Applying Systems Engineering Construct to Medical Simulation Development

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ABSTRACT

Systems engineering is a structured approach encompassing the lifecycle of product and technology development, from analyzing how the system is to be used until the system has been developed, verified, fielded, maintained, and disposed. It is perhaps best known for the "ilities", that is, a set of considerations that must be taken into account to ensure the best possible system. These considerations include utility, affordability, reliability, usability, and maintainability, among many others. Systems engineering is also known for its realistic approach to optimizing the most critical requirements, even at the expense of less critical requirements. The area between key requirement parameters "must haves", called thresholds, and "nice to haves", called objectives, is termed trade space. Optimizing requirements involves staying in that trade space for critical parameters. Further challenges arise when critical requirements for the same product and technology vary among a user community that spans military and civilian sectors with a range of levels of expertise; the trade space becomes even more complicated and narrow to truly optimize the product. Systems engineering has long been applied to modeling and simulation and more recently to medical simulation technology development. This paper presents a case for medical simulations posing unique challenges to the systems engineering process. A case study of a successful medical simulation development effort will demonstrate that these challenges can be overcome and how they can be navigated.

ABOUT THE AUTHORS

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Ed Stadler is a systems engineer and SIMETRI's Chief Engineer with 32 years of experience in the simulation and training industry. He has served as technical lead and chief engineer for complex simulation and training programs over the past 17 years and has extensive experience in the full life cycle development and production of simulation systems and products. Ed received his Bachelor of Science in Electrical Engineering from the University of Central Florida.

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INTRODUCTION

While cost, schedule, and performance are the key drivers of all acquisition programs, they are also important drivers of research efforts as well. Some research projects set threshold (minimum requirements) and objectives (desired goals) for various performance metrics, allowing developers trade space to optimize the overall system. Threshold and objective metrics are rare in research projects, however. Most modeling and simulation arenas have hard and fast rules of physics that can complicate trade space decisions. For example, gravity plays a role in ballistics and flight simulation. Developers must keep in mind that the downward acceleration gravity is approximately 9.81 meters per second squared at Earth's surface; no developer would ever alter that constant in order to meet a key performance parameter.

Human physiology is not governed by hard and fast constants but by rules and averages. As an example, a sudden loss of blood results in falling blood pressure and rising pulse rate (Gupta & Fahim, 2015). However, the degree to which systolic and diastolic pressure decrease and pulse rate increases is not a constant (Pacagnella et al., 2013). Human anatomy is likewise not governed by absolutes. Anthropometric data for US Army members is available (e.g., Gordon et al., 2016) but for all measurements there are ranges. In short, the variability in human anatomy and physiology allows the developer of a medical modeling and simulation training system some level of trade space.

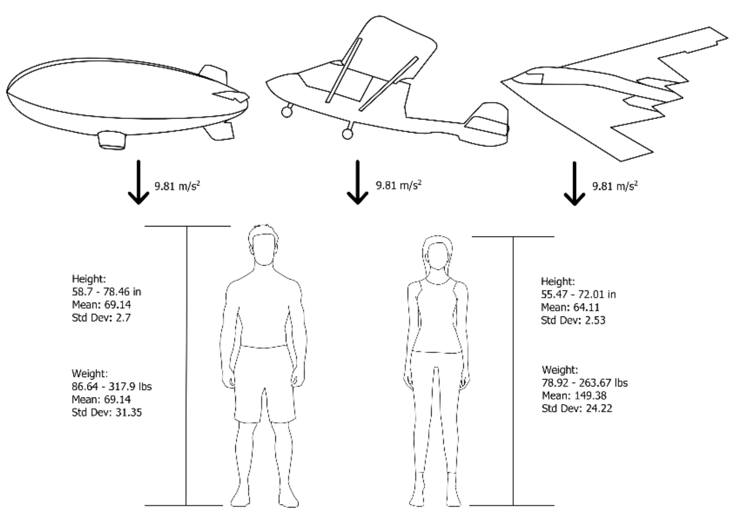

Figure 1. Physics Constant vs Anthropometric Ranges

BACKGROUND

From 2015 through 2020, the US Army DEVCOM Soldier Center Simulation and Training Technology Center (STTC), SIMETRI, and the Joint Special Operations Medical Training Center (JSOMTC) teamed to develop a part-task trainer designed to train Special Forces medics on how to perform a fasciotomy. A fasciotomy is a surgical procedure that relieves pressure in muscle compartments that have swollen due to internal bleeding (compartment syndrome). A surgeon cuts through skin to expose the fascia-covered muscle compartment, then incises the fascia to allow the blood to escape. If not performed timely, the patient could lose the limb; compartment syndrome may also be life-threatening. It is almost exclusively performed by surgeons in hospitals; however, Special Forces medics also perform fasciotomies, due to their warfighting role.

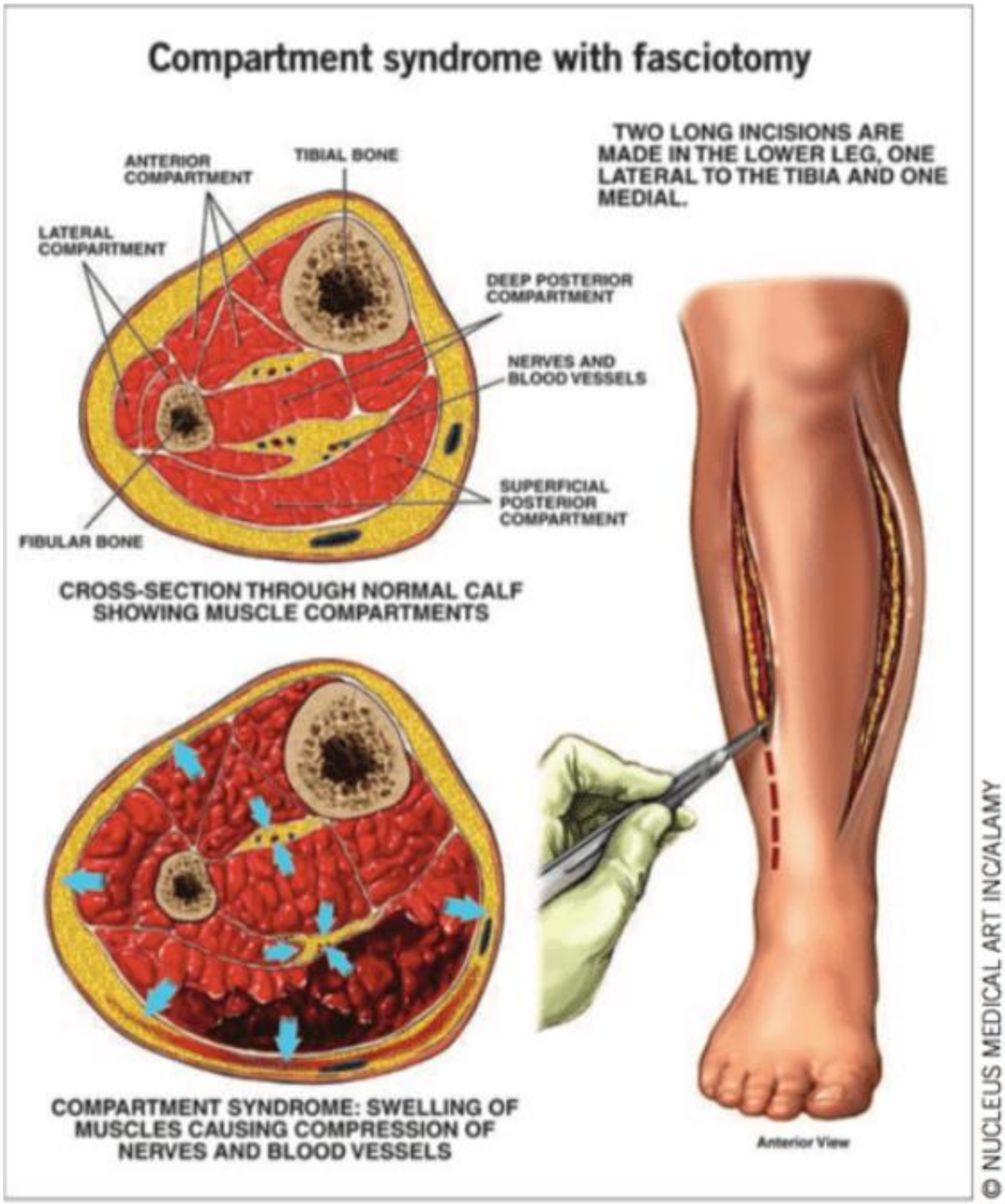

Figure 2. Physics Constant vs Anthropometric Ranges (from Kings County-Downstate Emergency Medicine, http://blog.clinicalmonster.com/2019/02/13/acute-extremity-compartment-syndrome-should-i-cut-it-open/)

As development began on the part-task trainer, the STTC, SIMETRI, and JSOMTC saw there would be trade-offs in order to produce a final prototype trainer within time and budget constraints. The Systems Engineering model provided and excellent methodology of evaluating those tradeoffs.

SYSTEMS ENGINEERING

The International Council on Systems Engineering (INCOSE) defines Systems Engineering as "a transdisciplinary and integrative approach to enable the successful realization, use, and retirement of engineered systems, using systems principles and concepts, and scientific, technological, and management methods" (INCOSE, n.d.) INCOSE further breaks down the four primary components of this definition.

- Transdisciplinary Approach. INCOSE indicates a "transdisciplinary" (as opposed to a cross-disciplinary, inter-disciplinary, or multi-disciplinary) approach is used to transcend the simple application of people with a variety of educational and experiential backgrounds to resolve a problem. Instead, the transdisiplinary approach seeks synergy from the various disciplines to holistically resolve the problem. The interdisciplinary team "organizes the effort around common purpose, shared understanding and 'learning together' in the context of real-world problems" (INCOSE, n.d.)'
- Integrative Approach. The role of the integrative approach is more multi-/cross-/or inter-disciplinary than the transdisciplinary approach, and acknowledges some problems are complex enough in nature to require larger project teams which may not allow for the same synergy that may come from a transdisciplinary approach. INCOSE acknowledges it has "long been used in systems engineering" (INCOSE, n.d.), indicating the transdisciplinary approach may be a more recent approach.
- Systems Principles and Concepts. The concepts that undergird the Systems Engineering approach have been taught and practices for many years. Systems Engineering has simply brought them together as a discipline. While the body of knowledge that composes the principles of systems thinking is beyond the scope of this paper, Adcock et al. (2020) present a good summary.
- Engineered Systems and Engineering. INCOSE prefers a wide definition of the concept of engineering, noting that both recent and ancient definitions should be drawn upon.
- Quality Attributes. Often called the "ilities", quality attributes define a system's performance. While different disciplines have added their own "ilities" over time, common examples include reliability, availability, and maintainability (Phister, Olwell, 2020). Applying the transdisciplinary approach indicates the "ilities" should be considered from the point of view of the engineered system as well as the end users, to include operators, maintainers, instructors, and future developers.

Model Based Systems Engineering

The International Council on Systems Engineering (INCOSE) defines Model-based systems engineering (MBSE) as a "formalized application of modeling to support system requirements, design, analysis, verification and validation activities beginning in the conceptual design phase and continuing throughout development and later life cycle phases [1]". MBSE is a discipline systems development methodology that relies on models that start at the System of Systems and ends at the components. The disciplined approach increases investment at the beginning of product development but results in lower costs during integration, testing, verification, and operational testing. Quality and productivity are increased while lowering risk and improving communication between development teams and customers.

In the case of the Lower Extremity Fasciotomy part-task trainer (PTT) developed for JSOMTC, the team elicited user requirements that became the baseline system requirements that were then decomposed and linked to the training goals, environment, and constraints. Some of these requirements included the ability for instructors to refurbish the simulator, reuse of as many components as possible, ruggedness/durability, and anatomical accuracy. The decomposed requirements were allocated to sub-system requirements which then were associated with designs. The system model flowed down and was interconnected with the subsystem requirements and emerging designs. The designs were created as different models that could evaluate governing anatomical, physics, and material constraints. The entire set of models were documented in SolidWorks so that their configuration was tracked electronically throughout the product development. With every iterative development phase, the baseline design was evaluated against the feedback received from the previous usability study conducted with the JSOMTC SMEs. If and when design changes were required, any subsequent impacts to the system model were evaluated before proceeding with development and modifications. This process forced the development team to focus on the system model that was created to reflect the stakeholders' product vision.

It was clear from the beginning that the team had to employ a collaborative, efficient, and modular approach to facilitate rapid prototyping and agile development in order to address the training gap. After studying the MBSE approach, the team decided to employ a model-based approach that would allow for maximizing innovative technology insertion. First, the team conducted a comprehensive assessment of the current "state of the art" coupled with user requirements and constraints, followed by defining a target product vision, identifying the gaps between the state of the art and the envisioned product, and finally developed a plan that addressed resources, tools, processes, and research as depicted in Figure 3.

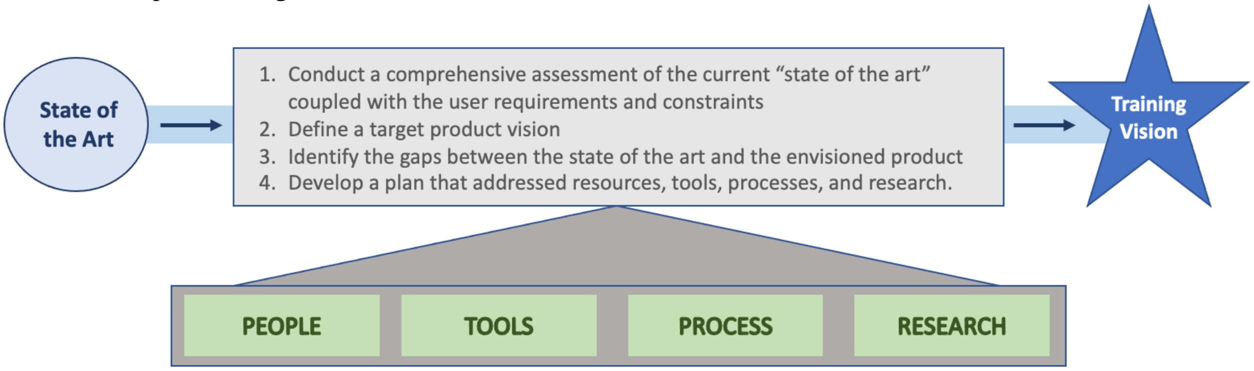

Figure 3. Using Model Based Systems Engineering to Develop a Development Plan

Systems Engineering Applied to Medical Training Devices

The topic of medical training devices can apply to several different categories, including medical tools and surgical instruments utilized in medical procedures, electronic scanning and monitoring systems, and representation of human anatomy and physiology. The development of medical training devices involves a mix of several different components, and designs and approaches, to realize each. Whereas the development of surgical instruments and medical devices can easily fall into one of the traditional systems engineering approaches, replicating human anatomy and physiology poses a significant challenge when applying a "traditional" systems engineering approach.

Past efforts to utilize a systems engineering approach were developed in compartmented segments and then an artistic overlay applied when anatomy was required, often resulting in the obvious integration of two disparate systems with obvious and unrealistic results. The success of the integration relies on the skill of the artist in creating the resultant anatomical model overlay. For example, consider developing a simple finger joint. Depending on the desired function or movement required, the joint could be developed with a flexible wire that could be physically bent into anatomically correct positions thus achieving the intent of the requirement. But if the finger is handled in any way, the user detects a soft mass underneath instead of a boney structure, making the finger a soft mass with a thin flexible wire running through the middle of the mass. When handled, the resulting fingers may be positioned to look anatomically correct, but they feel very soft and unrealistic to the touch.

Applying a systems engineering approach to the development of the "soft" anatomical systems is logical and required, especially when there is a mix of underlying infrastructure or systems that do follow a traditional systems engineering process during development. In fact, many of the "illities" become the key drivers in the design and development of anatomical structures to ensure that a realistic and life-like structure can be developed that also fully integrate the underlying infrastructure developed with traditional systems engineering approaches. Considerations of usability, maintainability, utility, affordability, and reliability all impact the look and feel of an anatomical structure. Applying a systems engineering approach to the development of the anatomical systems and structures helps the developers understand and quantify guidelines of anatomy and physiology which are not absolutes. Human bodies vary greatly in shape, size, and color but they do contain an underlying set of rules that can be applied in a systems engineering approach in the development of these structures. A developer can make a leg an entire inch longer than the original model to accommodate components without it looking odd, but a finger cannot be made an inch longer. As another example, pertinent to the fasciotomy simulator, the great saphenous vein in the lower leg (Figure 4) can be assumed to exist in all lower legs, but the size, location and routing can vary between patients. The shape of the lower leg is distinct enough to recognize between patients, but when the lower leg has an injury causing swelling it can vary greatly depending on the location and severity of the injury as well as the size and characteristics of the underlying anatomy. Consideration of these "ilities" as key factors help developers break down these design issues into logical segments allowing the systems engineering approach to be applied to these logical segments. Often systems engineers may look only at space constraints of the outward facing anatomy in the development of underlying electro-mechanical systems relying on the "magic" of an artist to create a realistic-looking overlay. This approach becomes more and more problematic as the medical training device moves from an external representation of an anatomical structure to internal representations of soft tissues and anatomical systems. As the "constraint" space becomes smaller and smaller, the development of realistic materials replicating the look and feel, which are key factors in usability, become key drivers in the systems engineering process, requiring disparate disciplines.

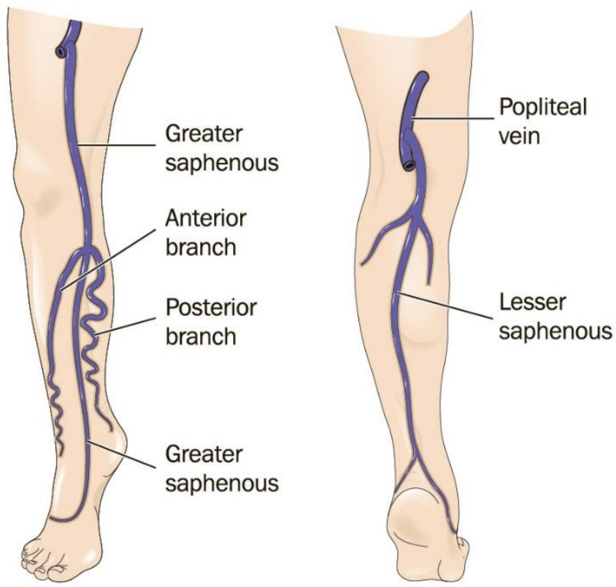

Figure 4. Great Saphenous Vein in Lower Leg (from Dr. Ricardo Ruiz, Vascular Surgeon, https://drricardoruz.com/condition/greater-or-lesser-saphenous-veins/)

Applying a systems engineering approach to these underlying anatomical and physiological systems can be intimidating to engineers not experienced in these disciplines. Addressing these laws of anatomy and physiology as constraints can be difficult when there is so much variability from patient to patient. Replicating realistic soft tissues and other key structures of anatomy should then become key drivers to the design. But just making these areas of the design a priority does not guarantee success of the product. Applying an iterative design approach utilizing trade studies and analysis as well as usability testing throughout the development lifecycle, helps to provide key inputs in the form of constraining requirements, refined requirements, and design decisions, among others. The use of trade studies or analysis is key in refining system requirements especially in areas where the lines between art and science become blurred, which is often the case when creating a medical training device.

Studying the medical procedure as a system itself can help identify key inputs and outputs for each step of the procedure. Applying this systems process view of the procedure can help the systems derivation by identifying the key inputs and outputs of each step of the procedure. Focusing on these inputs and outputs for each step of the procedure helps to break down the key requirement and design factors that will help drive the trades and analysis that will be conducted. Applying this design technique can also help identify the unique anatomy and physiology components at each step of the procedure as well as identify the common features that are present at each process step. This information proves to be vital input to the trade studies and analysis that help drive the requirements and design. This technique also provides an opportunity to dive deeper into each step of the procedure as required to ensure that the expected outputs are produced by the system under development at each step of the procedure.

SURGICAL PART TASK TRAINING DEVICE CASE STUDY

Medical simulation devices must mirror real human anatomy and physiology as accurately as possible to realistically replicate injuries, allow trainees to practice treatment, and indicate the treatment's success. The systems engineering approach requires developers to consider other factors, and perform trade-offs when necessary, optimizing such "ilities" as affordability, usability, maintainability, etc., against the realities of the need for anatomical and physiological accuracy. Figure 5 depicts an earlier version of the simulated fascia (a) and the final version of the simulated fascia (b) that proved to be less expensive, more realistic, and easier to use.

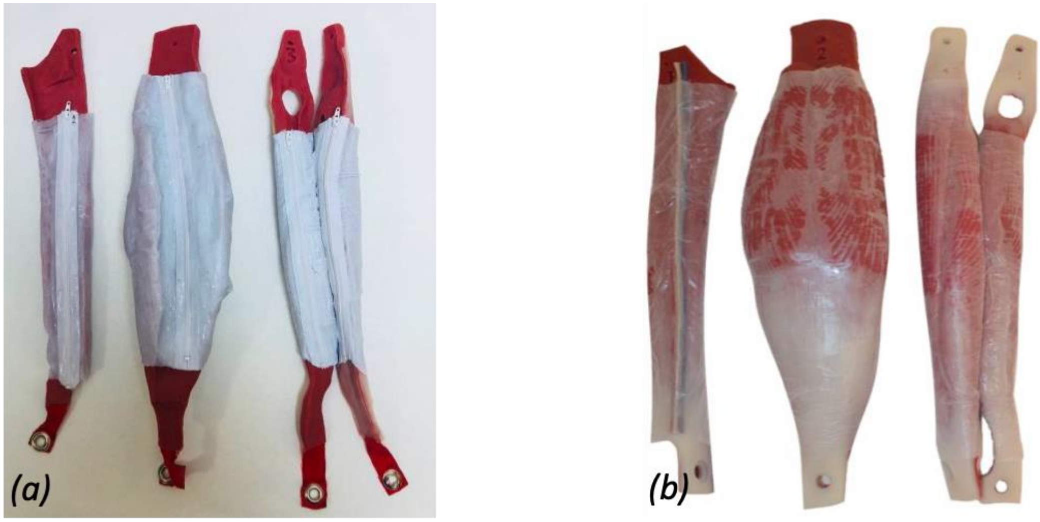

Figure 5. Optimization of the "ilities" through innovation

The STTC worked closely with JSOMTC to develop a part-task trainer for 18D (Special Forces Medical Sargent) students to master the performance of lower-limb fasciotomies. Development, which began in 2015, involved iteratively gathering and analyzing educational and operational requirements from JSOMTC instructors. The engineering team decomposed these requirements and applied them to the various subsystems (e.g., bones, muscles, nerves, veins, fascia, skin, and connectors). Each subsystem was prototyped, presented and refined based on input from the JSOMTC team.

JSOMTC instructors consistently stressed that quick and easy refurbishment was critical. Visual realism was also important. Tissue properties and bleeding were lower priorities. Early prototypes sought to simulate compartment syndrome pressures by including air bladders in the muscles. Muscles could be inflated, causing them to swell and become more rigid, thus simulating the effects of compartment syndrome. These bladders were fragile and subject to damage and failure. JSOMTC instructors ultimately decided that diagnosing compartment syndrome was not a critical capability in the simulator. The development team compromised by making muscles more rigid and swollen than normal muscles. The fascia demanded more refinement time than any other component. Trade-offs were required between look, feel, behavior, ease of replacement and cost.

Although cut during each fasciotomy, skins are reusable and can be glued back together after each use. Surgical staples were initially required to hold the repaired seam. Further refinements allowed for office staples, and the final skin version does not require any stapling. STTC and SIMETRI engineers were concerned that the resulting seam would present an obvious incision line. Internal testing showed that when the refurbished skin was pulled back onto the simulator, the seam did not necessarily line up with anatomical landmarks, resulting in no obvious incision line. The initial decision to ensure skins could be reused is an example of a very important "ility" – reusability – in medical modeling and simulation. The maturation from the initial requirement to use medical staples to the final product that does not require any staples demonstrates emphasis on maintainability (as the skin is easy to "repair") and even availability (as it is quicker to repair and put back in service)/

The great saphenous vein, neurovascular bundle, and superficial peroneal nerve were identified as critical landmarks for identifying specific muscle compartments during surgery. They can also cause major surgical complications if accidentally incised. The original prototype components were anchored at the top and bottom of the trainer but required complicated routing along the muscle compartments under, and on top of, the fascia after each use. The complex placement of these items enhanced anatomical accuracy, but also increased the difficulty and time involved in refurbishment, limiting the trainer's compliance with user requirements. These components were also highly susceptible to cuts from surgical tools which would require complete component replacement. These issues were addressed by simplifying the design. The neurovascular components located within the fascia on the muscle compartments were included as permanent items on the muscle design and were molded as components on the muscles themselves. Examples of the "ilities" in this case are manufacturability by reducing the manufacturing time, and maintainability by reducing the complexity of refurbishment as well as susceptibility to damage.

The product assembly requirements focused on usability—a simple and self-explanatory design which still allows the part task trainer to capture the human body's complexity. Attachment of each item to the main unit played a large role in simplifying the refurbishment process without reducing anatomical accuracy. To maintain realism, the skeletal components of the lower leg (patella, tibia, fibula, ankle, and foot) served as the main unit for attaching all other components. The initial prototype secured the muscles to the bone with a combination of metal hooks and pegs attached in areas not visible during the procedure. This design maintained visual realism and allowed an easy way to install and remove the muscle compartments, but the hooks and pegs were in an area frequently palpated during the procedure. At times, this caused landmark confusion. After weighing tradeoffs in accuracy with ease of refurbishment and durability, the team updated the design. The final iteration included minor muscle and bone revisions which facilitated the integration of mounting pegs that are held in position with magnets, flush with the muscle surface. These changes led to a product that was anatomically accurate, easy to refurbish, and durable while removing protruding mounting pegs and hooks that were sometimes confused with anatomical landmarks.

The next step was making the refurbishment process self-explanatory. Numbered muscle compartments visually communicate the order in which muscles should be attached without reference to the user manual. It was initially assumed that the similar shapes of the muscle and fascia would make it easy to match and assemble; however, user testing showed that further identifications would be needed to make it self-explanatory. Additional components were then given numbers corresponding to their specific muscle compartments.

LESSONS LEARNED AND RECOMMENDATIONS

The fasciotomy PTT research and development project demonstrated that medical modeling and simulation is as fertile a ground for the application of the systems engineering discipline as any other modeling and simulation problem space. By exploring the development process in hindsight, we realized we had followed a systems engineering approach faithfully at some points, but had strayed at other times. Regardless, some lessons learned resonated with the development team.

Anatomical landmarks and structures should be considered at varying levels of depth from the surface so that a full requirement set is developed. Several factors impact the physiological requirements such as time and type of interventions applied. These factors can be hard to analyze and apply during requirements elicitation and should be revisited throughout the development lifecycle to ensure that assumptions are holding at each review. Anatomical modeling in CAD systems and 3D printing of key systems can help to reduce artistic iterations as well as improve the overall look and feel of the end product. In the case of the fasciotomy PTT, during the course of the development, the SMEs began eliminating requirements as they began to evolve their plan of instruction (POI) to incorporate the PTT. As requirements were eliminated by the SMEs, the development team should have created a separate branch of that development that could have continued versus having to be restarted from scratch later. We later encountered other SMEs that were interested in those original features and functionality that we are now revisiting in an attempt to satisfy their training needs. We also found that it was important to develop the core, stand-alone technology with a goal of interoperability with third-party manikins and compatibility with other POIs. It will be interesting to revisit the SMEs at JSOMTC to elicit feedback regarding the product usability now that it has been in service for a year.

During the requirements solicitation phase, it is important for developers to understand from subject matter experts what is an inflexible law of anatomy or physiology, and what is a guideline. When quantifying, for development purposes, a guideline, developers must quantify the acceptable range. This may prove to be a difficult concept to understand for someone accustomed to developing modeling and simulation systems based on exact dimensions and laws of physics.

CONLCUSION

This development process serves as a perfect example of why the systems engineering process, even when abbreviated, is critical to the development of medical training devices. Limited resources regularly prevent development of an ideal system. Instead, developers must prioritize user requirements, keeping end-users constantly informed of necessary trade-offs. An initial understanding of key capability requirements, prioritized by the end user, is critical.

Enhancements may be added, as long as they do not impact these capabilities, and allow for maximizing the "ilities" described earlier. A key example of this was the initial attempt to inflate muscle bladders. While this resulted in a more realistic simulator, in that it simulated compartment syndrome pressures, it would not have been reliable, and diagnosing compartment syndrome was not a JSOMTC requirement. Perfection is not only the enemy of good enough, it is also the enemy of the trade space between customer needs and the "ilities".

While there are incontrovertible laws of human anatomy and physiology, there are seldom exact measurements that dictate development. Instead, there are ranges which allow for some trade space. Capturing realism and refurbish-ability was at the forefront of the research and design efforts. Each design iteration brought new ideas for production. The need to simplify the manufacturing steps ultimately reduced production cost. Each updated version maintained a similar size and shape. With a majority of the components consisting of silicon, the material costs changed minimally. However, labor hour costs significantly decreased with each iteration as the team worked in parallel to ensure commercial viability of the final product. Simplification of major component designs reduced the manufacturing and assembly time by 80% while continuing to meet the project requirements. Redesigning the fascia and skin reduced manufacturing time by 94% while concurrently improving realism. The engineers continued to optimize the manufacturing process and cost of materials, resulting in a reproducible and affordable product that is ready to meet the training needs of the JSOMTC. After a five-year cycle of development, testing, and refining the product, the fasciotomy trainer is being purchased by JSOMTC. Furthermore, it is well positioned for transition to a fielded product for other medical training commands, meeting a critical training need.

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