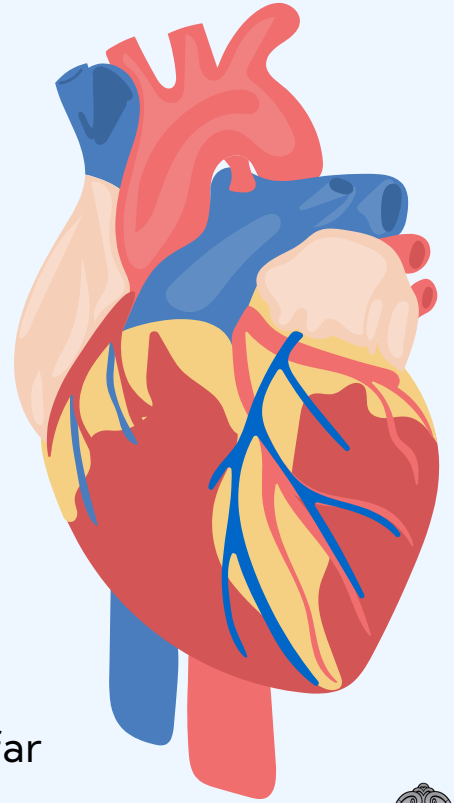
Stabilizer Device for Intracardiac Echocardiography (ICE)

to Assist Structural Heart Interventional Procedures



BME 400
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BME Design

OUTLINE

- Problem Statement
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- Design 1: Body Weight Holder
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PROBLEM STATEMENT

- Dr. Amish Raval – client/Interventional Cardiologist
- ICE Catheter instability
- Current method is wet paper towel or have a tech hold it
- Device must hold all types of ICE catheters and adjust it slightly

Figure 1: ICE Catheter [1]

BACKGROUND

Figure 2: 4D ICE Catheter insertion [2]

- Imaging Catheter
- Small, precise and clear images
- Femoral artery to inferior vena cava to see either right or left atria or ventricles [3]
- Patient is awake but local anesthesia

COMPETING DESIGNS

Figure 3: Abbott MitraClip Catheter with Stabilizer [4]

- Catheter held in place with screws
- Non-adjustable angled placement

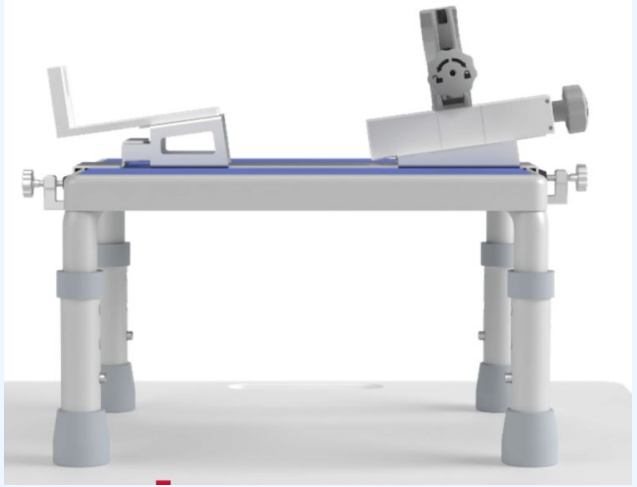


Figure 4: Edwards EVOQUE Stabilizer, base, and plate [5]

- 3 components

DESIGN SPECIFICATIONS

- Adjustable support fixture for the handle of ICE catheter
- Material must withstand ethylene oxide gas or heat sterilization [6]
- Adjustable height: 75 to 200 mm
- Adjustable angle: 0° to –30° from parallel to the operating table
- Translation: ±75 mm from point of insertion
- Allow for manipulation of the ICE handle controls while in stabilizer
- Compatible with different brands/models
- Manufacturing costs < $300

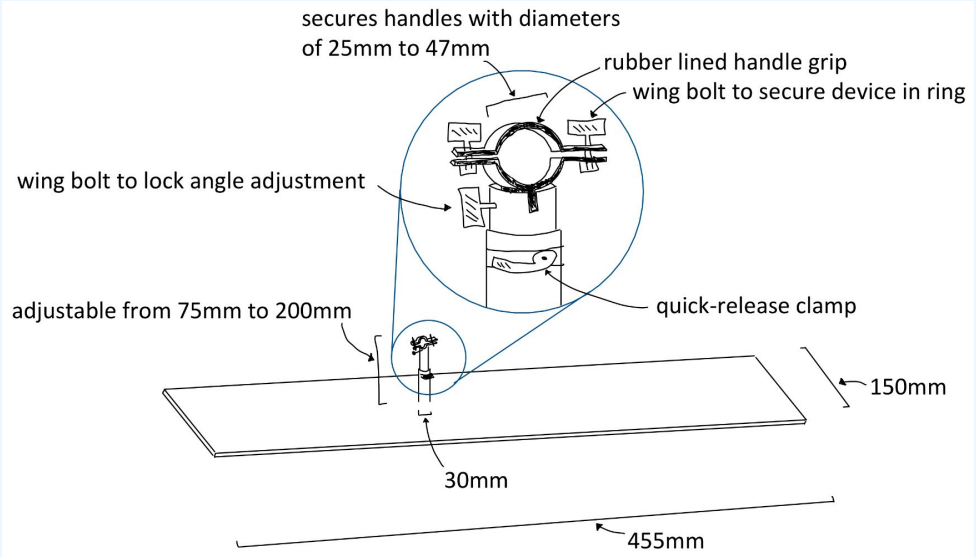
DESIGN 1: BODY WEIGHT HOLDER

Pros:

- Everything above sterile drape
- Reversible for either leg

Cons:

- Longer time to adjust angle
- Cumbersome translation adjustment
- Potentially bulky due to size



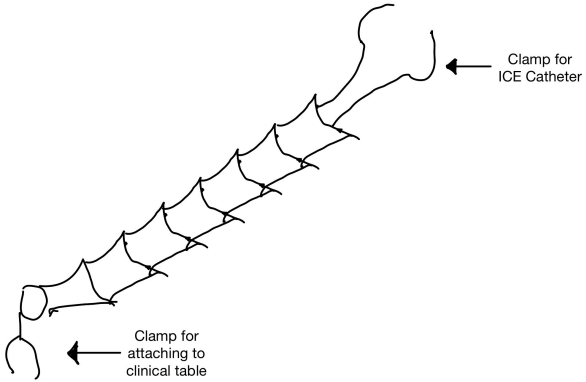
DESIGN 2: GOOSENECK

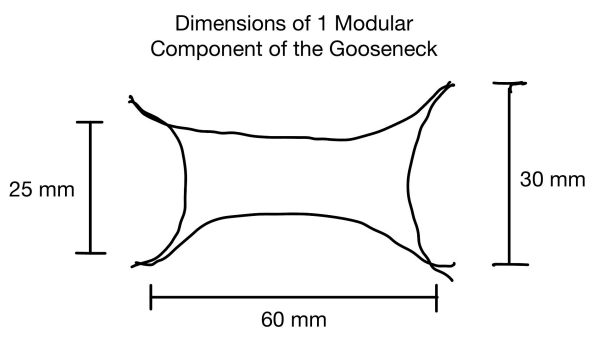
Pros:

- Highly adjustable (length, angle, position)
- Modular
- Low cost (~$2 per module)

Cons:

- Potential stability issues with long arm





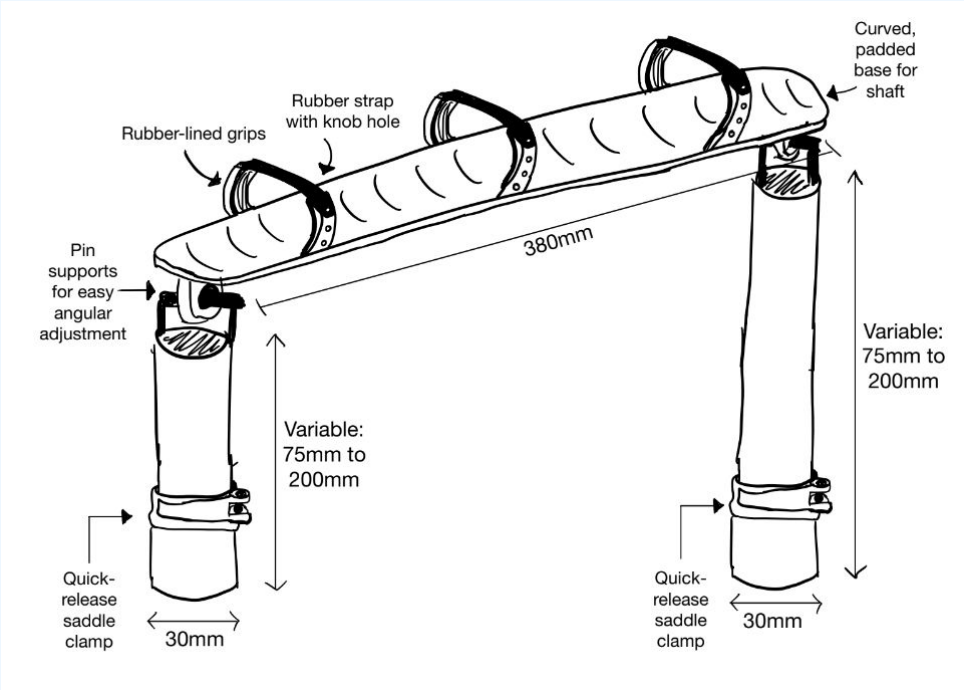
DESIGN 3: SLIDING LEGS

Pros:

- Simultaneous vertical and angular adjustment

Cons:

- Potential issues with security of rubber straps



DESIGN CRITERIA

Sterilizable [25] – ethylene oxide, heat, or gas methods

Usability [20] – ease of adjusting positioning, and ability to operate device controls

Adjustability [15] – range of motion (angular, vertical, translation)

Adaptability [15] – ability to be used for different models / devices

Cost [15] – cost of fabrication of production model

Ease of fabrication [5] – ease of prototype fabrication

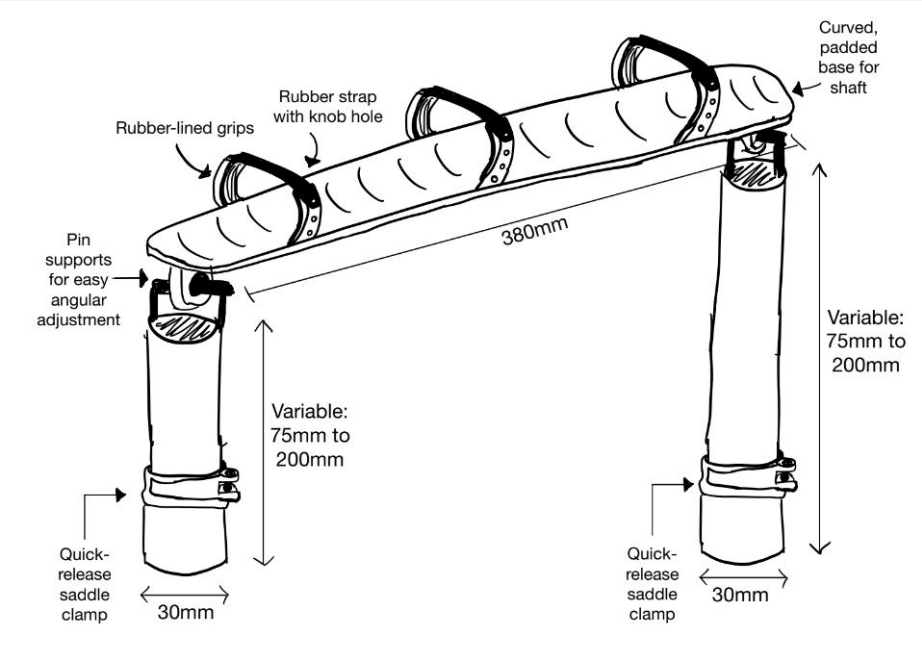
Safety [5] – low potential harms to patient from accidents or misuse

DESIGN MATRIX

Criteria	Weight	Design 1		Design 2		Design 3	
		Body Weight Holder		Gooseneck Arm		Sliding Legs	
Sterilizable	25	4 / 5	20	2 / 5	10	3 / 5	15
Usability	20	4 / 5	16	3 / 5	12	5 / 5	20
Adjustability	15	4 / 5	12	5 / 5	15	5 / 5	15
Adaptability	15	3 / 5	9	4 / 5	12	3 / 5	9
Cost	15	4 / 5	12	5 / 5	15	4 / 5	12
Ease of fabrication	5	3 / 5	3	5 / 5	5	3 / 5	3
Safety	5	4 / 5	4	3 / 5	3	5 / 5	5
Total	100	76		72		**79**	

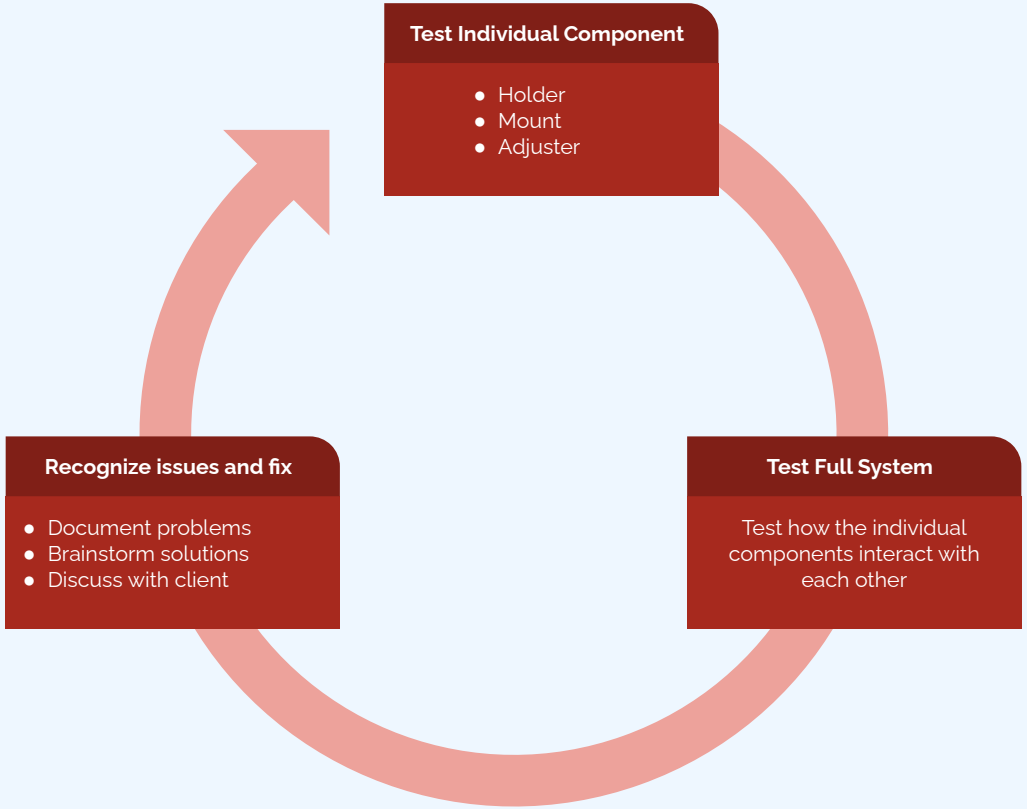
FINAL DESIGN

- Sliding Legs
- Refine 3 components:
  - Catheter holder
  - Height/Angle adjustment
  - Mount system
- Incorporate aspects of other designs



FUTURE WORK

- Implement design changes
- Communicate with client
- Design and build initial prototypes
- Follow testing cycle



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THANK YOU!

Questions?