The TubeClear® System – On the Market for Clearing Clogged Feeding Tubes – and Evaluating Increasingly Challenging Tubes in the Body: SBIR Funded Medical Device Platform

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ABSTRACT

For a variety of health reasons (e.g., cancer, traumatic injury, Parkinson, Alzheimer), patients may find themselves unable to self-feed. These patients depend on a life-saving device, a feeding tube, to receive their nutrition and/or medications on a daily basis. However for various causes, these critically important feeding tubes become clogged with feeding formula and/or medications. Attempting to clear a clogged feeding tube can be time consuming to a clinician and can lead patients to be without nutrition or medication for an extended period of time. Often, these tubes require replacement, causing the patient to undergo a painful procedure and possibly exposing them to additional risks (e.g., radiation, surgical procedure). The TubeClear® System is a patented, FDA-cleared and CE marked medical device, developed to clear clogged feeding and decompression tubes at a patient's bedside while the tube remains in the patient. Benchtop testing has shown the TubeClear System to be more efficient and faster than current feeding tube clearing methods.

Keywords: feeding tube, clog, medication, ICU, nutrition

Actuated Medical, Inc. (AMI) (Bellefonte, PA) developed the TubeClear® System (see **Figure 1**) for 10-18 Fr feeding tubes using NSF SBIR Phase I, IB, II and IIB funds and private investment. In a follow-on NIH/NICHD Phase II SBIR, Clearing Stem models for smaller French size feeding tubes are being developed that will be tested in a IRB-Approved clinical study at the Children's Hospital of Philadelphia (CHOP), starting in April 2016. The TubeClear System received FDA clearance in 2012 and then expanded its indications to other feeding tubes with an additional FDA clearance in 2013. To accomplish these commercialization milestones, AMI established a Quality Management System that is FDA cGMP compliant and is ISO 13485:2003 certified. AMI has also established a 3000 sq. ft. controlled manufacturing area. AMI has 7 issued US patents in the area of clearing artificial tubes in the body [1].

BACKGROUND

Individuals at risk of malnutrition and dehydration, due to their inability to ingest nutrition and/or medication orally, often become dependent on enteral nutrition as a life-saving device [2]. These feeding tubes, also known as enteral access devices, deliver critically needed nutrition and/or medication. However, due to various causes including narrow tube inner diameters, daily administration of feeding formula and/or medication, as well as other unknown causes, tubes may clog up to 35% of the time [2, 3]. Clogging is one of the most frequent mechanical complications of feeding tubes [3, 4]. In fact, the clogging rate of nasoenteral (NE) and nasogastric (NG) feeding tubes are considered to be underestimated and underreported, with actual rates likely being much higher [4]. Feeding tubes are more likely to become clogged when powdered, crushed, acidic, or alkaline medications or ground feeding formulas containing particulates are delivered through the small inner lumen, or when tubes are not routinely flushed following feedings [3].

Figure 1: A) TubeClear System is comprised of a reusable Control Box and Single-Use Clearing Stem. B) The TubeClear System set up at a patient's bedside. The System operates at a patient's bedside to clear clogged feeding tubes while the tube remains in the patient.

Dealing with clogs creates hassles and frustration for practitioners and anxiety and discomfort for patients who rely on the tubes to obtain nutrition and medication. This is especially true in high acuity or critically ill patients. Clogged feeding tubes often result in the interruption of a patient's nutrition and medication regimens, presenting a burden to both caregivers and patients. The lapse in nutrition and medication regimen may also negatively impact recovery [5]. Current techniques to clear clogged feeding tubes are time-consuming and often unsuccessful. This delays feeding, hydration, and medication, causing detrimental effects on overall patient health and healing [5].

When tube clearing methods fail, the tube will require replacement. The most common way to place NE (NG) feeding tubes is blind insertion, and has a reported 0.5-16% malposition rate [4]. Malposition into the trachea may cause pneumothoraxes and possibly death [4]. Though several methods exist for accurate tube placement verification, the most reliable is radiography [4], exposing patients to additional radiation and increased medical costs. Additionally, replacing clogged gastrostomy (G) and jejunostomy (J) feeding tubes may require additional endoscopic guidance or surgical procedures depending on tube type. Moreover, for patients living outside the hospital, a clogged feeding tube often results in transportation and admission costs to the payer and anxiety to the patient. Taking into account nursing time, tube replacement, radiographs and other miscellaneous costs, the capability to clear a clogged feeding tube while it remains in the patient, could represent substantial savings to a medical facility not to mention reduced pain and discomfort to the patient. Notably, among common medical procedures, patients rank NE tube insertion to be one of the most painful [6-8].

THE SOLUTION

The TubeClear System (see **Figure 1**), is a patented, FDA-cleared and CE marked medical device, developed to clear clogged feeding and decompression tubes at a patient's bedside while the tube remains in the patient. The system comprises a reusable Control Box that actuates a single-use Clearing Stem. The Clearing Stem is manually inserted into the feeding tube while the Control Box motor moves the specially designed Clearing Stem's flexible distal Wire Tip backward and forward. This motion mechanically disrupts the clog (see **Figure 2**) [9] and restores tube patency.

The single-use Clearing Stem is composed of a plastic Sheath covering a Wire with a permanently bonded depth control Collar along its length. This Collar is designed to stop the Clearing Stem's progression before the Clearing Stem exits the distal end of the feeding tube. Currently, 13 separate Clearing Stems models are available, dependent on the feeding tube's characteristics (Type, French Size and Length, see **Figure 3)** [10]. The TubeClear System is currently FDA cleared to unclog 10-18 Fr NE, NG, G (including PEG tubes) and J feeding tubes in adults at bedside while the tube remains in the patient. It is estimated that due to saved nursing time, tube replacement, radiographs and other costs, the TubeClear System can save a 500 bed hospital over $240k annually [9].

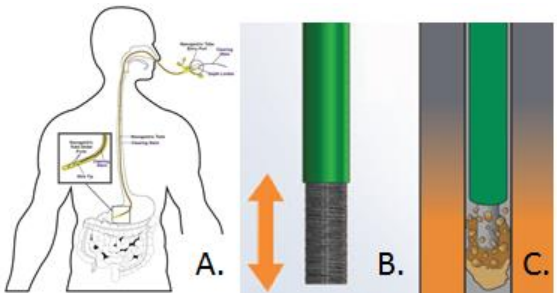

Figure 2: A) The Clearing Stem is inserted into the patients feeding tube. B) The Control Box motor applies a gentle backward and forward motion to the Clearing Stem Tip. B) The Clearing Stem Tip motion breaks up the clogged materials.

Nasoenteral and Nasogastric Tubes

French Size (Fr)	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
10 - 18	91	36	NE-1036	Yellow
10 - 18	107	42	NE-1042	Grey
10 - 18	109	43	NE-1043	Purple
10 - 18	114	45	NE-1045	Orange
10 - 18	122	48	NE-1048	Clear
10 - 18	127	50	NE-1050	Blue
10 - 18	140	55	NE-1055	Green

NE MODEL CLEARING STEMS HAVE WHITE HAND GRIPS AND STEM LABELS

Gastrostomy and Jejunostomy Tubes

French Size (Fr)	Tube Length (cm)	Tube Length (in)	Model #	Stem Color
10-18	20	8	G-1008	Yellow
10-18	23	9	G-1009	Grey
10-18	25	10	G-1010	Purple
10-18	28	11	G-1011	Orange
10-18	30	12	G-1012	Clear
10-18	36	14	G-1014	Blue

G MODEL CLEARING STEMS HAVE BLACK HAND GRIPS AND STEM LABELS

Figure 3: The TubeClear System Clearing Stem Models for 10-18 Fr feeding and decompression tubes.

BENCHTOP DATA

During benchtop testing with clogged Levin 14 Fr 48 inch long NE feeding tubes, the TubeClear System restored tube patency with 100% success and performed faster than other clearing methods tested (see **Figure 4**). Testing was conducted with clogs composed of a 2:1 ratio of coagulated protein and ground medication (Medication Clogs) and clogs composed of a 1:1 ratio of feeding formula and fiber (Formula Clogs). For Medication Clogs: the TubeClear System had 100% success in 2.8 min, while water-flushes had 86.7% success in 30.7 minutes and enzyme treatments had 100% success in 59.1 minutes. For Formula Clogs: the TubeClear System had 100% success in 2.8 min, while water-flushes had 86.7% success in 53.7 minutes and enzyme treatments had 93.3% success in 55.2 minutes. Consequently, the TubeClear System is more effective and faster than its competition in clearing more types of clogs. This is of special interest, as many of the current feeding tube clearing methods are only designed to be effective on certain types of clogs. For example, most enzyme treatments are only indicated for protein (feeding formula) based clogs.

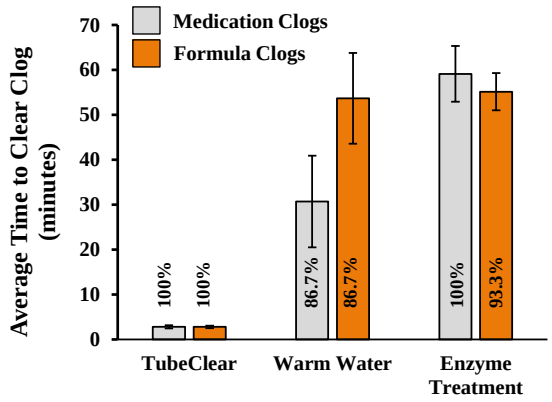

Figure 4: Average Procedure times for clearing Feeding tubes clogged with Medication (Gray Bars) or Formula Clogs (Orange Bars) by the TubeClear System, warm water flushes and enzyme treatments. Within each bar, Percentage of success is presented. N=15.

Benchtop testing evaluated the potential effects of an Operator selecting an inappropriate Clearing Stem Model, one that is longer than the feeding tube. In this situation, the Clearing Stem's Tip could exit past the distal end of the feeding tube, possibly making contact with gastrointestinal tissues. Purposefully over-inserting the Clearing Stem into porcine intestinal tissue at a controlled rate (N=30 trials) was unable to cause a tissue puncture; rather, the Clearing Stem Tip flexed upon contact with the tissue (see **Figure 5**). The maximum force recorded during testing under non-clinical conditions (gripping the Clearing Stem approximately 2 inches from the Tip to minimize flexion and driven by electromechanical test stand) was 3.270N. Under simulated use conditions (Operator gripping the Clearing Stem approximately eight inches from the Clearing Stem Tip) the recorded force that could be exerted by the Clearing Stem Tip was recorded (N=30 trials), and the average calculated as 1.357 ± 0.51 (Max force recorded = 2.364N; No tissue punctures were caused). A probability density function demonstrated the probability that the maximum force transmitted to the Clearing Stem Tip can create the maximum force observed under non-clinical conditions (3.270N) was 0.0007. Thus, the probability of exerting enough force during insertion to achieve the maximum force recorded of 3.270N, which did not cause tissue puncture, was 0.07% (see **Figure 6**).

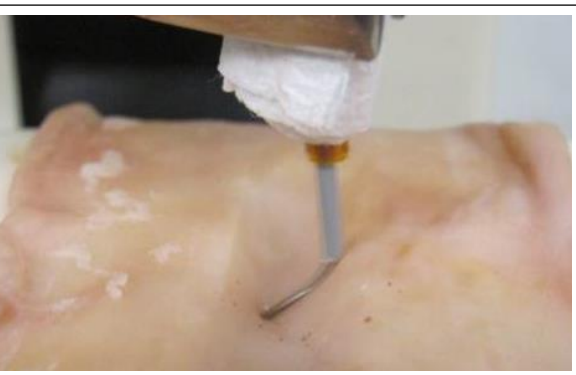

Figure 5: Over insertion of Clearing Stem Tip past the end of feeding tube, Note: the Tip buckled and did not puncture the tissue.

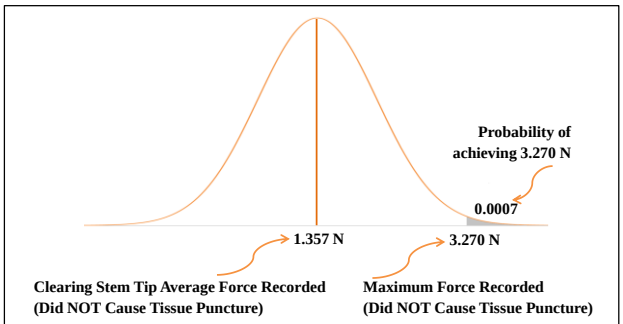

Figure 6: Probability of exerting enough force during Clearing Stem insertion to achieve maximum force recorded with porcine tissue testing.

During correct operation of the TubeClear System, the Clearing Stem moves along the inside of the feeding tube. Benchtop testing demonstrated the use of the TubeClear System did not compromise the feeding tube's integrity. Following operation of the TubeClear System, the surface integrity of a portion the tube's cross section was examined using optical microscopy. Twenty-two (22) of thirty (30) sections analyzed showed no visual inconsistencies (i.e., no tube puncture, marring, scratching, or other visual damage). Eight (8) samples showed minor inconsistencies that were determined not to be generated by the TubeClear System (determined to be water marks, inclusions within the extrusion of the tube itself, and artifacts from folding the dual lumen tube).

CLINICAL USE

The first in-human TubeClear System use was on a 27-year old soldier in the ICU at Walter Reed National Military Medical Center (IRB-approved clinical study). The clogged feeding tube was cleared and no discomfort was reported by the patient. In a recently released case report conducted by a single licensed critical care nurse specialist over an 11-month time period (May 2013 - April 2014) demonstrated that the TubeClear System is able to be used effectively in a clinical setting, in adult patients. The TubeClear System successfully restored tube patency to 100% of the attempted clogged small bore feeding tubes with no recorded adverse events [11] (see **Table 1**). Over the time period, patients' tubes became clogged following administration of feeding formula and/or medication. Following indicated use of the TubeClear System, tube patency was restored in a mean of 14 minutes.

Case	Sex	Age (yr)	Tube Size (Fr)	Time Lapsed from Tube Placement to Clog Appearance	Last Substance Passed Prior to Clogging	Total Procedure Time (minutes)	Patency Restored?
1	F	58	10F	-	medication (Protonix® (Pantoprazole))	10	Yes
2	M	66	10F	7 d	tube feed & meds (Protonix® (Pantoprazole))	20	Yes
3	F	48	10F	10 d	tube feed & meds (Protonix® (Pantoprazole))	20	Yes
4	M	85	10F	2 - 3 hrs	potassium	15	Yes
5	M	67	14F	2 d	nightly tube feeds	5	Yes
6	M	56	10F	2 hrs	tube feed / aspirin (ASA)	13	Yes
Median		62				Mean 14 Std. Dev. 6	

Supplemental Patients (n=6) ranged in age and gender. Tube placement information was not readily available at the time of document preparation.

Table 1: The TubeClear System Case Series Summary Table, presented in Belcher, M. An Active Device for Restoring Patency in Clogged Small Bore Feeding and Decompression Tubes, Case Report Series, 2016 [11].

SUMMARY

The TubeClear System was developed under NSF SBIR funding to clear clogged feeding tubes 10-18 Fr. It is patented, FDA cleared, and CE Marked. The system effectively clears clogged feeding tubes at the patient's bedside while the tube remains in the patient. Benchtop data demonstrated that it is more effective and faster than its competition. It is projected to save a 500 bed hospital over $240k, and has early sales across the USA [9]. New models to service smaller diameter feeding tubes are being developed with NIH/NICHD SBIR funds. Actuated Medical is also pursuing the technology platform of clearing artificial tubes in the body in more increasing difficult clinical applications such as clearing mucus from endotracheal tubes for neonatal patients (a NIH/NICHD Phase II SBIR).

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