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Facial Prosthetic Longevity Chamber

Abstract

The purpose of this project is to develop a storage chamber for facial prosthetics, with security and antimicrobial function, to help protect and disinfect prosthetics. The chamber will be used by both patients, to store their facial prosthetic when not in use, and by anaplastologists, to ship the prosthetics. We developed three designs to stabilize the prosthetic. Chamber construction consists of a polycarbonate, air-tight case and employs a Velcro attachment system. Our research indicates that silver ions can be easily used to sanitize both the chamber and the prosthetic. In the future, we hope to further construct our chosen design and begin testing its capabilities.

Problem Statement

Currently, silicone facial prostheses are removed at night, cleaned and stored in makeshift containers. Sometimes they are damaged by children or pets, inadvertently discarded in hospitals or if mailed or transported glued surfaces or delicate elements such as eyelashes become disturbed from tumbling because they are somewhat difficult to secure. Anaplastologists often spend considerable time creating methods to suspend the device in a disposable container. A standardized container with modifiable inner element for orbital, nasal, or auricular prosthesis to stabilize and safeguard the prosthesis upon closure and perhaps have an antimicrobial element and/or vacuum environment would be desired by thousands of prosthesis wearers.

Background

Prosthesis

Our client is an anaplastologist; this is a person involved in the production of facial prostheses (see Figure 1). A prosthetic is an artificial replica of a body part which is used as a replacement when someone loses a part from either a disease or an accident. Common prosthetics include auricular, nasal, and orbital replicas. Our client's patients mainly consist of people who have cancer, congenital defects or trauma. According to our client, 50% are cancer related, 25% are congenital and 2 5% are trauma related.

Figure 1. Prosthetic Ear

These life-like body parts do not come cheap. In fact a facial prosthetic can cost a person approximately $3000-$4000, mainly because prostheses are hard to make and each individual one that is produced is unique, as it is designed to only fit the specific users. Despite their high cost, facial prosthesis only last 2-3 years. This is mainly because of the following two factors: the prosthetic's inability to resist growth of fungi and bacteria, and more importantly, its storage (Gion interview).

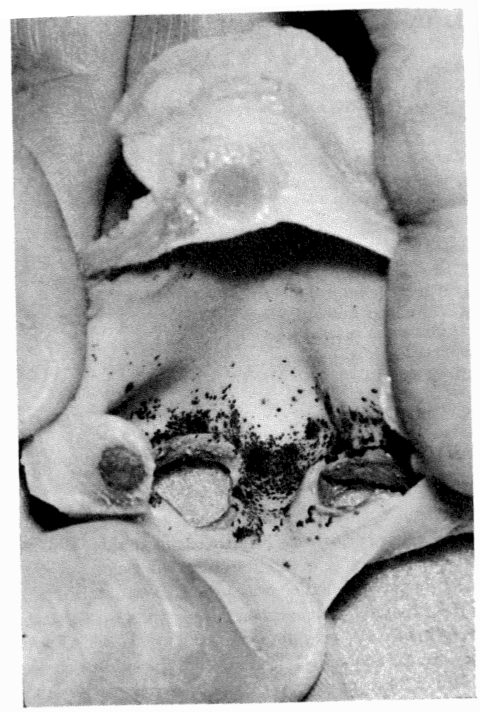

Figure 2. Black spotting from *Candida albicans* fungi on nasal prosthetic

Bacterial and fungal growth on the prosthetic can be attributed to the buildup of moisture on the prosthetic. Since the prosthetic is used by the person throughout the day, moisture from the person's skin builds up on the inside surface which gives the pathogens a suitable environment to grow on. Current cleaning methods are sufficient enough to get rid of most fungi and bacteria (see appendix A). However, one strain of fungus called *Candida albicans* has been shown to be quite resistant and is known to frequently grow on inner layers of prosthesis if they are not regularly cleaned (Pigno 297-302). The problem *with Candida albicans* is that once it forms on the prosthetic, it embeds itself into the silicone rubber of the prosthetic where it leaves black spots (see Figure 2). Once this occurs, the prosthetic can no longer be used.

Storage is a large limiting factor to the life span of a prosthetic because currently there is no standard container in which it is stored in. Instead they are stored in makeshift containers or boxes, which offer the prosthetic very little protection. This leads to the prosthetic being easily damaged, as prostheses are not stable in the container and have delicate parts which can be damaged if the box is accidently dropped or mishandled during shipment. Also, prostheses need to be protected from sunlight because UV light is known to decolorize and degrade prosthetic silicone.

Problem Motivation

Anaplastologists, like our client, have been incessantly trying to produce a container which can stabilize and store a prosthetic. Unfortunately, their efforts have yet to produce a standard container for this purpose. Today, they are stored in different kinds of common household containers, which crush very easily, and have nothing inside that can give the stabilization and support a prosthetic requires. Also, the prosthetic is vulnerable to different kinds of bacteria and fungi inside these temporary containers. Our goal is to create a standardized chamber that can store a variety of prosthesis of different types and sizes. This is because our client creates various shapes and sizes of prostheses.

This chamber should provide complete stabilization to the prosthetic and provide enough support from the bottom so that it does not become damaged during storage. The chamber should also restrict any motion of the prosthetic during a patient's day-to-day lifestyle. Yet, it should also be light and easy to carry. Additionally, it should have an antimicrobial element inside the chamber which can reduce, if not eliminate, the chance of the prosthetic from getting infected by any type of bacteria or fungi. This would complete our chamber and provide an effective defense against any sort of damage the prosthetic may incur.

Existing Models

Currently, there are no adequate means of storing and caring for facial prostheses. These poor storage methods can greatly reduce the life expectancy of costly silicone rubber prostheses. Delicate parts may be damaged beyond repair, intricate painting can be ruined, and fungal growth can leave silicone rubber prosthetics unusable. The existing storage models do not reflect the value of their contents nor offer enough stability to the prosthetic inside. This poses a large problem to our client seeing as he has no way to protect these detailed custom made works of art.

Existing models do not reflect the value and time that goes into creating these one of a kind prosthetics. Our client gives his patients a simple cardboard box that is padded with tissue paper. This provides minimal protection during shipping and only absorbs some moisture off the prosthetic after routine cleaning. The cardboard box can be lost or damaged easily if not carefully looked after. Other patients use a variety of means to store their prosthetics ranging from small trinket containers to old Sudafed boxes (Gion interview).

No commercial products are available for silicone rubber prosthetic storage. Another prosthetic company based out of Milwaukee WI, Medical Arts Resources, offers plastic orthodontic retainer cases to their patients (M.A.R. interview). Also, a hearing aid chamber, known as the Dry and Store® Pro, is in production. This chamber uses silica beads to absorb moisture and a warm air circulator to dry electronic components overnight. The device also uses a germicidal UV light exposure to kill bacteria (Freestreetonline).

Client Specifications

While designing a new facial prosthetic chamber certain client requirements will be met in order to maximize the efficiency and efficacy of this project (see appendix B for Product Design Specification).

1. **Aesthetics:** The chamber should reflect the value of the prosthetic while being attractive to a range of patients.

Our client would like a chamber that reflects the $3,000-4,000 price tag that these prosthetics carry (Gion interview). The chamber should be a neutral color and possibly textured in appearance to reduce the visibility of nicks and scratches.

2. **Variety of Prosthetics:** The chamber should accommodate different models of facial prosthetics.

   Our client designs auricular, nasal, and orbital prosthetics so the chamber should be standardized to fit any version a patient may have. A 4”x4”x4” container would be able to hold roughly 75% of his products (Gion interview).

3. **Reproduced Easily:** Our client must be able to reproduce the chamber with little technical know-how and relative ease.

   If possible the chamber should be made of pre-assembled and orderable parts. The reproduction of the chamber should not be time consuming, since our client sees 40-50 new patients a year (Gion interview)

4. **Safeguard and Stabilization:** The prosthetic should be stabilized to prevent any damage that may result either during everyday storage or shipping.

   Our client wants the case to support and stabilize the prosthetic to minimize the likelihood that delicate parts such as eyelashes or thin edges are damaged.

5. **Antimicrobial Element:** The chamber should include a form of antimicrobial protection.

To cut back on fungal growth the chamber should be fitted with some sort of antifungal agent that will reduce moisture in the environment or limit fungal growth.

Chamber Construction

The basic foundation of our chamber will remain constant through the design process. The material that the chamber is constructed from as well as how the prosthetic will be stabilized from the top will be the same regardless of which design option is chosen. Also, some additional aesthetic aspects will be the same in each design.

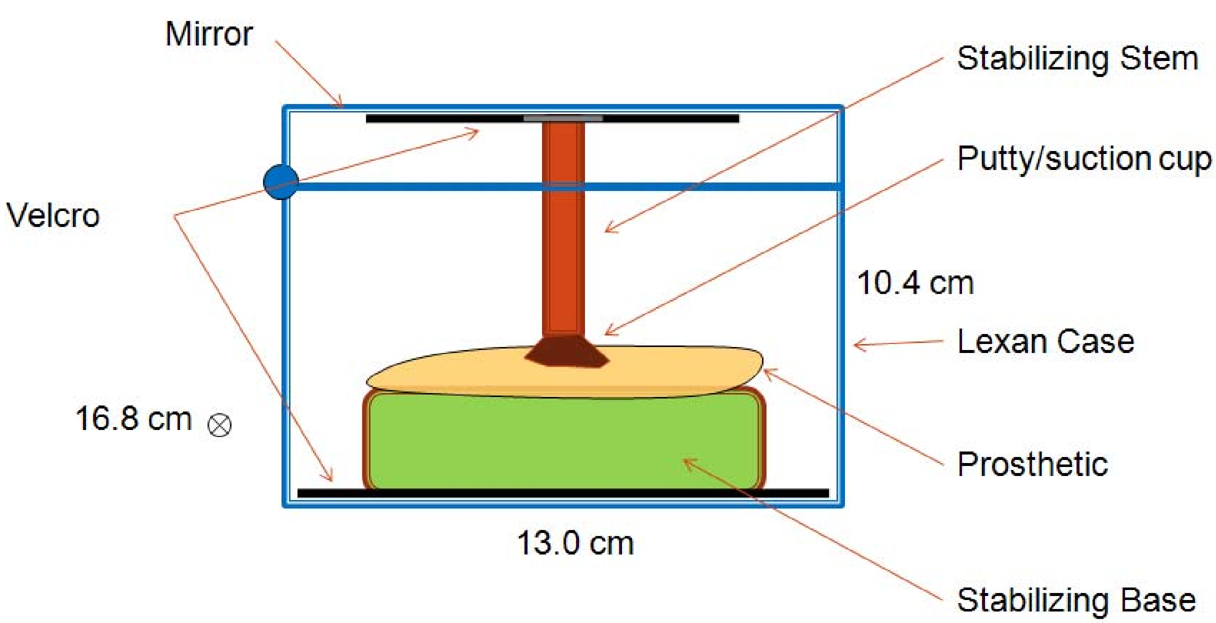

Figure 3. Schematic of chamber construction including component labels

A clear Lexan case that can be purchased at GSI Outdoors Co. will house the prosthetic. Lexan was originally designed by and manufactured by GE. It is an extremely strong polycarbonate that is abrasion resistant and UV resistant. It remains stable at a wide range of temperatures and is as clear as glass (Lexan),(Modern Plastics). Lexan, like all polycarbonates can be painted easily with many commercially available paints. For our chamber, the Lexan case will be painted from the inside reduce paint chipping.

The top stabilizer stem of our chamber will be made from three parts. A Velcro backing which will allow a custom fit to the top of the case, a plastic shaft, and either a soft putty mold or suction cup to fit the top of the prosthetic (see Figure 3). The Velcro backing will allow a custom placement in the chamber each time, making it very user friendly and let our client customize each box easily. The soft putty will be will be molded to a contour on the top of the auricular or nasal prosthetic. The suction cup will be used with orbital prosthetics to avoid damaging delicate eyelash pieces. This apparatus will hold the prosthetic firmly to some type of base.

If the Lexan is transparent enough, a mirror will be attached to the lid, facing outward. This will allow the patient to easily adjust their prosthetic thus adding value to the chamber.

Proposed Designs

To meet the client specifications and resolve the stabilization problem, we have developed the following designs:

1. Vacuum Forming

To create a base for the prosthetic, the first priority was stabilization. We needed a base that would keep the prosthetic from being damaged during storage. Our first instinct was to make a base that recreated the contours of the patient's face, since this is the shape the prosthetic is naturally sitting on while in use. Vacuum forming is one way to do this. Our client currently creates a plaster cast of his patients face. This allows him to create the prosthetic to fit on the part of the face his patient needs. The process starts by applying a soft, moldable putty to the patients face. This is then removed and allowed to harden; the client pours a plaster mixture into the mold and allows the plaster to dry and harden. After removing the plaster, the client now has a cast of this patients face (Gion interview). The shape of this cast is the same shape that we wish to make the base of our design;

unfortunately the plaster is not durable enough to simply employ our clients cast into the design. Therefore, vacuum molding offers us a means to recreate this cast.

The process starts out with a simple machine (see Figure 4) that can be made from common, relatively inexpensive parts found at Home Depot. First, a thin sheet of thermoplastic, such as high impact polystyrene (HPIS) or acrylic, is heated to a malleable state (see Figure 5). The plaster cast would be set onto the platform, which has air holes drilled through it. Once in place, the heated thermoplastic is set over the cast and platform. A vacuum is then applied to the system and draws air out through the holes in the platform. This negative pressure pulls the plastic down and around the cast, allowing the contours to come through (Throne). After allowing the plastic to cool and harden, it can be removed from the platform and cut to fit into the bottom of our chamber. The user would need to clean the surface of the mold periodically as dirt and contaminates accumulate; we suggest soapy water.

Figure 4. Vacuum molding machine

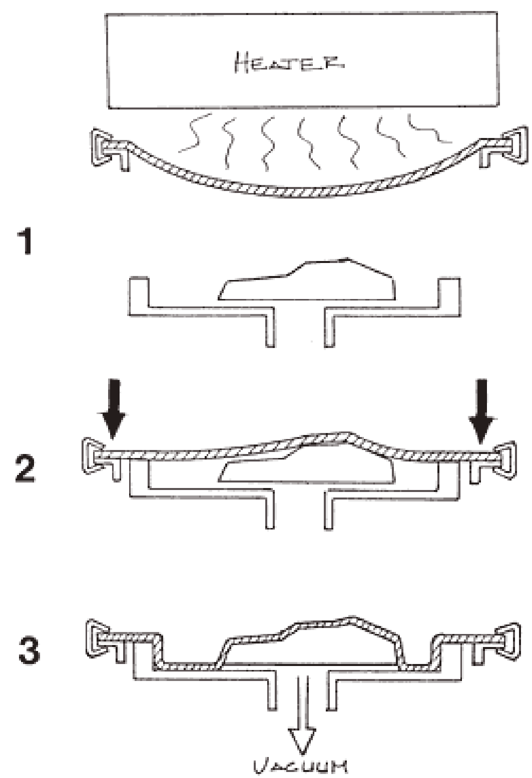

Figure 5. Side view of vacuum forming process

2. Impression Molding

To create a contoured surface for the prosthetic to sit on, we looked at using an impression mold material for this design. Using a type of silicone called vinyl polysiloxane, we can make an impression of the back of the prosthetic. This impression would be used as the stabilizing base in our chamber. This silicone material is the same impression material used by dentists to create molds of a person's teeth (see Figure 6). The manufacture is Sultan Healthcare and the silicone is a two part mixture that cures in 2 minutes 10 seconds (Sultan Healthcare). In this design we would mix the silicone together in a shallow dish that was similar in dimensions to the prosthetic being molded. The prosthetic would quickly be pushed into the mixture and held there while the silicone cured. After the cure time, the prosthetic would be removed and attached to the bottom of our chamber. This design would create a contoured surface from the prosthesis, not the face. Like the vacuum mold, the user would need to clean the surface of the mold periodically as dirt and contaminates accumulate; we suggest soapy water

Figure 6. Dental impression mold using vinyl polysiloxane

3. Polyurethane Foam

Our third design incorporates the use of polyurethane foam to stabilize the prosthetic within our chamber. This foam material is very common and inexpensive. It is used in a wide variety of consumer products, including furniture, insulation, shoes, and packing material. The foam can be produced to have preferred stiffness and density. This design would use a foam with approximately the same properties as a foam pillow (see Figure 7). A cube of foam would be cut to size according to the prosthetic size. The foam would be attached to the bottom of our chamber. The user would then place the prosthetic on the foam and close the lid. The stabilizing stem (see Figure 3) would push the prosthetic gently into the foam. The foam would contour to the back surface of the prosthetic. While in the chamber, the foam would absorb any

Figure 7. Example of common polyurethane foam

excess moisture from it, due to its porous nature. This design would require the user to replace the foam periodically. Since the foam is absorbing moisture and has a large surface area, it creates a good harboring medium for bacteria and fungi to grow in. We estimate replacement to be needed every 2-3 weeks or as seen fit (Kao interview). This disposal method wouldn't require the user to clean the base, as the first two designs did.

Design Selection

Design Alternatives: Stabilization Method

To evaluate which of these three designs would best meet the needs of the client, a design matrix (see Table 1) was created to evaluate each design. The three designs were graded on five different criteria to determine the best design for the base. The five criteria were cost, reproducibility, user-friendly, durability, and stabilization. Each criterion was assigned a weight based on its importance for the design. Then each design was given a rating of 1-10 for each criterion. These ratings were multiplied by the weight and summed together to give the total rating for that design

One of the most important criterions for the designs was the stabilization of the base. This is the most important characteristic that the client needs for the chamber. It is critical that the base is able to stabilize the prosthetic and reduce movement of it with everyday use and shipping to reduce the damage. This will help to increase the lifespan of the prosthetic. This is why the stabilization was rated as one of the highest at 0.25.

A first criterion was the cost of the base. This was weighted low at 0.05 out of a total of a 1 point scale because it is of small concern to the client. This is mainly due to high cost of a prosthetic. The chamber will be a small percentage of the cost of a prosthetic while its benefit is substantial. The prosthetics lifespan will increase making it less often the patient will have to buy a new, expensive prosthetic. The third criterion was the reproducibility. This is the ease that the client would be able to create a chamber for all of his patients. This was rated high at a 0.2 because the client needs to be able to reproduce the chamber easily for his 40-50 new customers each year. The fourth criterion was how user-friendly the chamber is for patients. This was weighted as one of the highest at a 0.25. This is because the patient should be able to easily place or remove the prosthetic on a daily basis. The fifth criterion was durability. This was weighted high at 0.2 because the chamber must be able to last as long as the prosthetic. This means that the chamber needs to be able to function for at least 5 years.

Design Option	**Cost** **(0.05)**	**Reproducibility** **(0.2)**	**User –Friendly** **(0.25)**	**Durability** **(0.2)**	**Stabilization** **(0.25)**	**Total**
Vacuum Form	**9** *.45*	**6** *1.2*	**7** *1.75*	**6** *1.2*	**6** *1.5*	**6.1**
Impression Mold	**7** *.35*	**5** *1.0*	**4** *1.0*	**8** *1.6*	**9** *2.25*	**6.2**
Polyurethane Foam	**5** *.25*	**9** *1.8*	**9** *2.25*	**7** *1.4*	**8** *2.0*	**7.70**

Table 1. Design matrix for evaluating base of chamber

The vacuum forming was the design that scored the lowest. This is mainly due to low ratings in reproducibility, stabilization and durability. It received a low rating in reproducibility because the client would have to create a second mold for each prosthetic. This would create extra work for the client. When the second mold is created using the vacuum form, it is common that it doesn't create a perfect mold of original mold. This will cause problems with the stabilization because the prosthetic might not lay uniform on the mold. This decreased the rating that the vacuum mold received in stabilization. This design was also rated low in durability because the mold can be broken if mishandled. However, the design did rate high in cost because all that is required is a sheet of polystyrene and the vacuum mold frame.

The second design graded was the impression mold base. This design received high ratings in stabilization and durability. Since the mold is a perfect fit of the prosthetic, they will be able to give enough support on the top and bottom of the prosthetic so there is no movement. However, because the mold is a perfect fit to the prosthetic it can be difficult for a patient to place the prosthetic back on the molds. This can be increasingly difficult for elderly patients that have low dexterity. The mold is relatively hard after it is set so durability of the mold lasting the life of the prosthetic is not a concern. Another concern with the mold is the reproducibility. It could be difficult for the client to form the mold perfectly around the prosthetic. Additionally, the molds would have to be place in a certain formation in the chamber for each prosthetic so that the top and bottom mold fit into the correct positions in the prosthetic.

The final design that was graded was the polyurethane foam. This design received on average the highest marks in all the categories. The only criterion that it received a low rate in was the cost. This is because the patient would have to buy enough foam so that it could be replaced on a regular basis. The foam received very high marks in both the user friendliness and the reproducibility. All that is required to reproduce the chamber is a supply of foam that would be placed on the bottom of the chamber and the stem to provide stabilization on the top. For user friendliness, this design received the highest rating of all three designs. This is because all the patients have to do is put the prosthetic on top of the foam in the chamber and close the top to secure the top of the prosthetic. This also makes it more likely the patient will use the chamber if there is less work required for them to store their prosthetic. The design also received a high mark in stabilization since the prosthetic is supported by the flexible foam on the bottom and the stem on the top. The flexible foam allows the use of all different kinds of prosthetics in the chamber. The durability was rated a little lower because the foam would have to be replaced on a regular basis. As it can be seen, the polyurethane foam ended up with the highest rating due to it being very easily reproduced and user friendliness for the patients.

Design Alternatives: Antimicrobial Element

The main objective of this project is to develop and design a chamber that can stabilize prosthetics so less damage occurs. However, the client expressed that a secondary objective could be to develop an antimicrobial element to prevent growth of fungi on the prosthetic. Through research, many antimicrobial elements were discovered that are effective in killing different fungi. However, the only two ideas that were usable are silica beads and silver spray. Other ideas were not usable based on damage that could be done to the prosthetic and the client's preference not to use them.

Silver Spray

Silver is a method of antimicrobial that is well understood in its ability to kill bacteria (Kao Interview). Silver ions have are known to kill all medically-relevant strains of bacteria, fungi, and viruses and killing 99.999% of organism in those strains. It is able to kill all strains by attacking up to ten sites in a cell which stop reproduction or cause death of bacteria (Silver Sanitizer). Silver is widely used by doctors, surgeons, and wound care specialists to kill bacteria on medical devices. In small concentrations of 0.001 ppm, the spray is nontoxic to human's cells and very safe (see Figure 8). This is the concretion of most sprays so that is safe to use. The silver also continues to disinfect after application. The silver would be applied to the base of prosthetic before placing in the chamber. This method would help complete a care method that is currently used by the client's patients to clean the prosthetic.

Figure 8. Silver ion spray used to sanitize surfaces

Silica Beads

Silica beads could also be used as an antimicrobial method because of their absorption of moisture properties. Silica is a harmless product made of silicon dioxide. It contains millions of tiny pores that can absorb and hold moisture. When in a moist environment, silica beads can absorb 40% of its weight in moisture and reduced the relative moisture in a closed container to 40% ("What is…"). It is a desiccant that is used in protection of dry atmosphere in pharmaceutical, engineering, and food packaging (Desiccant). It can also be restored so it can be used again by heating it above 300° F ("What is…"). This silica would be placed in the chamber in bags to help confine it for consideration of the patient carrying the chamber. Since fungi are grown on prosthetics due to moisture build up, silica beads would help reduce this growth by taking moisture out of the chamber.

Design Evaluation of Antimicrobial Element

To determine whether silver spray or silica beads are a better antimicrobial element, a design matrix (see Table 2) was formed just like the matrix for the base. The process stayed the same but two categories were changed. Durability was replaced by longevity and stabilization was replaced by sterilization. All rankings stayed the same except for sterilization because it is critical that the element is able to kill fungi growing to prevent decrease in lifespan of the prosthetic.

Design Option	Cost (0.05)	Reproducibility (0.2)	User –Friendly (0.2)	Longevity (0.2)	Sterilization (0.35)	Total
Silica Beads	**8** ***.4***	**8** ***1.6***	**7** ***1.4***	**6** ***1.2***	**5** ***1.75***	**6.35**
Silver Ion Spray	**7** ***.35***	**7** ***1.4***	**9** ***1.8***	**7** ***1.4***	**9** ***3.15***	**8.1**

Table 2. Design matrix to determine best antimicrobial element

Silica beads were the antimicrobial element that ended up getting the lower rating out of the two. It rated pretty similar to the silver spray in cost, reproducibility, and longevity.

However, it received low ratings in user-friendly, and sterilization. The low rating in user-friendly is because the beads can become full of moisture and need to be heat at 300°F to get rid of the moisture. This adds to the amount of work the patients is required to do which could possibly deter them from using the method. For the low rating in sterilization, the beads will reduce the moisture which is one of the main causes in fungi growth. However, they are not able to kill any fungi that have grown on the prosthetic that may have accumulated while the patient is using it.

The silver ion spray was the design that got the highest rating. Again, it was very similar to the silica beads in cost, reproducibility, and longevity but received high ratings in sterilization and user friendly. It received such a high rating in user-friendly because the patient is required to follow the same procedure by the client and also spray the base or the prosthetic will the silver spray. This will also encourage the patient to use this method of antimicrobial because it is only one step added onto the process they already do. The spray also received a high mark in sterilization. This is important because it is able to kill many different species of fungi on the prosthetic. So the silver spray is currently the best option for being used as an antimicrobial element.

It is possible that the antimicrobial element could include both the silver spray and the silica beads. The two elements have different advantages to them that can both benefit the prosthetic. The silica beads would be used to reduce the moisture while the spray would be used to kill any fungi that are present on the prosthetic.

Future Work

For the rest of the semester, the concentration is going to be placed on constructing the chamber and base. Also it's important that we perform a few tests to ensure the chamber is in working order. First, we need to determine how the Lexan box is going to be used with the polyurethane foam. The size and thickness of the foam needs to be determined to provide the best stabilization. The top stem to provide support on the top of the prosthetic also has to be determined how that will be situated in the box. Once the chamber is constructed, stabilization tests will be performed to ensure no movements or damage is done to the prosthetics.

Testing the silver spray for its antimicrobial effects is another important test that needs to be done by the end of the semester. It is important that the spray will in fact kill the *Candida albicans* that grows on prosthetics. The testing that could be done is getting a prosthetic that has fungus on it already but has not embedded in the silicon. The prosthetic could be sprayed once a day and stored in the chamber to see if the fungi are killed after a specified period of time.

Conclusion

In conclusion, we have selected a basic design for a foam stabilized chamber that will keep the prosthetic sanitary and stable, and reflect the value of prosthetic. Although several problems remain unresolved, we hope that by the end of this semester, we will have a functional chamber for our client to reproduce.

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Appendices

Appendix A: Prosthesis Care Instruction

2-PIECE ORBITAL PROSTHESIS CARE INSTRUCTION

- Wash the silicone insert with warm, soapy water. Lather it thoroughly in your hands, then rinse and dry completely. The insert can also be wiped with a gauze ad or cotton ball moistened in Listerine to act as an antiseptic.

- For the orbital prosthesis, use extra care when handling and cleaning, especially the painted surface. A soapy cotton swab can be used to loosen and lift dirt and oil from the surface. It is preferred that you rinse and dry without disturbing the artificial eyelashes to prevent eyelash deterioration. A cotton swab soaked in isopropyl alcohol should also be used occasionally to remove any oily residue from the surfaces.

- You should also remove the acrylic eye once or twice a month for cleaning. The recessed areas should be cleaned and dried carefully and swabbed with Listerine to disinfect. The eye should be soaped well, rinsed and buffed with a soft cloth. To aid in replacing the eyepiece, you may want to lubricate the lid opening and /or the eye with a film of liquid soap. This will help it to slip into place easier with less stress on the silicone and lashes.

- **DO NOT** store prosthesis wet or in moist environment.

- **DO NOT** store prosthesis in airtight container.

- **DO NOT** allow alcohol to seep around the eyepiece or be in constant contact with the eyepiece.

- **DO NOT** bend or fuss with the eyelashes excessively.

- **DO NOT** pull at thin margins to remove prosthesis.

Appendix B: Product Design Specifications (PDS)

The Product Design Specifications (10/22/08)

Facial Prosthetic Longevity Chamber

Team Members: Ozair Chaudhry, Evan Joyce, Adam Goon, Kenny Roggow

Function:

Currently, silicone facial prostheses are removed at night, cleaned and stored in makeshift containers such as gift boxes, travel soap containers, etc. Sometimes they are damaged by children or pets, inadvertently discarded in hospitals or if mailed or transported glued surfaces or delicate elements such as eyelashes become disturbed from tumbling because they are somewhat difficult to secure. Anaplastologists often spend considerable time creating methods to suspend the device in a disposable container. A standardized container with modifiable inner element for orbital, nasal, or auricular prosthesis to stabilize and safeguard the prosthesis upon closure and perhaps have an antimicrobial element and/or vacuum environment would be desired by thousands of prosthesis wearers.

Client Requirements:

- **Aesthetics:** The chamber should reflect the value of the prosthetic while being attractive to a range of patients.
- **Variety of Prosthetics:** The chamber should accommodate different models of facial prosthetics.
- **Reproduced Easily:** Our client must be able to reproduce the chamber with little technical know-how and relative ease.
- **Safeguard and Stabilization:** The prosthetic should be stabilized to prevent any damage that may result either during everyday storage or shipping.
- **Antimicrobial Element:** The chamber should include a form of antimicrobial protection.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements:*

The chamber must be able to secure the prosthetic so that it is not disturbed when the chamber is being carried. It must be able to withstand shipping and everyday use including removing and placing the prosthetic inside.

b. *Safety:*
The antimicrobial effect of the chamber must not harm the user. Also the chamber should not be able to cause any damage to the prosthetic or user when they are removing or inserting the prosthetic.

c. *Accuracy and Reliability:*
The chamber must hold the prosthetic in the same orientation during its entire use.

d. *Life in Service:*
The chamber must be durable enough to be used every day and also be able to hold a prosthetic for long storage if needed while keeping it clean and undamaged. The chamber should last at a minimum the life of the prosthetic (3 years).

e. Shelf Life:
The chamber should not be damaged while be carried or shipped and should not degrade while being stored (>3 years).

f. *Operating Environment:*
Temperature: Must be able to function optimally at room temperature (20 - 30 °C). It should be able to withstand warm temperatures of up to 60°C and cold temperatures as low as -30 °C. Sunlight: Must be able to withstand U.V rays from sunlight. Humidity: Must be able to resist build up of humidity inside the chamber. Dirt or Dust: May accumulate dirt or dust on the outside but should not collect inside the chamber. Corrosions from fluid/handling: Must not react with hydrophilic cleansing agents such as alcohol or water or hydrophobic (silicon) adhesive glue. It should be used to frequent handling .Operators: The box/container will be used by prosthetic products consumers. Durability: Must be unbreakable if dropped accidently on hard surfaces. Life-Span: Must last at least 4 years.

g. Ergonomics:
It should not cause harm to the operator's fingers when placing prosthetic in box/container. The operator should be able to place and remove prosthetic with ease.

h. *Size:*

The interior of the container should at least 4”x4”x4”. The box/container for our design is 13.0 cm X 16.8 cm X 10.4 cm.

i. *Weight*:
Weight parameters have not been finalized but the lighter the box, the better. The box/container for our design weighs 14.8 oz.

j. *Materials*:
Box/Container: polycarbonate called Lexan. Stabilizing Base: polyurethane foam. Attachment method: Velcrow.

k. *Aesthetics*, *Appearance, and Finish*:
Final product should be a dark colored box that is not lustrous, such as a matte finish. Should reflect the value of the prosthetic.

2. Production Characteristics

a. *Quantity*
One prototype for use by our client. Further production of additional models will be determined by the client.

b. *Target Product Cost:*
The model should have a production cost of less than $1500.00

3. Miscellaneous

a. *Standards and Specifications:*
Since this product will house a facial prosthesis, FDA approval may be required if manufactured on a large scale. The device needs to be non-toxic, user-friendly, and environmentally safe as well.

b. *Customer*:
The customer would prefer a discrete, small, transportable container to house a facial prosthesis. The container should be small enough so a spare prosthesis can easily be carried and durable enough to prevent any damage to the prosthesis.

c. Patient –related concerns:
The device will need to be cleaned periodically but should have anti-microbial properties to prevent bacteria build-up. The device will need to be built to house its contents securely and prevent any damage.

d. Competition:
The need for this device arose due to lack of a functional facial prosthesis storage chamber. A search of the USPTO’s patent database did not yield any

similar devices with patents. United States Patent 5201411 is for a prosthesis cleaning device; however, our facial prosthesis chamber is designed with storage in mind, not cleaning. Other anaplastologists offices (Medical Art Resources) offer their patients orthodontic retainer cases.