GUIDEWIRE ORGANIZER FOR ENDOVASCULAR PROCEDURES

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ABSTRACT Endovascular procedures require multiple guidewires to be used then stored. Guidewires must be stored neatly, which is a difficult task due to their spring-like nature. The team tested seven prototypes (LHold, VHold, XSHold, XtraHold, TRHold, ADHold, and LGHold) to solve this issue of organizing guidewires. The XSHold was determined most efficient after testing. The stand will be modified to be compatible with the final wheel, and an FDA approved material will be chosen for the market device.

Problem Statement

During an endovascular procedure, numerous guidewire types are used to navigate the vascular system and position catheters. After guidewires are removed, however, they can easily become tangled and disorganized, risking contamination and increasing time in the operating room. To address this problem, the team created a system to store and dispense guidewires during endovascular procedures.

Figure 1. Various guidewire styles and sizes. [1]

Background and Motivation

In many endovascular surgeries, the main concern is a dangerous and unorganized environment due to guidewires being difficult to store and manage. Each lost minute in a hospital operating room costs an average of $60 [3]. This device will decrease time spent on guidewire management, and decrease the number of duplicate wires used due to contamination, overall decreasing the amount of wasted time and money in the operating room (OR). This device will allow for better organization and a less hazardous setting in the OR.

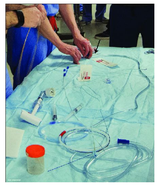

Figure 2. Unorganized Guidewires. [2]

Design Criteria

- Enables efficient guidewire loading and unloading
- Little to no learning curve for guidewire loading
- Stand design is able to hold 3 wheels with 1 guidewire in each wheel
- Guidewires stay organized and untangled while stored on wheel
- Guidewires are removable if the wheel is on or off stand
- Device able to hold guidewires with diameters of 0.014, 0.018, and 0.035 inch with varying stiffnesses
- Ability to remove wheel from stand once the guidewire is removed
- Final market device should be biocompatible, single use, and injection molded

Final Design

Description:

- The device includes 3 guidewire wheels and a stand.
- The wheel has a inner chimney to hold the guidewire in place

Progress:

- The team has made 7 prototypes (3 shown on right):
  - 4 designs incompatible with injection molding
  - 3 designs compatible with injection molding
- The team has tested all prototypes:
  - Loading and Unloading Time Test
  - Load/Unload Rating Scale (0-3)

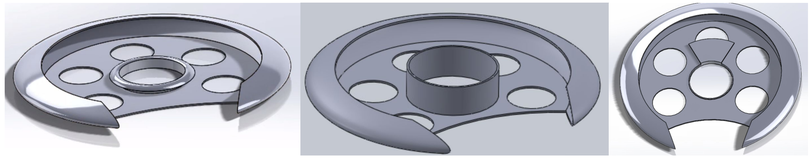

Figure 3-5 (*left to right*). XtraHold, XSHold, and LHold SolidWorks files.

Testing and Results

- **Goal**: Testing by all team members to determine which design to move forward with as the finalized design
- **User Ratings**
  - LHold, XSHold and XtraHold had the most occurrences of 3 graded loading
  - TRHold had the overall lowest loading grades
  - When surveyed, clinicians preferred the tab-like design of LHold
- **Loading Times**
  - XSHold had the most efficient loading times (avg 12.29s +/- 2.53s)
  - Closely followed by XtraHold (12.58s +/- 2.13s)
- **Data Signficance**
  - Significant difference between XSHold and TRHold & LGHold ($p = 0.028$, $p = 0.036$)
  - No significant difference between XSHold and ADHold ($p = 0.473$)

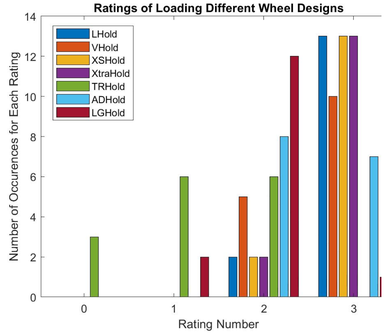

Figure 6. Data distribution of load ratings comparing all designs. All designs were rated on a scale from 1-3 (with 3 being the highest/best rating) based on the ability and efficiency of loading or unloading the guidewire. All group members performed three trials of loading/unloading for each device.

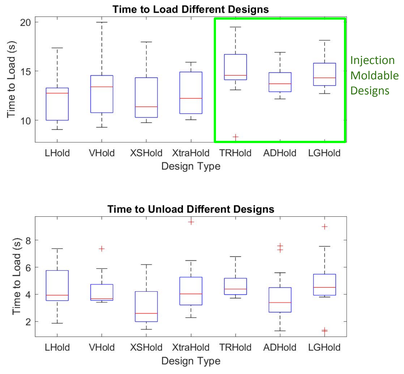

Figure 7. Data distribution of loading and unloading times comparing all designs

Future Work

- **Design**
  - Incorporate the diameter of the XSHold into the injection-moldable wheels
  - Finalize new design via testing with clinicians to ensure ease of use requirements are met
  - Obtain patent for wheel design
- **Manufacturing**
  - Choose a biocompatible material that can be injection molded to manufacture design
  - Mass produce the wheel using injection molding
- **Market**
  - Market wheel to physicians and hospitals

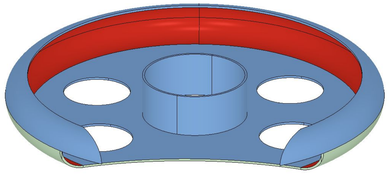

Figure 8 *(above)*. Manufacturing analysis of XSHold from Protolabs.

Conclusion

The XSHold loaded most efficiently, however this design is not injection moldable. The team plans to incorporate the reduced diameter of the XSHold into the different features of the TRHold, ADHold, and LGHold to finalize the wheel design.

References

[1] "Guidewires," *Spiros*. https://spirosind.com/guidewires/
[2] "Figure 2: Interventional Radiology fellow shows various types of..." *ResearchGate*.
[3] H. Gül, "Occupational health and safety in operating rooms," *IntechOpen*, https://www.intechopen.com/online-first/76118.
https://www.researchgate.net/figure/Interventional-Radiology-fellow-shows-various-types-of-angiography-catheters-and_fig2_320048703