Stabilizer Device for Intracardiac Echocardiography (ICE) to Assist Structural Heart Interventional Procedures

Team Members: Sara Morehouse (Team Leader), Max Aziz (Communicator), Noah Hamrin (BWIG and BPAG), and Kaden Kafar (BSAC)
Advisor: Dr. Darilis Suarez-Gonzalez
Client: Dr. Amish Raval, MD, UWSMPH
Fall 2024

ABSTRACT

Heart disease is the leading cause of death in the United States and many heart procedures are complex [1]. An intracardiac echocardiography (ICE) catheter is used during structural heart intervention procedures to observe the area of interest in the heart using ultrasound. Once inserted, the ICE catheter handle is either held by an assistant or held down by a wet towel to prevent the movement of the imaging crystal at the catheter tip. These methods allow for some movement of the image, however, causing issues and delays in the procedure. The team has been tasked with designing and fabricating a novel ICE catheter mount system that allows the doctors to secure the handle of any brand ICE catheter while allowing for height adjustment. The design must be fully sterilizable to ensure proper sanitation in the catheterization lab and allow for minimal movement of the ICE catheter to ensure the image from the catheter is steady. The proposed design features a height-adjustable pole which affixes via magnets to the handle saddle, which rests on top of the sterile drape and secures the handle with straps.

BACKGROUND & MOTIVATION

Background:
- Dr. Raval – Interventional Cardiologist
- Intracardiac Echocardiography (ICE) catheter is an imaging catheter
  - Small, precise, and clear images
  - Less invasive than transesophageal echocardiography
- Patient is awake

Fig. 1: 4D ICE Catheter insertion [2].

Motivation:
- ICE catheter instability
  - Inconvenient
  - Time
- Current methods:
  - Stabilize with a wet towel
  - Catheter held in place by hand

Fig. 2: Current method for stabilization.

DESIGN SPECIFICATIONS

- Adjustable support fixture for ICE catheter
- Allow for use of ICE handle controls
- Adjustable height: 22.8 cm to 34.3 cm
- Material must withstand ethylene oxide, gas, or heat sterilization
- Compatible with many models and brands of ICE catheter
- Must be able to keep the catheter secured from load of 2 N
- Manufacturing costs < $300

FINAL DESIGN

Base Part

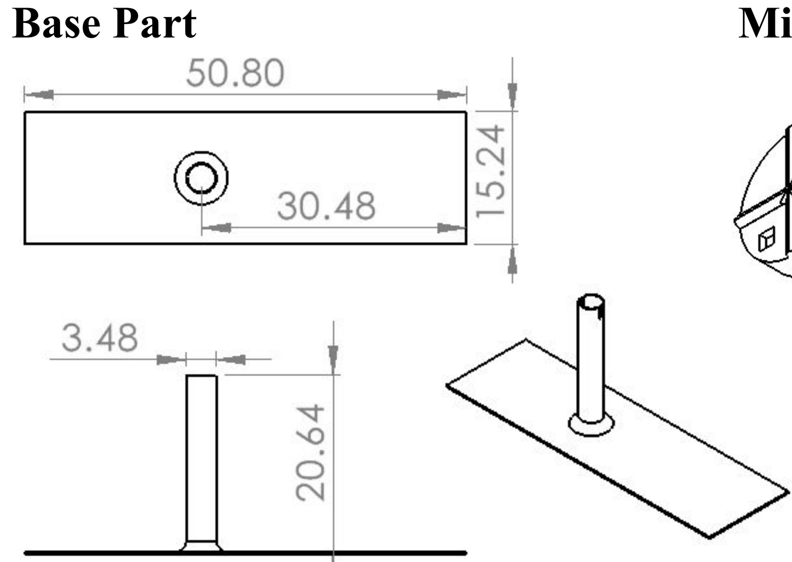

Fig. 3: Base part; the patient's legs shall rest atop the base plate on either side of the pole; dimensions listed in cm.

Middle Part

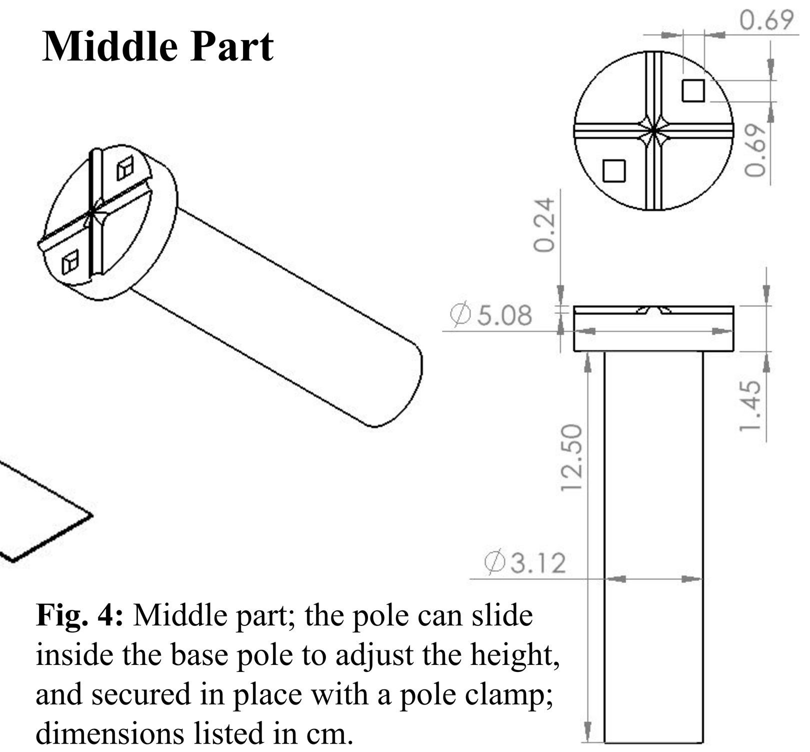

Fig. 4: Middle part; the pole can slide inside the base pole to adjust the height, and secured in place with a pole clamp; dimensions listed in cm.

Top Part

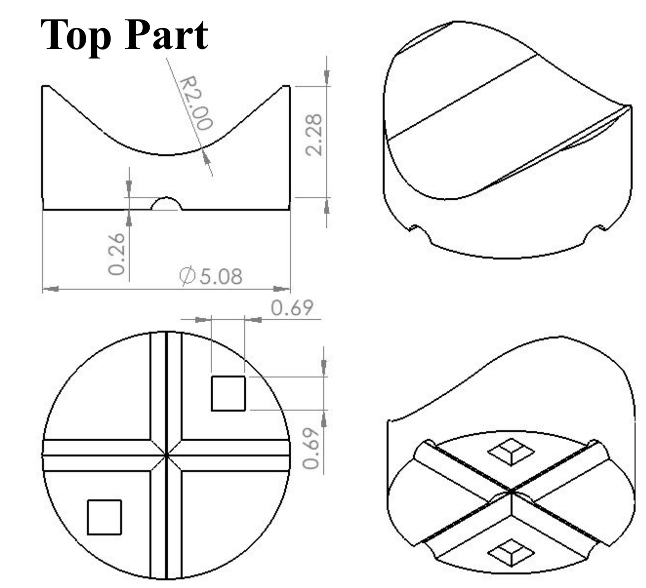

Fig. 5: Top part / catheter saddle; this piece magnetically attaches to the top of the middle piece over the sterile drape and holds the catheter handle on top; dimensions listed in cm.

Assembly

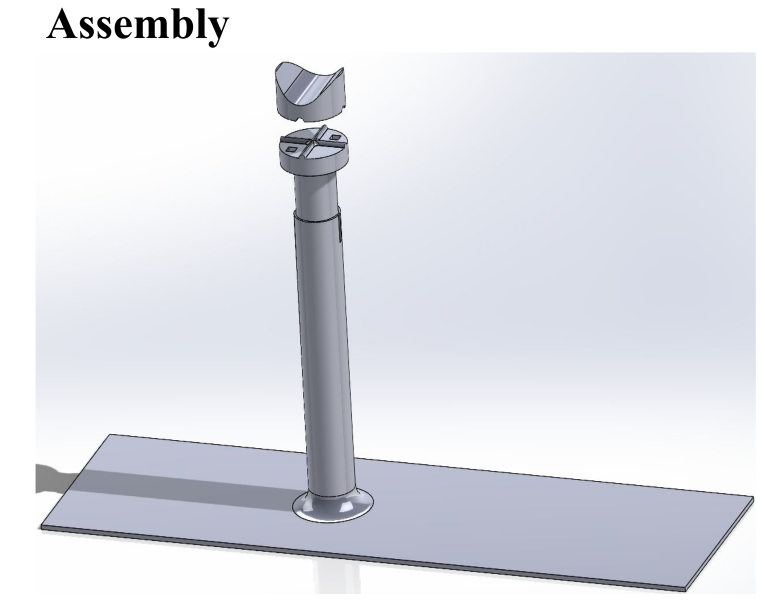

Fig. 6: Solidworks assembly; all three components combine to hold the catheter handle above the patient's leg and the sterile drape at the optimal height

Material & Fabrication:
- Polylactic Acid (PLA)
- 3D printed prototype
- Final prototype: ASTM 4130 stainless steel welded together
- Estimated cost: $140

Operation:
- Patient's legs rest on base plate on either side of the pole
- Height of middle part is manually adjusted and secured via quick-release clamp
- Sterile drape is laid over patient and middle part
- Top part is magnetically secured to middle part over the drape and the catheter handle secured with the strap

TESTING & RESULTS

Catheter Saddle Dislodging Force Testing:
- Purpose: Compare forces required to significantly dislodge the catheter from the saddle component vs. the wet towel, and 3D vs. 4D ICE catheter
- Loading:
  - Catheter in device: bending, torsional, & tensile
  - Catheter in wet towel: torsional & tensile
- Measured force via force gauge
- Results:
  - Significantly more force required to dislodge the saddle component compared to the wet towel ($p < 0.001$ for torsional & tensile loading)
  - N.S. difference between torsional & tensile dislodging forces for 3D vs. 4D catheter ($p > 0.05$)

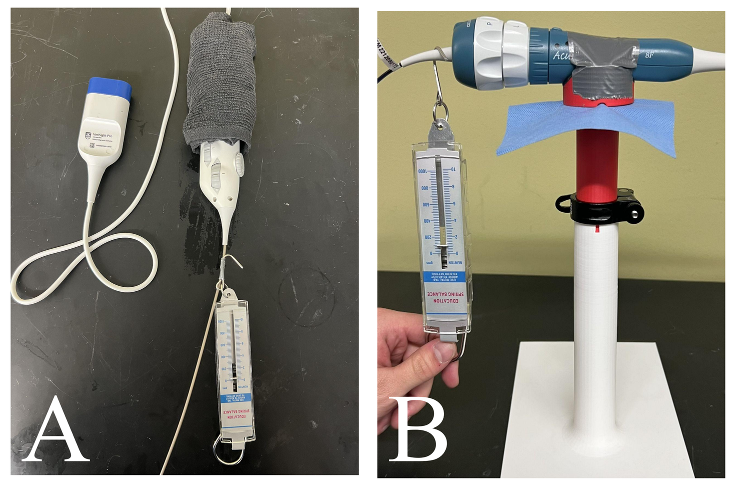

Fig. 7: A. 4D catheter in tensile test configuration with wet towels. B. 3D catheter in bending test configuration with device.

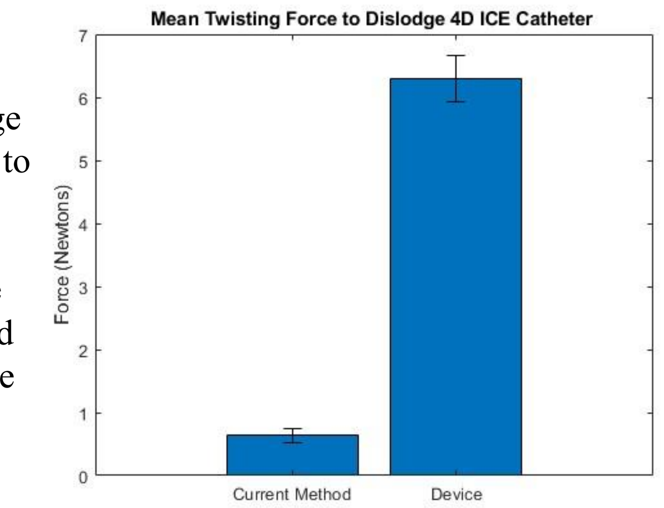

Fig. 8: Average twisting force to dislodge 4D catheter comparing the current method with the device ($p < 0.001$).

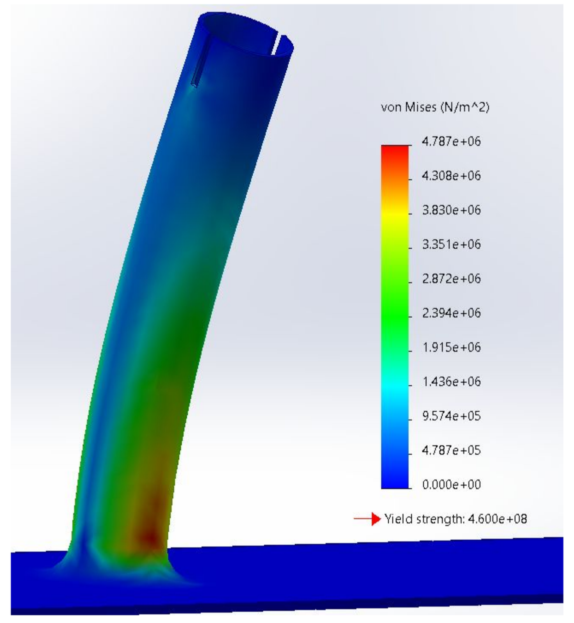

Fig. 9: Stress concentrations on base plate.

Weld Stress Concentration Analysis:
- Purpose: Assess strength of the weld between base plate and shaft
- Performed SolidWorks Static Simulation
  - Transverse 38N load applied to top of shaft [3,4]
  - Material: ASTM 4130 Steel (annealed) [S_Y = 460 MPa, S_U = 560 MPa]
- Results:
  - Highest stress: 4.8 MPa
  - FOS: 96.3

Surgical Drape Tensile Testing:
- Purpose: Measure load required to tear drape
  - Uniaxial tension configuration
- Results:
  - Load required to tear drape: 100.23 N
  - Load produced by magnets: 40 N

Table 1: Mechanical Properties of Surgical Drape

	Young's Modulus (MPa)	Max Load (N)	Max Strain
Average	7.65 ± 0.95	100.23 ± 8.33	0.55 ± 0.07

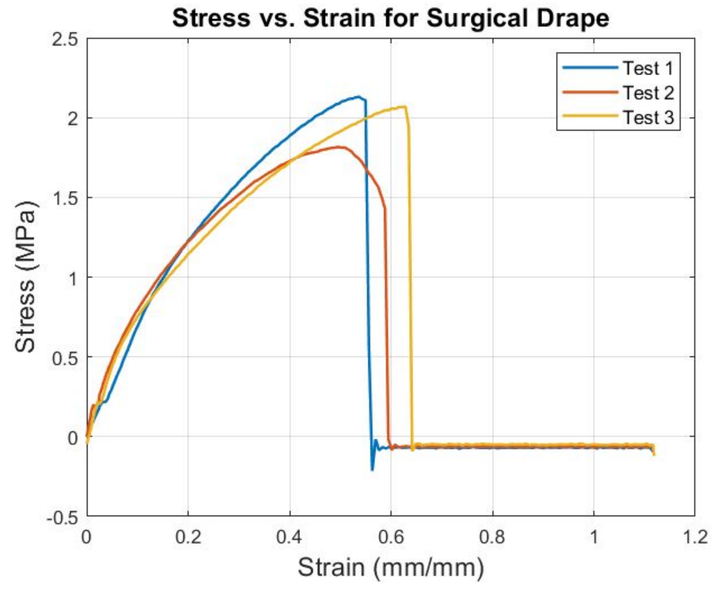

Fig. 10: Stress-strain curve for surgical drape.

FUTURE WORK

Prototyping:
- Apply client feedback to adjust design components
- Implement strap mechanism
- Adjust magnet size and strength
- Fabricate device out of stainless steel
  - Welding, CNC mill, and lathe

Testing:
- Conduct interference testing of magnets with echocardiography
- Use device in simulated procedure setting to assess overall efficacy
- Investigate compatibility of device with alternative catheters

ACKNOWLEDGEMENTS

Dr. Amish Raval
Dr. Darilis Suarez-Gonzalez
Jesse Darley (Design Hub Staff)
BME Design Faculty

REFERENCES

[1] Z. M. Hijazi, K. Shivkumar, and D. J. Sahn, "Intracardiac Echocardiography During Interventional and Electrophysiological Cardiac Catheterization," Circulation, vol. 119, no. 4, pp. 587–596, Feb. 2009, doi: https://doi.org/10.1161/circulationaha.107.753046.

[2] "AcuNav Lumos 4D ice catheter," AcuNav Lumos 4D ICE Catheter - Siemens Healthineers USA, https://www.siemens-healthineers.com/en-us/ultrasound/cardiovascular/acunav-lumos-catheter (Accessed Oct. 1, 2024).

[3] C. D. Fryar, D. Kruszon-Moran, Q. Gu, and C. Ogden, "Mean body weight, height, waist circumference, and body mass index among adults: United States, 1999–2000 through 2015–2016," National Center for Health Statistics, Hyattsville, MD, 2018. Accessed: Dec. 02, 2024. [Online]. Available: https://www.cdc.gov/nchs/data/nhsr/nhsr122-508.pdf.

[4] D. A. Winter, Biomechanics and motor control of human movement. Hoboken, N.J.: Wiley, 2009.