BME Design-Fall 2021 - TATUM RUBALD
Complete Notebook

PDF Version generated by

SERENA RAVAL

on

Dec 15, 2021 @12:43 PM CST

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Team contact Information

Alex PUDZISZ - Oct 19, 2021, 12:58 PM CDT

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
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Dupies	Addie	Communicator			N/A
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Project description

SERENA RAVAL - Oct 18, 2021, 9:41 PM CDT

Course Number: BME 200/300

Project Name: Guidewire organizer for endovascular catheter related surgeries

Short Name: Endo-Cath

Project description/problem statement:

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple guidewires and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

About the client:

Clinical Specialties

Dr. Yamanouchi specializes in vascular and endovascular surgery. He is board certified in angiology and endovascular surgery in Japan.

Dr. Yamanouchi specializes in open and endovascular techniques for the treatment of vascular diseases. His expertise includes treatments for aortic aneurysms, carotid disease, aortic dissection, peripheral arterial disease, and other vascular disorders.

Research Interests

Dr. Yamanouchi’s research interests include the pathogenesis of abdominal aortic aneurysm and restenosis after angioplasty including balloon angioplasty and stent placement. He is also devoted to the development of novel materials for vascular bypass graft and gene delivery method to treat the patients who suffer peripheral arterial disease. In addition, Dr. Yamanouchi serves as principal investigator on a number of clinical trials.

9/17 - Client Meeting 1

TATUM RUBALD - Sep 17, 2021, 4:58 PM CDT

Title: Initial Client Meeting

Date: 9/17/2021

Content by: Tatum Rubald

Present: Soniya, Addison, Serena, Alex, Tatum

Goals: We will discuss the project with our client Dr. Yamanouchi. I have prepared questions. Below is the proposed project presented to us.

PROJECT OBJECTIVE

Develop novel endovascular devices for endovascular procedures

PROJECT DESCRIPTION

There are two device ideas reserved for BME design project.

1. Vascular Access Sheath with retractable stopper to avoid accidental access site bleeding

2. Wire and Catheter holder with easy handling, storing, and organizing during complexed procedure

The base device concepts are already available and ready for this project.

Questions for Dr. Y;

1. Are we supposed to choose one device idea of the two listed?
2. What are specific accomplishments you want from this device? Any current ideas you would like us to work off of?
3. What does your device currently lack? What complications have you encountered?
4. What is the French size of the access sheath you use?
    1. What type of endovascular procedures are you wanting to preform with this device?
5. What are your procedure steps?
6. What is your access site
7. Is your stent Nitonol

Content:

1. Typically it is a blocked artiery
    1. use a balloon catheter to get the block open
    2. insert metal stent
        1. keeps the artery open
2. multiple wires are used
    1. each wire is unique -- frequently exchange wires
3. We are going to work on project 2

        1. 2 cm diameter of the hollow section
        2. 30 cm diameter of the entire wheel
        3. idea: hollow circle wheel where the wire can be inserted
            1. magnet in the middle
            2. hydrophobic surface
        4. bucket similar to a CD holder
            1. tip of the wire outside bucket
            2. water in bucket
    4. Expectations
        1. GOAL: PROTOTYPING AND PROOF OF CONCEPT
            1. mechanical side of the project -- no worries on the material yet
                1. steel will be the end goal
    5. prototype
        1. .035" wire
        2. .018" wire
        3. .014" wire
    6. then go down to proof of concept
        1. 3D printing does not have to
    7. vision: 3-4 prototypes
        1. final design
        2. use working prototype with wire
        3. larger scale prototype? because the actual may be very thing
            1. next step would be pursuing the real product
        4. Make Dr. Y aware of the final design before we actually chose it -- he wants to be involved

Contraints

1. lightweight plastic
2. Budget: $ none
3. Biocompatible - use the same plastic of the catheter
    1. serializable
4. No current ideas on the market

Conclusions/action items:

We will set up a team meeting and go over preliminary design ideas.

9/18/2021 - Client Interview

SERENA RAVAL - Oct 18, 2021, 9:37 PM CDT

Title: Client Introduction

Date: 09/17/2021

Content by: Serena Raval

Present: Dr. Yamanouchi

Goals: (1) Better understand what project Dr. Y is asking the team to work on.

(2) Create a team - client relationship.

(3) Ask Dr. Y initial questions about project background and future work.

(4) Pick up catheters and guidewires from Dr. Y at WIMR

Content:

1. Dr. Dai Yamanouchi - Vascular Surgeon at UW-Hospital
2. Catheter based procedures = needle into artery
3. Endovascular Procedure Background:
    1. Wire through needle to reach artery and then target vessel.
    2. Typically the target vessel is blocked so the wire has to get through the blocked region.
    3. **Catheter will enter blocked region** of the artery, blow up a balloon to open up the region, and then bring a **stent into the region to keep the vessel open**.
4. Blood pressure types to note: **systolic blood pressur**e (measures pressure in arteries when heart beats) and **diastolic blood pressure** (measures pressure in arteries when heart rests- between beats).

Goal of Project: Create a prototype / proof of concept of a wire and catheter holder with easy handling, storing and organizing during complicated procedures.

Resources: 3D printing, provided catheters and wires.

Size constraints: less than an inch depth, circular wheel size of dinner plate, lightweight, plastic that is sterilizable and biocompatible - should function as commercial product. 0.035 in wire, 0.018 in wire, and smallest, 0.014 in wire.

Conclusions/action items:

1. Begin research process on types of products as such that already exist.
2. Look into sterilizable and biocompatible materials that we could create our prototype with that would be testable in a hospital setting.
3. Brainstorm ways to follow Dr. Y's pre-existing plans.
4. Think about intellectual property patents and protecting research ideas.

9/24/21: Team Meeting PDS

TATUM RUBALD - Sep 24, 2021, 9:44 AM CDT

Title: Team Meeting PDS

Date: 9/24/21

Content by: Tatum Rubald

Present: Addison, Scottie, Soniya

Goals: We will finalize the PDS

Content:

We finalized the PDS. We sorted the sources and made sure language was consistent throughout the document.

Conclusions/action items:

We will upload the PDS to the website and email it to our client.

10/01/21: Team Meeting Preliminary Presentation Overview

SONIYA PATEL - Oct 19, 2021, 11:30 PM CDT

Title: Team Meeting 3

Date: 10/1/21

Content by: Soniya Patel

Present: all

Goals: brief meeting to discuss oral preliminary presentation goals and assign roles for powerpoint

Content:

- assigned sections of the presentation to complete by thursday
    - soniya - competing designs and PDS
    - tatum- problem statement,
    - serena- future work
    - alex- desgin matrix
    - scottie- design ideas
    - addie - background

Conclusions/action items:

Have your assigned section of presentation completed by Thursday. Make sure to include speaker notes in presentation. Once everyone completes their section, our team can meet and edit it and practice presenting

10/08/2021: Team Meeting Prelim Presentation

TATUM RUBALD - Oct 08, 2021, 1:32 PM CDT

Title: Team Meeting

Date: 10/08

Content by: Tatum Rubald

Present: Full Team

Goals:

1. Make sure everyone is on the same page about how we use our device
2. Have everyone look at new design
3. Go over slides
    1. Ensure everyone is taking about the crate where need-be

Content:

1. The guidewire is simultaneously pulled from its pre-packaged plastic casing and inserted into the patient
2. Once the guidewire is done being used inside the body, it is removed from the patient

It is my understanding that you are asking for a device to hold guidewires after steps 1 and 2 are completed, meaning that the guidewire is no longer in its plastic casing.

The device we are creating hold guidewires and organize them after being in the body, in the case that they must be used again. However, at this point, they are used without the plastic casing.

Conclusions/action items:

Everyone will come to Mondays meeting fully prepared for the preliminary presentation.

10/11/2021: Team Meeting Preliminary Presentation Review

ADDISON DUPIES - Oct 19, 2021, 3:16 PM CDT

Title: Team Meeting Preliminary Presentation Review

Date: 10/11/2021

Content by: Addison Dupies

Present: Addison, Tatum, Serena, Scottie, and Alex

Goals: Go over the presentation to ensure a smooth flow and make any edits if necessary

Content:

1. Make sure you address the person who just passed the presentation to you and then the person that is going after you in the presentation
2. Addie - make sure that you use the dispensing tubing in the presentation to show the current situation in an endovascular procedure
3. Scottie is giving a virtual presentation - needs to get video linked into the presentation but his slides are good
4. Soniya - text her to make sure she finishes slides and updates them to have less wording on the slides
5. Alex - add part with the new guidewire hoop that was just added to the design matrix
6. Tatum - Finish client slide

Conclusion/Action Items: Have good presentation and practice a lot before Friday!

10/18/2021: Team Meeting Preliminary Report

SERENA RAVAL - Oct 18, 2021, 9:35 PM CDT

Title: Team Meeting

Date: 10/18/2021

Content by: Serena Raval

Present: Full Team

Goals:

1. Make sure everyone is on the same page about how we use our device
2. Have everyone re-look at new design
3. Divide and discuss parts of Preliminary Report

Content:

See uploaded final Preliminary Report (due Wednesday October 20).

Conclusions/action items:

Everyone will come to tomorrow's meeting fully prepared to share individual portions of the Preliminary Report and will leave comments on other team members portions.

10/29/2021: Team Meeting Show and Tell

SERENA RAVAL - Nov 01, 2021, 8:18 PM CDT

Title: Team Meeting PDS

Date: 10/29/2021

Content by: Serena Raval

Present: Team

Goals: Understand the goal and requirements of show and tell.

Content:

- guidelines on BME website

- will find room number/ framework with show and tell

- look for more info posted during the week

- look at resources/show and tell section to get needed info

- put together pitch that describes project and plans for project and get peer/advisor feedback

- split groups - 3 listeners and 3 presenters at a time

- one minute presentations

- get feedback after

- not graded

- prototype optional

Conclusions/action items:

Meet with team on Monday at 8pm to go over show and tell plan for Friday.

11/01/2021: Team Meeting Show and Tell

SERENA RAVAL - Nov 01, 2021, 8:26 PM CDT

BME Design Courses
Instructions for the Show and Tell

This is a required event in the BME Design courses - report to your assigned classroom based on your advisor: http://bmedesign.engr.wisc.edu/course/advisors/

This event is confidential.

Objectives

You have all had the chance to see some of the design projects at the preliminary presentations. This is a chance for you to show your fellow classmates what you have accomplished since and use the collective knowledge of BME Design to obtain feedback on the first iterations of your prototype/design from a broader group. How does your design meet the need, how does it operate, are you using the appropriate tools, how can you test it to meet the constraints, etc.? This is also a chance to gain experience in evaluating the designs of others and providing constructive feedback from an outside perspective.

Requirements

This is a speed-dating style event (see logistics below) in which you will give a **one-minute** elevator pitch to your peers and then have four minutes to gather feedback.

- No formal slides or presentation
- Bring ONLY your current prototype and/or a representation of your final design
- Prepare a 60 second elevator pitch that every team member knows (see suggested guidelines below)
- Have a clear “call to action” for obtaining feedback and advice from your peers.

One minute ‘elevator’ pitch

You’ll have 60 seconds for your elevator pitch. These 60 seconds sound like a lot of time but once you start, the clock ticks faster. Plan your pitch, hit your key points, and practice!

Pitches consist of these main elements

- Call to action - start here to catch your audience’s attention.
    - What are you looking for or need help on?
    - What do you want to get out of this event and how can your peers help you?
    - This can evolve as the session progresses and you gather more feedback. Be prepared to adjust based on your audience and the solutions you receive from your peers.
- Demonstrate using your physical prototype/representation to illustrate your need
- Other elements that might be needed to provide context to your call to action:
    - What’s the Problem? (this should be extremely brief)
    - What’s your solution / major benefit?
    - What progress have you made? / What are your upcoming milestones?

‘Call to action’ ideas

- How do you use a specific tool needed for the design?
- How will you manufacture the device/solution?
- How will you test it to ensure it meets the PDS? Or specific PDS criteria?
- How will a user interact with the design?
- How are you going to commercialize (market, sell, etc.) it?

- What's the market opportunity?
- What makes this unique or defensible? Can I copy it? Does it stand out? Is it interesting in some way?

Resources and Examples

https://blog.toggl.com/elevator-pitch-examples/
https://www.thebalancesmb.com/writing-effective-elevator-pitch-2951691

Logistics

Each team will split into two groups and self-designate each as group A and group B. For BME 300/200, we recommend at least one BME 300 student in each group.

12:05 pm ~ 1:05 pm - For the first half of the Show and Tell

- Group A members will stay at a table by their prototype/project representation
- Group B members will rotate in a round-robin / speed dating style through all of the projects
- Rotations will happen every **5 minutes** as timed and organized by the moderator
- During each 5 minute block:
    - Group A will give their 1 minute elevator pitch
    - Group B will ask questions and help answer Group A's questions

~1:05 pm ~ 2:05 pm - The roles are reversed, group B stays to pitch their project and group A rotates

Any remaining time at the end of the session may be used to follow-up with teams or individuals as needed and/or discuss the results from the event with your team and **document it in the design notebook.**

- Call to action - start here to catch your audience's attention.
    - What are you looking for or need help on?
    - What do you want to get out of this event and how can your peers help you?
    - This can evolve as the session progresses and you gather more feedback. Be prepared to adjust based on your audience and the solutions you receive from your peers.
- Demonstrate using your physical prototype/representation to illustrate your need
- Other elements that might be needed to provide context to your call to action:
    - What's the Problem? (this should be extremely brief)
    - What's your solution / major benefit?
    - What progress have you made? / What are your upcoming milestones?

1 (Serena / Alex): In procedures requiring catheters and guidewires, there is an issue with the organization and transportation. We were tasked with creating a prototype of a guidewire organizer that will allow for easier access in a surgical setting.

Our solution is that we have created a magnetic ring that allows for easy storage and access of the wire. The major benefit of our design is the lowered time to store the wire and the holder's ability to be stacked in order to create an efficient and clean storage area.

2 (Tatum/Soniya): The internal concave lip of the wheel utilizes the radial force of the guidewire when coiled to contain the guidewire within the wheel. The internal concavity is magnetized to ensure that the guidewire will remain in contact with the wheel against the lip holding the wire stationary

There is a lack of guidewire organizers on the market right now. In fact, there are actually none that satisfy the requirements given to us by our client. Since there is such a lack of this type of organizer on the market, there may be a huge audience for our product.

3 (Addie/Scottie): Our team has begun the development of our preliminary prototype. We have had a consultation with the makerspace to begin 3D printing the guidewire hoop. We plan to test the preliminary guidewire hoop and evaluate its efficiency. We will amend the prototype as needed, and then 3D print the crate to evaluate the final prototype.

Any questions or suggestions for final design materials beyond the prototyping phase?

11/08/2021: Team Meeting Prototyping

TATUM RUBALD - Dec 14, 2021, 1:11 PM CST

Title: Team Meeting Prototyping

Date: 11/08/2021

Content by: Tatum Rubald

Present: Full team

Goals:

We will get protoyping completed

Content:

- Soniya will print our wheel with 30cm OD and 28 cm ID
    - She will do this within the next few days
- We will see if this protoype works
- We will not print the crate until right after final design is tested
- We will make necessary changes to the design once printed

Conclusions/action items:

Soniya will print the design, and we will meet as a team next week to see if it works.

11/15/2021: Team Meeting Preliminary Prototype Testing

ADDISON DUPIES - Dec 14, 2021, 2:33 PM CST

Title: Team Meeting Preliminary Prototype Testing

Date: 11/15/2021

Content by: Addison Dupies

Present: Full team

Goals:

Evaluate preliminary prototype.

Content:

- First preliminary prototype has too large of a diameter.
  - Cannot secure the soft or the stiff wire
  - Need to bring down the diameter and the width of the hoop as well
  - Make the hoop thinner so it is easier to hold and grab the wire from the wheel.
- We need to shrink the size of the hoop before testing
- Get prototype file to Makerspace before Thanksgiving break, so that we are able to test the week after.
- Final Dimensions: Outer Diameter 21 cm. Inner Diameter 20 cm.
- Have Alex write up a testing protocol for the prototype.
- Scottie - send SolidWorks file to Soniya.
- Soniya - going to print this week.

Conclusions/action items:

Once amended design is printed, we will test with the protocol Alex writes up for us.

11/22/2021 Team Meeting Testing

Scottie Waterfield - Dec 14, 2021, 6:33 PM CST

Title: Team Meeting Updated Prototype Testing

Date: 11/22/2021

Content by: Scott Waterfield

Present: Full team

Goals:

Evaluate newly innovated preliminary prototype.

Content:

- Newly printed design based off of innovations from previous design
  - Smaller diameters
    - Inner diameter 20cm, outer diameter 22cm, and width of 2cm.
  - Addition of magnetic tape inside of the concavity
    - Further improves the security of the guidewire in the organizer.
- Testing procedure
  - Loading/unloading both the hard and soft guidewires from their usual plastic casing, timing each trial.
  - Loading/unloading both the hard and soft guidewires into the newly printed prototype, timing each trial.
  - Travelling with the loaded prototype to test security and movement
  - Performed as a group with multiple trials per person conducted
- Testing Results

Final Device			**Original Casing**		
Type Of Wire: Test #	**Loading Duration**	**Unloading Duration**	**Type Of Wire: Test #**	**Loading Duration**	**Unloading Duration**
Soft Wire: Test 1	27.26	1.21	Soft Wire: Test 1	25.96	8.44
Soft Wire: Test 2	37.4	0.73	Soft Wire: Test 2	22.32	8.41
Soft Wire: Test 3	26.4	1.26	Soft Wire: Test 3	22.73	9.13
Soft Wire: Test 4	23.12	0.8	Soft Wire: Test 4	25.7	9.54
Soft Wire: Test 5	17.29	0.93	Soft Wire: Test 5	23.43	9.53
Soft Wire: Test 6	21.43	0.78	Soft Wire: Test 6	20.68	10.16
Soft Wire: Test 7	25.62	1.11	Soft Wire: Test 7	21.85	9.11
Soft Wire: Test 8	23.63	1.19	Soft Wire: Test 8	22.71	7.53
Soft Wire: Test 9	19.92	1.04	Soft Wire: Test 9	22.96	5.69

Hard Wire: Test 1	28.37	0.35	Hard Wire: Test 1	24.45	7.78
Hard Wire: Test 2	13.95	1.15	Hard Wire: Test 2	19.7	7.79
Hard Wire: Test 3	25.56	1.35	Hard Wire: Test 3	18.49	11.03
Hard Wire: Test 4	13.47	0.98	Hard Wire: Test 4	20.01	10.39
Hard Wire: Test 5	18.19	1.23	Hard Wire: Test 5	19.45	10.6
Hard Wire: Test 6	15.94	1.24	Hard Wire: Test 6	19.23	7.93
Hard Wire: Test 7	14.43	1.74	Hard Wire: Test 7	24.1	11.51
Hard Wire: Test 8	13.51	1.53	Hard Wire: Test 8	21.48	9.52
Hard Wire: Test 9	14.83	0.68	Hard Wire: Test 9	21.75	9.21

Test 2: Walking and Stairs Test

Walking Test Trial #	**Entanglement at Start?**	**Entanglement At End?**	**Stairs Test Trial #**	**Entanglement at Start?**	**Entanglement At End?**
1	No	No	1	No	No
2	No	No	2	No	No
3	No	No	3	No	No
4	No	No	4	No	No

5	No	No	5	No	No

Conclusions/action items:

With new prototype design and completion of testing, the analysis of results is up next to be completed. The initial testing was very efficient and the newly printed design showed great success in its performance of guidewire organization and containment. Additionally the next steps to finalizing our project is to complete final deliverables and present out prototype and testing results/analysis.

11/29/2021 Team Meeting Final Presentation Poster

Alex PUDZISZ - Dec 14, 2021, 4:12 PM CST

Title: Team Meeting Final Presentation Poster

Date: 11/29/2021

Content by: Alex Pudzisz

Present: Full Team

Goals: Assign Sections for Final Presentation Poster

Content:

- Met with the entire team in order to decide who would be in charge of each section and it was divided as follows:
  - Abstract and Problem Definition: Serena
  - Design criteria: Soniya
  - Final Design Progress: Alex
  - Results: Tatum
  - Discussion: Scottie
  - Future Work: Addie

We have decided to hold off assigning sections of the verbal portion of this until the written version is done to ensure that there are evenly timed sections. This section should be done in bullet points to follow the 6 bullet points at 6 words each rule.

Conclusions/action items:

Aim to have sections completed by the Tuesday before presentation time to allow adequate time to print.

12/07/2021 Team Meeting Final Deliverables and Presentation Practice

Alex PUDZISZ - Dec 14, 2021, 4:21 PM CST

Title: Team Meeting Final Deliverables and Presentation Practice

Date: 12/07/2021

Content by: Alex Pudzisz

Present: Full Team

Goals: Practice the presentation, and assign parts for the final report

Content:

This meeting we started by ensuring that each team member was comfortable with what they had to say in the presentation. This included possible questions and gestures to things during the presentation later that week. Once everyone was good with the presentation, we proceeded onto assigning parts for the final report. The sections are as follows:

- Testing: Alex
- Statistical Analysis: Tatum
- Implications: Serena
- Sources of error: Soniya
- Summary of Design: Scottie

This is in addition to the fact that everyone should read over their old sections to ensure that it is ok. We also have to update things from the old report that need to be fixed such as impact.

Conclusions/action items:

Finish final report sections before December 14th

12/13/2021 Team Meeting Completing Final Deliverables

SERENA RAVAL - Dec 14, 2021, 4:31 PM CST

Title: Team Meeting Completing Final Deliverables

Date: 12/13/2021

Content by: Serena Raval

Present: all

Goals: Discuss all final deliverables with team and assign roles.

Content:

Finish Final Report

Finish Team Notebook

Conclusions/action items:

Turn in Final Deliverables on Wedensday 12/15/2021

9/17 - Advisor Meeting 1

TATUM RUBALD - Sep 17, 2021, 1:57 PM CDT

Title: Initial Advisor Meeting

Date: 9/17/2021

Content by: Tatum Rubald

Present: Full Team

Goals: We will discuss goals, the course outline, and Dr. Ludwigs expectations from us.

Content:

- Class basics:
  - Schedule found on BME design website
  - Oral presentation -- look at grading rubric and make sure we have everything on there
  - Make sure we do everything early and stay ahead

Conclusions/action items:

We will start to discuss the PDS and get our project started. Also, we have our client meeting today at 4pm.

9/24 - Advisor Meeting 2

TATUM RUBALD - Sep 24, 2021, 2:01 PM CDT

Title: Advisor Meeting 2

Date: 9/24

Content by: Tatum Rubald

Present: Addie, Alex, Soniya, Scottie

Goals: Look at the PDS and go over due dates.

Content:

- Feedback on PDS next week.
  - Good shape with quantitive data
- Next week we have design matrix due
  - we will present these at the preliminary presentation
  - part of notebook and report due in 2 weeks
- Mid semester and final
  - same rubric
  - End semester is weighted more heavily
- Just write AT LEAST SOMETHING for each category in the lab notebook
- We will be doing a lot of testing and stats
- On team grading write the names in order they show up on their website
- Have different doctors test the device

Conclusions/action items:

We will start going through the design matrix.

10/1 - Advisor Meeting 3

TATUM RUBALD - Oct 01, 2021, 1:46 PM CDT

Title: Advisor Team Meeting 3

Date: 10/1

Content by: Tatum Rubald

Present: Alex, Addie, Soniya, Scottie, Tatum

Goals:

Go over design matrix and discuss future work for our project.

Content:

- Email from client about the selected design - outter rim?
- PDS performance requirements
    - design matrix should have a performance expectation
        - how to do an experiment and quantitate it
            - putting guidewire into wheel, carry it to the OR, unroll all guidewires
                - make sure nothing gets tangled
            - how long it takes to spool the wire
        - how will we do statistics?
            - confidence intervals
        - Does it get tangled when we walk?
- oral presentations
    - presentation in person
    - upload slides
        - can send Dr. Ludwig early for feedback
- Progress reports due Thursday at 5.
- Delivery items: due Friday at 5.

Conclusions/action items:

Download design matrix to website.

11/12: Advisor Meeting 4

TATUM RUBALD - Nov 12, 2021, 1:51 PM CST

Title: Advisor Meeting 4

Date: 11/12

Content by: Tatum Rubald

Present: Tatum, Addie, Alex

Goals: Discuss grades

Content:

- must have bullet points for EVERYTHING in lab notebook for final
    - look at rubric
    - must be individual
- PEER EVALS: MUST PUT EVERYONE IN ORDER AS LISTED ON BME WEBSITE
    - All points must add up to 6000
        - do this otherwise you will make Ludwig mad :(
    - hand in word document, rather than PDF
- Nothing due until poster presentation
    - have a month to do 75% of our grade
    - have experiments in early
- qualitative data
    - 1 min walk:
        - 1 - untangled
        - 0 - tangled
- quantative data
    - how long to wind
    - how long to unwind

Conclusions/action items:

We will start testing soon

Progress Report 1

SERENA RAVAL - Oct 18, 2021, 11:33 AM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: 10 September 2021 to 16 September 2021

Problem Statement

We will engineer an endovascular device for various endovascular procedures. Two potential projects include: creating a vascular access sheath with a retractable stopper intended to avoid accidental access site bleeding, and a holder for both wire and catheter to enhance handling of the system during procedures.

Brief Status Update

The team has organized a time to meet with Dr. Yamanouchi. We will start to brainstorm ideas after we meet with the client Friday afternoon.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Meeting set with Dr. Y for Friday, September 17th at 4 pm.
- Tatum Rubald
  - Organized team roles
  - Created team GroupMe for communication among team members
  - Set up team notebook in Lab archives
- Addison Dupies
  - Emailed client (Dr. Y) to set up a team touch base to learn more about the project. Set up a zoom meeting for the team to meet with Dr. Y. Brainstormed questions for Dr. Y for the meeting on Friday.
- Alex Pudzisz
  - Signed up to mentor for BSAC
- Scottie Waterfield
  - Completed mentorship sign up form
- Serena Raval
  - Updated website with newly assigned team roles.
- Soniya Patel
  - Signed up for the role of BPAG
  - Responsible for keeping track of purchased materials

Weekly/Ongoing Difficulties

None at this time.

Upcoming Team and Individual Goals

- Team:
  - Meet with Dr. Y and get an idea of what he is looking for from us as a team
- Tatum Rubald
  - Brainstorm ideas for the project

- Addison Dupies
    - Brainstorm and research prototype ideas for the project and decide on a time for the team to meet weekly outside of class.
- Alex Pudzisz
    - Meet with Dr. Y in order to understand what the project is about in detail
    - Research components of devices with properties similar
    - Brainstorm and draw ideas
- Scottie Waterfield
    - Meet with Dr. Ludwig this Friday at 11:00-11:50 am to discuss project progression and requirements needed to complete the project day by day. After discussing, report back to the team what is expected and needed from all of us.
- Serena Raval
    - Brainstorm ideas to begin the research process. Take notes on meeting with Dr. Y to get a better understanding of the goal of the project.
- Soniya Patel
    - Create an excel spreadsheet to keep track of project purchases
    - Initiate preliminary research and begin brainstorming ideas after meeting with Dr.Y and Dr. Ludwig

Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	N/A	All		
Preliminary Deliverables	N/A	All		
Show and Tell	N/A	All		
Poster Presentations	N/A	All		
Final Deliverables	N/A	All		

Expenses - Not applicable at this time

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 2

SERENA RAVAL - Oct 18, 2021, 11:37 AM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: 17 September 2021 to 23 September 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

The team discussed with Dr. Y last week the ideas for the project and any further information that was not disclosed within the project description. From there the team finished the Preliminary Design Specifications (PDS) for the product. The team is meeting Friday (9/24) to discuss the research they have done and to starting developing ideas for the prototype.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Met on zoom to discuss the PDS and establish sections to be completed.
- Tatum Rubald
  - Met on zoom with Dr. Y to understand his goals for our project
  - Completed the PDS and assisted team members
  - Developed an understanding of the design/product
- Addison Dupies
  - Communicated with Dr. Y a time for a team member to pick up guide wires that will assist with our project. Sent out meeting notes from our client to the team. Worked on assigned sections of the PDS.
- Alex Pudzisz
  - Worked on assigned sections of PDS. Researched regulations of guidance wire devices.
- Scottie Waterfield
  - Completed assigned sections of the PDS document in addition to the research of catheter related surgeries and how guidance wires can cause dilemmas in operating rooms.
- Serena Raval
  - Filled in assigned sections of the progress report.
  - Picked up the guidewires from Dr. Y to utilize in the fabrication process.
  - Completed assigned portions of the PDS.
- Soniya Patel
  - Worked on specific sections of the PDS document. Continued to research the functionality of guidewires during endovascular procedures as well as any competing designs for the guidewire organizer

Weekly/Ongoing Difficulties

None at this time.

Upcoming Team and Individual Goals

- Team:
  - Meet as a team to discuss research and ideas for the initial prototype.
- Tatum Rubald
  - Meet as a team in person to view the guidewires Dr. Y gave to us
  - Create a rough draft of the wheels and crate on solidworks
- Addison Dupies
  - Research competing designs and patents of other ideas that fall in the realm of our project.
- Alex Pudzisz
  - Research competing designs on the market. Clarify what kind of regulations the product must follow from the FDA. Work on researching types of plastics to print with and the minimum wall thickness for them.
- Scottie Waterfield
  - Gain a better understanding of what is necessary for our device to function in an actual operating room and begin to focus that knowledge into conceptualizing the prototype of the device.
- Serena Raval
  - Continue researching mechanism similar to our potential device
  - Update Website with new project information
- Soniya Patel
  - Begin thinking about more specific costs for this project as well as create a document to organize any purchases we may need to make.

Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/8/2021	All		
Preliminary Deliverables	10/13/2021	All		
Show and Tell	11/5/2021	All		
Poster Presentations	12/3/2021	All		
Final Deliverables	12/15/2021	All		

Expenses - Not applicable at this time

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 3

SERENA RAVAL - Oct 18, 2021, 11:38 AM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: 23 September 2021 to 30 September 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

This week we completed our design matrix, and were able to finalize a design for our prototype. The design matrix is attached at the end of this document.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Design matrix completion
- Tatum Rubald
  - Created a design for team called “Magnetic Wheel”
  - Met with the team and went over the design matrix
- Addison Dupies
  - Met with the team to create the design matrix. Created a potential design idea for the design matrix meeting.
- Alex Pudzisz
  - -Met with team to create design matrix. Created a design to be evaluated.
- Scottie Waterfield
  - - Did additional research on catheter/guidewire insertion and the specifics of mechanics upon insertion to relate the mechanics of insertion to the design of our product. Additionally worked with the rest of the team to complete the design matrix.
- Serena Raval
  -
- Soniya Patel
  - Created an excel document to keep track of project expenses
  - Started brainstorming ideas/designing guidewire organizer

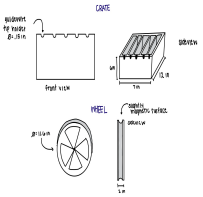
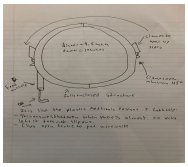
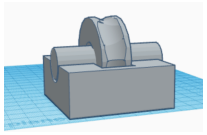
Weekly/Ongoing Difficulties

None at this time.

Upcoming Team and Individual Goals

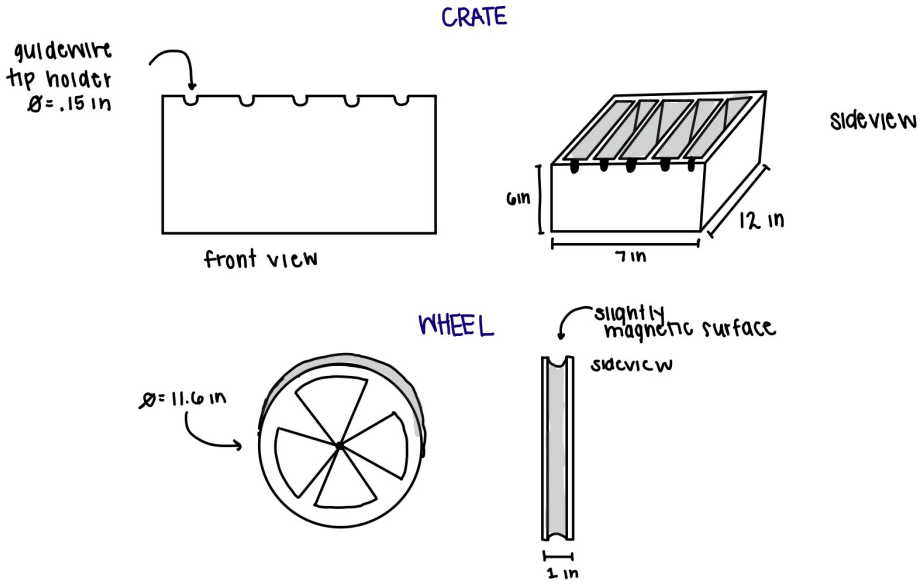
- Team:
  - We will go over oral presentation and assign roles
- Tatum Rubald
  - I will model my design on solidworks
  - I will start on my part of the preliminary presentation
- Addison Dupies
  - Continue researching competing designs and patents. Start working on preliminary presentations
- Alex Pudzisz
  - Research more metal cost and future marking of product. Also research more about problem. Work on preliminary presentation.
- Scottie Waterfield
  - I would like to be able to conceptualize a visualization of how the guidewire would be used in the chosen design from the design matrix to gain a greater understanding of the application of our product in the medical field.
- Serena Raval
  - Continue brainstorming ideas for the endovascular guidewire device.
  - Complete the Future Work slide
- Soniya Patel
  - Continue brainstorming and designing Guidewire Organizer

Endovascular Catheter Design Matrix

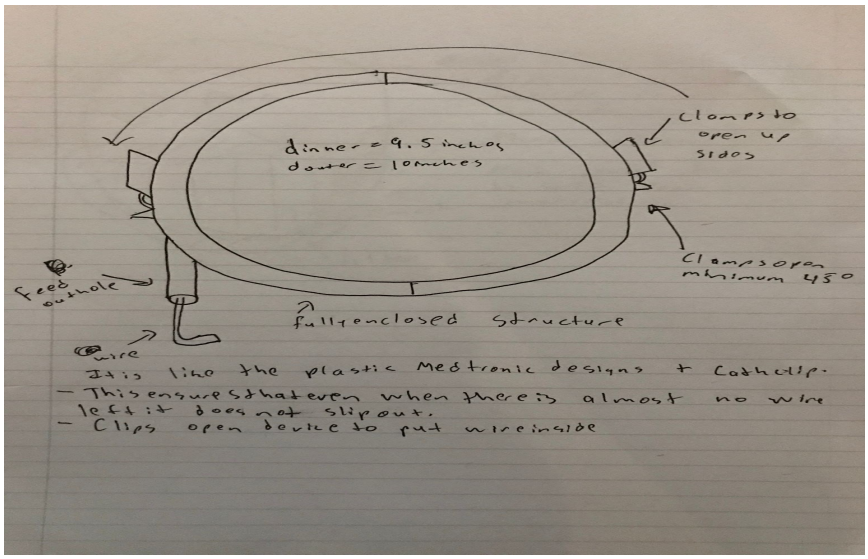
Design	 Magnetic wheel		 Clamped Wheel		 Wheel of Magic	
Feasibility (30%)	5/5	30	3/5	18	5/5	30
Efficiency (25%)	5/5	25	4/5	20	2/5	10
Durability (20%)	2/5	8	3/5	12	3/5	12

Safety (10%)	5/5	10	5/5	10	5/5	10
Learning Curve (10%)	5/5	10	4/5	8	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5
Total for each design:	**86**		**73**		**77**	

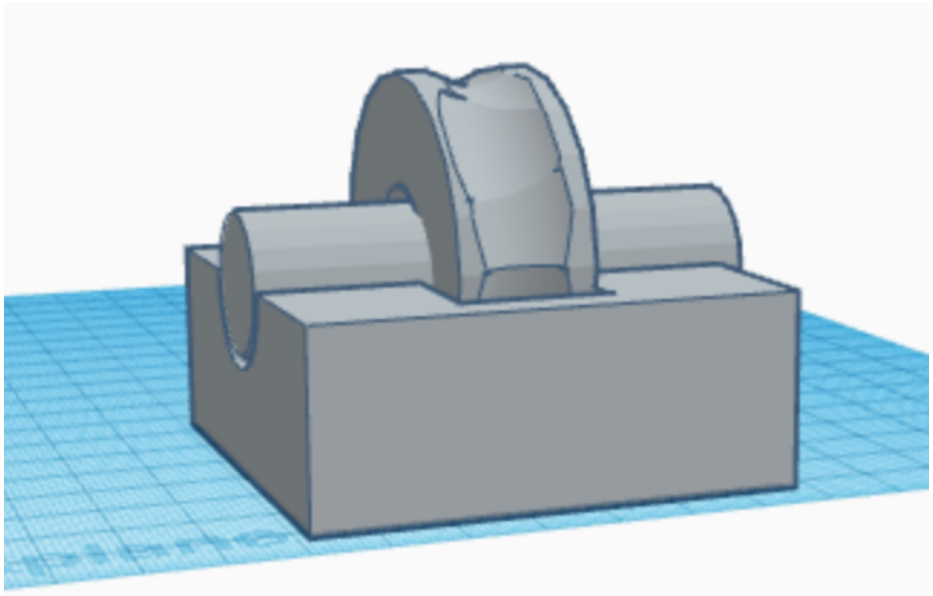
Feasibility: The client would like to have a prototype fabricated by the end of the semester. This criteria takes into account the given current situation with the pandemic, time limit of the semester, the limited tools available from the department of Engineering, and the difficulty of assembling the parts.The client's main goal is proof of concept so with the constraints mentioned above feasibility was weighted the highest at 30%.
Efficiency: The device should be more efficient than the current options that are available; most doctors do the process of organizing manually, and without the aid of any external device. The device should be able to efficiently load and unload the guidewires. This is weighted very heavily due to the fact that efficiency is the purpose of the device/project.
Durability: The criteria was included to assess the ability of the design to withstand stress upon operation. This category was given a weight of 20% due to its durability being important and a key feature for the design to last multiple operations.
Safety: The device must be safe to use on patients in a hospital operating room and should be safe enough to use by a doctor. The safety of the user is important; however, the all three designs have similar safety features, which is why safety is weighted at 10%
Learning Curve: Because a priority of this device is to increase efficiency, learning to use the device must be a quick and simple process. The operator of the device should not have to dedicate a significant amount of time to understand how to properly use the device. This is a relatively low priority due to the fact that the device will work in an intuitive manner. The surgeon should be able to learn and use the device with ease.
Cost: The cost of each design; the client did not give us a set budget, however. The low impact that price has on the overall outcome of this device encouraged the team to give this category the lowest weight.



Design 1: Magnetic Wheel
Design 2: Clamped Wheel



Design 3: Wheel of Magic



Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All		
Preliminary Deliverables	10/20/2021	All		
Show and Tell	11/5/2021	All		
Poster Presentations	12/3/2021	All		
Final Deliverables	12/15/2021	All		

Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 4

SERENA RAVAL - Oct 18, 2021, 11:38 AM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

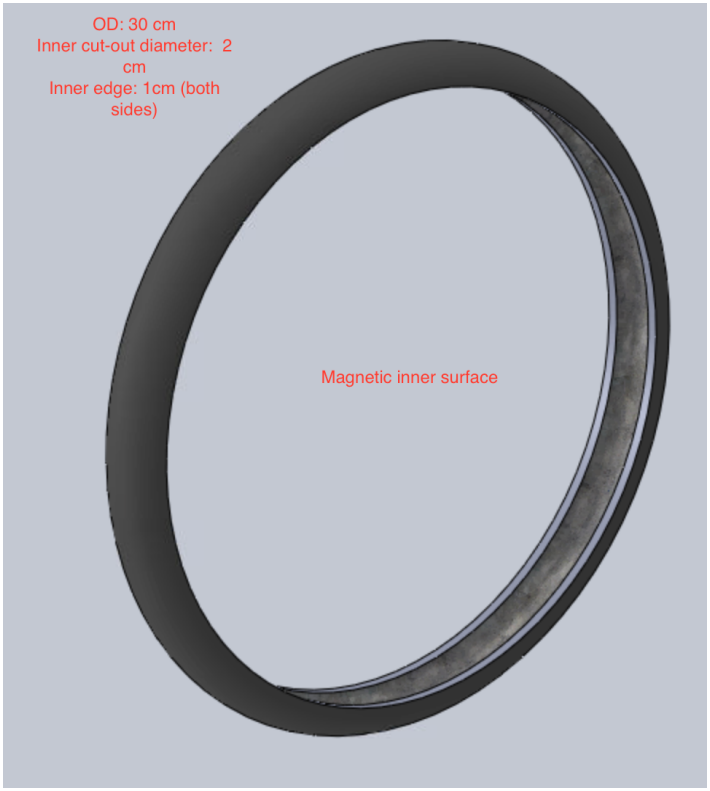
Date: 1 October 2021 to 7 October 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

This week we edited our design matrix to include a new design the client proposed. Additionally, we met to divide up the preliminary presentation. We will begin practice for the presentation this Monday after we meet to ensure we covered all crucial content. We also added an additional design, that is now our chosen final design. See below.



Summary of Weekly Team Member Design Accomplishments

- Team:
  - Met to assign preliminary presentation section and go through each section of the presentation
- Tatum Rubald
  - Met and discussed preliminary presentation
  - Modeled two of our four designs on solidworks
  - Modified and selected our final design
- Addison Dupies
  - Completed slides for preliminary presentation sections - continued research on previous topics
- Alex Pudzisz
  - Worked on preliminary presentation section and followed up on research from last week
- Scottie Waterfield
  - Continued to complete more research on catheter design and its application in operating rooms in addition to constructing my presentation slides.
- Serena Raval
  - Continue brainstorming ideas for the endovascular guidewire device.
  - Complete the Future Work slide
- Soniya Patel
  - Worked on assigned portion of preliminary design presentation

Weekly/Ongoing Difficulties

We were having difficulty finding times that work for all six of us to meet as a team, but this is now solved and Sunday nights will be our weekly mandatory meeting. We also had an issue with our first “final design” because the client did not believe it would hold the guidewire tightly enough. This design was modified and we worked with Dr. Y to figure out the best design option.

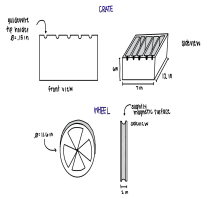
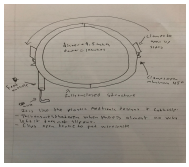
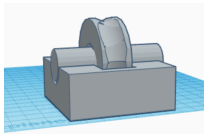
Upcoming Team and Individual Goals

- Team:
  - Practice a smooth and concise presentation for next Friday, October 15th. Also, stay ahead of deadlines and not fall behind.
  - Meet as a team friday afternoon to go over preliminary presentation
- Tatum Rubald
  - Create a solidworks drawing with the final design and all dimensions

    - Contact makerspace about printing our first prototype
    - Research good magnetic strengths for guidewires
- Addison Dupies
    - Practice and prepare for the preliminary presentation. Continue on research of competing designs.
- Alex Pudzisz
    - Practice preliminary presentation. Finish research goals from prior progress reports.
- Scottie Waterfield
    - I would like to be able to present my data/information in my presentation slides by the end of the week and have a firm understanding of the future steps in the process of creating our product. Additionally, the ability to have a plan as to how a physical prototype of the product would be a very large step in the process for our client, so additional insight to that would be ideal.
- Serena Raval
    - Continue brainstorming ideas for the endovascular guidewire device.
    - Complete the Future Work slide and practice presentation.
- Soniya Patel
    - Begin preparing for preliminary design presentation
    - Complete more research entries for lab notebook

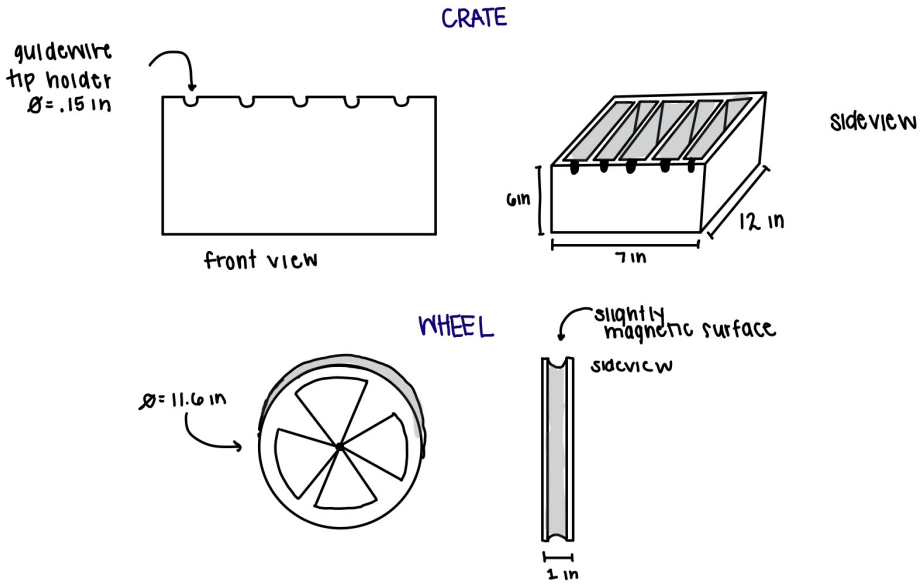
UPDATED

Endovascular Catheter Design Matrix

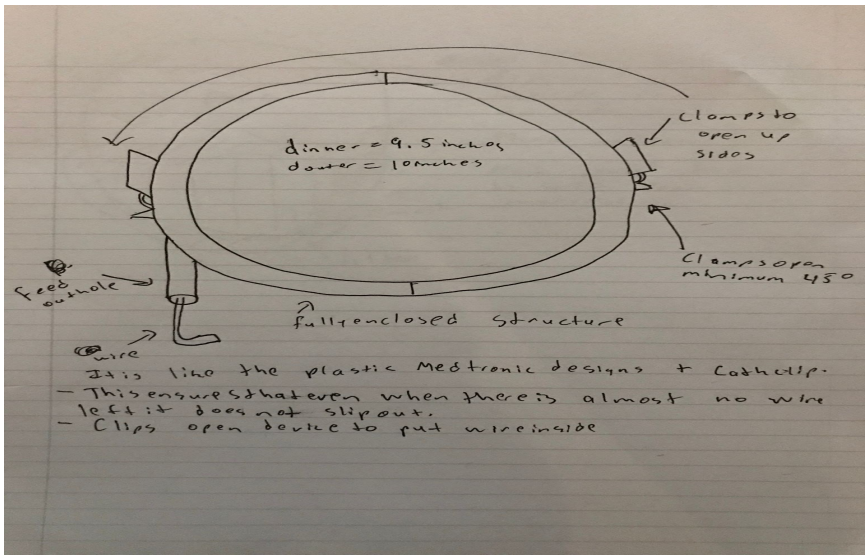
Design	 Magnetic wheel		 Clamped Wheel		 Wheel of Magic			
Feasibility (30%)	5/5	30	3/5	18	5/5	30	5/5	30
Efficiency (25%)	5/5	25	4/5	20	2/5	10	5/5	25
Durability (20%)	2/5	8	3/5	12	3/5	12	3/5	12
Safety (10%)	5/5	10	5/5	10	5/5	10	5/5	10

Learning Curve (10%)	5/5	10	4/5	8	5/5	10	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5	5/5	5
Total for each design:	**86**		**73**		**77**		**92**	

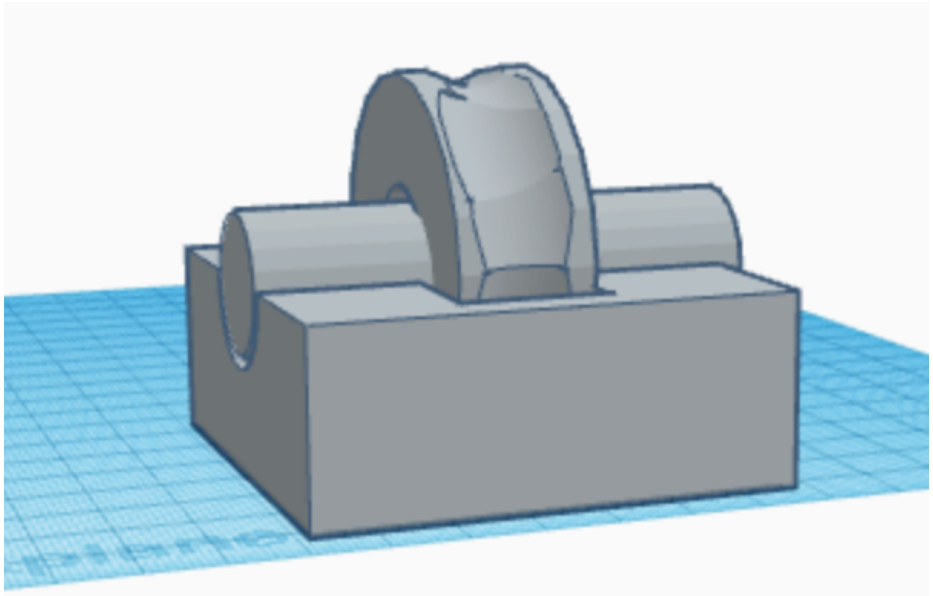
Feasibility: The client would like to have a prototype fabricated by the end of the semester. This criteria takes into account the given current situation with the pandemic, time limit of the semester, the limited tools available from the department of Engineering, and the difficulty of assembling the parts.The client's main goal is proof of concept so with the constraints mentioned above feasibility was weighted the highest at 30%.
Efficiency: The device should be more efficient than the current options that are available; most doctors do the process of organizing manually, and without the aid of any external device. The device should be able to efficiently load and unload the guidewires. This is weighted very heavily due to the fact that efficiency is the purpose of the device/project.
Durability: The criteria was included to assess the ability of the design to withstand stress upon operation. This category was given a weight of 20% due to its durability being important and a key feature for the design to last multiple operations.
Safety: The device must be safe to use on patients in a hospital operating room and should be safe enough to use by a doctor. The safety of the user is important; however, the all three designs have similar safety features, which is why safety is weighted at 10%
Learning Curve: Because a priority of this device is to increase efficiency, learning to use the device must be a quick and simple process. The operator of the device should not have to dedicate a significant amount of time to understand how to properly use the device. This is a relatively low priority due to the fact that the device will work in an intuitive manner. The surgeon should be able to learn and use the device with ease.
Cost: The cost of each design; the client did not give us a set budget, however. The low impact that price has on the overall outcome of this device encouraged the team to give this category the lowest weight.



Design 1: Magnetic Wheel
Design 2: Clamped Wheel



Design 3: Wheel of Magic



Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All		
Preliminary Deliverables	10/20/2021	All		
Show and Tell	11/5/2021	All		
Poster Presentations	12/3/2021	All		
Final Deliverables	12/15/2021	All		

Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 5

SERENA RAVAL - Oct 18, 2021, 11:39 AM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: 8 October 2021 to 14 October 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple guidewires and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

This week we completed our preliminary presentation slides and began to practice and finalize the presentation for this upcoming Friday (10/14).

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Preliminary presentation rehearsal and slide completion. Met on Monday to prepare for the presentation.
- Tatum Rubald
  - Preliminary presentation preparation
  - Modeled design on solidworks
- Addison Dupies
  - Met with the team to practice the preliminary presentation. Practiced on own time to ensure a smooth presentation.
- Alex Pudzisz
  - Worked on the design presentation. Practiced speech in preparation for presentation.
- Scottie Waterfield
  - Completed portion of the presentation due and reviewed design process for our prototype
- Serena Raval
  - Completed my portion of the design presentation.
  - Practiced and timed speaking portion of presentation.
- Soniya Patel
  - Finished editing preliminary presentation and practiced presenting

Weekly/Ongoing Difficulties

None at this time.

Upcoming Team and Individual Goals

- Team:
  - Give a success presentation Friday 10/15
  - Work on printing prototype in the makerspace
- Tatum Rubald
  - Review and update lab notebook
  - Pepare for the presentation Friday
- Addison Dupies
  - Review design notebook and begin working on prototype fabrication.
- Alex Pudzisz
  - Ensure the design notebook has all necessary requirements. Present presentation. Work on prototyping our finalized idea.
- Scottie Waterfield
  - Continue to gain understanding of guidewire application, and potentially brainstorm how the prototype can be innovated for future work.
- Serena Raval
  - Present Presentation on Friday.
  - Begin working on fabrication of prototype.
- Soniya Patel
  - Continue preparing for presentation and finishing gathering all necessary components of lab notebook

Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All	100%	Yes
Preliminary Deliverables	10/20/2021	All		
Show and Tell	11/5/2021	All		
Poster Presentations	12/3/2021	All		
Final Deliverables	12/15/2021	All		

Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 6

SERENA RAVAL - Oct 21, 2021, 7:41 PM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: 14 October 2021 to 21 October 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

This week we had all preliminary deliverables due including the preliminary presentation, preliminary report, and our peer evaluations. We gave our presentation and additionally decided our potential final guidewire design that we will further pursue

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Finished preliminary report
- Tatum Rubald
  - Completed all preliminary deliverables
- Addison Dupies
  - Completed preliminary deliverables and updated notebook.
- Alex Pudzisz
  - -Completed preliminary deliverable sections. Finalized updated notebook. Researched ethical guidelines for engineers.
- Scottie Waterfield
  - - Completed all of my preliminary deliverables for all my assigned sections and additionally did solidworks designs for the crate designs. I also completed more research on the guidewire final design and made new updates to the design with the whole team in agreement .
- Serena Raval
  - Completed assigned preliminary deliverables in report at Monday night team meeting.
  - Finalized notebook research and uploaded team documents.
  - Uploaded the team’s Preliminary Report and Notebook to the website.
- Soniya Patel
  - Completed assigned preliminary design report

- Finalized and submitted lab notebook

Weekly/Ongoing Difficulties

None.

Upcoming Team and Individual Goals

- Team:
  - Begin prototyping
- Tatum Rubald
  - I will finalize the design on solidworks
- Addison Dupies
  - Begin prototyping and testing.
- Alex Pudzisz
  - -Finalize first testing protocol with advisor. Help 3D print the design, and assemble. Research about the forces of the wire inside of the device.
- Scottie Waterfield
  - Start to work on both parts in solidworks for both structures, the wheel and the crate for the final, 3D printed design that will eventually be our prototype for our guidewire organizers. Also research more ways to innovate the design to further improve our design.
- Serena Raval
  - Make final decisions with prototyping and testing.
  - Upload progress report.
- Soniya Patel
  - Work with team to prototype and test designs

Project Timeline

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15	All	100%	Y
Preliminary Deliverables	10/20	All	100%	Y
Show and Tell	11/5	All	N/A	N
Poster Presentations	12/3	All	N/A	N
Final Deliverables	12/15	All	N/A	N

Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 7

SERENA RAVAL - Nov 01, 2021, 8:22 PM CDT

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: 21 October 2021 to 28 October 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

The team is finalizing the final design in order to start prototype fabrication.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - We met with our advisor and began to discuss show and tell.
- Tatum Rubald
  - Conducted research on 3D printing in the makerspace
- Addison Dupies
  - Continued to research competing designs and how the endovascular device market works.
- Alex Pudzisz
  - Continued research on materials
- Scottie Waterfield
  - Start solidworks design for the final product and gather materials for the prototype.
- Serena Raval
  - Submitted Progress Report.
- Soniya Patel
  - Continued research in order to 3D print prototype

Weekly/Ongoing Difficulties

None at this time.

Upcoming Team and Individual Goals

- Team:
    - Set up makerspace consultation to 3D print our final design.
- Tatum Rubald
    - Meet with Dr. Ludwig on Friday, and consider any edit suggestions given on our report
- Addison Dupies
    - Begin prototype fabrication. Set up a time to test the fabricated prototype.
- Alex Pudzisz
    - Work on prototype fabrication. Set up final tests for prototype
- Scottie Waterfield
    - To complete the final prototype design on solidworks and then have it printed for testing in the near future.
- Serena Raval
    - Help with Prototype Fabrication.
    - Update website.
- Soniya Patel
    - Start prototype fabrication and make plans to 3D print finished product

Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All	100%	Y
Preliminary Deliverables	10/20/2021	All	100%	Y
Show and Tell	11/5/2021	All		N
Poster Presentations	12/3/2021	All		N
Final Deliverables	12/15/2021	All		N

Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 8

SERENA RAVAL - Dec 14, 2021, 4:07 PM CST

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: Oct 28 2021 to Nov 4 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

We are working on getting our first prototype printed by the end of next week.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Team meeting on Monday to discuss show and tell
- Tatum Rubald
  - Modified the wheel to have the new (smaller) dimensions of the wheel
- Addison Dupies
  - Worked on presenting for show and tell.
- Alex Pudzisz
  - Worked on show and tell presentation. Price research on medical grade metals.
- Scottie Waterfield
  - Practiced for presentations on show and tell and continued research on materials for final product of guidewire if prototype works well.
- Serena Raval
  - Worked on show and tell minute speech for Friday.
- Soniya Patel
  - Worked on show and tell presentation
  - Started preparing for 3D printing

Weekly/Ongoing Difficulties

None at this time.

Upcoming Team and Individual Goals

- Team:
  - Get the prototype printed
- Tatum Rubald
  - Work with the Makerspace to print the solidworks design
- Addison Dupies
  - Begin to develop testing protocols and an in depth procedure for testing the prototype.
- Alex Pudzisz
  - Work on and finish testing protocols. Test product.
- Scottie Waterfield
  - Complete solidworks design of crate for the prototype and continue to price out materials.
- Serena Raval
  - Upload Progress Report.
- Soniya Patel
  - Figure out funding for 3D printing

Project Timeline - Not applicable at this time

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	N/A	All	100%	Y
Preliminary Deliverables	N/A	All	100%	Y
Show and Tell	N/A	All	99%	N
Poster Presentations	N/A	All	0%	N
Final Deliverables	N/A	All	0%	N

Expenses - Not applicable at this time

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 9

SERENA RAVAL - Dec 14, 2021, 4:09 PM CST

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: Nov 4 2021to Nov 11 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

We are working on getting our first prototype printed by the end of next week.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Presented at show and tell
- Tatum Rubald
  - Sent Soniya .stl file to 3D print design tomorrow (Friday)
- Addison Dupies
  - Presented at BME show and tell
  - Gave feedback to other teams about their projects
- Alex Pudzisz
  - Presented BME show and tell
  - Drew another design idea addition
- Scottie Waterfield
  - Took notes at the show and tell for BME projects and received a lot of feedback as to how we can further improve our design and magnetize our final prototype.
- Serena Raval
  - Presented at show and tell and got input from other BME 2/300 teams.
- Soniya Patel
  - Took part in show and tell presentation

Weekly/Ongoing Difficulties

None.

Upcoming Team and Individual Goals

- Team:
  - Get the prototype printed
- Tatum Rubald

    - Have a team meeting on Monday to view and “play” with the prototype
- Addison Dupies
    - Begin to write testing protocol.
- Alex Pudzisz
    - Construct Wheel
    - Test wheel load and access speed
- Scottie Waterfield
    - To finalize the plan of how to magnetize the wheel for our final product and continue to be in contact with the team about further steps in the project.
- Serena Raval
    - Submit Progress Report and Update Website
- Soniya Patel
    - 3D printing on Friday 11/12

Project Timeline -

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All	100%	Yes
Preliminary Deliverables	10/20/2021	All	100%	Yes
Show and Tell	11/5/2021	All	100%	Yes
Poster Presentations	12/3/2021	All	0%	No
Final Deliverables	12/15/2021	All	0%	No

Expenses -

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 10

SERENA RAVAL - Dec 14, 2021, 4:10 PM CST

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: Nov 12 2021to Nov 18 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

We are working on getting our first prototype printed by the end of next week.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Met to discuss testing
- Tatum Rubald
  - Printed guidewire wheel
- Addison
  - Gathered materials needed for testing - and continued research
- Alex Pudzisz
  - Continued research and thought up more scenarios for testing
- Scottie Waterfield
  - Further updated lab notebooks and kept in contact with the team about testing
- Serena Raval
  - Continued research to prep for team meeting and testing.
- Soniya Patel
  - 3D printed prototype

Weekly/Ongoing Difficulties

None.

Upcoming Team and Individual Goals

- Team:
  - Test as a team
- Tatum Rubald
  - Meet as a team to discuss testing
  - Test the wheel with a guidewire

- Addison Dupies
    - Test prototype
- Alex Pudzisz
    - Test prototype
- Scottie Waterfield
    - Meet to discuss all testing aspects and actually perform testing.
- Serena Raval
    - Upload Progress Report
    - Attend team meeting tomorrow.
- Soniya Patel
    - Test prototype

Project Timeline -

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All	100%	Yes
Preliminary Deliverables	10/20/2021	All	100%	Yes
Show and Tell	11/5/2021	All	100%	Yes
Poster Presentations	12/3/2021	All	0%	No
Final Deliverables	12/15/2021	All	0%	No

Expenses -

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Component 2								
Component 3								
TOTAL:								**$0.00**

Progress Report 11

SERENA RAVAL - Dec 14, 2021, 4:11 PM CST

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: Nov 18 2021to Dec 2 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

We are working on getting our first prototype printed by the end of next week.

Summary of Weekly Team Member Design Accomplishments

- Team:
  - Tested prototype
- Tatum Rubald
  - Started testing prototype
- Addison
  - Discussed testing protocol - tested prototype
- Alex Pudzisz
  - Finished Testing Protocol
  - Tested device
- Scottie Waterfield
  - Finished testing trials unloading and loading original guidewire into casing
  - Designed final prototype on solidworks
- Serena Raval
  - Finished testing of our prototype.
  - Met with the team Friday.
- Soniya Patel
  - 3d Printed new version of prototype

Weekly/Ongoing Difficulties

None.

Upcoming Team and Individual Goals

- Team:
  - Test as a team
- Tatum Rubald

        - Tested and discussed limitations of our prototype
            - May have to be loaded by 2 members
    - Addison Dupies
        - Meet as a team tomorrow to test
    - Alex Pudzisz
        - Meet as a team to make and practice final presentation
    - Scottie Waterfield
        - Finish all prototype testing and work on final presentation.
    - Serena Raval
        - Upload Progress Report
        - Meet with team over weekend to work on final parts of project.
    - Soniya Patel
        - Continue testing and collecting data
        - Work on final presentation poster

Project Timeline -

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All	100%	Yes
Preliminary Deliverables	10/20/2021	All	100%	Yes
Show and Tell	11/5/2021	All	100%	Yes
Poster Presentations	12/10/2021	All	0%	No
Final Deliverables	12/15/2021	All	0%	No

Expenses -

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
	Prototype 1	UW makerspace				12.00		
Component 2								
	Prototype 2	UW makerspace				8.00		
Component 3								
	Magnetic tape	Amazon				11.50		
TOTAL:								**$31.50**

Progress Report 12

SERENA RAVAL - Dec 14, 2021, 4:08 PM CST

Endovascular Devices for Cath Lab and Operating Room Procedures, Team ENDO CATH

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald: trubald@wisc.edu (Leader)
Addison Dupies: dupies@wisc.edu (Communicator)
Serena Raval: saraval@wisc.edu (BWIG)
Scottie Waterfield: sewaterfield@wisc.edu (BSAC)
Alex Pudzisz: pudzisz@wisc.edu (BSAC)
Soniya Patel: sapatel24@wisc.edu (BPAG)

Date: Dec 3 2021to Dec 9 2021

Problem Statement

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

Brief Status Update

Finalized prototype and testing. Compiled all work for Poster Presentation on Friday December 10.

Summary of Weekly Team Member Design Accomplishments

- Team:
  -
- Tatum Rubald
  -
- Addison
  - Finished testing
  - Practiced presentation
  - Printed poster for team
  - Met with team to work on final report and poster
- Alex Pudzisz
  - Finished testing
  - Met with team and finished preparation for poster presentation
  - Practiced speech
- Scottie Waterfield
  -
- Serena Raval
  - Finished testing and finalized poster.
  - Met with the team multiple times to prepare poster presentation.
- Soniya Patel
  - 3D printed the crate and an additional guidewire wheel
  - Prepared for poster presentation

Weekly/Ongoing Difficulties

None.

Upcoming Team and Individual Goals

- Team:
  - Poster Presentation Friday 12/10/2021
- Tatum Rubald
  -
- Addison Dupies
  - Complete final report
- Alex Pudzisz
  - Complete Final deliverables
- Scottie Waterfield
  -
- Serena Raval
  - Upload Progress Report
  - Meet with team over weekend to work on final parts of project.
- Soniya Patel
  - Complete final report

Project Timeline -

Project Goal	Deadline	Team Assigned	Progress	Completed
Preliminary Presentations	10/15/2021	All	100%	Yes
Preliminary Deliverables	10/20/2021	All	100%	Yes
Show and Tell	11/5/2021	All	100%	Yes
Poster Presentations	12/10/2021	All	0%	No
Final Deliverables	12/15/2021	All	0%	No

Expenses -

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
	Prototype 1	UW makerspace				19.76		
Component 2								
	Prototype 2	UW makerspace				7.68		
Component 3								
	Magnetic tape	Amazon				11.50		
	Prototype 2 (second wheel)	UW Makerspace				6.32		
	Guidewire Wheel Crate	UW Makerspace				61.84		
TOTAL:								**$107.10**

Material Cost

SERENA RAVAL - Dec 14, 2021, 4:22 PM CST

Title: Material Cost

Date: 12/20

Content by: Serena Raval

Present: all

Goals: determine total cost of materials

Content: Total Cost: $111.19

Item	Description	Quantity	Cost
Preliminary Guidewire Hoop	Initial Prototype	1	$19.76
Final Guidewire Hoop	Final Prototype	2	$7.68
Final Crate	Final Prototype	1	$61.84

Magnetic Tape	Magnetic tape for inner surface of hoop	1	$14.23

The Guidewire Hoop

SERENA RAVAL - Dec 14, 2021, 4:15 PM CST

Scottie Waterfield - Oct 20, 2021, 8:54 AM CDT

Title: Guidewire Hoop

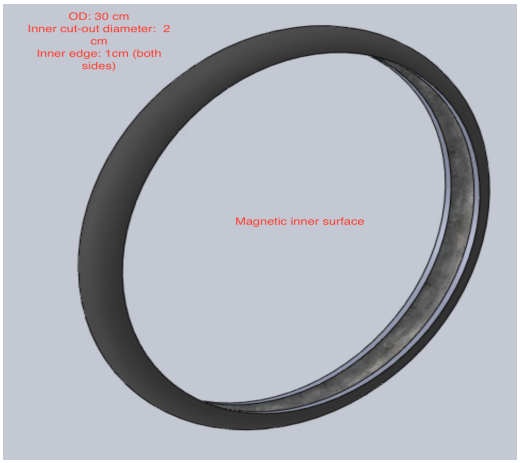
Date: 10/20/2021

Content by: All Team

Present: N/A

Goals: Analysis the Guidewire Hoop Design

Content:



- Magnetic hoop with internal concavity
- encased externally
- Guidewire inserted in concave area along perimeter

Conclusions/action items:

Our final design incorporates a lot of the innovative properties of the previous designs, as it is an internally magnetized wheel encasing the guidewire. The guidewire will press against the inner surface, and the radial force of the stiff wire pushing out will hold the wire stationary inside the hoop.

3D Printing

SERENA RAVAL - Dec 14, 2021, 4:17 PM CST

Title: 3D printing

Date: 12/14

Content by: Soniya Patel

Present: n/a

Goals: 3D printing overview

Content:

client stipulated the device must be 3d printed for proof of concept

items that were 3D printed by our team:

- guiewire wheel prototype 1
  - original design prototype
  - diameter was too large (21 cm)
  - soft guidewire was falling out
- guidewire wheel prototype 2 -
  - printed another wheel, same design except smaller diameter (20cm)
  - guidewire fits better
- crate -
  - printed crate which holds up to 4 wheels
- guidewire wheel prototype 2
  - printed another wheel for poster presentation

Conclusions/action items:

prepare for poster presentation

Final Design

SERENA RAVAL - Dec 14, 2021, 4:28 PM CST

Title: Final Design

Date: 12/10/2021

Content by: Serena Raval

Present: all

Goals: Clearly Represent Final Design on Final Poster Presentation

Content:

Final Design

Description:
- The device includes 4 guidewire hoops and a crate.
- The inner cavity of the hoop is magnetized.

Progress:
- The team has made two prototypes:
  - The first prototype was too large.
  - The second prototype amended this issue.
- The team has tested the second prototype:
  - Loading and Unloading Time Test.
  - Entanglement Test.

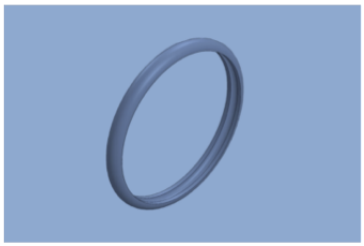


Figure 2. Final Design Guidewire Hoop. Outer Radius: 11 cm. Inner Radius: 10 cm.

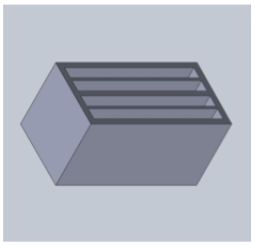


Figure 3. Final Design Crate. Dimensions: 12 cm x 24 cm x 12 cm

Conclusions/action items: consider future work

11/22/2021 Testing Outline and Raw Data

Alex PUDZISZ - Dec 14, 2021, 4:32 PM CST

Title: Testing Outline and Raw Data

Date: 11/22/2021

Content by: Alex Pudzisz

Present: Entire Team

Goals: Write Down Our Testing

Content:

- The team devised two tests in order to ensure an efficiency improvement between the original plastic casing and the final device. Test 1 was a timed test of loading and unloading the wire. This was done in both the original plastic casing and the final device. Each member of the team was required to test loading and unloading three times per device. The team members were timed by another team member in close proximity. Test 2 is an entanglement movement test, done to ensure that the device does not tangle the wire during transportation. This was done by two sets of five tests. The first set of tests involved walking the device around on the same floor, with approximately five minutes of walking. The second test involved moving up and down 5 flights of stairs. During both tests the wire was checked for entanglement before and after the specific test was done. The protocols for test one and test two can be found in Appendix
- Testing Results

Final Device			Original Casing		
Type Of Wire: Test #	**Loading Duration**	**Unloading Duration**	**Type Of Wire: Test #**	**Loading Duration**	**Unloading Duration**
Soft Wire: Test 1	27.26	1.21	Soft Wire: Test 1	25.96	8.44
Soft Wire: Test 2	37.4	0.73	Soft Wire: Test 2	22.32	8.41
Soft Wire: Test 3	26.4	1.26	Soft Wire: Test 3	22.73	9.13
Soft Wire: Test 4	23.12	0.8	Soft Wire: Test 4	25.7	9.54
Soft Wire: Test 5	17.29	0.93	Soft Wire: Test 5	23.43	9.53
Soft Wire: Test 6	21.43	0.78	Soft Wire: Test 6	20.68	10.16
Soft Wire: Test 7	25.62	1.11	Soft Wire: Test 7	21.85	9.11

Soft Wire: Test 8	23.63	1.19	Soft Wire: Test 8	22.71	7.53
Soft Wire: Test 9	19.92	1.04	Soft Wire: Test 9	22.96	5.69
Hard Wire: Test 1	28.37	0.35	Hard Wire: Test 1	24.45	7.78
Hard Wire: Test 2	13.95	1.15	Hard Wire: Test 2	19.7	7.79
Hard Wire: Test 3	25.56	1.35	Hard Wire: Test 3	18.49	11.03
Hard Wire: Test 4	13.47	0.98	Hard Wire: Test 4	20.01	10.39
Hard Wire: Test 5	18.19	1.23	Hard Wire: Test 5	19.45	10.6
Hard Wire: Test 6	15.94	1.24	Hard Wire: Test 6	19.23	7.93
Hard Wire: Test 7	14.43	1.74	Hard Wire: Test 7	24.1	11.51
Hard Wire: Test 8	13.51	1.53	Hard Wire: Test 8	21.48	9.52
Hard Wire: Test 9	14.83	0.68	Hard Wire: Test 9	21.75	9.21

Test 2: Walking and Stairs Test

Walking Test Trial #	Entanglement at Start?	Entanglement At End?	Stairs Test Trial #	Entanglement at Start?	Entanglement At End?
1	No	No	1	No	No
2	No	No	2	No	No

3	No	No	3	No	No
4	No	No	4	No	No
5	No	No	5	No	No

Conclusions/action items:

None

12/13/2021 Testing Raw Data

SERENA RAVAL - Dec 14, 2021, 4:39 PM CST

Title: Testing Raw Data

Date: 12/14/2021

Content by: all

Present: all

Goals: Test the prototype of the guidewire wheel to determine time efficiency and stability.

Content:

Instructions

Test 1: Loading and Unloading Instructions:

1. Give prototype and stiff guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
    a. Record time in notebook entry
5. Instruct participant to take wire out of the device
6. Start timer when participant is ready
7. Stop timer as the participant finishes taking wire out of the device
    a. Record time in notebook entry
8. Observe wire for any tangles or entwinements
    a. If obstructions exist record in notebook entry
9. Repeat Steps 1-8 an additional two times for a total of three trials
10. Repeat Steps 1-9 for soft guidewire
11. Repeat steps 1-10 with original catheter device

Test 2: Walking Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk on the same floor for a minimum of five minutes
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    a. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Test 2: Stairs Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk up and down five flights of stairs
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    a. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Results Table

Test 1: Loading And Unloading Results Table:

Final Device			**Original Casing**		
Type Of Wire: Test #	**Loading Duration**	**Unloading Duration**	**Type Of Wire: Test #**	**Loading Duration**	**Unloading Duration**
Soft Wire: Test 1	27.26	1.21	Soft Wire: Test 1	25.96	8.44
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Soft Wire: Test 4	23.12	0.8	Soft Wire: Test 4	25.7	9.54
Soft Wire: Test 5	17.29	0.93	Soft Wire: Test 5	23.43	9.53
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Hard Wire: Test 4	13.47	0.98	Hard Wire: Test 4	20.01	10.39
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Test 2: Walking and Stairs Test

Walking Test Trial #	Entanglement at Start?	Entanglement At End?	Stairs Test Trial #	Entanglement at Start?	Entanglement At End?
1	No	No	1	No	No
2	No	No	2	No	No
3	No	No	3	No	No
4	No	No	4	No	No
5	No	No	5	No	No

12/10/2021 Testing Data and Interpretation

SERENA RAVAL - Dec 14, 2021, 4:28 PM CST

Title: Testing Data and Interpretation

Date: 12/10/2021

Content by: Serena Raval

Present: all

Goals: Represent testing protocols and procedures on final poster as well as analysis of results.

Testing and Results

- ANOVA test found significantly different (p = .00617) loading times for the soft versus stiff wire.
    - Difference in loading time is an indication that using multiple devices for different wires, stiff and soft, may be needed to speed up the loading process of guidewires.
- Prototype had more efficient unloading times versus the original casing (p = 3.77E-9) for both the soft and stiff wire.
- Occurrence of the wire getting tangled was tested (n = 10) and 0/10 times the wire got tangled/fell out of the device.
- The prototype successfully kept guidewires organized.
    - Main goal of our client.

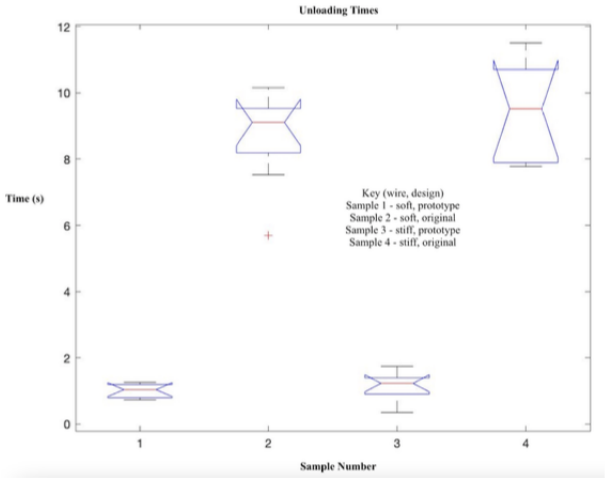

Figure 4. Data distribution of Unloading Times comparing 4 samples

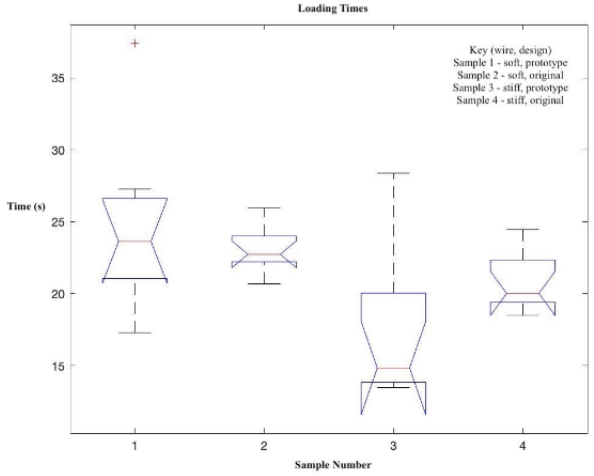

Figure 5. Data distribution of Loading Times comparing 4 samples

Content:

12/13/2021 Final Testing Protocol

Alex PUDZISZ - Dec 14, 2021, 4:33 PM CST

Title: Final Testing Protocol

Date: 12/13/2021

Content by: Alex Pudzisz

Present: Entire Team

Goals: Write Down our Final Protocol

Content:

Instructions

Test 1: Loading and Unloading Instructions:

1. Give prototype and stiff guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
    1. Record time in notebook entry
5. Instruct participant to take wire out of the device
6. Start timer when participant is ready
7. Stop timer as the participant finishes taking wire out of the device
    1. Record time in notebook entry
8. Observe wire for any tangles or entwinements
    1. If obstructions exist record in notebook entry
9. Repeat Steps 1-8 an additional two times for a total of three trials
10. Repeat Steps 1-9 for soft guidewire
11. Repeat steps 1-10 with original catheter device

Test 2: Walking Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk on the same floor for a minimum of five minutes
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    1. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Test 2: Stairs Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk up and down five flights of stairs
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    1. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Conclusions/action items:

None

12/13/2021 Matlab Analysis of Data

SERENA RAVAL - Dec 14, 2021, 4:36 PM CST

Title: Matlab Analysis of Data

Date: 12/03/2021

Content by: Serena Raval

Present: all

Goals: Use Matlab to analyze statistical significance of test results.

Content:

Matlab Code:

```
% Import the data
LoadData = readtable("/Users/tatumrubald/Downloads/Load Data.xlsx")
UnloadData = readtable("/Users/tatumrubald/Downloads/Unload Data.xlsx")

% Run Anova on Load Test Samples
[p,tbl,stats] = anova1(LoadData)
% Review Stats to find significant p-values for loading
LoadStats = multcompare(stats)


% Run Anova on Unload Test Samples
[p,tbl,stats] = anova1(UnloadData)
% Review Stats to find significant p-values for loading
UnloadStats = multcompare(stats)
```

Product Design Specifications

SE

Product Design Specifications

Date of Last Revision: 09/21/2021

Title: Guidewire Organizer for Operation Room
Client: Dr. Dai Yamanouchi
Advisor: Dr. Kip Ludwig
Team: Tatum Rubald, Addison Dupies, Serena Raval, Scottie Waterfield, Alex Pudzisz, Soniya Patel

Function:

n many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangle ncrease procedure efficiency and safety and decrease the time it takes for surgeons to organize the wires.

Client requirements:

- The device must be easy to use and increase organization in the operating room
- The device must consist of a main storing unit (the crate) to house 4-5 guidewire wheels
- The final device must ultimately have biocompatible properties*
- The final device must be sterilizable by autoclave or other alternatives*

*Clients main goal is a successful prototype and proof of concept

Design requirements:

1. Physical and Operational Characteristics
    a. *Performance requirements*: The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The whee guidewires with diameter sizes of 0.014 to 0.035 inches. Additionally, the guidewire must stay organized and unknotted when removed from the wheel; to d the edge of the crate for the guidewire to sit on. It must be easy to load and remove the wire into the wheel while in the operating room [1]. The wheels must removed from the crate.
    b. *Safety*: The device should be able to withstand heavy chemicals such as, glutaraldehyde, formaldehyde, ethylene oxide that are needed to sterilize medical t [2]. Additionally, there should be no risk for the user and all edges must be smooth to prevent the risk of cuts through medical gloves [1].
    c. *Accuracy and Reliability*: In order for the device to comply with the requirements made by the client, it must be able to fit 4-5 catheter guidewires, which id diameter of each wheel, and each wheel must be able to hold a 0.035, 0.018, 0.014 inch guidewire [1]. In addition to the precision it will take to design the d undergo surgeries and have the ability to keep the multiple guidewires used during surgery organized so the operating room workers can navigate the guidev device.
    d. *Life in Service*: This product is a prototype. The life of service should be long enough to confirm that it works and present to possible investors and to provi could be up to a year, but the minimum time under little stress should be a month. If the product is eventually made to be sold, and made out of medical grad last for at least a lifetime, or 100 years [3].
    e. *Shelf Life*: In order for our device to be practical for surgical use, and last at least 5 years, between uses the device will need to be autoclavable or some othe this in mind, the material used to design this device should be able to withstand sterilizable temperatures (121-132 °C) in order to maintain its shelf life after [4].
    f. *Operating Environment*:
    This device will be used within an operating room and be fully functional within standard operating room conditions. These include a relative humidity of 2 and 75 °F [5]. It should be stored in a designated sterile storage room.
    g. *Ergonomics*: The device should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. Post operatic inserted into an autoclave for sterilization. When not in use, the device should be easily stored away in a storage room.
    h. *Size*: The design consists of a circular wheel with a diameter of 11.8 inches. The crate for storing the wheels will be 12x7x6 in. The lip on the crate will be a inches [1].
    i. *Weight*: The prototype will be lightweight and under two pounds and easy to maneuver but able to withstand operating room size requirements and various t final product will be heavier as it will be made of stainless steel.
    j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [6]. Beyond the prototyping phase the material should make it possible to sterilize and reuse.
    k. *Aesthetics, Appearance, and Finish:* The client addresses the device may be 3D printed [1]. The final device should be FDA medical grade steel and should The prototype should also have a smooth, clean finish. The color will be consistent throughout.
2. Production Characteristics
    a. *Quantity*: One prototype is needed, yet the prototype needs to be conceptually and physically sound and able to be utilized in real time. The main focus will prototype to ensure proof of concept. In the future, this prototype will ideally be mass produced, so the ability to have steady organization of guidewires and operating rooms, which leads to the production of many devices.
    b. *Target Product Cost*: Taking into consideration the materials and size, we estimate that the approximate cost of the 3D printed Guidewire Organizer prototyp
3. Miscellaneous

a. *Standards and Specifications:*This product would likely be considered as a Class II medical device. There is no direct FDA regulation for this device, so it v same rules as a guide wire kit and guidewire torque device [8, 9]. Both of these are Class II and require premarket approval in the form of a 510k. There may does not require premarket approval, but the team would need further guidance to determine if it is possible [10].

b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine surg case due to the highly beneficial organization of the guidewires in endovascular catheter surgeries, as they are often misordered which leads to extended surg prototype appeal to those who want to avoid the disorganization of guidewires during surgical procedures. The effect of disorganized guidewires can potenti based on the insertion of the guidewire and where the wire leads to. Tips of a guidewire can break and the broken guidewire could harm the arterial wall that

c. *Patient-related concerns*: Because this device will be used in endovascular procedures, it is important to take into account patient safety. The guidewire hol wire can be inserted in a safe way so the patient's health is not at risk.

d. *Competition*: A guidewire organization device that currently exists is the Angio Assist™ Docking Station, by Teleflex which facilitates the introduction of g atherectomy burrs. This friction-fit guidewire holder is for the use of a single-operator and eliminates the need to touch or hold the stent during guidewire lo that facilitate the alignment of guidewires and catheters on this device. Another product is the Tierstein Edge Device Organizer, by Teleflex which has 6 fric and catheters and is designed to minimize loss of motion control of eternal guidewire as well as increase security of excess wires during procedures [12].

References:

[1] Dr. D. Yamanouchi, “Client Meeting One,” 17-Sep-2021.

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[9] “Product classification,” *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=953. [Accessed: 2

[10] Center for Devices and Radiological Health, “Convenience Kits Interim Regulatory guidance,” *U.S. Food and Drug Administration*. [Online]. Available: https://w information/search-fda-guidance-documents/convenience-kits-interim-regulatory-guidance. [Accessed: 23-Sep-2021].

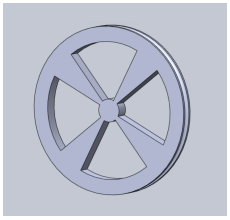
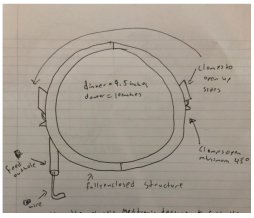
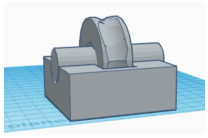
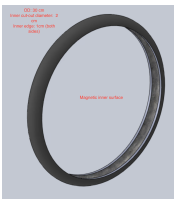
[11] S. Arora, V. Aggarwal, L. Maini, and A. Dhal, “Broken guidewire protruding into the hip joint: A bone endoscopic-assisted retrieval method,” Indian Journal of O 109–112, 2012.

[12] “Interventional Accessories: US.” *Teleflex*, Apr. 2018, teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.htr

Design Matrix

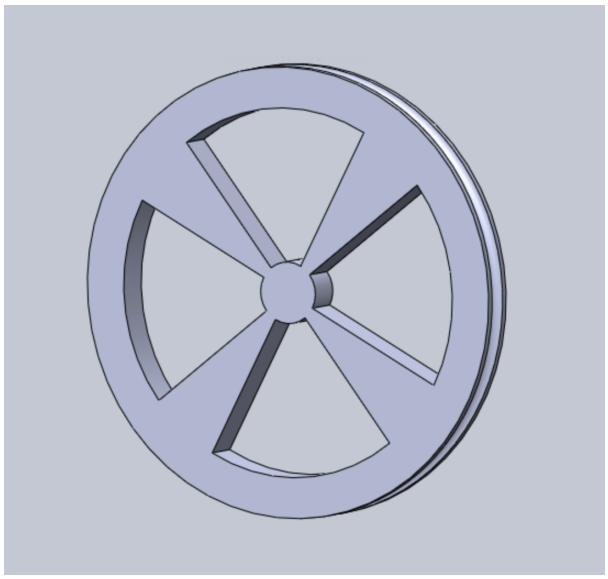
SERENA RAVAL - Oct 18, 2021, 12:33 PM CDT

Endovascular Catheter Design Matrix

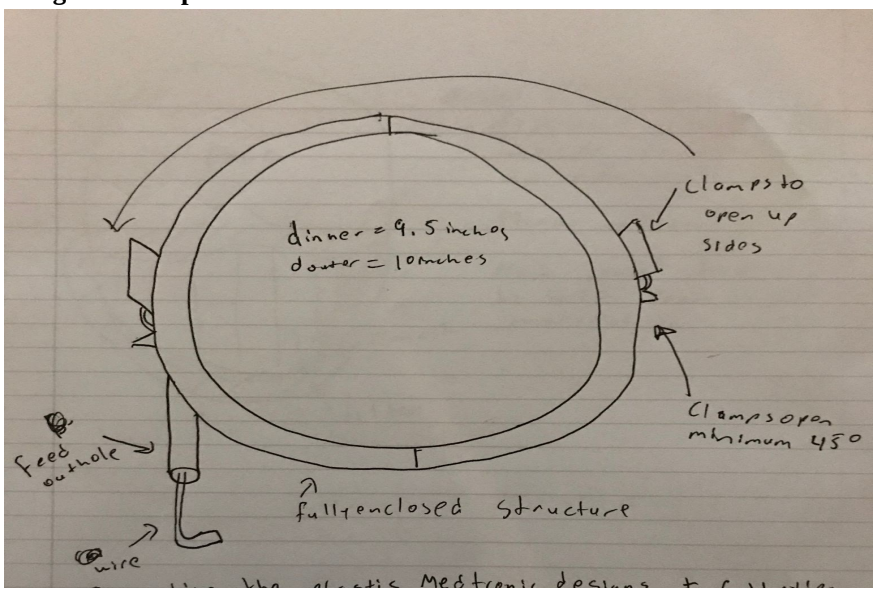
Design	Magnetic wheel		Clamped Wheel		Wheel of Magic		Guidewire Hoop	
								
Feasibility (30%)	4/5	24	3/5	18	4/5	24	5/5	30
Efficiency (25%)	3/5	15	4/5	20	2/5	10	5/5	25
Durability (20%)	3/5	12	3/5	12	3/5	12	4/5	16
Safety (10%)	5/5	10	5/5	10	5/5	10	5/5	10
Learning Curve (10%)	4/5	8	3/5	6	4/5	8	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5	4/5	4
Total for each design:	**72**		**71**		**69**		**95**	

Feasibility: The client would like to have a prototype fabricated by the end of the semester. This criteria takes into account the given current situation with the pandemic, time limit of the semester, the limited tools available from the department of Engineering, and the difficulty of assembling the parts.The client's main goal is proof of concept so with the constraints mentioned above feasibility was weighted the highest at 30%.
Efficiency: The device should be more efficient than the current options that are available; most doctors do the process of organizing manually, and without the aid of any external device. The device should be able to efficiently load and unload the guidewires. This is weighted very heavily due to the fact that efficiency is the purpose of the device/project.
Durability: The criteria was included to assess the ability of the design to withstand stress upon operation. This category was given a weight of 20% due to its durability being important and a key feature for the design to last multiple operations.
Safety: The device must be safe to use on patients in a hospital operating room and should be safe enough to use by a doctor. The safety of the user is important; however, the all three designs have similar safety features, which is why safety is weighted at 10%
Learning Curve: Because a priority of this device is to increase efficiency, learning to use the device must be a quick and simple process. The operator of the device should not have to dedicate a significant amount of time to understand how to properly use the device. This is a relatively low priority due to the fact that the device will work in an intuitive manner. The surgeon should be able to learn and use the device with ease.
Cost: The cost of each design; the client did not give us a set budget, however. The low impact that price has on the overall outcome of this device encouraged the team to give this category the lowest weight.

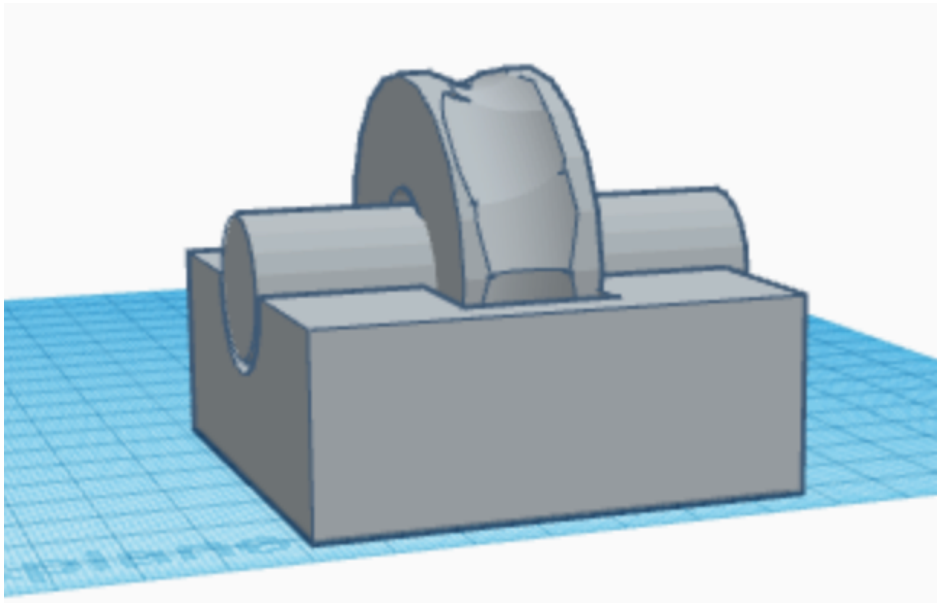
Design 1: Magnetic Wheel



Design 2: Clamped Wheel



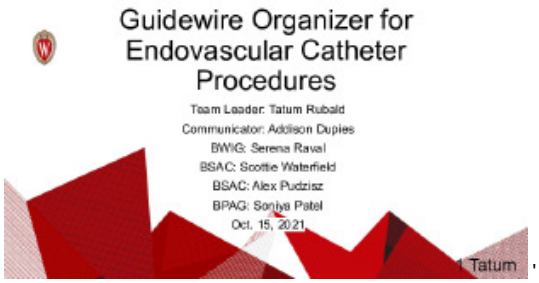
Design 3: Wheel of Magic



Design 4: Guidewire hoop

Preliminary Presentation

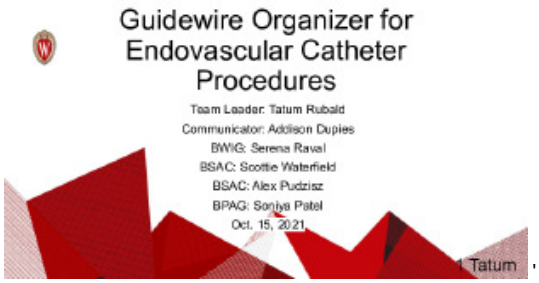
SERENA RAVAL - Oct 18, 2021, 12:33 PM CDT



Preliminary_Presentation.pdf(1.1 MB) - download

Poster Presentation

SERENA RAVAL - Dec 14, 2021, 4:02 PM CST



Preliminary_Presentation.pdf(1.1 MB) - download

Preliminary Report

SERENA RAVAL - Dec 14, 2021, 4:05 PM CST

Guidewire Organizer for Endovascular Procedures

BME 200/300
University of Wisconsin - Madison
Department of Biomedical Engineering
20 October 2020

Client: Dr. Dai Yamanouchi, MD, PhD
University of Wisconsin School of Medicine and Public Health
Department of Surgery

Advisor: Dr. Kip Ludwig
University of Wisconsin - Madison
Department of Biomedical Engineering

Tatum Rubald (Team Leader)
Addison Dupies (Communicator)
Sonjoo Patel (BPAG)
Serena Raval (BWIG)
Alex Padzisz & Scottie Waterfield (BSACs)

endo_cath_Preliminary_Report.pdf(1.9 MB) - download

10/17- Ethics of Engineers

TATUM RUBALD - Oct 17, 2021, 10:13 PM CDT

Title: Ethics

Date: 10/17

Content by: Tatum Rubald

Goals:

I will research general ethics guidelines for engineers.

Content:

I. Fundamental Canons
Engineers, in the fulfillment of their professional duties, shall:

1. Hold paramount the safety, health, and welfare of the public.
2. Perform services only in areas of their competence.
3. Issue public statements only in an objective and truthful manner.
4. Act for each employer or client as faithful agents or trustees.
5. Avoid deceptive acts.
6. Conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession.

Our product will not violate any of these ethical codes engineers must follow. We will also follow these ethics throughout the design process while working with Dr. Ludwig and Dr. Yamanouchi.

Conclusions/action items:

I will abide by these standards.

10/17: Endovascular procedures

TATUM RUBALD - Oct 18, 2021, 9:03 PM CDT

Title: Endovascular Catheter related procedures

Date: 10/17

Content by: Tatum Rubald

Goals:

I will research endovascular procedures and their size/demographic in the US.

Content:

- the global market for end-vascular treatment devices reached $2.0 billion in 2017
    - expected to grow to $2.8 billion by 2022

https://www.bccresearch.com/market-research/healthcare/endovascular-treatment-devices-evar-and-tevar-emphasis.html

This is a large market, which means our product may be well sought after.

Conclusions/action items:

This is a large market for us to work with. It makes our project even more applicable.

10/18/2021: Endovascular related procedures

TATUM RUBALD - Oct 18, 2021, 9:09 PM CDT

Title: Endovascular Related Procedures

Date: 10/18/2021

Content by: Tatum rubald

Goals: To research endovascular procedures

Content:

- less invasive procedure to treat problems involving blood vessels
- in the past conditions were treated by open surgery, and patients generally stayed in the hospital for 7-10 days
- procedure
    - you will use a sedative and regional anesthesia
    - small incision
    - guidewire is inserted through the incision and pushed through

https://www.ucsfhealth.org/treatments/endovascular-surgery

Conclusions/action items:

This is good background information about what an endovascular procedure consists of.

10/18/2021: Relevant Chemistry

TATUM RUBALD - Oct 18, 2021, 9:12 PM CDT

Title: Relevant Chemistry

Date: 10/18/2021

Content by: Tatum rubald

Goals:

I will specify any relevant chemistry for our project.

Content:

There is no relevant chemistry for our project because we are solely prototyping, and not creating a final design. If we did extend our project beyond this semester, we would have to look at biocompatible materials.

Conclusions/action items:

None.

12/15: Future work chemistry/biology

TATUM RUBALD - Dec 15, 2021, 10:25 AM CST

Title: Future work chemistry/biology

Date: 12/15

Content by: Tatum Rubald

Goals:

Identify any biological or chemical constraints that may be applicable for any future work.

Content:

We believe for if this design were to move into the actual medical device market, it will be used mutliple times, thus it will need to be stearlizable. For the final design material, the team intends to use stainless steel, specifically AISI 316L, commonly known as surgical steel because of its use in the medical field today. It is tough and corrosion resistant, and most scalpels are made out of this same metal. This material was chosen because it can withstand high heats, up to 400 degrees Celsius and is already used in surgeries. This material can be precisely machined and its high heat tolerance means the device can be autoclaved and reused after each use.

Conclusions/action items:

We will take this as an idea for any future work for this project.

10/19/2021: Angio Assist

TATUM RUBALD - Oct 19, 2021, 6:30 PM CDT

Title: Angio Assist

Date: 10/19

Content by: Tatum rubald

Goals: I will learn about this competing design

Content:

- facilitate introduction of guidewires into intervention devices
- slid-clips provide rapid, secure attachment to the operative field
- friendly design features a device loading area
    - facilitates alignment and introduction of 0.014" guidewires into catheters
- triangular guidewire slit secures the guidwirie in place

Conclusions/action items:

https://vascularnews.com/vascular-solutions-launches-the-angio-assist-docking-station-and-the-teirstein-edge-device-organizer/

I will site this source for use in our paper.

10/1 - Design Idea "Magnet Wheel"

TATUM RUBALD - Oct 01, 2021, 1:49 PM CDT

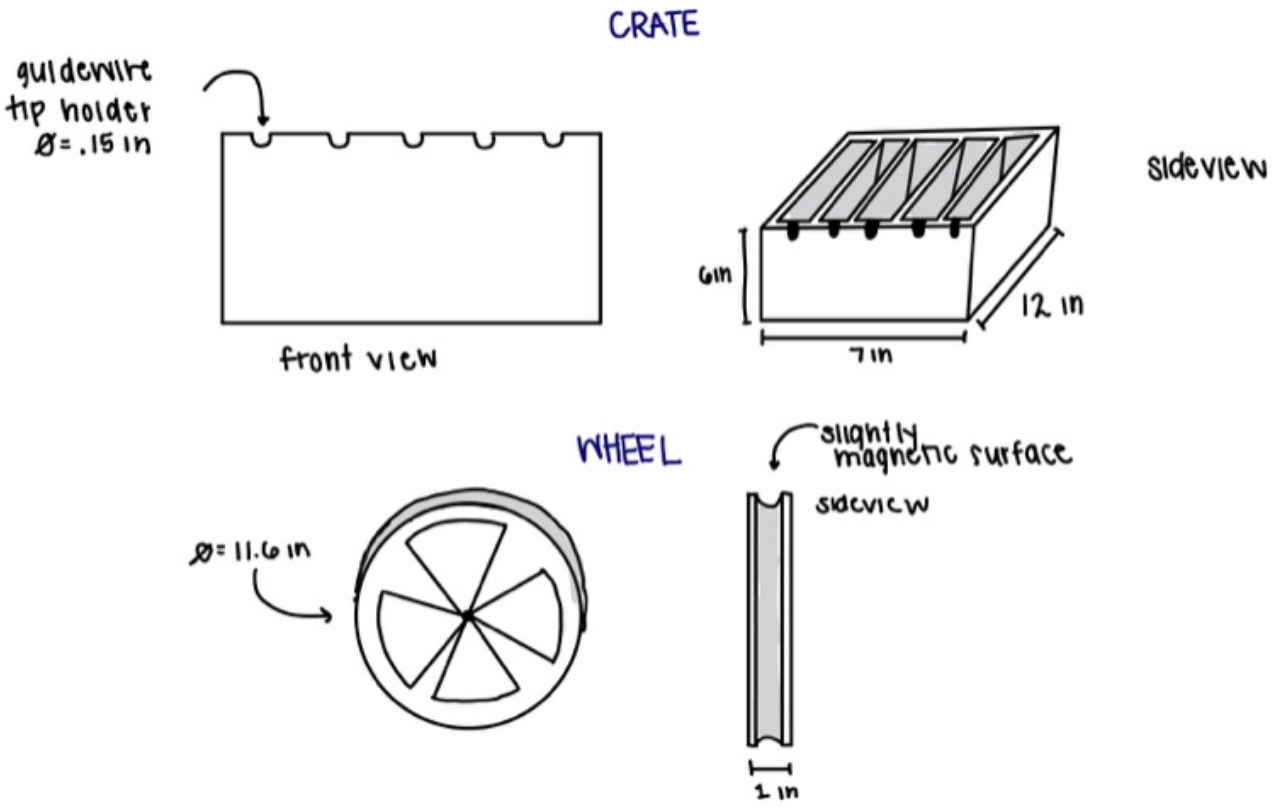
Title: Preliminary design idea

Date: 10/1/21

Content by: Tatum Rubald

Goals: I will present my design idea "Magnet Wheel"

Content:



This is both the wheel and crate.

Conclusions/action items:

Model the design on solidworks.

10/7 - Design Idea "Hula Hoop"

TATUM RUBALD - Oct 07, 2021, 10:52 PM CDT

Title: Hula Hoop

Date: 10/7

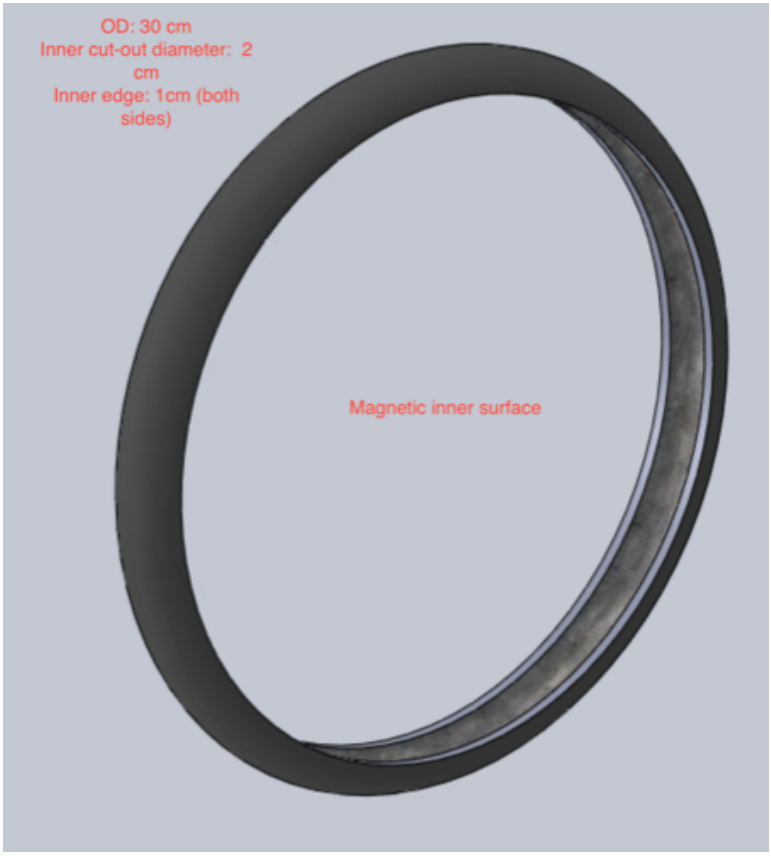
Content by: Tatum Rubald

Goals: To present our final prototype design the "Hula Hoop"

Content:

The hula hoop will be compatible with the crate presented in "Magnet Wheel" design.

This design is better at securing the guidewire because it will push radially on the inner surface of the wheel.



Conclusions/action items:

We will print this design in the 3D printers at the Makerspace.

10/19: FDA Standards for Med Devices

TATUM RUBALD - Oct 19, 2021, 11:42 PM CDT

Title: FDA Standards for Med Devices

Date: 10/19

Content by: Tatum Rubald

Goals: I will identify FDA standards that apply to our device.

Content:

- These are the specific standards that apply to medical devices:
  - "
  - ISO 13485, which is the standard for medical device quality management systems. ISO 13485:2016 is the most current version, and it's also harmonized in Europe.
  - ISO 14971, which is the standard for medical device risk management. The most current version is ISO 14971:2019, but it isn't yet harmonized in Europe.
  - ISO 9001, which is the standard for business quality management systems, and the most current version is ISO 9001:2015.
  - ISO 62304, which is the standard for software used in medical devices, and ISO 62304:2006 is the most current version.
  - ISO 10993, which has 23 parts, is the standard for biological evaluation of medical devices.
  - ISO 15223, which has two parts, is the standard for symbols to be used with medical device labels, labeling, and information to be supplied.
  - ISO 11135, which is the standard for ethylene oxide sterilization of medical devices, and ISO 11135:2014 is the most current version.
  - ISO 11137, which is the standard for sterilization of medical devices using radiation.
  - ISO 11607, which is the standard for sterilized product packaging for medical devices.
  - IEC 60601, which is published by the IEC. This standard applies to the safety and essential performance of medical electrical equipment. Every country has a different version, and devices must comply with the standards that apply in each market."
- This is a list I found online for common FDA standards for medical devices
  - since we aren't making a final product, we won't have to look into these right now
    - just for future reference

https://www.rqmplus.com/blog/quick-guide-to-medical-device-standards-iso-standards-and-beyond?__hstc=242632861.2badfe9afb52480db761b380b36c1db9.1622551449297.1623066707881.1623094016985.3&__hssc=242632861.3444752.1623094016985&__hsfp=1482902807

Conclusions/action items:

These FDA standards will not impact our project this semester because we are only prototyping. If we continue this project, we may need to focus more on these standards.

12/15: Revised Wheel

TATUM RUBALD - Dec 15, 2021, 10:11 AM CST

Title: Revised Wheel

Date: 12/15

Content by: Tatum Rubald

Goals:

To shrink the original protoype in order to hold the wire better.

Content:

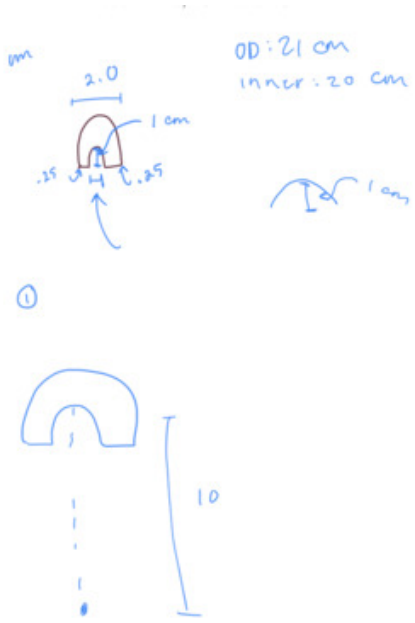
Attachment shows a rough sketch of our new wheel.

We will reduce the OD to 21 cm and the ID to 20 cm. The thickness will be 1.5 cm.

Conclusions/action items:

Print new design.

TATUM RUBALD - Dec 15, 2021, 10:10 AM CST



Screen_Shot_2021-12-15_at_10.10.22_AM.png(79.7 KB) - download

12/15: Future work

TATUM RUBALD - Dec 15, 2021, 10:14 AM CST

Title: Future Work Design

Date: 12/15

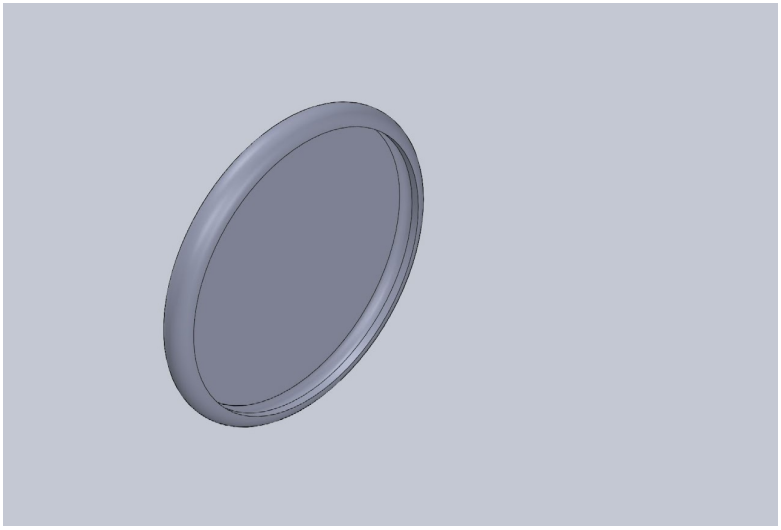
Content by: Tatum Rubald

Goals:

Brainstorm new ideas to make a better design in the future.

Content:

In order to help load our wheel more efficently, we will add a back to our wheel.



Here is the new wheel i prototyped for our group. The OD is 18cm and the ID is 17cm. We shrank it slightly and added the backing.

Conclusions/action items:

We will take this design to next semester if we decide to continue.

Test Methods - Math & Statistics

TATUM RUBALD - Oct 17, 2021, 10:09 PM CDT

Title: Test Method Ideas

Date: 10/17

Content by: Tatum Rubald

Goals:

I will brainstorm test method ideas to get quantize data in order to use statistics and mathematics to determine if the design is efficient.

Content:

Hypothesis: The wheel will decrease the time it takes for Dr.'s to organize guidewires into the wheel.

1. Have Dr. Y time how long it takes to organize guidewires without our product (initial time)
2. time how long it takes for Dr. Y to insert the guidewire into wheel and then crate (new time)
3. Have him do this three times then calculate percent reduction in time

% reduction = (initial time - new time) / initial time * 100%

Conclusions/action items:

I will propose this test method to the team on Monday.

12/07: Testing protocols

TATUM RUBALD - Dec 15, 2021, 10:29 AM CST

Title: Testing protocols

Date: 12/07

Content by: Tatum Rubald

Goals:

Create easy to follow testing protocols for our device. These must be easy to repeat and follow.

Content:

Instructions

Test 1: Loading and Unloading Instructions:

1. Give prototype and stiff guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
    1. Record time in notebook entry
5. Instruct participant to take wire out of the device
6. Start timer when participant is ready
7. Stop timer as the participant finishes taking wire out of the device
    1. Record time in notebook entry
8. Observe wire for any tangles or entwinements
    1. If obstructions exist record in notebook entry
9. Repeat Steps 1-8 an additional two times for a total of three trials
10. Repeat Steps 1-9 for soft guidewire
11. Repeat steps 1-10 with original catheter device

Test 2: Walking Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk on the same floor for a minimum of five minutes
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    1. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Test 2: Stairs Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk up and down five flights of stairs
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    1. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Conclusions/action items:

We will redo these tests if we were to carry this project on.

12/09: Testing results

TATUM RUBALD - Dec 15, 2021, 10:30 AM CST

Title: Testing results

Date: 12/09

Content by: Tatum Rubald

Goals:

To upload our testing data.

Content:

Results Table

Test 1: Loading And Unloading Results Table:

Final Device			Original Casing		
Type Of Wire: Test #	**Loading Duration**	**Unloading Duration**	**Type Of Wire: Test #**	**Loading Duration**	**Unloading Duration**
Soft Wire: Test 1	27.26	1.21	Soft Wire: Test 1	25.96	8.44
Soft Wire: Test 2	37.4	0.73	Soft Wire: Test 2	22.32	8.41
Soft Wire: Test 3	26.4	1.26	Soft Wire: Test 3	22.73	9.13
Soft Wire: Test 4	23.12	0.8	Soft Wire: Test 4	25.7	9.54
Soft Wire: Test 5	17.29	0.93	Soft Wire: Test 5	23.43	9.53
Soft Wire: Test 6	21.43	0.78	Soft Wire: Test 6	20.68	10.16
Soft Wire: Test 7	25.62	1.11	Soft Wire: Test 7	21.85	9.11
Soft Wire: Test 8	23.63	1.19	Soft Wire: Test 8	22.71	7.53
Soft Wire: Test 9	19.92	1.04	Soft Wire: Test 9	22.96	5.69
Hard Wire: Test 1	28.37	0.35	Hard Wire: Test 1	24.45	7.78

Hard Wire: Test 2	13.95	1.15	Hard Wire: Test 2	19.7	7.79
Hard Wire: Test 3	25.56	1.35	Hard Wire: Test 3	18.49	11.03
Hard Wire: Test 4	13.47	0.98	Hard Wire: Test 4	20.01	10.39
Hard Wire: Test 5	18.19	1.23	Hard Wire: Test 5	19.45	10.6
Hard Wire: Test 6	15.94	1.24	Hard Wire: Test 6	19.23	7.93
Hard Wire: Test 7	14.43	1.74	Hard Wire: Test 7	24.1	11.51
Hard Wire: Test 8	13.51	1.53	Hard Wire: Test 8	21.48	9.52
Hard Wire: Test 9	14.83	0.68	Hard Wire: Test 9	21.75	9.21

Test 2: Walking and Stairs Test

Walking Test Trial #	Entanglement at Start?	Entanglement At End?	Stairs Test Trial #	Entanglement at Start?	Entanglement At End?
1	No	No	1	No	No
2	No	No	2	No	No
3	No	No	3	No	No
4	No	No	4	No	No
5	No	No	5	No	No

Conclusions/action items:

We will analyze this data.

12/14- Matlab code for Anova

TATUM RUBALD - Dec 14, 2021, 1:05 PM CST

Title: Matlab code for anova

Date: 12/14

Content by: Tatum Rubald

Goals:

Generate a matlab code to analyze our data.

Content:

The ANOVA test found no significant loading time difference when we compared the loading times between the two devices. We did find a significant difference between the loading times of the stiff and soft wire (p = .00617). As for unloading data: there was a significant difference (3.76e-9) between unloading in our prototype vs the original casing. As for test 2, while moving and shaking the device, 0 out of 10 times our guidewire got tangled/fell out of the device.

The code I ran is found here:

```
% Import the data
LoadData = readtable("/Users/tatumrubald/Downloads/Load Data.xlsx")
UnloadData = readtable("/Users/tatumrubald/Downloads/Unload Data.xlsx")


% Run Anova on Load Test Samples
[p,tbl,stats] = anova1(LoadData)
% Review Stats to find significant p-values for loading
LoadStats = multcompare(stats)



% Run Anova on Unload Test Samples
[p,tbl,stats] = anova1(UnloadData)
% Review Stats to find significant p-values for loading
UnloadStats = multcompare(stats)
```

Conclusions/action items:

I will continue to review the findings and make conclusions.

12/14- Test Data Findings

TATUM RUBALD - Dec 14, 2021, 1:07 PM CST

Title: Test Data findings

Date: 12/14

Content by: Tatum Rubald

Goals:

To make conclusions based off of our findings.

Content:

1. Our device met proof of concept through our testing. We tested our prototype by timing how long it took to load the guidewire into it, and then separately timed how long it took to unload it. We did identical testing on the original guidewire casing as well. Our client also provided us with two different guidewires: a stiff wire and a soft wire. Thus, we also wanted to test the difference between these wires in our prototype.
2. These two graphs were generated on matlab and show the distribution of loading and unloading data for four samples. Sample 1 and 2 are the soft wire in the prototype and original casing respectively. Sample 3 and 4 are the stiff wire again in the prototype and original casing respectively.
3. We ran an ANOVA for the four samples, and found no significant loading time difference when we compared the loading times between the two devices.
4. We did find a significant difference between the loading times of the stiff and soft wire ($p = .00617$). This suggests to us that there may need to be a smaller wheel size that is able to hold the softer wire.
5. Moving onto unloading data: there was a significant difference between unloading in our prototype vs the original casing. This proved to us that our device efficiently unloads guidewires.
6. Lastly, we tested how well the wheel was able to keep the guidewire organized, as this was the main concern of our client. While moving and shaking the device, 0 out of 10 times our guidewire got tangled/fell out of the device. This proved that our device successfully organizes guidewires successfully accomplishing the clients goals.

Conclusions/action items:

I will bring these findings two our group.

12/15: Graphs

TATUM RUBALD - Dec 15, 2021, 10:19 AM CST

Title: Graphs from testing

Date: 12/15

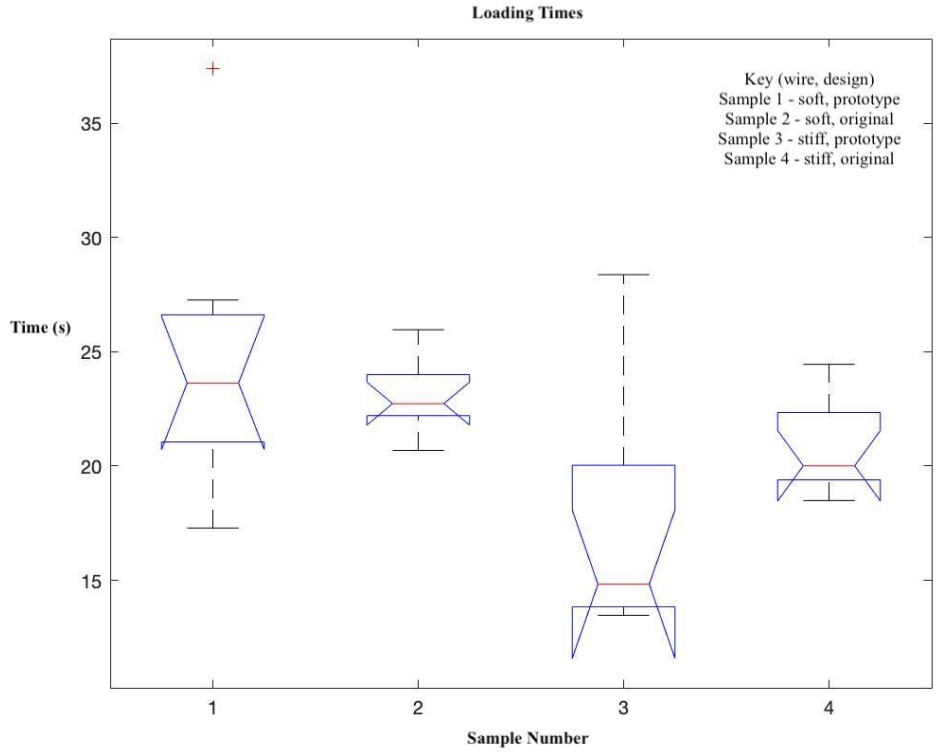
Content by: Tatum Rubald

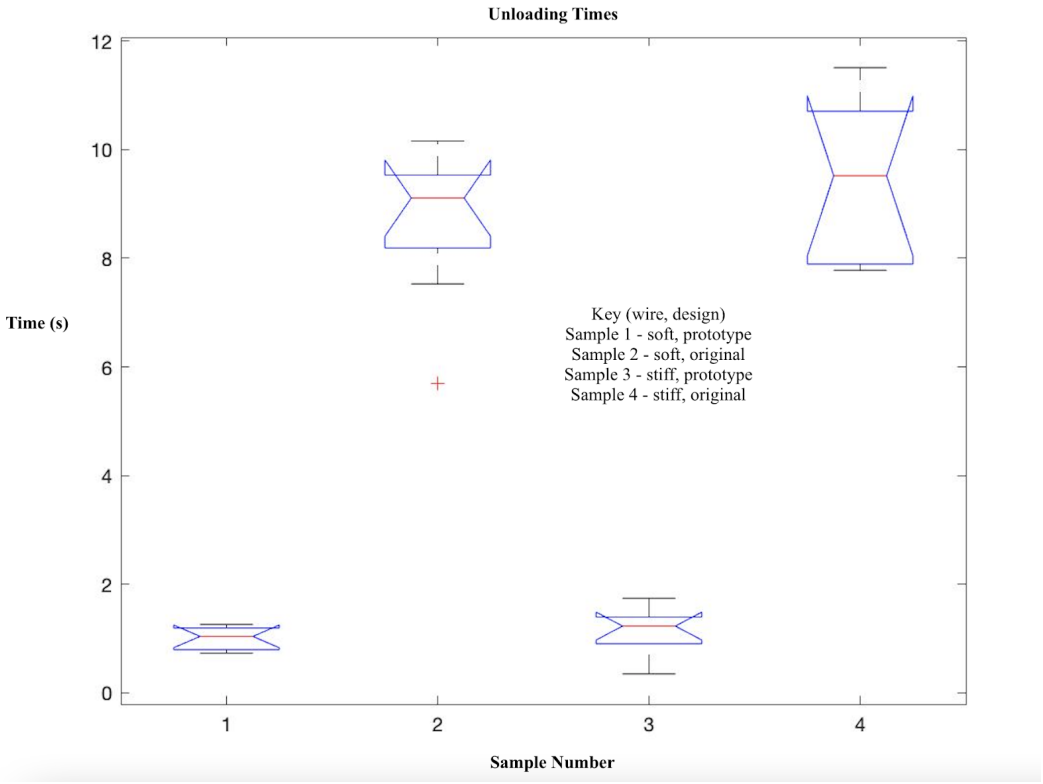
Goals:

To orgnaize the graphs generated on Matlab.

Content:

These are the graphs generated, and I added the labels and key. As we can see, the distribution of data for the loading times experienced a much larger spread. This tells us that we need to modify our device to create a consitiant loading time. We also see that the unloading times are significantly lower with our prototype than with the original casing.





Conclusions/action items:

We will create a future wheel to help with these complications

2021/10/1 Endovascular Market

ADDISON DUPIES - Oct 19, 2021, 3:41 PM CDT

Title: Endovascular Market

Date: 10/1/2021

Content by: Addie Dupies

Present: NONE

Goals: Explore the endovascular market and the potential for this product after proof of concept is achieved

Content:

- The Endovascular Treatment Devices Market segment had the largest market share In 2020.
- Top Endovascular Treatment Device Companies:
  - Boston Scientific
  - Cardinal Health
  - Cook Group Inc
  - Getinge AB
  - Terumo Corp
- In 2020, the global Endovascular Treatment Devices market size was USD 1910.1 million and it is expected to reach USD 2614.7 million by the end of 2027, with a CAGR of 4.1% between 2021 and 2027
- Endovascular treatment includes procedure types such as EVAR and TEVAR. Aneurysm types include infrarenal, juxtarenal and thoracic.

https://www.ktvn.com/story/44950252/endovascular-treatment-devices-market-size-in-2021-top-countries-data-with-41-cagr-global-industry-brief-analysis-by-top-key-companies-and-growth

Conclusion/Action Items: Look further into these companies and potential competing designs they have that could knock out our device

2021/10/8 Oliver’s Award-Winning Dual Hoop Catheter DISK

ADDISON DUPIES - Oct 19, 2021, 3:51 PM CDT

Title: Oliver’s Award-Winning Dual Hoop Catheter DISK

Date: 10/8/2021

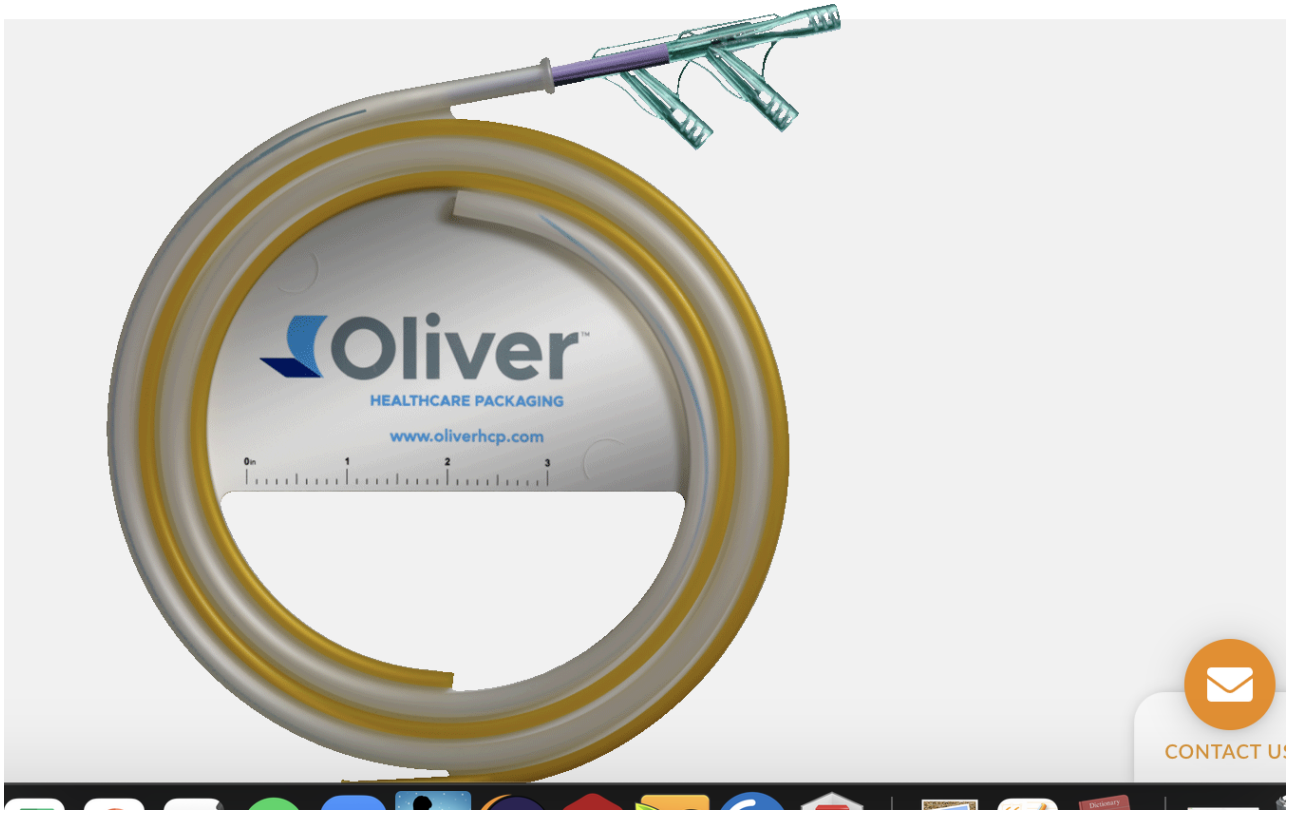
Content by: Addie Dupies

Present: NONE

Goals: Research Oliver’s Award-Winning Dual Hoop Catheter DISK competing design for guidewire organizer

Content:

- Dual Hoop Catheter DISK is cutting edge of medical device packaging design and was honored most recently as the winner of Packaging Design of the Year at the Healthcare Asia Medtech Awards 2021
- Catheter wires and procedural components are housed in one convenient system - eliminates the need for multiple pieces that can be lost or hazardous in the operating room
- Packaging waste is reduced by 20-30% and significant cost and time savings are realized by medical device manufacturers.
- Companies listed benefits:
    - Clipless
    - Dual Hoop Option for Multiple Size Devices in One System
    - Easily Contains Related Procedural Components
    - Increased Convenience for End Users
    - Reduces End User Time & Cost
    - Reduces Puncture Risk
- Companies listed features:
    - Flaring
    - Printing
    - Skiving & Hole Drilling
    - Up to 217" Long
- Can also sterilize the guidewire once after inserted into the patient and removed and put back in the storage tubing



https://www.oliverhcp.com/products/catheter-and-guidewire-dispensers

Conclusion/Action Items: Research other competing designs that might not be as similar as our chosen design - helps expand what the market looks like

2021/10/15 CathClip Competing Design

ADDISON DUPIES - Oct 19, 2021, 4:00 PM CDT

Title: Oliver's Award-Winning Dual Hoop Catheter DISK

Date: 10/15/2021

Content by: Addie Dupies

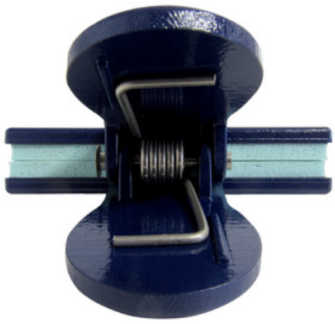
Present: NONE

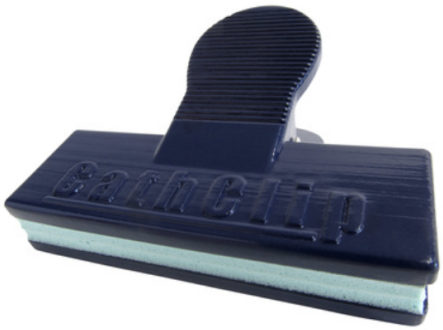
Goals: Research CathClip a competing design that is unique compared to many other storage options

Content:

- Very Unique compared to other guidewire storage options
- Looks very similar to a chip clip
- Lint-free single-use disposable
- Securely and gently holds any type of flexible elongated medical device, no matter what its particular characteristics are - can hold very stiff guidewires
- Measures approximately 2" x 2.25" x 1.25"
- Not environmentally friendly as is it plastic and not reusable
- Foam in between the two plastic clips in order to not damage the guidewire
- Involves no extra prep time or cleanup time - open sterile package, dip in saline, and then it ready to use
- Dispose of after the procedure
- Sterile, biocompatible, latex-free

How to use: dip gripping pads into saline - manually run the hydrated CathClip along a flexible elongated medical device to moisten the device and wipe it of adherent blood. If more wetness is desired, the gripping pads can be re-wet with saline.





https://www.cathclip.com/cathclip-product-information.html

Conclusion/Action Items: Begin to work on preliminary report with all information researched as a team

2021/09/24 What is a guidewire?

ADDISON DUPIES - Oct 19, 2021, 3:33 PM CDT

Title: What is a guidewire?

Date: 9/24/2021

Content by: Addie Dupies

Present: NONE

Goals: Dive into the guidewire market and research what a guidewire is

- There are many different types of different guidewires with different types of tips, flexibility of the wire, and size of the diameter
- During an endovascular procedure, many guidewires of different styles are used
    - In one procedure 4 different guidewires could be used
- Each guidewire has specific purpose, which is why there are so many different styles.
- The guidewire is inserted in the patient after being removed from the dispensing tubing
- Once the catheter is in place the guide is removed from the patient
- It must be kept in case it needs to be used later in the procedure
- It is hard to keep organized because they cannot easily be wound into a circle because it likes to spring out

https://www.bostonscientific.com/en-US/products/guidewires.html

Conclusion/Action Items: Look further into the guidewire market and how our product will compare to competing designs

2021/10/27 Impact of the device

ADDISON DUPIES - Dec 14, 2021, 3:02 PM CST

Title: Impact of the device

Date: 10/27/2021

Content by: Addie Dupies

Present: NONE

Goals: Consider the broader impact of this device on the medical field and the patients themselves

Content:

This device while the concept itself seems quite simple there is nothing on the market that is quite like it. The ability for doctors to store multiple guidewires that are needed for an endovascular procedure could revolutionize endovascular surgeries. This is because it could allow for fewer people to be in the operating room, which causes a great risk because of the possibility of contamination. Additionally, allowing for them to be stored in one place gives easy access to the surgeon that is utilizing the guidewire. The liability for the hospital also decreases because fewer people are in the operating room. The patients will benefit because the surgeon will be able to complete the procedure faster with the new device. They will not have to spend time fiddling with the guidewire to store it and make sure it is out of the way when not being used.

Conclusion/Action Items:

Do more research on why this solution has not been already made.

2021/10/27 Chemistry - none

ADDISON DUPIES - Dec 14, 2021, 3:04 PM CST

Title: Chemistry

Date: 10/27/2021

Content by: Addie Dupies

Present: NONE

Goals:

Content:

- There is no chemistry involved in this project.

2021/11/3 Social and Ethical Implications

ADDISON DUPIES - Dec 14, 2021, 3:08 PM CST

ADDISON DUPIES - Dec 14, 2021, 3:15 PM CST

Title: Social and Ethical Implications

Date: 11/3/2021

Content by: Addie Dupies

Present: NONE

Goals: Discuss social and ethical implications of the device

Content:

- When testing medical devices in a real-world setting it becomes very difficult
- Testing on patients would be the last step of testing this device, which is the hardest part
- Patients must consent to this testing because they are at higher risk of something going wrong
- Clinical research guidelines are in place to ensure that no patient is exploited for the purpose of research.
- There are seven main principles in place for clinical research
- The two principles that are crucial to clinical research involving premature infants are informed consent and a favorable risk-benefit ratio.
- Ethically, it becomes quite hard to conduct continuous clinical studies with devices as the risk-benefit ratio is not always positive.
- This device is fairly low risk, but ethics still must be considered

Source: https://clinicalcenter.nih.gov/recruit/ethics.html

Conclusion/Action Items: Research an ethical way for the final design to be tested in a real-world medical setting

2021/12/1 Testing Protocols

ADDISON DUPIES - Dec 14, 2021, 3:23 PM CST

Title: Testing Protocols

Date: 12/1/2021

Content by: Addie Dupies

Present: NONE

Goals: Go over testing protocols and how we will test the device

Content:

Testing together as a team.

Protocol and procedure for testing.

Test 1: Loading and Unloading Instructions:

1. Give prototype and stiff guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
5. Record time in notebook entry
6. Instruct participant to take wire out of the device
7. Start timer when participant is ready
8. Stop timer as the participant finishes taking wire out of the device
9. Record time in notebook entry
10. Observe wire for any tangles or entwinements
11. If obstructions exist record in notebook entry
12. Repeat Steps 1-8 an additional two times for a total of three trials
13. Repeat Steps 1-9 for soft guidewire
14. Repeat steps 1-10 with original catheter device

Test 2: Walking Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk on the same floor for a minimum of five minutes
4. Once they have done so, look at the wire to see if there is any new wire entanglement
5. Record the results in notebook entry
6. Repeat steps 1-4 for a total of five trials

Test 2: Stairs Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk up and down five flights of stairs
4. Once they have done so, look at the wire to see if there is any new wire entanglement
5. Record the results in notebook entry
6. Repeat steps 1-4 for a total of five trials

Conclusion/Action Items:

When we test on 12/5 we will use this protocol.

2021/12/08 MATLAB Analysis

ADDISON DUPIES - Dec 14, 2021, 3:53 PM CST

Title: MATLAB Analysis

Date: 12/8/2021

Content by: Addie Dupies

Present: NONE

Goals: Use Matlab to analyze data

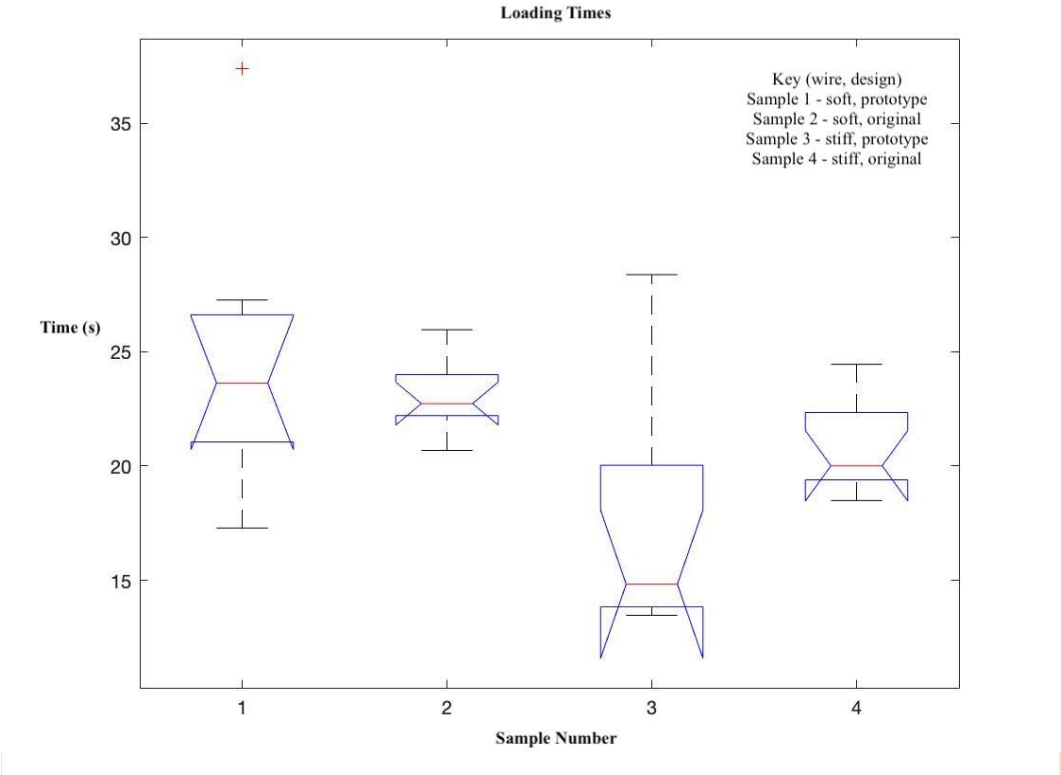
Content:

- The team ran a 4 way ANOVA test to analyze the data ran from testing
- The code used from MATLAB is below ran from Tatum's computer:

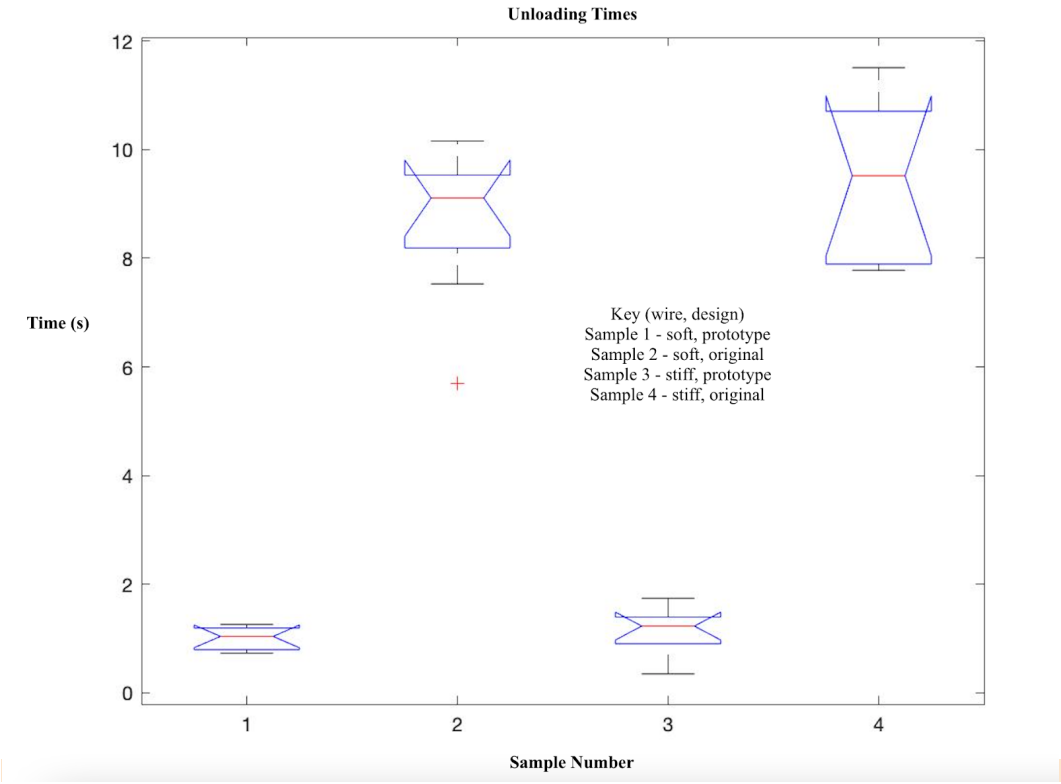
```
% Import the data

LoadData = readtable("/Users/tatumrubald/Downloads/Load Data.xlsx")

UnloadData = readtable("/Users/tatumrubald/Downloads/Unload Data.xlsx")

% Run Anova on Load Test Samples

[p,tbl,stats] = anova1(LoadData)

% Review Stats to find significant p-values for loading

LoadStats = multcompare(stats)

% Run Anova on Unload Test Samples

[p,tbl,stats] = anova1(UnloadData)

% Review Stats to find significant p-values for loading

UnloadStats = multcompare(stats)
```

- We found that there was a statistical difference between the unloading times of Guidewire hoop and current dispensing tubing.
- We found that there was not a statistical difference between the loading times of the guidewire hoop and the current dispensing tubing.
- We must discuss the modifications that must be made to the device to make it more efficient and more organized.

Loading Times data distribution from MATLAB



Unloading Times Data distribution from MATLAB



Conclusion/Action Items: Begin using this analysis to start writing poster presentations and final deliverables. Modifications must be made in order to make this device faster and more efficient, while also being safer.

2021/9/30 Design: Wheel of Magic

ADDISON DUPIES - Oct 19, 2021, 12:01 PM CDT

Title: Design Wheel of Magic

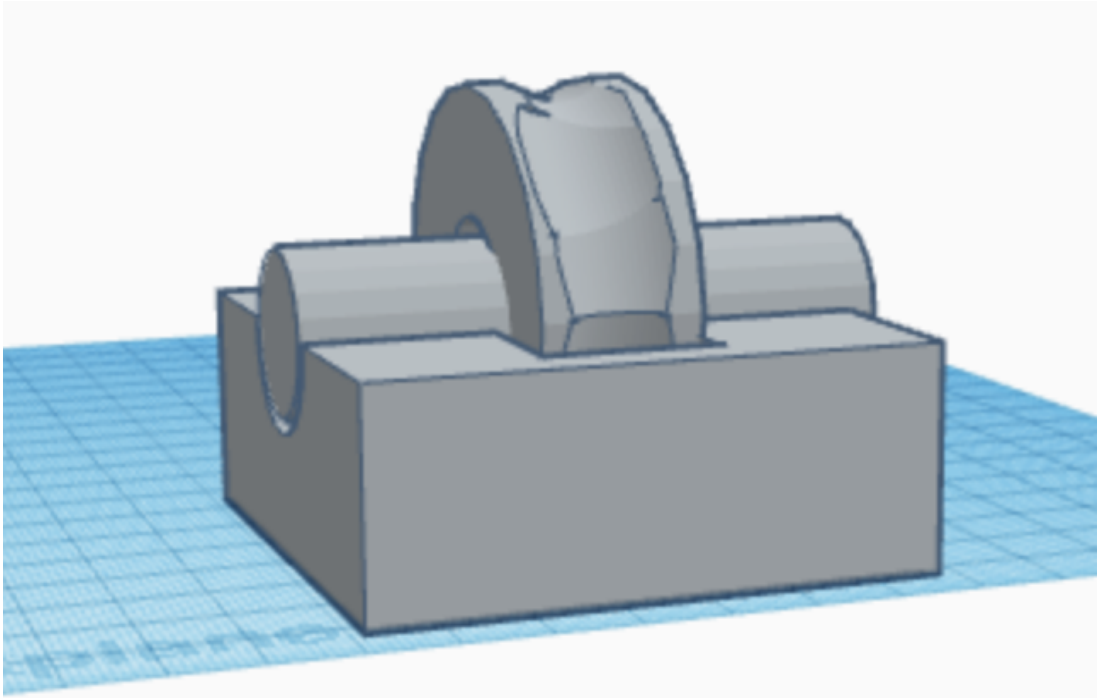
Date: 2021/09/30

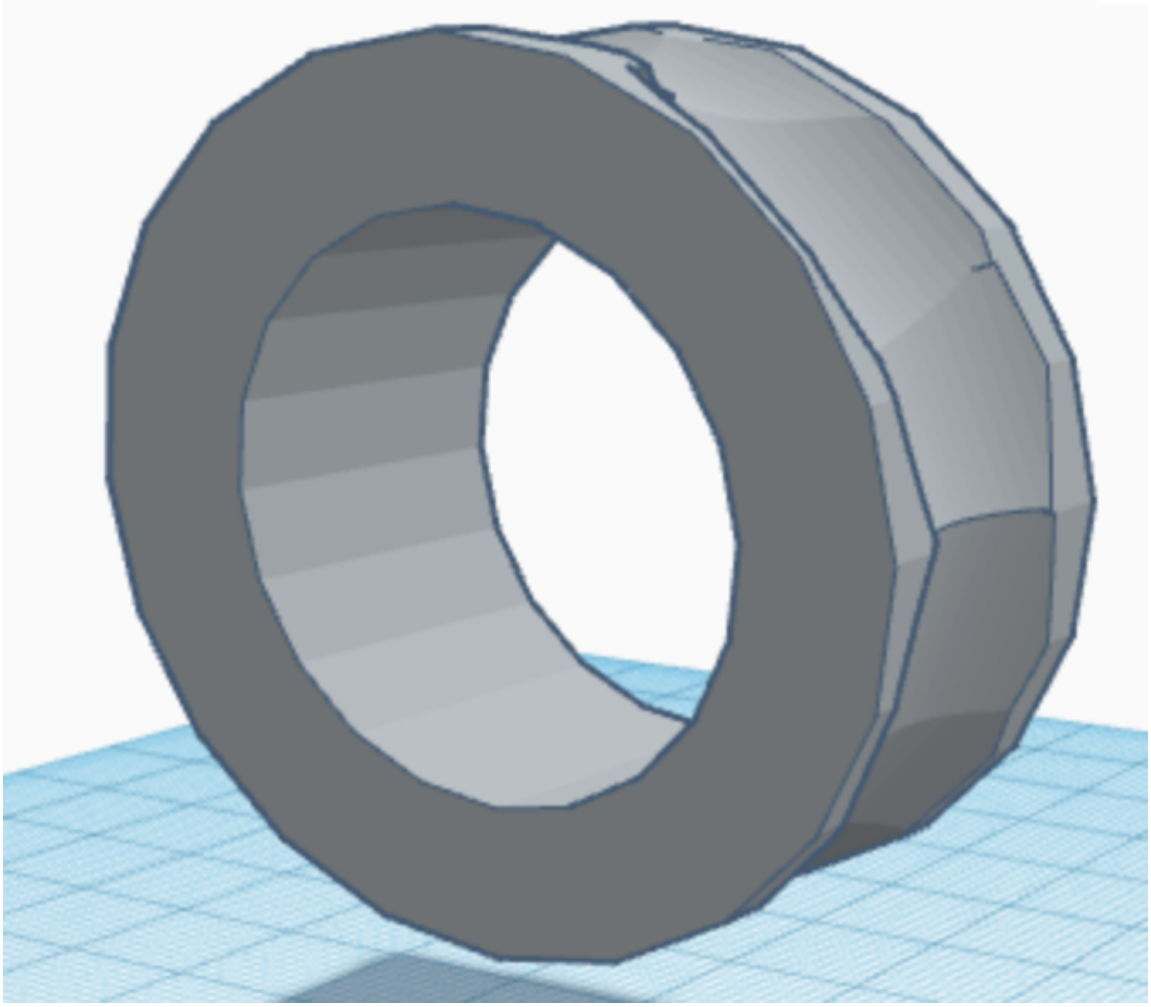
Content by: Addie

Present: None

Goals: To design a potential prototype option for the design matrix

Content:





Conclusion/Action Items: Create the design matrix with the teams other design ideas and weight criterion among the other designs.

2021/11/16 Preliminary Design Modifications

ADDISON DUPIES - Dec 14, 2021, 2:51 PM CST

Title: Preliminary Design Modification

Date: 11/16/2021

Content by: Addie Dupies

Present: NONE

Goals: Discuss why the Preliminary Design did not work and why improvements are needed.

Content:

- After meeting yesterday the team found that modifications must be made to the Guidewire hoop.
- The diameter must be decreased to better secure both guidewire sizes and stiffness that we were given by Dr. Yamanouchi.
- When the diameter is decreased, the width of the inner cavity must also be decreased.
- Both of these modifications should be able to better secure both the soft and the stiff wire
- Securing all sizes and stiffnesses is critical to this device
- Being able to use one device for all sizes and stiffnesses will allow for widespread production in the endovascular market once proof of concept is established.
- The stiff wire could feasibly use this first prototype, but it is still almost too large for dispensing the wire
- Both wires leave the inner surface of the wheel - maybe add a magnetic surface - tape or sticky magnet could work

C**onclusion/Action Items:**

Once the new prototype type is printed test to see if it works well with a smaller diameter. See if any further modifications must be made.

2021/11/27 Final Design

ADDISON DUPIES - Dec 14, 2021, 3:50 PM CST

ADDISON DUPIES - Dec 14, 2021, 3:52 PM CST

Title: Future Work

Date: 11/27/2021

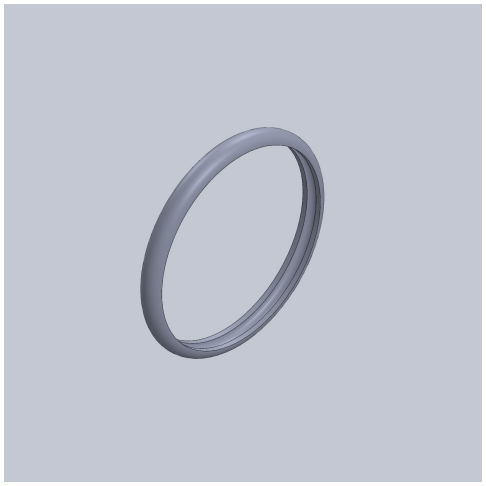
Content by: Addie Dupies

Present: NONE

Goals: Explain new design

Content:

- The new device is smaller in diameter: ID: 20 cm and OD: 22 cm
- This will better secure the wires
- Allow for better loading and unloading
- New Device:



Conclusion/Action Items: Test device.

2021/12/9 Future Work

ADDISON DUPIES - Dec 14, 2021, 3:44 PM CST

Title: Future Work

Date: 12/9/2021

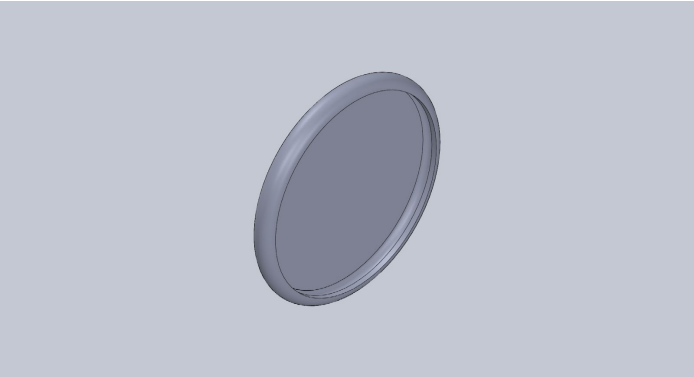
Content by: Addie Dupies

Present: NONE

Goals: Discuss modifications that must be made to continue improving the Guidewire Hoop

Content:

- After analyzing the data from testing the team plans to add a back plate to the guidewire hoop - this will better stabilize the loading of the guidewire into the hoop
- This will also make it much more efficient and able to be done by one person.
- Also, we want to deepen the inner cavity of the wheel to secure the soft wire better.
- If these don't work we will decrease the radius of the wheel
- If we decrease the wheel size we will decrease the crate size as well.



- Modified wheel.

Conclusion/Action Items: Begin next semester off with this design.

2021/09/17 First Client Meeting

ADDISON DUPIES - Sep 17, 2021, 4:49 PM CDT

Title: First Client Meeting

Date: 2021/09/17

Content by: Addie

Present: Tatum, Alex, Serena, Soniya

Goals: To establish the basis of the project and understand any further details that have not yet been communicated

Content:

- Vascular catheter: poking a needle and then going into the artery and small wire through the needle. The wire goes to the target vessel. Most of the time its blocked

- Balloon goes over and blows up to unblock the artery .

- The the metal stent goes in to keep the artery open

-Two options: dissection device and

- Systolic pressure is high pressure

Dystolic Is low pressure

In the lumen pressure is about the same

Turning two tubes into one tube

wire and catheter holder with easy

Wire needs to be out of the holder

and pulled out in the circle

Putting the wire back in a new tube and then doing it over and over again

Cath clip is one example

Why multiple wires?

- Guide wire is a u shape

0.035 wire

0.018 wire

0.014 wire

directional lead for research:

- look at competing ideas

Conclusions/action items:

H20 Torq

SERENA RAVAL - Sep 19, 2021, 9:09 PM CDT

Title: H20 Torq: guide wire torque device

Date: 09/19/2021

Content by: Serena Raval

Present: n/a

Goals: Learn about an existing product that aims to aid a catheter based procedure.

Content:

- works on PTFE, standard spring type, and hydrophilic guide wires without damaging the wire surface

- ergonomic torque device operable with one hand, designed to enhance manipulation and rotation of the guide wire tip

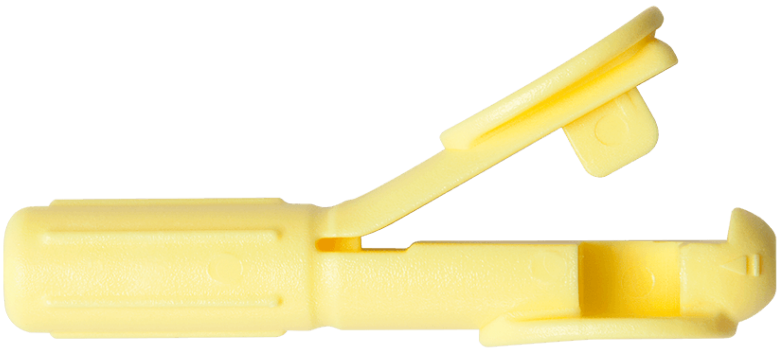
- grip ridges to enhance steering and torque performance

- easy removal from guide wire which facilitates wire/catheter placement and exchange

- saves time - no more stopping, screwing and unscrewing 2 pieces to move the device

- plastic - no metal components - helps minimize damage to hydrophilic coating and polymer jacket

- size preference: guide wires from .025" to .040" or from .010" to .020"



Conclusions/action items:

- Think about how to incorporate working parts of this design in line with our specifications for our product.

- This product will be used in the same setting as what our device would be used in.

- Look into patents and health-related specifications for a product as such.

https://www.merit.com/cardiac-intervention/angiography/guide-wire-accessories/h2o-torq-torque-device/#toggle-id-1-closed

SPINR

SERENA RAVAL - Sep 19, 2021, 9:14 PM CDT

Title: SPINR - HIGH-PERFORMANCE GUIDE WIRE CONTROLLER

Date: 09/19/2021

Content by: Serena Raval

Present: n/a

Goals: Learn about an existing product that aims to aid a catheter based procedure.

Content:

- Providing a wide range of versatility, the clinician can easily and precisely adjust rotational speed.

- Precision Control – Manipulate guide wire at adjustable speeds from 0 to 2,500 RPM

- Versatility – Intended for a wide range of procedures in both coronary and peripheral vasculature

- Adaptability – Compatible with your preferred high-torque 0.014”- 0.038” guide wire

- Time saver – Faster than traditional torque devices

- Cost saver – Less expensive than comparable electromechanical devices

Conclusions/action items:

- reflect on our product design and how we can compare factors such as control, versatility, adaptability, and time and cost saving into our plan

- this product is used in the same setting as what ours will be used in so look further into physical properties that allow for a product as such to be safely used in a surgery setting.

https://www.merit.com/cardiac-intervention/angiography/guide-wire-accessories/h2o-torq-torque-device/#toggle-id-1-closed

Angio Assist

SERENA RAVAL - Sep 23, 2021, 10:00 AM CDT

SERENA RAVAL - Sep 23, 2021, 10:04 AM CDT

Title: Angio Assist

Date: 09/23/2021

Content by: Serena Raval

Present: n/a

Goals: Understand how a pre-existing catheter organization device works functionally.

Content:

The Angio Assist™ Docking Station facilitates the introduction of guidewires into catheters and atherectomy burrs

- Friction-fit guidewire holder simplifies single-operator procedures
- Catheter loading area eliminates the need to touch or hold the stent during guidewire loading
- Two slots facilitate alignment and introduction of 0.014” guidewires into catheters
- Three grooves facilitate alignment and introduction of 0.014” guidewires into 1.25 mm–2.25 mm atherectomy burrs
- Designed with easy-to-use pinch clips for securing to drapes

“Interventional Accessories: US.” *Teleflex*, Apr. 2018, teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html.

Conclusions/action items:

Consider specific standards of working design when designing new product.

Teirstein Edge

SERENA RAVAL - Sep 23, 2021, 10:06 AM CDT

Title: Tierstein Edge

Date: 09/23/2021

Content by: Serena Raval

Present: n/a

Goals: Understand how a pre-existing catheter organization device works functionally.

Content:

The Teirstein Edge™ Device Organizer neatly organizes guidewires and catheters during interventional procedures

- Six friction fit slits secure guidewires and catheters
- Designed to minimize loss of guidewire position during procedure by tightly securing the wire in place
- Allows for controlled, micro movements of catheters and wires
- Provide easy-to-identify guidewire and catheter location for individual vessels
- Designed with easy-to-use pinch clips for securing to drapes

“Interventional Accessories: US.” *Teleflex*, Apr. 2018, teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html.

Conclusions/action items:

Consider specific standards of working design when designing new product.

09/17/2021 Client Introduction Meeting

SERENA RAVAL - Sep 17, 2021, 5:05 PM CDT

Title: Client Introduction Meeting

Date: 09/17/2021

Content by: Serena Raval

Present: Addie, Alex, Soniya, Tatum and Dr. Y

Goals: (1) Better understand what project Dr. Y is asking the team to work on.

(2) Create a team - client relationship.

(3) Ask Dr. Y initial questions about project background and future work.

Content:

1. Dr. Dai Yamanouchi - Vascular Surgeon at UW-Hospital
2. Catheter based procedures = needle into artery
3. Endovascular Procedure Background:
    1. Wire through needle to reach artery and then target vessel.
    2. Typically the target vessel is blocked so the wire has to get through the blocked region.
    3. **Catheter will enter blocked region** of the artery, blow up a balloon to open up the region, and then bring a **stent into the region to keep the vessel open**.
4. Blood pressure types to note: **systolic blood pressur**e (measures pressure in arteries when heart beats) and **diastolic blood pressure** (measures pressure in arteries when heart rests- between beats).

Goal of Project: Create a prototype / proof of concept of a wire and catheter holder with easy handling, storing and organizing during complicated procedures.

Resources: 3D printing, provided catheters and wires.

Size constraints: less than an inch depth, circular wheel size of dinner plate, lightweight, plastic that is sterilizable and biocompatible - should function as commercial product. 0.035 in wire, 0.018 in wire, and smallest, 0.014 in wire.

Conclusions/action items:

1. Begin research process on types of products as such that already exist.
2. Look into sterilizable and biocompatible materials that we could create our prototype with that would be testable in a hospital setting.
3. Brainstorm ways to follow Dr. Y's pre-existing plans.
4. Think about intellectual property patents and protecting research ideas.

Potential Materials

SERENA RAVAL - Sep 19, 2021, 9:17 PM CDT

SERENA RAVAL - Sep 19, 2021, 9:25 PM CDT

Title: Potential Materials

Date: 09/19/2021

Content by: Serena Raval

Present: n/a

Goals: Look into materials that we could potentially prototype with as well as use in a prototype that is able to be safely tested in a surgical setting.

Content:

Common sterilizing methods include:

- EtO (gas)–a chemical steriliant small enough to penetrate the microbial cells that destroying nuclear cell components
- 70/30 Alcohol
- **Cidex** (Activated Dialdehyde solution)
- Autoclaving (wet 121°C, 15PSI for 30 minutes)–Before autoclaving, verify that the caps are properly loosened or removed to prevent any accidental implosion. Carefully clean the items with distilled water before autoclaving, because some chemicals that are inert on plastic resins at room temperature causes deterioration at high temperatures.

This table shows a variety of materials and offers general guidelines for sterilizing parts manufactured from these materials.

Material	Autoclave	Max Temp	Brittle Temp	Appearance	Notes
Acrylic (PMMA)	no	50°C	20°C	Clear	Alcohol causes crazing and weakening
Fluoroelastomer Tubing (LPF)	yes*				*Once on a wet cycle
HDPE	no	120°C	-100°C	Translucent	High density polyethylene
LPDE	no	80°C	-100°C	Translucent	Low density polyethylene
Nylon	no				
PFA	yes				Can be autoclaved repeatedly at 121°C/15PSI, 15 min. cycles
Polyacetal	yes				Can be sterilized by EtO, steam and autoclave, but degrades under high energy radiation.
Polycarbonate (PC)	yes	135°C	-135°C	Transparent	Weakened by repeated autoclaving, and may not perform well in high stress applications like centrifuges. Rinse thoroughly before autoclaving, because detergent residues cause crazing and spotting. No more than 20min. at 121°C.
Polyester	no				Glass transition 80-85°C
Polyethylene (HPP) or HPP Tubing	no				
Polymethylpentene	yes				Can be autoclaved repeatedly at 121°C/15PSI, 15 min. cycles
Polypropylene	yes	135°C	0°C	Translucent	Can be autoclaved repeatedly at 121°C/15PSI, 15 min. cycles
Polypropylene copolymer	yes				Can be autoclaved repeatedly at 121°C/15PSI, 15 min. cycles
Polystyrene (PS)	no	90°C	-40°C	Clear	

Polysulfone (PSF)	yes				Weakened by repeated autoclaving
Polyurethane or Polyurethane tubing	no				This tubing is used in kit 500890
Polyvinyl Chloride (PVC)	no	70°C	-30°C	Clear	
PTFE (Teflon) or Teflon Tubing	yes	260°C	-100°C	Opaque	Can be repeatedly autoclaved. Do not run fluid through the tubing after autoclaving until the tubing has cooled to room temperature.
Silicone	yes				
Silicone tubing	yes*				*Once on a wet cycle (PeriStar Pro tubing)
Vinyl tubing	no	70°C	-30°C	Clear	No organic solvents
Viton	yes				

Fulghum, Lisa. “Sterilizing Plastic Parts and Pieces.” *World Precision Instruments*, World Precision Instruments, 3 June 2020, www.wpiinc.com/blog/post/sterilizing-plastic-parts-and-pieces.

Conclusions/action items:

- consider types of these materials for prototyping.

- ask client for preferred materials or any reccomendations.

What is a Catheter

SERENA RAVAL - Oct 08, 2021, 1:44 PM CDT

Title: Cardiac Catheterization

Date: 10/08/2021

Content by: Serena Raval

Present: n/a

Goals: Fully understand a Cardiac Catheterization with personal research to compare to what Dr. Y has explained to our team and the product he has asked our team to construct.

Content:

Cardiac catheterization is used to:

- Evaluate or confirm the presence of coronary artery disease, valve disease or disease of the aorta
- Evaluate heart muscle function
- Determine the need for further treatment (such as an interventional procedure or coronary artery bypass graft, or CABG, surgery)

Process of a cardiac catheterization:

1. a long, narrow tube called a catheter is inserted through a plastic introducer sheath (a short, hollow tube that is inserted into a blood vessel in your leg or arm)
2. the catheter is guided through the blood vessel to the coronary arteries with the aid of a special x-ray machine
3. Coronary Angiogram: *contrast material* is injected through the catheter and x-ray movies are created as the *contrast material* moves through the heart's chambers, valves and major vessels..
4. the coronary artery is opened, increasing blood flow to the heart
5. digital photographs of the *contrast material* are used to identify the site of the narrowing or blockage in the coronary artery

Additional imaging procedures:

- intra-vascular ultrasound (IVUS): a miniature sound-probe (transducer) is positioned on the tip of a coronary catheter. The catheter is threaded through the coronary arteries and, using high-frequency sound waves, produces detailed images of the inside walls of the arteries. IVUS produces an accurate picture of the location and extent of plaque.
- fractional flow reserve (FFR): a special wire is threaded through the artery and a vasodilator medication is given. This test is functionally performing a very high quality stress test for a short segment of the artery.

"Cardiac Catheterization: Procedure, Preparation, Duration & Risks." *Cleveland Clinic*, 14 May 2019, https://my.clevelandclinic.org/health/diagnostics/16832-cardiac-catheterization.

Conclusions/action items:

With the additional knowledge that I have gained of Catheter's, I am now able to better understand the environment in which our product will be used.

Relevant Biology and Chemistry

SERENA RAVAL - Dec 14, 2021, 4:13 PM CST

Title: Relevant Biology and Chemistry

Date: 12/14/2021

Content by: Serena Raval

Goals:

I will specify any relevant biology and/or chemistry in our project design process.

Content:

There is no relevant chemistry for our project because we are solely prototyping, and not creating a final design. If we did extend our project beyond this semester, we would have to look at biocompatible materials.

Conclusions/action items:

None.

Tatum's Design

SERENA RAVAL - Oct 08, 2021, 12:56 PM CDT

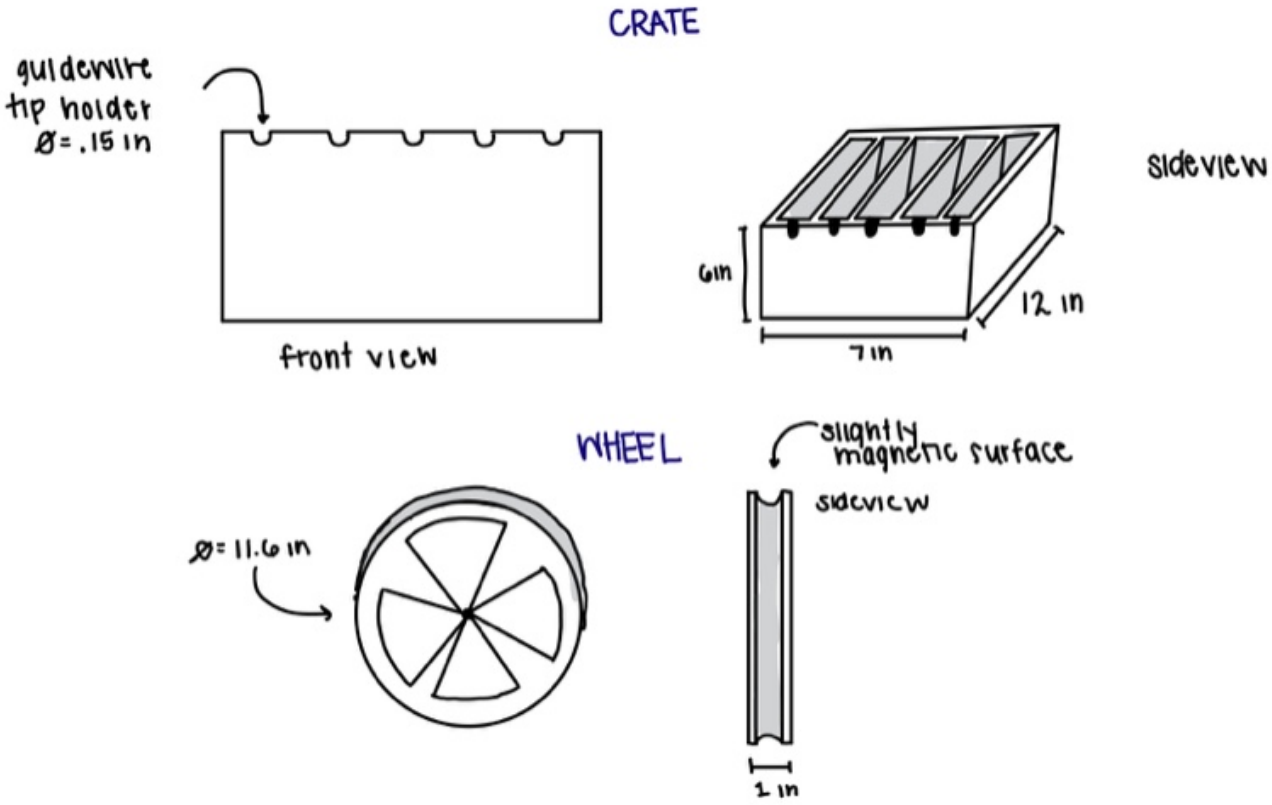
Title: Preliminary design

Date: 10/01/2021

Content by: Tatum Rubald

Goals: Magnet Wheel

Content:



Conclusions/action items:

Modify design with team. Ask Tatum Clarifying questions

Design Matrix

SERENA RAVAL - Oct 08, 2021, 1:04 PM CDT

Title: Design Matrix

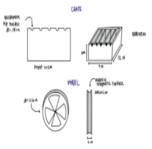
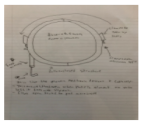
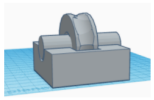
Date: 09/30/2021

Content by: Serena Raval

Present: All Team

Goals: Understand the design matrix to then move on forward with a prototype

Content:

Design	 Magnetic wheel		 Clamped Wheel		 Wheel of Magic			
Feasibility (30%)	5/5	30	3/5	18	5/5	30	5/5	30
Efficiency (25%)	5/5	25	4/5	20	2/5	10	5/5	25
Durability (20%)	2/5	8	3/5	12	3/5	12	3/5	12
Safety (10%)	5/5	10	5/5	10	5/5	10	5/5	10
Learning Curve (10%)	5/5	10	4/5	8	5/5	10	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5	5/5	5
Total for each design:	**86**		**73**		**77**		**92**	

Conclusions/action items: We see that the guidewire organizer that is the best design is the magnetic wheel. We will now need to begin prototyping this device and that way we can test the product in future steps of the design process.

Final Design

SERENA RAVAL - Oct 08, 2021, 1:14 PM CDT

Title: Final Design

Date: 10/08/2021

Content by: Serena Raval

Present: All team

Goals: Fully understand at team meeting how the final design works and go over preliminary presentation.

Content:

1. The guidewire is simultaneously pulled from its pre-packaged plastic casing and inserted into the patient
2. Once the guidewire is done being used inside the body, it is removed from the patient

It is my understanding that you are asking for a device to hold guidewires after steps 1 and 2 are completed, meaning that the guidewire is no longer in its plastic casing.

The device we are creating hold guidewires and organize them after being in the body, in the case that they must be used again. However, at this point, they are used without the plastic casing.

Guidewire Organizer Dimensions

SERENA RAVAL - Dec 14, 2021, 4:14 PM CST

Title: Serena Raval

Date: 10/14/2021

Content by: Serena Raval

Present: n/a

Goals: dimensional analysis of the guidewire organizer and gudewire

Content:

- guidewire organizer must hold guidewire sizes ranging from 0.014 to 0.035 inch
- the size of the organizer must be ensure that the organizer is lightweight and easy to store
- diameter of the wheel is 11.8 inches
- the crate for storing the wheels will be 12x7x6 in

Conclusions/action items:

use the dimensions create a final design

9/29/21-Guidewire Function in O.R

SONIYA PATEL - Oct 16, 2021, 4:58 PM CDT

Title: Guidewire Function in the Operating Room

Date: 9/29/21

Content by: Soniya Patel

Present: n/a

Goals: to understand how guidewires can be used in endovascular procedures

Content:

- Dr.Nora performs endovascular operating procedure using guidewire
  - Endovascular repair for aortic aneurysm which occurs when the aorta beneath the renal arteries and above the Illiac arteries has dilated. These aneurysms can rupture cause internal hemorage.
- advantages of endovascular repairs using a guidewire
  - less invasive
  - less blood loss/clots
  - faster recovery
- showed the insertion of guidewire into the patient as well as the removal of the guidewire after completion

citation:

UWHealthWI, “Endovascular repair for aortic aneurysms,” *YouTube*, 17-Feb-2015. [Online]. Available: https://www.youtube.com/watch?v=Y2a_cYvpf_U. [Accessed: 16-Oct-2021].

Conclusions/action items:

The recorded surgical procedure showed a specific example of a guidewire used in the operating room. I will continue to research more about how the guidewire is used in an operating room setting.

9/28/21-Biocompatible Materials

SONIYA PATEL - Oct 16, 2021, 4:19 PM CDT

Title: Biocompatible Materials

Date: 9/28/21

Content by: Soniya Patel

Present: n/a

Goals: determine what materials are safe to use for our device

Content:

Article: "Overview of Biomaterials and Their use in Medical Devices"

- some example categories of of biomaterials and their uses
    - Metals and alloys
        - 316L stainless Steel - fracture fixture, stents, surgical instruments
        - ni-Ti - bone plates, stents
    - Ceramics and glasses
        - alluminia - joint replacement, dental implants
        - carbons - percutaneous devices, heart valves
    - Polymers
    - Composites
- article provided in depth description of each type of material and their uses in medicine
- important mechanical properties of a biomaterial
    - elasticity
    - yield stress
    - ductility
    - toughness
    - time dependent deformation
    - creep
    - ultimate strength
    - fatigue strength
    - hardness
    - wear resistance
- important manufacturing details of a biomaterial
    - fabrication methods
    - consistency and conformity to all requirements
    - quality of raw materials
    - superior techniques to obtain excellent surface finish or texture
    - capability of material to get safe and efficient sterilization
    - cost of product
- compatibility aspects of a biomaterial
    - tissue reactions
    - change in properties
        - mechanical, physical, and chemical
    - degradation leads to
        - local deleterious changes
        - harmful systemic effects

citation:

“Overview of biomaterials and their use in medical devices.” [Online]. Available: https://www.asminternational.org/documents/10192/1849770/06974G_Chapter_1.pdf. [Accessed: 16-Oct-2021].

Conclusions/action items:

The guidewire organizer our team has set out to design will not be placed inside the patient at any time, only the Guidewire will be inserted into the patient. Therefore, we only need to worry about finding materials to use for our device that will withstand chemical sterilization of medical devices in the operating room. We should also keep in mind that our client prefers if our device is lightweight. Our team should discuss possible materials that are safe to use with Dr.Y.

10/15/21-Parts of a Guidewire

SONIYA PATEL - Oct 16, 2021, 4:27 PM CDT

Title: Parts of a Guidewire

Date: 10/15/21

Content by: Soniya Patel

Present: n/a

Goals: to learn about the different parts that make up the guidewire

Content:

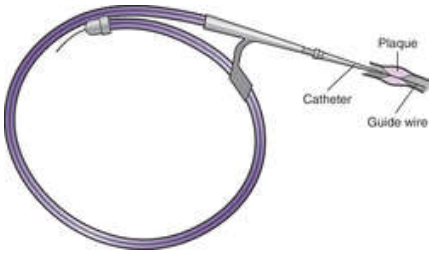


figure 1 - Shows a picture of a guidewire and catheter with labels

Conclusions/action items:

Use this knowledge to start designing a draft design for the guidewire organizer. Continue researching more about the functionality of the guidewire in the OR.

12/14/21 - Chemistry

SONIYA PATEL - Dec 14, 2021, 2:20 PM CST

Title: Chemistry

Date: 10/14/21

Content by: Soniya Patel

Present: n/a

Goals: discuss chemistry involved in project

Content:

For our project, we did not have to work with any chemicas. Neither did we have to worry about chemistry while designing our device. Since our device needed to be 3D printed for proof of concept, the device was not made from medical grade material. Under normal circumstances, we would need to test if the device would be able to withstand chemical sterilization.

Conclusions/action items:

disucss with group about materials

12/14/21 - Physics

SONIYA PATEL - Dec 14, 2021, 12:26 PM CST

Title: Physics

Date: 12/14/21

Content by: Soniya Patel

Present: N/a

Goals: describe how we took into account physics properties while designing guidewire wheel

Content:

- the guidewire will remain in place in the wheel due to the radial force of the guidewire (in its coiled form)
- the radial force presses against the inner rim of the wheel keeping the guidewire stationed within the whell while staionary or moving
- additonally, there will be magents in the inner rim of the wheel, that will ensure the guidewire will stick in the wheel

Conclusions/action items:

- buy magnet for guidewire wheel
- detemrine which size radius would be best to keep guideiwres with varying stiffness in wheel

9/29/21- Angio Assist Docking System

SONIYA PATEL - Sep 29, 2021, 8:14 PM CDT

Title: Angio Assist Docking System

Date: 9/29/21

Content by: Soniya Patel

Present: n/a

Goals: To learn about the functionality of Angio Assist Docking System, a competing design for the Guidewire Organizer.

Content:

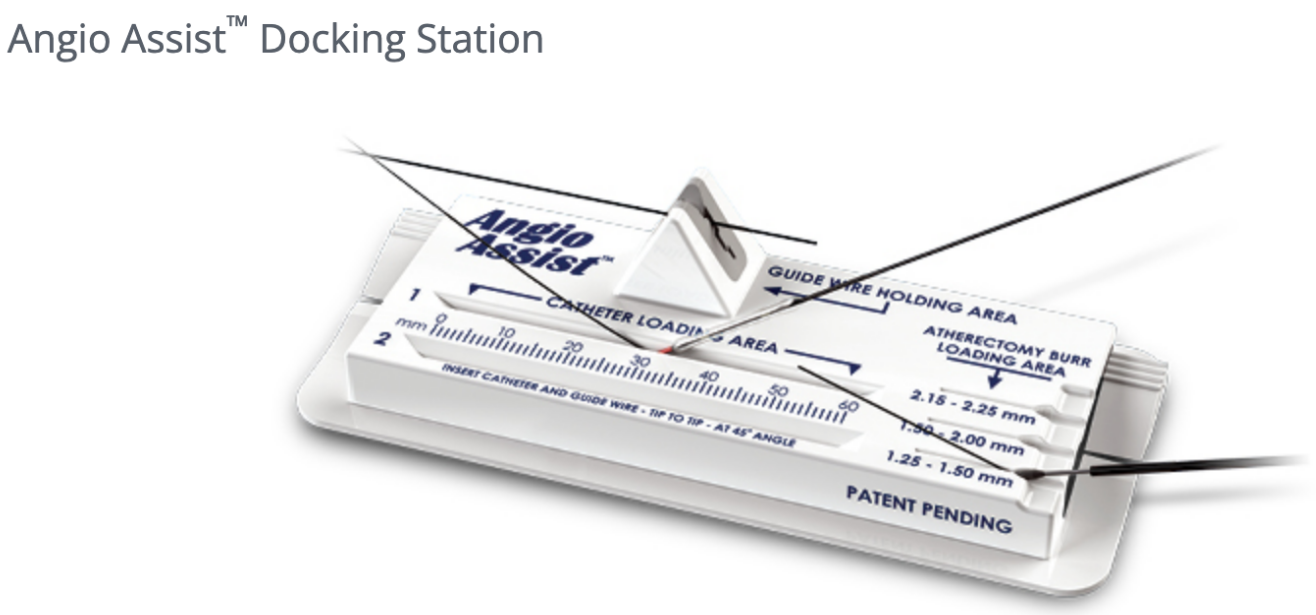


figure 1: depicts an image of the Angio Assist Docking Station

- company: Teleflex
- The Angio Assist™ Docking Station facilitates the introduction of guidewires into catheters and atherectomy burrs
- Friction-fit guidewire holder simplifies single-operator procedures
- Catheter loading area eliminates the need to touch or hold the stent during guidewire loading
- Two slots facilitate alignment and introduction of 0.014” guidewires into catheters
- Three grooves facilitate alignment and introduction of 0.014” guidewires into 1.25 mm–2.25 mm atherectomy burrs
- Designed with easy-to-use pinch clips for securing to drapes

citation:

“Interventional accessories: US,” *Teleflex*. [Online]. Available: https://teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html. [Accessed: 30-Sep-2021].

Conclusions/action items:

The Angio Assist Docking System is intended to load and stabilize guidewires and catheters during endovascular procedures. This design allows for loading of wire without touching or holding the stent. Our team can look into possibly adding the easy to pinch clips to our design.

9/29/21 - Teirstein Edge Device Organizer

SONIYA PATEL - Sep 29, 2021, 8:21 PM CDT

Title: Teirstein Edge Device Organizer

Date: 9/29/2021

Content by: Soniya Patel

Present: n/a

Goals: To understand how the Teirstein Edge Device Organizer, a competing design, functions in an operating room.

Content:

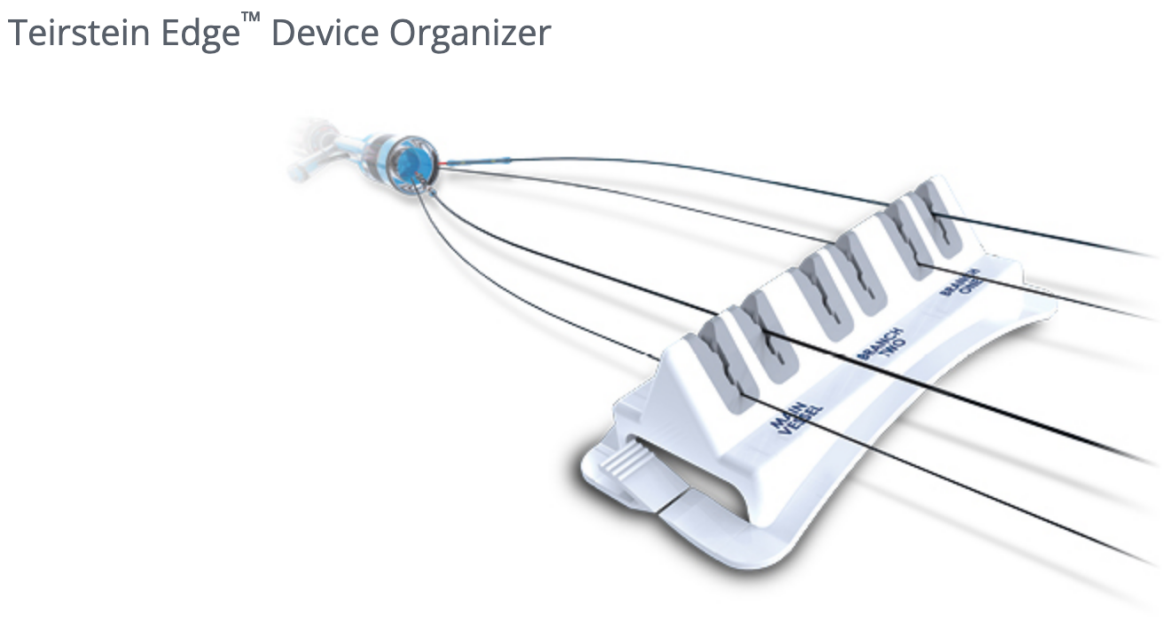


figure 1: depicts an image of the Teirstein Edge Device Organizer along with the guidewires & catheter attached

- Main function - The Teirstein Edge™ Device Organizer neatly organizes guidewires and catheters during interventional procedures
- Six friction fit slits secure guidewires and catheters
- Designed to minimize loss of guidewire position during procedure by tightly securing the wire in place
- Allows for controlled, micro movements of catheters and wires
- Provide easy-to-identify guidewire and catheter location for individual vessels
- Designed with easy-to-use pinch clips for securing to drapes

citation:

"Interventional accessories: US," *Teleflex*. [Online]. Available: https://teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html. [Accessed: 30-Sep-2021].

Conclusions/action items:

The Teirstein Edge Device Organizer is intended to load and stabilize guidewires and catheters during endovascular procedures. The device allows the wire to be securely clipped into place through 6 friction fit slits. The orientation of the slits allows the wires to remain organize as well as allow for controlled micro movements of wire. Our team should think about adding frictionless slits/holders made of rubber like material so the guidewire's movement can be small and controlled.

9/17/21 - Client Meeting 1

SONIYA PATEL - Sep 19, 2021, 12:32 PM CDT

Title: Client Meeting #1

Date: 9/17/21

Content by: Soniya Patel

Present: Addison, Tatum, Serena, Alex

Goals: Discuss the project goals with Dr.Y and ask any questions we may have about his project.

Content:

Project name : Wire and Catheter holder with easy handling, storing, and organizing during complexed procedure

1. physical and operational characteristics

- performance requirements: must be able to hold/organize wire and catheter during complex endovascular procedures.
- Safety: patient safety
- Accuracy and reliability: ?
- Life in Service: ?
- Shelf Life: ?
- Operating environment: must be compatible with operating room environment
- Ergonomics: forces from magnet, people, wire
- Size: 0.35, 0.018, 0.014 wire
- Weight: should ideally be lightweight
- Materials: biocompatible material; holder should be made of lightweight material.
- Aesthetics, Appearance, and Colors: tbd

2. production characteristics

- quantity: 1- 2 prototyped holders. need one wire
- target product cost: tbd

3. Miscellaneous

- standards and specifications:
- Customer:
- Patient Related Concerns:
- Competition:

Conclusions/action items:

In this client meeting, Dr.Y provided a detailed overview of the project we will be working on. Dr.Y excepts us to design and prototype a Wire and Catheter holder with easy handling, storage, and organizing during complex procedures. Dr.Y also wants us to provide proof of concept for our design. To conclude the meeting, our team and Dr.Y discussed possible future plans in designing a finalized product.

Using the information we compiled through our initial meeting with Dr.Y, our team must start drafting the product design specification. Our team also needs to get together and meet outside of lab times this week.

9/24/21 - Team Meeting 1

SONIYA PATEL - Oct 01, 2021, 2:25 PM CDT

Title: Team Meeting 1

Date: 9/24/21

Content by: Soniya Patel

Present: Tatum, Addie, Soniya

Goals: go through and edit PDS document

Content:

Conclusions/action items:

9/30/21 Team Meeting 2

SONIYA PATEL - Oct 04, 2021, 4:34 PM CDT

Title: Team Meeting 2

Date: 9/30/21

Content by: Soniya Patel

Present: could not attend due to class conflicts

Goals: review design matrix

Content:

** insert design matrix doc

Conclusions/action items:

10/01/21 - Team Meeting 3

SONIYA PATEL - Oct 19, 2021, 11:29 PM CDT

Title: Team Meeting 3

Date: 10/1/21

Content by: Soniya Patel

Present:

Goals: discuss oral preliminary presentation and assign roles for powerpoint

Content:

- assigned sections of the presentation to complete by thursday
    - soniya - competing designs and PDS
    - tatum- problem statement,
    - serena- future work
    - alex- desgin matrix
    - scottie- design ideas
    - addie - background

Conclusions/action items:

Have your assigned section of presentation completed by Thursday. Make sure to include speaker notes in presentation. Once everyone completes their section, our team can meet and edit it and practice presenting

10/8/21 Team Meeting 4

SONIYA PATEL - Oct 08, 2021, 1:35 PM CDT

Title: Team Meeting 4

Date: 10/8/21

Content by: Soniya Patel

Present: All team members

Goals:

1. make sure everyone is one same page about how to use our device

2. have everyone look at new design

3. go over slides. Ensure everyone is talking about the crate where need-be

Content:

How the device is used:

1. The guidewire is simultaneously pulled from its pre-packaged plastic casing and inserted into the patient
2. once the guidewire is done being used inside the body, it is removed from the patient

Conclusions/action items:

- finish editing preliminary design presentation and practice presenting

10/14/21 - 1 on 1 Meeting

SONIYA PATEL - Oct 16, 2021, 3:54 PM CDT

Title: Meeting

Date: 10/14/21

Content by: Soniya Patel

Present: Tatum, Soniya

Goals: 1 on 1 meeting to go over what In missed in last team meeting

Content:

- edited my preliminary presentation slides
- reviewed the presentation as a whole

Conclusions/action items:

finish preparing for presentation tomorrow

10/18/21 - Team Meeting 5

SONIYA PATEL - Oct 19, 2021, 11:18 PM CDT

Title: Team Meeting 5

Date: 10/18/21

Content by: Soniya Patel

Present: Soniya, Serena, Alex, Tatum, Addie, Scottie

Goals: to complete our preliminary design document

Content:

- each person was assigned a section to complete

- I worked on the PDS and Competing design portion

Conclusions/action items:

edit the document once everyone was done and submit before deadline

10/01/21 - Advisor Meeting 2

SONIYA PATEL - Oct 01, 2021, 1:45 PM CDT

Title: Advisor Meeting #2

Date: 10/1/21

Content by: Soniya Patel

Present: all team members

Goals: Touch base with Dr.Ludwig to talk about PDS, Design Matrix, and oral presentation

Content:

- Discussed PDS
  - brainstormed possible testing methods
  - how to set up expirement
  - must provide quantatative data
  - need to fix "performance requirements" section of PDS
- Discussed design matrix
- oral presentations
  - new deadline
  - must upload slides, presentation is in person

Conclusions/action items:

begin working on preliminary design presentation. send Dr.Ludwig rough draft of presentation on thursday so he can provide feedback.

10/01/21 - BPAG Meeting

SONIYA PATEL - Oct 19, 2021, 11:38 PM CDT

Title: BPAG Meeting

Date: 10/1/21

Content by: Soniya Patel

Present: BPAG members

Goals: to learn the purchasing guidelines for BPAG

Content:

- general concept
  - get your client to pay for you
  - you pay and get reimbursed
- keep track of all your purchases
- list of vendors available to UW clients (in powerpoint)
- reimbursement
  - only BPAG will be reimbursed
  - must provide hard copy receipts
  - 90 day rule
- create excel table for purchases

Conclusions/action items:

create excel spreadsheet for expenses

SONIYA PATEL - Oct 19, 2021, 11:38 PM CDT

BPAG_presentation.pdf(555.4 KB) - download

12/5/21 Social and Ethical Implications

SONIYA PATEL - Dec 14, 2021, 1:09 PM CST

Title: Social and Ethical Implications

Date: 12/5/21

Content by: Soniya Patel

Present: n/a

Goals: descirbe the social and ethical implications of our device

Content:

social implications of guidewire organizer: the social implication of our design include problems or matters that have a large influence over large population.

ethical implications of guidewire organizer: some ethical implications of our device incluce but are not limited to risk of distress, and potential injury/ physical harm to another individual (patient). If the guidewire is not contianed in the wheel during operating room procedures, it could cause potential harm.

Conclusions/action items:

take into account social and ethical implicaitons when finalizing design

12/8/21 - Planned Testing Methods

SONIYA PATEL - Dec 14, 2021, 2:09 PM CST

Title: Planned Testing Methods

Date: 12/14/21

Content by: soniya patel

Present: n/a

Goals: discuss/plan testing methods

Content:

tesitng protocol :

1. give prototype and guidewire to tester
2. participant will insert guiewire into device in a specific way (will be instructed how to do so)
3. time how long it takes to load guidewire into device (record time in excel file)
4. participant will take wire out of device
5. time how long it takes to unload guidewire out of device (record in excel file)
6. observe if the guidewire gets tangled or disoriented at all (if gets tangled, 1 will be entered into data table, otherwirse you will record 0)
7. Lastly, test original/current guidewire casing device. time loading and unloading of guidewire (record time in excel file)

note: both the stiff and soft guidewire will be tested by timing the loading and unloading of the guidewire into our device. later, data analysis will be conducted in order to detemrine the statistical significance of all of our data in the excel sheet

Conclusions/action items:

- discuss testing protocol with advisor and carry out methods next meeting

- once testing is completed, run anova and analyze the results

12/9/21 - Plan for Data Analysis

SONIYA PATEL - Dec 14, 2021, 2:07 PM CST

Title: Plan for Data Analysis

Date: 12/9/21

Content by: Soniya Patel

Present: n/a

Goals: describe how we are going to analyze data to determine statistical significance

Content:

- use anova to test data

- compare the loading our device to loading of original guidewire casing
- compare unloading of our device to loading of original guidewire casing
- determine significance of data by looking at p values
- if p <= 0.05 then significant, reject null hypothesis
- if p >=0.05 then not significant , accept null hypothesis

Conclusions/action items:

put data into anova and analyze results

10/15/21-Design 1 Magnetic Wheel

SONIYA PATEL - Oct 16, 2021, 4:37 PM CDT

Title: Design 1 - Magnetic Wheel

Date:

Content by: Soniya Patel

Present: n/a

Goals: explain magnetic wheel design

Content:

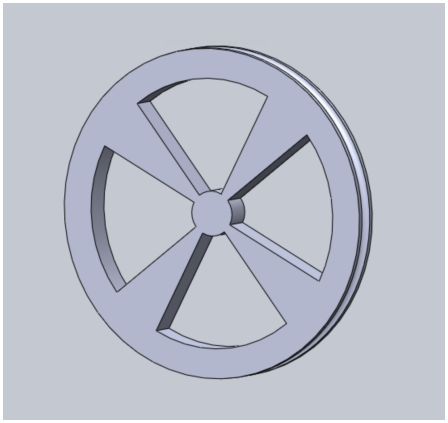


Figure 1: shows our teams magnetic wheel design.

- This design includes a magnetized wheel
- concaved lip around the perimeter to hold the guidewire
- wire spooled around the wheel

Conclusions/action items:

modify/go over design with team

10/15/21 - Design 2 Clamped Wheel

SONIYA PATEL - Oct 16, 2021, 4:47 PM CDT

Title: Design 2 - Clamped Wheel

Date:

Content by: Soniya Patel

Present: n/a

Goals: explain clamped wheel design

Content:

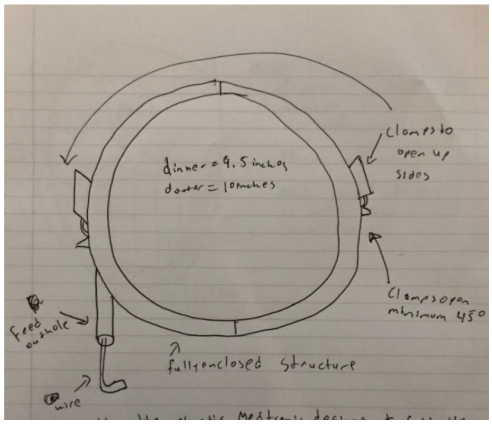


figure 1 - shows a pencil sketch of the clamped wheel design

- primarily plastic, hollow encasing on perimeter
- can be opened vertically for insertion of guidewire
- small opening for guidewire access

Conclusions/action items:

modify design with team

10/15/21 - Design 3 Wheel of Magic

SONIYA PATEL - Oct 16, 2021, 4:51 PM CDT

Title: Design 3 - Wheel of Magic

Date:

Content by: soniya patel

Present: n/a

Goals: explain the wheel of magic design

Content:

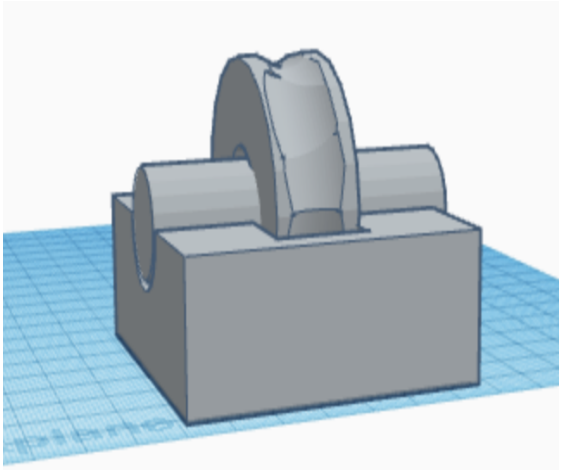


figure 1 - shows a 3D sketch of the Wheel of Magic design

- acts as a spool for guidewire
- guidewire access through the bottom encasing surrounding the wheel

Conclusions/action items:

modify/edit design with team

10/15/21 - Design 4 Guidewire Hoop

SONIYA PATEL - Oct 16, 2021, 4:54 PM CDT

Title: Design 4 - Guidewire hoop

Date:

Content by: Soniya Patel

Present: n/a

Goals: explain the Guidewire Hoop Design

Content:

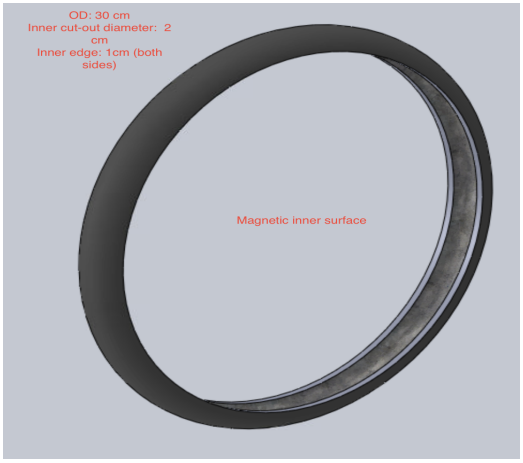


figure 1 - shows a 3D CAD sketch of the Guidewire Hoop Design

- magnetic hoop with internal concavity
- encased externally
- guidewire inserted in concave area along perimeter

Conclusions/action items:

modify/edit design with team

10/15/21 -Design Matrix

SONIYA PATEL - Oct 16, 2021, 4:57 PM CDT

Title: Design Matrix

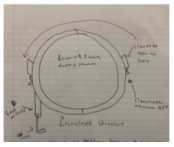
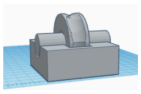
Date: 10/16/21

Content by: Soniya Patel

Present: n/a

Goals: present the design matrix

Content:

Design	 Magnetic wheel		 Clamped Wheel		 Wheel of Magic		 Guidewire Hoop	
Feasibility (30%)	4/5	24	3/5	18	4/5	24	5/5	30
Efficiency (25%)	3/5	15	4/5	20	2/5	10	5/5	25
Durability (20%)	3/5	12	3/5	12	3/5	12	4/5	16
Safety (10%)	5/5	10	5/5	10	5/5	10	5/5	10
Learning Curve (10%)	4/5	8	3/5	6	4/5	8	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5	4/5	4
Total for each design:	**72**		**71**		**69**		**95**	

Conclusions/action items:

The Guidewire Hoop design won as the best design given the scores in all the categories

10/1/21 - Guidewire Dimensions

SONIYA PATEL - Oct 19, 2021, 9:27 AM CDT

Title: Soniya Patel

Date: 10/1/21

Content by: Soniya Patel

Present: n/a

Goals: dimensional analysis of the guidewire organizer and gudewire

Content:

- guidewire organizer must hold guidewire sizes ranging from 0.014 to 0.035 inch
- the size of the organizer must be ensure that the organizer is lightweight and easy to store
- diameter of the wheel is 11.8 inches
- the crate for storing the wheels will be 12x7x6 in

Conclusions/action items:

use the dimensions create a final design

12/14/21 - 3D printing

SONIYA PATEL - Dec 14, 2021, 1:54 PM CST

Title: 3D printing

Date: 12/14

Content by: Soniya Patel

Present: n/a

Goals: 3D printing overview

Content:

client stipulated the device must be 3d printed for proof of concept

items that were 3D printed by our team:

- guiewire wheel prototype 1
  - original design prototype
  - diameter was too large (21 cm)
  - soft guidewire was falling out
- guidewire wheel prototype 2 -
  - printed another wheel, same design except smaller diameter (20cm)
  - guidewire fits better
- crate -
  - printed crate which holds up to 4 wheels
- guidewire wheel prototype 2
  - printed another wheel for poster presentation

Conclusions/action items:

prepare for poster presentation

2021/09/17 Cardiac Catheterization Biology

Alex PUDZISZ - Oct 19, 2021, 3:14 PM CDT

Title: Cardiac Catheterization Biology

Date: September 17th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To understand more about our project. We will be making the storage device for the wire used in this operation.

Search Term: Google Search: "Cardiac" AND "Catheterization"

Citation: “Cardiac catheterization,” *Johns Hopkins Medicine*. [Online]. Available: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/cardiac-catheterization. [Accessed: 17-Sep-2021].

Link: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/cardiac-catheterization

Content:

What happens during operation:

1. A wire is inserted into the blood vessel. The wire is then pathed up to the heart.

2. Once there it can do pressure measurements, take blood samples, or inject dye

3. While the wire is there other operations are possible such as: angioplasty, stent placement, fractional flow reverse, an intravascular ultrasound, or sample the heart tissue.

Reasons to have one done:

1. Clogged arteries, heart enlargement, congenital heart defects, heart failure, or heart valve disease

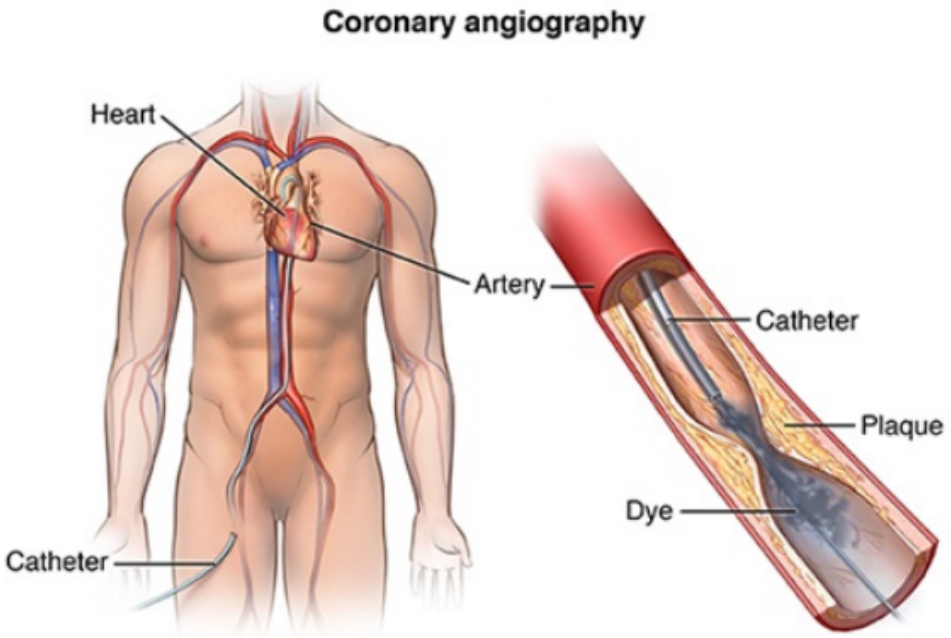
2. The symptoms that may lead a doctor towards it: chest pain, short of breath, dizzy, tiredness. (these all seem to suggest poor blood flow)

3. It can also be done after heart procedures and heart complications

Risks of the procedure:

-Bleeding and pain at injection site, infection, blockage or tear in artery, stroke

Picture below is from same source as cited for the contents section



Conclusions/action items:

Now I know what the wires function is and a common procedure with it. Now I can think more about the access of the wire. It does not seem like they will be changed out very often during the procedure, but the right one must be used. Organization may be more important. For now do more research into competing designs

2021/09/21 Cath Clip Competing Design

Alex PUDZISZ - Oct 19, 2021, 3:14 PM CDT

Title: Cath Clip Competing Design

Date: September 21st, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To learn more about Cath Clip and determine what is good or bad about it

Search Term: Google Search "Cath" AND "Clip"

Citation: “Dropped and damaged devices? Cathclip can help.,” *CathClip*. [Online]. Available: https://www.cathclip.com/. [Accessed: 21-Sep-2021].

Link: https://www.cathclip.com/

Content:

The device is very simple. It is a clip that guarantees that the wire does not move around. The device does not have a cost listed, however it comes in packs of 20. The pros of this device are that the device keeps the surgery area organized, and makes sure that there are not random wires on the floor. It is also small enough to fit into buckets, along with the wire, like shown above. The final pro is that it is incredibly simple to use and already used in over 20 hospitals in the US. The cons are that this is not what our client is looking for. Even in the bucket, it is still messy and wires can become tangled or hard to distinguish. The device the client wishes for must be stackable.The device also does not guarantee the size of the ring, which I am not sure matters. The final con is that it does not look to be sanitizable by easy but harsh means. That could be chemicals or extreme conditions.

Conclusions/action items:

This design is not what we can base our final project on. However, possibly adding a clip inside of the design can be put into consideration. I will keep looking for more competing designs.

2021/09/21 Japanese Holder Competing Design

Alex PUDZISZ - Oct 19, 2021, 3:25 PM CDT

Title: Japanese Holder Competing Design

Date: September 21st 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

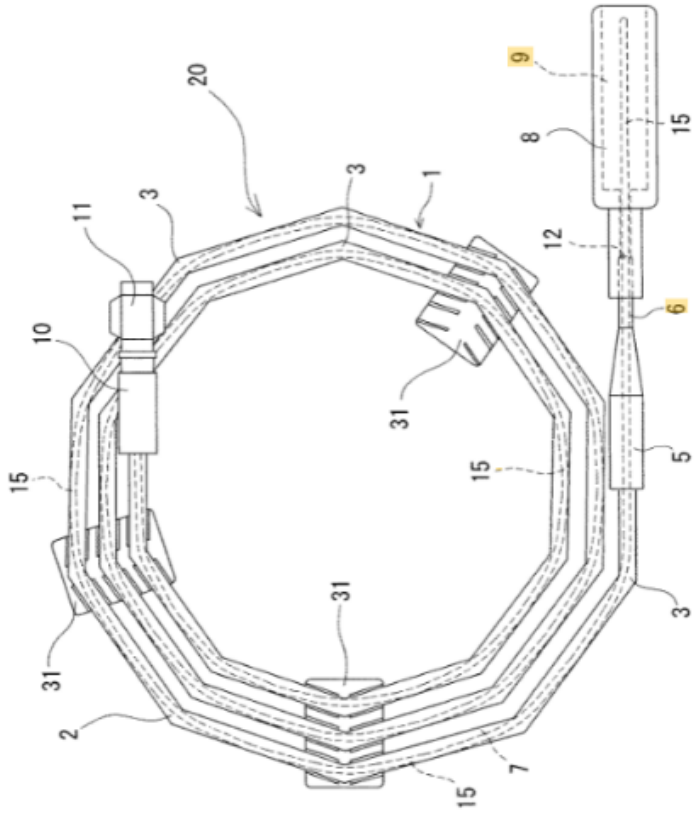
Goals: To learn more about this design and see the pros and cons in comparison to what we need

Search Term: Google Patents "Catheter" AND "Storage" AND "Wire"

Link: https://patents.google.com/patent/JP4280526B2/en?q=catheter+wire+holder&oq=catheter+wire+holder&page=1

Patent Number: JP4280526B2

Content:



This device is close to the most used storage device out there by Medtronic. I could not find the patent for that, so I found an innovation on their idea. The design is multiple loops that slowly get smaller. The catheter wire gets pushed through by point 8 and will slowly reach the center. The device is an improvement over the Medtronic device. This device coats the inside of the tube and used geometry to lessen the friction. One of the main problems with the Medtronic storage device is the large amount of friction when putting in or taking out the wire. One of the pros of this device, is that the doctor is already used to the original, so the slightly improved version will be very similar. Another pro is that the device does keep the wire organized and the loops of wire will always be the same size. This means that if someone wanted to make a storage device for these holders later it would likely be possible. There are a few cons with this device. The friction is still likely high. Although they got rid of part of the friction, the device does not claim to have gotten rid of most of the force required. This means that although it is easier to put in and take out it is still not easy. Another con is that the device is not symmetrical into and out of the page. This will lead to it being impossible to stack these holders. The final con is that the original method of inserting the wire and then pushing until it gets all the way through it still being used. The idea of our project is to make it faster and easier. This may be slightly easier, but by using the same method it is unlikely to get faster.

THERE IS A KEY POINT: GEOMETRY AFFECT FRICTION!

Conclusions/action items:

Keep in mind that the geometry of the device can have an impact on the friction. Look into the friction of different materials when it becomes relevant. Make my own design.

Alex PUDZISZ - Oct 19, 2021, 3:17 PM CDT

JP4280526B2_Patent_PDF.pdf(98.4 KB) - download

2021/09/23 Regulations and Standards Research

Alex PUDZISZ - Oct 19, 2021, 9:00 PM CDT

Title: Regulations and Standards Research

Date: September 23nd, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To find out what FDA standards we would need to make this a marketable project

Content:

There is only one way that I know of to find regulations. This is to go through the FDA and to search for similar products or product groupings. This product would likely be considered as a Class II medical device. This is because it does not cause great danger, but it is also part of the medical equipment in the procedural room. There is no direct FDA regulation for this device, so it will be assumed to follow the same rules as a guide wire kit and guidewire torque device [1, 2]. Both of these are Class II and require premarket approval in the form of a 510k. Normally we would be able to find an exact point of reference, but this item is almost always sold as a set. I tried looking into the regulations of things like Cath Clip, however it did not show and they are not fully patent ready yet. There may be a way to prove that it does not require premarket approval, but the team would need further guidance to determine if it is possible [3].

Sources:

[1] “Product classification,” accessdata.fda.gov. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=997. [Accessed: 23-Sep-2021].
[2] “Product classification,” accessdata.fda.gov. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=953. [Accessed: 23-Sep-2021].
[3] Center for Devices and Radiological Health, “Convenience Kits Interim Regulatory guidance,” U.S. Food and Drug Administration. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/convenience-kits-interim-regulatory-guidance. [Accessed: 23-Sep-2021].

Conclusions/action items:

Mark these regulations down inside of our PDS

2021/09/23 Guide Wire Storage Device Size Research

Alex PUDZISZ - Oct 19, 2021, 9:19 PM C

Title: Guide Wire Storage Device Size Research

Date: September 23, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To find out how big the outside of our device should be

Search Term: Google Search "Catheter" AND "WIRE" AND "HOLDER"

Link:https://www.dotmed.com/listing/disposables-general/medtronic/008418/ptfe-guide-wire,-160cm-(x)/2993028?utm_source=base&utm_medium=search&utm_campaign=Base&gclid=Cj0KCQjwqKuKBhCxARIsACf4XuHc3_OiUeVUkqSUC0EzCzyVlBQcEnz7hJgpC_qcjNE9VgAhG6uSbnMaAgoeEALw_v

Citation:"New medtronic 008418 PTFE Guide Wire, 160cm (x) disposables - general for sale - dotmed listing #2993028," DOTmed.com. [Online]. Available: https://www.dotmed.com/listing/disposables-general/medtronic/008418/ptfe-guide-wire,-160cm-(x)/2993028?utm_source=base&utm_medium=search&utm_campaign=Base&gclid=Cj0KCQjwqKuKBhCxARIsACf4XuHc3_OiUeVUkqSUC0EzCzyVlBQcEnz7hJgpC_qcjNE9VgAhG6uSbnMaAgoeEALw_v [Accessed: 23-Sep-2021].

Content:

I found that Medtronic usually has the wire storage device on the catheter wire prepackaged. I wanted to find out how large something that most surgeons have used was. In the citation above is given that the device is 160 cm long. There appears to be 2.5 loops before the device ends. This gives us a 160/2.5 = 64 cm per loop. Divide by pi to find the diameter and the device ends u being about 20 cm wide. Likely it would be a bit shorter due to my rough loop amount estimation. That means that our device should be about 8 inches wide.

Reference photo is attached.

Conclusions/action items:

Find an appropriate size for our own device

Alex PUDZISZ - Oct 19, 2021, 9:19 PM CDT

Screen_Shot_2021-10-19_at_9.19.09_PM.png(885.6 KB) - download

2021/09/27 Material Research

Alex PUDZISZ - Oct 19, 2021, 10:13 PM CDT

Title: Material Research

Date: September 27th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To find example materials for the project

Content:

This project will first be made out of plastics for the proof of concept, and the idea eventually is to make it out of medical grade steel. Below I will look into what the Makerspace has to offer for our plastic prototype. Afterwards, I will look into a couple of medical grade steels and which one would be most appropriate.

Link To MakerSpace Website: https://making.engr.wisc.edu/3d-printers/3dprint-cost/

Given the choices I will first eliminate a few. PLA tends to be brittle, so it will likely not be used as it can break more easily. PVA will also likely not be used as it can dissolve in water. This is not a property we want. Breakaway is meant to break, so again this is out. PP is flexible, which is again not a property we need. This means it give no advantages over the options that will be listed below. CPE is not needed as the prototype will not be under high temperature stress. Nylon will also likely not be used as it has less strength than the other options.

This leaves tough PLA and PC. Both are good options and I will talk to the team to see what preferences they have based on their properties and looks.

Next up is medical grade steel research.

Link:https://bergsen.com/medical-surgical-stainless-steel

Citation:“Medical Grade & Surgical Stainless Steel,” Bergsen Metal, 12-Jan-2021. [Online]. Available: https://bergsen.com/medical-surgical-stainless-steel. [Accessed: 27-Sep-2021].

This article talks about two types of medical grade steel 304 and 316. The difference in numbered steel is its composite that makes up the alloy. Regardless, it is the properties that matter. It says that 304 should be enough as it can be sterilized, however I believe 316 with its ability to resist harsh chemicals may be better. I will later have to research the cost of both of these steels. 316 does get used in surgical equipment, and if we wish to classify our device as one it may be best to use this.

Conclusions/action items:

Talk with the team about kind of material we want to use to print. Eventually talk with team about which steel to use.

2021/10/07 Chemistry In Project

Alex PUDZISZ - Oct 19, 2021, 10:47 PM CDT

Title: Chemistry In Project

Date: October 7th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Talk about the chemistry in our project

Content:

As of yet, we are not coating the prototype in any sort of chemical. The device in its steel form will not cause any chemical reactions, as it will likely be made of the same steel as surgical equipment. There is also no chemical testing or chemicals involved in the production of the prototype on our part. This leaves only one method using chemicals in this project, which is in cleaning or sterilizing the device. I will talk about how hospitals do so below.

Link:https://www.mindflowdesign.com/insights/chemical-resistance-of-plastics-in-hospitals/

Citation:A. Moulds, “How to choose plastics that will withstand harsh hospital cleaning processes,” Mindflow Design, 28-Apr-2021. [Online]. Available: https://www.mindflowdesign.com/insights/chemical-resistance-of-plastics-in-hospitals/. [Accessed: 07-Oct-2021].

The article talks about choosing plastics that will resist the harsh cleaning chemicals of hospitals. I will put a picture of the chemicals used in medical facilities under attachments. The article mentions that all plastics will crack and deform, but chemicals speed it up. Creep is when the plastic is exposed to constant force below its breaking point causing it to permanently deform. Cracks form in plastics around areas of imperfections. Mindflow (the website) does mention that they have a database of plastics vs chemicals (ranging from low to harsh). This may come in useful if we decide to send our prototype through a sterilization. It does mention that certain plastics should hold for years, even under chemical strain such as nylon 12, and pc+pet. I will have to take a look at the chemicals in the table attached below and see if any of them would affect steel. It is unlikely, however worth a check.

Conclusions/action items:

Look into the chemistry of coating the device / look for any more chemistry that could be involved.

Alex PUDZISZ - Oct 19, 2021, 10:47 PM CDT

Categories	Chemical	Use
Sterilants and high-level disinfectants	Formaldehyde (Formalin)	contact with body fluids
Sterilants and high-level disinfectants	Glutaraldehyde	High level disinfectant for medical equipment
Sterilants and high-level disinfectants	Ortho-phthalaldehyde (OPA)	–
Sterilants and high-level disinfectants	Hydrogen peroxide (H_2O_2)	surfaces
Sterilants and high-level disinfectants	Peracetic acid	–
Sterilants and high-level disinfectants	Hydrogen peroxide/peracetic acid combination	–
Intermediate-level disinfectants	Sodium Hypochlorite (Bleach)	blood
Intermediate-level disinfectants	Iodophors	antiseptic
Low-level disinfectants	Phenols	surfaces and non-critical medical devices
Low-level disinfectants	Quaternary ammonium compounds (Quats)	non-critical surfaces

'

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2021/10/13 Math In Project + 2021/12/14 Update

Alex PUDZISZ - Oct 19, 2021, 10:19 PM CDT

Title: Math in Project

Date: October 13th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To discuss what math can be used in our project.

Content:

There is little need for math inside of our project. There is no need to calculate for friction when practical tests will suit it far better. This means that testing it by hand will give much better data than guessing by arbitrary numbers. In the same account, there is not a need for integrals or higher level math in our project. The project is purely a proof of concept. The only math required will be for the statistics, the dimensions of the device, and the cost of the device. There is also the possibility of calculating force that our prototype can take, but for the current stage it is unnecessary. Finally, the last thing I can think of for math is to calculate the tension in the wire when it is inside of the guide wire hoop. This is just to ensure that no matter the weight of the wire it will stick. Overall I do not see a reason to involve higher level math in our project as of yet.

Conclusions/action items:

Finish lab notebook for notebook check.

Alex PUDZISZ - Dec 14, 2021, 4:47 PM CST

Title: Math in Project Update

Date: December 14th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To discuss what math was used in the project

Content:

We did not end up using any higher level math. There was no need to use friction, as the wires radial force (when large enough, already overcame the required force to keep the wire in place. The tricky part is that with softer wires we will need to in the future work on figuring out the tension produced. I still believe it to be better done by hand than be equation, as the wire will become more malleable over time (even a single semester).

Conclusions/action items:

Finish Final Notebook

2021/10/19 Engineering Ethics

Alex PUDZISZ - Oct 19, 2021, 3:50 PM CDT

Title: Abiding by Engineering Ethics

Date: October 19th 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: List the engineering ethics from the national society of professional engineers and say I am abiding by them

Search Term: Google Search "Engineering" AND "Ethics"

Citation: “Code of ethics,” *Code of Ethics | National Society of Professional Engineers*. [Online]. Available: https://www.nspe.org/resources/ethics/code-ethics. [Accessed: 19-Oct-2021].

Link: https://www.nspe.org/resources/ethics/code-ethics

Content:

The list of ethics on the website are as follows:

"I. Fundamental Canons
Engineers, in the fulfillment of their professional duties, shall:

1.Hold paramount the safety, health, and welfare of the public.
2.Perform services only in areas of their competence.
3.Issue public statements only in an objective and truthful manner.
4.Act for each employer or client as faithful agents or trustees.
5.Avoid deceptive acts.
6.Conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession."

I have not violated any of these ethics in my research or in my actions for this project this semester.

Conclusions/action items:

Continue abiding by the ethical guidelines.

2021/12/14 My Activity In Deliverables UPDATED

Alex PUDZISZ - Dec 14, 2021, 5:51 PM CST

Title: My Activity In Deliverables

Date: October 19th 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To write down my participation in the deliverable documents

Content:

PDS: Standards and Specifications, Quantity, Life in Service, Size, Materials

Design Matrix: Made clamped wheel design

Presentation: Design Matrix

Preliminary Report: Design Matrix and Evaluation Explanation, Testing

Testing: Came up with Test protocol and helped with Test 1, did Test 2 by myself

Poster: Progress Portion

Poster Presentation:Progress and description of device

Final Report: Testing and updating other sections.

Conclusions/action items:

None

2021/10/25 Physics in Project

Alex PUDZISZ - Dec 14, 2021, 4:55 PM CST

Title: Physics in Project

Date: October 25th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain physics in our project

Content:

There is not a lot of calculated physics in our project. The force that can be excerted on the casing of the prototype is irrelevent as it is a proof of concept. The medical grade steel that it will eventually be replaced with will be strong enough to support its cause (which is to simply be carried in a hosptial). Doing any calculations on a stress test for the prototype in a different material are pointless as it will never reach that point of use and it is not a selling point. Doing physics calculations such as radial force on the wire may give us a better idea of a starting point for the size of the wire holder, I believe it is probably better to allow the team to hold the wire and judge the size of the holder that way. That gives a better approximation for what someone at the hospital might be more comfortable with. We can always size it down later to increase radial force. The wire may also change due to being used and have less radial force later as it becomes used to bending.

Conclusions/action items:

None

2021/11/10 Impact Research

Alex PUDZISZ - Dec 14, 2021, 6:36 PM CST

Title: Impact Research

Date: 11/10/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Do research to understand more about the impact of our project

Content:

Search Term: Google Search "Hospital" AND "COST" AND "PER" AND "SURGERY"

Link:https://www.healthsystemtracker.org/chart-collection/how-do-healthcare-prices-and-use-in-the-u-s-compare-to-other-countries/

Citation: R. Kamal, and C. C., “How do healthcare prices and use in the U.S. compare to other countries?,” Peterson-KFF Health System Tracker, 25-Oct-2018. [Online]. Available: https://www.healthsystemtracker.org/chart-collection/how-do-healthcare-prices-and-use-in-the-u-s-compare-to-other-countries/. [Accessed: 10-Nov-2021].

The main point of this article is that surgeries in the USA cost more than almost anywhere else in the world. There is a lot of money that is spent every day when talking about this. Every minute that patients are in the hospital rack up more charges, and every minute is another minute a hospital could have another patient. In this case the cost of a coronary bypass in the US is over $60,000. Lowering this cost per patient would be very helpful if we could significantly reduce the time in the OR. Even if this is not possible, the less time someone spents cut open the better. There is less chance for infection or other complications. Below this rich text I will put a picture of USA costs for the aforementioned price vs other countries.

Search Term: Google Search "Hospital" AND "COST" AND "PER" AND "Minute"

Link:https://www.ajmc.com/view/what-are-the-implications-of-the-costs-of-operating-room-time

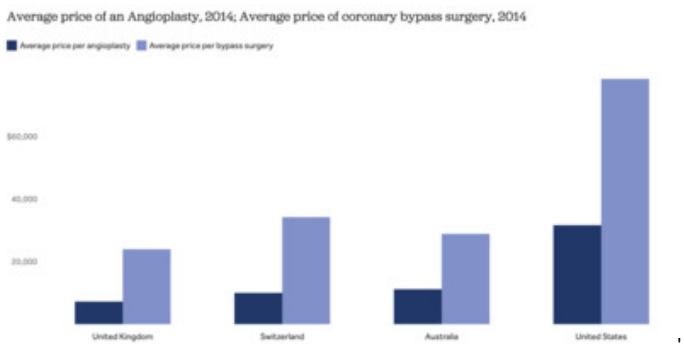
Citation: K. Ely, “What are the implications of the costs of operating room time?,” *AJMC*, 30-Jul-2020. [Online]. Available: https://www.ajmc.com/view/what-are-the-implications-of-the-costs-of-operating-room-time. [Accessed: 10-Dec-2021].

The average cost per minute in a hospital is between $36-7 in an OR. This is over double the minimum wage in WI per hour. That means that any time we reduce is incredibly beneficial for everyone, but moreso for low income households who will struggle even more substantially from the monetary burdens. The cost per minute is absurd, and it does not seem to vary across race or other factors.

Conclusions/action items:

Figure out how to maximize our impact / do more research on other impacts

Alex PUDZISZ - Dec 14, 2021, 6:36 PM CST



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2021/10/16 Planned Statistics And Testing

Alex PUDZISZ - Oct 19, 2021, 9:04 PM CDT

Title: Planned Statistics and Testing

Date: October 16th 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain one idea for testing and statistics to be taken from it

Content:

The idea would be to test using the protocol below. This would give us a baseline value for times and a time value for our product. This would also bring up any additional complications. The statistical test that can be run off of this is likely just a % difference across the averages. This would be the simplest and most obvious way to show a real change. We can also run tests if we have enough data points to ensure all the data points are valid, such as a t test or ANOVA. The hypothesis is that any device we make will have at least a 10% improvement over the original method.

Protocol:

1. Give prototype and guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
    1. Record time in notebook entry
5. Instruct participant to take wire out of the device
6. Start timer when participant is ready
7. Stop timer as the participant finishes taking wire out of the device
    1. Record time in notebook entry
8. Observe wire for any tangles or entwinements
    1. If obstructions exist record in notebook entry
9. Fill in table below as experiment is ran

Conclusions/action items:

Present to my advisor and ask if this seems right

2021/12/03 Statistics in Project

Alex PUDZISZ - Dec 14, 2021, 5:05 PM CST

Title: Statistics in Project

Date: 12/03/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To Explain Statistics in our project

Content:

Our team met with an alternate advisor, as Dr Ludwig was busy. We talked with him about the testing that we did and then we talked about our proposed statistical tests. The original plan was along the lines of doing a T-test and then doing a % improvement. After the call, however, as we changed from two tested groups to 4 it became that we had to do an ANOVA test. Tatum would do this as she was the best with statistics. We would also not do any statistical tests with the movement tests (as they are a yes or no answer and more qualitative). We will make them quanititative as we will mark the number of times it fails. The final plan is to do an ANOVA test and then add the percentage that it was changed by. The percentage change can be another statistic for the project

Conclusions/action items:

None

2021/12/13 Final Protocol

Alex PUDZISZ - Dec 14, 2021, 5:08 PM CST

Title: Final Testing Protocol

Date: 12/13/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To put my final protocol below

Content:

Instructions

Test 1: Loading and Unloading Instructions:

1. Give prototype and stiff guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
    1. Record time in notebook entry
5. Instruct participant to take wire out of the device
6. Start timer when participant is ready
7. Stop timer as the participant finishes taking wire out of the device
    1. Record time in notebook entry
8. Observe wire for any tangles or entwinements
    1. If obstructions exist record in notebook entry
9. Repeat Steps 1-8 an additional two times for a total of three trials
10. Repeat Steps 1-9 for soft guidewire
11. Repeat steps 1-10 with original catheter device

Test 2: Walking Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk on the same floor for a minimum of five minutes
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    1. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Test 2: Stairs Test Instructions:

1. Give prototype with guidewire preloaded to tester
2. Look at the wire to make sure that there is no wire entanglement
3. Instruct them to walk up and down five flights of stairs
4. Once they have done so, look at the wire to see if there is any new wire entanglement
    1. Record the results in notebook entry
5. Repeat steps 1-4 for a total of five trials

Conclusions/action items:

None

2021/12/03 Experiments / Testing Day

Alex PUDZISZ - Dec 14, 2021, 6:44 PM CST

Title: Experiments / Testing Day

Date: 12/03/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To write down how we tested and put down the raw data

Content:

There were two tests that were done. ALL EXPERIMENTS WERE DONE EXACTLY TO PROTOCOL (METHODICALLY). First a loading and unloading test of our device and the original. We were all at college library so it was easy. We paired into two's and then had one person time while the other followed the protocol. We collected all of the data (which I will paste below). We then tested the other type of wire with loading and unloading. The process was fast and smooth. The analysis will be done later. The second test I did by myself. It involved walking around my apartment building, both inside and outside, and the second half was walked up and down 5 flights of stairs. Doing the testing was very relaxing and the data looks perfect.

RAW DATA:

Test 1: Loading And Unloading Results Table:

Final Device			**Original Casing**		
Type Of Wire: Test #	**Loading Duration**	**Unloading Duration**	**Type Of Wire: Test #**	**Loading Duration**	**Unloading Duration**
Soft Wire: Test 1	27.26	1.21	Soft Wire: Test 1	25.96	8.44
Soft Wire: Test 2	37.4	0.73	Soft Wire: Test 2	22.32	8.41
Soft Wire: Test 3	26.4	1.26	Soft Wire: Test 3	22.73	9.13
Soft Wire: Test 4	23.12	0.8	Soft Wire: Test 4	25.7	9.54
Soft Wire: Test 5	17.29	0.93	Soft Wire: Test 5	23.43	9.53
Soft Wire: Test 6	21.43	0.78	Soft Wire: Test 6	20.68	10.16
Soft Wire: Test 7	25.62	1.11	Soft Wire: Test 7	21.85	9.11
Soft Wire: Test 8	23.63	1.19	Soft Wire: Test 8	22.71	7.53

Soft Wire: Test 9	19.92	1.04	Soft Wire: Test 9	22.96	5.69
Hard Wire: Test 1	28.37	0.35	Hard Wire: Test 1	24.45	7.78
Hard Wire: Test 2	13.95	1.15	Hard Wire: Test 2	19.7	7.79
Hard Wire: Test 3	25.56	1.35	Hard Wire: Test 3	18.49	11.03
Hard Wire: Test 4	13.47	0.98	Hard Wire: Test 4	20.01	10.39
Hard Wire: Test 5	18.19	1.23	Hard Wire: Test 5	19.45	10.6
Hard Wire: Test 6	15.94	1.24	Hard Wire: Test 6	19.23	7.93
Hard Wire: Test 7	14.43	1.74	Hard Wire: Test 7	24.1	11.51
Hard Wire: Test 8	13.51	1.53	Hard Wire: Test 8	21.48	9.52
Hard Wire: Test 9	14.83	0.68	Hard Wire: Test 9	21.75	9.21

Test 2: Walking and Stairs Test

Walking Test Trial #	Entanglement at Start?	Entanglement At End?	Stairs Test Trial #	Entanglement at Start?	Entanglement At End?
1	No	No	1	No	No
2	No	No	2	No	No
3	No	No	3	No	No
4	No	No	4	No	No
5	No	No	5	No	No

Conclusions/action items:

Write Analysis section

2021/12/11 Analysis (Statistics) and Conclusions of Analysis

Alex PUDZISZ - Dec 14, 2021, 7:30 PM CST

Title: Analysis and Conclusion of Analysis

Date: 12/11/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain my view of the analysis and conclusions

Content:

The MATLAB code used to make the ANOVA is available in the team section. The raw data is available in the testing day section. Tatum did the analysis and told our team of two significant results. 1. That there is a significant difference between the loading time of soft and stiff wire. and p = .00617 2. That there is a significant difference between the unloading in our prototype and the original casing p = 3.76e-9. For the movement test the analysis was that it had a 0 percent failure rate.

From here we must draw our conclusions. The first is that it is good that the unloading times are significant different. By looking at the data it is easy to see that ours was better than the original by several fold. The downside is that the loading times between the two devices were nonsignificantly different. This meant that we still have to do more work on the prototype to show results that are truly better in this regard. The team has come up with the future work of adding a back plate so that the wire does not overshoot the case when loading. This should mean a much better result. The other part of the conclusion is that there was no entanglements. That means that our device serves perfectly to hold it in place once it is put there. Overall the project has been a success, but there is still improvements to be made in the loading part of it. We may also consider a slight opening in the ring to allow for a hand to more easily come out from inside.

Conclusions/action items:

None, finish Final Notebook

2021/12/14 Conclusion of Project and Semester

Alex PUDZISZ - Dec 14, 2021, 7:29 PM CST

Title: Conclusion of Project and Semester

Date: 12/14/2001

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Write about my final thoughts

Content:

First off, happy birthday to me :D.

Next up is that I was very happy with this semester. The advice from our instructor has been very practical and actually usuable (much more than previous semesters). The other part is that this project seems about accurate for what the credit requirement suggests it to be. Finally the project itself seems to have gone well and I hope that it will be able to continue on. I would like to work with the same client again as I find his ideas very interesting and he brought up problems in the OR that I didn't know existed.

Conclusions/action items:

Say thank you to both the client and the advisor

2021/09/29 Clamped Wheel Design

Alex PUDZISZ - Oct 19, 2021, 1:27 PM CDT

Title: Clamped Wheel Design

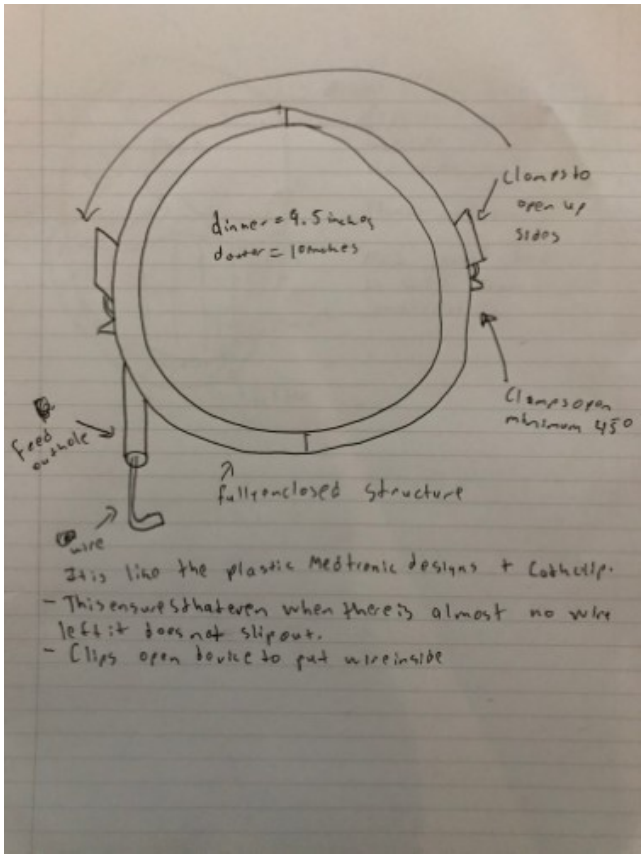
Date: September 29, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Show the design I came up with for our design matrix

Content:



This design is a circular ring. The ring can open and close because of the clamps on the side. I have not yet decided on how to stabilized them being open or if how much force will be required to open them. The hole on the bottom is optional. The idea is that it would allow you to put in the wire and then directly take it out from there as a secondary option. The rest of the notes are on the device picture above.

Conclusions/action items:

To show this design to my group during our design matrix meeting. Then to grade this design based on the criteria we set.

2021/10/19 Training + 2021/12/14 Training Update

Alex PUDZISZ - Oct 19, 2021, 1:31 PM CDT

Title: No Training Done

Date: October 19, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain the training I have done

Content:

I have training done from prior semesters, however it has not yet been necessary for this project. There is no need for HIPAA or chemical training. So far there is no certifications to report this semester.

Conclusions/action items:

Find out if there is any sort of trainings required for this semester's project.

Alex PUDZISZ - Dec 14, 2021, 4:41 PM CST

Title: Training Update

Date: 12/14/2001

Content by: Alex

Present: Alex

Goals: Explain Training

Content:

Even until the end of this project, no training through the university or otherwise was required.

Conclusions:

None

2021/11/07 PDS + Constraints

Alex PUDZISZ - Dec 14, 2021, 5:58 PM CST

Title: PDS + Constraints

Date: 11/07/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To put an individual section in my notebook that gives breif overview of PDS and constraints

Content:

These are the main things from our PDS:

Client requirements:

- The device must be easy to use and increase organization in the operating room
- The device must consist of a main storing unit (the crate) to house 4-5 guidewire wheels
- The final device must ultimately have biocompatible properties*
- The final device must be sterilizable by autoclave or other alternatives*

*Clients main goal is a successful prototype and proof of concept

The constraints of this project include several things: not spending too much (amount not specified, but lower is better as it is a proof of concept), the requirement for the device to be storable in groups (must have a fitting design), the need to increase efficiency (no complicated designs). This does not seem to be the most constricting project I have had to do, and the client seems to be very open to ideas. Overall the project is very open and allowing a lot of creativity with little real true boundaries.

Conclusions/action items:

None

2021/11/29 Final Design

Alex PUDZISZ - Dec 14, 2021, 7:33 PM CST

Title: Final Design

Date: 11/29/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To put down what our team decided as the final design

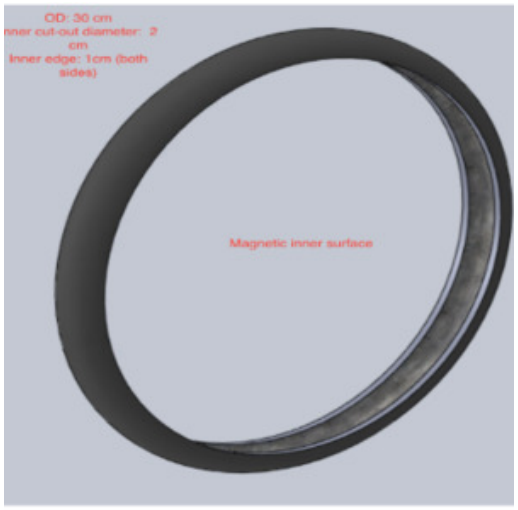
Content:

I am now marking down our final design as this is the one that the team intends to test. We are already ready to 3d print it, and I am finishing up the final testing protocol. The design is almost the exact same as we had back in the initial presentation. It is a ring, 22 cm in outer diameter, and 20 cm in inner diameter. It has a hollowed inside with a magnetic tape lining it. This design looks like a donut and allows one to put their hand in and release it so that the wire will move to the outer edges and be successfully stored. It successfully meets all of the requires PDS constraints and specifications.

Conclusions/action items:

None

Alex PUDZISZ - Dec 14, 2021, 6:16 PM CST



Screen_Shot_2021-12-14_at_6.19.55_PM.png(70.3 KB) - download

Guidewire Application/Use

Scottie Waterfield - Oct 13, 2021, 10:52 AM CDT

Title: Guidewire Application/Use

Date: 9/18

Content by: Scott Waterfield

Present: N/A

Goals: To learn how a guidewire is utilized in an operating room and notice difficulties

Content:

Main Content

- A walk through procedure of Endovascular Repair for Aortic Aneurysms provided by UW Health: Heart, Vascular, and Thoracic Care
    - Utilizes a guidewire through the leg of the patient to clear up arterial blockage
    - Is removed from plastic encasing and is a firm metallic wire
    - Is often left lying on the limbs of the patient or being moved out of the way in order to proceed with the operation
- The Constant moving of the guidewire is apparent during the procedure, my knowledge of thoracic surgery is not nearly extensive enough to understand the procedure, but the outline of the usage/disorganization of the guidewire is apparent in the walkthrough.

UWHealthWI. (2015, February 17). Endovascular repair for aortic aneurysms. YouTube. Retrieved October 12, 2021, from https://www.youtube.com/watch?v=Y2a_cYvpf_U.

Conclusions/action items:

In my observations, the guidewire is often left lying on the patient while inserted or is constantly being adjusted out of the way so the procedure can continue. This is clearly an issue of our client as well due to the concern Dr. Yamanouchi in our client meeting. My understanding of guidewires has increased significantly after this one video and now the process of creating a product to remove this dysfunction is underway.

Catheter use in Addition to Guidewire

Scottie Waterfield - Oct 13, 2021, 11:04 AM CDT

Title: Catheter Use in Addition to Guidewire

Date: 10/15

Content by: Scott Waterfield

Present: N/A

Goals: To understand the insertion of the guidewire into the patient via catheter, and the technique behind the catheter/guidewire insertion.

Content:

- Catheter Design
    - Small plastic tubing encasing the guidewire
    - Needle end with guidewire inside of the needle
    - Needle retracts with guidewire insertion, guidewire is moved up the artery, while avoiding pressing against the arterial lining
    - Once removed from tubing, the guidewire can also be retracted via the attached catheter
- Guidewire Usage
    - Once inserted via catheter, the guidewire is moved up the artery, with minimal/no traction against arterial lining, which can cause bruising or small tears in the lining
    - Once guidewire reaches destination, depending on the purpose of the guidewire, `the guidewire is utilized as intended for however long it is needed
        - In this instance, arterial blockage
    - Retracted from artery via catheter and rewound into plastic tubing which rests on patient or is taped to patient to keep steady.

Conclusions/action items:

Guidewires are inserted via catheters, primarily made with metallic needles and plastic tubing encasing the guidewire for an easier insertion job. The biomaterial needed is not very complex as long as the catheter and the guidewire are sterile upon use. This means that, in an operating room setting, the design of our guidewire organizer must be easily cleaned/sterilized for the guidewire before, during, and after usage to ensure infection is not a possibility. In addition, the guidewire organizer must be able to be easily adjusted, in terms of guidewire length from the organizer, as well as moved around the room for proper guidewire insertion angles to not get adjusted, ensuring there is no artery damage done.

Prototype Testing and Development

Scottie Waterfield - Dec 15, 2021, 10:53 AM CST

Title: Prototype Testing and Development

Date: 11/16

Content by: Scott Waterfield

Present: N/A

Goals: Ability to apply engineering design to produce solutions that meet specified needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors. At this time, redesigning the prototype, and creating a crate for the prototype.

Content:

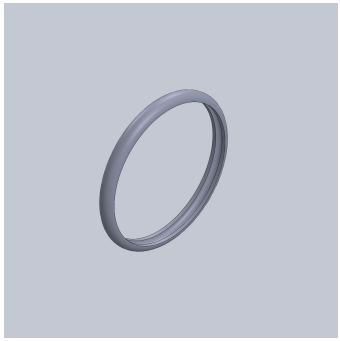
After looking at our initial prototype with the diameter of 30cm, the design was flawed:

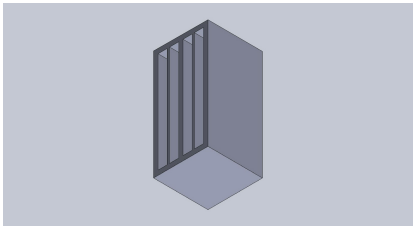
- The diameter of the hoop was too large and the loading process of the guidewire was ultimately not successful.
- A thinner hoop would be more beneficial for the unloading process of the guidewire from the hoop.

My task was to utilize my solidworks skills to redesign the prototype:

- To create the same conceptual design of the hoop
- To decrease the outer diameter of the hoop to 22cm and the inner diameter of the hoop to 20 cm
- Additionally to decrease the width of the hoop from 3cm to 2cm
- Design a crate to be able to hold multiple of the newly designed prototypes

Here are the designs completed:





Conclusions/action items:

Now that the solidworks files are completed and the crate dimensions are updated to be 12cmx24cmx12cm with four 2cmx22cmx10cm indentations to be able to contain the guidewire hoop printed. Both designs need to be sent to the makerspace lab to be 3d printed and tested immediately.

Guidewire Dimensional Analysis

Scottie Waterfield - Oct 13, 2021, 10:51 AM CDT

Title: Guidewire Dimensional Analysis

Date: 9/25

Content by: Scott Waterfield

Present: N/A

Goals: To further understand the dimensions of guidewires and the ranging designs

Content:

- Guidewire Dimensions
    - Range of Guidewire Diameters
        - 0.021 in
        - 0.025 in
        - 0.035 in
    - Range of Guidewire Lengths
        - 45 cm
        - 80 cm
    - Guidewire Structure
        - Plastic/Short Taper/Angle
        - Spring/Straight
        - Spring/J-Tip
        - Nitinol/Floppy Tip

The designs of varying guidewires will help me be able to come up with a design for our guidewire organizer for our client. The varying tip designs are important in understanding the use of the guidewire, be they for arterial blockage or for blood stream monitoring.

Terumo Interventional Systems. (n.d.). GLIDESHEATH™ hydrophilic coated introducer sheath. Terumo Interventional Systems. Retrieved October 12, 2021, from https://www.terumois.com/products/access/glidesheath.html.

Conclusions/action items:

The varying lengths and diameters of the guidewires indicate that the final design for the guidewire organizer has to be able to accommodate both 45 cm and 80 cm guidewires with diameters ranging from 0.021 inches to 0.035 inches. The real concern is the length of the guidewires being accommodated for since the range in diameters is not too large but the range of lengths is larger. The different tip designs of the guidewires should not be an issue since there is some flexibility of the guidewire and access to the tip will always be available.

Competing Design Structure

Scottie Waterfield - Oct 20, 2021, 8:41 AM CDT

Title: Competing Design Structure

Date: 10/18/21

Content by: Scott Waterfield

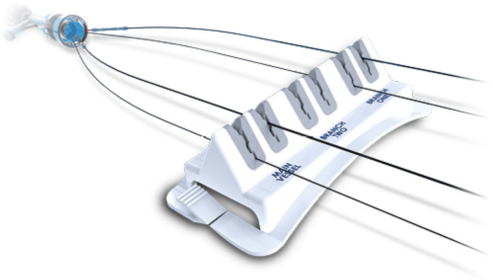
Present: N/A

Goals: Analysis of one of the competing design structures

Content:

- Teirstein Edge Device Organizer
    - Able to hold 6 different guidewires outside of their catheter
    - Uses friction slits for security of the wire, but also minimal mobility if needed
    - Separates each wire by a few centimeters
    - Does not hold tubing from the guidewire behind the edge device
- Flaws
    - The uncoiling of the guidewire is still a major possibility which is one of the main causes of disorganization.

Conclusions/action items:



Although a seemingly effective guidewire organizer, there lacks certain attention to the radial force of the guidewire, as the looser the guidewire is held, the more room for uncoiling there is, causing disorganization.

Designing the Initial Prototype

Scottie Waterfield - Dec 15, 2021, 10:52 AM CST

Title: Designing the Initial Prototype

Date: 11/10

Content by: Scott Waterfield

Present: N/A

Goals: Ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions. Specifically experimenting with the initial prototype and using our engineering intuition to conclude the effectiveness of the prototype.

Content:

The new steps for the project are to print the design made on solidworks to take it to testing.

- If the prototype is successful in handling the guidewire, as a group we need to design a testing procedure that best reveals the proof of concept for our organizer.
- Once the prototype is proven effective, develop a crate design for the prototype so the crate can carry more guidewire organizing hoops, preferably 3-4

Conclusions/action items:

With the show and tell portion of the project completed and our prototype is as modified as it can be for now, the next steps include ensuring that the prototype design works, and create a testing procedure for the design to provide proof of concept that our design does make handling guidewires easier and more efficient.

Design Idea

Scottie Waterfield - Oct 13, 2021, 10:50 AM CDT

Title: Design Idea

Date: 10/2

Content by: Scott Waterfield

Present: N/A

Goals: To create a design that is more innovative and organized than competing designs

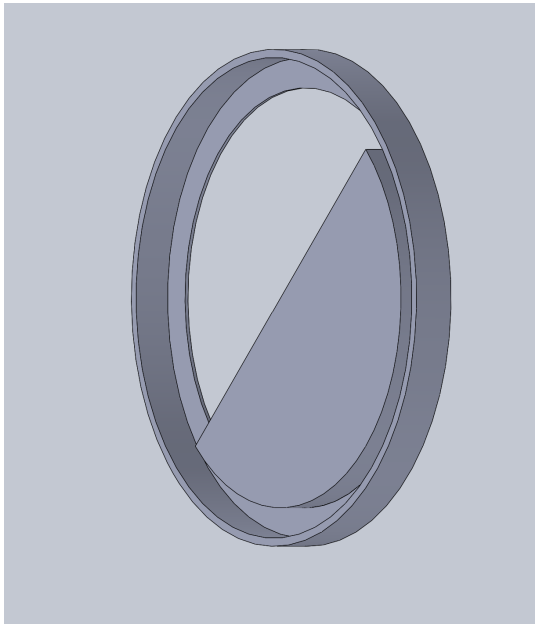
Content:

The key points of the design is to hold onto the guidewire while it is in use and have it be retractable, it also must contain the guidewire dimensions, diameter = 0.035in and length of at least 45 cm and at most 80 cm.

With previous talks with my group and looking over our client meeting it became apparent that a wheel design was the best course of action to spool the guidewire around and to have access to, making my design idea more concise.

Conclusions/action items:

The design below will have the guidewire looped and placed inside of the wheel with the removable semi-circle lid for easy on/off access, additionally there will be a hole made in the hoop for the tip to be placed through so the guidewire is easily accessible through the holding design, I used solidworks to come up with this brief prototype.



Crate Design for Guidewire Organizers

Scottie Waterfield - Oct 20, 2021, 8:32 AM CDT

Title: Crate Design for Guidewire Organizers

Date: 10/19/21

Content by: Scott Waterfield

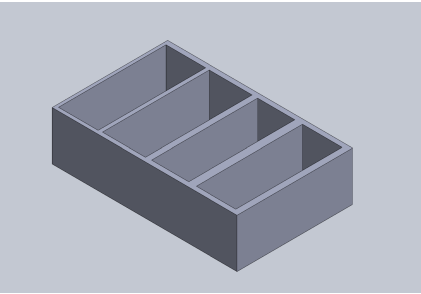
Present: N/A

Goals: To create a solidworks design that will be able to hold ¾ preliminary designs in one structure.

Content:

- Using solidworks to come up with a design, my first instinct was to create a rectangular prism.
    - This prism would be long enough to be able to fit 4 of the same guidewire organizers at least
    - 4 protruding cuts into the prism
        - Smaller rectangular prisms
        - Same width as the guidewire organizer design
        - Same depth as the outer radius of each design

Conclusions/action items:



This is the final design for the crate that will have each wheel placed in the internal cuts of the crate. Although not perfectly symmetrical for physical appeal, this is mainly conceptual and will have exact measurements once the dimensions of the proposed final guidewire organizer design is established.

Design Matrix

Scottie Waterfield - Oct 20, 2021, 8:49 AM CDT

Title: Design Matrix

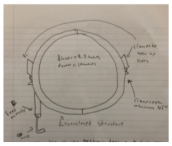
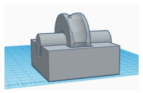
Date: 10/16/21

Content by: Scott Waterfield

Present: N/A

Goals: Analysis of Design Matrix

Content:

Design	 Magnetic wheel		 Clamped Wheel		 Wheel of Magic		 Guidewire Hoop	
Feasibility (30%)	4/5	24	3/5	18	4/5	24	5/5	30
Efficiency (25%)	3/5	15	4/5	20	2/5	10	5/5	25
Durability (20%)	3/5	12	3/5	12	3/5	12	4/5	16
Safety (10%)	5/5	10	5/5	10	5/5	10	5/5	10
Learning Curve (10%)	4/5	8	3/5	6	4/5	8	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5	4/5	4
Total for each design:	**72**		**71**		**69**		**95**	

- Each design was ranked in each category for how effective/easy it is to be used/created in each respective category.

Conclusions/action items:

The magnetic wheel was the best design out of the entire selection of designs because it uses the innovative properties of each design all incorporated into the one wheel, which uses the least material, is the safest, most durable, most efficient, and most feasible design out of all of the others.

The Magnetic Hoop

Scottie Waterfield - Oct 20, 2021, 8:54 AM CDT

Title: Guidewire Hoop

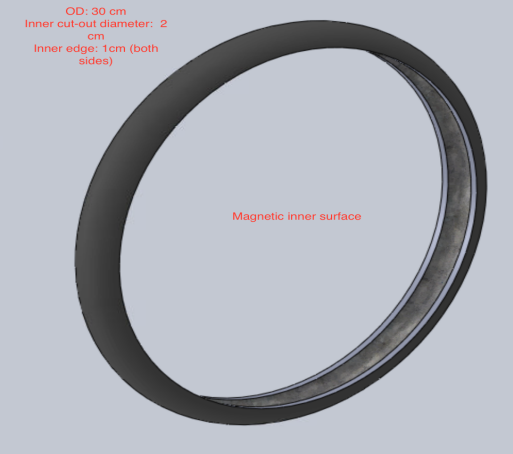
Date: 10/17/21

Content by: Scott Waterfield

Present: N/A

Goals: Analysis the Guidewire Hoop Design

Content:



- Magnetic hoop with internal concavity
- encased externally
- Guidewire inserted in concave area along perimeter

Conclusions/action items:

Our final design incorporates a lot of the innovative properties of the previous designs, as it is an internally magnetized wheel encasing the guidewire. The guidewire will press against the inner surface, and the radial force of the stiff wire pushing out will hold the wire stationary inside the hoop.

Show and Tell Presentation and Future Work

Scottie Waterfield - Dec 15, 2021, 10:51 AM CST

Title: Show and Tell Presentation and Future Work

Date: 11/01

Content by: Scott Waterfield

Present: N/A

Goals: An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts. In this specific instance, recognizing external insight on the project, and further innovating the project if needed based on the combination of outsider insight, and additionally my own insight.

Content:

Reflecting on the show and tell, there was a great deal of information and innovative ideas that came from the other BME students that can potentially be incorporated into the project:

- Individual magnetic placement on the final product inside of the perimeter of the guidewire organizer hoop
- Including an opening in the hoop for easy access to the very end of the guidewire
- Additional support bars that can enclose the guidewire in the organizer
- Testing the durability of the guidewire organizer
- Additional medical grade material suggestions for the final project

The key takeaways that I primarily noted from the show and tell

Innovations for Guidewire Hoop Design:

- Incorporating the individual piecing of magnets on the inside of the final product to reduce loss of magnetism
- Using medical grade steel for the final design if this project were to be continued

Overall Takeaways

- The introduction of outsider perspective in medical projects is highly beneficial for innovation of products
- The greater understanding of the material you have, the more effectively it can be presented to any audience

Conclusions/action items:

The show and tell gave a great deal of information on how to further improve our prototype before printing out the design, as there was a lot of great ideas coming from other students with proficient physics and medical backgrounds that provided details about our project that had never been considered. Using the magnetism ideas and introducing further development of our project into a real medically used design is a huge step in developing our prototype, as it has to be able to be replicated with those real materials.

Group Presentation Meeting

Scottie Waterfield - Oct 13, 2021, 10:49 AM CDT

Title: Group Presentation Meeting

Date: 10/11

Content by: Scott Waterfield

Present: Serena, Addison, Alex, Tatum, Scottie

Goals: Review Presentation and ensure that everyone is on the same page on presenting and understanding our final design and our whole process

Content:

- Initial meeting
    - Ensuring slides are mostly complete
    - Going over design ideas and making sure the design matrix makes sense
    - Reviewing rubric for presentation and adjusting slides as needed to fit rubric
- Presentation Scheduling
    - Deciding order of presentation, scripts of presentation, and important additional information to include
    - Inclusion of actual guidewires and props to use during presentation
- Brief run-through of presentation
    - Read off script to gain further understanding of what our presentation final result will be
    - Ensure that all notes/annotated scripts are well versed and fluent throughout the presentation
- Final Remarks
    - Letting each team member know their assignments and what needs to get done for the preliminary presentations
    - Continue to practice presentation and continue to create notebook entries for lab archives to help each other with the guidewire project

Conclusions/action items:

With a lot of deadlines rolling through as the process of design and presentation of our potential prototypes ramps up, it is imperative that we maintain a professional appearance and continue to work hard on our respective ends to ensure that, as a team, we create a beneficial and efficient product design and present that product accordingly.

Preparation for Show and Tell

Scottie Waterfield - Dec 15, 2021, 10:50 AM CST

Title: Preparation for Show and Tell

Date: 10/28

Content by: Scott Waterfield

Present: N/A

Goals: Ability to acquire and apply new knowledge as needed, using appropriate learning strategies. Specifically to show and tell and further knowledge of the project.

Content:

Upon learning the guidelines of show and tell and what is required of individuals for the presentation, roles and responsibilities were assigned to each member of the team. Myself specifically I aim to:

- Create an in depth understanding of how to professionally present our material
- Gain further knowledge on every aspect of our project, not just the design application
- Devise a plan on what to take away during the show and tell, and how to further improve our project from that gained knowledge.

Using these main goals to my benefit during the show and tell will allow for me to demonstrate my knowledge and gain insight from others to further improve my ability to professionally develop a presentation and gain insight from outside perspectives on how the project can be more innovative.

Conclusions/action items:

Practicing presenting information on a complex subject in a very brief period is an important skill in learning communication with audiences. The end result is to eloquently present the project while having my hand in each aspect of the project, and to keep in mind that the work done this week is primarily to develop presentation ability and innovate the project further using outsider insight.

Testing the Final Prototype

Scottie Waterfield - Dec 15, 2021, 10:54 AM CST

Title: Testing the Final Prototype

Date: 11/23

Content by: Scott Waterfield

Present: N/A

Goals: an ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics. In this instance, using the created testing procedure to reveal the effectiveness of the innovated prototype, and further analyze the raw data.

Content:

After going through the testing procedure created, the raw data collected revealed similar patterns amongst each trial, even when performed by different members of the group.

- The ability of the guidewire organizer to effectively encase the guidewire within the concavity while enduring relocation in addition to mild turbulence was effective.
- The loading time of the guidewire into its original container was relatively similar to the loading time of the guidewire into the prototyped design.
- The unloading time of the guidewire from the encasing was more time consuming than the unloading time of the guidewire from the prototype.

Although no statistically significant results have been found yet, it could be concluded that the guidewire organizer proved to be a safe and effective encasing for the guidewire, with a more efficient unloading process than the original encasing.

Conclusions/action items:

After going through testing as a group, the next steps of the project are to finalize our findings through raw data analysis, develop our conclusions based on the data, and to complete the final deliverables based on our progress.

Preparation for Presentation

Scottie Waterfield - Dec 15, 2021, 10:55 AM CST

Title: Preparation for Presentation

Date: 11/30

Content by: Scott Waterfield

Present: N/A

Goals: Ability to function effectively on a team whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives. For this presentation, it includes working as a team to delegate presentation responsibilities.

Content:

With our final presentation approaching, it was imperative that we practiced our presentation with our poster and delegated the workload amongst the team members. I was tasked with presenting the final design for our presentation, the materials the prototype was made out of, giving a demonstration of how the prototype works, and the cost of creating the prototype.

- The final prototype is the guidewire hoop with the smaller diameters, proven to be more effective at guidewire organization and security.
- The material used is going to be the stock plastic used for much of the 3d printing from the makerspace, where the design was printed using the solidworks file.
- The overall price of 3d printing the 1st prototype, 2nd prototype, an additional copy of the prototype, and the final crate design was approximately 111 dollars in total.

Using this knowledge of the project, I must eloquently present this known data and rely on the rest of the team to do the same for their assigned parts.

Conclusions/action items:

For the presentation, the course of action that must be taken is developing a very proficient script that talks about all three bullet points above in more depth, within a time range of 2 minutes, and practice using the guidewire organizer so the prototype is not shown in a bad light.

Presentation Development and Poster Creation

Scottie Waterfield - Dec 15, 2021, 10:56 AM CST

Title: Presentation Development and Poster Creation

Date: 12/09

Content by: Scott Waterfield

Present: N/A

Goals: Ability to communicate effectively with a range of audiences. This means presenting our final prototype and summation of work to a larger scale audience of BME students and faculty.

Content:

After devising a plan for presenting the final product, developing a script for presenting my portion of the project that encapsulated the entirety of the final design with a 2 minute speaking window was challenging. Eventually I felt very confident in my script:

Quality and function of prototype:

When 3D printed for use, the prototype for the project turned out to be very successful in its testing and ability to perform guidewire organization. The final prototype design is meant to encase the guidewire within the internal concavity of the guidewire hoop, as the radial force of the coiled wire will push against that concavity and hold the guidewire stable. Additionally, the internally placed magnet will increase the hold on the guidewire, ensuring more stability of the guidewire when placed in the organizer.

When using the 3D printers, the prototype material and overall quality of the prototype is not nearly as medical grade as the final product would be, but for the sake of concept testing and function, the plastic used for our prototype design worked just fine and proved the functionality of the guidewire organizer. Additionally, the internally placed magnetized tape is not at all what is planned to be used in the final product as well, yet for now, the magnetic tape will act as a substitute for a more efficient magnet in proving that the internal magnetism will benefit the organizer.

Prototype demonstration:

Load and unload original encasing for the hard guidewire -Much longer and harder to manage when outside of the organizer

Load and unload prototype - Much quicker storage and easier access to guidewire

Materials cost:

As a whole, the plastics used for our prototypes, printing costs, and the use of magnetic tape to design a guidewire organizer and proving the concept design for the prototype was rather inexpensive. Printing 2 prototypes in addition to the crate designed to hold multiple guidewire organizers was approximately 96 dollars, while the magnetic tape used was 15 dollars, totalling a 111 dollar tab.

My responsibility for the poster was to use screenshots of my solidworks files on the poster, and reveal the final product in a very brief bullet pointed list, and to show potential future work for the project:

- Additional support wall on the back of the wheel
- Deeper internal concavity
- Further shrinking the diameters of the prototype

Conclusions/action items:

To use the script as a base for presenting my portion of the project presentation and practicing presenting so there is little to no error. Also providing my knowledge of future improvements to further innovate the product, and present that to the audience as well.

Finalization of Project

Scottie Waterfield - Dec 15, 2021, 10:57 AM CST

Title: Finalization of Project

Date: 12/14

Content by: Scott Waterfield

Present: N/A

Goals: To complete all final deliverables and as a team conclude our work momentarily

Content:

All final deliverables have been completed thus far, as editing all work is the final steps that need to be taken to fully complete the project. Reflecting on this semester, BME has allowed me to gain a great understanding of the effectiveness of using multiple engineering problem solving abilities to develop great technological/conceptual advances in the world, and that engineering projects are more cooperative than individually completed.

Conclusions/action items:

To fix grammatical errors in all deliverables, finalize and upload all my individual and team notebooks, review my sections of the final report, and finalize all work as a team.

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

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: