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THE DESIGN AND USE OF A MINIMALLY-INVASIVE, EXPANDABLE RETRACTOR FOR DEEP-SEATED BRAIN LESIONS

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ABSTRACT

Access to deep-seated brain lesions (e.g., tumors, aneurysms, hematomas, and other malformations) is challenging due to the potential for retraction-induced injury. Traditionally, neurosurgeons use dissection and blade retractors to push apart tissue to visualize and operate on target lesions. These blades apply focal pressure onto the brain, resulting in ischemia, edema, and parenchymal trauma, leading to complications in up to 29% of cases. Tubular retractors were introduced to distribute forces radially and have led to improved safety and clinical outcomes. However, reports indicate that tubular retractors still led to complications in up to 9.1% of cases. Other concerns include significant pressure in the direction of insertion and the displacement of anatomic landmarks leading to inaccurate stereotaxis.

We present a novel, minimally-invasive brain retractor that utilizes an expandable soft balloon to further reduce retraction-induced injury and increase stereotactic accuracy with a minimal port of entry. The device consists of a balloon catheter system, a clear sheath, and integration with neuronavigation stylets. This approach can reduce the rate of iatrogenic injury and improve clinical outcomes for brain lesion operations. Furthermore, we illustrate the efficacy of this device in use compared to those of conventional tubular and blade retractors in a pig cadaver.

Keywords: neurosurgery, brain retraction, balloon catheter, retraction-induced injury, minimally-invasive, surgical tool

1. INTRODUCTION

In modern neurosurgery, minimally-invasive techniques have become more common in intracranial operations for lesions such as brain tumors, aneurysms, hematomas, and other malformations. Operations on deep-seated lesions may require the retraction of normal brain tissue in order to provide adequate surgical access and visualization. The most common approach today is to use blade retraction systems where surgeons dissect brain tissue and use thin metal blades to push apart normal brain parenchyma. However, such displacement of brain tissue may result in retraction-induced injury. Blade retractors apply focal pressure onto brain surfaces, compressing adjacent tissue and causing the deformation and closure of blood vessels [1]. Retraction-induced injury can take the form of ischemia, edema, and direct parenchymal trauma, leading to complications in up to 29% of cases [2]. Such injuries may be especially dangerous when operating on intraventricular lesions and those in the basal ganglia, due to their close proximity to critical structures.

Tubular retractors were first introduced by Kelly et al. in 1988 [3, 4]. Kelly described a stereotactically-guided cylindrical retractor that distributed force radially, reducing the risk of iatrogenic injury. This tool was inserted using an obturator that fit snugly within the cylindrical tube, and after the target lesion was reached, the obturator was removed, leaving an operative corridor through the tube. These tubular retractors and its many variants have helped neurosurgeons achieve reduced intracranial pressure, greater extent of resection, and shorter length of stay [2, 5, 6].

Tubular retractors can be safer alternatives to long-standing blade retraction; however, a study employing pre- and post-operative diffusion-weighted imaging of the brain has shown

evidence of cytotoxic edema through ischemic tissue and cell damage with the METRx® tubular retractor [7]. Other studies have reported complications such as memory loss, aphasia, hemiplegia, ischemia, hemorrhage, tract damage, and cortical infarction that are attributed to tubular retractor use in up to 9.1% of cases [5]. Furthermore, due to the rigidity and size of tubular retractors, there may be significant pressure in the direction of insertion, posing particular risk for solid or calcified tumors. Such large displacement of brain tissue upon insertion may also lead to a shift in anatomical structures when compared to preoperative images. We call this phenomenon "brain shift", and it can render some stereotactic approaches inaccurate.

Thus, the goals of a new retractor should be to further reduce the harmful pathophysiological impacts on brain tissue compared to those of current methods, provide improved surgical access, and increase surgeon usability. Our primary aim is to introduce the novel design of a balloon-assisted, expandable retractor that provides a minimal port of entry, gradual radial expansion of the surgical corridor, and integration with stereotactic stylets. Our secondary aim is to illustrate the efficacy of the device in use compared to that of blade and tubular retractors in a pig cadaver model.

2. MATERIALS AND METHODS

2.1 Design Overview

The design objectives of the device are to provide a minimal port of entry to minimize the risk of tissue damage and "brain shift" during insertion, gradual radial expansion to spread pressure over time, and mechanical integration with existing neuronavigation devices (Table 1). The device comprises two separate components: a balloon catheter system and a clear tubular sheath (Fig. 1). The balloon catheter shaft consists of a concentric double-lumen design. The inner lumen, with a luer lock opening on the proximal end, is modular and can be interfaced with a mechanical attachment for any neuronavigation probes, such as the Brainlab Navigated Disposable Stylet displayed. The outer lumen is used for inflation of the balloon catheter and attaches to a syringe. The balloon is made of polyurethane, with minimal tapers at the proximal and distal ends. The sheath is made of clear polycarbonate and has a diameter that closely fits the final diameter of the inflated balloon. Different sizes of the balloon and the sheath can be used to accommodate a multitude of surgical needs.

Design Criteria	Justification
<5mm diameter of entry	Reduces insertion trauma, deformation of blood vessels and fiber tracts, and "brain shift" for accurate stereotaxis
Gradual expansion to 17mm in < 15s	Spreads pressure over wider area over time; adjustable intraoperative diameter; 17mm is in range of desired widths for operative corridor diameters
Integrates with neuronavigation probes	Allows for accurate stereotactic targeting of the lesion

TABLE 1: Table outlining design criteria, given surgical and intracranial constraints.

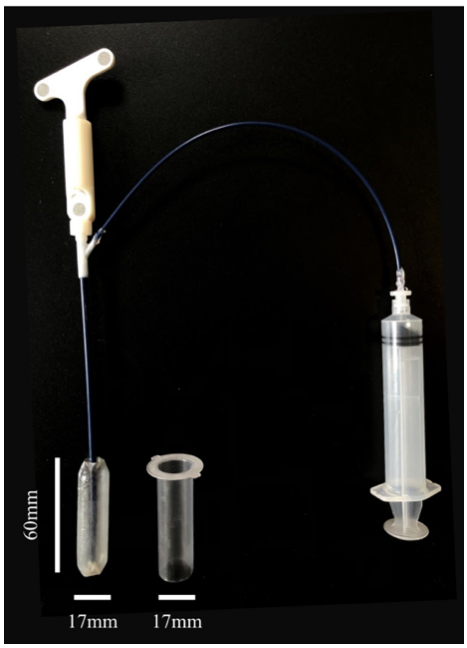

FIGURE 1: The Radiex prototype featuring (L to R): a balloon catheter system with a distal polyurethane balloon (distal) and an integrated neuronavigation probe (proximal, Brainlab Navigated Disposable Stylet); a tubular polycarbonate sheath; and a syringe.

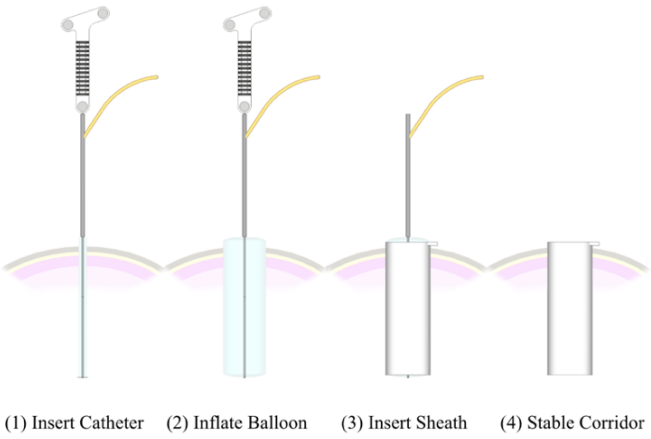

FIGURE 2: Device workflow. (1) The catheter is inserted into the brain using neuronavigation. (2) The balloon is inflated to its final diameter using 12 mL of saline. (3) The sheath is inserted. (4) The balloon catheter is removed, and a stable operative corridor remains.

2.2 Device Workflow

The balloon catheter is inserted into the brain in its deflated state, with the balloon thinly wrapped around the catheter shaft (Fig. 2). 12 mL of saline is pumped into the balloon using a syringe to gradually inflate it to its full volume and a 17 mm diameter. The clear sheath is then slid to reinforce the corridor, similar to a single outer-diameter dilation of the METRx® tubular retractor system [7]. The balloon catheter is deflated and removed, leaving a stable operative corridor. Surgeons may also prefer to deflate and remove the balloon catheter after its initial inflation and insert a sheath of a smaller diameter into the corridor.

2.3 Balloon Catheter Design

Our balloon is 17 mm in diameter and 60 mm in height. The shape of our balloon is cylindrical, with minimal tapers on the proximal and distal ends. With this shape, the volume of tissue displaced via gradual expansion is maximized at the distal end and is precisely located by the tip of the neuronavigation probe. This prevents the "cookie-cutting" of brain tissue with the sheath; aligning the distal end of the sheath the probe tip ensures the sheath cannot cut brain parenchyma past the length of balloon retraction. The balloon is made of polyurethane, a compliant material that is molded to a final inflated diameter and volume. The balloon surface is soft and smooth, minimizing any sharp edges, ensuring consistent inflation, and making it easier for saline to lubricate the surface prior to the sheath insertion. This use of elastic plastics in balloon catheters has been shown by Spena and Versari to be less traumatic to brain matter compared to rigid instruments (e.g., metal blades and tubular retractors) due to the material's consistency, profile, and better distribution of forces acting as a "supportive pillow" [8].

Our catheter consists of a double lumen design that is 3 mm in outer diameter, with an inner and outer lumen that holds a neuronavigation probe and allows for fluid exchange, respectively. The inner lumen of 2.5 mm diameter extends to the tip of the catheter to allow for high spatial accuracy by neuronavigation probes. In the event that the probe is shorter in length than the shaft, neuronavigation software generally allows for a "tip extension" to be virtually applied. The outer lumen is ring-shaped with a width of ~0.4 mm and is designed for saline fluid. To fill the balloon, saline rather than air was selected as it allows for better control over inflation and mitigates damage in case of balloon puncture or rupture. The balloon is inflated with 12 mL of fluid using a handheld syringe through a 10 cm long catheter.

2.4 Sheath Design

To hold back tissue, we have designed a clear, rigid polycarbonate sheath that can be slid over the balloon or inserted after the balloon is removed. The sheath matches the dimensions of the balloon: 17 mm diameter and 60 mm length. The clear material allows for visual assessment of surrounding tissue as well as light penetration through the surgical corridor. In addition, the rim at the top of the sheath allows the surgeon to stabilize bayoneted instruments and toggle or reposition the sheath intraoperatively. The diameter of our sheath is matched to the balloon diameter for a tight fit that permits smooth insertion without cutting or significantly shearing brain tissue. The distal edge is tapered to allow the sheath to be introduced between the balloon and brain tissue, avoiding the dissection of surrounding tissue.

2.5 Neuronavigation Integration

The 2.5 mm diameter inner lumen was designed to fit neuronavigation probes. This lumen is completely sealed from the fluid exchange lumen and ends in a luer lock at the top. We designed an attachment that fits on this luer lock and holds the BrainLab Navigated Disposable Stylet (Fig. 1, top left) [9]. It securely holds the stylet, maintains key grip points, and does not cover the passive marker geometry needed for recognition by navigation cameras. We envision this attachment to be modular, allowing for the use of other neuronavigation systems such as Medtronic's Stealthstation™ [10]. The alignment of the tip of these probes to the tip of the balloon catheter allows for accurate positioning of the sheath with stereotaxis.

2.6 Study Design

This study used a pig cadaver model to observe and illustrate the device in operation. Images of the device in situ were used to illustrate the workflow of the device and to compare with existing retractors: a traditional blade retractor, an elliptical tubular retractor with a blunt obturator, and a circular tubular retractor with a sharp obturator.

2.7 Sample Size and Subject Selection

The pig cadaver head was supplied by Large Animal Medicine at the Johns Hopkins University School of Medicine. The pig was sacrificed two hours prior to use in this study. Prior to sacrifice, the pig was used in a liver ablation study that did not affect brain structure or function. The pig was 12-14 weeks old at the time of death and weighed ~90 lbs. The species was domestic pig (Yorkshire), gender female.

3. RESULTS

The cadaver head was fixed using a 3-point Mayfield head holder. The head was draped, exposing the surgical field. A midline skin incision was done using a No. 10 blade. Two self-retaining retractors were applied to the skin, and the periosteum was elevated. A large free bone flap (6 cm x 4 cm) was made, centered over the midline using a Midas Rex drill and the dura was opened and reflected to the left side (Fig. 3).

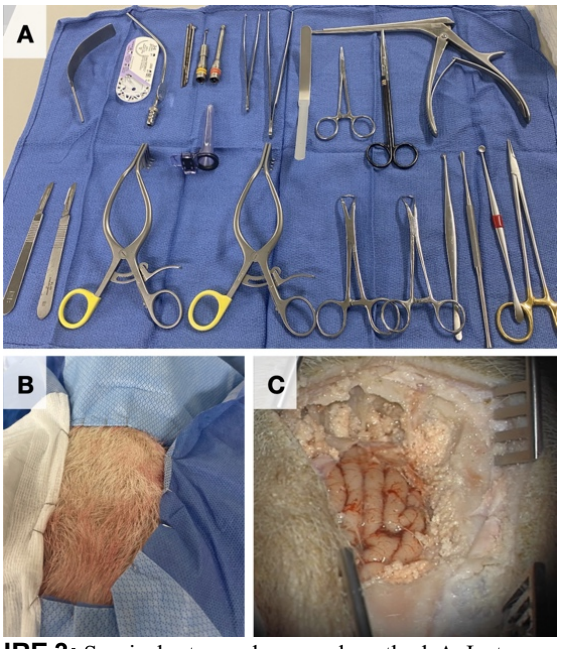

FIGURE 3: Surgical setup and approach method. A: Instrument setup. B: Draped pig head. C: Craniotomy with bone flap removed.

We inserted the device 1 cm to the right of the midline and inflated the balloon using a syringe filled with 12 mL normal saline solution and inserted the 17 mm sheath. We also inserted a blade retractor, an elliptical tubular retractor, and a circular tubular retractor. A microscope was used to image the surgical field at each major step (Fig. 4).

The insertion step was noticeably the smoothest and required less force with the novel device compared to the obturator insertion of tubular retractors. Minimal bleeding and direct parenchymal trauma were observed using the novel device, especially compared to the metal blade retractor. The balloon was able to be expanded in a timespan of ~15s, which was significantly more gradual than the 1-2 second insertion and corridor maintenance of the other devices. Furthermore, there was no difference noted in the degree of operative access and optical clarity of the device sheath compared to other tubular retractors. While we did not deploy full neuronavigation technology, we kept the BrainLab stylet and attachment on our device to show its potential use. After surgery, the pig cadaver head was sutured and disposed of per institutional protocol.

4. DISCUSSION

4.1 Device Comparison

The underlying motivation for the development of tubular retractors is that injury to the brain can be reduced by distributing pressure more uniformly around the circumference of a tube, while the sharp edges and rigidity of traditional blade retractors apply focal pressure that can lead to ischemia, edema, and direct trauma. Since the introduction of tubular retractors in 1988, we have also seen studies introducing a variety of retractor-introducer combinations, such as narrow tubular sheaths (6 mm) with metal stylets, polyester films that unrolls around a needle, and the index finger of a glove tied over a cannula and dilated [11, 12, 13]. However, there continues to be evidence of iatrogenic injury and retraction-induced complications in up to 9.1% of cases with tubular retraction (compared to up to 29% with traditional blade retraction) [2, 5]. The rigidity and size of the obturator introducer may cause significant pressure along the direction of insertion and shift anatomical landmarks away from locations identified on preoperative images.

Thus, we see our device having a number of unique advantages. The minimally-invasive insertion reduces insertion trauma, decreases risk of vascular and fiber tract deformation, and improves lesion targeting with neuronavigation. Secondly, this insertion workflow is similar to that of other minimally-invasive approaches (e.g., EVD), in which small amounts of adjustment or re-insertion can be made without significant harm. Lastly, the gradual inflation of the soft, compliant balloon may further reduce the overall focal pressure on the brain, reducing tissue trauma and minimizing the risk of bleeding, ischemia, and edema.

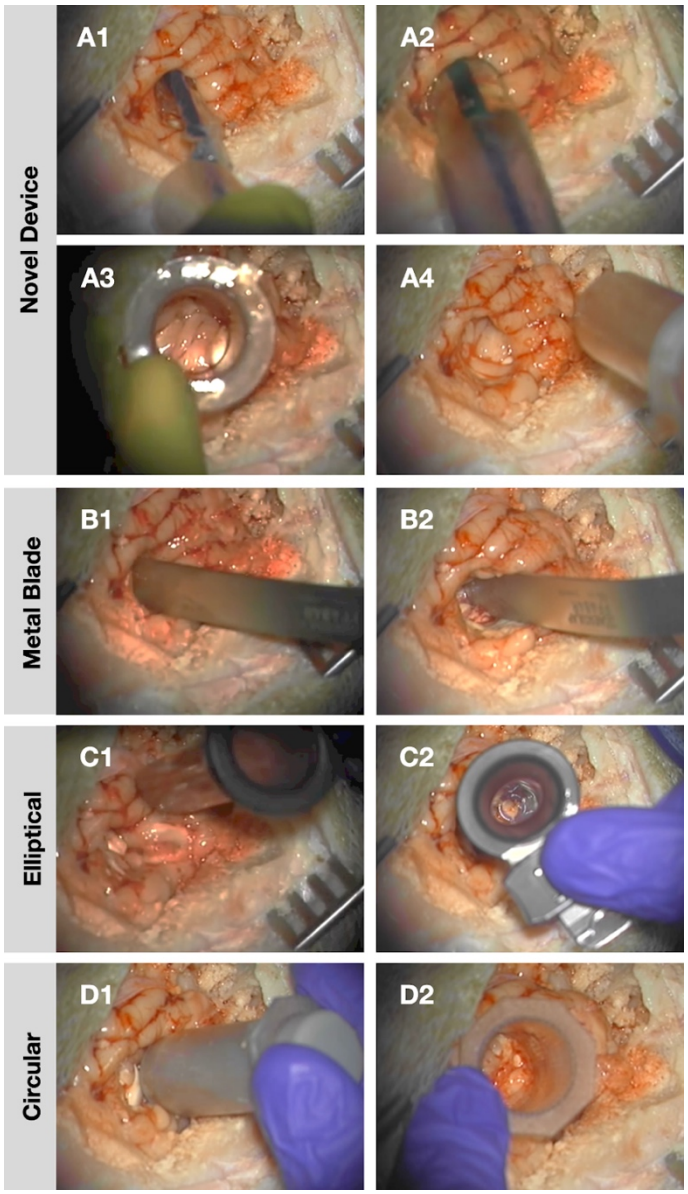

FIGURE 4: Images of surgical field taken with a microscope across all tested retractors. A1: Insertion of novel device A2: Inflation of balloon. A3: Insertion of sheath. A4: Surgical corridor after device is removed. B1-2: Insertion and retraction of metal blade retractor. C1-2: Insertion of elliptical tubular retractor. D1-2: Insertion of circular tubular retractor.

4.2 Study Limitations

A major limitation for this study was the lack of a facility for procuring fresh human cadavers. Pigs were chosen due to the similar material properties and anatomy to humans; however, size differences had to be considered. Traditionally, retractors would be inserted within the brain using a trans-sulcal approach; however, this approach was not possible with the pig brain as the sulci were too small. Additionally, the pig brain has a depth of 3-4 cm, so devices were not inserted fully lengthwise.

4.3 Future Steps

This study was meant to yield preliminary qualitative data in accordance with our purpose to illustrate the novel device and its workflow. To quantitatively study the benefits associated with our retractor, we plan to: (1) conduct benchtop force measurement studies to obtain a pressure profiles of the device's workflow compared to that of existing retractors; (2) pursue an in vivo pig study to compare the physiological effects of these retraction technologies through histology, imaging, tractography, and intracranial pressure monitoring; and (3) demonstrate the integration of the device with commercially available neuronavigation probes such as BrainLab Navigated Disposable Stylet or the Medtronic StealthStation™.

5. CONCLUSION

The balloon-assisted, expandable retractor has the potential to further reduce iatrogenic injury, ensure stereotactic accuracy, and improve clinical outcomes through a minimally-invasive approach.

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