with talar subsidence



---

---

---

---

---

---

---

---

IM Fusion with custom cage



---

---

---

---

---

---

---

---

Severe Subsidence with ST loss



---

---

---

---

---

---

---

---

IM Fixation – better and faster healing



---

---

---

---

---

---

---

---

Subtalar Fusion  
(Bone block fusion)



---

---

---

---

---

---

---

---

Calc Osteotomy and allograft  
bone block fusion-Nonunion



---

---

---

---

---

---

---

---

Custom ST implant with IM screw



---

---

---

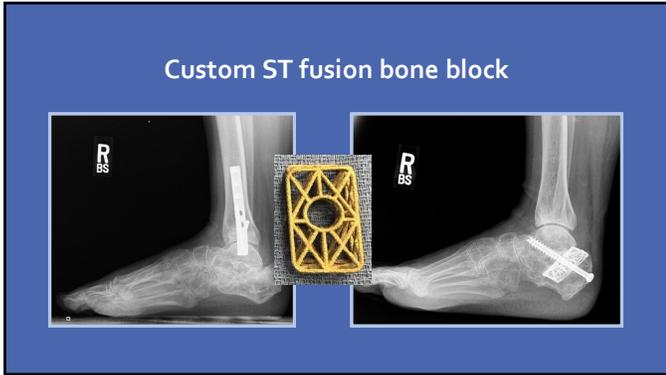
---

---

---

---

---



---

---

---

---

---

---

---

---

**Subtalar Fusion Rate in Patients with Previous Ipsilateral Ankle Arthrodesis**

Zanoli DH, Nunley JA, Easley ME. Foot Ankle Int. 2015 Sep;36(9):1025-8

- 61.5% fusion rate for ST joint after ankle fusion (8/13).
- 91% fusion rate for isolated ST joint

---

---

---

---

---

---

---

---



---

---

---

---

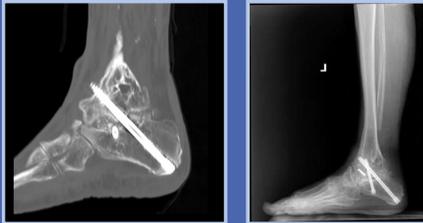
---

---

---

---

### ST Nonunion with Prev. Ankle Fusion



---

---

---

---

---

---

---

---

### ST Revision Fusion with Titanium Cage



---

---

---

---

---

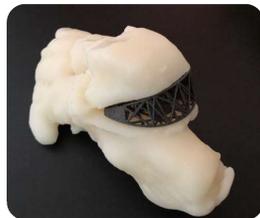
---

---

---

### Subtalar Cage Fusion: Heier Cases

- 13 subtalar fusion custom cages
- 13/13 fusions, 10-13 verified by CT scan
- No infections or wound problems
- Primary fusion: 1 patient
- Previous ST nonunion: 10 patients
- ST nonunion x2: 2 patients



---

---

---

---

---

---

---

---

### Severe Deformity Correction



---

---

---

---

---

---

---

---

### OTS Evans and Custom ST Implant



---

---

---

---

---

---

---

---

### Significant Correction



---

---

---

---

---

---

---

---

### What I've Learned After 20+ Custom Cases

- The **Larger** implants work best with Intramedullary Compression- design a hole for a screw in the cage
- Flat cuts work better than angled or wedged cuts
- Allograft (DBM) works well
- Don't overstuff the cage
- Resect enough bone to get to good healthy bone
- Works best under compression

---

---

---

---

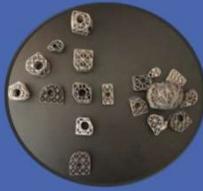
---

---

---

---

## THANK YOU



---

---

---

---

---

---

---

---

### 4WEB TITANIUM CAGES

Unlimited applications in Foot and Ankle Surgery – from the complex and disaster salvage, to the everyday simple osteotomies and fusions.



---

---

---

---

---

---

---

---