Endotracheal tube to reduce the incidence of ventilator associated pneumonia

Final Report

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Table of Contents

Product design specifications (PDS)
Fluid leakage testing protocol
Spectrophotometer testing protocol

Abstract

Mechanical ventilation is necessary to ensure proper oxygenation of the body for patients who are unable to perform spontaneous respiration. Unfortunately, patients requiring prolonged (>2 days) mechanical ventilation have a high incidence of lower airway infections with the risk of infection being directly proportional to the duration of ventilation. The most common infection associated with prolonged mechanical ventilation is ventilator associated pneumonia (VAP). VAP has been shown to affect 9-27% of all intubated patients and increases patient costs by up to $37,000. Additionally, conventional endotracheal tubes (ETT) have been criticized as the main conduit for pathogen colonization of the lungs. Our design group has designed three possible solutions to improve the efficacy of conventional ETTs in hopes of preventing VAP: a current coil, a cuff wrapper, and a sterile sleeve. Preliminary testing was done to elucidate the efficacy of the prototypes. The cuff wrapper was shown to improve the seal of the cuff by 100% in an anatomical model, however it was difficult to correctly position in the trachea. In a bench top model, the sterile sleeve reduced the amount of paint transplanted into the trachea by 82.5%. Future work includes determining the efficacy of the current coil in preventing bacterial growth and implementing design changes in order to commercialize the prototypes.

Introduction

Mechanical ventilation

Mechanical ventilation, the use of a mechanical respirator to inflate and deflate the lungs, is used when a patient is unable to maintain adequate oxygenation of the body on their own**.** A mechanical ventilator uses positive pressure breathing (increased pressure of the air source) to force air into the alveoli of the lungs where it can then be exchanged with the rest of the body.[11] A patient's inability to adequately oxygenate the body can occur for a variety of reasons with the most common being when they are under the influence of general anesthesia or as a result of serious illness or injury.[3] Mechanical ventilation can be used as either a short term solution (as in during an operation) or a long term solution (such as an home treatment of a chronic illness). Mechanical ventilation is accomplished through either the use of non-invasive or invasive techniques. Non-invasive mechanical ventilation normally consists of a physician or nurse compressing and releasing an air filled bag in order to force air into the lungs. This type of ventilation is normally used as an intermediate short-term solution to a ventilation problem or in circumstances where a ventilator machine is not present. Invasive mechanical ventilation is the primary type of ventilation used during surgery and consists of a ventilator machine designed to forcefully move air into and out of the lungs through an endotracheal tube (ETT), tracheostomy tube, or tracheal tube.[7]

While mechanical ventilation is at times a necessary life preserving process it is associated with several health risks that are a cause for concern. One of the most common health concerns with mechanical ventilation is the development of ventilator associated pneumonia (VAP). VAP is a common occurrence in elderly and young patients along with many in the ICU because of their compromised ability to fight off infections. Studies have shown that VAP risk increases with the duration of mechanical ventilation and is directly linked to the presence of either an endotracheal or tracheostomy tube in the patient's airway. The presence of the tube is believed to increase the risk of obtaining VAP as it both impairs the natural mucocilliary clearance process and disrupts the cough reflex. This inhibition consequently allows bacteria to more easily enter the lungs.[5]

VAP – What is it?

Ventilator associated pneumonia (VAP) is the most common and dangerous nosocomial infection in hospitals among all patients.[2,8,10,13,14,19] VAP is an infection defined as pneumonia occurring in an intubated patient 48 hours or more after mechanical ventilation and is observed in 9-27% of all intubated patients. It is further classified as either early onset (<96 hours after start of mechanical ventilation) or late onset (>96 hours after start of mechanical ventilation) with both variations posing an equal risk to the patient's health and safety.[13] Certain risk factors increase the likelihood of acquiring VAP including age, structural lung disease, prior tracheobonchial colonization, pneumonia severity, and reason for admittance to the ICU or ER (burns and multiple trauma injury), but no patients are completely risk free.[2,14] While mechanical ventilation through an ETT is necessary in life-saving situations, its presence within the trachea is known to produce injury in the trachea mucosa, introduce endogenous and exogenous bacteria, impede the cough reflex, prevent muscocilliary clearance, and provide a direct conduit for microaspirations of bacteria into the lungs.[2,13,14] Due to the differences in symptoms and patient response to VAP, diagnosis is often difficult and adds to the complications surrounding this deadly infection.

A prompt diagnosis of VAP and identification of the pathogen or pathogens responsible for its onset is crucial for proper treatment. Most diagnostic tests available are constantly evolving to ensure both quick and accurate conclusions, but most include a narrowly defined list of clinical observations and criteria. The Clinical Pulmonary Infection Score (CPIS) is one such method defined by six criterion including: a chest x-ray examination, body temperature reading, white blood cell count, tracheobronchial secretion analysis, pulmonary function impairment, and an absence of alternative sources of infection.[19] These criteria are evaluated collectively to define an episode of pneumonia. Another scored test used to predict VAP severity and mortality is the VAP PIRO system (Predisposition, Insult, Response, Organ dysfunction) which depends on four variables independently associated with mortality (presence of comorbidities, bacteremia, shock, and acute respiratory distress syndrome).[2] Scored systems may be used to predict the severity of a case of pneumonia or VAP, but it is also necessary to determine the bacteria or virus responsible to ensure proper treatment. Bacterial or viral classification is accomplished by either Gram staining or bacteria-specific agar culture testing.[2,10,14,19]

Aspiration of either bacterial or viral pathogens into the lungs is the primary mechanism by which a mechanically ventilated patient acquires VAP. The most common microorganisms responsible for VAP are *Staphylococcus aureus*, *Haemophilus influenza*, *Psuedomonas aeruginoa*, *Klebsiella sp.*, and *Escherichia coli*.[2,13,19] While these opportunistic bacteria may be either naturally present within the trachea or introduced exogenously (intubation process, gastrointestinal back-flow, esphogeal secretions, or oropharyngeal secretions), a lack of an immune response allows for rapid colonization of the lungs.[2,19] The well known ability for bacteria to adhere to biomedical polymers leads to an increase in the incidence of bacterial aspiration into the lungs.[8,10] Gram staining is often used for diagnosis of bacterial presence in the lungs and this also helps in determining a proper antibiotic treatment.

Treatment of VAP is largely limited to single antibiotic treatments, antibiotic cocktail treatments, or the immediate removal from ETT intubation and transfer to either tracheostomy or non-invasive mechanical ventilation.[2,13,14] Antibiotic routes of treatment include topical administration, intravenous delivery, and aerosolized sprays with most antibiotics falling into either broad-spectrum or targeted-therapy agent categories. With the ever-growing concern of antibiotic resistant microorganisms, current treatment recommendations favor the use of a single antibiotic agent for each pathogen present (targeted-therapy agents).[2] While general trends indicate most patients respond well to antibiotic treatments, a failure to respond to initial treatment is considered a serious event associated with excess adverse outcomes.[2,19] Both non-invasive and tracheostomy airways restore some host defense mechanisms and allow for easier cleaning of bacteria laden secretions in the throat and trachea; both methods have been shown to reduce the incidence of VAP.[13]

VAP – What causes it?

The presence of an ETT in the trachea prohibits the cough reflex and reduces muscocilliary clearance which indirectly leads to the collection of subglottic secretions in the trachea both above and below the inflatable ETT cuff.[13] Since the body lacks a mechanism to clear the excessive accumulation of thick, mucus-like secretions, if left for an extended period of time, it is inevitably aspirated into the lungs. Once aspirated into the lungs, rapid bacterial colonization may develop and result in VAP.[2,13,14] Normal day-to-day physiological processes allow a person to prevent aspiration of fluids. For example, if fluid enters the lungs it

will irritate sensitive cilia hairs that line the trachea below the vocal cords or the sensitive carina which is located where the two main bronchi branch, leading to a cough reflex to expel the insulting material. In addition to the cough reflex, resident tissue macrophages (alveolar macrophages), neutrophils, and phagocytotic immune cells in the lung tissue rapidly destroy any remaining bacteria.[1] Under homeostatic conditions bacteria present in the body do not pose a threat to one's health, but when the body is stressed benign and foreign bacteria may become opportunistic and hazardous.

Gastrointestinal tract back-flow, oropharyngeal/esphogeal secretions, and oral bacteria are the three main sources of pathogenic bacteria able to invade the trachea during prolonged mechanical ventilation.[2,14,19] The order of bacterial colonization in the body and an *in situ* ETT is the oropharynx, stomach, lower respiratory tract, and finally the ETT.[13] Usually, by the time bacteria have colonized the outside and inside lumens of the ETT, an intubated patient will already have, or be at high risk for developing, VAP. During mechanical ventilation normal digestion and stomach functions are often impaired and allow for a bacterial back-flow from both the normally highly acidic stomach and the bacteria rich gastrointestinal tract.[13,14] During periods of critical illness and high stress (such as an ER or ICU visit), the oral flora is dramatically altered with a marked increase in aerobic Gram-negative bacilli and *Staphylococcus aureus*. These bacteria are able to migrate through saliva and other bodily secretions to the subglottic sections pooled within the trachea or are directly inoculated into the trachea mucosa during the intubation process.[13] Pooled subglottic secretions in the trachea provide the perfect medium for bacteria growth and proliferation.

Mucus-like secretions and saliva pooled in the trachea along the ETT and above the inflatable cuff is a highly effective route of bacterial entry into the lungs. Aspiration of these pooled secretions past the inflatable cuff has been well documented as a primary cause of VAP during prolonged mechanical ventilation.[13,14] Thick secretions are difficult to remove through conventional means (thin suction tubing) and are continually secreted by tissues in the oropharynx and trachea as a means of lubrication. Secretions that bypass the ETT are often inhaled and exhaled through the inner lumen of the ETT during positive pressure ventilation and exhalation and thus allow for the final stage of bacterial colonization: biofilm formation.[13]

A biofilm can be defined as the mechanical attachment of a bacterial community to an inert, non-living object and is used as a means of protection and community communication.

Bacterial communities are able to lie in a dormant, hypometabolic sessile state surrounded by a protective polymeric extracellular matrix that provides protection from both the immune response and antibiotic treatments.[13,14] While the presence of a biofilm on *in vivo* biomedical devices has been correlated to prolonged infection it remains unclear as to whether or not biofilm formation poses a significant risk for acquiring VAP, but it is noted that ETT biofilm formation has been observed in numerous VAP case studies ranging from 70 – 100% of cases.[13,14] One possible route of entry is the partial or full detachment of a biofilm from the inner lumen of an ETT from the shear forces from the influx of ventilator inspiratory gases.[13] Preventing a biofilm from forming or its removal from the outside and inside lumens of an ETT may reduce the occurrence of VAP in mechanically ventilated patients.

VAP - Why fix it?

VAP and its potential causes are an active area of clinical research due to its frequency and severity. VAP is one of the most common hospital acquired infections, and the most common and deadly infection in the ICU. Nationally, there are nearly a quarter million cases annually resulting in over 35,000 deaths. Over 90% of all hospital acquired pneumonias occur in patients who have undergone mechanical ventilation.[6] Historically VAP occurs in 9-27% of all intubated patients.[4] On average, an incidence of VAP increases the length of ICU stay by 28% and is estimated to increase the cost of patient treatment by $10,000 to $37,000.[18] VAP is such an expensive and frequent problem that if an endotracheal tube could be developed to stop VAP it has been calculated that hospitals could spend upwards of $388 per tube for every surgery conducted and still save money when compared to the annual cost associated with VAP.[15]

Conventional ETT problems & overall goal

Since numerous studies have pointed to the ETT as the major pathogenesis in the development of VAP, it is only natural to assume there are potential improvements that could be implemented to reduce the risk factors associated with ETT induced VAP. As noted earlier the key risk factors associated with ETT induced VAP are: the implantation of exogenous and endogenous bacteria in the tracheal mucosa during intubation, inhibition of natural mucocilliary and cough reflexes from clearing subglottic secretions, pooling and aspiration of subglottic secretions, and biofilm formation on the ETT's interior and exterior surfaces. Current

endotracheal tubes leave room for improvement because they fall short in addressing these issues in the following ways:

- They allow subglottic secretions collected above the inflated ETT cuff to leak to the distal end of the ETT via longitudinal folds that form in the inflated cuff membrane. These secretions are subsequently aspirated into the lungs
- Because of the unwillingness to use selective decontamination, due to the fear of resistant strains of bacteria, current tubes have no way of completely decontaminating the subglottic space
- There has yet to be a cost effective method to prevent/remove biofilms from an ETTs exterior surface
- No method has been developed to prevent the transfer and deposition of endogenous bacteria from the mouth and upper throat into the tracheal mucosa during intubation
- Current ETT designs have no completely effective way to maintain a decontaminated environment in the inner lumen
- No way has been developed to mimic the mucocilliary clearance and cough reflex
- ETT's are unable to effectively minimize the pressure on the vocal cords and trachea endothelial cells

These noted short comings have paved the way for the development of a system (used in conjunction with ETTs currently on the market or a completely new ETT design) that addresses the major risk factors of VAP by improving the performance of the cuff, maintaining a more sterile environment in the inner and outer ETT surfaces, and minimizing the potential for contamination of the tracheal mucosa by the ETT during intubation. These potential areas of improvement, along with the danger and cost associated with VAP, are the driving force behind this project which looks to address the inadequacies of current ETT designs in order to create a tube that prevents VAP.

Existing Technology

Standard tubes

Endotracheal tubes have been used to supply oxygen to the lung alveoli during surgery for decades. Currently there are several different ETT types and sizes used during surgery. The most common types used are oral or nasal polyvinyl chloride (PVC) cuffed tubes (the cuff is used to seal the airway). The inner diameter of PVC oral tubes ranges from 2 to 10.5 mm. An un-cuffed oral tube may be used during surgery on a child because their trachea diameter is small enough that the presence of an ETT is enough to create an effective seal. In addition to the most commonly used ETT, anesthesiologists may choose to use a variety of specialty ETTs depending on surgical circumstances. Specialty tubes include RAE tubes (preformed to a specific curvature to reduce trachea pressure and improve insertion), reinforced tubes (for laser surgery), and double lumen tubes (used for single lung ventilation or intrathoracic surgery to collapse a lung).

VAP-reducing technology

In response to the growing concern about VAP and its close association with endotracheal tubes, several different ETTs have been developed in an attempt to reduce the incidence of VAP. The most effective and commonly used of these is the silver coated or impregnated tube. Silver acts as a natural antibacterial agent helping to eliminate biofilm formation and has been shown to significantly lower the rate of aerobic bacteria colonization on both the inner and outer lumen.[6] In addition to silver coated tubes, tubes have looked to use suction or friction to remove subglotic secretions on both the tubes inner and outer lumens. Specifically the Hi-Lo Evac tube and the Mucus Slurper look to use continuous subglotic secretion removal, from above and below the cuff respectively, while the Mucus Shaver uses periodic surface friction to remove biofilms or mucus on the inner ETT lumen. Furthermore, companies like Kimberly Clark, have replaced high volume low pressure (HVLP) PVC cuffs with lower density polyurethane and low volume high pressure (LVHP) silicone cuffs in hopes of eliminating the longitudinal folds that act as conduits allowing bacteria laden pharyngeal secretions to leak into the lungs. Finally, there are several patents that begin to introduce the use of various gels, anti-microbial elements, suction, electricity, and multiple cuffs in hopes of preventing bacteria from entering the lungs.

- USPTO application # 20090101152 (high surface area anti-microbial coated ETT)
- USP 5725510 (use of Ag salt, foil, or vapor deposited coatings on ETT's)
- USP 7452345 (use of antimicrobial coating, electrical current, or ultrasound)
- USPC 604150 (lavage put into trachea to suction out degradative gel)

Despite recent developments, there is currently no ETT on the market, or system that can be used in conjunction with existing tubes, with a design that combines a variety of both passive and active systems, capable of eliminating or minimizing the primary risks of ETT induced VAP.

Client Specifications

Overall design goals

Improve the design of current ETTs in order to reduce the significant risk factors associated with VAP. To be accomplished by addressing some or all of the three improvement areas listed below:

- Improve the ETT's cuff to minimize or eliminate the leakage of subglottic pharyngeal secretions into the lungs
- Minimize or eliminate the risk of tracheal mucosa exogenous bacterial contamination from the ETT as it passes through the mouth and pharynx during intubation
- Create and maintain a sterile environment above the ETT cuff
- Reduce or eliminate the formation of bacterial biofilms on the interior and exterior surfaces of the ETT

Design parameters

The previously mentioned design requirements deal with specific areas on the ETT that need to be improved. The remaining design parameters refer to a general semester outline and the project deliverables for the initial (prototype) phase:

- Concept development – develop a variety of concept designs aimed at addressing the three main improvement areas noted above
- Select the most promising and feasible design concepts for further development and prototyping

- Build preliminary prototype(s) for under $1000
- Do testing of prototype(s) and obtain preliminary data which demonstrates: system functionality, improved ETT performance, and patient safety

Additional client requirements and/or desires

- Prototype(s) can be either an add system designed to be used in conjunction with ETTs that are currently widely used in hospitals (most desirable) or an entirely new ETT design that incorporates the newly developed features
- If any aspect of the system is intended to reusable, prototype(s) must be compatible with hospital sterilization practices (MetriCide cleaning solution)
- Prototype must be safe for the patient and compatible with trachea endothelia cells
- If possible reduce the pressure on the vocal cords associated with intubation and the ETTs presence in the trachea

Preliminary Prototypes

Current coil

The current coil consists of silver-plated stainless steel wires in a double helix shape connected to a resistor and a battery. Numerous studies have shown that silver is a powerful anti-microbial agent and thus the incorporation of silver plated wires are in an attempt to kill VAP causing bacteria.[9,17] By sending a current through the wires silver ions are ejected from the wire and these ions act as anti-bacterial agents. With the current coil's design, there is only a complete circuit when mucus accumulates between each rung of the coil and thus it will only exert an anti-microbial effect when VAP causing bacteria are present.

The stainless steel compression coils were purchased from WB Jones Spring Company and were made of 302-stainless steel (product # 715). The coil was then platted by Professional Plating Inc. with a Silver Plate of 0.00015 inch minimum thickness per MIL-QQ-S-365D, over a Silver-Strike Flash plate of 0.00001 inch minimum thickness per MIL-QQ-S-365D. This ensures a uniform silver coating around the entire circumference of the stainless steel wires. Nickel-Sulfamate was also plated as a base coat to ensure that the silver would adhere to the steel wires.

Next, the steel coils were cut to a length of 11.43 cm to ensure a proper fit in the distal

one-third of the ETT. The silver-plated coil diameter was 7.94 mm which was chosen to ensure the current coil friction fit inside the ETT while the wire diameter of 0.67 mm was chosen so that the coil would remain rigid after insertion. The coil pitch was set at 2.89 mm to ensure an overlap of the coils. The anode is the area where the bacteria are destroyed by the silver ion particles so the pitch was selected at a distance of less than 5 mm to allow for anode overlap. This provides an anti-microbial effect to the entire coil.[16]

The construction of the double helix wires involved using two separate pieces of silver-plated wires and epoxy. Each coil piece was intertwined by hand around a ¼ in x 4 in hex-head bolt while maintaining a constant separation of 1.445 mm (half of the coil pitch) between any two rungs of the coil. This unit was then glued together with Gorilla Epoxy and held to air dry to ensure the pitch between successive wires did not change. Several units were made in a similar way to provide an adequate amount for testing.

A 4.8 mm x 1.5 mm 3V Lithium battery (Digi-Key part number P003CT-ND) was used to construct the current coil unit. A 271 kΩ resistor was placed in series with the battery to make a constant current source. This configuration produces roughly 9-10 µA and was done to ensure an adequate current at all times to generate enough silver ions to destroy bacteria based on a literature review.[9,16,17] The circuit was attached onto the double helix unit with the help of Peter Klomberg, who soldered it together. The current coil units can be seen in *Figure 1* below.

Figure 1: Two different length current coils with resistor and battery attached

In order to increase the ease and feasibility of both creating and inserting the double helix pieces, without the use of epoxy, a supplemental tool was designed.

Insertion tool

After the initial production of the test current coils it was determined that an insertion tool was needed (see *Figure 2* below) to not only allow for a more efficient production of the current coils, but to also allow for an easy insertion into the end of the ETT. The main objective of the insertion tool was to allow for the coils to be fabricated easily and inserted into the ETT while maintaining a constant pitch between the two intertwined helical coils. Maintaining a constant pitch between the coils is important for two reasons: 1) if the coils were to touch the circuit would short and the coil would be rendered useless and 2) the pitch between successive anodes must be kept below 5 mm to ensure a complete anti-microbial effect. The insertion tool solves both of these problems in two main ways: by providing a constant pitch to the coils through the use of screw-like grooves and by offering rigidity to the coil during insertion. The off-set grooves provide a track for the two coils to screw into, which allows them to be uniformly separated, by the acrylic insertion tool, along the coil's entire length. By separating the coils with a rigid plastic (acrylic), the tool not only prevents the coils from shorting out but also helps to preserve the shelf life of the battery by preventing any current flow between the wires during shipping and transport.

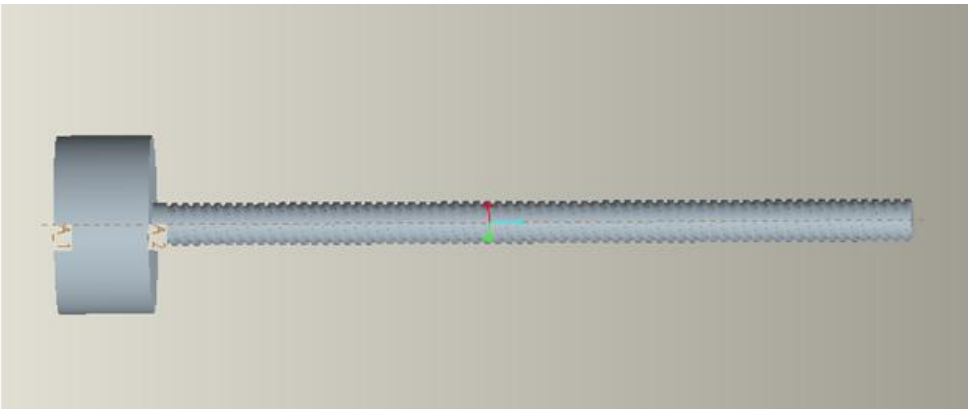

Figure 2: ProEngineering model of the insertion tool. Length of threads is 10.16 cm and the tool is made out of acrylic

Since the ratio of the length:wire diameter of the coil is relatively large the insertion tool was also needed to allow a physician to insert the coil into the distal end of the ETT. Without the use of the insertion tool the coil would simply bend and compress upon insertion which would force the coils together causing them to short out. Even if the bending and compressing did not force the coils together it would make the insertion of the coil a time consuming process and could cause the coil to lose other structural properties (*i.e.*, flaking of the silver plating). By allowing the coils to securely screw onto a solid core (see *Figure 3* below) the tool prevents the coils from compressing or bending and provides the physician with a handle from which they can provide the required insertion torque.

Figure 3: Insertion tool with both coils wrapped around it. Notice the constant pitch of the coils and the clear plastic between every rung

The insertion tool was designed on ProEngineering after discussions with Professor Amit Nimunkar and 3M engineer Mark Childs. The tool was manufactured by Doug Dummer at the UW-Madison Physics Machine Shop. The original specifications of the tool had a groove depth of ¾x the wire diameter, width of slightly larger than 1x wire diameter, and groove off-sets of 1.44 mm. After discussions with Doug Dummer it was determined that a pitch of 2.89 mm and groove width of 0.864 mm was needed to allow for the removal of the tool after insertion of the coil into the ETT. In addition to these changes the handle of the tool was elongated from 2.54 cm to 11.5 cm in order to allow the user the ability to more easily provide the required insertion force and removal torque. The grooves of the tool run 10.16 cm but eventually need to be elongated to 11.43 cm to allow for complete coil stability. Finally, the insertion tool was made from acrylic plastic because it is an easy plastic to machine and also provides the physical and mechanical properties which were required.

Cuff wrapper

Upon inserting the ETT, the cuff is inflated to prevent the flow of fluid into the lungs. However, folds in the ETT cuff create longitudinal columns in which fluid can pass. Effectively occluding the movement of fluid into the lungs would significantly reduce the incidence of VAP during intubation. The cuff wrapper consists of an elongated ring of an elastic and malleable material that fits over the cuff and expands with it when inflated. This fills up the gaps created by the cuff folds and prevent fluid from reaching the lung.

The wrapper prototype was made from 0.79 mm silicone with a diameter of 1.27 cm and a length of 5.0 cm. The wrapper is stretched and placed around the cuff prior to tube insertion. The tube is then inserted with the wrapper around the cuff, and once in place, the cuff is inflated as in normal ETT intubation. The wrapper is stretched as the cuff inflates and is compressed between the trachea wall and the cuff as depicted in *Figure 4* below. When the longitudinal gaps are formed, the wrapper fills in the dead space, and effectively partitions the trachea.

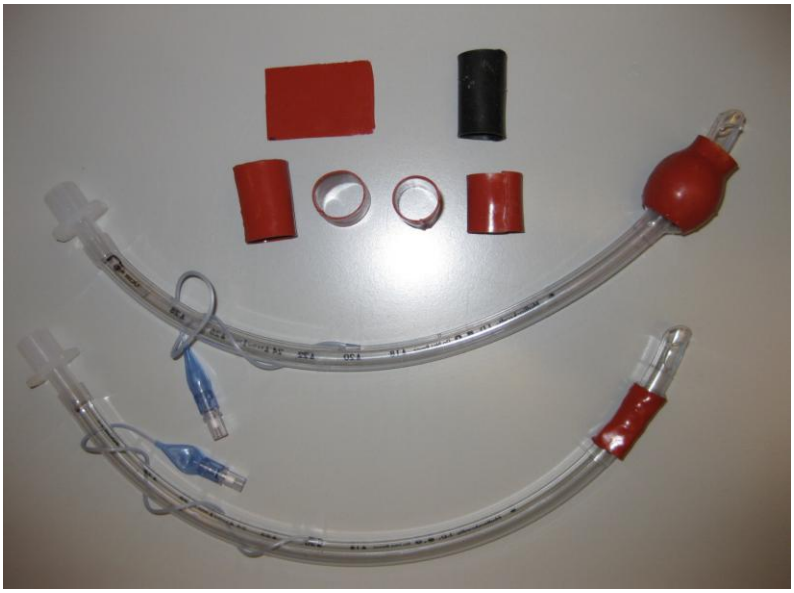

Figure 4: Cuff wrapper design and implementation on the cuff of a conventional ETT

Fabrication of the prototype involved cutting the silicone to specifications with an angled incision where the ends meet to make the ring. The angled incision prevents the formation of a large fold when the cuff is sealed. The ends were adhered using Krazy Glue®, and while this was effective, a custom made wrapper would increase its efficacy and biocompatibility. There is

currently no method to securely fix the wrapper to the tube other than the elastic recoil inherent to the material used and this design flaw is discussed in future work.

Sterile sleeve

Studies have shown that a significant amount of biofilm forming bacteria is collected from the mouth and throat upon initial ETT insertion.[13] The oral bacteria are transferred into the trachea where they can contaminate the mucosa and subsequently causes VAP in intubated patients. The sterile sleeve consists of using a thin plastic material to cover the ETT during insertion, and once inserted, tears away, removing the exogenous oral bacteria with the sleeve. This not only reduces the amount of exogenous oral bacteria in the trachea, it keeps the outer lumen of the ETT sterile until it is placed in the trachea.

The prototype is made of 12.7 μm polyethylene terephthalate (PET), shaped into a sleeve that has a 2.5 cm diameter and a length of 27 cm (*Figure 5* below). The sleeve is held in tube shape with medical grade double sided adhesive and a small fold is made at the end of the tube (approx. 2-3 cm) to keep the distal end of the ETT inside the sleeve until the sleeve is removed. The ETT is inserted into the sleeve prior to intubation. After insertion, the sleeve is torn away, leaving a clean ETT in the trachea.

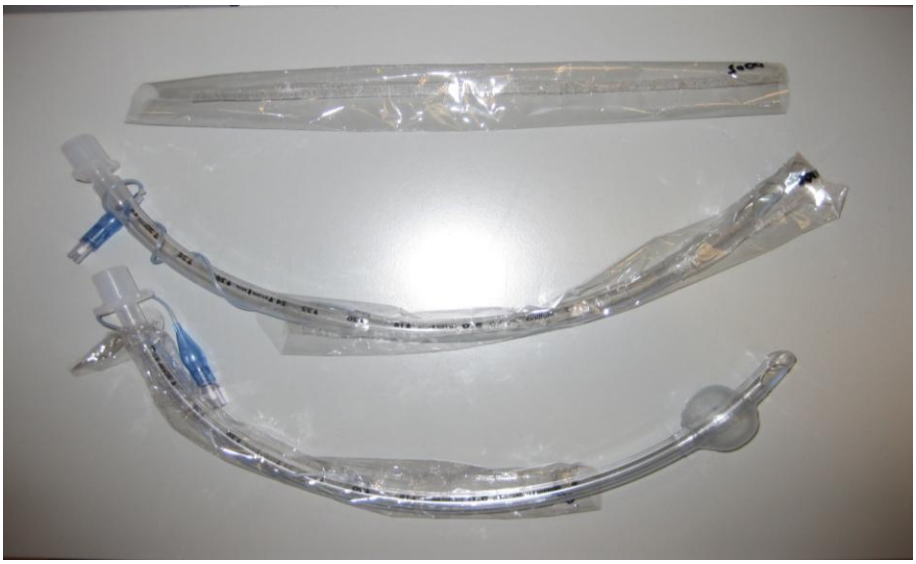

Figure 5: Sterile wrapper and method of use on a conventional ETT

To assist the operation of the prototype, the PET was cut to include a tab at the proximal end to which the person inserting the ETT can grip. Also, a small cut was made close to the tab to help the PET tear. There were some problems with the material used as the PET produced too much friction with the PVC tube and could not be efficiently removed. This was fixed by placing a strip of medical grade cellophane tape on the outside curve of the ETT, thereby reducing the friction enough to easily tear away the sleeve.

Testing

Cuff wrapper

To test the effectiveness of the cuff wrapper, a testing protocol was written that uses a bench top model silicone trachea to test whether or not a silicone rubber gel wrapper around the high volume low pressure (HVLP) ETT cuff is beneficial in preventing the leakage of oropharangeal secretions through longitudinal folds. Rather than use actual mucus or a liquid of similar viscosity, dyed water was used for its ease of use and ability to show quantitative results. As *Figure 6* shows, an ETT was inserted into a mechanically and anatomically similar silicone "trachea". The cuff of the ETT was inflated with 10 mL of air which is approximately equal to the amount inflated during normal ventilation (25-30 cm H_2O).[12] The hose was filled with a 10 cm column of dyed blue water. The water simulated the mucus and fluids that exist in the trachea above the cuff. The setup was left for 10 minutes and the change in water above the cuff was measured. This procedure was repeated for three different ETTs without the cuff wrapper and for the same three ETTs with the cuff wrapper. The entire protocol used can be found in the Appendix (*Fluid leakage testing protocol*). The results of this test indicated whether or not a silicone rubber cuff wrapper around the ETT's HVLP cuff prevented the leakage of subglottic secretions from the trachea and oropharyngeal region into the lower airway (bronchi and lungs).

Figure 6: Testing apparatus simulating trachea full of subglottic secretions without (left) and with (right) cuff wrapper

The results from the cuff wrapper testing were the change in height of the column of water above the ETT cuff. For the three ETTs without the cuff wrapper, the average change in water height was 2.17 cm. For the three ETTs with the cuff wrapper, the average change in water height was 0 cm. All three of the cuff wrapper tests had 0 cm of change in height of the water column and performed as they were designed to. From these results, it can be concluded that the use of a cuff wrapper may greatly decrease the amount of secretions that travel down past the cuff during ventilation. One problem that arose with this testing protocol was that using a cuff wrapper with an increased diameter increased the difficulty of ETT insertion and removal. This was due to the fact that an increased diameter caused the wrapper to stick more to the sides of the model silicone trachea.

Sterile sleeve

In order to test the efficacy of the sterile sleeve, an anatomically correct apparatus was made using polyvinyl chloride (PVC) tubing lined with sponges. This set-up can be seen in *Figure 7.* The sponges were soaked in red water-soluble paint. With the sponges in the PVC tubing, the diameter of the apparatus was similar to the average size of a male trachea (22 mm).[12] After the set-up was complete, the sponges were soaked in red paint and an ETT was inserted into the apparatus four times. Likewise, an ETT with the sterile sleeve surrounding it was inserted four times. The amount of paint found on the end of the ETT in each of the eight tests was quantified using spectrophotometry. The exact procedure used can be seen in the Appendix (*Spectrophotometer testing protocol).*

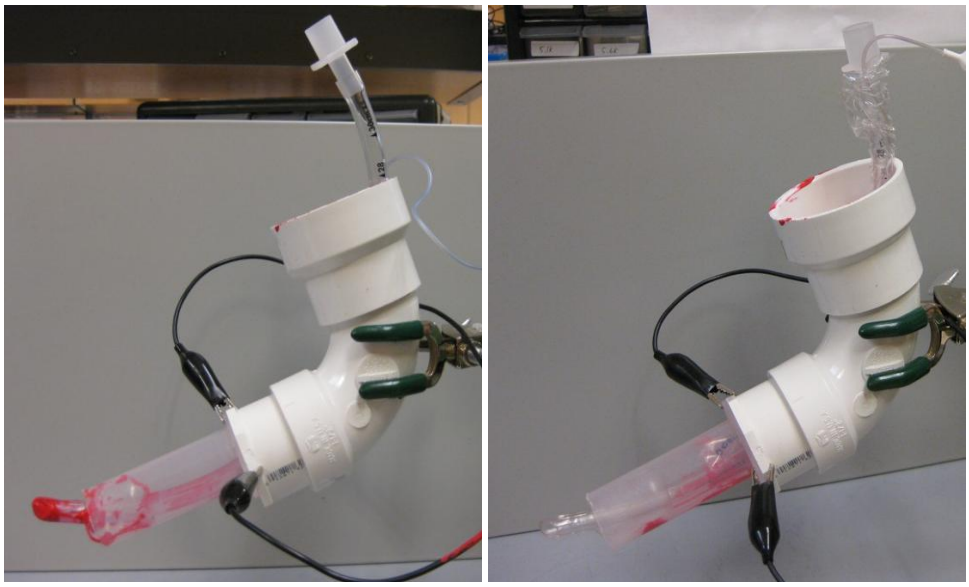

Figure 7: Testing apparatus during mock intubation without (above left) and with (above right) sterile sleeve. Note paint on distal tip of ETT without sterile sleeve

The results from the testing of the sterile sleeve can found in *Figure 8.* This figure shows the amount of paint deposited on each of the eight ETTs tested. The four ETTs tested without wrappers are labeled as ETT1, ETT2, ETT3, and ETT4. The average amount of residual paint on the ETTs without sterile sleeve wrappers was 21.2 mg. The four ETTs tested with sterile sleeve wrappers are labeled as Wrap1, Wrap2, Wrap3, and Wrap4. The average amount of residual paint on the ETTs with sleeve wrappers was 3.7 mg. From these results, we have concluded that using the sterile sleeve wrapper is approximately six times as efficient in decreasing the amount

of bacteria on the ETT during initial insertion or, looking at the results from a different perspective, the sterile sleeve reduced the amount of paint transplanted into the trachea by 82.5%.

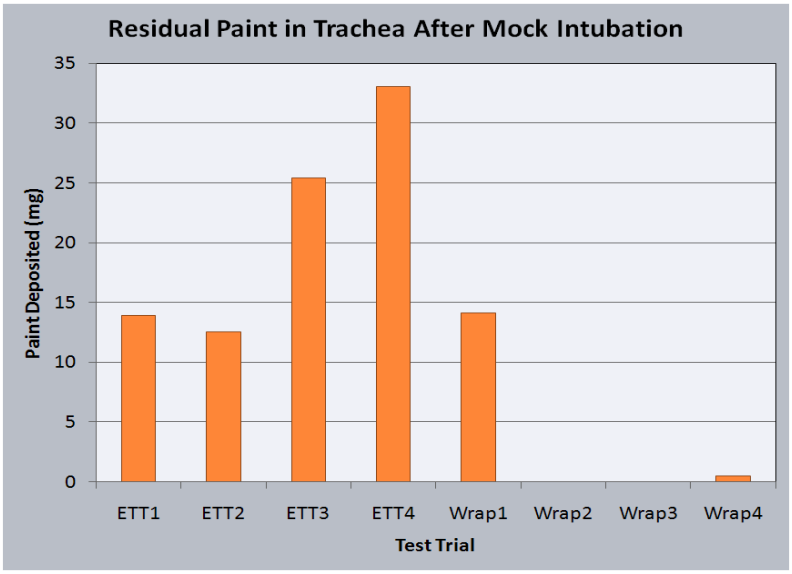

Figure 8: Results from sterile sleeve testing. ETT1, ETT2, ETT3, and ETT4 were tubes tested without a sterile sleeve while Wrap1, Wrap2, Wrap3, and Wrap4 were testing with a sterile sleeve

Cost Analysis

The overall cost of producing and testing the prototypes was $396.25, as shown in T*able 1* (below). It should be noted that this total includes all costs for all three prototypes. These expenditures were well below the $1000 dollar budget provided by Dr. Schroeder and the UW-Madison Anesthesiology Department. The most expensive item of the project was the $150 silver plating required to coat the current coil (this was a minimum charge and would not change significantly with increasing the number of coils coated). The reason that many of these prices are inflated is due to shipping and minimum purchasing prices. The batteries and springs (un-plated) actually only had a unit price of $1.91 and $1.68, respectively. All materials were also ordered in excess of what was required for prototype manufacturing, thereby increasing the overall project cost. The materials ordered for both the cuff wrapper and sterile sleeve would allow for dozens of prototypes to be fabricated resulting in an estimated unit cost of $1.85 per

sterile sleeve and cuff wrapper combination. Additionally, a large budget was allotted for testing equipment and this would obviously be excluded from cost calculations of the prototypes. This was done intentionally in order to ensure sufficient materials would be available in the event of unforeseen fabrication difficulties.

Table 1: Specific costs of materials used for the fabrication of all three prototypes

Item	**Cost**
Batteries	$35.13
Compression Springs	$61.39
Silver Plating	$150.00
Sleeve and Wrapper Materials	$66.63
Testing Equipment and Tools	$83.10
TOTAL	**$396.25**

Future Work

Current coil testing

Testing the current coil prototype is part of the future work that lies ahead for this project. This testing will be done under the supervision of Dr. David Andes, who is the head of the Infectious Diseases department at UW-Madison. The testing includes using *S. aureus* bacteria which Dr. Andes feels is a representative bacterium to use when trying to prove the efficacy of our new prototype. If the coil passes preliminary tests, future tests would be conducted using more resistant strains of bacteria linked to VAP. Each test will be conducted using a viscous "froth" of liquid which contains various salts (to promote conductivity), amino acids, and bacteria in a vibrating 50 ml torpedo tube. The current coil will be fully submerged in the bacteria but extra caution will be taken to ensure that the battery itself does not get wet. After set time intervals (6, 24, and 48 hours) Dr. Andes will run dilution tests to determine if the coil has either killed the bacteria or at least prevented new bacterial growth.

In addition to the various anti-microbial testing, further testing should be conducted to verify and optimize the efficacy of the current coil. Tests should look to identify the optimal current/voltage output and plating thicknesses to ensure the coil has a maximal antibacterial effect. Also testing should be done with several other forms of bacteria liked to VAP in order to identify any possible resistant strains. Finally, tests should be conducted using animal models and eventually humans in order to recognize any possible health hazards associated with the device.

Fabrication and patenting

Another area for future work is creating a more efficient way of producing the current coils. The current method used to create the test coils required a non conductive epoxy to be used in order to prevent the helices from touching. The design and fabrication of the insertion tool helped to ensure a constant pitch between the helices but did nothing to address the ease of connecting the coils to the current supply. Future designs should look to eliminate the time consuming process of soldering the small current source onto the helical coil. In addition to this, future models will require a suitable potting compound to ensure that the implanted battery will not be affected by the presence of liquid mucus.

The placement of the current coil inside the ETT needs to be done quickly and with ease. An area of work that can be done is creating a simple way for doctors or other medical personnel to be able to take the current coil and promptly place it in the distal end of the ETT without any difficulties. The current insertion tool needs to be modified to guarantee that the coil and tool are matched in length so that the tool can provide uniform support to the coil during insertion. This will help to prevent the coils ends from compressing and subsequently shorting out the circuit during insertion.

Streamlining the production of both the cuff wrapper and sterile sleeve remain as the prominent challenges associated with the two prototypes. Eliminating time consuming and error producing steps such as gluing, taping, and cutting materials by hand will allow for consistent and reproducible prototypes. Additionally, biocompatible materials must be utilized in all situations as the prototypes are designed to have contact with the delicate tracheal mucosa cells.

Feedback from Dr. Schroeder and his colleagues about each of our products will be collected before making any additional changes. This feedback will help direct our resources to

the prototype or prototypes which are seen as the most practical ones for implementation in a hospital setting. If any one of the prototypes is deemed to be successful at reducing bacteria and can be implemented in hospitals, we will have a meeting with WARF, where we can present our prototypes to them to check whether we have a patentable design.

Conclusion

In conclusion, three successful prototypes were developed to help protect against acquiring VAP during prolonged mechanical ventilation with a conventional ETT. Bench top testing of the sterile sleeve showed an 82.5% reduction in simulated bacteria transfer from the mouth to the trachea, while bench top testing of the cuff wrapper had a 100% success rate at preventing simulated subglottic secretions from entering the lower airway. Future work includes testing the current coil device *in vitro* to ensure it has anti-microbial effects as hypothesized, continued *in vitro* and *in vivo* testing of the sterile sleeve and cuff wrapper, and streamlining the production of biocompatible, ready to use products. All prototypes are preliminary designs that are meant to prove a concept rather than being functionally complete designs. Patenting prospects will also be pursued through WARF as all three prototypes are unique, novel ideas that have the potential to thwart VAP.

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Appendix

PDS

Function:

The aim of this project is to create an endotracheal tube (ETT), or an attachment to an endotracheal tube, that effectively delivers air to an intubated patient while maintaining a sanitized environment in the tracheal by reducing the formation of biofilms around the device. The prevention of bacterial formation will be accomplished by integrating a combination of effective biomaterials, anti-bacterial solutions, active sanitation systems and/or applying electrical current to the device. In doing this, patient risks of developing ventilator associated pneumonia (VAP) will be greatly reduced, increasing patient safety as well as costs of intubation.

Client Requirements:

- Improve the design of current endotracheal tubes (ETT) in order to reduce the significant risk factors associated with ventilator associated pneumonia (VAP). To be accomplished by addressing some or all of the three improvement areas listed below:
    - Improve the ETT's cuff to eliminate the leakage of biofilms into the lungs.
    - Create and maintain a sterile environment above the ETT cuff.
    - Reduce or eliminate formation of biofilms on ETT walls.
- Build a preliminary prototype for under $1000.
- Prototype can be either an add-on to currently used ETTs (most desirable) or an entirely new ETT.
- If reusable prototype must be compatible with hospital sterilization practices (MetriCide cleaning solution).
- Prototype must be safe for the patient and compatible with trachea endothelia cells.
- Obtain some preliminary data in order to prove antibacterial capabilities of the prototype.
- If possible reduce the pressure on the vocal cords associated with intubation.

1. Physical and Operational Characteristics

    a.) Performance requirement: The ETT should reduce the risk of patient acquiring VAP or other noscomial infections through both passive and active defense mechanisms.

Passive elements include bioadhesive resistant materials, antibiotics, silver embedded foams, and/or semi-viscous gels. Active elements include suctioning and lavage devices, UV sterilization methods, low dose electrical current, and/or any other user input required mechanism of sterilization.

b.) Safety: The ETT will be used *in vivo* and thus must meet all safety standards to ensure no adverse effects on the body. It should reliably prevent VAP formation while maintaining its primary function as an advanced airway.

c.) Accuracy and Reliability: The ETT should not prevent airflow to the patient. See *Safety* section above.

d.) Life in Service: Prolonged intubation (>48 hrs) greatly increases the risk of acquiring VAP so the ETT should be expected to be in situated within the trachea for a minimum of 48 hours for as long as the patient is intubated. ETT's are single-use and disposable.

e.) Shelf Life: A sterile environment shelf life of at least 5 years.

f.) Operating Environment:

g.) Ergonomics: The device should allow for intubation in a similar manner to existing ETT's. In addition, the geometry of the new ETT should be made to prevent any damage to the vocal cords, trachea, or any other part of the advanced airway.

h.) Size: ETT's range from 2-10.5 mm internal diameter, however the cuff of the ETT also needs to be compact enough to prevent damage to the vocal cords as it passes through the trachea.

i.) Weight: Weight should be comparable to the weight of current ETT's on the market.

j.) Materials: Current ETT's are made of polyvinyl chloride (PVC) medical tubing with a polyethylene (PE) cuff. All plastics, gels, foams, or metals used in the new device should be medically safe, FDA approved, and non-toxic.

2 Production Characteristics

a.) Quantity: One prototype ETT is the goal for this semester.

b.) Target Production Cost: A cost effective analysis of reduction of VAP using silver salt coated ETT's indicated that a break-even point for ETT cost is $388 per tube when VAP is prevented [2]. This should be set as a maximal per tube cost for a final end product.

3. Miscellaneous

a.) Standards and Specifications: FDA approval would be required before the product could be used *in vivo*

b.) Consumer: Medical practitioners and hospitals will be the primary consumer of our device however the ETT will be designed for patient intubation.

c.) Patient-Related Concerns: Sanitization of the trachea and surrounding airway is crucial in preventing the onset of VAP in patients. All defensive mechanism must be FDA approved prior to use *in vivo*.

d.) Competition: At this time, there are many different ETT's on the market, but none of them incorporate all of the ideas and solutions that our design would incorporate.

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Fluid leakage testing protocol

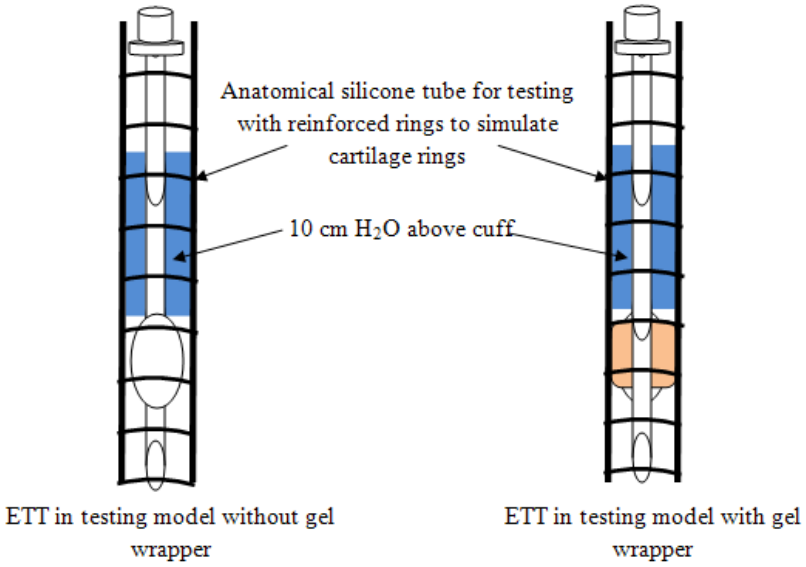
Introduction

Mucus-like secretions and saliva pooled in the trachea along the endotracheal tube (ETT) and above the inflatable high volume low pressure (HVLP) cuff is a highly effective route of bacterial entry into the lungs. Aspiration of these pooled secretions past an HVLP cuff has been well documented as a primary cause of VAP during prolonged mechanical ventilation.[2,3] Thick secretions are difficult to remove through conventional means (thin suction tubing) and are continually secreted by tissues in the oropharynx and trachea as a means of lubrication. Longitudinal folds almost always form in conventional HVLP cuffs due to shear and compressive forces from the trachea walls. To avoid damaging the trachea mucosa the pressure

in the ETTs HVLP cuff must be kept below 30 cm H_2O and thus a full trachea-cuff seal is impossible.[1]

Ideally, the prevention of longitudinal folds from forming could potentially prevent oropharyngeal secretions laden in bacteria from entering the lungs. Preventing shear and compressive forces from developing in the cuff are one possible way to circumvent these folds. Additionally, a gel-like wrapper that fills in the folds but is biologically compatible with the trachea wall could be used to essentially plug the gaps. This testing protocol will use a benchtop model trachea to test whether or not a silicone rubber gel wrapper around the HVLP ETT cuff is beneficial in preventing the leakage of oropharangeal secretions through longitudinal folds in an apparatus as described elsewhere and shown below.[1]

Testing model



Equipment

- 2.2 cm diameter silicone tubing from Laerdel Medical Silicones (part #87100)
- 2 endotracheal tube (8mm ID)
- Ruler
- Custom made silicone rubber gel wrapper
- 60 cc syringe for inflating HVLP cuff
- Tap water

Procedure

1. Each series of steps will be repeated for an ETT with and without a gel wrapper
2. Insert ETT into silicone testing apparatus and inflate HVLP cuff with 10 mL of air using a 60 cc syringe. This will act to simulate the 20-30 cm H_2O pressure exerted against the trachea wall in a typical intubation procedure
3. With ETT secured in tube, fill with a 10 cm column of colored H_2O ("subglottic secretions). Affix a ruler near the silicone tube to allow measurements to be made on the liquid column
4. After 20 minutes record final water level and repeat experiment as necessary

Conclusion

The results of this test will indicate whether or not a silicone rubber gel wrapper around the ETTs inflatable cuff will prevent the leakage of subglottic secretions from the trachea and oropharyngeal region into the lower airway (bronchi and lungs).

Sources

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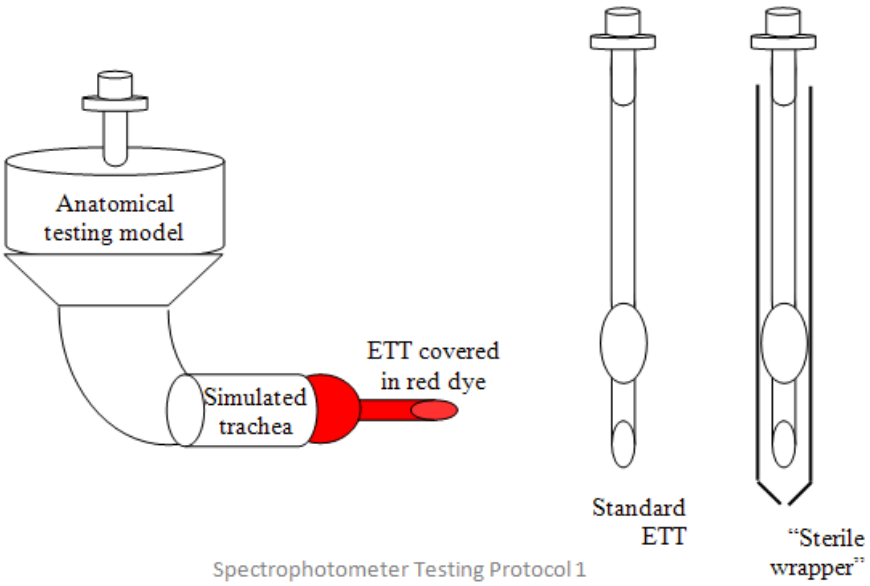
Spectrophotometer testing protocol

Introduction

The transfer and/or implantation of endogenous oral bacteria into the trachea mucosa has been linked to the occurrence of ventilator associated pneumonia (VAP) in patients intubated with an endotracheal tube (ETT).[1,4,5] While intubation is often a life-saving procedure, the act of inserting an ETT in the trachea can lead to trauma of the delicate mucosa which normally acts

as a protective host defense mechanism; the trachea mucosa secretes mucus to trap pathogens and particulates, is dense in phagocytoic alveolar macrophages, and is lined with cilia that sweep in an upward fashion to move mucus from the larynx up into the pharynx (cilliary escalator).[2] By reducing the transfer of opportunistic bacteria from the upper airway (oral cavity and pharynx) into the lower airway (trachea and bronchi) the potential of eliminating or delaying the onset of VAP could be dramatically increased. This testing procedure will help to elucidate the efficacy of a "sterile wrapper" modular add-on to currently existing ETTs.

Spectrophotometry can be used to determine the concentration of a substance (or substances) based upon the principle of absorbance. For this test a CHEM2000 Spectrophotometer (PC2000 PC Plug-in Fiber Optic Spectrometer, a tungsten–halogen light source with integrated cuvette holder, an optical fiber, and operating software) will be used to determine the concentration of a single solution of red, water soluble paint and tap water. In spectrophotometry, a multiple wavelength light source illuminates a sample that is placed in a cuvette. Not all of the light shone on the sample is transmitted through the sample, but the light that is able to pass through is collected and sent to a spectrometer (all wavelengths are transmitted through the sample in differing amounts) via a fiber. An ADC is used to convert the analog data into a digital signal that is displayed on a computer screen. Every substance has a characteristic absorptivity that is unique to the particles in the substance and thus light is absorbed in varying amounts depending upon both the substance and the wavelength of the light used in the spectrophotometry test. This protocol will use red paint to represent oral bacteria in an anatomically correct testing model as depicted below.



The figure in the above left shows an ETT inserted into an anatomically accurate testing model which is filled with paint soaked sponges. Paint will be collected from the distal end of the ETT to determine how much "oral bacteria" was transferred from the upper airway to lower airway. The two images to the right show ETTs with and without a "sterile wrapper" add-on as labeled above. The sterile wrapper will be left on during intubation and removed after the ETT is within the trachea but before the cuff is inflated. The wrapper will break away when pulled on from the proximal end of the ETT at the opening of the patient's mouth.

Theory

A single solution may be analyzed by passing light (spectrum of visible wavelengths) through a cuvette of known length (L) containing a sample of the solution. The light intensity entering the cuvette is known as the incident light intensity (I_o) and the light intensity exiting the cuvette is known as the transmitted light intensity (I). Transmittance (T) is defined as:

$$T = \frac{I}{I_o}$$

while percent transmittance (%T)is defined as:

$$\%T = \frac{I}{I_o}$$

The amount of light absorbed depends on the distance (L) of sample it has to travel through since a longer distance of travel will encounter more light absorbing molecules, which each absorb an

equal amount of light at a given wavelength. Thus the unit length (L_o) is inversely proportional to the concentration (C) of the sample. This relationship is expressed as:

$$L_o = \frac{1}{aC}$$

where a is a constant unique to the solution being tested.

Using the above relationships a substitution can be made as follows:

$$T = 10^{-(L/L_o)} = 10^{-LaC}$$

which is also used as the Beer-Lambert Law (logarithmic function of transmittance; absorbance (A)) defined as:

$$A = LaC = -\log(T)$$

where the constant a is further designated as the molar extinction coefficient or absorptivity of the solution and is unique to the solution being tested as a function of wavelength.[3]

Equipment

- Anatomically correct trachea model (PVC pipes)
- Sponge cut to fit in model and fill in dead space
- Red, water soluble craft paint
- Endotracheal tubes (6)
- Analytical balance
- Beaker or graduated cylinder
- CHEM2000 Spectrophotometer (PC2000 PC Plug-in Fiber Optic Spectrometer, a tungsten–halogen light source with integrated cuvette holder, an optical fiber, and operating software)
- Clean cuvette
- Kimwipes and paper towels
- 3-5 “sterile wrapper” prototypes
- Tap water (200 mL per test)
- Prepared stock solution of known paint concentration. Specific concentration does not matter; it will solely be used as a comparison to what is collected off the distal end of the test ETTs

Procedure

Stock solution

1. Prepare stock solution of known concentration paint and water mixture. Concentration units may be arbitrary (*i.e.*, *w* drops per *x* mL or *y* grams per *z* mL) but it is important to record specifically how much water was used (mL) and how much paint was used (drops or grams)
2. Create serial dilutions of stock solution as this will be used for a standard curve to determine unknown solution concentrations

Initial preparations

1. Plug in CHEM2000 Spectrophotometer and allow lamp to warm up for 20-30 minutes
2. With an empty cuvette in the sample slot take a reference spectrum (in scope mode) by clicking store reference spectrum
3. Completely block the light source (in scope mode) and take a dark spectrum by clicking store dark spectrum. Note if any program parameters are changed (*i.e.*, integration time) repeat steps 2 and 3.
4. Fill cuvette with prepared stock solution. Click the absorbance mode icon and save the spectrum with the save icon. Repeat for all dilutions
5. Soak sponge cut outs in red paint and place in testing apparatus just prior to next set of steps (below)

ETT tests

1. Using a standard ETT, mock intubate the PVC testing model (filled with paint soaked sponge) and inflate distal cuff. Take a picture of the distal end of the ETT. Deflate cuff and remove extension fake trachea from testing apparatus
2. Using a predetermined volume of warm tap water (volume must be constant for all tests or recorded if different; suggest 100 mL), quickly wash distal end of cuff and extension tube to remove all paint transferred from testing apparatus
3. Fill cuvette with sample of water from step 2 above, click the absorbance mode icon, and save the spectrum with the save icon

4. Repeat steps 1-3 at least three times for each condition being tested (“sterile wrapper” or standard endotracheal tube). Add paint before each new step 1 is repeated
5. Analyze data using Microsoft excel or MatLab to determine quantity of paint transferred to distal end of the ETT for each condition

Conclusion

The results of this test will indicate whether or not a “sterile wrapper” addition to current intubation protocols is a viable means of reducing the transfer of endogenous oral bacteria to the trachea mucosa which has the potential to reduce the alarming incidence of ventilator associated pneumonia in ICU and ER settings.

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