Facial Prosthetic Longevity Chamber

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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 as each takes accounts the various shapes of different kind of facial prosthetics. Chamber construction consists of a polycarbonate, air-tight case and employs a magnetic attachment system. Our designs improved stabilization of the prosthetics. Also, 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.

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Problem Statement

Our client is Greg Gion from the Medical Arts Prothetics Clinic L.L.C. He is an anaplastologist who is a person involved in the production facial prosthetics, 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

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 25% are trauma related.

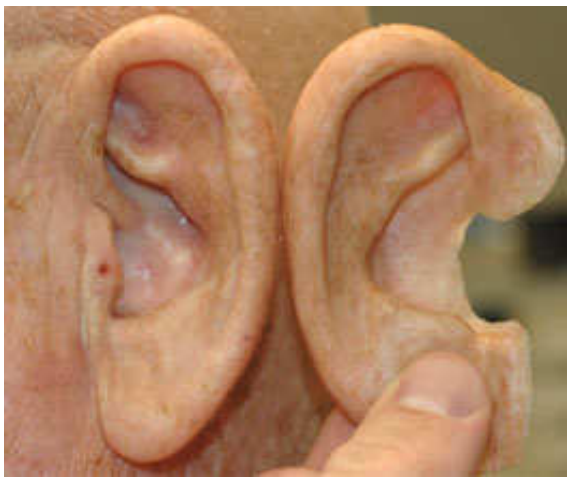


Figure 1. Real ear next to prosthetic ear

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).

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.

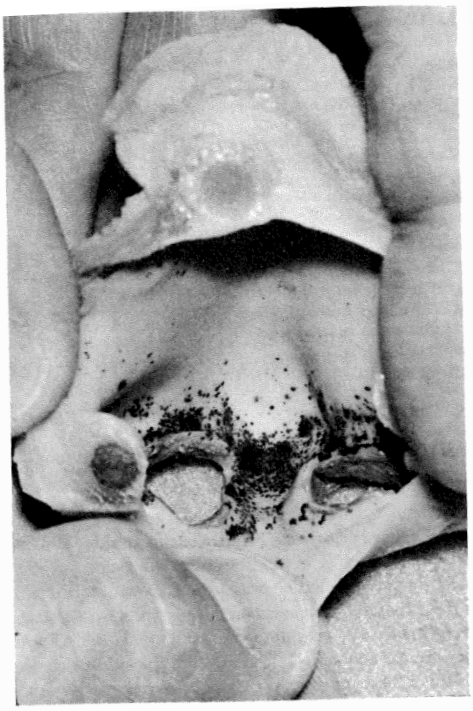


Figure 2. Black spotting from *Candida albicans* fungi on nasal prosthetic

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 rubber.

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.

Competition

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 10 x 10 x 10 cm 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

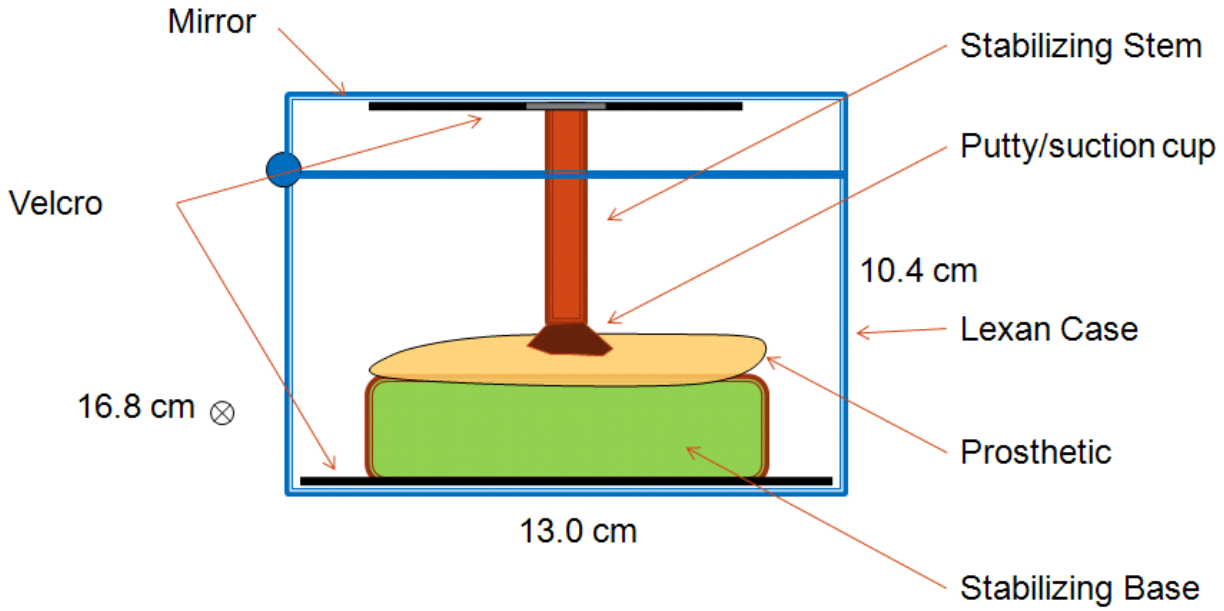


Figure 3. Schematic of chamber construction including component labels

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.

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 to 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 inside of 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 which heats the plastic and vacuum forms it

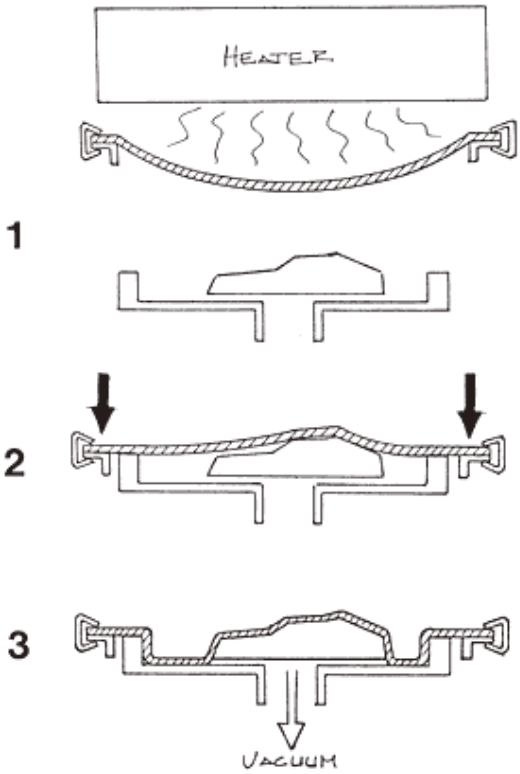


Figure 5. Side view of vacuum forming process where vacuum pulls down heated plastic

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

Figure 7. Example of common polyurethane foam

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 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: Antifungal 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 antifungal element to prevent growth of fungi on the prosthetic. Through research, many antifungal 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 antifungal 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 antifungal 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 their weight in moisture and reduce 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 150 ^{o}C ("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 Antifungal Element

To determine whether silver spray or silica beads are a better antifungal 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

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 antifungal element

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.

Silica beads were the antifungal 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 150 ^{o}C 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 antifungal 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 antifungal element.

It is possible that the antifungal 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.

Final Designs

The final design of the chamber used a combination of two of the design alternatives ideas listed earlier. The two alternatives used were the polyurethane foam and the molding or stabilizing stem. This was done to better accommodate the different characteristics of the three different prosthetics created by the client. So for the final prototype, combinations of the two different alternatives were used to create a different but very similar chamber for each of the three prosthetics. Again this was done to accommodate for different characteristics of the prosthetics like the thin edges of the nose and the flat firmer pieces on the bottom of the ear and eye.

Each design has its differences in the stabilization method but similarities in the chamber each method was used in. Each design used a Lexan polycarbonate plastic as the case (see figure 9). Lexan is a very durable, strong plastic that is nearly indestructible to everyday use which is why it was chosen as the case for the chamber. Another important aspect of Lexan is the fact that it is UV resistant. This is important for the storage of the prosthetics because UV light can damage and discolor the prosthetic. A few other components were added to the chamber for aesthetics and usefulness of the patient. The whole inside of the chamber was painted with black polycarbonate paint so it looks more elegant and the contents of the chamber are hidden from view. An acrylic mirror was also attached to the inside top cover of the case facing out with epoxy so that the patient could use the chamber to easy apply the prosthetic to their face. Two thin sheets of metal were also adhered to the bottom and top of the chamber with epoxy for attachment of the magnetic stabilization system. These sheets were centered on the top and bottom surface for central alignment of the prosthetics. The final similarity for each design was two pieces of the polyurethane foam placed on the top and bottom surface. Two rectangles were also cut out of the foam pieces so that parts of the thin metal sheets were exposed. The foam helps to minimize movement of the magnet stabilization system when the chamber is dropped by preventing sliding of the magnets on the metal sheet.

Figure 9: Lexan case used for chamber

The only differences between each design were the stabilization method used for the prosthetic (see figure 10). There were two different categories that the three different designs were sorted into. The first category was stem-to-foam design where the prosthetic was stabilized in-between a layer foam and a stabilizer stem connected to the top of the chamber. This design was best for use prosthetics with a flat, firm back like the eye and ear

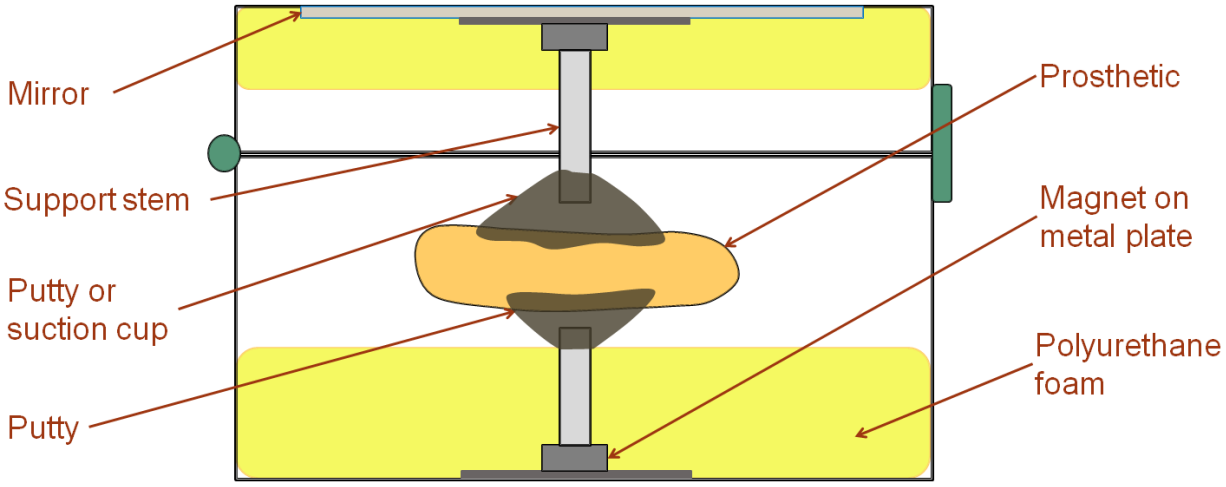


Figure 10: General diagram of chamber that incorporates all three different designs. The top stabilization stem could be putty or suction cup. The bottom stabilization stem is either the putty of polyurethane foam. The diagram also displays similarities for each design int eh mirror, metal plate for stabilization stem attachment.

prosthetic. The second category was a stem-to-stem design where the prosthetic was stabilized in-between two stabilization stems The only design used for this was the nose design because its thin edges cannot be compressed into the foam without damaging the prosthetic. For these two designs another layer of foam was added so that prosthetic would be compressed into it.

There were also two different types of stabilization stems used. They were a suction cup for the eye and a silicone mold for the ear and nose. Both types of stems had neodymium magnets attached to the ends so that they could be used in the magnetic stabilization system and attached to the top and bottom of the chamber. The magnets we chose are have an 8 pound strength which we found to be sufficient, however much stronger magnets can be obtained if needed. The suction cup could be directly attached to the acrylic eye on the eye prosthetic. The silicone putty, made by InstaMold®, consisted of a two part instant silicone mixture. The two parts could be mixed together and formed to shape of the prosthetic and before drying a plastic rod with the magnets attached was placed in the mixture so it would mold into the silicone. When the mixture was dry, it could be removed from the prosthetic and had the consistency of soft, somewhat springy silicone. This mold is would be very easy for the client to form to different prosthetics.

The nose design consisted of two stabilization stems with putty molds on each end. One mold was from the inside of the nose and the other was on the outside tip that went into the nostrils (see figure 11). These two stabilization stems provided support on the top and bottom of the prosthetic. When placing in the chamber, one magnetic stem could be attached to the bottom of the chamber. The lid could then be closed and the top stabilization magnet would attach to the top of the chamber. When completely closed, the top of the chamber would push the mold into the prosthetic so that it was compressed in-between both stems. When the chamber is opened, the prosthetic would stay attached to one of the stems so that it could easily be removed (see figure 11).

Figure 11: Picture of nose design with putty mold stabilization stem

Figure 12: Picture of nose design with putty mold stabilization stem on bottom and nose attached to top stabilization stem.

The eye design fit into the category of stem-to-foam stabilization method. The suction cup was used to attach to the acrylic eye (see figure 13). The suction cup magnetic stem could then be attached to the top metal sheet of the chamber. When the top of the chamber is

closed, the prosthetic is compressed into the foam by the stabilization stem causing it to be stabilized in-between the stabilization stem and the foam.

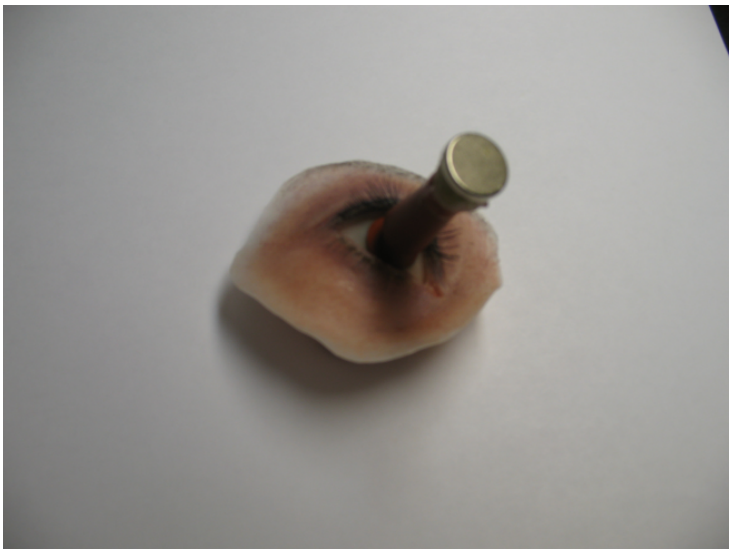


Figure 13: Picture of eye design with eye attached to suction cup stabilization stem on top of chamber.

Figure 14: Picture of eye design with extra layer of foam in bottom of chamber with eye attached to suction cup stabilization stem on top of chamber.

The ear design was similar to the eye design in that it fit into the stem-to-foam stabilization method. However, the ear used the silicone stabilization stem instead of the suction cup. The putty mold was formed into the inner ear cavity (see figure 15). With the putty mold inside the ear, it could attach to the chamber the same way as the eye by attaching it to the metal sheet on the top. When closed, the ear would be compressed in the foam and be stabilized in-between the stabilization stem and the foam.

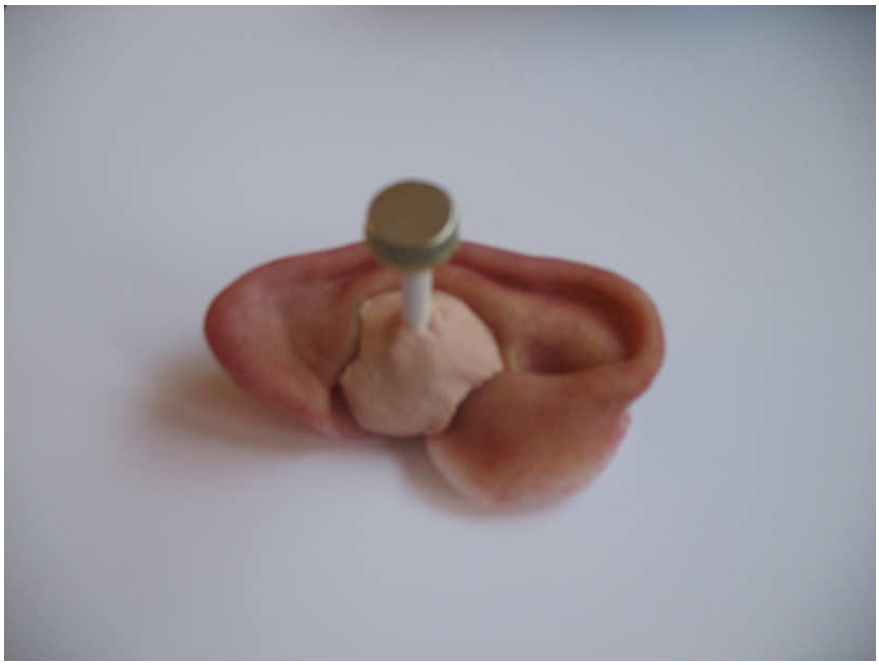


Figure 15: Picture of eye design with extra layer of foam on bottom of chamber with ear attached to putty mold stabilization stem on top of chamber.

Figure 16: Picture of eye design with extra layer of foam on bottom of chamber with ear attached to putty mold stabilization stem on top of chamber.

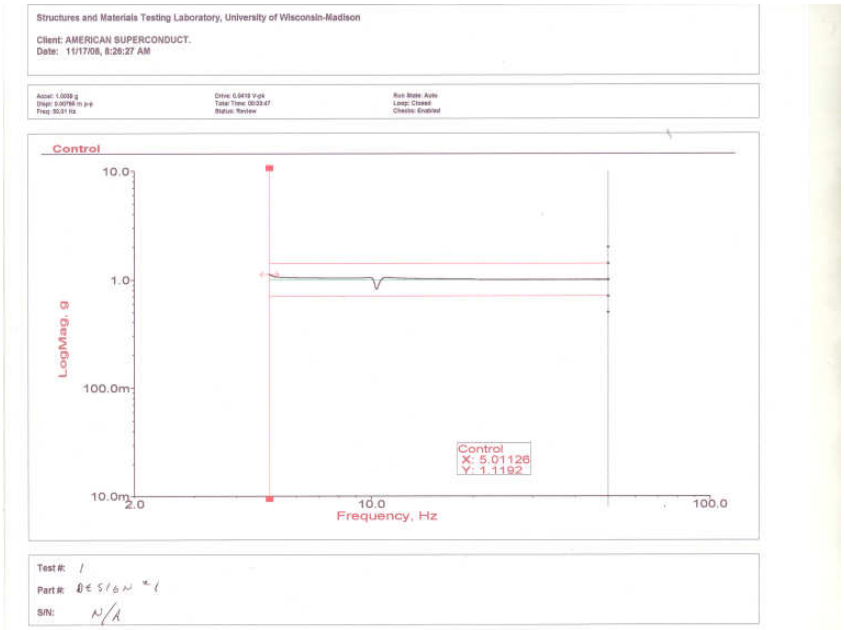
Testing

The primary purpose of the chamber is to stabilize the prosthetic, so to test the effectiveness of our designs we decided to execute two tests: a vibration and a shock test.

Vibration Testing:

The first test we performed was a mock transportation vibration test designed to simulate the same vibrations the chamber would experience during shipping and handling. This is important because our client plans to mail his prosthesis in these chambers to his clients. Working with the UW-Structures and Materials lab, we were able to use a shake-table to execute the test (see Figure 17). A shake table is essentially a giant load speaker. Using a computer based program, the frequency of the vibration surface can be controlled, along with the acceleration. We used a previously created computer test. The lab has had other clients run similar tests, so we used one of the pre-fabricated tests. The complete specifications of our test are found in appendix E. We bolted our chamber to the steel

Figure 17- Shock table used to execute mock transportation vibration testing. Shown is our chamber on top



Graph 1. Shows readings from accelerometer in mock transportation vibration test. The dip in the graph is where the shake table hit its resonant frequencies. The red lines are there as safety thresholds, so the machine doesn't experience dangerous

surface and attached an accelerometer to it. This allows us to measure any external accelerations or vibrations that aren't otherwise applied to the system, such as resonant frequencies. This test ran through a range of frequencies, starting at 5 Hz and ending at 50 Hz, over the duration of 4 minutes. The applied acceleration was kept constant at 1 g (9.81 m/s^2). Graph 1 measured acceleration readings from the accelerometer. Note the dip in the line; this is the resonant frequency of the shake table itself and therefore the accelerometer registered external accelerations. The criterion for our designs to pass this test was that the prosthetic needed to stay within the stabilization system. For the ear model it needed to stay between the putty-stem and the foam, for the nose model, it needed to stay between both putty-stems, and for the eye-model it needed to stay between the suction cup and the foam (and attached to the suction cup). All three designs passed the vibration test.

Shock Testing:

The second test we performed was a classical shock test designed to simulate the dropping of the chamber by its user. This was important because we needed to ensure that the chamber would keep the prosthesis stable even when dropped by the user in everyday life or if it fell from a shelf or table. We chose to drop our chamber from a height of 1 meter onto a concrete floor. This is a common counter-top height and a reasonable height if it fell from the user's hands. Each of the three designs was dropped a total of 20 times, 10 on each of its 2 axes. One axis was vertical and one horizontal, so that it fell on its side and

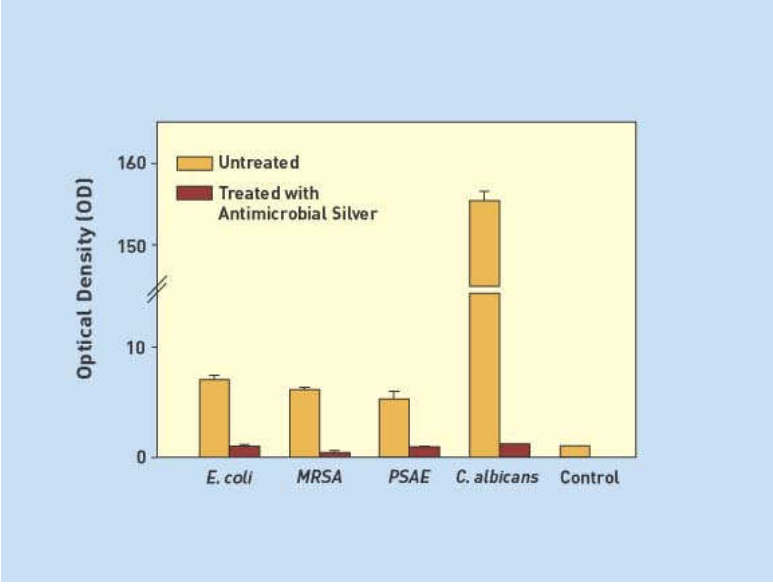
Position of Drop	Horizontal Drop Test		Vertical Drop Test	
	Pass Rate	Drop Count	Pass Rate	Drop Count
Nose Design	100%	10	100%	10
Ear Design	100%	10	100%	10
Eye Design	50%	10	20%	10

Table 3. Results of our shock test. A total of 60 trials were performed between the three designs

botom. Again, the pass criterion was the same as the vibration test; the prosthetic needed to stay within its support system. The results are shown in table 3. If the prosthetic was kept stable in the support, it passed. As you can see our results showed every nose and ear test passed. The eye design had lower pass percentage, mainly because for this design, the suction cup needed to stay stuck to the eye. Often times the eye was found in the same place; however the suction was lost so based on our pass criteria we had to award this situation a fail. We think that with a better suction device, the design could also have a perfect test percentage.

Antifungal testing:

A secondary objective from our client was to include an antifungal element with the chamber. After extensive research from literature and experts, we chose a silver-ion spray to disinfect the prosthetic and chamber called Silver Sanitizer. It has been proven to kill *Candida albicans* (see Graph 1-2) and a wide range of microbes, but we wanted to test this silver spray we chose with actual prosthetics. Unfortunately due to time and budget constraints we were unable to perform any testing, but we did create a test protocol that could easily we performed in another semester. Protocol covers background information, materials and where to obtain them, test procedure, and what the results would signify.



Graph 1-2. Research showing antimicrobial silver is effective at killing C. albicans.

Future Work

A first aspect of future work that would need to be done is testing the antifungal agent Silver Sanitizer. This could be accomplished by following the antifungal protocol that we already wrote out. The protocol overviews the importance of preventing *Candida albicans* on facial prosthetics by explaining why they grow on facial prosthetics as well as how silver is able to kill them. It then describes where each material needed for the test can be ordered online. Lastly the protocol outlines a procedure to test any antiseptic of interest; ours being Silver Sanitizer. Although we found research that proves silver ions are able to kill *C. albicans* we would still like to test the commercial product we obtained to prove its authenticity. We would like to test Silver Sanitizer as well as other antiseptics of interest such as clotrimazole, silica pellets, alcohol based cleaners, and soap and water solutions. Fungal growth could be compared in each situation to show the best method for keeping facial prosthetics free of *C. albicans*.

Another future work possibility is finding a stronger suction cup to use in conjunction with ocular facial prosthetics. A stronger suction cup that would not lose suction on the acrylic eye would vastly improve shock testing on the ocular prosthetics. Other options are available to replace the use of a suction cup however the suction cup is the best option because of two reasons: it will not damage the acrylic eye and it makes prosthetic attachment and removal extremely easy. The new suction cup could be directly implemented into our pre-existing design option for ocular facial prosthetics.

The last future work opportunity is finding both a custom chamber and custom foam manufacturer. By finding both a custom chamber and custom foam manufacturer we are able to help streamline the production of a one-fits-all prosthetic chamber. Currently, we had a custom chamber designed and produced through HP Manufacturing that would cost just over $12 per chamber; the price drops slightly when ordering in bulk (orders of 100). The chamber specifications were decided by our group and it is made of Lexan. HP Manufacturing is able to make this chamber is a variety of sizes as specified by our client.

The custom foam manufacturer would be able to do three things: have the foam precut to specified sizes (as dictated by the chamber size), produce a specific density foam that is soft enough for the prosthetic to be stabilized yet not damaged, and incorporate antifungal properties into the foam such as silver ion particles. The incorporation of antifungal properties in the foam would be dictated by the aforementioned antifungal testing.

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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 (12/12/08)

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 (silicone) 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 10 x 10 x 10 cm. The box/container for our design is 13.0 x 16.8 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 or putty-stem system. Attachment method: magnet and putty.

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. The cost of current prototype is estimated at $23.85

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 nontoxic, 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.

Appendix C: Anti-fungal Testing Protocol

Anti-Fungal Testing Protocol

Overview

Silicone rubber facial prosthetics are difficult to store over long periods of time due to growth of *Candida albicans*. *C. albicans* is a diploid fungus and an agent of opportunistic oral and genital infections in humans (**2**). Although cleaned after each use, facial prosthetics retain significant amounts of moisture leading the growth of spore colonies. Mucus acquired from the face as well as excess moisture from cleaning and improper drying makes the silicone rubber an excellent environment for the growth of fungus. *C. albicans* eventually impregnate into the silicone rubber thus rendering the prosthetic useless. Prosthetic contaminated with *C. albicans* need to be disposed of both due to safety concerns and cosmetic reasons. However, by developing a method to either inhibit or delay the growth of *C. albicans*, prosthetic wearers would be able to have a product that could last significantly longer. A longer lasting prosthetic would save a considerable amount of money since the typical prosthetic cost is upwards of three thousand dollars; sometimes up to ten thousand dollars.

Since the fungal growth environment is ideal after the prosthetic is cleaned and put away to be stored overnight or for some length of time, incorporating an anti-fungal mechanism in the storage chamber would be most suitable. A biofilm is a natural occurring phenomenon referring to bacterial colonies that live in highly organized communities and thus make ordinary bacteria much more pathogenic and dangerous. Studies have shown that silver ion use is an effective way of killing and preventing *C. albicans* biofilms from forming (**9**). Silver will be the focus of this testing protocol because of the considerable amount of research that has been done on it as well as its ease of use. This testing protocol will outline how to set up an anti-fungal test incorporating silver ions however will not actually perform the test due to monetary and time constraints. The purpose of this test is to determine if our source of silver ions (Silver Sanitizer) is an effective means of preventing fungal growth on silicone rubber facial prosthetics. The test may also be performed with an antifungal agent of interest.

Supplies, Retailers, and Cost

1. Silver ion test source: The silver source for the test is a commercially available product that claims a silver ion imbedded cloth will dissociate silver ions when mixed with distilled water (**8**, $30). The website gives detailed statistics on kill times for silver ions and various microorganisms as well as links to peer reviewed studies highlighting the effects of silver ions.

2. Prepared corn meal agar with polysorbate 80 plates or agar powder to prepare plates: Corn meal agar is a general-purpose medium for the cultivation of fungi. With the addition of polysorbate 80, it is utilized primarily for the testing of *Candida* species for their ability to produce chlamydospores (**3**). Corn meal agar with polysorbate 80 can be purchased in prepared ten packs or in powered form (**4**, prepared 10 pack $20.92 plus shipping). Corn meal agar can be purchased at a variety of online retailers in either gel (prepared) or powered (not prepared) form.
3. Live *Candida albicans* cultures: *C. albicans* are considered an infectious disease and can be commercially obtained with proper authentication. Purchasing cultures is expensive and is the major reason that we will not carry out the actual testing (**1**, 96 wells for $335 plus roughly $30 shipping **or 6**, 32 primer sets for $166 plus roughly $30 shipping). Other biological material supply companies exist and *C. albicans* can be purchased through a large number of online retailers.
4. Sterile silicone rubber facial prosthetic: Facial prosthetic obtainable from client. Either a facial prosthetic or a piece of silicone rubber would be autoclaved and used for the anti-fungal testing.
5. Petri dishes: Easily obtainable Petri dishes would be needed only if powdered, not prepared, agar was ordered. A set of 20, 100mm disposable, Petri dishes can be found at numerous websites and retailers (**5**, 20 pack for $5.50 plus shipping).
6. Bunsen burner, distilled water, incubator, autoclave, storage facility, masking tape, wax pencil, bleach, various other laboratory instruments: These tools and items could be obtained and used in the BME research labs. Professor Ogle offered to help plate fungal cultures as well as provide a lab.

**Total cost would be roughly $350.00 when factoring shipping costs at $10 per item listed. In addition to the cost of the supplies, laboratory time as well as help from Professors would need to be factored in. Unfortunately, the main focus of our facial prosthetic chamber is not the anti-fungal aspect so purchasing the supplies becomes unfeasible. Our client, however, could pursue this testing at a further date if desired.

Testing Procedure

First a control experiment must be done so the growth of *C. albicans* after using the Silver spray can be compared. This is done by placing a paper disk treated with an antiseptic known to kill *C. albicans* in the Petri dish. The dish is let rest for several days, and a halo will develop around the paper with no growth of fungus. This is known as the ring of inhibition and varies depending on the antiseptic used. This dish is then used for comparisons against Petri dishes with fungal growth on them.

1. Petri dishes with prepared corn meal agar with polysorbate 80 should be stored upside down in a refrigerator before being used (media in upper part of dish). The upside down storage

prevents the condensation that inevitably forms on the lid from contaminating the medium and thus disturbing the fungus growing surface.

2. When Petri dishes are going to be used, they should be warmed to room temperature; this usually takes about one hour.
3. Sterilized, distilled water also needs to be prepared. This can be done by boiling water and allowing it to cool to room temperature.
4. Antiseptic disks need to be prepared by creating paper disks made of filter paper or paper toweling. A disk is then soaked in the silver spray or antiseptic of interest, and kept in the antiseptic solution while the other steps are finished.
5. Once the fungus has reached room temperature, it can be collected with a sterile swab. One swab should be used for each spot that is going to be exposed to the fungus to prevent any contamination.
6. Use sterilized water to fill a test tube.
7. Dip fungus laden swab into the test tube of sterilized water to transfer the fungus into the water.
8. Pour the sterilized water and fungus solution into a Petri dish to cover the whole surface.
9. Place the antiseptic soaked paper disks inside the Petri dish that is covered with the film of water/fungus solution.
10. Place the cover on the dish, tape closed with masking tape, and store upside down in a warming oven (around 100 ^{o}F) for 72 hours. Make sure to mark each test Petri dish with a wax pencil to prevent any confusion.
11. After removing the Petri dish from the oven, a halo around the paper disk will be present. Measure the halo and compare it to the control both quantitatively and qualitatively to determine the effectiveness of the antiseptic of interest.
12. After testing is complete, the fungus should be destroyed by pouring a small amount of bleach in each dish to ensure all fungus is eradicated.

The above procedure was constructed with the guidance of Professor Ogle of the Biomedical Engineering program at UW-Madison as well as source **7.

Results

The results from the test show both qualitatively and quantitatively how effective the silver ion source (or antiseptic of interest) is. If for example, the test results indicate that the Silver Sanitizer effectively reduced the growth of *C. albicans* on the corn meal agar with polysorbate 80, then this product should be implemented in the prosthetic chamber. This Silver Sanitizer spray may also be compared to other common cleaning methods and antiseptics such as soap and water, alcohol based cleaners, and clotrimazole.

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Appendix D: Itemized Production Cost per Unit

Lexan case (polycarbonate)…….…….. $12.50

Insta-mold putty……. $3.00

Magnets…… $2.00

Stems/suction cup…….…….. $0.25

Mirror……. $1.25

Metal sheeting…….…… $0.50

Epoxy adhesive…… $1.50

Polyurethane foam…….. $0.35

Polycarbonate paint…….…… $2.50

Total……..$ 23.85

Appendix E: Vibration Test Certificate and Results (see next page)