Cost-effective, Simulated, Representative (Human) High-Fidelity Organosilicate Models

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ABSTRACT

Current methods employed for the manufacturing of manikins and analogue simulators are lacking accurate physiology, and do not benchmark against human tissue properties. We have created cost-effective, simulated, and representative (human) high-fidelity bench top models and manikins with realistic mechanical properties built from human biomechanics data. Our program creates analogue tissue models with material properties representative of human tissue that can be designed and benchmarked against our Human tissue-property database. Such models are generated from, and can be registered with, patient-specific VR 3-D models. A simple organosilicate is used as a template for the development of human tissue models. Organosilicate films that are exposed to an ultraviolet light source have at least a 10% or greater improvement in their mechanical properties (i.e., material hardness and elastic modulus) compared to as-deposited film. Additionally, organosilicates are ideal due to their x-ray reflectivity, making them good clinical model substitutes for ultrasound and fluoroscopy applications. Moreover, this soft matter can be layered like human tissue with no space between layers and wrinkles very similar to human skin. The goal of this project has the potential to replace animal models. The tissues can be shot, exposed to blast pressures, cut, burned, etc, and then "surgically repaired." They can be used independently or as hybrid models attached to standardized patients or confederates in training environments. They are relatively cheap, rapid to produce, and greatly exceed current simulator fidelity. The production methodology allows for imbedding of sensors or fiducials to capture data for user's performance relative to collision forces and location.

ABOUT THE AUTHORS

Troy E. Reihsen is the Operations Director of the Simulation Peri Operative Resource for Training and Learning (SimPORTAL) and the Center for Research in Education and Simulation Technologies (CREST). He has professional expertise in the fields of high and low fidelity human patient simulator use for individual and team training, task deconstruction, basic surgical skills education, low fidelity surgical simulator development, 3D video streaming, tele-education and mentoring, video editing and production. He has an Anaplastos Manikin Development Lab which creates patient specific models created with organosilicate-based artificial tissues benchmarked from our Human Tissue Database. He has over 8 years in Anesthesiology (clinical and animal) and Urologic Surgery (education) research. He also has over 20 years of military service as a 68W combat medic with combat zone experience.

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Robert M. Sweet, MD, FACS (PI) currently holds the positions of Associate Professor of Urology and Director of the Medical School's Training and Research Simulation Programs at the University of Minnesota. He practices Urology with a focus on robotics and endourology and his lab is actively engaged in simulation projects including the development of a human tissue property database, artificial tissue analogue development, development and validation of virtual reality applications in medicine, advanced real time and predictive modeling of human tissue and tool interactions and delivery systems for the dissemination of simulation technologies. He has leadership positions in the area of medical and surgical simulation within the American College of Surgeons, the Society for Laparoendoscopic Surgeons, the Society for Robotic Surgery, and the American Urological Association.

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BACKGROUND

The creation of simulation materials that accurately imitate actual human tissue is essential for the training of medical procedures for health care providers. Currently, manikins and artificial analogue trainers are the mainstay of task training in medicine. Unfortunately they lack the anatomic and physiologic fidelity that contribute to effective training transfer as they do not behave like actual human tissue due to discrepancies in parameters such as mechanical properties and aesthetics. In addition, current physical models lack embedded assessment methods for formative and summative feedback.

Live animal tissues are often used to imitate human tissues with limited success. Besides the ethical concerns regarding the use of live animals for medical training, they are expensive and difficult to house and maintain. Besides the obvious different gross morphologic differences between humans and animals, studies have shown that the inherent constitutive properties of human soft tissues are different than animal models (Brown, et al., 2003, Hocking, et al., 2010). Fresh frozen cadaveric tissue also offers practice with more anatomical accuracy but is costly and also lacks the above mentioned constitutive properties of fresh or live human tissue (Clavert, et al., 2001, Chow, et al., 2010). The factors that contribute to the variation in constitutive properties amongst fresh or live human tissue have been hypothesized but poorly documented. Fresh human tissue models are logistically difficult to obtain, store, process and also lack embedded assessment methods for formative and summative feedback.

The discrepancies between current simulator materials and actual human tissue can lead to reduced efficacy when the trainee moves from simulation to actual patient care. Training on inaccurate and unrealistic models has the potential for negative training transfer (Chandra, et al., 2008; Friedman, et al., 2008). This justifies efforts towards developing anatomically correct, patient specific models, with representative mechanical physiology based on tissue elasticity and modulus.

The basic properties that need to be considered for soft tissues include homogeneity, nonlinear large deformation, anisotropy, viscoelasticity, strain rate insensitivity and compressibility (Duck, 1990, p. 346; Fung, 1993, p. 568; Humphrey, 2002, p. 776). Our human tissue-property database includes tissue characteristics data that provide values for comparison with simulator materials.

The creation of a human tissue property database that helps define soft-tissue behavior is critical to the field of simulation in order to assure accurate constitutive computer simulation models of structures, injury and disease. To date, there is a need for readily available soft-tissue data for academia, clinicians and industry. Individuals in the health sciences are in need of soft-tissue data to draw upon in order to test new devices, clinical hypotheses, planned surgical approaches, and/or development of surgical skills.

The primary components affecting the creation of these models are the a) costs of current models and supplies, b) accurate anatomical modeling, c) knowledge of the mechanical properties of the represented tissues, d) choosing the right modeling materials, e) assemblage of the models in an accurate representation of human anatomy and f) model development based on educational principals and "backwards-design" with an embedded-assessment strategy to maximize to learning (Sweet, et al., 2010).

METHODS

Model Development Process

Before embarking on any development project, we begin by clearly defining the desired outcome and subsequent goals and objectives of the training model with the active participation of a diverse group of subject matter experts vested in the training. This clarifies its role in an overall curriculum, which leads to the development of focused metrics and other means of assessment (Sweet, et al., 2010).

A method for the creation of this desired artificial tissue simulators has been developed. Figure 1 shows the overall process beginning with patient data determining the material properties (Human Tissue Database) and shape (3D Printed Model) of the artificial tissue model.

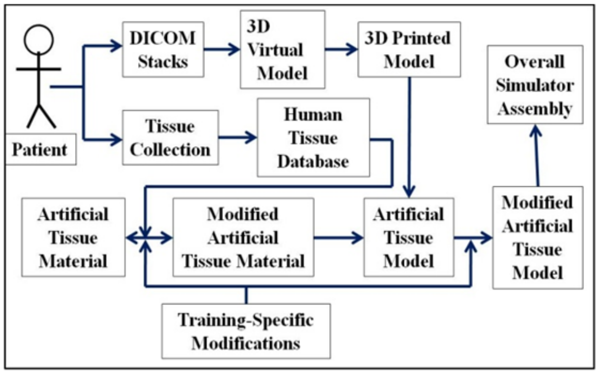

Figure 1. Simulator Development Method

The Human Tissue Database

The approach has been to harvest soft-tissue specimens within 24 hours of death for patients in our hospital. The specimens are warmed to body temperature and then we conduct uni-axial (and occasionally bi-axial) testing (Figure 2) for visco-elastic mechanical properties, and perform electro-conductive and thermo-conductive experiments on more than 30 different tissue types, with stratification as to gender, age, and body mass index (BMI).

Figure 2. Uniaxial Tissue Testing Apparatus

The Human Tissue Database is used to guide the formulation of the "organosilicate base" material with the objective of tailoring our recipes of the artificial tissues to match the properties of fresh human tissue.

Human Anatomy Modeling

In parallel, a patient specific 3D physical model is created. This is done via life casting or from CT and MRI datasets. DICOM imaging stacks are processed through compositing software (After Effects®) to identify and isolate the specific anatomical structure. The refined stack data is processed through image segmentation software (Mimics®) to create a coarse 3D model of the selected anatomy. The coarse model is brought into a 3D development package (Maya®) and used as a reference so that a new, clean model can be built over the previous. This model can be further refined to the desired level of detail. This process is guided by a physician.

The finalized virtual 3D model is sent to a 3D printer that utilizes stereolithographic techniques to produce a 3D printed model prototype. Figure 3 depicts the overall process of creating a 3D physical mold from patient specific data.

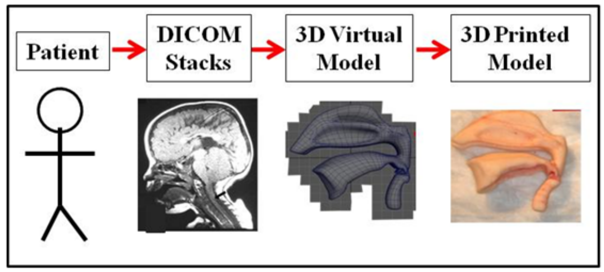

Figure 3. Human Anatomy Modeling Outline (Pediatric Airway)

Organosilicate base

The human tissue database results tailor the development of the organosilicate base. Many of our simulator models are produced using commercially available off-the-shelf (COTS) organosilicate materials. The base material can undergo modifications to change cross linking, electrical conductivity, thermal conductivity, reflectivity, indentation and color. Pigments and dyes are added to the organosilicate material to create anatomically accurate color mapping of the simulator model.

Next the 3-D printed model is casted with the tissue-specific organosilicate based material. The material conforms to the details of the model to create an exact replica of the patient specific anatomy. The material is added in layers to imitate the physiologically distinct layers found in skin and other human tissues. A thin layer of material is applied and allowed to cure. Subsequent layers are added over the first layer. Once the material has been added to the desired thickness the outer material is removed from the mold and sealed. Ultraviolet light sensitive coatings may be added on the between layers and outside of the model as a skill proficiency evaluation tool.

Black Light Assessment of Surgical Technique (BLAST - patent pending) represents a post-material development modification used to evaluate user performance is to apply polyurethane based coatings to the simulator models in lines, dots, or other patterns. While performing a specified task, the trainee is unaware of polyurethane based coating patterns on the simulator due to the transparent nature of the coatings under normal light. Following completion of a task by the trainee, an evaluation of his or her ability to perform a task can be made by viewing the simulator under UV black light where the polyurethane based coating pattern will appear in neon colors. These coatings are especially useful in skill assessment involving matching or aligning tissues

Lastly, the completed model is tested by subject matter experts in the training environment and inspected for anatomical deviations included poor color mapping, visible seams, extra material pieces, etc. Any abnormalities are noted and corrections are made to the protocol regarding the building of future models. As part of a curriculum, the models are assessed for validity.

RESULTS

Comparisons between the stress-strain relationships of trade secret organosilicate based recipes and human renal artery have shown similarities in modulus, yield stress, and yield strain. Figures 4 and 5 depict an example of stress-strain graphs for artificial tissue (Figure 4) and actual human renal artery (Figure 5). By comparing mechanical data obtained from these graphs, further improvement in human tissue to artificial tissue matching can be made.

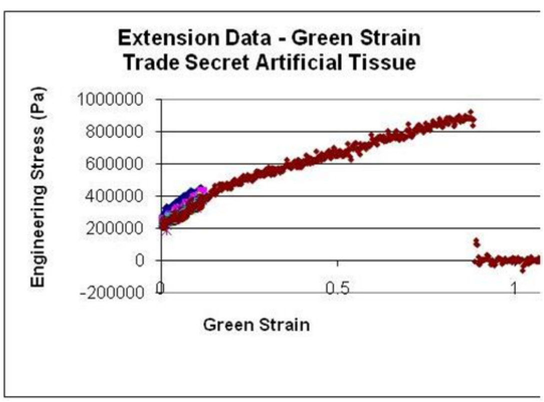

Figure 4. Stress-strain Relationship for Artificial Tissue

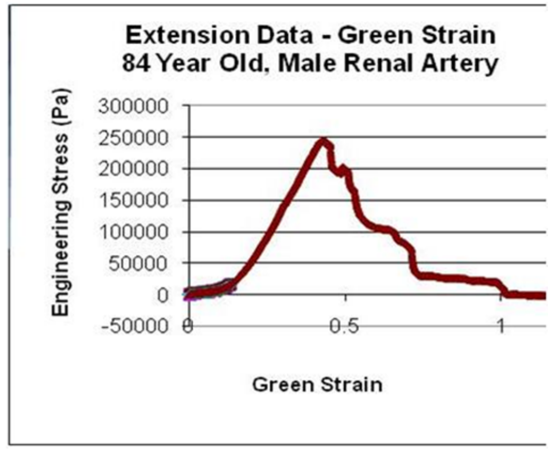

Figure 5. Stress-strain Relationship for Human Renal Artery

The simulator materials can also be implemented with indicators that evaluate the proficiency of a trainee to perform certain skills. Using photochromic or piezochromic materials allows color change based on pressure applied to the material. Figure 6 successfully demonstrates BLAST technology for embedding performance assessment in a model. In this case, lines invisible to the user are assessed after a tissue approximation exercise allowing his or her ability to perform a desired task.

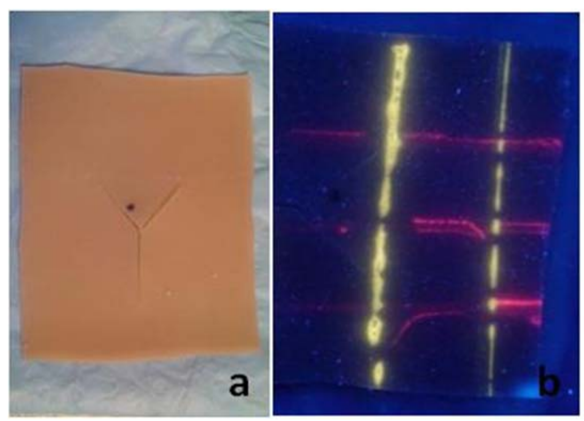

Figure 6. BLAST Skin Model with Polyurethane Based Coating Under Normal Light (a) and Under UV Black Light (b)

Current Simulator Model Examples

Renal Artery Simulator

Using an organosilicate based trade secret recipe, the successful creation of an artificial tissue training model has been created for renal artery (Figure 7) in order to meet the specifications of the American Urological Association for laparoscopic and robotic clip applying (Syverson, et al., 2011). The simulator tissue was color mapped to mimic human renal artery and filled with artificial blood to mean arterial pressure (MAP) 80±2mmHG. Solid black lines and dotted black lines were added for testing purposes to indicate areas for clipping and cutting respectively. The model was fitted into a mechanical apparatus to mimic a beating motion.

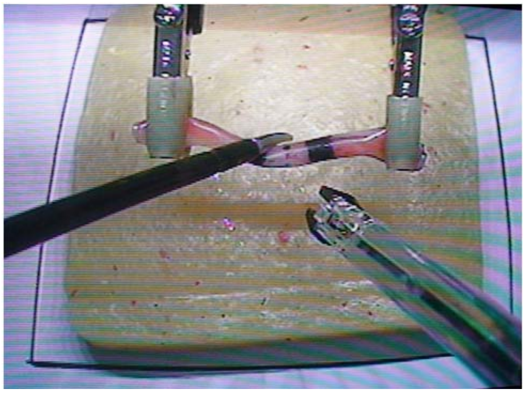

Figure 7. Animate Renal Artery Training Model with Blood

Kidney Simulator (Argun, et al., 2010)
Another successful example of the development method as described above is the kidney simulator (Figure 8).

Figure 8. Kidney Model for Endoscopy

The simulator utilizes renal tissue properties (from Human Tissue Database), accurate human anatomical modeling (stereolithographic prototyping) and color mapping to create realistic internal features such as the endoluminal ureter and the calyceal kidney collecting system. The model can be used in combination with artificial kidney stones and fluid to simulate procedures such as Ureteroscopy (Figure 9), retrograde pyelography, ureteral stent placement, nephro-lithotomy, laser and extracorporeal lithotripsy and kidney stone extraction. This model has undergone multi-institutional validity studies with results pending and is now the model utilized by the AUA post-graduate courses to train advanced ureterocopy.

Figure 9. Endoscopic Procedural Training

DISCUSSION

The materials used to create human tissue analogues need to meet many specifications in order to successfully emulate actual human tissues. Organosilicate materials were typically used as the base material for creating artificial tissues. The COTS organosilicate material based trade secret recipe underwent repeated cycles of revision by continually comparing the artificial tissue testing data to the Human Tissue Database.

Organosilicate materials are stable and do not require specialized storage or shipping. These materials are cost effective and are less expensive as compared to animal and cadaveric models. The material is durable and can often be reused which also adds to cost-effectiveness.

We have demonstrated that once a stable representative base is assigned for a specified tissue type, training modifications and coloring can be made to the simulator materials in order to meet the goals of a specific training procedure. These modifications can be made during the material development process or post-material development (during simulator assembly). These alterations are implemented to assist in meeting curricular goals and objectives as well as measurement and verification demands. These additives are based on the type of procedure that the artificial tissue will be used for and the type of indicators needed to evaluate the trainee's proficiency in a specified skill. When integrated into the organosilicate material, colors will not come off even after repeated use and exposure to fluids needed for simulation procedures.

Reflectivity is an important factor in ultrasound and fluoroscopy procedures. Our organosilicate materials have demonstrated ideal reflectivity properties. This allows the materials to be used in simulated procedures such as ultrasound and fluoroscopy procedures (Calomme & Vanden, 1997; Izquierdo-Barba, et al., 2008).

Possible modifications affecting viscoelastic properties include ratio changes, chemical additives and ultraviolet (UV) light exposure. For example, organosilicate films that are exposed to an ultraviolet light source have at least a 10% or greater improvement in their mechanical properties (i.e., material hardness and elastic modulus) compared to the as-deposited film (U.S. Patent No. 7,468,290). The UV light has been shown to cause increased cross-linking in the material which can increase the modulus and decrease the elasticity (Crowe-Willoughby et al., 2009).

The completed tissue models may be used in combination with other substances in order to replicate a clinical situation. The organosilicate based tissue models can be used in the absence of silicone spray and can instead be implemented with cheap clinical substitutive artificial blood, saliva, urine, or vomit.

Benefits of Stereolithography

Stereolithography is advantageous due to the ability to rapidly create prototypes (typically less than one day). The resulting prototypes are durable and reusable as a negative for tissue castings, adding to the cost-effectiveness of using stereolithography. In addition, the Medical Device Center at the University of Minnesota-Twin Cities owns a stereolithography machine which adds to the convenience of using this technique.

Prototypes created using stereolithography are anatomically accurate because of the detailed layer-by-layer process used to print the prototype. The printer has high resolution which allows precise anatomical structures to be depicted in the printed prototype. The 3D printed model is patient specific based on the original CT or MRI images used. The models can also be used as a functional base for anatomical deviations and pathophysiology. One approach is to add a layer of wax over the 3D printed model which is sculpted to create bumps, detailing, or other deviations that may be desired for a specific training model.

CONCLUSION

The uses for physiologically accurate tissue simulators are widespread. Organosilicate based materials can be subjected to extremes such as cuts, burns, gun shots, and blast pressures. They can then be repaired by the trainee as part of a simulated procedure.

The tissue simulators may be used independently or as hybrid models attached to standardized patients or confederates in training environments. The trainee is able to perform tasks such as needle sticks and suturing on the attached analogue tissues without harming the volunteer. The combination of patient interaction and accurate tissue simulation provides for an ideal training environment.

In conclusion, the overall method for developing artificial tissue simulators for training purposes provides accurate anatomical modeling and matching of tissue properties. The materials and fabrication techniques are cost-effective and allow for the integration of indicators to properly evaluate trainee skill acquisition. The resulting tissue simulators can be applied to countless tissue types and training strategies to improve patient care through better procedural practice and assessment.

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