

# **Ergonomic Prosthetic Ear Attachment Product Design Specifications**

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## **Problem Statement**

Greg Gion of Medical Art Prosthetics is looking for a new attachment method for auricular prostheses. A new attachment method is desired because the current bar-clip method and the magnet-abutment method are either too strong or too weak, respectively. These methods compromise the effectiveness of the prosthetic ear to mask the patient's deformity and they make the patient more prone to injury by damaging the underlying bone or tissue. Last semester the team designed and fabricated an attachment piece to be imbedded in a silicone auricular prosthesis. This attachment fits the client's needs only in ideal cases. The objective this semester is to modify the attachment method that was created last semester so that it works in almost all cases and to talk with companies to learn the possibility of manufacturing the device for market use.

## **Client Specifications**

Prosthesis should resist unintentional dislodgement

Must be low profile

Must be contained within the prosthesis

Able to withstand considerable anterior and posterior force – approximately 5 lbs

Adaptable /scalable to current abutment sizes – 4.4 mm diameter

Should require minimal effort to remove and attach prosthesis

Should apply to a variety of abutment orientations and head topographies

## **Design Requirements**

1. Physical and Operational Characteristics
  - a. Performance Requirements
    - i. Ear should stay in position throughout daily activities
    - ii. Withstand force in the posterior/anterior direction without unintentional dislodgement
  - b. Safety
    - i. Will not cause harm to compromised bone structure or remaining soft tissue when subjected to force
    - ii. Attachment should break before the bone or surgical implant is damaged
    - iii. Should be easy to clean to prevent infections
  - c. Accuracy and Reliability
    - i. Must fit previous abutment sizes (4.4 mm diameter) or be scalable to them
    - ii. Must not fail due to aging of components over the life span of the prosthesis itself
  - d. Life in Service
    - i. Approximately 3 years
    - ii. Materials should be able to withstand daily cleaning
  - e. Operating Environment
    - i. Rust and weather-proof
  - f. Ergonomics
    - i. Attachment and removal should require minimal effort
    - ii. Components should be easy to clean
  - g. Size

- i. Attachments should fit the current abutments
    - ii. Mechanism should fit within prosthesis
  - h. Weight
    - i. Device weight should not cause discomfort for user
    - ii. Patient should not feel any difference of weight due to new design (no more than 10% added weight)
  - i. Materials
    - i. Preferably composed of titanium, stainless steel
    - ii. Compatible with silicone and the body
  - j. Aesthetics
    - i. Should not be visible when attached
- 2. Production Characteristics
  - a. Quantity
    - i. One prototype
  - b. Target Product Costs
    - i. Preferably under \$500 although budget is flexible
- 3. Miscellaneous
  - a. Standards and Specifications
    - i. Materials used must be FDA approved
  - b. Customer
    - i. Should be available for patients regardless of age or ear size
  - c. Patient-related concerns
    - i. Ease of attachment and removal for users
    - ii. Cleaning process be simple
  - d. Competition
    - i. Various methods exist, but none completely satisfy the client's demands
    - ii. Existing methods include the bar-clip, magnetic, and snap-on
    - iii. No patents for this application could be found