Augmented-reality ultrasound-guided critical care procedures for the far-forward combat medic

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FINAL REPORT

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DECLARATION OF INTEREST

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RETROSPECTIVE COHORT STUDY OF BURN CASUALTIES TRANSPORTED BY THE US ARMY BURN FLIGHT TEAM (BFT) AND US AIR FORCE CRITICAL CARE AIR TRANSPORT TEAMS (CCATT)

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Current U/S guidance of venous cannulation is difficult to master and is not intuitive. Even under optional conditions, high error raters and complications of U/S guided venous cannulation are well documented. Real-time, accurate administration of targeted analgesia through conventional ultrasound (U/S)-guided peripheral nerve blocks is key to reduce systemic, sedating analgesic use. Our project aimed to create a minimally viable product (MVP), with the hypothesis that this U/S-guide MVP will enhance nerve block and venous cannulation success rates and reduce errors and/or complications compared to conventional ultrasound probe and needle techniques. We successfully developed the MVP, completed development of an ultrasound phantom, and performed initial testing of the assembled ultrasound prototype on the phantom.

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1.0 EXECUTIVE SUMMARY

Real-time, accurate administration of targeted analgesia through conventional ultrasound (U/S)-guided peripheral nerve blocks is difficult to master, yet is key to reduce systemic, sedating analgesic use, which has operational consequences on the battlefield and is associated with higher risks of long-term opioid addition in the Warfighter. Current U/S guidance of venous cannulation is difficult to master and is not intuitive. Even under optional conditions, high error raters and complications of U/S guided venous cannulation are well documented.

Our project aimed to create a minimally viable product (MVP), with the hypothesis that this U/S-guide MVP will enhance nerve block and venous cannulation success rates and reduce errors and/or complications compared to conventional ultrasound probe and needle techniques. We utilized an iterative systems engineering approach to incorporate a combination of statistical and physics-based methods, facilitating prediction of needle position and movement in the body. Despite technical challenges encountered, we successfully developed the MVP, completed development of an ultrasound phantom, and performed initial testing of the assembled ultrasound prototype on the phantom. We are continuing our development efforts in a funded, follow-on project.

2.0 INTRODUCTION

The rapid provision of life-saving care in the future battlespace, characterized by delayed evacuation and prolonged casualty care (PCC), will demand increased technical capabilities and cognitive resources delivered in the prehospital/Role 1 environment. Pain control and intravenous access are necessary capabilities for advanced trauma management. Further, parenteral analgesic administration is plagued by complications (e.g. respiratory depression, hypoxia, hypotension, inadequate pain control) and operational challenges. Peripheral nerve blocks are proposed alternatives to traditional parenteral analgesia but remain under-utilized due to technical skill requirements and lack of familiarity with point-of-care ultrasound. Augmented-reality may improve the accuracy and efficacy of ultrasound-guided anesthetic nerve blocks and venous cannulation for prehospital/Role 1 providers (1-9). Peripheral nerve block instruction is currently provided to Special Operations Forces (SOF) medics and some Role 1 providers, though actual use is infrequent. The Joint Trauma System (JTS) Clinical Practice Guideline (CPG), Analgesia and Sedation Management during Prolonged Field Care (PFC), specifically recommends peripheral nerve blocks as an ideal option for use in an austere, resource-constrained environment. Additionally, these guidelines can be utilized during future combat operations with potentially delayed evacuation such as Large-Scale Combat Operations (LSCO) or Multi-Domain Operations (MDO).

The objective of our study is to create a minimally viable product (MVP) for augmented-reality U/S-guided critical procedures (nerve blocks, peripheral venous cannulation, CVC). We hypothesize that the MVP will enhance procedural success rates and reduce errors/complications compared to conventional U/S probe and needle techniques. Our innovative U/S system is composed of a probe, needle guide with visible fiducials, and computer console that displays U/S images integrated with a computer-generated image of the needle. Our system employs an algorithm to integrate the observed position of the four fiducials on the needle guide and orient the position of the needle relative to the image. The critical innovation is a high-resolution, 300+ degree, computer-controlled optical camera coupled to a conventional U/S probe. This allows the computer to track the needle guide position and project the needle path before and while the needle is inserted into the patient. The operator may maneuver the probe and needle independently (i.e., ‘free hand’) for optimal patient access. The system is supported by two innovations: 1) machine vision techniques which allow the camera to visualize the fiducials on, and position of, the needle guide (separate from the background);and 2) a matrix transformation algorithm capable of mathematically converting needle position data tounambiguous spatial coordinates to rapidly synchronize with the operator’s movements. Our system is a lightweight, dedicated U/S imaging system

designed to increase U/S procedural accuracy. Its intended users are prehospital / Role 1 providers trained in critical resuscitations and does not require the extensive training of a specialist physician or dedicated U/S technician. It is designed to be rugged, portable (carried in a field resuscitation pack), inexpensive, and provide seamless workflow integration with current standards for U/S-guided procedures.

Combat medics across the Armed Forces increasingly have some degree of Point-of-Care Ultrasound (POCUS) proficiency (2,3). Training programs may use simulation-based learning to provide increased opportunities to practice procedural skills in a low-risk setting (4,5,6,7,8,9,10).

3.0 METHODS, ASSUMPTIONS AND PROCEDURES

3.1 Research Design

Our technical approach was to create a minimally viable product (MVP) in collaboration with partners at the CU Department of Bioengineering (Chair: Robin Shandas PhD), a group with a history of engineering novel ultrasound products. The primary challenge was to generate sufficient precision and accuracy in estimating needle trajectory. We incorporated a combination of statistical and physics-based approaches, facilitating prediction of needle position and movement in the body. We fabricated the phantoms for testing of the MVP.

3.2 Study Design

We leveraged an interactive engineering process to develop the MVP focused on the following steps:

- Identify appropriate components (i.e., camera and lens system with suitable size, focal distance,
- resolution, light sensitivity and frame rate for the precision needed for needle placement) and
- appropriate U/S probe design (frequency, bandwidth, geometry, etc)
- Manufacture mock-up of U/S probe (with camera) and needle holder. Identify the fixed relationship
- between the U/S image axis system and camera axis system.
- Computer vision: using camera on probe and convolutional neural network (CNN), identify the fiducials
- (separate points from background and return x,y coordinates of the four points)
- Spatial orientation: using deep learning algorithm, convert x,y coordinates of fiducials to 3D position
- and orientation of needle relative to axis system of camera.
- Use U/S probe to acquire tissue image in the axis system of the probe.
- Merge position information for the needle and U/S image and display in the user axis system.
- Calibration to account for geometry of camera and lens aberration.
- Acquire, align and knit multiple US images to create a 3D image of anatomy.
- Adjust depth and focus of ultrasound system for optimal imaging at needle dept

3.3 Data Management:

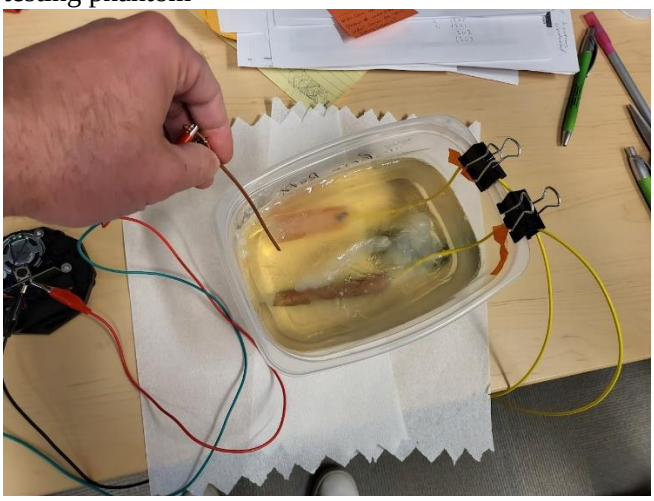
The design history of the Python code is recorded in GitHub.

4.0 MAJOR EVENTS/MILESTONES/SUCCESS

We successfully met the following milestones:

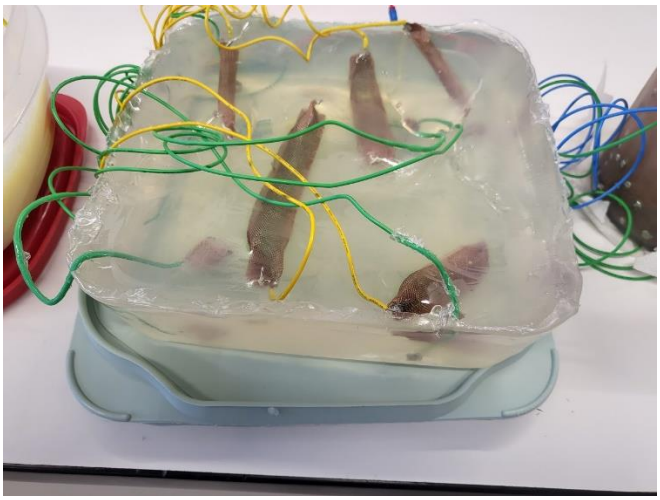
- Identified design goals for ultrasound phantom

- Found a phantom material that would satisfy all of the design goals and designed, built, and testing phantom

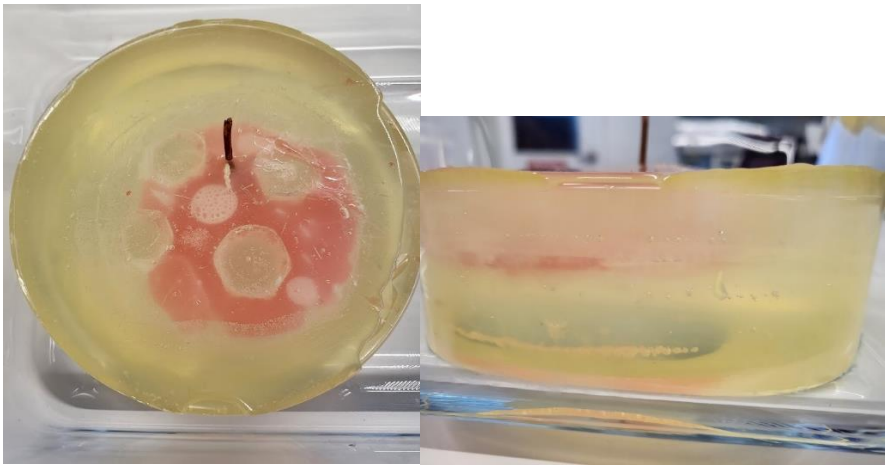


Initial ultrasound phantom prototype investigating the use of copper obstacles in gelatin.

Past ultrasound phantom prototype investigating the use of cocoa butter/palm oil mixture.



Past ultrasound phantom prototype investigating the use of copper obstacles in plastisol.

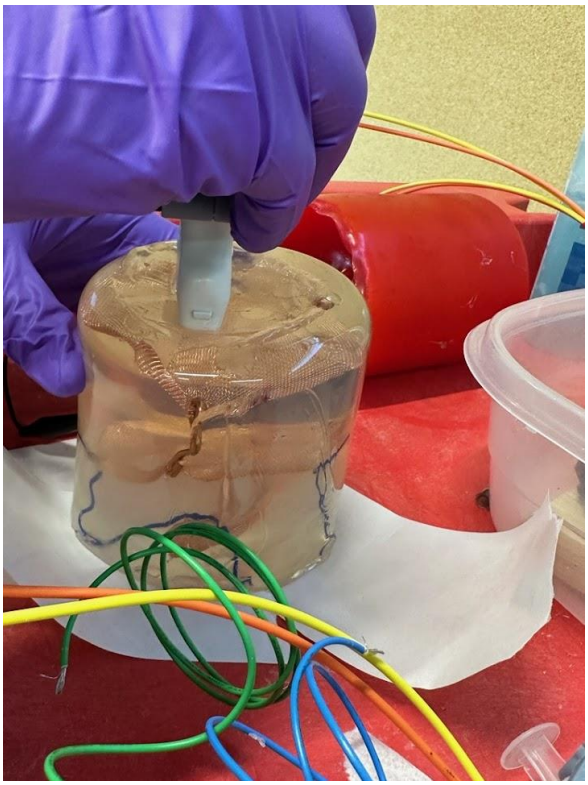


Top and side views of most recent ultrasound phantom prototype, made from electrically insulative plastisol (clear) with electrically conductive gelatin obstacle (red).

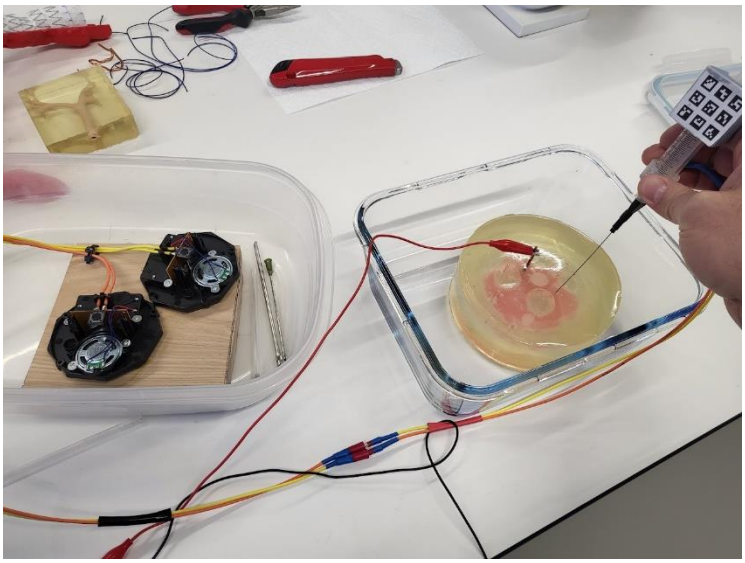
- Developed the tracking algorithm. Calibrations are repeatable, and validation results demonstrate accuracy. Team continues to iterate coding to speed up data transfer process in a follow-on project
- Identified appropriate components of optical visualization system, developed prototype, and performed calibration tests.
- Built a functional needle prototype
- Built a functional camera mount

Initial prototypes for ultrasound transducer camera mount (left) and ArUco marker mount with gamified syringe (right).

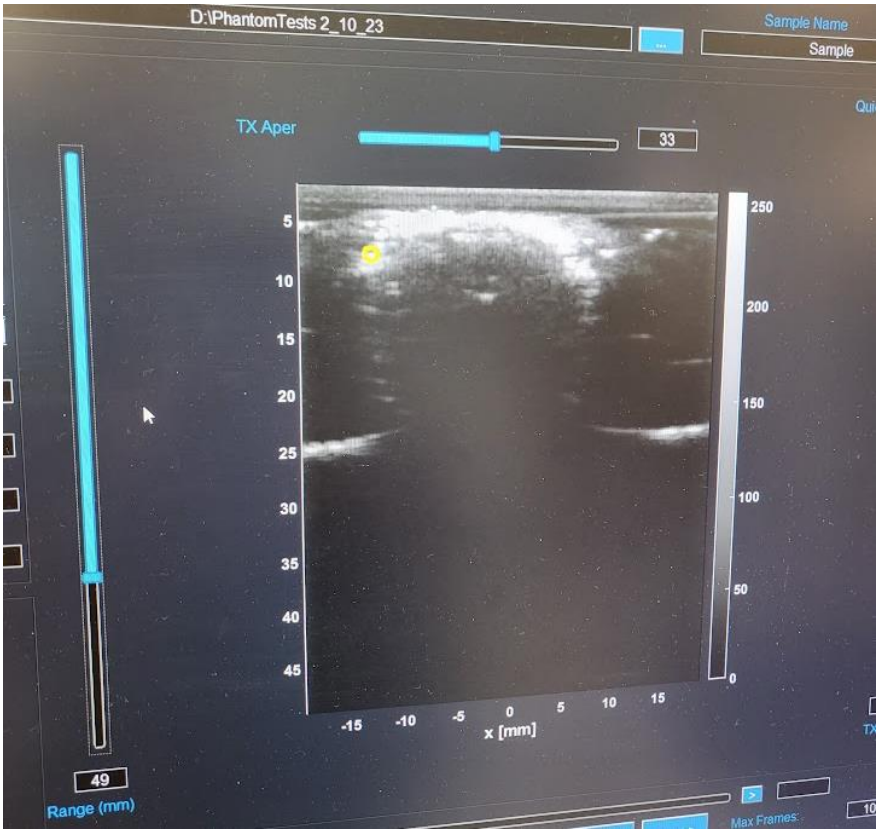
- Tested assembled hardware and software on ultrasound phantoms



Ultrasound testing on prototype.



Most recent ultrasound phantom prototype being tested with gamification components.



Ultrasound image of most recent phantom prototype with clear path through plastisol indicated with green circle and gelatin obstacles indicated with red circles.

5.0 RISK ASSESSMENT

5.1 Risk Analysis

Initial risk analysis indicated low risk for successful completion of the project. However, throughout the course of the project, additional risks were identified within component development. These risks were eventually realized, as detailed below, and were overcome.

5.2 Technical Challenges

Algorithmic complexity presented a technical challenge that caused delay in the originally proposed timelines. Early in the project, development of the tracking component proved to be more complex than initial analysis indicated. Due to later system integration dependencies on this component, we focused on addressing the software aspects of the tracking component prior to hardware development. Following identification of these realized risks, the study timeline was extended and work was successfully completed. A second technical challenge was identified in the construction of the phantoms. Phantoms are limited in that they do not include representations of complex anatomy or deep anatomy.

6.0 TRANSITION PLAN

6.1 Military Relevance

Our product augments existing U/S technology to facilitate peripheral nerve blocks and CVC placement by the prehospital or Role 1 provider without difficulty or complication to the injured Warfighter. Our proposal directly aligns with capability gaps identified in the Initial Capabilities Document for Combat Casualty Care Support of Future Operations including “The Joint Force has limited capability and capacity to provide sustained damage control surgery and resuscitative care throughout the continuum of care” and “The Joint Force lacks sufficient pain management and medical intervention approaches that allow for preservation of combat effectiveness”. We developed a simple, intuitive system with machine vision and augmented reality techniques to realize the full benefit of U/S imaging procedures, specifically nerve blocks and CVC. Our innovation may reduce the time and stress of CVC placement and mitigate the complication risks of this critical procedure.

6.2 Transition plan

We are continuing development of the MVP and conducting end user testing in a follow-on project that is currently being executed. With the proof of concept that will come from this work, we intend to form a company (NewCo) through CU Innovations. We will seek to fund NewCo through avenues including, federal grant funding for clinical trials; State of Colorado funding through the Advanced Industries grant program; traditional equity funding; and longer-term, an investment from an ultrasound partner organization. With funding in hand, NewCo will then focus on three keys points:

1) Securing a partnership with an existing MedTech company
2) Developing a commercially viable product
3) Developing and maintaining a patent portfolio

We believe this product will require a 510(k) clearance as opposed to a PMA and we will work to submit the appropriate regulatory documents.

7.0 RESULTS

We have successfully developed the necessary components for the MVP.

8.0 CONCLUSION/DISCUSSION

We continue to iterate and refine the prototype, as originally planned, in our follow-on project.

Finding a phantom material that would satisfy all of the design goals proved to be challenging. Material properties that provide good ultrasound transparency typically counter material properties needed for gamification. Several iterations of the ultrasound phantom using different materials were designed, built, and tested.

The tracking component of the project proved to be more complex than initially assumed. This results in an alteration to the planned schedule in order to ensure software components were operational prior to development and integration with the hardware. Despite early challenges, we successfully developed the software and hardware components, integrated them, and performed initial testing of the assembled prototype.

9.0 DELIVERABLES

We successfully developed the MVP for augmented-reality U/S including a functional needle prototype, functional camera mount, and integrated the hardware and software components into a functional prototype. We developed ultrasound phantoms and used these for testing the assembled prototype.

Publication: We will publish our scientific findings in a peer-reviewed scientific journal.

Presentation: we will present our findings in abstract format at relevant conferences. We will include lessons learned in reports submitted to relevant funding programmatic officers.

10. COST

This project was funded by DHA FY21 Restoral in the amount of $306,000. All funding executed.

11. REFERENCES

1. Brian J Ahern, SP, USA, Jonathan D Monti, DSc, PA-C, Jason F Naylor, SP, USA, Aaron J Cronin, SP, USA, Michael D Perreault, MC, USA, U.S. Army Combat Medic eFAST Performance with a Novel Versus Conventional Transducers: A Randomized, Crossover Trial, *Military Medicine*, Volume 185, Issue Supplement_1, January-February 2020, Pages 19–24, https://doi.org/10.1093/milmed/usz277

2. Brandon H. Backlund, Carl J. Bonnett, Jeffrey P. Faragher, Jason S. Haukoos & John L. Kendall (2010) Pilot Study to Determine the Feasibility of Training Army National Guard Medics to Perform Focused Cardiac Ultrasonography, Prehospital Emergency Care, 14:1, 118-123, DOI: 10.3109/10903120903349770

3. Evans L V., Dodge KL, Shah TD, et al. Simulation Training in Central Venous Catheter Insertion: Improved Performance in Clinical Practice. *Acad Med*. 2010;85(9):1462-1469. doi:10.1097/ACM.0b013e3181eac9a3

4. Lewiss RE, Hoffmann B, Beaulieu Y, et al. Point-of-care ultrasound education: the increasing role of simulation and multimedia resources. J Ultrasound Med. 2014;33:27-32. 37.

5. Knudson MM, Sisley AC. Training residents using simulation technology: experience with ultrasound for trauma. J Trauma. 2000;48:659-65. 42.

6. Damewood S, Jeanmonod D, Cadigan B. Comparison of a multimedia simulator to a human model for teaching FAST exam image interpretation and image acquisition. Acad Emerg Med. 2011;18:413-9. 43.

7. Soffler MI, Hayes MM, Smith CC. Central venous catheterization training: current perspectives on the role of simulation. *Adv Med Educ Pract*. 2018;9:395-403

https://doi.org/10.2147/AMEP.S142605

8. Mendiratta-Lala M, Williams T, de Quadros N, et al. The use of a simulation center to improve resident proficiency in performing ultrasound-guided procedures. Acad Radiol. 2010;17:535-40.

9. Sekiguchi H, Bhagra A, Gajic O, et al. A general Critical Care Ultrasonography workshop: results of a novel Web-based learning program combined with simulation-based hands-on training. J Crit Care. 2013;28:217.e7-12.

10. Uhaa, N., Jeschke, E. A., Gwynne, A. M., Hudson, I. L., Mendez, J., April, M. D., ... & Schauer, S. G. (2021). An Assessment of Combat Medic Supraglottic Airway Device Design Needs Using a Qualitative Methods Approach: A Preliminary Analysis. *Medical Journal, US Army Medical Center of Excellence (MEDCoE)*.

11. ACEP Emergency Ultrasound Guidelines. https://www.acep.org/globalassets/new-pdfs/policy-statements/ultrasound-guidelines---emergency-point-of-care-and-clinical-ultrasound-guidelines-in-medicine.pdf. Accessed April 2020.

12. LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

CNN: convolutional neural network

CPG: Clinical Practice Guideline

CVC: Central Venous Cannulation

JTS: Joint Trauma System

LSCO: Large-Scale Combat Operations

MDO: Multi-Domain Operations

MVP: Minimally Viable Product

PCC: Prolonged Casualty care

PFC: Prolonged Field Care

POCUS: Point of Care Ultrasound

SOF: Special Operations Forces

U/S: Ultrasound