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Work in progress report - Cardiac general

A new training set-up for trans-apical aortic valve replacement

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Abstract

Trans-apical aortic valve replacement (AVR) is a new and rapidly growing therapy. However, there are only few training opportunities. The objective of our work is to build an appropriate artificial model of the heart that can replace the use of animals for surgical training in trans-apical AVR procedures. To reduce the necessity for fluoroscopy, we pursued the goal of building a translucent model of the heart that has nature-like dimensions. A simplified 3D model of a human heart with its aortic root was created in silico using the SolidWorks Computer-Aided Design (CAD) program. This heart model was printed using a rapid prototyping system developed by the Fab@Home project and dip-coated two times with dispersion silicone. The translucency of the heart model allows the perception of the deployment area of the valved-stent without using heavy imaging support. The final model was then placed in a human manikin for surgical training on trans-apical AVR procedure. Trans-apical AVR with all the necessary steps (puncture, wiring, catheterization, ballooning etc.) can be realized repeatedly in this setting.

Keywords: Aortic valve replacement; Surgical training; Valved-stent; Translucent heart model; Stereolithography; Pulmonary valve replacement

1. Introduction

Trans-apical aortic valve replacement (AVR) is a new and rapidly growing therapeutic approach. Far more than one thousand clinical trans-apical AVRs have been realized worldwide so far. There is little doubt, that a high level of surgical skills is required for these procedures, and a learning curve is unavoidable. In the past, animals were used for training and were often combined with research and development. However, animal experiments are difficult to realize in large numbers for various reasons including ethical concerns and cost. Major efforts are made to replace the use of animals by artificial heart models or by animal-cadaveric-models for surgical training purposes [1–3]. Training on animal-cadaveric-models often proves to be complicated since it requires heavy material supports and standard slaughtering in abattoirs. On the other hand, current artificial heart models are not convenient for training of trans-apical AVR, given that they are made of polyurethane [2]. Therefore, they are not transparent, which involves considerable imaging equipment such as X-rays in order to visualize the area of deployment of the stent during the trans-apical AVR procedure.

A way to circumvent this restriction is to use translucent heart models that are made of silicone, which allows visualizing the introducer bearing the stent-valve throughout the operation, has some degree of elasticity, and is therefore easy to use. Thus, the main objective of this study is to build up a life-size compliant and translucent model of a complete human heart, in order to employ it for surgical training on trans-apical AVR.

2. Materials and methods

In order to create 3D geometries of the human heart we established a pseudo-volume-rendering method using SolidWorks 2007, a Computer-Aided Design (CAD) software (SolidWorks Corporation, Concord, MA, USA).

Basically, this method required to insert four representative CT-scan slices (Fig. 1a) of a human heart into the graphical zone of SolidWorks and to extrapolate from those images heart contours with spline curves. These latter are piecewise polynomial functions [4] and are particularly adapted for fitting complex shapes. Then the 3D wall of the heart is built up by a smoothing function that connects the spline curves (Fig. 1a and Video 1).

Thereafter, the complete model geometry was saved in STL format (Stereolithography) and constructed using a rapid prototyping system previously described by Kalejs and von Segesser [5]. This system consists of a 3D printer that includes several stepper motors that move a syringe filled with low-cost household silicone.

After printing, dip-coating of the entire heart model with dispersion silicone is performed two times so as to increase its mechanical strength, prior to its fitting within the heart trainer [3].

3. Results

Fig. 1b shows the final model of the human size heart which has been printed and coated in three days. The

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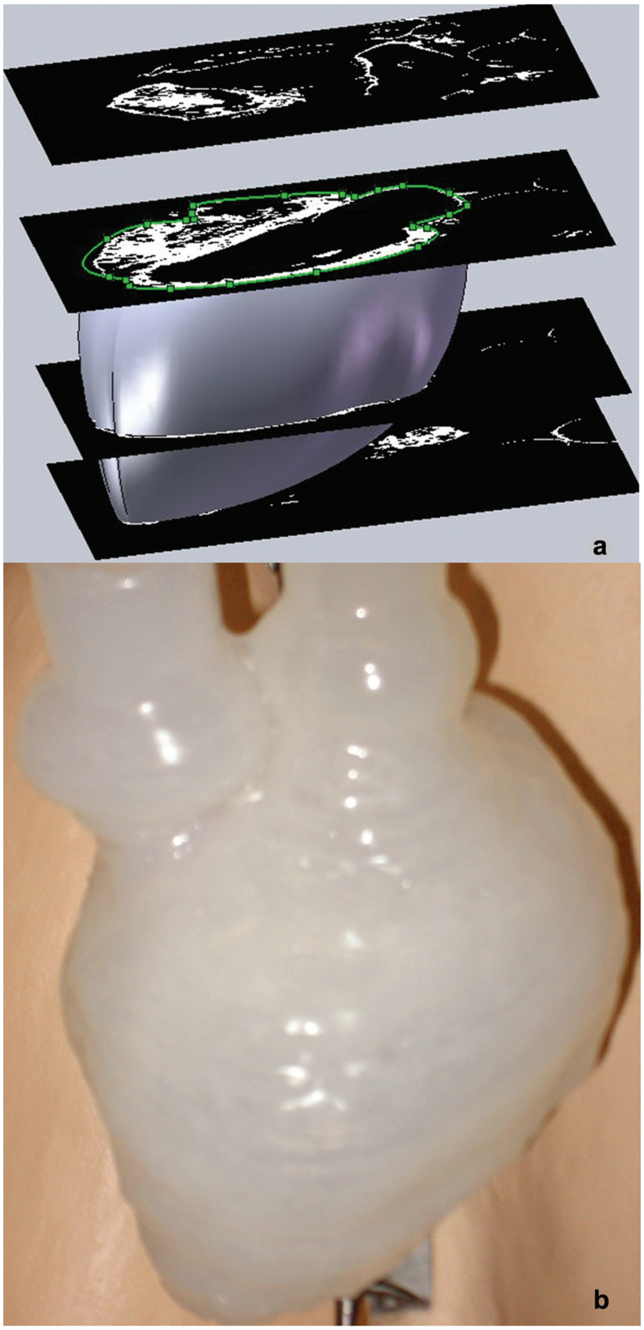
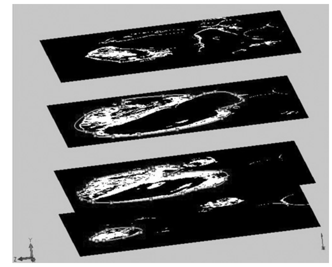


Fig. 1. (a) Graphical zone of SolidWorks, that includes the CT-scan images, the spline curves in green and the smoothed surface of the heart wall; (b) finalized heart model with its aortic roots.

realized design has a straight path from the left ventricular apex towards the aortic annulus, the aortic root with a realistic sinus portion [5], and the ascending aorta suitable for trans-apical AVR. For this purpose, the heart model is then fitted in an artificial adult-chest (Fig. 2a) for trans-apical stent-valve replacement training. In the chest manikin used, the built-in thoracic incisions are placed anatomically correct, so that the apex of the heart model can be easily accessed from the antero-lateral left thoracotomy. The superior midline sternal splitting incision is used to visualize the implant procedure. A light source is



Video 1. CAD modeling of the heart with CT-scan images and spline curves.

positioned behind the heart model in order to see by translucency the area of interest, during catheterization, positioning of the introducer that bears the valved-stent (Fig. 2b) and valve deployment (Fig. 2c).

Practically, the trans-apical AVR procedure is realized exactly like in the clinical setting [6, 7]. Through the left antero-lateral mini-thoracotomy, the apex is identified and punctured with a hollow needle. A soft J-type guide-wire is brought into the left ventricle, through the aortic annulus into the ascending aorta, all of this under visual control through the small superior sternotomy and the translucent aortic root. For implantation of a catheter mounted aortic valve prosthesis using the anterograde route [6], the guide wire has to be exchanged for a stiffer wire using a (pigtail-) catheter. Another pigtail catheter can be inserted in retrograde fashion for identification of the valve level. A balloon is then inserted in anterograde fashion and inflated for sizing. With the stiff wire in place, the balloon is exchanged for the large introducer allowing for insertion of the catheter, which carries the compressed valve. The latter can be either balloon expandable or self expandable (Symetis Ltd, Lausanne, Switzerland) like demonstrated here.

The same heart model can also be used for training on pulmonary valve replacement [8]. Whereas we perform this procedure in the clinical setting through a small epigastric incision, the cover of the phantom used here is exchanged for a cover with a full median sternotomy, in order to access the translucent heart through an inferior median sternotomy, and to visualize the anterograde pulmonary valve replacement within the infundibulum of the right ventricle and the pulmonary artery through a superior median sternotomy.

4. Discussion

The realistic setting in conjunction with the nature-like dimensions of the heart model and its translucency make it very appropriate for training on trans-apical valve replacement. Heavy imaging equipment is not necessary and a simple light source placed behind the heart model makes visualization easy. Furthermore, this model does not contain any biological tissue, thus its storage and transport is remarkably simple.

Up to now various transparent models made from silicone are already available; nevertheless, they are all built with casting methods, which are complicated to realize because producing hollow compliant hearts with these methods

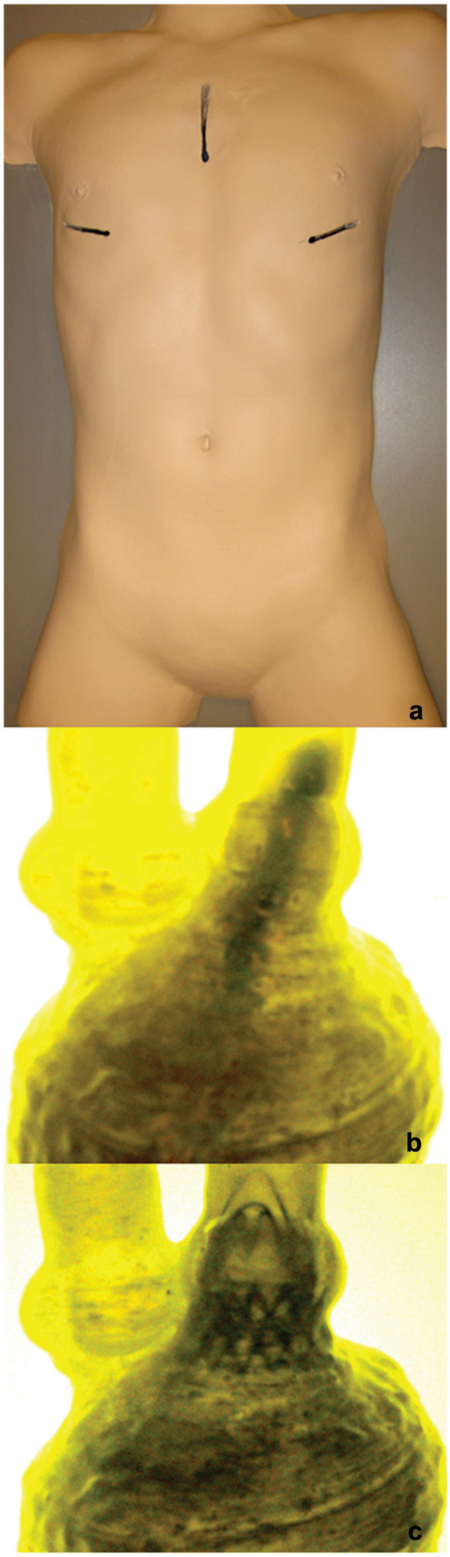


Fig. 2. (a) Artificial human chest of an adult; (b) catheter bearing the valved-stent seen by translucency and backlight; (c) self-expanding valved-stent released at the level of the annulus.

requires not only a mold but also a breakable or melting insert [5]. Furthermore, the casted models are usually made with cadaveric heart that are in contracture, while the method presented here is based on CT-scan of a living beating heart, and thus provides real-live dimensions.

Concerning CAD design, the simplicity of use of splines curves in SolidWorks, makes that it is much more suitable for rapid prototyping than any other volume-rendering programs. Indeed, despite the fact that the latter programs give more accurate reconstructions of the heart, they require a lot of work in image processing and segmentation, which is time consuming and needs considerable expertise.

The mechanical properties of the heart model can be varied as function of the number of dip-coatings performed, in order to match the compliance of natural tissue; as well as the mimicking of hard calcified, non-translucent areas (can be seen in the set-up with back-light and help for stent-valve positioning) in the valve region. This difficulty that might be encountered during trans-apical implantation, is set with additional silicone in target areas that give more stiffness at those regions.

We conclude that rapid prototyping of simplified heart models that are compliant, translucent, life-size, and realized with the Fab@Home 3D printer provide an excellent set-up for training of trans-apical valved-stents delivery on both, the left and the right side.

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