Treatment Device for Subdural Hemorrhage in Austere Environments

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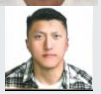
Julissa Reyes 	Michael Fitch 	Christopher Reeves	Jason Shen 
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Disclosures

- **Dr. Brody and co-inventors from JHU-APL currently hold a patent entitled "Automated Cranial Burr Hole Device and Method" with other patents pending**
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Disclaimer

The opinions and assertions expressed herein are those of the author(s) and do not reflect the official policy or position of the Uniformed Services University of the Health Sciences or the Department of War.

Regulatory Approvals

USUHS IACUC,

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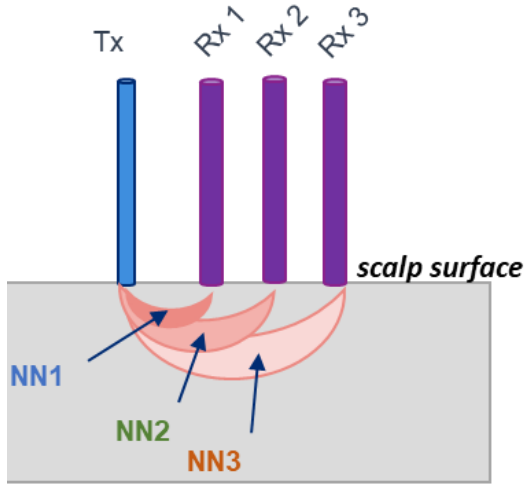
SOCOM Veterinary Medicine

The Problem

- Severe traumatic brain injury with subdural or epidural hematoma must be treated rapidly to avoid death or severe neurological disability.
- In well-equipped medical facilities, CT scans can be used to rapidly make the diagnoses, and neurosurgical treatment can begin immediately.
- However, in austere environments such as under prolonged field care and other remote locations, CT scans and neurosurgical treatments are not available, and there are no current effective treatments.

Our Proposed Solution

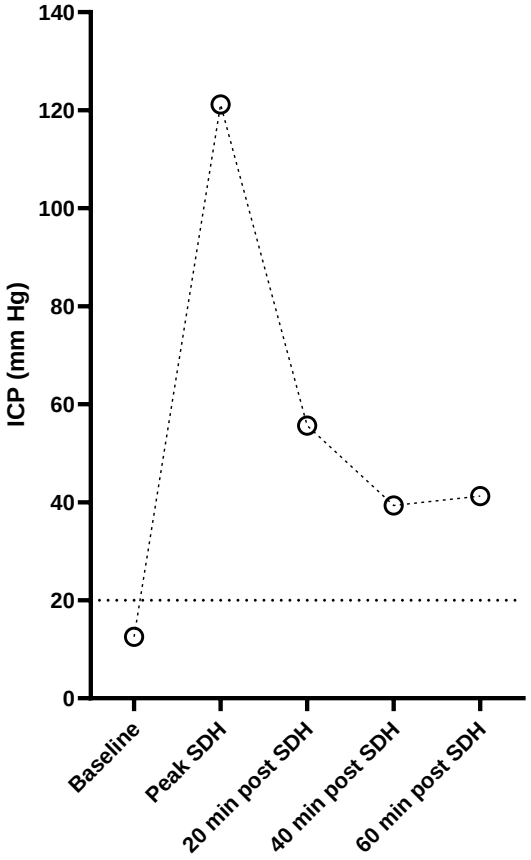
- We have developed a prototype hand-held infrared hemorrhage detection device that can be used to accurately detect and localize subdural and epidural hematomas.
- We have developed a prototype hand-held intracranial hemorrhage treatment device that can be used by a non-neurosurgeon to remove some of the subdural and epidural blood clot.
- We have tested these two new devices in a sheep model of life-threatening subdural hematoma with favorable results. (Sheep have similar skull thickness to humans)



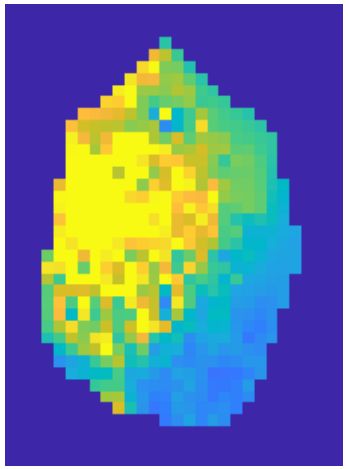
* pink areas depict the area probed by the NIR light detected at each fiber

Sheep Model of Life-threatening Subdural Hematoma (SDH)

Autologous blood injected at 1 ml each minute through a catheter placed in the subdural space, with a contralateral intracranial pressure monitor.

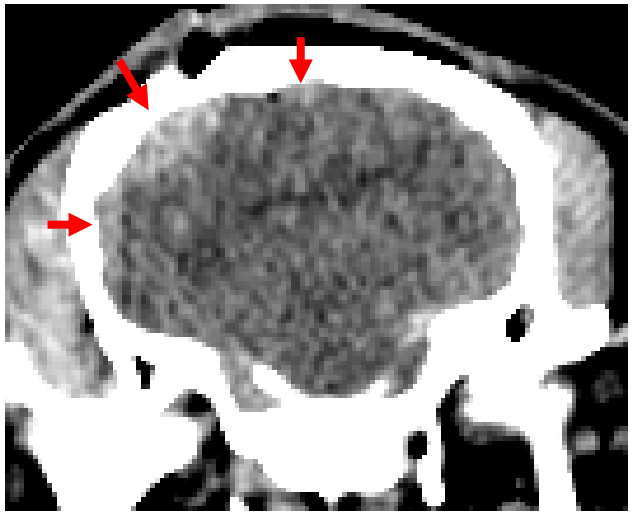


Intracranial Pressure (ICP) measurements

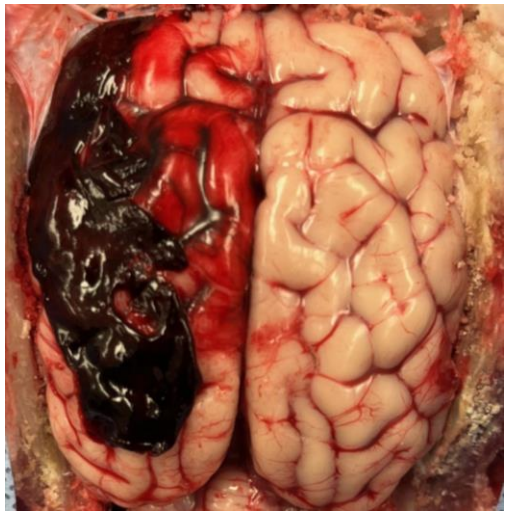


Infrared Intracranial Hemorrhage Detection Device

Validation:



CT scan



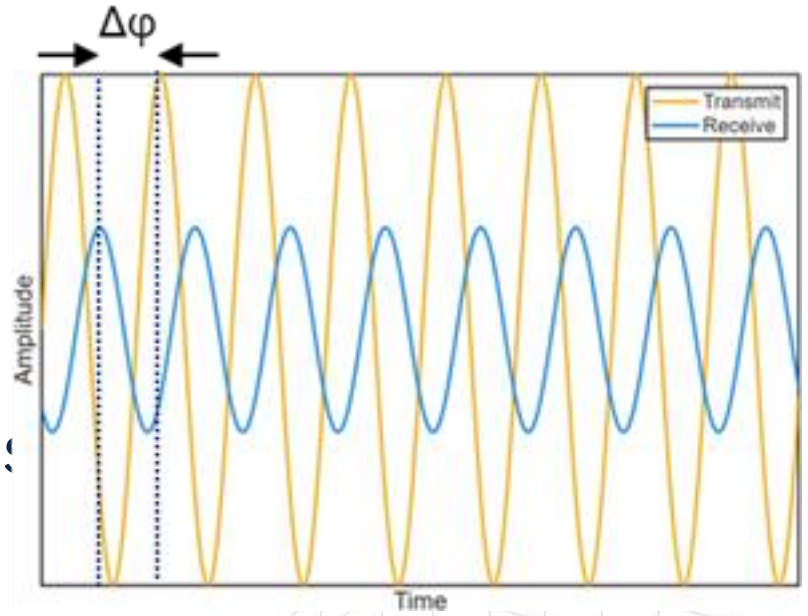
Post-mortem

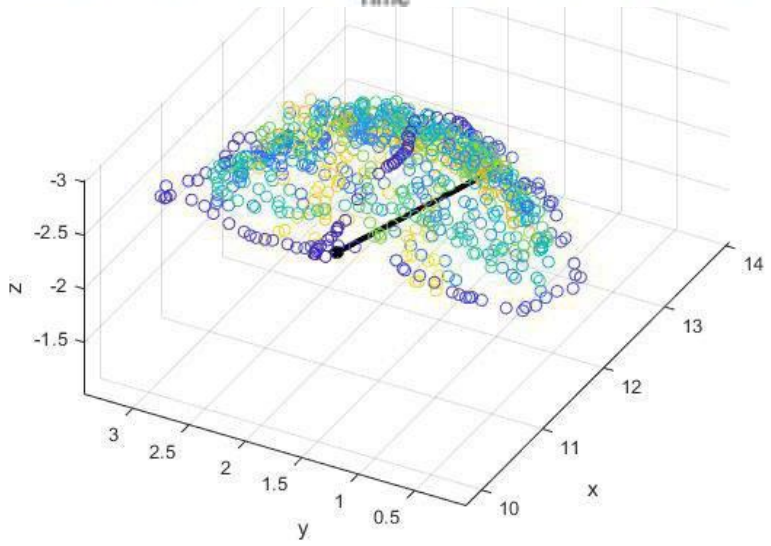
Mortality 50% at 72 h from apnea and severe neurological dysfunction

Brody et al., *manuscript in preparation*

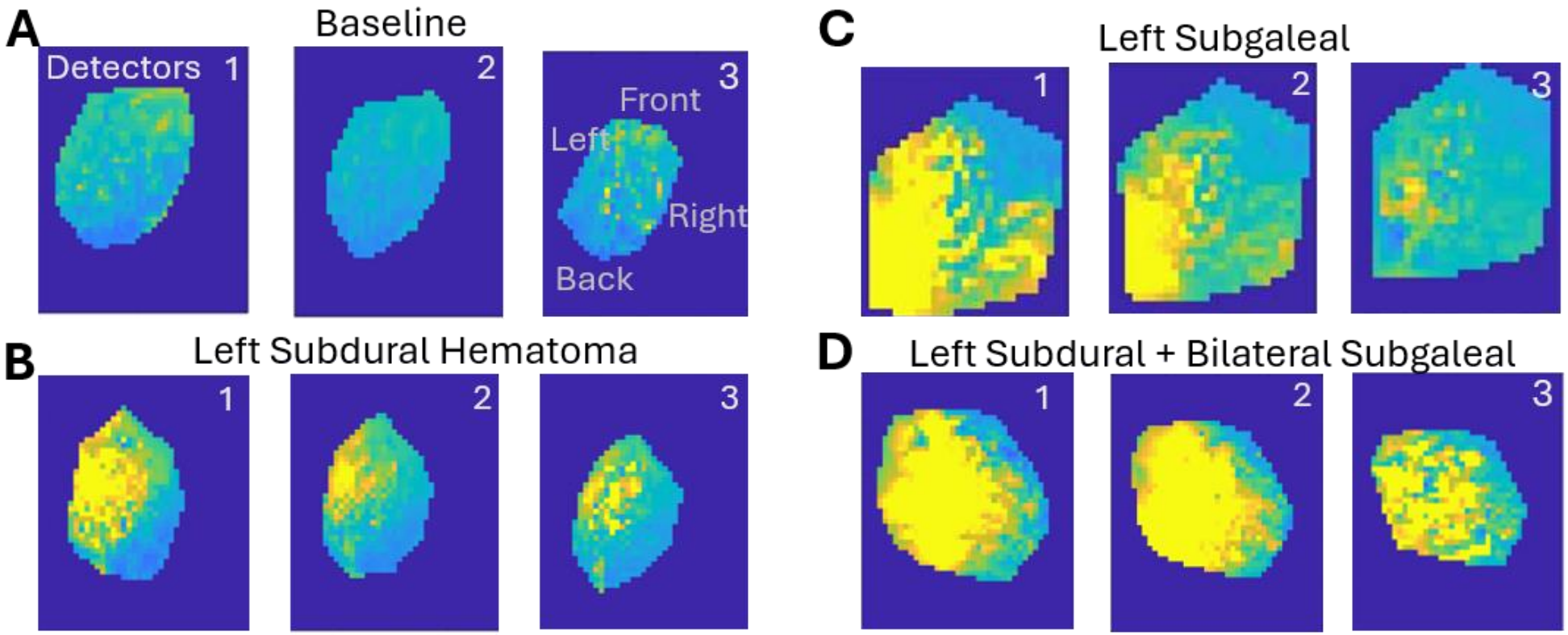
Infrared Hemorrhage Detection Device

- Frequency Domain Diffuse Optical Tomography system
  - 850 nm laser
  - 200 MHz modulation of amplitude
  - Phase shift and amplitude demodulation is done in digital signal processing
- Motion tracking data is acquired simultaneously to the optical data
  - Data spatially mapped on screen in real-time
  - Further data analysis is performed at the end of acquisition





Detection Device Testing

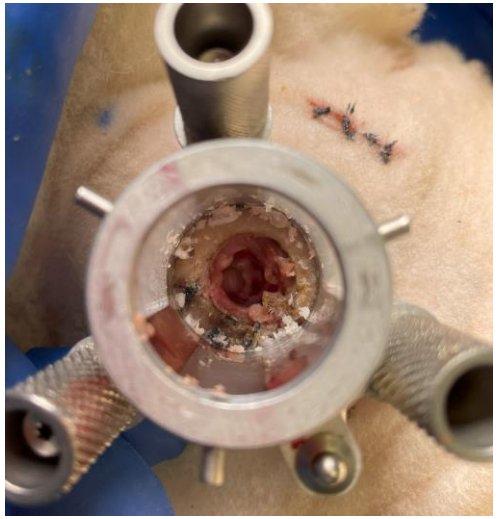


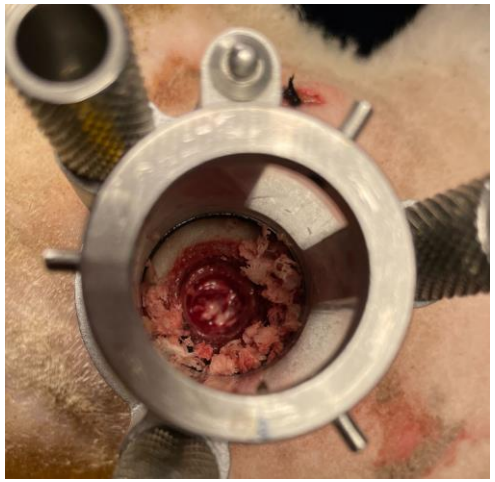
9 operators with skills and experience comparable to intended users (medics, corpsmen, other non-experts) were trained to use the detection device. Training required 30 min. Each assessment required <4 min.

Intracranial Hemorrhage Treatment Device

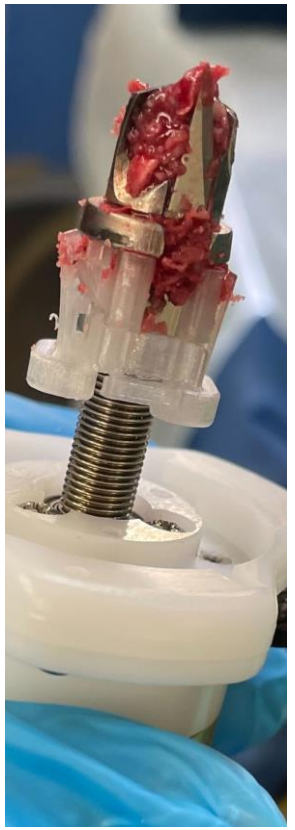
Base attachment with anchor screws into the skull, with tight gasket to reduce infection risk

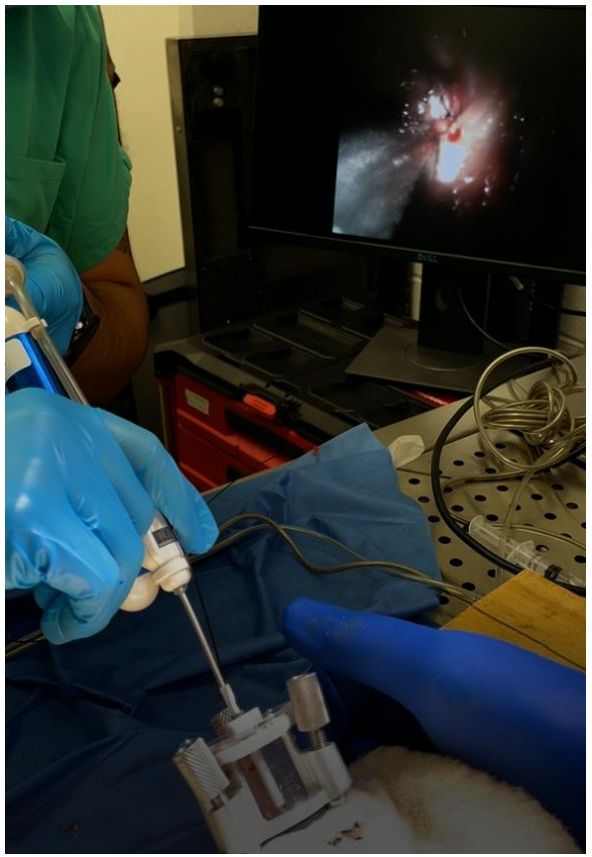
Cauterize and scalp resection





Create burr hole and puncture dura

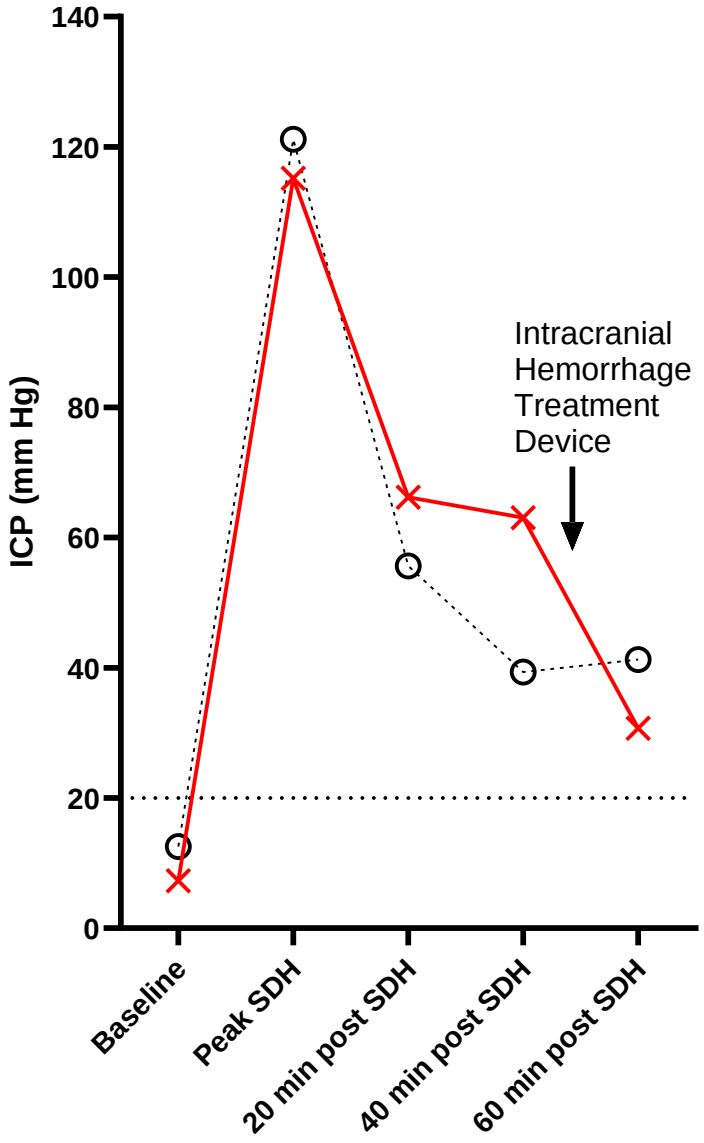


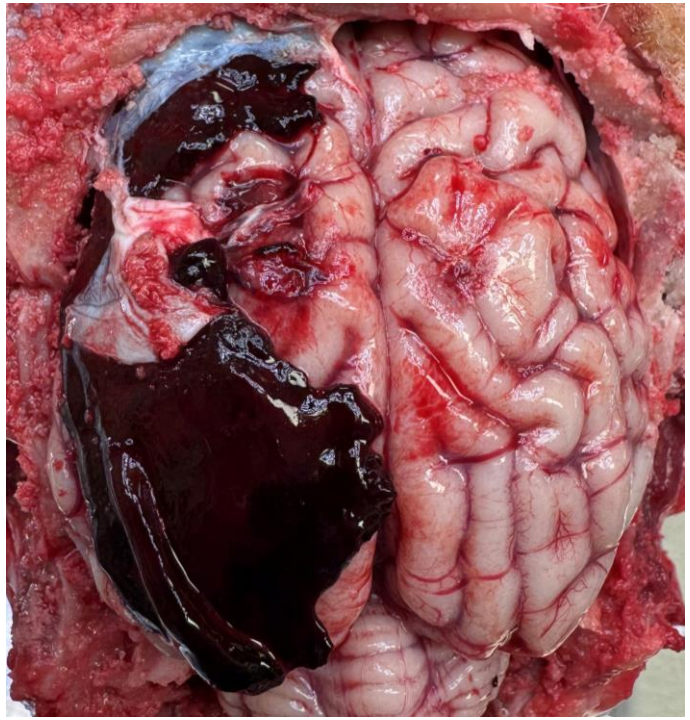


Provide access for treatment using
Nico (Stryker) Myriad alternating blade suction and morcellator, with light and camera

Brody et al., *manuscript in preparation*

Treatment of Sheep with Subdural Hematoma





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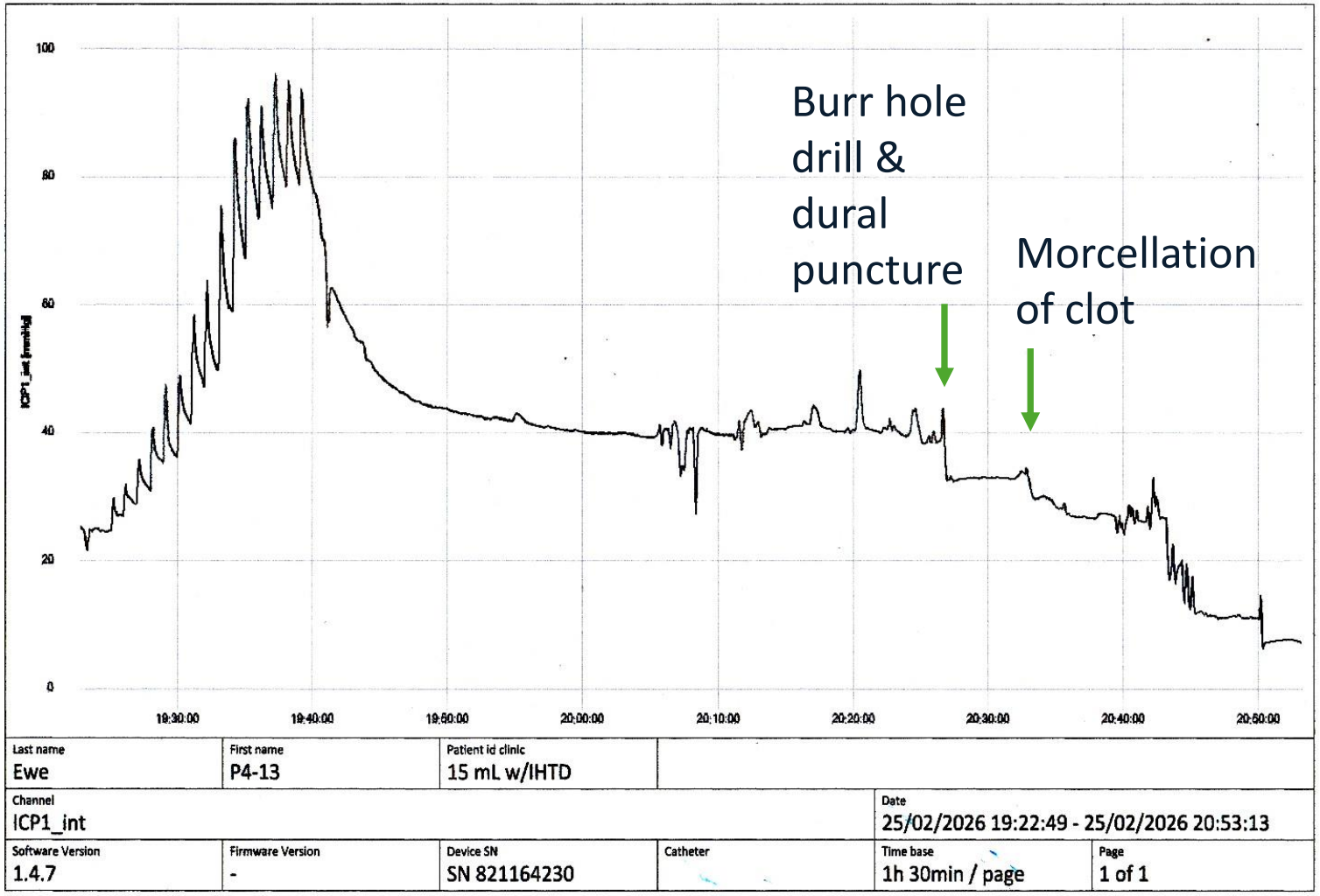
Randomized, Sham-Controlled Preclinical Trial

- Preregistered on Open Science Foundation
- Prespecified primary outcome measure: change in ICP at 60 min post injury
- Key secondary outcome measures include neurological status post injury and post-mortem histological markers of brain injury.
- Prespecified sample size of 6 qualifying sheep per group
- Block randomized to treatment vs sham after creation of the injury to avoid bias
- Neurological outcomes performed by blinded investigators

Intracranial Pressure Exemplar



Last name	First name	Patient id clinic			
Ewe	P4-13	15 mL w/IHTD			
Channel				Date	
ICP1_int				25/02/2026 19:22:49 - 25/02/2026 20:53:13	
Software Version	Firmware Version	Device SN	Catheter	Time base	Page
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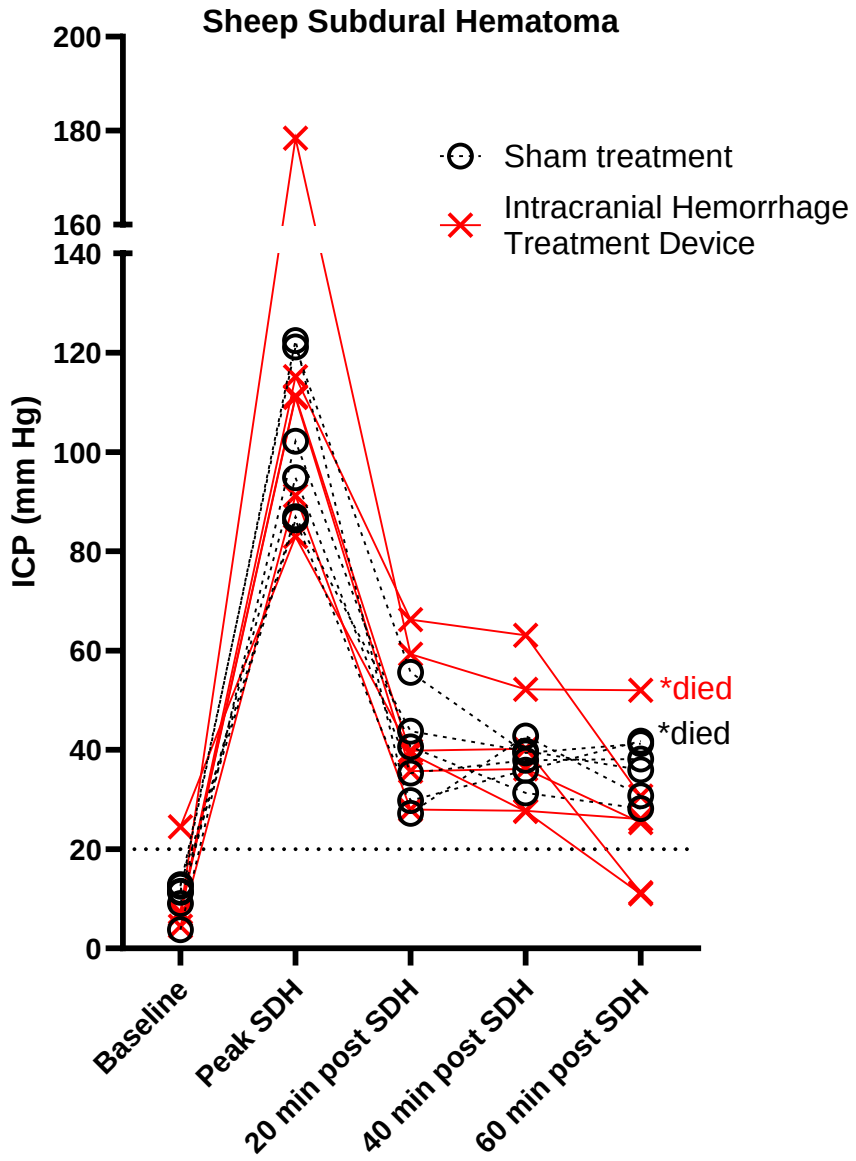
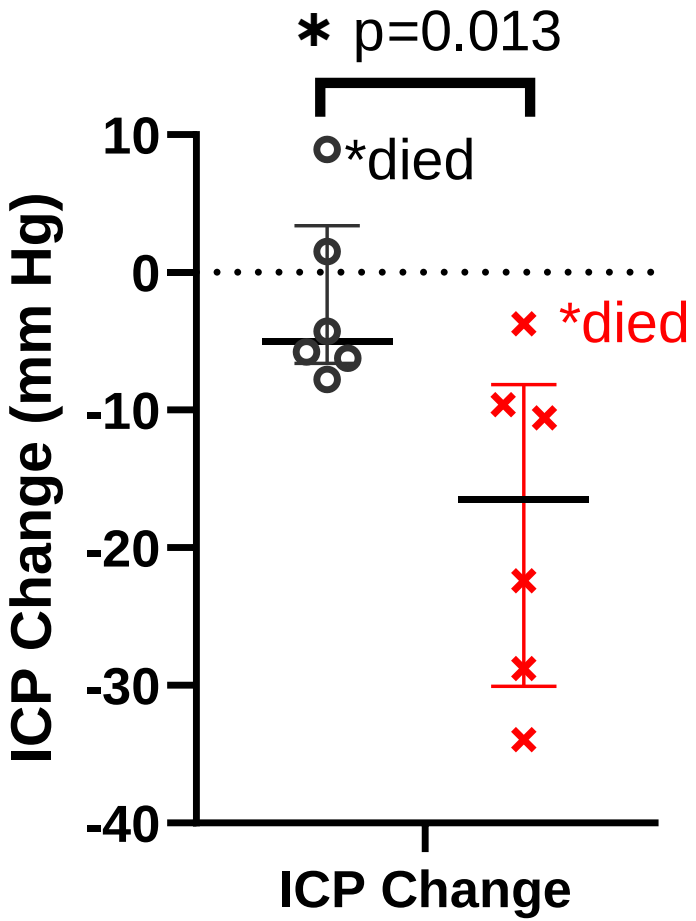
Some reduction in ICP from dural puncture.
Additional reduction in ICP from morcellation of clot.

Primary Outcome Measure: ICP



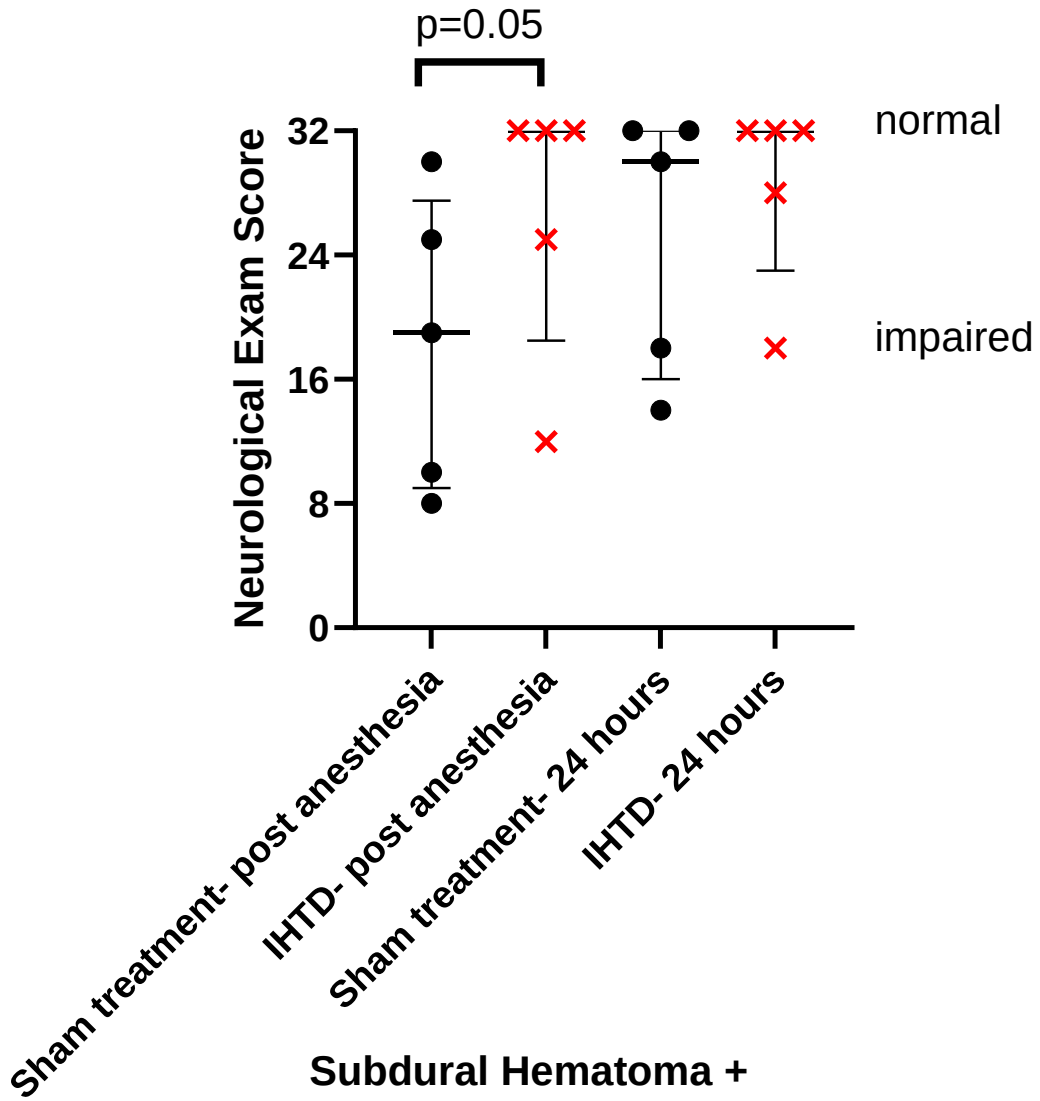


Statistically significant and clinically meaningful reduction in ICP by a median 11.5 mm Hg from 20-40 min vs. 60 minutes post SDH.

Treatments performed by one non-neurosurgeon user
10-20 minutes from decision to completion of procedure

Brody et al., *manuscript in preparation*

Key Secondary Outcome: Neurological Status

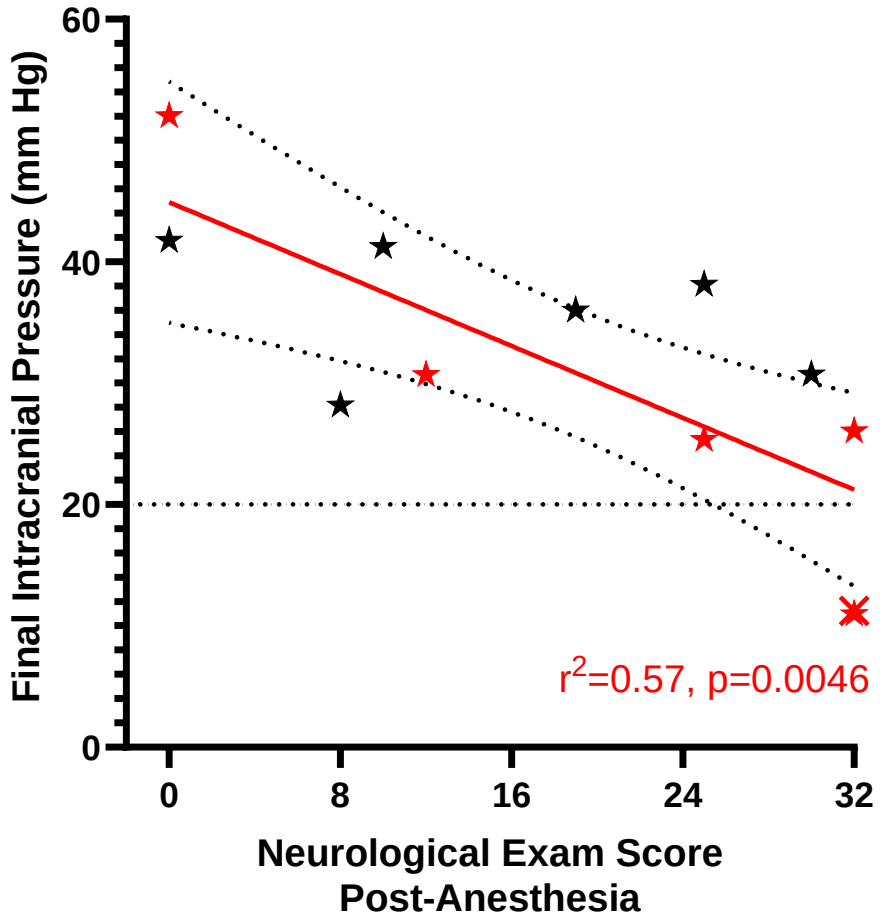


Statistically significant improvement in post-anesthesia neurological status.

Number needed to treat = 3.

Brody et al., *manuscript in preparation*

Neurological Status vs Intracranial Pressure



Lower final intracranial pressure correlates with better neurological outcomes. Driven by the data from the treatment group.

Brody et al., *manuscript in preparation*

Summary

- A hand-held infrared hemorrhage detection device can accurately detect and localize subdural hematoma in sheep.
- A hand-held intracranial hemorrhage treatment device can be used by a non-neurosurgeon to remove subdural blood, reducing intracranial pressure and improving neurological outcomes.

Interpretation

- These devices will not be a substitute for CT scanner and neurosurgeon.
- But when you don’t have a CT scanner and a neurosurgeon, these hand-held devices may be a good option.
- *If the results in sheep translate to humans, for every 3 patients treated, 1 would walk off independently, instead of being carried off on a stretcher or medically evacuated.*

The potential need

- *In the Special Operations Command:*
  - *Approximately 2,000 SOF medical providers*
- *In the regular military*
  - *Preparation for large scale combat operations*
  - *Over 2,000 severe TBIs in Ukraine from 2022-2024*
- *In civilian trauma care*
  - *80,000 cases of severe TBI per year in the US*
    - *Approximately 50% (range 40-70%) involve subdural or epidural hemorrhage*
    - *20% rural, >1 hour from a level 1 or level 2 trauma center (~3x higher mortality)*
    - *At least 8000 potential cases per year*
  - *493 level III & 923 level IV trauma centers without a neurosurgeon*
  - *Approximately 2,000 rural community hospitals*
  - *Approximately 16,000 rural EMS systems*
- *Worldwide*
  - *5.5 Million severe TBIs per year – mainly in the low- and middle-income countries / developing world without access to high level trauma care.*

Next steps

- *Further analyses, publications and presentations*
- *Commercial Partnerships*
- *Initial FDA consultation*
- *Additional grant applications*
- *Good Laboratory Practice testing in sheep, including infection risk.*
- *Cadaver and phantom testing*
- *FDA application as a breakthrough device*
- *Medical provider training*
  - *Special Operations Command*
  - *Rural Emergency Medicine*
  - *Developing world*