Ergonomic Prosthetic Ear Attachment

March 10, 2010

Team

Eamon Bernardoni – BSAC

Jim Mott – Leader

Samantha Paulsen – Communicator

Brooke Sampone – BWIG

Client

Greg Gion, MMS, CCA

Medical Art Prosthetics, LLC

Advisor

Professor Willis Tompkins

Professor, Biomedical Engineering

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 the silicone prosthesis. Though this method is easy to attach, remove, and clean, the prosthesis is easily displaced due to lateral forces. To overcome this issue, our group developed an attachment method where each abutment would have a corresponding track implanted into the prosthesis. Each track will be approximately 6.25 mm in diameter and will be made from titanium or stainless steel. The tracks will each have a small T-slot to lock the abutments in place. To attach the prosthesis a patient will line up the large openings on the lower half of each track with the abutment heads and simply slide the ear 3-4 mm downward into the locked position. The lips of the upper section of track are too narrow to allow the head of the abutment to pass through and will secure the prosthesis in place horizontally. A recessed magnet in the upper end of the track will help hold the prosthesis in place vertically. This design offers additional attachment strength while allowing the user to easily attach, remove and clean the prosthesis. Our group will test the durability of the tracks and the strength of both vertical and horizontal attachment.

TABLE OF CONTENTS

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. Auricular reconstruction is an option for patients with underdeveloped ears or ears that have been compromised by injury, disease, or surgery (Figure 2).

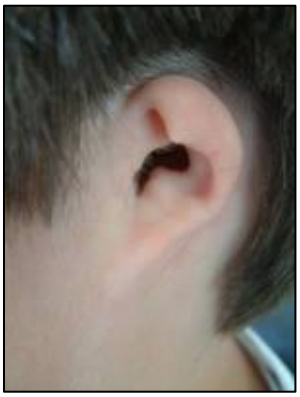

Figure 1: This is an example of microtia, where the outer ear is underdeveloped [4].

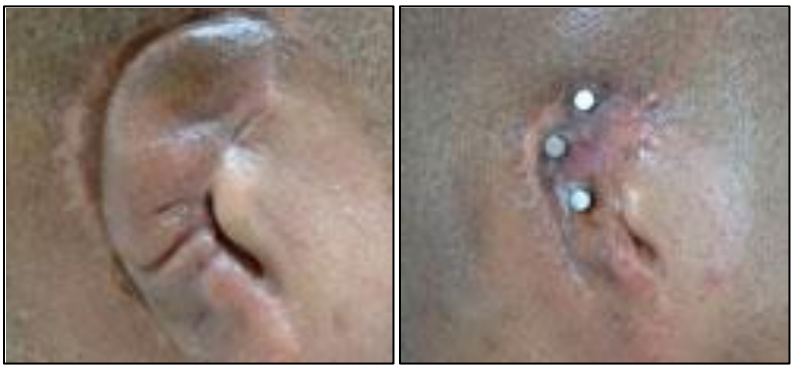

Figure 2: The picture on the left is an example outer ear damage resulting from ear trauma. As shown on the image on the right, the outer ear was removed and three abutments were implanted in the bone for the attachment of an auricular prosthesis. The implanted abutments have magnetic caps used in the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

In the US craniofacial implantology is a relatively new field, which 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 functions 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 freestanding 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 with certain patients.

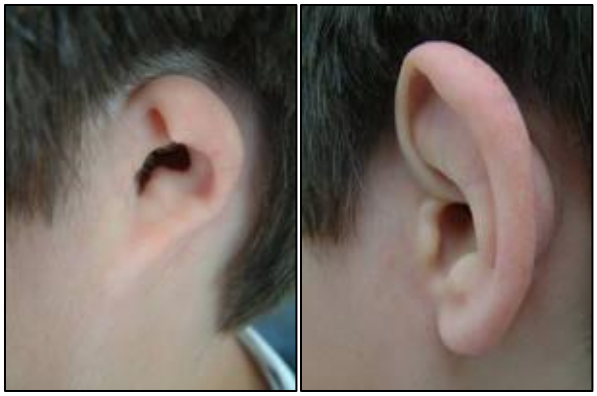

Figure 3: The figure on the right is an example of a slip-on auricular prosthesis, which disguises the microtia present in the image on the left [4].

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 freestanding 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 clips in the prosthetic 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 freestanding method utilizes a magnetic force system. The implants are secured in the bone and magnetic abutments are screwed into the implants (Figure 5). The magnets are typically made from titanium. The advantages of the magnetic attachment method compared to the bar-clip method includes that it is less bulky and easy to clean around, but there is no security in the attachment. In order to overcome this problem, o-rings have been attached to the magnetic attachments in the prosthesis to create a more secure magnetic lock. 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.

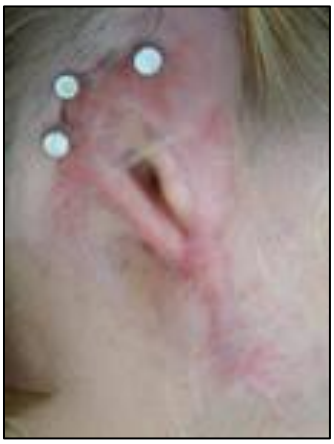

Figure 5: This is an example of the magnetic attachment method. Magnetic caps are screwed onto abutments that have been implanted in the bone. Matching magnets in the prosthesis then hold the ear in place [4].

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 attempted to create a spring and sheath design (Figure 6). This design provided lateral stability that is lacking in the freestanding method. The use of the spring also decreased the odds of sheath fracture. The sheath allowed for easy attachment and detachment, but overall, this design lacked magnets which decreased 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 prosthetic and creates difficulty for the patient during attachment and removal of the device. This design provides a secure attachment, but the twisting is not ideal.

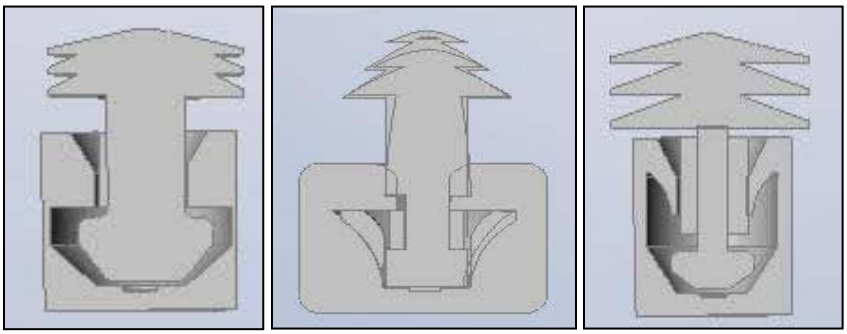

Figure 7: This image displays the prong and flange design, which was built of plastic and required the user to twist the ear during attachment and removal. This design was not ergonomically friendly and the materials were not sufficiently durable [6].

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 be completely contained within the prosthesis and be less than 7-8 mm^2 larger than the abutment heads. 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 prosthesis naturally slides back into place when adjusted vertically.

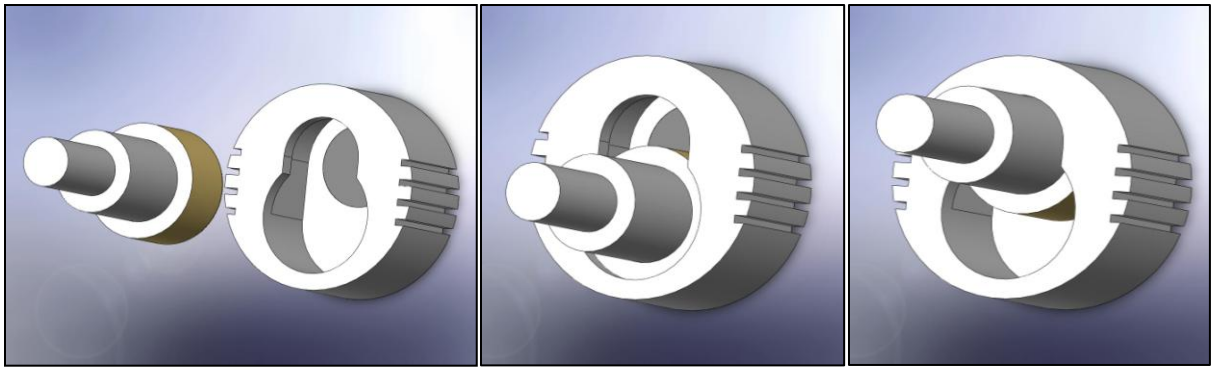

Figure 8: The image on the left shows a single track (which would be implanted into the silicone prosthesis) and an abutment (which would be screwed into the skull implants). The brass colored section of the abutment represents the magnetic cap of the abutment, while the shaded circle of the track represents 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.

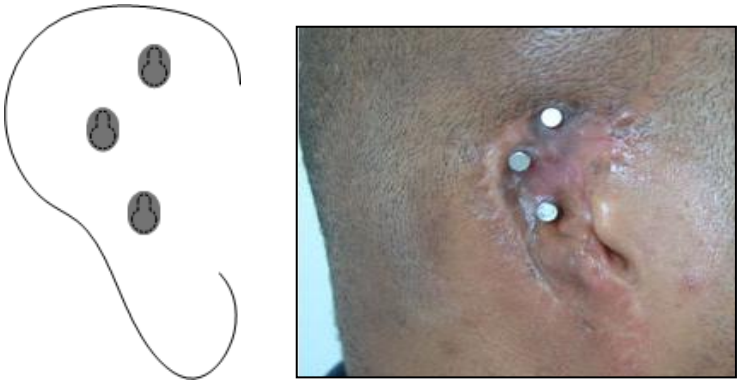

Figure 9: As shown on the left, three vertical tracks would be positioned in the prosthesis to match the implanted abutments, which are shown to the right [4].

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).

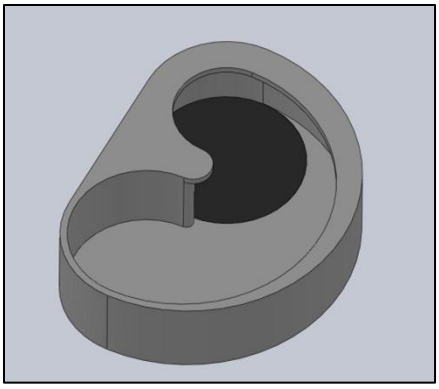

Figure 10: This image displays an individual curved track. The shaded black circle represents a recessed magnet.

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.

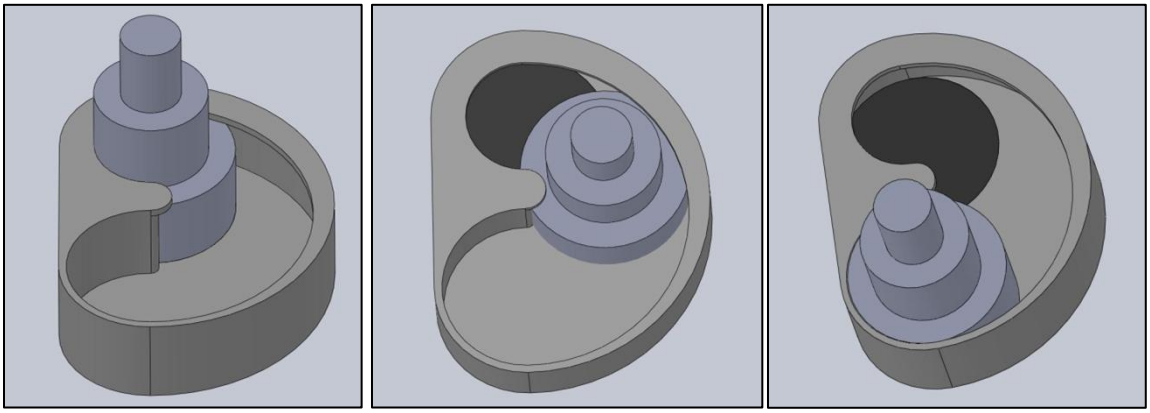

Figure 11: This succession of images shows the process of securing the abutment into the curved track

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).

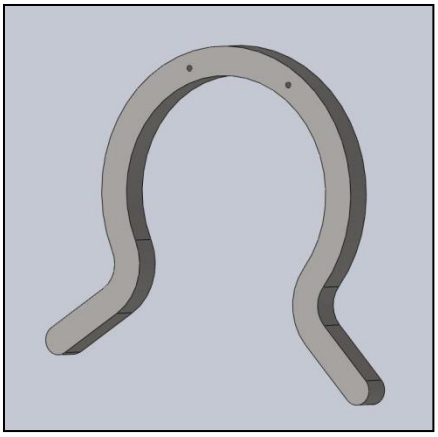

Figure 12: A C-retaining ring such as the one that would be used in the c-ring clip design

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.

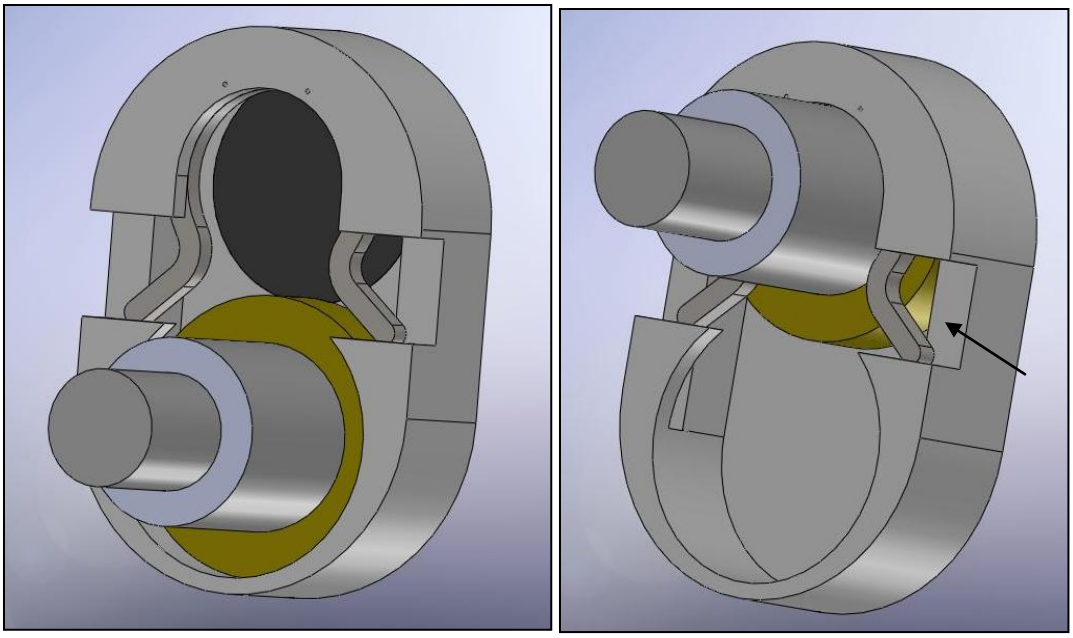

Figure 13: The figure on the left shows the c-ring clip in its unlocked position, while the image on the right shows the abutment in its locked position. The cut out (as indicated by the arrow) allows the legs of the c-ring to move outward as the shaft of the abutment slides past. The shaded circle shown 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 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 abutment 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 is 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 is for the user. The amount of time, force and prosthesis movement required for removal are 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 were 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 is for the user. The amount of time and effort required for prosthesis cleaning are 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 a 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 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 only slightly larger than the current magnet attachments used in prosthesis so they will fit easily inside 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 SolidWorks drawings. The plastic used in the rapid prototyping is weak when it is too thin. Because of this, the prototype designs were simplified and made three times as large as the final prototypes will be. 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.

Ergonomics

The device incorporates many aspects of universal design. The device will be symmetrical and have the capabilities 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.

The user of the prosthesis should be able to attach and remove the prosthesis with minimal effort. In the event that the prosthesis is taken off randomly, it should be easy enough to put back on without the aid of vision or a mirror. The prosthesis should be easy to line up on the abutments and take little time to do so. The proposed solution will be as easy to line up with the abutments as the current device since we are not changing how it is done. The device will contain no moving parts which will make the device intuitive to use and will avoid any user confusion. With no moving parts it will allow it to be easily implemented in the silicone during creation of the prosthesis. When bonding the device into the silicone, it is very easy to accidently get the silicone into the device which could gum up moving parts. For fabrication and mass production, minimizing the number and complexity of components simplifies the fabrication process, lowers cost, and benefits our design.

The device should not cause discomfort to the user. Discomfort could result in pinching of the skin underneath the abutment. It could also result in the skin on the side of the head being pulled or stretched downward while the prosthesis is being attached. 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. The device will have minimal clearance between it and the abutment when being attached causing no area for skin to be pinched.

To accommodate users of all literacy abilities, there will be no writing on the device. It will also be simple enough that an instruction manual on how to use the device will consist of pictures with no words to demonstrate each step of use.

One aspect of our design that needs to be further developed is to make it easy 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 usable life. The current method does not have a way to replace the attachment devices in the prosthesis without ruining the prosthesis. The current thought of how to make our design replaceable is to first cover the outside of the device with a hard enough silicone that would be able to be screwed into. Then we would have a small screw-hole in the device so that it could be screwed and unscrewed into the hard silicone with a small machining screw. The top of the screw head would be flush with the inside bottom of the device as shown in figure 15.

Figure 15: This figure shows a vertical track with a small machine screw. This screw would allow the track to be removed and replaced easily.

Fabrication Process

Fabrication of the final design prototype will be considerably difficult due to the size and materials of the individual tracks. Due to very small dimensions, the tolerances are forced very high. The overall dimensions are as shown in figure 16**.** All wall thickness will be at least 0.5 mm thick. The

device will be fabricated out of titanium or stainless steel. There will be two components, the body of the track and the magnet insert.

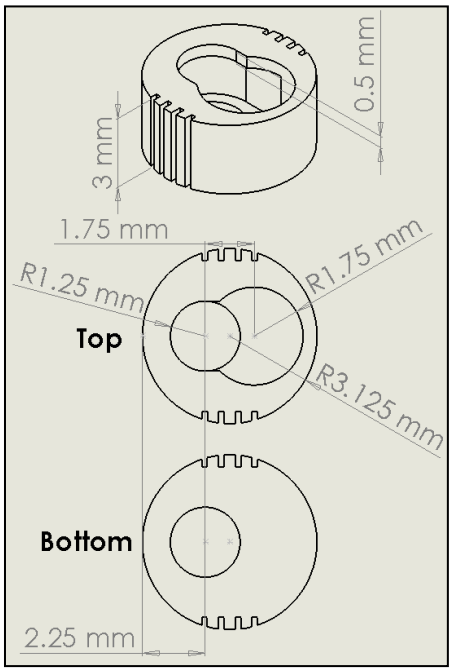

Figure 16: This figure shows the dimensions for each vertical track in mm.

Due to the small size of the project, the team's first concern was the possibility of fabricating a prototype. The design was looked at by a machinist and it was determined possible. The most preferable method of fabrication is to have it professionally made in the professional College of Engineering machine shop. As of yet, the team has not received a quote for fabrication costs, because absolute details for the dimensions have not been determined. The cost of having our design professionally machined will depend on the cost of any mill bits that must be bought or custom ordered. When the design is finalized, the team will get a fabrication quote and then discuss a plan of action with our client.

If it costs too much to have the part professionally fabricated due to cost of labor, the team will buy the necessary bits and machine it in the college of engineering student machine shop.

Outlined below are the steps necessary to machine the piece. The machining technique details have been left out of the outline. Also, steps will be added when the design of the magnet insert is finalized.

The first step to machining the part would be to secure a cube of the desired material in the vice on the mill with the top cube face above the top of the vice as shown in figure 17. The cube of material should be 30x30x30mm.

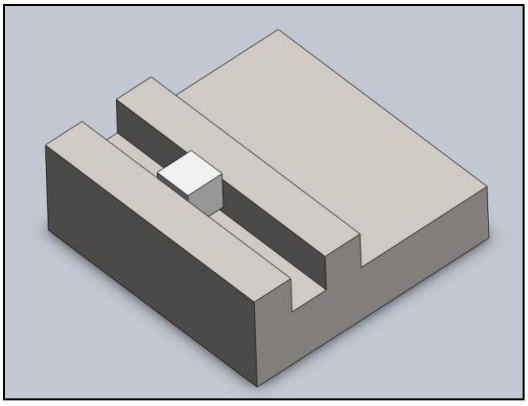

Figure 17: In the first step of the fabrication process, a 30x30x30 mm cube of base material would be secured in the mill vice.

After the material is secure, the top of the cube should be faced with an appropriate sized mill bit. The center of the top face of the cube should be located using a mill edge finder as shown in figure 18.

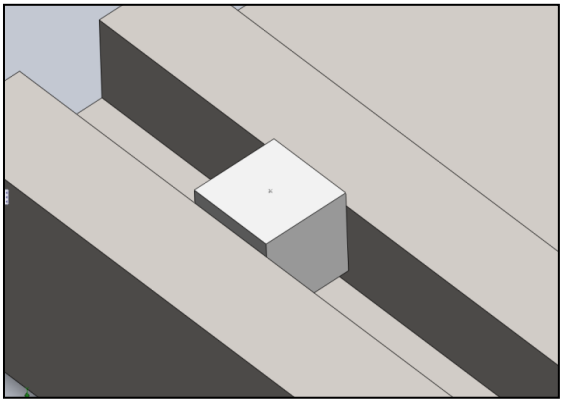

Figure 18: The top of the cube would then be faced and the edges would be located using an edge-finder.

Using a straight 3.5 mm diameter mill bit, a hole is milled 0.875 mm to the right of the center to a depth of 2.5 mm as shown in figure 19.

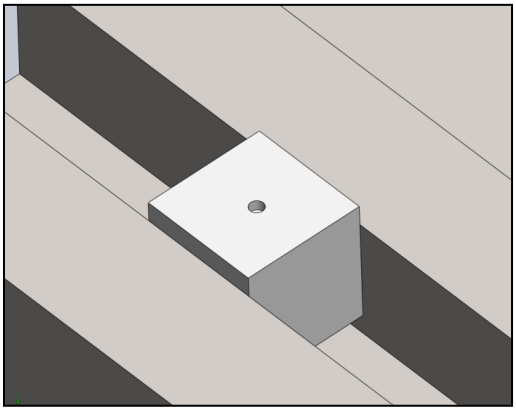

Figure 19: A 3.5 mm diameter, 2.5 mm deep hole will be drilled 0.875 mm to the right of center on the top face.

Using a straight 2.5 mm diameter mill bit, a hole is milled 0.875 mm to the left of the center to a depth of 2.5 mm and then brought to the center of the previously milled hole as shown in figure 20.

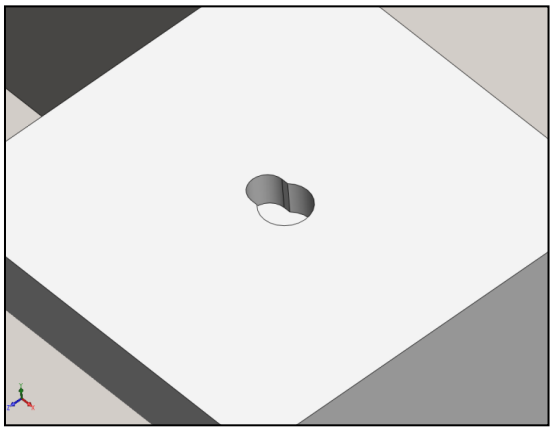

Figure 20: A 2.5 mm drill bit would then be used to mill a 2.5 mm deep slot from 0.875 mm to the left of center to the center of the previous hole.

Using a T-slot mill bit with a 3.5 mm head width, $\leq$ 2.5 mm diameter throat width, $\leq$ 2 mm head space, and a $\geq$ 2.5 mm throat depth a T-slot will be milled in the piece as shown in figure 21. Note: Refer to figure 22 to reference the dimensions of a T-slot mill bit.

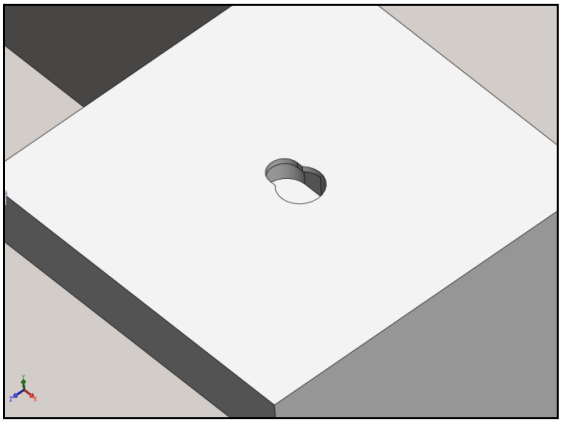

Figure 21: Next a T-slot bit would be used to cut out the lips of the slot.

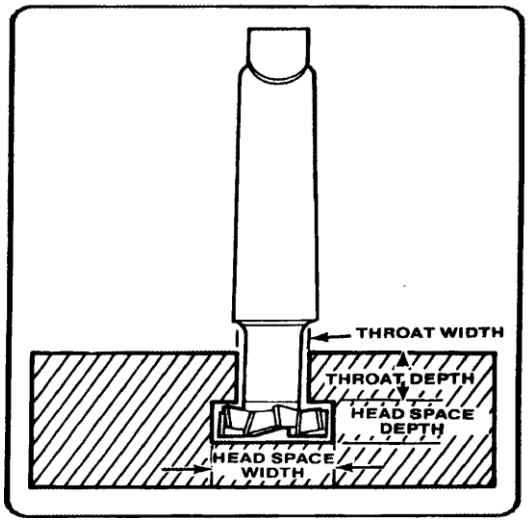

Figure 22: This figure shows the measurements for a T-slot mill bit which will used in the fabrication of the vertical slot design [7].

Using 10 mm end mill bit a 6.25 mm diameter circle should be cut around the piece to a depth of 3 mm as shown in figure 23.

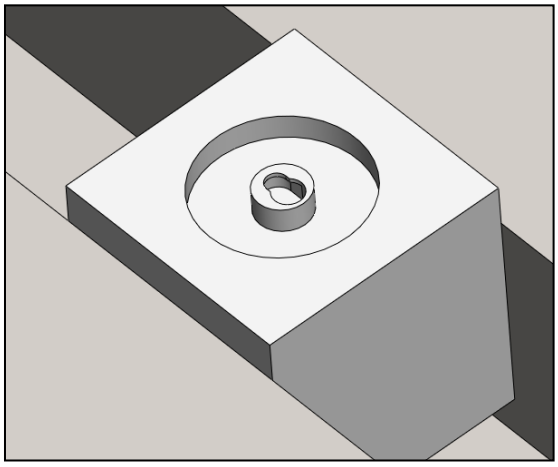

Figure 23: In step 6, a 6.25 mm diameter circle would be cut around the slot with a 10 mm end mill bit to a depth of 3 mm.

Then the cube should be removed from the mill and a 5 mm piece, which contains the milled portion, should be cut off the cube using a cut off saw as shown in figure 24. The rest of the cube can be used to make more pieces.

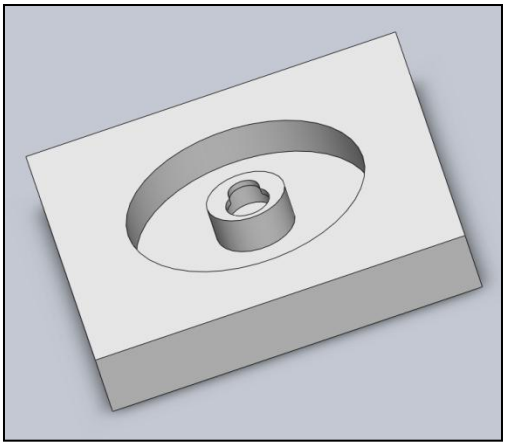

Figure 24: The unused section of the block has been removed with a cutoff saw.

Then the piece should be secured in the vice with the milled portion face down as shown in figure 25.

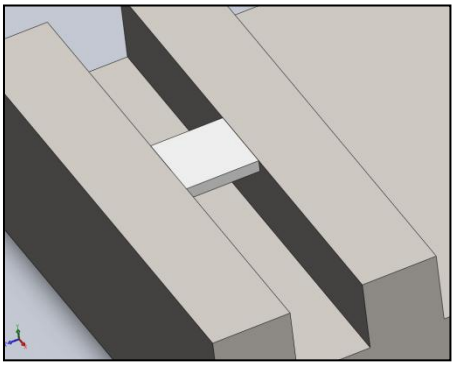

Figure 25: The remaining piece is re-secured upside down in the mill vice.

A 0.75 in straight mill bit will then be used to take material off the cube as shown in figure 26-left until the piece drops free as shown in figure 26-right. The final piece is shown in figure 27.

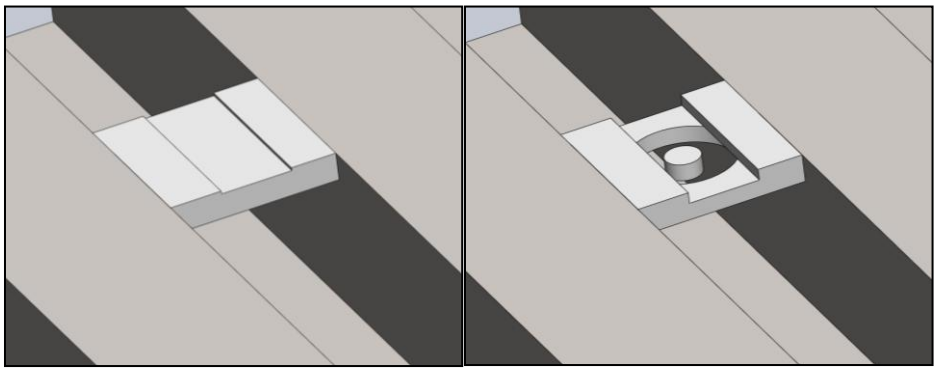

Figure 26: Excess material is removed using a 0.75 in mill bit until the slot drops free.

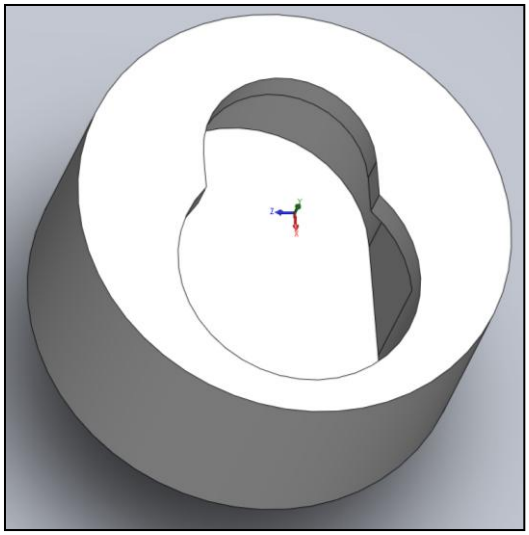

Figure 27: This image shows a completed vertical track using the fabrication process described above.

Testing

Our group will first test the spatial arrangement of the tracks in the prosthetic ear by molding three tracks into a silicone ear. We will use this test to ensure that our method of attachment can be used in all sizes of ears regardless of the arrangement of the abutments.

Then, using Cosmos Works testing we will calculate the force required to remove the abutment from a track in both the horizontal and vertical directions. We will also calculate the force required to break the tracks using Cosmos Works analysis.

After testing our device using a computer, we will construct a model skull with three magnetic abutments and mold a prosthesis with three corresponding tracks. We will then use a force gage to determine the forces required to remove the prosthesis in the horizontal and vertical directions. In order to test the durability of our device, we will repeat the same test after having attached and removed the ear a specified number of times. Lastly, using the same strain gage we will determine the force required to break the tracks and forcibly remove the prosthesis.

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

To continue this project, fabrication of the prototype is a major concern due to the small scale, materials, and complexity of the part. Before fabrication begins our group will work with machinists in the College of Engineering Instrument Shop to determine the best method of fabrication and discuss any design modifications that would greatly alleviate the fabrication process. We will also determine the best method of incorporating a magnet into each track.

After prototypes have been made for the tracks our group will need to determine the best method of incorporating theses tracks into a silicone ear. Currently there are two possible methods. The first method is to allow the tracks to adhere directly to the silicone of the prosthesis. This method would require us to construct the tracks out of titanium, and then use a primer to allow the titanium to bond with the silicone. In the second method our group would incorporate a layer of rigid silicone (shore-d hardness) into the prosthesis. The tracks would then be screwed into this tough plastic sheath using small machine screws. The second method would allow the tracks to be removed and replaced easily, and the tough silicone sheath would prevent the tracks from showing through the silicone.

Lastly, our group would determine a breaking point for the device in order to protect the abutments and the bone if the prosthesis were struck with a significant force. However, this safety measure is not of prime concern to our client.

References

[1] Eavey, R. D., Monroy, A., Nicolau, Y., and Shabdiz, F. 2006. Microtia repair: the case for surgical reconstruction. *J. Oral Maxillofac. Surg.* 64(11): 1655-1663.

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

[3] Gion, G. G. The Medical Art Prosthetics Clinic. [Online] http://medicalartprosthetics.com/.

[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] Figure from: http://www.metalwebnews.com/machine-tools/ch8.pdf

Appendix

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