Oral Endotracheal Tube Fastener with Tube Protection Sleeve: An Intensive Care Prospective Study

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Abstract

Rationale: Endotracheal tube design has advanced to include a pilot line and subglottic suction. AnchorFast Guard Select oral endotracheal tube fastener (Hollister Incorporated, Libertyville, Illinois) is an oral endotracheal tube fastener with an integrated tube protective sleeve. This design accommodates and helps protect the endotracheal tube and pilot line while allowing for the subglottic suction to remain consistently patent.

Objective: Assess the acceptability and usability of study product AnchorFast Guard Select oral endotracheal tube fastener by clinicians caring for orally intubated patients using an endotracheal tube with the integrated subglottic suction.

Methods: Open-label, prospective, observational clinical study conducted in intensive care unit settings at four hospitals in the United States. Eligible patients who met enrollment criteria had one study device placed. Study device remained in place until no longer deemed required by a clinician. Patient care was consistent with standard health care practices; no treatment was withheld or altered during the study.

Results: In 93% (28/30) of subjects evaluated, clinicians stated it was easy or very easy to apply study product to the patient's face. In all cases, clinicians noted no damage to the endotracheal tube, pilot line, or subglottic suction lumen while the study device was in place. All clinicians agreed the protective sleeve's ability to maintain endotracheal tube patency by preventing occlusion of the endotracheal tube was acceptable.

Conclusions: No new or additional risks with use of the study device were noted. The majority of clinicians indicated positive acceptability to overall experience of patient care with the study device.

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Introduction

Endotracheal intubation is a common procedure in the intensive care unit (ICU) wherein a flexible tube is inserted into the trachea through the mouth.[1,2] The primary purpose is to establish and maintain an open airway to allow for ventilation and oxygenation of patients with acute respiratory failure. Typically, the endotracheal tube (ETT) is secured to the patient with adhesive tape or a commercial tube holder.[2] The ETT itself is often held in place via a holding mechanism that possibly includes adhesive, yet the integrity of the ETT is often at risk due for oral trauma because of the lack of protection inside the mouth.[1,2] Depending on the patient's mental status, the ETT and/or pilot line can be damaged due to trauma caused by chewing or the patient biting the ETT. This can create an emergent leak in the closed circuit between the patient and the ventilator, requiring emergent ETT replacement. In addition to the ETT and pilot balloon (cuff inflation tube), many endotracheal tubes now also provide subglottic suction to help reduce the incidence of ventilator associated pneumonia. To address potential damage to any of the aforementioned tubes, AnchorFast Guard Select oral endotracheal tube fastener with an integrated tube protection sleeve, was developed to accommodate the endotracheal tube, pilot line and subglottic suction lumen. The objective of this clinical study was to assess the acceptability and usability of AnchorFast Guard Select oral endotracheal tube fastener by clinicians caring for orally intubated patients using an ET tube with integrated subglottic suction capability. In this study, the term 'clinician' refers to all healthcare providers (physician, respiratory therapists and nurses).

Methods

Study Product

The study product, AnchorFast Guard Select oral endotracheal tube fastener, is an oral endotracheal tube fastener with a tube protection sleeve (ie, bite block) designed to help reduce the potential incidence of damage or occlusion of ET tubes with an integrated subglottic suction lumen and cuff inflation tube (pilot balloon). The study product is indicated for use by healthcare professionals in securing oral endotracheal tubes ranging in size from 5.0 to 9.0 mm inner diameter and endotracheal tubes with integrated subglottic suction lumen sizes 6.0 to 8.0 mm inner diameter (AnchorFast oral endotracheal tube fastener portfolio website: www.hollister.com/en/anchorfast). The suitability of the oral endotracheal tube fastener must be assessed for each patient. Endotracheal tube holders are categorized as Class 1

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
· 18 years of age or older and require oral tracheal intubation with subglottic ET tube size 6.0-8.0mm. · Required the use of a bite block per the hospital's standard of care · Had intact skin on and around application site, including cheeks and lips · Oral cavity was free of open sores, ulcers, wounds, and lesions · Subject or LAR was able to provide informed consent for the study · Qualified to participate in the opinion of the Investigator, or designee	· Had actual or perceived loose teeth, was without teeth, or was unable to wear upper dentures. · Had facial hair that interferes with the adhesion of the skin barrier pads · Had a clinically significant skin disease or condition, or damaged skin on the application site, such as psoriasis, eczema, atopic dermatitis, active cancer, sores, sunburns, scars, moles · Had a medical condition, surgery or a procedure that prevented the proper application of the study product, including placement of the neck strap. · Had a known or stated allergy to adhesives · Concurrently participating in any clinical study which may affect the performance of the study product

medical devices in the United States and the study product bears a CE mark. Figure 1 displays an actor portrayal of wearing the study product with an ET tube with subglottic suction lumen and pilot line.

Study Design and Procedures

This was an open-label, prospective, observational clinical study where patients in ICU settings at four different hospitals in the United States who met eligibility criteria were enrolled as subjects in this study. One hospital was located in Fresno, California (Community Regional Medical Center) and the three remaining hospitals were part of the Legacy Health system (Mount Hood Medical Center in Gresham, Oregon; Emanuel Medical Center in Portland, Oregon; and Good Samaritan Medical Center in Portland, Oregon). The study objective was to assess the acceptability and usability of the study product where ET tubes had subglottic suctioning capability sizes 6.0-8.0mm. Each subject wore one study product until it either needed to be changed or was no longer deemed required by the clinicians. Patient care was consistent with standard health care practices. All clinicians received training as per the protocol and followed instructions for use for the study product. Per protocol, no treatment was withheld or altered during the course of the study.

Table 2. Patient Demographics at Enrollment

	n; %
Number of completed subjects	30
Gender (Male/Female)	17/13; 57%/43%
Age (years) [average; range]	52.5; 21 – 84
BMI (kg/m^2) [average; range]	28.9; 18.2 – 41.6
Size of ET tube with subglottic suctioning	
7.0 mm	6; 20%
7.5 mm	16; 53%
8.0 mm	8; 27%
Reason for intubation	
Respiratory failures / Pending respiratory failure	21; 70%
Post-operative	0; 0%
Other*	9; 30%
What type of subglottic suction was being used for this subject at the time of study product application?	
Low intermittent wall suctioning suction range 80-135mmHG	16; 53%
Continuous suctioning suction range 20-100mmHG	10; 33%
Manual suction	4; 14%

BMI: body mass index
*Sepsis; Cardiac arrest; Respiratory distress (x2); Airway protection (x5)

Figure 1. Actor portrayal of wearing an AnchorFast Guard Select oral endotracheal tube fastener, with a ET tube subglottic suction lumen and pilot line.

Consent was obtained either directly from the subject or, if the subject was unable to provide consent, by their Legally Authorized Representative (LAR; typically a family member). Subjects were then screened, and if qualified for the study, enrolled in the study. Subject demographic data were collected at enrollment. Assessments of the study product, and of the subject's well-being while wearing the study product, were collected at time of study product application, at each clinician shift during study product use, and at time of study product removal.

Ethics

This study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki (Declaration of Helsinki). The study was reviewed and approved by each clinical site's local Independent Review Board (IRB); all IRB documentation has been archived within the study files. The consent and Health Insurance Portability and Accountability Act of 1996 (HIPAA) Authorization processes were conducted as described in the study protocol (ClinicalTrials.gov NCT03328182, full protocol available at https://clinicaltrials.gov/ct2/show/NCT03328182). A copy of the fully executed Informed Consent was provided to all subjects.

Subjects

Subjects who were 18 years or older and deemed by the study investigators to be appropriate for an endotracheal tube holder with bite-block were eligible for this study. In order to be eligible for participation in this study, each participant had to meet the inclusion and exclusion criteria presented in Table 1.

Table 3. Experiences applying the study product

Question	Positive Response
How easy was it to apply the study product to the face?	28 of 30; 93%
How easy was it to place/insert all three tubes (ET, pilot line, and subglottic lumen) into the protective sleeve?	25 of 30; 83%
How easy was it to snap and click the clamp of the study product after wrapping the ET tube with the strap?	27 of 30; 90%
How securely was the ET tube held in place by the strap and clamp of the study product?	28 of 30; 93%
How easy was it to shuttle the study product from side to side at time of application?	27 of 30; 90%

Study Outcomes
The study objective was assessed via outcomes relating to study product application, ETT placement into protective sleeve, security of ETT, ETT shuttling, oral care, ETT functioning, capability of protective sleeve to protect ETT, integrated subglottic suction lumen, and cuff inflation tube (pilot balloon), and study product removal. Overall acceptability relating to general clinician experience with the study product was also captured.

Data Collection
Electronic Case Report Forms (eCRFs) created by the Sponsor were administered via the use of a cloud-based 21 CFR Part 11 compliant Electronic Data Capture system (Medrio EDC, San Francisco, California). Edit checks on the eCRFs were implemented to enforce data entry guidelines, data consistency, and compliance to the protocol and regulatory requirements. All study data were reviewed for accuracy prior to release for data analysis.

Data Analysis
The analyses datasets included data from enrolled subjects only; subjects who were not enrolled (ie, subjects who consented but failed screening) or withdrew due to improper enrollment were excluded from analysis. Study data were summarized using standard descriptive measures—frequency and percentage for categorical outcomes; average, standard deviation, and range for continuous outcomes. Statistical analyses were performed using SAS v9.4 (SAS Institute, Cary, North Carolina).

Sample Size
Thirty subjects were targeted for this study based on a literature review of two comparable studies and the FDA Human Factors Guidance.[3-5] Both studies aimed at comparing effectiveness of ET tube securement techniques. In the first study, a power analysis was performed before subject enrollment that determined 17 subjects would need to be enrolled to show a difference of one standard deviation from the mean between the two fixation techniques at 80% power and 5% type 1 error. The sample size of 30 subjects was chosen to increase the power of results and include a larger variety of patients undergoing different surgical procedures.[3] The second study, a randomized controlled study, included a sample of 90 patients with 30 in each arm to compare the effectiveness of three ET tube securement techniques (Twill, Adhesive, and Simple Bow) with respect to ET tube slippage, external jugular pressure measurement, oral mucosa and facial integrity and patient satisfaction after the fixation method.[4] Details regarding the power, type 1 error, and effect size sought were not provided.[4]

Results
Subject Characteristics
Thirty-four (34) subjects were enrolled into the study. Thirty (30) subjects completed the study; three subjects were discontinued prior to completing the study, and one subject's consent to participate was withdrawn by their LAR prior to application of the study product. The most common ET tube size was 7.5mm (Table 2). The majority of subjects were intubated due to respiratory failures. A variety of subglottic suctioning was used, with low intermittent wall suction the most common.

The study product was worn for an average of 87.2 hours (3.6 days) with wear time ranging from 1.7 hours – 286 hours (11.9 days). The majority of subjects (29/30=97%) wore the study product for 180 hours or less (7.5 days); one subject wore the study product for 286 hours.

Safety
Four Adverse Events (AE) from three subjects (3/30, 10%) were reported; three AEs were classified as 'Serious'. One serious AE (SAEs) was classified as 'Unrelated' to the study product because the subject expired due to disease progression. The two other SAEs were from a single subject and classified as 'Probably Not' related to the study product. This single subject experienced oral bleeding and loose teeth but the principal investigator determined probably not related to the study product per assessment of the subject's situation. The fourth adverse event was a Non-Serious AE and classified as 'Probably Not' related to the study product. The subject had a lesion above the lip, which may have possibly been a herpetic lesion or an underlying skin condition.

Study Product Performance
Assessments of the study product, and of the subject's well-being while wearing the study product, were collected at time of study product application, at each clinician shift during study product use, and at time of study product removal. The following sections summarize the clinicians' experiences with each phase of the study product. Unless noted otherwise, assessment responses were captured via the use of a standard 5-point Likert scale with a score of 5 being the most positive response. For the following tables, a positive response is defined as a score of 4 or 5.

Application
Table 3 displays the questions and the percentage of clinicians who responded positively. In 93% (28 of 30) of subjects evaluated, clinicians stated it was easy or very easy to apply the study product to the patient's face. Limitations noted by a few clinicians were related to untangling the tubes prior to putting them into the tube holder and separating the oral gastric (OG) tube prior to securing the clamp closed.

During Use
During study product use, at the end of each ICU shift, subjects were monitored for the events displayed in Table 4. The counts

Table 4. Observation Checklist

Event	n; %*
Biting occurred	11; 37%
Pilot line became displaced from the protective sleeve	4; 13%
Tongue Displacement occurred	3; 10%
Subglottic lumen became displaced from the protective sleeve	2; 7%
Difficulty shuttling the study product from side to side	2; 7%
Depth of ET tube was adjusted	1; 3%
Proper oral care was hindered or prevented by the study product	1; 3%
ET tube became displaced from the protective sleeve	0; 0.0%
Any of the three tubes (ET tube, subglottic suction lumen, or pilot line) were removed from the protective sleeve and not reinserted at any point during study product use	0; 0.0%
Occlusion of the ET tube occurred due to the study product	0; 0.0%
Subglottic suctioning was not working property due to the study product	0; 0.0%

*Percentages reflect the percentage of patients (out of 30) for which the event was observed (note that each event may have occurred multiple times)

in the table reflect the occurrence of the event and not the number of times an event occurred. For example, three subjects were noted to have tongue displacement during use of the study product. Each subject may have had tongue displacement occur multiple times during the use of the study product. The most frequently observed event by the clinician was a subject biting while being intubated (37%).

Product Removal

No report of tube migration, adhesive shifting on cheeks, or study product detachment from the face was reported. The most common reason for study product removal was that the subject no longer required intubation (19 of 30 subjects). In one instance, the subject pulled the tube through the clamp. In another instance, the subject self-extubated but there was no injury to the subject. In all cases, clinicians noted there was no damage to any of the three tubes (ET tube, pilot line, or subglottic suction lumen) during study product use. Clinician experiences with the study product, after removal, are presented in Table 5.

At the time of study product and ET tube removal, all lines were inspected and no damage to the ET tube, suction lumen, or pilot line was reported. There were six instances recorded where the three tubes did not remain in the protective sleeve. Subsequently, these clinicians were surveyed to further understand their experience with the three tubes (ET tube, pilot line, or subglottic suction lumen) not staying in place inside the protective sleeve during the course of use. Three of the six clinicians provided feedback. The feedback received from two of the three clinicians indicated that the pilot line and/or the subglottic suction lumen came out of the sleeve while the staff was either providing oral care or turning the subject. In these two cases, the clinicians decided no further action was needed and left the lines out of the sleeve. The third clinician described the pilot line coming out of the protective sleeve when the shuttle broke off of the track while turning the subject. The clinician proceeded to place the shuttle back on the track and leave the pilot line out of the protective sleeve.

In 83% of subjects who were evaluated (25/30 subjects), clinicians found it easy to shuttle the study product from side to side during the course of use. Most clinicians found the study product to be acceptable at facilitating access to the oral cavity to provide oral care (25/30 [83%]) and facilitating subglottic suctioning (30/30 [100%]). The most common limitation in both actions of shuttling the study product from side to side and access to oral cavity were a result of macroglossia and one report due to subject actively biting down on study product. Twenty-eight (28/30, 93%) found the overall performance of the study product to be acceptable. In 97% of the subjects evaluated, based on the clinicians overall experience with the study product, clinicians would like to see the study product used at their facility.

Discussion

Challenges in the current ET intubation environment exist. All intubated patients are at risk of damaging their ETT, pilot line or integrated subglottic suction due to biting or chewing. If the ETT or pilot balloon integrity is compromised, the patient may require emergency ETT replacement. Additionally, patients also can

Table 5. Experiences after removal of the study product

Question	Positive Response
How easy was it to remove the study product from the face?	25 of 28*; 89%
How acceptable was the protective's sleeve's ability to maintain the main airway by preventing occlusion of the ET tube?	30 of 30; 100%
In general, how easy was it to shuttle the study product from side to side during the course of use?	25 of 30; 83%
How acceptable was the study product at facilitating access to the oral cavity to provide oral care?	25 of 30; 83%
How acceptable was the study product at facilitating subglottic suctioning?	30 of 30; 100%
How acceptable to you is the overall performance of this study product?	28 of 30; 93%

*There were two instances in which the clinician did not remove the study product

cause tongue trauma due to the same chewing and biting while intubated. The objective of this clinical study was to evaluate the acceptability and usability of AnchorFast Guard Select oral endotracheal tube fastener, an ETT fastener that accommodates the ETT, pilot balloon and subglottic suction which was designed to help address these potential problems. In this open-label, multisite, prospective study of 30 patients, all ET tubes with subglottic suction ranged between 7.0-8.0 mm with the majority of suction being placed at low intermittent wall suctioning (80-135 mmHG). The average length of time the study product was worn was 87.2 hours with wear time ranging from 1.7 hours to 286 hours. The majority of subjects (29/30 = 97%) wore the study product for 180 hours or less (7.5 days); one subject wore the study product for 286 hours.

Of the 30 subjects, four AEs from three subjects were reported and evaluated by the investigators. Three AEs were classified as 'Serious': one 'Unrelated' to study product (subject expired due to disease progression), two were from a single subject and classified as 'Probably Not' related to study product (oral bleeding and loose teeth). The fourth Non-Serious AE was classified as 'Probably Not' related to study product (lip lesion).

Overall, the study product was given greater than 90% positivity rating for ease of placement to the subject's face, inserting all three tubes (ET, pilot line, and subglottic lumen) into the protective sleeve, and ability to snap and click the clamp after lines inserted. Limitations were related to untangling the tubes prior to putting them into the tube holder and separating the oral gastric (OG) tube prior to securing the clamp closed. There was no consensus among the study clinicians, regarding the specific order of inserting the three tubes (ETT, pilot line, subglottic suction) into the protection sleeve. In 57% of patients evaluated, clinicians placed all three tubes together into the protection sleeve, while in 43% of patients each tube was inserted separately. Regardless of insertion method there was 100% agreement that the ET tube was secure.

There was 83% agreement in ease of shuttling the ET tube from side to side during the course of the study application and 83% agreement the study product provided acceptable access to the oral cavity for oral care. The most common limitation for both of these actions were a result of macroglossia and one report due to subject actively biting down on study product.

The majority of study subjects were kept on the study product until an ET tube was no longer required. This included reasons such as respiratory function recovery, transition to comfort care, or tracheal tube placement. No report of tube migration, adhesive shifting on cheeks, or study product detachment from the face was reported. Other reasons for removal of the study product included: three subjects were transferred out of the ICU, one subject self-extubated, and one study product removed for proning therapy.

At the time of study product and ET tube removal, no damage to the ET tube, suction lumen, or pilot line was reported. In six instances, either the pilot or subglottic tubes were found displaced from its protective sleeve during some point of study; however, there were no reported concerns about the protective sleeve's ability to maintain ETT patency.

Limitations of this study include the small sample size and the absence of a control group. Furthermore, patient reported outcomes were not collected due to the nature of the ICU setting where this device is used. However, by gathering comprehensive study data in a structured and systematic way from intensive care clinicians, this study provided thorough feedback of study product acceptability and usability. Additionally, conducting this study at multiple centers (ie four hospitals) strengthens the study results in the observed patient population.

Conclusion

In the majority of subjects studied, clinicians and providers indicated positive acceptability relating to their overall experience with the study product and recorded they would like to see the study product used at their own facility. Study results did not indicate any new or additional risks with the study product above what would normally be expected with standard of care practice in the ICU setting.

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Author Contributions

RM and GS were involved in study design. AA, LV and BY were involved in data collection. GS was involved in data analysis. All authors were involved in the interpretation of results; writing of the manuscript; final approval of the manuscript; and in the decision to submit the manuscript for publication.

Conflicts of Interest

AA has no conflicts of interest to declare. LV has no conflicts of interest to declare. RM is an employee and shareholder of Hollister Incorporated. GS is an employee and shareholder of Hollister Incorporated. BY has no conflicts of interest to declare.

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