Prosthetic Ear Attachment Anchor

Cristian Naxi, Joseph Campagna, Kinzie Kujawa, Mitchell Glodowski, Anna Samuelsohn
Client: Gregory Gion, Medical Art Prosthetics
Advisors: Dr. Naomi Chesler, PhD, Dept. of Biomedical Engineering; Ashley Mulchrone

Abstract

Prosthetic ears are provided to thousands of people every year who have lost their ears due to trauma, cancer, or congenital disorders. Prosthetic ears are often secured to the skull via a surgically implanted metal abutment. A magnet is chemically bonded to the silicone prosthesis and attaches to the metal abutment. The chemical bond between the magnet and silicone is unreliable and leads to an unpredictable life span of prosthetic ears using this technique. Medical Art Prosthetics is seeking a method to mechanically attach the magnet to the silicone ear, providing a longer, more reliable lifespan for the prosthesis.Testing shows that a polycarbonate anchor can successfully increase the retention of a magnet inside of a silicone ear.

Background

- Microtia affects about 1 in 6,000 newborns[1]
- Silicone ear prostheses are made for individuals who are missing all, or a portion of their ear
- Medical Art Prosthetics delivers about 20 prosthetic ears per year
- Ear prostheses have inconsistent lifespans
  - Unreliable chemical bonding of magnet to silicone
- Magnets cannot be reattached to silicone

Figure 1a.

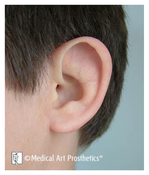

Figure 1b.

Figure 1: A patient with microtia before (a) and after (b) receiving a prosthetic ear[2].

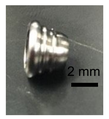

Figure 2: An auricular magnet that would be molded into a prosthetic ear.

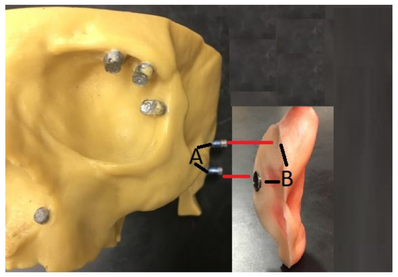

Figure 3: Titanium abutments are surgically placed into a patient's skull (A) and attach to magnets placed inside of the prosthetic ear (B).

Problem Statement

- Medical Art Prosthetics is seeking to increase the lifespan of their ear prostheses
- Current methods for molding magnets into silicone prostheses are unreliable
- A magnet anchor is necessary to retain the magnet in the prosthesis
- A fabrication procedure that can be used by Medical Art Prosthetics must accompany the design
- Anchor should versatile to fit ear prostheses of different sizes

Figure 4: A prosthetic ear from medical art prosthetics with an embedded magnet.

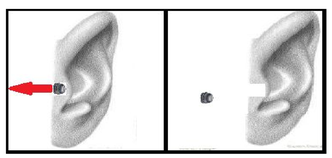

Figure 5: Magnet dislodges from prosthesis after continuous removal.

Design Specifications

- Attachment must:
  - Secure magnet in silicone ear
  - Fit differently sized magnets
  - Be 0.5 mm thick
  - Be inconspicuous
  - Withstand 200℉
  - Improve silicone ear lifespan to a minimum of two years

Final Design

Fabrication of Compression Mold and Anchor

- An aluminum compression mold was manufactured to fit auricular magnet
- A protocol was developed to fabricate anchor
  - Auricular magnet was placed in bottom half of mold
  - Polycarbonate pellets were placed on top of auricular magnet
  - Both halves of mold were placed in a 400℉ oven
  - Pellets were pressed down into magnet with the top half of mold
  - Magnet with anchor was embedded in silicone

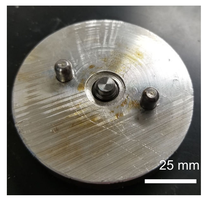

Figure 6a: Bottom half of the aluminum mold with an auricular magnet in the center.

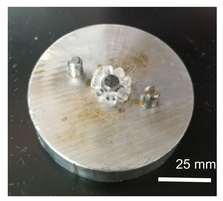

Figure 6b: Bottom half of the mold with magnet and polycarbonate beads placed in the center.

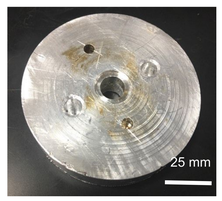

Figure 6c: Top half of the mold.

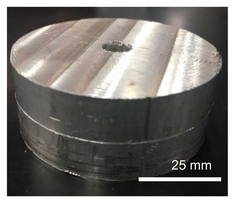

Figure 6d: Both halves of the mold pressed together.

Prototype

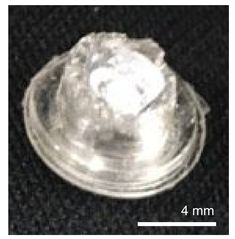

Figure 7: Auricular magnet with an anchor made of polycarbonate.

Figure 8: Cross-section of the anchor on an auricular magnet.

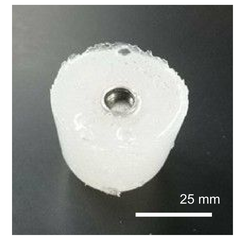

Figure 9: Auricular magnet with anchor embedded in silicone.

- The anchor is a plastic 'cap' on the magnet
- The anchor has a skirt that extends around the auricular magnet
- This skirt creates a larger area of contact with the inside of the silicone
- The process of making the anchor ensures that it is mechanically attached to the grooves of the magnet.
- Material on top of the magnet will help cloak the magnet inside prosthetic ears

Testing and Validation

Testing Methods:

- Fatigue Testing
  - Pulled magnet with silicone on and off the abutment 730 times, or until the magnet came out of the silicon.
- MTS Machine
  - Tension Test

Magnet	Results	Implications
Without anchor	Fatigue testing: Mean- 3 trials 95% CI [2-4 trials] MTS testing: Too weak to test* * <13 N (Breakaway force of magnet)	Not effective retention when tension applied
With anchor	Fatigue testing: Mean- >730 trials MTS testing: Mean- 44 N 95% CI [29-59 N]	The anchor greatly increases retention strength and durability

Results:

- Magnet with attachment has a mean breakaway force of 44N
- Magnet without attachment has a breakaway force of <13 N
- The magnet with anchor stayed in the ear for all of the fatigue testing
- The magnet without the attachment came out of the silicone after 4 tries

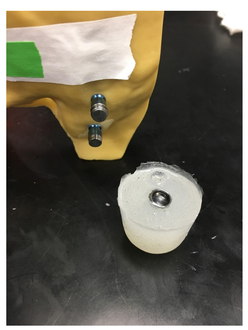

Figure 13: Silicone prototype and abutment used for fatigue testing

Figure 14: Silicone prototype undergoing testing in the MTS machine

Conclusions

- Polycarbonate anchors are effective in preventing auricular magnets from stripping out of silicone prostheses
- Compression molding is an effective method to create thin anchors around auricular magnets
- It is unsure whether the anchor is inconspicuous inside silicone ears

Future Work

- Use high flow material to optimize molding process
- Fabricate molds for differently sized magnets
- Perform mechanical testing on magnets with silicone primer and compare to acquired data
- Test how inconspicuous the anchor makes the magnet in a prosthetic ear

Acknowledgements

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References

1. Luquetti DV, Leoncini E, Mastroiacovo P. Microtia-Anotia: A Global Review of Prevalence Rates. *Birth Defects Research Part A, Clinical and Molecular Teratology*. 2011;91(9):813-822. doi:10.1002/bdra.20836.
2. Greg Gion, C. (2017). *Home - Medical Art Prosthetics*. [online] Medical Art Prosthetics. Available at: http://www.medicalartprosthetics.com/?gclid=CMXw8qjp2tYCFQW5wAod-XYG_A [Accessed 5 Oct. 2017].