The TubeClear **System**

Clinical Study of Mechanical Enteral Tube Declogging

August 2021

NeuroRestorative, Riverton, Utah

Robert Buckley RN, CCM

Steve Heisa, RN

TABLE OF CONTENTS

INTRODUCTION

The use of enteral feeding tubes has greatly enhanced delivery of nutrition, fluids and medications in the clinical setting. Despite the benefits, some of these enteral feeding devices are prone to clogging. These clogs are often related to delivery of crushed medications as well as enteral feeding formulas. Regardless of the cause, clinicians have very limited options for declogging these enteral tubes. The main limitation is getting any form of solvent to the clog as many tubes are thin in diameter and long in length. Many forms of declogging techniques have been attempted with solvents such as warm water, cola, meat tenderizer, enzymes and high pressure flushing. Studies have found that solvent efforts provide little benefit mainly due to the inability to get a solvent to the clog. High pressure flushing has been successful in certain tubes that have the strength to sustain high pressure. However, many tubes, particularly those made of silicone material, cannot withstand high pressure and may burst with such attempts.

In our clinical setting we serve many individuals of all ages requiring enteral feeding support. The loss of feeding access, due to tube clogging, presents a serious interruption to care. In addition, there is the physical discomfort of tube replacement as well as the significant associated financial costs when replacement requires interventional radiology. The increasing occurrence of tube clogs caused us to investigate alternative methods and technologies that may be available to address this problem. This led to the discovery of the TubeClear System (TubeClear) A mechanical feeding tube clearing technology manufactured by Actuated Medical, Inc. (Bellefonte, PA). Our inquiry into the TubeClear technology resulted in the opportunity to participate in an evaluation of this technology application in our clinical setting. This evaluation allowed us to assess the prophylactic use of TubeClear as well as the interventional use when clogs occurred.

PRODUCT/SERVICE/METHODOLOGY

The TubeClear System (TubeClear) comprises a reusable Control Box that provides the mechanical force action to a single-use Clearing Stem. The Clearing Stem contains an inner core that receives the mechanical force providing a forward and backward action to the exposed distal end of the Clearing Stem inner core. The Clearing Stems are indicated for specific feeding tube types and sizes. Actuated Medical provided the training videos, manuals and equipment that were utilized by our nursing managers in developing their competency for use of TubeClear. Clearing Stems were provided by Actuated Medical based on the information we provided regarding the feeding tube types and sizes within our patients. The sizing of Clearing Stems was specific to feeding tube type, diameter and length. Our study included standard gastrostomy, nasal gastrostomy, nasal jejunostomy, jejunal and gastro-jejunal (GJ) tubes. Each Clearing Stem is provided with an insertion depth limiter to prevent a Clearing Stem from passing through the distal end of a feeding tube and into the stomach or intestinal tissue. Therefore, all feeding tube lengths must be known in order to apply this service. Prophylactic use was applied one time weekly for a period of four weeks and interventional use was applied as needed over the same four-week period. Standard data regarding each participant such as gender, age, weight, time enteral support in use and enteral formula were recorded. In addition, each individual's feeding tube data regarding tube manufacturer, model, French size, length and tube time in service were recorded. The prophylactic use of TubeClear involved the utilization of a specified Clearing Stem inserted into the feeding tube to the depth limitation. Information regarding the ease or resistance of insertion as well as insertion technique, time and individual tolerance of the procedure were recorded. This data was compared to a similar study group of individuals receiving the customary standard of care service regarding clog prevention and declogging. Clog prophylaxis standard services included scheduled enzyme applications and water flushing frequency. Standard declogging included high pressure flushing/suction actions, extended time enzyme applications and other non-mechanical interventions. Each group, TubeClear and Standard of Care, consisted of 15 individuals.

KEY FINDINGS

Key Findings #1

The two most common clogging causes, during this study, were insufficiently crushed or granular medication administrations and suspected enteral formula precipitates (lipids and protein) adhering to the distal inner lumen of tubes. The feeding tube types most prone to these clogs were small lumen, usually 8 to 10 French, and longer in length such as naso-gastric, naso-jejunal. Gastro-Jejunal tubes in the 18 to 22 French sizes were also quite prone to the same types of clogs at or near the jejunal exit port(s). Staff gained experience in sensing the difference in these types of clogs and the effects each had on the handling of the Clearing Stem. Medication clogs provided a hard stop feel and sudden release when cleared by mechanical action. Precipitate clogs provided a soft or sluggish stop and slow sluggish clearing with additional flushing efforts during the clearing process.

Key Findings #2

Mechanical de-clogging was found to be far more effective than any other method of clearing a clog. During the four-week study period all clogs (3) were able to be cleared with TubeClear. One clog, that occurred in the standard of care group, was unable to be cleared utilizing standard methods. That clog was later successfully cleared using TubeClear. During the study no resident required a tube replacement due to an unresolved clog. This finding was especially important as two of the individuals, whose tubes clogged, would most likely have required transfer to the hospital for interventional radiology placement of new tubes (GJ type tubes).

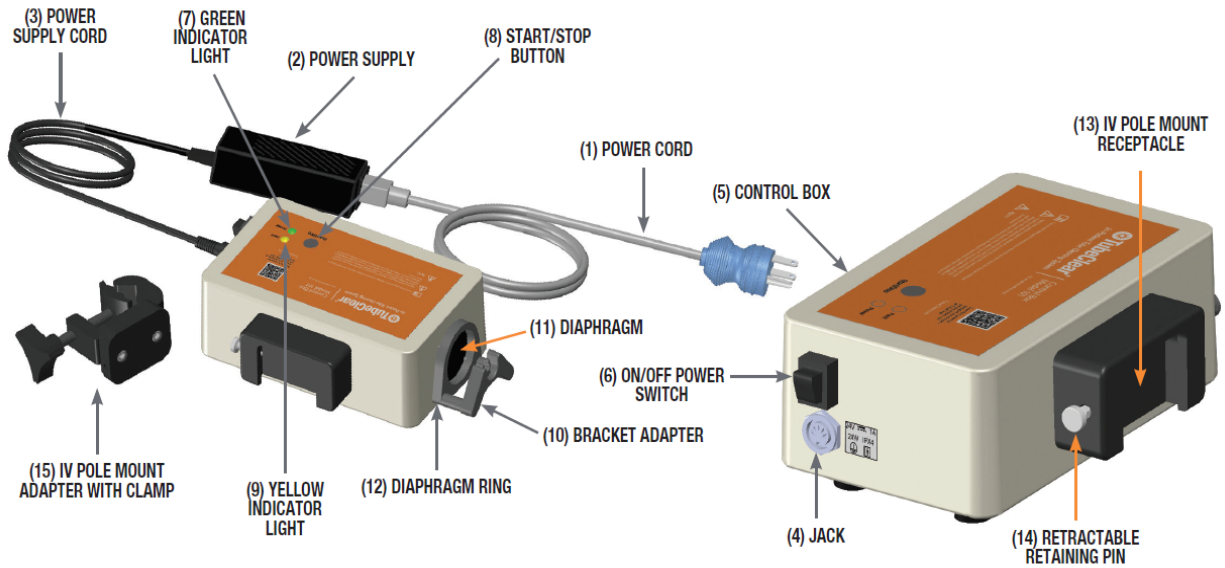
Key Findings #3

The type of tube and the material used in the construction of the tube play an important role in the declogging process. Naso-gastric and naso jejunal tubes are most often made from a vinyl plastic material. This allows a greater amount of pressure to be applied that can often clear medication clogs. Distal tube clogs from enteral formula precipitates are more difficult to clear without mechanical clearing. Gastro-jejunal (GJ) type tubes are most often made from silicone material and are quite prone to rupture if too much pressure is applied to clear a clog. Most clogs in these tubes occurred in the distal portion of the jejunal section of the tube near the exit port(s). The GJ Tube participants in this study received medications via the gastric port and no medication clogging occurred with these tubes. Long term experience in utilizing the silicone type tubes has demonstrated that tubes are most often replaced due to a rupture caused by efforts to clear a clog with increased pressure. Silicone tubes have also ruptured from enteral pump pressure when clogs occurred unnoticed by staff. Enteral pumps are equipped with pressure sensors that suspend administration and activate an alarm. It is quite possible that silicone tubes weakened by previous pressure applications may be the cause of pump related ruptures, where pressure did not rise to the point where sensors would activate a pause before the rupture occurred. Mechanical clog clearing, with TubeClear, proved to be the most effective and safest method for preventing or clearing clogs in silicone type tubes.

Visual Data

Item No.	Name	Description
1	Power Cord	Plugs into a standard outlet and into the Power Supply.
2	Power Supply	Reduces voltage to the Control Box.
3	Power Supply Cord	Plugs into the Jack on the Control Box.
4	Jack	Connector for Power Supply.
5	Control Box	Contains the Motor and drive electronics.
6	On/Off Power Switch	Allows power to the Control Box.
7	Green Indicator Light	Indicates power is available and is ready to start.
8	Start/Stop Button	Starts and stops the Motor inside the Control Box.
9	Yellow Indicator Light	Indicates an electrical fault. TubeClear will not operate when the yellow light is on.
10	Bracket Adapter	Holds and positions the Clearing Stem during use.
11	Diaphragm	Clearing Stem attachment point.
12	Diaphragm Ring	Feature to secure Diaphragm to Control Box.
13	IV Pole Mount Receptacle	Feature that slides over the IV Pole Mount Adapter to hold the Control Box on an IV pole.
14	Retractable Retaining Pin	Secures the IV Pole Mount Adapter in the IV Pole Mount Receptacle.
15	IV Pole Mount Adapter with Clamp	Mounts to an IV pole and holds the Control Box via the IV Pole Mount Receptacle.

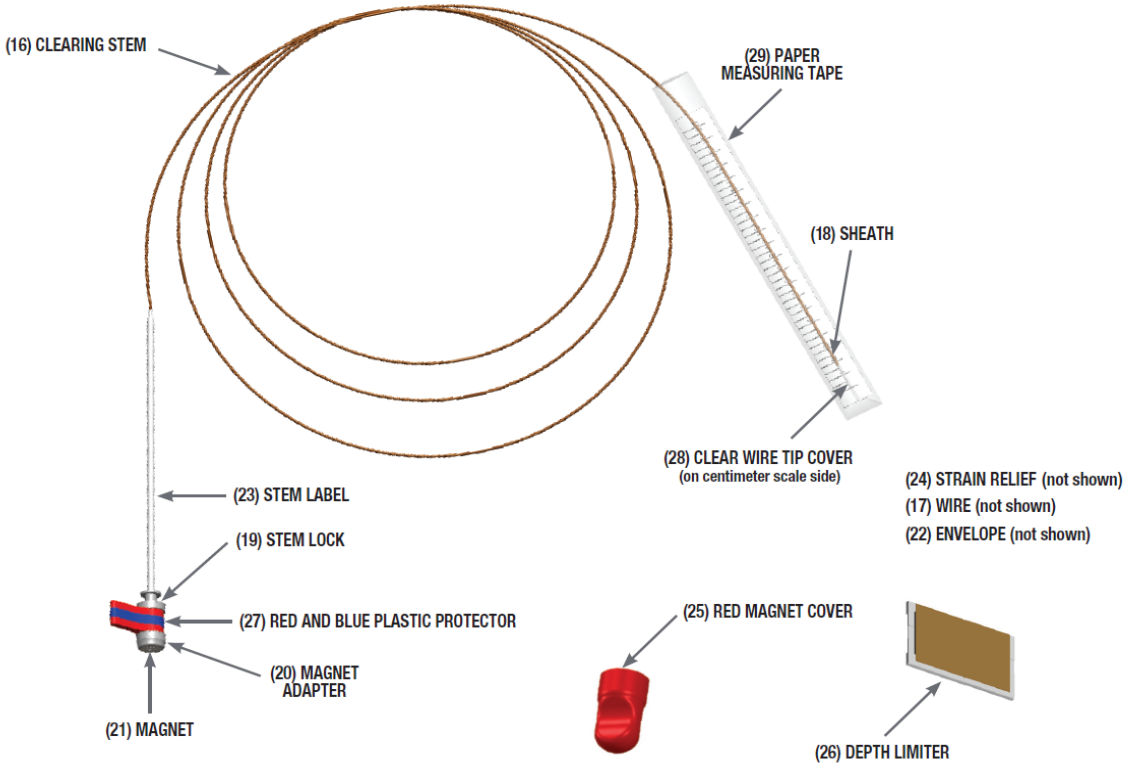
TubeClear Control Box Model 101 Component Locations.



Item No.	Name	Description
16	Clearing Stem	Inserts into the Patient's Tube to clear clogs, while the Tube remains inside the Patient.
17	Wire	Feature that interacts with the clog material.
18	Sheath	The flexible tubing that surrounds the Wire.
19	Stem Lock	Clips into the Bracket Adapter, secures the Clearing Stem.
20	Magnet Adapter	Secures the Magnet on the end of the Clearing Stem.
21	Magnet	Feature to attach Clearing Stem to Control Box.
22	Envelope	Covers Wire between Magnet Adapter and Stem Lock.
23	Stem Label	Provides product name and intellectual property information.
24	Strain Relief	Feature to minimize Clearing Stem bend at Control Box.
25	Red Magnet Cover	Covers and protects Magnet Adapter during storage.
26	Depth Limiter	Feature that Operator manually sets that corresponds to the length of the Tube to limit insertion depth of the Clearing Stem.
27	Red and Blue Plastic Protector	Packaging feature that protects Wire during storage and attachment to the Control Box.
28	Clear Wire Tip Cover (on centimeter scale side)	Packaging feature that protects Wire Tip during storage.
29	Paper Measuring Tape	Measuring Tape used to set Depth Limiter.

TubeClear TC Model Clearing Stem Component Locations.

NOTE: *Color of Sheath (18) and Stem Label (23) will vary between Models.*



CONCLUSION

Clogging of long term use enteral feeding tubes is almost inevitable even with the most effective management methods of non-mechanical prevention techniques. Enteral tubes most effected by clogging are narrow lumen i.e., 8-10 French and long length in nature i.e., 140 cm. (typical naso-gastric/jejunal tubes). Enteral tubes least likely to clog are of larger lumen i.e.,12 French and larger and short length in nature i.e., less than 25 cm. (typical gastrostomy or jejunostomy tubes). Silicone gastro-jejunal tubes are particularly difficult to de-clog by non-mechanical means due to the fragile nature of the tube to pressure. TubeClear is an effective and cost-efficient means of de-clogging enteral feeding tubes of all types.

The prophylactic use of TubeClear, as a clog prevention strategy, in cases of recurrent clogging and tube types that require interventional radiology for replacement, has proven to be cost effective as well. The residents we serve are mostly ventilator dependent. Therefore, they require ambulance transport when interventional radiology is needed for feeding tube replacement. That transportation cost alone is approximately $1,300. We often will provide a respiratory therapist to accompany a resident on the transport and during the procedure for feeding tube replacement, costing on average $250. The placement procedure has an average cost of $2,670.00, including professional fees. Our experience, during the course of the evaluation, likely resulted in prevention of at least two GJ tube replacements at the costs noted above.

The highest benefit, with our experience, in utilizing TubeClear is the comfort it has provided to the residents we care for. Tube clogging is experienced as a complication of care progress. In addition, it is a stressful experience as it can bring the anticipation of discomfort and costs associated with possible enteral tube replacement. The several tubes we were able to de-clog with TubeClear provided our residents a great sense of relief and a greater sense of confidence in our care abilities.

Key Takeaways

1. Aquiring, training and applying the TubeClear System for feeding tube de-clogging is simple and well within the skill capabilities of Licensed Nurses

2. The TubeClear System is a proven technology that is effective in clearing enteral feeding tube clogs.

3. The TubeClear System has proven to be a cost effective technology to apply in a long-term care environment.

4. The TubeClear System provides greater resident comfort and confidence in a provider's care service.

Financial Disclosure: Actuated Medical, Inc., the manufacturer of the TubeClear System, provided the training videos, manuals and equipment utilized by our nursing managers during the evaluation. Following the evaluation, NeuroRestorative purchased the Control Box and paid for the utilized Clearing Stems at a discounted price.