Biomechanics of a novel reversibly expandable dynamic craniotomy bone flap fixation plate

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OBJECTIVE Biomechanical evaluation of a novel expandable cranial fixation plate was assessed in cadavers. The dynamic craniotomy procedure uses low-profile reversibly expandable plates that allow cranial decompression by providing for intracranial volume expansion without removal of the bone flap. The plates allow reversible outward movement of the bone flap upon an increase in intracranial pressure (ICP) and also retract the bone flap and prevent it from sinking inside the cranium once the ICP normalizes.

METHODS A comparative evaluation of the extent of ICP control with an increase in intracranial volume between various bone flap fixation techniques was undertaken along with testing of the expandable plate compliance. Static compression tests of the plates were performed to assess bone flap fixation and prevention of sinking. Quasi-static shear tension testing of the plates was undertaken to test the tolerance of the plates for expansion. Fatigue shear tension evaluation of the plates was undertaken to assess tolerance for repetitive expansion and contraction.

RESULTS The dynamic craniotomy provided superior control of ICP with an increase in intracranial volume compared to the hinged craniotomy and standard craniotomy techniques ($p < 0.001$). Static compression results revealed that the plates withstood bone flap sinkage with a mean peak load of 643.3 ± 26.1 N and a mean inward bone flap displacement of 1.92 ± 0.09 mm. Static shear tension results indicated that the plates could withstand a peak expansion of 71.6 mm. Dynamic shear tension testing of the plates with repetitive 15-mm outward expansion and retraction for a total of up to 500 cycles revealed no cracking and no failure points.

CONCLUSIONS The reversibly expandable plates provide for a low-profile bone flap fixation with rigid restriction of bone flap sinking and also enable cranial decompression with a high tolerance for repetitive expansion and contraction.

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KEYWORDS cerebral edema; cranial fixation; plate; craniectomy; cranioplasty; decompressive craniotomy; intracranial hypertension; brain swelling; surgical technique

Decompressive craniotomy involves leaving a mobile craniotomy bone flap in place and provides for intracranial volume expansion. Several decompressive craniotomy techniques have been developed in order to reduce the need for a decompressive craniectomy along with the cumulative risks associated with a craniectomy as well as the mandated subsequent cranioplasty.[1,2,7,9–14,16,17,20,21] Currently utilized decompressive craniotomy techniques are limited because of their inability to prevent bone flap sinking[1,2,13,16] and their tendency to restrict the extent of intracranial volume expansion.[7,9,10,14,17,20,21]

More recently the procedure of dynamic craniotomy has been introduced, which involves fixating the bone flap with plates that allow for outward movement with brain swelling or increase in intracranial volume but also prevent the bone flap from sinking inside the skull.[12] Dynamic craniotomy involving cranial bone flap fixation with reversibly expandable low-profile plates provides another

ABBREVIATIONS ICP = intracranial pressure.
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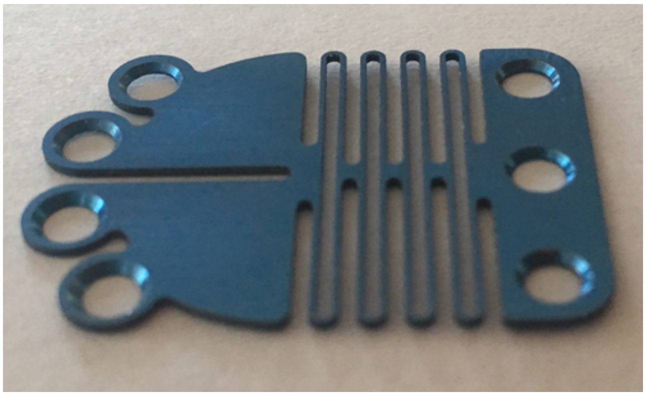

FIG. 1. Dynamic plate. Figure is available in color online only.

option in the management of postoperative complications related to brain swelling or intracranial hemorrhage with immediate cranial decompression without bone flap removal. We assessed the feasibility of this procedure and here we report the results of our biomechanical analysis evaluating the functionality and compliance of the dynamic reversibly expandable novel fixation plates.

Methods

The objective of the testing was to characterize the mechanical performance of the low-profile reversibly expandable cranial bone flap fixation plates (NeuroVention, LLC) in both quasi-static and fatigue shear tension. Static and dynamic shear tension testing was undertaken to characterize the mechanical integrity of the plates when subjected to cerebral swelling or increased intracranial pressure during the postoperative period. Static compression tests were also performed in craniotomized cadaver skulls to test the resistance to bone flap sinking. A feasibility evaluation of the dynamic craniotomy technique and extent of intracranial pressure (ICP) relief with progressive intracranial volume increase was also undertaken. Many aspects of the methods we used in this study have been reported in our previously published work.[12]

Dynamic Plate Characteristics

The dynamic plate (Fig. 1) comprises solid ends with holes for placement of screws into the bone flap at one end and the skull at the other end. The solid portions are connected with a configuration of flat interconnections that function similarly to a spring that reversibly expands and contracts as well as angulates, depending upon the tension exerted. The solid portion at one end of the plate has a longer configuration, and when positioned on the bone flap overlapping the craniotomy kerf, it prevents the bone flap from sinking inside the cranium. The plates allow outward bone flap movement to accommodate an increase in ICP and/or intracranial volume and retract the bone flap in a flush position once the ICP normalizes. The plate has a low profile and is made from titanium alloy for optimal CT/MRI compatibility. The plate functionality and bone flap outward movement with an increase in intracranial ICP/volume and subsequent anatomical retraction with decreasing of intracranial volume are shown in the video clip (Video 1).

VIDEO 1. Dynamic craniotomy video demonstrating the outward bone flap movement enabled by the dynamic plates with progressive increase in intracranial volume/ICP and anatomical flush retraction with resolution of the increased ICP. Copyright Rohit Khanna. Used with permission. Click here to view.

Surgical Technique

Five human cadaveric skull specimens were obtained from 3 women and 2 men with an age range from 70 to 87 years (mean 79 years). Specimens were obtained fresh frozen and thawed in a bath of normal saline at 30°C. The skull was attached to a block of laminated wood with rigid fixation so as not to allow any movement of the skull relative to the board. A craniotomy bone flap with beveled edges was performed in each specimen. The bone flap was then fixed to the skull using 3 expandable plates (Fig. 2). The larger solid plate end is positioned on the bone flap overlapping the craniotomy kerf (Fig. 3). To facilitate scalp expansion with outward migration of the bone flap, placing several slits in the galea and also degloving the scalp from the pericranium adjacent to the craniotomy is recommended.

Static Compression Testing

Static compression tests were performed after implantation of the dynamic plates for bone flap fixation in each cadaveric skull (Fig. 4A). After fixation of the plates to the bone flap and skull with screws, the bone flap mechanical integrity and bone flap sinking resistance were assessed with compression of the bone flap. Three dynamic plates on each bone flap were placed at equidistance around the perimeter of the craniotomy.

Each skull specimen was mounted to the platform of an electromechanical test machine (MTS Corp.) and a compressive load was applied by a pushrod that was connected to the crosshead of the test machine (Fig. 4B). The pushrod was a minimal friction universal joint unconstrained in bending and torsion. When loaded, the crossheads applied a resilient force to the bone flap and directed the load along the axis of the pushrod. The angle of the pushrod was adjusted such that the axis of the pushrod was perpendicular to the bone flap. This ensured maximum compressive displacement of the bone flap inside the craniotomy defect and therefore maximally loaded the plates.

A compressive load was applied to each skull bone flap using the electromechanical test machine at a rate of 5 mm/min under displacement control to a maximum displacement of 2 mm or until failure was achieved. The test was stopped after the onset of a failure mode, for which failure was defined as permanent deformation resulting from fracture, plastic deformation, or loosening that rendered the plates ineffective or unable to adequately resist load.

Load and displacement data were recorded at a relevant sampling rate throughout the test.

Static Shear Tension Compliance Testing

Static shear tension tests were performed to evaluate

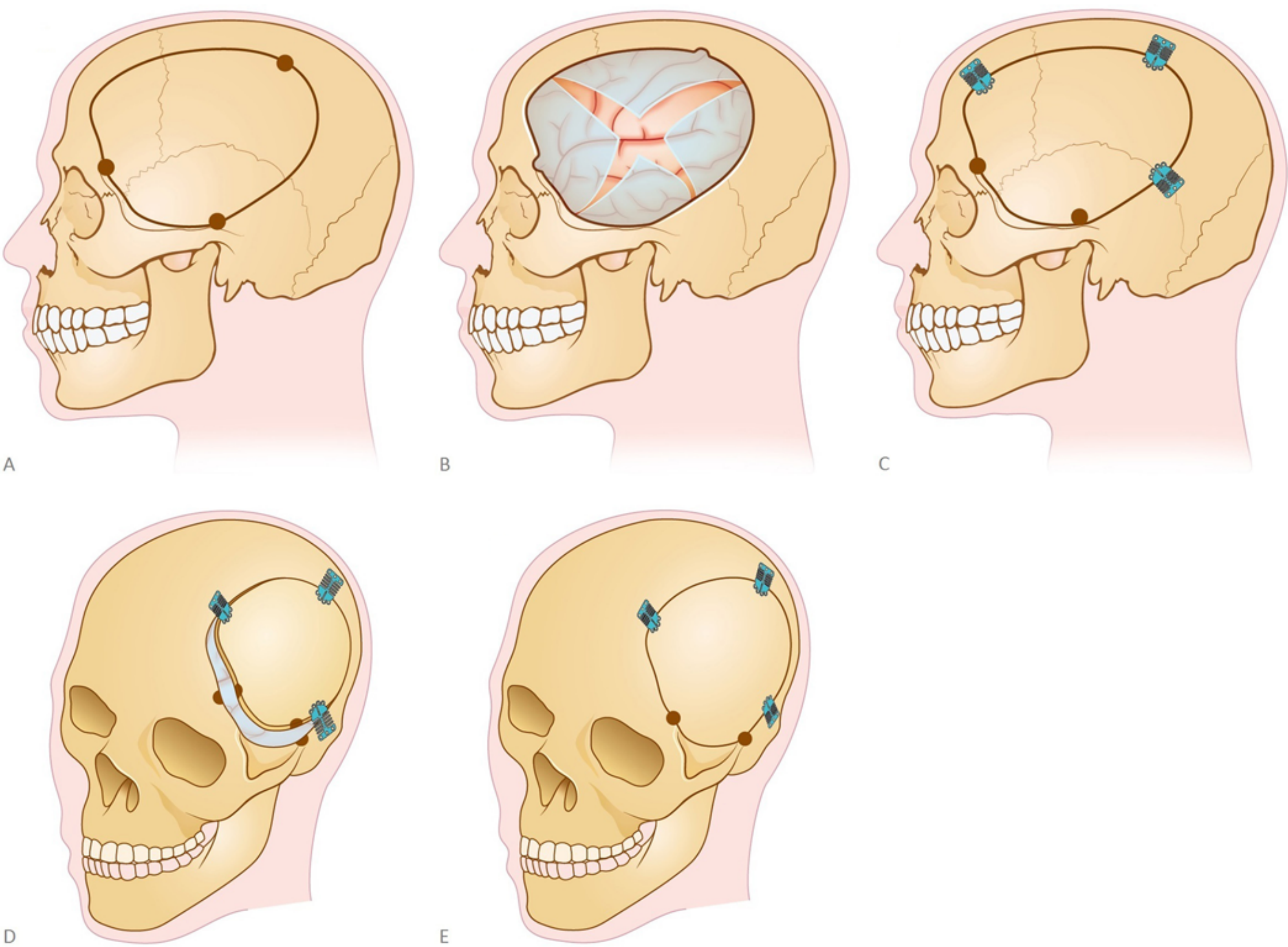

FIG. 2. Illustration of the dynamic craniotomy technique. **A:** Craniotomy with bone flap removal. **B:** Durotomy with dural expansive patch grafting. **C:** Fixation of bone flap with dynamic plates. **D:** Bone flap elevation to accommodate an increase in intracranial volume from brain swelling and/or intracranial hemorrhage. **E:** Retraction of bone flap in anatomical flush position after resolution of brain swelling. Copyright Rohit Khanna. Used with permission. Figure is available in color online only.

the extent of expansion that the plates could tolerate. The solid end portions of each plate intended for mounting onto the skull and bone flap were rigidly clamped into a static shear tension fixture. The static shear tension fixture was a dual clamp test fixture, with the first clamping apparatus mounted to the platform of the electromechanical test machine and the second clamping apparatus mounted to the test machine's crosshead and load cell (Fig. 5A). The clamps were placed adjacent to one another separated by the reversibly expandable portion of the plates (Fig. 5B). The clamp connected to the crosshead could translate parallel to the clamp mounted on the base of the test machine, creating a shear displacement between clamping fixtures. Prior to testing, each plate was placed into the clamps so that it was maximally flat and this location was set as the origin for the crosshead. The expandable portion of each plate was not altered or impinged upon in the fixture, thus allowing the expandable portion of each plate to freely operate as intended during translation of the crosshead.

Each plate was sheared with tension produced by the electromechanical test machine at a rate of 30 mm/min under displacement control until failure was achieved. The test was stopped after the onset of a failure mode. Failure was defined as permanent deformation that rendered the plate ineffective or unable to adequately resist load.

Load and displacement data were recorded at a relevant sampling rate throughout the test.

Dynamic Shear Tension Compliance Testing

Dynamic shear tension tests were performed to evaluate repetitive expansion with outward movement and retraction of the plate by using the electromechanical test machine in displacement control (Fig. 6A). The solid ends of the plate were fixated to the test machine and repetitively displaced back and forth from a neutral 0-mm position to 15-mm outward displacement between the 2 ends. The rate for applying the cyclical compressive load was 0.2 Hz for a duration of 500 cycles at a specified displacement of one solid end relative to the other solid end from 0 mm to 15 mm, which remained constant while testing (Fig. 6B). Load and displacement data were recorded at a relevant sampling rate throughout the test. The plates were dynamically tested until functional failure was achieved.

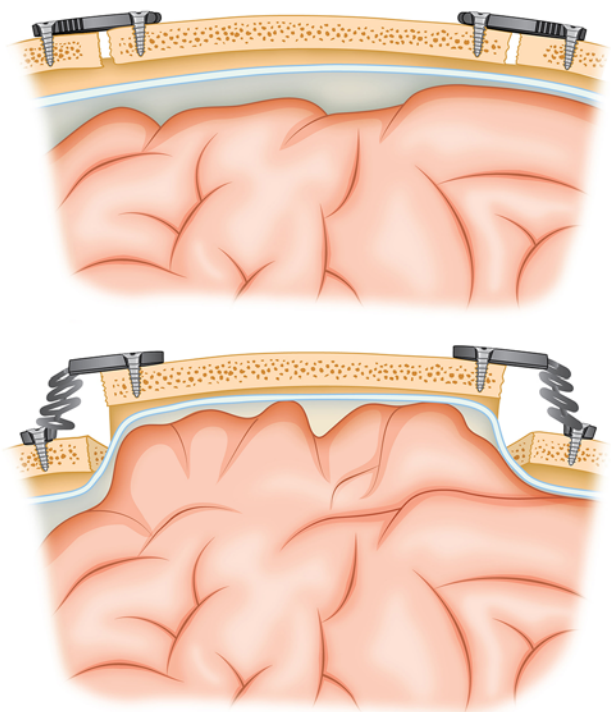

FIG. 3. Illustration of the dynamic craniotomy. **Upper:** Bone flap in anatomical position with the dynamic plates. The solid portion of the larger end overlaps the craniotomy kerf or burr hole defect, thus preventing the bone flap from sinking. **Lower:** Outward migration of the bone flap with brain swelling. Copyright Rohit Khanna. Used with permission. Figure is available in color online only.

Functional failure was defined as permanent deformation resulting from fracture or plastic deformation that rendered the plate ineffective or unable to adequately resist load. The failure mode was documented if failure occurred before 500 cycles.

Cranial Decompression Evaluation

An increase in ICP was achieved with a tissue expander (Mentor Worldwide, Inc.) inserted inside the skull in the subdural space prior to replacement of the bone flap. The tissue expander also comprised tubing through which saline was injected with a syringe. The pressure inside the skull was recorded with a digital manometer (Pyle). Testing of the dynamic plates was performed with the bone flaps attached to the skull using 3 plates. The tissue expander was serially dilated and the ICP was recorded.

The hinge craniotomy technique was also tested in another set of evaluations. The expandable plates were removed and the same bone flaps were attached to the skulls using a standard fixed Synthes plate on one side of the bone flap and 2 Synthes plates secured only to the bone flap on the other side to prevent bone flap sinking. The tissue expander was serially dilated and the ICP was recorded.

We also evaluated the standard craniotomy technique using the Synthes fixed cranial plates. For all 5 of the skull specimens tested with the previously described techniques, the same bone flap used in the previous tests was attached to the skull with 3 rigid cranial fixation plates. The tissue expander inside the skull was then sequentially dilated and the ICP recorded until it approached 100 mm Hg.

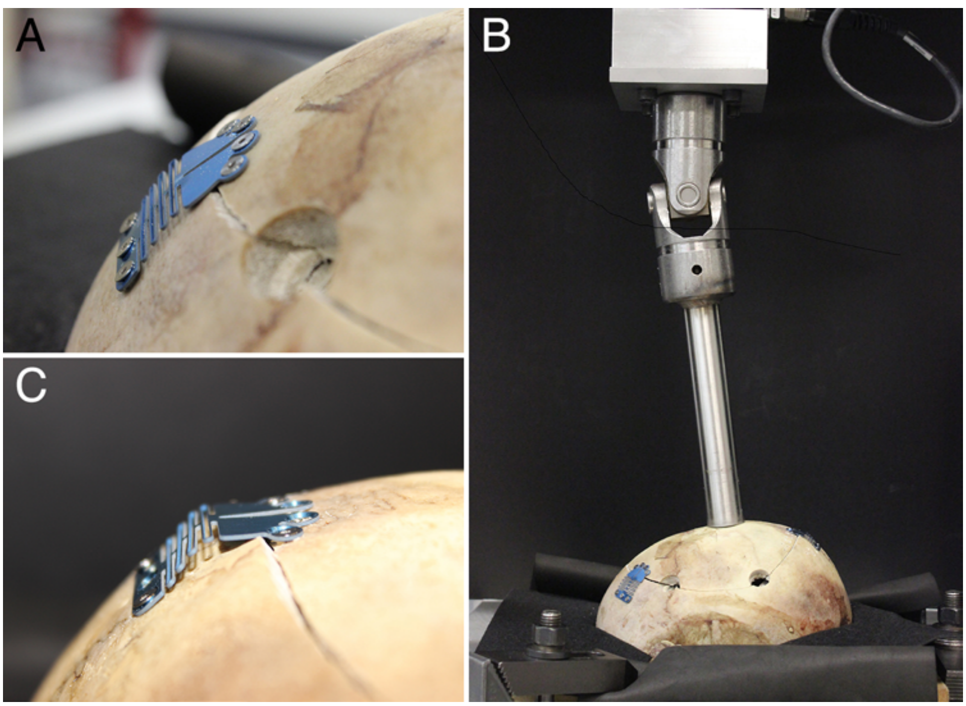

FIG. 4. **A:** Bone flap fixation with implanted dynamic plate on a cadaver skull. **B:** Static compression testing of a cadaver skull mounted to the platform of the electromagnetic test machine with a compressive load applied by a pushrod connected to the crosshead of the test machine. **C:** Failure point with plate bending over the craniotomy kerf defect after peak compressive loads. Figure is available in color online only.

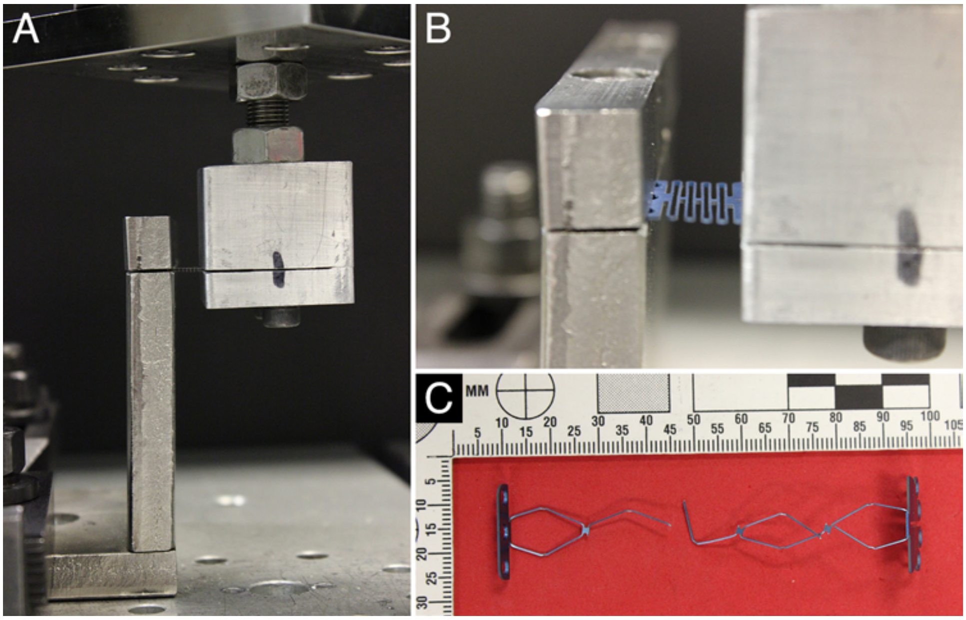

FIG. 5. A: Shear tension compliance testing with the solid plate ends rigidly clamped into a static shear tension fixture. **B:** Close-up view of the plate clamped to the electromechanical test machine. **C:** Failure point at peak displacement with several fractures at the connections of the expandable portion of the plate. Figure is available in color online only.

Results

Static Compression Testing

Static compression results indicate that the dynamic plates withstood a mean peak load of 643.3 ± 26.1 N with a mean inward bone flap displacement of 1.92 ± 0.09 mm with a beveled craniotomy. With straight craniotomy edges and a kerf width of 1 mm, the dynamic plates withstood a mean load of 402.2 ± 46.9 N with 1.82 ± 0.21 mm displacement. The failure mechanism for each specimen was variation of the degrees of plate bending over the craniotomy kerf defect (Fig. 4C). No plate failure, breakage, or screw pullout was noted. In comparison, studies testing rigid cranial fixation plates and clamps have reported a peak load tolerance of less than 300 N with a 2-mm displacement.[4,15]

Static Shear Tension Compliance Testing

Static shear tension results indicate that the dynamic plates can withstand a peak displacement of 71.6 mm. The failure mechanism in this test was several fractures at the connections of the expandable portion of the plate (Fig. 5C).

Dynamic Shear Tension Compliance Testing

The dynamic plate tested in dynamic shear tension of repetitive 0- to 15-mm displacement for 500 cycles at 0.2 Hz revealed no cracking or indications of failure. The reversibly expandable portion had a slight plastic deformation in the direction of the shear after 500 displacement cycles (Fig. 6C).

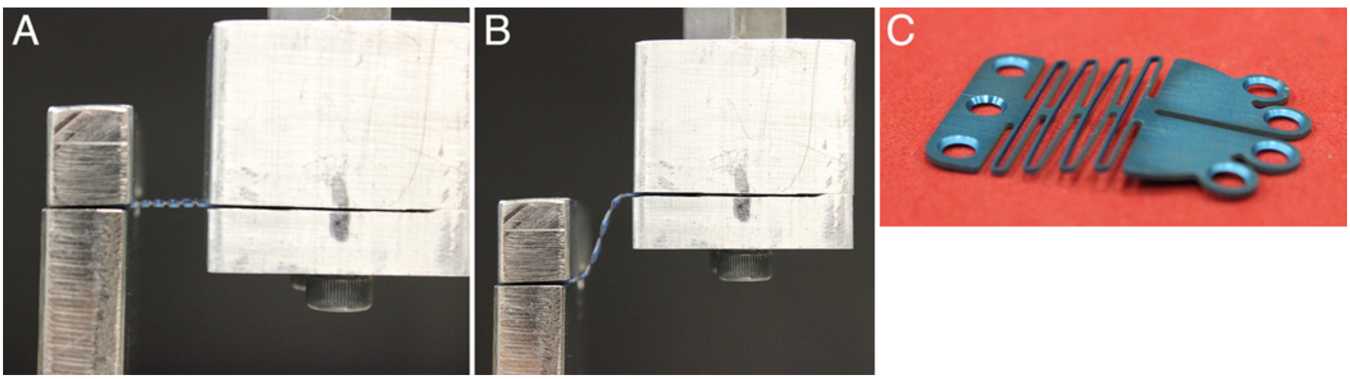

FIG. 6. A: Dynamic shear tension testing with a plate in a neutral position mounted on the electromechanical test machine set for displacement control. **B:** The mounted plates were subjected to repetitive outward movement and anatomical retraction of the solid plate ends for a total of up to 500 cycles. **C:** Failure point of the plate with slight plastic deformation in the direction of the shear after 500 displacement cycles. Figure is available in color online only.

TABLE 1. Comparative analysis of ICP compliance with change in intracranial volume between standard craniotomy, hinge craniotomy, and dynamic craniotomy techniques

Intracranial Vol Above Baseline (ml)	Standard FP (mean mm Hg)	Hinge Craniotomy (mean mm Hg)	Dynamic EP (mean mm Hg)	p Value*
40	5.54	2.96	4.02	0.066
80	8.74	3.96	5.34	0.024
120	15.58	8.9	6.06	<0.001
160	25.96	12.2	6.7	<0.001
180	41.46	14.98	7.78	<0.001
200	65.56	18.2	8.92	<0.001
220	87.44	22.34	10.18	<0.001
240	103.86	27	12.4	<0.001

EP = expandable plate; FP = fixed plate.
* ANOVA.

Cranial Decompression Evaluation

The comparative results between the standard cranial fixation, hinge craniotomy, and dynamic decompressive craniotomy are summarized in Table 1 and Fig. 7. With the standard fixed plate craniotomy, a progressive increase in intracranial volume led to a sequential increase in ICP. After reaching a threshold, even a small increase in intracranial volume led to a proportionally higher ICP, with a 120-ml increase in intracranial volume raising the ICP from 15.5 to 103.8 mm Hg. With the dynamic craniotomy, we noted a significant increase in the intracranial volume expansion due to compliance of the bone flap in comparison to the rigid bone flap fixation. With a progressive increase in intracranial volume, outward bone flap migration was noted with the dynamic craniotomy along with maintenance of a normal ICP (< 13 mm Hg), whereas with rigid bone flap fixation the same intracranial volume increase resulted in an ICP of 103.8 mm Hg (Fig. 7). Compared to the standard craniotomy, the dynamic craniotomy allowed an additional 120-ml intracranial volume increase while maintaining a normal ICP. Despite repetitive expansion and retraction of the bone flap, we did not notice any failure or breakage of the plates or screws. No screw pullout was noted either. Unhinged bone flap outward movement was seen with an increase in intracranial volume and subsequent flush retraction of the bone flap with normalization of the intracranial volume (Video 1). Delayed compliance of the plates was also tested by maintaining a 15-mm outward bone flap expansion for up to 2 weeks and no lateral bone flap migration with outward bone flap movement was noted with a flush anatomical bone flap return each time. We did not encounter any restriction of the expandable plate component from surrounding tissue entrapment. Since the plates are placed on the outer surface of the skull and bone flap, we also did not encounter any intracranial content impingement with expansion and contraction of the plates (Fig. 3). The dynamic plate compliance allowed maintenance of ICP in the normal range despite an acute increase in intracranial volume reflective of a postoperative hemorrhage or cerebral swelling. With the use of standard fixed plates, however, high ICPs that would lead to cerebral herniation in a clinical setting were noted along with similar degrees of intracranial volume increase. The hinged craniotomy also provided ICP control, although the dynamic craniotomy was more effective in maintaining ICP in the normal range. The dynamic craniotomy was able to accommodate an additional 40 ml of intracranial volume increase compared to the hinge craniotomy. The dynamic craniotomy also provided superior ICP control compared to the hinge craniotomy when the increase in intracranial volume exceeded 160 ml.

The testing of the implants was undertaken without an intact scalp since the scalp loses its elasticity with lack of blood supply. In a real-world clinical situation, it is possible that the full expansion allowed by the plates and the resulting decreases in ICP that were measured in these cadaveric specimens may not be achieved.

Discussion

Postoperative intracranial hemorrhage and brain swelling are the most common and serious complications encountered after a craniotomy. These complications predominantly occur within the first 24 hours but can also occur up to 7 days later[5,6,19] and are associated with 36%–61% severe morbidity and mortality.[3,5,8] The incidence of a postcraniotomy intracranial hemorrhage ranges from 10.8% to 50%[6,19] with up to 6.9% of the patients requiring a reoperation.[3]

Decompressive craniotomy provides for immediate ICP relief following a postcraniotomy complication. The concept of intracranial volume expansion without removal of the bone flap has intrigued neurosurgeons, as is evidenced by the development of several decompressive craniotomy techniques.[1,2,7,9–14,16,17,20,21] Unfortunately the bone flap fixation techniques that allow for outward movement also allow bone flap sinking with inward movement.[1,2,13,16] The hinge craniotomy seems to prevent bone flap sinking but also limits the extent of intracranial volume increase due to the hinged nature of the bone flap fixation.[7,9,10,14,17,20,21] The ideal decompressive craniotomy technique involves allowing unhinged outward bone flap movement for maximal intracranial volume expansion but also restricting sinking of the bone flap inside the skull.[12]

Biomechanical testing results of the reversibly expandable plates indicate that these plates provide the ideal scenario for the dynamic craniotomy technique. The plates allow for outward bone flap movement with an increase in intracranial volume or pressure with subsequent retraction into anatomical position of the bone flap along with resolution of the increased intracranial pressure without any risk of sinking.

In general, most decompressive craniotomy procedures provide 1–2 cm of outside bone flap migration, although as little as 0.5-cm outward bone flap movement can accommodate the malignant brain swelling from an ischemic stroke.[18] The reversibly expandable plates can tolerate bone flap outward migration up to 7 cm prior to failure.

The reversibly expandable plates tested to 500 cycles of repetitive expansion and contraction revealed no failures. In a typical clinical scenario repetitive outward and inward bone flap migration would not be encountered. Generally, with either a postoperative hemorrhage or cerebral swell-

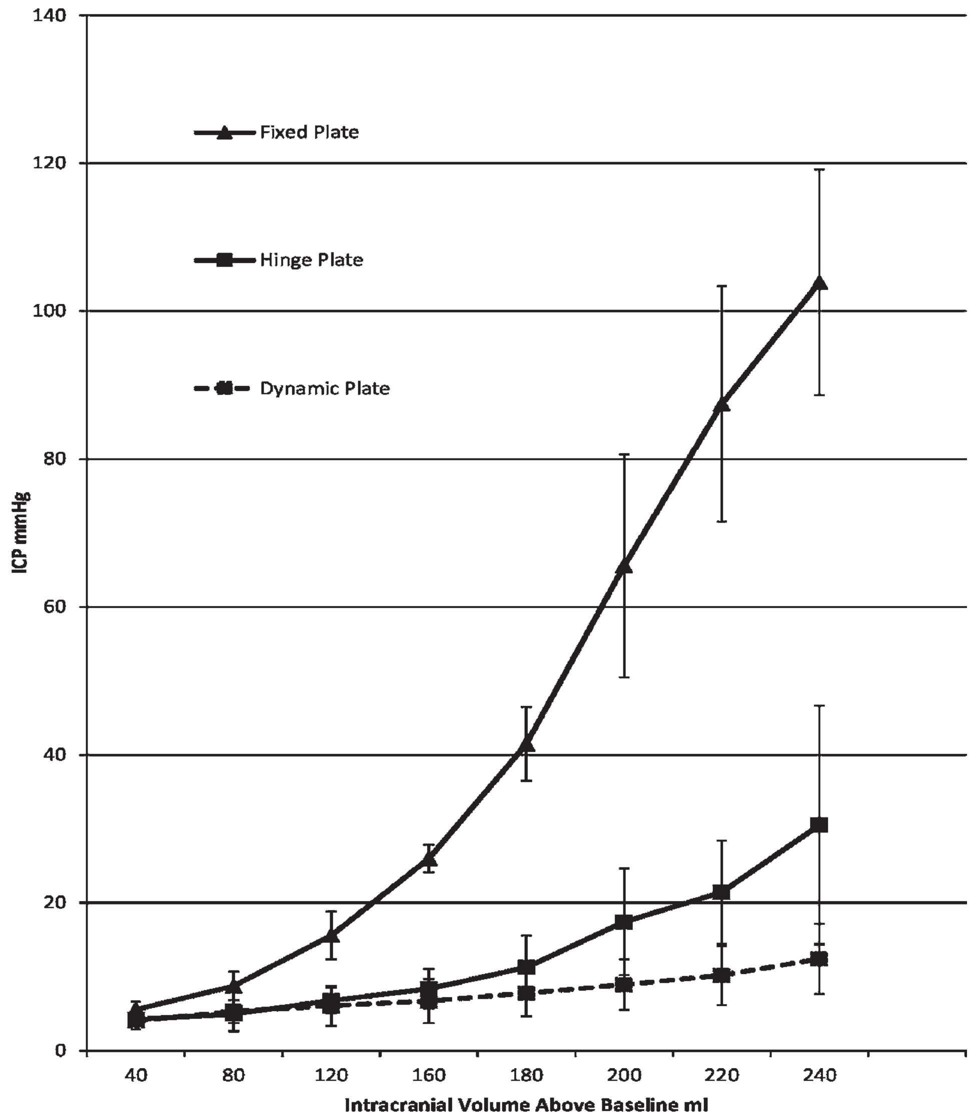

FIG. 7. Graphic depiction of the association between intracranial volume and ICP with fixed cranial plates, hinge craniotomy, and dynamic plates.

ing, the bone flap could migrate outward from the pressure exerted on the flap and once the swelling subsided over a matter of days to weeks, the bone flap would be retracted back into a flush position. While the dynamic craniotomy procedure is not meant to replace a decompressive craniectomy, it could potentially reduce the need for a postoperative bone flap removal or craniectomy and provide another tool in the armamentarium for the management of postoperative elevated ICP from either a rehemorrhage or cerebral edema.

Conclusions

Biomechanical functional analysis of novel reversibly expandable plates used for dynamic craniotomy was performed in this study. The mobile bone flap migration with reversible intracranial volume expansion allowed by the low-profile plates provides for control of high intracranial pressures associated with postoperative complications while also preventing the bone flap from sinking inside the skull. The dynamic plates can tolerate repetitive expansion and contraction as well as outward bone flap migration with tolerances beyond what would be expected in a clinical scenario.

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Disclosures

Dr. R. Khanna is the inventor of the dynamic plate and a founding member of NeuroVention, LLC, that manufactures the plates. Dr. R. Khanna also holds patents with CoolSpine, LLC. Dr. Ferrara received research support from NeuroVention, LLC, and is a consultant for OrthoKinetic Technologies.

Author Contributions

Conception and design: R Khanna, Ferrara. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: R Khanna. Critically revising the article: R Khanna. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: R Khanna. Statistical analysis: R Khanna. Study supervision: R Khanna, Ferrara.

Supplemental Information

Videos

Video 1. https://vimeo.com/289289158.

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