

BME:3710 Final Project Report

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Background/Motivation:

The ulnar collateral ligament (UCL), located in the thumb metacarpal phalangeal joint (MP), provides stability for static lateral pinching when grasping. The UCL joint is susceptible to be injured when hyperextended (Algar 2023). Figure 1 depicts the location of the UCL within the thumb MP.



Figure 1: Ulnar collateral ligament in thumb MP

Two common means to which the UCL is injured include, “Skiers thumb” and “Gamekeepers thumb”. Skiers thumb occurs when the UCL is forcefully abducted and hyperextended by a ski pole. Gamekeepers thumb is due to chronic cyclic loading caused by resistive grasping and twisting of a controller.

While game keepers' thumb and skiers' thumb are two common methods that injure the UCL, the injury has the highest incidence among athletes. Nearly 1 in 4 high school athletes will experience a UCL injury by graduation (Solomito 2024). A recent study showed that nearly 20,000 UCL injuries occurred between 2010 and 2019. Once injured, treatment for a torn or strained UCL includes surgery and/or immobilizing the thumb through a splint. Treating the UCL with a splint is less invasive and preferred method of treatment. The purpose of the splint is to immobilize the thumb to allow the UCL to heal with time. Immobilizing the MP joint in the thumb causes difficulty for patients completing daily living activities or ADLs. In turn this leads to a decrease in splint compliance and causes the UCL injury to persist for longer periods of time.

Our medical device was designed to assist UCL injured patients with their ADLs. Our design consists of a mounting platform to the base of the splint along with several removable attachments that assist the daily life of a hand splint wearing patient.

Need Statement:

Before beginning the design process our group developed a need statement to cover the problem, population and desired outcome for our device. The following is our need statement, “A way to increase splint compliance in UCL patients by developing a modular assistive device for ADLs.”

Existing Solutions:

1) **Title:** Power-operated straightening device

- a) **Patent Number:** JP5557529B2
- b) **Explanation of why you consider this prior art for your device:** While not a straightforward art piece, its ability to fix the thumb into place and then change the pointer and index, with a stiff formed piece cupping both the thumb and pointer finger. Allowing the thumb to be “untouched” or not participate in the pinching action is applicable to our device. A slightly different approach this can be lightly modified and compete with our device rail system

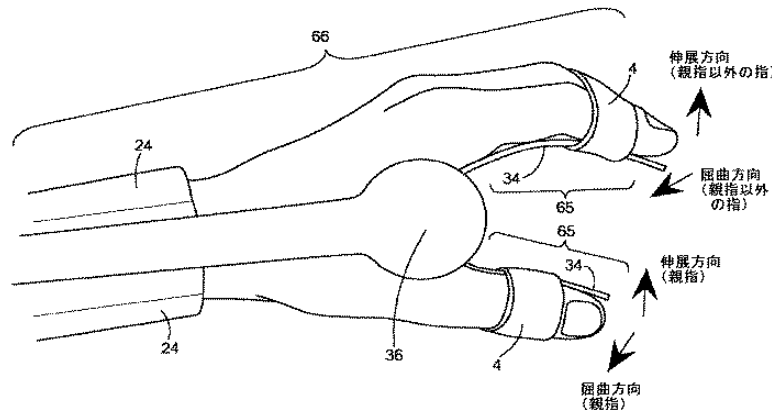


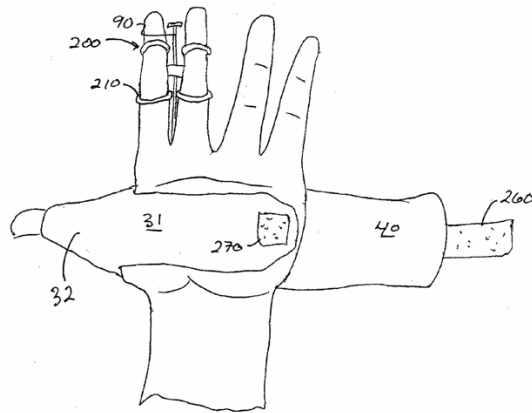
FIG. 18

c) Image of device:

2) **Title:** Functional low-profile dynamic extension splint and methods for its use and manufacture

- a) **Patent Number:** [US 2009/0062708 A1](#)
- b) **Explanation of why you consider this prior art for your device:** Device assists with flexor spasticity; it is termed as a dynamic extension splint. Helps with gripping and is simplistic. Art relates to our device because one of our attachments will have to articulate like the device bellow does.

c) **Image of device**



3) **Title:** Hand Orthosis

a) **Patent Number:** US7837641B2

b) **Explanation of article:** The orthosis is similar to the hook attachment and platform we constructed. The device is a gripping tool; the cavity around the four fingers and thumb is to assist individuals while they grab objects. One limitation of this device is that allows the user to have a free thumb. The user should have their thumb immobilized as to not reinjure the UCL.

c) **Image of device:**

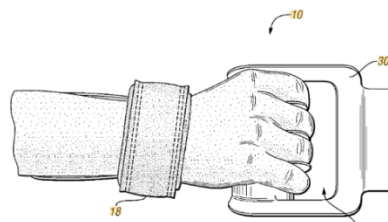


Fig. 5

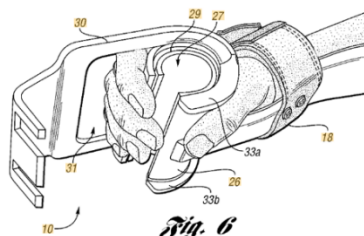


Fig. 6

Design Specifications:

- A mounting system (rail) that attaches to the splint
- The mounting system is a sliding rail made of acrylic and laser cut to the desired geometry
 - Dovetail geometry secures the attachment in place while in-use
 - The rail is 2 inches in length by 3/4in wide and very thin
- Attachments can be easily removed
- Three attachments attach to the rail system for ADL assistance.
 - The attachments are not exclusively designed out of acrylic
- Each attachment will weigh no more than 1-lb.
- Each attachment can fit in a pants pocket or small bag.
- Each attachment can be cleaned with soap and water.
- Attachments have a 2-lb load limit.

Hand Sketch of Designs:

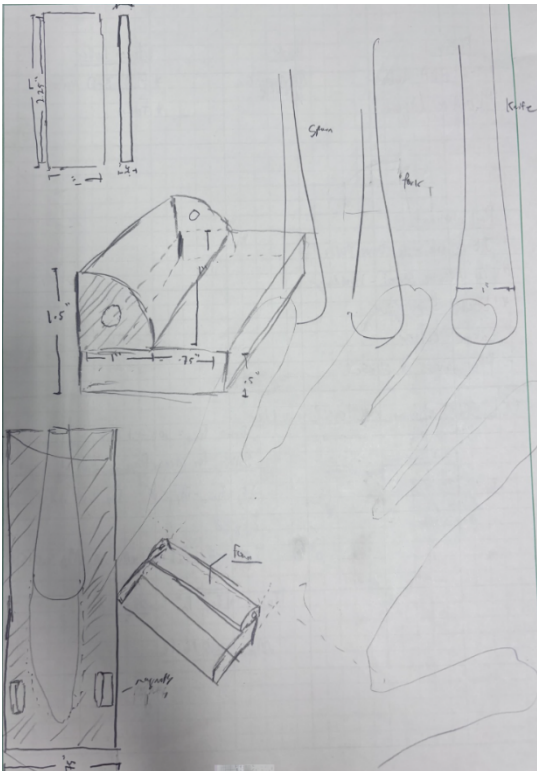


Figure 2: Utensil holder initial sketches

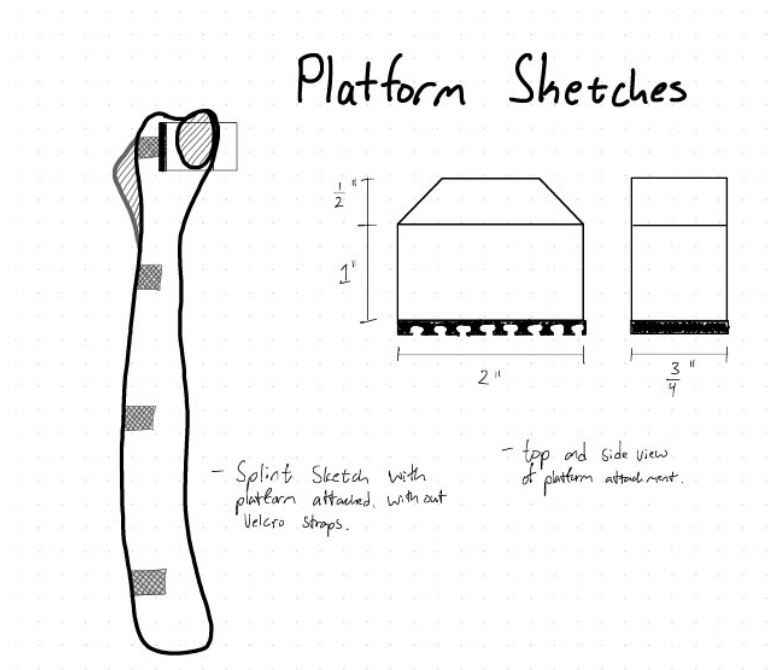
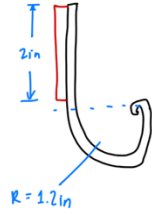
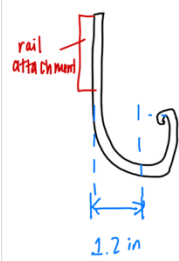


Figure 2: Platform initial sketches

J-Hook Attachment

→ side profiles



→ front profile

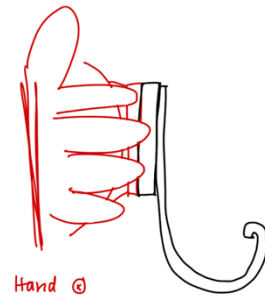
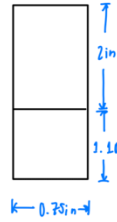


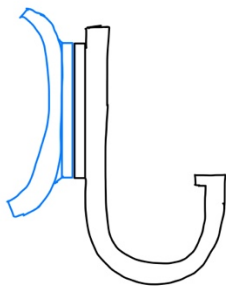
Figure 3: J-Hook Initial Sketches

Mathematical Modeling/Biomechanical Analysis:

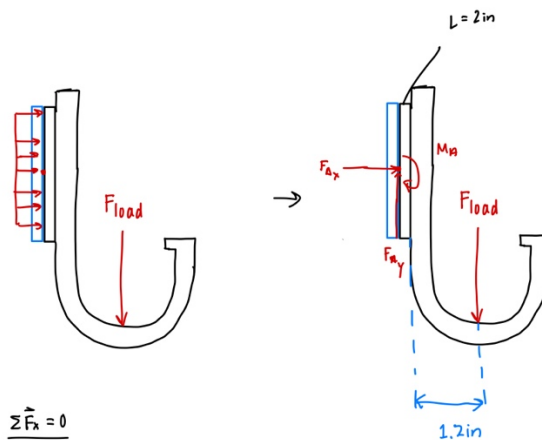
UCL Splint attachment: Utensil holder

$F_{load} = 0.8 - 1.1 \text{ lbf}$
 Solving for reaction forces at Rail attachment
 $\sum F_y = F_{load} - F_{Ay} = 0 \quad F_{Ay} = 0.8 - 1.1 \text{ lbf}$
 $\sum F_x = 0$
 $\sum M_A = -F_{load} \cdot (10'') + M_A = 0 \quad M_A = 0.75 \text{ lbf}$
 $|F_{Rail}| = \sqrt{F_{Ax}^2 + F_{Ay}^2} \approx 0.8 - 1.1 \text{ lbf}$
 $M_A = 0.75 \text{ lbf}$

J-Hook Biomechanical Model



$$F_{load} \leq 2 \text{ lbs}$$



$$\sum \vec{F}_x = 0$$

$$F_{Ax} = 0 \text{ lb}$$

$$\sum \vec{F}_y = 0$$

$$F_{Ay} - F_{load} = 0 \Rightarrow F_{Ay} = F_{load} = 2 \text{ lbs}$$

$$\sum M_A = 0$$

$$M_A - F_{load} (1.2 \text{ in}) = 0 \Rightarrow M_A = (2 \text{ lb})(1.2 \text{ in}) = 2.2 \text{ lb} \cdot \text{in}$$

Platform Analysis - kian

- For purposes of analysis, assume a vertical orientation of Splint, such that the far fingers are extending upward
- Assume point force applied to center of platform

Mechanical Design Specifications

- 21lb load max
- mounting cleat/rail $2 \times \frac{3}{4}$

Mechanical Analysis

- Walk through: force applied to the pad can be modeled as a point force F_{applied} . This creates a moment M_B and counter M_D resisting the platform from coming out of the rail system

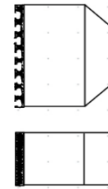
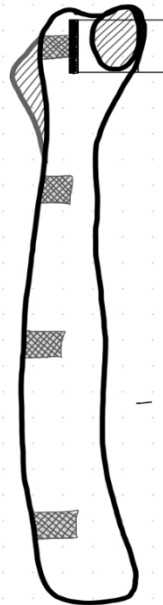
Calculations:

$$\sum F_y = F_A + F_{\text{Shear}} \rightarrow F_{\text{Shear}} = -F_A = 21\text{lbs}$$

$$\sum F_x = 0$$

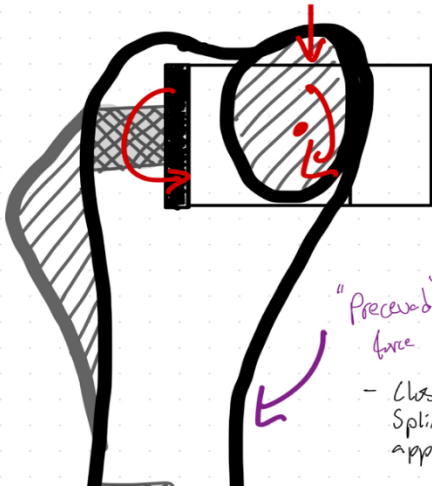
$$\sum M = M_B = -M_D = F_{\text{applied}} \times \text{Distance}$$

$$M_D = 21\text{lb} \times \frac{3}{4}\text{in} \times \frac{1}{12}\frac{\text{in}}{\text{ft}} = 0.125\text{ lb-ft}$$



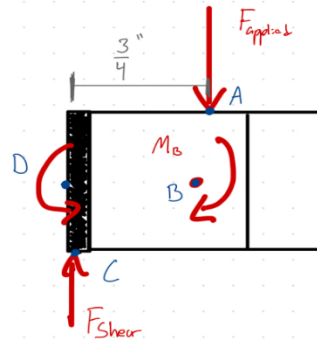
- top and side view of platform attachment.

- Splint Sketch with platform attached, with out Velcro Straps.



"Preced" force

- Close up view of Splint with forces applied.



- Force diagram for platform attachment.

Solution:

We designed attachments that can mount directly onto the splint. Based on the interview, there were multiple ADLs that the patient had difficulty completing. The main ADLs the user discussed in the interview were eating/feeding, brushing teeth, pinching, and ease of using the bathroom. Our idea was to design a device, a rail-attachment device that interfaced with the splint that is removable. We added plastic weld to create a flush surface to adhere the rail system to the splint

Platform:

The platform attachment is designed to be versatile, without any one task it mind in creates (dare I say it) a platform for the user to work off of. Allowing the user to pinch and grab objects against the platform, roughly replacing the functionality of the thumb. The platform is made from 80A rubber allowing for some give and grip without concern for over deformation with softer rubbers. Attached on the bottom is the glued-on rail system that allows it to interface with the splint.

Using a 1" * 1" * 6" 80A rubber piece, cut and shape the rubber given a 1" bottom section and 1/2" top section. Then superglue the rail onto the bottom



Figure 4: Splint with platform attachment. Several different angles show how the platform interacts with the split rail. Along with more perspectives for better visualization.



Figure 5: Platform attachment assisting in holding a can without the use of the thumb.

Hook:

A hook attachment was also designed to help with carry objects and assist with more independent bathroom usage.



Figure 6: Splint with hook attachment.



Figure 7: J-hook attachment lifting a lunchbox.

Utensil:

The final attachment designed was a utensil holder that normal utensils can be inserted into to assist with feeding. The utensil attachment is designed to assist splint wearing patients with feeding. It includes a 4,2,.5 inch platform attached to a hollow quarter cylinder (figure _). The base and quarter cylinder are 3-D printed from FDM resin. The dove tail rail is attached to the base with Loctite glue. The interior of the quarter cylinder is filled with foam. Utensils, such as forks, knives and spoons all can be inserted or removed from the foam.

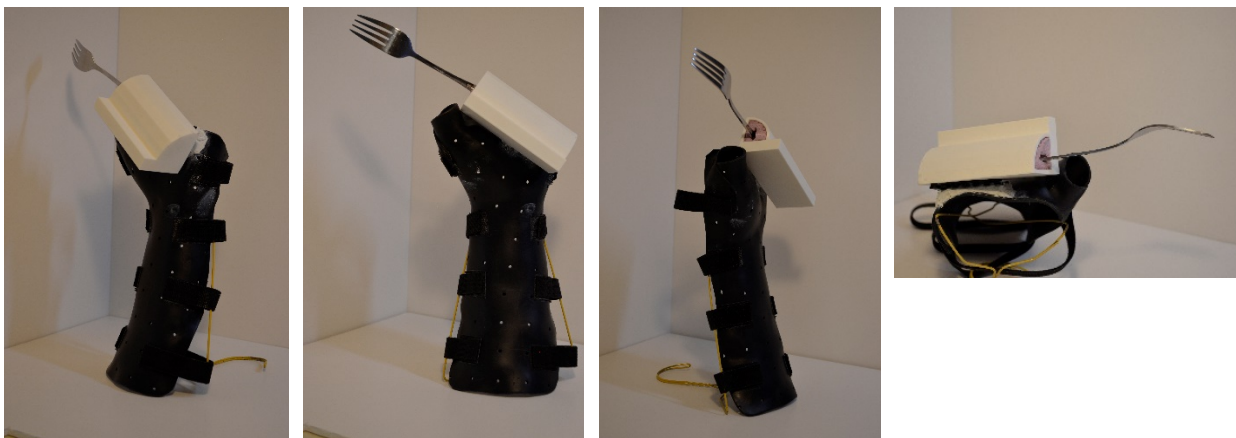


Figure 8: Splint with Fork/Utensil attachment

Bill of Materials

Description of Material	Intended Use	Quantity	Cost
Acrylic sheet	Dovetail rails	15	N/A
6"x1"x1" 80A Rubber	Platform attachment	1	\$16.46
12"x1"x1/16" Low Carbon Steel	Hook attachment	1	\$8.71
3D-printer filament	Utensil holder		N/A
Foam	Utensil holder cushion		N/A
Plastic Weld	Rail attachment to splint	1	\$9.00
Thermoplastic	Splint	1 sheet	N/A
Velcro	Splint	1 roll	N/A
Loctite Superglue	Adhere materials together	1	\$5.73
800 grit Sandpaper	Sand down attachments/rails	1	\$2.20
Gloves	Skin protection	2	\$0.20
TOTAL COST:			\$33.10

Classifications:

EU Classification: Class I

Based on the MDR rules for classification of medical devices outlined in annex VIII. Implementing rule 1 “All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.” Running through the following rules, our device does not modify biological or chemical composition of human components, we do not come into contact with injured skin or mucous membrane, non-invasive, non-active, nor software, and there are no special rules that apply. There are no other rulings to classify otherwise.

FDA Classification: Class I

Based on other similar devices that are already classified, and the previous reasons stated above. The FDA classification would follow a class I classification.

Standard Operating Procedure:

Our unique approach to assistive technology is based on a universal dovetail rail system. When purchasing the base system and rail attachments it is important to note that the rails are not male female but one in the same. Below is first how to attach a rail to your splint and then any special notes for rail attachments are below. **Before you begin, if you are the user of the split, a second pair of hands is helpful, but you are able to do it by yourself.** Given everyone unique size and shape, we feel it is ever important that your device be as customized as possible, with different hand types and divots. Taking the time to properly attach your rail is incredibly important, this system provides the best user experience.

Included:

- JB plastic weld putty
- A pair of safety gloves
- Sandpaper
- 2x free rails
- Hook attachment
- Platform attachment
- Utensil attachment

Splint-Side Rail Placement and Adherence:

1. use the provided sandpaper to “rough up” the surface of the splint, cover at least a 2.5inch by 1 inch area around the upper lip of the palm region. Note that this is to help secure the putty onto the splint, trying not to remove material from the splint.
2. Please follow the directions laid out on the JB weld, remembering to wear the provided gloves to protect your skin. Ensure you aerate the putty well enough before attempting to attach to the splint.
3. Place the putty onto the splint forming a level 2in by 1in surface
4. Place your rail onto the putty and press gently. Ensuring level contact with the entire rail but not to impress the dovetails into the putty.
5. Wait at least 24 hours before attempting to use your splint.

Platform Attachment:

The platform attachment is designed to be used as a grip assistive device, anything from brushing your teeth to picking up laundry. When you first put the platform on, play around with the device, use a pencil or pen, feel the edges of the platform and how much the rubber grips.

Electric Toothbrush: When attempting to use a toothbrush, predominantly an electric one as they typically have a larger bore, place the brush against the top of the pad and wrap your fingers around the brush pressing against the platform to secure the toothbrush.

General Holding: Most larger objects follow the toothbrush philosophy. Use the platform to rest the object and wrap your forefingers around it and press the object into the platform. Pinching smaller objects can be accomplished the same way. Place or hold the object with the forefingers against the platform.

Spray Bottle: A good test of ability is to use a spray bottle, weather using one with water or when you’re going to wash your windows. Place the platform on your splint, wrap your forefingers around the neck of the bottle with the back of the bottle neck being pressed up against the platform. Then trigger the bottle with your index finger.

Hook Attachment:

The hook attachment is designed to help the user complete pulling actions without using fingers to pull/grip onto the object of interest. The hook attachment was designed with the intent to assist with bathroom use. The hook can fit through a standard belt loop on pants, or it has a small lip that is able to catch the waistband of pants without belt loops. The hook attachment can

also be attached in two different directions to assist with pulling pants down or up. The hook also assists with holding backs or other objects with loops. To use, slide the hook attachment into the permanent rail whichever direction the user needs (downwards to pull objects down, upwards to pull objects up). Hook object through loop and pull the desired direction.

Utensil Attachment:

A variety of utensils may be inserted into the foam utensil attachment including but not limited to forks, knives and spoons. Once in place the utensil itself sits inferior to the thumb. Patients/users can grasp the attachment with every MP joint besides the thumb; this allows the utensil to remain stable while eating. Changing utensils is as simple as sliding the current one out and inserting the desired utensil.

Responsible Parties:

- User: end user being responsible for any actions taken with the device, UCL damaged patient
- Manufacturer: is responsible for parts being tested and shipped with appropriate specifications.

Improvements:

- Create metal one-piece rails, as their current design requires the glueing three together, this creates problems with glue stopping the tracks from moving smoothly.
- Potentially screw together the rail system into the attachment as to more securely hold the attachment.
- Design the rail system to lock into place.

Other applications and Markets:

The unique ability to customize this device gives for a very widespread use case. Given our attachments, a platform, hook, and fork holder; anyone who cannot perform ADL and who also has at least a wrist splint available (or cast). Anything from wrist fractures, ligament tears, dislocations, severe sprains, ganglion cysts, and much more may require a splint of some kind in order to properly heal.

On a larger scale, anyone in a wrist splint or cast could be a potential customer. A physician may be able to shed more light onto what kind of injuries that require a splint or cast, would be safe to secure our rail system onto. Spanning even wider, anyone who struggles with ADL's could use a splint with our device. People deal with any kind of muscle deficits in the hand or upper arms, carpal tunnel, arthritis, or tendonitis.

Working Drawings of all parts and assemblies:

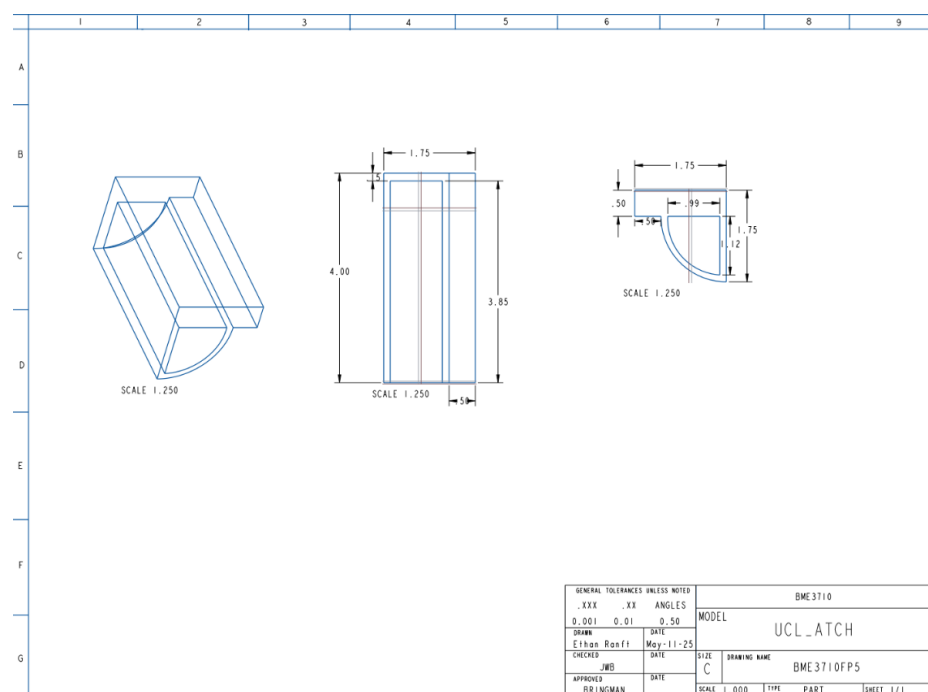


Figure 9: Utensil attachment, Working drawing.

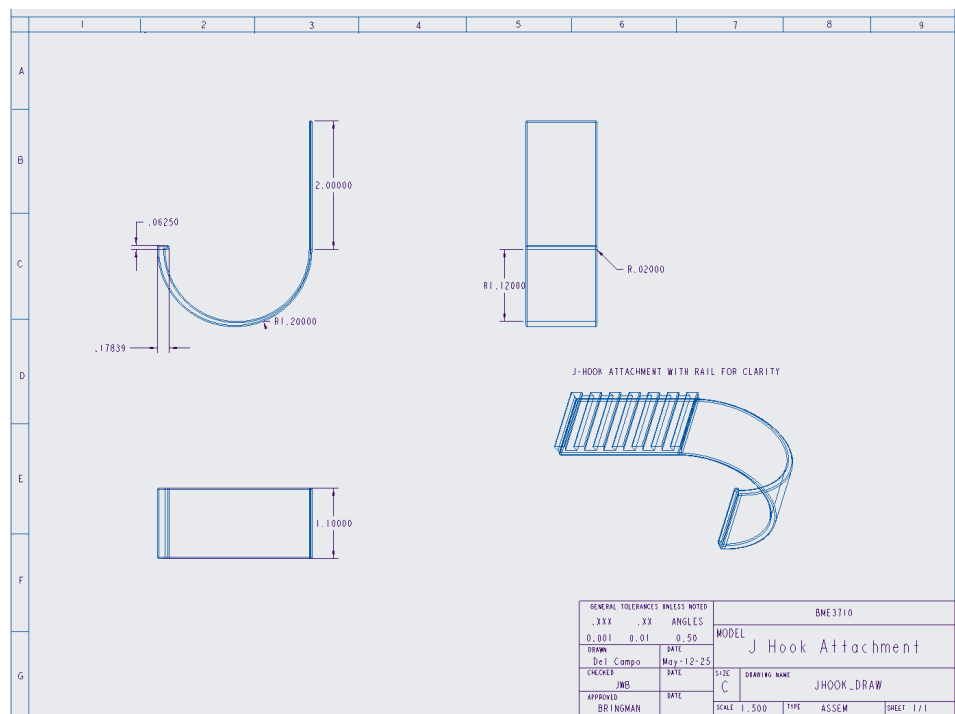


Figure 10: J-hook, Working drawing.

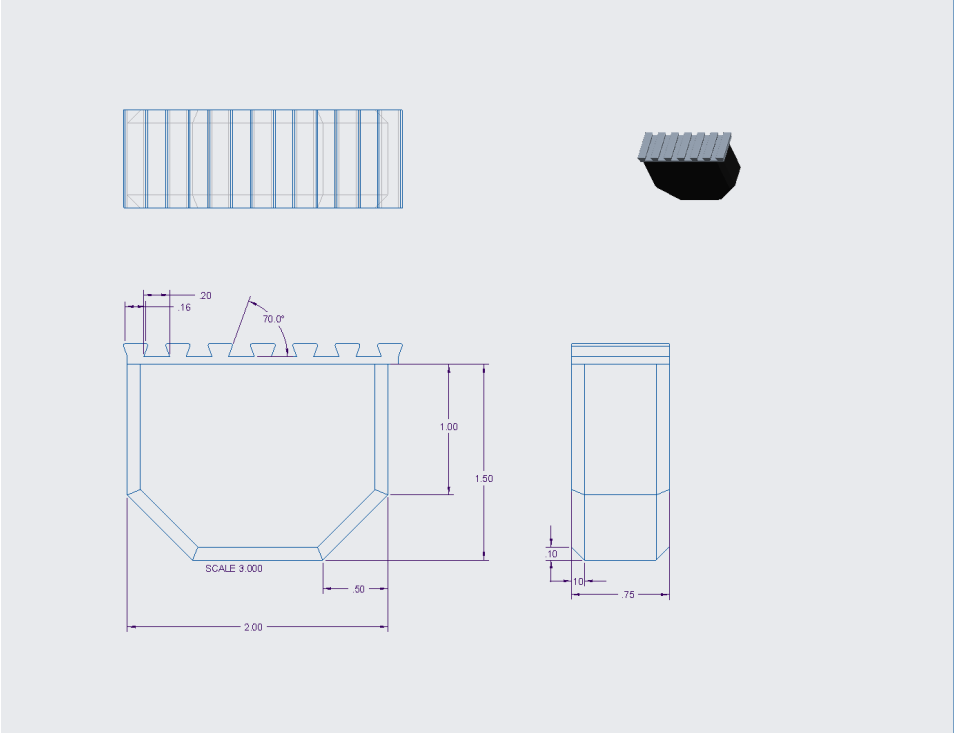


Figure 11: Platform, Working drawing.

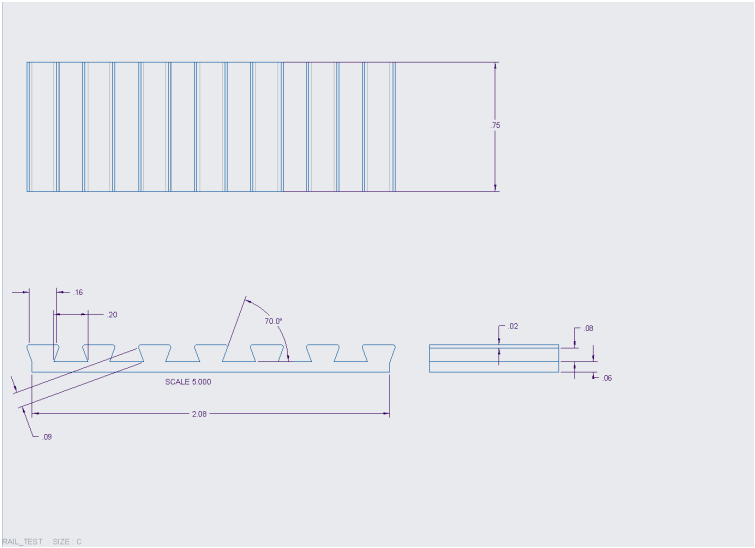


Figure 12: Rail, Working drawing.

References

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