Endotracheal tube to reduce the incidence of ventilator associated pneumonia

Mid-Semester Report

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Abstract

Mechanical ventilation is necessary to ensure proper oxygenation of the body for patients who are under general anesthesia or who for some other reason cannot adequately breathe for themselves. Mechanical ventilation carries with it the risk of acquiring infectious diseases due to an impediment of natural physiological defense mechanisms. These risks increase in direct relationship to the length of time a patient is on a respirator. The disease most commonly associated with the prolonged presence of an endotracheal tube (ETT) in the trachea is ventilator associated pneumonia (VAP). Numerous studies have identified three areas of improvement as possible ways to reduce the incidence of VAP: 1) maintaining sterility in the trachea above the ETT cuff, 2) minimize, or eliminating, the leakage of subglottic secretions around the cuff of the ETT and into the lower trachea, and 3) preventing the formation of biofilms on both the exterior and interior lumens of the ETT. Group brainstorming led to the development of three design categories related specifically to the three areas of improvement above, each of which with three or four design options for further consideration. After the design options were evaluated, using a design matrix, the designs chosen to be pursued this semester were: 1) a gel/putty wrapping around the ETT cuff, 2) a helical current carrying wire on the internal ETT lumen, 3) an external mucus shaver, and 4) a sterile, removable wrapper to be used during intubation. All four designs will be constructed in such a way that they could be used in conjunction with virtually any ETT that is currently available on the market. The next steps in the design process will be researching and finalizing our design options and then moving on to prototype fabrication and testing.

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.[2,8,10,12,13,16] 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.[12] 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.[2,13] 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.[2,12,13] 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.[16] 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.[2,10,13,16]

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*.[2,12,16] 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.[2,16] 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.[2,12,13] 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.[2,16] 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.[12]

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.[12] 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.[2,12,13] 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.[2,13,16] The order of bacterial colonization in the body and an *in situ* ETT is the oropharynx, stomach, lower respiratory tract, and finally the ETT.[12] 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.[12,13] 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.[12] 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.[12,13] 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.[12]

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.[12,13] 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.[12,13] 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.[12] 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.[15] 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.[14]

Current 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 lungs 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

Design Categories

Cuff related designs

The gel/putty wrapping idea attained the best score relative to the other ideas in this design matrix. This identifies it as the most effective choice to pursue and try to incorporate into the final design.

Cuff Related	Feasibility [15]	Patient Safety [20]	Efficacy [30]	Cost [20]	Ease of use [15]	Total [100]
Gel/putty wrapping	10	17	29	18	11	**85**
Subglottic secretion trap	13	18	21	15	10	77
Space filling gel/foam	8	13	19	15	13	68

1. *Gel/putty wrapping*

The gel/putty wrapping idea consists of using a material, gel or a putty, to 'seal up' the area around the cuff when it is inflated. The material used must be highly elastic and malleable, as well as non-toxic to ensure patient safety during intubation. The material would be formed into either a sleeve to slide over the cuff, or a sheet to roll around the cuff prior to the insertion of the ETT. Once the ETT is inserted, the cuff is inflated and the gel or putty stretches with the cuff and fills in where the cuff folds on itself.

This idea scored the best in both efficacy and cost due to the simple nature of the idea. Assuming a suitable material is found to use for the wrapping, it would provide an effective seal in the tracheal, preventing any flow of mucus from reaching the lungs. The cost of producing a sheet of procuring a polymer gel or putty would be reduced due to the simple formation of the design; a large amount could be purchased in a sheet and cut to scale. Where this idea didn't exceed the other ideas, it still scored well. Patient safety received a high score since the material would conform to the shape of the cuff, there would not be any added obtrusion when inserting the ETT. The feasibility of this design is only limited by the identification of an appropriate material to use, and the ease of use was not as high due to the process of fitting the material to the cuff and introduction of human error.

2. *Subglottic secretion trap*

The subglottic secretion trap consists of using a conical shaped piece of material to form to the sides of the trachea and prevent the flow of mucus past the cuff. The material would need to be elastic to fit the contours of the trachea but still provide enough shear strength to occlude the flow of mucus and hold it above the cuff. The material also needs to be non-toxic. The trap would be conical shaped in order facilitate both to better fit contour of the tracheal walls and to maintain appropriate shear strength from downward flow. The trap would be placed above the cuff prior to ETT insertion, the procedure of insertion would not change significantly.

The trap received the best score for patient safety due to the shape of the design. The disc would not add any extra obtrusion during insertion, and would have minimal contact with tissue to reduce any host response. The design also surpassed other ideas in feasibility; finding an appropriate material with the desired properties would not be difficult with the wide array of polymers and similar materials available. The efficacy of this design is highly subjective to the

shape of the trachea of each individual patient and therefore it scored low. The trap fell short on cost due to an increased cost arising from both procuring the material and forming it to the desired shape. Lastly, it scored low on ease of use due to the process required in extraction. In order to safely extract the ETT from the patient, the trap would need to be lifted up so that it didn't hit the vocal cords on the way out and cause damage.

3. *Space filling gel/foam*

The space filling gel/foam design consists of incorporating a material, potentially a gel or foam, which would expand in volume once inserted to fit between the vocal cords and the top of the cuff to absorb subglottic fluid above the cuff and with it, potentially harmful bacteria. The material would need to be able to be expanded and compressed in order to facilitate ETT insertion and extraction, have absorptive properties and be non-toxic to ensure patient safety. The shape of the design would expand to fit the shape of the trachea for a given distance of the tube to provide maximum absorption. The device would be placed on the tube prior to ETT insertion and upon insertion the gel/foam would be expanded over the course of intubation. Upon extraction, the material would be compressed to fit past the vocal cords without damaging them and pulled out with the ETT.

In the design of the space filling gel/foam device, a mechanism to expand and compress the material would need to be built in giving this design the highest score for ease of use. However, for all other criteria, this idea scored lowest. The material properties desired for this idea would be difficult to find in a non-toxic form, giving a low score for feasibility. Even upon finding the right material, there would be a saturation point to where the material would no longer absorb any fluid, giving a low score for efficacy. Also, upon compression of the material when extracting the ETT, the absorbed fluid would get squeezed out while still distal to the epiglottis. Lastly, the cost of producing such a mechanism that allows for both expansion and compression of a material, along with the cost of the material, would be increased relative to other design ideas.

Inner lumen related designs

The current-coil design scored the highest among all other inner lumen related designs. This design option will be pursued throughout the rest of the semester.

Inner Lumen	Feasibility [15]	Patient Safety [20]	Efficacy [30]	Cost [20]	Ease of use [15]	Total [100]
Current-coil	12	12	28	14	12	**78**
Silver/antimicrobial coating	7	16	25	14	14	76
Anti-adhesive polymer	7	18	18	18	14	75

1. *Current-coil*

The current-coil concept consists of running a low current (<10μA) through silver plated wires wrapped in a double helix formation and inserted into the inner lumen at the distal end of the ETT. The concept is based on numerous studies that have demonstrated the powerful antibacterial effects of weak direct current with little risk to mammalian tissue.[9] The lead wires will be connected to a to a power supply. The total length of the electrodes will be roughly one-third of the total length of the ETT, as again studies have shown that biofilms form quickly on the ETT lumen's distal third.[9] The polarity of the current will have to be periodically switched so that both legs of the double helix take turns as the anode, since the greatest antibacterial effect has been observed at the anode pole. A plastic insulator electrode retainer with an ETT attachment clip will be placed at the distal end of the tube to allow the wires to clamp on the ETT. The other end will have the lead wires soldered to electrode ends.

The construction of the current-coil ETT would not be too difficult and was given a sufficiently high score in feasibility, as seen above. However, the presence of a current inside a patient does warrant a potential safety concern, as current leakage directly to the patient (even at the extremely low currents being used) may damage the epithelial cell lining. Hence it was given a lower score for patient safety. A high score for efficacy was given due to the strong antibacterial effects electrical current possesses. Since the design construction is not complicated by nature, cost was given a low score. Finally, a low ease of use score was given, as this design has a current running in an invasive device.

2. *Silver/anti-microbial coating*

This method consists of coating the inner lumen of the ETT with silver, or any other anti-microbial element. This design is quite prevalent on the market today due to silver's strong anti-

bacterial effects along with its tendency of producing no bacterial resistance. This design would aim to decrease bacterial colonization in the inner lumen of the ETT.

The production of the silver/antimicrobial coating in the ETT would be arduous, giving it a low score for feasibility. Since silver has no known side effects, it would not be considered harmful to the patient, resulting in a high score for patient safety. Efficacy has a high score due to silver's anti-microbial effects, although not as high as the current-coil design. The silver/antimicrobial coated tube would be easy to use and so a high score is given in the last category, as shown in the inner lumen matrix above.

3. *Anti-adhesive polymer*

This design consists of decreasing bacterial adhesion in the ETT by using an anti-adhesive polymer. Studies have shown links between biofilm with bacterial virulence. With the use of an anti-adhesive polymer, the reduction of bacterial adhesion can occur, resulting in the reduction of biofilm formation in the ETT. Studies indicate that many techniques have demonstrated the ability to reduce bacterial adherence, some more than others.[8,10] A disadvantage of this design would be that it would not be as cost-effective as the other devices.

This design also has difficulty involved in its production, leading to a low score in feasibility. Since the polymer causes no threat to the patient, the patient safety score was rated high. Efficacy was rated lowest due to its questionable ability to prevent biofilm formation. Cost was given a high score as the polymers could be expensive, especially the ones more effective against the specific types of bacteria found in the trachea. Lastly, this device would be simple to use and was given a high score.

Miscellaneous designs

Overall, the two highest scoring designs from the miscellaneous matrix are the external mucus shaver and the sterile wrapper. Going forward, we will attempt to model and fabricate both of these designs since they can both be used as "add-ons" to the current most commonly used ETTs and are promising and innovative ideas.

Miscellaneous	Feasibility [15]	Patient Safety [20]	Efficacy [30]	Cost [20]	Ease of use [15]	Total [100]
Lavage & suction	8	17	24	12	13	74
Esophageal plug	7	14	18	12	10	61
External mucus shaver	13	19	25	17	14	**88**
Sterile wrapper	10	19	21	18	14	82

1. *Lavage & suction*

Several possible components of the design do not fit into the cuff related or inner lumen categories. The first of these designs is the lavage and suction design. This design includes an additional small separate tube that would be connected to the side of the ETT. An antibacterial fluid would be circulated on top of the cuff, similar to the way that mouthwash is used in the mouth. This design would be difficult to actually fabricate and carry out, especially if it is made as an attachment to a current ETT. However, if made, this design would most likely be fairly efficient in removing bacteria, thereby preventing biofilm formation. This design scored low in cost rating, because the type of anti-bacterial fluid needed for this design is unknown to the authors and would most likely not be very cost effective.

2. *Esophageal plug*

Another proposed design is the esophageal plug. The esophageal plug would be an attachment to the current ETT near where the trachea and esophagus diverge in the throat. This plug would prohibit fluids from the gastrointestinal (GI) tract from refluxing into the trachea and down into the lungs causing VAP. While the plug sounds promising, its feasibility will prove to be a problem, as it would be difficult to design a plug of some type (balloon-like, foam-like, or otherwise) that could be placed and removed without significant problems. Furthermore, its efficacy comes into question, since at its full potential it would only stop fluids from the GI tract and not from the mouth or throat which is the larger problem. The esophageal plug would most likely significantly raise the cost of the ETT since a great deal of research would need to be done to decide the best material to use.

3. *External mucus shaver*

The external mucus shaver is very similar to the previously discussed Mucus Shaver, except for that it would shave biofilm formation from the outer lumen rather than the inner

lumen. The external mucus shaver would work by sending down an elastic material that, once at the region just above the cuff, could be tightened and pulled up and out the throat. By pulling up the external mucus shaver, one would be removing any biofilm formed on the outer lumen. This design appears to be the most feasible to design and fabricate, especially since it could be an addition to any already existing ETTs. Furthermore, it would be efficient in removing biofilms formed from secretions that had come from the mouth or throat and a non-threat to the safety of the patient. Because an internal mucus shaver already exists in the market, costs would be minimal and healthcare personnel would have little difficulty in using the product.

4. *Sterile wrapper*

The final miscellaneous design is the sterile wrapper. This design can be likened to a "straw wrapper" that covers the entire tube. The sterile wrapper would cover the entire ETT before intubation. Directly after intubation, the wrapper would be pulled off of the ETT by the physician or nurse, so the ETT cuff could be inflated. The purpose of the sterile wrapper is to greatly reduce the amount of bacteria from the mouth and upper throat that would be transferred to the outer surface of the ETT during insertion. Studies have shown that a significant amount of the biofilm forming bacteria is collected from the mouth and throat upon initial ETT insertion.[12] They are then transferred into the trachea where they can contaminate the mucosa. The sterile wrapper would fix this problem by keeping the outer lumen of the ETT sterile until after it is correctly in place. This design appears promising and innovative. Its fabrication would not be too difficult and the patient would have very little risk of being harmed. The efficacy of this design is hurt somewhat by the fact that it is only used at the intitial insertion and if the patient were to be intubated for many days or weeks, risk of VAP would not decrease as much. However, sterile wrapper would mostly be made from a cheap material and would be easy to use in a clinical or hospital setting.

Proposed design

The final proposed design will include the gel/putty wrapping, current coil, sterile wrapper and external mucus shaver. In addition to these design ideas, if the final design is a completely new ETT, then the tube will be of a triangular shape, rather than the cylindrical shape

that is in current use. The purpose of the triangular tube design would be to reduce unnecessary pressure on the vocal cords.

Future Work

Prototype fabrication

The second half of the semester will be focused on manufacturing the endotracheal tube system and all of its components. The manufacturing of each component will be undertaken by 1 or 2 group members and seen through to completion. Currently it is the plan to meet with:

- Professors Webster and Nimunkar (University of Wisconsin-Madison)
- John J. Warinsky (Metallurgist 3M Company)
- Kris Godbey and/or Ray Kenney (Medical Adhesives Specialists 3M Company)

These professors and professions will provide advice on what materials to use and general knowledge about the design and manufacturing processes. In addition to manufacturing the actual endotracheal tube system the team will have to either borrow or build a model of a human trachea. This model will be used to complete prototype testing. After manufacturing is completed it is a goal to begin preliminary testing on each component and the system as a whole.

Preliminary testing ideas

To determine if the new gel cuff additions improve the seal on the cuff several tubes with the additions presented will be placed in the trachea model with the cuff inflated. A liquid with viscosity close to that of mucus will be placed above the sealed cuff and allowed to stay there for several days. After the end of the experiment the amount of liquid present in a distal end collecting plate will be measured in order to determine how well the seal held. The outer lumen design changes will also be tested in a similar way but instead of allowing the mucus to sit above the tube for several days the mucus shaver will be run along the outer lumen periodically to determine how much of the original mucus it can remove. The inner lumen current-coil design will be tested by implementing them in Petri dishes of clinically grown bacteria. The current will be allowed to permeate through the coils for 24 hours and then the diameter of the bacteria

inhibition will be measured (following the experimental outline in *A comparison of four electrical stimulation types on Staphylococcus aureus growth*).[9] The results from each test will then be compared to results obtained from control trials and other published data to determine the efficacy of our system.

Conclusion

After evaluating each prospective design idea, the inclusion of the current coil, the gel/putty wrapping, sterile wrapper and external mucus shaver were deemed both feasible and innovative ways to produce an ETT capable of safe and effective prolonged intubation. These ideas had their own respective merit and surpassed the alternate options in terms of feasibility, cost-effectiveness, efficacy, and ease of use. It is believed that these ideas will most effectively reduce the incidence of VAP in prolonged intubation and therefore increase patient safety and reduce costs. With the help of the team advisor and health professionals the fabrication of both a prototype and an appropriate testing apparatus will be the next steps to test the efficacy of the proposed design.

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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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