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14. ABSTRACT

The Regional Anesthesia (RA), Ventriculostomy (EVD), and Central Venous Access (CVA) mixed reality simulators are ready to be delivered to the DoD. All simulators exceed original specifications. The CVA simulator's preliminary data indicated a potential self-study option for self-debriefing to be successful. Most training scenarios occurred with a human instructor's supervision and minor intervention or interfacing.

A working proof of concept TransRectal UltraSound (TRUS)-Imaged Prostate Biopsy model has been produced and initial data shows a need for the simulator among urologists.

The SMARTS SDK has allowed implementation of new mixed/augmented reality simulators beyond the original five deliverables to the DoD.

15. SUBJECT TERMS
Integrated tutor, SDK, Self-study, Self-debriefing. Competency-Based Training

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INTRODUCTION

We are ultimately developing and delivering a modular set of five mixed reality/augmented reality (AR) simulators, each for a different application from a set of five "blind" and guided medical procedures: (1) Regional Anesthesia (RA), (2) Central Venous Access (CVA), (3) External Ventricular Drain (EVD; aka Ventriculostomy), (4) Chest Tube Insertion and (5) TransRectal UltraSound (TRUS)-Imaged, Manually-Guided Needle Biopsy of the Prostate. The AR is through visual augmentation, i.e., providing 3D, real-time, color visualization of the relevant anatomy, tools, cognitive aids and implements. Our purpose is to provide deployed and stateside medical military personnel and also civilian reservists and clinicians compact, lightweight, turnkey simulators designed to work in austere environments which may include environments where there are no instructors. These highly-portable/deployable simulators are designed to provide the ability to acquire/maintain skills in medical procedures, some of which may be specific to military medicine and therefore unfamiliar to reservists who practice primarily civilian medicine. The ultimate purpose is to provide through the military medical personnel trained via our simulators safer and better quality care (as measured by our proposed patient outcomes study) to US military personnel (deployed and stateside) and veterans. The scope of this research is deliberately wide; because the simulators are anatomic, they are not specific to military medical needs or protocols and can be readily repurposed for civilian medical training needs too. In addition, the modular nature of the system design (including the modular stand) and the recent development and addition of a software development kit (SDK) will allow ready implementation of new mixed/augmented reality simulators possibly by third parties beyond the original five to be delivered to DoD.

KEYWORDS

Integrated tutor, Needs assessment, Outcomes studies (learning, behavior, results, RoI), Augmented reality procedural simulators, Modular, Turnkey, Ultrasound imaging, Visual augmentation

ACCOMPLISHMENTS:

Major Goals and Objectives

The major goals and objectives for Phase II are:

- Design and conduct 4 outcome studies (based on the Kirkpatrick levels) with UF IRB and also HRPO oversight and approval:
  - Learning (Kirkpatrick Level 2)
  - Transfer of Learning (Kirkpatrick Level 3)
  - Patient Outcomes (Kirkpatrick Level 4)
  - Return on Investment – ROI ("Kirkpatrick Level 5", aka Kirkpatrick/Phillips)
- Design, build/upgrade and deliver 5 simulators: Chest Tube Insertion (CTI), Central Venous Access (CVA), External Ventricular Drain (EVD aka ventriculostomy), TransRectal UltraSound TRUS-Prostate Biopsy (TRUS-PB), Regional Anesthesia (RA)
- Finalize hardware/software specifications for 5 simulators above; deliver to DoD and in-service

Accomplishments Relative to Major Goals & Objectives

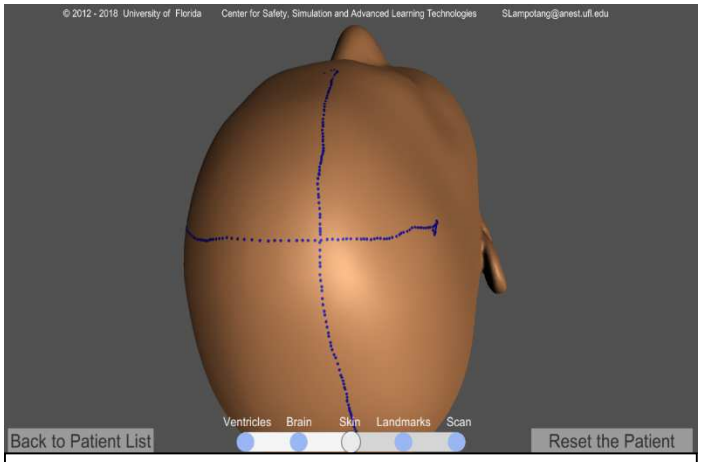
Needs assessments have been completed for all 5 simulators (RA, CVA, EVD, CTI, TRUS-PB).

A **ventriculostomy simulator, aka external ventricular drain (EVD)** has been completed. This robust, turnkey mixed reality simulator simulates part of an anatomically correct head and skull for practicing, learning, teaching and debriefing a ventriculostomy (external ventricular drain, EVD) procedure. It features a 3D-printed physical head and skull based on a CT scan, a virtual model of the anatomy of the brainstem, scalp, brain and ventricles, tracked instruments (needle, catheter loaded onto stylet, hand drill and virtual camera controller), a rejuvenable scalp, a replaceable skull cap insert with inner and outer tables and dura, an automated scoring algorithm and replay system, and a library of 61 interchangeable 3D brains based on real patient MRI scans with variable ventricle shapes and sizes. The simulator also includes a pre-drilled skull cap that can be used as a teaching tool for proper catheter trajectory, allowing users to skip the drilling part, if appropriate. During development, the drill from an actual EVD kit was redesigned to remove ferrous metals. Ferromagnetic materials interfere with the 6-DOF tracking performed in the SMARTS simulators with electromagnetic sensors from Ascension Technology Corporation. The drill was disassembled and each component was assessed to see whether it affected electromagnetic tracking; the drill chuck and drill shaft were identified as the two components causing electromagnetic tracking interference. The steel drill chuck was replaced with nylon, and the steel drill shaft was replaced with an

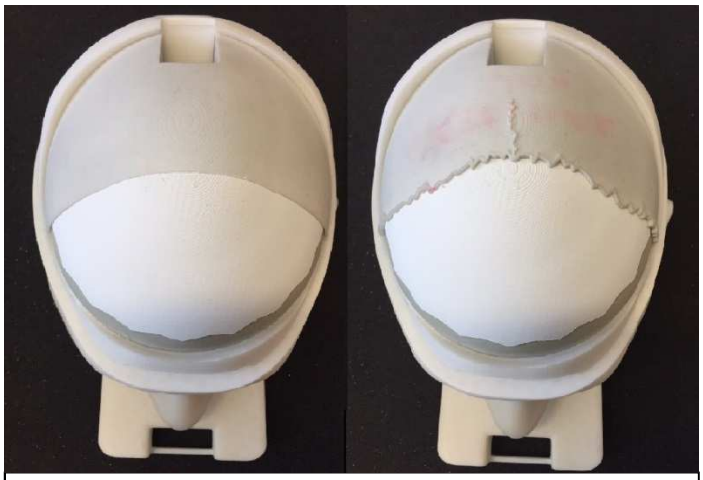
Dr. Hunaldo Villalobos, a clinical collaborator, using the SMARTS EVD simulator at the Florida Hospital Nicholson Simulation Center in Celebration, Florida.

aluminum shaft. Both material changes improved tracking compared to using the original ferrous drill head in the EVD drill and eliminated interference with tracking of the drill position and orientation. The virtual camera controller, in addition to changing the perspective of the 3D visualization, can also be used as a virtual skin marker. This functionality allows for positional tracking, recording, and scoring of a clinician's skin markings and is an alternative to an actual marker, which is messy and has the potential to leave permanent marks on the simulator scalp. The design of the coronal sutures was revised on the EVD simulator to make them more realistic anatomically, visually, and tactilely following feedback received from clinicians; the new coronal sutures are more obvious when palpated through the reusable scalp gel. Upon clinician feedback regarding the depth of the ventricles of some of the virtual 3D brains, 16 brains were removed due to segmentation errors that resulted in incorrect virtual anatomy being represented, leaving a library of 61 brains. The simulator was loaned to Florida Hospital and was used from 4/23/18 to 5/10/18 by Dr. Villalobos, a neurosurgeon at Florida Hospital, Orlando to train 3 physician assistants, 1 medical student, 2 neurosurgeons, and 1 general surgeon.

The new drill design with nonferrous materials (above), compared with old design (below).

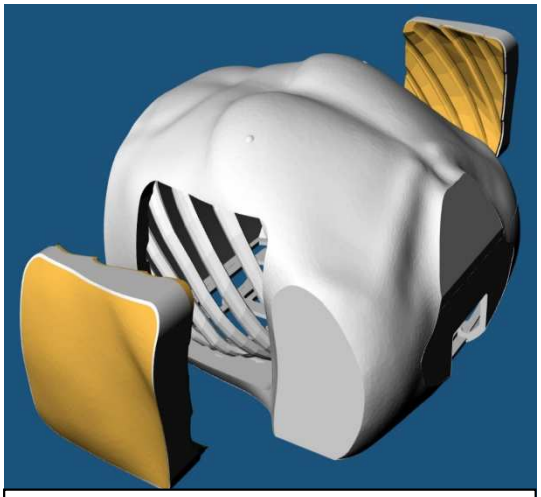


User-created virtual skin markings in the EVD 3D visualization.

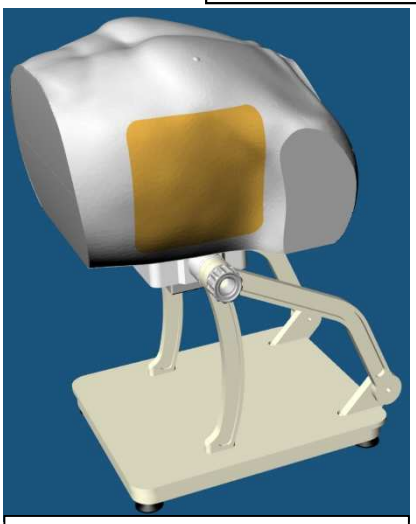


The old coronal suture design (left) and new coronal suture design (right).

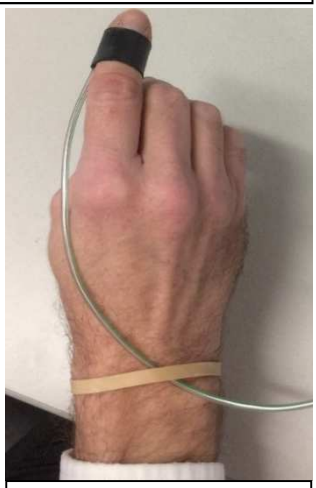
A **chest tube insertion (CTI) simulator** has had tracked tools developed, including a tracked Kelly clamp, chest tube, and a finger tracker. Currently the design for the physical mannequin, which includes the shoulders, axilla, chest, and upper abdomen, has been guided with help from multiple emergency medicine faculty and clinicians. The CAD design for the physical mannequin is currently being finalized for a 3D test print. A finger tracker for the CTI simulator was designed and built featuring an armored sensor, strain relief, and a design independent of the finger size of the trainee. The tracker is armored to protect the fragile sensor from strain and bending during use. A similar finger tracker design from another manufacturer, using the same sensor but without armor, has reliability issues. An alignment step in the CTI simulator software compensates for variable finger sizes. The straps are elastic and are "one size fits all". A chest tube tracker was designed and built featuring a strain-relief and crush-proof enclosure (to protect from Kelly clamp closing pressure) and a design that fits common adult chest tube sizes. The sensor is inserted and anchored at the distal end of the chest tube. The sensor insert is constrained at the proximal end of the chest tube.



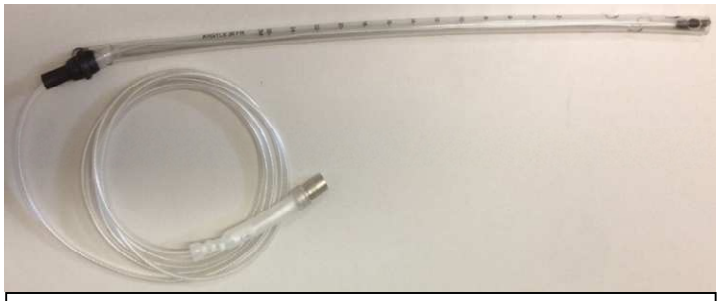
Physical mannequin for SMARTS CTI simulator features rejuvenable ballistic gel.



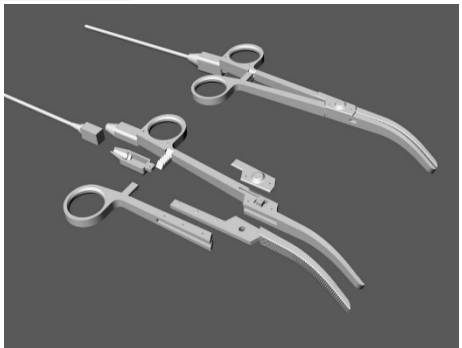
CAD rendering of the physical mannequin for the SMARTS CTI simulator on the SMARTS modular platform stand.



CTI simulator finger tracker, featuring an elastic "one size fits all" design attached to a user's index finger.

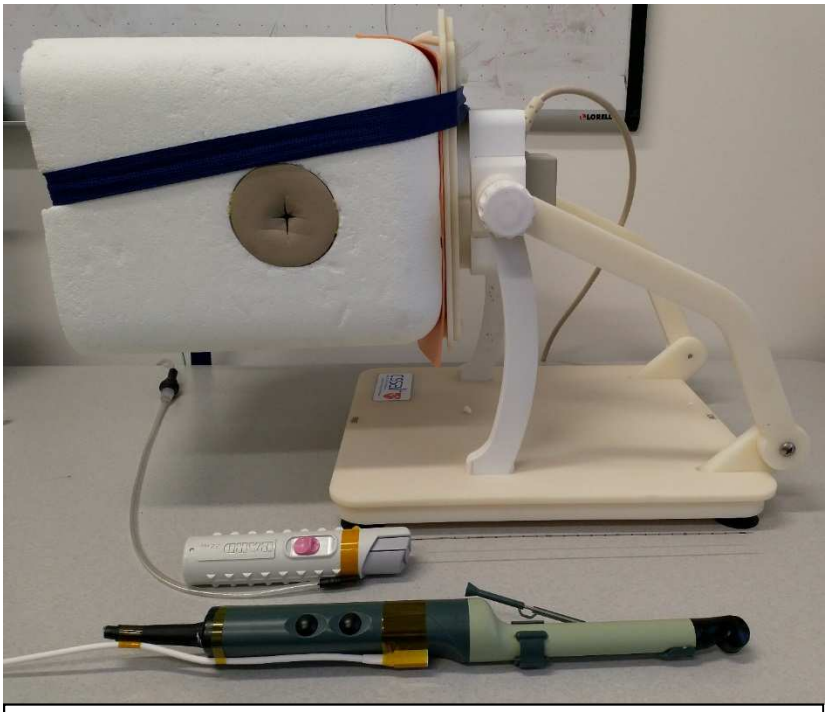


The chest tube tracker for the CTI simulator is inserted in the distal end of the chest tube and secured in the hub of the chest tube (left), while the armored sensor (right) detects the 6 DOF location of chest tube placement.



Overview of the Kelly clamp design for the CTI simulator, featuring a 6-DOF sensor and micro hub rotation sensor.

A working proof of concept TRUS-PB (TransRectal UltraSound Prostate Biopsy) simulator is operational since 7/19/18. Specifications were drafted in May 2018. Working with Drs. Su and Stringer of the UF Urology Department, we obtained tools (biopsy gun, needle guide, TRUS probe) to design and implement tracked tools for the simulator. A working prototype consisting of a tracked BK 8818 TRUS probe, a side-fire needle guide and a tracked biopsy needle gun was successfully demonstrated to Drs. Otto and Stringer on 7/19/18. Initial data collected from urologists seem to confirm our hypothesis that the TRUS-PB simulator is needed because a significant portion of urologists may be unconsciously incompetent in terms of the deviation of their biopsied samples from the intended location in a 12-core sextant biopsy template.



TRUS-PB SMARTS simulator working proof of concept prototype featuring a tracked needle gun (off white tool) and TRUS probe (green tool) with a side-fire needle guide.

The hardware for the SMARTS platform has undergone improvements for standardization per phase II specifications. The SMARTS platform now features a standard circuit board that can be used in all white boxes, standard inputs for exchanging various tools into the microcontroller, a separate internal

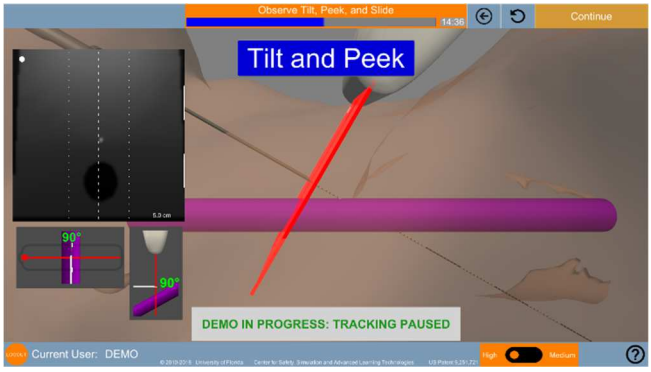
Unit E improved stand design with cutouts for weight reduction.

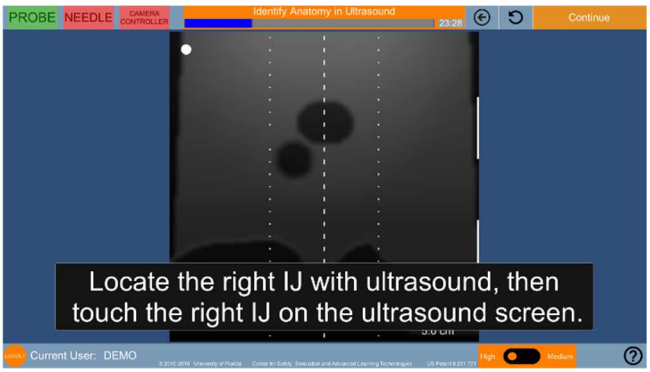
compartment to house the circuit board and microcontroller, and a standard wire holder bridge for strain relief.

A new version of the CVA simulator was developed for a mass intervention for central line providers at UF Health Gainesville as part of our CVA Patient Outcomes and ROI study. The software was based on the SMARTS SDK and new features include a fully independent self-study and self-debrief system, a coaching mode that provides active feedback and remediation exercises, and a more robust replay system that can focus on highlights of a procedure. It also features a reworked needle anisotropy exercise, curriculum teaching the Tilt, Peek, and Slide technique, and an ultrasound anatomy identification module. The physical mannequin was also redesigned to be made of rejuvenable ballistic gel.

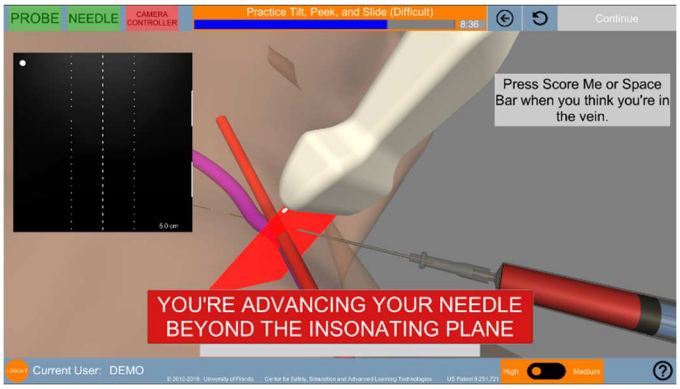
The newly redesigned ballistic gel physical mannequin mold for the SMARTS CVA simulator.

Emergency medicine resident participating in the CVA Mass Intervention.





- Five outcome studies (5 total: 2 learning outcomes, 1 transfer of learning outcome, 1 patient outcome, 1 return on investment (ROI) are currently in various stages of completion)
  - UF IRB02 Approval Number 2014-U-0658. HRPO Log Number A-18036.1 RA curriculum. Eighteen anesthesia residents participated in the study as of 8/22/17. This study was closed with UF IRB-02 on 12/1/17 and closed with HRPO on 2/6/18.
  - UF IRB02 Approval Number 2015-U-672, HRPO Log Number A-18036.2 - SP vs SP-oblique US-Guided TPVB. This study was closed with UF IRB-02 on 12/19/17 and closed with HRPO on 2/6/18. No subjects were enrolled in this study due to logistical difficulties (too great of a time commitment required of subjects)

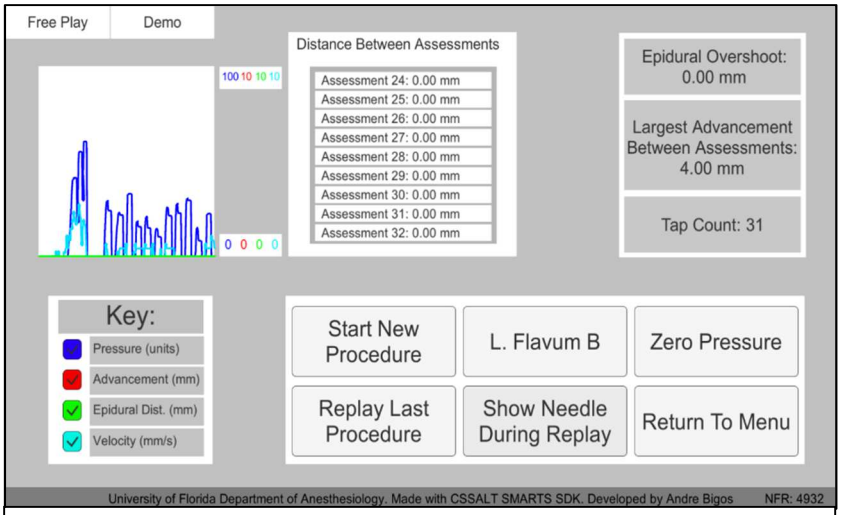


  - IRB201601147 – Mixed Reality Simulation Training for Central Venous Access (CVA): An Analysis of Retrospective Patient Outcomes. CVA Simulator: Retrospective Study of Patient Outcomes at UF Health – We have obtained some data from UF Health Gainesville and UF Health Jacksonville regarding general incidence rates of pneumothorax and arterial punctures associated with central line placement.
  - IRB201600595, HRPO Log Number A-18036.3 – Small Form Factor, Modular, DoD CVA Sim: Learning Outcome Study. Enrollment of subjects for this study resumed in August 2017 following improvements to the simulator and integrated tutor curriculum. Continuing reviews for UF IRB-02 and HRPO were completed on 1/23/18 and 2/5/18 respectively. In total, 27 residents received instruction from the integrated tutor and 27 residents received human instruction. The results from the study have been submitted and accepted for presentations at conferences for a number of different academic organizations, including the Florida Society of Anesthesiologists (presented), the American Society of Anesthesiologists (to be presented 10/18), and the Military Health System Research Symposium (presented 8/18).
  - IRB201702753, HRPO Log Number A-18036.4 - Small Form Factor, Modular, DoD CVA Sim: Patient Outcomes study. Study was approved by IRB-01 on 4/2/2018 and with HRPO on 4/17/2018. We have obtained some data for the 18-month pre-intervention period from UF Health Gainesville and UF Health Jacksonville. We are currently exploring different options for calculating incidence of arterial punctures during central venous access procedures, which was not captured in our initial strategy for obtaining data.
    IRB201801197 - Small Form Factor, Modular, DoD CVA Sim: Transfer of Learning. Study was submitted to IRB-01 for review on 7/17/18.

Accomplishments Above and Beyond Original Specific Deliverables

1. New needle design – soldered copper junction between pneumatic tube and needle hub.

2. A wet tap prevention training simulator was developed using the SMARTS SDK. This was then used in an IRB approved study (IRB201702551) to evaluate three different loss of resistance techniques and has led to multiple abstract submissions and a scientific exhibit at the upcoming American Society of Anesthesiologists annual meeting in October 2018.



Screenshot of wet tap prevention training simulator software. Developed using the SMARTS SDK and used in an IRB-approved study of anesthesia providers at UF Health Gainesville.

3. We developed and built a proof of concept mixed-reality simulator with the SMARTS SDK to train intravenous (IV) access in a peripheral vein. The simulator consists of a ballistic gel hand model, location tracked needle, catheter detection, vein access LED indicator, and virtual feedback. Even though it is one of the most common procedures, it is still not unusual for inexperienced nurses and physicians to need multiple attempts to access the vein. This simulator allows for realistic IV access along with physician backed feedback on how the user performed.

Intravenous access prototype with location tracked needle.

4. SDK – new features as of 7/31/18
    A. Microcontroller
        i. Improved the microcontroller code that allows software to communicate with the microcontroller
        ii. Improved reliability of the code to reduce errors with communications between software and microcontroller
    B. Ascension Technology Corporation (ATC)
        i. Improved the way the software talks to tracking system
    C. Blue Screen
        i. The blue screen errors provide more troubleshooting feedback to the type of error
    D. Ultrasound Manager
        i. Improvements will allow developers to quickly change the ultrasound insonation plane, size, and number of rays
        ii. Improved documentation on how the ultrasound manager works
    E. Replayer/Recorder
        i. Improved ability to easily allow developers to record custom simulations

F. Monitors
    i. Provide common modular algorithms that are useful for developers
G. Toasts
    i. Provide on-screen notifications with text-to-speech support
H. xAPI
    i. Provide support to learning management systems to allow our software to talk with common learning management systems (Learning Record Stores)
I. Sample Project
    i. Sample projects will allow a new developer to quickly learn how to use the SDK by viewing how features are implemented
J. Cognitive Aids
    i. Providing common cognitive aids to allow developers to re-purpose/implement into custom simulations
K. Documentation
    i. Provide documentation for developers to be able to learn and use the SDK

Opportunities Provided for Training and Professional Development

Year 4 (8/1/2017-7/31/2018)

The SMARTS mixed-reality simulators were demonstrated and/or used during Year 4 of grant W81XWH-14-1-0113 per the table below. Overall, 1,151 people were demoed or trained in Year 4.

Institution / Event	**Location**	**Simulators** •RA = Regional Anesthesia •CVA = Central Venous Access •UST = Ultrasonography • EVD = Ventriculostomy •SMARTS Platform	**Dates**	**Number of trainees**	**Point of Contact/ Clinician**
University of Florida College of Medicine (UFCOM) alumni event	UFCOM	UST	9/16/17	16	Dr. Lampotang
Demo for visiting professor, Dr. Cynthia Wong	UFCOM	RA, CVA	9/18/17	1	Dr. Lampotang
MOCA	UFCOM	RA	10/13/17	6	Dr. Lampotang
ASA MOCA event "Ultrasound-Guided Regional Anesthesia and Analgesia Techniques for Breast Surgery"	ASA 2017 – Boston, MA	RA	10/22/17	48	Dr. Le-Wendling, Dr. Nin
ASA MOCA event “Peripheral Nerve Blocks Workshop: Ultrasound, Simulation, Stimulation”	ASA 2017 – Boston, MA	RA	10/24/17	80	Dr. Le-Wendling, Dr. Nin
Demo to Dr. Lars Beattie, UF Emergency Medicine	UFCOM	CVA	11/2/17	1	Dr. Lampotang

Instruction to visiting UPenn faculty	UFCOM	RA	11/2/17	2	Dr. Ihnatsenka
"Regional anesthesia for the pediatric anesthesiologist" Workshop -Joint SickKids Pediatric Anesthesia & Canadian Pediatric Anesthesiologists Society (CPAS) meeting	Toronto, CA	RA	11/3/17	42	Dr. Lampotang
UFCOM Anesthesia Interest Group	UFCOM	RA	11/7/17	32	Dr. Zasimovich
Demo to Dr. Matthew Ryan, UF Emergency Medicine	UFCOM	CVA	11/14/17	1	Dr. Lampotang
MOCA	UFCOM	RA, CVA	12/2/17	9	Dr. Lampotang
Procedurepalooza	UFCOM	CVA	12/7/17	20	Dr. McGough
MOCA	UFCOM	RA, CVA	12/9/17	10	Dr. Lampotang
Anesthesiology residency candidates demo	UFCOM	RA	12/14/17	10	Tony DeStephens
Instruction of 4th year UFCOM medical students during Acute Pain Medicine course	UFCOM	RA	1/8/18	3	Dr. Cameron Smith
Exhibit Hall demonstration at IMSH 2018	IMSH 2018 (Los Angeles, CA)	CVA, RA, EVD, SDK	1/14/18-1/16/18	75	Dr. Lampotang
Demo to Gianluca Bertolizio (Anesthesiologist, McGill University) and Marta Garbin (Resident, UF College of Veterinary Medicine)	UFCOM	CVA, RA	1/23/18	2	Dr. Lampotang
Regional Anesthesia workshop	Maine Medical Center	RA	1/23/18 – 1/29/18	20	Dr. Ihnatsenka
Demo to UF Anesthesiology interns	UFCOM	RA	1/25/18	12	Dr. Lampotang
Demo to UF BME undergraduate students	UFCOM	RA, UST, SDK, CVA	2/1/18	12	Dr. Lampotang
Acute Pain Service instruction to UF Anesthesiology interns	UFCOM	RA	2/2/18	20	Dr. Cameron Smith
Demo to visiting professor Dr. Deepak Sharma MBBS, MD, DM	UFCOM	CVA, RA	2/12/18	2	Tony DeStephens
Instruction to UF undergraduate student	UFCOM	CVA	2/20/18	1	Dr. Sappenfield

Demo at Tennessee Society of Anesthesia meeting	Vanderbilt University	RA	2/20/18-2/28/18	12	Dr. David Edwards
Acute Pain Medicine & Regional Anesthesia Course for physicians, medical students, residents, acute pain fellows	Baltimore, MD	RA	3/23/18-3/25/18	50	Dr. Cam Smith
Demo for Dr. Daryl Reust	UFCOM	CVA, RA, Ventric	4/5/18	1	Dr. Lampotang
Demo for faculty applicant, Dr. Melissa Burger	UFCOM	CVA, RA, Ventric	4/6/18	1	Dr. Lampotang
Demo for visiting professor, Keith Ruskin, MD	UFCOM	CVA, RA, Ventric	4/9/18	2	Dr. Lampotang
Demo to train fellows	UFCOM	RA	4/11/18	7	Dr. Ihnatsenka
MOCA for anesthesiologists	UFCOM	RA	4/14/18	10	Tony DeStephens
ASRA World Congress – training conference attendees		RA	4/18/18	100	Dr. Ihnatsenka
Demo for Dr. Hunaldo Villalobos	Florida Hospital, Orlando, FL	Ventric	4/23/18	1	Dr. Lampotang
Evaluation of EVD simulator teaching 3 PA's, 1 medical student, 2 neurosurgeons, and 1 general surgeon	Florida Hospital, Celebration, FL	Ventric	4/23/18	7	Dr. Hunaldo Villalobos
Training for fellow	UFCOM	RA	4/24/18	1	Dr. Ihnatsenka
Evaluation by Emergency Medicine physicians	UFCOM	CVA MI	4/30/18	2	Dr. Lampotang
Training for 1 fellow	UFCOM	RA	4/30/18	1	Dr. Ihnatsenka
Demo/Tested with 1 DNP (Doctorate of nursing practice; i.e. nurse practitioner) student, 3 medical students (M4's)	UFCOM	CVA MI	5/1/18	4	Dr. Lampotang
Simulation and training for 1 fellow	UFCOM	RA	5/1/18	1	Dr. Ihnatsenka
Demo to Teleflex	UFCOM	CVA MI, RA, UST	5/2/18	4	Dr. Lampotang
Demo for Bill Levesque, Science Writer for UF Health Communications	UFCOM	CVA MI	5/3/18	1	Dr. Lampotang
Instruction for UF College of Medicine MS4 Anesthesiology-matched residents	UFCOM	CVA MI, RA, UST	5/7/18	8	Dr. Lampotang

Training for participants at Nin/University of Penn	Nin/University of Pennsylvania	RA	5/7/18-5/15/18	70	Dr. Nin
Demo for Anesthesia residents (HVN workroom)	UFCOM	CVA MI	5/14/18	15	Dr. Gravenstein
CVA Mass Intervention: Training of residents, fellows, and APPs (NPs and PAs)	UFCOM	CVA MI	5/9/18-7/31/18	159	Tony DeStephens, Desmond Zeng, Sara Croft, CSSALT Team
RA Anesthesia Regional Workshop (residents, fellows)	University of Pennsylvania	RA	5/14/18-6/2/18	25	Dr. Taras Grosh
Pediatric Regional Workshop	British Colombia Children's Hospital, Vancouver, BC	RA	6/5/18-7/2/18	25	Dr. Gill Lauder, MB BCh, FRCA, FRCPC, PG Dip (Med Ed)
Demo/Hands-on workshop for Pediatric RA's	British Colombia Children's Hospital, Vancouver, BC	UST, RA	6/6/18	13	Dr. Lampotang
Demo/Hands-on workshop for Pediatric RA's	British Colombia Children's Hospital, Vancouver, BC	UST, RA, CVA MI	6/7/18	11	Dr. Lampotang
Training session at Dwight D. Eisenhower Army Medical Center for 3 student Certified Nurse Anesthetists (SRNAs), 10 CRNAs, and 4 Anesthesiologists	Fort Gordon, GA	RA	6/11/18-6/22/18	17	Lt. Col Ferdinand Bacomo
CHOP Workshop	Philadelphia, PA	CVA MI	6/14/18	12	Dr. Lampotang
CHOP Workshop	Philadelphia, PA	CVA MI	6/15/18	11	Dr. Lampotang
Loan following following Dr. Lampotang's workshops for Pediatric anesthesiologists, surgeons, intensive care physicians, neonatologists,	Children's Hospital of Philadelphia (CHOP)	CVA MI	6/13/18-6/22/18	50	Harshad Gurnaney

and emergency care physicians					
"Meet @ the Cade" series – Biomimicry and Robots (8 physicians visiting from Michigan (one was UF Neurosurgeon), 51 students)	Cade Museum exhibit, Gainesville, FL	RA, UST	7/7/18	60	Dr. Lampotang and David Lizdas
Cade Museum for exhibit	Cade Museum, Gainesville, FL	RA, UST	7/6/18-7/16/18	N/A	David Lizdas
Demo to Student Science Training Program (SSTP) participants	UFCOM	RA	7/13/18	13	David Lizdas, CCSALT Team
Demo to SSTP participants	UFCOM	RA, CVA, UST	7/20/18	20	David Lizdas
Demo to Department of Anesthesiology members, Office of Research, and Administrative Office at UF	UFCOM	RA, CVA, UST/TRUS-PB prototype	7/25/18	12	Dr. Lampotang, David Lizdas

Dissemination to Communities of Interest

Year 4 (8/1/2017-7/31/2018)

Cade Museum (July 7, 2018) – Regional Anesthesia and Ultrasound Trainer simulators were presented at the week-long "Meet @ the Cade" series. Eight physicians visiting from Michigan, one UF Neurosurgery faculty member, and 51 students, some of whom were children, engaged in demos. It is most notable that children are not our usual academic target group.

Plan for Next Reporting Period to Meet Goals & Objectives

- Complete chest tube insertion simulator development and evaluation.
- Complete TRUS-guided prostate biopsy simulator and evaluation.
- Complete EVD simulator clinical evaluation with potential evaluation at University of Buffalo by Dr. Siddiqui
- Complete transfer, patient outcomes and return on investment studies
- Complete upgrades of simulators to Phase II specifications

IMPACT:

Year 4 (8/1/2017-7/31/2018)

We demonstrated that an integrated tutor was non-inferior to an average human instructor in learning specific central venous access procedures. This is impactful because the study demonstrated that availability of instructors does not need to remain a roadblock if we can design and build instructor-less simulators, analogous to driver-less cars, for self-study and self-debriefing. We are in the process of writing a manuscript for submission for peer-reviewed publication.

CHANGES/PROBLEMS:

Year 4 (8/1/2017-7/31/2018)
We have completed the Learning Outcomes and Mass Intervention steps and are now proceeding with Transfer of Learning. In the Transfer of Learning, we will be completing the study without a nurse, thus reducing costs and allowing allocated funding for simulator development.

On May 14, 2018 we began collaborating with Undergraduate Biomedical Engineering students in a senior design class for one year. The students will be utilizing the TRUS-PB prototype design to create a robust translational model that fits weight requirements. It will also use SMARTS SDK for software.

PRODUCTS:

Year 4 (8/1/2017-7/31/2018)
Number of peer-reviewed publications (include ones that are pending publication): 2

Published: Sappenfield JW, Smith WB, Cooper LA, Lizdas DE, Gonsalves DB, Gravenstein N, Lampotang S, Robinson AR: Visualization Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator. *Anest Analg* 127:1; 83-89, July 2018*

Accepted: Sappenfield J (mentee), Grek S, Cooper LA, Lampotang S: Reduced Complications of Supraclavicular Approach in Simulated Central Venous Access: Applicability to Military Medicine. Submitted 01/12/18 to *Journal of Military Medicine*

MHSRS

MHSRS Poster: Zimmerman M, Lizdas D, Avari K, Ihnatsenka B, Lampotang S - "*Military Medical Modeling & Simulation Applications of Medical Technology 'Realities' to improve training effectiveness – Deployed clinician self-study and self-debriefing in austere environments: An integrated tutor for a mixed reality simulator of thoracic regional anesthesia*". Presented as poster on 08/22/2017.

MHSRS Poster: Lampotang S, Lizdas D, Sappenfield J, Robinson A, Cooper LA - "*Military Medical Modeling & Simulation Applications of medical technology "realities" to improve training effectiveness – 3D visualization improves supraclavicular access to the subclavian vein in a mixed reality simulator*". Presented as poster on 08/22/2017.

MHSRS Abstract: McGough E, Sappenfield JW, Gravenstein N, Cooper LA, Lizdas DE, DeStephens AJ, Gifford A, Zeng D, Lampotang S. *"Ongoing assessment of a self-study, self-debriefing simulator for central venous access: Preliminary results"*. Abstract submitted 03/16/2018.

American Society of Anesthesiologists

ASA Poster – Sappenfield J, Cooper LA, Lizdas DE, Gravenstein N, Robinson A, Lampotang S "Visual Augmentation Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator". **Poster presented 10/21/2017.

ASA Abstract: McGough E, Sappenfield JW, Gravenstein N, Cooper LA, Lizdas DE, DeStephens AJ, Gifford A, Zeng D, Lampotang S. *"Non-inferiority Assessment of a Self-study, Self-debriefing Mixed Reality Simulator for Central Venous Access".* Abstract submitted 04/02/2018.

College of Medicine, Dept. of Anesthesiology Celebration of Research

McGough E, Sappenfield JW, Gravenstein N, Cooper LA, Lizdas DE, DeStephens AJ, Gifford A, Zeng D, Lampotang S. *"Ongoing assessment of a self-study, self-debriefing simulator for central venous access: Preliminary results"*. Abstract submitted 02/09/2018. Poster presented on 03/21/2018.

IMSH: Society for Simulation in Healthcare Abstract

Cooper LA, Bigos A, DeStephens AJ, Gravenstein N, Johnson W, Lizdas D, McGough E, Sappenfield JW, Zeng D, Lampotang S. *"Self-study and self-debriefing in a mixed reality simulator is non-inferior to human instruction for learning central venous access"*. Abstract submitted on 06/25/2018.

University of Florida, UF Health Patient & Safety Quality Week

McGough E, Sappenfield JW, Gravenstein N, Cooper LA, Lizdas DE, DeStephens AJ, Gifford A, Zeng D, Lampotang S. *"Ongoing assessment of a self-study, self-debriefing simulator for central venous access: Preliminary results"*. Abstract submission on 2/16/2018. Accepted and poster presented on 04/18/2018.

Advances in Medical Education, UF COM Jacksonville

McGough E, Sappenfield JW, Gravenstein N, Cooper LA, Lizdas DE, DeStephens AJ, Gifford A, Zeng D, Lampotang S. *"Assessment of a self-study, self-debriefing mixed reality simulator in central venous access".* Abstract submitted 04/02/2018. Poster presented 06/13/2018.

PRESENTATIONS:

Year 4 (8/1/2017 - 7/31/2018)

- ASA Annual Meeting poster presentation on 10/24/17 - "Visual Augmentation Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator"
- Medical Simulation & Information Systems Research Program (MSISRP) Joint Program Committee (JPC) - Interim Progress Review - 2/7/18
- Grand Rounds, British Colombia Children's Hospital – "Recent developments in simulation for procedural training" – 6/6/18
- Lecture, Department of Anesthesiology and Critical Care Medicine, Children's Hospital of Philadelphia – "Recent developments in simulation for procedural training" – 6/14/18

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

Year 4 (8/1/2017- 7/31/2018)

Hunaldo Villalobos, M.D., FAANS, FACS – Board certified neurosurgeon at Florida Health and Central Florida Neurosurgical Institute. Dr. Villalobos clinically evaluated the ventriculostomy simulator at the

Florida Hospital Nicholson Simulation Center in Celebration, FL and also borrowed the simulator to teach a variety of different neurosurgical trainees over the course of a week.

David Allan Edwards, MD – Chief of Division of Pain Medicine and Assistant Professor of Clinical Anesthesiology at Vanderbilt University Medical Center who continues to collaborate with us on loans of our RA simulator since the first year of the project. Dr. Edwards used the simulator in a Regional Anesthesia & Ultrasound workshop during the annual Tennessee Society of Anesthesia meeting in February 2018.

Lt. Cl. Ferdinand K. Bacomo – Medical Intensivist and Staff Anesthesiologist Chief, Anesthesia and Operative Services Chair, Critical Care Committee Dwight D. Eisenhower Army Medical Center from Fort Gordon, Georgia. Lt. Cl. Bacomo continues to collaborate with us on loans of our CVA simulator since the first the recent workshop conducted on June 11-22, 2018.

Harshad Gurnaney, MBBS, MPH – Attending anesthesiologist in the Department of Anesthesiology and Critical Care Medicine at Children's Hospital of Philadelphia (CHOP). With the expertise of Dr. Gurnaney, we created a Pediatric vessel target exercise for the Ultrasound trainer in June 2018.

Gill Lauder, MB BCh, FRCA, PG Dip (Med Ed) – Director of Pain Services at British Colombia's Children's Hospital. Dr. Lauder conducted a Pediatric Regional Workshop on using the regional anesthesia, ultrasound trainer, and CVA simulators for residents and fellows.

INTERIM PROGRESS REVIEW

Year 4 (8/1/2017-7/31/2018)

The PI, Samsun Lampotang, PhD, travelled to Ft. Detrick, MD to present, in person, progress on award W81XWH-14-1-0113 at an In Progress Review on 2/7/2018.

PUBLICATION, ACKNOWLEDGEMENT, AND PUBLIC RELEASE

The required and relevant annotation was added to publications except in cases where the limited amount of words allowed for abstracts precluded the boilerplate language from being added. We obtained written permission from the program officer in those instances to omit the boilerplate text because of word count restrictions.

APPENDICIES

Please see attached Quad Chart.

Section Editor: **Maxime Cannesson**

Visualization Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator

Joshua Warren Sappenfield, MD,* William Brit Smith, MD,* Lou Ann Cooper, PhD,†
David Lizdas, BSME,*‡§ Drew B. Gonsalves, MS,‡ Nikolaus Gravenstein, MD,*‡§
Samsun Lampotang, PhD,*‡§‖ and Albert R. Robinson III, MD*‡

BACKGROUND: We investigated whether visual augmentation (3D, real-time, color visualization) of a procedural simulator improved performance during training in the supraclavicular approach to the subclavian vein, not as widely known or used as its infraclavicular counterpart.

METHODS: To train anesthesiology residents to access a central vein, a mixed reality simulator with emulated ultrasound imaging was created using an anatomically authentic, 3D-printed, physical mannequin based on a computed tomographic scan of an actual human. The simulator has a corresponding 3D virtual model of the neck and upper chest anatomy. Hand-held instruments such as a needle, an ultrasound probe, and a virtual camera controller are directly manipulated by the trainee and tracked and recorded with submillimeter resolution via miniature, 6 degrees of freedom magnetic sensors. After Institutional Review Board approval, 69 anesthesiology residents and faculty were enrolled and received scripted instructions on how to perform subclavian venous access using the supraclavicular approach based on anatomic landmarks. The volunteers were randomized into 2 cohorts. The first used real-time 3D visualization concurrently with trial 1, but not during trial 2. The second did not use real-time 3D visualization concurrently with trial 1 or 2. However, after trial 2, they observed a 3D visualization playback of trial 2 before performing trial 3 without visualization. An automated scoring system based on time, success, and errors/complications generated objective performance scores. Nonparametric statistical methods were used to compare the scores between subsequent trials, differences between groups (real-time visualization versus no visualization versus delayed visualization), and improvement in scores between trials within groups.

RESULTS: Although the real-time visualization group demonstrated significantly better performance than the delayed visualization group on trial 1 ($P = .01$), there was no difference in gain scores, between performance on the first trial and performance on the final trial, that were dependent on group ($P = .13$). In the delayed visualization group, the difference in performance between trial 1 and trial 2 was not significant ($P = .09$); reviewing performance on trial 2 before trial 3 resulted in improved performance when compared to trial 1 ($P < .0001$). There was no significant difference in median scores ($P = .13$) between the real-time visualization and delayed visualization groups for the last trial after both groups had received visualization. Participants reported a significant improvement in confidence in performing supraclavicular access to the subclavian vein. Standard deviations of scores, a measure of performance variability, decreased in the delayed visualization group after viewing the visualization.

CONCLUSIONS: Real-time visual augmentation (3D visualization) in the mixed reality simulator improved performance during supraclavicular access to the subclavian vein. No difference was seen in the final trial of the group that received real-time visualization compared to the group that had delayed visualization playback of their prior attempt. Training with the mixed reality simulator improved participant confidence in performing an unfamiliar technique. (Anesth Analg 2018;127:83–9)

KEY POINTS

- **Question:** Does visual augmentation (3D color visualization) enhance learning and performance during central venous access in a mixed reality procedural simulator?
- **Findings:** Automatically generated performance scores improved significantly with real-time or delayed visualization.
- **Meaning:** Visualization is efficacious whether in real time or delayed in a mixed reality simulator that has both physical and virtual (visualization) components.

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The authors declare no conflicts of interest.

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Reprints will not be available from the authors.

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The supraclavicular approach to the subclavian vein (first described by Yoffa[1] in 1965) has a shorter distance and less tissue to traverse before access to the vein compared to the more familiar infraclavicular technique. The supraclavicular approach provides a larger cross-sectional area of the vein as a target, a larger margin of safety from accidental violation of the pleura, a lower rate of malpositioning, and some evidence of fewer complications.[2–4] Complications include arterial puncture and pneumothorax.[2] The largest barrier to adoption of the supraclavicular approach in clinical practice is likely the lack of familiarity compared to the internal jugular, femoral vein, or infraclavicular access to the subclavian.

The University of Florida central venous access (CVA) mixed reality simulator facilitates practice in learning to access the internal jugular and subclavian central veins.[5] This mixed reality simulator allows real-time or delayed 3D visualization of the needle's location inside soft tissue structures within a mannequin's virtual anatomy displayed on a computer screen while also providing tactile feedback for nondeformable (bony) structures on a modular anatomical block (Figure 1). The CVA simulator has a built-in automated scoring algorithm based on contact with or proximity to the lung/arteries/trachea, time to venous access, number of attempts, and number of skin punctures. Training with a task trainer enhanced acquiring and retaining clinical skills related to aseptic placement of central venous catheters.[6–9] Using a mixed reality simulator may not only provide a risk-free environment for training but also facilitate successful training for accessing the subclavian vein via the supraclavicular approach.

The hypotheses were as follows: (1) Three-dimensional visualization of internal structures improves the efficacy of simulation for trainees learning how to access a central vein and (2) real-time 3D visualization during a trainee's CVA attempt is superior to delayed 3D visualization playback.

METHODS

Participants were randomized into either the real-time visualization group (RTVG), with concurrent 3D visualization with their first attempt, or the delayed visualization group (DVG), with 3D visualization playback of their second attempt. Comparisons were made between the 2 group's scores for each attempt to investigate potential relationships.

The simulator used for the study is a turnkey, mixed reality simulator for practicing, learning, teaching, and debriefing CVA by the internal jugular, infraclavicular, supraclavicular, and axillary approaches with and without ultrasound (US) guidance. For more information, see Figure 1 and videos: http://simulation.health.ufl.edu/research/cva_sim.mp4 and https://www.youtube.com/watch?v=0lTIFbiiwRs.

The simulator uses mixed reality via an anatomically authentic, 3D-printed physical mannequin based on a computed tomographic scan of an actual human and a corresponding 3D virtual model of the anatomy of the neck and upper chest. Hand-held instruments such as a needle, an US probe, and a virtual camera controller are directly manipulated by the trainee and tracked and recorded with submillimeter resolution via miniature, 6 degrees of freedom magnetic sensors.[10] An automated scoring algorithm and a replay system allow self-debriefing.[10,11] Furthermore, the user can practice US-guided CVA by orientating the needle and the US probe out-of-plane or in-plane with reference to one another.

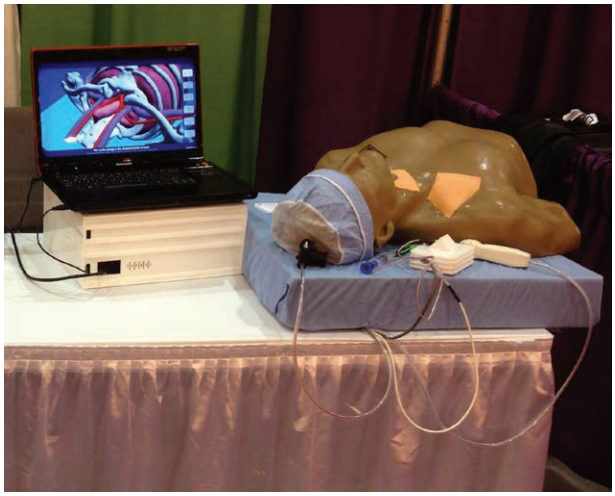

Figure 1. The mixed reality simulator of central venous access used in the study. The 3-dimensional visualization is displayed on the laptop screen.

Study Protocol

After Institutional Review Board approval and informed consent, volunteers (anesthesia trainees, emergency medicine trainees, and attending anesthesiologists) at the University of Florida took part in a study with the CVA simulator in performing the supraclavicular approach to the subclavian vein. Enrollment of participants was combined with 2 other studies evaluating participants' ability to access the internal jugular vein with simulated US and to access the subclavian vein using an infraclavicular approach. Individuals were free to refuse to take part in the study and were also excluded from analysis if they only wanted to receive training for CVA.

Participants completed a prestudy questionnaire to provide demographic data, including level of training, prior experience, and self-rated confidence in the ability to perform the supraclavicular approach. This was followed by a brief video that oriented them to the features of the CVA simulator and provided instructions on how to use it. All participants also received scripted instructions (video and text, but not verbal) on how to perform a supraclavicular approach. In addition, all participants had prior experience with the CVA simulator's elements while attempting to access the subclavian vein using the infraclavicular approach and the internal jugular vein with US before their first attempt at accessing the subclavian vein using the supraclavicular approach. Participants were then randomly assigned to one of 2 groups, the RTVG or the DVG. Neither group used US imaging for the supraclavicular approach to the subclavian vein. As shown in Figure 2, the RTVG was allowed to concurrently use real-time 3D visualization of soft tissue structures inside the simulator while performing venous access only for their first attempt (trial 1); the DVG performed the procedure 3 times, all without real-time 3D visualization. Participants were denied access to

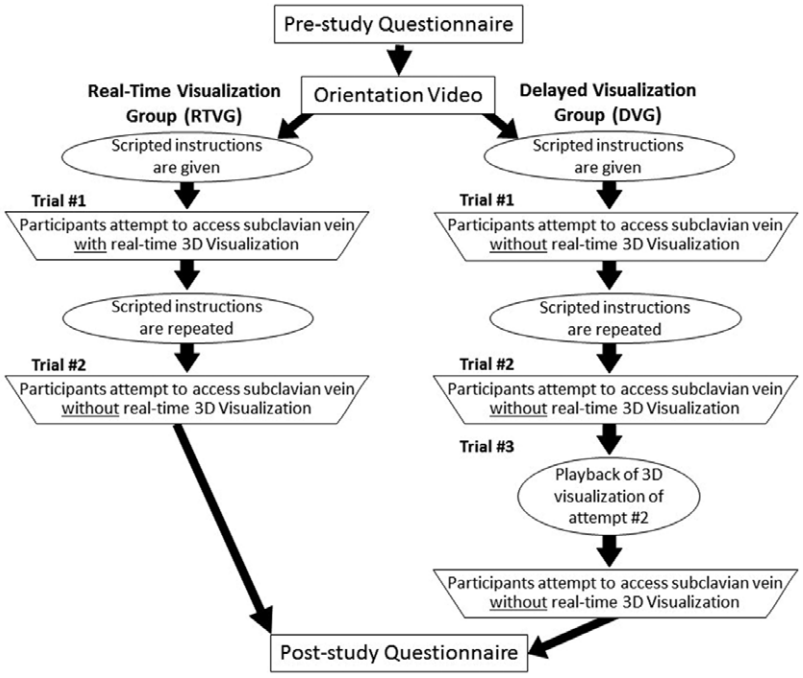

Figure 2. Supraclavicular access study design flow chart for groups A and B.

the real-time 3D visualization (displayed on the screen of a generic laptop computer running the simulator) by using the virtual camera controller to change the perspective of the virtual camera away from the virtual patient.

Participants in the DVG performed their initial attempt (trial 1) without real-time 3D visualization, which ended either with successful access or after 5 minutes had elapsed. This attempt was scored by the simulator's automated scoring algorithm. Participants were then allowed to rewatch the scripted video or reread the written instructions. Participants in the DVG were then given a second attempt (without real-time 3D visualization). Afterward, delayed 3D visualization of the DVG participant's second attempt (trial 2) was played back to the participant with an instructor present. Afterward, participants in the DVG were given a third attempt without real-time 3D visualization, which was also scored. The third attempt (trial 3) was to test our second hypothesis (see Figure 2) on whether real-time 3D visualization was superior to delayed 3D visualization playback after an attempt. The comparison between the final attempt in the DVG (trial 3) and RTVG (trial 2) evaluates each group's attempt immediately after their use of the 3D visualization and the participant's ability to access the vein based on information acquired from the 3D visualization.

Participants randomized to the RTVG watched the same instructional video and received the same written instructions as the DVG after the video orientation to the simulator. The participants from the RTVG were asked to access the subclavian vein via the supraclavicular approach while using the real-time 3D visualization of the simulator. Participants were then allowed to rewatch the video or reread the written instructions on how to access the subclavian vein using the supraclavicular approach. Afterward, RTVG participants performed a second attempt but without real-time 3D visualization.

An automated scoring algorithm is integrated into the simulator. The algorithm generates an objective numerical score by applying penalties associated with errors and potential complications such as pneumothorax, arterial puncture, back-walling the vein, too many needle passes, and taking too much time. Incidents that cause significant injury, such as arterial punctures and pneumothoraces, incur larger penalties, whereas lesser penalties are applied to less serious events such as taking too much time, back-walling the vein, or taking extra attempts. Unsafe near-misses are also penalized, that is, coming dangerously close to the artery or lung incurs penalties scaled to how close the needle tip came to causing injury. Penalties may be applied to needle trajectories outside predefined safe and acceptable zones ("cones of safety") that are specific to the type of approach for attaining CVA. Recorded CVA attempts from experts as well as substandard performance examples were used to tune the scoring algorithm. All attempts for both groups were scored. All participants completed a poststudy questionnaire and were debriefed.

Statistical Analysis

SAS, version 9.4 (SAS Institute, Cary, NC), was used for data analysis. Descriptive statistics, reported in Table 1, were calculated for baseline characteristics for the RTVG, DVG, and for all participants. Because the score distributions for the RTVG and DVG were negatively skewed and nonnormal, as assessed by the Shapiro–Wilk test (W; $P < .0001$), nonparametric statistical methods were used for analysis. The difference in algorithm scores for each participant between trial 1 and the final trial (trial 2 for RTVG and trial 3 for DVG) was calculated, and the Wilcoxon 2-sample rank sum test (equivalent to the Mann-Whitney U statistic) was used to test whether improvement in performance was dependent on group. Between-group differences were tested on the algorithm score on trial 1 (RTVG1 versus DVG1) and

Table 1. Baseline Demographic Characteristics for RTVG, DVG, and All Participants

	Real-Time Visualization		Delayed Visualization		All Participants	
	n	%	n	%	n	%
Experience						
Expert	3	11	11	26	14	20
Intermediate	18	67	20	48	38	55
Novice	6	22	11	26	17	25
Handedness						
Right	21	81	33	85	54	83
Left	5	19	6	15	11	17
Specialty						
Anesthesiology	24	89	28	67	52	75
Other (EM, FM, and MS)	2	7	7	17	9	13
Unidentified	1	4	7	17	8	12
	M (SD)		M (SD)		M (SD)	
Age	32.1 (6.7)		33.2 (7.8)		32.7 (7.3)	

Abbreviations: DVG, delayed visualization group; EM, emergency medicine; FM, family medicine; M, mean; MS, medical students; RTVG, real-time visualization group.

trial 2 (RTVG2 versus DVG2), and for final attempts (trial 2 for RTVG versus trial 3 for DVG). The Wilcoxon rank sum test was also used to test group differences on the computed difference variables (RTV1 – RTV2) versus (DV1 – DV2) and (RTV1 – RTV2) versus (DV1 – DV3). The Wilcoxon rank sum test does not assume that the difference between 2 independent samples is normally distributed or that the population variances are equal.[12] The Hodges–Lehman estimator was computed for the difference in medians and 95% confidence intervals (CIs) for the median difference.[12,13] The Wilcoxon signed rank test was used to determine if there was a significant improvement in scores between trials within each group. All statistical tests were 2 tailed, and the significance level was set at $\alpha = .05$.

The data collected on the supraclavicular approach were part of a larger study investigating additional approaches to CVA where in addition to group (RTVG versus DVG), a second between-subjects factor, level of training with 3 levels, was being studied. Based on our previous work with simulation for CVA, this study was planned for power = 0.80, assuming a 2-tailed test with significance level, $\alpha = .05$, a modest correlation between trials for the repeated measures ($\rho = 0.20$) to detect a moderately large effect size (ie, 0.60 in standard deviation [SD] units) for the CVA algorithm score. A priori power analysis suggested that 10 participants in each cell are sufficient to achieve target power (60 participants randomly assigned to visualization group by level of training). However, because only 2 participants reported any exposure to the supraclavicular approach, the level of training was not a factor and post hoc power analysis based on the visualization factor alone suggests that 28 participants in each group are sufficient to attain target power (N = 56).

RESULTS

Results are based on participants with signed informed consent and complete data (N = 69). The algorithm score range is from 0 to 600. The scores of 3 anesthesiologist coauthors (J.W.S., W.B.S., and A.R.R.), with a combined clinical experience of 25 years in CVA and all comfortable with the supraclavicular approach to the subclavian vein before the initiation of the study, for 3 attempts each at the supraclavicular approach without visualization yielded a mean of 578 and a median of 572. Although scores were reduced by errors and near-misses as described above, most participants lost points in the scoring algorithm due to the time penalty alone. As a result, score distributions were negatively skewed. Reported in Table 2 are descriptive statistics (medians, interquartile range, and 95% CIs for the medians), as well as the results of our hypothesis tests (Wilcoxon rank sum statistic, *S*, *P* values, the Hodges–Lehman estimator for the difference in medians, and 95% CIs for the median difference). Supplemental Digital Content, Figure 1, http://links.lww.com/AA/C84, shows a graphical representation of all the scores, which shows very little variation unless participants had a complication.

There was no difference in performance gains (trial 1 – trial 2) between the RTVG and the DVG ($P = .70$). The difference between the first trial (trial 1 for both groups) and the final trial (trial 2 for the RTVG and trial 3 for the DVG) was also not dependent on group ($P = .41$) as seen in Table 2.

Since the RTVG had 3D visualization while the DVG did not, there was a significant difference in performance between the groups at trial 1 ($P = .01$). The Hodges–Lehman estimator for the median difference with 95% CI is 10.20 (2.2–23.1). As hypothesized, there was also a significant difference in performance observed at trial 2 ($P = .007$). The group that received real-time visualization during trial 1 performed better than the group that would receive delayed visualization before trial 3. The estimated median difference and 95% CI is 10.75 (3.4–20.9). There was no difference in performance between the 2 groups on their final trial (trial 2 for RTVG and trial 3 for DVG), $P = .13$. The estimated median difference and 95% CI is 4.2 (−0.8 to 11.4).

Within-group comparisons show that for the RTVG, given the score range with a high score of 600, performance was extremely high for both attempts (medians for trial 1 = 584.8 versus trial 2 = 590.2). The difference in performance between trial 1 and trial 2 is not significant ($P = .08$). This suggests that high scores were produced on trial 1, with real-time 3D visualization available, and that the scores remained high on the second trial when visualization was not available to participants. For the DVG, there was no difference between trial 1 versus trial 2 ($P = .24$), both without visualization. Thus, there was no improvement in performance after a second attempt without 3D visualization. After viewing the delayed 3D visualization of their performance on trial 2 for the DVG, performance was significantly better on trial 3 when compared to trial 1 ($P = .0007$), but not for trial 3 versus trial 2 ($P = .17$).

Only 2 of the 69 participants reported that they had ever used the supraclavicular approach for central line placement. Despite this lack of familiarity, only 1 participant (DVG group) failed to access the subclavian vein on the first trial. All participants, regardless of group assignment (with or without real-time visualization), successfully accessed the subclavian vein on their final trial. Three participants required >1 attempt to access the vein (2, 6, and 8 attempts) on trial 1; only 1 participant needed >1 attempt on their last trial. Table 3 reports overall complications and scoring penalties. In addition to the participants who caused a

Table 2. Algorithm Scores for the Supraclavicular Approach Descriptive Statistics by Group (RTVG Versus DVG) and Statistical Comparisons

Trial/Group	RTV		DV	
	Median (95% CI)	IQR[a]	Median (95% CI)	IQR
Trial 1	584.8 (577.1–587.2)	17.4	565.6 (559.9–581.6)	34.3
Trial 2	590.2 (583.0–593.6)	24.4	576.7 (563.4–581.9)	30.7
Trial 3	…	…	584.1 (569.0–587.8)	28.0
Between-Group Comparisons	***W*[b]**	***P***	**Hodges–Lehman Estimator Difference in Medians (95% CI)**	
RTV1 – DV1	1146.0	.01	10.20 (2.2–23.1)	
RTV2 – DV2	1163.5	.007	10.75 (3.4–20.9)	
RTV2 – DV3	1069.0	.13	4.2 (−0.8 to 11.4)	
(RTV1 – RTV2) versus (DV1 – DV2)	976.5	.70	…	
(RTV1 – RTV2) versus (DV1 – DV3)	876.5	.41	…	
Within-Group Comparisons	***M*[c]**	***P***	**Median for the Difference Variables (95% CI)**	
RTV2 – RTV1	5.5	.05	5.8 (0.9–10.3)	
DV2 – DV1	6.0	.09	3.1 (−0.1 to 9.1)	
DV3 – DV1	14.0	<.0001	5.6 (2.85–15.4)	
DV3 – DV2	4.0	.28	1.2 (−0.9 to 6.3)	

Abbreviations: CI, confidence interval; DV, delayed visualization; DVG, delayed visualization group; DV1 = delayed visualization group, trial 1; DV2 = delayed visualization group, trial 2; DV3 = delayed visualization group, trial 3; IQR, interquartile range; RTV, real-time visualization; RTVG, real-time visualization group; RTV1 = real-time visualization group, trial 1; RTV2 = real-time visualization group, trial 2.

[a]The difference between upper and lower quartiles (Q1 – Q3, where Q2 is the median).

[b]*W* is the Wilcoxon rank sum test statistic; the *P* value is based on the normal approximation with continuity correction, an adjustment that is made when a discrete distribution is approximated by a continuous distribution.

[c]*M* is the Wilcoxon sign test statistic.

Table 3. Errors and Potential Complications by Approach Using the Mixed Reality Simulator

	Approach: Supraclavicular
Backwall	
Baseline	8
Final simulation trial	4
Pneumothorax	
Baseline	3
Final simulation trial	1
Arterial puncture	
Baseline	1
Final simulation trial	0
Extra attempts	
Baseline	3
Final simulation trial	1

pneumothorax, 3 additional participants received a penalty in the scoring algorithm for coming "close" (<1 cm from the lung) to causing a pneumothorax on trial 1 and 3 on their final trial. There was no overlap in these errors (the participants causing pneumothorax were not the same).

Study participants also completed surveys before and immediately after the simulator session; results reported in Table 4 show relevant items. Participants were overwhelmingly positive about simulator training for the supraclavicular approach to subclavian vein access both as an educational tool for trainees and as an aid to improve their own technical proficiency. Participants were also asked to rate their confidence in performing the supraclavicular approach for subclavian vein CVA pre- and posttraining on a 10-point scale where 1 = "not at all confident" and 10 = "completely confident." Not surprisingly, given the fact that only 2 participants reported any previous experience with this technique, on average, the confidence for all participants before training was 1.6 (SD = 1.1). Mean posttraining confidence rating was 7.2 (SD = 1.8). The median for the confidence gain scores, 6.0 (interquartile range = 3.0), was significantly >0 (Wilcoxon signed rank test, $S = 11.39$, $P < .0001$). Although confidence gains in the RTVG (median = 6.0) were greater than in the DVG (median = 5.0), the Wilcoxon rank sum test shows that this difference was not significant, $S = 876.5$, $P = .08$.

DISCUSSION

The original motivation for this study was to evaluate the learning outcomes and efficacy of a new mixed reality procedural simulator. This research was part of a larger study to investigate the efficacy of a mixed reality simulator with and without visual augmentation (real-time, 3D, and color visualization) for teaching various approaches to CVA. No statistically significant differences in performance between the 2 groups due to real-time 3D visualization were identified when comparing the gain scores between the first and last trials for each group (hypothesis 2). Despite not finding a significant benefit afforded by real-time 3D visualization compared to delayed 3D visualization, on average, participants improved significantly in their ability to successfully access the subclavian vein via the supraclavicular approach after interacting with the simulator. This finding is similar to the improvement found in other task trainers.[5–9] The availability of real-time 3D visualization was associated with significantly higher scores for the RTVG on attempt 1 compared to the DVG attempt 1. Although the comparison of the 2 groups on the gain score between trial 1 and trial 2 was not significant ($P = .70$), the algorithm scores for the RTVG remained significantly higher than the hDVG on trial 2 (even though the RTVG no longer had access to visualization), $P = .007$. These results indicate that the benefits of exposure to the real-time visualization (possibly in forming a 3D mental model of the relevant anatomy for the supraclavicular approach) may have been retained and that a second attempt alone is not enough to optimize performance.

Table 4. Participants' Reactions to Simulator Training for the Supraclavicular Approach to the Subclavian Vein

	Real-Time Visualization			Delayed Visualization			All Participants		
Survey Item	Agree[a]	Strongly Agree	Mean (SD)	Agree	Strongly Agree	Mean (SD)	Agree	Strongly Agree	Mean (SD)
Experience on this simulator could be useful in clinical practice for supraclavicular approach to obtaining subclavian central venous access.	33.3%	66.7%	4.67 (0.48)	12.0%	88.0%	4.88 (0.33)	25.4%	74.6%	4.75 (0.44)
The simulator should be used as a training/education tool to teach residents the supraclavicular technique of subclavian central venous access.	29.3%	70.7%	4.71 (0.46)	4.0%	96.0%	4.96 (0.20)	19.7%	80.3%	4.80 (0.40)
The training received with the simulator improved my technical proficiency in supraclavicular technique of subclavian central venous access.	28.6%	71.4%	4.71 (0.46)	8.0%	92.0%	4.92 (0.28)	20.9%	79.1%	4.79 (0.41)
	Yes	No		Yes	No		Yes	No	
Do you think that this experience with the simulator will help you perform supraclavicular technique for subclavian central venous access.	95.2%	4.8%		96.0%	4.0%		95.5%	4.5%	

For all questions in Table 2, there were no responses that were not 4 or 5.

[a]Response options for these questions evaluating the simulator training used a scale with 5 response options: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

Our findings indicate that 3D visualization is helpful in improving performance as measured by the scores, irrespective of whether the visualization was in real time or delayed, supporting our first hypothesis.

Users of the CVA procedural simulator reported a significant improvement in their self-rated confidence in supraclavicular access to the subclavian vein. This is very encouraging given the fact that only 2 participants reported any prior experience with the supraclavicular technique. This study is also, for most participants, their only exposure to the supraclavicular approach to the subclavian vein. With only 2–3 attempts by each participant, the CVA simulator, in combination with scripted video instructions, was able to show subjective evidence of the improvement in confidence, as well as a low complication rate (most penalties were from a time delay). This would suggest that the supraclavicular approach to the subclavian vein is a relatively easy procedure to learn and that simulation improved the participant's performance and their confidence in attempting it.

The findings of the study show a floor and ceiling effect for the algorithm scores. Providers may be uncomfortable accessing the subclavian using the supraclavicular approach because they never trained with it, but US imaging may increase a provider's confidence. Because US was not used in the referenced literature, it was not used in this study. However, using US guidance may help further improve confidence and decrease the potential for complications with the supraclavicular approach.

The safety and teachability of the supraclavicular approach were not the premises of this study, and as such, further study would be necessary to evaluate the supraclavicular approach compared to the infraclavicular approach. This approach may be advantageous in patients with a cervical collar in place and concomitant thoracic injuries and those undergoing cardiopulmonary resuscitation. Although the reason the infraclavicular approach is relatively more popular is not known, it may be because it was described earlier in the literature.[2] This is despite its high complication rate and the longer distance that needs to be traversed percutaneously to actually access the subclavian vein via the subclavian approach.

The Kirkpatrick[14] evaluation model has 4 levels where each level builds on the previous one. Assessment of adoption of training into daily clinical practice (Kirkpatrick level 3) as well as the directly attributable effect of the training on patient outcomes (Kirkpatrick level 4) are eventual goals of our research, but are beyond the scope of this article. The study we describe is at Kirkpatrick level 2 (learning outcomes). In a methodical process where each step builds on the previous Kirkpatrick level in a crawl, walk, run progression, we purposely limited our initial approach to a learning outcome study. The learning outcome study is needed to establish that training with the simulator improves learning to enable us to approach our hospital administration (and other educators) with hard evidence that may be of help in convincing our management that the 3D visualization–based training should be provided to all relevant clinical personnel.

CONCLUSIONS

The CVA simulator was efficacious for training clinicians to access the subclavian vein using the supraclavicular approach that was, for most participants, unfamiliar. The use of real-time 3D visualization during an access attempt showed significantly improved scores compared to the group without 3D visualization. Training with the CVA simulator did not prevent errors in technique, nor were significant differences found in using real-time 3D visual augmentation (visualization) while performing access attempts versus playing back prior attempts using delayed 3D visualization. More studies are necessary to determine whether the improved scores resulting from visual augmentation are clinically significant and will translate into better patient outcomes. Additional studies are needed to establish if the use of US imaging can decrease the complication rate with the supraclavicular approach in both simulated and actual clinical settings.

DISCLOSURES

Name: Joshua Warren Sappenfield, MD.
Contribution: This author helped with the conception of the work; design and conduct the study; analyze the data; draft, write, and review the manuscript; and approve the final manuscript.
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Contribution: This author helped with the conception of the work; design and conduct the study; draft, write, and review the manuscript; and approve the final manuscript.
Name: Lou Ann Cooper, PhD.
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Name: David Lizdas, BSME.
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Name: Albert R. Robinson III, MD.
Contribution: This author helped with the conception of the work; design and conduct the study; analyze the data; draft, write, and review the manuscript; and approve the final manuscript.
This manuscript was handled by: Maxime Cannesson, MD, PhD.

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A modular set of mixed reality simulators for "blind" and guided procedures

Medical Practice Initiative (MPI) Augmented Reality for Medical Applications (ARM) **Log Number 13318017**

W81XWH-14-1-0113 Year 4 (Yr4) Quad Chart

PI: Samsun (Sem) Lampotang, PhD **Org:** University of Florida **Award Amount: $1,673,156**

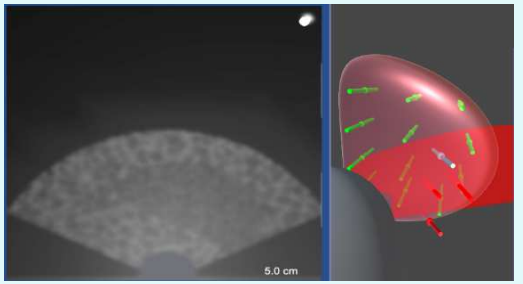
Study/Product Aim(s)

- Conduct evaluations and learning, behavior, patient and Return on Investment (ROI) outcome studies to assess CVA simulator efficacy
- Design, build/upgrade and deliver 5 simulators: Chest Tube Insertion (CTI), Central Venous Access (CVA), (External Ventricular Drain (EVD aka ventriculostomy), Trans Rectal UltraSound TRUS-Prostate Biopsy (TRUS-PB), Regional Anesthesia (RA)
- Finalize hardware/software specifications for 5 simulators above; deliver to DoD and in-service

Approach

The general approach is to evaluate the learning efficacy of the CVA simulator. If efficacious for learning, we then conduct patient and ROI studies at UFHealth Gainesville and UFHealth Jacksonville. We will design and build 3 new simulators in Phase II (CTI, EVD, TRUS-PB); no studies will be performed on these 3 new simulators within the scope of the grant.

UF Emergency Medicine Resident using the CVA MI simulator.



The screen capture (left) of the biopsy software showing 3D visualization (right) of correct biopsy targets and actual biopsies taken by the simulator user.

The SMARTS CVA simulator was modified to accommodate a ballistics gel anatomic block and to add self-study/debriefing features to the integrated tutor. We have successfully trained 159 residents, fellows, and advanced practice providers (APP's) as a part of the CVA Mass Intervention (MI) as of July 31, 2018.
The TRUS-PB simulator software and build are in progress.

Timeline and Cost

Activities	FY15	FY16	FY17	FY18	FY19
Conduct evals & learning, behavior, patient, ROI outcome studies CVA sim					
Design, build/upgrade and deliver 5 simulators: CTI, CVA, EVD, TRUS-PB, RA					
Finalize hw/sw specifications for 5 simulators; deliver to DoD and in-service					
Estimated Total Budget ($K)	**236**	**240**	**198**	**492**	**508**

Updated: 7/31/2018

Goals/Milestones

CY17 Goals – Complete ventriculostomy simulator build
☑ Final build and quality control of Phase I CVA & RA simulators
☑ Obtain IRB and HRPO approval of Patient Outcomes study
CY18 Goals – Complete chest tube insertion simulator build
☑ Begin design of CTI and TRUS-PB simulators
☐ Upgrade phase I simulators to phase II standards (in progress)
☐ Begin patient and ROI outcomes studies
CY19 Goals - Complete TRUS prostate biopsy simulator build
☐ Finalize hw/sw specifications for SMARTS SDK and platform
☐ Deliver 5 phase II specification simulators to DoD
☐ Complete patient and ROI outcomes studies

Comments/Challenges/Issues/Concerns

- Phase I to phase II simulator upgrade is in progress. Transfer of Learning study is IRB approved. HRPO to be submitted.

Budget Expenditure to Date

Projected Expenditure: $1,165,297
Actual Expenditure: $ 1,099,051 (through 7/31/2018)