Design of a Dressing for Gastrostomy Buttons in Pediatric Population

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I. Hypotheses and Specific Aims

Gastrostomy tube (G-tube) complications, such as granulation tissue formation and tube dislodgements, are frequent causes of emergency department visits. We have developed G-tube dressing designs using commercially available materials and products to decrease the risk of G-tube related complications. Our aim in this study is to pilot the novel G-tube dressings in patients with pre-existing G-tubes to gain parental feedback on device designs, ease of use and G-tube stability in preparation for a final design and trial.

II. Background and Significance:

The insertion of gastrostomy tubes (G-tubes) and buttons is common, with over 250,000 devices placed each year [1]. At Children's Hospital Colorado (CHCO) we place/replace about 1,500 G-tubes per year. Initial surgical placement of a G-tube is performed open, percutaneously, or with laparoscopic assistance. Unfortunately, all of these methods are associated with minor but troublesome postoperative complications with up to 3.9% of children undergoing G-tube placement estimated to have an emergency department visit within 30 days of discharge due to G-tube problems [2]. Maintaining and securing these devices to minimize granulation tissue formation while the tract matures, controlling leakage, appropriately up-sizing the length of the device as the child gains weight, and dealing with dislodged devices can be extremely challenging for patients, caregivers, and healthcare providers alike [3].

The most common G-tube related complications are granulation tissue formation and tube dislodgement, occurring in up to 59% and 28% of patients, respectively [4]. Granulation tissue is usually treated in an office setting with silver nitrate, but sometimes requires surgical excision if refractory to medical treatment. Early tube dislodgement causes significant morbidity and cost, requiring replacement of the tube under radiologic guidance or even surgery under general anesthesia if the tract is relatively new. Drainage around the tube is also common, with an incidence of up to 31% of patients, and often leads to peristomal skin irritation and breakdown [4]. The early fistula tract is composed of fragile granulation tissue supported by thin collagen fibers, and ulceration of this layer can disrupt the tract [5]. It is important, therefore, to keep the G-tube stable within the tract to ensure proper formation of the fistula [5]. Furthermore, the patient population that requires G-tube placement is often under-nourished, which can impair wound healing and lead to tract complications [6]. While retrospective studies have identified

risk factors for G-tube complications such as congenital heart disease, chronic respiratory failure, metabolic diseases and insurance status [4, 7], there have been no prospective trials to examine methods to secure G-tubes in an effort to prevent the types of complications described above.

We are collaborating with a group of graduate mechanical engineering students at the University of Colorado Boulder to develop a new G-tube dressing. While the overall goal of our novel G-tube dressing method is to decrease the risk of G-tube related complications, this initial study aims to collect preliminary data on the design, ease of use and overall impressions from parents on the designs.

III. **Preliminary Studies/Progress Report:**

A literature review on G-tube securement methods or dressings yielded very little information. Use of hydrofiber dressings has been shown to help heal peristomal ulcers in adult patients [5]. The author reported that its absorbent property in addition to providing moisture and minimal adherence to the wounds likely optimized wound healing. Traditionally, gauze is used to protect the skin around the G-tube and to secure the G-tube button to minimize movement. Gauze dressings do not, however, prevent skin irritation and may not be optimal to heal those that occur [5].

While there is lack of scientific data to support an optimal position for the G-tube, guidelines typically suggest that the external portion of the device should be 1-2mm above the skin surface to avoid excess tube movement and prevent the device from being too tight against the skin [8].

In our 30 years of surgical practice we have noticed, as have others [3], that properly sized G-tubes that are well positioned, secure and are not tugged upon, and do not torque or rub up and down in the tract (causing friction), tend to have fewer complications. We have also observed that if caregivers can be taught how to place a tic-tac-toe type dressing to secure the G-button, and then further secure the device by taping down the extension tubing with two or three underlying 2x2 gauze sponges to provide an additional point of fixation, that these devices do not move. The tract tends to mature with fewer complications (i.e. granulation tissue formation, leakage, local skin infection) and the quality of life for children with these devices is improved, the parents are happier and less care is required to manage these devices. Current typical dressing is a tic-tac-toe type dressing consisting of 2x2 gauze and tape.

IV. Research Methods

A. Outcome Measure(s):

Two questionnaires will be given to the subjects, and/or their caregivers. One will be given prior to first use of the two dressings (intervention) and one after the intervention. In the initial questionnaire we will ask questions about their current issues with G-tubes, current dressing method, the perceived benefits and disadvantages of the current dressing and overall satisfaction level. In the follow up questionnaire we will ask their overall satisfaction using the two types of dressings, the perceived benefits and disadvantages of using them, reactions or adverse events, and whether they would like to use them in the future. We will also review patient charts to look for any emergency department or office visits pertaining to issues with the G-tubes of the study subjects. We will also take photographs for objective assessment of peristomal conditions.

B. Description of Population to be Enrolled:

Inclusion criteria are patients aged 31 days to 25 years old with a pre-existing a G-tube and patients presenting to the G-tube or surgery clinic for G-tube replacement at CHCO, Aurora, CO. Patients admitted to the hospital with a pre-existing G-tube for reasons unrelated to the G-tube will be eligible for the study if they have issues with the G-tube site.

C. Study Design and Research Methods

The definition of a dressing by FDA which is, Class 1 - 510(k) exempt, is as following: A medical adhesive tape or adhesive bandage is a device intended for medical purposes that consists of a strip of fabric material or plastic, coated on one side with an adhesive, and may include a pad of surgical dressing without a disinfectant. The device is used to cover and protect wounds, to hold together the skin edges of a wound, to support an injured part of the body, or to secure objects to the skin [9].

In keeping with this definition and based on the results of our initial pilot study conducted under the same study protocol, a final design was developed. It was made to accommodate AMT MiniONE® Balloon Button, which is the standard gastrostomy button used at CHCO. Detailed information on the design of the dressing is provided in the Appendix.

This is a survey study using questionnaires before and after the use of the novel G-tube dressings. Eligible patients will be identified by a nurse practitioner or attending surgeon. The researcher will obtain consent from the patient or their parents/legal guardian. We will ask a series of questions regarding their current experience dressing and maintaining G-tube stomas. We aim to enroll up to 30 subjects, and approximately five of the new G-tube dressing will be provided to the patient or parent. Caregivers will be educated on the use of the dressing and will be given a number to call should they have any questions or concerns. Once the patient is enrolled and provided with dressings, we will perform a follow up telephone interview at one week to evaluate their experience and ensure they did not experience any adverse events. They will be given a second questionnaire to collect feedback on the dressings after two weeks either in person or over the telephone. They will be asked to provide feedback on advantages and disadvantages of each type and report adverse events. For inpatients, we will obtain opinions from parents, patients, nurses and doctors. Photographs will be obtained at each outpatient visit or during the inpatient period for objective comparison.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

There is a small risk of developing an allergic reaction to the dressing. We do not, however, expect the risk to be any higher than commercially available dressings. Some caregivers may find it difficult to apply the dressings, but we believe these dressings are easy to apply, and they will be given a number to call if they have questions. We will also provide them with a manual on how to use the dressings. If they continue to struggle, they can use their previous standard dressing.

There is a potential risk of patient information being accidentally seen by someone who is not on the research protocol. The risk is minimal. All protected information that is accessed and obtained as part of this protocol will be kept on a CHCO encrypted computer and server. Computer and server access at CHCO is encrypted and protected

with a password. The computers are kept in a badge access only area of the hospital (the administrative pavilion). Furthermore, protected health information will be kept separate from other research information. Once data analysis is complete, all data related to individual protected health information will be destroyed.

E. Potential Scientific Problems:

Since this study is not comparing to a control group, it is difficult to make statistical inference based on reports from the users. Also, the results may be biased because they are subjective assessments by the users, who may be accustomed to other types of dressings. These dressings are, however, easy to learn and use. Also, photographs will be used for objective assessment of peristomal wounds if there are any. Our study is primarily focused on evaluating parental feedback on the G-tube dressing methods and overall satisfaction, and then focus on development of the most optimal G-tube dressing.

F. Data Analysis Plan:

This is a qualitative research study. We will compare feedback from patients and parents who trial the new G-tube dressings, to traditional dressings. Their satisfaction will be scored using a scale covering various aspects of the dressings.

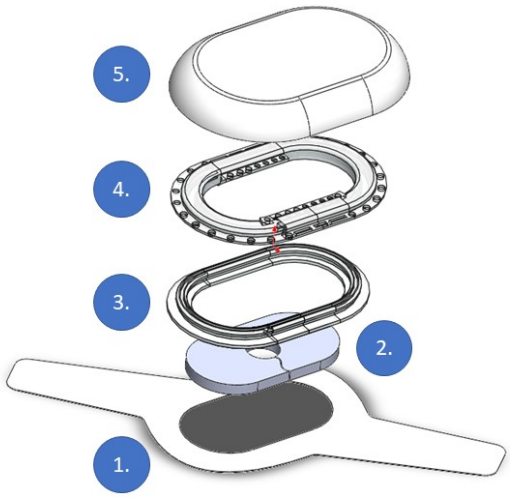
G. Summarize Knowledge to be Gained:

We will learn the overall experience of using these novel dressings from patients' and parents' perspectives. We will learn difficulties they faced as well as perceived benefits. This information will guide further development of a single best dressing method which will hopefully reduce the incidence of G-tube complications.

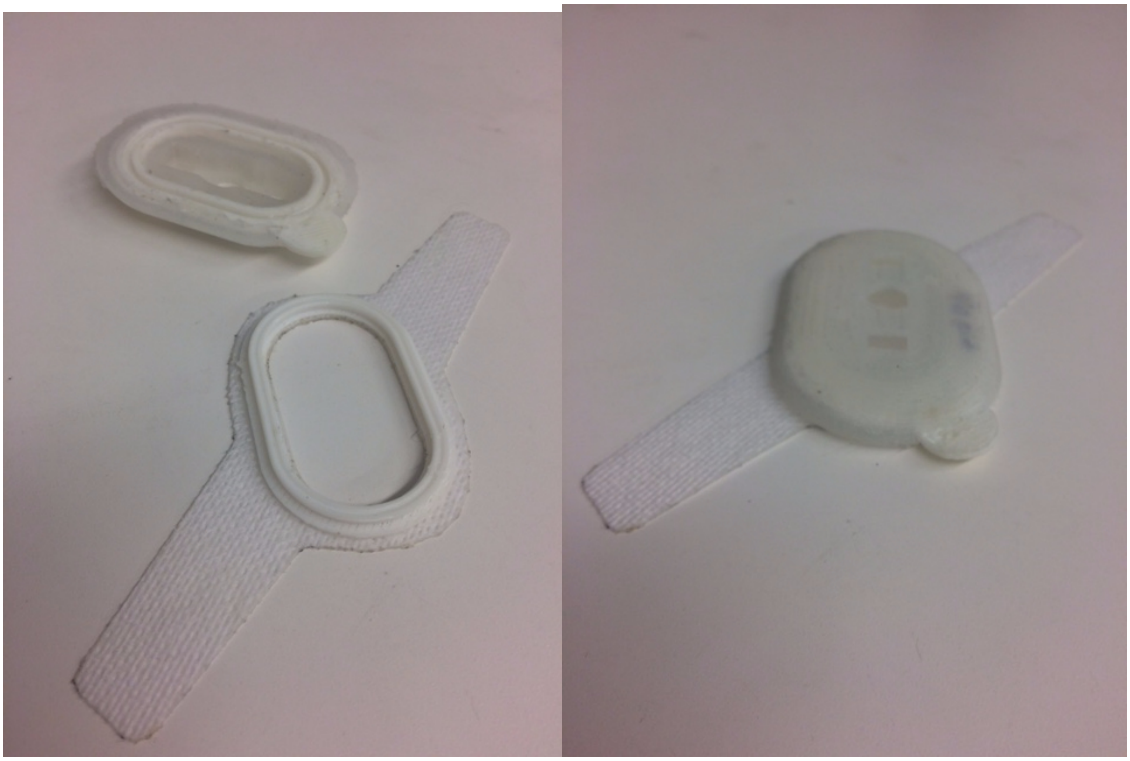
H. References:

1. Goldberg, E., et al., *Gastrostomy tubes: facts, fallacies, fistulas, and false tracts.* Gastroenterol Nurs, 2005. **28**(6): p. 485-93; quiz 493-4.
2. Goldin, A.B., et al., *Emergency Department Visits and Readmissions among Children after Gastrostomy Tube Placement.* J Pediatr, 2016. **174**: p. 139-145 e2.
3. McGrath, A., *Clinical review: Overcoming the challenge of over granulation.* Wounds, 2011. **7**(1): p. 42-9.
4. Naiditch, J.A., T. Lautz, and K.A. Barsness, *Postoperative complications in children undergoing gastrostomy tube placement.* J Laparoendosc Adv Surg Tech A, 2010. **20**(9): p. 781-5.
5. Owada, K., *Use of a hydrofiber dressing to manage PEG sites.* Adv Skin Wound Care, 2005. **18**(4): p. 183-4, 186, 188-9.
6. Singer, P., *Nutritional care to prevent and heal pressure ulcers.* Isr Med Assoc J, 2002. **4**(9): p. 713-6.
7. Arnbjornsson, E., L.T. Larsson, and T. Lindhagen, *Complications of laparoscopy-aided gastrostomies in pediatric practice.* J Pediatr Surg, 1999. **34**(12): p. 1843-6.
8. Best, C., *The correct positioning and role of an external fixation device on a PEG.* Nurs Times, 2004. **100**(18): p. 50-1.
9. FDA - U.S. Food and Drug Administration. *CFR - Code of Federal Regulations Title 21*. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=880.5240.

Appendix



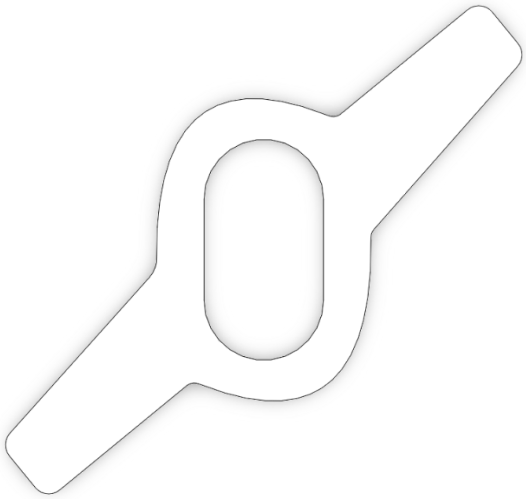
1. Lohmann DuploMed WM81170 (XP16.4) Adhesive with Non-Woven, Breathable Backing
2. DrawTex Absorbent
3. NinjaFlex 85A TPU 3D Printable Plastic (lower male side)
4. NinjaFlex 85A TPU 3D Printable Plastic (upper female side)
5. Smooth On Dragon Skin 10 Silicone



Details of Each Layer:

1. **Lohmann DuploMed WM81170 (XP16.4) Adhesive**

   This material is similar to what was used in the last clinical trial, except this adhesive is slightly stickier (5-7 day instead of 2-4 day). The top layer is the same material (non-woven, breathable mesh). This material will be laser cut on CU Boulder campus; the ergonomic shape will allow the device to best adhere around curved surfaces without any "tenting" or premature peeling. Design was influenced by the traditional rectangular band-aid shape.

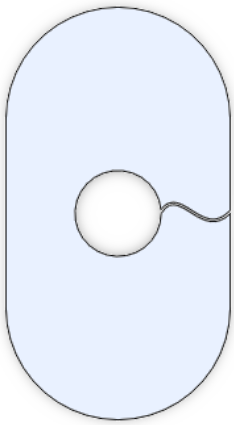


2. **DrawTex Absorbent**

   This material has not changed since the last clinical trial. We did not receive any negative feedback on this material last trial, so it will be used again. However, the material will be cut so that the surface area reaches within 1-2 mm of the stoma to allow any fluid to be wicked away from the skin. The prior design had a clearance of about 15mm, which may have allowed stoma fluid to pool up before it was absorbed, resulting in prolonged healing.

   Different patients have varying stoma leakage rates, so this key component will allow each patient to change the absorbent without having to dispose of the entire device (silicone and adhesive). Extra absorbent pieces will be provided with the kit.

DrawTex Absorbent material is designed and manufactured by the medical company, SteadMed. This will be cut into oval shapes that will fit onto the device. Denver Rubber Company will be knife and die cutting the material into the shapes; they have cut medical grade materials before, so cleanliness standards will be in place and will be checked by numerous quality assurance teams.



3/4. NinjaFlex 85A TPU 3D Printable Plastic (upper female and lower male sides)

This material is similar to what was used in the last clinical trial, except this plastic is softer, bendable, and conforms to the patient with ease. This material is also 3D printed using a "Lulzbot Mini" 3D printer. The datasheet for this NinjaFlex filament can be seen in the attached package. This material will be used to mate the removable silicone feeding pod to the skin adhesive.

As the silicon cover is curing, the female side of the plastic piece will be pressed in to form a mechanical bond with the silicon cover. The lower male side will be glued to the Lohmann adhesive. This is an oval shaped snap fit ring that was derived from the Ostomy Bag connection. Due to the unique shape, manufacturing method, and locking geometry, no patents were violated for this design.

5. Smooth On Dragon Skin 10 Silicone

This silicone material has a hardness rating of Shore 10A, which is equivalent to that of a rubber band. This material will be cast into the ergonomic oval shape seen in the image below. This material is soft enough to conform to the patient's skin and soft enough to absorb minor external forces. It is also durable enough to create a protective shell and casing around the G-Button and prevent any large movements. The Ninjaflex 3D printer female side will be pressed into the silicon during the molding process, so the plastic will be countersunk into the silicon material. As seen in the image below, there is adequate space for the G-Button underneath the cap. If an impact contacts this outer silicon layer, there is approximately 4-5 mm of space in the rectangular region that will protect the G-Button from significant movement.

This Smooth-On silicone material has a skin safe certification, as tested by ISO 10993; the certification material can be seen in the attached document.