Guided Craniotomy Device

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The Guided Craniotomy Device is a novel medical instrument designed to ease the stresses and strains that surgeons and dissectors experience when performing a craniotomy. By semi-automating the function of removing the calvaria, medical professionals can ensure that the vital portions of the brain and its surrounding area maintain their structural integrity. In craniotomies, preserving the dura mater and minimizing the possibility for scouring the brain are of the utmost importance. Through its simplified approach to the procedure, the Guided Craniotomy Device allows for human error to be minimized, and the quality of the approach to be maximized.

Why Build It?

The Guided Craniotomy Device's inception stems from the GCU Cadaver Lab's need for a more efficient method to remove brains without damaging the structures the lab hopes to study. Given that the traditional process involves a substantial amount of interaction with the skull post-scouring, the risk for error is too high for the process to be sustainable when inexperienced mentees are brought into the mix. So, to attenuate these risks and allow for a simpler brain removal process, the team set out to build a device that still allows for students to remove the calverial while also minimizing the potential for damaging the brain during the process.

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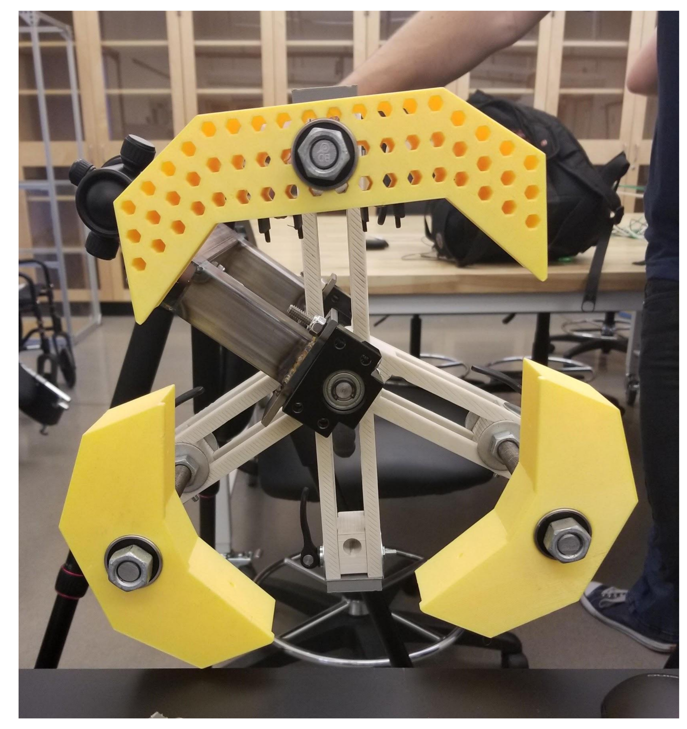
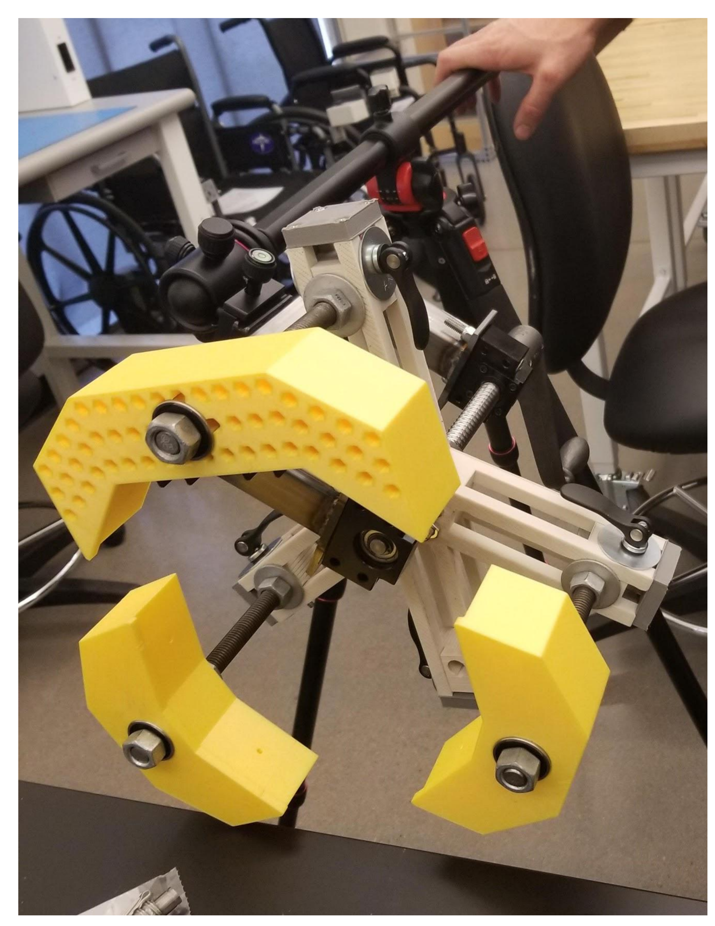




Functional Requirements

Requirement	Design Specifications
Maintain integrity of the brain and dura mater	Distributes force evenly around the base of the calvaria using 12 hooks
Ability to fit a variety of head sizes	Final design of the frame extends to 40 cm in diameter, well over the average head size
Apply force capable of removing calvaria	Min. applicable force of 200N Max. applicable force of 1,000N
Usable/durable for long stretches of time	Device must count with a wear test rating of 2,000 cycles
Can be effectively sanitized after each use	Final components are made from stainless steel which is autoclavable
Biocompatible with biological systems to avoid degradation post operation	Meets USP validation requirements and passes cytotoxicity, sensitization, pyrogenicity tests.

Engineering Standards

ISO 7539: Corrosion of Metals and Alloys

ISO 26843: Fracture Toughness (Chirpy)

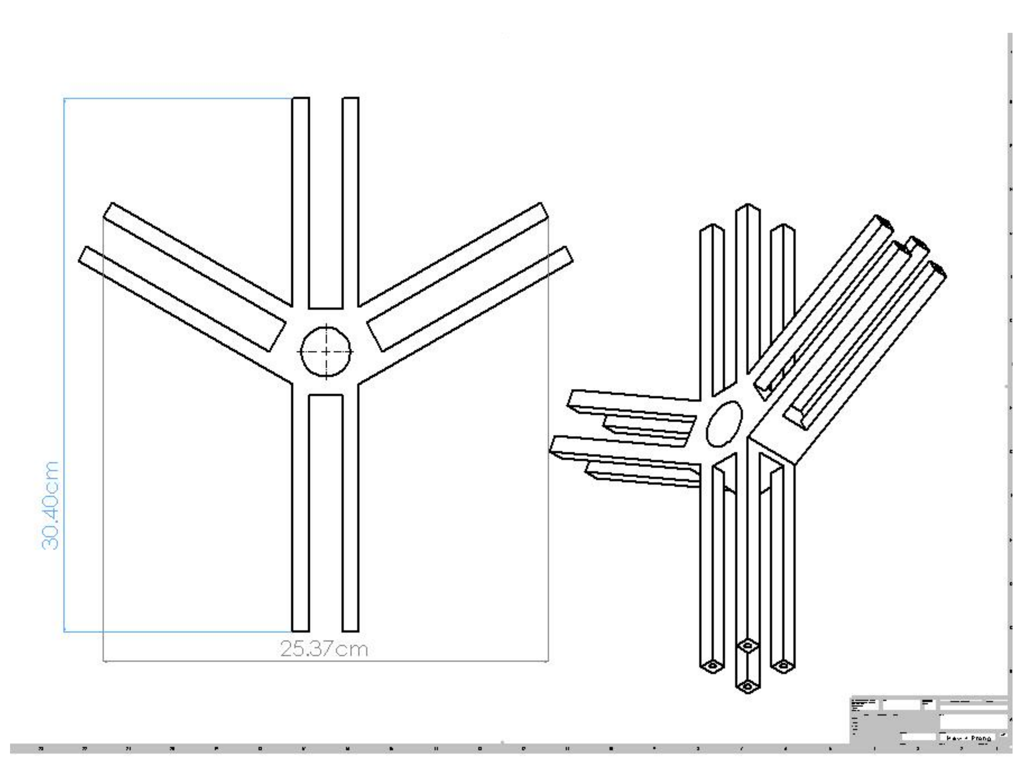
ASTM E466: Axial Loading and Fatigue Testing

ISO 11134: Moist Heat Sterilization

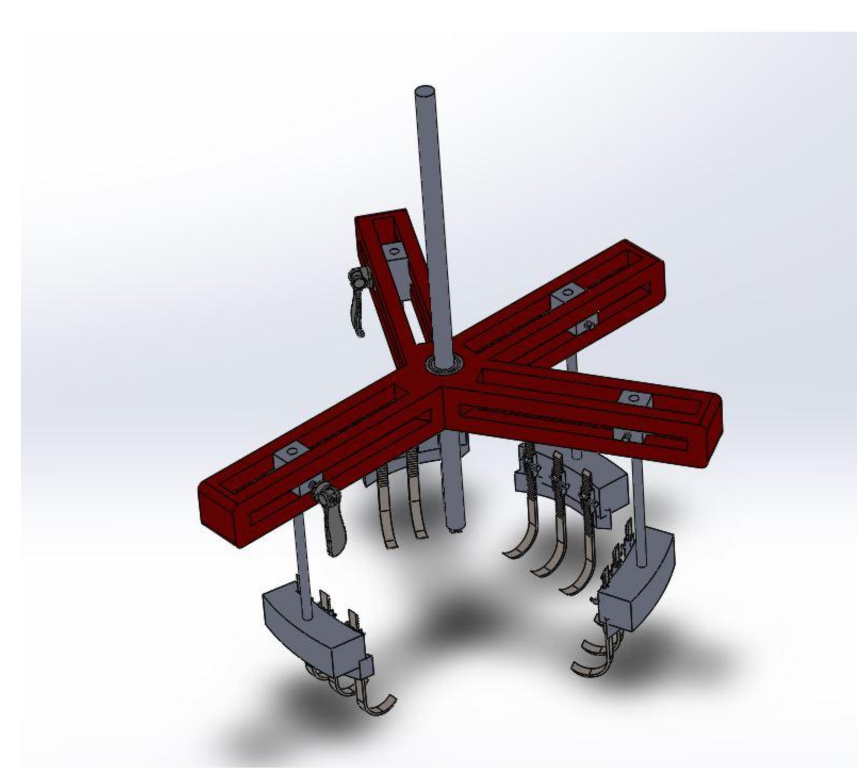
ISO 17752: Metal Corrosion Runoff Rates

The Design Process

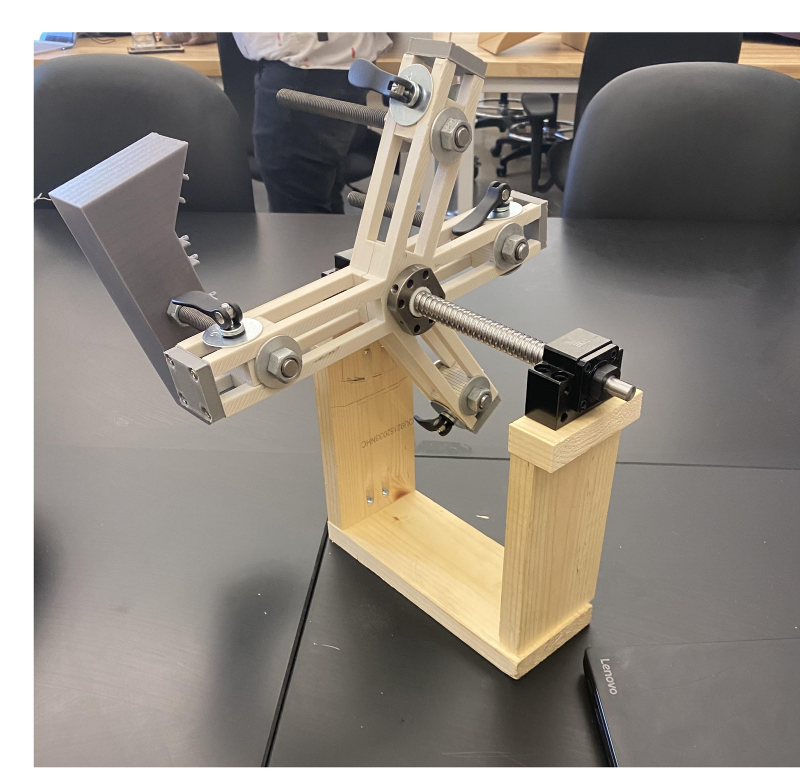
The inspiration for our initial design came from three prong gear pullers.



In order to adjust the device for head circumference, as well as make vertical adjustments to the hooks, we altered our design to use four prongs rather than the initial two.



The frame (red) allows the adjustment of the smaller support rods to fit the head of the subject. Attached to each of these four rods is a collar with three hooks. These hooks are inserted into the cut made into the skull at the base of the calvaria.



As the main drive rod in the center is rotated using a crank handle, the frame is displaced along the rod. This provides the pulling force to pry the calvaria from the skull.

Testing Summary

The team was unable to perform any of the verification tests due to the pandemic. The data that would have been collected is as follows:

- Melon/Cranial Test: maximum and minimum head radii supported by the device
- Force Test: measure the amount of force device can exert
- Axial Point Loading: determine the yield strength of material
- Sterility Test: presence (and if present, the amount) of bacteria after autoclave
- Corrosion Test: rates of corrosion of different material samples
- Fracture Toughness/Charpy Test:
  - measure the amount of energy absorbed before fracture and observe the type of fracture

Next Steps

A lot of work and effort was put into the design of this project, and we hope that future engineering teams our able to improve on our design and carry our vision forward. We feel that the next steps to be taken should include

- Full assembly using all stainless steel printed parts
- Completed verification testing, and design modifications to meet engineering standards and functional requirements
- Integration of support frame
  - Superior support of the device would come from using the surgical table to hold the support frame would provide improved stability and strength when performing a craniotomy
- Testing the final device with real cadavers

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