Expandable Nasogastric Tube

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Abstract

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

Key Words
Nasogastric tube, aspiration, silicone tubing, expandable, nasopharynx, stomach biocompatible.

Introduction

A nasogastric (NG) tube is a medical device used either for delivery of nutrition/medication to the stomach or for the aspiration of gastric contents. This project is focused on NG tubes used to aspirate gastric contents, often called nasogastric decompression tubes. Such devices are used millions of times annually in the United States alone. NG decompression tubes are used to relieve pressure in the stomach/small bowel when an obstruction is present and to remove gastric contents before gastrointestinal operations or if a toxin has been ingested [1]. To remove stomach contents, a NG decompression tube is inserted into the nostril and navigated through the nasal passageway, down the esophagus, into the stomach. Once in place, the tube is connected to wall suction, which removes the gastric contents. The two most critical aspects of NG decompression tube use are insertion and confirmation of placement within the stomach. NG decompression tubes are nearly twice the diameter (12-18 Fr or 4-6mm) of NG feeding tubes (5-10 French or 1.7-3.3 mm), making insertion uncomfortable for the patient [5]. A larger diameter is necessary to facilitate suction of semi-solids without causing tube blockage or collapse under the applied negative pressure. The larger diameter also makes it more difficult for clinicians to maneuver and it often takes a great deal of experience to master the proper insertion technique. Current tubes are also susceptible to

kinking or coiling in the back of the throat. Moreover, it is very critical to ensure that the NG tube is inserted in the stomach and that it has not passed down the trachea and into the lungs. Insertion into the lungs can cause extensive permanent damage to bronchioles and alveoli. There have also been cases where nasogastric tubes have penetrated the brain; surgery has then been required to remove the tube [6]. For our design the nasogastric tube is placed in a die and collapsed to have a small diameter during insertion. Once correctly inserted, the tube is expanded to make the NG tube functional (able to remove semisolids and resistant to blockage or collapse under suction). The initially collapsed tube makes the device stiffer, enabling easier insertion for the physician (reduced risk of coiling or kinking) and the smaller diameter is more comfortable for the patient. Thus, an expandable NG decompression tube benefits both physician and patient greatly.

Materials and Methods

To provide more patient comfort and solve the design problems presented to us two main designs were utilized for the expandable NG tube.

Heat Shrink Tubing

The final design consisted of three main components; the outside sheath, the inner tube, and the sheath removal mechanism. The inner tube is flexible medical grade silicone, Sani-tech 50 from Saint-Gobain. The tubes came in a variety of sizes and thicknesses but we finally settled on one with an inside diameter of 3.97 mm (5/32 in) and an outside diameter of 5.56 mm (7/32 in). This tubing is rigid enough to prevent collapse under suction but flexible enough that the heat shrink tubing is capable of collapsing and holding the inner tube in its collapsed state. The Sani-Tech material has great shape memory and after the sheath is removed it unfolds from a "U" shape into its normal circular shape with minimal deformation. The design shape can be seen in figure1. Shape recovery testing will be covered more thoroughly later in the paper.

Figure 1: CAD model of the cross section of the first design alternative, showing a folding inner tube with a sleeve

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

inside tubing in the process. The pressure exerted by the heat shrink tubing when it shrinks in on itself creates enough force to collapse the interior tube along the cable running down the length of the tube.

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

Silicone Bonding

The final design consists of four main components, the tip, the connector, and two types of silicone tubing. The smaller silicone tubing selected was the same as from the previous semester, the flexible medical grade silicone, Sani-tech 50 from Saint-Gobain. It has an inside diameter of 3.97 mm (5/32 in) and an outside diameter of 5.56 mm (7/32 in). As stated previously, it is ideal as this tubing is rigid enough to prevent collapse under suction but flexible enough that it can easily navigate the nasopharynx and esophagus down into the stomach. This tubing was placed in an aluminum die, folded, and adhered to itself with silicone adhesive. The Sani-Tech material has great shape memory and after the adhesive seal is burst it unfolds from the "U" shape into its normal circular shape with minimal deformation. The tube has folded dimensions of 4.16 mm by 5.00 mm, a 33% reduction in volume. The larger tubing has dimensions of 5.6mm in diameter.

Figure 2: Picture of the 3-D printed tip and connector design.

The distal end is the connective piece, which is produced with 3-D printer. A connective piece is needed because the wall vacuum does not fit the smaller tubing. The proximal end of the smaller tube is connected to a larger tube, which is connected to the tip. Our tip, adopted from an MIT design was also produced with a 3-D printer and allows better suction without clogging. Both the tip and connector, attached to the hose, and are pictured in figure 2. The overall design is shown in figure 3.

Figure 3: Picture of the final design.

Results

Heat Shrink Tubing

Inner Tube

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

Plastic Grade	Material	Tensile Modulus (MPa)	Shore A Hardness	Max. Recommended Operating Temp (°C)
Tygon 100-65	PVC	5.6	65	165
Versilic® SPX-50	Silicone	2.9	50	204
Tygon 3350	Silicone	1.9	50	204
Sani-Tech® 50	Silicone	1.2	50	260

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

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

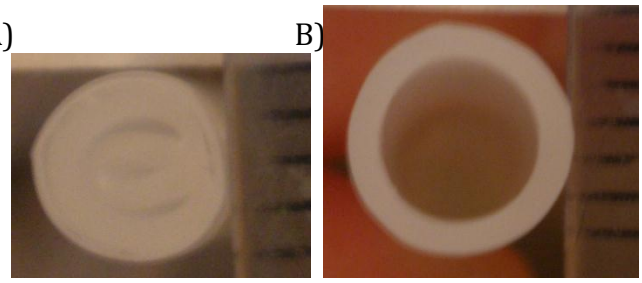

Figure 4: Recovery of Sani-Tech®50 material. A) Sani-Tech®50 shrunken in heat shrink sheath and B) Sani-Tech®50 after sheath removal.

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

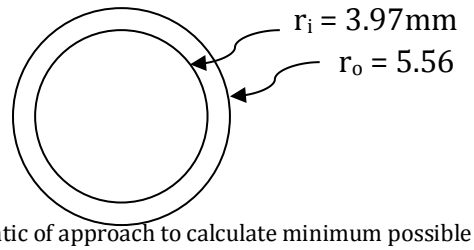

Figure 5: Schematic of approach to calculate minimum possible collapsed tube diameter.

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

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

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

Pressure to Collapse Inner Tube

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

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

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

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

Pressure testing was performed using the wall suction mount attachment at the hospital as shown in Figure 6. The pressure exerted on the tubing was increased in increments of 100 mmHg, until the maximum pressure allowable, about 500 mmHg, was reached. The deformation and diameter of the tubes were recorded at each step along the way. If the maximum deformation was reached the value this occurs at was recorded. The results of this testing are shown in Figure 5.

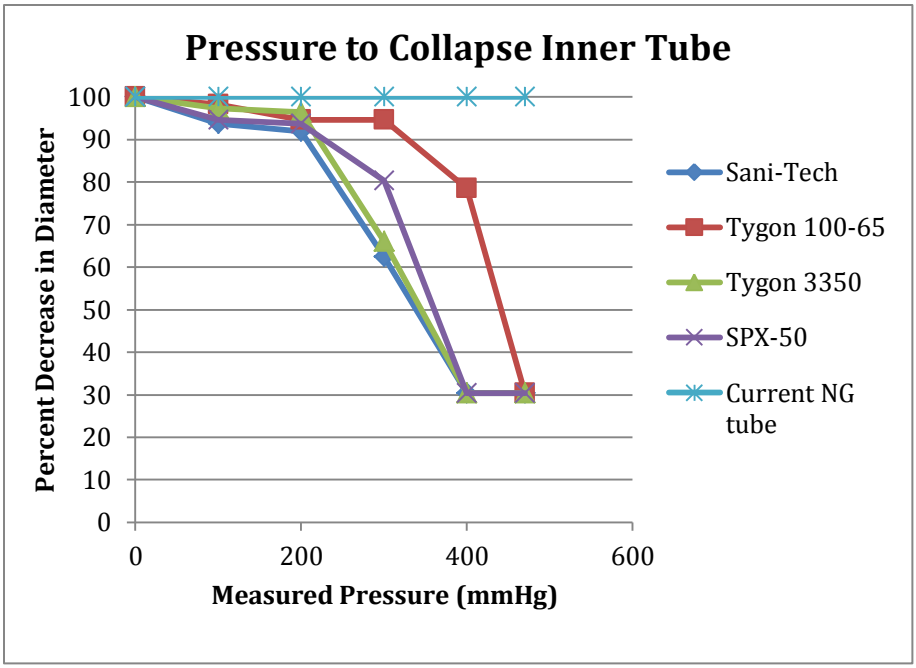

Figure 5: Plot of percent change in diameter with increasing pressure. Current NG tubes do not collapse at any pressure but testing samples collapse although at pressures above suction normally used.

Figure 6: Photo vacuum pump used for collapse pressure testing.

The measured pressure in Figure 5 is the pressure at 50% tube collapse. The results demonstrate that Equation 3 can accurately rank order collapse of the inner tube. The trend line equation could be used to predict actual pressure to collapse a tube to 50% of its original diameter based on the result of Equation 3.

Sheath Removal

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

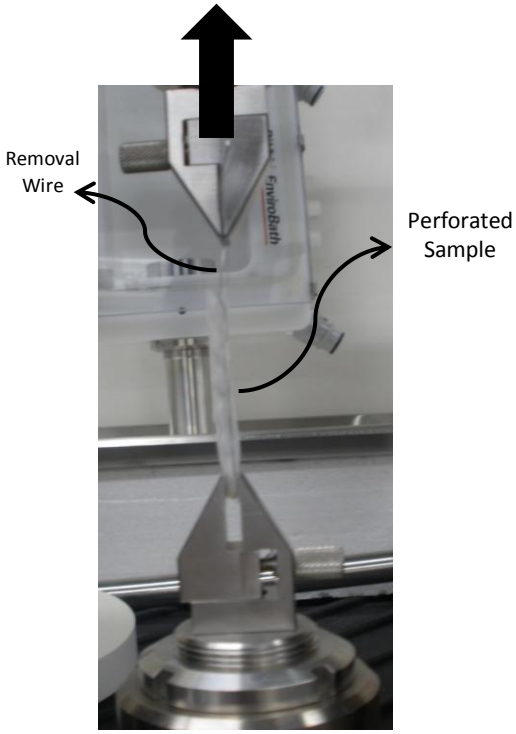

Figure 7: Photo testing setup for measuring force/work to tear HS tubing

round of prototypes using 28 gauge (.321 mm) steel wire for removal was fabricated.

The samples were tested on a MTS machine running Instron at a rate of 50 in/min (1270 mm/min.) The test setup is shown in Figure 7. The bottom grip held the end of the sample and the top grip held the ends of the wire. Care was taken to ensure that the bottom grip only held the silicone and HS tube, not the wire.

Results (shown in Figures 8 and 9) found that the peak force to remove the sheath was consistent across all samples. The work to tear was greatest for the 1 mm perforation, and dropped from there. While the shorter perforations took more work to tear, the larger perforations had torn edge were rougher (Figure 10). Additionally, at perforation lengths greater than 5 mm, the inner Sani-tech® tubing began to bulge out of the sheath when compressed.

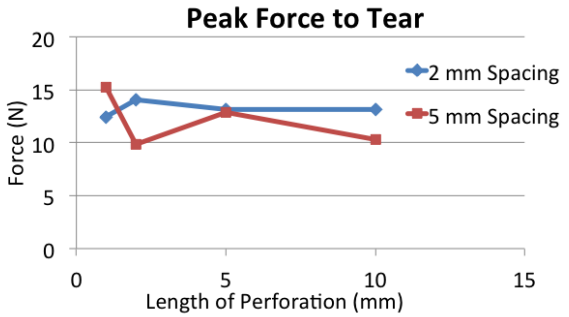

Figure 8: Plot of peak force to tear perforations, illustrating that force is independent of perforation length and spacing.

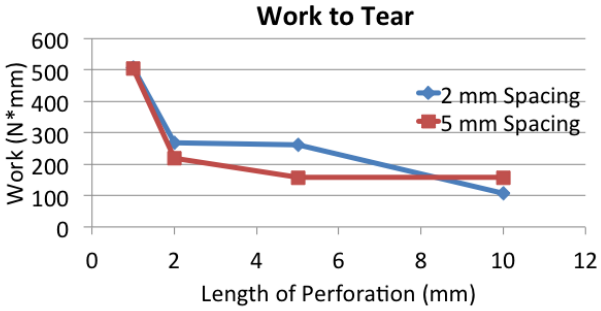

Figure 9: Plot of work to tear perforations, demonstrating that work decreases with increasing perforation length.

Figure 10: Photo of sample with 1 mm perforations with 2 mm spacing (left) and sample with 5 mm perforations with 2 mm spacing (right), demonstrating the bulging rough edge of the larger perforations and full expansion after sheath removal.

Silicone Adhesive

Needed Glue Distance to keep Tubing Compressed

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

tube was left open the expanded areas immediately propagated down the length of the tube. The continuous section remained closed until it was forced open.

Expansion of Tube after Pressurized Fluid Insertion

To test how well the tube expanded after it had been sealed, the tube was taken to the simulation lab at the UW Hospital. Water was injected using syringes with pressure applied at a constant force. Three differently sized syringes, 10, 30 and 60mL, were used with two fluids; one compressible fluid, air, and one incompressible fluid, water. To measure the success of expansion, a measurement was taken of the tube after it was taken out of the die as the zero percent expanded value; the 100 percent expanded value was the tube before gluing. Table 4 contains the values that were measured.

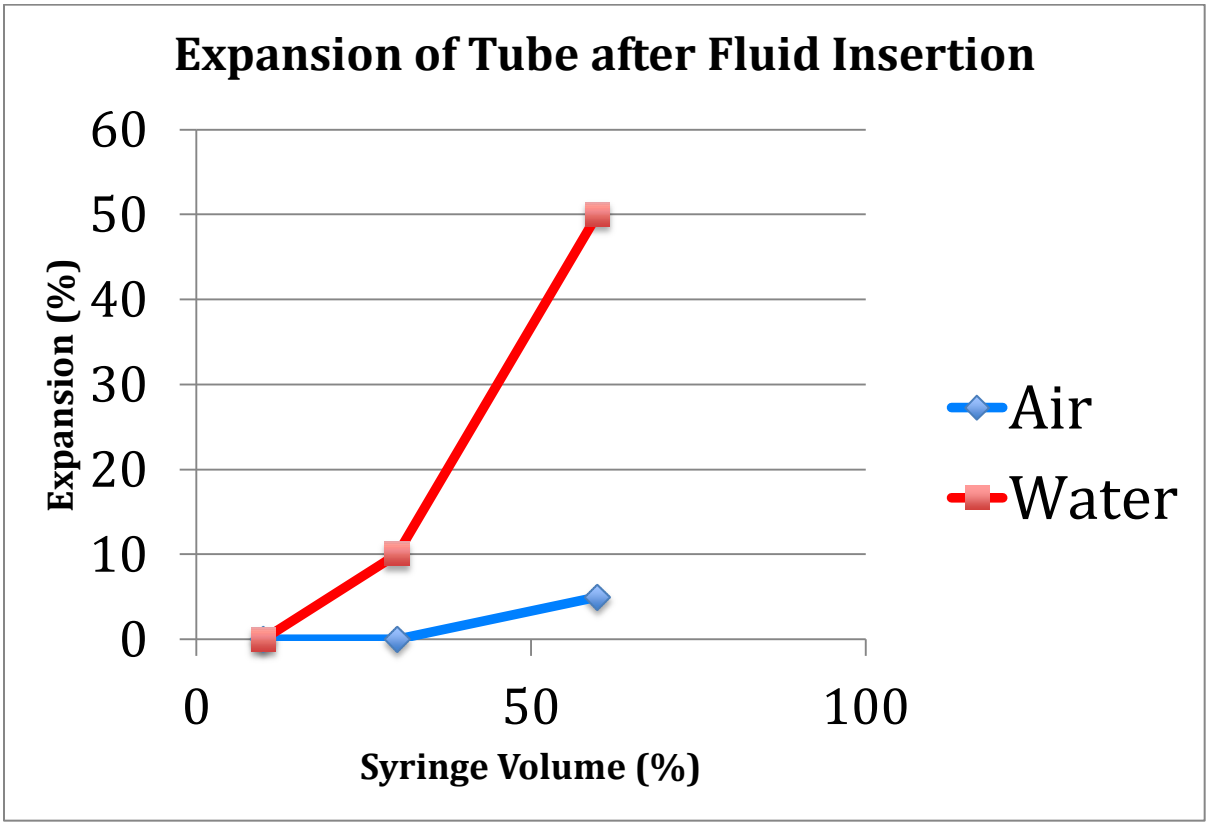

Figure 11: Showing tube expansion with insertion of both water and air.

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

Table 4: Tube measurements taken before expansion, before gluing, and of each scenario.

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

Discussion

As the testing demonstrates the heat shrink tubing required much too great of a force to pull the rip cord through the heat shrink tubing. To combat this force a counterweight would need to be placed at the distal end of the tubing to prevent the end from curling towards the distal and in the stomach and coming back up the esophagus. As the wire cable tears through the perforations in the heat shrink tubing it leaves sharp plastic edges exposed that might cut the esophagus or other tissues as it is being removed from the patient. As this would make the procedure more painful for the patient instead of more comfortable the silicone adhesive appears to be the better solution to the problem. While the silicone tubing does not completely unfold while water and air are being forced into it there are still some issues that need to be dealt with. 100% expansion is needed or it will not function properly. Also the silicone on the edge of the tube will irritate the patient upon removal, but to a much lower degree than the heat shrink tubing. Neither design is perfect and advancements to the design will continue to be made.

Acknowledgements

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