

Ergonomic Prosthetic Ear Attachment

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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. Our group developed an attachment method that allows the prosthesis to slide into a locked position. This design offers additional attachment strength while allowing the user to easily attach, remove, and clean the prosthesis. This semester the attachment method was further modified to be compatible with non-ideal abutment arrangements and to fail before the skull is damaged. Based on the results from testing this semester, it has been determined that the diameter of the breaking point for an acrylic abutment must be 0.153 mm. Since this diameter is so small, further material analysis is needed.

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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 in 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 amount 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. The objective is to incorporate a passive locking mechanism to safeguard the prosthetic ear from complete dislodgement due to posterior, anterior, superior and inferior applied forces. 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 abutment caps are screwed into the implants (Figure 5). Magnets corresponding to each abutment are embedded in 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. One 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].

Another 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.

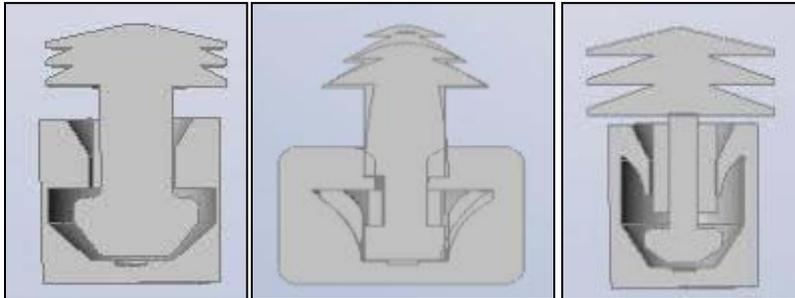


Figure 7: This image displays the prong and flange design which is made of plastic and requires the user to twist the ear during attachment and removal. This design is not ergonomically friendly and the materials are not sufficiently durable [6].

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, require minimal effort to attach and remove, and apply to a variety of abutment orientations and head topographies.

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 acknowledge the need to prevent prosthesis dislodgement, but do not adequately address anterior/posterior and superior/inferior forces, which is a goal of this project. However, the attachment should not inhibit the removal process. Also, if the device is not removed by an overwhelming force, some portion of the device should fail to protect the implants and underlying bone. The part that fails should be easily replaceable.

The attachment method needs to incorporate the currently used abutment implants which are 4.4 mm in diameter and feature female threads. 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.

Team's Original Work

Two semesters ago, the team developed an attachment method for the prosthesis known as the vertical track method. The vertical track design adds horizontal stability to the current attachment method by adding a track system to the attachments in the prosthesis. Each abutment features a cap that screws into the implant and leaves a 1 mm groove between the implant and the cap (Figure 8). In the vertical track attachment system each abutment has a corresponding track implanted in the prosthesis. The portion of the system that is implanted into the prosthesis is referred to as the attachment. When the ear is placed over the abutments and slid downwards, the lips of the track enter the grooves under the abutment caps, locking the prosthesis in place. To remove the ear, the user has 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 naturally slides back into place when adjusted vertically.

This attachment method ensures that the prosthesis is securely attached to the head and will not fall off during daily activities while also making attachment and removal easy for the user. However, there are several problems with this design. First, sliding the prosthesis only works if the implants are parallel to each other, which is rare due to the topography of the side of the head. This means that this design does not apply to normal abutment arrangements and would not work in most cases. Also, when the prosthesis is in the locked position, the attachment is strong enough that a large force delivered to the head would not remove the prosthesis, but could damage the implants or skull bone.

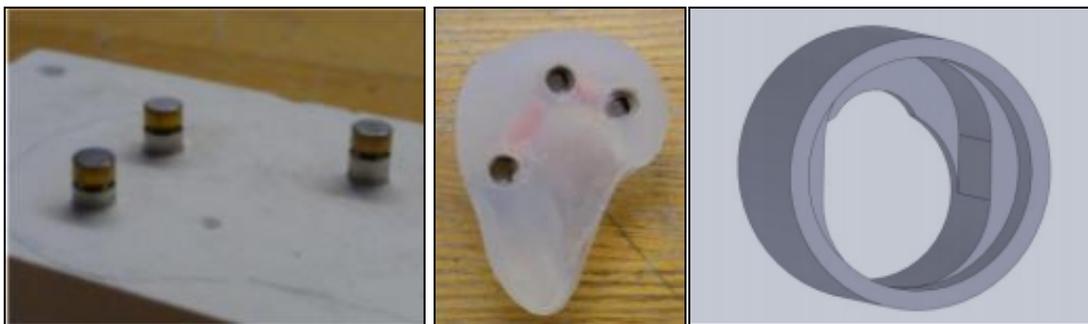


Figure 8. Left: Model of the head with abutment implants showing groove under abutment caps. Center: Vertical track attachments embedded in a silicone ear model. Right: Underside of the vertical track attachment. The sliding space and attachment lip are visible.

Overview of Design Alternatives

The re-design of the vertical track attachment method focused on two main problems. The attachment of the prosthesis must fail before bone is damaged and must apply to a variety of abutment orientations and head topographies. These two problems were approached separately while still considering the function of the entire system. Modifications to all components of the attachment system were considered, including the implants, the abutment cap and the prosthesis.

Breakaway Design Alternatives

Film Canister

In the film canister design, the attachment would be the first component to fail. The current implants and abutment caps would be used as in the vertical track design. The attachment would be made up of two parts: the attachment without its face and a piece that snaps into the attachment that contains the lip of the attachment (Figure 9).

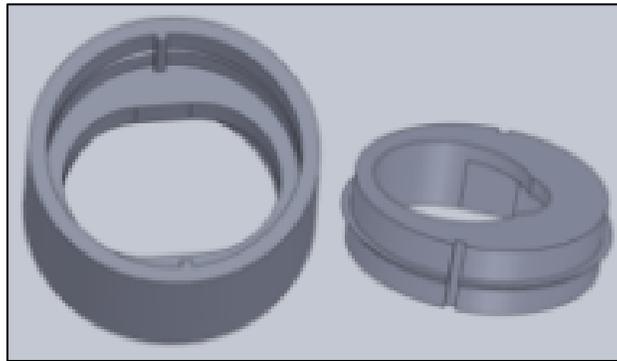


Figure 9. Film canister design showing the attachment and the snap-in attachment face. The attachment would be permanently embedded in the prosthesis while the face could be replaced if broken.

The attachment face would be made of a weaker material than the titanium attachment and abutment cap. When a large force is applied to the prosthesis, the attachment face would break allowing the prosthesis to fall off of the head before the implants or bone could be damaged. The user would then remove the remains of the broken attachment face from the prosthesis and replace it with another one. The installation of the attachment face would be similar to a film canister cap. The user

would press the attachment face into the attachment and it would lock into place. The attachment face would have a raised ridge around its circumference that snaps into a groove around the inside of the attachment. The features of the face and attachment would also ensure that the face could only be inserted in the correct orientation so that the abutment cap could slide under the attachment lip.

Circular Groove

In the circular groove design, the abutment cap would be the first component to fail. The current implants and our attachment would be used, but the abutment cap would be modified. Instead of the groove in the abutment being located right above the implant as in our current design (Figure 10 Left), there would be a portion of the cap directly above the implant. The groove would be located above this material (Figure 10 Right).

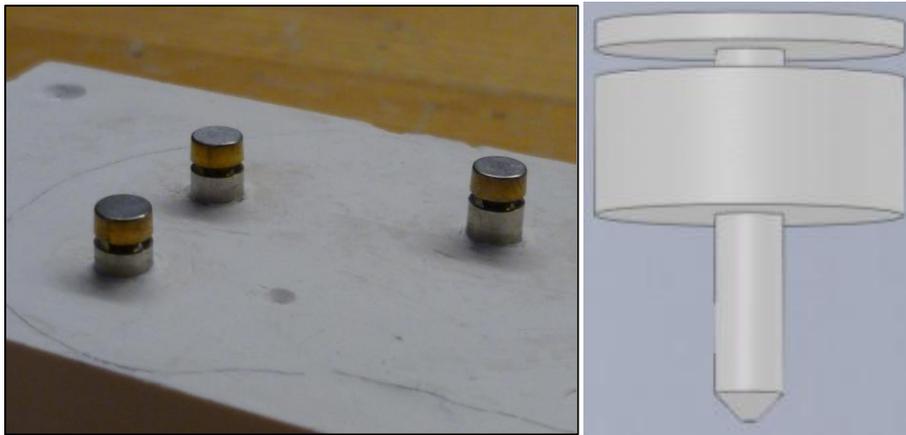


Figure 10. Left: Current abutment cap design. There is a groove located directly above the implant that allows the prosthesis to slide into a locked position. Right: Circular groove cap design. There would be material between the implant and the groove to simplify removal of the cap when it breaks.

This would be an important difference because if a large force is applied to the prosthesis, the cap would break at its thinnest point where the groove is located. Because there would be material between the implant and the groove, the cap could be easily unscrewed from the implant and replaced with a new cap. If the added material between the implant and cap was not present, only the threaded shaft would remain after the cap failed making it difficult to remove and replace.

Screw-in Attachment

In the screw-in attachment design, the attachment would be the first component to fail. The current implants and abutment cap would be used and our current attachment would be modified. In

this design, the attachment would not be permanently embedded in the prosthesis. A shell for the attachment would be permanently embedded that would have female threads. The attachment would have male threads allowing it to be screwed into the prosthesis (Figure 11).

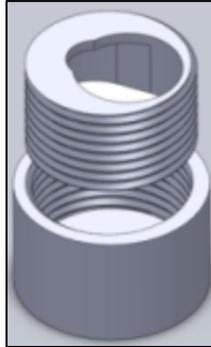


Figure 11. Screw-in attachment design. The attachment would screw into a shell permanently embedded in the prosthesis.

The attachment would be made of a material weaker than titanium and would break when a large force is applied to the prosthesis. The broken attachment could then be unscrewed from the shell and replaced with a new one.

Alignment Design Alternatives

Angled Cylinders

The angled cylinders design would allow all abutment cap grooves to be parallel to each other making it possible for the prosthesis to slide into a locked position when attached to the head. This would be accomplished by having an angled abutment cap and using the current implants and attachments. The cylindrical portion of the cap closest to the implant would be parallel to the axis of the implant, which might be positioned perpendicular to the side of the head or at any angle not perpendicular to the side of the head. The rest of the abutment cap, including the groove and the material above the groove, would not be parallel to the implant (Figure 12). It would be angled in such a way that it was perpendicular to the side of the head. With this design, all the ends of the abutment caps and the side of the head would be in parallel planes, even if the topography of the head was such that the implants were not all parallel to each other.

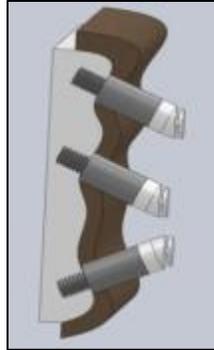


Figure 12. Angled Cylinder design. The abutment cap grooves would be parallel to each other, allowing the prosthesis to slide.

Spherical Cap

The spherical cap design makes it possible for the prosthesis to slide even if the implants and abutment caps are not parallel to each other. The current implants and attachments would be used but the abutment cap would be modified. The current abutment design has cylinders on either side of the groove, either both being part of the cap as in the circular groove design or one cylinder being the implant. This design only allows the lip of the attachment in the prosthesis to enter the groove from a limited set of angles because the lip must be almost perpendicular to the axis of the implant. The spherical cap design would replace the cylinders on either side of the groove with hemispheres (Figure 13). This shape change would remove much of the material closest to the groove, which would allow access to the groove from a larger range of angles. This would allow the prosthesis to slide onto the abutment even if they are not parallel to each other.

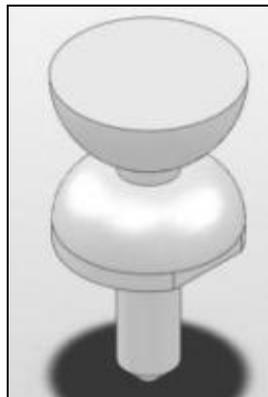


Figure 13. The spherical cap design. The shape of the cap would allow the attachment lip access to the groove from a larger range of angles.

Plate

The plate design ensures that all implants are parallel to each other even if the topography of the head is not flat. This design would use the current abutment caps and attachments but modify the implants. Instead of having the implants screwed directly into the skull as in the current method, the implants would screw into a flat plate would be screwed into the skull (Figure 14). This plate would be surgically inserted under the skin on the side of the head. This plate procedure is used for other craniofacial implants.

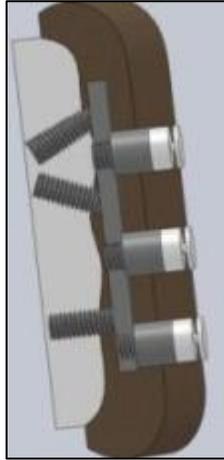


Figure 14. Plate design. The implants would be screwed into a plate under the skin instead of directly into the skull.

Evaluation of Design Alternatives

In order to choose the final design, two design matrices were created to rate the design options (Table 1). The first design matrix evaluated the three breakaway methods based on cost, feasibility, “replaceability”, and effectiveness. “Replaceability” refers to the ease of replacing the system if a force causes failure.

Table 1: Design Matrix of Breakaway Options

Criteria	Film Canister	Circular Groove	Screw-in Attachment
Cost (10)	7	6	2
Feasibility (25)	11	20	8
“Replaceability” (25)	16	21	15
Effectiveness (40)	26	35	26
Total	60	82	51

The circular groove method was ranked highest for feasibility since it would require the least amount of intricate fabrication. The screw-in attachment as well as the film canister would require precise fabrication so that the two parts of the attachment would fit together properly.

Both the screw-in attachment and the film canister would require redesign of the attachment as opposed to the circular groove option which would be a modification of the cap. Since it is easier to replace a broken cap than a broken attachment, the circular groove was awarded more points in the “replaceability” category. The attachments are difficult to replace because they are embedded within the silicone of the prosthetic ear. The current system would require the prosthetic to be completely redone if the attachment broke.

The circular groove also had the most points for effectiveness due to the fact that the groove could be sized to match the necessary breakaway force. Depending on the calculated breakaway force, the diameter of the shaft in the groove could be changed so that it broke at the desired amount of force. The circular groove was the highest scoring option, so this idea was incorporated into our final design.

The second design matrix compared the alignment options based on cost, feasibility, effectiveness, and compatibility (Table 2). Compatibility refers to how compatible the alignment method is with the breakaway methods. Options that could be integrated into one design change were preferred.

Table 2: Design Matrix of Alignment Options

Criteria	Angled Cylinders	Spherical Cap	Plate
Cost (10)	5	7	2
Feasibility (25)	18	18	6
Effectiveness (25)	10	19	23
Compatibility (40)	36	33	10
Total	69	77	41

Both the angled cylinders and the spherical cap ideas would be much more feasible than the plate option. The plate would not be feasible because it requires extra surgical procedures and extra

material implanted into the patient. Both of these characteristics are undesirable for feasibility issues as well as cost.

The plate would provide the most effective solution since it would be able to accommodate any patient's head topography whereas the other options would have some limitations on the range of angles which they could accommodate. The spherical cap could be more effective than the angled cylinders since one spherical cap could be used with all implants. Multiple cylinder configurations would need to be available in order for this solution to work.

The angled cylinder and the spherical cap ideas could be integrated with the breakaway solution much more effectively than the plate idea. Since the plate would be attached to the implants within the patient's head, this option would not be able to provide the calculated failure necessary to ensure that bone damage does not occur. Since the spherical cap method had the most points, it was incorporated into the final design.

Cap Fabrication Options

The team considered multiple fabrication options for the plastic caps. Injection molding was researched and it was found that a Simplotmatic PRO-63 Injection Molder was available on campus. However, in order to use any injection molder, first a mold must be created. Due to the small, rounded surfaces of the cap, the creation of a mold would have been very costly. This would require a very large first cost without any guarantee that the injection molder will be able to perform to the specifications necessary for the cap. Also, use of the injection molder would not allow incorporation of the screw. This would require an extra machining step.

Using an Epilog 40W Laser Cutter to create the caps was investigated. This machine was available through the biomedical engineering department. In order to laser cut the cap, a spindle apparatus was necessary and this piece of equipment was not available. Therefore, it was not possible to use the laser cutter without purchasing new equipment.

The team also attempted to fabricate the caps using the EMCO ConceptTurn 55 CNC Lathe which was available in the Mechanical Engineering department. Again, due to the small dimensions of the cap, the proper tools were not available with this CNC lathe. Two additional lathes, the Grizzly Manual Lathe and the Eisen Machinery CTL-618DT, were considered for the fabrication of the caps. The Grizzly Manual Lathe would introduce sources of variation and error in fabrication of caps due to the lack of a digital readout or automation. The Eisen lathe has a digital read out which allows fabrication of caps with significantly less variation. The Eisen lathe was the best fabrication option for this semester's work due

to the fact that no large initial costs were required and high precision was made possible with the digital readout of the lathe.

The most realistic of these fabrication options were compared using a design matrix (Table 3). The Eisen lathe was determined to be the best method of fabrication for the caps.

Table 3: Design Matrix of Fabrication Options

Criteria	Injection Molding	Mini CMC Lathe	Manual Lathe	Eisen Digital Readout Lathe
Cost (40)	5	20	35	35
Feasibility (20)	2	2	15	18
Repeatability (20)	20	20	15	19
Accuracy (20)	18	10	15	17
Total (100)	45	52	80	89

Final Design

We chose the spherical cap with the circular groove as our final design because, of the six design alternatives, it best meets the design specifications. The circular groove will provide the user with the assurance that if exposed to high levels of force, the narrow portion within the groove will break before any bone damage can occur. Also, the hemispherical cap will greatly increase the amount of cases for which the design will work. Since the hemispherical portions of the cap can accommodate angled implants, the implants are not required to be parallel to each other.

The final design is comprised of two pieces, a cap and an attachment. The cap was the main focus of design for this semester due to the fact that by modifying the cap, we could achieve both major design requirements. In order to allow the cap to break before bone damage occurs via the implants, the cap will be made primarily of plastic. The shaft of the cap must be threaded so that it remains compatible with the implants. Since the threads are too difficult to fabricate accurately in plastic, the shaft of the cap will incorporate a metal screw of proper thread specifications. The metal screw will be embedded into the plastic of the cap. The lower portion of the cap is not completely circular. The two flat faces in this area provide a surface for gripping if the shaft needs to be unscrewed.

After selecting our final design, we realized that a conical cap would function similarly to the hemispherical cap. Therefore, we eliminated excess material and obtained pieces for a large-scale model of the attachment and the conical cap (Figure 15). The conical cap will also be easier to fabricate. The model (three times larger than actual size) was helpful for analyzing our design. Once the model was put together to simulate the implants in the patient's head and the attachments in the prosthetic ear, we realized that the sloping surfaces of the conical cap allowed excess movement. With the conical geometry at the top of the cap, the ear could not lock into place. This makes our design nonfunctional, so redesign was required.

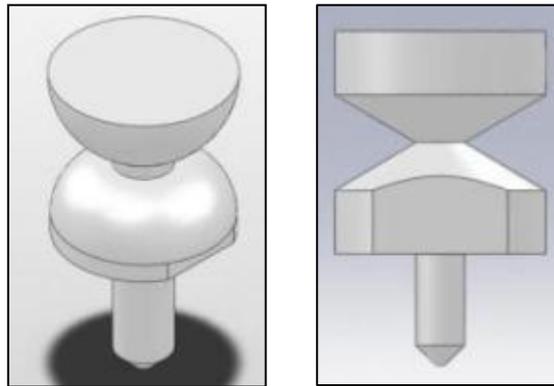


Figure 15: The SolidWorks model on the left shows the original spherical cap design. The SolidWorks model on the right shows the conical cap design.

In order to improve upon the design, the top cone was replaced with a cylinder (Figure 16). This still allows the abutments to be nonparallel while the caps can lock into place underneath the lip of the attachment. This concept was shown with a modified version of the first large scale model.

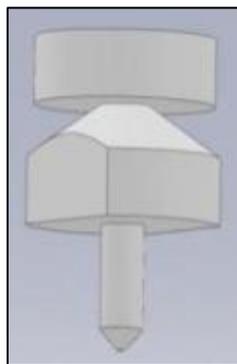


Figure 16: This figure shows a SolidWorks model of the final version of the cap.

If exposed to large forces, the cap will break at the segment joining the cone to the top cylinder since, with the exception of the metal threads, that is the narrowest portion of the cap. A worst case analysis of the implants in the bone found that in order to spare the patient from bone damage, our

design should break at forces of about 30 N. The average ultimate compression strength of human cranial bone in the tangential direction is 14,000 psi with a standard of deviation of 5,200 psi [8]. In order to do a worst case analysis, we used the low end of this strength (14,000- 5,200 = 8,800 psi). 8,800 psi converts to 61×10^6 Pa. We estimated the area to which forces may be applied to the bone. A smaller area will result in a lower force threshold; therefore, we estimated that the applicable area may be $1.5 \times 10^{-6} \text{ m}^2$. For this estimate, it was assumed that the force was applied to a rectangular surface instead of the curved side of a cylinder. Using these estimates, it was determined that the maximum allowable force was 91 N. If this entire force applied to the implant is transferred to the bone, the bone may break. We determined that a factor of safety of three was appropriate for our design. Therefore, the type of plastic and the dimensions of the cap will be modified so that the cap will break when exposed to 30 N or more.

Slight modifications were made to last semester's attachment to eliminate unnecessary fabrication steps. The opening for the cap was changed from two partially imposed circles to only one circle (Figure 17). The circle with the smaller radius was originally included to allow the abutment to slide in a longer track that was part of an early design idea. With the circular attachment it is unnecessary, so it was eliminated.

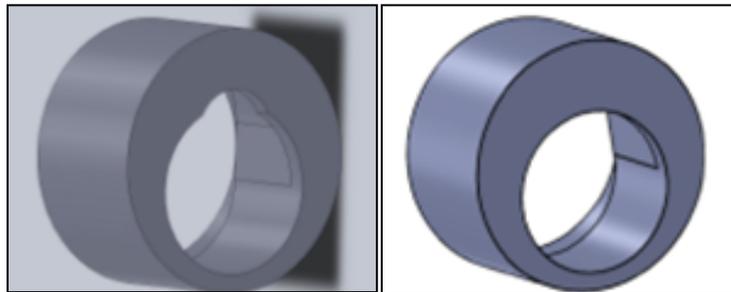


Figure 17: This figure shows the attachment from last semester (left) and the modified attachment (right).

Cost Analysis

The new design would include attachments similar to the attachments fabricated by Daniel Bye of TosaTool in the spring of 2010. The total cost per attachment was \$63.26 as compared to a cost of \$109.95 per attachment for the current magnet attachment method. The new design may possibly be cheaper due to the removal of several features from the design. The small groove in the attachment hole was removed. Also, the pocket the magnet rests in is unnecessary as a magnet is not incorporated in our new design. 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, causing the attachment from last semester decrease in cost per attachment from \$62.26 to less than \$15 (D. Bye, personal communication, May 4, 2010).

This semester all prototype hardware was either purchased or fabricated in the College of Engineering (CoE) Student Shop. All of the material was purchased from McMaster-Carr except for the cap screws which were donated as shown in Table 4. Labor costs are estimated at \$40.00 per hour for professional machining of the caps and the acrylic attachments. The prototype this semester was made with acrylic attachments as it is a cheaper prototype alternative than hiring TosaTool to create three more titanium attachments. Table 5 gives the cost analysis.

Table 4: Cost table showing cost of material and labor to fabricate the caps and the acrylic attachments for the prototype.

Product	Cost with shipping	Amount of material	Used per Piece	Cost per piece	Labor (h)	Labor Cost
0.06" Acrylic Sheet	\$7.96	12"x12"	0.5"x0.5"	\$0.01	0.333	\$13.32/acrylic Attachment
0.177" Acrylic Sheet	\$10.33	12"x12"	0.5"x0.5"	\$0.02		
Cap Screw	\$8.76	100	1	\$0.09	0.75	\$30.00/Acrylic Cap
0.5" Acrylic Rod	\$17.07	72"	0.5"	\$0.12		

Table 5: Cost of Titanium Attachment and hardware costs for different prototype options.

Products	Cost
Titanium Attachment	\$63.26
Three Caps and Three Acrylic Attachments	\$130.68
Three Caps and Three Titanium Attachments	\$280.40

Fabrication Process

Fabrication of the final design prototype requires advanced machining. Due to small dimensions, the tolerances are forced high. The overall dimensions of the attachment are as shown in Figure 17. All wall thicknesses are at least 0.5 mm thick and it is fabricated from Ti-6Al-4V titanium alloy.

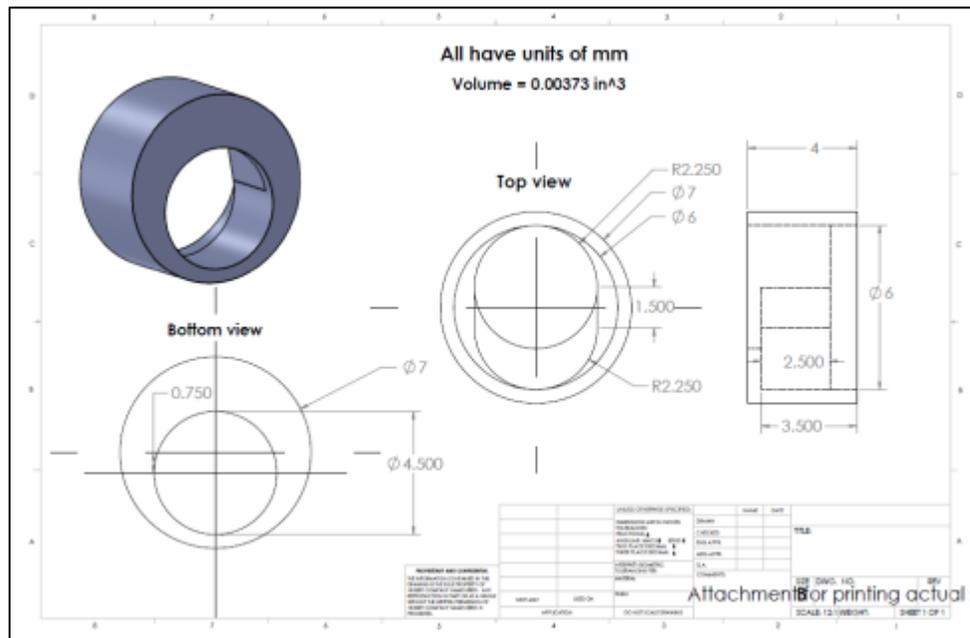


Figure 17: Drawing of new attachment design.

Outlined below are the steps necessary to machine the attachment. With the new design, the small notch in the opening of the attachment and the magnet pocket are unnecessary. However, they are still shown below. Removal of these two features will decrease cost of fabrication. 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 10 cm 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 18. 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.

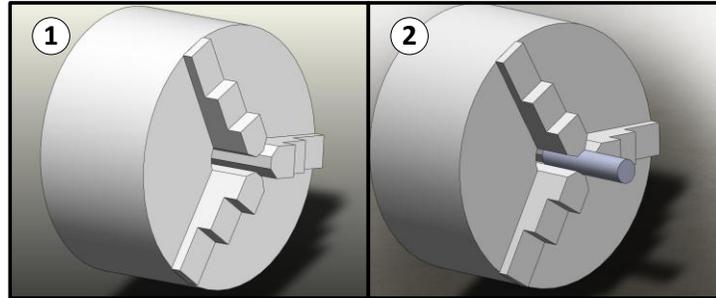


Figure 18: In the first step of the fabrication process, chuck a titanium rod with a diameter ≥ 7 mm.

After the material is secure, turn down the rod to 7 mm in diameter as shown in Figure 19. 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.

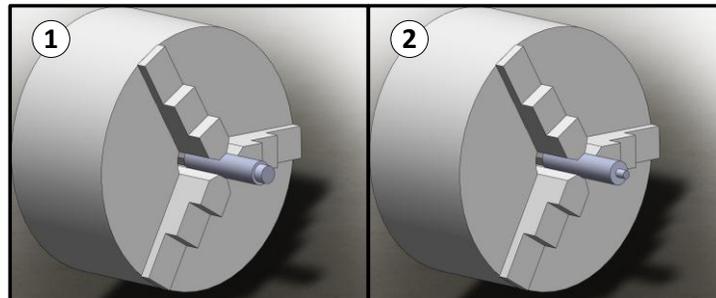


Figure 19: The rod is then turned down to 7mm in diameter with several passes.

Once the rod is turned down to 7 mm, clamp it securely into a milling vice as shown in Figure 20. Be sure to clamp it so the rod is orthogonal to the milling table.

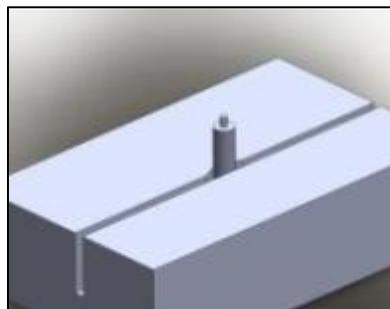


Figure 20: The rod is clamped in a milling vice, orthogonal to the table.

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 21(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 21(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. 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.

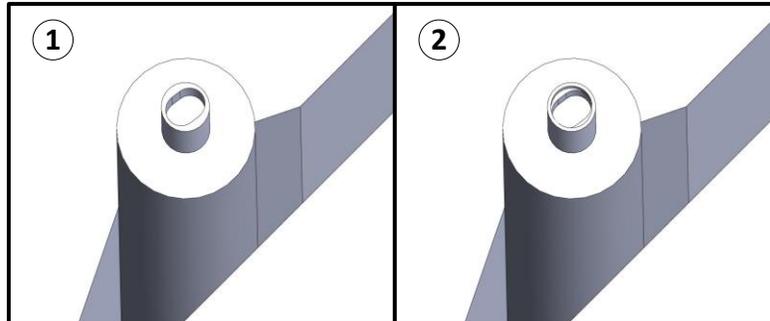


Figure 21: (1) A pocket is milled to a depth of 3.5mm through the center of the rod, each end has a radius of 2.25mm. (2) A 6mm diameter pocket is milled concentric with the center to a depth of 1mm.

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 22(1). It is important that this hole is exactly in line with one end of the first pocket milled, shown in Figure 21(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 22(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.

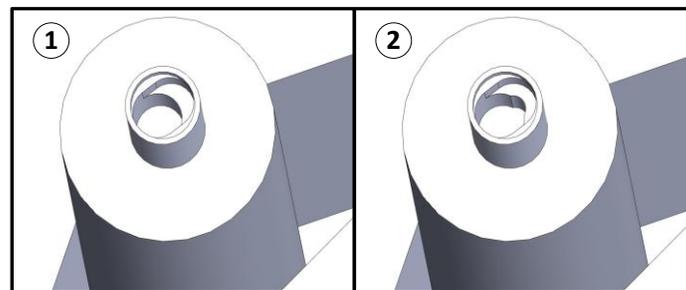


Figure 22: (1) A 4.5mm diameter hole is milled into the part. (2) A 1.2mm radius is milled into the part.

After all the pockets are milled, the rod is then put back into the lathe chuck for removal of the part (Figure 23).

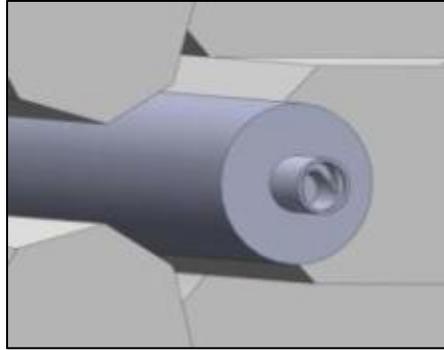


Figure 23: The part is secured in the lathe chuck, ready to be removed from the rod.

With a cutting tool, cut the piece off from the rod 4 mm from the end of the part (Figure 24).

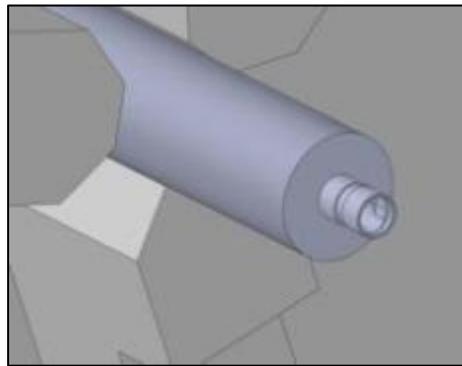


Figure 24: The part shown is partially removed from the rod 4mm from the end.

The finished piece is then cleared of any burrs with a fine file. It is now ready for the insertion of the magnet (Figure 25).

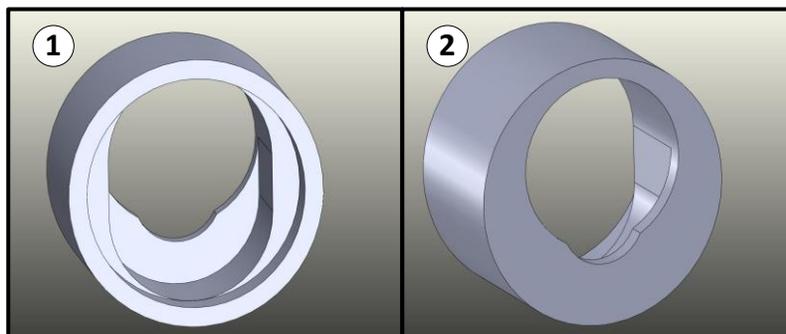


Figure 25: The part free and cleared of any burrs.

A 6 mm diameter magnet is pressure fitted in the 6 mm pocket. After the magnet is in place the part is complete (Figure 26).

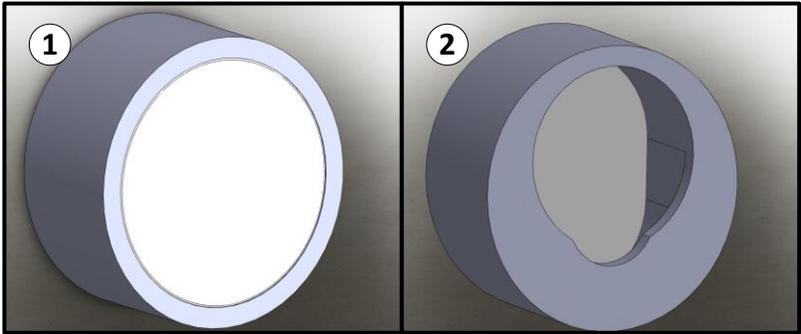


Figure 26: Completed part with magnet.

As stated previously, the small notch and magnet pocket are not necessary and can be left out to decrease fabrication costs.

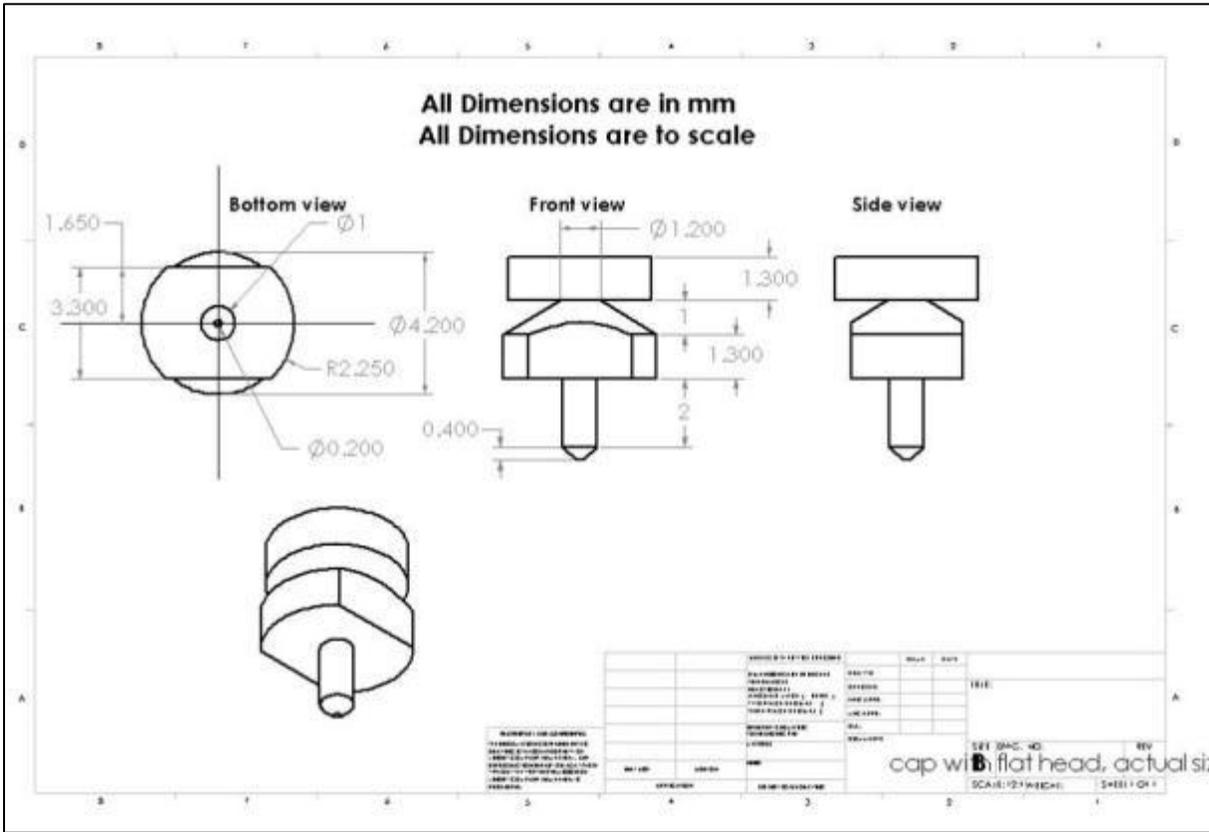


Figure 27: Drawing of Cap.

For proof of concept, a scaled model of the cap was produced. Rapid prototyping machines available are not able to print the to-scale model with decent resolution. When printed to scale, the caps are rough and brittle and were unable to fit in the attachments due to imperfections. To create a working model to check alignment, spatial relationships, and attachment quality, models scaled three

times of the cap and attachment were created in SolidWorks and printed with a rapid prototyping machine (Figure 28 and Figure 29).

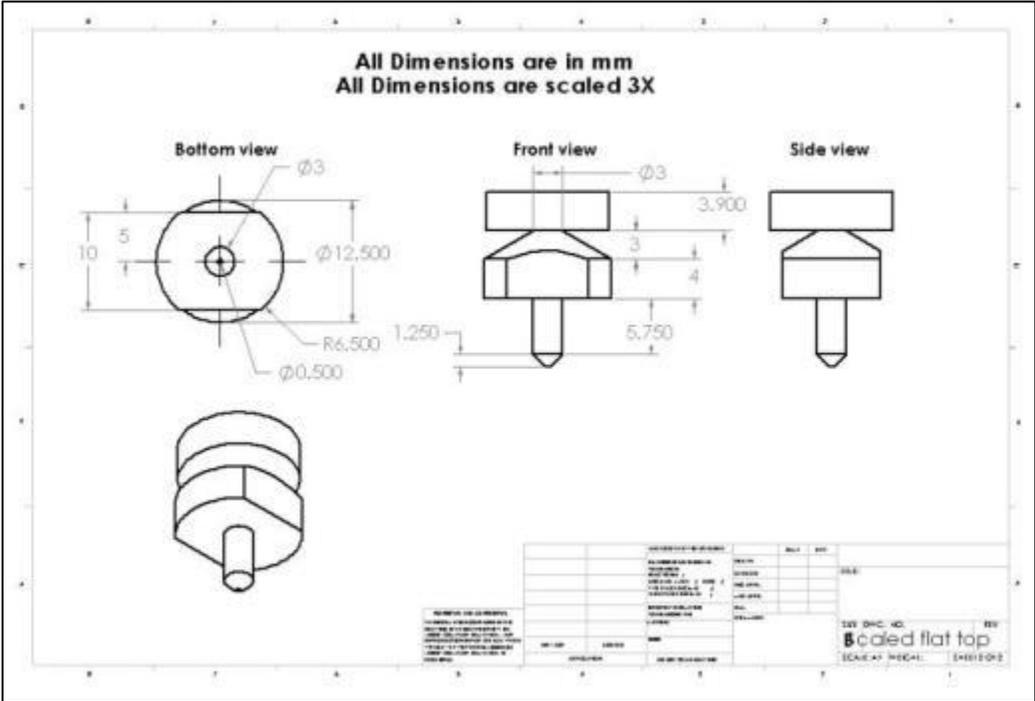


Figure 28: Drawing of cap scaled 3X rapid prototyped and used in prototype.

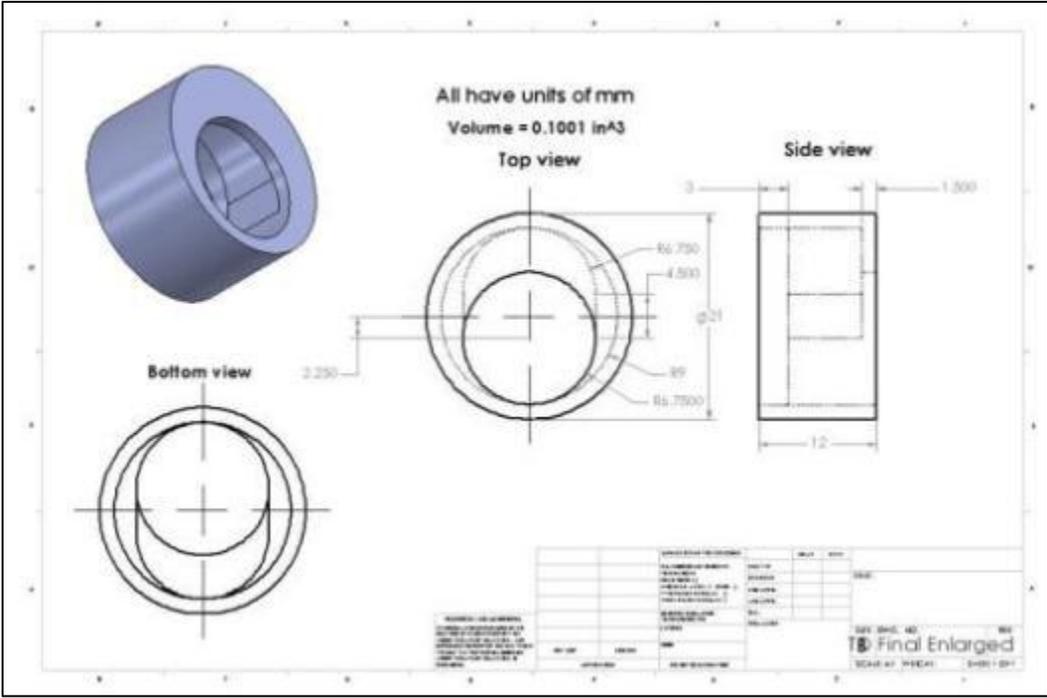


Figure 29: Drawing of attachment scaled 3X rapid prototyped and used in prototype.

The prototype was based on realistic implant angles derived from a model given to the team by the client, Greg Gion. The distance between implants in the model were measured and multiplied by a factor of three. A 6"x6"x1.5" piece of Styrofoam was used to represent the ear. The scaled location of the implants was marked on the piece of Styrofoam and $\frac{3}{4}$ " holes were drilled in each location and the caps were inserted in the same orientation, to allow a sliding motion. The same scaled location was marked on a second identical piece of Styrofoam and the caps were placed in each spot by poking the rod into the foam. Each cap was placed roughly at the same angle as appeared on the model from the client and glued in place. See Figure 30. The mock ear with the attachments and the mock head with the caps can be put together and slide several millimeters. When this is done, the two pieces are solidly locked together.

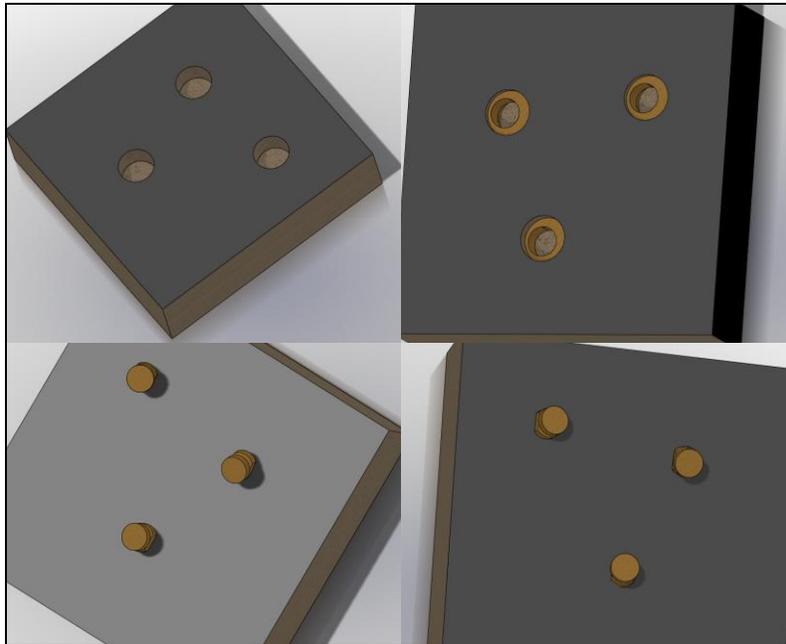


Figure 30: Prototype of head and ear scaled up 3 sizes.

In order to reduce costs, the fabrication of the final prototype attachments was done with an Epilog 40W Laser Cutter. The attachment was drawn in the program Corel Draw. There was no way to precisely assign a depth to each feature in the Corel Draw program. Depth was controlled by the laser speed and power settings in the program and the correct values were determined by trial and error. This file was then sent to the laser cutter which then cut out the attachment from a 0.177 in thick acrylic sheet. A disk of the attachment diameter was then cut out of a 0.06 in thick acrylic sheet. This disk was then super glued onto the back of the attachment where the magnet would have gone in the old attachment design. The tolerances of the laser cutter were not as high as desired. This was tolerable as

the acrylic attachments were only used in the prototype as a proof of concept. In patients, titanium attachments would be used as it would ensure the caps failed before the attachments.

The fabrication of the final prototype testing caps was done on an Eisen Machinery CTL-618DT digital readout lathe. For a picture demonstration refer to Figure 1 in Appendix B. First, the acrylic was turned to the proper diameter of the shear testing fixture hole so that each cap could be decently secured in the fixture. Then the larger diameter of the cap of 4.5 mm was turned. Next, the smaller diameter of 4.3 mm was turned. After this, the cap groove was made with a specialized cutting tool as shown in Figure 1 in Appendix B. The test cap was then cut off with a cut off tool.

To fabricate the final prototype caps, the same process used to create the test caps was used with a few modifications. The cap was fabricated from the reverse end so that the bottom of the cap was sticking out towards the cutting tool. Then a small hole was drilled in the bottom of the cap by placing a chuck and drill bit where the live center is placed. This was done for the screw head insertion. After the hole was drilled, the top of the cap was cut off of the stock material with a cut off tool. Then, while the cap was set upside down on the table, glue was applied to the screw head. The screw head was then gently lowered into the cap and aligned so that it was orthogonal to the bottom surface of the cap. The caps were then allowed to cure overnight.

Testing fixtures were created to test the caps in a tensile tester. As the standard grips for a tensile tester are not designed for shearing parts, it was necessary to design and fabricate a fixture that would convert the tensile tester into a shear tester. The fixtures were milled out of aluminum in the COE Student Shop. Drawings of the testing fixtures can be found in Figures 2 and 3 in Appendix B.

Testing

To conduct force testing, the cap was first modeled in SolidWorks. Stress analysis was done using Simulation Express which is a feature of SolidWorks. From analysis of the cap and attachment assembly, when in place, the attachment rests on the upper slant portion as well as under the cap ridge (See Figure 31).

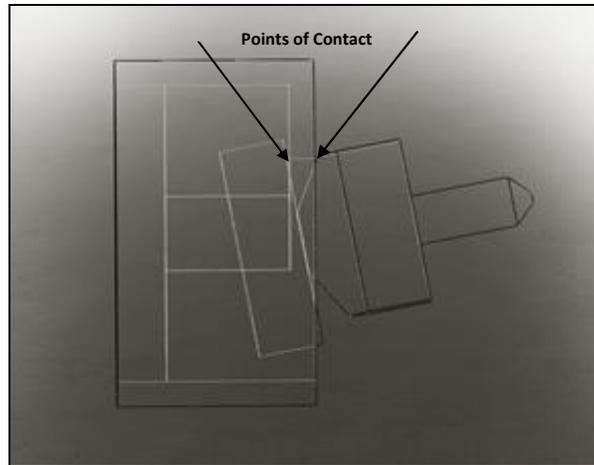


Figure 31: Transparent side view of cap and attachment assembly to view contact points.

The cap was then modeled to have different panels so the force could be placed in these contact areas only, making the tests more accurate. Three types of tests were conducted on six different plastics. The first two tests consisted of fixing the cap rod and bottom, Fixture 1. The third test fixed only the cap rod, Fixture 2 (See Figure 32). These surfaces were fixed during the simulations because they would be in contact with the implant and hold the cap in place on the head. Test 1 used Fixture 1 and a force of 30 N was placed on the left hand side of the cylinder and directed right as shown in Figure 33. Test 2 used Fixture 1 and a force of 30 N was distributed on the upper portion of the slant and the left underside of the ridge and directed to the right as shown in Figure 34. Test 3 used Fixture 2 with a force of 30 N placed underneath the ridge and was directed straight up as shown in Figure 35.

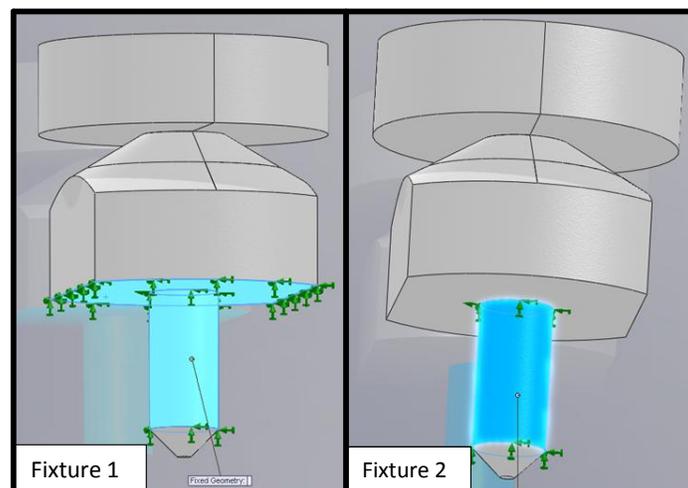


Figure 32: Fixture 1 and Fixture two. The highlighted surfaces were fixed in place in the simulations.

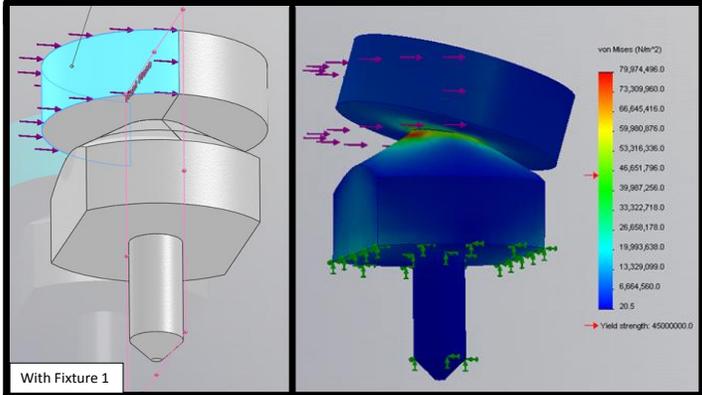


Figure 33: Test 1 with a force of 30 N placed on the cylinder.

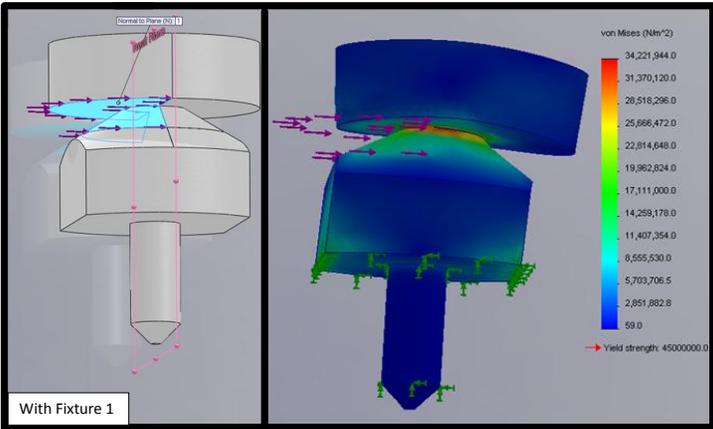


Figure 34: Test 2 with a force of 30 N total placed on the upper slant and bottom of ridge, both on the left side.

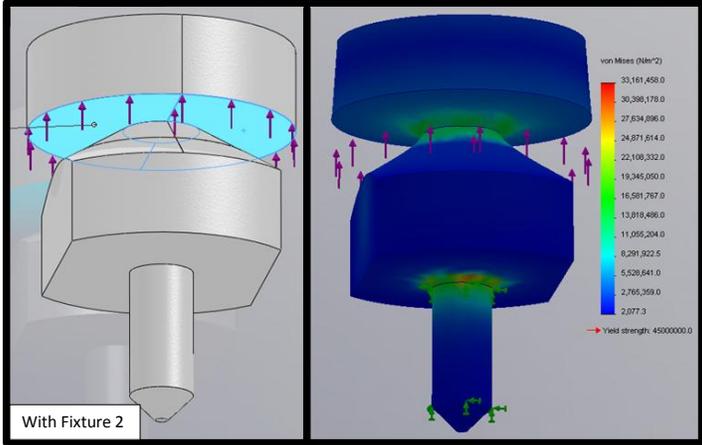


Figure 35: Test 3 with a force of 30 N placed underneath the ridge and directed upwards.

After each simulation, the lowest factor of safety on the part was recorded as well as the point of first failure. To determine the force which caused failure, the lowest factor of safety was multiplied by

30 N. See Table 1 in Appendix B for the complete data. With this data, we can determine the best plastic to use, and the correct cap dimensions to create a failure at 30 N. The graph below (Figure 36) shows a summary of the SolidWorks testing data from the fall semester of 2010.

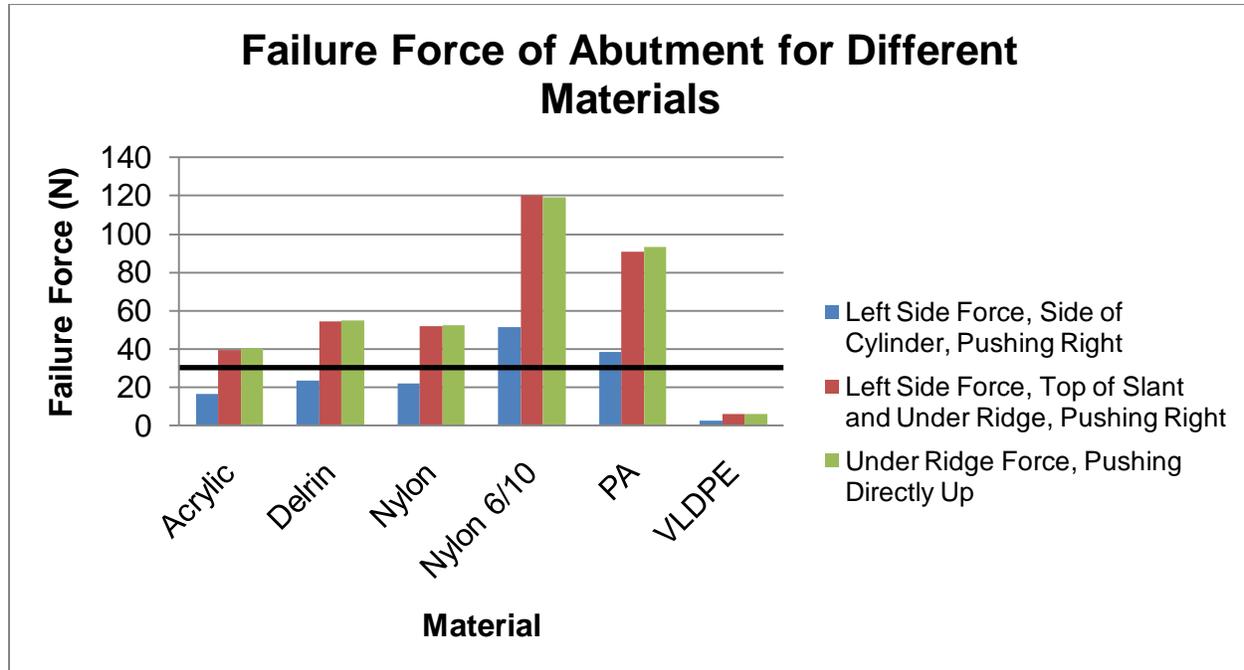


Figure 36: Failure force for different materials using SolidWorks modeling. Ideally we want failure to occur when a 30 N force is applied to the side of the abutment (black line).

In addition to the simulation testing performed in SolidWorks, the team fabricated caps and a testing fixture to perform failure testing. See Figure 4 in Appendix B for drawings of the testing fixture. The two piece testing fixture was clamped into the upper and lower grips of a tensile tester. The caps fabricated for testing were loaded into the testing fixture. The upper portion of the testing fixture simulates the attachment piece which would be in the prosthetic ear. The lower portion of the testing fixture simulates the implants in the patient's skull. A set screw was tightened to ensure that the caps were held into place. The tensile tester was then used to pull the two parts of the testing fixture apart which created a shear stress on the cap. Trials were run at a rate of 5.1 mm/minute until contact. Upon contact samples were run at a rate of 50 mm/ minute. Data was recorded regarding the failure behavior of the caps. Two sets of data were obtained.

The first set of data was obtained to assist with material selection. The team attempted to fabricate caps from acrylic, polycarbonate (PC), polystyrene (PS), polypropylene, and ultra high molecular weight polyethylene. Only the first three materials were machinable. Caps created from acrylic, PC, and PS were fabricated and tested using the testing fixture and the tensile tester (Figure 37).

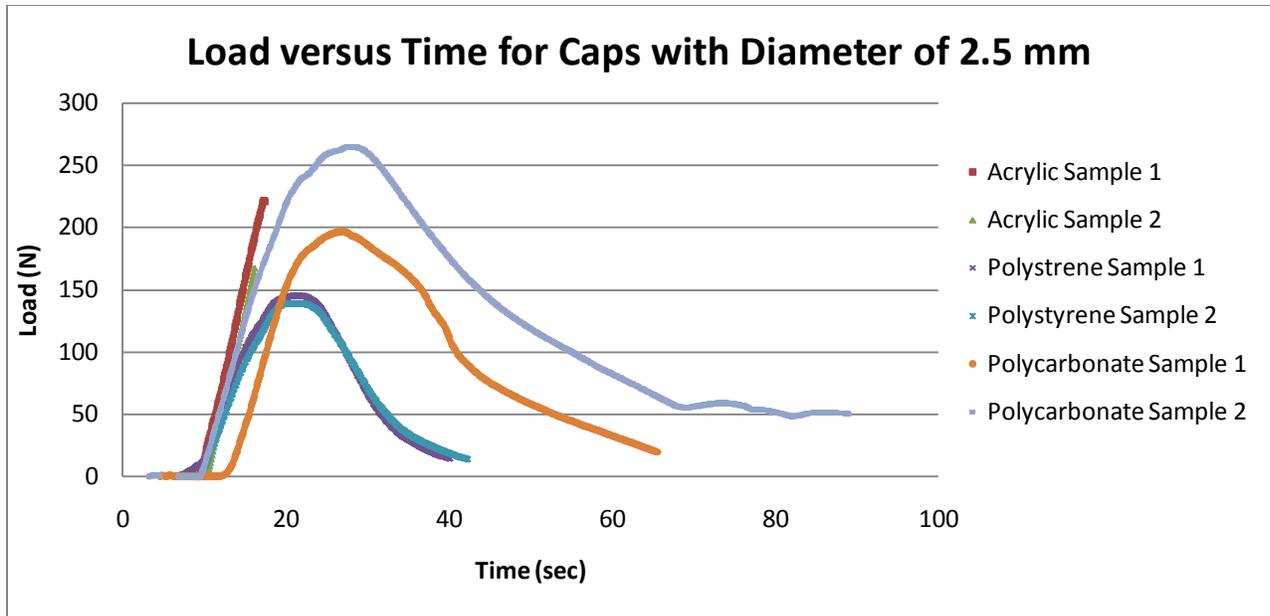


Figure 37: Failure ability of acrylic, polystyrene, and polycarbonate caps. Two caps of each material were tested and the results of load (N) vs. time (sec) were created.

The results show that PS and PC bent instead of breaking under shear stress. It is necessary for the caps to have a clean break if subjected to a large force so that the prosthetic ear will break away from the implants in the skull. Since acrylic demonstrated a clean break it was used as the material for additional testing.

Additional testing was necessary because the caps with 2.5 mm break point diameters that were used in the first round of testing failed at 221 N and 167 N. The targeted failure force is 30 N so additional caps were fabricated with narrower break point diameters. The break point diameter refers to the narrow portion of the cap between the upper cylindrical portion and the conical middle portion. If subjected to a force, this area is designed to be the first to fail. In order to facilitate failure at lower forces, the break point diameter was narrowed. Acrylic caps were fabricated for testing with break diameters ranging from 2.25 mm to 0.50 mm (Figure 38).

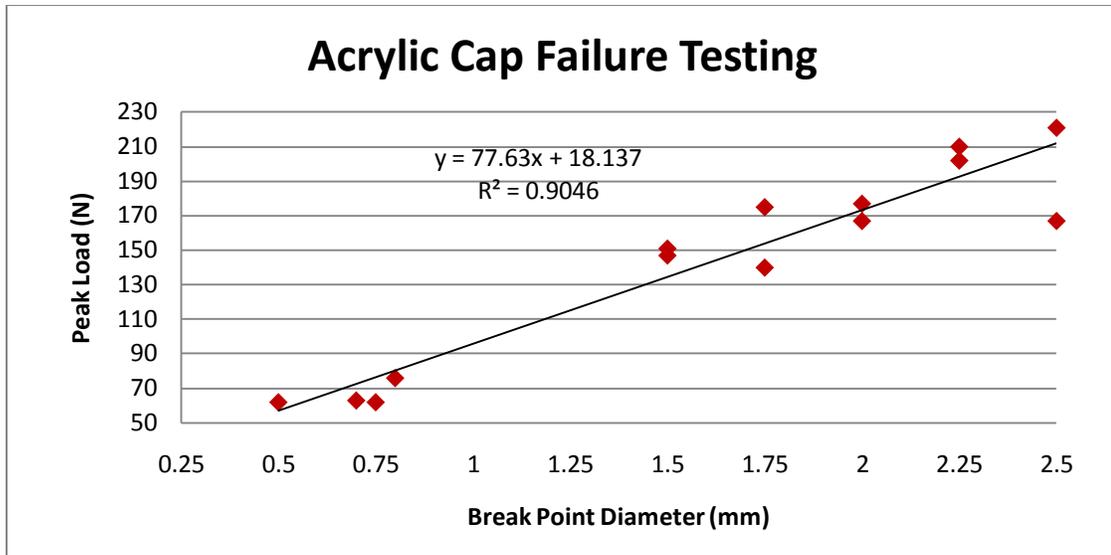


Figure 38: Failure testing of acrylic caps with various break point diameters. Failure load (N) is shown on the y-axis and break point diameter (mm) is shown on the x-axis. Linear regression of the data was used to find that a break point of 0.15 mm would be necessary for the caps to break at 30 N.

Caps with 0.8, 0.75, 0.7, 0.5 mm break point diameters did not break as cleanly as the others. There was more bending involved before reaching failure. Linear regression from this data showed that a much narrower break point diameter of 0.15 mm would be necessary for the caps to fail at the targeted 30 N.

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 this aspect was not changed. The device contains no moving parts which makes using the device intuitive and avoids any user confusion. 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 1.5 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.

The attachment system is designed so that if a large force is applied to the ear, the abutment cap will break before the attachment pieces within the ear. This would make the device considerably more ergonomic because it would allow the prosthesis to have a longer life in service.

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

Our new attachment method is almost ready for patient testing. We would like to have patients currently using the magnetic abutment or bar clip attachment methods to use our system for an extended period of time. We could obtain feedback from the patients regarding the ease of attachment, removal and cleaning of the prosthesis. Patients could also report on the comfort of wearing the prosthesis and if the sliding motion caused any problems. They could also tell us how the prosthesis responded to applied forces during daily activities, how often it broke and fell off and what they thought of the cap replacement process. This information would be valuable to keep improving the design. The prosthesis used for testing should contain titanium attachments which can be fabricated by a machinist.

In order to make the testing safer for the patient, further material analysis needs to be done to find the right combination of material and breaking point diameter so that the device fails under the correct load. The material used must be weaker than the acrylic used for our testing. Using acrylic, the diameter of the cap cannot easily be fabricated to the desired 0.153 mm because of melting of the material. A cap made of a weaker material could have a larger breaking diameter, which would make fabrication more feasible.

More in depth analysis of the failure of skull bone should be done as well. The 30 N value used in our design is an estimate because we did not have the resources or time available to conduct more accurate analysis. Ideally, the implants should be screwed into temporal bone or bone with similar mechanical properties. A prosthesis system that will not fail should be attached over the implants and loaded in various directions to determine how much force is necessary to cause the bone to fail. Using these results, an abutment cap of proper material and breaking diameter can be created. Force testing should be performed on the system so as to determine its performance in all common cases of contact to the prosthesis. This testing should be done on attachment systems with various abutment arrangements and head topographies.

To ease the process of implanting the attachments into the prosthesis, a system must be developed 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 38). The current method for implanting the attachments depends on trial and error and takes a considerable amount of time.

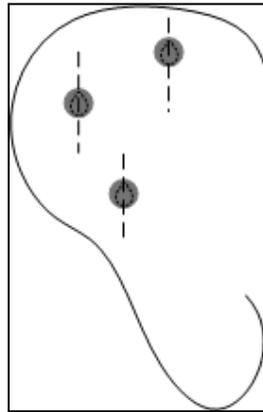


Figure 38: This figure shows the required parallel alignment of the attachments when implanted into the prosthesis. If the attachments are not oriented parallel to on another, the prosthesis will not slide.

Additionally, extra silicone often has to be added to the prosthesis 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.

Further work on this project would include resubmitting our design to WARF to see if they are interested in patenting our device with the changes made over the past year. In order for this

attachment method to be widely used, methods of mass producing the abutment caps and attachments would have to be created.

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Appendix A

Product Design Specifications: Ergonomic Prosthetic Ear Attachment

December 10, 2010

Eamon Bernardoni, Jim Mott, Brooke Sampone, Michelle Tutkowski

Problem Statement

Greg Gion of Medical Art Prosthetics is looking for a new attachment method for auricular prostheses. A new attachment method is desired because the current bar-clip method and the magnet-abutment method are either too strong or too weak, respectively. These methods compromise the effectiveness of the prosthetic ear to mask the patient's deformity and they make the patient more prone to injury by damaging the underlying bone or tissue. Last semester the team designed and fabricated an attachment piece to be imbedded in a silicone auricular prosthesis. This attachment fits the client's needs only in ideal cases. The objective this semester is to modify the attachment method that was created last semester so that it works in almost all cases and to talk with companies to learn the possibility of manufacturing the device for market use.

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

Should apply to a variety of abutment orientations and head topographies

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
 - iii. No patents for this application could be found

Appendix B

Fabrication Process

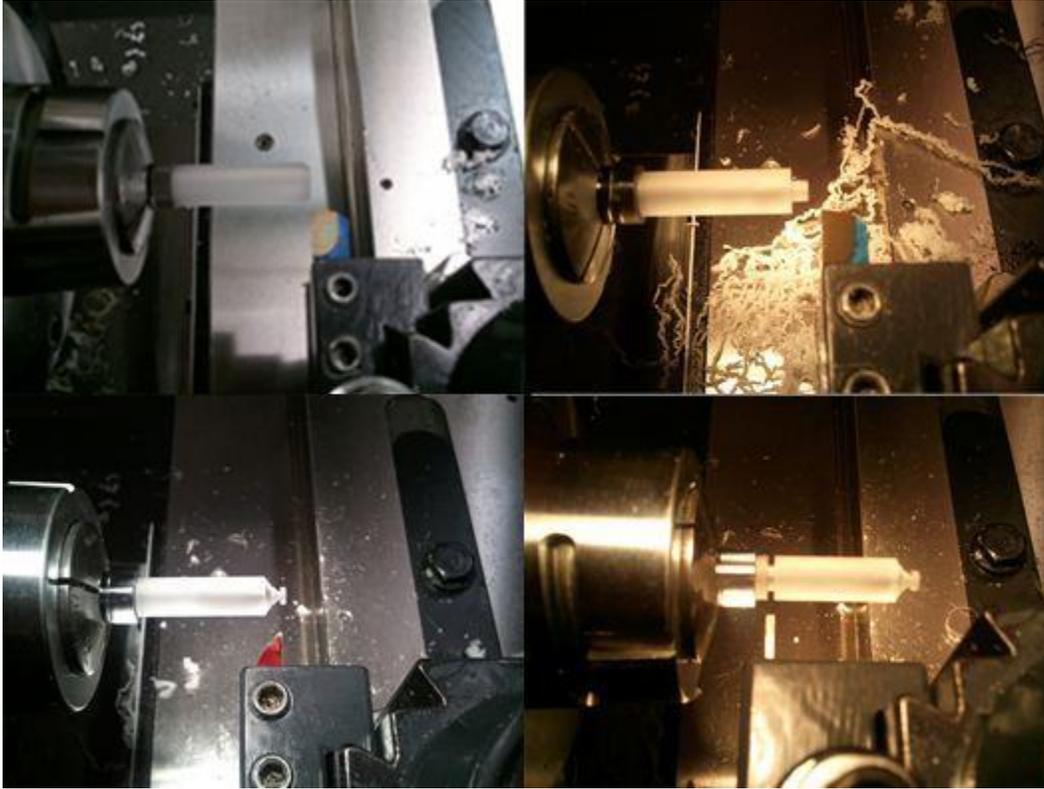


Figure 1: Fabrication of the testing caps.

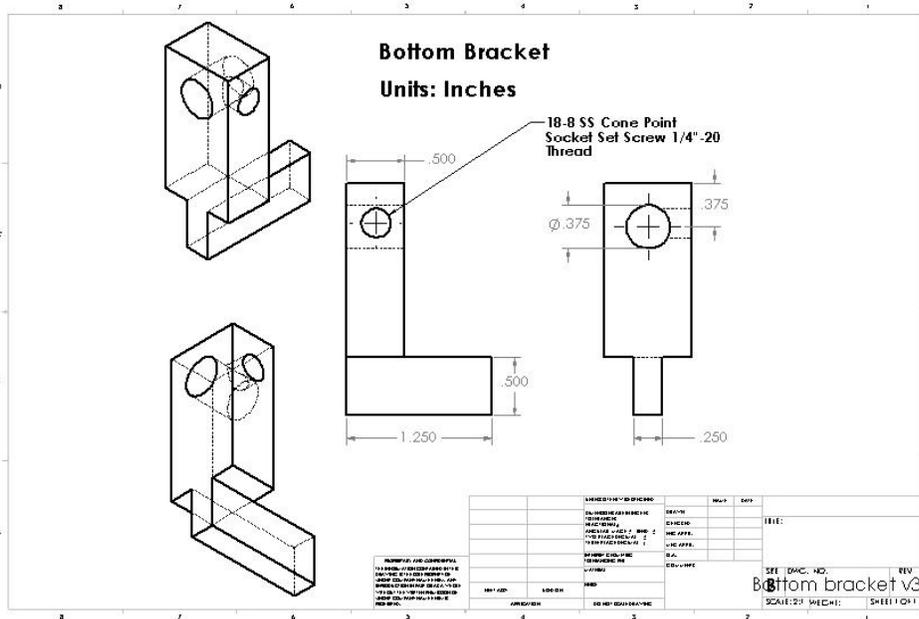


Figure 2: Lower portion of the testing fixture.

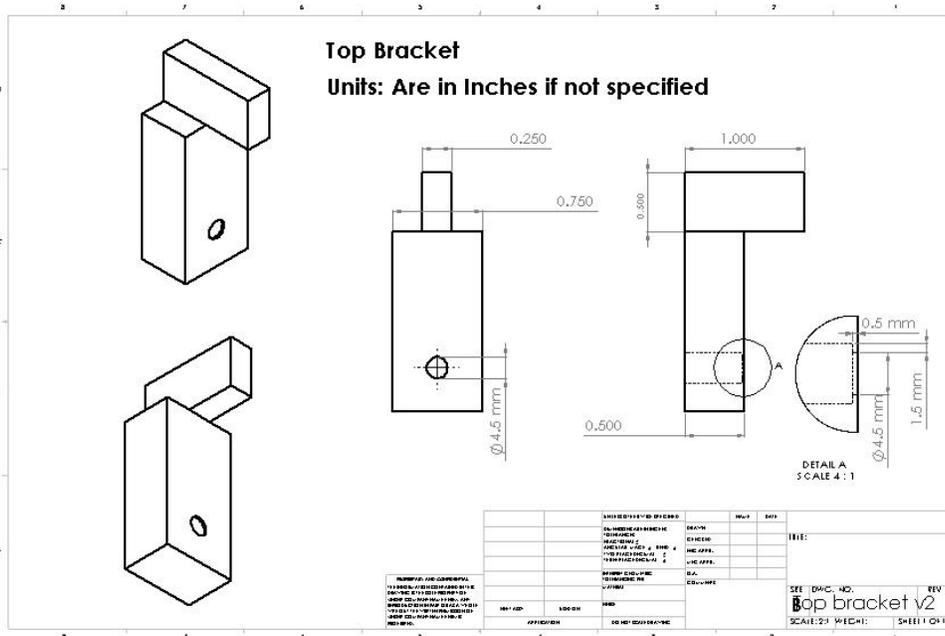


Figure 3: Upper portion of the testing fixture.

Testing Data

Table 1: Testing data from Simulation Express in SolidWorks.

Force 1 = Left side only, top of slant and under ridge, pushing right				Acrylic = Acrylic Medium-high impact	
Force 2 = Left side only, side of top cylinder, pushing right				Delrin = Delrin 2700 NX010 Low Viscosity Acetal Copolymer (SS)	
Force 3 = Under ridge, directly up				Nylon = Nylon 101	
				Nylon 6/10 = Nylon 6/10	
				PA = Pa Type 6	
Fixture 1 = Rod and bottom				VLDPE = Very Low Density PE (SS)	
Fixture 2 = Rod					
Material	Fixture	Force Distribution (30 N total)	Lowest factor of safety	Failure Force (N)	Point(s) of first failure
Acrylic	1	Force 1	1.31495	39.4485	Break away
Acrylic	1	Force 2	0.562679	16.88037	Break away
Acrylic	2	Force 3	1.357	40.71	Break away, top of rod
Delrin	1	Force 1	1.82239	54.6717	Break away
Delrin	1	Force 2	0.781495	23.44485	Break away
Delrin	2	Force 3	1.83479	55.0437	Break away, top of rod
Nylon	1	Force 1	1.73561	52.0683	Break away
Nylon	1	Force 2	0.744281	22.32843	Break away
Nylon	2	Force 3	1.74742	52.4226	Break away, top of rod
Nylon 6/10	1	Force 1	4.00325	120.0975	Break away
Nylon 6/10	1	Force 2	1.7187	51.561	Break away
Nylon 6/10	2	Force 3	3.97618	119.2854	Break away, top of rod
PA	1	Force 1	3.02313	90.6939	Break away
PA	1	Force 2	1.29407	38.8221	Break away
PA	2	Force 3	3.10424	93.1272	Break away, top of rod
VLDPE	1	Force 1	0.199443	5.98329	Break away, bottom edges of cap
VLDPE	1	Force 2	0.0855273	2.565819	Break away, cylinder, bottom edges of cap
VLDPE	2	Force 3	0.200801	6.02403	Break away, top of rod

Testing Pictures



Figure 4: Left-side view of testing fixture with acrylic cap in place for testing. Right- front view of testing fixture clamped into tensile tester with acrylic cap in place for testing.