Medical Prosthetics for Plastic Surgery-Adherent Interface System

Mid-Semester Paper
October 24, 2007

Team Members: Matt Kudek, Lindsey Carlson, Nicole Daehn, Paul Schildgen, Christopher Walker

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

Advisor: Professor Willis Tompkins, Ph.D.

Table of Contents:

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. The best designs, the clip-pack and double-syringe, were selected and prototypes of these are being developed. Future work includes ordering necessary supplies to construct dispensing methods as well as developing a protective barrier between the adhesive and prosthesis.

Problem Statement:

Our client, Greg Gion, has many problems with the types of prosthetic adhesives he has available to him. One of the primary problems Greg deals with is the fact that although two component adhesives are of a higher quality, Greg typically distributes one-component adhesives to his clients because the current dispensing method is difficult and tedious. 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 in practice, 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 easily susceptible to tearing. A torn prosthesis does not look natural and is less likely to be worn, effectively making it useless.

While Greg has some two-component adhesive options, dispensing methods 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. 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. 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. This method can be messy and produces waste when the adhesive cures to the paper. Another problem is that if an individual does not mix the components completely the adhesive will not be able to 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 look of the prosthesis.

Design Requirements:

Our product design must be lightweight and compact, allowing patients to take their adhesives in a purse or pocket. This will enable them to readjust their prostheses in the event it comes loose while in public. It is 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 is the clip pack. This design is a two-part flexible plastic pouch. Each half of the pouch holds a pre-measured amount of one of the two components in a one-to-one ratio. A plastic clip divides the pouch down the center, keeping the two components separate. To combine the components, the clip in the center is removed and the patient uses their hands to manually mix the two components of the adhesive together. By ripping off the perforated corner of the plastic pouch, the adhesive could then be applied directly to the prosthesis.

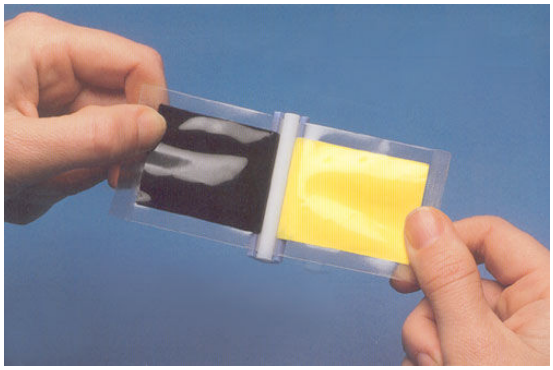

Figure 2: Clip pack
(www.adhsivepackaging.com)

There are many advantages to this design option. First, this clip pack would allow for very easy dispensing because the prosthetic adhesive could be mixed directly in the pouch eliminating mess. The patient would not have to use their fingers or any other equipment to mix the components together because they could be mixed directly in

the package. 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 to manufacture. Both the pouch and the clip are made out of only one type of material. This is also a relatively simple design, which makes it very easy to construct. The clip pack would also be inexpensive to make compared to any of the current adhesive dispensing methods that are being used. This is because this method does not require any expensive equipment to be purchased and because the materials used to create this pouch would also be inexpensive.

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. Each patient has a different size prosthesis that requires glue for application. Someone with a smaller prosthetic may not use the entire package of adhesive, therefore creating a lot of waste every time the adhesive was used. Once the package is opened, the adhesive cannot be used for a second time. The adhesive quickly becomes tacky once the chemical reaction occurs between the two components and will eventually dry out. Another downside of this proposed design is that a company must package these pouches. This would force the patient who needs this adhesive to buy these clip packs in bulk from the company who packages them unless our client purchased them in large amounts for the patient. 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. The plunger is then simultaneously moved up and down while being twisted, mixing 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.

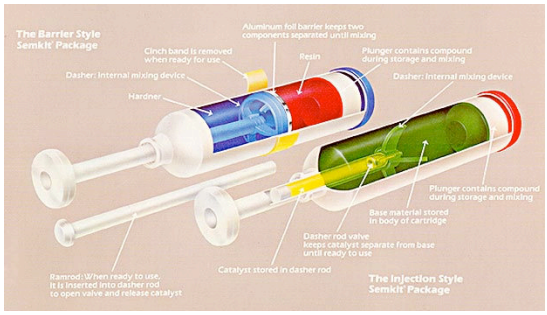

Figure 3: Schematic of One-tube Syringe (www.adhesivepackaging.com)

The one tube syringe is a relatively easy way for a prosthesis patient to use and apply their adhesive and has advantages. The plunger and thrasher do an effective job mixing the two components of the adhesive. Also, since the one tube syringe is machine packaged, the design is made for one time use and is therefore disposable, making cleaning up an easy task. Finally, being machine packaged ensures that the proportions of the two adhesives are always guaranteed to be accurate and consistent.

The first disadvantage is the one-tube syringe is a multiple piece design, a less simplistic design alternative compared to a system with a single component. Composed of the syringe, ramrod, and nozzle there are many components for the patient to keep track of while mixing and applying the adhesive. Although this design is disposable it is a relatively more expensive system for daily use due to the heavier plastic used in making it. Also, because it is disposable it creates the need for the patient to have many syringes

stored at a time. Finally, the amount of adhesive in the syringe is predetermined, meaning there is not a universal size that can be given to every patient without wasting adhesive. This makes it difficult for this design to be marketable for the client and overall more difficult to manufacture.

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.

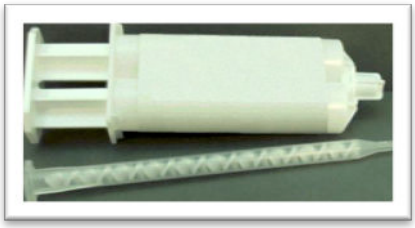

Figure 4: The Double-Barrel Syringe (http://www.vobaker.com/index.htm)

The double syringe is essentially a modification of this design but with a few slight but important modifications. The first modification is that the double syringe will not make use of the dispensing gun. The dispensing gun contributes to both the bulkiness and expense of the previous method. Therefore, to compensate for the dispensing gun's absence, 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. Consequently, the amount of adhesive that was actually applied to prosthesis was minimal compared to the amount remaining within the static mixing nozzle producing a

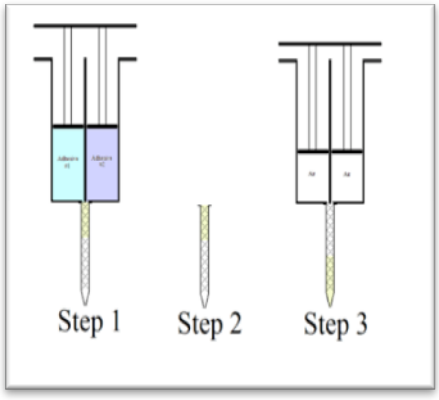

Figure 5: Step-by-step double- barrel syringe method.

considerable amount of waste. By only 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 not only mix the two components of the adhesive, but also to push the adhesive through the remainder of the static mixing nozzle. This process is illustrated in Figure 5.

The benefits of using the double syringe compared other dispensing methods are its 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 as well as the ability of this design to use controlled portions of adhesive, thus creating little to no waste. As for the double syringe's mixing capabilities, the double syringe uses the static mixing nozzle to mix the adhesive. Therefore, no outside work other than pushing the adhesive through the static mixing nozzle is required to properly mix the adhesives. In addition to its mixing capabilities, the static mixing nozzle allows for precise and controlled application of the adhesive to the prosthesis.

The drawbacks of this design compared to other dispensing methods are its complexity and bulkiness. The main cause of this is that the double syringe requires an empty syringe to push the adhesive through the static mixing nozzle. Since there are more parts to this system, it is most likely a little larger to carry and not ideal for on-the-go situations.

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 are: 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 mixing capability category, the double syringe received the highest rank because of the static mixing tube's ability to efficiently mix the two 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. The client also felt that some future marketability existed here, by way of selling to other providers in this field with similar problems. In the precision of application, both the one tube syringe and the double syringe received the highest score because the 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 but 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 to worry 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.

Future Work:

The future work for this project includes developing and constructing a prototype, with the hope of testing in a real patient environment. Also being explored by the team is a method to protect the prosthesis from the adhesives. Currently, the two component adhesives tend to be difficult to remove, and can tear the edges of the prosthesis when being removed. These adhesives also leave residue on the prosthesis, which can build up

over time. A possible solution to this problem may be to use another adhesive as a barrier on the prosthesis. This adhesive would be one that did not adhere well to skin in past attempts, but did adhere well to the prosthesis. Also, this adhesive would need to be able to be peeled off or be removed easily from the prosthesis. This adhesive could then be layered on the prosthesis before the two-component system would be used to attach the prosthesis to the patient. The nightly clean up would be made easier, because the “barrier adhesive” could be peeled off, removing both adhesive layers, which would leave a clean prosthesis.

References

Adhesive and Sealant Custom Packaging Services. Adhesive Packaging Specialties, Inc. 2007. 13 Oct. 2007. <http://www.adhesivepackaging.com/index.html>.

Cosmesil and Esefex Series Materials. Principality Medical Limited. 2005. 14 Sept. 2007. <http://www.cosmesil.co.uk/pdf/Principality_Medical_Cat.pdf>.

Custom/Contract Packaging. V.O. Baker Company. 2006. 22 Oct. 2007. <http://www.vobaker.com/index.htm>.

Dispensing and Dispensing Equipment. Adhere from Intertronics. 2007. 22 Oct. 2007. <http://www.intertronics.co.uk/products/xdisp.htm>.

Appendix 1

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

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

10-24-07

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.