Expandable Nasogastric Tube

Final Report

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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. Secondary objectives include incorporation of a lubricant/anesthetic to further improve patient comfort, a pH or CO_2 sensor to more easily confirm proper placement within the stomach, and the use of materials that can be recycled in some way to reduce medical waste. At this point, the team has developed a proof-of-concept prototype illustrating the mechanical expansion mechanism consisting of a folded tube contained within a smaller outer diameter sheath. The team also tested sheath removal mechanisms and inner tube recovery after containment. The next step is to turn the proof-of-concept into a full-size, functional prototype.

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].
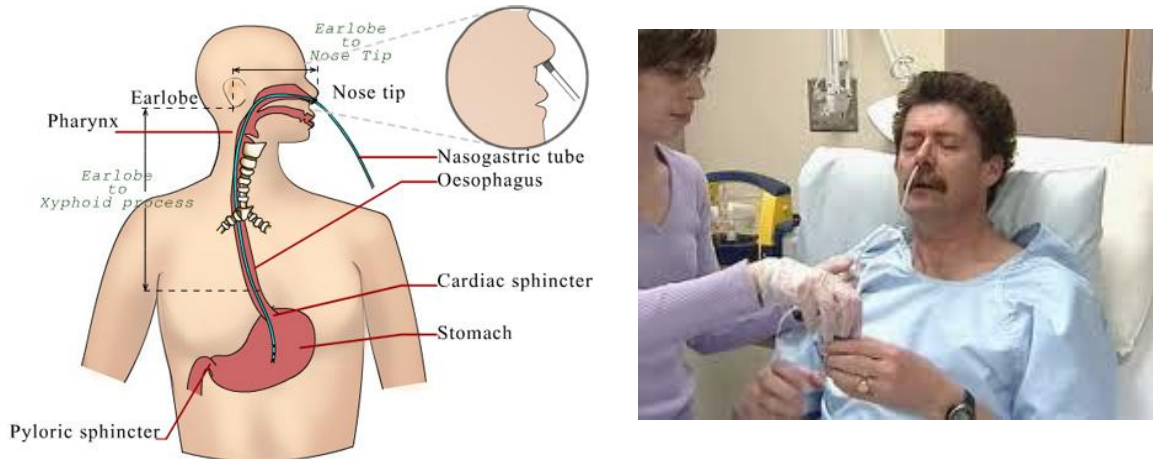

Figure 1: (Left) A diagram showing anatomically correct placement of a NG tube from nose tip, down the esophagus, and into the stomach [3]. (Right) A photo of a patient with a NG tube inserted [4].

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 is to focus on making an expandable nasogastric tube and second semester will focus more on manufacturing and eliminating the need for an X-ray with pH or CO_2 sensors.

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

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].

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.

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. 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.

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 6 mm 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. 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.

Design Alternatives

Sleeve

The first design, shown in Figure 3, is composed of a flexible inner tube folded into a slightly more rigid outer sleeve. The inner sleeve will have an approximate inner diameter of 4 mm and an outer diameter of 6 mm to correlate to a size 18 Fr NG tube. The inner tube will be compressed into the sleeve to give a final outer diameter of approximately 3mm. Wall thickness will be determined based on properties of the selected material.

The material suggested for use by Dr. Tim Osswald (a polymer expert on campus) was silicone rubber, which is available in a range of sizes and with varying moduli. A feasible manufacturing method would be to hold the inner tube in its folded shape and to extrude the outer sleeve over it. Silicone rubber is ideal for this application because it does not adhere to other materials during extrusion. This would enable easy removal of the inner tube from the sleeve.

Figure 3: CAD model of the cross section of the first design alternative, showing a folding inner tube with a sleeve. (image generated by Megan Halley).

Advantages of this design include the aforementioned manufacturing feature, as well as the fact that it can easily accommodate a pH sensor. The sensor could be pre-incorporated on the end of the outer sleeve so that when the sleeve is removed after insertion, the pH sensor can be read. Disadvantages of this design include extra effort and time to use, and heavy dependence on material properties. The ease of use is uncertain, but could be complicated due to the additional steps that would be required to remove the sleeve. It is possible that removing the sleeve could be uncomfortable or induce nausea or emesis in a patient. Additionally, the function of the design is largely dependent on material properties, which are difficult to quantify without experimental data. For example, the inner tube must be very thin to enabling folding but it is uncertain how well the thin tube would withstand the suction pressure.

Shape Memory Polymer

The second design alternative involves the use of shape memory polymers (SMPs) to create a nasogastric tube that expands after insertion. Research into SMPs is a relatively new field and investigation for use of SMPs in clinical applications has only begun in the last 10 years. SMPs are polymeric materials that can be designed to memorize a less constrained permanent shape, hold a temporary strained shape, and then revert back to the permanent shape in response to an environmental stimulus. For shape transition to occur, the polymer must have netpoints (hold permanent shape) and reversible switches that respond to the stimulus. This stimulus is usually heat but could also be light, moisture, a magnetic field or an electric field [8,9]. The shape memory effect has been investigated in many polymers including polyurethanes, epoxies, polyolefins, and polyesters [8, 10, 11, 12].

In biomedical applications, heat responsive SMPs are most commonly used and would be suitable for an expandable nasogastric tube. For heat-responsive SMPs, shape transition is controlled by the freezing of polymer chains below the glass transition (T_g) and the activation of polymer chain motion above the T_g [8]. The T_g is the temperature below which polymers become a glassy solid and above which polymers become rubbery and compliant. The shape-memory creation process involves processing (extrusion, injection molding, etc) the polymer into its desired permanent shape, heating the material above its T_g, applying stress to deform the material to its desired temporary shape, and cooling below the T_g while stressed to fix the temporary shape. The permanent shape is recovered by reheating the polymer above its T_g. The recoiling of polymer chains from

Figure 4: Macroscopic effect and molecular mechanism of heat-responsive shape memory effect. A) Recovery of SMP tube from a flat helix temporary shape. B) Schematic of shape memory creation process [10].

a strained configuration to a less strained state is the driving force behind shape transition [8, 10]. This process is shown in Figure 4.

For the nasogastric tube, a heat and moisture responsive thermoplastic polyurethane SMP is commercially available in pellet form from DiAPLEX Company, a subsidiary of Mitsubishi [13]. This SMP, is made from diphenylmethane-4,4'-diisocyanate, adipic acid, ethylene glycol, ethylene oxide, polypropylene oxide, 1,4-butanediol and bisphenol A [9]. In the literature, this composition has demonstrated sufficient shape memory effect and biocompatibility [9,14,15]. Furthermore, DiAPLEX sells the SMP with a variety of glass transition temperatures. For this application, the polyurethane with a T_g of 35°C would be selected so body temperature would trigger shape transition upon insertion. A nasogastric tube made of a SMP, would be inserted in its temporary shape, which would consist of a folded tube (cross-section similar to that shown in Figure 5A t = 0sec) with a maximum outer diameter of 3 mm. Once fully inserted, body temperature would cause the tube to assume its permanent shape, which would be a fully opened tube (cross-section as shown in Figure 5A t = 100sec) with a maximum outer diameter of 6 mm.
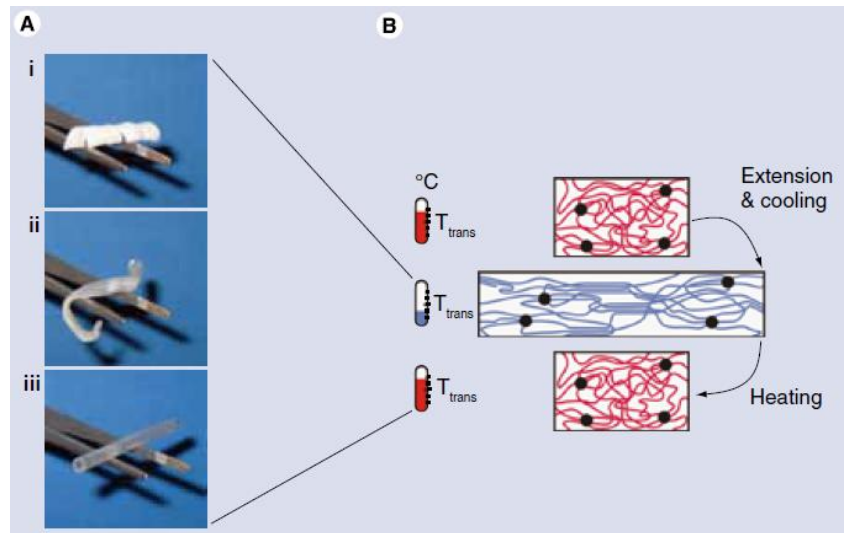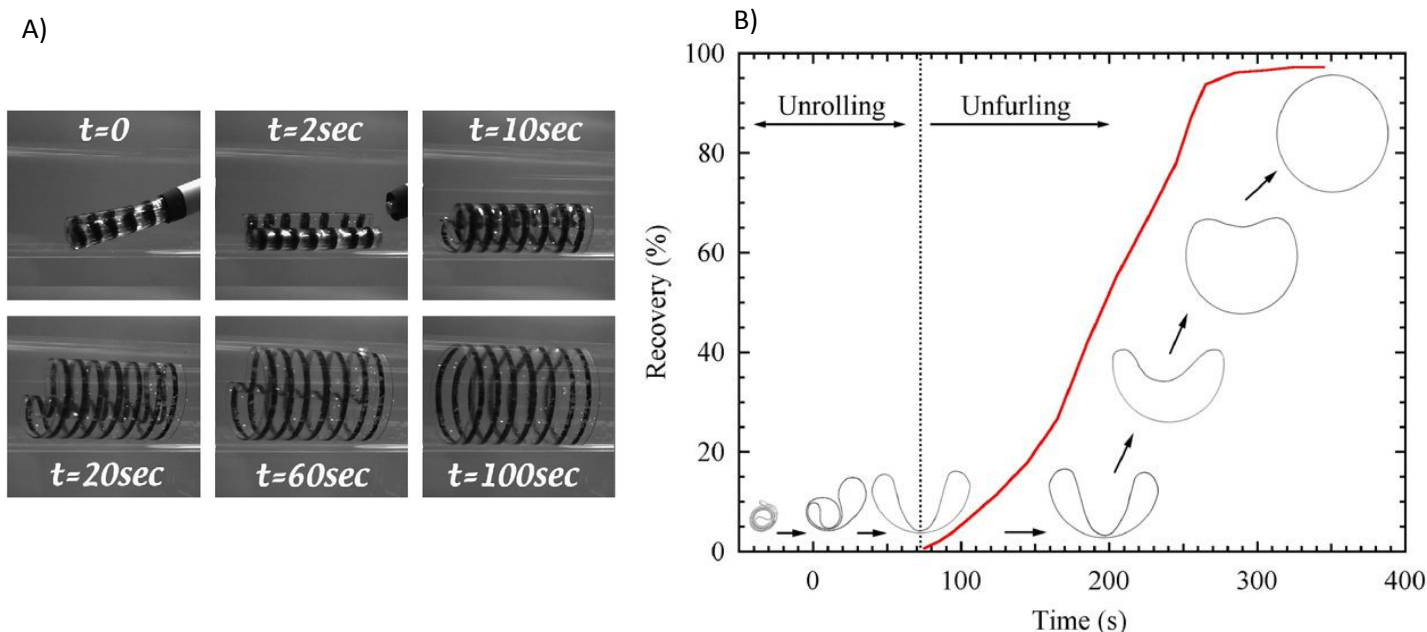
Figure 5: Recovery of an SMP stent from a rolled and furled temporary shape to a fully open tube. A) A compressed tube delivered via a 18 Fr (6 mm) diameter catheter into a 22 mm diameter glass tube expanded to its permanent shape in 100 seconds. B) Schematic of free recovery of SMP stent [11].

The main advantage of this design is its elegant and effortless expansion. The tube could be inserted at about half its fully expanded diameter, enhancing patient comfort and ease of insertion for clinicians. Furthermore, there is no extra sleeve or sheath that needs to be removed, enabling easier and quicker insertion. However, without the removable sleeve, a pH electrode could not be as easily incorporated as in the first design alternative.

There are a few other limitations of this design as well. First, there is only one commercially available SMP and it is sold in pellet form. Therefore, construction of a prototype would require extrusion and development of an appropriate extrusion die to create the tube, which would be expensive and difficult to implement for a first prototype. Second, the time for shape transition of the proposed tube is unknown because larger polymer designs tend to take longer to completely transition. For a SMP nasogastric tube, transition would have to occur after complete insertion but within a few minutes. Additionally, it is unknown whether this SMP material would have sufficient strength to withstand the suction used to remove gastric contents and testing would be required to determine this. Furthermore, if the DiAPLEX material did not fit the device requirements, there are no other SMPs commercially available and a different polymer would have to be synthesized from scratch. Lastly, SMPs are far more expensive than current nasogastric tubes, which would likely limit implementation at this time.

Expandable Coated Stent

The third and final design alternative was inspired by cardiovascular and airway stents and involved the use of an expandable coated stent that extends the length of the tube [16]. This design would be composed of a stainless steel wire frame with a thin polyurethane or silicone coating as shown in Figure 6. The tube would be inserted in its collapsed state as shown in Figure 7A, with a deflated balloon and guide wire inside. Once in the proper place, the tube would be expanded by inflating the balloon (Figure 7B), which with the guide wire, would then be removed. Many stents currently on the

market are composed of nickel titanium shape memory alloy, so they are self expanding. However, this material is prohibitively expensive for the size of a nasogastric tube.
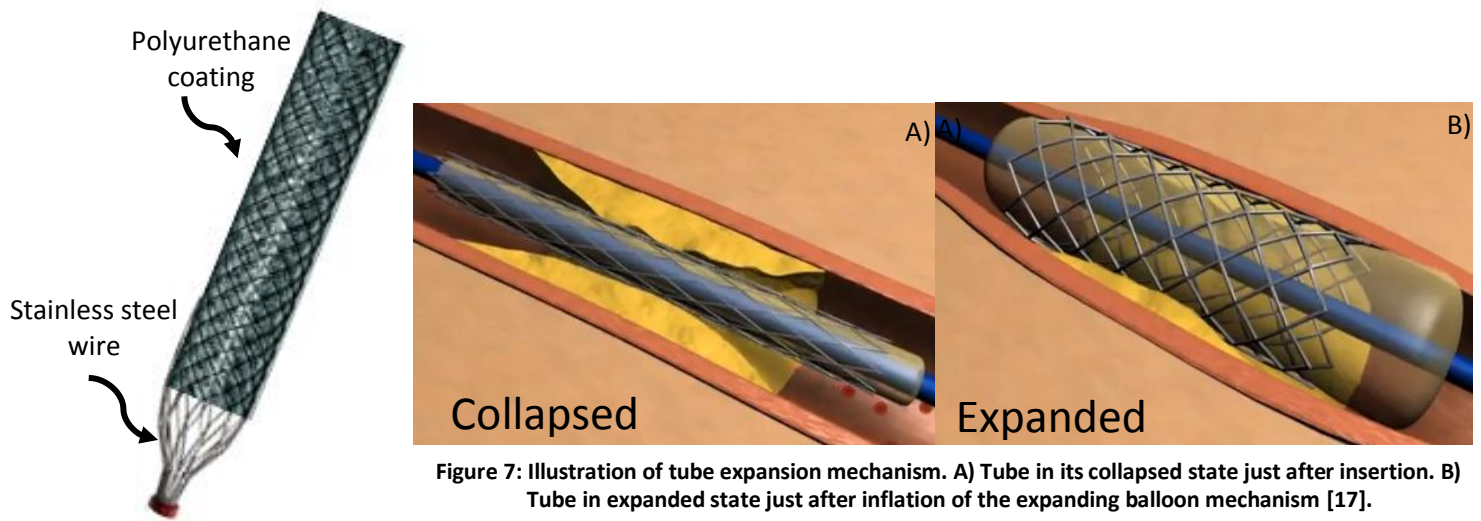

Figure 6: Rendering of the fully expanded coated stent tube near its tip [16].

Figure 7: Illustration of tube expansion mechanism. A) Tube in its collapsed state just after insertion. B) Tube in expanded state just after inflation of the expanding balloon mechanism [17].

The use of a coated stainless steel stent design provides several advantages for a nasogastric tube. First, the extended stent design would enable adequate expansion that is also controlled by the clinician; unlike shape memory polymers which transition on their own. Furthermore, the wire frame would provide extra resistance to collapse from the suction. Lastly, the stainless steel would be radio-opaque, this would allow clinicians to check placement of the nasogastric tube using an X-ray without adding extra material to the tube. Moreover, a pH sensor could be incorporated into the balloon mechanism or guide wire so that upon its removal clinicians could confirm placement in the stomach even before getting an X-ray. However, there are also several limitations to this design. First, the stainless steel may make the tube too rigid, preventing it from bending properly to pass through the nasopharynx and into the esophagus, or causing discomfort to the patient. Additionally, stents are usually fabricated by laser cutting, which is expensive. Laser cutting equipment is also not available on campus.

Design Matrix

Table 1: The design matrix, consisting of six categories comparing the three designs to the existing device.

Category	Weight	Sleeve	Shape Memory Polymer	Stent	Current Device
Cost	20	15	8	0	19
Expandability	20	15	16	19	0
Short-Term Manufacturing	10	6	2	1	8
Long-Term Manufacturing	10	7	7	5	8
Customizability	15	12	4	8	9
Stiffness	15	13	15	15	15
Ease of Use	10	4	9	6	8
Total	100	72	61	54	67

To determine the final design to pursue from the three alternatives outlined above, the team created a design matrix of the three alternatives, versus the current device as a method of comparison. This design matrix consisted of seven categories at different weights, totaling 100. Each design component was scored according to information gathered online, from the client, and/or from talking to nurses or other staff at the University Hospital.

The 'Cost' category received a weight of 20 because in order for the design to be taken seriously as a replacement device, it has to be cost effective as compared to current devices. The 'Expandability' category also received a weight of 20 as it is the client's main priority, and it is the all-around most important physical design aspect. Manufacturing was broken down into two different categories because the short and long-term aspects within the three designs varied greatly. The category as a whole received 20 points, but was broken up into two sub categories of 'Short-Term' and 'Long-Term', each receiving equal weights of 10. 'Short-Term' refers to the ability of this team to build the design and the 'Long-Term' refers to mass production of each device. The 'Customizability' category received a score of 15. This category scored each design's ability to allow incorporation of enhancement devices, such as a radio-opaque strip for x-ray detection or the placement of a pH sensor on the tip. The 'Stiffness' category was scored in two different ways. The first was the stiffness while being inserted. The device should be flexible enough to bend through the nasal passageways but stiff enough to prevent coiling. The second was the stiffness while performing the suction of stomach contents out of the patient. The device does should be stiff enough to withstand a maximum of 120 mmHg suction but not be too stiff so as to be uncomfortable. The final category was 'Ease of Use', which had to do with the ease with which a nurse or doctor could insert this device into a patient. This category received a weight of 10 because with enough training it would not be too difficult to insert any of the designs.

The first design, 'The Sleeve, 'received a total score of 72. It received high scores in cost and expandability, along with decent scores in the other categories. Although this design would consist of two pieces, if a pH sensor were incorporated into the outer sleeve, the hospital will no longer have to perform an x-ray to verify the tube is in the correct place of the stomach. This will reduce procedure cost. Because of the two pieces, manufacturing could be somewhat difficult but each device on its own would not be overly difficult to build and then assemble. The expandability of this device is promising as the inner tube is encapsulated and can be shrunk down. Customizability for the sleeve is high because the pH sensor could be attached to the tip and the pH can be read in one step. Stiffness scored well because the outer sleeve will be able to bend due to the silicone material, yet stiff enough to insert

10

down the nasopharynx because of the inner tube reinforcement. The ease of use was lowest for this design because removal of the sleeve requires an additional step for clinicians. Also, removal of the sleeve while keeping the inner tube in the correct place may be difficult.

The second design, "Shape Memory Polymer" received a total score of 61. The cost of this device is very high as polymer pellets will have to be bought and then molded into the shape of the NG tube. Because of the properties of the polymer, a device that expands once it reaches core human body temperature could be developed, making the possible expansion very good. Furthermore, advanced processing would be required to transform the pellets into the desired shape and access to such processing equipment is not readily available. However, long-term prospects are good as the team anticipates it would not be difficult for a company to mass-produce these. But, there is still a great deal of research to be done on these polymers. The customizability of this design is low, as it would require the team to design a secondary system to carry the pH probe to check placement. Also, because the tube is made of one material, the insertion of a radio strip would either hinder the expanding of the tube or again require a secondary device. Stiffness of this design received top marks because it would be feasible to customize the stiffness of the tube at its starting and final positions. Ease of use of this device also scored well as insertion is very similar to the current device and would not involve any additional steps.

The third design, "The Stent," received a total score of 54. The cost of stents is extremely high at lengths much less than the proposed design; therefore, this design received a score of zero for cost. Stents are also difficult to fabricate, which is reflected in the price, and is why this design received such low scores for short-term manufacture. The team would have to come up with a new method to manufacture stents of this length that comes with the ability to bend during insertion. However, once a method is developed, larger companies would be able to replicate this on a larger scale. The customization of this device is right in the middle because a pH sensor could be incorporated on the balloon mechanism and the material is already radio-opaque. Because once a stent is put into place it is locked at a certain diameter, this design received high marks for stiffness, as there is little risk of collapse due to negative pressure. This design also scored in the middle for ease of use as it is unclear how difficult it would be to train nurses and doctors for insertion of the device. The difficulty would largely depend on the stiffness of the device during insertion as it may be very rigid and would need for great precision.

After looking at the totals of the three design alternatives, the 'The Sleeve' design scored the highest and will be the design that is pursued for the remained of this project.

Final Design

With good scores for cost and expandability, along with great scores for customizability and stiffness, the 'The Sleeve' design has been selected as the final design for the remainder of this project. The ability to customize the inner tube, as well as the outer tube, will give the team the best opportunity to fabricate, test and to adapt to unanticipated problems moving forward. Successful implementation of 'The Sleeve' design will ultimately lead improved patient comfort during nasogastric intubation.

The final design consists 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.

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 melting point of the silicone. 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 gauge 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.

Testing

Prototype Development

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

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 2, 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 6 inch 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 2: List of inner tube materials investigated and their relevant properties [18-21].

The objective in selecting these materials 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. Of the materials tested, Tygon 100-65 was the most difficult to fold into the U-shape during insertion into the sheath because of its higher modulus and hardness. Thus, a tube modulus of approximately 3 MPa or less, and a shore A hardness of about 50 are desired for this application. The lower hardness and stiffness values would also improve comfort during wear for the patient. However, the Tygon 100-65 was less tacky than the silicone tube options, enabling better glide into the sheath. Lastly, because Tygon 100-65 is made of PVC, a thermoplastic with a melting range of 100-210°C, heating the material to its softening point could easily create a tapered tip NG tube. However, this melting range is below the temperature needed to shrink the sheath so PVC material cannot be used for the inner tube. The silicone alternatives do not melt with the heat required to shrink the tube, but a tapered tip cannot be formed from standard tubing. A custom tube will need to be extruded or injection molded.

Sheath

For the sheath, the team selected to use heat shrink (HS) tubing to enable easy insertion of the inner tube followed by shrinkage. Several HS materials were tested before the final selection was made. First, the team attempted to create a proof-of-concept prototype using electrical HS tubing purchased from the hardware store. This tubing had an expanded inner diameter of 6.35 mm and could shrink to 3.17 mm with 120°C heat. Therefore, it was easy insert the 5.56 mm inner tube in the HS material and shrink it, even with the PVC material. However, the HS tubing was very elastic and did not exert enough force to collapse the inner tube.

Next, the team ordered samples of various medical grade HS tubing from Zeus Inc. and Vention Medical. The tested materials are listed in Table 3, along with their dimensions. The objective was to obtain a HS tube that had enough strength to hold and force the inner tube in/into a collapsed state. This would be done while keeping the wall thickness as thin as possible, to reduce overall product diameter. Furthermore, the team wanted a HS tube that could shrink to an outer diameter of at least 3 mm. The tube also required an expanded inner diameter large enough to insert the collapsed tube. To estimate the minimum diameter the inner tube could be collapsed to (minimum possible sheath inner diameter), the cross-sectional area of the inner tube material was calculated by Equation 1. The cross-sectional area of the tubing tested was 11.9 mm^2, meaning that the minimum collapsed diameter of the tube could be 3.89 mm according to Equation 2. Thus, any heat shrink tubing ordered must have an inner diameter of no less than 3.89 mm. However, this calculation assumed that the material was incompressible. Since silicone is elastic, it is able to compress significantly more than calculated. Therefore, HS tubing with less than this inner diameter were also tested.

$$\text{Equation 1: } Tube\ Area = \pi r_o{}^2 - \pi r_i{}^2 \qquad \text{Equation 2: } Min\ Collapsed\ Diameter$$
$$= 2 \times \sqrt{\frac{Tube\ Area}{\pi}}$$
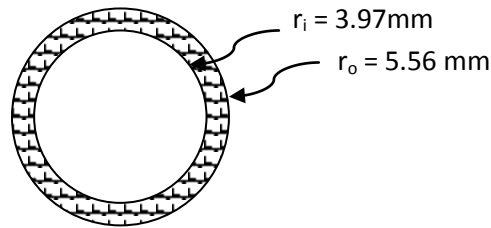
$r_i = 3.97mm$

$r_o = 5.56\ mm$

Figure 8: Schematic of approach to calculate minimum possible collapsed tube diameter.

Table 3: List of HS materials tested and their relevant properties [22-23].

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

The team found that the teflon (PTFE) HS tubing diameter was too small to insert the inner tube easily. Furthermore, this material required application of heat significantly above the working temperature of the inner tube material. Next, the team tested the Vention Medical polyethylene terephthalate (PET) material. However, the extremely thin wall thickness of 3 of the samples gave the tubing the consistency of a plastic bag. Thus, the material was easily torn and could not exert enough force to collapse the inner tube. The Vention Medical sample with the .025 mm wall thickness would have been more suitable, but it again, was too small to insert the inner tube. Finally, Zeus Inc. sent the team another sample of fluorinated ethylene polypropylene (FEP), with a larger inner diameter and lower required heat to shrink than the PTFE. The inner tube was successfully inserted and shrunken but a final outer diameter of 3 mm was not attainable. In the future, HS tubing with a slight smaller inner diameter can be ordered that would reduce the overall product diameter. However, for this semester material options were limited because the team was only testing samples the suppliers had in-stock and were able to donate.

Inner Tube to Sheath Insertion Mechanism

After determining that silicone would be used for the inner tube and the FEP HS tubing would be used for the sheath, the team worked to develop a method to insert the silicone into the HS material. The first attempt involved folding the silicone into the U-shape and pushing it into the FEP sheath.

Because of the friction between the materials, the silicone could only be inserted about 25 mm. With the addition of a water-based lubricant, the inner tube could still only be inserted about 50 mm. The team also tested cutting the HS tubing to make it easier to fit around the inner tube. For example, the HS tubing was cut into a spiral and wrapped around the silicone tube. However, the shrinkage of the HS material was significantly reduced and the inner tube could no longer be collapsed.

A slightly more successful attempt involved using a vacuum to flatten the tube to enable easier folding and to hold the tube in the collapsed shape. In this test, one end of the silicone tubing was plugged and a plastic syringe was attached to the other. Pulling back on the syringe and holding it in place created a vacuum strong enough to flatten the silicone. The silicone tube was then folded and manually held in a U-shape. The HS sheath was then slide over the plugged end and incrementally progressed up the folded tube toward the syringe end. The sample tested was only 50 mm long but insertion into the sheath was much easier than pushing alone. However, this method would be more challenging for longer samples and required 2-3 people or machinery to hold all the equipment and tubing. Therefore, a new approach to tube insertion was taken, namely pulling rather than pushing. In the first attempt of pulling, 28 gauge steel wire was wrapped around the first 25 mm of the silicone tubing, leaving a long enough piece of wire attached to pull through the sheath. But, during testing the wire slipped off the silicone. The team then tested threading the wire through the silicone tube and pulling. In this case, the wire simply tore through the silicone material because the frictional forces between the inner tube and sheath were greater than the strength of the silicone. This led the team to wrap the end of the silicone tube, thread the wire through the tube 3 times, and use lubrication as described in the fabrication section. The team then created samples as described in the fabrication section and began prototype testing.

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 4.

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

Table 4: 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 9. 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 is shown in Figure 10.

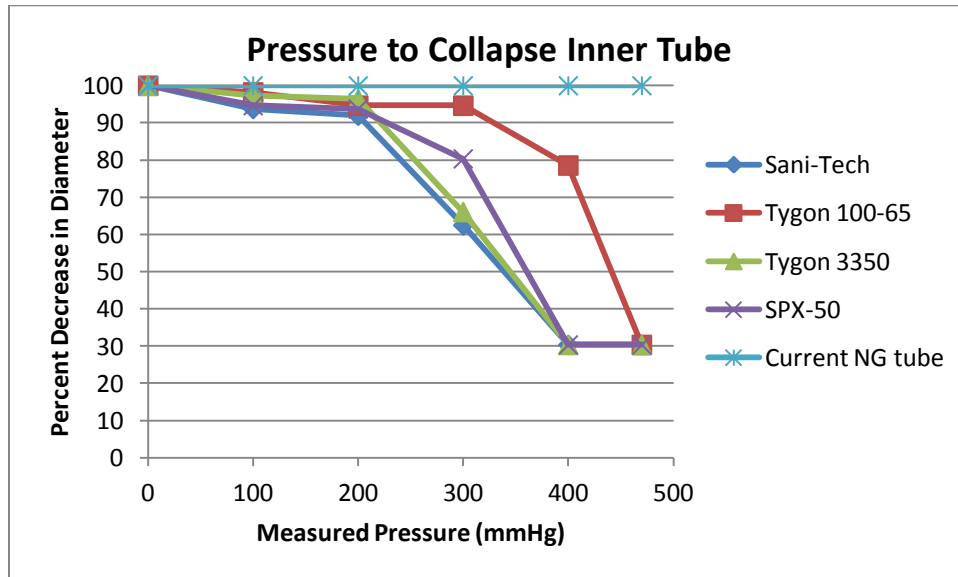**Figure 9: Photo vacuum pump used for collapse pressure testing.**

Figure 10: 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

Figure 11 compares the results of measured pressure to the predicted collapse pressure in Table 4. The measured pressure in Figure 10 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 a the result of Equation 3.
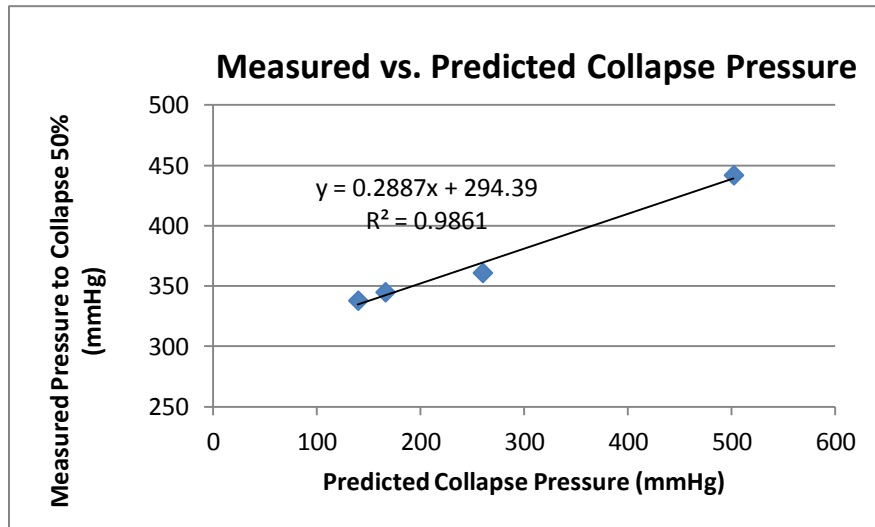
Figure 11: Plot of predicted collapse pressure vs. measured collapse pressure demonstrating a high correlation.

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 12. 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.
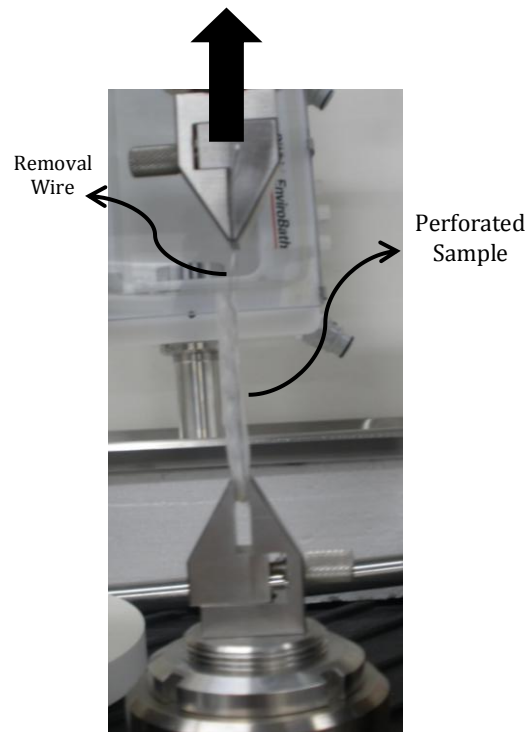

Figure 12: Photo testing setup for measuring force/work to tear HS tubing

Results (shown in Figures 13 and 14) 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 15). Additionally, at perforation lengths greater than 5 mm, the inner Sani-tech® tubing began to bulge out of the sheath when compressed.
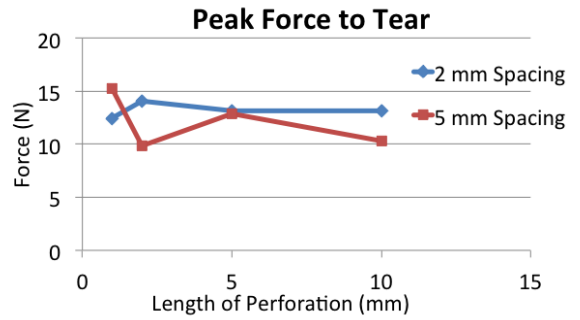

Figure 13: Plot of peak force to tear perforations, illustrating that force is independent of perforation
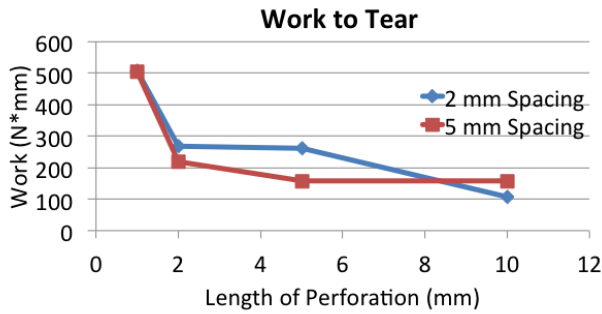

Figure 14: Plot of work to tear perforations, demonstrating that work decreases with increasing perforation length.

Figure 15: Photo of sample with 1 mm

Inner Tube Recovery After Shrinkage
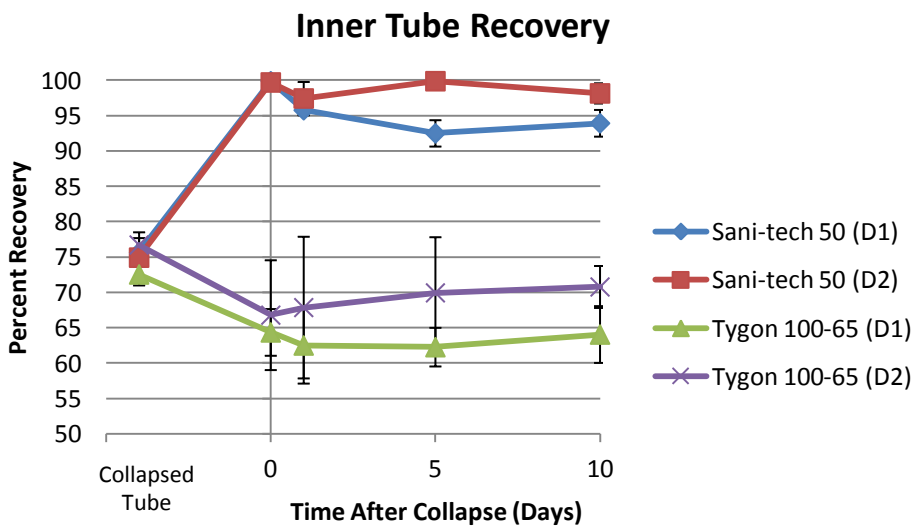

Figure 16: Cross-section of Sani-Tech® 50 sample for recovery test, demonstrating D1 and D2 measurements.

Figure 17: Plot of inner tube recovery after being collapsed in heat shrink sheath for Tygon 100-65 and Sani-Tech®50.

Another critical aspect of the design is that it must fully expand after being collapsed within the sheath, even for extended periods of time. To test the ability of the inner tube to recover, samples of each Sani-Tech® 50 and Tygon 100-65 were prepared using the fabrication process outlined above. These two materials were selected for testing because they were the extremes of material stiffness and were also the most abundant. To save the limited available heat shrink material, each sample was only 2 inches long and only 4 samples of each material were made. The shrunken diameter of the samples was recorded at 3 points along the specimen in the D1 and D2 directions, as shown in Figure 16. The expansion was then assessed 1 day, 5 days, and 10 days after shrinkage by removing the sheath and measuring the diameter of the inner tube at 3 locations in the D1 and D2 directions, within 1 minute of sheath removal. The results of this testing are shown in Figure 17. As illustrated in the graph, the Sani-Tech® 50 material exhibits significantly higher recovery of initial diameter (5.56 mm for both materials) than the Tygon 100-65. Sani-Tech® 50 recovers nearly completely, and this recovery is immediate after the sheath is removed, as shown in Figure 18. On the other hand, Tygon 100-65 melts with the application of heat used to shrink the sheath, resulting in plastic deformation. Thus, there is no recovery, and the diameter of the inner tube after sheath removal is smaller than shrunken sample itself, as shown in Figure 19. The uneven melting of this material also led to the large standard deviations shown on the plot. Additionally, the D2 direction demonstrates better recovery for both materials tested.
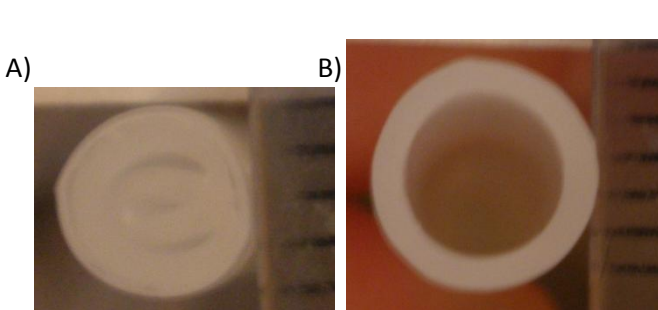
A)   B)   B)

A)

Figure 18: Recovery of Sani-Tech®50 material. A) Sani-Tech®50 shrunken in heat shrink sheath and B) Sani-Tech®50 after sheath removal.
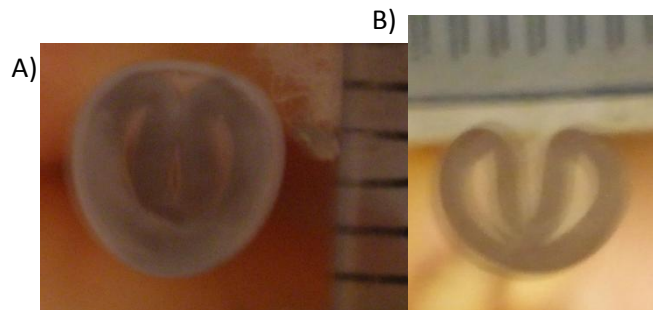
Figure 19: Recovery of Tygon 100-65 material. A) Tygon 100-65 shrunken in heat shrink sheath and B) Tygon 100-65 after sheath removal.

Fabrication and Budget

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.

Assembly of the expandable nasogastric tube consists of inserting the silicone tubing into the heat shrink tubing and heating the tubing to the desired diameter. The 28 AWG steel wire, that spans twice the length of the heat shrink tubing, is then 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 this semester's nasogastric tubing is shown below, Figure 20. Next 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.

Ergonomics

Nasogastric tubes have many constraints since the tube is interacting with visceral organs and epithelial tissue of human subjects. The tube has 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.

Future Work

Next semester there will be more focus on the manufacturing and optimization of certain parts for this design. While the material has been selected for both the inner and outer tube, the best wire material for the removal of the sleeve still needs to be determined. The wire material will need to be tough enough to rip through the heat shrink tubing, but flexible and soft enough so that it can be packaged for shipping and storage, and will also remain comfortable while being removed from the patient. Another part that will have to be optimized is the wall thickness on the inner tube. The optimization will allow for the most comfort of the patient during insertion, but also will still have to be thick enough as to not collapse under the pressure during the procedure.

After the optimized parts of the design have been determined, additional features will be looked at to add to the design. These include a pH sensor and a radiopaque strip that would allow the determination of the correct position of the tube in the stomach after insertion. As the wire material for sleeve removal has not been decided, it may be an advantage to find a material that is radiopaque for spotting during x-rays.

Finally, outside companies will be contacted and worked with for the manufacturing of the design. A closed end with side holes will be added to avoid adhesion to the stomach wall, as well as a second lumen to relieve possible pressure build up in the main tube. This semester, the two manufacturing processes that have been talked about to create this design are extrusion and injection molding. So, next semester more research will have to be done to learn what will work best for the project.

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Appendix A – Product Design Specifications

Project Design Specifications
Expandable Nasogastric Tube
October 24, 2012

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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
- incorporate a color indicator that confirms when tube is in the low pH environment of the stomach
- contain materials that are recyclable or made from recycled materials

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 and would also ideally include a pH sensor to further confirm placement in the stomach. 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. Furthermore, the tube must have a method to confirm proper placement in the stomach such as a radio-opaque strip and pH or CO2 sensor.

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 CO_2 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.