Medical Prosthetics for Plastic Surgery-Adherent Interface System

Final Paper
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Client: Gregory G. Gion, Medical Art Prosthetics, LLC

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Abstract:

Gregory Gion is the owner of Medical Art Prosthetics, LLC and has specialized in custom-made facial and somato prosthetics since 1985. His goal is to incorporate more adhesive options for patient use. The purpose of this project is to design a dispensing method for two-component platinum-cured adhesives using lightweight and compact equipment for easier use. Three design alternatives have been considered: a clip pack, a one-tube syringe, and a double-tube syringe. Each design was evaluated using a design matrix, comparing design criteria given by the client. Upon developing and testing the prototype of the double syringe, it was determined that this design was not feasible for use with this adhesive. The clip-pack design was then modified and constructed as a prototype.

Problem Statement:

Our client, Greg Gion, has many problems with the types of prosthetic adhesives available to him. One of the primary problems is his inability to use two-component platinum-cured adhesives that are of higher quality due to use of expensive equipment. Instead, Greg typically distributes one-component adhesives to his clients that create other problems. The purpose of our project is to create an efficient method to effectively mix and dispense a platinum-cured, two-component adhesive for prosthetic use. Platinum curing involves a silicone curing system, which utilizes a platinum catalyst to start the reaction (Cosmesil & Esefex 2005).

Client Motivation:

Currently, Greg distributes a one-component adhesive that is water-based. While the adhesive dries clear, it has many disadvantages. One of the main problems is that the glue tends to set too quickly so placement of the prosthesis on the face needs to be exact during its first application and cannot be readjusted. Another problem with this adhesive is its tendency to damage the silicone of the prosthesis. Since these prostheses are made to look as realistic as possible, they are often constructed with many thin edges, which make them susceptible to tearing. A torn prosthesis does not look natural and is less likely to be worn, therefore making it useless.

While Greg has some two-component adhesive options, dispensing methods for these adhesives are inadequate. The two-component systems that are platinum-cured require a mixing gun and static mixing tube. One of the current methods being used to mix and dispense prosthetic adhesive is a side-by-side double syringe cartridge connected to a dispensing gun with a static mixing nozzle attached (Figure 1). However, this equipment is costly for an individual to purchase for use at home. A static mixing gun from 3M costs approximately $100. Second, this method produces a lot of waste because any adhesive remaining in the static mixing tube hardens in the tube and is unusable at a later time. The waste that accumulates in the static mixing tube during each application exceeds the amount of adhesive that the patient actually uses. This system also prevents public use because it is too bulky to keep in a purse or pocket.

Figure 1: Mixing Gun
(http://www.intertronics.co.uk/products/xdisp.htm)

Another option Greg currently has for a two-component system requires hand mixing. The two components are dispensed onto a piece of paper and mixed manually with a spatula or finger. This method can be messy and produces waste when the adhesive cures to the paper. Without proper solvent, the adhesive adheres to the skin for up to seven days. Another problem is that if an individual does not mix the components completely the adhesive does not properly cure and may run during an application.

Background:

Our client, Greg Gion has owned Medical Art Prosthetics for over twenty years. Allison Long has recently joined him in his practice in his Madison and Dallas facilities. Greg and Allison are both anoplastologists, individuals who custom design facial and somato prostheses. They both work with medical and dental specialists in order to create realistic and comfortable prostheses for their patients. These prostheses can be made out of silicone or polyurethane, while layers of paint and silicone are used to create the life-like appearance of the prosthesis.

Design Requirements:

At our first meeting, the client specified certain criteria for the dispensing system. Our product design must be lightweight and compact, allowing patients to carry their adhesives in a purse or pocket, enabling them to readjust their prostheses in the event it comes loose while in public. It is also important for our dispenser to effectively mix the components to ensure that the adhesive cures properly and does not run after application. The design should minimize waste and cost. In addition, the dispensing of the adherent system will be easy and precise. Finally, the dispenser will accurately dispense proper proportions of each component to ensure the reaction goes to completion. Refer to Appendix 1 for complete design specifications.

Preliminary Design Ideas:

Design 1: Clip Pack

The first proposed design for the adhesive dispenser was the clip pack as shown in figure 2. This design is a two-part flexible plastic pouch, with each half holding a pre-measured amount of one of the two components in a 1:1 ratio. A plastic clip separates the components until they are ready to be mixed. First, the clip is removed and the contents of the package are mixed by using either your hands or rubbing along a 90 degree surface. By ripping off the perforated corner of the plastic pouch, the adhesive can then be applied directly to the prosthesis.

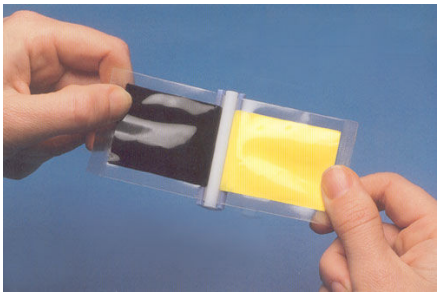

Figure 2: Clip pack
(www.adhesivepackaging.com)

There are many advantages to this design option. First, this clip pack would allow for very easy mixing and dispensing because the prosthetic adhesive could be mixed directly in the pouch. The clip that divides the pouch could also be used as an applicator, which makes application of the adhesive very easy as well. Once the adhesive is put on the prosthesis, the clip could be used to spread it out into a thin layer before the prosthesis is applied to the skin. Another advantage to this design is that this device is very easy and inexpensive to manufacture. Both the pouch and the clip are made out of only one type of material, and the simple design makes it very easy to construct.

There are also a few drawbacks to the clip pack design. One of the negative aspects of this design is that the amount of adhesive in each package is predetermined so that a variety of clip pack sizes would be necessary to meet the needs of each individual patient. Also, once the package is opened, the adhesive cannot be used a second time. The adhesive quickly becomes tacky once the chemical reaction occurs between the two components and will eventually dry out. A third disadvantage of this design is that these packages have the possibility of bursting prior to application.

Design 2: One-Tube Syringe

The second design alternative is a one-tube syringe. This design is a single barreled syringe with an aluminum foil seal separating the two adhesive components. When the adhesive is to be synthesized, the aluminum foil barrier is broken by pushing a ramrod through a hole located at the top of the plunger. This plunger is then used to mix the two components. Finally, the adhesive is applied by removing the cap and replacing it with a nozzle to ensure a clean and easy application process.

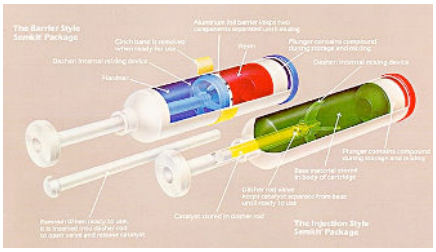

Figure 3: Schematic of One-tube Syringe
(www.adhesivepackaging.com)

One advantage of this system includes its ability to mix the adhesive effectively. Finally, being machine packaged ensures that the proportions of the two adhesives are always guaranteed to be accurate and consistent.

The first disadvantage of the one-tube syringe is its complex design as compared to the clip-pack. Although this design is disposable it is a relatively more expensive system for daily use due to the heavier plastic used in making it and the more complicated manufacturing process. Finally, the amount of adhesive in the syringe is predetermined. Therefore each patient would have to purchase this system directly from the manufacturer in order to receive a specific amount of adhesive. This makes it difficult for this design to be marketable for the client.

Design 3: Double Syringe

The double syringe is a two-component platinum curing adhesive system that combines both components of the adhesive within a static mixing nozzle as shown in figure 4.

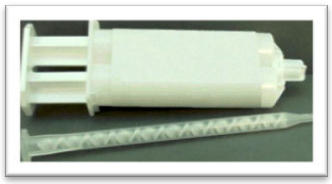

Figure 4: The Double-Barrel Syringe
(http://www.vobaker.com/index.htm)

The double syringe is essentially a modification of the existing dispensing method. The first modification is the elimination of the use of a dispensing gun. This elimination is import because the dispensing gun contributes to both the bulkiness and expense of the previous method. Instead, regular syringe plungers will be used (Figure 4). The second modification to the previous method is that the static mixing nozzle is only filled with the desired amount of adhesive. In the previous method, a continuous flow of adhesive was used to force the adhesive through the static mixing nozzle. By filling the static mixing nozzle with the desired amount of adhesive, relatively no waste is produced. Once the desired amount of adhesive is within the static mixing nozzle the nozzle is removed from the double syringe and placed on an empty syringe filled with air.

The air within the syringe is then used to force the adhesive through the mixing tube, which also mixes the components together. This process is illustrated in Figure 5.

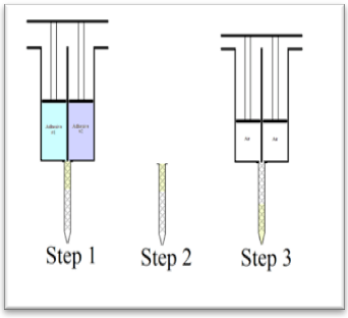

Figure 5: Step-by-step double- barrel syringe method.

The benefits of using the double syringe compared other dispensing methods are cost effectiveness, mixing capabilities, and its ability to precisely apply adhesive. The cost effectiveness of the double syringe is accomplished by replacing the dispensing gun with syringe plungers. Waste is minimized by only filling the static mixing tube with a controlled amount of adhesive, this also contributes to cost effectiveness. Use of the static mixing nozzle effectively mixes to the two components of adhesive. The narrow tip of the nozzle allows for precise application to the prosthesis.

A drawback of this design compared to other dispensing methods is its use of multiple steps that require extra equipment. In addition to the double syringe, a single tube syringe is needed to dispense the adhesive from the static mixing tube using air pressure. Public use of this system is not ideal because of the size and amount of components.

Design Matrix:

	Clip Pack	One-Tube Syringe	Double Barrel Syringe
Mixing Capability	6	8	9
Client Interest/Future Marketability	9	5	9
Precision of Application	6	8	8
Ease of Use	9	6	5
Minimal Waste	7	5	9
Total	**37**	**32**	**40**

Figure 6: Design Matrix

In the design matrix, five criteria were chosen to rank the three proposed designs. The five criteria were all equally weighted, and were scaled 1-10. The five criteria include: the ability of the design to mix the two components efficiently, the client's interest and potential to market the final product, the ability of the product to precisely apply the adhesive, the ease of use of the design, and the amount of waste that the design left after each use.

In the first category, the double syringe received the highest rank because of the static mixing tube's ability to efficiently mix the two components. The extensive length and the corkscrew configuration of the static mixing tube ensures thorough mixing of the components. In client interest / future marketability, both the clip pack and double syringe received the highest mark because the client showed notable interest in these two designs over the third. These designs are simple and easy to manufacture. The client also expressed interest in marketing these products to other professionals with similar problems. In the precision of application, both the one tube syringe and the double

syringe received the highest score because the narrow applicator tip would allow for more precision in placing the mixed adhesive than the clip pack would. The clip pack received the highest score in the ease of use category because of its simplistic design and seemingly simple mixing procedure. Finally, the double syringe design received the highest score in the minimal waste category, because only the amount of adhesive desired would be placed into the static mixing tube before being forced out with air. This means that there would be no adhesive waste during each application. Also, all components of the system with the exception of the static mixing tube could be reused in subsequent applications.

Once the scores were summed in the design matrix, it was noted that the clip pack and double syringe had similar scores. Rather than choosing one of the design alternatives to be used in all situations, the team felt a better approach would be to pursue the clip pack and double syringe as a joint system, where the double syringe would be used in an at-home environment, and the clip pack would be used in an on-the-go situation. The double syringe would allow for precise application of adhesive without having worrying about the size of the system. The clip pack would then be used by a patient in an on-the-go situation, providing a discrete way for a patient to perform a quick 'touch-up', if needed.

Prototype design/testing:

Initially, the team decided to pursue the double syringe/forced air system. A design was proposed in which a static mixing tube would be filled with the necessary amount of adhesive and then removed from the adhesive supply and attached to a syringe

filled with air to force the adhesive out. To test this design, the desired amount of the proposed platinum curing adhesive was placed into the static mixing nozzle using the static mixing gun. Then using a one-tube syringe filled with air, an attempt was made to force the adhesive through the remainder of the static mixing nozzle using air pressure. After testing it was discovered that the adhesive was too viscous. As a result, the air pressure built up in the system until the air eventually burst through the adhesive. This created an air tunnel through the tube where air could travel out of the static mixing nozzle without dispensing the adhesive. In order to confirm that this design failed due to the viscosity of the adhesive, other substances with various viscosities were tested within the system. These substances included toothpaste, antibacterial cream, and water. After performing these tests, it was found that the substances with low viscosity (water, antibacterial cream) were able to pass through the static mixing nozzle, but a substance with a higher viscosity (toothpaste) similar to that of the adhesive, would not pass through the nozzle. Therefore, after repeated tests on this system, it was determined that this design was no longer useful for the platinum curing adhesive, and the clip pack design was explored.

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Final Design:

Our final design is the clip-pack, which has the possibility of being manufactured by a packaging company. Modifications were made to the preliminary design to allow the use of a small amount of each component (approximately 2-3cc) of the adhesive. The design was modified into a thinner tube because of the tacky gel properties of the adhesive. The thinner design allows the adhesive to help dispense itself making the system easier and more efficient. We started by constructing a tube made out of tougher

polypropylene straw folded in half. However, the material was too stiff and not durable enough to hold the adhesive or withstand mixing. Therefore, a softer, more flexible and durable material like low-density polyethylene (LDPE) was more ideal. In addition to the tube construction, we explored two options for manufacturing (see figure 7). One design included a self-manufactured pouch where patients could insert each component into a resealable pouch on either side of a divider clip. This option was not constructed into a prototype because resealable pouches are not as reliable as sealed pouches. It is also difficult for the patients to measure out the correct proportions of each component ensuring proper adhesive synthesis.

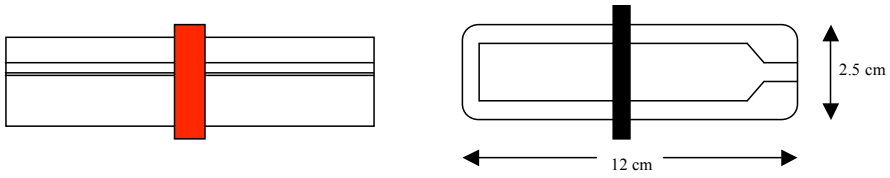

Figure 7: A schematic diagram of the two final clip-pack modifications.

The other clip-pack modification includes an easily manufactured product. It includes two sheets of LDPE sealed around the edges with a divider clip that separates the components. The design would also include indented sealing on one end to create a nozzle for more precise dispensing as shown in figure 7. Too large of an opening would cause the adhesive to ball-up and continue to adhere to itself instead of dispensing onto the prosthesis.

When constructing the prototype, we wanted to make sure that all of the clip packs were of a standard size. We achieved this by creating a frame from a metal bracket. This bracket was folded at two locations so that the edges of the frame enclosed

the adhesive components of the package. This was accomplished by placing the bracket on the edge of a 90 degree surface and bending with pliers. A notch in the center of the bracket was cut out using a band saw so that the bracket could fit over the clip in the center of the adhesive package. By placing this frame over the folded piece of LDPE plastic, we created a uniform width for all of the clip packs. The long edge of the plastic was then ironed down creating a thin tube. A plastic clip was then placed in the center to keep the two adhesive components separate. Two cubic centimeters of each component were then measured and inserted into the tube using two small syringes, one on each side of the center clip. The frame was again placed over the package, and the two remaining edges were sealed.

The final design is show in figure 8. For application, the clip is removed, and the components are mixed by running your fingers along the tube for about a minute. Next, using a scissors, the patient cuts a small corner off of the package. The adhesive is then squeezed out onto the prosthesis. After application the empty package is disposed of and the clips can be saved for further use.

Figure 8: The final prototype: modified clip pack.

Conclusion:

Over the course of the semester, our team developed a system to effectively mix and dispense and platinum cured, two-component adhesive. This was achieved by our first design, the modified clip pack. The clip-pack consists of thin, flexible plastic tube divided in the center by a plastic removable clip. The package holds two cc's of each component on either side of the clip. The components can be effectively mixed after removing the clip and easily dispensed onto the prosthesis by clipping off the corner of the package.

In the future, our group plans to continue testing and modifying this design. Future tests include measurements of durability to ensure that the package does not burst prior to use. Also, we plan to test the mixing capabilities of the packaging system to determine how long the components must be mixed. The ideal future goal is to propose our design to a packaging company to manufacture this product for patient use.

Ethical considerations should be examined when testing our packaging system because the adhesive may cause irritation on human subjects. The adhesive we were using is a platinum-cured two component tacky gel from Nusil. In order to do further testing on the package Scott Huelskamp, a representative from Nusil, would need to be contacted to obtain further information on the chemical composition of each component.

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Appendix 1

Medical Skin Prosthesis Adherent Interface System Project Design Specifications (PDS)*

Lindsey Carlson, Nicole Daehn, Matt Kudek, Paul Schildgen, Chris Walker

12/12/2007

Function: To determine an alternative method of effectively mixing components of a platinum cured prosthetic adhesive. This device should be low cost, compact, minimize waste, and allow for easy and precise application.

Client Requirements:

- Lightweight
- Compact Size
- Effective mixing
- Minimize waste and cost for patients
- Proper proportions of components

Design requirements:

Physical and Operational Characteristics

Performance Requirements: The device should be easily used (not too hard to push or mix). The product should be able to set the amount of adhesive to be used for each patient. The product should keep the components separated until needed. This method should also effectively the two components of the adhesive to allow the chemical reaction to go to completion.

Safety: Safe to dispose in garbage.

Accuracy and Reliability: Should mix the components thoroughly before it is dispensed on skin or prosthetic. The dispensing tip should allow precise application directly to prosthesis after mixing.

Shelf-life: For the clip pack, the plastic pouch should be disposable. For the double syringe, the device should be reusable without wasting the adhesive contents.

Operating environment: Feasible for at-home or public use.

Ergonomics: All patients' should be able to easily mix the adhesive.

Size: Both designs should be small enough to transport in a pocket or purse.

Weight: Lightweight.

Materials: Plastic tubing or plastic sheets.

Production Characteristics

Quantity: One product for each design.

Target Product Cost: Not specified.

Miscellaneous

Customer: Be able to be used for patient's preferred adhesive product.

Competition: No device meeting the customer's specifications has been developed yet.