Patient Safety in Surgery

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A novel minimally invasive neurosurgical cranial fixation device for improved accuracy of intraventricular catheter placement: an experimental animal study

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Abstract

Background External ventricular drain (EVD) insertion is one of the most commonly performed neurosurgical procedures. Herein, we introduce a new concept of a cranial fixation device for insertion of EVDs, that reduces reliance on freehand placement and drilling techniques and provides a simple, minimally invasive approach that provides strong fixation to minimal thickness skulls.

Methods An experimental device for catheter insertion and fixation was designed and tested in both ex-vivo and in-vivo conditions to assess accurate cannulation of the ventricle and to test the strength of fixation to the skull. The ex-vivo experiments were conducted at *Ben-Gurion University of the Negev (BGU)* in Be'er Sheva, Israel. These experiments included functionality bench testing and pullout force measurements for the ball mechanism and catheter fixation. For the in-vivo experiments the fixation device was initially tested at the *Cincinnati Children's Hospital Medical Center (CCHMC)* in Cincinnati, Ohio on one day of life 1 (DOL 1) male control lamb. Additional experiments were conducted on 3 hydrocephalic DOL 0 lambs (1 male 2 female) at the *Jesús Usón Minimally Invasive Surgery Centre (JUMISC)* in Caceres, Spain. The hydrocephalic animal model used for this study was created with in utero intracisternal injection of BioGlue in fetal lambs. The catheter insertion trajectory was determined using MR imaging to assess the device's impact on the placement accuracy. The fixation device was evaluated on reaching the ventricle and enabling extraction of CSF for all 7 fixations placed. For 5 of the fixation devices, post-mortem pullout force was measured. The general functionality of the device was also evaluated.

Results In the experiments, 7/7 (100%) catheter trajectories successfully reached the ventricle without any apparent complications related to the device or the procedure. The cranial fixation device base demonstrated significant strength in withstanding an average pull-out force of 4.18kgf (STD ± 0.72, $N=5$) without detachment from the subject's skull for all 5 devices included in this test. Additionally, the EVD catheter pull test was conducted with the

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addition of a safety loop which did not allow movement of the EVD to a force of 3.6kgf. At this force the catheter tore but did not release from its fixation point.

Conclusion The newly designed experimental device demonstrates initial proof of concept from ex vivo and in vivo testing. It appears suitable for accurate ventricular catheter placement and cranial fixation.

Keywords Catheter insertion, Catheter placement, Cranial fixation, External ventricular drain, Pediatric hydrocephalus, Ventricular catheter

Introduction

Cerebrospinal fluid (CSF) was described as early as 3000 to 2500 BC in Edwin Smith's Surgical Papyrus [1]. Since that original description, Hippocrates, Galen, and Magendie studied CSF and described separate theories about CSF. Claude-Nicholas Le Cat was the first to document the placement of an external ventricular drain (EVD) in 1744. Ingraham and Campbell subsequently described the first closed system for ventricular drainage in 1941 [2–4]. Today, contemporary medical literature estimates that in the United States, over 20,000 EVDs are inserted each year [5]. The procedure is typically performed in urgent or emergent clinical scenarios by junior neurosurgical trainees when the intracranial pressure (ICP) is deemed to be elevated [6]. Common indications for EVD placement include hydrocephalus, severe traumatic brain injury, subarachnoid hemorrhage, brain tumor, and infection. Currently, the standard of care for EVD insertion is the use of a freehand drilling technique typically performed at Kocher's point (3 cm lateral to midline and 1 cm anterior to the coronal suture) [7] with tunnelling of the catheter to a separate exit site on the scalp [8]. Another approach for catheter insertion consists of the use of a bolt-connected EVD which has been shown to provide good results regarding optimal placement, CSF leakage and infection prevention, in addition to lessening the chance of accidental disconnection [9, 10]. The tunneled EVD has shown higher complication rates leading to reinsertion in contrast to the bolt-connected EVD with no significant difference in infection rates [11]. Additional techniques and surgical adjuncts have been developed to improve accuracy and safety [2, 12–16]. Common complications have been described which include CSF leak, hemorrhage, infection, inaccurate placement of the catheter leading to malfunction or obstruction, loosening of the sutures used on the scalp leading to movement of the catheter intracranially, in addition to neurologic injury and the need for additional surgery [4, 17–19].

Herein, we describe a novel experimental concept to assist in the placement of EVDs while aiming to address some issues currently encountered in clinical practice. The overall design and functionality involve an approach that addresses several key benefits. These include minimal invasiveness, reduced reliance on the freehand drilling technique whereby the entry angle can unintentionally change during the drilling step, safe fixation to the skull, and improved capability to lock the catheter externally and decrease the possibility of inadvertent pull-out of the catheter from the ventricular environment. The approach was developed to be time-efficient and without need for additional technologies such as stereotaxis, ultrasound, or other surgical visual or radiographic adjuncts when employed in urgent clinical scenarios.

Methods

An experimental device for catheter insertion and fixation to the skull was designed, constructed, and tested under both ex-vivo and in-vivo conditions. The aim was to evaluate its capability for accurate cannulation of the ventricle and to assess the strength of its fixation to the skull.

General fixation design and parts

The fixation device is comprised of a 3-legged base with each leg containing a single 1.6 mm self-tapping titanium screw that provides even distribution of force on the skull (Fig. 1). The small diameter titanium screws are inserted directly through the skin into the outer table of the cranium and do not require additional incisions.

To provide 2 degrees of freedom (DOF), the fixation base was designed as a socket that houses a trajectory control ball which allows full control of the planned insertion after cranial fixation is accomplished (Fig. 2A). Apart from the titanium screws, all components were 3D printed using Stereolithography (SLA) printer (Formlabs, Somerville, MA, USA) with designated biocompatible material (Formlabs Biomed-Amber and Biomed Durable resins).

After the trajectory is determined, it is then locked by using the locking handle (Fig. 2B-C). Once the catheter is inserted, the catheter guide, ball, and cap mechanism (Fig. 3A-D) are used to secure the catheter at its target site without obstructing the flow of CSF and without requiring the use of sutures. The additional design of the catheter guide ears and locking pin within the locking socket further assist in the prevention of accidental removal when the cap is on (Fig. 3D).

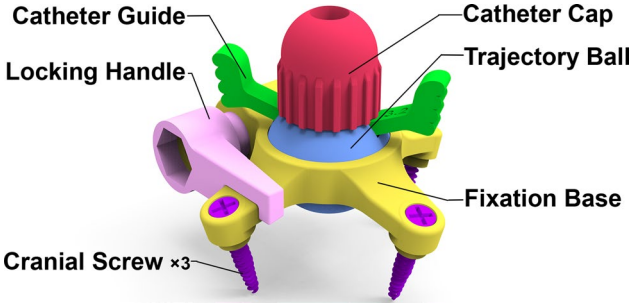

Fig. 1 Fixation device main parts assembly

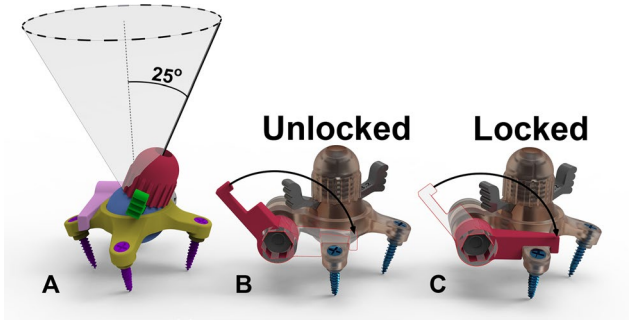

Fig. 2 Fixation device mechanism schematics. **A**: Trajectory ball 2 angular degrees of freedom (DOF). **B**: Ball mechanism at unlocked state. **C**: Ball mechanism at locked state

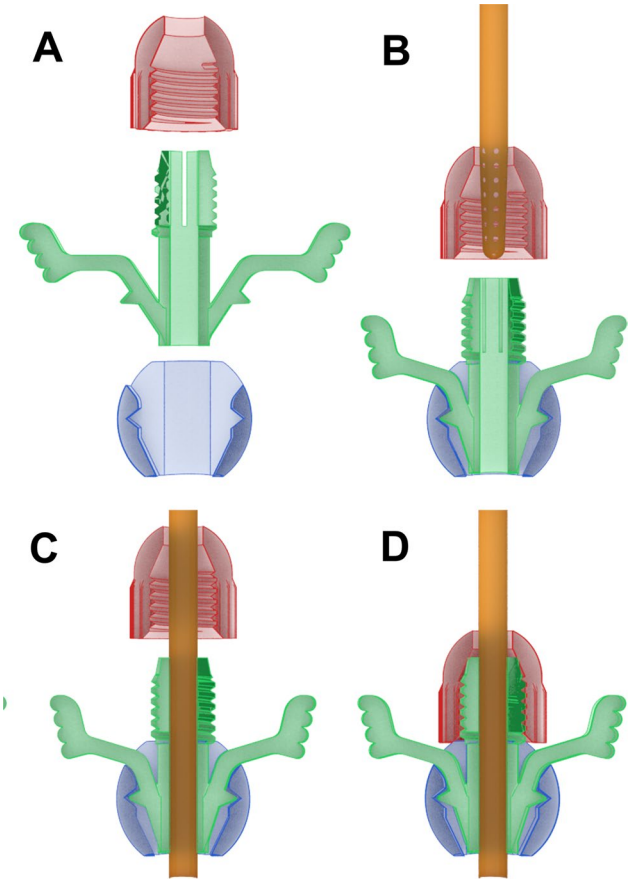

Fig. 3 Catheter Guide (green), trajectory ball (blue), catheter (orange) and cap (red) assembly. **A**: Trajectory Ball, Catheter Guide and Cap in exploded view. **B**: Catheter guide is inserted to the trajectory ball pressing the guide ears while inserting. **C**: The catheter is inserted through the catheter guide to the desired depth. **D**: Cap is placed over the catheter and locks it in place. The cap also prevents the catheter guide from being removed by mechanically blocking the guide ears

Fixation and detailed catheter placement procedure

The placement of the fixation device is comprised of multiple steps as shown in Fig. 4A-E. In our experiments, the EVD guide is initially positioned over Kocher's point equivalent on the lamb and fixed to the skull using three 1.6 mm diameter titanium screws. The screws are inserted into the skull to the desired depth while keeping the fixation base away from the scalp to prevent pressure and potential necrosis and tissue damage when EVD drainage is required for extended periods of time.

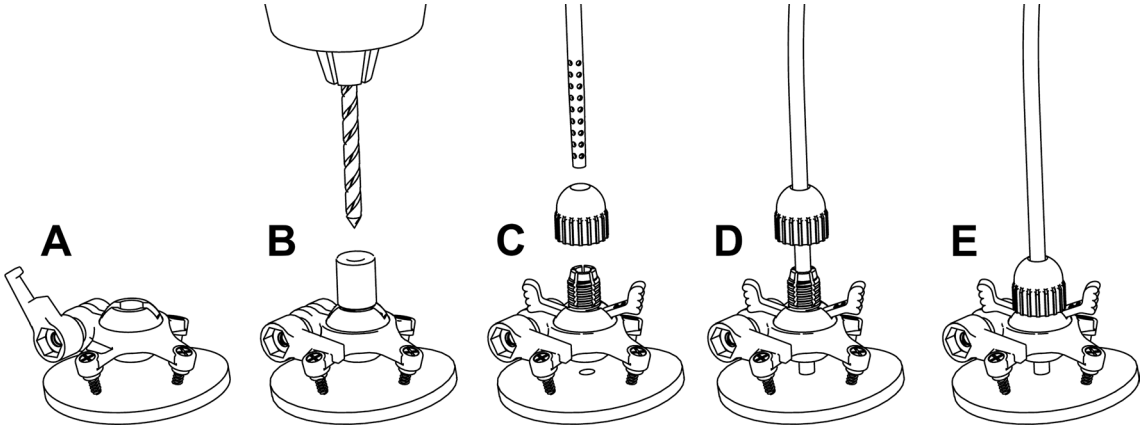

Fig. 4 Fixation Procedure Steps. **A**: the fixation device is positioned, and the insertion trajectory is determined. **B**: the trajectory ball is locked in place, the drill guide inserted, and a drill is used in the desired trajectory. **C**: the catheter guide is inserted. **D**-**E**: the catheter is inserted to the desired depth and the cap is locked to the catheter guide

After the EVD guide is fixed to the skull, the trajectory ball is used to select the desired insertion trajectory for the catheter. The trajectory is locked in position using the locking handle (Fig. 4A-B). The drill guide is used to create a burr hole craniostomy that will be aiming directly at the desired target. The diameter of the drill guide cylinder enables drilling of a craniostomy with the exact diameter necessary for placement of the desired EVD type which enables the appropriate fit for the catheter. Once the craniostomy is complete, the drill guide is exchanged for the catheter guide which is then inserted and locked into the trajectory ball (Fig. 4B-C). The EVD is inserted in standard fashion to the desired measured depth as determined by preoperative imaging (Fig. 4D). The cap is locked to the catheter guide to prevent unintentional disconnection and inadvertent pull-back from the ventricular space while allowing free flow of CSF through its inner diameter (Fig. 4E). A catheter loop can additionally be used to further ensure catheter coupling to the guide base.

Ex-vivo experiments

The bench-side ex-vivo experiments were designed to evaluate the ability of the fixation device to facilitate the insertion and secure fixation of ventricular catheters.

These experiments included both basic functionality testing and pull-out strength tests that were conducted at the Bio-Inspired and Medical Robotics Lab at the department of Mechanical Engineering at *Ben Gurion University of the Negev* (BGU) in Be'er-Sheva, Israel, during 2023. The ex-vivo fixation functionality experiments were completed using 3D printed simulation skull models created from Computed Tomography (CT) scans of the human head printed in ABS material. These experiments did not provide any measurable data but played a crucial role in ensuring that troubleshooting and identifying design improvements were tested ex-vivo. During these trials, the senior author was able to successfully insert the EVD in a short time frame (3–5 min) from initial fixation of the guide to the simulated skull to securing the inserted catheter to the guide.

Two sets of ex-vivo experiments were designed to test the ball pullout and the catheter pullout strength using an *Enpaix EFG500* digital force gauge, with an accuracy of ±0.1 kgf. In the first set of experiments the fixation device was attached to the fixed base using the 3 titanium screws. The force gauge was connected to the trajectory ball using a designated fitting and pulled until the ball exited the base. The maximal force in each pull was recorded. The ball pullout strength was tested 30 times and statistical significance was evaluated using Student's t-test with a confidence interval (CI) of 95%. In the second set of experiments, the catheter pullout strength was tested in 2 different methods. These included the direct catheter pull and the safety loop method, as shown in Fig. 5. The direct pull was measured 30 times at three different angles (10 measurements per angle). Statistical significance was evaluated in the same manner as the ball pull test.

In-vivo experiments

The in-vivo experiments were conducted to evaluate the performance of the fixation device in a live setting. These experiments tested the device's ability to enable accurate ventricular cannulation, measured the pullout force of the fixation ball for comparison with ex-vivo results, and assessed the skull fixation strength.

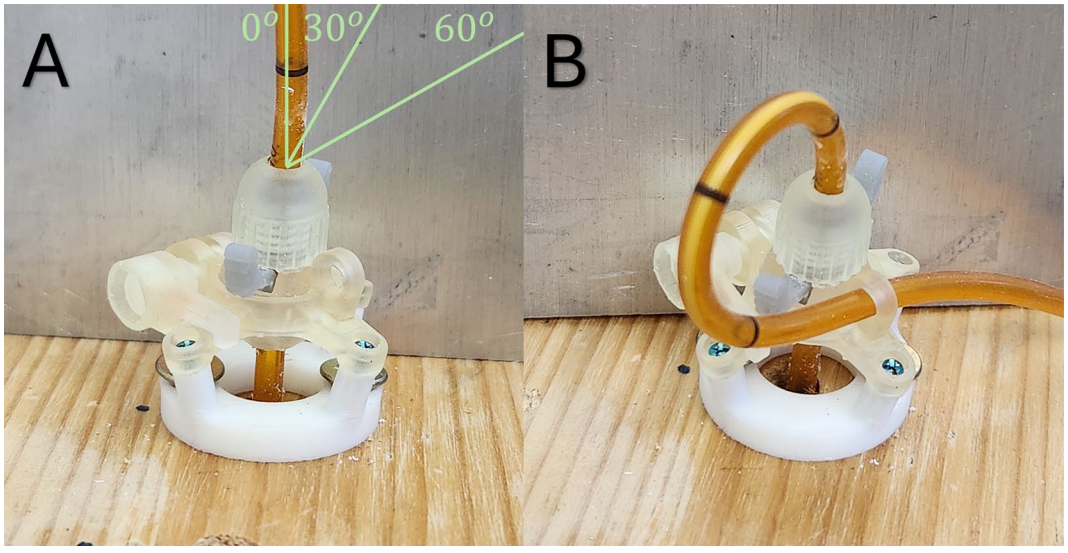

Fig. 5 Fixation device used without (**A**) and with (**B**) a safety loop. Free catheter pull angles are marked in A

All experiments conducted in this work followed the guidelines for animal research and were approved by the Institutional Animal Care and Use Committee (IACUC) through CCHMC (2021-0008) and JUMISC (ES100370001499).

The fixation device underwent preliminary in-vivo testing in February 2023 on a single day of life (DOL) 1 control male lamb at *Cincinnati Children's Hospital Medical Center* (CCHMC) in Cincinnati, Ohio, USA. During this test, a single fixation device was used, and a ventricular catheter was inserted into the ventricular system. An endoscope (CLARUS NeuroPen, Minneapolis, MN, USA) was subsequently inserted to provide visual confirmation of entry into the ventricle. The subject then was imaged with T1 and T2-weighted magnetic resonance imaging (MRI) sequences to further validate the catheter placement before the *postmortem* analysis.

Another set of in-vivo experiments were conducted in November 2023 at *Jesús Usón Minimally Invasive Surgery Centre (JUMISC)* in Caceres, Spain. The experiments were conducted on three DOL 0 infant hydrocephalic lambs (1 male 2 female) at delivery on placental support using ex-utero intrapartum treatment (EXIT) procedure. Hydrocephalus was created by intracisternal injection of a BioGlue in the fetal stages which induced obstructive hydrocephalus at birth by blockage of the CSF pathways resulting in ventriculomegaly without causing an neuroinflammatory response as described previously by Soner et al. [20, 21].

Hydrocephalus was evaluated by fetal MRI obtained prior to each EXIT procedure. Six bilaterally placed EVD guides and catheters were tested. For each subject two separate 2.8 mm catheters (Integra, Princeton, NJ, USA) were inserted using two fixation devices (one left sided and one right sided). Two subjects underwent post procedure MRIs to validate correct placement of the catheter. Furthermore, all subjects had *post-mortem* examinations including evaluation of the fixation device in terms of screw placement and strength of screw fixation. Finally, we performed a gross examination of the skull, cortical mantle, and trajectory into the ventricles to evaluate for potential complications such as intraparenchymal injury or hemorrhage.

The pullout strength experiments were completed with the same *Enpaix EFG500* digital force gauge. Testing of each subject occurred *postmortem*. As we applied a force to the fixation device's ball using the designated fitting, the ball exited from the base prior to the screws being detached from the skull. This experiment allowed us to measure the maximum pulling force that the ball can resist. In addition, after each ball pull, the remaining base was pulled from a single screw to test individual screw pullout strength from the skull. Of note, the screw pullout test was performed after the trajectory ball pullout test. As a result, the maximal pullout force of each individual screw was reduced. Therefore, we would expect the actual single screw pullout force to be at minimum equal to the measured value we report. The pullout strength was tested 5 times for the fixation device base and 5 times for a single screw.

Table 1 Ex vivo ball pullout results ($N=30$)

	Mean [kgf]	SD [kgf]	Margin of Error (95%CI) [kgf]
Ball Exit Pullout Force	4.52	±1.21	±0.45

CI = confidence interval

Table 2 Ex vivo catheter pullout results

	Without Safety Loop				With Loop
Angle	**60° ($N=10$)**	**30° ($N=10$)**	**0° ($N=10$)**	**All ($N=30$)**	**All ($N=10$)**
Mean [kgf]	1.12	0.91	0.75	0.93	> 3.00
SD [kgf]	0.18	0.19	0.19	0.24	-
Margin of Error (95% CI)	-	-	-	±0.09	-

Results

Ex-vivo results

The fixation placement tests conducted in the laboratory demonstrated appropriate function of the device. The 3 titanium screws achieved a good purchase to the skull model and kept the fixation base above the skull as intended. The fixation ball enabled 2 DOF post fixation with appropriate trajectory ball locking ability. The catheter locking ability of the device prevented inadvertent dislodgement of the tubing. The laboratory ex vivo pull-out force experiment results for the EVD base are listed in Table 1.

The laboratory ex vivo pull-out force results for the free catheter pulls, without the safety loop, resulted in a mean pull force of 0.93 kgf and 95% CI standard error of 0.09 kgf. Additional results are listed in Table 2.

When the catheter pull test was conducted with the safety loop, the device remained securely fixed even when the catheter became torn at a force of 3.6 kgf. Following this, the device was tested 10 additional times, with each test pulling the catheter until the force exceeded 3 kgf. During these tests, the catheter exhibited significant deformation, and the fluid flow was blocked, yet no movement was detected at the catheter tip.

In-vivo evd insertion results

During the preliminary control animal experiment at CCHMC, the fixation device functioned as expected and enabled firm fixation to the subject's skull (Fig. 6A-B). The inserted catheter was able to reach the ventricle accurately with one intracranial pass. This was validated endoscopically, by the post procedure MRI and by

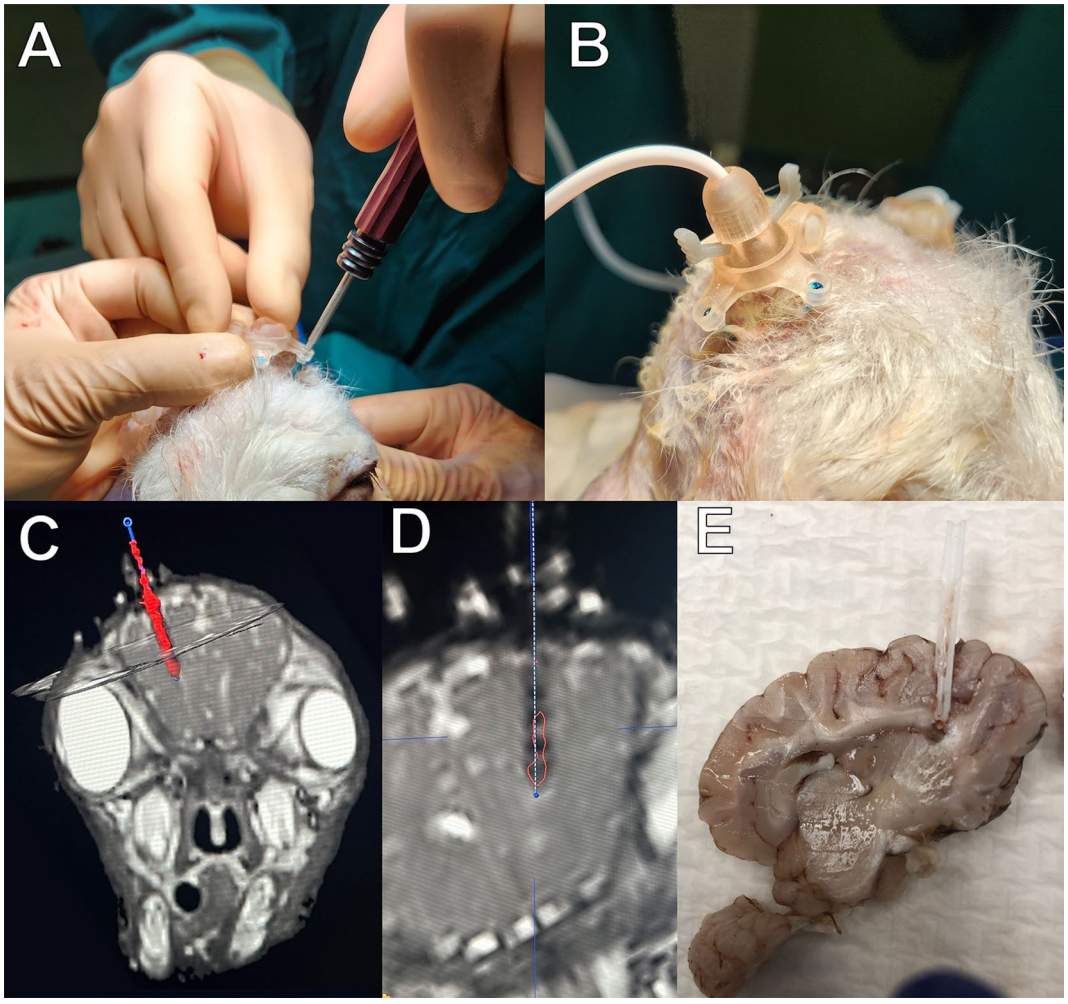

Fig. 6 Fixation placement and catheter insertion validation. **A**: Device placement and fixation to the skull. **B**: Post procedure fixation device with inserted catheter. **C**-**D**: Post procedure MRI for the desired trajectory (blue) and the actual trajectory (red) for a single catheter. **E**: Postmortem analysis of the subject's brain section

postmortem analysis (Fig. 6C-E). During the follow up in-vivo experiment at JUMISC, bifrontal fixation devices were secured to the skull of each of the 3 subjects. All 6 fixation devices functioned properly and enabled access into the subjects' brain and ventricles. This was corroborated both by the immediate egress of CSF and by the post procedure MRI as demonstrated in Fig. 7A and B. Additional validation was achieved using an intraventricular endoscope inserted through the EVD slotted ventricular catheter. In one of the HCP subjects the endoscope was inserted through one catheter and not only did it provide evidence that it was indeed intraventricular, but it also allowed observation of the contralateral catheter (Fig. 7C).

Post-mortem pullout strength results

The EVD base pullout strength tests were performed on 5 out of the 6 cranial fixation devices. The sixth device was set in a manner that did not allow an adequate grip to perform the pull test.

All 5 devices were pulled until the ball exited the base, in addition, a single screw from each device was pulled. In both pulls the maximal force was obtained as listed in Table 3. None of the devices failed prior to the ball/socket mechanism failing.

Postmortem analysis

We analyzed the subjects for evidence of tissue damage including the scalp, cranium, dura, cortical trajectory, and ventricular environment in the context of the innovative methods of the procedure (Fig. 8A-B). We noted no significant hemorrhage from the fixation placement nor from the transcortical EVD pass (Fig. 8A-B). The ventricular system was also free of blood products. In addition, we were able to directly measure the subjects' skull thickness which was approximately 2 mm (Fig. 8C).

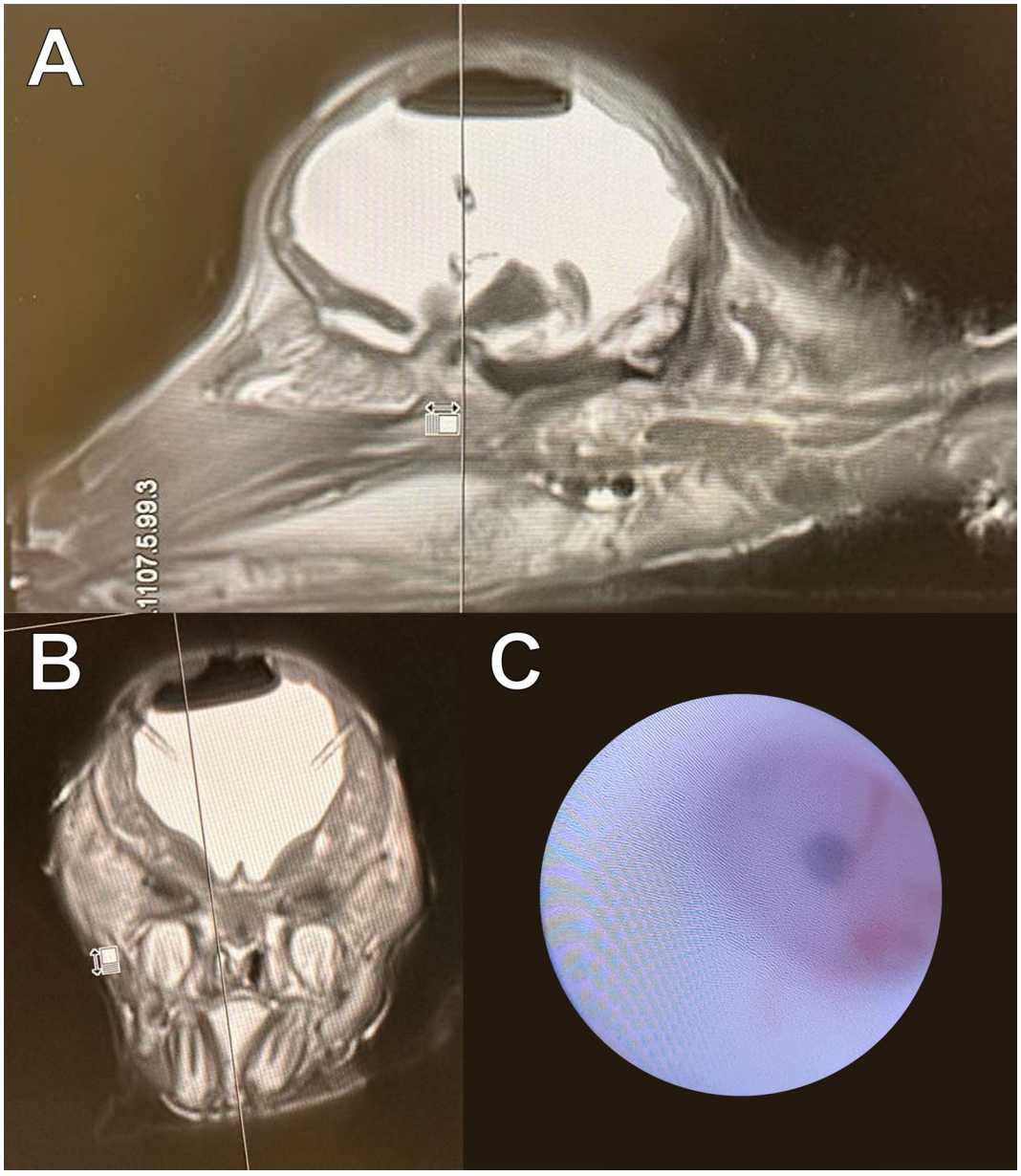

Fig. 7 MRI and endoscope images showing the catheters within the ventricle of the hydrocephalic lamb. **A**-**B**: Post procedure MRI exhibiting both catheters inside the subject's ventricle. **C**: Endoscope image showing the choroid plexus within the ventricular system

Table 3 *Post-mortem* pullout results ($N=5$)

	Single Pull Force [kgf]					Mean [kgf]	SD [kgf]
Ball Exit Pullout Force	5.07	4.29	4.07	4.39	3.09	4.18	± 0.73
Single Screw Pullout Force	7.10	5.98	4.01	3.89	3.66	4.93	± 1.53

Discussion

Design considerations and advancements

The experimental concept of a novel fixation device was designed to provide a new approach to the insertion of EVDs. The current concept of the device avoids the need for a surgical incision and instead relies on screw fixation and drilling of a craniostomy. The design incorporates several potential improvements to the current standard. These include: (1) a strong fixation to the skull at a thickness of 2 mm without producing undue pressure on the scalp (2) two angular DOF after fixation to allow for determination of optimal insertion trajectory and the ability to lock that trajectory so that the proceduralist will not unintentionally change it during the drilling process

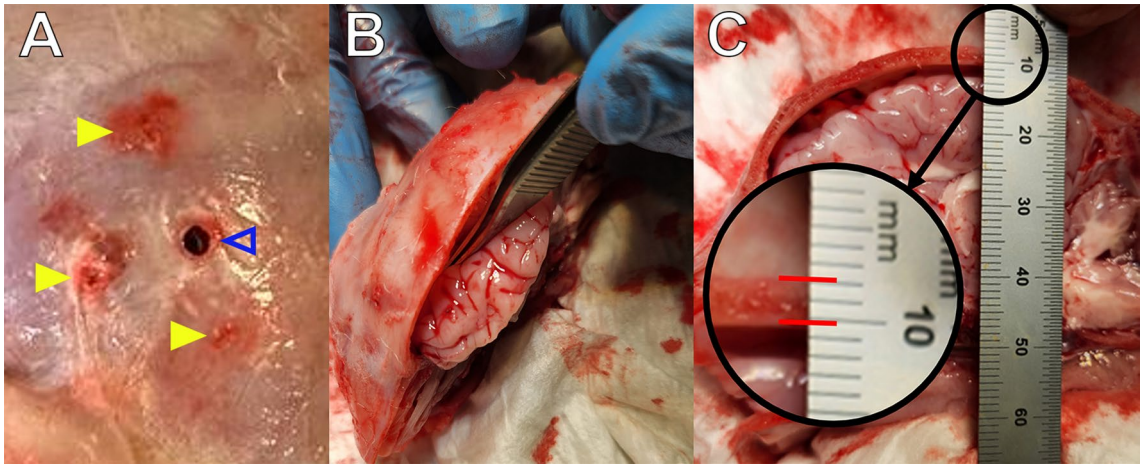

Fig. 8 Postmortem dissection photos. **A**: Frontal bone after fixation device removal (yellow arrowhead) and craniostomy site (blue arrowhead) are visible. **B**: Brain tissue at the catheter insertion site. **C**: Skull thickness at the catheter insertion site

(3) a suture-less fixating mechanism that doesn't obstruct CSF flow and does not allow inadvertent removal of the catheter from the intraventricular compartment.

Strength testing of the device base and catheter

Given the need for fixation to the skull, it was critical that the guide base would not be easily dislodged or cause pressure on the scalp, which could in turn create potential harm to the subject. The three titanium screw system proved practical to a thickness of 2 mm in newborn lambs (Mean: 4.9 kgf for single screw). The ball socket mechanism located at the center of the device allowed for pull out of this ball socket mechanism (mean: 4.8kgf) rather than the whole EVD base being extracted from the skull. In a specific clinical scenario, the significant force measured to dislodge the system during these experiments would be unlikely to result from inadvertent movement by the patient or a medical professional assisting the patient thereby creating a safety measure that is currently not available. In future prototype models, this feature could be tailored to dislodge at a specific force thus further ensuring the patient's safety.

As a second safety feature we instituted a catheter loop in our system which made the system safer against removal of the catheter itself. In contrast, the common standard of care uses a tunneling technique that secures the catheter to the scalp with sutures. As previously published in pig models, these sutures have shown fixation to the scalp at strengths of 0.4kgf for a single suture and 1.2kgf for multiple sutures [12]. The prototype described with the safety loop provided drastically stronger fixation of the catheter itself with a strength greater than 3kgf.

External ventricular catheter trajectory

Use of this device requires that the surgeon understand basic craniometric anatomic measurements for placement of the guide over the entry point as well as the final trajectory. However, once the trajectory is chosen and locked in position the remaining portions of the procedure are completed without the possibility of target displacement. In contrast, the current standard of care typically involves a junior member of the neurosurgical staff using a twist drill to aim the craniostomy toward the ventricle [6]. In general, once the entry point is chosen, the trajectory is one that aims the drill perpendicular to the skull, toward the medial canthus of the ipsilateral eye, and 1 cm anterior to the tragus in the sagittal plane. This technique is challenging because a change in the angle of a few degrees at the skull can create a significant change to the target that is usually 4–6 cm from the surface. For example, a bolt-connected EVD does not allow to alter the trajectory after the bolt is inserted through the skull. Therefore, if the original trajectory is not accurate, the proceduralist may need to attempt a new trajectory at a second surgical site, thereby increasing surgical time, morbidity and potential additional risk of complications. An inaccurate trajectory when using the standard procedure has been studied as a major reason for misplaced and misguided EVDs [22]. The final variable that requires a measurement is the distance to target which can be measured from the imaging studies and subtracted from the distance of the catheter insertion site to the scalp which is ~ 2 cm.

An additional benefit of the system is that the ball mechanism accommodates various inserts that can be used with different diameter drills and catheters. As a result, the appropriate ventricular catheter or EVD can be chosen in each specific scenario. Once the desired catheter is inserted, the durotomy will only be as large or slightly larger than the catheter itself, thereby, preventing a significant risk of CSF draining around the tube. Finally, we also aimed to improve all the procedural steps so that

EVD insertion could be completed in a short period of time and be reasonably easy to perform. Other available clinical options have generally not been adopted widely due to complex methods of insertion compared to the standard of care [12, 14, 23, 24]. Subjectively, we performed the procedure in a laboratory environment in a relatively short period of time (3–5 min).

Technical considerations and future work

In this small preclinical experimental pilot study, the placement of the fixation device and insertion of an EVD was shown to be technically simple in both ex-vivo and in-vivo conditions. The surgeon successfully accessed the ventricle with a single intracranial pass with every attempt whether the subject was a newborn normal control or suffered from hydrocephalus. No apparent complications were noted related to the device or the procedure. We believe that this was partly due to non-reliance on the free hand technique of drilling. Of note, our experiments employed a battery powered handheld drill which did not add morbidity to the procedure. We also report cranial fixation data on 2 mm thickness skulls. The data provides initial evidence for potential suitability of use across various age groups expanding further indications for treatment of neurosurgical disease. For example, the possible use of this system for continuous CSF drainage in the fragile neonatal population could provide additional management options, which are not currently the standard of care, with the goal of reducing long term deficits and decreasing shunt rates [25].

Although the guide was designed to be used independent of any other technology, its design does allow for potential integration with stereotaxis and other advanced registration technologies. For example, the device's known geometry and 3-point fixation to the skull makes it ideal for image registration in an augmented reality (AR) field. Securing the device prior to brain imaging may provide a constant 3D marker for AR software recognition [26]. Moreover, the potential ability to assimilate it with a robotic catheter guiding system could reduce the human factor further and ensure correct catheter placement even in challenging or intricate cases allowing potential expansion of indications for tumor or intracranial hemorrhage management [27]. The option of inserting an endoscope through the inserted catheter may allow for further possibilities in the management of specific patients with hydrocephalus. Finally, by simplifying the catheter insertion procedure, the fixation device could be well-suited for deployment in diverse, demanding and urgent settings such as combat zones and various trauma scenarios. In these cases, it may provide vital support for medical professionals facing challenging situations offering health care providers an immediate solution for reducing the ICP in traumatic brain injured patients.

Conclusion

This study provides initial preclinical proof of concept data for a novel EVD guide placement system. Rigid skull fixation was noted with 2 mm outer-inner table skull thickness and suture-less catheter coupling to the system was successfully shown. The experiments conducted and the results reported here provide a foundation for future research in the experimental and clinical management of CSF disorders and raise the possibilities of integration of the prototype into other technologies.

Abbreviations

CSF	cerebrospinal fluid
EVD	external ventricular drain
ICP	intracranial pressure
DOF	degrees of freedom
SLA	Stereolithography
CT	Computed Tomography
CI	confidence interval
DOL	day of life
MRI	magnetic resonance imaging
EXIT	ex-utero intrapartum treatment
AR	augmented reality

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Author contributions

Conceptualization –AD, DZ, FTM, SP, BGFixation Design – AD, MC, DZ, and FTMData Analysis – AD, DZ and FTMConducting Ex-vivo Experiments – AD, MC, DZ and FTM.Conducting in-vivo Experiments – AD, SD, JLP, EA, CMD and FTMPatient Imaging and Analysis – JLL and FTMAnimal model-vivo – SD and JLPWriting and Editing – AD, DZ and FTMPrincipal Investigators – DZ and FTM.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

All experiments conducted in this work followed the guidelines for animal research and were approved by the Institutional Animal Care and Use Committee (IACUC) through CCHMC (2021-0008) and JUMISC (ES100370001499).

Consent for publication

Not applicable.

Competing interests

AD, DZ, FTM, SP, and BG disclose being listed as inventors on the PCT patent application related to this work (PCT/IB2023/062295) which was filed in December 2023.No other conflicts of interest, financial or otherwise, are reported by the remaining authors.

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