Designing a G-tube Stabilizer: A Device to Stabilize the Percutaneous Endoscopic Gastrostomy (PEG) Tube Stoma

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Group 5

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Background

Gastronomy tubes, also known as G-tubes, are medical devices that serve as an aid in feeding patients who require the assistance. This device placed in a patient during a Percutaneous Endoscopic Gastrostomy procedure. During this procedure, an endoscope is inserted through the mouth all the way to the stomach of the patient. The physician will then use it to monitor the insertion of the G-tube through the lining of the stomach, entering from a stoma on the external skin outside of the abdomen, to ensure correct placement.

G-tubes allow nutrition, medication, and fluids to be delivered directly to the stomach while bypassing the mouth and esophagus and is used by individuals of all ages for a variety of different medical purposes. For example, infants with congenital problems—abnormalities that they are born with—regarding the mouth or esophagus tend to require G-tubes to provide direct access to their stomachs to ensure that they are receiving enough nutrition at that early stage in their lives [1]. One major congenital problem that often requires the usage of G-tubes in infants are cleft lips or cleft palate, as it is imperative that the infants still receive adequate nutrition while they wait for surgical correction [2]. Infants may also need to use G-tubes if they are not strong enough to breastfeed or if they are not gaining weight at a healthy rate.

This device has also been found to children who have difficulty chewing or consuming enough nutrition to grow. As with infants, it is imperative for children to consume adequate nutrition in order to build healthy immune systems, have enough energy, grow at a normal rate, and to develop of their bodies [3]. In fact, this prevalence was demonstrated in a press release from the Feeding Tube Awareness Foundation, which stated in a study from 2017 that about 40% of the people using feeding tubes were pediatric patients [4].

In addition to infants and children, G-tubes are often used in the elderly. It is quite common for G-tubes to be used by stroke victims or by those with neurological disorders such as Parkinson's or Alzheimer's, which are mostly found in elderly individuals [5]. The reason behind the correlation is that patients with these disorders tend to lose the ability to chew and swallow in later stages of dementia. Without the ability to chew and swallow properly, one can easily choke on their food as it travels through the mouth and esophagus, presenting a major safety hazard. If the individual completely loses their ability to chew and swallow, it is necessary to deliver nutrition through a different method than oral consumption, hence the need for G-tubes.

This previously mentioned list of associated abnormalities and disorders generally found across several age groups clearly demonstrates the vast audience that G-tubes serve. It also demonstrates its many applications in the medical field. G-tubes are extremely beneficial to individuals of all ages and have solved many problems for those who experience the inability to consume nutrition, medication, and fluids through the mouth and esophagus on their own, however, this device does exhibit some limitations to it.

During a Percutaneous Endoscopic Gastrostomy procedure, G-tubes are inserted through the stomach lining and exit from a stoma on the surface of the abdomen where the feeding, medication, and fluid ports are located. In order to ensure that the food is being delivered to the stomach properly, certain components of G-tubes are placed flush against the outer skin, but this could lead to some major adverse effects. If it is placed too tightly, the friction of the device against the skin can cause irritation of the surrounding skin and produce an inflammatory response at the insertion site. On the contrary, if certain components of the G-tube are not placed tightly enough against the outer skin, the open exposure of the insertion site can cause leakage

and provoke infections. Some signs of an infection at the insertion site include redness, swelling, abscess under the skin, or even a thick discharge leaking from the stoma [6]. It is important to prevent infections by keeping the insertion site as dry as possible and preventing any leakage. These are just some of the issues associated with the placement of a gastronomy tube against the outer skin.

Deformation of a G-tube is another significant issue that patients experience involving the design of the G-tube itself. Currently, most variations of this device are made out of silicone rubber, a material that is commonly used in the medical field. Silicone rubber has often been the preferred material of choice when it comes to medical devices due to the fact that this material is highly flexible and also has inert response to heat or chemicals — it does not exhibit adverse reactions in response to changes in certain conditions such as temperature. Although silicone rubber can undergo a large amount of elongation before reaching a breaking point, it does tend to have a low elastic modulus [7]. The elastic modulus value defines the amount of stress per strain that a material can endure before failing. The low elastic modulus of silicone rubber signifies that the material can endure high strains resulting in elongation but will reach its failure point under low stress, which is the force per unit area of the material. In the long run, silicone rubber is weak in tensile strength and durability since external forces or pressures can tear or puncture the device without much resistance. Another biomaterial that is being used increasingly in the medical field and is sometimes used in G-tubes is polyurethane rubber [8]. This material is becoming more common in medical devices due to the fact that it is biocompatible, hemocompatible (compatible when the device comes in contact with blood), and has a higher elastic modulus. The downside to polyurethane rubber is that it is not as resistant to changes in

environmental conditions such as heat or pH as silicone rubber. With either material, G-tubes cannot endure a significant amount of mechanical stress without reaching a breaking or failure point. Thus, G-tubes are largely susceptible to deformation, tears, and punctures, which prove to be a large inconvenience for the patient. When this device is damaged and cannot function as it is intended to, the patient will be required to undergo another procedure in order to insert a new G-tube that will resume the feeding assistance that the patient needs. In the case that an external force pulls the G-tubes out of the stomach, which can lead to several complications, another procedure will again be required to insert a new G-tube into the stomach.

Although a G-tube is primarily comprised of a feeding tube that runs through a stoma into the stomach of a patient, a G-tube also consists of multiple other components. On the side of the outer skin, there is an external bumper around the insertion site. The tube runs through the external bumper and stoma and is reinforced to the lining of the stomach from the inside using an internal bumper. This internal bumper is intended to prevent the tube from being pulled out of the stomach by an external force; however, it does not always work as it should. Hence, two solutions were created to solve this specific issue. The first solution is the break-way PEG tube which uses a connector between two tubing segments so that if the tube is pulled on by an external force, a segment further from the insertion site will be pulled out but not the segment at the point of attachment [9]. This prevents the accidental removal of the G-tube all the way from inside the stomach of the patient.

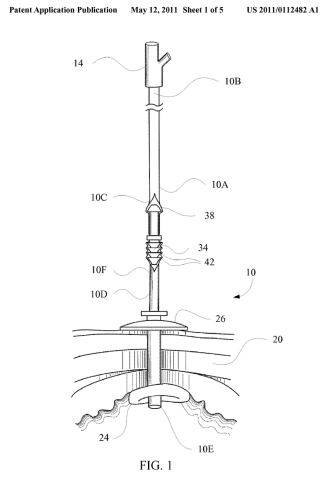
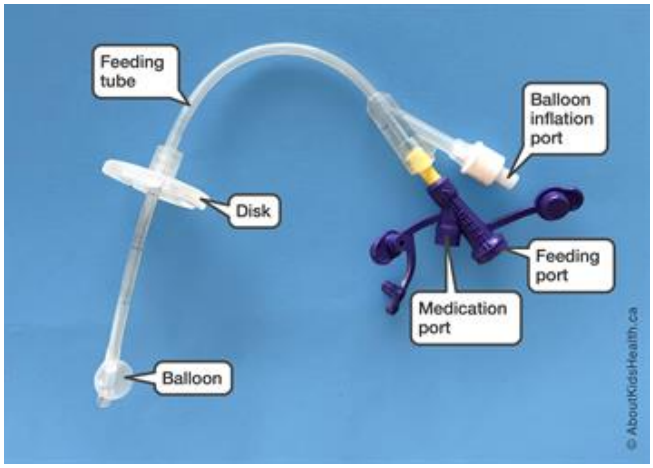


FIG. 1

[10]

Another solution that was also designed to avoid accidental removal of this device is the balloon G-tube. The balloon G-tube consists of a balloon on the internal end of the G-tube and does not allow the G-tube from being pulled out of the stomach. Unfortunately, the balloon in this design can break, leak, or deflate which defeats the purpose of the design.



[11]

A study was done on the healthcare costs associated with percutaneous endoscopic gastronomy. According to the study, the average daily cost of feeding with a G-tube is roughly

$87.21 with an average yearly cost of about $31,832 [12]. The total cost for one year was also broken down into three main components. The first main component, which contributes roughly 29.4% to this large annual cost, is the PEG procedure; the second main component, which contributes about 24.9% to the yearly cost, is the enteral formula; and the final main component, which contributes 33.4% of the cost for the annual cost, are the hospital expenses due to major medical complications.

It is evident that there are several benefits to G-tubes, as they serve as a feeding aid for a variety of disabilities associated with multiple age groups. However, as mentioned above, there are several limitations to G-tubes which include the adverse effects that patients may experience due to G-tube usage. Two solutions to these problems were also discussed in this section as well as their current limitations in solving the issues in a variety of situations. Hence, this G-tube stabilizer was designed to prevent several of these issues explained above. The G-tube stabilizer will also eliminate the need to use the break-way PEG-tube or the balloon G-tube as our new device will be able to solve the issues on its own. Finally, our G-tube stabilizer will have socioeconomic benefits as well; as previously mentioned, medical complications tend to account for 33.4% of the estimated annual cost of using a G-tube. Covering the insertion site with the G-tube stabilizer will prevent many of the medical complications from arising, thus cutting down the estimated yearly cost of G-tube usage. The G-tube stabilizer is a device that has been designed to maximize the effectiveness of G-tubes and to make the use and maintenance of G-tubes much easier for the patient.

Design Criteria

When designing the G-tube stabilizer, we must identify the explicit goals that ought to be attained during the design process. As previously mentioned, G-tubes are most commonly used in hospital settings when dealing with patients who cannot receive nutrition through standard means (i.e., their mouth has restricted access and using it for eating would yield risks for the patient). Thus, the patient's comfort is inherently one of the most essential design criteria that must be considered.

Comfortability in this context mostly refers to the irritation that is commonly felt by patients at the insertion site of the G-tube, usually on the abdomen. The most common form of irritation tends to be an allergic reaction to the material of the G-tube stabilizer, or the tape that is used to hold it down onto the patient. Patients often do not have allergic reactions to the G-tube itself, which is most commonly made of polyurethane or silicone. However, reactions to medical tape are notoriously bad and can cause severe rashes and even breakouts around the stoma (similar to pimples) [13]. Our design subsequently will not utilize a tape-like adhesive, so the "sticky irritation" that patients often complain about will be eliminated from the equation. The skin of the patient can additionally become quite itchy, which is mostly problematic with children, who lack the mental capacity to resist scratching the irritated spot. The scratching often leads to a removal of the G-tube and is exactly what we are trying to avoid.

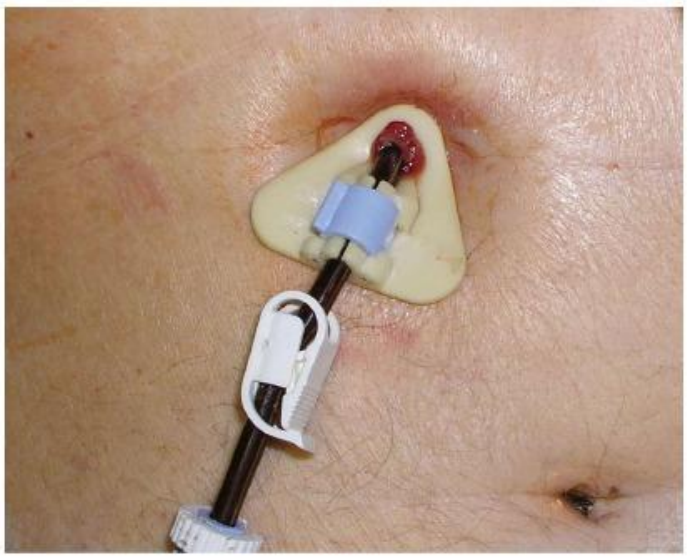
Irritation and uncomfortability can also be due to prolonged contact between the G-tube and the patient. As previously mentioned, G-tubes are most commonly held to the patient by an adhesive, where the tube is in direct contact with the patient's skin for extended periods of time. As a result, the patient starts to feel immense discomfort from the friction between the tube and

the skin [14]. This excessive movement of the tube around the stoma is mostly due to the fact that medical tape is not the most reliable adhesive that keeps instruments (like G-tubes) intact. They are often used for securing smaller instruments that do not require surgical incisions (hence our design being built specifically for G-tubes and not general purpose).

Common treatments to such irritations include the use of foam or a pad that increases the distance between the skin and tube. Both methods reduce the adhesiveness of the tube and make the probability of the tube falling out more likely. Medicinal cream, such as Hydrocortisone 0.5% (or 1%) is also an option [13], but if this is used with the medical tape, it is likely that the tape will lose its adhesiveness over time due to the slippery nature of the cream. This would require the patient or the caretaker to replace the medical tape more often than necessary. Our design would provide sufficient elevation of the G-tube off of the patient's stoma, such that the tube would be securely fastened with the stabilizer itself and the patient will not experience any excessive contact with the tube (other than the obvious contact at the insertion site). This also prevents any allergic reaction the patient might have with the tube's material as it will not be spread all over their abdomen.

As discussed in our summary, another method commonly used for stabilizing G-tubes is the use of a balloon G-tube, where a small balloon is inserted into the patient's abdomen, serving as a bumper that prevents the G-tube itself from detaching. However, the balloon method is not entirely reliable because it can cause leaking and can lead to Buried Bumper Syndrome, a complication where the internal bumper compresses too much with the external tissue, also causing a leakage [15]. Below is a picture of real-life symptoms of Buried Bumper Syndrome, as well as a graph representing the influence of the position of the external fixator (loose-tight) on

the risk of complications (stoma infection, buried bumper syndrome and peritoneal leakage) as a function of time [15].



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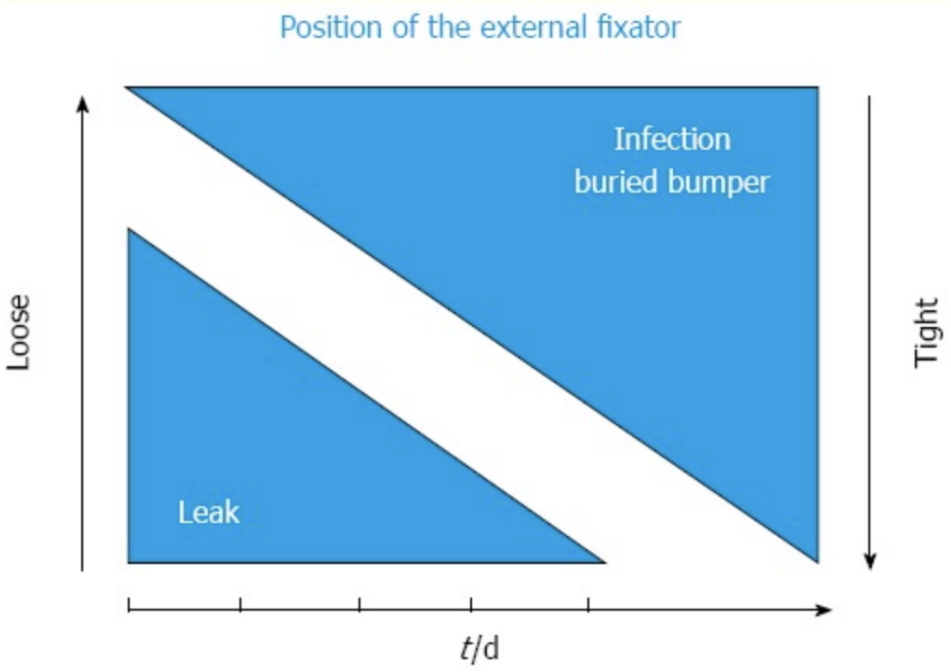


[15]

The bumper or disc also has a tendency to migrate within the tract of the stoma and can migrate anywhere from the stomach mucosa (mucous membrane layer of the stomach) to the surface of the skin [15]. Our product would want the stabilizer to be a fixed instrument on the patient. If the stabilizer itself is afloat, there is little to no guarantee that we can keep the G-tube firmly inserted into the patient's abdomen.

Patients that have received the endoscopic procedure often do not need to be bedridden and prefer to retain their mobility. Ensuring that the patient is able to move around while minimizing the physical restriction of the G-tube was a pivotal requirement taken into consideration when developing the best design for a G-tube stabilizer.

Minimizing the size of the stabilizer itself is the first step to retaining the mobility of the patient. By making our stabilizer as small as possible, it would allow us to reduce the restrictive effects of the G-tube (in comparison to other common stabilizing techniques) and we can still keep it firmly attached to the patient via an external bumper (as opposed to the internal balloon G-tube method). Given that G-tubes are produced in a variety of sizes, we would want our design to be good in-between size such that most G-tubes can be used with our stabilizer.

The shape of the stabilizer is equally crucial to maximizing mobility. We would want the stabilizer to sit on the patient's abdomen with a rounded design, allowing it to conform to the natural contour of the patient's body. A rectangular or box-like structure would have sharper edges that reduce the patient's range of motion and restrict their maximum angle of rotation and may also dig uncomfortably into the skin.

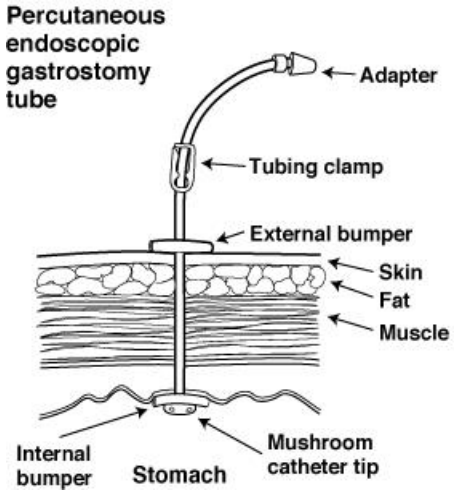
Finally, the stabilizer must be able to withstand substantial mechanical stress as our last design criterion. For this, we must decide upon a material that can not only withstand the weight of the patient, but one that does not stimulate any of the bodily reactions described earlier (e.g. the allergic reactions and the appearance of rashes). The silicone that is used in the G-tube itself is actually a viable candidate for this material. For the most part, it yields no significant allergic reaction or irritation to the patient, and is popularly known in the medical field for its great elongation and low compression set, but can fall short in handling higher levels of mechanical stress due to its relatively low tensile strength [16]. In terms of biocompatibility however, it would allow us to maintain great consistency of material between the tube and the stabilizer, ensuring that there will not be any unwanted reaction between the two instruments. Another viable option could be engineered cellulose fibers. The fibers are derivative of plant cell walls and are molecularly arranged in a perfectly tight knit thread that has been tested to be significantly stronger than spider webs [17].

The culmination of the aforementioned design criteria help understand the fundamentals of what the design itself should contain and also informs us on what methods have proven to be more useful than others. Since our product is going to be designed largely for hospital and patient use, it's in our best interest to make sure that the logistics of our model not only fundamentally agree with the surgical procedures but maintain function.

Design

The G-tube is a common hospital device that provides nutrition straight to the patient's stomach. However, G-tubes are susceptible to inadvertent removal since they are not designed to

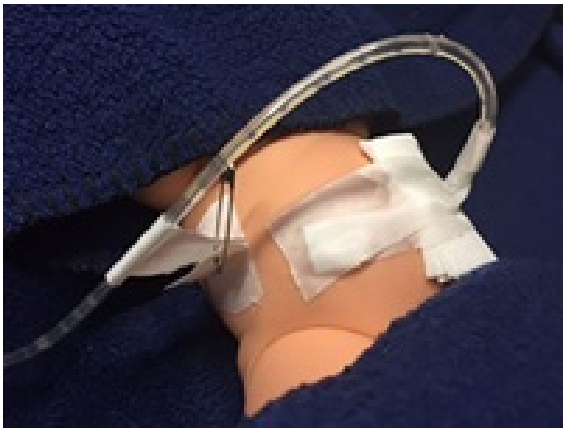
handle a significant amount of mechanical stress. As stated in the background, the inadvertent removal of the G-tube causes a plethora of problems. This is the problem that the G-tube stabilizer is trying to address: the tube needs to be stabilized at its insertion point in order to prevent any unwanted removals. At its core, the problem can be broken down into analyzing just the G-tube in three parts: the internal bumper, the external bumper, and the tube itself. Each part has an important function and provides the constraints for this project. The internal bumper has the important function of securing the G-tube to the gastric wall and serves to prevent it from sliding out. However, it is not meant to handle the stresses put on it during an inadvertent removal. The tube is there for the transportation of nutrients, medication, and fluids into the stomach. However, since G-tubes are used so widespreadly, it would not make sense to alter the tube itself or the internal bumper even though the internal bumper can sometimes be replaced by a medical balloon. The external bumper is there to cover the insertion site and provide stability the G-tube itself. Since the external bumper is located on the outside, it would make more sense to alter or add on to the external bumper in order to solve the problem.



[18]

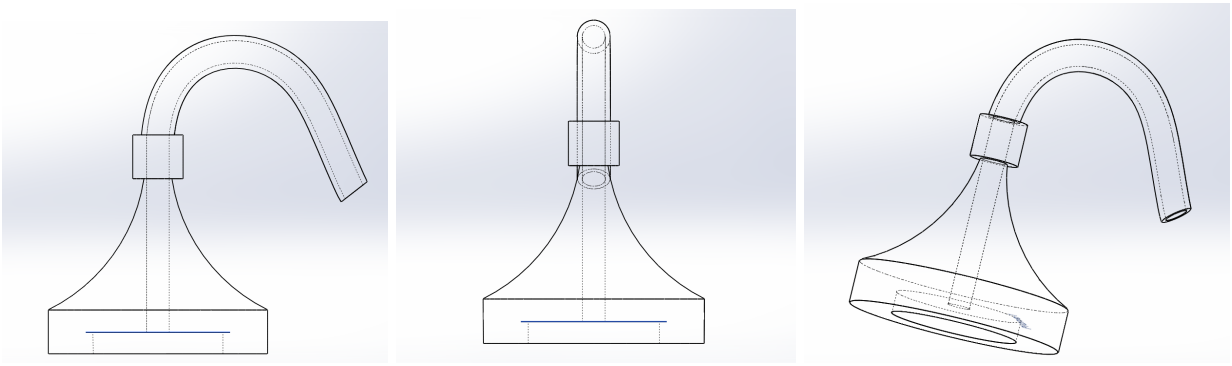
Hence, the focus of the design was on the external bumper and the insertion site; a device that would stabilize the G-tube from the insertion site. Existing solutions that try to address the problem provided guidelines when designing the stabilizer. As explained in the background section, one of the already existing solutions that attempts to address this issue is the break-way PEG tube. The break-way PEG tube adds another connection to the G-tube itself so that the connection will break instead of the tube at the insertion site when a large external force is applied [9]. Another important feature of the break-way PEG tube is that it has a sliding mechanism that allows the physician performing the procedure to adjust how much force it will take to remove the G-tube when it is pulled on. However, this mechanism does not work if the G-tube is pulled on directly at the insertion site. This flaw in the break-way PEG tube is what inspired the design of the G-tube stabilizer. In fact, a device that would create a pinching mechanism to prevent leakage of gastric fluid and reinforce the tube to the insertion site was the initial ideal design. However, our design evolved and took a new approach at solving the problem.

For the design, research was performed to see how each design criteria could be fulfilled. Different materials and shapes were considered to determine what would potentially work best for the design of the stabilizer and how to mount the device onto the skin. According to the Milwaukee Children's Hospital, a technique often used by nurses to stabilize the tube is to utilize a tension loop as shown below [19].



[19]

During the design process, the G-tube stabilizer was designed to mimic a tensile loop without using the medical tape and pins normally used. In the depictions below, the tube exiting from the stabilizer is curved in a similar angle to that of a tension loop.



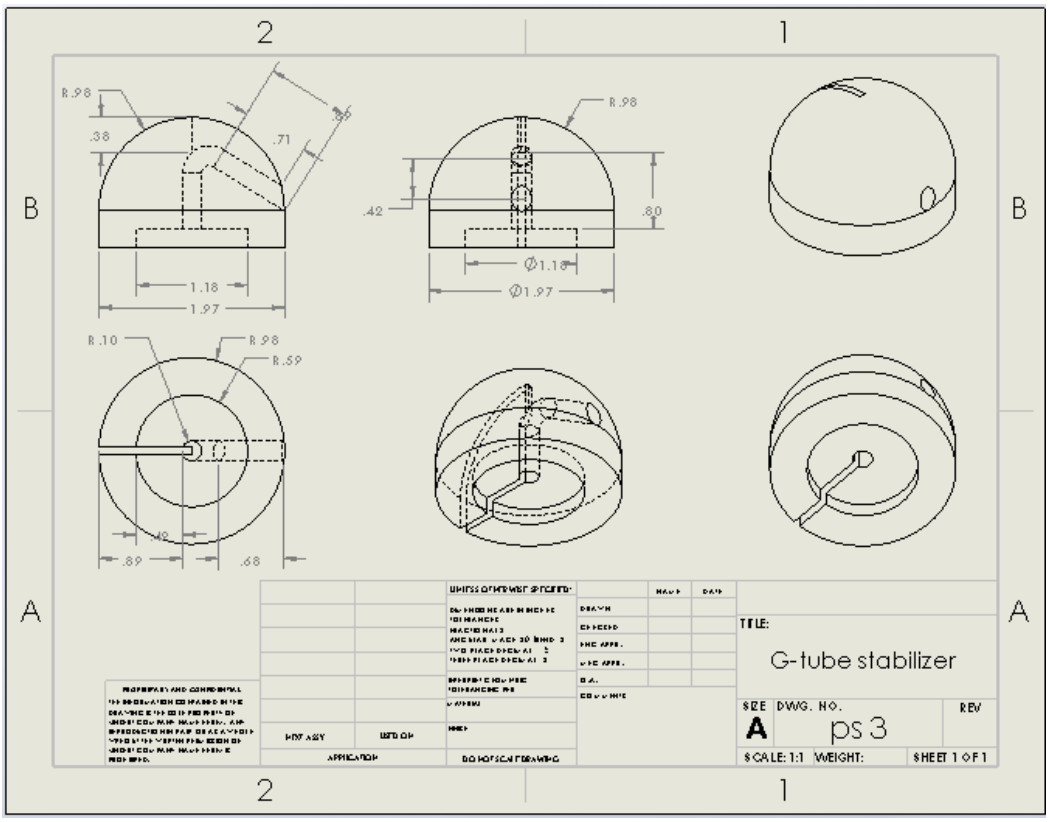
The early designs were all drawn up on the CAD software Solidworks. This first design was also supposed to fit over the G-tube (the external portion), which is something that was carried through each iteration of the design. The first design was made for a G-tube with a tube diameter of 16 Fr. (french size), which converts to 5.33 mm. The diameter of the bumper varied from G-tube to G-tube, so the diameter of the part that fits over the bumper was made 1.18 cm in diameter, which was an approximation that was made until concrete dimensions were obtained.

However, a flaw found with this design was that it was too bulky and was not necessarily convenient to wear each day. There were also spots on the design where the patient had the ability to get ahold of something and pull with enough force and cause some damage. Since the stabilizer needed to be more compact, the design was modified to have fewer edges and bends. The shape that minimizes both edges and bends is a sphere, so for our purposes a hemisphere was the shape chosen in the end. The problem, however, was to incorporate the tension loop into the design. This problem was solved by creating a pathway through the solid hemisphere that resembles a U bend and the beginning of the bend was moved closer to the bumper itself (0.8 mm from the bumper).

However, there were new problems with placing the tube through the bend pathway as it could prove to be troubling for the nurse or physician whose job it is to place the stabilizer over the G-tube. Hence, during the third iteration, a small slot was designed on the opposite side of where the pathway for the tube ends. This slot has a dimension of 2 mm, and its purpose is to allow the nurse or physician to snap this device onto the G-tube if the stabilizer is made out of a material with high elasticity like rubber. Another viable option was to have some kind of joint at the opening for the tube and have bolts with threads on opposite ends, so the design can be fitted over the G-tube and tightened. The first option was chosen to allow to reduce complexity in the design.

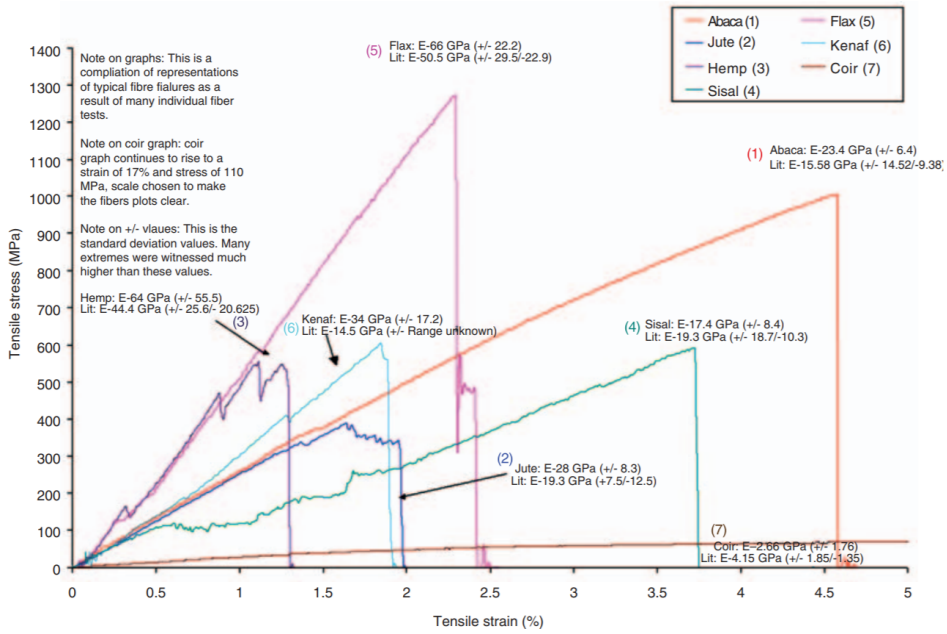
For mounting this device onto the skin of the person, there was a need for an adhesive that is biocompatible, but also strong in terms of adhesive strength. A good candidate for the adhesive that can be used on the insertion site is Pros-Aide adhesive from ADMTronics, which is an adhesive used for securing on professional medical prosthetics [20]. As for the stabilizer

itself, the material used had to be something that would be elastic and able to endure a significant amount of mechanical stress. According to research on biomaterials, a material that was found to be a good fit was engineered cellulose fibers, which has both the tensile strength needed for this project as well as the elasticity. Engineered cellulose fibers has been shown to be stronger than the spider webs, which were once taught to be the toughest material in nature [17].



To make sure that our components, as well as the design itself, exceed industry standards there will be several tests performed on the stabilizer to discover as well as fix any problems that arise from the materials or the stabilizer. To start off, a stress test on different points of the stabilizer would be required to determine if there are any weak points in the stabilizer itself. This will be done by applying forces equivalent to realistic external forces. Since the average weight of an American male is 197.6 pounds (89.82 kg) the stabilizer should be able to withstand a

weight of this magnitude in the case that the patient's entire weight is put on the stabilizer, for example if the patient falls on his or her anterior/ventral side [21]. If the patient were to fall like this, the stabilizer should be able to retain its structure and not damage the G-tube on the inside either as it could be the first point of contact with the ground since it is an attachment that slightly protrudes outwards. If the stabilizer were to break while the patient was falling down, pieces of the device could pierce into the patient. While this may seem like a stretch, irritation is quite common with G-tubes and a pierce of the site could lead to acidic stomach contents leaking and cause an infection that is quite difficult to treat [13]. If the G-tube were to dislocate in the process of the device breaking, the patient would require surgery once again to fix any of the complications. This test would be performed using many types of cellulose fibers to determine which can endure the highest tensile stress while also taking into account the tensile strain. The cellulose fibers themselves come from nature but engineering properties are applied to enhance the already high tensile stress that the material can endure.



[22]

As shown in the comparative stress-strain plot above, the Elastic Modulus values of various engineered cellulose fibers were compared. After this testing, the material that was decided on was a flax fiber modified using engineering principles. This was the material picked because it had the highest Elastic Modulus and due to its high tensile stress, paired alongside its relatively high tensile strain.

In addition to the material of the G-tube stabilizer, the comfort of the design requires testing. This is done through having patients use the stabilizer for an extended period of time and collecting reviews from them about the design, the size, and any improvements that can be made to make sure that the patient is as comfortable as possible. To be able to conduct this study an IDE approval is necessary from the FDA [23]. At the beginning of the study, the stabilizer will be used after a couple of weeks to make sure that the patient has no adverse reaction to the initial surgery. After the stabilizer is put into place, the patients will then be carefully monitored to

make sure that the adhesive or any other biomaterials used in the stabilizer do not cause any skin irritation or have any other harmful effects on the patients. Once it is determined that the material does not cause irritation to the patients, they will be told to go through their days as per usual since one focal point of the design is to have little to no impact on mobility as well as daily tasks. At the end of each day, the patients will be asked to write an anonymous review on how the day went with the stabilizer in order to prevent any bias by having their name associated with the review. They will be asked to describe their comfort level, the actions they performed throughout the day, any major concerns about the G-tube stabilizer and lastly if the stabilizer stopped them from performing any tasks that they normally would have been able to perform. This study will carry on through multiple weeks to allow the patients to get acclimated to the stabilizer, as well as allow the researchers to gain a wide range of feedback. After multiple trials, the introduction of the device will be moved forward to almost immediately after the initial surgery to allow the patients to acclimate to the device as quickly as possible since this will result in a decrease in the number of complications that occur with a G-tube. A decrease in the number of complications will directly result in a decrease in the overall cost of getting a G-tube, since complications after the initial procedure account for 33.4% of the annual cost of getting a G-tube as mentioned previously in the background. These will be considered the pilot and traditional feasibility stages of the study [24]. They will result in enough feedback which will allow any major points or problems with the device to be resolved, and allow for the pivotal stage in the study. Once this is completed any final adjustments will be made and after gaining FDA approval, the G-tube stabilizer will be released to the market and postmarket studies will start to make sure that the stabilizer is in the best state possible.

Medical Devices		
Stage	**Subjects**	**Purpose**
Pilot / Early Feasibility / First-in-Human	10 - 30	• Small study to collect preliminary safety & device performance data in humans. • Guides device modifications &/or future study design.
Traditional Feasibility	20 - 30	• Assess safety & efficacy of the near-final or final device design in patients. • Guides the design of the pivotal study.
Pivotal	100's	• Large study to confirm clinical efficacy, safety & risks. • Statistically driven.
Post-Market	1000's	• Monitor long term effectiveness, safety & usage in the general population.

[24]

Summary

Our goal was to create a device that could stabilize a G-tube. To accomplish this, three design criteria were established and applied to several different models; previous iterations included a flexible neck, a base with the G-tube protruding directly outward, and different biomaterials. However, these ideas did not address all our design criteria, which aimed to strengthen the area around the insertion site and make the more mobile and comfortable on the whole for the patient. and were either integrated or replaced, culminating in the current design model. This culminated in the current design model, which includes several aspects chosen to address the different design criteria we chose: a compact hub housing the tension loop and

bumper, rounded to maximize volume while minimizing surface area; a tension loop, to increase the mechanical load it can bear; and biomaterials and adhesives, to counteract any negative reactions associated with prolonged skin contact. However, this model can still definitely can be improved on certain fronts. One thing we did not specifically look at was the strength of the G-tube itself, which can become broken or worn down. G-tubes are typically replaced after about 8 to 12 months to address this, but a thin, lightweight, protective sheath could be added to our design to provide protection along the entire length of the tubing [25]. An additional idea we had, as a way to counteract skin irritation and maintain sanitation, was to have a stretchy, adhesive, and waterproof patch—similar to kinesiology tape—affixing the stabilizer to the patient that could be lifted off to clean the skin underneath, thus counteracting normal concerns associated with more permanent taping manners, and replaced if need be. Utilizing the iterative design model, we would test this method against the current design, which has the stabilizer directly adhered to the skin, in order to determine which yields more favorable results in terms of both comfort and mobility. For a future, market-ready design, we would like to address more such complications associated with G-tubes, as well as ensure that we fall within FDA constraints.

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