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

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Feeding Tube Clearing System

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]
[1]Actuated Medical, Inc., [2]TubeClear System, 320 Rolling Ridge Dr., Bellefonte, PA 16823

Abstract

Introduction: Enteral nutrition (EN) is provided for patients who have a functioning lower gastrointestinal tract but are unable to orally ingest nutrients and medication and are at risk of malnutrition. Conditions necessitating long-term EN can include prematurity, gastrointestinal dysfunction, failure to thrive, cancer treatment, cystic fibrosis, neurological disorders, congenital heart disease, and congenital metabolic abnormalities. When long-term enteral access is needed, percutaneous gastrostomy (G), jejunostomy (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 improved nutrient uptake is desired. In the US, there are over 400,000 home enteral nutrition (HEN) patients and >200k long-term Tubes placed annually, with an estimated 12,000 being 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.

Purpose: Objectives were to explore home use of the Actuated Device (Device) to maintain Tube patency for a patient with a history of repeated Tube clogging. Historically, literature lacks data of HEN clogging events, successful resolution methods, and implications for unresolved clogs. It is hypothesized the Device will provide a successful method of restoring Tube patency for HEN patients.

Methods: A 3-month (N=19) home evaluation was completed with a single patient (66-year-old female) with an 18 Fr, 30 cm GJ tube receiving overnight feeds (85 mL/hr 1.5 Cal). For each clog, the Operator applied standard declogging strategies. Following unsuccessful clearings, the Device (The TubeClear System®, Bellefonte, PA) was utilized in attempt to unclog the Tube. The Operator was trained to use the Device. Metrics recorded included success of clearing, time of use, patient satisfaction, and patient discomfort.

Results: The evaluation proved the hypothesis to be true. During the evaluation, the patient presented 19 times with either a partly or fully clogged Tube. For each clog, the applied standard declogging strategies were unsuccessful, therefore requiring Device use. Eighteen (18) of 19 clogged Tubes were successfully cleared with the Device in less than 30 minutes (95%). For the unresolved clog, the Operator allowed the Tube to dwell overnight (~8 hours) before successfully clearing the Tube with the Device (15 minutes). The average Device use was ~14 minutes (range 1 – 35). No safety issues were reported by the Operator or patient following Device use. Patient was satisfied and reported no discomfort during evaluation.

Discussion: In this evaluation, the Device was significantly more successful (100%) at resolving clogs compared to standard declogging strategies (0%) in the home. Since the Device cleared all the clogs, there were no required Tube replacements thus avoiding patient transportation from home to a medical facility and readmission necessitated by 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.

Conclusion: In the months prior to conducting this evaluation, the patient presented with multiple clogging events occurring almost weekly and taking on average 2-3 hours to resolve, with one event taking 10 hours, and another event requiring a GJ Tube replacement. In this evaluation, the Device was significantly more successful at resolving clogs compared to standard declogging strategies. Having an effective alternative to standard declogging strategies proved beneficial to this patient, saving the patient from having to be transported to a facility for a potential Tube replacement. The ability to restore patency using a more effective technique at home, lead the patient to state, “I feel more in charge of my healthcare now that I have the Actuated Device at home and this allows me to focus on the rest of my day.” The patient describes her ability to restore patency without hours of effort as, “life changing,” and stated, “I am thinking about taking a trip to the beach to visit my family now that I have the Actuated Device, and I am less concerned about my Tube clogging.” For the thousands of patients utilizing HEN, having alternatives available to alleviate Tube clogging issues can be significantly valuable to their continuance of care in the home.

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 (G), jejunostomy (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]
  - >200,000 long-term Tubes placed annually, with ~ 12,000 being GJ / J Tubes.
+ GJ and J Tubes occlusion rates have been cited as high as 35%.[3,4] due to:
  - Small bore,
  - Tube length, and
  - Convoluted geometries
+ Standard Tube declogging techniques include:
  - Warm water flushes
  - Chemical enzymes
+ Standard Tube declogging techniques are:
  - Time-consuming
  - Often unsuccessful and require Tube replacement

+ HEN patients in which patency cannot be restored, may require the patient to be transported to a medical facility
+ **Our organization developed an Actuated Mechanical Device that uses oscillating motion to unclog in-dwelling Tubes.**

Methods: 3-Month in-home Evaluation

Participant Details:

+ Single Participant (66-yr old female)
+ 18 Fr, 30 cm GJ Tube (Avanos Mic®, 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 hr to resolve,
  - One event taking ~10 hr
  - Another event requiring a GJ Tube replacement.

+ N= 19 Clogging Events
+ For each clog, standard declogging strategies initially attempted.
+ Following unsuccessful clearings, the TubeClear System (Actuated Medical Inc, Bellefonte, PA) was utilized in attempt to unclog the Tube.
+ The Operator was trained to use the Device.
+ Recorded Metrics:
  - Clearing success
  - Time of use
  - Participant satisfaction
  - Participant discomfort

Results

+ N=19 Partial or fully clogged Tubes
  - Following unsuccessful (0/19) standard declogging strategy attempts, Device use was attempted.
+ Device successfully cleared 18/19 clogs (95%) in under 30 min.
+ Single unresolved clog
  - Tube dwelled overnight (~8 hr) before clearing in morning with the Device (15 min).
+ No safety issues were reported by Operator or Participant following Device use.
+ Participant was satisfied and reported no discomfort during evaluation.

Metrics	
Clearing Attempts	N=19
Clearing Success with Standard Strategies	0/19 = 0%
Clearing Success with Device	19/19 = 100%
Avg Device Use Time (min)	~14 min (Range: 1–35 min)

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.”

Study Participant

References, Acknowledgements, Disclosures

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