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LAUNCHING INNOVATION THROUGH MEDICAL MODELING AND SIMULATION TECHNOLOGIES

Special Edition

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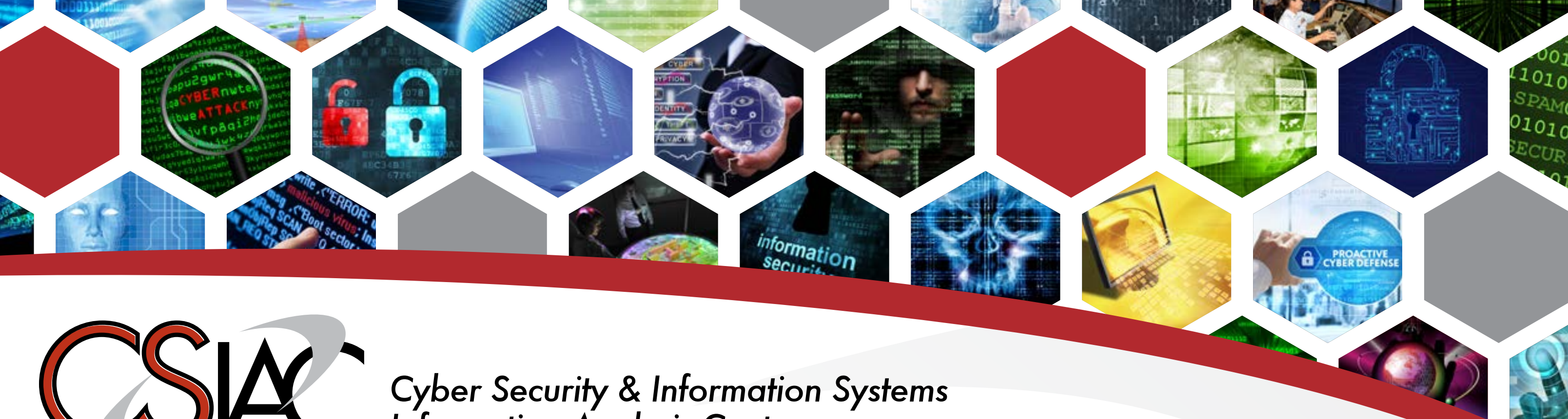

CSIAC

Cyber Security & Information Systems Information Analysis Center

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Journal of Cyber Security and Information Systems

Launching Innovation through Medical Modeling and Simulation Technologies

LAUNCHING INNOVATION

through Medical Modeling and Simulation Technologies

By: Teresita M. Sotomayor, Ph.D., Senior Engineer, Medical Simulations and Performance Branch

The field of medical simulation originated in ancient times, where simple models of human patients were portrayed in clay and stone to represent clinical features of disease progression and its effects on humans. Historical data from the Middle Ages documents the use of animals for training surgical procedures. However, it was not until the 20th century that human patient simulators (HPS) were developed for education and training.

Modern medical simulation has blossomed since the 1930s, facilitated by successes in flight simulators. Current advances in biomedical technologies have enabled the development of highly realistic, anatomically correct, physiologically based, and cost-effective simulations to support the training of medical personnel.

Over the last century, battlefield casualty survival rates have improved from 80 percent during World War II to 90 percent in recent conflicts. This is attributed to several factors, such as advancements in personnel protective equipment, and deployable trauma treatment technologies. It is also important to note that simulation-based training has been instrumental in training military medical personnel to save lives.

The Department of Defense relies heavily on the use of modeling and simulation to train the warfighter, especially in the medical field. In the past 20 years, there has been a push to increase the fidelity of medical training systems. During training, soldiers are given opportunities to master their cognitive and psychomotor skills. As students move in the training continuum towards proficiency, fidelity becomes more important for creating a realistic stressful and immersive environment. The ultimate goal is complete suspension of disbelief to achieve stress inoculation.

The medical modeling and simulation field continues to make strides with simulation-based solutions. A prominent example is the improvement over the years with HPS capabilities. Early HPSs were tethered, which made field training events difficult. HPSs are now wireless and incorporate advanced features including motion, facial expressions, and vocalization to indicate signs of life and pain, while forcing trainees to communicate with the patient.

This special edition will provide a glimpse into current efforts to improve military medical training. The first two articles provide interesting insights on how the Navy is utilizing medical modeling and simulation as an education and training modality. The article titled “Capabilities of the Naval Medical Center Portsmouth Medical Simulation Center” provides an overview of the medical simulation capabilities

at the Navy's premier medical training center and describes how these capabilities support the training of individual and team skills to reduce the number of preventable medical errors. The article titled "Navy Medical Modeling and Simulation in a DHA-Service world" describes the role of the Defense Health Agency in centralizing, coordinating, and consolidating medical modeling and simulation requirements.

The Army is adding malodors to create training environments as realistic and difficult as encountered on the battlefield. The article titled "Reliability and Feasibility Considerations in the Assessment of a Malodor Adaptation Technique: A Pilot Study" which was published recently in the "Military Medicine Journal" assesses the impact of malodors in the performance of complex tasks.

The Special Operations community is working with the Army to develop high fidelity surgical simulations with lifelike synthetic materials that look, feel, and even smell like human tissue. The goal is to create a training environment that blurs the boundary between real life and simulation. The article titled "High-Fidelity Surgical Fasciotomy Simulator for Training Special Operations Medics" describes an effort to develop a high fidelity part task trainer for SOF medics to master a procedure to relieve acute compartment syndrome of the lower extremities.

Data from current and previous conflicts show that 90% of all combat deaths occur before a casualty reaches a definitive care facility. Pre-hospital care plays a vital role in battlefield medicine and focuses on improving medical care at the point of injury. Trends indicate that female trauma survival rates may differ from males. The article titled "Saving Female Lives using Simulation: Elevating the Training Experience" describes what the Army is doing to increase the survival of female casualties at the point of injury. It provides an overview of the literature on female simulation, anecdotal evidence of the current training gap, and explains current trends highlighting the need for female simulation.

The Department of Defense is the single largest provider of simulation-based medical training worldwide. Providing this training requires the complex coordination of time and resources to support the full continuum of care, from austere environments to military hospitals and treatment facilities at home. Medical simulations are an integral part of the military health system, providing opportunities for skills development and performance assessment of both individual and team-level medical-related tasks. The different services within DoD support a variety of medical roles, including both medical professionals as well as support staff who must communicate effectively. As technology improves, both military and civilian health systems can benefit by consistently identifying gaps in performance and capabilities, and working together to develop solutions to continuously improve.

CAPABILITIES OF THE

NAVAL MEDICAL CENTER PORTSMOUTH MEDICAL SIMULATION CENTER

By: CAPT Michael T. Spooner, MC, USN, Healthcare Simulation and Bioskills Training Center, Naval Medical Center;
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A RECENT STUDY (MAKARY & DANIEL, 2016) OF MEDICAL ERRORS HAVE ESTIMATED PREVENTABLE MEDICAL ERRORS MAY ACCOUNT FOR AS MANY AS 251,000 DEATHS ANNUALLY IN THE UNITED STATES (U.S.).

They are also the third cause of death in the U.S. behind by cancer and cardiovascular disease. These errors result from breakdown in teamwork and communication primarily but there are also gaps at times in knowledge and technical skill. Innovative medical educational approaches are warranted to target all these areas and decrease this number. A valuable tool to assist with the safe delivery of health care and improvement in individual and team skills is medical simulation. This article presents an overview of the medical simulation capabilities of the Naval Medical Center Portsmouth and highlights its unique importance in the training of clinical personnel to bridge the transformation to a High Reliability Organization.


HEALTHCARE
SIMULATION
Competency
Patient Safety
CENTER
CABAN
CAUTION
OXYGEN IN USE
NO OPEN FLAMES

INTRODUCTION

Naval Medical Center Portsmouth Healthcare Simulation and Bio-skills Training Center (NMCP HSBTC) has over 8,000 square feet of physical space and encompasses 5,720 square feet of contiguous space. It offers an immersive state of the art environment training room that accommodates a multitude of simulation related capabilities ranging from basic skills practice and training to large scale mass casualty scenario simulations. Simulation rooms for pediatrics, anesthesia, obstetrics, and virtual surgery are also available.

The simulation center maintains two multimedia related training conference rooms that have the ability to facilitate lecture, discussion, debriefs, webinars, and hands-on training. Staffing for the simulation center includes: NMCP HSBTC Director, Deputy Director, Manager, Nurse Educators, Simulation Technicians, and Research Scientist.

The simulation center is an integral part of 14 graduate medical education programs administered at NMCP. It provides weekly multi-disciplinary training sessions through the facilitation of safety and team-based trainings to all disciplines and specialties, and sustainment skills to hospital personnel. The center also provides immersive combat causality care training to deploying troops.

The simulation center was established in 2006 primarily to complement NMCP Graduate Medical Education programs. Over the past 12 years, the center has continued to strengthen the educational rigor of its curricular offerings. Specifically, it expanded into new and exciting areas of pre-deployment courses for military trauma surgical teams, and patient safety instructional programs that advance the teamwork and skill levels of the medical teams at NMCP. Importantly, during this period of growth, the simulation center was accredited by the American College of Surgeons in 2015.

NMCP HSBTC has provided simulation related training to over 26,000 Department of Defense (DoD) and civilian healthcare professionals since its inception. It has also expanded its simulation capabilities to over 50 different simulators. Simulation capabilities include: low and high-fidelity mannequins, task trainers, cut suits, standardized patients, and the latest in three-dimensional virtual simulation.

> *"NMCP HSBTC has provided simulation related training to over 26,000 Department of Defense (DoD) and civilian healthcare professionals since its inception."*

TARGETED TRAINING CURRICULA

The center has played an integral part in the development of several new simulation curricula: operational readiness for medical providers, corpsman and team-based simulation, nursing skill sustainment, and inter-professional team training evolutions such as the Perinatal Safety Stand-down.

In 2014, a seminal moment occurred when the Navy Specialty Leader for Interns requested that the simulation center develop a course for outgoing general medical officers that provided them with the opportunity, via a variety of medical simulators, to learn, rehearse, and be evaluated on their new core privileges prior to departure from NMCP. The end product of this tasker was the STOMP (Simulation Training for Operational Medicine Providers) curriculum, which has been administered at the simulation center for the past four years. Other DoD sites have also incorporated this curriculum into their training.

After the development and implementation of the STOMP curriculum, other areas developed similar skills curricula. Navy enlisted leadership developed a curriculum designed for corpsman who were transitioning back to the fleet. This simulation skills curricula are an integral part of the simulation center's ongoing training and is titled HM FIRST (Corpsman Fleet Instructional Readiness and Simulation Training). The NESST (Nursing Enhanced Skills and Simulation Training) came to fruition through the efforts of the nursing staff to address nursing simulation needs for all newly arriving nurses and corpsman to the medical center. Internal medicine physicians also developed and implemented a simulation curriculum specific to their requirements necessary to maintain their core privileges in preparation for future deployments.

In addition, the center has facilitated multiple operational simulation courses, including Fleet Surgical Team pre-deployment training, Expeditionary Resuscitative Surgical System pre-deployment training, Role Two Light Maneuver, and Special Forces medic training. Table 1 presents an overview of the medical simulation training curricula at NMCP.

READINESS THROUGH RESEARCH

Research-related efforts at the HSBTC focus on maximizing the readiness of our medical teams to promote patient safety and optimize quality health care delivered to operational forces and their families through simulation modalities.

NMCP simulation center research endeavors are all IRB approved and fall into the following categories: Operational/ in-garrison care, MTF-based simulation

Table 1. Overview of Medical Simulation Training Curricula at NMCP

Title	Overview	Audience
Operational Medical Providers (STOMP)	This provides an opportunity to rehearse and practice non-trauma primary care medicine skills in a proctored setting before practicing independently.	Physicians
Hospital Corpsman Fleet Instructional Readiness (HM FIRST)	This curriculum focuses on areas such as rapid assessment, physical examination, documentation, nail removal, wound closure, urinary catheterization and intravenous access.	Corpsman
Nursing Educational and Skills (NESST)	This simulation provides a proctored setting for the actual hands-on practice of day-to-day tasks that are expected of nurses who work the floors of the medical center.	Nurses and Corpsman
Fleet Surgical Teams	This program ensures Fleet Surgical Teams integrate with the crew of the amphibious assault ships (LHDs/LHAs) through rehearsal of trauma casualties using simulated patient and high-fidelity manikin exercises in preparation for primary Role 2 support activity during deployment.	Physicians, Nurses, and Corpsman
Expeditionary Surgical Resuscitative Surgical Systems (ESRSS) or Role Two Light Maneuver (R2LM)	This training is geared specifically for the smaller seven- to nine-person Damage Control Surgery Teams that may be called on to perform Role 2 capabilities on a wide range of diverse platforms at sea or ashore with team performance and resiliency goals similar to those of the Fleet Surgical Team Training.	Physicians, Nurses, and Corpsman

Table 2. NMCP Research Endeavors

Category	Overview
Operational/in-garrison care	Examine the effectiveness of simulation training to improve in-garrison care by corpsmen (HM First), General Medical Officers (STOMP), and Internal Medicine physicians (IM Sustain).
MTF-based simulation research	IRB-approved protocols investigating application-based training for crash cart familiarization, obstetric simulation training and teamwork (OB-STaT) to reduce postpartum hemorrhage, the simulated Electronic Fetal Monitoring app in conjunction with the University of Tennessee-Knoxville, and pediatric confidence and skill in managing high-risk, low-volume pediatric emergency scenarios.
Combat & Casualty Care	Collaborating with investigators from Old Dominion University on a protocol entitled "The Development of an Innovative Role 2 CPG-based Trauma Patient Knowledge-Assessment Instrument and Training Materials that utilize Deliberative Practice and Mastery Training." This protocol is developing a game-based assessment of trauma knowledge for healthcare providers in Role 2 environments. A second collaborative project that will be initiated shortly with investigators from Purdue University will investigate the effectiveness of tele-mentoring in trauma surgeries and is entitled "See-What-I-Do: Increasing Mentor and Trainee Sense of Co-presence in Trauma Surgeries with the STAR platform.

research, and Combat & Casualty Care. Table 2 presents an overview of the NMCP research endeavors.

Previous research efforts supported by the simulation center centered on improving tactical combat casualty care (TCCC) and included simulation training that investigated skill retention in the use of the ITClamp™ for junctional hemorrhage, training and communication for en-route care providers, device stability in simulated casualty movement, and the use of tension pneumothorax cadaver models to determine optimum location of needle decompression.

Future related research areas of interest include: the impact of noise on team performance in austere environments, junctional hemorrhage control with REBOA, bleeding control skills for non-medical personnel, and more TCCC-related issues.

MEDICAL SIMULATION MANNEQUINS

Medical simulation technology and the use of high-fidelity patient simulators are a key ingredient to the center's immersive training curricula. The NMCP medical simulation center has a full array of these high-fidelity mannequins. For obstetric and birthing simulation, the simulation center employs the NOELLE® S550 Maternal and Neonatal teaching system (Gaumard, Inc.), permitting students to appreciate the complete birthing experience from the onset of labor, to delivery, along with treatment of the mother and neonate after delivery. It provides capabilities in ALS, obstetrics, and neonatal resuscitation protocols. Features of the system are presented in Table 3.

Another regularly used mannequin at the NMCP simulation center is the SimMan 3G (Laerdal, Inc.). This simulator is an advanced adult patient simulation system that facilitates training of basic and advanced life support, as well as allowing a full array of patient examination techniques and complex patient-care scenarios. The system allows the instructor to effectively assess the learner's individual and teamwork skills in a realistic clinical scenario.

> *"Medical simulation technology and the use of high-fidelity patient simulators are a key ingredient to the center's immersive training curricula."*

NOELLE® S550 Maternal and Neonatal teaching system

SimMan 3G Simulation System

Table 3. NOELLE® S550 Maternal and Neonatal teaching system features

NOELLE® S550 Maternal and Neonatal Teaching System Features		
Full size articulating full-body female	Intubatable airway with chest rise	IV arm for meds/fluids
Removable stomach cover	Practice Leopold Maneuvers	Multiple fetal heart sounds
Automatic birthing system	Measures head descent and cervical dilation	Multiple placenta locations
Replaceable dilating cervices	Practice postpartum suturing on vulval inserts	One articulating birthing baby with placenta

Table 4. SimMan 3G simulation system features

SimMan 3G Simulation System Features		
advanced configurable airway	Eyes that respond to light	Palpable Pulses
Lung, Heart, and Bowel Sounds	Convulsions simulate seizures or small hand movements	Bleeding and Wound Modules are fed from an internal blood reservoir
Vascular Access (intra-osseous) via the tibia and sternum	Auto-measurement of volume and concentration for drugs and IV fluids.	RFID Technology for automatic recognition of drugs and airway devices
Simulated Secretions: Sweat, tears, froth, urine and ear fluids are fed from an internal fluid reservoir.		

SimMan 3G allows observation and recognition of most vital signs and invasive hemodynamic parameters. This can be achieved through clinical interaction with the mannequin, as well as observation of the mannequin's homonymic status as viewed on the SimMan 3G Patient Monitor PC. Features of the SimMan 3G simulation system are presented in Table 4.

TRAINING NUMBERS

As the largest military healthcare simulation laboratory in the Hampton Roads, Virginia area, the NMCP Simulation Center has continued to expand its support to both internal medical center trainees as well as operational forces in the region. In 2017, the simulation center provided 28,316 prep hours and 11,883 man training hours for simulation activities to a total of 3,196 participants (2025 providers, 336 nurses, and 835 others). The training sessions continue to be ranked highly by learners in terms of 1) objectives/information, 2) support, 3) ability to problem solve, 4) feedback; and 5) fidelity with 2018 average scores of 4.68 on a 5-point validated simulation quality scale.

CONCLUSION

The NMCP Medical Simulation Center provides a safe and controlled environment to teach a wide variety of technical and non-technical skills to medical personnel and to assess individual and team performance. The NMCP HSBTC remains at the forefront of medical simulation training, providing medical education consistent with highest educational standards and ethical principles on a daily basis. As Military Medicine begins to embrace "high-reliability" principles, interactive simulation education and rehearsal will become key to reducing variance in a complex patient-delivery system ashore, afloat, and in forward-deployed environments.

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ABOUT THE AUTHORS

CAPT MICHAEL SPOONER serves as the Director for the Healthcare Simulation and Bioskills Training Center at the Naval Medical Center, Portsmouth, Virginia, a position he has held for the past 5 years. In his current role, he coordinates a broad range of training activities to include simulation, bioskills, and standardized patient support for U.S. Navy medical activities in the Tidewater, Virginia area. His programs directly support Graduate Medical Education (GME), patient safety and skills sustainment initiatives, as well as combat casualty care predeployment training. His staff has designed multiple curricula in support of in-hospital initiates as well as in-situ military mass casualty training for Fleet assets. As a board-certified and practicing electrophysiologist and invasive cardiologist, Dr. Spooner's professional interests and contributions vary from analyzing rare cardiac electrical abnormalities to developing and studying a comprehensive skills curriculum for the U.S. Navy's independent practitioners. He has been involved in simulation education for over 12 years, and currently serves as the Chair of the Society for Simulation in Healthcare's Directors Interest Group as well as the Co-chair of the American College of Cardiology's Simulation Work Group.

CDR JOY GREER graduated from Eastern Virginia Medical School in 2001 and completed a transitional internship followed by residency in obstetrics and gynecology at Naval Medical Center Portsmouth in 2005. She served at Naval Hospital Camp Lejeune for 5 years as a staff obstetrician and gynecologist and teaching faculty of the family medicine residency. While there, she was a member of the Tissue and Transfusion Committee, chair of the Bioethics Committee, and then served as Chair, Executive Committee of the Medical Staff. She then completed a fellowship in Female Pelvic Medicine and Reconstructive Surgery and the certificate program in Clinical Research at the University of Pennsylvania in June 2013. During her fellowship, she received the Fellow Teaching Award from the OB/GYN residents. In 2013, she returned to Naval Medical Center Portsmouth as a Female Pelvic Medicine and Reconstructive Surgeon and faculty member of the obstetrics and gynecology residency program. She was appointed the Deputy Director for the Healthcare Simulation and Bioskills Training Center at Naval Medical Center Portsmouth in 2016. Her research interests include the impact of pelvic floor disorders in the military beneficiary population and simulation in Obstetrics and Gynecology.

DR. DON DELOREY is the Naval Medical Center Portsmouth Simulation Center's Research Scientist and has held this position since early 2017. He received his Ph.D. in Psychology from Walden University, MS in Health Physics from Georgia Institute of Technology, MAS in Human Factors from Embry-Riddle Aeronautical University, and MS in Meteorology from Florida State University. Dr. Delorey directs a variety of scientific research, publication and academic endeavors in the simulation center which contribute to the science of medical simulation. He also assists with the development and study of evaluation tools that support medical simulation as it relates to research of new training modalities and methods.

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(A non-exhaustive set of topics)

NAVY MEDICAL MODELING AND SIMULATION

in a DHA-Service world

By: Robert M. Selvester, MD, Commander, Medical Corps, United States Navy

TO THE OUTSIDER, THE PHRASE "MEDICAL MODELING AND SIMULATION" ENGENDERS THOUGHTS OF ... NOTHING.

For others, cardiopulmonary resuscitation (CPR) training on a new-found friend with a relatable name like Chris, Anne, or wee-baby Timmy comes to mind. But MM&S has a profound impact, albeit in the background, in the life of every Sailor, Coastie, Airman, Marine, and Soldier. For the medically-oriented servicemember, simulation is an intrinsic part of developing, refining, and mastering skills and processes without placing a human patient at risk. In an environment where paradigms like "Train the Way We Fight" drive requirements for more lifelike, physiologically-responsive (collectively, "high fidelity") equipment, the MM&S community drives innovation.

This article reviews the background, scope, equipment, and organization of MM&S, placing particular emphasis on the evolving relationship between Readiness-oriented and Clinical Benefit-oriented training.

The history of medical modeling and simulation is relatively contemporary, but has roots in antiquity. The Greek physician Galen, in the 1st Century, used a monkey model as the basis for his teachings on anatomy and physiology. His teachings were radically transformed when Vesalius, a Flemish physician in the 16th Century, studied human cadaveric models. Moulage, the simulation of wounds, has similarly been used since the early 18th Century, first as wax models. In the late 1950s, the Norwegian toymaker Laerdal first began creating moulage, then shortly after, a life-sized manikin. A proliferation of manikins of varying fidelity has followed from the 1990s to present day. But, in modern medical training, simulation is more than just manikins.

A variety of simulation technologies or platforms are in use currently. Partial task trainers are purpose-specific devices typically used to teach one or a few skills. An example would be a simulated hand for practicing the placement of intravenous (IV) lines. Full-body manikins range in sophistication from plastic and latex shells to highly interactive, computer-driven devices with built in physiology engines that respond to treatment interventions. Standardized patients, scripted actors presenting role-based scenarios, are commonly used in graduate medical education, are the professional counterpart to the untrained soldier-actors in field exercises who are instructed "go crazy when the Doc touches you." Screen-based simulators range from defibrillators that project a cardiac rhythm to ultrasound training systems to Augmented Reality-driven applied ("serious") medical games. Even larger systems (and systems of systems), analogous to the command and control simulations used by the Line are being developed. The Joint Evacuation and

Transport Simulation system (JETS) is one example in which participants who may be geographically separated may (synchronously or asynchronously) play a role in the medical care, hand-offs, and transportation of a casualty from a battlefield point of injury to a stateside military treatment facility.

Simulation is just one piece of a holistic approach to developing a Ready Medical Force. Real life patient care remains the gold standard for mastery of medical procedural skills, but it is nearly impossible to fully standardize and training errors can bring negative medical consequences to real people. Simulation overcomes these challenges, so MM&S has an increasing role in education and training. Just as the aviation community may desire that the first flight is a perfect flight for a trainee, the medical trainee is expected to "get it right" the first time, ideally every time. Simulation is excellent for first exposure to new skills, for learning the steps in complex procedures, practicing team skills, and learning or refreshing skills on uncommon or rare medical procedures.

Medical modeling and simulation are used in several other contexts, as well. In pharmacy formulary management, modeling is frequently employed to estimate cost: benefit or return-on-investment through Monte Carlo simulations. Additionally, medical operational planners employ modeling of anticipated future battle scenarios based on a myriad of medical and non-medical intelligence sources. Anatomic modeling is used in surgical preparation for medical and dental procedures. These illustrative applications are acknowledged but will not be further discussed in this essay.

"Medical operational planners employ modeling of anticipated future battle scenarios based on a myriad of medical and non-medical intelligence sources."

Medical modeling and simulation as an education and training modality within Navy Medicine (Budget Submitting Office (BSO)-18, aka BUMED) is currently overseen and supported by a central program office, guided by a Central Simulation Committee. Validated and resourced training requirements may come from a variety of sources (e.g. Fleet Forces, the Surgeon General, etc.) and are intended to drive program development—an application of the Navy Education and Training Command End-to-End process. However, validation and resourcing of requirements often lag behind the practical need for training, so training programs and curricula are developed and launched prior to validated requirements or resources. This reality often promotes a "Tyranny of the Urgent"-type priority system and places systematic program development and standardization at risk (with apologies to Oswalt Chambers).

Conceptually, there are four broad categories of training for which military medical simulation may be a useful training modality—initial technical training; clinical skills sustainment; resuscitation training; and Readiness (or Operational) training. Initial technical training involves the acquisition of new skills—basic Hospital Corps School; C School training; Internship, Residency, or Fellowship; or targeted training for a new discipline-specific procedural skill (e.g. placing a newly-marketed contraceptive device under the skin). Sustainment training involves the refresh and demonstration of currency in skills previously acquired. For example, hospital-based nursing staff must demonstrate proficiency in a series of clinical tasks on an annual basis. Resuscitation training encompasses a blend of initial and sustainment training and includes courses like Basic and Advanced Life Support (BLS, ACLS, respectively). Readiness-training for Navy Medicine includes a series of training evolutions analogous to the Basic Phase of the Optimized Fleet Response Plan (OFRP) for sea-going sailors.

Drilling down further, simulation may be used not only to train, but also to evaluate individuals, teams, or large groups within those categories. Skills Validation for individuals involves the individuals proving that they are capable of meeting the demands of the particular job which they are being assigned. For example, a pharmacy technician filling a Hospital Corpsman 3rd Class (HM3) billet would need to demonstrate the skills involved in dispensing medications safely and managing a deployment pharmacy's inventory. There is no analogous step in the OFRP, but because of the highly technical and often unique nature of each position on a life-saving medical team, Skills Validation may be instituted in Navy Medicine. Operational Readiness Exercises for deployment platforms are unit level evaluations ranging from small teams (e.g. Role Two Light Maneuverable (R2LM) teams; formerly called Expeditionary Resuscitative Surgical Squads) to large organizations (e.g. Expeditionary Medical Facility-150s; formerly called Fleet Hospitals). For example, an R2LM team might demonstrate proficiency as a team in dealing with a mass casualty event in a simulated environment similar to the locale in which they are set to deploy, analogous to the Fast Cruise of READ-E 4 of the OFRP.

Currently, throughout Navy MM&S, training is predominantly decentralized. Military treatment facilities are organized in a regional tiered-mentorship structure based on extent of graduate medical education offered at each site. However, the variety of simulated training, simulation equipment, and experienced simulation personnel (primarily simulation operators and educators) varies considerably from site-to-site based on the site's unique mission-set. Funding is a blend of local, central, and grant-based. Further, funding is more typically urgency-based than programmed and predictable. Readiness training is delivered at MTF sites as well as dedicated training centers organized under the Naval Medical Operational Training Command. Finally, more than 60% of Navy medical personnel are aligned under organizations other than BUMED and their training is managed by their sponsoring organization. Much of this paradigm is changing with centralization and standardization of simulation centers' personnel, curricula, equipment, and funding.

The National Defense Authorization Act of 2017 brought sweeping reorganization to military medicine. Most of the related provisions took effect on or before 01 Oct 2018. In broad strokes, the Defense Health Agency (DHA) was placed in charge of all services deemed related to the Clinical Benefit, including management of military treatment facilities. Additionally, DHA was charged with coordinating joint and shared-services. The Navy, as for the other Services, retained responsibility for service-unique Readiness related training. As part of this reorganization, a Defense Medical Modeling and Simulation Office (DMMSO) was created and aligned under the DHA Deputy Assistant Director/Education and Training (J7).

In August of 2018, DOD Instruction 6000.18 (Medical Modeling and Simulation Requirements Management) was signed with purposes of centralizing, coordinating, and consolidating MMS requirements; and eliminating unnecessary duplication of costs, among other things. DMMSO was charged with aligning MMS requirements processes with the Joint Capabilities Integration and Development System (JCIDS). A DHA Requirements Management System (RMS) was modified to specifically support medical simulation needs.

When a Service program office identifies a new simulation requirement, the need is entered into the RMS. It is categorized as Clinical Benefit, shared/joint service, or Service-unique. If submitted as Service-unique, the DMMSO gatekeeper compares it against known requirements to ensure that no solution already exists and to certify that it should not be a shared/joint requirement. If there is concurrence, the requirement returns to the Service and the requirement solution is funded through Service operating funds (rather than Defense Health Program) after it is passed through JCIDS. This "triage" should take less than a week, exclusive of JCIDS. If a previous solution is identified, the requirement is returned to the Service with a recommendation for the identified solution after it is passed through JCIDS. Should the Service reject the recommended solution, it may pursue development with its own operating funds, if desired. If a requirement is re-categorized as shared/joint, DMMSO consults the Senior Service Requirements Board (functionally, the Directors of each Service's MMAST program), then routes the requirement based on the anticipated cost of the solution. For solutions with anticipated RDT&E needs below $10 million and Acquisitions needs below $40 million, an approval process internal to DHA J7 is followed after clearing JCIDS. This process takes a minimum of 14 weeks, plus dwell times at JCIDS. For initiatives above these thresholds, approval is sought through Senior Military Health System governance.

"When a Service program office identifies a new simulation requirement, the need is entered into the RMS."

Previously validated or recurring requirements will be handled much as they have been prior to the creation of DMMSO, to a point. Simulation activities—whether military treatment facilities, operational training sites, or other organizations—draft requisition documents (e.g. NAVMED 6700/13, Expense Equipment Request, multiple vendor bids, etc.) and route them through their facilities approval chain. Rather than executing the purchase locally, the completed package is submitted through DMMSO. This is important to MTFs, in particular, because the discretionary local funds that have historically been used for a majority of simulation purchases will now be controlled by the DHA rather than the Service. DMMSO coordinates with the Service MMAST then funds are allocated from the appropriate Line of Accounting. This will be relatively straightforward for the Air Force which is coming from a strong centrally-funded paradigm, but more nebulous for the Navy and Army who have previously relied on multiple funding streams. Many of the procedural details have not yet been ironed-out, but a DHA Procedural Instruction is being drafted and will be challenged in the first year of transition when 8 MTFs of varying size and Service pilot the new organizational relationship.

Looking forward, the future is bright. There is already a great deal of cooperation as DMMSO and the Air Force and Navy MMAST programs are co-located and collegial. New collaborations are being developed between the medical and Line simulation communities. Partnerships with industry and academia are also being developed. These all share the goal of modernizing military medical education and training, focusing on the identification and prudent use of appropriate technology to improve acquisition and retention of life-saving skills. A Ready Medical Force will meet the needs and exceed the expectations of the Line that it serves.

ROBERT SELVESTER enlisted in the Navy as a Hospital Corpsman in 1987, days after high school graduation. He served as a Aerospace Medical Technician for both Navy and Marine Corps rotary and fixed wing platforms, earning Enlisted Aviation Warfare Specialist and Fleet Marine Force designations, and taught Search and Rescue. As a Hospital Corpsman First Class he completed his undergraduate degree in Biology-Chemistry and accepted a commission upon acceptance to medical school at Case Western Reserve University, where he ultimately graduated with Honors and Distinction. He completed Residency training in Family Medicine at Naval Hospital Camp Pendleton. He has served in a number of clinical billets as well as teaching at the Interservice Physician Assistant Program and serving as Physician Consultant to the Formulary Management Branch (Pharmacy) at the Defense Health Agency. Prior to assuming his present position as Director of Navy Medical Modeling and Simulation Training he was the Senior Medical Officer at Joint Task Force Guantanamo Bay, Cuba.

HIGH-FIDELITY SURGICAL FASCIOTOMY SIMULATOR

for Training Special Operations Medics

By: Jordan Coulter, SIMETRI Inc.;
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Richard Kelly, Joint Special Operations Medical Training Center

FASCIA, A FIBROUS CONNECTIVE TISSUE, IS RESPONSIBLE FOR ALLOCATING SKELETAL MUSCLES AND CORRESPONDING NEUROVASCULATURE INTO FUNCTION-BASED COMPARTMENTS.

Pressure is capable of accumulating within these compartments, initiating the onset of a condition commonly referred to as compartment syndrome. When the pressure within the compartment compromises the arterial supply, it prevents perfusion of oxygen into the surrounding tissues, leading to tissue necrosis, or tissue death. Once diagnosed, a fasciotomy must be performed immediately to prevent severe complications.

A recent study evaluated the incidence of fasciotomies performed during Operations Enduring Freedom and Iraqi Freedom and found that of 4,332 casualties to the extremities, 669 (15%) underwent a fasciotomy. According to the Joint Special Operations Medical Training Center (JSOMTC), the current training methods are insufficient for practicing the surgical technique, while other methods, such as cadaveric and live tissue training, are cost-prohibitive for the number of students that require annual training. The U.S. Army Research Laboratory Human Research and Engineering Directorate Advanced Training and Simulation Division (ARL HRED ATSD) identified the requirement to develop a next-generation lower extremity fasciotomy Part-Task Trainer (PTT) in response to JSOMTC's need for a more realistic, durable, and cost-effective training approach. The paper will describe the research conducted to satisfy these requirements, including identifying, developing, and validating the essential anatomy and physiology required to provide a realistic and effective next-generation surgical PTT. Additionally, the paper will explore how innovations in novel synthetic materials provided realism approaching traditional methods while greatly minimizing cost and maximizing training opportunities.

This paper was originally submitted for the Interservice/Industry Training, Simulation and Education Conference (I/ITSEC) by its authors, Jordan Coulter, Angela Alban, William Pike, Jack Norfleet, and Richard Kelly. The paper is from I/ITSEC 2017, and is reprinted with permission: [Pike, W., et al. (2017). High-Fidelity Surgical Fasciotomy Simulator for Training Special Operations Medics. I/ITSEC Knowledge Repository, proceedings of the 2017 Interservice/Industry Training, Simulation, and Education Conference (I/ITSEC). Arlington, VA: National Training and Simulation Association.]

INTRODUCTION

A fibrous connective tissue, known as fascia, surrounds human skeletal muscle, encasing it and the corresponding neurovasculature while separating these tissues into compartments. Fascia is tough and inelastic, which introduces pressure in the muscle compartments in response to a traumatic event or collection of fluid. As the pressures increase in the muscle compartments, the arterial supply and coinciding perfusion rates are compromised, leading to tissue necrosis, or tissue death. The etiology of acute compartment syndrome often stems from traumatic injuries commonly seen during combat, such as fractures or blast injuries. Presentation of compartment syndrome includes pain, palpable tightness, tenderness, paresthesia, and paralysis, and once diagnosed, a fasciotomy must be performed immediately to prevent further complication (Compartment Syndrome (CS) and the Role of Fasciotomy in Extremity War Wounds, 2012). Todd Ulmer (2002) discovered that if one of these clinical symptoms is present, there is a 25% chance of the patient having compartment syndrome; this percentage increases to 93% if three of the aforementioned clinical findings are present. Evaluation of the clinical signs and symptoms is the preferred method of diagnosing acute compartment syndrome; however, testing the pressure within each myofascial compartment is becoming increasingly common as an additional diagnostic method. If treatment is delayed, complications such as muscle excision, amputation, and mortality can arise, with some of these complications occurring less than six hours after onset of increased compartmental pressure (Compartment Syndrome, 2017). This time constraint sometimes expires before a patient can be evacuated, requiring that Special Operations Medics be trained to perform the procedure if a surgeon is unavailable.

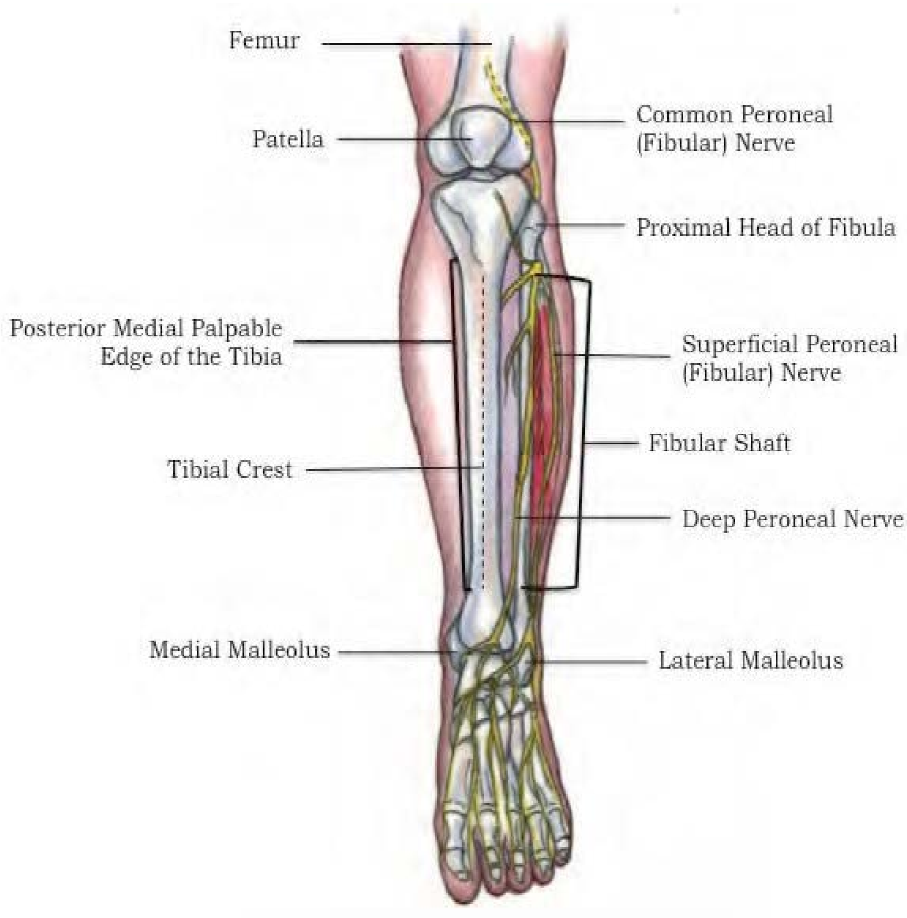

Figure 1: Landmarks and Structures for the Fasciotomy Procedure – *Source: Author*

Kragh et al. conducted a study that evaluated the incidence of fasciotomies performed during Operation Enduring Freedom and Operation Iraqi Freedom. The study found that of 4,332 casualties to the extremities, 669 (15%) underwent a fasciotomy (Kragh et al., 2011). Another study found that fasciotomy rates have been significantly increasing over time. They determined that in 2001, no casualty reported to a military trauma registry received a fasciotomy, whereas in 2010 approximately 26% of 17,166 reported casualties received a fasciotomy (Kragh et al., 2016). Previous studies have demonstrated that ample training and experience are essential to performing a successful fasciotomy. Current training methods include video instruction, classroom training, and educational programs to aid in diagnosing the condition (Kragh et al., 2013). According to the Joint Special Operations Medical Training Center (JSOMTC), the current training methods of instruction for the fasciotomy procedure, such as cadaveric and live tissue training, are inadequate and cost-prohibitive.

"Previous studies have demonstrated that ample training and experience are essential to performing a successful fasciotomy."

TECHNICAL OBJECTIVES

JSOMTC asked the U.S. Army Research Laboratory Human Research and

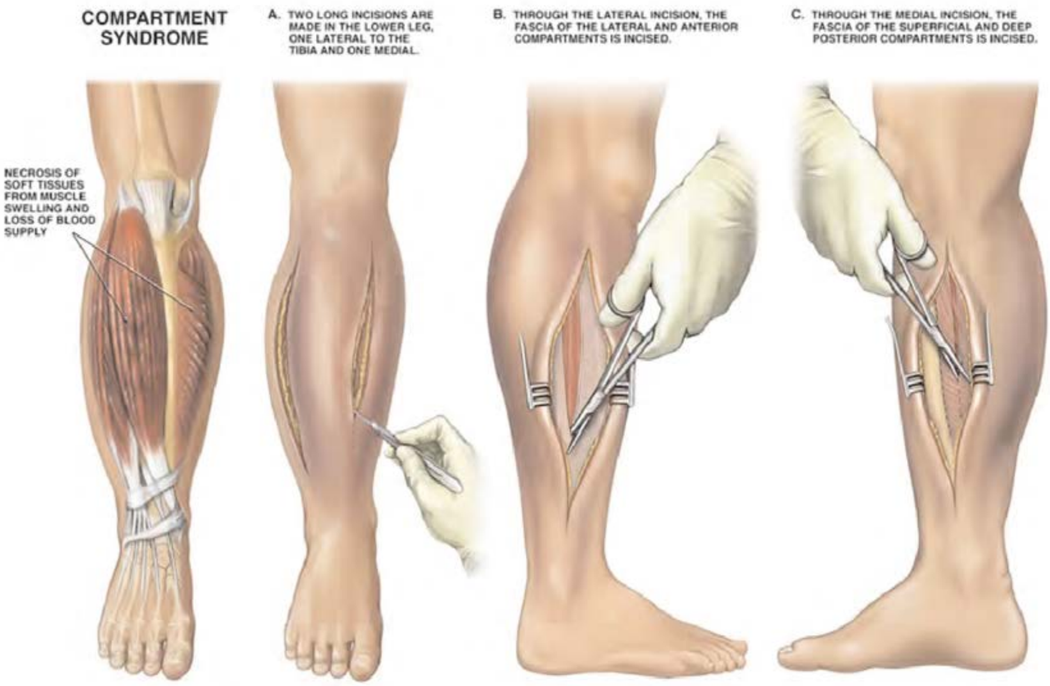

Figure 2: Demonstration of Fasciotomy Incisions – *Source: Nucleus Medical Art, Inc. (2001, February 1). Four Compartment Fasciotomy Procedure [digital image]. Retrieved from: http://www.alamy.com/stock-photo-four-compartment-fasciotomy-procedure-7711954.html*

Engineering Directorate Advanced Training and Simulation Division (ARL HRED ATSD) to evaluate the feasibility of developing a realistic, durable, and cost-effective lower extremity fasciotomy Part-Task Trainer (PTT). Other studies have validated this requirement in stating that more research is needed to improve clinical performance for fasciotomies and continued research is necessary to investigate valid alternatives for live tissue training (Kragh et al., 2013 & Sakezles et al., 2008).

The need for a more realistic, durable, and cost-effective training approach highlighted the urgency for a nextgeneration fasciotomy PTT to address:

- **Relevance:** the occurrence of fasciotomies performed on casualties to the extremities during Operation Enduring Freedom and Iraqi Freedom was 15%.
- Insufficient training methods: according to the Joint Special Operations Medical Training Center (JSOMTC), the current training methods (video instruction and educational programs) are insufficient for practicing surgical technique.
- **Cost-efficacy:** Other training methods, such as cadaveric and live tissue training, are cost-prohibitive for the number of students that require annual training.

In response to the need, the team outlined the following research aims and objectives:

- **Identify, develop, and validate the essential anatomy and physiology** required to provide a realistic and effective next-generation surgical PTT for the treatment of lower extremity compartment syndrome.
- **Research and develop new synthetic materials and methodologies** that provide realism similar to cadaveric or live tissue training.
- **Minimize cost and maximizing training availability** while ensuring a durable and easily refurbished product.
- **Validate the PTT design and training relevance** through consultation with Subject Matter Experts (SMEs) and usability studies.

REQUIREMENTS AND CRITICAL TASK ANALYSIS

The development team met with SMEs at JSOMTC and the Medical Simulation Training Center (MSTC) at Fort Bragg. The team elicited requirements from instructors at both training centers to better understand the Program of Instruction (POI), logistical constraints, and opportunities for improvement. The POI was reviewed and decomposed to outline the critical tasks and skills required to perform the procedure in order for the team to identify training gaps and opportunities for improving the current training model. Current training models include cadaveric and live tissue training as well as a fasciotomy training device that requires refurbishment by the manufacturer after each use. Due to the cost and time required to refurbish the existing fasciotomy trainer, it is no longer utilized as part of the POI.

Including essential and anatomically accurate landmarks in the PTT is critical to performing a successful fasciotomy. Identification and replication of these key landmarks orient the medical provider with the anatomy prior to making the initial incisions and ensuring that only the proper structures are cut during the procedure. Figure 1 demonstrates some of the key landmarks and structures that require identification for the fasciotomy procedure. If incorrectly identified, the provider may unintentionally cut important nerves or vessels that are identified as critical landmarks in the POI. To begin the procedure, the shaft of the fibula is the first anatomical landmark identified. The provider must palpate the proximal and distal ends of the fibula to locate the shaft of the long bone, from which the lateral incision should be made two centimeters anterior. After making the lateral incision, the anterior intermuscular septum must be identified; it separates the anterior and lateral compartments. The tibial crest, or palpable portion of the tibia, must then be identified so that a small horizontal incision is made midway between it and the anterior intermuscular septum. The superficial peroneal nerve must then be identified as it sits near the anterior intermuscular septum and is at high risk of being injured during this part of the procedure. Severing the superficial peroneal nerve could result in foot drop, which is a loss of the ability to pull the toes and foot upwards, and a loss of sensation to the anterior and lateral parts of the leg. A bony prominence on the lateral part of the ankle, referred to as the lateral malleolus, is identified next. The scissors are pointed toward the lateral malleolus as the fascia of the lateral compartment is cut to keep the instrument posterior to the nerve to avoid damage. For the medial incision of the skin, the posterior medial edge of the tibia must be palpated and the incision made two centimeters posterior to this landmark to avoid the great saphenous vein. During the anterior fasciotomy, the scissors are directed towards the patella, or kneecap, to avoid damaging the proximal neurovasculature to prevent the morbidities associated with nerve damage. SMEs at JSOMTC requested that the gastrocsoleal complex (composed of the gastrocnemius and soleus muscles) and its attachment to the posterior border of the tibia be included because it must be released to access the deep posterior compartment of the leg.

Aside from the skin, muscles, and fascia, it is also important to include adipose tissue and neurovasculature of the lower leg. When surgeons cut through the dermal layers and adipose tissue, they must successfully identify the neurovasculature to avoid causing permanent damage to the patient. This can be one of the most challenging aspects of performing a fasciotomy. Proper tactile feedback and anatomical accuracy will aid in creating essential muscle memory for those who train for fasciotomies. If there is damage to a nerve or vessel, the patient can bleed excessively or have a loss of function in certain muscles possibly coupled with a loss of sensation in the skin. These potential morbidities can lead to a decreased quality of life for the patient, or even amputation of the affected limb. Figure 2 demonstrates the incisions for a four-compartment fasciotomy of the lower extremity.

A market survey of the current fasciotomy trainers was conducted to understand the state of the art and limitations of modern training systems. The market survey compared the commercially available fasciotomy trainers to the requirements elicited from SMEs and the POI. Meetings with SMEs were held to confirm the initial critical task analysis conducted by the team after evaluating the POI. These meetings were informal but included detailed discussions with training aides as well as demonstration of the fasciotomy procedure. Factors such as anatomical accuracy, refurbishment, and reusability were considered during the market survey, which concluded that none of the existing training devices evaluated were found to realistically simulate the fasciotomy procedure of the leg while meeting the requirements associated with cost and refurbishment time. Multiple training devices were software based and did not provide hands-on training, while others were not field-serviceable, requiring that they be sent to the manufacturer for refurbishment after a single use.

"Proper tactile feedback and anatomical accuracy will aid in creating essential muscle memory for those who train for fasciotomies."

MATERIALS RESEARCH AND DEVELOPMENT

Realistic appearance and accurate tactile feedback are necessary to effectively train emergency medical personnel on the fasciotomy procedure. It is also crucial that the PTT is durable, has the capability of being used and refurbished in the field, and is easily stored when compared to live tissue or cadaver training. These considerations lead the team to explore new and existing materials and methodologies that offer the desired results. Materials commonly used in the industry, as well as readily available everyday materials were tested to evaluate options for all required simulated tissue and anatomical structures of the PTT.

Skin, adipose, and muscle tissues were the first to undergo testing. Silicone was the first material evaluated because it is often used in the industry and it offers characteristics that align with the requirements of the training system. Several samples of silicone rubber were evaluated based on durometer, tear strength, and the time and cost to manufacture the samples. Silicone foams were assessed based on their viscosity and volume expansion. Silicone is flexible, strong, compatible with other materials, easy to shape, compatible with pigments, and can exhibit fine details. It also has self-healing qualities and the ability to be repaired, which were favorable characteristics for the fasciotomy PTT. The team evaluated gelatin as another option for the skin, adipose, and muscle components of the PTT. Gelatin is inexpensive, compatible with other materials, demonstrates a high level of detail, and can be resealed with heat. Unfortunately, gelatin can be distorted at extreme temperatures or when used with fluids, which were both considerations for the fasciotomy PTT. Although the PTT is designed for a classroom setting, this

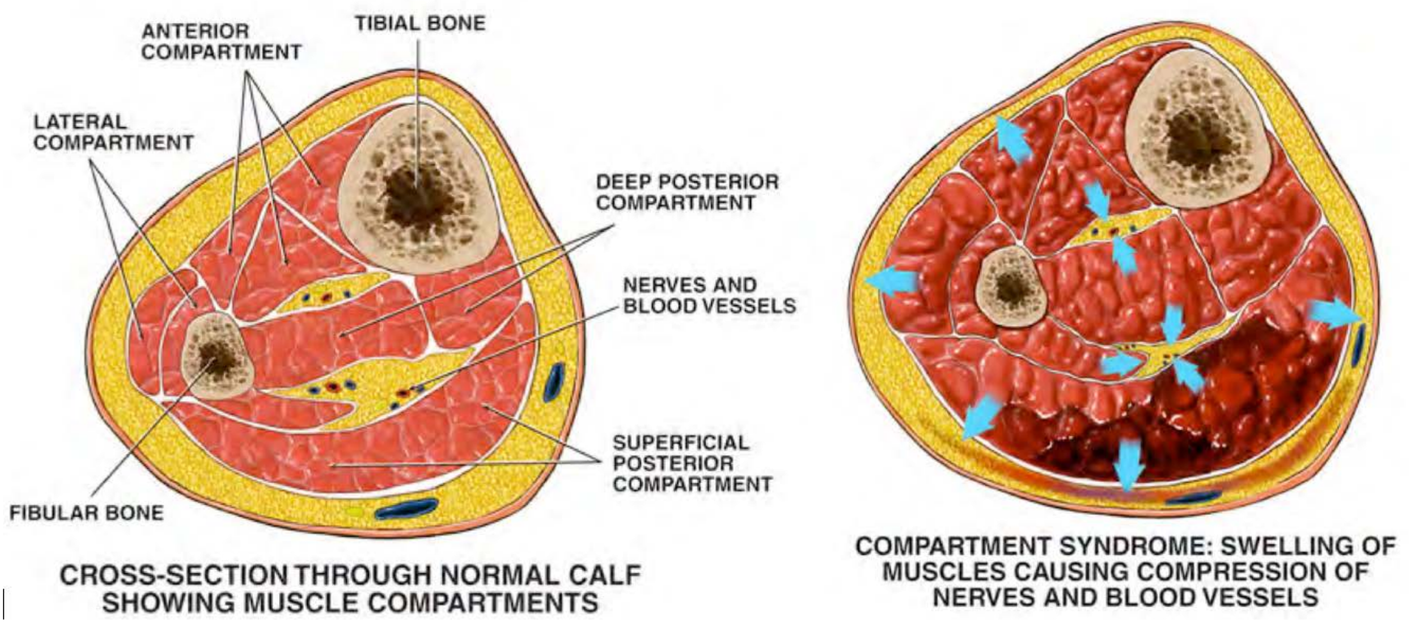

Figure 3: Lower Extremity Compartment Syndrome and Muscle Compartments – *Source: Nucleus Medical Art, Inc. (2001, January 3). Compartment Syndrome with Fasciotomy Procedure [digital image]. Retrieved from: http://www.alamy.com/stock-photo-compartment-syndrome-with-fasciotomy-procedure-7712213.html*

characteristic could pose a conflict when considering storage and long-term use.

Fascia is a thick, dense connective tissue that differs from skin, adipose, and muscles tissues. A variety of materials, including commercially available simulated fascia, were evaluated for the PTT. Fascia separates the four muscle compartments of the lower extremity as depicted in Figure 3. It is sensitive to hydrostatic pressures and demonstrates minimal, if not absent, elasticity. Fascia is slightly translucent, pearl-white in color, and must be strong enough to contain the pressure that accumulates during an acute compartment syndrome, taut enough to fit around the defined muscle compartments, and flexible enough to be easily replaced after a training session. Materials such as vinyl, silicone, mesh fabrics impregnated with silicone, silk impregnated with silicone, latex, and shrink-wrap were evaluated based on the previously mentioned properties of fascia. The requirements for fascial tissue proved challenging, as most samples of simulated fascia demonstrated too much elasticity or were too stiff to conform around the muscle compartments. SMEs provided feedback regarding appearance and tactile response after completing the procedure on an initial prototype (which requires cutting the fascia); their feedback was used to adjust the formula and combination of materials used to simulate fascia more accurately. This iterative process resulted in highly realistic fascia, both in terms of appearance and response to cutting and stretching.

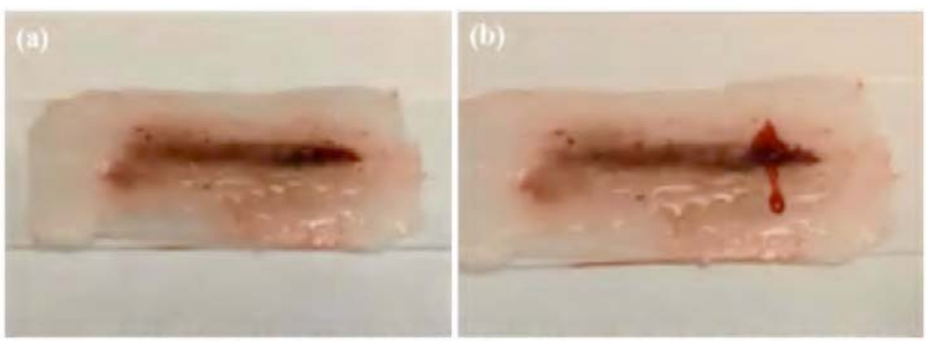

Figure 4: Hydrogel-Embedded Skin (a) Before; and (b) After Cutting – *Source: Author*

Nerves, veins, and tendons are often encased by adipose tissue for protection or are found just beneath the fascia, making their tactile feedback and authentic appearance necessary for landmark identification. As a result, the team evaluated materials that could be used to simulate these vital structures during the fasciotomy procedure. It was important that the simulated structures were similar in tensile strength to the human tissue counterparts to provide a realistic sense of injury during training scenarios. Different varieties of silicone, some embedded with additional materials, were evaluated for the role of veins, nerves, and tendons in the PTT. The samples were evaluated based on appearance, tactile feedback, and tensile strength by physicians and SMEs who provided subjective feedback during informal interviews and after physically examining the simulated tissues.

The University of Central Florida (UCF) Advanced Materials Processing and Analysis Center (AMPAC) conducted

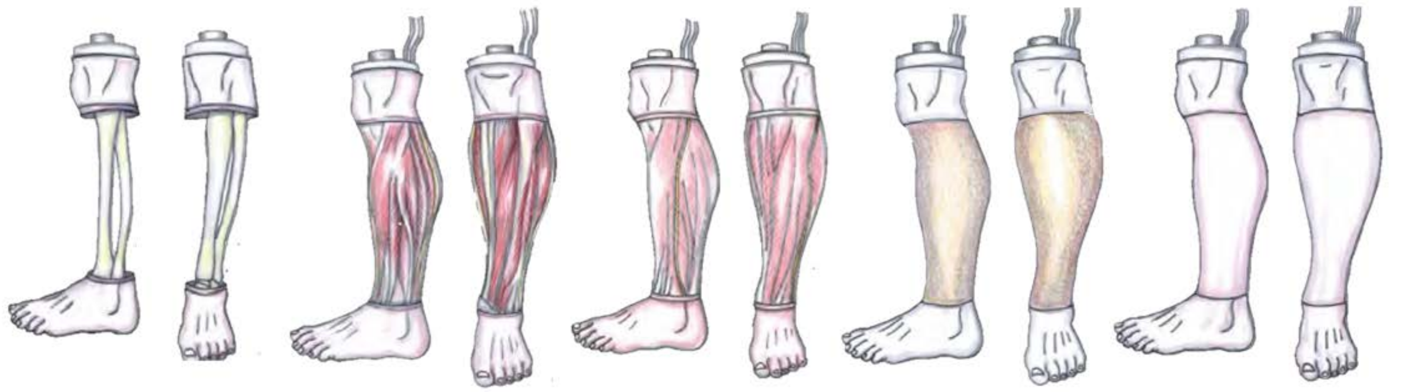

Figure 5: Initial Sketches of Concept Multi-Layered Design – *Source: Author*

basic research to simulate the bleeding caused by incision through the superficial capillaries as depicted in Figure 4b. AMPAC developed a proof-of-concept synthetic skin using hydrogels and lipid nanotube technology. Figure 4a shows an example of the simulated blood embedded in the hydrogel under the skin layer. When the skin layer and matrix of the hydrogel is severed, the entrapped simulated blood is released, giving the appearance of bleeding or oozing. The hydrogel concept provides realistic behavior but requires complicated formulas and processes to produce the desired results. The team performed a cost-benefit analysis to determine if this is a desired capability for the PTT and concluded that the manufacturing and lifecycle/sustainment costs exceeded the target costs recommended by the JSOMTC SMEs for the PTT. The materials and methodologies required far exceeded the cost of the current training devices since they required specialized skill, equipment, and materials that are not easily sourced or available on the open market.

" AMPAC developed a proof-of-concept synthetic skin using hydrogels and lipid nanotube technology."

PROTOTYPE DEVELOPMENT

After initial meetings with SMEs at JSOMTC, the team developed a concept for the PTT that met their training requirements, constraints, and training gaps. The SMEs primarily rely on a live tissue or cadaver model, which limits the level of realism (in the case of the live tissue model) and access to training (in both cases). The prototype concept was decided to be a standalone PTT that didn't require specialized storage or tooling to reset it between uses. Initial concepts were sketched, as depicted in Figure 5, to illustrate design and concept of multiple layers of anatomical structures that could be used to teach the procedure from start to finish. The initial prototype was meant to support the evaluation of different simulated tissue samples, but instead resulted in a proof of concept PTT that also provided SMEs with the opportunity to provide feedback regarding how the PTT addressed the requirements as well as simulated the landmarks, structures, and tissue.

The initial design of the prototype included a foot that was fixed in place at the inferior end, and a partial knee at the superior end. Simplicity was a key design consideration for the PTT (Figure 6) because it could impact cost and refurbishment. Some training systems evaluated during the market analysis require they be sent back to the manufacturer to be refurbished. The development team designed the PTT such that it can be refurbished rapidly with minimal effort to maximize available training time and limit additional instructor workload. Commercially available components, such as the simulated tibia and fibula bones for the core of the trainer, were sought out when appropriate. The commercially available simulated bone adds to the realism of the PTT due to the extraordinary level of detail provided by the manufacturer. Due to a shortened development cycle, the muscles on the initial prototype were grouped together for each of the four muscular compartments and surrounded by a single outer fascia to facilitate SME feedback. This design simplified refurbishment and was approved by SMEs for utilization in the continued development of the prototype. The highest level of detail was devoted to the anatomical structures with which the trainee will interact with when performing the fasciotomy including procedural landmarks, fascia, and neurovasculature. The structures are inclusive of those previously mentioned as important landmarks for the procedure. Fluids were not integrated into the initial prototype and after receiving feedback from SMEs, it was indicated that fluids were not necessary and could add additional sustainment and lifecycle cost consideration with little added training benefit.

The ability to use the PTT to simulate compartment syndrome was another key requirement. Controlling the amount of pressure within each muscular compartment provides trainees with

Figure 6: Proof of Concept PTT – *Source: Author*

the ability to learn how to identify compartment syndrome by palpating a rigid compartment under extreme tension. Although the initial prototype required that the muscle compartments be inflated manually, it did allow for each of the compartments to be inflated individually permitting instructors to teach trainees to examine, assess, and treat compartment syndrome in patients. Initial designs to simulate increased pressure within the muscular compartments involve insertion of an air bladder within the simulated muscle, which allowed for incremental increases in pressure. The initial air bladder design proved challenging and required a reinforced design to be developed. Another method considered for simulating compartment syndrome was to mold muscles for a patient under normal conditions and another set of muscles for a patient with compartment syndrome. This method, however, would increase the cost for the user and potentially pose for a more difficult refurbishment process. The team continues to investigate other methods of simulating compartment syndrome as well as improvements in air bladder design for future iterations of the PTT.

Although a significant amount of time and effort was placed on identifying the ideal simulated fluids for the PTT, the SMEs at JSOMTC determined that it was not necessary to simulate fluids, especially if that capability added cost and further complicated maintenance, refurbishment, and sustainment of the PTT. After performing a cost-benefit analysis, the added training value did not justify the additional cost. Based on the results of iterative testing and SME feedback, several simulated tissue samples developed for the fasciotomy prototype were eliminated as nonfunctional for the continuing development of the PTT. After evaluating several forms of gelatin in variable conditions, the development team determined that silicone is the preferred solution for the PTT. Silicone met several requirements for the PTT including cost-efficiency and durability. The gelatin, although initially promising due to its easy repair, proved problematic due to the changes when placed in liquid environments and extreme temperatures. The samples tested for nerves need further investigation, as the current samples were eliminated for use in the proof of concept PTT demonstrated in Figure 6. The initial samples evaluated were too durable and somewhat difficult to cut. Utilizing them in the trainer could result in negative training since they would be more difficult to cut than a real human nerve.

CHALLENGES

The destructive nature of the procedure limits the number of potential options for refurbishment. Currently, the components of the trainer that undergo significant damage (e.g. skin and fascia) are completely replaced. Other layers, such as underlying muscle, nerves, veins, and tendons, will have the capability to be replaced if damaged. If the procedure is performed correctly, they should last indefinitely. Additional research and testing is being conducted on the viability of skin and fascia repairs to lower lifecycle costs of the PTT.

The air bladders that were integrated into the simulated muscle compartments proved to be unreliable because the air leaked from where the tubing attached to the silicone muscle. When the simulated muscle compartments were pressurized over a prolonged period, the bladder system would slowly deflate. An improved method and design will have to be evaluated that offers increased reliability for maintaining the simulated muscle compartments while pressurized.

"Controlling the amount of pressure within each muscular compartment provides trainees with the ability to learn how to identify compartment syndrome."

SUBJECT MATTER EXPERT FEEDBACK AND EVALUATION

During a visit to JSOMTC at Ft. Bragg, the team received feedback from SMEs after performing a fasciotomy on the initial prototype of the lower extremity fasciotomy PTT (Figure 7). The development team asked the SMEs questions about the prototype's design

Figure 7: SME Testing and Feedback – *Source: Author*

and conducted a focus group discussion about the components of the PTT. Vital feedback on the thickness of the skin, adipose, and fascial layers, as well as the bones, were provided to the development team. Several key items were identified and prioritized for addressing in the next iterations of the prototype. The skin and fascial layers were identified as being approximately 5% too thick. The skin on the proximal part of the trainer was identified as needing tightening. SMEs also recommended making the nerves less mobile to give them added accuracy and specified the importance of the attachment of the gastrocsoleus complex to the posterior border of the tibia, as previously mentioned. The remainder of comments made by SMEs were about a path forward into the following phases and additional capabilities. A second visit to JSOMTC focused on newly developed muscle compartments and fascia samples, which were reviewed and approved by the SMEs. It was stated that the focus of Phase II is on replacement at low cost and rapid refurbishment, while Phase III will focus on interoperability with existing Human Patient Simulators (HPSs) or manikins. A possible capability of the trainer would be to look at utilizing fluid filled bladders instead of air to potentially include ultrasound concepts for detecting a Deep Vein Thrombosis (DVT). Another easily executed capability would be the inclusion of multiple skin tones to represent different ethnicities. SME feedback and evaluations will be considered for continual development of the prototype during future phases.

"Phase II is on replacement at low cost and rapid refurbishment, while Phase III will focus on interoperability with existing Human Patient Simulators (HPSs) or manikins."

SME input proved to be an asset in focusing the team's development efforts. Although SMEs provided a wide variety of inputs, they were condensed through collaboration between the SMEs and the development team to enhance the focus on the key requirements for the PTT. The list below summarizes the primary and guiding inputs from the SMEs:

Reset or Refurbishment Time: The ability to reset the PTT for conducting the next procedure in a short period of time is a primary concern of the SMEs. Initially a reset time of 5 minutes was requested, but after further discussions and use case exploration, being able to reset the leg in the field so that training could occur twice in the same day was acceptable.

Inclusion of Appropriate Landmarks: Including soft tissues and underlying bone structures distal to the tibial plateau is required to provide landmarks for palpating and locating incision locations. At least 3" of anatomy (skin/bone) above the knee is required as a visual indicator for orientation purposes.

Muscle Compartments: Development of muscles should be focused at the compartment level and not necessarily at the individual muscle level.

Skin and Adipose: Development of the skin and adipose should be combined as they are cut and moved together, not separately. Thickness of the skin is also key and should be reduced if possible.

Fascia: Ensuring that the fascia does not expand or has high resistance to stretching or expansion is a key characteristic of the material. A translucent material that allows the trainee to visualize underlying muscle allows for the proper appearance for the PTT.

The feedback gathered during sample and procedure testing was as essential as the guidance provided by the SMEs. By providing an initial prototype and iterative samples, the SMEs enabled the team to narrow material options and focus research and development on a decreasing subset until appropriate soft tissue representations were developed.

CONCLUSIONS

The team set out to fulfil the primary requirements of creating a PTT that is anatomically correct, accurately represents the conditions present in a lower extremity compartment syndrome, facilitates the execution of the fasciotomy procedure, and is easily and cost-effectively refurbished in the field. Systems engineering processes were applied which resulted in a singular, verifiable set of requirements that guided the creation of the PTT throughout the development lifecycle.

The team utilized iterative research and development techniques in the production of several different materials that make up the skeletal system and soft tissues of the PTT. Skin and adipose are vastly different from the fascia surrounding the muscle compartments, which is exceedingly different from the muscle tissue itself. The team constructed an outer skin and adipose layer that is realistic and reacts appropriately under conditions representative of compartment syndrome. The skin and adipose layer are silicone based and take advantage of years of research and development of simulated tissues undertaken by the team. The fascia is comprised of a unique material that resists stretching or expansion, is translucent, and provides for movement between surfaces. Development of the fascia consumed a significant amount of research and iterative development hours. The resulting fascia has a high degree of realism in visual appearance and tactile feedback, and received high praise from the SME evaluators. The underlying muscle tissues are also silicone based and were chosen due to the ability to add realistic details, as well as the expansion properties needed to accurately represent compartment syndrome. Several iterations of research and development of the muscle structures were required to perfect the internal bladders and overall function of the muscles.

Throughout the development cycle the team gathered feedback from Subject Matter Experts (SME) that proved invaluable in guiding and course-correcting the development of the PTT. Initial skin and adipose layers were modified to better represent the tissues and expected reactions when performing a fasciotomy. The fascia development was guided by SME input throughout the development cycle and resulted in a realistic fascia that is also cost effective. Finally, SME inputs helped identify the key requirements allowing the team to focus on the most critical aspects of the PTT development.

An anatomically accurate and realistic PTT has been developed through application of sound systems engineering processes, materials research, and incorporation of SME feedback throughout the development process. The final design is based on permanent and consumable components that represent the look, feel, and reactions of a lower leg presenting with compartment syndrome. The final design incorporates consumable skins and fascia developed for each muscle compartment that are replaced after each use. The rigid structures of the leg, its supporting components, and the soft muscle tissues are reused after each fasciotomy procedure is performed. The design centers on providing the appropriate landmarks for identifying where the incisions and cuts are to be made, and then the accurate look, feel, and reactions of the tissues and underlying structures as the procedure is performed.

" An anatomically accurate and realistic PTT has been developed through application of sound systems engineering processes."

PATH FORWARD

Additional research is needed to develop the materials for the PTT to increase the level of realism, anatomical accuracy, and physiological responses while considering cost, durability, and field refurbishment. Some of the tissue types, such as nerves, that were evaluated did not have any samples that successfully represented real human tissues with regards to the prototype. The materials used for these tissues will need further investigation and feedback to find a viable option to be researched and ultimately utilized in the PTT.

The development team will research the use of sensors embedded in vital neurovasculature structures to provide the capability to monitor and assess trainee performance throughout the duration of the training scenarios. The sensors would also support stimulation of physiological responses such as fluid release and changes in pulse rate, if practical. Self-healing capabilities of silicone will be further tested and evaluated to determine their applicability to a fasciotomy PTT, as current methods do not yet satisfy all requirements in this area. Although the tissues have been successfully repaired, the repair process is either extensive, or the marks from the initial use are still visible after repair. Since finding a balance between realism and low-cost replaceable components that are destroyed during the procedure is a significant challenge to the development of the prototype, self-healing or repairable silicone will continue to be investigated.

The development team will build upon the initial prototype and continue to develop and demonstrate a prototype PTT while engaging SMEs and the team's extensive background in anatomical models for medical education. System requirements will be regularly updated and the PTT will be designed to reflect the updated requirements. The prototype will improve proof-of concept tissue layers and the initial prototype design and functionality.

ACKNOWLEDGEMENTS

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Saving Female Lives using Simulation:

ELEVATING THE TRAINING EXPERIENCE

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AS OF 2016, 18.3% OF THE UNITED STATES' ACTIVE-DUTY MILITARY FORCE WAS COMPOSED OF FEMALES.

(Office of the Under Secretary of Defense, Personnel and Readiness Report, 2016)

Although women have traditionally been excluded from combat roles in the past, female engagement teams played a prominent role in conflicts over the past ten years. With the recent acceptance of women in combat arms roles, this trend is shifting. Recent studies have shown that military female casualties are far more likely to die of their wounds than males, in contrast with civilian reports of females exhibiting higher survival rates than males with comparable injuries (Cross, Johnson, Wenke, Bosse, & Ficke, 2011).

Current Simulation-Based Training (SBT) for the military is unable to simulate female battlefield trauma in part-task trainers, due to limited anatomical models; most simulations are male-centric. At the point of injury, when a male emergency care provider is required to expose and/or touch a female Soldier's body parts, lack of proper training can induce hesitation and potentially compromise treatment of a critically injured female Soldier. The lack of a realistic female simulation model, in conjunction with ingrained societal taboos, impact the ability of male medical personnel to react and provide immediate medical attention to female patients in life-threatening situations.

In order to effectively train Soldiers to feel comfortable providing medical care to females, and to react without hesitation in life-threatening situations, trainees should be given the opportunity to train with realistic female anatomical models and be exposed to female severe trauma injury patterns observed at the point of injury.

This paper will highlight relevant female casualty research and current efforts to develop multiple solutions to fill this training gap. Specific to this paper, the research will discuss the literature on female simulation, provide anecdotal evidence of the training gap, and explain current trends highlighting the need for female simulation. It is expected that results from this research will translate into a more comprehensive training experience for all service members.

BACKGROUND

Pre-hospital care plays a vital role in battlefield medicine. Tactical Combat Casualty Care (TC3) principles have become the standard of care on the battlefield establishing when and how much care can be provided based on the tactical situation. These principles have proven highly effective and resulted in lower mortality rates (Butler, 2010).

In March 2015, the US Department of Defense (DoD) Defense Health Board (DHB) published a report on Combat Trauma Lessons Learned from Military Operations of 2001-2013, documenting findings from the conflicts in Iraq and Afghanistan. The report acknowledges that the survival rate of Service members injured in combat has significantly improved due to advances in trauma care and knowledge gained by military medical personnel in the pre-hospital, far-forward environment (Defense Health Board [DHB], 2015).

The DHB committee emphasized that trauma training should be integrated into operational and tactical training, and include training exercises that are emotionally demanding, physically intense and realistic. Scenario-based exercises must include basic critical tasks and focus on mastery of skills, not merely familiarization. Therefore, military medical personnel must be trained in a realistically accurate combat environment to ensure they have the necessary decision-making and teamwork skills to treat the wounded effectively (Lateef, 2010). An effective method includes SBT, which plays a major role in the development of psychomotor skills necessary to treat severe trauma on the battlefield. Further, SBT paired with existing training coursework provides an effective teaching method (Beal, Kinnear, Anderson, Martin, Wamboldt, and Hooper, 2017) based on the user's education or instructional goals (Kim, Park, and Shin, 2016).

The primary mission of military medical personnel is to treat the wounded and save lives. First responders (also known as Combat Medics or Combat Life Savers) are responsible for providing the first line of medical care to casualties at the point of injury. Data from the theater show that the majority of casualties who die in combat do so before reaching a definitive care facility (Eastridge, et al., 2012). Therefore, decisions made and the treatments applied during pre-hospital care directly impact the survivability of the casualty. Severe trauma produces major challenges to front line medical providers because many are not mentally, psychologically, or technically prepared to treat such emotionally disturbing wounds. Soldiers treating such wounds must be trained in a realistically accurate combat environment to ensure they have the necessary skills to effectively treat casualties.

"Lack of a realistic female simulation model, in conjunction with ingrained societal taboos, impact the ability of male medical personnel to react and provide immediate medical attention to female patients in life-threatening situations."

According to the Deputy Director of the Department of Combat Medic Training at Fort Sam Houston TX, Mr. Donald Parsons remarks:

> Trauma simulation needs to be realistic. Students should have the ability to practice life-saving interventions on a realistic manikin to develop skills and confidence. The first time they have to care for a casualty with bilateral amputations should not be on a real person. Having treated similar wounds on a simulator gives them a little picture in the back of their mind that they have done this before, successfully, and they now have the confidence to perform. (Feb 2016)

Military medical personnel must be trained in a realistic and accurate combat environment to ensure they have the necessary skills to treat the wounded effectively. Current research should focus on developing the most realistic, physiologically based, and cost effective simulation technologies in order to give our Soldiers the most realism possible to support stress inoculation training.

Stress inoculation, also referred to as desensitization, is needed during training to reduce the emotional reaction or shock the medic experiences in response to blast trauma at the point of injury in operational environments. Such reactions may cause the medic to hesitate or otherwise interfere with his/her performance in saving lives through prompt and effective medical response. An inexperienced medic's natural response, when facing these traumatic injuries for the first time, is a reluctance to treat the casualty. The negative effect on performance associated with dealing with such disturbing wounds can directly impact the survivability of the injured.

Trauma training should incorporate gender specific differences to allow first responders to practice their critical thinking skills and build muscle memory. Simulating injury patterns that take into consideration female anatomical and physiological differences provide opportunities to psychologically prepare Soldiers to deal with the challenges posed by these types of injuries. Providing operationally relevant training scenarios allow soldiers to develop critical thinking and psychomotor skills within the context of situations that they might encounter in theater.

Current human patient simulation models used to train first responders are decidedly masculine in appearance. Female simulation is unrealistic, and frequently a mere adjunct to the male-centric training device. Capabilities in the training environment should incorporate realistic female anatomy and severe trauma injury patterns in order to make both male and female Soldiers more comfortable with providing care to females and reduce the sensitivity to their anatomy.

Critically, in addition to these considerations, any potential training solution must be rugged enough to endure thousands of uses per year, require minimal logistical support, and be cost-effective. This presents an engineering challenge to develop more effective and realistic training systems, at the appropriate level of fidelity, while supporting specific training objectives in a limited resource environment.

Table 1. Proportion of female deaths compared to female casualties (Cross, et al., 2011).

Operation	Total deaths	Female deaths	Female proportion
OCO	5141	122	2.4%
OIF	4329	103	2.4%
OEF	812	19	2.3%

OCO = Overseas Contingency Operations; OIF = Operation Iraqi Freedom; OEF = Operating Enduring Freedom.

HOW DO GENDER DIFFERENCES IMPACT THE TRAINING ENVIRONMENT?

Modern medicine has become more aware of the anatomical and physiological differences between men and women, aside from just reproductive systems. And it's really looking at what that means for emergency medicine, particularly for health outcomes.

These differences are not reflected in the training literature. For example, in the Prehospital Trauma Life Support (PHTLS) military manual, developed by the National Association of Emergency Medical Technicians (NAEMT) in the early 1980s in cooperation with the American College of Surgeons Committee on Trauma (ACS-COT), female casualties are underrepresented. Female representation made up only approximately 24% of graphics depicting casualties or procedures (72 females and 237 males) and there is no discussion of physiological variation between genders (Prehospital Trauma Life Support [PHTLS], 2014).

THROUGH PRACTICE

Anecdotal data gathered from a previously deployed Combat Medic in the United States Army provides a poignant example of the impact

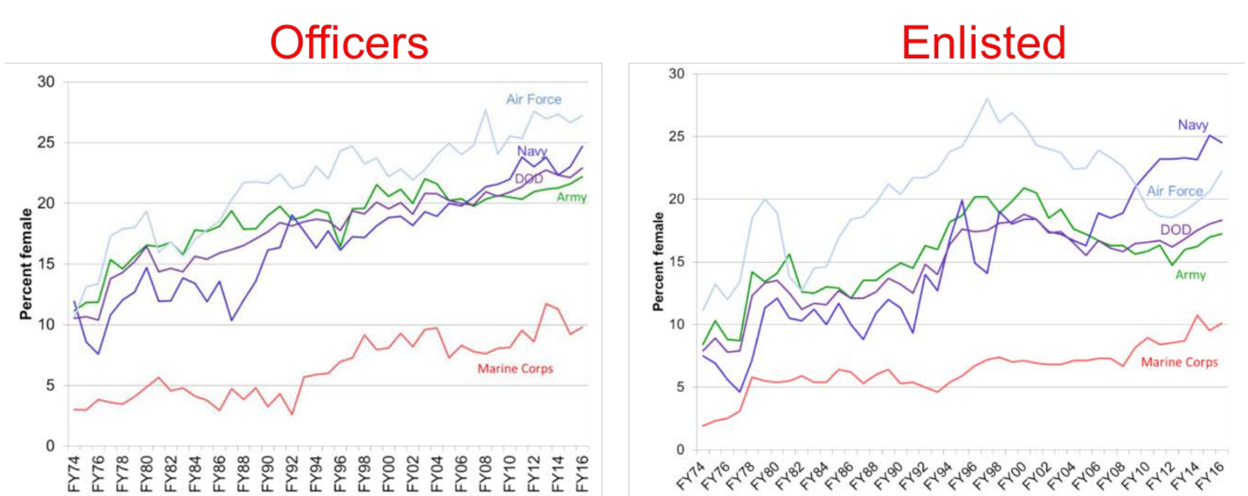

Figure 1: Office of the Under Secretary of Defense, Personnel and Readiness Report, 2016.

Figure 2: (A) Original HPS Skin Overlay vs New Female Skin Overlay (B) Female Face Overlay

of gender differences in battlefield medicine, and the need for action:

> "I treated a female with a full amputation right arm above the elbow at Point Of Injury in Iraq. I pulled out my SOFTT and began applying it to the stump. After I began to tighten the tourniquet, I realized that the windlass would not secure due to the fact that her arms were small. I had to have her hold the windlass while I applied a CAT tourniquet above the SOFTT. After this incidence I began training my medics differently and also changed the way I did medicine. Women are built differently, their joints are smaller and typically they have a smaller frame. This is a common fact that we must address to ensure we are providing the safest life-saving measures available."

THROUGH SURVIVABILITY RATES

A literature review revealed critical information in regards to survivability differences between male and female in a combat environment. According to Cross, et al. (2011), data from the Joint Theatre Trauma Registry dating from 2001 to 2009 (Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) showed that battle-injured females had a lower survivability rate compared to their male counterparts (OEF 35.9% vs 17%; OIF 14.5% vs 12%). A significant proportion of female casualties' injuries were located in the abdominal and chest region, compared to their male counterparts who survived. One plausible explanation is that the higher death rate of females may be a result of them encountering explosives during supporting roles, rather than a result of gunshot wounds where body armor is worn (Cross, et al., 2011). The following table illustrates the proportion of females' death compared to female casualties.

Additionally, Belmont et al. (2010), conducted a 15 month study to determine combat casualties and injuries of Soldiers deployed in Iraq. Females consisted of a smaller population percentage (7.9%), while accounting for 12.5% of Disease Nonbattle Injuries (DNBI). Females had a significantly higher incidence rate of 408.6 per 1,000 combat years, in comparison to males' 244.0 per 1,000 combat years. Females had significantly higher rates for being a DNBI casualty requiring MEDEVAC. Thirty-five of the 325 females that required MEDEVAC were due to reproductive issues. Overall, the results indicated that 75% more Soldiers were lost due to DNBI than combat casualties in the battlefield (Belmont, Goodman, Waterman, DeZee, Burks, and Owens, 2010). As of August 2018, survivability rates still show lower numbers for female casualties (OIF: 14.9% vs 12.1%; OEF: 11.5% vs 10.5%; Operation Freedom's Sentinel (OFS) 25% vs 14%) (Defense Manpower Data Center [DMDC], 2018).

Survival rates for casualties have improved over the past century, from 80% in World War II, to 84% in Vietnam, to an unprecedented historical level of 90% in Iraq and Afghanistan. However, 18% of deaths on the battlefield are preventable by proper medical interventions. A recent review (2001 to 2011) identified exsanguination as the number one leading cause of preventable death followed by airway obstruction and tension pneumothorax (Eastridge, et al., 2012). In a study of sucking chest wounds and other traumatic chest injuries, data showed that when assessed by gender, the needle chest decompression (NCD) procedure, which is used to relieve a tension pneumothorax, had a higher success rate in males than females (Inaba, Branco, Eckstein, Shatz, Martin, Green, Noguchi, & Demetriades, 2011). This could be attributed to anatomical differences between males and females. Sanchez, et al. (2011), reported that when considering gender differences in a civilian environment, women had shorter distances from skin to pleura compared to men. On the other hand, a study conducted in a military trauma center (Givens, Ayotte,

& Manifold, 2004) showed that on average, women had thicker chest walls compared to male counterparts.

THROUGH ANATOMICAL DIFFERENCES

In regards to physiological differences, research from civilian medical studies have concluded that hormonally active women benefit from their estrogen powering immune system (Frink, Pape, van Griensven, Krettek, Chaudry, & Hildebrand, 2007), have a better physiologic (hemodynamic and tissue perfusion) response to similar degrees of shock and trauma than their male counterparts (Deitch, Livingston, Lavery, Monaghan, Bongu, & Machiedo, 2007); and demonstrate a higher survival rate than males with comparable injury (Cross, et al., 2011). These results seem contradictory to what we are observing at point of injury (combat environment) where females are far more likely to die of their wounds than males. As a result, the authors surmise that at the point of injury, during which a male emergency care provider might be required to expose and/or touch a female Soldier's body parts, lack of proper training can induce hesitation, which could potentially compromise the chance of performing a thorough assessment of injuries and jeopardize saving a critically injured female Soldier.

A GROWING TREND

Recent studies have highlighted a need to explore the impact of sex and gender in clinical training to improve outcomes for female patients (McGregor and Choo, 2015). Following Defense Secretary Leon Panetta's decision to lift the ban of women serving in combat arms in 2013, the number of females in combat roles is projected to increase drastically in the next few years (Hylden, Johnson, and Rivera, 2014; Office of the Undersecretary of Defense, Personnel and Readiness [OUSD(P&R)], 2016).

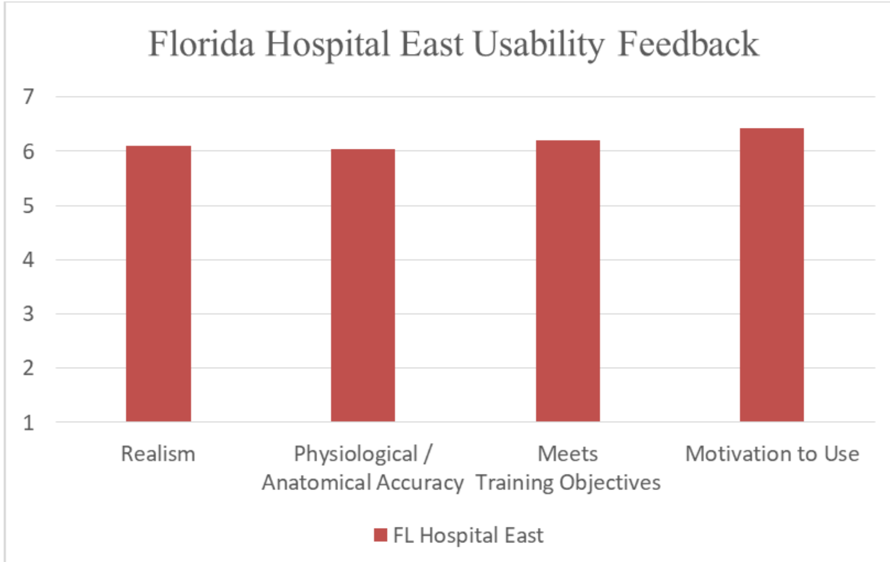

Figure 3: Florida Hospital East Feedback by Category.

Within two years of Army recruitment, more than 640 women entered previously closed Infantry, Field Artillery, Ordnance and Combat Engineer branches. Thought must also be given to the other branches of service as the Marine Corp recruited 236 women to fill previously closed infantry roles. With over 300,000 woman being deployed since September 11, 2001 to Iraq and Afghanistan; 166 killed in combat and over 1,000 wounded, this number is guaranteed to rise without proper desensitization training for the first responders. The number of women currently in the training pipeline is growing and as this female population catapults past 15% of the military population, medical training with gender specific training models must be at the forefront. (Service Women's Action Network, 2017).

With the shift in combat roles, military training needs to be assessed. A former combat medic who deployed with 3rd Cavalry Regiment in 2010 believes that with the placement of females in combat roles as Infantry Soldiers there needs to be an adjustment of the way the medical field trains interventions and treatments. She explained that in Advanced Individual Training (AIT) she trained on male-centric mannequins and when the question was asked she said the response was "There are no males and females… there are only Soldiers." She states, "If the military doesn't think this approach will be reflected on the battlefield in medical care, they are wrong. Males do hesitate to treat females, even if only for a second, to contemplate the touching of a female. I have witnessed hesitation. I have been asked to step in and relieve a male treating a female Soldier. I have also been asked to see females for basic sick call functions because the male medics are uncomfortable." She went on to say that "Leadership needs to understand that just because we have always trained a certain way doesn't mean it is the best approach. Research needs to be done to ensure we provide the very best POI care to everyone."

As female numbers continue to increase in combat roles, more research is needed to investigate biological differences (i.e., males vs. females), mechanisms of injury,

Table 2: Mean Responses by Category.

Category	Response
Realism	6.11
Physiological/Anatomical Accuracy	6.03
Meets Training Objectives	6.20
Motivation to Use	**6.42**
All Categories	**6.19**

and treatment plans. Further, psychosocial factors (e.g., differences in symptom reporting; Farace and Alves, 2000) and perceptual issues in regards to hesitation are also a matter of consideration.

This compilation of evidence points to the need for training programs to change. The examples of adjusting procedures to compensate for physical differences, the trend of lower survivability rates in major conflicts, and anatomical differences beneath the skin's surface, combined with the rising proportion of female Soldiers, indicates that the Department of Defense could potentially face significantly diminished survivability in future conflicts. This evidence warrants a comprehensive analysis to determine the primary drivers impacting the survivability of female Soldiers. Results from such a study can inform programs of instruction on how best to incorporate gender differences during training. It is essential for the joint military community to eliminate gender as a variable with respect to survival at the point of injury, and throughout prolonged field care (PFC).

The following is a list of required features identified by the military medical training community to support their programs of instruction. Any potential training solution must:

- Support established TC3 training objectives;
- Provide a capability to judge proficiency performance;
- Support practice of both cognitive and psychomotor skills;
- Include palpable anatomical landmarks to support the practice of TC3 procedures;
- Include realistic female simulated anatomical features to augment physical exam and scenario training; and
- Simulate female physiological responses; and
- Support training for long-term treatment during prolonged field care (PFC)

Currently, the Army is managing four efforts to develop a highly realistic female-centric simulation-based model. One of the efforts is focusing on developing a female model to interface with existing male-centric human patient simulation models. This capability will provide an immediate solution using current resources. The other three ongoing efforts are part of a Small Business Innovation Research (SBIR) topic to develop additional capabilities.

"Stress inoculation, also referred to as desensitization, is needed during training to reduce the emotional reaction or shock the medic experiences in response to blast trauma at the point of injury in operational environments."

HOW IS THE US ARMY ADDRESSING THE CURRENT TRAINING GAP?

The US Army is currently conducting research and development of a female simulation model exhibiting high-fidelity anatomical and physiological structures. The targeted training audience are non-physician first responders. Specifically, current efforts focus on the development and evaluation of a low-cost female simulation-based model to support the training of Combat Lifesavers and Combat Medics in the development of psychomotor skills to treat severe trauma on female casualties at the point of injury.

INITIAL CAPABILITY

One of the challenges in providing realistic human patient simulations is providing training models at the appropriate level of fidelity to cause stress inoculation, while also controlling costs. The DoD invests significant capital to acquire and maintain sophisticated human patient simulators (HPS) for point of injury training. Unfortunately, even these simulators do not meet the goals of realism and stress inoculation capability with respect to their female components.

Considering this significant investment, the Army decided to augment these already-existing HPS systems with more realistic anatomy with as little logistical footprint as possible by developing an interoperable add-on kit. This effort involved researching materials to obtain desired performance capabilities (e.g. self-healing skin that does not show holes from previous needle punctures), and increase the fidelity of female anatomical structures, while also greatly controlling costs.

The initial prototype consists of a torso and face overlays (as shown below in Figure 1) which interface with existing HPS systems used at the Army's Medical Simulation and Training Centers (MSTCs).

A usability study was performed on the initial prototype on a noninterference basis with physicians from Florida Hospital East in Orlando, Florida (n = 22). This study focused on evaluating system usability to support training objectives and to assess if the system is intuitive, effective, and subjectively acceptable to users (Nielsen, 1993). Responses were obtained through a questionnaire that assessed the system with respect to benefit to training, usability, realism, physiological and anatomical accuracy, and motivation to use. Responses were reported using a 7-point Likert scale, with 7 indicating the most positive response. Initial usability testing indicated a strong level of user acceptance, as shown in Table 2 and Figure 2.

Based on the initial study findings, the system design was improved to incorporate a realistic face mask to slip on top of the existing face, as well as more realistic genitalia inserts to support catheterization training.

Successive usability testing continued to indicate a strong level of user acceptance using the same survey instrument. Feedback was obtained from a variety of potential end-users, including seven Combat Medics (68Ws) and 26 paramedics and EMTs (Mazzeo, Sotomayor, Coulter & Alban, 2018). On a 7-point Likert scale, 68Ws gave the system a score of 5.91, with 7 being the highest possible score. Physicians rated the system even more favorably at 6.19, while paramedics and EMTs rated it less favorably at 5.39.

This evaluation comprised a larger study population, as well as three different types of potential users. The original group consisted only of physicians from Florida Hospital East, whereas the successive groups consisted of a mix of combat medics, as well as paramedics and EMTs. These different groups might help explain the differences in reported scores for the system. An analysis of the data revealed the presence of a bimodal distribution of scores within the group of paramedics and EMTs from Estero Fire Rescue; roughly half of the participants reported a high level of acceptance, while the other half reported a low level of acceptance. This bifurcation explains the lower average score when compared to the first group's usability data.

In addition to the usability data, several anecdotal observations were made during the course of this study involving 68Ws:

- Most trainees showed an initial pause when presented with the bra during patient assessment.
- Over half of the trainees did not remove the bra while assessing the patient.
- Most of the trainees that did remove the bra, spent time covering the breast or re-fastening the bra after the wound had been treated.
- One of the male trainees placed the occlusive dressing over the bra, making it ineffective. The instructor verbally told him that air was escaping from the dressing and he began to place a second dressing right on top of the previous one. The instructor used it as a teaching point that the occlusive dressing is only effective if it is placed on skin with no leaks. At that point the trainee moved the bra to the side and repositioned the dressing but still would not fully remove the bra. At this point the trainee was allowed to progress to the next training prompt.
- Overall, it appeared that the bra added another dimension of training and should be included in training scenarios moving forward.
- One participant seemed to struggle with counting the intercostal spaces. It is unclear if the overlay prevented proper palpation.
- One female participant approached the researchers after the simulation and stated that she really enjoyed using the female simulation system. She also mentioned that even as a female, she did not know what she was supposed to do in regards to the bra. She did not know if she was supposed to expose her or leave the bra on.

Over the course of the usability evaluation with the paramedics and EMTs from Estero Fire Rescue, several additional anecdotal observations were reported:

- Some participants removed the bra, but failed to properly assess the chest area.
- Out of 26 total participants, all but two failed to identify an injury close to the breast on the patient (a large bruise).
- Most participants felt that the face mask was not realistic enough to represent a female – it still appeared very masculine to them.

> *"Leadership needs to understand that just because we have always trained a certain way doesn't mean it is the best approach. "*

Through developing and testing a low-cost system to introduce female anatomy at an appropriate level of fidelity, not only did users find the system very usable, it also revealed a variety of potential psychomotor difficulties that would have been entirely absent without a realistic female model as part of the training regimen.

FUTURE CAPABILITY

In addition to a rapidly deployable, low-cost training capability, the US Army is also investing in several additional capabilities through the Small Business Innovative Research (SBIR) Program. Three efforts are currently exploring how to incorporate female anatomy and physiology as it relates to combat trauma, under the topic entitled "Severe Trauma Female Simulation Training System." The objective of this SBIR topic is to develop a realistic SBT system to support the development of psychomotor skills to treat severe trauma at point of injury. The capabilities developed under this SBIR will support not only the practice of cognitive and psychomotor skills, but also the ability to judge proficiency and performance through the use of software, sensing technologies, and physiology engines.

This research is ongoing, and initial capabilities will be available for assessment in FY2020. At that time, the direction of research will turn to evaluating the effectiveness of these capabilities in a relevant training environment. Concurrently, literature research will also be expanded to include additional data regarding male and female survivability rates with respect to battlefield injuries. The current survivability rates reported do not take into consideration factors such as the mechanism of injury, complications that arise as a result of injury, injury context with respect to roles (whether combat or non-combat roles), and differentiating between mortality as a result of combat and mortality as a result of non-battle related activities. For all of these factors, frequency and severity should be compared

CONCLUSION

Pre-hospital care plays a vital role in battlefield medicine. First responders must be trained in a realistic and accurate combat environment to ensure they have the necessary skills to treat the wounded effectively. Although women have typically been excluded from combat arms roles in the past, recently they have been represented in significant numbers in front-line positions. As aforementioned, following Defense Secretary Leon Panetta's decision to lift the ban of women serving in combat arms in 2013, the number of females in combat roles is projected to increase in the next few years. In order to make male Soldiers more comfortable with providing care to female casualties, and more capable of reacting without hesitation in life-threatening situations, all trainees should be given the opportunity to train using realistic female anatomy models and be exposed to female severe trauma injury patterns prevalent at point of injury. The motivation behind this initiative is to provide Soldiers with the necessary tools and experiences in an immersive and realistic training environment to expose them to the realities of war including gender specific challenges.

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