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

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Client: Dr. Amish Raval, MD, UWSMPH
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BACKGROUND

- Dr. Raval – Interventional Cardiologist
- Heart disease remains the leading cause of death in the United States, with many heart procedures being complex [1].
- Intracardiac Echocardiography (ICE) catheter is an imaging catheter
  - Small, precise, and clear images
  - Less invasive than transesophageal echocardiography
- Patient is awake

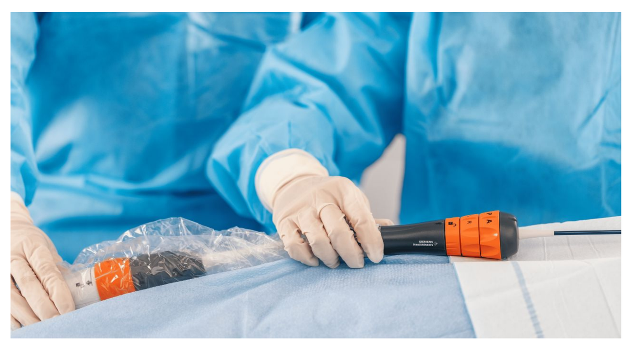

Fig. 1: 4D ICE Catheter insertion [2].

PROBLEM MOTIVATION

Motivation:

- ICE catheter instability & movement
  - Image instability
  - Inconvenient
  - Procedural delays
- Current methods:
  - Stabilize with a wet towel
  - Catheter held in place by hand

Task:

- Design and fabricate a novel ICE catheter mount system
- Device must secure the handle of any brand of ICE catheter & minimize catheter movement to maintain steady imaging

Fig. 2: Current method for stabilization.

DESIGN SPECIFICATIONS

- Allow for use of ICE handle controls
- Adjustable height: ~20 cm to 35 cm
- Material above sterile drape must withstand ethylene oxide, gas, or heat sterilization
- Compatible with different models and brands of ICE catheter
- Must be able to keep the catheter secured from load of at least 2 N
- Manufacturing costs < $300

FINAL DESIGN

Base & Middle Part

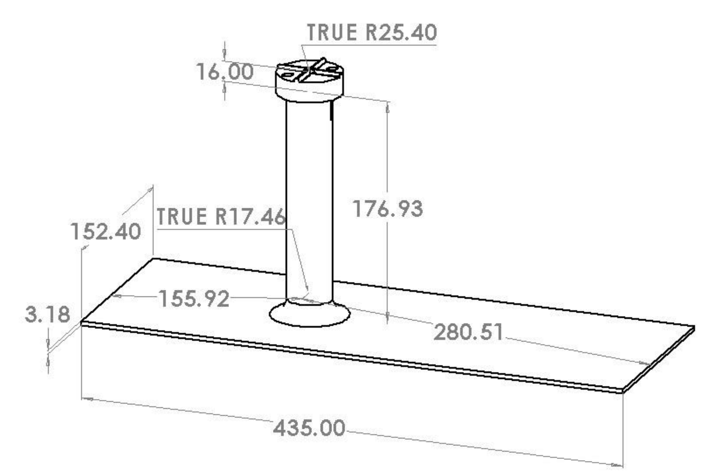

Fig. 3: Dimensioned drawing of assembled base and middle part. All dimensions are in mm.

Top Parts

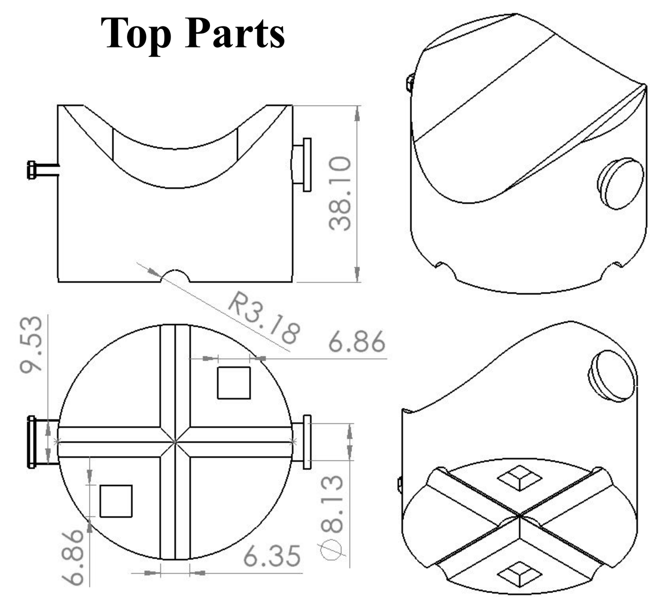

Fig. 4: Dimensioned drawing of top piece / saddle (medium size). All dimensions are in mm.

Metal Prototype

Fig. 5: Final prototype of device painted with top part angled and base and middle part off-centered

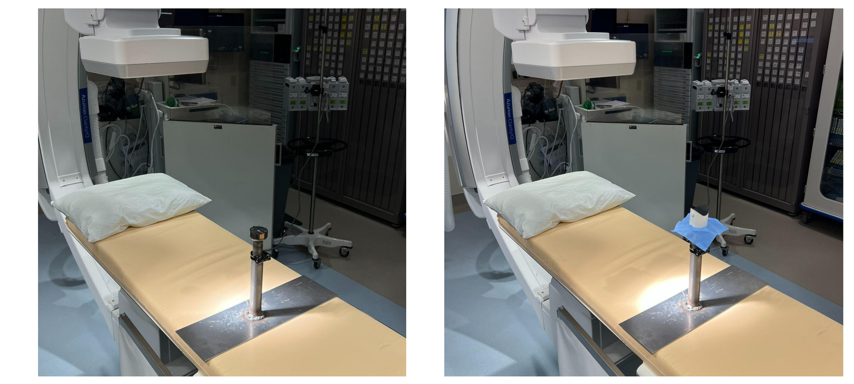

Fig. 6: Device laid on catheterization lab table prior to patient laying down.

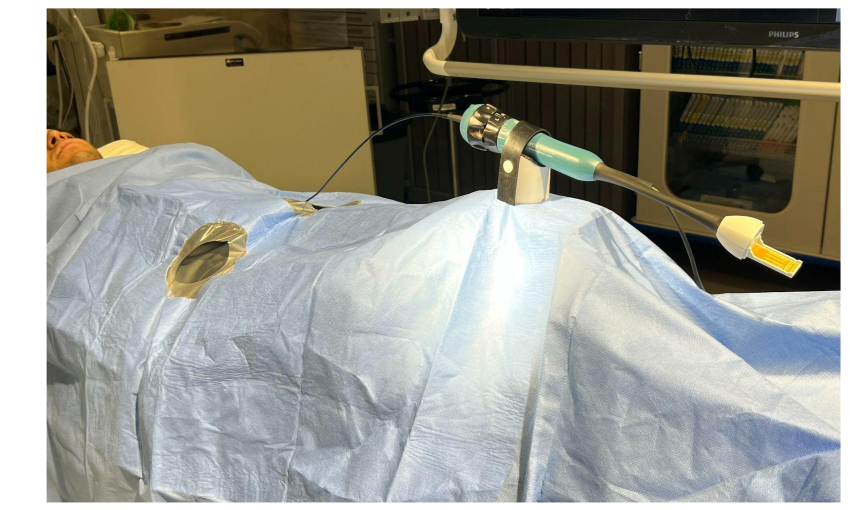

Fig. 7: Device in use with catheter and patient.

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

Total Cost: $152

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 ($p < 0.00001$ for torsional & tensile loading)
  - N.S. difference between torsional & tensile dislodging forces for 3D vs. 4D catheter at small height ($p > 0.05$)

Fig. 8: Tensile force testing setup.

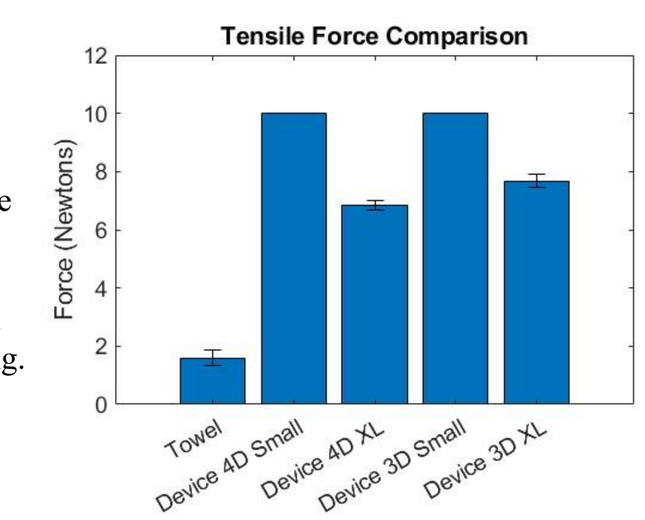

Fig. 9: Force required to dislodge catheters in tensile loading.

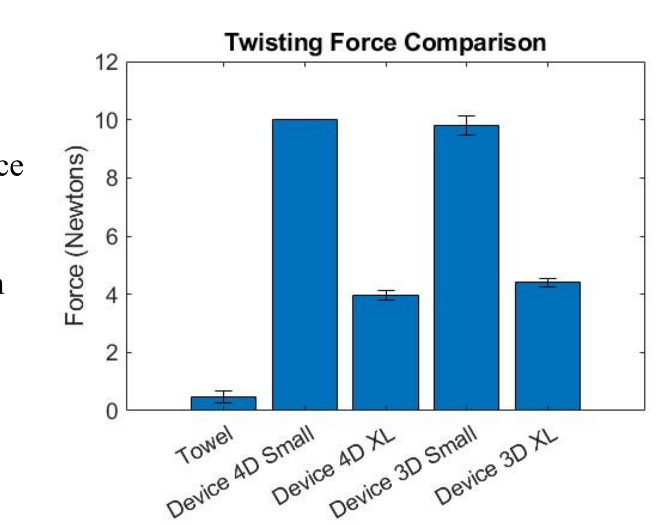

Fig. 10: Force required to dislodge catheters in twisting (torsional) loading.

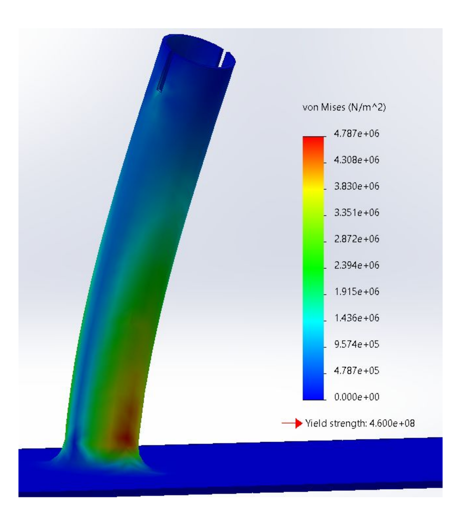

Fig. 11: Stress concentrations on base plate.

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

Client Feedback Survey:

- Purpose: To assess the prototype against qualitative design specifications
  - Ease of use, adjustability
  - 1-5 scale (1 = negative, 5 = positive)
- Results:

Table 2: Evaluation of prototype by client

Criteria	Score
Height adjustment	5
Catheter security	5
Device placement	4
Overall ease of use	4

FUTURE WORK

- Gain further feedback from physicians and operators
  - Test prototype in mock procedure
  - Revise design accordingly
  - Explore different applications with other procedures and catheters
- Develop algorithm for approximate placement of base plate based on patient height, weight, and other metrics
- Complete patent process
- Explore production manufacturing and distribution options

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