Corticosteroid Eluting Endotracheal Tube to Mitigate Airway Inflammation Associated with COVID-19

ACAT: Medical Project Management ACQ phase: S&T Research/Discovery 59 MDW ST

Capability Description: A drug-eluting endotracheal tube (ET) that reduces inflammation in injured laryngotracheal tissues will be evaluated. The ET will deliver dexamethasone, hydroxychloroquine, antivirals (valacyclovir), Roxadustat (FG-4592), and anti-SMAD3 siRNA using a polymer mesh coated ET-Tube in an animal model. Optimized dosing and response data across variables will be established.

Problem: No devices exist to deliver therapeutics to the laryngotracheal complex and upper airway and prevent intubation complications in prolonged intubation.

Impact: Need for prolonged intubation continues to present challenges in the management of ARDS from emerging infectious disease such as COVID-19 or traditional influenza, complex laryngotracheal injuries, airway compromise from inhalation burns, and polytrauma. This device will minimize airway damage in an intensive care setting while delivering therapeutics; such a device is imperative as future conflicts are expected to necessitate prolonged field care stabilization.

MDA: DHA

Last/Next MS: Pre MDD, TBD (modernization & optimization)

Program of Record: No

TRL: TRL 4 at Start; TRL 5 at Completion

Role(s) of Care: Roles 2-5; intubation & airway management is an issue at multiple locations- austere and fixed facility

FDA approved/cleared: No (will be FDA EUA submission)

Alignment to Priorities: Operational Readiness; Better Care; Delayed Evacuation; Austere Medicine; COVID19

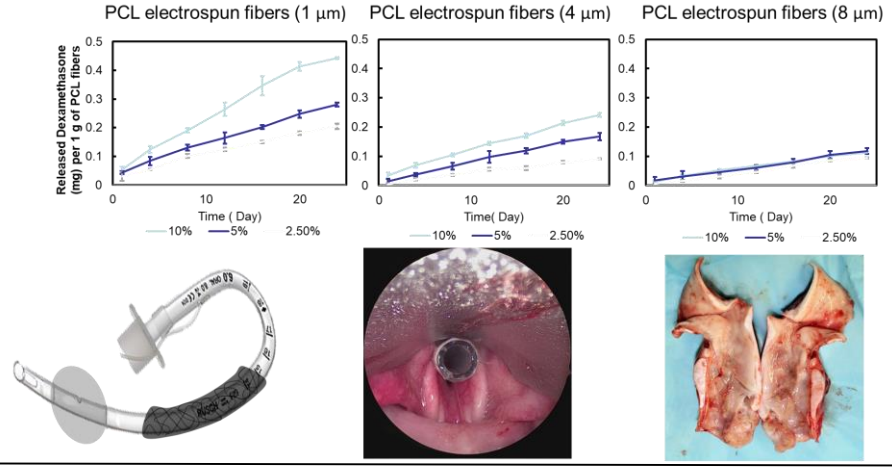
Proposed Deliverable: Produce and demonstrate efficacy of a drug-eluting endotracheal tube that reduces inflammation in injured laryngotracheal tissues.

Requirements: 2006 TC3 ICD; intubation and associated issues.

Is there a Transition Partner: Joint service combat medics; SAMMHS leaders with procurement decision authority

Ongoing Clinical Study: No

Preliminary Results



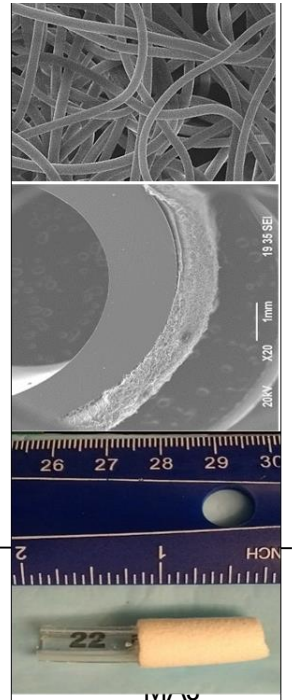


Figure 1. ***Coated Endotracheal tube.*** Scanning electron microscope images of ET tube coating and a sample coated tube.

Budget: $2.1k, Cares Act

AD Role; Performers, type of agreement, role

- Air Force 59th MDW (PI and lead agency)
- PI: Dr. Diana del Monaco (59MDW/ST) & Gregory Dion (USA-ISR)
- University of Texas, San Antonio

Status & Key Events:

FY20:

- IACUC and ACURO completed, swine controls

FY21:

- Assess laryngotracheal tissue response, systemic absorption, and wound healing
- Optimize dosing and response data across variables and submit for human clinical trials

Future Aims:

FDA – 510K, Commercial Partnership

The views expressed in this poster are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government. This work was funded by the Air Force 59th Medical Wing using work unit number G1718. U.S. Government Work (17 USC 105). The authors are employees of the US Government or military service members. This work was prepared as part of their official duties. Title 17 USC §105 provides that 'copyright protection under this title is not available for any work of the US Government.' Title 17 USC §101 defines a US Government work as a work prepared by a military service member or employee of the US Government as part of that person's official duties. Approved for public release; Distribution is unlimited.

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