Development and Evaluation of a Venipuncture and Phlebotomy Training System

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ABSTRACT

The U.S. Army has invested significantly in manikin technology to train procedural skills associated with military medical training in diverse simulated environments. Training equipment needs to be rugged and reliable to endure austere conditions but refined enough to provide training solutions with appropriate fidelity. A manikin or Part-Task Trainer (PTT) possessing those qualities that accurately trains venipuncture and injection procedures has historically been a challenge. The goal of the U.S. Army Medical Simulation Training Centers (MSTCs) is to provide Army personnel with more effective technology, tools, and techniques for training Army personnel. As a result, the U.S. Army Research Laboratory Human Research and Engineering Directorate (ARL-HRED) Simulation and Training Technology Center (STTC) was sponsored by the U.S. Army Program Executive Office for Simulation, Training and Instrumentation (PEO STRI) to develop a next-generation venipuncture and injection PTT, that is more realistic, durable, and cost effective to teach these lifesaving skills. The primary objective is to develop a proof of concept device that demonstrates the viability of the materials, the electrical/mechanical design, and the technical approach. 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 first responders 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 training system and 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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1.0 Introduction

Combat medicine lessons learned from recent engagements have led to a heightened awareness within the military medical community of the need for incorporating warrior tasks during medical skills training and increased immersion in relevant training scenarios. Furthermore, as with virtually all Military Occupational Specialties (MOSs), U.S. Army 68Ws (combat medics) require sustainment training. After initial training, combat medics are assigned to infantry units versus medical units. This creates challenges because resources to support remote low density MOS sustainment training are scarce. The current battlefield in Afghanistan has not changed with respect to the types of wounds that soldiers sustain since World War I. The leading cause of preventable death is exsanguination (extensive blood loss due to internal or external hemorrhage). The second and third leading causes of preventable death are tension pneumothorax (an abnormal collection of air or gas in the pleural space that causes an uncoupling of the lung from the chest wall) and airway obstruction, respectively. The Army and other Department of Defense services have enhanced training battlefield medical tasks within combat medic training programs, including the Tactical Combat Casualty Care (TCCC) courses. TCCC was developed in response to the growing recognition that medical care on the battlefield requires different skills and mindsets compared to civilian approaches.

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. Data from the Afghanistan conflict indicate that the methods of providing battlefield training and care are working, although there are still training gaps specially in the area of Intravenous (IV) infusion: need for hands-on training; decision-making (critical thinking skills) training; and low cost training solutions. Over the last 20 years there has been little innovation or improvement in the IV training models as many are of the same design and utilize the same materials. Current capabilities are anatomically incorrect as they do not represent accurate shape, size and color as those found in the human arm.

2.0 Background

The U.S. Army has invested significantly in developing technology to train procedural skills associated with military medical training. Training equipment needs to be rugged and reliable to endure austere conditions but refined and robust enough to provide training solutions that could be used in diverse simulated environments with appropriate fidelity. The goal of the U.S. Army Medical Simulation Training Centers (MSTCs) is to provide Army personnel with more effective technology, tools, and techniques for training Army personnel. A Part-Task Trainer (PTT) possessing those qualities that accurately trains venipuncture and injection procedures has historically been a challenge, therefore, the Simulation and Training Technology Center (STTC) has been sponsored by the U.S. Army Program Executive Office for Simulation, Training and Instrumentation (PEO STRI) Product Manager Medical Simulation (PDM MedSim) to develop a next-generation venipuncture and injection arm PTT in response to the need for a more realistic, durable, and cost effective approach to teaching these lifesaving skills.

The objective of the "Next-Generation Venipuncture and Injection Part Task Trainer" effort is to perform research and prototype development of a venipuncture and injection arm part-task trainer that provides hands-on psychomotor skill training with objective performance feedback for the pre-deployment and refresher training of combat medics and combat lifesavers. The primary goal of the program is to develop a proof of concept device that demonstrates the viability of the materials, the electrical/mechanical design, and the technical approach. The instrumented prototype supports the following objectives:

- Provide hands-on training to support training requirements
- Provide low-cost training to maintain the level of fidelity needed
- Provide decision-making training to build knowledge and understanding and avoid underuse, overuse, and misuse
- Provide objective performance feedback

The effort focuses in improving and enhancing the stand-alone training and providing objective performance feedback of IV infusion procedures. In order to assess the feasibility of using the technology to provide the warfighter additional opportunities to prepare to make medical decisions within an operational environment more effectively, the team conducted usability evaluations at several training facilities.

2.1 Military Relevance

This program aims to provide a more effective IV insertion and phlebotomy training for U.S. Army medical personnel. The results from this research are expected to impact current training by incorporating a higher fidelity and more realistic training model in the current program of instruction. Additional benefits that could potentially be realized are increased medical efficacy in the field and reductions in casualties at point of injury. Through this work, combat medics and other military medical first responders will have access to the following benefits:

- Higher fidelity, more realistic training in IV insertion procedures.
- State of the art in realistic representation of veins, skin, electronics, and fluids in anatomical models to support hands on training.

3. Technical Objectives

As part of the effort, the research team focused on developing innovative technologies to produce a PTT that would incorporate several key features that have been missing or are of lower fidelity in current training capabilities:

- Realism of skin, veins, and fluids is key for positive training. For example, trainees must look for straight, “bouncy” (non-rolling) veins that are not at a bifurcation site.
- Common errors, including catheter outside the vein, solution not flowing, solution retained within the arm, and missing the vein entirely, will be simulated accurately and with appropriate cues to the trainee.
- Provide the right cues such as blood release and flash.
- Provide vessels that are puncture resistant, have high tensile strength, and have elasticity.

3.1 Program of Instruction and Training Methodology

All tasks to be trained on the PTT must be part of the 68W curriculum at the MSTCs and the capabilities provided must support training objectives. The team reviewed the system requirements provided by PEO STRI and traveled to Ft. Lewis and Ft. Bragg MSTCs to observe training. The team engaged in discussions with Subject Matter Experts (SMEs) and included the following questions:

- What techniques, if any, are used in training venipuncture and infusion procedures?
- What size needles are used?
- What other equipment is used?
- What is the typical anatomy of patients, and which locations on the arm are used for venipuncture and infusion?
- How frequently does training occur at each user site?

Ft. Lewis (Seattle) training focuses on clinical skills. SMEs stated that the next generation IV trainer must support the following:

- Provide visual flash cue.
- Support 18 gauge needle.
- Be rugged with minimum reset time.
- Support different scenarios other than young and healthy soldiers.

Ft. Lewis typically has class sizes of 42 trainees but their maximum seating capacity per class is 50 trainees. Their instructor to student ratio is approximately 1/15. Phlebotomy is not trained at the Ft. Lewis MSTC, but trainees need to know how to do it. Currently, trainees at this MSTC are provided with a refresher course on IV and they use each other for IV training since the IV models available for training are not realistic and are difficult to reset.

The second user site visit took place at Ft. Bragg in Fayetteville, North Carolina. Their focus is mainly on medical trauma skills. The team was able to observe the combat medics during outdoor lane training. They train approximately 8000 students a year and their preferred instructor to student for hands on training is 1/15. In Ft. Bragg, students use IV arm models to practice and culminate their training performing IVs on each other. In addition to the capabilities identified by Ft. Lewis, they identified the following:

- Simulated skins need to be more durable.
- Minimum logistic support.

4. Research and Development

Research and development of the PTT system was conducted in three distinct phases: Requirements Analysis, Technology Development, and Prototype Development. An important component of the research and development effort involved conducting site surveys and holding discussions with Subject Matter Experts as well as Instructors at various U.S. Army medical training facilities and municipal First Responder groups. The discussions and observations of current training helped to outline the desired capabilities and maintenance/logistics concerns to be incorporated in the design.

4.1 Requirements Analysis

Prior to finalizing requirements, it was important to conduct a task analysis as well as develop a thorough understanding of the relevant anatomical structures and physiology to facilitate designing a prototype consisting of simulated tissue with appropriate structures and characteristics.

Blood supply is the driving force of the artery and vein system in the arm. The arteries, however, are more sensitive and need more protection than veins. Arteries are located deep within the tissue and wrapped up by muscles to reduce the chance of hemorrhaging and severe injury. In certain parts of the body, however, arteries are found closer to the surfaces of the human skin. This is true in places such that of the arm. Blood is supplied to the arm by the brachial artery, which originates from the axillary artery located in the neck as seen in Figure 1. The brachial artery clears the shoulder to the inner aspect of the elbow. The location where the elbow bends is where the brachial artery descends deeply into the cubital fossa. Below the elbow, the brachial artery branches off forming the radial artery of which supplies the lateral and ulnar arteries. The collection of blood and intravenous catheter insertion involves venous access. Venipuncture for the purposes of blood collection is typically performed on superficial veins in the lower forearm and hand. The area where the forearm meets the elbow is the cubital and the shallow, triangular shaped area on the anterior of the upper forearm is the fossa. Together this region of the arm is referred to the antecubital fossa. The location on the upper arm is critical in finding the veins most commonly recommended for venipuncture. The three veins in the cubital fossa are the median cubital vein, the cephalic vein, and the basilica vein as illustrated in Figure 2.

When blood is not able to drain in the cubital fossa, veins on the back of the hand and in the lower arm are used. Placement of the needle and catheter insertion is a critical task in intravenous infusion and injection because the anatomy of the arm is complex and has an intricate system of arteries and nerves supplying, blood flow and oxygen.

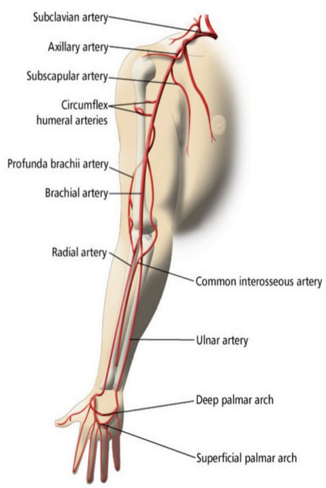

Figure 1. Major Arteries in the Arm

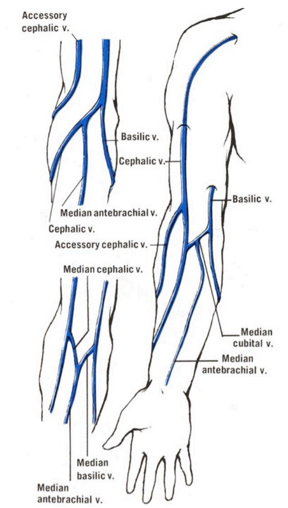

Figure 2. Major Veins in the Arm

Observations of current training at the MSTCs helped to outline the desired capabilities and maintenance/logistics concerns for the personnel at the sites. After combining the findings of both the anatomy and physiology with the training aims and constraints, a comprehensive list of system requirements was developed which focused on a rugged and cost effective solution.

4.2 Technology Development

During the technology development phase, the team identified elements that were critical to maximize functionality of the prototype PTT:

- Realistic skin, internal vein system, and internal fluids and blood supply.
- Simulated tissue wearable by a mannequin
- Sensor technology for performance assessment
- Packaged for easy transport

Simulated tissue wearable by a mannequin, sensor technology for performance assessment, and packaging will be the focus of future development.

4.2.1 Materials Research

When training for venipuncture is it important to learn how to assess and palpate the skin. Recognition of tactile cues such as the rolling of veins and the sensation of a “pop” as a needle enters a vein are critical skills to develop. The team concentrated their effort in conducting materials research on critical elements of the PTT such as skin, veins, and fluids.

4.2.1.1. Skin

Since skin is the largest organ in the human body, it is vital that it is represented as realistically as possible, both aesthetically and texturally. The skin is composed of many layers starting with the outer layer. The epidermis is a translucent layer made of cells to protect from the environment. The most superficial portion contains dead skin cells that are continually shed. The deepest portion contains basal cells that are responsible for skin renewal. The skin contains a protein called keratin that serves to protect the skin from harmful bacteria or chemicals. Melanin, also found in the skin, gives skin its color pigmentation. The middle layer also known as the dermis contains elastin and collagen. Collagen is the most abundant protein in the skin. It makes up 75% of human skin. The elastin protein is found together with collagen and is responsible for giving structure to skin and organs. As with collagen, elastin is affected over time and because of the elements. The hypodermis layer is the fatty layer, which lies between the dermis and the muscles and bones. It contains the blood vessels that expand and contract to help keep the body at a constant temperature. Knowing the functions of these intricate layers provided a better understanding of the physiological functions of the human skin.

Simulating skin that acts, feels, and looks like skin was one of the aims of this research effort. Another critical physical component of the PTT is the skin thickness around the arm. It is difficult to determine the actual skin thickness for humans since it varies based on several factors such as body size. Moreover, exposure to the sun, age, ethnicity, and/or underlying tissues (i.e. muscle and fat percentages) has a significant role in determining approximate skin properties in the epidermis layer. Exposure to the sun can lead to a “leathering” or toughening of the skin. With age, the skin and underlying veins become thinner and weaker. It is harder to penetrate the veins of individuals with large muscle masses. A male’s forearm skin thickness is much thicker than that of a female due to average size.

In order to simulate the skin, different materials were tested to include platinum cure rubber silicones and water based urethanes. These materials were selected because they are durable and have flexible physical characteristics. Platinum cure silicone is typically recommended for reproducing molds, special effects prosthetics, and casting components. It exhibits extremely low shrinkage and physical properties that make it a highly workable material. Urethane rubber is an alternative material which offers superior physical and performance properties. Typically, urethanes serve for molds, sculpture reproduction, architectural elements, special effects applications, toys and general prototypes. Water based urethane is a material that is highly malleable and provides the strength and consistency of the epidermis skin layer. The key challenge in creating realistic skin is determining the thickness between layers such that the simulated skin is soft and tactile but durable enough for needle catheters to remain in the skin and for tubing to remain intact after repeated needle punctures.

4.2.1.2. Veins

The vein system found in the human arm was studied in order to develop simulated tissue with veins that provide visual and haptic realism with appropriate functionality. To represent an average male in the military, it was important to study the veins and arm anatomy as shown in Figure 3 below.

Normal Veins *Pronounced Veins*

Figure 3. Human Male Arm Vein Structure

Typically, normal veins are subtle but visible on the exterior of the skin. Although blood is red, veins appear blue and green under the skin due to the properties of light absorption and reflection. Research encompassed evaluating the best tubing to simulate veins to include an analysis of the multitude of materials used to make the simulated veins. Pre-manufactured simulated veins and conventional tubing were analyzed and compared against the system requirements to determine the best approach. Tubing is an integral part of the prototype’s form, fit, and function. Creating the channels for blood to pass through the veins and arteries is essential in simulating the venipuncture process. A medical grade tubing was selected because of its flexibility and non-porous characteristics. It can withstand extreme heat, has a resistance to tearing, and comes in different harnesses, inner diameters, and colors.

4.2.1.3. Blood

It is important to research the composition of blood to recreate simulated blood that is similar in consistency and physical properties to real human blood. Research shows that blood contains a nonliving fluid matrix (plasma) in which living cells (formed elements) are suspended. Formed elements consist of blood cells and platelets and are so named because they are enclosed in a plasma membrane and have a definite structure and shape. Formed elements include erythrocytes (red blood cells), leukocytes (white blood cells), and platelets. Blood contains 55% plasma and 45% formed elements. Plasma is over 90% water. It also contains electrolytes (salts), plasma proteins, and substances transported by blood (i.e. nutrients, hormones, etc.). Since red blood cells make up 45% of the blood and the rest is plasma, the simulated blood must contain a large concentration of water compared to simulated blood. After comparing several available simulated blood samples, a commercially available product was selected for simulating realistic human blood for this application.

4.3. Prototype Development

Venipuncture requires assessing and palpating the skin around the desired injection site. Many hospitals and medical professionals utilize training aids to assess, maintain and demonstrate the accuracy of performing this basic clinical function. After completing the requirements analysis phase, it was clear that the design needed to include a very realistic arm with replaceable consumable parts and also provide different vein sizes and simulated adipose tissue. The design evolved as research and analysis identified which materials were best suited for the application. To keep the prototype design as streamlined as possible while maintaining a realistic appearance, the design focused on ease of use and functionality of the skin overlays, reusability of the simulated veins, and low development costs. The initial proof of concept prototype consists of a static arm to scale attached to a base that facilitates tabletop training. The antecubital area of the arm is most visible, where the basilic, cephalic and medial cubital veins are most prominent and usually near the surface of the skin. At this time, the arm has a rectangular insert that can be replaced once too many punctures have degraded the skin or the punctures are visible to trainees. The simulated veins and simulated skin at the incision site are easily accessible. Although the plug represents the consumable components, the materials were chosen for their durability and ability to resist punctures and contain the simulated fluids as much as possible. The realistic skin patch facilitates needle catheter insertion without requiring immediate replacement. The skin patch can be punctured more than one hundred fifty times without requiring replacement and the base arm structure does not require replacement. The veins are simulated with a resilient tubing system that can be clamped when needed and filled with simulated fluid providing flash and bleeding. Although simple in design, the concept of using soft tubing and soft tissue are key design elements for the proof of concept prototype depicted in Figure 4.

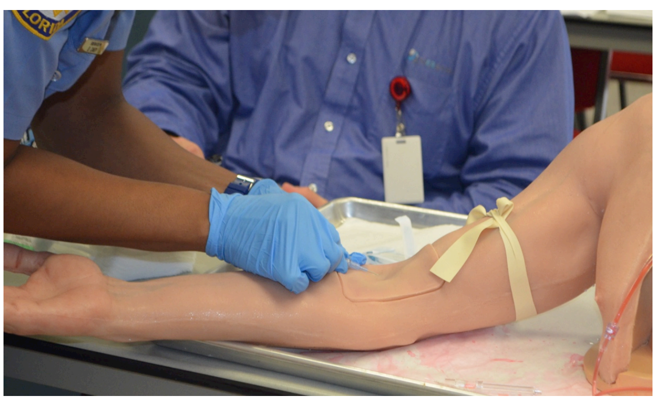

Figure 4. Proof of Concept Prototype

5. User Evaluations

A usability study was conducted with first responders to gather feedback and assess whether the initial prototype met training requirements identified by SMEs. Initial evaluations were conducted at the Orange County Fire Department and at the City of Orlando Fire Department on a noninterference basis with pre-hospital and emergency care training. Participants included Emergency Medical Technicians (EMT) and Paramedics. The purpose of the evaluation was to assess the usability of the system in supporting training objectives established by the program of instruction. The study consisted of three major activities:

- Demonstration of the capabilities of the system to potential users (trainees and trainers).
- Observation of trainees and trainers interacting with the system while executing different tasks.
- Feedback on participants' reactions captured through surveys and structured focus group interviews after interacting with the system.

The surveys collected detailed user feedback. The focus group discussions provided additional feedback. The current design of the PTT will be updated taking into consideration the feedback received during the evaluations and a final study will be conducted later in the year at one of the Army Medical Simulations Training Centers (MSTC).

5.1 Methodology

Initial usability studies were performed in May 2015 at the Orange County Fire Department, the City of Orlando Fire Department, and Orlando Medical Institute on a noninterference basis. Test users included EMTs, Paramedics, and Instructors. Additional evaluations will be conducted later at Florida Hospital and the U.S. Army Medical Simulation Medical Training Centers (MSTCs). 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 Next Generation Venipuncture and Phlebotomy initial prototype. Following the demonstration, the SMEs were asked to insert an IV catheter and in some cases, draw blood using the PTT. The SMEs were observed during their execution of the different tasks.
2. Feedback on their reactions was captured through surveys and participation in structured focus group interview - 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 user feedback in terms of: Benefit to Training, System Usability (ease of use), Anatomical Accuracy, Physiological Accuracy, Realism, and Motivation to use.

5.2 Data Acquisition

The primary purpose of the usability evaluation was to observe users performing the procedure on the PTT and gather data regarding system functionality. Participants had the opportunity to interact with the system and provided concrete feedback regarding their experience using a survey questionnaire with 21 usability questions. Participants were asked to evaluate their experience with the Next Generation Venipuncture and Phlebotomy PTT by selecting options on a scale from 0 (strongly disagree) to 8 (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.

To complement the questionnaires, users were also asked to provide their opinions about the prototype during focus group discussions. They provided feedback in regards to 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. A total of 38 subjects participated in the study. A summary of the calculated mean responses obtained from the students and instructors on the initial prototype is provided in Table 1.

Table 1. Summary of Results (Mean Responses)

Category	Avg. Response	Orange County Fire Department n=6	City of Orlando Fire Department n=15	Orlando Medical Institute n=17
Benefit to training/Meeting training objectives	6.53	6.75	6.12	6.74
Usability	6.54	6.87	6.22	6.53
Realism	6.08	5.85	5.82	6.57
Physiological/Anatomical Accuracy	6.52	6.35	6.43	6.78
Motivation to Use	7.15	7.33	6.67	7.46

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

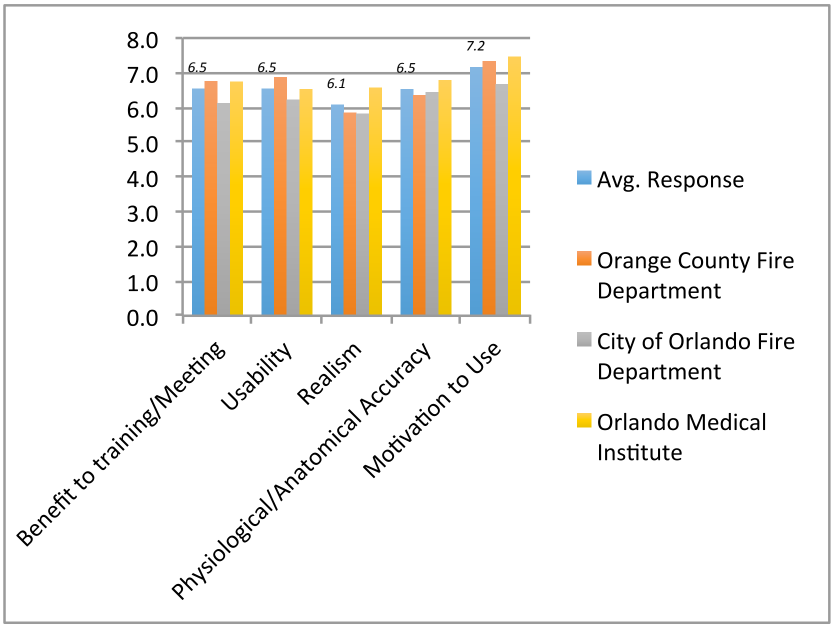

Figure 5. Average Scores per Group

Below is a list of significant findings obtained through both the questionnaires and these focus groups:

- The participants commented that the Venipuncture and Phlebotomy training system could be beneficial to the current training curriculum.
- Overall, the participants concluded that the system was user friendly, easy to maintain, and minimized the 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.
- Most trainees stated that the PTT has more realistic skin texture and appearance and that they could not see visible marks from previous punctures.

It is interesting to note that the highest scores obtained were from the Orlando Medical Institute, which consisted of paramedic students finishing the course of study. It is possible that the higher scores they provided were due to the fact that they have not performed the procedure on live patients as much as the more experienced EMTs and Paramedics from the other two groups.

Number of Punctures

During the course of both days of testing, the number of punctures was recorded to collect durability data which will help determine life cycle costs for the Venipuncture and Phlebotomy PTT. The same skin patch and tubing were used for all three test groups and a total of 144 punctures were recorded using different gauge needle catheters ranging from 16 to 24 gauge as depicted in Table 2.

Table 2. Punctures Noted during Usability Testing

Participant #	Guage Needle					Total Punctures by Participant
	16	18	20	22	24	
Total By Gauge	2	59	39	31	13	144

The number of punctures far exceeded the requirement and the skin patch and tubing used for the testing not only sustained 144 punctures, but also still retained its shape and appearance as depicted in Figure 6.

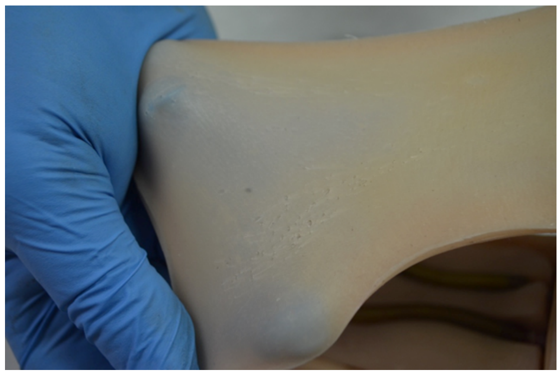

Figure 6. Skin Patch after 144 Punctures

6. Lessons Learned

Few challenges were encountered in the course of designing and developing this prototype. The major challenge involved scheduling and confirming participant availability for the usability studies, but since this effort was started early in the timeline, the team was able to successfully conduct three studies with three different groups. In future phases, it is expected that the challenge will be in conducting more thorough trade off analyses to determine whether hyper realistic anatomy and physiological response is more important than life cycle costs and sustainment.

7. Conclusion and Future Work

The research and development project resulted in a proof of concept prototype for the Next Generation Venipuncture and Phlebotomy Part Task Trainer that satisfies the requirements identified after task analysis and interviews with SMEs. The final prototype is a stand-alone PTT that was developed with the aim to provide users with a realistic and haptic training experience. The current design focused on addressing the gaps and development costs for venipuncture and phlebotomy training identified by SMEs at the U.S. Army MSTCs. Usability testing data gathered from paramedics employed at local fire departments and student paramedics at a technical school indicate that the prototype has potential to improve the current training capabilities available to the warfighter. Future activities involve the validation of the concept at an MSTC and identification of improvements to the design.

Having visited several MSTCs and observed how the end user trains intravenous infusions and injections, the following design considerations should be explored during future development of the PTT:

- Static arm with removable skin cartridges that will provide veins of different sizes and tactile feeling on multiple locations on the arm.
- Static arm in different sizes and skin tones representative of different demographics.
- Simulated veins will be located at various depths within the skin.

- Simulated veins that roll underneath the skin.

8. Acknowledgments

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