



Guidewire Organizer for Endovascular Procedures

BME 200/300

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Abstract

During an endovascular procedure, many guidewires of different styles are used. The guidewire is removed from dispensing tubing and inserted into the patient. The catheter is secured in place and the guidewire is then removed from its casing. After the guidewire is removed, a problem arises. The guidewire can become easily tangled and disorganized. As a result the team has been tasked with creating a device that allows for better organization, storage, and dispensing of guidewires during endovascular procedures. The team came up with four designs: Magnetic Wheel, Clamped Wheel, Wheel of Magic, and Guidewire Hoop. Ultimately, the team chose the Guidewire Hoop as the final design. The proposed design is a ring-like device with a magnetic inner surface in order to keep the guidewire secure at all times and a small hole to thread the guidewire through. The team plans on testing the prototype through timed testing trials of efficiency of storing and removing the guidewire from the Guidewire Hoop. The team evaluated the Guidewire Hoop by using an ANOVA test to compare the loading and unloading times of the guidewire into the Guidewire Hoop to the current practice of using the dispensing tubing. The team found that modifications must be made with the addition of a back plate and deeper inner cavity. These modifications will further secure all guidewire sizes and stiffness and create a more efficient process of storing and organizing guidewires.

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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 almost every hospital is efficiency [2]. All of this additional work does not simply throw away money, but also diverts residents, surgeons, physicians, and nurses from performing other necessary tasks and taking care of patients.

This device will decrease the amount of the time a surgeon spends in the operating room; therefore, decreasing the amount of wasted time and money in the operating room (OR). Additionally, this device will allow for better organization and a less hazardous setting in the OR. The endovascular treatment device market is currently over \$2.0 billion and is projected to reach \$2.2 billion by 2022 [3]. We hope to eventually bring this device to market, making it a popular device that surgeons choose over the current guidewire dispensing tubing.

1.2 Current Competing Systems

There are two main competing designs for the guidewire organizer: Angio Assist Docking System and Teirstein Edge Device Organizer, both of which were designed by Teleflex. The Angio Assist Docking System is designed to hold up to one guidewire and one catheter at a time. The product contains slots to facilitate the alignment and introduction of 0.014” guidewires into the catheters [4]. The Teirstein Device Organizer is designed to hold up to six catheters and six guidewires. The guidewires are held by six friction slits which allow for controlled, micro movements of the guidewire. Both designs use easy-to-pinch clips for securing to drapes in the operating room [5].

There are key differences between what these designs offer and what our client is looking for within the guidewire organizer. The device our client suggested should be designed so that each guidewire is coiled up and organized separately and alone. This is so each guidewire will not get tangled with the others.

1.3 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 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.

2. Background

2.1 Relevant Physiology and Biology

As stated previously, our device will assist in the ease of organization of guidewires in endovascular catheter related surgeries. The baseline procedure is called Cardiac Catheterization, which is used to evaluate or confirm the presence of coronary artery disease, valve disease, or disease of the aorta. Cardiac Catheterizations are also used to evaluate heart muscle function as well as determine the need for further treatment (such as an interventional procedure or coronary artery bypass graft, or CABG, surgery) [6].

A Cardiac Catheterization is performed in a standard hospital operation room. A guidewire will be inserted into a vein, and snaked to the region of interest for the surgery [7]. Following this, a long, narrow metal 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) and over the guidewire. Then, the surgeon will guide the catheter through the blood vessel to the coronary arteries with the aid of a special x-ray machine as an assisting person unwinds the excess catheter [8].

The next step is a Coronary Angiogram, where *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. Finally, the coronary artery is opened, increasing blood flow to the heart and digital photographs of the *contrast material* are used to identify the site of the narrowing or blockage in the coronary artery [8].

2.2 Materials and Machines

For this project, the prototype will be 3D printed at the MakerSpace. The printer selected will be the Ultimaker S5. The Ultimaker S5 has a large build volume (33.0 x 24.0 x 30.0 cm) [9], and since our product is fairly large, this 3D printer is ideal for our product. We will use Ultimaker PLA for the printing filament due to its ease of use, high strength, and high stiffness. It is also cost effective and efficient [10], two features that are ideal for prototyping.

2.3 Client Information

Dr. Dai Yamanouchi, MD, PhD, is a surgeon at UW-Health. He specializes in vascular and endovascular related procedures, as well as research relating to aneurysm post angioplasty including balloon angioplasty and stent placement. He is passionate about creating a device for his operating room issue of tangled guidewires [11].

2.4 Design Specifications

Some important categories of the product design specification include performance requirements, safety, accuracy and reliability, and overall size. The device will consist of two parts: 4 guidewire hoops (wheel) and a crate to store all the wheels. Each guidewire will be placed within its own individual wheel. The wheel itself will have a 30 cm diameter, and must be

able to hold guidewires with diameter sizes of 0.014 to 0.035 inch. Overall, the guidewire must stay organized and unknotted when inserted and removed from the wheel in the operating room. Lastly, the final device must withstand heavy chemicals needed to sterilize medical devices. Please refer to the full PDS in Appendix 10.1 for more information on design specifications.

3. Preliminary Designs

Introduction

Before introducing our 4 initial guidewire organizer designs, it is important to preface the apparatus used for 3 of the 4 designs. The Magnetic Wheel, Clamped Wheel, and the Guidewire Hoop are all compatible with our crate design that has 4 slots for 4 wheels of each design when placed in an operating room setting. The crate is important for keeping guidewires separate when multiple are in use, as it can fit each wheel with a width of 3 cm.

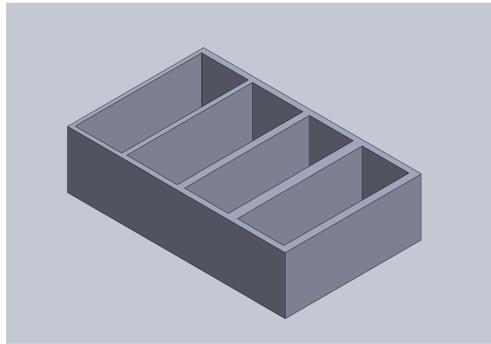


Figure 1. *Storage Crate.* Dimensions: 13x30x15cm

3.1 Magnetic Wheel

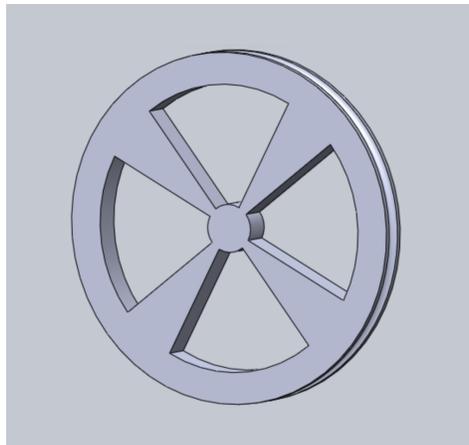


Figure 2. *Magnetic Wheel.*
Dimensions: Outer Diameter: 30cm. Inner Diameter: 28cm.

The Magnetic wheel design shown in Figure 2 was the initial design idea. The goal of the design was to use a magnetized outer ring to keep the metallic guidewire in contact with the

wheel while coiled around the magnetized wheel, in order to prevent uncoiling of the guidewire, and to have easier access to the guidewire. The design has an outer diameter of 30 cm with a concave semicircle cutout around the circumference of the wheel that acts as a lip to contain the guidewire when it is spooled around the wheel. It has an internal diameter of 28 cm. Within the walls of the cutout, there will be a magnetic strip that will attract the metallic guidewire, keeping it in close contact with the wheel at all times, not allowing for the uncoiling of the guidewire when wrapped around the wheel. When the wheel is placed into the crate, the wheel can be accessed through the top of the crate where the wheel is exposed. The wheel can be removed, and the guidewire can be unspooled.

3.2 Clamped Wheel

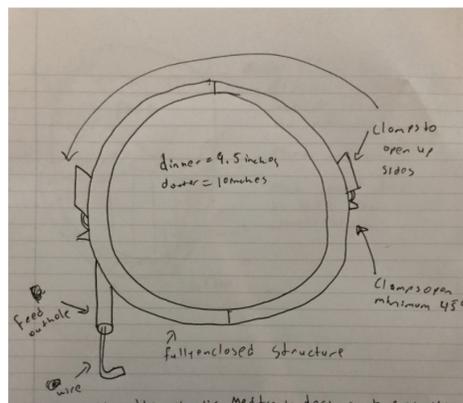


Figure 3. Clamped Wheel.

Dimensions: Outer Diameter: 25.4 cm. Inner Diameter: 24.13 cm.

The Clamped Wheel design, Figure 3, utilizes a different mechanism for containing the guidewire when the guidewire is placed inside of the wheel. Instead of the guidewire being spooled around the wheel, there is a clamp on the circumference of the wheel that can snap open and closed once the guidewire is placed inside. The hollow circumference of the wheel will contain the guidewire once it is clamped shut, as the guidewire must be coiled and placed into the wheel prior to shutting the clamp. The wheel also has a small protruding tube extending from the hollow interior of the perimeter of the wheel, which will contain the very tip of the guidewire for easier access to the wire, as the tip of the wire can be pulled to uncoil the wire without having to unclamp the wheel. The outer diameter of the wheel is 25.4 cm, and the inner diameter of the wheel is 24.13 cm, and in between those diameters is the hollow surface that contains the guidewire.

3.3 Wheel of Magic

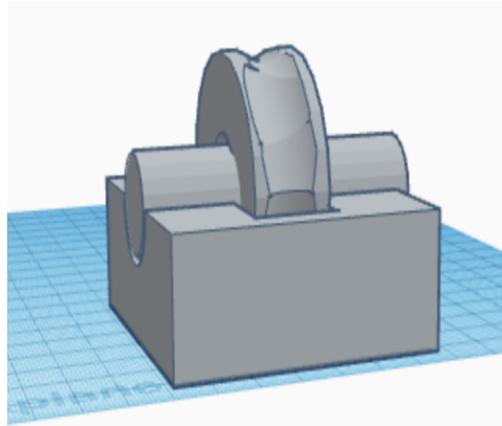


Figure 4: *Wheel of Magic.*

Dimensions: Outer Diameter: 30 cm. Inner Diameter: 15 cm.

The Wheel of Magic, Figure 4, design has a more unique function in comparison to the other preliminary designs. The Wheel of Magic has three structures: the wheel, the middle rotating handles, and the lower crate portion. The wheel portion is used as a guide for the guidewire to be spooled around and has protruding handles on both sides to have easier access to rotate the wheel, allowing for hands-free uncoiling of the guidewire. The Wheel has an outside diameter of 30 cm with a concave lip cut into the width of the wheel that ends with an internal diameter of 15 cm. The guidewire is then spooled around the wheel within the concave lip and then placed into the lower crate. The crate for this design is different from the crate that is used for the other preliminary designs because it only fits one wheel per crate and has a ‘U’ shaped cut to account for the protruding handles on both sides. The purpose of the crate, in addition to keeping the guidewire separate from other guidewires, is to contain the guidewire by using the radial force applied by the guidewire to the crate internally, which does not allow for the uncoiling of the guidewire on the top of the wheel. The guidewire access point is where the top of the crate no longer encloses the wheel, and the handles can be used to slowly uncoil the guidewire from the design.

3.4 Guidewire Hoop

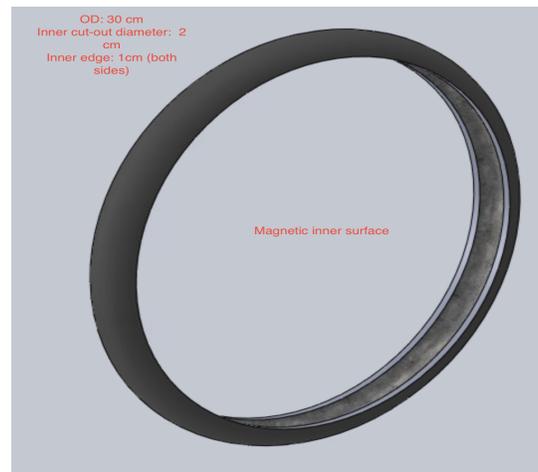


Figure 5: *Guidewire Hoop*. Dimensions: Outer Diameter: 30cm. Inner Diameter: 29 cm.

The Guidewire Hoop in Figure 5, and was heavily influenced by the three previous designs. Using the innovative properties of the magnetized wheel in addition to the recognition of the radial force the guidewire exerts when coiled, this design aims to prevent the uncoiling of the guidewire internally. This design, instead of having a concave lip externally cut into the wheel, has an internal concave lip that is magnetized. The internal concave lip utilizes the radial force of the guidewire when coiled to contain the guidewire within the wheel, as the wire presses against the external wall of the wheel. In addition, the internal concavity is magnetized to ensure that the guidewire will remain in contact with the wheel against the lip, keeping the wire as stationary as possible to prevent the incidental uncoiling of the wire.

4. Preliminary Design Evaluation

4.1 Design Matrix

The Design Matrix Criteria:

Feasibility (30%):

Feasibility is the team's ability to produce the design as a working prototype in the next two months. This takes into account the team's time, equipment, and assembly constraints. The goal of the project is to create a working proof of concept, or prototype, that can then be mass produced in order to start a company. This criteria describes that goal exactly, and is given the highest percentage contribution of 30%.

Efficiency (25%):

Efficiency is determined by how fast the wire can be stored and accessed. This criteria is the other major section of the goal of the project. The prototype must work and must be proven

to be faster and more convenient to the client. This gives it a purpose and a method to market it as a company in the future.

Durability (20%):

Durability is another important aspect to this project. The product will be used in a location and situation where lives can be lost. The device must not break or malfunction during this time. The device must be able to withstand multiple surgeries, cleanings, and accidents. These accidents can involve things such as being dropped. In addition to the importance during surgery, the durability is also important for the lifetime of the product. This will give the product another aspect to market.

Safety (10%):

The safety criteria measures the threat to the doctor's and the patient's safety. The products will be in the surgery room and must not interfere with any of the procedures and the equipment surrounding the doctors. The criteria is worth a lower percentage as the products should be safe. The prototypes do not include electronics or other parts that can malfunction.

Learning Curve (10%):

The learning curve is determined by the time needed to become accustomed to the new device. The devices should not have a long time to learn their functions and should be quick to pick up. The devices are meant to be intuitive and to save the doctors time, not to give them something else to think about during surgery. The lower percentage for this criteria is because the devices are all relatively uncomplex.

Cost (5%):

The cost is the final criteria. It was given the lowest percentage as the client has decided that the current project will be purely a proof of concept. This means that the cost of the device does not have to represent the final cost of the product. The client has also determined that the cost of prototyping is not an issue. The cost is further lowered as the process of prototyping is done by 3D printing with cheap plastics.

Design Matrix Evaluation:

In the feasibility criteria, the winner was the Guidewire Hoop. This design was evaluated to be the most likely to have a working prototype by the end of the semester. This design consists of a 3D print, followed by a magnetic strip on the inside of the ring. By comparison, the other designs have a part of them that would make it more complicated to construct. The Clamped Wheel would require the team to find a compatible clamp, and then find a method of combining it with a plastic shell in a way that ensures zero error. The Magnetic Wheel would require an appropriate strength magnet to counteract the wire's tendency to straighten and to find a method

to ensure that the magnets would not fall off over time. The Wheel of Magic would require three prints with a low margin of error to ensure that the product works properly.

Efficiency was also evaluated. The Guidewire Hoop was the winner as it was estimated to be the fastest design to insert and remove the wire from. The quick wire storage comes from the ability of tension and magnets to hold the wire in place. This means after releasing the wire on the inside cavity, tension and magnets would hold it in place. The Wheel of Magic and Magnetic Wheel scored lower as they require manually coiling the wire around the device, and uncoiling it afterward. This makes the devices only slightly better than the original method. Finally, the Clamped Wheel made access very simple as it only requires opening a clamp. The issue with this design would be that both clamps must be opened simultaneously in order to keep the guidewire from springing out and unwinding hazardously.

Durability is a very significant criterion. The designs needed to ensure that, in a high-stakes setting, they do not break. The Guidewire Hoop, again, was the winner. The design is one continuous piece, meaning that there are no moving parts to break. The Clamped Wheel's clamps have a possibility of breaking, giving it a lower score. The Magnetic Wheel has magnets on the outside and has spokes on the center that are also more likely to break. Finally, the Wheel of Magic has three parts that are separated and if chipped may not slide as easily as before.

Safety is an important issue, especially in a place where lives are saved. The devices all scored a perfect score as they did not directly affect the patient's or doctor's safety. The devices would have the wire taken out prior to using it in surgery, so it would not be used, as a surgery device, during the operation. The devices may lie inside the room, but they do not have any toxic material or anything else that could affect the health of those nearby.

The learning curve is the estimated time to become accustomed to the device. The winner for this criteria was the guidewire hoop. This design took what doctors were already accustomed to doing, wrapping the wire in a loop around their hands, and only required them to release that loop into the device. The Wheel of Magic and Magnetic Wheel were only slightly lower as instead of looping it around their hand, they would be required to loop it around the new devices. This may feel foreign at first, but given that the devices are not complex is estimated to take little time. The Clamped Wheel was rated the lowest as operating both clamps would be required in order to open the device. This is a more difficult task, and is not something the doctors are familiar with doing.

Finally, the cost is a small issue as the device is a proof of concept, and not representative of the true device in material. The Guidewire Hoop and the Magnetic Wheel were rated the lowest. This is due to the additional cost of magnets. The other two devices only required the cost of the print or other cheap materials, giving them a higher rating. The full design matrix with the numerical scores can be found in Appendix 10.2.

4.2 Proposed Final Design: Guidewire Hoop

The proposed final design was chosen from the preliminary Guidewire Hoop design, seen in Figure 5. The Guidewire Hoop was the best design, using minimal material and the innovative

idea of using the radial force of the guidewire to secure it within the wheel. The magnetized interior, in addition to the utilization of the radial symmetry, made it clear that this design would be the most secure organizer for the guidewire, while still being able to uncoil/remove the wire efficiently.

In the preliminary design, there are a few missing aspects to the design that need to be added in order to make the Guidewire Hoop the most innovative and useful guidewire organizer. To further innovate the final prototype, the outer and inner diameters of the hoop will each be decreased. The outer diameter will be decreased to 22cm, and the inner diameter will be decreased to 20cm in order to hold the guidewire more securely, as the more coiled the guidewire is, the more radial force it will apply to the internal concavity, making the guidewire more secure when placed in the organizer. The final design will also have a width of 2cm, and the internal concavity will have a depth of 1cm to contain the coiled guidewire.

5. Fabrication/Development Process

5.1 Materials

The proposed final design, the Guidewire Hoop, has a simple composition. However, there are specific requirements that the materials must meet in order for them to be viable options. This material must be able to withstand any force, within reason, either by the operator or guidewire itself. In addition, the final material must be biologically inert. The prototype of both the crate and the hoop will be 3D printed and made of Ultimaker PLA. This is the most cost effective material that fulfills the criteria. A magnetic strip will also be glued onto the inner surface of the hoop using superglue.

5.2 Methods

Five wheels will be printed along with the crate, with the dimensions specified in section 4.2 “Proposed Final Design: Guidewire Hoop”. After the wheels are printed, a 2 cm wide magnetic strip will be glued to the inner surface of the wheel. These wheels will be placed in the crate once sufficiently dried.

5.3 Final Prototype

The final prototype design uses the radial force of the guidewire in addition to the internally placed magnet to secure the guidewire in the guidewire organizer. The design uses a circular hoop, with an internal semicircular concavity where the guidewire can be placed once coiled up to the proper diameter to fit the prototype. The outer diameter of the final prototype is 22 cm, the inner diameter of the prototype is 20cm, and the width of the hoop is 2cm.



Figure 6. *Finalized Guidewire Hoop prototype.*
Dimensions: Outer Diameter: 22 cm. Inner Diameter: 20 cm.

5.4 Testing

The team devised two tests to evaluate efficiency and organization between the original plastic casing and the final device. The protocols for test one and test two can be found in Appendix 10.3. 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. Raw data for both tests can be found in Appendix 10.4.

6. Results

6.1 Statistical Analysis

Test 1 generated expected and unexpected results. We ran an ANOVA test on MATLAB for our 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. Figures 7 and 8 show the distribution of data for our unloading and loading testing.

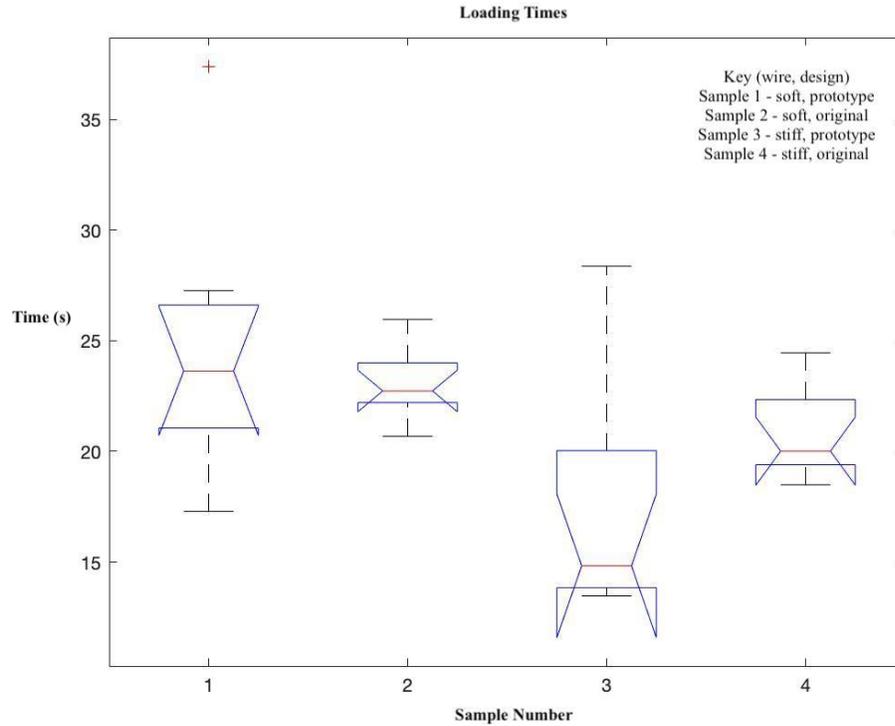


Figure 7. Data distribution of four independent samples for Loading test.

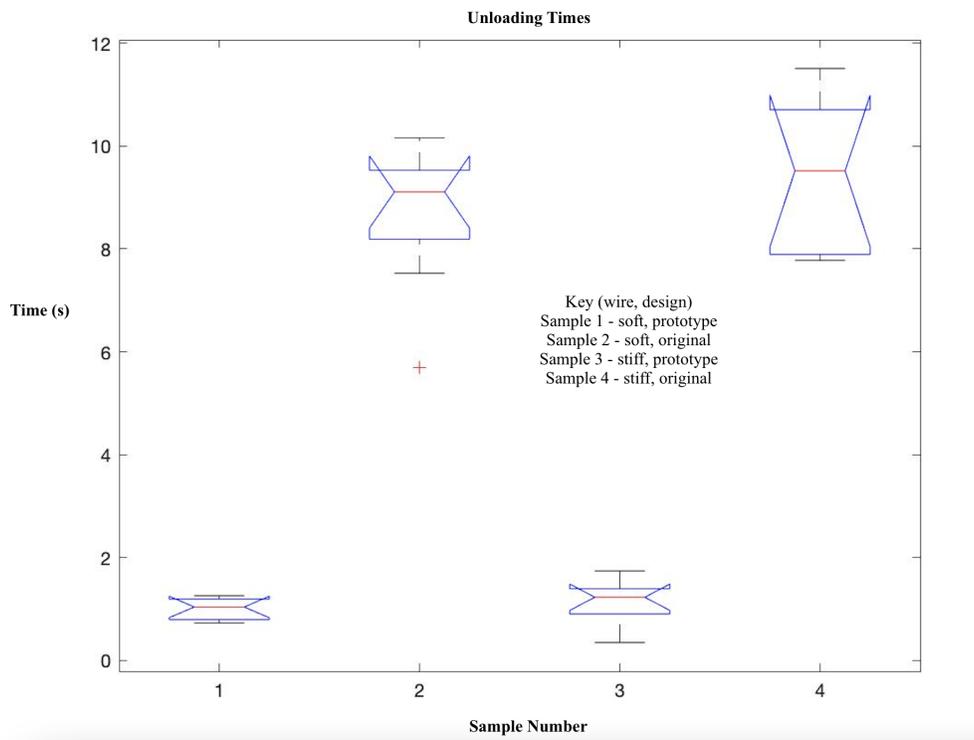


Figure 8. Data distribution of four independent samples for Unloading test.

The ANOVA test (code can be found in Appendix 10.5) 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.

7. Discussion

7.1 Implications of Results

The ANOVA test results gave a significant difference between loading and unloading the guidewires from the original plastic casing vs. the Guidewire Hoop Device. With the significant difference between the loading times of the stiff and soft wire ($p = .00617$), it can be inferred that modifications must be made so that one device can be used for various sizes and stiffnesses of guidewires. As for unloading times, the Guidewire Hoop Device is much more time efficient than the original casing which meets the main goal of our client: eliminate time wasted on guidewire storage and utilization in the operating room. With this in mind, it is important to note the clinical significance of these findings: In the operating room, each wasted minute averages to about \$60 being lost [1], so this proved that even a 10 second unloading difference is effective in saving money for hospitals.

The second constraint criteria that was tested was whether or not the device could keep the guidewire organized and untangled while stationed within the Guidewire Hoop. Due to radial forces of the guidewire looped in the ring, as well as the magnetism due to the magnetic tape in the inner circumference, our team ensured that there would be no chance of the guidewire falling out of the device and/or getting tangled. Theoretically in the OR, devices and materials for procedures are handled with precision by hospital staff and doctors and are not tossed around. This being said, to ensure security our team took moving and shaking the device to an extreme and had a member moving rapidly with the guidewire up and down stairs. Even under extreme circumstances during testing, the guidewire was tangled zero times in the total 10 trials.

7.2 Sources of Error During Testing

There were several sources of error that may have affected the testing of the prototyped device. There were issues with the 3D printing of the prototype. The makerspace ran out of the material midway through the print. As a result, the top of the crate is unfinished, so the infill is exposed. Unfortunately, we were unable to reprint the crate due to time constraints. In addition, the diameter of 3D printed wheels were too big to encompass the varying guidewire stiffnesses. To help alleviate this issue, our team 3D printed a second guidewire wheel prototype which had a smaller diameter. During testing, our team found that it was still difficult to load the guidewire in the wheel due to the size of the guidewire wheel and the stiffness of the guidewire. From this, we

can conclude that further evaluation needs to be done to determine the correct guidewire wheel size for different guidewires stiffnesses. Another source of error is from the loading method of the guidewire. Each team member was responsible for timing the loading of the guidewire. The variability in loading techniques could affect the consistency of the results.

7.3 Ethical Considerations

When testing and implementing new devices into the medical field there are 7 main principles of clinical research [12]. 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 it acts as it should 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 nor 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. 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

Incorporating all innovative properties of previous designs created throughout the semester, the final design for the guidewire organizer has been presented and effectively organizes and stores guidewires for easier access. The final prototype based off of Figure 5 (of the preliminary design) is the exact same design but with smaller diameter and width. The final product has an internal diameter of 22 cm and an inner diameter of 20 cm. The final prototype design is meant to encase the guidewire within the internal concavity of the guidewire hoop, like the previous guidewire hoop design, as the radial force of the coiled wire will push against the concavity and hold the guidewire stable. Additionally, an internally placed magnet placed inside of the guidewire organizer will increase the hold on the guidewire while in the concavity, ensuring more stability of the guidewire when placed in the organizer. The updated design shown in Figure 6 with a smaller diameter than the original guidewire hoop design further increases the radial force of the guidewire applied to the hoop when tightly coiled and placed into the organizer. This allows for more secure storage of the guidewire while being transported and does not interfere with the unloading process of the guidewire.

8.2 Future Work

Throughout the semester, our team has successfully designed, prototyped, and tested a guidewire organizer that is more efficient than the current method of guidewire dispensing and storage in the operating room. We then analyzed the data collected from testing using MATLAB.

From the data analysis, we found that modifications must be made. These modifications to the guidewire hoop will accommodate all sizes and stiffness of guidewires.

The team plans to add a back plate shown in Figure 9 to the guidewire hoop to make loading the guidewires into the hoop easier and able to be done by one person. This wall will decrease the amount of time it takes to load the guidewires into the wheel, further increasing efficiency. Additionally, the team will deepen the inner cavity of the guidewire hoop to better secure the soft guidewire into the ring. If these two modifications do not perform as we expect, we will decrease the radius of the ring to better secure the soft guide wire to and to allow for easier loading and unloading. With the soft guidewire performing less efficiently, these modifications aim to fix the difference in loading times between the stiff and the soft wire, so that in the future one device can be used for all guidewire sizes and stiffness. If the radius of the ring decreases, we then decrease the size of the crate shown in Figure 10 to give easier access and less movement of the guidewire hoops.

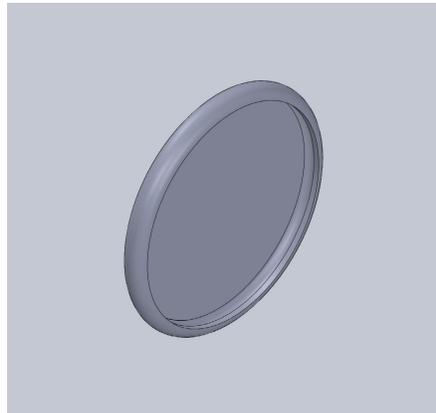


Figure 9. Modified Guidewire Hoop with add back plate for easier loading.
Dimensions: Outer Diameter: 22 cm. Inner Diameter: 20 cm.

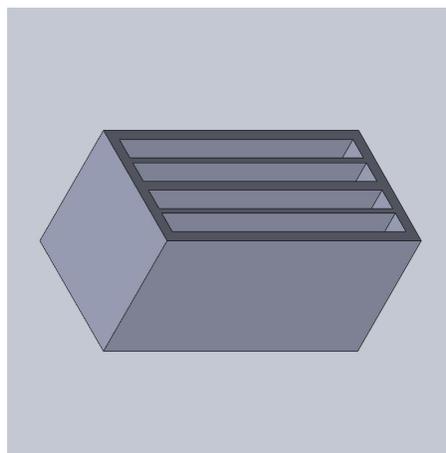


Figure 10. Modified Crate for easier access and less movement.
Dimensions: 10 cm x 20 cm x 10 cm.

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10. Appendix

10.1 Product Design Specification

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:

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 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 wheel must be able to hold 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 do this there will be a lip on 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 also be easily placed and 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 tools in the operating room [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 ideally fit within the 11.8 inch 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 device, it also must be able to undergo surgeries and have the ability to keep the multiple guidewires used during surgery organized so the operating room workers can navigate the guidewires easier than without the 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 provide proof of concept. This 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 grade stainless steel, it should 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 other form of sterilizable. With 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 being used for the first time [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 20 to 60%, and a temperature between 68 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 operation, this device should be easily 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 semicircle with a diameter of .15 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 table setting environments [6]. The 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 be medical grade stainless steel to 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 have a smooth, clean finish [7]. The prototype should also have a smooth, clean finish. The color will be consistent throughout.

2. Production Characteristics

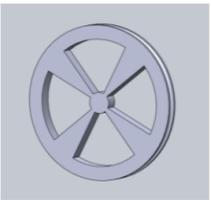
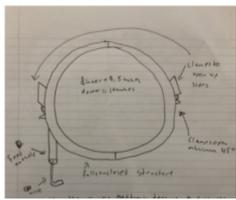
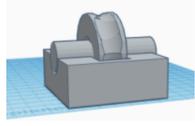
- a. *Quantity*: One prototype is needed, yet the prototype needs to be conceptually and physically sound and able to be utilized in real time. The main focus will be producing a single prototype to ensure proof of concept. In the future, this prototype will ideally be mass produced, so the ability to have steady organization of guidewires and catheters is available in all 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 prototype to be around 200 USD.
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 will be assumed to follow the 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 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 [10].
 - b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine 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 [11].
 - c. *Patient-related concerns*: Because this device will be used in endovascular procedures, it is important to take into account patient safety. The guidewire holder should ensure that the 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 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 external guidewire as well as increase security of excess wires during procedures [12].

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10.2 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	

10.3 Testing Protocol

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

10.4 Raw Testing 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

10.5 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)
```