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Design and experimental evaluation of an anti-leak feeding tube

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ABSTRACT

Background: Enteral feeding via gastrostomy or jejunostomy tube is often required to adequately treat patients with cancer, gastrointestinal disorders, and cerebral vascular accident. Although sufficient to provide adequate caloric intake, the present design of a gastrostomy tube is inadequate. Leakage of gastric contents onto the skin is commonplace prompting emergency department visits and skin damage that requires costly nonoperative and operative intervention. We introduce a new gastrostomy tube design and prototype that inhibits leakage by using an adjustable external retaining member, which compresses against the feeding tube shaft thereby preventing dynamic friction.

Methods: A conventional external retaining member of a 22 French gastrostomy tube was tested against a novel compression-fitting external retaining member. Each gastrostomy tube was clamped to a scale and the external retaining member moved to slide along the tubing at a constant rate, and the applied frictional force was recorded. Thirty repetitions were performed.

Results: The experimental prototype generated $\times 2.5$–3 the frictional force preventing tube excursion. Mean (standard deviation) forces were 18 (3) *versus* 46 (4) ounces ($n = 10$, $P = 2.57E\text{-}13$) and 15 (4) *versus* 48 (4) ounces ($n = 10$, $P = 1.90E\text{-}13$) for conventional and experimental designs, respectively. Simulated *in situ* environment mean forces were 19 (3) *versus* 39 (3) ounces ($n = 10$, $P = 3.30E\text{-}11$) for conventional and experimental designs, respectively.

Conclusions: The experimental design created an increased static frictional force that inhibited the movement of the external retaining member against the gastrostomy tube. Clinical implementation is the next step to evaluate for reduced feeding tube morbidity and healthcare expenses by preventing leakage of gastric contents.

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1. Introduction

Gastric and small intestine tube feeding is a standard method in supporting nutritional needs for patients unable to ingest food. This occurs in a variety of clinical conditions such as patients diagnosed with traumatic brain injury, cerebral vascular accident, cancer, and certain gastrointestinal disorders. In the United States of America alone, an estimated 300,000 initial or replacement percutaneous endoscopic gastrostomies (PEGs) are performed annually [1].

Maintenance and care of a gastrostomy or jejunostomy feeding tube and the associated stoma site is labor intensive and generates significant healthcare expenditures. Stoma site leakage around the feeding tube is a recognized complaint in up to 78% of PEG patients [2]. Improper feeding tube and stoma care can result in costly emergency department visits, hospital admissions, and morbidity.

Different methods exist for placing enteral feeding tubes, including surgical, endoscopic, and radiologic methods. If placed into the stomach, all three methods result in the gastric wall being juxtaposed to the abdominal wall through a tunneled tract. As an alternative to open surgery, a common method for insertion of a gastrostomy tube is the PEG placement [3–5].

Despite the indication, the size required, or the vendor, gastrostomy feeding tubes are manufactured commonly from biocompatible polymers (silicone, polyurethane) and have an internal retention member (e.g., a gastric balloon or bumper) and an external retaining member (e.g., flange). To prevent leakage of gastric contents from the gastric lumen around the tube and onto the skin, the internal retention member must be against the gastric mucosa occluding the fistula. In the immediate postplacement period, gastric leakage is uncommon for two reasons. The edema from tissue injury at the placement site causes an initially snug fit between the internal retention member and external retaining member. Second, the static coefficient of friction, μ, generated by the inner smooth surface of the external retaining member and external smooth polymer surface of the gastrostomy tube is optimized when initially placed because the materials are new. Thus, the combination of postoperative swelling and the optimal frictional force between the device components typically prevents immediate postoperative leakage. It is also common practice during the gastrostomy tube procedure to place a silk suture tightly around the neck portion of an external retaining member to increase the frictional force against the gastric tube because it is widely recognized that, with time, the static friction between the tube shaft and external retaining member will inevitably be overcome by dynamic friction. As swelling reduces and the tube materials wear, the gastrostomy balloon is able to move away from the gastric wall allowing gastric contents to leak out around the gastrostomy tube and onto the skin (Fig. 1). Emergency department visits for immediate treatment are often prompted when this occurs.

In view of the current problems, a compelling need exists for a gastric feeding tube device that can be easily adjusted to accommodate for tissue change around both fistula and stoma. A second-generation device would have an ergonomic design that is comfortable to wear, easy to place, and is used no differently than conventional devices. Furthermore, such a gastrostomy feeding tube would be adjustable by a healthcare provider or patient without surgical intervention.

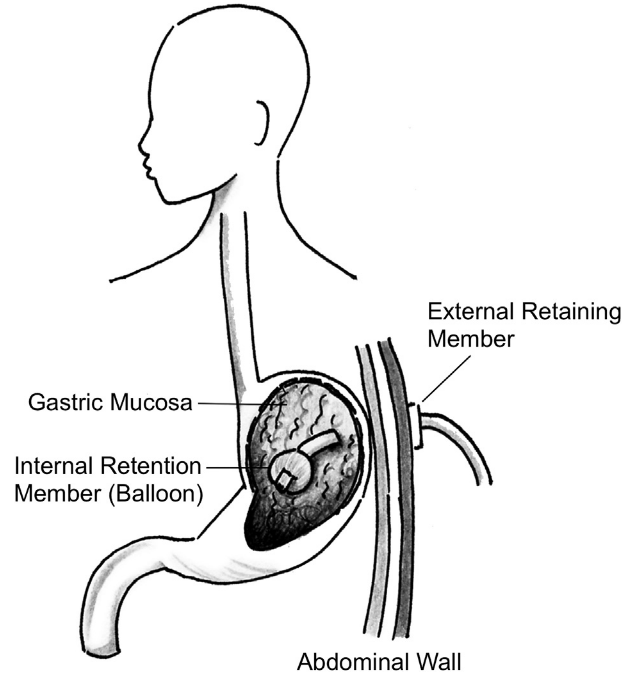

Fig. 1 – A coronal section of the peritoneal cavity demonstrating a gastrostomy tube internal retention member not juxtaposed to the gastric mucosa allowing leakage of gastric contents.

In this study, we introduce a new gastrostomy tube design, which inhibits leakage by using an adjustable external retaining member that compresses against the feeding tube shaft, and, thereby overcomes dynamic friction leading to leakage of gastric contents.

2. Materials and methods

2.1. *Experimental external retaining member design and material*

The external retaining member design is a compression fitting that exerts a radial force on the feeding tube as the compression nut is tightened (Fig. 2). The initial and tested design is a rigid material as compared with a conventional pliable silicone. 3D printing allows cost-effective prototyping. However, it is limited to materials that are rigid. Second, to demonstrate function and efficacy, a rigid material is initially optimal so that the compression nut can easily engage the threads and compress the tabs against the wall of the tubing offering an optimal frictional force.

The prototype material for the experimental external retaining member is DurusWhite, a polypropylene-like material commonly implemented for 3D printing (Stratasys Ltd, Eden Prairie, MN, North America) [6]. The external retaining