Pediatric Gastrostomy Button with Leakage Reducing Secondary Balloon
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Introduction

Eighty percent of pediatric patients with delayed development have some form of feeding disorder. Severe consequences result, such as growth retardation and even death.1 To combat this problem, gastrostomy buttons (silicone feeding devices) are implanted in the abdominal wall. The gastrostomy button brings nutritional formula and medication directly into the stomach of patients who have neurological, metabolic, swallowing, or general feeding disorders. Gastrostomy buttons can be replaced at home rather than in a clinical setting, and have an incremental range of diameter (12-24 Fr) and length (0.8-6.5cm) sizes. They often utilize a flexible silicone balloon that receives distilled water via the balloon port, anchoring the button in place. Leakage is a major complication that can result from a breakage or deflation of the balloon, a round balloon shape, and/or improper fit. When the balloon breaks and deflates, it may not block gastric contents from traveling up the stoma to the skin. Additionally, the tube may become dislodged and require immediate replacement. A balloon that is not flat may also fail to block the stoma and induce leakage. As a result of limited sizing, an excessively long tube can result in a loose-fitting balloon and leakage; meanwhile, an overly narrow girth can yield excess stoma space, allowing leakage fluid to reach the skin. Leakage has many negative consequences including skin irritation or infection, discomfort from necessary replacement, and financial cost for replacements and infection medication.

Current Technology Analysis

MIC-KETY*: • Round, breakable silicone balloon • Lasts ~3 months with no leakage • Costs ~$130 per set • Easy home replacement AMT Mini ONE®: • Flat, leakage-reducing balloon • Same cost, longevity, and replacement ease as MIC-KETY*

Capsule Non-Balloonic Mini ONE®3 • Insertion: Top pull tab tears degradable capsule that releases a silicone anchor • Removal: Requires extra apparatus; painful • Can last several years

Need Statement

A way to prevent tube leakage in pediatric buttons to maximize patient comfort and device longevity.

Need Specifications

Must Have: • Reduced leakage (<1 mL per day) • Device longevity (at least 3 months) • Patient Comfort (determined by consumer survey)

Nice to Have: • Low profile & patient mobility (<15mm skin protrusion)

Concept Analysis


Conclusion

The goal of our new tube was to reduce incidents of leakage caused by inadequate tube girth fit in the stoma. The new design features a secondary balloon around the tube of the gastrostomy button, allowing for a better stoma fit and reducing the possibility of fluid leakage. In the future, we would develop a working model of our device that patients can actually feed through, a button that incorporates the major aspects of our three top-ranked concepts, and a balloon material that does not break as frequently as the current technology.

References


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