

Spring 5-6-2015

New Design of Nasogastric Decompression Tube That Incorporates a Self-Cleaning Brushing Mechanism

Nichole Abla

University of South Carolina - Columbia

Lindsay Rucker

University of South Carolina - Columbia

Paige Schroder

University of South Carolina - Columbia

Director of Thesis: Abdel Bayoumi

Second Reader: Caroline Horton

Follow this and additional works at: https://scholarcommons.sc.edu/senior_theses



Part of the [Biomedical Engineering and Bioengineering Commons](#)

Recommended Citation

Abla, Nichole; Rucker, Lindsay; and Schroder, Paige, "New Design of Nasogastric Decompression Tube That Incorporates a Self-Cleaning Brushing Mechanism" (2015). *Senior Theses*. 51.

https://scholarcommons.sc.edu/senior_theses/51

This Thesis is brought to you by the Honors College at Scholar Commons. It has been accepted for inclusion in Senior Theses by an authorized administrator of Scholar Commons. For more information, please contact digres@mailbox.sc.edu.



Many hospitalized patients require the removal of secretions that accumulate in the stomach. To do this, a sump tube is inserted through the nose and into the stomach. Unfortunately, this tube often becomes clogged causing the tube to become ineffective. This report outlines the redesign of the nasogastric tube that will ideally prevent nasogastric tube clogging.

Final Report

A Redesign of the Nasogastric Tube

Nichole Abila – Team Leader/CAD Expert

Kasey Catalano – Research/Financial Expert

Jonathan Peterson – Mechanics/Prototyping Expert

Lindsay Rucker – Business Consultant and Research Expert

Paige Schroder – Research/Anatomy Expert



Contents

1. Introduction	4
1.1 Problem Definition	4
1.2 Alternative Solutions	6
1.2.1 Automated Flushing System	6
1.2.2 External Vibrating Mechanism	7
1.3 Goals and Objectives	7
2. Design	7
2.1 Nasogastric Tube	8
2.1.1 Helical Tip	8
2.1.2 Dual Lumen Tube	9
2.2 Brush Cleaning Mechanism	12
2.2.1 Brush Tube	14
2.2.2 Brush Bristles	14
2.2.3 Linear Actuator	17
2.3 Budget	18
3. Methodology	18
3.1 Nasogastric Tube with Brush Cleaning Mechanism Fabrication	19
3.2 Artificial Stomach Setup	21
3.3 Clog Prevention Testing	21
3.4 Analysis	22
4. Results	23
4.1 Clog Prevention Results	23
4.2 Statistical Analysis	24
5. Conclusion	25
6. Future Plans	25
6.1 Ideal Manufacturing of Extruded Nasogastric Tubes	25
6.1.1 Ideal Dual Lumen Nasogastric Tube with Helical Tip	25
6.1.2 Brush Tube with Bristles	26
6.2 Insertion Testing	26
6.3 Endurance Testing	27

6.4 Acceptance Testing.....	27
6.5 Conformance Testing.....	27
6.6 Market Analysis	28
6.7 Alternative Viable Clog Prevention Option: Automated Contracting Tip Cleaning Mechanism	29
7. References.....	32
8. Appendix	34

1. Introduction

1.1 Problem Definition

A nasogastric tube is a medical device, which is used either to deliver nutrition to the stomach or to aspirate gastric contents. Nasogastric tubes used for aspiration are often referred to as nasogastric decompression tubes. More than 1.2 million nasogastric decompression tubes are used in the United States each year.^[1] These tubes typically have a diameter of 6mm, approximately twice that of nasogastric feeding tubes.^[2] A larger diameter is needed in order to suction food particles and maximize usage time before clogging.^[2] The small diameter nasogastric feeding tube would be inefficient if used as a nasogastric decompression tube because it would clog too quickly. However, a larger tube diameter also causes patient discomfort and difficult insertion for physicians. Nasogastric decompression tubes are used in cases of small bowel obstruction (SBO) in order to relieve pressure, to remove gastric contents before gastrointestinal operations, and to remove an ingested toxin from a patient's system.^[3]

The technique of utilizing negative pressure to suction gastric contents out of a patient through a tube has been used since the late 18th century.^[3] The use of the nasogastric tube is the only non-invasive method used by healthcare professionals to remove gastric contents.^[3] However, nasogastric tubes commonly become clogged which can lead to serious complications including mucosal injury if stomach mucosa is suctioned, reflux build-up, and gastric fluid aspiration.^[3] Aspiration of acidic gastric contents can cause bronchial injury and inflammation, airway obstruction, and even death by asphyxiation.^[3] Nasogastric tubes become occluded if the tube suctions the stomach mucosa or if food particles get lodged in the holes of the tube tip, which can be seen in Figure 1.^[2]

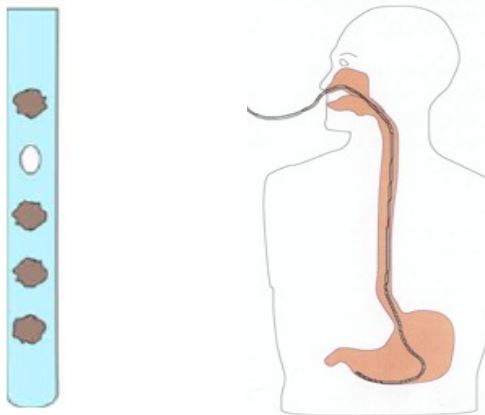


Figure 1. Figure A shows the nasogastric tube becoming occluded by the adherence of food particles. Figure B shows the nasogastric tube becoming occluded by the suctioning of the stomach mucosa.^[1]

The only way healthcare professionals currently deal with nasogastric tube clogging is by flushing the tube with water or saline, and if ineffective, they proceed to tube removal.^[2] Once the tube has been removed and cleaned, the patient has to be re-intubated, which can be very painful.

The only major improvement to address tube clogging has been the development of a dual lumen suction system, which decreases suctioning of the stomach mucosa, which can be seen in Figure 2.^[2] In the dual lumen design, one lumen is used for suction, and the second lumen allows atmospheric air irrigation of the stomach, which aids in the prevention of suctioning the stomach mucosa.^[2] The second lumen also provides an outlet for air pressure build up in a distended stomach. Although the dual lumen design was a great step forward in the prevention of nasogastric tube clogging, even these systems eventually become clogged.^[2] In a study conducted at MIT by Dr. James Ankrum and associates, the Salem Sump tube, the market standard for dual lumen suction tubes, was found to clog at a rate of 4 clogs per 6 minute testing interval.^[2]

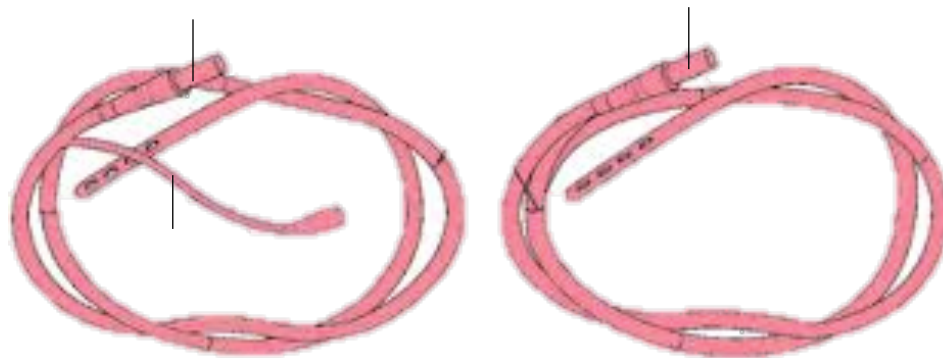


Figure 2. Figure A shows the a dual lumen nasogastric tube. Figure B shows a single lumen nasogastric tube.^[4]

Currently, there are four nasogastric decompression tubes on the market: the Salem Sump tube, the Levin Tube, the Cantor Tube, and the BARD PreVent® tube.^{[3][5][6]} The Levin tube is the simplest nasogastric tube with only one lumen. It has holes on the distal end of the tube for stomach content suction.^[6] The Cantor tube is a single lumen tube that has a bag containing mercury on one end. The pressure induced by the mercury aids in guiding the tube through the gastrointestinal tract.^[2] Because both the Levin and the Cantor tubes have single lumens, they can easily become completely occluded by the stomach mucosa which can injure the mucosa.^[7] The Salem Sump tube has a dual lumen design, which allows for continuous suction of gastric contents.^[3] The Salem Sump tube also can include an anti-reflux valve, which reduces the risk of exposure to gastric contents.^[2] The BARD PreVent® tube is also dual lumen, but what makes it unique is its employment of the Anti-Reflux Filter. The Anti-Reflux filter is used to identify when the nasogastric tube is clogging. The filter allows air to escape the stomach for

decompression, but traps gastric secretions so a healthcare professional can take the appropriate action before the build-up of reflux leads to gastric fluid aspiration.^[5] Both dual lumen tubes have distal holes on the tip through which gastric contents enter the tube during suction.^{[2][5]} However, as shown in the study conducted at MIT, even these dual lumen systems become clogged.^[2]

Although these new designs are improvements, they only partially address the problem because all of these designs eventually become clogged during the duration of patient use. If the nasogastric tubes continue to clog, recurrent human monitoring of this device while in use is necessary for device success. Once the tube clogs, someone must take the tube out, clean it, and re-intubate the patient, which is not efficient for health care professionals. As previously noted, nasogastric tubes become occluded by suctioning of the stomach mucosa and by adherence of food particles on the tube tip. Although the dual lumen system has made strides in preventing tube occlusion by suctioning of the stomach mucosa, the problem of clogging due to adhered food particles is largely unaddressed. Until both of these problems are addressed, nasogastric tubes will continue to become occluded which will require tube removal and patient re-intubation. Therefore, there is still a demand for a nasogastric decompression tube that effectively prevents or corrects tube clogging, specifically focusing on prevention of food particles adhering to the tube tip. To address this, Beats Biomedical has developed a novel design for preventative cleaning of the nasogastric tube tip in an effort to eliminate clogging. This design incorporates a cylindrical brush with flexible bristles to scrub away any adhered food particles. Automation of this design through attachment to a linear actuator reduces the need for clinician monitoring and assistance in the cleaning of clogged nasogastric tubes.

1.2 Alternative Solutions

Prior to finalizing the current design solution, Beats Biomedical explored other possibilities for solving the problems experienced with nasogastric tube clogging. These options included: the incorporation of an automated flushing system and an external vibrating mechanism.

1.2.1 Automated Flushing System

The first option explored was the incorporation of an automated flushing system. The flushing system would have been contained in a closed structure to reduce the risk of exposure to stomach contents. One main component of its design would have been to periodically disconnect the vacuum line to facilitate suction so that the two actions weren't counterproductive. At optimal time intervals for the prevention of clogs, determined through testing, the vacuum line would be disconnected, and the flush of 30 mL of saline would be pushed through the tube.^[2] Automation of this procedure would eliminate the need for action by a medical professional to unclog the nasogastric tube while utilizing the same method previously used to clean the tubes. However, because flushing fluid through the tube does not provide enough force to completely dislodge all adhered food particles from the tube tip, this solution was discarded.^[2]

1.2.2 External Vibrating Mechanism

The second alternative solution was the incorporation of an external vibrating mechanism that would either break up or shake loose adhered particles on the tip. Optimization of this solution would require that the vibration of the tube be at a frequency high enough to dislodge particles without being able to be felt by the patient. After speaking with clinicians, Beats Biomedical decided that there may not be a frequency that exists that would cause the tube to vibrate enough to provide the mechanical response needed without causing patient discomfort. Also, the given budget would not allow Beats Biomedical to purchase a motor that would vibrate at the high frequencies being studied. The combination of these two concerns caused Beats Biomedical to discard this solution.

1.3 Goals and Objectives

Beats Biomedical's first main goal was to reduce the rate of clogging of nasogastric tubes, which would allow for less frequent tube removal and re-intubation and offered a less painful experience for the patient. The specific aims to achieve this included eliminating complete clogs of the nasogastric tube and maintaining the average extraction rate of stomach contents through the nasogastric tube.

Beats Biomedical's second main goal was to create a self-cleaning mechanism to prevent complete clogging of the nasogastric tube that required less monitoring to be successful. The specific aims included removing adhered particles from the tube tip, determining the optimal time between cleanings, and automating the cleaning mechanism to operate at the optimal rate.

2. Design

Although nasogastric tube clogging is due to suctioning of the stomach mucosa and adherence of food particles to the tube tip, Beats Biomedical chose to focus on reducing the adherence of food particles to the tube tip because after reviewing literature, this seemed to be the more under-addressed problem. To solve this problem, Beats Biomedical designed a cleaning brush to act as a preventative measure against nasogastric tube tip clogging.

Beats Biomedical's cleaning mechanism with the nasogastric tube is made up of 5 different parts, which can be seen in Table 1. Table 1 includes information about how each part was manufactured, where each part was made, and the material of each part.

Table 1. Comprehensive list of parts used to assemble a dual lumen nasogastric tube with a brush cleaning mechanism.

#	Part	Manufactured	Source	Material
1	Brush Tube	Extrusion	Zeus	PTFE
2	Brush Bristles	Manually	Beats Biomedical	Liquid Silicone
3	Helical Tip	3-D Printing	BMEN Dpt.	Visijet Tough
4	Multi-lumen Tube	-	Covidien Salem Sump Tube	Medical Grade Silicone
5	Linear Actuator	-	Firgelli Automations	-

2.1 Nasogastric Tube

After researching previous designs, Beats Biomedical chose to use a nasogastric tube with a dual lumen design and a helical tip in conjunction with the cleaning mechanism. The dual lumen design features a suction lumen and a vent lumen. The suction lumen is connected to the vacuum line and provides the lumen for suctioning of the gastric contents.^[2] The vent lumen allows air into the stomach and provides an outlet for air pressure build up in the distended stomach.^[2] This additional vent lumen decreases suctioning of the stomach mucosa.^[2] The helical tip provides helical slits as the inlet for gastric contents to enter the nasogastric tube. Because these helical slits provide inlets that twist around the tip, they cannot become completely occluded due to suctioning of the stomach mucosa.^[2] These two design choices minimize tube clogging due to suctioning of the stomach mucosa which allowed Beats Biomedical to focus on addressing the problem of tube clogging due to food particle adhesion to the tip.

2.1.1 Helical Tip

Currently, most nasogastric tubes on the market, including the Salem Sump tube, which was used as the control, have a tip geometry that can be seen in Figure 3. This nasogastric tube design has holes on the distal end that serve as inlets for food particles during suction.



Figure 3. Distal tip of Salem Sump Tube with holes that serve as inlets for gastric contents. These holes are the sites of food particle adhesion and were found to clog at a rate of 4 clogs per 6 minutes by Ankrum and his team at MIT.^[2]

However, a study performed at MIT found that a nasogastric tube with a tip featuring helical slits as the inlet holes, as shown in Figure 4, has a reduced clogging rate as compared to nasogastric tubes with holes at the distal tip as in Figure 3.^[2]



Figure 4. Distal tip of nasogastric tube designed by Ankrum and his team at MIT.^[2] This tip features helical slits in place of holes that serve as inlets for the suctioned gastric contents. These helical slits clog at a lesser rate, 1 clog per 6 minutes, than that of the Salem Sump Tube tip shown in Figure 3.

This study found that the nasogastric tube with the tip design shown in Figure 3 had a clogging rate of 4 clogs per 6 minutes while the nasogastric tube with the tip design shown in Figure 4 had a clogging rate of 1 clog per six minutes.^[2] The results of this study favored the usage of a tube tip with helical slits as the inlet holes for the Beats Biomedical nasogastric tube. Also, this tip design was thought to be better suited for use in conjunction with a mechanical cleaning method because any mechanical cleaning device is less likely to become trapped and damaged by a helical slit than a circular pore. Therefore, Beats Biomedical chose to use this helical tip design for their nasogastric tube to use in combination with the cleaning mechanism. The specific dimensions of the helical tip were adopted from the MIT design and can be seen in Figure 5.^[2]

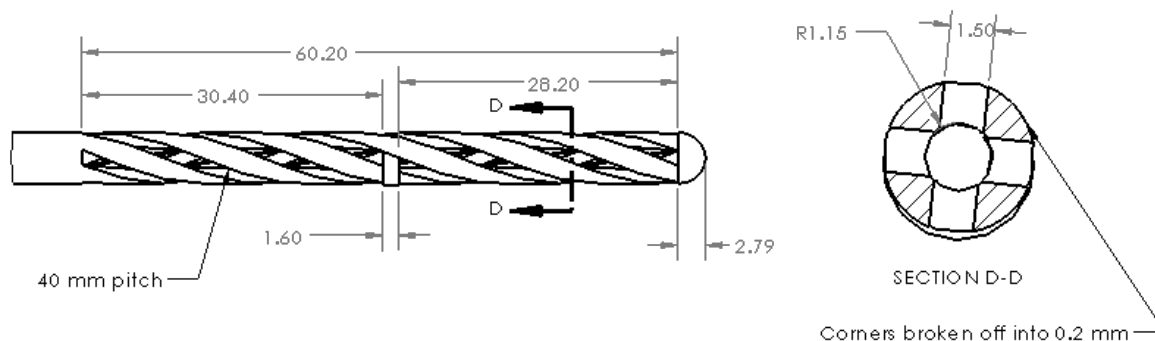


Figure 5. Engineering drawing including specific dimensions of the helical tip Beats Biomedical used with their nasogastric tube. Dimensions were adopted from the design by Ankrum and his team at MIT.^[2]

The helical tips were 3D printed, which will be explained in Sections 3.1. These tips were printed with a cylindrical extension proximal to the helical slits, which can be seen in Figure 5. This cylindrical extension was used for attachment to the multi-lumen tube.

2.1.2 Dual Lumen Tube

As previously noted, nasogastric tube clogging due to the suctioning of the stomach mucosa has already been addressed. The only major improvement of the nasogastric tube design has been the

development of a dual lumen suction system, which decreases suctioning of the stomach mucosa.^[2] In this dual lumen design, of which the cross section can be seen in Figure 6, one lumen is used for suction and the second lumen allows air into the stomach, which aids in the prevention of suctioning the stomach mucosa.^[2] The second lumen also provides an outlet for air pressure build up in a distended stomach, but even dual lumen systems eventually become clogged.^[2]

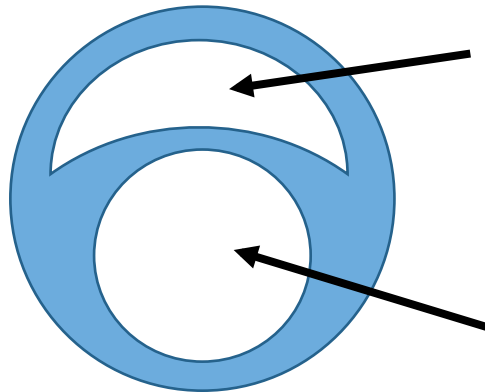


Figure 6. Cross section view of a dual lumen nasogastric tube.

Beats Biomedical wanted to focus on reducing clogging due to food particles adhering to the tube tip, so it was important to minimize clogging of the nasogastric tube caused by any other sources. Because this dual lumen design is an effective way to reduce clogging of the nasogastric tube due to suctioning of the stomach mucosa, Beats Biomedical chose to incorporate this dual lumen design into their nasogastric tube used in combination with the cleaning mechanism.

Unfortunately, Beats Biomedical could not find a company to produce a custom multi-lumen extruded tube within the given budget. Beats Biomedical explored other options to create a multi-lumen tube with the desired custom dimensions. The best option was to create a four-part device comprised of three tubes and multiple disks that kept the three tubes in place relative to one another. The three tubes included a vent tube, a suction tube, and an outside tube that enclosed the other three parts, which can be seen in Figure 7.

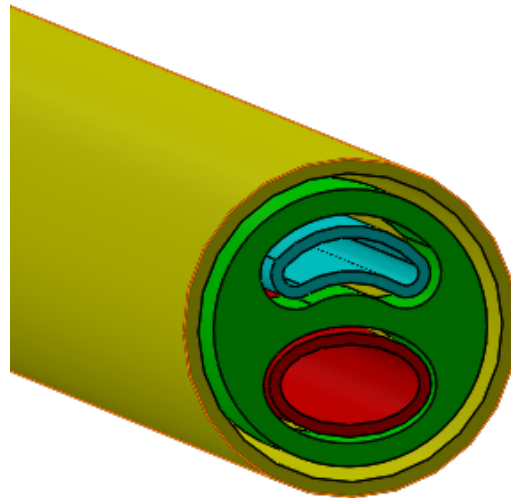


Figure 7. Inside view of the four part multi-lumen tube substitute. The blue tube, red tube, and yellow tube are the vent lumen, suction lumen, and outside tube respectively. The green disk holds all three tubes in place.

However, this device was unsuccessful because of its inherent tendency to kink due to the space between disks, which made it difficult for other tubes to slide over it.

Instead, Beats Biomedical used the dual-lumen portion of the Salem Sump tube produced by Covidien as the multi-lumen tube. Although Beats Biomedical was unable to adjust the diameter of each lumen and the outer diameter of the whole tube, a functional multi-lumen tube was able to be used in conjunction with the helical tip and the automated brushing mechanism. The multi-lumen tube can be seen in Figure 8.

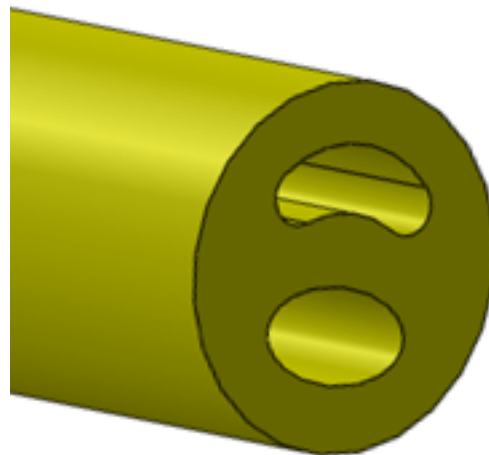


Figure 8. CAD model of Covidien's multi-lumen tube portion of the Salem Sump tube.

The top lumen serves as the vent lumen, a critical part of the nasogastric tube that allows air into the stomach during suctioning of the stomach contents. It provides an outlet for air pressure build up in the distended stomach, reducing the clogging of the nasogastric tube tip by the suctioning of the stomach mucosa. The vent lumen has a cross sectional area of 2.45 mm^2 . The bottom lumen serves as the suction lumen, which is connected to the vacuum line. This lumen provides the pathway for the stomach contents to travel up out of the stomach to the collection container. The suction lumen has a cross sectional area of 2.64 mm^2 . The multi-lumen Salem Sump tube has an outer diameter of 5 mm^2 . The assembly of the nasogastric tube will be explained in Section 3.1.

2.2 Brush Cleaning Mechanism

Beats Biomedical designed a brush cleaning mechanism that could be used in conjunction with the nasogastric tube described in Section 2.1. The original plan was to design a brush cleaning mechanism that would be operated manually. Then, after performing clog prevention testing (see Section 3.3), Beats Biomedical would adjust the design to incorporate automation.

The first manual brush cleaning mechanism in conjunction with the nasogastric tube described in Section 2.1 was comprised of 7 parts, which can be seen in Figure 9. Figure 9A shows the nasogastric tube in the suction position. In this position, the spring is relaxed, there is no pressure on the wire push button, and the helical tip is exposed. This figure also shows the multi-lumen tube, which attaches to the helical tip. When the nasogastric tube is in this position, the suction lumen of the multi-lumen tube is connected to the vacuum line and gastric contents are being suctioned out of the patient. Figure 9B shows the nasogastric tube in the brushing position. In this position, force has been applied to the wire push button, compressing the spring. The tube of the wire push button pushes on the brush tube, moving the portion of this tube that contains the bristles, over the helical tip to remove any adhered particles. The outer tube and the shaft enclose the entire device so no moving parts would be in contact with the esophagus.



Figure 9. Nasogastric tube in suction position (A) and in cleaning position (B).

However, once Beats Biomedical incorporated the idea of automation, the design became simpler, consisting of only 5 parts (see Table 1). This design can be seen in Figure 10.

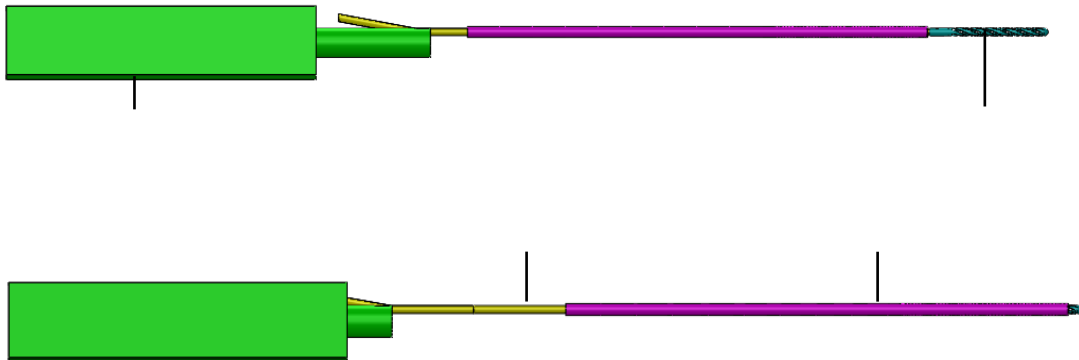


Figure 10. Nasogastric tube in suction position (A) and in cleaning position (B).

Figure 10A shows the nasogastric tube in the suction position. In this position, the linear actuator is not activated, and the helical tip is exposed. When the nasogastric tube is in this position, the suction lumen of the multi-lumen tube is connected to the vacuum line and gastric contents are being suctioned out of the patient. Figure 10B shows the nasogastric tube in the brushing position. In this position, the linear actuator is activated, causing a pulling force at the proximal end of the multi-lumen tube, which is connected to the helical tip. This causes the nasogastric tube to retract into the brush tube through the bristles, removing any adhered particles. Once the actuator pulls the entirety of its stroke length, it creates a pushing motion at the proximal end of the multi-lumen tube. This causes the nasogastric tube to push back out of the brush in the reverse motion. The outer tube described in the previous design (Figure 9) was no longer needed because the brush tube remains stationary, so there would be no moving parts in contact with the esophagus. This design is better than the previous one shown in Figure A because it reduces the overall diameter of the device and incorporates automation.

Figure 11 shows an up-close view of the inside of the device, including how the multi-lumen tube fits into the brush tube and how the helical tip attaches.

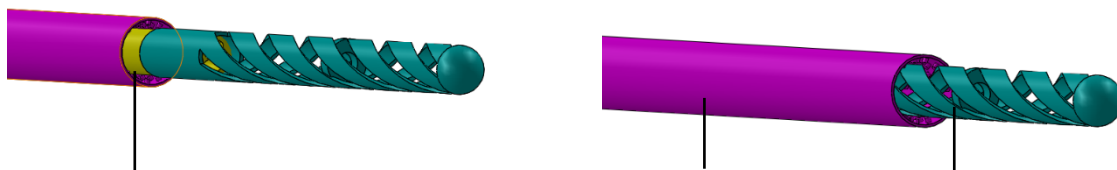


Figure 11. Inside view of the multi-lumen tube, attachment of the helical tip, and the brush tube. Figure A shows the nasogastric tube in the suction position. Figure B shows the nasogastric tube in the brush position, with the automated brushing mechanism starting to deploy.

The multi-lumen tube with the attached helical tip fits inside of the brush tube, which has bristles only on the distal end.

2.2.1 Brush Tube

The brush tube is the part of the device that moves over the nasogastric tube when it needs to be cleaned. It only has bristles (see Section 2.2.2) on the distal end, which can be seen in Figure 12B.



Figure 12. Figure A shows the brush tube from the outside. Figure B shows the cross section of the brush tube from the right plane. This view shows the inside of the brush tube with bristles only on the distal end.

When the actuator is turned on, it pulls the nasogastric tube from the proximal end, causing the nasogastric tube and the helical tip to move up into the brush tube and move through the silicone drops inside the distal end of the brush tube, removing any adhered food particles. This tube is essential to the cleaning of the helical tip. It is also stationary, enclosing all of the moving parts inside of the patient, protecting the esophagus from any harm. This tube is size AWG 2 with a wall thickness of 0.01" and is made out of PTFE.

2.2.2 Brush Bristles

The design of the distal end of the brush tube took multiple iterations before a successful design was obtained. The first attempt involved creating a sheet of bristles via injection molding using liquid silicone and epoxying the sheet to the inside of the brush tube. Figure 13 shows the cross section.

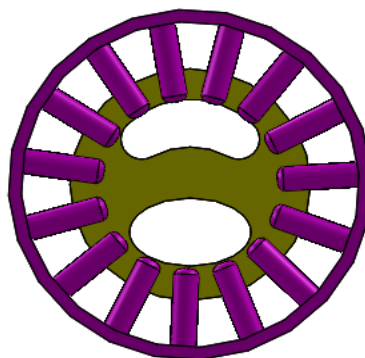


Figure 13. This figure shows the how sheet of bristles was rolled up to form a cylinder. Then the cylinder of bristles was epoxied to the brush tube to create one piece.

The mold was created using a 3D printer. The CAD model for the bristles can be seen in Figure 14

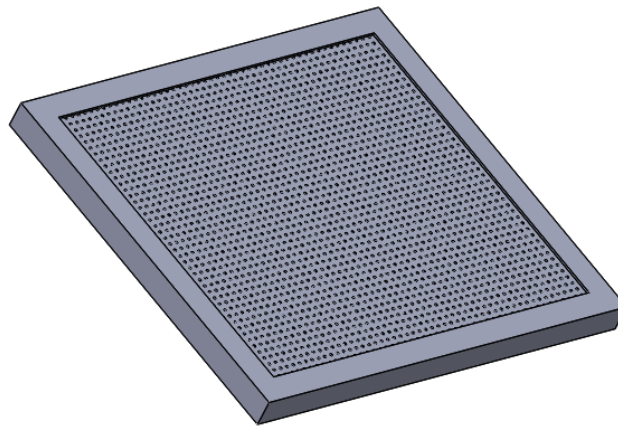


Figure 14. CAD model of the mold that is used to injection mold the bristles.

For the bristles to fit inside the brush tube while allowing enough space for the helical tip to pass through, the bristles needed to be very small, approximately 0.5 mm in diameter and 1.6 mm in length. Once the liquid silicone was poured into the mold and set, the bristles could not be removed from the mold without breaking. Therefore, Beats Biomedical had to find a different design solution for the distal end of the brush tube.

The next iteration of the distal end of the brush came in the form of a studded brush with small semi-spherical extrusions lining the inside of the tube. This part was 3D printed from Visijet Tough, which has similar material properties to ABS plastic. The studded brush also had an attachment cap so it could easily fit on the end of the brush tube. The studded brush can be seen in Figure 15.

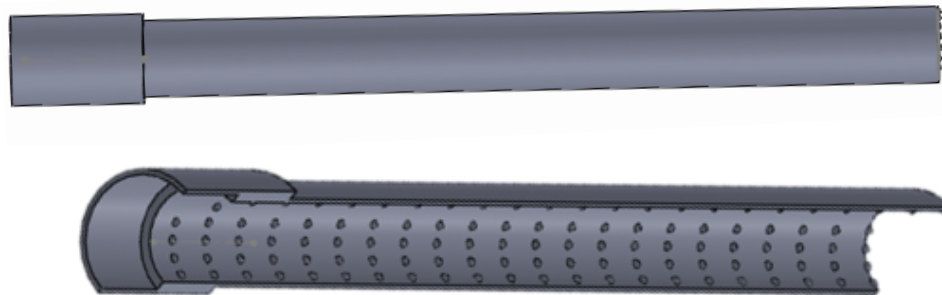


Figure 15. CAD model of the studded brush.

However, because the semi-spherical extrusions were not flexible, they were not able to make contact with the helical tip to clean it without breaking the tip. Because of this, Beats Biomedical discarded this design of the brush.

The next iteration of the brush became a part called the slit cap. This piece was a small attachment for the end of the brush tube. The slit cap can be seen in Figure 16.

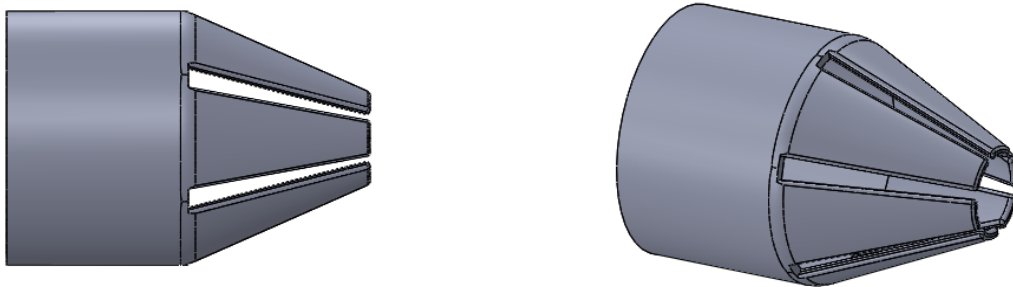


Figure 16. CAD model of the slit cap.

The cylindrical part of the slit cap fit over the brush tube and was epoxied to stay in place. It was thought that when the helical tip moved through the slit cap, the tabs would bend outward, allowing the helical tip to move through the opening at the distal end, while staying flush to the helical tip sides to scrape off any adhered food particles. Because the only resource available to Beats Biomedical to create this part on such a small scale was the 3D printer in Dr. Rocheleau's lab, the slit cap had to be made out of Visijet Tough. Unfortunately, there was no thickness of the tab walls that allowed them to be flexible enough to allow the helical tip to pass through the opening on the distal end without breaking. This issue was solely due to the material's lack of flexibility. However, because Beats Biomedical was not able to manufacture this part in any material other than Visijet Tough, this iteration of the brush was abandoned.

The final design for the distal end of the brush tube included deforming the inside of the brush tube surface and manually applying small silicone beads on the inside of the brush tube. The application process is explained in Section 3.1. These beads were much shorter in length as compared to the injection-molded bristles. The view of how all of the parts concentrically fit together on the distal end can be seen in Figure 17.

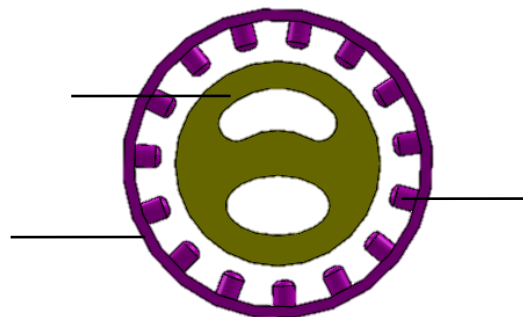


Figure 17. This figure shows the silicone drops that serve as the brush bristles attached to the inside of the brush tube. It also shows how brush tube with bristles and the multi-lumen tube concentrically fit together.

The bristles extend approximately 70 mm along the length of the distal end of the brush tube. When the helical tip passes through the brush tube, these bristles pass over the helical slits to remove adhered food particles.

2.2.3 Linear Actuator

The linear actuator is the key to the automation of the brush mechanism. The moving arm of the actuator attaches close to the proximal end of the nasogastric tube. The actuator is switch operated and has the capability to be connected to a relay system so it can be completely automated in operation. When the actuator is turned on, the moving arm begins retracting and pulls the nasogastric tube from the proximal end. This causes the nasogastric tube and the helical tip to move into the brush tube and through the silicone drops inside the brush tube, removing any adhered food particles. Once the linear actuator moves through its stroke, the motion is reversed. This part is important because it allows the mechanism to be completely automated, eliminating the need for monitoring and assistance. It also keeps the brushing mechanism motion consistent. For each automated deployment of the brush mechanism, the actuator moves through one pull stroke and one push stroke.

The Sleek Rod Actuator Beats Biomedical used in their design can be seen in Figure 18.

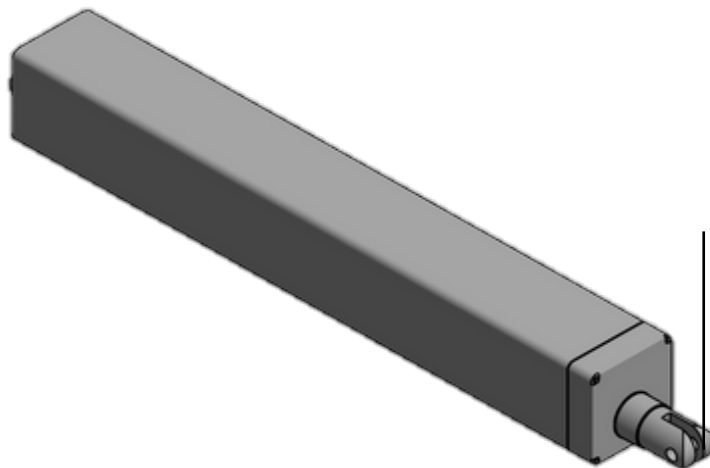


Figure 18. This figure shows a CAD model of the sleek rod actuator manufactured by Firgelli Automations.^[8]

This Sleek Rod Actuator is manufactured by Firgelli Automations. It is 8 in in length, 1.77 in in width, and 1.77 in in height. The stroke length is 3 in and it moves at 1 in/s.

2.3 Budget

Beats Biomedical incurred multiple expenses during the design process. The costs necessary to go through the prototyping and design process to reach the finalized nasogastric tube with automated brushing mechanism can be seen in Table 2.

Table 2. Budget of expenditures Beats Biomedical incurred throughout the design process.

Part	Units	Total Cost
3D Printing (\$8/in ³)	-	\$30
Zeus Tubing*	~5950 mm length	\$0
Liquid Silicone	1	\$55
Drive Medical Suction Machine	1	\$190
Artificial Stomach Contents	-	\$15
Artificial Stomach Environment**	1	\$15
Linear Actuator	1	\$75
Salem Sump Tube**	3	\$0
Bushing Mechanism Components	-	\$96
TOTAL	-	\$476

*Donated by Zeus Inc.

**Donated by Steven Hermiz, MD

3. Methodology

Research and literature review was completed in order to identify the optimal tube material, based on ideal material parameters including thickness, flexibility, biocompatibility, and rigidity. The design phase of the project included the design of an automated device to decrease clogging of the nasogastric tube caused by adherence of food particles to the tip of the tube. The ideal geometry of the tube and tip was determined, but the prototype created has slightly different dimensions due to budget constraints. Once the cleaning mechanism in conjunction with the determined nasogastric tube design was assembled, testing was performed in order to compare the brushing mechanism with the nasogastric tube to the control Salem Sump tube. Testing was performed in order to evaluate the efficiency of each device in suctioning stomach contents. To measure suctioning efficiency accurately, the same test set-up and procedure was followed for both devices. The testing rig simulated human anatomy, form, and function. The pseudo-stomach unit was secured to a board stand, and the portable heavy-duty suction machine was placed on a table. Both the testing rig and the tubes had to be durable to allow for repeated testing. Then statistical analysis was performed on the obtained data to determine whether the new design was a significant improvement.

3.1 Nasogastric Tube with Brush Cleaning Mechanism Fabrication

The parts in Table 1 were used to create the nasogastric tube with the brush cleaning mechanism. The PTFE tubing used for the brush tube, linear actuator, and the Salem Sump tube used for the multi-lumen tube were all purchased or donated by external companies, which can be seen in Table 1. The helical tips were manufactured by the Biomedical Engineering Department using a 3D printing process. The brush bristles on the distal end of the brush were manually manufactured by Beats Biomedical using a liquid silicone.

To create the helical tips via 3D printing, first the CAD models of the tip were converted into STL files. Then, using the Visijet 3D printer in Dr. Rocheleau's lab, multiple helical tips were printed out of a material called Visijet Tough that has similar material properties to ABS plastic. Once the support material was cleaned off, the parts were ready to use.

Beats Biomedical manually created the brush bristles. The first step was to make a cut about 70 mm long starting at the distal end of the brush tube. Then, a rough surface had to be created on the inside of the brush tube on the distal end. To do this, the inside of the brush tube was etched using a small pushpin. However, this did not create a rough enough surface for the liquid silicone to adhere well to the PTFE tubing. To increase surface roughness, a small pushpin was used to apply force to the outside of the brush tube. This caused the tube wall to deform and create small bumps on the inside of the brush tube, which can be seen in Figure 19.

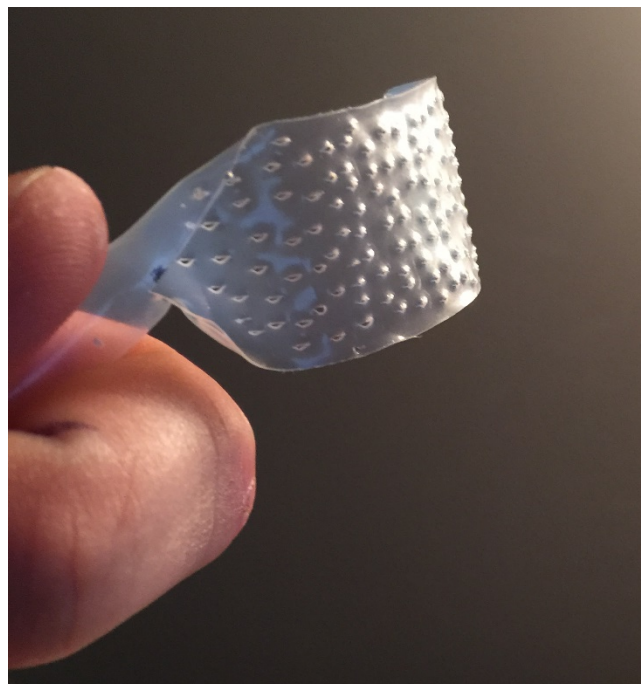


Figure 19. This figure shows the deformed wall of the PTFE tubing before the liquid silicone application.

Then, liquid silicone was applied to the inner surface of the PTFE tubing over the small wall deformations, which can be seen in Figure 20.



Figure 20. This figure shows the liquid silicone application on deformed wall of the PTFE tubing.

Once the liquid silicone set, the open distal end of the brush tube was rolled back into a cylinder and epoxied back into its original formation. Electrical tape was then applied on the outside of the distal end of the brush tube to aid in the closure.

After all of the parts were acquired, assembly of the tube could begin. First, the dual-lumen nasogastric tube was assembled. The first step was to cut off the tip of the Salem Sump tube to create the multi-lumen tube. Then, epoxy was applied on the inside of the cylindrical extension of the helical tip. Next, the distal end of the multi-lumen tube was attached to the proximal end of the helical tip by inserting it into the cylindrical extension. The epoxy was allowed to dry for 1 hour. This completed the assembly of the nasogastric tube.

Next, the nasogastric tube could be combined with the automated cleaning mechanism. First, the outside of the nasogastric tube was coated with lubricant to aid in insertion. Then, the nasogastric tube was inserted into the brush tube. The helical tip of the nasogastric tube and the bristles of the brush tube were both located at the distal end of the device. The vacuum line connection of the suction lumen and the vent lumen of the multi-lumen tube were at the proximal end. Finally, the nasogastric tube was attached to the linear actuator near the proximal end, while allowing the suction lumen to attach to the vacuum line and the vent lumen to be unobstructed. Refer to Figure 10 for correct orientation. For testing purposes, the brush tube and the linear actuator were immobilized. Once all of

these steps were completed, the nasogastric tube with the brush cleaning mechanism was ready for testing.

3.2 Artificial Stomach Setup

A controlled environment was necessary to best model the human stomach. A hot water bottle filled with a mixture resembling native stomach contents was used to act as the stomach. This mixture consisted of 2 cups water, 12 tablespoons flour, 3 tablespoons cornstarch, and 2 crumbled crackers. This recipe was used in nasogastric tube testing performed under similar conditions at MIT by Dr. James Ankrum and his colleagues.^[2] This mixture was prepared by the same person before each trial in order to maintain a consistent mixture throughout testing. To be precise, each ingredient was measured by mass. First, 474 g of water was measured in a large measuring container. Next, 120 g of flour was measured and added to this same container. After the flour was added, 24 g of cornstarch was measured and added to the container with the water and flour. Finally, 5 g of crumbled crackers were added to this same container, completing the 623 g mixture. The mixture was stirred for 30 seconds, and then poured into the hot water bottle to ensure mixing to the same consistency each time. The hot water bottle was then secured on to the testing set-up. The cornstarch gave the mixture a gelatinous texture to simulate mucous in the human stomach, which is prone to clogging the nasogastric tube tip. Adding hydrochloric acid to the mixture was not necessary because the tube tip material is already known to be a biocompatible, medical grade silicone, which would not be affected by stomach acid.

3.3 Clog Prevention Testing

Testing began with collecting data for the control, the Salem Sump tube. To prepare for this testing, the test setup was assembled as shown in Figure 21. The proximal end of the nasogastric tube was connected to the collection container of the heavy-duty suction machine. Then, the distal end of the tube tip was inserted into the esophagus tube and then into the hot water bottle. Suction testing began when the vacuum pump was turned on to approximately 8 cmHg. Trials ran for 6 minutes, during which, the occurrence of tube obstruction, mass of extracted contents, and the time to clog were recorded. Every 60 seconds during test trials, the hot water bottle was gently compressed to increase chances of clogging and to simulate the churning of the stomach. This allowed Beats Biomedical to ensure that its tube design would be effective even in conditions prone to clogging.

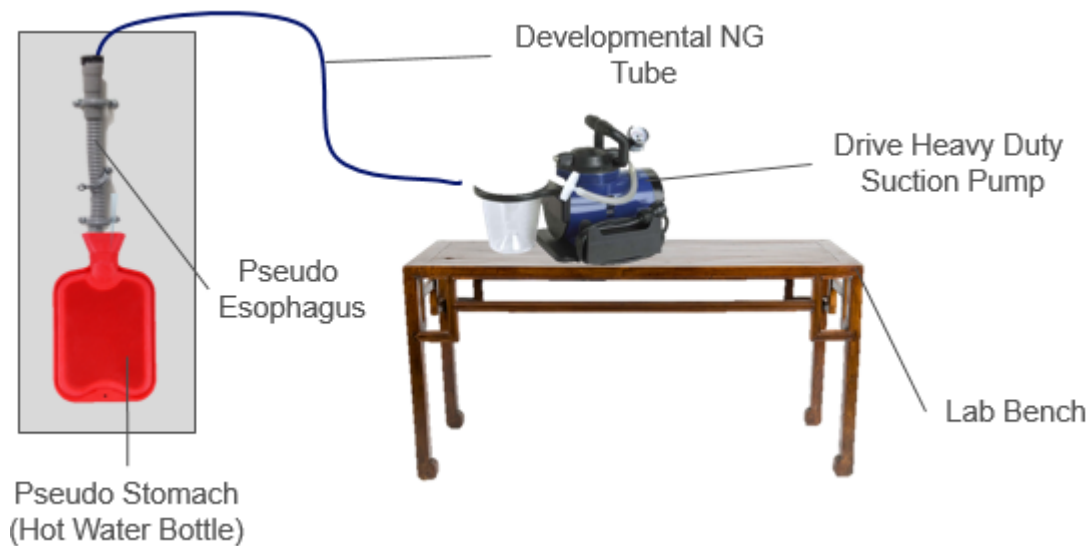


Figure 21. Clog Prevention Testing Setup

Several different factors were measured during these 6-minute trials including the amount of time it takes for a tube to first clog, the percent mass extracted of artificial stomach contents, and the number of complete clog occurrences. Ten trials were carried out for the Salem Sump and the Salem Sump with helical tip. Only five trials were carried out for the new nasogastric tube with helical tip and brushing mechanism due to material limitations. From these measurements, the optimal brush deployment rate for the brushing tube mechanism to avoid clogging was determined.

3.4 Analysis

Statistical analysis was performed in order to calculate if Beats Biomedical's design showed a significant difference in clogging rate, time to clog, and percent of contents extracted, compared to the control tube, the Salem Sump, and the Salem Sump with a helical tip. See Section 4.3 for detailed explanations of the t-tests performed and what was considered statistically significant. Comparing the final tube design against the Salem Sump with helical tip and the control Salem Sump allowed Beats Biomedical to determine how effective the helical tip was by itself and with the added brushing mechanism. The main goal of testing was to obtain data that would allow Beats Biomedical to develop the best design to reduce clogging of the nasogastric tube tip. After collecting the data from all 25 trials, Beats Biomedical performed statistical analysis using t-tests.

4. Results

4.1 Clog Prevention Results

The Salem Sump tube was expected to clog completely at approximately 90 seconds (1.5 minutes) after starting suction and clog completely 4 times in the 6-minute trial (0.67 clogs/min), based on the results from the study performed by Anrkum and associates at MIT.^[2] In Beats Biomedical's testing of the Salem Sump tube, an average of 3.7 complete clogs occurred during a 6-minute trial (0.617 clogs/min). The average time to complete clog for the Salem Sump tube was calculated to be 152.7 seconds (2.55 minutes). In the testing of the Salem Sump with helical tip alone (no brushing mechanism), the tube clogged an average of 2.6 times during a 6-minute trial (0.433 clogs/min) with an average time to complete clog of 145.6 seconds (2.43 minutes). The nasogastric tube with helical tip and brushing mechanism deployed every minute had an average of 0.2 clogs in six minutes (0.033 clogs/min). The average time to complete clog was calculated using 360 seconds (6 minutes) as the time if no clogs occurred within the 6-minute trial. Using this value, the average time to complete clog for the tube with brushing mechanism was calculated to be 331.2 seconds (5.52 minutes). Average extraction percentages of stomach contents were 48.5%, 49.6%, and 47.9% for the Salem Sump, helical tip, and brushing mechanism tube respectively. Figures 22 and 23 visually compare the average number of clogs data and average time to clog data respectively.

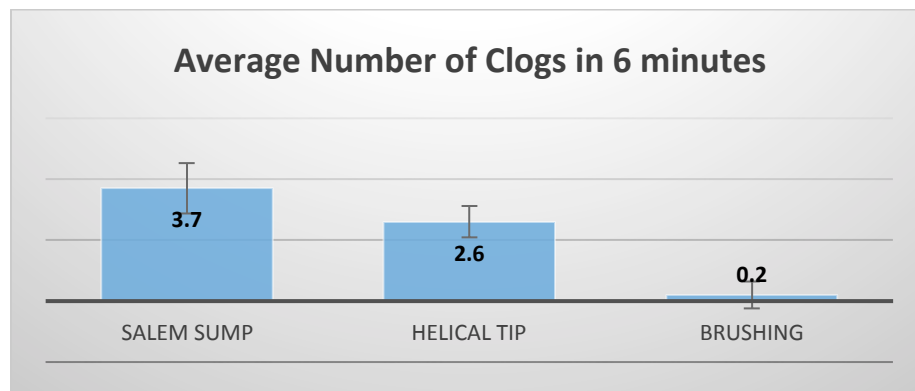


Figure 22. Averages for the calculated number of complete clogs in the 6-minute trials. The Salem Sump, helical tip, and brushing tubes clogged 3.7, 2.6, and 0.2 times respectively.

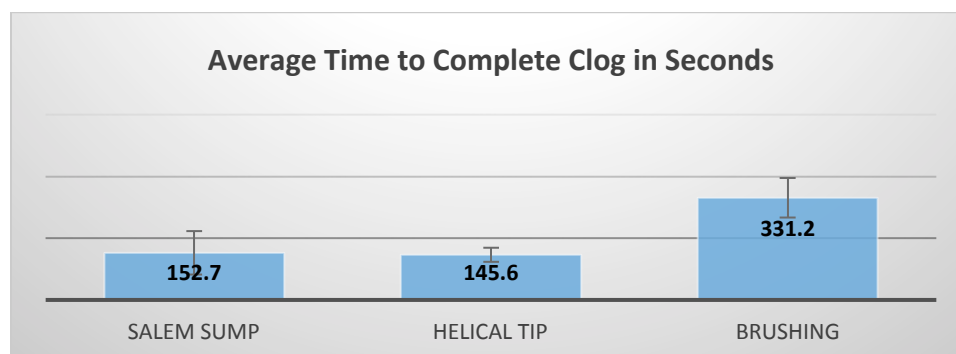


Figure 23. Averages for the time in seconds to the first complete clog in the 6-minute trials. The Salem Sump and helical tip clogged at 152.7 and 145.6 times respectively. The time for the brushing tube was calculated to be 331.2 seconds with no clogs being considered 360 seconds to complete clog.

4.2 Statistical Analysis

A Welch's t-test was used to compare the clogging rate sample means of the brushing mechanism tube with the control Salem Sump and with the Salem Sump with helical tip tube. When comparing the clogging rate of the brushing mechanism tube to the Salem Sump, the test yielded a p-value of 1.01497E-07, which is less than a 0.05 level of significance. When comparing the clogging rate of the brushing tube to the Salem Sump with helical tip tube, the test yielded a p-value of 5.29106E-06, which is also less than a 0.05 level of significance. This confirms that the brushing mechanism tube exhibits a statistically significant reduction in the rate of clogging when compared to both the control Salem Sump tube and the Salem Sump with helical tip.

Another Welch's t-test was used to compare the time to complete clog among the three tube designs. When comparing the time to clog of the brushing mechanism tube to the control Salem Sump, the test yielded a p-value of 0.000897139, which is less than a 0.05 level of significance. When comparing the time to clog of the brushing mechanism tube to the Salem Sump with helical tip tube, the test yielded a p-value of 0.002213725, which is also less than a 0.05 level of significance. This confirms that the brushing mechanism tube exhibits a statistically significant increase in the amount of time to complete clog when compared to both the Salem Sump tube and the Salem Sump with helical tip tube.

The Welch's t-test was also used to compare the extraction percentage of the brushing mechanism tube to the control Salem Sump and the Salem Sump with helical tip tube. The p-value was greater than a 0.05 level of significance when comparing the brushing mechanism tube to both Salem Sump designs. This confirms that there is no statistically significant difference in the extraction percentage of the brushing mechanism tube when compared to both the Salem Sump tube and the Salem Sump with helical tip tube.

5. Conclusion

In order to address problems with current nasogastric tubes, it was necessary to redesign in an attempt to reduce the rate of clogging, increase the time to clog, maintain the extraction rate, and create a self-cleaning mechanism. The nasogastric tube with a brush cleaning mechanism was developed in an effort to reduce the rate of complete clogs, increase the time to complete clog, and remove adhered particles from the tube tip. This project was successful because Beats Biomedical's new nasogastric tube design with a brushing mechanism met these objectives. This new tube proved effective during testing in removing adhered particles from the tube tip, had a time to clog statistically significantly higher than both the Salem Sump tube and the Salem Sump with helical tip tube. The new brushing mechanism tube also had a clog rate statistically significantly lower than both the Salem Sump tube and the Salem Sump with helical tip tube. While the extraction percentage did not increase significantly with the new design, the extraction rate remained within an acceptable range of both the Salem Sump tube and the Salem Sump with helical tip tube. Beats Biomedical's objective to reduce the rate of clogging was achieved. Once the linear actuator is automated, the nasogastric tube with the cleaning mechanism will be self-cleaning and able to prevent complete clogs. When this occurs, the second objective will be achieved. Although the linear actuator used in Beats Biomedical's testing could not be completely automated due to time constraints, a simple DPDT relay set on a time delay can be attached to achieve this. The brushing mechanism tube meets the clogging reduction objectives and will be automated in the near future. Therefore, Beats Biomedical is considering this project a success.

6. Future Plans

6.1 Ideal Manufacturing of Extruded Nasogastric Tubes

Due to limitations in the budget and resources, Beats Biomedical was forced to assemble the dual lumen nasogastric tube with an automated brushing mechanism in a non-ideal way. In the future, a prototype of a multi-lumen nasogastric tube with an automated brushing mechanism would need to be manufactured. The ideal specifications for each part are explained in Sections 2.1-2.2.2.

6.1.1 Ideal Dual Lumen Nasogastric Tube with Helical Tip

In the future, it would be better to manufacture the dual lumen nasogastric tube and the helical tip together as one part. This would be done using an extrusion process. This single nasogastric tube with helical tip would be made out of medical grade silicone instead of Visijet Tough and PTFE. The usage of silicone would increase the flexibility of the tip and the multi-lumen tube portions of the device. This would allow the device to undergo insertion testing (see Section 6.2) to validate the ease of insertion of the device. Combining the multi-lumen tube and the helical tip into a single functional nasogastric tube would also decrease the diameter. This diameter decrease is due to the ability to

customize the inner lumen dimensions and wall thickness of the nasogastric tube and discarding the attachment cylindrical extension of the original helical tip described in Section 2.1.1.

6.1.2 Brush Tube with Bristles

In the future, it would be better to also manufacture the brush tube and bristles together as one part. This would be done using an extrusion and molding process. The single brush tube with bristles would be made out of medical grade silicone instead of silicone adhered to PTFE. Creating a brush tube with bristles as one part out of the same material will eliminate the issue of poor bristle adherence to the inside of the brush tube. Also, using a molding process, the bristles would be more uniform which would improve the performance of the device.

6.1.3 Linear Actuator

The Sleek Rod Actuator manufactured by Firgelli Automations would work well with the other idealized design changes described in Sections 2.2.3. However, the possibility of a linear actuator that would be smaller or better suited for the hospital environment could be explored in the future. Also, a linear actuator attachment specific to the nasogastric tube with brushing mechanism part dimensions could be created so that the device could be used with multiple types of actuators.

6.2 Insertion Testing

Once the nasogastric tube with an automated brushing mechanism could be manufactured out of the appropriate materials, insertion testing could be performed to validate the ease of insertion of the device. Testing would begin by collecting data for the control, the Salem Sump tube. Figure 24 shows the intubation test mannequin and hot water bottle system that would represent the patient. A clinician would be given the Salem Sump tube and asked to insert the distal end of the tube tip through the nostril of the mannequin, down its esophagus, and into the hot water bottle (see Figure 24). The clinician would then be asked to rate the ease of insertion from 1-10 (1 being very difficult to insert and 10 being very easy to insert). Multiple clinicians would be asked to perform this test. This procedure then would be repeated using the nasogastric tube with the brushing mechanism.

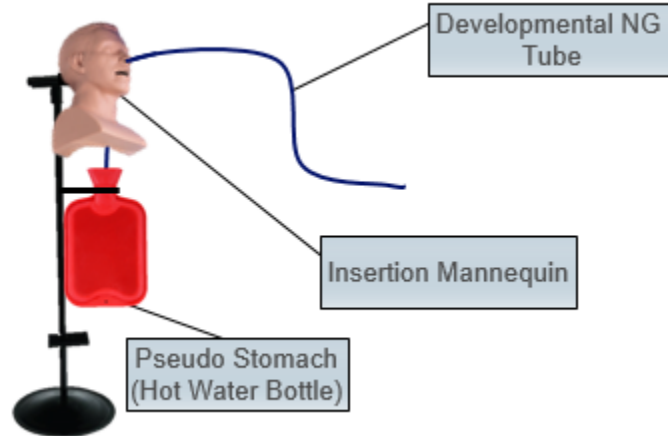


Figure 24. Insertion Testing Setup

6.3 Endurance Testing

Cyclic endurance testing would be performed on the automated brushing mechanism. The goal of this testing would be to determine the longevity of Beats Biomedical's new nasogastric tube. The cycles to failure of the design would be calculated and compared to the control Salem Sump tube. Minimal accepted performance parameters would be set for the new device.

6.4 Acceptance Testing

The set parameters achieved through the endurance testing would be used to create minimal performance restrictions for the device. The acceptance testing would be performed under normal operating conditions. The number of clogs per minute, extraction efficiency, and the optimal self-cleaning rate would be determined. Recorded data would be compared to the minimal acceptable operating parameters of each device.

6.5 Conformance Testing

Once the device passes endurance and acceptance testing, the nasogastric tube with the automated brushing mechanism would undergo conformance testing. This would be to ensure that the design would meet all standards for medical devices, including but not limited to: ASTM, ISO, and FDA regulations.

6.6 Market Analysis

Market analysis was performed to estimate if Beats Biomedical's new nasogastric tube design would be cost effective and competitive with the current standard, the Salem Sump tube. This analysis was based on producing the new nasogastric tube with brush mechanism from ideal manufacturing processes and materials. Currently, the Salem Sump tube typically costs approximately \$2.97 per tube.^[4] Beats Biomedical's new tube with brush mechanism would cost more than this simply because it requires more material to produce. An extrusion process would need to be used to produce not only the dual-lumen nasogastric tube, but also the brush tube. These would both be made out of medical grade silicone. Quotes from Zeus estimate that cost for these extrusions to manufacture 5000 devices would be approximately \$6752.32, including the project start-up fee. The helical tips and brush bristles would also be made out of medical grade silicone but would be manufactured using an injection molding process. The MoldMax Liquid Silicone that Beats Biomedical purchased for injection molding cost \$11 per pound. According to Silicone Pro, medical grade silicone cost 5 times more than this, putting it at approximately \$55 per pound.^[9] To produce a helical tip and bristle sheet for one device, 0.0273 cubic inches of silicone would be needed. With a density of 0.041 lb per cubic inch, the amount of silicone necessary would be approximately 0.00112 lb. At \$55 per pound, producing 5000 devices would cost approximately \$304 for these two parts (helical tips and bristle sheets).^[10] Therefore, with the exception of the automation equipment, Beats Biomedical's new brushing mechanism tube could sell at a price of approximately \$4.

Cost analysis was based on a hospital purchasing 10 linear actuators to automate the new nasogastric tubes. Assuming design advancements would allow for use of cheaper linear actuators than the one used in testing, a hospital would have to spend approximately \$400 (\$40 per unit x 10) as a one-time expenditure to obtain the necessary automation equipment. Beats Biomedical's project sponsor, Dr. Fry, estimated that on average, about 6 patients at one time require a nasogastric decompression tube during a week at a single hospital, and a nurse would spend about 3 hours per patient monitoring, cleaning, and replacing the tube. Assuming the starting salary for a nurse, \$22.27 per hour, 3 hours of work would mean \$66.81 could be saved per patient with the new automated design that does not require nurse monitoring and cleaning. For an average week with 6 patients using the device, this would save the hospital approximately \$400.86, so the hospital would make up for the \$400 cost of linear actuators in just one week. With continued saving from device automation, hospitals could allocate extra funds to other projects. Therefore, although Beats Biomedical's device is more expensive than the current Salem Sump per unit (\$4 vs. \$2.97 respectively), a hospital could save enough money by requiring less nursing staff that the new device would end up being more cost effective than the Salem Sump if ideal manufacturing conditions were possible.

6.7 Alternative Viable Clog Prevention Option: Automated Contracting Tip Cleaning Mechanism

Beats Biomedical created an alternative solution to solve the problem of nasogastric tube clogging due to food particle adhesion. This solution involved creating an automated contracting tip cleaning mechanism that would dislodge any adhered food particles from the helical tip. To do this, the nasogastric tube would have four wires running through the entire length of the tube, including the helical tip. The cross section of the nasogastric tube with the wires can be seen in Figure 25.

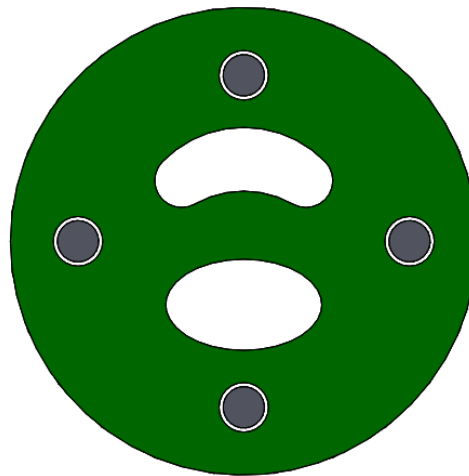


Figure 25. This figure shows a cross section of the nasogastric tube with 6 lumens: a scution lumen, a vent lumen, and 4 lumens for the wires.

The four wires would converge at the proximal end of the nasogastric tube where they would be attached to a linear actuator, which can be seen in Figure 26.



Figure 26. Overview of the dual lumen nasogastric tube with a contracting tip cleaning mechanism. The linear actuator would be connected to the proximal end (left side) of the device.

When the wires were relaxed, the helical tip would be in the suction position. While in this position, the suction lumen is connected to the vacuum line and gastric contents are being suctioned out of the patient. When the linear actuator is activated, the wires are pulled, causing the helical tip to contract. To be successful, the force of this contraction would have to be enough to remove any

adhered food particles from the helical slits of the tip. Figures 27A and 27B show the helical tip in the suction position and the contracting position respectively.

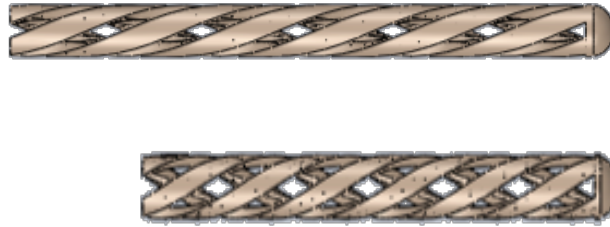


Figure 27. Nasogastric tube in suction position (A) and in contracting position (B).

Manufacturing this design required the use of custom multi-lumen extruded tubes and complex molding procedures to create the helical tips with wires running through the walls. Unfortunately, Beats Biomedical could not find a company to produce a multi-lumen extruded tube within the given budget. Instead, Beats Biomedical attempted to make a four-part device that would serve in place of a multi-lumen extruded tube, see Figure 28. However, this device was unsuccessful because of its inherent tendency to kink due to the space between disks, which made it difficult for other tubes to slide over it.

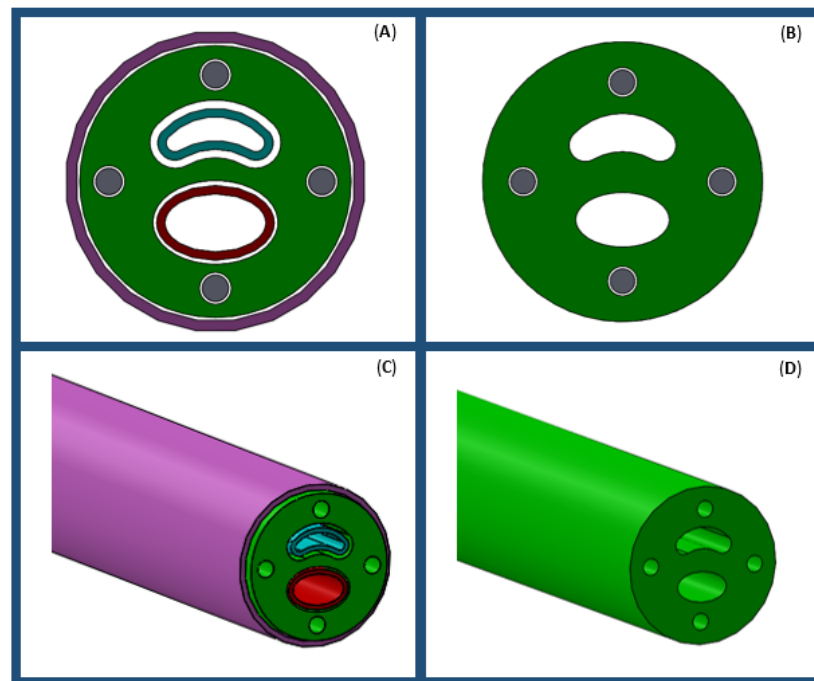


Figure 28. Figures A and C show the four parts that were going to be used as a substitute for the multi-lumen tube: the green disks, the purple outer tube, the blue vent lumen and the red suction lumen. Figures B and D show what the actual multi-lumen extruded tube would have looked like if the budget allowed for it to be manufactured. As a functional product, the four parts shown in Figure A and C would all be combined into the single tube shown in Figures B and D.

Manufacturing the helical tip with wires running through its walls also caused problems. The best resource available to Beats Biomedical to create something accurately on a very small scale was a 3D printer. However, because the helical tip had to have wires running through the walls, 3D printing was not an option. Instead, the next viable option was to 3D print molds and use liquid silicone to create the helical tips via injection molding. The molds needed to be multi-part molds that included tracks for the wires. The detail required to produce accurate molds for these parts was too much for the 3D printer available to Beats Biomedical to accurately create. These manufacturing difficulties led Beats Biomedical to abandon this design solution. However, with the necessary resources, Beats Biomedical believes that this design could be a viable solution to the problem of nasogastric tube clogging due to food particle adhesion.

7. References

- [1] Krenitsky, Joe. "Blind bedside placement of feeding tubes: treatment or threat?." *Practical Gastroenterology* (2011): 32.)
- [2] Ankrum, A., Canseco, J., Greenblatt, E., Olechowski, A., Nasogastric Tube Design to Reduce Clogging and Simplify Flushing. Proceedings of the 2011 Design of Medical Devices Conference. 2011; 1-7.
- [3] Phillips, N. Nasogastric Tubes: An Historical Context. *MedSurg Nursing*. 2006; 15(2), 84-88.
- [4] Ignatavicius, Donna D. *Medical-surgical Nursing: Critical Thinking for Collaborative Care*. 5th ed. St. Louis, Mo.: Elsevier Saunders, 2006. Print.
- [5] Bard Medical Division. (2004). The PreVent Anti-Reflux Filter Advantage [Brochure]. Covington, GA: C.R. Bard Inc.
- [6] Roberts, James R., Jerris R. Hedges, and Arjun S. Chanmugam. *Clinical Procedures in Emergency Medicine*. Philadelphia, PA: W.B. Saunders, 2004. Print.
- [7] Linder, G. (1997). US Patent 5,643,230. Pacific Palisades, CA: U.S. Patent and Trademark Office.
- [8] "Sleek Rod Tubular Linear Actuators No Slot." *Firgelli Automations*. Web. 1 Apr. 2015.
- [9] "Is Medical Silicone More Expensive than Thermal Plastic Elastomers? - Silicone.pro - Medical Silicone, Liquid Silicone Molding." *Siliconepro Medical Silicone Liquid Silicone Molding*. 7 Aug. 2012. Web. 1 Apr. 2015.
- [10] "Cost Estimator." *Injection Molding Cost Calculator*. Web. 1 Apr. 2015.
- [11] Ingraham, S. (1987). US Patent 4,634,435. Bowling Green, OH: U.S. Patent and Trademark Office.
- [12] Geiss, A. (1989). US Patent 4,834,724. Greer Neck, NY: U.S. Patent and Trademark Office.
- [13] Yarger, R. (1994). US Patent 5,360,414. Yakima, WA: U.S. Patent and Trademark Office.
- [14] Maercovich, J. (2006). U.S. Patent 7028977. Los Angeles, CA: U.S. Patent and Trademark Office.
- [15] "Kendall Argyle Indwell Polyurethane Nasogastric Feeding Tubes - 6.5 Fr - 36 Inch." Nutritional Supplements. First Option Medical, 2014. Web. 8 Sept. 2014.
- [16] "Kendall: Argyle Salem Sump Nasogastric Tube." TheEMSStore, 2014. Web. 8 Sept. 2014.
- [17] "Portable Gastric Pump W/1100ML Disp. Canister - BF01222701 - Each." DME Supply Group, 1 Jan. 2012. Web. 8 Sept. 2014.
- [18] "Hydrochloric Acid, ACS - 1L." Mansion Schools, 1 Jan. 2014. Web. 8 Sept. 2014.
- [19] Deutsch, H. (2006). US Patent App. 10/566,693. Encino, CA: U.S. Patent and Trademark Office.

[20] "Platinum – Cured Silicone Tubing." ThermoplasticBioLogic, 2015. Web. 20 Feb. 2015.

[21] "Polymer Extrusions." Zeus. Catalog 11, 2014. Web. 20 Feb. 2015.

8. Appendix

Table 3. Raw data and statistics for number of complete clogs in the 6-minute trials.

Clogs			
	Salem Sump	Helical Tip	Brushing
	3	3	0
	3	3	1
	3	2	
	5	3	
	3	2	0
	4	2	0
	3	3	0
	4	3	
	5	2	
	4	3	
count	10	10	5
mean	3.7	2.6	0.2
dev	0.823272602	0.516397779	0.447214
variance	0.677777778	0.266666667	0.2
	Salem vs. Brushing	Helical vs. Brushing	
P value	1.01497E-07	5.29106E-06	
Difference	TRUE	TRUE	

Table 4. Raw data and statistics for extraction percent in the 6-minute trials.

Extraction %			
	Salem Sump	Helical Tip	Brushing
	38.5596904	47.95423315	52.79373536
	88.33674528	52.86183011	47.61321535
	22.85538013	45.3760356	
	78.24827336	53.42269834	
	36.87708573	48.74264469	48.3006515
	49.51694071	51.23100793	49.1029879
	37.99882218	48.51510138	41.88196027
	41.44352647	49.77705488	
	51.73439561	48.44989607	
	39.42517291	49.91727194	
count	10	10	5
mean	48.49960328	49.62477741	47.93851007
dev	20.04825009	2.399625939	3.932174328
variance	401.9323317	5.758204647	15.46199495
	Salem vs. Brushing	Helical vs. Brushing	
P value	0.933671177	0.415159827	
Difference	FALSE	FALSE	

Table 5. Raw data and statistics for time to complete clog in the 6-minute trials.

Time to Clog (s)			
	Salem Sump	Helical Tip	Brushing
	227	128	360
	218	145	216
	190	131	
	141	185	
	244	140	360
	70	133	360
	196	132	360
	98	190	
	62	143	
	81	129	
count	10	10	5
mean	152.7	145.6	331.2
dev	70.49200112	22.86287627	64.39876
variance	4969.122222	522.7111111	4147.2
	Salem vs. Brushing	Helical vs. Brushing	
P value	0.000897139	0.002213725	
Difference	TRUE	TRUE	



Figure 29. Actual testing setup with pseudostomach, esophagus, and Drive Medical suction machine.

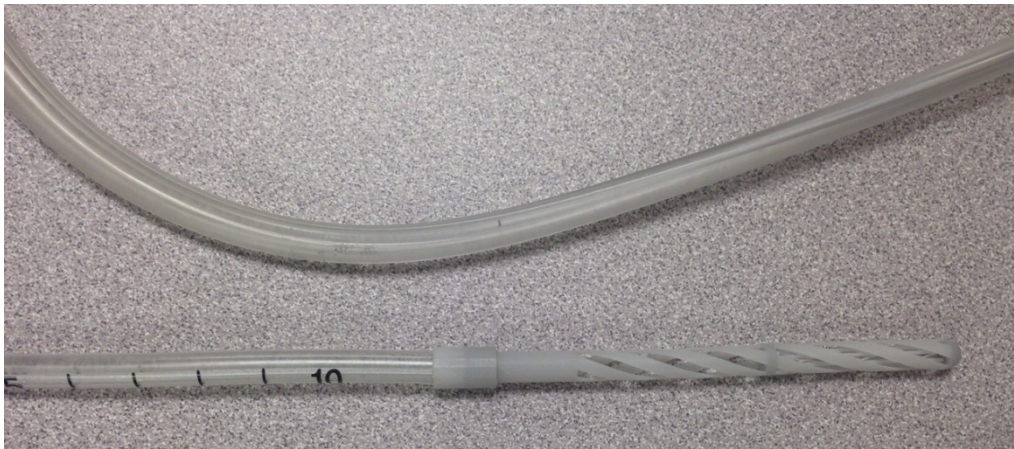


Figure 30. The 3D printed helical tip affixed to a Salem Sump extruded tube. The manufacturing of this tube is referenced in Section 3.1.

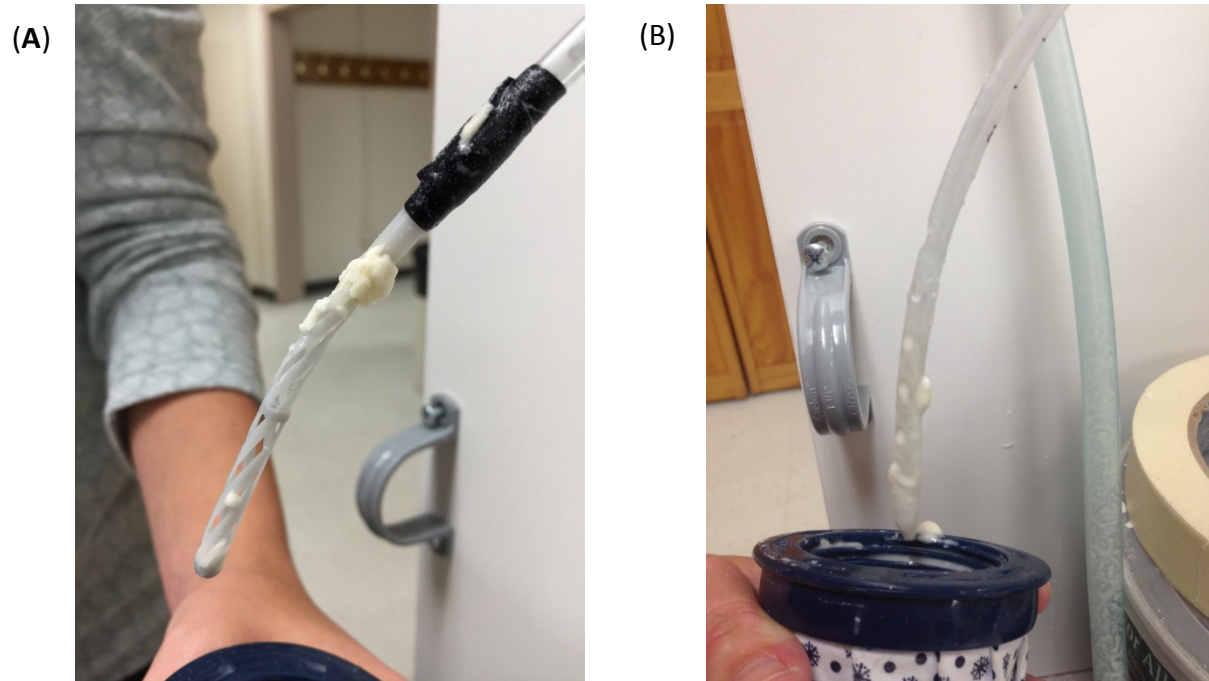


Figure 31. Figures A and B show helical tip and the Salem Sump tube tip respectively. Figures A and B show the clogging of the nasogastric tube tip with food particles during testing.