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# First-In-Human Experience With Integration of Wireless Intracranial Pressure Monitoring Device Within a Customized Cranial Implant

**BACKGROUND:** Decompressive craniectomy is a lifesaving treatment for intractable intracranial hypertension. For patients who survive, a second surgery for cranial reconstruction (cranioplasty) is required. The effect of cranioplasty on intracranial pressure (ICP) is unknown.

**OBJECTIVE:** To integrate the recently Food and Drug Administration-approved, fully implantable, noninvasive ICP sensor within a customized cranial implant (CCI) for postoperative monitoring in patients at high risk for intracranial hypertension.

**METHODS:** A 16-yr-old female presented for cranioplasty 4-mo after decompressive hemicraniectomy for craniocerebral gunshot wound. Given the persistent transcranial herniation with concomitant subdural hygroma, there was concern for intracranial hypertension following cranioplasty. Thus, cranial reconstruction was performed utilizing a CCI with an integrated wireless ICP sensor, and noninvasive postoperative monitoring was performed.

**RESULTS:** Intermittent ICP measurements were obtained twice daily using a wireless, handheld monitor. The ICP ranged from 2 to 10 mmHg in the supine position and from −5 to 4 mmHg in the sitting position. Interestingly, an average of 7 mmHg difference was consistently noted between the sitting and supine measurements.

**CONCLUSION:** This first-in-human experience demonstrates several notable findings, including (1) newfound safety and efficacy of integrating a wireless ICP sensor within a CCI for perioperative neuromonitoring; (2) proven restoration of normal ICP postcranioplasty despite severe preoperative transcranial herniation; and (3) proven restoration of postural ICP adaptations following cranioplasty. To the best of our knowledge, this is the first case demonstrating these intriguing findings with the potential to fundamentally alter the paradigm of cranial reconstruction.

**KEY WORDS:** Intracranial, Pressure, ICP, Cranioplasty, Neurotechnology, Cranial, Skull, Implant, Monitoring

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Traumatic brain injury (TBI) is the leading cause of death and disability worldwide.[1] Intracranial hypertension is independently associated with an increased risk of death and poor outcomes following TBI.[2-4] For patients with medically-refractory intracranial hypertension or impending brain herniation, decompressive craniectomy (DC) is a lifesaving treatment. DC involves surgical removal of a large cranial bone segment, accompanied by dural opening to increase intracranial space and relieve life-threatening pressure elevation.[2,5,6]

Following DC, patients remain at risk for infection, hemorrhage, and cerebrospinal fluid (CSF) disturbances and are vulnerable to trauma until skull reconstruction (ie, cranioplasty) is performed.[7] However, there is no objective data on the short- or long-term effects on intracranial pressure (ICP), in part because of the paucity of

**ABBREVIATIONS: CCI,** customized cranial implant; **CSF,** cerebrospinal fluid; **CT,** computed tomography; **DC,** decompressive craniectomy; **FDA,** Food and Drug Administration; **ICP,** intracranial pressure; **LID,** low-profile intracranial device; **NCCU,** neurosurgical critical care unit; **PMMA,** polymethyl methacrylate; **3D,** 3-dimensional; **TBI,** Traumatic brain injury

available technology for noninvasive monitoring. As such, cranioplasty is typically performed after cerebral swelling subsides, when there is less risk of elevating ICP and causing secondary injury at time of bone flap replacement or cranial implant insertion. However, a prolonged time interval between craniotomy and cranioplasty must be balanced against risk for developing associated complications such as hygromas, hydrocephalus, and/or "Syndrome of the Trephined"/"sinking skin flap syndrome."[8]

Given the lack of bony architectural support, the majority of patients develop a sunken scalp flap after DC. Thus, there is ample space for a cranial implant to be placed for reconstruction. However, a subset of patients has persistent cystic encephalomalacia and/or hygromas with transcranial herniation via the craniectomy defect, even after prolonged time intervals. Cranioplasty in this particular scenario necessitates manual reduction of the parenchyma within the cranial defect, with a risk of causing ICP elevation. Current practice is to delay reconstruction until resolution of extra-axial fluid collections (which can often be a delay of several months) or placement of a shunt if there is concern for intracranial hypertension.[9]

Recently, the Food and Drug Administration (FDA) approved a fully implantable, wireless ICP sensor (AURA™ ICP Monitoring System, Branchpoint Technologies, Irvine, California) that, for the first time in the United States, enables noninvasive, mobile ICP monitoring.[10] Given this newly available technology, we aimed to integrate an ICP sensor within a customized cranial implant (CCI) for postoperative monitoring of patients at risk for intracranial hypertension after cranioplasty.

CCIs, designed by way of virtual design planning and computer-assisted manufacturing, were first introduced near the end of the twentieth century. CCIs are prefabricated using computed tomography (CT) scan data, thereby enabling replacement of missing cranial bone with near-perfect precision. Furthermore, regardless of the biomaterial chosen, they provide patient-specific anatomical replacement, as opposed to "off-the-shelf, one-size-fits-all" options, such as titanium mesh, which "bridge the gap" rather than replace. For the last 2 decades, cranial implants have remained completely solid in design, with no added functionality beyond replacement of bone.[11,12] Recently, as part of a new paradigm shift led by the burgeoning field of neuroplastic surgery, we have demonstrated newfound functionalities of CCIs by incorporating neurotechnology devices such as high-profile hydrocephalus shunts or neuromodulatory devices for refractory epilepsy.[13,14] These advances are based on strategic utilization of the skull space, with the accompanying benefits of reducing scalp-related complications and preventing visible contour deformity, extrusion, infection, and explantation. With this in mind, our objective was to integrate the first ever FDA-approved wireless ICP monitoring device within a CCI (acronym "LID-ICP," for "low-profile intracranial device for ICP monitoring") for utilization in patients at risk for intracranial hypertension after cranioplasty.

Here, we report a first-in-human cranioplasty experience utilizing a LID-ICP in a patient with transcranial herniation after DC. The objectives were to (1) provide noninvasive, objective data for postcranioplasty management, and (2) evaluate ICP dynamics following large-sized cranioplasty.

## METHODS

This study was performed under active Institutional Review Board approval from the School of Medicine. Written informed consent was obtained from the patient's legal guardian for photograph inclusion. The sentinel patient was a 16-yr-old female 4-mo after decompressive hemicraniectomy and suboccipital craniectomy for craniocerebral gunshot wound management, presenting for cranioplasty. The patient had remarkable neurologic recovery, regaining baseline speech and independent ambulation. Despite the prolonged interval, there was persistent severe transcranial herniation with concomitant cystic encephalomalacia and subdural hygroma (Figure 1).

Given that cranioplasty would necessitate manual manipulation and reduction of the herniated brain within the intracranial space, with an unclear effect on ICP, a multidisciplinary approach was coordinated between neuroplastic surgery and neurosurgery. A plan was construed to design and fabricate a translucent poly(methyl methacrylate) (PMMA) CCI (Longeviti Neuro Solutions, Hunt Valley, Maryland) and to place an FDA-approved wireless ICP monitoring device (AURA™ ICP Monitoring System, Branchpoint Technologies, Irvine, California) within the implant.[10,15] At the time of surgery, the ICP sensor was strategically integrated within the cranial implant for postoperative, noninvasive wireless monitoring.[10] Table describes the features of the 2 commercially available, wireless ICP monitoring devices, of which only one is currently approved by the FDA for use in the United States.

There were several considerations for proceeding with device design and surgical plan as delineated. Firstly, if there was an unexplained decline in neurologic function with presumed ICP elevation postcranioplasty, this novel construct would provide objective evidence for additional invasive procedures, up to and including shunt placement and/or cranial implant removal. Secondly, if the patient complained of severe headache or demonstrated other findings concerning for clinical decline, but with normal ICP measurements found objectively, then we could avoid any unnecessary surgery. This was with the understanding that cranial fluid can accumulate in multiple compartments, and ICP measurements would be interpreted in conjunction with appropriate clinical and imaging findings (such as ultrasound and/or CT scan) to guide decision-making. Notably, we have previously demonstrated that the translucent PMMA implant utilized herein is sonolucent, thus enabling brain imaging with bedside ultrasound and providing another avenue for noninvasive monitoring.[15] Lastly, until recently, current practice for ICP investigation mandated an inpatient admission for invasive monitoring (placed either intraventricular or intraparenchymal) with the accompanying risks of scalp/cranial implant infection, meningitis, hemorrhage, and neurological deficits, and the limitation of only short-term utility (typically can only be used for a few days).[13] Thus, at the time this procedure was performed, there was an optimal convergence of novel ICP technology availability, advances in CCI manufacturing, and, importantly, a critical patient need.

Surgical placement of the CCI was performed in standard fashion with appropriate modifications for ICP device integration. Specifically, the implant was designed preoperatively based on 3-dimensional

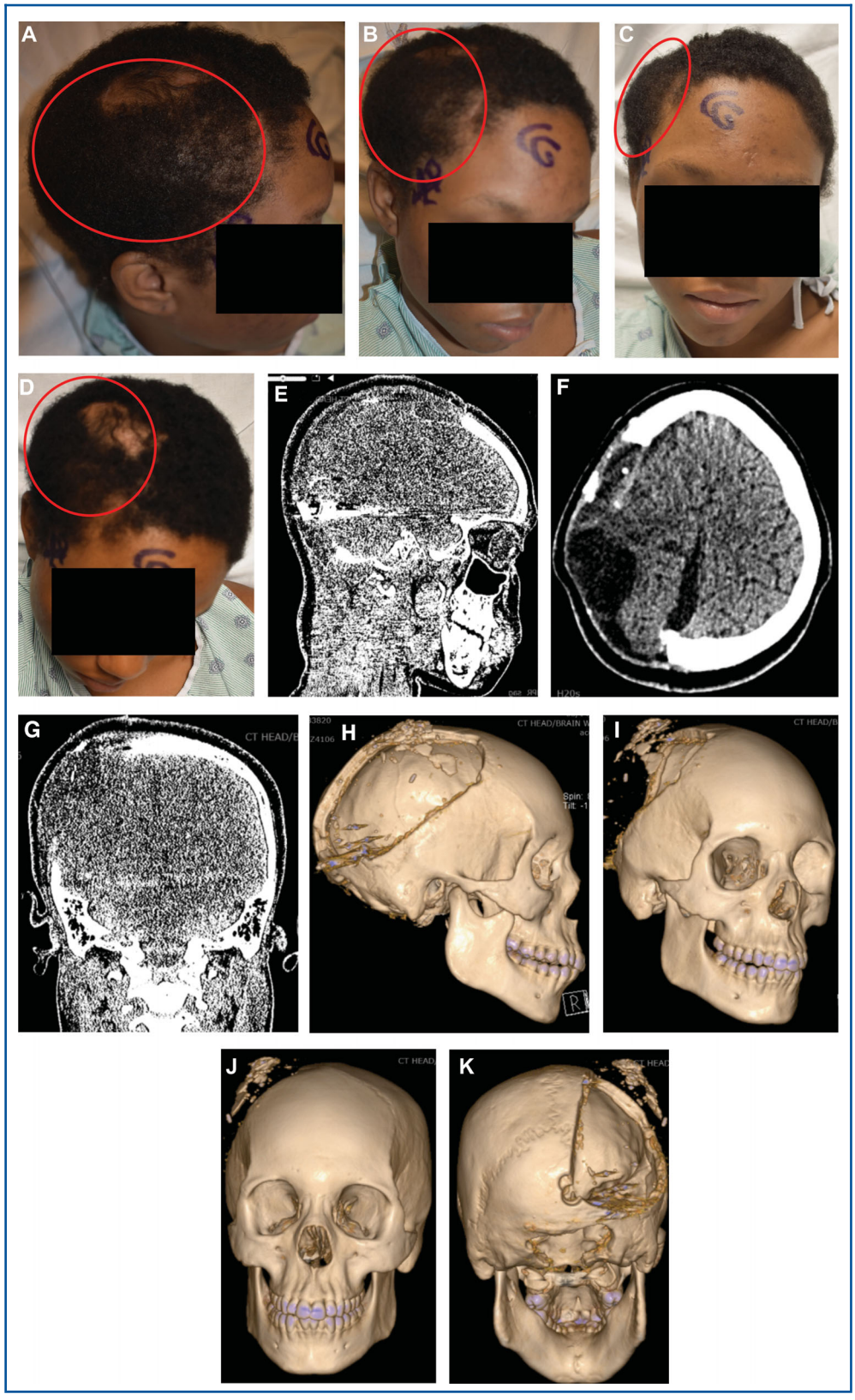


**FIGURE 1.** *Preoperative photographs and radiographic imaging of the sentinel patient presenting for cranioplasty.* **A-D**, *Preoperative photographs of the patient in lateral, oblique, frontal, and bird's eye views. The red circle in each photograph denotes the area of brain herniation from the craniectomy defect.* **E-G**, *Representative CT scan images of the brain after decompressive hemicraniectomy and suboccipital craniectomy (sagittal, axial, and coronal views, respectively). Note the large hemicraniectomy defect, with cystic encephalomalacia within the herniated brain parenchyma, as well as subdural hygroma. Also note the extensive metallic debris from the retained bullet in the right occipital lobe and frontoparietal lobe.* **H-K**, *3-D CT reconstruction imaging used for designing CCI. Note the hemicraniectomy defect, as well as the smaller suboccipital craniectomy defect visible from the posterior view* **K**.

**TABLE. List of All Commercially Available, Wireless ICP Devices Worldwide**

| Product name | Commercial manufacturer | FDA-approved (for sale in United States) | CE-marked (for sale in Europe) | Additional data (in addition to ICP) |
|---|---|---|---|---|
| Aura | Branchpoint Technologies, Irvine, California | Yes | No | No |
| Neurovent-P | Raumedic, Mills River, North Carolina | No | Yes | Temperature, Oxygen Partial Pressure |

(3D)-CT (Figures 1H-1K and 2) and fabricated with PMMA material.[16] Scalp dissection and cranial defect exposure was performed using our previously described pericranial-onlay technique.[16,17]

Briefly, the scalp incision was designed parallel to the craniectomy defect, such that the incision would not be directly overlying the defect (and therefore the implant) (Figure 3A). Importantly, the scalp overlying the cranial defect was meticulously elevated in a subgaleal plane, such that a vascularized pericranial-onlay flap remained undisturbed on the dura. After the defect was exposed, the cranial implant was prepared by burring a circular cavity (on a sterile back table) to allow precise placement and countersinking of the high-profile ICP sensor (Figure 3B). A nylon stay suture was used to secure the device vertically. A spinal needle was used to create a durotomy for insertion of the probe within the brain parenchyma. The implant, with the integrated ICP sensor, was then secured into place using standard fixation hardware (Figure 3C). Of note, the translucent properties of the CCI allowed uninterrupted visualization of the ICP device position and optimal parenchymal contact, assured hemostasis, and confirmed absent CSF leakage from the time of placement until scalp closure.

ICP readings were obtained before and after scalp closure, utilizing a small handheld wand positioned in close proximity to the implanted sensor for wireless data transmission (Figure 4). Additional ICP measurements were obtained postoperatively an hour after extubation, then at 12-h intervals for 3 consecutive d (while hospitalized), and at 3 and 6 wk postoperatively (outpatient). Measurements were obtained in both supine (0 degrees) and sitting (30 degrees) positions.

## RESULTS

The first-in-human cranioplasty utilizing a LID-ICP for a patient with acquired skull defect after DC was performed without complication. Figure 1 shows the preoperative patient photographs and imaging studies; note the significant brain herniation from the craniectomy defect causing a large bulge on the right side. Also note the subdural hygroma and cystic encephalomalacia visible on the preoperative CT scan (Figure 1F). Virtual surgical planning was used to design the CCI (Figure 2). Intraoperative photographs are provided to demonstrate the implantation of the ICP device within the translucent CCI (Figure 3A-3C). ICP was measured before and after scalp closure, as demonstrated in Figure 4. Note the improved cranial contour on the postoperative imaging and photographs, although this is somewhat marred by the suboptimal, high-profile design of ICP device despite our attempts at countersinking (Figure 5). Postoperative care was performed according to standard protocol.[16] The patient was extubated in the operating room and transported to the neurosurgical critical care unit (NCCU) for postoperative care. On postoperative day 1, she was transferred from the NCCU to the surgical ward and discharged home on postoperative day 3.

The first ICP measurement prior to scalp closure was 7 mmHg (patient in supine position) and 10 mmHg after scalp closure. Interestingly, postoperative ICP measurements obtained 1 h after extubation were 10 mmHg supine and 3 mmHg sitting. Over the following 3 d, subsequent ICP measurements ranged from 2 to 10 mmHg supine and −5 to 4 mmHg sitting. Notably, there was a consistent difference of average 7 mmHg when the patient moved from a supine to sitting position, indicating acute restoration of postural ICP changes after cranioplasty (Figure 6; Video). Measurements were also obtained in the outpatient setting at postoperative weeks 3 and 6. At 3 wk postoperatively, measurements were 5 mmHg supine and −6 mmHg sitting, and at 6 wk, they were 7 mmHg supine and −5 mmHg. The postural ICP difference was notably greater at

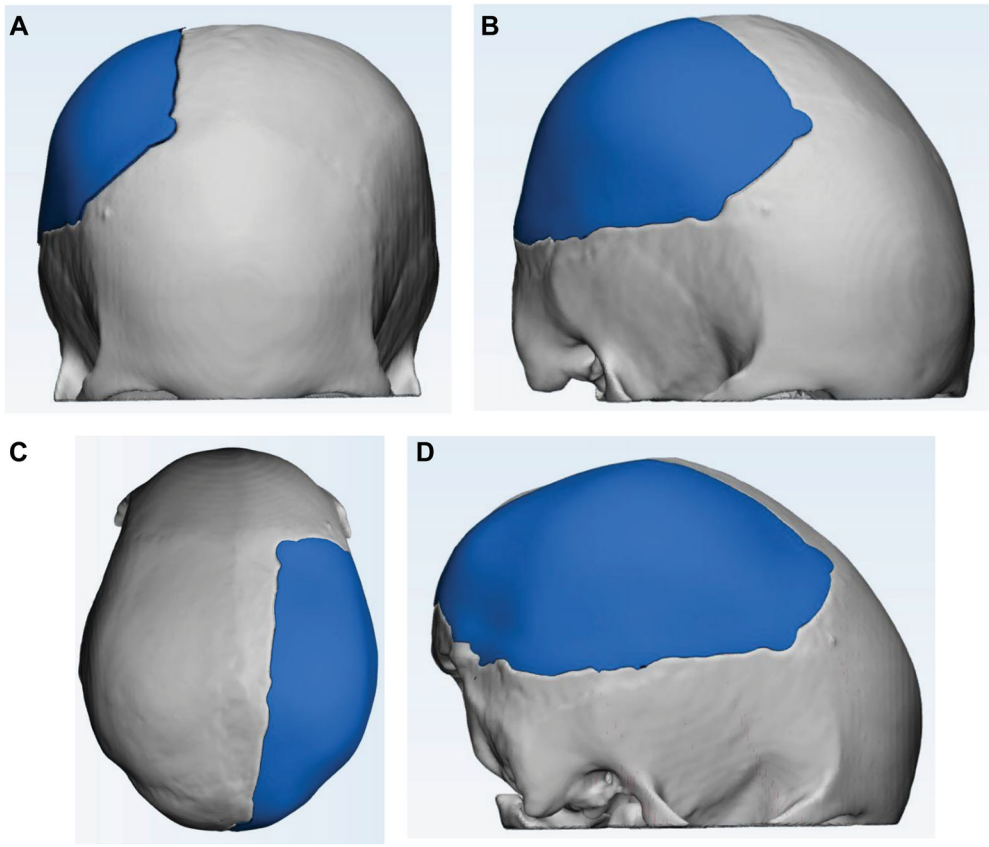



**FIGURE 2.** *Virtual surgical planning images based on 3D-CT scans for CCI creation. The implant is fabricated from translucent PMMA in a computer-assisted process (4-mm thickness for this specific patient) then sterilized prior to implantation. The proposed implant design is shown in blue on each image.* **A**, *Coronal view;* **B**, *oblique view;* **C**, *horizontal view; and* **D**, *lateral view.*

later time points postoperatively (11 and 12 mmHg at 3 and 6 wk, respectively, compared to 6-7 mmHg at acute time points).

## DISCUSSION

Multiple large cohort studies have demonstrated that intracranial hypertension is independently associated with an increased risk of death and poor neurological outcome following TBI.[4,18] In 1908, Harvey Cushing[19] published a report showing significant mortality reduction in patients treated with subtemporal DC. More recently, several major randomized control trials led to an international consensus meeting to develop guidelines for DC in the setting of TBI.[2,6,20] DC is also an integral treatment option in the management of intracranial hypertension secondary to acute ischemic stroke.[21,22] Indeed, pooled subgroup analysis from multiple randomized control trialss have demonstrated consistent and significant mortality benefit of DC for malignant middle cerebral artery stroke, with a risk reduction of almost 50%.[23] Given the renewed support and research aimed at optimizing DC, parallel efforts need to be undertaken to optimize cranial reconstruction and to develop "smart" implants capable of neuromonitoring, especially for TBI and ischemic stroke patients at risk for secondary sequelae such as intracranial hypertension, hydrocephalus, and epilepsy.

Whether autologous or alloplastic, cranial implants have historically been "basic" in design and purpose, meaning they simply substitute missing bone with no additional functionality. In contrast, as the world of cranioplasty and cranial implants remained stagnant, wearable technologies have been revolutionized exponentially, with the advent of numerous "smart" devices.[24,25] For example, the human skull (and standard CCI) is the same thickness as a cellular phone, yet one has no imbedded functionality, whereas the other has undoubtedly changed our everyday lives. As such, over the past several years, our neuroplastic surgery team has been dedicated to transitioning modern-day cranial implants from "basic" to "smart."

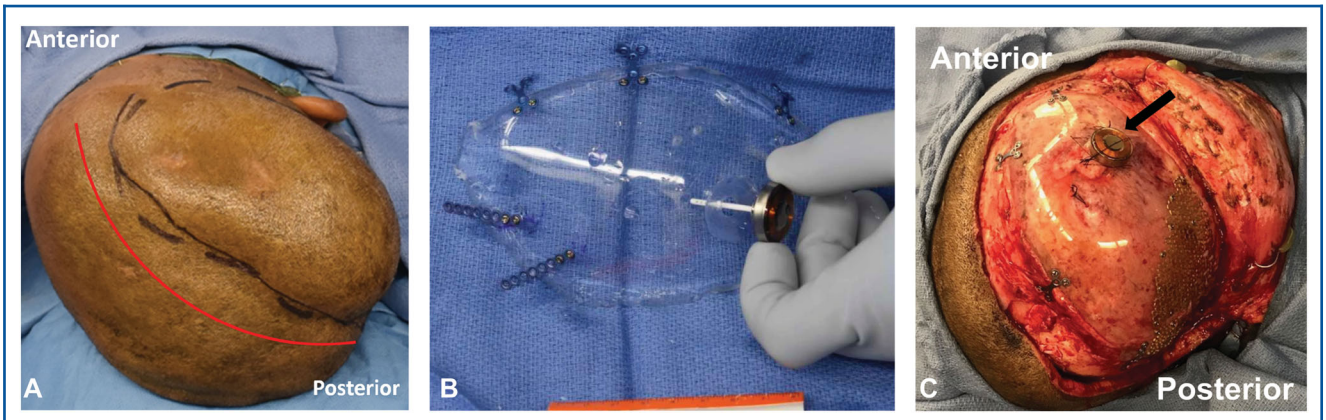



**FIGURE 3.** *Select intraoperative photographs.* **A**, *Note the large right-sided hemicraniectomy defect and extracranial parenchymal herniation. The black dashed-line surgical markings demonstrate the palpable cranial defect. The solid black line is an outline of the previous scalp incision. Note that if the previous scalp incision was utilized, it would be directly overlying the defect and hence the implant. As such, a new incision was designed parallel to the defect to allow the implant to be completely covered by healthy scalp (incision demonstrated by red line). Despite historical concerns that parallel scalp incisions may cause vascular necrosis of the skin bridge, in our experience, we have not found this to be the case in scalp flaps. The translucent PMMA CCI was preplated on the back table, and a handheld burr used to create a recess for countersinking of the ICP sensor, as shown* **B**. *After the scalp was elevated such that a pericranial-onlay flap remained over the dura, the LID-ICP was secured in place with titanium hardware* **C**.

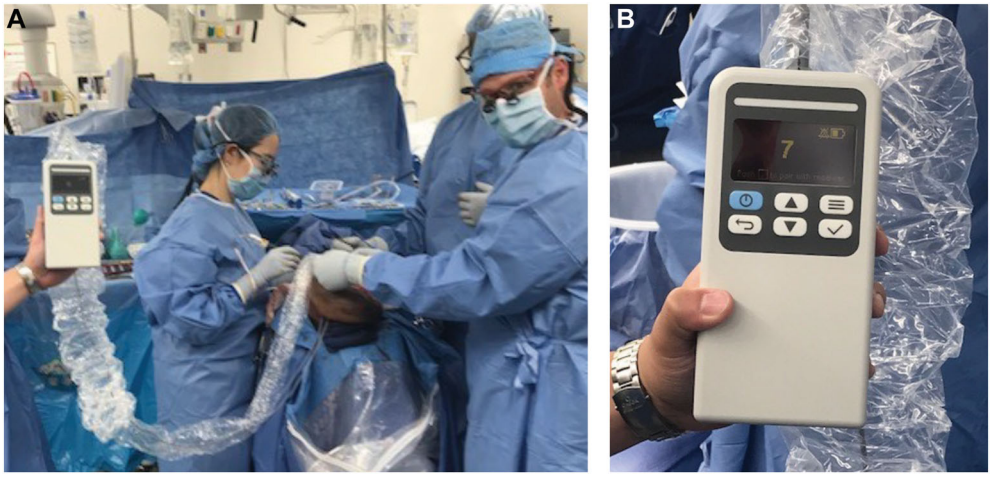



**FIGURE 4.** *Intraoperative photograph of handheld monitoring device and wireless wand being employed at completion of cranioplasty reconstruction* **A**. *Of note, the display screen shows an intraoperative ICP measurement of 7 mmHg following manual brain reduction, cranial implant placement, and complex scalp closure* **B**.

For instance, we described first-in-human experiences integrating neuromodulation devices and hydrocephalus shunts within CCIs.[13,14] Together with the current study, these reports demonstrate an obvious role for also integrating functional devices within cranial implants for improved neuromonitoring and biosensing. Indeed, technological advances in cardiac surgery have enabled real-time recording of heart rhythm signals via smart phone-compatible implanted sensors and signal transmission to a remote secure server for physician interpretation.[26,27] Given the vast potential technological capabilities of device integration within CCI, it is time for the field of neuro-cranial reconstruction to move beyond antiquated "basic" cranial implants. Biosensors and implant neurotechnologies, housed within translucent CCIs, will undoubtedly change the art and science of cranioplasty.

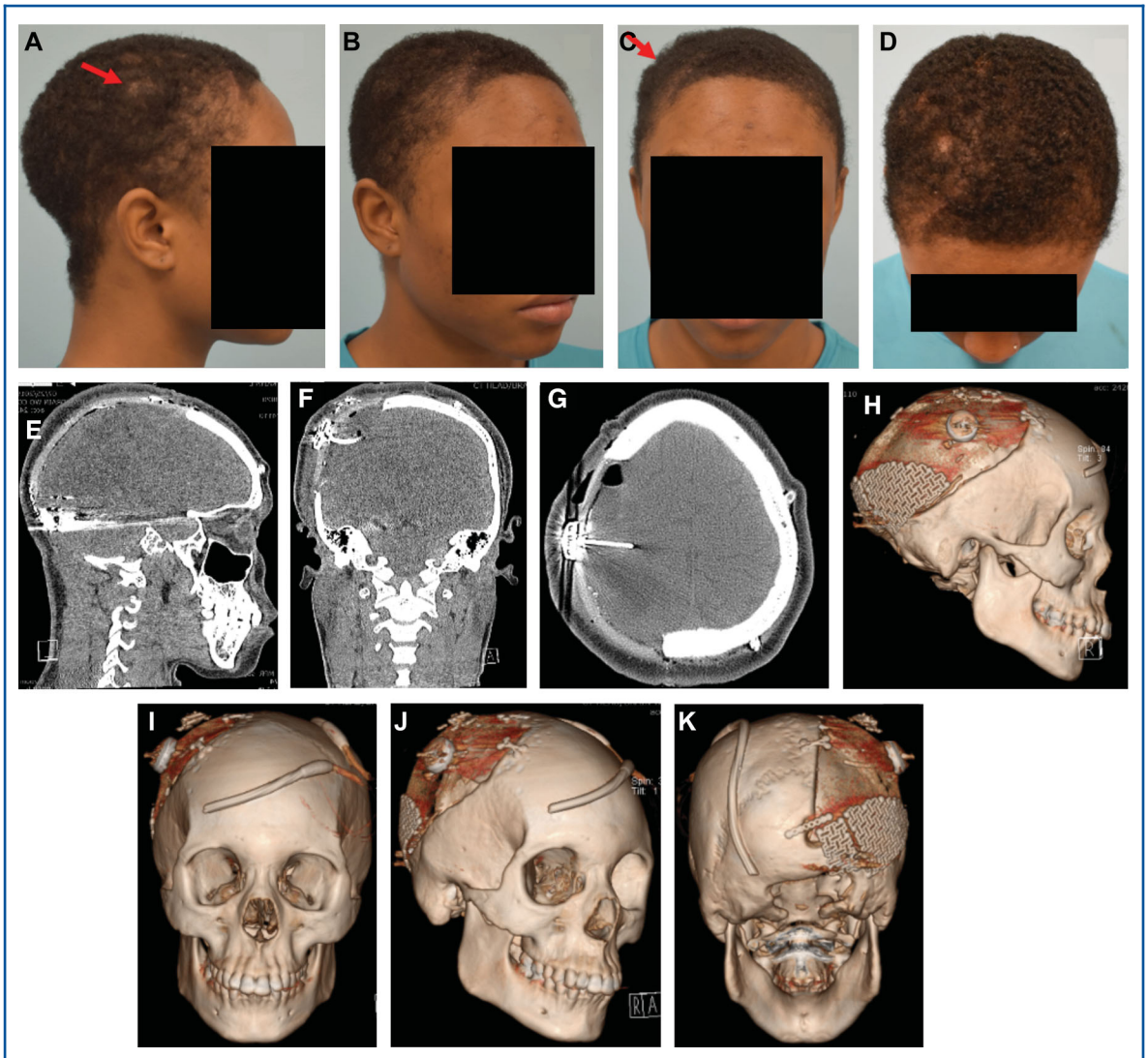



**FIGURE 5.** *Postoperative photographs and relevant imaging.* **A-D**, *Postoperative photographs showing improved cranial contour despite visible ICP monitoring device (red arrows).* **E-G**, *Representative sagittal, coronal, and axial postoperative CT scan images of the brain showing decrease in intraparenchymal cyst. Also note the positioning of the ICP sensor within the brain and the improved cranial contour provided by the implant.* **H-K**, *Postoperative 3D-CT reconstruction showing device placement, although the translucent CCI is not readily apparent in this view. Also visible are the subgaleal suction drains utilized as part of our standard cranioplasty technique (removed on postoperative days 2 and 3 before the patient is discharged to home).*

In addition to restoring aesthetic appearance and adding vital brain protection, cranioplasty restores the integrity of the calvarial vault for normalization of CSF flow, cerebral blood flow dynamics, and glymphatic circulation.[28,29] As such, cranioplasty is typically performed as early as possible, with the clinical criteria being resolution of brain swelling, adequate sinking of scalp flap, resolution of critical medical issues, and no evidence of infection.[30] Most studies suggest cranioplasty within 90 d after initial DC, with longer time periods associated with increased risk of infection and seizures.[31] However, in this particular instance, despite a 4-mo-time interval, this patient had persistent herniation from the craniectomy defect, with concomitant ipsilateral subdural hygroma. Given this, we determined that the bone flap was no longer ideal following prolonged storage and that a customized implant was indicated. Additionally, our team envisioned that postcranioplasty ICP monitoring would be an invaluable metric to guide decision-making by the neurocritical and surgical care teams. Notably, this report is a key example of the intersection of technological innovation and judicious clinical applicability; until recently, there was no available FDA-approved

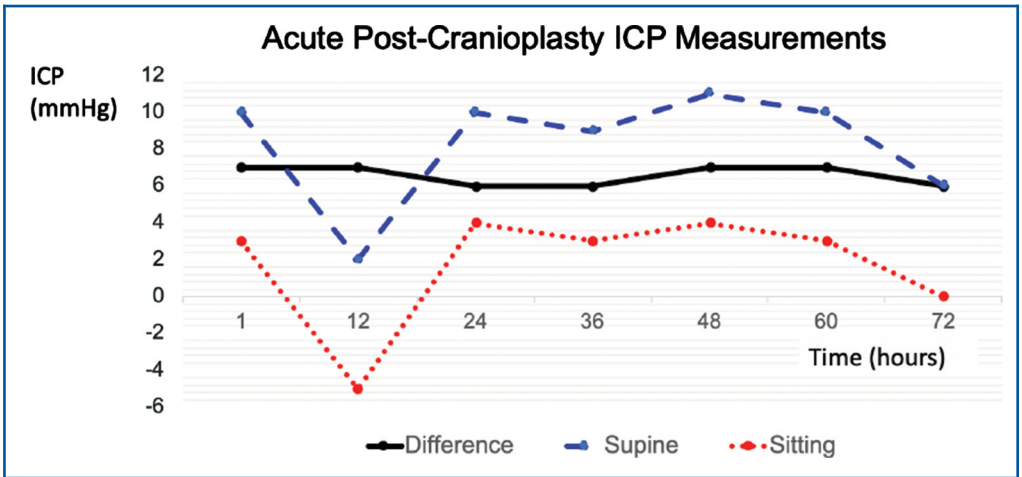
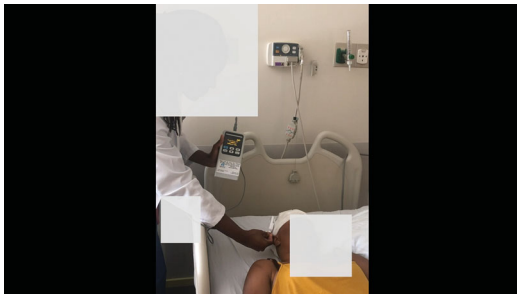



**FIGURE 6.** *Trending graph depicting ICP measurements in supine (0 degree, blue dashed line) and sitting (30 degree, red dotted line) positions from 1 to 36 h postcranioplasty. The first measurements were obtained 1 h after the patient was extubated. Note that even at this acute time point, there is postural ICP difference (black solid line). At 2 wk postcranioplasty in the outpatient clinic setting (not shown on graph), ICP measured 10 mmHg sitting and 4 mmHg supine, which is similar to the values shown here.*



**VIDEO.** *Obtaining postoperative wireless, ICP measurements at bedside on post-operative day 3.*

wireless ICP monitoring device in the United States. As such, this was the first time such a device was successfully integrated within a CCI to create a LID-ICP and utilized for postcranioplasty monitoring in a patient at high risk for developing intracranial hypertension.

Multiple critical findings were noted during postcranioplasty ICP monitoring. Firstly, given the ethical concerns of invasive ICP measurements in healthy individuals, a reference range for normal ICP has not yet been clearly defined given the lack of objective insight for those ambulating outside of the hospital. However, normal ICP values are generally extrapolated to be 7 to 15 mmHg in the supine position.[32] The ICP measurements in this patient were well within this range of "normal," indicating the cranioplasty did not increase ICP despite the drastic reduction in intracranial space. To the best of our knowledge, this is the first study demonstrating that cranioplasty in the setting of transcranial brain herniation, in a clinically stable patient, does not increase ICP. Thus, these findings have the potential to guide future protocols for timing cranioplasty, because it may not be necessary to wait until herniation is completely resolved if the patient is otherwise stable.

Secondly, the postural ICP change noted here was an intriguing finding given the paucity of literature on this subject, especially as it relates to cranioplasty. It has previously been shown that there is a difference of about 7 mmHg in ICP measured in the supine and sitting positions, consistent with our measurements.[33] However, in a recent study, Lilja-Cyron et al[34] demonstrated that postural ICP change is abolished in patients with large craniectomy defects. This is somewhat intuitive given that DC creates a large low-resistance defect in the rigid supratentorial cranial vault, invalidating the Monro-Kellie[35,36] doctrine that the sum of the contents of the skull is a fixed volume. Although we do not have preoperative ICP measurements for our patient (this would have required an unindicated invasive procedure), most likely this patient also lost postural ICP adaptation as a result of DC. As such, the results from postcranioplasty ICP measurements indicate that cranioplasty restores postural ICP adaptation in patients with history of DC. To our knowledge, this is also the first study demonstrating this phenomenon and warrants further investigation, as it may provide insight into the pathologic derangement of intracranial physiology after DC and the role of cranioplasty in restoring neurophysiologic homeostasis.

## Limitations

Despite these promising findings, there are some limitations to this study. Firstly, a disadvantage of the ICP sensor is the need for durotomy for implantation, which poses the additional risk for

CSF leak postcranioplasty. This risk is likely negligible, given the supratentorial location and small size of the durotomy and that it is "plugged" with the device sensor itself. Another modifiable disadvantage is the high-profile nature of the device, which was visible and palpable on the scalp despite countersinking. Besides the visual deformity, which can contribute to negative social stigma, this type of suboptimal design leads to supraphysiologic pressures on the overlying scalp, which, in turn, leads to localized ischemia and increased risk for device extrusion.[13,14] However, in a case such as the one presented here – severe brain herniation, encephalomalacia, subdural hygroma, and large cranial defect following hemicraniectomy decompression – the benefits of providing a cranial implant with an embedded wireless, ICP-monitoring device, far outweighed the risks. Furthermore, given the successful outcomes from this case, our team will remain dedicated to investigating different approaches for ICP sensor integration for improved outcomes and safety.

## CONCLUSION

The importance of cranioplasty following DC extends well beyond cosmesis. In addition to restoring premorbid appearance and protecting the brain, cranioplasty helps to optimize physiologic and clinical neurological recovery. Here, we present a first-in-human report of a LID-ICP for management of patients at high risk for intracranial hypertension after cranioplasty. Although this study was performed in the setting of TBI, this is undoubtedly applicable to DC for other pathologies, including ischemic stroke and subarachnoid hemorrhage. Herein, we demonstrate the novel findings of restored normal ICP following DC for TBI and staged cranioplasty, as well as restoration of postural ICP adaptation after cranioplasty. Despite the need for further studies to optimize the LID-ICP design, this study provides important proof of concept for integrating an ICP device within a custom cranial implant, and the potential to significantly impact the algorithm for cranial reconstruction following DC by way of introducing "smart" cranial implants with embedded technologies.

### Disclosures

Dr Gordon is a consultant for Longeviti Neuro Solutions. Dr Huang, Dr Anderson, and Dr Gordon are stockholders in Longeviti Neuro Solutions. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. Dr Gordon is a consultant for Depuy-Synthes/Johnson and Johnson, OsteoMed, and Stryker. Dr Anderson is an active paid consultant for Globus Medical.

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