ENDOTRACHEAL TUBE TO REDUCE VENTILATOR ASSOCIATED PNEUMONIA

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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.[1,2] 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 sterile sleeve, and a cuff wrapper. Preliminary testing was done to elucidate the efficacy of the prototypes. In a bench top model, the sterile sleeve reduced the amount of paint transplanted into the trachea by 82.5%. 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. Future work includes determining the efficacy of the current coil in preventing bacterial growth and implementing design changes in order to commercialize the prototypes.

Background

Motivation

- Ventilator Associated Pneumonia (VAP): Nosocomial pneumonia occurring in patients after 48 hours of mechanical ventilation
    - Occurs in 9-27% of all intubated patients [1]
    - ICU stay increases by 28% and patient cost increases by $9,000-$37,000 [2]
- Conventional ETTs have been identified as the main conduit for bacteria entry into the lungs [1-4]

Existing Technology

- VAP-reducing ETTs
    - Silver coated/impregnated tubes
    - Secretion removal
    - Ultra-thin polyurethane cuffs

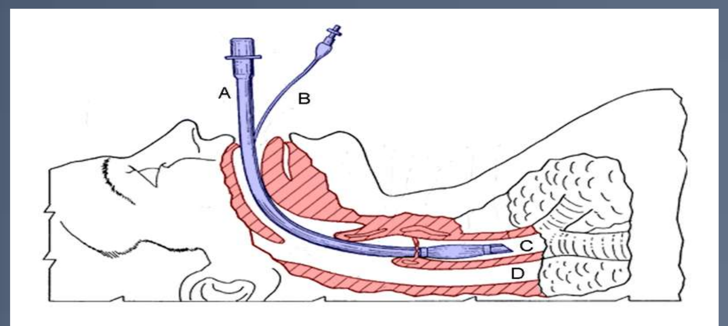


Figure 1: Placement of an ETT in the trachea for extended durations has been linked to VAP [5]

Design Requirements

- Make significant improvements/modifications to current ETTs:
    - Improve ETT cuff to prevent leakage of subglottic secretions into the lungs
    - Create and maintain a sterile environment above the ETT cuff
    - Prevent or eliminate formation of biofilms on ETT lumen
- Build a preliminary prototype for under $500
- Prototype must be safe for the patient and compatible with trachea endothelial cells
- Perform preliminary tests in order to prove efficacy of the prototype

Cost Analysis

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

Prototypes

Current Coil

Design:

- 10 μA current through double helix stainless steel coil plated in silver
- Silver is a well known antibacterial agent; silver ions ejected from anode proven to eliminate bacteria [2]

Specifications:

Length: 11.43 cm
Wire diameter: 0.67 mm
Coil OD: 7.94 mm
Pitch: 2.89 mm
Lithium battery: 2.5 V
Resistor: 271 kΩ

Figure 2: Two different sized current coils (left and center) and a coil attached to insertion tool (right)

Insertion Tool

Design:

- Allows for easy insertion of current coil into ETT while maintaining proper coil pitch
- Acrylic ramrod ensures ultra-tight friction fit between current coil and ETT (8 mm ID)

Specifications:

Groove width: 0.86 mm
Groove depth: 0.50 mm
Inter groove offset: 1.44 mm
Groove pitch: 2.89 mm

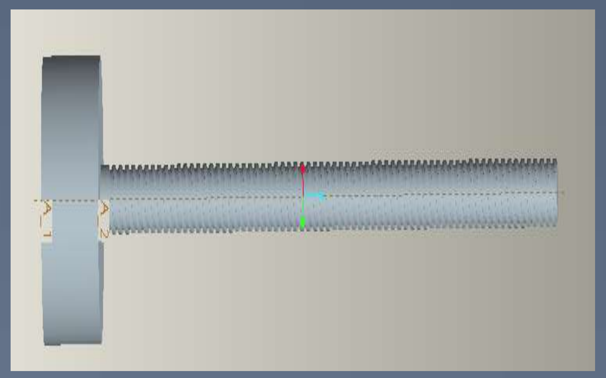


Figure 3: SolidWorks model of insertion tool used to insert current coil into ETT

Figure 4: Sterile sleeve (top), on ETT (middle), and pulled back with inflated cuff (bottom)

Sterile Sleeve

Design:

- Prevent transfer of oral bacteria to the distal tip of the ETT during intubation
- Polyethylene terephthalate (PET) tube sealed with medical grade double sided tape
- Keeps ETT cuff sterile until it is correctly in place

Specifications:

Diameter: 2.50 cm
Length: 27.00 cm
Thickness: 12.70 μm
3M Hi–Tack Conformable Double Coated Tape

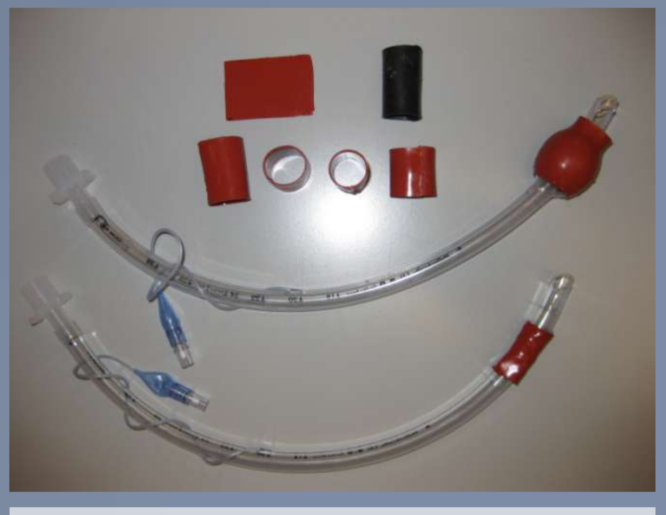


Figure 5: Assortment of cuff wrappers (top), ETT with inflated cuff (middle), and ETT with snuggly fitting cuff wrapper (bottom)

Cuff Wrapper

Design:

- Seals up longitudinal columns created along the walls of the trachea formed when the cuff is inflated
- Made of elastic material such as silicone or polyurethane
- Secured around the cuff prior to insertion, kept on for the duration of ventilation and removed with the tube during extubation

Specifications:

Diameter: 1.27 cm
Length: 5.00 cm
Thickness: 0.79 mm

Testing

Sterile Sleeve Testing

Method:

- Anatomically correct apparatus lined with sponge soaked in water soluble paint
- ETT w/o and with sleeves inserted and residual paint quantified with spectrophotometry

Results:

- Average residual paint on ETT w/o sleeve: 21.2 mg (n=4)
- Average residual paint on ETT with sleeve: 3.7 mg (n=4)

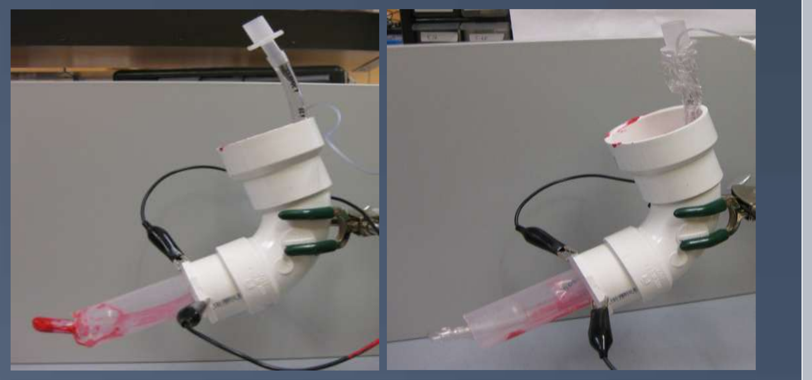
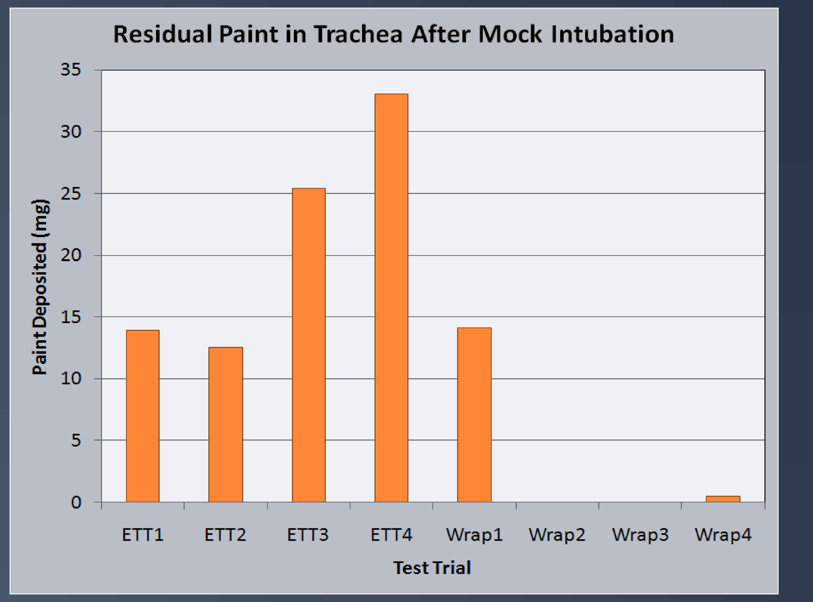


Figure 6: Testing apparatus during mock intubation w/o (above left) and with (above right) sterile sleeve. Note paint on distal tip of ETT w/o sterile sleeve. Graph (right) shows all 8 test runs w/o (ETT#) and with (Wrap#) sterile sleeve



Cuff Wrapper Testing

Method:

- ETT inserted into a silicone hose mechanically similar to the trachea
- Cuff inflated with 10 mL of air, and hose filled with a 10 cm column of water
- Testing setup left for 10 minutes

Results:

- ΔHeight of water column:
    - No wrapper: 2.17 cm (n=3)
    - Wrapper: 0 cm (n=3)
- Increased diameter of cuff wrapper increased difficulty of ETT insertion

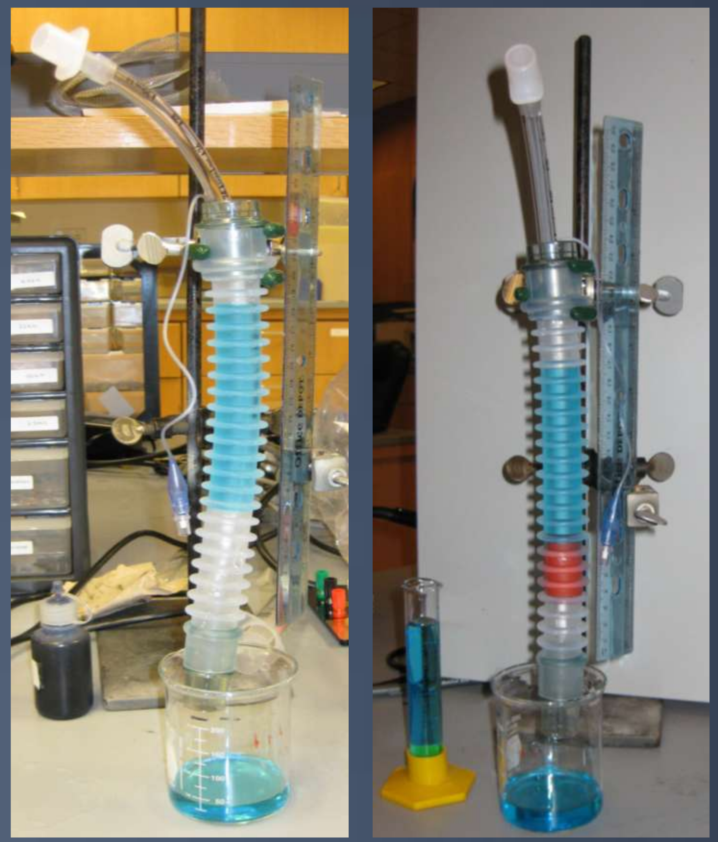


Figure 7: Testing apparatus simulating trachea full of subglottic secretions w/o (left) and with (right) cuff wrapper

Future Work

- Test current coil for antibacterial efficacy with Dr. Andes
- Test cuff wrapper and sterile sleeve with mucus-like liquid
- Streamline production of current coil, sterile sleeve, and cuff wrapper
- Obtain feedback from our client and his colleagues about each prototype
- Discuss patentability with WARF

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[5]http://upload.wikimedia.org/wikipedia/commons/5/5d/Endotracheal_tube_colored.png