

l o n g e v i t i

Implantation of Ultrasound Penetrable Cranioplasty Plates

Presenter: Erez Nossek, MD

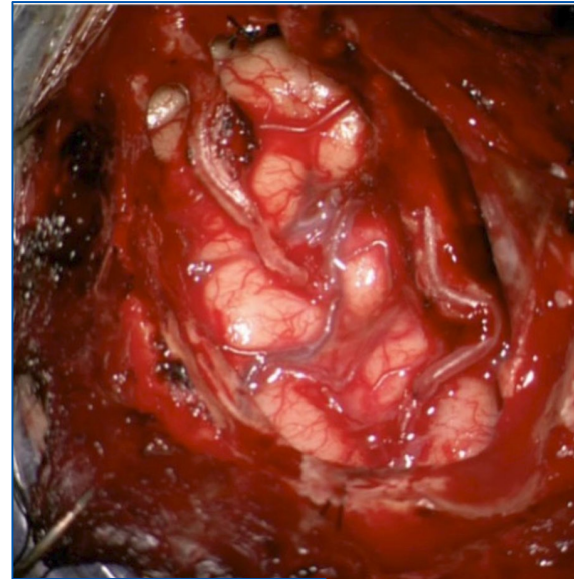
September 13th, 2022

*ICD-10 Coordination and
Maintenance Committee Meeting*

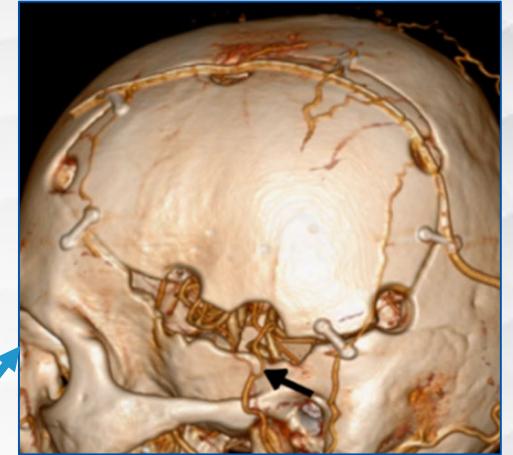


Cranial Reconstruction

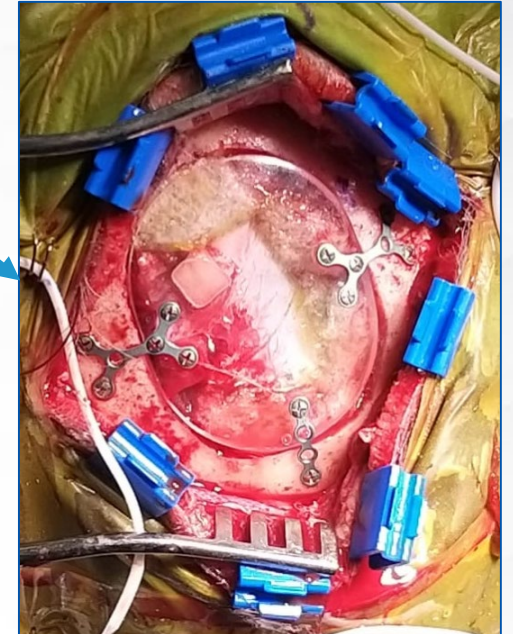
- In order to perform open brain surgery, a portion of the skull is removed (craniectomy) to access the brain.
- The cranial defect is reconstructed after the surgery by
 - replacing the removed skull (craniotomy) and fastening it with alloplastic fixation
 - Or, reconstructing the bony void with a cranial prosthetic (cranioplasty)
- Cranial Reconstruction plays a critical role in protecting the brain



Craniectomy



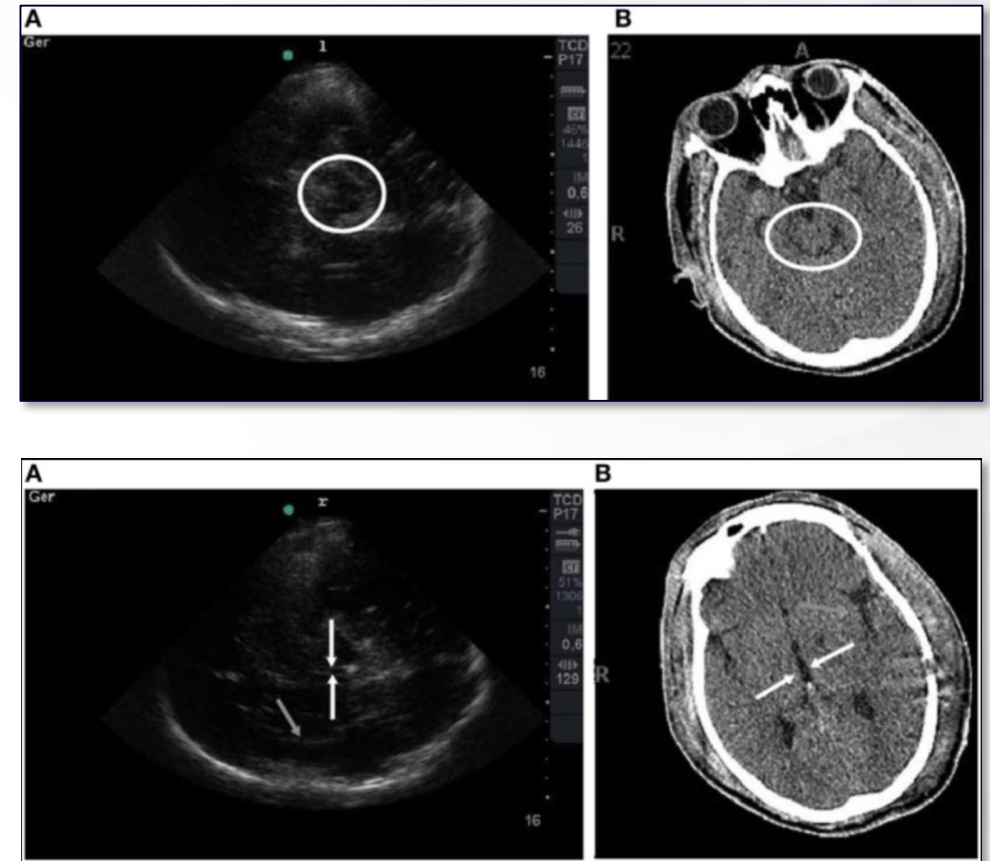
Craniotomy



Cranioplasty

Trans-Cranial Ultrasound - History

- Post Operative Cranial Ultrasound is exclusive to patients with cranial defects
 - Pediatric patients with open fontanelle
 - Traumatic brain injury patients who receive a decompressive craniectomy up until their reconstruction
- Transcranial Sonography (TCS) is a common monitoring options in **pediatric patients with open fontanelles**.

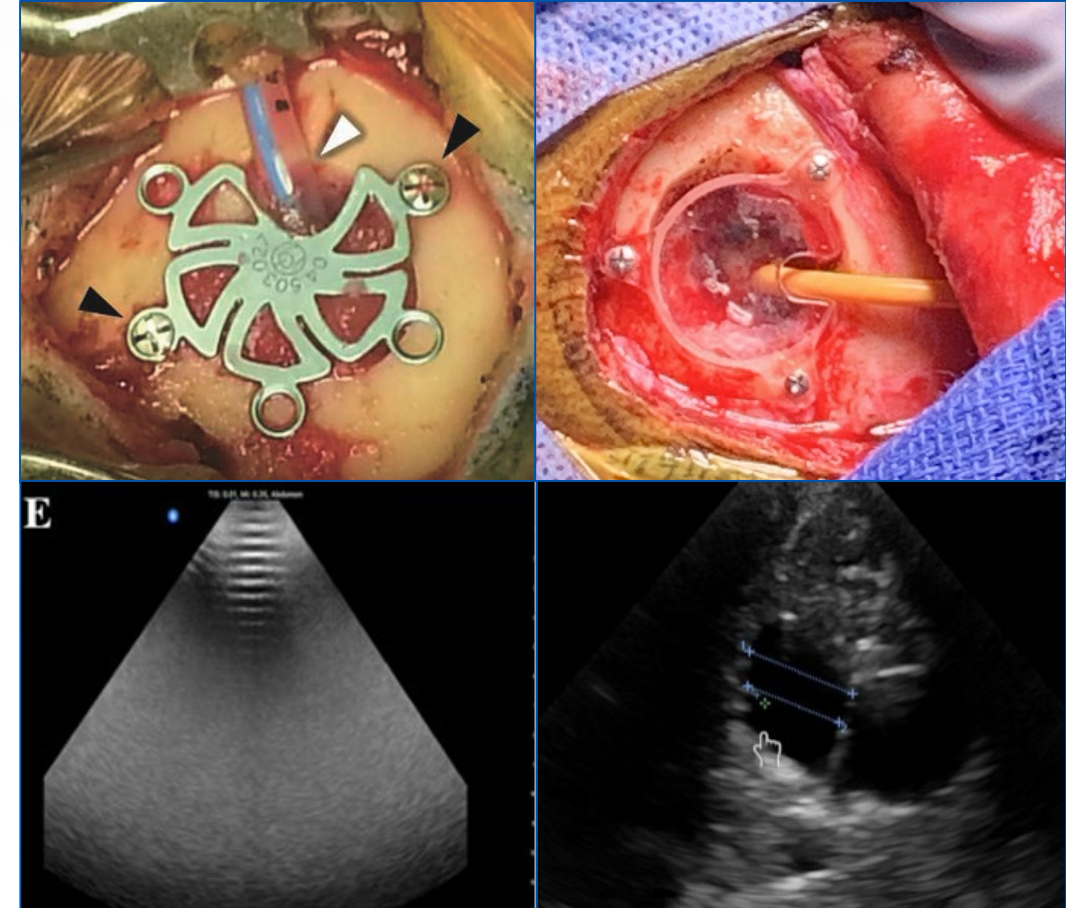


Trans-Cranioplasty Ultrasound (TCUS)

- Replacing a titanium fixation plate “burr hole cover” or the bone removed during the craniectomy enables TCUS
 - TCUS is an adjunct screening tool that compliments, and in some cases replaces, Standard of Care imaging

SOC Imaging modalities for Neurosurgery

- CT
- CT Angiography
- MRI
- MR Angiography
- Digital subtraction angiography

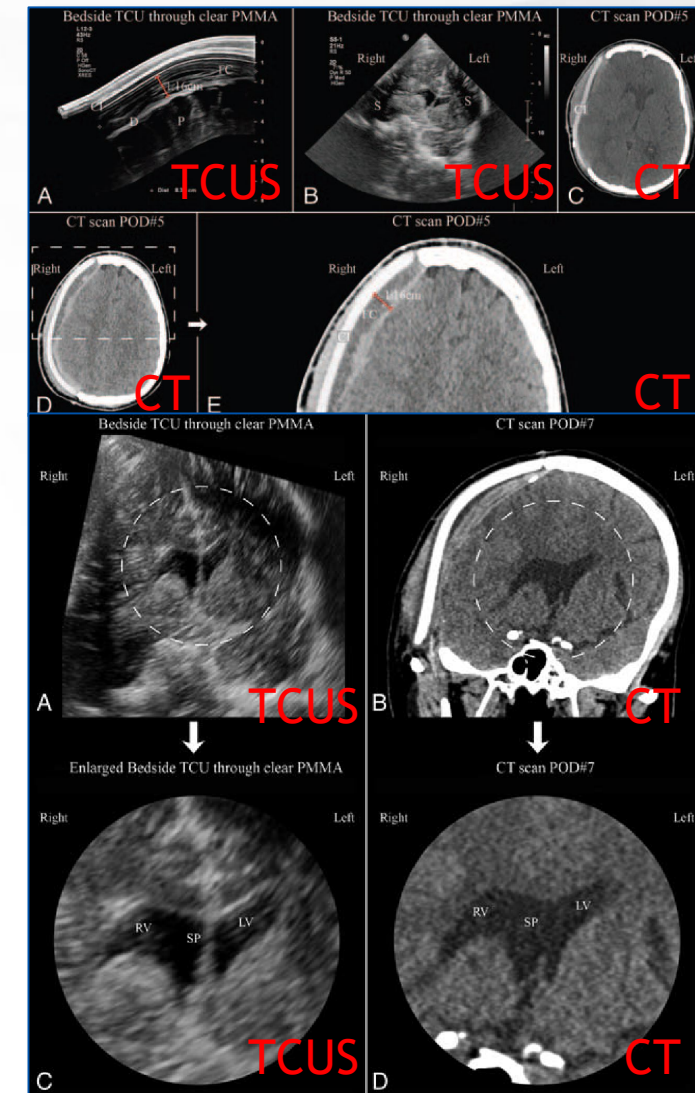


Trans-Cranioplasty Ultrasound (TCUS)

ClearFit® PMMA cranioplasty implants enable bedside non-invasive, real-time, post-surgical monitoring of neurosurgery patients. Ultrasound as an imaging modality is affordable, and accessible, obviating the need for:

- repeated imaging with its associated costs
- radiation exposure
- patient transport associated adverse event risks and costs¹.

There is significant literature demonstrating no clinically significant differences between alloplastic and autograft for cranial reconstruction². These results have been similar in the ClearFit studies conducted to date.



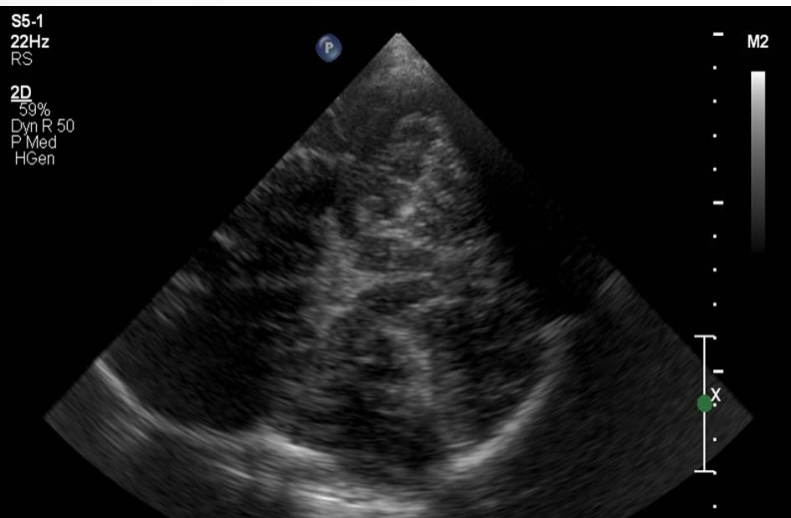
1. Belzberg M, Shalom NB, Yuhanna E, Manbachi A, Tekes A, Huang J, Brem H, Gordon CR. Sonolucent Cranial Implants: Cadaveric Study and Clinical Findings Supporting Diagnostic and Therapeutic Transcranioplasty Ultrasound. J Craniofac Surg. 2019 Jul;30(5):1456-1461. doi: 10.1097/SCS.00000000000005454. PMID: 31299743; PMCID: PMC7329202.

2. Honeybul S, Morrison DA, Ho KM, Lind CRP, Geelhoed E. A randomised controlled trial comparing autologous cranioplasty with custom-made titanium cranioplasty: long-term follow-up. Acta Neurochir (Wien). 2018 May;160(5):885-891. doi: 10.1007/s00701-018-3514-z. Epub 2018 Mar 15. PMID: 29546554.

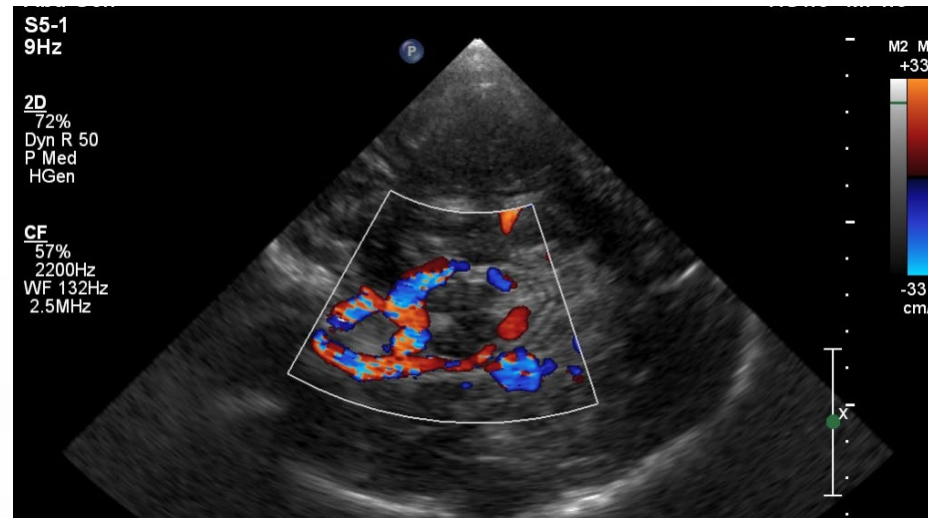
Trans-Cranioplasty Ultrasound Imaging Modes

Key Points

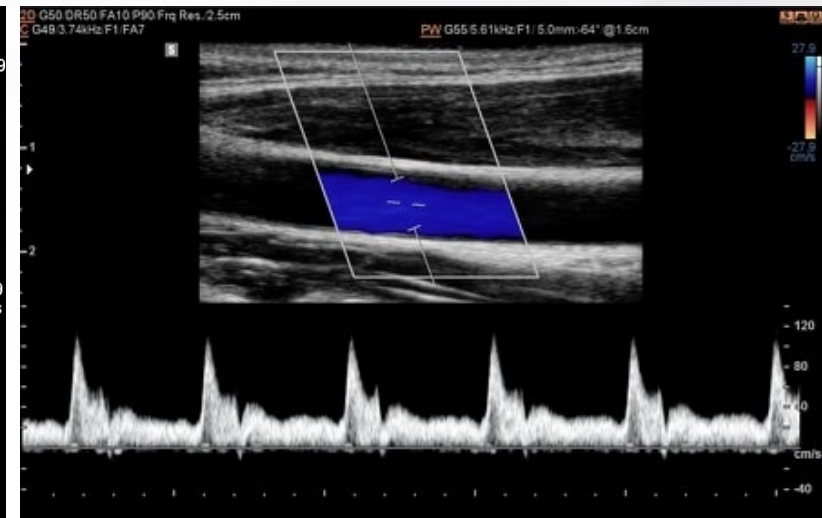
- ❖ B-Mode is a 2-D black and white image
- ❖ Color doppler displays motion (to or away)
- ❖ Pulse wave doppler measures at one point



B-Mode



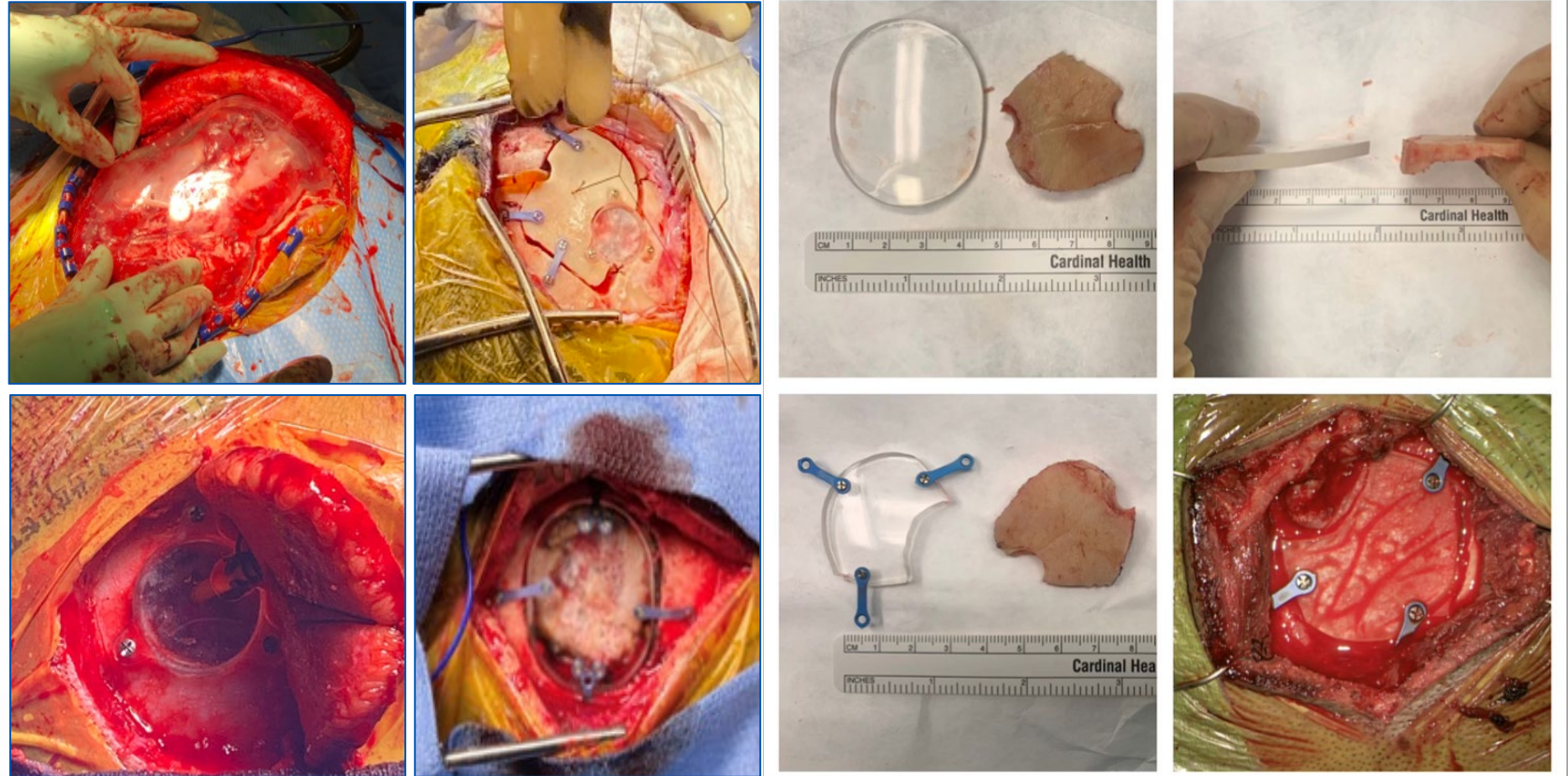
Color Doppler



Pulse Wave Doppler

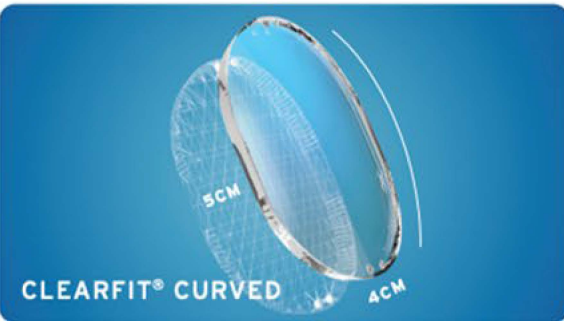
ClearFit® Device

- Longeviti ClearFit® Cranial Implants are manufactured to correct and/or restore bony voids and/or defects of the cranium (K170410, K121210, K202901, K210616, K212058)
- Longeviti ClearFit® Cranial Implants have lower attenuation than cranial bone which enables post-operative ultrasound (K203349)



ClearFit® DISC

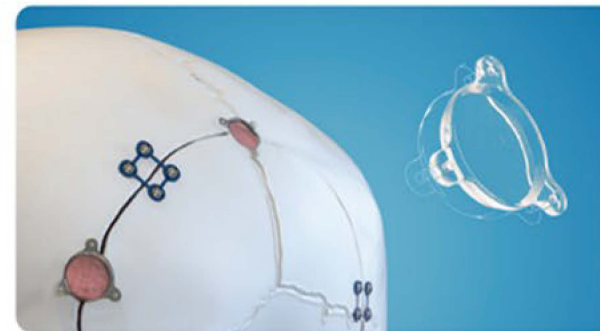
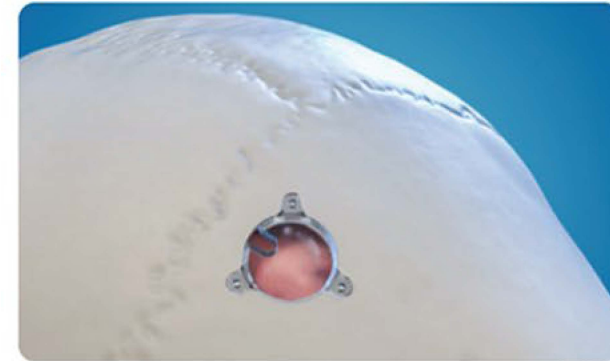
Clearfit® Disc implants
are intended to restore cranial
bone voids.



171708: ClearFit® XS Curved | 171709: ClearFit® XS Flat

ClearFit® COVER

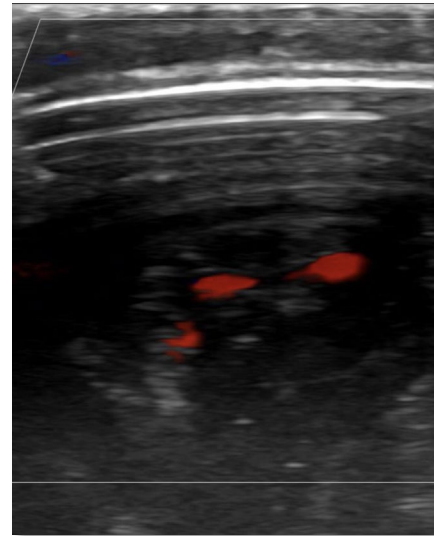
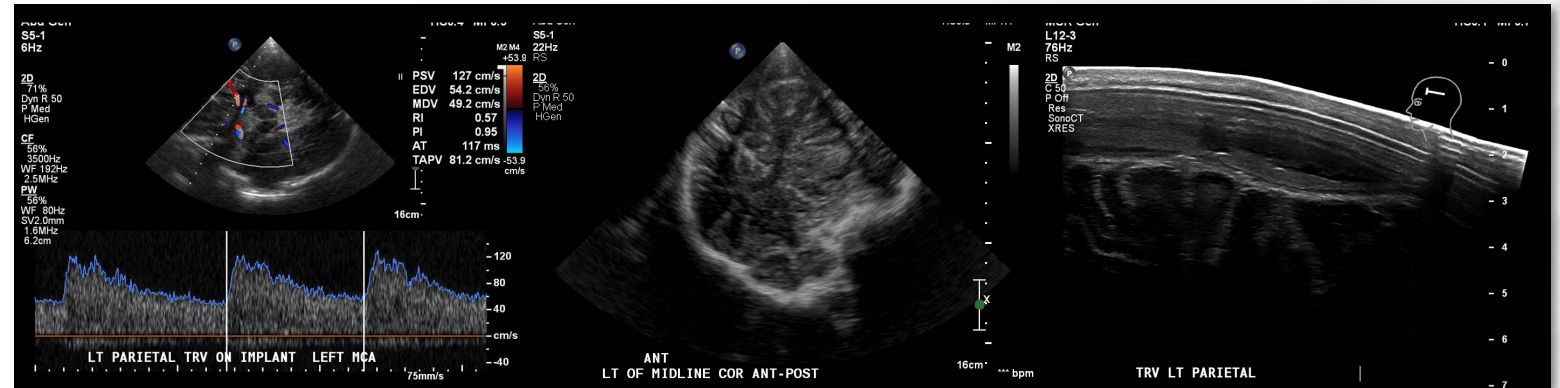
ClearFit® Cover implants are
designed to be low-profile while
allowing for visualization.



171706: ClearFit® Cover | 171707: ClearFit® Cover w/ Slot

ClearFit® Device Enable Trans-Cranioplasty Ultrasound

- ClearFit® Sonolucent Implants enable enhanced diagnostic applications previously limited by cranial bone
- TCUS correlates with catheter angiogram



ClearFit® Device Indications by Pathology

Tumor

- Adjunct Screening tool to assess tumor recurrence

Vascular

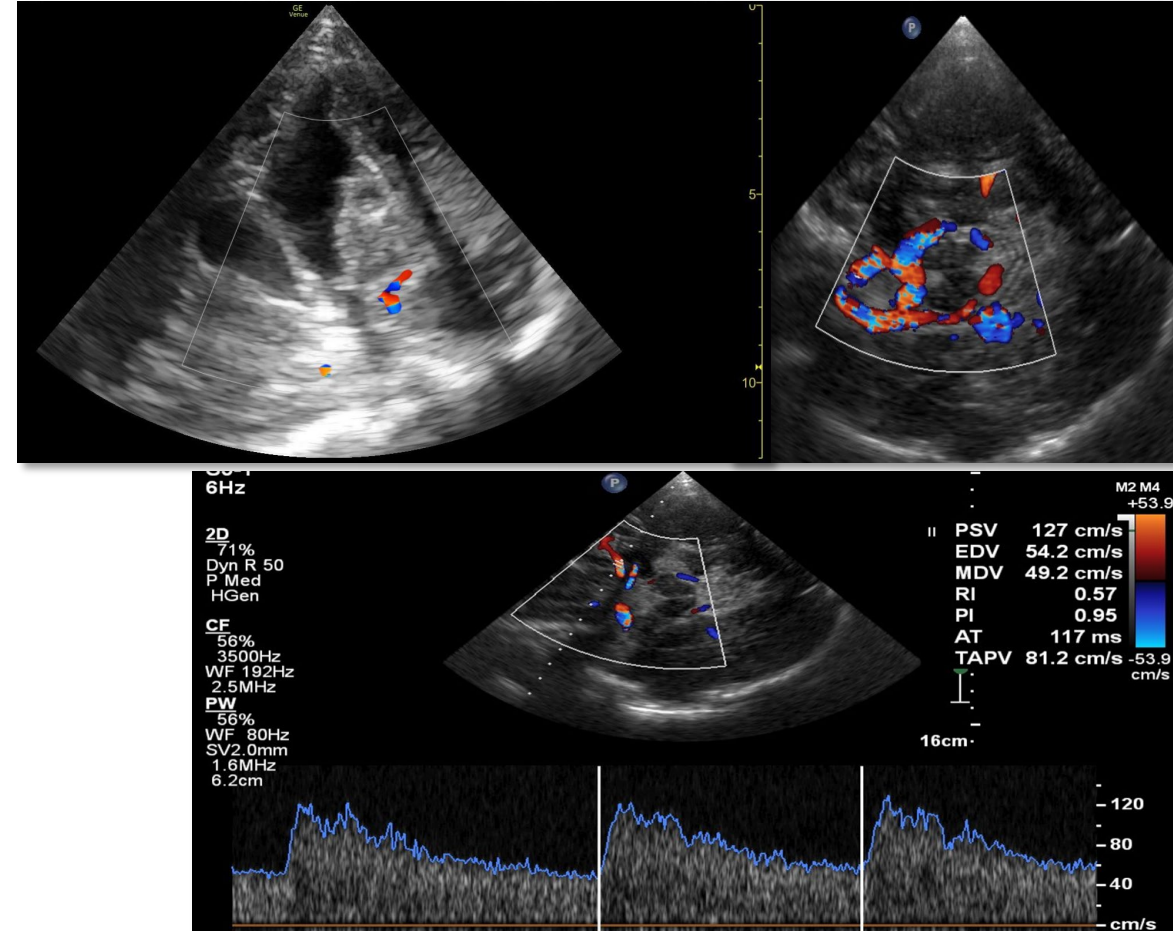
- Cranial Bypass - assess vessel & graft patency
- Aneurysm - consistent Trans-cranial doppler window to assess vaso-spasm

Hydrocephalus & Extra Ventricular Drain (EVD)

- Measure changes in ventricular size
- Confirm Ventricular catheter location

Post ICH Evacuation

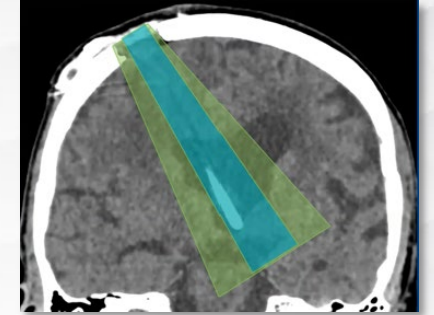
- Adjunct screening to confirm hemostasis and control for rebleed



ClearFit® Implantation Technique

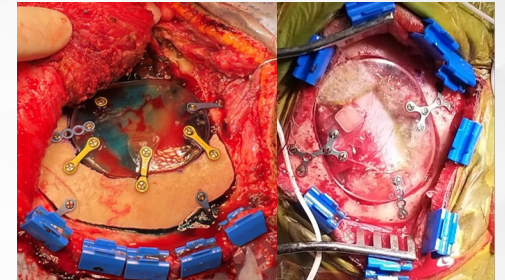
Small ClearFit® Implant

- Create Burr hole with commercially available perforators, drills, and cutting accessories
- Replace the burr hole cover with the best line of site with a ClearFit Device



Medium ClearFit® Implant

- Perform Craniectomy with commercially available perforators, drills, and cutting accessories
- Restore the entire defect or replace a portion of the removed bone with a ClearFit Device



Large ClearFit® Implant

- Cranial defect will be present at time of surgery because it was already removed for decompression
- Restore the entire defect with a ClearFit



TCUS Technique

While scanning

- On immediately post-op patients use sterile gel while scanning over new incisions, consider adding a barrier (sterile sleeve or Tegaderm) and wear appropriate PPE
- On follow up exams and/or clinic scanning use appropriate PPE and barriers for infection prevention.

After scanning

- Wipe gel from patient with appropriate sterile gel or towel as directed
- Wipe gel from probe with any towel and then clean the probe with approved cleaners. This is generally any medical cleaning wipe (CaviWipe, Sani-Cloth, etc) without bleach and Isopropyl Alcohol content below 30%.

Biosafety


- There are no known adverse effects caused by exposure to diagnostic ultrasound.
- Professional bodies make the following recommendations:
 - Ultrasound should be performed under the supervision or approval of a physician
 - ALARA Principle - As Low As Reasonably Achievable...an optimal image should be acquired with the lowest power and highest gain (exam presets are designed using this principle).

Operative Report

NAME OF OPERATION: Right indirect extracranial to intracranial bypass and encephalo-duro-synangiosis.

PREOPERATIVE DIAGNOSIS: Moyamoya.

POSTOPERATIVE DIAGNOSIS: Moyamoya.



The incision was then carried down through the subcutaneous tissue and the galea carefully under the microscope to expose the superficial temporal artery. This was taken down towards the zygoma and up towards the superior temporal line. We exposed the artery with a combination of sharp dissection using the 15 blade as well as tenotomy scissors. Once we had exposed the artery, we separated it from the surrounding subcutaneous tissue circumferentially using a combination of sharp dissection and electrocautery. Special care was taken to ensure patency of the vessel and to preserve its surrounding tissue. Once the artery was dissected out, it was protected using a cottonoid patty and the microscope was brought out. We then proceeded to place a burr hole at the superior temporal line using a round cutting burr and then used a side cutting craniotome to make a circular craniotomy in the planned area of anastomosis. The bone was elevated using Penfield dissectors and the field was irrigated copiously. We then opened the dura in a Y-shaped fashion and brought the microscope back in. Under the microscope, the arachnoid over the visible MCA branches was incised sharply using microscissors and the arachnoid was dissected free so that the pial surface and MCA vessels were exposed. The STA was then brought into the field, to get sufficient length this required us to separate it from the posterior branch. We then used 9-0 Prolene sutures to oppose the perivascular tissue to the separated arachnoid mater to stabilize the artery. Hemostasis was found to be excellent on the field using a couple pieces of Nu-Knit. We then infolded the surrounding dura folding it up underneath the bone edges as a dural anastomosis. Duragen was placed over the artery and brain. An ultrasound penetrable replacement cranial plate was plated with titanium plates and placed over the craniotomy defect. This had been shaped to ensure that the proximal and distal ends of the vessel would not be compressed. The incision was then irrigated copiously with antibiotic-containing solution. The muscle was closed using 2-0 Vicryl sutures. The galea was then closed using 3-0 Vicryl inverted interrupted sutures and the skin was closed using staples. At the conclusion of the case, all counts were found to be correct. The patient was extubated and found to be at their neurologic baseline.

Regulatory Status

Longeviti® ClearFit Implants are FDA Cleared. In 2020 acoustically transparent properties of ClearFit® Devices were cleared by the FDA (K203349)

510(K) NUMBER	PRODUCT	COMPANY	APPROVAL DATE
K170410	Longeviti PMMA Static Cranial Implant	Longeviti Neuro Solutions LLC	3/23/2018
K191210	Longeviti ClearFit Cranial Implant	Longeviti Neuro Solutions LLC	1/9/2020
K202901	Longeviti ClearFit Cranial Implant	Longeviti Neuro Solutions LLC	10/30/2020
K203349	Longeviti ClearFit Cranial Implant	Longeviti Neuro Solutions LLC	12/16/2020
K210616	Longeviti PMMA Static Cranial Implant	Longeviti Neuro Solutions LLC	3/31/2021
K212058	Longeviti ClearFit OTS Cranial Implants	Longeviti Neuro Solutions LLC	9/8/2021

Relevant Publications

1. Belzberg M, Mitchell KA, Ben-Shalom N, Asemota AO, Wolff AY, Santiago GF, Shay T, Huang J, Manson PN, Brem H, Gordon CR. Cranioplasty Outcomes From 500 Consecutive Neuroplastic Surgery Patients. *J Craniofac Surg*. 2022 Mar 4. doi: 10.1097/SCS.00000000000008546. Epub ahead of print. PMID: 35245275.
2. Belzberg M, Shalom NB, Yuhanna E, Manbachi A, Tekes A, Huang J, Brem H, Gordon CR. Sonolucent Cranial Implants: Cadaveric Study and Clinical Findings Supporting Diagnostic and Therapeutic Transcranioplasty Ultrasound. *J Craniofac Surg*. 2019 Jul;30(5):1456-1461. doi: 10.1097/SCS.00000000000005454. PMID: 31299743; PMCID: PMC7329202
3. Belzberg M, Shalom NB, Lu A, Yuhanna E, Manbachi A, Tekes A, Huang J, Brem H, Gordon C. Transcranioplasty Ultrasound Through a Sonolucent Cranial Implant Made of Polymethyl Methacrylate: Phantom Study Comparing Ultrasound, Computed Tomography, and Magnetic Resonance Imaging. *J Craniofac Surg*. 2019 Oct;30(7):e626-e629. doi: 10.1097/SCS.00000000000005651. PMID: 31188246.
4. Hadley C, North R, Srinivasan V, Kan P, Burkhardt JK. Elective Sonolucent Cranioplasty for Real-Time Ultrasound Monitoring of Flow and Patency of an Extra- to Intracranial Bypass. *J Craniofac Surg*. 2020 May/Jun;31(3):622-624. doi: 10.1097/SCS.00000000000006225. PMID: 32149973; PMCID: PMC7329201.
5. Srinivasan VM, Kan P, Huang AT, Burkhardt JK. Occipital Artery to Middle Cerebral Artery Bypass Using the Descending Branch of the Lateral Circumflex Femoral Artery as an Interposition Graft for Blood Flow Augmentation in Progressive Moyamoya Disease. *World Neurosurg*. 2020 Jul;139:208-214. doi: 10.1016/j.wneu.2020.03.136. Epub 2020 Apr 3. PMID: 32251811.
6. Shay T, Mitchell KA, Belzberg M, Zelko I, Mahapatra S, Qian J, Mendoza L, Huang J, Brem H, Gordon C. Translucent Customized Cranial Implants Made of Clear Polymethylmethacrylate: An Early Outcome Analysis of 55 Consecutive Cranioplasty Cases. *Ann Plast Surg*. 2020 Dec;85(6):e27-e36. doi: 10.1097/SAP.0000000000002441. PMID: 33170582.
7. Flores AR, Srinivasan VM, Seeley J, Huggins C, Kan P, Burkhardt JK. Safety, Feasibility, and Patient-Rated Outcome of Sonolucent Cranioplasty in Extracranial-Intracranial Bypass Surgery to Allow for Transcranioplasty Ultrasound Assessment. *World Neurosurg*. 2020 Dec;144:e277-e284. doi: 10.1016/j.wneu.2020.08.114. Epub 2020 Aug 20. PMID: 32827747; PMCID: PMC7438362.
8. Ben-Shalom N, Asemota AO, Belzberg M, Harnof S, Huang J, Lim M, Brem H, Gordon C. Cranioplasty With Customized Craniofacial Implants and Intraoperative Resizing for Single-Stage Reconstruction Following Oncologic Resection of Skull Neoplasms. *J Craniofac Surg*. 2022 Mar 14. doi: 10.1097/SCS.00000000000008541. Epub ahead of print. PMID: 35288504.
9. Belzberg M, Mitchell KA, Ben-Shalom N, Asemota AO, Wolff AY, Santiago GF, Shay T, Huang J, Manson PN, Brem H, Gordon CR. Cranioplasty Outcomes From 500 Consecutive Neuroplastic Surgery Patients. *J Craniofac Surg*. 2022 Mar 4. doi: 10.1097/SCS.00000000000008546. Epub ahead of print. PMID: 35245275.

longevity

Thank you.

Open Discussion

