Ergonomic Prosthetic Ear Attachment Product Design Specifications

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Problem Statement

During the previous two semesters, the team designed and fabricated an attachment piece to be imbedded in a silicone auricular prosthesis. Last semester, the attachment and cap were modified and fabricated on a large scale. This attachment system fits the client's needs, but perfecting the device is required. The initial need for a new attachment method was required because the current bar and clip method and the magnet-abutment method were too strong and too weak, respectively. These methods are disadvantages because they can 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. The objective is to fabricate the attachment system (cap and attachment) at the actual size level to further test and improve upon the effectiveness of the attachment method.

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 7 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