NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

DEVELOPMENT AND ANALYSIS OF AN ENDOTRACHEAL TUBE STABILIZATION DEVICE (ETSD) INDICATED FOR THE PATIENT WITH MAXILLOFACIAL BURN INJURIES

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BIOMEDICAL SYSTEMS ENGINEERING AND EVALUATION
COMBAT CASUALTY CARE AND OPERATIONAL MEDICINE

NAMRU-SA REPORT # 2021-301

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01/05/2021	Technical Report	07/1/19-12/31/20

4. TITLE AND SUBTITLE
DEVELOPMENT AND ANALYSIS OF AN ENDOTRACHEAL TUBE STABILIZATION DEVICE (ETSD) INDICATED FOR THE PATIENT WITH MAXILLOFACIAL BURN INJURIES

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER
G1021

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Medical Research Unit San Antonio
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JBSA Fort Sam Houston, TX
78234-6315

8. PERFORMING ORGANIZATION REPORT NUMBER
21-301

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Advanced Medical Development Program
Naval Medical Research Center
503 Robert Grant Ave BLDG 500
Silver Spring, MD

10. SPONSOR/MONITOR'S ACRONYM(S)
AMD

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

13. SUPPLEMENTARY NOTES
This work relates to a pending patent submission, do not upload, cite, or publish until application is submitted.

14. ABSTRACT
Background: Maxillofacial burns are a common injury among servicemembers. Burn patients often require endotracheal intubation and the fixation of the endotracheal tube can be a problem for patients with facial tissue damage. The current solutions for this problem often result in longer treatment times, facial scarring, and more tissue damage, while also requiring extensive effort from the care providers.
Objective: The goal of this project was to develop a device that could stabilize an endotracheal tube while reducing the localized pressure on the vulnerable regions of the head. Additionally, it was important to design the device to be ergonomic

15. SUBJECT TERMS
Airway access, endotracheal tube stabilization, combat casualty care, prolonged field care maxillofacial burns

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Andrew Vaughn, CO, NAMRU-SA
UNCL	UNCL	UNCL	UNCL	30	19b. TELEPHONE NUMBER *(Include area code)* COMM/DSN: 210-539-5334 (DSN: 389)

DECLARATION OF INTEREST

The views expressed in this article are those of the authors 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 supported by the Naval Medical Research Center's Naval Advanced Medical Development Program Work Unit number G1021. Authors are employees and contract employees of the US Government. 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.

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ABBREVIATIONS

BICU	Burn Intensive Care Unit
CAD	Computer Aided Design
CCC	Combat Casualty Care
CONUS	Continental United States
COVID-19	Coronavirus 19
ET	Endotracheal
ETH	Endotracheal Tube Holder
ETSD	Endotracheal Tube Stabilization Device
psi	Pounds per square inch
RT	Respiratory Therapist
SLA	Stereolithography
USB	Universal Serial Bus

EXECUTIVE SUMMARY

Background: Maxillofacial burns are a common injury among service members. Burn patients often require endotracheal intubation and the fixation of the endotracheal tube can be a problem for patients with facial tissue damage. The current solutions for this problem often result in longer treatment times, facial scarring, and more tissue damage, while also requiring extensive effort from the care providers.

Objective: The goal of this project was to develop a device that could stabilize an endotracheal tube while reducing the localized pressure on the vulnerable regions of the head. Additionally, it was important to design the device to be ergonomic in nature for the sake of the health care providers.

Methods: The body of the device was designed through computer-aided design software and then 3D printed. The straps of the device were hand cut and sewn. The design went through several iterations using feedback from the staff at the Brooke Army Medical Center Burn Intensive Care Unit (BICU). Once the design was considered satisfactory from an end user perspective, the prototype, along with the BICU twill tape method and the Tube Tamer device, underwent performance testing. This testing evaluated the pressure on the corners of the mouth and the ears as well as the force required to extubate a patient.

Results: The testing showed that the novel Endotracheal Tube Holder (ETH) design applied less pressure to the corners of the mouth and the ears than the BICU method. It was also capable of withstanding similar extubation forces.

Conclusions: The team concluded that the novel ETH design achieved the goal of reducing localized pressure, which could lead to a reduction in facial scarring and further tissue damage. Further iterations and testing will refine the design and have the potential to create a large impact on the care of maxillofacial burn patients.

INTRODUCTION

Over the last few decades, civilian and military hospitals have observed an increase in traumatic injuries that disrupt airway management practices. In fact, nearly 10% of all casualties in recent US military conflicts have suffered severe burns, and an increasing number are located in the craniofacial region (Savitsky 2012). Additionally, an estimated 50% of civilian burn injuries also occur in the craniofacial region (Ward 1990). Burn injuries in the craniofacial region are often co-morbid with other injuries, such as smoke inhalation, that compromise the tissue lining of the airway, prompting clinicians to use various methods to treat casualties.

Intubating a patient ensures that clinicians can provide oxygen, ventilation support, and administer medications to the affected casualty. During endotracheal intubation, an endotracheal (ET) tube is inserted through the oral cavity into the upper airway, securing the ability to mechanically ventilate the lungs of the casualty without airway obstruction. However, for those with maxillofacial burns, placing the strap or twill tie on intact skin is not always possible and can result in complications such as infection, longer healing times, and facial scarring (Davis 2004). Unfortunately, some medical devices that anchor the ET tube in place, such as the ErgoMed Tube Tamer, are designed using very thin strips of fabric, which contact the scarred burn tissue of a casualty's face. Other devices, such as the Hollister Anchor Fast, include adhesive sites that can potentially adhere to and tear burn tissue. Additionally, the adhesive material may deteriorate due to the prolonged contact with blood, exudate, etc. during recovery. The deterioration of the adhesive can cause issues securing the ET tube and may require clinicians to apply another Anchor Fast device. Some hospitals have responded by altering existing devices to address the aforementioned problems, but none have found a commercial device that address the issues that are specific to maxillofacial burn patients.

The US Army Institute of Surgical Research Burn Intensive Care Unit (BICU) currently uses a modified holder consisting of a bite block secured in place with non-adhesive twill tape to tie the ET tube in place (Personal interview 2015) To prevent unintentional extubation, i.e., the removal of the ET tube, clinicians wrap twill tape tightly across the face and around the circumference of the patient's head. The tape must frequently be replaced to accommodate facial swelling fluctuations and to prevent tissue damage and infections where contact is made between the tape and patient's lips and cheeks. Replacement of the tape or any adjustment to the ET tube is tedious and can take two respiratory therapists (RT) up to 20 minutes, during which the ET tube

is not secured. Additionally, prolonged use of the twill tape method has been known to give casualties long-term scarring above the ear and on the corners of the mouth. The semi-flexible plastic ET tube must be protected from the patient's bite, which can kink the tube, cutting off airflow and, in extreme cases, may sever the tube completely. This need is especially relevant for patients under the care of military clinicians, as current military guidelines recommend sedation to be titrated at lower levels than many civilian burn centers.

The objective of this study was to develop and evaluate a novel endotracheal tube stabilization device (ETSD) that meets the unique requirements of the maxillofacial burn injury patient population by minimizing compromised tissue damage from the use of current ETSDs while improving upon the current standard. To accomplish this goal, the device and straps were designed to reduce the localized pressure on the skin and face. Additionally, the design incorporates a burn-compatible material that lines the inside of the straps to avoid irritating burned facial tissue. The design of the device itself prevents the casualty's teeth from consciously or unconsciously clamping down on the ET tube by including a bite block. This feature also provides stability to the ET tube within a casualty's trachea. By redesigning the ETSD, as well as the strap used to secure the device to the patient, the new design has the potential to decrease the instances of both acute and chronic comorbidities from endotracheal intubation.

MATERIALS AND METHODS

Instrumentation

SynDaver™ Synthetic Airway Trainer (SynDaver™ Labs, Tampa, FL). The airway trainer is a sophisticated human anatomical and physiological replica of the oral cavity (Figure 1a). Each component is designed to mimic the geometry as well as the physical properties of their respective tissues, including the fiber content; modulus in tension, compression, and shear; and coefficients of friction (Sakezles 2009). The airway trainer also features a hard and soft palate, tongue, uvula, epiglottis and vocal cords (Figure 1b). This unique synthetic cadaver system allows for a thorough evaluation of the placement of an ET tube/device that is not possible with previous manikin systems. When compared to a whole-body trainer, this model allows the user to observe where the tube was placed (trachea or esophagus) and verify through the tubes that protrude out of the upper torso. This model also provides a platform for repeatability studies that would not be safely feasible for extended durations with human subjects.

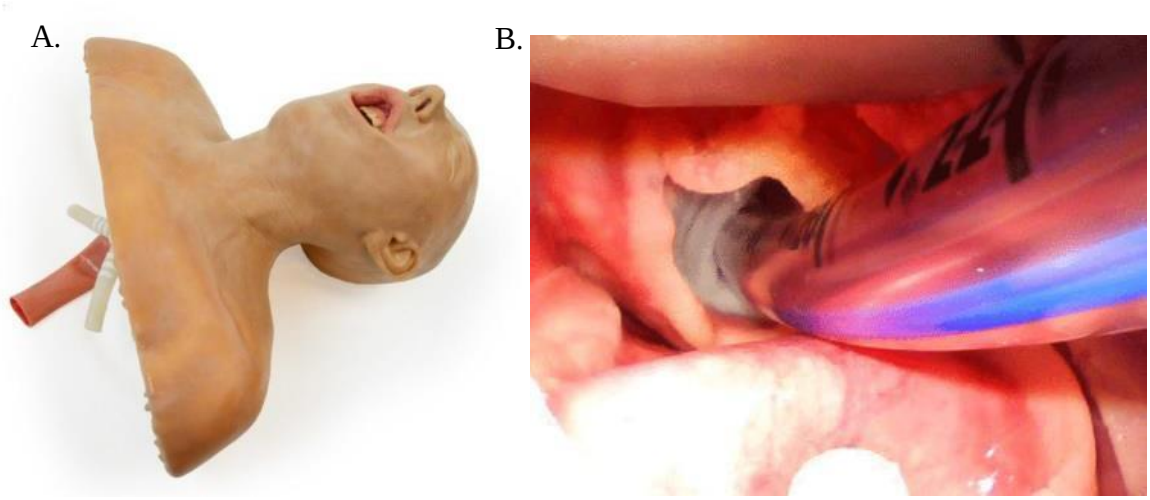

Figure 1. SynDaver™ Synthetic Human Airway Trainer. (A) Airway trainer anatomy is shown, including the skin and trachea. The Airway Trainer is comprised of individual tissues designed to mimic the mechanical properties of living tissues. (B) The tracheal airway of the SynDaver with proper ET tube insertion.

I-Scan® Pressure Measurement System (Tekscan®, South Boston, Massachusetts). The I-Scan® is a force and pressure measurement system which displays and records dynamic and static interface pressure distribution data (Figure 2). The system includes Windows-based software, scanning electronics, and pressure sensors. The scanning electronics rapidly record pressure data from an array of independent sensing elements contained within each sensor. A Model 5101 sensor was used to measure and map the pressure exerted by the various ETSDs. The specific sensors used in this testing were rated for 50 psi. Shown in Figure 2, the Model 5101 has a 4.40” x 4.40” sensing matrix, which contains 1,936 individual sensing elements, to provide a spatial resolution of 100 elements per square inch. Data from the sensors was collected at a rate of 1 Hz and analyzed to determine the pressure distributions and the average contact pressures exerted on the sensing matrices.

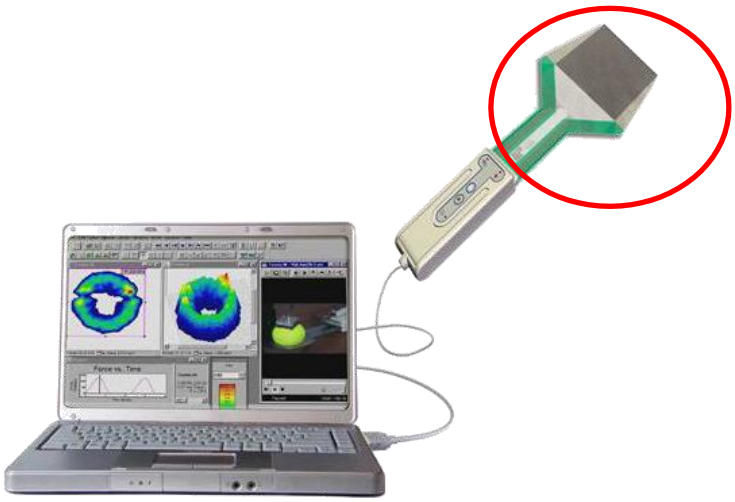

Figure 2. I-Scan® Pressure Measurement System. The I-Scan® pressure measurement system records and maps pressure distributions across its sensing surface. The scanning electronics rapidly record data from an array of independent sensing elements contained within each sensor. This image illustrates the 5101 model Tekscan pad (red circle) synced with a receiver and computer.

Formlabs Form 2: Affordable Desktop SLA 3D Printer (Formlabs®, Somerville, Massachusetts). The Formlabs Form 2® machine (Figure 3) is a desktop 3D printer that uses stereolithography (SLA) to cure solid isotropic parts from a liquid photopolymer resin. The printer includes a resin tank, a build platform, a finish kit, and the PreForm® Windows-compatible software. Additionally, various proprietary resins were obtained from Formlabs to print prototypes of the novel ETH for preliminary evaluation. "Durable" resin, in particular, was picked as a suitable resin for prototyping due to its ability to withstand considerable compression and tensional loads when compared to other Formlabs resins.

Figure 3. Formlabs Form 2. The Formlabs Form 2: Affordable desktop SLA 3D printer allows for multiple copies of the ETSD to be printed at once due to its large printing platform.

PCE Instruments-Digital Force Gauge N 200 (PCE Instruments®, Jupiter, Florida). The PCE Instruments digital force gauge (Figure 4) is a digital force meter that allows for precise compression and tensile force measurements with a resolution of 0.1 N. This device includes multiple compression and tensile measuring adapters, an extension bar, power supply, USB data cable, and data analysis software. The digital gauge was secured in place over a fully intubated SynDaver Airway Trainer and was manually tested with each ET tube device. The data recorded was transferred from the force gauge to a laptop through the USB cable for analysis.

Figure 4. PCE Instruments digital force gauge N 200 with calibration certificate and attachments. The PCE Instruments digital force gauge possesses an internal storage option of 100 measured values and a USB interface available for data transmission. The PCE Instruments Digital Force gauge also has a 1600 Hz sampling rate and a graphical analysis display included.

ET Tube Stabilization Techniques

The ET tube holder methods tested were the BICU Twill Tie Method (US Army Institute of Surgical Research Burn Intensive Care Unit, San Antonio, TX), the ErgoMed Tube Tamer model B7013 (Tube Securing Devices, ErgoMed Inc, San Antonio, TX), and the novel Endotracheal Tube Holder (ETH; Version 6.7; Naval Medical Research Unit, San Antonio, TX).

The BICU Twill Tie Method. The BICU method involves drilling holes into a commercially available bite block (Southmedic, Inc., Ontario, CA) and wrapping non-adhesive twill tie around

the face of the patient in order to fix the ET tube in place (Figure 5). The method requires the modification and combination of multiple products and the application can vary depending on the provider who applies it. The provider must tie the twill tape tight in order to maintain stabilization of the ET tube. It should be noted that the RT recently reported an update to this method that was not in place at the inception of this work. Self-adhesive silicone gel pads marketed for scar treatment (Cica-Care, Smith & Nephew, Watford, UK) are now added under the twill tape at the corners of the mouth. This is intended to reduce the pressure and cutting effect at the corners of the mouth, but was still not an ideal configuration as the pads were only secured in place by the pressure of the twill tape on the face in that area. The gel pads are prone to dislodging, especially once burn cream is applied to the area. One RT stated that they have tried to staple the pads to the twill tape, but that it was difficult to achieve proper positioning, could damage the skin if not done correctly and required extra equipment (a stapler and staples). To evaluate the most current BICU method, testing was performed with the gel pads in place.

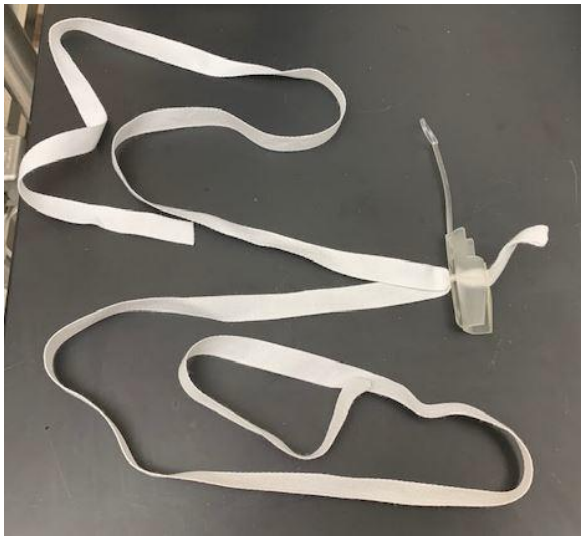

Figure 5. Commercial Bite Block with Non-Adhesive Twill Tape. Clinicians at the ISR BICU augment a hole in this bite block and thread twill tape through to secure the ET tube. The bite block prevents the casualty from biting through the ET tube and the twill tape wraps around the head of the patient, causing scarring at the corners of the mouth and superior portion of the ears.

The ErgoMed, Inc. Tube Tamer. The Tube Tamer (Figure 6) is an ET tube fastener device that was created to address the ET tube stabilization issue when caring for intubated patients. This device incorporates a simple tape wrap and pad.

Figure 6. The ErgoMed, Inc. Tube Tamer. The Tube Tamer shown in use on a sedated patient**.**

The NAMRU-SA Endotracheal Tube Holder. The *NAMRU-SA ETH* (Figure 7) is an endotracheal tube stabilization device that was designed using feedback from the BICU. This design incorporates an endotracheal tube holder with an integrated bite block. The device is comprised of a cylindrical channel (Figure 7A and 7C) in which the ET tube is inserted. An opening to the channel (Figure 7A and 7C) allows the device to be fitted onto the endotracheal tube from the side, after the tube has been inserted into the patient. The front of the channel opening widens to help guide the device onto the endotracheal tube during application. Two rotating wings (Figure 7A, 7B and 7C) extend on either side of the device, proximal to the bite block section (Figure 7A and 7C). The wings on the device have two slots at their periphery (Figure 7A and 7C) which interface with a fabric strap assembly (Figure 7D) that wraps around the patient's head. Additionally, this design allows the wings to be rotated independently about the axis of the ET tube, securing it in place. Behind the wings, the bite block section partially extends into the oral cavity, past the incisors. The bite block section has a square outer shape in order to distribute the bite pressure between multiple teeth to minimize potential dental damage when the block is bitten by the patient. Additionally, the device consists of a tube grip section (Figure 7A and 7C) which is comprised of a semicircular barrel channel that surrounds the endotracheal tube. A grip pattern (Figure 7A) lines the inner wall while the outside contains an adjustable cable tie fastener (Figure 7A and 7C). Upon inserting the device onto the endotracheal tube, the adjustable cable tie is tightened, engaging the grip within this section and locking the tube in place in relation to the

device. The cable tie allows the use of multiple endotracheal tube sizes. The raised feature on the bottom of the device (Figure 7C) provides an area to tape an oral gastric tube. The fabric strap assembly (Figure 7D) is made up of a large pad that rests against the back of the patient's head and a set of 4 straps that can be independently loosened or tightened as necessary. These straps are outfitted with hook-and-loop fasteners to allow for easy adjustments by the respiratory therapists.

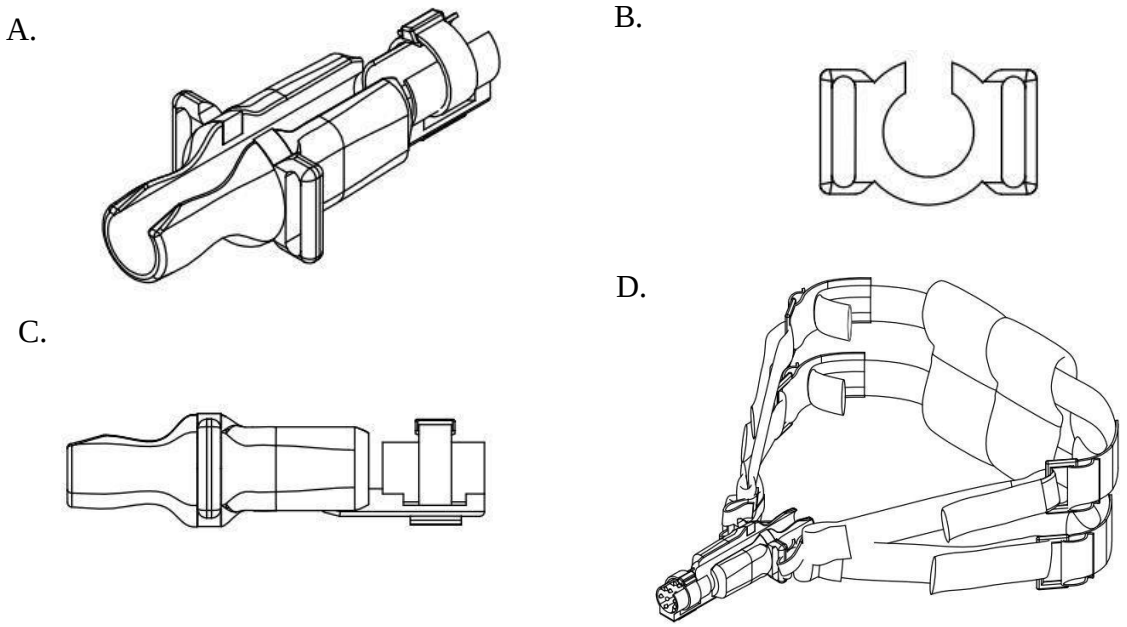

Figure 7. The Endotracheal Tube Holder (ETH) with securing straps and pressure padding. A. The ETH assembly, without the strap. B. ETH wing. The wing rotates around that axis of the ETH body. C. Side view of the assembly. D. Full ETH assembly, including the straps. This shows the ETH in its dual strap configuration. A single strap variation is not shown.

Test Procedures

Bite Force Simulation Testing. Material types used to 3D print the ETH device prototypes are not intended to be the final material used for manufacturing. Therefore, material properties of three plastics commonly used in medical devices were chosen to be simulated: ABS, polypropylene and polyethylene (Kucklick 2013). As previously stated, casualties with maxillofacial burns are very often intubated to protect their airway. The BICU stated that, when intubated, their protocol is to sedate their patient. Bite forces of sedated patients differ from that of fully conscious subjects. Past research has shown that patient bite force increases with the administration of sedatives (Matsuura 2017). Variables such as the medication(s) selected and the

dose administered are a factor. The highest bite force seen in the Matsuura review of intravenously sedated dental patients (1500 N) was used as references to simulate teeth compression on the bite block. This data was primarily used in the design and development of the bite block cross-sectional form factor. Performance of each prototype design iteration of the ETH bite block section were tested under static bite force loads of 1500 N within the force simulation component of the Solidworks CAD software (SimulationXpress, Solidworks, Dassault Systemes, Waltham, MA). Material property values for the bite block were selected to represent materials that may be chosen for the final device. Bite forces were then applied to the model and the resulting stress measurements were evaluated for future iteration design changes.

Test Platform Overview. The test platform system was designed to fit and secure the SynDaver Airway Trainer in place (Figure 8). The frame consists of a rigid plastic board which the SynDaver was placed on to take measurements. Holes were drilled into the board in order to install a strap system which fixed the head and shoulders of the SynDaver manikin in place. Rolled towels were placed under the neck to position the head in a more appropriate anatomical position, raising the chin away from the chest. This simulated the position of an intubated Burn ICU patient resting in a hospital bed.

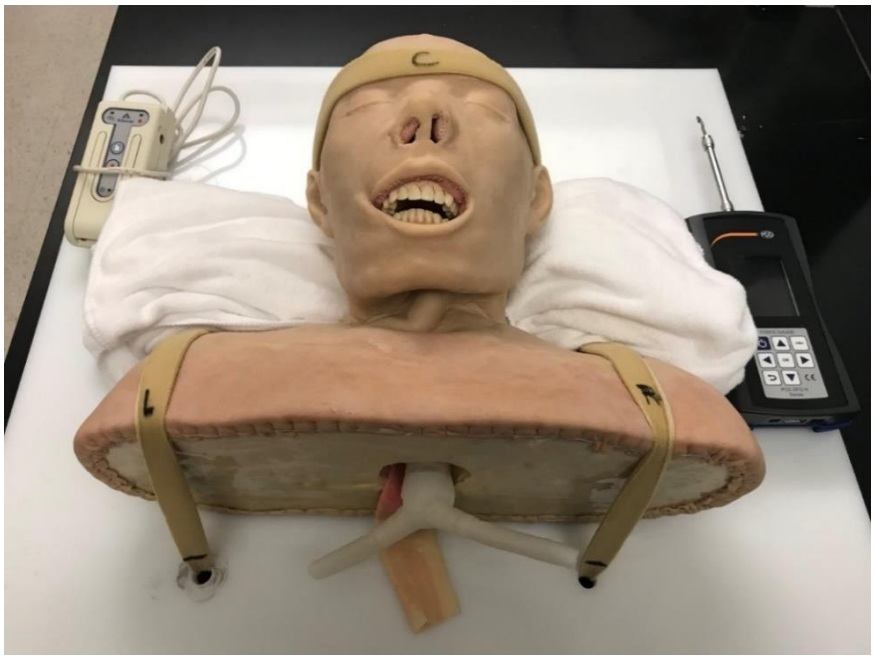

Figure 8. Test Platform Configuration. The test platform is pictured above in the evaluation configuration with the digital force gauge and a pressure mapping receiver.

The order in which each device was tested was as follows: the device was applied and secured to the SynDaver and ET tube, pressure mapping was performed at the corners of the mouth and ears, and an extubation force measurement was taken. This procedure was completed four times per method before moving on to the next device. The same person ran all four tests on all devices to control for inter-person variability as this was not intended to be a factor in the assessment at this time. Specific steps for each procedure are detailed below.

Device Application. Effort was taken to ensure devices were applied and tightened to clinically relevant levels for each specific device. The BICU device was applied and tightened by a trained BICU RT with experience in applying and assessing proper tightness and placement on a BICU patient. The Tube Tamer was applied per manufacturer instructions for use, by a researcher with experience caring for intubated patients. The instructions did not indicate a specific tightness, so it was tightened to what was estimated to be used in a clinical environment. The ETH was also applied by a researcher, and tightened to the level required to properly function as designed, aligning the bite block portion of the device with the Syndaver top incisors.

Pressure Map Testing. Once the manikin was secured to the board, two model 5101 pressure pads (50 psi) were placed in the desired locations (one folded into the right corner of the mouth and the other covering the left ear or left jaw for the Tube Tamer) on the manikin and fixed in place using medical tape. The sensor on the corner of the mouth was attached to the I-Scan receiver, connecting the pad to the I-Scan software. Once the pads were secured in place and the software was ready to collect data, the manikin was intubated with an ET tube and the fixation method was applied to the manikin to keep the tube in place. A real-time pressure map was then recorded to capture the pressure applied to the sensor. A rectangular selection area was placed on the pressure map in the first region of interest, the corner of the mouth. Once the recording was saved, the receiver was then switched to the second pressure sensor covering the ear. A real-time pressure map was again recorded and a region of interest box representing the location of the ear was created. Once the pressure on both regions was recorded and saved, the extubation force testing described below was performed on the same fixation method. The BICU twill tie method was the first to be tested, as this method was hypothesized to create the largest amount of localized pressure on the regions of interest (corner of the mouth and the ear). The pads were set to read relative pressure. The pressure pads used during this testing are rated for 50 psi, which is much higher than the pressure applied by a typical ETSD. Because of this, the sensitivity of the pads had

to be set to a very high level. The first trial on the BICU method was used to set the sensitivity level of the pressure sensor to ensure a full range of pressures could be recorded and the sensitivity level was then documented for use in the remainder of the trials.

Extubation Force Testing. For extubation force testing, a hole was drilled in the distal end of the ET tube. Twill tape was then routed through the hole and the ends tied, creating a loop (Figure 9). This allowed the ET tube to be pulled from the center of the cross section of the tube.

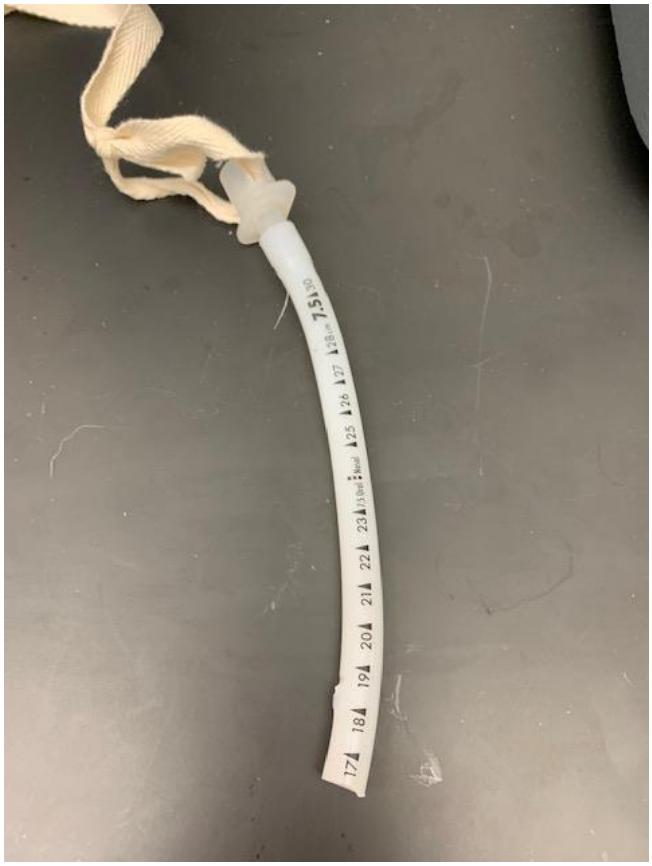

Figure 9. The ET tube with twill tape used for Extubation Testing. The ET tube was augmented with a twill tie loop through the distal end to facilitate pulling the ET tube using the force gauge with a hook attachment.

The twill tape that was looped through the ET tube was secured to the force gauge and the device was placed in very slight tension perpendicular to the ET tube. Based on previous studies, a two cm movement was classified as "extubation" (Wagner, 2014). The ET tube contained markings at 1 cm increments which were used to gauge movement. The ET tube depth at the level of the manikin's incisors was noted. Recording started when pulling on the force gauge commenced and the fore gauge was pulled away from the manikin at a steady rate with constant force. When the tube had moved out of the mouth by two cm relative to the starting measurement,

the extubation force recording was stopped. Once the extubation force data had been saved for that trial, the device was removed from the manikin and another round of pressure testing as described previously was performed. This combined procedure was performed four times for each device.

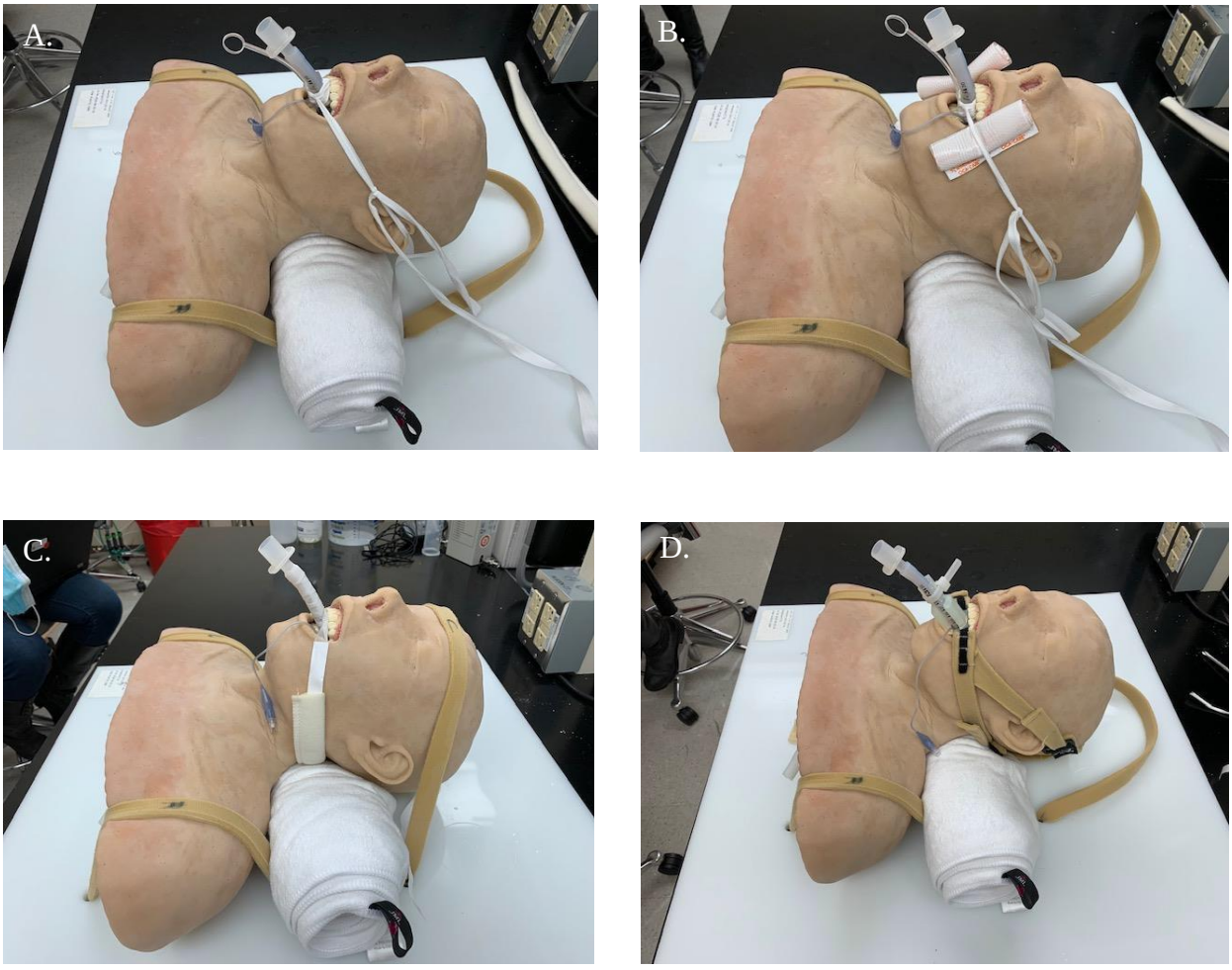

Figure 10. The test platform with all four devices. The test platform is pictured above with the airway trainer intubated and devices secured for evaluation. A. The BICU device without gel pads. B. The BICU device with gel pads. C. The Tube Tamer device and D. The ETH in the two strap configuration.

RESULTS AND DISCUSSION

Bite Force Simulation Testing. Bite force simulation testing was limited to the ETH, and not used to compare the three methods tested in this study (Figure 11). Three common materials used in injection molded medical devices were simulated: ABS, polypropylene and polyethylene. Von Mises load stress testing was performed to examine each material's ability to withstand

bending caused by a patient's bite. The results were used to validate the integrity of the bite block cross-sectional shape during iterative prototyping.

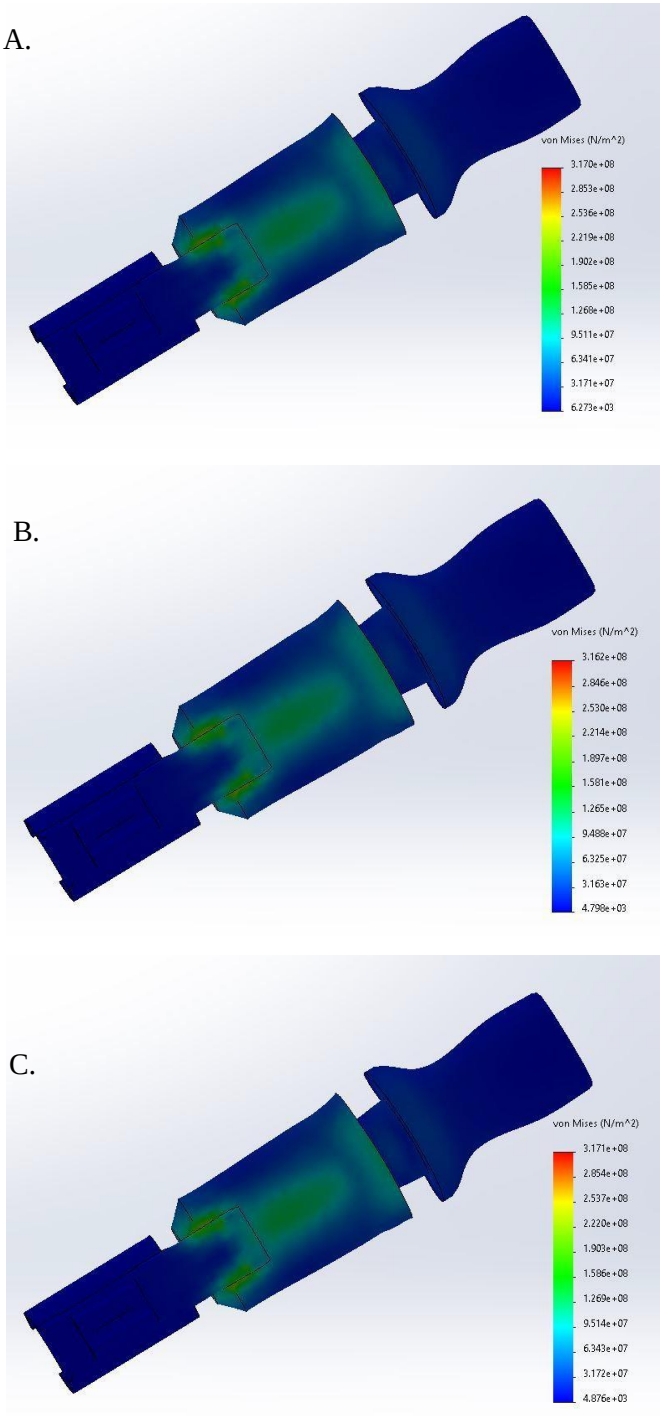

Figure 11. Current prototype stress test results. An external load of 1500 N was exerted on the bite block and a von Mises pressure map was created. Three materials were simulated: A. ABS. B. Polypropylene Copolymer and C. Low-Medium Density Polyethylene. Areas of highest stress appear as yellow-green. Each material sufficiently withstood bite forces of 1500 N.

The results for all three material simulations with the prototype design were similar. The weakest point in the design was shown to be the surface perpendicular to the bite force applied. It was shown to absorb the force by flexing a very small amount. No materials experienced stresses high enough to cause breakage. It is also important to note that bending of the surface in question is possible due to a 7 mm open slot on the opposite surface of the bite block. When a force is applied, the slot closes and further bending is not possible unless the load is increased far above that seen in the bite of a patient. Physical bite force analysis was not performed because the 3D printing material options for the Form2 3D printer did not include materials likely to be used on a manufactured device. Instead, the device will be injection molded for mass production. Material selection will be finalized in future advanced development.

Pressure Map Testing. Skin-to-device localized pressure map testing compared raw data scores between the three methods. Results were reported in the I-Scan software as a visual pressure map and raw data tables. For illustration purposes, the pressure maps of the corners of the mouth and the ear/jaw were manually stitched together (Figures 12-14). An outline representating the strap, mouth corner and ear was superimposed over the pressure map to represent anatomical landmarks of the face.

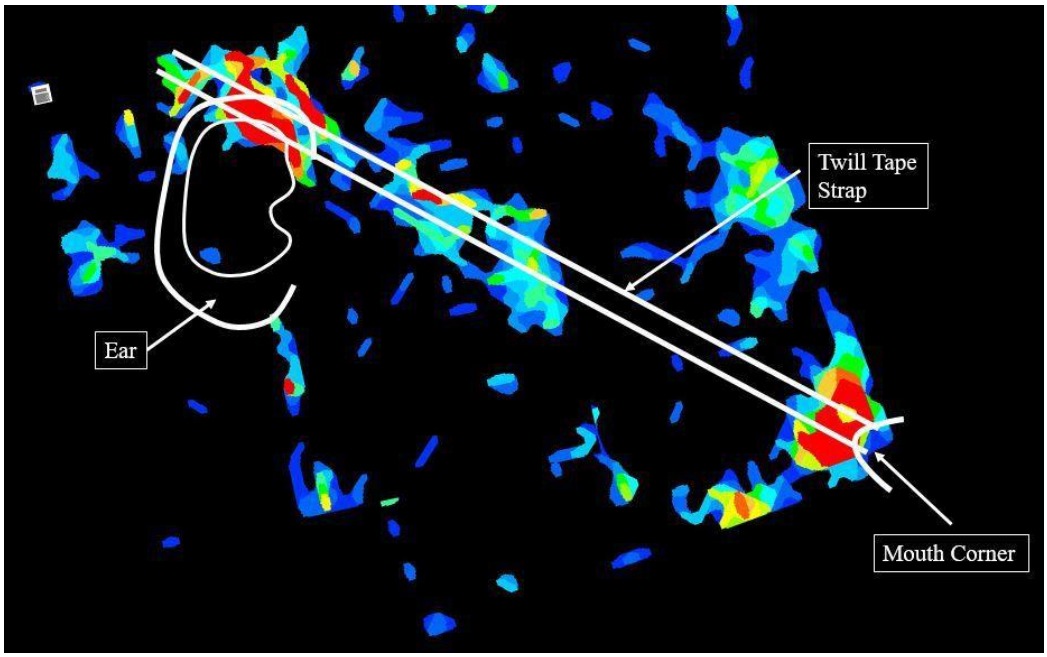

Figure 12. Pressure mapping of the BICU method. The updated BICU method with silicone pads. A large area of high pressure is seen at the mouth corner and helix of the ear.

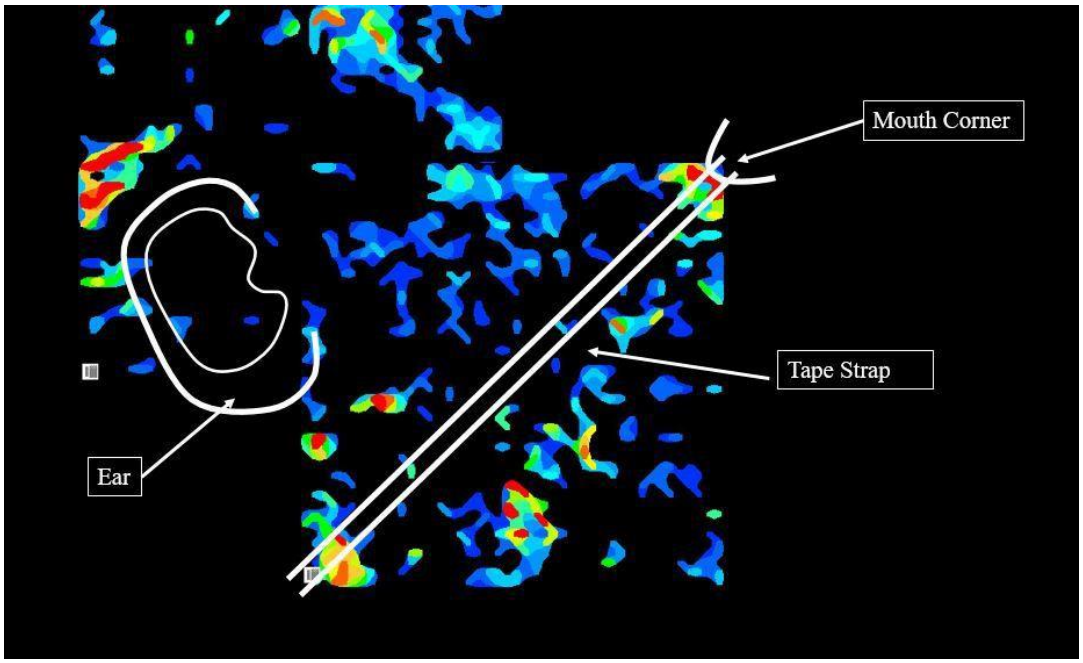

Figure 13. Pressure mapping of the Tube Tamer. The Tube Tamer wraps around the base of the neck. Localized pressure in the mouth corner is small in area compared to the BICU and ETH method.

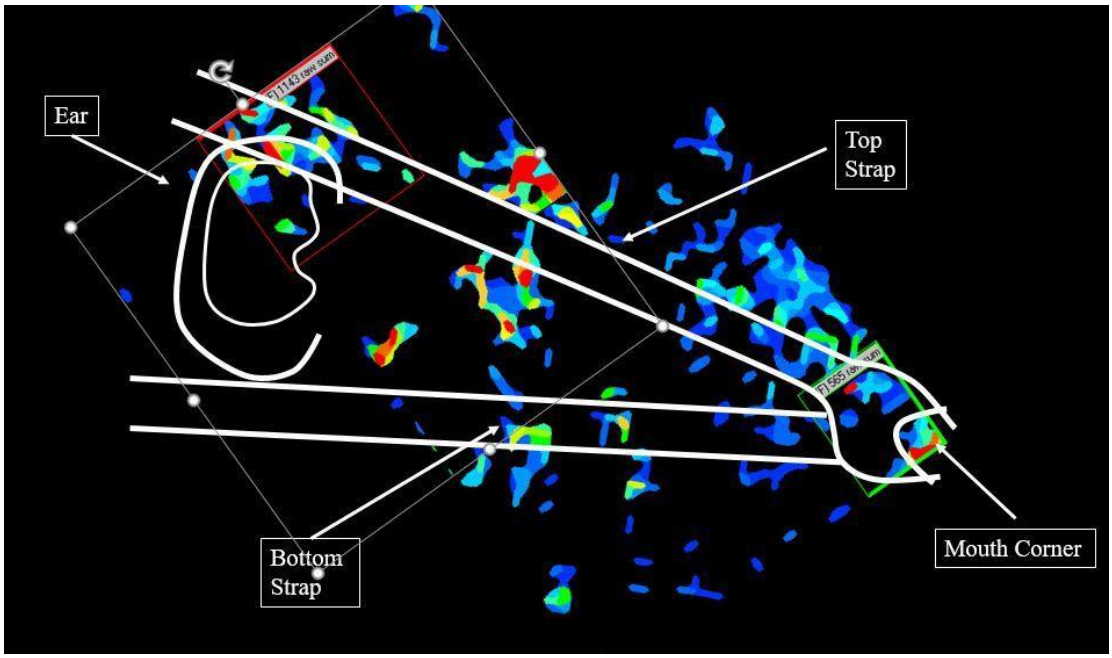

Figure 14. Pressure mapping of the ETH. A pressure map of the ETH at the ear and the corner of the mouth. There is a slight concentration of pressure at the corner of the mouth and at the helix of the ear.

Testing confirmed the initial hypothesis, which predicted that the BICU method would have the highest pressures at the two regions of interest, the corners of the mouth and ear (Figures 15-16).

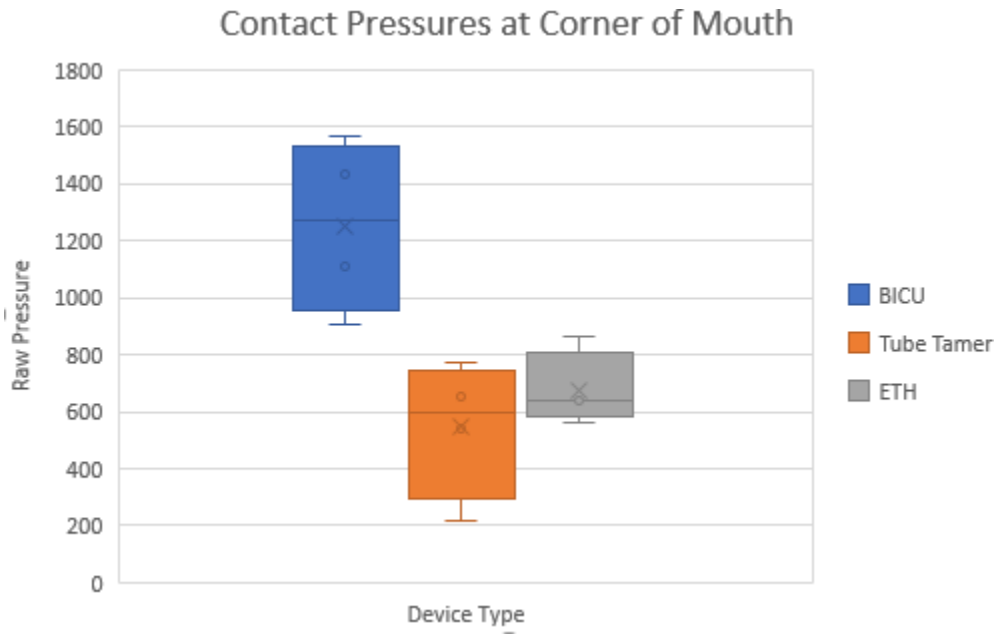

Figure 15. Pressure Mapping Results from the Corner of the Mouth on the SynDaver manikin. Each box plot shows the average amount of pressure applied to the mouth by the 3 devices as well as the standard deviations. The graph depicts which devices applied the most (BICU) and least (Tube Tamer) pressure. These raw pressure measurements are not calibrated to a pressure standard.

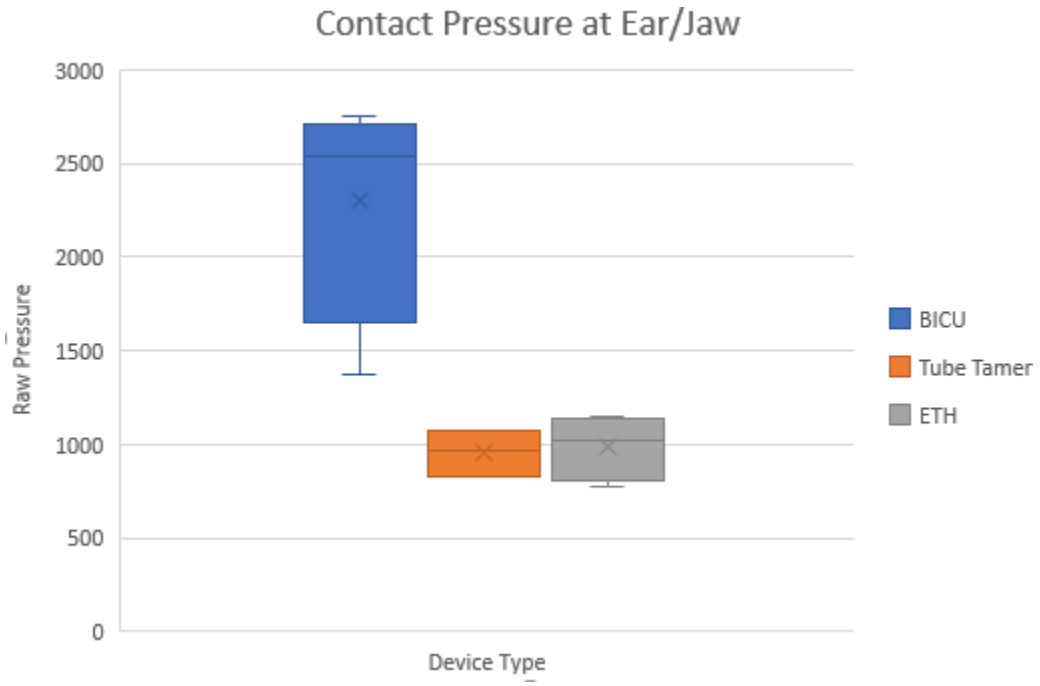

Figure 16. Pressure Mapping Results from the Ear* on the SynDaver manikin. *Tube Tamer measurements came from the corner of the jaw; the device does not cover the ear. Each box plot shows the average amount of pressure applied by the 3 devices, as well as the standard deviations. The graph depicts which devices applied the most (BICU) and least (Tube Tamer and ETH) pressure. These raw pressure measurements are not calibrated to a pressure standard.

The average pressure the BICU method applied at the corner of the mouth was 1253 ± 301, while the pressures in the same location for the ETH and Tube Tamer were 677 ± 131 and 546 ± 241, respectively. Note, these raw pressure measurements are relative, not calibrated to a pressure standard, and are therefore dimensionless. While the cutting effect on the corners of the mouth was clinically found to decrease with the use of the silicone pads, contact pressures in that area remained higher than that of both the Tube Tamer and the ETH. The Tube Tamer device was found to have the lowest average pressure, 546 ± 241, at the mouth corners. This was believed to be due to the method of application, wrapping of adhesive tape up the distal end of the ET tube, forcing the tape away from the mouth.

The Tube Tamer did not apply any pressure in the ear region, as the strap was routed around the neck with no contact at the ear (Figure 13). During the pressure testing on the Tube Tamer, the "ear" pressure was instead measured at the spot of highest pressure on the corner of the jaw. The average pressure placed on the corner of the jaw, 957 ± 138, was comparable to the pressure the ETH applied to the ear, 988 ± 184. The contact pressure of the BICU method at the ear, 2303 ± 629, was the highest. While the Tube Tamer kept pressure at the corners of the mouth and ears to a minimum, addressing one of the BICU complaints, it was at the expense of extubation force, which is described below.

Extubation Force Testing. The extubation force testing was an important aspect of the development of the ETH prototype (Figure 17).

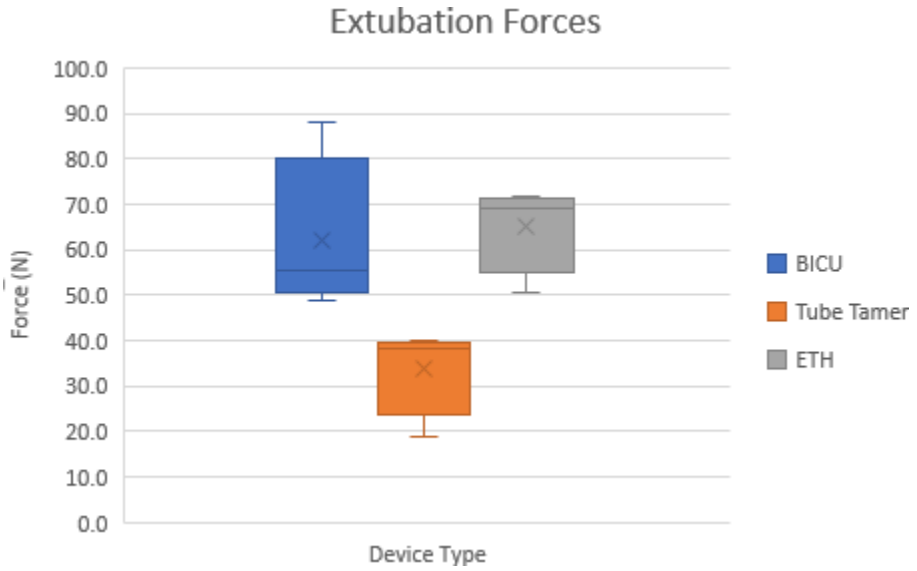

Figure 17. Extubation Forces of Each Device. Each box represents the average extubation forces of the 3 devices as well as the standard deviations.

The Tube Tamer had the lowest average extubation force at 33.9 ± 10.0 N. The BICU twill tape method averaged 62.0 ± 17.6 N of extubation force and 65.2 ± 9.7 N for the ETH. As noted previously, the patients in the BICU are often lightly sedated, increasing the possibility of extubation. As hypothesized, the Tube Tamer, while having lower device-to-face pressures than the other two methods, was also extubated with less force. This, and the lack of a bite block in the Tube Tamer design, would potentially present issues for the lightly sedated burn patients prone to self-extubation and biting of the ET tube. The ETH extubation forces were comparable to the BICU method, which provides confidence that the design is capable of preventing extubation in a similar manner as the BICU method while reducing the localized facial contact pressure. It is also important to note that informal extubation force testing by BICU staff, manually pulling on the tube while the ETH was secured to the SynDaver, received positive feedback. The RTs stated that the ETH felt secure enough to be effective, based on their clinical experience. Additionally, previous studies have shown that perpendicular extubation forces demonstrated by other fixation methods average from 31 ± 7.7 N to 209 ± 0.0 N for a 2 cm tube displacement (Wagner, 2014).

The extubation force testing on the ETH was performed by gripping the device itself as opposed to the distal portion of the tube like the other two devices. The goal was to test the ability of the devices to prevent extubation. The ETH prototype is 3D printed, therefore, not made of a material representing its final form and the 3D print material does not grip the ET tube well. However, extubation forces were still able to be measured by pulling from the body of the device. It should also be noted that the sample size obtained during this testing (N=4) was not large enough to make any statistically significant claims of performance. Despite this, the research team believes that the prototype performed well enough to establish confidence as a proof-of-concept. The ability of the ETH to decrease the pressure applied to the ears and mouth compared to the BICU technique in preliminary studies while successfully securing an ET tube achieved the goals of this project.

The current test platform was sufficient for evaluating a 3D printed, proof-of-concept prototype, but it will be upgraded for future revisions of the ETH to provide more consistent and technically appropriate measurements. The SynDaver manikin that was used for this testing is made with a synthetic skin material that requires submersion in water to avoid mold growth and material degradation. This requirement prevents any electronics from being permanently or semi-permanently fixed to the manikin. Therefore, the pressure sensing pads had to be taped onto the face of the manikin, which may have contributed to minor deviations in measurements as tape does

not stick well to the synthetic skin. In the future, the team plans to develop or obtain an instrumented manikin that is capable of making more accurate and precise pressure measurements. The specific manikin that was used for this testing also has a severe overbite which may have affected results and is likely not representative of the majority of patients. Additionally, the pressure pads that were used during this testing were rated for 50 psi, which was far too high for this testing. The pads were also slightly too large and not flexible enough to accommodate the contours of the human face. Sensors with specifications more appropriate for the anticipated measurements will be used in future testing. The pressure sensors were not calibrated prior to use and were only used for relative pressure measurements; however, in the future, the pressure instrumentation will be calibrated to provide context to the applied pressure of the ETH. The extubation force testing was performed manually. Although the same engineer performed each extubation trial to conserve reproducibility, a more precise and repeatable test method will be developed in the future. This can be done through the use of a test stand or pulley system to ensure consistent angles and pull forces.

Upon the development of a more robust test platform, further refinement and minor design changes will be identified, such as tolerance changes or alterations to the features of the straps. The team anticipates the body of the ETH to be manufactured through injection molding, so the CAD model of the device will be updated to support the injection molding process. Final materials will also be identified through materials testing. These changes are anticipated to build upon the promising results shown during the presented testing, increasing the device's potential to positively affect the short- and long-term outcomes for maxillofacial burn patients while vastly increasing the ease of use for their care providers. These patients will ideally have minimized facial irritation and infection due to ET tube fixation as well as facial scarring. The RTs and nurses will be able to quickly and efficiently apply the ETH to their patients as well as make easy fitment adjustments as necessary.

The goal of this project was to develop a prototype device that would address the concerns of the staff at the BAMC Burn ICU regarding the fixation of endotracheal tubes for their intubated patients with maxillofacial burns. The BICU's method of stabilizing the ET tube consists of combining and altering multiple off-the-shelf devices, so the integration of each component of their solution into a single device was another goal of this work. The result of these efforts was the development of a single device, the ETH, which mimics the positive aspects of the BICU's method

such as effectively preventing extubation and ET tube kinking, while showing promising preliminary evidence of mitigating most of the negatives, such as facial scarring and poor usability.

MILITARY SIGNIFICANCE

As battlefield personal protective equipment evolves and improves, there has been a shift in the types of injuries seen in theater. While thoraco-abdominal injuries are decreasing, the prevalence of oral-maxillofacial injuries has increased due to the lack of protection to the face (Mitchener, 2010). Burn injuries of the head and neck accounted for roughly 10% of all burn injuries sustained during combat between 2001 and 2011 (Johnson, 2015). Due to the mechanism of injury, there is a high probability of airway burns comorbid with maxillofacial burns. Smoke inhalation often causes damage to the sensitive tissue lining the airway, causing rapid swelling and airway obstruction. Compounding this is the fact that fluid resuscitation is indicated for burn treatment, which can cause edema and further compromise the airway if access is not quickly established. Thus, it is imperative that the casualty's airway is protected and a patent airway is maintained to prevent severe complications or death.

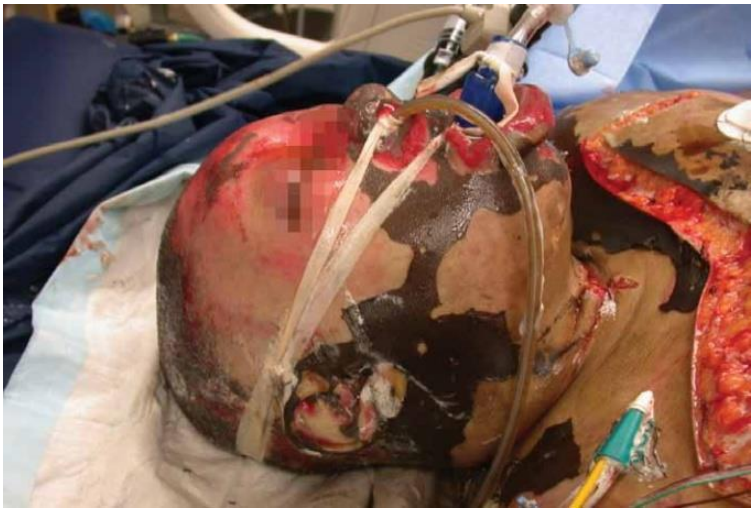

Figure 18. Photograph of the BICU fixation method. Note the "cutting" effect the twill tape produces at the corner of the mouth and Helix of the ear.

Since these injuries often occur in austere pre-hospital environments, field medics are typically responsible for establishing initial airway access through ET intubation. In an effort to prevent early, unwanted removal of the ET tube, ETSDs are used to anchor the ET tube in place. However, ETSDs come with their own set of problems, further damaging burned facial tissue and increasing the possibility of infection. While this is challenging enough to manage in the hospital

setting, it is particularly concerning in austere environments, where the time to evacuation is estimated to increase in future conflicts.

Due to the complicated nature of managing burn casualties, these patients are evacuated to CONUS at the earliest opportunity. Leading burn intensivists across the country have tried a myriad of different ETSDs on the market in their attempt to find a device which meets the unique requirements seen in patients with head and maxillofacial burns. Thus far, no commercially available device has met these requirements. Instead, the current procedure used by the US Army Institute of Surgical Research BICU is to use twill tape, which is a thin, fabric, non-adhesive, inelastic band. The clinician ties the twill tape to an altered plastic bite block in which a slot has been cut. While effective in stabilizing the ET tube, it poses other problems for both the clinician and the patient. Varying levels of facial swelling in burn patients, due to the inflammation and fluid resuscitation, require the ETSD to be frequently adjusted to either remove slack or resolve excess tightness. To do so, RTs must cut the twill tape, and redo the entire process of applying new twill tape. This requires two therapists, as one must ensure tube placement is maintained while the other reapplies new tape. The drawback of the twill tape for patients is that the thin tape must be tight enough to stabilize the ET tube, which causes it to cut into the already damaged facial surfaces such as the corners of the mouth, cheeks and tops of the ears. This can lead to both additional injury and infection in the short term, and irreversible facial scarring in the long term. Following usability interviews, RTs from the BICU have requested the design of a new device which meets the needs of their patient population. The device must minimize the likelihood of damage and infection, as well as ease the application and adjustment process.

While the device presented in this report has been requested for the Role 5 setting of the military medical system, particularly the BICU, it will be beneficial as far forward as Role 2 as well as in the treatment of civilian maxillofacial burn injuries. The United States Army Institute of Surgical Research Burn Center, during a 2 year period, treated 751 burn patients, 64% of which were civilian patients (Wolf 2006), indicating a potential gap in the civilian population as well.

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