

Ear Prosthesis Attachment Mechanism Product Design Specification (PDS)

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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