

Development and Evaluation of a Humeral Head Intraosseous Training System

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ABSTRACT

Over the past few years, the British Medical Emergency Response Team (MERT) and U.S. Air Force Search and Rescue Unit (also known as PEDRO) have been administering fluids to patients at point of injury and en route through the use of intraosseous (IO) devices in the humeral head. The MERT includes an Emergency Medicine residency trained physician. The PEDRO includes pararescue trained medical providers who are afforded the opportunity to train on cadavers prior to deployment. The U.S. Army Center for Predeployment Medicine (CPDM) at Fort Sam Houston, Texas provides medical training to providers of all levels. CPDM currently does not have an adequate training model for the humeral head intraosseous device. The U.S. Army Research Laboratory (ARL) executed a Small Business Innovative Research (SBIR) initiative to analyze the scientific, technical, and commercial merit, and feasibility of using a low-cost medical simulator for training medical personnel in Army Combat Training Schools. As part the initial phase, ARL conducted research and developed a capability to fill the gap in training this procedure. The research focused on identifying innovative technologies, technical risks of the approach, costs, and benefits associated with development and demonstration of the prototype. Additionally, a usability study was conducted with emergency medicine residents to gather feedback and assess whether the initial prototype met training requirements. This paper will discuss in detail how training requirements impacted the design of the humeral head intraosseous training system. It will also explore the criteria used to develop the overall design, as well as the identification of specific capabilities. In addition, it will explain how subject matter expertise was utilized to develop requirements and performance metrics used to evaluate the feasibility of the concept. Finally, it will review results from usability evaluations and lessons learned from the development and implementation of this project.

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Ms. Angela M. Alban is President and CEO of SIMETRI, Inc., based in Winter Park, Florida. She has extensive experience in a wide range of disciplines (research, development, production, business development, and management), enabling her to oversee all SIMETRI initiatives, including medical training and treatment by merging medical science with modeling and simulation technology. Ms. Salva has a degree in Mathematics and Computer Science from Emory University and a Master of Science in Computer Engineering from the University of Central Florida. She completed the Defense Systems Management College Advanced Program Manager's Course to parallel 19 years of experience in the Simulation and Training Industry.

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INTRODUCTION

The Army's increasing incorporation of and reliance on simulation for training of its warfighters can be seen as at odds with the current political climate for budgetary restraint. Economic austerity has increased the focus on developing affordable innovations in life-saving technology and training. The U.S. Army Research Laboratory (ARL) Human Research and Engineering Directorate (HRED) Simulation and Training Technology Center (STTC) has established partnerships with various organizations and facilities to develop and implement new technologies for simulation-based training environments to conduct Army medical training. In support of these research and development efforts, STTC contracts with a wide variety of solution providers to develop technology, tools, and techniques for more effective medical training for Army personnel. Traumatic life-threatening injuries often need immediate intravenous access for the delivery of fluids and medications. The hazards of combat environments introduce new and heightened difficulties in performing any procedures especially the treatment of critical injuries. Although medics, nurses, and physicians are highly trained in obtaining intravenous access, when access is difficult or altogether impossible to achieve, alternative methods to accomplish fluid and medication administration are essential.

In support of this initiative, STTC is currently executing a Small Business Innovative Research effort to develop a prototype, proof-of-concept device that will demonstrate the means to meet the Army's expectations for a humeral head intraosseous (IO) insertion Part Task Trainer (PTT). Humeral head IO infusion is the process of injecting fluids directly into the marrow of the humerus, or upper arm bone (also known as greater tubercle of the humerus (Figure 1)) to provide a non-collapsible entry point into the circulatory system. This technique is used in emergency situations to provide fluids and medication quickly when intravenous (IV) access is not available or not feasible (Tobias & Ross, 2010). The PTT will teach students to find the correct anatomical landmarks, to insert the IO needle at the correct location and proper angle, to verify proper insertion, and to prepare the catheter correctly to introduce fluids.

Relying on Subject Matter Experts (SMEs), the required research, design, and validation of the PTT device prototype was developed to satisfy the specific learning objectives desired for Army medical training in proximal humeral head IO insertion. This paper will discuss in detail how training requirements impacted the design of the humeral head IO training system. It will explore the criteria used to develop the overall design, as well as the identification of specific capabilities and how subject matter expertise was utilized to develop requirements, performance metrics and evaluate the feasibility of the concept.

BACKGROUND

Higher echelons of care professionals need to understand the realities of combat related trauma at the point of injury. Several programs have been developed to introduce pre-hospital trauma care to military medical providers (Physician Assistants (PA), nurses, and doctors). The Tactical Combat Medical Care (TCMC) course, part of the Department of Medical Science at Fort Sam Houston, provides the medical provider and senior medical Non-Commissioned Officer (NCO) a practical working knowledge of how to deal with the injured patient in a combat environment. The course is based on known trauma resuscitation methods, lessons learned from past and current combat environments and from newly developed technology. Training consists of didactic lecture and hands-on practical training (TCMC, 2013) on Tactical Combat Casualty Care (TCCC) principles.

IO infusion is a technique used to access blood vessels within the bone marrow typically concealed in a structured bony wall that is rigid in nature. Unlike the body's peripheral veins, the IO space does not collapse when the patient is in shock (Communicore, 2006). An IO insertion can be performed at several different points on a patient's body, including the sternum, tibia, and humeral head (Figure 1). The location of IO insertion depends on the equipment available. Even though the use of IO was prevalent within the U.S. military during the Second World War, its use faded with the introduction of the plastic intravenous (IV) catheter. IO access re-emerged as a viable field alternative to IV fluid introduction during the recent conflicts in Iraq and Afghanistan. As of 2010, the U.S. Committee on the TCCC guidelines recommends using IO infusion in any resuscitation scenario in which IV access is not feasible. (Weiser et al., 2012)

Role I battlefield medical care is delivered from the point of injury through the battalion aid station or brigade support medical company until the casualty is delivered to surgical care. The program of instruction at TCMC for Role I providers includes training on humeral head IO infusion on live tissue. Role I providers include injured combat medics, flight medics, battalion surgeons and physician assistants. The limitation on wider availability is a lack of training outside the TCMC, which currently has a limited EZ-IO training curriculum. By making IO insertion training available to all soldiers, the Army can expect to see a reduction in casualties through the appropriate use of IO devices in the field. A low-cost, hands-on training capability is needed, with sufficient fidelity to train soldiers effectively in the field use of IO devices for humeral head insertions, and provide them with "muscle memory" for this task.

The U.S. Army currently utilizes the EZ-IO Intraosseous Infusion System for humeral head IO insertions to deliver fluids in critical care situations. An insertion time by trained operators of as little as 20-40 seconds makes this technology particularly attractive for use on the battlefield to reduce casualties. (Weiser et al., 2012; Carness et al., 2012; Sarkar & Philbeck, 2009). This system is currently included only in TCMC Role I medical equipment sets for the U.S. Army, but a greater distribution of this life-saving technology within the Army is desired.

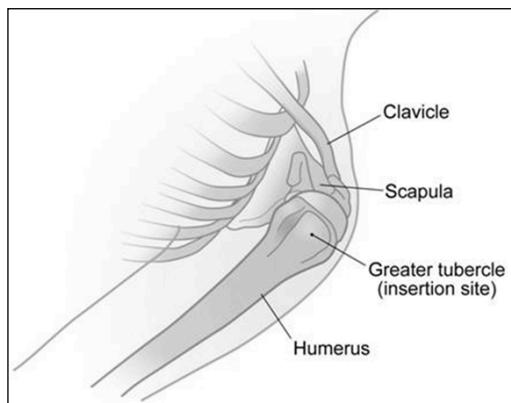


Figure 1. Diagram of the humeral head area. (Vidacare, n.d.)

TECHNICAL OBJECTIVES

The research team worked closely with representatives from TCMC to define technical objectives for the program. An initial set of requirements were defined for the humeral head intraosseous PTT in order to make effective use of the EZ-IO system in training:

- Accurate and realistic feel of the humerus underneath the skin/muscle tissue layers, to allow trainees to palpate the bone and identify the greater tubercle.
- Ability to incorrectly/correctly position the needle and puncture through simulated skin/muscle tissue at the correct/incorrect angle.
- Ability to incorrectly/correctly insert the 45mm EZ-IO needle through the simulated skin/muscle tissue and simulated bone using the EZ-IO Power Driver (or manually, if such training is desired), with appropriate feel and resistance.

- Support for multiple insertions with minimal need to change components.
- Ability to anchor the catheter into the simulated arm.
- Ability to attach a syringe and apply negative pressure for confirmation of correct needle location (through visual indication of red fluid being pulled into the tubing).
- Ability to introduce fluids through the EZ-IO catheter which will be consumed by the device.
- Skin that resists the use of iodine and/or alcohol without breaking down or discoloring.

The technical objectives were decomposed into a revised list of requirements that were based on the Program of Instruction (POI) and refined with SME inputs during the requirements analysis phase of the program. A prototype, proof-of-concept device was developed to explore and demonstrate the means to meet the Army's requirements for training. The PTT was designed to teach students to find the correct anatomical landmarks, to insert the IO needle at the correct location and proper angle, to verify proper insertion, and to prepare the catheter correctly to introduce fluids. The first phase of the program focused on providing reusable and replaceable simulated skin, muscle, and bone. A modular approach minimizes the expendable items that must be replaced throughout the life of the device.

The proof-of-concept PTT consists of a single arm, and has the following major components:

- Simulated bones (replaceable) and joints with realistic feel and appropriate anatomical landmarks.
- Simulated muscle and skin with realistic haptic feedback.
- Base to position arm and hold arm in place during medical procedure.

RESEARCH AND DEVELOPMENT

The development of the PTT system followed a systems engineering approach (Figure 2), which consisted of several phases, to include: Gap Analysis and Requirements Definition (Phase I), Technology Development (Phase II), User Evaluations (Phase III), and Prototype Refinements (Phase IV).

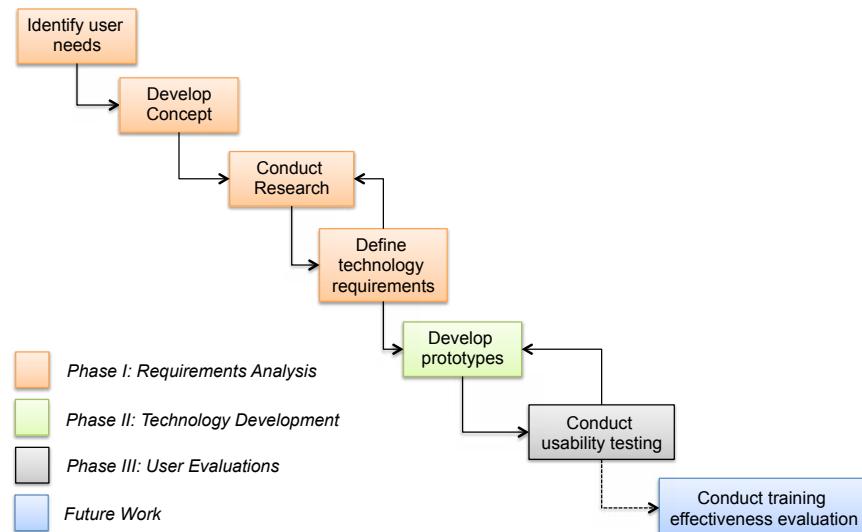


Figure 2. Systems Engineering Approach

Phase I: Requirements Analysis

During development of the PTT system the team performed a comprehensive requirements analysis with instructors from TCMC. The purpose of the analysis was to identify current gaps in training and to prioritize capabilities to support the program of instruction. During the requirements definition process it was important to engage with SMEs to identify the capabilities that could support their mission.

The gap analysis and requirement definition phase consisted of the following main activities:

- Structured SME discussions
- Observation of training at TCMC to identify training objectives
- Task analysis

Training Methodology and Program of Instruction

While remaining a low-cost solution, the PTT must be capable of allowing students to build “muscle memory” for a task which will likely be performed in a high-stress situation. For this reason, the PTT must be able to afford the use of the actual EZ-IO Power Driver and 45mm needles. An important part of the EZ-IO insertion procedure is verification of correct needle length by observation of skin depth before bone penetration is attempted (Day, 2011); the capability to perform this check will also need to be supported by the PTT through the use of realistic skin, muscle, and fat.



Figure 3. Humeral head IO insertion using the EZ-IO drill.

The PTT should also provide appropriate feedback to student actions, with adverse effects when common errors are committed as well as visible results to represent success, so that proficiency can be observed and judged. There are several means of confirming a proper humeral head IO insertion listed in the EZ-IO training materials (Vidacare, n.d.) and in the literature (Allman et al., 2009; Day, 2011; Luck et al., 2010):

1. Convincing “give” on entering the marrow cavity.
2. Firmly seated catheter.
3. Observed blood on the stylet tip.
4. Blood noted at the catheter hub.
5. Blood or marrow can be aspirated with a syringe.
6. Drugs or fluids flow without difficulty, with no signs of leakage into tissue.
7. Effects of administered drugs noted.
8. X-Ray confirmation.

Based on the requirements analysis and feedback from SMEs at TCMC, the PTT should support effects 1, 2, 5, and 6; effects 3 and 4 would require external flow of a blood-like substance; effect 7 is beyond the scope; effect 8 is inappropriate for field care. Effects 1 and 2 were realized as a result of using realistic underlying bone structure; materials were carefully selected for accurate representation in this area. Effects 5 and 6 were achieved using state-of-the-art methods and technology.

It was important to outline how the humeral head IO insertion procedure is performed as well as understand the steps involved in locating the correct physical landmarks prior to inserting the drill into the humeral head bone. The anatomical landmarks of the humeral head are identified by first putting the patient in a supine position. The next step is to expose the shoulder and adduct humerus by placing the patient's arm against the patient's body. The elbow should be resting on the stretcher, bed, or ground and the forearm should rest on the abdomen. Palpating toward the proximal aspect or insertion site identifies the mid-shaft humerus. The base of the greater tubercle insertion site is the small protrusion near the shoulder. The opposite hand should then squeeze the anterior and inferior aspects of the humeral head while confirming the identification of the greater tubercle. This ensures correct identification of the midline of the humerus itself.

The EZ-IO Power Driver is the primary device being used by the U.S. Army to perform the humeral head intraosseous insertion procedure. This power drill has a built-in lithium battery that will allow for 1000 insertions and requires no battery replacement or recharging. In order to use the power drill for the procedure, the needles for adults in the 45mm size are used to forge into the skin, muscle, and bone marrow of the incision site. Once the drill has forced the needle into place, the user is instructed to remove the stylet of the needle by grasping the catheter hub while gently removing it.

Phase II: Technology Development

During phase II, the team conducted a gap analysis of current technologies needed for the prototype system and compared it against the list of requirements identified during phase I (Requirements Analysis). This phase also included the development of a concept, materials research, trade-off analysis, system design and prototype development. The overall design for the system was developed to address all requirements identified during phase I. The design was guided by standard anthropomorphic measurements for Soldiers which include weight, dimensions and reach.

Materials Research

The PTT development effort began with detailed research in two areas: the most effective methods and characteristics to be incorporated into the PTT, and the best materials to be used in realizing those methods and characteristics. Both these avenues of research commenced with an extensive review of lessons learned from related documented work, and continued with specific research methods.

Research was conducted to explore the techniques and materials used in current PTTs of similar scope. Special effects engineering have been used in the film industry for over 100 years but it hasn't been until recent decades that the medical, military, and special effects disciplines merged together in producing and applying prosthetic appliances. Over the years, understanding the importance of human anatomy, design, lifecasting, sculpting and molding has helped refine these innovative special effects appliance techniques. Mastering these skills is important in improving the production of these items but innovation and creativity are crucial to maintaining the craft. The most common prosthetic appliance technique is called lifecasting. This involves taking a live model and molding of a body part to use as a base for sculpting the prosthetic.

The lifecasting process of manufacturing special effect prosthetics has been used in the industry for multiple decades however the materials used in producing state of the art prosthetics are ever growing and ever changing. The materials that are commonly used are materials that have long shelf lives, are easy to pour into molds, can be manipulated to have slow or fast cure times and have easy mixing ratios. The most popular materials in prosthetic appliance production typically range from foam, latex, resin, urethane, and silicone rubbers. Initially, regular household items such as gauze, cotton, horsehair, and food items were used in making prosthetic appliances. When special effects became a trend in Hollywood movies, foam and latex rubbers were used for age makeup and gelatin and color pigments were used for gore and monster film. In more recent years, silicone materials have provided more realism and durability to the art. Silicone can be translucent, pigmented, textured, softened, hardened, and flexible to resemble human skin. Since appliance prosthetics are mostly used on live actors or mannequins, blending the appliance to each surface so it looks seamless is the advantage of using silicone.

The ultimate goal of the materials research was to arrive at the best set of components for the PTT, comprising COTS parts along with custom fabrications as appropriate, to maintain low cost while realizing the training methods and goals that have already been identified.

Trade-off Analysis

For the PTT, appropriate trade-offs of materials and mechanical components were evaluated and decided between the highest possible realism and affordability / maintainability. A durometer analysis of skin, muscle, and fat was performed and supported with literature review, observation of animal samples, and comparison with silicone alternatives. A trade-off analysis of materials such as rubbers, urethanes, and resins and their properties was

conducted to determine what materials could provide the most realistic human skin, muscle, tendon, and bone. A second tier analysis was conducted of the potential materials for the simulated muscles, tendons, and bone.

The equipment required to perform a humeral head IO was also evaluated and examined during laboratory testing to better understand its function and mechanical properties.

Prototype Development

Based upon the completed materials and methods research, a prototype PTT was developed. For Phase I the prototype consists of an arm only, with appropriate structures and characteristics. The design process focused on durability, realism, reusability, and low lifecycle costs. Training with the PTT had to involve the use of the EZ-IO Power Driver from a standard EZ-IO manufacturer's kit (Figure 4).



Figure 4. Humeral head IO insertion demonstration using EZ-IO Power Driver on PTT prototype.

The PTT was constructed to minimize waste and use of expendables, in order to control long term costs. This aspect of the design was closely evaluated and addressed with respect to the bone, skin, and underlying tissue that must be poked, prodded, and drilled as a normal part of training. The prototype PTT was designed with considerations for future attachment in mind. Although the prototype arm will be a standalone device for Phase I, it will need to be easily attached to the torso that is projected to be produced in Phase II, if awarded. The design for the PTT is modular to facilitate attachment and replacement as well as to minimize the scope and cost of consumables.

Phase III: User Evaluations

Initial usability studies were performed at the University of Florida College of Medicine Center for Simulation Education and Safety Research, Orange County Fire Department, and City of Orlando Fire Department on a noninterference basis with pre-hospital and emergency care training. Test users included Emergency Medical Technicians (EMT), Paramedics, and Trauma Physicians. Additional evaluations will be conducted later in the year at TCMC. The focus of the evaluation was to evaluate the usability of the system to support training objectives and to assess if the system is intuitive, effective, and subjectively acceptable to users (Nielsen, 1993). The usability study consisted of two major activities:

1. Observation of trainees and trainers interacting with the system - SMEs were briefed on the capabilities of the Humeral Head initial prototype. Following the demonstration, the SMEs were asked to perform the IO procedure on the part task trainer. The SMEs were observed during their execution of the different tasks.
2. Feedback on their reactions captured through surveys and participation in structured focus group interviews- Once they had completed the procedures, the SMEs were asked to complete a questionnaire to assess system usability and reaction to the training system. A focus group was conducted to assess if the training system supports the training objectives of the program of instruction. The data collected provided

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user feedback in terms of: Benefit to Training, System Usability (ease of use), Anatomical Accuracy, Physiological Accuracy, Realism, and Motivation to use.

None of the data collected included any personally identifiable information.

Data Acquisition and Results

Study I – City of Orlando Fire Department Emergency Management Services (EMS) Division

A usability evaluation of the Humeral Head initial prototype was conducted in May 2014 at the City of Orlando Fire Department EMS Division. The primary purpose of this evaluation was to observe users performing the procedure on the PTT and gather data regarding system functionality. Thirteen SMEs participated in the study. Six participants provided concrete feedback using a survey questionnaire. All participants participated in a focus group discussion regarding their evaluation of the system, and provided feedback regarding features and functionalities as well as specific details with respect to the program of instruction within their organization. Users were given as much time as possible to perform each procedure and to evaluate the capabilities of the system. Data was collected via questionnaires and focus group discussions.

Study II – Orange County Fire and Rescue

A usability evaluation of the Humeral Head initial prototype was conducted in May 2014 at the Orange County Fire and Rescue Training Center and Command School. The primary purpose of this evaluation was to observe users performing the procedure on the PTT and gather data regarding system functionality. Eight SMEs participated in the study. Eight participants provided concrete feedback using a survey questionnaire. All participants participated in a focus group discussion regarding their evaluation of the system, and provided feedback regarding features and functionalities as well as specific details with respect to the program of instruction within their organization. Users were given as much time as possible to perform each procedure and to evaluate the capabilities of the system. Data was collected via questionnaires and focus group discussions.

Study III – University of Florida Department of Emergency Medicine

A usability evaluation of the Humeral Head initial prototype was conducted in May 2014 at the University of Florida Department of Emergency Medicine in Jacksonville,. The primary purpose of this evaluation was to observe users performing the procedure on the PTT and gather data regarding system functionality. Twenty-nine SMEs participated in the study. Twenty-nine participants provided concrete feedback using a survey questionnaire. All participants participated in a focus group discussion regarding their evaluation of the system, and provided feedback regarding features and functionalities as well as specific details with respect to the program of instruction within their organization. Users were given as much time as possible to perform each procedure and to evaluate the capabilities of the system. Data was collected via questionnaires and focus group discussions.

After thorough inspection, users were given one survey questionnaire with 20 usability questions. Participants were asked to evaluate their experience with the Humeral Head IO PTT by responding to questions regarding the critical tasks required to perform the procedure that can be performed using the system. Participants answered the questions by selecting options on a scale from 1 (strongly disagree) to 7 (strongly agree), with higher scores signifying a better experience. The questionnaires developed as part of this effort included questions regarding five different constructs: Meets Training Objectives, Usability, Realism, Physiological/Anatomical Accuracy, and Motivation to Use. These constructs were selected because the system must be able to meet the training objectives identified by SMEs. Anatomical and physiological accuracy are crucial in enhancing realism and immersion during scenario-based training. A summary of the calculated mean responses obtained from the students and instructors on the initial prototype is provided in Table 1.

Factor	Paramedics		Physicians
	City of Orlando	Orange County	UF College of Medicine
Meets Training Objectives	6.67	6.74	6.32
Usability	6.31	6.26	6.07
Realism	5.59	5.86	5.23
Physiological/Anatomical Accuracy	5.15	6.00	5.60
Motivation to Use	6.83	6.80	6.07

A summary of the average responses per group obtained from the students and instructors on the initial prototype is provided in Figure 5.

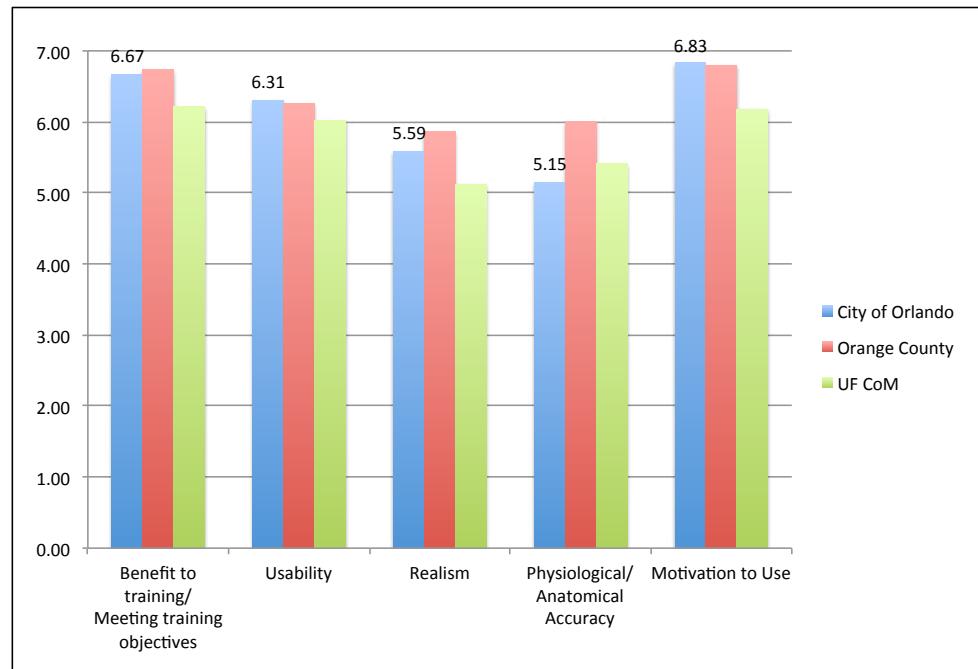


Figure 5. Average Scores per Group

To complement the questionnaires, users were also asked to provide their opinions about the prototype during focus group discussions. Below is a list of significant findings obtained through both the questionnaires and these focus groups:

- The participants commented that the Humeral Head I/O training system could be beneficial to the current training curriculum.
- Overall, the participants concluded that the system was user friendly, easy to maintain, and reset between uses.
- The majority of the participants responded positively to questions regarding the system's ability to meet training objectives.
- The highest scores were observed in the category of "Motivation to Use" for all groups; it is expected that this is the case because no realistic training system exists on the market.

COST AND BENEFIT ANALYSIS

The full-torso humeral head IO PTT total lifecycle costs will be evaluated as an adjunct to the U.S. Army POI. The projected costs of acquiring and operating the system were assessed along with the expected benefits of the associated training program. The immediate commercial application of the technology developed through this effort is more realistic training for civilian and military first responders in the IO procedure. Training devices and methodologies evaluated as a part of this research are very low fidelity, and are less likely to lead to practitioner confidence in performing the procedure in emergency situations. A higher-fidelity training device will better prepare emergency medical personnel for smooth performance of the IO procedure in high-stress situations.

At Fort Sam Houston, the armed services train approximately 12,500 Army combat medics, Navy corpsmen, and Air Force medical technicians a year. About 20,000 combat medics serve on active duty in the Army and 20,000 in the National Guard and Reserves. In addition to these potential military medical trainees, the Army would like to familiarize all soldiers with the use of IO devices in the field, further increasing demand for these training devices. On the civilian side, the market for vascular access devices in general was about \$3 billion in 2009, and is projected to be over \$4.6 billion by 2016 (PR Newswire, 2013). A significant percentage of this market will be represented by IO devices, and users of those devices must be trained effectively in order for them to be effective in the field.

Although there are training devices for the humeral head IO procedure in existence (such as the training kit available from Vidacare, the manufacturer of the EZ-IO system), none are of high fidelity.

LESSONS LEARNED

The feedback gathered during initial meetings with SMEs proved to be invaluable in the system design of the Humeral Head IO training system. At the same time, despite the number of hours spent eliciting requirements from SMEs, we still encountered procedural nuisances across different programs of instruction. For example, the Instructors at the City of Orlando Fire Department and Orange County Fire and Rescue do not extract bone marrow (also referred to as flash) after inserting the needle catheter into the humeral head. They skip this step, which is a critical task in the Army program of instruction. Had the research team not met with Army SMEs prior to designing the system and limited requirements to those of these two fire and rescue departments, critical requirements would not have been incorporated into the system. By conducting the usability study across users from different organizations and functions, more comprehensive feedback from various levels of expertise was gathered. Users who participated in the system evaluation included both paramedics and physicians. By conducting usability studies early in the development cycle, potential issues were prevented from being identified late in the cycle. As a result, the team was able to modify design early, thus mitigating cost and schedule risks.

CONCLUSIONS

Traumatic life-threatening injuries often need immediate intravenous access for the delivery of fluids and medications. In combat environments, the urgency of such procedures is often heightened in treating critical injuries. Although medics, nurses, and physicians are highly trained in obtaining intravenous access, when access is difficult or altogether impossible to achieve, alternative methods to accomplish fluid and medication administration are essential. The Humeral Head IO training system offers a high fidelity training capability for this life-saving procedure. The limited performance of this procedure is due to a lack of training because no anatomically and physiologically accurate training device exists. By making IO insertion training available to all soldiers, the Army can expect to see a reduction in casualties through the appropriate use of IO devices in the field. A low-cost, hands-on training capability with sufficient fidelity to train soldiers effectively in the field use of IO devices for humeral head insertions, providing them with "muscle memory" for this task, is needed. Severe trauma at the point of injury creates major challenges to first responders as they are not mentally prepared to treat the injuries encounter on the battlefield. The research that the STTC is conducting under SBIR will result in realistic training focusing on

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anatomical and physiological accuracy as well as providing a training capability for a medical procedure being introduced in theater.

Results from the usability evaluations conducted with the City of Orlando Fire Department, Orange County Fire and Rescue, and University of Florida Department of Emergency Medicine indicate that the system is easy to use and an improvement on what is being used in the current program of instruction. Usability areas explored included Meets Training Objectives, Usability, Realism, Physiological/Anatomical Accuracy, and Motivation to Use. Feedback from the focus group discussions is being evaluated and incorporated into the system design. The intent of the usability study was to collect quantitative and qualitative metrics to better understand the impact of increasing fidelity during training.

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REFERENCES

Allman, K., McIndoe, A., & Wilson, I. (2009). *Emergencies in Anaesthesia*. New York: Oxford University Press.

Carness, J.M., Russell, J.L., Lima, R.M., Navarro, L.H., & Kramer, G.C. (2012). Fluid resuscitation using the intraosseous route: Infusion with lactated ringers and hetastarch. *Military Medicine*, 177(2), 222-228.

Communicore (2006). Emergency Vascular Access: Technology, Economics, and Deployment in a Multi-Dimensional Setting, Washington: Communicore.

Day, M. W. (2001). Intraosseous devices for intravascular access in adult trauma patients. *Crit Care Nurse*, 31(2), 76-90.

Luck, R. P., Haines, C., & Mull, C. C. (2010). Intraosseous access. *Journal of Emergency Medicine*, 39(4), 468-75.

PR Newswire (2013). Vascular access device market in the U.S. to reach over \$4.6 billion by 2016. June 22, 2013, Retrieved from <http://www.prnewswire.com/news-releases/vascular-access-device-market-in-the-us-to-reach-over-46-billion-by-2016-88899132.html>

Sarkar, D., & Philbeck, T. (2009). The use of multiple intraosseous catheters in combat casualty resuscitation. *Military Medicine*, 174(2), 106-108.

Tobias, J. D., & Ross, A. K. (2010). Intraosseous infusions: a review for the anesthesiologist with a focus on pediatric use. *Anesthesia & Analgesia*, 110 (2), 391–401.

Vidacare Corporation (n.d.). EZ-IO AD® Proximal Humeral Access Training Program.

Weiser, G., Hoffman, Y., Galbraith, R., & Shavit, I. (2012). Current advances in intraosseous infusion – A systematic review. *Resuscitation*, 83, 20-26.