Attachment of prosthetic ear to cranial implant abutments

Mid-Semester Report

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ABSTRACT

The goal for this semester is to design an auricular prosthesis attachment mechanism. The design will enable the user to attach and remove the prosthesis with ease while preserving a secure attachment to the surgically implanted cranial abutments. The simplicity and everyday functionality of the mechanism will be critical to the success of any design. Each of our designs attempts to improve on the current attachment mechanisms, many of which lack the following criteria: security, ease of attachment and ease of removal. Each design is also tailored to fit the industry standard 4.4mm abutment diameter. In addition, we employed the use of a flat spring to allow for absorption of additional force, a crumple sheath rather than a magnet cap to provide extra stability, and various other combinations of these ideas. Future work will entail performing preliminary testing to determine how much force is required to dislodge the prosthesis while it is attached by each method discussed below.

PROBLEM STATEMENT

The goal of this project is to develop an auricular prosthesis attachment mechanism that is able to improve on the current design in various aspects of functionality. The design will ensure a strong hold to the surgically implanted abutments while withstanding the stresses of everyday use, but releasing in the presence of excess force. Additionally, the patient will be able to affix and remove the prosthesis with ease.

BACKGROUND

Ear prostheses are a considered alternative to surgical restoration for several different craniofacial conditions. People seeking auricular prostheses typically have one of the following conditions: microtia, hemifacial microsomia, or loss of tissue due to effects of cancer, injury, or trauma. Microtia is a congenital defect that occurs when one or both ears have not formed correctly. Microtia can be as simple as a small bump on the ear or as severe as a partially formed ear (*Figure 1*). In most cases, this defect occurs with only one of the ears and is known as unilateral microtia. However, when this occurs with both ears it is known as bilateral microtia. Unilateral microtia occurs in one out of every 8,000 births and bilateral microtia occurs in one out of every 25,000 births [2]. Another congenital defect that often leads to an auricular prosthesis is hemifacial mircosomia. Hemifacial microsomia is a congenital defect when the tissue on one side of the face is underdeveloped, affecting primarily the aural (ear), oral (mouth), and mandibular (jaw) areas. This condition can also affect one or both sides of the face. When this condition affects both sides of the face it is known as Goldenhaar syndrome [3]. Hemifacial microsomia, much like microtia, can vary in severity from minimal deformation to complete underdevelopment of the ear and other parts of the front and side of the face. It is the second most common birth defect after clefts and occurs in one out of every

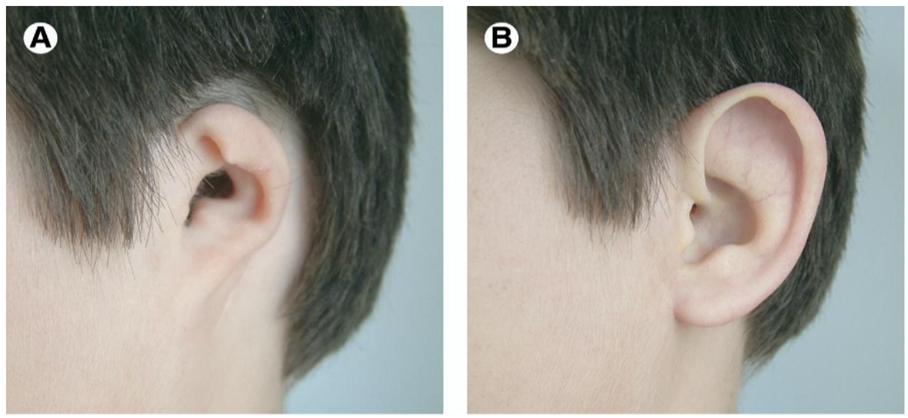

Figure 1. A. Example of left ear microtia **B**. Slip-on prosthetic in situ [1]

3,500 births [4]. In addition to the congenital defects that can eventually lead to an auricular prosthesis, other unfortunate events can occur later in a person's life, such as cancer or serious trauma to the ear. Each of these situations can also range in severity and location of deformation, but are generally successfully treated by auricular prostheses.

Patients with these conditions are given the choice of reconstructive surgery or an auricular prosthesis. This decision is largely based on the severity of the condition and the individual's preference. In many cases, prostheses are chosen for their ability to provide better symmetry than even the most skilled surgeon can construct. The downside to the prosthetic option is that it needs to be attached to the head in a way that it is secure, but easy to attach and remove for daily maintenance [1].

There are several current methods commonly used in the attachment of silicone auricular prostheses, each with their own distinct advantages and disadvantages. In the past, biocompatible drying adhesives were used, but this method has been phased out in favor of other more reliable processes. In the sleeve or slip-on method, the prosthesis can be attached simply by slipping it over the remaining tissue. The prosthesis fits over the tissue like a glove, requiring no further means of attachment [1]. While this is generally effective, it is only applicable when the patient has enough remaining tissue to allow for a secure fit. The bar-clip method, currently the most widely-used system, involves a metal bar that bridges several osseointegrated abutments. A clip imbedded in the prosthesis fits around this bar and holds the ear in place. While this method provides a secure attachment mechanism, it poses a few problems. The bar makes it difficult for the user to clean the area around the implant and the whole apparatus is somewhat bulky, leaving a less than perfect aesthetic appearance.

The retention method we will focus on improving the most is the magnetic attachment. Our client, Gregory Gion, currently uses this technique to attach his silicone prostheses. Magnetic caps are molded into the prosthesis, one for each surgically implanted abutment. The abutments are osseointegrated into the mastoid region of the temporal bone in the skull as shown in Figure 2. Osseointegration can be defined as "the process of bone growing tightly around titanium fixtures, so that they can be used as an anchor for a prosthetic device" [5]. The abutments consist of a housing unit and the actual abutment shaft which sticks out of the skull. In the magnetic attachment method, each abutment has a top magnetic cap, available in various sizes. The abutment cap is magnetically attracted to the cap molded in the ear. This method is very discrete and easy for the patient to use and clean, but the retention provided by the magnetic attachment is not ideal. Our goal is to provide a more secure attachment mechanism with a pleasing aesthetic appearance, while maintaining ease of attachment and removal.

Figure 2. Osseointegrated cranial abutments with magnetic caps [1]

CLIENT SPECIFICATIONS

Our client, Gregory Gion, has several key aspects that he needs from this design in order for it to be viable. The prosthesis must be able to resist unintentional dislodgement. That is, it should only come off when the user wants it to. The design must be low profile and aesthetically pleasing; it should not be overly bulky, heavy, or noticeable to others in normal social situations. In addition, it should be able to withstand both anterior and posterior forces, in the range of 5 to 10 pounds. We will get a better picture of exactly what force should be withstood through experimental testing of the current mechanism. Mr. Gion did not want us to modify the original osseointegrated abutments in any way, so it is necessary that our design is adaptable to the current abutments (4.4 mm in diameter). Finally, the design must be easy for the patient to affix and remove without extra tools or complicated steps.

DESIGNS

After brainstorming possible attachment mechanisms over a period of four weeks and discussing them with the client, we narrowed our ideas into five viable designs. Each design was named and classified according to the main functionality of its attachment method.

Flat Spring and Magnet Cap

The design incorporates a flat spring and housing cap, in addition to the modification of the preexisting magnetic cap. The housing cap is securely molded into the prosthesis and attached to the flat spring by either a laser weld or a custom screw assembly. The spring is then secured to the magnet cap in a similar fashion without affecting the cap's original functionality. The magnet cap is the standard Maxi size which fits onto the larger abutment cap. All three components fit inside the prosthesis, but only the housing cap is secured directly to the silicone ear. The spring lies inside the housing cap while at rest, but after the prosthesis is subjected to substantial anterior or posterior force, the spring is activated and extends out of its housing to dissipate the force. A notable flaw with this design is the poor retention strength of the original magnetic cap. The client is trying to modify and move away from this current method. The cap would only be held on as strongly as the magnet's retention force, with the spring being the only feature increasing the security of this attachment mechanism.

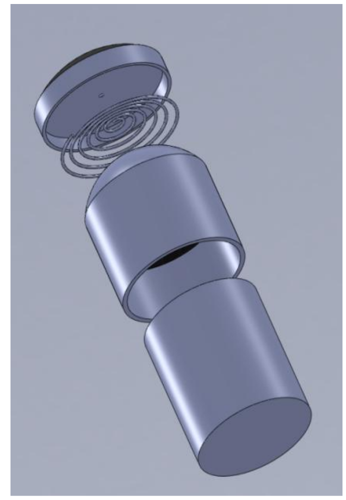

Figure 3. SolidWorks drawing of Flat Spring and Magnet Cap

Flat Spring and Sheath

This design is very similar to the previous spring and cap design because it implements the same flat spring and housing cap, but uses a sheath-style friction fit rather than a magnetic connection. The sheath fits over the abutment tight enough to prevent any lateral translation and cannot be removed by applying a force perpendicular to the abutment. The spring is still contained in the housing cap at rest and extends after force is applied. The sheath allows for more stability than the magnet cap because the friction fit limits attachment and removal to one direction

Figure 4. SolidWorks drawing of Flat Spring and Sheath

(normal to top face of abutment).   The design also allows for the capability of integrating a shearing security mechanism. If the force applied to the ear exceeds an experimental maximum, which will be determined in preliminary testing, the sheath would fracture and prevent damage to the prosthesis and more importantly, the implanted cranial abutments. A potential difficulty lies in the sheath fit. If the force required to remove the ear exceeds the spring's extension force, the spring will stretch before the sheath is released from the abutment and potentially break the mechanism. Testing will have to be performed on the friction forces involved in sheath removal to ensure proper function.

Rigid Shearing Sheath

The design is very similar to the previous Flat Spring and Sheath attachment mechanism, but it has a few major differences. The Rigid Shearing Sheath does not use a spring of any kind and requires slight modifications to the sheath and housing cap mentioned above. As seen in Figure 5, the housing cap for this design is considerably deeper than the cap seen in Figures 3 and 4. The extra depth allows for the sheath, which is threaded on the outer surface, to screw into the housing cap with matching threading.   The key feature of this design is the shearing mechanism, similar to the one introduced in the previous design. When the sheath is affixed onto the abutment, it will not slide on far enough for the top of the abutment to become flush with the inside of the sheath. The small distance left between the top of the abutment and the overlap from the

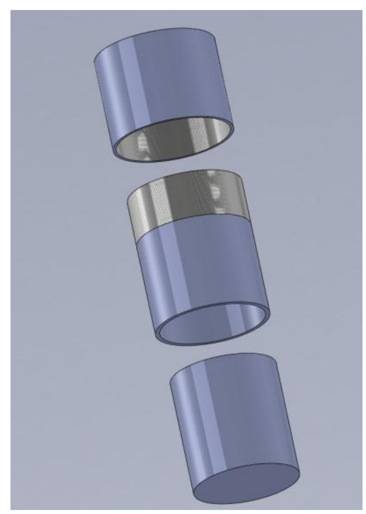

Figure 5. SolidWorks drawing of Rigid Shearing Sheath

housing cap will allow for a clean shear if the mechanism is subjected to the maximum experimental force. The problems with this design arise with security and material cost. In the event that the sheath is fractured, the remaining piece of the sheath would be unscrewed from the housing cap and replaced. Depending on the patient's usage, constant replacement of the custom sheaths could become expensive. In addition to the cost, this method does not completely satisfy the client's security requirement. If each of the three sheaths are broken, the prosthesis will completely separate from the head, resulting in loss of the prosthesis and possible embarrassment for the patient.

Active Clip with Magnet

A more unique design is the Active Clip with Magnet. The previous designs are all passive locking systems and do not require any additional mechanism to release the prosthesis after attachment. This design requires modification of the same Maxi size abutment cap as referred to in the Flat Spring and Magnet Cap. Instead of attaching a spring, the o-ring latching feature of the Maxi cap would be converted into an active locking mechanism. There are various ways to accomplish an active lock. The most viable method is by creating a system that can clip or snap onto the lip of a large abutment cap size. The issue with this method is that it would require an additional

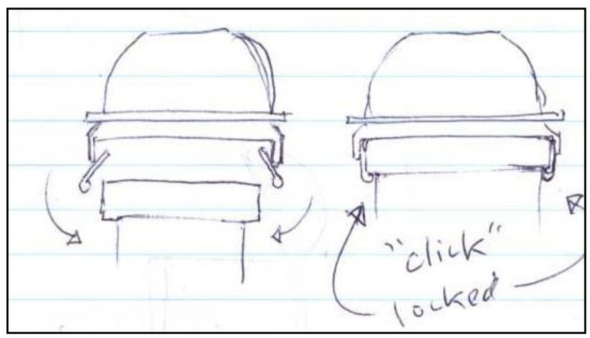

Figure 6. SolidWorks drawing of Active Clip with Magnet

step to unlock the mechanism. We have yet to determine an efficient and user-friendly mechanism for release that does not overcomplicate the process.

Cylindrical Spring as Sheath

Our final design is the simplest design. It features a cylindrical spring that would act as the sheath and slide over the abutment. The top of the spring would attach to the ear and the bottom would slide over the abutment. This design is not too involved, so it would be easy to make and would have low material cost. Since the sheath itself is a spring, it would absorb forces applied to the ear and relieve some stress from the abutments and point of attachment. The principal disadvantage of this design is the lack of security of the attachment to the abutment. The spring would need to be secure around the abutment, stabilizing the prosthesis and preventing unintentional dislodgement. The spring would also need to be loose enough for the user to be able to attach and remove the ear with ease. Correlating security, ease of removal, and ease of attachment will prove to be difficult to accomplish with this design.

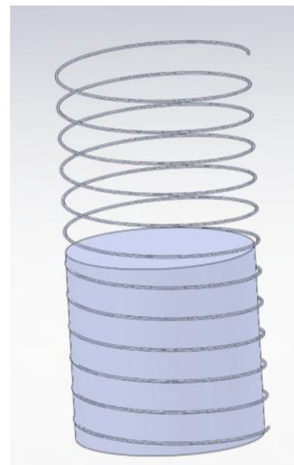

Figure 7. SolidWorks drawing of Cylindrical Spring as Sheath

DESIGN MATRIX

We rated our five designs on a scale from 0 to 100 using a design matrix (Figure 8). We had several criteria that were weighted differently based on the importance of each and its necessity to the design. The most important criteria were security of attachment, ease of attachment, ease of removal, and aesthetics. The design, based on the client's specifications, needs to be securely attached to the abutments. However, the design also needs to be easy enough for the user to attach and remove the prosthesis. The design needs to be compact enough so that it can fit inside the prosthesis. The main desire for patients using these auricular prostheses is to gain the appearance of an actual ear. Therefore the design will need to maintain the authenticity of the prosthesis so that it will not be noticed by others in close proximity. Fulfilling all of the specifications simultaneously will prove to be the biggest obstacle to overcome.

The Flat Spring and Sheath had the highest total in the design matrix. As a result, our group has decided to pursue this design. It rated highly in all of the main categories and our client was also in favor of this proposal. Several other mechanisms scored similarly in the matrix and as a result, our final design will likely incorporate different aspects from each.

	Security [20]	Ease of Attachment [15]	Ease of Removal [15]	Simplicity [10]	Durability [5]	Cleanability [5]	Ease of Fabrication [10]	Aesthetics [15]	Material Cost [5]	Total [100]
Flat Spring and Magnet Cap	15	13	11	8	4	3	7	13	3	77
Flat Spring and Sheath	17	10	13	8	3	3	8	13	4	79
Cylindrical Spring as Cap	11	12	10	9	4	2	5	12	4	69
Active Clip with Magnet	19	13	9	6	4	4	6	12	3	76
Rigid Shearing Sheath	12	10	14	10	1	4	9	11	5	76

Figure 8. Design matrix. Criteria scores totaled out of 100pts.

FUTURE WORK

Our future work will be largely determined by the continual feedback we receive from our client. For example, he has suggested the use of silicone as a replacement for the spring in our design. The silicone would be able to stretch and compress just like the spring, absorbing forces applied to the ear. The benefit from this design is that it would make the design more aesthetically pleasing. Our group is researching this possibility to see if it is better than designs involving the spring.

We will also be assembling the parts needed to fabricate our designs. We have already ordered some parts, and will continue to do so. Once we have the parts, we will fabricate our designs and begin testing them. Our client has given us some sample abutments that have been molded into a model skull. We will test to see how easy our designs are able to attach and remove from the abutments. We will also apply different strains of force and different angles of force to see how the designs react under those conditions. Our client also plans to give us a sample of the current magnetic attachment mechanism so we can use it as a control model to test as well. Through these tests we will be able to see the problems with each design and make the necessary improvements to produce a functioning and viable prototype.

We have completed our mid-semester presentation and presented it to our client. He is pleased with the direction we are heading and hopes to continue developing the most promising designs. He is aware of the time restrictions this semester, but hopes to have a functioning prototype and model completed by the end of the semester. Finally, as we move into the testing and fabrication stages of the design process, we hope to collect valuable data and information that will guide us towards the most viable and practical design solution.

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APPENDIX A- Product Design Specifications

Ear Prosthesis Attachment Mechanism Product Design Specification (PDS)

10/8/09

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Function: To develop an auricular prosthesis attachment mechanism that is able to improve on the current design in various aspects of functionality. The design will ensure a strong hold to the surgically implanted abutments while withstanding the stresses of everyday use, but releasing in the presence of excess force. Additionally, the patient will be able to affix and remove the prosthesis with ease.

Client Specifications

- Prosthesis should resist unintentional dislodgement
- Must be low profile
- Aesthetically pleasing
- Able to withstand considerable anterior and posterior force—approx. 5-10 lbs
- Adaptable to current abutment sizes—4.4mm diameter

Design Requirements

1.) Physical and Operational Characteristics
   a.) Performance Requirements
      i. Withstand normal daily activity (waking hrs)
      ii. Withstand 5-10lbs of lateral force without unintentional dislodgement
   b.) Safety
      i. Will not cause harm to bone structure when subjected to force
      ii. Mechanism cannot cause harm to patient (pinching, protrusions, etc)
   c.) Accuracy and Reliability
      i. Must fit previous abutment sizes (4.4mm diameter)
      ii. Is satisfying and comfortable to patient
   d.) Life in Service
      i. Approximately 3-5 yrs (due to paint wear on prosthesis)
      ii. Maintainable and cleanable materials
   e.) Shelf Life
      i. N/A
   f.) Operating Environment
      i. Endure normal daily conditions
      ii. Rust and weather-proof

g.) Ergonomics
   i. Low profile with respect to prosthesis and facial members
   ii. Match same size as unaffected ear (proportional)
h.) Size
   i. Should coincide with abutment size
   ii. Should be fully imbedded inside of molded prosthesis
i.) Weight
   i. Should not increase size of entire prosthesis with respect to current market designs
   ii. Patient should not feel any difference of weight due to new design (no more than 10% added weight)
j.) Materials
   i. Biocompatible metals, plastics, or ceramics (i.e. titanium, silicone, silver, stainless steel)
k.) Aesthetics
   i. Mechanism should be unnoticeable when attached
   ii. Modeled to resemble real ear

2.) Production Characteristics
   a.) Quantity
      i. One prototype this semester
   b.) Target Product Costs
      i. Competitive with current market prices
      ii. Client willing to fund any amount depending on viability of product (Goal of less than $500)
3.) Miscellaneous
   a.) Standards and Specifications
      i. Materials used must be FDA approved
   b.) Customer
      i. Cost-effective and potentially marketable
      ii. Ease of integration into prosthetic molding process
   c.) Patient-Related Concerns
      i. Ease of attachment and removal for untrained user
      ii. Easily cleanable
      iii. Maintain a low, realistic profile
   d.) Competition
      i. Various methods exist, but none completely satisfy the patient's or client's demands
      ii. Existing methods: bar-clip, magnetic, and snap-on