Medical Art Prosthetics: Prosthetic Ear Attachment Anchor

BME 200/300 Mid-Semester Report | October 11, 2017

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ABSTRACT

Prosthetic ears are provided to thousands of people every year who have lost their ears due to trauma, cancer, or congenital disorders. Prosthetic ears are often secured to the skull via a surgically implanted metal abutment. A magnet is chemically bonded to the silicone prosthesis and attaches to the metal abutment. The chemical bond between the magnet and silicone is unreliable and leads to an unpredictable life span of prosthetic ears using this technique. Medical Art Prosthetics is seeking a method to mechanically attach the magnet to the silicone ear, providing a longer, more reliable lifespan for the prosthesis.

INTRODUCTION

Motivation

Every 1 in 6,000 people are born with microtia, a congenital disorder in which a person is born without part or all of their outer, and sometimes inner, ear [1]. In addition, some people lose an ear due to cancer or trauma [2]. Many of these people get prosthetic ears from places such as *Medical Art Prosthetics*. One current method of attachment of the prosthesis is through magnetic abutments placed in the skull and corresponding magnetic pieces placed in the prosthetic ear [3]. While this is a common method, it is not without fault. The magnet is placed in the ear during manufacturing and is chemically bonded to the silicone with a primer. However, this chemical bond can degrade over time as the ear is taken off repeatedly, and once the magnet becomes dislodged, there is no way to place it back in the ear [4]. This causes the attachment method to have an unreliable lifespan. There is a need to improve the method of attachment of the magnet to the silicone of the ear so that patients of Medical Art Prosthetics have more reliable prosthetic ears and thereby reduces cost and inconvenience.

Existing Devices

Though there are no current devices on the market that are made to fit over a magnet with the purpose of anchoring the magnet within the prosthetic ear, *Factor II, Inc.* has a magnet with built in wings [5]. The wings on the magnet are designed to help distribute the force the user puts on the magnet. With a redistributed force, the magnet is less likely to fall out of the prosthesis. The client does not use these magnets due to the fact that they are too big to fit in some prostheses and are not able to be grinded down easily because of the type of material.

Currently, the client uses magnets from Factor II, Inc. without wings, so that they fit comfortably in prostheses. These magnets are then chemically bonded to the silicone, though this practice has been unreliable and inconsistent [3].

Problem Statement

Silicone ear prostheses are created and provided to individuals born with microtia, suffered loss of an ear due to cancer, or trauma patients who have sustained amputation of the ear. Current attachments utilize chemical bonding with a primer to attach a magnet to a silicone prosthesis. This can cause an early attachment failure due to minimal mechanical attachment. Patients travel a great distance for the specialized prosthetic results of Medical Art Prosthetics, so a stronger method of attachment is desired to improve retention and durability of the prosthesis. The goal is to develop multiple attachment designs, fabricate 3D models, and perform computational and mechanical testing.

BACKGROUND

Projects similar to the ear attachment anchor for prosthetic silicone ears have been conducted by BME Design teams in the past. All of these previous projects were looking to replace the bar-clip methods along with the magnet abutment method [3]. One project attempted to replace the magnet in the silicone prosthesis entirely by using a spring and sheath (Figure 1). Another design used a conical cap that inserted into a vertical track attachment (Figure 2). The Prong Generation 2 design used a flexible prong to insert into the silicone prosthesis (Figure 3). Our client determined that these designs are not better functioning than traditional attachment via a magnet, so our client has tasked us with improving the attachment of the magnet's connection in the silicone mold.

Figure 1. Spring and sheath design intended to replace the entirety of the magnet.

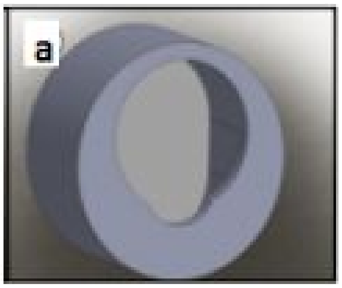


Figure 2a. One of the three vertical track attachments that would be inserted into a prosthetic silicone ear. A sliding space allows the conical cap to snap into place.
Figure 2b. The conical cap that is inserted into the vertical track attachment.

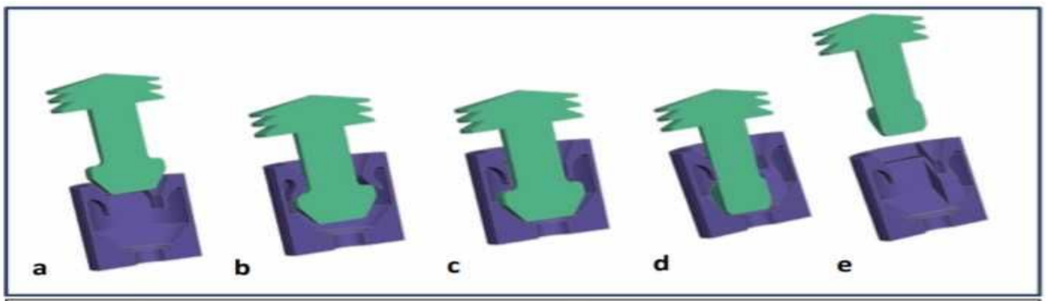


Figure 3. Prong Generation 2 design uses a flexible prong in order to insert into the abutment and then sits underneath the ledges.

Client Information

Mr. Greg Gion earned both his BA degree from Northern Illinois University as a Talented Student Art Scholar and his BS degree in BioCommunication Arts from the University of Illinois Medical Center in Chicago [6].

In 2005, Mr. Gion opened the Medical Art Prosthetics Clinic in Madison, Wisconsin where he has been working ever since. He also sees patients at other locations in the US including Chicago, Los Angeles, and New York City [6].

Design Specifications

The ear attachment anchor must be designed to increase the lifetime of the prosthetic ear to at least two years. The anchor must withstand a force greater than 4 N which is the breakaway force of the magnet from the osseointegrated abutments. The anchor must also withstand the removal of a silicone ear prosthesis at least once a day for cleaning of the prosthesis. In terms of ergonomics, the user should not have difficulties removing material from the anchor prior to attaching it onto the magnet during the silicone molding process.

The attachment should ideally fit four sizes of magnets from *Factor II, Inc.* including the following: Mini M1-S, Midi M2-S, Maxi ME-S, and Auricular MLL3-OR-S. A plastic material with the ability of being colored should be used for the ear attachment anchor. A key component of a viable ear attachment anchor is the ability to withstand 200℉. The product development should cost no more than $500. The cost to produce the anchor is projected to be less than $10. If the attachment has the potential to be sold in the market, the selling price is assumed to be $10-$50. A full list of all product design specifications can be found in Appendix A.

PRELIMINARY DESIGNS

Design 1 - Cap and Ring

Design 1 is comprised of two pieces that attach to the magnet from the top. The cap fits loosely around the magnet with grooves that line up with the grooves on the magnet and a lip that reaches around the bottom of the magnet. The ring has an internal diameter slightly smaller than the external diameter of the cap piece such that when the ring is slid over the top of the cap, it pushes the bottom of the cap together. When the bottom of the cap is pushed together, it pinches firmly around the magnet preventing it from moving. The ring is the primary source of attachment to the silicone of the prosthetic ear. The ring has holes that will fill with silicone during the molding process that allow for more area of contact between the silicone and the ring.

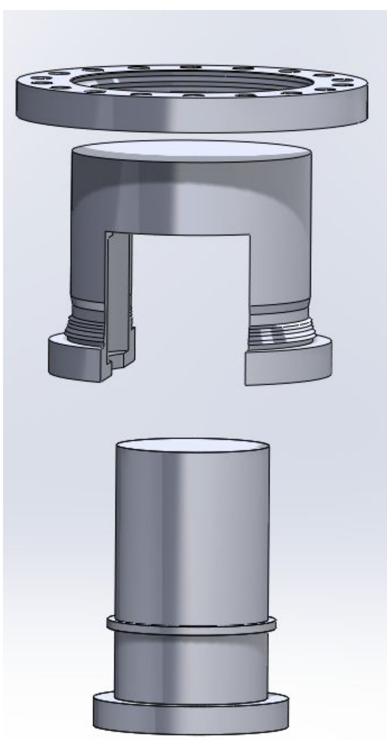


Figure 4. The cap and ring design with the magnet underneath.

Design 2 - The Buckle

Design 2 is comprised of two pieces that click into each other horizontally. These pieces pinch the magnet into place when slid into each other. The inner piece of the buckle has grooves on the inside that line up with grooves on the magnet in order to prevent the magnet from sliding out the bottom. This design has protrusions that serve a similar function to the ring in design 1 with regards to attachment to the silicone prosthesis. The protrusions can be shaved down to fit various sized ears and have holes that fill with silicone during molding to facilitate attachment.

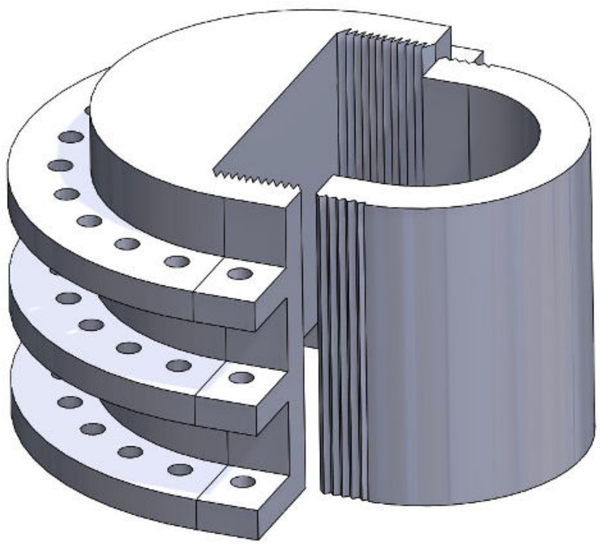
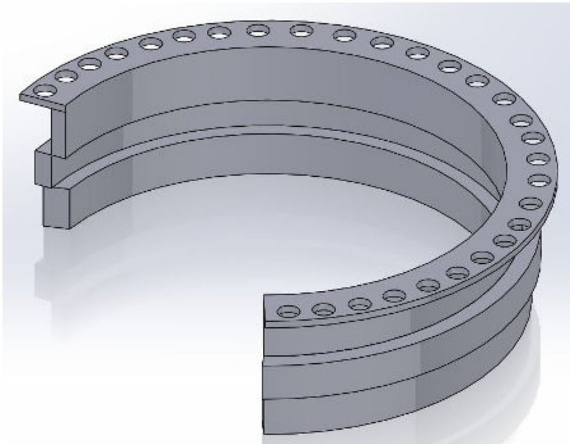


Figure 5. The two pieces of the buckle design that slide together to pinch the magnet into place.

Design 3 - C-Clip

The C-Clip is loosely based off the mechanical action of keck clips which are used in securing distillation setups as seen in figure _. It is semi-circular, but enough past 180 degrees that it is able to reliably latch onto a circular object from the side. At the very top, there are the holes that would function as the mechanical attachment to the silicone of the ear. The second ring would fit snugly around a magnet just above the bottom groove of the magnet. The third ring with a larger diameter accounts for the bottom groove, and the bottom ring fits securely beneath the bottom of the magnet effectively locking the magnet into place.



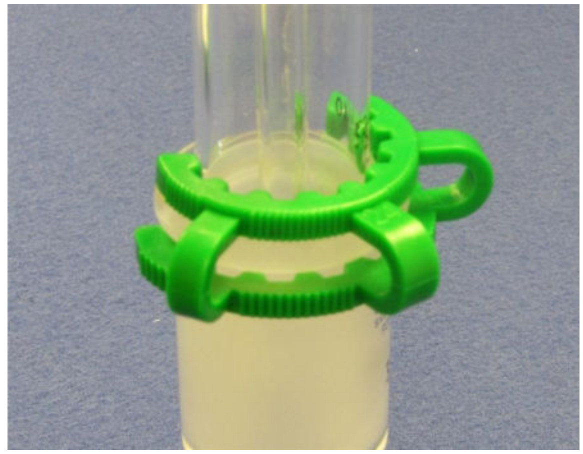
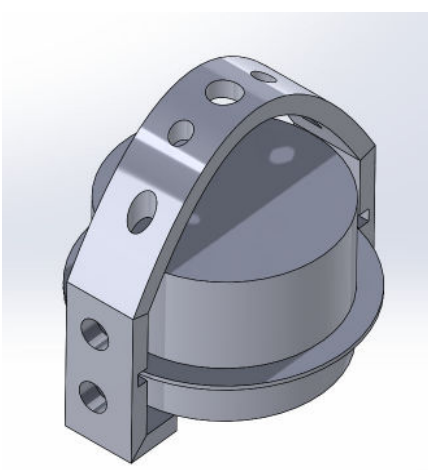


Figure 6. The C-Clip.

Figure 7. Keck Clip securing a distillation setup

Design 4 - Snap In

Design 4 utilizes a simple conical one piece design which utilizes the flex of the material chosen. When pressing this design over the top of a magnet it will flex outward around the lip of the magnet and then snap down and around both a portion of the bottom and and the lip. This device will also have holes through on all sides of its surface in order to create additional strength of bonding when the silicone fills the holes. Although the figure shown does not include it, this design would also include a wing around the perimeter in order to secure the magnet more mechanically to the silicon.



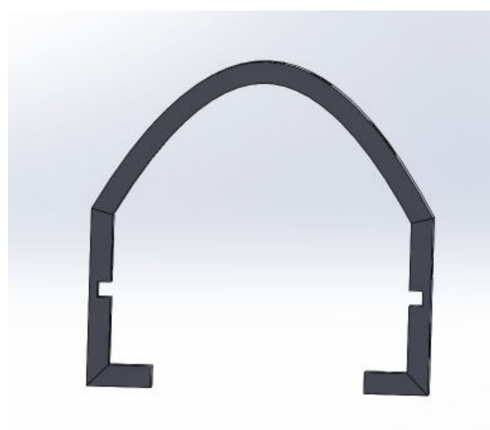
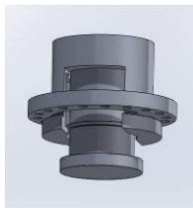
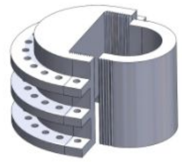
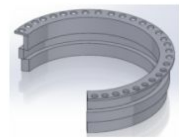
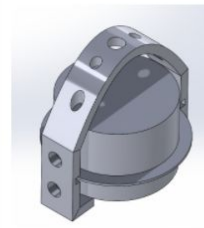


Figure 8. Shows a small section of the design. Actual design would be revolved around surface. Does not contain the wings which would surround its perimeter.

Figure 9. Cross Section at the middle of the design.

PRELIMINARY DESIGN EVALUATION

Criteria (weight)	**Design 1- Cap and Ring**		**Design 2- The Buckle**		**Design 3- C-Clip**		**Design 4- Snap-In**	
								
Attachment to Magnet/Silicone (30)	3/5	18	5/5	30	2/5	12	3/5	18
Durability (25)	4/5	20	4/5	20	5/5	25	3/5	15
Versatility (15)	4/5	12	4/5	12	3/5	9	1/5	3
Ergonomics (10)	4/5	12	4/5	8	5/5	10	4/5	8
Ease of Fabrication (10)	4/5	8	4/5	8	5/5	10	4/5	8
Aesthetic (5)	2/5	2	4/5	4	4/5	4	5/5	5
Cost (5)	4/5	4	4/5	4	5/5	5	5/5	5
Total (100)	**72**		**80**		**75**		**62**	

*Scores are out of 5. Displayed as: score | weighted score

Table 1. Although the C-Clip design won the majority of the categories, it did poorly in the highest rated category, the Attachment to Magnet/ Silicone. This led the buckle to be superior to all other designs as it score a 5/5 in the highest weighted category.

Attachment to Magnet/Silicone

The strength of attachment of the anchor to the magnet and silicone are critical for the success of the design. If the anchor comes loose from either the magnet or the silicone prematurely, the design has failed to improve the existing design.

Durability

A durable anchor is necessary in order to provide a consistent lifespan for the prosthesis. If any part of the anchor breaks or wears down, it is likely that it would fail to properly anchor the magnet into the silicone.

Ergonomics

For evaluating the designs, ergonomics is defined as the ease with which the practitioner can incorporate the anchor into their fabrication process. In other words, the anchor must not be too difficult to attach to the magnet or to be molded into the silicone.

Ease of Fabrication

In order to produce the device within a semester, the device will need to have a simple fabrication process. Similarly, a simple fabrication process will aid in the possibility of a mass produced product. All of the designs can be 3D printed in the CoE shop.

Aesthetic

Aesthetic refers to how inconspicuous the anchor is inside the silicone and how well the anchor covers the color of the magnet.

Cost

The cost of fabrication of the final design should be within a $10-$50 price range.

Proposed Final Design

The final design is The Buckle. It will consist of two separate pieces that click together and tightly fit around the magnet. Each piece will have small notches, making the fit around the magnet strong. There will also be protrusions on the outside of the attachment with holes allowing for the silicone to seep through them during the attachment process to the prosthesis. The protrusions will be able to be grinded down in order for the attachment to fit comfortably in any sized ear.

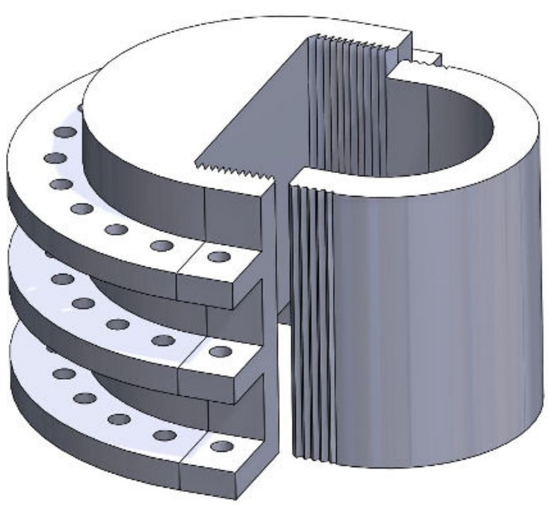


Figure 10: The two attachments click into each other via the notches, which then form tightly around the magnet. The protrusions with holes allow for a better attachment to the silicone helping the attachment and magnet stay in place.

FABRICATION & DEVELOPMENT PROCESS

Materials

The design will consist of two 3D printed plastic components. The inner piece, which has grooves to hold the magnet in place vertically, and the outer piece, which slides around the inner piece and pinches the magnet into place horizontally. Both pieces will be made with PMMA.

Methods

Testing

Both computational and mechanical testing will need to performed in order to asses the effectiveness of the final design. Computational testing will be done first in order to predict where and when the part will fail first before doing mechanical tests. Then mechanical tests such as tension and fatigue testing will be done. A tension test will need to be performed to see how the 3D printed part will fail and at what force. Then fatigue testing will need to be done in order to see how the part withstands repeated forces over time. The mechanical tests will probably be performed on an MTS machine with special attachments considering the unique shape and function of the part. Ideally there will be at least three samples for each test in order to have results with statistical significance, however, this is dependent on manufacturing costs.

CONCLUSIONS

Medical Art Prosthetics designs and supplies prosthetic ears to clients. These prostheses are attached to abutments with magnets, but the magnets currently have an inconsistent lifespan. The magnets are chemically bonded in the prosthesis which has been shown to not be a reliable tactic. If the magnet is dislodged from the prosthesis, the prosthesis is then deemed useless since there is no way to reattach the magnet without damaging the ear. Mr. Gion has asked for a device that can be attached to the magnets in prostheses with the goal of prolonging the life to a minimum of two years.

The design that will be fabricated will consist of two pieces that click together and fit tightly around differently sized magnets. It will also have rings on the outside with holes where the silicone can settle in, allowing for a better anchor to the ear prosthesis.The material of the device will also be able to be grinded down so that the user can fit the attachment in smaller ears.

In the weeks to come, the team needs to meet with Mr. Gion to update him on the team's work. While the team is meeting with the client, they will also need to take measurements of the different sized magnets that the client uses. This will help to determine the dimensions of the attachment. Additionally, the team needs to finalize the material being used and the color of the material. After fabrication is done, both computational modeling and mechanical testing will be done to make sure the attachment can withstand the forces and daily wear once in a prosthesis.

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[6] G. Gion, "Meet the Team - Medical Art Prosthetics", *Medical Art Prosthetics*, 2017. [Online]. Available: http://www.medicalartprosthetics.com/about-us/meet-the-staff/. [Accessed: 07- Oct-2017].

APPENDIX

Appendix A. Product Design Specifications

Client Requirements:

- Device should be incorporated into existing prosthetic ear design
- Device should not be visible through the silicone prosthesis
- Budget of $500

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements: The device must increase prosthetic ear lifetime to two years under normal use. Prostheses are typically removed once per day for cleaning with a breakaway force of 4 N.

b. Safety: The device should not have any sharp edges where the user could cut themselves.

c. Accuracy and Reliability: The device should secure the magnetic clip to the silicone ear. It should not come off the prosthetic ear when users take off the ear.

d. Life in Service: The prosthesis will ideally be worn everyday except while sleeping and doing rigorous exercise. Since prosthetic ears usually get replaced every two years, the attachment should last for two years minimum.

e. Shelf Life: The ear attachment should be kept in a cool dry space, considering the metal components of the design.

f. Operating Environment: The attachment needs to withstand 200℉ during the molding process. The attachment must withstand the humidity and be corrosion resistant once it’s attached to the patient.

g. Ergonomics: The attachment needs to last two years under normal use conditions. The product should allow more force to be applied on the magnets without causing the prosthesis to rip or straining the skull abutments.

h. Size: The device should be small enough that it fits on the ear without showing. It should also be able to fit around the following magnets from Factor II: Mini M1-S, Midi M2-S, Maxi ME-S, and Auricular MLL3-OR-S.[5] The client would like if the product is grindable (able to be filed down) so it can fit differently sized ears.

i. Weight: The device should weigh less than five grams. A weight larger than five may make the silicone ear too heavy and uncomfortable for the user.

j. Materials: The device should be made of metal or plastic that will withstand the molding process of the prosthesis.

k. Aesthetics, Appearance, and Finish: The device should be either transparent, the same color as the prosthesis, or small enough so that it can not be seen through the silicone of the prosthesis.

2. Production Characteristics

a. Quantity: One working prototype is required for testing.

b. Target Product Cost: The product development and finished device will cost no more than $500. If the attachment has the potential to be sold in the market, the selling price is to be $10-$50.

3. Miscellaneous

a. Standards and Specifications: This product would not fall into any sort of classification of medical device because we are not looking at any tool which will be installing an abutment on the skull and instead a connection off the existing mount. If anything a 510(k) process is required which is a premarket approval process to ensure safety to the consumer.

b. Customer: The device should be easy to attach to the magnet currently used in his prosthetics and should be easily incorporated into their fabrication process.The client also wants work to remain confidential so that the work will not be seen by competitors.

c. Patient-related concerns: The device should extend the life of the patient’s prostheses to at least two years while remaining undetectable through the silicone. It should also not increase difficulty of daily use of the prosthetic.

d. Competition: There are existing modifications to anchor prosthetic ears to the silicone more mechanically, such as Factor II; however, their performance has not been determined, and are more costly than current methods being used by this client.

Appendix B. Cap and Ring Design Schematics

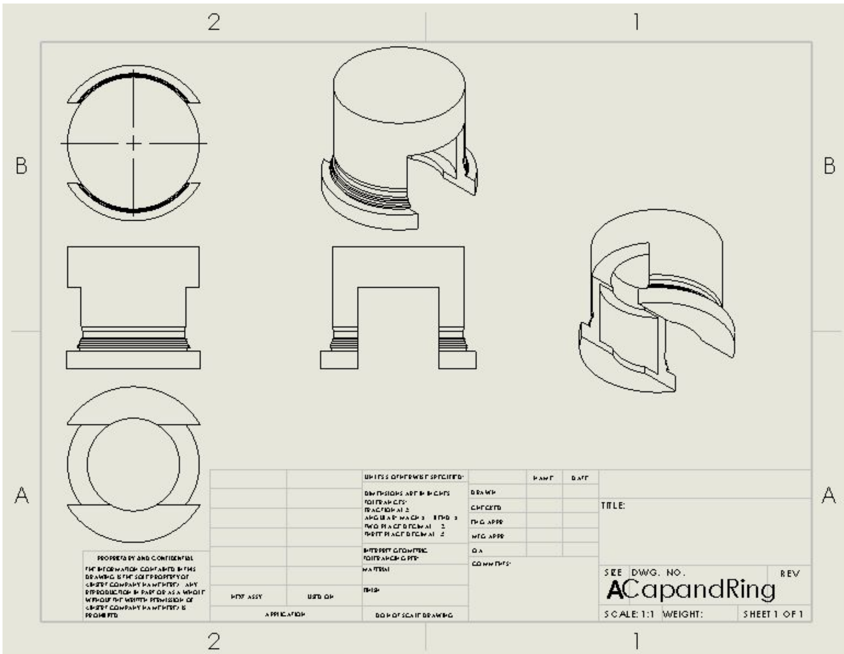

Figure 1: Solidworks drawing of the cap half of the cap and ring design.

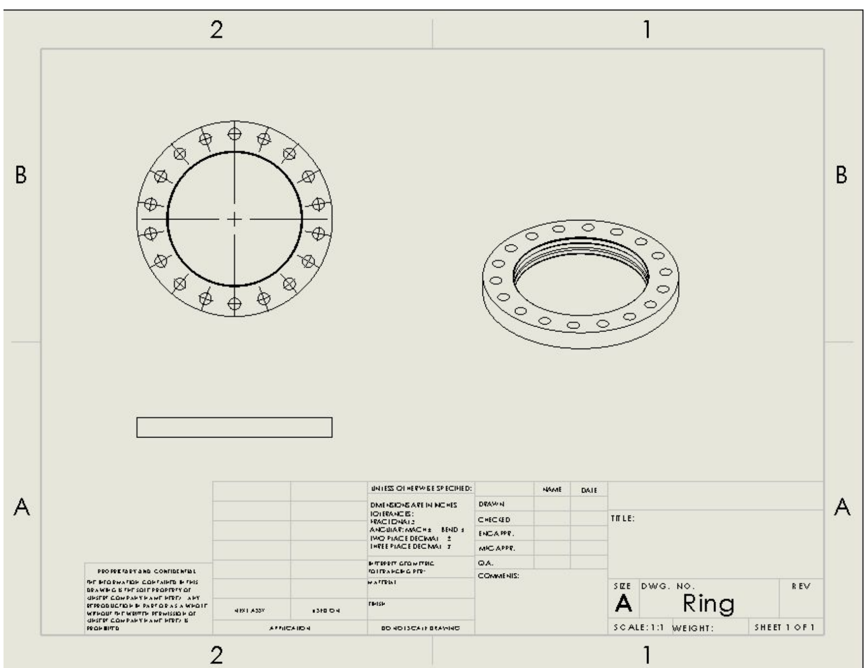

Figure 2: Solidworks drawing of the ring that will slide over the cap in the cap and ring design.

Appendix C. The Buckle Design Schematics

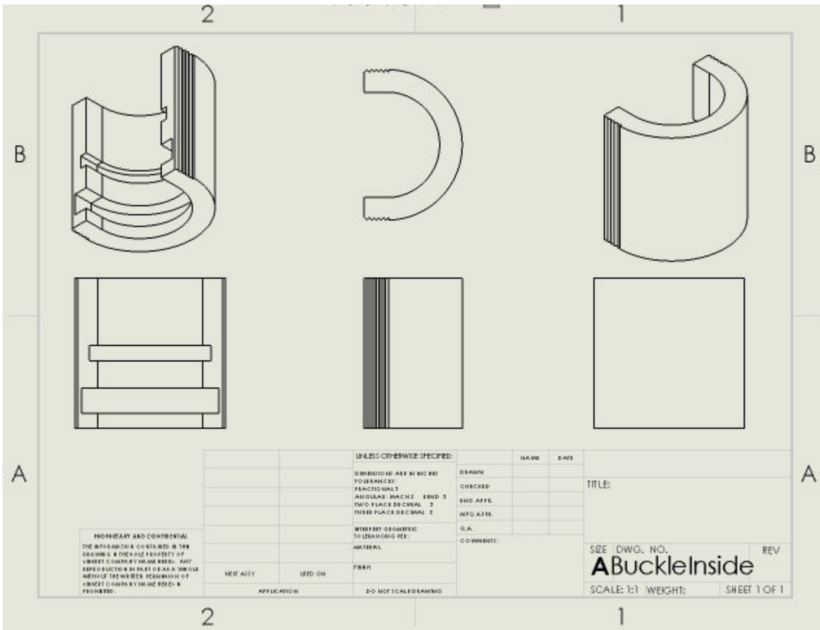

Figure 1: Solidworks drawing of the inside half of the buckle design that will go around the magnet.

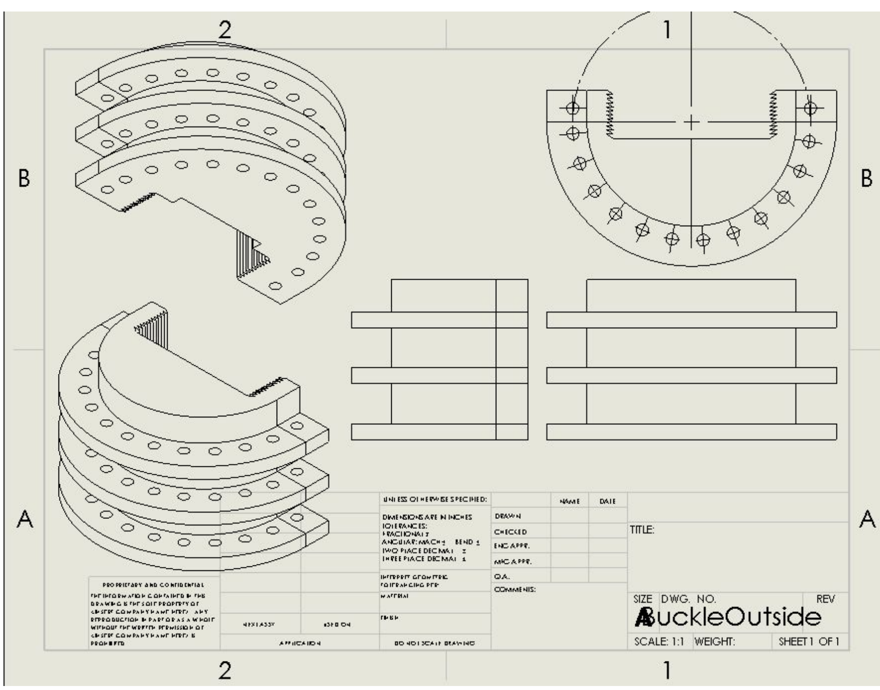

Figure 2: Solidworks drawing of the outer half of the buckle design that surrounds the inner piece and the magnet.

Appendix C. C-Clip Design Schematics

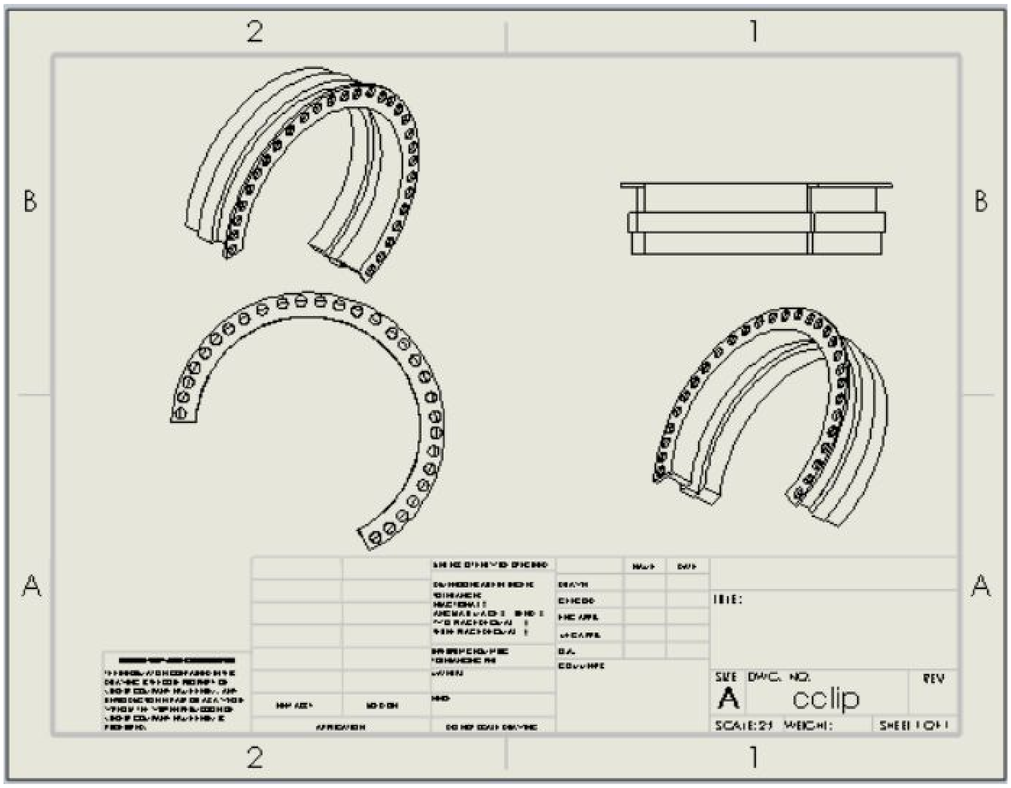

Figure 1: Solidworks Drawing of top, side, and isometric views of the C Clip design.

Appendix D. Snap-In Design Schematics

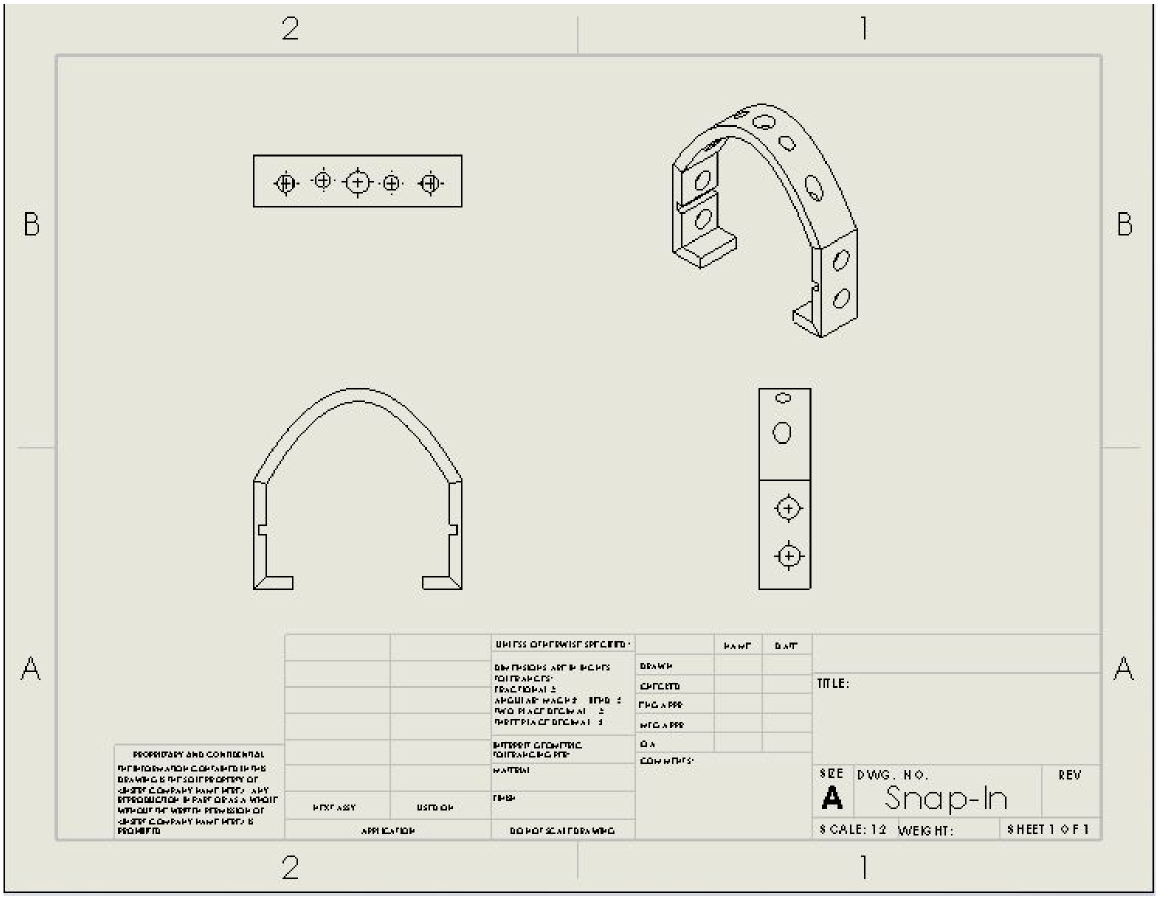

Figure 1: Solidworks drawing of a simplified version of the snap-in design.