Development of a Novel Device for Decompressive Craniectomy: An Experimental and Cadaveric Study and Preliminary Clinical Application

Luigi Valentino Berra, MD
Guido Cedrone, MD
Valerio Di Norcia, MD
Luca D'Angelo, MD
Floriana Brunetto, MD
Pietro Familiari, MD
Mauro Palmieri, MD
Mattia Capobianco, MD
Federica Pappone, MD
Antonio Santoro, MD

Department of Neurosurgery, Policlinico Umberto I, Sapienza Università di Roma, Roma, Italy

Correspondence:
Luigi Valentino Berra, MD,
Policlinico Umberto I,
Sapienza Università di Roma,
Viale del Policlinico 155,
Roma 00163, Italy.
Email: luigivalentinoberra@gmail.com

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BACKGROUND: Decompressive craniectomy is an intervention of established efficacy in patients with intractable cerebral edema.

OBJECTIVE: To evaluate a new device used in alternative to decompressive craniectomy. This device is designed to perform an augmentative craniotomy by keeping the bone flap elevated using specific cranial suspension titanium plates and giving the brain enough room to swell.

METHODS: We tested the mechanical characteristics of the cranial brackets on dried skulls, on 3D-printed skull models, and on a preserved cadaver head. The resistance of the device was examined through dynamometric testing, and the feasibility of the surgical technique, including the suspension of the bone flap and the skin closure, was investigated on the cadaveric model. A preliminary clinical series of 2 patients is also reported.

RESULTS: The laboratory tests have shown that this system allows an adequate expansion of the intracranial volume and it could withstand a force up to 637 ± 13 N in the synthetic model and up to 658 ± 9 N in the human skull without dislocation or failure of the brackets nor fractures of the bone ridges. Preliminary application in the clinical setting has shown that augmentative craniotomy is effective in the control of intracranial hypertension and could reduce the costs and complications associated with the classical decompressive craniectomy technique.

CONCLUSION: Preliminary laboratory and clinical results show augmentative craniotomy to be a promising, alternative technique to decompressive craniectomy. Further clinical studies will be needed to validate its efficacy.

KEY WORDS: Decompressive craniectomy, Augmentative craniotomy, Intracranial hypertension, Hinge craniotomy, Cerebral edema, Cranial fixation, Craniectomy, Cranioplasty, Brain swelling, Surgical technique

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Decompressive craniectomy (DC) is an intervention of recognized efficacy in reducing the increase in intracranial pressure (ICP) in patients with large ischemic or hemorrhagic stroke or in those with severe head trauma and refractory intracranial hypertension.

Despite the enormous advantages represented by osteodural decompression, this procedure is associated with a high rate of serious complications, which occur in approximately 20% of cases.[1] These complications include ipsilateral or contralateral hemorrhage, neuronal stretch injury, and compression of cortical vessels from brain herniation through the craniectomy defect, which in turn can produce a secondary ischemic insult, contusion expansion, hemorrhagic transformation of an ischemic stroke, hygroma, hydrocephalus, and syndrome of the trephined.[1,2] Even the subsequent cranioplasty operation is not without risks as it can be accompanied by cortical damage caused by the dissection of tenacious scar adhesions, postoperative bleeding, and resorption of the bone flap.[1,2] Because some of these complications are closely related to the removal of the bone flap, alternative strategies such as hinge and floating craniotomy or fixation of the flap with telescopic or expandable devices have been suggested, and their effectiveness in reducing intracranial pressure has been shown to

ABBREVIATIONS: ABS, acrylonitrile butadiene styrene; **DC,** decompressive craniectomy.

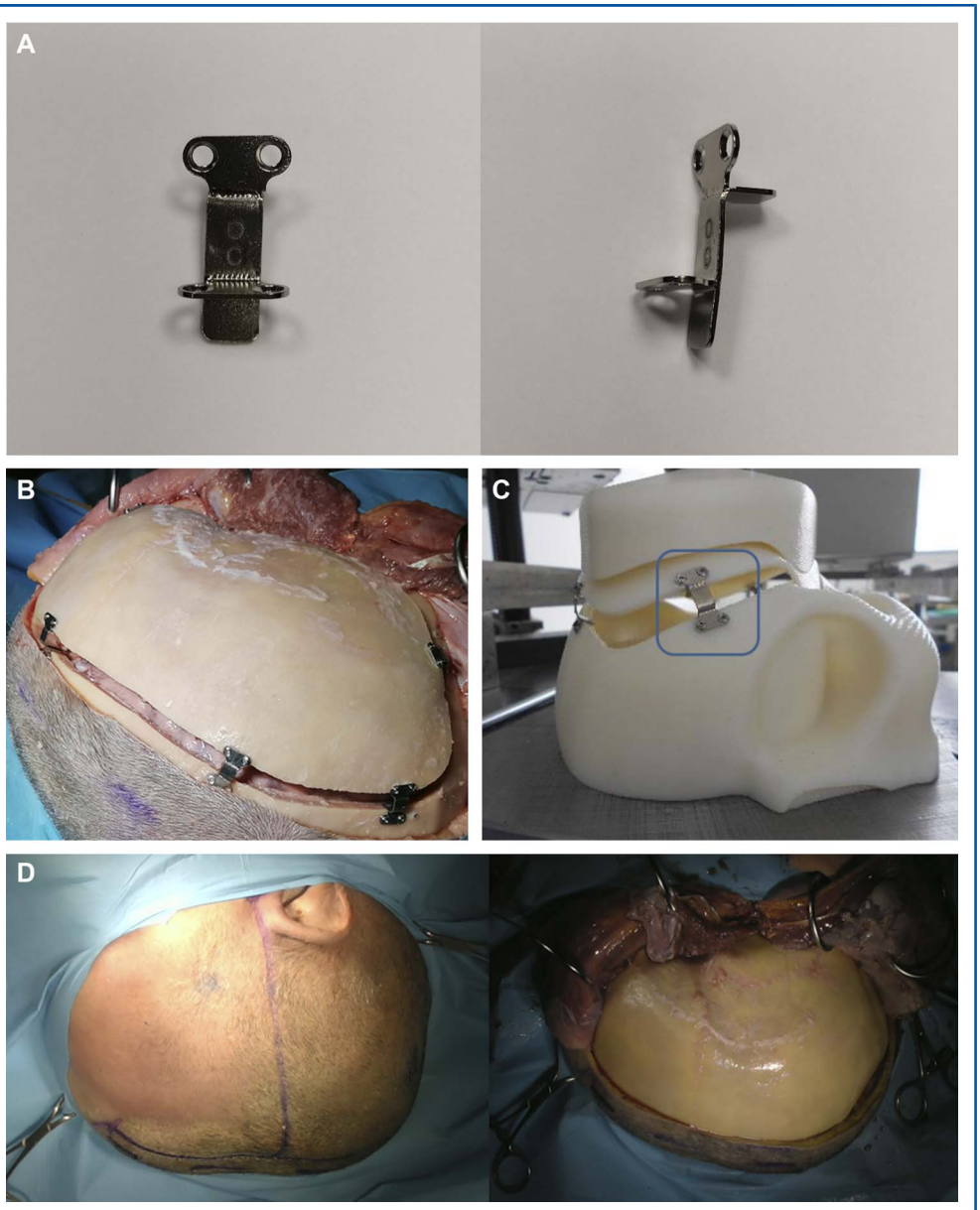

FIGURE 1. **A**, *Brackets.* **B**, *Final positioning of the brackets in the cadaver.* **C**, *Extent of cranial expansion with fixed brackets.* **D**, *Modifed Kempe incision.*

be not inferior to that of classical craniectomy.[3-8] Additional advantages of these techniques are the elimination of the need for an additional cranioplasty surgical procedure and associated costs. In the present work, we describe a new device based on an innovative concept that allows the expansion of the intracranial volume, without removing the bone flap. The feasibility of this procedure and the mechanical resistance of the device were tested on skull models and in a cadaveric context. A preliminary surgical series of 2 patients is also reported.

METHODS

The aim of this study was to evaluate the mechanical resistance of the cranial brackets and screws (Rialto, Cizeta Surgical—NTPlast) to centripetal and shear stresses applied to the bone flap, which simulates trauma and external manipulations (Figure 1A). The Rialto device has Conformité Européenne certification, so it is authorized for use in the European Union. It currently does not yet have Food and Drug Administration certification, so it can be used off-label in the United States. These tests were performed in 3 different settings: on a 3D-printed skull

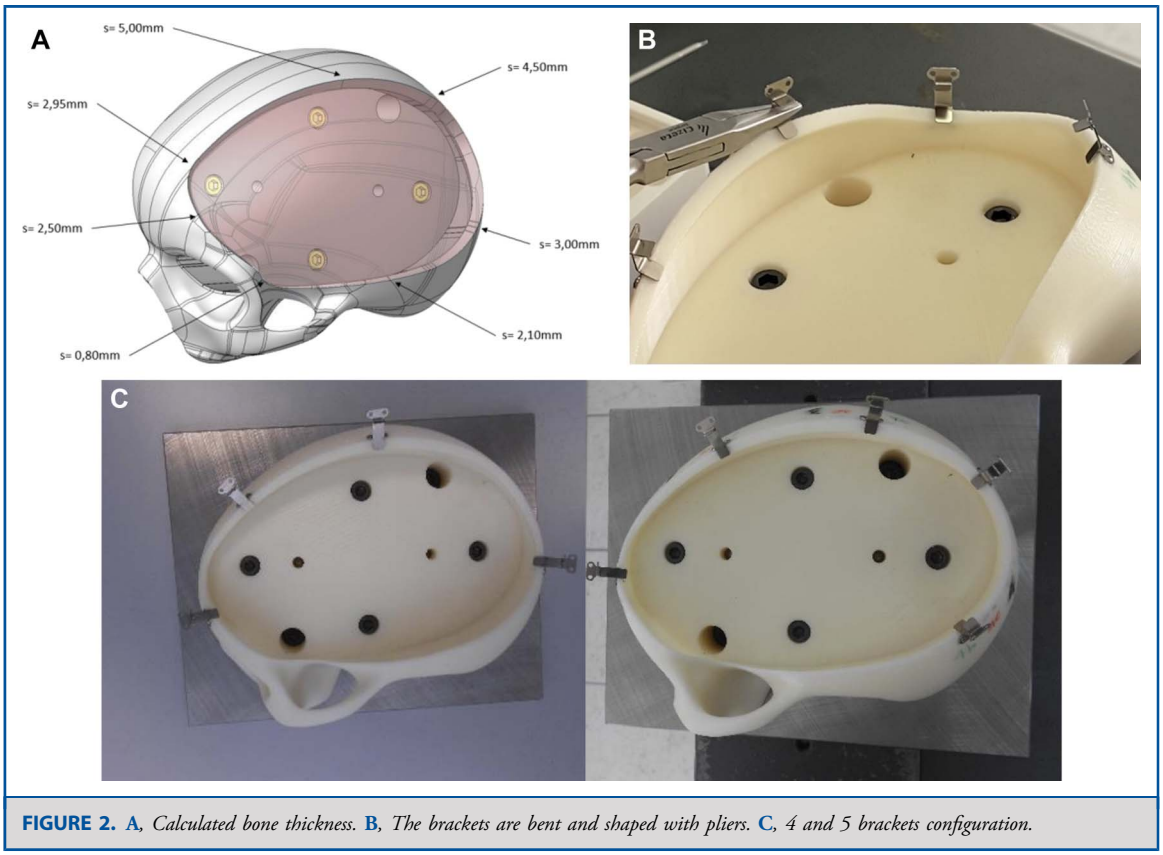

FIGURE 2. A, *Calculated bone thickness.* B, *The brackets are bent and shaped with pliers.* C, *4 and 5 brackets configuration.*

model made with plastic material acrylonitrile butadiene styrene (ABS), based on a thin-layer brain computed tomography (CT) scan of a 58-year-old female patient; on a dried human skull; and on the preserved head of a 67-year-old Caucasian male (2 sides). A preliminary series of 2 patients, a 59-year-old man with car traffic accident and a 78-year-old woman with malignant middle cerebral artery ischemic stroke, is reported. Patients have consented to the procedure and to the use of clinical data anonymously for scientific purposes. The patients consented to publication of their images. Institutional review board/ethics committee approval was not necessary for this study, according to the local regulations and guidelines. Permission was obtained appropriately for the publication of the cadaveric images.

Cranial Brackets Characteristics

These are titanium brackets, characterized by the presence of shelves and holes for screw fixation on the skull and on the bone flap, and are designed to be malleable and adaptable to the bone flap (Figure 1B). The height of the brackets and subsequent elevation of the cranial flap are designed to allow for significant expansion of the brain in the amount necessary to control intracranial pressure (Figure 1C).

Surgical Technique

The operative technique adopts the preferential use of the modified Kempe incision, which guarantees a better vascularization and a greater degree of extension of the myocutaneous flap facilitating the skin closure. The largest possible craniectomy is recommended. The bone flap must include frontal, parietal, and temporo-occipital bones and, as currently indicated by the guidelines of the Brain Trauma Foundation, has dimensions of at least 12 × 15 cm^2. Augmentation duroplasty is performed according to the preferred technique. Each bracket is fixed with 4 screws, 2 on the skull and 2 on the bone flap (Figure 2). Five brackets are positioned on the skull first, fixing the portion marked with the letter C (Cranial) with the screws (Figure 3). It is recommended to avoid positioning the brackets on the basal portion of the craniotomy, where the bone is thinner (Figure 3A). The brackets are shaped and bent with pliers until they fit perfectly to the bone flap, which will rest on the shelves (Figure 3B). At this point, each bracket is fixed with 2 screws to the bone flap. To facilitate the expansion and closure of the scalp, 2 additional procedures can be executed, although, in our experience, it was not necessary: Several perpendicular cuts can be made in the galea, and the pericranium can be detached from the scalp adjacent to the craniotomy. The myocutaneous flap is finally closed in the usual way.

Mechanical Testing

Mechanical tests were performed on the bone flap fixed by the brackets positioned in different numbers (4 or 5 brackets) and in different positions on the skull and bone flap (Figure 3C). The skull models were fixed on a steel plate and a perpendicular or lateral force was applied to the bone operculum through an ABS pusher fixed to a steel pin with speeds ranging from 1 mm/min to 500 mm/min until failure, defined as permanent deformation of the brackets, was achieved. A Zwick-Roell dynamometer (load cell 10KN mod. K) was used for the measurement. Load and displacement data were recorded continuously during the tests.

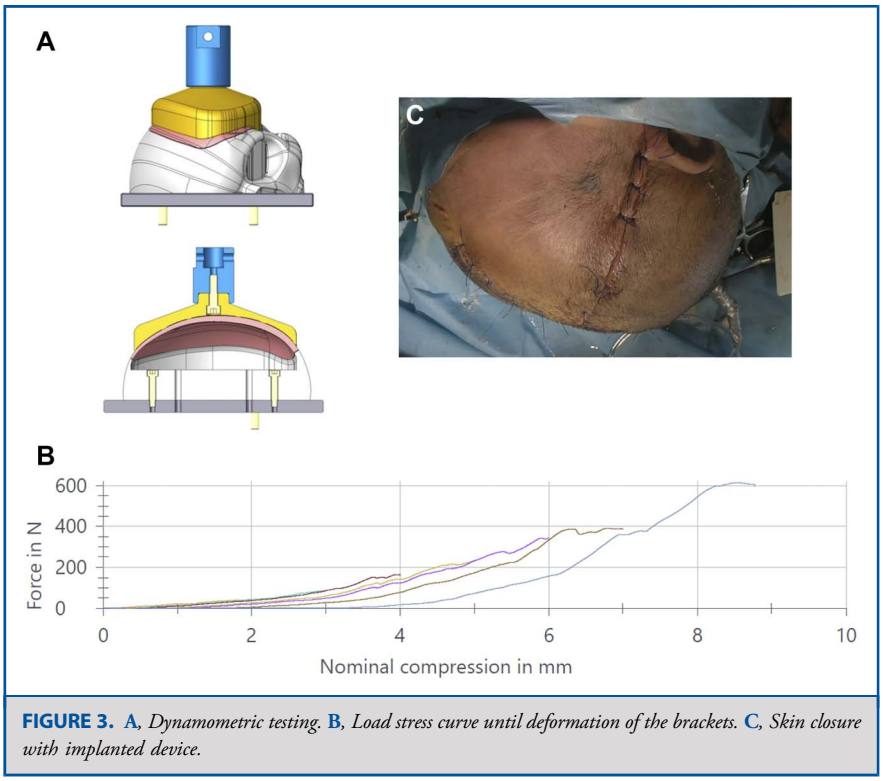

FIGURE 3. A, *Dynamometric testing.* B, *Load stress curve until deformation of the brackets.* C, *Skin closure with implanted device.*

RESULTS

Permanent deformation of brackets was achieved in ABS skull models at 402 ± 9 N in the configuration with 4 brackets and 637 ± 13 N in the configuration with 5 brackets. Deformation usually occurred in 1 or at most 2 brackets, and there has never been a rupture of the bracket, breakage of 1 or more screws or screw pull-out. In the human skull, which was only tested in the configuration with 5 brackets, the mechanical loads supported were higher than those on the ABS model, equal to 658 ± 9 N. The different speed of application of the compression and shear forces did not significantly modify the deformation resistance of the brackets. The repositioning and suturing of the myocutaneous flap, which aroused some concern from the theoretical point of view, proved instead to be easily feasible in the anatomic specimen, and even in clinical cases, no particular difficulties were encountered in the closure and the wounds healed adequately.

Preliminary Case Series

Clinical Case 1

A 59-year-old man arrived at our hospital after a car accident. On admission, he was Glasgow Coma Scale 13 and the initial CT scan showed a thin acute subdural flap of the left convexity, a linear skull fracture and small frontotemporal cortical contusions on the left. Over the next hours, there was progressive neurological deterioration to coma and the patient was sedated, intubated, and a transducer was placed for ICP monitoring. CT showed a progression of the cerebral contusions. ICP was initially controlled with osmotic diuretics but subsequently increased up to 30 mm Hg. The CT scan showed a midline shift of approximately 5 mm, so it was decided to perform an augmentative craniotomy. After surgery, there was a decrease in ICP to values stably below 15 mm Hg and normalization of brain shift. After 12 days, the ICP transducer was removed. In the early postoperative period, the bone operculum was esthetically acceptable (Figure 4). At 3 months, the patient had moderate disability (Glasgow Outcome Score Extended 5). The patient died at 4 months from surgery for general medical complications.

Clinical Case 2

A 72-year-old woman presented with left hemiplegia, and findings showed massive ischemia of the right middle cerebral artery territory. The National Institutes of Health Stroke Scale score was 13. The patient did not fit the criteria for arterial thrombectomy because of the clinical and radiological image and the time window. At 30 hours after admission, there was a deterioration in the level of consciousness. Brain CT scan showed demarcation of the ischemic area with midline shift of approximately 7 mm, and indication for augmentation craniotomy was given. Postoperative brain CT showed shift reduction to 3 mm. The patient was weaned off the ventilator and extubated. CT scan at 2 months showed ischemic outcome and absence of complications. At 6 months, the patient has severe disability (Glasgow Outcome Score Extended 4). It was not necessary to reposition the bone operculum as well in this case because it was esthetically acceptable (Figure 5).

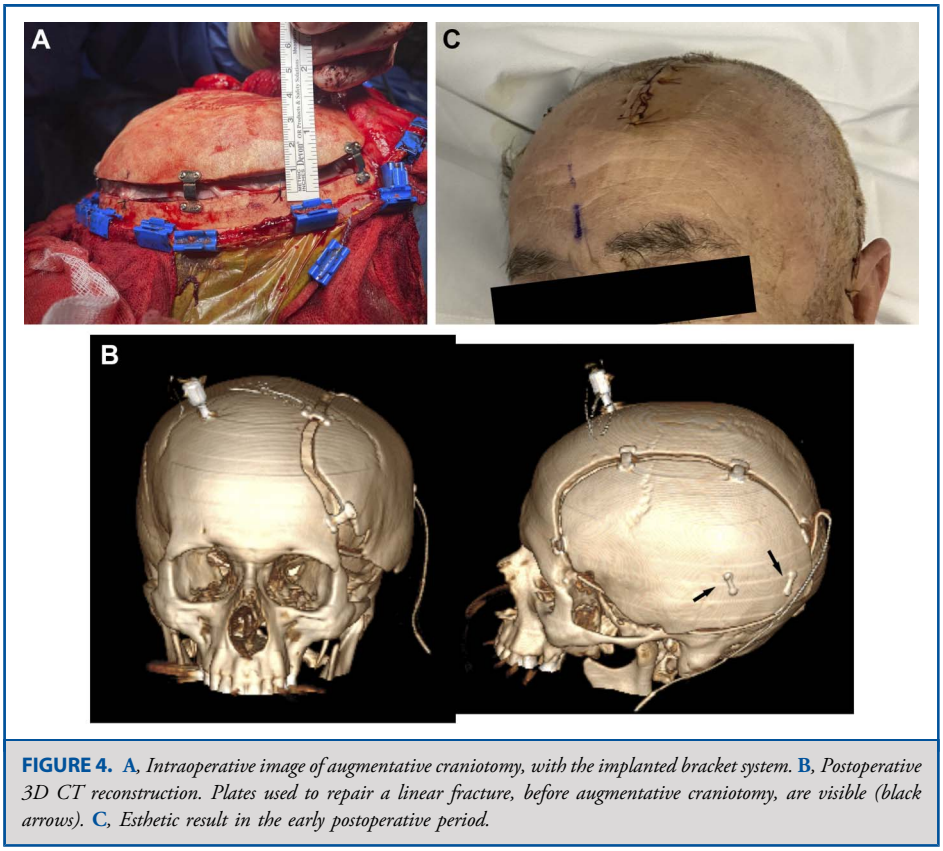

FIGURE 4. **A**, *Intraoperative image of augmentative craniotomy, with the implanted bracket system.* **B**, *Postoperative 3D CT reconstruction. Plates used to repair a linear fracture, before augmentative craniotomy, are visible (black arrows).* **C**, *Esthetic result in the early postoperative period.*

DISCUSSION

The role of DC in reducing intracranial pressure and improving outcome in a number of diseases that include cerebral edema secondary to head trauma, aneurysmal subarachnoid hemorrhage, malignant cerebral ischemia of middle cerebral artery territory, intraparenchymal hematomas, tumors, and infections has been widely documented.[1] However, this surgery is associated with several complications related to the removal of the operculum. In addition, the cranioplasty surgery can be difficult and not free from complications because of the presence of tenacious adhesions between the muscular and subcutaneous tissues and the dura mater and the cerebral cortex.[1] Finally, the cost of storing the operculum or the production of a custom-made prosthesis is not negligible. For these reasons, several alternatives to classical DC have been proposed in which the bone flap is left in place after craniotomy. These are the hinge craniotomy, the floating craniectomy, and other techniques in which the bone is fixed with expandable plates. All these cases have in common that brain expansion and herniation must overcome the resistance given by the closed flap, and compared with the classical DC, the space available for brain expansion is reduced by the encumbrance of the bone flap itself. The advantages of these techniques are the possibility of avoiding reoperation, as in hinge craniotomy, or, in any case, being able to perform a simplified procedure to reposition the bone flap, and the reduction of costs. The effectiveness of the hinged and floating DC has been shown to be not inferior to that of the classic DC, although there are no randomized comparison trials. In this study, we evaluated the biomechanical reliability of a novel bracket system designed to keep the bony operculum elevated after a craniotomy for decompression purposes. This type of surgery, which we refer to as augmentative craniotomy, is based on a different mechanism than both classic DC and hinge craniotomy or floating craniectomy. In these cases, the intracranial pressure must overcome the elasticity of the flap to cause an increase in intracranial volume. Furthermore, in the case of hinge craniotomy, flap expansion can only occur on 1 side of the craniotomy. In our proposed technique, the intracranial volume is increased by elevating the operculum with the brackets and eliminating soft tissue springback. The amount of lifting required to ensure adequate intracranial volume expansion was derived by taking into account data collected from both a series of clinical cases (unpublished data) and the literature.[9-12] Clinical studies have shown that an expansion of the brain parenchyma of at least 5 mm, which allowed for an average herniation volume of 39.5 ± 23.6 mL, is sufficient to reduce intracranial pressure in cases of DC for malignant middle cerebral artery cerebral ischemia and traumatic brain injury.[11,12] We also analyzed our case series

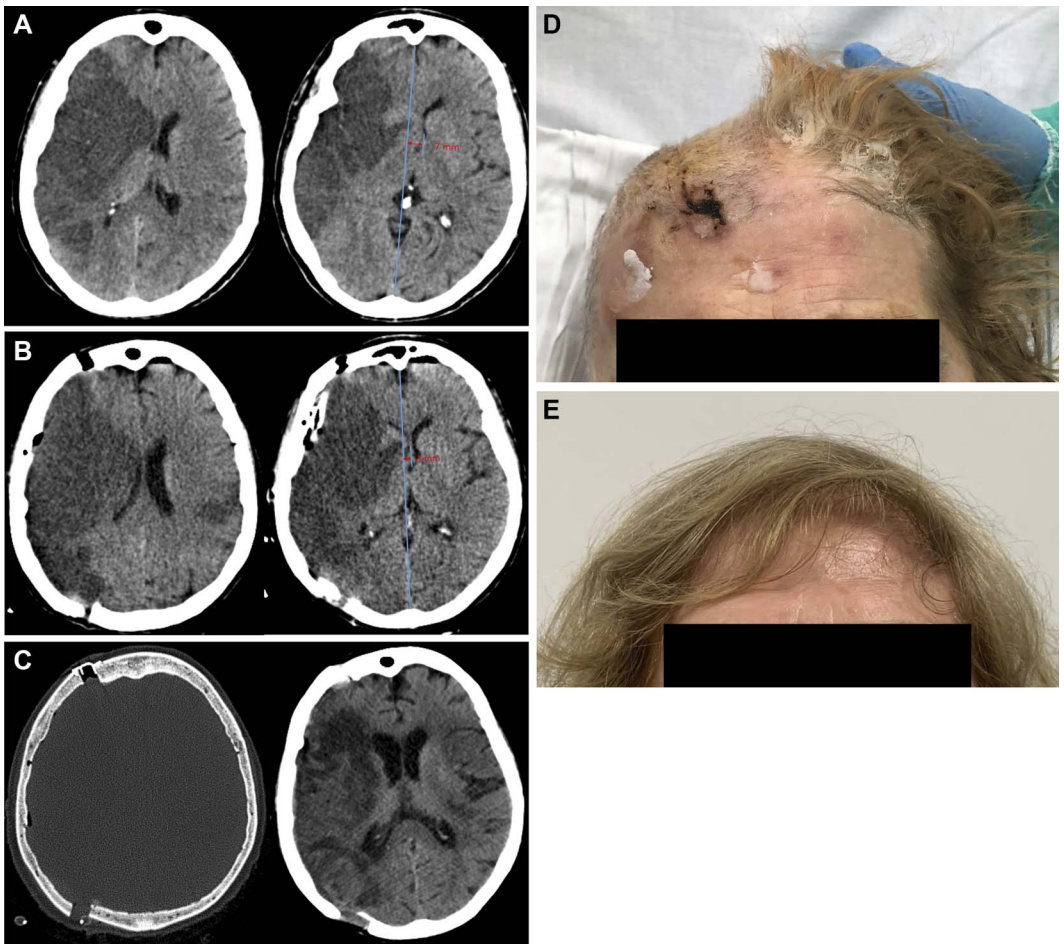

FIGURE 5. **A**, *Preoperative CT of patient with right middle cerebral artery stroke.* **B**, *Day 1 postoperative CT scan showing reduction of the midline shift.* **C**, *Three months postoperative CT scan showing the ischemic chronic injury and the absence of complications such as hygromas, hydrocephalus, or brain shift.* **D**, *Esthetic result in the early postoperative period.* **E**, *Esthetic result 6 months after the intervention. CT, computed tomography.*

of patients who underwent DC and found similar values of brain herniation (not yet published data). Rialto brackets are 10-mm long and when molded provide at least 7 to 8 mm of flap lift from the outer cranial surface, making these values far exceeded. Additional advantages, compared with the classic DC, are the reduction of the risk of flap bleeding because of the hemostatic effect of its compression against the bone and the possibility of avoiding a cranioplasty reintervention, thereby reducing the overall morbidity of craniectomized patients and related costs, being it either flap storage costs or the making of a customized prosthesis and the duration of the procedure. From the point of view of esthetic outcome, in our limited experience, it seems that augmentative craniotomy confers an acceptable esthetic appearance. However, it should be pointed out that a permanently expanded skull may be only acceptable in a patient with thick hair and scalps. However, in patients with thin or receding hairlines (and thinner scalps), this may not be an acceptable long-term outcome as scalps tend to contract over time and scar into existing skull defects. To clarify this point, a longer follow-up of 6 to 12 months and a larger number of cases will be needed. Should bone repositioning become necessary, however, it seems advantageous and cost-effective to be able to use the autologous operculum and reduce manipulation of the dura mater, which is often tenaciously adhered to the myocutaneous flap, and avoid the consequent risks of bleeding and cortical injury. Regarding the mechanical stability, we found that the configuration with 4 brackets already guarantees an adequate stability of the bone operculum, higher than that reported for other systems currently used and available on the market that presented a mechanical resistance to compression lower than 300 N.[8] The addition of a bracket, switching from the 4-bracket to the 5-bracket conformation, showed a significant increase in mechanical stability, which was more than 50%

higher, going from 400 N to 600 N. During the tests, no bracket breakage or screw pull-out was noticed. At the maximum load, deformation of 1 or 2 brackets was achieved.

Limitations

Overall, the results of our study demonstrate that augmentative craniotomy could become another tool in the armamentarium of neurosurgeons for the management of intracranial hypertension. Further studies will be needed to validate the efficacy of this new technique in the clinical setting.

CONCLUSION

In this study, we performed functional biomechanical analysis and preliminary clinical evaluation of a new device designed to keep the bone flap elevated from the skull to expand intracranial volume. This technique has been shown to be feasible in the experimental and cadaveric setting, and the mechanical stability is adequate for use in clinical cases. Preliminary clinical results are encouraging.

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Disclosures

Dr Berra is the inventor and has intellectual property of the Rialto device. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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COMMENT

The authors present a novel plating system that holds an autologous craniotomy flap in a rigid, suspended position, allowing for some degree of cerebral decompression. This system bears similarity to the hinge craniotomy in performing a "partial decompression" without full removal of the flap. Conceptually this is also similar to a laminoplasty in the spine. This is an interesting idea however I feel that further prospective in vivo study will be needed to inform putative advantages and disadvantages of this technology.

There are some theoretical disadvantages. This would likely require an additional surgery to replace the bone flap in a flush anatomical position once brain swelling has resolved, although the authors did not feel the need to do this within the period of follow-up reported for the 2 patients they presented. There is also a risk that the devascularized bone flap and the void that will develop beneath it will lead to an increased risk of infection. By contrast, a hinge craniotomy allows for dynamic decompression, avoids a void and generally does not require a second procedure for full fixation of the bone flap. In neurotrauma there is currently a lot of academic interest in the reabsorption of cranial bone flaps and there is some basis to suspect that this plating system could promote reabsorption and loss of the bone flap. There is also a theoretical risk that closing the scalp could be problematic with this technique, or that cranial wound dehiscence could be more likely in a wound under increased tension.

This plating system would avoid the placement of bone flaps in the freezer or the morbidity of placing a flap in the abdomen or thigh. It would be particularly attractive if this means of plating helped to reduce the incidence of syndrome of the trephined as compared with craniectomy. Ultimately I agree with the authors' conclusion that "further clinical studies will be needed to validate its efficacy."

Gregory W. J. Hawryluk
Akron, Ohio, USA