



INNOVATION
THROUGH ART
AND SCIENCE



U.S. ARMY
RDECOM

ARL

Developing Medical Training Technology with Commercialization in Mind

ITEC - April 2018

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Agenda

- Background
- Objectives
- Requirements
- Development
- Rapid Prototyping
- Path to Commercialization
- Conclusions





Background

- The proximal humerus is a superior location providing maximum fluid infusion flow rates.
- Humeral head intraosseous infusions are often performed to rapidly provide medications and fluids.
- Two pre-hospital studies found that successful insertions in the humeral head were lower than that of the tibial site.
- Lower success rates in the studies were attributed to problems with training.



Background

- Opportunities to practice the Humeral Head Intraosseous (HHIO) procedure are limited because existing training models lack realistic anatomical landmarks and soft tissue
- Some training methods do not accurately simulate the amount of force required to penetrate the bone and surrounding soft tissues
- Cadaveric training is cost-prohibitive and not easily accessible

Training gaps highlighted the need to develop a Part-Task Trainer (PTT) to train the HHIO procedure



Objectives

- Provide accurate and realistic feel of the humeral head underneath the skin/muscle tissue layers
- Provide the ability to position the needle and puncture through simulated skin/muscle tissue at the correct/incorrect angle
- Provide the ability to insert the needle catheter through the simulated skin/muscle tissue and simulated bone with appropriate feel and resistance
- Reduce dependence on live tissue training



Rapid Prototype Engineering





Rapid Prototyping Requirements



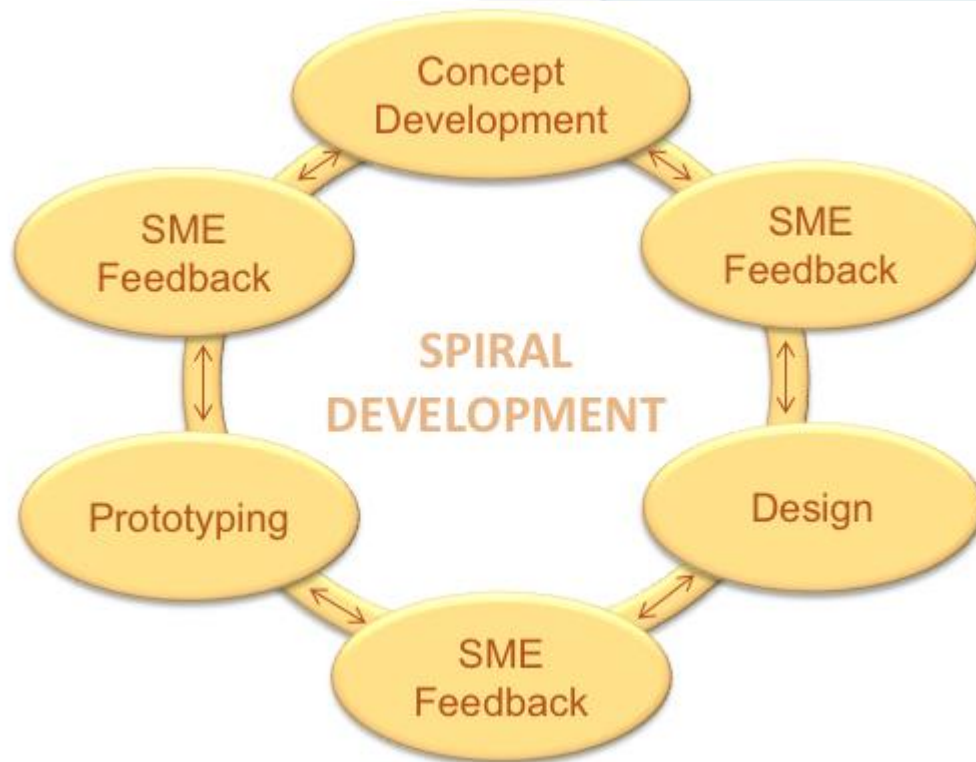


Humeral Head Intraosseous Training System Requirements

- Conduct literature review
- Identify stakeholders and user community
- Outline procedure critical tasks, conditions, and standards
- Conduct Critical Task Analysis (CTA) with Subject Matter Experts (SMEs)
- Identify relevant state of the art training capabilities/technologies and shortfalls
- Define target market and desired products



Rapid Prototyping Spiral Development

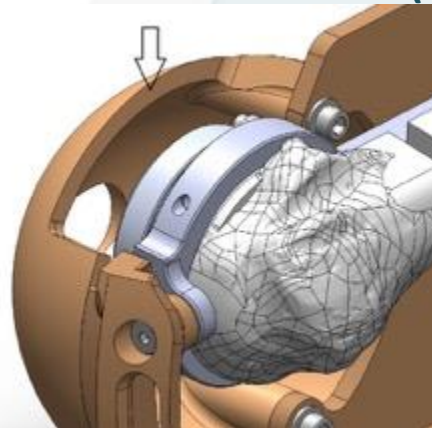
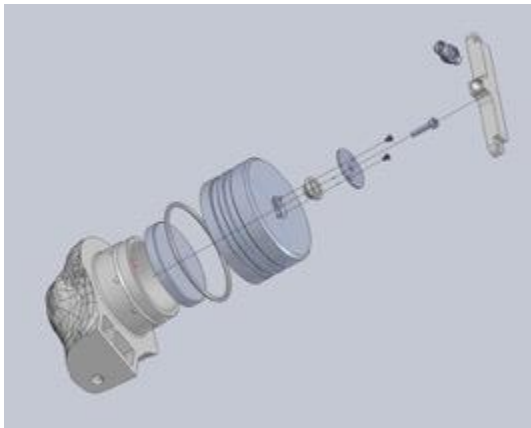




Humeral Head Intraosseous Training System

Spiral Development

Small Business Innovative Research (SBIR)



Phase IIB (24 mos.)

- Incorporate recommendations, findings, and new requirements elicited from end users and SMEs
- Reduce production costs and lead time:
 - Vacuum form molding of torso
 - Injection molding of consumable bones
 - Maximize 3D printing utilizing additives
- Simplify end-user operation, maintenance, and logistic support
- Develop product line that offers different levels of fidelity and cost to secure wider market share



Humeral Head Intraosseous Training System

Spiral Development

Small Business Innovative Research (SBIR)

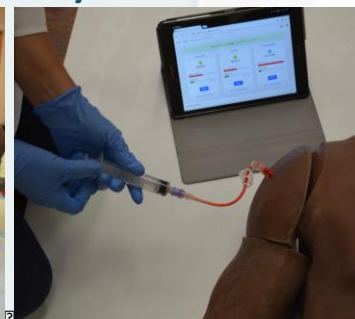


Phase I (6 mos.)

- Accurate and realistic humerus underneath the skin/muscle tissue layers
- Ability to position the needle and puncture through simulated skin/muscle tissue at the correct/incorrect angle with appropriate feel and resistance
- Multiple insertions with minimal and reusable consumables
- Ability to attach a syringe and apply negative pressure for confirmation of correct needle location
- Ability to infuse fluids through the needle catheter which will be consumed by the device
- Ability to position arms over the umbilicus, with realistic arm range of motion and keeping the elbow adducted and posteriorly located
- Ability to perform sternal insertions

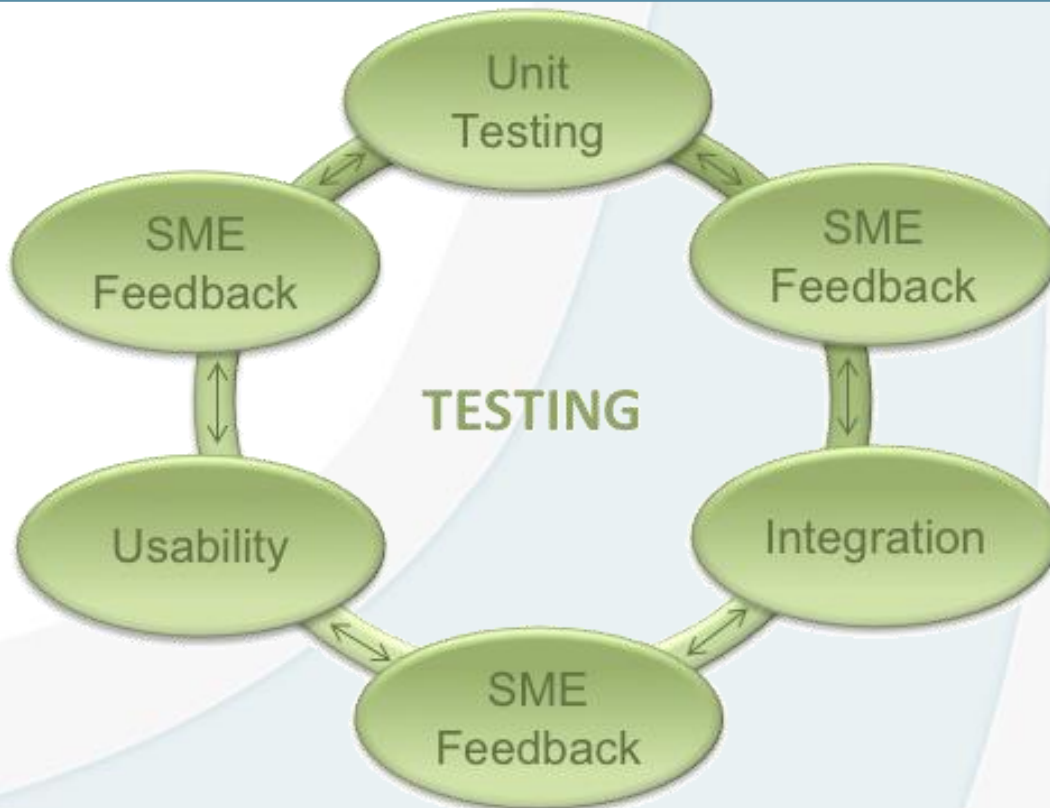


Phase II (24 mos.)





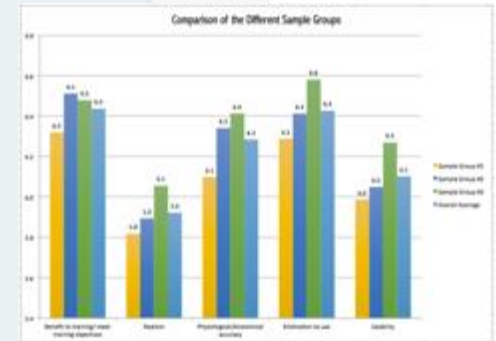
Rapid Prototyping Testing





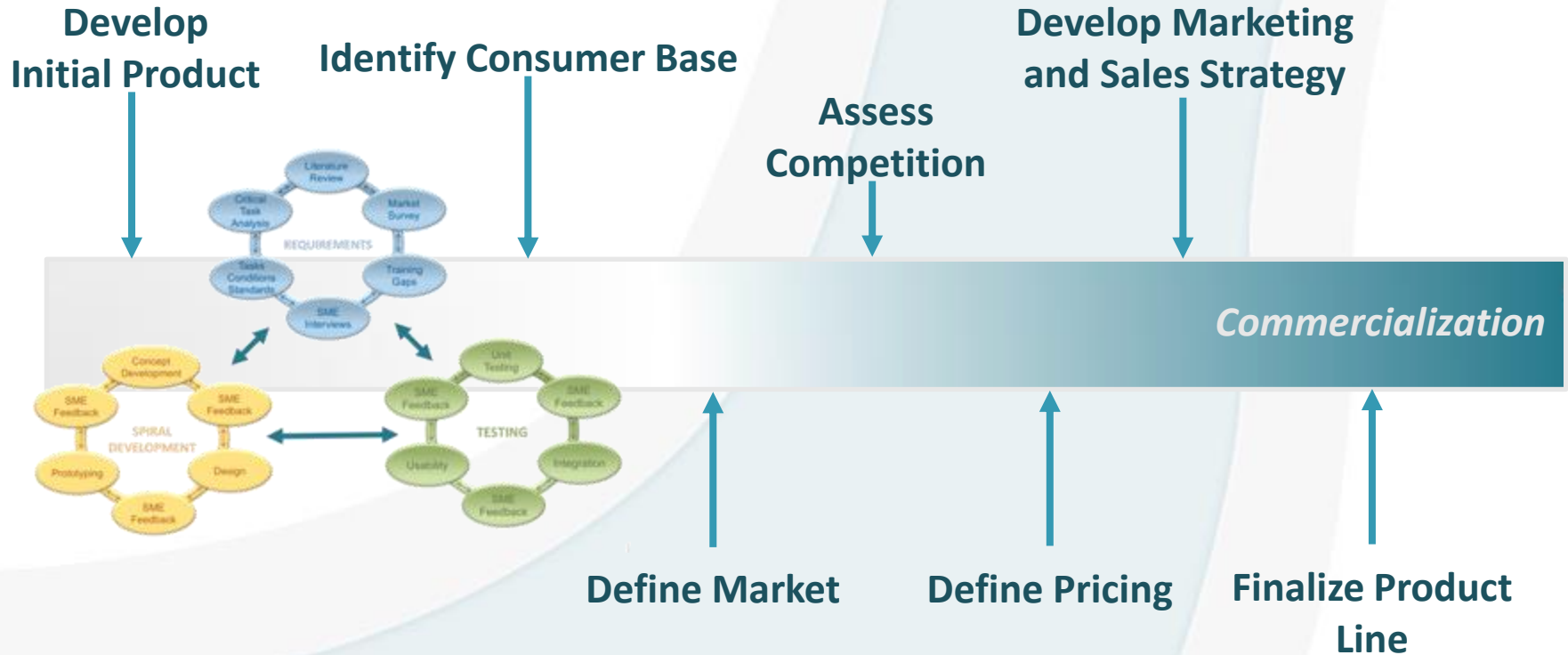
Humeral Head Intraosseous Training System Testing

- Conducted usability studies with stakeholders and users
- Average scores of the different sample groups per question category were as follows:
 - Meet Training Objectives: 6.43
 - Realism: 5.93
 - Physiological Anatomical Accuracy: 6.27
 - Motivation to Use: 6.43
 - Usability: 6.1
- The overall score for the PTT across all categories and sample groups was 6.22 out of 7.





Path to Commercialization





Humeral Head Intraosseous Training System

Consumer Base

Stakeholders:

- Department of the Army, Center for Pre-Hospital Medicine Tactical Combat Medical Care (TCMC)
- University of Florida, Emergency Department
- City of Orlando Fire Department
- Orange County (Florida) Fire Department
- U.S. Army Medical Simulation Training Centers (MSTCs)

Target Customers:

- Fluid Infusion Medical Device Manufacturers
- Civilian First Responders and Emergency Medical Centers
- Department of Defense and Foreign Military Sales



Humeral Head Intraosseous Training System

Consumer Base

- The target market for the HHIO Training System will be Graduate Medical Education (GME) and First Responder medical training centers
 - Medical school training centers (26.2%)
 - Military training centers (17.1%)
 - Hospital training centers (11.9%)
 - EMS (7%)
- The HHIO Training System will be marketable to 62.2% of the medical training center market

Target Market: Trauma Medicine Training Centers



Humeral Head Intraosseous Training System Market

- Military Medical Training Centers
- Veterans Health Administration (VHA)
- Department of Homeland Security
- Fluid Infusion Device Manufacturers
- Civilian First Responders (e.g. Fire Departments, Hospitals, Graduate Medical Education (GME) programs)
- Private/public technical schools/programs for First Responder
- Graduate Medical Education Institutions/programs
- Public Sector Emergency Preparedness Organizations

Target Market: Trauma Medicine Training Centers



Humeral Head Intraosseous Training System Competition

Sawbones

- Currently provides the bone with a latex skin patch that is low fidelity and skin patch shows previous punctures immediately

Strategic Operations

- SBIR Phase I and Phase II awardee for same topic
- Training system still under development
- Plan to assess capabilities when available

Manikin OEMs

- Most don't offer HHIO training capability
- The HHIO training capability offered by some OEMs is low fidelity and inadequate for teaching critical tasks



Humeral Head Intraosseous Training System

Develop High Fidelity Full Functionality



- Full torso with two articulating arms (Sternal IO option available)
- Instructorless operation with automated fluid flow
- Mobile application for operation and maintenance
- Consumables: reusable soft tissue and bones



Humeral Head Intraosseous Training System

Reduce Size and Complexity



- Half torso with one articulating arm
- Gravity fed fluid flow
- Mobile application for operation and maintenance
- Consumables: reusable soft tissue and bones



Humeral Head Intraosseous Training System

Enhance Existing OEM Manikins through Retrofit

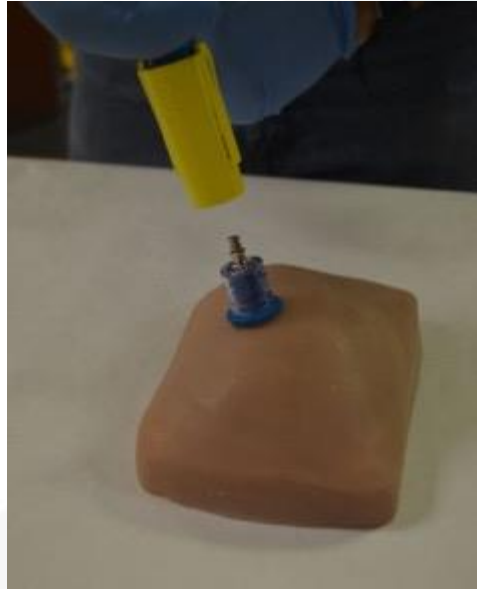


- Palpable landmarks
- Fluid option available
- Consumables: reusable soft tissue and bones



Humeral Head Intraosseous Training System

Target Basic Skills with Static Humerus and Skin



- Palpable landmark
- Fluid option available
- Consumables: reusable soft tissue and bones



Humeral Head Intraosseous Training System

Provide Familiarization with Mobile Instructional Game



- iOS and Android compatible mobile game
- Mobile Computer-Based Training (CBT) for HHIO critical tasks



Humeral Head Intraosseous Training System

Marketing and Sales Strategy

Strategic Alliances and Partnerships

- Fluid Infusion Device Manufacturers
 - Demonstrators and bundled sales with other product lines
- Manikin OEMs
 - Develop HHIO Retrofit for existing training devices and manikins
- Outside Sales Channel Partners



Humeral Head Intraosseous Training System

Marketing and Sales Strategy

- Publish papers in journals and conference proceedings
- Continue building brand and product line using social media channels
- Advertise in journals and trade publications
- Exhibit and launch product line at trade shows
- On-line retail sales on company website
- Outside marketing and sales



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