Ergonomic Prosthetic Ear Attachment

May 5, 2010

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Abstract

Auricular prostheses are often used to correct deformities of the ear resulting from physical trauma, cancer, or birth defects such as microtia. When reconstructive surgery or slip-on prostheses are not an option, the remaining ear is often removed and a new prosthetic ear is made. To hold the prosthetic ear in place, magnetic abutments are implanted into the skull while matching magnets are set into a silicone prosthesis. Though the prosthesis is easy to attach with this method, it is easily displaced due to posterior or anterior forces. To overcome this issue, our group developed an attachment method where three abutments will have a corresponding track implanted into the prosthesis which also incorporates a recessed magnet. Each track is 4.5 mm wide, 6 mm long and is made from Ti-6Al-4V titanium. Each attachment is 7 mm in diameter and 4 mm tall. This design offers additional attachment strength while allowing the user to easily attach, remove and clean the prosthesis. Testing proved our design has better attachment capabilities compared to the magnetic attachment method.

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Introduction

Background and Motivation

Ear deformities can be the result of physical trauma or a congenital disorder experienced at birth. One in every 10,000 children is born with a condition called microtia, with a higher incident rate in children of diabetic mothers and infants exposed to intrauterine varicella [1]. Microtia is characterized by a severely deformed external ear lacking an external auditory canal, meatus, or tragus (Figure 1). The auricle is commonly reduced in size with an abnormal shape, vertical orientation, and an abnormal location [1]. Specific syndromes associated with microtia include Treacher Collins Syndrome, Branchial-oto-renal syndrome, and Goldenhar's Syndrome. Each is associated with underdeveloped external ears among other deformities. Deformities of the ear are traumatizing for young children in challenging social situations and public realms. Furthermore, functioning at any age level presents challenges to the individual with a facial defect. Prosthetic reconstruction is an option for patients with underdeveloped ears or ears that have been compromised by injury, disease, or surgery (Figure 2).

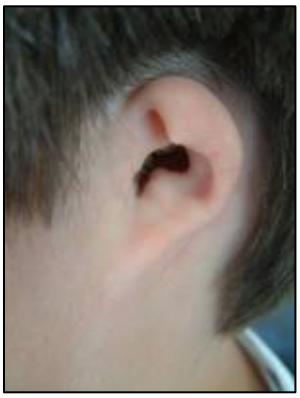

Figure 1: This is an example of microtia, where the outer ear is underdeveloped [4].

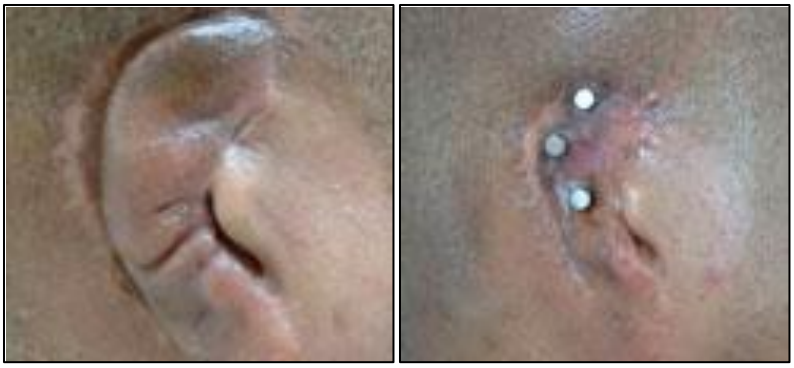

Figure 2: The picture on the left is an example of outer ear damage resulting from ear trauma. As shown on the image on the right, the outer ear was removed and three abutments were implanted in the bone for the attachment of an auricular prosthesis. The implanted abutments have magnetic caps used in the magnetic attachment method [4].

In the United States, craniofacial implantology is a relatively new field that erupted roughly 30 years ago. Professionals in the field are called anaplastologists and they work to create and apply prosthetic materials for the construction and/or reconstruction of a missing body part [2]. Anaplastologists stress visual and functional integration for those viewing the prosthesis and those who must be comfortable wearing the prosthesis. An important aspect of craniofacial implantology is creating a symmetrical device which appears as if it were the original, intact tissue. Attachment to the body, especially in terms of facial prosthetics, requires advanced techniques and perfection so that the prosthesis is not noticed due to poor visual integration. An auricular prosthesis is difficult to attach to the body due to the limited about of material to work with and the diverse forces subjected to the ear during a typical day. Therefore, continual development and improvement of prosthetic ear attachment methods is necessary to fully accommodate patients in need of these devices.

Reasons for a New Device

Facial trauma is a dramatic event in a person's life both physically and psychologically. Trauma to the face could be the result of surgical removal of tissue due to cancer or an accident. In other cases, people may be born with facial deformities as is often the case with children's ears. There are different options for fixing these deformities including surgical implants or non-implant alternatives.

Our goal is to find a method to securely attach auricular prostheses when the surgical implant method is used. The purpose is to design and fabricate an attachment to augment the magnetic components currently used to retain silicone auricular prostheses. The current bar-clip and magnetic techniques both have disadvantages. It is desired to retain the current magnetic attachments and the magnetic caps that mount on each abutment. The objective is to incorporate a passive locking mechanism to safeguard the prosthetic ear from complete dislodgement due to a posterior or anterior

applied force. Additionally, when the locking mechanism is not engaged, minimal effort should be required to remove and attach the ear to the surgical implants.

Current Devices

Currently, the simplest attachment methods are the slip-on prosthesis and the prosthesis attached with an adhesive (Figure 3). These methods do not require surgical implants, thus, they will not be the focus of our discussion despite their advantages and relevance for certain patients.

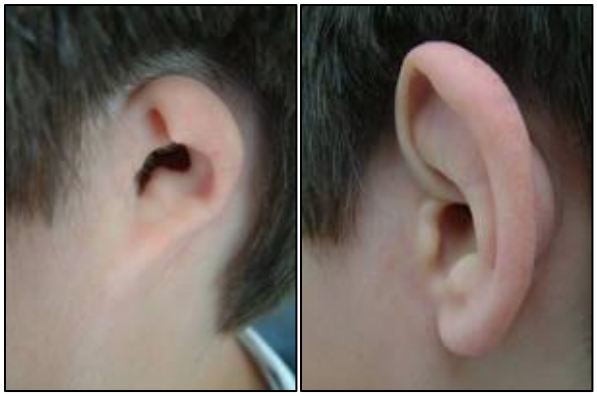

Figure 3: The figure on the right is an example of a slip-on auricular prosthesis, which disguises the microtia present in the image on the left [4].

There are several methods available to attach an auricular prosthesis to an implant. The two most common methods are the bar-clip method and the magnetic attachment method. In the bar-clip method, the implants are integrated into the bone and a titanium bar is screwed into the implants (Figure 4). Clips in the prosthesis clip onto the bar. However, this method is difficult to clean and the clips in the prosthesis often fracture due to wear. Additionally, each bar must be custom made since the placement of the abutments varies from patient to patient. This makes fabrication of the prosthesis time consuming and expensive [2].

Figure 4: This image displays an example of the bar-clip attachment method. For this attachment method a bar was screwed into a surgical implant. Clips in the prosthesis snap onto the bar to hold the prosthesis in place [4].

The magnetic attachment method utilizes a magnetic force system. The implants are secured in the bone and magnetic abutments are screwed into the implants (Figure 5). Magnets corresponding to each abutment are bonded into the prosthesis. The advantage of the magnetic attachment method compared to the bar-clip method is that it is less bulky and easier to clean around, but there is no security in the attachment. In order to overcome this problem, o-rings have been placed in the magnetic attachments in the prosthesis to create a more secure fit between the prosthesis and abutments. However, this creates an attachment that is too strong and makes the prosthetic ear difficult to remove. Using excessive force to remove the prosthesis increases the chance of breaking the implants, which would require additional surgery for the patient.

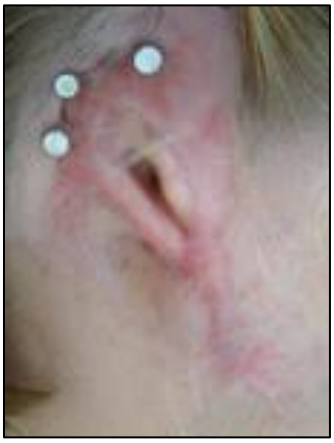

Figure 5: This is an example of the magnetic attachment method. Magnetic caps are screwed onto abutments that have been implanted in the bone. Matching magnets in the prosthesis then hold the ear in place [4].

Previous design teams have tried to engineer a new method of attachment to no avail. Their methods have both advantages and disadvantages. Last semester a design team created a spring and sheath design (Figure 6). This design provides lateral stability that is lacking in the magnetic attachment

method. The use of the spring also decreases the odds of sheath fracture. The sheath allows for easy attachment and detachment but lacks magnets which decreases the attachment strength. A major point the team forgot to consider was that during the making of the prosthesis silicone is poured into the mold which contains the attachment mechanisms. Silicone could leak into the spring and sheath which compromised this method of attachment.

Figure 6: This is an image of the spring and sheath attachment design. This design prevents lateral displacement of the prosthesis, but it does not contain magnets to hold the prosthesis securely [5].

Two years ago, a design team developed the prong and flange design (Figure 7). This mechanism is made from a plastic which compromises the strength and durability of the attachment. This design also requires the user to twist the ear slightly during attachment. This requires precise placement of the attachments in the prosthesis and makes attachment and removal of the device difficult for the patient. This design provides a secure attachment, but the twisting is not ideal.

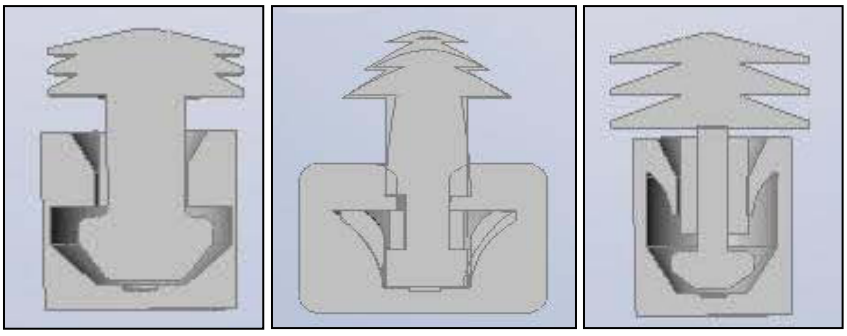

Figure 7: This image displays the prong and flange design, which is made of plastic and requires the user to twist the ear during attachment and removal. This design is not ergonomically friendly and the materials are not sufficiently durable [6].

Design Criteria

Key aspects of the design should address the following points: the device should resist unintentional dislodgement, be low profile, be completely contained within the prosthetic ear, be able to withstand considerable anterior and posterior forces, and require minimal effort to attach and remove.

The prosthesis should not be disrupted by daily activities. These could include putting on clothes, giving or receiving a hug, being bumped by a passerby, or other casual contact. Current devices seem to acknowledge superior/inferior and medial/lateral forces, but the current methods do not adequately address anterior/posterior forces, which is a goal of this project. However, the attachment should not inhibit the removal process. One objective is for the attachment mechanism to break due to an overwhelming force to protect the abutments and underlying bone.

The device needs to fit with the commonly used abutment sizes which are 4.4 mm in diameter. Other size restraints include that the mechanism must be completely contained within the prosthesis and be no larger than the current magnetic attachments. Anything larger than this creates difficulties in concealing the mechanisms in the prosthesis.

The materials used must be compatible with silicone and the body. This implies that the device would be rust and weather-proof. Preferably, titanium or surgical grade stainless steel would be used. Materials used must be FDA approved because they will be used in a medical setting.

On an ergonomic front, the prosthesis should be easy to attach and remove with the new attachment system. The patient should not be required to spend a significant amount of time, force, or attention to detail when attaching and detaching the ear. Similarly, all components should be easy to clean.

Overview of Design Alternatives

Vertical Track Design

The vertical track design would add horizontal stability to the current attachment method by adding a track system to support the current magnetic abutments. Each abutment implanted in the skull features a magnetic cap with a slightly larger diameter than the abutment shaft. In this attachment system each abutment would have a corresponding track implanted in the prosthesis as shown in Figure 9. Each track would have a diameter of 6.25 mm and would be made of surgical grade stainless steel or

titanium. Each track would additionally have a small T-slot, with an opening on the lower end, large enough for the entire head of the abutment to fit through, and a narrower opening on the upper end, which is only wide enough for the shaft (Figure 8). As the ear is slid downwards into the locked position the lips of the track would hold the abutment in place horizontally, while a small recessed magnet (shown as a shaded circle in Figure 8) in the narrow end of the track would hold the prosthesis in place vertically. To remove the ear, patients would have to slide the ear upwards and pull the ear away from their head to remove the abutments from the tracks. The motion is simple and helps prevent unintentional vertical dislodgement of the ear, because the prosthesis would naturally slide back into place when adjusted vertically.

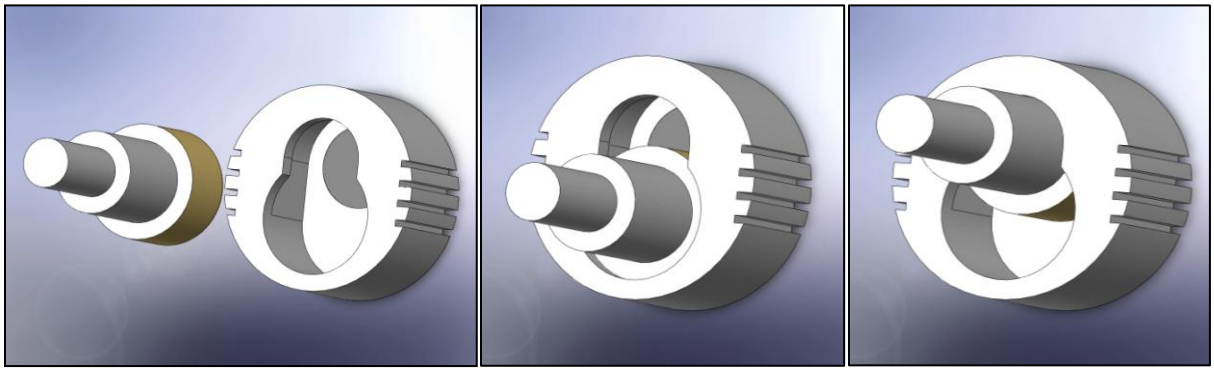

Figure 8: The image on the left shows a single track, which would be implanted into the silicone prosthesis, and an abutment, which would be screwed into the skull implants. The brass colored section of the abutment represents the magnetic cap of the abutment, while the shaded circle of the track represents the recessed magnet for the track. This succession of images shows how the vertical track design would slide from the unlocked to the locked position.

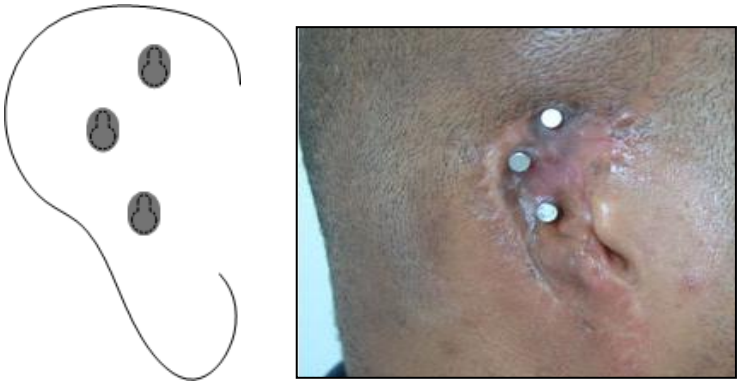

Figure 9: As shown on the left, three vertical tracks would be positioned in the prosthesis to match the implanted abutments, which are shown to the right [4].

Curved Track Design

The curved track design would use the same concept as the vertical track design except the track would be curved instead of linear. The attachment would be a mostly hollowed out curved half cylinder made of stainless steel or titanium (Figure 10). There would be a circular opening near the bottom of the

top face of the attachment with a diameter slightly larger than the abutment head diameter. The inside of the attachment would feature a track with a width slightly larger than the abutment head diameter so that the abutment could slide along the track. A circular opening for a magnet would be present on the bottom face of the attachment. The diameter of this opening and the magnet would be the same as the diameter of the abutment head. The track would allow the abutment to be positioned over this magnet. The top face of the attachment would have a cut with a width slightly larger than the abutment shaft that is aligned with the hollowed out track to allow the abutment to slide along the track. The width of the cut would be less than the diameter of the head of the abutment so that when the abutment is anywhere along the track it cannot be removed from the attachment (Figure 11).

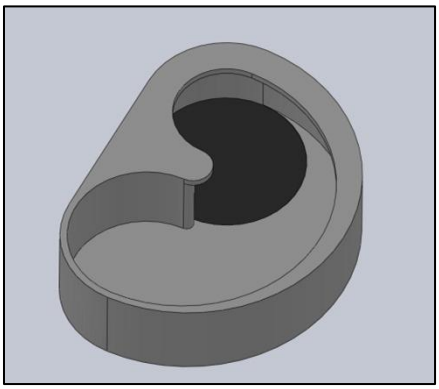

Figure 10: This image displays an individual curved track. The shaded black circle represents a recessed magnet.

Three attachments would be positioned in the prosthesis so that they align with the abutments implanted in the skull. Magnets would be placed in the prosthesis under each attachment so that they align with the openings on the bottom face of the attachments. To attach the prosthesis, the user would position the wide sections of the track over the abutments as shown in Figure 11. The prosthesis would then be moved in a semicircle motion until the magnet was positioned over the abutment. To remove the prosthesis, the user would move the prosthesis so that the abutments were aligned with the wide sections of the track again.

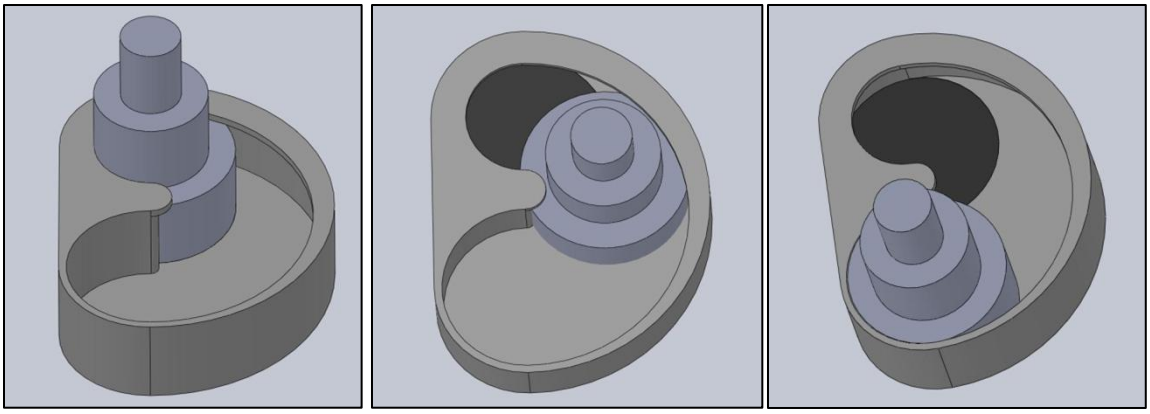

Figure 11: This succession of images shows the process of securing the abutment into the curved track

C-Ring Clip Design

The c-ring clip design is a modification of the vertical track design. The c-retaining ring design was designed to house a c-retaining ring in addition to the magnet (Figure 12).

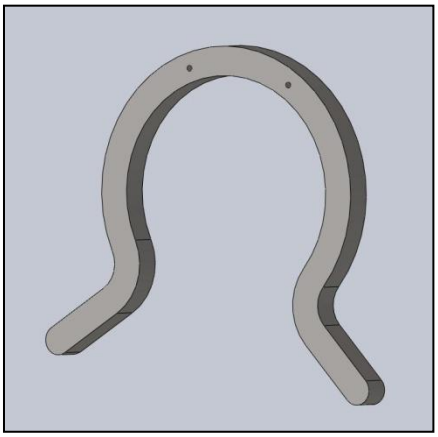

Figure 12: A c-retaining ring such as the one that would be used in the c-ring clip design

The c-ring would be located in the track as shown in Figure 13**.** It would be anchored at the top of the track which would allow the two legs of the clip to move outward while it is pushed over the shaft of the abutment. In order for the legs to move outward, part of the track would have to be cut out so the legs do not hit the sides, refer to Figure 13. The track would have to be slightly deeper and longer than the vertical track to accommodate the width and length of the c-ring.

To attach the device to the abutment, it would be the same as the vertical track method except it would take slightly more force to push the prosthesis downward onto the abutments. The extra force results from forcing apart the c-ring legs as the c-ring slides over the abutment shaft.

The purpose of the c-ring is to add more surface area to the lip of the abutment than the vertical track as the c-ring would wrap around more than 180^{o} the shaft. It would also make it harder for the prosthesis to be pushed upwards.

A method for replacing the c-ring while leaving the rest of the track in place would be necessary, because after continual use it could become weak and break. The c-ring would be small and made of steel.

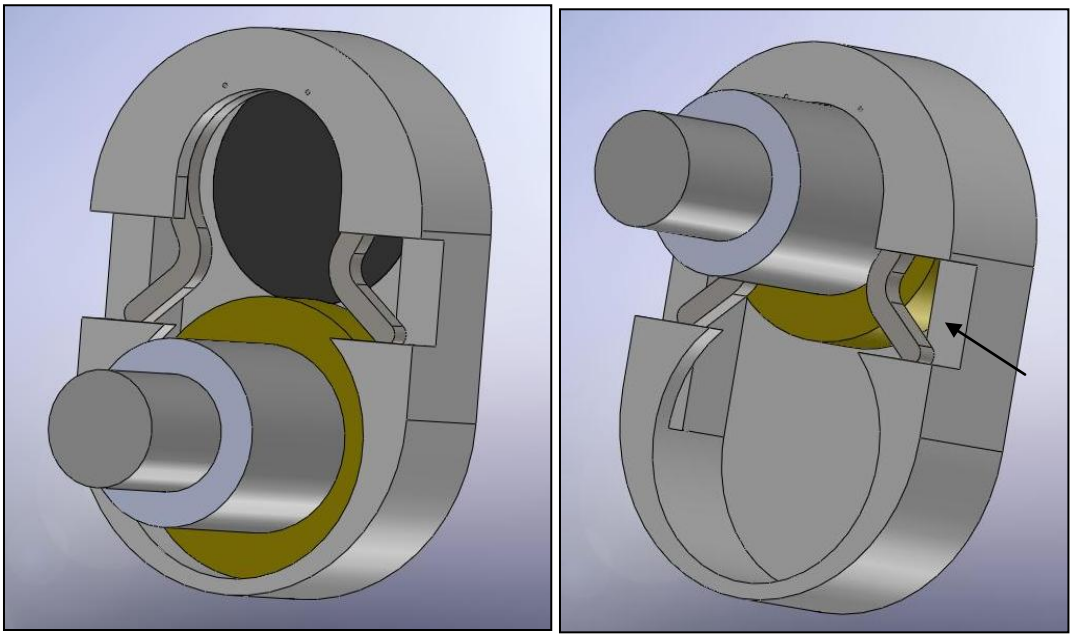

Figure 13: The figure on the left shows the c-ring clip in its unlocked position, while the image on the right shows the abutment in its locked position. The cut out (as indicated by the arrow) allows the legs of the c-ring to move outward as the shaft of the abutment slides past. The shaded circle shown in the left hand image represents a recessed magnet.

Evaluation of Design Alternatives

In order to choose the final design, a design matrix was created that rated each design alternative on six criteria: quality of attachment, ease of attachment, ease of removal, ease of cleaning, feasibility, and cost. The most weight was given to the quality of attachment, ease of attachment and ease of removal categories, because these three criteria are most important to the patient (Table 1).

The quality of attachment rating reflects how reliably the prosthesis would stay attached to the head and resist unintentional dislodgement. This category was given the most weight because the main purpose of designing a new attachment is to ensure that the prosthesis remains in place throughout daily activities. The vertical track design would have a high quality of attachment because the positioning

of the prosthesis' magnet over the abutment would hold the prosthesis in position throughout normal motion of the body and head. If any downward, anterior or posterior force is applied to the prosthesis, the walls of the attachment would prevent movement of the prosthesis relative to the head. If the prosthesis is pulled away from the head, the lips of the abutment head would come in contact with the track because the track is narrower than the diameter of the abutment as long as the magnet is positioned over the abutment. The disadvantage of the vertical track design is that if an upward force is applied to the prosthesis, the abutment could detach from the magnet and move into the wide section of the track, increasing the chances of the prosthesis detaching completely. The curved track and c-ring clip designs have the same quality of attachment features as the vertical track except they would be more resistant to detachment due to an upward force. A prosthesis attached using the curved track design would have to be moved in a semicircle motion to position the abutment in the wide section of the track. If the prosthesis is forced in such a way that the abutment becomes detached from the magnet, the lips of the abutment would still come in contact with the curved portion of the track. This makes it much less likely that the prosthesis would be removed unintentionally. A prosthesis with the c-ring design would be more secure because the c-ring would provide resistance to an upward force, making it less likely for the abutment to move into the wider section of the track.

The ease of attachment rating reflects how simple and efficient attachment of the prosthesis would be for the user. The amount of time, force, and motion required for attachment were considered. This category was given considerable weight because after keeping the prosthesis in place, the next most important aspect of our design is that it does not make use of the prosthesis complicated or tedious. Attachment using all three designs would require the user to position the wide sections of the tracks over the abutments. After that step, the ease of attachment would vary with each design. The vertical track design would provide the easiest attachment. The user would only need to pull down on the prosthesis to bring the magnet over the abutment. Gravity, along with the attraction between the abutment and the magnet, would make this process almost effortless. A prosthesis with the c-ring design would be more difficult to attach because the user would have to apply enough force for the c-ring to snap over the abutment. A prosthesis with the curved track design would be the most difficult to attach because the user would have to move the prosthesis in a semicircle motion to position the magnet over the abutment instead of the simple downward motion required by the other two designs.

The ease of removal rating reflects how simple and efficient removal of the prosthesis would be for the user. The amount of time, force and prosthesis movement required for removal were considered.

This category was given a lot of weight because the use of the prosthesis cannot be complicated or tedious for the user. Removal using all three designs would require the user to position the prosthesis so that the wide sections of the tracks are in line with the abutments. Getting the prosthesis to this position would require a different degree of difficulty with each design. The vertical track design would provide the easiest removal. The user would only have to apply an upward force to the prosthesis with enough magnitude to overcome the magnetic force between the abutment and magnet. The curved track design would provide a slightly more difficult removal because in addition to overcoming the magnetic force, the user would have to move the prosthesis in a semicircular motion. A prosthesis with the c-ring design would be the most difficult to remove because a much larger amount of force would be required to remove the abutment from the c-ring.

The ease of cleaning rating reflects how simple and efficient cleaning of the prosthesis would be for the user. The amount of time and effort required for prosthesis cleaning were considered. This category was given less weight than the other ease of use categories because all three designs should be relatively easy to clean. The vertical track and curved track designs would be simple to clean because the attachment would be one continuous surface. The c-ring clip design would be more tedious to clean because the c-ring would be attached to the main track part, leaving small crevices that would be difficult to clean.

The feasibility rating reflects the ease of fabrication and the likelihood that three attachments fit in the prosthesis. This category was not given a lot of weight because our client is more focused on having an innovative idea than a working prototype. Also, all of our designs should be small enough to fit in an auricular prosthesis. The vertical track design would be the most feasible because it would be the least complicated design to fabricate and would also be the smallest design. The c-ring design would be larger than the vertical slot to incorporate the c-ring and more difficult to fabricate because the c-ring would have to be attached to the main part. The curved track design would be the least feasible because it would be larger than the other two designs and may not fit in small child-sized prostheses. The curve of the track would also make fabrication more difficult because different designs would have to be used for a left and a right ear.

The cost rating reflects the anticipated cost of materials and fabrication for each design. This category was given little weight due to the flexible budget for the project. The vertical track design would be the most inexpensive option because it would require the least amount of material and consist of one part. The curved track design would be slightly more expensive because it is larger and requires

more material. The c-ring clip design would be the most expensive because it would require two separate parts and a method of attaching those two parts.

Aesthetics was not considered in our evaluation because all three designs would be contained inside the prosthesis and would be unnoticeable when the prosthesis is in use.

Table 1: Design Matrix

Criteria	Vertical Track	Curved Track	C-Ring Clip
Quality of Attachment (30)	25	27	27
Cost (5)	5	3	2
Feasibility (10)	6	3	2
Ease of Attachment (20)	17	13	16
Ease of Removal (20)	18	16	14
Ease of Cleaning (15)	14	14	12
TOTAL (100)	**87**	**76**	**77**

Final Design

We chose the vertical track design as our final design because, of the three design alternatives, it best meets the design specifications. With the combination of the magnet and the contact between the abutment and the track, the vertical track attachment will ensure that the prosthesis is secure on the head and resistant to unintentional removal. The vertical track attachments provide the user with a quick and easy attachment and removal process. Also, the attachments are slightly smaller than the current magnetic attachments so they will easily fit into the prosthesis.

An initial prototype of the vertical slot design was created to validate the concept of the design and to demonstrate the use of a prosthesis using this attachment method (Figure 14). Multiple attachment devices and abutments were rapid prototyped using a SolidWorks part file. The plastic used in rapid prototyping is weak when it is thin. Because of this, the prototype designs were simplified and made three times as large as the final prototype. Three holes for the abutments were drilled in a piece of plastic to represent the user's head. Three more holes for the attachments were drilled in the same pattern in another piece of plastic to represent the prosthesis.

Figure 14: This is an image of the initial enlarged prototype of the vertical track design. Three vertical slots have been implanted in the smaller piece, which represents the ear. The larger piece represents the skull and has three enlarged abutments.

Our final design acquired some changes after the initial prototype was created. First, the final attachment prototype is made of a titanium alloy, Ti-6Al-4V, which, when used in low to moderate temperatures, has high strength, is light weight, and has great corrosion resistance. For these reasons Ti-6Al-4V titanium is often used in medical applications and is a suitable material for the attachment [7].

A SolidWorks model of an attachment is shown in Figure 15 and a SolidWorks drawing with the dimensions of the attachment is shown in Figure 16. The attachment is compatible with standard mini abutment caps, which have a diameter of 4.4 mm and a thickness of 2.1 mm. The outer diameter of the attachment has been changed from 6.25 mm to 7 mm to increase the length of the track. The attachment is 4 mm thick, which includes 1mm for the thickness of the magnet, 2.5 mm for the height of the abutment head, and 0.5 mm for the final wall thickness.

The largest change to the attachment is the increased size of the magnet used to hold the abutment head in place. The magnet used in the final design is a 1 mm thick, 6 mm diameter neodymium magnet, which is press-fit into a 1mm deep, 6 mm diameter hole in the attachment. The increased size of the magnet avoids centering problems that could occur when using a magnet with a diameter equal to that of the abutment head. The larger magnet also helped reduce fabrication costs by eliminating the need for a custom ordered T-slot mill bit, since the large pocket allowed machinists to cut the interior slot from the back face.

Additionally, 18-8 stainless steel general purpose flat washers are added to the threads of the magnacap to act as spacers and increase the gap between the head and shaft of the abutment. This gap is sufficient to allow the 0.5 mm thick face of the attachments to slide with minimal friction.

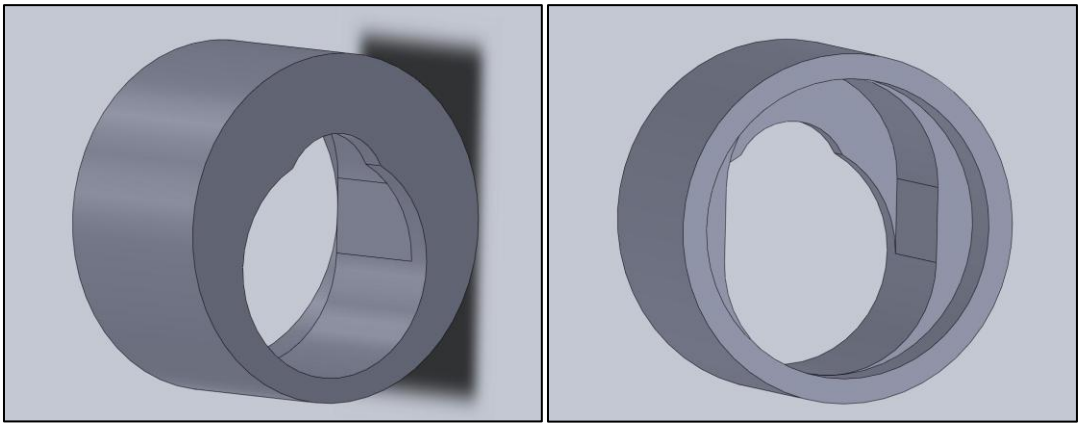

Figure 15: This figure shows a SolidWorks model of the final vertical track attachment.

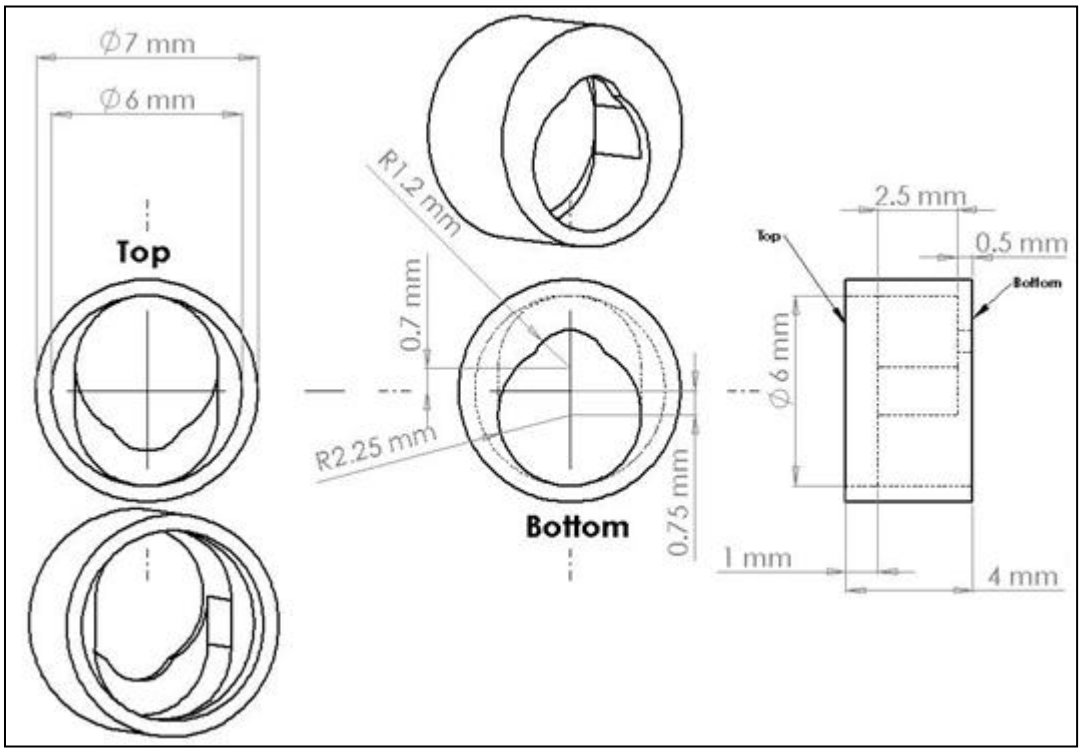

Figure 16: This figure shows the dimensions for the vertical track in mm.

Cost Analysis

Our team purchased 25 stainless steel washers from McMaster-Carr, three neodymium magnets from gaussboys.com, and had three attachments fabricated for a total of $196.97 (Table 2). The

attachments were fabricated by Daniel Bye of TosaTool. The total cost per attachment was $63.26 as compared to a cost of $109.95 per attachment for the current method. Our client, Greg Gion, estimates that about 10,000 attachments could be sold per year (personal communication, April 28, 2010). The fabrication of a large quantity of attachments would be significantly cheaper, decreasing the cost per attachment from $62.26 to less than $15 (D. Bye, personal communication, May 4, 2010).

Table 2: Cost table showing individual item costs as well as total cost per prototype and total cost per attachment.

Item	Manufacturer	Cost
3 Custom machined vertical slot attachments	Dan Bye of TosaTool	$185
3 6mm x 1mm N83 Nickel Plated Neodymium Magnet Discs (Model D0601)	Gaussboys.com	$0.21
25 18-8 stainless steel general purpose flat washers, No 00 screw size, 7/64" OD, 0.01-0.02" thick (part 92141A207)	McMaster-Carr	$11.55
		Total Cost: 196.76 Added Costs: material shipping
		Cost per Attachment: 63.26
		Cost per Attachment for Current Method: 109.95

Ergonomics

The device incorporates several aspects of universal design. The device is symmetrical and has the capability of being used on either side of the head. This simplifies the process of implanting the attachment mechanism into the prosthesis and shortens the attachment time required for the patient. To accommodate users of all literacy abilities, there is no writing on the device. It is also simple enough that an instruction manual on how to use the device could consist of pictures with no words to demonstrate each step of use.

The patient should be able to attach and remove the prosthesis with minimal effort and without the aid of vision or a mirror. The new device is as easy to line up with the abutments as the current

device since the team did not change how it is done. The device contains no moving parts which makes using the device intuitive and avoids any user confusion. With no moving parts the device is easily implemented in the silicone during creation of the prosthesis. The design features only a small number of simple components which simplifies the fabrication process and lowers the cost for mass production.

The device should not cause discomfort to the user. There is a small possibility that the device could pull or stretch the skin on the side of the head downward while the prosthesis is slid the 2 mm required for engaging the device. The potential for discomfort will not be known until testing on patients is done. The limited motion needed to correctly position the prosthesis on the head should not pull the skin enough to cause noticeable displacement of the skin to bystanders. The device has minimal clearance between it and the abutment when being attached causing no area for skin to be pinched.

Our group needs to develop the potential to replace the attachment device within the prosthesis if it breaks. This would make the device considerably more ergonomic because it would allow the prosthesis to have a longer life in service. The current method does not have a way to replace the attachment devices in the prosthesis without ruining the prosthesis. The current idea for making our device replaceable is to have each of the attachments threaded on the outside (Figure 17). There would be a female cap that would have matching threads inside it where the attachment devices would screw into (Figure 18). The cap would be imbedded into the silicone prosthesis.

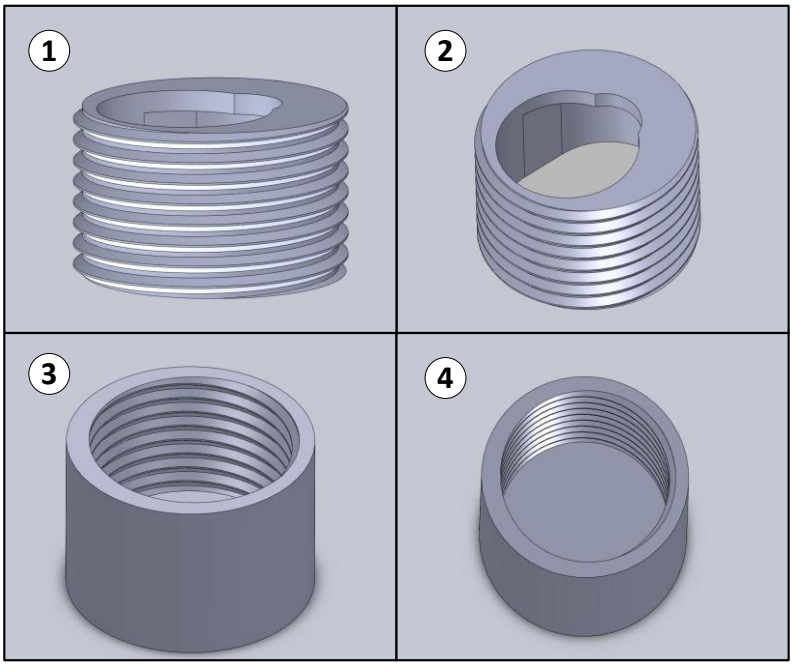

Figure 17: (1&2) Here the attachment is threaded. (3&4) This is an example of the small female cap with threads.

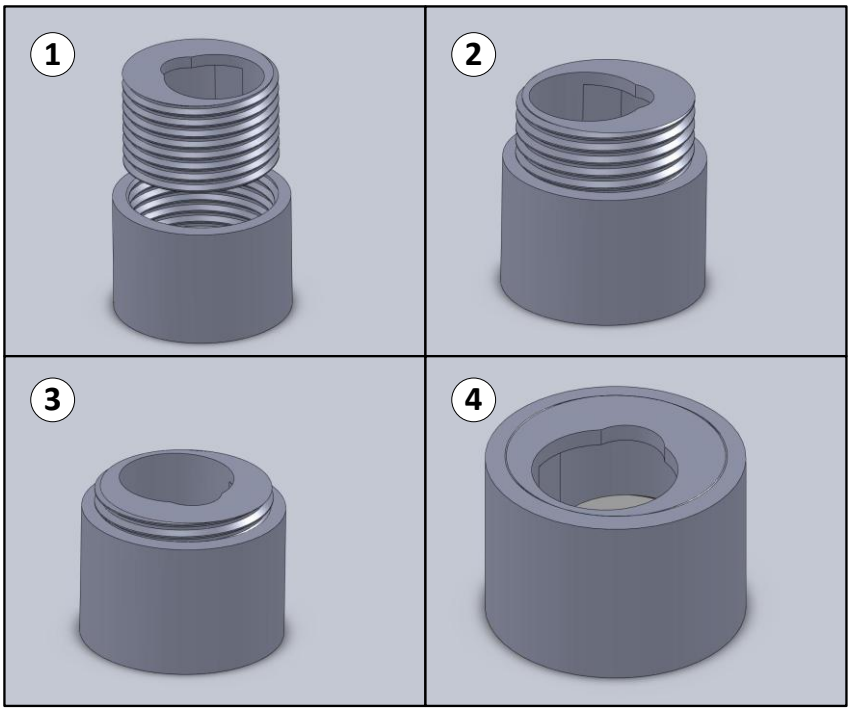

Figure 18: (1) The attachment and the cap are aligned. (2&3) The attachment is then threaded into the cap which is imbedded in silicone. (4) The attachment is screwed in until the tops of the attachment and the cap are flush.

Fabrication Process

Fabrication of the final design prototype requires advanced machining. Due to small dimensions, the tolerances are forced high. The overall dimensions are as shown in Figure 16**.** All wall thicknesses are at least 0.5 mm thick and it is fabricated from Ti-6Al-4V titanium alloy. There are two components, the body of the track and the magnet insert.

Due to the small size of the project, a big concern was the cost of fabricating a prototype. We sent our design drawings and specifications to several professional machine shops as well as the professional College of Engineering machine shop. The winning bid for machining the three parts was $185.00 from TosaTool located in Madison, WI.

Outlined below are the steps necessary to machine the piece. The machining technique details have been left out of the outline due to the experience needed to complete the part. All milling depths are referenced from the top surface of the part. The materials required are neodymium, nickel plated magnets that are 6mm in diameter and 1 mm thick and a Ti-6Al-4V rod that is at least 7mm in diameter

and 10cm long. All inside pockets should be at least the dimensions specified. Any tolerance errors should be made so the dimensions are larger than specified.

The first step to machining the part is to chuck a rod of titanium into the lathe chuck as shown in Figure 19. The rod's diameter should be greater than or equal to 7 mm. If the rod has a diameter larger than 7 mm it can be turned to the specified diameter in the following steps.

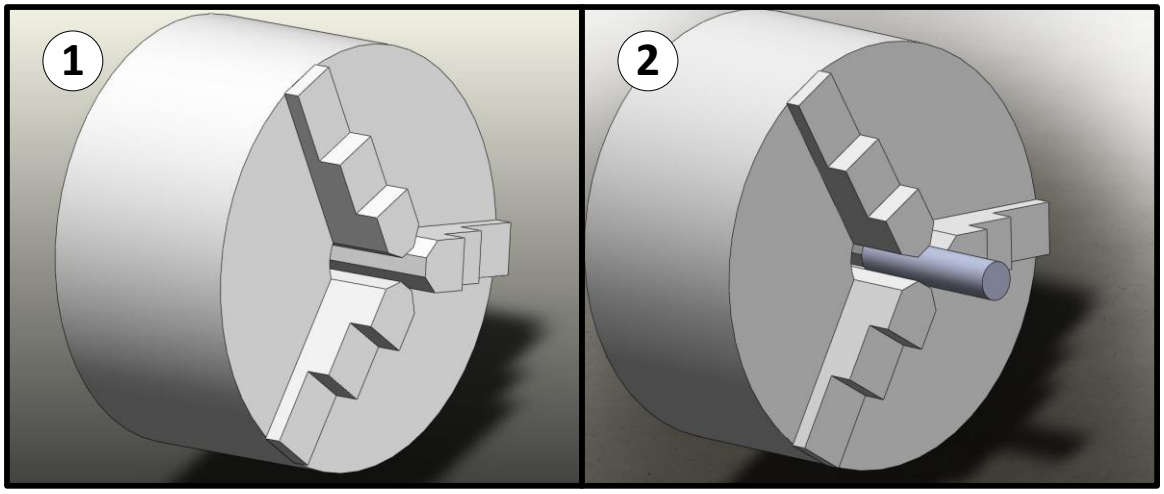

Figure 15: In the first step of the fabrication process, chuck a titanium rod with a diameter ≥ 7 mm.

After the material is secure, turn down the rod to 7 mm in diameter as shown in Figure 20. For thicker rods, take many passes to reach the final diameter to ensure the rod is not bent due to too much force from the carbide cutter. Only turn down the rod to a length of about 8 mm to add strength to the part during milling.

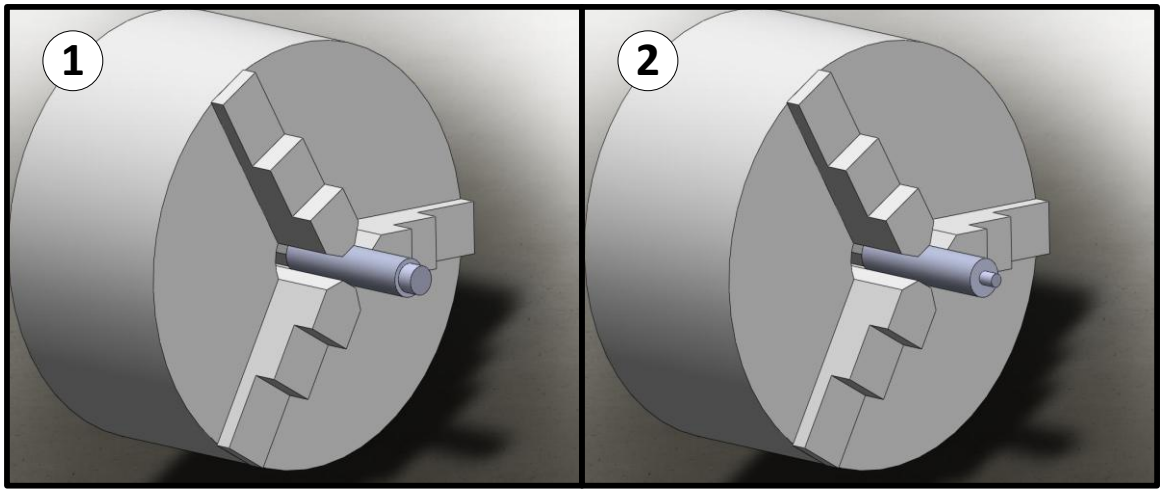

Figure 16: The rod is then turned down to 7mm in diameter with several passes.

Once the rod is turned down to 7 mm, clamp it securely into a milling vice as shown in Figure 21. Be sure to clamp it so the rod is orthogonal to the milling table.

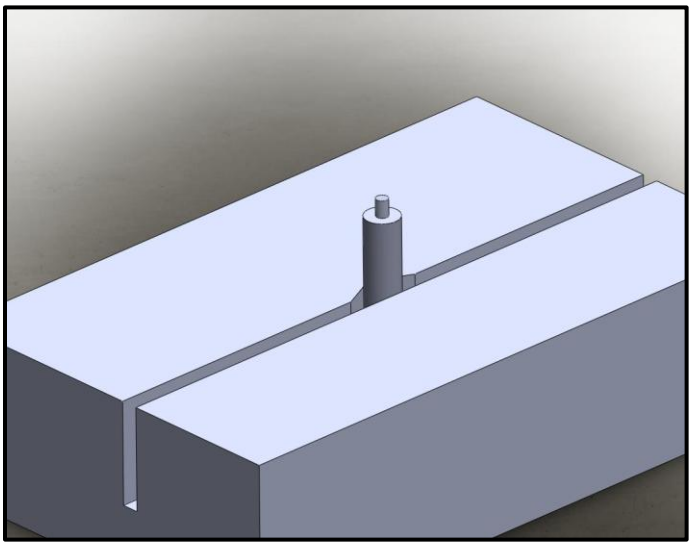

Figure 17: The rod is clamped in a milling vice, orthogonal to the table.

Using a straight mill bit, a 4.5 mm wide pocket is milled through the center of the rod and 0.5 mm from each edge to a depth of 3.5 mm as shown in Figure 22(1). The pocket should have ends with a radius of 2.25 mm. Next, a 6 mm diameter pocket is milled concentric with the rod to a depth of 1 mm as shown in Figure 22(2). This is where the 6 mm magnet will go. It is best if it is milled to just under 6 mm in diameter so the magnet can be pressure fit in. Test the size with a magnet until a magnet can be pressure fit in, but do not get the magnet stuck until after piece is completed.

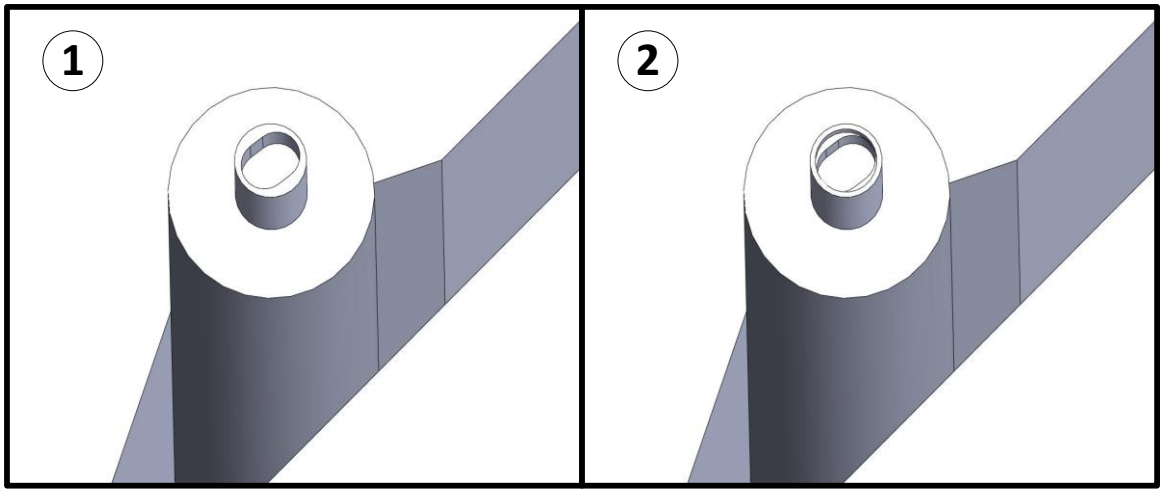

Figure 18: (1) A pocket is milled to a depth of 3.5mm through the center of the rod, each end has a radius of 2.25mm. (2) A 6mm diameter pocket is milled concentric with the center to a depth of 1mm.

A 4.5 mm hole is then milled through one end of the track to a depth of at least 5 mm as shown in Figure 23(1). It is important that this hole is exactly in line with one end of the first pocket milled, shown in Figure 22(1). The center of this hole is 0.75 mm from the center of the rod and is coincident with the axis of the first pocket. Next, a 1.2 mm radius is milled to a depth of at least 5 mm into the part as shown in Figure 23(2). The radius has a center that is 0.7 mm from the center of the rod in the opposite direction of the 4.5 mm diameter hole. The center of the radius is coincident with the axis of the first pocket.

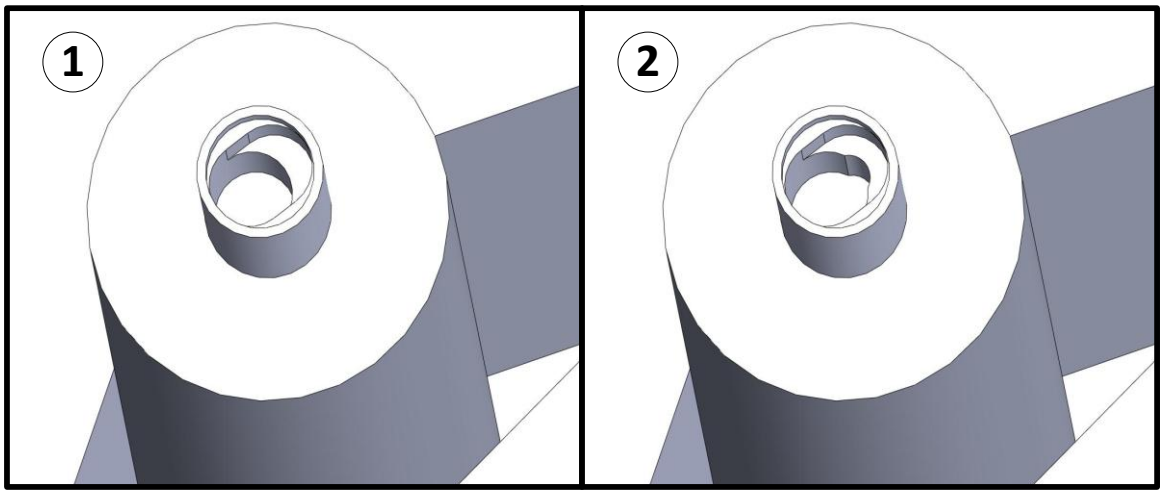

Figure 19: (1) A 4.5mm diameter hole is milled into the part. (2) A 1.2mm radius is milled into the part.

After all the pockets are milled, the rod is then put back into the lathe chuck for removal of the part (Figure 24).

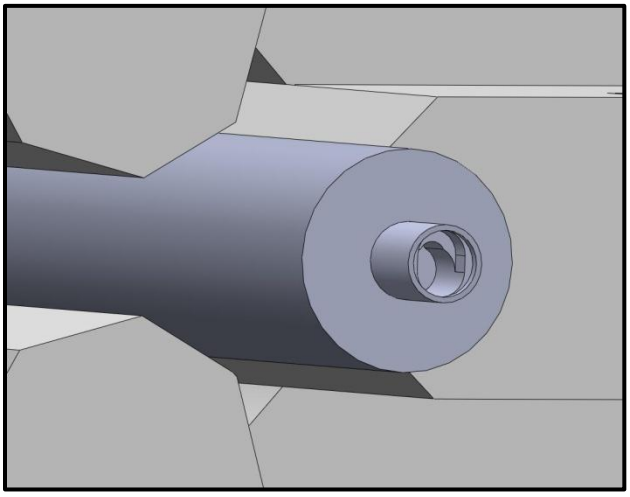

Figure 20: The part is secured in the lathe chuck, ready to be removed from the rod.

With a cutting tool, cut the piece off from the rod 4 mm from the end of the part as shown in Figure 25.

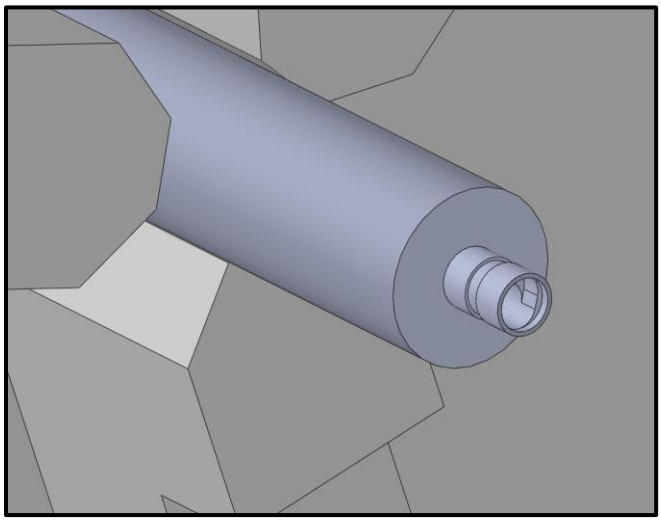

Figure 21: The part shown is partially removed from the rod 4mm from the end.

The finished piece is then cleared of any burrs with a fine file. It is now ready for the insertion of the magnet (Figure 26).

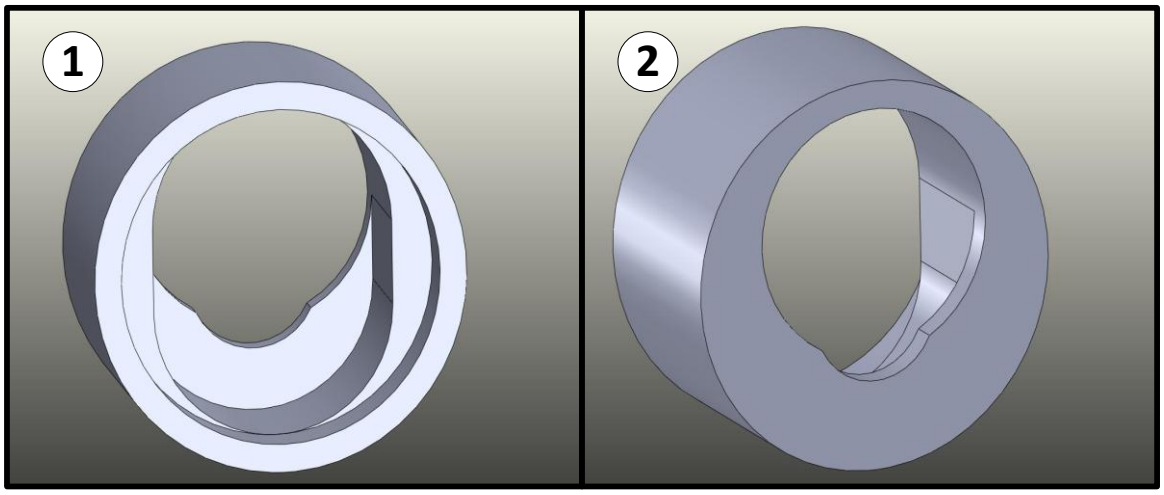

Figure 22: The part free and cleared of any burrs.

A 6 mm diameter magnet is pressure fitted in the 6 mm pocket. After the magnet is in place the part is complete as shown in Figure 27.

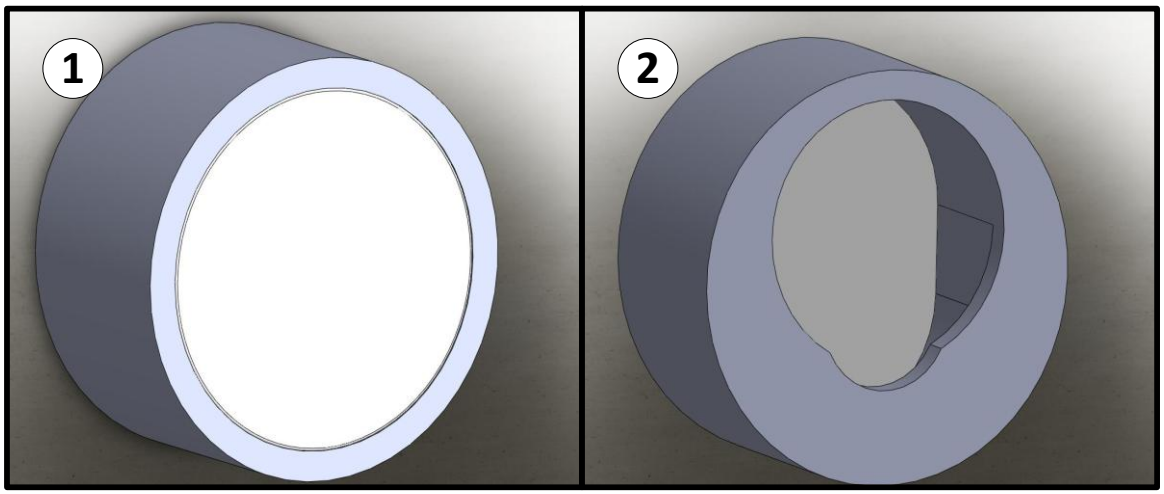

Figure 23: Completed part with magnet.

Testing

The main objective in the design of a new attachment method was to decrease the likelihood of the prosthesis being detached unintentionally. The testing of our prototype focused on the amount of force applied in various directions required to remove the prosthesis. Two prostheses, one using the current magnetic attachment method and one using our sliding attachment method, were compared. The attachments were arranged as most commonly used in current applications, with the two attachments toward the back of the prosthesis using the current magnetic method contained O-rings. Posterior and anterior forces, the two most common causes of unintentional removal, were tested first. Other directions tested were upward, downward, lateral outward from the body, and 30 degrees outward from the back. The prostheses were attached to abutment replicas implanted in a head model. The head model was positioned vertically and clamped to a table (Figure 28). The prosthesis was pushed with a force gauge until it was removed from the abutments. For the lateral outward trials, a string was attached under the center of the prosthesis and the force gauge was pulled away from the head model (Figure 29).

Figure 24: Head model and prosthesis clamped to table.

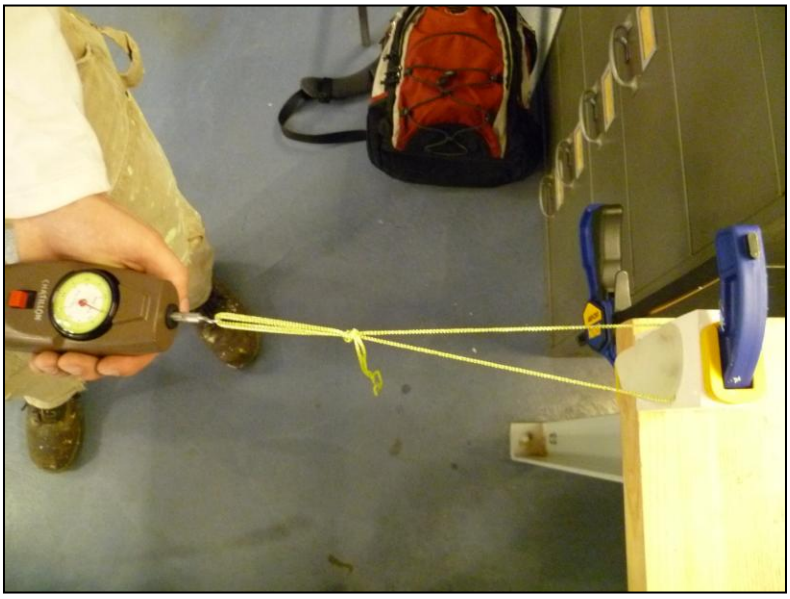

Figure 25: Test setup for lateral outward force test.

Ten trials were performed on both prostheses in each direction and the force required to remove the prosthesis was recorded. Forces were measured in kilogram-force (kgf). One kgf is equal to 9.81 N. The results of each trial can be found in Appendix B. The average force required to remove the prostheses in each direction can be seen in Figure 30. The prosthesis containing our attachment system was never dislodged from the model during testing. We decided not to apply more than 5 kgf (2.5 kgf for

lateral outward) to our prototype in order to avoid damaging the silicone. Even with this limitation the results show that our attachment method can withstand much greater forces than the current magnet method. The average forces withstood by the prosthesis containing the magnetic attachments are summarized in Table 3.

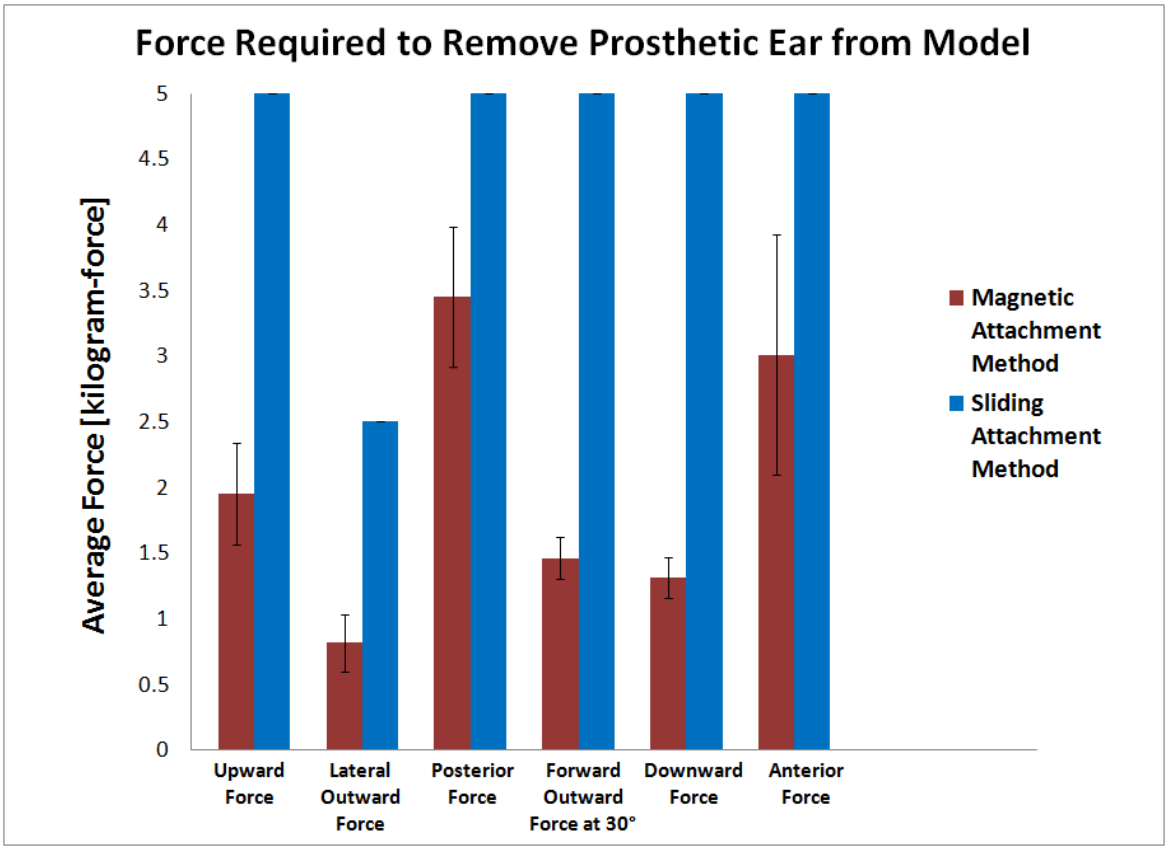

Figure 26: Average force required to remove the prosthetic ear with standard deviation bars. The sliding attachment model requires greater force than shown for removal. It was never removed from the head model to avoid damaging the prototype.

Table 3: Average forces withstood by the prosthesis containing magnetic attachments.

Force Direction	Average Force (kgf)
Upward	1.95 ± 0.39
Lateral Outward	0.81 ± 0.22
Anterior	3.46 ± 0.53
Forward Outward at 30°	1.46 ± 0.16
Downward	1.32 ± 0.15
Posterior	3.01 ± 0.92

A paired t-test was performed to compare the attachment strength of our design to that of the current method. The p-values for each force direction can be found in Table 4. These low p-values show that our attachment method has significantly better attachment strength than the magnetic attachment method.

Table 4: P-values

Force Direction	p-value
Upward	6.843E-10
Lateral Outward	7.496E-10
Anterior	3.647E-06
Forward Outward at 30°	6.743E-14
Downward	3.23E-14
Posterior	1.064E-07

Ethical Considerations

The primary ethical concern for this project is patient safety in the event the prosthesis is struck with considerable force. Due to chemotherapy or previous physical trauma the bone into which the abutments are implanted is often compromised and therefore weaker than normal bone. If the prosthesis is struck with significant force our device should break, allowing the ear to be torn away without damaging the abutments or the underlying tissue.

Future Work

Before continuing with the project, or making alterations to the design our group would like to continue testing. We would first like to conduct force testing on the bar and clip attachment method to determine the amount of force required to remove the prosthesis from six different angles. Additionally, we would like to conduct usability testing with patients to determine any unexpected problems in attaching or removing the device. We anticipate that most complaints about the device would result from complications in removing the prosthesis. If a patient attempts to remove the prosthesis at an angle, rather than horizontally, the prosthesis is difficult to remove. For this reason, our group would suggest making the abutment entry larger, perhaps an oval shape to facilitate attachment and removal. To test our device using patients, our group would first need to obtain permission in the form of an IRB. However, obtaining an IRB could take a considerable amount of time and our group must plan testing accordingly.

To ease the process of implanting the attachments into the prosthesis, our group would develop a system for aligning the attachments during the implantation process. This is essential to a successful product, because, for the prosthesis to slide into a locking position, all three attachments must be aligned parallel to each other (Figure 31). The current method for implanting the attachments depends on trial and error and takes a considerable amount of time. Additionally, prostheses must often be designed around the implanted attachments because the gray titanium can be seen through the silicone. To correct this, our group would like to find a method to disguise the attachments with a flesh-colored coating. This would alleviate the implantation process and ensure the prosthesis looks as lifelike as possible.

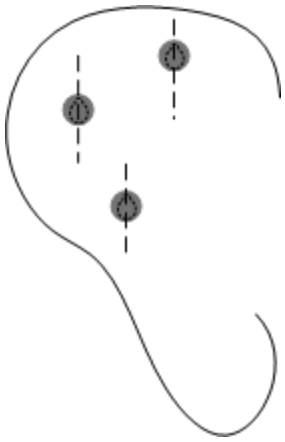

Figure 27: This figure shows the required parallel alignment of the attachments when implanted into the prosthesis. If the attachments are not oriented parallel to on another, the prosthesis will not slide.

Lastly, our group would like to develop a safety feature that causes the attachment to break if struck with significant force. Since many of the patients have compromised bone due to chemotherapy or trauma, this feature would have the attachment break before damage is done to the abutments or underlying bone. Testing would also be conducted to find out how much force is required to break the attachment, the abutment cap, and bone. Additionally, developing a system that allows for easy replacement of the attachments would allow patients to replace worn or broken attachments without replacing the entire prosthesis. This system would be especially useful in tandem with the safety feature allowing the attachments to break under significant stress.

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[2] Gion, G. G. 2006. Surgical versus prosthetic reconstruction of microtia: the case for prosthetic reconstruction. *J. Oral Maxillofac. Surg.* 64(11): 1639-1654.

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[4] Figure from: http://medicalartprosthetics.com/content.php?page=galleries&gallery=auricular

[5] Figure from: http://homepages.cae.wisc.edu/~bme300/ear_attachment_f09/secure/reports/BME_300-Final_Report1.pdf

[6] Figure from: http://homepages.cae.wisc.edu/~bme300/ear_prosthesis_f08/secure/reports/Ear_Prosthesis_Final_Report.pdf

[7] Titanium Allow Ti-6Al-4V. Cartech. 1st July 2000. 7th April, 2010 <http://cartech.ides.com/datasheet.aspx?i=101&E=269 >

Appendix A

Product Design Specifications: Ergonomic Prosthetic Ear Attachment

February 3, 2010

Eamon Bernardoni, Jim Mott, Sam Paulsen, Brooke Sampone

Problem Statement

The purpose is to design and fabricate an attachment to augment the magnetic components that are currently in use to retain silicone auricular prostheses. The bar-clip and magnet-abutment cap techniques currently in use both have disadvantages. It is desired to retain the current magnetic attachments and the magnetic caps that mount on each abutment. The objective is to incorporate a passive locking mechanism to safeguard the prosthetic ear from complete dislodgement due to a posterior or anterior applied force. Additionally, when the locking mechanism is not engaged, minimal effort should be required to remove and attach the ear to the surgical implant.

Client Specifications

Prosthesis should resist unintentional dislodgement
Must be low profile
Must be contained within the prosthesis
Able to withstand considerable anterior and posterior force – approximately 5 lbs
Adaptable /scalable to current abutment sizes – 4.4 mm diameter
Should require minimal effort to remove and attach prosthesis

Design Requirements

1. Physical and Operational Characteristics
    a. Performance Requirements
        i. Ear should stay in position throughout daily activities
        ii. Withstand force in the posterior/anterior direction without unintentional dislodgement
    b. Safety
        i. Will not cause harm to compromised bone structure or remaining soft tissue when subjected to force
        ii. Attachment should break before the bone or surgical implant is damaged
        iii. Should be easy to clean to prevent infections
    c. Accuracy and Reliability
        i. Must fit previous abutment sizes (4.4 mm diameter) or be scalable to them
        ii. Must not fail due to aging of components over the life span of the prosthesis itself
    d. Life in Service
        i. Approximately 3 years
        ii. Materials should be able to withstand daily cleaning
    e. Operating Environment
        i. Rust and weather-proof
    f. Ergonomics
        i. Attachment and removal should require minimal effort

        ii. Components should be easy to clean
    g. Size
        i. Attachments should fit the current abutments
        ii. Mechanism should fit within prosthesis
    h. Weight
        i. Device weight should not cause discomfort for user
        ii. Patient should not feel any difference of weight due to new design (no more than 10% added weight)
    i. Materials
        i. Preferably composed of titanium, stainless steel
        ii. Compatible with silicone and the body
    j. Aesthetics
        i. Should not be visible when attached
2. Production Characteristics
    a. Quantity
        i. One prototype
    b. Target Product Costs
        i. Preferably under $500 although budget is flexible
3. Miscellaneous
    a. Standards and Specifications
        i. Materials used must be FDA approved
    b. Customer
        i. Should be available for patients regardless of age or ear size
    c. Patient-related concerns
        i. Ease of attachment and removal for users
        ii. Cleaning process be simple
    d. Competition
        i. Various methods exist, but none completely satisfy the client's demands
        ii. Existing methods include the bar-clip, magnetic, and snap-on

Appendix B

Testing Data

Anterior	Magnetic Attachment	Our design
Trial # 1	3.1 (kgf)	5 (kgf)
2	3.6	5
3	3.6	5
4	3.95	5
5	3.5	5
6	3.25	5
7	3.95	5
8	4.25	5
9	2.65	5
10	2.7	5
Push from back at 30 deg	Magnetic Attachment	Our Design
1	1.4	5
2	1.35	5
3	1.45	5
4	1.35	5
5	1.3	5
6	1.4	5
7	1.7	5
8	1.8	5
9	1.4	5
10	1.45	5
Downward	Magnetic Attachment	Our Design
1	1.35	5
2	1.05	5
3	1.15	5
4	1.6	5
5	1.4	5
6	1.25	5
7	1.25	5
8	1.35	5
9	1.45	5
10	1.3	5
Posterior	Magnetic Attachment	Our Design

1	2.3	5
2	2.65	5
3	2.75	5
4	3.5	5
5	3	5
6	3.95	5
7	3	5
8	3.05	5
9	2.95	5
10	2.95	5
Upward	Magnetic Attachment	Our Design
1	2.1	5
2	2.3	5
3	2.75	5
4	1.75	5
5	2.2	5
6	1.7	5
7	1.7	5
8	1.4	5
9	1.75	5
10	1.85	5
Lateral, Outward	Magnetic Attachment	Our Design Engaged
1	0.75	2.5
2	0.85	2.5
3	1.2	2.5
4	0.6	2.5
5	0.75	2.5
6	0.7	2.5
7	0.7	2.5
8	0.6	2.5
9	0.8	2.5
10	1.2	2.5