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Assessment of Tattoo and Silicone Wounds in Terms of Time of Treatment and Perceived Treatment Quality

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ASSESSMENT OF TATTOO AND SILICONE WOUNDS

IN TERMS OF TIME OF TREATMENT

AND PERCEIVED TREATMENT QUALITY

by

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ABSTRACT

At the point of injury, critical medical tasks include locating and identifying an injury as well as applying the appropriate initial care. Over the past decade, to increase the fidelity of wound representation and ultimately the quality of medical care, a considerable amount of research and development has occurred to improve simulated wounds during training, primarily at the point of injury. As material and techniques mature and as more relevant data is collected on tissue properties, examining what fidelity is required for training at the point of injury is crucial. The main objective of this effort was to assess a three dimensional silicone wound versus a two dimensional tattoo wound for training and to examine differences in user perceptions and treatment time.

This was accomplished with a test population of 158 City of Orlando Fire Department First Responders which were randomly assigned to each group (three dimensional silicone wound group versus a two dimensional tattoo wound group). The data analyses incorporated the use of non-parametric statistics (Mann-Whitney U Test) to compare the differences between the two groups on depth perception, sense of urgency, immersion, and time on task.

Other factors that were examined included the costs for the average tattoo wound and silicone wound as well as the number of uses before the synthetic wound is visibly damaged. The data results indicated that at the point of injury, there were relatively few statistically significant differences in the survey data or time on task between the silicone and tattoo wounds. Additionally, the cost analysis revealed that the silicone wound is significantly more expensive than the tattoo wound. Supporting the military and civilian first responder communities, the

results of this study provides statistically reliable data on the use of trauma tattoos as a tool for mastering point of injury treatment during training exercises.

Dedicated to my daughter, Elise – hoping to inspire her to never give up on her dreams! "I can do ALL things through Christ who strengthens me." Philippians 4:14

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I am grateful to my God, the ultimate source of strength, perseverance and wisdom. – "Study to show thyself approved." 2 Timothy 2:15

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LIST OF ACRONYMS AND ABBREVIATIONS

2D	Two Dimensional
3D	Three Dimensional
ARL	Army Research Lab
ATLS	Advanced Trauma Life Support
ATO	Army Technology Objective
CITI	Collaborative Institutional Training Initiative
EMT	Emergency Medical Technician
Gen 1	General Statement 1 on Survey Instrument
H	Hypothesis
ICF	Informed Consent Form
IED	Improvised Explosive Devices
Immtotal	Average of the totals of the immersion scores
IRB	Institutional Review Board
K-S	Kolmogorov-Smirnov significance
M	Mean
Mdn	Median
M/F	Male/Female
N	Sample size
OFD	Orlando Fire Department
p value	Probability of the occurrence of a given event
r	Effect size
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
TAM	Technology Assessment Model
U	Mann-Whitney U Test Result; a measure of the central tendencies of the two groups
UCF	University of Central Florida
USAMRMC	U.S. Army Medical Research and Materiel Command
z	Amount of standard deviations an item is from the mean

CHAPTER ONE: INTRODUCTION

Moulage, the art and science of depicting fake or simulated wounds for the purpose of training, has been around since ca. 2050 B.C. Egypt (Schnalke, 1995), but appears to have been documented and refined in the early 1700's by Abraham Chovett in London (Micozzi, 1997; M. B. H. Pettitt, 2015). According to Merriam Webster (Webster, 2016), the term *moulage* is of French origin and means to build mock injuries from a mold or from a molding process. Wax has historically been used to provide the basic shape of wounds (Schnalke, 1995). Prior to the 1990's, the only option for synthetic wounds or moulage was to use molded plastics or to individually craft pieces using the ancient practice of hand worked wax. The plastic moulage pieces, although durable were not visually realistic (Figure 1). Alternatively, the wax moulage was typically very visually realistic (Figure 2), but could only be used until a bandage compressed the wax as shown in Figure 3, or until temperatures were high enough to cause the wax to deform.

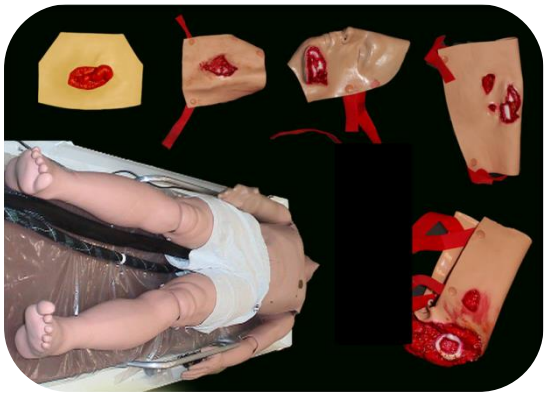

Figure 1: Plastic Moulage

Figure 2: Creation of Wax Moulage

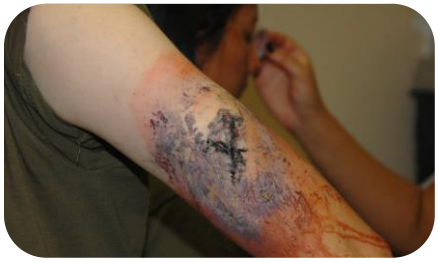

Figure 3: Wax Moulage after applying a Bandage One Time

Additionally, wax moulage had limited re-use since each wound was uniquely created by a specially trained artist using special tools, wax, and paints. Driven by the Severe Trauma Army Technology Objective (Norfleet, 2006), the U.S. Army conducted research from 2007 to 2010 to improve upon the state-of-the-art in moulage resulting in a revolution in moulage development and production. This research matured the process of silicone sculpting, coloring, and manufacturing and enabled the production of highly realistic dimensional wound facsimiles and bleeding moulage for training wound identification and hemorrhage control tasks.

Silicone and Tattoo Moulage

Previous research has been conducted on the usability and training effectiveness of high fidelity dimensional silicone moulage (Figure 4) (Sotomayor & Salva, 2009; Wiederhold, Salva, Sotomayor, Coiro, & Wiederhold, 2009). Part of this research included observational studies

that focused on durability of the wounds as well as timed studies on applying high fidelity wounds to actors during training exercises. According to Sotomayor et al, (2009) and Wiederhold et al, (2009), these efforts indicated definite substantial training benefit in using high fidelity silicone wounds over the previous method of hand crafted, one time use wax wounds.

Figure 4: Silicone Moulage

According to Sotomayor et al, (2009) total application and removal times for silicone moulage was approximately 23 to 28 minutes (see Table 1 and Table 2) compared to the minimum application time for wax moulage of one hour. The results indicated that the silicone moulage needed little to no reapplication during an eight hour military training day with temperatures 80 degree or higher.

Table 1: Time Data with Human Actors

Step	Time
Application	10 Minutes
Set Up Kit	10 Minutes
Removal	3 Minutes
Clean Up Kit	5 Minutes

Table 2: Time Data with Patient Simulators

Step	Time
Glue Application	2.6 Minutes
Glue Dry Time	6.3 Minutes
Make Up Time	9.4 Minutes
Clean Up Kit	4.8 Minutes

Note: Data in Table 1 and Table 2 derived from Sotomayor, et al, 2009.

Although the silicone wounds have proven effective, there remains a need to create inexpensive synthetic wounds with faster and easier application processes. An inexpensive solution is the use of tattoo moulage. One potential application illustrating the use of tattoo moulage may be found in a live military training exercise, where a patient actor needs to quickly display a wound sustained during the scenario. The tattoo could be easily accessed from a pocket and quickly applied with water by the patient actor. Another potential use of tattoo moulage can occur when the same patient actor (or mannequin) is simulating several different

types of wounds for sequential events, and tattoos need to be quickly updated to reflect different wounds in each event.

The idea of using children's temporary tattoo technology to create inexpensive, quick, and easy to apply wounds (Figure 5) appears to be a relatively new idea, possibly originating in 2011 with a creative use of Halloween tattoos as shown in Figure 6 and makeup (Zachary, 2011).

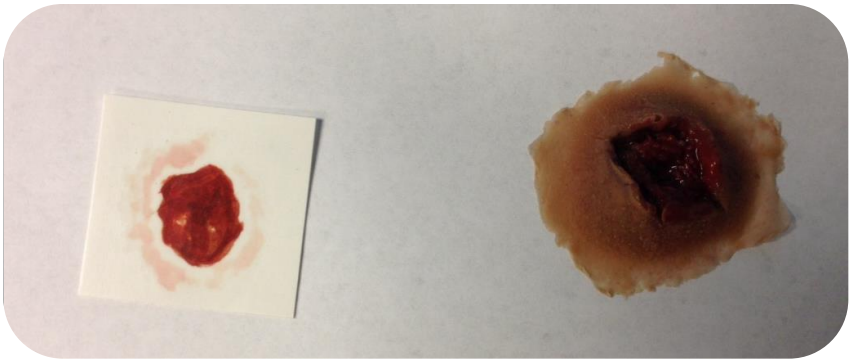

Figure 5: Tattoo (left) vs Dimensional Silicone (right) Wound

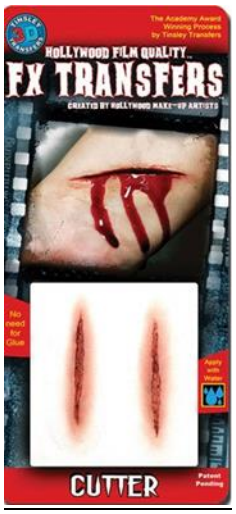

Figure 6: Tattoos for Halloween

Note: Image in Figure 6 is from a web site (Transfers, 2016).

Additionally, a small business operated in Central Florida has recently experimented with creating realistic trauma tattoos based on actual wounds (Simetri, 2014). After a thorough review of the literature, it appears that no formal studies have been completed on the usability or training value of two dimensional trauma tattoos. An initial self-application of the trauma tattoos indicates a maximum of 2 to 3 minute application time and a 12 plus hour durability on clean, smooth skin (Body hair and body oils as well as sweat will prevent the tattoo from fully adhering). One of the obvious differences between the silicone and tattoo moulage technologies is that the trauma tattoos have little to no depth or texture. Dimensional silicone moulage provides a tactile presence that can be detected in the dark. Further, it also provides tactile queues when doing a body sweep procedure where the medical provider passes their hands in areas of the body where vision may be obstructed, such as under clothes or on the surface of the body closest to the ground. Dimensional silicone moulage also provides a three dimensional cavity that can be packed with gauze to slow bleeding. The trauma tattoos provide only a slight difference in texture when applied to a surface. One of the questions is whether or not wound depth and tactile sensation are required for effective training of tasks at the point of injury. What effect do visual and haptic feedback have on the accurate assessment of wounds by trainees?

Anecdotal Use Data on Trauma Tattoos

A first responder training exercise was conducted July 16th, 2014 in Orlando, Florida (see Figure 7), where preliminary durability and application time data was collected on the tattoos. Over the course of the morning, seven separate groups were sequentially exposed to the tattoo wound moulage as depicted in Table 3.

Figure 7: First Responder Exercise Using Tattoo Moulage

Table 3: Initial Trauma Tattoo Use

Time Start	Time End	Total Time	Activity
8:20am	8:55am	35 minutes	Apply 2-3 wounds to each of 4 human actors
8:55am	9:10am	15 minutes	Apply 1-2 wounds each and coagulated blood to 3 mannequins
9:10am	9:25am	15 minutes	Add coagulated blood to wounds on 4 human actors
9:30am	12:00pm	150 minutes	Exercise with 7 different training groups

Three groups of law enforcement officers and another four groups combining law enforcement officers with fire and rescue groups found the casualties and assessed the patients at the point of injury. The synthetic wounds were not bandaged, as treatment was not the goal of this training exercise. No touch-ups were required between scenarios. Based on observations, these two-dimensional wounds appeared to provide the necessary queues for the first responders to follow the appropriate treatment procedures.

Initial Cost Analysis

The cost of individual trauma tattoo pieces ranges from 50 cents to $3.00, where smaller wounds are cheaper, and larger wounds are more expensive. Additional costs to apply these wounds include alcohol pads to clean the area prior to application. The silicone moulage is available as a commercial kit. A standard kit contains 25 wounds with adhesive, blending wax, simulated blood, moulage make-up and blending tools. It is available for approximately $3000 ("Simulaids," 2014). This averages to $120 for each individual silicone wound. The price comparison between tattoo and silicone moulage however is not as simple as comparing price points ($120 to $3). The silicone dimensional wounds may be reapplied for additional training sessions over several days whereas each trauma tattoo may only be reused over the course of a day. Also, some of the silicone wounds have an embedded tube which support the extra feature of simulated bleeding. The tattoo moulage can give the appearance of bleeding by applying simulated blood on top of the tattoo attached to the patient actor or mannequin.

Table 4 illustrates the projected cumulative costs of using the reusable silicone wound and the trauma tattoo moulage over the course of five years. According to one manufacturer, the silicone moulage should last at least ten uses (A. Alban, personal communication, April 5, 2016), depending on the amount of adhesive and whether or not the silicone moulage is properly cleaned after each use. With a very conservative estimate in the calculations below of twenty uses per silicone wound and only one use for each tattoo, and with the assumptions on simulated wounds required per year, the silicone moulage appears to be *twice* as expensive to use as the trauma tattoos. Based on this cost difference and the findings from the initial usability studies, additional research is warranted.

Table 4: Cost Comparison of Reusable Silicone Wounds vs. Disposable Trauma Tattoos

Year	Simulated Wounds Per Training Session	Training Sessions Per Year	Simulated Wounds Required Per Year	Silicone Wounds Cost Per Year (20 sessions/wound)	Silicone Wounds Cumulative Cost	Trauma Tattoo Cost Per Year (High = $3/tattoo)	Trauma Tattoo Cumulative Cost (High)	Trauma Tattoo Cost Per Year (Low = $0.50/tattoo)	Trauma Tattoo Cumulative Cost (Low)
1	25	100	2500	$15,000	$15,000	$7,500	$7,500	$1,250	$1,250
2	25	100	2500	$15,000	$30,000	$7,500	$15,000	$1,250	$2,500
3	25	100	2500	$15,000	$45,000	$7,500	$ 22,500	$1,250	$3,750
4	25	100	2500	$15,000	$60,000	$7,500	$30,000	$1,250	$5,000
5	25	100	2500	$15,000	$75,000	$7,500	$37,500	$1,250	$6,250

CHAPTER TWO: LITERATURE REVIEW

The literature review focuses on several relevant areas that investigate the usability of moulage for training. First, the need for better simulations at the point of injury will be explored, followed by documenting past research and development efforts to enhance training of severe trauma. Next, a summary of the validity and history of using patient actors, mannequins, cadavers, as well as live tissue for medical training is presented. Additionally, the history and use of both moulage and temporary tattoos will be explored. Finally, findings from a recent usability study are discussed.

The Need for Better Simulations at the Point of Injury

Reviewing the historical causes of death at trauma centers (Acosta Md et al., 1998) reveals that incorrect identification of injuries during the initial diagnosis accounts for 30% of deaths at a typical trauma center. According to Merriam Webster (Webster, 2016), *trauma centers* are defined as a hospital unit specializing in the treatment of patients with acute and life-threatening traumatic injuries. The point of injury (either military or civilian) to the initial assessment at a trauma center is the primary focus of this literature review. This includes the first responder at the point of injury, the ground or air evacuation, and the initial assessment at a fixed facility as well as transferring the patient from one treatment location to the next.

Previous studies (National Academies of Sciences et al., 2016; Trunkey & Lim, 1974) have focused primarily on preventable deaths, and as a result overlooked critical information regarding initial diagnosis and treatment at the point of injury. The 1998 Acosta study is more

relevant to the military's point of injury diagnosis and care because it reviewed eleven years' worth of patient data on patient deaths, including those who died on the way to the trauma center or within the first few moments of arriving at the trauma center. The study revealed that there was a *higher* mortality rate for penetrating wounds, where the skin is broken, than for blunt trauma, where the skin is not broken, but internal bleeding or severe bruising may occur. The results showed that the cause of death changed greatly as the minutes and days passed. Initially, in the first 10 minutes to 1 hour after the injury, also referred to as the "platinum 10 minutes" to "golden hour" (Rogers, Rittenhouse, & Gross, 2015), death was typically attributed to rapid blood loss and/or lack of oxygen. As time passed, death was related to multiple injuries and secondary effects such as infections. This highlights the need for more focused training on the care of wounds as well as examining the effectiveness of tools, methods and approaches.

Further demonstrating the need for better training tools, a series of military trauma cases were photographed and documented in 2008 (Nessen, Lounsbury, & Hetz, 2008), highlighting numerous examples of the severity of injuries and the need to enhance training. With 80 case studies, severe injuries are shown on almost all areas of the body, demonstrating a need for a wide range of medical skills and procedures, and consequently training devices and systems. Nessen, et al, (2009) also provides an in-depth and realistic pictorial representation of various injuries to detail the representation of trauma and support the modeling of synthetic wounds.

Another study based on the "The Joint Theater Trauma Registry" (Owens et al., 2008) analyzed 1,566 U.S. combatants with a total of 6,609 combat wounds from conflicts in the Middle East. Eight percent were related to head wounds, 6% related to the eyes, 3% to the ears, 10% to the face, 3% to the neck, 6% to the thorax, 11% to the abdomen, and 53% to the

extremities. Gunshot wounds accounted for 18% of these wounds, while explosions were 78% of the wounds. The study conclusions suggest that the wounding patterns are similar to previous conflicts, except that there is *greater* frequency in head and neck wounds. Additionally, with 78% of the injuries originating from an explosive mechanism, blast injuries account for the *highest* proportion of all injuries in any large-scale conflict to date. These facts led to the prioritization of wound types for modeling penetrating wounds in training casualty care. Next, recent and emerging research in the area of severe trauma simulation will be examined.

Research and Development Focused on Severe Trauma Simulations

Acknowledging the need for better simulations of severe trauma, from 2007 to 2010, the U.S. Army Research Development and Engineering Command Simulation and Training Technology Center led a joint Army Technology Objective (ATO) with the U.S. Army Medical Research and Materiel Command (USAMRMC), titled Severe Trauma Simulations (M. B. H. Pettitt, Norfleet, Jack E., Pike, William Y., 2013). The initial purpose of the ATO was to research and develop innovative technologies to realistically simulate the look, feel, and smell of severe trauma to prepare medics, combat lifesavers, and Soldiers to deal with the injuries encountered on the battlefield. The military users that participated in the test events of these efforts saw immediate training program benefits and the users helped to quickly transition these efforts to field use (Blackman, 2009). The innovative technologies included:

- Simulator worn gunshot wounds, amputations, and a flail chest (i.e., a medical condition that occurs when part of the rib cage breaks under extreme stress and becomes detached from the rest of the chest wall) were created with new silicone techniques;

- Static (non-bleeding) and dynamic (bleeding) kits for attaching customized silicone wounds to various parts of a mannequin or patient actor;
- Poly trauma scenarios composed of facial/airway trauma, flail chest and multiple gunshot wounds to the leg;
- Reusable injury creation kits and prosthetics for use over multiple training sessions;
- Improved realism in representing skin, flesh, bone and blood; and
- Robotic amputations introducing movement to indicate agony and provide a visible sign of life.

One outcome of these severe trauma projects was the research and development of the Multi Amputee Trauma Trainer (MATT). The MATT system has animatronics enabling both legs to move via remote control. This system was proven to be an effective training device (Allen, 2011). It has been fielded to both civilian and military first responder training communities.

Additionally, there are numerous trauma trainers in use (Kaufmann & Liu, 2001). One example is the Trauma-man system which is a surgical trainer for chest tube insertion, cricothyroidomy, needle decompression, tracheostomy, pericardiocentesis and diagnostic peritoneal lavage. The Trauma-man has been assessed in a study with 128 participants against traditional classroom instruction and proven effective (J. S. Davis et al., 2012), specifically for chest-tube insertion. Although, there is evidence that systems like the Trauma-man provide training value, they are full task trainers and not just pieces of moulage. Many of these systems have a high initial purchase price. Additionally, many of these systems are expensive to refurbish and repair, and some require that the equipment be sent back to the manufacturer. These challenges continue to point to a possible use for the tattoo moulage in training.

Medical Training Using Patient Actors, Mannequins, Cadavers and Live Tissue

Many of the medical training and skill assessment classes have historically been conducted using dimensional moulage and well-trained patient actors (Collicott & Hughes, 1980); (Trauma, 1997); (Tostaine & Fareed, 2010). A patient actor with moulage may simulate an actual trauma patient, however, a typical healthy patient actor cannot depict the same physiology (heart rate, pulse, etc.) of an injured or sick patient; thus a moderator or instructor is still needed to provide information regarding changes in vital signs.

A computerized patient simulator may create a more realistic training scenario because it provides accurate and consistent real-time changes based upon trainee interventions. Patient simulators exist with varying fidelity. Non-electronic mannequins as shown in Figure 8 (image from NASCO website (NASCO)) represent the low end of patient simulator capabilities and are still used today for basic skills training (*Adult Life Suppport ALS*, 2015). Since the 1990's, sophisticated patient simulators, originally developed for anesthesia training, have been incorporated in medical training (Kapur & Steadman, 1998). These simulators physically mimic the human form and often have complex mathematical models to represent different injuries, illnesses, and treatments. They are used for training basic lifesaving skills to surgical interventions. Moulage and limbs representing a variety of trauma can be added to these simulators to match specific training objectives (see Figure 9).

Figure 8: Low Fidelity Mannequin Used for Basic Skills Training

Figure 9: High Fidelity Mannequins

Several studies have compared the increase in trauma management skills of medical students operating on a patient simulator to students taught only with a traditional, classroom-based lecture. In early studies (Gilbart, Hutchison, Cusimano, & Regehr, 2000) when the goals of the medical communities were to insure that new mannequins were "at least as good" as the traditional training, the increase in trauma management skills of medical students were compared to students trained on patient simulators and students taught through lecture. Both training groups outperformed the control group receiving no instruction; however no significant difference in trauma assessment test scores was shown in the two trained groups. The authors concluded that the fact that the simulators did not produce a negative training outcome was

considered positive. In another study (Marshall et al., 2001), a patient simulator was successfully used to train military emergency personnel in trauma assessment skills. In this study, trauma management skill scores increased 23% in critical treatment decisions, 25% in potential for adverse outcomes, and 47% in team behavior after the course using a high fidelity patient simulator.

An advantage has been shown in using a computer-controlled simulator to train students from a remote site, distant from the actual simulator (Treloar, Hawayek, Montgomery, & Russel, 2001). In this early study, using video and audio feeds, students remotely assessed and prescribed treatments for their patient, represented by a high fidelity patient simulator. They observed the results from the remote treatments made on the patient simulator and adjusted care as appropriate. Using a pre- and post-test of perceived training value, students rated this training highly and more beneficial than their previous traditional classroom training.

Many other studies have been conducted validating the use of patient simulators to train and test trauma assessment. Simulators have been used in trauma scenario tests with surgery interns after a standard Advanced Trauma Life Support (ATLS) course (Ali, Gana, & Howard, 2000) (Marshall et al., 2001). After ATLS training, the ratings in critical treatment decisions improved. Similarly, in a study (Holcomb et al., 2002) on trauma team performance using an advanced patient simulator, it was shown that the patient simulator could be effectively used for testing trauma assessment. None of these studies, however, compared training or testing methods with a patient simulator to conventional methods involving patients with moulage.

In 2003, the first randomized comparison of trauma assessment training methods using a mannequin-based patient simulator versus a moulaged patient (Lee et al., 2003) was conducted. Using a test population of sixty, this study showed that interns who trained with a simulator demonstrated a small but statistically significant improvement on individual trauma assessment tests. Specifically, simulator training resulted in higher scores in the identification and management of the injury. Higher scores suggest that there may be advantages to trauma assessment training in a scenario where physiologic changes are observed and hospital type monitoring equipment provide constant information regarding patient vital signs; therefore eliminating or minimizing the need for a moderator. Additionally, the computer-controlled capabilities of a patient simulator provided reproducible trauma scenarios, compared with the potential variability with a verbal moderator and patient actor.

In 2010, a study was published that compared two-dimensional traditional classroom training with three-dimensional moulage on patient actors for a dermatology teaching course (Garg, Haley, & Hatem, 2010). The objective of this course was to teach students to identify common skin problems. With a sample size of 90 trainees, results showed a definite advantage to the three dimensional moulage on patient actors over the two dimensional textbook style instruction. This study provide foundational research from which this dissertation leverages using two dimensional trauma tattoos. The differences between the previous and the proposed study is that traditional text book learning lack exposure to a patient actor or to a simulator which provides an extra level of immersion and increases the perceived importance of a correct diagnosis. Further, the latter study was based on skin abnormalities, not on trauma.

Cadavers and live tissue (animals) have also been used for trauma training (Kaufmann & Liu, 2001). However, application of traditional moulage is not used on cadavers or animals since the tissue itself can depict the trauma. During cadaver training events, fresh cadavers are preferred to minimize the tissue degradation that occurs in older preserved cadavers. There is little to no repeatability since once a cadaver is used for a particular training scenario, tissues are damaged or destroyed making it unlikely to be reused. Other limitations for its use include: cadaver tissue and vessels texture as well as appearance are very different from living tissue and vessels. Further, cadaver tissue is typically the wrong color, dehydrated, and the cadaver vessels have often collapsed.

More recently training events have been conducted with perfused cadavers (Aboud et al., 2011). In this training, fresh cadavers were hooked to pumps, fluids, and ventilators to simulate body fluids, breathing, and heartbeat. Traumatic wounds were inflicted on the tissues, allowing trauma teams to rapidly assess and treat the wounds. Overall, the training received high scores for realism, but trainees still noted that the cadaver tissue did not look, feel, behave or smell like living human or animal tissue. Smell is not a focus of the research for this project, however, studies have shown that malodors effect performance (Pike, 2017), so unusual or inappropriate odors are noted as a concern for future studies.

Trauma training with live tissue (typically goats or pigs) has been done for many years (Porter, 1999). The use of animals for medical training has also been highly criticized and questioned (English, 1989), yet there is unquantifiable value in the use of live tissue training. Essential military trauma training course reports the use of live tissue as a culminating event to a multi-day course (Sohn et al., 2007). During the study period, 327 soldiers participated and

completed the entire course. Based on data collected with surveys, pre- and post-tests, and after-action comments, 97% of the trainees indicated that their confidence and ability to treat combat casualties improved. Another study also showed a definite pathophysiological benefit to live tissue training because the trainees are treating a living creature (Reeds, 2010). Even with current and emerging technologies, the sense of *immersion* and *urgency* generated from treating a live being still appears challenging to recreate with any type of simulation system. However, there are several notable negative training issues with live tissue. The anatomy of a goat or pig is different from that of a human, especially when managing the airway or when treating trauma on the extremities. The neck and throat of animals are also anatomically different from humans as goats and pigs tend to have longer necks. The leg structures of the animals tend to be smaller and leaner than human arms and legs. Also, the presence of fur, horns, and hoofs can be distracting. Additionally, the physiology of these animals is distinct from humans, for example, pigs absorb drugs more quickly than humans, and require closer monitoring and increase doses of medicine (Kararli, 1995). Observing that there are still issues with many of the current methods for exhibiting trauma for training providers at the point of injury, other creative and innovative solutions are still sought.

Other Uses of Moulage and Tattoo Technology

The art of decorating the body with ink and paint has existed since ancient Egyptian times (Chaudhri & Jain, 2009). This practice was primarily done to enhance the appearance of beauty as perceived by the particular culture. The use of special effects make-up for entertainment dates back to 5th century BC Greek theatre (Hartnoll & Brater, 2012) where stage

make-up was primarily used to exaggerate expression and emotions. The use of special effects and make-up had a revolution with the advent of film in the early 1900's (Vinther, 2003). Like many areas of moulage and special effects, the film industry is lacking in scientific data on the effectiveness of these special effects. Most of the studies that have been done on special effects in film, have focused on the "how to's" and the emotional connection that is created from realistic moulage (Rooney, Benson, & Hennessy, 2012; Tan, 2008). Since the industry has continued to advance and become very successful and profitable allowing the production of more films, one can also deduce that moulage use is effective from an immersion and entertainment perspective. Some of the first films to use special effects and moulage include the *Hunchback of Notre Dame* in 1923 and the *Phantom of the Opera* in 1925 (Debreceni, 2013). Some of the more recent successes include *Avatar, Star Wars, Star Trek* and the entire genre of current horror films.

The use of inexpensive, temporary tattoos to quickly decorate the body is a much more recent custom (Kosut, 2006). As shown in Figure 10, these tattoos have most often been used to easily apply festive decorations to children. Additionally, children's temporary tattoos have been used and shown to add a sense of immersion and ownership in treating children's injuries (Franck, Allen, & Oulton, 2007), allowing children to point to a level of pain depicted on a temporary tattoo of a pain meter on their skin.

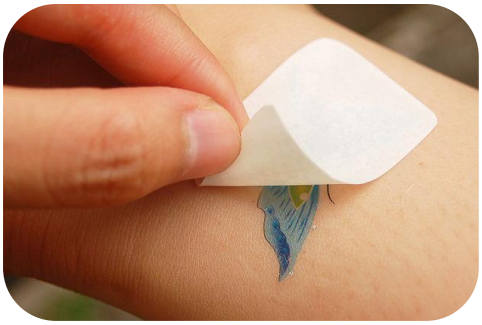

Figure 10: Application of a Decorative Tattoo

Note: Image in Figure 10 from website (wikihow.com, 2014)

Tattoos depicting trauma (Simetri, 2014) have recently been introduced as a trauma training option. These tattoos are based on the exact same technology as decorative children's tattoos, where images are printed on specialized paper ("Decal Paper," 2015). The images are transferred to the skin (or mannequin) with water. The tattoos are easily removed from the skin with soap and water. As a result, trauma tattoos easy to apply, disposable, and desirable as a training tool. They may be a low cost alternative to silicone wounds depending on the durability of silicone-based wounds. The cost comparison of the silicone-based wounds and trauma tattoos is captured in Table 4. However, costs may be irrelevant if the tattoos are not similarly effective in training at the point of injury. In response to moulage use and current applications, the following question needs to be addressed: are two-dimensional tattoos of wounds sufficient to support triage training at the point of injury?

Determination of User Population

As discussed in this literature review, the fidelity of simulated wounds at the point of injury is the focus of this research. The point of injury implies field level care where medical

supplies are limited and quick actions are required to stabilize the injury and sustain life (*Roles of Medical Care*). Tattoo wounds seem to be appropriate at this level of care because they provide a visual representation of the simulated wound on the arm. This allows the first responder to make the critical initial decisions on what type of field care is required.

Studies have indicated that there is a definite stress inoculation benefit to pre-exposing individuals to the graphic visuals of a military conflict (Hourani et al., 2011; Stetz, Long, Wiederhold, & Turner, 2008), prior to deployment. In these studies, training using detailed visuals was done while assessing stress levels (through objective measures such as heart rate monitors and subjective measures such as questionnaires). Trainees reported feeling better prepared, and for those that had already been deployed, better able to cope with past experiences. Deployed military personnel have also reported that the most meaningful and useful medical training occurs when the simulation devices provide training very similar to what medical personnel have seen in a real world situation (Sotomayor, 2009).

Usability Study

In September of 2015, a usability study of trauma tattoos was done in conjunction with an Anti-Terrorism Exercise in Orlando, Florida. The usability study focused on:

- User testing to assess general perceptions and acceptance of the tattoo moulage; and
- User testing to assess general tattoo wear and ease of removal on a patient actor.

Institutional Review Board (IRB) was requested and this study was found exempt (see Appendix A). Three groups were exposed to the same mass casualty scene with six casualties.

All the casualties had one to three simulated bullet wounds. Some casualties had bullet wounds on the extremities (see Figure 11), in general representing less severe wounds.

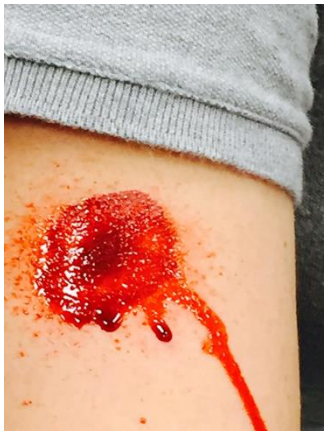

Figure 11: Simulated Bullet Wound to the Extremity

Other casualties had multiple bullet wounds to the torso (see Figure 12), in general representing more severe wounds, with the greater potential for loss of life. Wounds were represented by exit bullet wound tattoos and were not replaced between exercises. Simulated blood was sprayed on the wounds. Eleven first responders located the casualties, assessed the severity of the wounds, and provided immediate medical care as appropriate.

Figure 12: Bullet Wounds to the Torso

Before the training, participants were informed that they would be observed and photographed during the training and that participating in the study was optional. After each round of the training exercise, IRB approved Usability Questionnaires (Appendix B) were administered to the trainees. At the end of the entire exercise, IRB approved Usability Questionnaires (Appendix B) were administered to the patient actors. A 7-point Likert scale was used to increase fidelity and validity on the subjective evaluation of the survey topic statements. Participant results from the survey instrument are shown in Table 5. Participants provided responses to their impressions of the moulage using a scale of one to seven (with one representing least favorable and seven representing most favorable). The sample size was 11, with all participants being males. Table 6 presents the results of the survey statements for the patient actors. The sample size was six, with two females and four males.

Table 5: Participant Results from Usability Study

Participant	improve the training experience	provide meaningful visual information	2D was appropriate	Provide enough detail to identify the wound	wound feels realistic	wound provides perceptual depth	tattoo was anatomically correct	accurate representation and location of landmarks	Benefit to training
1A	7	7	7	7	7	7	7	7	7
1B	7	7	6	6	5	4	5	5	7
1C	7	6	6	6	4	4	5	6	6
1D	3	6	5	4	3	4	4	5	5
1E	7	7	7	7	5	6	6	7	7
2A	7	7	7	6	6	5	5	5	6
2B	7	7	7	6	6	6	7	7	7
2C	6	6	6	6	6	6	6	6	6
2D	6	7	7	7	5	4	7	7	7
2E	7	7	7	7	7	7	7	7	7
3	7	7	7	7	7	7	7	7	7
Mean	6.45	6.7	6.5	6.3	5.5	5.45	6	6.3	6.5

Table 6: Usability Study Patient Actor Feedback

Participant	Easy to Apply	Comfortable to Wear	Easy to Remove
1	7	7	7
2	7	7	6
3	7	7	6
4	7	7	7
5	7	7	5
6	6	7	3
Mean	6.8	7.0	5.7

From the trainee feedback shown in Table 5, questions 1 and 9 highlighted the overall training value construct, yielding a mean score of 6.5 with a standard deviation (*SD*) = .95. Visual accuracy was indicated by the responses to questions 2, 7, and 8, providing a mean score of 6.33 with a *SD* = .82. Providing the appropriate depth for diagnosis was indicated by questions 3 and 6, providing a mean score of 6 with a *SD* = .99. Finally, whether or not the wound looked and felt right was indicated by questions 4 and 5, providing a mean score of 5.91 with a *SD* = 1.1.

From the patient actor feedback in Table 6, question one assessed the ease of application, yielding a mean score of 6.83 with a *SD* = .4. Question 2 assessed how comfortable the tattoo wounds were to wear, yielding an mean score of 7. Question 3 assessed how easy it was to remove the tattoo wound and provided an mean score of 5.67 with a *SD* = 1.5.

According to "Sample sizes for usability studies: Additional considerations" (Lewis, 1994), a sample size of five will show general trends This theory has been both supported (Nielsen & Landauer, 1993) and disputed (Spool & Schroeder, 2001). For the purpose of the Usability study, a sample size of 11 trainees and 7 casualties was sufficient to reveal trends

pointing to the need for additional survey statements as well as modifying the design of the experiment.

One observation from this usability study was that first responders treated all wounds and casualties as though they were not life threatening, even with multiple bullet wounds to the chest. Based on this observation, there was a need to add statements to the survey that allow the participant to rate the severity of the simulated wounds. A second observation made was after three rounds of assessment and treatment, the tattoos showed wear (Figure 13). Areas of the tattoos, especially the edges were worn off. This was most likely caused by a combination of applying the simulated liquid blood making the tattoos soft, applying bandages over the tattoos and leaving the bandages on (holding the moisture against the tattoo) for at least 30 minutes. A

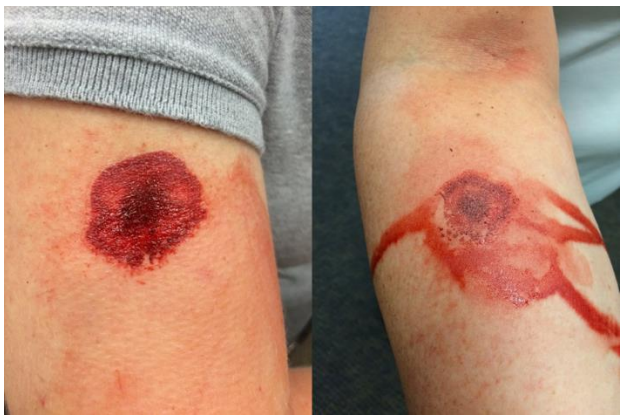

Figure 13: Tattoos after 3 Training Sessions

third observation from conversations with the patient actors is that the tattoos themselves were not likely the issue noted in the "Easy to Remove" category. The simulated blood, however was likely the problem as it stained the skin until the patient actors were able to remove it with a more thorough bathing in soap and water.

Purpose

The purpose of this study is to conduct an experiment that examines the training utility of two-dimensional tattoo moulage at the point of injury. Previous studies and published research on the use of moulage in training or entertainment is very limited and therefore the literature review for this effort is finite (Stokes-Parish, Duvivier, & Jolly, 2017). The literature indicates that this novel use of the tattoo has had no scientific evaluation to examine the utility of this technology. As a result, proven technologies such as silicone based three dimensional moulage wounds will be leveraged to complete this task. Additionally, research findings on patient actors, mannequins, and moulage in general will be leveraged as a starting point for this new research. Supporting the larger goal of identifying and testing a less expensive moulage for point of injury training, the objective of this study is to assess the differences in trainee treatment time and perception of the simulated wound when asked to treat a three dimensional silicone wound and a two dimensional tattoo wound.

CHAPTER THREE: METHODOLOGY

Building on the research and usability studies already discussed, several data collection activities were completed to explore the training utility of the two-dimensional trauma tattoo moulage compared to three-dimensional silicone moulage. The same simulated wound was used for both types of moulage and included a participant group of EMT's. Three different simulated wounds were considered for this study. These injuries were based on injuries typically trained in military exercises (e.g., bullet wounds, blunt trauma, and lacerations from improvised explosive devices or IED's). The three simulated wounds considered were:

1. Bullet entry wound with no simulated bleeding (as shown in Figure 5);
2. Blunt trauma causing bruising with no abrasion or broken skin, possibly including swelling (also referred to as a hematoma); preliminary concepts shown in Figure 14 and Figure 15; and
3. Large laceration through the fatty tissue (see Figure 16) with simulated bleeding.

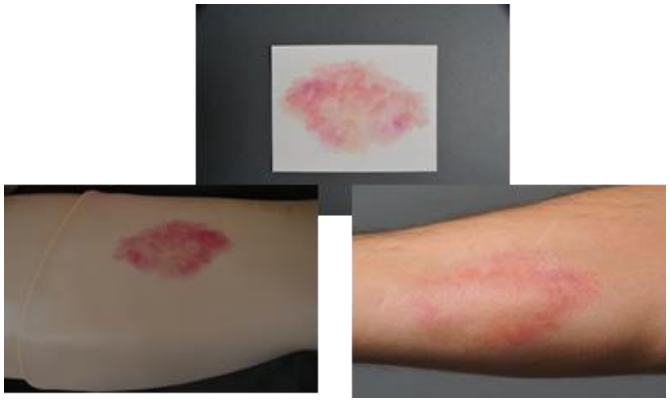

Figure 14: Bruise Tattoo on Simulator (left) and Person (right)

Figure 15: Silicone Bruise Moulage

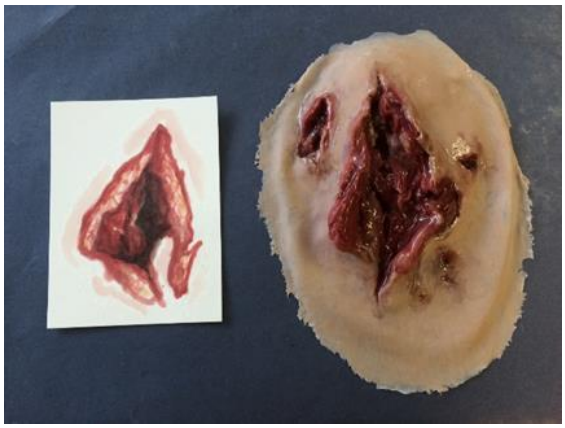

Figure 16: Laceration through the Fatty Tissue

A low cost wound with perceived depth was desired for this experiment. The cost of producing the silicone wounds is driven by the variation in color, depth complexity, and the size of the wound. Because bleeding and depth were desirable for the first assessment of the tattoos and because a smaller silicone wound is less expensive, a simulated bullet wound was chosen. Every effort was made to insure that the silicone and tattoo moulage matched in scale, color, and appearance as closely as possible.

Hypothesis Discussion

This research examines the differences between a flat tattoo type wound and a three-dimensional silicone wound to understand the impact of immersion, sense of urgency, visual cues and time on task at the point of injury. According to Merriam Webster (Webster, 2016), *immersion* is defined as complete involvement in an activity. This sense of immersion has been further defined as having three distinct stages (Jennett et al., 2008), engagement, followed by engrossment, then complete immersion. Engagement occurs when the user takes interest and attempts to understand the system or situation. Engrossment occurs when the user begins to accept the system or situation as real. Complete immersion occurs when the user is no longer aware of their surroundings and is focused on the system or situation. Several survey statements were structured to assess immersion and urgency. Sense of urgency has been shown to be related to immersion. Typically, as someone becomes more immersed, their focus increases and they more quickly perform the task at hand. Urgency or time on task was assessed by measuring the time to actually treat the simulated patient. Urgency was also assessed with several statements on the survey instrument. Visual cue identification varies by individual and circumstance (Jacobs, 2002). Circumstances that cause this variability include inconsistencies in the environment and whether or not the visual representation changes inappropriately or too frequently. For the trauma moulage, inconsistent visual cues may be attributed to the location of the wound, for example placing a simulated bullet wound directly over the heart, which does not result in a quick simulated death. Dynamic visuals to trauma moulage may result in changing shape or color in an unrealistic manner. These two visual factors were regulated by placing the trauma in non-life threatening locations and replacing the trauma moulage when it began to show signs of wear.

Since participant reported data on sense of immersion, sense of urgency, and visual cues are desired, previously proven survey instruments were assessed and leveraged. Several published survey instruments have been used and proven to indicate immersion (Jacobs, 2002; Witmer & Singer, 1998). The Technology Assessment Model or TAM (F. D. Davis & Venkatesh, 1996) has also been shown to accurately assess self-reporting perceptions on realism and ease of use. A survey instrument was developed specifically for this experiment which included a combination of the findings from these three standardized questionnaires that specifically targets the user perceptions of the tattoo and silicone moulage. (Appendix C).

The following section elaborates on the research and null hypothesis, independent and dependent variables as well as identifying potential confounding variables.

Research hypotheses:

H1 - At the point of injury, a tattoo wound provides the same *visual depth cues* as a 3D silicone wound of the same injury.

H2 – At the point of injury, a tattoo wound provides the same *sense of urgency* as a 3D silicone wound of the same injury.

H3 – At the point of injury, a tattoo wound provides the same *immersion* as a 3D silicone wound of the same injury

H4 - At the point of injury, a tattoo wound provides the same *general perceptions* as a 3D silicone wound of the same injury.

H5 - At the point of injury, a tattoo wound provides the same *treatment times* as a 3D silicone wound of the same injury.

Null hypothesis: At the point of injury, three dimensional silicone wounds will have a statistically significant difference in sense of immersion, sense of urgency, and awareness of dimensional cues than a tattoo wound of the same injury.

Independent variables: Variables that may affect outcome include simulated bleeding at the injury site and type of moulage material (i.e., silicone or tattoo).

Dependent variables: Variables influenced include perception of depth, sense of urgency, sense of immersion, general perceptions, and time to complete medical treatment.

Identifying confounding variables: To minimize variability in the test subjects, testing was done during a three week training exercise using the City of Orlando Fire Department (OFD) First Responders. Participants were randomly assigned to two separate groups. Half of the participants experienced the tattoo wounds while the other half of the participants experienced the silicone wounds. Survey instruments included a questionnaire regarding years of experience and/or training to clarify experience levels. To further minimize variability in the training site, the amount of simulated bleeding at the injury was standardized by spraying the same amount of simulated blood on the simulated wound before each participant. The location was a temperature controlled training building with two side-by-side adjoining rooms. This standardized the environmental conditions such as lighting, noise and temperature. Finally, the intention was to replace the tattoos wounds after every use to avoid any differences in appearance or texture from

repeated use. The plan also included repairing or replacing the silicone wounds as needed, or after three of four uses per the manufacturer's recommendation.

IRB Procedures

As human subjects were used in the training exercises, an IRB was required. The Army Research Lab (ARL) sponsored this research and was able to conduct an IRB review process. The IRB determined that a full review was required and all paper work was completed. Data collection approval was granted on 16 September 2016 (Appendix D). Appendix D also contains the University of Central Florida (UCF) IRB concurrence with the ARL IRB approval.

In accordance with APA guidelines (Knapp, 2012), all data collectors were CITI (Collaborative Institutional Training Initiative) certified. The IRB protocol maintained that all participants' were given an "informed consent form" to read, date, and sign explaining the details of the research study to further the science of wound treatment, and that their identification would be kept anonymous (Appendix E). Per the informed consent, participation was voluntary and if the decision was made not to participant, the participant had the right to leave. As requested by the City of Orlando Fire Department District Chief, a brief scenario was read to the participants to put the simulated wound treatment in an appropriate context (Appendix F). Per IRB guidelines, only a nominal snack of candy, apples and water bottles was offered for their time and effort to complete the study.

Experiment Details

For the experiment, a between-subjects design was selected to prevent the introduction of confounding results from exposing each participant to more than one type of wound. To prevent the potential for Type II errors in this study, the goal for statistical power was set to the conventional level of 0.80. The alpha level was set to 0.05 to achieve 95% confidence. Since this study involved a comparison between the two groups (i.e., tattoo vs. silicone) and the null hypothesis was anticipated to be noticeable, a medium effect size of 0.50 was selected. Group A (tattoos) required a minimum sample of 64 participants. Group B (silicone) also required a minimum sample of 64 participants (Cohen, 1992).

During this experiment, the trainees (participants) were exposed to one type of simulated wound during a training exercise illustrated in Table 7 (Ormrod & Leedy, 2005). The subjects were divided into two groups of equal size. Each subject was exposed to one simulated trauma and asked to complete, IRB approved Survey (Appendix B). Two trainees participated in the experiment simultaneously, but in separate rooms (see Figure 17). Overall, the minimum number of desired participants totaled 128.

Table 7: Between-Subjects Design

Independent Variable	**Simulated Bullet Wound**	**Dependent Variables**			
		Time	**Immersion**	**Urgency**	**Depth**
Injury Dimension	2D (Tattoo)	$N = 64$			
	3D (Silicone)	$N = 64$			

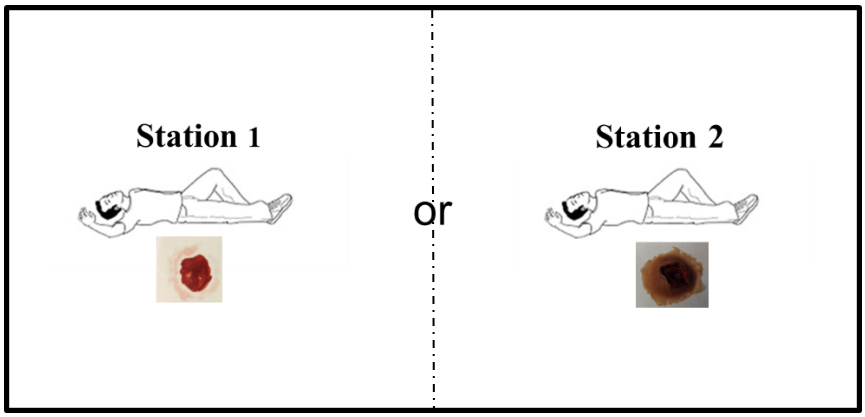

Figure 17: Notional Experiment Set-up

Because of the potential for data collection issues and sampling error, the desired sample size was increased to 150 trainees. The UCF College of Nursing was the first choice for an experiment site, because of their willingness to support and because of a similar skill set. However, the City of Orlando Fire Department approached the experiment team volunteering their Emergency Medical Technicians (EMT's) because of a planned city wide training event for the fall of 2016, making them an ideal local test population, with 100's of participants over several months.

To objectively assess the level of immersion provided by the two types of wounds, time to identify and treat was recorded. Observers with stop watches collected the following information for each test subject using either the tattoo or the silicone wound.

- Due to experimental set-up, overall time was defined as the time the participant enters the room, locates the wound, completes the treatment, and confirms with the observer that they are done.

- Due to the experiment set-up, time was defined as the time the participant locates the wound, completes the treatment, and confirms with the observer that they are done.

Trainee demographics to quantify age, gender and experience, along with subjective measures were also collected with the surveys created specifically for this experiment (see Appendix B). To increase fidelity and validity on the subjective evaluation of the survey topic statements, a 7-point Likert scale was used. The descriptors are given below:

- 1 = Strongly Disagree
- 2 = Disagree
- 3 = Somewhat Disagree
- 4 = Neutral (neither agree nor disagree)
- 5 = Somewhat Agree
- 6 = Agree
- 7 = Strongly Agree

The survey instrument created for this experiment consisted of 14 statements to assess general perceptions, depth cues, urgency, and immersion. The following two statements assessed general perceptions:

- The trauma moulage improves the training experience.
- There is a benefit from using the wound moulage for other training.

The following four statements were used to assess visual depth cues:

- The trauma moulage provides meaningful visual information on the type of wound.
- The wound moulage provides perceptual depth.

- The wound moulage feels realistic.
- The wound moulage is anatomically accurate.

The following four statements were used to assess sense of urgency:

- The wound moulage provides enough detail to identify the wound and treatment needed.
- Immediate medical care of the wound moulage is required.
- The amount of simulated blood affected my desire to assess and treat the simulated wound.
- I wanted to take care of the simulated patient.

The following four statements were used to assess immersion:

- The training held my attention.
- I lost track of time.
- I felt emotionally attached to the simulated patient.
- I was focused on the training.

The following statement was used to allow for open-ended comments: "Please provide any additional feedback on the simulated trauma you cared for."

Experiment Instructions for Participants

Before entering the room with the moulaged mannequins, basic instructions on managing the wound was given to the participant. Proper care of a bullet is documented in several military manuals (*Prehospital trauma life support (phtls) 8th edition (military) manuals*, 2015) (*Soldiers Manual and Trainer's Guide – MOS 68W Health Care Specialist*). Since this experiment used civilian first responders, basic care instructions were provided by the City of Orlando Fire

Department. For a wound with minimal bleeding (Hemorrhage – Life Threatening), general procedures for proper assessment and care include applying direct pressure and using either standard gauze or hemostatic agent impregnated gauze dressing. The details from the City of Orlando Fire Department training manual are shown in Figure 18.

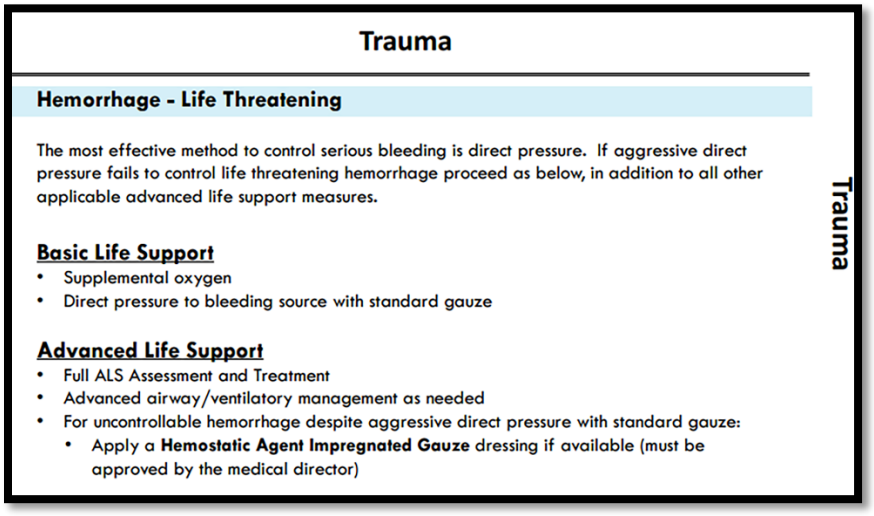

Figure 18: City of Orlando Fire Department Instructions on Hemorrhage Control

Materials Required

The City of Orlando Fire Department specified the desired materials for field dressings. This included one roll each of rolled gauze and simulated clotting rolled gauze, and two extra-large sized rubber gloves per simulated wound assessment as well as a pair of medical scissors for each of the two treatment stations. Two hundred and fifty tattoos wounds and 30 silicone wounds were ordered. Each individual tattoo was projected to last for two applications. The silicone wounds were projected to last a minimum of five applications. Appropriate adhesive gel and adhesive remover for the silicone wounds was ordered as well as simulated blood for the

bullet wounds. Alcohol, paper towels, and WD40 were also acquired to clean the mannequins. A summary of the pilot and experiment expenses is presented in Table 8. Finally, paper surveys and clipboards were used for data collection. Stop watches were also used to measure time on task. Time data was manually recorded on paper by experiment observers.

Table 8: Pilot and Experiment Expenses

Item	**Quantity Ordered**	**Per Box/ Package**	**Total Ordered**	**Individual Cost ($)**	**Cost ($)**
Gauze	12 boxes	12	144	13.24	79.44
Gloves	4 boxes	100	400	18.98	75.92
Silicone Wound	3 packages	10	30	35.99	107.97
Silicone Adhesive					76.97
Tattoo Wound	250		250	*.42	105.29
* Discounted because of quantity				**TOTAL**	**$445.59**

Proposed Data Analyses Plan

Descriptive statistics using the Statistical Package for the Social Sciences (S.P.S.S) was used to assess overall means and standard deviations. It was also used to test for assumptions of normality, unexpected results, and the existence of any outliers in the silicone and tattoo moulage data. Additionally, Cronbach's alpha was calculated to assess the internal consistency or reliability of the questionnaire utilized in this research initiative (because no standardized metric exists for this data assessment).

Because the surveys provided ordinal data (or data where numbers are assigned to labels to provide rank order) (Mendenhall, Ott, & Ott, 1980) and the data distributions were skewed, a non-parametric approach was needed. The following approach was used to analyze the data and the statistical steps using S.P.S.S. was adopted from (Pallant, 2010):

1. Confirm that the data distributions are not normal by calculating the Kolmogorov-Smirnov (K-S) significance value. A K-S value > .05 is required to show a normal distribution of data, so anything less than .05 is considered non-parametric.
2. Next perform the non-parametric Mann-Whitney U test to compare the sample means of the silicone and tattoo wounds for depth perception, sense of urgency, immersion and general perceptions. A Mann-Whitney U test is equivalent to parametric data, independent samples t-test (Pallant, 2010). Using a Mann-Whitney U test requires that four assumptions be met.
    a. The dependent variables should be measured as either ordinal (e.g. Likert scale) or continuous (time date).
    b. The independent variables should be two separate variables (e.g. Tattoo and Silicone).
    c. There must be totally different participants in each group so that participants in the "Tattoo Group" are not exposed to the same stimulus as the participants "Silicone Group".
    d. The data should lack a normal distribution.

    For the Mann-Whitney U test a p value > .05 indicates that there is no statistical difference.

3. If any of the dependent values show significance, calculate and compare the median scores. For non-normal data distributions, the median scores can provide more clarity on differences.
4. Calculate effect size for all three dependent variables. A small or insignificant effect size is < .1. A large effect size is > .5.

Pilot Study

A pilot study was conducted on October 14, 2016 with local EMT's and Paramedics through the City of Orlando Fire Department. The purpose of this study was to assess the experiment protocols including the test instrument and required resources. The experiment team was given access to a conference room for conducting the study. The pilot was done in conjunction with planning activities for the larger Exercise that started in November of 2016. These daily planning activities were expected to include 10-15 EMT Fire Fighters. The OFD had planned to provide the research team with mannequins, but the two mannequins available were not close in appearance, size, or general functionality, and therefore not appropriate for the study. Two of the researchers assumed the roles of patient actors for this day long initiative. Participants were held outside of the conference room where they signed the Informed Consent Document. Immediately before they entered the room, the participants were given a brief scenario that was provided by the OFD. Participants were allowed into the conference room, two at a time. There was a patient actor positioned on each side of the table (see Figure 19) and two experiment observers timed the participant's treatment.

Figure 19: Pilot Test; Right Photo Shows Silicone on the Top Arm and Tattoo on the Bottom Arm

The goal of the pilot study was to have a minimum sample of 12 participants (comparable to standard usability tests) to observe novel trends emerging from the data. Based on the survey data collected, a total of 17 test subjects participated in the pilot test with nine assigned to the silicone simulated wound and eight assigned to the tattoo simulated wound. All 17 participants were males with a mean age, $M = 36.29$ and $SD = 8.70$. The data showed that the tattoo participants were on average 11 years older.

The demographics revealed that all but one of the participants had actually seen a real bullet wound. In regards to time on task, the findings showed on average, participants took an additional 13 seconds to treat the silicone wound. This suggested a difference in how the participants perceived the silicone versus the tattoo moulage. Additional data on demographics and time on task are summarized in Table 9.

Table 9: Summary of Pilot Time Data and Demographics

Simulated Wound Type	Average Time on Task (secs)	M/F	Average Age (Years)	EMT	Para-medic	Seen Actual Bullet Wound
Tattoo (N=8)	76.72	8/0	41	5	4	8
Silicone (N=9)	89.81	9/0	32	2	7	8

Next, the compiled data was transferred to S.P.S.S. for data analysis. The tests for normality showed that the objective time data had a normal distribution with Kolmogorov-Smirnov (K-S) significance value calculated as .2 (greater than .05), indicating normality. The subjective responses to the survey instrument, however, varied by survey statement, with a few statements showing normal tendencies and most falling below the required K-S significance value of greater than .05. Therefore the pilot data indicates that a non-parametric approach may be required for the experiment data analysis. This non-normal distribution of the response data is partly due to the fact that most of the participants provided high numerical values to the statements on the survey. This skewed most of the data to the right of the mean. An example of this is illustrated in Figure 20, which shows the distribution of responses to the "Gen 1" (statement assessing general perception) statement from the silicone wound. There were several outliers in the responses to the statements on urgency, depth, and immersion. All of these data points were left in the analyzed data set because in all instances the mean and the 5% trimmed mean were very close (Pallant, 2010).

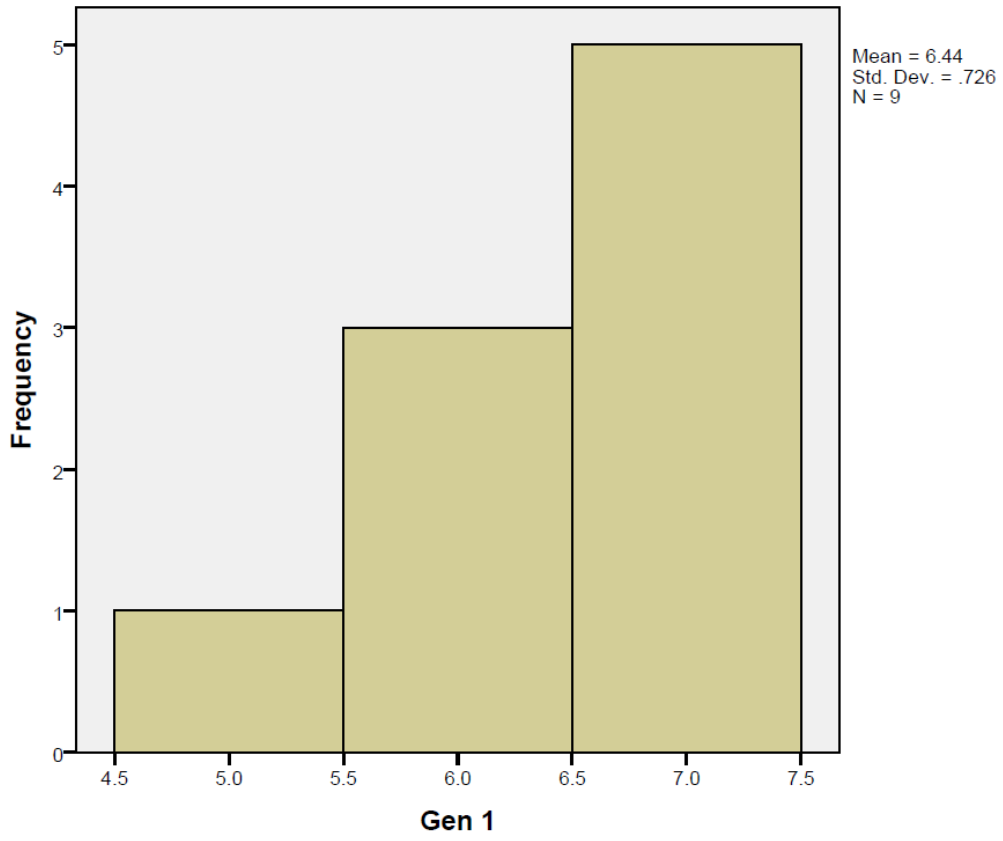

Figure 20: Histogram of General Statement 1 Responses from Silicone

The survey data was analyzed for reliability (Cronbach's alpha) to determine if any relationships exist within the questions that measure the same construct (e.g., immersion). Based on previous research, a minimum value of .7 or higher is considered appropriate (Field, 2009). Cronbach's alpha for the pilot was calculated as .936, validating the survey instrument for use in the experiment.

Table 10 summarized the means and standard deviations of the pilot data. It appears that the responses to the questions were fairly uniform and deviated little from the mean. Two possible exceptions to this conclusion are the responses to the statements on immersion. These statements focused on affective states which seemed to have created a more varied response.

This trend will be further explored in the analysis of the Experiment data, where the sample size is much larger.

Table 10: Pilot Data Mean and Standard Deviation

		General Perception		Visual Depth Cues				Sense of Urgency				Immersion			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Silicone N = 9	Mean	6.4	6.4	6.6	6.1	5.9	6.0	5.9	6.1	5.0	6.4	6.4	1.9	2.6	6.7
	SD	.73	.53	.73	.93	1.2	1.0	1.6	.78	1.8	.53	.53	1.3	1.4	.50
Tattoo N = 8	Mean	6.1	6.3	6.3	6.0	5.8	6.4	6.0	6.0	5.3	6.3	6.3	2.9	3.4	6.4
	SD	1.1	.89	.71	1.1	.89	.52	.76	.76	2.1	1.0	1.0	2.3	1.8	.52

There were very few open ended comments from the pilot participants. Several participants from both the tattoo and silicone groups mentioned the desire to have more synthetic blood on the scene to enhance realism. However, because the pilot was done in a City of Orlando Fire Department conference room, the research team limited the amount of synthetic blood to avoid damaging the furniture or facilities. Participants treating the silicone wound commented positively on the realism and value of the simulation.

Pilot Lessons Learned

The pilot study demonstrated the need for a three member research data collection team. (i.e., two data collectors, one with each simulated bullet wound and a third to administer the informed consent and redo moulage or assist the participants where necessary). With this three

member team, it was possible to complete the entire experiment for eight participants an hour, if the participants were available. This included the wound moulage reset time.

From the Pilot Study, minor changes were made to the experimental design:

- Because several of the participants wrote in "paramedic" under the demographics section of the survey, this option was added to the updated survey demographics.
- Observing the variability that occurred in the selection of simulated quick clot, regular gauze, or both for wound treatment, the time recordings data sheet also included the type of gauze each participant used.
- Several participants asked if they "passed," so a statement was added to the scenario script indicating that they would not be graded.
- Many of the first responders seemed to compete with each other to finish quickly. As a result, during the true experiment the research team informed the participants that speed was not the goal of the experiment; and for the true experiment, space was provided to place the wounded mannequins in two separate rooms, making it more difficult to know the other participants speed.
- Several lessons were learned from assessing and reapplying the moulage between participants:
    - The quicker the bandage was removed after each participant, the less damage occurred to the moulage, specifically the edges.
    - The tattoos needed a minimum of 5 minutes to dry when applied.

- The silicone adhesive that was designed for humans dried much quicker and held better than the silicone adhesive that was designed for mannequins.

Experiment Data Collection Efforts

In November of 2016, over the course of several training days, 158 first responders participated in the experiment. The experiment team consisted of three individuals. "Experimenter 1" of the experiment team performed the required consent process, asking participants to review and sign the Informed Consent Form (ICF), reviewed the forms for signature and read the OFD provided scenario to no more than two EMT's at one time. Experimenter 1 escorted the two participants into the experiment rooms, where they were handed a card with basic instructions on bullet wound treatment (see Figure 18). After Experimenter 1 escorted the two participants into the room, this individual would check for the participants consent to be photographed, take pictures when the participant concurred, and prepare the ICF's for the next two participants.

After the participants completed their review of the basis instructions, and handed the card to another experimenter of the experiment team (Experimenter 2 or 3), the participants would begin treatment. As specified by the OFD, the participants were provided with a roll of regular gauze, a roll of simulated self-clotting gauze, a box of rubber gloves and a pair of scissors (for cutting the gauze). Experimenters 2 and 3 started timing when the participant handed the basic instruction card back and stopped timing when the participated finished bandaging the wound. As soon as the participants completed the treatment, they were asked by

Experimenter 2 or 3 to respond to the experiment survey. While the participants were filling in the survey, all members of the experiment team would remove the bandages, replace moulage when needed and reset all equipment for the next two participants. Finally, the participants were thanked for their participation and offered a nominal snack

CHAPTER FOUR: FINDINGS

Participants

In November of 2016, a total of 158 test subjects participated in the experiment with 79 assigned to the silicone simulated wound and 79 assigned to the tattoo simulated wound (see Figure 21). All but seven of the 158 participants were males. A summary of the demographics is shown in Table 11. The data showed that the tattoo and silicone wound participants were comparable in age with a mean age across the entire population of 41.4 and a *SD* = 7.76. The mix of EMT and paramedic experience across the two wound types was also comparable. The demographics also revealed that all but seven of the participants had actually seen a real bullet wound.

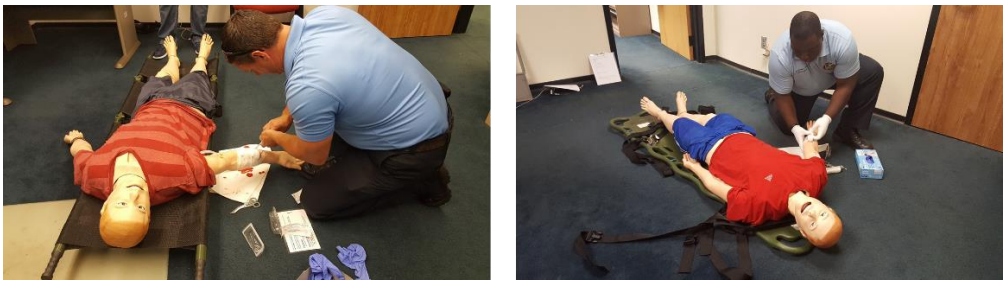

Figure 21: Testing of the Tattoo and Silicone Wounds

Table 11: Summary of Experiment Demographics

Simulated Wound Type	Male/ Female	Average Age (Years)	EMT	Para-medic	Seen Actual Bullet Wound
Tattoo (n=79)	76/3	41	32	46	77
Silicone (n=79)	75/4	42	37	42	77

Preliminary Observations

Initial observations revealed little difference in the objective data collected (see Table 12). There was no notable difference between the material chosen to bind the wound between the tattoo and the silicone wound participants. The compiled experiment data was transferred to an excel spreadsheet, then to IBM's S.P.S.S. version 24 for analysis.

Table 12: Summary of Experiment Objective Data

Simulated Wound Type	Average Time on Task (seconds)	Plain Gauze	Clotting Gauze	Both Plain and Clotting Gauze
Tattoo	107.6	61	51	33
Silicone	104.4	52	55	29

Descriptive Statistics

The descriptive statistics were investigated, identifying the means and standard deviations. The descriptive statistics were also examined for normality, unexpected results, and the existence of any outliers. Cronbach's alpha for the experiment data was calculated to assess the internal consistency or reliability of the survey instrument, since it was not a standardized tool. Table 13 summarizes the means and standard deviations of the 14 survey statements from both the tattoo and silicone wound assessments.

Table 13: Mean Values of Experiment Subjective Data

		General Perception		Visual Depth Cues				Sense of Urgency				Immersion			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14
Silicone N = 79	Mean	5.7	5.9	6.1	5.8	5.4	5.7	5.6	5.6	5.5	5.9	6.0	3.0	2.5	5.8
	SD	1.2	.89	.87	.85	1.5	.87	1.4	1.4	1.3	.53	.38	2.8	2.4	1.1
Tattoo N = 79	Mean	5.8	6.0	5.9	5.2	4.7	5.6	5.7	5.6	4.9	5.6	5.8	2.9	2.4	5.8
	SD	1.3	.61	.71	.8	2.7	1.0	1.2	.96	2.1	1.0	1.1	2.1	2.0	1.0

The experiment data was assessed for outliers, unexpected results, and normality. Analyzing the statistical results revealed that the silicone wound "general training value" had a Mean (*M)* = 5.8 with a *SD* = 0.95. There was one outlier in the silicone wound group with *M* = 1.0. This data point was left in because the survey responses from this individual for depth, urgency and immersion fell within one standard deviation of the mean of all the participants.

The statistical results revealed that the depth score for the tattoo wound *M* = 5.3 with a *SD* = .99. For the silicone wound the depth had a *M* = 5.8 with a *SD* = .69. There were several outliers, mostly from the tattoo wound sample group with mean depth scores between 3.0 and 3.25. Since assessing depth is a critical part of this experiment, the outlier data points were included. The urgency scores were similar to the depth scores, with a few outliers, fairly equally distributed between the silicone and tattoo wound participants. Because there was a fairly equal

distribution between the two groups, the outlier data points were also included in the data set for analysis.

Immersion appeared to have a more normal looking distribution (Figure 22). This assessment included statements related to emotions and resulted in an unanticipated lower score from some participants. The two statements "I lost track of time" and "I felt emotionally attached to the simulated patient" yielded consistently low scores (2.4 to 3.0 out of 7). These statements were taken from validated survey instruments used to assess immersion (Jacobs, 2002; Witmer & Singer, 1998); however, with this particular audience these statements may not have evoked the desired response as it may have implied a lack of control of the situation, and acknowledgment of their emotions.

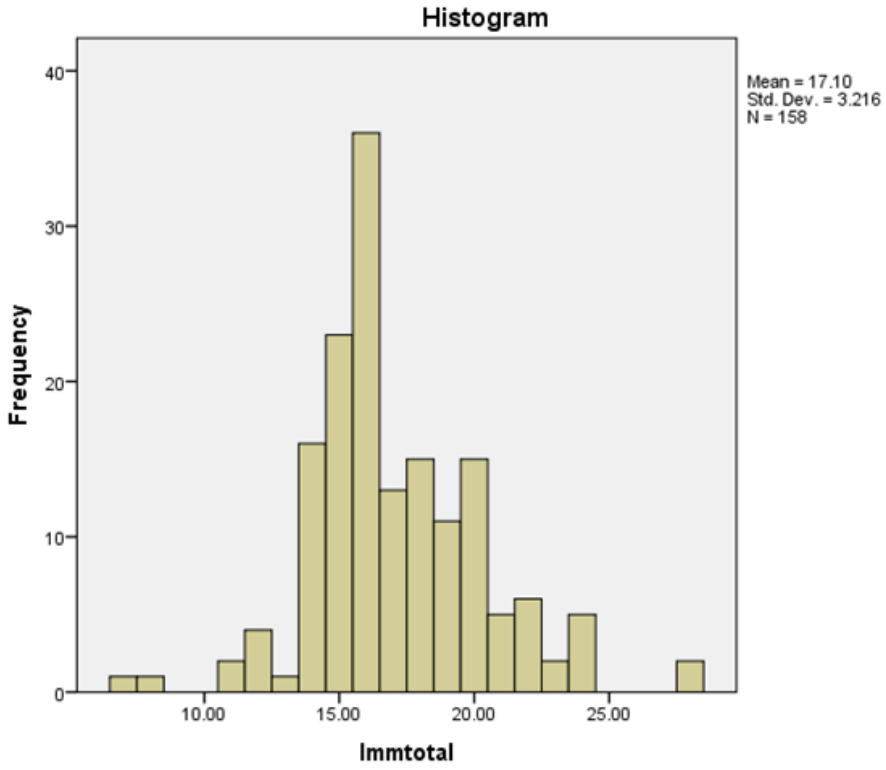

Figure 22: SPSS Histogram of Immersion Scores

Time on task for the silicone wound had an *M* = 104.4 seconds with a *SD* = 29.77, and for tattoo wound had an *M* = 107.6 seconds with a *SD* = 28.90. The time on task data had two outliers. These two data points were included in the final analysis because one of the outliers was in the tattoo group and one was in the silicone group, and they both had large time values (time > 200 seconds). Additionally, they were within the 5% trim mean tolerances.

Cronbach's Alpha Evaluation

The 158 survey responses from the experiment were used to assess and test the reliability (Cronbach's alpha). Based on previous research, a minimum value of .7 or higher is considered appropriate (Field, 2009). Cronbach's alpha for the experiment was calculated as .876,

confirming that the survey instrument appropriately assessed the general perceptions, depth perception, sense of urgency, and immersion.

Non-Parametric Analysis

The tests for normality showed that none of the objective or subjective data had a normal distribution with Kolmogorov-Smirnov (K-S) significance value calculated as .00, less than the required .05 or greater. The data remained untransformed because of the large sample size with N>30 for each condition (Field, 2009; Glass, Peckham, & Sanders, 1972). Instead, the experiment data confirmed that a non-parametric approach is better suited for the experiment data analysis.

Since the data was non-parametric, a Mann-Whitney U test (equivalent to parametric data, independent samples t-test) was done to compare the central tendencies of the silicone and tattoo wounds for depth perception, sense of urgency, and immersion. The Mann-Whitney U test indicated that for depth perception for the tattoo (*Mdn* = 22) and the silicone (*Mdn* = 24), with a U= 2272.50, z = -.447, p = .003, and r = -.838, showed statistical significance. The results showed that the silicone wounds had a higher total depth median score than tattoo wounds. From the Mann-Whitney U tests, the only dependent variable with a notable effect size was depth perception. With an effect size significantly above the .5 threshold for a large effect, depth data shows a significant effect.

The Mann-Whitney U Test, revealed no significant differences in sense of urgency for the tattoo (*Mdn* = 23) and the silicone (*Mdn* = 23), U= 2704.50, z = -1.464, p = .143, and effect size (r) = -.116. For immersion, the Mann-Whitney U test revealed no significant differences for

the tattoo (*Mdn* = 16) and the silicone (*Mdn* = 16), U= 2993.00, z = -.447, p = .655, and r = -.036. The Mann-Whitney U test indicated no statistical difference in the general perceptions scores for the tattoo group (*Mdn* = 12.0) and the silicone (*Mdn* = 12.0), with U= 2992.0, z = -.472, p = .637, and r = .051. The Mann-Whitney U test indicated that for treatment times there is no significant difference in the tattoo group (*Mdn* = 106.53) and the silicone (*Mdn* = 102), U=2839, z = -.979, p = .328, and r = -.078. All of the Mann-Whitney U test data is summarized in a chart included in Appendix G.

Cost Analysis

Prior to using the moulage in the experiment, the silicone wounds were expected to last through for three to four trials. The tattoo wounds were expected to last for one to two trials. Based on the use data collected during the experiment with 158 iterations, the silicone wounds had to be replaced an average of every 6.4 trials and the tattoo wounds had to be replaced an average of every 4.4 trials (M. B. H. Pettitt, 2017). Based on the cost data given in Table 8, and the life expectancy of the moulage recorded during this experiment, the overall cost of conducting a point of injury training event for an example of 100 participants with silicone and tattoo moulage is illustrated in Table 14.

Table 14: Comparison of Actual Costs

	Cost Per Moulage Piece ($)	Adhesive Cost Per Moulage Piece ($)	Total Cost per Moulage Piece ($)	Treatments/ Application	**Total Cost for 100 Participants**
Silicone	3.6	2.57	6.17	6.4	$96.40
Tattoo	0.42	N/A	0.42	4.4	$9.55

Note: The average gauze and glove usage for tattoo and silicone participants was almost identical, so it was not included in the calculations. Also, synthetic blood was used equivalently for both types of moulage, so it was excluded from the cost calculations.

Exploratory Analysis

Searching for other relationships in the data, several correlation analysis were completed. Because the data was non-parametric, a Spearman's correlation analysis was used. For the tattoo

group, the correlation analyses of immersion and urgency revealed a moderate positive correlation r = .554, N = 79, p<.01 suggesting that as sense of immersion increases, urgency increases for the participants. For the silicone group, the correlation analyses immersion and urgency also revealed a moderate positive correlation r = .495, N = 79, p<.01 suggesting that as sense of immersion increases, urgency increases for the participants. Figure 23 shows how as immersion increases, urgency also increases for both the tattoo (left) and the silicone (right).

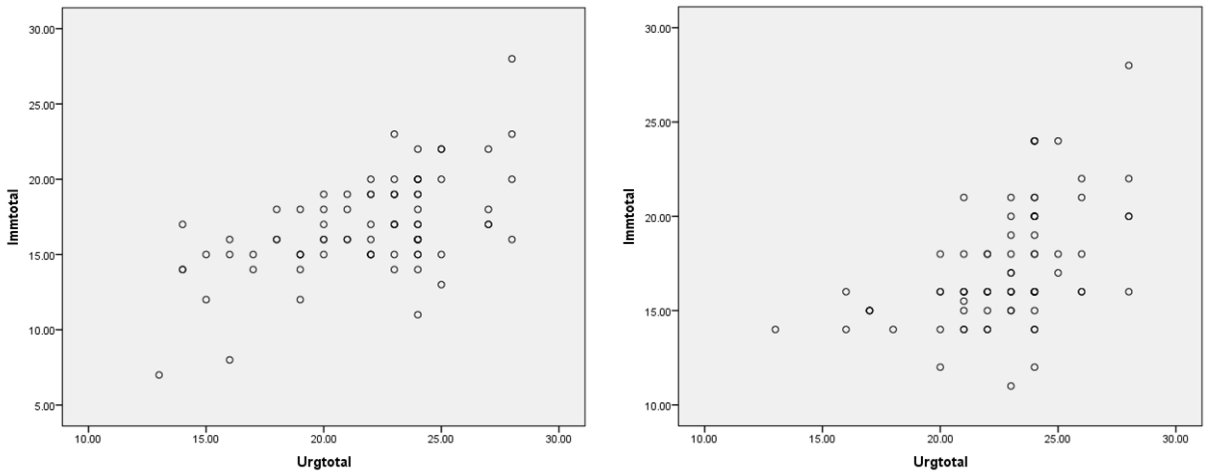

Figure 23: Scatter Plots Showing a Moderate Positive Correlation between Immersion and Urgency for Tattoos (left) and Silicone (right)

A Spearman's correlation was also done between time and urgency, as well as time and immersion. For the tattoo group, the correlation analyses of time and urgency revealed a weak, negative correlation r = -.229, N = 79, p<.05 suggesting that as the sense of urgency increases, time decreases for participants in the tattoo (see Appendix G for scatter plot). There was no statistically significant correlation between time and urgency for the silicone. A Spearman's correlation was also done between time and immersion. There was no statistically significant correlation between time and immersion for either the silicone or the tattoo.

CHAPTER FIVE: DISCUSSION

To understand the research findings from this experiment, the hypotheses and trends were investigated using statistical methods. Additionally, the associated costs were assessed from the moulage data findings during the experiment. Finally, the limitations and participant comments are discussed.

H1 states that at the point of injury, a tattoo wound provides the same *visual depth cues* as a 3D silicone wound of the same injury. The analysis indicates that the data refutes this hypothesis, because there was a statistically significant difference between the participants survey response to the silicone and tattoo moulage for depth perception.

Since the perception of depth is a significant concern when using a tattoo for medical training, the statistical findings for depth, points to the potential limitations (such as the inability to feel the wound or effectively pack it with gauze) of this type of moulage. However, as has been noted previously, at the point of injury, the tattoo appears to give enough detail for first responders to assess and treat the simulated wound. Even though there was a statistically significant difference in the tattoo and silicone survey results for depth, the "general perceptions" assessed from the first two survey statements, were still relatively high. Additionally, the lowest average score for the four depth perception related questions was a 4.7 for the tattoo and a 5.4 for the silicone, indicating that the participants were "neutral" to "somewhat agreeing" with the value of the visual depth queues.

H2 states that at the point of injury, a tattoo wound provides the same sense of *urgency* as a 3D silicone wound of the same injury. The data analysis indicated that the data supported this

hypothesis, because there was no statistically significant difference between the participants survey response to the silicone and tattoo moulage for sense of urgency. A possible explanation for this, was that with little variation in average scores between the silicone and the tattoo moulage respondents, the overall scene seemed to have provided enough detail for the participants to appropriately respond to the simulated wound. Additionally, the participants were told that the simulated patients had sustained gunshot wounds, so the appearance of the actual moulage may have had a limited effect on the urgency scores and ultimately performance.

H3 states that at the point of injury, a tattoo wound provides the same *immersion* as a 3D silicone wound of the same injury. The analysis indicated that the data supported this hypothesis, because there was no statistically significant difference between the participants survey response to the silicone and tattoo moulage for immersion. Based on the observed focus that the participants demonstrated, both the silicone and tattoo moulage appeared to provide the appropriate details to immerse the participants.

Immersion results from this study were interesting. For this particular set of participants, two of the four survey statements, related more to affective conditions, yielded very low scores (3 or less out of 7). The other two statements, related to attention and focus, yielded very high scores (close to 6 out of 7 for both the tattoo and the silicone). Even though the results were not statistically significant between the tattoo and silicone, the data indicates that both types of moulage provided a relatively high level of attention and focus.

H4 states that at the point of injury, a tattoo wound provides the same general perceptions or experience as a 3D silicone wound two statements were included in the post treatment survey. The analysis indicated that the data supported this hypothesis, because there was no statistically

significant difference between the participants survey response to the silicone and tattoo moulage for general perception. Based on the similarity of the two simulated patients, both with a bullet wound to an area of the arm that was not life threatening and the overall scene consistencies, similar perceptions for the tattoo and silicone wound moulage are a likely outcome.

H5 states that at the point of injury, a tattoo wound provides the same *treatment times* as a 3D silicone wound, time was objectively measured by experiment team members. The analysis indicated that the data supported this hypothesis suggesting there was no statistically significant difference between the participants survey response to the silicone and tattoo moulage for treatment times. Based on the similarity in the overall scene and appearance of the two simulated patients, similar treatment times for the tattoo and silicone wound moulage are not surprising.

A future effort may examine the similarity of the median scores for all the subjective and objective measures assessed and may require additional statements that address each dependent variable in greater detail or higher degree of accuracy. Including additional statements as well as varied statements would further parse out the responses.

Other Observations

One interesting outcome of the experiment was the time difference that occurred in the pilot which used patient actors and the actual experiment which employed mannequins (Table 15). The time was significantly less for the pilot participants than for the silicone participants.

Table 15: Pilot and Experiment Times

	Pilot Time (seconds)	Experiment Time (seconds)
Tattoo	76.2	107.6
Silicone	89.91	104.4

There are several plausible explanations. One is that during the pilot testing, the participants could see each other and there was a slight competitive nature between participants. The other possible explanation is that because the pilot was using real people as opposed to mannequins, the participants felt it was more important to quickly treat the simulated injuries. This confirms past studies (Sohn et al., 2007; Tostaine & Fareed, 2010) indicating that live tissue creates a more urgent and immersive training environment.

Costs

For a point of injury training exercise with 100 participants, the cost of using silicone moulage is estimated to be 10 times more expensive than using tattoos (see Table 14). Based on the analysis, this represents a significant difference in training exercise cost dependent on the moulage chosen. One factor that was not addressed in the cost analysis was the potentially reusability of the silicone moulage. Once the silicone moulage begins to detach from the

mannequin or the patient actor, it can be removed, cleaned and reused if the edges or other parts of the moulage are not torn or damaged. Estimates suggest that the same piece of silicone moulage can be re-applied at least two to three times. This would reduce the estimated cost of the silicone moulage; however, each piece of silicone moulage would have to be re-applied ten times with 6.4 treatments each time (totaling approximately 64 trainees). Based on the wear data from this experiment as well as others cited in the *Introduction* section (Sotomayor & Salva, 2009; Wiederhold et al., 2009) it is unlikely that the silicone moulage will remain useful for enough training sessions to make it comparable in price to the tattoo moulage. The data shows very little difference in user perceptions of the two wounds and supports the use of tattoos at point of injury training.

Notably, both types of wounds lasted much longer than anticipated. The longevity of the wounds was plausible because the bandages were immediately removed after each application, preventing the bandages from holding the simulated blood tight against the moulage, which would loosen the moulage from the surface. Further, the longevity of the tattoos was taken from the manufacturer's estimate or recommendation and had not been previously tested.

Participant Comments

Some of the participants from both the silicone and tattoo group included personal thoughts in the "open ended comments" section (see Table 16). These comments fall in the general categories of remarks regarding the simulated blood, simulation/manikin/scenario details, and specific comments regarding the realism of the simulated wound. In general, there were more comments related to the tattoo than the silicone. Additionally, the comments from the

silicone wound were slightly more positive, suggesting a higher degree of satisfaction with the overall silicone wound experience.

Table 16: Summary of Open-Ended Comments

	Silicone Feedback	Tattoo Feedback
Blood	The look was realistic, blood was consistent to wound in that area; The wound was realistic but didn't require much bleeding control.	The amount of blood did not alert me for the need for a hemostatic agent.
General Simulation Limitations	Training on manikins is tough as they do not communicate all injuries to you; Would appreciate an explanation of what proper treatment would be after completion of the scenario.	The scene didn't look real enough to me; The bandaging I was provided is not practical or what I would use if I was treating a gunshot victim; You needed to know more info about patient to accurately train/treat i.e. mental status and vitals; Not realistic medical supplies on hand.
Specific Simulated Wound Comments	Good training; Moulage was appropriate and accurate; It definitely helps portray wounds; The wound looks like a bad mosquito bite; This type of training is always beneficial; Realistic helped determine actual detriment of the patient; Very realistic	The wound is good for a visual cue of a GSW. But no other benefit; Moulage provided some patient information as to condition. More is needed; Good training; Depth difficult to assess; Need some form of "dimension" to wound; A deeper wound would be more realistic; Moulage was a good visual resource. But not representative of a true treatable bullet wound; With all of the other treatments and assessments we have to perform, the wound and the treatments available might not be realistic.

Some of the main differences in the silicone and tattoo comments, can be seen in the "Specific Simulated Wound Comments" and "Blood." The simulated silicone wound is described as very realistic and beneficial where the tattoo comments point to the need for more depth and realistic appearance. Additionally, the silicone wound is described as having appropriate amount of blood, where the tattoo comments indicate that more blood is needed.

Under “General Simulation Limitations” both silicone and tattoo participants also made comments that training with non-responsive mannequins is challenging. This again confirms previous studies (Sohn et al., 2007; Tostaine & Fareed, 2010) where live tissue provides more urgency and immersion than traditional mannequins.

Limitations

These section highlights lessons learned, as well as areas that could be improved and adopted for future experiments. First, there were seven individuals involved in the data collection and the roles of these individuals varied. It would be beneficial to standardize the procedures with both written procedures and demonstrations for timing of participants, consenting participants and specific instructions for replacing damaged moulage for the experimenters. Secondly, the room layout had two separated spaces for data collection however, both participants had to walk into the first room and then one participant went on to the second room. The participant going to the second room had the opportunity to briefly preview the simulated patient and wound. Also, the participants could still slightly hear each other. There was also still an occasional slight competition between the two participants in the rooms. Two separate rooms with two separate entrances are recommended and would solve these potential issues. Thirdly, the written comments noted several times on the survey, was that the supplies were not appropriate for the injury. Although the OFD management particularly specified the supplies provided, it may be beneficial to survey several of the actual instructors concerning what supplies are really required for treating the different types of injuries.

CHAPTER SIX: CONCLUSION

The hypotheses that at the point of injury, a two dimensional (2D) tattoo wound provides the same immersion, sense of urgency and general perceptions as a three dimensional (3D) silicone wound of the same injury finds support (or merit) based on the data analysis. The hypothesis that at the point of injury, a two dimensional (2D) tattoo wound provides the same visual depth queues as a three dimensional (3D) silicone wound of the same injury was not supported based on the data analysis. However, both silicone and tattoo simulated wounds have applications for training. On one hand, tattoos are relatively inexpensive and easy to apply. Tattoos provide a visual representation of a wound indicating a specific treatment protocol required by the medical provider. On the other hand, silicone provides visual and tactile depth that is not possible with tattoos. The silicone wound can potentially facilitate the treatment of a larger variety of wounds, especially where depth is required (e.g., packing a wound to control bleeding).

Because the tattoos are easy, quick, and inexpensive to apply and remove from both human actors, and mannequins or partial task trainers, they may provide training utility in many areas. Consideration of other uses and requirements of the tattoo technology, suggests tattoos have potential for visually indicating several medical conditions with a minimal need for visual depth queues, including:

- Bruises and scrapes in a clinical setting;
- Phases of healing, both proper and inadequate;

- Cyanosis (bluing around the lips) in a clinical setting; and

- A transparent overlay on patient actors or mannequins as shown in Figure 24, to show the location and orientation of underlying vessels and organs.

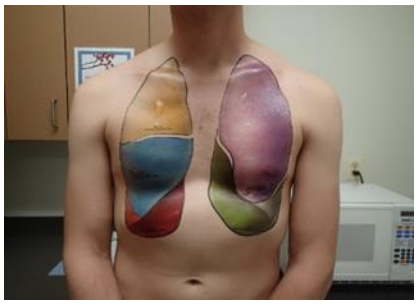

Figure 24: Tattoos Depicting Underlying Anatomy

Note: The image in Figure 24 is from a private collection (Weissbrod, 2015).

The coloring of bruises and scrapes is an important diagnostic indicator and is not easily depicted in training exercises. In addition to bruises and scrapes, indicating medical issues beneath the surface of the skin, phases of healing can also be indicated by the changing colors of bruises, etc. Indicating cyanosis in training scenarios has been an unmet challenge for many years. Mastering how to indicate changes in skin color with these temporary tattoos could also lead to a more accurate depiction of cyanosis (visual indicator around the mouth of a lack of oxygen). Additionally, understanding the three dimensional anatomy underneath the skin has always been a challenge for medical providers. Tattoos may offer an affective visual training aid to assist the trainee in visualizing the size and location of the underlying anatomy. It is possible that a simple tattoo offers an inexpensive and easy to use solution for these and many other medical conditions where a change of skin tone or a deeper understanding of anatomy is important.

Tattoos may be considered a valuable training tool for remote locations. Tattoos may be printed with a normal color printer and special tattoo paper, allowing medical images to be emailed and quickly printed to help train medical personnel for everything from treating uncommon skin ailments to preparing for surgery. These are examples that can be included in future research studies.

Additionally, future research may include adding other types of simulated wounds to the experiment. It would be valuable to assess the impact of a large laceration through the fatty tissue with a great deal of bleeding. Another good candidate is a blunt trauma with no broken skin or swelling. This simulated wound would only have discoloration, and a slightly hard and raised surface.

To further assess **H3** (immersion) and **H4** (urgency), two other variations of the experiment are recommended. One would be to place both a tattoo and silicone representation of the same wound on one patient and assess the difference in treatment time, survey results and other details. The second would be to use a simulated wound that bleeds profusely, creating a life threatening situation, where the likely simulated outcome is death. Examples of this type of simulated wound include a head injury or multiple penetrating wounds to the chest area.

In addition to different types of wounds, different levels of care should be evaluated with the different types of wounds. It can be postulated, that as the level of care increases beyond the point of injury, the tattoos will be a less effective training tool. Also, as previously noted (Blackman, 2009; Marshall et al., 2001) fidelity can affect medical performance, so the influence of varying fidelities (possibly introduced by colors, dimension, and odors) could affect performance outcomes. Future research should also include a training effectiveness evaluation

examining the differences in knowledge acquired for treating a specific type of injury when using the silicone and tattoo simulated wounds.

APPENDIX A: USABILITLY IRB APPROVAL

DEPARTMENT OF THE ARMY
US ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND
ARMY RESEARCH LABORATORY
BUILDING 459
ABERDEEN PROVING GROUND MD 21005-5425

REPLY TO
ATTENTION TO

RDRL-HRS 8 September 2015

MEMORANDUM FOR: M. Beth Pettitt, STTC, ARL-HRED, Orlando, FL

FROM: Theresa M. Straut, Human Protection Administrator, ARL, APG, MD

SUBJECT: Administrative Determination Review, ARL 15-092

Project Title: Usability Study for Trauma Tattoos Moulage Technology
Submission Type: Initial study plan

The purpose of this memorandum is to notify you that your study, identified above, has been determined to not constitute research. The Common Rule defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The purpose of this activity is to assess if a flat or two-dimensional representation of a wound is adequate to perform the typical medical tasks performed at the point of injury. It was determined that this study did not meet the criteria of being generalizable and therefore did not meet the criteria of being research per the Common Rule.

You are required to report changes in the procedures so that a determination may be made that the changes do not alter the determination that the study is not research.

Good luck with your project.

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Date: 2015.09.08 13:36:43 -04'00'

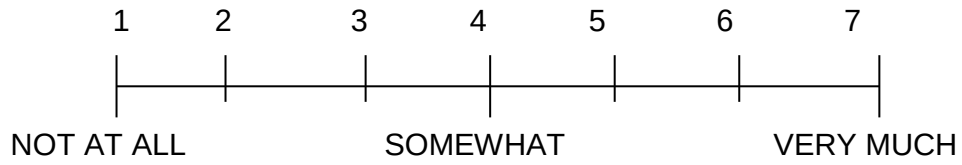
THERESA M. STRAUT, CIP, RAC
Human Protection Administrator, ARL

APPENDIX B: USABILITLY QUESTIONARE

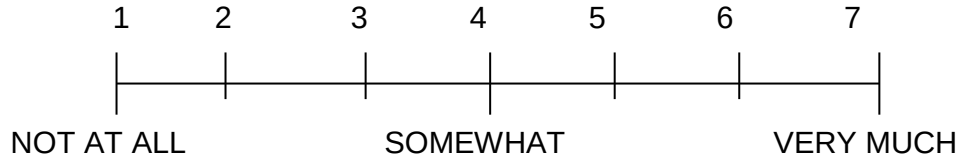
USABILITY QUESTIONNAIRE **PARTICIPANT # ____**

PLEASE CIRCLE THE NUMBER WHICH BEST INDICATES YOUR RESPONSE.

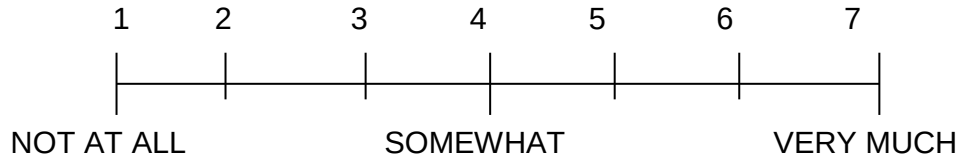
1. DO YOU FEEL THAT THE TRAUMA TATTOOS WOULD IMPROVE THE TRAINING EXPERIENCE?



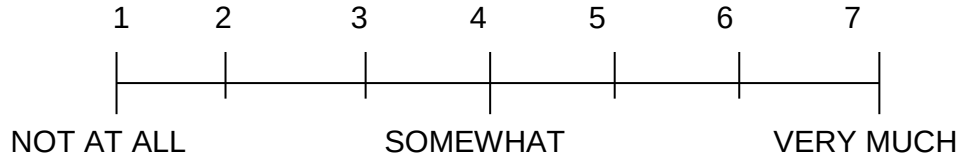
2. TO WHAT EXTENT DO YOU FEEL THE TRAUMA TATTOOS PROVIDE MEANINGFUL VISUAL INFORMATION ON THE TYPE OF WOUND?



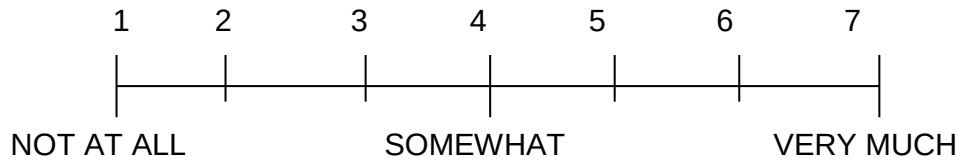
3. THE FLAT OR TWO-DIMENSIONAL NATURE OF THE TATTOO WOUNDS WAS APPROPRIATE FOR THE LEVEL OF CARE REQUIRED.



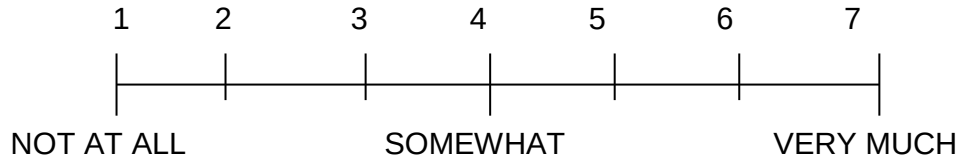
4. THE TRAUMA TATTOOS PROVIDED ENOUGH DETAIL TO IDENTIFY THE WOUND AND TREATMENT NEEDED.



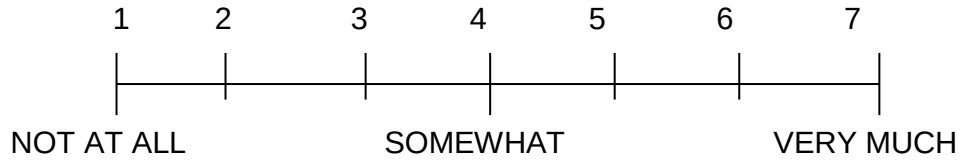
5. THE TRAUMA TATTOO WOUNDS FEEL REALISTIC.



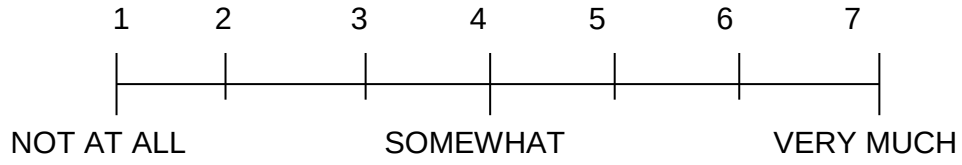
6. THE TRAUMA TATTOOS PROVIDED PERCEPTUAL DEPTH.



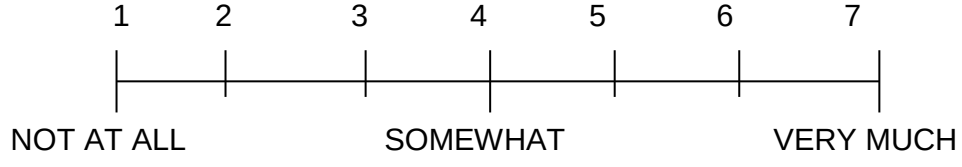
7. DID YOU FEEL THE TRAUMA TATTOO WAS ANATOMICALLY ACCURATE?



8. DID YOU FEEL THE TRAUMA TATTOOS PROVIDED AN ACCURATE REPRESENTATION AND LOCATION OF LANDMARKS CRITICAL TO PERFORMING THE PROCEDURE?

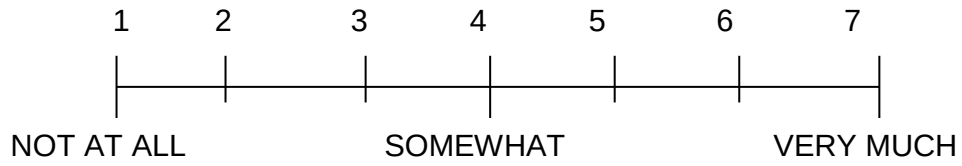


9. DO YOU FEEL YOU WOULD BENEFIT FROM USING THE TRAUMA TATTOOS FOR OTHER TRAINING?

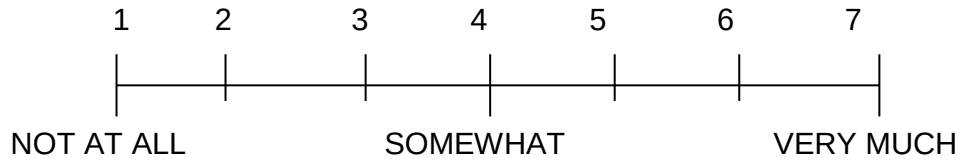


ONLY RESPOND TO THE FOLLOWING THREE QUESTIONS IF YOU <u>WORE</u> THE TATTOOS.

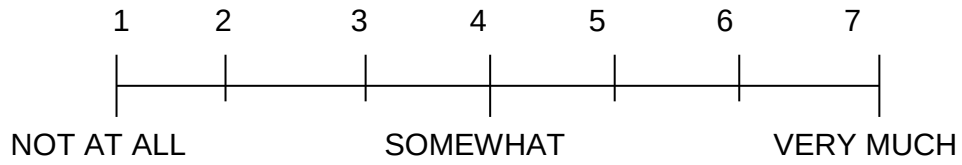
10. WERE THE TRAUMA TATTOOS EASY TO APPLY?



11. WERE THE TRAUMA TATTOOS COMFORTABLE TO WEAR?



12. WAS REMOVING THE TRAUMA TATTOOS EASY?



APPENDIX C: SURVEY INSTRUMENT

MOULAGE SURVEY **Station _____ Participant # _____**

Information about you:

_____Male

_____Female

Age ____

Medical Certifications/Degrees:

_____ EMT; _____ Paramedic

_____ Other: _____

Please indicate how many years of college you have:

_____ 0

_____ 1

_____ 2

_____ 3

_____ 4

Have you ever seen or treated an actual bullet wound?

_____Yes

_____No

INSTRUCTIONS

Using the scale given below, please completely fill in the circle which best indicates your response to the following statements.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

1. The trauma moulage improves the training experience.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

2. There is a benefit from using the wound moulage for other training.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

3. The trauma moulage provides meaningful visual information on the type of wound.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

4. The wound moulage provides perceptual depth.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

5. The wound moulage feels realistic.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

6. The wound moulage is anatomically accurate.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

7. The wound moulage provides enough detail to identify the wound and treatment needed.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

8. Immediate medical care of the wound moulage is required.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

9. The amount of simulated blood affected my desire to assess and treat the simulated wound.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

10. I wanted to take care of the simulated patient.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

11. The training held my attention.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

12. I lost track of time.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

13. I felt emotionally attached to the simulated patient.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

14. I was focused on the training.

Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Some what agree	Agree	Strongly agree
○	○	○	○	○	○	○

Please provide any additional feedback on the simulated trauma you cared for.

_____

_____

_____

_____

APPENDIX D: PILOT AND EXPERIMENT IRB APPROVAL

DEPARTMENT OF THE ARMY
U.S. ARMY RESEARCH, DEVELOPMENT AND ENGINEERING COMMAND
ARMY RESEARCH LABORATORY
ABERDEEN PROVING GROUND MD 21005-5067

REPLY TO
ATTENTION TO

RDRL-HR 19 Sep 2016

MEMORANDUM FOR: M Beth H. Pettitt, ARL-HRED, Orlando, FL

FROM: Daniel Cassenti, IRB Co-Chair, ARL IRB

SUBJECT: Approval of Research Study, ARL 16-075

Project Title: Assessment of Tattoo and Silicone Wounds in Terms of Time of Treatment and Perceived Treatment Quality – Study I Pilot and Study II Experiment
Submission Type: Initial Protocol
Approval Period: 16 September 2016 to 15 September 2017

The purpose of this memorandum is to notify you that the research project identified above was determined to be minimal risk and has been approved by the ARL Institutional Review Board (IRB) by expedited review under category 7 on 16 Sep 2016.

The project documents were initially reviewed on 8 September 2016:

- Protocol cover sheet
- Protocol
- Consent
- 3 scientific reviews
- Memo addressing scientific reviewers comments
- CV, CITI certificates, and COI forms for research personnel

The IRB reviewer requested changes in order to secure approval. On 16 Sep 2016 the following modified documents were reviewed and the study was approved:

- Revised protocol
- Revised consent form
- CV for Kurtis Palata

As principal investigator, you are responsible for ensuring that the study is conducted in accordance with the final version of your protocol. You cannot delegate your

supervisory responsibility to anyone else associated with the project. If you leave the project a new principal investigator should be designated for the research. Designation of a new principal investigator should be reported to the IRB.

In addition, you must report the following to the IRB:

- You must report changes in research personnel, including the principal investigator, involved in the study.
- You must report changes in the research procedures before they are initiated. You can report minor changes by completing the ARL amendment form.
- You may make changes in research procedures implemented to eliminate immediate hazards to the subjects, but they must be reported within 10 days of their implementation on the amendment form.
- You must report completion or discontinuation of your study by submitting a completion or discontinuation report to the IRB.
- You must report plans to continue your study beyond the expiration date before you attain that date, by submission of a continuing review form 30 days before the expiration date.
- You must promptly report any injury or Unanticipated Problems Involving Risks to Participants or Others (UPIRTSO) to the IRB within 24 hours (via phone message, e-mail, or written report) of the incident. This should be followed by a full written report within 10 business days.

A UPIRTSO is defined in DODI 3216.02, Glossary as "Any incident, experience, or outcome that meets ALL three of the following conditions:

- Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.
- Is related or possibly related to participation in the research. *Possibly related* means there is a reasonable likelihood that the incident, experience, or outcome may have been caused by the procedures involved in the research.
- Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

RDRL-HR
Subject: Approval of Research Study, ARL 16-075

The ARL IRB approved consent form, dated 16 Sep 2016, is included with this correspondence. Use this version when consenting subjects for your study.

Good luck with your research.

CASSENTI.DANIEL.N.1276013528 Digitally signed by CASSENTI.DANIEL.N.1276013528 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=CASSENTI.DANIEL.N.1276013528 Date: 2016.09.19 10:02:20 -04'00'

DANIEL CASSENTI
ARL IRB Co-Chair

University of Central Florida Institutional Review Board
Office of Research & Commercialization
12201 Research Parkway, Suite 501
Orlando, Florida 32826-3246
Telephone: 407-823-2901, 407-882-2901 or 407-882-2276
www.research.ucf.edu/compliance/irb.html

Notice that UCF will Rely Upon Other IRB for Review and Approval

From : **UCF Institutional Review Board**
FWA00000351, IRB00001138

To : **M. Pettitt**

Date : **October 06, 2017**

IRB Number: **SBE-17-13486**

Study Title: **ASSESSMENT OF TATTOO AND SILICONE WOUNDS IN TERMS OF TIME OF TREATMENT AND PERCEIVED TREATMENT QUALITY**

Dear Researcher:

The research protocol noted above was reviewed by the University of Central Florida IRB Designated Reviewer on October 06, 2017. The UCF IRB accepts the Army Research Laboratory's Institutional Review Board review and approval of this study for the protection of human subjects in research. **The expiration date will be the date assigned by the Army Research Laboratory's Institutional Review Board and the consent process will be the process approved by that IRB.**

This project may move forward as described in the protocol. It is understood that the Army Research Laboratory's IRB is the IRB of Record for this study, but local issues involving the UCF population should be brought to the attention of the UCF IRB as well for local oversight, if needed.

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

Failure to provide a continuing review report for renewal of the study to the Army Research Laboratory's IRB could lead to study suspension, a loss of funding and/or publication possibilities, or a report of noncompliance to sponsors or funding agencies. If this study is funded by any branch of the Department of Health and Human Services (DHHS), an Office for Human Research Protections (OHRP) IRB Authorization form must be signed by the signatory officials of both institutions and a copy of the form must be kept on file at the IRB office of both institutions.

On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

Signature applied by Patria Davis on 10/06/2017 01:03:16 PM EDT

IRB Manager

APPENDIX E: CONSENT FORM

Site of Research: Orange County Emergency Medical Services (EMS) Training Sites, Orlando, FL

RESEARCH PARTICIPANT CONSENT FORM
ARMY RESEARCH LABORATORY

Project Title:	Assessment of Tattoo and Silicone Wounds in Terms of Time of Treatment and Perceived Treatment Quality - Study I Pilot and Study II Experiment
Sponsor:	Department of Defense
Principal Investigator:	M. Beth H. Pettitt, 12423 Research Parkway, Orlando, FL, 32826, 407-208-3011, merry.b.pettitt.civ@mail.mil

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You are being asked to join a research study. This consent form explains the research study and your part in it. Please read this form carefully before you decide to take part. You can take as much time as you need. Please ask questions at any time about anything you do not understand. You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part right now or you can quit at any time later on.

Why is this research being done?

This study involves research to assess if at the point of injury, a two dimensional tattoo wound provides the same immersion, sense of urgency, and visual cues as a three dimensional silicone wound of the same injury. You are being invited to participate because you are in the first responder community.

What will happen if you join this study?

Below is an outline of the steps of the research study.
1 - Before entering the room with the trauma moulage, you will be given the option to not participate.
2 – After agreeing to participate, you will be given basic instruction on managing the wound.
3 – You will be randomly assigned to assess one type of simulated injury. Half of the subjects will be exposed to the 3D silicone and the other half to the 2D tattoo.
4 – You will be timed by an observer with a stopwatch recording both the time to reach the casualty and the time to treat the wound.
5 - You will complete an electronic survey assessing depth cues, sense of urgency and immersion after treating the simulated trauma.

The study will be run in coordination with a larger training exercise. You may withdraw from this study, but not the training exercise.

After treating the simulated wound, you will be asked to fill out basic demographic information and complete a nine statement survey. This information will be collected electronically using a University of Central Florida survey system called Qualtrics. None of the data collected will include any personally identifiable information (PII).

How much time will the study take?

Your total participation will take no more than 20 minutes. Review of treatment procedures and treating the simulated casualty will take approximately 15 minutes. Filling out the brief survey will take approximately 5 minutes.

What are the risks or discomforts of the study?

While we anticipate no risk of bodily harm, we acknowledge that privacy is a potential concern. Your identity and privacy will be protected (see below).

Are there benefits to being in the study?

There are no anticipated benefits to the subject from participation in this study.

Will you be paid if you join this study?

You will receive no monetary payment for taking part in this study. A nominal snack will be offered at the end of the study.

How will your privacy be protected?

Your participation in this research is confidential. The data will be stored and secured at the Army Research Lab in a secured and a password protected file. In the event of a publication or presentation resulting from the research, no personally identifiable information will be shared, unless you give permission below in the section requesting consent for us to photograph you. After transfer of the data to a computer file, the paper copies of the data will be shredded. This consent form will be retained by the principal investigator for a minimum of three years.

The research staff will protect your data from disclosure to people not connected with the study. However, complete confidentiality cannot be guaranteed because officials of the U. S. Army Human Research Protections Office and the Army Research Laboratory's Institutional Review Board are permitted by law to inspect the records obtained in this study to insure compliance with laws and regulations covering experiments using human subjects.

We would like your permission to take pictures during the experimental session. The recording will be used to demonstrate the experimental set-up and procedures. Images of faces or other identifying information will be avoided and when in the field of view of the picture will be

blurred. Please indicate below if you will agree to allow us to photograph you. You can still be in the study if you prefer not to be photographed.

I give consent to be photographed during this study: ___Yes ___No please initial:____

Where can I get more information?

You have the right to obtain answers to any questions you might have about this research both while you take part in the study and after you leave the research site. Please contact anyone listed at the top of the first page of this consent form for more information about this study. You may also contact the Human Protection Administrator (HPA) of the Army Research Laboratory Institution Review Board, at (410) 278-5928 with questions, complaints, or concerns about this research, or if you feel this study has harmed you. The HPA can also answer questions about your rights as a research participant. You may also call the HPA if you cannot reach the research team or wish to talk to someone who is not a member of the research team.

What other things should I know about this research study?

Voluntary Participation

Your decision to be in this research is voluntary. You can stop at any time. You do not have to answer any questions you do not want to answer. Refusal to take part in or withdrawal from this study will involve no penalty or loss of benefits you would receive by staying in it. Civilian or contractor personnel cannot receive administrative sanctions for choosing not to participate in or withdrawing from this study.

Once your questions about the study have been answered, and if you want to continue your participation in this study, please sign below.

WE WILL GIVE YOU A COPY OF THIS CONSENT FORM

Signature of Participant	Printed Name	Date

Signature of Person Obtaining Consent	Printed Name	Date

APPENDIX F: EXPERIMENT SCENARIO

First – Did you participate in a similar effort at the Primrose Training site?? (if so, dismiss participant)

Experiment Script

You were called to a scene where two males received gunshot wounds. The police have told you the scene is safe.

Scientists running the experiment will not be able to help you in treating the casualty.

We will hand you a laminated card with your treatment protocol when you walk into the room. Please review the protocol. When you hand the card back to the scientist in the room, timing will begin. When you take your hands off the patient after treating the wound, timing will end.

Speed is not the goal of this experiment.

You will not be graded.

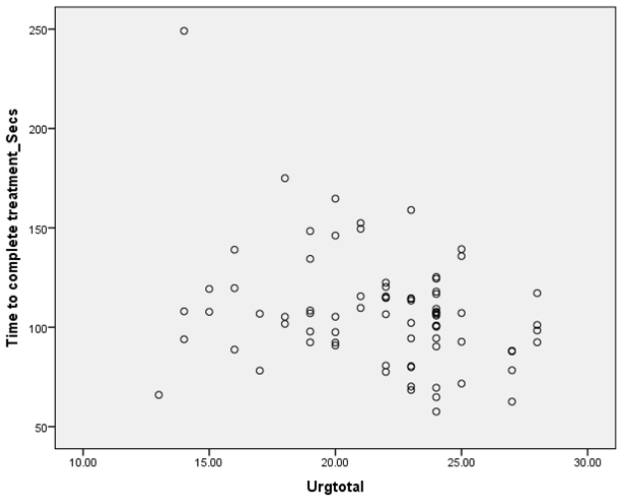
You will each treat a patient individually.

APPENDIX G: ADDITIONAL ANALYSIS GRAPHICS

	Mdn Score					
	Tattoo	Silicone	Mann-Whitney U	z, standard deviation	p, probability	r, effect size *
H1, Depth	22	24	2272.50	-.447	.003	-.838
H2, Urgency	23	23	2704.50	-1.464	.143	-.116
H3, Immersion	16	16	2993.00	-.477	.655	-.036
H4, General	12	12	2992.0	-.472	.637	.051
H5, Time	106.53	102	2839.0	-.979	.328	.078

Summary of Mann-Whitney U Test Results

***an effect size greater than .5 indicates a large effect**



Scatter Plot showing weak correlation between time and urgency for tattoos

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