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Pinch Clamp Clipping Ergonomic Device

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The purpose of this project was to design a device to reduce the risk of osteoarthritis in nurses who have to routinely clip pinch clamps on tubing by improving the ergonomics of clipping. This was a continuation of a project begun in MEMS 411 Senior Design in Fall 2023, where students generated several prototypes. For this independent study, the design of a pinch clamp clipping (PCC) ergonomic (ergo) device was completed. The PCC ergo device alleviates the risk of osteoarthritis and is ready to be produced on a small scale. The total cost per device comes out to under $1. Computer-aided design (CAD) files for 3D printing, along with instructions for 3D printing and assembly, are included with this report.

LIN, Jaimie

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1 Introduction

In hospitals, many devices such as dialysis machines, IVs, and catheters transport liquid through plastic tubes. Frequently, liquid flow through these tubes must be temporarily blocked. This is done using pinch clamps that are manually clipped by nurses many times a day. The process of clipping pinch clamps by hand, when performed many times over years of work, leaves nurses at severe risk of osteoarthritis in their CMC joints. To combat this, we have designed a device that takes the strain off of the joints in nurses' hands while still allowing them to efficiently clip and unclip several pinch clamps in a row, many times per day.

2 Problem Understanding

2.1 Pinch Clamp Description

Pinch clamps come in many sizes and have slightly different geometries, however, most operate in a similar way. A tube is fed through the clamp and force is applied to the top in order to engage a latch. This forces two pinch points together, squeezing the tube until there is no space for liquid to pass through. Figure 1 shows the exact pinch clamps that were used for this project.

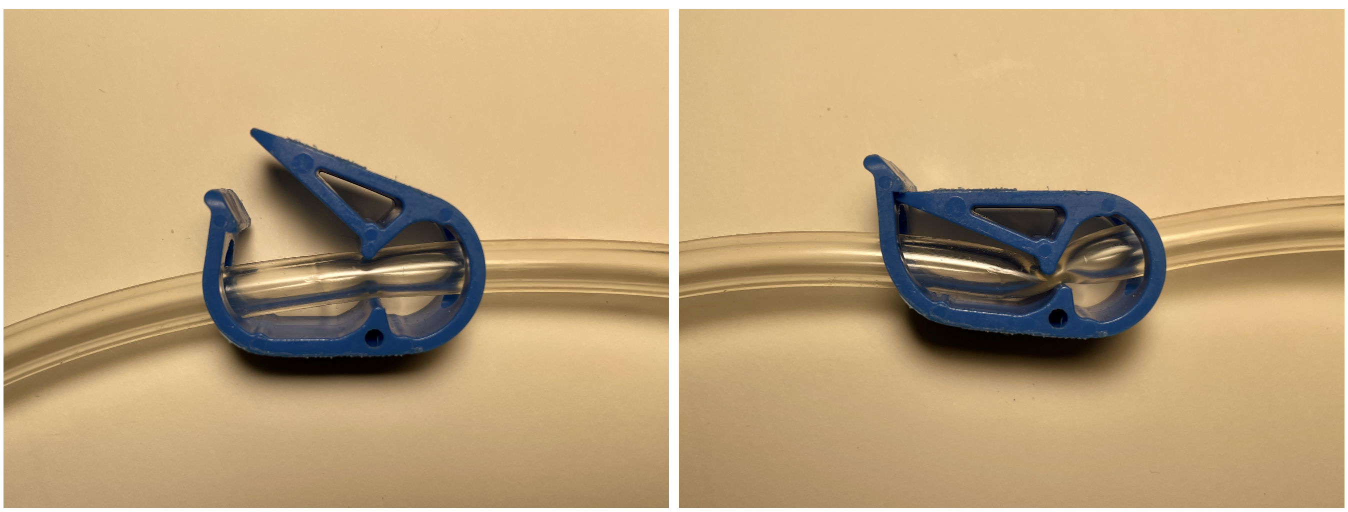


Figure 1: Pinch Clamp Used for this Project.

2.1.1 Patent US6234448B1

This is a patent for one model of pinch clamp that is similar to the clamps the tool will have to work with. The patent includes several possible designs and sizes of clamps.

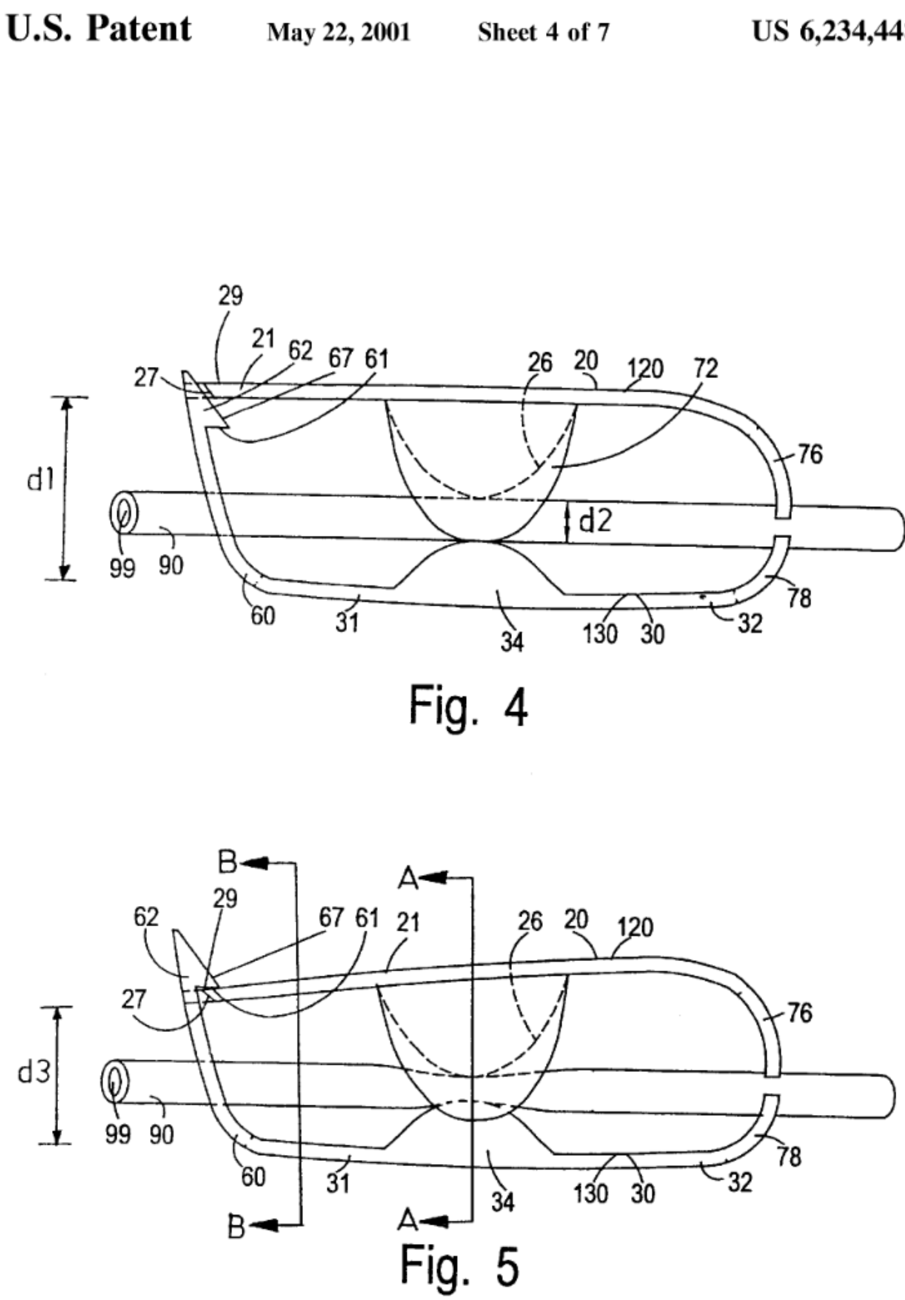


Figure 2: Pinch Clamp Patent.

2.2 User Needs

Through an interview in Fall 2023, the user needs of the PCC ergo device were determined.

2.2.1 Customer Interview

Interviewees: OTR Shona N. and OT student Sydney Livermore
Location: Zoom
Date: September 8^{th}, 2023
Setting: We talked with the interviewees about their thoughts, needs, and expectations for a device. The whole interview was conducted over Zoom, and took ∼ 1 hour.

Interview Notes:
What is the primary objective of the device?

- The goal of the device is to reduce the force required from the thumb joint to close the pinch clamps. Repetitive use of the pinch clamps could lead to the development of osteoarthritis in the CMC joint. This is a concern for nurses who have to clip a lot of clamps during their shifts. The device does not need to unclip the clamps, as that is fairly easy to do by hand.

Would it be possible to build something replacing the pinch clamp or would it have to work in tandem with the clamp?

- The pinch clamp is industry standard in hospitals, so it would be very difficult to administer a switch to a completely new device. Introducing a tool that can be used with the pinch clamps would be a much easier transition.

What setting would the device be used in?

- The device would be used with pinch clamps on dialysis tubing. The device should be capable of fitting into awkward spaces since there's a lot of tubing and other things around the pinch clamps.

How do nurses typically use the pinch clamps? How often are they clipped? Are multiple clamps clipped in a row?

- Nurses clip the pinch clamps in a wide variety of patterns, ranging from clipping many clamps in a row for all of their patients, to just a single clamp between paperwork. There are multiple clamp sizes, and nurses will switch between a variety of clamps often. Because of this, it is preferable to have one versatile tool that can switch between different types of clips. We discussed the possibility of making a kit for different sizes (like an Allen key set), but that would deter nurses from using the device at all since it takes significantly more time and effort to switch between several devices.

Are there any features of the current method that should be preserved?

- It is important that the clamps can clipped one-handed and with either hand. They mentioned including a loop or handle to stabilize the device while it's being used.

Are there any size, weight, and portability requirements?

- The device should be portable and easy for nurses to carry around while they work. We discussed the device being pocket-sized, and attached to a keychain or lanyard.

Are there any cost considerations?

- The device should be as economical as possible, without having to worry about functionality. They don't need the cheapest option, but it has to work well to be successful in the hospital industry.

Could we get our hands on a clamp and comparable tube to test on?

- Yes, they can mail several pinch clamps and tubes for us to test on. The ones that they use in their hospital only have one ridge for clipping (not multiple ratcheting steps like the larger clips we have).

How durable does it need to be? Are there any common damages you expect it to incur?

- They don't expect the device to be used roughly. It should be somewhat durable but is not expected to withstand high stress.

How intuitive and fast does the device need to be?

- They can conduct a brief ($\sim$ 1 hour) training to teach nurses how to use the device. It does not need to be the most user-friendly, as there can be some education. However, the device cannot add any time to the process. It needs to be just as fast as clipping with your hand or else there will be resistance from the nurses.

Are there any requirements for devices designed for use in hospitals?

- The device must be easy to clean and shouldn't be able to harm someone. All corners should be rounded and the overall device should be sleek. Chunky, abrasive, and sharp features should be avoided.

2.2.2 Interpreted User Needs

Based on the customer interview, a list of interpreted user needs was compiled as seen below in Table 1. The level of importance of each user need was also estimated on a scale of 1 through 5, with 5 being very important and 1 being not very important.

Table 1: Interpreted Customer Needs.

Need Number	Need	Importance
1	Can clip pinch clamps	5
2	Can clip quickly	5
3	Takes stress of clipping off joints	5
4	Can be used one-handed	5
5	Can be used in either hand	3
6	Can be used for multiple pinch clamp sizes	4
7	Is portable	4
8	Is inexpensive	2
9	Is easy to clean	5
10	Is safe for use in a hospital	5
11	Is durable	2
12	Is simple to use	1

2.3 Design Metrics

Based on the identified user needs, a set of design metrics were determined, as seen below in Table 2. These metrics consist of target specifications and tests to determine whether the user need was met.

Table 2: Design Metrics.

Metric Number	Associated Needs	Metric	Units	Acceptable	Ideal
1	1	Can clip pinch clamps	binary	Pass	Pass
2	2	Time to clip one pinch clamp	seconds	Same as by hand	< by hand
3	2	Time to clip five pinch clamps	seconds	Same as by hand	< by hand
4	3	Clamping force needed	Newtons	50% of by hand	25% of by hand
5	4, 5	Can be used by either hand alone	binary	Pass	Pass
6	6	Number of pinch clamp sizes device is usable for	integer	2 sizes	All standard sizes
7	7	Mass	g	< 200	< 50
8	7	Volume	cm^3	< 100	< 50
9	8	Cost per tool	USD	< 50	< 20
10	9, 10	Time to sanitize	minutes	< 2	< 1
11	10, 11	Device can be sat on with no damage to user or device	binary	Pass	Pass
12	11	Survives being dropped 20 times at chest height	binary	Pass	Pass
13	12	Time for new user to learn how to use device	minutes	< 90	< 30

2.4 Previous Work

Based on the identified user needs and design metrics, several prototypes were created by various groups throughout the course of MEMS 411 Senior Design in Fall 2023. Several of the completed prototypes were sent to OTR Shona N. for review. A few notable prototypes are outlined below.

2.4.1 Previous Prototype #1: Pliers

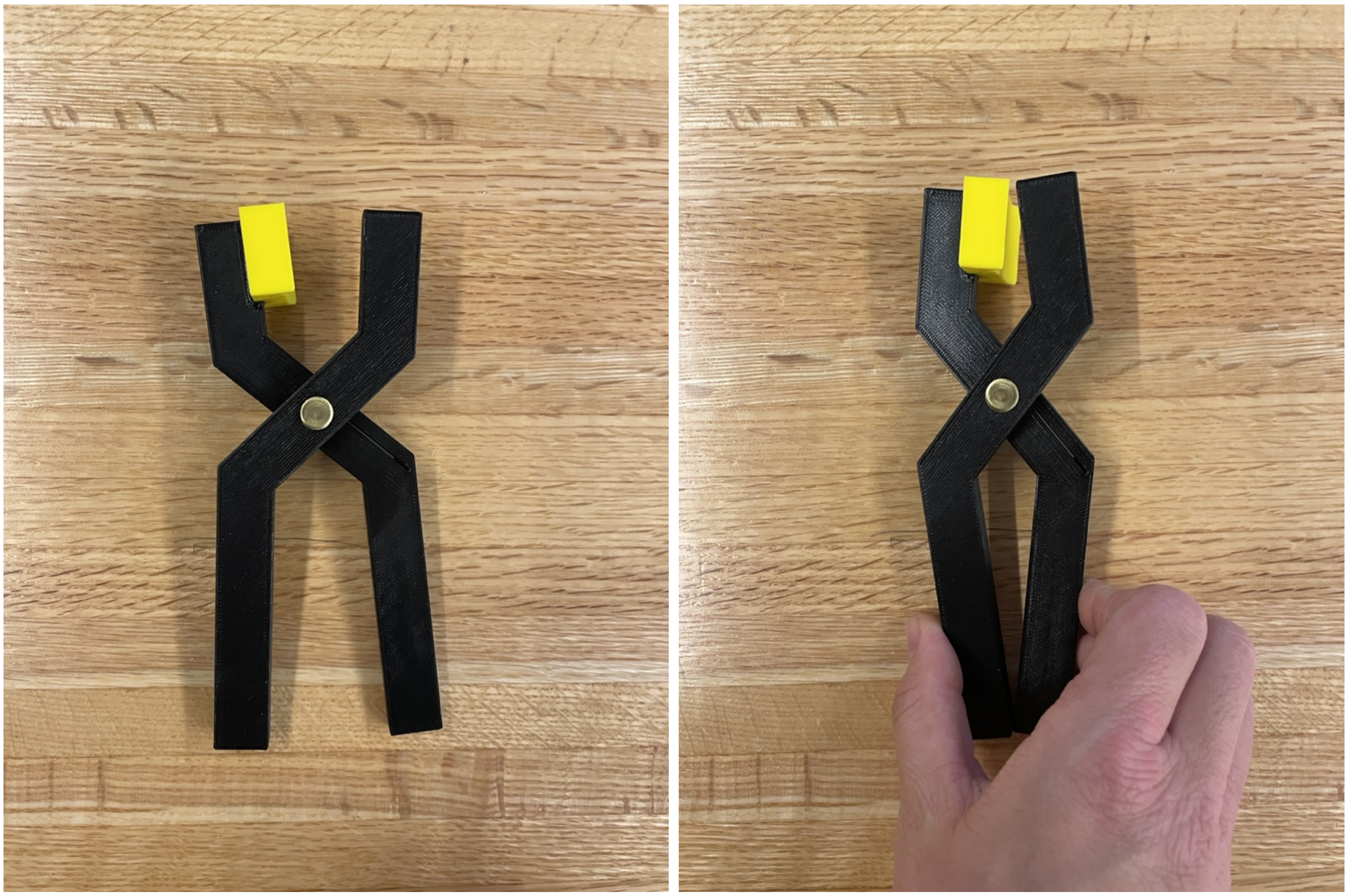


Figure 3: Pliers Prototype.

Description: This prototype was designed by students for MEMS 411 Senior Design in Fall 2023. Two handles are attached at a pivot point near the center of the device. A torsion spring sandwiched between the two handles keeps them open when no force is applied. A guide on one handle cups the back of the pinch clamp and the other handle pushes on the top to close the clamp. Several prototypes using a similar mechanism were created by other groups in the course.

2.4.2 Previous Prototype #2: Nutcracker

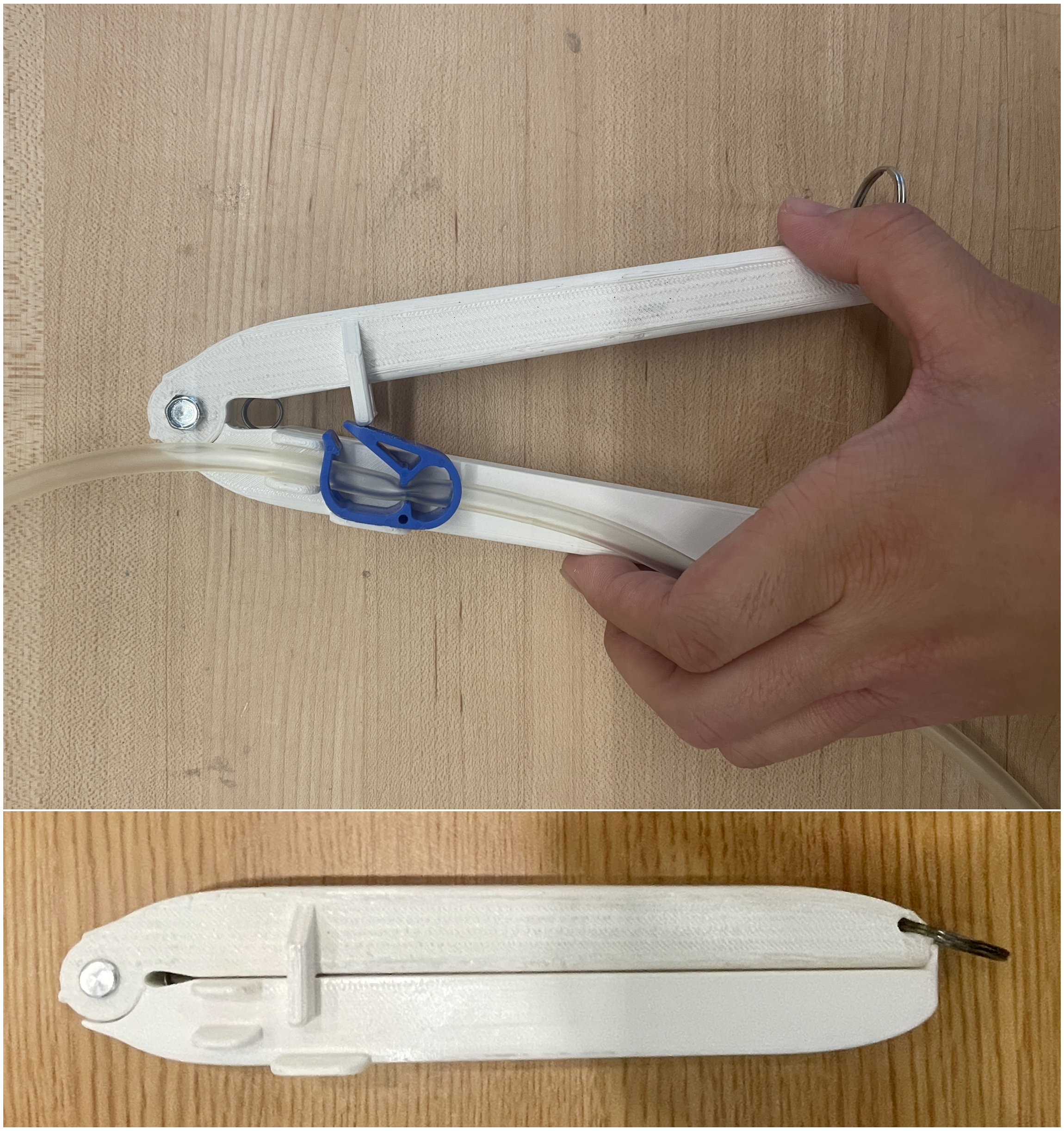


Figure 4: Nutcracker Prototype.

Description: This prototype was designed by Jaimie Lin, Mackenzie Molina, and Oliver Avery for MEMS 411 Senior Design in Fall 2023. Two handles are attached at a low-friction hinge held by a clevis pin. An embedded torsion spring keeps the handles open when no force is applied. The bottom handle has a built-in surface to support the bottom of the clamp, as well as a guide for the tube to make it easier to align the clip in the device. The top handle has a rounded pin to concentrate force on the appropriate spot on the clamp to efficiently clip it.

2.4.3 Previous Prototype #3: Locking Pliers

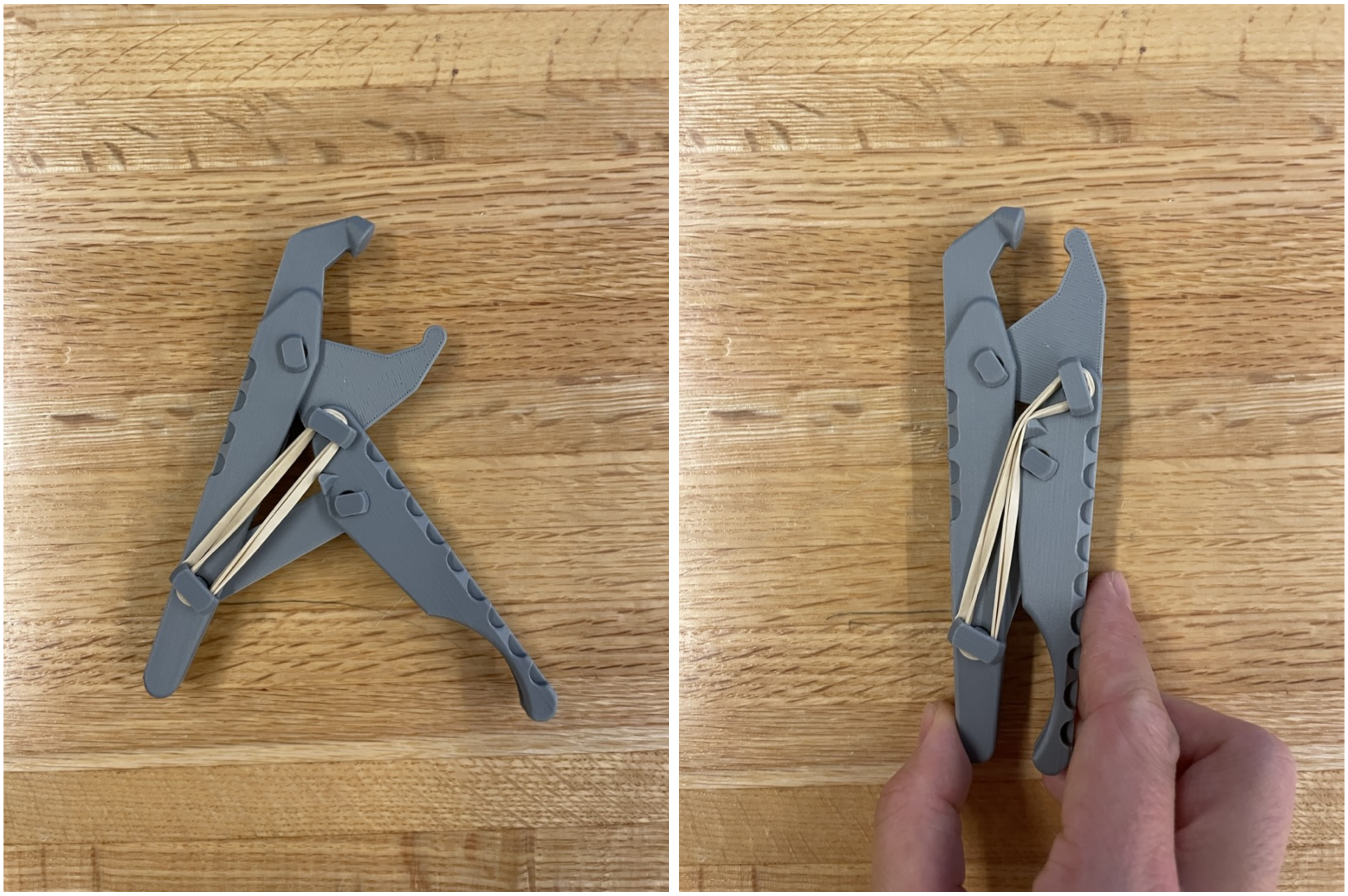


Figure 5: Locking Pliers Prototype.

Description: This prototype was designed by Dr. Potter in Fall 2023. It utilizes a four-bar mechanism, very similar to the mechanism in locking pliers. Locking pliers stay closed around an object without requiring pressure on the handles using the ”over-center” principle [1]. While being closed, the mechanism passes through a point of maximum clamping. This occurs exactly when three of the pins align. As the handles are closed further, the jaws release slightly and the mechanism reaches a secondary stable position. The jaws remain in that locked position until they are opened slightly, past the point of maximum clamping, at which point they spring all the way open again [2]. This particular prototype uses an elastic band to keep the device open. It can be stored in an inactive position by moving the elastic band over the protruding nub on the lever.

3 Redesign Process

3.1 User Feedback

After reviewing the various prototypes from MEMS 411, OTR Shona N. sent feedback via email correspondence. The preferred device was the Locking Pliers prototype, but the primary issue was that the device did not reopen automatically after clipping. This increased the clipping time, since the user needed to manually pull the handles apart after clipping every pinch clamp.

From: Shona N.
Sent: Friday, March 1, 2024 12:19 PM
To: Jackson Potter
Cc: Sydney Livermore
Subject: Clamp feedback

Jackson and Sydney,

[A nurse] came over to share his feedback. They liked the 3 pictured, but each have some issues. The all black/black and blue both broke. You can see on the black and blue one, the side clamp broke right off. The other all black one developed a crack in the pin. The red and yellow one is quite good but locks when used on the clamp in the closed position. This requires the user to manually open it. These two designs were the favourites as they could be used when coming at the clamp from left or right. The last all red one was good as well, but as it is offset it lost points as it can only be used heading in from one direction. The feedback was that they liked the cradle for the base of the clamp.

Does this help? Not sure of next steps?
Shona

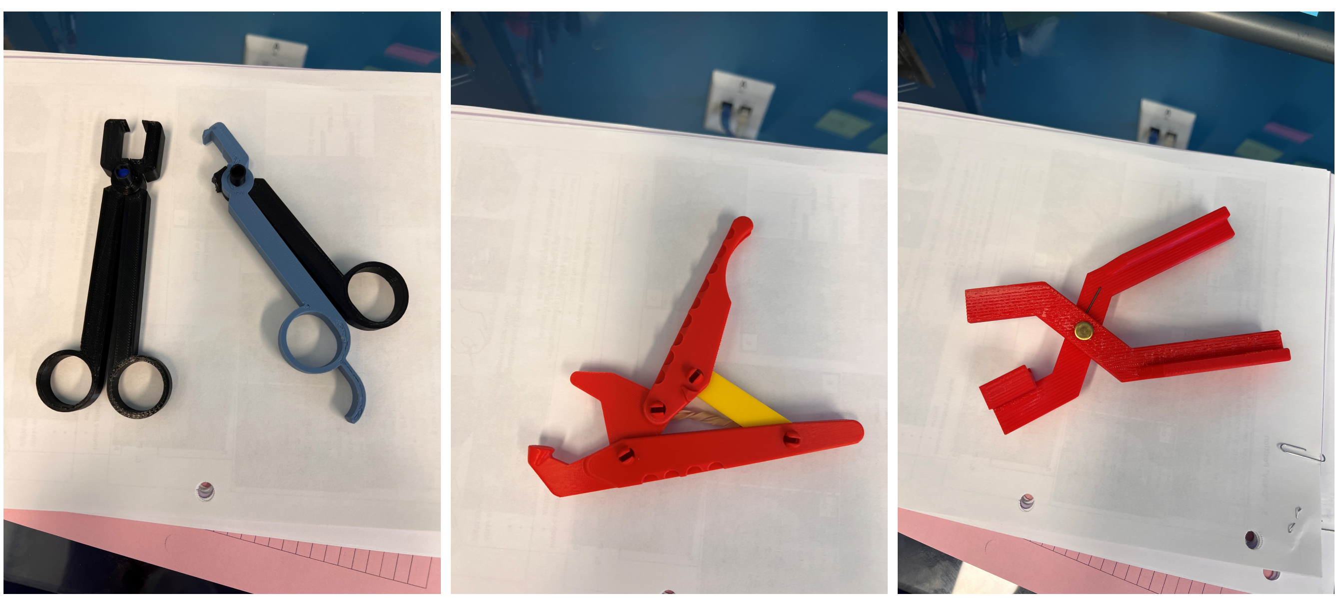


Figure 6: Prototypes Given Feedback.

From: Jackson Potter
Sent: Saturday, March 2, 2024 9:08 AM
To: Shona N.
Cc: Sydney Livermore, Jaimie Lin
Subject: Clamp feedback

Shona,

Thank you for the feedback! Any information like this is critical to making the device as useful as we possibly can. Jaimie Lin (copied) is working with me this semester on the design.

So based on your experiences with the prototypes and feedback from others, do you think that the yellow-and-red prototype is the one we should spend time developing further? Imagine that we could make a revised version that is able to open itself back up after clamping (while still keeping the feature of closing when not in use), and a few other minor improvements.

Jackson

From: Shona N.
Sent: Tuesday, March 5, 2024 12:18 PM
To: Jackson Potter
Subject: Clamp feedback

The red and yellow was very user friendly. If it didn't lock when clamped down it would have been the favourite. Features: can go in from either side, fits all hand sizes, clamp size small enough to put pressure where needed. It also seems sturdy. I do have some concerns about the elastics drying out (as we know they do quickly) and loosing effectiveness- elastic alternatives?? It would also be good if it was easier to replace the elastics- the pin has to be loosened significantly- not a huge issue, but a point where there could be plastic fatigue over time from pushing the ends of the pin together to loosen. This didn't have a metal spring, but I don't think I'd want one added (corrosion/longevity). When I put a piece of material in to keep it from fully closing, it didn't lock. Could be as simple as a block to just stop full closure.

Shona

3.2 Prototype Performance Goals

The prototype performance goals are a set of metrics that can be easily tested and measured. They are used to measure the success of each iteration of the device. The three performance goals that were selected for this device are as follows:

1. To close the clamp, the device requires a maximum applied force that is $\leq 1/4$ of the maximum force needed without the device
2. The device weights $\leq$ 4 oz.

3. In $\leq$ 5 seconds, the device can be removed from a pocket and used to close three separate clamps on the large tubing
    (a) This test must be completed with one hand
    (b) This test must be performed once with the user's dominant hand and once with the user's non-dominant hand

3.3 Design Changes

Based on the feedback on previous prototypes, the Locking Pliers prototype was chosen to move forward with. Design changes primarily focused on preventing the device from locking after clipping. First, we tried adding something on the Lever to increase the amount of tension in the elastic band when the device was in the closed position. The idea was that the increased force from the rubber band would be able to reopen the jaws. A random, red piece was glued onto a previous prototype to test the viability of this concept, as seen in Fig. 7. This did not solve the issue, and the device still locked after clipping.

Figure 7: Increased Rubber Band Tension Proof of Concept.

Next, we tried adding a hard stop to prevent the device from closing all the way. A screw was glued in the Lever of the previous prototype to test the viability of this concept, as seen in Fig. 8. This was successful in preventing the device from locking.

Figure 8: Hard Stop Proof of Concept.

After this proof of concept, we then tried to integrate a hard stop into the 3D-printed device itself. The original prototype was modeled in Fusion 360, however we thought that it might be beneficial to remodel the device in SolidWorks. A hard stop was integrated into the end of the Lever by adding a bend in the SolidWorks version, as seen in Fig. 9.

Another issue that was mentioned in the feedback was about the pins holding the elastic band. Previously, the pins needed to be fully removed to replace the elastic band, which was physically difficult, time consuming, and was likely to cause the pins to break from the repetitive stress. We tested out new pins with a v-shaped spool to hold the elastic band. As seen in Fig. 9, the pins that originally enclosed the elastic band were replaced by the spool-type pins.

The remodelled device in SolidWorks was close, but not quite as effective as the original Fusion 360 model. In particular, the exact jaw geometry was difficult to replicate. We returned to a modified version of the original Fusion 360 model for the final prototype.

Figure 9: Intermediate SolidWorks Prototype.

The integrated hard stop was somewhat successful in preventing the jaws from locking. About half of the time, the jaws would automatically reopen, but at other times the jaws would get a little stuck. This was likely due to increased friction preventing the initial opening of the jaws, since any disturbance caused the device to spring open again. The reason for the increased friction was unclear, but may have been due to print quality. Instead of a hard stop on the end of the handles, the location of the second pin on the Lever was adjusted so that even when fully closed, the mechanism would not move past the point of maximum clamping. This prevents the mechanism from reaching the secondary stable position and locking.

The spool-type pins worked well and securely held the elastic band while still allowing easy removal without requiring the pins to be taken out. All of the pins were subsequently replaced by the spool-type pins, to reduce the number of different parts. We also decided to switch the print orientation of the pins so that they could be printed completely round instead of with a flat side. The flat side created sharp corners that were uncomfortable to hold and made removing the pins painful.

By comparing to older prototypes, it was determined at this point that the jaws did not need to have a rounded nub to be able to close the pinch clamp from various angles. There was actually more room for misalignment when the jaws were made completely flat. Also, the SolidWorks model had clean, smooth edges instead of scalloped edges like in previous Fusion 360 models. The smooth edges felt better when holding the device. In the final prototype, the scalloped edges were removed to simplify the handles and make them easier to clean.

3.4 Final Prototype

The final prototype, as seen in Figure 10, was successful overall. The greatest improvement from the original prototype was that the device no longer locks after clipping a pinch clamp. Other notable improvements include making the elastic band easier to remove, changing the geometry of the jaws for more reliable clipping, and removing the scalloping on the edges.

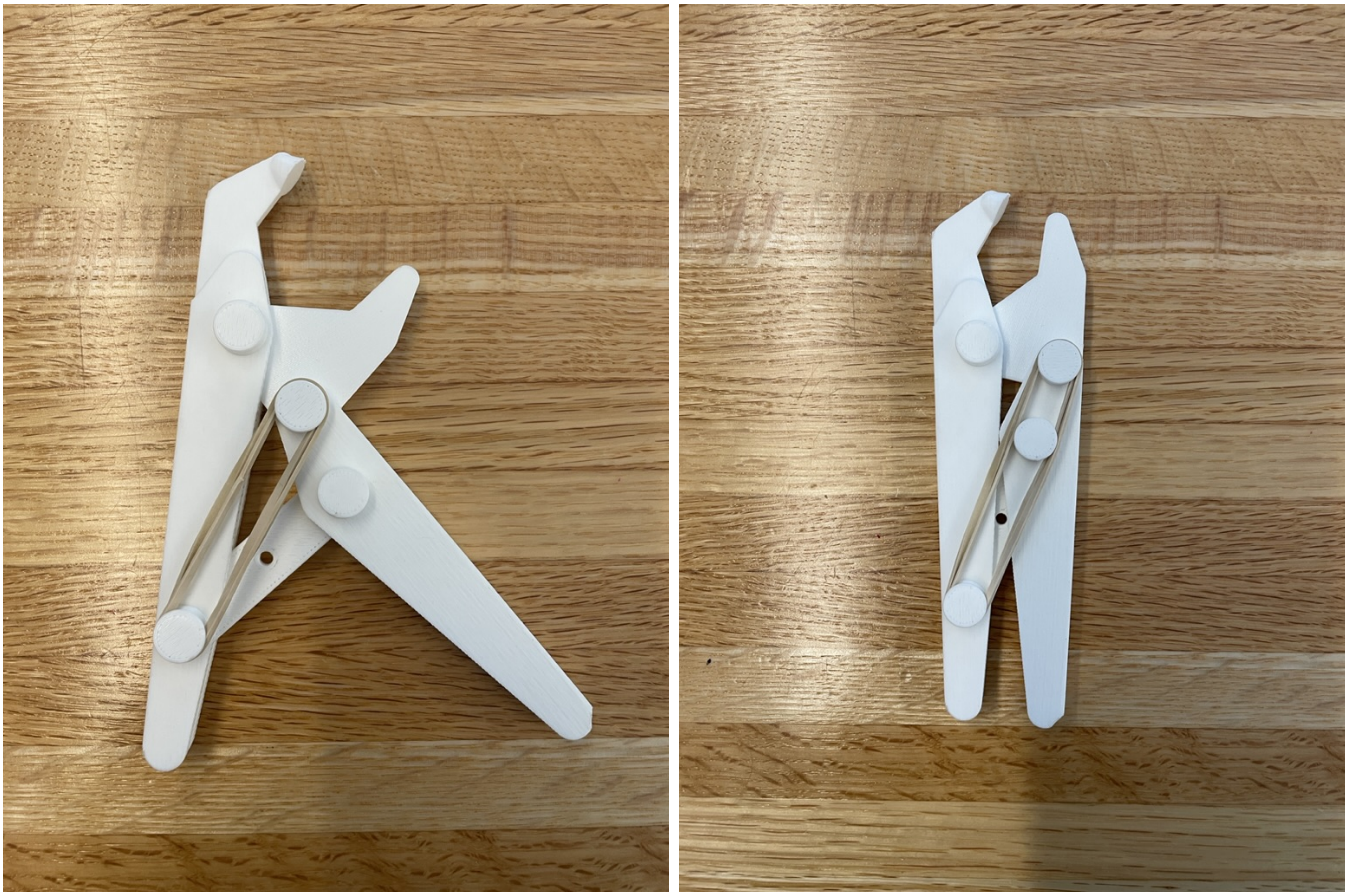


Figure 10: Final PCC Ergo Device.

4 Design Considerations

Throughout the design process, the device was developed with safety, usability, manufacturability, and adaptability in mind.

4.1 Safety

Every device or system can fail in some way, and failure can result in damage to people and/or property. In order to ensure that the device is as safe as possible, a few of the PCC ergo device's possible risks were identified and analyzed.

4.1.1 Risk #1: Pinching

Description: A body part (e.g. finger) or delicate object is caught in the device and pinched
Severity: Marginal
Probability: Occasional
Mitigating Steps: Make the pinching surface rounded and prevent the jaws from closing all the way.

4.1.2 Risk #2: Flying Rubber Band

Description: The rubber band escapes from the pins, flies off, and hits somebody or something
Severity: Marginal
Probability: Likely
Mitigating Steps: Secure the rubber band and don't put enough tension in the rubber band to cause serious injury.

4.1.3 Risk #3: Device Fracture

Description: The device fractures into potentially sharp pieces
Severity: Catastrophic
Probability: Unlikely
Mitigating Steps: Reinforce all parts of the device so that they can withstand more than the expected load.

4.1.4 Risk #4: Breaks Clamp or Cuts Tube

Description: The device supplies enough force to break the clamp or cut the tube.
Severity: Catastrophic
Probability: Unlikely
Mitigating Steps: Design for and test device on all clip sizes that will be used. Ensure that the maximum force applied is just enough to close the clamp and not enough to break it. Remove sharp features and prevent the device from closing enough to cut a tube.

4.1.5 Risk #5: Overuse Injury

Description: Constant use of the device over years leads to osteoarthritis in the hands.
Severity: Catastrophic
Probability: Seldom
Mitigating Steps: Ensure the device takes force off the hands as intended. Carefully consider the required motion to use the device and consult with nurses.

4.1.6 Risk Heat Map

Severity of risk	Probability that something will go wrong				
Category	**Frequent** Likely to occur immediately or in a short period of time; expected to occur frequently	**Likely** Quite likely to occur in time	**Occasional** May occur in time	**Seldom** Not likely to occur but possible	**Unlikely** Unlikely to occur
Catastrophic				Overuse Injury	Device Fracture Breaks Clamp or Cuts Tube
Critical					
Marginal		Flying Rubber Band	Pinching		
Negligible hazard presents a minimal threat to safety, health, and well-being of participants; trivial					

Figure 11: Risk Assessment Heat Map.

4.2 Usability

Vision Impairment: A vision impairment may influence the usability of our device. There should be no influence on the device's usability for someone who is colorblind as the device is not color-coded. However, the device could be harder or more dangerous to operate for someone with presbyopia as they could have more trouble lining up the device and could pinch themselves. This issue was reduced by removing sharp features from the device and preventing the jaws from closing all the way.

Hearing Impairment: A hearing impairment (such as presbycutia) may influence the usability of the device. Nurses may rely on the auditory feedback of the "click" noise to indicate that the clamp has been closed, thus having a hearing impairment could hinder someone's ability to recognize when the pinch clamp is fully closed. This issue was mitigated by adding tactile feedback and removing the need for the user to use precise feedback to know when to stop clipping. This was done by adjusting the distance between the jaws so that the jaws are narrow enough to clip the pinch clamp, but not narrow enough to damage the clamp when when the jaws are in the fully closed position. This allows the user to know that the pinch clamp is clipped when the lever and handle no longer move. Also, there is essentially no risk of squeezing too hard and breaking the clamp.

Physical Impairment: A physical impairment (such as arthritis, muscle weakness, or limb immobilization) may influence the usability of the device as it does involve exerting a force of some kind on the device. Someone with a physical impairment, especially one where they lose strength or function in their hand would likely have trouble operating the device. The purpose of the device is to help prevent osteoarthritis, though nurses may have already contracted this impairment and may struggle with hand strength. This issue was lessened by ensuring that the maximum mechanical advantage occurs when the pinch clamp is almost clipped, which reduces the maximum force required from the user.

Control Impairment: A control impairment (such as those caused by distraction, excessive fatigue, intoxication, or medication side effects) may influence the usability of our device. Someone with a control impairment is more likely to misalign the device and pinch themselves. Again, this was mediated by removing sharp features and preventing the jaws from closing completely. Also, the geometry of the device was optimized to allow the pinch clamp to be clipped from a wide variety of angles and orientations, so precise alignment is not as necessary.

4.3 Manufacturability

This design currently consists of 9 parts: 1 Handle, 1 Lever, 1 Jaw, 1 Link, 4 Pins and 1 Elastic Band. The Theoretical Necessary Components (TNC) without considering fasteners or other joinery are:

1. Handle
2. Jaw
3. Lever
4. Link
5. Elastic Band

The Handle, Jaw, Lever, and Link must all be separate pieces since the base of this device is a 4-bar linkage that closes around the pinch clamp. The Elastic Band must be a separate piece from the handles so that it can be made out of a different material. The handles are 3D printed with PLA, which does not have the required material properties to withstand the repeated load of opening and closing the device. For this reason, an Elastic Band made of rubber must be used.

The design could be changed to get closer to the minimum number of components by integrating the pins directly into the Handle, Jaw, Lever, and Link. Fully 3D printed hinges are feasible, and integrating them into our design could result in a device that requires no assembly and is nearly ready to use right out of the 3D printer. However, the trade-off would be increased print complexity and it would most likely require the addition of support material. The increased printing time and additional time required to remove support material is probably not worth the benefit of reducing the number of components. Therefore, this device has seemingly reached the optimal number of parts.

4.4 Adaptability

In order to accommodate pinch clamps sizes other than those used for this specific project, the width of the jaws in the closed position can be adjusted. The distance between the center of the two holes in the Link can be decreased to accommodate larger clamps, and increased to accommodate smaller clamps. Figure 12 shows the relationship between the distance of the holes on the Link and the width of the jaws in the closed position. This plot was created by simulating different hole-to-hole distances and measuring the corresponding jaw width in Fusion 360. The files provided include links with hole distances of 1.75, 1.8, and 1.85 inches, which work on clamps with closed widths of approximately 0.5, 0.4, and 0.3 inches respectively. The default length is 1.8 inches, which is ideal for the specific pinch clamps used for this project.

Figure 12: Link Hole Distance vs. Closed Jaw Width.

In order to better accommodate a variety of grip sizes, a second version of the Lever was created with a 45-degree bend near the end, as seen in Fig. 13. The bend makes it easier to grip the handles when the device is in the open position by reducing the distance that the user must reach with their pinky and ring finger.

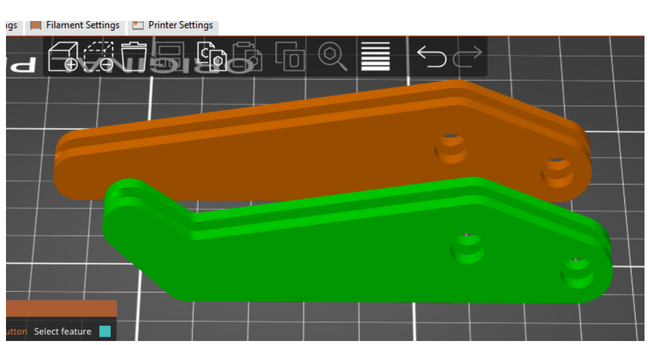


Figure 13: Straight and Bent Levers.

Bibliography

[1] *Bistability*. 2023. URL: https://en.wikipedia.org/wiki/Bistability.

[2] *Locking Pliers*. 2024. URL: https://en.wikipedia.org/wiki/Locking_pliers.

A Summary of Parts

The final device contains a total of 9 parts: 8 3D printed parts and 1 store-bought part, as summarized in Tab. 3. The total cost per device comes out to under $1.

Table 3: Parts List.

	Part	Source	Material	Part Specs	Unit Price	Quantity	Total Price
a	Handle	3D Printed	PLA	Weight: 10.49 g Time: 1 hr 38 min	$0.36	1	$0.36
b	Jaw	3D Printed	PLA	Weight: 2.36 g Time: 22 min	$0.08	1	$0.08
c	Lever	3D Printed	PLA	Weight: 8.73 g Time: 1 hr 17 min	$0.30	1	$0.30
d	Link	3D Printed	PLA	Weight: 1.90 g Time: 19 min	$0.07	1	$0.07
e	Pins	3D Printed	PLA	Weight: 0.60 g Time: 10 min	$0.02	4	$0.08
f	Elastic Band	Amazon	Rubber	Alliance Rubber 26314 Advantage Rubber Bands Size #31 (2 1/2" x 1/8")	$0.01	1	$0.01
Total							$0.91

Each 3D printed part is identified in Fig. 14.

Figure 14: 3D Printed Parts.

B Instructions for 3D Printing

The 3D printed parts for this project were printed in PLA on an Original Prusa i3 MK3(S/S+). The print settings used were: 0.15 mm layer height, 0.8 mm wall thickness, 15% infill density, and no rafts or supports. The recommended 3D printing orientation of all the parts is shown in Fig. 15. The total combined print time is 3 hours and 57 minutes. The total combined filament weight is 26.05 g and the cost is $0.90.

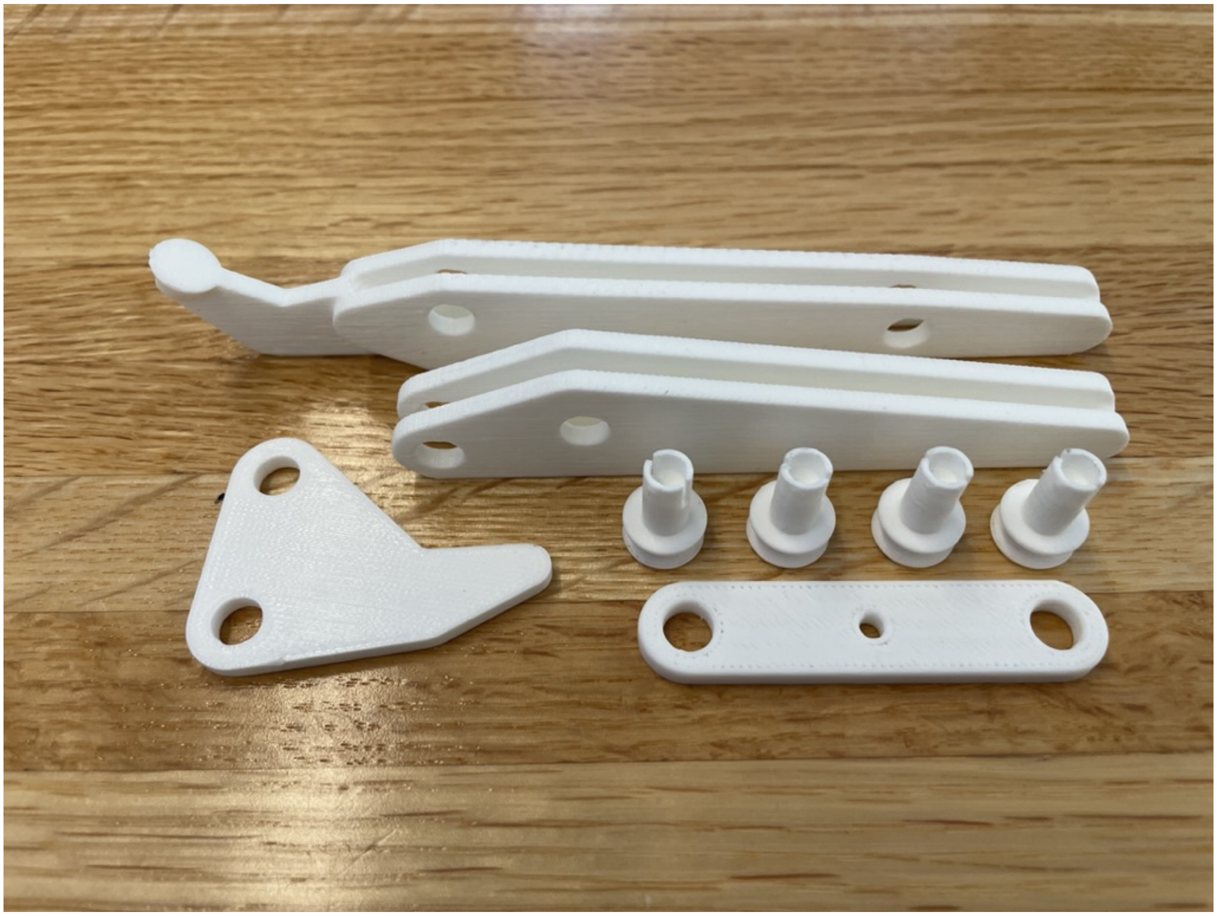


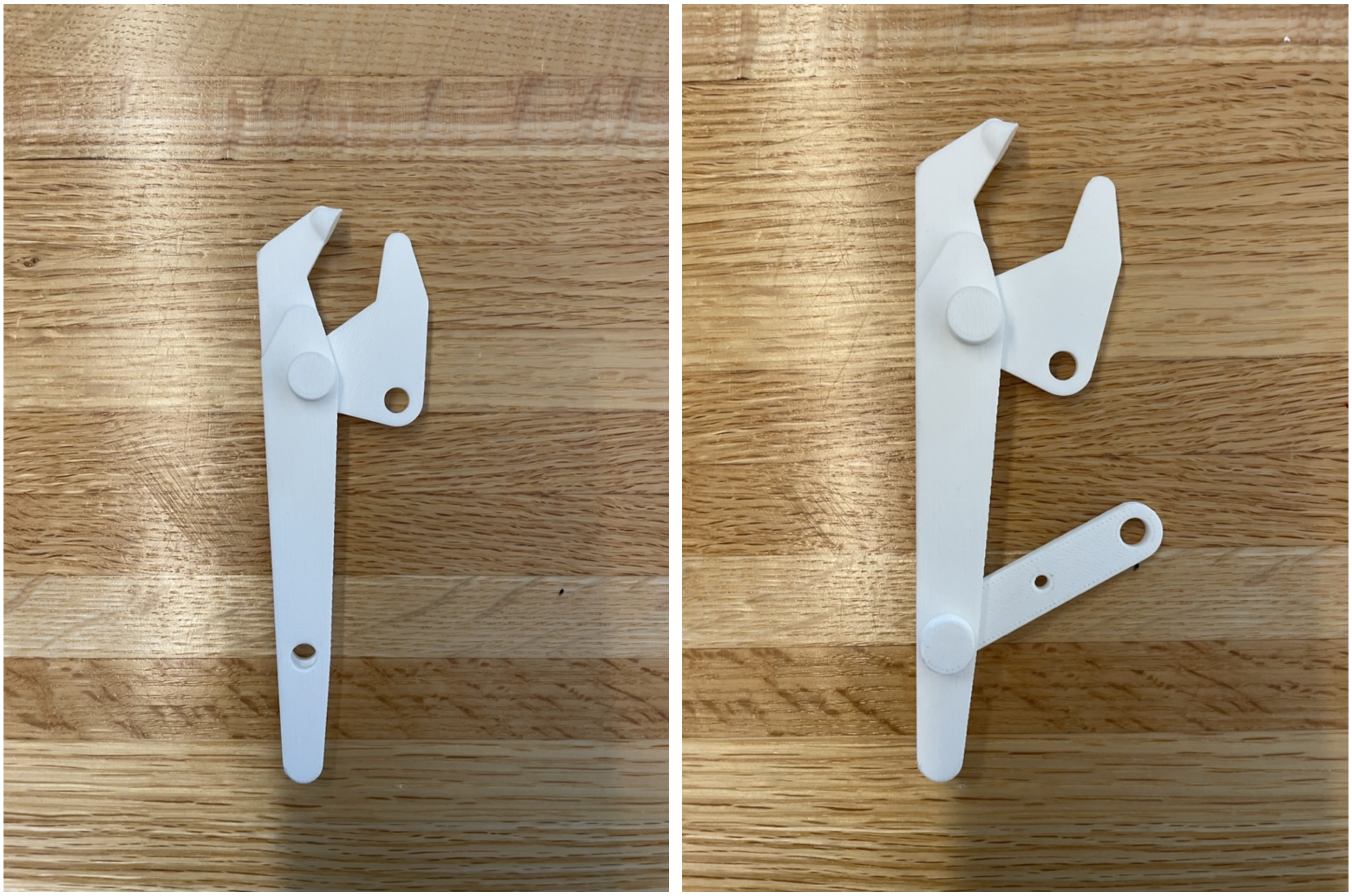
Figure 15: Recommended Print Orientation.

Note. Consider printing 5 or 6 pins instead of the required 4. They require very little material to print, and it's helpful to have a few extra in case they are misplaced or break during installation.

C Instructions for Assembly

Step 1. Insert the Jaw into the Handle and place a Pin through both parts.

Step 2. Insert the Link into the Handle and place a Pin through both parts.



(a) Assembly Step 1. (b) Assembly Step 2.

Figure 16: Assembly Steps 1 and 2.

Step 3. Insert the Jaw into the Lever and place a Pin through both parts.

Step 4. Insert the Link into the Lever and place a Pin through both parts.

(a) Assembly Step 3.

(b) Assembly Step 4.

Figure 17: Assembly Steps 3 and 4.

Step 5. Double over the Elastic Band and loop around the relevant spools.

Figure 18: Assembly Step 5.

Note. The order that the Pins are placed is trivial. The order presented in this guide is just an example of one way to assemble the device.