Attachment of prosthetic ear to cranial implant abutments

Final Report

December 10, 2009

Marc Egeland (Team Leader)

Paul Fossum (BSAC)

Nick Shiley (BWIG)

Nick Thate (Communicator)

Client: Gregory G. Gion, MMS, CCA

Advisor: Professor Willis Tompkins

Table of Contents

ABSTRACT

The goal for this semester was 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. We employed the use of a spring to allow for absorption of additional force and a crumple sheath rather than a magnet cap to provide extra stability. By testing our design against the current magnetic mechanism, we were able to determine that a spring-sheath design can withstand approximately four times the amount of lateral force before being dislodged from the abutments. For example, in the pulling test, our spring-sheath design absorbed up to 17.2 lbs before being dislodged, while the control was only able to absorb 4.5 lbs. While not perfect, our mechanism was successful in improving the amount of lateral forces that the ear prosthesis could withstand, and with future development could potentially improve the daily life of patients with ear prostheses.

PROBLEM STATEMENT

The purpose 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 will release 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

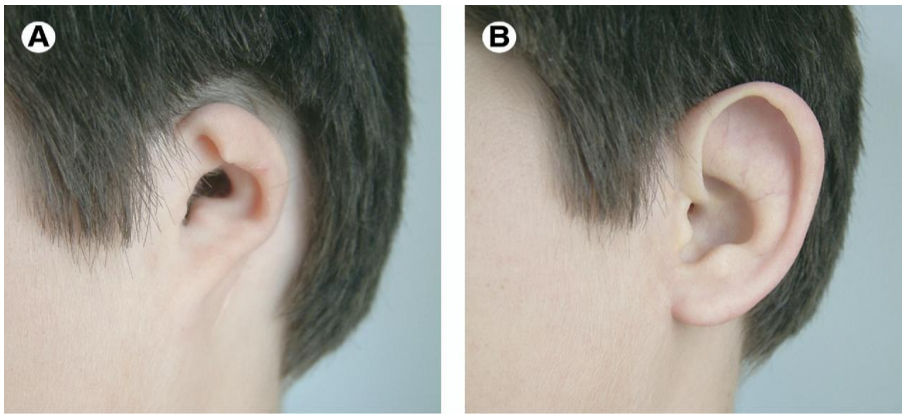

Figure 1. A. Example of left ear microtia **B**. Slip-on prosthetic in situ [1]

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. After research of the forces required for bone fracture and consultation with our client, it was determined that the abutment shaft is specially designed to fracture before the force transferred to the implant is great enough to cause harm to the bone structure. 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.

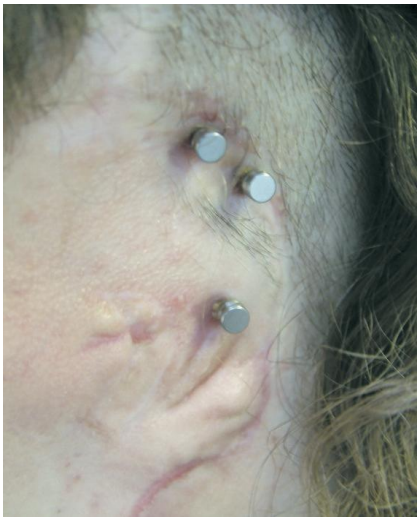

Figure 2. Osseointegrated cranial abutments with magnetic caps [1]

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 detach when the user desires. The design must be low profile and aesthetically pleasing; it should not be overly bulky, heavy, or noticeable to others in normal social situations. It should be able to withstand more force in any direction than the control design, which was determined to be approximately 5 pounds through testing. Mr. Gion did not want us to modify the original osseointegrated abutments in any way, so it is necessary that our design is adaptable or scalable to the current abutments (4.4 mm in diameter). Furthermore, the attachment mechanism should not inhibit the patient's ability to clean and maintain his/her prosthesis. Finally, the design must be easy for the patient to affix and remove without extra tools or complicated steps.

PRELIMINARY DESIGNS

After brainstorming possible attachment mechanisms for over four weeks and discussing them with the client, we narrowed our ideas into five possible 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.

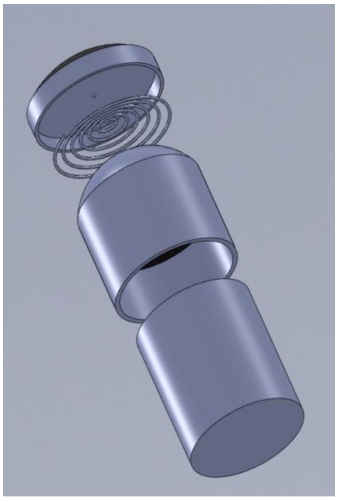

Figure 3. SolidWorks drawing of Flat Spring and Magnet Cap

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

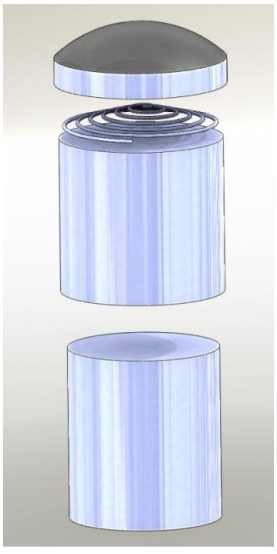

Figure 4. SolidWorks drawing of Flat Spring and Sheath

the friction fit limits attachment and removal to one direction (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

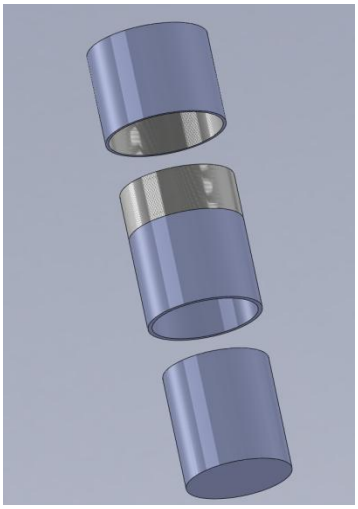

Figure 5. SolidWorks drawing of Rigid Shearing Sheath

the sheath. The small distance left between the top of the abutment and the overlap from the 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

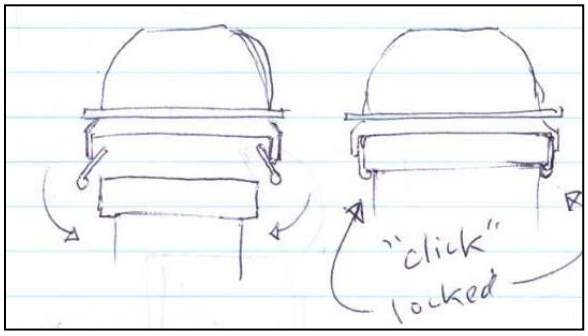

Figure 6. SolidWorks drawing of Active Clip with Magnet

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.

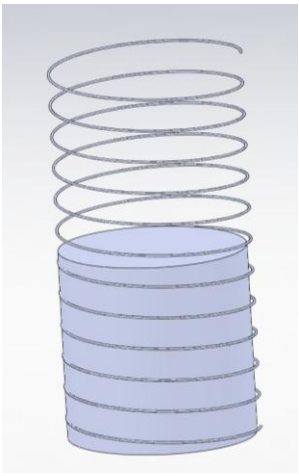

Figure 7. SolidWorks drawing of Cylindrical Spring as Sheath

DESIGN MATRIX

We rated our five preliminary designs on a scale from 0 to 100 using a design matrix (Figure 8). We had several criteria that were weighted differently based on its importance and 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; therefore, our group decided to pursue this design. It rated highly in all of the main categories and our client showed interest in its pursuit. 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.

FINAL DESIGN

The final design we tested and presented to the client was an adaptation of the Flat Spring and Sheath design, which is pictured in Figure 9. This design included a brass deep-drawn inner sheath that was ordered from Braxton Manufacturing Company, Inc (Watertown, Connecticut), a precision deep-drawn component manufacturer. This sheath was then cut down in order to fit into the outer steel cap. Approximately four to five coils were cut off from a standard size 16 steel tension spring and one end of the spring was positioned inside a small hole that was drilled into the side of the sheath, as shown in Figure 10. This sheath and spring mechanism was made to fit into an outer steel cap. The steel outer cap was turned down on a Hardinge lathe from a ¼ inch steel rod to an outside diameter of 0.215 inches. A 3/16 inch drill bit was used to bore out an inner diameter of 0.1875 inches, giving the cap a thickness of 0.0275 inches. This cap then had an overall length of 0.35 inches, with the depth of the boring being 0.32 inches allowing the spring and sheath mechanism to fit within, as shown in Figures 9 and 10. The spring and sheath mechanism was attached to the steel outer cap by placing the end of the spring through a small hole that had been drilled in the center of the top of the steel cap.

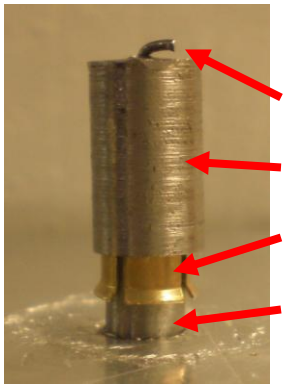

Figure 9. Spring and Sheath Design.

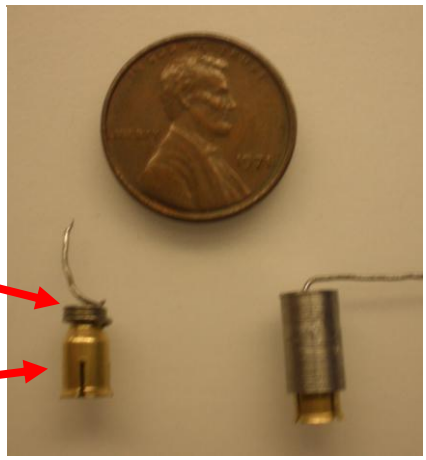

Figure 10. Spring and sheath design with and without the outer cap.

Key Aspects of Final Design

This final design had several key advantages over the magnetically attached prosthesis our client currently uses. One major advantage is that this design provided additional lateral stability as the testing and results show. Additionally, the use of the spring in the design decreases the likelihood of sheath fracture, causing the need to get the whole prosthesis replaced. However, on that same note, the four phalanges on each sheath do allow for the sheath to fracture with significant amounts of force applied (approximately 17 pounds, as found in testing). Finally, the sheath improves the ability for a patient to easily remove his/her prosthesis when desired.

Despite the fact that this spring and sheath design has several advantages, there are a few issues with this design. The lack of magnets increases difficulty for the patient to locate the three abutments for prosthesis attachment. An additional issue with this design, unforeseen in its preliminary design and fabrication, is the leaking of silicone into the spring and sheath during the molding of the ear prosthesis. This leaking inhibits the spring from having full functionality. As mentioned earlier, one final concern with this design is the fact that when part of any sheath breaks the entire prosthesis is compromised, requiring the patient to acquire an entirely new prosthesis.

TESTING AND RESULTS

Since the spring-sheath design was chosen mainly through qualitative analysis, testing was performed to back our ideas up with numerical data. The goal was to examine how much force it took to dislodge a prosthetic from various angles. The spring-sheath design was tested

against a simple sheath design (to see what effects the spring component would have in retaining the prosthesis), as well as against the control magnetic attachment currently used by our client. To create the testing prostheses for the spring-sheath and simple sheath design, the attachment mechanisms were placed on three tight fitting mock abutments imbedded in an aluminum block (base). An ear-shaped mold, made from dental stone, was then placed over the top of the base and filled with 10-30 Shore A durometer silicone, resulting in a mock ear prosthesis with the attachments securely imbedded within it. The control ear used in testing, along with its own matching base, was acquired from our client as a model of the current magnetic attachment mechanism.

Each model prosthesis was placed on its respective base, secured to the table with a C-clamp, and put through three tests to determine its retentive capabilities. These tests were chosen for their ability to mimic situations and forces by which ear prostheses may be dislodged. Each of the tests used a Chatillon force gauge, model DPP-5 KG, to measure the force applied. Figure 11 shows our designation of each abutment location, in order to better describe the testing methods. In the first test, a loop of string (attached to the force gauge) was wrapped around the top half of the model prosthesis and pulled, with the force centered near abutment 2. We designated this as

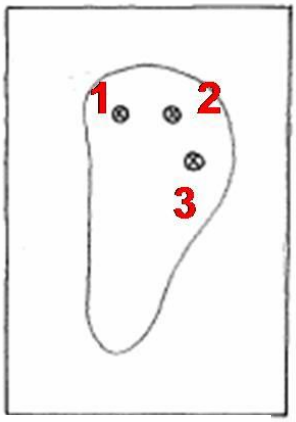

Figure 11. Locations of the abutments and corresponding sheath.

Figure 12. Example of *Pulling* test.

the *pulling* test and it can be seen in Figure 12. The remaining two tests, designated *pushing 1* and *pushing 2,* involved directly applying the probe of the force gauge onto the model prosthesis in two separate locations. The force for *pushing 1* was applied between abutments 2 and 3, while the force for *pushing 2* was applied below abutment 3 in the direction of the top of the prosthesis. Both pushing tests were applied at a level parallel to the surface of the base. These two tests can be seen in Figure 13 and Figure 14, respectively. We never tested pushing or pulling the ear directly perpendicular to the base, as that direction should have minimal resistance to ensure easy removal. Force values at the time of dislodgement were recorded for five trials per test type for each of the three attachment mechanisms, and the average of these five trials was calculated. It should be noted that two of the flanges on the sheath over abutment 1 within the spring-sheath prosthetic model broke off after the first trial of the *pulling* test; therefore, this value was substituted for the average. In the pulling test, the spring-sheath absorbed 17.20 lbs before detaching, compared to 16.48 lbs on average for the sheath alone and 4.54 lbs for the control magnetic attachment. In *pushing 1*, the spring-sheath withstood an average of 8.81 lbs of force. The simple sheath attachment was dislodged after 8.73 lbs of force, while the control only withstood 2.39 lbs. Finally, for *pushing 2*, the spring-sheath absorbed an average of 10.49 lbs before detaching from the base, compared to 8.08 and

Figure 13. Example of *Pushing 1* test

Figure 14. Example of *Pushing 2* test

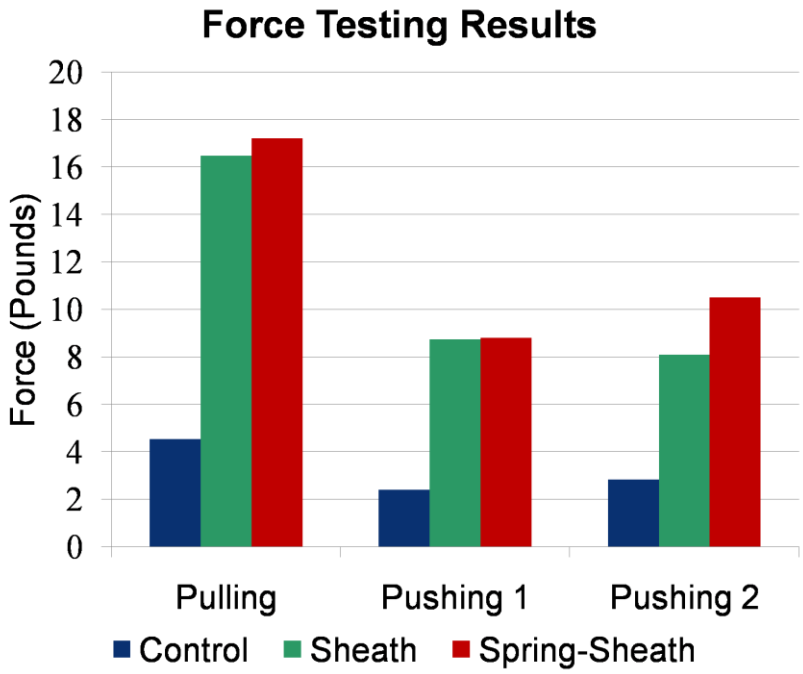

Figure 15. Graph comparing results from each testing method.

2.02 lbs for the simple sheath and control, respectively. A chart of the total data gathered during testing can be seen in Appendix A.

It is clear that the spring-sheath design, as well as the sheaths alone, were both able to absorb four times more force than the control design in all three tests. One factor that could have skewed our results would be the discrepancy in the abutment and model size of our design compared to the control. The other two model prostheses were significantly larger than the control model, which could have contributed to their greater retention. However, based on the large difference in the recorded values, we feel confident that our design is more securely affixed to the abutments than the control design, and the spring does contribute to additional force absorption.

FUTURE WORK

Though the final design was a success and met most of the client's specifications, there are some modifications that can be made to improve the design and make it more marketable. One modification would be the incorporation of a flat spring instead of a regular tension spring. The flat spring would decrease the size of the design, allowing it to be more easily molded into the silicone ear and improving the aesthetic appearance. The flat spring would also decrease the probability of excess silicone leaking into the spring compartment. When the client creates the ear prostheses, he injects silicone into a pre-formed ear mold. During the molding of our test models with sheath and spring inside, silicone found its way into the design caps, slightly hindering the spring functionality.

Another modification is to increase the diameter of the design to fit around a standard 4.4mm medical-grade abutment. The Braxton sheaths we used were only 3.6mm in diameter which made our mechanism smaller in diameter than the desired final design. A final modification would be to have all components of the design made of standard biocompatible materials.

In addition to design modifications, further testing is required to obtain more accurate and consistent data. Using a mechanical testing system, constant forces could be applied to the designs in order to more accurately determine the forces required to dislodge the designs from the abutments.

CONCLUSION

Overall the semester was a success. The final prototype met most of the client's specifications. Due to the lack of resources and time, the final prototype was slightly larger in height than desired. In addition, the attachment mechanism was slightly smaller in diameter than the 4.4 mm standard abutments. However, the prototype was still useful in analyzing the advantages and disadvantages of the design. In the end, the mechanism was a simple, cheap, and light-weight design with potential for future marketability. The device was produced for a cost of less than 15 dollars, well below the original budget of $500. More importantly, the device improved the security of attachment of the prosthetic ear to the abutments.

As a design team, we would like to thank our client, Gregory Gion, for this opportunity and for all the help he provided us with. We would also like to thank our advisor, Professor Willis Tompkins, for his aid in the design process as well as Professor Thomas Yen for his assistance in fabrication and testing.

REFERENCES

[1] Gion, G. “Surgical Versus Prosthetic Reconstruction of Microtia: The Case for Prosthetic Reconstruction.” Journal of Oral Maxillofacial Surgery. 2006. 64: 1639-1654

[2] “Microtia.” FACES: The National Craniofacial Association. 2009. [online]. http://www.faces-cranio.org/Disord/Microtia.htm

[3] “Hemifacial Microsomia.” Children’s Hospital of Wisconsin. 2009. [online]. http://www.chw.org/display/PPF/DocID/21821/Nav/1/router.asp

[4] Fearon, J. “A Guide to Understanding Hemifacial Microsomia.” Children’s Craniofacial Association. 1993. [online]. http://www.ccakids.com/Syndrome/Microsomia.PDF

[5] Brown, J. “Patient Resources: Terminology.” Medical Art Resources, Inc. 2006. [online]. www.facialprosthetics.com/resources/terminology.html

APPENDIX A- Testing Data

*All test data is shown in pounds (lbs)

	Magnets (Control)	Sheath	Sheath w/spring
	4.19	17.35	17.20
	4.28	15.52	7.17
	4.54	17.28	4.30
	5.05	16.14	5.29
	4.65	16.12	5.91
Average	4.54	16.48	7.97
Std. Dev.	0.34	0.80	5.26

Results from *Pulling* test trials

	Magnets (Control)	Sheath	Sheath w/spring
	2.60	7.47	8.18
	2.56	11.77	9.17
	2.20	8.38	8.91
	2.36	8.25	9.39
	2.23	7.80	8.38
Average	2.39	8.73	8.81
Std. Dev.	0.18	1.74	0.52

Results from *Pushing 1* test trials

	Magnets (Control)	Sheath	Sheath w/spring
	3.31	9.06	11.00
	2.78	7.28	10.41
	2.43	7.76	7.50
	2.95	8.60	11.64
	2.65	7.72	11.93
Average	2.82	8.08	10.49
Std. Dev.	0.33	0.73	1.78

Results from *Pushing 2* test trials

APPENDIX B- Product Design Specifications

Ear Prosthesis Attachment Mechanism Product Design Specification (PDS)

12/9/09

Marc Egeland, Paul Fossum, Nick Thate, Nick Shiley

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 lbs
- Adaptable /scalable to current abutment sizes—4.4 mm diameter

Design Requirements

1.) Physical and Operational Characteristics
   a.) Performance Requirements
      i. Withstand normal daily activity (waking hrs)
      ii. Withstand 5 lbs of lateral force without unintentional dislodgement
   b.) Safety
      i. Will not cause harm to bone structure when subjected to force (client assured us that medical abutment is designed to fail before bone structure is damaged)
      ii. Mechanism cannot cause harm to patient (pinching, protrusions, etc)
   c.) Accuracy and Reliability
      i. Must fit previous abutment sizes (4.4 mm diameter) or be scalable to them
      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