3D Printing and Engineering Tools Relevant to Plan a Transcatheter Procedure

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Abstract

Advance cardiac imaging techniques such as three-dimensional (3D) printing technology and engineering tools have experienced a rapid development over the last decade in many surgical and interventional settings. In presence of complex cardiac and extra-cardiac anatomies, the creation of a physical, patient-specific model is useful to better understand the anatomical spatial relationships and formulate the best surgical or interventional plan. Although many case reports and small series have been published over this topic, at the present time, there is still a lack of strong scientific evidence of the benefit of 3D models and advance engineering tools, including virtual and augmented reality, in clinical practice and only qualitative evaluation of the models has been used to investigate their clinical use.

Patient specific 3D models can be printed in many different materials including rigid, flexible and transparent materials, depending on their application. To plan interventional procedure, transparent materials may be preferred in order to better evaluate the device or stent landing zone. 3D models can also be used as an input for augmented and virtual reality application and advance fluido-dynamic simulation, which aim to support the interventional cardiologist before entering the cath-lab.

The aim of this chapter is to present an overview on how 3D printing, extended reality platforms and the most common computational engineering methodologies – finite element and computational fluid dynamics – are currently used to support percutaneous procedures in congenital heart disease (CHD), with examples from the scientific literature.

Introduction

Over the past few decades, advances in imaging technologies and computing power have been exponential, providing us with more and more detailed information about the structure and function of the heart and vasculature. This, along with general progress in medicine, biomedical research and device design, has allowed us to improve our diagnostic and treatment ability, exploring approaches and implementing solution to patient care not feasible before.

Despite the wealth of information provided by advances cardiovascular imaging modalities, until 10-15 years ago, common cardiovascular practice relied on 2D flat screens to visualise complex 3D anatomical structures, thus relying on the expertise of trained cardiologists and surgeons to create 3D pictures in their mind, and evaluate/predict outcomes of different treatment options. This presented limitations related to perception, interpretation, communication and limited uptake of new technologies. In the past two decades, engineering tools such as 3D printing, extended reality and computational modelling have tried to overcome these limitations, and have been applied to cardiovascular problems, to support decision-making process, surgical and transcatheter planning, training and education, and overall to better comprehend the cardiovascular system function and dysfunction (1). These methodologies can help solve complex problems and generate innovative solutions, by developing new device designs, and improving patient safety and procedural efficiency.

In this Chapter, we aim to present an overview on how 3D printing, extended reality platforms and the most common computational engineering methodologies – finite element and computational fluid dynamics – are currently used to support percutaneous procedures in congenital heart disease (CHD), with examples from the scientific literature.

3D printing

Patient-specific 3D printing is a fast growing technology that allows building of solid plastic replica of the patient anatomy by 'printing' successive layers of material. Input cardiovascular anatomies are provided by postprocessing of routine diagnostic 3D clinical images, in particular cardiovascular magnetic resonance (CMR) and computer tomography (CT) imaging. Case reports and small case series have suggested that 3D printed models can be used to plan surgical and percutaneous interventions by facilitating the decision-making process in complex cases (2-6). Qualitative analysis of the models by means of satisfaction questionnaires has so far been used to evaluate their benefit. The largest multicentre prospective study aimed to evaluate the impact of 3D printing in planning 40 complex CHD surgeries, providing surgeons with a 3D printed model after a first multidisciplinary discussion, showed a change in surgical strategy in 19/40 cases (3). In catheterisation procedures, meaningful clinical applications include:

1) Visualization of the size of the pathological structures in presence of rare congenital abnormalities.

2) Three-dimensional visualization of intra cardiac structure

3) Understanding of the spatial relationship of the great vessels in cases of complex CHD, particularly in post surgical anatomies.

Percutaneous pulmonary valve implantation. 3D printing has been first successfully employed for interventional planning to assess the right ventricular outflow tract in patients with pulmonary valve regurgitation, as a tool to aid clinicians in selecting patients eligible for percutaneous pulmonary valve implantation (PPVI) (Figure 1) (7).

A crucial step in PPVI planning consists of identifying the adequate landing zone. This can be done with the help of 3D-printed patient-specific models, with well documented strengths and weaknesses (Figure 2). Known limitations of these models include the difficulty in obtaining adequate still-frames needed to print the 3D model from the patient-specific CMR imaging, routinely acquired for PPVI patient assessment, as well as the innate differences between the features of native tissues and those of elastomeric materials.

Frame acquisition is usually done during the diastolic resting phase in order to benefit from the least cardiac motion, which could result in motion artefacts, and to facilitate inspection for cardiac defects (Figure 3). However, due to its failure to reliably mimic the large deformation occurring between the RVOT and the pulmonary artery, the 3D-printed diastolic-model may underestimate the necessary implant dimensions. Moreover, dysfunctional RVOT present great amount of movement and size variation throughout the cardiac cycle. Thus multidetector CT imaging has been employed more recently by some Centres to produce multi phase rapid prototyping models and compliant 3d printed models to test in vitro feasibility of the percutaneous procedure and assure a safe landing zone for the device (6, 8)

Pulmonary arteries and pulmonary veins. 3D printed mock circulatory models have been produce to study the haemodynamic of the pulmonary vascular tree, in particular to study the differential split flow at the pulmonary bifurcation and to test different clinical scenarios by increasing the pulmonary vascular resistance (Figure 4) (9). The evaluation of the pulmonary vascular tree poses major technical challenges in performing percutaneous intervention. The procedure requires extensive planning and intraprocedural precise visualization of the stenotic pulmonary branches; however, the pulmonary vascular tree is difficult to visualize in the catheterisation laboratory with conventional planar angiography. New approaches for 3D visualization of medical data, such as 3D printing and extended reality experiences have been used as preoperative planning tools. In a proof of concept study, a 3D-printed pulmonary artery model has been used successfully employed in order to better select the target lesions, avoid vessel injury caused by oversized balloons, provide more complete revascularization, and decrease the volume of contrast medium (10). The use of 3D printed models has also been reported in planning complex percutaneous procedures on pulmonary vein baffle in a case of TGA post atrial switch with Mustard procedure and obstructed pulmonary vein baffle (11).

Major aorto-pulmonary collaterals. Planning of intervention and surgery in patients with major aortopulmonary collateral arteries (MAPCAs) is challenging as the anatomy of the collateral vessels is often complex and unique to each patient. To deliver successful embolisation coiling via catheter, a 3D map of the colleteral pathways and adjecent structure needs to be evaluated prior to entering the cathlb. 3D printed models of these small vessel structures built from CT scans can help reduce bypass, anestesia and fluoroscopy time, thus decreasing complications and improving outcomes(12, 13).

Atrial septal defects and ventricular septal defects Atrial and ventricular septal defects are some of the most common CHD, and can present either isolated or in combination with complex cardiac anomalies. When large and haemodynamically relevant, treatment is indicated either via surgical closure or by inserting a percutaneous closure device, nowadays considered a safe alternative (Figure 5). Simple ASD closure is usually guided by trans-oesophageal echocardiography and rarely requires advance pre-procedural planning. However in complex cases, 3D printing of the anatomical structures surrounding the defect, from 3D echocardiography, CMR or CT guides the selection of the most adequate treatment technique and allows better understanding of the positioning of the device within the neighbouring structures, due to the high variability in morphology, location and presence of adjacent structures (Figure 6).

In particular, patient specific 3D printed models have been used to introduce stenting of the superior vena cava-right atrium junction in superior sinus venosus atrial septal defects, which are commonly associated with partial anomalous pulmonary venous drainage. Patients who present with low complexity of this pathology are surgically corrected with excellent results. However, for those high complexity patients with co-morbidities who cannot tolerate surgery, meticulous planning through 3D modelling can guide the percutaneous intervention (14) (15).

3D printing has also proven greatly beneficial in the navigation of the occluder device and the optimization of patch sizing. In the case of atrial septal defects, the dimensions of the surrounding rim play an important role in the selection of occluder devices, since misplacement can lead to complications. 3D-printed models allow for occlude device sizing, preoperative evaluation of the defect and in some cases can serve as the subject for an occlusion trial, in order to prevent an unnecessary transcatheter closure.

A 3D-printed model of ventricular septal defect can aid in crossing the defect in cases of congenital muscular ventricular septal defects. It can also prove useful in bench testing occluder device selection and successful in vivo deployment in the case of post-myocardial infarction ventricular septal defects. In these cases, although rare, percutaneous closure devices are preferred over surgical repair, due to the latter's high mortality in the context of a myocardial infarction (16).

Patent ductus arteriosus Both in paediatric and adult cases, patent ductus arteriosus may present a wide anatomical variability. A small case series described the use of 3D printed hollow models in procedural planning of PDA closure supporting the device selection and shortening the fluoroscopic and total procedural times in transcatheter PDA closure (17).

Aortic Coarctation Aortic coarctation stenting is a treatment option in patients with recoactation after initial surgical repair or adult native coarctation. Depending on the aortic arch anatomy, 3D printing models may be useful to select the best stent landing zone in complex aortic coartation and to better appreciate the spatial relationship with the left subclavian artery or in cases of aortic arch hypoplasia (Figure 7) (5). 3D printed models have been used to simulate the endovascular procedure under fluoroscopy and identify the best device size in case of complex aortic coarctation in order to predict the risk of infolding of large stent grafts (18).

Extended realities

Recent technological advances have enabled clinicians to use advance 3d visualization tools such as extended realities, thanks to the development of high resolution display technology with relatively low costs and a very user friendly interface. Extended reality technologies have found several applications in medicine, ranging from telemedicine and education to emergency response, patient point of care, rehabilitation, procedural planning and intraprocedural visualisation. Extended reality encompasses two main different experiences: virtual reality (VR) and augmented reality (AR). VR consists of a fully synthetic environment that replaces the user's auditory and visual fields, while AR interferes to a minimal level with the normal field of vision by presenting an annotated "window-on-the-world". The AR interface has very little interference with the user field of view and experience since it is activated on demand only when needed by the user and does not replace the user surroundings allowing the clinician to continue with their activity (surgery, cath intervention,..). In the medical setting, this translates to presenting relevant graphics, 3D anatomical models, patient information and reference data alongside the physical surroundings of the physician, giving the user full control over both the virtual and real-time scenarios.

The use of VR setup in congenital cardiology has been described in planning complex surgical procedures such as the biventricular repair of double outlet right ventricle with uncommitted ventricular septal defect (19). In the setting of interventional procedures, the use of AR with holograms created form 3D echocardiography or angiography has been reported to guide structural valve disease intervention such as transcatheter aortic valve implantation (20-22).

Computational modelling

Computational models have been extensively developed to investigate cardiovascular problems and predict clinical outcomes, thus enriching the information provided by clinical advanced imaging to improve understanding of pathophysiology, support surgical as well as interventional planning, and develop new device solutions (23, 24). Patient-specific computational tools, combining clinical imaging and numerical methods with individual patient data to build realistic simulations, foster precision medicine, particularly relevant in CHD. Translation of these computational technologies – mainly finite element (FE) and computational fluid dynamics (CFD) analyses – into routine clinical practice depends on large scale testing and validation, which remain a major challenge for CHD studies (25). However, in the last decade, patient-specific computational models have become increasingly realistic, taking into account anatomical variability, implantation site data, and specific pathophysiologic conditions, thus raising the interest of regulatory agencies and medical device Industry, and gaining wider clinical acceptance.

Finite Element (FE) analysis is used to define how a structure deforms under given loading conditions and how structures interact with each other, by defining the relationship between stress and strain, force and deformation. The core principle of FE is that of reducing a complex problem into a number of small, finite parts, which are assembled together and interconnected by nodes. The deformation of these finite parts (elements) affects the behaviour of adjacent elements, resulting in a local approximate solution for the initial problem. The overall behaviour of the structure is defined by a global approximate solution from all the local approximate solutions of the FE analysis. The end output of FE models is a detailed visualization of the stresses and deformations affecting the structures and their distribution (26-28).

Computational fluid dynamics (CFD) examines and quantifies fluid flow patterns and behaviour by utilising different computational techniques and physical properties, such as temperature, velocity, density, pressure and viscosity. In a closed system, the physical properties of a fluid (mass, energy, and momentum) are stable constants, which allow CFD to provide valuable hemodynamic parameters for the clinical assessment of heart performance, the diagnosis of heart dysfunction and the comparison between different treatments.

FE and CFD can be combined together to simulate fluid-structure interaction (FSI), a more advanced numerical technique where fluid flow and tissue mechanics are coupled to mimic more realistically the cardiovascular function. For example FSI is used to reproduce blood circulation in compliant vessels, or the pumping action of the ventricle resulting in blood flowing through the valve leaflets opening and closing during the cardiac cycle. FSI cardiovascular models are numerically highly complex and, therefore, mainly confined to the engineering development domain, and less mature than FE and CFD methods for use in clinical practice.

Patient-specific computational methodologies have been adopted in several examples of procedural planning for CHD transcatheter procedures, as they allow to investigate and quantify clinically relevant risks associated to the percutaneous intervention.

For example, as already explained in the 3D printing paragraph above, successful PPVI requires accurate pre-procedural patient evaluation to minimise risks of device dislodgment, arterial dissection, coronary artery compression, or other adjacent structure interference and injury. All these PPVI related adverse events have been studied and assessed using FE models (29, 30). The methodology has been used not only to support PPVI planning in specific patients, but also to study PPVI stent mechanical behaviour, design new devices and enhance safety in the compassionate use of prototype devices (8, 31-33).

Surgical or percutaneous treatment of aortic coarctation (CoA), despite successful in the short-term, results in late hypertension, which has been linked to several factors such as aortic arch geometry, attenuated baroreceptor reflex sensitivity or persistent abnormalities of central aortic biomechanics. Because of this, virtually reproducing the percutaneous procedure through patient-specific numerical models might improve our knowledge on the effects of the procedure on the surrounding anatomy. While CFD studies based on postoperative imaging can only be used for ex post quantifications of the fluid dynamic effects of the CoA treatment, FE analysis based on pre-operative imaging allows for ex ante predictions, which support further procedure planning (34).

In order to accurately estimate the impact of CoA stenting on aortic post-stenting biomechanics and geometry, the FE analysis must take into account some key modelling aspects. First, since the aorta is never unloaded throughout the cardiac cycle, the anatomical configuration reconstructed from CT images should be consistent with the pressure loads and stresses acting on it. This is possible by computing the corresponding prestresses field. Second, in the FE simulation of the stenting of a severe aortic obstruction the quality of aortic wall elements could deteriorate due to their massive circumferential stretching, thus hampering further progress of the simulation (35, 36).

Advance CFD methodologies for cardiovascular disease applications have recently been applied for the development of the first successful clinical trial and subsequent FDA approved simulation platform in 2014 (HeartFlow Inc.) which is based on the use of patient CT imaging datasets and CFD analysis based fraction flow reserve to evaluate the significance of coronary artery stenosis in ischemic heart disease noninvasively (37-39).

Discussion

Three-dimensional modelling has become an important tool to support clinical decision-making in selected cases. In complex cases, the collaboration between clinicians and biomedical engineers can better address clinical problems and improve the confidence of the operator and the success of complex procedures. Modelling and simulation can provide the clinician with quantitative information before entering the cathlab and improve the understanding of the patient specific haemodynamic.

Machine learning algorithms that will improve the segmentation of the cardiac and extra-cardiac structures will reduce the processing time and improve the accessibility and integration of these biomedical tools into the clinical workflow.

Mostly in congenital heart disease, where the anatomy is often unique for each individual patient, the use of 3d modelling and computational modelling is also supporting the development of new devices and also new materials by the use of bioprinting.

Despite many case studies and small case series report the use of engineering tools in supporting interventional procedures, these techniques are not widely available yet; this is mainly due to the initial costs, for instance related to the 3d printing, the relatively long processing time required to create a 3d model or complete a CFD simulation, but also the need of a close integration of the biomedical engineering team into the hospital setting. Moreover, although modelling techniques have been now available for decades, their use and their benefits still remain limited to case reports and small case series and there is still the need of large prospective clinical trials to support their use on larger scale.

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Figures:

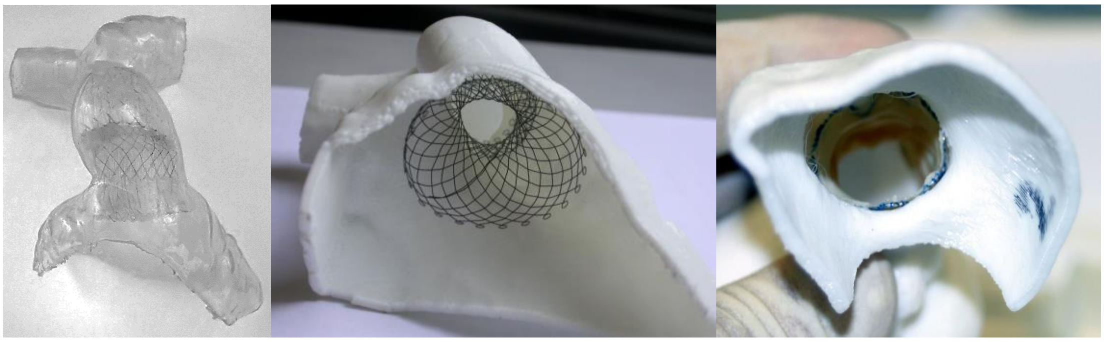

Figure 1. PPVI 3D printing

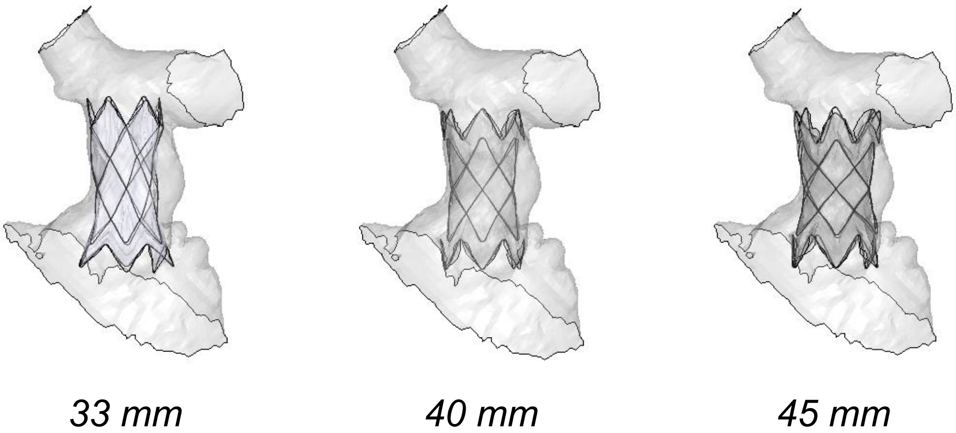

Figure 2. PPVI simulation of different stent sizes

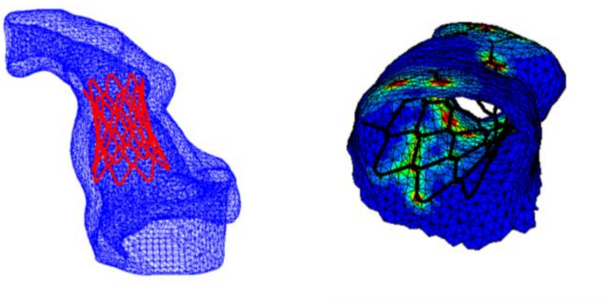

Figure 3. PPVI simulation for stress distribution

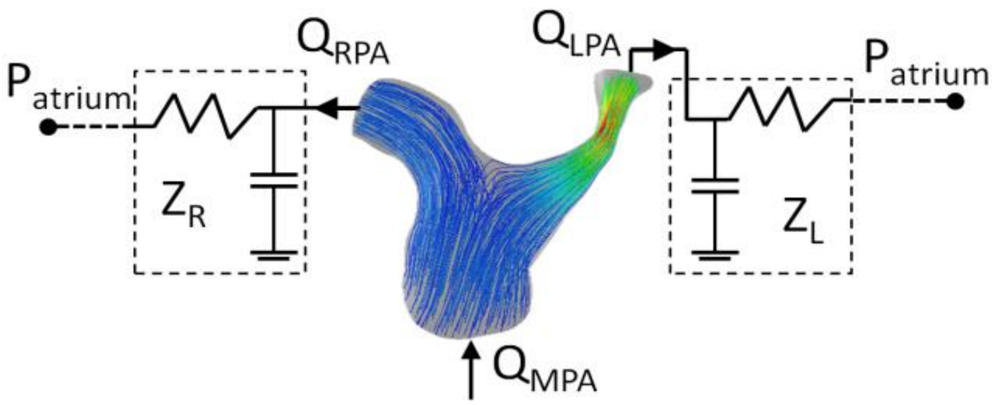

Figure 4. Simulation of flow split in PAs in TGA using CFD and lumped parameter networks

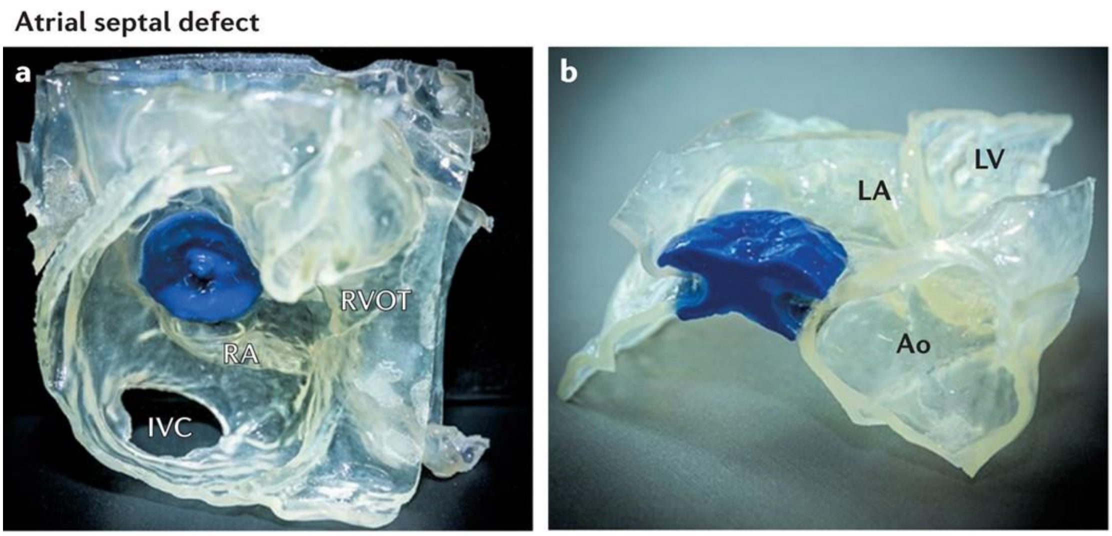

Figure 5. Ostium secundum atrial septal defect being adequately filled by a CT-derived 3D-printed model. There is no interference with the venous inlets (a). The countercluder is in contact, but does not indent the left atrium roof or the aortic wall (b).

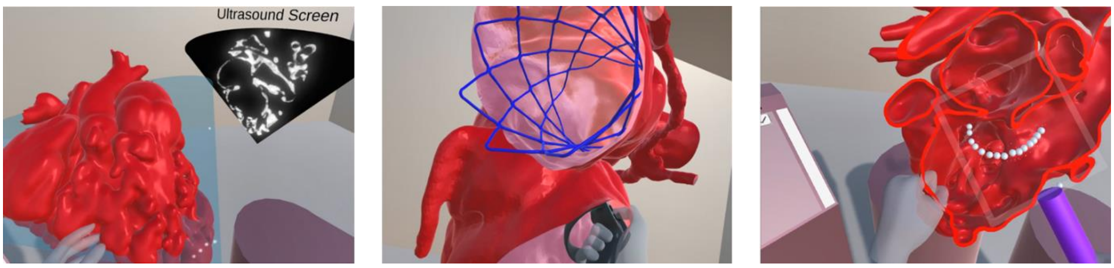

Figure 6.

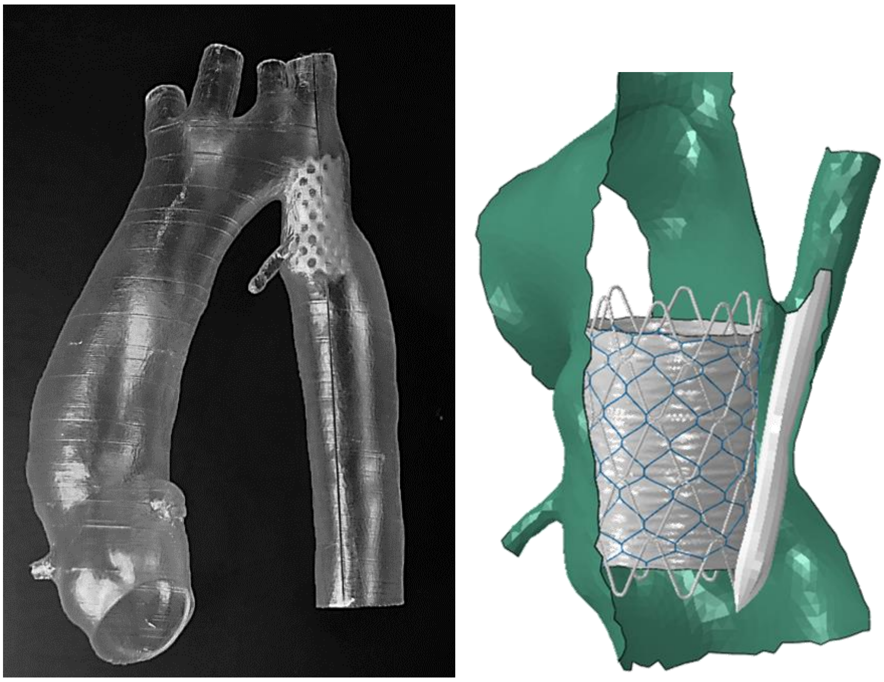

Figure 7. CoA 3D printing and FE simulation