Title:
Development of a Reconfigurable Thoracentesis Training Mannequin

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Introduction:
Parametric CAD models combined with Additive Manufacturing (AM) processes are providing new means to improve biomedical prototypes and products. One example of this is the development of a reconfigurable thoracentesis training mannequin. Currently, training for this procedure uses an inflexible, costly, or unrealistic model. The goal of this research is to develop a more representative model for training that is reconfigurable for different patient sizes and weights. To achieve this goal, parametric models are developed for both the key human anatomy and the manufacturing molds. This research shows the potential of creating flexible, reconfigurable products, to improve medical training using a methodology centered on advanced CAD and Additive Manufacturing techniques.

When the proper function of the lungs is impaired due to a pooling of fluid in the pleural space (the space between the two layers of a membrane called the pleura, that enclose the lungs), it is referred to as a pleural effusion. Shortness of breath, chest pain, and dizziness are common symptoms of a pleural effusion (Fig. 1(a)). To drain this fluid, a thoracentesis is performed; where a wide bore needle is inserted through the chest wall, into the pleural space to drain the fluid (Fig. 1(b)). The 18-20-gauge, 3.5 in. (89 mm) catheter/needle is typically inserted normal to the skin approximately one inch (25 mm) deep, depending on chest wall thickness. Some of the risks of thoracentesis are bleeding (due to the needle being inserted incorrectly) or transfer of infection from the skin to the lungs. The other major risk due to an error during the procedure is a pneumothorax, which is air in the pleural space from the punctured lung. Huang G.-C. et al. have stated that most Internal Medicine (IM) residents express feelings of increased discomfort with this procedure, especially given its invasive, and unnerving, nature [4].

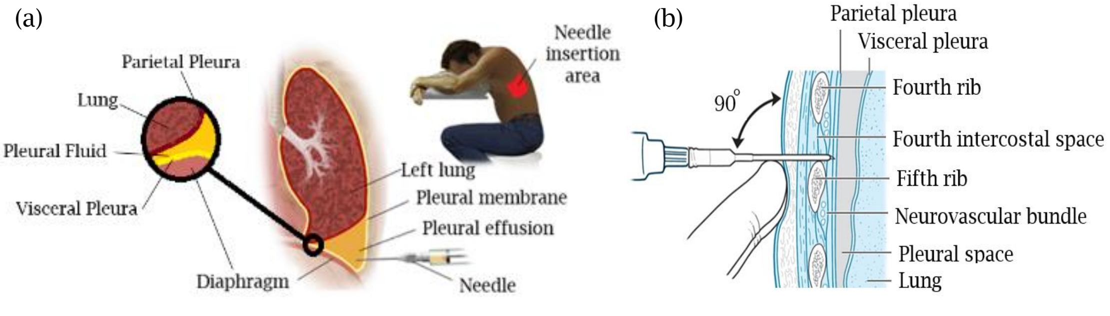

Fig. 1: (a) Pleural effusion, (b) Insertion of thoracentesis needle.

In the United States, an estimated 178,000 thoracenteses are performed yearly. Mynarek G. et al. showed that the patient population distribution is skewed towards older adults (Fig. 2, in red); however, a notable percentage of cases between 0-9 years of age (Fig. 2, in red) have been reported [6], and this younger population is particularly problematic [2]. Nevertheless, the majority of training methods available to IM residents are geared towards a typical 30-year-old male (Fig. 2, green).

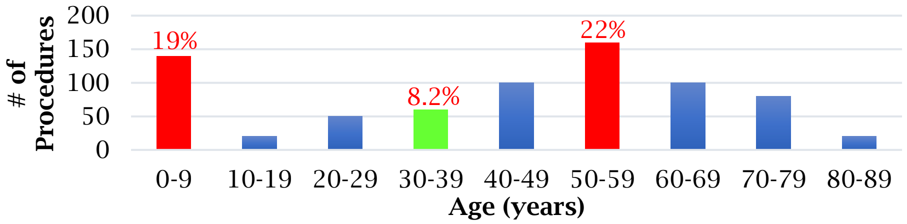

Fig. 2: Age distribution of thoracentesis (adapted from Mynarek G. et al.).

Not only are there noteworthy age and size differentials for the thoracentesis patients, Harcke H.-T. et al. have shown that the thoracic wall thickness varies greatly between individuals. In Fig. 3(a), two extreme regions are highlighted. The thoracic wall thickness range varies from 3.07 cm to 9.35 cm [3]. Furthermore, in the United States, obesity rates are a serious concern. With more than 1/3 adults, and 1/6 children classified as overweight [7] (Fig. 3(b)), the chest wall thickness, and "feel" during the puncture is highly variable, and this must be considered as well.

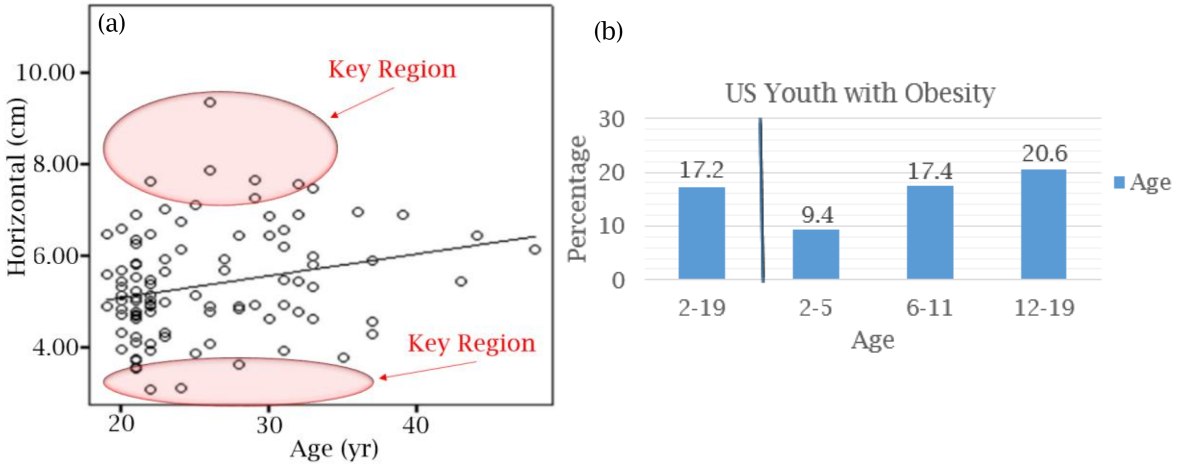

Fig. 3: (a) Chest wall thickness variation with age (adapted from [3]), (b) US youth obesity [11].

To help prepare IM residents, training mannequins are utilized. These mannequins however, are typically crude representations of the human physiology (Fig. 4(a) and Fig. 4(b)), and not adaptable to represent the size variations observed for all demographics. The characteristics for the model currently in use at the Schulich School of Medicine & Dentistry-Windsor Campus is presented in Tab. 1.

As the aim of this research is to develop a reconfigurable design and fabrication solution for a thoracentesis training mannequin that accommodates the high degree of variability in the patient demographic, advanced design and flexible fabrication solutions need to be employed. Scaling factors are determined by the medical community via consultation and literature, and implemented into the parametric model. Puncture resistance forces are determined experimentally. Flexible manufacturing techniques are to be used to fabricate alpha prototypes, which are compared to the current educational training prototype. The general process flow for this research is illustrated in Fig. 5.

Strengths	Weaknesses
Portable	Unrealistic lung (Fig. 1 (a) versus Fig. 4 (a))
Easy-fill/drain fluids for feedback (proper procedure yields fluid release)	Flat ribcage (Fig. 4 (b))
Self-sealing (reusable)	Represents only one side/size of patient
	No clavicle for palpation
	Unrealistic scapula (Fig. 4 (b))
	“2D” solution to a “3D” problem

Tab. 1: Summary of current University mannequin.

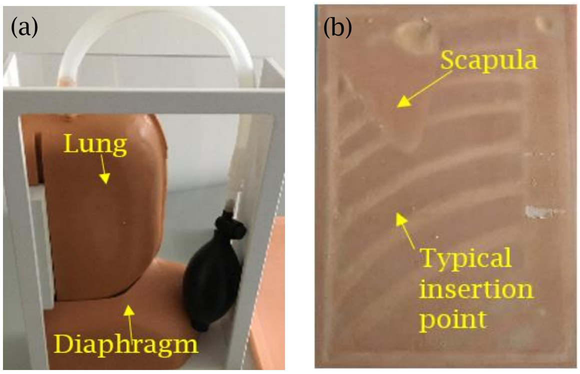

Fig. 4: (a) Ultrasound Thoracentesis Model (THM-30) (Simulab Corporation), (b) Flat rib cage “sheet”.

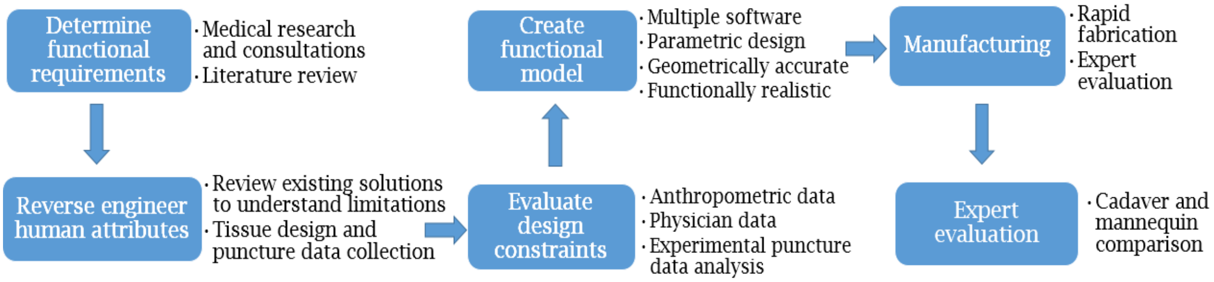

Fig. 5: Reconfigurable design process.

Research Methodology:

Consultations with a medical team were conducted to determine the essential functional requirements, which are: (i) the model must contain realistic anatomical reference points, or landmarks, necessary for the proper palpation sequence; (ii) there should be realistic puncture resistances (with a tough outer “skin” and softer internal tissues), (iii) a feedback mechanism (a liquid removal system); (iv) the sizes and shapes should be realistic, and (iv) the mannequin ‘tissue’ must be self-resealing (for multiple uses).

A literature review was conducted in the medical and mechanical CAD modelling domains. Selected literature is presented here. Scaling information for the skeletal structures of patients with age and sex is gained from Weaver A. et al. [11] and Mcgraw A. et al. [5], who validated a quasi-linear scaling of the clavicle and rib cage with age (as seen in Tab. 2), which demonstrates linear growth up to adulthood, at which point growth slows significantly. Data manipulation from CT scans [9] and CAD modeling strategies for anatomical structures [8] have been employed, and similar methods are utilized here, but a systems approach is being taken. The CAD models for the skeletal structure are linked to the artificial skin and adipose tissue mold modeling. Various ‘wall thicknesses’ or obesity levels can be configured. Therefore, changing the skeletal structure and / or the tissue thickness will change the mold models and insert.

Age	Size
→ 3 Years	
→ 20 Years	
→ 40 Years	
→ 50 Years	

Tab. 2: Rib cage growth patterns with age (adapted from Weaver A. et al.).

The reverse engineering for the tissue attributes is summarized in Fig. 6. A transducer-fitted thoracentesis needle was used to perform punctures on a cadaver to obtain puncture force data at 1000 Hz using a WIDACs (WIreless Data ACquisition) system. This data is used to determine appropriate durometer levels for the implementation of realistic silicone tissues for the training mannequin.

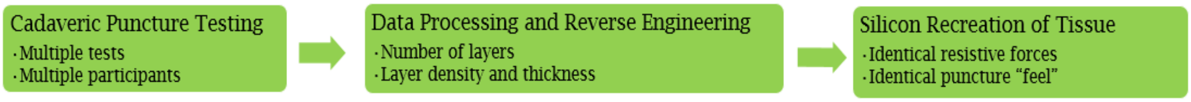

Fig. 6: Summary of reverse engineering procedures for tissue development.

Open source models from Cadnav.com [1] were employed, and extensive mesh modification, repair, reconstruction, and stitching operations were performed to create watertight models. An 'overmold' core and cavity, along with a modifiable secondary tissue insert were designed by associating the key skeletal components to the mold geometry. Parametric relationships between the tissues and the molding elements to alter the thickness of artificial tissues in the prototype were implemented (Fig. 7).

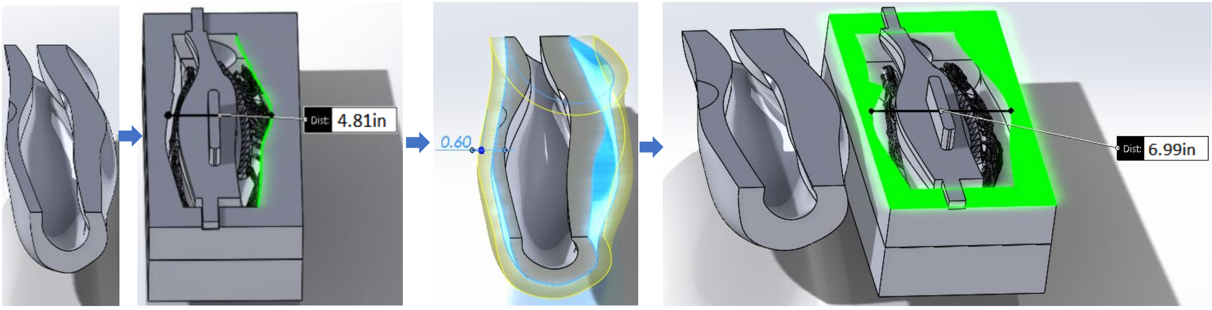

Fig. 7: Parametric relationship between tissues and mold elements.

The completed models are manufactured using the Fortus 400 fused deposition modeling (FDM) process and ABS-M30 materials. The FDM process enabled the production of multiple prototypes for the skeletal (Fig. 8 (a)) and the overmolding component variants (Fig. 8 (b)). Dual silicone layers, to emulate the resistances observed in the cadaveric puncture data, are included, and an alpha prototype is developed, with the necessary landmarks for the palpation sequence, for testing (Fig. 8 (c)).

<u>Conclusions:</u>
From the medical literature, performance scores of students who underwent 'standard' simulator training increased by 71% [10]. However, for a thoracentesis procedure, 19% of patients are between 0 – 9 years old, and there is a high likelihood of a potential patient being obese. Existing training mannequins do not reflect these patient variations. The implementation of scaling factors and parametric CAD models, combined with flexible manufacturing solutions, allow for reconfigurations for both the patient and fabrication mold models.

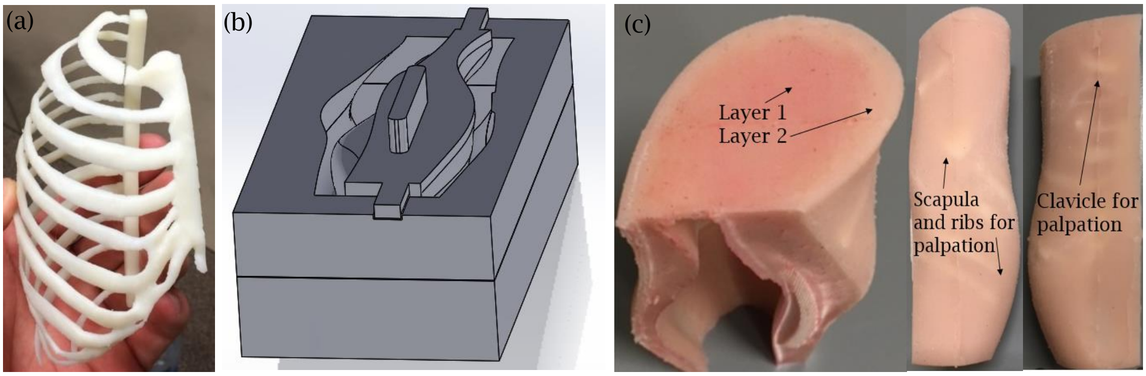

Fig. 8: (a) Rib cage, (b) Mold core and cavity (c) Curved, dual layer, anatomically correct alpha prototype.

The methodology detailed in this research allows for the development of superior training mannequins, as proven by preliminary testing of this prototype, which yielded puncture profiles that closer resembled those of the cadaver, in terms of peak force as well as pulse width, when compared to the THM-30 (Simulab Corporation) in use at the University of Windsor. The strategies implemented in this research are suitable for a wide array of applications in the medical training mannequin domain. Better models and simulations of different types of patients better prepares medical personnel to handle varying real-life cases. This has the potential to improve thoracentesis, and other procedures and reduce errors. These design and manufacturing techniques can provide the opportunity for other innovative solutions for current medical training problems.

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