Cranioplasty With Customized Craniofacial Implants and Intraoperative Resizing for Single-Stage Reconstruction Following Oncologic Resection of Skull Neoplasms

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Background: Craniectomies requiring skull reconstruction are indicated following oncological resection of masses involving the underlying brain and/or skull. Immediate cranioplasties have previously been performed using suboptimal hand-bending or molding techniques using "off – the – shelf" products. Today with computer – aided design, customized craniofacial implants have become widely available for personalized reconstruction of resected bone and soft tissue. We present here the largest series to date of single stage reconstruction using alloplastic biomaterials in consecutive patient series with oversized customized implants.

Methods: A single-surgeon, retrospective, 8-year study was conducted on all consecutive patients undergoing single stage cranioplasty with prefabricated implants using a myriad of biomaterials. All outcomes were analyzed in detail and compared with previous studies utilizing similar alloplastic implants.

Results: In total, 56 patients underwent resection of skull neoplasms and subsequent cranioplasty reconstruction using customized implants. The most common neoplasms were meningiomas (39%). The most common complications seen among patients were dehiscence – (7%), and extrusion of implant – (3.5%). There was no significant difference in the incidence of postoperative complications between patients who had postoperative chemotherapy/radiotherapy versus those that did not (22.2% versus 13.1%, $P = 0.39$). One-year follow-up revealed acceptable cranial contour and symmetry in all 56 cases.

Conclusions: This is a consecutive case series of prefabricated single-stage cranioplasty, following resection of brain tumors with bone extension or skull bone neoplasm, demonstrating excellent results with regards to safety and patient satisfaction. There are several advantages such as comprehensive resection and reconstruction plan using 3D models, shorter operative time, and better restoration of complex anatomy.

Key Words: Bone neoplasm, cranial, craniofacial, cranioplasty, implant, single stage, skull tumor

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Tumors of the craniofacial skeleton require oncological resection, and therefore make up a portion of one's neurosurgical practice. These lesions may be primary malignant tumors, meta-static tumors or benign lesions. Nearly 250,000 primary brain tumors/skull neoplasms are diagnosed each year resulting in a range of 4500–5000 second stage implant cranioplasties per year.[1] In fact, intracranial meningiomas may show hyperostosis in up to 44% of cases, and radical resection should include aggressive removal of invaded bone resulting in large size skull defects.[2,3] Neurocranial reconstruction in cancer patients can present many reconstructive challenges, such as adjuvant radiation therapy and/or complex surgery such as, limited local soft-tissue coverage and systemic chemotherapy to list a few. In such cases, reconstructive strategies must be threefold; to create an anatomic and functional seal between the intracranial and extracranial contents, to create a watertight dural closure that prevents Cerebrospinal Fluid (CSF) leak and durability to withstand adjuvant therapy, and to restore the protective function of the skull and scalp.

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.[4] In modern times, we have developed a variety of materials to reconstruct large cranial defects, some of these materials can be hand – molded and/or shaped in the operating room to approximate concave defects, but with computer-aided design and computer-aided modeling, (CAD/ CAM) the shape of the customized cranial implants (CCI) can be ordered and prefabricated to exactly match the expected defect with ideal contour and appearance. There are several distinct benefits specific to CCI's including the ability to correct skull and coexisting soft tissue deformities with dual-purpose craniofacial implants, and a newfound ability to integrate functional neurotechnology within the implant.[5,6]

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In fact, CCI's have been shown to improve cosmesis, decrease operative time and enhance patient satisfaction in multiple studies, by achieving ideal contour and restoration of deformed areas with complex anatomy, such as the sphenoorbital and temporal regions.[7,8,9]

Craniectomy of diseased bone followed by neuro-cranial reconstruction presents an opportunity to replace the involved bone with numerous types of biomaterials. The most common of which are titanium mesh, polymethylmethacrylate (PMMA), and polyetheretherketone (PEEK). Of note, the most common "off-the shelf" solution used is titanium mesh implant bent to serve as a "bridge" -simply spanning the skull defect from one side to another to create a nonspecific curvature and protection barrier for the brain.[10] The titanium mesh (which is 1–2 millimeters thick versus the normal skull thickness of 4–5 millimeters) accompanies several drawbacks and limitations including: (1) nonanatomical thickness, and secondary dead space can cause local brain mushrooming through the bone edges and post craniotomy headaches due to dural impingement, (2) a need to overlap neighboring skull areas for bridging and stability which can lead to visible deformities and scalp irregularities within the anterior craniofacial regions, and (3) a high risk of extrusion through the scalp when placed under thin and /or irradiated scalps, due to chronic microinjury from sharp "knife-like" edges within.

The engineered combination of 3D processing steps, together with the operating surgeon preplanning, foster the optimization of complex neurocranial reconstruction. Furthermore, synthetic customized implants offer several advantages including lower complication rates and the ability to correct coexisting soft and hard tissue volume deficiencies. The experience of neuroplastic surgery with intraop hand – trimmed modifications led to the first large series of oncological single-stage cranioplasty with CCI published in 2016 Using CAD/CAM fabrication. Near perfectly shaped custom cranial implants can be ordered and prefabricated with exact patient specific curvatures to an oversized dimension, and then modified around the edges intraoperatively for an exact fit following bone/ brain tumor resection.[11–14]

There are a several case reports in the literature, where immediate reconstruction with CCI's were performed for benign and malignant skull neoplasms following bone tumor resection (i.e., meningioma, fibrous dysplasia, metastasis). All of these studies are favorable and report acceptable outcomes, a trend towards decreased operative times, and less overall surgery by avoiding a need for secondary cranioplasty or revision surgery.[15–19] Our objective is to report a single surgeon's experience with CCIs in 56 consecutive patients that involved single-stage reconstruction for patients with benign and malignant skull neoplasms. By publishing our results, in combination with our previous experiences we aim to provide significant insight and support to the growing body of literature using computer-aided designed implants for single-stage resection and reconstruction of skull invading tumors.

METHODS

An institutional review board-approved retrospective study was conducted, examining all single stage cranioplasties implanted by the senior author (CG) for an 8-year period (2010 to 2018) of neurosurgical patients who underwent skull tumor resection and needed single-staged reconstruction. Variables were abstracted from patient records including demographic data, medical history and surgical history.

To allow for single-stage reconstruction, the surgery was preceded by a virtual planning phase during which preoperative computed tomography (CT) scans were analyzed and a patient-specific implant then fabricated to extend beyond the anticipated skull defect, while maintaining the patient-specific curvature, thickness, and 3-dimensional shape. Radiographic assessments of the area of the neoplasm in contact with bone, and of the associated skull defect size were made by measuring the largest dimensions in the axial and sagittal planes. This protocol ensured that neither the oncologic resection nor defect repair would be limited by a predetermined implant size and this is why prefabricated cutting guides are not recommended based on experience.[20]

The incision is planned to allow adequate exposure needed to perform the operation safely, without concern for suboptimal visualization and to ensure no foreign material (plates, screws, hardware, and implants) lies directly under the scalp incision. Pedicled fascio-cutaneous scalp and pericranial flaps are strategically designed and elevated resecting a layer of pericranium above the diseased bone as an oncological barrier, in en-block fashion. In addition, if there was dural resection due to tumor involvement, dural reconstruction was performed with either autologous rectus fascia, pericranial graft, or synthetic material. Regardless of the material choice, all efforts were made to ensure a watertight dural closure. Also, autologous scalp augmentation, as first described by our neuroplastic surgery group, was employed in areas of abnormally thin scalp tissue secondary to multiple surgery and/or irradi-ation.[21,22]

Subsequent postoperative evaluation was obtained on all patients and reviewed. Major surgical complications defined as any unanticipated events which required additional surgical intervention were identified. In addition, patients in whom recurrences of the primary pathology occurred were noted. Descriptive analyses were performed on all data points and statistical associations tested at level of significance of $P < 0.05$.

Implant Design and Intraop Modifications

As mentioned in the setting of single-stage cranioplasty the algorithm has been modified to add 5 cms of additional material around the borders, to allow for unplanned resection. Of note the preoperative 3D CT scan images are used to virtually plan the surgical corridor with respect to the individual's exact craniofacial convexity and curvature, equating to minimal to no deformity after surgery (see Fig. 1). During surgery the surgeon

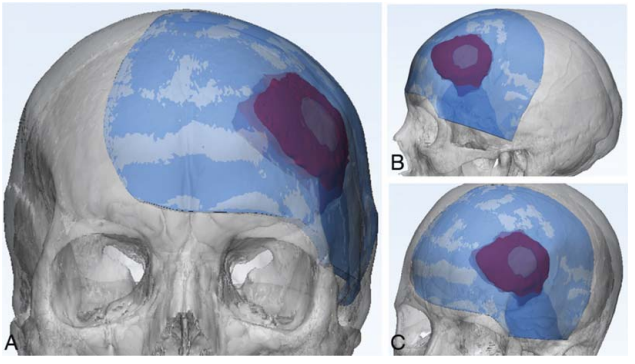

FIGURE 1. A. Coronal. B. Sagittal. C. Oblique, Preoperative 3D segmented design proposal model. Patient's skull (grey), Neoplasm in (purple). The modified implant (blue) adding 5 cm additional material and compensation for any soft tissue loss in the temporal region. This design is made to virtually plan the surgical corridor with respect to the individual's exact craniofacial convexity and curvature, equating to minimal to no deformity after surgery.

can choose to modify the implant size and shape including altering the orbital apex diameter for potential optic nerve swelling following medial sphenoid wing meningiomas or intraoperative contour manipulation of spheno-orbital meningiomas (see Case Example 1). All implants in the present study were patient specific and custom generated by validated software that allowed mirroring of the contralateral fronto-orbital region to correct both the bone and soft tissue abnormalities to overcome temporal hollowing. Materials respective manufacturers included PEEK (Synthes, West Chester, PA, Kallidium, Connecticut), Opaque PMMA/ porous polyethylene (Stryker- Kalamazoo MI,) and Clear PMMA (Longeviti, Hunt Valley, MD). To precisely match the final cranial bone defect, we leveraged the transparent property of the PMMA implant to streamline the modification process, as opposed to the standard, labor-intense process experienced previously with opaque cranial implants. By aligning the implant directly over the cranial bone defect (easily visualized through the implant), one can trace the necessary line of customization with a sterile marking pen directly onto the implant (see Case Example 2 and 3).

RESULTS

In total, 56 patients underwent resection of malignant and benign skull-based neoplasms and subsequent immediate, single-staged cranioplasty using CCI (i.e., PEEK, PMMA, or porous Polyethylene implants) for reconstruction. The average patient age was 53.7 years (range 21–85, SD 16.2). Demographic data for the 56 single-staged cranioplasties are presented in (Supplementary Digital Content, Table 1, http://links.lww.com/SCS/D857). The frequently reported comorbid conditions among patients were hypertension (37%), diabetes mellitus (20%), metastatic cancer (18%), and thyroid disorder (16%). A history of smoking was reported in 7% of patients. Overall, 25.0% of patients received chemotherapy and/ or underwent radiotherapy preoperatively.

Regarding tumor characteristics, majority were benign (71%), followed by malignant (25%), and uncertain (3.5%). Specifically, the most common neoplasms were meningiomas (39%), osteomas (11%), hemangiomas (7%), metastatic thyroid cancer (7%), Langerhans cell histiocytosis (5%), and multiple myeloma/plasmacytoma (5%). Overall, tumors involved the left hemicranium in 43%, right hemicranium in 34%, and were bilateral in 23%. Tumors were mostly frontal (45%), occipital (14%), parietal (14%), and sphenoid wing (11%) in location. These characteristics are summarized in (Supplementary Digital Content, Table 2, http://links.lww.com/SCS/D857).

Review of preoperative CT-imaging scans revealed tumors on average measured 4.51 × 4.64 cm in diameter taken in the axial and sagittal planes and extending on average over an area of 25.94 cm^2. Radiographic evaluation of the portion of scalp overlying the tumor revealed an average thickness of approximately 5.70 mm ([SD = 1.95]; range [2.3 – 11.1mm]). Radiographic assessment of the postoperative CT-scans also revealed the average perimeter of the associated skull defect associated with tumor resection was 7.71 × 7.53 cm in its widest diameter taken in both axial and sagittal planes. Summary of all radiographic measurements are shown in (Supplementary Digital Content, Table 3, http://links.lww.com/SCS/D857)

Intraoperative/Surgery

The CCI materials employed in reconstruction were PEEK (45%) followed by porous polyethylene (25.0%) and Clear PMMA (23%) (Supplementary Digital Content, Table 4, http://links.lww.-com/SCS/D857). Following tumor resection, the area of the skull defect requiring reconstruction was on average 65.52 cm^2 in size. In all cases, the extent of the skull resection was larger than anticipated, therefore all implants were designed with oversized diameter size and in cases where there was still a gap, segments of low-profile titanium mesh were used (Stryker Inc. – Kalamazoo, MI and Synthes – West Chester PA). Dural reconstruction with primary closure was performed in 17.86%, with synthetic dural substitutes in 28.57%, temporal fascia in 8.93%, pericranium in 5.36%, as well as a combination of pericranium plus synthetic substitutes in 1.79%. There was no involvement or breach of the dura in 32.14%. The overall mean duration of surgery from incision to closure of the skin was 277.55 minutes (SD 94.07; range 55–499 minutes) (Supplementary Digital Content, Table 5, http://links.lww.com/SCS/D857). There were no significant differences in mean pre- and post-operative GOS ($P = 0.31$) and MRS ($P = 0.97$) scores, respectively.

Postoperative/Follow-Up

Overall, there were major surgical complications reported in 16% of cases. The common complications seen among patients were scalp dehiscence – (7%), extrusion of implant – (3.6%), pneumocephalus – (3.6%), CSF leak – (1.8%), and surgical site infection – (1.9%). In general, medical complications occurred in 7% of cases (Supplementary Digital Content, Table 6, http://links.lww.com/SCS/D857). Postoperatively, all 56 patients reported high satisfaction following surgery and were followed up in clinic for an average duration of 365 days (range 2 -1640 days). Clinical assessment in follow-up clinic visits revealed acceptable cranial contour and symmetry in all 56 cases, and preoperative exophthalmos was corrected in all sphenoorbital meningioma patients (8 cases). In all patients, postoperative evaluation revealed adequate cranial reconstruction for anatomically complex areas, with good functional globe position, satisfactory extraocular muscle function, and excellent postoperative cosmetic appearance. There were no contour irregularities reported in the postoperative period. Mortality occurred in 1 patient during the follow-up period from cause unrelated to the tumor and/or surgery. In total, tumor recurrence occurred among 5 patients (8.9%), and was significantly less likely among patients with benign tumors (2.5%) versus malignant (21.4%) or uncertain (50.0%), ($P < 0.001$). The occurrence of postoperative complications did not demonstrate significant association with character of the tumor ($P = 0.30$) (See Fig. 2). Postoperatively, 32.1% of patients underwent chemotherapy and/or radiotherapy treatment. There was no significant difference in the incidence of postoperative

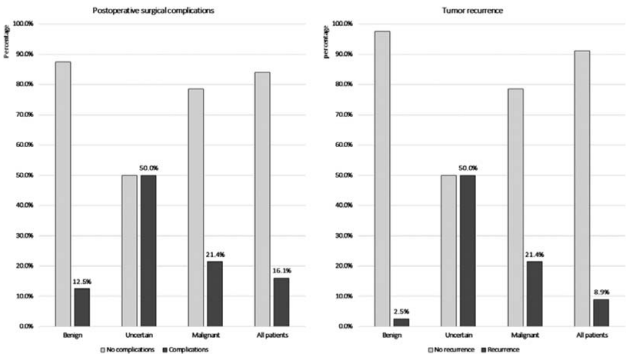

FIGURE 2. Postoperative complications and tumor recurrence after skull tumor resection.

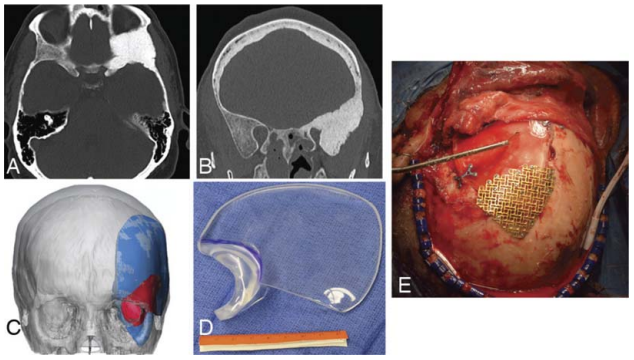

FIGURE 3. Case Example 1. A. Axial, and B. Coronal CT bone window demonstrating hyperostotic sphenoid wing meningioma compressing the lateral orbit and narrowing the left optic canal. C. 3D rendering design proposal of left spheno-orbital implant (blue), and the meningioma component (red) to help plan the approach and reconstruction. D. Implant made of clear PMMA including lateral orbital wall. E. Status post removal of left side of involved bone and reconstruction using clear alloplastic implant, fixated with a piece of titanium mesh. CT, computed tomography; PMMA, polymethylmethacrylate.

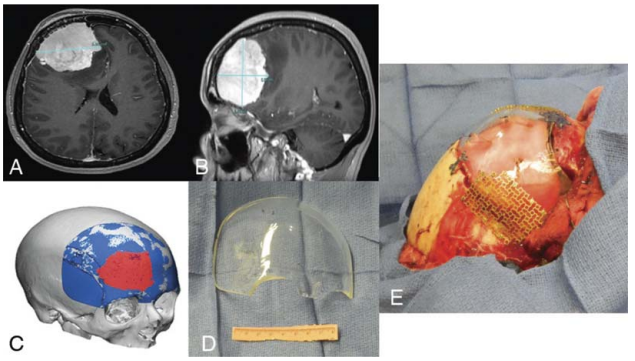

FIGURE 4. Case Example 2. A. Axial and B. Sagittal T1 contrast enhanced MRI, demonstrating a right Extra-Axial frontal convexity meningioma with right frontal bone and soft tissue involvement. C. 3D design proposal of alloplastic implant (blue) and meningioma (red) to help plan the surgical corridor. D. Clear implant made of PMMA including the bilateral orbital rims, modified to add 5 cm of additional material around the borders to allow for unplanned resection. E. intra-op Implant fixation following complete removal of meningioma and involved bone. MRI, magnetic resonance imaging; PMMA, polymethylmethacrylate.

complications between patients who had postoperative chemotherapy/radiotherapy versus those that did not (22. 2% versus 13.1%, $P = 0.39$).

Case Example 1 (See Fig. 3)

Involves a 67-year-old female, evaluated for progressive vision loss on her left eye and over a year of intermittent eye pain. Neuroimaging showed a left sphenoid wing hyperostotic meningioma narrowing the orbital apex and superior orbital fissure. In order to identify the ideal approach, a 3D digital model was obtained painting the tumor in red and resection margins with expected skull defect. A multidisciplinary team including neurosurgery, neuro-ophthalmology and Neuroplastic surgery were involved in the preoperative planning. In the OR, access was gained via a modified orbitozygomatic craniotomy. Following successful tumor removal and orbit decompression using combination of high-speed drills and neuronavigation, careful attention was paid to reconstruct the involved dura. Then a large craniofacial implant made of clear PMMA was inserted into the defect to recreate the resected sphenoid. the implant was stabilized in a three-dimensional space and was fixated using a small segment of titanium mesh. The anteriorly reflected temporalis muscle was anchored to the titanium mesh. This allowed us ideal temporal reconstruction to prevent postoperative temporal hollowing and left us with 100% vascularized tissue over the lateral orbit for excommunication of the orbit and the cranial implant. 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.

Case Example 2 (see Fig. 4)

This is a case of a 49-year-old woman who was diagnosed with a right frontal convexity meningioma with hyperostotic frontal bone involvement. Due to persistent headaches and a new onset seizure, she was elected to undergo resection. Access was gained through a bicoronal incision. The underlying pericranium on the right was invaded by the tumor and therefore resected in en-bloc fashion. On the left side, a 25 cm × 10 cm pericranial flap was preserved for dural reconstruction. Both orbital rims and naso-frontal sutures were exposed. The craniectomy was performed using neuronavigation to avoid frontal sinus breach and the meningioma resected. A gross total resection was achieved and the brain was quite relaxed at the conclusion of the operation. Using the Neuronavigation the bone mass was noticed to be larger than originally expected and the bone was further resected. Once it was done, there was a large skull defect in the right frontotemporoparietal region. A dural defect was patched using the left pericranial flap. Then an oversized clear PMMA implant was modified to fit in a key and locked fashion. The clear PMMA implant was secured using multiple plates and 4 mm screws. The scalp was closed in a layered fashion. The patient went on to heal without complications and with a favorable aesthetic result.

Case Example 3 (See Fig. 5)

This case involves a 73-year-old female with a known left frontal convexity meningioma that doubled in size over 1 year follow up and was associated with new onset headaches, memory decline and anomic aphasia. The patient elected to undergo resection with single stage reconstruction of her involved hyperostotic bone with customized cranial implant. A left fasciocutaneous scalp flap based on the left superficial temporal artery was created and elevated, leaving behind a vascularized pericranium graft for subsequent dural reconstruction. Using neuronavigation the boundaries of the extra-axial tumor as well as the areas of hyperostosis and dural enhancement was marked. In addition the boundaries of the frontal sinus were marked. Left craniectomy was performed, and gross total resection of the meningioma achieved. Next the harvested pericranial graft was then mobilized and sutured in place with running and interrupted 4–0 Nurolon's into the dural defect. Next the 8 × 9 cm fronto-temporal cranial defect was addressed using the prefabricated clear PMMA implant. With a sterile marking pen, the single stage defect was outlined directly over the craniectomy and then the oversized customized implant was modified on the back table using hand contour burr in order to allow single stage reconstruction to proceed. After hand-held and eye coordination, the modified clear customized implant fit very well within the defect, and then fixated with low-profile plates and screws and a thin piece of titanium mesh.

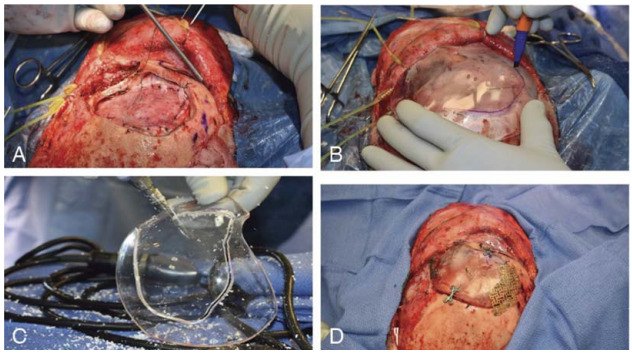

FIGURE 5. Case Example 3. **A.** Craniectomy defect following resection of convexity meningioma with skull expansion and dural reconstruction using pericranium. **B.** The single stage defect is outlined with blue pen directly over the craniectomy and then the oversized customized implant is modified on the back table using hand contour burr **C.** in order to allow single stage reconstruction to proceed **D**.

DISCUSSION

To best of our knowledge, this is the largest patient series to date, to examine outcomes after single stage cranioplasty specifically of neurocranial reconstruction following tumor resection with oversized custom implant. Single stage resection uses CCI as opposed to off the shelf methods such as titanium mesh, is a new facet of adult craniofacial surgery. Cancer patients undergoing single stage reconstruction differ from patients with defects attributable to other causes in that many cancer patients require adjuvant therapy, and often have concurrent soft-tissue defects which can complicate reconstruction.[23] When looking specifically at oncologic craniofacial reconstruction, both Hussein et al and Moreira-Gonzalez et al found that cancer patients had a higher rate of complications than patients requiring adult craniofacial reconstruction for other indications (38 percent versus 15 percent, and 31.3 percent versus 23.6 percent, respectively). As such the field of craniofacial surgery, which is primarily focused on pediatric patients is limited when applied to this complex subset of patients.[24,25]

In our experience, the single stage cranioplasty approach following skull tumor resection is a safe and practicable approach in the properly selected patient and requires only a small aspect of an artistic eye which is consisted with neuroplastic surgery. Primary skull tumors, intraosseous and hyperostotic meningiomas and metastatic disease involving the calvarium lend themselves particularly well to this approach. Patients such as those presented in our series are treated by adjuvant modalities, including radiation and chemotherapy. Therefore, being able to perform a single-stage cranioplasty with ideal form and appearance prior to any radiation treatment, will minimize tissue retraction, wound healing delay, and need for a de novo cranioplasty in a suboptimal, irradiated field. We have found that customized cranial implants are not only effective in restoring cranial bone defects, but also at preventing radiation induced soft tissue contraction leading to temporal hollowing deformities. These solid, nonmesh implants have the advantage of being preoperatively tailored to the exact size of the cranial and soft tissue defect, thus allowing a shorter operating time, improved postoperative stability, and incomparable cosmetic results.[26–28]

Single stage reconstruction plays a unique reconstructive challenge in cases of hyperostotic bone reaction in the sphenoorbital region. Often performed primarily, the standard of care is to reconstruct the spheno-orbital defects with sub-optimal ontable manipulation using a varying combination of titanium mesh, liquid PMMA and pourus polyethylene pterional implants, without addressing soft tissue and/or complex 3D bony anatomy. The new three-dimensional implant design algorithm, allows for 2 virtual models to be fabricated and fused into 1 alloplastic implant. The inner model replaces the missing cranial bone, while the outer model provides an equal three-dimensional volume restoration for any missing soft tissue based on the patient's unaffected contralateral anatomy.[5]

Supporting our findings, Gerbino et al in their series used 3D printed PEEK implants with great aesthetic results and argue against the use of autogenous tissue for primary reconstruction because of the donor site morbidity and the increased difficulty and time required.[29] Chambless et al described 12 patients with sphenoorbital meningiomas resected and primarily reconstructed with customized 1 mm porous polyethylene sheets with only 1 patient suffered surgical site infection.[30] In our opinion, this is undoubtedly a better reconstruction strategy than using "off the shelf" solutions, but we claim-that the designed implant should address temporal deformity associated with such craniotomies, therefore reducing the need for additional surgery to correct any temporal Hollowing, as patented by the senior author.[5] We believe additional concern for implant infection should be noted when the frontal sinus is communicating with the neoplasm. Sullivan et al reported that any sinus exposure to the defect site likely will result in eventual implant infection.[31] Therefore, we advocate inspection and cranialization of the frontal sinus when the sinus is breached or invaded by the tumor.[32] "Off-the-shelf" solution, such as liquid PMMA, liquid HA and bone cement replacement is effective in many cases, but in our experience, is suboptimal with respect to radiation therapy patients, and those affected by anterior or temporal contour irregularities.

An acute postoperative infection related to the alloplastic material is devastating and could potentially delay radiation treatment and further leave patients with nonreconstructed cranial defects affecting everyday activities. In our institution, however, the use of a multidisciplinary approach for single stage cranioplasty seems to be a viable option leading to improved outcomes and minimal complication and adds only a small amount of time to the case. Of note, our protocol mandates meticulous aseptic technique, pericranial onlay flap creation, and scalp closure by an experienced neuroplastic surgeon, when using titanium mesh and/or alloplastic implants.[21,33]

Based on our P.I.'s extensive experience, the overall risk for implant infection should be *equivalent or lower* than the overall acute infection rate (< 30 days post-op) associated with non-CCI materials and therefore the utilization of adjuvant therapies is not being jeopardized. As such, numerous reports confirm that implant infections most often occur in the long-term postoperative period.[34] For instance, Lee and colleagues 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 dehiscence 2%. a > 30-day infection rate of 4% and dehiscence 3%. So similar to "on table" molding of alloplastic implant materials, the risk of an immediate CCI cranioplasty should be comparable and safe.[35]

In summary, we present here our data on surgical approaches and state-of-the-art materials to re-enforce the importance of cranioplasty reconstruction management plan, from peri- to post-procedural care, discuss recent advances in neurocranial reconstruction, and review how one may incorporate them into their practice.

When it comes to the extradural anatomy, following skull/brain tumor resection, it is inevitable to correct any expected postneurosurgical skull and scalp defects using a collaborative effort to improve all aspects of neuro-cranial reconstruction. The overarching neuroplastic surgery principles for single stage cranioplasty include: (1) returning vital protection to the brain, (2) restoring symmetrical contour and appearance consistent with that preresection (aiming to prevent all forms of hard tissue asymmetry and soft tissue temporal hollowing), and (3) Creating a durable and longstanding reconstruction solution for cancer patients undergoing adjuvant chemo-radiation treatments. The reconstructive approach for this complex subset of patients should combine the skill and precision of both neurosurgery and neuroplastic surgery, in order to safely navigate the delicate intra and extracranial structures. It is our goal to ensure tumor patients have complete preservations of not only their neurological status, but also restoration of their preoperative appearance. As we continue to develop strategies for precision and personalized medicine for tumor patients, we believe that using state of the art 3D technology, together with a multidisciplinary reconstruction plan, should be widely adopted, to precisely restore the involved bony and soft tissue defects, following oncological resection.

Choice of Material

Computer-designed alloplastic implants have revolutionized the conceptualization and approach to complex cranioplasty and have become a reliable alternative. These implants have the advantage of being preoperatively tailored to the exact size of the cranial defect, thus allowing a shorter operating time improved postoperative stability, and incomparable cosmetic results. Due to its transparency, single stage intra-op modification of a CCI with oversized diameter is most effortless when one can see the excited defect underneath (See case example 3). Furthermore, as mentioned above, the prefabricated implant can be designed to overcome anticipated soft tissue loss and to prevent the need for additional surgery.[5] Furthermore, the 3D printed customized cranial implants can assist physicians with preoperative planning and surgical practice in complex anatomical area such as the pterion and spheno-orbital tumors where cranial and orbital contouring represents a challenge and are difficult to re-create precisely, without a patient specific CAD/CAM design.

The choice of implant is dependent on various factors such as cost, availability, surgeon preference and patient discussion. Our team has one of largest experiences with solid, prefabricated PMMA CCIs. PMMA's main benefits stem from its low cost, long-standing track record dating back to the 1940s, and bio-mechanical properties featuring greater compressive and torsional strength than bone. Furthermore, it evokes minimal inflammatory response when placed in the pre-fabricated, solid form.[21] 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, due to unpreventable scalp contracture as a result of radiation and microinjury the deep scalp surface. First, the thickness of the titanium mesh (0.6–2 mm) does not replace the full thickness of the skull, therefore creating a dead space and potential soft tissue contraction following radiation to the reconstructed area. In contrast, CCIs require only a few fixations 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.

Additionally, single-stage cranioplasty presents a newfound opportunity for neurosurgeons to create a synthetic acoustic window by replacing normal bone with a, clear-colored polymethyl methacrylate (PMMA) implant composed of a material providing minimal to no obstruction of ultrasonic waves which presents an additional diagnostic application following brain tumor removal such as detecting brain tumor recurrence, monitoring cerebral blood flow and measuring ventricular size for hydrocephalus.[36,37] Based on preliminary investigation, Trans-cranioplasty ultrasound has been successfully performed (after scalp closure) for real-time assessment of epidural bleeding, midline shift, ventriculomegaly, and cerebral bypass graft monitoring.[38,39]

A criticism against the use of CCI is the associated cost compared to on table construction using titanium mesh ± liquid methyl methacrylate. However, pre-bent titanium mesh (i.e., 200 × 200) used for fronto-parietal regions is often equally expensive to a pre-fabricated CCI. Any additional costs for a CCI can partially be offset by decreasing total operative times, providing advantageous full-thickness reconstruction, lending less risk for revision surgery, and potentially lower infection rates as already proved by large systemic reviews.[40,41] 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.

Limitations

Limitations of the current study are the retrospective data collection in only 56 patients; however, it serves as proof of a concept and adds to the current body of literature. It will likely be impossible to perform a large enough randomized prospective study but we deem it important to continue reporting the outcomes to eventually allow for a systematic review on the topic. Our experience to the best of our knowledge will be the largest series encompassing single stage cranioplasty reconstruction with customized implants following benign and malignant neoplasm excisions. We postulate that with decreasing costs, increased surgeon familiarity, patient preference, and a wider acceptance of CAD/ CAM techniques, CCIs will be more commonly used for patients following resection of bony masses – especially in complex anatomy includes spheno-orbital and fronto-temporal regions. Postoperative complications including CSF fistulas, meningitis, and wound infections can be prevented by well-designed and well-placed neuro-cranial reconstructive techniques.[21]

CONCLUSIONS

There are several advantages of the present technique (1) the preoperative 3D digital model allows the surgeon to plan the resection and neuro-reconstruction before surgery; (2) single-stage resection and reconstruction shortens operative time, decreases morbidity associated with adjuvant therapy; and (3) the implant accurately restores the complex 3D structure of the resected bone and soft tissue. In this study, we were able to show that immediate implant cranioplasty techniques, by way of careful planning and intraoperative modification, is safe and feasible with minimal morbidity in the setting of craniofacial resection for benign/malignant skull neoplasms. We have also found that customized cranial implants are not only effective in restoring cranial bone defects, but also at preventing and/or correcting persistent temporal hollowing deformities.[5] We believe that all neurosurgical patients deserve to have their original appearance post-neurosurgery and should have a discussion with both the neurosurgeon and the neuroplastic surgeon at time of surgery.[33]

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