In vivo evaluation of an actuated mechanical device for patency restoration of clogged gastrostomy-jejunostomy feeding tubes

Paula Mulhall, RPN, RGN, RN,1,2 Abigail M. DeLellis,1,2 Olga M. Ocon-Grove, Ph.D.,1,2 and Maureen L. Mulvihill, Ph.D.1,2
1Actuated Medical, Inc., 2TubeClear System, 320 Rolling Ridge Dr., Bellefonte, PA 16823

Abstract

Introduction: External nutrition (EN) is provided for patients who have a functioning lower gastrointestinal tract but are unable to orally ingest nutrients and medications and are at risk of malnutrition. Conditions necessitating long-term EN can include prematurity, congenital disorders, neural dysfunctions, failure to thrive, cancer treatment, cyclic fibrosis, neurological disorders, congenital heart disease, and congenital metabolic abnormalities. When long-term enteral access is needed, percutaneous gastrostomy (GJ), jejunctomy (J), or gastrostomy-jejunostomy (GJ) feeding tubes (Tubes) are often surgically placed. GJ and J Tubes are indicated when gastric complications are present and when transporting gastric content is desired. In the US, there are over 400,000 home enteral nutrition (HEN) patients and >200,000 long-term Tubes placed annually, resulting in 12,000 long-term GJ/J Tubes. Due to the small bore, considerable length, and convoluted geometries, occlusion rates of GJ and J Tubes have been cited as high as 35%. Clinical staff will attempt to unclog Tubes using standard bedside techniques including warm water flushes or chemical enzymes. However, these practices are time-consuming, often unsuccessful, and require Tube replacement. For HEN patients, a clogged Tube, in which patency cannot be restored, may require the patient to be transported to a medical facility for continued Tube declogging or replacement. Our organization developed an Actuated Device that uses mechanical motion to unclog in-dwelling Tubes.

Study Purpose

Objectives were to explore home use of the Actuated Mechanical Device (Device) to maintain Tube patency for a consumer with a history of repeated Tube clogging.

Introduction

Tubes are used to deliver enteral nutrition therapy to patients unable to safely ingest nutrition, hydration, or medications orally. Tube fed patients are at elevated risk of malnutrition and dehydration.1 Percutaneous gastrostomy (GJ), jejunctomy (J), or gastrostomy-jejunostomy (GJ) feeding tubes are often surgically placed for long-term enteral access. There are over 400,000 home enteral nutrition (HEN) patients in the US.2

Methods: 3-Month in-home Evaluation

Participant Details:
- Single Participant (66 yr old female)
- 18 FR, 30 cm GJ Tube (Avanos Medical, Inc., Alpharetta, GA)
- Overnight feeds (85 mL/hr 1.5 Cal)
- Months prior to conducting evaluation, participant presented with:
  - Multiple clogging events, almost weekly
  - Requiring on average 2-3 hours to resolve, one event taking 10 hours
  - Another event requiring a GJ Tube replacement.

Evaluation:
- N=19 Clogging Events
  - For each clog, standard declogging strategies initially attempted.
  - Following unsuccessful (0/19) standard declogging strategy attempts, Device use was attempted.
  - The Operator was trained to use the Device.

Results

Discussion/Conclusion

The Device was significantly more successful (100%) at resolving clogs compared to standard declogging strategies (0%) in the home.

- No required Tube replacements
- Avoided participant transportation from home to a medical facility and readmission for Tube replacements
- Further evaluations with a larger sample size may provide additional evidence that the Device can be used successfully by HEN patients as an alternative method of restoring Tube patency.

- For the thousands of HEN consumers, having alternatives available to alleviate Tube clogging issues can be significantly valuable to their quality and continuance of care in the home.

- Ability to restore Tube patency without hours of effort described as “life changing.”

I feel more in charge of my healthcare now that I have the Device at home, and this allows me to focus on the rest of my day.

I am thinking about taking a trip to the beach to visit my family now that I have the Device, and I am less concerned about my Tube clogging.

References, Acknowledgements, Disclosures


Development work was sponsored by the National Science Foundation (NSF) Small Business Innovation Research (SBIR) grant IIP-0923881 and National Institutes of Health’s Institute of Child Health & Human Development (NIH-NICHD) SBIR grant HD065056. The content is solely the responsibility of the authors and does not necessarily represent the official views of NSF or NIH.

Pat. actuattedmedical.com/p

Disclosure: All authors employed by Actuated Medical, Inc.