Auricular Implant Locking Mechanism

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Abstract

To treat the absence of an ear, whether lost by congenital conditions, cancer, or accidents, osseointegrated auricular implants are typically utilized. These implants, made of titanium, are precisely fitted into the mastoid bone of a patient to create a 'stage' consisting of three titanium pins rising above the skin. It is at these sites that an auricular prosthetic can be attached. The typical locking mechanism currently used is a type of o-ring snap-fit which attaches a titanium magnetic housing to the pins. Within this housing is a neodymium magnet which serves to help position and reinforce the locking mechanism. However, this current design faces problems involving wear from friction, due to it being a snap-fit design, and also complicates active lifestyles as lateral forces may disengage the prosthetic from the head. Therefore, the design team has developed three designs to overcome these shortcomings. Three possible solutions utilize magnetic/gravity induced locking, a sliding pin lock, and a snap-fit design. Through prioritizing design factors from our PDS and assigning values to them, the magnetic locking mechanism was deemed the best design.

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Design Motivation

The motivation behind this project is to replace the currently implemented locking mechanism of an auricular prosthetic. Auricular implants are used as an alternative to surgical reconstruction of an ear, which typically results in unsatisfactory results and difficulties. Contemporary mechanisms of prosthetic attachment include a bar-clip and a magnetic attachment system. Preceding these mechanisms, adhesives and special support glasses were utilized. Currently, the locking mechanism used by the client relies on a magnetic housing supplemented by an o-ring snap-fit. Friction arising from repetitive use causes excessive wear on the exterior of the prosthetic as well as the o-ring snap fit mechanism. Further, the o-ring snap fit is not suited to withstand lateral force. Though this locking mechanism ensures a natural aesthetic quality, it inhibits an active lifestyle. The design team's goal is to create a locking mechanism that will supersede the current o-ring snap-fit while incorporating the current housing.

Problem Statement

Our Client is Dr. Greg Gion, who currently works for The Medical Art Prosthetics Clinic and is also on the Board for Certification in Clinical Anaplastology (BCCA). Dr. Gion has established himself in the field of medical prosthetics through university appointments, developing hospital programs, private industry practice, and peer reviewed publications. Dr. Gion has requested a mechanism to replace the current o-ring magnetic sleeve used to attach auricular prostheses to the mounting pins attached at the patient's mastoid bone. The current method utilizes an o-ring housed sleeve which allows for good attachment and rigidity. However, the design requires significant force to place and remove which causes excessive wear and tear on the prosthesis. An ideal design would maintain the already in place stable connection while refining the ease of attachment and removal.

Background

Several reasons an auricular prosthetic device may be required include congenital defects, cancer treatment, or accidents. Although reconstructive plastic surgery is possible in some cases, usually the results are unsatisfactory, healing is difficult, it requires multiple major surgeries, and the amount of bone and cartilage available to work with is often inadequate for functionality and appearance.[1,2] Because of these challenges, the social and psychological issues arising from the loss of an ear may not be sufficiently addressed by plastic surgery.[3, 4] In such cases, osseointegrated prosthetics can be an effective treatment.[6]

The first osseointegrated auricular prosthetics consisted of a bar and clip device; currently, magnetic systems are used permissively to retain retention longer despite bar clips having an initially higher retention.[7,8] Magnetic systems are also used as opposed to a bar clip because the bar clip is more susceptible to fracture.[9] Another important advantage of a magnetic mounting system is an improvement in hygienic maintenance.[8]

Once the decision to adopt an osseointegrated implant is made, several surgeries are undertaken. Acting as a surgical guide, a molded guide is created of the area where the mastoid pins will be located. In addition to this molded impression, an accurate working model of the

patients' ear is created to help guide the placement of the mastoid pins. In surgery, titanium implants are placed in the mastoid bone and temporary healing abutments are placed on the titanium implants. During a period of 3-6 months the bone, as well as the skin, are given time to adapt to and heal around the pins/healing abutments. Afterwards, permanent abutments replace the temporary abutments. Upon these permanent pins, the housing contained within the prosthetic ear can interface and snap on securely. Finally, the prosthesis is symmetrically and aesthetically aligned to coordinate with the individuals' features.[10]

Current Practices

Currently two methods are used to secure auricular prosthetics the head. One utilizes a bar-clip attachment which involves implanting three metal pieces into the mastoid bone to act as a base for the locking mechanism.[14] A titanium bar is attached to the head by screwing the bar into the implants.[14] This bar acts as a male end of the connection while the prosthesis houses the female end of the device. This consists of four metal clips that snap onto the titanium bar.[14] This method is rarely used due to issues with customizability of the bar system. Each installment necessitates a customized attachment location due to varied bone strengths between patients. However, the bar system also needs connections at specific locations. The optimal location for implants in the mastoid bone does not always match up with the optimized locations for the connections on the bar. Furthermore, this system is difficult to clean and is prone to mechanical wear through repeated use. This wear ultimately causes part of the system to break which requires replacement.

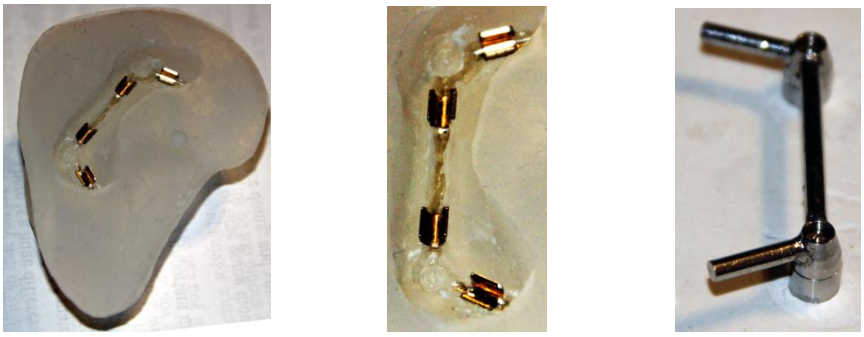

Figure 1: (Left) Bar system in mock prosthetic. (Center) Close up of clips within mock prototype. (Right) Bar implanted into clay base.

The second method of attachment uses an o-ring and magnet system for prosthetic retention.[14] Similar implants used for the bar system are implanted into the mastoid bone. However, instead of a bar, three separate abutments (pins) are screwed into the implants.[14] The prosthesis houses three female ended caps that go over the abutments. These caps are magnetically attached to the pins and secured with an o-ring which prevents accidental removal of the implants.[14] This system is more customizable than the bar-clip attachment and is easier to clean. However, it is difficult to attach and remove. The required force to use this device induces wear on the prosthetic which also affects the aesthetics.

Figure 2: (Left) O-ring system within mock prosthetic. (Center) Outside of a single O-ring magnetic cap. (Right) 3 abutments that are implanted into a clay base.

Previous Biomedical Engineering Designs

Multiple teams have designed several solutions for prosthetic retention. One uses a gravitational locking force with a magnetic cap to attach the prosthetic. This device contains a hole that can fit over the abutment and a smaller circular sector that fits around the abutment neck but not over the abutment head (Fig. 3). The prosthesis can be placed over the pins and pulled downward into a locked position.[15] Once attached, the ear is held in place through a combination of the housed magnet, gravity, and the smaller radii being unable to move past the abutment head.[15] This system was effective in an ideal situation with a planar surface, but was impractical due to the various contours on the side of a patients head which did not allow for proper alignment.

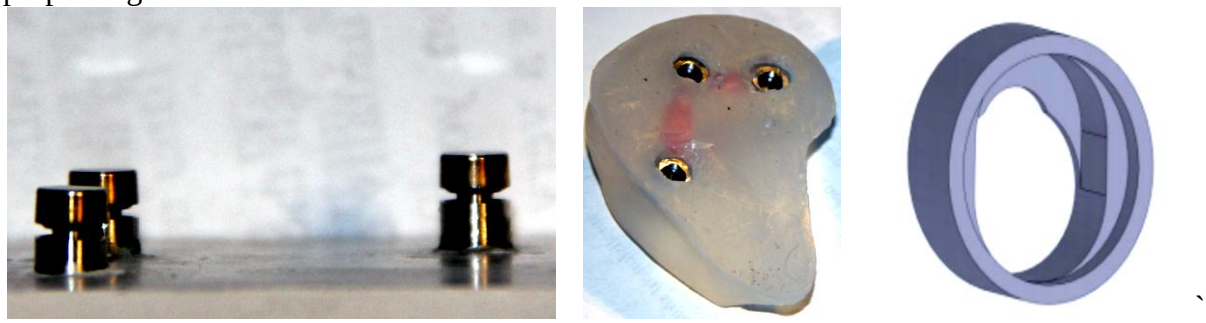

Figure 3: (Left) Existing magnetic abutments with spacer attached to a clay base. (Center) Gravity lock device within mock prototype. (Right) Profile of the gravity system, which is pulled down over an abutment to lock in place.[15]

A second design involved a change in the three magnet pin system. The middle pin was switched out for a wider pin that also included a male ended threading.[16] The prosthetic housed two magnets (top and bottom) and one female ended housing that screwed into the middle pin.[16] The prosthetic was attached through a single rotation and positioned in the correct orientation with the top and bottom magnets.[16] The screw-like qualities of the middle pin provides retention of the ear while the magnetic upper and lower pins provide alignment. This system requires a uniform surface and also cannot work with the contours of the skull.

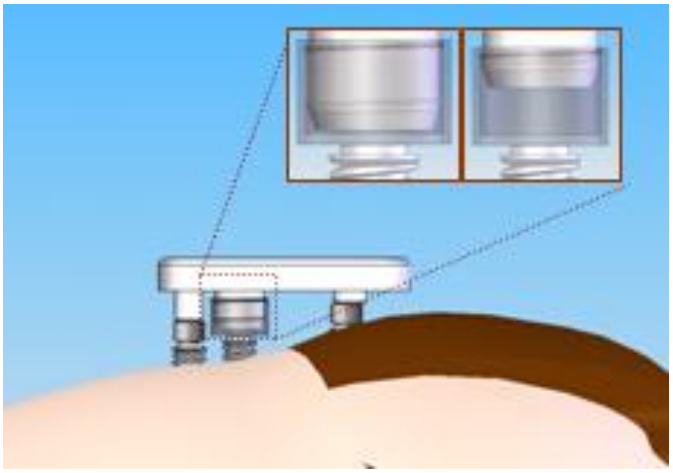

Figure 4: Three-pin system to attach prosthetic. Middle pin involves 360 degree rotation for attachment and removal. Top and bottom magnetic pins allow for alignment.[16]

Design Requirements

Several factors for an effective solution were considered. First, a solid attachment between the mastoid bone and the prosthetic is required. The device should sustain lateral, vertical, and horizontal forces without detaching.

The device should incorporate the current three pin system. The surgical implant procedure is defined and the parts easily acquired. The client prefers to continue with these current practices and thus the design must reflect this.

Previous designs have been able to meet these requirements but have lacked ergonomically and practically. To distinguish this design, it should be easy to attach and remove with minimal force exerted on the prosthetic. This alone will result in a more ergonomic retention system. Also, the design should installable on a contoured surface.

Finally, the design must maintain the aesthetics of the ear prosthetic. Prosthetic aesthetics contribute to realism which is critical for the social effects for the patient. Aesthetic preservation involves two factors. First, the design should minimize exterior mechanical devices. All parts of the system would ideally be contained within the prosthetic. Second, the design should not require routine force being exerted on the prosthetic exterior. The ear is painted to reflect the features of the patient's skin and any wear may expose the underlying silicon.

Proposed Designs

I. Snap-fit System

Similar to currently employed methods, the snap-fit system is a two-part system composed of a housing along with an attachment point (abutment). An external view of the snap-fit housing yields an identical resemblance to the currently employed O-ring system (Fig. 5a). Note that every aspect of the snap-fit design is identical to that of the O-ring design, that is, it has the same dimensions as well as a magnetic center piece on its' interior (not shown). The only exception is the actual securing mechanism. As previously mentioned, the primary securing mechanism for the O-ring system is a rubber O-ring which lines the inside of the housing; in contrast, the snap fit system employs a small elastic polymer rim on the inside of the housing which snaps onto the abutment. Figure 5b shows the approximate location of the polymer ring. Again, note that this location is the exact location of the O-ring in the current design.

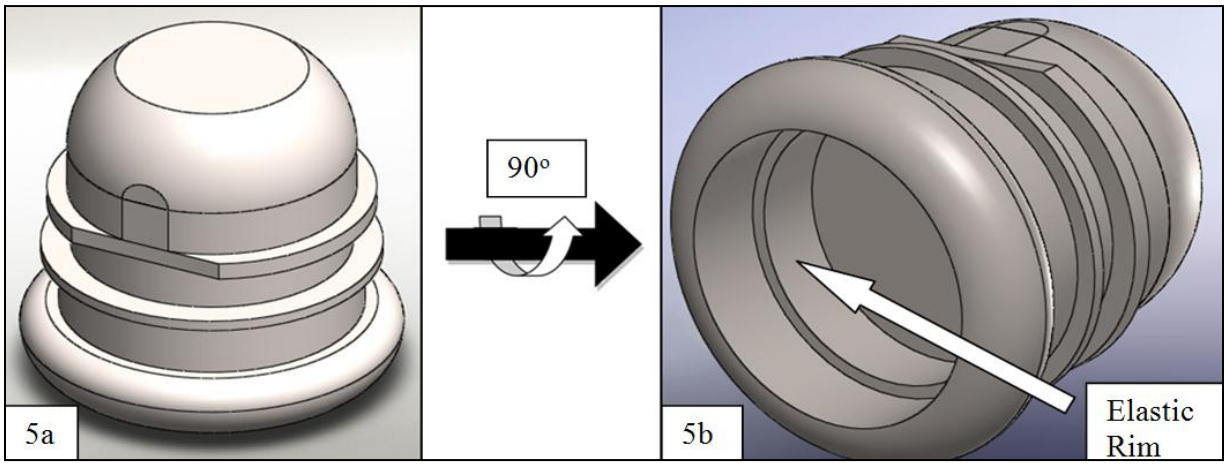

Figure 5: (a) Shows the exterior of the snap fit housing. (b) A conceptual view of the elastic polymer rim

The general premise for the locking mechanism, shown in figure 6, can be divided into three separate steps. Note that figure 6 shows a cross section of the housing to allow for a more conceptual view. Beginning the process, the snap-fit system is orthogonally brought towards the face of the abutments (Fig. 6a,). Next an external force (red arrow) is exerted on the device which will cause deflection of the polymer rim (Fig. 6b). Slight deflection allows for the device to further be pushed onto the abutment until the rim locks in place (Fig. 6c). To further clarify, when the rim locks into place it will return to its' original confirmation, due to its' elastic properties.

Finally, to dislodge the prosthetic, a simple releasing method is employed to deflect the rim enough to remove from the abutment. The exact release mechanism has not been deeply investigated, and thus is not offered in this report.

One of the primary goals for creating a new locking system is to incorporate a large amount of the already in place hardware. Of any of the created designs, the snap-fit system fulfills this goal the best. With the exception of the elastic polymer rim, every aspect of this system is identical to the currently used O-ring snap fit system. The major problem with this design is the

lack of evident releasing mechanisms. For the snap-fit system to be deemed successful, the releasing mechanism would have to be one that did not require a large amount of force from the patient, otherwise this system would be synonymous with the O-ring system. However, no such releasing system could be found.

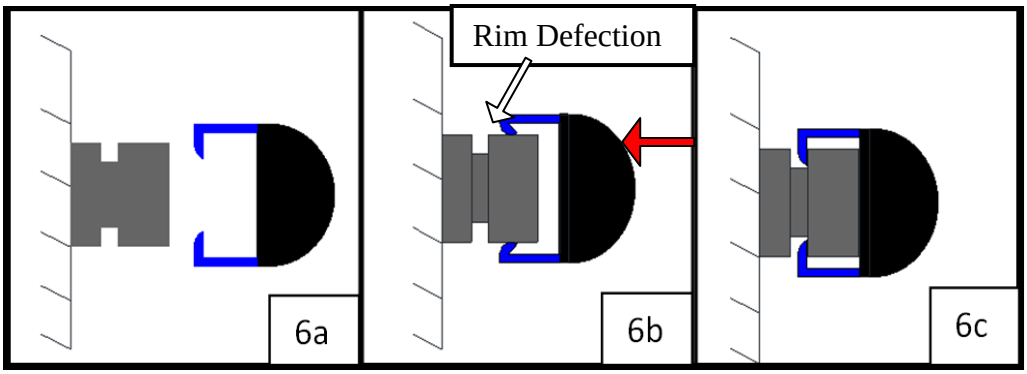

Figure 6: A cross-sectional view of the snap-fit system housing going through a step by step view of the locking mechanism. 6a) The housing is brought towards the exterior abutment. 6b) An external force (Red arrow) is applied to deflect the elastic polymer rim. 6c) The elastic polymer rim returns to its original orientation as it locks onto the abutment.

II. Pin Secured System

Instead of wrapping around the abutment, as the O-ring system and snap-fit system do, another method for attachment is to lock through the abutment. The push pin system revolves around this logic as it utilizes a pin which locks into the abutment. A majority of the currently used design would be implemented into the push pin system.

To begin, two minor adjustments need to be made to the currently used housing. First, the diameter of the bottom of the housing would be made slightly larger. This enlargement would allow the housing to easily slide on and off of the abutment when the pin secured system is not initiated. For a path through the silicone prosthetic, a second adjustment is made in the form of a compartment protruding from the housing (Fig. 7). One critical part of this compartment is that it must be open to the external environment of the prosthetic, which will allow for external activation to the internally located pin (Figure 8). Figure 7 also shows how the pin would be inserted into this extension. Not that for this design to be successful the pin would have to somehow be regulated to ensure that while it can be pushed into the abutment it cannot be pushed too far or pulled completely out of the housing/prosthetic.

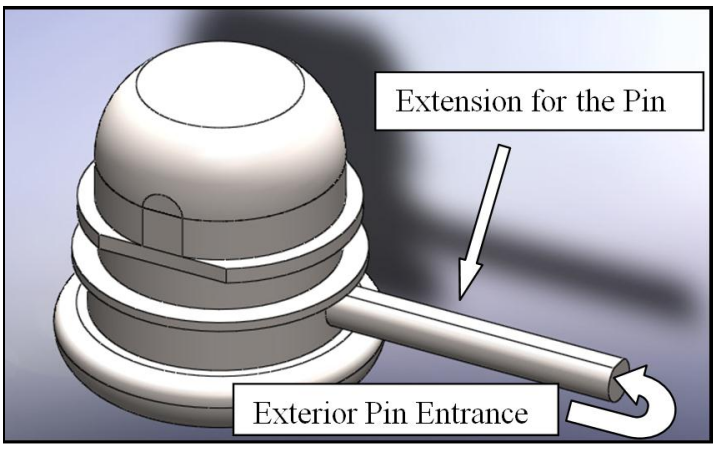

Figure 7: Depiction of the housing with the external cylinder used to contain the pin. The cylinder provides a path from the inside of the housing to the external environment, thus allowing the pin to be secured from the outside of the ear.

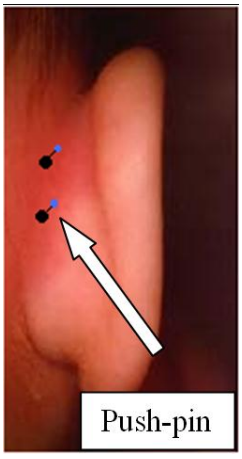

Figure 8: Shows approximate location of where the pins would be for the pin secured system. The blue circles are the tops of the pins which would be pushed into the opening of the extension on the housing (black circle).

One implication of this design is that a hole must be made in the abutment. This hole must have an orientation specific to the inserted pin (Fig. 9). Ensuring that the connection from the pin to the abutment is not only strong but also easy to put on/take off is the key for this design to be successful. Further, it is imperative that the link be as homogeneous/tight as possible to ensure durability and negate any movement while the patient is walking or performing any other activity. To ensure these properties, the system is compact and made of titanium.

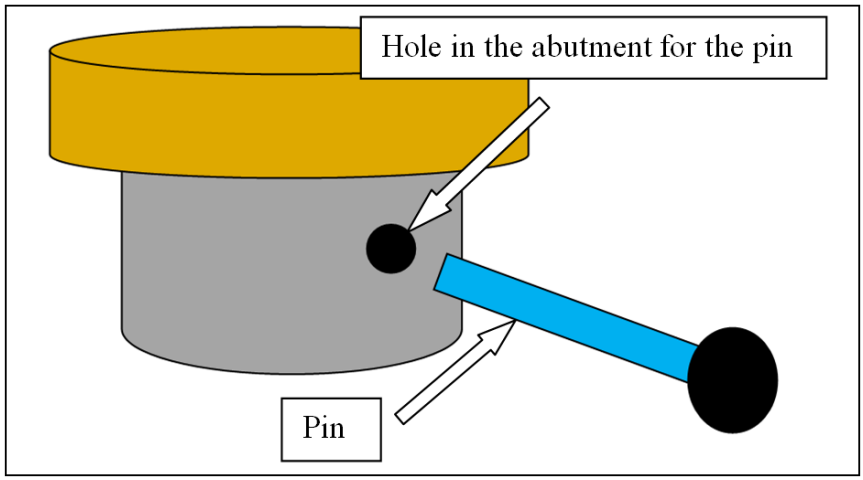

Figure 9: A depiction of the hole that would have to be made in the abutment along with the pin that would be inserted. The pin would be guided into the hole by the pin compartment of the housing.

All of the previously stated components create a system that is easy to put on and take off when the pin is disengaged, but is also secure when the pin is engaged. The actual process to initiate this system is shown in figure 10. Figure 10 does not depict the housing that would surround the pin. Similar to previous designs the prosthetic is placed over the abutment. Once the prosthetic is in place the pin can be pushed into the abutment, which will subsequently lock the prosthetic onto the abutment (Fig. 10). To disengage the prosthetic, the pin is simply pulled back out of the abutment and the prosthetic can easily be taken off.

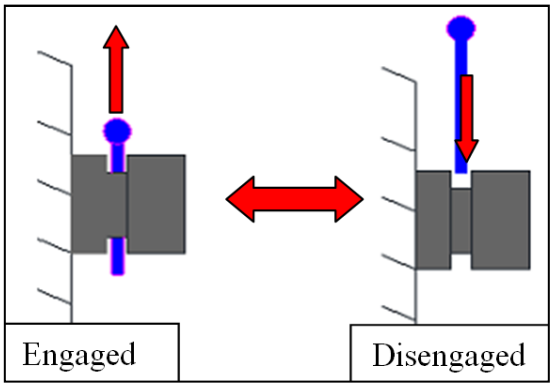

Figure 10: A picture of the pin secured system without the surrounding housing or prosthetic. The system is both in the engaged (left) and disengaged (right) state. The red arrows show the direction the pin (blue) must be pushed to be for the system to be in the opposite state.

III. Magnetic Locking Mechanism

The motivation for the magnetic locking mechanism was the need to eliminate external contact with the prosthetic, which will ensure its' aesthetics and longevity. Instead of using an external force to lock the prosthetic in place, this system intertwines gravity with magnetism to give a secure and easy locking mechanism. Similar to the other designs, the magnetic locking design makes small adjustments to the already in place housing system. To fully conceptualize how this design works it is important to start with the basis of the securing system: a ferrous metallic crescent shaped piece termed the slider (Fig. 11). This slider secures the prosthetic by sliding around the abutment.

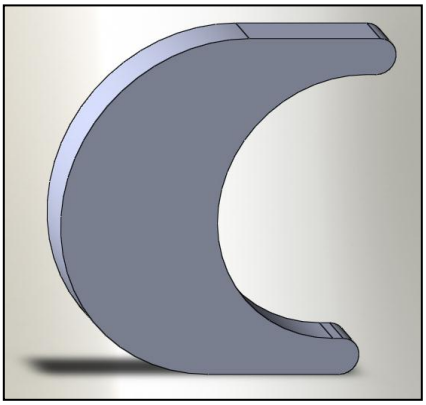

Figure 11: An image of the ferrous magnet, which is the primary component used to secure the prosthetic.

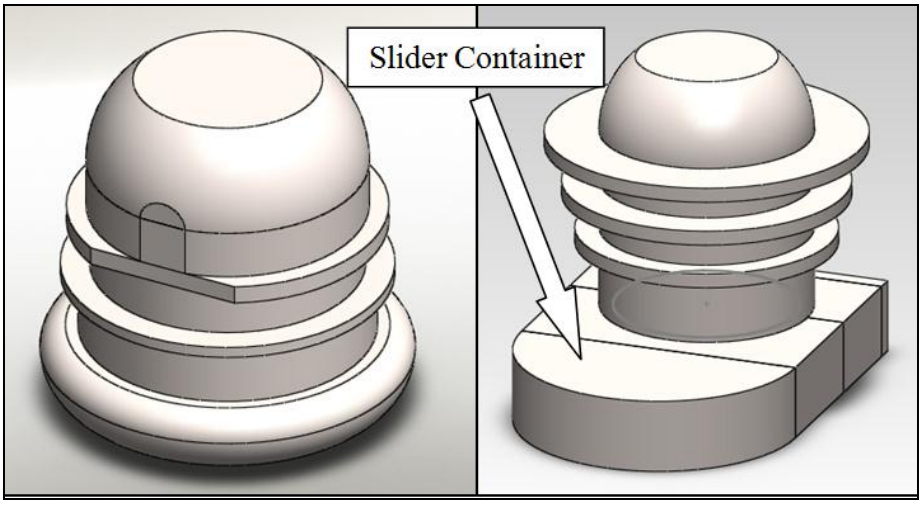

Figure 12: 12a. An image of the currently used housing. 12b. Image of the housing used for the magnetic locking mechanism. The slider container is the primary difference between the currently used locking system.

To accommodate the slider, an extra compartment, termed the slider container or housing, is attached to the currently used housing (Fig. 12b). This extra compartment is large enough to house the entire slider. Thus, when the slider is fully housed within the compartment, the entrance to the housing is completely unobstructed and thus the abutment can smoothly fit inside.

One component of this design that is different than any other design is the need to use an external piece that is completely separate from the housing itself. This piece is a neodymium magnet which would be used by the patient to control the ferrous slider. Figure 13 depicts the premise of this controlling mechanism. The first important concept to observe from this figure is the orientation of the housing from the "top" picture. When being placed on the abutment, the slider compartment will be the highest point of the housing. This is one of the critical aspects that must be taken into account when this device is implanted into the prosthetic.

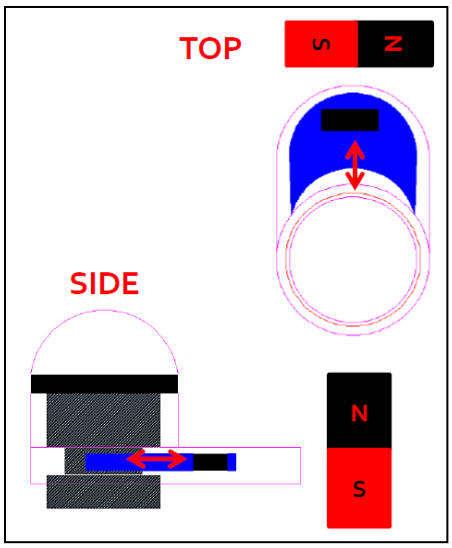

Figure 13: The general premise behind the magnetic locking mechanism. The top view shows the orientation of the housing when it is in the prosthetic and attached to the abutments. Bringing a magnet close to the ferrous slider (blue) will cause it to go up into the housing.

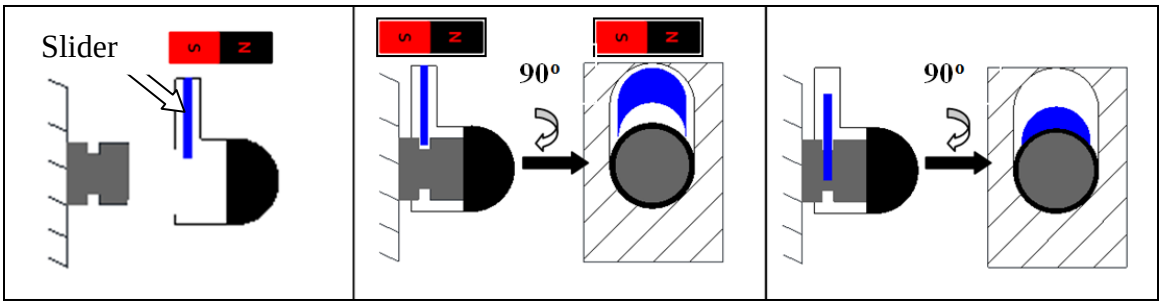

Figure 14: The mechanism of action for the magnetic locking mechanism is depicted. 14a) The housing is brought towards the abutment (gray) with an external magnet in the proper orientation to lift the slider (blue).14b) With the slider fully retracted the housing can easily fit over the abutment. 14c) When the magnet is removed, the slider falls down and locks around the abutment.

Placing this design onto the prosthetic can be broken down into three steps (Fig. 14). First the neodymium magnet must be placed over the prosthetic (and thus the housing) to draw the slider up into the compartment (Fig 14a). Once the slider is drawn up into the slider container the entrance for the abutment is unobstructed; thus, the prosthetic can be placed onto the abutments

with no resistance (Fig. 14b). Now that the housing is over the abutment, the neodymium magnet can be removed and the slider will fall around the abutment creating a secure attachment (Fig. 14c). To further release the connection the magnet is re-placed over the prosthetic pulling each magnetic locking piece back into its' respective container. The prosthetic can then be removed.

To properly implement this mechanism, one quintessential aspect that must be addressed is the convenience factor of having to use an externally placed magnet to disengage the system. Some possible ways to work with this hindrance are: using a system in the form of a ring that can be worn by the patient on his/her finger, creating a fob that can be attached to a patient's key chain, or by simply offering magnet carrying cases that can easily associate with a purse, hand-bag, wallet, or other "every-day" item.

Design Matrix

Criteria		**Possible Designs**		
Considerations	Weight	Magnet	Pin	Snap-fit
Safety	10	10	10	10
Durability	20	18	18	10
Ergonomics	20	14	16	12
Feasibility	25	20	18	16
Client Preference	10	10	8	6
Ease of Concealment	15	13	8	15
Total	100	85	78	69

Figure 15: The design matrix used to quantitatively assess the different designs. Assessment is based on criteria that were seen as essential for a successful design. The matrix shows the magnetic locking mechanism has the potential to be the best product.

To determine which one of the designs would best meet the requirements of the project and still be feasible, a design matrix was created analyzing the three preliminary designs based on six different parameters. These parameters included safety, durability, ergonomics, feasibility, client preference and ease of concealment. After accounting for these factors, it can be seen in figure 15 that the magnetic locking system is the best choice of design.

Since this device is used by human subjects, it is imperative that there is no source of danger with any of the mechanisms proposed. This was the case with the three mechanisms; therefore they all received the highest score possible in this category. Durability is another important factor due to the repetitiveness of attaching and removing the prosthetic each day. While the magnetic and pin designs received high scores due to their robust materials, the snap fit design was determined to be the least durable. It would rely on the bending of a material for attachment and removal which would increase wear on the material. Along with this, it requires heavy contact to the surface of the prosthetic causing a wearing of paint on the prosthetic, reducing its lifespan. Human use and repetitiveness require an ergonomically friendly system.

The snap fit design would require more force than the other designs to both attach and remove the prosthetic, thus lowering the score it received. The pin and magnet systems fared slightly better with the magnetic design being less ergonomic due to its two part system. Size restraints can further complicate the proposed designs. Therefore feasibility is an issue that needed to be taken into account. While all designs scored well in this category, the magnet system was determined to be the most feasible. The pin design would require a high level of precision and the snap fit design would need a complicated detachment system. Since this device is intended to be sold by the client, his input is valued and must be taken into account. Finally, this prosthetics main purpose is to improve the life of the patient by simply looking like an ear. Because of this, it is necessary that the mechanism is nearly, if not completely concealed in the prosthetic itself. The pin system would require a small piece to be visible, which greatly reduced its ease of concealment score. The magnet system would require a slightly larger housing, but still should be fairly easy to conceal. The snap fit's small and simple design would be the smallest and most concealable.

Final design

As our design matrix indicates, the final design we chose is the magnetic slider system. The mechanism for attachment and removal is described earlier in the proposed design sections and has remained unchanged. The housing, on the other hand, has undergone a few transformations. The first aspect is the enlargement of the concentric rings around the housing. These rings can be seen around the cylinder shaped portion in figure 16. This will provide a greater hold in the prosthetic which in turn will lengthen the life span. Secondly, the material for the housing has changed. In order to allow for more freedom with the shape, a polymer was chosen since it simply needs a mold. The prototype in figure17 is made from ABS in a rapid prototyping machine, which is only meant to be an actual scale model. The finished product would be cast in a mold and made from a different type of plastic.

Figure 16: Actual Size Prototype. Note the large rings towards the top used to hold the housing in the prosthetic's silicone.

Figure 17: The Three Pieces of the Design. The housing (top), bottom cap (left) and slider (right) can be seen.

The design also consists of a sliding piece and a bottom cap. In figure 17, these pieces can be seen. Once again, these pieces are simply models. The actual mechanism would require the slider to be made at least partially of a ferrous material to allow the magnet to pull it up. The bottom cap would ideally allow for removal from the housing in case the slider was to get stuck. The finalization of the bottom cap has yet to be determined and will merit further designing. One final piece of the design is the magnet used to unlock the slider. Since it is important to make this process as easy as possible, a strong magnet must be used in order to ensure the slider is lifted. Neodymium magnets are the strongest permanent magnets made today and for this reason this is the type of magnet that will be used to lift the slider. Figure18 shows the magnet purchased and used for testing. While this magnet would be functional, it is not the ideal shape. A magnet that would better fit the contour of the top of the prosthetic would allow for greater pull of the slider due to closer proximity. Once again this piece would require a little more work to establish the best shape.

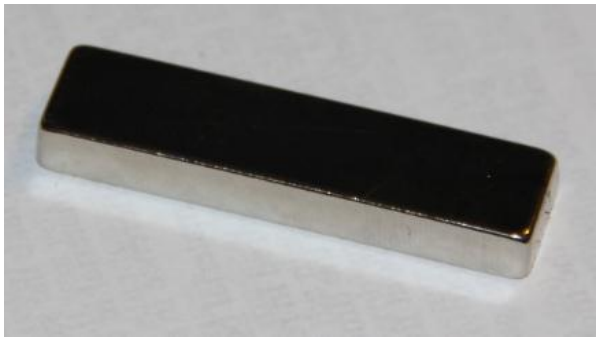

Figure 18: Neodynium Magnet. A picture of the purchased magnet used for testing and actual scale prototypes.

The final design fulfills nearly all the design requirements for the project. It provides a solid attachment that will prevent force coming in any direction from knocking the prosthetic off the patient. This is important to prevent any potentially embarrassing situations for the wearer of the device. It also uses the existing three-pin system, allowing for immediate use in the current market. This will also reduce the cost by not having to redesign the entire system. Longevity of the prosthetic is another requirement that needed to be met. With the no contact lifting of the slider, the ear prosthetic can be simply slid off. This reduces the amount of force placed on the silicone, thus protecting the decorative paint. Finally, the device is concealable. While slightly larger than the existing systems, it will still allow for full embedding in the silicone. Correct placement should retain the aesthetics of the prosthetics.

Testing

I. Proof of Concept

To ensure that the design worked, a blown up scale model was fabricated (Fig. 19a). A slider was created by filing down a washer (Fig. 19b) along with a model of the abutment (Fig. 19c). The basic magnetic displacement was demonstrated using a cow magnet. Then, a to-scale prototype was fabricated and the same test was performed, further proving the concept of the design (Fig. 20).

Figure 19: 19a) A display of the enlarged version of the magnetic secured housing. 19b) The ferrous slider model was made by grinding down an iron washer. 19c) Enlarged model of the abutment. The wood block simulates the mastoidal base of the abutment while the cork cylinder models the abutment itself.

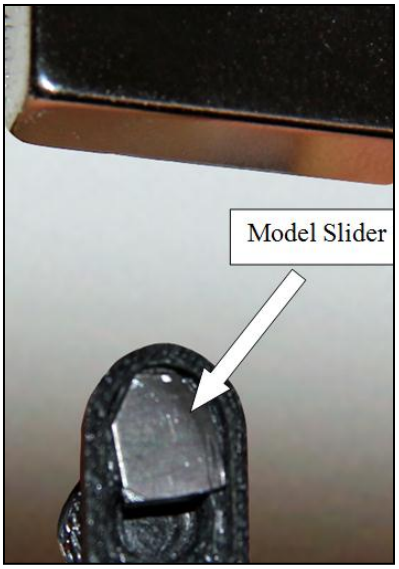

Figure 20: Proof of concept using the actual sized prototype. The Neodymium magnet is shown on the top within about 1.2 cm of the prototype. The Ferrous slider is a model and thus does not have the cutout needed to attach to the abutment. Note that a cover would typically cover the slider. This figure shows a complete retraction of the model slider.

II. Analysis of the locking mechanism

Once the concept was proved using enlarged and actual sized models, the interaction of the magnet and slider was analyzed. A baseline distance from the top of the slider to the magnet was established. Practicality of the distance when the device was in use was taken into account. This is formulated by observation of the distance where the magnet would actually be applied on the prosthetic to the point of the slider housing. If the neodymium magnet is able to retract the slider at this distance then the design concept would be proven. This distance was determined to be 1.0 cm; however, to fully ensure consistent performance, a working distance of 1.2 cm is required.

Working angles from the vertical axis of the slider housing in a horizontal position where examined in order to establish an angular range that the magnet would consistently retract the slider over (Fig. 20). To test this, the prototype was placed in the orientation it would actually be used in (Fig. 21). A piece of iron was then used to model the slider (Fig. 20) and the cover was secured on the housing with a rubber band.

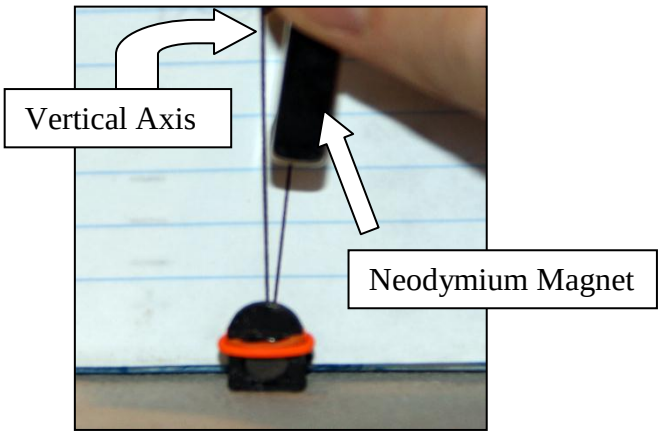

Figure 21: Display of the testing conditions used to analyze how the angle the neodymium magnet affects the ability of the slider to retract. The housing is held together using a rubber band while the magnet is brought towards the housing at an angle of 6^{o} from the vertical axis.

Next, a neodymium magnet approached the housing from different angles until the slider was retracted. The first angle was 0^{o}, or straight down the vertical axis of the container. The angles were then increased in increments of 3^{o} until 30^{o} was reached. Figure 21 shows the testing conditions, and a magnet applied at a 6^{o} angle.

Table 1 and Figure 22 show the distance needed to retract the slider decreases as the angle from the vertical axis increases. This demonstrates the ability of the magnet to retract the slider will decrease as the magnet approaches at increasing angles from the vertical axis. However, comparing this data with the performance distance of 1.2 cm, Figure 22 shows that at an angle of 14^{o} the magnet is capable of retracting the slider. Applying 14^{o} to both sides of the vertical gives an operable area of 28^{o}.

Distance to Retract Slider with Varying Angles		
Angle (degrees)	Average Distance for Retraction (cm)	Standard Deviation
0	1.65	0.46
3	1.36	0.26
6	1.39	0.16
9	1.40	0.20
12	1.37	0.15
15	1.11	0.19
18	1.08	0.14
21	0.87	0.28
24	0.91	0.22
27	0.56	0.35
30	0.25	0.27

Table 1: This table shows how the distance to retract the slider changes when the angle of magnet presentation varies. As the angle from the vertical axis increases, the magnet needs to be brought closer to the housing to fully retract the slider.

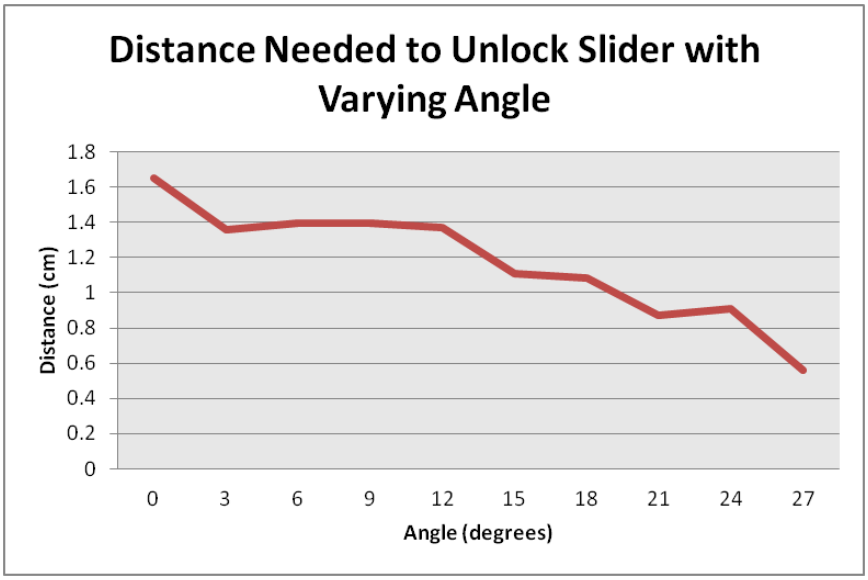

Figure 22: Plot from the data presented in table 1. When the magnet is within 1.2 cm of the slider, an angle of 14^{o} is sufficient to retract the slider.

A conclusion can be made in reference to the operable area where the magnet can retract the slider: the slider will be retracted when the magnet is brought within 1.2 cm and is within 14^{o} in either direction of the vertical axis. A conceptual depiction of this conclusion can be seen in Figure 23 (red dots symbolize the location of the housing pieces.

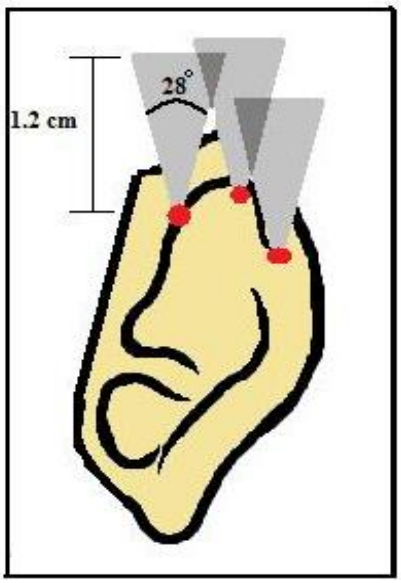

Figure 23: Depiction of the area that will be utilized for magnetically induced retraction of the ferrous slider. The red dots signify the approximate location of the three magnetic locking pieces. If a magnet is placed within the area indicated by the gray triangles then it will be able to retract the slider.

A notable observation is that in some prosthetics it is possible that the magnet will not be in range to retract the slider. However, one possible solution would be to use a magnetic cap, like currently used O-ring system, but without the O-ring.

Future Work

The proof of concept of the design has been carried out. However, several factors must be explored in future development. First, by milling a to-scale model out of metal, a mold can be made for scaled production using polymer casting. The rapid prototypes would have been viable for molds however some features came out on the limit of resolution resulting in incomplete formation. A metal would guarantee the precision of the detailed features at the resolution desired. As stated in the design section, the slider must also be made of magnetically inducible metal in order to allow the remote displacement necessary to allow the design to work.

Another technicality that must be solved is the connection of the bottom lid of the slider housing. For demonstration purposes, the prototypes were made with a detached bottom lid. As opposed to having a permanently attached bottom lid, allowing it to be detached ensures the ease of replacing a broken slider. By creating a threshold breaking point for the sliding mechanism, the ear can fall off if a threshold external force is applied. If the prosthetic fail threshold, damage can be done to the prosthetic, the abutments, or even the mastoid bone. Another advantage of a detachable bottom lid is open access for cleaning purposes. The device relies upon a clean path for the slider to travel. However, if this path is obstructed the device ceases to function.

Finally, a convenient solution is needed to incorporate the external magnet. This idea is already utilized within the prosthetic industry. For example, the pupil dilation of a prosthetic eye can be changed through external magnetic induction. For convenience, the external magnet was

made into a ring which the patient could wear. A magnetic ring, or similar device, may be plausible for the design discussed in this paper.

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Appendix

I

Passive-Locking Implant Retained Auricular Prosthesis Attachment

9/11/11

Taylor Jaraczewski, Daniel Dissing, Stephen Kernien, Cody Bindl

Function:

The client, Gregory Gion, has requested a mechanism to replace the current o-ring magnetic sleeve used to attach auricular prosthesis to the mounting pins attached at the patient's mastoid bone. The current method utilizing the o-ring housed sleeve has good attachment and rigidity but requires significant force to place and remove which causes excessive wear and tear on the prosthesis. An ideal design would maintain the already in place stable connection while refining the ease of attachment and removal.

Client Requirements:

Must create solid attachment of prosthetic

Must be easily applied and removed by the patient

Must be hypo-allergenic

Must be low profile

Design Requirements:

1. **Physical and Operational Characteristics**

a. *Performance requirements*

i. The mechanism must firmly hold the auricular prosthetic in position.

ii. The mechanism must allow for ease of attachment and removal.

b. *Safety*

i. The device must be made out of hypo-allergenic materials.

ii. The device must operate within the proper range of force tolerance so as not to compromise the mounting pins.

c. *Accuracy and Reliability*

i. The device should work in all cases.

d. *Life in Service*

i. The mechanism should be operational for the entirety of a prosthetic's lifespan.

e. *Shelf life*

i. The mechanism should match or exceed the shelf life of the existing prosthetic.

f. *Operating Environment*

i. Connects to mounting pins attached to the mastoid bone.

ii. Housed within an auricular prosthetic.

g. *Ergonomics*

i. Must create rigid connection.

ii. Must be easily attached and removed.

h. *Size*

i. Low profile.

ii. Can be housed within the auricular prosthetic.

i. *Weight*

i. Light enough to avoid excessive tension on the pins caused by gravitational pull.

j. *Materials*

i. Must utilize hypo-allergenic materials.

ii. Final design made with client specified materials of stainless steel and titanium.

k. *Aesthetics, appearance, and finish*

i. The mechanism should be housed within the prosthetic and thus should not be seen.

2. **Production Characteristics**

a. *Quantity*

i. At least one proof of concept prototype.

ii. Ability for eventual mass production.

b. *Target Product Cost*

i. Flexible.

3. **Miscellaneous**

a. *Standards and Specifications*

i. Have to meet FDA health standards.

ii. Ideally will fit the existing three pin system.

b. *Customer*

i. Preferential use of magnet housed system.

c. *Patient-related concerns*

i. Easily sterilized between uses.

ii. Must be hypo-allergenic.

iii. Minimize force required for use.

d. *Competition*

i. Existing attachment designs include a bar system, magnetic housed o-ring system, plain magnetic attachment (VistafixTM), and previous design project prototypes.