Deliverable F: Design Constraints and Prototype 2

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Introduction

In this deliverable, the client feedback from prototype 1, and our in-class design review, allowed us to come up with a better solution, which is our prototype 2. The latter is accompanied by critical product assumptions and different prototype testing was done to validate them. The objective of prototype 2 was to assess the compression subsystem and implement feedback from the deliverable E presentation and in-class design review, which was done by 3D printing the prototype to evaluate the compression force, structure, and overall ease of use. By having a physical model, the movement necessary to close the clips can be evaluated, which is important as the main reason this specific design was chosen was to reduce the use of the thumb joint and reduce strain. During the design of prototype 2 and considering various feedback received from the previous prototypes, important non-functional constraints were identified. This led to the modification of the design to remove the constraints and make a better prototype.

F.1 Design Constraints

Non-functional Design Constraints

After prototype one we set out to identify 2 non-functional constraints that are critical to the development of our design. We will use this information to finalize our plan for prototype 2 and to make modifications to our current design.

Design Constraint 1: Accommodating to varying hand sizes

As of yet, our prototypes have received much feedback regarding the capabilities of users with varying hand sizes using the device. The main complaint was the shape and size of the device, that is because of its comparison to a Rubik's cube. This causes discomfort over a long period of time, which defeats the purpose of the device. In addition, another common piece of feedback was that the device was too tall. These are substantial constraints because they greatly limit the usability and comfort of the device, rendering it worse than using bare hands, and making it useless.

Changes to Be Made to Satisfy Constraint

To fix these issues, the shape of the device would need to be adjusted to be more ergonomic and fit better in the palm of every user's hand. In addition, the height of the device would need to be reduced so that it can fit every hand size. The maximum height should be no more than 36mm to fit every hand. However, the height cannot be over-reduced as the gap must fit every clip size. To increase the ergonomics, the finger grooves could be deeper to increase the user's grip, the plunger could be reshaped to rest more comfortably. The sharp edges could be smoothed to increase the comfort and reduce possible injuries. With all these changes in place, the device wouldn't be constrained to any one-hand size, but rather be able to be used by anyone.

Proof of Effectiveness of Change

The total length should be no more than 36mm in order to rest comfortably in the hands of all users. The average hand depths are in the range of 33.7mm to 36mm. Any more than this would be stretching, which leads to cramps and potential injury over prolonged periods of use. Also, over long periods of time, the large applied force paired with the sharp edges would cause injury to the users' hands.

Resources:

(Roland), A. (2016, April 15). Ergonomic handle design: An introduction. ergonomics blog. https://ergonomicsblog.uk/ergonomic-handle-design/ Osborn, C. O. (2023, February 3). Pain in hand: 10 possible causes.Healthline. https://www.healthline.com/health/hand-pain#trauma

Design Constraint 2: Quick and Effective Cleaning of Device

Currently, our device has two major cleaning difficulties. The first is that the device has many odd curves and edges which render disinfecting take much unnecessary time. Because of this, the users would waste a significant amount of time to complete a trivial yet important task, which cannot be avoided at any cost. The second, difficulty of cleaning comes with the current material being used. The device is now being made by 3D printing using a PLA-based material, which is very porous and hollow. Because of this, it is impossible to clean entirely with disinfecting wipes. If the device is unable to be sterilized, it is useless.

Changes to Be Made to Satisfy Constraint

To solve the first issue, a reworked design would need to include smooth edges with fewer overhangs to allow easier, more consistent disinfecting to occur. To alleviate the second problem, the device would have to be made of a different material. The ideal material would be medical-grade ABS, which would be perfect for the hospital setting and is often used in the medical space. In addition, it would be incredibly durable due to its strength, easy to sanitize, and resistant to corrosion.

Proof of Effectiveness of Change

The proposed changes to the device's design and material address the identified cleaning challenges directly and effectively. By smoothing out edges and reducing overhangs, the redesigned device offers a more uniform surface, which has been scientifically proven to facilitate faster and more thorough cleaning, as validated in studies comparing cleaning times and efficacy across various medical tool designs. The shift to medical-grade ABS is substantiated by its widespread adoption in healthcare due to its non-porosity, which ensures that disinfectants can completely sanitize the surface—a fact supported by its use in sterile environments and success in passing rigorous infection control protocols. Furthermore, the durability and corrosion resistance of ABS not only extend the device's life span but also maintain its integrity through repeated cleaning cycles, preventing degradation that could harbor bacteria, as evidenced in longevity tests of medical equipment. Lastly, this transition to a more hygienic design and material is corroborated by case studies from medical facilities that have observed a decrease in cross-contamination incidents after introducing similar changes in their equipment.

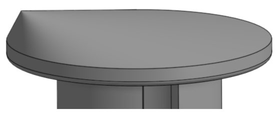
Resources Linked:

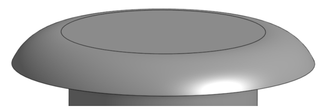
1. *A study published in the **Journal of Hospital Infection** found that medical-grade ABS is a suitable material for manufacturing medical equipment due to its non-porous nature, which makes it easy to clean and disinfect.*

2. *Another study published in the **Journal of Medical Engineering & Technology** compared the cleaning efficacy of medical equipment made from different materials and found that equipment made from ABS was easier to clean and had a lower bacterial load than equipment made from other materials*.
3. *A case study published in the **American Journal of Infection Control** reported a significant reduction in the number of cross-contamination incidents after a hospital introduced medical equipment made from ABS*.

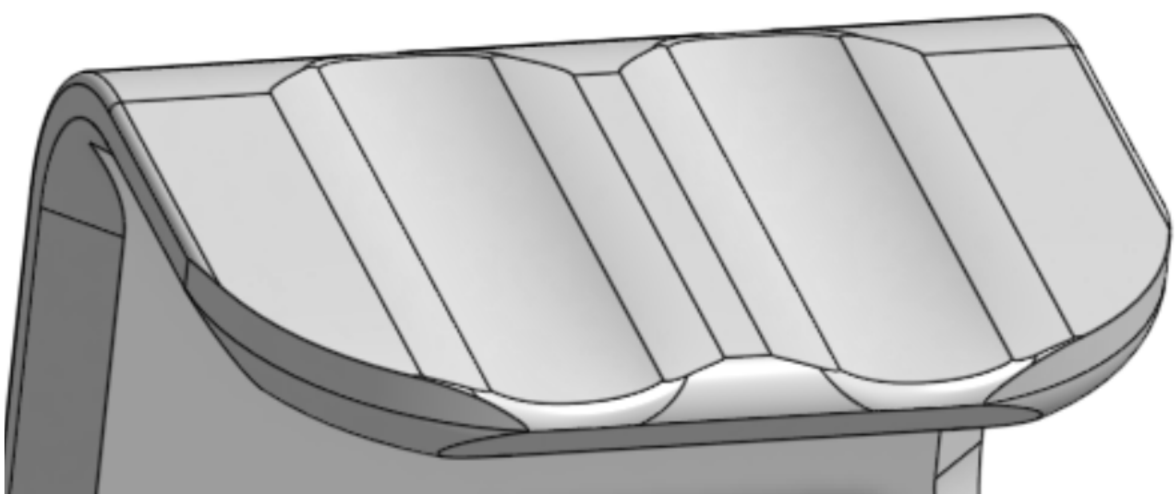
Updated CAD Design

After conducting thorough research and with the feedback received, we made several modifications to the design of the initial device to improve its ability to meet the non-functional requirements. Recognizing the importance of ergonomics, we modified the top of the plunger to conform to the natural shape of the hand ensuring that the device would still be ambidextrous. This change was to alleviate pressure points and minimize the risk of injuries during device operation.


New Plunger Head Design


Old Plunger Head Design

Furthermore, we increased the depth of the finger grooves on the bottom of the device. By doing so, we sought to provide users with a more secure grip, enhancing their control and facilitating smoother operation.



In addition, we made structural modifications to allow easier cleaning of the device. This involved increasing access to the spring for thorough cleaning and removing unnecessary curves on the structure. These changes will reduce cleaning time and improve the overall cleanliness of the device.

F2: Prototype 2

New Client Feedback

As of the current stage in our project development, we have not received new feedback directly from the client, since our second client meeting, summarized in a previous deliverable. This is due to the fact that we have not been in recent contact with them. However, our design's first few iterations of prototype 1 have undergone an in-depth review during an in-class session with Jason from JMTS. His feedback has been invaluable, and it is important that we integrate his insights into our design process, and take into account any comments he has made about our design. Below is a summary of the key takeaways from Jason's review and the subsequent actions that need to be taken to refine our design.

Key Takeaways from the Design Review with Jason:

1. **Affordability and Replaceability**: Our design is appreciated for its cost-effectiveness and easy replaceability. This is a strength that we will continue to preserve in our design updates.
2. **Ergonomics and Usability**: The ergonomic aspects, particularly the tactile feel of the ridges, have received positive feedback. We will ensure that this feature remains prominent in our design refinements.
3. **Design Adjustments for Functionality**:
   - **Travel distance of the Punch**: We need to adjust the travel distance of the punch to accommodate the largest clip without overextending when clipping down. This will be factored into our design revisions.
   - **Plunge Depth**: A shallower plunge depth has been recommended to conserve space and simplify manufacturing. We will explore how we can implement this without affecting the functionality.
   - **Spring Mechanism**: We must reassess the compression spring's size to ensure it does not consume unnecessary space and allows for proper retraction. Design adjustments will be made accordingly.
4. **Potential Issues and Testing**:
   - **Pinching Concerns**: Testing will be conducted to evaluate the risk of pinching and whether the spring mechanism can accommodate dimensional variations without causing injury or discomfort.
   - **Window Jamming**: The risk of jamming due to off-center force application is noted. We will reconsider the depth-to-diameter ratio and the spring force's capability to prevent and correct jamming.
5. **Mechanical Considerations**:
   - **Shape of Plunge**: The possibility of a square plunge to manage orientation will be examined for its feasibility.
6. **Support and Alignment**:
   - **Central Support**: The necessity of central support for mechanism integrity will be a priority in our design iteration.
   - **Parallel Faces**: We will ensure that the faces impacting each other are parallel to avoid jamming.
7. **Manufacturing and Assembly**:
   - **Orientation in 3D Printing**: The orientation of the plunger in the 3D printing process will be adjusted to enhance product quality.
   - **Component Assembly**: We will continue to print parts separately and adhere to recommendations for component assembly, like gluing the mushroom cap post-printing.
8. **Material Considerations**:
   - **Sanitization and Material Porosity**: We will consult with the client regarding the concerns of sanitizing 3D-printed parts and decide if material porosity could be an issue.Issue raised by Jason.
   - **Material Choice**: PETG will be considered for its printing advantages. The possibility of using metal components will also be evaluated carefully.
9. **Miscellaneous Concerns**:
   - **Spring Size**: Correct spring size selection will be critical and will be addressed in the design modifications.

The insights provided by Jason are instrumental in guiding our next steps. Each point of feedback has been taken into account, and specific changes will be integrated into an updated detailed design. These changes aim to enhance the product's functionality, user experience, and maintainability. We will proceed with the necessary modifications and plan to engage with the client at the earliest opportunity to ensure alignment with their expectations and needs.

Critical Product Assumptions

After carefully reviewing our design and prototype 1, we identified a significant issue with the compression system. The cylindrical plunge used to actuate the compression plate had a sliding action that was assumed to be completely vertical. However, we discovered that there was a considerable amount of backlash in the system, leading to potential jamming and difficulty in returning to the initial position. During our design review, we learned that to solve this problem we need to make the the hole height three times the diameter of the plunge. Because our tool was meant to fit in the user's hand this was not feasible.

To address this problem, we made several improvements in prototype 2. Firstly, we squared off the inside of the design to allow the compression plate to slide along the sides of the wall, preventing movement and rotation. This adjustment helped minimize backlash. However, the compression system still had the potential to be pushed away from the user, so we relocated the plunger further away from the center of the box. This change naturally caused the user to exert pressure in the opposite direction of the play in the system, increasing the chance of proper functionality.

Prototype 2

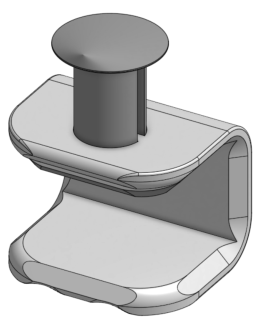
For our second set of prototypes, we developed three designs to further improve the compression system. This set of prototypes will help with testing our critical product assumptions made, and help choose which is the optimal compression system for our final design.

Then, for each prototype that we made, we had a plan for testing the prototypes to test assumptions.

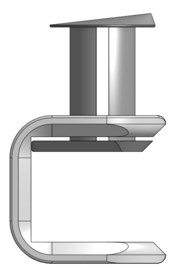
Testing Critical Product Assumptions Made

Test 1 Design

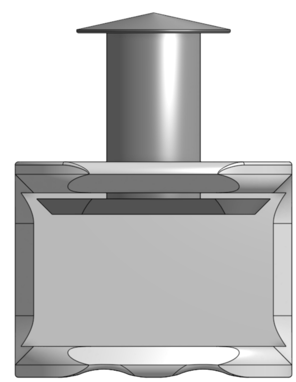
The first design involved a large-diameter plunger with an internal spring. Despite anticipating backlash due to the size difference between the 15 mm diameter and the 5 mm hole, we wanted to confirm if the backlash would interfere with the spring's ability to push the plunger back to its initial position. To incorporate the spring into the design, we modified the g-code to pause the print midway, allowing us to manually add the spring inside the plunger. This prototype aimed to validate the impact of backlash on the spring.



Test 1 Compression Design



Squared Insides

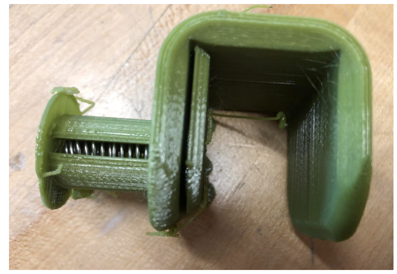


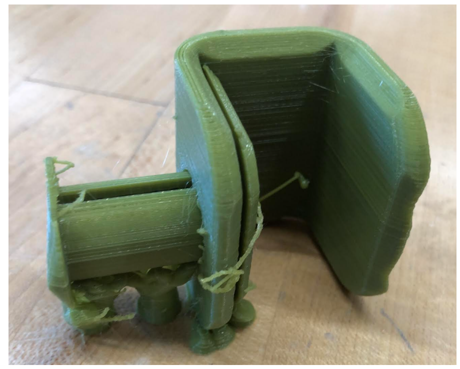
Large Diameter Plunger

Execution of Test 1 and Lessons Learned From Test

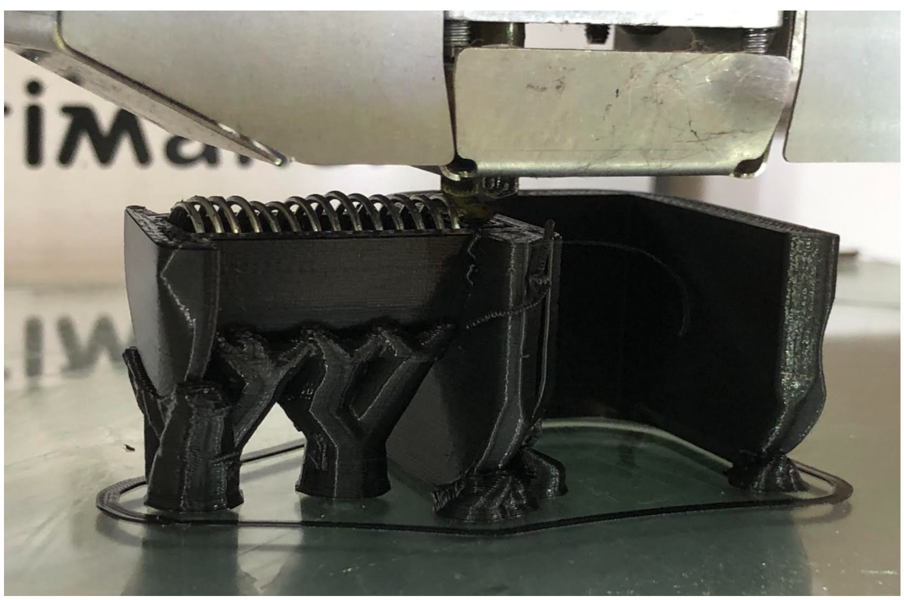
Test 1 was to test if the backlash in the prototype was enough to prevent the plunger from returning back to its original position. The prototype turned out, however, the printer that we used had a flaw where it only extruded 80% of the filament that was required causing the prototype to have a rougher exterior compared to prototype 1.

The main test for this prototype was to press the plunger down and see if it would return to its original position. Originally, the test did get stuck halfway down but after properly clearing out the gap between the plunger and the structure the plunger went up and down without fail. From this prototype, we learned that the backlash in the system would not be as much of a problem as possible. Instead, the main problem would be the consistency of the prints since just a little fluctuation in printers could cause the tool to bind to the structure.





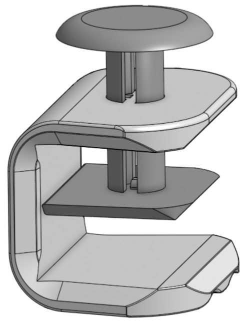
Another lesson we learned from test 1 was some tips and tricks for inserting the spring in the design halfway through printing. The first problem we ran into was stopping the print halfway to add the spring did not allow enough clearance between the printer and the spring, causing the spring to be pushed out of the way. This meant that we needed to stop the print once it had gone slightly past the halfway mark. Furthermore, we found that it was hard to place the spring in perfectly the first time. Originally we only programmed one stop into the print which meant that you only had one chance and place the spring in. After some failed attempts we came up with the idea that we would program 2-3 stops to allow for modifications without spoiling the print.

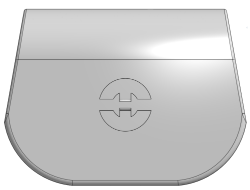


3D printing the spring into the renal device

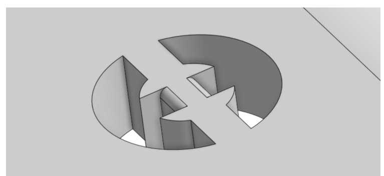
Test 2 and 4 Design

The second design aimed to eliminate the need for a spring by replacing it with an elastic at the bottom of the device. By using an elastic, we could reduce the diameter and subsequently decrease backlash. Additionally, we altered the shape of the physical structure to a parallelogram to test some feedback received for prototype 1. For this test, we also printed the parts separately to examine if a more accurate fit could reduce backlash by printing them individually.

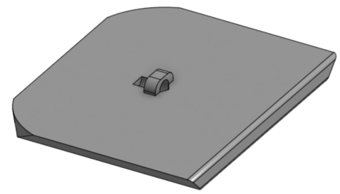




Modified Shape



Elastic Hook: Physical Structure



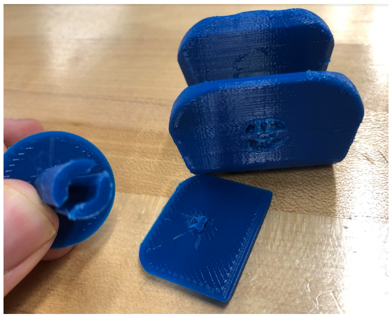
Elastic Hook: Compression Plate

Execution of Test 2 and Lessons Learned From Test

The purpose of test 2 was to verify some design modifications that we had. The first idea was to make the shape of the design into a parallelogram shape. Once printing the design it became evident that this shape would be impractical as it would prevent the clips from being able to sit flat in the device. In addition, the shape added weight by 7 grams.

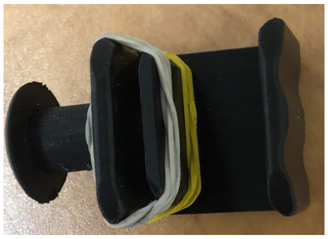
The second change we made to this design was the actual way in which we printed it out. Instead of printing it out as a single species, we broke the design into three separate pieces. The idea was that it would allow for more accurate printing of the part and as a result reduce backlash. This did not prove to be the case since the parts ended up being odd shapes and the horizontal printing of the cylinder added friction to the compression system. In order to get the parts to fit we had to increase the tolerance which ironically increased backlash.

The second purpose of test 2 was to try using elastics to operate the compression system. This design had the elastic in the same place as the original spring except the elastic would be on the opposite side. After the print and design failed in multiple areas we decided that the design severely failed. Some areas included the elastic hooks preventing full closure of the device and structural failure. Hence, after learning from this test we replanned a test 4 with an elastic that involved using a previous prototype to test the elastic mechanism.



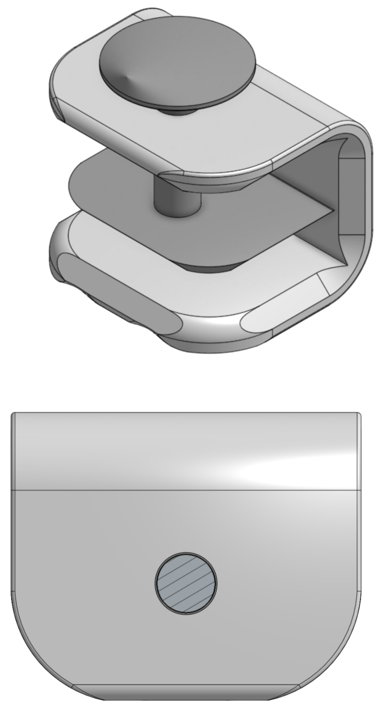
Replanned Test 4 After Failure of Test 2

After complications with test 2, we came up with a plan to implement the design using one of our prototypes from test 2. This involved adding two elastic bands to the compression system by wrapping the elastic around the top of the box and the compression plate. To test the device we found that the elastics did a good job and improving the backlash from the cylinder since they applied force on both sides of the plate preventing tears between the plunger and C structure. One problem we ran into was the elastics quickly snapped due to rubbing against the rough 3D print. Also, it was found that two elastics required too much force to operate the device.

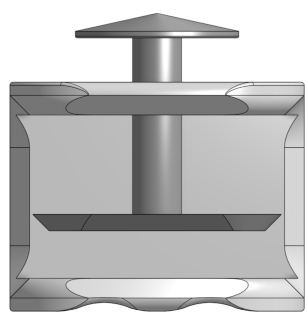


Test 3 Design

Our final design focused on testing the assumption that a smaller cylinder would reduce backlash in the system and that an alternative elastic design would provide enough force to reset our device. In our initial design, we created a design with a very small diameter that used an external spring. However, considering the difficulty of cleaning around it we had changed the design to an internal spring. The key objective of this prototype was to determine the extent of backlash reduction due to the smaller diameter as well as see if an alternative springless solution was/is a better solution. Additionally, we needed to ensure that the small diameter cylinder would not compromise the strength of the compression system. This prototype was critical in obtaining data to strike a balance between backlash reduction and system strength.



No internal Spring



Small Plunger

Execution of Test 3 and Lessons Learned From Test

The primary aim of this experiment was to determine whether adjusting the diameter could effectively minimize backlash in the compression system and to assess the feasibility of an alternative elastic system.

Initial testing involved applying a force in the opposite direction to the plunger, aiming to observe a reduction in backlash. Ideally, the compression system should resist this force and maintain a vertical position. However, the results were contrary to expectations, as the smaller diameter led to an increase in backlash. The plate could be pulled away from the structure by approximately 3 mm. This observation suggests that the tolerance error in the 3D printing process was the likely cause of the backlash within the system. Decreasing the cylinder's diameter inadvertently magnified the impact of the printing error, revealing that a smaller diameter was not a solution to address backlash issues.

Moving on to the second analysis, we assessed the overall strength of the compression system after removing material to reinforce the cylinder. The objective was to ensure that the system would not fail under normal working conditions. To conduct this test, we placed a rigid object underneath the compression plate and applied force to the plunger. However, repeated attempts resulted in the compression plate breaking. This outcome can be attributed to the reduced support provided by the cylinder, given that the 2 mm thick compression plate lacked sufficient reinforcement to withstand the load.

In summary, this experiment demonstrated that a smaller diameter cylinder proved to be less effective than the original design. The flexibility of the shaft and the repercussions of the printing error increased the jamming problem. Consequently, this prototype suggested that a larger diameter would be more suitable for our design.

Trial 1: Backlash

Trial 2: Weak Compression Plate

Test Comparison to Target Specifications

#	Metric	Units	Value	Test 1	Test 2	Test 3	Test 4
1	Number of clips the device can close before failure	# of clips	>700,000	500,000	500	250,000	1,000
2	Reduction in thumb joint stress (compared to manual operation)	%	>75	75	75	75	50
3	Time taken to apply a clip using the device	seconds (s)	<3	3	4	4	4

#	Metric	Units	Value	Test 1	Test 2	Test 3	Test 4
	(should not exceed manual operation time)						
4	Time taken to adjust the device for different tubing and clip sizes	s	<10	0	0	0	0
5	Ability to be used with both left and right hand (binary: yes or no)	binary	Yes	Yes	Yes	Yes	Yes
6	Ability to maneuver in space of X cm width (binary: yes or no)	cm	20	19	19	20	19.5
7	Resistance to alcohol-based cleaning agents (no degradation after X wipes)	# of wipes	500,000	500,000	500	500,000	500
8	Compatibility with different hand sizes (e.g., can be used with X% of adult hand sizes)	%	>85	80	80	80	80
9	Total volume of the device	cm^3	<45	45	55	40	50
10	Total weight of the device	g	<50	30	40	32	38
11	Number of operations using thumb (should be 0)	#	0	0	0	0	0
12	Manufacturing cost of the device	CAD $	<50	6.10	7.8	6.44	7.46
13	The lifespan of the device under normal daily use	years	>8	3	3	3	1 month
14	Adjusts to a number of different standard renal clip sizes.	cm	1-5	1-3	1-3	1-3	1-3
15	Dimension of Device	mm	<50x50x50	45x35x40	50x55x40	45x35x40	45x45x45

To acquire values for the target specifications the following techniques were used. The following number corresponds to the metric value in the table above.

1. This number was based on the overall strength of the device before failure. For instance, the elastic bands would wear out after approximately 1000 replications.

2. Reduction in thumb joint stress was determined by the actual use of the thumb in the design. Because all the designs are similar the value is the same except for test 4. Test 4 was given a lower grading because of how hard the clip was to use; it increased the effort required to close.
3. Determined through timing the clipping process during prototype testing.
4. value is zero since the design incorporates a multi-clip function.
5. All devices are binary for users.
6. Values were determined after running a test to see how small an opening we could use the device could be used. Naturally, the devices with larger surface aires scored slightly lower than the smaller surface area devices.
7. ABS plastic does not degrade with alcohol so the resistance will surpass the lifespan of the device. However, tests 2 and 4 which use elastic bands will most likely get damaged during cleaning shorting the lifespan of the device.
8. Determined through a focus group
9. Values calculated from 3D design.
10. Using a scale at Makerspace.
11. All devices do not require the thumb to operate the compression system.
12. The price for ABS or carbon fiber is $0.17 per gram. Using this price and the weight of the device we calculated the cost of production of each device. This cost does not include labor but does factor in the cost of spring.
13. Because the device is made from plastic we expect the lifespan to be less than our benchmarked devices. However, this does not mean that this assumption is accurate, and more testing in this regard will be performed.
14. Based on the size of the opening on the device.
15. Acquired from 3D files.

Key Takeaways From Prototype Testing

The prototyping process has revealed several critical lessons that can shape the direction of our compression system design. These lessons are essential for addressing the issue of backlash in the system and optimizing the usability and performance of the device.

1. **Backlash Challenge**: The prototypes revealed that addressing backlash in the system is a critical challenge. The initial assumption of vertical plunger movement proved incorrect, leading to potential jamming and usability issues.
2. **Design Adjustments Matter**: Design modifications, such as squaring off the device's interior to minimize backlash, played a significant role in improving the device's performance. These adjustments highlighted the importance of refining the device's geometry.
3. **Plunger Placement**: Relocating the plunger to increase user pressure in the opposite direction of play in the system was a strategic move, enhancing the device's functionality and usability.
4. **3D Printing Challenges**: Printing flaws, including under-extrusion, impacted the device's functionality and finish. Understanding 3D printing intricacies and addressing these challenges is crucial for achieving consistent results.
5. **Spring and Elastic Mechanisms**: Experimenting with resetting mechanisms, including springs and elastics, provided insights. While springs posed challenges during printing, elastics showed promise in addressing backlash and usability issues. However, the spring has a longer lifespan and a more reasonable compressive force.

In summary, the prototyping process has been instrumental in uncovering critical design flaws and providing valuable insights into addressing backlash, optimizing 3D printing, and fine-tuning the device for improved usability and durability. The lessons learned from these prototypes will guide the next steps in your design and development process, ultimately leading to a more refined and functional compression system.

Preparation for Next Client Meet (Design Day)

Our upcoming client meeting marks a significant milestone in showcasing our ongoing progress and the enhancements we've made. We've decided to present prototypes 1 and 4, as they offer the most comprehensive view of our solution. These different compression systems have distinct advantages and disadvantages, and we believe that involving our client in the evaluation process will provide valuable insights to determine the most suitable option.

One of the primary challenges we anticipate is facilitating a hands-on demonstration for our virtual client. The absence of in-person interactions poses a unique hurdle that we must be well-prepared to address. To overcome this challenge, we have devised a plan to effectively convey the capabilities of our prototypes during the virtual meeting.

Our approach involves leveraging video conferencing technology to showcase the prototypes in detail. We will walk our client through the design specifications, elucidating the specific parameters and values that each prototype should be capable of handling. To make this information more tangible, we will provide real-life examples and comparisons to help our client quantify and understand the measurements effectively.

Furthermore, our design is inherently 3D printable, and we see this as an opportunity for our client to engage directly in the testing and validation process. We will offer the 3D files for our prototypes, enabling our client to 3D print and physically test them on their end. This collaborative approach ensures that our client not only comprehends the design but also actively participates in the validation process, fostering a deeper understanding and a sense of ownership.

In summary, while the virtual client interaction presents a challenge, our strategy is focused on enhancing the engagement and understanding of our prototypes. By utilizing video conferencing, clear explanations, and the opportunity for hands-on testing, we aim to provide our client with a comprehensive and immersive experience during our milestone meeting.

Wrike Link

Wrike snapshot: https://www.wrike.com/frontend/ganttchart/index.html?snapshotId=Qw55dtZZ5UiUvjMMQvhgwHjP216RRbg6%7CIE2DSNZVHA2DELSTGIYA

Conclusion

In conclusion, after taking into consideration the client, design review, and deliverable E presentation feedback, the 2nd prototype was developed and tested through four prototype tests to verify the design modifications, plunger backlash, compression system, and feasibility of an elastic system to minimize backlash in the compression system. Furthermore, this has helped in uncovering certain design flaws and learning how to address them while adjusting the design specifications based on client and user feedback. Overall, the team is on track to creating a better and more efficient solution.