Auricular Implant Locking Mechanism

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Client: *Greg G. Gion MMS, CCA, The Medical Art Prosthetics Clinic*

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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 due to friction, since it is a snap-fit design, and inhibits the pursuit of active lifestyles as lateral forces may still 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 to address the qualities in question.

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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 still utilizing the current housing.

Client Information

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).

Problem Statement

The client, Gregory 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, it 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. Microtia is one such congenital defect where part of or all of one or both ears may be absent. 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]

Auricular prostheses originally were retained on the head by way of adhesives or spectacle; however, these methods were not particularly suited to the task as they would move abnormally, lose retention, or cause allergic reactions.[4] In the late 1970s, the first osseointegrated implants came into use initially as a support system for using bone conduction to aid in hearing.[5] This advent led to improvements in more natural retention of prosthetics in general.

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 separate means of securing auricular prosthetics to the desired location are utilized. The first method consists of a bar-clip attachment. This method involves a surgically integrated implant within the mastoid bone[10]. A titanium bar is further attached to these implants with metal screws (Fig.1)[10]. The prosthesis itself houses a female end of a clip that attaches around the implanted titanium bar[10]. This method is rarely used due to problems with customizability. Each patient necessitates a customized attachment location due to varied bone strengths. Furthermore, this system is difficult to clean and is prone to mechanical degradation through continuous use.

Figure 1: This image showcases the titanium bar attached to the three surgical implants. A prosthetic would further be attached around this bar [10].

The second method of attachment utilizes an incased magnetic system for prosthetic retention[10]. Similar implants used for the bar system are implanted into the mastoid bone. However, instead of a bar, three separate magnetic abutments (pins) are screwed into the implants (Fig. 2)[10]. Three female ended caps located on the interior of the prosthesis go over the abutments[10]. These caps are magnetically attached to the pins and secured with an o-ring snap-fit, which prevents against forceful or accidental removal of the implants[10]. This system is more customizable than the bar-clip attachment and is easier to clean; however, it is difficult to clip on and remove. Additional force necessary for this (dis)engagemnt creates unwanted wear and tear on the prosthetic itself and detrimentally affects the aesthetics of the prosthesis.

Figure 2: This image shows the three magnetic abutments attached to the mastoid bone implants. A male ended magnet utilizing an o-ring retention system would attach the prosthetic in place[10].

Requirements and Design Constraints

Throughout the design of a more effective retention device, several requirements must be considered. First, the device must create a solid attachment between the patient's mastoid bone and the prosthetic. Contralateral and lateral force exerted on the prosthesis should not be able to break or remove the prosthesis.

The design should implement the existing three abutment system s currently used for implant retention. Minor modifications are acceptable, and furthermore encouraged. However, the implantation process is well defined; thus, the client wishes to continue with the standard methods. It is the goal of the team to comply with this request by creating a device that adds to these methods rather than change them.

Previous designs have been able to meet the aforementioned requirements, but have lacked in the realm of ergonomics and practicality. For these reasons, the design should be put on and removed with minimal force exertion on the exterior of the prosthetic, thereby creating a more "user-friendly" retention system.

Finally, the device should optimally maintain the aesthetics of the ear prosthetic itself. Prosthetic aesthetics are pivotal for realism of the ear; thus, it is important that the final design minimize any artificial exposure, which would detract from the aforementioned realism. Aesthetic maintenance involves two parts. First, the system should minimize any exterior mechanical devices. Ideally all parts of the system would be contained within the prosthetic itself. The system should also minimize frequent pressure and friction being placed onto any exterior portion of the ear. The ear is painted to reflect the tone of the patient's skin and any wear caused by excessive touching will expose the underlying polymer.

Previous Biomedical Engineering Designs

Creating an ideal attachment for ear prosthetics is complicated and for this reason, multiple teams have tried to create a more effective system of auricular prosthetic retention. One such design utilized a gravitational locking force in conjunction with a magnetic cap to attach the prosthetic. The prosthesis would be placed over the implanted pins and pulled downward into a locked position. Once attached, the ear was held in place by the housed magnet, gravity, and friction. This system proved to be effective in an ideal situation with a planar surface; however, was impractical in reality due to the various angles and curves on the side of a patients head.

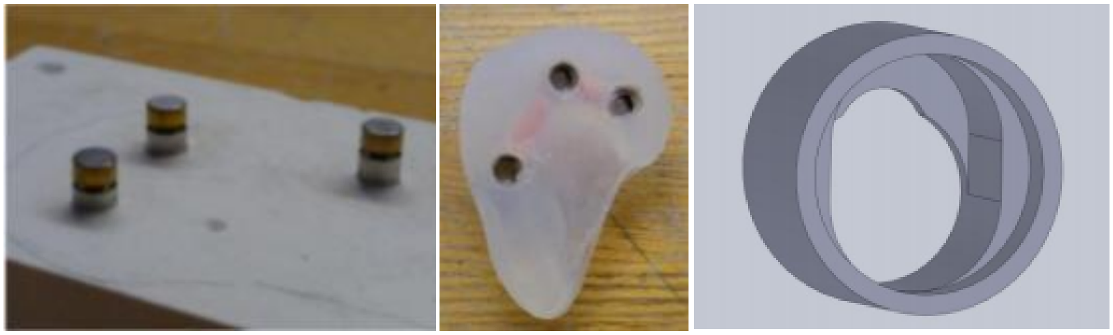

Figure 3: (Left) existing magnetic abutments. (Center) prototype showing the incorporation of the gravity retention system within a polymer prosthetic. (Right) profile of the gravity system which is pulled down to lock in place.

A second attempt at solving this problem involved a small change in the existing three magnet pin system. The middle pin was changed out for a wider pin that also included a male ended screw-like groove. The prosthetic housed two magnets (top and bottom) and one female ended housing that screwed into the middle pin. The prosthetic was attached through a single rotation and positioned in the correct orientation with the top and bottom magnets. This system again needs a uniform surface and cannot work properly with the contours of a human head.

Figure 4: three-pin system to attach prosthetic. Middle pin involves 360 degree rotation for attachment and removal.

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 (pin). In contrast to the O-ring attachment mechanism used currently, the snap-fit system uses a small elastic rim on the inside of the housing to lock to the attachment point. The rest of the housing is identical to what is currently implemented, that is, it has the same dimensions as well as a magnetic center piece on its' interior. Conveniently, the attachment point only needs a minor adjustment in the form of a shallow cut in the middle of the base to create a location for the housing to connect (Fig. 5).

Figure 6 shows the general premise behind this locking system. To begin attachment, the prosthesis is brought to the attachment site and carefully placed over the pins. An external force is subsequently exerted on the prosthesis to deflect the rim. Slight deflection allows for the rim to lock in place on the pins. 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 attachment point. The exact release mechanism has not been deeply investigated, and thus is not offered in this report.

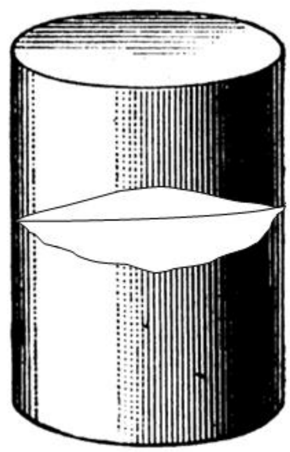

Figure 5: A pin attachment point utilized for the snap-fit system. It includes a cut out portion where the snap-fit housing would attach[11].

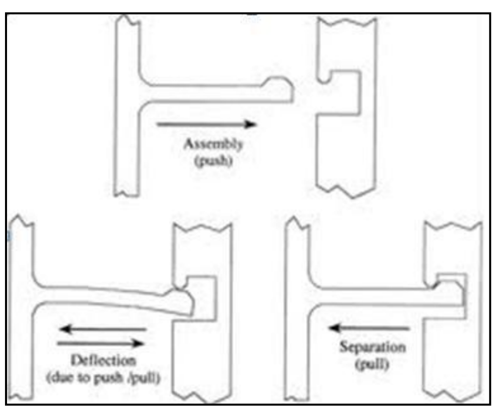

Figure 6: A cross-sectioned depiction of the general mechanism of action for the snap-fit system. As can be seen in the bottom left image, the housing is given an external force, which causes deflection of the rim. The bottom right position shows the locking state[12].

II. Pin Secured System

The general premise behind the push pin system is that it utilizes an internal assortment of locks which are initiated via an externally located push-pin system. For effective coupling the attachment points (pins) used currently are adjusted to ensure that the final outcome of lock initiation is a secure connection of prosthetic to attachment point. This is done by drilling connections for the locking system. A plausible analogy to the pin secured system is a coder pin locking system, which is depicted in figure 7. While the final design is not synonymous with this system, the overall concept of pushing an externally located pin into the attachment point to create a seemingly homogeneous link can still be understood. It is imperative that the link be as homogeneous 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. Further investigation into this system could lead to potentially implementing a permissive magnetic system to further guarantee effectiveness.

Figure 7: A coder pin locking system is a reasonable analogy to the pin-secured system. Simply, the pin is pushed into the attachment point to initiate locking and subsequently taken out to release[13].

III. Magnetic Locking Mechanism

The motivation for the magnetic locking mechanism was the need to eliminate external contact with the prosthetic to 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. Figure 8 depicts the main component of this mechanism: three small magnetic locking pieces (blue) which lock around the base of the attachment point. Dislodging of the attachment piece is performed by holding an externally placed magnet above the prosthetic to lift the locking pieces up.

With the absence of the o-ring, the housing unit currently implemented would not offer any resistance when placed onto the attachment point. Thus, the prosthetic is easily placed onto the attachment points on the head as long as an external magnet is used to lift the locking pieces (see orientation of top view in figure 8). Moving the magnet away from the prosthetic will allow the locking pieces to release and lock around the attachment point (in a horseshoe fashion). Therefore, with no effort, a secure and durable locking mechanism is implemented. 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.

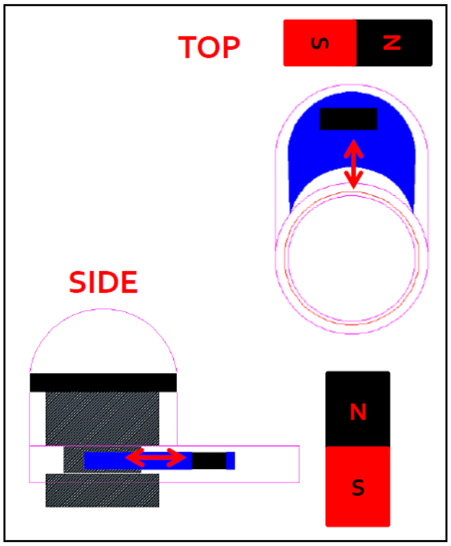

Figure 8: A depiction of the mechanism by which the magnetic locking mechanism works. The top view shows the blue locking piece with a small black magnetic piece located toward the edge of the prosthesis. The side view shows the sliding lock process.

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 9: 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 5 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.

Ethical Considerations

Using pictures of patients to properly display the premise of this design was a main ethical consideration in the process thus far. All images were taken from medicalartprosthetics.com, which is the primary web page of our client Mr. Greg Gion. Each image had direct written consent from the patient that the rights of the image could be used by Mr. Gion.

In the future, it is the desire of this design team to implement the prototype into an actual working prosthesis. This could potentially lead to some human trials and thus human trial training will be required as well as documentation of anonymity of the patient.

Future Work

The first step needed after choosing the final design is to create a proof of concept. To do this, a rapid prototyper will be used to create a large scale model made of acrylonitrile butadiene styrene. A magnet will be added to make a functioning model. Once this proof of concept validates the mechanism, actual scale models can be manufactured. These models are going to be machined by the client. Testing will then be performed on the actual scale prototypes and current models of attachment for comparison. Since the goal of this device is to create a more secure attachment of the prosthetic, the force required to dislodge it will be tested. Different types and directions of forces will be needed to create a holistic comparison. This includes both steady and impulse dislodging forces as well as lateral force. The ergonomics of the new system is another important area needing testing. The success rate of unlocking the magnetic sliders must be determined due to the repetitive use of the device. This can be done by simply placing the unlocking magnet in the correct location above the ear and determining whether or not the system unlocked. Locking of the device must also be consistent. A range of angles at which the head can be with the sliders still in the locked position is important in determining the range of motion a person can have. This will be tested by inspection at certain angles. Finally, the magnetic slider will need to be strong enough to withstand repeated forces. Subjecting the slider to periodic forces will establish its' durability. This attachment mechanism is to be used in an actual prosthetic; thus, the final step of this design process will be to implement the final prototype into a real prosthetic to ensure it works in an actual model.

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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:

a. Must create solid attachment of prosthetic

b. Must be easily applied and removed by the patient

c. Must be hypo-allergenic

d. 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.