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Rapid Prototyping for Training Purposes in Cardiovascular Surgery

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1. Introduction

The emergence of new and rapidly growing therapies in cardiovascular surgery requires larger training opportunities and a precise identification of the heart structures and its disease. Nowadays, imaging techniques such as computed tomography, magnetic resonance imaging and others allow the virtual reconstruction of hearts in a three-dimensional conformation. Those techniques are being used for mainly for diagnostic purposes (Olson, Lange et al. 2007) and for operation planning (Gasparovic, Rybicki et al. 2005) as well as for educational training (Lermusiaux, Leroux et al. 2001). However, they do not give tangible practice in surgical simulation. This explains, why currently, animals are still widely used for training and are often involved in 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 biomodels or by animal-cadaveric-models for surgical training purposes. Training on animal-cadaveric-models often proves to be complicated since it requires heavy material supports and standard slaughtering in abattoirs.

Artificial biomodeling appears to be a more and more promising alternative for training in cardiovascular surgery. Indeed, the realization in solid-replica of patient-specific and life-size hearts contributes to the realism of the surgical procedure and facilitates recognition of the 3D structures, hence improving clinical performance. The procedure of heart biomodeling can be summarized as follows: (1) The acquisition of heart images, (2) the data processing and (3) the printing of the solid replica of the heart (Figure 1).

In this chapter we will present a literature review of last progresses of rapid prototyping in the field of cardiovascular surgery and cardiology. In particular, concerns regarding to the methodology and processing of modeling, limitations, applications and perspectives will be emphasized.

2. Rapid prototyping methodology

2.1 Heart imaging

In recent years, 3D imaging has rapidly entered the clinical world of cardiology and cardiovascular surgery. Indeed, several imaging modalities including magnetic resonance imaging (MRI), computed tomography (CT) and echocardiography have undergone significant advancements in imaging soft tissues, which allowed faithful volume renderings

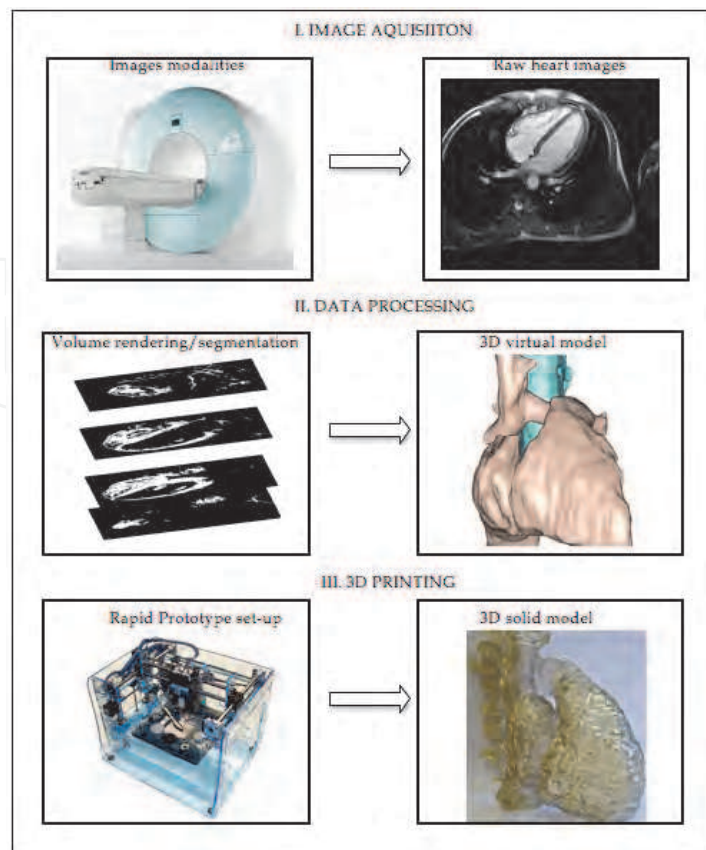


Fig. 1. The three major steps of heart prototyping

of heart structures through the stacking of multi-planar images acquired from those modalities (Figure 2). This trend from the 2D to the 3D is partly due to ambiguous interpretations that might be encountered in 2D images, which become crucial when considering options for surgical treatment (Riesenkampff, Rietdorf et al. 2009).

Virtual 3D reconstructions are used for diagnostic purposes, for operation planning as well as for education and training. They are particularly useful to visualize patient's heart with complex structural problems, such as congenital defects and aneurysms (Kellenberger, Yoo et al. 2007; Ou, Celermajer et al. 2007; Spevak, Johnson et al. 2008). However, incongruities between real anatomical structures and interpretation of virtual reconstructed three-dimensional (3D) images still remain (Shiraishi, Yamagishi et al. 2010). This drives surgeons to realize solid replicas of hearts with structural defects, which would convey better and more tangible information about spatial relationships between heart structures.

Rapid prototyping (RP) is used to build up solid replicas of hearts. This process involves the conversion of medical images to a Stereolithography (STL) file format. This file format describes triangulated surfaces of the heart model in a 3D Cartesian coordinate system and is utilized in CAD manufacturing and by RP machines. The medical image files are in a Digital Imaging and Communications in Medicine (DICOM) format. This file format is standard for images of MRI, CT, echocardiography or other imaging modalities¹. The 3D

¹ For the download and the exercise heart modeling, one can refer to the following online database of MRI/CT images, where various set of adult heart image files can be found (Casimage Database, Geneva University Hospital, <http://pubimage.hcuge.ch:8080/>).

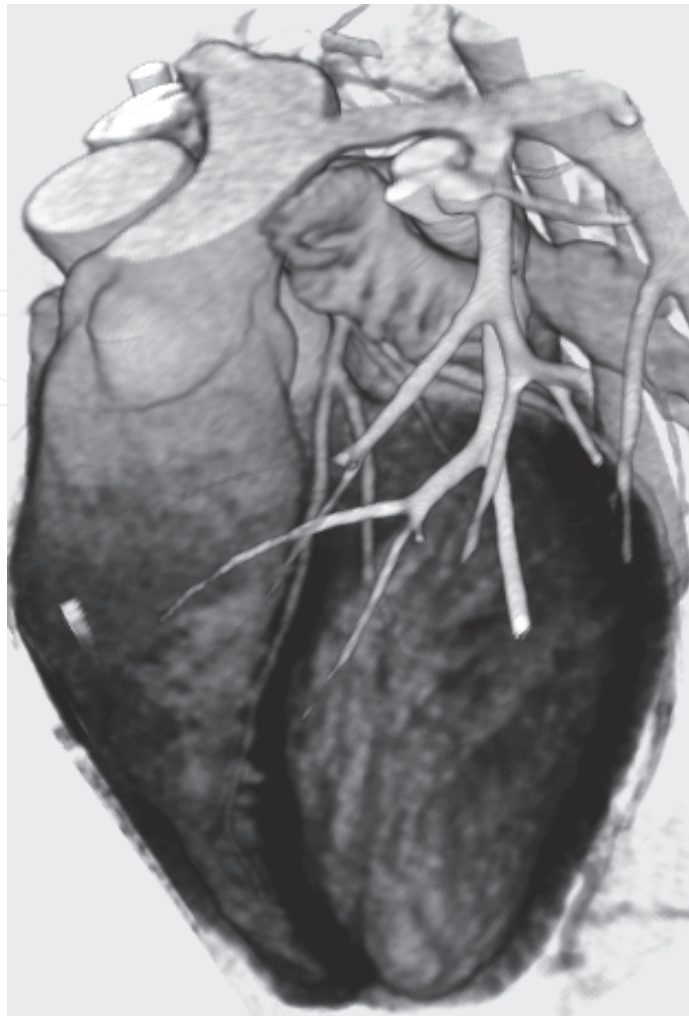


Fig. 2. Image of a volume rendering of a heart. The raw data come from a coronary angiogram recorded on a 64-detector CT scanner.

DICOM data must be of high resolution to make an accurate RP model. The following section aims to discuss the processing of DICOM data to isolate the structure of interest and turn it into an STL file, that will be upload to rapid prototyping machine to produce the solid 3D model.

2.2 Data processing for heart modeling

Several research groups have reported their utilization of user-friendly software packages for the processing of medical images, such as Jacobs et al who used Mimics software (Materialise NV, USA) to segment the medical images and to produce finished STL files (Jacobs, Grunert et al. 2008). Likewise Markert et al used MeVisLab software (MeVis Medical Solutions, Germany) to convert and finish the medical image file (Markert, Weber et al. 2007) and many others as well. However, in heart modeling literature, it is noticeable that a lack of information exists regarding to the methods of post-acquisition processing. Usually, the authors mention only the Computer-Aided Design (CAD) software they use for the processing of the images and their conversion to a STL. Hence, a significant missing part is the methodology of images segmentation. The dataset is a series of DICOM images, that when stacked together represent the heart with the surroundings tissues. The segmentation

is the processing that allows isolating the structure of interest in the data files, i.e. it identifies voxels from a dataset corresponding to the desired tissue and removes the surrounding undesirable tissues.

2.2.1 Automatic segmentation

Automatic segmentation consists of applying pre-defined filters to the data set so that it isolates directly the desired heart structures. However this automatic process is defective, because it depends on the quality of the data images, especially the artifacts introduced by the imaging modalities could induce errors in the segmentation. Most of the automatic segmentations are based on threshold techniques, which give satisfactory results only in isolating inner boundaries of the heart between myocardium and blood. However, they do not adequately locate the outer boundary of the heart, because the outer boundary is not well defined at some places.

As example of automatic segmentations, we would like to present here a preview of the methods existing in VolView software package (Figure 3) from the National Library of Medicine Insight Segmentation and Registration Toolkit (ITK). ITK is an open-source, cross-platform system that provides developers with an extensive suite of software tools for image analysis.

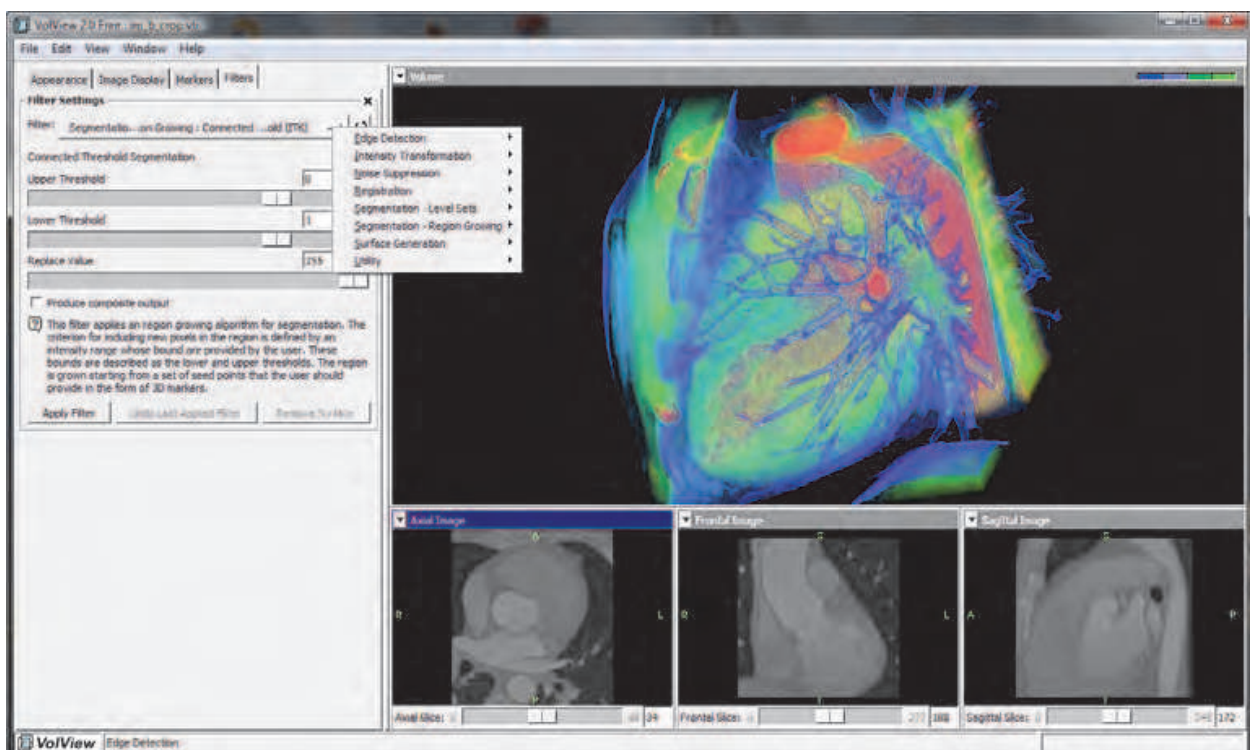


Fig. 3. View of the VolView panel. Several pre-programmed filters are available, among which some are defined for edge detection, noise suppression and segmentation of region growing.

Other than filters for noise suppression and edge detection, VolView software has two specific categories of segmentation filters. The first one has several algorithms based on the level sets concept and the second one has algorithms based on the region-growing concept. Briefly, statistical algorithms are applied to identify the voxels that might be admitted to the

segmented region based on the distribution of voxel contrasts within defined regions. Those methods provide good results; the heart wall is clearly visible as well as major veins and arteries.

However, this automatic process has the disadvantage of detecting also surrounding structures, whose grey level is similar to cardiac muscle, including thus sometimes parts of ribs, spinal cord and the pulmonary branches within the lungs (Figure3). The algorithm also produces so-called false negatives within the heart muscle tissue, i.e. the algorithm removes parts of the heart that should not be removed from the volume of interest. The effort required to correct the errors produced by the algorithm remains high. This is why it would be equally efficient to perform a manual segmentation voxel by voxel.

2.2.2 Manuel segmentation

As example to illustrate a manual segmentation, we would like to present methods present in Amira (Visage Imaging GmbH, Berlin, Germany), a software package proposed for processing biological images. Its Segmentation Editor has several tools available, including thresholding and laso tools that use the gradient of the image to detect boundaries. However, the more performing way to segment the heart remains to use the paintbrush, thanks to which one can trace specifically the boundaries of the heart in each slice (Figure 4). Nevertheless this technique is time consuming since it requires the processing one image at a time.

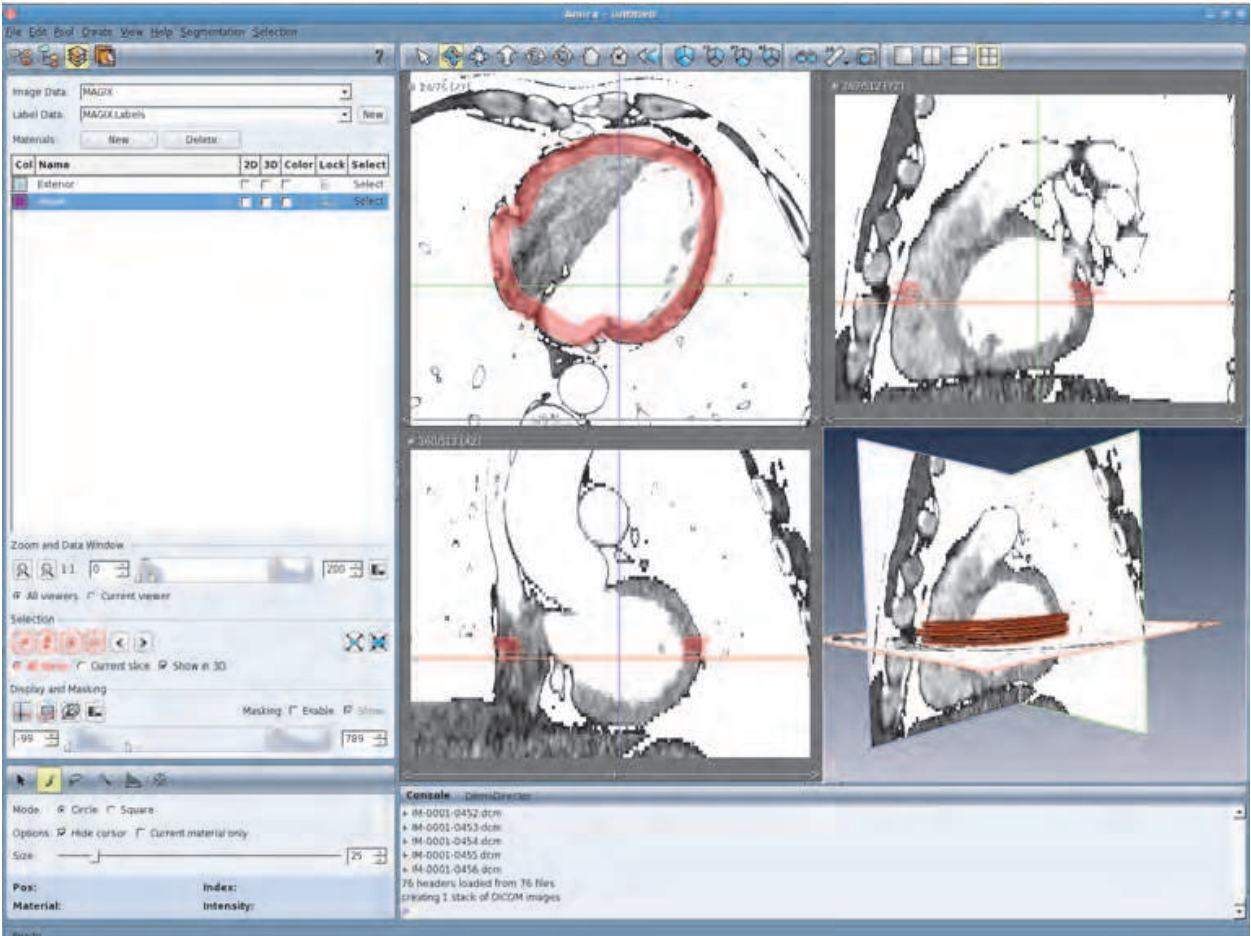


Fig. 4. A view of the manual segmentation.

The current use of manual segmentation is only because it has not been developed yet a satisfactory automatic or semi- automatic methods. The fact that each set of images has its own specificities would explain why there is no unified protocol for heart segmentation. The final segmented heart is saved then in a STL file for the 3D printing.

2.3 The model printing

The reconstruction of the solid model is made from the STL file, which can be in principle read by any rapid prototyping machine, and is accomplished by the addition of material layer by layer according to the virtual design (Peltola, Melchels et al. 2008). Each layer, which corresponds to a virtual cross section from the CAD model, is solidified using different solidifying agents, such as UV lasers or liquid binders. All the solidified layers joined together create the final shape. An advantage of this additive process is its ability to create complex shapes or particular geometric features. The concept of “rapid” is relative, because the additive process described above can typically produce models in few hours whereas reconstruction of models with contemporary methods can take days. But even for the additive process, the reconstruction time depends primarily on the size and complexity of the model and the RP printer type.

3D printing counts several manufacturing techniques among which some have already been used in cardiovascular surgery. Firstly comes the Stereolithography (SLA), which uses photopolymers that can be cured by UV laser. Lermusiaux et al. produced models on an SLA 250 stereolithography apparatus (3D Systems Corp., Valencia, CA). This prototyping device creates 3-D replicas of aortic aneurysm using epoxy resin. A low-powered but highly collimated laser beam is focused on the surface of a container filled with liquid resin. The laser draws a cross section of the model, converting the thin layer of the liquid resin to solid. The model was used for the development of new endovascular techniques for repair of abdominal aortic aneurysm (Lermusiaux, Leroux et al. 2001). Shiraishi et al. used ultraviolet laser beam to polymerize a selectively photosensitive polymeric liquid plastic solution to produce models used for simulative operations on congenital heart disease (Shiraishi, Yamagishi et al. 2010)

Other than Stereolithography there are other rapid prototyping systems such as Laser Sintering methods, which are based on small particles of metal, plastic or glass that are fused by a high power laser. As well, there is Fused Deposition methods that extrude small beads of fused thermoplastic materials that immediately attach to the below layer. Finally, Inkjet printing techniques, which use pistons to seed layers with fine powders; then an adhesive liquid dropped by another piston bonds the parts of these layers belonging to the 3D object. Depending on the manufacturing technique it is possible to combine materials of different elasticity or color in one model, which might help to create more realistic models in educational or training purposes (Rengier, Mehndiratta et al. 2010).

2.4 Rapid prototyping benefits for surgical training

Although RP application and benefit in craniofacial and maxillofacial surgery has been proven (Wagner, Baack et al. 2004), in cardiovascular surgery RP modeling is still in its early stage. However, its great potential to produce accurate models of heart and its structure of interest proves usefulness in cardiovascular surgery. Various studies using RP in adult and pediatric heart modeling have been already accomplished (Armilotta, Bonhoeffer et al. 2007; Jacobs, Grunert et al. 2008; Sodian, Weber et al. 2008; Shiraishi, Yamagishi et al. 2010).

These studies showed that tangible 3D models (1) allow a better identification of structural abnormalities, (2) help to determine the best surgical option as treatment and (3) improve surgical skills of young surgeons by an intensive training simulating in vivo conditions without any risk of patient complications.

3. Training of the trans-apical aortic valve replacement

3.1 The 3D printing technology of the Fab@Home project

As previously mentioned, several rapid prototyping machines can be used to make models from STL files. A particularly interesting machine is the open-source rapid prototyping system developed by the Fab@Home project (<http://fabathome.org>) and distributed by Koba Industries (Albuquerque, NM, USA). It consists of a 3D printer, which main component is a syringe used as a deposition tool and moved by several stepper motors (Figure 5).

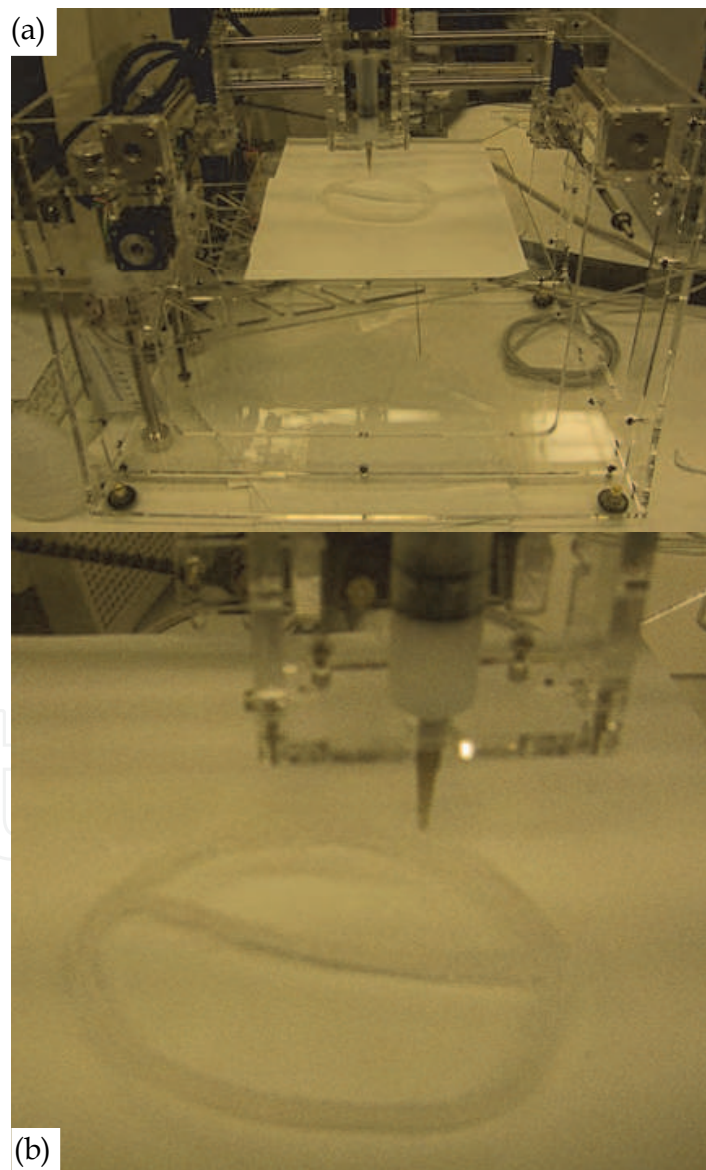


Fig. 5. (a) The Fab@Home 3D printer. (b) The syringe of the printer deposits silicone in building a heart model.

This printer is the only 3D printer capable of using any viscous substance as a building material (Kalejs and von Segesser 2009), and for this reason it is particularly useful to build up from silicone a translucent model of a complete human heart. The property of translucency given by the silicone is important for the surgical training of trans-apical aortic valve replacement (AVR), because the translucency of the heart model is a way to circumvent the use of X-rays to visualize the area of deployment of the stent during the trans-apical AVR (Abdel-Sayed, Kalejs et al. 2009).

The training of the trans-apical AVR is essential because far more than one thousand clinical trans-apical AVRs have been realized worldwide so far, and there is still little doubt that a high level of surgical skills is required for these procedures, which implies an unavoidable learning curve. In the past, animal experimentations were used for training, however, there are difficult to realize in large numbers for various reasons including ethical concerns and cost. Hence the importance to develop heart models that are life-size, compliant and translucent.

3.2 Pseudo-volume rendering method for heart prototyping

Unlike what has been presented before in this chapter for the modeling of the heart, a new pseudo-volume-rendering method has been established to create 3D geometries of the heart (Abdel-Sayed, Kalejs et al. 2009). This method uses SolidWorks 2007 CAD software (SolidWorks Corporation, Concord, MA, USA), and is more simple and less time consuming than conventional methods of segmentation and modeling. Basically, it requires the insertion into the graphical zone of SolidWorks only four representative CT-scan slices of a human heart. Heart contours are then extrapolate from those images thanks to spline curves, which consist of piecewise polynomial functions that allow the fitting complex shapes. Then the 3D wall of the heart is built up by a smoothing function that connects the spline curves (Figure 6).

Thereafter, the complete model geometry is saved in STL format and constructed using the printing set-up of Figure 5. As a material for 3D fabrication common house-hold (sanitary) silicone (Forbo international, Schoenenwerd, Switzerland) has been used. 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 The surgical procedure

The realized heart model (Figure 6) has a straight path from the left ventricular apex towards the aortic annulus, the aortic root with a realistic sinus portion, and the ascending aorta suitable for trans-apical AVR. For this purpose, the heart model is then fitted in an artificial adult-chest (Figure 7) for trans-apical stent-valve replacement training.

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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

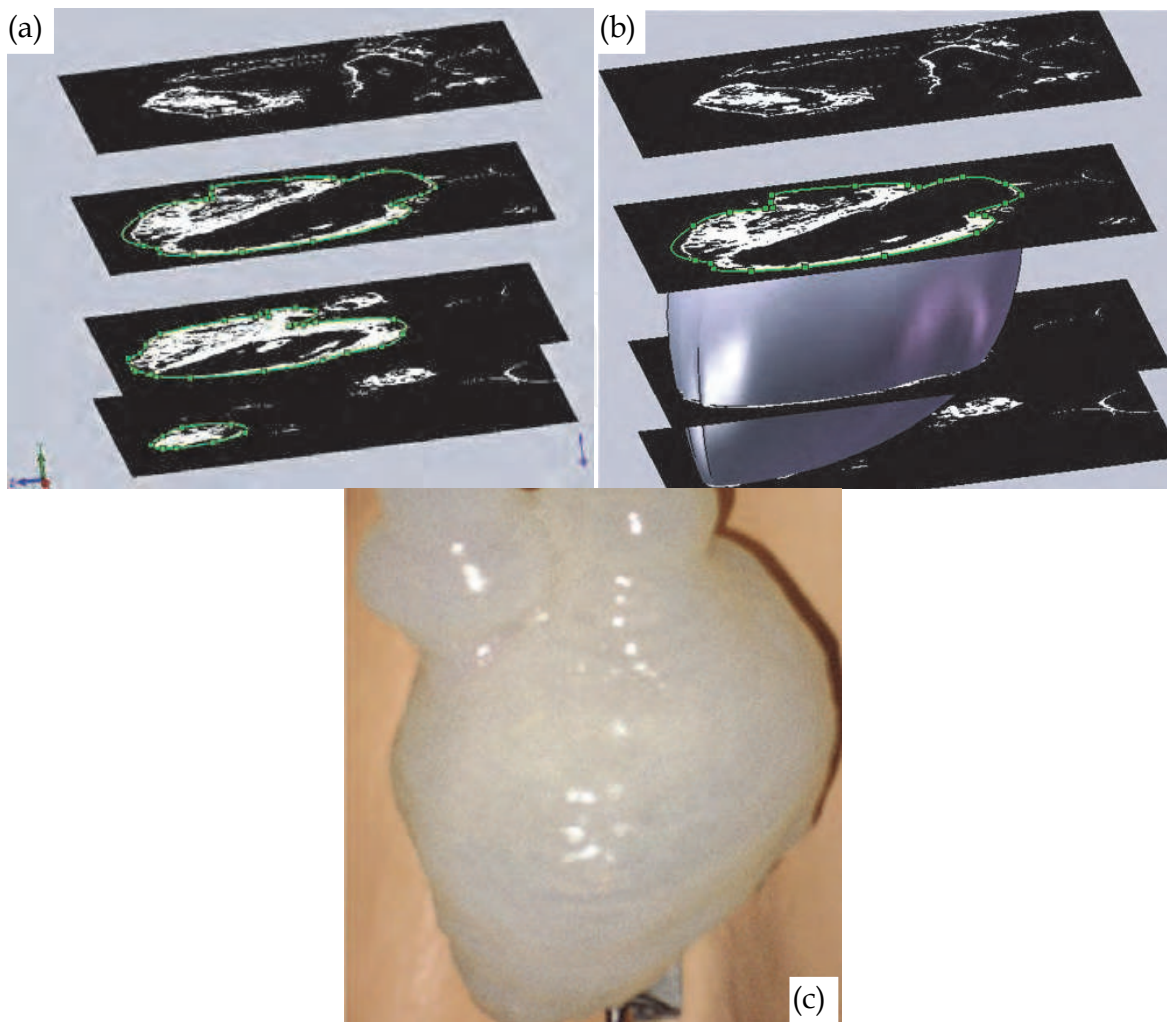


Fig. 6. Overview of the pseudo-volume rendering method. (a) Graphical zone of SolidWorks, that includes the CT-scan images, the spline curves in green. (b) The smoothed surface of the heart wall from the spline curves. (c) finalized heart model with its aortic roots. Reproduced from Abdel-Sayed P, Kalejs M, von Segesser LK. A new training set-up for trans-apical aortic valve replacement. *Interac CardioVasc Thorac Surg* 2009; 8: 599-601, with permission of the European Association of Cardio-Thoracic Surgery.

procedure. A light source is 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 and valve deployment (Figure 8).

Practically, the trans-apical AVR procedure is realized exactly like in the clinical setting. 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, 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

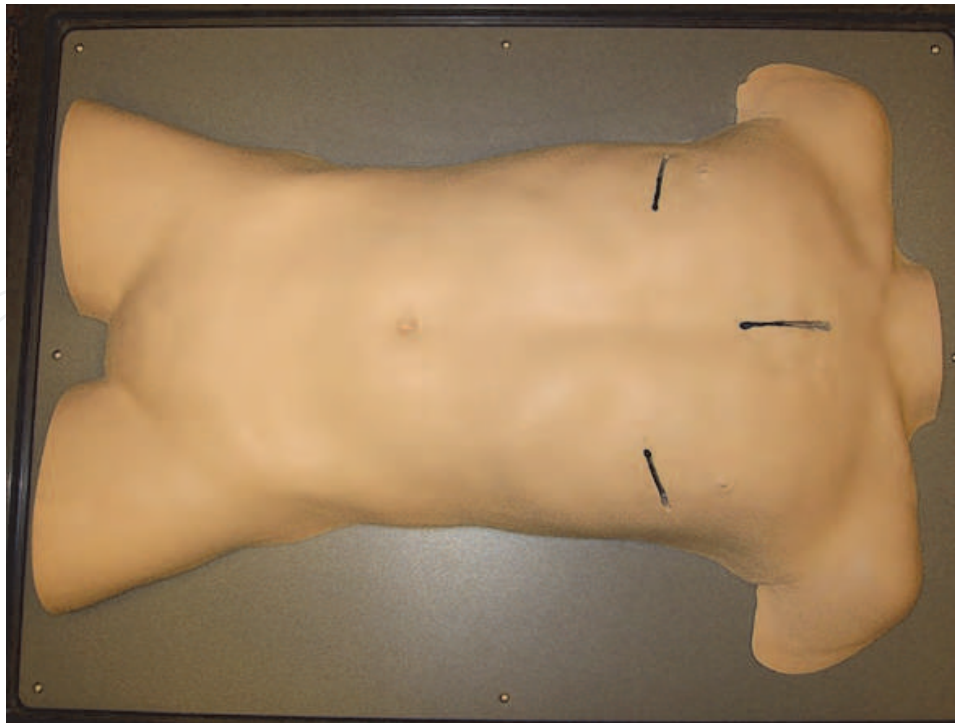


Fig. 7. Artificial adult-chest used for the training of trans-apical AVR.

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. 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 (Figure 9).

4. Current limitations of heart biomodels

The limitations of artificial heart models come first from the resolution and accuracy of the images from which the heart model is reconstructed. To make the better biomodels of the cardiovascular systems, image acquisition done for instance by multi-slice CT technique provides highly contrasted images compared with other techniques such as MRI and echocardiography. However, the major concern of multi-slice CT is exposure of patients to ionising radiation. So the improvements of artificial heart model are dependant on the development of images modalities and the balance between good images and the safeness of the acquisition procedure.

Nevertheless, the most important limitations of heart prototyping lay within the artifacts occurring during the segmentation procedure. Moreover the segmentation of soft tissues such as heart is difficult and time consuming. Those limitations can be reduced with a pseudo-volume rendering method presented in this chapter, however in this case the models would lost in accuracy and specificity to the real heart.

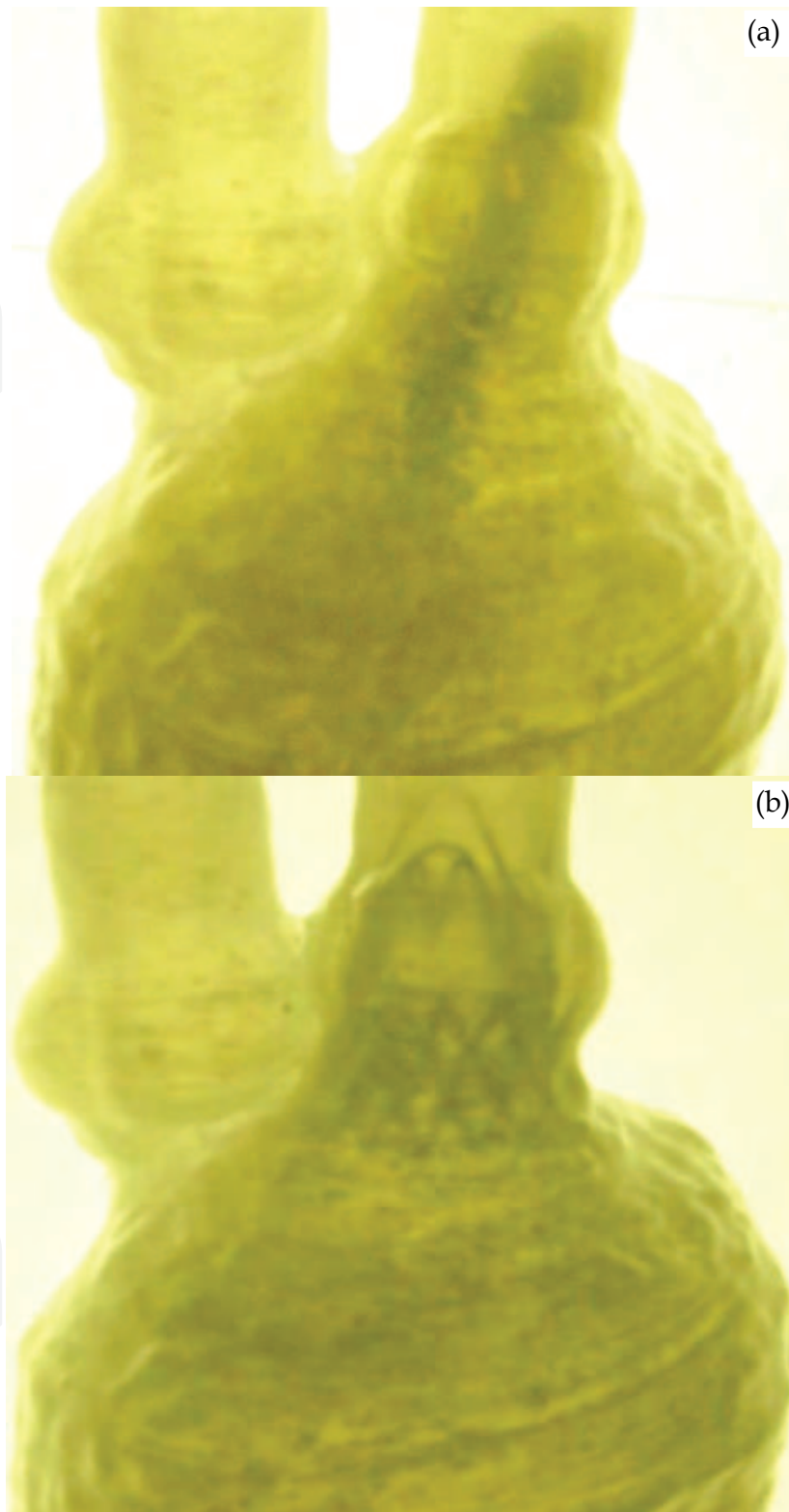


Fig. 8. (a) Catheter bearing the valved- stent seen by translucency and backlight; (b) self-expanding valved-stent released at the level of the annulus. Reproduced from Abdel-Sayed P, Kalejs M, von Segesser LK. A new training set-up for trans-apical aortic valve replacement. *Interac CardioVasc Thorac Surg* 2009; 8: 599-601, with permission of the European Association of Cardio-Thoracic Surgery.

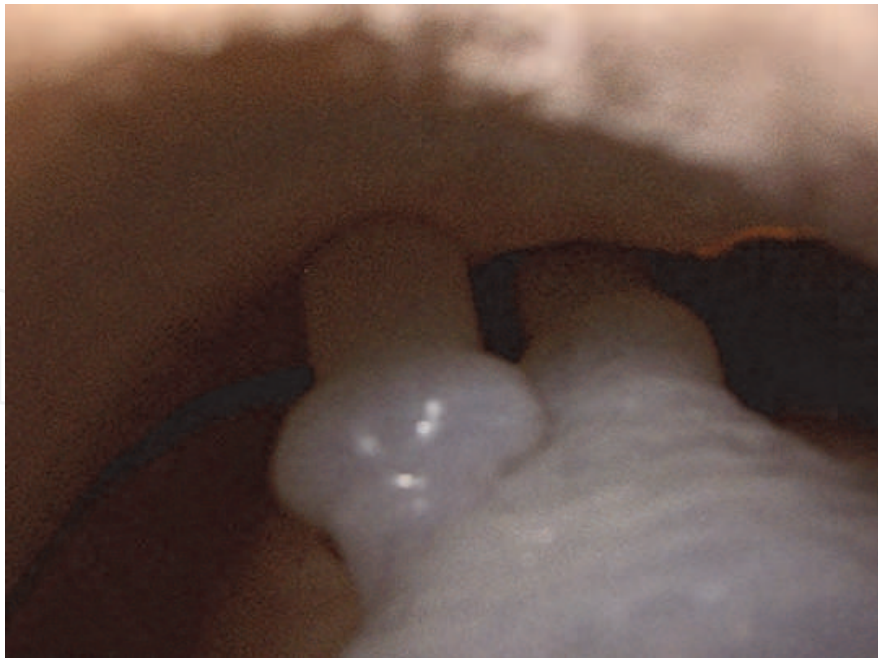


Fig. 9. View of the model valves through the manikin sternotomy.

Another major limitation of rapid prototyping comes from the costs for the generation of 3D hearts. Up to now, a use of rapid prototyping at large scale for surgical planning or training does not seem to be justified since standard planning procedures are in most of the cases satisfactory, though in some complex cases, additional costs of RP may be compensated by reduced operating times and higher success rate of the surgical procedure. The time needed for producing a patient-specific solid heart also limits its use in surgery to specific cases and is not appropriate for emergency cases.

Finally, the conviction of surgeons by the utility of these models in cardiovascular surgery still remains weak for some of them, because those models cannot mimic critical aspects such as bleeding and complications that surgeons might encounter during operation. Also, sometimes the flexibility, durability and texture of materials are not satisfactory to mimic heart and great vessels.

5. Other applications and perspectives of rapid prototyping in cardiology

Artificial heart models are not only useful for surgical training but they are also serving in the preparation of patient-specific cardiac implants (e.g. Titanium merged by laser for mitral valves rings). This customization of implant might be sometimes necessary for patients whose disease involves special requirements, or need implant size that is out of the standard range. Indeed, only 15% percent of the cases requiring percutaneous pulmonary valves implantations were apt with current devices, because of the wide variety of site morphology, size and dynamics (Capelli, Taylor et al. 2010). This percentage of patients, who could benefit from minimally invasive procedure such as percutaneous pulmonary valves implantations, can be improved with new-valved stent graft that would be designed on biomodels. Improved surgical outcome because of adequate match with individual anatomical needs emphasize the evolution towards a more patient's specific implant design that can be performed on biomodels reconstructed from images taken from the patient himself.

Furthermore, heart biomodeling might be useful for the design of preformed 3D patches that would be used in cardiomyoplasty to correct complex malformations (Tsuchikane, Taketani et al. 2008). Also, for endovascular procedures more and more common (Althoff, Knebel et al. 2008), measurements taken on prototypes corresponding to patients could open new perspectives. For the planning procedure of these interventions, the assessment of collisions problems as well as the adequacy of customized implants might be performed on heart models (Harrison, Estefan-Ventura et al. 2007). Finally, issues related to growth that could be simulated with computational fluid dynamics and validated with in vitro tests performed solid prototypes.

Maybe the most promising medical perspective for rapid prototyping is the so-called "bioprinting" of heart structures. Bioprinting combine the deposition of biomaterials with cells into spatial orientations and complexities that physiologically emulate the organ geometries. This has been already initiated to bioprint vessel-like constructs using hyaluronan hydrogels crosslinked with polyethylene glycol tetracrylates (Skardal, Zhang et al. 2010). The overarching goal of this application of rapid prototyping in creating scaffolds for cellular growth and tissue engineering would be to generate a whole functional and living organ adapted to the individual patient anatomy and needs. Organ engineering would overcome the human organ deficiency for transplantation, and would allow building complex in-vitro tissue models promoting drug discovery (Boland, Xu et al. 2006; Mironov, Kasyanov et al. 2008). However, further research and development are needed until functional and viable tissues or organs can be created.

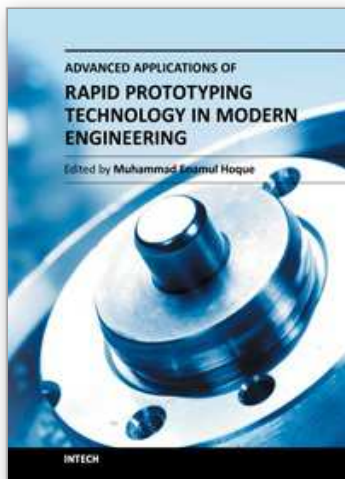
6. Conclusions

Rapid prototyping is a promising technique with numerous applications in cardiovascular surgery ranging from surgical training to designing of implants. Currently, research is in going to improve the limitations of this technique, which does not allow yet a common use in clinical practice. Nevertheless, the vast potential of this technique promises a growing use and development, not only in cardiovascular surgery, but also in other biomedical fields and academic activities.

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Rapid prototyping (RP) technology has been widely known and appreciated due to its flexible and customized manufacturing capabilities. The widely studied RP techniques include stereolithography apparatus (SLA), selective laser sintering (SLS), three-dimensional printing (3DP), fused deposition modeling (FDM), 3D plotting, solid ground curing (SGC), multiphase jet solidification (MJS), laminated object manufacturing (LOM). Different techniques are associated with different materials and/or processing principles and thus are devoted to specific applications. RP technology has no longer been only for prototype building rather has been extended for real industrial manufacturing solutions. Today, the RP technology has contributed to almost all engineering areas that include mechanical, materials, industrial, aerospace, electrical and most recently biomedical engineering. This book aims to present the advanced development of RP technologies in various engineering areas as the solutions to the real world engineering problems.

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