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Reduced Diameter Nasogastric Tube With Guide Wire Support

BME 301
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Abstract

Nasogastric tubes are used for stomach decompression via insertion 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. There are two main competitors on the market focused on increasing patient comfort: 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. Through mathematical analysis and testing, we have found that a smaller diameter tube is sufficient for our client's use. This smaller diameter, more pliable tube needs a guide wire to help with placement. When the procedure is completed, the guide wire is removed. Polyvinyl chloride (PVC) and silicone tubing were used in force, suction, and surface roughness testing. Testing has shown that this design puts the least amount of pressure on the nasal cavity. Due to risks of chemical leaching from PVC materials, the silicone tubing was determined to be the most effective solution.

Contents

Background

Aspirating nasogastric tubes are available for a wide variety of uses. The most common use is for stomach decompression to treat 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).

Placement Procedure

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 ten centimeters 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 into the nasopharynx. (Benson, 2012). Stiffness was quantified using a deflection index. These comparisons can be found in Appendix D. This initial insertion and passage through the nasal conchea is the most painful part of the procedure. The large tube diameter makes it difficult to navigate the nasal cavity and increases shear stress on the surrounding tissues. Insertion is also painful when the tube makes the curve near the pharyngeal tonsils into the pharynx because the tube is applying a normal force to the tissue (Seidel, 2003).

After 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).

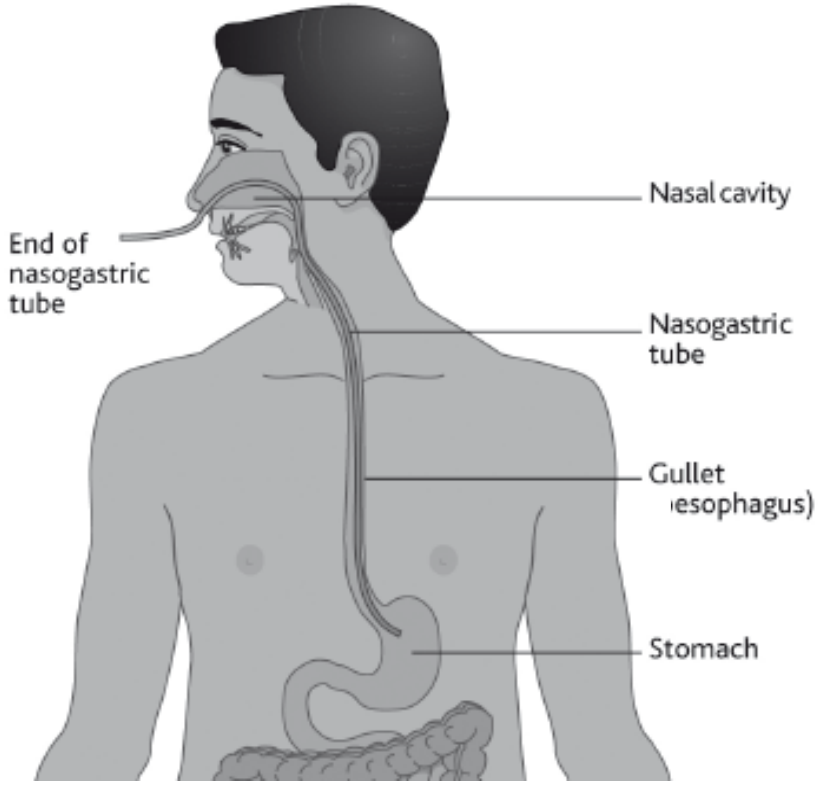

Figure 1. The path of the nasogastric tube insertion begins in the nasal cavity and ends in the stomach (Merland, 2012).

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). The smaller tube diameter increases the ease which the nasogastric tube passes into the small opening of the esophagus. The smaller diameter, preferably combined with a less stiff tube, allows more room in the esophagus to be correctly placed and will decrease the force the tube can exert on the epiglottis incorrectly move into the trachea.

Physiology

The nasogastric tube comes in contact with a variety of tissues as it travels through the body (Figure 1). After entering the nasal cavity, the tube travels an average of 13 cm through the nasal cavity until hitting the back wall and beginning of the nasopharynx (Hidle, 2010). Within the nasal cavity it is possible for the tube to come in contact with the Sphenoid Sinus, the Middle Nasal Conchus, Orbital Lamina, and the Carotid Canal. The normal pathway for the tube is through the vestible near the inferior turbinate, into the concha. Finally it contacts the pharyngeal tonsil before moving into the nasopharynx (Figure 2). It is important that the tube does not exert large forces that could break these anatomical structures. It takes a force of 7N to break the Middle Nasal Conchus (Wagner et al, 2005). Therefore our design has to exert less than 7N of force as it travels past this most fragile point.

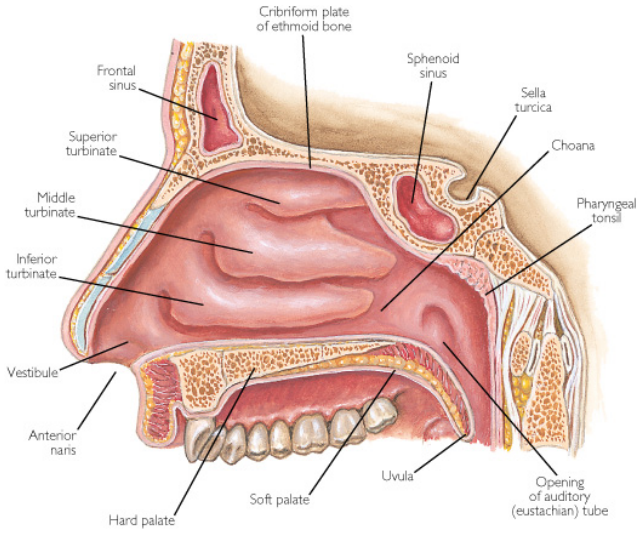

Figure 2. The nasal cavity which the nasogastric tube passes through in route to the stomach (Seidel, 2003).

Once the tube reaches the nasopharynx, it begins to make the curve further down into the pharynx. This is the point of insertion where the tube will exert the most force on any tissue in the body. The tissue of the nasopharynx where this force is exerted will be damaged at pressures of roughly 10 kPa (Payan, 2003). The average length of the adult pharynx is 150 mm (Roberts, 2005) and its average width is 3mm (Hibbert, 1979). This makes the average area of the pharynx 450 mm^2. Force is a product of area and pressure, therefore a 4.5 N force exerted by the tube will cause damage to the pharynx.

Problem Statement

Our client, Dr. Steven Yale of the Marshfield Clinic Research Foundation, would like our team to design a nasogastric tube that reduces the diameter from 6 mm (currently used) to 3 mm. The reduction in diameter will reduce patient discomfort from insertion, and help reduce the risk of improper tracheal placement of the nasogastric tube. Improper placement 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 external tube diameter is 3 mm. This would decrease patient discomfort while maintaining enough lumen area to evacuate the stomach contents in a timely manner. The reduction in diameter must be accomplished through the entire 130 cm 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). The design's reduced diameter tube will decrease the probability that the tube will enter the trachea (Benson, 2012). This will reduce the amount of error that will occur during placement. It will allow health care professionals to guide the tube back into the nasopharynx with more ease (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 sterilizable, either by heat or ultraviolet methods.

Competition

Currently there are no nasogastric tubes on the market that are inserted with a 3 mm diameter with a guide wire. 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 an otherwise standard tube with a hydrophilic lubricant. This lubricant allows easier and more comfortable application by decreasing the friction of the tube on the internal anatomy of the patient. The lubricant of the tube however does not significantly increase the cost of the tube. The cost increases to $18, which is within the average 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 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. 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 greatly increases comfort, it is rarely used due its extreme cost when compared to the devices listed above.

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.

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. Four proved to be applicable to our various design alternatives: shape memory polymers, silicone, PVC and shape memory metallic alloys.

Shape memory polymers can be deformed at room temperature, but when heated above the transition temperature, revert back to the set shape (Behl, 2007). 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 body temperatures (97 - 100º F).(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. For instance, Nitinol is a well-established material used in self-expanding vascular stents. 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 (Stoeckel, 2012). These difficulties give Nitinol a disadvantage in comparison to other materials.

After testing and calculations, both shape memory plastics and metals proved to be unrealistic for design consideration. In order to offer a more practical, realistic design, other materials were considered. Polyvinyl chloride (PVC) has been used in medical equipment such as tubing and medical collection. However, the polymer is very stiff and brittle without added chemicals. When manufactured into pliable tubing, plasticizers are added to soften the material into a deformable yet stable tube. However, the plasticizers added can leach out over time, and so steps must be taken to ensure plasticizers used do not cause significant clinical problems (Curtis, 2008).

Another popular material used for medical tubing is silicone. Silicone plastics have been growing in popularity due to their intrinsic biocompatible properties. The chemical stability of the silicon-oxygen bond that forms the backbone of the polymer gives the plastic its durable and biocompatible properties. Tubing can be manufactured using a variety of processing techniques such as molding, dipping, or extrusion, followed by cross linking to provide further chemical stability (Curtis, 2008).

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 4).

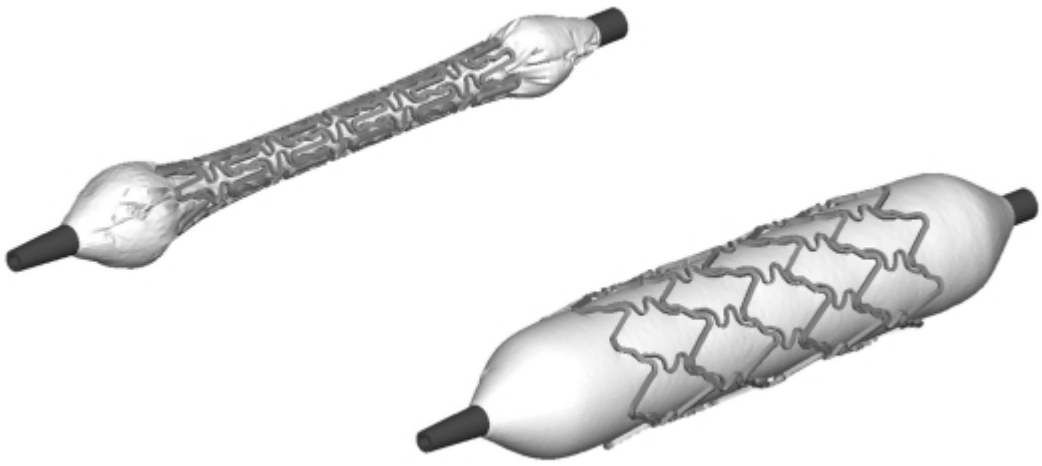

Figure 3: A mechanical stent before and after the balloon expands the stent (De Beule, 2012).

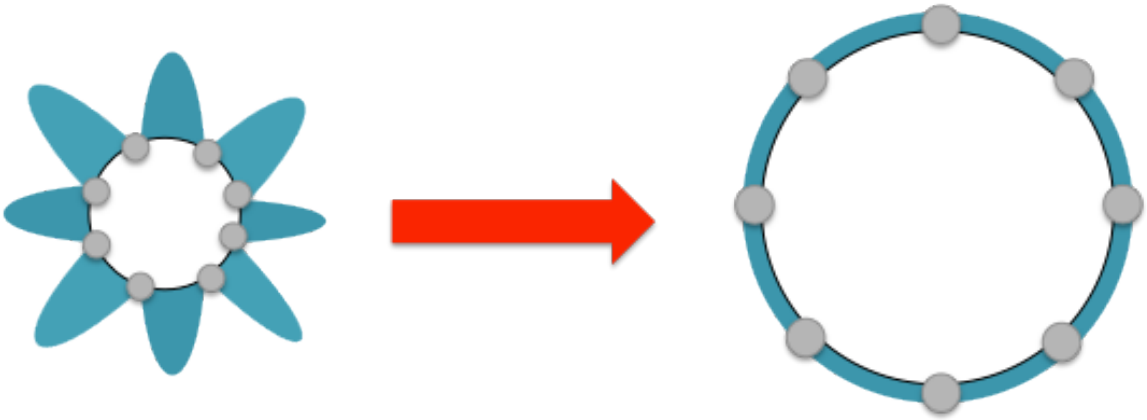

Figure 4: The bubble stent design before and after expansion, on the left and right respectively. The small gray circles indicate the locations of attachments between the polymer and the stent. The white area is the lumen and the blue areas represent the polymer. In this diagram the polymer folds are 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 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. Figure 5 shows the expansion system including the removal of the sheath.

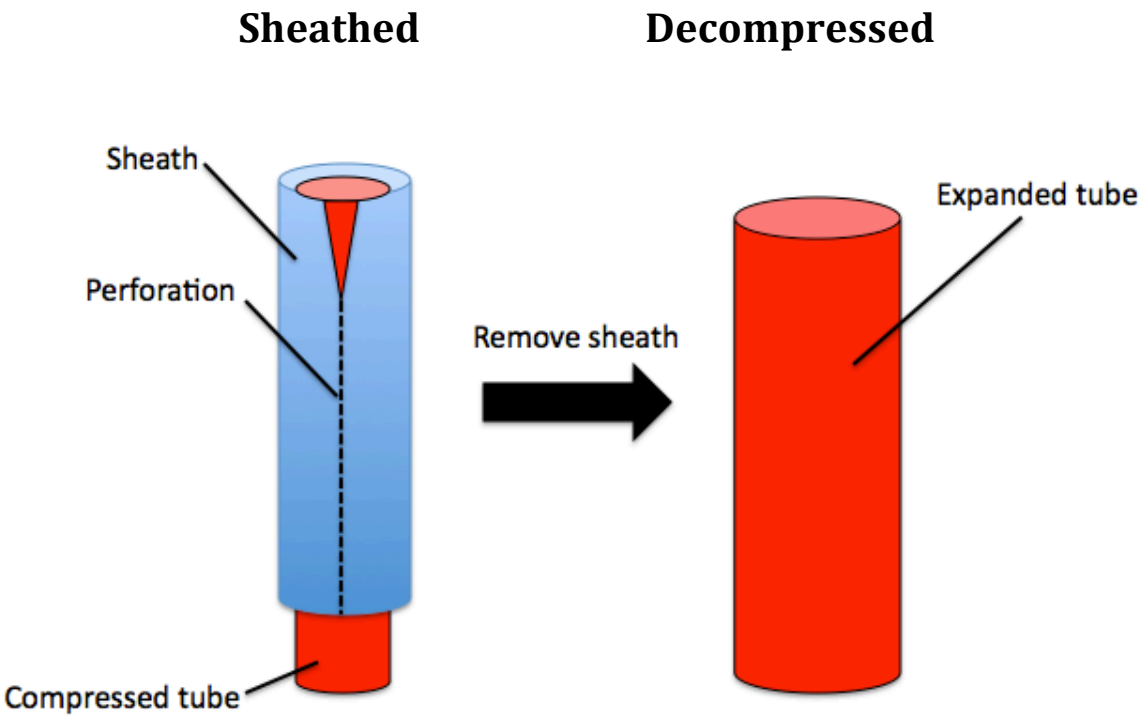

Figure 5: The shape memory polymer tube is compressed into a sheath. That sheath can then be sliced open for easy removal and allow the tube to expand.

Stretchy Coil

The third 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.

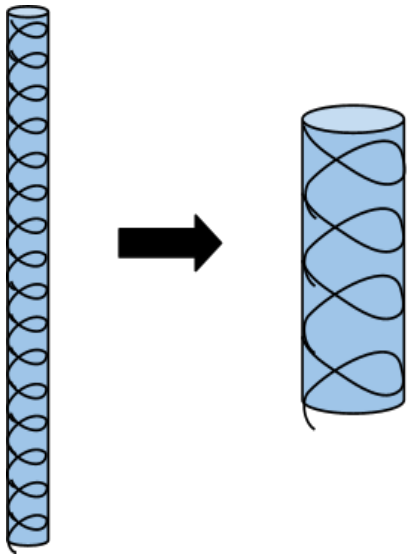

Figure 6: The coiled tube is stretched out to make the diameter of the tube smaller for insertion. The coil is allowed to return to normal tension for expansion of the tube once inside the patient.

Guide wire

Originally, there were only three alternative designs that were considered for the final design and the shape memory polymer was chosen to be the final design. However, several complications occurred that proved this design was not feasible to be the final design. Shape memory polymers are not currently available for commercial purchase, and the temperature change from room temperature to body temperature would not be a large enough change to cause the polymer to change shape. The team also performed preliminary testing by attempting to insert a 6.4 mm diameter tube into a 3.2 mm tube. This test was performed with both PVC and silicone tubing. The farthest achieved insertion was 0.5 cm. After finding that the sheath was not feasible, the team designed the fourth alternative; the guide wire inserted tube (Figure 7).

This tube design utilizes a 3.2 mm tube made of either PVC or silicone. In order to increase the stiffness of the tube for insertion a coiled, stainless steel guide wire will be placed inside the tube for insertion. Once inserted, the guide wire can be easily removed. Although this tube is not capable of expansion, its reduced diameter will still increase patient comfort and it will be able to work at the clinical flow rate given by the client under negative suction pressure (further explained in Testing).

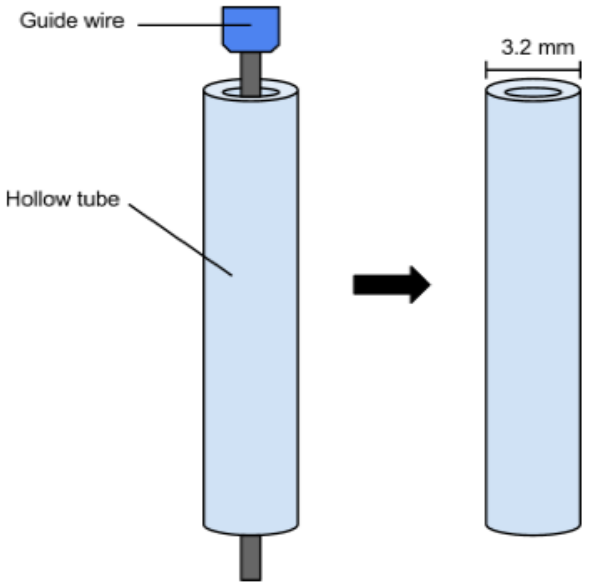

Figure 7: Small diameter tubing with inserted steel guide wire for insertion support, which is then removed for normal tube function.

Design Matrix

	Weight	Stent Bubble Device	Shape Memory	Stretchy Coil	Guide wire
Comfort	1	3	4	4	4
Diameter	1	4	3	4	4
Modifications	1	1	4	2	4
Cost	1	2	4	3	5
Ease of Use	0.75	1	5	2	4
Manufacturability	0.5	3	4	3	5
Expandability	0.5	4	3	4	0
Feasability	0.25	2	3	3	4
Total	**30**	**12.25**	**20.75**	**16**	**23**

Table 1: Evaluation of design alternatives in a weighted matrix.

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. The minimum compressed diameter was a very important factor because not all of our design alternatvies were able to met our design criteria of a 3mm compressed diameter. 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 for patient safety. Again the designs with metal incorporated ranked lower because of the stiffness of the metal and additional steps of expansion.

Manufacturability was weighted 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 metal and polymer materials. Alternatively, the shape memory polymer just has to be manufactured in a heat controlled 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 guide wire ranked the lowest since the design is not built for any expansion, 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. The team will have to focus efforts on aspects that are attainable for our level of expertise.

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

Testing

Mathematical Modeling

To begin the mathematical modeling to evaluate our different materials and diameters, the quality of flow needed to be determined. Assuming that the maximum viscosity of the fluid in the stomach would be chyme, viscosity of 3.5Cp (Aguilera, 2011), and using the Reynolds calculation, it was determined that our tube would have laminar flow (Eq. 1).

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Equation 1. Reynolds calculation, where ρ is the density of the stomach contents (Madigan, 2011), v is the fluid velocity, d is the maximum length of the tube, and μ is the viscosity of the fluid (Aguilera, 2011).

The laminar flow of the fluid within the tube signifies that Poiseuille flow can be used to determine the needed pressure to cause our desired flow rate. The needed pressure was calculated to be 13.995KPa using Poiseuille's equation (Eq. 2).

$$\Delta P = \frac{8 \mu L Q}{\pi r^4} + \rho g h$$

Equation 2. Poiseuille flow equation where L is the length of the tube, μ is the viscosity of the fluid, Q is the flow rate, and r is the inner radius of the tube.

Since the nasogastric tube is intended to be used within a medical setting, a safety factor of 2 was assumed; thus bringing the target pressure to 28889.0Pa. Then the pressure needed to cause tube collapse was calculated for different tube wall thicknesses, diameters, and materials (Eq. 3).

$$P_c = 2E\left(\frac{T}{D}\right)^3 * \frac{1}{1-m^2}$$

Equation 3. Pressure of collapse equation where Pc is the pressure of collapse, E is the Young's modulus, m is the Poisson ratio, T is the wall thickness, and D is the external tube diameter.

These values were then compared to the calculated value of 28.889kPa to determine whether the tubes would collapse under the desired conditions. Using this data, it was determined that Silicone and PVC tubing would provide the best resistance to tube collapse at the desired external tube diameter of 3.2 mm, and a wall thickness of 0.79 mm.

$$I = \frac{\pi}{4}\left(r_o^4 - r_i^4\right)$$

Equation 4. Equation for the area moment of inertia where I is the area moment of inertia, r_o is the outer radius, and r_i is the inner radius.

$$V_{max} = \frac{PL^3}{3EI}$$

Equation 5. Equation for material deflection where V_{max} is the largest deflection, P is the load applied, E is the Young's modulus, and I is the area moment of inertia.

Following the calculations of the pressure of collapse, the deflection of the tube was calculated to evaluate how well the tubes would bend around the corner in the nasopharynx. The area moment of inertia of the tubes was calculated using Equation 4. Then, using the area moment of inertia, the deflection of the tubes was calculated (Eq. 5). During calculations, the force applied to the material was treated as a constant to create an index of deflection to compare the various materials where a larger index of deflection signifies a more flexible material. The results of this modeling showed that the silicone tubing had a smaller deflection index than the PVC tubing (Table 2).

Material	Diameter (mm)	Deflection Index
PVC	6.4	0.0053
PVC	3.2	0.086
Silicone	6.4	9.5×10^{-5}
Silicone	3.2	0.0015

Table 2. Selective results of deflection index calculations.

Anatomical Testing

Through the mathematical testing, it was determined that an outer diameter of 6.4mm and 3.2mm and a wall thickness of 0.79 mm would function for our desired criteria in both silicone and PVC tubing.

In order to further test the different tubes, an anatomical model was created out of wood that has the same dimensions as the average human nasal cavity and nasopharynx.

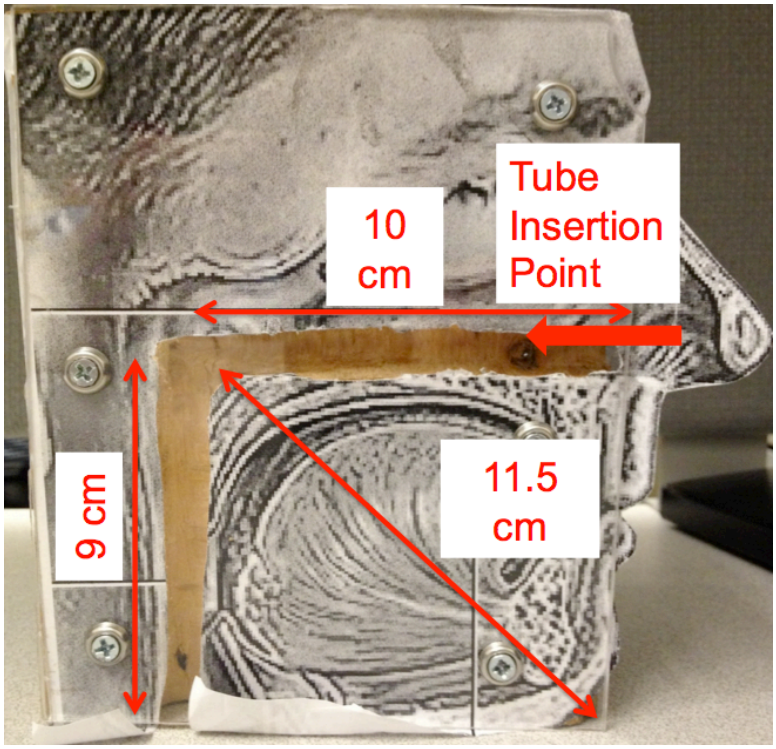

Figure 8. Anatomical representative model, fabricated from wood, using dimensions of average person.

Qualitative testing was performed to determine which tubes inserted most easily into the anatomical model (Figure 8). As a control, the original nasogastric tube was inserted into the model. A Bard nasogastric tube inserted with great difficulty.

After some initial testing, it was determined that a steel guide wire was necessary to provide added stiffness for both the PVC and silicone tubing. Vaseline was also used as a test to simulate the use of 2% viscous Lidocaine. The 3.2 mm diameter tubes of both silicone and PVC performed the best in the experiment, both outperformed the original tube (Table 3).

Material	Condition	Result
6.4 mm Silicone	Dry	Did not work
6.4 mm Silicone	Vaseline	Did not work
6.4 mm Silicone	With Guide wire and Vaseline	Inserted with difficulty
6.4 mm PVC	Dry	Did not work

6.4 mm PVC	Vaseline	Did not work
6.4 mm PVC	With Guide wire and Vaseline	Inserted with difficulty
3.2 mm Silicone	Dry	Did not work
3.2 mm Silicone	Vaseline	Inserted
3.2 mm Silicone	With Guide wire and Vaseline	Inserted easily
3.2 mm PVC	Dry	Did not work
3.2 mm PVC	Vaseline	Inserted
3.2 mm PVC	With Guide wire and	Inserted easily.
Bard Nasogastric Tube	With Vaseline	Inserted with difficulty

Table 3. Results of Anatomical Model Testing.

Suction Testing

After performing mathematical modeling of tube collapse, physical testing of our tubes was performed. Each of the tubes were inserted in to the anatomical model, then 500 mL of fluid was aspirated through the tubes at a rate of 600 mL/minute (Appendix C). This is significantly higher than the clinical flow rate of 2L/day (Yale, 2012). Through this testing, it was found that none of the tubes collapsed.

Force Testing

Testing was performed to determine the maximum pressure that each of our tubes could apply. These results are important for determining whether the redesigned nasogastric tube would cause tissue damage when inserted. To test the force applied, a set up was constructed to equate buoyant forces to the forces applied by each of the tubes. A 500 mL beaker was filled with 300 mL of water. A 200 mL beaker was then fitted, upright, inside the 500 mL beaker. The known weights of 100 g, 150 g, and 180 g were added to the 200 mL beaker (Figure 9). The amount of water displaced was then measured. Using this data, a regression equation was then created (Eq. 6). The original nasogastric tube and the 3.2 mm silicone and PVC tubes with the guide wire were tested using this setup (Table 4).

$$y=0.0604x + 0.3779, R^2=0.999$$

Equation 6. The regression equation that was calculated from the water displacement caused by known weights.

Tube	Force Applied (N)
Original Nasogastric Tube	1.83

3.2 mm Silicone with guide wire	1.10
3.2 mm PVC with guide wire	1.16

Table 4. Forces generated by nasogastric tubes.

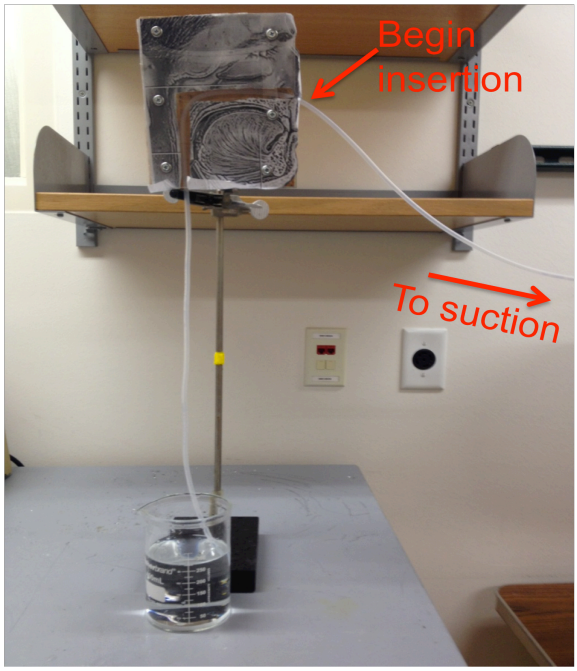

Figure 9. Suction testing setup.

Surface Property Testing

The final area of testing was on the surface area properties of the three tubes: Silcone, PVC, and the Bard tube composed of PVC. To test the surfaces, an Alicona 3D Optical Metrology System profilometer was used. The profilometer generates a 3D image of the section of tube and uses this image to calculate the roughness. This system measures both the linear and area roughness of the surface. The values of these roughness's, given in nm, are in table 5. Overall, the silicone tubing had the lowest surface roughness, meaning that it would generate the smallest amount of friction when the nasogastric tube is removed.

Tube	Area Roughness (nm)	Surface Roughness (nm)
Silcone	37.945	72.239
PVC	49.984	85.498
Bard PVC nasogastric tube	72.240	136.140

Table 5. Results of profilometer.

Final Design

After analysis, we came to the conclusion that a smaller diameter would be able to withstand the pressure of the vacuum and be able to evacuate the necessary amount of fluid, 4 liters over the course of 2 days (Yale, 2012), the final design was modified. During testing we found that a 3.2 mm diameter tube with a guide wire could navigate the esophageal turn the easiest. After further research, it was determined that silicone would exert the least amount of pressure on the tissue. Research has shown that silicone tubing carries a much smaller chance of nosocomial infection compared to plasticized PVC (Colas, 2004). Silicone tubing also does not have any chemical leaching problems that are associated with plasticized PVC.

Based on our testing and analysis we recommend that nasogastric tubes be made with a smaller diameter (3.2 mm) and out of silicone rather than PVC. These modifications along with the use of viscous Lidocaine will make the procedure more comfortable for patients.

With our reduced diameter, our design will have a cross-sectional area of 3.217×10^{-5} m^2. This is a 75.01% reduction in the cross-sectional area of the nasogastric tube (Eq. 7).

$$\%\,\text{reduction} = \frac{A - B}{A} * 100\%$$

Equation 7. The percent reduction calculated using the original cross-sectional area (A) and the new cross-sectional area (B).

For the most part, the procedure for inserting the nasogastric tube would remain unchanged. To begin, the hospital staff would lubricate the first 10 cm of the nasogastric tube with 2% viscous lidocaine and apply the lidocaine spray to the patient's nasal passage. The nasogastric tube would then be inserted and, once the tube has reached the stomach, the guide wire would be removed using the plastic tab at the end of the wire (Figure 10). The consistency with the current procedure will increase the marketability of our new design because it is not necessary for the hospital staff to learn a new skill.

Figure 10: Shortened silicone tube and steel guide wire used in testing and for proof of concept of the final tube design.

The cost of our design will be about $21.53. These costs were estimated using the material cost of silicone (US Plastic, 2012) and the cost of current nasogastric tube (Bard, 2012). The cost of guide wires when bought in bulk and non-sterilized was estimated by a manufacturer (Allen, 2012).

Future Work

Our team still has to look into professional manufacturing options for the tube. The manufacturing should not be too difficult since we are just decreasing the external diameter by an eighth of an inch and creating the tube out of silicon. Silicone has a higher melting temperature and can be slightly more difficult to mold, so this will have to be taken into consideration.

We would also have to look into the marketability of our product and the implementation into hospitals. The current model of nasopharynx tubes are widely used and we would have to stress the importance of comfort for the patients and the safety benefits. Personnel would also have to be trained on the guide wire technique. Luckily this is not very difficult and should be easy to add into the current process of placing nasogastric tubes. Although due to the introduction of the guide wired into the tubing, our device would have to undergo additional FDA approval.

Conclusion

The implementation of a nasogastric tube that can withstand the suction necessary for intestinal drainage, yet pliable enough to reduce patient discomfort during insertion would greatly reduce clinical challenges and complications associated with nasogastric insertion. The tube must also be able to withstand the environments of the nasal cavity and the stomach while maintaining functional integrity. Through considerations of economic and manufacturing practicality, as well as calculations for the minimum required tube dimensions, a 3.2 mm diameter silicone tube with guide wire-assisted insertion has been selected as the best solution. Testing has revealed that this design allows for easy insertion that minimizes forces exerted in the nasal cavity that will decrease patient discomfort. After insertion, the guide wire can be removed and the tube will successfully withstand the pressures encountered in the procedure.

In moving forward with the project, manufacturing procedures must be determined, as well as incorporating custom suction ports to the end of the tube. Marketability and implementation into hospital settings must also be approached with the completed device.

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Appendix A:

Project Design Specifications
#3- Reduced Diameter nasogastric tube with guide wire support
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 has a reduced outside diameter of 3mm. This will significantly decrease patient discomfort while improving the correct placement of the device, by increasing the stiffness 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. External diameter: 3mm
        ii. 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:

$$\text{Re} = \rho v d / \mu = 1.051 \text{ g/cm}^3 * 0.044 \text{ cm/sec} * 0.57 \text{ cm} / 3.5 \text{ cP} = 283 \quad \text{(Eq.1)}$$

Where ρ is the density (Madigan, 2012) of the stomach contents, v is the fluid velocity, d is the maximum length of the tube, and μ is the viscosity of the fluid (Aguilera, 2011).

$$\Delta P = 8 L \mu Q / \pi r^4 = 8 * 1.21 \text{ m} * 0.0035 \text{ Pa·s} * 2.3167 \times 10^{-5} \text{ m}^3/\text{s} / \pi (0.002056 \text{ m})^4 + 1.051 \text{ g/cm}^3 * 9.81 \text{ m/s}^2 * 1.21 \text{ m} = 14000 \text{ Pa} \quad \text{(Eq. 2)}$$

Where L is the length of the tube, μ is the viscosity of the fluid, Q is the flow rate, and r is the inner radius of the tube.

$$\text{Re} = 2 r 1 - r 2 * (1 \text{ rpm} - 1) 3 \quad \text{(Eq. 3)}$$

Where Pc is the pressure of collapse, E is the Young's modulus, m is the Poisson ratio, T is the wall thickness, and D is the external tube diameter.

$$\square = \square(\square\square 4 - \square\square 4)4 \quad \text{(Eq. 4)}$$

Where I is the area moment of inertia, ro is the outer radius, and ri is the inner radius.

$$\square\square\square\square = \square\square 33\square\square \quad \text{(Eq. 5)}$$

Where Vmax is the largest deflection, P is the load applied, E is the Young's modulus, and I is the area moment of inertia.

$$y = 0.0604x + 0.3779,\ R^2 = 0.999 \quad \text{(Eq. 6)}$$

The regression equation that was calculated from the water displacement caused by known weights. 9.8*y is the force applied by each tube, x is the displacement of water (mm).

$$\%\square\square\square\square\square\square\square\square\square\square = \square - \square\square * 100\% = 3.22\square 10 - 5\ \square 2 - 8.04\square 10 - 6\ \square 23.22\square 10 - 5\ \square 2 * 100\% = 75.0\%$$

(Eq. 7)

The percent reduction calculated using the original cross-sectional area (A) and the new cross-sectional area (B).

Appendix C.

Table C. Results of All Testing.

Material	Outer Diameter	Placement with Guide Wire	Suction	Insertion Force	Average Surface Roughness
Silicone	3.2 mm	Easily inserted	Suction with no kinking	1.1631 N	72.24 nm
Silicone	6.4 mm	Easily inserted	Kinks slightly, 50% obscured	N/A	72.24 nm
PVC	3.2 mm	Easily inserted	Suction with no kinking	1.1027 N	85.45 nm
PVC	6.4 mm	Easily inserted	Suction with no kinking	N/A	85.45 nm
Original NG Tube	6.4 mm	Inserted with difficulty	N/A	1.8275 N	136.14 nm

Appendix D.

Please see attached excel sheet.