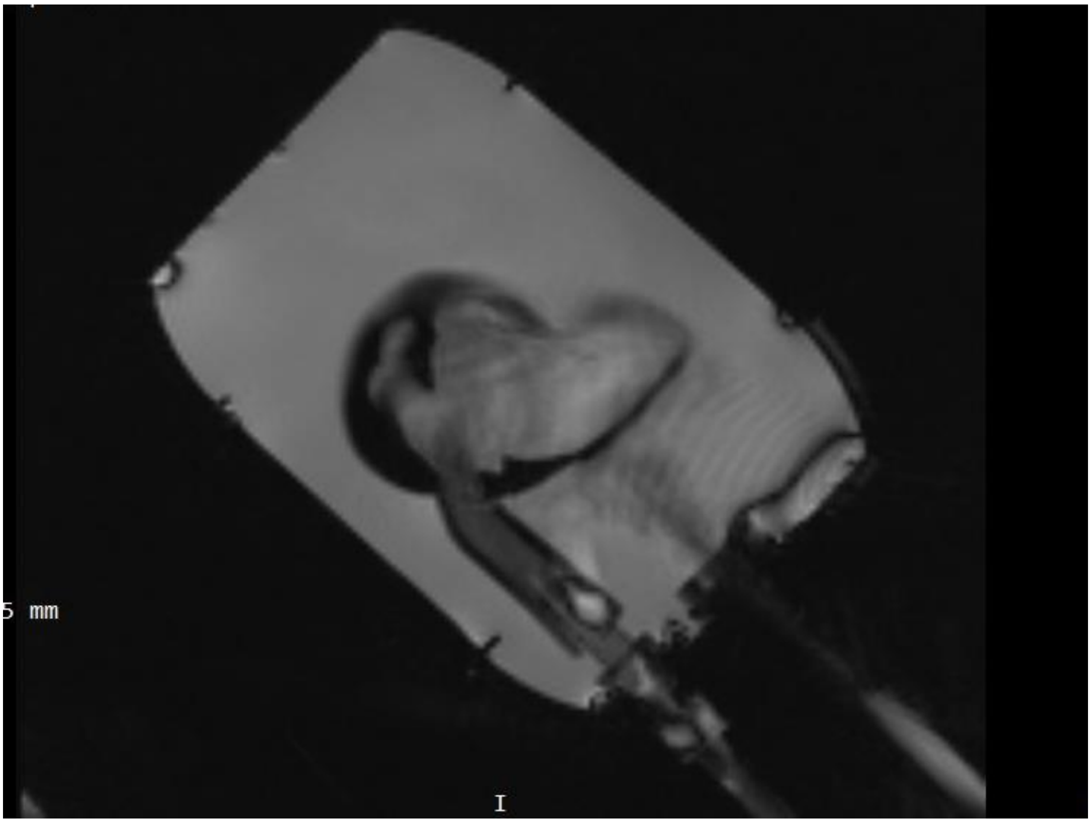
Optimizing the design of a dynamic cardiac phantom for MR-guided intervention training



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Abstract
Cardiac Magnetic Resonance (CMR) is a offers advantages over CT or ultrasound, particularly in guiding minimally invasive procedures, such as trans aortic valve implantation (TAVI) or radiofrequency (RF) ablation. With limitations on animal testing for training clinicians, there is a growing need for alternative solutions. In a response, a dynamic cardiac phantom with anatomical accuracy has been developed, to facilitate minimally invasive testing under MRI guidance. The phantom comprises a 3D printed outer phantom and an integrated heart model. By filling both the outer phantom and heart model with water, pressure measurements were conducted. The following values were obtained: max/min = 24.7/9.0 mmHg. The cardiac phantom also enabled visualization of cardiac contraction on an MRI scan. As contractions were possible, a dynamic cardiac phantom was designed. This is a promising tool for the training in cardiac interventions can and help clinicians to gain knowledge about the anatomical structure of the heart. As the phantom is designed to be adaptable, the heart model can even be replaced with patient-specific models in the future.

Abbreviations

AS: Aortic Stenosis
CMR: Cardiac Magnetic resonance
TAVI: Transcatheter aortic valve implementation
IVC: Inferior vena cava
LV: Left ventricle
RV: Right ventricle
SVC: Superior vena cava

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1. Introduction

Worldwide, cardiovascular disease is responsible for the highest number of deaths. Even in the Netherlands, approximately 1.7 million people suffer from cardiovascular disease (1). With atrial fibrillation and heart valve abnormalities being the most common (2). Clinicians prefer to treat these diseases minimal invasive. This approach helps to minimize damage to the body, complications, pain and shortens the recovery period. However, during such interventions, clinicians heavily rely on their hand-eye coordination and require a comprehensive understanding of the heart's anatomy, while image guided by imaging techniques such as CT or MRI.

Cardiac Magnetic Resonance (CMR) has emerged as a viable tool in treating cardiovascular disease, offering advantages over image guidance tools like CT or ultrasound. CMR enables real-time imaging, providing direct visualization of the heart's anatomy during procedures. It also offers excellent tissue contrast and can even detect complications during the procedure. This is advantageous particularly to visualize for detailed images of the heart's structure including the valves. Additionally, it has no risk of radiation, which is beneficial for both patients and clinicians (3). Furthermore, CMR offers the advantage of providing direct feedback on the hand-eye coordination of the practitioner, enabling more precise device placement during interventions(4). However, the limited availability of MR-safe materials hinders the advancement of CMR technology in clinical practice, preventing cardiac interventions that could benefit from CMR guidance.

Another arising problem is the limitation of testing minimally invasive procedures on large animals. While animal testing can model the human cardiovascular system and the biocompatibility of tools. However, since testing on animals has become increasingly limited due to regulatory and ethical constrains, alternative solutions are sought to improve methodological development and training. Patient-specific 3D printed models have become increasingly popular for visualising anatomy, yet they currently lack the capability to replicate contractions. These changes in the field of cardiac disease, have created an urgent need for a solution.

To address this issue the following research question will be answered: *How can a dynamic and anatomically realistic cardiac phantom be designed to enable image guidance in cardiovascular magnetic resonance (CMR) and ultimately be used for minimally invasive catheter trials in CMR?*

The phantom must facilitate testing of minimally invasive interventions on a beating heart model, guided by magnetic resonance imaging. Specifically, it should support training for procedures such as trans aortic valve implantations (TAVI) or radiofrequency (RF) ablations. This tool should aid clinicians in preparing for minimally invasive procedures and enhancing their understanding of the heart anatomy and physiology, serving as a valuable pre-operative training in the medical field.

To answer the research, question a literature review had been conducted, to gain understanding of the issue. The design of the outer phantom was based on Bietenbeck's research, which was selected as a starting point after reviewing various studies(5). After completing the final design of the phantom, some tests were carried out to validate the phantom's functioning, such as using a wedge pressure catheter to measure the pressure inside the phantom. The systolic and diastolic pressures were obtained through these tests. MRI measurements were conducted, to validate that the phantom was dynamic and allowed contraction. By following the basic design cycle, a MR safe dynamic cardiac phantom was designed. Which could serve as a promising tool in the field training of cardiac interventions.

This report is organized into several chapters to detail the process of designing a cardiac MR-safe phantom. The state of art section will review various studies that have designed similar phantoms, emphasizing any gaps in the literature. The methodology section will highlight the key requirements and describe the design process, outlining how adjustments were made in each iteration of the design cycle to arrive at the final design. Additionally, this section will list all materials, programs, devices and the CMR program used for each cycle. Subsequently, the results chapter will present the findings when visualising the phantom in an MRI scan, followed by a discussion, conclusion, and recommendations for future research.

1.1 Literature research

This section aims to provide a comprehensive understanding of the anatomy and physiology of the heart. Following this, the text discusses the treatment of conditions such as atrial ablation and Transcatheter valve implementation (TAVI). This information will aid in the process of designing a phantom that can be used to assist in such procedures.

Anatomy and physiology of the heart

The heart's function is to pump blood through the body, providing organs with oxygen-rich blood and removing metabolic waste from tissues. Therefore, it plays a crucial role in the circulatory system. The heart is composed of four compartments: the two upper chambers, known as the atria, and the two lower chambers known as the ventricles. Each chamber contains a valve which keeps the blood flowing in the right direction. Deoxygenated blood enters the right atrium, through the ascending inferior vena cava (IVC) and descending superior vena cava (SVC). Following this, blood is released into the right ventricle and then pushed through the pulmonary valve into the pulmonary artery. Once oxygenated in the lungs, the blood flows back into the left atrium via the pulmonary veins. After which it is released into the left ventricle. The left ventricle has a thicker wall as it needs to push blood through the aortic valve into the aorta, which then supplies oxygen rich blood to the entire body.

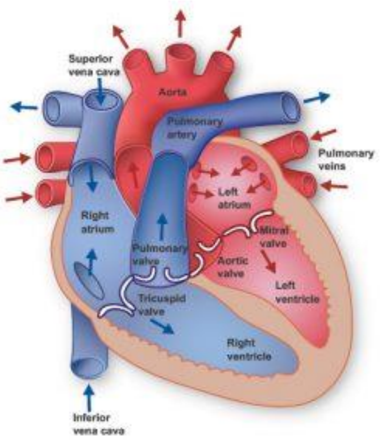

Figure 1 Anatomy of the heart

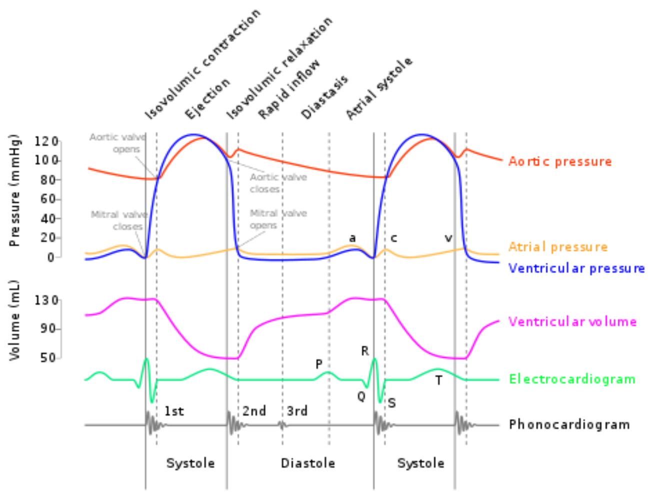

Figure 2 Cardiac cycle

The contraction of both atria and ventricles is responsible for the heartbeat. When the atria pumps blood into the ventricles, the valve between the atria and the ventricles close, preventing backflow of the blood. This makes the first sound. When the ventricles contract, blood is pumped away from the heart, through the pulmonary and the aortic valves. The closure of these valves creates the second sound. When measuring the blood pressure, two values are recorded: systolic and diastolic pressure. The systolic pressure, the pressure during heart contraction, should ideally be less than 120 mm Hg.

Diastolic pressure, the pressure in the arteries when the heart relaxes, should be less than 80 mm Hg (6).

Atrial ablation

Atrial fibrillation (AF), this is a type of arrhythmia, in which the heart beats too slowly or too quickly, resulting in an irregular heartbeat. There are several mechanisms responsible for the development of AF, as it is caused by both electrical and structural remodelling of the atrial tissue. AF is caused by ectopic activity that leads to spontaneous depolarisation of atrial tissue outside the sinoatrial node at rates faster than the sinus rhythm. The most common intervention for this arrhythmia is catheter ablation of the pulmonary vein ostia isolation (PVI) (7).

Atrial fibrillation is treated with an ablation therapy which combines minimally invasive surgical and catheter-based techniques. This intervention aims at eliminating the trigger which initiates AF using heat (radiofrequency ablation) of freezing (cryoablation). During such procedures the physician will guide the catheter through the body into the heart to solve the heart arrythmia. This is performed under image guidance such as fluoroscopy, CT or cardiac magnetic resonance (CMR).

Transcatheter aortic valve implementation

Aortic stenosis is one of the most common valvular conditions, leading to ventricular outflow obstruction. It is frequently observed in the ageing population due to calcification. Aortic stenosis (AS) is characterised by a narrowing of the aortic valve and left ventricular hypertrophy. The valve leaflets undergo remodelling and thicken, this can lead to increased stiffness that may affect valve closure. The pressure increase resulting from this condition, may cause thickening of the left ventricular wall due enlarged heart muscle cells (myocytes). This can trigger fibrotic response in the myocardium. This cascade of changes in the heart, may result in heart failure, if the left ventricular wall becomes too thick to efficiently pump blood through the valve (8).

As the cause of AS is not fully understood and the progression of the disease cannot be properly predicted, it is a worrying condition. Especially since the aortic valve plays a vital role in pumping oxygen-rich blood from the heart to the rest of the body. Since the disease can’t be helped with medical treatment, interventions are needed. During a TAVI the aortic valve is replaced with a mechanical heart valve.

Access route TAVI

During a TAVI procedure there are multiple access routes for the catheter to get to aortic valve. The most common route is to via the femoral artery (9). The physician will make a small incision in the groin, and place an introducer sheath in the femoral artery, after this a guidewire can move up through the sheath towards the aorta. Then a catheter can be placed which goes through the guidewire, via the aortic valve to the left ventricle. The catheter contains a balloon which will inflate and push the valve tissue to the sides, by stretching it. After the catheter with the balloon is removed this another catheter comes in, to place the new aortic valve with support of a mesh stent, which will eventually take over the function of the aortic valve. In some cases, a TAVI must be performed in the opposite direction of the blood flow. This is mostly performed via the subclavian artery which comes out as the third branch from the aortic arch. This procedure is performed less frequently, because the shape of the subclavian arteria is not ideal.

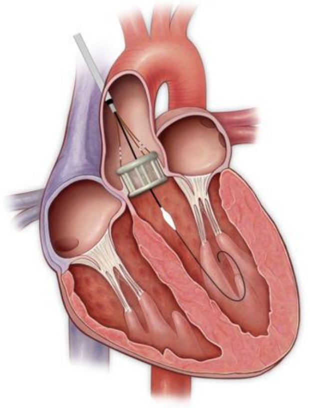

Figure 3 Valve implantation via the ascending aorta

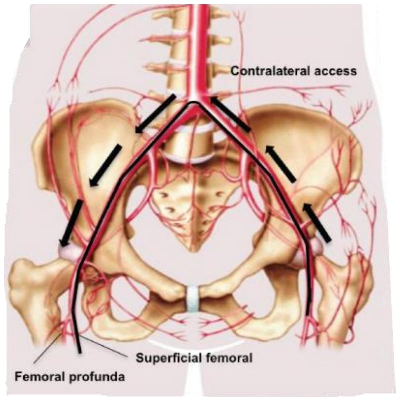

Figure 4 Access route of TAVI

Challenges in TAVI

The most common complications during a TAVI procedure is paravalvular leak (PVL) this occurs when the blood is flowing through a channel between a structure of the implanted valve and cardiac tissue, this is the result of a lack of sealing (10). Meaning, that the valve is not completely closed and covered over the native valve anulus and thus regurgitation occurs around the edges. Other complications can be irregularities in the anatomy like calcification of the arteries. TAVI is limited in its capacity to visually access the valve and identify the appropriate transcatheter heart valve, compared to an open-heart surgery. Therefore, image guidance is needed such as CT or MRI. MRI offers good perspective, post placement imaging enabled immediate evaluation of valve performance (11).

1.2 State of Art

The following section provides an overview of various studies that have developed a heart phantom, enabling surgical planning, training, and validation of device techniques. This will help to understand the important factors that should be considered when designing a phantom. There are several requirements the phantom should meet, such as being dynamic. A dynamic heart phantom could be useful for surgical training, as these minimally invasive procedures are currently performed while the heart is still beating, as mentioned above. To address these target applications, the main requirements for the cardiac phantom that will be designed during this research are as follows:

- It should be compatible with magnetic resonance imaging to enable guidance.
- It should be dynamic, following the pressure-volume curve of a human heart.
- It should be anatomically accurate.

Cardiac magnetic resonance (CMR) has become an increasingly attractive option for guiding complex cardiac procedures. For the past 60 years, interventional cardiology has relied on fluoroscopic x-ray imaging to guide cardiac catheterization. While X-rays provides clear images of device placement, they offer poor contrast for soft tissue anatomy. Furthermore, patients are exposed to radiation, which not only affects them but also indirectly affects clinicians. Ultrasound can also guide cardiac interventions, although its use is limited due to poor soft tissue contrast.

The aim of cardiac interventions is to visualize complex pathologies. Therefore, the demand of enhanced image guidance has become evident. CMR offers improved soft tissue contrast and allows for direct visualization of the heart's structure. Additionally, CMR provides procedural guidance and feedback for hand-eye coordination, which improves device placement. Although CMR offers significant benefits, a major challenge is the unavailability of MRI-compatible devices, which is also true for interventional cardiology testing phantoms. This hinders the advancement of CMR technology in clinical practice, preventing cardiac interventions that could benefit from CMR guidance(12).

Patient-specific 3D printed models have also gained popularity in the field of cardiac surgery. They aid in procedural planning and clinical training, particularly for heart diseases that vary between patients. Clinicians may find it challenging to obtain a comprehensive understanding of cardiac structures based on image visualisations. When 3D printed models are derived from a patient's cardiac imaging data, this overcomes limitations and improves spatial visualization. It can also assist in preoperative planning and simulation of cardiac procedures, making it a useful tool in medical education and training (13). A dynamic 3D printed model, can enhance training for minimally invasive interventions even further, as these procedures are performed while the heart is still beating. However, dynamic 3D printed models, are rarely available yet.

Liang's patient-specific heart phantom

In Liang's recent study, a patient-specific heart phantom was created. The aim of this phantom was to simulate a MitralClip procedure for clinical training and procedure planning (14). The phantom was created, using multiple materials, such as PVA-C or silicone. The phantom consists out of a flexible silicone mold, an internal blood pool model and integrated valve models. The outer flexible silicone mold was created by pouring Smooth-On Mold Star 16 Fast silicone around the 3-D printed model into the 3-D printed mold housing. The inner model represents the internal blood pool of the heart. The results of this research indicated that silicone would be more desirable to use than PVA-C. This is because it remains stable in both air and water, while PVA-C would shrink if not kept in a hydrated state. This results in an unpredictable phantom size. In addition, silicone is easier to visualize than normal myocardial tissue under fluoroscopic, making it more suitable for training. The phantom was designed, containing no metal, and using materials that do not distort imaging of the 3D anatomical model within the chamber. This makes the phantom compatible with imaging modalities such as CMR.

The phantom has a total length of 15.24 cm, and is integrated in a cylindrical container with an outer diameter of 25.5 cm and an inner diameter of 22.86 cm. The container has 5 access point to the inside of the model, which are located at the inferior and superior vena cava, right ventricle and in line with the aortic arch. The access points can be used to simulate catheter interventions and allow access with tools up to 1.47 cm in diameter. In addition, the anatomical model is secured to the inside of the phantom, by eight nylon screws each of which connects the flange of the model to the wall of the phantom. The main limitations of this phantom were the manufacturing time of the silicone or PVA-C model. No pressure was exerted on the phantom, indicating that it was not dynamic.

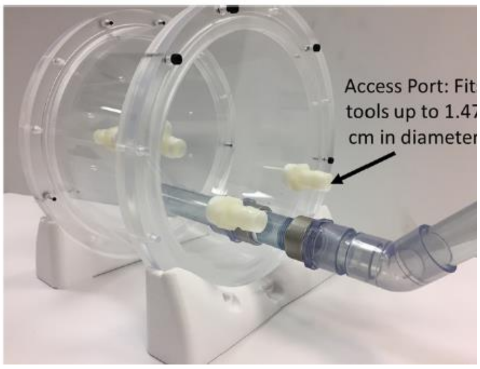

Figure 5 Cardiac phantom access points

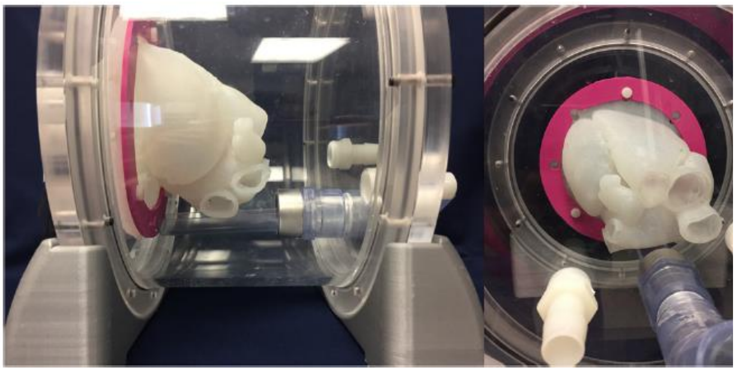

Figure 6 Phantom with 3D anatomical model and flange seal holding it in place.

Bietenbeck's CMR-conditional cardiac phantom

In the design research of Bietenbeck a dynamic heart phantom was created (5). The aim of the study was to develop a CMR-conditional cardiac phantom that simulates both cardiac anatomy and function. The phantom should enable training of interventional CMR procedures such as right heart catheterization. It is made of MR-safe materials and ensures that the device is adaptable, allowing individual components to be replaced when required. The phantom comprises two atrial and ventricular chambers, interconnected by four cardiac valves. The ventricular wall is made elastic using a mixture of polyurethane, allowing it to move and contract during systole. To make it dynamic a constant pressure to the ventricular walls was applied, causing movement of the elastic membrane, and thus achieving systole. Diastolic relaxation is achieved by stopping the application of external air pressure, which causes an elastic recoil of the polyurethane walls.

The phantom has four access points, these were elastic tubes which were used to so simulate the inferior vena cava, pulmonary artery, the (single) pulmonary vein and the aorta. The single pulmonary vein was directly connected to the pulmonary artery. It contains an external pump, responsible for generating fluid pressure to simulate systolic contraction, enabling the adjustment of both systolic and diastolic cycle lengths through a remote-control device. Predefined imaging views were used to guide the wedge pressure catheter into the right atrium, then into the right ventricle and pulmonary artery. The procedure was performed using an artificial femoral access site, which was positioned on the right side of the phantom. To validate the phantom, pulmonary artery pressure was measured, resulting in pressure waveforms and values very similar to those in humans.

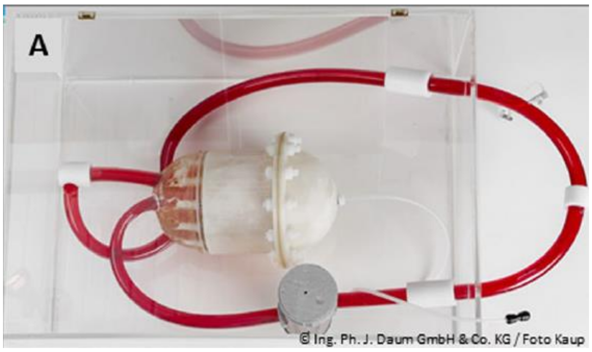

Figure 8 CMR- conditional phantom top view

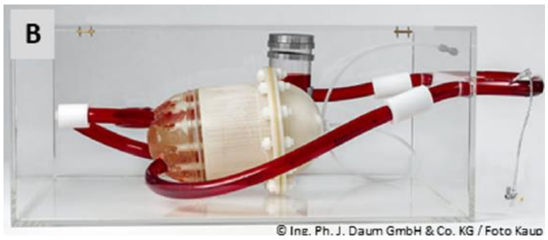

Figure 7 CMR-conditional phantom side view

Several challenges were observed during the study. Firstly, the symmetry of both atrial and ventricular chambers restricts the variation between the systemic and pulmonary circulations. Additionally, the model struggles to accurately simulate the beating heart as it does not accurately mimic the different blood flow conditions in the left and right ventricles. Furthermore, artefacts were noticed at the level of the cardiac valves, which may originate from captured air in the surrounding area of the valves.

After visiting the heart clinic in Munster, some limitations about the design of the phantom were observed. The article mentioned volumetric values resembling those of a child's heart, leading to the assumption that the cardiac phantom's size would not exceed 250mm. However, it turned out to be significantly larger than anticipated. The phantom was not precisely measured, but a reference image of a hand is shown in the figure below in Figure 9. The cardiac phantom was put inside a bigger plastic box which was see through, this was probably done to capture any escaping liquid from the phantom.

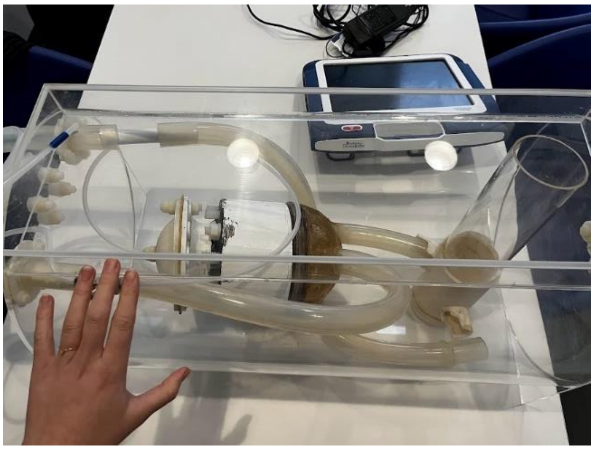

Figure 9 Reference image of CMR-conditional phantom

The design, consisted out of four large compartments with four layers in between, mimicking the chambers of the heart. The upper dome contained long rods that connected all four layers to the middle compartment. However, this proved difficult to (dis)assemble. Furthermore, the cardiac valves (bio prostheses) were inserted into the phantom, preventing blood from flowing backwards in the wrong direction. Some artifacts were observed at the level of the cardiac valve, due to captured air surrounding the valves.

Figure 10 Upper dome of cardiac phantom, containing long rods.

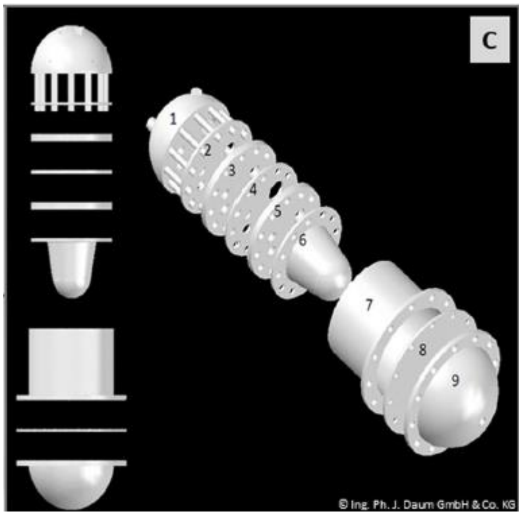

Figure 11 Assembly of cardiac phantom parts.

Furthermore, the cardiac phantom contained an elastic ventricular wall made of a polyurethane mixture. Contraction of the left and right ventricle is achieved through external pressure, which causes movement of an elastic membrane. This movement compresses the fluid in the chambers above. However, it became clear that the ventricles were quite stiff, as it was difficult to compress it manually. Consequently, higher pressure was required to cause contraction in the ventricles, leading to breakage of compartments.

The successful performance of right heart catheterization indicates that this phantom could be a viable alternative for planning and training minimally invasive interventions. However, due to its large dimensions, it is less user-friendly. Additionally, the phantom lacks anatomical accuracy as the heart is constructed from layers and an elastic cone, and therefore requires further improvement.

Vannelli's dynamic heart phantom

In the research of Vannelli a phantom was designed to provide realistic image data for beating heart interventions, such as left ventricle (LV) and valve procedures (15). The primary goal of the design is to mimic the imaging properties of the left ventricular valves and simulating the blood flow through the heart. The blood should flow from the atrial reservoir, across the mitral valve to the LV, exiting through the aortic valve and aortic root, and finally return to the atrial reservoir. The phantom has three access routes into the atrial reservoir, including retrograde (backwards) access to the aortic valve. Additionally, it provides access to the mitral valve and apical access to the left ventricle. This is advantageous for surgical interventions. The phantom mimics the human heart closely, however it only allows ultrasound imaging guidance, since cylinder materials were used which were unsuitable for MRI. Furthermore, there is a low pressure inside the phantom because there is no mock circulatory loop present, to simulate resistance.

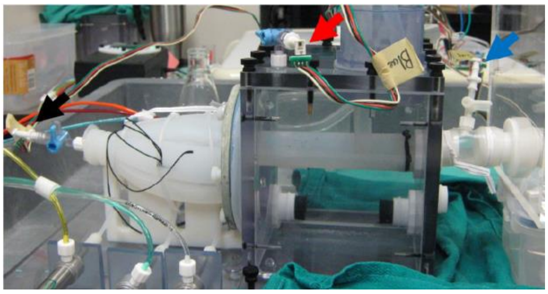

Figure 12 Cardiac phantom with pressure sensors attached to ports on the phantom to measure the ventricular, aortic, and atrial pressures.

2. Method

In this research the following research question will be addressed: *How can a dynamic and anatomically realistic cardiac phantom be designed to enable image guidance in cardiovascular magnetic resonance (CMR) and ultimately be used for minimally invasive catheter trials in CMR?*

To come to a final design, multiple design cycles were undertaken, with adjustments made after each cycle. In the first cycle, a scale model was created to understand the function of its compartments. The second cycle involved simplified drawings of the heart model and finding a solution to connect it to the outer phantom. Integration of the created heart model into the outer phantom using SolidWorks was the focus of the third cycle. The fourth cycle addressed achieving one-directional flow in the phantom. Finally, in the last cycle, final adjustments were made to the outer phantom, and it underwent evaluation under MRI. For each cycle all materials and programs used will be listed.

2.1 Requirements

Prior to the design process, a list of requirements was created and divided into three categories. The first category relates to the end use of the phantom. These requirements describe what the purpose of the phantom is and what it should enable. The second category describes the requirements for the outer phantom. The last category of requirements describes the criteria that the heart model should meet. This list can be found in appendix I. The primary requirements specify that the phantom must facilitate training for interventional CMR procedures, enable MRI visualization, and allow for contraction of an anatomical accurate heart model. Additional requirements were identified during one of the design cycles and were subsequently added to the list.

2.2 Design process

Several phases were followed to arrive at the final design. The basic design cycle was followed during this process (16). This includes the following stages: analyse, synthesise, simulate, evaluation, and

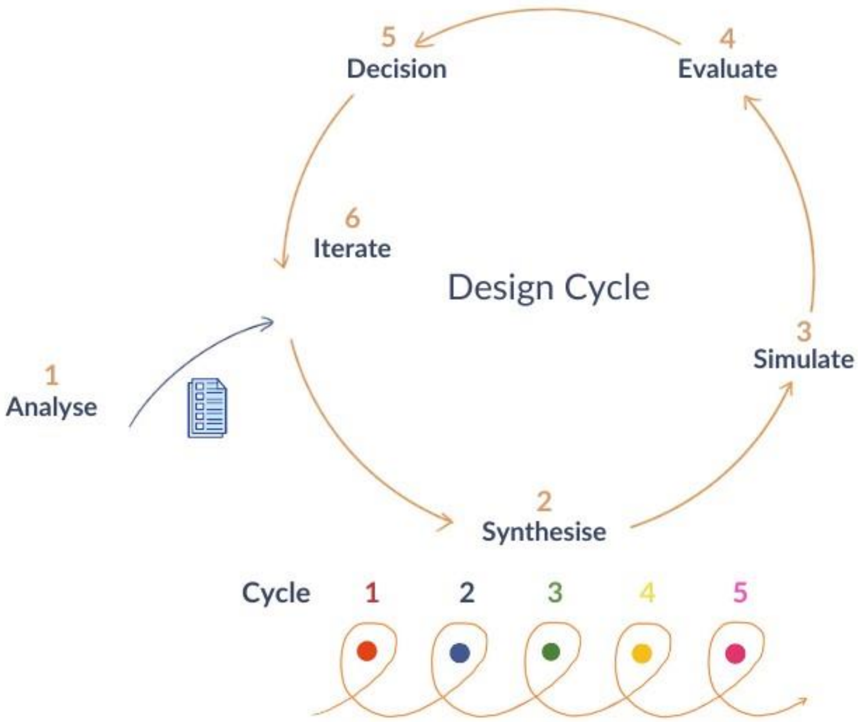

Figure 13 Basic design cycle

decision. At the end of each cycle, the design was evaluated, and the next cycle of the same stages started, until the final design of the outer phantom that met most requirements was developed. First, the different stages of the design process are described:

The first stage is *analysis*, during which the aspects related to the design goal are analysed and different design criteria are formulated that the design should meet. In the stage of *synthesise*, various solutions were generated, resulting in different ideas. The third stage is *simulation*, where a new design is developed and the ideas from the previous stage are modelled to aid in defining the expected properties of the design. During the fourth stage, the design criteria are *evaluated* to assess the design. Finally, a *decision* is made as to whether the design is acceptable or not. If not, iterations are made to the design and the same stages are repeated until a final design is developed which meets all the necessary criteria.

Cycle 1.

Analyse

After a visit to the heart clinic in Munster, it became evident that the size of the phantom exceeded expectations, making it less user friendly. Consequently, a requirement was set that the phantom should not exceed a length of 250 mm.

Synthesise

The design of Bietenbeck served as the initial framework for the outer phantom. This choice was made because it met some key criteria, including enabling contraction and facilitating guidance by magnetic resonance imaging. However, there was still room for improvement since it was not anatomical accurate.

Simulate

To gain a deeper understanding of the phantom, a smaller scale model was simulated using SolidWorks and then 3D printed. This scale model comprised multiple parts. The first dome included rods for assembling the parts, while the cone represented the ventricles. Unlike the flexible material used in the Bietenbeck design, the cone in this scale model was 3D printed from PLA and was rigid. Additionally, holes were added to the surfaces of the different parts, to facilitate assembly.

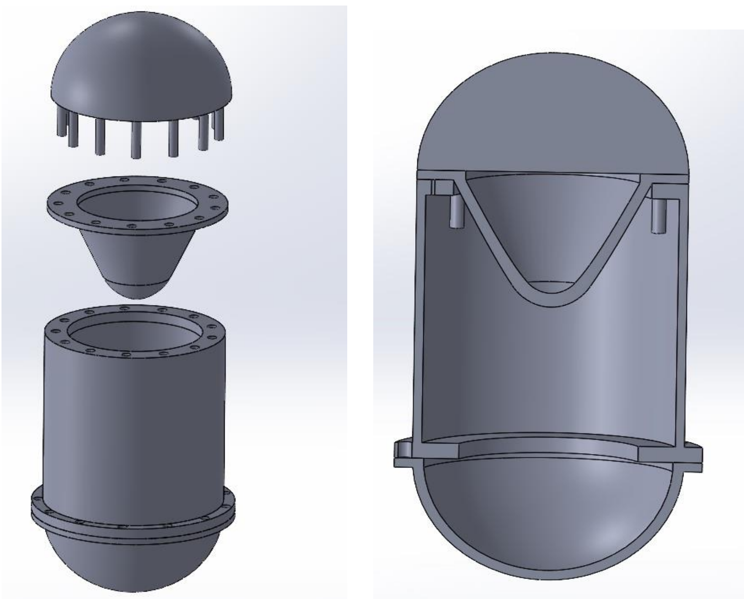

Figure 14 Scale model of outer phantom

Evaluation and decisions

Upon evaluation, it was noted that the holes were printed too close to the edges of the material and were too small. Furthermore, it was decided to remove the rods for assembling al parts due to their tendency to break. It was also determined that the cone could be removed and replaced with an anatomically accurate heart model that would also facilitate contraction, thus complying with the design criteria.

Cycle 2.

Analyse

During the second cycle, 2D drawings were created in Procreate, to ascertain the dimensions of the outer phantom. The outer phantom's design should allow integration of an anatomical heart model while maintaining specific dimensions crucial for obtaining contraction. It was observed that in the Bietenbeck design, the ventricles were simulated using an elastic cone; however, for this design, ensuring anatomical accuracy was considered essential and an elastic heart model will be created.

Synthesise

To understand the physiology of the heart, some drawings were produced to visualize the blood flow and identify possible access points for integrating it into the outer phantom. The sketches can be seen in Figure 15.

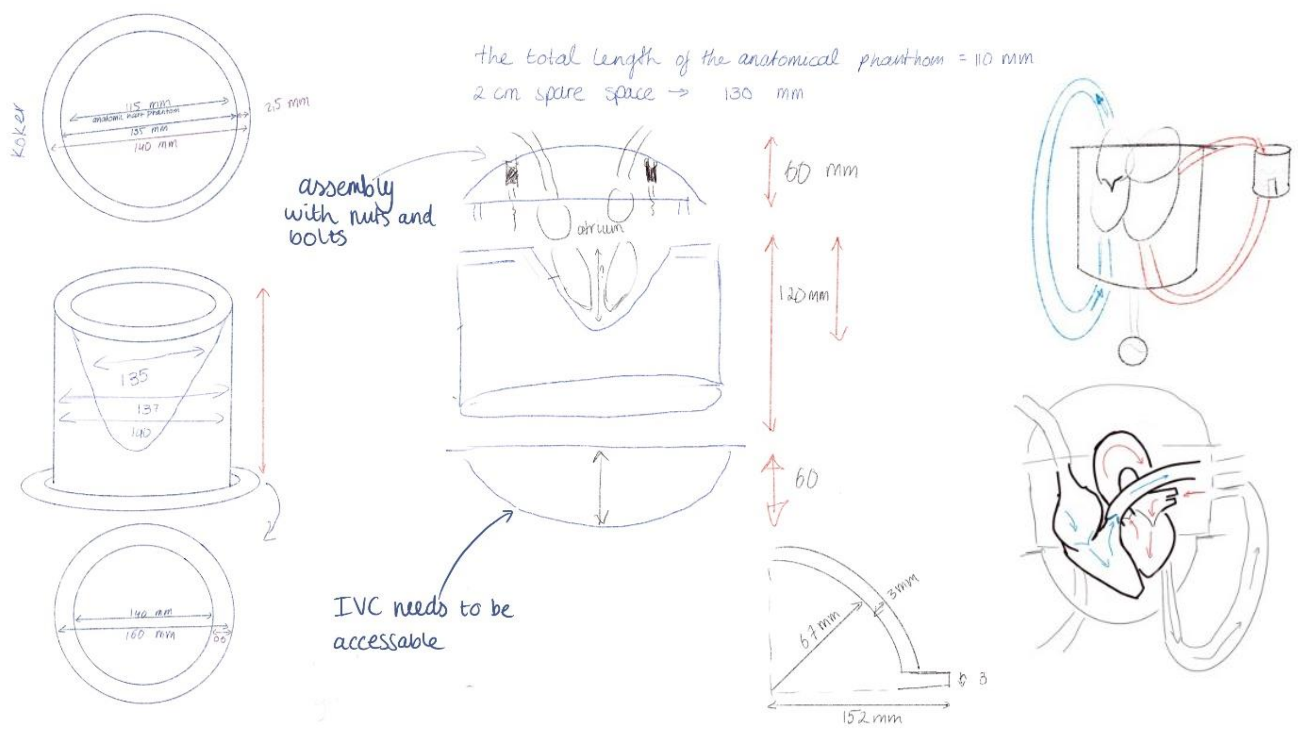

Figure 15 sketches of possible constructions of heart model in outer phantom and flow through the heart model

Simulate

To facilitate easier assembly of the components, rods were replaced with bolts and nuts, an M8 bolt was selected with a length of 20mm. This facilitated the assembly of the parts. The outer phantom was then simulated in SolidWorks. Holes were carefully made in the upper dome, with measurements taken to ensure they were not too close to the edge.

Evaluation and decisions

During the evaluation stage, sketches illustrating the blood flow through the heart led to the exploration of alternative options, especially since the lungs did not need to be included in the model and it would complicate the simulation. Therefore, adjustments will be made in the following design. After a failed 3D print of the hollow cylindrical tube, it became apparent that a thickness of 2.5mm was too thin and required adjustment. It also became clear that adjustments to the upper dome had to made. Integrating the heart model into the upper dome posed a challenge due to its solid structure, unlike the lower dome which was hollow. This would require a hole of precise dimensions to be made, to allow integration of the heart model into the phantom. It would also require a significant increase in printing time.

Cycle 3.

Analyse

After analysing the flow through the heart, it was necessary to simplify the heart model while ensuring anatomical accuracy. Additionally, an essential requirement emerged: the phantom must be watertight, as pressure will be applied using water.

Synthesise

After some ideation, it was determined that the placement of O-rings could achieve watertightness for the outer phantom. Consequently, grooves were integrated into both the hollow cylindrical tube and dome. Furthermore, simplifications to the heart could be made by removing certain components.

Simulate

A heart model was created using data from previous research in 3D slicer. Given that the phantom's intended application is for RF ablation or TAVI procedures, typically involving access to the heart through the femoral vein (9). For a TAVI the catheter enters the heart through the aorta where a new valve will be placed. For a RF ablation the heart is accessed through the IVC. Therefore, these are the most important artery and vein to be present in the heart model, and the SVC could be excluded. As it is not essential for this process, blood does not need to be oxygenated by the lungs. Therefore, the pulmonary artery and vein are also excluded from this model. The right ventricle is now directly connected to the left atrium. This allows the blood to flow into the left ventricle and exit the heart through the aorta. Figure 16 shows a schematic representation of the flow through the heart model.

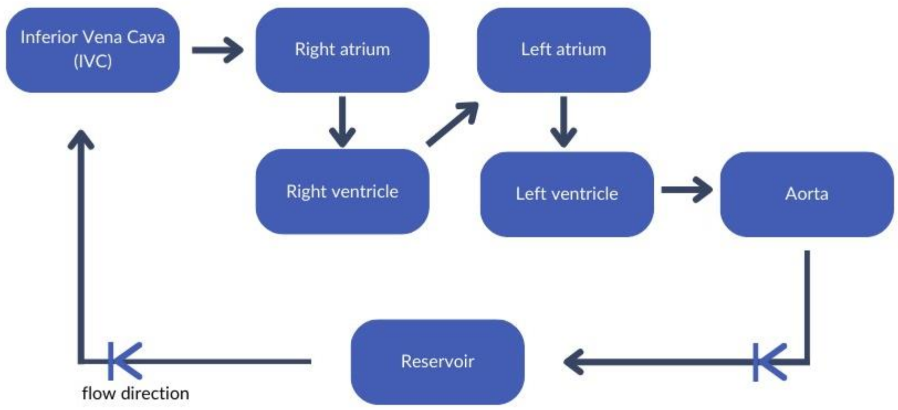

Figure 16 Schematic representation of flow through the heart model

After the heart model was made in 3D slicer, it could be transferred to SolidWorks for visualization of its integration into the outer phantom. This helped with visualizing how the heart model can be integrated into the phantom, with maximum accuracy. It also assisted in determining the placement of access points to connect the aorta and IVC had to be placed. To facilitate integration, the upper dome was designed to be hollow.

Evaluation and decisions
When integrating the heart model into the outer phantom using SolidWorks, it was evident that the model was too large to fit within the specified dimensions. Adjustments to the model were needed to meet the requirement that the phantom should not exceed a diameter of 150mm. Additionally the length of the hollow cylindrical tube needed to be reduced to minimize unnecessary space.

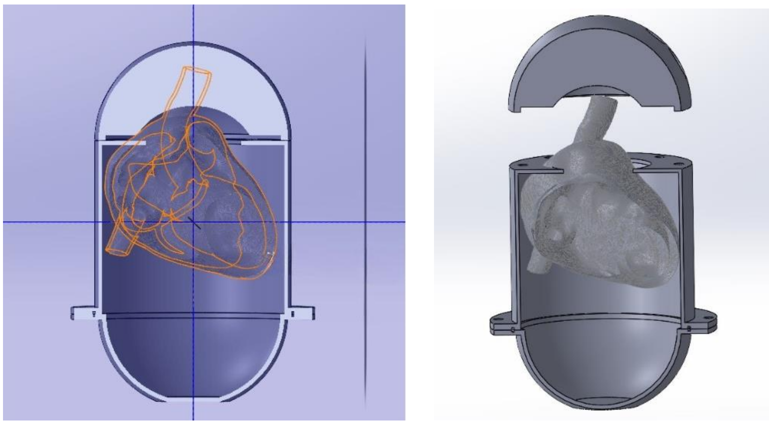

Figure 18 integration of heart model into the outer phantom using SolidWorks

Figure 17 Elastic 3D printed heart model.

Materials and programs
The heart model was created by using data from previous research. It was made by Dr. Ir. Brink using the Slicer 5.6.1 program, which allows for direct visualization and processing of medical images. The model was then printed by 3D medical support, using an elastic resin. It is made of MR safe material, to allow CMR guidance. Furthermore, SolidWorks 2023 was used.

Cycle 4.

Analyse
In the previous design iteration, it was evident that the heart model was too large for the phantom, a reduction in size was necessary. Additionally, challenges arose regarding how to connect the heart model to the outer phantom without causing water leakage. Another requirement was ensuring that the heart model replicated the physiological conditions of the blood flow, including one-directional flow to prevent backflow. Since the printed heart model lacked valves, a solution had to be found.

Synthesise
After ideation, a hose pilar design was conceptualized in SolidWorks to connect the heart model to the outer phantom effectively. However, there were some concerns about its strength when exposed to pressure, since it would be 3D printed. Consequently, a connecting tube was made to connect already available hose pillars made of PVC, which would be stronger. The upper and lower domes were flattened to accommodate the connection of the hose pillars and the connecting tube, which is showed in Figure 20.

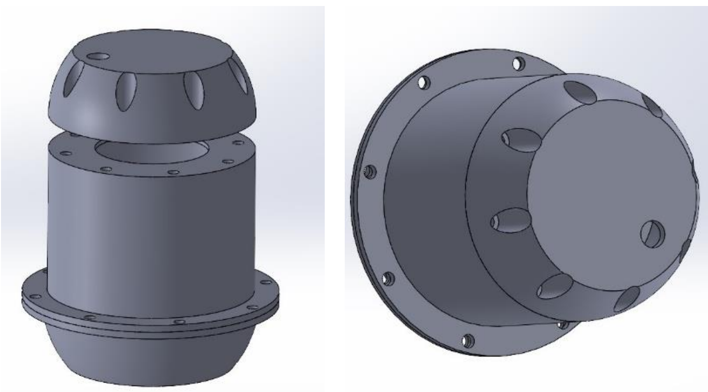

Figure 20 Outer phantom with flattened domes

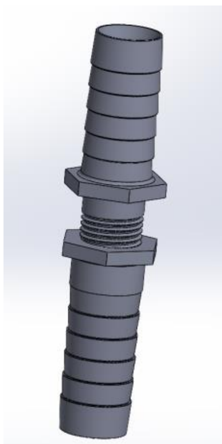

Figure 19 hose pillar designed in SolidWorks, but not used.

Additionally, to address the one directional flow requirement, different valve options were explored such as the caged-ball prosthesis and ribbon valve principles (17). These types of valves can be seen in Figure 21. Eventually the caged-ball principle would be too difficult to integrate into tubes and a valve was designed based on the ribbon valve principle.

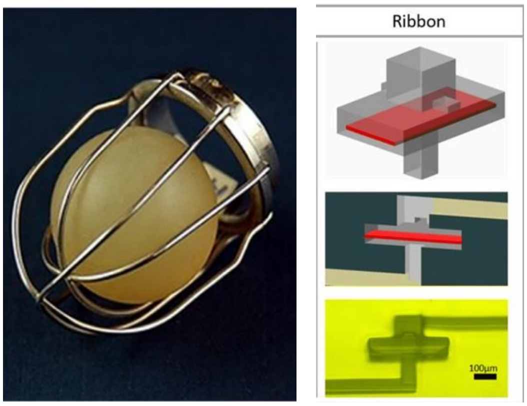

Figure 21 Ball in a cage principle and ribbon-based valve.

Simulate

The designed valve features an inlet and an outlet port with a membrane-like coin in between to regulate one-directional flow. The outlet port features ribs to prevent the membrane from obstructing it. In Figure 22 the valve design is shown. The red arrow shows the direction of the flow through the valve. The valve allows water to flow further, with the membrane moving up to allow it to pass. If water flows backwards, the membrane moves downwards, blocking the water to flow in the wrong direction. This creates a fluidic diode and regulates the flow direction of the water in the phantom. The valves will be connected to a plastic tube. One valve is connected to the aorta and the other valve to the IVC. When the pump is connected to the outer phantom, simulating the heartbeat. The check valves should guide the water into the right direction.

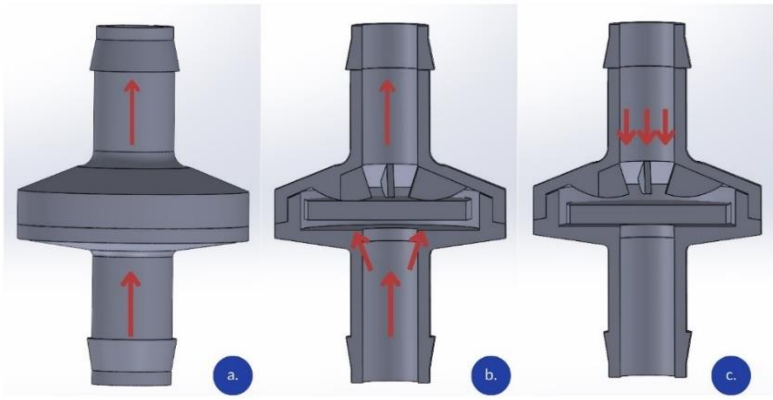

Figure 22 a) flow directions through vale, b) cross section of check valve and flow direction, c) No backward flow possible

Evaluation and decisions

To evaluate the system, all components were assembled, including the outer phantom, heart model, plastic tubes, this was then filled with water. The anatomical heart model was printed at 80% of its original size which allowed for integration. It was discovered that the phantom encountered leakage issues due to the absence of O-rings on both sides of the hollow cylindrical tubes, and the holes for the bolts were placed on the inside of the top dome. Additionally, issues were observed with the dimensions of O-ring groove, which was too small. These observations highlighted the need for modifications in the next design iteration to address these issues and enhance the overall functionality of the system.

Materials and programs

Both outer phantom and valves were designed using SolidWorks 2023. The outer phantom was printed using PLA with an infill density of 20% on an Ultimaker Cura 3D printer. The heart valves were printed with an infill density of 50% on a Bambu Lab X1 3D printer.

Cycle 5.

Simulate

To arrive at a final design, some modifications had to be made to improve the outer phantom's watertightness. Therefore, the upper dome was made the same as the lower dome, making it symmetrical. Furthermore, both sides of the hollow cylindrical tube contained an O-ring groove, to seal the phantom. Extra support was also added to the phantom, to make it more stable.

Plastic tubes and hose pillars are used to create a loop through which the water will circulate. Once the heart model is integrated in the outer phantom, the phantom will be filled with water. Pressure can be applied manually by a hand pump. Because of pressure difference, the heart model will contract and push the water through the model. This model is schematically presented in Figure 23. The flow is going in the right direction by placing the valves in the loop, between the plastic tubes. To conduct pressure measurements, a balloon wedge pressure catheter will be inserted into the pressure inlet. This will allow for the measurement of pressure inside the phantom during both contraction and relaxation of the heart.

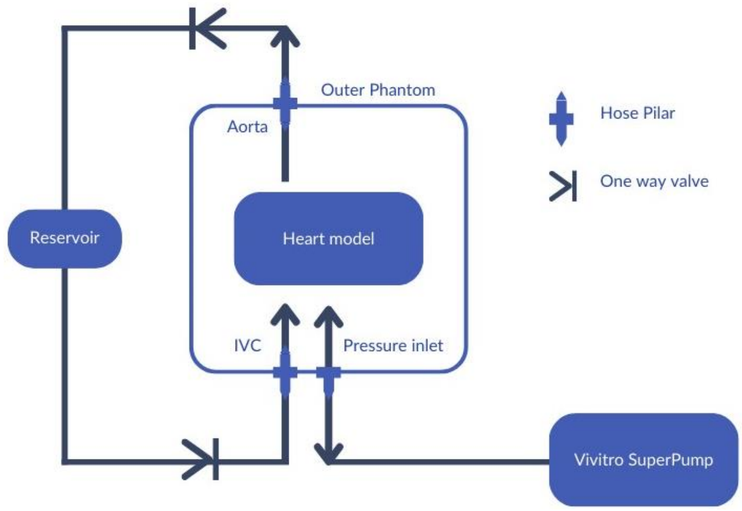

Figure 23 Schematic representation of flow through the outer phantom

Evaluation and decisions

To evaluate the system, pressure was applied manually to achieve contraction. It was evident that the 3D printed material was not waterproof due to its porosity, allowing water to seep through. Additionally, there was leakage around the O-rings. To address this issue, the material was treated with epoxy in post processing, and a silicone ring was created to provide a better seal. Finally, the system was assembled, including the valves and the heart model, after it was filled with water some tests were conducted. First a pressure measurement was done by inserting a wedge pressure catheter after this, it was visualized with MRI to see if contraction was possible.

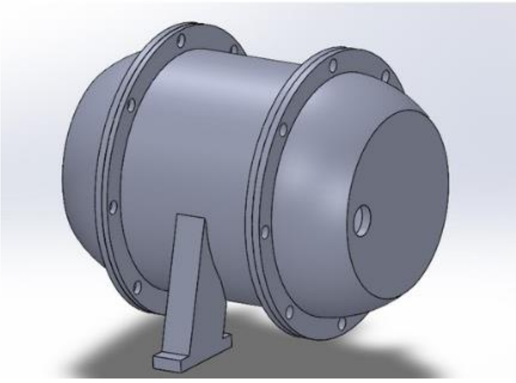

Figure 24 Final Design of the outer phantom. On the left the SolidWorks model is shown, on the right the 3D printed model is shown.

Materials and programs

The outer phantom was designed using SolidWorks 2023. The compartments of the outer phantom were made of PLA with a 50% infill density to withstand higher pressures, up to 2 Bar. All compartments were printed by the Ultimaker printer in Design Lab. The pressure measurement was conducted, using a wedge pressure catheter and a manometer.

CMR protocol

The CMR studies were performed on a 1.5T Siemens Magnetom Aera scanner. The scanner enabled real time imaging, to obtain dynamical data. The phantom was externally driven by a manual pump, therefore there was no fixed heart rate. To capture images of the heart model during contraction, it was scanned both along the long axis and the short axis. The short axis view displays all four chambers of the heart, while the scan along the long axis only displays the right ventricle and atria in a two-chamber view. The following sequence settings were used: TR = 1.97 ms, TR = 394.00 ms, FA = 70°, ST= 10 and the FoV read of 300 mm.

3. Results

The test results will be presented in the following section. First, a pressure measurement was preformed, followed by an MRI scan, which recorded the contraction in the heart model.

Final set up of cardiac phantom

The figure below shows the final configuration of the cardiac phantom. The phantom is linked to external plastic tubes and valves. Each component is numbered and listed in Table 1. The white arrows indicate the IVC and aorta, while the double-sided arrow indicates the pressure inlet. In the final setup, the heart model was driven externally by a manual pressure pump *(number 5)*. Squeezing the pump, creates a pressure difference on the inside of the phantom, resulting in the contraction and relaxation of the heart model. This caused a flow of water to pass through the heart model, guided by the heart valves *(number 6)*. The MRI scanner was used to visualise the internal structure of the phantom.

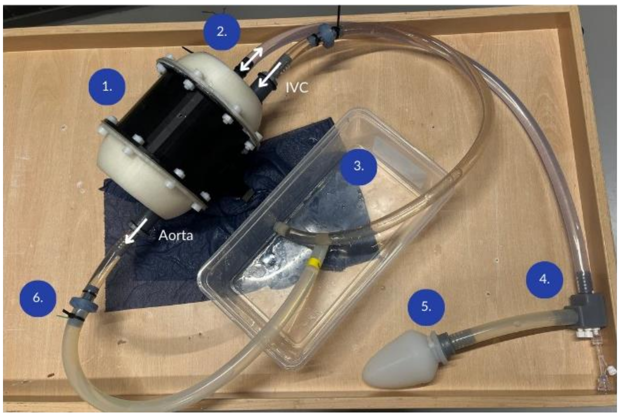

Figure 25 Cardiac phantom setup for use in MRI

Table 1 Components of cardiac phantom

Number	Component
1.	Outer phantom
2.	Pressure inlet
3.	Waterreservoir
4.	Catether inlet
5.	Manual pressure pump
6.	Heart valve

Pressure measurement

Before the cardiac phantom was visualized by MRI, a pressure measurement was conducted with a manometer. By implementing a pressure measurement in the created phantom, the physiological conditions could be simulated more accurately. Exerting pressure in the form of water, mimics the forces experienced during contraction. It was achieved by inserting a wedge-pressure catheter through the catheter inlet *(number 4)* to the inside of the phantom *(number 2)*. The pressure was applied by squeezing the manual pressure pump. The systolic pressure was measured at the end of contraction. And diastolic pressure was measured at the end of relaxation. The following pressures were measured:

Table 2 Pressure measurement inside the cardiac phantom

	Systolic pressure	Diastolic pressure
Pressure in bar	0.033 Bar	0.012 Bar
Pressure in mmHg	24.75 mmHg	9.00 mmHg

MRI scan of cardiac phantom

After filling the outer phantom and the heart model with water, it was visualised in an MRI scan. The scans were taken along the short and the long axis. Prior to conducting dynamic scans, non-moving scans were preformed to visualize the cardiac phantom without contraction and relaxation occurrence. Figure 26 shows a scan that clearly visualises the aorta and the connection of the heart model to the outside of the phantom, connected by hose pillars. The figure below indicates the aorta, right atrium (RA), right ventricle (RV), left atrium (LA), and left ventricle (LV).

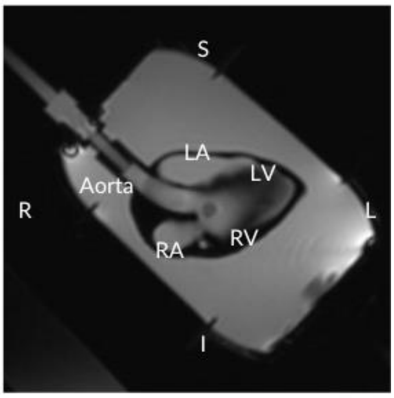

Figure 26 MRI scan, visualizing the aorta and heart model.

The figures below show the various phases of heart model contraction. Scans are made along the long axis and show a two-chamber view, the right atria and ventricle. During the MRI scan, the manual pressure pump was used to induce contraction in the heart model. The contraction took place in a few seconds. The duration of contraction depended on how fast the pressure pump was operated. Figure 27 shows the contraction and relaxation of the heart model, scanned along the long axis. The inferior vena cava (IVC) and the pressure inlet are visible on this scan. B) shows the contraction of the heart model, it can also be seen that water is entering the phantom, causing it to contract. When contraction takes place, the scan shows that only movement in the right ventricle occurs. However, both ventricles should allow movement during contraction. Furthermore, during contraction air is entering the heart model, which can be seen by de darker shades of grey. Some artifacts are seen at the bottom of the IVC.

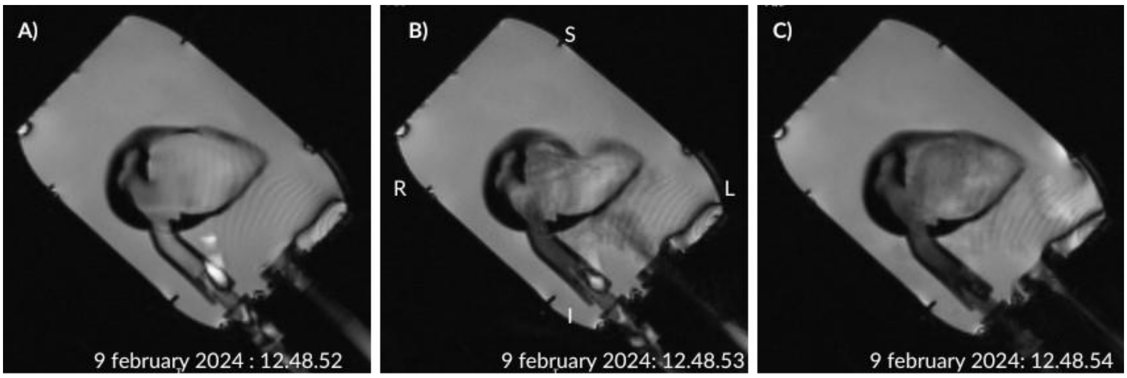

Figure 27 Scan along the long axis during contraction and relaxation in cardiac phantom

Figure 28 shows the contraction and relaxation of the heart model, scanned along the short axis. A indicates the end of diastole, B indicates the end of systole and C indicated the beginning of diastole. The scans show that the right ventricle (RV) allows movement, while the left ventricle (LV) remains still during contraction. However, they should both allow movement. It can also be seen that some air is captured on the inside of the heart phantom. Before contraction, the LV and RV are both even coloured grey, however during and after contraction the right ventricle turns a darker shade of grey, due to air. This can also be observed around the level of the aorta.

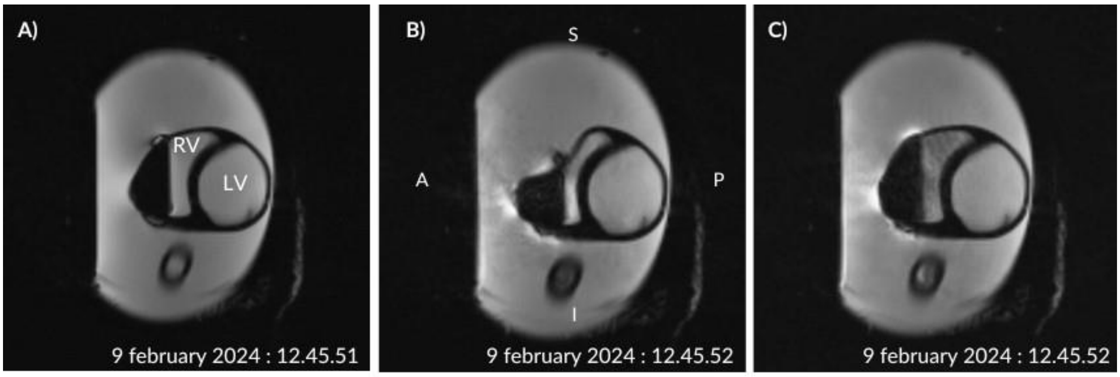

Figure 28 Scan along the short axis during contraction and relaxation in cardiac phantom

4. Discussion

This chapter analyses the results presented in the previous chapter and discusses the main limitations and challenges.

Interpretation of the results

After performing pressure measurements, it was found that the systolic pressure and diastolic pressures were lower than expected. Normally, the blood pressure in the heart is 120/80 mmHg, the measured values in this phantom were: max/min = 25/9 mm/Hg. The reliability of the recorded values may be comprised due to several factors. Firstly, the pressure was applied manually, resulting in an inconsistent pumping interval. This irregularity can affect the measured pressure. Additionally, water leakage was observed from the phantom. Despite the pressure loss, the phantom still allowed for contraction, enabling a dynamic cardiac phantom which was recorded on an MRI scan.

In the Bietenbeck design, a pressure measurement was conducted at the level of the pulmonary artery, also by using a wedge pressure catheter which was connected to an external amplifier. The following pressures were measured: max/min/mean = 16/10/12 mmHg. These values are in the same range as the measured values of this research. However, their pressure was measured at the level of the PA, while this pressure was measured on the inside of the phantom and not inside the heart model. Furthermore, there phantom was driven automatically and not manually.

After scanning the phantom using the Siemens Aera 1.5T, the scans were compared to real cardiac MRI scans. It was observed that only the right ventricle underwent contraction. Which can be seen in Figure 27 and Figure 28. In this 3D printed heart model the pulmonary artery is excluded, resulting in a direct connection between the right ventricle and left atria. During a normal cardiac cycle, electrical potentials cause contraction in the right and left ventricles. However, in this model contraction occurs due to pressure differences, causing the most vulnerable point to contract and displace water. Therefore, if only one ventricle contracts, it is enough to push the water through the model. This deviation from anatomical and physiological correctness, could potentially affect the phantom's functionality. Furthermore, in a human heart, the wall of the left ventricle is thicker due to its pumping function, measuring between 12-15 mm, compared to the right ventricle which measures between 3-5mm. In this model, the thickness of the left ventricle wall was reduced to 2mm, equalizing it with the right ventricle. This adjustment was essential to prevent excessive stiffness that could hinder contraction. However, despite these changes, contraction still did not occur in the LV.

It can also be seen on the MRI scans, that air was trapped inside the heart model. When filling the heart model, it can be difficult to remove all air bubbles from the inside once it has been integrated into the outer phantom. Air bubbles should be removed as much as possible because it can cause artifacts. The captured air inside the heart model, could also be a possible explanation for a deviation in the pump function of the heart.

Limitations and challenges

One of the main challenges was the lack of waterproofness of the 3D printed material, which affected the results. This was due to the presence of small pores resulting from the layer-by-layer printing process. Even when pressure was exerted manually on the phantom, water seeped through the material. Another problem that occurred was leakage around the O-rings. Since the material was not completely sealed off by the O-ring. An O-ring can ensure waterproofness if both surfaces are even. However, this was not the case, since the hollow cylinder and domes were 3D printed and post-processed with epoxy. Therefore, the O-ring did not work properly, and a silicone ring was made. Additionally, a thicker O-ring would be preferable to offer resistance at higher pressures and volumes of water.

In addition to the outer phantom, the anatomic heart model was printed using a resin printer. During such process it is important that the model contains a hole, through which the resin can escape during the curing process. Due to its complex structure, it is likely that resin residue remained within the heart, potentially affecting its contractability.

5. Conclusion and recommendations

During this research the following research question was addressed: *How can a dynamic and anatomically realistic cardiac phantom be designed to enable image guidance in cardiovascular magnetic resonance (CMR) and ultimately be used for minimally invasive catheter trials in CMR?*

To answer the research question, a literary study was conducted to review previous work in the field of CMR. Bietenbeck's design was selected as a starting point for optimizing the design. The phantom was designed using SolidWorks and then 3D printed. The heart model was created using data from previous research. Despite simplifications such as excluding the SVC and pulmonary artery, the heart model remains anatomically realistic by retaining all four chambers and their complex structures.

In conclusion, a dynamic and anatomically realistic cardiac phantom has successfully been developed. This could aid in providing test methods for interventional cardiology as it allows for CMR guidance. Since CMR offers great visualization of the heart's structure and of this phantom, device positioning can be trained. The phantom was designed to be anatomically accurate and dynamic, allowing for contraction. Additionally, the phantom was made to be adaptable, enabling replacement of the heart model with a patient-specific model, which could facilitate testing of minimally invasive interventions.

Several recommendations are proposed to further enhance the functionality and utility of the cardiac phantom. For future research it is recommended to test the functionality of the phantom by connecting it to a pulsatile pump that simulates a beating heart. This will provide more reliable pressure measurements and determine the extent to which the phantom can withstand certain pressures. In addition, it is recommended to conduct heart flow measurements. If volumetric values are obtained, such as the end-diastolic volume, ejection fraction and the stroke volume, a more accurate comparison can be made to the values of the human heart, providing a better indication of phantom function.

As the phantom was designed for training in minimally invasive procedures, such as TAVI or RF ablation, it is recommended to use test it for such a procedure under MRI guidance. This could improve the phantom's usefulness for these procedures. Furthermore, the heart valves could be optimized and test its functioning by conducting a flow measurement.

For practical suggestions, it would be advisable to post-process the 3D printed material directly, to ensure watertightness. Alternative options for the current used method with epoxy, is to post process it with Ethyl acetate vapor. This penetrates the pores of the material; this creates a water-resistant surface. It would be a better option to smooth PLA prints, it is less time consuming but more flammable, making it more dangerous to use (18). Since printing it at an infill density of 100%, won't ensure a watertight material, it is suggested to look at other options of manufacturing the outer phantom.

Furthermore, the SolidWorks software was used to create the outer phantom. This program enables the creation and testing of a model to determine its ability to withstand specific forces, pressures or conduct a flow simulation. It is recommended to conduct the tests in the software beforehand, to fasten the design process. The results may suggest specific measures in the outer phantom that are appropriate or require modification.

Additionally, it is recommended to improve the elastic heart model to enhance its functionality. The current resin-based heart model is fragile and printed imprecise. Further research should focus on improving the model's precision to allow for contraction in both ventricles and to make it suitable for testing patient-specific cases.

Acknowledgements

I would like to express my sincere gratitude to my supervisor Wyger Bring, for taking the time to guide and support me throughout the course of this research project. His expertise and dedication have been a real help to me in navigating through various challenges during this project. I am also thankful for the opportunity to work on this project, which gave me valuable new insights and knowledge.

I am excited about the future and eager to learn more about the development of medical devices with the potential to make a meaningful impact in the medical field.

Sincerely,
Anna Geurtsen

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Appendix I

Table 3 Requirements final use of cardiac phantom

1. Requirements for the final use of the phantom	
1.1	The phantom should enable image guidance such as CMR during a TAVI procedure of RF ablation.
1.2	The phantom should enable clinicians to train for interventional CMR procedures.
1.3	The phantom should provide anatomical understanding during the training of minimally invasive interventions.

Table 4 Requirements outer phantom

2. Outer phantom requirements	
2.1	The phantom should prevent water leakage.
2.2	The phantom should be below 250mm in size.
2.3	The phantom should be adaptable to allow comparison between different designs.
2.4	The phantom should be able to withstand if pressure is applied.
2.5	The phantom should include access points to allow minimally invasive catheterization.
2.6	The phantom should be made of materials that are compatible with MRI.
2.7	The phantom should facilitate tools with dimensions up to 1.5 cm to enter.
2.8	The phantom should allow integration of the heart model.

Table 5 Requirements heart model

3. Heart model requirements	
3.1	The heart model should replicate the physiological conditions of blood flow through the heart.
3.2	The heart model should allow movement of the ventricles.
3.3	The heart model should be made of materials that are compatible with MRI.
3.4	The heart model should have the dimensions of a human heart.
3.5	The heart model should be anatomical accurate and include at least the inferior vena cava, superior vena cava, aorta, and pulmonary artery.
3.6	The heart model must allow for one-way water flow.

Appendix II

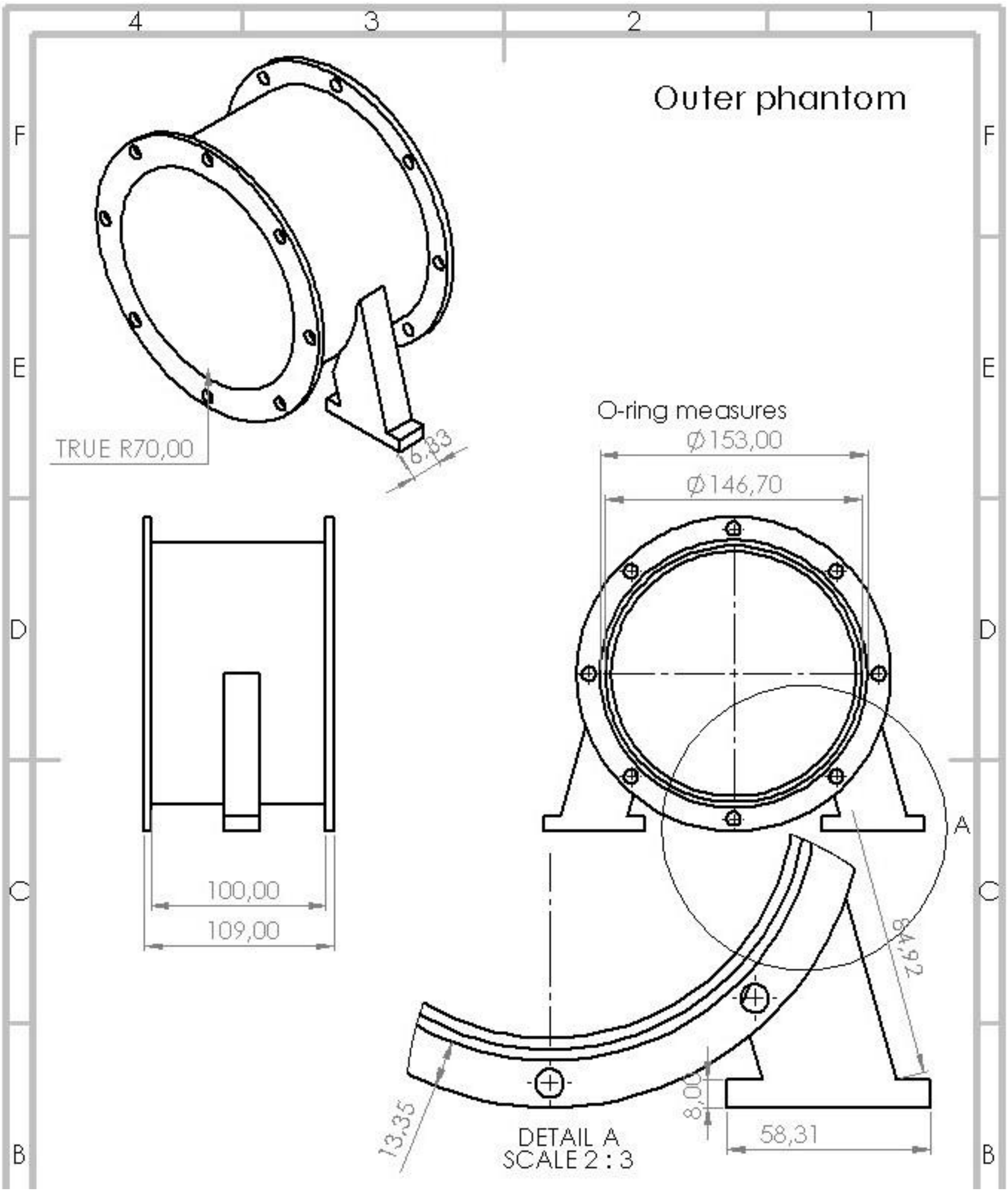

Figure 29 2D drawing of outer phantom, hollow cylindric tube, scale 1:3

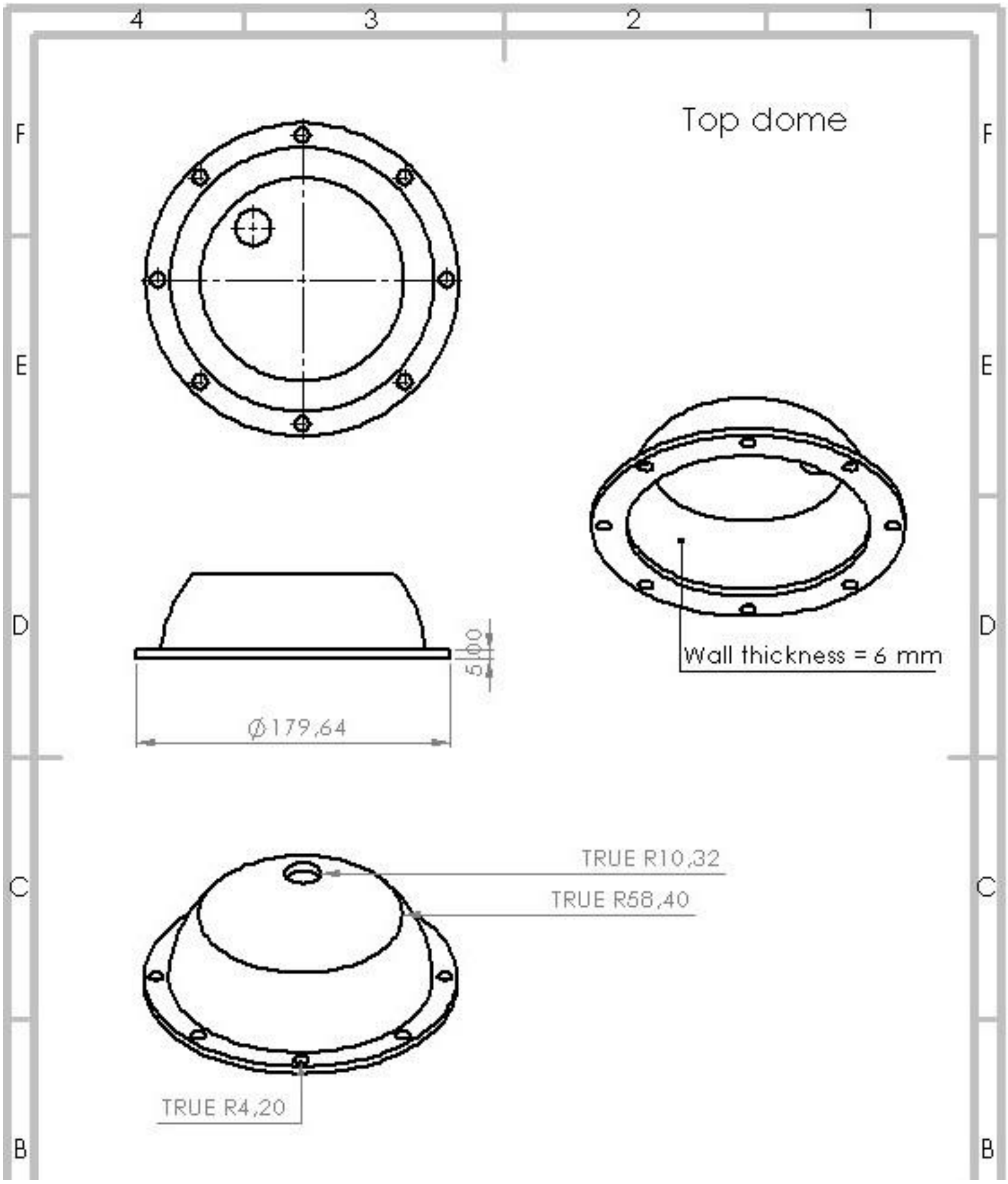

Figure 30 2D drawing of outer phantom top dome, scale 1:3

Table 6 measurements of elements used to assemble the phantom

Elements	Measures
O-ring	Thickness of 3.0 mm
Bolts and nuts	M8 bolt, 20mm long
Hose pillar	19mm

Appendix III

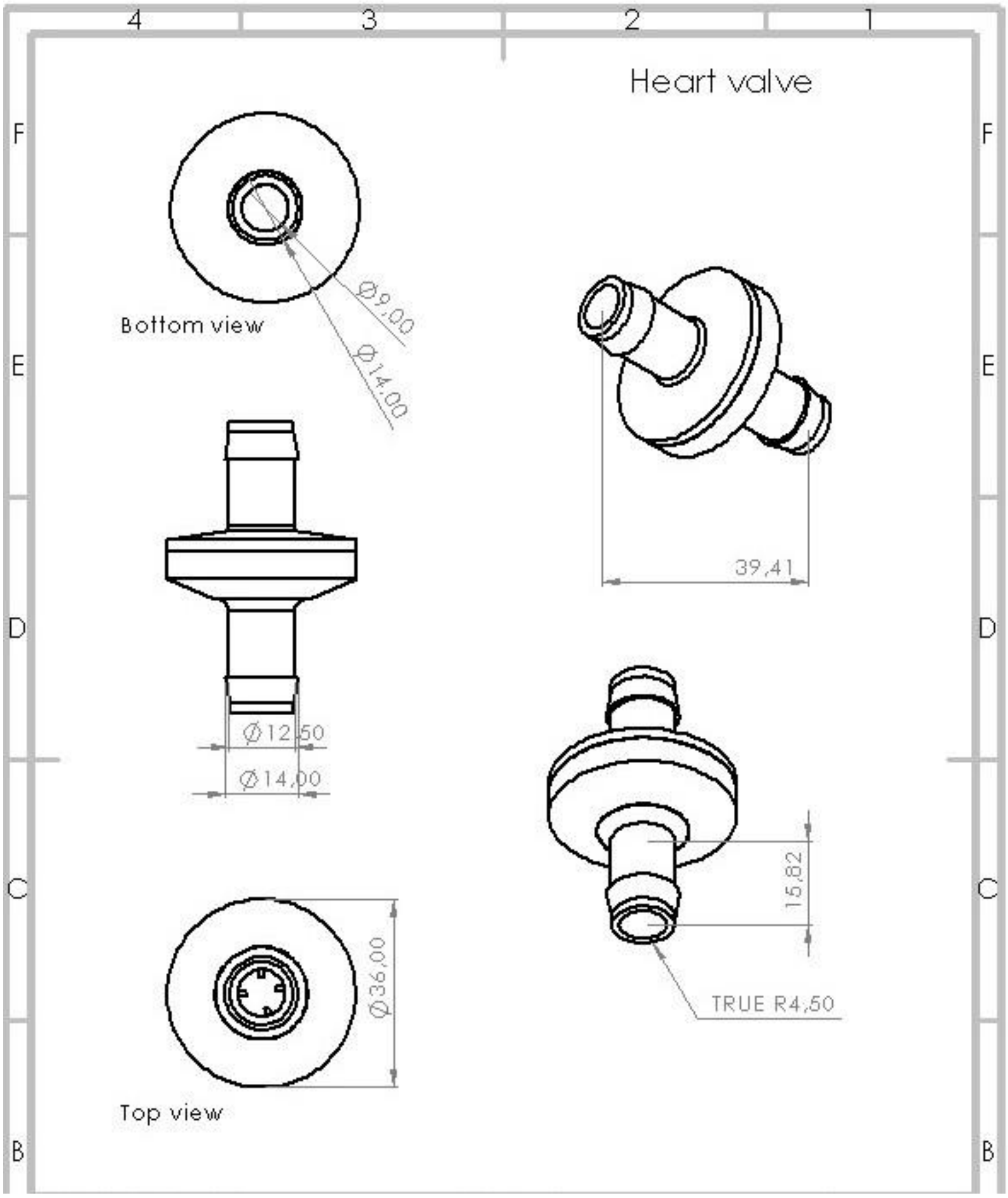

Figure 31 2D drawing of heart valves, scale 1:1