

An Autosuture Device for Septoplasty and Rhinoplasty

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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 our project was 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. After considering many different design possibilities including a stitching device and medical adhesive, our team chose to build a new surgical stapler which models the type of device that can be manufactured in large quantities. The results of early testing show a rate of 95% of shots fired being successful. Some modifications will need to be made before mass producing the device, including using absorbable staples and running clinical trials.

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Problem Statement

Our goal was to develop a device which would automatically deploy a suture to a specific region of the nose that 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 causing extra OR time to become 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

Millions of corrective nasal surgeries are performed in the United States each year. Causes for these surgeries can vary from changing the patient's appearance to the correction of a birth defect or injury to the nose in hopes of relieving any problems with breathing. More and more Otorhinolaryngologists are finding these corrective surgeries to be part of their daily task as general ear, nose, and throat doctors.

Rhinoplasty surgery is used to modify the shape and size of a patient's nose. 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.

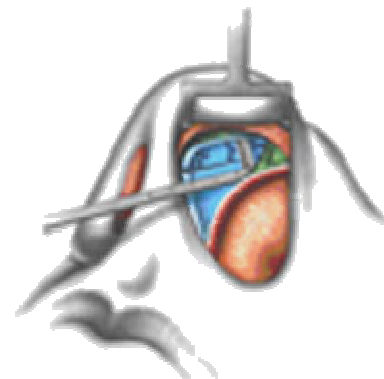


Figure 1: Skin flap detached from septum 3 of 19

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).

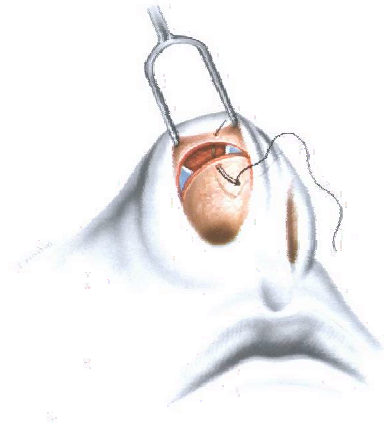


Figure 2: Skin flap detached from septum

Suturing is the surgical method in which fine threads or other materials, such as staples, are used to join two surfaces and edges together along a line. 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 theoretically have accomplished our goals of reducing the



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

amount of time and effort necessary to securely suture within the nose, while bearing in mind the safety of the patient and comfort of the surgeon. Devices like those made by



Figure 4: US Surgical GIA Reloadable Stapler

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 Device⁵ 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 needs to be sutured during nasal surgery requires a completely different type of suture than the ones that the autosuture devices on the market (including those by other companies) are capable of.

The GIA Reloadable Stapler⁴ and others of its kind¹ are simple in design but have tips that average approximately 40mm long, while the space we are trying to suture is only about 20mm in length. They also aren’t designed to curve so that the skin at the front of the nose is not compressed as the devices closes on the area to be stapled. The possibility existed of adapting one of these for use in the nose, but individual parts for these devices are not produced separately from the staplers themselves. This made modifying certain regions of the stapler difficult without disassembling the whole thing.

Design Guidelines and Constraints

Our device, when completed, should be able to close the incision created during the nasal surgeries of rhinoplasty and septoplasty. This 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 (about 20x17mm). 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.

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 following are the most important design criteria as required by our client.

- Device should be as accurate and reliable in closing the wound as the surgeon is.
- Device must be small enough to fit in the nasal passage.
- Device should perform equally to current standard procedure – must cover skin flap area of 20mm x 17mm.
- Safety of patient and surgeon must not be diminished if using the device.
- Materials must be autoclavable and be able to be sterilized if reusable.
- Can cost as much as \$300 for a single time use device and as much as \$1500 for a reloadable, reusable, device.

Alternate 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



5/8  27 mm

Figure 5: Syneture™ Tapering needle

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. Also, the stitches would be very similar to the current procedure making the surgeon confident in the accuracy and reliability of the work. Another feature of the design is 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 is used for. The greatest flaw to this design plan was the necessity for many complex working parts. In essence, a mini sewing machine would need to be built, a very hard task to do with the resources provided to us. Because of the difficulty of modifying a current device (which are made for very specific surgical needs, with complex parts), 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.

Alternate 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



Figure 6: Fibrin “super” glue

market that are slowly replacing suturing in many invasive and minimally-invasive surgeries. 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 Israel⁶ 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 Michigan² 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 our device will need to be used 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 Syndrome³ – 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.

Design 3: Surgical Stapler

Our third 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).

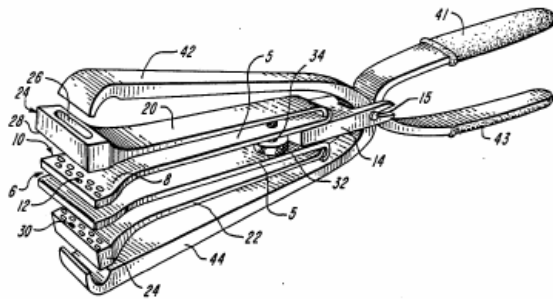


Figure 7: 1989 schematic from US Patent # 4930674 ¹

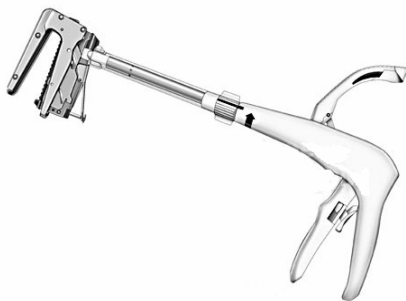


Figure 8: Sketch of a more recent surgical stapler

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 they are often made in sizes that are particular to a certain model.

The very simple mechanical nature of this device made it ideal for manipulation and especially flexible in its potential surgery involvement. Additionally, having the option of investing in single-use devices or reusable models ensures that sterility needs

will be met, and gives surgeons the ability to get comfortable using a particular style. However, as we stated earlier, most existing devices have tips that average approximately are too long or broad for the dimensions (20mm x 17mm) that our device will need to cover. They also aren't designed to curve so that the skin at the front of the nose is not compressed as the devices closes on the area to be stapled. These modifications would need to be made if we decided on this option.

Design Solution

After carefully weighing the design constraints, materials, and amount of time we had to complete the project, we decided on the design solution that would be the most mechanically simple while still meeting all of the goals we set for the device: the surgical stapler (see Design Matrix on next page). With this device, we could 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 looked at different companies for absorbable staples that would fit into our device or a similar device with proper modification. While the ideal solution would be to exactly replicate the suture design that surgeons currently use in the operating room, we felt 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). Our original computer sketches of the device can be found attached as Appendix B.

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

Prototype Details

The final design for our device is comprised of a modified steel hemostat, three aluminum plates, and steel rods to allow the plunging motion that pushes the staples through. The device's function is much like an ordinary paper stapler, but it fires three staples at a time and fits in the nasal cavity. The most important thing to note about our prototype is that, obviously, our number one priority was that this device would fit easily into the nose while leaving the surgeon's spare hand free to guide the staples to their target. We met these goals and built our model based around the exact dimensions of the nasal septum (5-8mm wide), choosing a staple to fit while leaving room to crimp at the ends. It does actually fit in to the nasal passage and still houses the staple length needed to complete our task.



Figure 9: Hemostat body

The body of this device (see Figure 9) is a modified steel hemostat, which has been bent to allow penetration into the nasal cavity without compressing the skin at the tip of the nose.

The top plate (see Figure 10) has been designed with raised posts which can push the loaded staples all the way through the middle plate, forcing them through the septum as well.

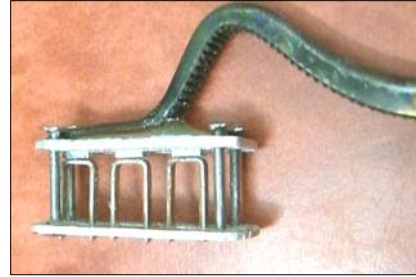


Figure 10: Top plate

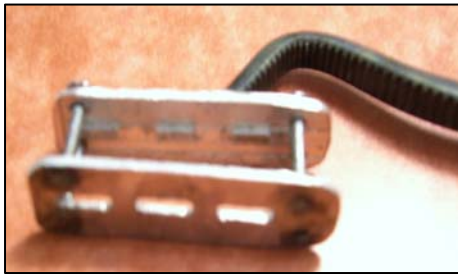


Figure 11: Middle Plate

The middle plate (see Figure 11) has been designed to hold the staples in place when the device is open and loaded, then to allow them to be pushed through by the top plate and direct them in a straight path through the skin and septum as the stapler is closed.

The middle plate also creates pressure by holding the skin in place.

The bottom plate (see Figure 12) holds the opposite skin flap in place next to the septum and stops the staple when it has reached the other side. Ideally the bottom plate will be designed to crimp the staples in place as pressure is applied.



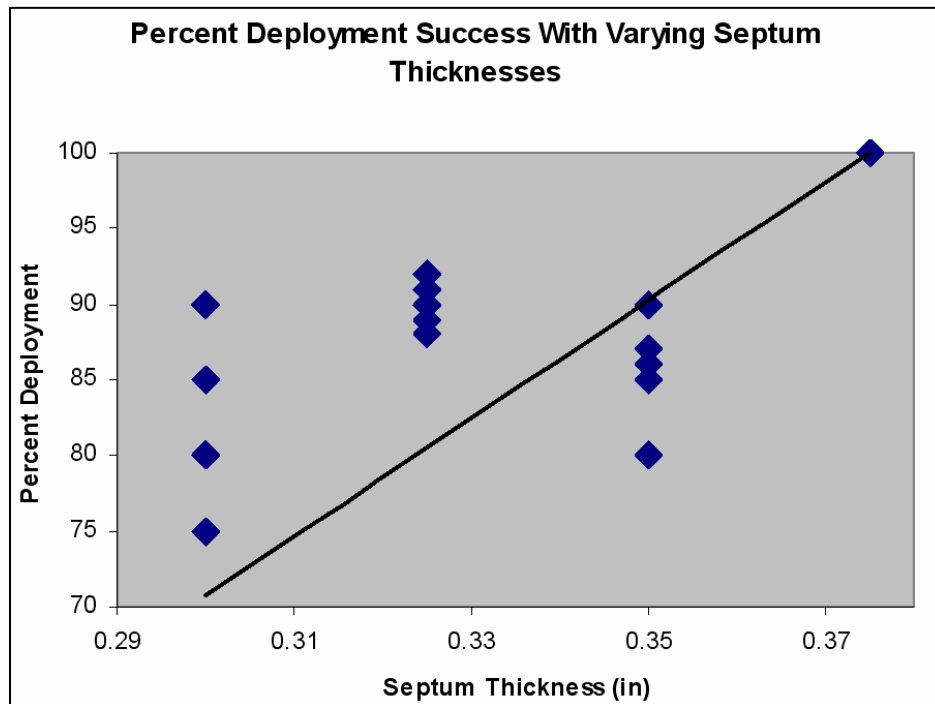
Figure 12: Bottom Plate

This prototype design is an effective solution to the problem of closing up wounds in the nose in the least amount of time possible. The light, handheld design allows the surgeon the efficiency of using only one hand to deploy the staples while leaving the other free to guide the device to the exact position desired. This allows for the greatest possible accuracy and therefore greater patient safety, both in the suturing of the wound and in its healing. Our prototype also has been built to the exact specifications needed to fit into the nose, and with two parallel deployments of staples cover the whole 20mm x 17mm area of the cut can be covered.

Costs of building this device are minimal, especially given the ability of large corporations to mass-produce inexpensive single use devices that can then be thrown away. The prototype itself cost only \$20.00 to build, and even given markup of 200%-300% by retailers, costs should still fit easily into hospital budgets. The possibility of making the handles out of plastic can also cut the price of this item drastically.

Prototype testing was conducted as follows:

- Stapler was fired twenty times into four different thicknesses of Play-Doh™, which simulated different septum widths.
- Percentage deployment was measured by the amount of the staple that was not flush with the plane of the septum after being fired.
- Misfires were counted as 0% deployment.
- This will need to be re-tested when the bottom plate can be modified to crimp the staples.



Generally, the thicker the septum the more of the staple was actually pushed through. Of the 20 tests performed, only one complete misfire occurred (at the thinnest septum width). These results are promising in that respect but further testing will need to be completed when the tools are acquired to adjust the bottom plate to crimp staples. Hopefully this will solve the problem of the staples not going all the way through the thin septums. Also, if absorbable stapes are able to be created to fit our device, they may be easier to fold or crimp at the ends than the steel stapes we currently use.

Conclusion

While the current prototype is far from being used in the operating room, the device does prove to be a feasible solution to the current problem. Our most critical design requirements were met: device size, cost, comfort, and sterility. The only criterion which was not met was in-depth testing of the performance of the device in actual surgeries, but a few more modifications need to be made before that can be accomplished.

Before such testing can be performed, some adjustments need to be made to the prototype. In order to get the staples to deploy entirely through the septum and hold in place, a crimping mechanism must be designed. Modifying the bottom plate of the current device to have semi-circle indentation much like a common paper stapler could be the simplest solution. Also, the current metal staples should ideally be replaced with absorbable staples of the same dimensions which do not exist at this time. More precise manufacturing of the prototype by industrial manufacturers would likely improve the current prototype firing success rate of 95%.

Implementation of the device into the operating room must be precluded by a rigorous testing period in which all aspects of the device need to be examined. One point of concern is the use of absorbable staples in the nose. Because staples have never been used in the nose, it is unknown how the tissue will react. Testing must also be done to determine how well the staples close the wound. Because the current procedure is tedious and takes a relatively long time, there is the possibility that surgeons would be willing to sacrifice quality for expediency. Therefore, the stapling device must be shown to be a legitimate method for closing the wound before its integration into surgery.

References

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Appendix A: Product Design Specification

(Updated December 10, 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 as accurate and reliable in closing the wound as the surgeon is
- Device must be small enough to fit in the nasal passage
- Device should perform equally to current standard procedure
- Safety of patient and surgeon should be maintained up to current level
- Materials must be autoclavable and be able to be sterilized if reusable
- Can cost as much as \$300 for a single time use device and as much as \$1500 for a reloadable, reusable, 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 and misfires
- iii. Suitable grip to prevent slipping

c. Accuracy and Reliability:

Comparable accuracy and reliability to current surgical methods (i.e. Surgeon's stitches) 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 performed with a single device based on further research

e. Shelf Life:

Device will be kept in operation room at room temperature for no longer than 6 months

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. Two popular devices are US surgical endo stitch™ single use suture device and the US surgical GIA reloadable stapler.

Appendix B: Computer Design of Stapler

