

OPEN

Discussion of Elective Sonolucent Cranioplasty for Real-Time Ultrasound Monitoring of Flow and Patency of an Extra- to Intracranial Bypass

Chad Gordon, DO, FACS^{*†}

“Often we look so long at the closed door that we do not see the one that has been opened for us.” —Helen Keller

Since the very first craniotomy was performed, bone flaps have always remained the “door” to the brain. Analogous to a mechanic opening the hood for an exotic car, the neurosurgeon’s mission is to improve, modify and/or somehow alter the engine’s awe-inspiring function. In parallel, neurosurgeons depend on costly, time-consuming, and/or radiation-accompanying modalities for assistance with “engine diagnoses”—like magnetic resonance imaging (MRI) or computed topography (CT) scanning, for example.

The story goes that Enzo Ferrari, the visionary and founder of the well-known Italian car company, was often asked at many of his popular car shows - to repeatedly open the rear-hood of his early day race cars by the car enthusiasts in attendance, and to show off his beautiful hand-built engine. As time passed, astounded onlookers would consistently joke with Enzo, “*your engine is so beautiful, why don’t you build a glass hood to save yourself the effort of having to open the hood?*” And so, in 1999, when the Ferrari 360 and its formula one racing-inspired, mid-rear-mounted v8 engine was released to replace the 355, Ferrari displayed its first-ever glass bonnet proudly featuring a “direct view” as a way for one to visually appreciate its highly-acclaimed, red-colored engine¹ (Fig. 1).

Now, fast forward to today, pediatric neuroradiologists use the open fontanelle as a “window of opportunity” to evaluate the growing brain through an immature skull. Ultrasonography has allowed the field of pediatric neuroradiology to blossom

exponentially, simply because the ultrasound waves are unimpeded by the open fontanelle versus the intact cranial bone. Their approach is similar to that of Enzo Ferrari. Direct visualization trumps everything else.

This leads us to the exciting work presented by Burkhardt and colleagues. In their landmark article entitled “Elective sonolucent cranioplasty for real-time ultrasound monitoring of flow and patency of an extra- to intracranial bypass,” the team presents a newfound opportunity for neurovascular surgeons performing extra-anatomical bypass for cerebral insufficiency in the case of moyamoya disease.² This innovative group describes the first-ever demonstration of post-operative graft flow and patency confirmation via real-time ultrasound, as opposed to the more commonly-used options like angiogram, CT, and MRI. All made possible by simply replacing a portion of the patient’s autologous bone flap (at time of closing) with a clear-colored, sonolucent implant made of polymethyl methacrylate (PMMA). Their report goes on to describe transcranioplasty ultrasound (TCU) as being “an effective, bedside modality in confirming bypass patency, allowing quantitative flow measurements, and excluding post-operative hemorrhage,” all of which are critical and time-sensitive. But how did we get here? What previous developments in cranial implant technology led us to this breakthrough in peri-operative monitoring? What was the impetus for this milestone discovery, for which may forever change the way we monitor our neurovascular patients?

In 2010, I was a craniofacial surgery fellow being trained by Dr. Michael Yaremchuk at Massachusetts General Hospital/Harvard Medical School as to the complexities of facial asymmetry, facial augmentation with subperiosteal implants, and methods to correct post-neurosurgical temporal hollowing with a liquid PMMA and

From the ^{*}Neuroplastic and Reconstructive Surgery Program, Department of Plastic and Reconstructive Surgery; and [†]Department of Neurosurgery, Johns Hopkins University School of Medicine, Baltimore, MD.

Received November 18, 2019.

Accepted for publication November 29, 2019.

Address correspondence and reprint request to Chad Gordon, DO, FACS, Neuroplastic and Reconstructive Surgery Program, Johns Hopkins University School of Medicine, 8th Floor, JHOC, 601N. Caroline Street, Baltimore, MD 21287; E-mail: cgordon@jhmi.edu

Johns Hopkins University and Dr. Gordon are entitled to potential royalties on several inventions and U.S. patents disclosed in this presentation. Dr. Gordon is a paid consultant for Depuy-Synthes, OsteoMed, Longeviti Neuro Solutions, Medtronic, and Stryker. Dr. Gordon is a shareholder of Longeviti.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Copyright © 2020 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of Mutaz B. Habal, MD

ISSN: 1049-2275

DOI: 10.1097/SCS.0000000000006255

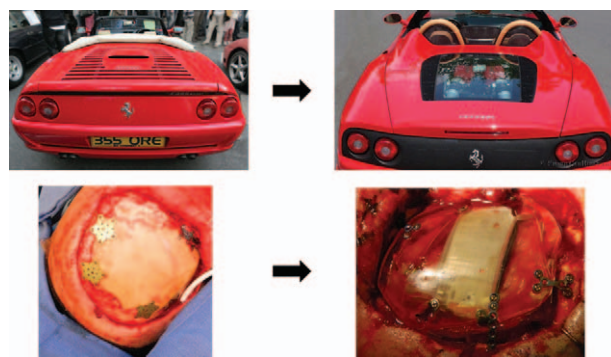


FIGURE 1. Photograph of evolution involving the Ferrari 355’s opaque, rear-engine bonnet next to the Ferrari 360’s clear-colored, rear engine bonnet - and the analogy of an opaque solid cranial implant in-situ compared to a clear-colored, solid PMMA cranial implant with embedded neurotechnology.

titanium screw fixation method analogous to rebar utilization and laying cement.³ From here, I was empowered to move forward and correct the ever-present design flaw in modern-day custom cranial implant design, for which since 1999, ignored the soft tissue atrophy component and concentrated solely on the bony defect's mirror image for computer-assisted design/computer-assisted modeling, thus leaving most cranioplasty patients with asymmetry and soft tissue temporal deformities. Soon thereafter, a United States patent was issued entitled "patient-specific craniofacial implants" and the dual-purpose design, proving additional bulk to areas nearby or above the craniofacial bone defects, was introduced to the neurosurgical community.^{4,5} From here, the common pterional cranial implant became thicker and more effective in an effort "to prevent and/or correct" the co-existing temporal deficiency status-post cranioplasty. Of note, this was the first time the FDA approved this secondary indication for cranial implants, in parallel to the more common indication, craniofacial bone replacement.

Soon thereafter, this led to an idea of using the newfound potential space within the bulked-out cranial implant segment, as a novel delivery platform for embedded neurotechnologies in situations of co-existing neurological disease (Fig. 2). With numerous extramural grants and a highly-talented multidisciplinary team, this evolved into several "first-in-human" articles describing our preliminary experience in Baltimore, employing the skull's anatomical space (contained within a customized cranial implant) to inset

- (1) functional neuromodulation devices for medicine-resistant epilepsy,
- (2) high-profile programmable shunts for obstructive hydrocephalus, and
- (3) wireless, intracranial pressure devices for intracranial hypertension monitoring following severe traumatic brain injury.^{6–8}

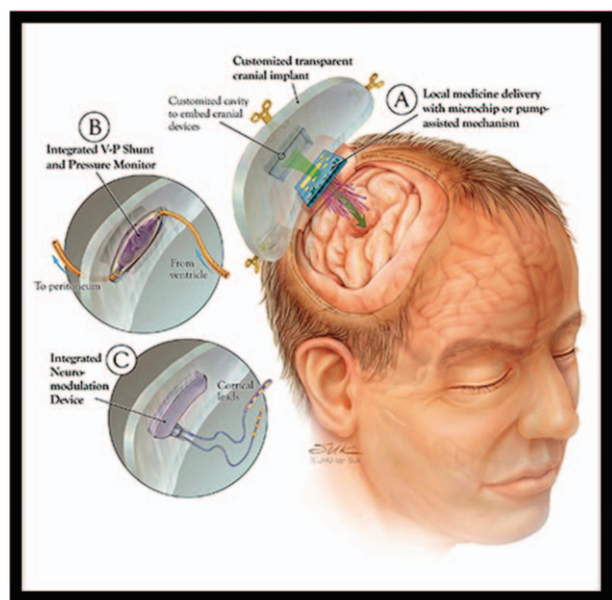


FIGURE 2. Featured artistic illustration of a novel concept to utilize one's valuable intercranial space found within a customized cranial implant, following limited-size craniectomy, to offer neurosurgical patients an improved method of implanting devices with an enhanced profile – for disease types such as (A) malignant brain tumors (local chemotherapy delivery), (B) hydrocephalus (shunt valve/intracranial pressure monitor), and (C) medicine-resistant epilepsy (neuromodulation device); which is important for optimizing patient satisfaction and preventing scalp breakdown, device extrusion, pain, visual deformity, and accompanying social stigma. Reproduced with permission from the cover of *Operative Neurosurgery*, December 2019.

In parallel, as similar to Enzo's constant engine modifications and aesthetic enhancements, it became obvious to us that the new burgeoning field of Neuroplastic Surgery and low-profile intercranial devices (LIDs) could and should require an implant material to be visually "clear," providing the surgeon an invaluable view of the life-changing core components at time of implantation.⁹ It seemed quite intuitive given the delicate nature of the groundbreaking technology within, and the newfound visualization for critical anatomy underneath, analogous to the Italian car show enthusiasts seeing the updated, red-painted racing engine for the very first time.¹⁰ This advantages quickly became evident and soon thereafter the solid PMMA cranial implant was preferably altered from opaque to clear-colored. After all, which surgeon does not want to see the dural pulsations, intact dura, absent cerebrospinal fluid leak/hemorrhage, and vascularized intact pericranium at time of cranioplasty reconstruction?

However, one often asks how did you go from clear-colored PMMA implants to the sonolucent aspects which are now being presented by the neurosurgical team at Baylor? It was during our preliminary surgeries for medicine-resistant epilepsy at Hopkins, for which we moved the neuromodulation device from the standard inlay position (in patients presenting with co-existing skull defects for whom needed the device, we used full-thickness defects for placement) to an underlay position for an enhanced contour and head shape. In this, we realized that the one millimeter of clear-colored PMMA encasing the device provided zero obstruction to the wireless electrocorticography (ECOG) radio signals being transferred from the brain to the external wand being held above the closed scalp. It made us think, "If the wireless ECOG radio signals from the brain to the external wand could be transmitted effortlessly through the clear-colored, PMMA cranial implant, why wouldn't the implant be able to pass unimpeded sound waves from a handheld transducer in the reverse direction, from an external ultrasound device sending image signals from the external scalp down towards the brain?" In short, this is how we arrived at the tipping point. Several reports were quickly published by our team demonstrating that our hypothesis was in fact correct – that the clear PMMA implant were not only visibly translucent and radiolucent, but sonolucent as well.^{11,12}

Therefore, I would like to wholeheartedly congratulate Dr. Burkhardt and his exemplary team for showing us the utility of elective sonolucent cranioplasty for real-time ultrasound monitoring following bypass surgery. This requires hard work and dedication to push the boundaries of modern-day medicine, and therefore, kudos to them for helping us take this leap. Having the newfound ability to monitor neurovascular bypass grafts with an easy, bedside alternative, at a reduced cost potential versus MRI, CT or angiogram, seems like a "game changer." Interestingly, it does not stop there. At our most recent Neuroplastic Surgery Symposium held at Harvard Medical School (November 2019), a team of neuroradiologists presented their work with bedside transcranial ultrasound as a method to monitor brain tumor progression and recurrence following craniotomy, in an instance where the autologous bone flap was replaced with a clear-colored, sonolucent implant.¹³

With this, the potential breakthroughs become exponential and one can only be excited for the future beyond. As Helen Keller astutely pointed out, we often look at a closed door and fail to see the one that has been opened for us. Therefore, perhaps neurosurgeons have been looking way too long at the "closed door" represented by the autologous bone flap, and that the sonolucent clear-colored implant represents a new "open door" for all neurosurgical patients. This new door will undoubtedly lead to innovation, collaboration, and improved patient care.

REFERENCES

1. Adler D. Ferrari: 70 years. Minneapolis, MN: Quarto; 2016;264
2. Hadley C, North R, Srinivasan V, et al. Elective sonolucent cranioplasty for real-time ultrasound monitoring of flow and patency of an extra- to intracranial bypass. *J Craniofac Surg* 2020;31:622–624
3. Gordon CR, Yaremchuk MJ. Temporal augmentation with methyl methacrylate. *Aesth Surg J* 2011;31:827–833
4. Gordon CR, Bryndza JR, Bisic T. Patient-specific craniofacial implants. US Patent #10,080,662
5. Zhong S, Huang GJ, Susarla SM, et al. Quantitative analysis of dual-purpose, patient-specific craniofacial implants for correction of temporal deformity. *Oper Neurosurg* 2015;11:205–212
6. Gordon CR, et al. First-in-human experience with complete integration of neuromodulation device within a customized cranial implant. *Oper Neurosurg* 2017;15:39–45
7. Gordon CR, et al. First-in-human experience with integration of a hydrocephalus shunt device within a customized cranial implant. *Oper Neurosurg* 2019;17:608–615
8. Mitchell KA, et al. First-in-human experience with integration of wireless intracranial pressure monitoring device within a customized cranial implant. *Oper Neurosurg* 2019;15:39–45
9. Gordon CR, Huang J, Brem H. Neuroplastic surgery. *J Craniofac Surg* 2018;29:4–5
10. Gordon CR. Low-profile Intercranial device (L.I.D.). US Patent Application 20180338835. Filed May 2, 2016. Published Nov 29, 2018
11. Belzberg M, Shalom NB, Lu A, et al. 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;30:626–629
12. Belzberg M, Shalom NB, Yuhanna E, et al. Sonolucent cranial implants cadaveric study and clinical findings supporting diagnostic and therapeutic transcranioplasty ultrasound. *J Craniofac Surg* 2019;30:1456–1461
13. Machnitz A, Tekes A. Sonolucent cranial implants. Invited lecture. Selected Topics in Neuroplastic and Reconstructive Surgery: An International Symposium on Cranioplasty and Implantable Neurotechnology. Boston, MA: Harvard Medical School, November 2, 2019

