Fall 2023

MEMS 411: Medical Clamp

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Mechanical Engineering Design Project
MEMS 411, Fall 2023

Clamping Aid Group C

The goal of the team was to design a plier that would be able to clamp down a medical clamp used for a dialysis machine. Ideally the plier should be able to clamp down 3 medical clamps on three separate dialysis tubes in less than 5 seconds, reduce the force required to clamp those clamps by 4 times, and weigh less than 113 grams. The product design was broken down into 3 separate concepts, with four options for each component. The most preferable option of each component was chosen and several risk factors were taken in consideration so that the pliers can be as safe as possible. Rick factor includes the damaging of the dialysis tubes, contamination, inaccurate pressure control, user fatigue, and last but not least mechanical failure of pliers. Once all those risks were taken into consideration and all the necessary dimensions were recorded, mock ups and prototypes were made and they can be seen in section 3 of the report. After some trial and error, our final design was made with taking all the best aspects of the mock ups and initial prototypes in addition to adding another placeholder for one of you fingers to allow a more comfortable feel while operating the device.
Specifically, the designed clamp-aid pliers was able achieve a 4.6 times force reduction, while allowing for a one-handed clamping time of less than 5 seconds 17% of the time with either hand, at a mass of 23 grams.

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1 Introduction

Medical clamps are indispensable tools in healthcare, commonly employed for tasks ranging from wound closure to tissue manipulation during surgeries and medical procedures. To enhance their usability and efficiency, a complementary accessory can be developed. This accessory, which could fall under the category of "Medical Clamp Assistive Devices" (code: 71), has the potential to simplify clamp handling and reduce the risk of fatigue or errors among healthcare professionals. Insights from customer interviews, particularly with nurses who regularly use medical clamps in their roles, have highlighted the need for ergonomic and user-friendly accessories that can streamline their workflow and enhance patient care. While existing instruments like forceps and hemostats share some functions with medical clamps, a dedicated clamp accessory could offer distinct advantages, making it an innovative and valuable addition to the medical toolkit. In this context, the development of such an accessory presents an opportunity to improve the efficiency and effectiveness of medical clamp usage across various healthcare settings. +

2 Problem Understanding

2.1 Existing Devices

Sed ut perspiciatis unde omnis iste natus error sit voluptatem accusantium doloremque laudantium, totam rem aperiam, eaque ipsa quae ab illo inventore veritatis et quasi architecto beatae vitae dicta sunt explicabo.

2.1.1 Existing Device #1: Surgical Forceps

Figure 1: Set of Surgical Forceps (Source: GerMedUSA Inc.)

Link: https://www.germedusa.com/p-12930-mouth-and-throat-forceps.aspx
Description: Surgical forceps are precision instruments commonly used in the medical field for various tasks during surgical procedures. They are a type of handheld, hinged tool with two opposing blades and a mechanism that allows them to be locked in a closed position, similar in concept to a pair of tweezers or pliers. These forceps come in a wide range of shapes, sizes, and designs, each

tailored for specific purposes within the surgical environment. Surgical forceps are typically made of high-quality stainless steel to ensure durability, corrosion resistance, and ease of sterilization. They feature a slender, elongated body with two blades at one end and handles at the other end. The blades come in various shapes, including straight, curved, serrated, or toothed, depending on the intended use. There are numerous types of surgical forceps, each designed for a particular task. Some common types include hemostatic forceps (used to clamp blood vessels or tissues to control bleeding), tissue grasping forceps (designed to hold and manipulate delicate tissues), and adson forceps (fine, toothed forceps often used in plastic surgery and delicate procedures). Before each use, surgical forceps must undergo rigorous sterilization procedures to prevent the transmission of infections. This is typically achieved through autoclaving, a process that uses steam and high pressure to kill any microorganisms.

2.1.2 Existing Device #2: Multi Purpose Clamp

Figure 2: Armor-Tool Auto Adjust Multi Purpose Clamp (Source: Armor Store)

Link: https://www.amazon.com/Armor-Tool-6MP-70-Adjust-Multi-Purpose/dp/B074WF5FKD
The Armor-Tool multi-purpose clamp allows for quick, one-handed clamping action, and has a soft, grip-aid covering on the handle to make using the device more comfortable. The clamp works in a similar ways to pliers or scissors, with the difference being, the force is concentrated at its tips and functions more as extra strong fingers for holding onto things. The clamp applies a force of 25 to 250 lbf, with consistent pressure at the clamping tips. The clamp automatically adjusts itself to clamp objects of different thicknesses. The clamps also allows user to adjust the amount of pressure it applies via a pressure screw.

2.1.3 Existing Device #3: Precision Trigger Clamp

Figure 3: Precision Bar Clamps (Source: GreatNeck Store)

Link: https://www.amazon.com/Great-Neck-GreatNeck-Precision-Clamps/dp/B0B7SHDG1V?th=1 This trigger clamp provides a 300-pound clamping force. The clamps comes equipped with comfort grip handles that reduces strain on hand. The trigger clamp is oriented vertically, with two thin plates acting as the "clampers." The top plate (where the handle is not) would press onto the object to be clamped, while the bottom plate would then be moved to secure the object in place.

2.2 Patents

2.2.1 Electrical Wire Stripper Pliers (US4244067A)

This patent talks about the use and features of this specific electrical stripper pliers. The tool is a all for one for all basic needs when working with electrical wiring. Such as cutting, stripping, removing dielectric, pushing on fittings, crimping, decrimping, removing connectors, and tightening and loosening connectors. The tool has two jaws, both of which have elements for removing dielectrics and for stripping cable. Also it has two handles, both of which have elements for crimping and for decrimping. One handle has a wrench like open end for removing fittings while the other has a threaded element with a center hole for connecting and for removing cable.

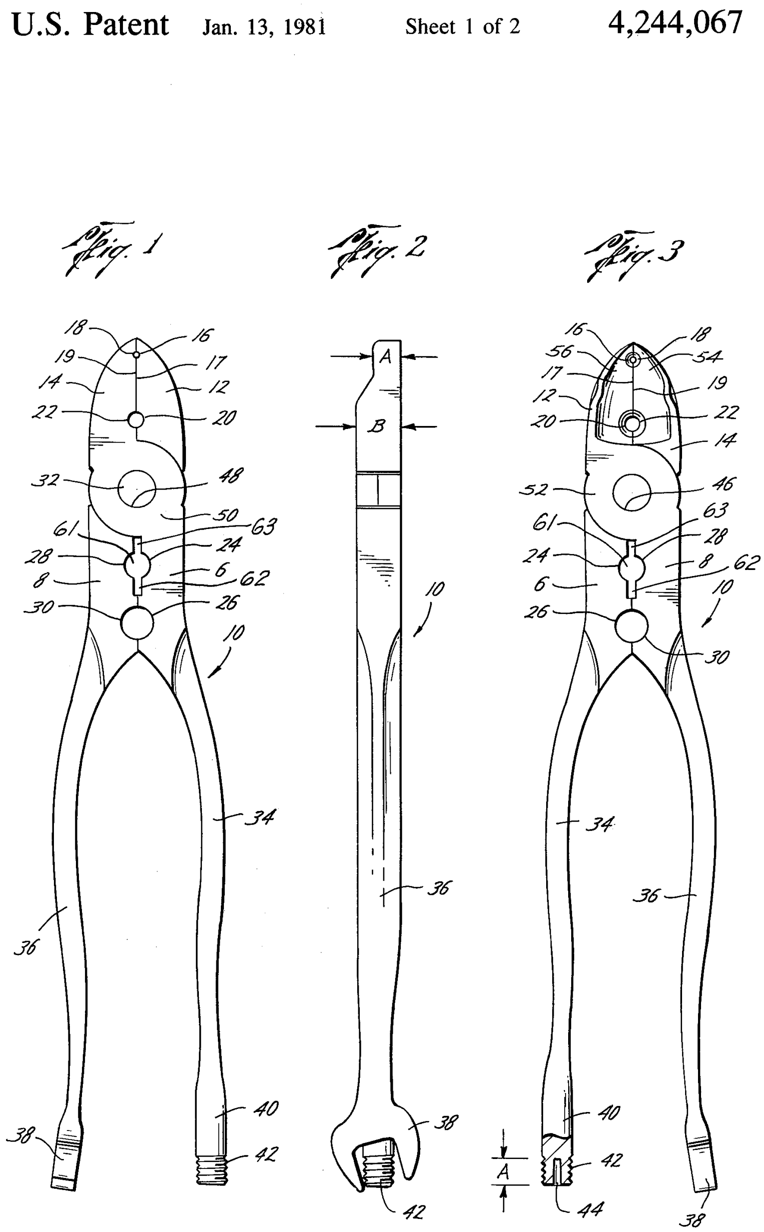

Figure 4: Patent Images for electrical wire strippers

2.2.2 Electrical Terminal Assembly Spring Clamp (US9142902B2)

The "Electrical Terminal Assembly Spring Clamp" patent represents a significant advancement in electrical engineering, offering an innovative solution to the challenges posed by traditional terminal connectors. This patent introduces a novel spring clamp mechanism designed to securely and reliably hold electrical conductors in place without the need for external fasteners. This device is designed to simplify and enhance the process of connecting electrical conductors securely. It consists of a specially designed clamp mechanism made from durable materials, typically stainless steel or copper. The key innovation lies in the spring mechanism within the clamp, where when a conductor, such as a wire or cable, is inserted into the clamp, the spring exerts controlled pressure, securely gripping the conductor without causing damage or deformation. This spring-based clamping action ensures a reliable and low-resistance electrical connection. Unlike traditional connectors that rely on screws or other external fasteners, the Electrical Terminal Assembly Spring Clamp eliminates the need for such components, simplifying installation and reducing the risk of loosening over time.

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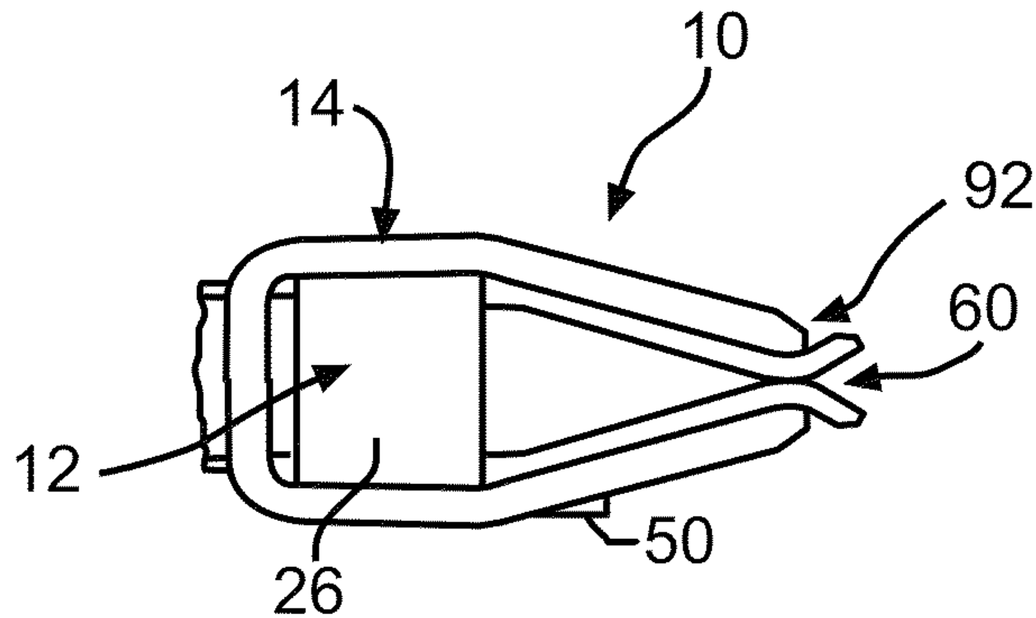

Figure 5: Mini Spring Clamp Patent Image

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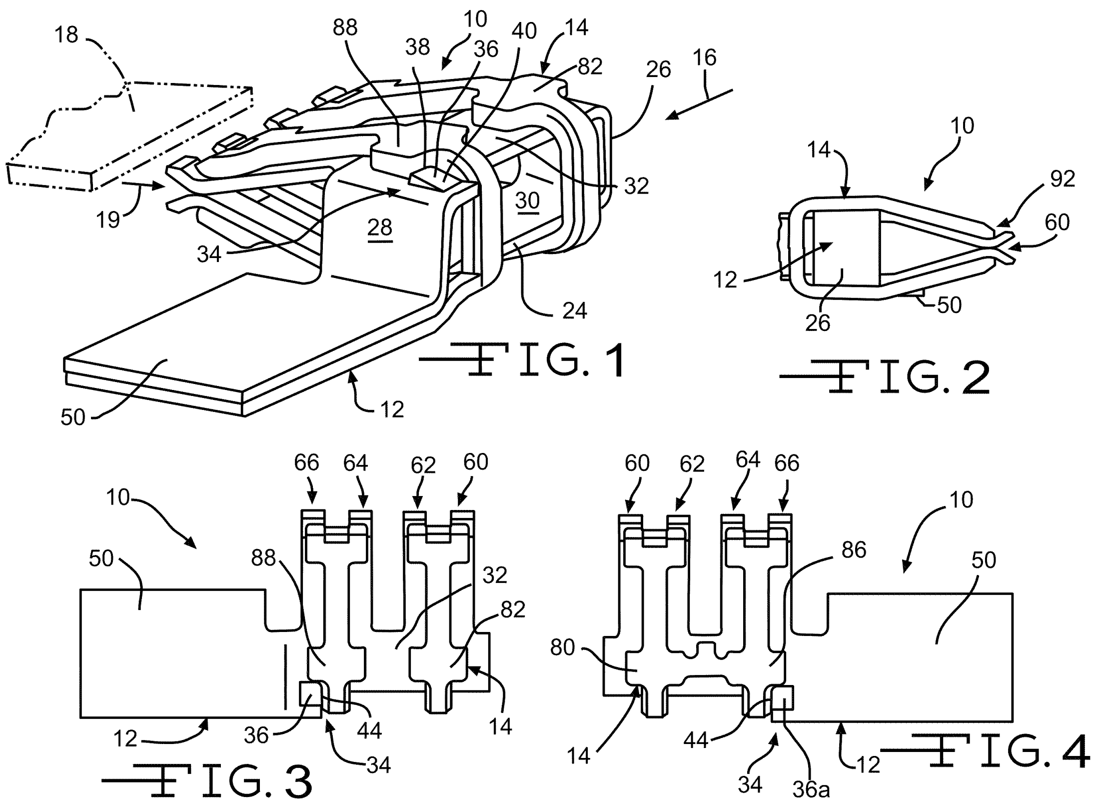

Figure 6: Mini Spring Clamp Patent Detailed Image

2.3 Codes & Standards

2.3.1 Sterilization (ISO 17664)

ISO 17664 standard requires that testing be conduction and information provided to users on the suitable sterilization methods, maximum number of sterilization cycle, and the level of sterility of the material for each method to ensure the device is suitable for its intended use. We need to ensure the material used in device will be resistant to the type of disinfection or sterilization process the device will be expected to undergo. We need to pay particular attention to the adhesive we will use in the device (if any) that it will still work after the chemical disinfecting/sterilizing.

2.3.2 Biocompatability Testing (ISO 10993)

ISO 10993 series of standards sets the guidelines for the biological safety testing of medical devices. The recommended tests are dependent on the nature of body contact and contact duration. ISO 10993-5, 10993-10 and ISO 10993-23 in particular cover tests for the testing for cellular damage, skin sensitization and skin irritation respectively. The device we are designing will be used by nurses with bare hands, so falls under the surface-contact with intact skin category and are covered by these three parts of the ISO 10993 standards.

2.4 User Needs

Medical clips play a vital role in the efficient and safe operation of dialysis machines by securing tubing, preventing leaks, maintaining sterile connections, and ensuring proper blood access management. These clips help healthcare professionals provide effective dialysis treatment while minimizing the risk of complications. Unfortunately, nurses and healthcare professionals, including those who frequently use medical clips in their work, may sometimes experience thumb joint problems or discomfort due to repetitive motions, such as clipping or unclipping various medical devices or tubing. This condition is often referred to as "nurse's thumb" or "nurse's thumb arthritis." It can be related to the repetitive stress placed on the thumb joints during their daily tasks.

2.4.1 Customer Interview

Interviewee: Dr. James Jackson Potter and Canadian Nurses
Location: Urbauer 310, Washington University in St. Louis, Danforth Campus
Date: September 8^{th}, 2023
Setting: We held a virtual meeting via Zoom, where the Interviwee brought a prototype and illustrated how to use the device. The whole interview was conducted in his office, and took about∼50 min.

Interview Notes:
What is the intended use for the device?

- The device should help nurses press down on the clamps by taking away the amount of load applied by the CMC thumb joint.

Are there precision ridges on the clamps?

- No, it's one clamp on the way down.

Does the device need to be able to declamp?

- No, nurses are able to do this with minimal difficulty and is not a priority

What are the current likes and dislikes of the current product solution?

- The prototype (from the UK) has a rubber band that allows the device to revert back to its original position, which is good. However, the device is too big and requires both hands to use (one hand to support the tube and clamp/hold it in place, and the other hand to apply force to the device). The prototype have edges that could be dangerous. The prototype also too widely distributed the force instead of only applying it at the tip as necessary to close the clamps. It is also not portable.

  Using pliers a makeshift solution was breaking the clamps.

What are the requirements on the device's portability?

- The device needs to be small, able to fit into small spaces, on desks or work stations that the nurses can easily reached. Pocket sized meant to be carried around is also OK. It needs to be lightweight.

How easy to use should the device be?

– An orientation is planned for the device, so it doesn't have to be something that makes sense how to use immediately, but it shouldn't be something that takes a long time to fully adapt to.

What is the speed the device needs to work at?

– There will be push-back from the nurses if the device takes too long as compared to just using their thumbs regularly without the device. It is preferable to be at the same speed or as close to the same speed as just using thumbs.

What is the price range of the device?

– Something somewhat cheap that can be supplied to all nurses, but it can be slightly expensive and shared use.

2.4.2 Interpreted User Needs

A Handheld tool that would be able to clip medical clips that are attached on blood tubing while alleviating stress off the thumb joint allowing nurses to help individuals in need while not putting their own health at risk.

Table 1: Interpreted Customer Needs

Need Number	Need	Importance
1	The device reduces stress on thumb and other finger joints	5
2	The device is user friendly, requiring only a simple introduction to learn how to use	4
3	The device is durable	2
4	The device works speedily	4
5	The device is ergonomic	3
6	The device requires only one hand to operate	4
7	The device focuses the force only at the tip	3
8	The device is rounded with no sharp edges	3
9	The device is easy to transport	3
10	The device is portable and takes up minimal space	4
11	The device works on different sizes of clamps	2
12	The device is cheap to produce	1
13	The device functions properly after disinfection and be sterile enough for intended use	5

To reduce the risk of "nurse's thumb" or thumb joint problems in healthcare professionals, especially those who frequently use medical clips or engage in repetitive thumb movements, various ergonomic strategies can be employed. It would be much better for there to be a specific device designed solely to prevent nurse's thumb.

2.5 Design Metrics

Table 2: Target Specifications

Metric Number	Associated Needs	Metric	Units	Acceptable	Ideal
1	9,10,12	Total weight	kg	0.5	0.2
2	9,10,12	Total volume	in^3	< 40	< 20
3	2	Average time of learning how to use the device	minutes	< 10	< 5
4	3	Maximum amount of use before breaking	integer	> 20	> 100
5	12	Total Cost	Dollars	< 30	< 10
6	11	Compatibility with different size clamps	integer	> 1	1
7	4	Clamping time per clamp	sec	< 5	< 2
8	1,5	Number of nurses complaint about nurses thumb	percentage	< 50	< 20
9	7	Area of tip where the force will press down on the clamps	cm^2	< 1	< 0.5
10	13	Level of sterility of the device after disinfection	SAL	$10 - 3$	$< 10 - 3$

2.6 Project Management

The Gantt chart in Figure 7 gives an overview of the project schedule.

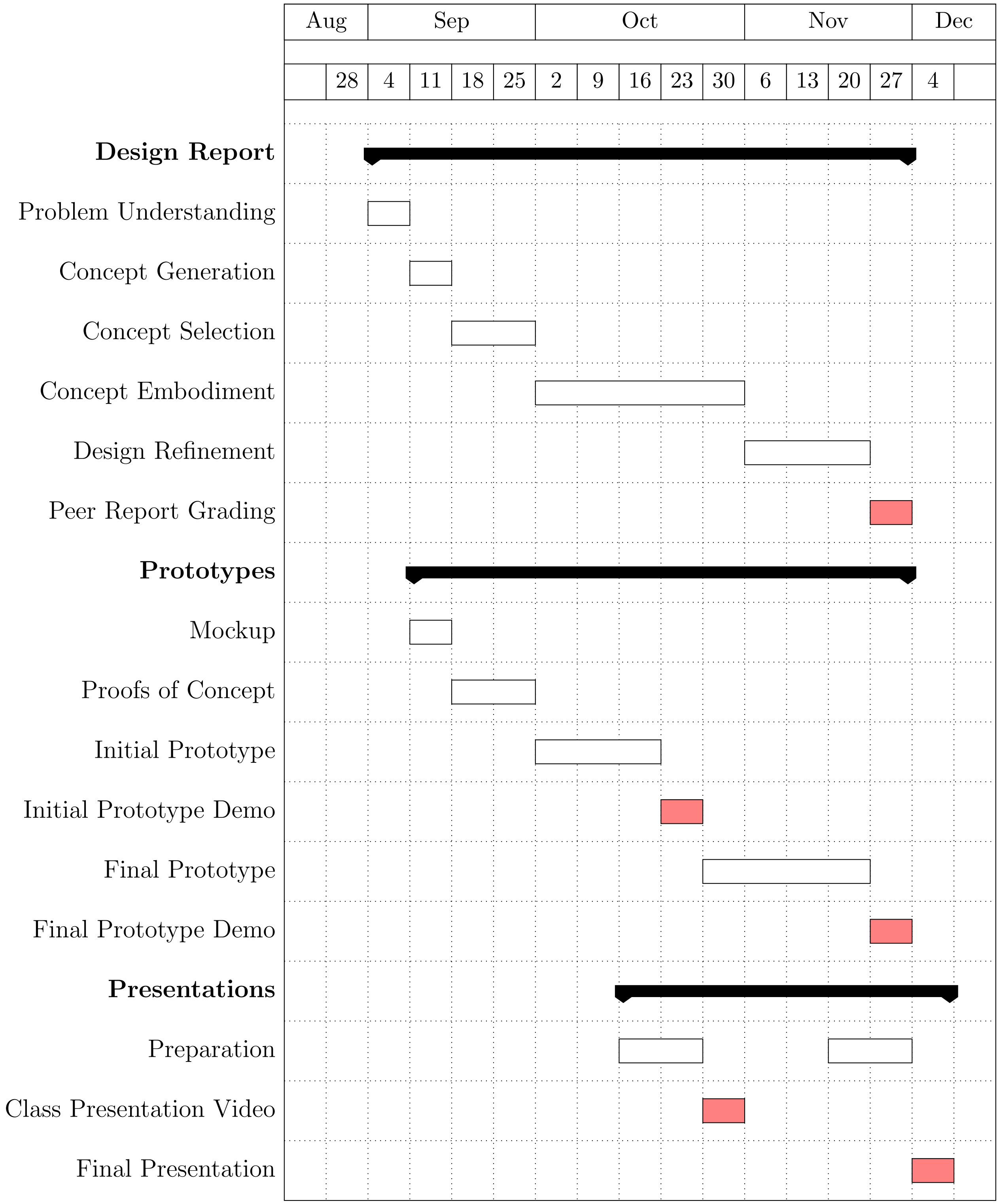

Figure 7: Gantt chart for design project

3 Concept Generation

3.1 Mockup Prototype

The mockups below influenced our thoughts on how our device should look like. Our device will have a flat end nose that will prevent people from accidentally hurting themselves or others. The end part of the tip will touch when the pliers are in the close position allowing for the user to close as hard as they can while not breaking the medical clamp in the process. There will be a hole in the middle of the pliers allowing for the medical clamps to be held and clamped with minimum force on thumb joint. The handle will have an ergonomically shape allowing for them to be used over and over again with minimum fatigue.

Figure 8: Picture of The Different Pliers Attempted

Figure 9: Picture of The Choice Pliers-Mockup In Open Position

Figure 10: Picture of The Choice Pliers-Mockup In Closed Position

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3.2 Functional Decomposition

The function tree outlines the primary, secondary, and tertiary functions involved in designing bio pliers intended to alleviate thumb strain experienced by nurses when using clips on dialysis machines. At its core, the primary function is to reduce thumb strain through ergonomic handle design, adjustable jaw mechanisms, durability, safety features, ease of use, compatibility, and portability. Secondary functions encompass hygiene, maintenance, clip storage, user instructions, and packaging. Tertiary functions address branding and marketing aspects, including logos, product names, marketing materials, user feedback, and warranty support. This function tree serves as a structured guide for product development, ensuring that all essential aspects are considered to create an effective and user-friendly solution for nurses.

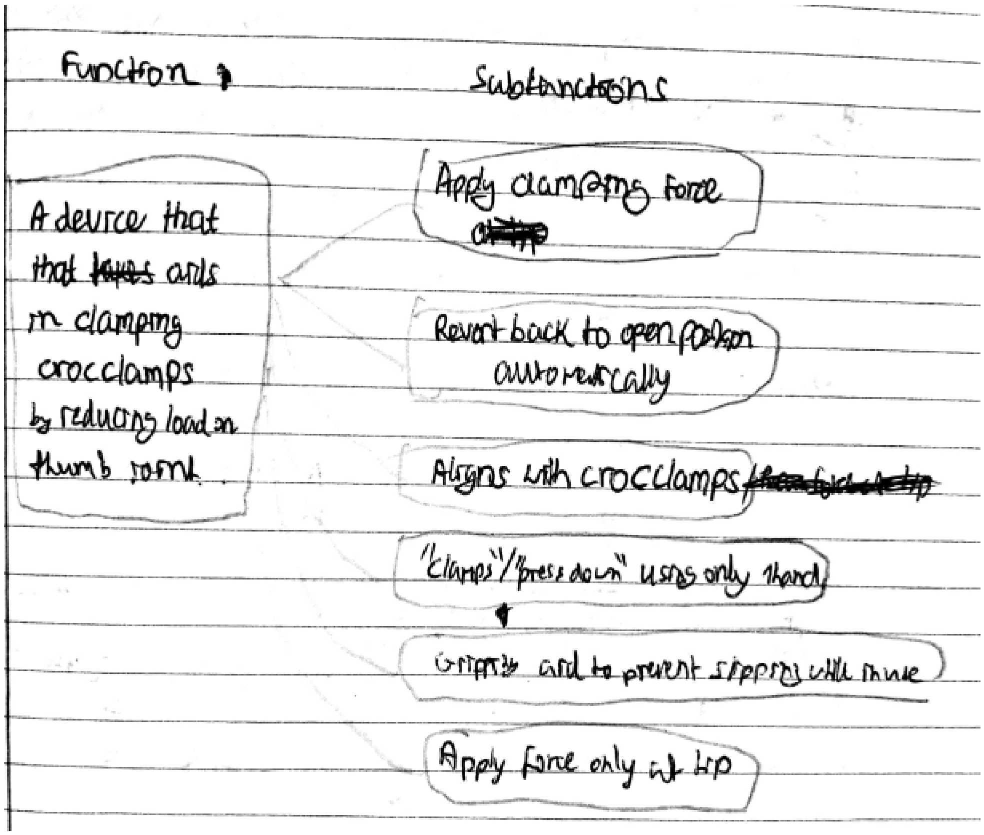


Figure 11: Function tree for Clamping Aid

3.3 Morphological Chart

The figure below provides the morphological chart detailing possible solutions for each subfunctions listed previously.

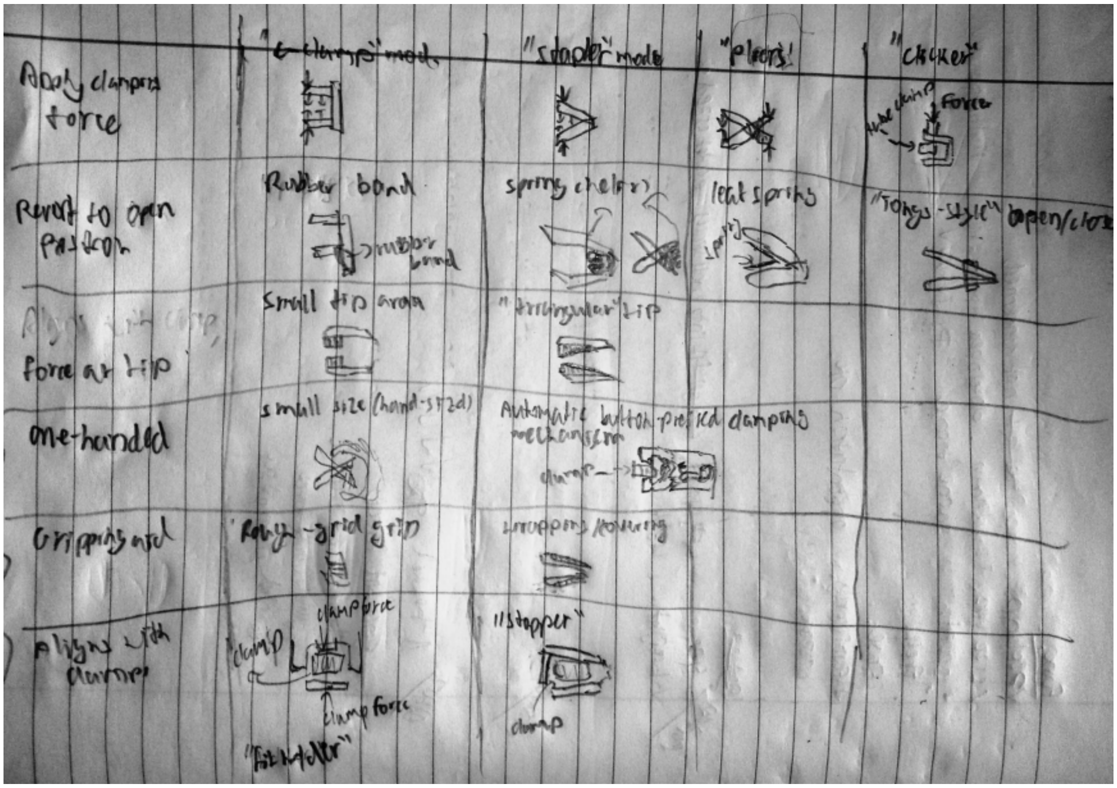


Figure 12: Morphological Chart for Clamping Aid

3.4 Alternative Design Concepts

3.4.1 Concept #1: Modified Pliers

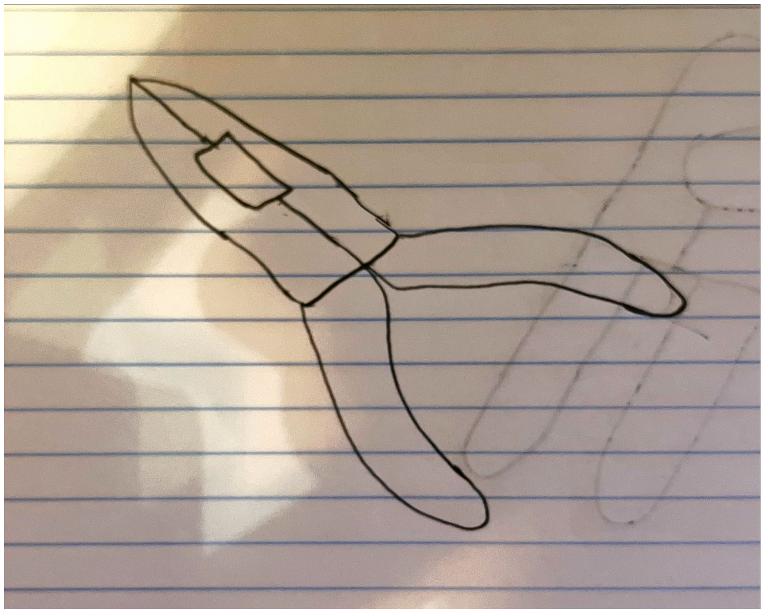


Figure 13: Modified Pliers

Description: Its standard tip design, along with precision, double-action mechanisms, and ergonomic handles These pliers typically feature a slender and elongated design with two arms that come together at the tips.

3.4.2 Concept #2: Automatic Clamping Pliers

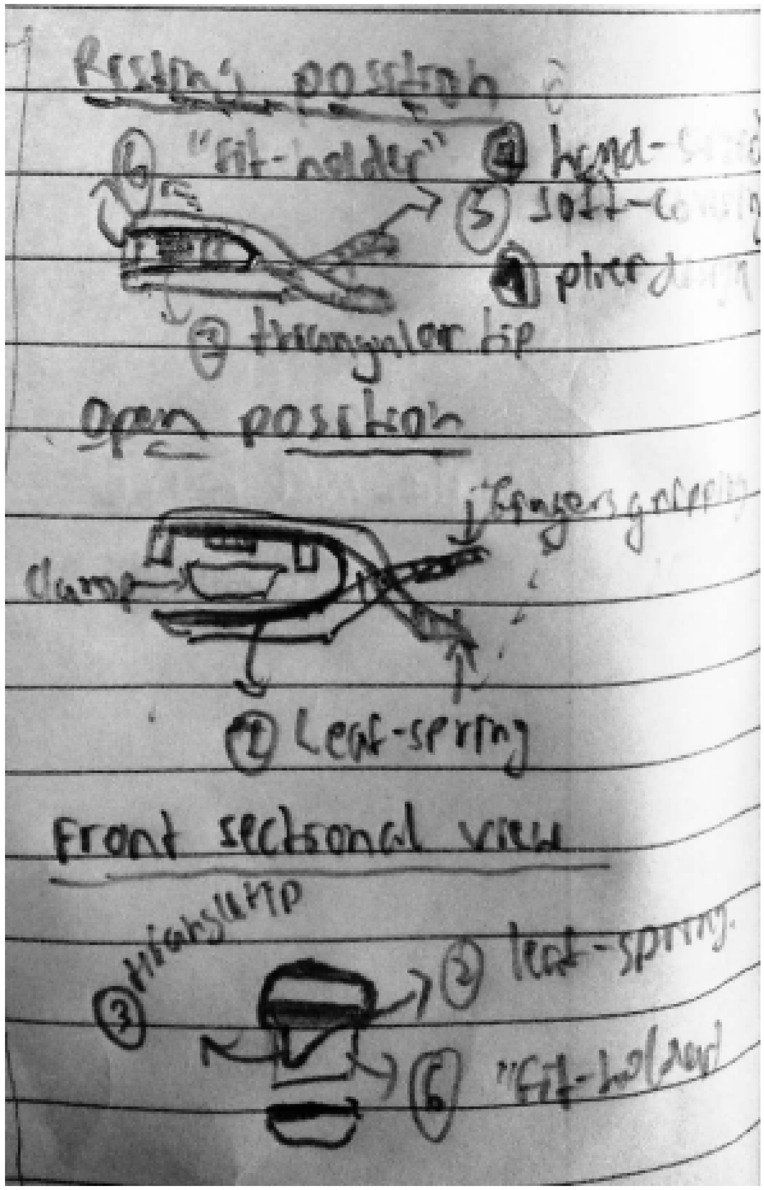


Figure 14: Automatic Clamping Pliers

Description: The automatic clamping pliers is a modified form of pliers where the jaws are spring-loaded and adjustable, accommodating various clip types and sizes. Safety features include a locking mechanism, blunt-edged jaws, and a non-slip grip for secure handling. The pliers also prioritize user comfort by employing a contoured handle with a rubber grip that minimizes thumb strain during prolonged use. The pliers are designed for one-handed operation, with a quick-release feature for efficient clip placement. Additionally, the pliers are compatible with a wide range of dialysis machines and incorporate a compact, portable design. Hygiene and maintenance aspects are addressed with easy-to-clean materials and replaceable parts. Usage of the device is easy and quick, requiring little to no familiarization time.

3.4.3 Concept #3: VersaClip

Description: The VersaClip Assist design concept offers versatility and adaptability. These pliers feature a modular handle system that allows nurses to customize the handle shape and size for a perfect fit. The jaw mechanism is designed to be easily interchangeable, accommodating various clip types and clinical needs. Users can select from different tension settings to suit their preferences. Safety is paramount, with an intuitive locking mechanism and a choice between blunt-edged or fine-tipped jaws. The VersaClip Assist includes a comprehensive maintenance kit for replacing parts, and user instructions are provided in a variety of languages. The packaging is minimalistic and recyclable, contributing to environmental sustainability.

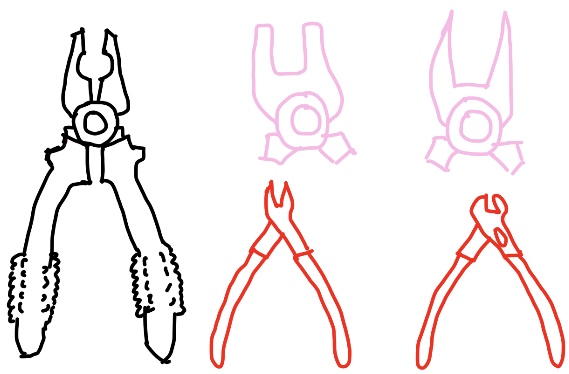


Figure 15: VersaClip drawing with different plier heads

3.4.4 Concept #4: IntelliGrip

Description: The IntelliGrip Smart Pliers take a technology-oriented approach to thumb strain reduction. These pliers feature a handle equipped with sensors and a small display screen. Nurses can personalize the grip settings by adjusting the handle's shape and size using the integrated controls. The jaws are designed for quick, automated clip placement with adjustable tension. Safety is enhanced with an intelligent locking system that can detect anomalies in clip placement and prevent errors. The pliers connect wirelessly to a smartphone app that provides usage instructions, maintenance alerts, and safety reminders. The packaging includes a QR code for easy app download, and user feedback is actively collected to improve product performance.

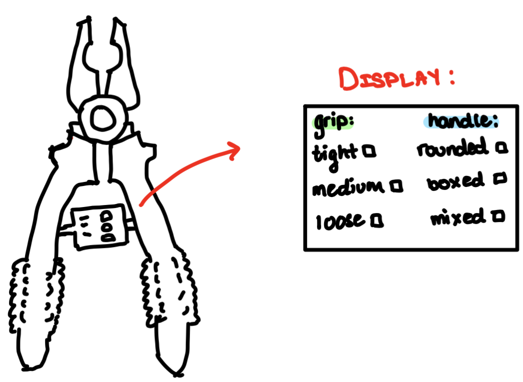


Figure 16: IntelliGrip with display screen settings

4 Concept Selection

4.1 Selection Criteria

Figure 28 below shows the hierarchy of importance of five criteria, which will be used to score each concept. Criterion explanation:

- Minimize Force - Refers to the reduction of force on the thumb joint as as well as the overall force required to use to operate the device.
- Minimize Size - Refers to the portability of the device, the device's ability to fit onto small sections of nurse work station/desks, and the device's size allowing it to be used with only one-hand.
- Minimize Usage Time - Refers to the ability to operate the device quickly and speedily.
- Minimize Cost - Refers to the cost of production for each device.
- Maximize Durability - Refers to the device's ability to endure constant usage as well as sterilization process while still functioning properly.

	Minimize Force	Minimize Size	Minimize Usage Time	Minimize Cost	Maximize Durability		Row Total	Weight Value	Weight (%)
Minimize Force	1.00	1.00	3.00	5.00	0.33		10.33	0.28	**27.67**
Minimize Size	1.00	1.00	1.00	1.00	1.00		5.00	0.13	**13.39**
Minimize Usage Time	0.33	1.00	1.00	7.00	1.00		10.33	0.28	**27.67**
Minimize Cost	0.20	1.00	0.14	1.00	0.33		2.68	0.07	**7.17**
Maximize Durability	3.00	1.00	1.00	3.00	**1.00**		9.00	0.24	**24.10**
					Column Total:		**37.34**	**1.00**	**100.00**

Figure 17: Analytic Hierarchy Process (AHP) to determine scoring matrix weights

Numerical rating explanation:

- 9.00 - Extremely more important
- 7.00 - Very strongly more important
- 5.00 - Strongly more important
- 3.00 - Moderately more important

- 1.00 - Equally important
- 0.33 - Moderately less important
- 0.20 - Strongly less important
- 0.14 - Very strongly less important
- 0.11 - Extremely less important

4.2 Concept Evaluation

Figure 18 below shows the weighted scoring matrix for choosing between alternative concepts for pliers that will be used to clamp medical clamps. The selection criteria are minimizing force, minimize the size, minimize usage time, minimize the cost, and maximize the durability of the pliers. Concept 1 has the highest score of 4.072 meaning this concept fits the best with our criteria.

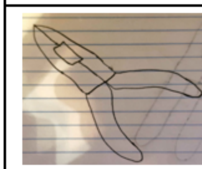
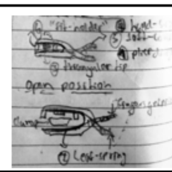
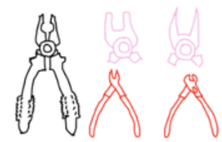
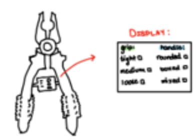
Alternative Design Concepts		#1 - Modified Pliers		#2 - Automatic Pliers		#3 - VersaClip		#4 - IntelliGrip	
									
Selection Criterion	**Weight (%)**	**Rating**	**Weighted**	**Rating**	**Weighted**	**Rating**	**Weighted**	**Rating**	**Weighted**
Minimize Force	27.67	4	1.11	4	1.11	3	0.83	4	1.11
Minimize Size	13.39	4	0.54	4	0.54	4	0.54	3	0.40
Minimize Usage Time	27.67	4	1.11	4	1.11	3	0.83	3	0.83
Minimize Cost	7.17	5	0.36	4	0.29	3	0.22	1	0.07
Maximize Durability	24.10	4	0.96	4	0.96	3	0.72	2	0.48
	Total score	**4.072**		**4.000**		**3.134**		**2.892**	
	Rank	**1**		**2**		**3**		**4**	

Figure 18: Weighted Scoring Matrix (WSM) for choosing between alternative concepts

4.3 Evaluation Results

According to the evaluation, Concept #1 (Modified Pliers) received the highest total score and is ranked 1st, making it the preferred design concept. Concept #2 (Automatic Pliers) is ranked 2nd, Concept #3 (VersaClip) is ranked 3rd, and Concept #4 (IntelliGrip) is ranked 4th. With The criteria used we determined that minimizing force, minimizing usage time, and maximizing durability are considered crucial factors, as they carry higher weights. These factors contributed significantly to the top-ranking of Concept #1.

Concept #1 received the highest ranking for force minimization because it demonstrated the most effective reduction in the force required to operate the pliers, making it easier on nurses' thumbs. It also was efficient in minimizing the time needed for its usage, which is essential for nurses working in a fast-paced environment For minimizing cost, the modified pliers receives the highest rating of 5, because the other concepts are basically the modified pliers with more components, thereby more cost for production. The modified pliers having the least components also gives it a better rating of 4 in the durability and size criteria.

As with any WSM evaluation, the choice of criteria and their weights align with the project's objectives and priorities. This process helps us in selecting the most suitable design concept for further development.the WSM analysis provides a structured approach to compare and rank alternative design concepts based on predefined criteria. Concept 1's top ranking suggests its potential as a promising solution to address the issue of nurse's thumb strain, but practical implementation and user feedback will be critical in confirming its efficacy.

4.4 Engineering Models/Relationships

4.4.1 Model #1 - Force-Lever Balance

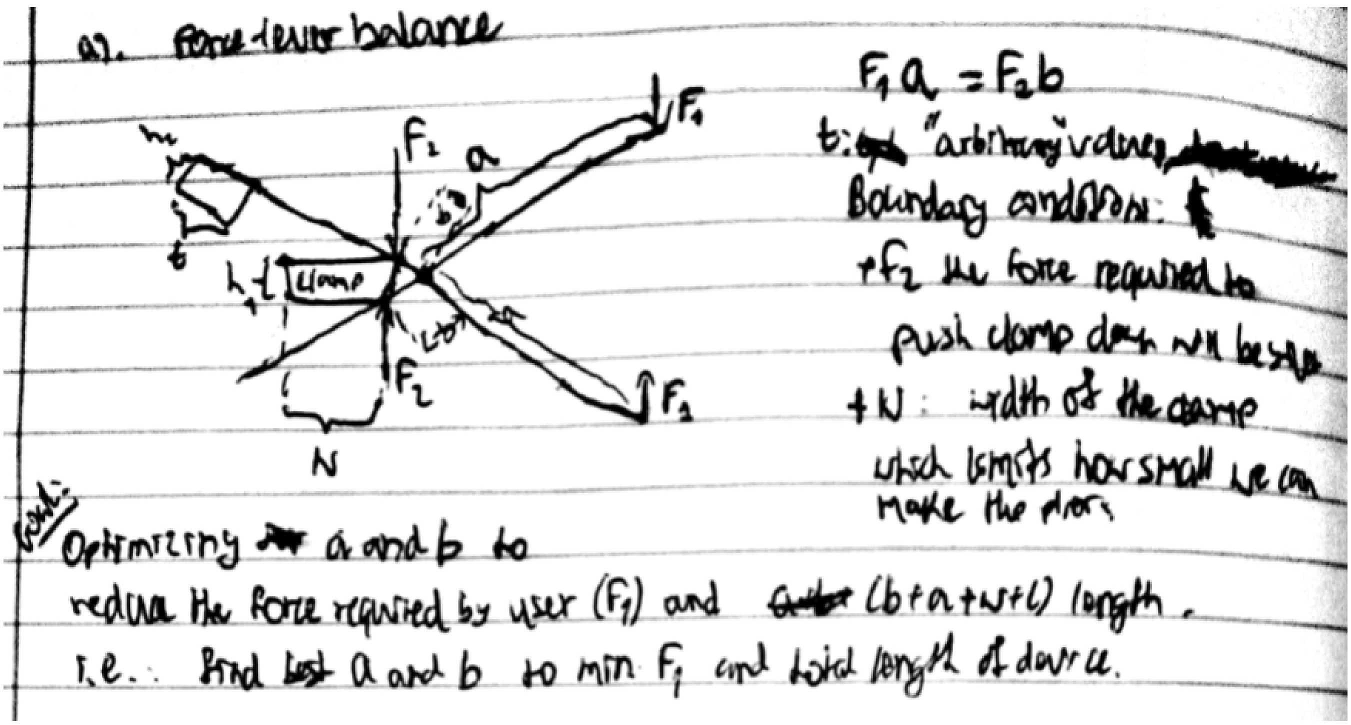


Figure 19: Force-Lever Balance

4.4.2 Model #2

Biomechanical Model for Thumb Stress Analysis:

This model pertains to the mechanical stress and strain experienced by the nurse's thumb while using the bio pliers. It helps in understanding the ergonomic design of the pliers to minimize thumb stress.

Parameters:

Force applied by the nurse's thumb (F) Length of the bio pliers handle (L) Thumb contact area on the pliers (A) Material properties of the pliers (e.g., Young's modulus, E) Unknown Values:

Stress on the nurse's thumb (σ) Strain experienced by the thumb (ϵ) Optimal handle length (Loptimal) to minimize stress Mathematical Representation: Using Hooke's Law for stress (σ = F / A) and strain ($\epsilon = \sigma$ / E), this model can help calculate the stress and strain on the thumb for different handle lengths (L). The goal is to find the optimal handle length (Loptimal) that minimizes the stress experienced by the nurse's thumb.

Figure 20: bio model

4.4.3 Model #3

Torque:

The perpendicular length of the plier to the pin (r) times the perpendicular force applied by the user (F) will give us the torque applied by the pliers (T). We would be given the medical clamps while we would have to build the pliers and find the length of the pliers and the force needed to close the medical clamps down.

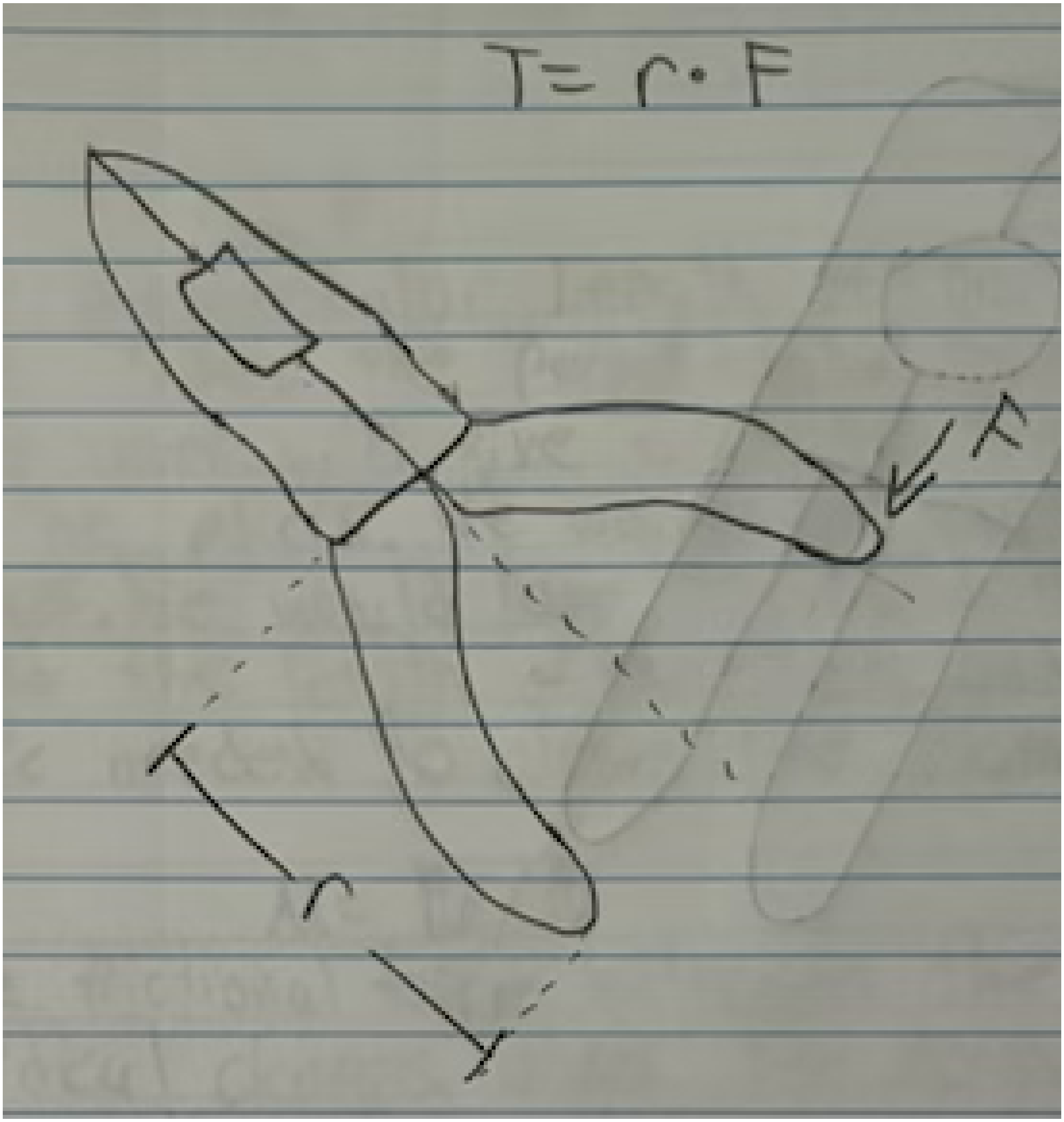


Figure 21: Torque

5 Concept Embodiment

5.1 Initial Embodiment

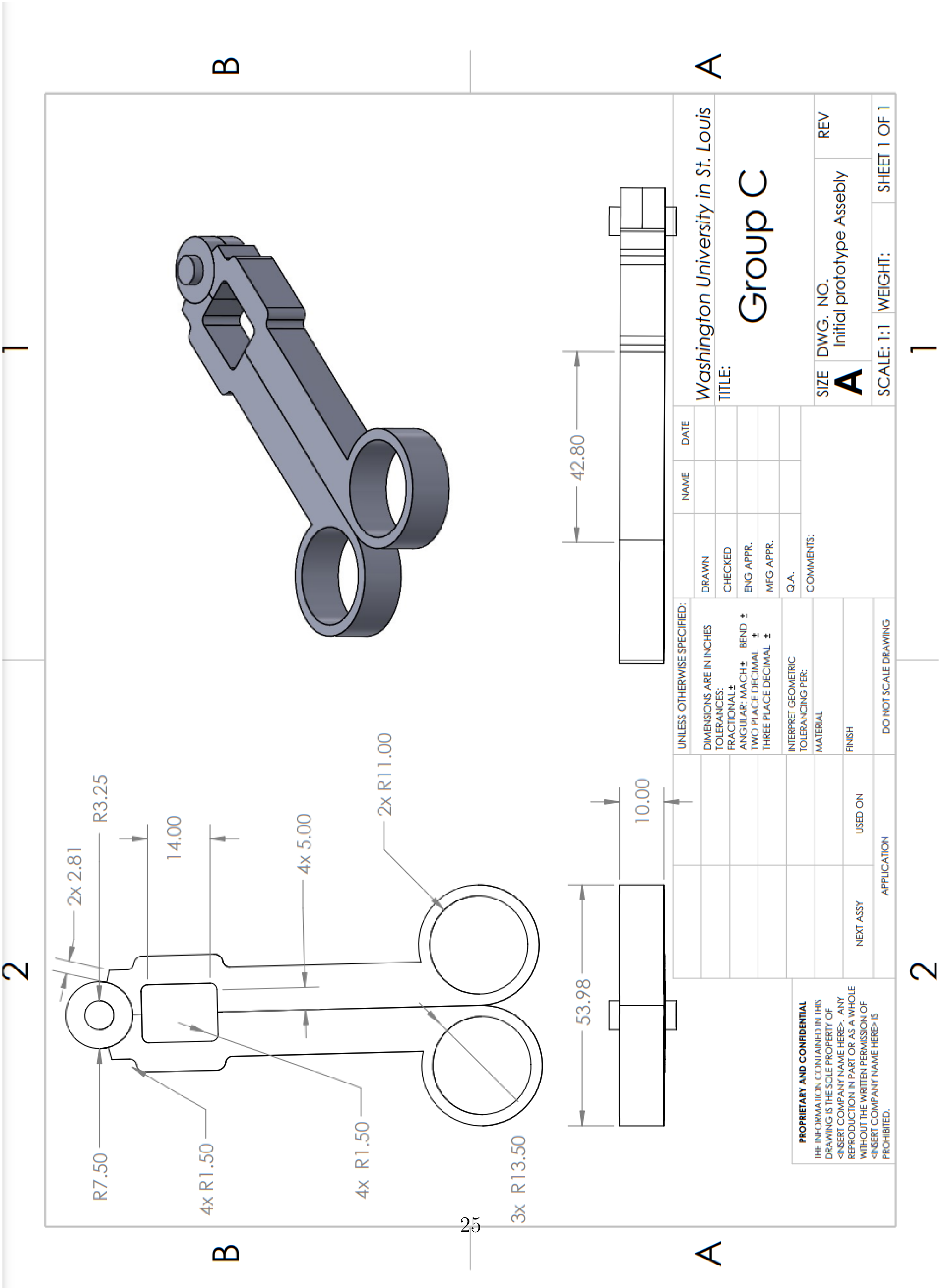


Figure 23: Assembled isometric view with bill of materials (BOM)

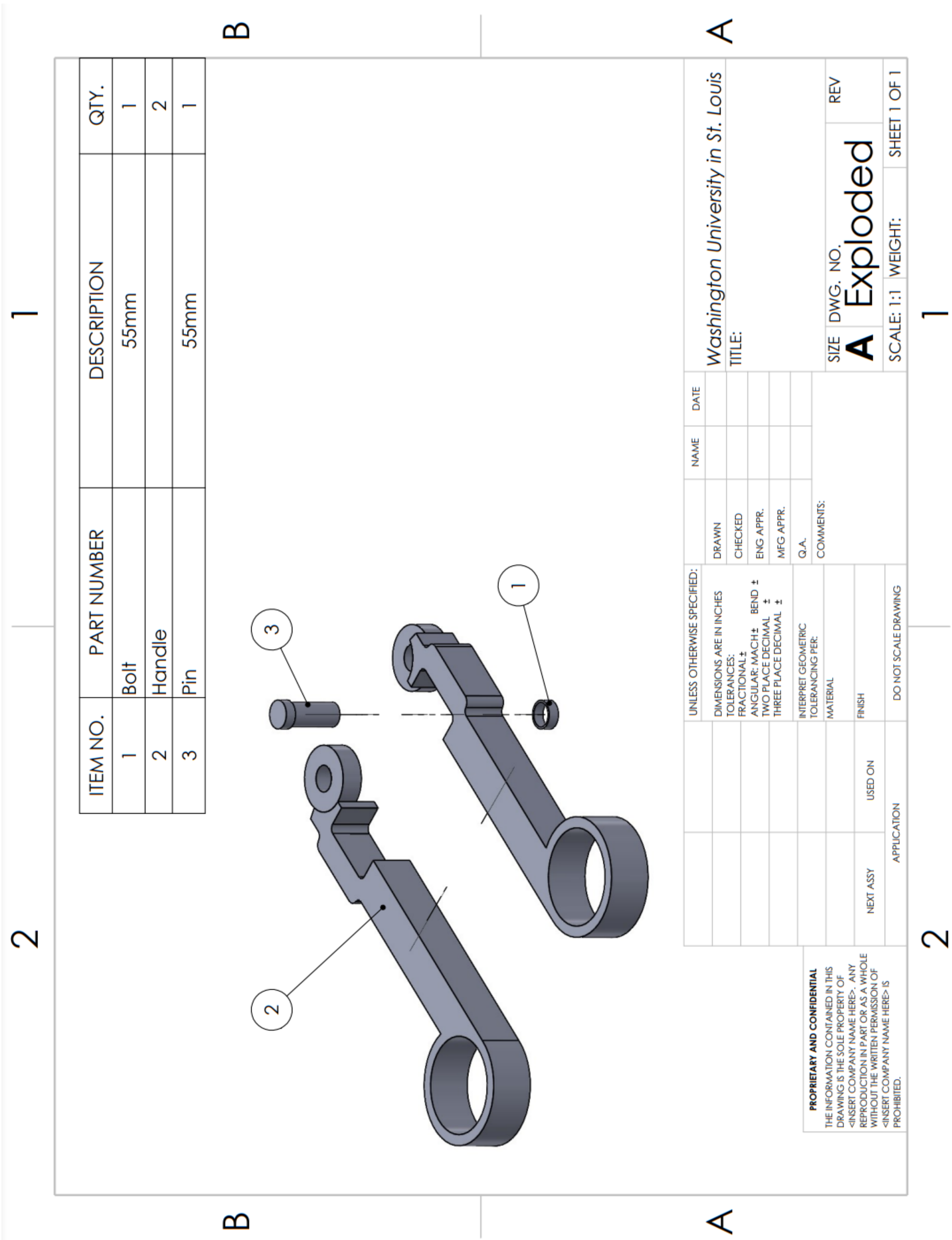


Figure 24: Exploded view with callout to BOM

5.2 Proofs-of-Concept

At the project's inception, our primary objective was the development of a single-handed pliers tool that could effectively mitigate the force required for clamping, as opposed to manual hand clamping. Nevertheless, as we conducted a series of rigorous tests to attain the predefined performance benchmarks, we came to the realization that certain aspects of our project goals were not being satisfactorily met. This necessitated a comprehensive exploration of diverse design options to determine which handheld device configuration would yield the most favorable outcomes. While some design iterations displayed commendable practicality and efficiency with respect to clamping speed, the desired force reduction remained elusive.

Remarkably, we consistently achieved the targeted weight parameter throughout the design iterations, which served as a positive indicator that our prototypes and designs were progressing in a favorable direction. It was through the refinement process that our final Nutcracker design emerged, enabling us to critically evaluate the strengths and weaknesses of our previous 3D-printed models. Subsequently, we decided to revert to a plier-like design concept, albeit with larger dimensions, in order to address the fragility and the inadequacy of the previous prototypes in achieving a 4-fold reduction in clamping force.

As a result of these iterative developments, we now find ourselves in a position where all three of our predefined performance goals are well within our reach, and our initial prototype is poised to fulfill its intended purpose effectively.

5.3 Design Changes

The initial concept selected was a simple modified pliers, where the front of the pliers has a square-shaped hole cut through, fitted to the size of the clamp when it is closed. This was to allow for the pliers to clamp down till it closes the clamp, but not more than that.

The current prototype is a nut-cracker-esque device with a hole cut through that allows for the closing of the clamp and has the addition of handles to allow for one-handed use.

Both the initial concept and the initial prototype is based on the idea of using leverage to apply more force. The change made from the selected plier concept to the nut cracker prototype was due to three main reasons:

- In testing, the nut-cracker device's force amplification was closer to that of the theoretical design value. At a leverage distance different of 3.5, it was able to achieve 3.1 times the force), whereas for the same theoretical 3.5x force amplification, the plier-shaped device only achieve slightly above 2x. The force required to apply also varied more than in the case of the nut-cracker. One possible cause of this is due to the friction created between the two pliers pieces at the joint.
- At the same thickness and infill of the 3d printed test devices, the pliers were more prone to breaking. This indicates higher durability of the nut cracker device.
- The nut cracker has less volume and corresponding less mass (as it is essentially the pliers without the head).

It is possible that we will return to the pliers design in our following prototyping, due to the inability of our current prototype to meet the usage time requirement. Our initial prototype's mass is much less than the maximum set by the performance goals. This means that we are not concerned of the mass increase due to points 2 and 3 above.

6 Design Refinement

6.1 Model-Based Design Decisions

Rational #1: The size of the opening in the pliers is an important aspect of our pliers because, it allows the medical clamp to be clamped as well as preventing any damage to the medical clamps. The dimensions of the medical clamp is about 17mm in height and about 13mm in width. With the clamp in the tube our pliers needed to be able to open up at least 27mm and closed down to at least 13mm, the height of the clamp in its closed position, but not much more to prevent damage to the tube and clamp. After trial and error, we noticed that having the opening to be about 18.5mm length (5.5mm larger than its width) and about 12mm in height (1mm less than closed height) gave us the best results.

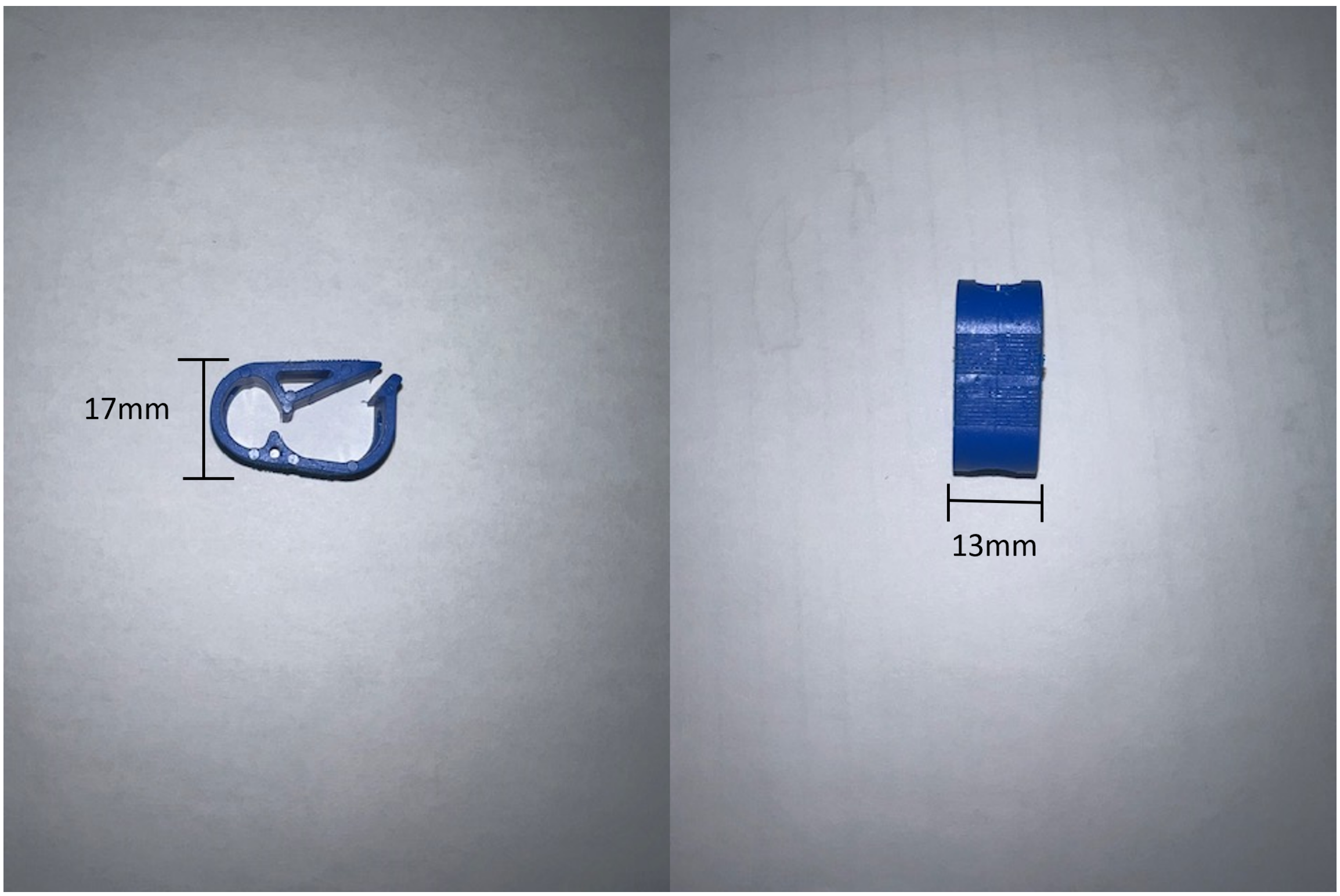


Figure 25: Leverage Calculation

Rational #2:

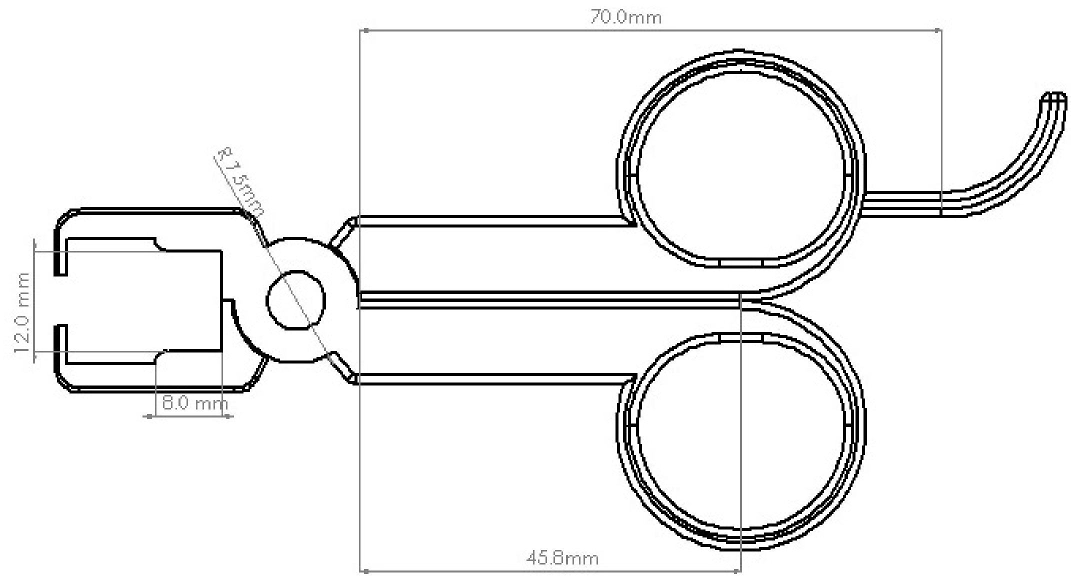


Figure 26: Leverage Calculation

Assumptions:

- Force on the clamp will happen at the middle of the protrusion in the clamping spot, at 4.0 mm from base. The base itself is 1.5 mm thick.
- The force applied by the user will be divided equally between both sides of the pliers.
- Force applied by the side of the fingers will be divided equally between the finger in the hole and finger on the extra leverage.
- Force applied by user will act on the middle part of the handle holes, at a distance of 45.8 mm from the pivot, and at 70.0 mm for the extra leverage.
- Force applied is constant and occurs at the same point throughout the process.

Below is the torque equivalence equation:

$$F_{clamp}(4.0+1.5+8.0) = (0.5)(F_{hand})(8.0+45.8)+(0.25)(F_{hand})(8.0+45.8)+(0.25)(F_{hand})(8.0+70.0) \quad (1)$$

From this, we get:

$$\text{Force Amplification} = \frac{F_{user}}{F_{clamp}} = \frac{(0.5)(8.0+45.8)+(0.25)(8.0+45.8)+(0.25)(8.0+70.0)}{(4.0+1.5+8.0)} \quad (2)$$

$$\text{Force Amplification} = \frac{59.85}{13.5} = 4.56 \quad (3)$$

This was designed to be 4.56x instead of 4x, because in tests of previous prototypes, we observed that the pliers experimentally achieve 1.1 times less amplification than theoretically predicted. This puts our predicted force amplification at 4.15x.

6.2 Design for Saftey

6.2.1 Risk #1: Tube Damage

Description: This risk involves the possibility of damaging the medical tubing during clamping with pliers. The tubing could be punctured, kinked, or crushed, leading to compromised fluid flow or even complete failure of the tubing.

Severity: Critical. Damage to the medical tubing can result in the interruption of crucial fluid delivery, leading to potential harm to the patient.

Probability: Seldom. The use of pliers, especially if applied with excessive force or without precision, increases the likelihood of damaging the relatively delicate medical tubing. However, our device is specifically designed to prevent something like that from occurring.

Mitigating Steps: Use specially designed clamps for medical tubing that are equipped with adjustable pressure settings to ensure gentle yet effective clamping. Training healthcare personnel on proper clamping techniques and the use of appropriate tools can also mitigate this risk.

6.2.2 Risk #2: Contamination

Description: There is a risk of introducing contaminants to the medical tubing when using pliers. This can occur if the pliers are not properly cleaned and sanitized, leading to the transmission of harmful substances to the patient through the tubing.

Severity: Marginal. While the introduction of contaminants can pose health risks, the severity is not as immediate or critical as some other potential risks. We are expecting the nurses to be well trained in sanitizing tools used frequently.

Probability: Occasional. Contamination is more likely if proper cleaning protocols for the pliers are not consistently followed.

Mitigating Steps: Implement strict cleaning and sterilization procedures for any tools that come into contact with medical tubing. Regular training and reminders about hygiene protocols can help reduce the likelihood of contamination.

6.2.3 Risk #3: Inaccurate Pressure Control

Description: Pliers may lack precision in controlling the clamping pressure on medical tubing, leading to either insufficient or excessive pressure. This can impact the fluid flow rate and compromise the intended medical treatment.

Severity: Critical. Incorrect pressure control can directly impact patient health by either impeding the required fluid flow or causing damage to the tubing.

Probability: Frequent. Pliers are not designed with medical applications in mind, making it challenging to achieve the required precision in pressure control.

Mitigating Steps: Utilize purpose-built medical clamps with adjustable pressure settings to ensure accurate and controlled clamping. Provide training to healthcare staff on the importance of precise pressure application.

6.2.4 Risk #4: User Fatigue

Description: Prolonged use of pliers for clamping medical tubing may lead to user fatigue, reducing the operator's ability to maintain consistent and accurate pressure over time.

Severity: Marginal. While fatigue may compromise the quality of clamping, it might not result in immediate critical consequences.

Probability: Occasional. Fatigue is more likely during extended use, especially in situations where there is a high demand for repeated clamping.

Mitigating Steps: Rotate personnel involved in clamping tasks to prevent excessive fatigue. Introduce ergonomic tools or provide frequent breaks to reduce the impact of user fatigue.

6.2.5 Risk #5: Mechanical Failure of Pliers

Description: Pliers, not usually designed for medical applications, may suffer mechanical failures such as breakage or misalignment during use. This can result in unpredictable clamping forces and potential harm to the medical tubing.

Severity: Critical. Mechanical failure can lead to uncontrolled clamping, causing damage to the tubing and disrupting essential medical processes.

Probability: Unlikely. Our pliers are designed for medical use, pliers are generally robust tools, and failures are less common if used within their intended capacity.

Mitigating Steps: Regularly inspect and replace pliers that show signs of wear or damage. Invest in purpose-built medical clamps with higher reliability and durability for critical applications.

6.2.6 Heat Map

Below in Figure 27, we see a heat map illustrating the components spoken about previously when it comes to deigns regarding user and client safety. Based on the heat map, our group decided it would be in our best interest to focus on pressure control alongside contamination, tube damage and user fatigue, as these are things that fall within the red and yellow zones of the heat map. However, when it comes to our actual design of the product, things regarding user protocol and habits such as contamination and user fatigue are more so in the hands of our customers that will be using the product. Whether that be by having in depth procedures for cleaning the product (and we ensure that it works effectively after this cleaning process) or even having personnel rotate in the clamping process (although our product can still be designed to combat fatigue entirely with new stability and comfortability metrics.

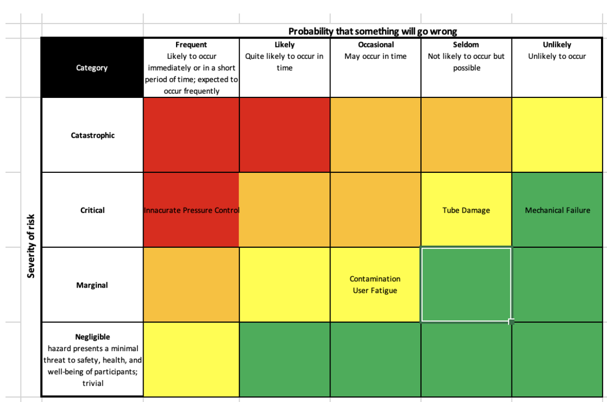


Figure 27: Heat Map of Designs for Safety

6.3 Design for Manufacturing

The prototype has 4 parts, two of the plier parts, one pin, and one bolt. The design has no threaded fasteners. The theoretically necessary components are the two plier parts, and the bolt that helps lock the two together. The pin does not necessarily have to be a separate piece, it can be made a part of one of the plier parts. The bolt would still be necessary to secure the two parts together. It's also possible to keep the two parts with holes through them, and instead made the pin and bolt one piece from an elastic material that allows it to squeeze through the hole.

6.4 Design for Usability

1. Vision Impairment (e.g., Red-Green Color Blindness, Presbyopia):

- Influence: Vision impairments like color blindness would not affect one's ability to use device, while presbyopia (age-related farsightedness) could reduce hand eye cordination.
- Modification: Use distinct shapes or textures instead of relying solely on color coding. For presbyopia, ensure that any text is large and clear, and consider using high-contrast colors.

2. Hearing Impairment (e.g., Presbycusis):

- Influence: Hearing impairments will not directly affect the use of a manual device like bio pliers unless the device has auditory feedback or alarms.
- Modification: the device does not uses sound for alerts or instructions, visuals are provide. The only area were this might not be true is relying on the click to know it is closed.

3. Physical Impairment (e.g., Arthritis, Muscle Weakness, Limb Immobilization):

- Influence: Arthritis or muscle weakness can limit hand strength and dexterity, making it difficult to grip and manipulate standard pliers. Limb immobilization could restrict the ability to use the device with both hands.
- Modification: Design the pliers with ergonomic handles that are easy to grip and do not require significant force to operate. Consider a mechanism that reduces the need for continuous grip strength, like a locking mechanism.

4. Control Impairment (e.g., Distraction, Fatigue, Intoxication, Medication Side Effects):

- Influence: These impairments can affect coordination and focus, increasing the risk of errors or accidents when using the device.
- Modification: Ensure the device is intuitive and requires minimal complex manipulation. Safety features like automatic shut-off or error alerts could be beneficial but not necessary in this design. The design should be such that it minimizes the need for precision in control under these conditions.

6.5 Design Considerations

Table 3: Factors considered for design solution

Design Factor	Applicable	Not Applicable
Public Health	x	
Safety	X	
Welfare	x	
Global		x
Cultural		x
Societal	x	
Environmental	x	
Economic	x	

Table 4: Contexts considered for ethical judgments

Situation	Applicable	Not Applicable
Global context		X
Economic context	X	
Environmental context	x	...
Societal context	x	

7 Final Prototype

7.1 Overview

The figure below shows a 3D print of our final prototype. The three performance goals tested on this device were:

- Mass of less than 4 oz or 113 grams. We achieved **23 grams (0.8 oz)**.
- Force reduction of at least 4x or more. We achieved **4.6x**.
- Can close three clamps while one-handed with either hand in 5 seconds or less. We achieved this at **17% success rate**.

Figure 28: Picture of the Final Tested Prototype

7.2 Documentation

Below is the dimensions of the device.

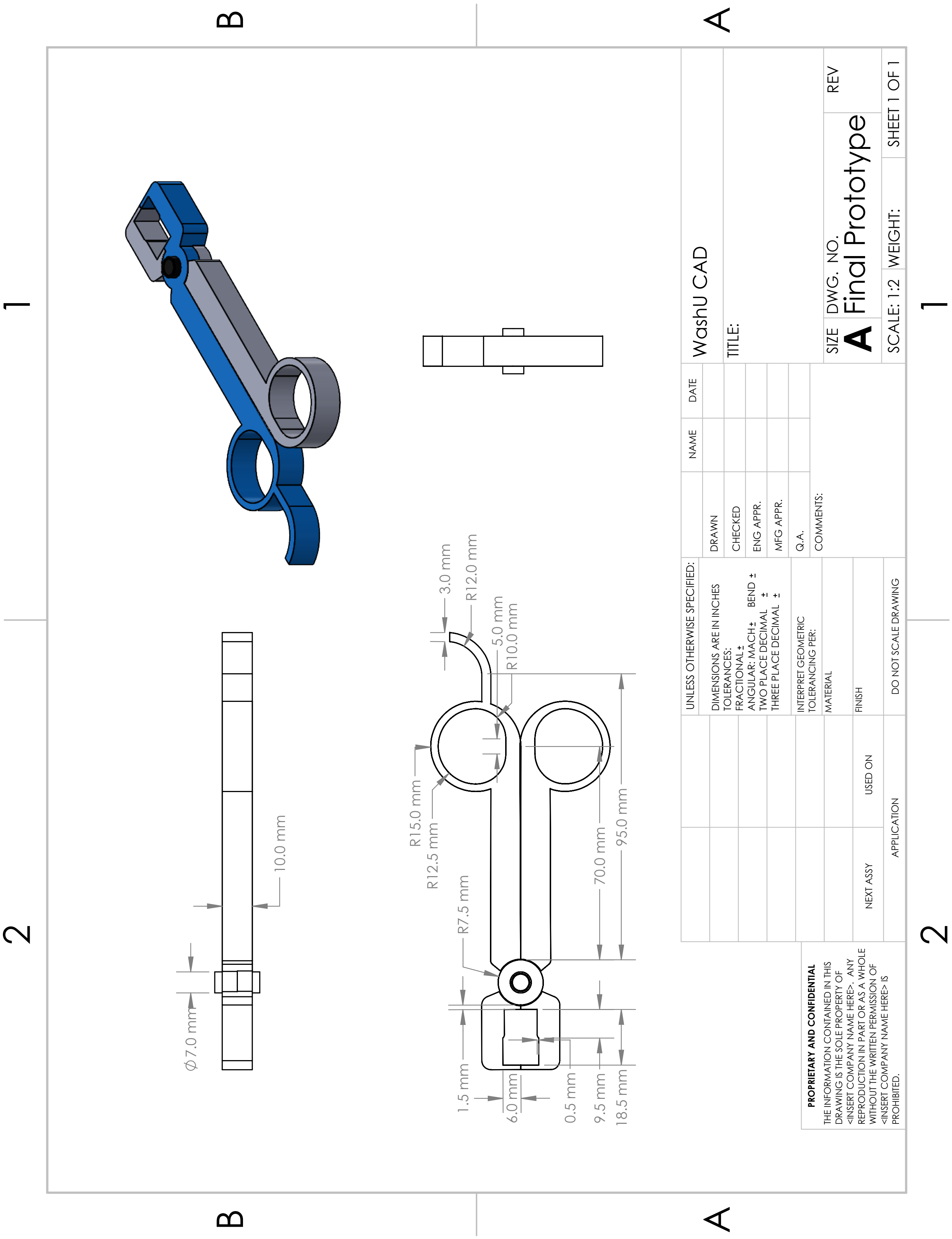


Figure 29: Dimensioned Drawings with Isometric and Standard Three Views