Team 11 – Ear Prosthetic Attachment

Claire Flanagan – *Team Leader*
Sarah Offutt – *Communicator*
Adam Rieves – *BWIG*
Josh White – *BSAC*
BME 400

Client – Greg Gion, BA, BS, MMS, CCA
The Medical Art Prosthetics Clinic

Advisor – William Murphy, PhD
Department of Biomedical Engineering, University of Wisconsin-Madison

December 12, 2008

Table of Contents

Abstract

Prosthetic ears are created for patients with microtia, a congenital defect that affects 1 in 10,000 births, as well as patients that have ears removed due to cancer and trauma. The current standard for ear prostheses is osseointegrated abutments and either magnets or bar clip prosthetic attachments. Osseointegration is a technology that grew out of the dental industry and was not effectively translated to other prosthetic applications. The magnet and bar clip attachments are not ideal because they do not adequately support an active lifestyle. To optimize the ear prosthesis attachment; two generations of designs were created. The mechanism for both is the same; the attachment is snapped into place and is secured by the flanges of the abutment cap. To remove, the attachment is rotated and pulled along two slits that function as guiding tracks until it is freed from the abutment cap. The final generation was constructed from polyethylene, which allows for increased flexibility. Tensile tests were completed using an Instron to compare the retentive strengths of the final prototype to the Maxi-magnet and O-ring magnet. In future generations, the aim is to improve the mating mechanism and perform other mechanical tests including impact, shear and fatigue.

Motivation

Osseointegrated ear prostheses have been an option for patients since 1979 and have been known to significantly improve the quality of life for those who receive them. Microtia, a congenital defect, affects around 1 in 10,000 live births (Eavey *et al.* 2006). The condition results in small malformed ears and can be distressing to childrens' parents or caregivers. The two major options for patients with microtia and other auricular defects, such as injury or amputation due to injury, are reconstruction and prostheses. Each option has its own unique advantages and disadvantages. If a prosthesis is chosen, based on the patient's medical history and individual preference, the anaplastologist must decide how to attach it. This can be accomplished by either magnets or clips. Each of these will be discussed further in a later section.

A recent survey of the satisfaction of patients with prosthetic ears (Westin *et al.* 1999) found that 6% of patients are currently unsatisfied with their prostheses. Although this number is not a large percentage, it may be because patients don't know that there may be a better mechanism. The two main mechanisms for attaching the prostheses have both been transplanted from the dental industry; however, the magnitude and directions of the forces applied to an ear are completely different from those in the mouth. Chewing involves mostly axial forces; therefore the implants are designed to be strongest in that direction. Also, dental implants are not designed to be removed regularly as ear prostheses. In contrast, ear prostheses are subjected to more complex forces than in the oral cavity. The ear can be loaded in a shearing manner, as in removing clothing; torsion, as in removing glasses; and bending. The current systems of attachment are inadequate for these complex forces, so in order to give patients the most effective prosthesis possible, it is necessary to investigate novel attachment mechanisms.

Background Information

Surgical Reconstruction versus Prosthesis

There is an ongoing debate for patients who have an ear deformation requiring treatment. Surgical reconstruction of the ear using various techniques is one option, while a prosthesis is the other treatment option. Each technique has its own unique set of advantages and disadvantages, as found in Table 1. Wilkes and Wolfaard (1994) recommend specific indications for both reconstruction and prostheses. Reconstruction is indicated for patients with classic microtia, patients where the lower third of the ear remains intact and in patients who are not likely to comply with the hygienic requirements of a prosthesis. The indications for prostheses include major cancer resection, radiotherapy, absence of the lower half of the ear, severely compromised tissue, failed reconstruction, and operative risk (comorbidity). Both options also hinge on patient preference. The authors concede that the patient's preference can be a result of the bias of the clinician. There is evidence from this paper that this bias can be reduced by having the same surgeon perform both types of procedures, but a greater awareness of the field of osseointegration will be necessary in order for this to take effect. The psychological impact of the decision to pursue a prosthesis should not be underestimated, particularly in older patients. In order to fit an osseointegrated prosthesis, the patient must elect to amputate the remaining ear tissue. The decision for a patient to undergo reconstructive surgery or opt for a prosthesis is a very personal decision and it is the duty of the practitioner to manage his or her expectations to ensure the best possible outcome.

Table 1. Advantages and disadvantages of reconstructive and prostheses as treatment options

	Advantages	Disadvantages
Reconstruction	• Uses patient's own tissues • Low-maintenance • Performed shortly after birth	• Scars • Long recovery • Difficult procedure • Asymmetry
Prosthesis	• Best cosmetic results • Symmetry	• Daily cleaning required • Amputation of residual ear • Dependant on ear for "normal" appearance • 3 year replacement period

Osseointegration

Osseointegration is a technique for interfacing titanium implants with bone. Dr. Per Ingvar Branemark pioneered this technique in the late 1970s, and in 1977 he inserted the first implant into the temporal bone to connect to a bone conduction hearing processor, a predecessor to the Bone Anchored Hearing Aid (BAHA). Today, the design of implanted "abutments" has changed only slightly, and they resemble the figure shown at right (Figure 1).

Several studies have been performed on the histologic/histomorphometric interface between bone and the implant. The term osseointegration implies that after the healing period, the bone grows into the titanium oxide layer and cannot be separated without fracture (Branemark 1983). Osseointegration has expanded its applications to nearly all parts of the body. Finger and hand implants

as well as lower extremity prostheses can be attached using this mechanism. The osseointegrated implant for an ear prosthesis is FDA-approved and consists of a titanium abutment with a 3 mm female thread. This is advantageous for this project because any attachment mechanism we design can interface with the fixture as long as it has a 3 mm male thread. To that end, the design we create will be scalable to nearly any commercial prosthetic.

Osseointegrated prostheses have benefits that extend beyond simply aesthetics. They can serve to hold up glasses for patients who can't wear contacts. They also significantly improve the quality of life for those who wear them by giving patients a normal appearance, and can allow them to interact more comfortably than before they received their prosthesis.

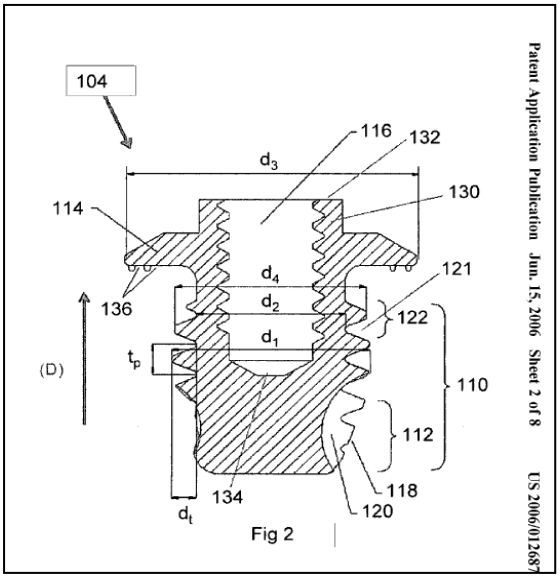


Figure 1. Drawing of an abutment from a recent US Patent.

Relevant terms

The physical components of implants and attachments involved in osseointegration are crucial to the understanding of the technique, but their names vary slightly throughout the literature. To ensure clarity and consistency for the purposes of this paper, we have chosen the names below:

- *Abutment* – the titanium implant that the surgeon places into a patient's temporal bone. The abutment is typically comprised of one end that is roughened to interface with the patient's native tissue and promote bone healing. The other end contains a small cylinder with a 3 mm deep female thread.
- *Abutment cap* – this piece has a male thread connection that affixes to the abutment once implanted. The abutment cap does not physically interact with the patient's tissue, but it does contribute to the retention of the attachment.
- *Attachment* – this piece is embedded into the back of the prosthetic ear and connects to the abutment cap through one of two mechanisms, as described in the following section.

Current Options

The magnetic attachment system and the bar-clip attachment system are currently the two major abutment cap options for ear prostheses. Figures 2a and Figure 2b show examples of these systems. Generally, the osseointegrated abutments are implanted into the skull, without regard to the attachment mechanism. The abutment caps change from one system to the other, but the attachments are implanted into the prosthetic ear and cannot be changed within

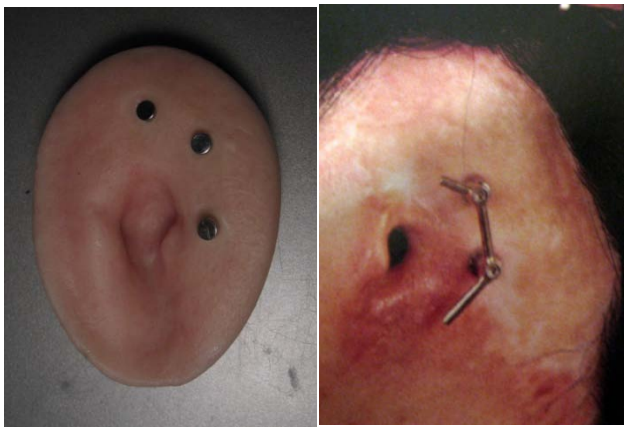


Figure 2a (left). The magnetic system

Figure 2b (right). The bar clip design, both used for attaching prosthetic ears.

the same ear. The patient may only switch systems when they receive a new prosthesis.

Magnetic attachments

The magnetic attachment system uses two or three magnets at varying locations around the auricle. Either two or three magnets are typically used in this system depending on the number of fixtures determined by the surgeon for implantation in the skull. The magnets used can come in a variety of forms, as in Figure 3. The most basic magnet is a spherical magnet, in which two planar magnets interact. Telescopic magnets are a design where one magnet is a conic section, in which the top has been sliced off, and the other magnet is a receptacle for that magnet. This design can resist lateral forces, unlike spherical magnets. Telescopic magnets also provide guidance for the user while attaching their prosthesis. Finally, an O-Ring has been attached to a telescopic magnet in recent designs. This creates a seal around the magnet and creates a partial vacuum where the magnets interact. This dramatically increases the attachment strength because the negative pressure combines with the magnetic force to keep the implant in place. The main issue with this system is the force required to remove the implant. When the user desires to remove the implant he or she will need to pull forcibly on the skull. If a patient has brittle bones due to osteoporosis or radiation therapy, this type of retention system would be contraindicated. One study performed by Voigt *et al.* (2008) measured the retention forces of different configurations of magnetic attachment mechanisms. In this study the authors concluded that the maximal retention force occurs when two spherical magnets are used with a telescopic magnet. Each spherical magnet had an individual magnetic strength of 3 N and the telescopic magnet had an attachment strength of 1.4 N. The magnetic system is easy to use because it provides the user tactile feedback for donning.

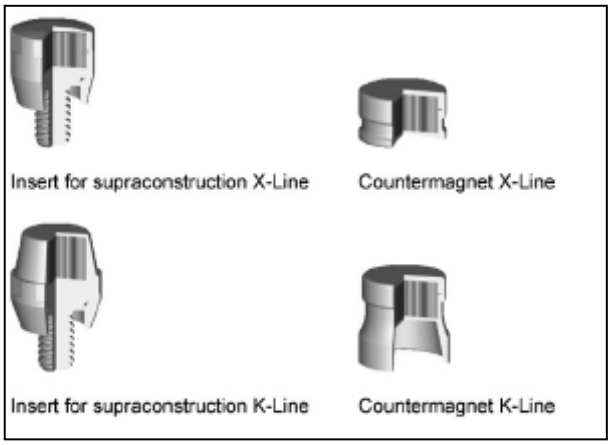
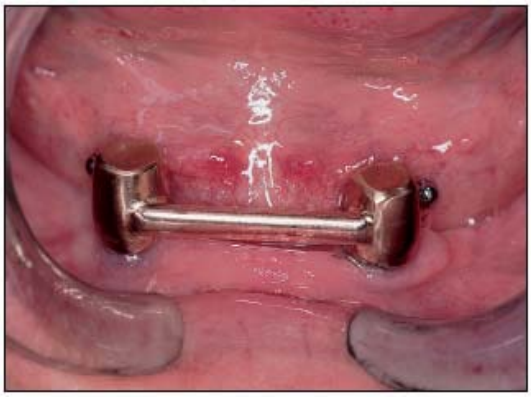


Figure 3. Construction of both spherical magnets (top) and telescopic magnets (bottom).

Bar-Clips

The other type of attachment system is the bar clip attachment mechanism. In this system a bar is affixed between either two or three posts on the skull. These attachments come in splinted and non-splinted



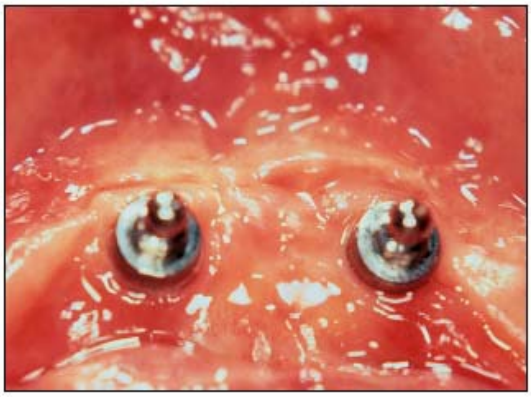


Figure 4a (top). Example of splinted oral clip design

Figure 4b (bottom). Example of non-splinted oral clip design

designs, as shown in Figures 4a and 4b, respectively. Attached to the ear is a C-shaped metal bar that clips onto the bar affixed to the posts. This system gives good retention characteristics, but is not without its problems. The system is more difficult to attach than the magnetic system because there is less tactile and visual feedback about the location during placement. Bar clips do have higher attachment strengths than magnetic attachments (de Sousa, et al. 2008). The main problem with bar clips, however, is material fatigue. The average implant is retained for three years, averaging three insertion and removal cycles per day. The bar system with two clips lost 60.8% of its original retention strength; however, all systems demonstrated the ability to keep the prosthesis attached for a three-year period (de Sousa et al., 2008). Williams et al. found that a non-splinted design retained the prosthesis much better than the splinted design. The range of retention for three clips in this study was 33.36 N to 55.1 N. This range is significantly higher than the reported range for magnetic attachments.

Summary

Magnets and bar clips are both adequate systems for attaching prostheses; however the principles underlying these devices can be used in combination to create a mechanism that addresses the shortcomings of each. Magnets attach strongly, but require the same force to remove them as to attach them. Clipping designs suffer from fatigue and may or may not be stronger than magnets. Current clipping mechanisms also require the same force to remove them as to attach them. An ideal device would be able to be attached with little or no effort, stay attached as long as the user desires, and then be removed when the user desires.

Design Constraints

Our client required that the drawbacks of current design be improved upon; specifically, he desired a stronger attachment mechanism that allows patients to live a more active lifestyle. Taking his preferences into consideration, we developed the following design constraints based on performance, safety and aesthetic specifications. Most importantly, the attachment and abutment cap should maintain stable connection without correction to prevent dislodgement by daily activities. To achieve this, the design should be able to withstand approximately 7.5N (1.68 lbs) of tension as well as be able to support shear, compression, bending, and torsion stresses. However, the importance of the retentive strength should not diminish the instinctive nature of the attachment and release mechanisms. In particular, there should be a near-zero force requirement to remove the ear attachment from the abutment cap. This will limit wear of all parts of the design to increase longevity as well as eliminate forces that deteriorate the temporal bone-abutment interface. Currently, 86% of users wear a device for more than ten hours per day over a period of three years. Thus, our device should be sustainable for three years, either by easy replacement of fatigued parts or demonstrated durability for three years. In addition to longevity, the material and final design should be chemically and mechanically safe for prolonged wear. In order for our device to usable, it must be able to be adapted to the FDA-approved abutment. For cosmetic purposes, our attachment must be easily concealable by the ear. This means that it should be able to fit within a volume of 7mm3.

Generation 0

Based on the design constraints, we developed generation zero by mid-semester. In this design, the attachment is placed into the ear prosthetic and the abutment cap is threaded into the implanted abutment. The attachment portion is dome-shaped and contains two prongs. One of the prongs is fixed and the other recoils into the wall. We determined two options for the prong that recoils - either a spring or two magnets with the same pole facing each other. Both are intended to perform the same function, but the strength of each was going to be empirically determined later in the semester. For the abutment cap portion, the bottom part is threaded to screw into the abutment. The abutment cap contains the track. The track has a straight portion and an arched portion. Where those two portions meet, an additional security feature is added (Figure 5). The straight portion extends farther than where the arched portion meets. In this way, the removal of the ear needs to be intentional to curve off the abutment cap; otherwise it remains in the straight portion of the abutment cap.

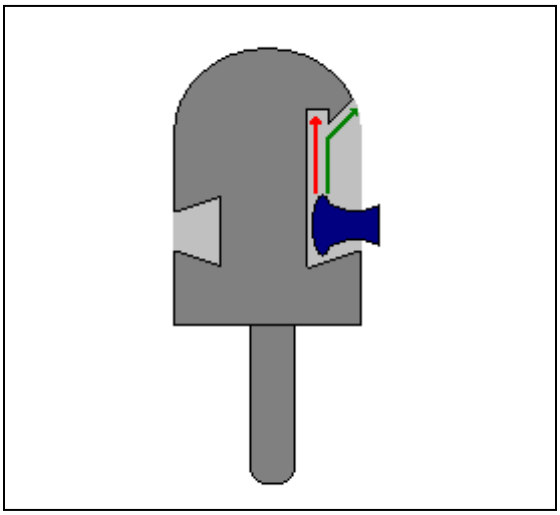


Figure 5. Increasing the length of the vertical portion of the track adds an extra safety feature by causing the prong to lock into place if accidentally dislodged. In the figure, red indicates the path of the safety feature, while green indicates the path of natural removal.

The mechanism of this design is natural and easy for the user. The user snaps the prosthetic ear containing the attachment onto the abutment cap, as shown in the leftmost cutout of figure 6 (a). The attachment is secured to the abutment cap by two prongs in the attachment. To remove, the user must follow the remaining sequence shown in the figure. First the user pulls the attachment toward the red prong (b). The prong recoils into the attachment, thus freeing the fixed prong. In this position the red prong is free to move upward along the constrained track in the abutment cap (c). As the prong is lifted, the device will naturally rotate (d) until it completely releases from the abutment (e).

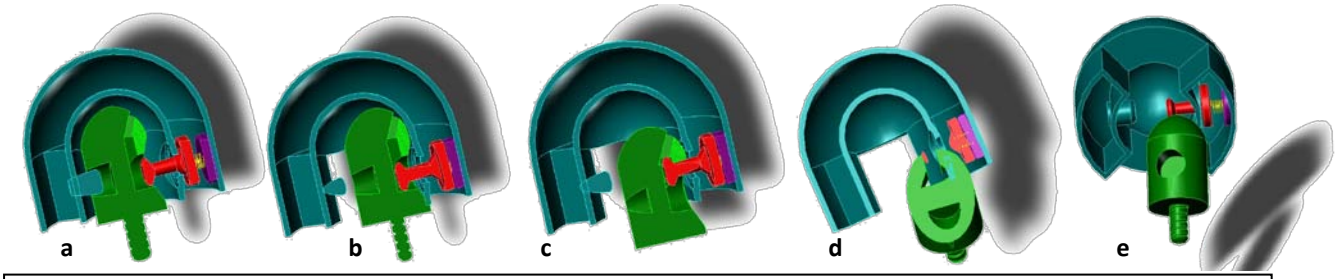


Figure 6. a) The attachment snaps onto the abutment cap. The attachment is retained by two prongs (red and teal). b) To remove, the user pulls the attachment toward the red prong, freeing the fixed prong. c) The red prong freely moves upward along the constrained track. d) The device naturally rotates toward the opening. e) The attachment is released.

The advantages of this design are that it has intuitive attachment and release. When the user desires to remove the ear, it is a simple passive mechanism. In the locked position, the ear is highly constrained to provide a stable and reliable connection. This attachment is only intended to be used in one of the three abutments, which means that two other simple magnets can be utilized for added support. Lastly, this design can be easily adapted to other osseointegrated implants.

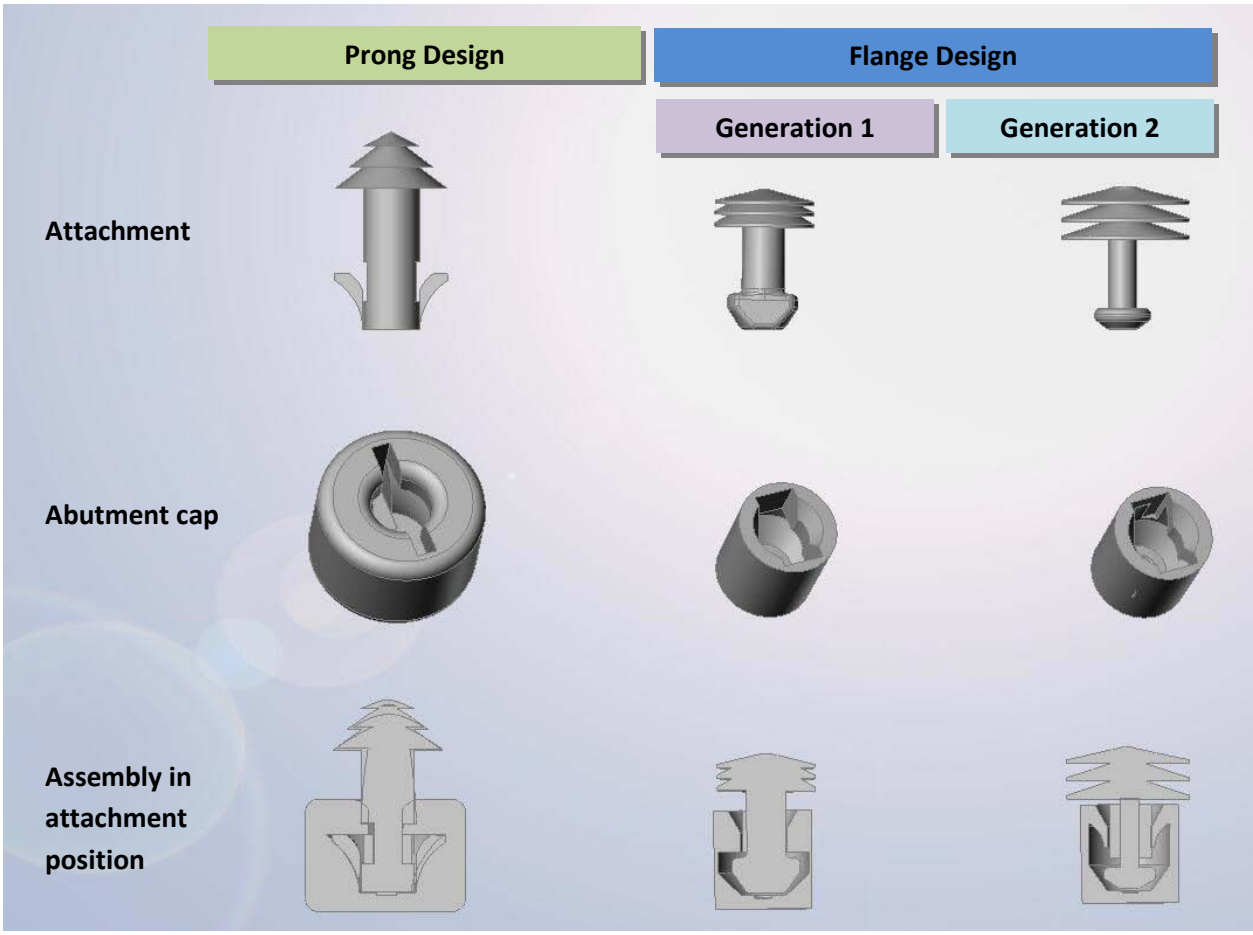
However, discussions with the machine shop and online research led us to determine that the small components within the device would be difficult to machine. Furthermore, a new parameter was placed on the size constraints for our design after mid-semester: the dimensions had to be no more than 2 mm wider than any current design. We had previously believed that additional silicon could be added around the prosthetic attachment fixture to protect and conceal it; however, our client revealed that the prosthetic was made in a plaster-cast mold that could not be adjusted to accommodate attachments of larger dimensions. Thus, we immediately acted on the need to scale down our initial design.

After extensive research, we found dovetail cutters (Figure 7) that would be capable of machining a track, but current commercial options limit the width of the track to 1/8 inches (approximately 3.18 mm), opposed to the less than 1mm that would be required to meet client specifications. Similarly, magnets and springs were found at nearly the size scale desired, but we became concerned that the magnetic field and the force of the spring would be compromised at this scale. Equally concerning was the conclusion that, even if the components could be found at the desired size scale, the dimensions of the peg responsible for attaching the device would be too small to be capable of appropriate attachment strength.

Figure 7. An example of the tool required to cut the track in Prototype Generation 0.

Final Design

To move forward from Generation 0 and to account for its dimensional limitations, a different attachment mechanism was conceived. We continued to believe that the mechanism of a snap attachment and a passive release was superior to current technologies, so we conserved its general premise. The design went through three revisions, and the progression of these can be viewed in Figure 8 below. As shown, the revisions culminated with the fabrication and testing of our current, Generation 2 prototype. The common differences between these designs and the Generation 0 design is the elimination of internal components and a reduction in the amount of negative space (i.e. the region housing the internal components), which allows for more appropriate design dimensions.



Alterations from previous generation	Fixed prongs to attachment, eliminated track, eliminated alignment issue, reversed orientation for placement in prosthetic, added rivets to attachment for retention in prosthetic, designed with no post-manufacturing modifications	Fixed prongs to abutment cap, widened release slit, modified attachment for better retention in abutment cap, added rotational barrier, modified rivet design for better retention in prosthesis, updated dimensions, increased tolerances	Changed material, altered design of flanges, decreased dimensions, adjusted size and shape of rivets

Figure 8. This graphic depicts the two major phases of our designs after mid-semester and the modifications that distinguish each.

Mechanism

Similar to the design presented at mid-semester, the mechanism of these prototypes begins with snapping the upper attachment into the lower abutment cap by pushing two prongs/flanges against a fixed wall to cause their deflection. However, unlike the original design, the prongs/flanges are fixed in place and require physical deformation rather than retraction into a cavity to permit motion of the attachment. In all of the designs, the prongs/flanges hold the attachment in place, and in both of the flange designs, a small wedge barrier further protects the attachment from accidental release. To intentionally release the device, the user rotates the prosthesis with attachment until the attachment is

parallel to two slits cut away from the abutment cap wall. This readily frees the attachment. A visual of the general mechanism is shown below (Figure 9).

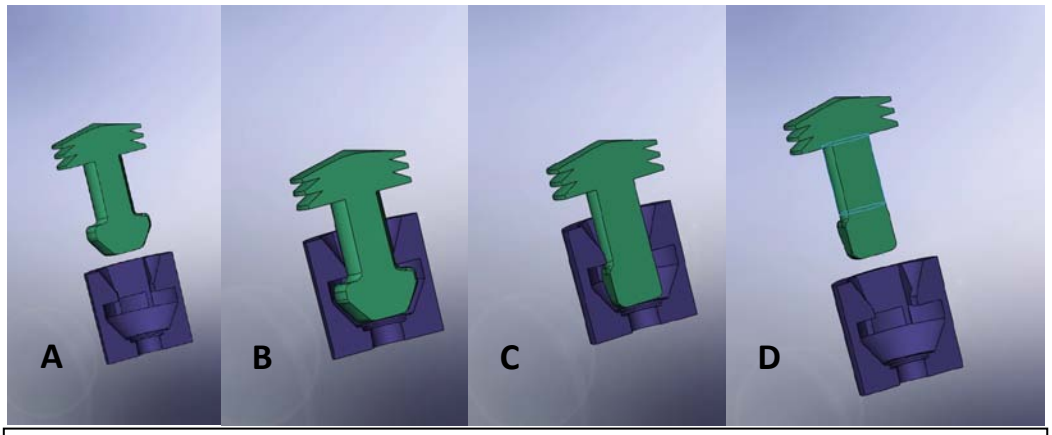


Figure 9. Mechanism of operation, utilizing Generation 1 of flange design as an example. a) Attachment snaps to abutment cap. b) Prongs/flanges hold attachment in place. c) User rotates attachment to align with slits. d) User pulls prosthetic to release attachment from abutment cap.

Prong Design

The prong design was significant because it merged the design mechanism perfected in the first phase of the semester with the realistic construction parameters developed in the second phase. The feedback resulting from this design directly led to the final iterations of the design that were actually prototyped and, therefore, shows the gradual progression of creative brainstorming that occurred throughout the semester. However, once the prong design had been completely developed as a concept, we quickly realized that several modifications would be necessary to transform the concept into a readily prototyped design. These additional modifications primarily focused on features to optimize the retentive strength of the design.

Nonetheless, notable modifications were also developed in the prong design. Specifically, retentive strength was improved in four ways: by reversing the orientation so that the most robust component was attached to the implant, by removing the track to eliminate the size constraint it introduced, by adding rivets to the attachment to improve integration into the prosthesis, and by fixing the prongs to the attachment rather than relying on additional components to physically move the prongs. Furthermore, it was brought to our attention (personal interview with Dr. Michael Bentz, October 2, 2008) that proper alignment of attachment device is important for any design that is not symmetrical. His concern was dealt with by countersinking a hole for a screw in the base of the new design. With this modification, the surgeon would not need to be concerned about the orientation of the abutment when it is placed in a patient's temporal bone; nor does the anaplastologist need to be concerned about the orientation of the attachment when he/she places it in the prosthetic. Finally, we realized that manufacturing this design as a polymer-based product could utilize injection molding or a similar, inexpensive method – resulting in a novel class of replaceable prosthetic attachments.

Flange Design

Utilizing flexible flanges to retain the attachment was the turning point in the design process. This modification drastically minimized the overall space required for the device and improved the retentive strength within the abutment cap in both Generation 1 and Generation 2. Further, the use of flanges on the abutment cap versus prongs on the attachment allowed us to add more mass to the attachment without increasing its overall surface area. This decreased the likelihood for failure at the junction between the prosthesis and the attachment. We also added a "rotational barrier," which resembles a small wedge protruding from the inner wall at the base of the abutment cap (Figure 10). This addition is designed provide tactile feedback for the user so that they know how far to rotate the design in order to release the attachment. With these modifications, we felt confident that rapid prototyping the design would yield a functional prototype, so we worked with Midwest Prototyping (Blue Mounds, WI) to fabricate our Generation 1 prototype from polypropylene resin. We chose polypropylene from the three available resins because it exhibited intermediate plasticity (% elongation at breakage was relatively high); yet, it also had a fairly high tensile strength (Table 2).

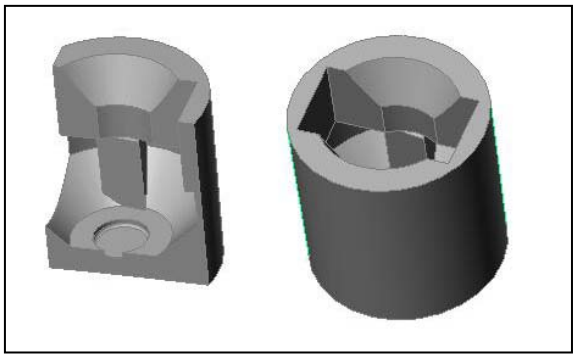


Figure 10. On the left is a view of the rotational barrier in a cutaway model. On the right is the full abutment cap, for reference.

Table 2. Material properties of the stereolithography resins available from Midwest Prototyping. The box outlined in blue indicates the material chosen for the Generation 1 prototype. (Taken from Midwest Prototyping's website.)

	Simulates	Tensile Strength	Tensile Modulus	Elong. @ Breakage (%)	Flexural Strength	Flexural Modulus	Impact Strength (Izod)	Hardness (Shore D)
		ASTM D 638	ASTM D 638	ASTM D 638	ASTM D 790	ASTM D 790	ASTM D 256	
3D Systems Accura 60	transparent polycorbonate	58 - 68 MPa (8410 - 9860 PSI)	2690 - 3100 MPa (390 - 450 KSI)	5 - 13 %	87 - 101 MPa (12620 - 14650 PSI)	2700 - 3000 MPa (392 - 435 KSI)	15 - 25 J/m (0.3 - 0.5 ft-lb/in)	86
3D Systems Accura 25	opaque white polypropylene	38 MPa (5,450 - 5,570 PSI)	1,590 - 1,660 MPa (230 - 240 KSI)	13 - 20 %	55 - 58 MPa (7,960 - 8,410 PSI)	1,380 - 1,660 MPa (200 - 240 KSI)	19-24 J/m (0.4 ft- lb/in)	80
Somos 8120 Epoxy Photopolymer	polyethylene	26 Mpa	246-703 Mpa	27%	26 MPa	690 MPa	59 J/m	76

Upon analysis of the physical prototype, we recognized several areas of improvement that ultimately led to the development of our Generation 2 design; however, the driving force in developing a second-generation prototype was that the flanges did not prove to be as flexible as we had anticipated. To compensate, we made additional modifications to the flange geometry and took greater care to research the material properties of the available resins (Table 2).

Material Considerations

A material appropriate for our application requires an entirely new set of design constraints. It must be flexible but strong, bioinert, and relatively resistant to both mechanical degradation (due to fatigue) and chemical degradation (due to cleaning solvents, for example). Furthermore, it should be as inexpensive as possible and capable of being processed for precision applications.

For this semester, we focused on choosing between the resins available from Midwest Prototyping. Of the three offered, only two (polypropylene and polyethylene) showed any signs of being appropriate since the third (polycarbonate) was clearly too rigid for our device. Based on the findings from Generation 1, we needed to determine whether the rigidity of the flanges observed in the resulting prototype was due to the material, the design geometry, or a combination of the two.

From our research, we found several reasons why polyethylene fit the material design constraints more appropriately than polypropylene. First, its stiffness and strength can be more tightly modulated than polypropylene, due to the widespread availability of several types that are differentiated by molecular weight, molecular weight distribution, linearity, and density. For our purposes, we would require a medium to high-density polyethylene (MDPE), which has a reasonable degree of elasticity. MDPE's Young's modulus is typically between 263-518 MPa. For reference, the Young's modulus of rubber is between 0.7-4 MPa, while the modulus of polypropylene if between 7590-10350 MPa. Furthermore, it may elongate up to 150% of its original length before failure, whereas rubber elongates between 100-800% of its original length and conventional polypropylene is only capable of 2-5% elongation. Finally, the advantages in elasticity needed to be weighed against the decreased tensile strength. Standard values for polyethylene are approximately 10-20 MPa, while those for rubber are 1-7 MPa and for polypropylene are 58 – 104 MPa. The considerable improvements to the overall elasticity of the material were determined to outweigh the loss of tensile strength (efunda.com).

There are a few additional material properties of polyethylene that make it a suitable material to pursue. First, it is bioinert, which makes it useful for skin-contacting applications. Also, its low static charge is lower than polypropylene's, which makes it less likely to attract dirt and thus, easier to clean. Additionally, it has a fairly low melting point, which makes it capable of being injection molded for precision applications. And finally, it is known as the least expensive polymers in industry due to its ease of production and its prevalence in commercial markets. MDPE is frequently used for piping, wire and cable sheaths, storage tanks, and kitchen storage containers (Thermoplastics 1997).

We determined that the high-density polyethylene available from Midwest Prototyping would be a suitable choice, especially if we made the minor changes in geometry previously suggested.

Flange Geometry

We recognized that the design of the flanges in the Generation 1 design mandated that the material would be flexible. Instead of requiring the material to compress against itself, we surmised that it would be more effective if the flanges could compress against a less resistive material – namely, air. Thus, we removed a small amount of material between the flanges and the inner wall of the abutment to permit greater deflection of the flanges toward the inner wall of the abutment. Despite the loss of material, we reasoned that this design would still result in greater attachment strength than the original post design. First the fixed portion of the flanges is wider and stronger than the post design could allow. Furthermore, the fixed portion is curved (Figure 11), which eliminates sharp corners and offers additional strength to the flange when it deflects. Finally, the curvilinear edge of the flange itself serves the same purpose. Below is a diagram depicting the mechanism of the final, Generation 2 device. Note that the only distinction between this image and Figure 12 is that there is a noticeable deflection of the flanges in part b of the figure below, while there is no such change in the first diagram.

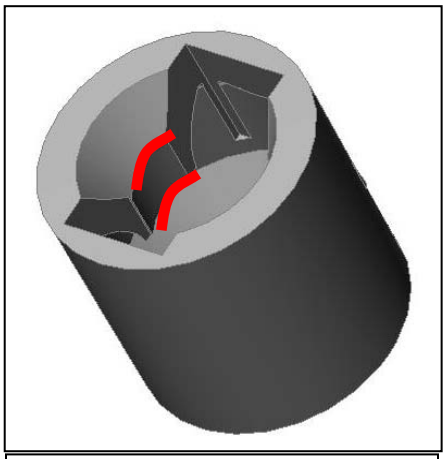


Figure 11. Curve (shown in red) on abutment increases strength of flange despite decreased material fixing the flange to the abutment cap.

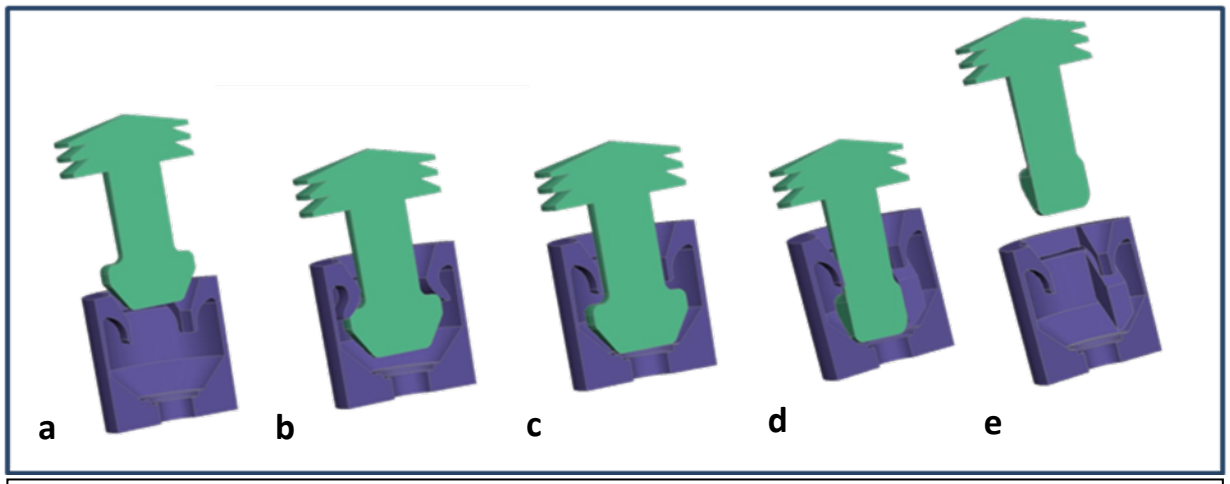


Figure 12. Mechanism of Generation 2 prototype. a) Attachment is brought into contact with abutment cap. b) Flanges deflect, allowing attachment to snap into abutment cap. c) Prongs/flanges hold attachment in place. d) User rotates attachment to align with slits. e) User pulls prosthetic to release attachment from abutment cap.

Flange Design Modifications

The distinctions between the two generations of the flange design are summarized in Table 3. With each of these changes taken into account, we were able to create a prototype that is both functional and aesthetic, a perfect complement to a prosthetic that meets the same objectives.

Table 3. Generation 2 was developed as a way to optimize the performance of Generation 1. This table states the different modifications that were required and what specifically was accomplished.

	Function	**Generation 1**	**Generation 2**
Material	Flexible but strong	Polypropylene	Polyethylene
Dimensions	Small enough to contain device within prosthesis	7 mm tall, 7 mm diameter	2 mm shorter to make more discrete
Flanges	Flex during attachment; provide barrier against vertical displacement	Flanges horizontally connect to inner wall	Flanges slope upward to increase flexibility
Tolerance	Involves strategic use of open space to permit simple, passive release	2.7 mm tolerance in release slits; 0.5 mm tolerance in cavity	3.7 mm tolerance in release slits; 0.75 mm tolerance in cavity
Integration with Prosthesis	Prevents forcible removal or rotation of attachment with respect to prosthesis	Tiered rivet prevents forcible removal, but not rotation	Tiered rivet prevents forcible removal and rotation
Barrier Mechanism	Prevents accidental release due to rotation in direction of gravity	Block design provides strong barrier	Wedge design is more space-efficient without diminishing strength
Advantages over G_0		No post-manufacture modifications, cost effective, replaceable	Generation 1 advantages & less brittle

Testing

Tensile testing

Tensile testing was conducted on an Instron Model 1000 Tester in the University of Wisconsin-Madison Structures and Materials Testing laboratory. The general test setup is shown in Figure 13: the abutment cap portion (2) was secured into the fixed grips and the attachment (1) was clamped into the crosshead (upper grips). In the figure, the grips that hold the osseointegrated abutment do not translate; however, the crosshead is capable of translating upward via screw driven actuators. As the crosshead moves upward, it creates tensile stresses within the specimen and eventually causes separation/failure. While the crosshead is translating upward, the machine simultaneously records the applied load at all points in time.

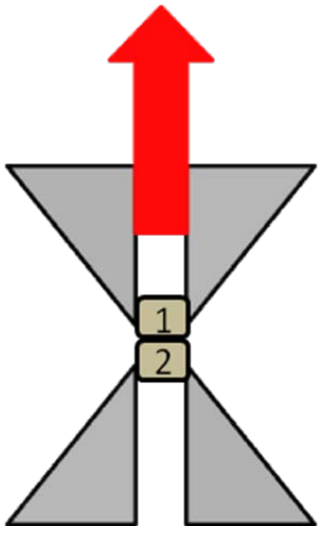


Figure 13. Simplified Instron test schematic.

We conducted testing on the Maxi-magnet (spherical), O-ring magnet (telescopic) and prototype to determine the loads where separation/failure occurred between the osseointegrated abutment cap and portion attached to prosthetic ear. Four tests each were conducted on the Maxi- and O-ring magnets at a crosshead velocity of 10 mm/min and 500 mm/min. Similarly, three tests were conducted on the prototype with a crosshead speed of 10 mm/min and five tests at 500 mm/min. The 10 mm/min crosshead velocity was used to represent a slow and steady removal similar to one a patient would use to remove the prosthesis; on the other hand, the 500 mm/min is more representational of an impact force. The results for the experiments are recorded in Table 4.

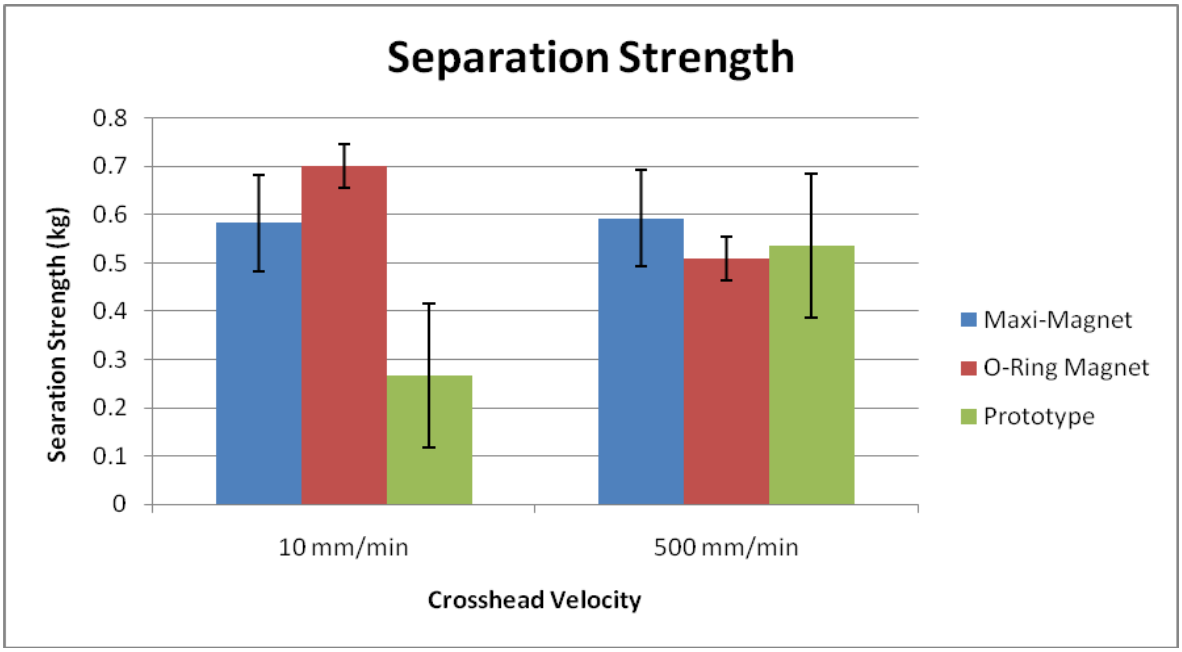
Table 4. Raw Instron testing data

	Maxi-Magnet		**O-Ring Magnet**		**Prototype**	
Test	**Speed (mm/min)**	**Separation (kg)**	**Speed (mm/min)**	**Separation (kg)**	**Speed (mm/min)**	**Separation (kg)**
1	10	0.65	10	0.65	10	0.3
2	10	0.5	10	0.75	10	0.23
3	10	0.69	10	0.66	10	0.27
4	10	0.49	10	0.74	500	0.97
5	500	0.69	500	0.48	500	0.47
6	500	0.51	500	0.48	500	0.68
7	500	0.49	500	0.56	500	0.31
8	500	0.68	500	0.51	500	0.25

After collecting raw data, the results were analyzed to determine average separation forces for each of the designs and the results are summarized in Table 5 and plotted in Graph 1.

Table 5. Average Instron testing values

Speed	**Maxi-Magnet**		**O-Ring Magnet**		**Prototype**	
10 mm/min	Average Separation (kg)	0.583	Average Separation (kg)	0.700	Average Separation (kg)	0.27
	Standard Deviation	0.102	Standard Deviation	0.052	Standard Deviation	0.04
500 mm/min	Average Separation (kg)	0.593	Average Separation (kg)	0.510	Average Separation (kg)	0.54
	Standard Deviation	0.107	Standard Deviation	0.038	Standard Deviation	0.29



Graph 1. Plot of separation strengths (kg) at 10 and 500 mm/min crosshead velocities for Maxi- and O-Ring magnets compared to Generation 2 Prototype.

As can be seen from the summary table and graph above, both magnetic attachments tended to outperform the generation 2 prototype when tested at a crosshead velocity of 10 mm/min. The average separation forces for the Maxi-magnet, O-ring magnet and prototype were 0.583kg, 0.700kg, and 0.270kg. Despite the fact that the magnets were capable of withstanding greater tensile loads, these results may not give an accurate comparison to the actual tensile capabilities of the prototype. The magnetic attachments are very easy to align within the machine because the two oppositely charged magnetic poles simply have to be placed into contact and separated. These magnets are also easily secured into the Instron grips. However, the prototype is more difficult to align in the proper orientation within the Instron machine due to the limited capabilities of the clamp to hold abnormally shaped objects such as the oval, toothed rivet on the post. In fact, the equipment specifications state that the object should occupy half of the grip's length to reduce slipping. Therefore, it is very likely that the prongs on the post were not properly aligned with the flanges on the abutment cap. If this were to happen, the prong may rotate or tilt to release. In turn, the force required to remove the prong from the cap would be minimized, much like that seen during testing. Nonetheless, the results indicate that the prototype may have lower separation strength than the magnetic attachments, despite the inadequate test setup.

In particular, for the lower speed, it appears that these values may contradict the functionality of the flanged attachment. However, the slow crosshead speed was chosen to represent similar behavior to patient removal. While the patient is removing the attachment, it is desirable to minimize the force required to detach the ear because unnecessary tensile, shear and torsion stresses tend to fatigue the abutment much more rapidly. Therefore, the lower detachment load is actually an unforeseen benefit to the design and may help to justify our results.

Despite the fact that the prototype separated at smaller loads when the crosshead moved at 10 mm/min, it achieved similar separation strengths to magnets at a 500 mm/min crosshead speed. As can be seen from the data, the average separation loads for the Maxi-magnet, O-ring magnet, and prototype were 0.593kg, 0.510kg and 0.540kg, respectively. Furthermore, the prototype had the largest singular load of all three samples at 0.97kg. As can be seen, the generation 2 prototype exhibited the capability to perform equally well or better than the existing magnet designs. The 500 mm/min crosshead velocity tests represent greater impact forces, and it is desirable to have higher separation forces in order to retain the prosthesis during times the ear receives a glancing blow. Because the prototype exhibited the capability to withstand higher forces under faster strain rates, we are confident in the ability of the snap-fastener design to resist impact forces and remain attached.

In addition to force analysis, we also noted that the magnetic designs tended to perform more consistently than the generation 2 prototype. The data shows the Maxi-magnet to be the most consistent design with approximately equal separations of 0.583 and 0.593kg at the different crosshead velocities. Furthermore, the raw data was more normally distributed and lends itself to consistent behavior. The O-ring magnet was also very consistent with standard deviations of 0.052 and 0.038 for crosshead velocities of 10 mm/min and 500 mm/min, respectively. Therefore, its separations at 0.700 and 0.510kg are very representative of the forces expected in actual patient setting. Finally, the generation 2 prototype tended to behave inconsistently during testing. Not only did the design show drastic improvements from the 10 mm/min crosshead velocity to the 500 mm/min velocity, but the values for maximum tension were much more dispersed than the magnets.

Because the prototype data was inconsistent compared to the magnets, it supports the argument that the separation strength of the prototype is very dependent on the orientation/mating between the abutment-cap and the post. If the prongs on the post are improperly aligned with the flanges on the abutment cap, the post is easily able to translate out of the cap. The prototype separated at approximately 0.27kg at the 10 mm/min crosshead velocity; and it is likely that the prongs did not have sufficient contact with the cap flanges during this testing. This occurrence is similar to the actual patient's use of the device when detaching the prosthesis. The intended design is for the patient to be able to rotate the ear such that the post can freely slide out of tracks in the cap. Therefore, improperly aligning the device in the Instron apparatus would achieve similar results as a patient that had semi-rotated their prosthesis for removal. Further supporting the argument that the post was not consistently aligned within the machine are the prototype results at a 500 mm/min crosshead velocity. As can be seen in **Table 4**, the prototype separation loads ranged from 0.25 - 0.97kg. The lower extreme is similar to the loads achieved by the prototype at the slower crosshead velocity. However, the prototype also demonstrated great capability to endure higher tensile stresses. Clearly, other factors including prong orientation play an important role in the retentive capabilities of the device.

COSMOS Testing

In order to ensure that the ear prosthetic attachment will provide sufficient strength, we performed a software analysis of mechanical strength on the central feature of the design – the abutment cap. Our SolidWorks$_{TM}$ model of the abutment cap was analyzed with COSMOS (collaboration with Alan G. Gomez, UW Madison) using high-density polyethylene (HDPE) as the material, since its properties in the SolidWorks$_{TM}$ materials database matched those defined on the Midwest Prototyping website reasonably well. A stress test was performed by placing a restraint on the base of the abutment cap, under the assumption that the cap would be constrained to a vertical orientation once the screw is tightened into the implanted abutment. Then, a force of 10 pounds was placed on the tip of the threaded portion. This value was set by our client as a promising target. Based on these parameters,

the software was able to determine interpretations of material stress, strain, and displacement as shown in the figures below (Figure 14 a-c).

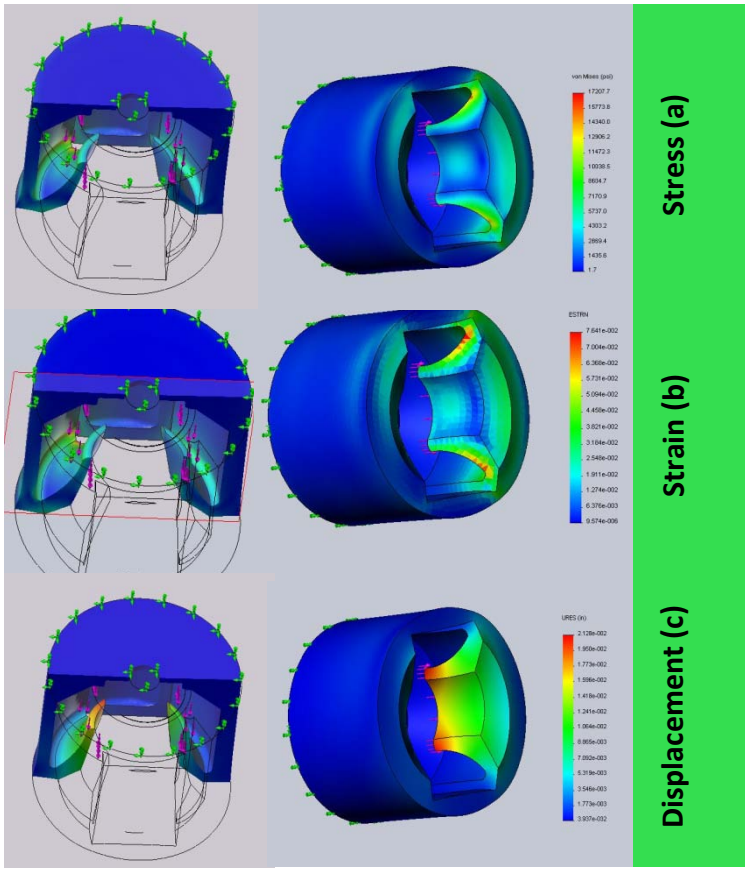


Figure 14. Static Nodal Stress for abutment cap when a force of 10 pounds is applied. The color gradient from red to blue represents the weakest and strongest areas, respectively, within the design.

The colors shown in figures a-c represent the distribution of stress, strain, and displacement of the flanges, respectively, with red being a concentration of one of these parameters. Note that none of these analyses seem to indicate failure of the device, but rather, stress risers that may fatigue over time. The specific values associated with this color gradient could potentially be useful if we compared them to a failure analysis of a known object; so for all practical purposes, the overall strength was determined based on the deformations visually observed in the analysis readout. Based on these initial results, we have determined that the device will withstand a 10 pound force applied instantaneously to the prosthesis, in which a motion pulls the ear away from the implanted abutments. This testing was used as a way to enhance the results of physical mechanical testing performed using the rapid-prototyped model, since neither showed structural failure.

Patient Feedback

In addition to collecting data regarding the prototype failure strengths, we were also able to gather feedback from our client's patients. Several of these feedback letters are shown in the Appendix. As can be seen from this clientele sample, although small, there is high overall satisfaction with current magnetic attachments. However, two comments demonstrate the magnetic clips' greatest shortcomings. In the second letter, the patient recommends using stronger magnets to achieve better retention because he has had problems knocking his ear off when removing his shirt. Also, the patient in

the third letter mentions she displaced her ear when she bumped it while carrying a forty-pound bag of dog food over her shoulder.

Reviewing these letters has shed insight into actual patient desires regarding the functionality of the prosthetic. First, the attachment must be strong enough to retain the prosthesis when it experiences large forces such as removing clothing and striking the ear. Second, the device should be easy to attach/detach at all times. Our device accomplishes both of these traits. As shown by our tensile testing data, the prototype has the capability to withstand greater forces than current magnetic mechanisms. Furthermore, the prototype also offers the easy attach/detach mechanisms; by pressing the prototype into place it becomes securely fastened, but a simple twisting action frees the two components and allows an easy, passive release. There are three areas in which the patient survey may not lend a completely accurate perspective on limitations of the current attachment. First, there was no information gathered to determine whether the patients lived a more active or a more sedentary lifestyle, which could dramatically shift their responses. Also, the patients may take instinctive precautions to protect their prosthesis during daily activity, so they may not be aware of instances where their quality of life may be improved. Finally, the survey was administered and collected by a biased source (their trusted anaplastologist) so some pathos may have factored into their responses.

Future Work

Technology

Although a small/passive force for removal has been demonstrated, we acknowledge the fact that the post – abutment-cap interaction must be improved. In our first generation prototype, we designed the abutment cap and post with excess material so that we could remove it if necessary, and as a result the prong did not properly fit into the cap. In order to avoid repeating this mistake, we fabricated the second generation prototype with built-in tolerances to ensure the post could easily slide past the flanges when rotated. As a result, we over-designed the tolerances and provided too little contact between the post and flange. Due to this, we observed that the prong was able to translate and rotate somewhat freely in the cap instead of having a more desirable snug fit. Therefore, in future iterations we will closely analyze the required tolerances to achieve most efficient interaction for retention and passive release.

One of the most critical areas for improvement will be the post – abutment-cap interface. Our data has shown that the prototype has the capability to outperform currently used magnetic attachments, but only when correctly aligned in the current state. Because the second generation prototype was over-designed to ensure the post would fit into the abutment cap, the post does not have the desirable snug fit that prevents rotation when the two components are mated together. Currently, the post portion is designed to have an outer diameter of 2mm while the slot in the abutment cap has a width of 3mm. In the future, we will closely examine the tolerances that will allow insertion but also prevent movement when fully incorporated into the abutment cap. While working with Midwest Prototyping, we observed the accuracy of their fabrication methods and believe we can alter the post to have a radius of 2.95mm and allow for a tolerance of ±0.05mm. For reference, the tolerances stated by Midwest Prototyping are less than 0.025 mm. In doing so, the post will be guaranteed to fit into the device and at the same time will have more contact with the flanges on the abutment cap for better attachment.

Furthermore, we have already begun and will continue to explore resistive materials that can be added into the retaining portion of the abutment cap for added support, if necessary. Adding a resistive

and deformable material into the bottom of the abutment cap will provide more stability by minimizing the distance over which the post can move. We already observed that beeswax has significantly improved the prototype stability and in the future we will expand the materials to include polymers and O-rings.

In addition to analyzing the mating mechanism of the individual components, we will evaluate the effectiveness of incorporating the prototype into a silicon model with currently used magnetic fasteners. Since the beginning, the idea has been to replace one of the magnetic posts on the ear with our prototype. In doing so, the patient will be able to attach the ear in the current fashion; however, to remove the ear they will simply have to disconnect the magnetic portions, twist the ear ninety degrees, and pull off. Our client has recently fabricated a working model of our prototype and preliminary qualitative testing has shown that the stability is greatly increased by incorporating the prototype into the ear. To verify our current qualitative results, we will perform further tensile testing as well as subjecting to a variety of other stresses including torsion and shear.

Another aspect we will consider in future work will be the implantation of the post into the silicon ear. In the past, our client has mentioned his concerns about his ability to properly secure and align the post into the prosthetic. Our Generation 2 prototype has taken these doubts into consideration and we fabricated the riveted portion into an oval shape to prevent rotation in the silicon. Our Generation 1 prototype had circular rivets and, while it had sufficient contact with the ear to prevent unwanted vertical movement, the circular aspect was not enough to stop the post from rotating. This is especially important because the post must be properly aligned with the abutment-cap in order for it to function correctly. Therefore, the irregular and oval shape is intended to fully prevent both twisting (thereby maintaining alignment) in the ear and vertical movement to remove the post from the ear. This future work will have several components. First, we will analyze differently shaped rivets on the prong to determine the most effective manner in which to prevent rotation and vertical translation. Additionally, we will investigate the possibility of creating a mating mechanism into which the post can be inserted into the silicon portion. For example, we may be able to machine a screw fastener that has better retentive capabilities and allows easy insertion and removal of the post portion. Furthermore, if we are able to fabricate a mating mechanism, we will analyze the possibility of creating the corresponding tool that allows an anaplastologist to attach and remove the post portion from the silicon ear.

Finally, our most important goal is to perform long-term patient-usability and fatigue testing. Our current testing has provided us with information regarding the ultimate separation strength; however, we do not currently have an understanding of the long-term potential for this product. By working with a patient population, we will be able to gather feedback about the advantages and disadvantages of the prototype and re-tailor the device in an appropriate manner. Additionally, by performing fatigue testing we will be able to analyze the life-span of the abutment cap to determine how often it should be replaced.

Translation

In addition to technological changes, we will also conduct future work that translates into other fields. One of our primary goals was to create a prototype that could be applied to multiple prosthetics, and we believe our concept can be extrapolated to do so. Therefore, we will have to conduct more research into currently used techniques to determine how the design must be modified to accommodate other facial and limb prostheses.

Conclusion

Over the course of the semester, we have demonstrated that a snap-fastener design is both a feasible and effective attachment mechanism for use in ear prostheses. Currently used attachment mechanisms incorporate an O-Ring, telescopic, spherical magnets as well as splinted and un-splinted clip designs into an FDA-approved osseointegrated abutment. These designs translated from the dental industry, which consistently uses osseointegrated mechanisms for dental implants. However, these devices do not properly address the needs of the auricular prosthetic industry because of the different environments that each is exposed to. Magnetic or clip attachments are perfectly adapted to dental implants because the forces are almost entirely axial compressive loads. Compressive loads do not weaken the device and cannot displace the tooth. However, because the ear is exposed to such a variety of forces including compressive, tensile, shear, bending, torsion and a combination of the aforementioned forces, better attachments are needed to retain the device. Furthermore, because the device is consistently removed for cleaning, it should not require excessive force to remove because these high removal forces can potentially weaken the osseointegration between the skull and abutment. Taking these constraints into consideration, we developed a snap fastener design that offers high retention under impacting tensile forces. Furthermore, the twist-and-release mechanism offers a negligible resistance to removal at the appropriate orientation so the osseointegration should not deteriorate. Because the prototype was successful in preliminary experimentation, we are confident that future iterations can be tailored to offer better retention under all stress states. Furthermore, materials and designs will be analyzed to determine prototype durability and product lifespan. Finally, one of the overall goals will be to analyze the possibility of expanding this snap-fastener design to be used in other prosthetic industries such as orbital, chin, nose and other non-craniofacial prostheses.

References

Bashford, David. *Thermoplastics: Directory and Databook*. New York, NY: Springer, 1997.

Bentz, Michael. Personal interview. 2 October 2008.

Branemark P. Osseointegration and its experimental background. J Prosthet Dent 1983 (50):399-408

Eavey R., Monroy A., Nicolau Y., Shabdiz F. Surgical versus Prosthetic Reconstruction of Microtia: The Case for Surgical Reconstruction. Journal of Oral Maxillofacial Surgery 2006(64);1655-1663

de Sousa A., Mattos B. Magnetic Retention and Bar-Clip Attachment of a Implant-Retained Auricular Prostheses: A Comparative Analysis. Int'l J Prosthodontics 2003(21) 233-237

Polymer lists. http://www.efunda.com/. Accessed 08 December 2008.

Mechanical Properties of Common Solid Materials. http://www.efunda.com/. Accessed 08 December 2008.

Voigt A., Klein C. Experimental evaluation of retention forces of different magnetic devices for bone-anchored auricular facial prostheses. Int'l J Oral and Maxillofacial Surg 2008:37 664-668

Westin T., Tjellostrom A., Hammerlid E., Bergstrom K., Rangert B. Long-term study of quality and safety of osseointegration for the retention of auricular prostheses. Otolaryngol Head Neck Surg 1999;121: 133-43.

Wilkes G., Wolfaard J. Osseointegrated Alloplastic versus Autologous Ear Reconstruction: Criteria for Treatment Selection. Plast. Reconstr. Surg. 93: 967, 1994.

Appendix 1 – Patient Feedback Letters

I Received my prosthesis in July of 2008. It has only been 3 months and everything is going well. It is to soon and to new to have any problems

My only suggestion is that the magnets might be stronger. From time to time, I have knocked my ear prosthesis off when pulling a T-shirt over my head. Other then that, I haven't had a problem – and that is a very small problem. I'm grateful to both of you for what you did for me. Keep up the good work! [redacted]

Greg/Allison 10/2008

My prosthetic has come off only once. I was lifting a 40lb bag of dog food onto my shoulder. I lifted it too much, it hit me on the head, slid down, and knocked my prosthetic off. I put the bag down, picked up the prosthetic, and snapped it back on, piece of cake!

Other than that - prosthetic has been GREAT!

Appendix 2 – PDS

Product Design Specifications

Title: Ear Prosthesis

Team:

Claire Flanagan- Team Leader
Sarah Offutt- Communicator
Adam Rieves- BWIG
Josh White - BSAC

Function: There will always be a clinical need for replacement of damaged tissues, either by surgery or prosthetics. However, for ear reconstruction, surgery options are severely limited because the ear is such a complex organ; therefore, osseointegrated implants have begun to be used. Osseointegrated prostheses originated in the dental industry, and they offer the most optimal interface between native tissue and the artificial material. These concepts have translated into other prosthetic applications; however, they have less effective results. By taking an engineering perspective, our goal is to identify the mechanical, cosmetic, and material requirements to optimize the technology for ear prostheses. A broader goal is to generalize this design to other prostheses that utilize the osseoimplanted technique

Client requirements: Our client, Greg Gion, works in the medical cosmetics industry and has been creating ear prostheses for 25 years. Through his experiences, he has discovered shortcomings to the existing design. Most importantly, the attachment mechanism is insufficiently strong for patients living active lifestyles. However, the attachment is constrained by the placement/style of the FDA-approved attachment studs and the need for the device to be removed daily for cleaning. Ideally, the device will be able to withstand greater forces without being dislodged and will be able to do so in an anatomically similar fashion.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*

Must be able to withstand approximately 7.5 N (1.68 lbs) of tension and also be able to support shear, compressive, bending, and torsion stresses using a combination of three attachment points. Strength of attachment should be the main mechanism by which this is achieved. The device must also feature a passive release mechanism. Device must not wear during mildly abrasive cleaning.

b.*Safety*

Ensure that device is safe for prolonged wear. 86% of users wear the device for more than 8-10 hours per day for the three year lifespan of the prosthesis. Conform to FDA regulations for the osseoimplanted portion of the device. Meets all Class 1 medical device requirements. Features should have dull/rounded edges in the case of dislodgement.

c. *Accuracy and Reliability*

The device should be able to stay in its position whenever it is attached, and it should reliably stay attached. Natural wear and tear of the device should not affect the attachment mechanism.

d. *Life in Service*

The device is designed to be replaceable. Thus, the device should be sustainable for 3 years, either by easy replacement of fatigued parts or demonstrated durability for 3 years (approximately 3240 cycles of attachment/detachment).

e. *Shelf Life*

The devices should be able to be kept under ambient conditions without degrading.

f. *Operating Environment*

The attachment should allow the patient to perform normal, everyday activities. This includes, but is not limited to, playing sports and contact with water.

g. *Size*

The attachment must be able to fit in the FDA-approved stud and small enough to be concealed by the silicon prosthesis. This volume approximates a 7 mm^3 region.

j. *Materials*

The abutment itself is titanium, so the attachment device must be able to maintain its mechanical and chemical properties when integrated. Also, the material should be hypoallergenic and should not otherwise cause any irritation to native tissue.

k. *Aesthetics*, *Appearance, and Finish*

Attachment device should maintain standard size and proportions for ears. The design should accommodate all ranges of users, and have a professional appearance.

l. *Ergonomics*

The device should be quick and simple to attach and also simple to intentionally remove.

2. Production Characteristics

a. *Quantity*

Product should be developed with the intent of mass-production. Furthermore, it should be capable of being adapted for use in other prostheses.

b. *Target Product Cost*

The price for production for the prototype should be $5-10, if possible. This estimate is based upon initial models produced using the rapid prototyping technique. However, it is likely that using a technique like injection molding would decrease the cost even more.

3. Miscellaneous

a. *Standards and Specifications*

Product should meet requirements for a Class I medical device. Product must be able to be easily translated into mass production. Product must improve patient quality of life, to be evaluated with a patient survey post-development.

b. *Customer*

People suffering from microtia, severe burns, and other injuries causing a loss of the outer ear. Also, cancer patients that have received radiation treatments are good candidates for this technique.

c. *Patient-related concerns*

Product should not interfere with patient's daily life.

d. *Competition*

Surgical reconstruction; Maxi-Magnet, Locater, and Hader attachment mechanisms