DrIFT 2 STUDY: DISPLACEMENT IN FEEDING TUBES

Principal Investigator: Jan Powers PhD, RN, CCNS, CCRN, CNRN, NE-BC, FCCM
Director of Nursing Research and Professional Practice
Parkview Health System
11109 Parkview Plaza Drive
Fort Wayne, IN 46845
260-266-7761
jan.powers@parkview.com

Sub-Investigators: Janette Richardson MSN, RN, AG-CNS, CCRN
Clinical Nurse Specialist Inpatient Surgical ICU
Parkview Health System

Jennifer Rechter MSN, RN, AG-CNS
Clinical Nurse Specialist MICU and Progressive
Parkview Health System

Elaine Pettit RN
Clinical Nurse Surgical Intensive Care Unit
Parkview Regional Medical Center

Brandon T. McDaniel, PhD
Senior Research Scientist
Parkview Mirro Center for Research & Innovation

Non-affiliated Investigator Annette Bourgault PhD, RN, CNL
University of Central Florida
12201 Research Parkway, Suite 300, Orlando, FL 32826
407-823-1055
Annette.bourgault@ucf.edu

Research Coordinator(s) Danielle Payne BSBio, MSN, RN, FNP-BC, BC-ADM

Study Site(s) Parkview Health
11109 Parkview Plaza Drive
Fort Wayne, IN 46845

Sponsor: n/a

Study Product: Cortrak Enteral Access System (EAS) 2

Protocol Number: NUR23-1127DrIFT2

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List of Abbreviations:
FT: feeding tube
Sub-I: Sub-investigator
EMR: electronic health record
PI: Principal investigator

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PV: Parkview Health

1 Study Title

DrIFT 2 Study: Displacement In Feeding Tubes 2.0

2. Background and Significance

Small bore feeding tubes (FT) are frequently used to provide nutrition to acutely ill patients. In addition to liquid formula, medications are frequently administered through the FT. Placement of the distal end of the FT is important to minimize risk for aspiration and promote absorption of liquid formula and medications. Ideal FT placement is often dependent on patient acuity. In critically ill patients, small bowel placement (duodenum or jejunum) is often required [1] and in patients with fewer risk factors, gastric (stomach) placement is considered satisfactory.

Current practice guidelines from the American Association of Critical-Care Nurses (AACN) call for verification of distal tube placement every 4 hours using multiple methods [2], yet there are no valid methods available to perform this assessment. Existing tube verification methods such as pH measure, capnography, observation of gastric aspirate, and signs of respiratory distress have lacked validity [3-5]. The tradition-based method of auscultation has insufficient sensitivity and specificity to identify FT placement and should no longer be used [5-7]. Although these verification methods pose little risk for patient harm, they are resource intensive (financial and clinician time). Clinicians are encouraged to question whether current practices are based on research evidence or if they are tradition-based [8]. Tradition-based practices should then be assessed to determine if they should be de-implemented (stopped), changed, or replaced [8].

A gap in the literature is whether FTs migrate over time. Forward migration is known to occur due to normal gastric motility [9] and has been documented numerous times by radiographic confirmation. In fact, clinicians often rely on this naturally occurring forward migration to assist with FT placement into the small bowel in instances where gastric placement has been confirmed and small bowel FT placement remains elusive. Reverse migration could potentially pose greater risk to the patient if the FT migrated from the small bowel into the stomach [1]. In this instance, formula and medications may not be well absorbed or tolerated, leaving the patient deficient in nutrition and necessary medications and putting them at risk for aspiration should the volume of gastric contents become too great. Additionally, reverse migration from the stomach to the esophagus may place the patient at an even higher risk of aspirating formula and/or medications into the pulmonary system. Pulmonary aspiration has led to pneumonia and has also resulted in death [11].

The proposed study will use an electromagnetic placement device (EMPD), Cortrak* 2 Enteral Access System (EAS™), Avanos Medical, to verify FT position on a daily basis to assess for migration. The EMPD provides real-time FT placement data. A sensor located on the distal end of the FT guidewire communicates with a receiver unit which sits on the patient's abdomen. Three visual insertion tracings with varying views (anterior, lateral, and depth/cross-section) can be saved and printed for comparison. (See Figure 1)

Two previous studies have been completed with similar methodology. A pilot study of 50 subjects was performed using the original Cortrak* (2 insertion views) and found only minimal forward migration [9]. No reverse migration was reported in the Powers study.

A pilot study of 20 patients with 62 feeding tube assessment identified 8 migration events (5 retrograde and 3 forward), these events only occurred within the small bowel [10]. Based on this data, a recommendation could be made that there is no need to check feeding tube placement routinely q4hours. However, due to the small sample size, additional research is needed to confirm this finding. It is also unknown if there may be more migration with positioning changes, for example, up in the chair or prone position.

The proposed study will use an electromagnetic placement device (EMPD), Cortrak* 2 Enteral Access System (EAS™), Avanos Medical, to verify FT position on a daily basis to assess for migration. The proposed study will take place in critical care units at Parkview Health. The primary aim will be to determine if replication of the pilot study results in similar findings. We will also explore other factors that may be associated with FT migration, such as patient mobility (ambulation or sitting at bedside or prone position) and transporting out of the critical care unit for diagnostic procedures. We anticipate that results from this study will provide a better understanding of FT position and migration over time and ultimately influence recommendations for practice for frequency of routine FT verification. Standard of care for assessing feeding tube placement location every 4 hours will remain in place. The study will add an additional assessment for feeding tube location daily. This study will expand on the findings from the initial pilot study with a larger sample size.

3 Primary Objective

Determine if small bore FTs migrate over time in critically ill adults receiving usual care.

3.1 Secondary Objectives

1. Identify factors associated such as mobility and position changes that may affect feeding tube migration.
2. Findings may inform recommendations for clinical practice regarding the frequency for FT placement verification.
3. Validate current dual verification process for feeding tube confirmation.

4. Study Population

The sample recruited for this study will include adult patients in critical care with small bore feeding tubes (FT) in acute and critical care. All participants must be able to understand and fluently speak English.

Investigators will review patient census and data from cortrak to identify new small bore feeding tube insertions in adult patients on the designated study units and will assess eligibility criteria. We are aiming for a sample of 120 feeding tubes.

Parkview Health, Fort Wayne, IN

- Surgical trauma ICU (STICU) and Medical ICU (MICU)

4.1 Inclusion Criteria

- Adult ≥18 years old
- Critical care patients with small bore feeding tube inserted within last 24-48 hours
- Initial Cortrak insertion tracings: all 3 views available
- Cortrak guidewire available (these are typically saved in a plastic bag in the patient room following FT insertion).

Ethic/racial diversity, age, or sex are not anticipated to play a role, so our recruitment will not focus on a diverse sample.

4.2 Exclusion Criteria

- <18 years old
- Identified as "Doe"
- Unable to speak or understand English language
- Pregnancy
- Prisoners
- FT anticipated to be removed within 24 hours
- Contraindications to placing a mark on the abdomen for top foot of receiver unit (large dressings, open abdomen, halo vest, etc.)
- Original guidewire unavailable

5. Vulnerable Populations

No vulnerable populations will be targeted for enrollment but may be included except for pregnant patients and prisoners, which will be excluded.

6. Study Design

This study will use a longitudinal, repeated measures design replication study from previous pilot study.

An investigator will perform recruitment and data collection. Additional data collectors will be used as needed to ensure that data collection is performed daily, including weekends. Since this practice was safely completed in a pilot study as well as a previous study and is currently standard practice to assess tube location as needed, a waiver of written informed consent is being requested. Explanation will be provided to patients/family that we are evaluating the tube daily to assess any movement of the feeding tube.

6.1 Sample Size

The sample size of 120 participants for this study was selected based on feasibility and consultation with a biostatistician. A sample size of 120 will detect feeding tube migration over time (effect size 0.18, 80% power, alpha 0.05) using mixed effects model. The effect size was calculated by a statistician based on preliminary data from our original pilot study.

6.2 Recruitment

Investigators will review patient information daily (from census list or cortrak machine) to identify any patients in the study units with a new feeding tube placement. and will assess patient eligibility. Screening for new participants will take place for the duration of the study until the target sample size has been reached.

6.3 Data Collection

Data collection will be an ongoing process and take place every 24 hours (+/- 6 hours) following enrollment. A 6-hour window before or after the designated 24-hour data collection period was allowed for feasibility of data collection. Data collection will continue daily for the duration of the feeding tube or until Day 5. If the patient is transferred off the study unit to a medical or surgical unit at PRMC, data collection will continue. Data collection will cease at 5 days or when the feeding tube is removed.

6.4 Methods: PI or Sub-I

- Investigators will discuss the study with the patient or designated family member so they understand the process steps.
- Label original Cortrak* guidewire with tape ("DrIFT Study") near orange Cortrak connector port.
- Obtain insertion tracings from original feeding tube insertion.

6.4.1 Subsequent Insertions:

- Verify that original guidewire is available (see tag on proximal end).
- Position patient supine, HOB elevated 30 degrees. If unable to place supine, document position
- Connect Cortrak to guidewire. Wipe guidewire with alcohol before insertion
- Position Cortrak receiver unit on abdomen. At the time of the first data collection, a surgical marker will be used to indicate location for placement of the top foot of the receiver unit (see image attached) on the patient's abdomen. Subsequent data collection will align the top foot of receiver unit with the mark on the patient's abdomen.
- Flush FT with 30ml water per institutional protocol.
- Insert guidewire into FT and obtain Cortrak insertion tracing to determine position of distal tip of feeding tube.
- Print 3 insertion tracings (anterior, lateral, depth/cross section). Write unique identifier on the back of each tracing printout. Do not write any other information on the insertion tracing.
- Remove guidewire, wipe with alcohol and leave in bag at the bedside.
- If tubes are found to be pulled back, this will be documented along with precipitating factors. Tube will then be advanced and will continue data collection noting the change in position on data collection form.

Other study data will be entered onto a hard copy, printed data collection form and stored temporarily in the locked office of the site Sub-II. Study data will be obtained from patient observation, discussion with the nurse, and the EMR.

7. Study Duration/ Study Timeline

The proposed study will take place over a 10 month period after IRB approval. Dissemination of study findings will take place via poster or podium presentation at an appropriate conference and also published in a peer-reviewed journal.

Study Timeline

	Dec	Jan 2024	Feb	March	April	May	June	July	Aug	Sept
IRB Submission										
Recruit Participants										
Perform /Data Collection										

Data Analysis										
Dissemination by poster/manuscript										

8. Statistical Analysis Plan

The sample size of 120 participants for this study was selected based on feasibility and consultation with a biostatistician. A sample size of 120 will detect feeding tube migration over time (effect size 0.18, 80% power, alpha 0.05) using mixed effects model. The effect size was calculated by a statistician based on preliminary data from our original pilot study.

Bivariate descriptive characteristics of the study population will be compared according to feeding tube migration status (yes/no). Differences in patient's clinical and demographic characteristics between the groups will be assessed by chi-square statistics for categorical variables and two-sample t-tests (or Wilcoxon for nonparametric) for continuous variables.

Time to feeding tube migration will be assessed via the Kaplan-Meier (KM) method for repeated events in 24-hour blocks [11]. Patients who experience feeding tube migration may also have additional forward/backward migration in subsequent 24-hour periods. Thus, the nonparametric estimate of the survival function has to accommodate the potential for repeated events. The likelihood of feeding tube migration according to time will be obtained by the KM estimator (no migration) and cumulative distribution function (migration), respectively. Other analyses may be performed if necessary.

8.1 Data Analysis

Data analysis will be performed using the appropriate statistical analysis software, such as IBM SPSS, SAS, etc. Descriptive statistics will be used to discuss demographics of the participants. An alpha level of 0.05 will be used to determine statistical significance for all analyses.

Outcome variable:

- Feeding tube migration (yes/no).
    - Number of hours from insertion to tube movement
    - Forward migration/backward migration
    - Zone of the FT distal tip (figure 1)

Figure 1. FT Placement/Migration Zones

Independent variables: These variables that possibly have an association with FT migration will be collected and will help to inform the design of a larger R01 study.

- Patient bedside observation
    - Date/time of data collection
    - Date/time of feeding tube insertion
        - Documentation of dual verification at initial insertion

- Length of feeding tube
- Diameter of feeding tube 10 FR, 8 FR, other
- Rate of formula ____ml/hr
- Bolus via FT yes/no, volume _____ml/hr, frequency: every ___ hours
- Cortrak device serial number
- Length of FT inserted ____cm
- Mark present on abdomen for receiver unit placement? If not, apply mark using surgical marker and indicated date/time.
- bridle present (yes/no)
- Patient position supine/HOB elevated 30 degrees (yes/no). If no, identify position.

- EMR
  - Medical record number on enrollment form that is linked to unique study number. Do not write MRN on data collection form.
  - Was dual verification performed (yes/no).
  - Was x-ray obtained for verification (yes/no)
  - CM mark at nares at time of original insertion
  - Patient demographics
    - Sex
    - Age
    - Weight
    - Diagnosis
    - Height in cm
    - Factors that may impact motility: abdominal compartment syndrome, gastric ileus, abdominal distension, ascites or hepatic enlargement
  - Metoclopramide (yes/no)
  - Erythromycin (yes/no)
  - Vasopressors: identify by name.
  - Vomiting/retching (yes/no)
  - Excessive coughing (yes/no) ask nurse
  - Observed pulling on FT (yes/no)
  - Ambulation (yes/no)
  - Sitting on side of bed or up in chair (yes/no)
  - Prone position
  - Transfer off unit for diagnostic test/surgery or procedure (yes/no) name of test_____ date/time_____
  - Endotracheal tube removed (yes/no) date/time_____
  - Endotracheal tube replaced (yes/no) date/time_____

9. Informed Consent Process

The primary risk for this study is microbial contamination with insertion of the stylet [12] – to mitigate this risk, the stylet will be cleaned with alcohol before every insertion. This study presents low risk level to the patients and a waiver of written informed consent is being requested.

10. Privacy and Confidentiality

Each participant will be assigned a unique study number, which will be known only to the site specific Sub-I and PI. This study number will be used to identify all data collected for the purpose of research. Data collection will be performed on printed forms by the PI or Sub-I. Data collection forms will contain only the participant's unique study number and will be de-

identified. Data collection forms will be stored temporarily during the data collection period in a locked office of the Sub-I. Data will then be entered into a spreadsheet on a password protected Parkview computer. Data will be maintained for a minimum of five years after the completion of the study. Only the investigators will have access to the study data.

Cortrak insertion tracings will be scanned for electronic storage. De-identified insertion tracings from each site, labeled with the file name containing unique study numbers only, will be sent to the other study site for confirmation of FT placement. Having two Sub-Is identify FT placement will increase fidelity of the study. If both Sub-Is are not in agreement regarding the zone of the distal FT tip, the other investigators on the study team (PI and Sub-I) will assess and come to consensus. Transmission of scanned insertion tracings will be sent by institutional email using the confidential setting.

An electronic file linking patient identifiers (human subjects' name, MRN, and study site) and unique study number will be kept in a file on the password protected computer of the PI. Only the principal investigator will have access to this file. The participant identification number will be kept separate from the data collected.

11. Risk/Benefit

11.1 Risk to Participants:

There are minimal risks associated with this study. Insertion of the FT guidewire and verification of FT placement using Cortrak is a standard procedure that can be performed any time that the clinician is uncertain about the position of a FT. The risk to the patient are primarily during the initial insertion, this study will only enroll patients who have the feeding tube currently in place.

The primary risk for this study is microbial contamination with insertion of the stylet [12] – to mitigate this risk, the stylet will be cleaned with alcohol before every insertion.

Loss of confidentiality is always a risk, participation in the study will remain confidential. All demographics and data collected for research purposes will remain confidential. Only the assigned unique study number will be used. Measures will be in place to mitigate the risk for loss of confidentiality, data will be stored on a password protected Parkview computer. Any paper data collection forms will be kept in a locked drawer in a locked investigators office.

11.2 Benefits to Participants*:*

There may not be any direct benefits to individual participants in this study. There may be benefits for future patients with small bore feeding tubes since findings from this study have the potential to influence frequency of feeding tube verification. Knowledge obtained from this study may be beneficial not only for the study sites, but internationally.

12. Safety Monitoring, Interim Analysis, and Stopping Rules

Our study contains no more than minimal risk to the participants.

13. Conflict of Interest

There is no conflict of interest with any of the researchers involved with this study.

14. Publication and Presentation Plans

Findings from this study will be presented by poster or podium at a national meeting, such as the National Teaching Institute (NTI) of the American Association of Critical-Care Nurses (AACN). Findings will also be disseminated in a publication, such as American Journal of Critical Care. Also, as per OH policy, we will plan to present the findings from this study at a Center for Nursing Research meeting.

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15. Appendices

n/a

FIGURE 1:
Cortrak machine

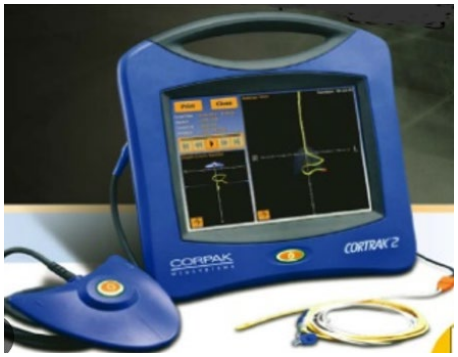

FIGURE 2
Receiver on Cortrak. Top of triangle (top foot) is placed at xyphoid process