BME Design-Fall 2024 - SARA MOREHOUSE
Complete Notebook

PDF Version generated by

NOAH HAMRIN

on

Dec 11, 2024 @10:27 PM CST

Table of Contents

Project Information 2
Team contact Information 2
Project description 3
Team activities 4
Client Meetings 4
13Sep24 - Client Meeting 1 4
14Oct24 - Client Meeting 2 8
2024/11/01 - Shadowing 10
Advisor Meetings 11
13Sep24 Meeting 11
2024/9/27 - BPAG Meeting 12
9/27/24 - Meeting 13
11/8/24 Advisor Meeting 14
Design Process 15
23 Sep 24 - Design Matrix Brainstorming 15
23 Oct 24 - Design Consultation 16
11/8/24 Design Work 18
2024/11/22 - Final Solidworks Model 19
12/11/2024 - Ethical Consideration 21
Materials and Expenses 22
2024/11/8 - Materials List 22
12/11/24 - Expense Spreadsheet 23
Fabrication 24
10/30/2024 - 3D printing 24
11/15/24 - 3D printing procedure 26
12/2/24 - Prototype Fabrication 27
Testing and Results 28
Protocols 28
12/5/24 SolidWorks Stress Analysis Protocol 28
12/3/24 - Force Testing Protocol 29
12/3/24 - Drape Tensile Testing Protocol 31
12/11/24 - Stainless Steel Prototype Fabrication 32
Experimentation 34
12/5/24 SolidWorks Stress Analysis Results 34
12/3/24 - Force Testing Results 35
12/3/24 - Drape Tensile Testing Results 37
Sara Morehouse 39
Research Notes 39
Biology and Physiology 39
9Sep24 - Use of Intracardiac Echocardiography in Interventional Cardiology: Working With the Anatomy Rather Than Fighting It 39
11Sep24 - Preventing complicated transseptal puncture with intracardiac echocardiography: case report 41
16Sep24 - Sterilization of Objects, Products, and Packaging Surfaces and Their Characterization in Different Fields of Industry: The Status in 2020 43
16Sep24 - Understanding Functional Failures: The Impact of Repeated Sterilization Techniques 45
21Nov24 - Research on movement of diaphragm produced by breathing 46
Competing Designs 47
11Sep24 - Mitral Valve Clip Procedure 47

Codes, Standards, Regulations 49
11Sep24 CFR Regulations 49
Design Ideas 50
22Sep24 - Design Idea 1 50
Training Documentation 51
12Nov24 - CNC Training Documentation 51
Max Aziz 52
Research Notes 52
Biology and Physiology 52
2024/9/11 - Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization 52
2024/9/11 - The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: Meta-analysis of efficiency, effectiveness, and safety outcomes 53
2024/9/11 - Why is intracardiac echocardiography helpful? Benefits, costs, and how to learn 54
2024/9/16 - Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization 55
Competing Designs 56
2024/9/18 - TriClip G4 Stabilizer 56
Design Ideas 57
11/14/24 - Material Choice Research 57
Training Documentation 58
10/28/24 - MIG Welding Permit 58
Noah Hamrin 59
Research Notes 59
Biology and Physiology 59
2024/9/11 - Surgical Procedure for Applicaiton of MitraClip 59
2024/9/11 - Intracardiac Echocardiography 60
Competing Designs 62
2024/9/11 - Mitra Clip Guide Procedure 62
2024/09/16 - EVOQUE Stabilizer, Base, Plate 63
Design Ideas 64
2024/9/25 - Gooseneck Arm 64
2024/9/25 - Body Weight Holder 66
2024/10/28 - Solidworks Model V1 68
Training Documentation 70
2024/11/7 - CNC Training Upgrades 70
Kaden Kafar 71
Research Notes 71
Biology and Physiology 71
Ice Catheter Research 71
Clamping Mechanisms 72
Competing Designs 73
Mitraclip 73
Evoque 74
2014/11/03-Entry guidelines 75
2014/11/03 - Template 76

Team contact Information

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 4:34 PM CDT

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
Suarez-Gonzalez	Darilis	Advisor			
Raval	Amish	Client			
Morehouse	Sara	Leader	smorehouse2@wisc.edu	920-252-5749	
Aziz	Max	Communicator	mmaziz@wisc.edu	630-945-7456	
Kafar	Kaden	BSAC	Kafar@wisc.edu	262-492-2287	
Hamrin	Noah	BWIG	Hamrin@wisc.edu	(414) 403-5014	N/A
Hamrin	Noah	BPAG	Hamrin@wisc.edu	(414) 403-5014	N/A

Project description

SARA MOREHOUSE - Sep 16, 2024, 7:48 PM CDT

Course Number:

BME 400

Project Name:

Stabilizer device for intra-cardiac echocardiography (ICE) to assist structural heart interventional procedures

Short Name:

ICE Stabilizer

Project description/problem statement:

Intracardiac echocardiography (ICE) is a technique commonly used during catheter-based interventional procedures to treat congenital heart disease, valvular heart disease and myocardial disease. Typically, the ICE catheter is advanced into the right atrial from a femoral vein, where it is positioned for imaging purposes. A separate catheter to perform the interventional procedure such as a transseptal needle or Watchman left atrial appendage occluder delivery system is then introduced. Many times, the ICE catheter drifts out of place, the imaging perspective is lost and the ICE catheter needs to be readjusted. Therefore, there exists a need for a simple re-sterilizable device to stabilize a variety of commercially available ICE catheters during interventional procedures. The device must prevent movement of the ICE catheter so that it does not migrate out of place when in use.

About the client:

Dr. Amish Raval is a faculty member in the Division of Cardiovascular Medicine within the Department of Medicine and holds an affiliate appointment with the Department of Biomedical Engineering in the College of Engineering. He is the recipient of many awards, including NIH R01 and U01 grants and the Wisconsin Alumni Research Foundation Innovation Award for “Best Inventor”. Dr. Raval is board certified in internal medicine and cardiovascular diseases. He also holds certification of Added Qualification in Interventional Cardiology. He is a member of numerous professional societies including the Society for Cardiac Angiography and Intervention, American College of Cardiology and the American Heart Association. Dr. Raval specializes in interventional cardiology, working to minimize the effects of coronary artery disease and valvular heart disease. He performs heart catheterizations to correct valvular and congenital defects and cardiomyopathies, coronary angiography, coronary revascularization and related coronary and pulmonary procedures. He is the Medical Director of the UW Health STEMI program.

13Sep24 - Client Meeting 1

SARA MOREHOUSE - Sep 13, 2024, 10:50 AM CDT

Title: Client Meeting 1

Date: 13 Sep 24

Content by: Sara Morehouse, Max Aziz, Noah Hamrin

Present: Sara Morehouse, Max Aziz, Noah Hamrin (Kaden sick with Covid)

Goals: To meet our client, Dr. Amish Raval, and learn more about our project for the semester.

Content:

- Current method to hold the ICE device in place:
  - Wet towels, tech holds it in place by hand
- Essential to keep the ICE device still in order to gain a clear picture
- Look to MitraClip stabilizer:
  - Clamps
  - Steel
  - single-use screws (not sterilizable)
  - 13-14lbs
  - Screws allow the device to lock into place, be adjustable
- EVOQUE valve stabilizer
  - Platform above the leg, underneath the sterile drape
  - Stabilizer on top of platform above sterile drape
- No stabilizer exists for the ICE catheter
- Device should work on either the left or right side of the body
- Want to be able to set the device down once it's in place and forget about it
- Platform above patients leg or clamp that attaches to the table
  - Clamp would allow the device to slide, move
  - Platform would be stationary
    - Platform has adjustable-length legs
- Needs to hold the torque of the ICE in place
- **Anything above the sterile drape must be sterile**
  - Using gas sterilization techniques
  - **Sterilizable materials**
  - **Materials and geometry must be easy sterilizable**
  - Sterile sleeve could be an option
- Have some tolerance for if patient moves
- Potential adjustment to move in/out?

- Knobs to adjust height, angle of device? Catheter is inserted at an angle so need to account for that
- Another device is ceiling mounting arm that they use in radiology
- ICE device is ~$8000
  - **Stabilizer should be cheap**
  - **Under $300 for manufacturing costs**
- **Adjustable height, angle, must be able to translate (fully adjustable)**
- **Has to allow the ICE to translate and torque within the device**
- **Must not conceal/obstruct the knobs on the ICE**
- **Must be able to be applied to either leg**
  - ICE is performed via either leg so device must be adjustable
- **Should not interfere with therapeutic device**
- $1000 budget for R&D costs
- Insert through femoral vein, then once he gets to the heart (right atria) he makes it more firm, then at area he leaves it, but still may need to move device due to drift or movement
- **Adaptable for different brands/models**

Additional questions:

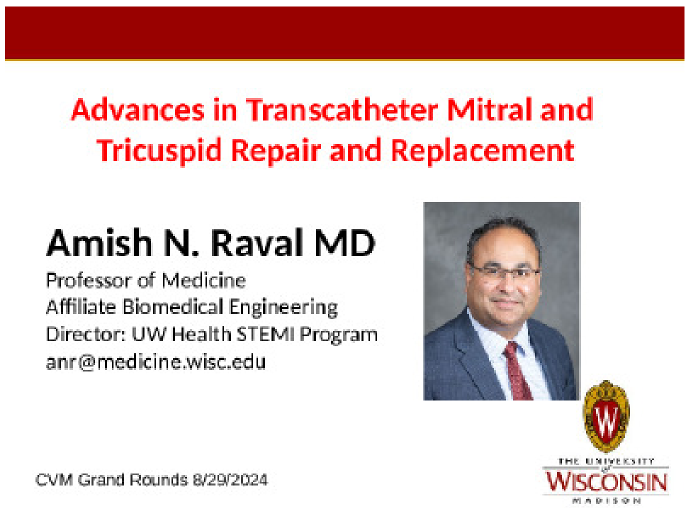
- What are the causes of the ICE catheter drifting out of place?
  - Respiratory motion drifts
  - Contact with other surgical instruments also in atrium
- What is the function you envision this device to have?
  - Is there a specific tolerance/requirement for values that the drift of the catheter needs to remain within?
    - 3-4mm of movement makes a big difference for the image displayed
- Any material requirements?
  - re-sterilizable
- Size or weight requirements?
  - How much variety is there for size of ICE catheters?
    - Adjust for / fits various sizes of handles (4D, 2D, etc)
- Is there a specific budget for the team?
  - 1000$
- Overall goal for the project: unique, one-of-a-kind device for your use only, or a marketable product that could eventually be patented and sold?
  - Eventually bring to market
  - Nothing out there that addresses this specific need currently (to Dr. Raval’s knowledge)
- How should we not interfere with the Doppler signal
- Rough angles/amounts of adjustment?
  - 5-6 inches above the leg

- Suction cup and articulating arm?
- How to create a device that does not interfere with his work?
    - Clamp could be on the opposite side of the table
    - Not that far of a reach
    - Could also do a suction cup to the table
    - Clamp would not be sterile so not ideal
- Consumable devices can have "nooks and crannies" but reusable needs to be smooth surfaces so it can be sterilized.

Conclusions/action items:

Dr. Raval gave a very helpful introduction to the project and the requirements he had for us. Additionally, he sent us a presentation that contains some images of similar devices for other catheters, and suggested some topics to research. We plan to meet with him on an as-needed basis, potentially getting inside the cath lab next time to see the equipment setup.

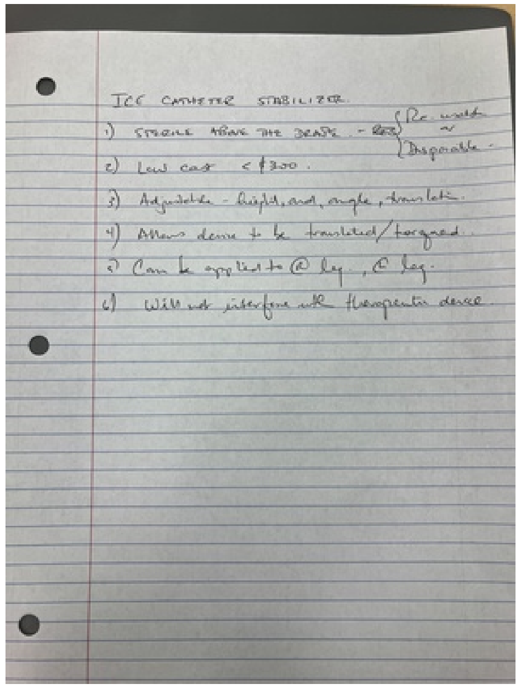
SARA MOREHOUSE - Sep 13, 2024, 10:59 AM CDT



Download

Mitral_and_Tricuspid_Repair_and_Replacement_Updates-2024-8-24.pptx (112 MB) Presentation with some background information provided by Dr. Raval.

SARA MOREHOUSE - Sep 13, 2024, 10:58 AM CDT



Download

IMG_5149.JPG (4.37 MB) List of requirements provided by the client

14Oct24 - Client Meeting 2

SARA MOREHOUSE - Nov 15, 2024, 2:54 PM CST

Title: Client Meeting 2

Date: 10/14/24

Content by: Sara Morehouse

Present: all

Goals: To share our designs and get feedback from Dr. Raval. Additionally, we hope to make a final decision about which design to proceed with.

Content:

- platform on the table, then towel on platform, then drape, then stabilizer on top.

Gooseneck:

- out of the way
- How to get it firm enough to prevent drifting of the catheter handle, prevent it being nudged
- Has to be moveable, but can't drift
-

Bodyweight holder:

- one support might not be sufficiently stable (but could be fine. would just have to test)
- He like the bodyweight part - not sterile
- Part that protrudes up would have to be sterilizable
- Leg strap? wouldn't have to be sterile
- How would we cut a hole in the drape?
    - The drape comes with a hole for the physician to access the leg. The hole interfaces with the skin that is prepped with sterilizing solution, positioned over the femoral vein so they can access it.
    - The holes have adhesive on the edges, 4-5 in diameter
- Could connect through the drape but can't tear it
- as long as no exposure is possible
- Magnets could be ok to attach it - do some research if it interferes with the electrical impulse of the ICE catheter. Would have to test.
- Might not have enough space for the base.

Sliding Legs:

- Seems cumbersome, kind of clunky-looking
- Would have to manufacture the pieces
- Could be more than what is necessary
- Could do heavy metal brick/plate to hold the legs, rounded corners, or individual plates for each leg
- Not simply to use
- Less straps/attachments for the user to secure
- One attachment point is probably enough.

Better to have the device positioned right over the center of the body, between the legs.

He is most interested in the Bodyweight Holder device.

- Make the attachment at the top like a hinge jaw piece, instead of 2 wing bolts. Would be easier if it's just one piece to attach. Also, a clip instead of a bolt.
- It's ok if it's not one-size-fits-all. Minor deviations in catheter diameter could be addressed via a spongy foam or rubber that can deform to fit multiple sized catheters

The handle will most likely be parallel to the thigh. height adjustability is most important, angle adjustability is not essential.

Conclusions/action items:

This meeting gave us helpful insight into Dr. Raval's thoughts about the designs we have proposed. Moving forward, we will proceed with the bodyweight holder and redesign some of the elements that Dr. Raval noted.

2024/11/01 - Shadowing

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 10:32 PM CST

Title: Shadowing Dr. Raval

Date: 11/01/2024

Content by: Max Aziz

Present: Max, Noah, and Sara

Goals: To gather ideas and plan on how our device will be used during a procedure.

Content:

- Plexiglass plate under the patient's body
- Metal plate on top of the plexiglass plate and under patients leg's
- Pole needs to be taller - 2 10 in sections, min height of 10 in, max height of 20 in
- Quick-release clamp
    - Outer shaft diameter = 40 mm - need to adjust based on clamp that we order

Conclusions/action items: We learned that we need to make our dimensions bigger than what we currently thought. Also, there is a plexiglass plate, which provides an extra stability for our device and will be used in further design considerations.

13Sep24 Meeting

SARA MOREHOUSE - Sep 16, 2024, 7:49 PM CDT

Title: Meeting 1

Date: 13 Sep 24

Content by: Sara Morehouse

Present: Max, Noah, Sara, Dr. Suarez

Goals: To discuss the goals of the project and requirements.

Content:

- practicing working with metal in MakerSpace, TEAM Lab

- clamp arm, platform with metal holder, consumable holder

- does the platform go with that specific catheter? or can that be reused

- figure out a plan for ordering materials early on

Conclusions/action items:

In this meeting, we introduced the requirements of the project to Dr. Suarez. We also discussed a plan for the upcoming weeks, mainly focused on early designing, prototyping, and ordering materials in order to ensure that we can fabricate a working prototype by the end of the semester.

2024/9/27 - BPAG Meeting

NOAH HAMRIN - Sep 27, 2024, 12:29 PM CDT

Title: BPAG Meeting

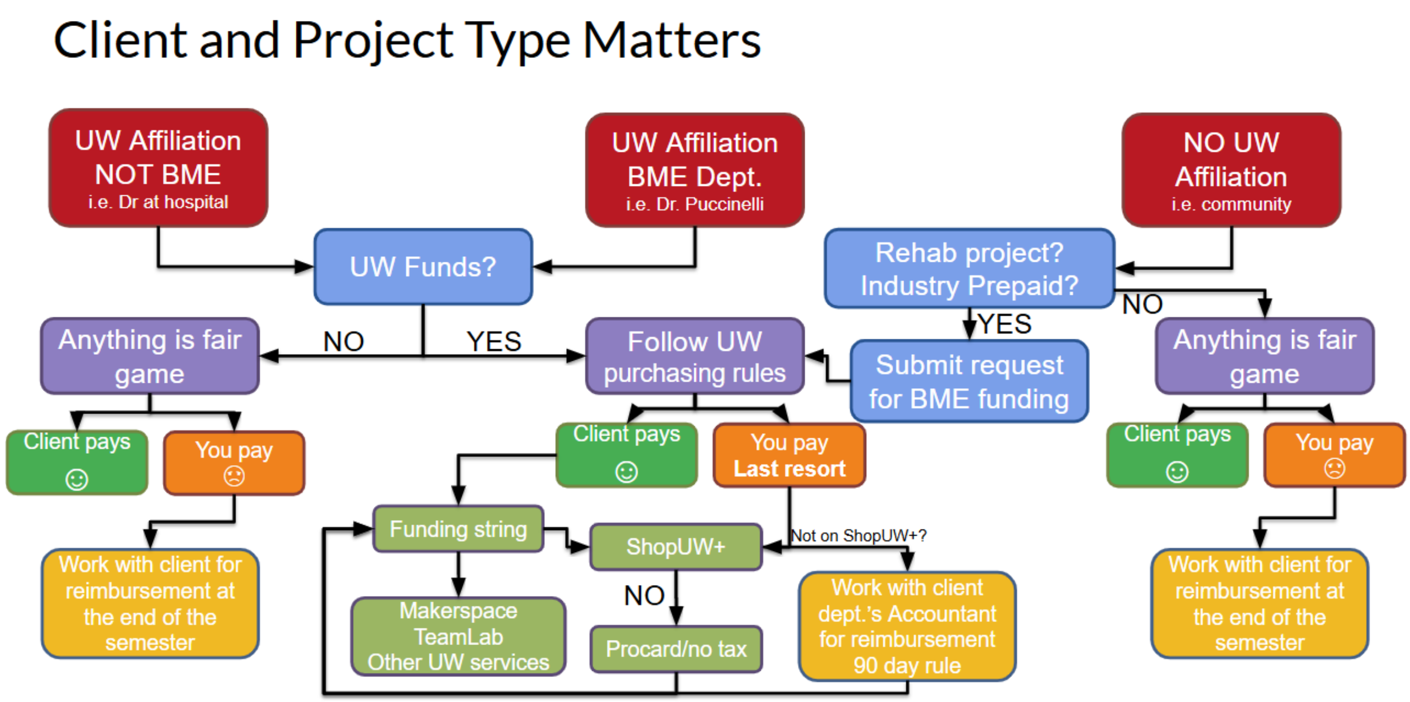
Date: 9/27/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Take notes

Content:



No more fee for makerspace or teamlab

Each team has $50 budget for makerspace from University

List of vendors: https://shopuwplus.wisc.edu/catalog-suppliers/

Conclusions/action items:

Use info learned for our project

9/27/24 - Meeting

SARA MOREHOUSE - Sep 27, 2024, 1:53 PM CDT

Title: Advisor Meeting

Date: 9/27/24

Content by: Team

Present: all

Goals: To update on progress and discuss designs.

Content:

- Med students could be helpful for testing, provide information on their experiences with ICE catheters
- Ask client about payment method
- 50$ credit for Makerspace
- Provide slides by Wednesday morning
- 2nd design - how much movement will the straps induce when it is initially tightened?

Conclusions/action items:

Address content of the meeting in the near future, send slides by Wednesday morning.

11/8/24 Advisor Meeting

SARA MOREHOUSE - Nov 08, 2024, 2:45 PM CST

Title: Advisor Meeting 11/8/24

Date: 11/8/24

Content by: Sara Morehouse, Max Aziz, Noah Hamrin

Present: Sara Morehouse, Max Aziz, Noah Hamrin

Goals: To discuss progress and make a plan for the upcoming weeks.

Content:

- Practice welding before we do the real thing
- Testing -
  - Magnets - see if they interfere with the signal of the catheter
  - Force testing - see how much force is would require to displace/dislodge the top piece
    - Check literature to see how much force breathing produces, compare to force testing
    - Statistics!!
  - Survey for the client to assess prototype
    - Ease of use
  - Test how well different catheters fit into the device
    - Pass/fail, or ranking system
    - Researching other possible applications
  - Ask client about testing ideas
- Assignment - NOTEBOOK ENTRIES - UPDATE FOR NEXT WEEK
  - Individual contributions
  - Documenting your work
  - # of entries
  - 2 examples of entries that are good
    - Following template
    - Content is enough that Dr. S can follow what happened

Conclusions/action items:

In this meeting, we brainstormed some good ideas for testing our device. The main focus of the next week is to fabricate our prototype and begin testing as soon as possible once this is achieved. The team is in a good position as far as welding/CNC training, and should be able to fabricate the device as soon as materials arrive.

23 Sep 24 - Design Matrix Brainstorming

SARA MOREHOUSE - Nov 13, 2024, 11:05 PM CST

Title: Design Matrix Brainstorming

Date: 23 September 2024

Content by: Sara Morehouse

Present: Max, Kaden, Sara, Noah

Goals: To brainstorm design ideas, criteria, and begin the design matrix.

Content:

Criteria:

- sterilizable - 25
- cost - 15
- safety - 5
- adjustability - 15
- adaptability - 15
- Usability - 20
- Ease of fabrication - 5

Design ideas:

- goose neck arm that clamps onto the table with an attachment at the end to hold the handle
- sliding legs
- body weight holder with vertical adjustment

Conclusions/action items:

The purpose of this meeting was to determine the weighting of the criteria that we used to evaluate our preliminary designs. Next, we will work on completing the preliminary report.

23 Oct 24 - Design Consultation

SARA MOREHOUSE - Nov 08, 2024, 2:46 PM CST

Title: Design Consultation

Date: 23 October 24

Content by: Noah Hamrin

Present: Noah, Kaden

Goals: Bounce current design ideas off of design consultant and get feedback and alternative ideas

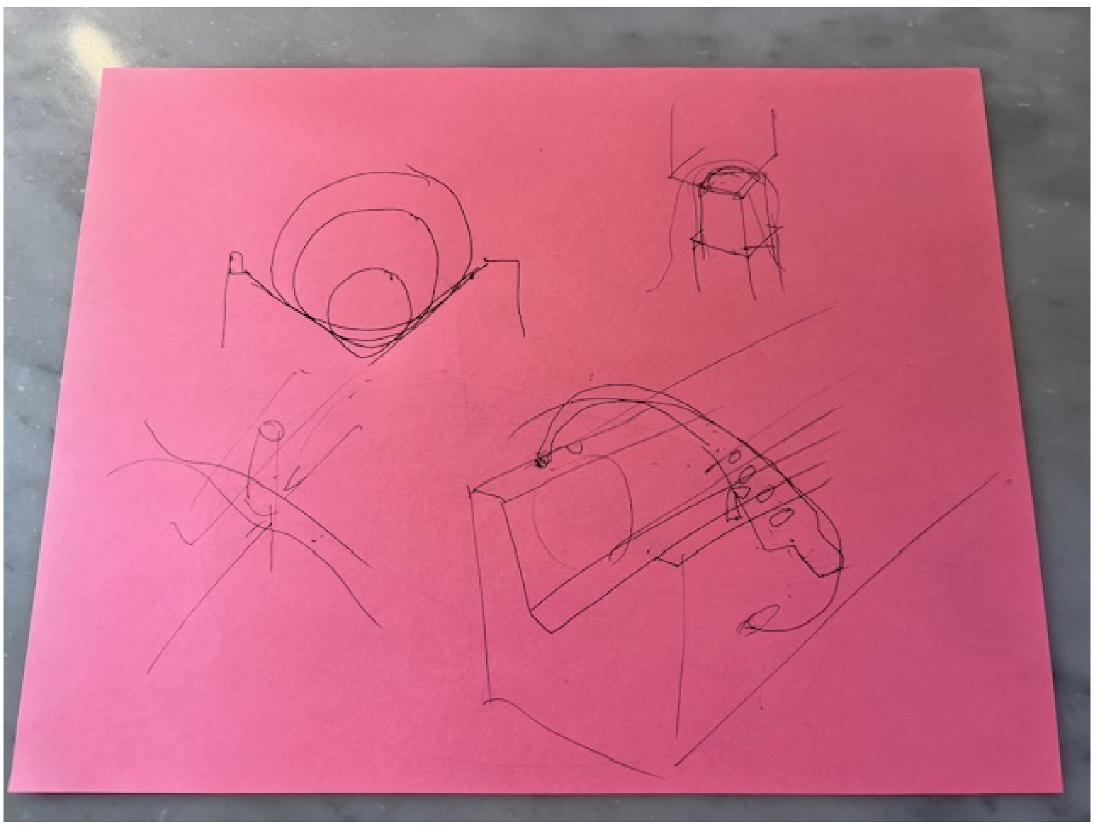
Content:

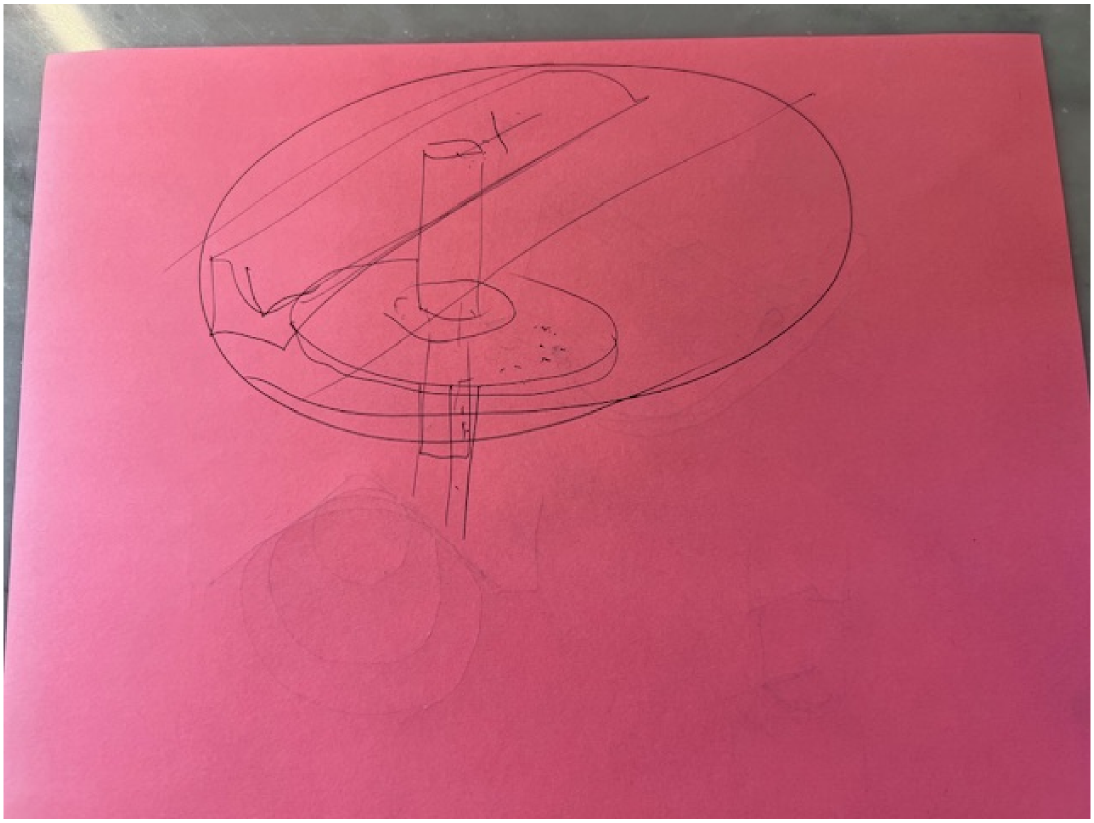
Several new potential design ideas:

- different locking mechanism for either side of magnetic plates

- silicon securing strap over a 'V' shaped holder to account for different diameters

- buy telescoping pole instead of fabricating





Conclusions/action items: Share with group and discuss potentially integrating these designs

11/8/24 Design Work

SARA MOREHOUSE - Nov 13, 2024, 10:14 PM CST

Title: Design Work

Date: 11/8/24

Content by: Sara Morehouse

Present: Max Aziz, Sara Morehouse, Noah Hamrin

Goals: To implement changes based off of information from shadowing, to choose materials and place order, and make a plan for the next week

Content:

- Design changes
- Materials to order - need to order via Guy
    - Amazon.com: PLATT Bike Seat Post Clamp Aluminium Alloy Bicycle Quick Release Seatpost Collar 28.6mm / 31.8mm /34.9mm : Sports & Outdoors - 34.9mm size
    - Magnets
        - 5848K11 https://www.mcmaster.com/5848K11 ¼"x ¼" x ⅛" - quantity 2 (2.7lbs lifting)
        - 5848K15 https://www.mcmaster.com/5848K15 ⅜" x ⅜"x ⅛" - quantity 2 (4 lbs lifting)
        - 5848K83 https://www.mcmaster.com/5848K83 ¼" x ¾"x ¼" - quantity 2 (9 lbs lifting)
    - Amazon.com: DGSL Neoprene Rubber Sheet, Solid Rubber Sheets, Rolls & Strips for DIY Gaskets, Crafts, Pads, Flooring, Protection, Supports, Leveling, Anti-Vibration, Anti-Slip (1" Wide x 1/8" Thick x 10' Long) : Industrial & Scientific
    - Amazon.com: Adhesive Rubber Strips Neoprene Rubber Sheets, Rolls & Strips with Adhesive Backing Rubber Pads Self Stick Seal Rubber Gasket Adhesive Back for Matting Padding - 1" Wide x 1/8" Thick x 10' Long : Industrial & Scientific
    - McMaster 89955K169 shaft 1 ft https://www.mcmaster.com/89955K169 1-⅜" OD
- McMaster 89955K959 shaft 1 ft https://www.mcmaster.com/89955K959 1-⅛" OD

Conclusions/action items:

Following this meeting, we will update the Solidworks file, order the materials, and begin fabrication.

2024/11/22 - Final Solidworks Model

NOAH HAMRIN - Dec 03, 2024, 11:31 AM CST

Title: Final Solidworks Model

Date: 11/22/2024

Content by: Noah Hamrin

Present: All

Goals: Document final solidworks model

Content:

The three finished solidworks parts and the accompanying assembly file are attached.

Conclusions/action items:

3D print prototype and begin testing.

NOAH HAMRIN - Dec 03, 2024, 11:32 AM CST

Download

base_plate_and_pole.SLDPRT (109 kB)

NOAH HAMRIN - Dec 03, 2024, 11:32 AM CST

Download

ICE__Stabilizer.SLDASM (153 kB)

NOAH HAMRIN - Dec 03, 2024, 11:32 AM CST

Download

sliding_pole_and_magnet_top.SLDPRT (149 kB)

NOAH HAMRIN - Dec 03, 2024, 11:32 AM CST

Download

top_mount.SLDPRT (169 kB)

12/11/2024 - Ethical Consideration

MAX AZIZ (mmaziz@wisc.edu) - Dec 11, 2024, 10:09 PM CST

Title: Ethical Consideration

Date: 12/11/2024

Content by: Max

Present: n/a

Goals: To consider important ethical dilemmas when building this device.

Content:

Although the device needs to be sterilizable, there are serious ethical considerations. One is that the hospital will mainly use ethylene oxide to sterilize the stabilizer. Ethylene oxide is a possible carcinogen that can have serious effects on the reproductive system, skin, and nerves. Another concern is that the stabilizer fails and the catheter perforates the aorta. This can be irrecoverable and the patient could die. Therefore, the device must be tested thoroughly and properly.

Conclusions/action items: It is important that our device be sterilizable, but it can be sterilizable using other methods besides ethylene oxide. Also, it is important that our device does not move the catheter a considerable amount. Otherwise, there are clear adverse effects.

2024/11/8 - Materials List

NOAH HAMRIN - Nov 08, 2024, 2:17 PM CST

Title: Material List

Date: 11/8/2024

Content by: Noah Hamrin

Present: Noah, Sara, and Max

Goals: Create a list of raw materials to order

Content:

- 1 flat metal base plate (355mm x 200mm x 3mm)

- 1 hollow tube (inner diameter: , outer diameter: 34mm)

- 1 hollow tube (inner diameter: , outer diameter:)

- quick release (bike seat) clamp

- rubber strip with adhesive backing

- rubber straps with holes

Conclusions/action items:

Share this design with the team and discuss.

12/11/24 - Expense Spreadsheet

NOAH HAMRIN - Dec 11, 2024, 10:22 PM CST

Title: Expense Spreadsheet - Final

Date: 12/11/24

Content by: Sara Morehouse

Present: N/A

Goals: To list all materials used for the prototype and provide a cost estimate.

Content:

Material	Cost	Price Estimate	Vendor	Part Number
3D printed prototype	$6.97	$6.97	MakerSpace	n/a
Bike seat post clamp (34.9 mm size)	$8.99	$8.99	Amazon	769135257429
¼”x ¼” x ⅛” magnet (2)	$2.57	$5.14	McMaster-Carr	5848K11
¼” x ¾”x ¼” magnet (2)	$6.76	$13.52	McMaster-Carr	5848K83
1" Wide x 1/16" Thick x 10' Long Rubber sheet	$9.99	$0.42	Amazon	B08QZH58KD
2" Wide x 1/16" Thick x 10' Long Rubber sheet with adhesive backing	$12.98	$0.22	Amazon	B0BFHBXCRX
1-⅜” OD 4130 steel shaft - 1ft long	$29.37	$29.37	McMaster-Carr	89955K169
Sheet metal 4130 easy-to-weld steel 6”x36”	$63.80	$63.80	McMaster-Carr	4459T188
4130 steel rod 2”x1ft	$88.65	$88.65	McMaster-Carr	6673T34
Total		$143.21		

Conclusions/action items:

This entry lists all materials that were used/will be used in the final prototype.

10/30/2024 - 3D printing

MAX AZIZ (mmaziz@wisc.edu) - Nov 15, 2024, 5:49 PM CST

Title: 3D Printing Model

Date: 10/30/2024 & 10/31/2024

Content by: Max Aziz

Present: n/a

Goals: To 3D print a model of our device

Content:

- I went to the makerspace and printed used Bambu printer
- STL files of the parts were uploaded to the Bambu slicing software with a flash drive. The following settings were used, and then the file was sliced and submitted for printing.
    - Printing parameters:
        - Material: PLA
        - Infill: 20%
        - Resolution: 0.4mm
        - Support type: regular/normal
- The pieces took 7 hours to print
- Pictures attached

Conclusions/action items: Our crude prototype was printed, so we can get feedback during show and tell. As one can see from the last picture, it is able to hold one ICE catheter, but there are still some things to be worked on to ensure the catheter is more stable.

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 11:03 PM CST

Download

IMG_8196.HEIC (1.54 MB)

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 11:03 PM CST

Download

IMG_8194.HEIC (1.46 MB)

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 11:03 PM CST

Download

IMG_8259.HEIC (1.38 MB)

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 11:04 PM CST

Download

IMG_8193.HEIC (1.55 MB)

11/15/24 - 3D printing procedure

SARA MOREHOUSE - Nov 15, 2024, 1:05 PM CST

Title: 3D Printing Procedure

Date: 11/15/24

Content by: Sara Morehouse

Present: Kaden Kafar, Noah Hamrin, Max Aziz

Goals: To define a procedure for 3D-printing a prototype.

Content:

Materials:

- SolidWorks file
- Flash drive
- Computer

Procedure:

1. Convert SolidWorks models to STL file and save to flash drive.
2. Open STL files and import into 3D printer slicing software.
3. Place pieces on the build plate and set printing parameters.
    a. Layer thickness -
    b. Infill -
    c. Support type - organic
4. Slice the file, export to flash drive.
5. Complete payment information with Makerspace form.
6. Start 3D print on the printer.

Conclusions/action items:

The purpose of this entry is to define what procedure will we use to 3D print a prototype. I will fill in the exact parameters that we choose when we 3D print. We are choosing to 3D print another prototype before manufacturing out of metal in order to gain a better sense of the functionality of the device first. This will allow us to make modifications prior to fabricating out of expensive materials that cannot be modified.

12/2/24 - Prototype Fabrication

NOAH HAMRIN - Dec 11, 2024, 10:10 PM CST

Title: Prototype Fabrication

Date: 12/2/24

Content by: Noah Hamrin

Present: Kaden Kafar, Noah Hamrin

Goals: Document fabrication of prototype

Content:

Materials:

- Three 3D printed parts
- Pole clamp
- Adhesive rubber straps
- Magnets

Procedure:

1. Tighten pole clamp bolt until just snug around top of the pole of the base part
2. Slide pole of middle part into pole of base part and tighten pole clamp lever
3. Apply hot glue into magnet slots on the top and middle parts
4. Insert magnets with opposite polarities facing out on the top and middle parts and allow to dry

Conclusions/action items:

Complete force testing on the prototype.

12/5/24 SolidWorks Stress Analysis Protocol

SARA MOREHOUSE - Dec 11, 2024, 4:38 PM CST

Title: SolidWorks Stress Analysis Protocol

Date: 12/5/24

Content by: Sara Morehouse

Present: n/a

Goals: To define the protocol for performing a stress simulation on our model.

Content:

Materials:

- SolidWorks model of prototype

Procedure:

1. Open model in SolidWorks.
2. Open SimulationXpress Analysis Wizard.
3. Apply a fixture to the bottom of the base plate of the device.
4. Apply a transverse load of 38N to the top 20mm of the shaft.
5. Apply the material: AISI 4130 (annealed) Steel
6. Run Simulation.
7. Click to show Stress results (von Mises stress)

Conclusions/action items:

This protocol yielded results for stress and a factor of safety, which are explained more in detail in the Experimentation section.

12/3/24 - Force Testing Protocol

SARA MOREHOUSE - Dec 11, 2024, 9:06 PM CST

Title: Force Testing Protocol

Date: 12/3/24

Content by: Sara Morehouse, Noah Hamrin, Max Aziz

Present: Noah Hamrin, Max Aziz

Goals: To outline the protocol for performing force testing on the prototype.

Content:

Materials:

- 4D ICE Catheter
- 3D ICE Catheter
- Prototype
- Duct tape
- Spring force gauge
- Wet towels (2)

Procedure:

1. Place 3D ICE catheter into the saddle of the prototype. Use duct tape to secure the catheter onto the saddle.
2. Hook the spring gauge onto the front end of the catheter in the vertical direction, perpendicular to the axis of the catheter.
3. Apply a downward force with the spring gauge until the magnets in the prototype become disconnected. Record this force value.
4. Repeat step 3 for a total of 5 trials.
5. Hook the spring gauge onto the front end of the catheter in the transverse horizontal direction, perpendicular to the axis of the catheter.
6. Apply a transverse (twisting) force to the prototype via the spring gauge until the magnetic saddle twists off of the prototype. Record this force value.
7. Repeat steps 5-6 for a total of 5 trials.
8. Tape the hook of the spring gauge to the front end of the catheter in the axial direction.
9. Apply a tensile force with the spring gauge to the catheter until the magnets in the prototype become disconnected. Record this force value.
10. Repeat steps 8-9 for a total of 5 trials.
11. Repeat steps 1-10 with the 4D ICE catheter.
12. Wrap the 3D ICE catheter with one of the wet towels, then drape the second towel over the top of the 1st towel.
13. Repeat steps 5-10 with the 3D catheter in the towels.
14. Repeat step 12 with the 4D ICE catheter.
15. Repeat steps 5-10 with the 4D catheter in the towels.
16. Once all force values have been collected, upload data into MATLAB.
    a. The following code can be used to graph the data:

```
device_4d_twisting = [6.9, 6.2, 6.3, 5.9, 6.2]
towel_4d_twisting = [0.8, 0.6, 0.7, 0.6, 0.5]
mean_device_d4_twisting = mean(device_4d_twisting)
mean_towel_4d_twisting = mean(towel_4d_twisting)
std_device_d4_twisting = std(device_4d_twisting)
std_towel_4d_twisting = std(towel_4d_twisting)
```

```
%%
means = [mean_towel_4d_twisting, mean_device_d4_twisting];
stds = [std_towel_4d_twisting, std_device_d4_twisting];
figure (1);
bar(means);
hold on;
errorbar(means, stds, 'k', 'LineStyle', 'none', 'CapSize', 10);
xticks([1 2]);
xticklabels({'Current Method', 'Device'});
ylabel('Force (Newtons)');
hold off;
```

b. The following code can be used to obtain p-values for the data:

```
%% Force testing
% Device vs. Towel
[h,p] = ttest2(Tensile4D_t,Tensile_d)
[h,p] = ttest2(Twisting4D_t,Twisting4D_d)
[h,p] = ttest2(Tensile3D_t,Tensile_d)
[h,p] = ttest2(Twisting3D_t,Twisting3D_d)



% 4D vs 3D
[h,p] = ttest2(Bending3D_d,Bending4D_d)
[h,p] = ttest2(Twisting3D_d,Twisting4D_d)
% for tensile, p>0.05



% Mean values
bending4D_d_mean = mean(Bending4D_d)
bending3D_d_mean = mean(Bending3D_d)
twisting4D_d_mean = mean(Twisting4D_d)
twisting3D_d_mean = mean(Twisting3D_d)
tensile4D_t_mean = mean(Tensile4D_t)
tensile3D_t_mean = mean(Tensile3D_t)
twisting4D_t_mean = mean(Twisting4D_t)
twisting3D_t_mean = mean(Twisting3D_t)
```

Conclusions/action items:

This test is used to verify that the prototype is capable of keeping the catheter secured better than the previous method that was used (wet towels). The data will be analyzed with a T-test to check whether significantly more force is required to displace the catheters from the prototype than from the towels.

12/3/24 - Drape Tensile Testing Protocol

SARA MOREHOUSE - Dec 11, 2024, 9:18 PM CST

Title: Drape Tensile Testing Protocol

Date: 12/3/24

Content by: Kaden Kafar

Present: Kaden Kafar

Goals: To outline the procedure for performing MTS tensile testing on the surgical drape.

Content:

Materials:

- Drape
- Scissors
- Ruler/Tape Measure
- MTS machine
- Tensile Grips
- 10 kN load cell

Procedure:

1. Cut drape into 3 samples of 5 cm by 10 cm
2. Check to ensure proper load cell and tensile grips are attached to the MTS machine. If not remove previous load cell and grips and replace with proper equipment.
3. Turn on both the MTS machine and MTS software. Load up a tensile test format on the software and set speed at 1 mm/s
4. Load a drape sample into tensile clamps ensuring no slipping out of grip will happen. It should leave about 5 cm of gauge length to displace.
5. Turn off the lock on the MTS controls and move the crosshead up until the load appears positive on the software then zero both the crosshead and the load.
6. Click run test and enter data for the sample (width: 50 mm, thickness: 1 mm, gauge length: 50 mm, target strain: 100%). Click enter once all information is ensured to be correct. This will commence the test and cause the crosshead to raise. Once the break has happened, hit stop test and reset to zero.
7. Remove broken drape sample and load up new sample and repeat for all samples.
8. Export raw data for calculations and MATLAB graphing.
9. Clean up the MTS machine and ensure everything is restored to how you found it.

Conclusions/action items:

This procedure will be performed and the material properties of the drape will be calculated.

12/11/24 - Stainless Steel Prototype Fabrication

MAX AZIZ (mmaziz@wisc.edu) - Dec 11, 2024, 10:14 PM CST

Title: Stainless Steel Fabrication Protocol

Date: 12/11/2024

Content by: Max Aziz

Present: n/a

Goals: To make a protocol in order to safely fabricate the stainless steel prototype

Content:

Materials:

- SolidWorks File
- CNC Lathe
- CNC Mill
- MIG Welding
- Permits for CNC
- Permits for MIG Welding
- 4130 steel rod 2”x1ft
- Sheet metal 4130 easy-to-weld steel 6”x36”

CNC Lathe:

1. Open SolidWorks file of the solid middle tube
2. Obtain 4130 steel rod 2”x1ft
3. Convert SolidWorks file into G code
4. Select correct tools and speeds
5. Secure part in spindle and load tools
6. Begin program
7. Repeat the process for hollow middle tube and top part

CNC Mill:

1. Open SolidWorks file of Solid Middle tube
2. Obtain solid middle tube after it is done with CNC Lathe and Sheet metal 4130 easy-to-weld steel 6”x36”
3. Convert SolidWorks file into G code
4. Isolate the top part with the magnets
5. Create toolpaths, selecting optimal end mill bits
6. Upload G code to CNC mills
7. Secure part in vice and load correct tools into the machine
8. Begin program
9. Repeat the process for top part, hollow middle tube, and base

MIG Welding:

1. Obtain hollow middle part and base
2. Use PPE
3. Turn on MIG machine

4. Ensure the filling is appropriate
5. Use 90% argon and 10% carbon dioxide
6. Use 175 amps
7. Make sure hollow middle part and base are in appropriate placement based on SolidWorks (off-centered by 30.48 cm)
8. Put gun 45 degrees between base and hollow middle tube
9. Begin weld
10. Cool weld and check that it looks sufficient
11. Turn everything off

Conclusions/action items: This can be used for next semester for the team to safely build the stainless steel proof-of-concept prototype.

12/5/24 SolidWorks Stress Analysis Results

SARA MOREHOUSE - Dec 11, 2024, 4:41 PM CST

Title: SolidWorks Stress Analysis Results

Date: 12/5/24

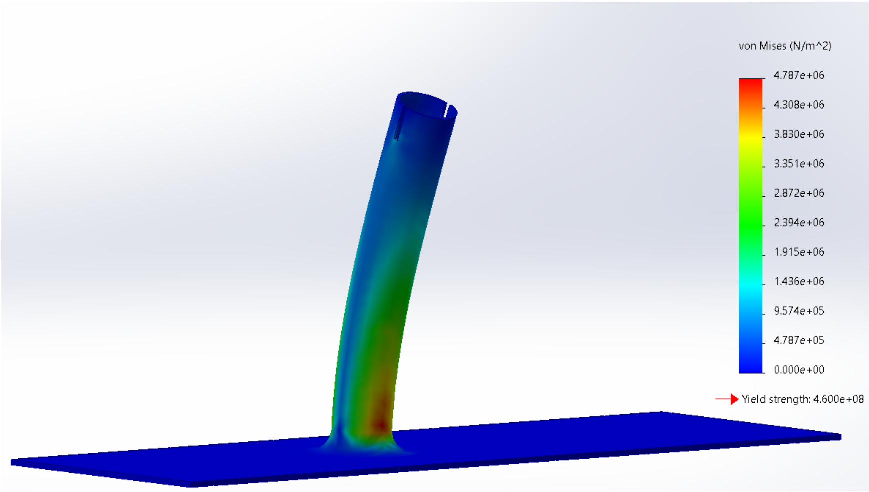
Content by: Sara Morehouse

Present: n/a

Goals: To summarize and explain the results of the SolidWorks simulation.

Content:

- Peak stress value of 4.8 MPa at the stress concentration along the weld
  - Calculated equivalent Von Mises stress that accounts for all states of stress.
- AISI 4130:
  - yield strength of 460 MPa
  - ultimate strength of 560 MPa
- FOS: 96.3 based on Distortion Energy Theory
  - Typical safety factors range from 1.25 - 4
  - indicates little possibility of the weld between the shaft and the base breaking.



Conclusions/action items:

This testing was successfully performed, and the results suggest that the weld between the base plate and the shaft will be strong enough to prevent breaking.

12/3/24 - Force Testing Results

SARA MOREHOUSE - Dec 11, 2024, 9:16 PM CST

Title: Force Testing Results

Date: 12/3/24

Content by: Max Aziz, Sara Morehouse

Present: Max Aziz, Noah Hamrin, Sara Morehouse

Goals: To explain the results of the force testing.

Content:

Experiment setup:

4D ICE Catheter in Device			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	3.2	10+	6.9
2	2.6	-	6.2
3	2	-	6.3
4	3	-	5.9
5	2.8	-	6.2
Mean:	2.72		6.3
3D ICE Catheter in Device			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	4.4	10+	5.4
2	3.9	-	6.5
3	4	-	6.1
4	4.6	-	5.8
5	3.8	-	5.4

Mean:	4.14		5.84
4D ICE Catheter with Wet Towels			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	n/a	1.1	0.8
2	n/a	1.2	0.6
3	n/a	1.6	0.7
4	n/a	1.7	0.6
5	n/a	1.9	0.5
Mean:		1.5	0.64
3D ICE Catheter with Wet Towels			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	n/a	1.4	0.2
2	n/a	1.8	0.4
3	n/a	1.6	0.3
4	n/a	1.8	0.4
5	n/a	1.9	0.3
Mean:		1.7	0.32

Device vs. Towel			4D vs. 3D	
	p-value			p-value
Tensile 4D:	1.14E-11		Bending	5.56E-04
Twisting 4D:	7.95E-10		Tensile	>0.05
Tensile 3D:	2.03E-13		Twisting	0.1239
Twisting 3D:	5.57E-09			

Conclusions/action items:

The force testing revealed that significantly more force was required to dislodge the saddle component compared to the wet towel ($p < 0.001$ for torsional & tensile loading). Bending loading could not be compared between the wet towel and the prototype because with the towel setup, a bending force could not be applied. Additionally, the force values obtained for tensile testing with the prototype exceeded the maximum value of the gauge, so the force was recorded as 10+ N. The results of this testing shows that the prototype meets the criteria of keeping the catheter secured for a force of 2 N, and shows that the prototype significantly improves on the old method of stabilizing the catheter.

Additionally, we compared the results between the 4D and the 3D ICE catheters. The force values were not significantly different for tensile and twisting loading, which shows that the prototype can successfully stabilize multiple types/brands of ICE catheters, which was another design criteria.

12/3/24 - Drape Tensile Testing Results

SARA MOREHOUSE - Dec 11, 2024, 9:24 PM CST

Title: Drape Tensile Testing Results

Date: 12/3/24

Content by: Kaden Kafar

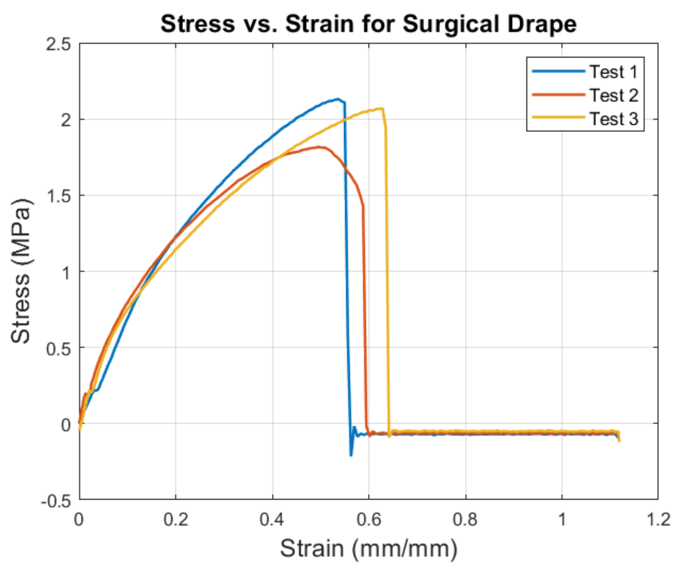
Present: Kaden Kafar

Goals: To present the results of the MTS tensile testing of the surgical drape.

Content:

- 3 samples of 5 cm by 10 cm
- Average Young's Modulus = 7.65 MPa
- Max load =100.23 N
- Max strain = .55.
- Compared to other materials:
  - Young's Modulus and ultimate strain of the drape is similar to nylon and the max load is similar to that of cotton
  - Drape material is strong in comparison to most other fabric materials
  - Surgical drape is very tear resistant for a textile
- Device has little to no chance of propagating a tear in the material

	Young's Modulus (MPa)	Max Load (N)	Max Strain
Average	7.65 ± 0.95	100.23±8.33	.55±.007



Conclusions/action items:

The tensile testing of the surgical drape revealed that the drape material is very strong and thus there is little-to-no chance that the magnets or the grooves of the device will tear through the drape.

9Sep24 - Use of Intracardiac Echocardiography in Interventional Cardiology: Working With the Anatomy Rather Than Fighting It

SARA MOREHOUSE - Sep 09, 2024, 10:47 PM CDT

Title: Use of Intracardiac Echocardiography in Interventional Cardiology: Working With the Anatomy Rather Than Fighting It

Date: 9Sep24

Content by: Sara Morehouse

Present: n/a

Goals: To learn more about what intracardiac echocardiography is and how it is used.

Citation:

[1] A. Enriquez *et al.*, "Use of Intracardiac Echocardiography in Interventional Cardiology," *Circulation*, vol. 137, no. 21, pp. 2278–2294, May 2018, doi: https://doi.org/10.1161/circulationaha.117.031343.

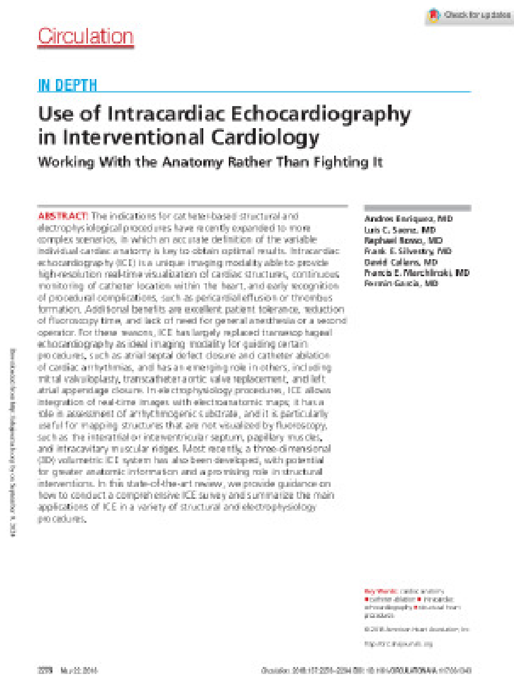
Content:

- Enables high-resolution real-time visualization of cardiac structures
- Allows for continuous monitoring of the location of catheters in the heart
- Helps to recognize complications during procedures
- Does not require general anesthesia
- Eliminates need for endotracheal intubation that was required for transesophageal echocardiography
- 2 different types of ICE technology:
  - radial/rotational ICE
    - piezoelectric crystal at the tip of a catheter
    - rotating transducer provides cross-sectional images
  - Phased-array ICE
    - 64-element transducer mounted on distal end of a steerable catheter
    - can be deflected in 4 directions
    - produces wedge-shaped image
    - greater depth of penetration, maneuverability, Doppler and color flow imaging
    - preferred technology
- Inserted via a standard femoral venous introducer
  - Catheter travels through the femoral vein to the heart
- Basic rule for advancing the catheter in vascular or cardiac chambers:
  - always maintain an echographic clear space (black) ahead of the catheter and avoid pushing when an echogenic space is ahead of the catheter.
  - if an acute angle is observed at the tip of the transducer, apply gentle retroflection to maintain view of the vein
  - if an obtuse angle is ahead of the transducer, apply anteroflection
- "Home view" is obtained when the ICE catheter is placed in the mid-right atrium
  - provides imaging of the RA, tricuspid valve, right ventricle and a short-axis view of the aortic valve
  - Color flow Doppler used to evaluate tricuspid regurgitation
  - Continuous wave Doppler used to estimate RV systolic pressure
- Rotating the catheter reveals additional visualization of the valves, ventricles, and atria

Conclusions/action items:

This article gives a basic background into how ICE works and goes into great detail about the specific method of using ICE for many common procedures. It was helpful to gain a basic understanding of what ICE is. Going forward, I will look more into the importance of ensuring the catheter does not drift out of place and investigating how that can affect the results of a procedure.

SARA MOREHOUSE - Sep 09, 2024, 10:48 PM CDT



Circulation

IN DEPTH

Use of Intracardiac Echocardiography in Interventional Cardiology

Working With the Anatomy Rather Than Fighting It

ABSTRACT: The indications for catheter-based structural and electrophysiological procedures have recently expanded to more complex scenarios, in which an accurate definition of the variable individual cardiac anatomy is key to obtain optimal results. Intracardiac echocardiography (ICE) is a unique imaging modality able to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of catheter location within the heart, and early recognition of procedural complications, such as pericardial effusion or thrombus formation. Additional benefits are excellent patient tolerance, reduction of fluoroscopy time, and lack of need for general anesthesia or a second operator. For these reasons, ICE has largely replaced transesophageal echocardiography as ideal imaging modality for guiding certain procedures, such as atrial septal defect closure and catheter ablation of cardiac arrhythmias, and has an emerging role in others, including mitral valvuloplasty, transcatheter aortic valve replacement, and left atrial appendage closure. In electrophysiology procedures, ICE allows integration of real-time images with electroanatomic maps; it has a role in assessment of arrhythmogenic substrate, and it is particularly useful for mapping structures that are not visualized by fluoroscopy, such as the interatrial or interventricular septum, papillary muscles, and intracavitary muscular ridges. Most recently, a three-dimensional (3D) volumetric ICE system has also been developed, with potential for greater anatomic information and a promising role in structural interventions. In this state-of-the-art review, we provide guidance on how to conduct a comprehensive ICE survey and summarize the main applications of ICE in a variety of structural and electrophysiology procedures.

Andres Enriquez, MD
Luis C. Saenz, MD
Raphael Rosso, MD
Frank E. Silvestry, MD
David Callans, MD
Francis E. Marchlinski, MD
Fermin Garcia, MD

[Download](#)

enriquez-et-al-2018-use-of-intracardiac-echocardiography-in-interventional-cardiology.pdf (881 kB)

11Sep24 - Preventing complicated transseptal puncture with intracardiac echocardiography: case report

SARA MOREHOUSE - Sep 11, 2024, 6:44 PM CDT

Title: Preventing complicated transseptal puncture with intracardiac echocardiography: case report

Date: 11 Sep 24

Content by: Sara Morehouse

Present: N/A

Goals: To understand how intracardiac echocardiography is used for transseptal puncture.

Citation:

[1]T. N. Shalganov, D. Paprika, S. Borbás, A. Temesvári, and T. Szili-Török, “Preventing complicated transseptal puncture with intracardiac echocardiography: case report,” Cardiovascular Ultrasound, vol. 3, no. 1, Mar. 2005, doi: https://doi.org/10.1186/1476-7120-3-5.

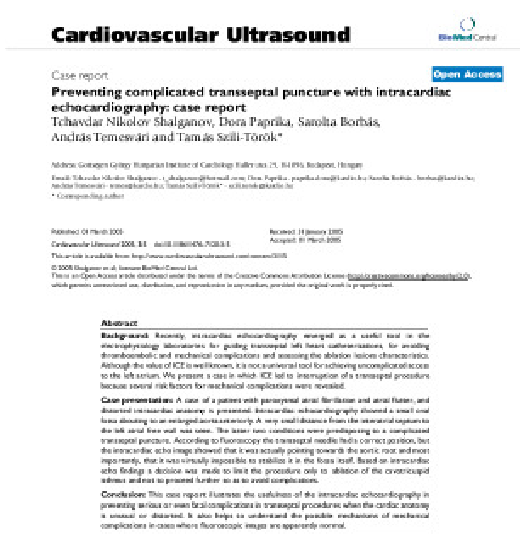
Content:

- ICE is useful in preventing complications during transseptal procedures
- ICE can provide a more detailed picture about cardiac anatomy and possible complications than TEE, which happened with this patient. The procedure was deemed feasible based on information collected via TEE, but when ICE was performed, it was found that the transeptal procedure would be potentially dangerous.
- ICE allows for continuous monitoring of the pericardial space during electrophysiologic procedures, which allows for faster detection of a pericardial effusion, which can then be treated faster, which prevents complications.

Conclusions/action items:

This article gave strong reasoning as to why ICE is useful and preferred over other methods such as TEE, however it did not give me a good sense of the physical techniques required to perform ICE and issues that can arise with it drifting out of place.

SARA MOREHOUSE - Sep 11, 2024, 5:48 PM CDT



Cardiovascular Ultrasound

BioMed Central

Case report

Open Access

Preventing complicated transseptal puncture with intracardiac echocardiography: case report

Tchavdar Nikolov Shalganov, Dora Paprika, Sarolta Borbás, András Temesvári and Tamás Szili-Török*

Address: Gottsegen György Hungarian Institute of Cardiology Haller utca 29, H-1096, Budapest, Hungary

* Corresponding author

Published: 01 March 2005

Cardiovascular Ultrasound 2005, 3:5 doi:10.1186/1476-7120-3-5

Received: 11 January 2005

Accepted: 01 March 2005

Abstract

Background: Recently, intracardiac echocardiography emerged as a useful tool in the electrophysiology laboratories for guiding transseptal left heart catheterizations, for avoiding thromboembolic and mechanical complications and assessing the ablation lesions characteristics. Although the value of ICE is well known, it is not a universal tool for achieving uncomplicated access to the left atrium. We present a case in which ICE led to interruption of a transseptal procedure because several risk factors for mechanical complications were revealed.

Case presentation: A case of a patient with paroxysmal atrial fibrillation and atrial flutter, and distorted intracardiac anatomy is presented. Intracardiac echocardiography showed a small oval fossa abutting to an enlarged aorta anteriorly. A very small distance from the interatrial septum to the left atrial free wall was seen. The latter two conditions were predisposing to a complicated transseptal puncture. According to fluoroscopy the transseptal needle had a correct position, but the intracardiac echo image showed that it was actually pointing towards the aortic root and most importantly, that it was virtually impossible to stabilize it in the fossa itself. Based on intracardiac echo findings a decision was made to limit the procedure only to ablation of the cavotricuspid isthmus and not to proceed further so as to avoid complications.

Conclusion: This case report illustrates the usefulness of the intracardiac echocardiography in preventing serious or even fatal complications in transseptal procedures when the cardiac anatomy is unusual or distorted. It also helps to understand the possible mechanisms of mechanical complications in cases where fluoroscopic images are apparently normal.

Background

Since the advent of ICE in the electrophysiology practice it proved its value in guiding transseptal procedures with providing an extra safety margin for the patients. The possibility to visualize the oval fossa, the LA free wall and the aortic root helps in preventing mechanical complications. ICE can visualize also intracardiac thrombus and spontaneous echocontrast, which is helpful in avoiding thromboembolic complications. Although the value of ICE is well known, it is rather hard to admit that it is a universal tool for achieving uncomplicated access to the left atrium. The aim of this case presentation is to show that ICE can

Page 1 of 4
(page number not for citation purposes)

Download

Preventing_complicated_transseptal_puncture_with_intracardiac_echocardiography__case_report.pdf (688 kB)

16Sep24 - Sterilization of Objects, Products, and Packaging Surfaces and Their Characterization in Different Fields of Industry: The Status in 2020

SARA MOREHOUSE - Sep 16, 2024, 8:26 PM CDT

Title: Sterilization of Objects, Products, and Packaging Surfaces and Their Characterization in Different Fields of Industry: The Status in 2020

Date: 16 Sep 24

Content by: Sara Morehouse

Present: n/a

Goals: To understand more about how gas sterilization works in order to better understand the "life in service" requirements for our project.

Citation:

[1]Z. B. Jildeh, P. H. Wagner, and M. J. Schöning, "Sterilization of Objects, Products, and Packaging Surfaces and Their Characterization in Different Fields of Industry: The Status in 2020," physica status solidi (a), vol. 218, no. 13, p. 2000732, Mar. 2021, doi: https://doi.org/10.1002/pssa.202000732.

Content:

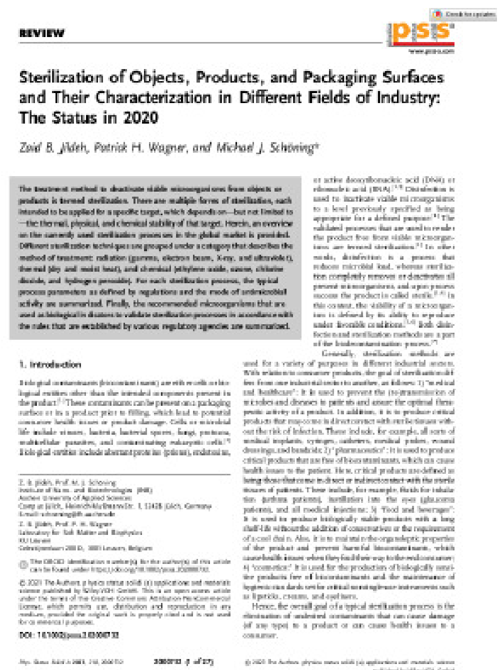
- Multiple different application methods for chemical surface sterilization:
  - Liquid phase - spraying nozzles and immersion baths
  - Gas phase - gas generators working at atmospheric or low-pressure conditions
  - Mixed phase - surface condensation is during the sterilization cycle due to the thermophysical properties of the chemical sterilant, the lower surface temperature of the object, or due to the reduction of the surrounding pressure
- Gas or vapor sterilization is most common in healthcare/medical industries
- Sterilization process usually includes:
  - Conditioning
    - assures the optimal temperature of the object to be sterilized and its (surface) relative humidity
    - prepares the object to receive the sterilization process so that a reproducible sterility level is achieved
  - Sterilization
    - treatment of the object's surfaces by the sterilant
  - Post-treatment
    - After sterilization, traces of the sterilant remain on the surface
    - post-treatment and multiple aeration cycles are required to remove these residues and guarantee an acceptable residual level according to regulations
- Difference between gas and vapor sterilization:
  - Gas - no condensation is possible due to the state of the sterilant at normal temperature and pressure (ex: CO_2, EtO
  - Gas sterilization shows stronger penetration than vapor sterilization
- Ethylene oxide:
  - Gas at room temp

- Strong microbicidal properties
- high penetration in paper, cloth
- Cold sterilization technique
- used to sterilize heat- and radiation-sensitive polymers, surgical instruments
- A sterilization cycle is 1-6 hours at 37-63 °C, relative humidity of 40-80%
- concentration of EtO for these conditions is 450-1200 mg/L mixed with an inert gas
- requires a post-treatment step to remove EtO residues from the chamber and the object as the residues are toxic

Conclusions/action items:

This article gave a helpful background on the parameters of ethylene oxide sterilization.

SARA MOREHOUSE - Sep 16, 2024, 8:09 PM CDT



REVIEW

Sterilization of Objects, Products, and Packaging Surfaces and Their Characterization in Different Fields of Industry: The Status in 2020

Zaid B. Jildeh, Patrick H. Wagner, and Michael J. Schöning*

The treatment method to deactivate viable microorganisms from objects or products is termed sterilization. There are multiple forms of sterilization, each intended to be applied for a specific target, which depends on—but not limited to—the thermal, physical, and chemical stability of that target. Herein, an overview on the currently used sterilization processes in the global market is provided. Different sterilization techniques are grouped under a category that describes the method of treatment: radiation (gamma, electron beam, X-ray, and ultraviolet), thermal (dry and moist heat), and chemical (ethylene oxide, ozone, chlorine dioxide, and hydrogen peroxide). For each sterilization process, the typical process parameters as defined by regulations and the mode of antimicrobial activity are summarized. Finally, the recommended microorganisms that are used as biological indicators to validate sterilization processes in accordance with the rules that are established by various regulatory agencies are summarized.

1. Introduction

Download

Physica_Status_Solidi_a_-_2021_-_Jildeh_-_Sterilization_of_Objects_Products_and_Packaging_Surfaces_and_Their.pdf (5.55 MB)

16Sep24 - Understanding Functional Failures: The Impact of Repeated Sterilization Techniques

SARA MOREHOUSE - Sep 16, 2024, 8:28 PM CDT

Title: Understanding Functional Failures: The Impact of Repeated Sterilization Techniques

and Sterilization of 20 billion medical devices by ethylene oxide (ETO): Consequences of ETO closures and alternative sterilization technologies/solutions

Date: 16 Sep 24

Content by: Sara Morehouse

Present: n/a

Goals: To better understand how repeated sterilization affects surgical instrument material integrity.

Citations:

[1] W. A. Rutala and D. J. Weber, "Sterilization of 20 billion medical devices by ethylene oxide (ETO): Consequences of ETO closures and alternative sterilization technologies/solutions," *American Journal of Infection Control*, vol. 51, no. 11, pp. A82–A95, Nov. 2023, doi: https://doi.org/10.1016/j.ajic.2023.01.020.

[1]J. Jennings, "Understanding Functional Failures: The Impact of Repeated Sterilization Techniques | SteriLogix," SteriLogix, Jun. 05, 2024. https://sterilogix.com/blog/understanding-functional-failures-the-impact-of-repeated-sterilization-techniques/ (accessed Sep. 17, 2024).

Content:

- Study by Jones et. al. (2020) revealed that prolonged exposure to ETO resulted in the formation of corrosion pits on instrument surfaces, compromising their structural integrity and longevity
- EtO has strong material compatibility with almost all commonly used polymers

Conclusions/action items:

It seems like there are not many unique requirements for a device to be able to be sterilized by EtO. It has broad material compatibility and does not use high heat or humidity, which allows it to sterilize heat-sensitive materials.

21Nov24 - Research on movement of diaphragm produced by breathing

SARA MOREHOUSE - Nov 21, 2024, 11:16 PM CST

Title: Movements of the thoracic cage and diaphragm in respiration

Date: 11/21/24

Content by: Sara Morehouse

Present: n/a

Goals: To find a literature value for how much the diaphragm moves during respiration to use a basis for our testing.

Citation: Wade, O. L., (1954), Movements of the thoracic cage and diaphragm in respiration*. The Journal of Physiology, 124 doi: 10.1113/jphysiol.1954.sp005099.

Movements of the thoracic cage and diaphragm in respiration*

Content:

Mean diaphragmatic movement in supine position: 1.70cm on the right side, 1.78cm on the left side.

Study information:

- 10 male subjects

- ages 24-36

- mean chest circumference = 90.5cm

- mean weight and height: 73kg, 175cm

Conclusions/action items:

This will be helpful when we are testing to be able to compare movement to these measurements.

11Sep24 - Mitral Valve Clip Procedure

SARA MOREHOUSE - Sep 11, 2024, 7:04 PM CDT

Title: Mitral Valve Clip Procedure

Date: 11 Sep 24

Content by: Sara Morehouse

Present: n/a

Goals: To understand how the MitraClip device works, as it includes a stabilizer device that was given as an example that could be similar to what we are designing.

Citation:

[1] "What You Need to Know About the Mitral Valve Clip Procedure," *Verywell Health*. https://www.verywellhealth.com/mitral-valve-clip-5092874

Content:

- minimally invasive, non-surgical method to repair a mitral valve
- performed percutaneously (through vein in the groin)
- Catheter guides a small metal clip coated in polyester fabric up the vein
- Significantly reduces mitral valve regurgitation

Conclusions/action items:

This source was clearly written to explain the what the MitraClip is to a patient. It was helpful to gain and understanding of what it is for, but not very helpful for understanding the mechanics of the stabilizer device included in the system. Next I will research standards and CFR sections that are relevant to this project.

11Sep24 CFR Regulations

SARA MOREHOUSE - Sep 11, 2024, 8:17 PM CDT

Title: Research on CFR Regulations

Date: 11 Sep 24

Content by: Sara Morehouse

Present: N/A

Goals: To learn more about relevant CFR regulations for this project.

eCFR :: 21 CFR Chapter I Subchapter H -- Medical Devices

Content:

- Percutaneous catheters are classified as Class II (performance standards) (21 CFR Part 870)
- A Steerable Catheter Control System "is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter."
    - Class II (performance standards) (21 CFR Part 870)
- Intravascular Catheter Securement Device
    - "a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin." (21 CFR Part 880)
    - Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. (21 CFR Part 880)
- "A custom device is exempt from premarket notification requirements of this subpart if the device is within the meaning of section 520(b) of the Federal Food, Drug, and Cosmetic Act.

  (1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

  (2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons)." (21 CFR Part 807, Subpart E)

Conclusions/action items:

At first glance it seems that our device may fall under Class I devices - but will do more research in the future to confirm.

22Sep24 - Design Idea 1

SARA MOREHOUSE - Sep 22, 2024, 5:40 PM CDT

Title: Design Idea 1

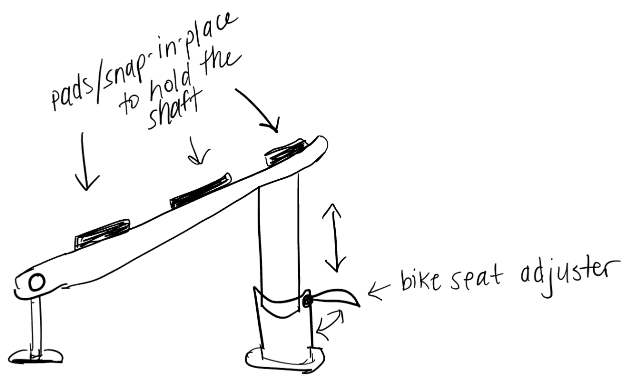
Date: 22 Sep 24

Content by: Sara Morehouse

Present: n/a

Goals: To come up with an initial design idea before meeting with the team

Content:



The term "bike seat adjuster" refers to a quick-release saddle clamp, similar to the ones that are used to adjust the height of a bike seat. This element would allow the height of the device to be adjusted. This could also be incorporated on the front post, although that is not depicted here. Additionally, the front and back of the top plate could be fixed with pins at each end, which would allow it to rotate freely depending on the angle and heights that the front and back are adjusted to.

<---- Quick release saddle clamp

Conclusions/action items:

This design idea can be modeled in SolidWorks and discussed with the team during our next meeting.

12Nov24 - CNC Training Documentation

SARA MOREHOUSE - Nov 13, 2024, 11:10 PM CST

Title: CNC 1 Training Documentation

Date: 11/12/24

Content by: Sara Morehouse

Present: n/a

Goals: To provide a record of my completed CNC training.

Content:

Sara Morehouse

ID Number: 9083120205

Eligibility: CoE Students

Profile

My Memberships

Membership Type	Start Date	Expiry Date	Renew	Card Info
CNC Mill I	Tue, Aug 20 2024	Permanent	Not Renewable	N/A
Access Fee	Mon, May 22 2023	Sun, Dec 31 2023	Not Renewable	N/A
Machining	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Lab Orientation	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Laser Cutter	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Shop Tools	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A

Conclusions/action items:

Complete the CNC 2 upgrade.

2024/9/11 - Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 5:06 PM CDT

Title: Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization

Date: 11 September 2024

Content by: Max Aziz

Present: n/a

Goals: I want to learn more about the procedure to get background about what I need to consider in making this clip device.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761099/

Citation:

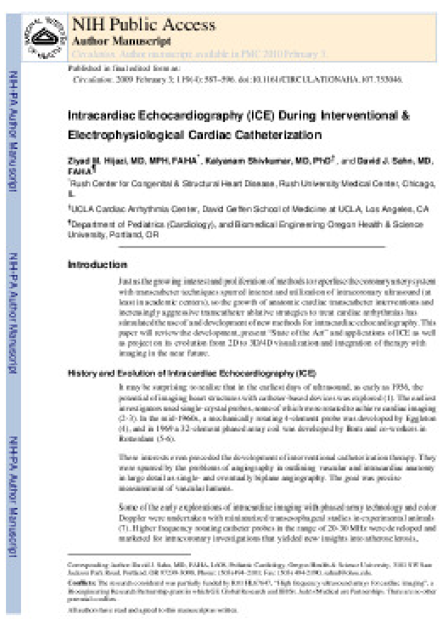
[1] Z. M. Hijazi, K. Shivkumar, and D. J. Sahn, “Intracardiac echocardiography during interventional and electrophysiological cardiac catheterization,” Circulation, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761099/ (accessed Sep. 11, 2024).

Content:

- The ICE has helped the field to go from 2D to 3D/4D
- ICE catheter is rigid
- Uses Doppler to obtain images
- It contains a lock position, but I am assuming this is where the issues come in and why the client wants the team's help
- Handle of ICE catheter moves in a certain way once it gets into the lock position
- ICE catheter is used for ablation procedures

Conclusions/action items: I learned that this device is used for ablation procedure. Thus, in designing the device, we must consider smaller than usual vessels and blood flow. Additionally, due to the device having a lock position, we must consider the mechanisms of the device so that it is not interrupted during its normal use.

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 5:04 PM CDT



NIH Public Access
Author Manuscript

Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization

Ziyad M. Hijazi, MD, MPH, FAHA, Kalyanam Shivkumar, MD, PhD, and David J. Sahn, MD, FAHA

Rush Center for Congenital & Structural Heart Disease, Rush University Medical Center, Chicago, IL

UCLA Cardiac Arrhythmia Center, David Geffen School of Medicine at UCLA, Los Angeles, CA

Department of Pediatrics (Cardiology), and Biomedical Engineering Oregon Health & Science University, Portland, OR

Introduction

History and Evolution of Intracardiac Echocardiography (ICE)

[Download](#)

Intracardiac_Echocardiography_ICE_During_Interventional_Electrophysiological_Cardiac_Catheterization.pdf (2.34 MB)

2024/9/11 - The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: Meta-analysis of efficiency, effectiveness, and safety outcomes

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 5:

Title: The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: Meta-analysis of efficiency, effectiveness, and safety outcomes

Date: 11 September 2024

Content by: Max Aziz

Present: n/a

Goals: I want to learn more about the uses of the ICE device to get background about what I need to consider in making this clip device.

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7078927/#:~:text=Intracardiac%20echocardiography%20(ICE)%20has%20multiple,of%20overheating%2C%20thereby%20preventing%20c

Citation:

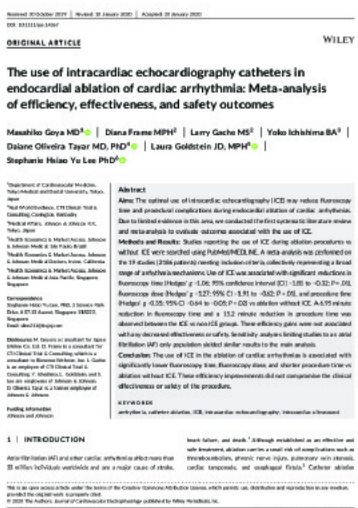
[1] M. Goya et al., "The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: Meta-analysis of efficiency, effectiveness, and safety outcomes," Jou cardiovascular electrophysiology, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7078927/#:~:text=Intracardiac%20echocardiography%20(ICE)%20has%20multiple,of%20overheating%2C%20thereby%20preventing%20c (accessed Sep. 11, 2024).

Content:

- The ICE catheter has the ability to guide transseptal puncture
- It can provide guidance for cardiac anatomy
- It can detect microbubbles, which can prevent complications
- Device helps with efficiency of procedure
- Significant less radiation compared to what they were doing before
- Device efficacy can vary from physician to physician

Conclusions/action items: I learned that ICE is a more novel and better device in this field. However, there is variance between physicians. Thus, when considering designing the device, this r into account

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 5:37 PM CDT



ORIGINAL ARTICLE

WILEY

The use of intracardiac echocardiography catheters in endocardial ablation of cardiac arrhythmia: Meta-analysis of efficiency, effectiveness, and safety outcomes

1 | INTRODUCTION

Download

Journal_of_Cardiovascular_Electrophysiology.pdf (941 kB)

2024/9/11 - Why is intracardiac echocardiography helpful? Benefits, costs, and how to learn

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 6:07 PM CDT

Title: Why is intracardiac echocardiography helpful? Benefits, costs, and how to learn

Date: 11 September 2024

Content by: Max Aziz

Present: n/a

Goals: I want to learn more about the general use and gather more background to help concoct questions and design ideas.

Link: https://pubmed.ncbi.nlm.nih.gov/24144789/

Citation:

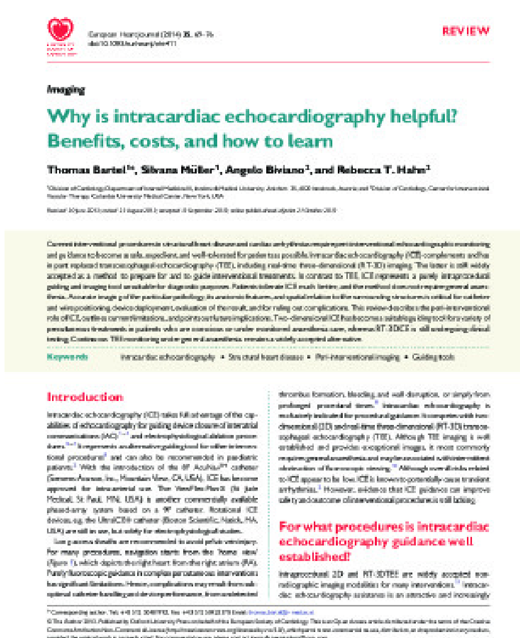
[1] T. Bartel, S. Muller, A. Biviano, and R. T. Hahn, "Why is intracardiac echocardiography helpful? benefits, costs, and how to learn," European heart journal, https://pubmed.ncbi.nlm.nih.gov/24144789/ (accessed Sep. 11, 2024).

Content:

- The ICE catheter probe gets positioned in the right atrium
- ICE confirms correct position and acquires information about correct balloon sizing
- ICE was meant to improve safety by preventing complications such as pericardial effusion
- It provides 3D imaging
- Its big limitation is it is used differently between physicians

Conclusions/action items: I learned that this device is extremely variable but can get the job done. Hence, the device made should help all users be more comfortable when using this addition. Additionally, the device enters into the heart. Therefore, bloodflow and obstruction must be considered when designing.

MAX AZIZ (mmaziz@wisc.edu) - Sep 11, 2024, 6:07 PM CDT



REVIEW

Imaging

Why is intracardiac echocardiography helpful? Benefits, costs, and how to learn

Thomas Bartel, Silvana Müller, Angelo Biviano, and Rebecca T. Hahn

Introduction

For what procedures is intracardiac echocardiography guidance well established?

Download

Why_is_intracardiac_echocardiography_helpful__Benefits_costs_and_how_to_learn.pdf (1.77 MB)

2024/9/16 - Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization

MAX AZIZ (mmaziz@wisc.edu) - Sep 16, 2024, 11:39 PM CDT

Title: Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization

Date: 16 September 2024

Content by: Max Aziz

Present: n/a

Goals: I want to learn about issues that physicians could run into with the ICE catheter

Link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761099/

Citation:

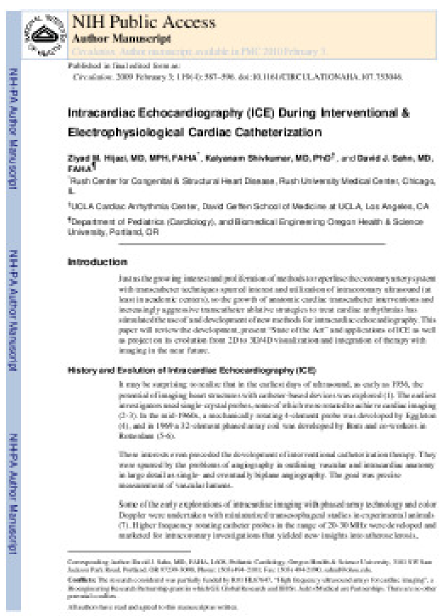
[1] Z. M. Hijazi, K. Shivkumar, and D. J. Sahn, “Intracardiac echocardiography during interventional and electrophysiological cardiac catheterization,” Circulation, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2761099/ (accessed Sep. 16, 2024).

Content:

- ICE can perforate the artery or aorta
- ICE can cause atrioesophageal fistula formation
- ICE can cause interference with the therapeutic catheter if not stayed in place

Conclusions/action items: I learned that when the device is used improperly, it can cause serious and life threatening complications. Therefore, the team and I must perform appropriate testing to ensure that the stabilizer is safe and stable before use.

MAX AZIZ (mmaziz@wisc.edu) - Sep 16, 2024, 11:43 PM CDT



NIH Public Access
Author Manuscript

NIH-PA Author Manuscript

Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization

Ziyad M. Hijazi, MD, MPH, FAHA, Kalyanam Shivkumar, MD, PhD, and David J. Sahn, MD, FAHA

Rush Center for Congenital & Structural Heart Disease, Rush University Medical Center, Chicago, IL

UCLA Cardiac Arrhythmia Center, David Geffen School of Medicine at UCLA, Los Angeles, CA

Department of Pediatrics (Cardiology), and Biomedical Engineering Oregon Health & Science University, Portland, OR

Introduction

History and Evolution of Intracardiac Echocardiography (ICE)

Download

nihms126500.pdf (2.34 MB)

2024/9/18 - TriClip G4 Stabilizer

MAX AZIZ (mmaziz@wisc.edu) - Sep 18, 2024, 4:50 PM CDT

Title: TriClip G4 Stabilizer

Date: 18 September 2024

Content by: Max Aziz

Present: n/a

Goals: I want to learn about a stabilizer for a different catheter and its effectiveness

Link: https://www.cardiovascular.abbott/int/en/hcp/products/structural-heart/transcatheter-valve-solutions/triclip.html

Citation:

[1] “TRICLIP transcatheter tricuspid valve repair,” Abbott, https://www.cardiovascular.abbott/int/en/hcp/products/structural-heart/transcatheter-valve-solutions/triclip.html (accessed Sep. 18, 2024).

Content:

- In the TriClip, the height can be adjusted, so that the catheter can be used while stabilized for a variety of different patients
- TriClip showed to be superior to medical therapy alone in improving Quality of Life
- They have a stabilizer for the catheter and a support plate to ensure no movement
- The support plate is one piece with only the knobs that cannot be sterilized

Conclusions/action items: I learned that the stabilizer and support are two separate devices. Additionally, stabilizing the catheter seemed to improve its effectiveness. Also, I learned that the device can be adjusted for it and the majority of it can be stabilized due to the material and the smoothness of the device.

MAX AZIZ (mmaziz@wisc.edu) - Sep 18, 2024, 4:30 PM CDT

Download

TriClip_Transcatheter_Tricuspid_Valve_Repair___Abbott.pdf (407 kB)

11/14/24 - Material Choice Research

MAX AZIZ (mmaziz@wisc.edu) - Nov 15, 2024, 4:51 PM CST

Title: Material Choice Research

Date: 11/14/24

Content by: Max Aziz

Present: n/a

Goals: To determine which material to use for our prototype.

Source:

[1]Azom, “AISI 4130 Alloy Steel (UNS G41300),” AZoM.com, Jan. 18, 2016. https://www.azom.com/article.aspx?ArticleID=6742

Content:

- AISI 4130 is a steel alloy containing chromium and molybdenum (strengthening agents)
- Low carbon content
- Easily weldable
- Components:
    -

Element	Content (%)
Iron, Fe	97.03 – 98.22
Chromium, Cr	0.80 – 1.10
Manganese, Mn	0.40 – 0.60
Carbon, C	0.280 – 0.330
Silicon, Si	0.15 – 0.30
Molybdenum, Mo	0.15 – 0.25
Sulfur, S	0.040
Phosphorous, P	0.035

- Density - 7.85g/cm^3
- Ultimate strength = 560 MPa
- Yield strength = 460 MPa
- 70% machinability
    - Machining this alloy is easy using conventional methods
    - issues can arise when the hardness of the steel is increased
- Welding can be performed easily with any conventional method
- Typically used for structural applications such as gears and fasteners

Conclusions/action items:

After researching 4130 steel, this material seems to be a good choice for our project because it is compatible with both welding and machining. For our device, we plan to both weld and machine the material, so this is essential. Additionally, strength of the material is not a major concern as our device will not be under any significant loading or stresses.

10/28/24 - MIG Welding Permit

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 11:12 PM CST

Title: MIG Welding Permit

Date: 10/28/2024

Content by: Max Aziz

Present: n/a

Goals: To get my welding permit in order to weld for our design.

Content:

- I did the online training to get my MIG welding
- I went in person to complete the in person portion of my training.

Membership Type	Start Date	Expiry Date	Renew	Card Info
MIG Welding	Mon, Oct 28 2024	Permanent	Not Renewable	N/A
MIG Welding - Training Eligible	Tue, Aug 20 2024	Wed, Dec 31 3000	Not Renewable	N/A
Access Fee	Mon, May 22 2023	Sun, Dec 31 2023	Not Renewable	N/A
Lab Orientation	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Machining	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Shop Tools	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A

Conclusions/action items: Now I can help the team with welding parts of the projects. This will be crucial as we are designing parts that use metal.

2024/9/11 - Surgical Procedure for Applicaiton of MitraClip

NOAH HAMRIN - Sep 11, 2024, 3:30 PM CDT

Title: Surgical Procedure for Application of MitraClip

Date: 9/11/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Learn about the procedure of deploying the MitraClip

Content:

The deployment of the MitraClip is a similar procedure to the positioning of the Intracardiac echo. Our client also stated the MitraClip guide could be an inspiration for our design.

The wall of the left atrium is punctured and the hole enlarged to allow the steerable guide to enter the atrium and position itself above the mitral valve. A second probe is then inserted through the guide to perform the procedure.

Transcatheter Edge-to-Edge Repair with MitraClip™ G4 - YouTube

Conclusions/action items:

Ask client how similar this procedure is to the ones involving an Intracardiac echo, and how he envisioned incorporating aspects from the guide into our design.

2024/9/11 - Intracardiac Echocardiography

NOAH HAMRIN - Sep 11, 2024, 5:13 PM CDT

Title: Intracardiac Echocardiography (ICE)

Date: 9/11/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Learn about the uses and methods of utilizing intracardiac echocardiography (ICE)

Content:

As catheter-based surgical treatments rose in popularity due to advances in technology and decreased bodily trauma, more efficient catheter-based imaging devices have been developed to allow the surgeon to better view the site. Intracardiac echocardiography (ICE) is an ultrasound-tipped catheter that can provide imaging of the heart from within the heart, inserted via a vein. Since its invention, ICE has evolved from 2D to 3D visualization. Its largest stimulus to growth in popularity is the increasingly complex procedures necessitating catheter imaging, including mitral annulus resizing, mitral annulus repair, and EP procedures. The main advantage ICE has over transesophageal echocardiography (TEE) is that the patient does not have to be under general anesthesia for a prolonged procedure.

The ICE ideally has the following features:

- user and patient friendly with simple mechanics

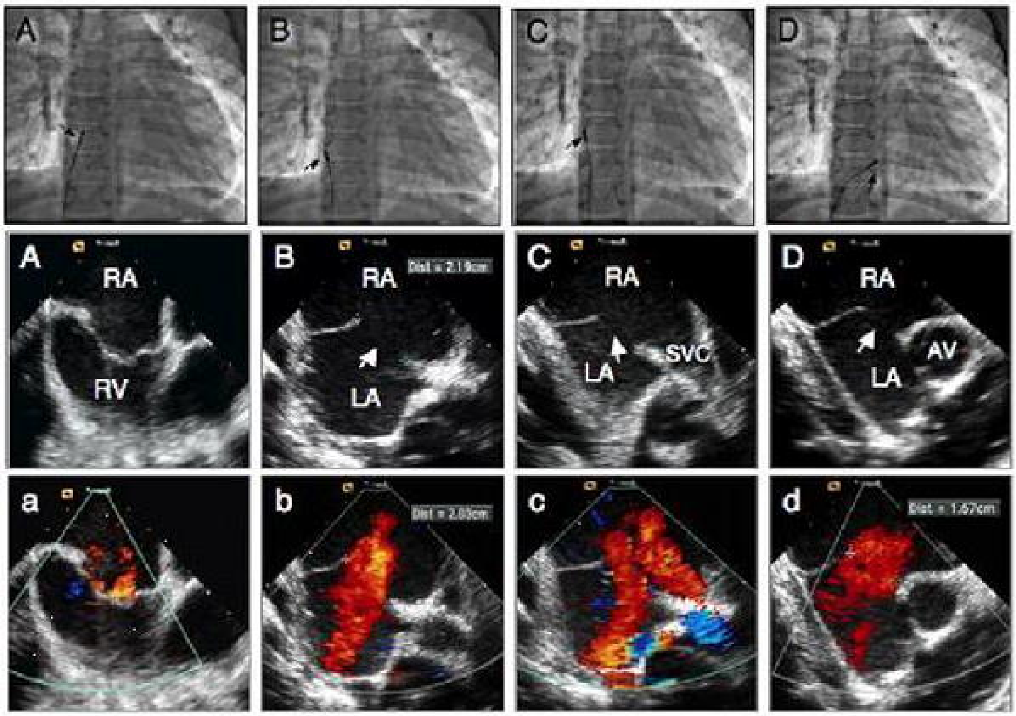
- full color and Doppler capabilities

- small delivery sheath to enable its use in small children (for vascular use) *

- interventionalist has full control of imaging

- provides adequate depth penetration (8-10 cm)

- comparable if not superior image quality to TEE



It is inserted into the heart under fluoroscopic guidance.

Intracardiac Echocardiography (ICE) During Interventional & Electrophysiological Cardiac Catheterization - PMC (nih.gov)

Conclusions/action items:

Our device could potentially attach to the delivery sheath* to secure the catheter in place. Talk with client and team about this possibility.

2024/9/11 - Mitra Clip Guide Procedure

NOAH HAMRIN - Sep 11, 2024, 3:16 PM CDT

Title: Mitra Clip Guide Procedure

Date: 9/11/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Learn about the application of the MitraClip Guide, which is a similar product to the one we are to design

Content:

The MitraClip guide is part of the MitraClip system and allows for the delivery of the MitraClip itself into the left atrium. It features a moveable ("steerable") tip that can bend to enter the atrium and is hollow to allow a second probe to insert the clip. It does not, however, appear to anchor or secure anything in place and instead allows for a clean path for the MitraClip to easily travel through the vein.

Chapter-26-Step-by-step-MitraClip-FNL-March-2-2018.pdf (acc.org)

P100009c.pdf (fda.gov)

Conclusions/action items:

Ask client on Friday which aspect from the MitraClip guide he envisioned incorporated into this project.

2024/09/16 - EVOQUE Stabilizer, Base, Plate

NOAH HAMRIN - Sep 16, 2024, 2:17 PM CDT

Title: EVOQUE Stabilizer, Base, Plate

Date: 9/16/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Learn about how EVOQUE solved a similar problem with their stabilizer

Content:

Edwards' EVOQUE Tricuspid Valve Replacement System utilizes a 4-legged stand with each leg height adjustable, allowing for vertical and angular adjustment. Clamped onto this adjustable table is a stabilizer to hold the catheter handle, including a knob to advance and retract the catheter.

Transcatheter Tricuspid Valve Replacement With the Evoque Valve - Cardiac Interventions Today (citoday.com)

Conclusions/action items:

Discuss with team if we should include any of these features in our design.

2024/9/25 - Gooseneck Arm

NOAH HAMRIN - Sep 25, 2024, 1:05 PM CDT

Title: Gooseneck Arm

Date: 9/25/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Explain a design idea incorporating a gooseneck design

Content:

One design idea could be a flexible yet stable articulating arm that clamps onto the ICE handle at one end, and is secured to the operating table at the other end either via suction cup or a clamp. The arm pieces could be modular, and snap together to elongate or shorten the arm as needed, if they were to be made of plastic. This would also allow them to be taken apart to be more easily sterilized. The option to fabricate them sterile and out of plastic, therefore allowing them to be disposable could be explored. This would eliminate the need to take them apart to be sterilized and would potentially be more profitable as a business.

The inspiration for this design came from my GoPro's articulating gooseneck mount pictured below.

Benefits to this design are the ease of adjustment and positioning.

Potential issues with this design include stability and the ability to withstand forces, holding the ICE handle steadily in place. I see the potential for bumps to the table causing the handle to sway, which would not be ideal for imaging purposes.

Conclusions/action items:

Share this design with the team and discuss.

2024/9/25 - Body Weight Holder

NOAH HAMRIN - Sep 25, 2024, 1:05 PM CDT

Title: Body Weight Holder

Date: 9/25/2024

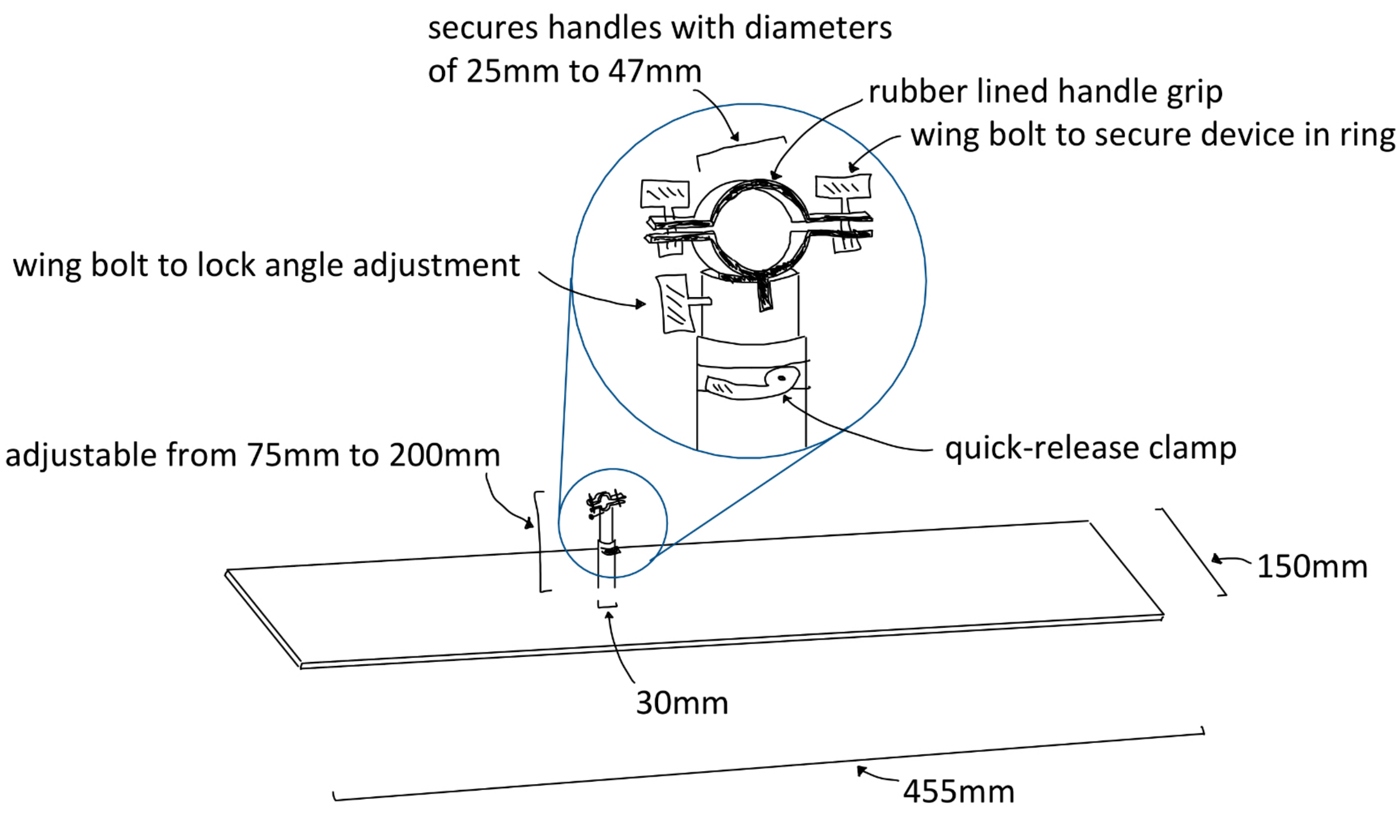
Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Explain a design idea utilizing the patient's legs as securement for the handle

Content:

Another design idea is a flat stainless-steel plate which is positioned in between the patient's legs and the operating table. Off-centered on the plate protrudes a pole, with a smaller pole emerging from the top. A quick-release clamp secures the second pole in place, but allows it to be adjusted to different heights. At the top of the second pole is a pole clamp that clamps onto the ICE handle. This is secured to the top pole using a single horizontal bolt, which is tightened to secure it at a specific adjustable angle. A sketch of this design is included below.



The advantages to this design are that everything sits above the drape, and so the entirety of the device can be treated as sterile. It is also reversable so as to be used next to the other leg. The generic pole clamp that secures the ICE handle could also be used with many other instruments, making it modular.

Potential issues with this design include the design being large and cumbersome to sterilize and move about the cath lab.

Conclusions/action items:

Share this design with the team and discuss.

2024/10/28 - Solidworks Model V1

NOAH HAMRIN - Nov 07, 2024, 6:08 PM CST

Title: Solidworks Model Version 1

Date: 10/28/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Complete an initial solidworks model of our final design

Content:

The three finished solidworks parts and the accompanying assembly file are attached.

Conclusions/action items:

Share with team, 3d print the parts, and adjust the dimensions as needed.

NOAH HAMRIN - Nov 07, 2024, 6:09 PM CST

Download

base_plate_and_pole.SLDPRT (94 kB)

NOAH HAMRIN - Nov 07, 2024, 6:09 PM CST

Download

ICE__Stabilizer.SLDASM (113 kB)

NOAH HAMRIN - Nov 07, 2024, 6:09 PM CST

Download

sliding_pole_and_magnet_top.SLDPRT (93.5 kB)

NOAH HAMRIN - Nov 07, 2024, 6:09 PM CST

Download

top_mount.SLDPRT (149 kB)

2024/11/7 - CNC Training Upgrades

NOAH HAMRIN - Nov 14, 2024, 10:13 AM CST

Title: CNC Taining Upgrades

Date: 11/7/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Complete CNC training at least through Mill II Upgrade

Content:

Membership Type	Start Date	Expiry Date	Renew	Card Info
CNC Mill II	Mon, Nov 4 2024	Permanent	Not Renewable	N/A
CNC Mill I	Tue, Aug 20 2024	Permanent	Not Renewable	N/A
CNC Mill I - Training Eligible	Tue, Aug 20 2024	Wed, Dec 31 3000	Not Renewable	N/A
Access Fee	Mon, May 22 2023	Sun, Dec 31 2023	Not Renewable	N/A
Machining	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Lab Orientation	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Laser Cutter	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Shop Tools	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A

Conclusions/action items:

Determine if CNC III Upgrade is needed and use to fabricate prototype.

Ice Catheter Research

KADEN KAFAR - Nov 15, 2024, 11:45 AM CST

Title: Ice Catheter Resarch

Date: 11/15/2024

Content by: Kaden Kafar

Present: N/A

Goals:
Conduct research on what an Ice Catheter is

Content:

It is a medical device with an ultrasound transducer tip

It is typically inserted in the femoral vein

Provide good quality real time imaging of the heart

It enhances safety and accuracy in cardiology

Conclusions/action items:

Conduct more research on clamping designs.

Clamping Mechanisms

KADEN KAFAR - Nov 15, 2024, 11:48 AM CST

Title: Clamping Mechanisms

Date: 11/15/24

Content by: Kaden Kafar

Present: N/A

Goals:

Conduct research on clamping designs

Content:

Screw Clamps

Use screw to generate clamping force

Difficult in sterile setting

Lever Clamps

uses a lever to generate force

Quick and easy good be good in sterile setting.

Cam Clamps

Could be used but would be tricky

Spring Clamps

Might be difficult in sterile environment

Conclusions/action items:

Conduct more reserach on height adjustment options.

Mitraclip

KADEN KAFAR - Nov 15, 2024, 11:31 AM CST

Title: MitraClip

Date: 11/15/2024

Content by: Kaden Kafar

Present: N/A

Goals:

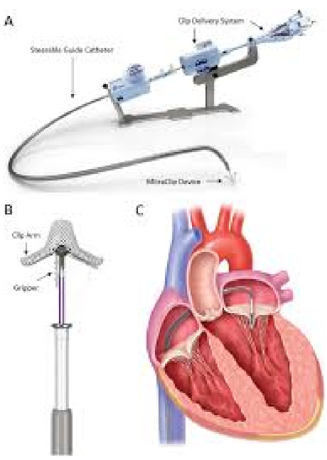
Conduct research on copeting designs

Content:

Has a designed stand for a specifc catheter.

Angle is set with not a lot of variation in height.

Allows good access to all controls of the catheter



r

Conclusions/action items:

Find other competing design ideas.

Evoque

KADEN KAFAR - Nov 15, 2024, 11:37 AM CST

Title: Evoque

Date: 11/15/24

Content by: Kaden Kafar

Present: N/A

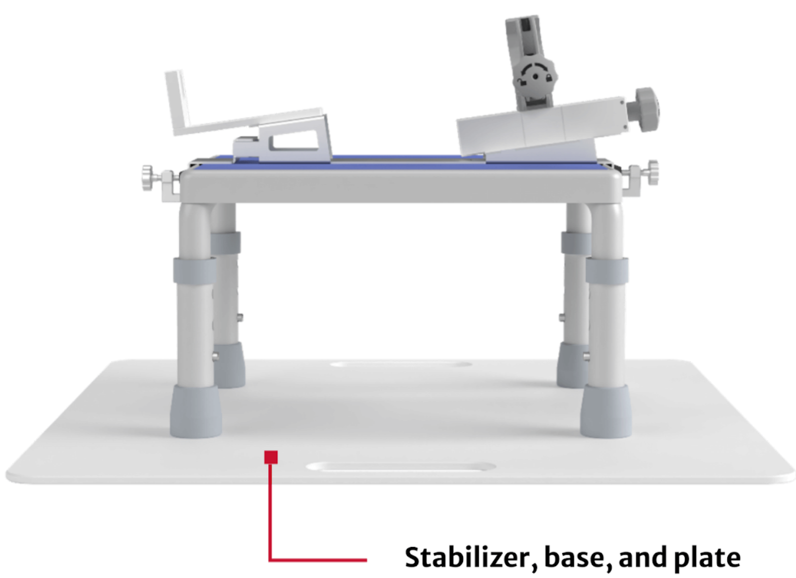
Goals:
Find competing design ideas for the project.

Content:

Large plate that stabilizes around a patients leg.

Height and angle adjustments available.

Also only designed for one specific catheter.



Conclusions/action items:

Find more competing designs

Conduct more background research.

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03 - Template

NOAH HAMRIN - Sep 16, 2024, 2:04 PM CDT

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: