UNIVERSITY OF WISCONSIN – MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 402 – DESIGN

Expandable Nasogastric Tube

Final Report

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Client: Dr. Steven Yale

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Abstract

Nasogastric (NG) tubes are used to either deliver nutrients/medication to the stomach or aspirate gastric contents. These tubes are inserted in the nostril and are navigated through the nasal passageway, down the esophagus, and into the stomach. The diameter of the NG tubes used to remove gastric contents (often called NG decompression tubes) is approximately 6 mm, nearly twice the diameter of NG feeding tubes, resulting in patient discomfort and difficult insertion for clinicians. A larger diameter is necessary to facilitate suction of semi-solids without causing tube blockage or collapse under the applied negative pressure. Therefore, the main objective of this project is to develop a NG tube that can be inserted at a small diameter (approximately the size of NG feeding tubes) and expand after placement to the diameter of current NG decompression tubes. Our design utilized the shape holding abilities of silicone tubing though the compression of an NG tube and future expansion once inserted into its proper functional position.

Background

A nasogastric (NG) tube is a medical device used either for delivery of nutrition/medication to the stomach or for the aspiration of gastric contents. This project is focused on NG tubes used to aspirate gastric contents, often called nasogastric decompression tubes. Such devices are used millions of times annually in the United States alone. NG decompression tubes are used to relieve pressure in the stomach/small bowel when an obstruction is present and to remove gastric contents before gastrointestinal operations or if a toxin has been ingested [1].

To remove stomach contents, a NG decompression tube is inserted into the nostril and navigated through the nasal passageway, down the esophagus, into the stomach. An insertion pathway diagram and a photo of a patient using a NG tube are shown in Figure 1. Once in place, the tube is connected to wall suction, which removes the gastric contents. The general procedure for using a NG decompression tube is as follows. First, the clinician determines the correct insertion distance to properly place the tube in the stomach by measuring the distance from the tip of the patient's nose, to behind their ear, and then down to their xyphoid process. This length is marked on the tube. The tube is then lubricated and coiled near the tip so it will more easily pass from the nasal cavity down into the nasopharynx. Once the NG tube has been inserted and has reached the esophagus, the patient drinks water to help pull the NG tube past the cardiac sphincter into the stomach. The clinician continues to insert the tube until the determined insertion depth is achieved. Next, proper placement in the stomach must be confirmed. The placement is confirmed by pushing air into the NG tube and listening for a “swoosh” sound with a stethoscope over the stomach. Further confirmation is obtained by removing a small amount of gastric contents and measuring the pH (should be less than 4 if in the stomach), and/or performing an X-ray. Once confirmation of the placement in the stomach is obtained, the tube is connected to a continuous suction of 30-40 mmHg or intermittent suction of 120 mmHg, depending on the circumstances. Finally, the NG decompression tube is taped to the patient's face and is usually left in place for anywhere from a few hours to 3 days but could be remain in the patient for up to one week. If continued treatment is needed another NG tube is inserted through the opposite nostril, as extended use in the same nostril can be painful and irritate nasal tissue [2].

The two most critical aspects of NG decompression tube use are insertion and confirmation of placement within the stomach. NG decompression tubes are nearly twice the diameter (12-18 Fr or 4-6mm) of NG feeding tubes (5-10 Fr or 1.7-3.3 mm), making insertion uncomfortable for the patient [5]. A larger diameter is necessary to facilitate suction of semi-solids without causing tube blockage or collapse under the applied negative pressure. The larger diameter also makes it more difficult for clinicians to maneuver and it often takes a great deal of experience to master the proper insertion technique.

Current tubes are also susceptible to kinking or coiling in the back of the throat. Moreover, it is very critical to ensure that the NG tube is inserted in the stomach and that it has not passed down the trachea and into the lungs. Insertion into the lungs can cause extensive permanent damage to bronchioles and alveoli. There have also been cases where nasogastric tubes have penetrated the brain; surgery has then been required to remove the tube [6].

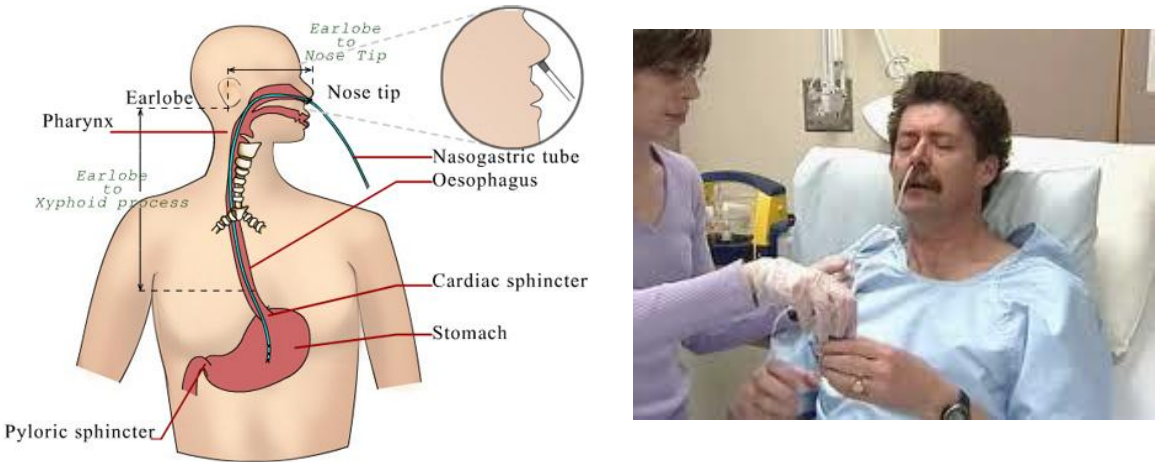

Figure 1: (Left) A diagram showing anatomically correct placement of a NG tube from nose tip, down the esophagus, and into the stomach [3]. (Right) A photo of a patient with a NG tube inserted [4].

Project Statement and Motivation

Although NG tubes are relatively safe and effective in removing gastric contents and relieving stomach distension, there is still room for improvement, especially in the areas of insertion, comfort during the operation and placement confirmation. For example, current NG decompression tubes are uncomfortable for the patient, require sufficient physician skill/experience to properly insert, and often require an X-ray to confirm placement, which adds to medical costs. Aiming to please patients, physicians, and to lower medical costs, the team is pursuing the development of a NG tube that is easier to insert for the physician, more comfortable for the patient, and does not require an X-ray to confirm correct positioning in the stomach. The many constraints of nasogastric tubes will be difficult to overcome, but it is feasible to create a more comfortable and equally effective NG tube as compared to current devices. The client for this project, Dr. Steven Yale, would like the team to pursue an expandable NG tube. In this scenario, the nasogastric tube would be collapsed or have a small diameter during insertion. Once correctly inserted, the tube would expand to make the NG tube functional (able to remove semisolids and resistant to blockage or collapse under suction). The initially collapsed tube would make the device stiffer, enabling easier insertion for the physician (reduced risk of coiling or kinking) and the smaller diameter would be more comfortable for the patient. Thus, an expandable NG decompression tube would benefit both physician and patient greatly. The goal for the first semester of this project was to focus on making an expandable nasogastric tube and the aim of second semester was to focus more on either refining that design, or use the conclusions that had been made and come up with a better design.

Current Devices

Currently there are four different types of nasogastric tubes: the Levin tube, the Salem-Sump tube, the Miller-Abbott tube, and Cantor tube [7]. The most common nasogastric tube is the Levin tube, which is the simplest tube as well. It only has one lumen, and is useful for instilling material into the stomach. The Salem-Sump tube is a two lumina tube; one tube is open to the atmosphere and the other tube is used for aspiration of gastric contents. The advantage of the two lumina system is that it allows for continuous suction of gastric contents [7]. The second lumen also serves as a port to input air to confirm placement in the stomach and to force the tip of the NG tube away from the stomach lining before applying suction. This lumen also allows air pressure to escape from a distended stomach. The Miller-Abbott tube is a two lumina tube as well but is mostly used to evacuate contents of the small intestine. It has a balloon attached to the tip of one tube, and once inside the stomach, the balloon is inflated. Then with the peristaltic movements of the stomach, the balloon and aspiration tube are guided through intestinal tract to remove the contents [7]. The Cantor tube is a single lumen nasogastric tube that has a bag on the end that is injected with mercury. The pressure created by the bag of mercury helps guide the tube along the intestinal tract [7]. Dr. Steven Yale, the client for this project, currently uses a Salem-Sump tube, as shown in Figure 2, so the team is aiming to replicate the function of this particular NG tube.

Figure 2: Currently used NG Salem-Sump tube, manufactured by Bard Medical. This device has two lumina (for air and gastric contents), a closed tip, and an anti-reflex valve to prevent gastric contents from escaping the air lumen [5].

Current NG decompression tubes are made of either polyvinyl chloride (PVC), polyurethane (PU), or silicone. They are between 12-18 Fr (4-6 mm outer diameter) and around 100 cm long. Some more advanced NG tubes have attachments that prevent liquid reflux of gastric contents, which can occur if the lumen becomes blocked. The tips of the nasogastric tube are closed off and the holes for gastric aspiration are on the side of the tube to prevent the tube adhering to the lining of the stomach and causing damage. The tips can also be weighted on the end to help clinicians guide the tube during insertion. Currently, all nasogastric tubes have a radio-opaque strip that runs down the length of the tube to increase visibility on an X-ray. To further confirm placement in the stomach, pH and CO_2 sensor attachments are available. Current tubes range in price from $4 to $40 depending on the type of tube, size of tube, and quantity of order.

Ergonomics

Nasogastric tubes have many constraints since the tube is interacting with visceral organs and epithelial tissue of human subjects. The tube and adhesive that end are used have to be composed of a non-irritating material that is approved for medical use. Since the tube is inserted through the nose, the only way the physician can insert it is by segmental pushing of the tube outside of the nose. The amount of torque a physician can use is small so as not to penetrate and damage the epithelial lining. If the physician is using too much torque, it can be assumed that the tube is not being properly inserted. The tube needs to be flexible enough so it can bend around the junction between the nasal cavity and

nasopharynx. The tube also has to be stiff enough so the physician can guide the nasogastric tube to the stomach without the tube collapsing or coiling up.

Client Requirements

The developed NG tube needs to fulfill several requirements as specified by the client. The first priority of this project is to design a NG tube which minimizes patient discomfort during its insertion. Since the size is one of the biggest factors causing discomfort, the objective is to make the outer diameter of the tube smaller during insertion. A NG feeding tube is less uncomfortable during insertion, so that is the metric being used to determine an ideal outer diameter. A NG feeding tube has a diameter of about 3 mm. The tube also needs to be functional, in that it must enable aspiration of gastric or small bowel contents without collapsing or harming the patient. A feeding tube alone cannot effectively accomplish this aim, because the tube needs to have a large enough inner diameter to remove semisolids. A 6 mm inner diameter has been shown to be sufficient for removal of semisolids. Therefore, the developed design should have an initial outer diameter of 3 mm and expand to a 6 mm outer diameter after insertion. Creating a smaller diameter tube will also improve ease of insertion for clinicians. Additionally, the material chosen for manufacture needs to be stiff enough to resist collapse under the applied suction, yet soft enough to remain comfortable.

Second priority requirements, that will further improve the procedure in general, include providing a method of confirming tube placement in the stomach. This can be accomplished using the industry standard, x-ray, or incorporation of a pH/CO_2 sensor into the device. Another secondary requirement is the incorporation of an anesthetic or lubricant to the tube tip to further improve comfort during insertion. If possible, the client also desires the device to incorporate an element of green thinking. For example, the tube could be made of recycled materials or be recyclable itself. The device should also be cost competitive with existing devices, either through the negation of the need for an expensive x-ray procedure or through decreased fabrication/material cost. However, for prototype development the client would like the team to spend no more than $1000.

Final Design – Last Semester (Fall 2012)

The final design consisted of three main components; the outside sheath, the inner tube, and the sheath removal mechanism. The inner tube is flexible medical grade silicone, Sani-tech 50 from Saint-Gobain. The tubes came in a variety of sizes and thicknesses but we finally settled on one with an inside diameter of 3.97 mm (5/32 in) and an outside diameter of 5.56 mm (7/32 in). This tubing is rigid enough to prevent collapse under suction but flexible enough that the heat shrink tubing is capable of collapsing and holding the inner tube in its collapsed state. The Sani-Tech material has great shape memory and after the sheath is removed it unfolds from a “U” shape into its normal circular shape with minimal deformation. Shape recovery testing will be covered more thoroughly later in the paper.

Figure 3: CAD model of the cross section of the first design alternative, showing a folding inner tube with a sleeve.

Once the silicone tubing was selected, the material for the sheath was selected. The sheath has to be strong enough to hold up to the pressure of the compressed inside tube, but also flexible and subtle enough to slide down the patient's nasogastric passage. Fluorinated ethylene polypropylene (FEP) heat shrink tubing from Zeus Medical was selected for the final design. It has an expanded inside diameter of .197 in, or 5 mm, and a minimum inside diameter after shrinkage of .158 in, or 4.01 mm. The wall thickness is a mere .007 in, or .18 mm, so it adds very little total width to the tube after it is applied. The heat shrink tubing requires 215° C to actively shrink, much lower than the upper safe operating temperature of the silicone tubing at 260° C. This allows heat to be applied liberally without worrying about damaging the inside tubing in the process. The pressure exerted by the heat shrink tubing when it shrinks in on itself creates enough force to collapse the interior tube along the cable running down the length of the tube.

This cable running down the length of the tube is the mechanism for sheath removal. It is 28 gauge (.321 mm) wire that is inserted in the proximal end, through the tube along the perforations to the distal end, and loops back to the proximal end on the outside of the tube. As the heat shrink tubing is perforated every 1 mm out of every 3 mm, when the wire pulls through the perforation, the inner tube releases from the sheath and allows it to immediately expand. The sheath is left in the patient mostly wrapped around the NG tube, until the whole thing can be taken out at once.

Previous Testing

Prototype Development

A majority of the team's time last semester was spent developing and testing the materials and methods of fabrication for the final design described above (2012).

Inner Tube

Medical grade PVC and silicone manufactured by Saint-Gobain were the materials investigated for use as the inner tube. Four different grades of material, as shown in Table 1, were obtained for testing. The materials had a range of stiffness' and all have significantly lower hardness values than NG tubes currently on the market. Several feet of Tygon 100-65, a PVC tubing, and Sani-Tech® 50, a silicone tubing, were ordered. Tygon 3350 and Versilic® SPX-50, both silicone tubing, were only received as 15 cm samples. The dimensions of these tubes were all 3.97 mm inner diameter and 5.56 mm outer diameter.

Plastic Grade	Material	Tensile Modulus (MPa)	Shore A Hardness	Max. Recommended Operating Temp (°C)
Tygon 100-65	PVC	5.6	65	165
Versilic® SPX-50	Silicone	2.9	50	204
Tygon 3350	Silicone	1.9	50	204

Sani-Tech® 50	Silicone	1.2	50	260

Table 1: List of inner tube materials investigated and their relevant properties [8-11].

The objective in selecting this material was to maintain the same inner diameter as NG tubes currently on the market but reduce wall thickness as much as possible. A wall thickness of .795 mm is the smallest off-the-shelf thickness available. If a thinner wall is desired, the tube will need to be custom manufactured. The silicone tube does not melt with the heat required to shrink the tube, but a tapered tip cannot be formed from standard tubing. A custom tube, including the tip design, will need to be extruded or injection molded.

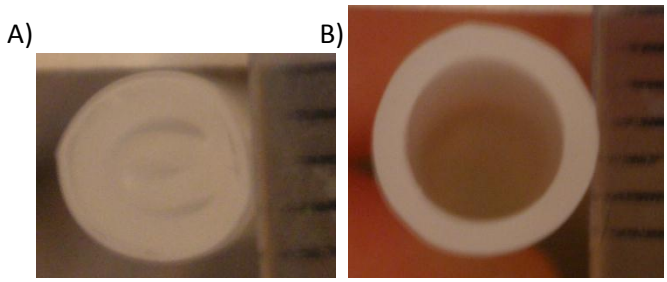

Figure 4: Recovery of Sani-Tech®50 material. A) Sani-Tech®50 shrunken in heat shrink sheath and B) Sani-Tech®50 after sheath removal.

$$Equation\ 1:\ Tube\ Area = \pi {r_o}^2 - \pi {r_i}^2 \qquad Equation\ 2:\ Min\ Collapsed\ Diameter = 2 \times \sqrt{\frac{Tube\ Area}{\pi}}$$

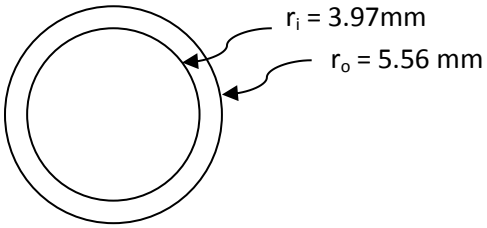

Figure 5: Schematic of approach to calculate minimum possible collapsed tube diameter.

Material	Supplier	Expanded inner diameter (mm)	Possible Shrunken inner diameter (mm)	Wall Thickness (mm)	Heat Needed to Shrink (°C)
PFTE	Zeus Inc.	3.556	2.032	.4064	340
PET	Vention	3.556	2.667	.00635	100-190
PET	Vention	3.302	2.477	.00635	100-190
PET	Vention	4.064	3.048	.00635	100-190
PET	Vention	3.556	2.667	.025	100-190
FEP	Zeus Inc.	5.004	4.013	.2032	215

Table 2: List of HS materials tested and their relevant properties [12-13].

Zeus Inc. sent the team a sample of fluorinated ethylene polypropylene (FEP) The inner tube was successfully inserted and shrunken but a final outer diameter of 3 mm was not attainable.

Pressure to Collapse Inner Tube

Prior to physical testing, the pressure to cause collapse of the 4 inner tube materials above was calculated using Equation 2, where E is the young's modulus, v is poisson's ratio, D is the tube outer diameter, and t is wall thickness. Equation 3 can also be used to calculate the minimum tube wall thickness if 120 mmHg (maximum suction pressure used) is inputted for the collapse pressure. The results are shown in Table 3.

$$Equation\ 3: \qquad P_c = \frac{2E}{(1-v^2)} \times \left(\frac{1}{\frac{D}{t}-1}\right)^3$$

Table 3: Calculated collapse pressures and minimum wall thickness for inner tube materials.

Material	Poisson's Ratio	Collapse Pressure (mmHg)	Min Wall Thickness (mm)
Tygon 100-65	0.33	502.21	.518
SPX-50	0.49	260.07	.635
Tygon 3350	0.49	166.18	.719
Sani-Tech 50	0.49	139.89	.736

Pressure testing was performed using the wall suction mount attachment at the hospital as shown in Figure 7. The pressure exerted on the tubing was increased in increments of 100 mmHg, until the maximum pressure allowable, about 500 mmHg, was reached. The deformation and diameter of the tubes were recorded at each step along the way. If the maximum deformation was reached the value this occurs at was recorded. The results of this testing are shown in Figure 6.

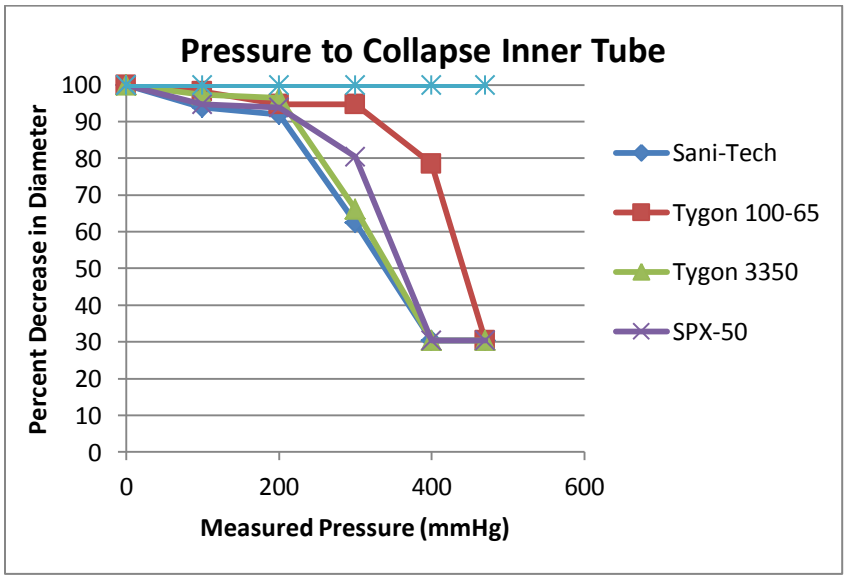

Figure 6: Plot of percent change in diameter with increasing pressure. Current NG tubes do not collapse at any pressure but testing samples collapse although at pressures above suction normally used.

Figure 7: Photo vacuum pump used for collapse pressure testing.

The measured pressure in Figure 6 is the pressure at 50% tube collapse. The results demonstrate that Equation 3 can accurately rank order collapse of the inner tube. The trend line equation could be used to predict actual pressure to collapse a tube to 50% of its original diameter based on the result of Equation 3.

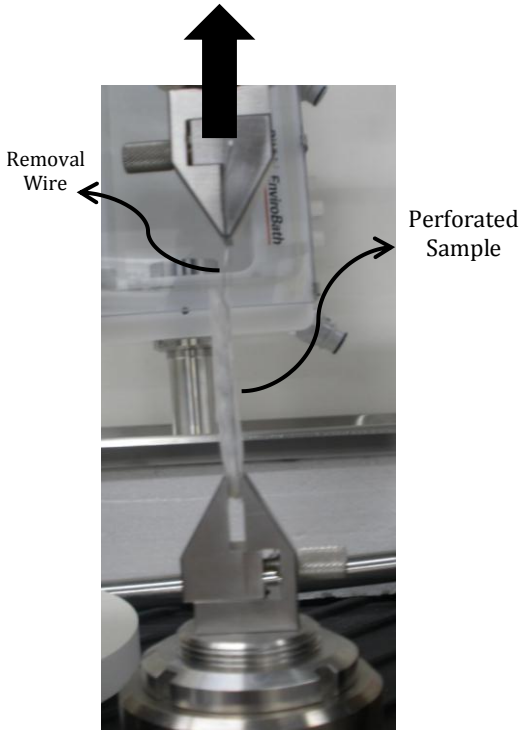

Figure 8: Photo testing setup for measuring force/work to tear HS tubing

Sheath Removal

To aid in design of the sheath removal mechanism, the force and work to remove the sheath was tested with varying perforation patterns. To accomplish this, eight 5 cm prototypes were fabricated, using the method detailed in the upcoming fabrication section. Sani-tech® silicone tubing and FEP heat shrink tubing were used in the samples. Samples were fabricated using two different separation distances, 2 mm and 5 mm, with four samples each. The perforation lengths tested were 1, 2, 5, and 10 mm. In the initial round of testing, prototypes were fabricated using dental floss for the removal thread to replicate sutures. However, the floss failed repeatedly at the grip attachment, so a second round of prototypes using 28 gauge (.321 mm) steel wire for removal was fabricated.

The samples were tested on a MTS machine running Instron at a rate of 50 in/min (1270 mm/min.) The test setup is shown in Figure 8. The bottom grip held the end of the sample and the top grip held the ends of the wire. Care was taken to ensure that the bottom grip only held the silicone and HS tube, not the wire.

Results (shown in Figures 9 and 10) found that the peak force to remove the sheath was consistent across all samples. The work to tear was greatest for the 1 mm perforation, and dropped from there. While the shorter perforations took more work to tear, the larger perforations had torn edge were rougher (Figure 11). Additionally, at perforation lengths greater than 5 mm, the inner Sani-tech® tubing began to bulge out of the sheath when compressed.

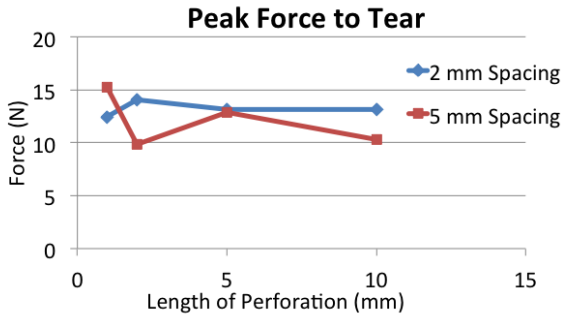

Figure 9: Plot of peak force to tear perforations, illustrating that force is independent of perforation length and spacing.

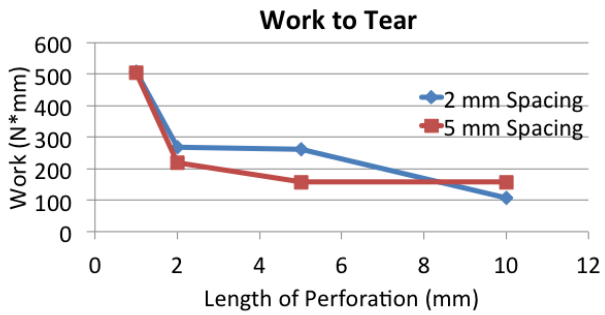

Figure 10: Plot of work to tear perforations, demonstrating that work decreases with increasing perforation length.

Figure 11: Photo of sample with 1 mm perforations with 2 mm spacing (left) and sample with 5 mm perforations with 2 mm spacing (right), demonstrating the bulging rough edge of the larger perforations and full expansion after sheath removal.

Fabrication and Budget – Last Semester (Fall 2012)

Fabrication and assembly of the expandable nasogastric tube begins by gathering the necessary materials as listed below:

Bill of Materials

One-time use:

- 120cm of FEP heat shrink tubing – Preshrunk - 5mm Inner Diameter, 5.36mm Outer Diameter - Shrunk - 4.10mm Outer Diameter
  - $6.93 (with 200 ft, 60.96 m minimum)
- 145cm of medical grade silicone tubing: Sani-tech® 50 – 3.97mm ID, 5.56mm Outer Diameter
  - $13.05
- 260cm + 217.6cm 28 gauge (.321 mm) AWG steel wire
  - $2.04

  Total= $22.02

Repeated use:

- Wooden Dowel – 4.5mm Outer Diameter
  - $0.12
- Medical grade lubricant
  - $6.49
- Utility knife
  - $8.00
- Pipe cleaner(s)
  - $4.99
- Heat gun or hair dryer

- $23.00
- Ruler
  - $1.99
- Marker
  - $4.99

Total= 49.58

The first part of fabrication is to prepare the heat shrink tubing. A length of Fluorinated Ethylene Propylene (FEP) heat shrink tubing is measured and cut to 120cm. The wooden dowel is inserted in the heat shrink tubing to provide a solid cutting surface. A straight line is drawn down the length of the heat shrink tubing. Perforations are measured with a ruler and cut with a utility knife. The perforations are 1mm long with 2mm of separation between cuts. At the ends of the heat shrink tubing, a notch is cut in line with the perforations to anchor the steel wire. A piece of 28 AWG steel wire, that spans twice the length of the heat shrink tubing, with an extra 20 cm, is measured and cut. Applying medical grade lubricant to a pipe cleaner and inserting the pipe cleaner through the heat shrink tubing lubricates the inside of the heat shrink tubing. The entire inner wall of the heat shrink tubing is sufficiently lubricated for ease of assembly.

The second part of fabrication is preparing the silicone tubing. A length of medical grade silicone tubing, Sani-tech® 50, is measured and cut to 145cm. A piece of 28 AWG steel wire is measured and cut to roughly 1.5 times the size of heat shrink tubing. The steel wire is wrapped around one end of the silicone tubing so the silicone tubing is collapsed onto itself in a U-shape. The length of exposed wire is used to pull the silicone tubing through the heat shrink tubing. The assembler lubricates the silicone tubing by rubbing medical grade lubricant along the span of the silicone tubing.

The 28 AWG steel wire, that spans twice the length of the heat shrink tubing, is first fed through the heat shrink tubing. The midpoint of the wire is anchored in the notch of the end of the heat shrink tubing and wrapped around the outside of the tubing. If done properly, the two ends of the wire meet together at the other end of the tubing. Next, the silicone tubing that has steel wire wrapped around one end is fed through the length of heat shrink tubing. The wire attached to the silicone tubing is pulled through the heat shrink tubing. A second person holds the wire that is anchored in the notch of the heat shrink tubing to keep the wire from sliding out of place. Once the silicone tubing is all the way through the heat shrink tubing, the ends of the silicone tubing are cut flush with the heat shrink tubing. The wire inside the heat shrink tubing is adjusted to be in line with the perforations. Two people keep tension on the ends of the steel wire while a third person uses a hair dryer to shrink the tubing. The hair dryer is set to the hottest and highest setting for the quickest shrink time. Heat is applied back and forth down the length of tubing while the two people holding the ends rotate the tubing to ensure even heat application. After three to four minutes of constant heat from the hair dryer, a person then forces the silicone tubing to collapse onto itself in a U-shape. This is done by pushing down with a fingernail on the perforation of one end. Once one end of the silicone tubing is in the U-shape, heat is slowly applied down the length of the tubing to force the remainder of silicone tubing to collapse into the U-shape. Heat is applied for another 6-7 minutes to shrink the two tubes down to a diameter of D_1=3.81mm±0.12, D_2=4.51mm±0.09 (D_2-major axis, D_1-minor axis).

Once the silicone tubing is collapsed onto itself in a U-shape for the entire length of the tubing and the heat shrink tubing is a uniform diameter, the assembly is complete. The assembly for last semester's nasogastric tubing is shown below, Figure 12. This semester a tip will be added, as well as the part on the other end that attaches to the vacuum pump.

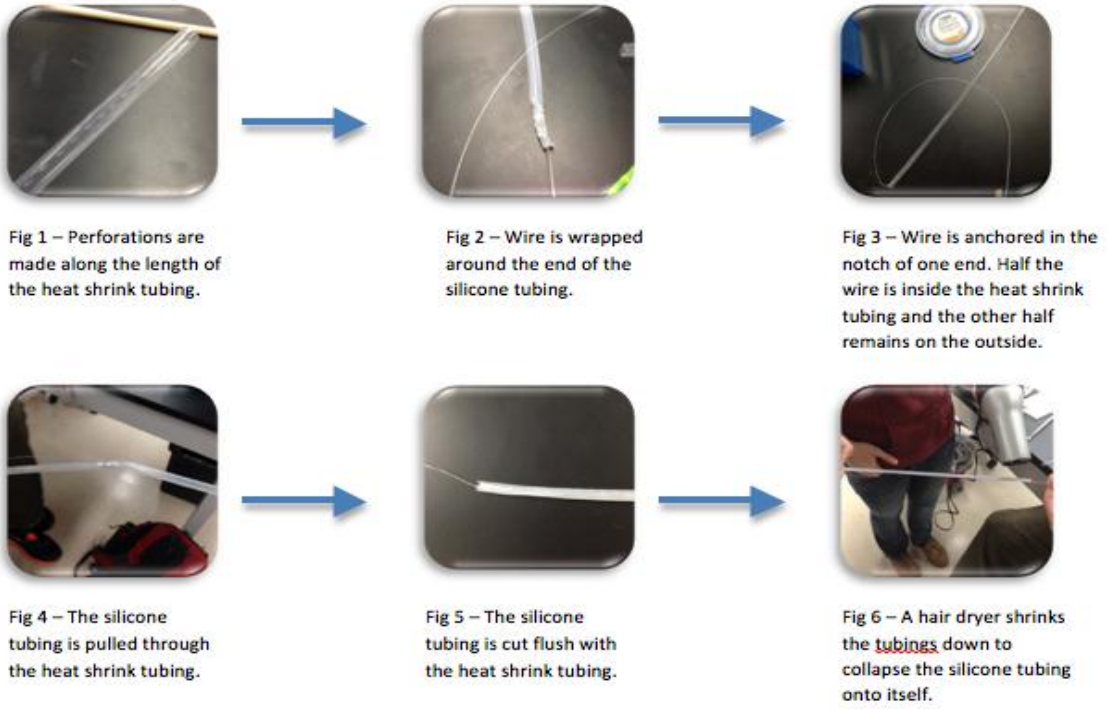

Fig 1 – Perforations are made along the length of the heat shrink tubing.

Fig 2 – Wire is wrapped around the end of the silicone tubing.

Fig 3 – Wire is anchored in the notch of one end. Half the wire is inside the heat shrink tubing and the other half remains on the outside.

Fig 4 – The silicone tubing is pulled through the heat shrink tubing.

Fig 5 – The silicone tubing is cut flush with the heat shrink tubing.

Fig 6 – A hair dryer shrinks the tubings down to collapse the silicone tubing onto itself.

Figure 12: The fabrication process from last semester.

Problems from Last Semester

The heat shrink tubing, when cut by the metal wire, had sharp edges between two perforations; the sharp edges could be irritating to the tissue it's in contact with, shown in figure 13. These sharp edges could also lacerate soft tissue of the stomach, esophagus, pharynx, and nasal passage when the NG tube is pulled out of the patient. The basic function of the heat shrink tubing was to hold the silicone tubing in its collapsed position, so if we could find a better solution for holding the silicone tubing in its collapsed position, we could eliminate the heat shrink tubing all together. No heat shrink tubing will make our NG tube safer; the simpler the product, the better.

Figure 13: Pictures of sample heat shrink tubing tears with sharp edges. The perforations were closer together on in the tube on the right.

Another problem with the heat shrink tubing was its difficulty of removal. Figure 9 shows that it takes up to 15 N of force to initially rip the heat shrink tubing. This equates to over

a 3-pound force. When the tube is inside the stomach, there is no anchor point to oppose the opening force coming from the ripping motion. Because of this, we feel that the ripping motion will only cause the tube to bend upwards causing physical discomfort and will not cause the outer tube to tear. Obviously, some improvements will be needed for this device.

Improvements

To hold the silicone tubing in its collapsed position, there needed to be a silicone-to-silicone bond between the collapsed peaks of the tube. We explored different methods of creating a bond. This bond had to be strong enough to hold the tube in its collapsed position, but weak enough to break when we wanted to expand the tube for functional use; this is the ideal range. The approach was to engineer a method of bonding and engineer a failure to break the bond for functional use.

Silicone Sealant

Silicone sealant is a silicone-based adhesive that bonds to silicone. The silicone that is being used was purchased from Home Depot, and is not meant to be inside the human body. It is toxic, which is not ideal, but the availability, cost, and efficacy of the silicone sealant make this a good option to design a prototype/proof of concept. Application variation methods can be used to determine the best method of reaching this ideal range. With this data grade adhesives can be explored knowing what bond strength is needed.

Biopharmaceutical Silicone Adhesives

To make our ideal NG tube, the components of our product needed to be compatible with soft tissue inside the human body. Using silicone sealant form Home Depot would not make our NG tube safe to use. Using an adhesive that is biopharmaceutical grade would make our NG tube safe for use; the grade needs to be appropriate for being in contact with soft tissue. This past semester, Dow Corning was searched a for silicone based adhesive, a company that specializes in biopharmaceutical silicone products and silicone technologies. Dow Corning offers test samples of different silicone adhesives; samples are 0.45kg (~1lb) and are non-irritating. The ideal silicone adhesive, Silastic Medical Adhesive Silicone, Type A, was found that is biopharmaceutical grade and can be used for our NG tube design.

Die

The heat shrink tubing from last semester was designed to collapse the silicone tubing during heat treatment. Since the heat shrink tubing was eliminated, a method of holding the tube in its collapsed position was needed. The solution was to create a die that would hold the tube in its collapsed position. Our first die was constructed of a 1" x 1" piece of green treated wood. A square of $\frac{1}{4}'' x \frac{1}{4}''$ was cut out of one face of the wood down the length of the wood in the center. A notch of $\frac{1}{8}'' x \frac{1}{8}''$ was cut down the center of the same face. The silicone tube would lay flat in the larger square, down the length of the die. A thin metal dowel (< $\frac{1}{8}''$) is placed on top of the tube, parallel with the length of the die. The dowel is pushed down to force the silicone tubing into the smaller notch; force exerted on the center of the tube causes an upward and inward force on the sides of the tube, collapsing it into a U-

shaped position. The tube is collapsed and stuck in the smaller notch, exposing the collapsed peaks that make contact to form the U-shape. This is where the bond is created with the adhesive.

Final Design

The final design consists of four main components, the tip, the connector, and two types of silicone tubing. The smaller silicone tubing selected was the same as from the previous semester, the flexible medical grade silicone, Sani-tech 50 from Saint-Gobain. It has an inside diameter of 3.97 mm (5/32 in) and an outside diameter of 5.56 mm (7/32 in). As stated previously, it is ideal as this tubing is rigid enough to prevent collapse under suction but flexible enough that it can easily navigate the nasopharynx and esophagus down into the stomach. This tubing was placed in an aluminum die, folded, and adhered to itself with silicone adhesive. The Sani-Tech material has great shape memory and after the adhesive seal is burst it unfolds from the "U" shape into its normal circular shape with minimal deformation. The tube has folded dimensions of 4.16 mm by 5.00 mm, a 33% reduction in volume. The larger tubing is the same type of tubing, Sani-tech 50, but has larger dimensions. The inner diameter is 3.97 mm (5/32 in) and has an outer diameter of 11.0 mm (14/32 in).

Figure 14: Picture of the 3-D printed tip and connector design.

The distal end is the connective piece, which is produced with 3-D printer. A connective piece is needed because the wall vacuum does not fit the smaller tubing. The proximal end of the smaller tube is connected to a larger tube, which is connected to the tip. Our tip, adopted from an MIT design was also produced with a 3-D printer and allows better suction without clogging. Both the tip and connector, attached to the hose, and are pictured in figure 14. The whole design is shown in figure 15.

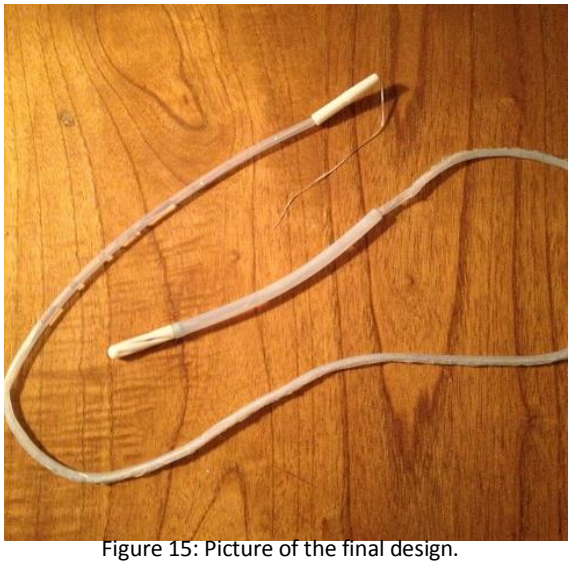

Figure 15: Picture of the final design.

Fabrication and Budget

Budget

Store/Distributor	Purchase	Cost
Home Depot	Silicone Adhesive, Durasteel wire, Silicone Caulk, Green treated Wood, Plastic Glue	$26.22
Walgreen	Ethyl Alcohol	$3.15
Precision Oiler Plus	Precision Applicators	$10.51
Saint-Gobain	Sani-Tech Silicone Tubing: 25' of STHT-C-156-1 & 25' of STHT-C-156-3	$82.16
Grainger	1"x1"x3' square stock Aluminum	$39.71
BME Design	3D printing - tip and connector	$0
Dorn True Value	Hobby knife set	$13.69
	Total	$175.44

Table 4: The budget is split up between the store, the purchases at each store and the cost of those purchases.

Die

As of mid-semester, one die made of wood had been made. A more precise and longer lasting die was later constructed out of aluminum with the accessibility of the College of Engineering Student Shop. The first die was cut with a table saw. The blade of the table saw is $\frac{1}{8}''$ which is why these measurements are in multiples of $\frac{1}{8}''$. The blade was lowered to a height of $\frac{1}{4}''$ (only $\frac{1}{4}''$ of the saw blade is exposed). Two saw passes were made down the length of the wood to cut out the $\frac{1}{4}''$ notch, taking off $\frac{1}{8}'' x \frac{1}{4}''$ each pass. The blade was then raised to $\frac{3}{8}''$, and one saw pass was made down the center of the wood to create the smaller notch of $\frac{1}{8}''$. After fabricating two test silicone pieces using the wooden die, observations showed the dimensions of the tubing was not perfect as the wood deformed and small slits are cut into it if the tubing has to be removed with a razor blade. The aluminum die solved this problem. A chunk of aluminum one square inch by 3 feet was milled down with the same process as the wood die to a tube channel of 5/32” wide with a depth of 7/32”. The aluminum die with the tube inserted and glued is pictured in figure 16.

Figure 16: Picture of the constructed aluminum die.

Fabrication of Connector Piece

Fabricating the connector piece required Solidworks and the FDM 3D printer. Sketching the connector was simply drawing lines that contoured to the outside of the tube, down its length. The sketch was then revolved around a central axis, with the wall thickness adjusted accordingly, and the piece was completed.

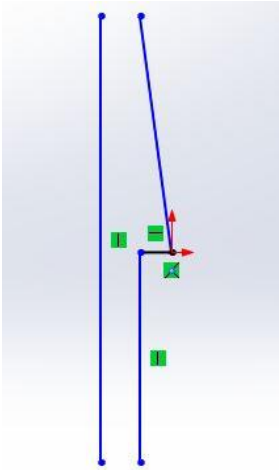

Figure 17: Solidworks sketch of the connector piece before revolving. Right line contours to the outside of connector. Left Line is axis of revolution.

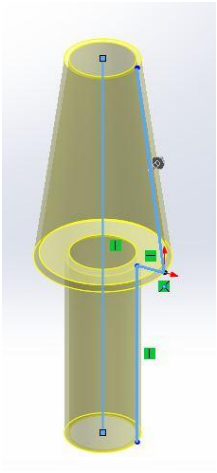

Figure 18: Solidworks revolution of connector piece.

Fabrication of the Tip

Fabricating the tip also required Solidworks and the FDM 3D printer. It was started by sketching the cross sectional area of the hollow tube and extruded to form a hollow cylinder. Then a plane was created that was tangent to the outside of the tubing and in which, angled slots were sketched. Using the wrap feature, the sketch was wrapped around the hollow tubing and the angled slots were then debossed to penetrate into the lumen of the hollow tubing. The dome feature was then used to create the end of the tip. The connection between the tip and the larger silicone tubing was created by sketching two concentric circles and extruding them to the desired length.

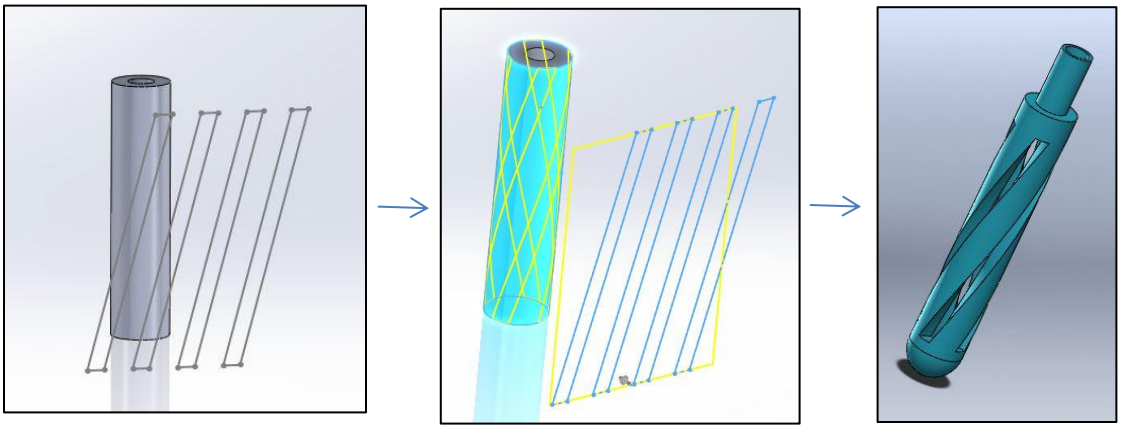

Figure 19: Solidworks progression of NG tip. Left picture is the sketch of the angled slots. Middle picture is the sketch being wrapped onto hollow cylinder. Right picture is final assembly of tip with dome at the distal end and a connector to the larger silicone tubing on the proximal end.

Tube Adhesion

Before testing the silicone sealant on the silicone tubing, the tube was cleaned with 70% ethyl alcohol. The ethanol primes and cleans the silicone and helps prevent the silicone from bonding to the aluminum die. The ideal cleaning agent would react with the outer layer of the silicone tubing to expose the molecular structure; this would make a better bond with the adhesive.

Testing

Needed Glue Distance to keep Tubing Compressed

To keep the tube compressed after it had been glued, glue was placed at different intervals along the tubing. The die was broken up into three different sections of equal length that came out to be 10.2 cm, with three different gluing varieties. The first section had a continuous layer of glue. The second section contained one mm of glue on and one mm off. The third section had 1.5 mm of glue on and 1.5 mm of glue off. The glue was allowed to dry for 24 hours with the tube remaining in the die. When the tubing was removed from the die, immediate expansion was seen in the latter two sections. This showed that if any area of the tube was left open the expanded areas immediately propagated down the length of the tube. The continuous section remained closed until it was forced open.

Expansion of Tube after Pressurized Fluid Insertion

To test how well the tube expanded after it had been sealed, the tube was taken to the simulation lab at the UW Hospital. Water was injected using syringes with pressure applied at a constant force, see figure 20. Three differently sized syringes, 10, 30 and 60mL, were used with two fluids; one compressible fluid, air, and one incompressible fluid, water. To measure the success of expansion, a measurement was taken of the tube after it was taken out of the die as the zero percent expanded value; the 100 percent expanded value was the tube before gluing. Table XX contains the values that were measured.

			Air			Water		
	Initial Values	Max Values	10mL	30mL	60mL	10mL	30mL	60mL
x (average, mm)	4.16	5.00	4.16	4.16	4.20	4.16	4.24	4.58
y (average, mm)	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
Expansion (%)	0	100	0	0	5	0	10	50

Table 5: Tube measurements taken before expansion, before gluing, and of each scenario.

Figure 20: Shows a picture of the expansion procedure. Pictured is the 60mL syringe and air.

The expansion values show that air was very unsuccessful at expanding the tube. The water showed better results, which is expected with an incompressible versus a compressible fluid. However 50 percent expansion is not the needed 100 percent that this design requires to be operational. The conclusions that were made were not that the expansion mechanism would fail, but that the adhesive was applied at different thicknesses throughout the tubing. Bulges in the tubing were created with the water, showing that the pressure to break the adhesive were greater than the tensile strength of the smaller Sani-tech® 50 tubing. Future work is needed to either select a new adhesive or come up with a process that applies a uniformly thick layer of the adhesive.

Future Work

The project will be continued over the summer to achieve a more marketable design that can reach a larger client base, including patients who are awake and those under anesthesia. The tube must be stiff enough to allow insertion into patients whose muscles are relaxed while asleep and also provide comfort while awake. One way to achieve this would be through a custom extruded silicone tube. An ideal design will include a taper from a large thickness at the distal end to the current smaller thickness at the proximal end. This custom extrusion would also be able to incorporate the tip into the tube design. The biocompatibility of the design must also be maintained, while ensuring the device can be easily inserted to both sets of clients. A radiopaque strip incorporated into the design, either through extrusion or after, will allow physicians to continue using their current method of tube placement analysis.

Working with the current design, a method of adhesive application must be used that applies an even seal throughout the entire length of the tube. An applicator could be used to expel an even amount of adhesive while it is being consistently moved down the length of the tube, with the tip inserted evenly into the fold of the two sides.

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Appendix A – Product Design Specifications

Project Design Specifications

Expandable Nasogastric Tube
October 24, 2012

Team Members
Darren Klaty – BSAC
Michael Rossmiller – Leader
Alex Broderick – BWIG and Communicator

Problem Statement
Nasogastric tubes (NG tubes) are commonly used for aspiration of gastric contents and gastric decompression in patients with small bowel obstruction. Placement of a NG tube causes discomfort and pain during insertion due in part to the large diameter of the tube. This project requires a nasogastric tube which is small enough to reduce discomfort, while still being functional. Secondary design specifications include pH sensitivity to allow visual confirmation of when the tube reaches the stomach, incorporation of a lubricant/anesthetic, and recyclability.

Client Requirements
The developed nasogastric tube must:

- minimize patient discomfort upon insertion by reducing tube diameter and/or incorporating an anesthetic or lubricating agent
- increase ease of insertion for the physician
- enable aspiration of stomach/small bowel contents without collapsing or harming patient
- be visible on x-rays used to confirm proper tube positioning
- contain materials that are recyclable or made from recycled materials if possible

Design Requirements

1. Physical and Operational Characteristics

a. Performance requirements: The developed NG tube must be able to remove gastric contents as well or better than current models. This means the diameter of the tube must be large enough to prevent excessive blockages and the tube material must be stiff enough to withstand suction pressures up to 120 mmHg. Additionally, the NG tube should be approximately 3 mm in diameter during insertion and expand to approximately 6 mm in diameter once in place. Furthermore, the tube must be able to withstand acidities as low as a pH of 2, as it will be exposed to the conditions within the stomach. In addition, the tube must be flexible enough to be manipulated through the nose, down the esophagus, and into the stomach but stiff enough to prevent coiling or kinking during insertion. The tube must also include a radio-opaque strip to confirm tube placement on X-rays. Other ideal requirements include incorporation of a lubricant or anesthetic to enhance insertion comfort and the use to materials that enable the tube to be recycled. Currently, tubes are used once and thrown away.

b. *Safety:* The tube must be non-allergenic (no latex). It also must not have any sharp ends/edges to prevent laceration of any body tissues upon insertion. The design should also not require suction greater than 120 mmHg to prevent injury to the stomach lining of the patient.

c. *Accuracy and Reliability:* The tube should have markings every inch so that physicians can consistently measure how far the tube has been inserted into the patient. F

d. *Life in Service:* The tube must last up to one week in the environment of the stomach through the nasal passageway.

e. *Shelf Life:* The tube must last at least 3 months on the shelf.

f. O*perating Environment:* The nasogastric tube is currently used in hospitals and medical clinics. It will be stored at room temperature with little exposure to humidity and pressure. This device will be inside the body, touching visceral organs, so while it is in use, it will have to withstand core body temperatures, ~100º F, and the acidity of the stomach, ~2 pH. The device can be in the body for up to one week so it will have to be completely resistant to corrosion at these temperature and acidity conditions.

g. *Ergonomics*: There are many ergonomic restrictions since the device will be used inside the human body. The nasogastric tube will be guided through the nasopharynx into the esophagus, so the torque required to bend the tube must be limited to prevent tissue damage. Furthermore, the diameter of the tube has to be small enough to fit inside of the nose. Additionally, the tube must have enough stiffness so the physician can use minimal force during insertion and removal without worrying about kinking or coiling.

h. *Size:* The device will be 120 cm long. Ideally, the developed tube will expand from an initial diameter of approximately 10 Fr (~3 mm) which is the size of current NG feeding tubes to a diameter of about 18 Fr (~6 mm) , the current diameter of NG decompression tubes.

i. *Weight:* The device should weigh less than 2 kg.

j. *Materials:* All materials must be non-allergenic, non-irritable, and biocompatible. The selected materials must also be able withstand initial sterilization likely by ethylene oxide. Tube materials will most likely be made of polyurethane or polyvinylchloride, like current NG tubes.

k. *Aesthetics, Appearance, and Finish:* The device should look professional, the finish and appearance is not a factor, since function is 100% of the focus.

2. Production Characteristics

a. *Quantity*: One prototype is needed at this time. There is the possibility of mass production in the future.

b. *Target Product Cost:* Target cost for device is kept to a minimum. The budget for prototyping the design is $1000. This tube mass-produced and on the market should cost less than $20.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required for the device before mass production. IRB approval and HIPAA requirements must be met for future patient testing.

b. *Customer*: The developed NG tube will be used by physicians and nurses who perform procedures involving removal of gastric contents and/or small bowel obstructions.

c. *Patient-related concerns*: The tube must have a small diameter to improve patient comfort and smooth end/edges to prevent injury. Furthermore, the tube must be non-allergenic. The device will initially be sterile and only used once so there is no potential for disease transfer. There is no patient data storage so no such safeguards are necessary.

d. *Competition*: There are a wide variety of NG decompression tube models created by several different companies on the market. Most of these tubes are constructed of PVC or PU and have large diameters, causing discomfort to the patient. These tubes vary in gauges and lengths. The average cost per device is between $12 and $20. There are also pH and CO2 sensors that can be attached to these tubes to confirm placement within stomach. However, there are no tubes on the market that expand once inserted.