Guidewire Organizer for Endovascular Procedures

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Abstract

Endovascular procedures require multiple guidewires of varying diameters, lengths and stiffnesses depending on the blood vessel they are inserted into. Currently, once the guidewires are removed from the body, they are stored under a wet towel for possible later use. However, due to the guidewire's spring-like nature, they are easily tangled and deformed; which in turn, can increase the time spent in the operating room, as well as divert the attention of the medical professionals from performing necessary tasks. Additionally, storing the guidewire underneath a wet towel poses a risk for contamination as the lint from the towel may enter the patient's body. To address these problems, the team designed a device to optimize the organization and storage of the guidewire in a sterile, isolated environment. Overall, this device aims to decrease the time it takes for surgeons to organize the wires, increase procedure efficiency, and increase patient safety. The device consists of two parts, (1) a guidewire wheel that securely holds a guidewire in place and (2) a stand that will hold three separate wheels. The current stand design that will be modified to be compatible with the final wheel. For the wheel design, the team tested seven prototypes for the efficiency of loading and unloading. The results of these tests deemed XSHold as the most efficient design. The team plans to move forward in the design process by incorporating XSHold's differentiating features into injection moldable designs (TRHold, ADHold, and LGHold) in order to mass produce the guidewire organizer.

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1. Introduction

1.1 Motivation

Each lost minute in a hospital operating room costs an average of $60 [1]. Operating rooms are expensive to run, and the main goal of every hospital is efficiency and safety [2]. All of this additional work does not only throw away money, but also diverts residents, surgeons, physicians, and nurses from performing other necessary tasks and taking care of patients.

This guidewire wheel and stand will decrease the amount of time a surgeon spends in the operating room; therefore, the amount of wasted time and money in the operating room (OR) will be decreased. Additionally, this device will allow for better organization and storage, creating a less hazardous setting in the OR. In regards to safety, this device has other added benefits such as the ability to decrease contamination within the OR. To use guidewires more than once during a procedure, guidewires must remain uncontaminated and within the sterile field if intended for later use. Currently, most doctors store used guidewires under a wet towel. However, these towels may shed fibers onto the wire, and these fibers have the potential to be displaced into the body. Lint contamination can cause serious harm to the patient, and lint related complications include: thrombogenesis, infections, amplified inflammation, poor wound healing, granulomas, adhesions and capsule formation [3]. The current lack of storage for guidewires extends beyond patient complications and is a cause of disruption within the operating room due to them being hard to manage as they can get tangled and disorderly.

The endovascular device market is currently over $2.0 billion and is projected to reach $2.2 billion by the end of 2022 [4]. The growing market suggests a need for innovation to ensure well-done and efficient procedures. The team hopes to bring this device to market, making it a popular device that surgeons choose over the current guidewire dispensing tubing and other competing devices.

1.2 Current Competing Systems

There are two main competing systems that exist in the guidewire organization market. The first is the Cath Clip, shown below in **Figure 1**. This single-use device reduces the time spent operating the device by an average of 80%, allowing surgeons to focus on the patient rather than device management [5]. The Cath Clip is lint-free, reducing contamination from potential cotton fibers of towels and other garments [5]. To use the Cath Clip, the operating technician must wind the guidewire into a neat circle and clip it together. The Cath Clip is not the best option since it can lead to disorganization, as the guidewires do not stay separated when placed on the table. Since there is no additional storage unit included for the device, the device can fall onto the floor if bumped or not secured.

Figure 1. Cath Clip with wound-up guidewire [4].

The second device is a Guidewire Storage Bowl that is manufactured and distributed by Medline Industries. The five interior tabs shown in **Figure 2** allow the guidewires to be held securely in the bowl, but they can still tangle while inside the bowl. The open top allows the device to be filled with fluid, such as saline, to sterilize the individual guidewires. This device is marketed as a single bowl or a set with various diameters. The smallest bowl is 8.5" in diameter with an internal volume of 2,500 mL [6]. The largest bowl is 11" in diameter with an internal volume of 5,000 mL [6]. This device comes sterilized [6].

Figure 2. Medline Guidewire Storage Bowl [5].

1.3 Problem Statement

In many endovascular surgeries, surgeons must use multiple guidewires during a single procedure. This product aims to decrease the time it takes for surgeons to organize the wires and increase procedure efficiency and patient safety. Thus, the team will engineer a device to organize and store multiple guidewires and solve this issue. The device will consist of two parts: (1) a stand to store guidewire wheels and (2) three wheels in which the guidewires will be placed. The guidewire must stay organized and untangled when inserted and removed from the wheel. It must

be easy to remove the wire from the wheel while stored on the stand or in the operating technician's hand. The wheels must also be easily placed and removed from the stand. The learning curve for the loading and unloading of the guidewire (GW) from the wheel should be small. The device will be able to be mass produced through injection molding as a single use device (the device may be used multiple times during the procedure, but once the procedure is complete, the wheel will be disposed of).

2. Background

2.1 Relevant Physiology and Biology

The use of guidewires spans a variety of different surgical sectors including, but not limited to: angioplasty, stenting, pacemaker insertion, electrophysiology studies, atherectomy, thrombolysis, and endourology and therapeutic endoscopy of the gastrointestinal system [7]. In each endovascular procedure, up to 4 guidewires can be used [8]. Each of these guidewires can vary in diameter and stiffness, as they have different purposes in the procedure. For example, during a coronary angioplasty, a flexible GW is used in very angled vessels where as a high support GW is used to provide more support in cases of tortuous anatomy and distal lesions [9]. A guidewire is inserted into the patient and then directed to the area of interest. From there, the catheter is fed along the guidewire to the correct area, and once the catheter is in the correct position, the guidewire is removed. **Figure 3** shows how a guidewire and catheter interact during an endovascular procedure. The guidewire must be stored in case it is used again during the same procedure. Endovascular procedures are minimally invasive, as the guidewire and catheter are inserted through a small incision, lowering health risks that arise during alternative surgeries [10].
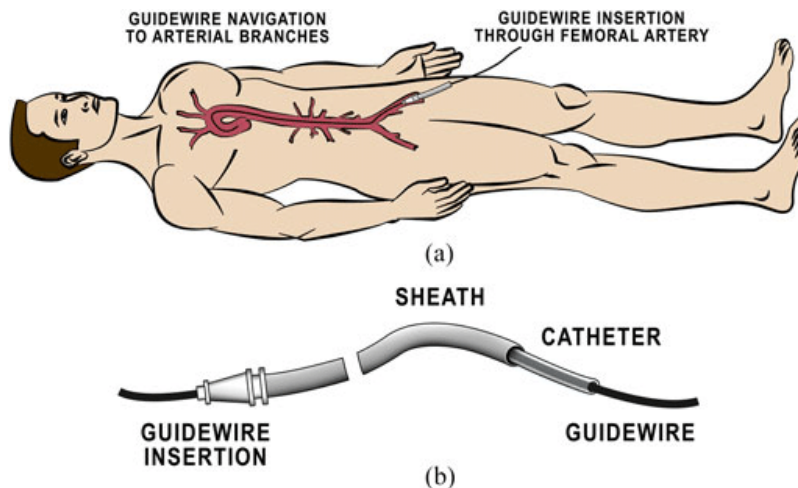
Figure 3. Guidewire and catheter being inserted into the body [11].

2.2 Prototyping Materials and Machines

For this project, the prototypes are 3D printed at the MakerSpace. The printer selected is the Ultimaker S5. The team used Ultimaker PLA and PVA inner supports for the printing filament due to its ease of use, high strength, and high stiffness which are all ideal for the large number of test subjects that used the wheel. The PVA supports will be dissolved using a warm water bath. It is also cost-effective and efficient [12], two features that are ideal for prototyping.

2.3 Client Information

Dr. Dai Yamanouchi, MD, PhD, is a surgeon at UW-Health [13]. He specializes in vascular and endovascular-related procedures, as well as research relating to aneurysm post angioplasty including balloon angioplasty and stent placement [13]. He is passionate about creating a device for his operating room to solve the issue of tangled guidewires [13].

2.4 Design Specifications

The wheel must be able to load and unload guidewires of varying stiffnesses with diameters of 0.014, 0.018, and 0.035 inches without the entanglement of the wires [13]. The stand should hold three guidewire wheels as well as allow the guidewires to be removed from the wheel while stored in the stand or with the wheel in hand. Both the wheel and stand are single use devices. The average male surgeon's hand circumference is 21.35 cm and female is 18.95 cm [14]. The wheel should take these dimensions into consideration to optimize the grip of the surgeon on the wheel. For the design to be competitive in the market and meet the client's requirements, production costs of a single wheel should not exceed roughly $2. A complete list of specifications can be found in **Appendix A**.

3. Preliminary Designs
Introduction

3.1 Wheel Function

This section aims to describe to the reader how a wheel is used during a procedure. See **Figure 4** for photographs of the loading process.

| A | B | C |
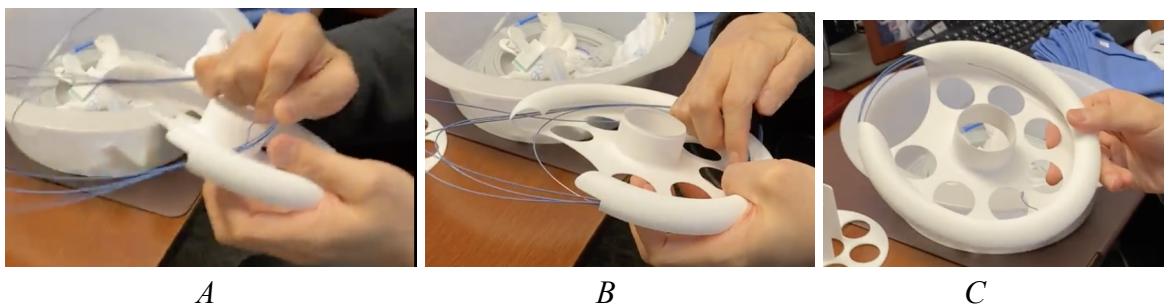
Figure 4. Insertion of guidewire into wheel.

1. After a guidewire is removed from a patient during a procedure, the guidewire is handed over to an operator.
2. The wire is wound by the operator by hand.
    a. The operator is then in charge of storing the guidewire safely and promptly.
3. Wound GW is slid into the wheel and expands toward the walls.
    a. It is then placed on the stand.
4. If the guidewire is reused during the procedure, it must be removed from the wheel.
    a. It can be unloaded while on the stand, or
    b. The wheel can be taken off the stand before removing the guidewire.
5. To unload the guidewire, the guidewire is simply threaded out from the opening.

3.2 Control Wheel Design: VHold

VHold (**Figure 5**) is the team's control design. VHold exemplifies the necessary features for the device to work correctly. These important features are described in **Table 1**. All the design variations discussed in the coming section are based on this control design.
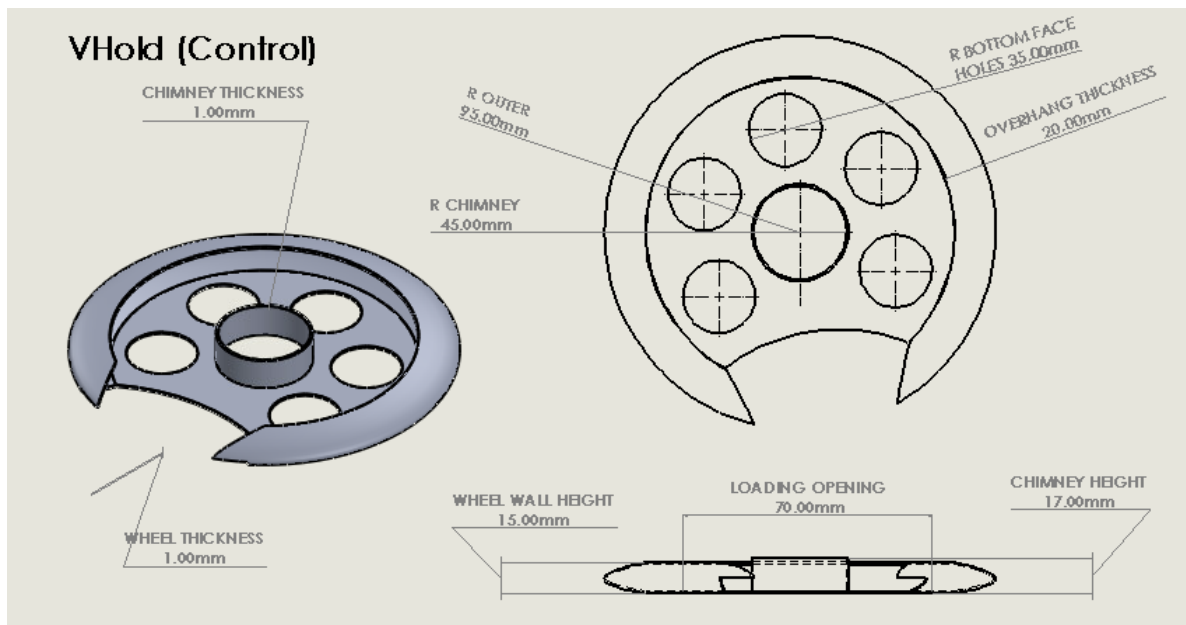
Figure 5. VHold prototype wheel design in SolidWorks.

Table 1. Important Design Features.

Chimney	- Holds the guidewire in place as it is unloaded by preventing the guidewire from popping out, acting as a spool. - The chimney can get in the way of the hand as guidewire is loaded

Bottom Face Holes	- The circular holes on the face of the wheel allow saline to flow through the wheel - Cannot be too large or wires can slip through and get tangled
Wheel Outer Diameter	- Small enough for the guidewire to stay in place and have easy load and unload - Cannot be too large or the guidewire will not have enough radial force to stay in the cavity
Manufactuability	- Aim to be injection moldable with a lower cost mold - If injection molding is not the most efficient method for a low cost mold, device must be easily mass manufacturable using another method

3.3 Wheel Design Variations

A. XSHold

The first design variation seen in **Figure 6** is similar to the control design VHold with a smaller outer diameter. The smaller outside diameter of this design allows for a tighter hold of the guidewire as there is more force applied to the outer wall of the device. Less material is also needed to build this wheel, which reduces manufacturing costs.
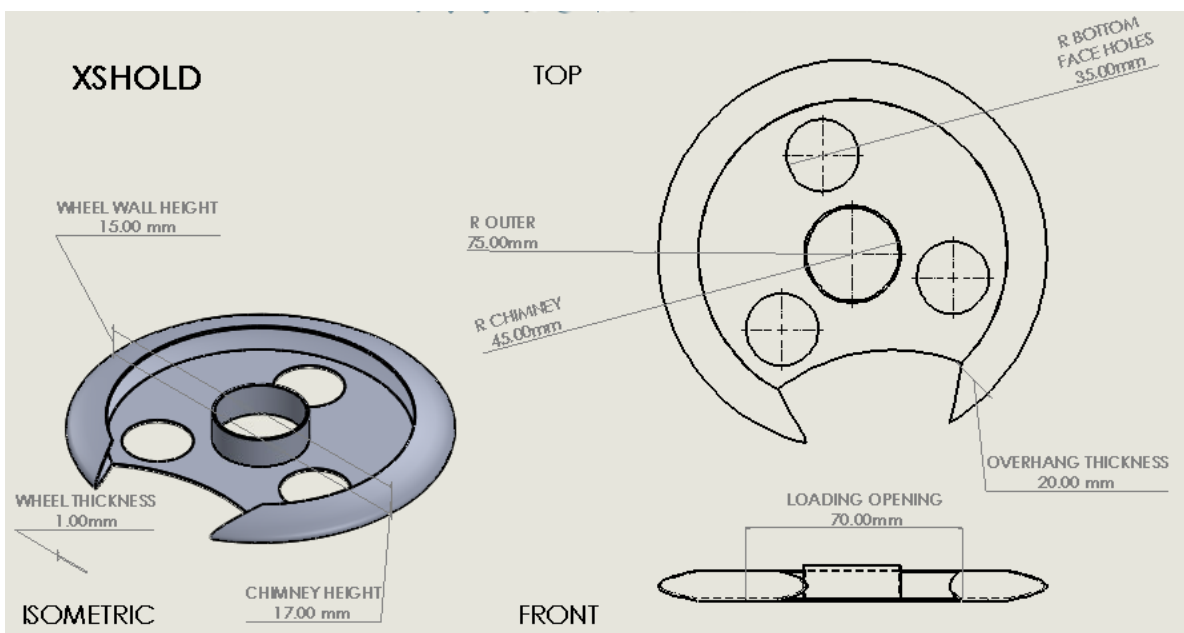
Figure 6. XSHold SolidWorks design.

B. XtraHold

The second design variation seen in **Figure 7** features a redesigned chimney. The outside diameter and height is the same as the VHold, however the chimney is shorter and features a curved overhang piece around the top. The shorter chimney allows for easier and more comfortable guidewire loading, and the overhang keeps the guidewire steady in place during guidewire removal. The wall also has a deeper cavity along the outside of the device to ensure tight guidewire storage.
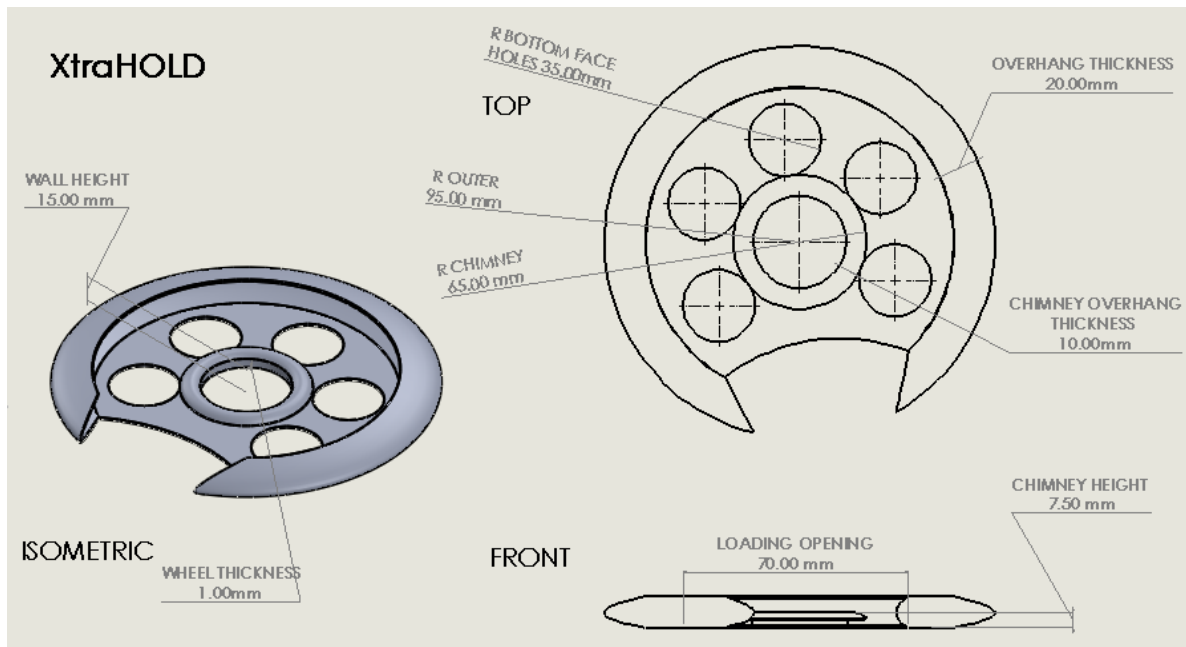
Figure 7. XtraHold SolidWorks design.

C. LHold

The third design variation seen in **Figure 8** features a unique overhanging clip piece in place of the cylindrical chimney utilized in VHold. The outer diameter and height of this device are the same as the VHold. Removing the chimney eliminates the obstruction that the chimney imposes on the user while loading the guidewire. The overhanging piece in the back allows the guidewire to be removed efficiently while staying in place within the device. LHold also contains a deeper cavity along the outer wall, similar to XtraHold.

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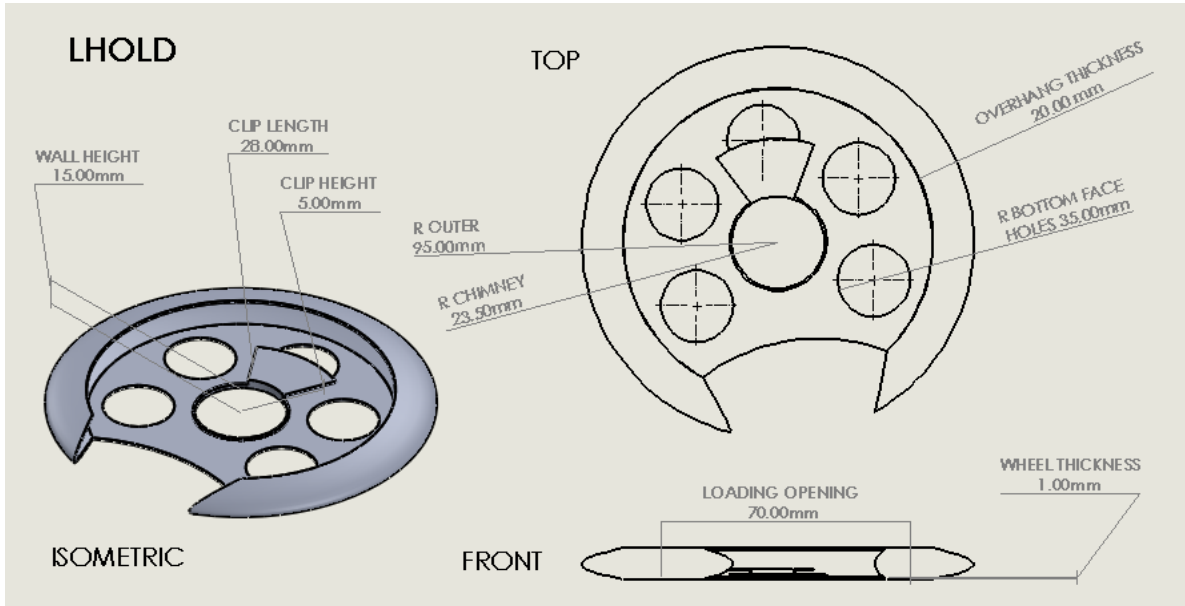
Figure 8. LHold SolidWorks design.

3.4 Stand Design

The stand design seen in **Figure 9** will be used in conjunction with the final wheel design. The stand features a base plate with holes to allow for easy flow of saline around the guidewire. There is also a long chimney in the center of the base plate to stack up to three guidewire wheels at one time. The hollow chimney allows for minimal material to be used, minimizing manufacturing costs.
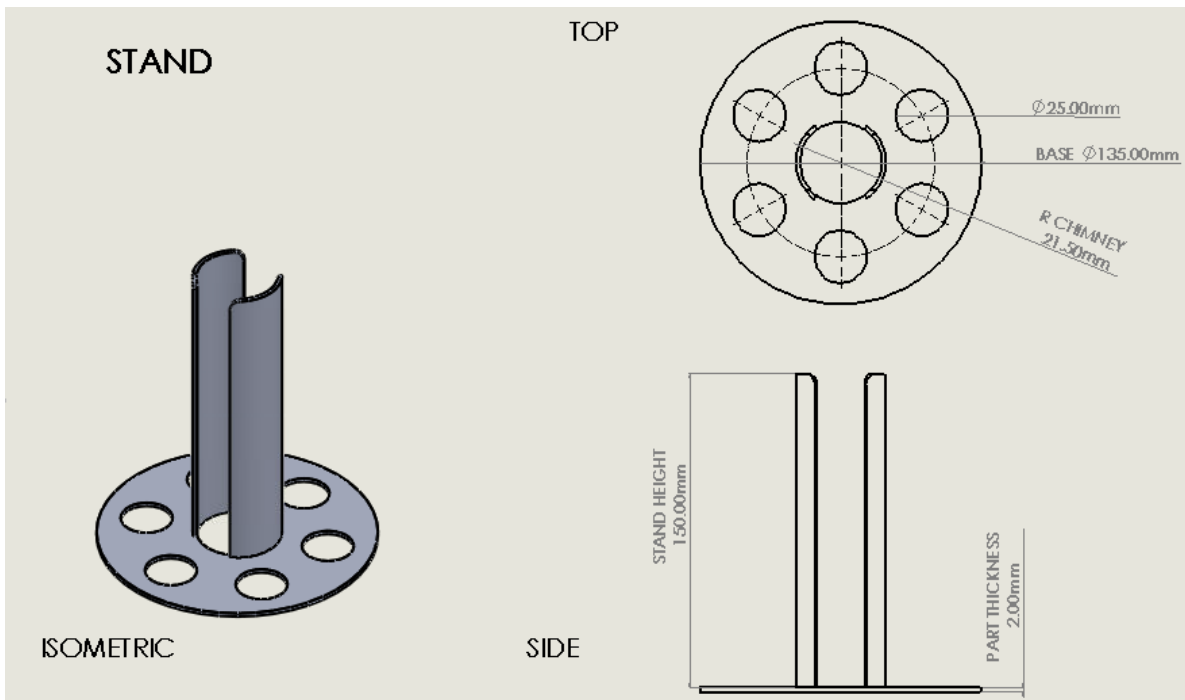
Figure 9. Stand SolidWorks design to hold guidewire organizers.

4. Preliminary Design Evaluation

4.1 Alternative Design Matrix

The team opted out of conducting a formal design matrix for the wheels this semester. This is because all designs would score equally in traditional design matrix criteria since only slight variations are being made to the control design; The criteria are: safety, cost, efficiency, durability, and learning curve. Formal definitions of these criteria are found in **Appendix B.**

This being said, the team chose to move forward with all four designs: VHold, XSHold, XtraHold and LHold. The main focus this semester was the manufacturing methods of each design, and the designs were modified based on their manufacturability (discussed further in Sections 5.1 and 5.2).

The team's alternative design matrix is a pros, cons, and manufacturing table seen below in **Table 2**. Factors that aren't traditionally evaluated within a design matrix were discussed. **Table 2** will be kept in consideration moving forward with testing and manufacturing.

Table 2. Alternative Design Matrix.

Design	Pros	Cons	Manufacturing Method
VHold (control design)	- Hand opening optimal for both male and female surgeon hand	N/A	- Injection mold in two pieces
XSHold	- Small radius allows for tighter hold on GW - Less material	- Tall chimney makes loading difficult	- Injection mold in two pieces
XtraHold	- Shorter chimney allows for more comfortable GW loading	- Overhang of chimney could be hard to manufacture	- 3D print
LHold	- Chimney replaced with clip to rid design of hand obstruction	- Clip could snap if hit too hard	- Injection mold in two pieces

4.2 Manufacturing Design Matrix

In order to mass produce the final design, the final manufacturing process must be cost and time efficient. In **Table 3**, the team compared three different manufacturing processes: injection molding, 3D printing, and thermoforming. Each manufacturing process was ranked by its ability to fulfill six criteria based on the design specifications outlined in **Appendix A.**

I. *Production Efficiency (25%):* Production efficiency is the time it takes to produce one part. This is weighted as the highest criteria in **Table 3** because the final market device will be mass produced as a single-use product to fulfill the demand of the increasing endovascular device market. It is estimated that 1,020,067 vascular procedures would be done in 2020 [15].

Injection molding scored the highest for production efficiency as it is the most common and time-efficient process used to mass produce parts [16]. Depending on the size of the desired product, the injection molding process can take two seconds to two minutes to produce a part [16]. Thermoforming involves loading a single material sheet into the machine and then heating it to glass transition temperature before each pull. This makes the process take a longer to complete than injection molding [17]. Additionally, due to the geometry of the wheel, the design would need to be cut horizontally, manufactured in two parts and then welded together. 3D printing was ranked ⅕, because the process is extremely inefficient for our design. In Spring 2022, it took three hours to 3D print the device in PVA. Additionally, the inner supports of the overhang had to be dissolved away which took an additional two days.

II. *Ease of Manufacturing (20%):* Ease of manufacturing denotes the amount of additional tooling prototyping and initial costs to begin production of the final market device.

3D printing scored the highest in ease of manufacturing because it does not require additional prototyping or tooling costs. Injection molding and thermoforming are both mold forming processes. There is additional tooling prototyping to create the mold before the device can be mass manufactured. The cost of tooling for injection molding is more expensive than thermoforming because it is made out of a higher grade metal.

III. *Cost Per Part (20%):* The cost of production of the final design should not exceed 2$.

Injection molding scored the highest because it has the lowest cost per part. As seen in **Appendix E**, the team received a quote from Protolabs where the cost of production for one part is $2.88. Thermoforming scored 3⁄5 because there is excess material from the sheet that is accounted for in the cost per part. 3D printing scored the lowest, in Spring 2022, it costs 6$ to print the part.

IV. *Material Compatibility (15%):* Availability of materials compatible for production.

Injection molding is ranked the highest as it is compatible with a wide range of thermoplastic, thermosets, or elastomers [18]. Though 3D printing is also compatible with a wide

range of materials, is ranked ⅘ due to cost of using these materials in 3D printing. Thermoforming is ranked the lowest as it has restrictions on the thickness and temperature characteristics for compatible materials.
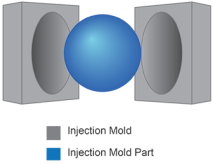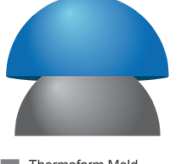
V.   Lead Time (10%): The estimated lead time from now to final market device production.

3D printing the final market design was ranked the highest because there would be no additional prototyping steps to make our design compatible for 3D printing. The lead time for prototyping the tooling for injection molding is 12-16 weeks, and for thermoforming it is 0-8 weeks [19].

VI.   Accuracy (10%): The degree of precision, or tolerance of the manufacturing process achieves.

Injection molding scored the highest for accuracy as it is ideal for creating smaller, more intricate and complex parts; it can accommodate tolerances +/- .005 mm [20]. Thermoforming scored ⅖ as it bends a sheet of plastic around the mold, it works best with larger parts with more basic designs [20]. 3D also scored ⅖ because it is difficult to dissolve the supports entirely, creating greater tolerances between parts.

Table 3. Manufacturing Process Design Matrix. Individual criteria were graded on a scale of 1(Low) - 5(High), these scores were then multiplied by the predetermined weight of the criteria to calculate the weighted score. The highest scores for criteria are highlighted in yellow and total scores are out of 100.

Manufacturing Process		Injection Molding [6]		3D Printing		Thermoforming [6]
Production Efficiency (25)	5/5	25	1/5	5	4/5	20
Ease of Manufacturing (20)	3/5	12	5/5	20	4/5	16
Cost Per Part (20)	4/5	16	2/5	8	3/5	12
Material Compatibility (15)	5/5	15	4/5	12	2/5	9

Lead time (10)	2/5	4	**5/5**	**10**	3/5	6
Accuracy (10)	**5/5**	**10**	2/5	4	2/5	4
Total	**82/ 100**	**82**	59/ 100	59	67/ 100	67

4.3 Proposed Final Wheel Designs

The team moved forward with all four wheels: VHold, HSHold, XtraHold, and LHold. However, due to their complex geometry, none of these wheels in their current state are injection moldable. The team's decision to move forward and test these wheels, even though they cannot be manufactured with the desired method, came from the idea that certain characteristics of these wheels proved to be important to the efficiency and effectiveness of the device. Once certain characteristics of the wheels are proven to be important (i.e. diameter, chimney design/height, overhang, etc.), the team focused on implementing these design choices into injection moldable designs.

5. Fabrication/Development Process

5.1 Materials

The final market device will be fabricated with injection molding to be single-use. The proposed final market device will need a material that provides strength, stability, and flexibility. Additionally, the material will be a cost-efficient thermoplastic compatible with injection molding.

5.2 Methods

Injection molding is a forming process using molds [16]. This process works by loading thermoplastic, thermosets, or elastomer pellets into the cylindrical cavity of the machine where the material is heated and pressurized to a molten state. Once the material is liquified, it is forced through the nozzle of the injection unit that feeds into a channel in the mold. As soon as the molten material enters the mold, it begins to cool and the solidified part is ejected. Most molds used for injection molding consist of two pieces, the core and the cavity. The geometry of the core creates the interior form of the part and contains the ejection mechanism to push out the completed piece. The cavity is the void inside the mold that the plastic fills and it typically forms the exterior side of the part. In order to create the tooling mold for the endovascular guidewire organizer the dimensions of the wheel need to be optimized through testing and prototyping.

A. *Injection Molding: Undercuts*

The VHold, XSHold, XtraHold, and LHold designs all share a similar overhang feature to keep the guidewire within the wheel cavity. However, injection molding of this specific feature is

not feasible, as the formed device is unable to be removed from the mold. **Figure 10** illustrates the manufacturing analysis done by Protolabs on the XSHold. The red area denotes the feature of the prototype that is not able to be injection molded (any single vertical plane cut from the device can only touch the material once). If the overhang was printed, it would ultimately crack any thermoplastic or thermoset material when removed from the mold. To avoid this, the team explored samples of elastomers that would be able to withstand stretching when removing the wheel from the mold without permanent deformation. The team found that the texture of an elastomer decreases the overall functionality of the wheel as the guidewire stuck to the material samples. In order to injection mold the VHold, XSHold, XtraHold or LHold prototypes, the overhang must be eliminated. If the team wanted to print the overhang, the device would have to be molded in two pieces (**Figure 11**).
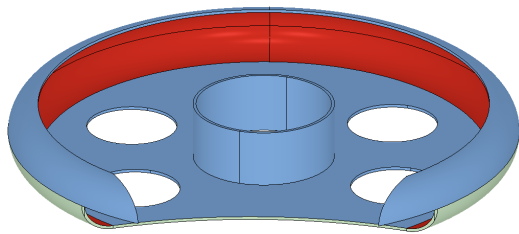
Figure 10: Manufacturing analysis of XSHold from Protolabs.
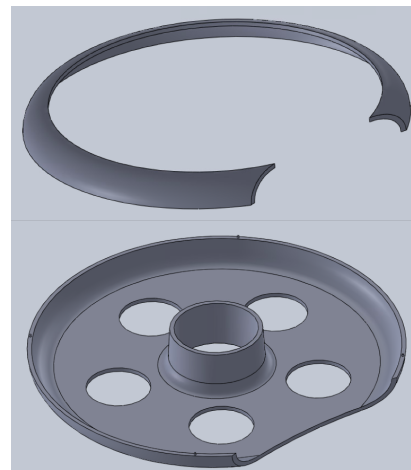
Figure 11: XSHold cut in half for injection molding.

5.3 New Wheel Designs

In order for injection molding to be a feasible manufacturing method for the team, the designs needed to have characteristics that allowed the two parts of the molds to come apart after filling the mold. Due to this, the design cannot have undercuts, needs a slight draft angle for any straight edges, and should not contain many sharp edges. The team created designs that had the characteristics necessary to be feasible for injection molding.

A. LGHold

The design variation seen in **Figure 12** eliminates the overhang. This allows the device to be injection moldable without any further modifications. The device is feasible in terms of manufacturing, but may not be the best option in terms of loading and unloading efficiency due to the ability for the wire to spring from the device at any time.
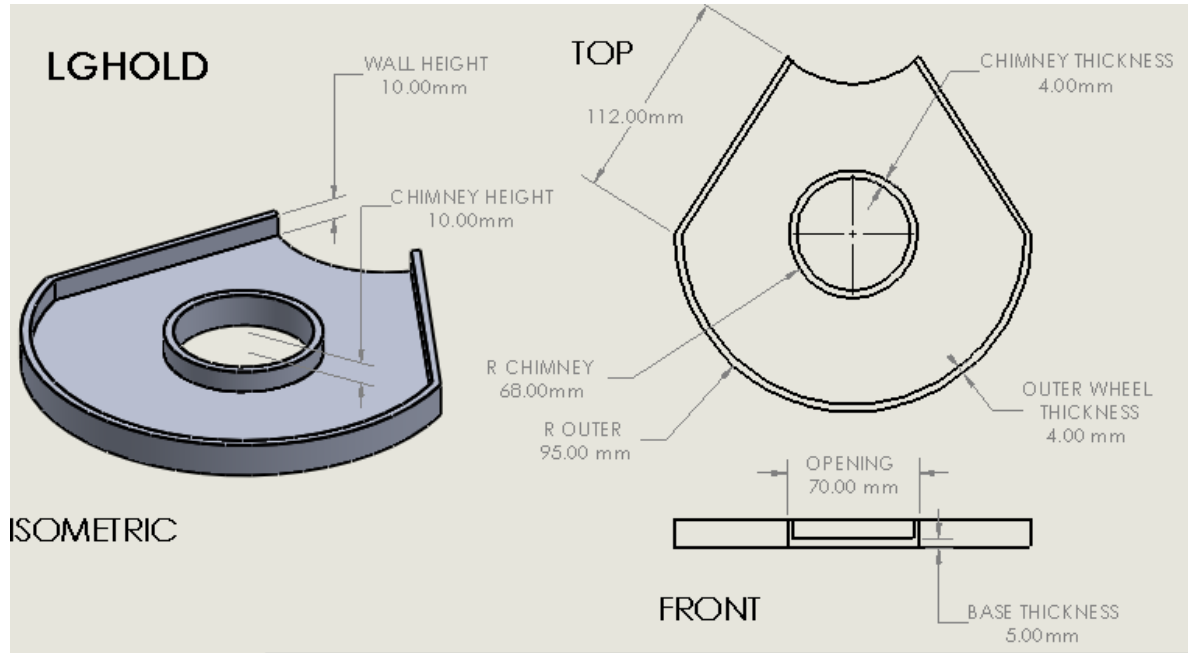
Figure 12: LGHold SolidWorks Drawing.

B. ADHold

The design variation seen in **Figure 13** is modeled very similar to the geometry of a frisbee. This device has a very slight curvature, which allows the device to be injection molded and also hold the guidewire within the device.
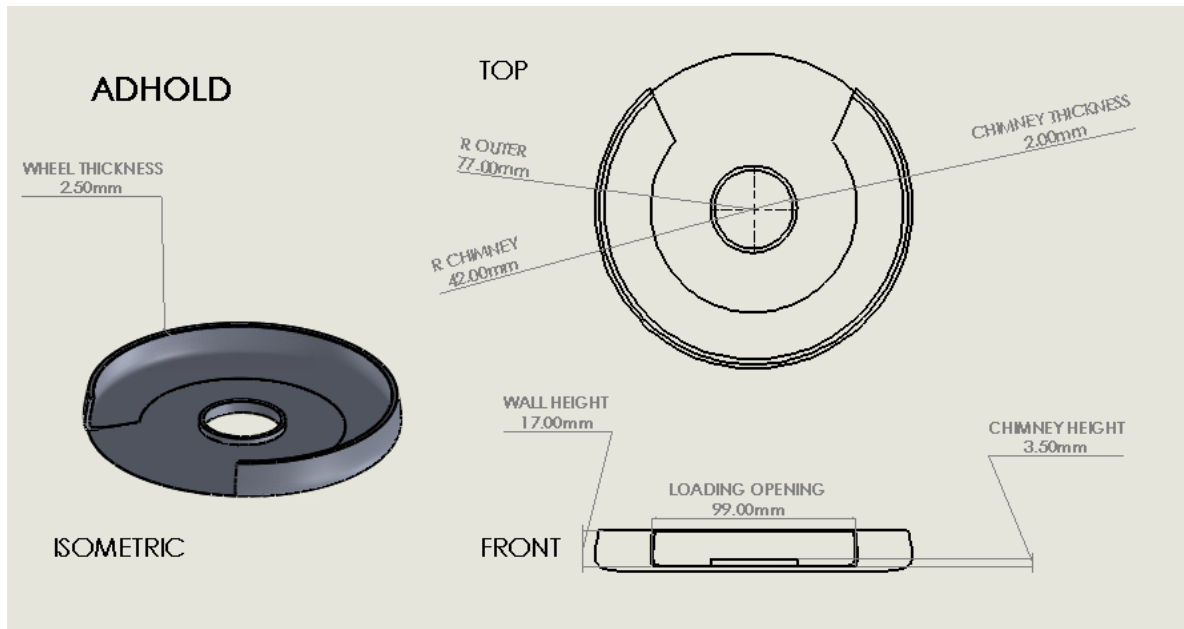
Figure 13: ADHold SolidWorks design.

C. TRHold

The design variation seen in **Figure 14** attempts to eliminate overhangs that prevent the device from being injection molded. This device features cutouts below any tab-like extrusions in order to allow the device to be punched out of the injection mold. The tabs are able to hold the guidewire within the wheel while loading and unloading the wire.
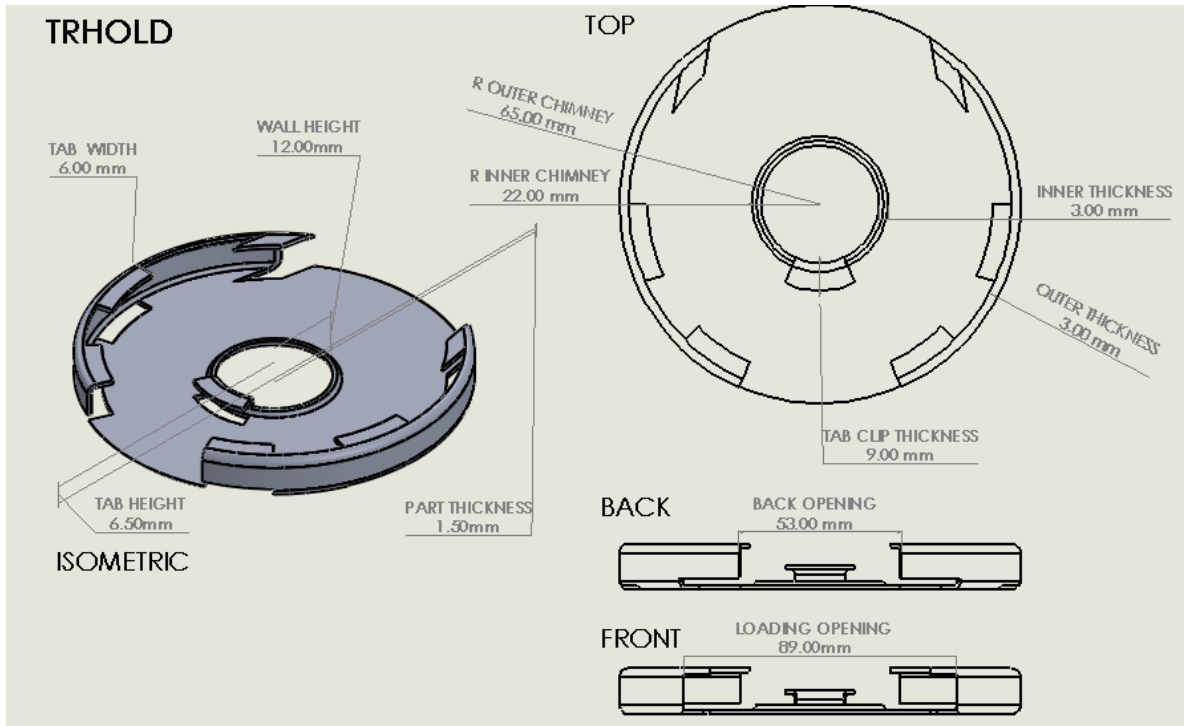
Figure 14. TRHold SolidWorks design.

5.4 Testing

Testing data consists of loading and unloading times of the wheel done by the team. These timed tests allow for quantitative analysis of the efficiency of the device. The test administrator is required to rate how the device performs in each run. If there are complications, such as entanglements or the wire coming out of the wheel, then the device is scored to defined rankings in the test protocol in **Appendix C**. For this rating scale, a three on the testing scale is the best, meaning a perfect run, and a zero is the worst, meaning a mistrial. The order in which guidewires are used in the runs are randomized and noted during testing. The team aims to ensure that every combination is tested equally in this regard to guarantee that there are minimal effects of learning in between trials. Additionally, medical professionals and residents evaluated the design variations in an informal round-table discussion.

6. Results

6.1 Statistical Analysis

   Upon completion of testing, the team analyzed the loading and unloading ratings and times data across all seven designs. Since loading the guidewires into the wheel is the most important factor to consider for the design, those data points were the main focus of the analysis. The LHold, XSHold, and XtraHold all tied for receiving perfect scores of three 13 out of 15 trials. This was the most out of all the designs, implying the guidewire could be inserted into the wheel most easily without many complications compared to the other wheel designs. The TRHold wheel design introduced complications for loading the guidewire as it received the only 0s and the most 1s recorded during testing over the 15 trials. From this qualitative data, it can be concluded that the TRHold design is the most inefficient for loading the guidewires while the LHold, XSHold, and XtraHold were the most efficient. Earlier in the semester, clinicians were asked which design they preferred. It was found that the clinicians liked the LHold design the best due to its intuitiveness (**Appendix D**). From this, it can be concluded the high-rated wheels are most preferred by the user. **Figure 15** below shows the data distribution of load ratings across all designs.
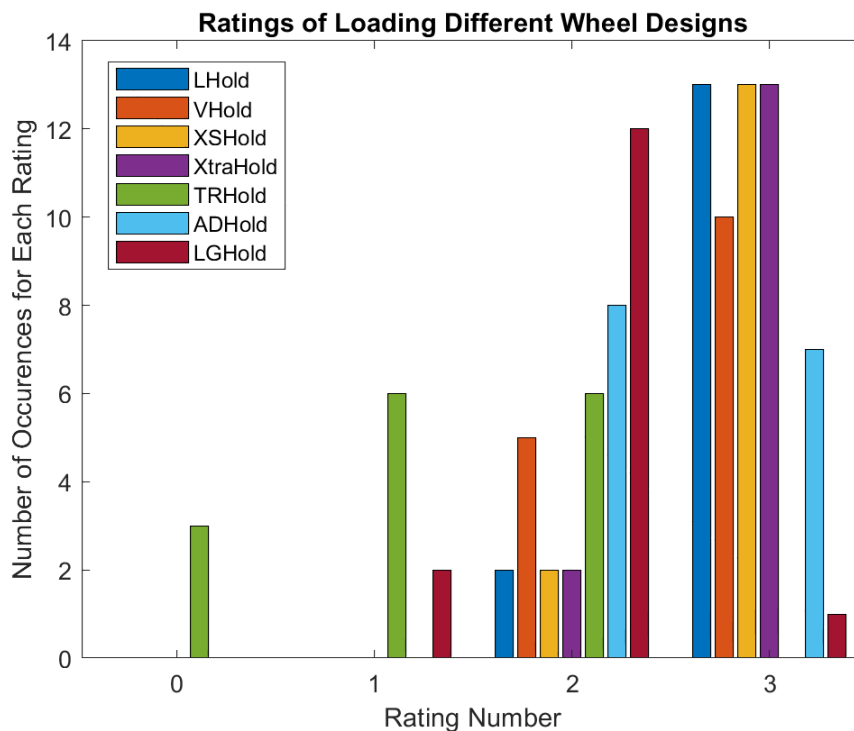
Figure 15: The loading ratings for all designs.

   The XSHold had the fastest average loading time (12.29 +/- 2.53 s), but the LHold and XtraHold were close behind with average loading times of 12.45 +/- 2.47 s and 12.58 +/- 2.53 s respectively. These were all faster than the average loading time across all designs (13.53 +/-

2.47 s). The TRHold exhibited the slowest average loading time of 15.07 +/- 2.66 s. In **Figure 16** shown below, the data distribution of loading times across all designs is displayed. All collected data can be found in **Appendix F** and the MATLAB code for data analysis can be found in **Appendix G**.
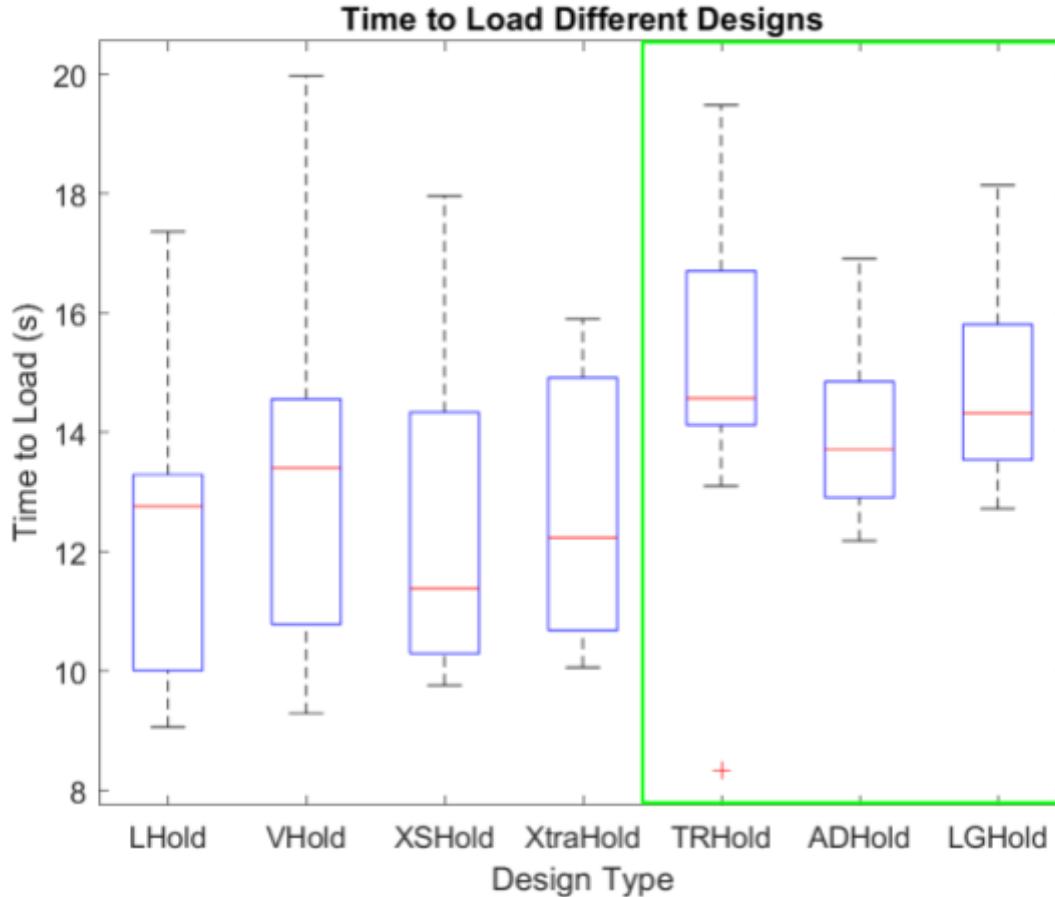
Figure 16: The loading times for all designs. The highlight region represents the designs that are injection moldable.

An ANOVA test was also completed to compare the loading times across all designs to determine the data's significance. This statistical analysis showed that there was no significant difference between the XSHold and ADHold loading times ($p = 0.473$), but there were significant difference between the XSHold and TRHold and XSHold and LGHold loading times ($p = 0.028$, $p = 0.036$). All ANOVA results can be found in **Appendix G**.

7. Discussion

7.1 Implications of Results

The data collected from testing showed that the XSHold was the most efficient design. The XSHold has the fastest average loading time and was one of the designs that scored the

highest since few complications were introduced during loading across all 15 trials. The LHold and XtraHold are also efficient designs since they scored similarly to the XSHold and had slightly slower average loading times.

7.2 Sources of Error During Testing

There are multiple sources of error that could have occurred during testing. The main source of error is the timing system of the testing. The team used an iPhone stopwatch to record the time for loading and unloading trials. This is due to human error, as there is no precise technique to record time. Another source of error was the uniformity of teaching the test subjects how to load and unload the guidewires into the wheels. If the procedure was understood differently by each subject, they easily could have made mistakes during testing, which could have increased loading and unloading times or biased the ratings. Lastly, the guidewires could have been a potential source of error during testing. The guidewires are easily deformable, sometimes making loading and unloading more difficult. As more trials were carried out across test subjects with each design, the wheels could have been bent or changed shape near the end of testing, making it more challenging for the final test subjects. This could have increased loading and unloading times as well as skewed the subject's perception of difficulty or ease of loading and unloading the wires and changing the ranking results across the designs.

7.3 Ethical Considerations

When testing and implementing new devices in the medical field there are seven main principles of clinical research [21]. There are two principles that are crucial for testing this device: consent and risk-benefit ratio. Although the device itself falls within the engineering field, testing this device on patients in the operating room will occur to ensure its functionality during an endovascular procedure. This is the final step before bringing a device to market. The device must ensure that it is not harmful to the patient or the surgeon. Additionally, the patient must consent to the use of a new device that is not typically used and is currently in the process of testing. The device must be compatible in the operating room and able to be sterilizable. The device should be tested to ensure it is able to be used on many different guidewires of varying sizes and stiffnesses to be able to accommodate many different operations and patient considerations. Lastly, the risk-benefit ratio presented for this device is positive in terms of benefit, which allows for this device to be tested in the operating room.

8. Conclusion

8.1 Summary of Design

The device consists of a stand and wheels. The stand will be modified after a final wheel dimension is determined. The stand will store three guidewire wheels. The guidewires are able to be removed from the wheel while on the stand. The team will be moving forward with a combination of designs. The XSHold was the most efficient design, however, cannot be

manufactured by injection molding. Thus, the team will incorporate the diameter of the XSHold into the injection moldable features of the ADHold, TRHold, and LGHold. These features include a smaller overhang and back cut-outs. The final design will be best formed through injection molding for mass production and manufacturing as well as future marketability.

8.2 Future Work

The team will continue to move forward with the design process to model prototypes that combine the specific features of XSHold with the injection moldable characteristics of the ADHold, LGHold, and TRHold. Once this design is modeled, the team will work with an injection molding company to create a tooling mold of the finalized device.

The material used to fabricate the market device must be compatible with the design and injection molding. The team plans to select a material that has been approved previously by the FDA to decrease the material approval process that would take place if the team chose a material that has not been previously approved by the FDA. The source of injection molding the team will work with also needs to be finalized. The team has been in discussion with Protolabs, but once the design is finalized additional quotes will be acquired from other companies in order to find the most cost-effective manufacturing process.

Once the wheel and stand designs are finalized, the team will continue testing the device with the grade scale and timing with physicians and CathLab technicians. They will practice loading and unloading the device 10 times before the trials begin. This is done to reach the plateau of the learning curve, which will give the most accurate results of how the device would be used in the field. Finally, the team will work closely with the client on the business side to discover the best ways to make this marketable in the industry starting with patenting the device through WARF.

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10. Appendix
10.1 Appendix A: Product Design Specifications
Product Design Specifications
Date of Last Revision: September 22, 2022

Title: Guidewire Organizer for Operation Room
Client: Dr. Dai Yamanouchi
Advisor: Dr. Darilis Suarez-Gonzalez
Team: Tatum Rubald, Addison Dupies, Rachel Krueger, Victoria Heiligenthal, Lily Gallagher, and Benjamin Smith
Section Number: BME 400, Lab 309

Function:
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 guidewires.

Client requirements:
- The project consists of two pieces: a guidewire wheel and wheel stand.
- The team will determine and finalize the dimensions (diameter, wall thickness and hand slot) of the current guidewire wheel design.
- The wheel will successfully load guidewires of varying stiffnesses.
- The wheel stand will stack three guidewire wheels.
- Guidewires must be able to be removed from the wheel while the wheel is stored on the stand.
- Single use device (SUD).
- The final market device must be able to be mass produced and released into the market in an FDA approved material at a low cost.

Design requirements:
1. Physical and Operational Characteristics
   a. *Performance requirements*: The device will consist of two pieces: (1) a stand to store 3 wheels in which the guidewires will be placed. The wheel must be able to hold guidewires with diameter sizes of 0.014 to 0.035 inches and varying stiffnesses. Additionally, the guidewire must stay organized and unknotted when removed from the wheel while on the stand. It must be easy to load and remove the wire into the wheel while in the operating room [1]. The wheels must be easily placed and removed from the stand. The stand must hold the 3 wheels at once. The stand should allow easy access to the guidewire at any point during a procedure.

b.   *Safety*: 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, the device must be able to fit 3 catheter guidewires, which ideally fit within the finalized optimized diameter of each wheel, and each wheel must be able to hold various guidewire sizes separately [1]. In addition to the precision it will take to design the device, it also must be able to undergo surgeries and have the ability to keep the multiple guidewires used during surgery organized. This will allow the operating room workers to navigate the guidewires easier than without the device. The stand should not interfere with the performance of the wheel. The stand should keep the wheel firm in place to allow for efficient loading and unloading.

d. *Life in Service*: The final product will be a SUD. It must be able to withstand the loading and unloading of a guidewire 3-5 times during a single procedure.

e. *Shelf Life*: Although the final market device will be discarded after each use, the product must last at least two years on the shelf. To ensure the material of the device will not degrade, the device will be stored in an environment where the humidity and temperature are regulated to the material's specifications.

f. *Operating Environment*: The final market device will be used within an operating room and be fully functional within standard operating room conditions. These include a relative humidity of 20 to 60%, and a temperature between 68°F and 75°F [2].

g. *Ergonomics*: The wheel should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. A surgeon's hand should be able to easily slide into the wheel to load the guidewire. The average male surgeon's hand circumference is 21.35 cm and female is 18.95 cm [3]. The hand opening should take these dimensions into consideration. The circular wheel and storage devices should have a minimum learning curve to hasten the use. The stand device should not slip on surfaces.

h. *Size*: The design consists of a circular wheel with a diameter of 15-25cm and an inner diameter cutout of 10-25 cm for maximum control by the operator [3]. The circular wheel will have a thickness of 3-8 mm. The stand will have dimensions that will be determined based on the wheel dimensions

i. *Weight*: The final wheel design will be lightweight and easy to maneuver by the operator. The stand must fit within operating room size requirements and various table setting environments [4]. The stand must be heavier than the wheel design so it does not tip over while holding the wheels.

j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [4]. The stand may require weights in the base. The final product will be made out of an FDA approved polymer that can be mass manufactured while

fulfilling weight, size, and shelf life requirements.

    k. *Aesthetics*, *Appearance, and Finish:* The final market device should be an FDA approved plastic and should have a smooth, clean finish [5]. 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 final design will consist of 3 wheels and a stand, which will house the wheels. However, the final manufactured design will be mass produced.

    b. *Target Product Cost*: Taking into consideration the materials and size, the estimated cost of the final product will be approximately $2 per wheel and $5 per stand [1].

3. Miscellaneous

    a. *Standards and Specifications*: This product would likely be considered as a Class I medical device. There is no direct FDA regulation for this device; both the stand and wheel are assumed to be a Class I device and may require premarket approval in the form of a 510(k) [6].

    b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine endovascular surgeries. This would be the case due to the highly beneficial organization of the guidewires in endovascular catheter surgeries, as they are often misordered which leads to extended surgery time, making this prototype appeal to those who want to avoid the disorganization of guidewires during surgical procedures. The effect of disorganized guidewires can potentially lead to internal damage 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 it is placed in [7].

    c. *Packaging*: The client wants the product to be packaged with guidewires and distributed in conjunction with guidewires [1]. It will be assembled and packaged in a clean room environment. The stand will be purchased separately.

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

    e. *Competition*: A main competing guidewire organization device is the Cath Clip. To use the Cath Clip, an operating technician winds the guidewire into a neat circle and clips it together using the device. Cath Clip is a single-use and lint-free device device. The Cath Clip can lead to disorganization as the guidewires do not stay separated when placed on the table. Since there is no additional storage unit included for the device, after it is placed on the table it can fall onto the floor if bumped or not secured [8]. Another guidewire organization device produced by Medline Industries is the Guidewire Bowl. This device comes in various sizes ranging from 8.5 inches

to 11 inches in diameter. These bowls have 5 interior tabs that overhang to hold various guidewires within the bowl while submerged in saline. This device is also plastic and single use [9]. A guidewire organization device that currently exists is the Angio Assist™ Docking Station by Teleflex, which facilitates the introduction of guidewires into catheters and 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 loading. There are two slots that facilitate the alignment of guidewires and catheters on this device. Another product is the Tierstein Edge Device Organizer, by Teleflex which has 6 friction fit slots for guidewires and catheters and is designed to minimize loss of motion control of eternal guidewire as well as increase security of excess wires during procedures [10].

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10.2 Appendix B: Design Matrix Definitions

Safety, cost, efficiency, durability, and learning curve.

Safety: The device must be safe to use on patients in a hospital operating room and should be safe to use by a doctor. With safety, the wheel must not break in the process of unloading or loading the guidewire wheels.

Cost: The cost of each design; the client did not give us a set budget. However, the production of a single wheel in the final stages should not be more than $2.

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 guidewire wheels.

Durability: The ability of the design to withstand stress upon operation. The final market device must be able to withstand a single procedure.

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. The device will not be successful in the market if doctors have to spend any significant amount of time learning how to use it.

10.3 Appendix C: Testing Protocol
Guidewire Holder Test Method

Loading
1. Start timer
2. Wind guidewire by hand
3. Pick up wheel from table
4. Use one hand to hold wheel, one to hold wire-loop
5. Slide wire-loop into wheel
6. When guidewire is fully secured within the wheel, place wheel in one hand
7. Stop timer

*If the guidewire is not able to load properly, record load time as MT (mistrial)

Grade the Load Trial (0-3)
0 - Unable to load guidewire
1 - The wire slid into the wheel, but there were some issues (i.e. the tip of the wire hangs out too far, had to manually maneuver the wire to fit into the wheel, e.g.)
2 - Wire slid into the wheel with ease, but the wheel itself made the sliding motion uncomfortable/less time efficient
3 - Wire slid into wheel without complications

Unloading
1. Start timer
2. Use one hand to hold wheel, and one hand to thread guidewire out of loop
3. When wire is fully out of wheel, stop timer

DO NOT STICK FINGERS THROUGH CENTER OF WHEEL TO AID IN REMOVAL. MUST REMOVE WIRE WITHOUT TOUCHING
*If the guidewire is not able to unload properly, record load time as MT (mistrial)

Grade the Unload (Thread trial) (0-3)
0 - Unable to unload the guidewire
1 - The guidewire was partially removed from the wheel before tangling and popping out
2 - The guidewire was removed from the wheel without tangling but partially falls out of wheel during unloading
3 - The guidewire was removed without complications

Unloading Pull
1. Use one hand to hold wheel, and one hand to remove guidewire out of loop
2. When wire is fully out of wheel rate the difficulty of removing the guidewire

Grade the Unload Trial (Pull Trial)(0-3)
0 - Unable to unload the guidewire
1 - The guidewire was removed from the wheel but significant effort was needed (2 hands, extra person utilized)
2 - The guidewire was removed from the wheel but was caught on middle chimney
3 - The guidewire was removed without complications

Record the following values for each trial:
- Member or Participant Number
- Design Used
- Guidewire Used
- Load time
- Unload time
- Grade

10.4 Appendix D: Notes/Feedback From Physician Round Table
- Person #1
  - Trial 1: Lhold
    - Load: 4s
    - Unload: 5s
    - Comments
      - Like L-hold design the best
      - "Intuitive"
      - "Know where to put the wire"
  - Trial 2: Xtrahold
    - Load: 4s
    - Unload: 2s
  - Trial 3: Vhold
    - Load: 5s

- Unload: 5s
- Person #2
  - Trial 1: Lhold
  - Loading: 2s
  - Unloading: 5s
  - Guide popped wire came on unload
    - Intuitive
- Person #3
  - Intuitively push it in verses pulling it in
  - Point the wheel downwards to ensure that no contamination occurs
  - Did not say which design was favored *implied it was Lhold

Teams Comments:
- Xtrahold did not keep the wires in as well as the other designs
  - Possibly due to the shorter chimney
- Everyone seemed to favor the Vhold design because it was intuitive on how you load the wire
- We need to alter the opening edges to allow for the wire to open up more
  - Like how it is on the control
- Each person held the device a different way, initial response to push the wire in, however, we want to pull the wrapped guidewire around the middle piece and let go.
- Maybe add arrows?
- Print Vhold with the edited opening in multiple different sizes, then test again

10.5 Appendix E: Protolabs Injection Molding Quote

10.6 Appendix F: Raw Testing Data

Design Number:	Member Number:	Trial Number:	Loading Time:	Loading Grade (0-3):	Unloading time (not on stand):	Unloading Grade (0-3)
1	4	1	10.69	3	3.63	3
1	4	2	14.27	2	3.47	3
1	4	3	19.97	2	3.42	3
0	4	4	16.35	3	4	3
0	4	5	12.76	2	2.76	3
0	4	6	9.06	3	1.86	3
2	4	7	10.29	3	3.45	3
2	4	8	10.25	3	1.42	3
2	4	9	10.3	3	1.9	3
3	4	10	12.23	3	3.4	3
3	4	11	10.06	3	4.03	2
3	4	12	13.75	3	4.32	3
4	4	13	15.69	2	4.35	2
4	4	14	14.47	1	3.97	2
4	4	15	14.82	2	3.72	2
5	4	16	13.28	2	2.96	2
5	4	17	13.84	2	3.39	2
5	4	18	12.88	3	3.13	3
6	4	19	15.97	2	4.51	2
6	4	20	15.32	2	1.34	1
6	4	21	14.71	2	3.8	2
2	1	1	10.52	3	2.36	3
2	1	2	10.31	3	2.11	3
2	1	3	10.03	3	1.94	3
5	1	4	12.42	2	1.3	2
5	1	5	13.72	2	2.78	2
5	1	6	12.18	3	2.43	2
6	1	7	13.32	2	4.59	2
6	1	8	13.76	2	4.04	2
6	1	9	13.33	2	1.26	1
1	1	10	13.4	2	3.78	3
1	1	11	9.29	3	3.99	3
1	1	12	11.86	2	3.55	2
3	1	13	10.66	3	3.27	2
3	1	14	10.2	3	2.67	3
3	1	15	10.73	3	2.28	3
4	1	16	16.89	1	4.64	1
4	1	17	14.57	2	3.92	1
4	1	18	14.12	2	4.39	2
0	1	19	13.15	3	3.94	3
0	1	20	13.34	3	3.47	3
0	1	21	9.45	3	3.56	3
3	3	1	12.07	3	4.04	3
3	3	2	12.25	2	3.2	3
3	3	3	10.07	3	3.26	3
0	3	4	12.25	3	3.65	3

KEY:

Member	Member #	Number of Trials
Addie (R)	1	21
Ben (R)	2	0
Rachel (L)	3	21
Tatum (R)	4	21
Victoria (R)	5	21
Lily (R)	6	21
Design	Design #	
LHold	0	15
VHold	1	15
XSHold	2	15
XtraHold	3	15
TRHold	4	15
ADHold	5	15
LGHold	6	15

Design Number:	Member Number:	Trial Number:	Loading Time:	Loading Grade (0-3):	Unloading time (not on stand):	Unloading Grade (0-3)
0	3	5	10.93	3	4.13	3
0	3	6	12.5	3	3.53	3
2	3	7	14.5	2	4.26	3
2	3	8	17.96	2	4.07	3
2	3	9	14.48	3	3.73	3
6	3	10	13.46	2	5.5	3
6	3	11	12.72	3	4.43	3
6	3	12	18.14	2	5.46	2
4	3	13	19.48	1	5.23	2
4	3	14	18.5	0	4.01	2
4	3	15	18	0	6.13	2
5	3	16	16.3	2	3.82	2
5	3	17	16.91	3	4.08	3
5	3	18	12.31	3	3.72	3
1	3	19	9.94	3	4.54	3
1	3	20	11.06	3	3.56	3
1	3	21	10	3	3.41	3
4	6	1	8.33	2	6.79	1
4	6	2	13.1	1	5.07	3
4	6	3	14.2	1	5.75	2
2	6	4	15.69	3	5.41	3
2	6	5	13.9	3	5.75	3
2	6	6	13.4	3	6.2	3
6	6	7	14.32	1	3.9	2
6	6	8	14	2	4.4	2
6	6	9	16.66	2	9	3
3	6	10	15.3	3	6.5	3
3	6	11	13.45	3	6.3	2
3	6	12	15.9	3	9.36	2
5	6	13	15.35	3	7.28	1
5	6	14	13.92	3	7.59	1
5	6	15	12.98	3	5.6	1
0	6	16	14.46	3	6.43	3
0	6	17	13.07	3	6.31	3
0	6	18	9.35	3	7.38	3
1	6	19	14.61	3	5.9	3
1	6	20	11.96	3	7.37	3
1	6	21	14.01	3	5.74	3
1	5	1	18.76	3	3.6	2
1	5	2	14.4	3	4.8	3
1	5	3	16.45	2	3.68	3
3	5	4	15.34	3	4.43	3
3	5	5	15.37	2	2.75	3
3	5	6	11.3	3	5.55	2
4	5	7	16.15	0	4.63	1
4	5	8	14.12	2	3.88	2

Design Number:	Member Number:	Trial Number:	Loading Time:	Loading Grade (0-3):	Unloading time (not on stand):	Unloading Grade (0-3)
4	5	9	13.64	1	4.37	2
2	5	10	11.54	3	2.59	3
2	5	11	11.38	3	2.4	3
2	5	12	9.76	3	1.87	3
6	5	13	16.21	2	7.55	2
6	5	14	17.95	1	5.81	2
6	5	15	15.02	2	4.72	2
5	5	16	14	2	4.64	2
5	5	17	15.16	2	2.29	2
5	5	18	13.92	2	2.65	2
0	5	19	13.06	3	6.24	3
0	5	20	17.36	2	4.34	3
0	5	21	9.7	3	3.86	3

10.7 Appendix G: MATLAB Code for Data Analysis

```
%% Fall 2022
clear
clc
close all

%% Load data
[ dataFile, dataDir ] = uigetfile( '*.xlsx', 'Select excel file containing your study data') ;
wheelData = xlsread( dataFile ) ;
```

```matlab
designNum = wheelData( :, 1 ) ;
memberNum = wheelData( :, 2 ) ;
trialNum = wheelData( :, 3) ;
loadTime = wheelData( :, 4 ) ;
loadGrade = wheelData( :, 5 ) ;
unloadTime = wheelData( :, 6) ;
unloadGrade = wheelData( :, 7 ) ;


wheel0 = find(designNum == 0);
wheel0 = wheelData(wheel0,:);

wheel1 = find(designNum == 1);
wheel1 = wheelData(wheel1,:);

wheel2 = find(designNum == 2);
wheel2 = wheelData(wheel2,:);

wheel3 = find(designNum == 3);
wheel3 = wheelData(wheel3,:);

wheel4 = find(designNum == 4);
wheel4 = wheelData(wheel4,:);

wheel5 = find(designNum == 5);
wheel5 = wheelData(wheel5,:);

wheel6 = find(designNum == 6);
wheel6 = wheelData(wheel6,:);

%Getting number of occurences of each rating for loading
[row, col] = size(wheelData);
loadGRTable = cell(row+1, 3);
for x = 0:6
    designRun = find(designNum == x);
    designRun = wheelData(designRun,:);
    xLoad = unique(designRun(1:15,5)); %Change when run everything
    NLoad = numel(xLoad);
    countLoad = zeros(NLoad,1);
        for k = 1:NLoad
            countLoad(k) = sum(designRun(1:15,5)==xLoad(k)); %Change when run everything
        end
    emptyData = cellfun(@isempty, loadGRTable);
    emptyRows = find(emptyData(:,1)==1);
```

```matlab
    nextRow = emptyRows(1);
    occurLoad =  [xLoad(:),countLoad ];
    occurLoad = num2cell(occurLoad);
    numRun = repmat({x}, height(occurLoad), 1);
    loadGRTable(nextRow:nextRow+height(numRun)-1, 3) = numRun; %Change nextrow with all
data
    loadGRTable( nextRow:nextRow+height(occurLoad) -1 ,1) = occurLoad(1:end,1); %Rate is
first
    loadGRTable( nextRow:nextRow+height(occurLoad)-1 ,2) = occurLoad(1:end,2);
%Occurences is second

end
%% try
%Getting number of occurences of each rating for unloading
[row, col] = size(wheelData);
unloadGRTable = cell(row+1, 3);

for u = 0:6
    designunRun = find(designNum == u);
    designunRun = wheelData(designunRun,:);
    xunLoad = unique(designunRun(1:15,7)); %Change when run everything, should be 1:18
    NunLoad = numel(xunLoad);
    countunLoad = zeros(NunLoad,1);
        for k = 1:NunLoad
            countunLoad(k) = sum(designunRun(1:15,7)==xunLoad(k)); %Change when run
everything
        end
    emptyData = cellfun(@isempty, unloadGRTable);
    emptyRows = find(emptyData(:,1)==1);
    nextRow = emptyRows(1);
    occurUnLoad =  [xunLoad(:),countunLoad ];
    occurUnLoad = num2cell(occurUnLoad);
    numRunUn = repmat({u}, height(occurUnLoad), 1);
    unloadGRTable(nextRow:nextRow+height(numRunUn)-1, 3) = numRunUn;
    unloadGRTable( nextRow:nextRow+height(occurUnLoad) -1,1) = occurUnLoad(1:end,1);
%Rate is first
    unloadGRTable( nextRow:nextRow+height(occurUnLoad)-1 ,2) = occurUnLoad(1:end,2);
%Occurences is second

end

%% Plotting

figure(1);
```

```matlab
rate_load = [0 ;1; 2; 3]; %Rating number
occur_load=[0,0,0,0,3,0,0; 0,0,0,0,6,0,2; 2,5,2,2,6,8,12; 13,10,13,13,0,7,1]; %[Rating 0, for each
individiual design in order]%[# of times for 0 rate for each design; number of 1 rate for each
design;
bar(rate_load, occur_load);
xlabel('Rating Number');
ylabel('Number of Occurences for Each Rating');
title('Ratings of Loading Different Wheel Designs');
legend('LHold',          'VHold','XSHold', 'XtraHold','TRHold','ADHold','LGHold');

figure(2);
rate_unload = [0 1 2 3]; %Rating number
occur_unload=[0,0,0,0,0,0,0; 0,0,0,0,4,0,2; 0,2,0,5,10,9,10; 15,13,15,10,1,3,3]; %Number of
occurences of each rating - Take from loadGRTable manually
bar(rate_unload, occur_unload);
xlabel('Rating Number');
ylabel('Number of Occurences for Each Rating');
title('Ratings of Unloading Different Wheel Designs');
legend('LHold',          'VHold','XSHold', 'XtraHold','TRHold','ADHold','LGHold');


%% Person Data
mem1 = find(memberNum == 1);
mem1 = wheelData(mem1,:);
timeData1 = mem1(:, [1,4,6]);

mem2 = find(memberNum == 2);
mem2 = wheelData(mem2,:);
timeData2 = mem2(:, [1,4,6]);

mem3 = find(memberNum == 3);
mem3 = wheelData(mem3,:);
timeData3 = mem3(:, [1,4,6]);

mem4 = find(memberNum == 4);
mem4 = wheelData(mem4,:);
timeData4 = mem4(:, [1,4,6]);

mem5 = find(memberNum == 5);
mem5 = wheelData(mem5,:);
timeData5 = mem5(:, [1,4,6]);

mem6 = find(memberNum == 6);
mem6 = wheelData(mem6,:);
```

```matlab
timeData6 = mem6(:, [1,4,6]);

%Plotting of times
figure(3);
subplot(1,2,1)
timeLoad=[13.14 13.34 9.45 12.25 10.93 12.5 16.35 12.76 9.06 13.06 17.36 9.7 14.46 13.07
9.35; 13.4 9.29 11.86 9.94 11.06 10  10.69 14.27 19.97 18.76 14.4 16.45 14.61 11.96 14.01...
%Designs 0,1
   ;10.52 10.31 10.03 17.96 14.48 14.5 10.29 10.25 10.3 11.54 11.38 9.76 15.69 13.9 13.4;
10.66 10.2 10.73 12.07 12.25 10.07 12.23 10.06 13.75 15.34 15.37 11.3 15.3 12.45
15.9...%Designs 2,3
   ;16.89 14.57 14.12 19.48 18.5 18 15.69 14.47 14.82 16.15 14.12 13.64 8.33 13.1 14.2; 12.42
13.72 12.18 16.3 16.91 12.31 13.28 13.84 12.88 15.16 13.92 13.06 15.35 13.92 12.98...
%Designs 4,5
   ;13.32 13.76 13.33 13.46 12.72 18.14 15.97 15.32 14.71 17.95 15.02 14 14.32 14 16.66]';
%time to load,%Designs 6
boxplot(timeLoad);
designs = {'LHold',      'VHold','XSHold', 'XtraHold','TRHold','ADHold','LGHold'};
set(gca, 'xtick', [1:7], 'xticklabel', designs);
xlabel('Design Type');
ylabel('Time to Load (s)');
title('Time to Load Different Designs');


subplot(1,2,2)
timeunLoad=[3.94 3.47 3.56 3.65 4.13 3.53 4 2.76 1.86 6.24 4.34 3.86 6.43 6.31 7.38; 3.78 3.99
3.55 4.54 3.56 3.41 3.63 3.47 3.42 3.6 4.8 3.68 5.9 7.37 5.74...
   ;2.36 2.11 1.94 4.26 4.07 3.73 3.45 1.41 1.9 2.59 2.4 1.87 5.41 5.75 6.2; 3.27 2.67 2.28 4.04
3.2 3.26 3.4 4.03 4.32 4.43 2.75 5.55 6.5 6.3 9.36...
   ;4.64 3.92 4.39 5.23 4.01 6.13 4.35 3.97 3.72 4.63 3.88 4.37 6.79 5.07 5.75; 2.78 1.3 2.43
3.82 4.08 3.72 2.96 3.39 3.13 4.64 2.29 2.65 7.28 7.59 5.6...
   ;4.59 4.04 1.26 5.5 4.43 5.46 4.51 1.34 3.8 7.55 5.81 4.72 4.4 9 3.9]'; %time to load
boxplot(timeunLoad);
designs = {'LHold',      'VHold','XSHold', 'XtraHold','TRHold','ADHold','LGHold'};
set(gca, 'xtick', [1:7], 'xticklabel', designs);
xlabel('Design Type');
ylabel('Time to Load (s)');
title('Time to Unload Different Designs');


%% Statistics
%All wheel times mean and stds
averageLoad = mean(loadTime);
averageunLoad = mean(unloadTime);
stdLoad = std(loadTime);
```

```matlab
stdunLoad = std(unloadTime);

allLoadData = [wheel0(1:15,4),wheel1(1:15, 4),wheel2(1:15 ,4),wheel3(1:15, 4),wheel4(1:15
,4),wheel5(1:15, 4),wheel6(1:15 ,4)];
[p,tbl,stats] = anova1(allLoadData);

[c,m,h,gnames] = multcompare(stats);
c1 = multcompare(stats);
tbl = array2table(c1,"VariableNames", ...
    ["Design 1","Design 2","Lower Limit","1-2","Upper Limit","P-value"]);
tbl.("Design 1") = gnames(tbl.("Design 1"));
tbl.("Design 2") = gnames(tbl.("Design 2"));

designs = {'LHold',     'VHold','XSHold', 'XtraHold','TRHold','ADHold','LGHold'};
set(gca, 'xtick', [1:7], 'xticklabel', designs);
xlabel('Design Type');
ylabel('Time to Load (s)');
title('ANOVA Box Plot Results');
%Column 4 being extracted is loading time
%Column 5 being extracted is unloading time
%Using rows 1:15 and 1:105 (all data) because that was the number of total trials run
%Indivial wheel times means and stds
wheelAvg =mean(wheelData(1:105, [4,6]));
wheel0Avg = mean(wheel0(1:15, [4,6]));
wheel1Avg = mean(wheel1(1:15, [4,6]));
wheel2Avg = mean(wheel2(1:15, [4,6]));
wheel3Avg = mean(wheel3(1:15, [4,6]));
wheel4Avg = mean(wheel4(1:15, [4,6]));
wheel5Avg = mean(wheel5(1:15, [4,6]));
wheel6Avg = mean(wheel6(1:15, [4,6]));

wheel0Std = std(wheel0(1:15, [4,6]));
wheel1Std = std(wheel1(1:15, [4,6]));
wheel2Std = std(wheel2(1:15, [4,6]));
wheel3Std = std(wheel3(1:15, [4,6]));
wheel4Std = std(wheel4(1:15, [4,6]));
wheel5Std = std(wheel5(1:15, [4,6]));
wheel6Std = std(wheel6(1:15, [4,6]));
```

10.8 Appendix H: ANOVA Results From Testing

Design 1	Design 2	P-value		Design Number Key:	
1	2	0.93506			
1	3	0.999996		1	LHold
1	4	0.999999		2	VHold
1	5	0.047204		3	XSHold
1	6	0.599838		4	XtraHold
1	7	0.060217		5	TRHold
2	3	0.867164		6	ADHold
2	4	0.967624		7	LGHold
2	5	0.446063			
2	6	0.99459			
2	7	0.505609			
3	4	0.999877			
3	5	0.027677			
3	6	0.473338			
3	7	0.035915			
4	5	0.069212			
4	6	0.694543			
4	7	0.087081			
5	6	0.848126			
5	7	1			
6	7	0.887523			

10.9 Appendix I: Semester Expense Report

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
All Prototype Wheels								
Wheel Iteration 1	Modification of current design	UW MakerSpace	N/A	10/19/22	1	$12.44	$12.44	UW-Maker Space
Component 2								
Wheel Iteration 2	Modification of current design	UW MakerSpace	N/A	10/20/222	1	$8.14	$8.14	See above

Component 3								
Wheel Iteration 3	Modification of current design	UW MakerSpace	N/A	10/20/22	1	$11.76	$11.76	See above
Component 4								
Wheel Iteration 4	Modification of current design	UW MakerSpace	N/A	10/21/22	1	$11.46	$11.46	See above
Component 5								
Wheel Iteration 5	Modification of current design	UW MakerSpace	N/A	11/7/22	1	$5.82	$5.82	See above
Component 6								
Wheel Iteration 6	Modification of current design	UW MakerSpace	N/A	11/10/22	1	$5.65	$5.65	See above
Component 7								
Wheel Iteration 7	Modification of current design	UW MakerSpace	N/A	11/15/22	1	$5.61	$5.61	See above
Component 8								

Wheel Iteration 8	Modification of current design	UW MakerSpace	N/A	11/17/22	1	$7.12	$7.12	See above
Component 9								
Wheel Iteration 9	Modification of current design	UW MakerSpace	N/A	11/29/22	1	$5.20	$5.20	See above
TOTAL:	**$73.20**							