SIMETRI

INNOVATION THROUGH ART AND SCIENCE

The Art of Designing and Rapidly Prototyping Medical Training Technologies

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Agenda

- Background
- Objectives
- Approach
  - Requirements & Critical Task Analysis
  - Spiral Development
  - Testing
- Lessons Learned

Background

- Additive manufacturing and miniaturization of processors and sensor technology have evolved medical training device development
- Advanced manufacturing capabilities can benefit medical training by accelerating the iterative design and manufacturing process
- Physical training models that at one time lacked fidelity or were cumbersome to maintain and use, can now be perfected through rapid and iterative design and development

Background

- Rapid prototyping facilitates affordably developing and integrating sub-assemblies prior to final production
- Rapid prototyping and sampling of different materials facilitates focused efforts to objectively simulate haptic forces required to interact with skeletal and soft tissue components

Moving rapidly from a concept to implementation accelerates medical training technology development

Problem Space

- Current training curricula consist of lectures and observation of an experienced clinician performing the technique
- The market lacks high-fidelity training devices that enable learners to have multiple opportunities for skill practice and feedback using a repeatable and inexpensive training platform
- Medical training gaps are often encountered due to the nature of the injuries when compared to the capabilities of current simulators

Problem Space

- Current simulator capabilities include sophisticated and accurate physiological models mimicking a broad array of medical conditions, but they often lack specific detailed anatomy required to properly diagnose and treat common battlefield injuries
- Many of the injuries and required treatments involve destructive procedures (e.g. cutting, drilling, or puncturing skin and underlying tissues)

Problem Space

Rapid Prototype Engineering

- High training throughput requirements to obtain these skills quickly becomes cost prohibitive when applied to current simulators
- Durability and low lifecycle cost become key drivers for training common battlefield injuries so that repetitive training cycles can be performed

Objectives

- Provide accurate anatomical models to include realistic feel of underlying soft tissues and skeletal components
- Provide accurate haptic cues present with anatomical model(s)
    - Tactile, aural, olfactory, visual
- Provide affordable capabilities that are easy to use and maintain
- Reduce dependence on live tissue training

Approach

Rapid Prototype Engineering

- Utilize a rapid prototype engineering approach to all aspects of medical training systems development
- Consider end user testing during initial requirement development to ensure design completeness
- Utilize rapid prototyping and manufacturing capabilities to aide spiral development of medical training systems
- Incorporate SME and user feedback as key spiral inputs to guide design and subsequent iteration goals

Approach
Rapid Prototype Engineering

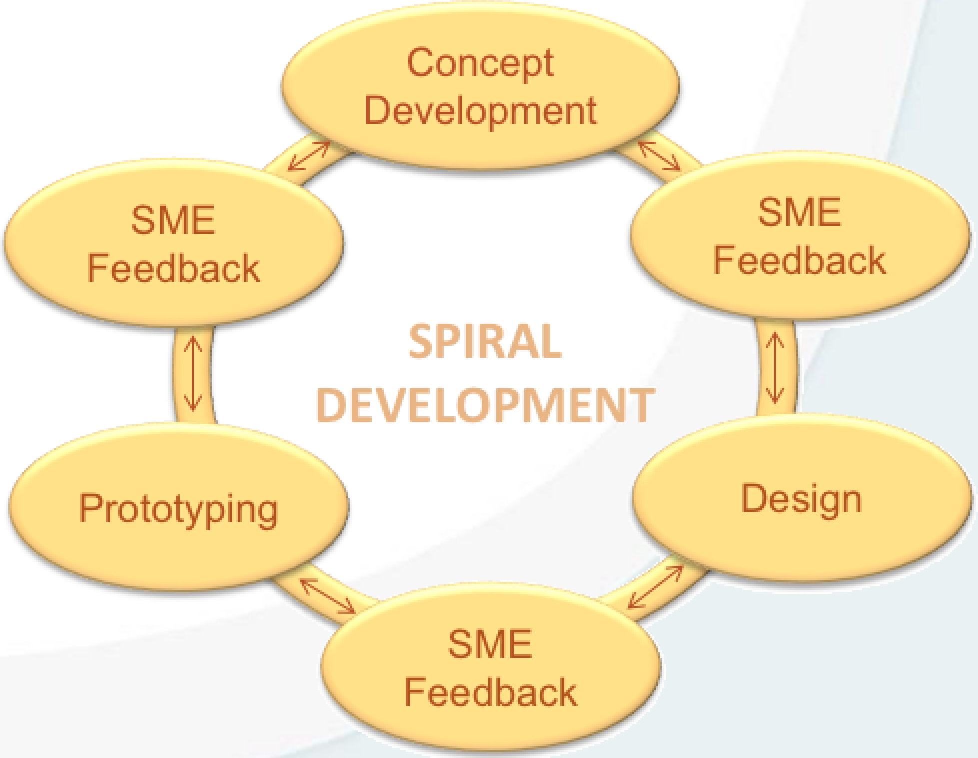
Rapid Prototype Engineering
Requirements & Critical Task Analysis

A disciplined engineering process coupled with initial investment in critical needs analysis can result in refined requirements that facilitate rapid and iterative prototyping of simulators that can address training gaps.

Rapid Prototype Engineering
Requirements

- Identify stakeholders and user community
- Conduct literature review
  - Identify current training methods and relevant state of the art training capabilities/technologies and shortfalls
  - Define target market and desired products
- Conduct Critical Task Analysis (CTA)
  - Outline procedure critical tasks, conditions, and standards
  - Key desired components
  - Outline patient/provider interaction

Rapid Prototype Engineering
Spiral Development



Prototypes are designed and developed using 3D printing and other additive manufacturing techniques fostering rapid and iterative collaboration between the engineering team and SMEs.

Rapid Prototype Engineering
Spiral Development

- Requirements are mapped to subsystems as well as integration and test procedures to ensure that the system is complete and testable
- Integration of skeletal and soft tissue components is prioritized to ensure end product benefits from multiple design iterations
    - Design issues can be identified and resolved earlier in the spiral allowing for a more complete and accurate design by addressing critical issues as early as possible.

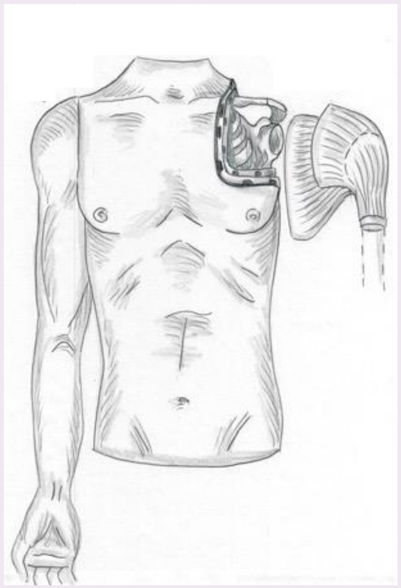
Rapid Prototype Engineering
Spiral Development

- Rapid prototyping and manufacturing processes are employed to facilitate multiple prototyping iterations allowing both technical and user evaluations to influence requirement and design updates for successive iterations
- 3D printing and other manufacturing techniques are utilized in each iteration allowing quick turn and testing of new design concepts based on incremental integration and testing at subsystem and system levels

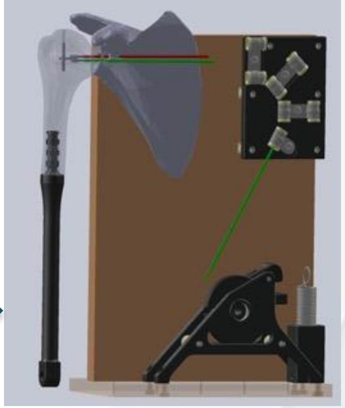
Rapid Prototype Engineering
Spiral Development

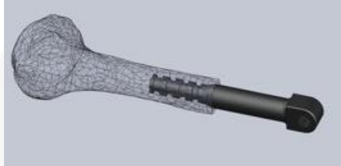
- Primary interfaces are targeted and developed for early integration and test of high risk components
  - 3D printing of mating and complementary components allows early integration and test of form fit and function
  - Subsystems can be matured in a non linear fashion through effectively simulating surrounding components
  - Prototyping and simulation of electronics and communications systems supports early integration of sensors and certain haptics

Rapid Prototype Engineering
Spiral Development



Concept



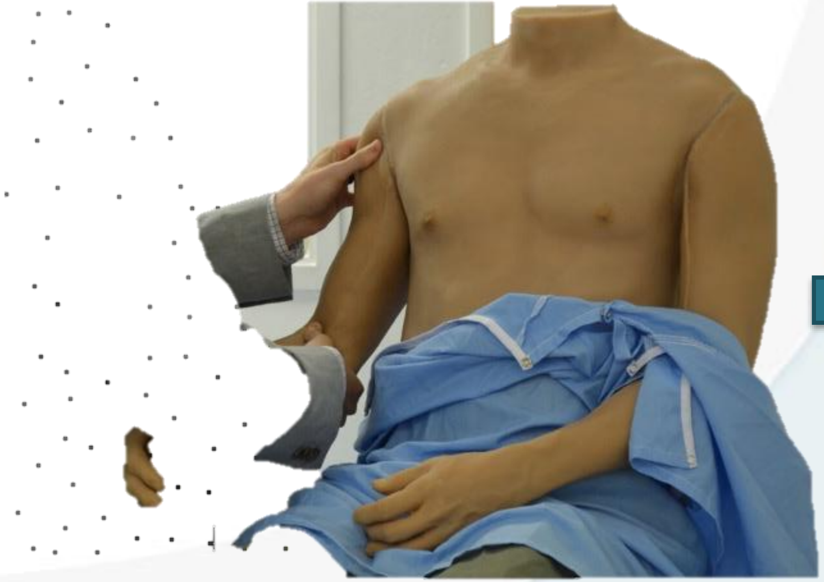


Design

Prototype

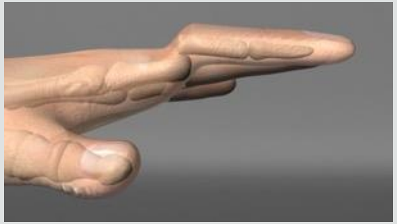
Concepts matured to designs based on research and 3D printed prototypes.

Rapid Prototype Engineering
Spiral Development



Shoulder Joint Reduction

Elbow Joint Reduction



Finger Joint Reduction

Rapid Prototyping
Testing

A collaborative partnership with stakeholders, users, and sponsors contribute to the success of the technology development. Iterative testing facilitates incorporating expert feedback, lessons learned, and recommendations for iterative spirals.

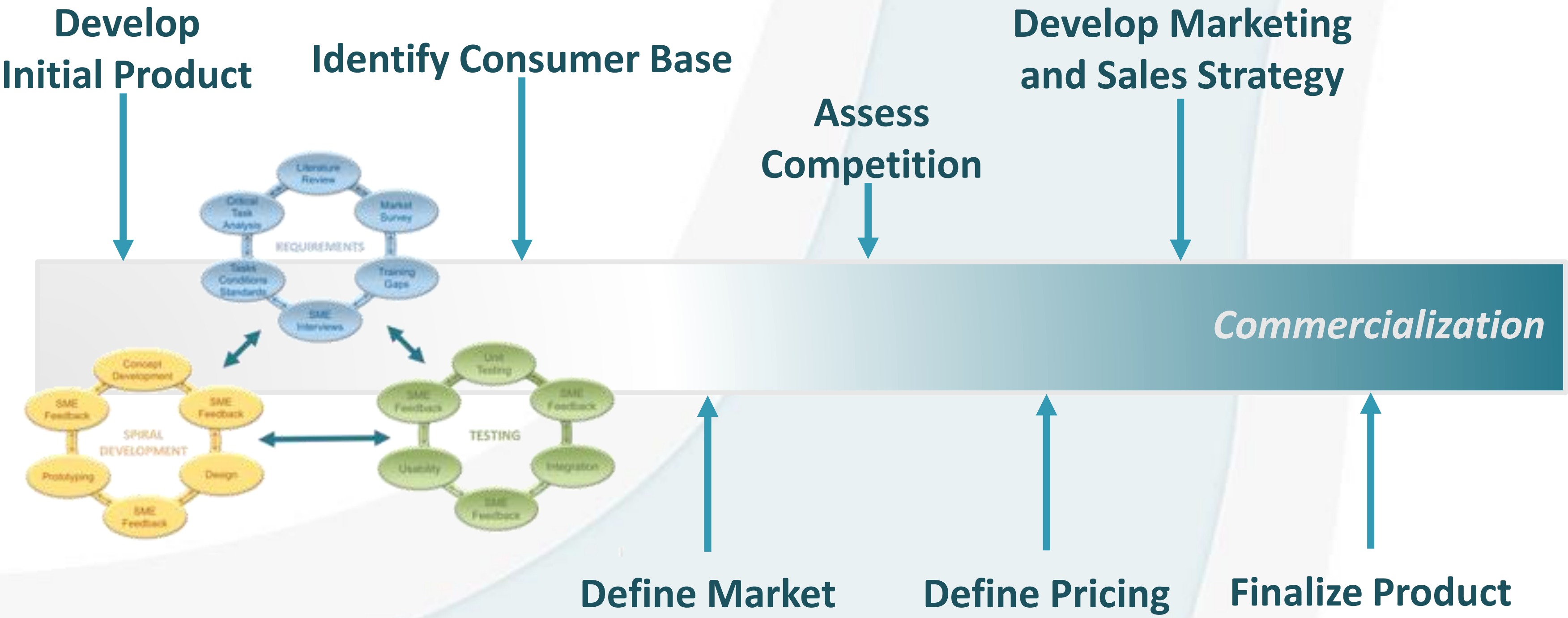
Rapid Prototyping
Testing

- Integration and unit testing are conducted in a laboratory setting during each iteration of design
  - Understanding the system level testing method early helps shape the extent of each iterative test
- Usability studies are conducted with stakeholders and users at various training centers using the prototypes at different phases of development
  - User feedback exposes unforeseen or unexpected outcomes and allows design updates to be implemented prior to final integration and test

Rapid Prototyping
Testing

- Testing with SMEs focuses on comparing the fidelity and functionality of the prototype simulator to the clinicians experience with a patient
  - Whenever possible SMEs are exposed to early prototypes ensuring form, fit, and function are addressed in the subsequent iterations

Lessons Learned



Lessons Learned
Benefits

- Rapid prototyping improves product design through rapid feedback and design update iterations
  - Design updates timelines are greatly reduced with 3D printing and rapid prototyping techniques
  - Flawed or problematic designs are identified earlier in the development process reducing the cost to correct
  - SME and user feedback is introduced much earlier in the development process improving overall fidelity and functionality of the end product

Lessons Learned
Pitfalls

- Rapid prototyping can also present challenges to the development lifecycle if not monitored and controlled
  - Continual updates of design can impact overall schedule
  - Continual improvement may surpass appropriate fidelity level, increasing end product cost unnecessarily
  - SME and user feedback can easily introduce desired functionality vs required functionality increasing design complexity and end product costs

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