Prosthesis Disinfectant and Deodorizer

Midsemester Report

Andrew Bertram, Aaron Freis, Jenna Spaeth, Jason Tham
Client: Dr. John Allen
Advisor: Prof. Willis Tompkins
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Abstract

The purpose of our project is to simplify the prosthetic liner cleaning process. Our client has proposed using ultraviolet radiation to sanitize and deodorize prosthetic liners. Before a prototype can be designed, testing must be conducted in order to determine if cleaning prosthetic liners by ultraviolet radiation is plausible. We have decided to perform germicidal, degradation, and odor reduction tests. The results of these three tests should allow our client to more easily develop his idea, and eventually create a prototype.

Background

Silicone Liners

Silicone liners in prosthetics serve two primary purposes – comfort and performance. Comfort is important, especially in load-bearing prostheses, and the cushioned gel of the liner aids in the comfort of the wearer. Performance is also important, since poor-fitting liners can hinder movement and cause skin irritation. Liners require regular sanitation to prevent infection and discomfort since they are in direct contact with the body.

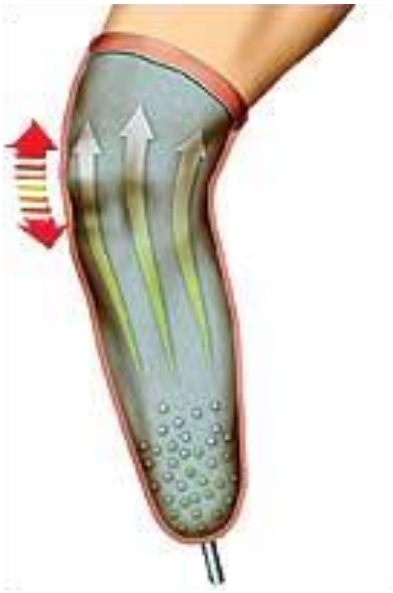

Figure 1 - Prosthetic liner diagram

Current Problems

The biggest problems prosthesis wearers have are infection and odor. Improper or inadequate sterilization techniques can lead to an increase in bacterial growth and possibility of infection. In some cases, the infection requires surgical intervention to prevent exacerbation. Along the same lines, bacteria typically results in substandard aromatic appeal due to the increase in odor.

Current Cleansing Methods

Currently, the most common practice of disinfecting the liner is with mild soap and water – this is what most prostheses companies suggest. Alcohol swabbing is also a common technique many wearers use. Neither of these methods is completely effective, considering the persistence of infection. Irregular sanitation and missing spots when cleaning by hand contribute to a heightened risk of infection.

Ultraviolet (UV) Radiation

UV radiation has a shorter wavelength than visible light and is used in a number of applications. It is currently used as a purifier in air and water applications, such as drinking water and aquariums. These uses rely on the fact that UV light is able to alter the structure of bacterial DNA, effectively killing the cell. It is because of this special quality of UV radiation that our client chose to use it to sterilize the silicone liner of the prosthesis. His daughter actually uses a UV light (coined the "Kelly Light" after her) to sterilize her prosthetic leg; she does not use a liner. UV light is also responsible for some harmful effects to the skin and eyes, including sunburn, skin cancer, cataracts, and macular degeneration. The dangerous qualities of UV light make it imperative that we incorporate safety precautions when dealing with the light.

Titanium Dioxide (TiO_2)

Titanium dioxide is a photocatalyst. When activated by UV light, titanium dioxide serves to aid in killing and decomposing bacteria. This occurs through a photoreaction, in which the free radicals generated from titanium dioxide (as a photocatalyst) oxidize organic matter to kill bacteria. Titanium dioxide also serves to catalyze the oxidation of noxious chemical odors, acting as an effective deodorizing agent. We hope to determine whether or not this added benefit is cost effective to the method.

Problem Statement

Prosthetic liners require regular cleansing and disinfecting. The current prosthetic liner cleaning method involves the use of mild soap, water, and rubbing alcohol. This process can be time consuming, inefficient, and can lead to infection if not performed properly and daily. The use of ultraviolet radiation could potentially simplify the disinfecting process through a timely automated method, but its effects must be verified. Testing must be performed to determine the impact of UV light on silicone, the optimal duration of exposure and bulb wattage, and the deodorizing effect of titanium dioxide before the process can be implemented.

Design Constraints

The testing that we perform and the resulting cleaning process must satisfy all of our design constraints, which consist of performance, safety, accuracy, and reliability requirements.

Safety is the most important constraint. We will constantly be working with ultraviolet radiation, which is harmful to a person's eyes and skin. In order to prevent exposure, the light must be shielded when it is turned on. The ultraviolet light bulb can become very hot when used for long periods of time. This means it may be necessary to monitor temperatures around the bulb during extended testing. Due to high temperatures, our tests must be designed so that the risk of fire is minimized.

Performance requirements are important. If the current cleaning process is properly performed, it will effectively sanitize and deodorize prosthetic liners to a safe level. Our goal is to simplify this method, but performance cannot be sacrificed for convenience. The use of ultraviolet radiation with or without titanium dioxide must sanitize and deodorize the liner just as effectively as the current process. The liner should not be damaged during the cleaning process. If it is found through testing that the ultraviolet radiation does damage the prosthetic liner, preventative measures must be studied and enacted to mitigate deterioration.

Accuracy and reliability are required in our test processes. The tests that we design and conduct must be repeatable, reliable and accurate. The quantitative data should be justified in every test for further development of the concept. These measures ensure our client can use our results and easily reproduce them in the future if needed.

Testing

Degradation Test

Purpose: To determine the magnitude of degradation caused by UV light and titanium dioxide on silicone prosthetic liners.

Background: The silicone found in most prosthetic liners is considered to be hypersensitive to UV radiation. In extended periods of time, UV radiation can change the properties of the silicone in such a way that it will lose its appeal for liner wearers. UV radiation has similar effects as that of heat aging; the silicone materials will increase in hardness and decrease in elongation. Over time, the tensile strength of the silicone will also increase, but decrease substantially soon after. Such property changes are not suitable for continued liner use; liners must be replaced to regain desired properties of soft, pliable silicone material.

A typical prosthetic liner has a warranty for six months and can cost around $250 to replace. If the UV radiation adds the benefit of disinfecting and deodorizing the liner, but cannot make the liner last its normal lifetime of six months, a question of convenience versus cost arises.

Procedure: The degradation test will resolve this debate of convenience versus cost by incorporating a test protocol to quantitatively describe the condition of one liner in comparison to another. The material properties of elongation and tensile strength will be tested using the biomechanics tensile test machine located in Engineering Hall (See **Figure 2**). The degradation test protocol includes two new, yet different, types of silicone prosthetic liners that will be exposed to different wattages of UV irradiation over a period of extended timeframes. Physical degradation and temperature observations will be recorded during the testing timeframe; however, once exposed for a certain amount of time, the liners will be placed in the tensile test machine and tested until failure.

Figure 2 - Tensile testing machine in biomechanics lab; used to elongate the liners until failure in order to measure relative elongation and tensile strength properties of the material.

The tensile test machine, integrated with a computer software program, will record the elongation strains and relative strength of each liner. Once all liners are tested, the quantitative data will be compared and analyzed. Timeframes of interest include exposure of one week, two weeks, and three weeks. A testing system will be built to house the liners and UV light source during the exposure testing to maintain consistent environmental conditions. Preventative measures will be taken to achieve maximum levels of safety with the understanding that UV radiation causes increased heat levels.

Microbial Content Test

Purpose: To determine the sterilizing effects of UV radiation on prosthetic silicone liners compared with those of current methods.

Background: Streptococci and staphylococci bacteria are common causes of skin infection. These bacteria must be regularly eradicated from the liner to prevent infection. Both strains visibly grow in sheep's blood agar, shown in figure 3. A typical method for culturing staph and strep is to incubate the strain in the agar for 24 to 48 hours, after which visible cells can be seen.
Procedure: The microbial content test will require eight equal-sized pieces of liner; a 3" X 3" square should be adequate. Streptococci or staphylococci, obtained from Sally Gallagher (Teaching Assistant for Biology 151), will be cultured onto each liner at 37˚ Celsius for 24 hours. After this time, the eight liners will be divided into four groups of two. Each group will be subjected to a different method of sterilization. The first group will be the control and will not have any cleansing done. The second will be cleansed with mild soap and water, the third with alcohol swabs, and the fourth with ultraviolet radiation. The ultraviolet radiation will be applied for 20 seconds from inside a cinder block. At this point, the samples will be rinsed with distilled or deionized water into its own sheep's blood agar dish. These dishes will then be placed in the 37˚ incubator for 48 more hours. They will then be collected and viewed with the naked eye for relative sizes of bacterial colonies and then under a microscope for estimated number of cells. A simplified schematic is shown below. The cultures can also be sniffed to compare different levels of odor for each sterilization method. Hopefully, the microbial content test will yield results that indicate ultraviolet light is as, if not more, effective than the current methods in practice.

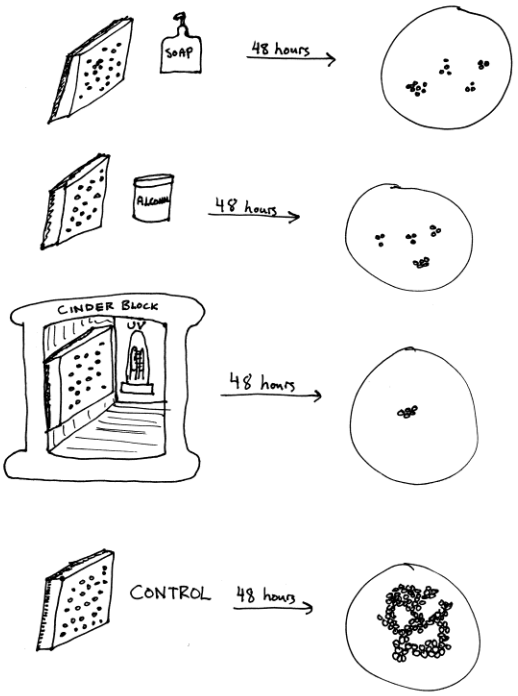

Figure 3 - Microbial content test diagram

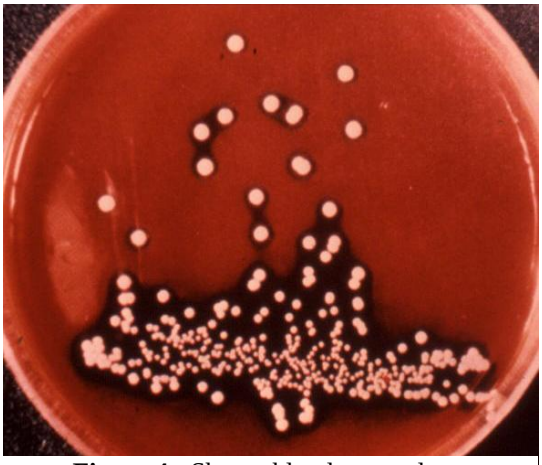

Figure 4 - Sheeps blood agar culture

Titanium Dioxide Odor Test

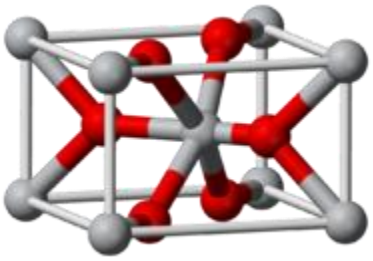

Figure 5 - Molecular view of titanium dioxide

Purpose: To determine if the deodorizing effect resulting from the use of titanium dioxide in addition to ultraviolet radiation is cost effective.

Background: Prosthetic liners obtain odor after daily use. Currently wearers deodorize their liners by cleaning them with water, mild soap, and rubbing alcohol. Another liner deodorization possibility is the use of UV activated titanium dioxide for its photocatalyst effects. Titanium dioxide catalyzes a reaction to break down noxious chemical smells, making it an effective deodorizer.

Procedure: First, an array of test samples will be set up. We will cut pieces from both of the new prosthetic liners that we have so that both of the materials can be tested. Nine pieces from each liner will be required. We will then odorize the eighteen samples. The strength of odor on each sample will be judged after odorization using the previously mentioned scale. Before the participants evaluate the odorized samples, they will smell a piece of liner that has not been exposed to any odor. The samples will then be deodorized by the methods specified in Table 1. After deodorization the same group of people will again judge the odor of each sample. We then will be able to statistically analyze our results, which should give us sufficient data to draw conclusions about which method is optimal, and if the titanium dioxide will be cost effective.

Sample #	**Deodorizing Method**
1	Water, soap, alcohol
2	UV light alone, at wattage=*a*, duration=*z*
3	UV light alone, at wattage=*b*, duration=*z*
4	UV + TIO2, at wattage=*a*, duration=*z*
5	UV + TIO2, at wattage=*b*, duration=*z*
6	UV light alone, at duration=*x*, wattage=*c*
7	UV light alone, at duration=*y*, wattage=*c*
8	UV + TIO2, at duration=*x*, wattage=*c*
9	UV + TIO2, at duration=*y*, wattage=*c*

**Wattages a, b, and c, and durations x, y, and z still to be determined*

Due to the difficulty of actual small-scale odor strength measurement through particle concentrations, we have decided that the next best way for us to quantify odor strength is through a sniff survey. The sniff survey will be conducted three times: before odorization, after odorization, and after deodorization.

The process of odorization has not yet been decided upon, but thus far we have come up with two ideas. The first is that we transfer a smelly substance (such as dead fish, sour milk, etc.) to each sample. This will ensure that the samples will have a strong odor, but it may be unrealistically strong and thus more difficult to deodorize than normal conditions would be. The second process is that we literally wear part of the liner for an extended period of time. An advantage of this

method is that real conditions could be simulated, but the disadvantage is that this odorization is much more difficult to repeat consistently for future testing.

Test Priority

In order to determine priority of the aforementioned tests, a testing matrix was implemented. The test matrix evaluated the capability of each test to cover the factors shown in the table. The factors were safety, germs, degradation, odor, wattage effect, exposure effect, repeatability, cost and time. Safety was mandatory for each test as UV light can be hazardous. Germs are an important variable to be tested. Germicidal irradiation is the main step in sanitation and verifies protection from infection. Degradation is a key element in verifying the efficacy of sanitization and deodorization. Degradation is to be tested with respect to UV radiation and titanium dioxide exposure. Odor is the capacity to produce determinate deodorant data. Wattage and Exposure effects are variables implemented to determine the impact of UV radiation at various luminosities and lengths of time. Repeatability shows the ease of which a test is accurately reproduced. Cost and time are factors we need to be aware of, as both are limited.

Test Factors	Weight	Degradation Test	Germ Test	Odor Test
Safety	Must	Yes	Yes	Yes
Germs	18	0	16	3
Degradation	18	15	1	3
Odor	12	3	6	9
Wattage effect	8	6	4	3
Exposure effect	8	7	7	5
Repeatability	18	16	14	9
Cost	6	5	3	2
Time	12	5	10	11
Total	100	57	61	45

Figure 6 - Test matrix

As the matrix indicates, the germ test is of the highest priority. The germ test will be indicative of the germicidal effect of radiation and contribute to the determination of odor reduction by UV and titanium dioxide. For this test, we must maintain safety precautions. After we begin this test, we can focus on the degradation test. This test is indicative of the wear caused by the UV light and titanium dioxide cleansing methods. Finally, we hope to implement the odor test. Our goal is to instate every test before the end of the year, but time and costs could put a limit on the amount of data we are able to collect.

Materials and Costs

The test setups we anticipate using will require materials at a cost. We already have a light fixture, test liners and a prosthetic limb. For the degradation testing, we will use lab equipment available on campus. The germ test will require petri dishes to culture bacteria samples. These dishes are available at cost. We will also need bacterial strains to infect the liner. For the odor test, we must obtain an odorizing agent and implement a survey to rank the stench. Additional costs will arise in the construction of a test setup that applies UV radiation and titanium dioxide in consistent dosages. Our budget for this project is $200.

Conclusion

Our preparation for testing has been fluid. Test protocol write-ups are to commence in the next phase of our project. We plan to address the germ test, followed by the degradation test and then the odor test. By focusing on testing, we will be able to address the effect of UV light and titanium dioxide in sanitization procedures of prosthetic liners. We will focus keenly on negative impacts of the irradiation and the efficacy of the cleansing process. By doing so, we hope to achieve a simple sanitation procedure that does not harm silicone prosthetic liners. This procedure will save time for the patient and provide an incentive to disinfect the liner on a regular basis.

Future Work

Testing is the main aspect to be addressed in the near future. Our first step is to write protocols for the high priority tests. The protocols will structure the testing in a format conducive to analysis. After our high priority tests, we will write protocols for low priority tests. Test setups will then be constructed as defined by each protocol. Once built, testing will commence. The data collected during the tests will be analyzed and conclusions will be drawn from the information. If there are any ambiguities in the results, protocols should be refined and tests retaken. When all tests have been conducted and verified, we will be able to address whether UV irradiation and titanium dioxide are effective methods of sanitizing and deodorizing. If time permits, additional tests may be implemented.

Appendix A - References

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Appendix B - PDS

Function: The liners of prosthetic devices must be sterilized and/or deodorized on a regular basis. Currently, this process is lengthy, inefficient and inconvenient. This can lead to unsterile conditions if proper maintenance is not applied and consequently infections may result. The goal of the project is to research, test and design a method that simplifies cleaning/disinfecting prosthetics. The scope of the project includes the investigation of germicidal lamps and deodorizing substances such as titanium dioxide.

Client requirements:

- Determine optimum wattage and duration of exposure for different silicone materials through testing
- Determine effect of UV-irradiation and quantitative analysis on silicone materials
- Determine effect of titanium dioxide on prosthetic liners
- Determine effective methods of deodorizing silicone liners

Test setup / design requirements:

1. Physical and Operational Characteristics

a. *Test protocol and setup performance requirements*:

- Must be easy to reproduce experimental data
- Must investigate deodorization to satisfactory level
- Must investigate sterilization of prosthetic liners to safe predetermined scales
- Must not damage prosthetic materials
- Must not radiate extensive heat

b. *Safety*:

- UV radiation is harmful to the eyes and skin that is exposed; prototype must incorporate safety precautions during use considering the target audience
- Temperature or long duration induced auto-shutoff
- Stable bases to prevent falling over

c. *Accuracy and Reliability*:

- Tests must be reproducible
- Data collected must be accurate
- Testing reports must be documented in detail

- Quantified data must be justified

d. *Life in Service*:

- Determined by testing setup demand; at least 3 years

e. *Shelf Life*:

- Determined testing setup demand; at least 10 years

f. *Operating Environment*:

- Prepared for use in dusty environment
- Must function safely indoors

g. *Size*:

- Must accommodate several samples of liners
- Must be storable
- Must be mobile to test at different locations

h. *Weight*:

- Weight is under 12 lbs

i. *Materials*:

- Oil may not be used in any form
- Plastics that will not melt under UV-irradiation
- Metals
- Titanium Dioxide
- Silicone
- TUV bulbs
- Electrical wiring

j. *Aesthetics, Appearance, and Finish*:

- Just make it functional and accurate

2. Production Characteristics

a. *Quantity*: one

b. *Target Product Cost*: $200