Adult Cranioplasty Reconstruction With Customized Cranial Implants: Preferred Technique, Timing, and Biomaterials

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Introduction: Complex cranial defects requiring delayed reconstruction present numerous challenges. Delayed cranioplasties accompany frequent complications approaching an incidence of 35 to 40%. Therefore, the authors sought to collate their experience in hopes of sharing their perspective on several topics including technique, timing, and preferred biomaterials.

Methods: The authors' 5-year consecutive experience over 430 customized cranial implants is described herein. Since its inception in 2012, the authors' team has employed the pericranial-onlay cranioplasty technique instead of the standard epidural approach. Optimal timing for cranioplasty is determined using objective criteria such as scalp healing and parenchymal edema, close collaboration with neuroplastic surgery, conversion from autologous bone to sterile implant in instances of questionable viability/storage, and the first-line use of solid poly(methylmethacrylate) implants for uncomplicated, delayed cases, first-line porous polyethylene (MEDPOR) implants for single-stage cranioplasty, and first-line polyether-ether-ketone implants for cases with short notice. Furthermore, the use of the pterional design algorithm with temporal bulking for all customized implants has helped to correct and/or prevent temporal hollowing deformities.

Results: The authors' team has observed a three-fold reduction in reported complications as compared with the existing literature, with a major complication rate of 11%. The multidisciplinary center has provided an optimal stage for synergy and improved outcomes versus standard cranioplasty techniques.

Conclusion: Secondary cranial reconstruction, or cranioplasty, can be challenging due to numerous reasons. These best practices, developed in collaboration with neuroplastic surgery and neurosurgery, appear to encompass the largest published experience to date. The authors find this approach to be both safe and reliable.

Key Words: Cranial implant, cranial reconstruction, cranioplasty, delayed reconstruction, MEDPOR, pericranial onlay technique, pterional plus PEEK–polyether ether ketone PMMA–poly (methylmethacrylate) porous polyethylene

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Large-sized cranial defects, which necessitate delayed reconstruction known as cranioplasty, may result from a variety of primary etiologies. Common etiologies include acquired defects following emergent decompressive craniectomy, postcraniotomy bone flap infections with osteomyelitis requiring removal, sterile bone resorption with or without soft tissue atrophy leading to acquired deformity, brain neoplasms with calvarial extension, and/or postoperative head irradiation/chemotherapy leading to wound dehiscence and necessitated bone-flap removal.[1,2]

Regardless of etiology, there are many approaches used currently for replacing large-sized defects of the cranial skeleton, if and when the patient's own bone flap is no longer viable. Some surgeons employ split-calvarial bone grafts obtained via a contralateral craniotomy, while others prefer cadaveric bone allograft. However, most commonly, surgeons choose either an approach with "cranial defect bridging" using off-the-shelf, hand-cut pieces of one millimeter thick titanium mesh or "anatomical replacement" by the way of prefabricated, computer-aided-designed and manufactured, patient-specific customized cranial implants (CCIs).

Regardless of approach, the overarching principles for cranioplasty should include returning vital protection to the brain, restoring symmetrical contour and appearance to that consistent of preneurosurgery, and reversing any neurological dysfunction associated with absent cranial bone known as "Syndrome of the Trephined." In fact, our recent work identified 4 mechanisms for reversible disability including: craniocaudal cerebrospinal fluid flow inhibition, sinus venous congestion, abnormal atmospheric pressures, and alterations in cellular metabolism.[3] Therefore, in general, cranioplasty surgery should always be considered either "functional," "restorative," or "reconstructive," rather than one using misleading terms like "elective" or "cosmetic."[1–9]

TIMING AND METHOD

There is ever-lasting controversy as to when exactly is the best timing interval for each patient in need of delayed cranioplasty reconstruction. However, the main reason for this never-ending

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debate is the great diversity and coexisting variables among all craniectomy patients. For instance, some are perfectly healthy, young individual's status-post isolated traumatic brain injury, versus others who are quite ill with multiple comorbidities further complicated by intracranial bleeding. As such, based on our experience, we believe a multidisciplinary team with various degrees of expertise is best to handle these complex scenarios, especially when caring for a wide array of adult patients (as opposed to a single surgeon). From here, we have also found that most cranioplasty patients fall within 1 of 5 main categories including craniectomy status-post trauma or bleeding decompression for acute brain expansion/swelling, craniectomy for access/resection of brain and/or skull pathology, craniectomy for the management of intracranial infection and/or bone flap osteomyelitis, craniectomy for sterile bone flap resorption, and craniectomy for various functional neurological procedures.

Specific to these cases involving cranio-cerebral trauma, some centers prefer a short time interval (ie, "early") cranioplasty versus others who choose to wait for all parenchymal swelling to resolve.[10,11] With respect to "early" versus "late," there are numerous studies to support either of the 2 approaches.[12,13] For neurosurgical patients undergoing craniectomy for reasons other than surgical site infection, studies do support "early" cranioplasty—using 3 months as the cutoff between early and late.[14,15] For example, in a 10-year retrospective study (n = 157) comparing early (<12 weeks) versus late (>12 weeks) cranioplasty, the infection rate was 8% in the early cohort versus 14% in the late cranioplasty cohort. Bone graft resorption was also lower in the early (15%) versus late cohort (19%) respectively, while complications such as hydrocephalus (8% early vs. 1% late) and postoperative hematoma (4% early vs. 1% late) were higher in the early group.[16] However, most significant was that the overall complication rate was around 35% for both cohorts regardless of timing—thus demonstrating the need for multidisciplinary collaboration and the large accepted complication risk profile accompanying implant-based cranioplasties.[16]

Another similar study compared "early" versus "late" intervals in hemorrhagic stroke patients and found the overall complication rate and infection rate in early versus late cohorts to be 22% versus 16%, respectively.[17] As such, the delayed approach in the infected craniectomy population is well accepted and often includes a full 6-week course of culture-directed intravenous antibiotics prior to cranioplasty. In fact, for our neuroplastic surgery team, we advocate a time interval ranging between 3 and 12 months depending on the isolated bacteria and/or fungus, as well as full clearance from our infectious disease colleagues.[18–20] Similarly, a retrospective study by our team, analyzing the safety of time-interval reduction for implant-based cranioplasties, found the overall infection rate to be consistently around 4%—for both the early-delayed group (<90–179 days) and late-delayed group (>180 days).[18]

On the other hand, many teams advocate early cranioplasty based on several reasons, many of which are related to unpreventable scalp contracture (ie, sunken scalp)—which has always been problematic to neurosurgeons. For this, several authors describe the challenging difficulty of achieving a tension-free scalp closure in light of unpreventable scalp contraction.[21,22] As such, we introduced the "pericranial-onlay technique" (employing scalp component separation via the surpa-pericranial plane in conjunction with fine dissection under loupe magnification and needle-point electrocautery) as a way to facilitate a tensionless closure in the delayed setting (ie, "late"), which allows the healthy scalp to adhere densely to the dura underneath and remain uninjured. This approach assists with recruiting additional scalp laxity via the release of subfascial (subgaleal) ligaments during the fascia-skin flap elevation, while, at the same time, leaves underneath an undisturbed, vascularized pericranial-onlay flap.[22,23]

MULTIDISCIPLINARY APPROACH

Since the introduction of the Multidisciplinary Adult Cranioplasty Center (MACC) in 2012, our 5-year consecutive single-surgeon experience (CG) with 437 cranioplasties has observed a 3-fold reduction in reported complications when compared with the literature with a major complication rate of 11%.[16] Our traditional workup begins with a thorough scalp examination. In doing so, we note the following findings: open wounds (new and old), incisional scabs, delayed wound healing, areas of alopecia, inherent scalp mobility, scalp thickness, and signs of previous surgical incisions or prior scalp reconstruction. Next, a fine-cut cranioplasty protocol computed tomography (CT) is obtained to assess the three-dimensional cranial defect for surgical planning and to quantify any coexisting soft tissue atrophy within the pterional region that may also be present (Fig. 1). This type of CT scan is also used for custom implant design/fabrication, which helps to prevent duplicated radiation and/or unnecessary imaging expenses.[24]

If the patient's bone is unsuitable for use due to resorption risk and/or contamination, then a custom cranial implant is ordered made of either poly (methylmethacrylate) (PMMA), porous polyethylene (MEDPOR), or polyether-ether-ketone (PEEK). For this, we prefer our published algorithm to design a dual-purpose implant (ie, Pterional PLUS) capable of correcting and preventing persistent temporal hollowing (PTH).[24] With CT scan DICOM data and the implant vendor's engineering team, we obtain an implant with an outer, augmented shell to account for temporalis muscle and temporal fat atrophy—for either a single-stage cranioplasty and/or delayed cranioplasty case.[25,26] Our preference is to use solid PMMA implants for all uncomplicated, delayed cases, use porous polyethylene for single-stage reconstruction cases (in instances where the exact bone defect is undefined and required ""back-table shape modification"), and use CCIs made of PEEK when the referral comes with short notice and timing is crucial. Of note, this Pterional PLUS (Stryker Craniomaxillofacial, Kalamazoo, MI) algorithm—with strategic compensation for temporal hollowing stemming from missing or atrophied soft tissue—is only safe and reliable when one engages an implant vendor whose in-house biomedical engineers are well versed with this type of dual-purpose approach.[1,25,26]

Regardless of the implant material and/or vendor selected, all CCIs should be designed to compensate and/or prevent soft tissue deformity in the pterional region to prevent risk for necessary revision. Now, with an exhaustive amount of published literature from neurosurgeons worldwide, it is only fair to our patients that we aim to eradicate and/or prevent the social stigmata for which accompanies temporal hollowing deformities status-post neurosurgery. Without question, this should be done in a similar fashion to the way we approach the breast cancer patient population following

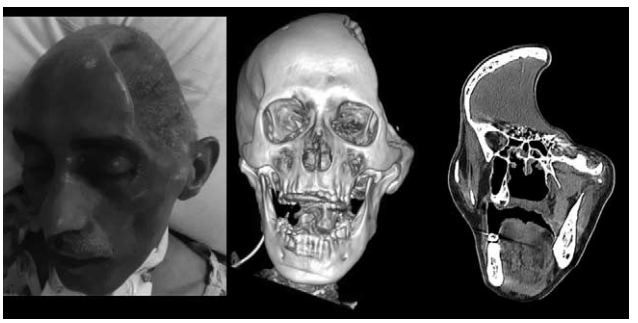

FIGURE 1. Preoperative cranioplasty evaluation begins with computed tomography imaging and three-dimensional reconstruction to adequately assess any co-existing soft and hard tissue deformities for the purpose of implant design and surgical planning.

oncologic breast surgery—analogous to restorative breast reconstruction and goals for absent deformity. As such, one could argue that that the craniofacial deformity postneurosurgery is even more critical for one's recovery and overall well-being. With this in mind, the older variety of customized cranial implants introduced nearly 2 decades ago (by all leading companies)—which only accounts for missing bone by mirroring the contralateral hard tissue anatomy—are essentially outdated and fail to fully account for the potential complication in regards to "PTH" or "temporal wasting." [24]

The dreaded complication of temporal wasting/hollowing is now being reported at an all-time high, and is now considered the number one reported complication across the neurosurgical literature—with an incidence approaching 52%.[27] As such, this visible asymmetry is not only detrimental to the patients, it negatively affects their supportive family and loved ones on various levels, as elucidated by Rosenthal et al.[28] Also, the increased need for repeat or corrective procedures places a significant financial burden on the health care system at large.[29] Furthermore, in the most extreme cases, PTH can lead to low self-esteem, chronic depression, and even suicidal ideations.[23,24,27,28]

In addition to assessing the ipsilateral temporal soft tissue within the pterional region, we obtain a detailed history regarding past infections, radiation, and/or cranial surgeries—since all of these variables somehow affect the quality of overlying soft tissue, our ability to achieve tension-free scalp closure at the time of cranioplasty, and may require additional surgical planning in advance using complex component separation, adjacent tissue transfer with rotation, and/or full-thickness skin grafting. Without question, a healthy, tension-free, scalp coverage is absolute when placing a new CCI into position.[22] In our experience, many cases referred to our center have signs of unfortunate scalp dehiscence and are incorrectly labeled as "problematic implant cases related to infection," when, in fact, one can tell on straightforward examination that there were initial inadequacies related to either the durability of scalp closure at the time of implant placement and/or incidental invasion within the frontal sinus during craniotomy/cranioplasty.

Surgical Site Preparation

Given the extreme consequences and associated morbidity surrounding surgical site infections in the setting of implant-based cranioplasty, the senior author (CG) chooses to be present for, and directly participate in, conduct a 3-stage surgical sterilization and detailed draping process in the beginning of surgery. While these tasks could be easily delegated to other staff and/or trainees, we believe good technique and consistency is imperative to ensure that this crucial step of the procedure is performed judiciously.

Before surgery the scalp is shaved gently to determine all previous scalp incisions, allow visual inspection of an ideal cranial contour during reconstruction, and expose any epidermal sloughing. After shaving, the scalp is scrubbed with iodine solution-containing surgical-scrub brushes, followed by a wet iodine-based prep. The final preparation is performed with Iodine Povacrylex solution (Duraprep, 3 M, Maplewood, MN). All the previous incisions are marked with a surgical marker using a solid line, and the bony defect is demarcated using broad hash marks (Fig. 2).[22] A 50:50 mixture of 1% lidocaine with epinephrine and sterile saline is injected into the surrounding scalp as preemptive anesthesia—with extreme care taken to inject parallel and away from the underlying brain. A #15 blade is used to make a partial-thickness incision, just deep to the level of the hair follicles, always following the patient's previous neurosurgical incision. Colorado needle cautery is used to complete the incision down to stable bone. Wide undermining of the scalp is performed with a periosteal elevator and cautery to ensure scalp mobility, with galeal scoring as needed. Once the scalp has been fully mobilized over the areas of native skull, the full-thickness scalp overlying the brain and skull defect is meticulously dissected in a supra-pericranial plane leaving behind a vascularized pericranial-onlay flap, which remains undisturbed above the dura.[22] With this technique, it is important to remain in the proper plane to avoid durotomy/brain injury or scalp perfusion interruption.

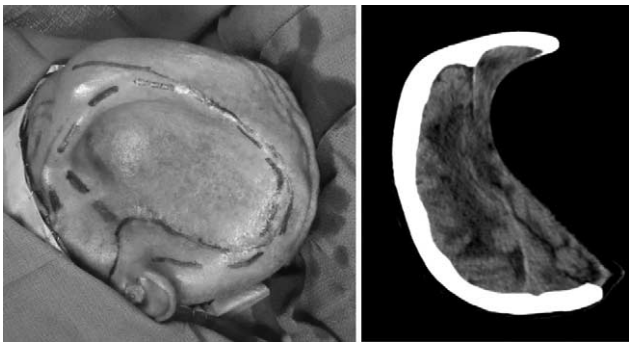

FIGURE 2. Photograph (left) demonstrates intraoperative drawings demarcating cranial bone norder (hash marking) and previous neurological incision used for decompressive hemicraniectomy (solid line). Corresponding preoperative computed tomography scan demonstrates severe encephalomalacia and sunken scalp contracture (right).

Preferred Biomaterials

There are various biomaterials for safe use in cranioplasty reconstruction. The ideal biomaterial is durable, time-tested, holds a constant shape with respect to time, provides mechanical strength for cerebral protection, is thermally nonconducive, is biocompatible, maintains a low risk profile for infection, is cost-effective, is easy to artistically contour with handheld burr for single-stage reconstruction, is readily available, and is magnetic resonance imaging/radiation therapy compatible. However, there remains just 1 missing, ideal characteristic of all 3 of our commonly used biomaterials—which is them not being completely clear and fully transparent. This attribute, in turn, allows our team the desired ability to visualize beneath and to assess all pertinent details such as dural/brain pulsations, sagittal sinus bleeding, and cerebrospinal fluid leaking from durotomy suture line. Furthermore, it provides optimal clarity for neuromodulation devices incorporated within for cases involving cortical mapping, localized medicine delivery, hydrocephalus shunting, etc.[30] As such, we will further review the various characteristics of the 3 preferred biomaterials used most often by our neuroplastic surgery team (Table 1).

Porous Polyethylene (MEDPOR)

High density porous polyethylene, or MEDPOR (Stryker CMF, Kalamazoo, MI) comes in various shapes with variable thickness.[31] This material accompanies a high degree of porosity with implant pore volume around 50%. It has an average pore size of 80 to 100 μm, which allows it to uniquely promote tissue ingrowth for increased stability and minimized risk for infection.[32,33] Other advantages are that it is easy to modify and easy to fixate with screws. Some newer MEDPOR implants are of a "composite type" with embedded titanium mesh within the material to provide additional support. This material does not cause imaging artifacts and may be ordered as a custom, dual-purpose cranial implant (ie, Pterional PLUS design) to allow for simultaneous correction and/or prevention of temporal hollowing deformities in areas of soft tissue atrophy either nearby or overlying the targeted skull defect (Fig. 3).[33]

TABLE 1. Comparison of Common Various Biomaterials Chosen for Customized Cranial Implant Fabrication

Implant Type	Benefits	Drawbacks
Autogenous bone		Unpredictable resorption
	Potential revascularization, Osseo-integration and viability	
	Immuno-matching	Infection
		Poor cosmesis
		Not able to design for temporal hollowing correction and/or prevention
Titanium mesh	Strength and stiffness	Painful, sharp edges
	Malleable	Hard to retrieve
	Easy to handle	Image scattering
		Suboptimal for radiated scalps
		Poor cosmesis in thin skin or large contour areas
PEEK		
	Strength and stiffness,	
	Biocompatibility	Prone to seromas
	Excellent cosmesis	Needs hospital sterilization
	Short production time	
HDPE (Medpor)	Native tissue in growth	
	Stability	
	Biocompatibility	Hard to retrieve
	Easy to contour	3-week time for production
PMMA	Strength and stiffness	Lack of bioactive properties
	CCI preformed (no exothermia)	
	Biocompatibility	3-week time for production
	Excellent cosmesis	
	Easy to handle	
	Soft tissue adherence	
	Easy to modify in the operation room	
	Radiopaque with no scattering	

CCI, custom cranial implant; PE, porous polyethylene; PEEK, polyetheretherketone; HDPE, high-density polyethylene; PMMA, poly(methyl methacrylate).

A disadvantage is that this material may take up to 3 to 4 weeks from the time of order placement to delivery receipt. Another drawback is, for instances, of persistent temporal hollowing, we must avoid our preferred technique using liquid PMMA and screw fixation in an effort to avoid hybridization of biomaterials.[24] And so

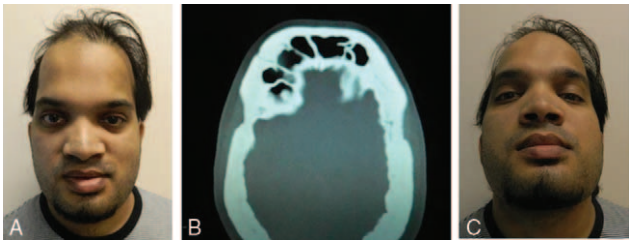

FIGURE 3. Preoperative frontal photograph of young patient with large, bilateral, frontal bone neoplasm (A), axial computed tomography scan image of skull neoplasm (B), and worm's eye photograph demonstrating preoperative bilateral temporal hollowing deformity (C).

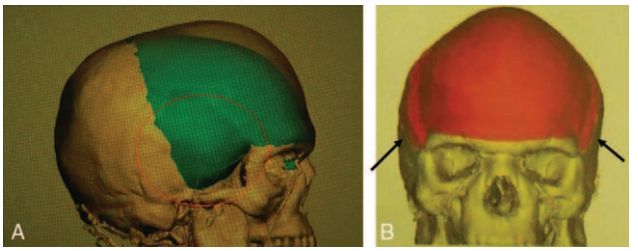

FIGURE 4. Virtual design images of complex single-stage cranioplasty case involving planned resection of bilateral skull neoplasm (A). Design images show bilateral, oversized Medpor PLUS implants and strategic bulking for the correction and prevention of persistent temporal hollowing (B).

for these cases, we use our second-line method employing various stacks of MEDPOR for asymmetry correction, but the solid nature of the MEDPOR limits its effectiveness in filling in small contour irregularities, when compared with liquid PMMA. Furthermore, this material is often times more expensive in comparison with PMMA or PEEK implants, but ultimately this depends on institution-specific pricing arrangements.

In summary, we prefer porous polyethylene implants for all the single-stage cranioplasty cases when we have at least 3 weeks-notice beforehand, due to easy handling and modification characteristics, which makes it ideal for planned skull neoplasm resection/single-stage cranioplasty in the setting of unknown final skull defect dimensions (Figs. 4 and 5).[34]

Polyether Ether Ketone

Polyether ether ketone was first introduced to medicine in the late 1990s following its initial use in the automotive and electrical industries.[35] Polyether ether ketone is an aromatic polymer with ether and ketone chains. As of today, it is a commonly used material for CCI fabrication and offered by numerous companies. Advantages include strength and stiffness, durability over time, and thermal nonconductivity. Of note, an additional benefit is the short turnaround and availability of this biomaterial—which relates to its manufacturing process. As opposed to solid PMMA and MEDPOR cranial implants, "PEEK Priority" (Stryker Craniomaxillofacial, Kalamazoo, MI) implants can be delivered in hand within just 1 week's time versus the normal 3 to 4 week time interval. A potential disadvantage is PEEK's hydrophobic smooth surface, which, in our experience, is potentially the source of increased seroma incidence

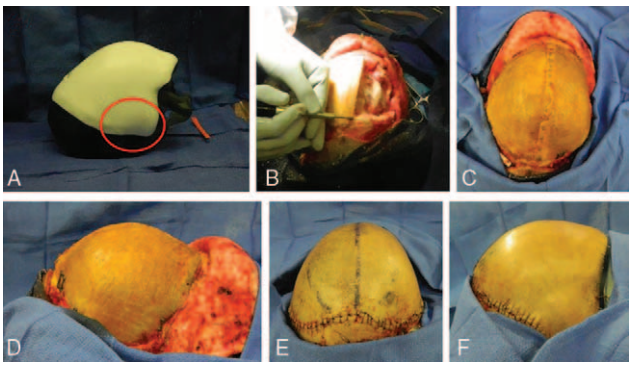

FIGURE 5. Right-side Medpor PLUS implant on host bone model (A), left-side Medpor PLUS implant being modified in situ (B), 2-piece single-stage Medpor cranioplasty completed (C), right-sided lateral view of complicated reconstruction (D), bird's eye view showing on-table symmetry and temporal hollowing correction (E), and right-sided view following scalp closure and effectiveness of strategic temporal bulking (F).

versus our experience with PMMA.[1] Another disadvantage is that it has only been on the market for 2 decades, which accompanies less evidenced-based data for time-tested safety—versus other materials like PMMA, which dates back to the 1960s.[1]

In a series by Rosenthal et al (n = 66), PEEK CCIs had a complication rate of 13%, infection rate of 8%, implant removal rate of 10%, and hematoma/seroma rate of 3%.[1,28] Consequently, with the available literature showing a slightly higher complication profile with PEEK, it is our second choice material behind solid PMMA implants (for delayed cranioplasty cases) and MEDPOR implants (for single-stage cranioplasty cases) with adequate time preparation. However, in instances of short notice (<3 weeks), PEEK implants remain our first-line choice versus using nonanatomical titanium mesh, especially in instances where radiation may be a factor.

Poly-Methyl-Methacrylate

To date, PMMA remains the most commonly used biomaterial worldwide for secondary cranial reconstruction.[35] It has been in use in the medical industry since the 1940s and has the longest evidence-based data for cranial reconstruction dating back over 7 decades.[36] Poly-methyl-methacrylate implants come in 2 forms, liquid and solid. The liquid methyl-methacrylate item is a potential irritant and undergoes an exothermic reaction during the curing process from liquid to solid, which therefore requires irrigation to prevent nearby soft tissue burns. Therefore, we prefer to use solid prefabricated PMMA customized cranial implants for all pre-existing skull defects (with or without nearby soft tissue atrophy), which avoids the curing process altogether.[37,38] However, a distinct advantage of liquid PMMA remains its unique property for artistic placement as a liquid, moldable product which allows us to use it as a cement-like substrate on top of any prefabricated implant. This is particularly useful for filling in irregular contour/soft tissue deficiencies within the pterional region.

For the solid, patient-specific PMMA custom implant, the 3-stage fabrication processes have evolved significantly over the years. Overall, it is well advanced versus the previously stated method of intraoperative hand molding like cement. The first step involves a "computer-designed prefabrication" process in collaboration with the manufacturer's engineering team using virtual software, followed by template-printing and then liquid mold injection.

Poly-methyl-methacrylate, like PEEK, is biocompatible, durable, thermally nonconductive, and does not interfere with postoperative magnetic resonance imaging and/or radiation treatment. When compared with PEEK, PMMA has a more textured surface (both macroscopically and microscopically) which potentially adds to its stability via soft tissue adherence and lowers the incidence of seroma.[1] Poly-methyl-methacrylate, as opposed to other alloplastic material (PEEK, MEDPOR), is radiopaque, but it does not cause imaging artifact and scattering compared with other radiopaque materials like titanium mesh. The disadvantage of solid PMMA implants is their "length of time" for fabrication (from time of order placement), often requiring a minimum of 3 weeks. Of note, we recently conducted a retrospective economic analysis study at our institution and showed that solid PMMA implants, with dual purpose design for temporal hollowing prevention/correction, are less expensive overall when compared with prebent titanium mesh, especially when one factors in the costly consequences of revision surgery related to postoperative, PTH and risk for patient dissatisfaction.[29]

In our experience, solid PMMA CCIs are associated with both a low major and low minor complication rate, 9% and 1% respectively.[1] The most common "major" complication early on was related to visible pterional deformities requiring surgical revision (related to unaddressed temporal hollowing) due to poor patient satisfaction, which was the main impetus behind our team developing and publishing the unique dual-purpose design algorithm in 2015 (exclusively offered by Stryker Craniomaxillofacial).[1,24]

In reviewing 41 articles (over 4000 implants) for the purpose of this manuscript, we found that the average infection rate for all 3, aforementioned materials to range between 2% and 11%.[39] We therefore conclude that the differences among all 3 biomaterials mentioned within are insignificant. Instead, we believe factors such as surgical technique, previous infections, and durable quality of scalp closure are instead much more critical and have a greater impact on infection rates, versus the current understanding. Furthermore, our team believes that the newest generation of solid PMMA CCIs with dual-purpose design—previously referred to as "fourth-generation" custom cranial implants[1]—hold exciting potential, provide optimal aesthetics, and accompany a safe, low complication profile. For this reason, solid PMMA CCIs remain our team's first choice for all planned cases involving secondary cranioplasty reconstruction.

Data Analysis

During the years between 2012 and 2017, a total of 437 cranioplasties were performed. A summary of patient characteristics, neurological pathologies, and biomaterials used for reconstruction is presented in Table 2. Overall, the majority of cases involved tumor resection (47%) followed by trauma and vascular pathologies (23%, 19% respectively). The pterional defect was the most common type of deformity corrected (40%), followed by hemi-craniectomy (32%). Overall, 11% of the cases had a bilateral defect component requiring more than 1 cranioplasty performed in a staged fashion. Furthermore, a relatively large subgroup of cases (29%) had reconstruction at the same time of their tumor craniectomy (ie, single-stage cranioplasty).[34] Biomaterials for cranioplasty implants included PMMA (37%), MEDPOR (17%), and PEEK (10%). Most importantly, our team observed a 3-fold reduction in reported complications as compared with the existing literature, with a major complication rate of 11%. One explanation is that our multidisciplinary center has provided an optimal stage for synergy and improved outcomes versus standard cranioplasty techniques.

DISCUSSION

Since the development of the pericranial-onlay cranioplasty technique, our neuroplastic surgery team has enjoyed great success with minimal complications.[22] Optimal timing for cranioplasty is determined by our group using several critical endpoints such as complete incisional healing of the scalp, minimized edema seen within the brain parenchyma (in the area of the skull defect), and preferably waiting until there is some degree of sunken scalp flap. Other pertinent method details include an accelerated conversion from autologous bone to sterile customized cranial implant in situations greater than 1 month after craniotomy/craniectomy and/or based on bone flap size (less than 120 square centimeters), cranial implant designing via the Pterional PLUS algorithm for correction/prevention of PTH, full optimization of pre-existing medical conditions, and the first-line use of solid PMMA implants for delayed cases, Medpor implants for single-stage, tumor-extirpation cases, and PEEK implants for cases with short notice (<3 weeks).

As such, our team is excited to report a 3-fold reduction in complications as compared with the literature, with a rate of 11% (vs. 30–40%). Furthermore, based on our 437 CCI cranioplasty

TABLE 2. Summary of Patients Demographics, Technique and Type of Implants

		No.	%
No. of patients		376	
Total no. of implants		437	
Average age (Y)		49	
Gender			
	Female	192	51
	Male	184	49
Location of craniotomy			
	Bi-lateral craniotomies	43	11
	Frontal	84	22
	Fronto-temporal	9	3
	Temporal (pterional)	150	40
	Hemi-craniectomy	121	32
	Occipital	12	3
Type of pathology			
	Aneurysm	15	4
	AVM	1	
	Brain abscess	3	1
	CS	5	1
	ICH	14	4
	Ischemic stroke	30	8
	SAH	19	5
	SDH	7	2
	Functional neurosurgery	15	4
	Mucopyocele	2	
	Trauma	87	23
	Tumor resection	178	47
Type of implant			
	Autogenous bone	23	5
	Liquid PMMA	23	5
	MEDPOR	74	17
	PEEK	43	10
	PMMA	163	37
	Titanium mesh	111	26
Time interval			
	Single-stage cases	129	29
	Average time interval for staged approach (months)	7	

AVM, arterio-venous malformation; CS, craniosynostosis; ICH, intracerebral hemorrhage; SAH/SDH, subarachnoid/dura hemorrhage; PE, porous polyethylene; PEEK, polyetheretherketone; HDPE, high-density polyethylene; PMMA, poly(methyl metacrylate).

experience since 2012, the methods described herein—built around a strong collaborative, multidisciplinary approach with neuroplastic surgery—appear to show promising results and above-average outcomes when compared with the state of the art. In addition, it appears that custom implants made of solid PMMA offer the very best outcomes in our hands along with the smallest incidence of complication, based on this retrospective analysis (research protocol approved by the Institutional Review Board at Johns Hopkins University School of Medicine).

However, 1 important, suboptimal feature of these solid PMMA implants is their "opaque" color—versus them instead being "clear." Ideally, one could manufacture these clear PMMA implants with an identical chemical composition and maintain all aforementioned qualities. Obviously, this potential advance is not an option for implants made of either PEEK or Medpor. Thus, having a completely translucent, solid, customized implant made of PMMA appears to be the superior implant from all perspectives, including our experience with several

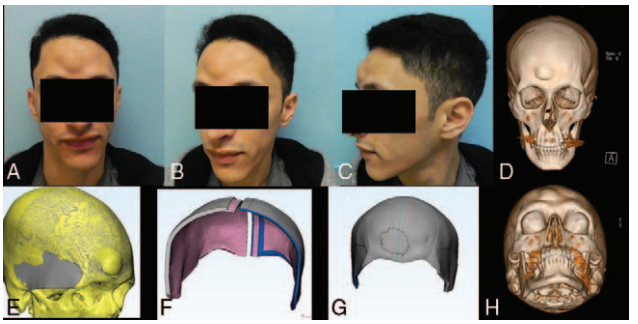

FIGURE 6. Preoperative photographs (A–C), computed tomography scan imaging (D, E), and virtual planning of 2-piece cranial implants for bilateral frontal skull neoplasm resection and single-stage cranioplasty (F–H).

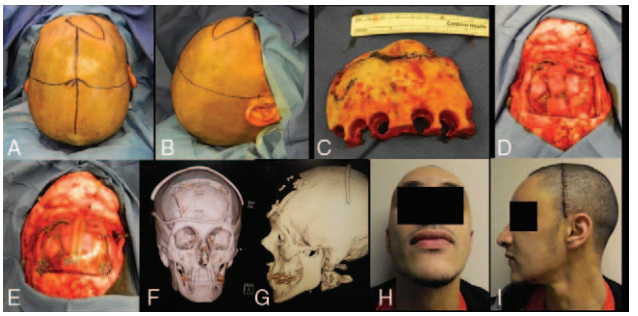

FIGURE 7. Intraoperative (A–E) and postoperative images (F–I) demonstrating single-stage cranioplasty with 2-piece, clear customized cranial implants made of poly-methylmethacrylate. Of note, enhanced visualization of brain and potential bleeding from resection cavity can be appreciated by the translucent implant characteristic (E).

preliminary cases (Figs. 6 and 7). Clear PMMA implants provide unprecedented visualization of underlying brain pulsation, accurate assessment of potential bleeding within brain tumor cavities or sinus structures, and invaluable views of various implantable neurotechnology devices located within or underneath the implant (Fig. 8). An advancement in biomaterial manufacturing, such as this, would allow the neurosurgical community to move forward with novel neurotechnology developments—for instances such as encapsulating neuromodulation devices for epilepsy management, brain tumor medication delivery, shunt hardware for hydrocephalus, and monitoring devices for intracranial pathology underneath.[30] Figure 9 summarizes our

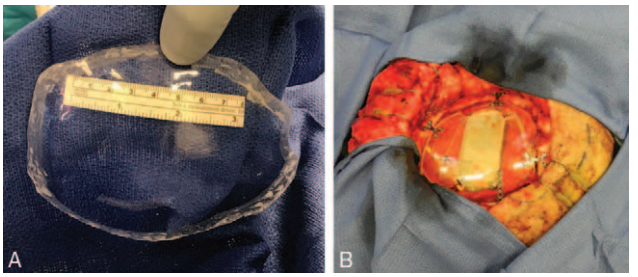

FIGURE 8. Clear poly-methylmethacrylate implant on sterile back table with ruler underneath to demonstrate improved visualization (A). Intraoperative photograph showing encapsulated neuromodulation device and several lead wires underneath the implant (B).

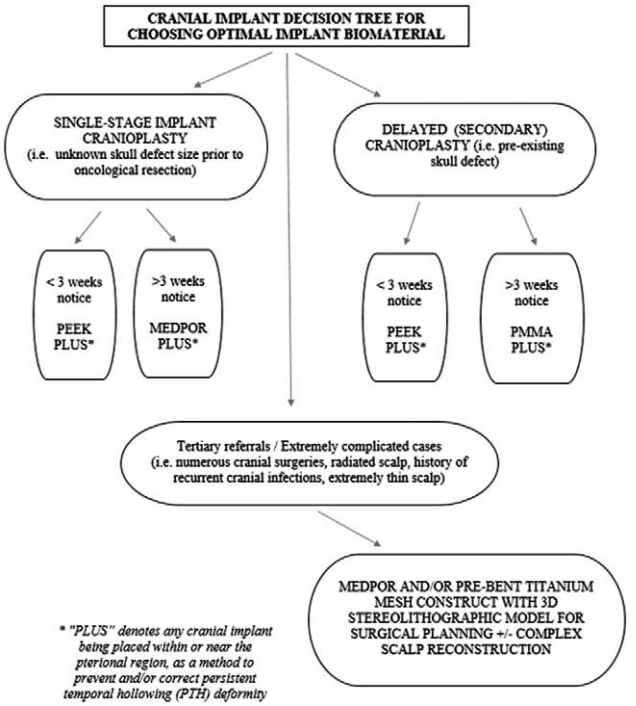

FIGURE 9. Flow chart summarizing our cranial implant algorithm for single-stage cranioplasties, delayed cranioplasties, and extremely complicated cranioplasties. Regardless of biomaterial chosen, a "Pterional PLUS" shape is preferred for correcting or preventing persistent temporal hollowing.

algorithm approach for both single-stage or delayed-style cranioplasty.

CONCLUSION

Secondary cranial reconstruction, or cranioplasty, can be challenging due to various reasons. These best practices—as related to timing, techniques, and preferred biomaterials—are based on our retrospective review of 437 cranioplasties performed over the last 5 years. This 3-fold reduction in complications is a product of our center's dedication to improving outcomes, our neuroplastic surgery expertise, and the intense collaboration with neurosurgery. Clear customized implants, made of PMMA, seam to offer the lowest complication profile and greatest potential for future developments in neurotechnology.

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