

Non-Invasive Frameless Immobilizer for MRI Guided Focused Ultrasound (Under NDA)

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Client: Henry Ford Health Faculty Advisor: Dr. Daniel Morris

Background

Henry Ford Health started performing a new type of brain surgery called MRI-guided focused ultrasound (MRgFUS) Shown conceptually in Figure 1.

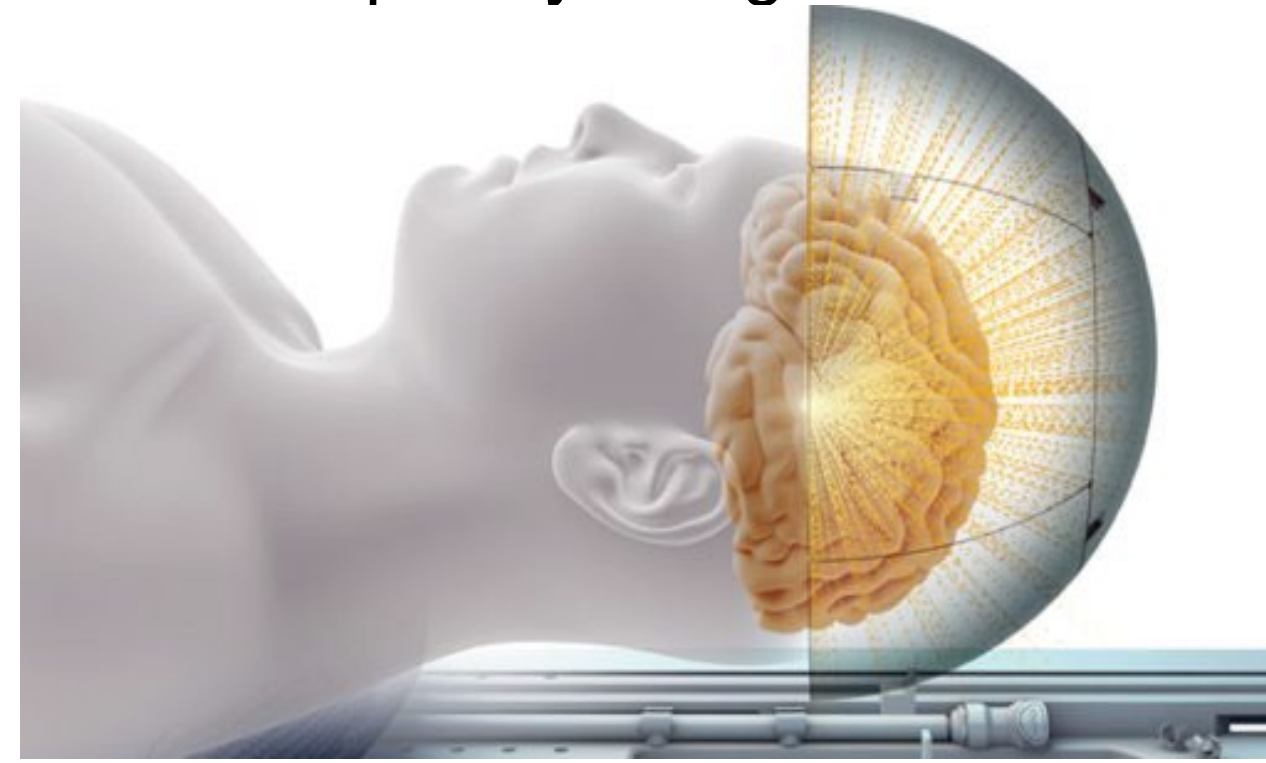


Figure 1: Theoretical approach to MRgFUS including the use of many ultrasound waves focused to ablate one target in 3D space.

- (MRgFUS) is a non-invasive procedure used to treat Essential Tremor and Parkinson's disease
- High-intensity ultrasound thermally ablates targeted brain regions, reducing tremors by up to 70% [1]
- Precise targeting requires complete patient immobilization

MRgFUS is a life changing procedure; patient outcomes are shown in Figure 2.



Figure 2: Patient writing examination before and after MRgFUS. The current method of immobilization is the stereotactic headframe shown in Figure 3.



Figure 3: An example of the MRgFUS procedure's stereotactic head frame secured to the skull with titanium screws [2].

The problems with the frame include:

- Invasive - screws are drilled into the patient's skull
- Deters patients from undergoing procedure
- Added risk of infection
- Limits access to patient airway
- High cost

Problem Statement

This project aims to design and evaluate a frameless immobilization device that improves patient comfort while reducing the clinical costs associated with the procedure.

Objectives

The following design objectives were identified based on client feedback:

- Must be noninvasive
- Must minimize movement while maintaining submillimeter accuracy
- Cannot interfere with the other equipment present
- Should take patient pain levels to less than a 5 on a 1-10 scale
- Should allow access to patient airway within 5 seconds

Constraints

- Design constraints include:
 - Must weigh < 10 lbs [5]
 - Nonferromagnetic materials
 - Compatible with Insightec ExAblate Prime system
 - Must cost < \$3,000
- Performance constraints include:
 - Maximum static displacement of less than 0.5 mm [3]
 - Maximum dynamic displacement of less than 2 mm [3]
 - Materials need to be safe for continuous skin contact for at least 3 hours [4]

Design Alternatives

Literature review identified four design alternatives shown in Figure 4.

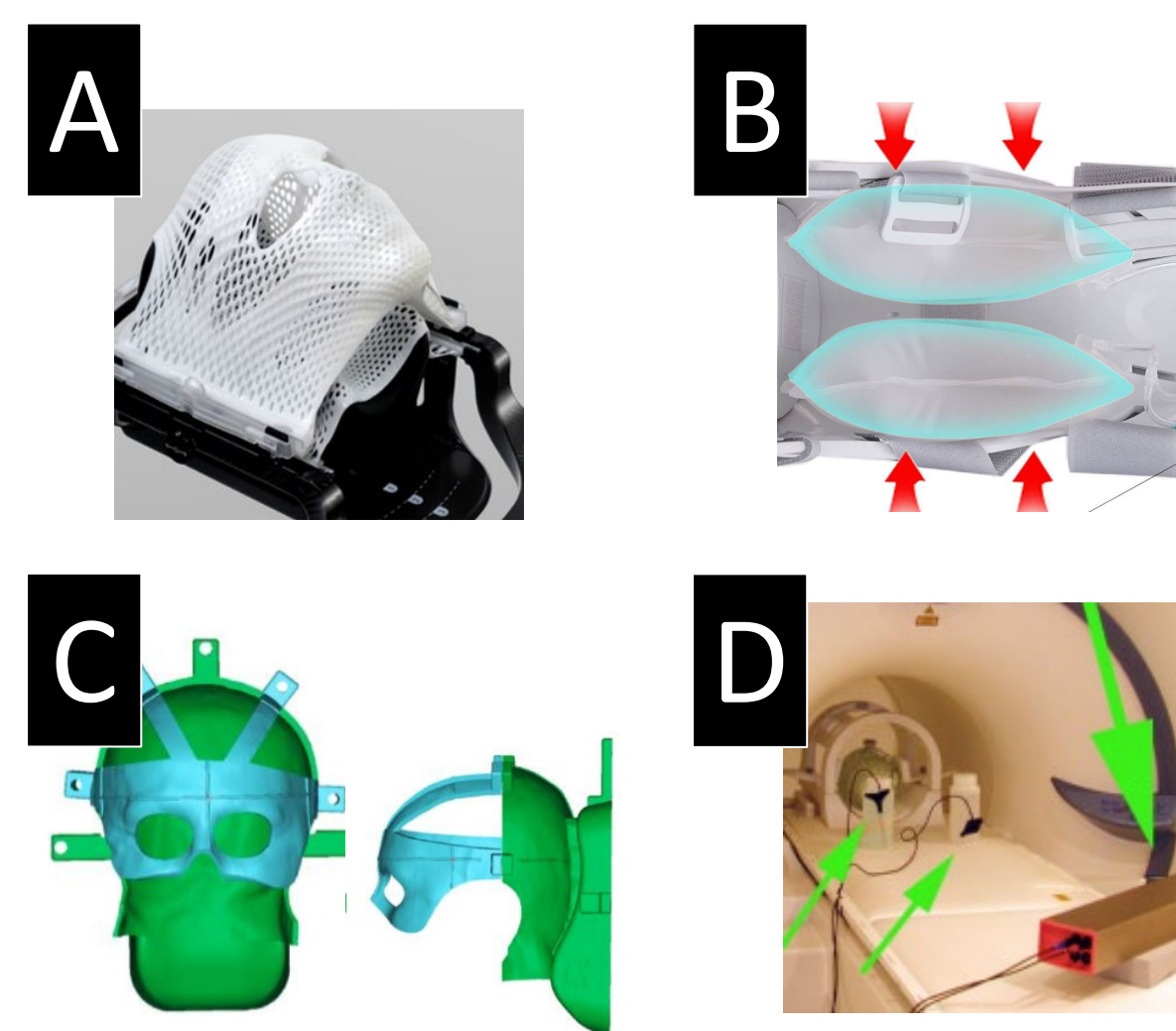


Figure 4: Design alternatives considered for immobilization A) Radiosurgery mask adaptation B) Air bladder stabilization system C) Custom patient molded mask D) Live 3D patient tracking.

Decision Matrix

Table 1: Matrix comparing four design alternatives

Criteria	Weight	A	B	C	D
Risk To Patient	25%	7	7	3	3
Design Feasibility	20%	10	10	5	3
Ease of Integration	15%	7	7	5	5
Patient Comfort	15%	7	7	10	5
Access to Airway	10%	10	5	10	5
Set-up Time	10%	7	3	5	5
Cost	5%	10	5	7	7
Total Score (0-10)	100%	8.05	6.90	5.85	4.20
Rank		1	2	3	4

Selected Design

Based on decision matrix results and client input, the radiosurgery mask was chosen.

- Based on standard clinical mask system
- Modified to improve access and usability
 - Top section removed for cranial exposure

Figure 5 compares the original and adapted mask design.

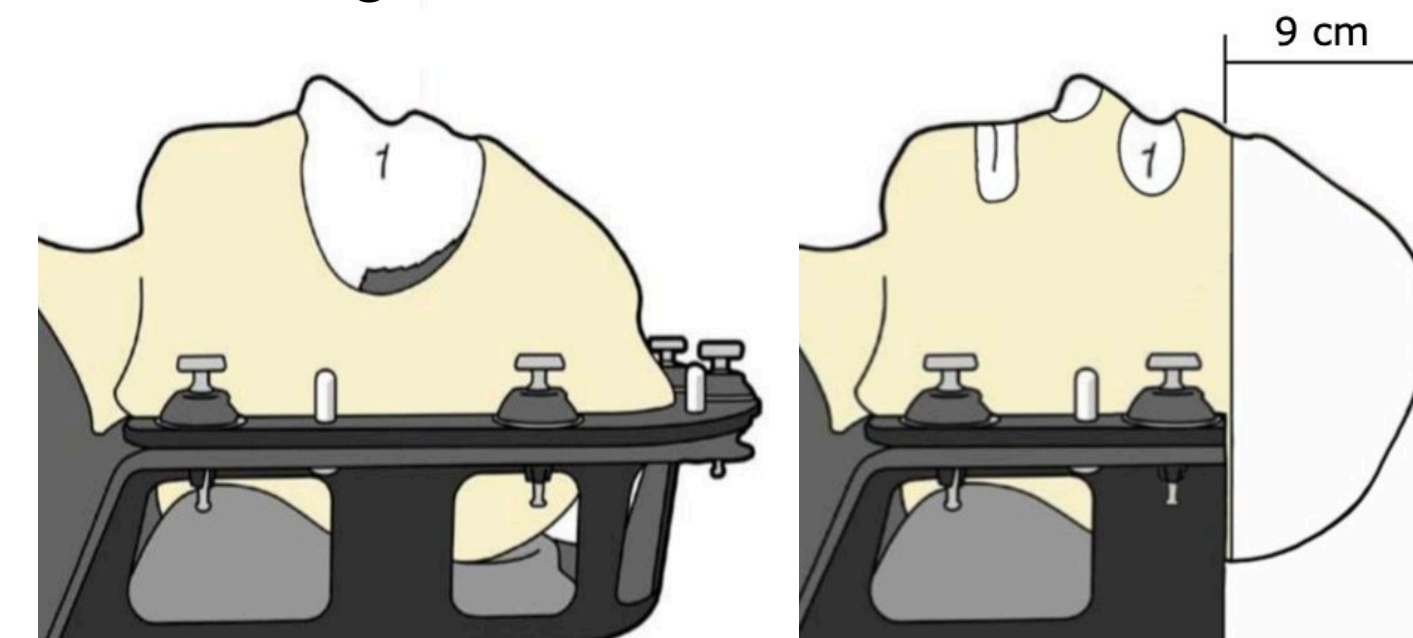


Figure 5: The original CQ Medical radiosurgery mask compared to the ideal, modified radiosurgery mask

Procedure

The experimental setup was designed to evaluate mask stability under applied loads:

- Custom oak platform built to mimic radiosurgery table
- Mask fitted to ballistic gel skull model
- Dowel rod inserted and secured to platform
- Load cell used to measure applied force via string system
- Forces (0-100 N) applied in four directions: up, down, left, right

The full experimental configuration is shown in Figure 6.

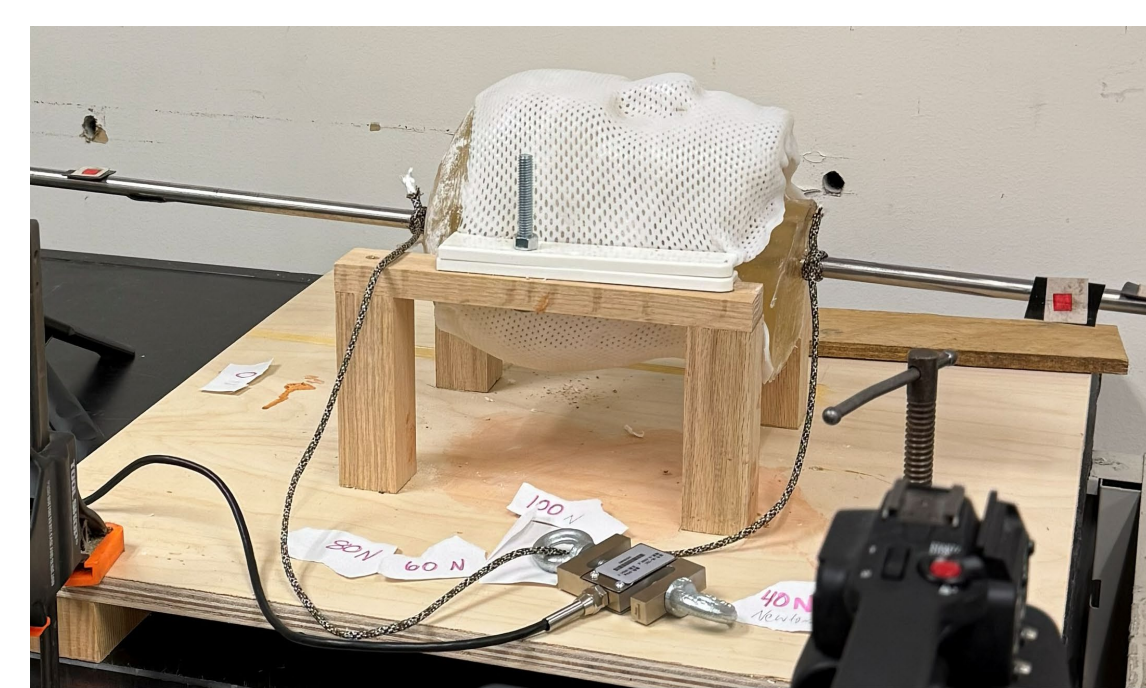


Figure 6: Ballistic gel skull in the altered radiosurgery mask bolted to the wooden testing platform.

Force measured with a load cell system:

- Load cell measures force (0-100 N)
- Calibration converts output to force
- Signal conditioning using a HX711 amplifier
- Data acquisition using an Arduino

Figure 7 shows the load cell system and calibration.

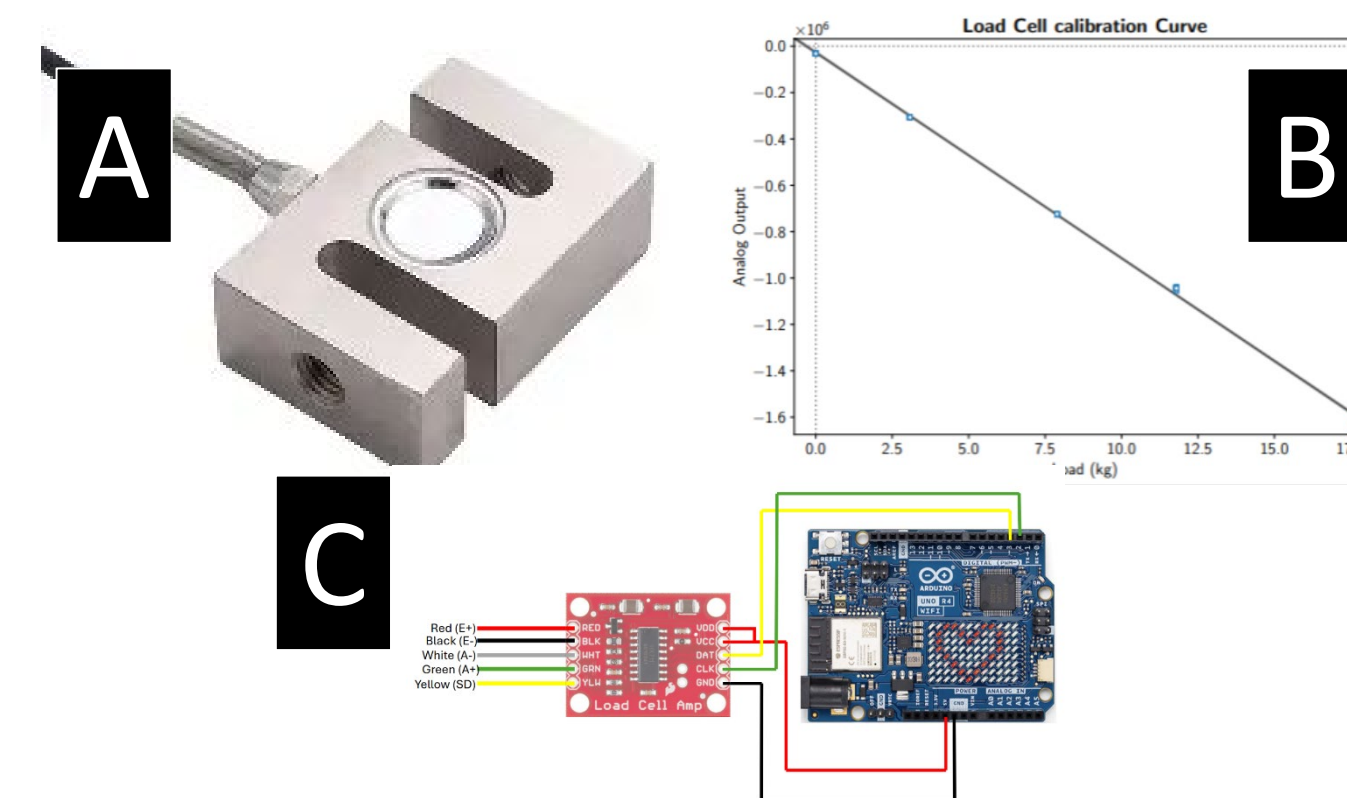


Figure 7: Load cell system. A) Load cell sensor that measures applied force B) Calibration curve relating sensor output to applied load C) Electrical diagram for signal amplification and data acquisition.

Procedure (Contd)

Displacement measured using image-based tracking:

- 1 cm marker used for spatial calibration
- Images captured at baseline and applied loads
- Baseline and loaded images overlaid (50% opacity)
- Pixel displacement measured between images
- Converted to physical displacement (mm)

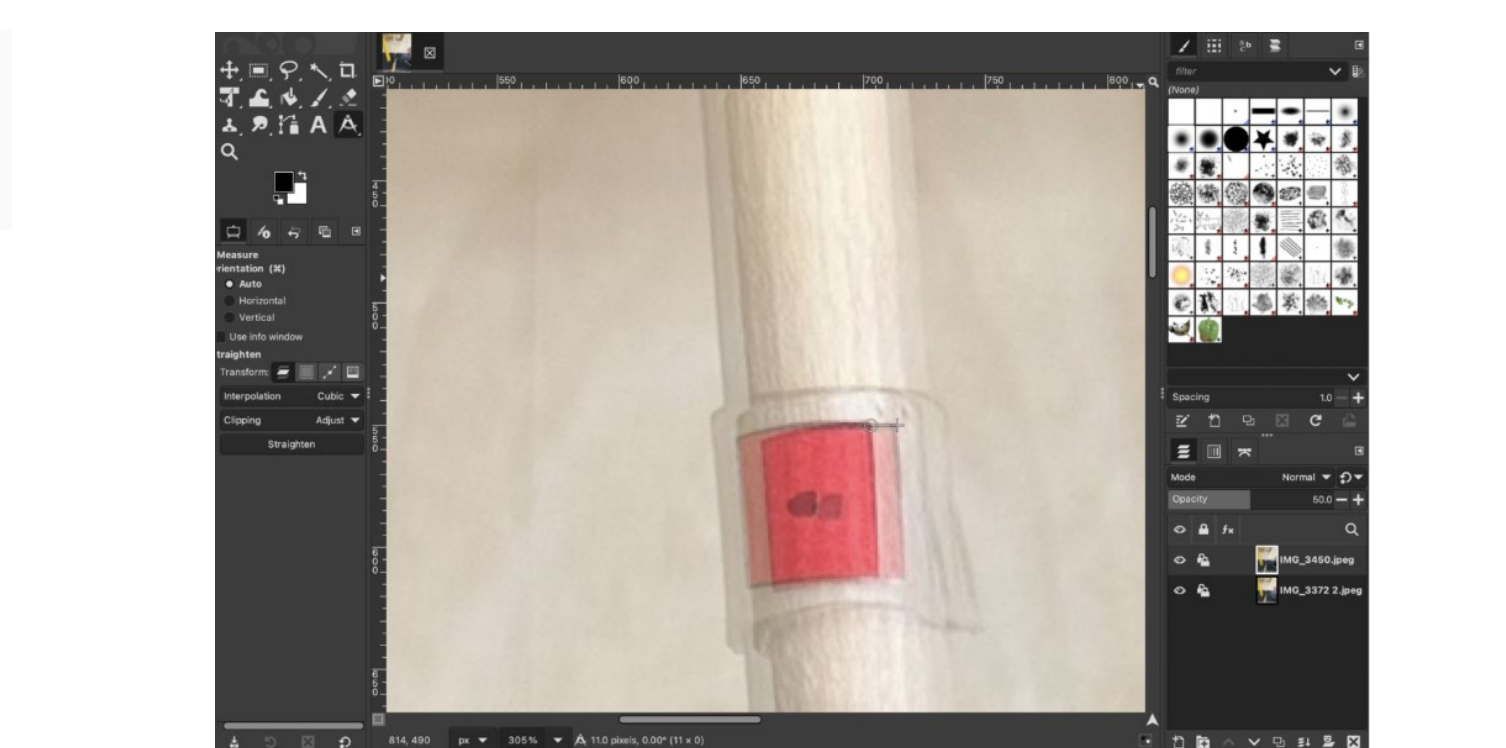


Figure 8: Image overlay used to calculate displacement.

Results

The mask successfully immobilized the experimental subject to under 1 cm of movement.

- Unanticipated trend where higher displacement seen at intermediate force shown in figure 9
- Residuals show large gap from client requested immobilization numbers in figure 10

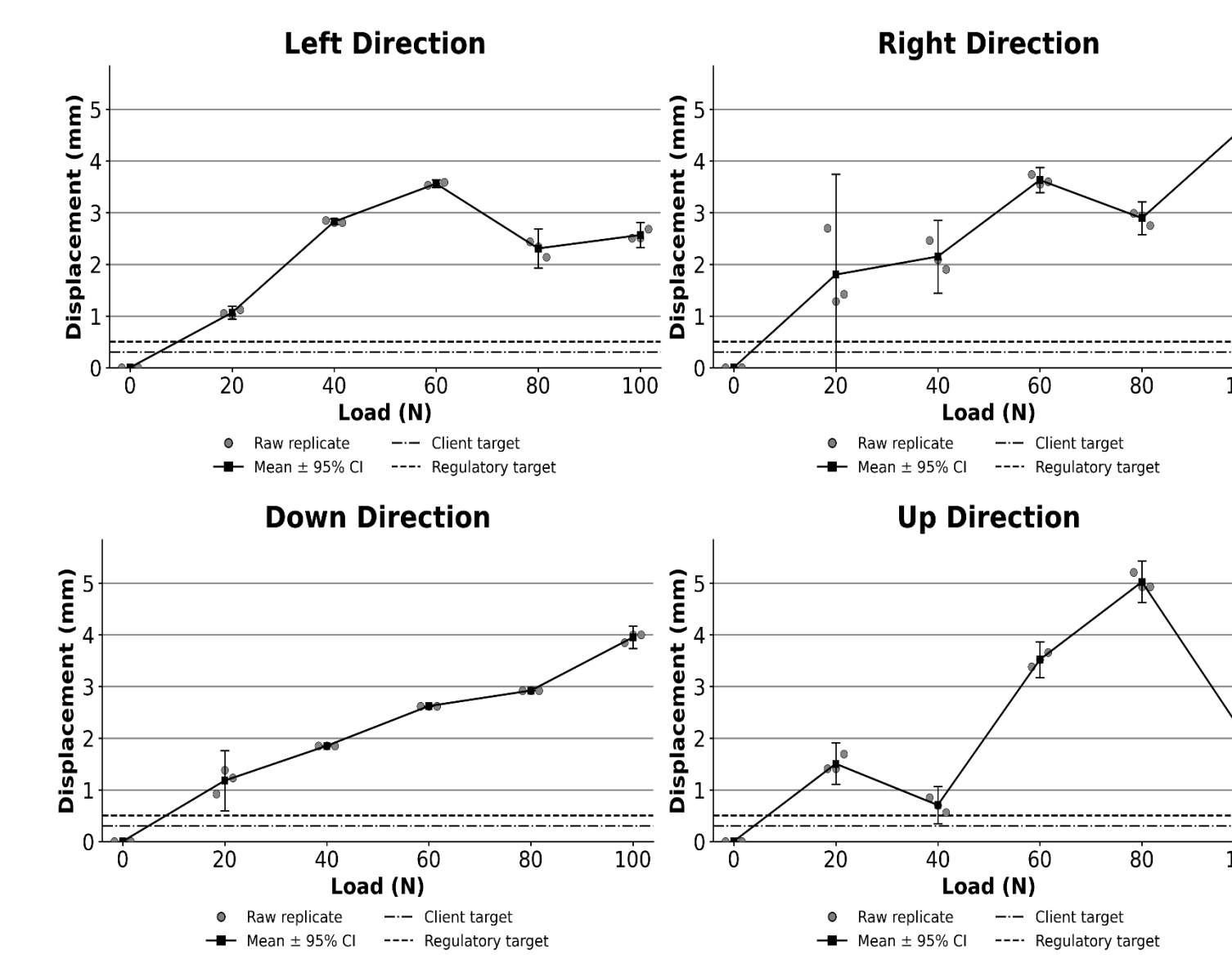


Figure 9: Experimental head displacement under incremental load in four directions.

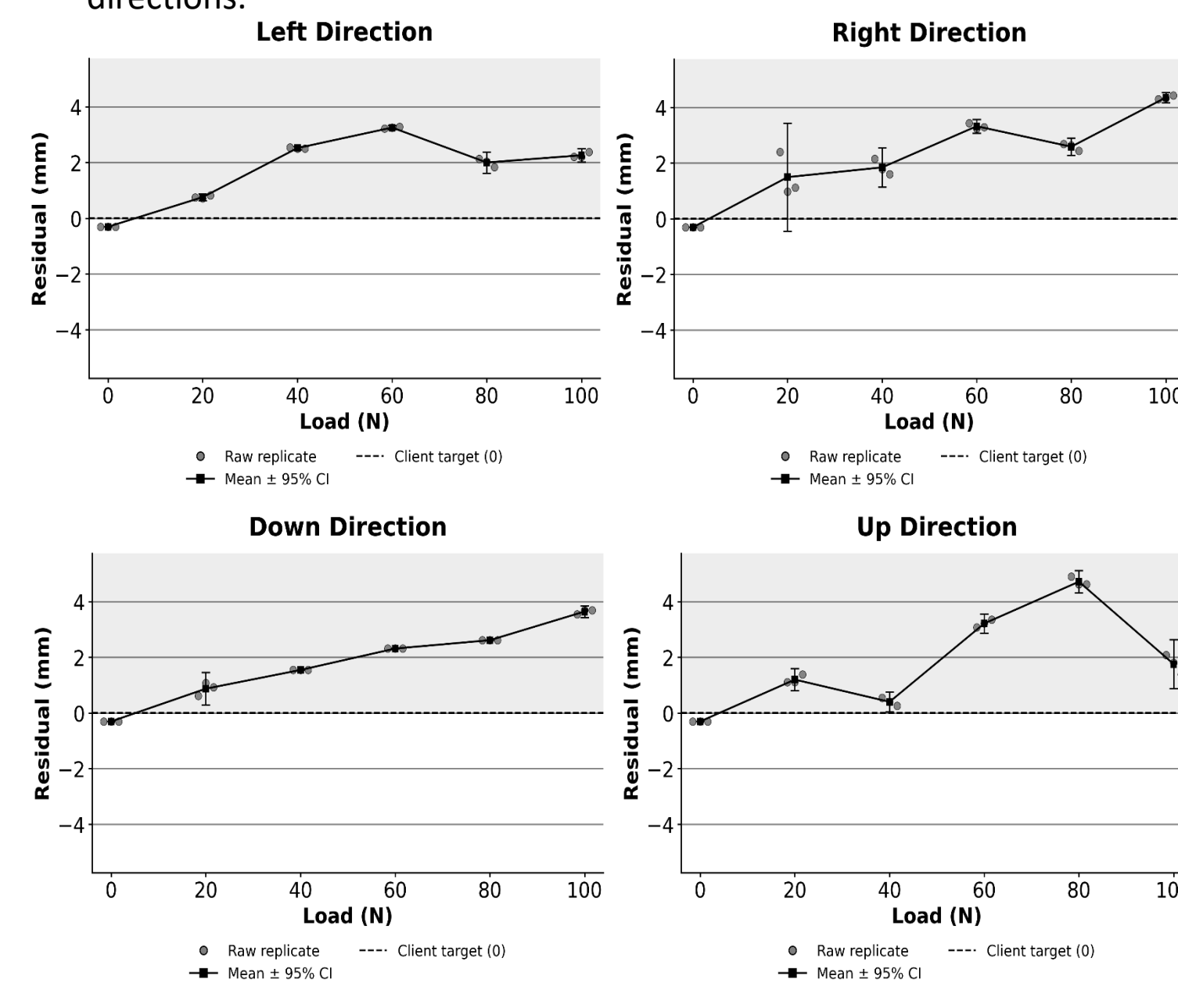


Figure 10: Experimental head displacement residuals from client desired target displacement (0.3mm).

Limitations

Several limitations hinder the accuracy and generalizability of the results.

- Ballistic gel limitations
- Mask quality and application issues
- Rod attachment compliance
- Load cell calibration drift
- Single dimension motion measurement

Future Work

Next steps to improve system accuracy and clinical relevance:

- Develop anatomically accurate skull model for realistic testing
- Implement multi-axis displacement tracking (3D motion)
- Improve mask design for increased conformity and stability
- Evaluate additional mask materials and configurations
- Automate displacement measurement
- Validate system against clinical standards (FDA)

Economics

Current frame design:

- Sterilized screws cost \$3,000, driven by manufacturing sterilization process
- Per mask cost estimated at \$1,000
- Production variability across suppliers may result in waste

Other cost-benefit analysis factors for consideration:

- Improved patient experience
- Scalability and licensing
- Reproducibility

Acknowledgements

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Select References

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