Discussion on: Usefulness of an Osteotomy Template for Skull Tumorectomy and Simultaneous Skull Reconstruction

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This is an invited discussion of an article by Oji et al,[1] entitled "Usefulness of an Osteotomy Template for Skull Tumourectomy and Simultaneous Skull Reconstruction", that is published in the journal. In summary, their consecutive case series of 3 patients receiving "custom implant cranioplasty" following standard benign skull neoplasm tumor resection describes a retrospective analysis of *nonrandomized, noncontrolled* outcomes for patients receiving single-stage reconstruction with prefabricated, patient-specific implants and cutting guide templates. Their study concluded that this method of using prefabricated, surgical cutting guides made of hydroxyapatite could improve ultimate positioning and final placement of custom cranial implants with *minimized trimming of implant* and left behind only minute gaps between implant and native skull. However, the authors do make a note that this cohort included only those patients with benign pathology. While the clinical outcomes of this study are excellent, the study is neither controlled nor randomized, offering little evidence that their conclusions are justified. Similarly, our group has several concerns related to their method and principles related to standard oncological practice.

Currently, there are around 160,000 craniotomies being performed annually in our country.[2] Of them, a significant portion of these cases are related to addressing metastatic brain and/or skull disease. With the advent of personalized therapies, targeted therapies, and immunotherapies, patients are now living longer and one's postoperative appearance (ie, cosmesis) is an important outcome to consider in treatment planning. Unfortunately, the fixed space within the cranium limits the safe boundaries of growing tumors invading one's inner cranium. In fact, our team has had some experience treating patients like these—both with benign and malignant skull tumors.[3] In contrast, we often use either *oversized* customized implants for single-stage reconstruction made of polyethyl-ethyl-ketone or porous polyethylene rather than hydroxyapatite, but we do not see any reason to believe one material is significantly better than the other. Our choice of biomaterial is often dictated by the timeline of fabrication for several companies, which in some cases, is material-specific and can range from 2 days to 3 weeks.

Similarly, the authors mention that for malignant tumors, they prefer to use "off-the-shelf" materials, such as titanium mesh, for single-stage cranioplasty reconstruction following neoplasm resection. Interestingly, in some isolated cases, some surgeons have used a 2-stage approach by first performing malignant tumor resection, and then at a later date, used customized cranial implants in hopes of achieving an ideal, symmetrical reconstruction.[4] Although the second option provides an improved form of patient-specific reconstruction, the need for a second surgery and additional hospital admission severely detracts from its overall benefits. However, we applaud this small group of surgeons in Japan for their attempts to push the boundary with customized implants and agree wholeheartedly with the final outcomes surrounding prefabricated, patient-specific implants—in instances of large skull defect reconstruction, especially in areas of non-hair bearing regions (ie, forehead, temporal). Furthermore, we agree that patient-specific implants provide both an option for improved aesthetics, and at the same time, a more durable option in instances of planned irradiation and scalp thinning.

Of note, however, our team has a slightly different technique when it comes to combining tumor resection and custom implant cranioplasty reconstruction.[3] We design in advance an *oversized*, patient-specific, customized craniofacial implant (CCI) based on virtual surgery and CAD/CAM design, and add several centimeters along the perceived perimeter, so as to assure the surgeon of excess material needed for any additional resection. Specifically, this is different as to what is being described here by Oji et al, since their CCIs are designed to an identical shape and size matching their predesigned, surgical cutting guides for resection. For our craniofacial tumor resections, virtual planning is coordinated by both the craniofacial plastic surgeon and neurosurgeon, so that both are aware of each other's thoughts in instances of frontal sinus invasion, orbital apex relation, designing local scalp flaps, etc. We believe the most critical principle of neuro-oncology surgery *must* stay true in line and remain a team priority over our parallel mission to improve aesthetic results (via prefabricated custom implants), and as such, we avoid adjusting our mindset during tumor extirpation and remain unhindered by the preoperative imaging and/or prefabricated cutting guides in hopes of eradicating all visible disease. We consider the oncological portion of the skull tumor resection to only be complete *if and when all* "abnormal-appearing pericranium, bone, dura, and regional tissues" are fully resected, thereby minimizing all chances of local tumor recurrence (Fig. 1).

From a craniofacial perspective, the goal of cranioplasty reconstruction with custom implants is not only to provide strong and durable neurologic protection, but also to restore our patients to their "preoperative appearance".[3–7] However, this should *not* come at the cost of possibly leaving behind tumor-ridden tissue (ie,

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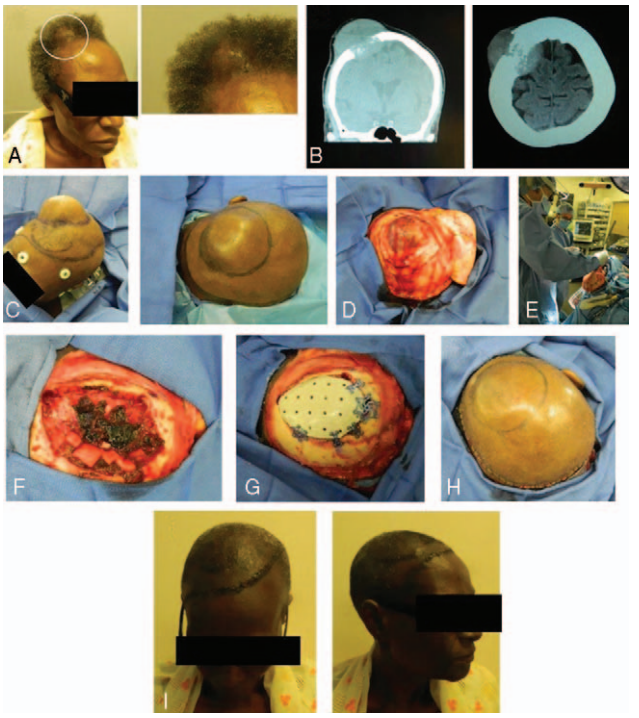

FIGURE 1. Preoperative photograph of a patient presenting with a large symptomatic skull neoplasm (A); preoperative computed tomography scan images demonstrating an acquired, full-thickness skull deformity related to metastatic disease secondary to Stage IV breast carcinoma (B); intraoperative photograph of large-sized skull neoplasm (C) and strategic fasciocutaneous scalp flap design based on right superficial temporary artery system (D); use of intraoperative imaging to identify and confirm safe margins with normal-appearing bone following tumor resection via "inside-out type" style extirpation, in an attempt to minimize any risk of recurrence (E); photograph of large-sized skull defect following resection (F) and placement of hand-modified, oversized, patient-specific, prefabricated, customized cranial implant (CCI) into ideal position using real-time size-adjustment by way of a handheld burr (G); intraoperative photograph of cranium demonstrating ideal symmetry following scalp flap inset (H), postoperative photograph of satisfied patient with no concerns for titanium mesh extrusion following local irradiation and optimized cosmesis (I).

cranial bone) in hopes of making our prefabricated custom implant fit properly. Instead, we have decided to engage our university engineers to codevelop computer-assisted and robot-assisted technologies to possibly overcome these modern-day hurdles. As such, we are not quite sure this approach by Oji et al[1], in relation to achieving ideal skull tumor resection by way of predesigned, cutting guides, is ideal. For example, their group reports that ''perioperative trimming of the implant or bone defect was not required in any case, and good cosmetic outcomes were obtained in all cases, without any complications.'' With 2 cases involving fibrous dysplasia and 1 meningioma, it will take significant time to see if and when local recurrence presents itself. Furthermore, there are no descriptions of the actual tumor regions in their article indicating significant concern for postoperative deformity/asymmetry and the need to use custom implants (vs titanium mesh). Equally concerning is that their patient cohort involved just 3 patients with an unknown duration of follow-up.

For those who perform this type of surgery commonly, it is well known that hair-bearing regions in the posterior region following skull tumor resection would most likely do equally well with simpler and less costly materials such as ''off-the-shelf'' titanium mesh. However, in instances of planned irradiation and/or thin scalp coverage placing them at higher risk for extrusion, the scenario is much different and in most instances warrants the more intricate and costly process of custom-made implants. As such, limiting the study in discussion to 3 patients, with short follow-up, seems suboptimal for any study evaluating a new technique. Therefore, we are not sure how one can interpret the results provided in this encouraging article.

Our team's approach is quite similar in that we prefer customized implants; however, our approach for tumor resection is different. The skull tumor is addressed by way of time-tested oncological resection with all abnormal tissue being removed, regardless of any limits displayed on preoperative imaging. We do *not* use prefabricated cutting guides in anyway when it comes to the tumor resection, regardless of whether it is benign or malignant. In addition, we use intraoperative navigation (ie, Brainlab, Munich, Germany) to help inspect the bone integrity in real-time on intraoperative visual monitors. Furthermore, if the dura has been invaded and/or surrounding scalp, then this is resected as well. Only then do we continue with patient-specific, custom cranial implant reconstruction. This unfortunately entails a craniofacial plastic surgeon spending significant time to modify the oversized implant by hand and eye guidance. The obvious downside to this, however, is that there is significant time added to the operation to allow for artistic, hand-shaving of the oversized implants (range of 10 to 80 minutes depending on size and location of skull tumor).[3]

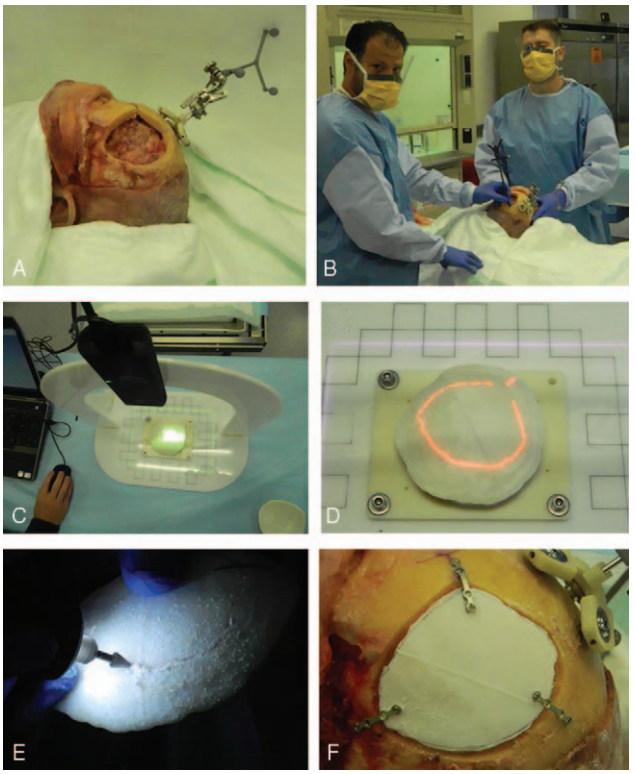

FIGURE 2. Photographs of patent-pending, computer-assisted technology built in collaboration with engineers at Johns Hopkins University, known as a "craniomaxillofacial surgical assistance workstation (C-SAW)"—built to improve and quicken the process of computer-assisted, single-stage cranioplasty reconstruction with customized cranial implants (CCIs). A, This shows large-sized cranial defect representing a tumor resection and the cranial reference mount. B, Shows the surgeon tracing out the defect margins after complete oncological resection. C, Shows the craniomaxillofacial surgical assistance workstation with connection to a mounted camera projector. D, Shows the laser image being projected onto the oversized, prefabricated, patient-specific, customized cranial implant. E, shows the surgeon using a handheld burr to shave down the implant per the laser image guidance and marking pen tracing. F, Shows a near-perfect fit between cranial bone defect and real-time modified custom implant.

As a way of looking forward and acknowledging the inherent benefits of computer-assisted technology—and in hopes of decreasing operative times and accompanying morbidity—we sought out an experienced team of university engineers and recently developed a technique now referred to as "single-stage, computer-assisted cranioplasty".[8,9] This novel method uses a craniofacial surgical-assistance workstation (C-SAW) capable of providing real-time, laser-pointed guidance for the surgeon to perform intraoperative modification of a prefabricated, oversized, patient-specific implant (Fig. 2). The inherent value, as opposed to using predetermined cutting guides based on radiographic imaging per the group of Oji et al, is that the neurosurgeon maintains a limitless boundary for oncological skull resection and can at the same time, stay true to the mission to remove all abnormal-appearing bone and local invasive tissue in hopes of preventing all forms of tumor recurrence.[9] Once the tumor is removed, the craniofacial surgeon can then trace the borders of the complex, three-dimensional defect and then transpose the true dimensions onto the implant's surface using a laser-pointed image. Currently, we are in the midst of translating the technology, built, tested, and validated within human cadaver specimens, and have plans to perform our first preliminary study in live humans in the near future.

Either way, the team from Japan that conducted this IRB-approved study should be commended for their dedication in investigating the use of customized cranial implants following benign skull tumorectomies via prefabricated surgical guides. We applaud them for their efforts in investigating their preliminary outcomes from an objective standpoint and for expanding the indications of patient-specific implants in instances of skull tumor resection as opposed to more common approaches. Future investigation in skull tumor resection techniques and implant-based cranioplasties, with this type of objectivity, is undoubtedly warranted so that surgeons may work together in unison to improve outcomes. More than ever, our patients seek full restoration back to their presurgical appearance following skull tumor resection and single-stage cranioplasty; thus, any study like this by Oji et al should be highly respected in our pursuit to prevent all visible contour deformities and in providing time-tested, durable reconstructions for our neurosurgical patients.

In conclusion, the use of prefabricated cutting guides for combined skull tumor resection and single-stage, custom implant-based cranioplasty is suboptimal given the theoretical constraints hindering true oncological principle and unlimited neoplasm extirpation. As such, we are optimistic that future developments—in both "computer-assisted" and "robotic-assisted" technologies—will help to improve current-day methods for achieving ideal outcomes.

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