Contract Number: W81XWH-17-P-0022
Support the (TCCCR) Task Area for Research and Development of Medical Equipment to Clear and Maintain a Combat Airway

A Report on Deliverable Three: Determine a Standard Performance Test for Military Suction Device Use

Report Authors:
Priya Jain, BS[1]
R. Lyle Hood, PhD[2]
Robert A. De Lorenzo, MD, MSCI, MSM, FACEP[3]

[1]Department of Biomedical Engineering, University of Texas at San Antonio
[2]Department of Mechanical Engineering, University of Texas at San Antonio
[3]Department of Emergency Medicine, UT Health San Antonio

20 September 2017

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Objective of the Report

Develop a standard performance test for combat suction validation that accounts for parameters including suction flow rate, pressure, size, weight, and battery life. Suction devices for prehospital combat casualty care have unique performance requirements and should be tested in a manner that effectively simulates the anticipated pathophysiology. The development of a standard performance test will be derived from research including previous methods used to test suction devices and input from combat caregivers. The study meets applicable ethical and legal requirements for research and is feasibly implementable.

Background

[Readers are referred to the following for a more detailed overview and background on portable suction for use in prehospital combat casualty care: *A Report on Deliverable One: Determine Required Performance Characteristics [of Suction] for Management Of Prehospital Combat Casualty Care Injuries.* Contract Number: W81XWH-17-P-0022 Support the (TCCCR) Task Area for Research and Development of Medical Equipment to Clear and Maintain a Combat Airway. Report Author: Robert A. De Lorenzo, MD, MSCI, MSM, FACEP, Department of Emergency Medicine, UT Health San Antonio, February 22, 2017.]

Tactical airway management often determines survival in both trauma and medical patients. Skilled interventions often make the critical difference in survival for patients with actual or impending airway compromise. Managing airways in the tactical environment presents an additional level of unique and complex challenges for any emergency provider. Hazardous or confined spaces and hostile action inherently limit the ability to intervene with an artificial airway or assisted ventilation. Loss of patient airway in tactical and combat environments commonly occurs. The proximate cause can be direct trauma to the airway structures or indirectly from traumatic shock or brain injury and the subsequent loss of airway protective reflexes.

There is limited information on the types, if any, of portable suction units carried by combat medics in the far-forward combat area. Anecdotal information suggests that powered suction devices are simply too heavy to be carried in the combat medic's aid kit. Manual powered devices, while lightweight, offer limited capability and require the use of a hand or foot to operate, limiting efficiency of the provider. Fielding data from military logistics agencies on the number and types of suction units employed in the field is not available, and prior experience suggests even if obtained, the data shows only total purchases and not where and when fielded.

Existing portable suction standards are civilian-oriented, lack a detailed base of evidentiary support, and in any case do not satisfy the critical needs of combat casualty care. Importantly, there is little data on performance testing standards forsuction units used in this setting. We will review the available literature and guidelines on suction performance tests. We will also propose a protocol draft that can be used to standardize performance testing for a suction device.

Summary of the Background Section

- There is no standard for performance tests of suction devices specific to the prehospital combat use of suction devices.
- This report will focus on performance test guidelines, with an emphasis on weight, dimensions, and battery life.

Recommendations of Background Section

- None specified.

Casualties Requiring Suction Devices

According to Kotwal et al., airway obstruction is one of three leading causes of preventable battlefield death[1]. This is attributed to improper identification and assessment of the need for airway securement. Even if the initial need for airway securement is recognized, follow-up assessments to keep airways unobstructed are frequently not conducted[1]. Lack of knowledge and improper use of suction devices or intubation could also lead to more serious injuries. Clearing the airway is important for several reasons: 1) it allows for improved visualization for intubation or needed advanced airway intervention; 2) it can also improve visualization to find and control bleeding in airway passages.

Figure: Technique of suctioning a casualty as detailed in a combat medic textbook.

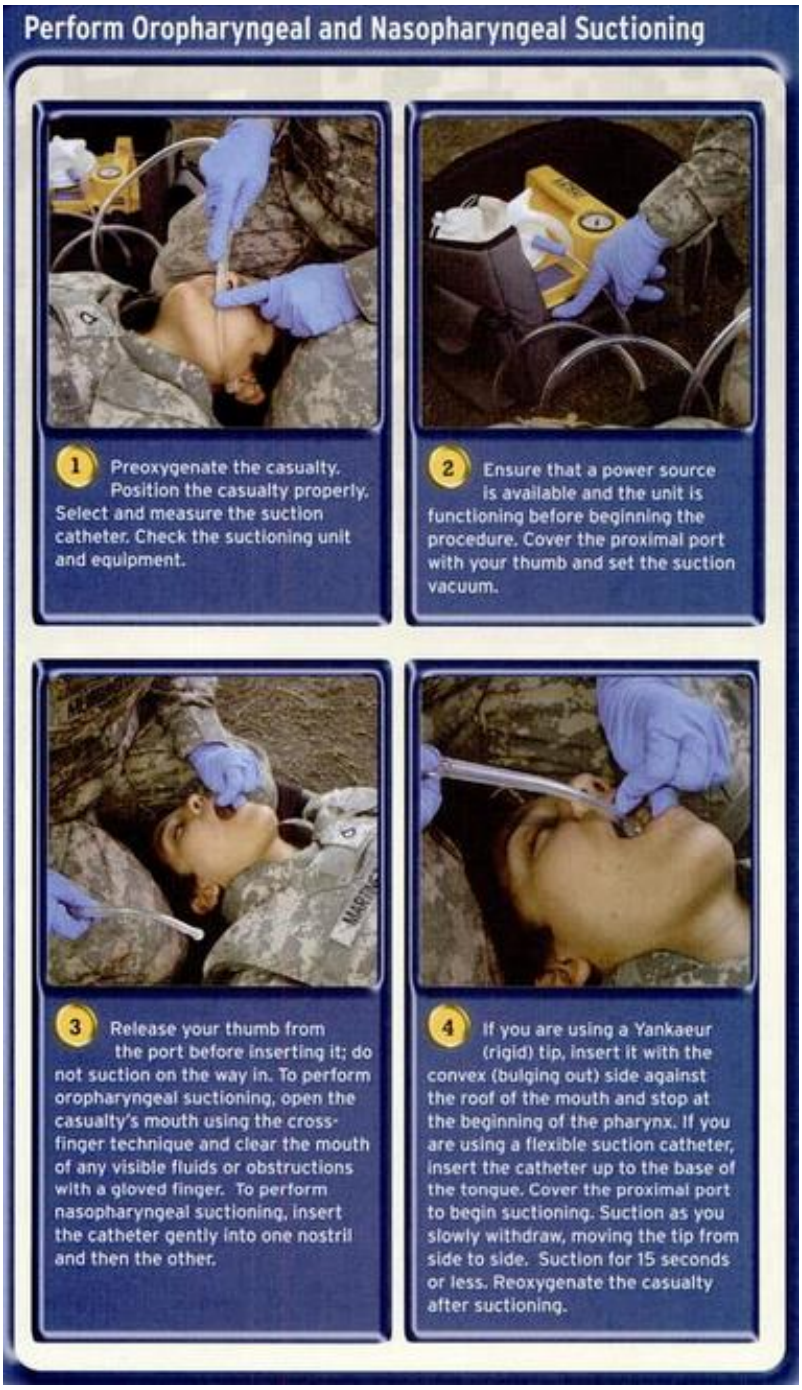

Photo Credit: US Army. 68W Advanced Field Craft: Combat Medic Skills 1st ed. Jones & Bartlett Learning; 1 edition, 2009, Burlington, MA.
COPYRIGHTED FIGURE – PERMISSION PENDING – NOT FOR PUBLICATION

A review of civilian EMT and paramedic textbooks as well as a select sample of textbooks in the fields of respiratory therapy, anesthesia, and emergency medicine reveals a paucity of safety information relevant to suctioning in tactical combat casualty care. One notable exception is Roberts and Hedges' Clinical Procedures in Emergency Medicine[2]. It notes several points related to avoidance of adverse effects in the performance of suction:

- There are no contraindications to suctioning, however prolonged (>15s) suctioning can lead to hypoxia.
- To avoid hypoxia, consider supplemental oxygen during suctioning, or hyperventilate with oxygen before suction.
- Suction only under direct vision as blind suction can cause tissue damage or convert a partial obstruction to a complete one.

There are several injury types and subsequent conditions that result in the need for suction devices. These can range anywhere from airway obstruction to burn injuries. Airway obstruction occurs when build-up of bodily fluids (vomit, blood, saliva, bile, etc.) and debris (broken teeth, fracture bones, etc.) accumulate at the oropharynx and/or nasopharynx block airway passages and prevent ventilation. As much as a fourth of a mouthful of vomitous fluid (about 0.4 mL/kg) is enough to cause serious airway obstructions[3]. Hypoxia occurs when the amount of oxygen reaching the blood is reduced due to airway obstructions, and hypercarbia results from a build-up of carbon dioxide due to the reduced oxygen levels reaching the blood stream[4]. Burn injuries can cause swelling of airways due to inflammation from burns or inhalation of a large amount of smoke or gas[4]. The leading cause of airway deaths on the battlefield is maxillofacial injuries[5]. Due to deformed facial features from injuries such as fractures, swollen tongues, or debris blocking the airway[4], suctioning and intubation can be difficult. These atypical presentation scenarios are challenging for combat medics, who receive relatively limited training related to intubation[5]. Suction devices may be needed in other instances as well, such as for tracheal suction for intubated patients, gastric suctioning for patients with nasogastric or orogastric tubes, or build-up of fluids in the pleural cavities of the chest.

Summary of the Casualties Requiring Suction Devices Section

- Airway obstruction could lead to death in survivable cases.
- Clearing the airways is important for improved visualization.
- Suction devices could be needed in several cases including, but not limited to, obstructed airways, ventilatory failure, hypoxia, hypercarbia, burn injuries, and maxillofacial injuries.

Recommendations of the Casualties Requiring Suction Devices Section

- Combat medics should receive additional training beyond what is currently available in the manuals pertaining to airway securement and suction

Military Requirements for Suction Devices

There are no set military standards for medical suction devices. Tactical Combat Casualty Care (TCCC) guidelines are updated annually, which means military requirements are changing regularly. There are also different medical personnel with various needs, which render it difficult to standardize requirements. For example, medics working in the front-line will require a lightweight, compact suction device design that is easy to carry. Medics working from ambulances can carry heavier or larger equipment, and also have more options for power supply. Because of these different needs, there is no single standard or list of specifications that can be recommended. Any currently listed specifications should remain flexible to the various combat medic roles and changing TCCC guidelines. With these in mind, there are some important performance measures that should be taken into account including weight, dimensions, portability, sterilization, air flow and vacuum pressure, collection canister volume, and whether the pump is battery operated.

Combat situations can be stressful with many confounding mission, field, and environmental variables such as extreme temperatures, different tactical situations, difficult terrains, and combat search and rescue (CSAR) operations. Airway suction device performance under various environmental parameters should be assessed, such as altitude, vibration, temperature, and humidity. Furthermore, device suction should be assessed when the device itself is wet or in a strong electric field. In high casualty scenarios, a suction device that can be operated without any prior medical training is highly preferred[4]. Because of these variables, there are several military requirements for airway suction devices to be suitable for field use. Due to the diverse terrains and tactical situations, the device must be durable, easy to transport, and easy to sterilize[6]. Tubing for the suction device must be clear to allow for constant monitoring of the suction process and any clogging of the device. Large-bore tubing is preferred to smaller tubing, as the latter can only be used to suction low viscosity fluids with little to no debris[7]. Similar suction efficacy should be available to combat medics as in civilian clinical settings[8], which eliminates the use of manual, unpowered suction devices. Manually-powered suction devices do not provide as much flow rate their electrical-driven counterparts, although they may be more lightweight and portable. In addition, combat-ready suction devices must differ from their civilian counterparts by being compact, rugged, and quiet (reduced IR/noise signatures)[8]. The maximum weight for a

military suction device should ideally be as light as possible; a realistic weight for a battery-operated, rugged device is a kilogram or less. Because of sterility issues on the field, it may be easier to have disposable tubing and collection chambers.

There are currently no suction devices specifically designed for regular military field use. A surgical suction pump currently used at aid stations and hospitals is manufactured by Impact Instrumentation Inc. and is called Impact 326M Portable Continuous/Intermittent Surgical Suction Pump Aspirator. This suction device has the ability to work continuously when plugged into an AC/DC power supply or for a limited number of hours on battery power, which is rechargeable by plugging into an AC/DC power source. It is lightweight, versatile, compact, and can hold 2000 mL fluid per canister. This device is too heavy (12 lbs) and bulky (11.5” x 9.5” x 4.87”) for a field medic to carry. Additionally, the range of operating temperatures (-4 °F to 120 °F) does not cover extreme cases. Another device that is currently employed in ambulances is also manufactured by Impact Instrumentations Inc. and is called Impact 325M Portable Suction Unit with Gauge/Regulator. This device also comes with a compact carry unit but is heavier. It can be operated in a range of extreme temperatures and runs on AC/DC power supplies. Due to the heavy weight (13 lbs), bulky dimensions (10” x 13.5” x 6.125”), and limited battery-power (60 minutes on high power) before requiring recharging, this device is also not feasible for medical field use.

Summary of the Military Requirements for Suction Devices Section

- There are no set military standards for suction units; however, there are important performance standards that need to be maintained when manufacturing a device, including weight, dimensions, portability, sterilization, air flow and vacuum pressure, collection canister volume, and whether the pump is battery operated.
- Suction devices must be built for use on different terrains and extreme weather situations. They should be rugged with an extended battery life that is easy to change without the need of a power supply for recharge.
- There are currently no devices built for use on the field specifically. The device used at aid stations and in hospitals is the Impact 326M, which is unsuitable for field use because it is heavy, bulky, and inoperable in extreme temperatures. The device used in ambulances is 325M, which is unsuitable for field use because it is heavy bulky, and has a short battery life.

Recommendations of the Military Requirements for Suction Devices Section

- Standards should be established relevant to universal use for military personnel with different needs. Some important design concepts to consider are:
    - Size, weight, and ergonomics
    - Vacuum pressure similar to that in clinical use
    - Battery operated and easily replaceable batteries
    - Rugged
    - Extreme weather conditions

Manufacturing Standards on Suction Device Test Methods

A review of the available literature reveals no standards, either proposed, validated or accepted for the safety or avoidance of adverse effects portable suction devices for use in combat casualty care. Similarly, there are no accepted standards to guide the safe use and anticipated adverse effects of suction for use in prehospital or emergency care. There are, however some sources that inform the discussion.

ISO 10079 Medical Suction Equipment Overview

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. ISO normally focuses on technical and engineering aspects of a machine and in general, they do not address medical standards, *per se*. ISO is generally used by manufacturers seeking to document they have produced products that have met certain standardization guidelines. ISO is not normally considered applicable to the actual practice of patient care in the clinical environment.

ISO 10079 is a standard with the most recent available date of 2014-15 (the range reflects the different subparts of the ISO document)[9-11]. Compliance with ISO is voluntary but generally expected since a governmental body (e.g., Food and Drug Administration) requires it.

It is important to recognize that ISO 10079 covers suction devices in general, that is, it encompasses the universe of all medical suction devices. Suction devices for use in prehospital care are just a subset and not all of ISO 10079 is relevant to this environment, let alone combat. In fact, much of the ISO standard represents good manufacturing practice, safety standards, and design implications that would all likely be

transparent to the clinician. Nevertheless, the standard contains a number of relevant patient safety requirements for portable suction devices that may or may not apply to the combat casualty care environment. A select list of characteristics follows; readers are referred to the full ISO document for additional details.

ISO 10079 represents a minimum standard for portable manual and electrically powered suction devices. There is little indication in the standard that these minimums are satisfactory patient safety parameters for either prehospital or combat casualty care use.

A large manufacturer of medical suction devices publishes a guide entitled “The Principles of Vacuum and Clinical Application in the Hospital Environment.”**Error! Bookmark not defined.** It provides this nonspecific safety guidance: “The clinician must be cautious when determining the amount of negative pressure applied to the patient. The minimum amount of negative pressure necessary to accomplish the suctioning procedure should be used. When additional flow is necessary, changes in other suction variables, such as tubing length and diameter should be considered before increasing negative pressure.” For airway suctioning, it provides this additional recommendation, but does not provide the evidentiary support: “Keep pressure below 80-120 mmHg; Make sure outer diameter of catheter is; no more than half the inner diameter of airway; Give supplemental oxygen and deep breaths.”

Suction Device Testing Methods Found in Literature

Two key literature sources were identified that provide specific and detailed discussion of testing suction devices for the military environment. Costello et al. discusses the mechanical testing of a portable suction pump. The reported weights were measured using a triple beam balance, and the dimensions were measured manually with a ruler.[6] The canister volume and fluid capacity were determined by measuring the displacement of water and how much water the canister could hold before overflow occurred, respectively. Suction pressure was measured using a 128KB Smart Reader Plus pressure transducer and data-logger. The peak vacuum was assessed in various conditions, included dry (air) and wet (fluid) suction.[6] Cream of mushroom soup was used to represent vomitus fluid in the wet experiments.[6,12]

Bruckart et al. discusses electrical and environmental testing for a suction system. Battery longevity was assessed while the suction device was operating at maximum power consumption. Environmental testing was conducted through wet suctioning of 550 ml of water under a variety of different conditions including altitude, vibration, temperature, and humidity. Altitude testing was conducted using a Tenney Engineering

model 64S altitude chamber simulating 15,000 ft above sea level.[13] Vibration testing was conducted using an Unholts-Dickey model TA115-40/CSTA system to determine how the device would work on a rotary wing aircraft during CSAR. Extreme temperature (-46 °C -71 °C) and humidity (0-20%) testing was conducted using a Tenney Engineering model ZWUL-10107D Walk-in Controlled Environment Chamber. Another series of tests were conducted inside an electromagnetic interference chamber, wherein the device suctioned fluid while subjected to electric field strengths up to 10 V/m produced by radiotransmission emitters.[13]

Suggested Improvements to ISO 10079 for Military Readiness Testing

There are two parts to ISO 10079: 1) electrically powered and 2) manually powered suction equipment. The focus of this report is on Part 1, which is more extensive and relevant to the proposed systems. The test methods discussed in this section are drawn from Appendix A of the ISO 10079-1 document. Specific mention is made of methods needing improvement.

The drop test in section A.5 of Appendix A discusses dropping the suction unit from a height of 1 m onto a hard surface such as concrete in a worst case mode. This should be increased to a 2 m drop height dropped onto several surfaces such as concrete, gravel, and uneven rocks prior to re-testing the device to see if it meets compliance requirements. This will simulate the likely scenario in which a person 6 foot tall drops a device held overhead (such as when it was being retrieved from a high shelf or vehicle) onto a variety of surfaces.

In Section A.15.1.1, the simulated vomitus fluid suggested is made by using xanthan gum and adding glass beads (1 mm) to replicate debris that could be found in the fluid. Due to the viscosity variations between different secretions such as blood, saliva, and vomitus fluids, this test should be expanded to cover a variety of viscosities. Because there is also a possibility of broken teeth being among the debris in maxillofacial injuries, the size of the glass beads should vary within a wider range reaching up to 15-20 mm in size. The hardness of the debris also needs to be varied to better simulate the diverse conglomerate of vomited debris found during airway clearance. This could include particles as hard as glass beads and as soft as baby food. Previous groups have employed soups such as “Cream of Mushroom,” but any similarly diverse mixture would be a better simulating material than the current ISO standard.[6]

Testing in different potential military environmental scenarios as outlined by Bruckart et al. would greatly improve assessment. Compliance experiments evaluating battery life and suction performance under different altitude, vibration, temperature, humidity, and

electric field environments would substantially improve certification for military employment. Furthermore, evaluating device suction while either wetted or completely immersed is highly important to predict performance in battlefield scenarios.

Summary of the Manufacturing Standards for Suction Device Test Methods Section

- ISO 10079 provides detailed manufacturing standards for suction devices intended for use in emergency and prehospital care. These have not been clinically validated and do not consider combat use.
- ISO 10079-1 test methods identified for improvement include a revised drop test and use of a validated vomitus simulant.
- Two published sources were listed that discussed mechanical, electrical, and environmental testing of suction pumps.

Recommendations of the Manufacturing Standards for Suction Device Test Methods Section

- Establish improved test methods for suction device performance evaluations to include
    - Size, weight and ergonomics standards specific to prehospital combat use
    - Increased drop height in drop testing
    - Increased diversity of particle size and hardness in vomitus suction testing, and validate the simulated vomitus to human-derived data.
    - Assessing battery life
    - More variety of operational scenarios in suction performance testing including orientation, altitude, vibration, temperature, humidity, and electric field exposure
    - Assessing water resistance

Summary and Conclusions

Airway suction is a critical component of airway management, which is the second leading cause of preventable battlefield death. There are several varieties of battlefield injury that require suction devices, but there are not any sufficiently portable and powerful suction devices for inclusion in combat medic kits. Past these parameters, suction devices for military use must perform under a variety of extreme conditions, such as altitude, vibration, temperature, humidity, wetness, etc. The current ISO manufacturing standards for assessing airway suction device performance are reviewed, as well as some relevant literature evaluating device operation under various

military relevant conditions. Recommendation for addendums to the ISO standards are described, which include more rigorous drop testing, a more diverse and relevant mixture of simulated vomit for suction testing, and conducting suction testing under a variety of extreme environmental conditions.

Acknowledgements

The author wishes to acknowledge the administrative and editorial skill, tireless effort and patience of Heather Wantuch, MPA; and the technical advice, support and background information of Bruce Adams, MD and Yusheng Feng, PhD.

Appendix A - Section Summaries and Recommendations

Summary of the Background Section

- There is no standard for performance tests of suction devices specific to the prehospital combat use of suction devices.
- This report will focus on performance test guidelines, with an emphasis on weight, dimensions, and battery life.

Recommendations of Background Section

- None specified.

Summary of the Casualties Requiring Suction Devices Section

- Airway obstruction could lead to death in survivable cases.
- Clearing the airways is important for improved visualization.
- Suction devices could be needed in several cases including, but not limited to, obstructed airways, ventilatory failure, hypoxia, hypercarbia, burn injuries, and maxillofacial injuries.

Recommendations of the Casualties Requiring Suction Devices Section

- Combat medics should receive additional training beyond what is currently available in the manuals pertaining to airway securement and suction

Summary of the Military Requirements for Suction Devices Section

- There are no set military standards for suction units; however, there are important performance standards that need to be maintained when manufacturing a device, including weight, dimensions, portability, sterilization, air flow and vacuum pressure, collection canister volume, and whether the pump is battery operated.
- Suction devices must be built for use on different terrains and extreme weather situations. They should be rugged with an extended battery life that is easy to change without the need of a power supply for recharge.
- There are currently no devices built for use on the field specifically. The device used at aid stations and in hospitals is the Impact 326M, which is unsuitable for field use because it is heavy, bulky, and inoperable in extreme temperatures. The

device used in ambulances is 325M, which is unsuitable for field use because it is heavy bulky, and has a short battery life.

Recommendations of the Military Requirements for Suction Devices Section

- Standards should be established relevant to universal use for military personnel with different needs. Some important design concepts to consider are:
    - Size, weight, and ergonomics
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    - Battery operated and easily replaceable batteries
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    - Extreme weather conditions

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Recommendations of the Manufacturing Standards for Suction Device Test Methods Section

- Establish improved test methods for suction device performance evaluations to include
    - Size, weight and ergonomics standards specific to prehospital combat use
    - Increased drop height in drop testing
    - Increased diversity of particle size and hardness in vomitus suction testing, and validate the simulated vomitus to human-derived data.
    - Assessing battery life
    - More variety of operational scenarios in suction performance testing including orientation, altitude, vibration, temperature, humidity, and electric field exposure
      Assessing water resistance

Appendix B - Key Task of the Report

Develop a standard performance test for combat suction validation. Suction devices for prehospital combat casualty care have unique performance requirements and should be tested in a manner that effectively simulates the anticipated pathophysiology. The study must meet applicable ethical and legal requirements for research and be feasibly implementable. Deliverables will be: 1) A report of a test of combat suction performance, and 2) Written protocol of study that is ready for regulatory review.

Appendix C - Technical Approach

Existing and projected (future) military medical requirements relevant to the expected combat and operational scenarios (such as prolonged field care) are identified. The required performance characteristics of a suction unit intended for prehospital combat casualty care is ascertained based on these anticipated operational scenarios. The key characteristics searched include vacuum suction flow rate, pressure, and capacity to evacuate the expected fluid/particle viscosity/size (e.g., saliva, blood, vomitus, mud, gravel, broken teeth) for management of prehospital Combat Casualty Care injuries. Source documents were extracted from 1980-present and analyzed for title content. If relevant, the article was reviewed in detail. Secondary references prior to 1980 were selectively searched based on the title and the likelihood of topical relevance. Specific sources searched include but are not limited to:

- Committee on Combat Casualty Care (CoTCCC)
- Medical literature using Medline or equivalent with search terms including
    - *Suction*
    - *Vacuum*
    - *Aspiration*
    - *Airway, airway management*
    - *Airway obstruction*
    - Modifier terms including *safety, efficacy, and performance*
- Engineering literature using Academic Search (EBSCO), or equivalent using similar search terms as above
- Defense Technical Information Center (DTIC)
- Retrievable information from conferences and meetings focused on combat casualty care, prehospital care, and airway management.
- Government standards including FDA
- Industry and government standards clearinghouses including ISO

Where necessary to fill in information gaps, existing requirements were supplemented with proposed requirements vetted against local expert military and civilian medical consultations. UT Health San Antonio maintains a robust panel of US military experts in emergency medicine and prehospital care that can be consulted. Additionally, UT Health San Antonio is in close proximity to and maintains a healthy relationship with

JBSA-Fort Sam Houston which is the US military's key hub of combat casualty care and trauma training, and UT Health San Antonio retains the ability to consult with the organizations and personnel within this installation as well as other US military installations worldwide.

The available information is organized, critically appraised, and synthesized into a narrative report that summarizes the performance characteristics for management of prehospital combat

Appendix D – Proposed Research Protocol to Test Suction Performance

PROTOCOL TITLE: Prehospital Upper Airway Suctioning Testing Methods – A Guideline for Performance Testing for Field-Use Military Suction Devices

BACKGROUND

Study Aim: The primary goal of this study is to explore key performance requirements regarding suction devices for military use in a prehospital combat casualty care environment. For purposes of this protocol, the following parameters and assumptions are established:

- Scope is limited to the clinical application of suctioning the oronasopharyngeal airway for purposes of airway clearance for basic life support in preparation for advanced airway procedures such as orotracheal intubation.
- Mechanisms of potential injury will focus on local trauma as a result of catheter mechanics and/or vacuum pressure effects and flowrates.
- Not examined are systemic or distant effects such as hypoxemia or atelectasis.

Background and Review of the Literature: Tactical airway management often determines survival in both trauma and medical patients. Skilled interventions often make the critical difference in survival for patients with actual or impending airway compromise. Managing airways in the tactical environment presents an additional level of unique and complex challenges for any emergency provider. Hazardous or confined spaces and hostile action inherently limit the ability to intervene with an artificial airway or assisted ventilation. Loss of patient airway in tactical and combat environments commonly occurs. The proximate cause can be direct trauma to the airway structures or indirectly from traumatic shock or brain injury and the subsequent loss of airway protective reflexes.

In the Vietnam War, 6% of all soldiers killed in action only had an airway obstruction. More recent conflicts, notably Operation Iraqi Freedom (OIF), have shown an increase in primary injuries to the airway. In OIF, 27% of wounded in action suffered injuries only to the head, neck or airway structures [14]. This increase in airway trauma is likely due to the excellent torso protection of body armor and a subsequent diversion of injuries towards less armored areas such as the neck and face. The Registry of Emergency Airways at Combat Hospitals study (REACH) shows that prehospital cricothyrotomies are performed ten times more often on the battlefield as compared to civilian trauma systems. (5.8% vs. 0.5%) [2]. A recent study highlights the high incidence of combat airway injury in combat maxillofacial trauma [14]. In these and other trauma cases, airway management requires a low threshold for airway stabilization to include tracheal intubation and cricothyrotomy or tracheostomy. A major reason for this dramatically higher rate of surgical airways is poor visualization of the injured airway with current inadequate suction devices available on the battlefield.

Aspiration of as little as 25 mL (approximately ¼ mouthful) of vomitus can cause significant pulmonary aspiration injury, and a massive aspiration carries a mortality as high as 70%[15,16]. Delays in suction can presumably increase the risk of aspiration, obstruction-related hypoxia, and make visualized intubation of the trachea impossible, so the availability and performance of suction can be viewed as essential. Despite this, there is a paucity of high-quality evidence on the techniques of suction. A 2009 Cochrane review on suctioning of patients revealed limited scope of data[17]. Practice guidelines from 2001 on hyperoxygenation, hyperinflation, use of a ventilator circuit adaptor and subglottic suctioning were validated. In the review, new evidence was identified with respect to indications for suctioning, open suction versus closed suction systems, use of medications and infection control. Virtually all of the data was focused on in-hospital suctioning of primarily mechanically ventilated patients. There were no high-quality reports focusing on prehospital or emergency care in the Cochrane review.

The combat experience of the last dozen years clearly demonstrates that airway obstruction is the leading cause of preventable combat casualty deaths behind only hemorrhagic shock. Between 6-10% of battlefield deaths could have been prevented with adequate airway management[18]. Because of vastly improved body armor and the enemy's shift towards direct fire and improvised explosive devices, the injury pattern today is much different than in previous wars. Airway management in this austere environment is notoriously difficult for many reasons but especially because of inadequate airway equipment.

Nonhuman primates are considered the standard model for the human airway, but these species are not available for study. Large animals such as swine approximate adult human cardiorespiratory physiology, but lack anatomic correlation. Smaller animals such as cats and ferrets have anatomy similar to small children, but this is not the population of interest. Given the overall experimental situation, the most pragmatic compromise is a young swine. It is available, cost-effective, and offers reasonable local tissue similarity in the areas of interest.

Significance: In comparison to the advances in many areas of prehospital equipment, the current suction devices on the market have not achieved the level of performance required in civilian prehospital care, let alone battlefield care. It is telling that a recent 5 page review article on an advances in technology and concepts in tactical combat casualty care, there was no mention of suction and had only this to say about airway management advances in general:

Airway Protection: A skill common to all physicians deploying on the MERT Medical Emergency Response Team (MERT)] is that they must be proficient at airway assessment and competent to definitively secure an airway if required. Generally, this takes the form of a rapid sequence induction using direct laryngoscopy. Several rescue devices are also available as alternatives or for use in a failed intubation such as supraglottic airways, optical laryngoscopes, and cricothyroidotomy.

Perhaps reflecting the perceived lack of effectiveness of prehospital suction devices, Kozak reported on a survey of paramedics carrying suction equipment to the scene of medical aid calls less than 25% of the time, and once on scene, suction equipment was utilized on only 50% of advanced airway procedures. It seems the available off-the-shelf devices do not possess the proper balance of tradeoffs between portability, effectiveness and cost to be effective in tactical care.

To help answer questions regarding suction device performance in the prehospital combat environment, a series of laboratory testing methods are proposed to test selected performance measures.

Literature Sources Searched: Literature review was completed with the assistance of Dr. DeLorenzo as well as database searches. The databases searched included: the Google Scholar database system, Pub Med/Medline, and the UTSA library database system.

Key Words of Search: Suction; Vacuum; Airway; Oropharyngeal; Nasopharyngeal, Tracheal; Performance Test; Obstruction; Intubation. Boolean combinations and fuzzy logic were used as allowed by the search engines.

Results of Search: The literature search revealed two published sources referring to military testing of suction devices. These methods are not standardized, and each source focused on a different subset of testing: mechanical, electrical, and environmental.

OBJECTIVE: Research and review current test methods outlined in ISO 10079 and published journal articles. Suggest improved methods to aid in suction devices meeting military requirements for field use in prehospital combat casualty care.

MILITARY RELEVANCE:

There is limited information on the types, if any, of portable suction units carried by combat medics in the far-forward combat area. Anecdotal information suggests that powered suction devices are simply too heavy to be carried in the combat medic's aid kit. Manual powered devices, while lightweight, offer limited capability and require the use of a hand or foot to operate, limiting efficiency of the provider. Fielding data from military logistics agencies on the number and types of suction units employed in the field is not available, and prior experience suggests even if obtained, the data shows only total purchases and not where and when fielded.

Existing portable suction standards are civilian-oriented, lack a detailed base of evidentiary support, and in any case do not satisfy the critical needs of combat casualty care. We propose a set of performance standards that meet the needs of prehospital combat casualty care that could support a future development of a portable suction design that meets all of the combat medic's needs.

MATERIALS AND METHODS

Experimental Design and General Procedures

Materials: Suction pumps already on the market 6 lbs or lighter that are battery-powered with the option to be recharged will be selected for performance testing to establish and standardize laboratory testing. If determined feasible, data collected during laboratory testing will be used to test and hypothesize suction pump use on the field.

Experimental Methodology: Record initial measurements such as weight, vacuum pressure, suction tubing diameter, and battery power before each performance test for each suction device. Record measurements after conducting each performance test as well for data analysis.

Drop test for durability: Drop each pump from a height of 2 m onto concrete, gravel, and uneven rocky surfaces. The laboratory personnel conducting the drop tests should remain constant for all test. Test each airway suction device n=3 times, recording measurements after each drop, to account for human error.

Battery life test: Run each device at minimum and maximum flow rate until the battery dies; record the run time. Record the length of time required to recharge the device to maximum battery power. Conduct this test n=30 times at minimum and maximum flow rate to account for battery wear time.

Flow rate test: Test different using different concentrations of food grade xanthan gum in 1 L of distilled water. Dissolve 3 g, 7 g, 10 g, and 15 g of xanthan gum in 1 L of water. A mixture of 15 g of 1 mm, 5 mm, 10 mm, and 20 mm beads each will be added to each mixture of xanthan gum to replicate the variety of debris sizes that could be found in vomitus fluids for maxillofacial injuries. To replicate the variety of hardness found in debris, a mixture of 20 g of corn kernels and 20 g of diced mushrooms will be added to each mixture of xanthan gum as well. The flow rate will be tested at the low and high vacuum pressures identified by the manufacturer for each suction device. Repeat each test n=3 times to verify how fast the flow rate is for each viscosity.

Environmental and electrical test methods including altitude, vibration, extreme temperature, and electric field tests will be conducted as discussed in Bruckart et al[13]. These testing methods are briefly laid out in the Suction Device Testing Methods Found in Literature subsection of the Manufacturing Standards for Suction Test Methods section of this document (page 10)***:***

> Environmental testing was conducted through wet suctioning of 550 ml of water under a variety of different conditions including altitude, vibration, temperature, and humidity. Altitude testing was conducted using a Tenney Engineering model 64S altitude chamber simulating 15,000 ft above sea level. Vibration testing was conducted using an Unholts-Dickey model TA115-40/CSTA system to determine how the device would work on a rotary wing aircraft during CSAR. Extreme temperature (-46 °C -71 °C) and humidity (0-20%) testing was conducted using a

Tenney Engineering model ZWUL-10107D Walk-in Controlled Environment Chamber. Another series of tests were conducted inside an electromagnetic interference chamber, wherein the device suctioned fluid while subjected to electric field strengths up to 10 V/m produced by radiotransmission emitters.

ISO 10079-1 guidelines will be followed for all other suction pump tests such as noise testing, overfill capability testing, and suction tubing degree of collapse[9].

Data Analysis: This investigation is limited to laboratory testing. Data analysis will be calculated by comparing initial measurements taken for each device to the average measurements taken in each performance test.

STUDY PERSONNEL QUALIFICATIONS AND TRAINING:

All investigators / research personnel involved in this study should familiarize themselves with ISO 10079-1 test methods and should have laboratory access. At least one laboratory member is needed to conduct all drop tests for uniformity.

BIOHAZARD/SAFETY: All personnel participating in this protocol are currently enrolled in an Occupational Health and Safety Program, have received a risk assessment relative to protocol related hazards, and have been cleared to conduct all proposed activities listed. This is considered minimal risk because all tests will be conducted in a laboratory setting. All lab personnel must wear proper personal protective equipment (PPE) at all times. Because xanthan gum may cause irritation and is slippery when wet, PPE will include gloves and non-slip shoes.

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