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# Design Automation and Additive Manufacturing for Anatomically Diversified Medical Simulators

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## Abstract

The education and continuous exercise of manual skills in invasive medical procedures requires training environments that are safe, cost efficient and realistic. While body parts of humans and animals offer the most realism they are expensive and challenging in storage, handling and disposal. Therefore, training scenarios for medical staff commonly use artificial simulators to practice individual skills and team performance. These simulators usually do not reflect the diversity in human anatomy. Simulators for a certain task are commonly offered only in one shape and size to reduce cost in design and manufacturing. A more diverse anatomy could improve the training of medical staff. This work uses additive manufacturing for the cost efficient production of molds and components for silicone casted customized simulators. Furthermore a design automated approach is presented that allows non-engineers to specify the desired anatomy. The process chain is validated on a simulator for pneumothorax decompression. The main element of the simulator is an insert, which is cut and stitched during the procedure. The insert is a single-use disposable representing ribs, muscles, fat and skin. The new simulator insert offers improved aesthetic and tactile properties. The automated design and additive manufacturing allow non-engineers to adapt the insert to body mass index, age, gender and ethnicity.

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## Nomenclature

$a$	age in [years]
$A$	amplitude of rib expression in [mm]
$BMI$	body mass index in [ $\frac{kg}{m^2}$ ]
$t_{Fat}$	layer thickness of fat tissue in [mm]
$t_{Muscle}$	layer thickness of muscle tissue in [mm]
$t_{Skin}$	layer thickness of skin in [mm]

## 1. Simulators in medical training

The education and training of medical staff requires more than the teaching of explicit knowledge on anatomy and procedures. The medical staff needs opportunities to exercise individual tasks and team scenarios to build up manual skills and experience. While training environments vary in layout depending on the scenarios, all include a form of representation of a patient. Ziv et al. [1] classified the tools and approaches for this representation into five groups: low-tech simulators for simple procedures, simulated/standardized patients roll-played by actors, screen-based computer simulators, complex task train-

ers that integrate real and virtual elements, and realistic patient simulators with computer-driven full length mannequins [1]. These medical simulators represent the anatomy of a body or part and consist of metal, plastic and flexible materials like silicone. They often include sensors and indicators to provide feedback on the performance of the trainees. Complex task trainers and computer-driven mannequins also use actuators to simulate a physical response to the treatment [2]. Another method dedicated to practice invasive surgical skills is the use of human or animal cadavers [3–5].

Training medical staff on simulators helps to reduce errors in clinical practice and therefore improves patient safety [1,6]. Medical simulations offer the possibility to practice methods and team processes without exposing real patients to risk. In simulations, it is possible to confront the staff with rare conditions and uncommon clinical developments without relying on their occurrence in real life.

Nevertheless, there are limitations to medical simulators, which can be improved. While cadavers offer the most realism, they are expensive and challenging in acquisition, storage and handling. Therefore, artificial simulators are generally preferred, although they are limited in their ability to represent living anatomical structures.

Developers and manufacturers of simulators strive to provide trainees with a realistic learning experience while following a design for manufacturing approach that allows producing simu-

lators at reasonable costs and efforts. The design of a simulator also has to take the requirements of a training facility into account by making a simulator easy to maintain and repair e.g. by adding inserts for sections that are cut or punctured during medical procedures.

A typical compromise to manufacturing and training operations is choosing a monolithic material that is durable and easy to clean over a multi-material layout that better mimics the haptics and aesthetics of a human body. Another compromise made is to provide only one design of a medical simulator. The manufacturers are able to increase the production volume and benefit from an economy of scale, but the variety in anatomy is no longer present in the medical training.

## 2. Additive manufacturing and design automation

Additive manufacturing (AM) is an approach to avoid both compromises. AM has very few restrictions on the production of complex geometries while costs are almost independent of the lot size of a part [7,8]. These advantages over conventional manufacturing technologies allow the production of individualized, complex 3D objects.

While AM overcomes the restrictions in production the high efforts remain of manually designing individualized, complex 3D objects. This issue can be addressed by replacing repetitive design tasks in CAD with automated processes. Instead of repeatedly adapting a CAD model to create variations of a part engineers develop a generic high-level template that creates variations based on meaningful, user-centered inputs [9–11].

Combining additive manufacturing and design automation offers a significant improvement to medical simulators. The diversity in anatomy can be increased without reoccurring costs for design variations and small lot size production. A methodological approach is developed to implement a user-centered design and manufacturing process chain. To demonstrate the approach a case study is performed on the insert of a computer-driven full-length mannequin marked in Fig. 1. The selected insert allows surgeons to drain a pneumothorax.

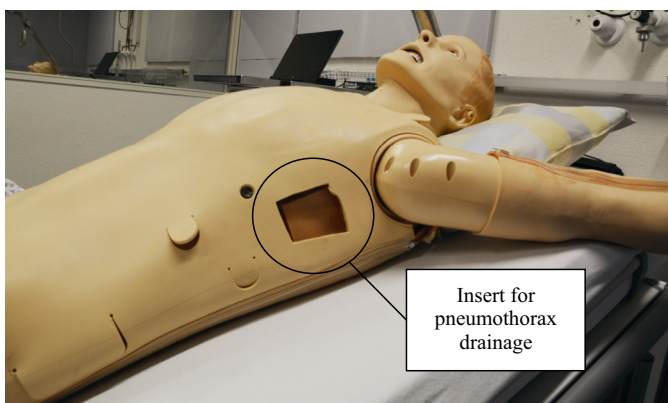


Fig. 1. Computer-driven full-length mannequin for medical simulations

## 3. Medical simulator for pneumothorax decompression

Between a healthy lung and the chest wall lies a small gap called the pleural space. This gap is filled with just enough liquid to allow a sliding movement between the visceral pleurae on

the lung and the parietal pleura on the chest wall during breathing. The negative interpleural pressure of this liquid inflates the lung and attaches it to the chest wall without connecting tissue that might hinder the respiratory movement [12]. If air enters the pleural space, the negative pressure is lost and the lung collapses. The presence of air in the pleural space is called a pneumothorax. Pneumothoraxes can occur spontaneous, traumatic or iatrogenic and exhibit typical symptoms like chest pain and dyspnoea.

The treatment of a pneumothorax depends on the amount of air and the rate at which air enters the pleural space [13]. Pneumothoraxes that are large or progressive require an intervention to drain the air [14,15]. For this procedure, a small cut is made into skin and fat tissue on the side of the chest. The surgeon locates the gap between two ribs and spreads and tears the intercostal muscle with scissors above the lower rib until he reaches the parietal pleura on the inside of the ribs. A push with the blunt tip of the scissors pops the pleura. The opening is widened to introduce a tube a few centimeter into the pleural space. Fig. 2 shows the anatomy of ribs and lung with the location of a drainage. A few stitches seal the skin against the tube and fixate it. The tube is connected to a suction unit and reestablishes the negative interpleural pressure. The difficulty of installing an adequate drainage increases with the thickness of the chest wall [16].

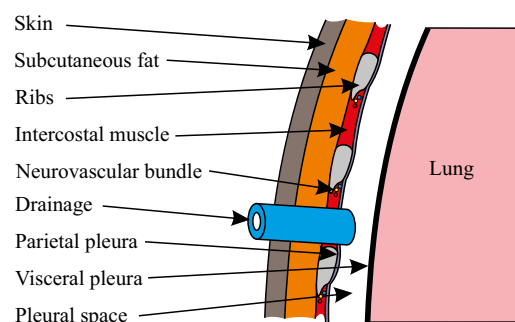


Fig. 2. Simplified anatomy of a pneumothorax with intercostal drainage

Training the installation of a drainage to relief a pneumothorax on a dedicated simulator improves the success rate [17]. Some of the more general simulators allow this procedure as well. Because it requires an incision into skin, fat and intercostal muscle the respective section of the simulator is designed with an insert that can be replaced after the training. Fig. 3 shows such an insert for the medical simulators of the company Laerdal. The insert is used in Laerdal's medical simulators ALS Simulator, SimMan ALS, SimMan Essential, and SimMan 3G. It consists of an injection-molded model of 2 ribs, a red tape to indicate the intercostal muscle and a 3mm layer of foam representing subcutaneous fat tissue (Fig. 3(b)). This insert is placed into a skin-colored silicone pocket (Fig. 3(a)).

## 4. Materials and manufacturing concept for a diversified training insert

The interaction of a surgeon with the insert consists of four steps: locating the ribs for correctly positioning the drainage, making the incision through skin, fat and muscle tissue, introducing the tube and suturing the skin. To simulate this procedure the insert needs to realistically represent the haptics of

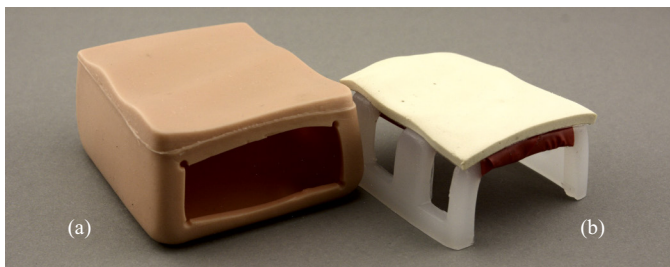


Fig. 3. Insert to perform a thorax drainage: skin pocket (a) and internal structure to mimic subcutaneous fat, intercostal muscles and ribs (b)

the intercostal gap under the skin, the cutting properties of each soft tissue, the rheology between the tissues and a tube, and the mechanical interaction between needle, thread and skin tissue.

The three types of soft tissues and a hard bone structure as they are mimicked in the existing insert in Fig. 3 are sufficient for simulating the placing of a thorax drainage. Nevertheless, the realism of the representation can be improved in two aspects: (1) The materials of the insert exhibit very different properties compared to real skin, fat and muscles. (2) The mannequin and its insert represent a rather athletic young man, which represents only a subgroup of all patients that acquire a pneumothorax [18].

A key element to a diversified, realistic training inserts for pneumothorax drainage is the materials and manufacturing concept. The insert is a combination of hard and soft materials and the manufacturing process for the them should allow design variations based on different anatomies. This requirement for diversity rules out processes that require expensive tooling or skilled manual labor. Additive manufacturing is a suitable approach although not in the direct manufacturing of the whole insert. There are AM processes for soft materials [19], but this application requires a multi-material process that exceeds the capabilities of current commercial systems. Therefore, a combination of direct and indirect AM processes is chosen that requires only one type of AM machine and material [20]. The soft tissues are produced from different room temperature curing silicones, which are casted in additive manufactured molds.

#### 4.1. Material

Silicones are a suitable material to produce parts that simulate tissue. They can be casted into molds to form complex anatomical objects with a high level of detail. This casting process does not require expensive equipment or specialized staff. Silicones offer a wide range of mechanical properties, which can be further tuned with additives to match the requirements of an application.

There are silicones commercially available that are developed for simulating human tissue. In this case study, these silicones are used according to the instructions of the manufacturer Smooth-on [21]. The skin consists of Ecoflex30 with a textile mesh to prevent the tear-out of the thread during suture. For the subcutaneous fat Dragonskin10 is mixed with a slacker agent to soften the material. Dragonskin10 is used without slacker for the muscles. All mixtures are colored with silicone pigments to match the color of each tissue. Other materials were tested, eg. silicone foam for fat tissue and cotton wool in the skin silicone, but did not succeed in the validation.

The ribs are additive manufactured from ivory-colored acry-

lonitrile butadiene styrene (ABS) by fused deposition modeling (FDM). The same process and material is used for the components of the mold.

#### 4.2. Manufacturing

The simulator insert with the three layers of tissue is silicone casted. The mold is separated in two parts to ease the demolding of the finished insert. It consists of a lid, which forms the profile of the ribs on the skin and a frame which defines the lateral dimensions of the insert and position of the ribs.

Fig. 4 (a-d) show the production process of the insert. An artificial leather patch is fixed to the lid for a more natural structure of the skin layer. Both elements of the mold are connected by screws and sealed. Fig. 4(a) shows this step. The mixed components of the skin silicone are poured into the mold and cured for a few hours according to the instructions of the supplier. A textile mesh is placed on the cured silicone of the skin (Fig. 4(b)). The silicone representing fat tissue is casted over it. After the curing of this layer the plastic model of the ribs is hung into two recesses of the mold as shown in Fig. 4(c). Red silicone is poured over the ribs until they are covered by a thin layer of silicone (Fig. 4(d)). In this consecutive casting process, each new layer connects to the previous one. The ribs are held by form fit. Once all layers of silicone are cured the lid is removed and the insert is pushed out of the mold.

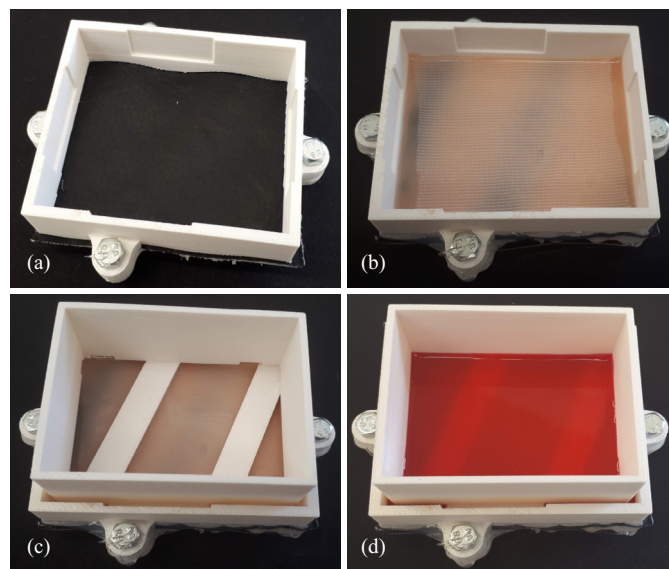


Fig. 4. Production process: assembled mold with textured insert (a), casted skin with mesh (b), fat silicones and ribs insert (c), casted muscle silicone (d)

## 5. Parametric model and design automation

The specification of materials, design and manufacturing process provides the basis for automating the design of the insert. The next steps are to define the scope in diversity to be reflected in the medical simulation and to identify the resulting variations in anatomy. By linking both to user-centric input variables, it is possible to setup a design automation that matches the requirements and experience of the staff in a medical training facility.

Pneumothoraxes occur across all groups of age, gender and ethnicity [18]. From the perspective of a medical training facil-

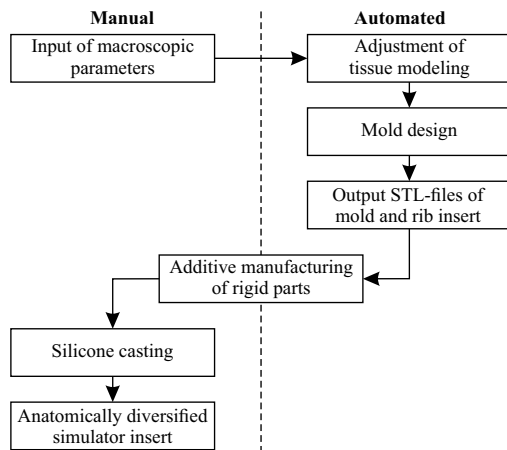


Fig. 5. Flow chart of the process from macroscopic properties to produced insert

ity this large population can be reduced to anatomies that introduce a normal or higher level of difficulty into the procedure. In particular locating the correct position for the chest tube, the incision and the suture are steps that affect the time management and stress level in a medical simulation. Anatomical details that affect the appearance and haptics of the ribs on the skin impact the locating task while the thickness of skin and fat tissue affect the surgical tasks from incision to suture.

Scenarios of medical simulations are based on macroscopic properties of a patient like age, gender and medical conditions rather than geometric properties of tissue layers. Therefore, the design automation needs to derive the geometry of the simulator insert from the macroscopic properties. The following subsections describe how the features are influenced by body mass index (BMI), age, gender, and ethnicity. Not all of these relationships are documented in literature for the location of the insert on the mannequin, thus it is necessary to transfer insights of other body regions.

### 5.1. Skin

All four discussed influence factors affect the skin thickness and shape. The influence of ethnicity on the geometry of the skin layer is neglected because reported differences in skin structure [22,23] are below the accuracy of the silicone casting process. Ethnicity is reflected in the simulator insert by the ratio between flesh-colored and brown silicone pigments.

The skin thickness varies with age and gender. Shuster et al. show for the skin on the forearm a linear relationship between the skin thickness of men from age 20 onward while women exhibit an almost constant skin thickness from age 20 to 60 followed by a steeper decrease [24]. This behavior is combined with skin thickness measurements of Lee and Hwang in 28 body regions on men and women [22].

Eq. 1 describes the relationship between the skin thickness  $t_{\text{Skin}}$  in millimeters and the age  $a$  in years for men and women.

$$t_{\text{Skin}} = \begin{cases} 1.33 - 4.17 \cdot 10^{-3} \cdot a, & \text{for men, age } a > 20 \\ 1.13 - 1.25 \cdot 10^{-3} \cdot a, & \text{for women, age } a = 20 \text{ to } 60 \\ 1.5 - 7.5 \cdot 10^{-3} \cdot a, & \text{for woman, age } a > 60 \end{cases} \quad (1)$$

Another macroscopic property that affects the design of the skin is the amount of subcutaneous fat. The ribs of skinny people form hills and valleys on the surface of their skin while obese people show no expression of their ribs. The shape of the ribs on the skin is modeled by a sine wave with an amplitude  $A$  that depends on the thickness of the fat layer  $t_{\text{Fat}}$  underneath as shown in Eq. 2. For  $A \leq 0$  the amplitude is set to  $A = 0$ .

$$A = 1.37 - 1.17 \cdot 10^{-1} \cdot t_{\text{Fat}} \quad (2)$$

The following subsection describes how the thickness of the fat layer  $t_{\text{Fat}}$  is calculated from macroscopic properties.

### 5.2. Subcutaneous fat

The thickness of the fat layer  $t_{\text{Fat}}$  at the insert position depends not only on the weight of a person but also on the allocation of fat tissue in the body. This distribution changes significantly with age and gender [25–28].

A common index to describe and compare body fatness is the body mass index  $BMI$  [29]. The  $BMI$  is defined for adults as fraction of the mass and squared height of a body. Because of its widespread application, the  $BMI$  is used as user input in the automated design process to describe the body constitution of a patient.

Two studies measured the subcutaneous fat at the position of the insert for young men [30] and young and middle-aged women [31]. These studies provide the baseline to determine the thickness of fat  $t_{\text{Fat}}$  from the user inputs  $BMI$ , gender, and age. Ludescher et al. found a linear relationship between  $BMI$  and the amount of subcutaneous fat tissue [25]. The different slopes for men and women are used to extrapolate the values of young men and women to other  $BMI$ .

The influence of age is adapted from a study by Kanehisa et al. [27] which measured abdominal, subcutaneous fat on young and old people of both genders. A linear increase is assumed from young to old people and the gradients for men and women are applied to incorporate the influence of age  $a$  on the thickness of fat  $t_{\text{Fat}}$ .

Eq. 3 describes the resulting relationship between the thickness of fat  $t_{\text{Fat}}$ , body mass index  $BMI$  and age  $a$ .

$$t_{\text{Fat}} = \begin{cases} (1.1 \cdot BMI - 20.94) \cdot (5.76 \cdot 10^{-3} \cdot a + 0.86), & \text{for men} \\ (1.7 \cdot BMI - 29.32) \cdot (15.2 \cdot 10^{-3} \cdot a + 0.65), & \text{for women} \end{cases} \quad (3)$$

### 5.3. Intercostal muscle

The last layer of silicone in the simulator insert represents the intercostal muscles between the ribs. An influence of age [32] and activity [33] on the thickness is documented. The described variation in thickness is small compared to the tolerances of silicone casting, therefore the thickness  $t_{\text{Muscle}}$  is assumed to be constant.



#### 5.4. Ribs

In the placement of a chest tube the surgeon aims at the gap between the ribs and should not interact with the ribs besides locating them from the outside. Therefore the ribs themselves are modeled as a constant geometry based on the averages reported by Abrams et al. [34].

The additive manufactured ribs also provide the interface to the simulator mannequin. For a realistic appearance of the torso it is necessary to match the skin levels of insert to the mannequin. In order to fit the insert into the mannequin the height of the frame with the ribs is adjusted to compensate for changes in layer thicknesses  $t_{\text{Skin}}$  and  $t_{\text{Fat}}$ .

#### 5.5. Implementation in CAD

Based on the described rules and relationships, a parametric CAD model is set up in Siemens NX. After defining the main input parameters such as BMI, age and gender the CAD model automatically applies the rules to generate the two components of the mold. The height of the frame results from the sum of layer thicknesses. A sine wave with the amplitude  $A$  is added to lid to form the expression of the ribs into the skin. On the outside of the lid a text is placed to display the design inputs  $BMI$ , age  $a$  and gender and the calculated masses of each silicone formulation. The height of the ribs insert is adjusted to match the skin levels of insert and mannequin. A macro exports the three 3D models into STL files. The following preparation of the fused deposition modeling build job is performed manually. Automating this step is possible but not economical for the expected production volume.

### 6. Validation

The anatomically differentiated insert to train the drainage of a pneumothorax was validated in four steps.

First, the materials and their layup were validated by producing patches consisting of the three layers muscle, fat and skin. These patches were evaluated by 7 physicians at the university hospital. Criteria for the evaluation were appearance (color representation, surface structure, layup), mechanical properties (compression, shear, cutting, suture, spreading), usability and overall impression. Each criteria was evaluated compared to real human tissue on a scale from 1 worst representation to 5 best representation. The recommended materials of the silicone manufacturer [21] exceeded other approaches with an average score of 3.9.

Second, an insert and a corresponding mold were designed and manufactured to validate the manufacturing process and the general design concept of the insert. A static CAD model was sufficient for this step.

For the third step, the relationships described in Sec. 5 were implemented in Siemens NX to automate the design process. A number of parameter sets of body mass index, age and gender were entered to test the model stability across the whole range of allowable values. A selection of inserts was manufactured to confirm the manufacturing process for different layer thicknesses. Fig. 6 depicts the produced inserts.

In the last step of validation, inserts were installed into a mannequin at the medical training facility of the university hos-

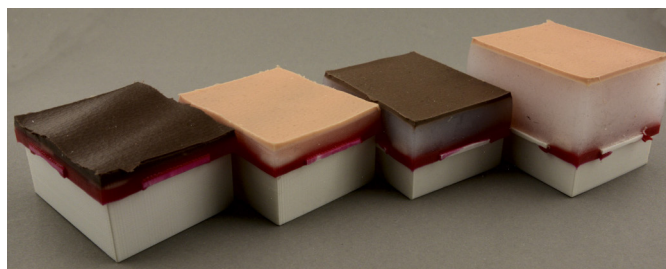


Fig. 6. Silicone casted simulator inserts automatically designed based on body mass index, age and gender

pital. A surgeon performed the procedure on two inserts and evaluated the appearance and haptics of the insert. His feedback was very positive with minor recommendations to improve realism. For example lubricating the inside of the muscle layer would give it the slippery feeling of the pleura.

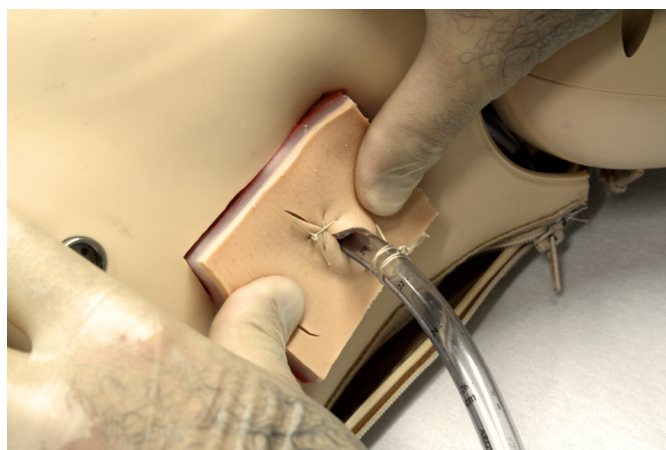


Fig. 7. Placed chest tube to drain a pneumothorax

Requests for further optimizations of the insert are a guidance for the chest tube inside the thorax of the mannequin and a differentiation of the puncturing behavior of the pleura based on age. Currently the pleura is not included into the design of the insert. The mechanical resistance during the puncture originates from the silicone of the muscle and matches the pleura of young people. The pleura of elderly exhibits a reduced elasticity and pops more easily. To incorporate this age-dependent behavior would require an additional layer of silicone to be casted on the muscle layer.

### 7. Conclusion

Medical simulators play an important role in training practical and organizational skills of medical personnel. A realistic training environment helps the participants to immerse into the scenario and increases the learning experience. Current medical simulators can be highly sophisticated but often lack to represent the anatomical diversity of real patients. The presented case study of an insert for pneumothorax drainage addresses this need by combining the capabilities of additive manufacturing and design automation in a user-centered approach. They allow efficiently individualizing designs and producing them at small lot sizes. Additive manufacturing is used to directly and indirectly produce an insert for a full-length mannequin. The soft tissues are created by casting layers of silicones into an AM

mold. For the design automation, input parameters were chosen which are familiar to medical professionals. Age, body mass index and gender are used to calculate the thickness of skin, fat and muscle tissue while ethnicity is incorporated into the design through different pigmentations of silicone for the skin layer. A step-wise development and validation process proved to be a useful approach. First, silicones were evaluated to identify suitable mixtures for the required tissues. Second, a part design and a manufacturing process were established. Third, an automated design approach was implemented linking the medical inputs to geometric properties. The files for additive manufacturing are automatically derived from this design. Each of these three steps was validated before proceeding with the next step. The demonstrated approach can be transferred to other parts of medical simulators. It enables medical training facilities to adapt and produce components based on their needs. Objectives for further developments are to add liquid filled blood vessels to the casting process and to incorporate sound properties into the material design.

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