Electro-Magnetic Needle Passer for Nasal Surgery

Advisor: Professor Mitch Tyler
Department of Biomedical Engineering

Client: Dr. Benjamin Marcus
Department of Otololaryngology

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

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Abstract

Septoplasty is a common nasal surgery that corrects a deviated septum. To correct the deformity, the mucous membrane must be separated from the septum. Once the deformities have been corrected, the mucous membrane must be reattached tightly to the septum. This is accomplished by inserting a purse-string suture. The suturing process is somewhat lengthy when performed manually, taking approximately 15 to 30 minutes. With operating room costs at about $60 per minute, the suturing time is quite costly. Our goal is to develop a device to reduce the time it takes to place the suture. Our final design concept is an electro-magnetic needle passer that passes a double ended needle between two magnetic coils. The needle is mechanically driven into the septum with a clamping device and held in place with a magnetic field. As the jaws open up, the needle is fully extracted from the septum and this process is repeated until the suture is complete. This term was spent proving our concept of a magnetic needle passer with an up scaled prototype and quantifying the force required to pull the needle from the septum, which was 0.145 lb.

Background

Project Motivation

The goal of this project to is develop a device to reduce the suturing time during nasal surgery. Septoplasty is a common nasal surgery that corrects a deviation in the septum, which is the cartilage in the center of the nose. During a septoplasty, the lining surrounding the septum is removed to expose the septum and correct the deformity. Once the cartilage is reshaped, sutures are used to reattach the lining to the septum. The suturing process can take the surgeon 15 to 30 minutes. With operating room costs being

about $60 per minute, the suturing procedure alone can cost $900 to $1800. The development of an auto-suture device would reduce the suturing time and operating room costs. The surgeon would also free up more time that could be spent on treating more patients.

Nasal Features

The nose is the protuberance that houses the nostrils required for airflow. The septum is the elastic quadrangular cartilage barrier that divides the nose into two chambers. It is approximately 3 to 5 mm wide and is surrounded by a mucous membrane. The elastic modulus of cartilage is approximately 10 MPa, but the properties of the septum can vary from person to person with one having a thick and stiff septum and another having a thin and brittle septum. The nostrils that are on either side of the septum are approximately 10 to 15 mm wide and are very flexible. When there are obstructions of the nasal passageways due to a birth defect or trauma, corrective surgery is often required. [4] [6] [8] [11] [14]

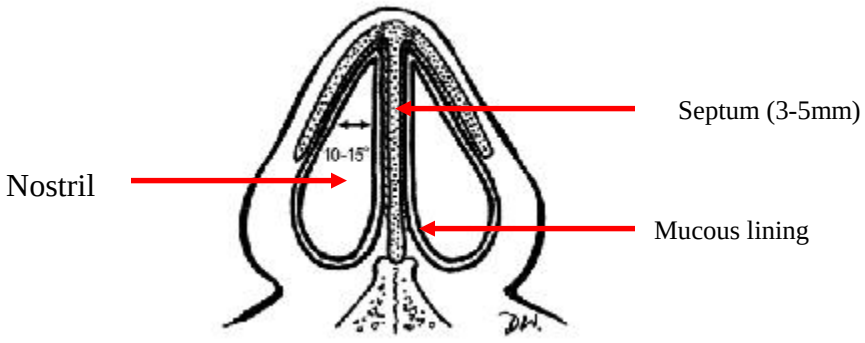

Fig 1: Shown above is a diagram of the nose. The septum is seen in the middle, dividing the nose into two chambers. On either side of the septum is a nostril.

Septoplasty Proce

A misalignment of the nose from the midline, known as a deviated septum (Figure 2), often causes difficulty in breathing and sleeping. The deviated septum leaves a disproportionate opening in the nostrils, leaving one larger than the other. The smaller nostril experiences an impaired flow of air. Though it may seem that the larger nostril would receive a greater flow of air, the opposite is actually true. The mucous of the larger nostril often becomes dried out, often leaving the larger nostril with less air flow than the smaller nostril. A deviation of the septum can be treated with a procedure known as a septoplasty. An initial incision is made along the base of the nose to expose the caudal end of the septum as shown in Figure 3. The surgeon must then decide which portions of the cartilage must be cut, and which must be removed to allow the nose to be straightened (Figure 4). The reason that the cartilage must be removed is to prevent the overriding of the cartilage onto itself in the straightening of the nose. A right angle knife is used to excise the selected sections of the cartilage (Figure 5), and the septum is then swung into alignment. Since cartilage is known to have a "position memory," a Teflon splint is often used to secure the cartilage into alignment to prevent the septum from re-deviating (Figure 6). The initial incision is then sutured in a purse-string suture pattern using nylon absorbable sutures. [10] [11]

Figure 2: Shown above is how a deviated septum may appear on a patient.

Figure 3: An initial incision is made along the base of the nose to expose the caudal end of the septum.

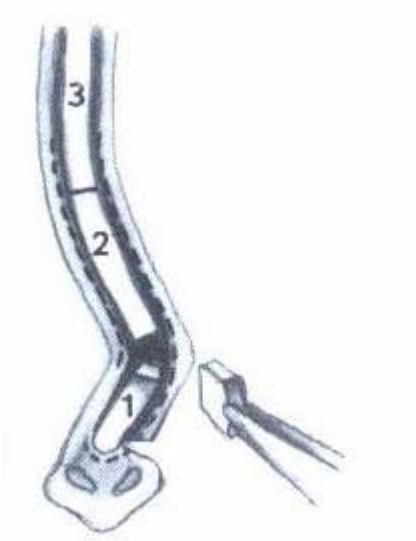

Figure 4: A portion of the cartilage is removed or shaped to straighten the appearance of the nose. The labels on the cartilage are used for surgical purposes.

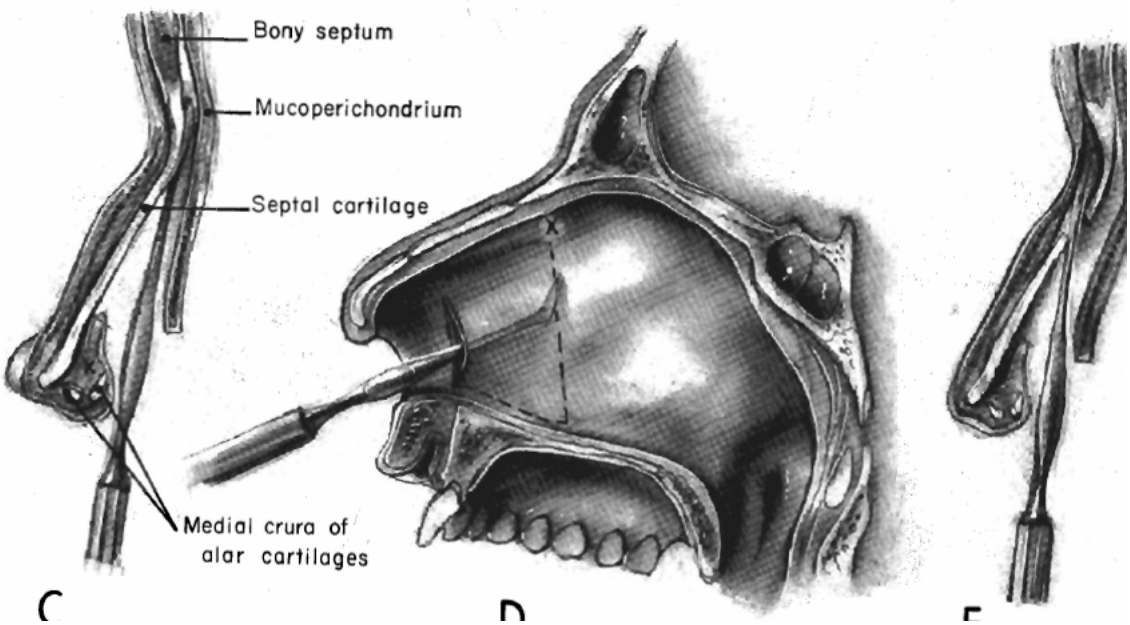

Figure 5: A right-angle knife is used to excise selected sections of cartilage.

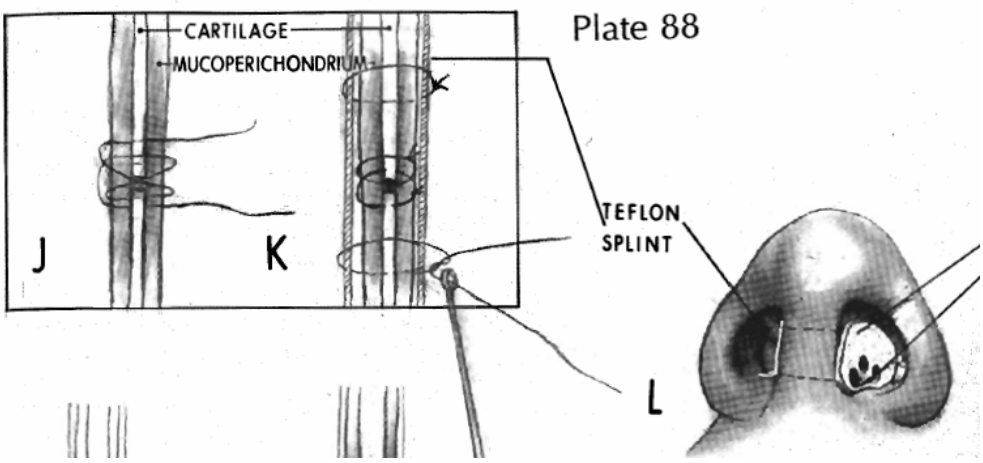

Figure 6: A Teflon splint can be used to secure the septum into alignment and prevent it from re-deviating.

Sutures

Suturing is the surgical method in which polymer fibers are used to join two surfaces. Similar to sewing, suturing is performed with a thread and needle. The needle is typically made of an alloy. The thread can be manufactured to serve many different purposes depending on their use. Sutures must be strong enough to effectively hold together the joined tissue. They must be non-toxic and hypoallergenic to reduce the body's reaction to the material. Additionally, they must be flexible to withstand movement of the tissues. Suture types are categorized according to the type of material they are made of, the permanence of the material (sutures that the body eventually absorbs or non-absorbable sutures that need to be removed at a later date), and their construction (braided, twisted, monofilament). For septoplasty, the sutures used are typically nylon, absorbable, and braided. [6] [16]

Figure 7: A diagram of a braided suture is shown above. Note the multiple fibers are braided together to from a strong thread.

Sutures can be placed in a variety of patterns depending on the procedure. The suturing pattern used in septoplasty to reattach the mucous membrane to the septum is called a purse-string suture. This suture pattern is continuous across the septum and forms a circle (Figure 8). The needle is inverted across the septum to produce this pattern and once the suture is returned to the beginning of the pattern it is cinched tight. This pattern creates a tight hold of the mucous membrane to the septum so proper healing will ensue. [6] [13] [16]

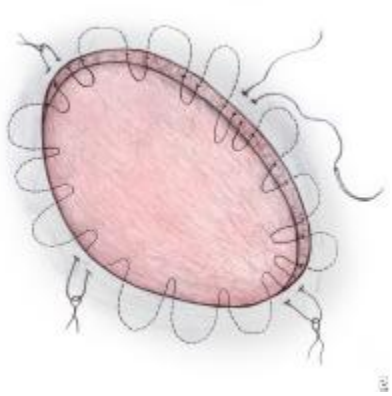

Figure 8: Shown above is a diagram of a purse-string suture pattern. The suture is continuous and circular, returning to the position started in.

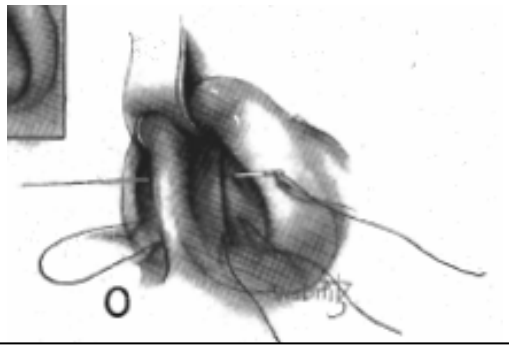

Figure 9: The suturing process in the nose is continuous across the septum and in a circular pattern from the front to the back of the nose and finishing in the front.

Current Device

There are many auto sutures available commercially. However these devices are made for large scale surgeries such as bowel surgery. These devices are much too large for use in nasal surgery. The procedure for these auto suture devices is also different from the nasal procedure. As described in the background on the procedure, the needle passes from one side of the septum to the other. In procedures such as bowel surgery, two flaps of skin from an incision are sutured together. Figure 10 below shows the difference between the two surgeries.

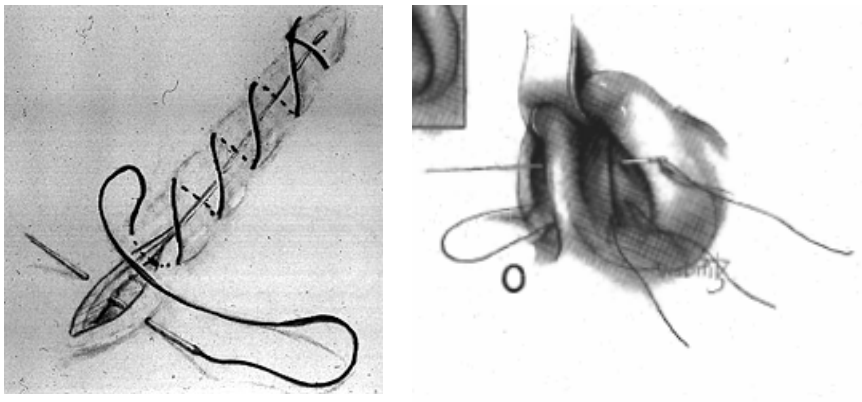

Figure 10: The difference between suturing in endoscopic surgery and nasal surgery. In nasal surgery, the suture is placed across the septum and in endoscopic surgery, tissue is stitched together.

One current device that is too large for the nasal surgery but has a mechanism similar to what we are interested in is the Endostitch by Tyco.

Figure 11: The Endostitch by Tyco is shown here. The needle is passed between the left end and controlled from the right.

The device is shown above in Figure 11 and with more detail in Figure 12. When the bar, labeled 21, is pulled down it causes the two arms to come together at the distal end. As they come to together, the element in the middle (70) rotates which shifts the inner rod (46a) in the top arm up and the inner rod (48b) in bottom arm down. As the rod in the bottom arm moves down the needle (36) is forced out of the opening, and the needle will slide into a slot in the top arm (34a) and lock into place. With release of the lever, the two arms separate and the needle is pulled to the opposite side of the tissue.

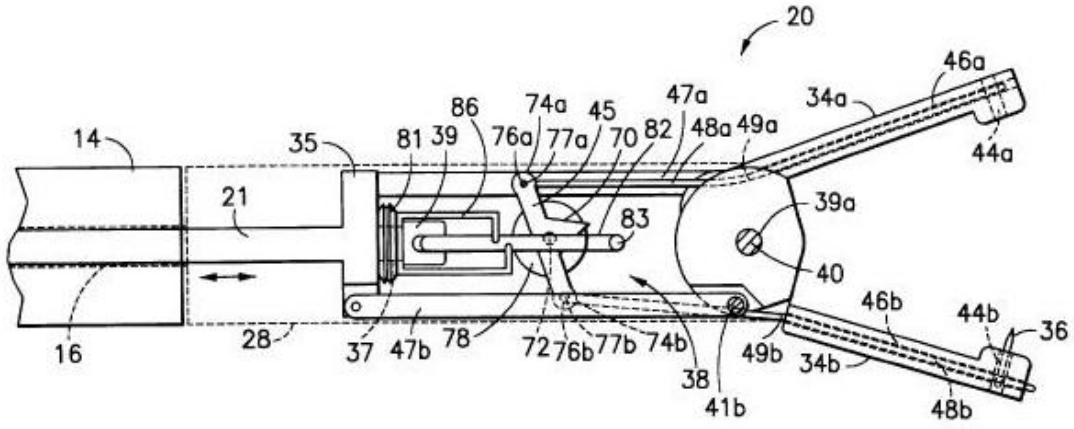

Figure 12: Here the mechanism of the Endostitch is shown in detail. The needle is passed from 48b to 46a.

Figure 13 shows the distal end of the device and the mechanism that locks the needle into place. As the rods (48b) slide up and down, the needle (62a) will slide into a slot on the opposite side of the device. A lock (52b) will move down into the groove of the needle and lock it into place. While the Endostitch will not work for our client because of its size, the mechanism that it utilizes has been helpful to understand how some auto sutures work. [1] [9]

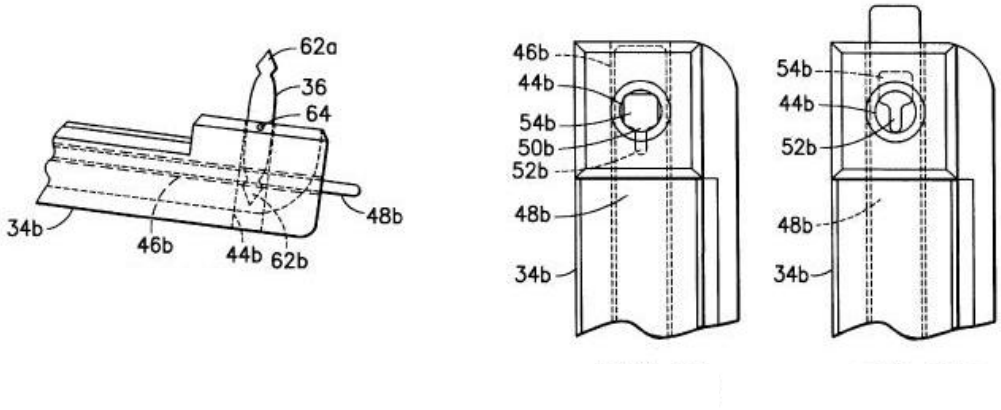

Figure 13: The distal end of the Endostitch is shown. The rod, 48b, slides to release the needle which will lock into place at 52b.

Design Constraints

The main areas to consider when developing the auto-suture device are its performance, its safety to the patient, and the size and cost of the device.

Performance

The main constraint of this design is that is must reduce the suturing time of the current manual procedure. Currently, it takes the surgeon 15 to 30 minutes to suture the patient. Our client would like the suturing time to take a maximum of 10 minutes, but would prefer the shortest time possible. The device must be reliable, meaning that it should not fail or malfunction during the procedure. Additionally it should mimic the current

suturing procedure to ensure the security of the suture. Also, by developing a product that closely mimics the current procedure, surgeons are more likely to accept it into their practice.

Force

Our design uses a mechanical clamping device to drive the needle into the septum and requires the electromagnet on the other side to hold onto the needle as it is pulled from the septum. The force the magnet is required to generate to adequately pull the needle from the septum is about 0.8 N.

Patient Safety

Because the device is used in an invasive operation, it must either be one-time use or autoclavable, which greatly influences our material choices. Also, it must be sterile upon use to reduce incidence of infection. The device should be easy to operate and contain a mechanism that ensures that the needle can't be misplaced and potentially harm the patient.

Size

The device must fit within the confines of the base of the nose, which is about 10 to 15 mm on either side of the septum. Since the suturing takes place right at the base of the nose, there is some flexibility in the size provided that the part that holds the needle be able to fit in the above area, while the rest of the device could be outside. Also, it must be able to penetrate the septum which is 3 to 5 mm thick and composed of cartilage.

Cost

If the device is one-time use, it should cost no more than $300. If it is for multiple uses, it should cost no more than $1500.

Materials

To construct our device, material selection is dependent upon whether the device will be a multiple or one time use device. If it is a multiple use device, then an autoclavable material like metal or medical grade plastic can be used. These materials must withstand heat up to 121 ^{o}C and pressures up to 15 psi for 15 min. If however, the device is one-time use, a sterilizable plastic can be used. Additionally a multiple use device would have to be made of a durable material to increase its lifetime. Because the surgeon is handling and maneuvering the device in a precise manner, the device should be lightweight and therefore made of a material with a small density. To reduce costs, the price of the material must also be considered, but performance is the main factor. [2] [3] [12]

	Titanium Composite	**Stainless Steel Grade 420**	**Medical Grade Plastic (PEEK)**
Density	4.42 g/cm3	7.75 g/cm3	1.32 g/cm3
Working Temperature	450°C	400°C	249°C

Table 1: In the table above, three materials could be considered for an autoclavable device. Note, the lightest is medical grade plastic and the one with the highest working temperature is titanium.

Alternate Designs

Prior to choosing an electro-magnetic needle passer, we analyzed several other options.

Design I: Mechanical Needle Passer

Design I uses a mechanism similar to the current device used on bowel surgeries, the Endostitch. It utilizes a needle with two arrow-head endings and a hole in the middle to hold the suture. The physician would push down a button that is attached to a compression spring which attaches to the two arms of the device. This will cause the two arms to move together. As the button is compressed the physician will pull back on the lever with his thumb. This will rotate a pin and cause a rod in the left arm of the device to move up, and the rod in the right arm to move down. As the left rod moves up, the needle will be released from the notch and be forced out by an incline within the needle slot. Meanwhile, the right rod will slide down and the notch will lock the other end of the needle into place within the right arm. When the button is released, and the two arms come apart, the needle will be on the opposite side of the septum. Even though the button has been released, the lever is still in the upper position. To move the needle back to the other side of the septum, the button will be compressed again by the physician. As the button is compressed, the physician will move the lever back down into the original position. This will cause the rod in the right arm to move up and release the needle, while the rod in the left arm will move down and relock the needle on the original side. When the button is released, the arms will move apart and the needle will be on the original side of the septum. Figure 14 shows design I.

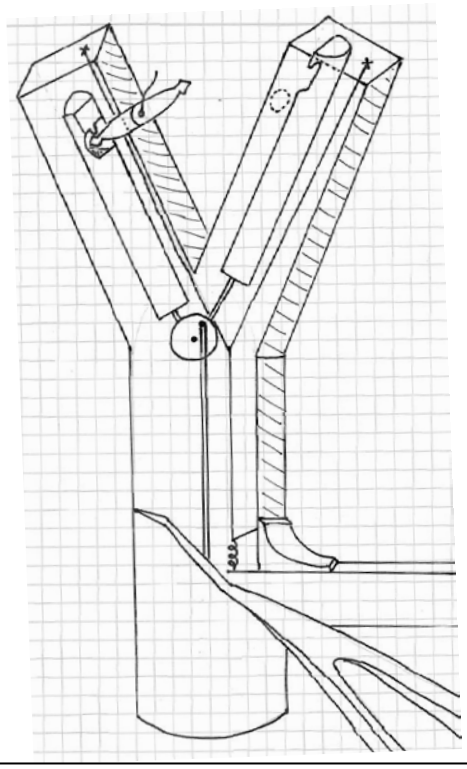

Figure 14: Design I is shown above. The needle is passed from each arm. When the button is pressed, the drum rotates which moves one bar up and the other down. At the same time, the lever is pulled back to bring the arms together and the needle is effectively locked into place with notches in the arm.

One advantage of this device is that it would allow the surgeon to mimic the current procedure so it would be more easily accepted by physicians. It is also easy for the physician to vary the size and number of sutures depending on the individual surgery and the size of the septum. However, this design contains many small parts which will make it difficult to manufacture and also difficult to autoclave if constructed as a multi-use device. Another drawback to this design is that it involves two different mechanisms to operate, the button and the lever. This will require some dexterity from the physician.

Design II: Mechanical Clamp

Our second design is a circular mechanical clamp. This clamp would be contoured to the shape of the nose where the suture needs to be placed. On one side of the clamp there are raised hollow blocks and the other side has complementing slots creating a channel when the clamp is placed together. The clamp is inserted on either side of the septum which allows the septum to create a pattern of peaks and valleys where the suture is needed to be placed. With this pattern formed, the suture can be manually inserted through the hollow blocks which allow it to only pass through the peaks and avoid the valleys. The clamp is removed and a purse-string suture pattern is in place. This device eliminates the manual passing between nostrils across the septum and allows the suture to be inserted in a straight manner, which would decrease suturing time.

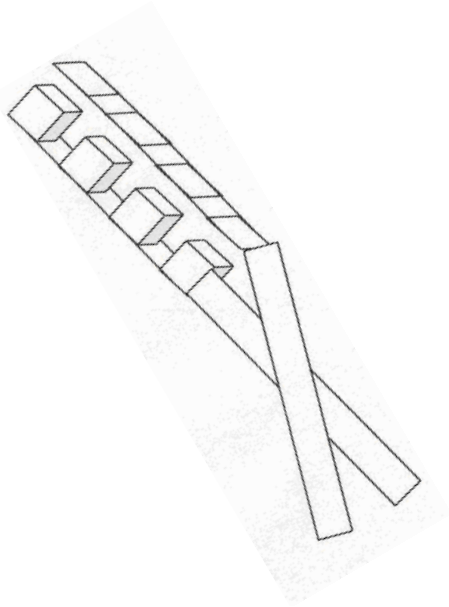

Figure 15: The clamping device is shown above. The clamp would be circular, only a straight portion is shown. On one side there are hollow blocks and the other are slots to fit between the blocks. The septum forms around the blocks when the clamp is placed on either side.

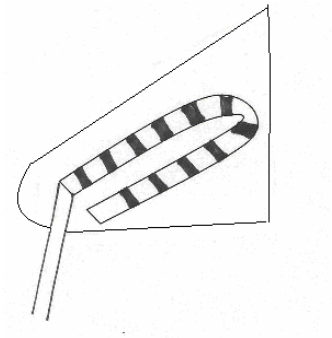

Figure 16: Here is a side profile of the nose with the clamp in place to show the shape of the clamp. The septum would be raised in the portions that are not shaded.

This design is a very simple mechanism which would allow it to be manufactured fairly easily and inexpensively. Additionally, because the surgeon is manually inserting the suture, it is as safe as the current procedure. A drawback of this design is that it is not adjustable to the size and shape of specific noses or to the number of sutures that the surgeon may require. Therefore the design may not be suitable for all patients. Also, because the surgeon is manually inserting the suture, the device is not automatic and merely assists the positioning of the sutures.

Design III: Magnetic Needle Passer

Our chosen design is much like our first design alternative in that it passes a needle back and forth between the two arms of the device. The difference in this design is how it works. This design utilizes magnetic fields to secure the needle in either arm. Coils of wire are located in the ends of each arm. When a voltage is applied to the coils, they generate a magnetic field. A switch inside of the device, controlled by a button on the handle, would complete or break the circuit to each arm every time it is pressed. This will turn on a coil in one arm while turning off the coil in the other arm.

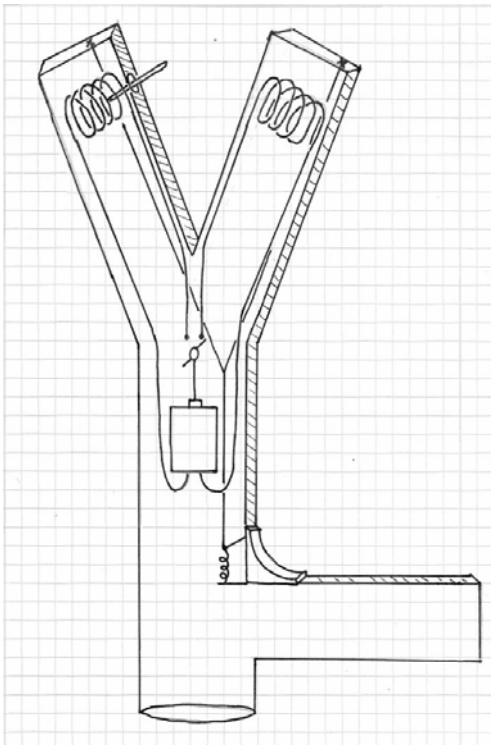

Figure 17: Shown above is the Magnetic Needle passer. The needle is held into place by a magnetic filed that is turned on or off on one arm.

The best quality about this design is the simplicity of the mechanism. By having very few moving parts, this design would be much easier to manufacture than our first design. Having only one switch, this device would also be slightly easier to operate. The design also mimics the actions of the doctor during the current procedure which increases the chances that our product would be accepted into the medical workplace. The design would also allow the doctor to place a variable number of sutures as different size noses require a different number of sutures.

The biggest problem with this device is trying to design coils that will produce a strong enough magnetic field to hold the needle securely. Designing the coils to produce this field could require the device to be too large or produce too much heat for practical

use. Currently, we can calculate the value of the magnetic field due to the coils and correspondingly the force on the needle.

Design Matrix

The design matrix below shows the criteria by which we judged our designs. When deciding how to weight each category, we decided that the time it takes to perform the sutures was the most important, as this is the entire goal of our project. Safety is always important in a design, but we also decided to weight the similarity of our designs' actions to the current procedure. Doctors are hesitant to change their current practices, and by mimicking the current procedure with our design the chances that they will adopt our device are improved. We weighted size less because all our designs were created to fit in the confines of the nose, and their ranking is based on how much extra room they would offer. As shown in the matrix, our third design beat out the other two designs. When presenting our designs to our client we will stress that this was the design we think best suits his needs.

	Design I	**Design II**	**Design III**
Suturing time (15)	11	8	13
Cost (5)	4	5	4
Manufacturability (5)	1	4	3
Safety (10)	7	9	6
Mimic procedure (10)	8	5	8
Size (5)	4	1	3
Total (50)	**35**	**32**	**37**

Table 2: The table above shows the evaluation of our three designs. The designs were rated on suturing time, cost, manufacturability, how well it mimics the procedure, safety and size. The third design received the most amount of points from the design matrix.

Force Testing

After receiving input from our client and analyzing our design matrix, we chose to pursue the magnetic needle passer. This design mechanically drives the needle into the septum and requires the magnet on the other side to pull the needle from the septum. Our major design constraint for this device is the amount of force our magnet must generate to pull the needle from the septum. We measured this force using a strain gage in a Wheatstone bridge configuration mounted on a cantilever beam.

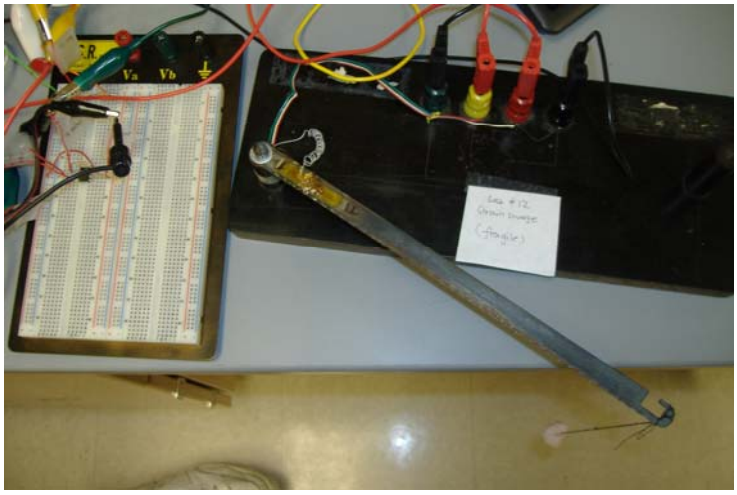

Figure 18: The strain gage setup is shown here. The end of the cantilever beam shows the needle connected with the sample.

We calibrated the strain gage by attaching known weights to the end of the beam and recording its corresponding voltage. We obtained a linear calibration curve as seen below.

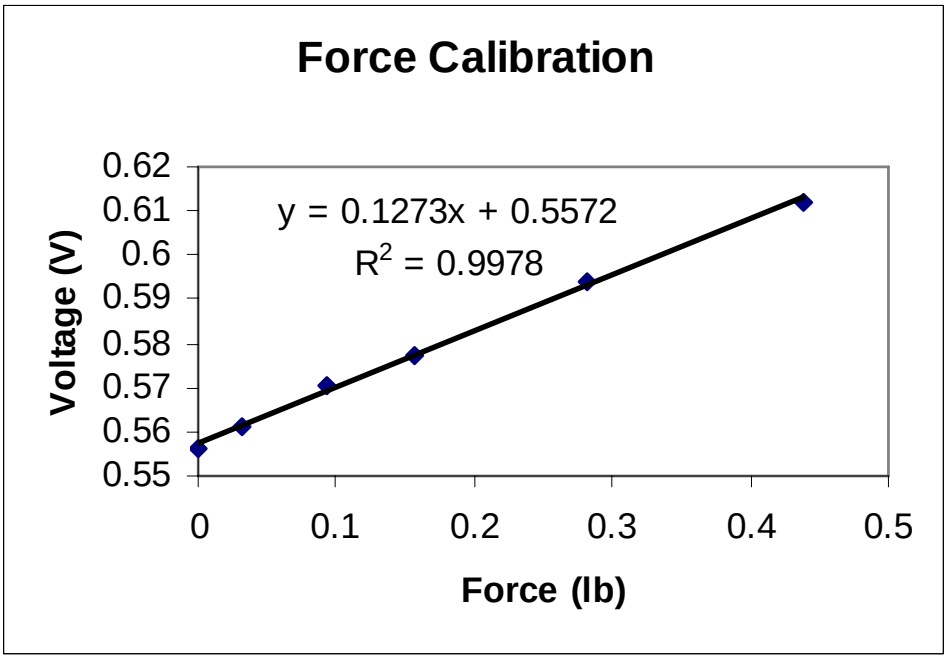

Figure 19: The calibration curve shown above was obtained from recording the voltage outputs associated with known weights. The data was fit with a linear regression: y=0.1273x+0.5572

We tested three materials: salt pork was used to model septal cartilage which was recommended to us by our client; we also tested chicken breast and ham steak to observe material differences. The test was performed by attaching a needle to the end of the beam and inserting into a 6 mm thick portion of meat. The needle was then gradually displaced until it was removed from the material and the maximum output voltage was recorded. The test was performed ten times for each material and the results are shown below.

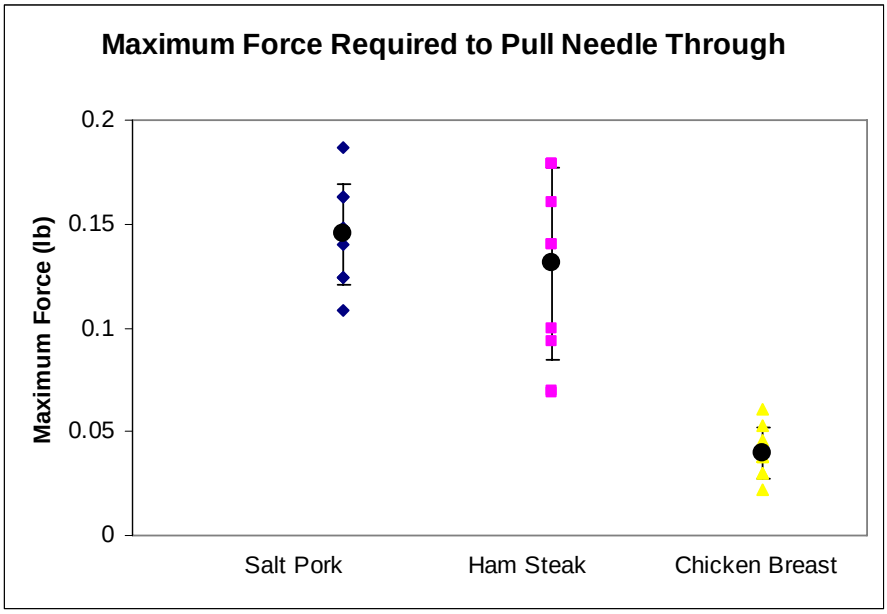

Figure 20: The results from the three materials are shown above with the mean in black with plus or minus 1 standard deviation.

The three materials ranged in pull force and consistency. The chicken breast required the least amount of force and was the most consistent which indicates a relatively homogeneous material. The salt pork required the most force and was fairly inconsistent which indicates a more heterogeneous material. The ham steak required slightly less force than the salt pork and was the most inconsistent. Because of individual differences in cartilage composition, we expect the force required to pull the needle from the septum to range within these values. To ensure that our device adequately removes the needle from the septum, we will require the magnet to produce a pull force of the maximum force recorded which is 0.187 lb.

Electro-Magnet Prototype

Our electromagnets consist of just a coil of wire wound around a spindle. When current is passed through the wire, a magnetic field is generated that runs through the center of the spindle. By inserting a magnetic core, the field strength in the center can be increased because the metal concentrates the magnetic flux lines. The equations that govern magnetic fields show that the field strength inside the spindle is proportional to the turns of wire per unit length. So, when scaling down our prototype, the field inside the core will be the same, assuming the same gauge wire and amperes are used. The field strength outside of the center of the spindle is proportional to one over the radius of the loops of wire. When scaling down our prototype we will be reducing the radius of the loops and therefore increasing the strength of the field outside of the core.

The design that we chose to focus on is represented by our prototype. It consists of two electromagnets, two coils of wire with a metal bolt for a core, mounted in a pair of tongs used to represent our clamping mechanism. The prototype uses 22 AWG wire with about 160 turns around the spindle. Four volts are applied across the ends yielding around four amps through the wire. These magnets can hold onto the needle with around .083 N of force. The physician would mechanically clamp the jaws closed, forcing the needle partway through the septum. The magnet on the other side of the septum would then turn on, holding the needle as the jaws are opened pulling the needle all the way out of the septum. The physician would then clamp the jaws closed again and this procedure would be repeated 10-12 times until the full purse string suture had been created. Figure 21 shows a sequence of how our device works.

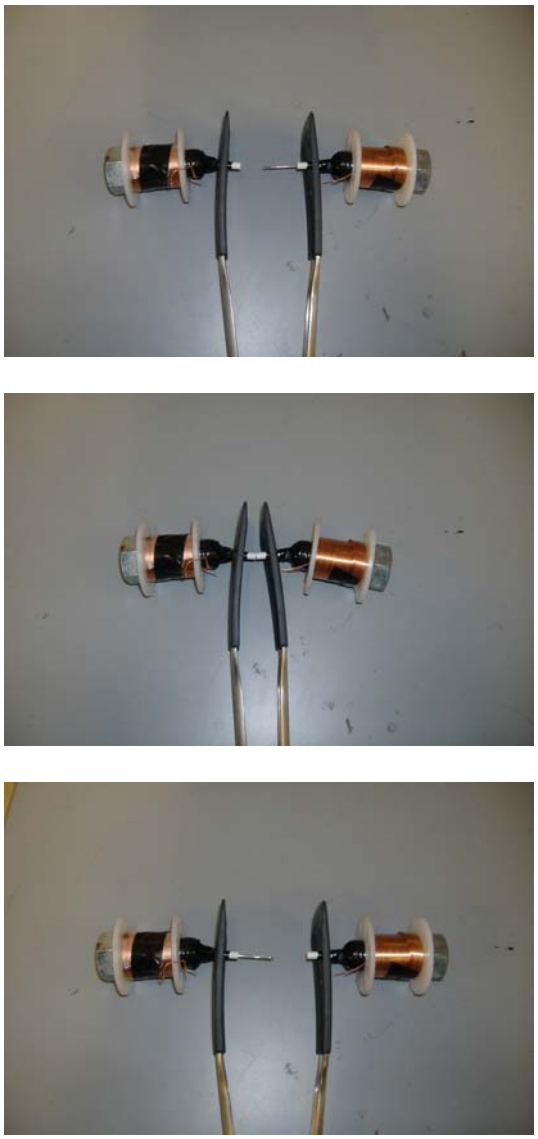

Figure 21: When the needle is on one side of the device with that electromagnet holding it in place. The clamp is then closed until the two sides meet. The power supply is then applied to the opposing electromagnet and the clamp is released leaving the needle in the opposite side.

Materials and Cost

Our material costs were minimal this semester. The table below shows our total as $55, however the power supply would me a one time cost because it could be reused and could potentially be adapted to current hospital equipment. The disposable items only cost $15, which is far less than out allotted budget.

Material	Amount	Cost ($)
Coil	2	5.00
Iron bolt	2	3.00
Switch	1	2.00
Tongs	1	5.00
Power Supply	1	40.00
Total		55.00

Table 3: The above table shows a list of materials and costs associated with our prototype. The costs were minimal for this first generation prototype.

Future Work

While our current prototype does effectively pass the needle from one electromagnetic coil to the other, it will need to be scaled down. The device tip must be small enough to fit within each nostril which range from 10 to 15 mm in width. Because most of the suturing takes place at the very tip of the septum, the entire device does not have to fit within the nose. A typical needle used in a septoplasty is 0.07mm in diameter. Our needle will need to have two sharp ends so it can move from one nostril to the other through the septum. It will need a hole between the two ends to hold the suture as the needle moves through the septum until the purse string suture pattern is complete. The current needle used in this surgery is curved, and we are not sure that we will be able to find a needle that will meet our specifications. If we cannot find a needle that will work, we may need to construct our own. Also, the electromagnetic coils will need to be reduced in size to around 1 cm wide. While the coils do not actually need to fit within

the nostril, the reduction in size will make the device much easier for the physician to handle.

As mentioned previously, the downscaling in size will actually increase the magnetic field generated by the coils. However, the force currently generated by our device is not sufficient to pull the needle though the septum, even when the magnetic field is increased by the size reduction. We have already begun looking into use of permanent magnets that will be mechanically moved to help pass the needle. The combination of permanent magnets in correlation with the electromagnets will increase the force on the needle and help pull it though the septum. The permanent magnets are only about 1 cm in width and they generate about 0.1 lb force.

We would like to develop a plastic casing around the clamping mechanism. This casing would house an automatic switch. When the device is clamped together, a switch would flip simultaneously turning the desired coil on and the opposite coil off. This will pull the needle to the desired side of the septum before the clamping mechanism is released and the needle will end up on the desired side of the device and septum. We also want to look into a reverse polarity switch that will actually cause one coil to repel the needle while the other attracts it. This will also increase the amount of force acting on the needle to help it pass through the septum.

Once we build a more complete prototype that generates enough force to consistently hold onto the needle as it is pulled from a portion of salt pork, we would like to test our device on human cartilage.

Ethics

Because there are auto-suture devices on the market for large scale surgeries, there must be consideration to not infringe the intellectual properties on those designs. Our electro-magnet prototype is not similar to the mechanical devices on the market, but if our design changes in the future we need ensure that the design is not similar to the Endositch by Tyco. [1] [5]

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Appendix A

Product Design Specification

Auto Suture Device

(February 8, 2007)

Members:

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

Problem Statement:

Our goal is to develop a device which will automatically deploy a purse-string suture to close an incision in the nose which commonly detached in nasal surgeries. The traditional suturing procedure is tedious and time consuming, often taking 15 minutes or more. Our client would like to develop a device which will automatically suture the desired location with minimal surgeon involvement.

Client Requirements:

√ Device should be accurate and reliable: The client requires a device that replicates the current suturing procedure that includes about 10 passes of the suture in an area of 2 cm x 2.5 cm where the lining is stripped from the septum. For the device to be effective, the device should close the area in less time than it takes to do manually. Reliability indicates that the device will not fail during the procedure and accuracy indicates that lining of the septum will be secured.

√ Safety of patient and surgeon should be maintained: The device must contain proper safety features to ensure that the needle does not puncture the patient or surgeon while using. Also, the device should only close the desired area and not inflict any additional injury.

√ Materials must be auto-clavable and/or be able to be sterilized: Because the device is used in a medical procedure, it must be sterilizable. Either a material that can withstand the high temperature of the autoclave (121ºC) or Ethylene oxide sterilization is acceptable which can include plastics.

√ Can cost as much as $500 per device: The cost of operating rooms is at least $60/min. The current manual suturing of the nose takes 10-15 minutes, costing$600-$900. The device must reduce the time it takes to suture manually so there is incentive to buy the product and in turn save money spent on the operating room.

1. Physical Requirements:

a. *Performance:*

i. Either a one time device or a reusable device is acceptable
ii. The device must reduce the manual suturing time

b. *Safety:*

i. Unnecessary sharp end or edge must be avoided. The suture needle should be the only sharp edge on the device so no harm to the surgeon or patient is accidentally induced.
ii. If the device is automated, a lock should exist to prevent slipping of needle before the auto suture is activated so the suture doesn't pucture an area that it is not supposed to. If the device is semi-automatic or manual, the surgeon will have control over the placement of the needle.
iii. Suitable grip to prevent slipping should be included so the surgeon does not drop the device and inadvertently puncture the patient.

c. *Accuracy and Reliability:*

The device should be accurate in the sense that the sutures are deployed in the same manner as manually. The device should be reliable in that it can not fail during a surgery. In general, the device should be as accurate and reliable as the surgeon.

d. *Life in Service:*

i. If disposable, one use only.
ii. If reusable, the device should last for 5 years, or a maximum number of surgeries as to be determined by the performing surgeon.

e. *Shelf Life:*

Device will be kept in operation room at room temperature (25˚C)

f. *Operating Environment:*

i. Device should only be used within the operating room
ii. Function is performed in the nasal area, therefore must not be porous or contaminated. After the surgery, the device must be sterilized.

g. *Size*:

i. Grip: Suitable size for comfortable gripping (8 – 10cm)
ii. Tip: Maximum length should fit in the nose (2.0-2.5cm)
iii. Suture size: one absorbable suture is used and each pass varies between 3-5mm in length; suture passes in and out of cartilage approximately 10 times in a circular pattern.

h. *Weight:*

Must not exceed 2 lbs

i. *Materials:*

Materials compatible with sterility: plastic or surgical stainless steel grade 420 with a tempering temperatures between 204˚C and 650˚C

Must be disposable or autoclavable (must withstand 121˚C).

2. Operational Requirements:

a. *Quantity:*

One prototype

b. *Target Production Cost:*

i. Up to $300 for a disposable device that can be used on one patient only.
ii. Up to $1500 is acceptable for a re-usable device that could have a small, inexpensive disposable part.

3. Miscellaneous:

a. *Standards and Specifications:*

i. Most likely our device would fall into an FDA Class II category. This would mean before we could sell our product, we would submit a Pre-Market Approval form. Our device would then be reviewed by a panel of scientists for qualities such as meeting the devices stated standards, local and/or systemic toxicity after use, and irritation and sensitization, among other concerns. All of these can be found by visiting the FDA site. Since our device will consist of (mainly) a needle, as long as our device has a safeguard where the needle always enters and exits the skin where it is placed and there is little or no chance of accidental stabbing, there shouldn't be too much concern about meeting these standards.

b. *Patient-related concerns:*

i. The device must be sterile, either coming from a new package if disposable, or be able to withstand standard hospital sterilization techniques. These techniques can either be chemical or pressure and heat induced. Therefore, the material must be able to withstand chemical degradation along with pressures of up to 15 psi and temperatures up to 121 ^{o}C.

ii. The device must also have a safeguard (most likely a covering for the needle) where the patient or physician will not get accidentally punctured.

c. *Competition:*

i. Research of similar products has yielded devices that perform sutures automatically. These devices, though, have been designed for specific surgeries and are not able to be adapted easily to perform the sutures required by our client in the confined area of the nasal cavities. As such, our device would be fulfilling a need that could not be performed by devices currently on the market.

Appendix B

Magnetic Force Calculations

Assumptions:

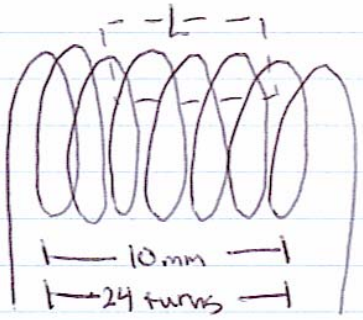
1) the end of our device could not be more than 1 cm in width

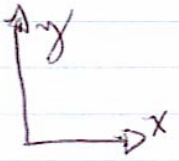
2) use a 9V battery = 50mA in short circuit

3) smallest dia. wire that holds 50 mA = .2032 mm

↳ double to include insulation = .4064

↳ $.4064\,mm \cdot N = 10\,mm$ $\quad N \cong 24$ turns





→ to figure out magnetic field inside coil we use ~~A~~ Amperes Law

$\oint_c \vec{B} \cdot d\vec{\ell} = \mu_0 I N \qquad \vec{B} = \hat{a}_x B_x \qquad d\vec{\ell} = \hat{a}_x dx$

↳ $\int_0^L B_x dx = B_x (x)_0^L) = L B_x = \mu_0 I N$

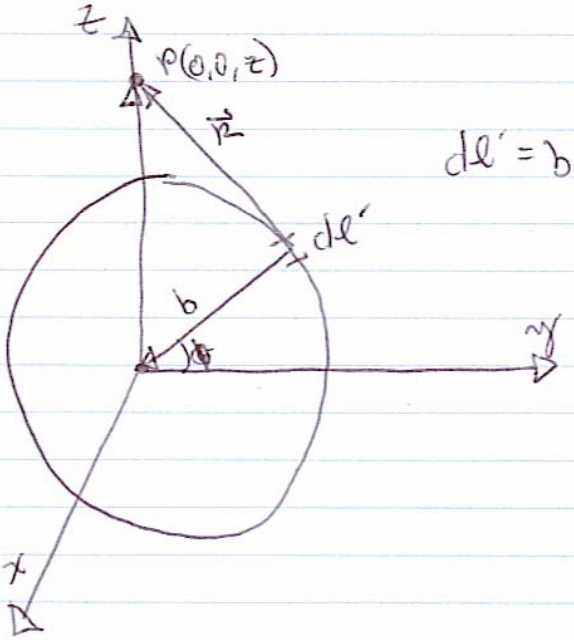
↳ $\vec{B} = \hat{a}_x \mu_0 I \frac{N}{L}$

↳ $\vec{B} = \hat{a}_x (.05A)\left(\frac{24}{.01m}\right)\left(4\pi \times 10^{-7} \frac{H}{m}\right) = \boxed{1.5 \times 10^{-4}\ T}$

→ We would also like to know value of magnetic field outside the coil. We need two additional assumptions to calculate this value:

1) We only need to know the value along the axis extending through the center of the coil (this is where the needle would lie)

2) The contribution from one ~~co~~ loop can be multiplied by 24 to get the field produced by the whole coil



Biot - Savart Law:

$$d\vec{B} = \frac{\mu_0 I}{4\pi}\left(\frac{d\ell' \times \vec{R}}{R^3}\right)$$

$$d\ell' = \hat{a}_\phi\, b\, d\phi' \qquad \vec{R} = -\hat{a}_r b + \hat{a}_z z \qquad |R| = (b^2 + z^2)^{1/2}$$

$$d\vec{\ell}' \times \vec{R} = \hat{a}_\phi b\, d\phi' \times (-\hat{a}_r b + \hat{a}_z z)$$

$$= \frac{1}{r}\begin{vmatrix} \hat{a}_r & \hat{a}_\phi r & \hat{a}_z \\ 0 & b\,d\phi' & 0 \\ -b & 0 & z \end{vmatrix} = \frac{r(bz\,d\phi')}{r} - 0 + \frac{r b^2 d\phi'}{r}$$

$$= \hat{a}_r \cancel{bz\,d\phi'}^{\,0} + \hat{a}_z b^2 d\phi'$$

→ due to symmetry, all contributions in $\hat{a}_r$ direct cancel

↳ $\vec{B} = \frac{\mu_0 I}{4\pi} \int_0^{2\pi} \hat{a}_z \frac{b^2 d\phi'}{(b^2+z^2)^{3/2}}$

↳ $\vec{B} = \frac{\mu_0 I}{2\cancel{4}\pi}\left[\frac{2\cancel{\pi} b^2}{(b^2+z^2)^{3/2}}\right] = \boxed{\frac{\mu_0 I b^2}{2(b^2+z^2)^{3/2}}}$

b = radius of loops
z = distance from center of loop

⇒ $\vec{B} \times 24$ = field due to entire coil

↳ using $b = 5_{mm}$ and $z = 5_{mm}$

$$\boxed{\vec{B} = 5.33 \times 10^{-5}\ T}$$

☆ Permanent magnets can generate fields on the order of 100s of mT at their surface (much greater than our coils could generate)

Appendix C

Force Testing Data

Calibration

Force (lb)	Force (N)	Voltage
0	0	0.556
0.03125	0.139	0.561
0.09375	0.417	0.5704
0.15625	0.695	0.577
0.28125	1.251	0.594
0.4375	1.946	0.612

Salt Pork

Voltage	Force (lb)
0.576	0.148
0.573	0.124
0.578	0.163
0.575	0.14
0.581	0.187
0.576	0.148
0.573	0.124
0.571	0.108
0.578	0.163

Mean: 0.145
SD: 0.024

Ham Steak

Voltage	Force (lb)
0.57	0.1
0.58	0.179
0.566	0.069
0.5661	0.07
0.575	0.14
0.569	0.093
0.575	0.14
0.58	0.16
0.58	0.179
0.58	0.179

Mean: 0.1309
SD: 0.04478

Chicken Breast:

Voltage	Force (lb)
0.562	0.038
0.561	0.03
0.565	0.061
0.563	0.046
0.562	0.038
0.562	0.038
0.56	0.022
0.564	0.053
0.561	0.03

Mean: 0.0396
SD: 0.121