



Cranioplasty Outcomes From 500 Consecutive Neuroplastic Surgery Patients

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Background: Cranioplasty is critical to cerebral protection and restoring intracranial physiology, yet this procedure is fraught with a high risk of complications. The field of neuroplastic surgery was created to improve skull and scalp reconstruction outcomes in adult neurosurgical patients, with the hypothesis that a multidisciplinary team approach could help decrease complications.

Objective: To determine outcomes from a cohort of cranioplasty surgeries performed by a neuroplastic surgery team using a consistent surgical technique and approach.

Methods: The authors reviewed 500 consecutive adult neuroplastic surgery cranioplasties that were performed between January 2012 and September 2020. Data were abstracted from a prospectively maintained database. Univariate analysis was performed to determine association between demographic, medical, and surgical factors and odds of revision surgery.

Results: Patients were followed for an average of 24 months. Overall, there was a reoperation rate of 15.2% (n = 76), with the most frequent complications being infection (7.8%, n = 39), epidural hematoma (2.2%, n = 11), and wound dehiscence (1.8%, n = 9). New onset seizures occurred in 6 (1.2%) patients.

Several variables were associated with increased odds of revision surgery, including lower body mass ratio, 2 or more cranial surgeries, presence of hydrocephalus shunts, scalp tissue defects, large-sized skull defect, and autologous bone flaps. Importantly, implants with embedded neurotechnology were not associated with increased odds of reoperation.

Conclusions: These results allow for comparison of multiple factors that impact risk of complications after cranioplasty and lay the foundation for development of a cranioplasty risk stratification scheme. Further research in neuroplastic surgery is warranted to examine how designated centers concentrating on adult neuro-cranial reconstruction and multidisciplinary collaboration may lead to improved cranioplasty outcomes and decreased risks of complications in neurosurgical patients.

Key Words: Complication, cranial, craniectomy, cranioplasty, implant, neuroplastic, outcome, reconstruction, surgery

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Cranioplasty provides critical cerebral protection, restores intracranial fluid dynamics, and reduces visual stigma via facial symmetry restoration.^{1–5} However, the procedure is fraught with a high risk of complications, with series and meta-analyses reporting complication rates approaching 37%.^{6–9} Similarly, a wide range of risk factors have been reported, thereby limiting surgeons and patients from making an informed decision regarding the risks and benefits of cranioplasty.^{7,10–15} Previous comparison studies have been additionally limited by differences in complication criteria, inclusion of multiple surgeons, inconsistent surgical technique, and uncertain follow up.^{1–19} Additionally, to our knowledge, no study has yet assessed outcomes with new “functional” or fifth generation cranial implants, that is, implants with embedded neurotechnology, which were first introduced by this group.^{20–25}

Over the last 6 years, a multidisciplinary team of clinicians, scientists, and engineers has created a new medical subspecialty termed neuroplastic surgery to improve adult scalp and skull reconstruction outcomes and develop novel technologies that leverage opportunities created by replacing bone with synthetic skull implants.^{24,25} Innovations born from this collaborative approach include patient specific synthetic skull implants able to correct both skull and co-existing soft tissue deformities, the pericranial onlay surgical technique, fifth generation skull implants, and “sonolucent” cranial implants that permit transcranioplasty ultrasound of the intracranial space.^{20,21,32,33,22,23,26–31} We present a review of the first 500 consecutive patients with complex skull and/or soft tissue defects referred to a tertiary care center for skull and scalp reconstruction

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by a neuroplastic surgery team. Specifically, we examine incidences of complications and association with patient-specific factors following cranioplasty performed with a well-defined, consistent technique and postoperative follow-up. Additionally, we examine complications following placement of fourth and fifth generation cranial implants.²¹ Our hypothesis is that this systematic, multidisciplinary team approach to caring for this complex population will ultimately lead to improved patient outcomes.

METHODS

A retrospective chart review was performed on an Institutional Review Board-approved, prospectively maintained database of all adult neurosurgical patients who were referred for cranioplasty reconstruction by the neuroplastic surgery team between January 2012 and September 2020. Inclusion criteria were large size skull defects ($> 25 \text{ cm}^2$), complex skull and/or soft tissue defects, and/or neuropathology requiring skull implant with embedded neurotechnology.

All surgeries were performed by the neuroplastic surgery team in conjunction with 1 of 14 neurosurgeons, with the senior author (CG) performing the pericranial onlay dissection, cranial defect exposure final reconstruction, and scalp closure. The previously described pericranial onlay technique was utilized in all cases.^{28,29} This is a critical difference between the standard, 100-year old cranioplasty technique used by neurosurgery and the neuroplastic surgery technique: in the standard, multigenerational technique, the scalp is dissected bluntly from the brain in the plane between the pericranium and the dura by the neurosurgeon, using a periosteal elevator. In the pericranial-onlay technique, both the scalp incision of choice and soft tissue dissection is performed entirely by the Neuroplastic surgeon under loupe magnification and needle-point electrocautery, that is, in the plane between the galeal and the pericranium. Thus, a vascularized pericranial flap is left intact over the dura. This is of importance since this technique changes the cranioplasty surgery from a “brain” surgery, (ie, a more invasive exposure) to a “scalp” based surgery where the brain is relatively undisturbed (ie, a less invasive exposure). Furthermore, in cases of decompressive craniectomy where the dura is intentionally left open and healing occurs with the scalp-pericranium scarred to the brain, a pericranial dissection leaves an invaluable vascularized pericranial flap over the brain in contrast to a standard cranioplasty dissection, which in some instances requires the use of a dural-onlay/substitute for assistance with desired scarring and plane formation.

Another key difference between the standard cranioplasty technique and the neuroplastic surgery technique is the management of the temporalis muscle in cases of decompressive craniectomies. Typically, after craniectomy the muscle is often scarred down and retracted. In the standard 100-year old dissection, the muscle is dissected from the dura and attempts are often made to re-suspend the muscle to its anatomic position by attaching it to the inferior outer surface of the implant. Unfortunately, denervation and devascularization following mobilization leads to an unstable amount of muscle volume with respect to time and unpreventable temporal asymmetry in the long term. In the neuroplastic surgery technique, whenever an alloplastic implant is used in delayed fashion, the dissection is performed superficial to the temporalis muscle and the deep temporal fascia (of note, the deep temporal fascia is contiguous with the pericranium, thereby providing a safe and effective dissection from top to bottom). The patient-specific implant is then customized and strategically bulked to replace not only the bone, but also the muscle based on the contralateral side volumes seen on preoperative imaging.^{26,27} Its design extends well beyond the

limits of the original cranial defect and acts as an overlay extending beyond the bone defect towards the lateral orbital rim, as an overlay extension. Thus, this dissection allows the temporalis muscle to remain within its newly healed location, preserves any formed neoangiogenesis to the nearby parenchyma, camouflages the defect with the dual-purpose implant, and prevents trismus or muscle impingement. Notably, this technique only applies to alloplastic implants and cannot be utilized when the bone flap is being replaced (since there needs to be a customized window/space to allow for the muscle to remain undisturbed, and this limit includes an anatomical vector extending from the zygomaticofrontal suture to the external acoustic meatus).²⁷

In cases with co-existing scalp deficiencies and high tension during incisional closure, reconstruction was performed using neuroplastic surgery techniques including adjacent tissue transfer (+/- full thickness skin graft to local donor site), component separation with release of scalp retaining ligaments, and fascia grafting (for scalp augmentation).^{28,29} In the most challenging cases, free vascularized tissue transfer was employed as indicated but very few instances were identified ($< 2\%$). Of note, tissue expanders were not used in any of the 500 cases. It is the senior author's opinion (CG) that tissue expansion over time leads to unpreventable subgaleal contamination with bacteria and thereby accompanies additional challenges with respect to alloplastic craniofacial implants and long-term infection risk.

All patients were followed with periodic clinical visits for a duration time (mean 24 months) calculated from date of cranioplasty surgery to the most recent clinical visit. Abstracted variables included demographic data, medical and surgical history, and intraoperative and postoperative data. Preoperative and postoperative Glasgow outcome scores (GOS) were assigned ranging from 1 denoting death to 5 denoting normal life with minor neurological and physiological deficits.

The primary outcome assessed was the incidence of surgical complications categorized as either “major” or “minor.” A major complication was defined as any event requiring an unplanned reoperation, whereas “minor” complications were those self-limiting events managed with either observation, antibiotics, and/or local wound care. A diagnosis of infection required a positive culture. Abstraction of complications, that is, chart review and recording of complications were performed independently by researchers (AW and MB) during database creation, with any conflicts resolved by a third researcher (KM). The occurrence of postoperative new onset seizures was also recorded. Recurrences of the indication for index craniotomy/craniectomy (ie, tumor recurrence) were not considered cranioplasty related complications.

Standard descriptive analyses were performed. Standard *t* tests were used to assess significant differences across continuous variables. Chi-squared tests and Fisher exact tests examined significant differences across categorical variables. Major and minor complications were calculated for the entire study population and subgroups as well as by implant material. Odds-ratios and 95% confidence intervals (95% CI) were reported for identified risk factors. Factors found to be significantly associated with an increased risk of revision surgery following univariate analyses were re-analyzed with stratification of all variables by the identified risk factor. In all analyses, $P < 0.05$ was considered statistically significant. Analyses were performed using Excel 16.36 (Microsoft, Redmond, WA).

RESULTS

Between January 2012 and September 2020, 500 consecutive patients underwent cranioplasty reconstruction. The mean patient age was 49 years (standard deviation ± 16.3 , range 9–92 years)

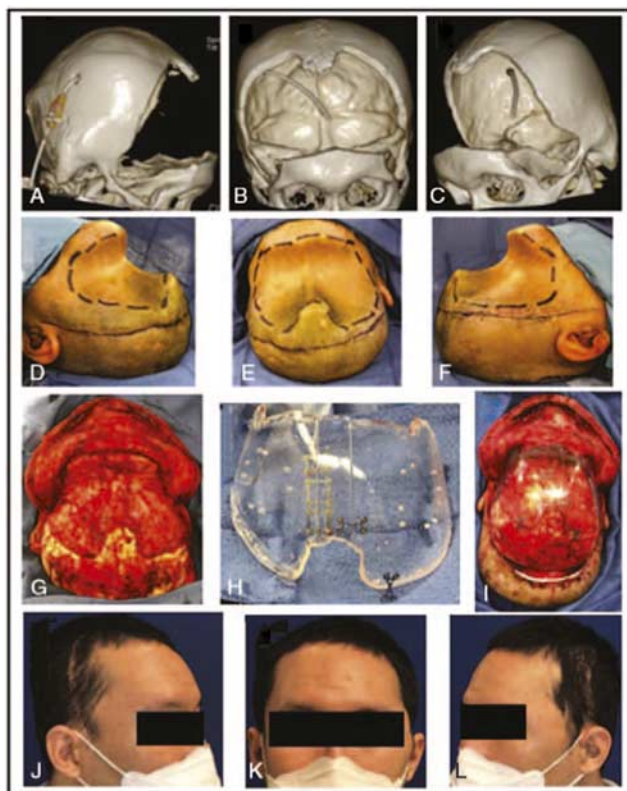


FIGURE 1. Representative photographs and CT scan images of a Neuroplastic Surgery patient who underwent reconstruction of a bifrontal craniectomy using clear PMMA implant. This is a 30-year-old male who was involved in a motor vehicle collision, sustaining a traumatic brain injury for which he underwent bifrontal craniectomy. His course was complicated by hydrocephalus for which a ventriculoperitoneal shunt was placed. He also had syndrome of the trephined with slowed speech and difficulty performing activities of daily living, with significant improvement after cranioplasty. (A-C) Lateral, frontal and oblique 3D-CT scan images showing craniectomy defect. (D-F) On table preoperative photographs showing the palpable craniectomy defect (dashed line), and the scar from his previous surgery (solid line). (G-I) Intraoperative photographs showing pericranial onlay dissection (G); customized clear PMMA implant, which was made in 2 segments and secured together with titanium plates and screws, then preplaced on the back table (H); and implant in place, prior to scalp closure (I). (J-L) Postoperative photographs demonstrating restoration of cranial contour. 3D-CT, three-dimensional computed tomography; PMMA, polymethyl methacrylate.

with the majority (99%, $n = 495$) of patients older than or equal to 18 years old. There was near-equal sex representation (51% female). With regards to racial distribution, the majority of patients identified as White (67%) with 19% Black, 6% Hispanic, 4% Asian, 2% Middle Eastern, and 7% other. These results are demonstrated in Supplementary Digital Content, Table 1, <http://links.lww.com/SCS/D873>. A representative case example of a patient with a bifrontal craniectomy who underwent cranioplasty reconstruction using a customized clear PMMA implant is shown in Figure 1. Figure 2 demonstrates a patient with drug resistant epilepsy who underwent cranioplasty reconstruction with a customized clear PMMA implant and an embedded Responsive Neurostimulator (RNS) system. Figure 3 shows a patient who underwent single-stage cranioplasty, that is, cranioplasty with clear PMMA implant placed during the same operation as the craniectomy (as opposed to performing the craniectomy and implant cranioplasty as separate surgeries given there is predefined skull defect).

Overall, there was a 15.2% rate of major complication, defined as cases associated with mortality or requiring a reoper-

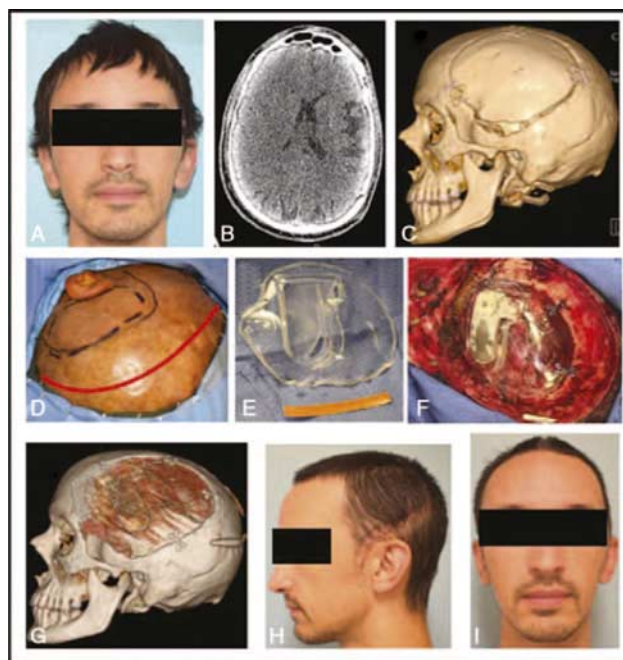


FIGURE 2. Photographs and CT scan images from a patient who underwent cranioplasty with a customized clear PMMA implant with embedded Responsive Neurostimulator (RNS) system. This is a 28-year-old male with a history of drug resistant epilepsy for which he previously underwent resection of the seizure focus. He continued to have seizures; however, due to the residual foci being in eloquent areas of the brain, he was not a candidate for further resective therapy. He was evaluated by a multidisciplinary epilepsy treatment team and determined to be a candidate for RNS. After placement of the device, he was noted to have a 70% reduction in seizure frequency 3 months after the operation. (A-C) Preoperative photograph, representative horizontal CT scan showing area of previous left temporal lobe resection, and 3D CT scan showing prior craniotomy site, respectively. (D-F) Intraoperative photographs. (D) shows preoperative markings. Note the craniotomy site outlined with the dashed lines, the previous scar outlined by the solid black line, and the placement of the new incision demonstrated by the red line. A new incision was used to prevent placement of the incision directly over the cranial implant. (E-F) shows the custom implant on the back table, and after placement with the embedded RNS device, prior to scalp closure. (G) Postoperative 3D-CT scan showing the implant with embedded RNS device. (H-I) Early postoperative photographs of the patient showing healing incision, with excellent symmetry and cranial contour. 3D-CT, three-dimensional computed tomography.

ation. Infection was the most common cause of a major complication (7.8%, $n = 39$), followed by epidural hematoma (2.2%, $n = 11$) and wound dehiscence (1.8%, $n = 9$). There were a few cases complicated by cerebrospinal fluid leak, bone resorption, subdural hematoma, pneumocephalus, and epidural fluid collection, as detailed in Supplementary Digital Content, Table 2, <http://links.lww.com/SCS/D873>. There was 1 mortality following an intracerebral hemorrhage including complex tumor resection. Minor complications were predominantly superficial surgical site infection, and transient alteration in mentation occurred in 18 patients (3.6%). New onset seizures occurred in 6 (1.2%) patients.

A univariate analysis was performed to determine demographic factors associated with risks of major complication. Interestingly, with regards to race, White was associated with a statistically significantly greater odds of major complication (odds ratio [OR] 1.9, CI 1.1–3.3), whereas identifying as Black was associated with a lower odds of major complications (OR 0.4, CI 0.2–1). Results remained significant with sub stratification analyses. Body mass ratio (BMI) also appeared to be

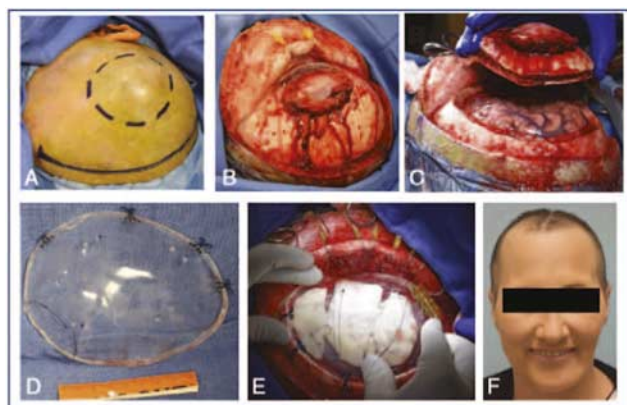


FIGURE 3. (A-F) Photographs demonstrating resection of an intraosseous meningioma with immediate reconstruction with customized clear PMMA implant. An oversized implant was created based on preoperative imaging, then intraoperatively cut down to size to fit the defect. (A) On table photograph showing an outline of the visible and palpable mass (dash line), and the planned incision (solid line). (B) The scalp was elevated in a sub-pericranial plane initially, then transitioned to a subgaleal plane over the mass, such that the pericranium would be resected en bloc with the tumor. (C) Photograph showing en bloc tumor resection, which includes pericranium, bone and dura. (D) Clear PMMA implant intraoperatively customized and plated on the back table. (E) Implant secured in place. Note the dural tack-up sutures, which are secured to the dura at the edge of the defect. Gel foam is also placed between the brain and the implant, which acts as a hemostatic agent as well as helps to reduce dead space. (F) Early postoperative photograph showing restored cranial symmetry and contour, and well healing incision.

associated with odds of having a major complication, with both underweight (OR 4.8, CI 1.8–12.7) and normal (OR 2.2, CI 1.3–3.6) BMI associated with significantly increased odds ratios, whereas overweight (OR 0.5, CI 0.3–0.9) and obese (OR 0.4, CI 0.2–0.7) were associated with decreased odds. Again, results remained significant with sub stratification analyses.

History of calvarial irradiation prior to cranioplasty was associated with a significantly increased odds of major complication (OR 2, CI 1–3.9) in univariate analysis, however, upon sub stratification analyses precranioplasty radiation was not found to be independently associated with increased risk of revision surgery. There was no association between age, sex, chemotherapy treatment, or postoperative radiation and odds of having a major complication. (Supplementary Digital Content, Table 1, <http://links.lww.com/SCS/D873>). Regarding the effect of medical comorbidities, a univariate analysis was also performed to evaluate a number of different disease processes present in patients undergoing neurocranial reconstruction (ie, cranioplasty) (Supplementary Digital Content, Table 3, <http://links.lww.com/SCS/D873>). Of these, only long-term anticoagulation therapy (OR 2.3, CI 1.3–4.3) and liver disease (OR 2.4, CI 1.1–5.5) were shown to have an effect and remain significant with sub stratification analyses.

An analysis was also performed to evaluate whether the specific factors in patients' surgical history were associated with the odds of having a major complication. The majority of patients in this cohort underwent index craniotomy for tumor resection (44%, $n = 221$). It should be noted that this population consisted of both single stage reconstructions (ie, patients with intraosseous tumors that were reconstructed during the same operation as the tumor resection), and patients who were referred because of complications after tumor resections (such as hardware exposure, infection, or radiation injury). The indication for the remaining patients was vascular (25%, $n = 123$), trauma (23%, $n = 115$), or other (3.6%, $n = 18$) (Supplementary Digital Content, Table 4, <http://links.lww.com/SCS/D873>). Of

these indications, only trauma had an association with odds of having a major complication, with a significantly increased odds ratio (OR 1.8, CI 1.1–3.1).

The anatomical site of reconstruction also appeared to play a significant role in the odds of having a major complication. Interestingly, cranioplasty in the frontal bone (OR 5.1, CI 1.715.6) was associated with significantly increased odds of a major complication. However, there was no association between frontal sinus involvement and odds of major complication. Conversely, cranioplasty involving the occipital region (OR 0.3, CI 0.1–0.8) or bilateral sites (OR 0.4, CI 0.2–0.9) were both associated with a decreased odds of major complication. No significant difference was seen in cranioplasties involving the parietotemporal bone (OR 1.5, CI 0.9–2.7). Small defects ($< 50 \text{ cm}^2$) had decreased odds (OR 0.4, CI 0.2–0.8), whereas large defects ($> 150 \text{ cm}^2$) were associated with increased odds (OR 2.3, CI 1.3–3.9) of having a major complication. A surgical history of 2 or more previous scalp/skull surgeries was also associated with increased risk of major complication (OR 3.7, CI 2.1–6.4). In contrast 1 or less previous scalp/ skull surgery was associated with decreased odds of a major complication (OR 0.2, CI 0.1–0.5). History of ventriculoperitoneal shunting or presence of hydrocephalus shunt valves increased the odds of a major complication (OR 2.4, CI 1.3–4.5).

The quality of the scalp soft tissue also affected the odds of having a major complication. A sunken scalp flap (OR 3.8, CI 2–7.2), soft tissue graft (OR 3.31, CI 1.7–6.3) or the presence of a soft tissue defect (OR 7.2, CI 3.9–13.2) were each associated with an increased odds of having a major complication. Although the preoperative American Society of Anesthesiologists physical status classification status did not have a significant association, GOS greater than 5 (better neurologic baseline) was associated with significantly decreased odds (OR 0.4, CI 0.3–0.8), whereas GOS of 2 (poor neurologic baseline) was associated with significantly increased odds of a major complication (OR 2.7, CI 1.2–6.0). With regards to the effect of procedure timing on risk of complications, procedures performed in a single stage were associated with a significantly decreased odds of major complication. There was no association between case duration and odds of major complication.

An interesting finding from this study was the association between implant material and risk of major complication (Supplementary Digital Content, Table 5, <http://links.lww.com/SCS/D873>). The use of stored autologous bone flaps was associated with a significantly increased odds of having a major complication (OR 2.6, CI 1.0–6.5), whereas synthetic implant material was associated with a significantly decreased odds of a major complication. In a subanalysis of the various types of synthetic implant materials, there was no association between any of the individual synthetic materials and odds of major complications. Additionally, there was no increased incidence of major complications in either 4th generation implant with strategic temporal bulking or with additional with insertion of embedded neurotechnology known as fifth generation implants.³² Embedded intracranial pressure monitors ($n = 1$), Utah array electrodes ($n = 1$), neuropore devices ($n = 8$), and recessed shunt valves ($n = 5$) were not found to significantly influence risk of revision surgery.^{30,31,32}

DISCUSSION

To our knowledge, this retrospective analysis of 500 consecutive patients undergoing cranioplasty by a neuroplastic surgery team by way of a consistent surgical technique and approach is the

largest such case series in the literature. We have extensively identified all complications and evaluated the association between all specific risk factors and odds of complications. In addition, by reporting a single-team experience, many confounding factors related to inconsistent cranioplasty techniques, different institutions, varying perioperative protocols, and nonstandardized patient evaluations, have all been removed.^{34–36} In fact, Van de Vijfeijken et al¹⁹ in particular lamented that a meta-analysis of cranioplasty outcomes is limited due to considerable heterogeneity among studies. In our experience, it is just as critical as to how the scalp is mobilized, pericranial onlay flap dissection, and scalp closure, as to how the cranial implant is designed and placed (Supplementary Digital Content, Video 1, <http://links.lww.com/SCS/D872>). This is why neuroplastic surgery adds value to the current health care mode (Supplementary Digital Content, Table 6, <http://links.lww.com/SCS/D873>). As such a takeaway of this paper based on the senior author's experience, is that adult patients requiring complex neuro-cranial reconstruction, may benefit from designated centers focusing on multidisciplinary collaboration, to offer a holistic approach to this distinct patient population. By incorporating systematic algorithms and surgical techniques available in the neuroplastic surgery armamentarium, our data suggests improved cranioplasty results and decreased risks of complications in neurosurgical patients. The burgeoning field of neuroplastic and reconstructive surgery was born out of this need to improve cranioplasty outcomes and created to bridge the gap between plastic surgery and neurosurgery. Therefore, as this field continues to evolve, refined techniques will continue to reduce complications, improve outcomes and improve patient satisfaction.

Complication Rate

Across both Neurosurgery and Plastic surgery literature, a wide range of complication rates following cranioplasty are reported, with larger studies noting implant failure rates of 25%–40%.^{5,9,16,37} In particular, a longitudinal study of 8275 patients across the United States calculated, found implant failure rate of 37%.⁶ Thus, one of the most notable findings from this study is the significant reduction of major complications (15%), as compared to many previous studies.

Demographic Factors

The finding that lower BMI was associated with an increased odds of complication may be related to the known effect of malnutrition with respect to wound healing. Although pre- and perioperative prealbumin and albumin levels were not specifically evaluated in this study, it is possible that lower BMI was associated with protein malnutrition. Another possibility may be that increased subcutaneous fat in obese individuals may provide improved soft tissue coverage (ie, more volume) over the implants, therefore, leading to a lower risk of scalp thinning and device exposure following localized trauma. Of note, we observed patients with increased BMI to be at particularly lower odds of infection. Pronounced increased subdermal inflammation has previously been observed in obese compared to nonobese skin samples, suggesting that baseline differences in inflammation may confer greater protection from infection.³⁸ Future, studies are important to better understand the role of BMI and scalp thickness in influencing outcomes in cranioplasty. Furthermore, it is unclear why racial identity affected the odds of having a major complication following cranioplasty. Previous studies have observed differences in soft tissue properties between White and Black patients, however, their effect on wound healing requires further investigation.^{38–40}

Cranial Surgical History

Major complications were found to significantly correlate with number of prior cranial procedures requiring a scalp incision. This is consistent with our previous report, wherein we demonstrated a 6fold increase in complications when more than 3 previous scalp surgeries were performed.⁴¹ This finding is intuitive given that multiple scalp scars and repeated procedures jeopardize the blood supply to the scalp, compromise the soft tissue envelope above the cranioplasty site, and compound the amount of tension at time of scalp closure.

Implant Material

Compared to synthetic implants as a group, the use of stored autologous bone flaps was associated with a significantly increased odds of having a major complication. These results are consistent with published data from different investigators demonstrating greater complications with stored autologous bone compared to alloplastic implants.^{9,19,42} The term “bone flap” is a misnomer since it simply refers to the patient's cranial bone removed during a craniotomy. It is not truly a “flap” since it does not have its own blood supply and is instead simply a bone graft, or essentially an avascular piece of bone. Thus, it makes sense that cranial reconstructions with large pieces of dead bone stored in a freezer or in nonanatomical abdominal subcutaneous planes for a prolonged time period would be more prone to complications such as infections and/or aseptic resorption.

In one of the largest studies using autologous bone for cranial reconstruction, Cabbad et al¹⁷ reported a 0% complication rate in their series. However, it must be noted that 46% of the patients in that series were in the pediatric population.¹⁷ Another important factor was that they utilized true bone “flaps,” that is, bones harvested with their native blood supplied and reconstructed with microvascular anastomoses, or fresh bone grafts, that is, bone harvested and used for reconstruction in the same operation rather than stored and utilized in a delayed fashion. These findings support the notion that if cranial reconstruction is being done in a delayed fashion, or if the native calvarium is compromised as in osseous tumor invasion or trauma, the use of synthetic material may present a superior option with regards to outcomes. Further studies are needed to define the specific parameters for stored bone flap versus alloplastic cranial implant.

Perhaps most importantly, these findings suggest there is no increased risk of major complications using implants with either a dual-purpose design (ie, fourth generation implants) and/or implants with embedded neurotechnology, also referred to as fifth generation implants.^{45,46} As these “functional” cranial implants are further developed, additional studies are merited to evaluate if specific technologies or parameters are associated with increased or decreased risk of revision surgery.

Radiation

Irradiation therapy before or after cranioplasty has been shown to correlate with poor outcomes.¹² Prior studies have shown radiation reduces blood supply to the entire zone including scalp, leading to stiffer, more friable tissue, and preventing tension-free closure.^{11,43,44} In our oncology subgroup population, neither preoperative nor postoperative scalp radiation were associated with significantly increased risk of revision surgery. With newer neuroplastic surgery techniques incorporating component separation of the scalp, adjacent tissue transfer with full-thickness skin grafting locally, and rectus fascia grafting for scalp augmentation, a tensionfree closure can be achieved for essential long-term durability at a higher rate,

which may explain the absence of a significant association between scalp radiation and cranioplasty failure.^{28,45}

Study Limitations

Limitations to this study include the retrospective nature, as well as a single-team/center experience. However, this allowed an unprecedented comparison of a number of factors that may impact cranioplasty outcomes, including implant material, without the confounding influence of multiple surgical teams with varying cranioplasty techniques at several institutions. Another limitation is that this study specifically evaluated surgical outcomes and did not include patient-reported outcomes (PRO). It is well recognized that assessing PROs can help establish accurate and efficient analyses of patient-reported symptoms and other health outcomes, as well as aid in monitoring health care qualities for long-term improvement.⁴⁶ Thus, future studies focused on evaluating PRO are needed.

Another factor that may limit the generalizability of these outcomes is that the surgeons' experience played a major role in selection of implant material based on patient specific characteristics.^{47–50} In this series, a surgeon preference was observed with respect to patient-specific implants (most commonly solid PMMA) over off-the-shelf, standard implants such as titanium mesh. True material randomization may not be feasible given that surgeons are limited by hospital administration/value analysis committees in choosing a material and/or vendor. Thus, we acknowledge that this advantage is not necessarily available to all surgical teams.

CONCLUSIONS

We present here a single-surgeon, outcome review of 500 consecutive patients who underwent cranioplasty by a neuroplastic surgery team and an analysis of factors associated with reoperation over 8 years duration. The most remarkable finding was the significantly lower incidence of major complications (15%) compared to many previously reported studies. This data set also revealed statistically significant independent correlations between major complications and BMI, soft tissue defects, and the number of previous cranioplasty attempts or prior scalp-incision surgeries. These results suggest it is critical to optimize outcomes at the first cranioplasty surgery, and a multidisciplinary collaborative approach may improve outcomes. Further studies are needed to evaluate the reproducibility of these findings across multiple institutions. Importantly, the data presented here can serve

1. As a guide to inform patients in preoperative risk-to-benefit discussions
2. Provide a baseline for future studies aimed at risk stratification algorithms to optimize cranioplasty outcomes
3. To help increase awareness of the value of interdisciplinary teams caring for adult neuroplastic surgery patients.

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