An Autosuture Device for Septoplasty and Rhinoplasty

Tim Pearce, Team Leader
Kuya Takami, Communicator
Mollie Lange, BSAC
Peter Ma, BWIG

Client
Dr. Benjamin Marcus
Department of Otolaryngology
Univ. of Wisconsin Clinical Science Center

Advisor
Professor Kristyn Masters
Department of Biomedical Engineering

Abstract:

Suturing of some kind is required for nearly every form of nasal surgery. In many other surgical disciplines, machines have been developed that can deploy sutures in less time and with much less effort than when done by hand. No such device exists for septoplasty or rhinoplasty, two very common operations that require similar suturing techniques after surgery. To this point, the small size of the nasal passage as well as difficulty in maneuvering have prevented nasal autosuture devices from being designed. The goal of a new product will be to reduce the amount of time and effort necessary to securely suture within the nose, bearing in mind the safety of the patient and comfort of the surgeon.

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Problem Statement

Our goal is to develop a device which will automatically deploy a suture to a specific region of the nose which is detached during two common nasal surgeries, rhinoplasty and septoplasty. The current procedure is tedious and time consuming for the performing surgeon, often taking 15 minutes or more and making OR time very costly to the patient. Our client would like to develop a device which will automatically suture the desired location with minimal surgeon involvement. The ideal device would reduce both surgeon error and operating time, resulting in a more effective suture.

Background Information

The nose is the extreme outpost of the face and is located between and below the eyes. In the complex nasal cavity behind it, vital functions such as breathing and smelling are performed. Because of its prominence, the modification of the shape and size of noses is a common procedure in plastic and reconstructive surgery.

Rhinoplasty surgery is used to modify the shape and size of a patient's nose. This surgery can be performed for vanity, or as correction of a birth defect or injury to the nose in hopes of relieving any problems with breathing. During this operation, skin from the inside of the nose is separated from the bone and cartilage (see Figures 1 and 2) which are the major structures to make up the nose.

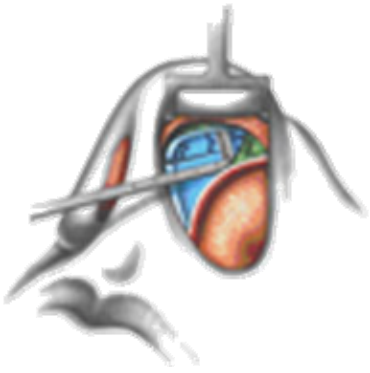

Figure 1: Skin flap detached from septum

Septoplasty is a surgery that corrects any deformation of nasal septum (the straight bone down the center of the nose). Any abnormal development of the nasal septum may influence the appearance of the nose or block the nasal airways (see Figures 1 and 2).

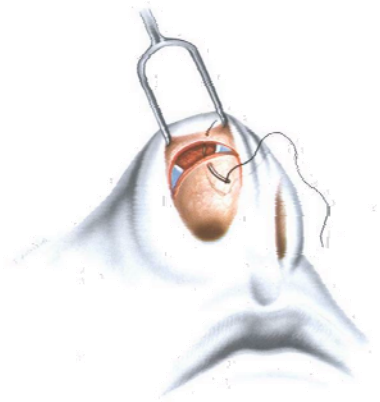

Figure 2: Skin flap detached from septum

Suturing is the surgical method in which fine threads or other materials, such as staples, to join two surfaces and edges together along a line. The first suture idea was introduced by the ancient Egyptians in about 2000 B.C. Suturing needles are usually made of alloy. The thread, which is commonly fused into one end of the needles, can be manufactured to serve many different purposes depending on their use. Suture types are categorized according to the type of material from which they are made (natural or synthetic); the permanence of material, that is if it is absorbable or non-absorbable; and construction process (braided, twisted, monofilament). Suture variables include tensile strength, knot security, diameter, strength retention, flexibility, shelf life, tissue drag and infection potential.

In some cases, the use of surgical staplers can facilitate the closure of large incisions with much more ease than stitching (especially in Caesarean sections and intestinal surgery). Additionally, small staplers can be used in ophthalmology and endoscopy. The fast-growing field of minimally invasive surgery has recently created a very great demand for surgical staplers. Similarly to suturing materials, staples can be found in both absorbable and non-absorbable varieties.

Current Devices

Currently, there are several products on the market that could accomplish our goals but they have not been modified for use in nasal cavities. Devices like those made by US Surgical (see Figures 3 and 4) have made suturing of intestinal tissue, bowels, and surface skin much more efficient through the assistance of single-use or reloadable instruments. The Single Use Suture Device is designed for tissues and can place a circular suture that will attach two "tube-shaped" or "flat" sections together. It is not made, however, to physically pass a needle through something and back through in the other direction. The area that would need to be sutured during nasal surgery would require a completely different type of suture than the ones that the autosuture devices on the market (including those by other companies) are capable of.

Figure 3: US Surgical Endo Stitch™ Single Use Suture device

Figure 4: US Surgical GIA Reloadable Stapler

The GIA Reloadable Stapler and others of its kind are simple in design but have tips that are too broad for use in the nose and which cannot be lined up properly as they are presently found. The possibility exists of adapting one of these devices for use in the nose, but it may require parts that are smaller than those currently being manufactured or additional, more specific modifications.

Design Guidelines and Constraints

Our device should be able to close the incision created during the nasal surgeries of rhinoplasty and septoplasty. This close up process commonly takes around 15 minutes which is relatively long compared to a 30 minute surgery. For any patient, these incisions are typically made in an identical part of the nose and are very similar in size. A device which could minimize the time spent closing the incision could potentially save around $100 per minute of Operating Room time. Besides the huge monetary benefit, the surgeon would be free to spend their time doing something more substantial than tedious suturing. Because of the time that could be saved by using this device, each could cost up to $300 to manufacture.

An autosuture device would give a surgeon confidence that the suture would be uniform every single time. Although the procedure is not complicated, there is a fair amount of skill involved with creating a good suture as well as a need for attention to detail. While most surgeons understand the importance making a good suture, some surgeons either lack the skill or attention to detail to create one during every procedure. The suture device would help these surgeons by giving them the tools to complete the procedure well every time.

The device should be as accurate and reliable as the current procedure done by the surgeon. Size and weight of the device must allow for easy use by the surgeon, suggesting a light weight and a small enough size to allow for a good suture. Both the patient and surgeon must be safety must be maintained while using this device and all materials involved must be single-use or autoclavable and sterilizable. For a more detailed summary of design constraints see the PDS in the appendix.

Design 1: Autosuture

Our client's original idea was to create a device that could pass a needle back and forth through the folds of skin, attaching them to the septum in an identical pattern to the methods currently induced by the hand of the surgeon. It could be created with a circular needle (needles in existence curve as sharply as 5/8 of a circle – see Figure 5) that would curve sharply back through the septum and create a "coil" type of suture up the middle of the nose; or, theoretically, a very small linear needle could be passed back and forth to mimic the actions of a surgeon tying each knot by hand. The advantages to this design were that it would be widely accepted by surgeons, who by reputation are relatively unwilling to give up a commonly practiced technique in lieu of new technology. It also would ensure the safety of the patient since the casing of the instrument could be constructed so that the needle, even during a malfunction, could not go off course and do any damage. Another feature of the design was that several different types of suturing material – non-absorbable or absorbable with varying absorption times – could be used depending on the needs of the specific surgery it was used for. The greatest flaw to this design plan is that it is probably not something that could be accomplished during the length of time we've been given. Because of the difficulty of modifying this device (which is made for very specific surgical needs), a change as drastic as what we would need would most likely require the manufacture of a totally unique device or custom creation of new parts.

Figure 5: Syneture™ Tapering needle

Design 2: Medical Glue

Another initial design that seemed like it would fit the needs of the suture was the use of Medical Glue (see Figure 6). There are several different types of glue on the market that are slowly replacing suturing in many surgeries, both invasive and minimally-invasive. Absorption and drying time both vary depending on the exact glue used, which can be ordered in large quantities and usually has a long shelf life. A December 2002 study by Assaf Harofeh Medical Center in Isreal experimented with the use of Fibrin glue to replace suturing or nasal packing (the stuffing of gauze or other absorptive material up the nose) in nasal surgery patients. The study concluded that the glue was as effective, if not more effective than the other leading options. Another study by the University of Michigan found similarly that the use of medical "super" glue was an effective alternative to suturing external wounds, and one that saved a great deal of time. After speaking with our client, however, we found out that in the particular surgeries we will need to use our device for, certain angles of pressure must be evenly applied in order for the wound to heal as it should. Medical glue could be an option if coupled with nasal packing to sustain the pressure, but the risk of Toxic Shock Syndrome – a rare but serious form of blood poisoning due to bacteria in clotting blood – has been connected to packing and the practice has been discontinued in most situations. Because of this risk to the patient, we decided that other options should be considered if at all possible.

Figure 6: Fibrin "super" glue

Design 3: Surgical Stapler

Our final design plan was the generation or modification of a surgical stapler, of which there were many different types to choose from and, most likely, a stapling system similar to what we were looking for. The original idea for the device was relatively similar in function to an everyday paper stapler (see Figure 7); as time has progressed, technology has allowed for additional options and single-use versions, but the idea has remained the same (see Figure 8).

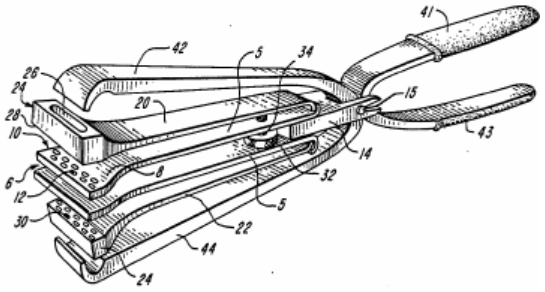

Figure 7: 1989 schematic from US Patent # 4930674

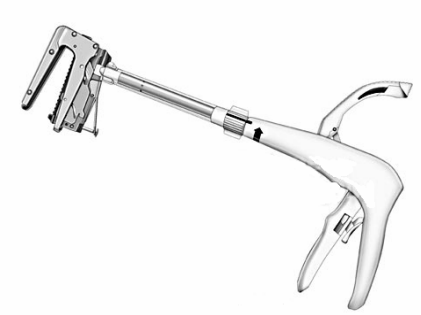

Figure 8: Sketch of a more recent surgical stapler

Staplers have become commonplace in such operations as Cesarean Sections and intestinal surgery, as well as many other surgeries for which the gap is too long or oddly skewed for traditional suturing methods. They have been perfected over the past twenty years for both general and specific use, and because of this there are numerous different shapes and sizes available on the market. Both non-absorbable and absorbable staples exist, but are often made in sizes that are particular to a certain model.

The very simple mechanical nature of this device makes it ideal for manipulation and especially flexible in its potential surgery involvement. Additionally, having the option of investing in single-use devices or reloadable models ensures that sterility needs will be met, and gives surgeons the ability to get comfortable using a particular style.

Design Solution

After carefully weighing the design constraints, materials, and amount of time we have to complete the project, we decided on the design solution that will be the most mechanically simple while still meeting all of the goals we set for the device: the surgical stapler (see Design Matrix below). With this device, we can be properly assured of sterility, safety, and accuracy without sacrificing any other important components, such as cost. We also were able to procure a sample device for the purpose of evaluating the exact mechanics, and are looking at different companies for absorbable staples that will fit into our device or a similar device with proper modification. While the ideal solution would be to replicate the suture design that surgeons currently use in the operating room, we feel that the amount of time and money that can be saved through the stapling device will be enough to convince doctors to try it, should it successfully pass through clinical trials. With OR time costing up to one hundred dollars per minute, cutting even five minutes out of a 15-minute suture time will save money (provided that the cost of the device is less than the money saved).

Design Matrix

Criteria (item weight)	**Autosuture Design**	**Medical Glue Design**	**Surgical Stapler Design**
Sterilizable (3)	5x3 = **15**	5x3 = **15**	5x3 = **15**
Patient/Surgeon Safety (3)	5x3 = **15**	2x3 = **6**	4x3 = **12**
Accuracy (3)	4x3 = **12**	3x3 = **9**	4x3 = **12**
Strength of Suture (2)	4x2 = **8**	4x2 = **8**	4x2 = **8**
Adjustable device (2)	3x2 = **6**	4x2 = **8**	4x2 = **8**
Patient Comfort (2)	4x2 = **8**	3x2 = **6**	5x2 = **10**
Time needed (2)	4x2 = **8**	5x2 = **10**	4x2 = **8**
Cost (1)	3x1 = **3**	5x1 = **5**	4x1 = **4**
Shelf Life (1)	3x1 = **3**	4x1 = **4**	5x1 = **5**
Attractiveness (1)	5x1 = **5**	5x1 = **5**	5x1 = **5**
Total (Max score = 100)	**83**	**76**	**87**

Conclusion

The safety issue is very crucial to the patient. The device will be produced based on many factors. Material is one of the factors. First, using the material which a patient does not have any allergy. Also, it is important to make sure that the device is possible to be sterilized or disposable. That would prevent the patient getting infected from other patient's disease. Another factor is that how the staples can hold the cut after the surgery. The staple should be able to hold the skin even if there is some movement on the nose. For example, it should hold while patient is sleeping and mistakenly pushed their nose to the bed.

Future Development

The modification of the existing suture device can potentially cause a number of problems. Our design will heavily depend on what the suture device's intrinsic characteristics are (how it functions normally). While some modifications can potentially be made, there will be some unchangeable features which may not be ideal for our project which we must work with or around. For example, the firing mechanism may not be able to be modified to accept the different staple pattern we will ideally like to use.

Due to the small size of the device, any modifications will need to be made on a very small scale. Because the size constraints are unavoidable we may need to simplify the design to make it feasible. Using absorbable staples instead of the standard metal will require testing to determine the effects of this change. Unfortunately the device sent to us will only be capable of being fired once so gaining a strong understanding of how it works will be limited.

The final step in the design will be to make a device which can actually be used in the emergency room. To accomplish this we must have a device which can be tested to ensure the suture is safe and effective. Making such a device will require that we make the device reusable, perhaps by making the staple cartridges release after each use to allow a new cartridge to be loaded. Establishing a relationship with US Surgical to get a sufficient number of devices to test may be necessary to see this project to completion.

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Appendix A: Product Design Specification

(October 19th 2006)

Members:
Team Leader: Tim Pearce
Communicator: Kuya Takami
BSAC: Mollie Lange
BWIG: Peter Ma

Problem Statement:

Our goal is to develop a device which will automatically deploy a close up of an incision to a specific region of the nose which is commonly detached in two common nasal surgeries, rhinoplasty and septoplasty. The traditional closing up procedure is tedious and time consuming for the performing surgeon, often taking 15 minutes or more. Our client would like to develop a device which will automatically close up the desired location with minimal surgeon involvement. This will cut down on surgeon's error, and make a more effective suture.

Client Requirements:

- Device should be accurate and reliable
- Device must be concise enough to fit in the nasal passage
- Device should perform equally to current standard procedure
- Safety of patient and surgeon should be maintained
- Materials must be autoclavable and be able to be sterilized
- Can cost as much as $300 per device

1. Physical Requirements:

a. *Performance:*
   i. Either a one time device or a reusable device is acceptable
   ii. Methods of loading a new suture cartridge can be addressed

b. *Safety:*
   i. Unnecessary sharp end or edge must be avoided
   ii. Lock should exist to prevent slipping
   iii. Suitable grip to prevent slipping

c. *Accuracy and Reliability:*
   Comparable accuracy and reliability should be achieved by the device.

d. *Life in Service:*
   i. If disposable, one use only.

ii. If reusable, a maximum number of surgeries should be preformed with a single device based on further research.

e. *Shelf Life:*

Device will be kept in operation room at room temperature

f. *Operating Environment:*

i. Device should only be used within the operating room
ii. Function is performed in the nasal area.

g. *Size*:

i. Grip: Suitable size for comfortable gripping (8 – 10cm)
ii. Tip: Maximum length should fit in the nose (2.0-2.5cm)

h. *Weight:*

Must not exceed 1 lb

i. *Materials:*

Materials compatible with sterility: plastic, surgical stainless steel
Must be disposable or autoclavable.

2. Operational Requirements:

a. *Quantity:*

One prototype

b. *Target Production Cost:*

$300

3. Miscellaneous:

a. *Standards and Specifications:*

If successful, federal standards will need to be addressed.

b. *Patient-related concerns:*

Must be new or sterilized before use.

c. *Competition:*

There are auto-suture devices but none for nasal surgery.