Attachment of prosthetic ear to cranial implant abutments

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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 4 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.

Background/Motivation

Why are Ear Prostheses Needed?

- Microtia
  - Congenital defect that occurs unilaterally (1 in 8,000 births) [2]
- Loss of tissue due to cancer effects
- Hemifacial microsomia (Goldenhar's syndrome)
  - Can vary in severity from minimal deformation to complete underdevelopment of the ear and other parts of the front and side of the face
  - Second most common birth defect (1 out of 4,000) [2]
- Trauma or other injury

Problems with Current Designs

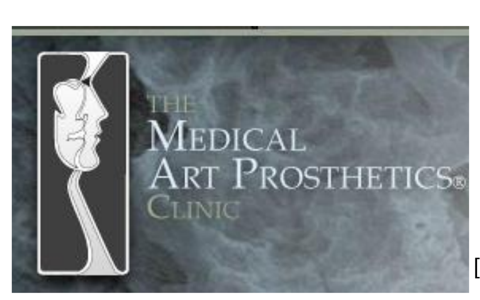
- Bar-clip design
  - Bulky, difficult to clean, not aesthetically pleasing
- Sleeve/slip-on design
  - Only applicable in limited number of cases
- Magnet design
  - Issues with security of attachment


[1]


[1]

Design Criteria

- Prosthesis must resist unintentional dislodgement
- Must remain low-profile and aesthetically pleasing
- Able to withstand 5 lb of force in any direction
  - Approximately the force allowed by the current three magnet and o-ring design, as determined by testing
- Adaptable/scalable to current 4.4 mm abutments
- Easy to attach and remove
- Easy to maintain and clean



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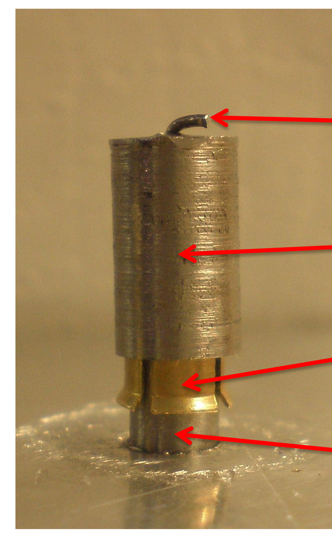
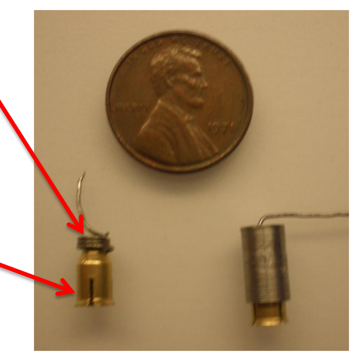
Final Design and Testing

Spring and Sheath Design





Fabrication

- Outer cap turned down on Hardinge lathe from 1/4" steel rod
- Inner sheath ordered from precision deep-drawn components manufacturer
- Testing abutment turned down on Hardinge lathe from 3/16" plated steel rod
- Cylindrical spring cut down from standard size 16 steel tension spring

Design Advantages

- Sheath provides additional lateral stability
- Spring reduces probability of sheath fracture
- Sheath improves ability for patient to easily remove prosthesis when desired
- Phalanges allow for sheath fracture and replacement

Design Disadvantages

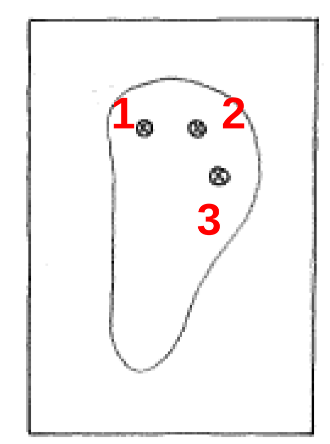
- Lack of magnets increases difficulty in locating abutments for prosthesis attachment
- Sheath fracture requires replacement
- Silicone leakage during molding inhibits full spring functionality

Testing Methods

Pulling- The force was applied with a string wound around the top half of the ear, creating a distributed load near abutment 2.

Pushing 1- The force was applied pushing between abutments 2 and 3. The gauge was kept at a level parallel to the base.

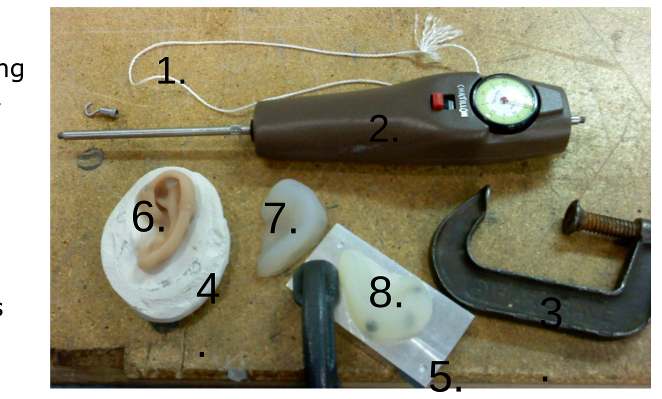
Pushing 2- Similar to that for *Pushing 1* except for the force was applied away from the ear lobe, below abutment 3.



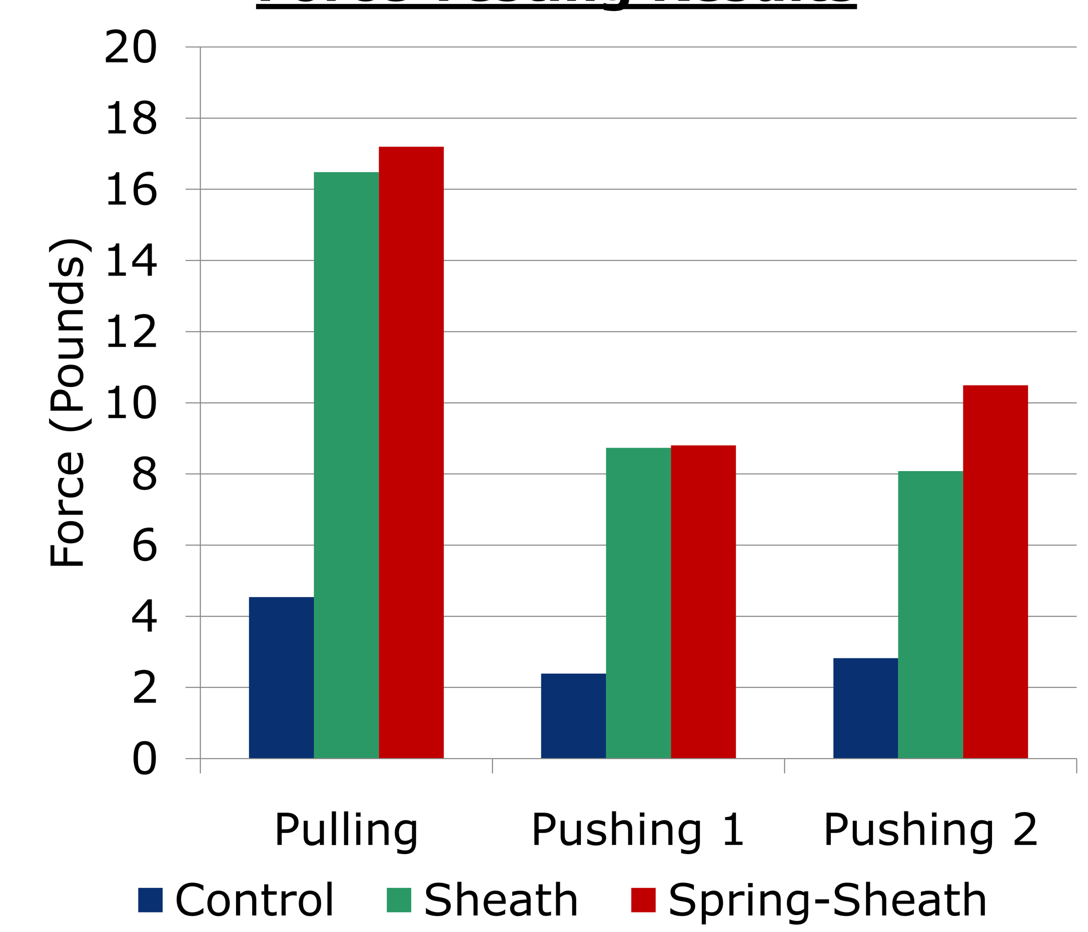
Reference to abutment and correlating sheath locations

Testing Materials

1. Force Distribution String
2. Chatillon Force Gauge, Model DPP-5 KG
3. C-clamp
4. Base 1
5. Base 2
6. Control Ear
7. Ear w/ Sheaths
8. Ear w/ Spring-Sheaths



Force Testing Results



Discussion of Results

- The values shown in the graphs are the average of five trials with each set-up

NOTE: The Spring-Sheath value of 17.2 lbs was the only valid result from the Pulling test able to be recorded, due to the fracture of two phalanges on *Sheath 1* during the *Pulling Test*

- Spring-Sheath and Sheath designs absorbed more force before being removed from base than the control in all three tests
- Each of the three tests was chosen for its ability to mimic common situations in which an ear prosthesis could be dislodged in everyday life
- The amount of force needed to remove the prosthesis straight off of the abutments was not measured because our goal was to remove restrictions on intentional removal

Future Work

Design Aspects

- Final design would incorporate a flat spring, making attachment less bulky with decreased possibility for silicone leakage
- Design would be made to fit on actual 4.4mm medical-grade abutments
  - Increases consistency and accuracy of testing results
- All components would be made of standard biocompatible materials

Marketing and Ergonomics

- More advanced testing would be used for more accurate data
- Marketed towards prosthetic ear manufacturers and surgeons
- Used on a test basis to determine patient satisfaction

References/Acknowledgements

[1] http://www.medicalartprosthetics.com/
[2] FACES: The National Craniofacial Association

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