Spring | 12

Expandable Nasogastric Tube

BME 301

Client: Dr. Steven Yale, Marshfield Clinic
Advisor: Tracy Puccinelli
Kelsey Duxstad, Rachel O'Connel, Ashley Quinn, Mike Stitgen

Abstract

Nasogastric tubes are used for stomach evacuation and decompression. They must be inserted through the nasal cavity and into the stomach. This is a very uncomfortable procedure for the patient, and could be alleviated with a tube that is inserted with a smaller diameter, and expands to the necessary size following insertion. There are two main competitors on the market. A Nano Vibronix tube that generates vibrations during insertion, and a Kimberly-Clark tube that utilizes a silicone balloon to maintain placement in the stomach. Our team proposed three design alternatives for final design consideration. These designs utilized Nitinol stents, shape-memory polymers, and shape-memory metal coils. Through evaluation of patient comfort, expandability, manufacturability, cost, and other important factors, a design consisting of a shape-memory polymer tube has been selected as the best solution. This design utilizes a 6mm diameter thermoplastic polyurethane tube that will be folded to a 3mm diameter shape by collapsing the lumen. This will then be placed in a plastic sheath for insertion. When the procedure is completed, the sheath is removed and the tube is allowed to revert to the original 6mm tube shape. Material purchasing and testing will be completed to reach the final design

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Background:

Aspirating nasogastric tubes are available for a wide variety of uses. The two most common uses are for stomach evacuations and decompressions. Stomach evacuations are necessary when a patient has ingested poison or other fluids that need to be quickly removed from the stomach. The other use, stomach decompression, is used during the treatment of gastric immobility. During gastric immobility, fluids begin to accumulate within the stomach and increase the pressure. At this point, a nasogastric tube is inserted to suction the fluids out of the stomach, thus relieving the pressure (Shalamovitz, 2011).

The placement of a nasogastric tube is a very uncomfortable process for the patient. To alleviate some of this discomfort, local anesthesia is applied. This application may be performed in one of two ways. First, the sniff and swallow method is performed by injecting 10mL of 2.0% lidocaine jelly into the nasal cavity (Shalamovitz, 2011). After the anesthesia is injected, the hospital staff will wait five to ten minutes to ensure onset of the lidocaine. The second method is the application of a 2.0% lidocaine jelly directly onto the nasogastric tube ("Nasogastric Tube Insertion," 2003). The application is performed on the first four inches of the tube. The jelly acts to lubricate the tube as well as anesthetize the nasal cavity.

Following the treatment of anesthesia, the necessary length of the nasogastric tube is estimated. The medical staff will measure from the tip of the nose to the earlobe, then from the earlobe down to the sternum ("Nasogastric Tube Insertion," 2003). They will then put a mark on the outside of the tube to inform the staff when the general area of the stomach has been reached.

The nasogastric tube is inserted through one of the nostrils, then into the back of the nasal cavity (Figure 1). Stiffness of the tube is important to allow the medical professional to follow along the back of the nasal cavity (Benson, 2012). At this point, the medical staff will ask the patient to swallow water to close the epiglottis. While the patient is swallowing, the nasogastric tube is inserted the down the esophagus and into the stomach (Shalamovitz, 2011).

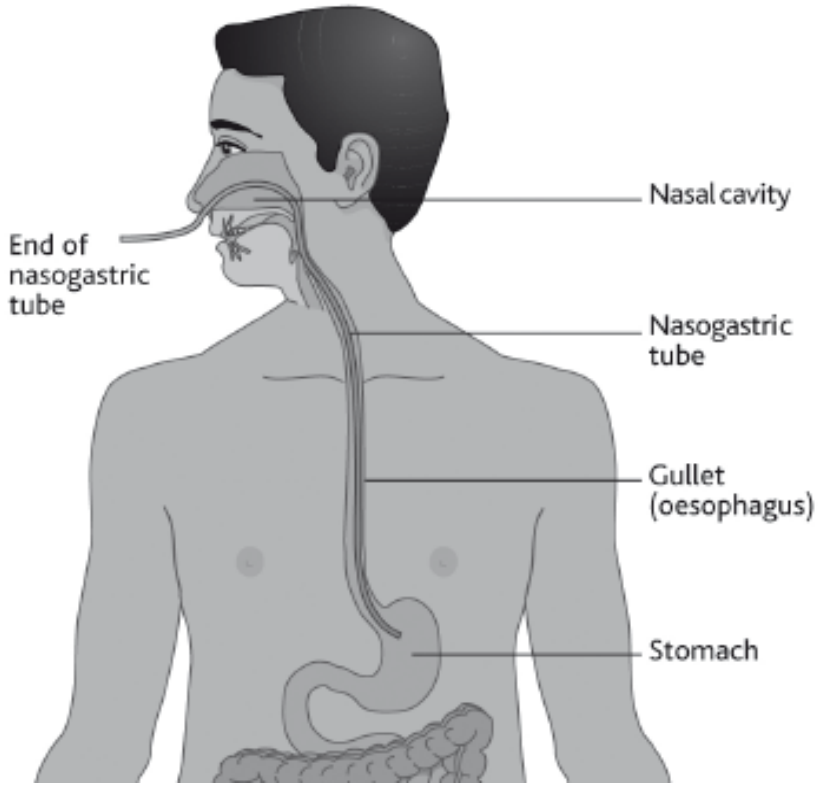

Figure 1. The path of the nasogastric tube insertion begins in the nasal cavity and ends in the stomach. <http://nursingcrib.com/wp-content/uploads/image/ngt.gif?9d7bd4>

Although the patient is drinking water, closing the epiglottis, there is a chance that the nasogastric tube may circumvent this membrane and move into the trachea instead of the stomach. Improper insertion of the nasogastric tube can lead to complications such as pneumonia. In the United States approximately 0.3% of patients that have nasogastric tubes placed will die of complications from the procedure (Kassias, 1998).

Problem Statement:

Our client, Dr. Steven Yale of the Marshfield Clinic Research Foundation, would like our team to design a nasogastric tube, which will expand from a 3 mm diameter to a 6 mm diameter after it has been placed within the patient. This expansion will greatly reduce the patient's discomfort upon insertion. It will also help reduce the risk of the nasogastric tube being placed in the trachea, which can cause complications such as pneumonia and even death. Our device needs to be accurate, reliable, and easy to use.

Design Criteria:

Our design must meet a number of criteria, for both medical and manufacturing purposes. The criteria ensure and enhance the basic purpose of the tube, which is to

remove fluid contents from the stomach of patients with an obstructed gastrointestinal system.

The most important criteria is that the tube expands from 3 mm to 6 mm in diameter. This would decrease patient discomfort while maintaining enough lumen area to evacuate the stomach contents in a timely manner. This expansion must be accomplished through the entire 130cm length of the tube.

Additional criteria need to be met since the tube will be used within the body. It cannot contain any latex or toxic materials. Also, it cannot undergo degradation, despite the acidic environment of the stomach. These conditions must be met for up to 72 hours (Ray, 2008).

The placement of the tube is a very exacting process and our design should make it easier. Misplacement into the lungs causes pneumonia or death (Kassias, 1998).This product will not kink or bend during placement and will have be stiffer than the current tubes. This will allow health care professionals to guide the tube back into the nasopharynx with more ease. The stiffness will also ensure that the tube does not enter the lungs and continues in the straight path, past the epiglottis, to the stomach (Portsmouth Hospitals, 2009). However the tube should still be flexible enough to navigate the nasal cavity and esophagus.

Manufacturing criteria must also be met. This design needs to be produced for under thirty dollars in order to be competitive in the market. It also has to be sterilized, either by heat or ultraviolet methods.

Competition:

Currently there are no nasogastric tubes on the market that have the ability to expand from a small to large diameter. The nasogastric tube market is being driven by reducing the misplacement of the tubes and mortality caused by this event. In addition to increased safety, patient comfort is also a high market driver (Collins, 2011). With this in mind, there are few products on the market that are aimed to increase patient comfort for insertion of tubes.

There is a simple tube made by the Kendall and Corvidien merger that coats the tube with a hydrophilic lubricant. This lubricant allows easier and more comfortable application. The lubricant of the tube however does not significantly increase the cost of the tube. The price is raised to $18, which is with the normal twenty dollar range of tubes (Collins, 2011).

A more sophisticated nasogastric tube is sold by Kimberly-Clark. This nasogastric tube is made out of silicone, a material change that contributes to additional patient comfort. The tube comes with a variety of stoma tube lengths which can be fitted to the patients needs. Additionally, the tube utilizes a small silicone balloon that can be expanded inside the body to maintain placement (Collins, 2011).

The biggest competitor for increased patient comfort is a device called the NG-Shield by Nanovibronix. Attached to the nasogastric tube is a small, hand-held device that generates acoustic surface vibrations as seen in Figure 2. These vibrations decrease the friction caused by the tube passing through the body, allowing it to be inserted easier and increasing comfort for the patient. The largest problem is that this device significantly raises the price of the nasogastric tube to more than $100 (Collins, 2011). Although this

device increases greatly increases comfort, it is rarely used due its extreme cost when compared to the devices listed above.

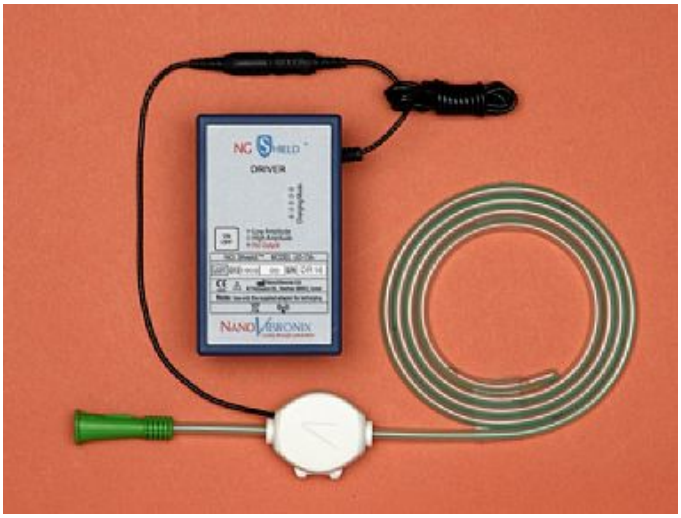

Figure 2: A NG-Shield device that generates acoustic surface vibrations to decrease the friction of the nasogastric tube upon insertion. <http://www.nanovibronix.com/Nano/Templates/showpage.asp?DBID=1&LNGID=1&TMID=84&FID=568>

Ethical Considerations:

There are many ethical considerations that pertain to this project. Care must be taken to not infringe upon any current copyrights or patents of nasogastric tubes,their modifications, or other similar products, such as stents. It is critical that all design modifications be original. Although the expansion mechanism of our product is a novel concept, the modifications we add to the expandable tubing (venting, suction attachments, etc.) must not violate copyright rules.

In addition, to ethically test the product on human subjects Institution Review Board approval must be obtained before the design is implemented in a hospital setting. Finally our main concern is patient safety and comfort. The purpose of this design is to decrease patient death and patient discomfort. It must be proven that our design will fulfill these criteria.

Materials:

A variety of materials were investigated for application in our design. Two proved to be applicable to our various design alternatives: shape memory polymers and shape memory metallic alloys.

Shape memory polymers can be deformed at room temperature, but when heated above the transition temperature, reverts back to the set shape (Behl, 2007). There are a

few materials that meet this description such as polyurethanes and polyetheresters. The transition temperature can be either the glass transition temperature or the melting temperature of the polymer, which would be set below the standard range of temperatures of body (97 - 100° F) in our design by choosing the polymer accordingly (Elert, 2012). These polymers are sterilizable and are non-toxic (Lim, 2004).

Similarly, shape memory metal alloys respond to increased temperature by reverting back to the permanent pre-designed state. A very successful alloy, Nitinol, is a well-established material used in self-expanding vascular stents. The alloys is composed of 55% nickel and 45% titantium giving is super-elastic and shape-memory properties. When the alloy is cooled, the metal transitions from the strong Austenitic phase to a weaker Martensitic phase. Furthermore, strong intermolecular bonds minimize undesirable biological reactions to the alloy. The prevention of an immunological reaction makes Nitinol a biocompatible material that also resists corrosion. However, Nitinol is difficult to process because any change in composition will alter the transformation properties. Also, titanium is highly reactive to oxygen and must be worked in a vacuum (Stoeckel, 2012). These difficulties give Nitinol a disadvantage in practicality for our purposes.

Design Alternatives:

Stent Bubble Device:

This design is based off the client's original project idea which applies stent technology to the original nasogastric tube. A stent is an artificial tube that can be mechanically expanded through the inflation of an internal balloon (Figure 3). The stent would be incorporated into the inside of the nasogastric tube, so that when the balloon expands the stent, the nasogastric tube expands with it.

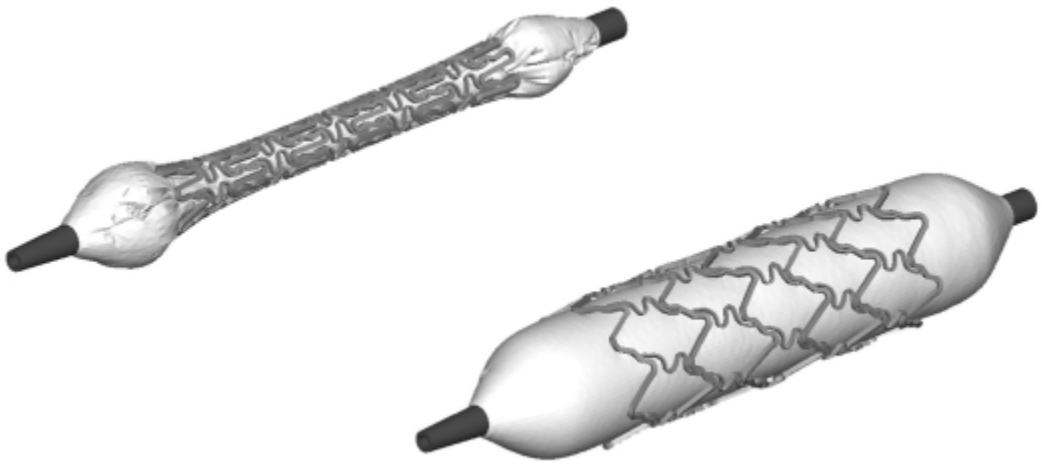

Figure 3: A mechanical stent before and after the balloon expands the stent. <http://www.feops.com/fea_stent_expansion.jpg>

The stent would be fixed to the inside of the polymer tube at specific attachment points. This fixation could be done by either by embedding the stent into the polymer, or by looping the polymer though the meshes of the stent. The attachment points would force the

larger diameter polymer tube to be pulled inward to the size of the smaller diameter stent. The excess polymer between attachment points would leave folds of polymer around the stent as seen in Figure 4. These folds would have to be secured close to the stent in order to minimize the space they take up and allow for a smaller insertion diameter. Once the tube has been inserted into the patient, a balloon would be used to expand the stent, which will pull the polymer taut. Upon removal of the balloon, the tube would be able to function as a normal nasogastric tube and be at the same diameter as the one currently used.

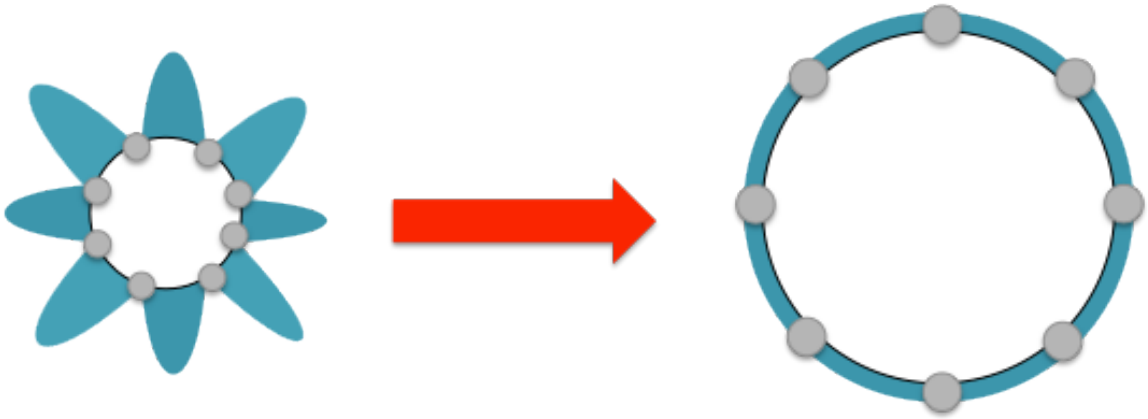

Figure 4: The bubble stent design before and after expansion. The small gray circles indicate the locations of securement between the polymer and the stent. In this diagram the polymer folds are not secured in the pre-expanded form.

This design is rather complicated and has the potential to become very expensive for the client. It is unlikely that the team would be able to fabricate a working prototype of the the tube design within the course of the semester.

Shape Memory Polymer:

This design revolves around the shape memory polymer. These polymers can be shaped under heat and will retain that shape once cooled. The polymer can then be deformed but will return to the original shape once heated past the transition temperature (Cornerstone Research, 2001). A polymer that has a threshold set at or below normal human body temperature, could be made into a suitable expandable nasogastric tube. The tube would be set in its expanded, normal form and could then be folded into a smaller diameter at room temperature for insertion. Once the tube is heated inside the body cavity, it will expand into its original form with the larger diameter.

This design requires a system to keep the polymer tightly compressed in the smaller diameter shape. To achieve this, a small diameter sheath will enclose the polymer tube. This tube will be as thin as possible to ensure that it does not add any significant width to the compressed tube diameter. Once the tube has been placed inside the patient, it must be removed to allow for expansion of the nasogastric tube. This will be done by simultaneously cutting open the top end of the sheath while removing it from the insertion path, ensuring that the nasogastric tube within it stays in place. Figure 5 shows the expansion system including the removal of the sheath.

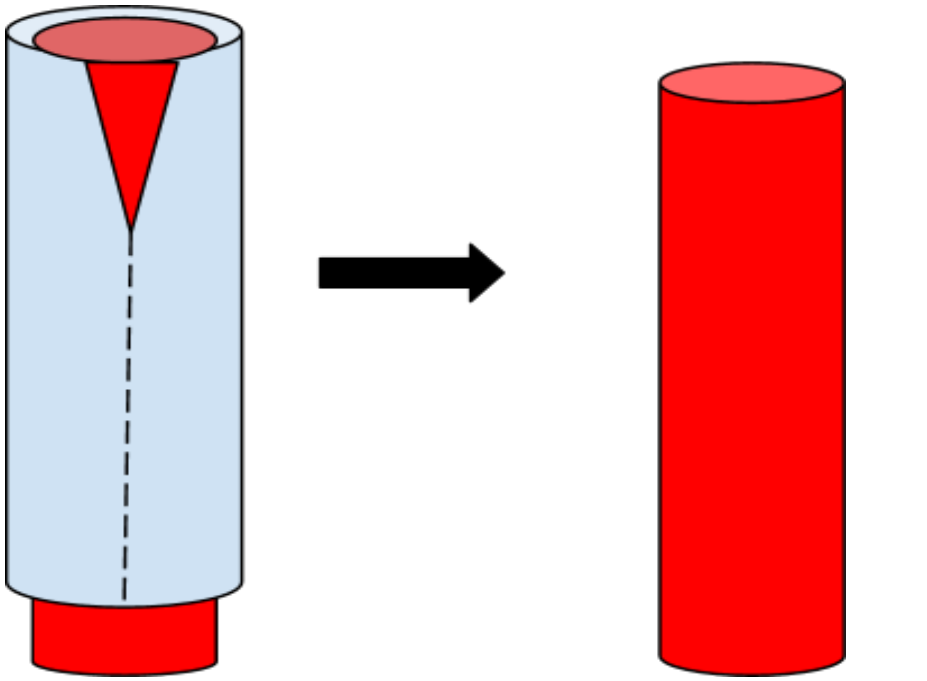

Figure 5: The shape memory polymer tube is compressed into a sheath. That sheath can then be sliced open for removal and expansion of the tube.

Stretchy Coil:

The last design alternative for the tube is to embed a shape-memory metal coil into an elastic polymer tube. The metal coil would be thermally set to a 6 mm diameter, the same size as the expanded tube. The coil and surrounding polymer tube could then be deformed via stretching to make the diameter thinner. After insertion, the body temperature would heat the coil past the threshold temperature, causing it to return to the original 6 mm diameter shape (Figure 6). The polymer used in this design must be elastic so that it can stretch with coil without the coil perforating any part of the tube. A heat memory metal could be utilized to increase the durability of the coil.

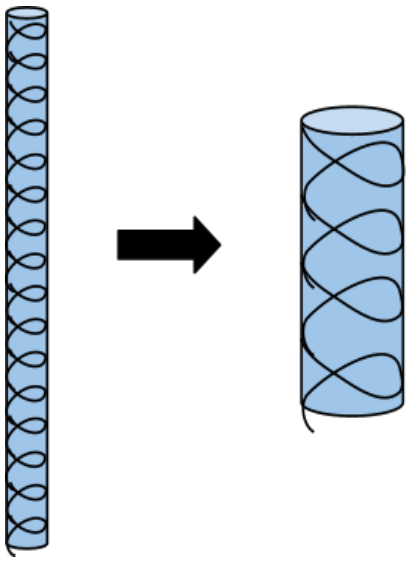

Figure 6: The coiled tube is stretched out to make the diameter of the tube smaller for insertion. The coil is allowed to return to normal tension for expansion of the tube once inside the patient.

Design Matrix:

	Weight	Stent Bubble Device	Shape Memory	Stretchy Coil
Comfort	1	3	4	4
Diameter	1	4	3	4
Modifications	1	1	4	2
Cost	1	2	4	3
Ease of Use	0.75	1	5	2
Manufacturability	0.5	3	4	3
Expandability	0.5	4	3	4
Feasability	0.25	2	3	3
Total	**30**	**12.25**	**20.75**	**16**

Many factors were taken into account for our design matrix. They were all weighted from .25 to 1 and then this factor was multiplied by the scale of 1-5. On this scale a perfect score would be a 30.

Comfort was ranked the highest because of the importance of patient comfort and safety. Increasing comfort also decreases undesired patient outcomes. For similar reasons diameter was a very important factor. Diameter is directly correlated with patient comfort

and safety. All designs received approximately the same rankings although the stent bubble's rigid design could be uncomfortable and the shape memory polymer is the least compressible.

Modifications and cost were also weighted the highest. All designs must be able to have aspiration ports and attachment tubes added on. They also need to be produced for under $30 to be productive in the market. The stent bubble design and stretchy coil designs received the relatively few points in these categories because the metal is costly and makes it more difficult to add on the modifications.

Ease of use is important so that the health care professionals can properly insert our device. This category is very important due to patient safety. Again the designs with metal incorporated ranked lower because of the stiffness of the metal and additional steps of expansion.

Manufacturability was rated lower because although some may be more difficult to produce than others, how the final product functions is most important. All designs have similar values in this category, although the metal designs have extra complications due to the composite of both a metal and polymer materials. Alternatively, the shape memory polymer just has to be manufactured in a heat sensitive environment.

Expandability analyzes the ability of the design to obtain a wider diameter. It is similar to the diameter criterion but emphasizes the final expansion instead the initial diameter. The shape memory polymer ranked the lowest, whereas the other designs have better mechanisms to obtain additional expansion.

Feasibility is the least important aspect of the matrix. All designs will be difficult to finalize and produce. We will have to focus our efforts on aspects that are attainable for our level of expertise.

Taking all of these aspects into account, the shape memory polymer received the highest ranking. It did not win in all the categories, but overall will perform the best.

Final Design:

After evaluating the design matrix, it was clear that the shape-memory polymer would be our final design. This design incorporates a shape-memory polymer to compose the nasogastric tube and a sheath to maintain the compressed shape during insertion.

After further research, a thermoplastic polyurethane was selected as the polymer to create the nasogastric tube. Thermoplastic polyurethane is a biocompatible polymer formed in a mold, similar to non-thermoplastic polyurethanes (Sokolowski, 2005). By varying the composition of the polymer, the glass transition temperature can be modified to a temperature slightly below 37ºC. Once the polymer reaches its glass transition temperature, it will return to the shape at which it was originally formed (Sokolowski, 2005).

After forming the thermoplastic polyurethane into the desired shape, the lumen will be collapsed to achieve the smallest possible insertion diameter. The expanded outer diameter of the nasogastric tube is 6 mm, giving it a cross-sectional area of 28.27mm^2 (Appendix B). By collapsing the lumen, the cross-section area can undergo a 44.4% decrease to 15.71mm^2.

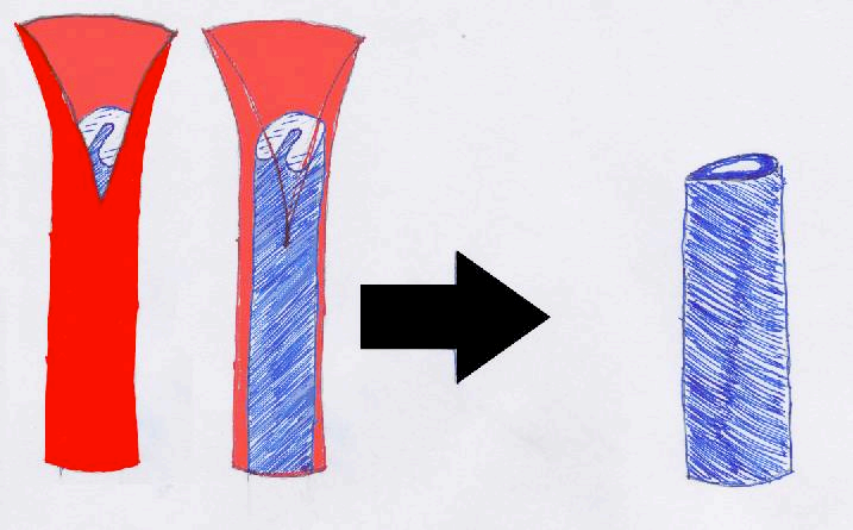

Figure 7. Thermoplastic polyurethane nasogastric tube compressed within the sheath and uncompressed.

To maintain the nasogastric tube in its compressed shape during insertion, a thin sheath will be utilized (Figure 7). The sheath would guarantee that the polymer does not begin expanding until the nasogastric tube has been fully inserted. This sheath will be removed following successful placement of the nasogastric tube in the stomach. The medical staff will cut the end of the sheath while holding the end of the nasogastric tube in place. While this will add a few minutes to the procedural time, the sheath is necessary to decrease patient discomfort by maintaining the reduced insertion diameter throughout the procedure.

Future Work:

Looking forward to the rest of the semester, most of the effort will be committed to the fabrication and testing the final product. The thermoplastic polyurethane will have to be purchased and tested on the properties related to an expandable nasogastric tube. The sheath will also have to be fabricated and tested. Finally the team will have to look into professional manufacturing options for the tube and sheath as a product. Within the next two weeks, our team will order the thermoplastic polyurethane and begin testing. The testing will be performed over the following three weeks.

Polymer Testing:

In order for the shape memory polymer to be acceptable as an expandable nasogastric tube, various properties must be tested. The most important of these is if the polymer will be able to return to its original shape at a normal body temperature. The tube will have to be set into original form as the expanded, normal NG tube diameter. The tube with then be compressed into the sheath. If the sheath is not ready for this stage of testing, a straw could be used as an acceptable substitute. The tube and sheath will be placed into a 37ºC environment where the sheath will then be removed. In order to be viable, the tube will have to expand in this heated environment. Testing of the polymer will then continue being tested under negative pressure. Under this condition, the tube must be able to uptake fluids with a large range of viscosities. This test will assess if the tube has the proper

strength and Reynolds number to act as an NG tube should. The Reynolds number of gastric fluid is very low. Therefore gastric fluid can be assumed to have Newtonian fluid characteristics and Poissuelle flow (Aguilera, 2011).

Sheath Testing:

Ideally sheath testing would occur simultaneously with the polymer testing to accomplish a whole product test. The sheath must be tested with the shape memory polymer to asses if it is strong enough to hold the polymer in its compressed form, but also be easy to remove without moving the tube itself. The sheath also needs to be easy for the health care staff to remove without causing them an inconvenience or additional discomfort to the patient. This particular test will help determine the preferred method of removal, either by pinching the sheath to slip off or by cutting the sheath the open as it is pulled off.

Conclusion:

The implementation of an expandable nasogastric tube that is inserted with a smaller diameter will greatly reduce patient discomfort and potential complications during insertion. The tube must be able to withstand the environments of the nasal cavity and the stomach while maintaining functional integrity. Through considerations of patient comfort, expandability, manufacturability, cost, and other important factors, a design consisting of a shape-memory polymer tube collapsed into a sheath has been selected as the best solution. In moving forward with the project, materials need to be ordered and tested to reach the final design.

References:

1. Aguilera, Jose. Food Engineering Interfaces. New York: Springer, 2011. Online.

2. Behl, Marc. 2007. "Shape-Memory Polymers." Center for biomaterial development.

3. Bensen, Mark. 2012. Personal Communication.

4. Collins, Jack. "Nasogastric Tube Market Report". April 21 2011.

5. Cornerstone Research Group Inc. Shape Memory Polymers - An Overview. 2001. http://www.crgrp.com/technology/overviews/smp1.shtml

6. Elert, Glenn. "First Aid & Emergencies." Body Temperature: Normal Body Temperature, Fever, and Thermometer Types. Web. 13 Mar. 2012. <http://firstaid.webmd.com/body-temperature>.

7. Kassias, AJ. "A Prospective Study of Tracheopulmonary Complication Associated with the Placement of Narrow-bore Feeding Tubes." Critical Care. 1998; 2(1): 25-28.

8. "Nasogastric Tube Insertion". 2003. University of Ottawa.

9. Lim, Issel A. "Biocompatibility of Stent Materials." MURJ 11 (2004): 33-37. Web. 2 Feb. 2012. <http://web.mit.edu/murj/ www/v11/v11-Features/v11- f5.pdf>.

10. Portsmouth Hospitals. "Insertion and Maintenance of Fine Bore Nasogastric Feeding Tube". Hospital Protocols. Dec.2009.

11. Ray, Louie. "Nasogastric Tube Insertion and Removal." July 3, 2008.

12. Shalamovitz, Gil. 2011. "Nasogastric Tube." Medscape.

13. Sokolowski, Witold. 2005. "Medical Applications of Shape Memory Polymers." California Institute of Technology.

14. Stoeckel, Dieter. "Self-Expanding Nitinol Stents - Material and Design Considerations." European Radiology (2003): 1-12. Web. 16 Feb. 2012. <http://www.nitinol.com/wp-content/ uploads2010/05/2003_Stoeckel_Self_Expanding_Nitinol_ Stents.pdf>.

Appendix A:

Project Design Specifications
#3- Expandable Nasogastric Tube
March 14, 2012

Team: Kelsey Duxstad, Rachel O'Connell, Michael Stitgen, Ashley Quinn
Client: Dr. Steven Yale
Advisor: Professor Tracy Puccinelli

Function:
Evacuation nasogastric tubes are used to remove fluid contents from the stomach in patients that have an obstructed gastrointestinal system. Our mission is to design an evacuation nasogastric tube that, after placed in the patient, expands from a 3mm diameter to a 6mm diameter. This expandable system will significantly decrease patient discomfort while improving the correct placement of the device.

Client Requirements:
- Cost effective
- Reduces patient discomfort
- Reliable

Design Requirements
1) Physical and Operational Characteristics
    a. Performance requirements
        i. Allows for evacuation of fluid contents of stomach
        ii. Does not degrade in acidic stomach environment
        iii. Does not kink or bend during placement
    b. Safety
        i. Reduces patient discomfort with placement
        ii. Contains no toxic materials
    c. Accuracy and Reliability
        i. Nasogastric tube must not degrade while in patient
        ii. Must allow for accurate placement in stomach
    d. Life in Service
        i. 1-5 days
    e. Shelf Life
        i. 1-2 years
    f. Operating Environment
        i. Nasal Cavity, Esophagus, and Stomach
    g. Ergonomics
        i. Easy for nurse or doctor to correctly place in stomach
    h. Size
        i. Unexpanded diameter: 3mm
        ii. Expanded diameter: 6mm
        iii. Length: 130cm
    i. Materials
        i. No latex
        ii. Water impermeable

iii. Acid resistant
iv. Stiff

j. Weight
i. Less than 1 kg

2) Production Characteristics
a. Quantity
i. One model
b. Target Production Cost
i. Under $30

3) Miscellaneous
a. Standards and Specifications
i. Must be tested to ensure patient comfort and reliability
b. Customer
i. Hospitals
ii. Clinics
c. Patient-related Concerns
i. Discomfort
ii. Allergic reaction
d. Competition
i. Covidien
ii. Bard
iii. Dale
iv. Rusch

Appendix B:

Shape-memory polymer cross-sectional area calculations.

$$Area_{Expanded} = \pi r^2 = \pi 3^2 = 28.27 mm^2$$

$$Area_{Collasped} = Area_{Expanded} - Area_{lumen} = 28.27 mm^2 - \pi 2^2 = 15.71 mm^2$$

Percent reduction

$$15.71 mm^2 / 28.27 mm^2 = 44.4\%$$