GNG2101

User and Product Manual for Renal Care Device

Submitted by:

ClipFit Group 2.3

Steven Dunbar, 300329484

Zachary Chaloux 300299671

Valentin Mugabo 300038960

Aaditya Shah, 300236230

Farah El Siss, 300168267

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University of Ottawa

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Table 1. Acronyms

Acronym	Definition
BOM	Bill Of Materials
CF	ClipFit
ABS	Acrylonitrile Butadiene Styrene

1 Introduction

This User and Product Manual (UPM) provides the information necessary for the client and other engineers to effectively use and recreate the ClipFit (CF) and for prototype documentation.

Nurses are required to clip hundreds of blood tubing clips on dialysis machines every day. This repetitive yet strenuous motion causes arthritis to form in these nurses' thumb joints. A solution is required which removes the load from this region and disperses it throughout one's hand. This device must be easily sanitized, highly usable and durable, ambidextrous and easily maneuverable in tight spaces while not detracting from the efficiency of using one's bare hands.

This document is comprised of four parts with an introduction and conclusion. These four parts include an overview, which gives the reader the bulk of the information surrounding the background of the problem and the solution created, as well as conventions and cautions. The next part is a general walkthrough of the CF with plenty of considerations as well as detailed information surrounding each function of the CF. After there is troubleshooting and support which covers common error behaviors, special considerations, maintenance, and support. Finally, there is product documentation, which covers the choice of material, subsystems, the BOM, the equipment list, instructions, description, and results for each prototype and how they compare to the target specifications.

Before use, read this user manual of the ClipFit to ensure correct usage through understanding as incorrect handling could result in personal injury or physical damage and the manufacturer assumes no responsibility for any damage caused by mishandling. After use of this manual, please store it in a safe place for future reference.

2 Overview

The problem ClipFit seeks to solve is the cause of arthritis in nurses' thumb joints from closing blood tubing clips. Every day nurses must close over a hundred of these clips, which they currently use their thumb joints to secure. To close these clips, approximately twelve pounds of force is required, which with repetitive use over time builds up and causes arthritis. Once arthritis arrives, the nurse's job becomes much more challenging, painful and time consuming and becomes a deadly cycle. Thus, the statement "Nurses are facing thumb osteoarthritis from repetitively attaching renal clips on blood tubing, highlighting a need for a portable, adaptable, durable device that alleviates thumb strain, and ensures ambidexterity and quick operation, while withstanding frequent sanitization." arose. Currently there have been no attempts to solve this problem, and there are no similar products.

Figure 1 – Final Prototype

Figure 2 – Band locking indentation

The design of the ClipFit is an ABS shell which is the shape of a "C" that fits comfortably in the user's hand. The main mechanism is a plunger which rests on the palm while the base of the CF rests on the user's fingers. This plunger is connected to a plate which sits on the top of the interior of the shell, that pushes down when a compressive force is applied to the plunger. An elastic attached to the plunger plate and the roof of the shell returns the plunger to its initial position. As mentioned, the only action required is to squeeze the plunger once the clip is aligned with the center of the CF, and it will be tightly secured. Next is to slide up the tube to the next clip and repeat until all are secured.

2.1 Cautions & Warnings

1. Device Intended Use:

- This product is designed specifically for the purpose of closing renal clips in medical applications. Any other use is not recommended and may result in ineffective or unintended outcomes.

2. Proper Technique:

- Ensure that the user is familiar with and follows the recommended technique for using the product. Incorrect usage may result in injury.

3. Inspect for Damage:

- Before each use, visually inspect the device for any signs of damage or wear. Do not use the product if any defects are observed, as it may compromise its functionality.

4. Maintenance and Cleaning:

- Follow the provided maintenance and cleaning instructions to ensure the longevity and effectiveness of the product. Failure to do so may lead to contamination and compromise the integrity of the renal clip closure.

5. Storage Conditions:

- Store the product in a cool, dry place, away from direct sunlight and extreme temperatures. Do not expose the device to harsh chemicals or solvents.

3 Getting started

3.1 Configuration Considerations

This device is printed as one piece reducing the need for assembly. The device is comprised of three main components as described in “System Organization & Navigation”. The device operates by an elastic band. When the user applies pressure onto the device the elastic is stretched once the clip has been closed the elastic pulls the compression plate back to its original position. Given the simplicity of the design no tools are required to set up or operate this device.

Figure 3 - Device fully extended

3.2 User Access Considerations

This prototype is meant for testing my dialysis nurses. This device is designed for closing renal clips. Any other use of the device could lead to device failure or safety hazard. The device is designed to work with a variety of hands and can be used for both left and right hand. However, given the nature of the design individuals with smaller hands may find the device uncomfortable to use.

3.3 Setting up the System

To set up the system the user must put a rubber band in the groove of the device. The rubber band is the part of the device that resets the compression system after each compression from the user. To install the user must stretch the rubber band over the top of the cylinder and let the rubber band rest in the groove of the device. The rubber band should be snug but not lose. If the band is too tight the elastic will break faster, and the device will be harder to operate. If the band is too loose it could fall off or the device could not work properly.

Step 1: Stretch the elastic over the device

Step 2: Drop the elastic in the groove of the device

Step3: Ensure that the elastic is not too loss or too tight

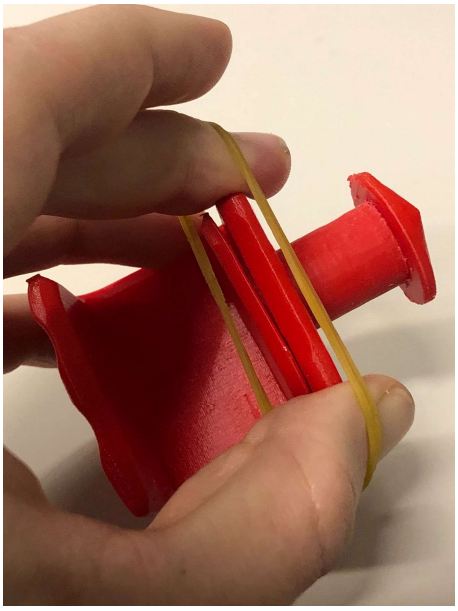

Figure 4 - Applying the elastic

Figure 5 - Proper elastic application

3.4 System Organization & Navigation

The renal care device is comprised of three main components. These components are printed as one single piece with one moving part. The main component of the device is the C structure of the device. The compression plunger is connected to the structure as it fits in the hole in the top of the device. Finally, the compression plate is fastened to the bottom of the compression plunger making the whole system one single part (see figures below)

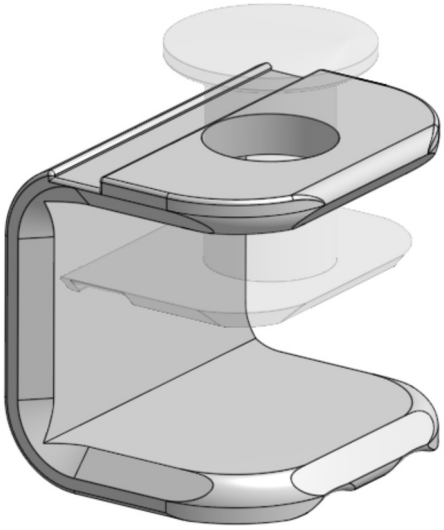

Figure 6 - C Structure

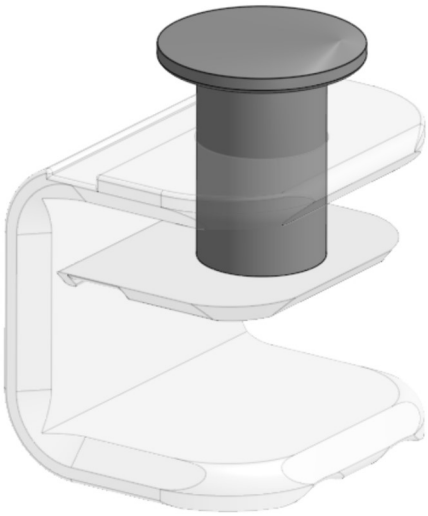

Figure 7 - Compression Plunger

Figure 8 - Compression Plate

3.5 Storing The System

For storing the system after use, we recommend keeping the device in a relatively sterile environment to ensure proper cleanliness of the device for future use. The device if left over a prolonged period the elastic should be replaced to avoid snapping.

The use of our device is meant to be user friendly and easy to use. There is only one moving part on the device and the hand conforming shapes of the device guide users to hold the device properly.

3.6 Compression System

The compression system is what the user applies force to close the clip. The compression system is directly connected to the compression plate which distributes the force of the user onto the clip. The top of this compression system is tapered to conform to the user's palm. This shape fits both left and right hands. Due to backlash in the compression system if the part is of poor quality the user will find that the system jams while trying to operate.

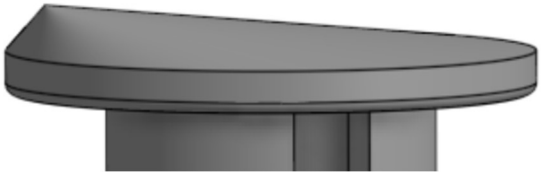

Figure 9 - Updated Ergonomic plunger design

To activate the compression system the user puts the device in their hand and then squeezes the device. This in turn applies pressure to the system and the device closes (see figures below).

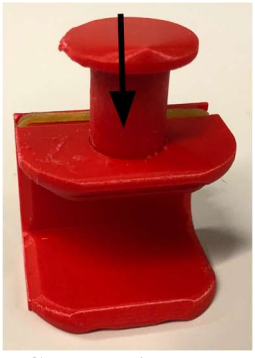

Figure 10 - Compression system in action

Figure 11 - Example of compression system

3.6.1 Grip Feature

The device is designed to fit the natural shape of the hand. This improves ergonomics while making the device easy to use. The C shape of the body of the device matches the curvature of the hand when in a closed position. Then on the bottom of the device there are finger grooves to indicate device hand placement and to add comfort (see figures below).

Figure 12 - Example grip

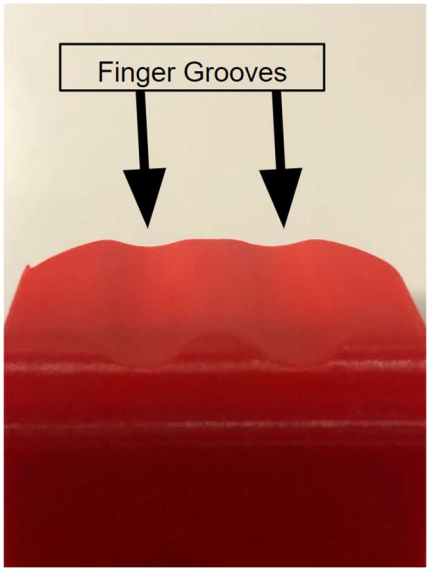

Figure 13 - Groove design feature

3.6.2 Compression Plate

The compression plate is attached to the compression system. The purpose of the compression plate is to distribute the force from the compression system. The plate also is one of the pieces that the elastic is attached to return the compression system back to its original position.

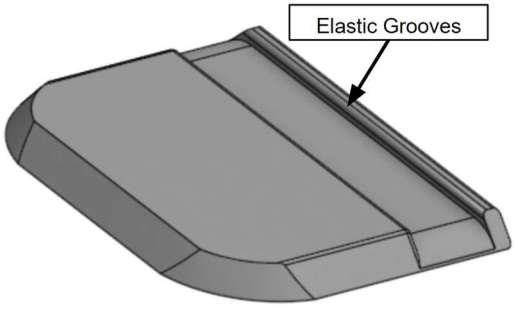

Figure 14 - Compression Plate

4 Troubleshooting & Support

Use the following section if you run into any issues with your renal device.

4.1 Error Behaviors

Jamming: The most common device error is the jamming of the compression system. This problem is likely to occur when the device has been recently made. The devices need to be warned in and properly scraped to avoid jamming. However, inaccurate printing or low-quality printing can render the device unable to fix this problem. If you are unable to fix the jamming of the print through scraping and sanding, consider printing the device at a higher definition.

Note: Spring design has a higher probability of jamming. Try using different springs and higher definition printers.

Wearing through the elastic: The second most common issue is elastic snapping frequently. This can be caused by old elastics or rough edges on the print. Try sanding or filing the sides where the elastic comes in contact. The elastic will wear faster where there is a pointed edge.

4.2 Special Considerations

Because these devices are 3D printed there can be a large variance in prints depending on the printer that you use. If your printer is not calibrated properly or is unable to produce high quality prints your renal device may have significant printer error contributing to the jamming or rough edges of the print. In this case you will need to find a better option for 3D Printing.

Also, unfortunately the client was unable to send the actual renal clips for us to test in our prototype therefore the design may need some modifications to work properly with the clips. Some potential problems would be that the surface of the device is too smooth causing the clip to come out of the device without closing. If this is the case, we recommend applying a rubber coating to the inside of the device to increase grip.

4.3 Maintenance

Regular cleaning of the device is recommended to avoid bacteria. The device can be cleaned with alcohol cleaners and hot water. Note: it is not recommended to put this device in a sterilizing machine since this has not been tested.

4.4 Support

If in the event of printing issues or significant device failures feel free to reach out to the following people:

Steven Dunbar sdunb089@uottawa.ca

5 Product Documentation

5.1 Choice of Material

The decision to use ABS (Acrylonitrile Butadiene Styrene) plastic in the production of our medical device, the ClipFit, was based on careful consideration of several important factors. ABS is widely recognized for its exceptional strength, durability, and resistance to impacts, making it an excellent choice for a precision medical tool that demands reliability. Its ability to maintain its structural integrity even with repeated use aligns perfectly with the intended function of the ClipFit, which involves mechanically compressing renal clips.

Furthermore, ABS is known for its biocompatibility, ensuring that it meets crucial safety standards for medical devices. This guarantees that the material is compatible with the human body and does not pose any adverse reactions or risks to patients. The ease of 3D printing with ABS allowed for a streamlined prototyping process, enabling rapid design iterations and optimization. This facilitated efficient development and refinement of the ClipFit, ensuring it meets the necessary performance and quality standards.

The cost-effectiveness of ABS also played a significant role in material selection. Its affordability makes large-scale production of the ClipFit economically feasible, enhancing its accessibility and practicality in medical settings. This makes the device an effective solution within the constraints of medical budgets. The choice to use ABS plastic in the production of the ClipFit reflects a strategic balance between mechanical strength, biocompatibility, and manufacturing efficiency. This ensures that the device is reliable, effective, and safe for renal clip closure procedures.

5.2 Subsystem 1 of Prototype

Physical Structure:
The physical structure subsystem has to do with anything related to the structure and general shape of the design. We went with the C shape design of our prototype to avoid the device being bulky or hard to maneuver.

Hand Grip:
This subsystem has to do with any part of the device that the users will use to hold or handle the device. The subsystem must be ergonomic and designed to have the minimal amounts of stress to

the user's hand. For this system our prototype has thumb groves on the bottom of the device as well as a specially shaped to decrease pressure points when operating the device.

Compression Device:
The compression subsystem is for the mechanical action of closing/compressing the clip. This subsystem design goal is creating a design that requires the minimal amount of force possible to close the clip. For this subsystem, we when with a cylinder which is connected to the compression plate. To operate the device, pressure is applied on the top of the device.

5.2.1 BOM (Bill of Materials)

Item #	Part Name	Quantity	Material	Description	Unit Cost
1	Physical Structure - Frame	1	ABS Plastic Filament (1.75mm)	40 mm x 40mm x 40mm	$28
2	Elastic band	1	Rubber	60mm circumference	$2.95/ unit (comes in a pack of 30)
3	Plunger	1	ABS Plastic Filament	25mm in height and diameter of hole plunged is ~11 mm.	Same as #1
4	Compression Plate	1	ABS Plastic Filament	33mmx33mmx 2.5mm plate.	Same as #1
				Total Cost =	**$45.97**

Table 2 - Bill Of Materials

- ABS Plastic Filament - link
- Rubber Band – Dollarama

5.2.2 Equipment list

The list of equipment required to construct this device is as follows:

- Filament 3D printer 0.6 nozzle or smaller
- Pair of pliers

- Sandpaper
- Utility Knife

5.2.3 Instructions

To make a ClipFit device you will need the materials listed in the bill of materials and the equipment from the list above. Finally, you will need the slicing software associated with your printer. (Note: the quality of the product does depend on the quality of the printer.)

Step 1: Download the STL file found at this link

Step 2: Import the STL file to your slicing software for your printer.

Step 3: Go into the settings of your slicer and set the infill to 100%, add supports, and print with adhesion. See figure 15.

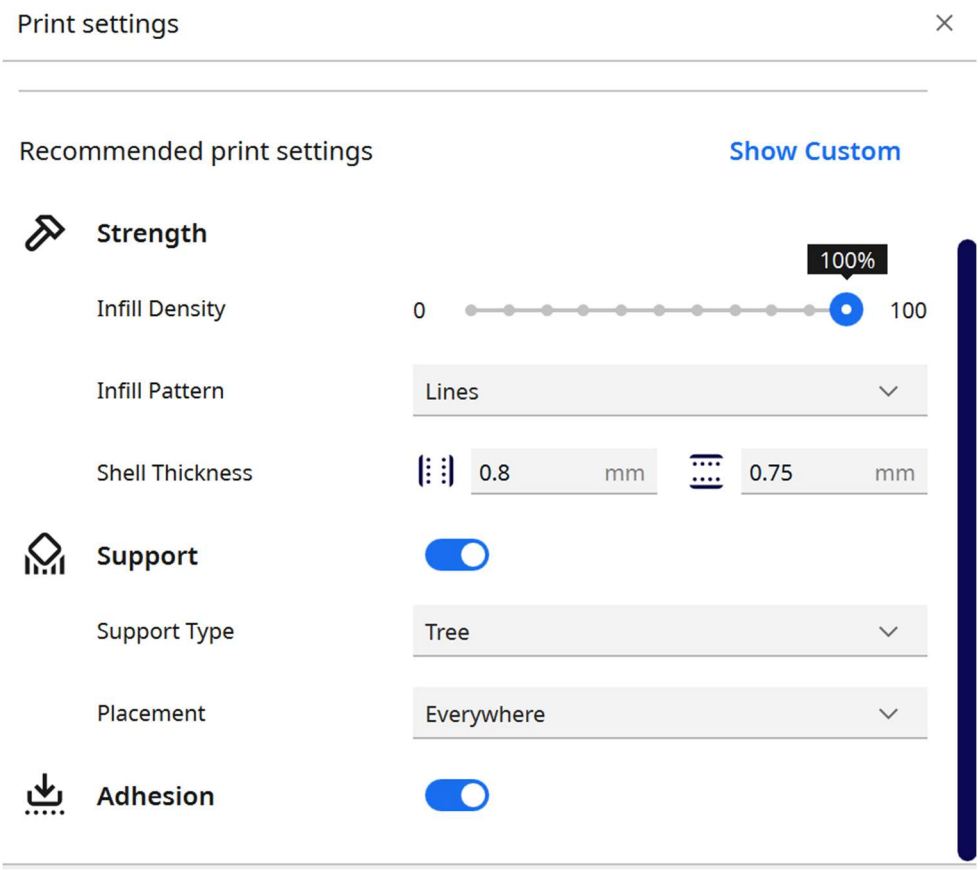

Figure 15 - 3D Printer Settings

Step 4: Set the support type to tree if your printer is compatible.

Step 5: Make sure that the print is printing on its side. See example below:

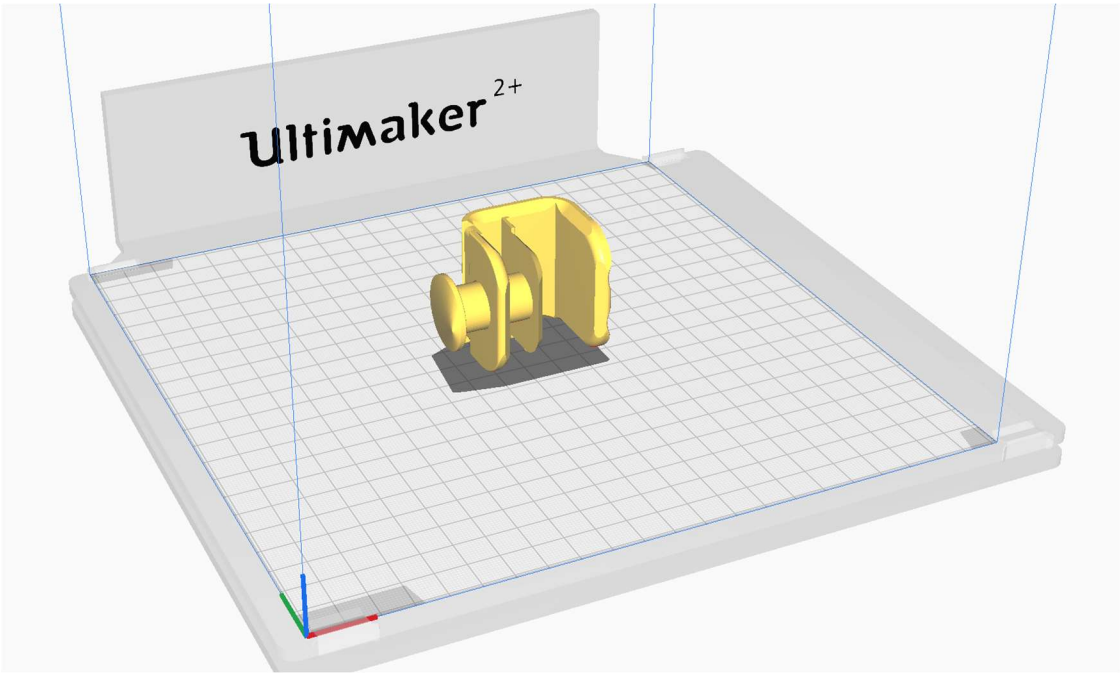

Figure 16 - Printer placement to optimize Quality

Step 5: Slice the print and upload to printer. Should look similar to figure 16

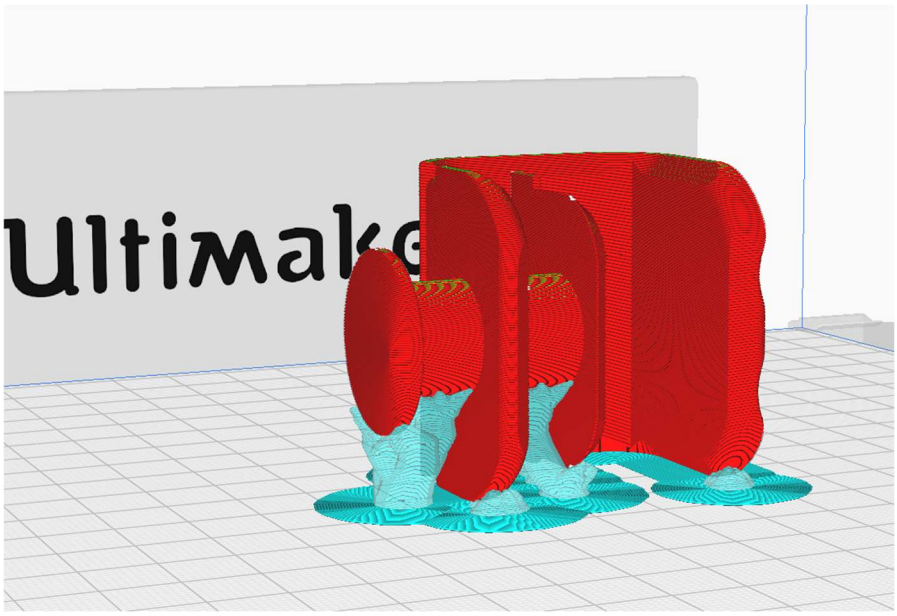

Figure 17 - 3D Printing Supports

Step 6: Start the print. Wait until the first couple of layers are completed on the printer to avoid failed prints.

Step 7: Using a pair of pliers break the support off the device.

Step 8: Because all the subsystems print as one part, they are partially fused together during the printing process. The best time to free the parts is directly after it is done printing since the part has not yet cooled off. To free the parts, start by wiggling the parts. You can also insert a screwdriver between the compression plate to free the device (be careful as this may break the compression plate). Another useful tip in freeing the fused part is the apply pressure to force the compression plate away from the back wall of the device this is a weak point in the device (see figure 18). If all else fails, you can attempt to use a large pair of pliers to force the compression plate to close (warning this may break the print).

Figure 18 - Device preparation and cleanup

Step 9: After the part is free scrape the cylinder with the blade of the utility knife to smooth out the edges of the cylinder. Make sure you wear proper safety protection.

Step 10: File down any rough spots on the print specifically where the supports were attached.

Step 11: Add the elastic band and test the device. If the device is sticking, then go back to step 9.

Additional Instructions for Spring Design

- Download this STL file link
- Repeat steps above except when you get to the slicer you need to modify the g-code to stop halfway through the print (figure below). With this modification to the g-code the printer will stop halfway through the print which will allow you to add the spring in the center of the device.

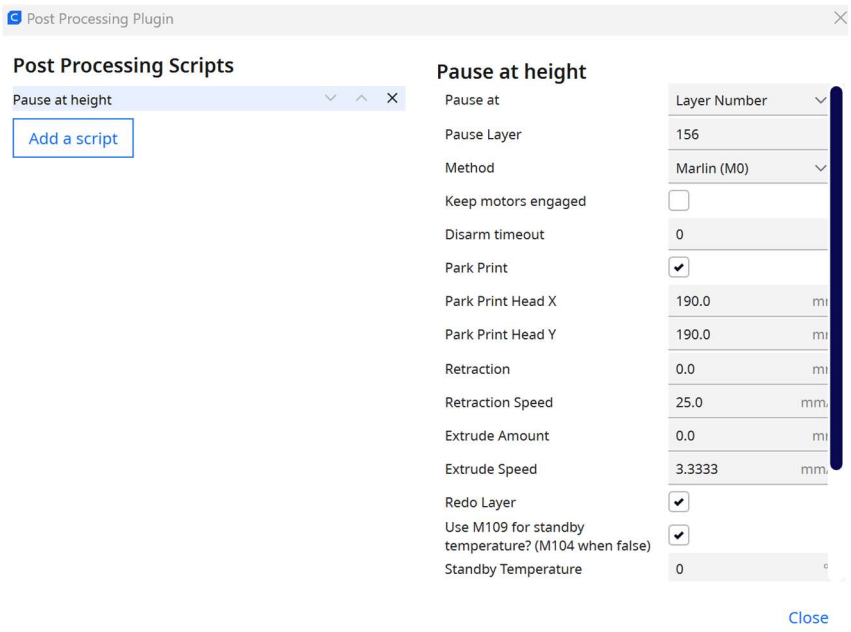

Figure 19 - G Code script section

- Once the printer has paused at the halfway point add the spring in the center of the device and resume the printer. Make sure that you watch the printer to ensure that the spring does not get entangled in the printer.! Important you need to put the spring in 1 to 2 minutes after the printer has paused otherwise the layers will cool and the print will not bond to the next layer (see figure below).

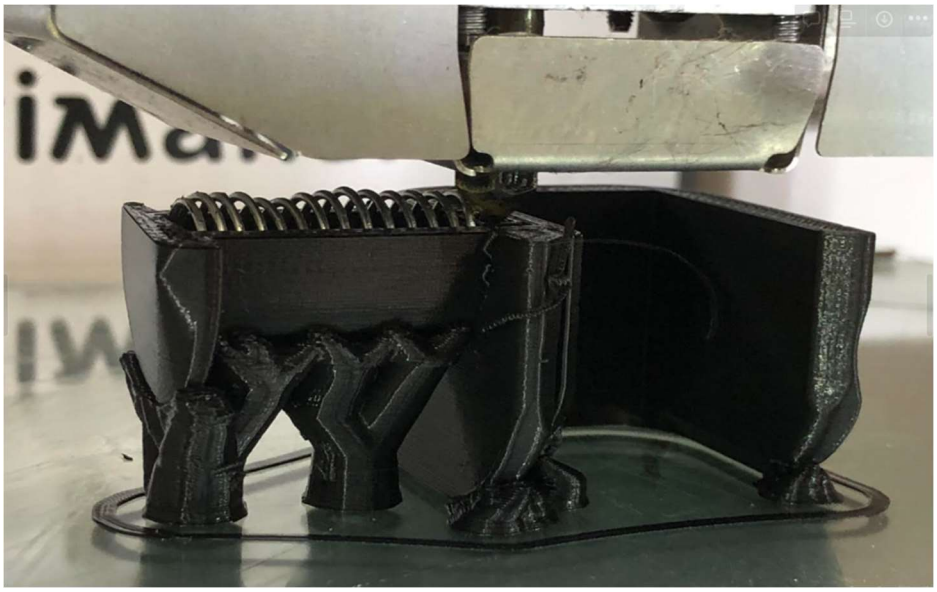

Figure 20 - Example Print with spring compression system

- After printing is complete due the same steps for freeing and finishing off the print listed above.

5.3 Testing & Validation

For testing of our design idea, we conducted two rounds of prototypes. Each round had multiple tests but focused on a particular subsystem.

5.3.1 Prototype 1

To address the ergonomic needs of our device, we decided to focus on the hand grip subsystem for the first prototype. The primary goal is to test and refine our design specifications, specifically in terms of dimensions, weight, and shape. We also want to validate our assumption that this device will provide an ergonomic solution to closing clips. While our design specifications were initially based on the maximum allowable values, it is important to note that these values may not necessarily represent the ideal specifications for the device. Therefore, with prototype 1, our aim is to identify the design specifications that will optimize the ergonomics of the device.

To effectively analyze the ergonomics, a physical model is required for prototype 1 as it allows for a hands-on evaluation. We will utilize 3D printing to materialize our CAD design. With the physical model, we will assess the comfort, weight, and overall shape of the device. This will enable us to identify areas where material can be removed to reduce weight without compromising strength.

Because our device should work for a diverse range of hand sizes and shapes, achieving universality is crucial. To further understand how we can enhance the comfort of the device, we will present our prototype to an external group. Their feedback will provide insights and suggestions on potential improvements that can be made to enhance comfort.

Finally, by having a physical model we can simulate the movement necessary required by our device to close the clips. This is important as one of the main reasons we chose this design was the complete reduction of the thumb joint. However, because this idea has not been used in any of our benchmarking, we need to validate our assumption that our device will be more ergonomic.

5.3.1.1 Prototype 1 Test 1 - Dimensions of Tool

The primary goal of test 1 was to determine the dimensions of the renal device. We wanted to ensure that the tool would fit comfortably in the palm of the user's hand. This would be accomplished by using a test group of people to see if they thought the tool was too large or too small for their hand. We then would use this data to find the dimensions of the tool to provide a universal fit for different sizes of hands.

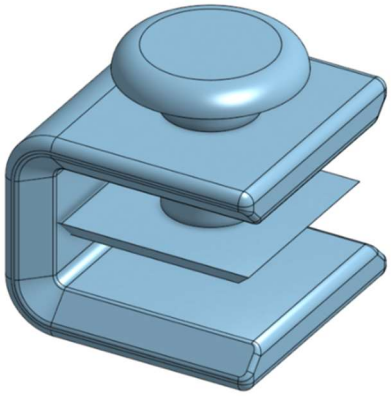

Figure 21 - CAD design of P1 Test 1

Figure 22 - Physical Model of P1 Test 1

Our initial CAD design dimensions for test 1 were inspired by the size of a Rubik's cube. However, we quickly realized that the tool turned out to be considerably larger than expected during the first trial print. To prevent wastage of material, we made the decision to abort the print. To accurately determine the needed dimensions, we measured the length of one of our hands and divided this measurement by 3. This calculation provided us with the dimensions for a 55x55x55 mm cube, which we used as the basis for remodeling the design.

From test 1, we arrived at a valuable lesson of the importance of finding alternative ways to define design specifications accurately without relying on prototypes. This was because we did not want to waste any more time and effort building prototypes simply because of a bad estimation of the tool's dimensions. Furthermore, we decided that the box shape could be enhanced by incorporating finger grooves on the bottom surface of the tool. These grooves would not only increase the overall grip but also improve comfort during usage.

During the printing process of the device, we chose to use a 10% infill, resulting in a considerable amount of flexibility in the structure. Recognizing this, we made the decision to add more material to test 2. However, to reduce weight, we decided to trim the front edges of the tool and thin out the back portion. We wanted to find a balance between the weight and strength of the device.

5.3.1.2 Prototype 1 Test 2

After editing the CAD design based on what we learned from test 1 we made test 2 so that we could evaluate the ergonomics of the device. We would evaluate the device on the overall weight, pressure points, and ease of maneuverability. For the weight, we wanted to know the minimum amount of plastic needed to ensure the strength of the device in operations. Test 2 also will be used to test for ergonomics of the repetitive motion of the plunger and the maneuverability of the tool.

Figure 23 - Physical Model of P1 Test 2

Figure 24 - Changed Ergonomics of P1 Test 2

Figure 25 - Plunger of P1 Test 2 uncompressed

Figure 26 - Plunger of P1 Test 2 compressed

Test two exhibited significant improvement by addressing the size issue and increasing the overall strength of the tool. However, during the evaluation, we discovered that test two was slightly heavy due to the high infill density chosen for the print. This prompted a discussion on finding a balance between strength and weight, as we contemplated reducing more material while considering the potential compromise on the overall strength of the device.

During the evaluation of test two, we found that the device was relatively comfortable to hold in our hands. However, we identified a flaw in the design the finger grooves on the bottom of the device were too small. One team member suggested exploring an alternative shape for the top of the plunger to reduce the pressure points on the palm of the hand.

Once we had evaluated the device, we decided to show our device to our focus group. This step in the process would enable us to refine the design further to avoid oversights in the design.

After seeking feedback from friends and our TA, we discovered several valuable ideas for improvement. The main suggestion was that the tool was too large for their hands, particularly emphasizing its excessive length. This observation was likely due to the fact that we had originally designed the device as a cubic shape, whereas the natural shape of a hand tends to be more rectangular. Additionally, we noticed that the individuals who mentioned the size concern generally had smaller hands.

Another critique we received was that the shape of the tool should align with the natural curvature of the hand, as opposed to its current box-like shape. In considering how to improve the shape, we concluded that by curving the backside of the device, we could not only improve its conformity to the hand's shape but also reduce the amount of material used and create a more rounded overall shape.

5.3.1.3 Further Analysis on Test 1 and Test 2

To test the device for ergonomics we need to repeat the motion required by our device to close the clips. In order to make the test as real life as possible we 3D printed a renal clip to simulate the closing action. We were unable to obtain any of the tubing which would also increase the force required to close the clip. We then tried closing the clip 40 times with our thumb then after a break we repeated the process but with our tool. This test proved that the clips were in fact easier to close with our tool than opposed to using just your thumb. On a side note, we noticed that the hard plastic surface of the clip on the tool created for the clip to slide around as you applied force. So, we noted this behavior as something to look into when we analyze the grip subsystem of the device. After doing this test we noted all the

Figure 27 - First test of a Renal clip

pressure or sore spots that we got when using the device. One such spot was the round top of the plunger did not fit that well in the hand so over time it created a sore spot.

For the next test, we wanted to see how easy the device was to maneuver. We did this by using the clip in a small space. We found an area where only our arm could reach through then using the tool, we attempted to maneuver the tool over the clip in the small space. This test was extremely successful as the tool seemed to work like an extension of your hand. One thing we learned from this test was that any slightly sharp edges on the tool cause discomfort to the hand when in tight spaces. To solve this, we sanded down the edges of the design.

Our final test was easy for portability and use. We wanted to get an idea of how easy this tool would be to carry around while you worked on other tasks. This test was done by carrying the device in our pockets while performing daily tasks. After doing this for a day we found that while the tool was pocket size the corners of the tool were rather uncomfortable if they were pressed against in your pocket. Also, we found that the top being extended out made the device harder to transfer than when it was in its square form. This promoted talk about how we could go about curving the edges of the design and potentially design a way for the plunger to be locked down into place when the device was not in use.

Some positive feedback we received indicated that the tool was highly compact and easy to maneuver. Taking the feedback into consideration, we plan to integrate the suggested improvements into our next prototype. By addressing the size concerns by modifying the overall dimensions and incorporating a more ergonomic shape, we will get a device that is better suited for individuals of varying hand sizes.

5.3.1.4 Updated Design Specifications

After completing test 1 and test 2 it became apparent that our original design specifications did not fit our design. Thus, based on feedback and analysis we determined the following values.

Design Specification	Units	Original Value	New Value
Reduction in thumb joint stress (compared to manual operation)	%	>75	>75
Compatibility with different hand sizes (e.g., can be used with X% of adult hand sizes)	%	>95	>85
Total volume of the device	cm^3	<200	<45
Total weight of the device	g	<300	<50
Dimensions of the device	mm	undetermined	<50x50x50
Number of operations using thumb (should be 0)	#	0	0

Table 3 - Updated Design Specifications from P1

Reduction in thumb joint stress and number of operations using the thumb remains the same as the original specifications. We changed compatibility because our design fits in the palm of the user's hand. It is impractical to think that we can make a device that will fit most hands perfectly. If we were making a scissors design, then 95% would be a reasonable goal. Instead, once we have the max and min dimensions of the clips, we can design a device that has the smallest opening possible. Since, this device might be too small we will investigate figuring out how the device could be scalable to allow maximum comfort.

The volume was changed because the design uses less material than previously benchmarked designs. The dimensions were found by measuring the length of one of our hands and then dividing the value by 3. This gave a good estimate of the max length the sides of the cube could be before it would stretch the hand past is natural size.

Finally, the weight of the device was determined to be under 45 grams. After holding test 2 we found that 48 grams while light was slightly heavy if we were able to get under 45 without compromising the structural integrity of the tool then we could increase the ergonomics of the tool.

5.3.1.5 Prototype 1 Conclusions

The development of test 1 and test 2 (prototype 1) served as a critical step in identifying the optimal design specifications for our ergonomic tool. Through testing and analysis of design specifications, we gained valuable insights into the dimensions, weight, and overall ergonomics of the renal device. Although the initial dimensions of the prototype were larger than expected, we quickly adjusted

them based on hand measurements and feedback from the focus group. The incorporation of finger grooves and modifications to the shape improved the grip and reduced pressure points on the hand. Our prototype testing showed promising results in reducing thumb joint stress and eliminating the need for thumb operation. By continually refining and adapting our design specifications based on user feedback, we are confident in creating a universal and efficient tool for individuals with different hand sizes.

5.3.2 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 identifying problems in the actuation of the plunger design.

5.3.2.1 Prototype 2 Test 1

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.

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.

Figure 28 - P2 Test 1 with spring

Figure 29 - P2 Test 1 with spring from a horizontal angle

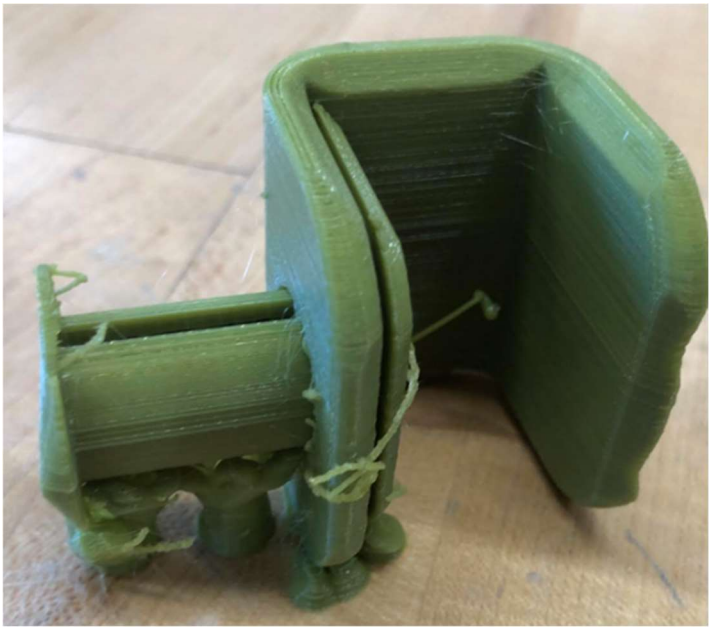

Figure 30 - P2 Test 1 hot off the 3D Printer

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 when 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 perfectly the first time. Originally, we only programed one stop into the print which meant that you only had one chance and placing 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.

5.3.2.2 Prototype 2 Test 2

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.

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 horizonal printing of the cylinder added friction to the compression system. 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 on 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.

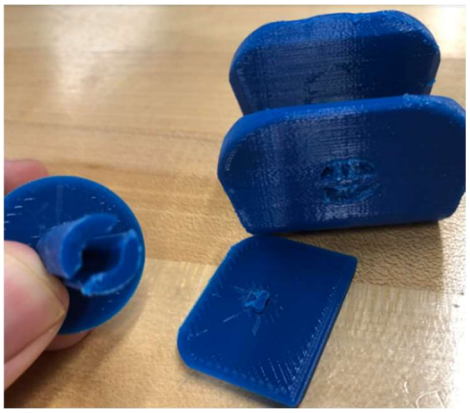

Figure 31 - P2 Test 2 Point of failure

Figure 32 - P2 Test 2 Point of failure on body

5.3.2.3 Prototype 2 Test 3

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 the more suitable for our design.

Figure 33 - Damaged compression plate

Figure 34 - P2 Test 3 printed model

Figure 35 - P2 Test 3 Surface finish

5.3.2.4 Prototype 2 Test 4

After complications with test 2 we came up with a plan to implement the design using one of our prototypes from test two. 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 backlash from the cylinder since they applied force on both sides of the plate preventing backlash between the plunger and C structure. Some problems we ran into was the elastics quickly snapped do to rubbing against the rough 3D print. Also, it was found that two elastics required too much force to operate the device.

Figure 36 - P2 Test 4 Elastic Band design

Figure 37 - P2 Test 4 plate design

Figure 38 - P2 Test 4 Elastic Band rebound test

5.3.2.5 Prototype 2 Lessons Learned

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. Elastic was easy to use than the spring and made the device more compact.

5.3.2.6 Compared 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 (should not exceed manual operation time)	seconds (s)	<3	3	4	4	4
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

Table 4 - All tests compared to Design Specifications

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 replication.
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 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 design incorporates a multiclip 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 area 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, test 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.

5.3.2.7 Prototype 2 Conclusion

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.

6 Conclusions and Recommendations for Future Work

6.1 Lessons Learned

- Backlash Challenge: Addressing backlash in the compression system proved to be a critical challenge, requiring careful consideration in design modifications.
- Design Adjustments Matter: Modifying the device's geometry, such as squaring off the interior, played a significant role in improving performance.
- Plunger Placement: Relocating the plunger to increase user pressure in the opposite direction was a strategic move, enhancing functionality and usability.
- 3D Printing Challenges: Printing flaws impacted functionality and finish, emphasizing the need to understand and address 3D printing intricacies.
- Spring and Elastic Mechanisms: Experimenting with resetting mechanisms, including springs and elastics, provided valuable insights. While springs posed challenges during printing, elastics showed promise in addressing backlash and usability issues.

6.2 Work Related to Prototypes

- Prototype 1 (Ergonomics): Focused on ergonomic needs, dimensions, weight, and shape. Incorporated finger grooves and shape modifications based on user feedback.
- Prototype 2 (Compression System): Explored three designs to improve the compression system, including a plunger with an internal spring, an elastic-based design, and adjustments to cylinder diameter.

6.3 Suggestions for Future Work

- Explore Mechanical Mechanism: Given the abandonment of the spring idea, future work could involve exploring and developing a mechanical mechanism that eliminates the need for the elastic.
- A future design could eliminate the plunger system which would prevent backlash issues.
- Further Refinement of Elastic Mechanism: As elastics showed promise in addressing backlash and usability issues, dedicating more time to refine and optimize the lifespan of the elastic would be beneficial.
- Address 3D Printing Challenges: Allocate time to investigate and address 3D printing challenges, including under-extrusion, to enhance the consistency and finish of the printed devices.
- Extended Testing for Durability: Perform extended testing to assess the durability and lifespan of the device, especially considering the use of elastic bands, which may be prone to wear and damage during cleaning.
- Iterative User Feedback: Continue to gather user feedback through iterative testing, involving potential users to ensure the design meets their needs and expectations.

- Cost Optimization: Further explore avenues for cost optimization in production, considering alternative materials or printing methods that maintain structural integrity while reducing costs.

6.4 If More Time Were Available

- Iterative Prototyping: Conduct additional rounds of prototyping to refine and iterate on the design based on continuous testing and user feedback.
- Advanced Materials Exploration: Investigate the use of advanced materials that may enhance both the structural integrity and the overall performance of the device.
- Collaboration with Medical Professionals: Collaborate with medical professionals to ensure the device meets the specific requirements and standards of the medical field.
- Extended User Testing: Extend the duration and scope of user testing to thoroughly evaluate the device's usability, comfort, and efficiency in real-world scenarios.

6.5 Summary

The user manual for the ClipFit provides a detailed overview of the device, guiding users through its various aspects, including its structure, ergonomics, and troubleshooting procedures. It highlights our commitment to user-friendly design by meticulously explaining each subsystem, such as the ergonomic hand grip and compression system, ensuring a seamless user experience.

The manual also sheds light on the extensive testing and validation process, emphasizing the iterative nature of prototyping and the pursuit of design perfection. Valuable insights gained from prototype tests, particularly regarding the compression system, are shared, highlighting the challenges faced and the innovative solutions devised.

To enhance user understanding, the manual outlines stylistic and command syntax conventions that should be followed. Additionally, it incorporates lessons learned from addressing backlash challenges and optimizing 3D printing techniques, providing a solid foundation for future improvements.

Our vision for the ClipFit extends beyond the present manual. We anticipate the device being used in a more refined and specialized medical tool in the hands of future developers and groups. Given more time, we would explore mechanisms that eliminate the plunger, and alternative materials.

APPENDICES

7 APPENDIX I: Design Files

Table 5. Referenced Documents

Document Name	Document Location and/or URL	Issuance Date
ClipFit MakerRepo page	https://makerepo.com/dunbar/1853.clipfitrenal-care-device	25/08/23
Renal Care Device MakerRepo Project Page	https://makerepo.com/project_proposals/384.renal-care-device	17/11/23
STL File Elastic FitClip	https://drive.google.com/file/d/1-v2jfff9x-2NJ8RhtIno8GqXP1IQLY9A/view?usp=sharing	29/11/23
STL File Spring FitClip	https://drive.google.com/file/d/1qSdvGt6o3eh-62yXNoC2stnmgD2rIAEU/view?usp=sharing	29/11/23