UNIVERSITY OF WISCONSIN – MADISON
DEPARTMENT OF BIOMEDICAL ENGINEERING
BME 400 – DESIGN

Expandable Nasogastric Tube

Mid-Semester 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, 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 upon 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 materials that can be recycled in some way to reduce medical waste. At this point, the team has researched several tubular expansion mechanisms and has chosen to purse a design that involves a folded tube within an outer sleeve that would expand upon removal of the sleeve after NG intubation. For the remainder of the semester, the team will be developing a proof of concept prototype including ordering tubing materials and testing the materials' ability to withstand suction and mechanically expand.

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 gastriointestinal operations or if a toxin has been ingested [1].

To remove stomach contents, a NG decompression tube is inserted into the nostril and are 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 is 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 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 pyloric 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. Placement is confirmed by pushing air into the NG tube and listening for swoosh sound where the stomach is located with a stethoscope. 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 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 (12-18Fr 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/coiling in the back of the throat. Moreover, it is very critical to ensure that 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, and surgery has then be required to remove the tube [6].

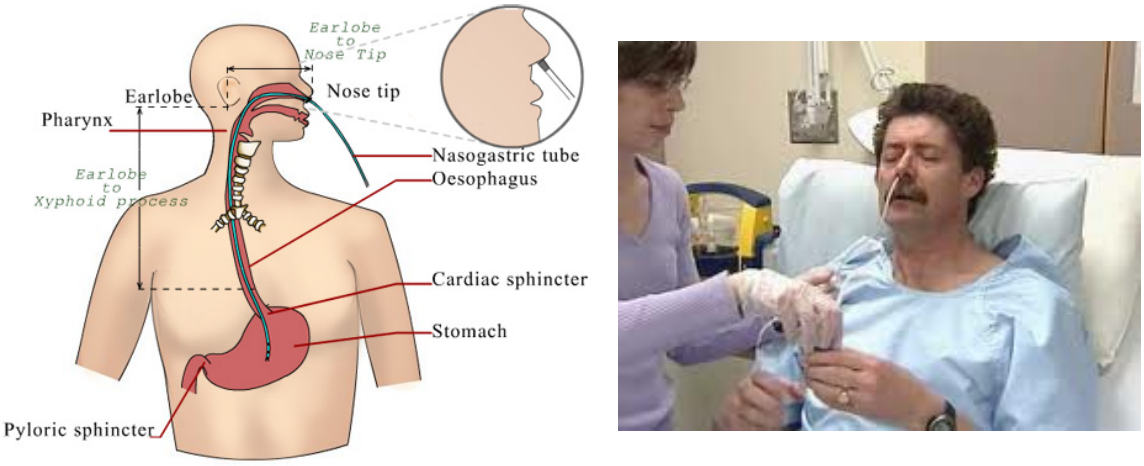

Figure 1: (Left) A diagram showing anatomically correct placement of a NG tube from nose tip, down the esophagus. and into the stomach [3]. (Right) A photo of a patient with a NG tube inserted [4].

Project Statement/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 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 medical costs. Catering towards patients, physicians, and lower medical costs, the team is actively 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 an initially collapsed tube would make the device stiffer, enabling easier insertion for the physician (reduced risk of coiling/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 lumen tube; one tube is open to the atmosphere and the other tube is used for aspiration of gastric contents. The advantage of the two lumen 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 lumen 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 and 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 one lumen nasogastric tube that has a bag on the end that is injected with mercury. The pressure created by the bag of mercury helps 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.

Current NG decompression tubes are made of either polyvinyl chloride (PVC), polyurethane (PU), or silicone. They are between 12-18 Fr (4-6mm 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 a 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 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 tub 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.

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 insertion comfort. 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 sleeve will have an outer diameter of 3 mm. The inner sleeve will have an approximate outer diameter of 4 mm to correlate to a size 18 Fr NG tube, which has an outer diameter of 6 mm and a wall thickness ranging from .75 mm on the "inner" end and 1 mm on the "outer" end. Wall thickness will be determined based on properties of the selected material.

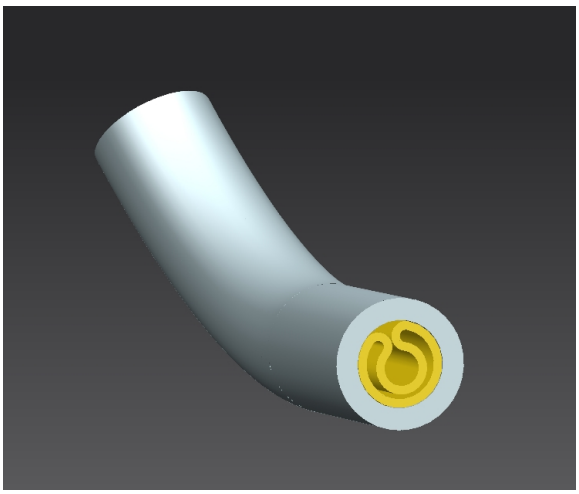

Figure 3: CAD model of the cross section of the first design alternative, showing a folding inner tube with a sleeve. (image generated by Megan Halley).

The material suggested for use by Dr. Time 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.

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 end of the outer sleeve so that when the sleeve is removed after insertion, the pH sensor could be read. Disadvantages of this design include extra effort/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 heart-responsive SMPs, shape transition is controlled by freezing of polymer chains below the glass transition (T_g) and activation of polymer chain motion above the T_g [8]. The T_g is the temperature below which polymers are a glassy solid and above which polymers 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 a strained configuration to a less strained state is the driving force behind shape transition [8, 10]. This process is shown in Figure 4.

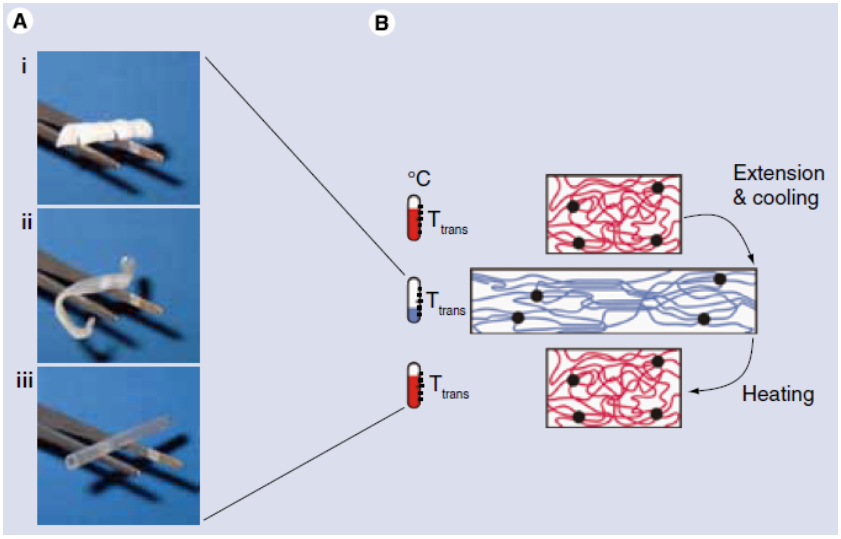

Figure 4: Macroscopic effect and molecular mechanism of heat-responsive shape memory effect. A) Reovery of SMP tube from a flat helix temporary shape. B) Schematic of shape memory creation process [10].

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.

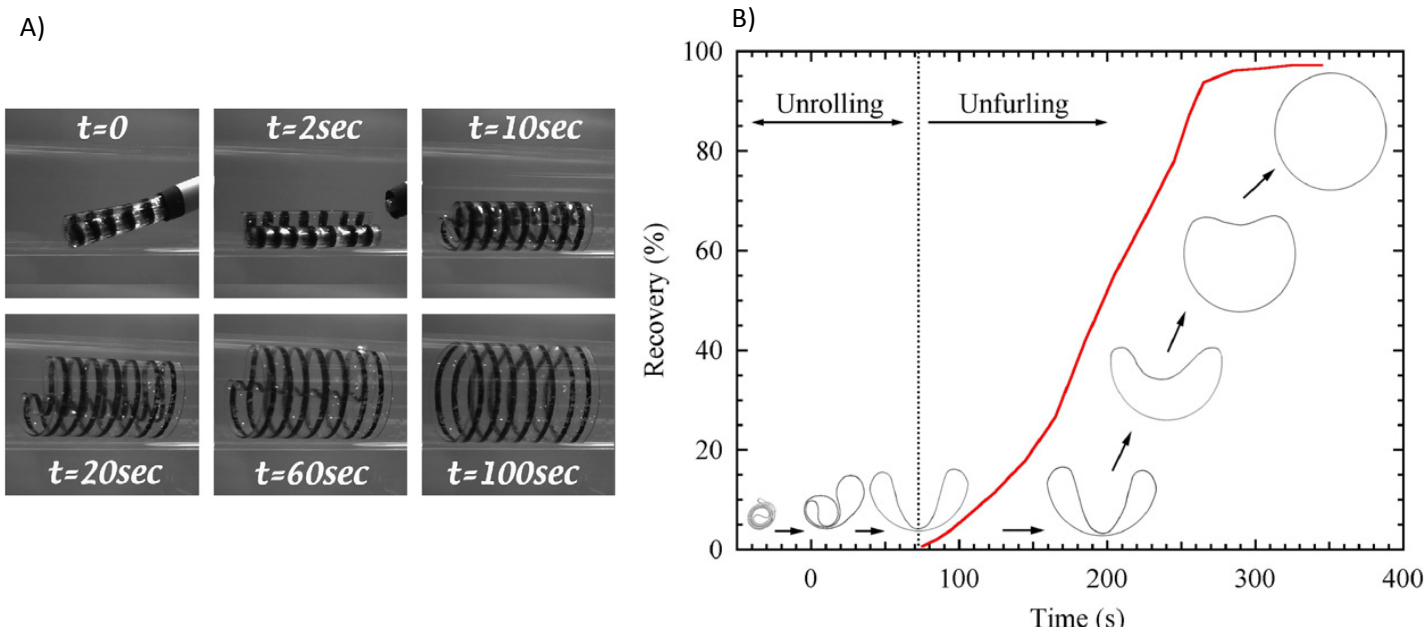

Figure 5: Recovery an SMP stent from a rolled and furled temporary shape to a fully open tube. A) A compressed tube delivered via a 18 Fr (6 mm) diameter catheter into a 22 mm diameter glass tube expanded to its permanent shape in 100 seconds. B) Schematic of free recovery of SMP stent [11].

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 very 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. Thus, SMPs are an excellent option for the future, but is likely not feasible to implement them in the time frame of this project.

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 show 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 a nasogastric tube.

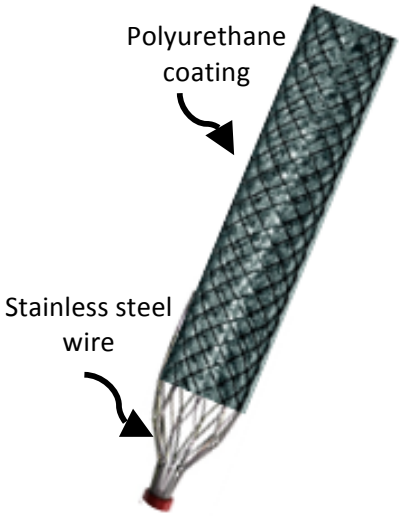

Figure 6: Rendering of the fully expanded coated stent tube near its tip [16].

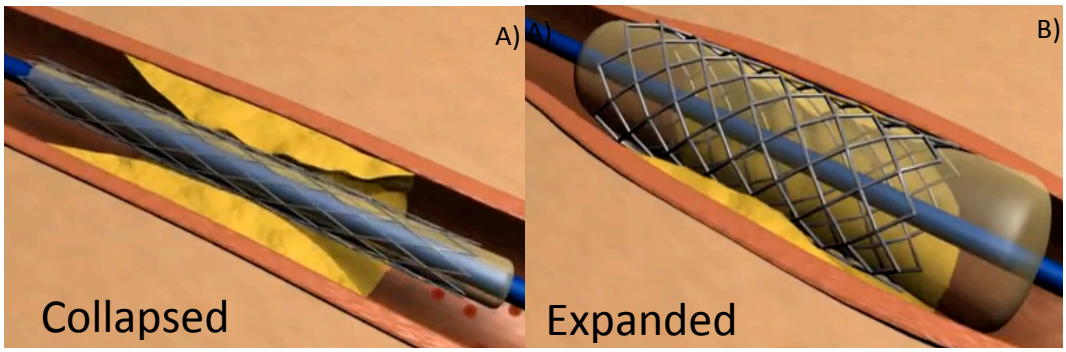

Figure 7: Illustration of tube expansion mechanism. A) Tube in its collapsed state just after insertion. B) Tube in expanded state just after inflation of the expanding balloon mechanism [17].

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 provided extra resistance to collapse from the suction. Lastly, the stainless steel would be radio-opaque, therefore allowing clinicians to check placement of the nasogastric tube using an X-ray without adding extra material to 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 and laser cutting equipment is not available on campus. Lastly, fabrication costs in addition to the cost of stainless steel and the balloon mechanism would make this design too costly for a NG tube.

Design Matrix

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, 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 weights of 10. 'Short-Term' refers to the ability of the 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 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 of 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 an pH sensor is incorporated into the outer sleeve, then 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 build and then assemble. The expandability of this device is promising as the inner tube is encapsulated and can be shrunk down by many factors. Customizability for the sleeve is high because the pH sensor attached to the tip so pH can be read in one easy step. Stiffness scored well the outer sleeve will be bendable due to the silicone material yet stiff enough to insert because of the inner tube reinforcement. The ease of use was lowest for this design because removal of the sleeve requires and additional step for clinicians and 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. There is still a great deal of research to be done on these polymers. 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. 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 it 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.

Ethical Considerations

There will be no direct contact with patients during the first semester of development for this NG so there are few ethical considerations the team must consider. In the short-term, the team must keep in mind safety of the patient in selecting materials and design components. In the long-term, any human testing will require proper authorization and will be conducted by a certified clinician. NG tubes should not be used in patients who have recent history of facial fracture, bleeding or perforated esophagus, or a perforated pharyngeal pouch. Additionally, NG tubes should be used with caution in unconscious patients, who cannot cough to alert the clinician of misplacement in the airway [2,3,4].

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-irritable 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 through 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 stomach without the tube collapsing or coiling up.

Future Work

Because this project worked on for two semester, the team has broken up future work into two sections: tasks to be accomplished this semester and tasks to be accomplished next spring. At this point, the team has selected the final design and will soon begin ordering of materials to begin a proof of concept prototype.

This semester, the team will determine the material to be used in both the outer and the inner sleeve. Based on consultations from a polymer expert on campus, silicone rubber will likely be pursued as the main material for fabrication. However, the specific type and stiffness of the silicone has yet to be

selected. In addition, the team must determine the optimal diameter and wall thickness of the inner and outer tube through experimental testing with actual wall suction devices and mannequins used to train clinicians how to use NG tubes. Optimizing these components will allow the final design to have the smallest possible diameter while still allowing adequate NG tube function. Thus, improving patient comfort. The team will test and select test the folding patterns for the inner tube during insertion this semester. The design of a folded or twisted inner tube must be chosen that will minimize the insertion diameter yet expand upon removal of the sleeve. At semester's end the team should be able to show the finished inner and outer tubes independently from each other.

Next semester the team plans to focus on the manufacturing of the final design. As opposed to focusing on the inner and outer tubes independently, the team will focus on putting the project together as a whole. The team will determine the best way lock the inner tube into the outer sleeve and how to detach the sleeve when it is placed correctly in the stomach. When the expansion design is completed, the team will look at adding attachments like the pH sensor, radio-opaque strip, and lubricant or anesthetic. Next semester, the team will also consider ways to use recycled materials or recycle the NG tube after use. Finally, the team will conduct full testing of the developed NG tube on mannequins and eventually human patients.

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Appendix A – Product Design Specifications

Project Design Specifications

Expandable Nasogastric Tube
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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 48 inches 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.

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.