Syringe for Injectable Fillers

Client: Dr. Justin Piasecki
Advisor: Dr. Paul Thompson

Therese Rollmann: Team Leader
Joseph Cabelka: Communicator
Jennifer Wager: BWIG
Mark Yarmarkovich: BSAC

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Table of Contents

Abstract····4

Background Information

Project Motivation····4

Procedure ····5

Injectable Fillers····8

Force ····9

Current Device ····9

Previous Design: Step-Meister 1.0····10

Design Constraints ····11

Materials····12

Alternate Designs

Step-Meister 2.0 ····13

Design II ····15

Design III····16

Design Matrix ····17

Manufacturing ····18

Testing ····22

Materials and Costs ····24

Future Work ····26

Ethical and Intellectual Property Considerations····28

References····29

Appendix

A·····30

B·····31

C·····32

D·····33

Abstract

Current plastic surgery procedures for lipoatrophy restoration, lip augmentations, and other cosmetic procedures are performed based on skills from the surgeon's experience and/or the general feel of the procedure. Our client has requested a device that would administer a known volume of injectable filler with each depression of the plunger. This would standardize the procedure and aid the physician in monitoring the progress of the procedure. The two fillers that are used the most with our client are autologous fat and Sculptra®. Our client uses syringes that range in size from 1cc to 5cc and would like an increment of 0.050-0.10 mL administered with each depression. We developed three different designs and based them on criteria including whether the design can be assembled easily, handle back pressure, be adjusted for variable increments, and have minimal operation required by the physician. Based on these criteria we chose our second design and completed and tested a prototype. We designed our prototype to have 0.1mL increment sizes, and when the increment size was tested we found the accuracy of our final design had an average increment volume of 0.098mL with a standard deviation of 0.004 (+/- 4%). Future work on this design requires using more sophisticated machining methods to produce custom parts that fit the components more securely and decreasing the increment size.

Background Information

Project Motivation

The goal of this device is to make the process of using injectable fillers by plastic surgeons easier and more standardized. The current procedure requires the surgeon to

constantly monitor the amount of filler being injected. A device dispensing a known amount with each depression of the plunger would allow the surgeon to focus their attention on the placement of the filler under the patient's skin. The varying densities of the skin layers require an increase in force applied to the plunger and may result in an uneven application of filler if misjudged. In addition, one filler in particular – fat – has proven difficult at times due to the varied sizes of fat particles. If a fat particle is larger than the diameter of the needle, it may become lodged and require more force to be expelled. The result can be too much filler injected under the skin at one spot leading to a lumpy and uneven appearance.

Procedure

The current procedure for injectable fillers varies from one patient to another. Most of our client's patients use injectable fillers in the facial area. These fillers augment lips as well as remove wrinkle lines and fill hollowing of the cheeks. The procedure takes approximately 15 minutes on average and is relatively simple, allowing the patient to be in and out in an hour. Depending on the area and depth of augmentation, different fillers are used. Fat is primarily used for large augmentations, such as filling nasolabial folds or sunken cheeks. Sculptra® is used to fill hollowing cheeks common to HIV patients. Sculptra® stimulates a natural increase in dermal thickness by promoting natural collagen growth [12]. Fillers containing varying levels of hyaluronic acid are the most versatile for filling fine lines, wrinkles and deep folds. Collagen is also used, but because a small percentage of patients have an allergic reaction to it, it is becoming less common. Injectable fillers are beneficial because the procedure is less invasive than face lifts and the results are not permanent (lasting six to 48 months) [8].

One of the fillers primarily used by our client is autologous fat. A small amount of fat is harvested from the abdomen or thighs, or it is obtained from a concurrent liposuction procedure, as seen in Fig. I. The fat is then placed on gauze in a sterile environment and cleansed in a sterile saline solution. Once the fat has been rinsed, it is transferred to a 1cc, 3cc, or 5cc syringe.

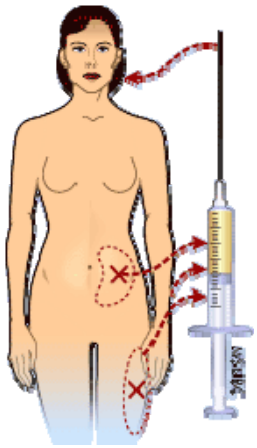


Fig. I: *Diagram of Sources of Autologous Fat.* Fat is harvested from the abdomen, buttock, and thigh.

Depending on the location of the injections, the procedure for fillers varies. The most common procedure is removing wrinkles from the outside of the eye and forehead as well as the nasolabial folds (Fig. II).

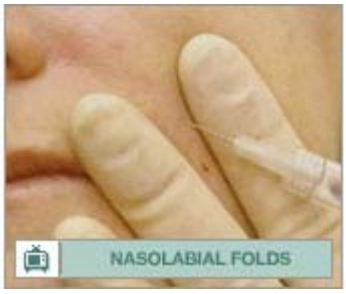


Fig. II: *Nasolabial Fold Augmentation*. Physician injects filler into the fold to diminish its appearance.

For example, in a procedure using fat as the filler, the doctor will use an 18 gauge needle and make as few insertions as possible. The needle is inserted into the subcutaneous fat layer, which is below the dermis and epidermis. The doctor steadily applies pressure to the syringe while pulling slowly out of the subcutaneous fat layer [7]. The doctor will reinsert the syringe back into the subcutaneous fat layer many times to make a fan-like pattern (Fig. III). Once the fan pattern is established, the doctor removes the needle completely from the skin and reinserts it at a location near the first injection site. This creates another fan pattern that is applied on top of the previous layer to make a cross-hatch fan pattern [8].

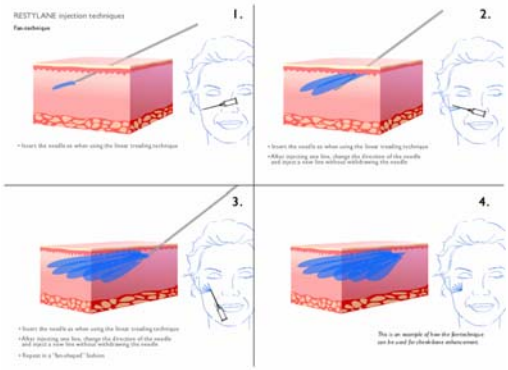


Fig. III: *Diagram of Fan Pattern.* The surgeon inserts needle into the dermis and rotates side to side to create fan pattern.

There are very few risks associated with this procedure, especially when used with fat filler. There is no risk of rejection or allergic reaction in the patient because the fat is harvested from his or her own body [7]. With the other products that are used there is a low risk of a reaction. There may be some puffiness around the injection area that will disappear within a couple days. As with all surgical procedures, there is a risk of infection near the injected areas, but this is also rare because the injection wound is smaller than an incision in the skin [7].

Injectable Fillers

A common injectable filler is adipose or fatty tissue. This is the main storage site for fat. The fat cells in adipose tissue can be unilocular or multilocular. Unilocular cells contain a single lipid droplet and can range in size from 25 to 200 microns. Multilocular cells contain many small lipid droplets and can reach a diameter of 60 microns [12]. Typically twice the volume of adipose tissue is removed as is required because only a 40-50% rate of fat cell survival is expected [9]. Fat tissue has a wide range of properties. Tissue mass is a function of cell number and size [12]. The typical dynamic viscosity of subcutaneous visceral (abdomen) fat is about 3 Pascal seconds. This viscosity is less than that of collagen, most likely because the extra cellular matrix surrounds the cells in the adipose tissue [5].

Sculptra® is a synthetic sculpting agent composed of poly-L-lactic acid. It is used to treat lipoatrophy, which is the hollowing of the face commonly found in HIV patients. Lipoatrophy causes symptoms such as fat loss behind the skin, sunken cheeks (Fig IV), indentations and hollow eyes.

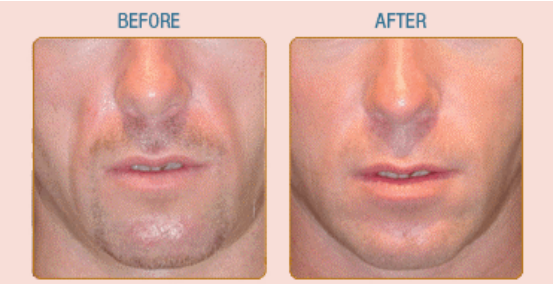


Fig. IV: *Lipoatrophy before and after.* The injection of Sculptra results in restored dermal thickness.

Sculptra® is the first product to be FDA approved for lipoatrophy. Injection of Sculptra® is a very quick procedure with minimal side effects which are limited to injection related symptoms such as bleeding, inflammation and discomfort. Sculptra® works by first filling the depressed area with the injected volume, which is followed by

water absorption, causing the reappearance of the depression several days after the procedure. Within several weeks, Sculptra® is able to stimulate a natural increase in dermal thickness. Poly-L-lactic acid is a biocompatible material, meaning it will not cause any adverse effects in the body; it is also biodegradable, so it will be naturally broken down by the body. The results typically last about 2 years, compared to other products which usually last 6 to 9 months [14].

Force

The force that is required to expel the injectable filler from the syringe is an important parameter that must be considered in the design of the device to ensure it is strong enough to expel the filler. To determine the force needed, we used a simple gravity test in which varying weights were placed on a syringe filled with expired collagen from INAMED. We determined that the minimum weight to expel the collagen was 427 grams giving a force of 4.19N. After extensive research, we found few explicit viscosities. The viscosity of human fat was found to be 3 Pa•s [5], but the variability in the diameter of the fat particles may still cause the force required to increase. Because collagen is more viscous than fat [5] and Sculptra®, this can be used to establish the minimum force required to expel a viscous material through the syringe.

Current Device

Byron Medical manufactures the Dispos-a-Ject™ System (Fig. V), a device currently on the market that is very similar to what the client has requested. This device is expensive at $375 for the system and fits both a 1cc syringe and 10cc syringe. The syringes used for this device are Becton-Dickinson Luer Lock syringes. The material used is surgical grade stainless steel and the complete unit weighs 2-3oz. The device

expels about 0.9cc's with a full pull on the 10cc syringe, requiring 11 full pulls to empty the syringe. This is similar for the 1cc syringe, expelling about 0.1cc per full pull. The company sold 59 systems during the year of 2004 and has sold 42 last year up until September 16, 2005. The device is not limited to fat injections, but is also used for the application of hair glue [3]. The client has requested a device that is less expensive and more compact.

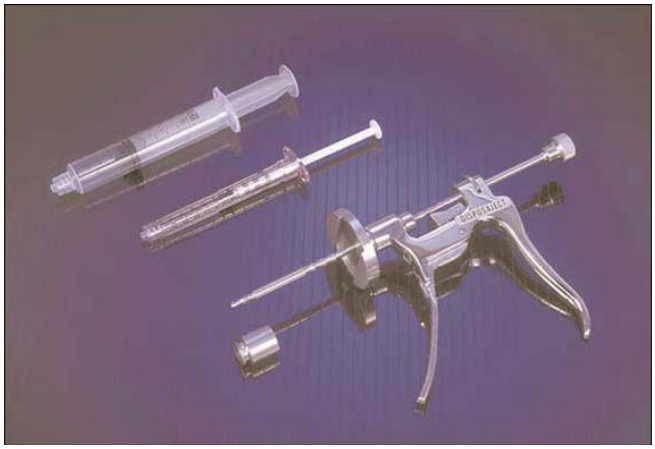


Fig. V: *Dispos-A-Ject*™. This is the current device is on the market. Our client would like us to design a more compact design with movements similar to common syringe movements.

Previous Design: Step-Meister 1.0

Our design from last semester is a device that expels an increment of 100µL with each depression of the plunger. It incorporates a tube that locks into the existing finger grips of the syringe (a friction fit groove). The inside of the tube contains diagonal grooves connected by horizontal grooves. When the physician pushes the device's plunger, it rotates down the diagonal grooves and pushes on the syringe's plunger, which expels the filler. The plunger will rotate down until it hits the horizontal section where the physician will manually rotate the plunger back the other way. The physician will then be able to expel more filler in increments with the same repeating motion.

Fig. VI: *The Step-Meister 1.0* Our design from last semester incorporated an increment size that was controlled by a diagonal groove.

After seeing and testing our device, the client had a few suggestions. He liked knowing the increment size was precise and accurate, and he also liked the size and weight of the device. However, the procedure requires precision, which was hindered by the manual rotation. This introduced some movement which could affect the visual results or the comfort of the patient. He also commented on the ergonomics, especially that the plunger's thumb holder should be larger.

Design Constraints

The primary design constraints as defined by our client include: delivering a known volume with each increment (0.050-0.10mL), withstanding the high temperatures of an autoclave (121°C) or being disposable, accommodating syringes of 1cc or 5cc, and minimizing the number of moving parts to facilitate easier sterilization and cleanup. Each increment should expel the same amount of filler within an error margin of 5-10% and precision is preferred over accuracy. The device should be made of a non-porous sterile metal and last up to 2500 uses. Alternatively, the device could be made of disposable plastic for one time use. The total weight of the device and syringe should not exceed 500g. There should be no obstructions at least 5cm from the distal end of the syringe and if necessary a window should be included in the design to allow the surgeon

to monitor the amount of material remaining in the syringe. Only one prototype is requested at this time. The client has also requested that finger rings be added for stability.

Materials

Two materials we considered for construction of our prototype are stainless steel and plastic, specifically flouropolymers. Our client had no preference between these two options. If the device is made of steel or another metal it would be autoclaved, allowing for multiple uses. On the other hand, a plastic device would be for one time use and disposable. Important properties of these materials are their density, temperature constraints, elastic modulus, and cost.

The main type of stainless steel used in medical applications is stainless steel grade 420. One of the distinguishing characteristics of this material is that it must contain between 12% and 14% chromium to render the metal more corrosion resistant. The typical tempering temperatures for grade 420 range from 204ºC to 650ºC. The different tempering ranges give the metal different inherent properties related to tensile strength (between 655-1600MPa). When autoclaved the characteristics of the metal will be unchanged. The density is approximately 7.750g/cm^3 - an important property that will determine the weight of our final product. The elastic modulus, a measure of the force required to elongate the material, is 200GPa and is sufficient for the requirements of the device [2].

Fluoropolymers are a group of plastics that are easy to machine. This plastic would be ideal for the construction of our device because it is inexpensive and strong. The elastic modulus is 0.393 GPa which is significantly lower than steel. However, with

a one-time use, deformation would not be a problem. Fluoropolymers can operate in a maximum temperature of 327ºC, allowing them to be autoclaved if necessary[15]. The density of this material 1.5 g/cm^3 and its cost is \$2.41 cost/in^3 [13]. Because of its cost and density fluoropolymers would create a lighter and less expensive device than steel.

Alternative Designs

Step-Meister 2.0

Our first design is a modified Step-Meister. It utilizes the same concepts that were behind the original step-meister, however it incorporates a few improvements. The groove increment size would become smaller, moving from 100 to 70µL with each depression, however the groove diameter would still be the same. The manual rotation would also be eliminated by the use of a torsion spring. A straight, vertical groove would be added and would run the length of the diagonal groove. One end of a torsion spring would lock in to this groove while the other end would be placed on the plunger rod. As the plunger rotates down the diagonal, it will also be rotating away from the vertical groove. The tension will build in the spring until the plunger hits the horizontal groove. To release the tension, the spring will automatically rotate back into the top of the next diagonal groove and is ready for the next depression.

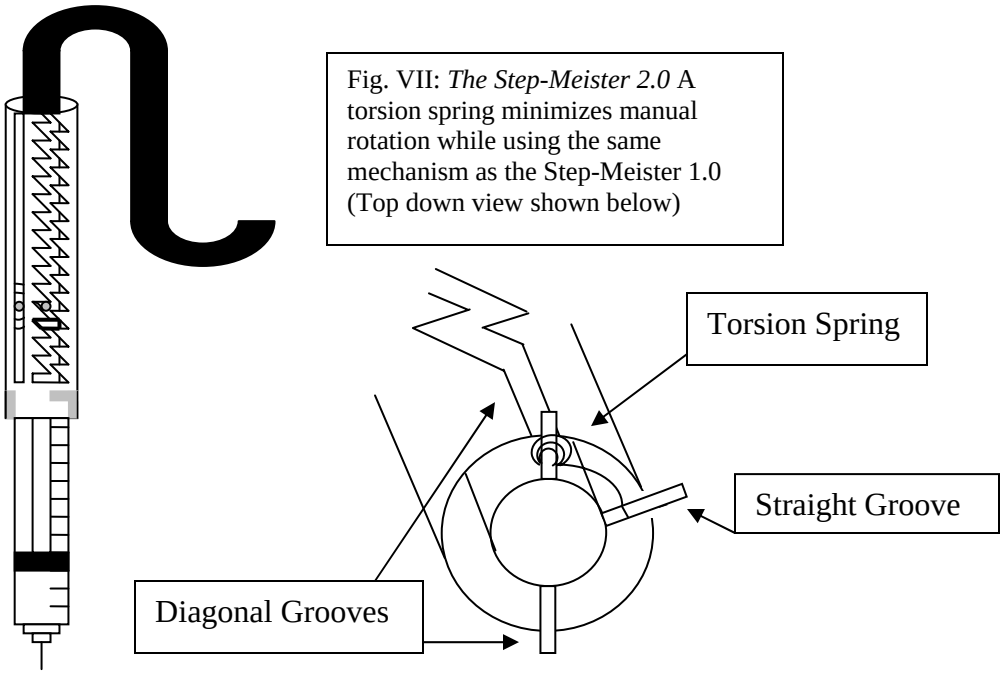


Fig. VII: *The Step-Meister 2.0* A torsion spring minimizes manual rotation while using the same mechanism as the Step-Meister 1.0 (Top down view shown below)

The advantages to this design are that the manual rotation and the increment size have both been improved from our previous design. Also, the physician still has complete control over how fast each increment is delivered. He also will be able to tactilely determine the expulsion of each increment, by the pulling of the torsion spring on the plunger rod at the end of each increment, without taking his attention off of the patient. It is also an advantage that our team is familiar with the manufacturing of this design. Knowing how to make part of our prototype will also help to make visual and mechanical improvements. However, with the reduced increment size, it will be more difficult for us to manufacture. Making a groove that is smaller than 100 µL could be beyond the capabilities of our team, requiring professional help to make this groove and increasing the cost of the prototype. The other disadvantage of this design is that the use of the torsion spring may cause unwanted movement during the procedure. When the spring pulls the plunger back into place, even a small jerk could be risky to the procedure.

Design II

Our second design is similar to a mechanical eraser. Teeth are cut running down the length of the tube into which a complimentary bar can lock. The device uses a button to advance the plunger. A spring that locks into each increment is pushed down while the user slides the button forward to the next increment, and when the button is let up the spring locks into the next increment. The increment size would depend on the spacing of the teeth; this could be easily changed to fit our client's specifications on increment size.

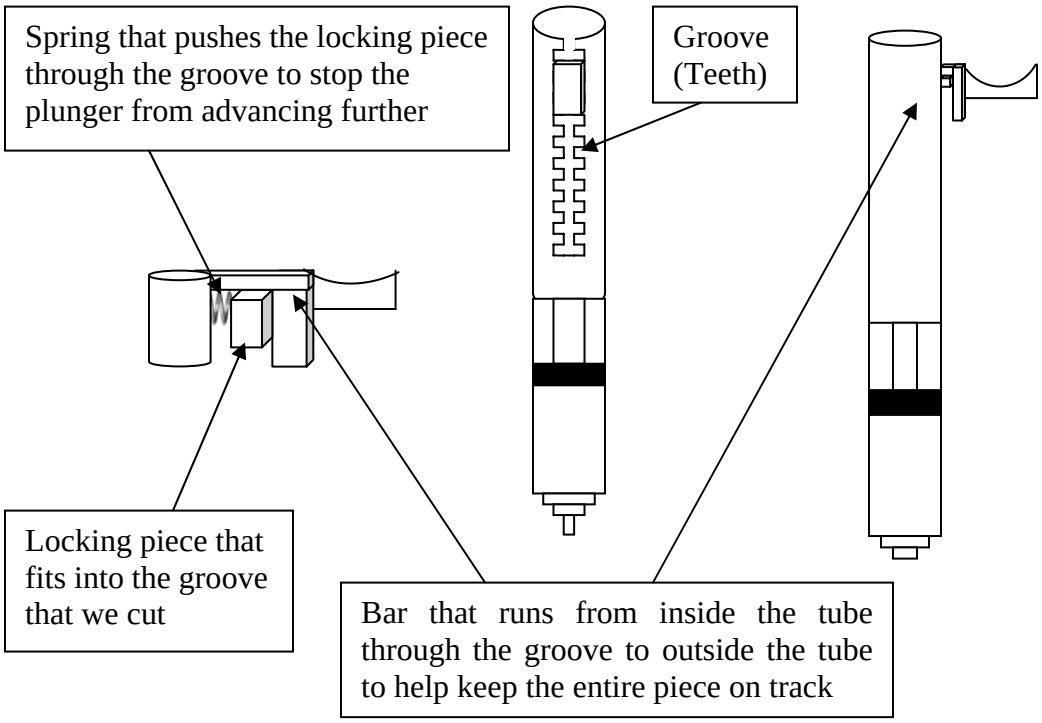


Fig. VIII: *Design II*
This design incorporates a button that locks into teeth cut along the tube

One advantage of this device is that it can offer varied increments. If the physician wants multiple increments they can simply keep the button depressed as they slide it down until the appropriate amount has been expelled. This could, however, be

problematic if the physician unintentionally keeps the button depressed and too much filler is expelled. The way the physician manipulates this design is similar to pushing a normal syringe and would therefore be an easy transition. This device would take some practice to accurately push down and let up on the button to give the desired amount of filler. Another advantage of this device is that there are relatively few small parts making construction less difficult.

Design III

Our third design uses a tube that fits over the back of the syringe. Tabs would be set into the tube where the physician would put his or her fingers to hold onto the device. As he or she applies pressure to these tabs, connecting rods pull down an L-shaped wing near the top of the tube. These wings lock into teeth cut into a second plunger which sits on top of the syringe's plunger and prevent the doctor from expelling more filler. Once the L-shaped wings are pulled down, the physician would then be free to push down the device plunger to inject one or more increments of filler. Once they release pressure on the tabs, springs in compression push the L-wings back into place. The wings would then catch on notches cut into the device's plunger, which would prevent the doctor from advancing the plunger.

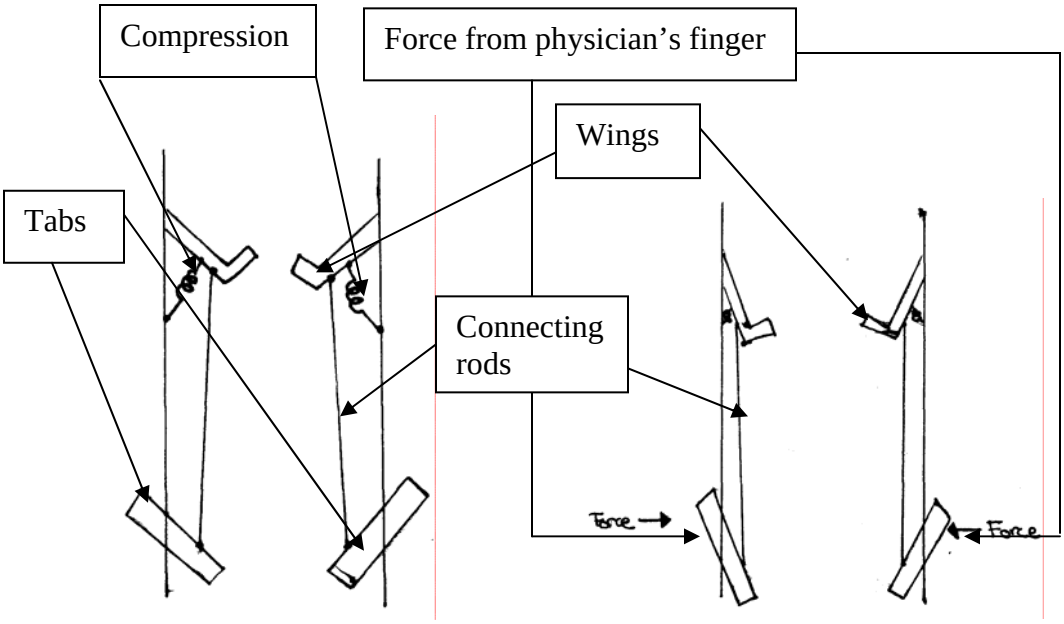


Fig IX: *Design III* This design uses L-shaped wings to lock the plunger into each increment

One advantage of this device is that it allows the doctor to use his discretion if he wishes to expel more than one increment at a time. The mechanism employed in operating the device is also fairly simple, and thus reliable. Unfortunately, the parts required to make this device are quite small. While they may not be difficult to manufacture individually, assembling them into a working prototype would be a challenge. The device retains the normal movement of using a syringe for the doctor, but complicates the procedure by adding an additional motion to make the device work.

Design Matrix

Our design matrix for this project is slightly different than a standard matrix created in a design project. Our primary design constraints of delivering a known amount of filler each time, withstanding the high temperatures of an autoclave (121°C) (or being

disposable), accommodating 1cc or 5cc syringes, and be made of a metal or plastic were all accounted for in every design. The variables we considered were size and ease of use. The current device by Bryon Medical and our previous design, Step-Meister 1.0, introduced unwanted and unfamiliar movement which we will try to minimize with our design. The categories of the design matrix included because of the variability in each of the designs with respect to these factors. We assigned a weighted maximum point value to each parameter to emphasize the constraints that are more important to our client. A low value signifies that the design does not address the parameter well, while a high value indicates that the design excels in the particular category. The scoring of the matrix will heavily influence our choice in a final design.

	Step-Meister 2.0	Design II	Design III
Many, small parts (10)	8	6	3
Ability to Handle Backward Pressure Caused by the Syringe (5)	5	4	4
Easily Variable Increment Size (5)	2	4	5
Manipulation (10)	5	7	5
Total (30)	20	21	17

Manufacturing

After discussing our designs with our client and evaluating our design matrix, we decided to construct design II. It fulfilled the requirements of our client by eliminating rotation and expelling a known increment size with each depression. Although we knew

this design would be a challenge for us to manufacture because of the small parts and the incorporation of the spring, this was the design that would best suit our client's needs.

The materials posed a challenge for us. We used a ½" outer diameter steel tube because it was easily machinable and it met the size requirements set by our client. We made the inner piece that holds the spring and the button out of ABS (acrylonitrile-butadiene-styrene) polymer. The rod that moves down the groove and connects the inner piece with the outer button was made of steel. We used two springs from inside of a mechanical eraser that lock into the slots as the syringe is depressed. We chose to use two springs because we were unable to mill a groove small enough to allow only one spring to lock into place. To reduce the force required to depress the plunger, we used the belt sander to adjust the spring dimensions to accommodate our groove.

Figure X : *CNC Milling Machine* CNC machine milling the groove onto the tube of our device

Using a CNC milling machine we plotted out the points for the outer tube which contains ten increments as shown below in Figure XI. We used a 3/32" diameter end mill to make our groove. The slots for each increment that hold the spring deviated 0.1" from the center.

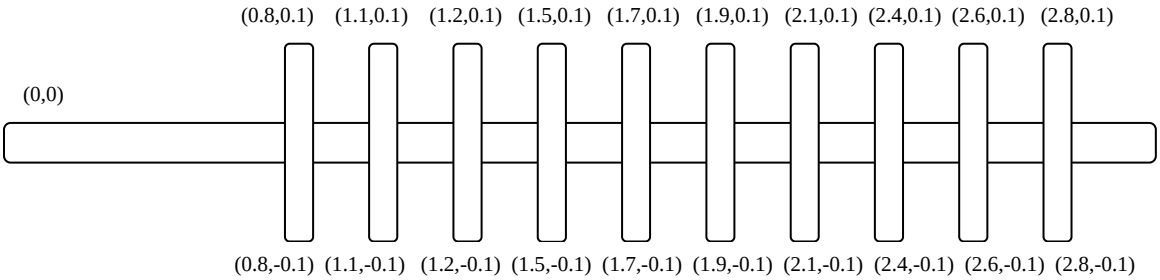


Figure XI : *Plotted Points for CNC Milling Machine*
Dimensions and points for the groove on the tube of prototype

The largest challenge was determining the dimensions and machining the inner piece. Because of the height of the spring and the small inner diameter of the tube, the inner plastic piece had to be small. We wanted the only the top of the spring to fit into the slots, and we needed to make sure that it would slide easily in and out of the slots. The plastic piece also had to be long enough to hold the spring and have a site for attachment to the outer button. The piece was cut out of plastic with the CNC mill using a 1/8" diameter end mill. The dimensions cut were 1.25" x 0.36" x 0.22" (length x width x height). A channel was cut in the top of the piece to hold the springs at the appropriate depth of 0.12", and a 3/32" diameter hole was drilled 0.17" from the top of the inner piece to hold the rod that slides down the center of the groove.

We then JB welded the two springs together. We had some difficulty trying to find a way to attach the spring to the plastic piece. Because both parts were small and we did not have a simple way to attach metal to plastic easily, we decided to use wire to attach the two pieces together. This worked well because it still allowed the spring to move freely up and down while restricting horizontal motion.

We constructed the outer button, which was also made of plastic, to the dimensions 1.0" x 0.5" x 0.22". We milled this out and drilled another 3/32" diameter

hole lengthwise that would encase the rod to connect the inner piece with the outer button.

We then milled the attachment site for the syringe. We used a friction fit groove so that the syringe can slide up into the device and slide over to lock creating a secure fit. A mill bit size of 5/64” was used for this cut. The friction fit was cut 0.38” into the tube. We then milled horizontal grooves with a 1/16” end mill 0.13” long allowing the syringe to twist and lock into place as seen below in Figure XII.

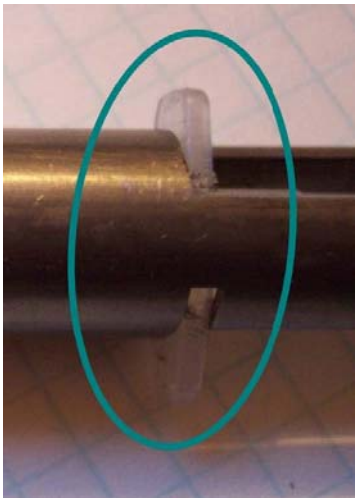
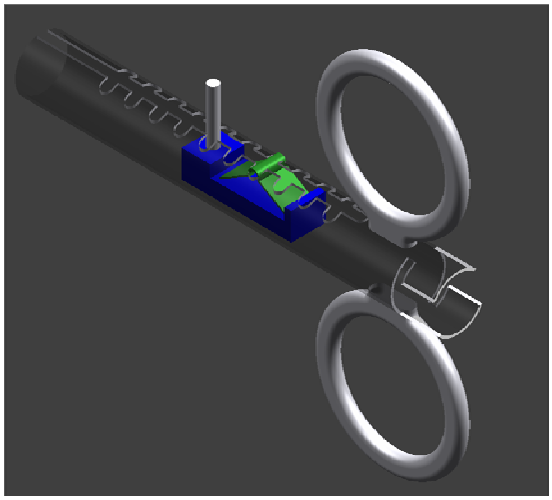


Fig. XII: *Friction Fit Slot.* The syringe’s finger grips, circled, rotate into a friction fit slot that keeps the syringe from falling out.

Finally, we JB welded the finger grips onto the side of the device to provide the client with more stability when gripping the device.



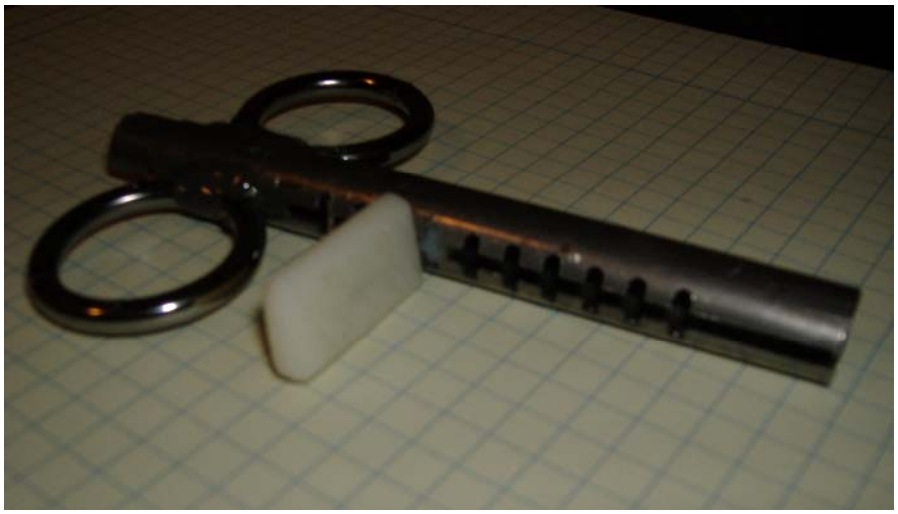


Figure XIII : *Final Design and Final Prototype* **Top**: Final design drawing of prototype **Bottom**: Final completed prototype

Testing

Once the prototype was completed, we tested the increment accuracy of the device. The initial goal was to have increments of 0.1mL. To test this, we simply loaded the 1cc syringe with water and used an analytical scale to find the mass of the amount of water expelled in each increment.

Figure XIV : *Increment Volume Testing*
Water is expelled and each increment size is recorded by an analytical balance

This mass was then converted to volume using the density of water, which is 1g/mL. We performed four trials with the same procedure and averaged the data for each trial. We found it difficult to mass all of the water from each increment due to adhesion to the syringe which caused some errors in our data. We found the average increment size to be 0.098mL with a standard deviation of ± 0.004mL. Each trial is shown graphically below in Figure XV.

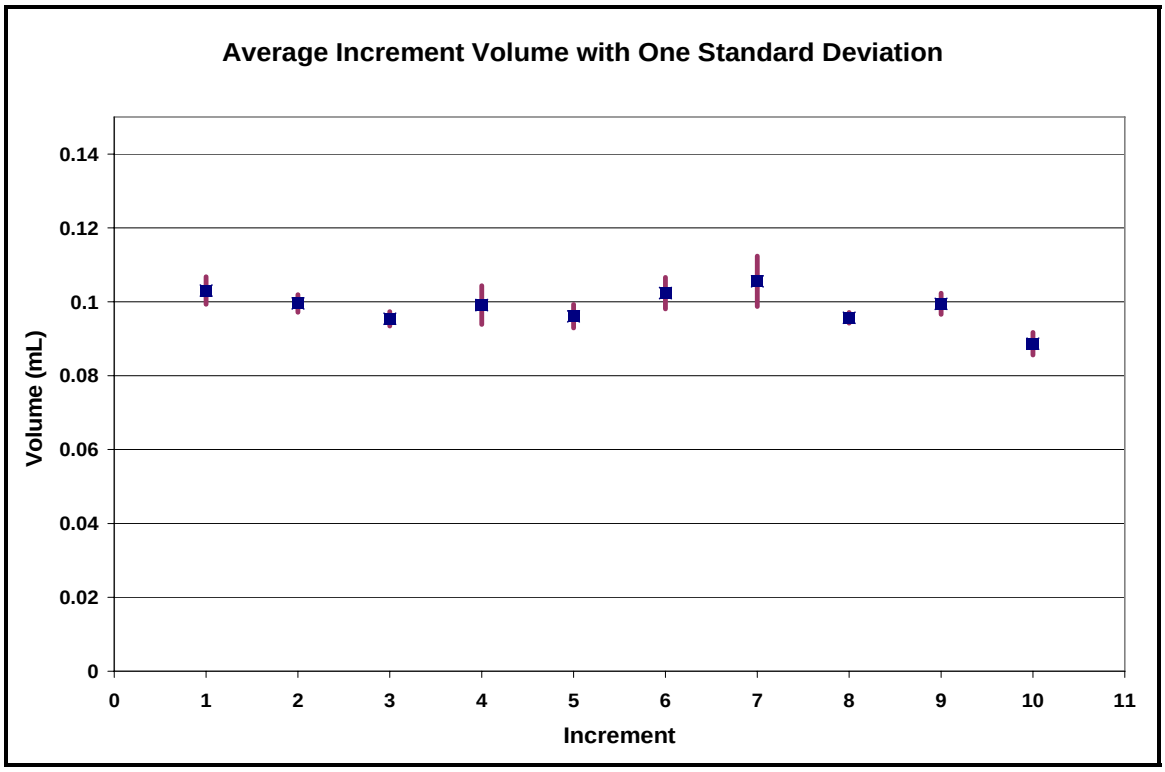


Fig XV *Results of Increment Testing.* The average volume per increment over four trials is shown in the blue squares with standard deviation error bars shown in purple. Each value is approximately 0.098 mL +/- 0.004 mL.

Materials and Costs

In choosing our materials for the outer tube portion of our final design, our options were narrowed down to plastic or steel depending on whether the device was to be disposable or autoclavable. We decided to use the steel due to its higher rigidity which would facilitate the milling of the hollow tube. Since the client did not express a preference to either material, the plastic tube was rejected because it is brittle and less rigid than the steel, allowing us fewer options in the methods of manufacturing the device. Another reason for this choice was that we would not need to purchase extra

materials for the tube since we still had the steel tube from the past design. The amount of steel we had allowed us room for error and optimization of the design.

The inner sliding piece consists of ABS (acrylonitrile-butadiene-styrene) polymer. This was chosen based on its relatively low elastic modulus, which would allow us to manipulate the material by hand if needed. This material was inexpensive, costing only $5.66 for a 0.5”x6”x6” block. This would also allow us to experiment with different dimensions without concerning ourselves with cost or material abundance.

The spring attached to the inner block was simply taken from a mechanical eraser. Since it would be very difficult to obtain a custom spring with these specifications, we adjusted our design based on the dimensions and elastic properties of the given spring. Since we were unable to create a groove thin enough to accommodate a single spring, we used two springs connected side by side to each other with JB weld purchased for $4.42. The mechanical erasers cost $1.65 each, totaling at $3.30 for both springs.

The rod used to guide the inner slider was also left over from the previous design. This piece was chosen based on its appropriate diameter that fit into our groove. We purchased two steel rings that were attached to serve as finger grips that cost $1.38 for two.

Because we could utilize already purchased materials from a previous semester, our expenses for this semester was minimal summing to $14.76, far lower than our permissible budget of $500.

Material	Company	Unit	Cost ($)
Steel Tube 0.5” diameter	McMaster-Carr	6’	14.85
Steel Rod 0.0935” diameter	McMaster-Carr	2.25”	1.74
spring	University Bookstore	2	3.30
ABS block 0.5”x6”x6”	McMaster-Carr	1	5.66
Steel rings	Menards	2	1.38
JB Weld	Home Depot	1	4.42
		Total Cost	29.70
		Unit Cost	9.52

Future Work

For our prototype to be used in practice, many improvements based on manufacturing would have to be made. The main improvement would be to use injection molding to form the inner plastic component of the device. Injection molding involves taking plastic in the form of granules or pellets and melting it. The melted mixture is then placed in a mold until it dries [11]. The custom molded piece would be able to fit the spring more securely to allow for a smoother motion when the plunger is depressed. In addition, the outer button could be molded with the piece. Having the inner component and button be composed of one part instead of two would allow greater durability and more stability when using the device. A small improvement would be to custom design a spring to fit the device instead of fashioning it out of two separate springs.

The main improvement would be to use more advanced manufacturing processes that could be used to produce a smaller increment size and increase the accuracy of each increment. Three processes were researched: Electrical discharge machining or EDM, plasma cutting, and Laser Engineered Net Shaping (LENS®). EDM uses electrical discharges controlled by CNC to erode the material. EDM is more accurate than CNC milling and requires a minimum wall thickness of 0.01 inches [10]. Another type of manufacturing is plasma cutting. Plasma cutting uses a high velocity jet of ionized gas delivered through a constricting orifice. The plasma conducts electricity from the tip of the torch to the metal to sever the material as seen in through conducting materials less than one inch thick [13]. LENS® uses metal powder to build the device in a similar method as rapid prototyping. A high powered laser melts the powdered metal and the device is built one layer at a time [14]. The incorporation of these improvements would provide a reliable and useful device available for many different uses that require constant increment volumes.

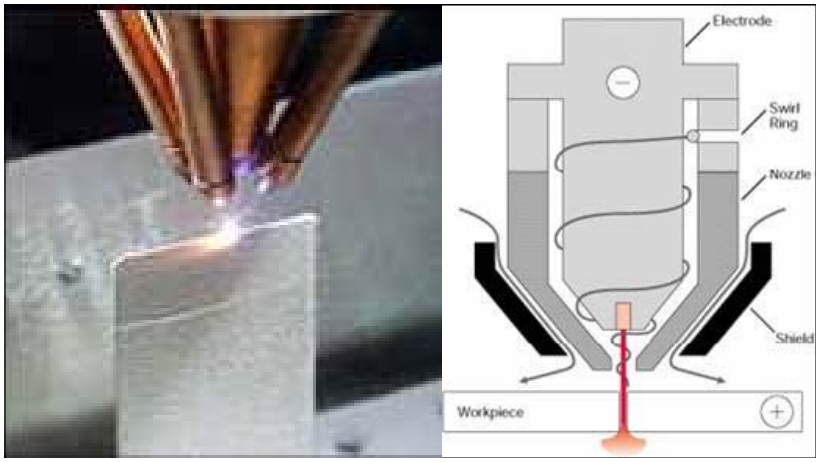


Fig. XVI: *Possible Manufacturing Processes*. **Left:** Plasma cutting may be able to cut out the metal tube at a faster, cheaper rate than milling. **Right:** Using LENS® technology may be another way in which to make this design.

Ethical and Intellectual Property Considerations

Although our device does not actually enter the human patient, it is possible that the injectable fillers that would be entering the patient would be in contact with our device. For this reason, it is important that we autoclave the device after each surgery and design it to make this possible. We would also need to make sure that it would not be abused for applications other than the original intention. There is a current device on the market made by Byron Medical. Our device should not infringe on any patents and our design should be unique and distinct from the Dispos-a-Ject™ product sold by Byron Medical.

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Appendix A

Dimensions of mechanical eraser:

Spring width: 0.1220in

Groove width at max: 0.1585in

Groove width at min: 0.0770in

A: 0.0930in

B: 0.7680in

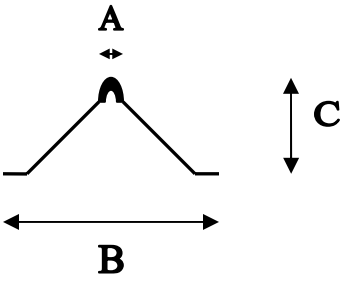
C: 0.2210in

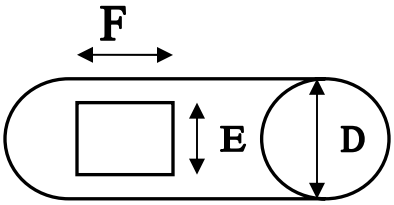
Thickness of spring: 0.0085in

D: 0.2280in

E: 0.1430in

F: 0.1170in





Appendix B

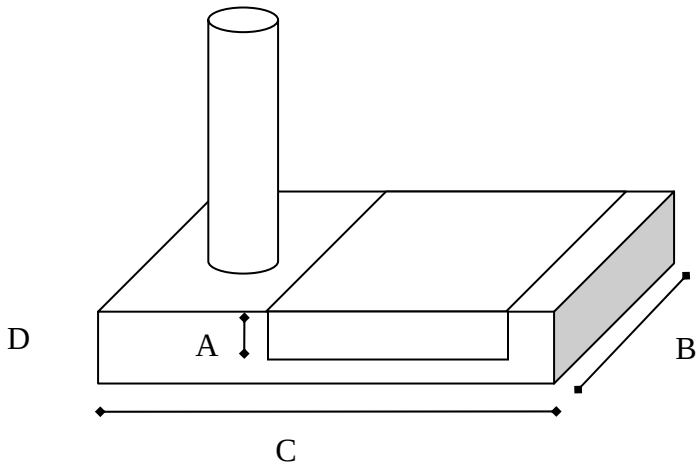
Groove Program for CNC mill

Tool diameter= 0.09375

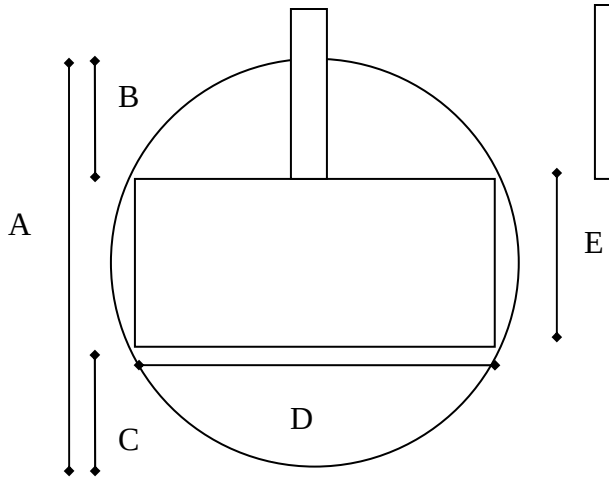
X	Y	X	Y
0	0	2.13	-0.1
0.77	0	2.13	0
0.77	0.1	2.36	0
0.77	-0.1	2.36	0.1
0.77	0	2.36	-0.1
1.1	0	2.36	0
1.1	0.1	2.58	0
1.1	-0.1	2.58	0.1
1.1	0	2.58	-0.1
1.22	0	2.58	0
1.22	0.1	2.81	0
1.22	-0.1	2.81	0.1
1.22	0	2.81	-0.1
1.45	0	2.81	0
1.45	0.1	3.03	0
1.45	-0.1	2.36	0
1.45	0	2.58	0
1.67	0		
1.67	0.1		
1.67	-0.1		
1.67	0		
1.9	0		
1.9	0.1		
1.9	-0.1		
1.9	0		
2.13	0		
2.13	0.1		

Appendix C

Inner piece dimensions



A = 0.12”
B = 0.36”
C = 1.25”
D = 0.22”



A = 0.44”
B = C = 0.11”
D = 0.36”
E = 0.22”

Appendix D

Syringe for Injectable Fillers
(2/3/06)

Team Members: Therese Rollmann, Jennifer Wager, Joseph Cabelka, and Mark Yarmarkovich
Advisor: Professor Thompson
Client: Justin Piasecki, M.D.

Function: The goal of this project is to develop a syringe that is used in plastic surgery and delivers a known increment of injectable filler, such as autonomous fat or Sculptra®, without regard to the pressure applied to the plunger of the syringe. These fillers are injected into various tissues of varying densities and as the needle moves from a more dense tissue (dermis) to a less dense tissue (subcutaneous fat), the pressure required on the plunger is significantly decreased. One filler in particular, human fat, can clump requiring a large force to dispel it. Due to this increased force or decreased density of the tissue, excess can be injected into the patient and lead to an uneven look under the skin. In addition to the aesthetics of this procedure, a more standard method of injecting fillers is preferred for plastic surgeons. If a consistent amount is delivered each time without regarding various human errors and ranges, the procedure is easier to perform and oversee. The incremental mechanism of this device will also allow the physician to focus on the location of the needle under the skin instead of the amount left in the syringe. There is a current device on the market similar to what we have been asked to develop. The device should be disposable or made of an autoclavable material such as metal.

Client Requirements:
- Delivers known amount of filler with one depression of plunger
- Compact design
- Syringe volume of 1cc and 5cc
- Made of metal or disposable

Design Requirements:

1. Physical and Operational Characteristics

A. *Performance Requirements* – The volume of each increment should be from 50 to 100 µL, preferably closer to 50 µL. If the product is made of plastic, it will only be a one-time use. If metal is used, it should withstand use and abuse for at least 10 years.

B. *Safety* – A standard needle will be attached so appropriate caution should be used when handling the device. There should be no sharp edges on the device. If the device is disposable; no safety legislations apply since only the needle is invasive. If the device is for continued use, sterilization measures would apply.

C. *Accuracy and Reliability* – The range of error must lie within 5-10%, and a consistent error is preferred over imprecise values.

D. *Life in Service* - If the device is made of plastic, it will be disposable. The same device may be used multiple times for one patient during one operation. If it is made of metal, it should last up to 2500 uses.

E. *Shelf Life* – The shelf life of the device should be 5-10 years.

F. *Operating Environment* – The device will be stored and operated in room temp (~20°C). While in operation the environment will be sterile, also requiring syringe and/or device to be sterile. Syringe/device must withstand an autoclave temperature of 121°C or be disposable.

G. *Ergonomics* – Strain on the fine hand and forearm muscles should be reduced as much as possible. Rotation of the thumb in operation should be minimal.

H. *Size* – A handheld device with no obstructions at least 5 cm from the distal end of the syringe. The device should be fit either a 1cc or 5cc syringe.

I. *Weight* – The total weight of the syringe and device should be less than 500g.

J. *Materials* – The syringe should be made of a non-porous material. Medical grade plastic, titanium, and stainless steel are possibilities.

K. *Aesthetics, Appearance, and Finish* – A window is necessary on the device in order to see the volume of filler left in the syringe. The finish should be matte to reduce glare. There should be some attempt to make it attractive to patients.

2. Production Characteristics:

A. *Quantity* – Only one prototype is requested at this time.

B. *Target Product Cost* – The cost should be kept to a minimum, but a budget of $500 is provided by the client

3. Miscellaneous:

A. *Standards and Specifications* – There are no known standards for a syringe of this type at this moment.

B. *Customer* – The client would prefer that finger rings are attached to the end of the syringe where it is held. This increases the stability of the syringe. Metal is preferred over plastic for durability. Rotation of the thumb should be minimal.

C. *Patient-related Concerns* – The syringe will need to be autoclaved between

uses in patients.

D. *Competition* – Byron Medical is a company that makes the device, the Disposa-Ject™, which is very similar to what our client is requesting.