DuraSecure

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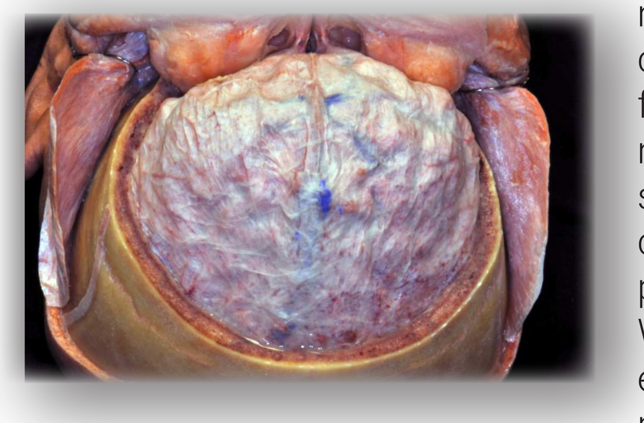
INTRODUCTION



During intracranial surgery one of the most potentially dangerious and time consuming portions can be repairing fenestrations (openings) in the dura mater. Current methods include suturing the fenestration which is time consuming, costly to the patient and potentially dangerous if mishaps occur. We were tasked with creating a quick efficient and safe solution to this problem.

PROBLEM

- Failure of watertight dural closure - Cerebral Spinal Fluid leakage causing meningitis.
- Current techniques take at 15 - 30min to apply.
- Closing techniques and materials cost >$750

SOLUTION

- A quickly deployable device that eliminates sutures and leakage.
- Application of device allows for proper seal and can be actuated roughly 1 minute prep work

EXPERIMENTS

Test Chamber: Simulated intercranial pressure (ICP) utilizing the pressure chamber and a sythetic membrane in place of dura mater. Increasing pressure from 9 cm of H2O (the minimum normal human ICP) to pathologic levels (>20 cm H2O).

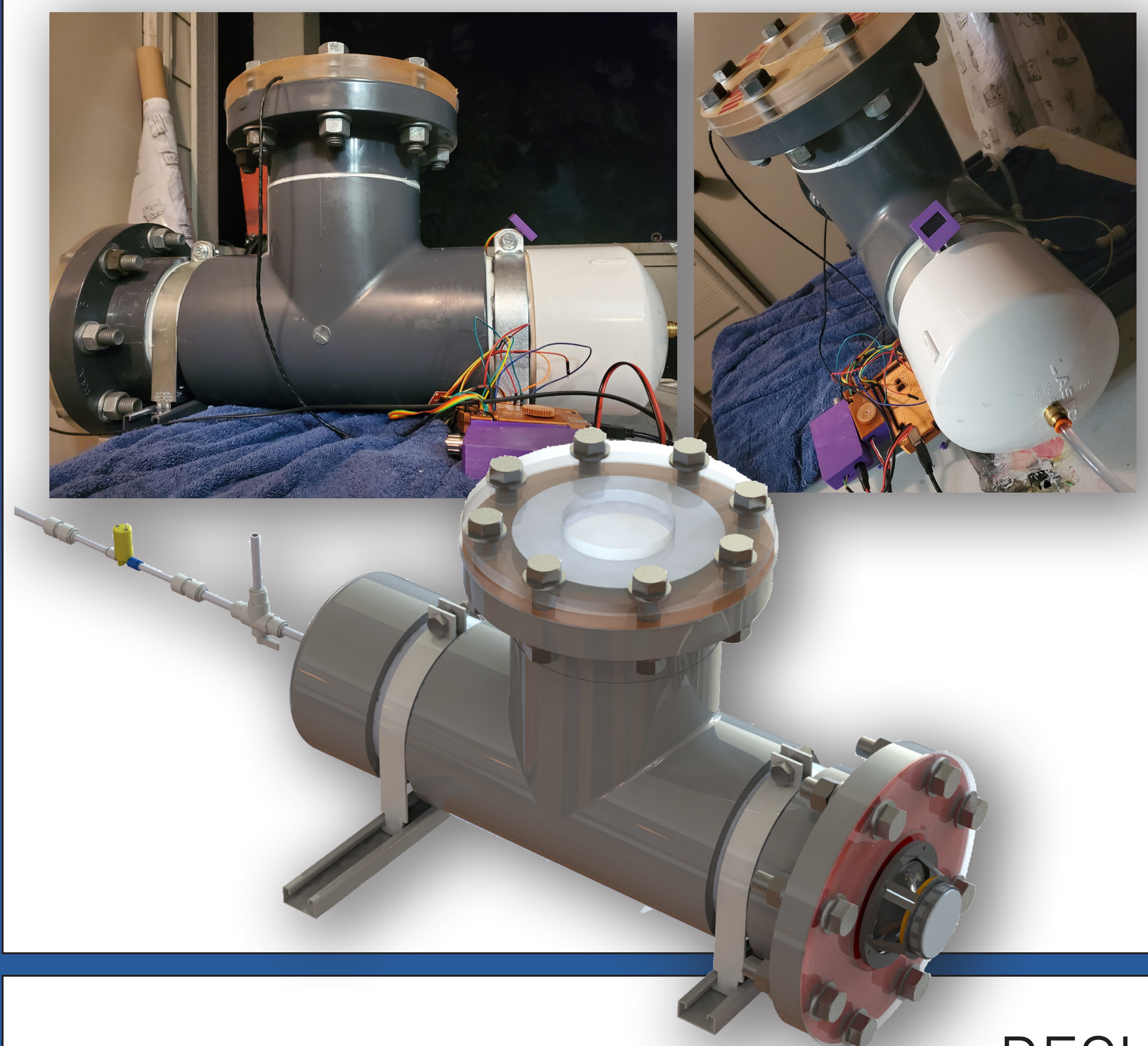
Pig Studies: In order to determine the efficacy of the design, testing would need to be carried out on dura matter. Swine and bovine dura mater closely resembles human dura. Once extracted SEM and qualitative test were conducted to choose a synthetic material with material characteristics similar to dura.

CONSTRAINTS

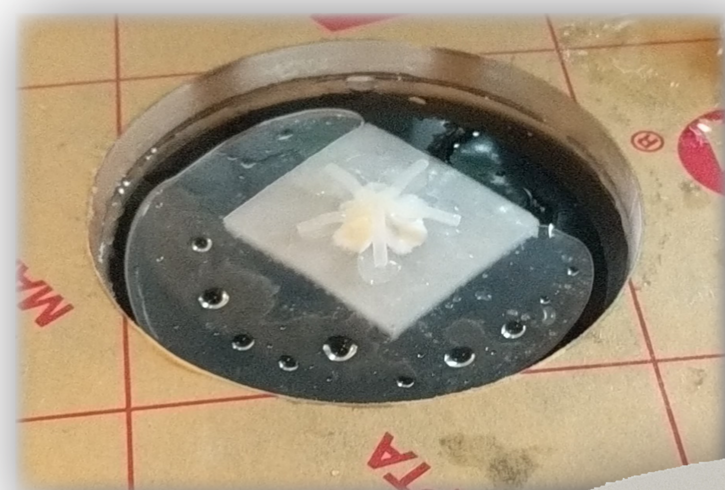
- Bioabsorbable Materials
- Minimally invasive
- Scaleable to different procedures
- Intuitive to Use
- Quicker than suturing

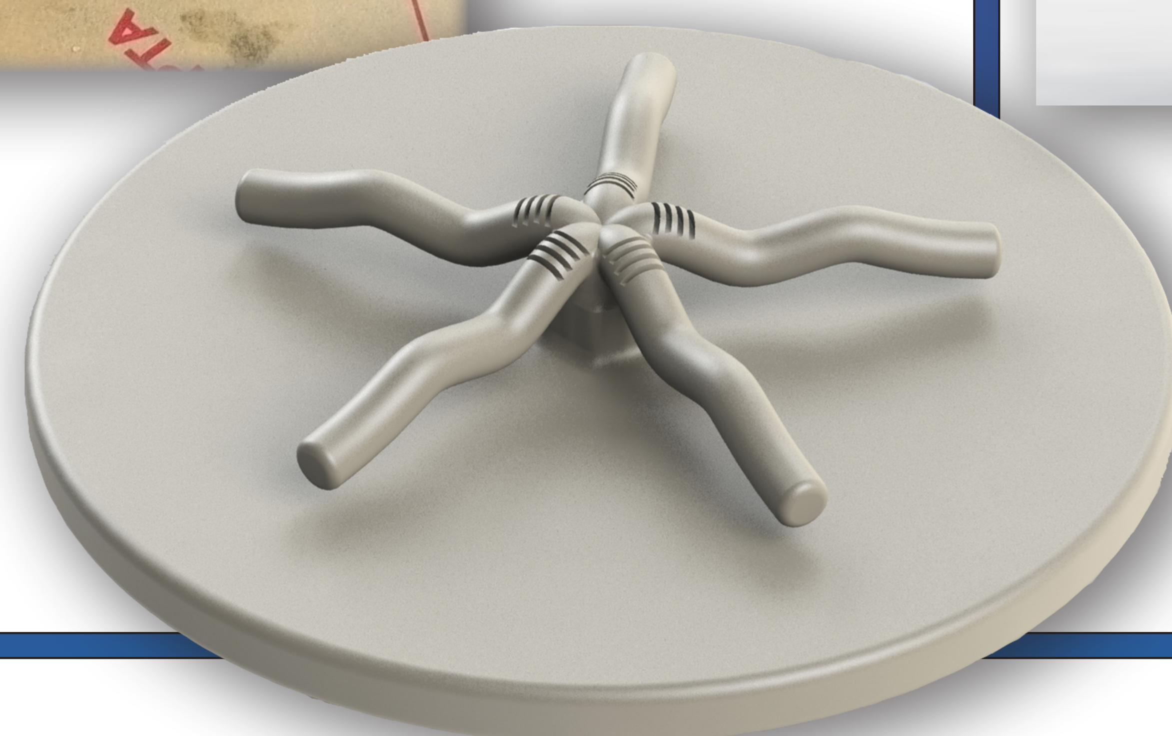
DESIGN

Pressure Chamber

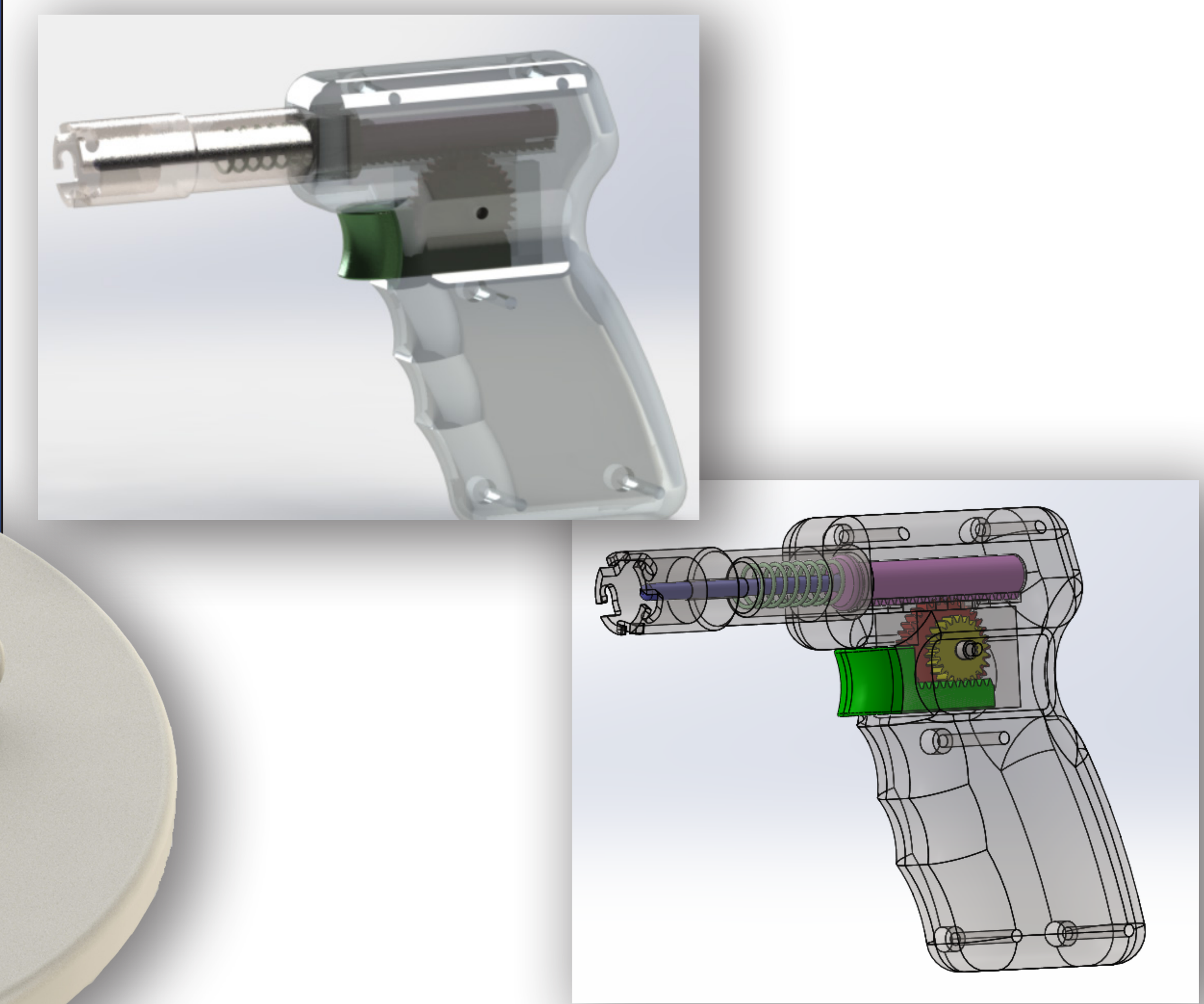


DuraSecure





Applicator



DESIGN

Pressure Chamber
- Simulate proof of concept Closure Devices
- Detect low pressure vairances
- Record data and export to txt
- Vary pressure lengths
- Incorportate Intercranial pressure wavefor

Base piece
- DuraGen Suturable™ collagen patches
- Folded up like origami
- Allowed to expand back out to flat sheet
- Holds CSF back from leaking out

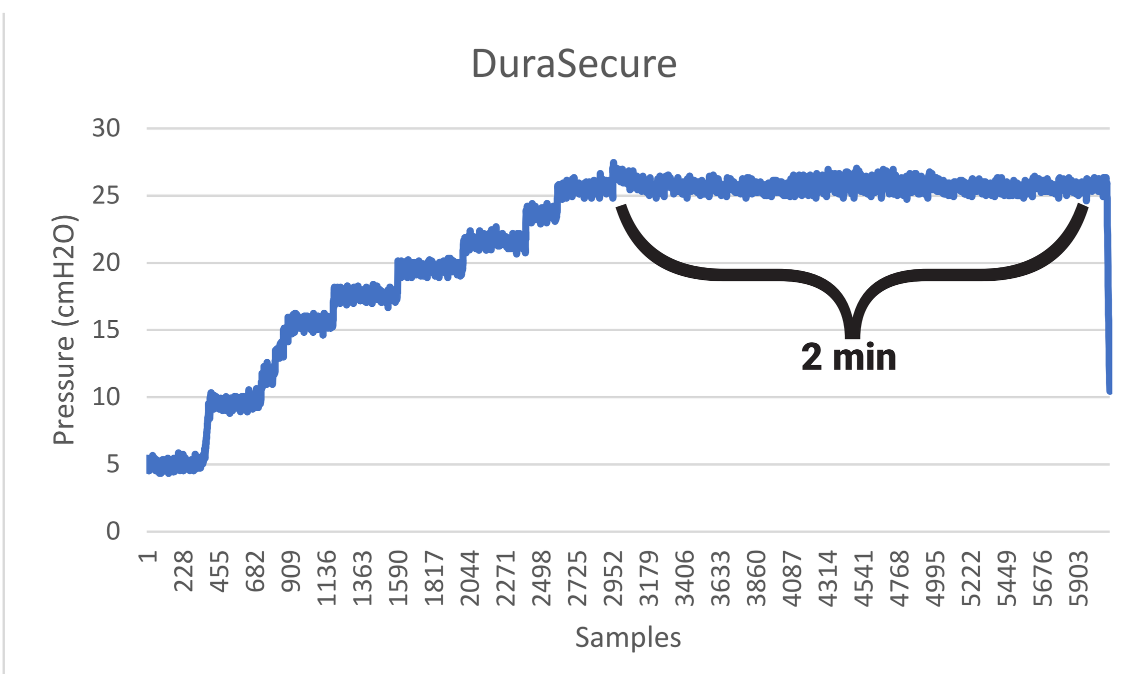
Arms
- Made of low density Polylactic-co-glycolic acid (PLGA)
- 5 "Bobby Pin" style arms arching out from center
- Clasps down on exterior of Dura
- Holds Basepiece in place so it does not come lose or shift down

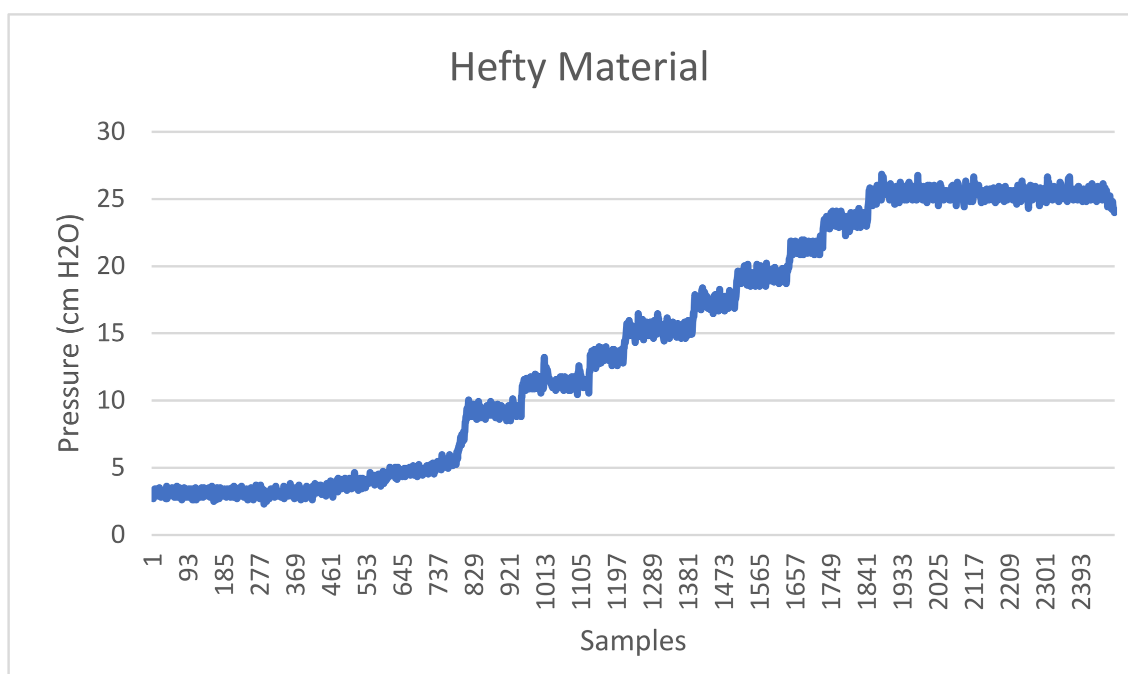
Applicator:
- Mechanically actuated through reduction gears and racks
- Holds the arms back within cylinder
- Released through central push rod
- Hooked ends for repositioning and removal of device

ANALYSIS

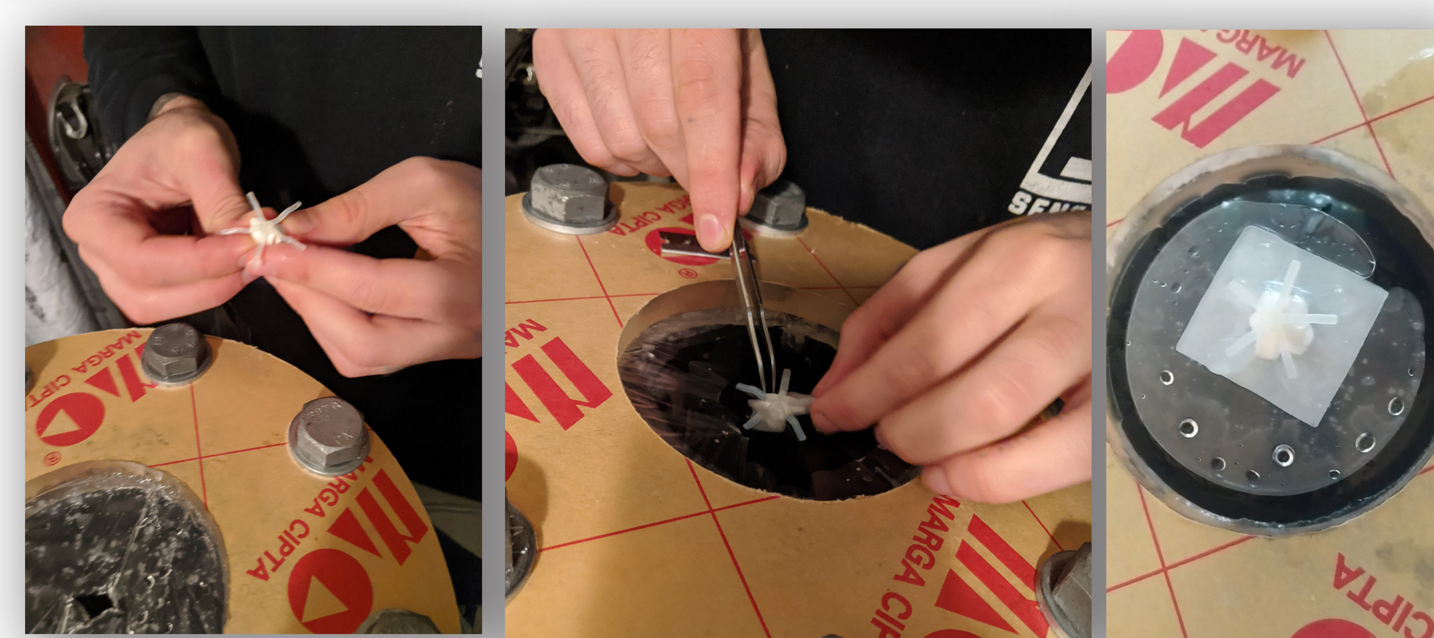
- Design held pressure at 9 cm H2O (standard ICP).
- Held consistent pressure increments of 2 cm H2O every 10 second interval up to 25 CM H2O (High end ICP).
- Withstood pressure at 25 cm H2O for 2 minutes.
- Maintained composure of fluctuate pressure
- Proof of concept was successful, allowing future iteration to applied on organic material.

RESULT





APPLICATION



FUTURE WORK

At this point we have demonstrated proof of concept, where a purely mechanically actuated device would effectively reduce leakage and hold pressure up to 25 cm H2O. We also demonstrated an application where the device is deployed from the applicator on to the fenestration site. Due to material constraints we were not able to combine these two concepts into one. Moving forward we will utilize PLGA (polylactic-co-glycolic acid) as the material for deployable arms or a cologen matrix similar to the base at a higher density. The PLGA is a bio-absorbable material approved by the FDA for human use in dura injury applciation. The material properties make it an excellent choice as it is flexible, durable, and resilient under these conditions.

ACKNOWLEDGEMENTS

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