Immediate Single-Stage Cranioplasty Following Calvarial Resection for Benign and Malignant Skull Neoplasms Using Customized Craniofacial Implants

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Abstract: Craniectomy defects following resection of calvarial lesions are most often reconstructed using on-table manufacturing. With the advent of computer-aided design/manufacturing and customized craniofacial implants (CCIs), there seems to be more suited alternatives. In this study, the authors report their institutional experience and outcome using immediate, single-stage, CCI-based reconstruction for benign and malignant skull neoplasm defects.

Methods: A retrospective review of a prospectively maintained database of all implant cranioplasties performed between 2011 and 2014, by a single craniofacial surgeon at a tertiary academic medical institution was performed. Preoperative and postoperative computed tomography scans with 3D reconstruction were performed for the purpose of assessing adequate resection and reconstructive outcomes. Primary endpoints included length of surgery, predicted defect versus postoperative implant surface area, contour irregularities, and complications.

Results: Of the 108 patients with cranioplasty identified, 7 patients were found to undergo immediate CCI-based reconstruction for calvarial neoplasms; 4 patients (4/7, 57%) presented with malignant pathology. All defects were $>5\,cm^2$. As compared with their original size, all implants were modified intraoperatively between 0.2% and 40.8%, with a mean of 13.8%. With follow-up ranging between 1 and 16 months, there were no implant-related complications identified. The immediate and long-term aesthetic results, as well as patient satisfaction, were ideal.

Conclusion: With this preliminary experience, the authors have successfully demonstrated that immediate customized implant reconstructive techniques, by way of intraoperative modification, are both safe and feasible for benign and malignant skull neoplasms. The authors believe that with wider acceptance of this multidisciplinary approach and increased surgeon familiarity, this technique will soon become the reconstructive standard of care.

Key Words: Bone neoplasm, calvarial reconstruction, craniofacial surgery, cranioplasty, customized craniofacial implant, polyetheretherketone, polymethylmethacrylate, single stage, skull tumor

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The first attempts at cranial reconstruction date back to the pre-Columbian cultures of the Americas, during which skull defects were reconstructed with gold and silver plates.[1] In modern times, we have developed a variety of materials to reconstruct large cranial defects, including titanium mesh, porous hydroxyapatite (HA), polymethylmethacrylate (PMMA), and polyetheretherketone (PEEK) (Table 1). Some of these materials can be molded and/or shaped in the operating room to approximate concave defects, especially in instances $>5\,cm^2$ in size. Furthermore, computer-aided design (CAD) and computer-aided modeling (CAM) add another dimension to the material chosen for reconstruction—by allowing one to match the contralateral, nonoperated side for ideal contour and appearance.[2] With CAD/CAM fabrication, near-perfectly shaped customized craniofacial implants (CCIs) can be ordered and prefabricated based on fine cut preoperative computed tomography (CT) scans and three-dimensional reconstruction (±stereolithographic [SLG] models). In fact, recent reports suggest that CCIs have the ability to improve cosmesis, decrease operative times, and enhance patient satisfaction.[2,3]

Craniectomies requiring cranioplasty are either decompressive following stroke/trauma, or occur as a result of oncological ablation for masses involving the bony calvarium. In the setting of trauma with cerebral edema, stroke with bleeding, or autologous bone flap infections requiring removal, delayed cranioplasties are necessary at a secondary stage. For tumor ablative surgery, however, in which

TABLE 1. Summary of Materials Available for Single-Stage Cranioplasty Reconstruction

CCI Material	Advantages	Disadvantages	Relative Costs, USD**
Titanium mesh	Cost	Creating dead space	15–24,000
	Malleable	Extrusion	
		More screws needed for fixation	
Solid PEEK	FDA-approved for cranioplasties	Infection risk	15–30,000
	Comes perforated	No use in pediatrics	
Solid PMMA	FDA-approved for cranioplasties	Non-FDA approved	10–25,000
	Textured surface	Infection risk	
	Easy modification with burr	No use in pediatrics	
Porous polyethylene	Vascular ingrowth	Use in pediatrics	15–30,000
Porous hydroxyapatite	Osteoconductive	Brittle	
	Less infections	Contraindicated in nasal/sinus regions	
	Use in pediatrics		

CCI, customized craniofacial implant; FDA, Food and Drug Administration; PEEK, polyetheretherketone; PMMA, polymethylmethacrylate; USD, United States Dollar.

tumors and/or processes involve the bony calvarium, cranioplasties are most often performed primarily using suboptimal hand-molding techniques. At the time of this writing, the standard of care is to reconstruct the cranial defects with on-table manipulation using a varying combination of titanium mesh, liquid PMMA, liquid HA, and/or autologous split-thickness cranial bone grafts.[2,4–6] Of note, the most frequently used material next to titanium mesh is liquid PMMA, which is used alone for small defects and/or in conjunction with titanium mesh for larger defects. It is affordable, time-tested, and easy to use.[4,7]

In the literature, there are only a few case reports in which immediate reconstruction with CCIs were performed for benign skull neoplasms following resection (ie, meningioma, fibrous dysplasia).[1,8–13] All of these studies are favorable and report acceptable outcomes, a trend toward decreased operative times, and less overall surgery, by avoiding revision surgery. In patients with malignant neoplasms involving the bony calvarium, secondary cranioplasty (after surgical margins have been cleared) is advocated.[10] According to our review, however, there is only 1 successful case report of immediate CCI reconstruction following resection of an Ewing sarcoma.[14]

Therefore, our objective is to report a single surgeon's experience with CCIs in 7 consecutive patients that involved single-stage reconstruction for patients with benign and malignant skull neoplasms. By publishing our results, in combination with the previous experiences by Eppley[8] and Castle et al,[14] we aim to provide significant insight and support to the growing body of literature.

METHODS

A retrospective review of a prospectively maintained database of all implant cranioplasties performed between 2011 and 2014, by a single craniofacial surgeon at a tertiary academic medical institution was performed. Approval of the institutional review board was obtained from the Johns Hopkins University School of Medicine before data extraction. Overall, we identified 108 patients with cranioplasty for which 62 patients had undergone CCI reconstruction (62/108, 57%). Of these, 7 (7/62, 11%) were performed as a single-stage cranioplasty following benign/malignant skull neoplasm resection (Fig. 1). Preoperative and postoperative CT scans with 3D reconstruction were obtained for the purpose of assessing adequate resection and cranial reconstructive outcomes. Primary endpoints included length of surgery, predicted defect versus postoperative implant surface area, contour irregularities, and major/minor complications. Major complications were defined as cerebrospinal fluid (CSF) leak, seizures, cerebral infarct, hematoma, infection, and hardware extrusion.

Implant

All patients underwent preoperative fine-cut (2 mm) CT scanning with three-dimensional reconstructions. The predicted skull resection was planned using mock surgery with SLG models to assess nearby critical structures and then discussed with the neurosurgeons involved with each patient. All pertinent information identified during this process was then conveyed to the company providing the implant (PEEK CCIs; Kelyniam, Canton, CT and PMMA/Medpor CCIs; Stryker, Kalamazoo, MI]). In all of the patients (7/7, 100%), the craniofacial surgeon chose to modify the implant's size and shape (PEEK, PMMA, or Medpor) because of intraoperative expectations and/or positioning. This included altering the orbital apex diameter for potential optic nerve edema following sphenoid wing resection (n = 1 patient) and circumferential overestimation (around 1 cm) to accommodate both interim tumor growth and intraoperative contour manipulation with high-speed burr (n = 7 patients) (Fig. 2).

Operative Technique

All patients were consented preoperatively by both the neurosurgical service and the craniofacial plastic surgery team. Depending on the location and/or use of intraoperative neuroguidance (Brainlab AG, Feldkirch, Germany), the patient's head was pinned

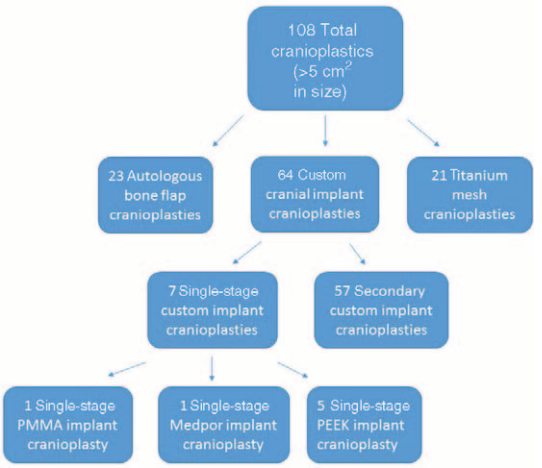

FIGURE 1. Case collection and statistical breakdown of total implant cranioplasty experience at the Johns Hopkins Hospital during this study timeframe. PEEK, polyetheretherketone; PMMA, polymethylmethacrylate.

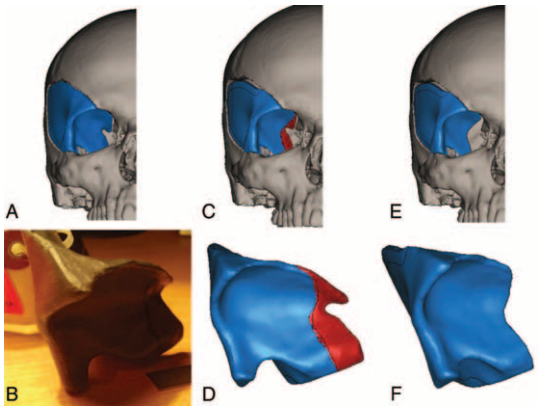

FIGURE 2. Computer-assisted manufacturing of CCI using computer-assisted design (case example 1). CCI, customized craniofacial implant.

within either a Mayfield skull retractor or held within a Mayfield horseshoe. Head shaving and a thorough disinfection of the operative field with Povidone-iodine topical solution scrub and solution were performed. Once draped, the skull was disinfected secondarily with an iodine povacrylex scrub stick. A preoperative dose of antibiotic was administered intravenously before skin incision. Pedicled fasciocutaneous scalp and pericranial flaps were strategically designed and elevated by the senior author (C.R.G.)[3] in an effort to sandwich all implants with healthy, vascularized tissue. Next, the CCI was placed on the skull and used as template to draw out the planned tumor resection. Once the neoplasm was resected with our neurosurgical colleagues in en bloc fashion, the skull edges were defined and inspected for inconsistencies, and frontal sinus communication was carefully assessed for all frontal bone tumors. Dural reconstruction was performed in instances in which primary repair was not feasible.

Resection margins were confirmed in some patients using intraoperative navigation by assessing CT bone characteristics. After oncological ablation was assured, all team members changed gloves, and the customized implant was removed from the sterile packaging. A sterile back table was prepared for intraoperative alteration. Excess implant material was marked and removed using a 5-mm egg burr on 50% intensity (ie, 20,000 rpm) (see Supplemental Digital Content, Video, http://links.lww.com/SCS/A157). In some instances, a host bone model was used for implant orientation. Once ideal shape and position were confirmed, the implant was preplated on the back table using standard titanium plates and 4-mm screws (Stryker). Following implant inset, coverage was augmented by way of a regional pericranial flap. The scalp was closed in a tension-free manner using wide subpericranial dissection, galeal scoring, and 3 layers of sutures (3–0 interrupted galeal polyglyconate, a running deep dermal 3 to 0 polyglactin and interrupted 3 to 0 nylon stitches). Closed suction drains were also placed to avoid unwanted dead space and to minimize fluid accumulation around the implant.[3] In complex instances in which the frontal sinus was invaded by the neoplasm, we meticulously resected all of the mucosa extending down within the outflow tract and obliterated the entire cavity with autologous cancellous bone graft, vascularized pericranium, and fibrin glue. Cranialization with removal of the posterior table was also performed with the drill. In addition, to minimize all risk of contamination, the implant was not opened until the sinus was completely obliterated and the field reprepped with povidone-iodine topical solution.

RESULTS

A total of 7 immediate, single-stage cranioplasties following resection of malignant and benign skull-based neoplasms were performed, using customized implants made of either PEEK, solid PMMA, or Medpor CCIs (n = 7). All of the patient demographics are summarized in Table 2. Neoplasm specifics included 4 patients (4/7, 57%) with malignant pathology and 3 were found to be benign (3/7, 43%). A total of 5 patients (5/7, 71%) underwent reconstruction with implants made of PEEK (Kelyniam, Canton, CT). One patient was reconstructed with a solid PMMA implant (1/7, 14%) and 1 patient with a porous polyethylene (Medpor) implant (1/7, 14%) (Stryker).

All defects were all $>5\,cm^2$ (7/7, 100%), and tumor locations were widespread. These included an anterior sphenoid skull base intraosseous meningioma (1/7, 14%), 2 frontal bone–based intraosseous meningiomas (2/7, 28%), a recurrent epithelioid hemangioendothelioma (1/7, 14%), and a singular metastatic papillary thyroid carcinoma of the right pterion with dural invasion (1/7, 14%). For the 2 remaining patients, 1 underwent a single-stage cranioplasty with Medpor implant for resection of a plasmacytoma located in the diploic space of the left temporal bone, which extended into both the intracranial compartment and the extracranial compartment at the level of the temporal fossa. Unfortunately, the extent of the resection was larger than anticipated (because of unanticipated interim tumor growth), so the implant was covered with low-profile titanium mesh. The final patient underwent resection of a high-grade pleomorphic sarcoma of the anterior scalp overlying the frontal bone with dural invasion. The dura was reconstructed with a tensor fascia lata graft.

The dura was violated in 6 of the 7 patients (86%, patients 1–7). Of these patients, 1 was repaired with simple interrupted 5 to 0 braided nylon stitches and reinforced with fibrin glue (patient 1). Four patients required more extensive repair using a synthetic dural patch (1/6, 17%, patient 6), pedicled pericranial flap (1/6, 17%, patient 5), temporalis fascial graft (2/6, 33%, patients 2 and 3), tensor fascia lata graft (1/6, 17%, patient 7), or vascularized pericranial flap (1/6, 17%, patient 5). In this same patient, the PEEK implant was further covered with a second pericranial flap and an "open-book" temporalis fascia flap. Of the 6 dural violations, 5 were because of tumor extension into the dura, and 1 was because of a difficult dissection plane following previous craniotomy at an outside institution. Two patients (2/7, 28%, patients 5 and 7) required fasciocutaneous rotational scalp flaps based on the superficial temporal artery for closure (Table 3).

Other than the 1 small dural tear, there were no other intraoperative complications identified. On average, total length of surgery was 270 ± 53 minutes for all 7 patients, which includes time spent for scalp dissection, pericranial onlay flap exposure, calvarial tumor extirpation, back-table implant refinement, and single-stage cranioplasty reconstruction with fixation. Overall, the implant was very close to the predicted skull defect following neoplasm resection. Predicted defect versus postoperative implant surface area was 4433 ± 2748 and $3590 \pm 2030\,mm^2$, respectively (Table 4). All patients resulted in acceptable cranial contour and symmetry. No contour irregularities were reported by any of the patients (0/7, 0%). All patients reported high satisfaction following single-stage cranioplasty (7/7, 100%).

All 7 implants (7/7, 100%) required some form of contour modification using a high-speed drill with cutting burr. The additional operative time ranged between 10 and 80 minutes. Neurological exams were intact in all patients in the immediate postoperative period, and recovery was uneventful for all patients (7/7, 100%), with a length of hospital stay ranging from 2 to 8 days (mean of 3.5 days). There were no major postoperative complications, and no implants required removal secondary to infection. The patient who was reconstructed with the PMMA implant following high-grade sarcoma resection presented to her local tertiary hospital at 6 months with local brain recurrence requiring

TABLE 2. Summary of Patient Demographics

	Age, y	Sex	Smoker	DM	Diagnosis	Location	Implant Material
1	70	M	Former	N	Meningioma	Right anterior wing of sphenoid, lateral orbital wall	PEEK
2	75	F	Active	N	Meningioma	Left frontal bone	PEEK
3	66	F	Former	N	Meningioma	Left frontal bone	PEEK
4	36	F	Never	N	Epithelioid hemangioendothelioma	Left frontoparietal bone	PEEK/titanium
5	65	F	Never	N	Metastatic thyroid carcinoma	Right pterion with extension into the dura	PEEK
6	63	M	Never	N	Plasmacytoma	Left squamous temporal bone	Medpor
7	67	F	Never	N	High-grade pleomorphic sarcoma	Anterior scalp and frontal bone	PMMA

DM, diabetes mellitus; PEEK, polyetheretherketone; PMMA, polymethylmethacrylate.

partial frontal lobectomy. During the course of that treatment, the original CCI was replaced with a second one (patient 7). For all of the 7 implants that had to be reshaped, the surface area of the implants was reduced by a range of 0.002% to 40.8% with a mean of 13.8% as compared with their original size. The postoperative measured surface areas were reduced by a range of 3 to 3188 mm^2 with a mean of 842 mm^2.

There was no numeric difference in intraoperative complication rate between the 3 materials. All solid PMMA and PEEK implants required no additional materials. The porous polyethylene (Medpor) implant required a titanium mesh segment to cover the circumferential defect (2–3 mm width) because of unanticipated tumor growth. One patient had parenchymal recurrence of sarcoma requiring partial lobectomy. All patients were satisfied with their aesthetic appearance and symmetry of their cranium. The follow-up period ranged between 1 and 16 months.

For those patients resected and reconstructed by our team, we identified no major complications in our series. We found no incidences of postoperative CSF leak, new onset seizures, cerebral infarct, hematoma, implant infection, and/or hardware extrusion. Patient 7 (frontal bone sarcoma invading dura) was unfortunately found to have local brain recurrence requiring partial frontal lobectomy at 1 year after operation. Because of geographic travel constraints related to adjuvant therapy, she chose to have this second surgery at a local institution closer to her home.

Patient 1

Patient 1 a 71-year-old man with a 5-year history of right-sided proptosis and temporal prominence (Fig. 3A–B). Neuroimaging showed a meningioma of the right greater sphenoid wing (Fig. 3C–D). To identify the ideal approach, we obtained a SLG model and designed the CCI based upon this model surgery. A multidisciplinary team including neurosurgery, neuroophthalmology, and craniofacial plastic surgery were involved in the preoperative planning (Fig. 3E). In the operating room (OR), access was gained via a three-fourth coronal incision. Careful attention was paid to stay along the deep temporal fascia to preserve the frontal branch of the facial nerve. In doing so, we preserved a posterior pericranial flap along the right parietal temporal area, as well as the pericranial flap along the anterior frontal bone. At the temporal crest region, the muscle was dissected and reflected anteriorly. The right sphenoid tumor was identified and removed using a high-speed burr to remove the anterior skull base tumor (Fig. 4A). A large posterior lateral orbit defect, as well as dural defect was covered partly with a left anteriorly based 11×4 cm pericranial flap (Fig. 4B). A right posterior based 9×5 cm pericranial flap from the right parietal region covered the posterior aspect of the dura. Pericranial flaps were then fixed together using a 3 to 0 Maxon (Maxon by Covidien, Dublin, Ireland) suture in an interrupted fashion. This left us with 100% vascularized tissue over the lateral orbit dissection area for excommunication of the orbit and the cranial implant (Fig. 4C). The PEEK implant was inserted into the defect to recreate the resected sphenoid (Fig. 4D). In this patient, the implant was stabilized in a three-dimensional space and was covered with a titanium mesh (Fig. 4E). The anteriorly reflected temporalis muscle was anchored to the titanium mesh (Fig. 4F). This allowed us ideal temporal reconstruction to prevent postoperative temporal hollowing. The scalp was closed in a layered fashion. The patient went on to heal with a favorable aesthetic and functional result. On follow-up, there were no symptoms of enophthalmos, dystopia, or diplopia (Fig. 3F–I).

Patient 2

This is a case of a 74-year-old woman who was diagnosed with a frontal meningioma (Fig. 5A–E). Because of persistent headaches, she was scheduled to undergo resection. Access was gained through a bicoronal incision. The underlying pericranium on the left was attached to the tumor and therefore resected in en bloc fashion (Fig. 6A–B). On the right side, a 26×13 cm pericranial flap was preserved. Both orbital rims and nasofrontal sutures were exposed. The calvarial mass was resected, and it was noted that the resection extended into the frontal sinus, which was then obliterated using cancellous bone graft, a right pedicled pericranial flap, and fibrin

TABLE 3. Summary of Outcomes Following 7 Consecutive Single-Stage Cranioplasties

	Frontal Sinus Obliterated	Dural Tear	Dural Tumor Involvement	Operative Time, min	Scalp Flap	Postoperative Complications	LOS, d
1	No	Yes	No	361	No	None	4
2	Yes	No	Yes	247	No	None	3
3	Yes	No	Yes	296	No	None	2
4	No	No	No	307	No	None	3
5	No	No	Yes	318	Yes	None	2
6	No	No	No	202	No	None	3
7	No	No	Yes	251	Yes	None	8

LOS, length of stay.

TABLE 4. Summary of Custom Implant Surface Area Modification

	Preoperative, mm^2	Postoperative, mm^2	Reduction, mm^2	Reduction, %
1	7271	6041	1230	16.92
2	5368	4462	906	16.88
3	5440	5397	43	0.79
4	1753	1753	3	0.002
5	2589	2066	523	20.20
6	7823	4635	3188	40.75
7	785	781	4	0.51
Average reduction (mm^2, %)			842	13.72
SD (mm^2, %)			1140.89	14.85

glue. A dural defect was patched using right temporal fascial graft (Fig. 6C). The PEEK implant was then burred into the ideal shape and inset. The PEEK implant was secured using multiple plates and 4-mm screws (Fig. 6D). The scalp was closed in a layered fashion. The patient went on to heal without complications and a favorable aesthetic result (Fig. 5F–I).

DISCUSSION

Patient Selection

In our experience, the single-stage cranioplasty approach following skull tumor resection is a safe and practicable approach in the properly selected patient. Well-circumscribed primary bone and dural and/or cerebral lesions involving the calvarium lend themselves particularly well to this approach but is challenged by other authors. For example, Jalbert et al[10] states to always use a 2-step approach in malignant processes. In our opinion, this is undoubtedly a safe statement but we claim that conceptually speaking, there is little morbidity associated with a primary reconstruction even in the rare case that a patient should need further surgery because of positive margins. One could argue that adding a second surgery is counterintuitive in that most patients need some form of adjuvant therapy based on pathological tumor grade and extent. More often than not, patients such as those presented in our series are treated by adjuvant modalities, including chemoradiation therapy. Therefore, being able to perform a single-stage cranioplasty with ideal symmetrical form and appearance, before any radiation treatment, will minimize tissue retraction, wound healing delay, and need for a de novo cranioplasty in a suboptimal, irradiated field. In addition, the risk of using a CCI is comparable to those risks accompanying the standard modalities such as liquid PMMA, liquid HA, and/or titanium mesh. Thus, perhaps the alloplastic material risk associated with a PEEK, PMMA, or porous polyethylene (Medpor) CCI during single-stage approach is equivocal and nonexistent.

In both scenarios, either 2-stage or single-stage, an acute postoperative infection related to the alloplastic material is devastating. In all of the patients, the safest remedy for infection clearance is to remove all foreign material, which could potentially delay radiation treatment and further leave patients with nonreconstructed cranial defects affecting everyday activities. In our institution, however, the

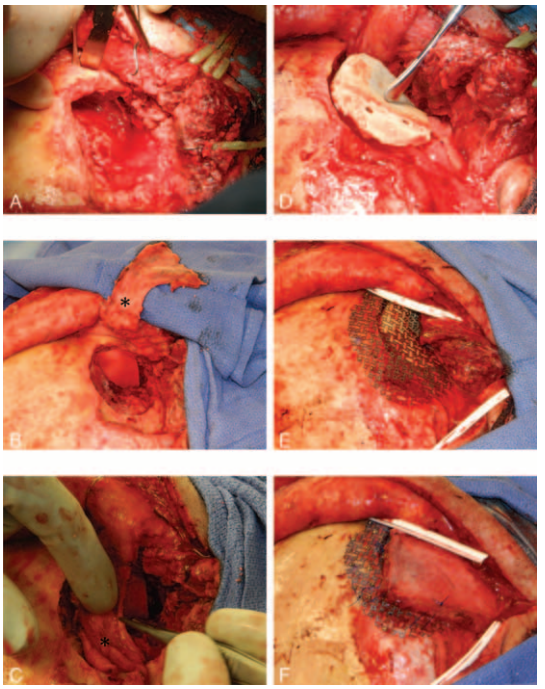

FIGURE 4. Intraoperative photographs from case example 1 including complex defect following resection (A), use of pericranial flaps to obliterate posterior lateral orbit defect (B–C), insertion of customized implant after on-table modification (D), fixation of implant with standard titanium mesh, and resuspension of the temporalis muscle to the titanium plate with permanent sutures (F).

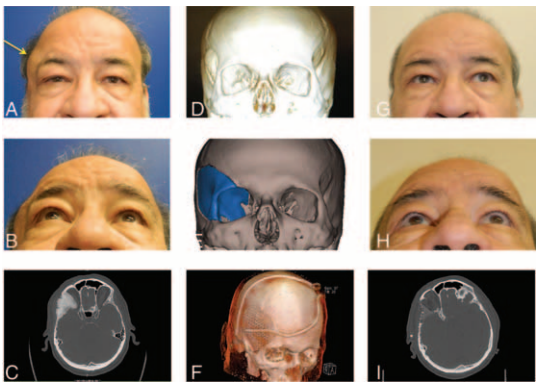

FIGURE 3. Preoperative and postoperative comparative images for case example 1 including preoperative appearance and axial CT findings (A–C), preoperative and postoperative 3-D imaging (D–F), and postoperative appearance and axial CT findings (G–I). CT, computed tomography.

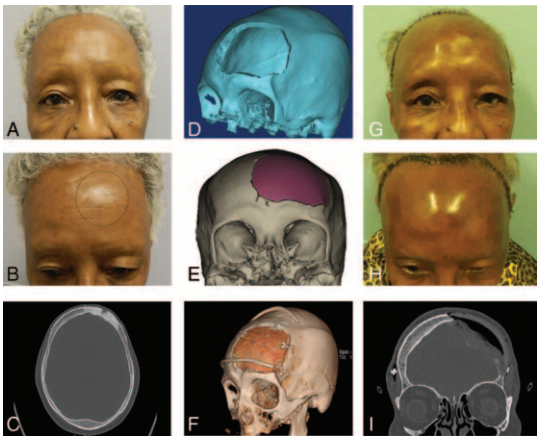

FIGURE 5. Preoperative and postoperative comparative images for case example 2 including preoperative appearance and axial view CT scan findings (A–C), preoperative and postoperative three-dimensional CT scan imaging (D–F), and postoperative appearance and axial CT scan findings (H–J). CT, computed tomography.

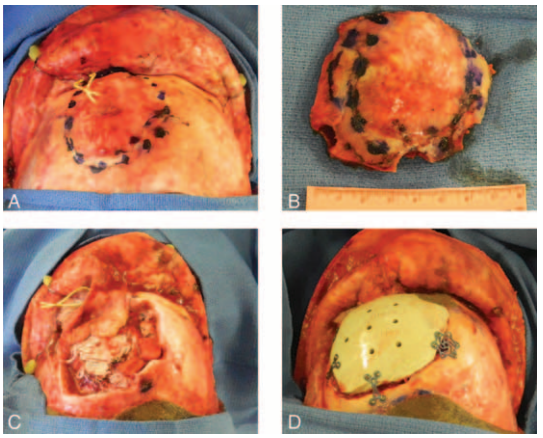

FIGURE 6. Intraoperative photographs from case example 1 including outlined resection margins based on preoperative planning (A), resected specimen containing skull neoplasm (B), defect following resection and frontal sinus outflow tract obliteration with cranialization (C), and custom implant in situ with contralateral pericranial flap within frontal sinus cavity (D).

use of a multidisciplinary approach for single-stage cranioplasty seems to be a viable option leading to improved outcomes and minimal complication. Of note, our technique mandates meticulous aseptic technique, strategic pericranial flap design, and scalp reconstruction by an experienced craniofacial plastic surgeon.

Based on our primary investigator's extensive experience, performing 108 CCI cranioplasties since 2011, the overall risk for implant infection should be equivalent or lower than the overall acute infection rate (<30 days after operation) associated with non-CCI materials, and therefore the use of adjuvant therapies is not being jeopardized. As such, numerous reports confirm that implant infections most often occur in the long-term postoperative period.[4,6] For instance, Lee et al[6] presented their work with 269 patients undergoing non-CCI cranioplasty after resection of cerebral and/or calvarial malignancies (by using a variety of alloplastic materials) and found a <30-day infection rate of 3% and a >30-day infection rate of 4%. So similar to "on-table" molding of alloplastic implant materials, the risk of an immediate CCI cranioplasty should be comparable and safe. The risk of potential delay for radiation and/or chemotherapy treatment, however, following CCI single-stage cranioplasty for malignant neoplasms should be discussed thoroughly during the consent process. We believe additional concern for implant infection should be noted when the frontal sinus is communicating with the neoplasm, and therefore an experienced surgeon is invaluable in this instance. Each patient should be assessed for cranial tumor location and the associated challenges for obtaining an ideal symmetric reconstruction. In our opinion, a calvarial malignancy should not be considered a contraindication to single-stage CCI cranioplasty.

Choice of Material

The choice of implant is dependent on various factors such as availability, surgeon's preference, and patient discussion. Overall, liquid PMMA is the second most commonly used material in cranioplasty behind titanium mesh. In fact, our team has one of the largest experiences with solid, prefabricated PMMA CCIs.[15] CCIs made of solid PMMA are favorable based a long-standing track record dating back to the 1940s. Furthermore, it evokes minimal inflammatory response when placed in the prefabricated, solid form.[4,5] Both PEEK and solid PMMA CCIs are nonthermoconductive and form-stable.[4,5] As compared with PEEK implants, PMMA has a more irregular textured surface, which in our anecdotal experience allows for better tissue adhesion and decreased incidence of seroma.[15] Both materials, however, are considered "smooth" implants. In addition, solid PMMA CCIs seem to be easier to contour on the sterile back table with a contour burr. Although solid PMMA implants have the advantage of being delivered sterile, PEEK implants can be ordered with premade perforations to allow deeper fluid collections to shift planes.

Porous polyethylene has the unique advantage of bearing small holes within thereby allowing advantageous tissue ingrowth, as a method to reduce implant infection. Porous polyethylene has been widely used as implant for facial rejuvenation and reconstruction.[16] Its pore size promotes vascularization of tissue and has some osteoconductive capacity.[4,17] Contrary to HA, it has long-term structural stability and lacks reabsorption. Of note, we used all 3 aforementioned materials in this case series. We did not use any prefabricated porous HA implants, however, because of increased cost.[12] Although HA can be molded into an implant intraoperatively in the liquid form, which has lower material costs, larger defect size and extra time required precludes its use (Table 1). Porous HA is an especially good choice in children in whom growth potential must be taken into consideration, but all 7 patients described here were >18 years old with mature calvariums.[18]

To adhere to the principle of replacing "like with like," it seems intuitive that using an alloplastic implant, with identical shape and size to the normal anatomy being resected (irrespective of PEEK, PMMA, or porous polyethylene components), is advantageous over using a fine titanium mesh with sharp edges in an area planning irradiation. First, the thickness of the titanium mesh (0.1–1 mm) does not replace the full-thickness defect in true anatomical fashion, whereas other alloplastic implants can be ordered to the exact thickness of the defect (4–5 mm). This in turn obliterates significant dead space and thereby eliminates the need to fill underlying gaps with methyl methacrylate or HA. This is particularly beneficial in the setting of irradiation, in which the implant prevents major contraction and therefore yields better cosmetic results with ideal symmetry. In addition, when fixating a titanium mesh, an abundance of expensive, convex screws are needed, which not only adds to the overall cost, but also accompanies an exponential increase in potential wound breakdown sites and extrusion in the "thin scalp." In contrast, CCIs require only a few fixation plates, which in our opinion should be placed far away from any incision, in an effort to decrease risk for wound dehiscence, material extrusion, and/or hardware infection. The use of less extraneous titanium mesh also eliminates artifact and improves the quality of CT and magnetic resonance imaging scans for postoperative monitoring, making CCIs particularly favorable when dealing with malignant neoplasms.[7]

A criticism against the use of CCI is the associated cost compared with on-table construction using titanium mesh ± liquid liquid methyl methacrylate (Table 1). Additional costs for a CCI, however, can partially be offset by decreasing total operative times, providing advantageous full-thickness reconstruction, lending less risk for revision surgery, improving patient satisfaction related to appearance, and potentially lower infection rates. The latter, however, is yet to be proven with high-level investigation. With increasing financial accountability and limitations, we as surgeons must be aware of the financial implications. Instances most convincing to benefit from a CCI include nonhair-bearing regions along the frontoorbital and orbitozygomatic regions; areas of actual or predicted male pattern alopecia; potential areas of thin, irradiated scalps at risk for material extrusion.

In our series, none of the PEEK implants required any additional materials and sufficiently covered the predicted defect. The solid PMMA implant was fixated using a small portion of low titanium mesh. Only the Medpor implant required additional material to fill

in circumferential gaps following a larger-than-predicted tumor. Of note, the PMMA and Medpor cases were performed at the earlier period of this series, and we have since learned how important it is to overestimate the predicted resection area. Furthermore, the time between the "preoperative CT scan and ordering of the implant" and "the actual surgery" should be kept as narrow as possible to account for interim growth of the tumor. A third potential reason could be that the CCI was ordered from a different provider. Working closely with the industry bioengineers will potentially ensure a more consistent outcome.

In our study, we used 3-D CT scans and mock SLG model surgery in advance to delineate the resection margin and proximity to critical structures (ie, orbital apex, frontal sinus). Similarly, there are other authors who describe the use of an SLG model and/or production of cutting guides.[8,11,12] For a more simple approach, we now use the actual implant to mark out the resection lines. This can be confirmed with intraoperative navigation if in question. In instances in which the frontal sinus and/or orbital apex is not involved, we feel that the extra cost and step of producing an SLG model and cutting guides are not warranted.

Limitations

Limitations of the current study are the short follow-up period and the small cohort of patients. As such, we are unable to perform any meaningful statistical analysis. This preliminary experience, however, does provide a "proof of concept" and adds to the current body of literature. In fact, a large randomized prospective study would be ideal, but in this instance, we deem it equally important to continue reporting our outcomes so as to allow for a systematic review on this topic in the future. More importantly, our experience detailed here will be the largest series encompassing single-stage cranioplasty reconstruction following benign and malignant neoplasm resection. Furthermore, the small number of patients with malignant tumors receiving immediate CCI reconstruction can neither support nor reject the conclusion that this approach could potentially delay radiation and/or chemotherapy treatment, and it is therefore up to each surgical team to weigh the accompanying risks and benefits. We do, however, challenge the dogma that a malignant tumor is an absolute contraindication.

Vision

We postulate that with decreasing costs, increased surgeon familiarity, patient preference for an ideal appearance, and a wider acceptance of CAD/CAM techniques moving forward, CCIs will replace "on-table" manufacturing as the standard of care for patients following the resection of calvarial neoplasms, especially in aesthetically sensitive, nonhair-bearing regions.[19] This includes frontoorbital and frontotemporal regions, as well as the parietal cranium, in patients with existing or predicted male pattern alopecia. Therefore, it seems critically important to report our ongoing experience and widen the current indications being considered for CCIs.

CONCLUSION

In this preliminary study, we show that immediate, single-stage implant cranioplasty reconstruction, by way of careful planning and intraoperative modification, is safe and feasible and accompanies minimal morbidity following calvarial neoplasm resection for both benign and malignant pathologies. We believe that with wider acceptance of this multidisciplinary approach and increased surgeon familiarity, this technique for cranioplasty reconstruction will soon become the reconstructive standard of care.

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