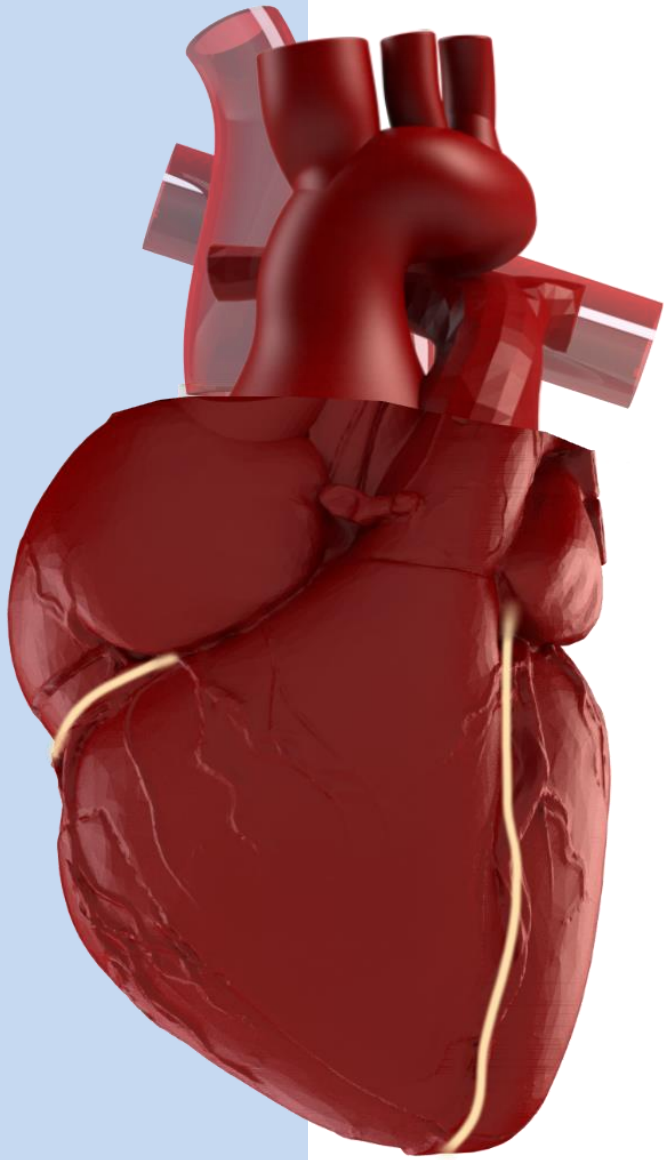
-Master thesis-

Development of a Fluid-driven Off-pump Coronary Artery Bypass Simulator

Enabling Hemodynamic Feedback



Helena N. Pels

Industrial Design Engineering

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UNIVERSITY OF TWENTE.

Cardiac Surgery Innovations Lab
Engineering Organ Support Technologies

BDDP Biomedical Device Design & Production

MST

THORAX CENTRUM TWENTE

Development of a fluid-driven off-pump coronary artery bypass simulator

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Autor	Helena N. Pels Industrial Design Engineering
Educational details	Faculty of Engineering Technology Department of Biomechanical Engineering Engineering Organ Support Technologies Biomedical Device Design and Production
Educational institution	University of Twente Drienerlolaan 5 7522 NB Enschede
Examination date	10/07/2024
Examination committee	Prof. Dr. Ir. Gabriëlle Tuijthof (Chair) Ir. Edsko Hekman (Supervisor) Dr. Frank Halfwerk (Supervisor) Ir. Ilanit Lutters (External member)

Declaration

I hereby declare that I have written this thesis independently. Only the sources and aids expressly named in the thesis have been used. I have marked as such any ideas taken over verbatim or in spirit.

Enschede, 26-06-2024 _____ _____

Place, Date Signature

Preface

During my studies in Industrial Design Engineering, I started to gain more interest in the medical field of design. This all started during my minor when I began researching heart surgery simulators with Edsko Hekman as supervisor. During that time I got to know the students working on the development of the OPCAB simulator. Now a few years later, I myself finished my master thesis in the Engineering Organ Support technologies research group, developing a new prototype of this OPCAB simulator.

I would like to thank my supervisors Edsko and Frank, for their support and guidance during the work of my thesis. Providing me with feedback and opportunities during my research. I would also like to thank Ana for showing me the ways in the lab and for always being interested in how my prototype was doing.

A nice experience of doing my thesis here at the university was that I got to know the other students working here in “Het Hok”. I always had nice conversations, tea breaks, and lunches with them.

I would like to thank my family and friends for listening to me rambling on about my work and showing them pictures of the parts I had been working on. But also for their help and support during my struggles, especially to Maren and Marjolijn. Special thanks to my dad who read my whole thesis for feedback, and helped me rewrite some beautiful grammar mistakes. Lastly I would like to thank Kai for being my best supporter through it all, for going climbing together to get out some stress and just in generally being there for me.

Abstract

This master thesis addresses the design of a training simulator to be used for Off-pump Coronary Artery Bypass (OPCAB) surgery training. OPCAB is a surgical treatment which is used to treat Coronary Artery Disease (CAD). During OPCAB surgery a bypass of the occluded coronary artery is made to restore the blood flow to the heart, while the heart of the patient is still beating. Mastering this surgery is difficult and takes repetition to be able to provide benefits compared to other treatments.

The University of Twente has been developing a training simulator to train OPCAB surgery, allowing surgeons to practice and refine their skills without risking patient safety. This thesis encompassed a further improvement of the current prototype. Analyses, among which a fidelity level assessment, were performed to determine opportunities for improvement of the prototype. The results of the analyses provided the primary objective of this thesis, to develop an improved prototype OPCAB simulator that functions as a proof of concept, featuring a life-like beating heart and an integrated hemodynamic feedback mechanism.

The result of this thesis includes the successful development of a final proof-of-concept design for a beating heart OPCAB simulator with an included hemodynamic feedback system. Also, the design was enlarged and a switch from TPU to silicone for manufacturing was accomplished. The new design has been evaluated and shows improvements in requirements and fidelity level classification. Ranking 2 out of 6 in the fidelity. Recommendations for future work have been identified to further improve the design and to implement customization features to the simulator.

By integrating future improvements into the OPCAB simulator, a contribution to the field of medical simulator training will be provided. This cutting-edge simulator addresses a gap in the current available OPCAB simulators, providing training opportunities for cardiothoracic surgeons.

Keywords

OPCAB simulator, Medical simulation, Hemodynamic feedback, Design innovation, Fidelity analysis

Content

1 General Thesis Introduction

Globally, Coronary Artery Disease (CAD) is the number one cause of death. CAD is responsible for 16% of the world's total deaths [1], causing 9.44 million deaths in 2021 [2]. The characteristic of CAD is narrowing or even occlusion of the coronary artery. This narrowing of the arteries is caused by the deposition of fatty plaque that builds up progressively. Eventually, the buildup of this plaque causes an obstruction of the coronary arteries, limiting the blood supply to the heart muscles. When a region of the heart muscle receives insufficient oxygen and nutrients, it degrades, a condition known as ischemia. This can lead to a myocardial infarction, commonly known as a heart attack.

Coronary bypass surgery can be performed to bypass an occluded coronary artery, thereby restoring the oxygen supply to the heart. Advancements have made it possible to perform bypass surgery without the need to stop the heart, allowing the anastomosis to be performed on a beating heart. The beating heart adds complexity to the surgery, making it necessary for surgeons to be well-trained. Currently, the training of Off-Pump Coronary Artery Bypass (OPCAB) surgery, is performed on real-life patients. An OPCAB simulator can provide the possibility to improve the skills necessary to be able to confidently perform this surgery, without the risks of training on an actual patient during a real-life procedure.

This thesis aims to improve the development of the OPCAB simulator from the Engineering Organ Support Technologies (EOST) research group of the University of Twente. The focus is on improving the beating heart and incorporating a hemodynamic feedback system. In the end, a proof-of-concept prototype has been developed and evaluated.

1.1 Design Methodology

The project as described in this thesis builds upon the work of previous students. The first model made by De Vries [3] will not frequently be mentioned during the thesis, as the prototype was no longer available and functional, and the work of two other students has since replaced it. De Jong [4] developed an origami-inspired beating heart and Buitenhuis [5] implemented a new movement mechanism for the beating heart.

Throughout this thesis, a design methodology was used that combined rapid prototype ideology with non-linear design thinking. Rapid prototyping methodology involves quickly creating iterative versions of a design to test, review and refine concepts efficiently. This allows for problems to be identified early on in the design process, creating fast and easy feedback and adjustments to improve the final design. Non-linear design thinking involves taking steps back to revisit and iterate on the design. Both approaches result in the easy implementation of new ideas and continuous

improvement. Figure 1-1 shows an overview of the workflow of the rapid prototyping methodology and non-linear design thinking, the methodologies used during this thesis.

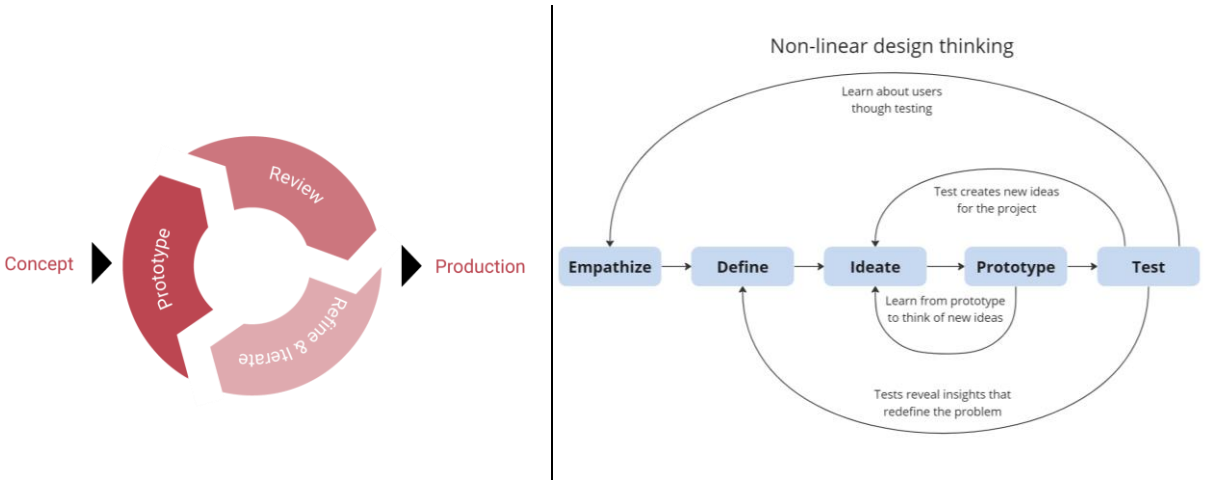

Figure 1-1: Overview of rapid prototype methodology and non-linear design thinking.

1.2 Thesis Outline

The structure of the thesis is as follows: Chapter 2 provides background information on related subjects of OPCAB surgery needed to better understand the thesis. Chapter 1 contains a recapitulation of the stakeholder analysis performed by Moejes [6] and a user needs check of the current OPCAB simulator. Then, Chapter 1 presents a fidelity-level analysis of the currently developed OPCAB simulators. An overall fidelity classification of the OPCAB simulators mentioned in the literature as well as in the previous prototypes is provided. Chapter 5 uses the information from the analyses of the previous chapter to establish the problem definition and define the specific design goal. Chapter 6 presents a function analysis of the OPCAB simulator to be developed and the created program of requirements. Chapter 1 contains a material analysis of the current simulated heart of the OPCAB simulator, looking into options to change and improve the current design. Having the background information of these previous chapters, chapter 8 covers the design phase of the OPCAB simulator. This chapter ends with a concept to take to the next phase of the development, which is the prototype phase. Chapter 1 contains information on this prototype phase, providing information on the development of the functional prototype of the OPCAB simulator. Section 9.1 presents the final design and Chapter 1 provides information on different verification tests of the final designed prototype. Finally, Chapter 1 contains discussions and limitations of the project, as well as recommendations for future work. The chapter ends with the conclusion of the work of the total thesis.

2 Background

To get a better understanding of the aspects correlated to the thesis, this chapter provides the necessary background information. Firstly, information on the anatomy, pumping system and coronary system will be given. After that there is some general information on hemodynamics and how this plays a role during OPCAB surgery. Then, details on coronary artery disease are provided. Finally, OPCAB surgery is described and a comparison between OPCAB vs. ONCAB surgery.

2.1 Heart Anatomy

The heart is the main organ when it comes to the blood supply to the body. The heart is located in the middle of the thoracic cavity and is attached to the great vessels [7]. The thoracic cavity is the hollow area situated between the ribcage and the diaphragm. The great vessels are the vessels that bring blood to and from the heart. The great vessels are the aorta, the vena cava, the pulmonary veins and the pulmonary trunk.

The inside of the heart is divided into 4 chambers consisting of 2 atria and 2 ventricles (Figure 2-1). The left atrium and the right atrium are thin-walled chambers that receive blood from the great vessels. The atria are located above the left and right ventricle. Ventricles are thick-walled chambers that receive blood from the atria. Heart valves are located between the atria and the ventricles; the right ventricle and the pulmonary trunk; and the left ventricle and the aorta [8]. The heart is a vital organ protected by the ribcage and the pericardium [8].

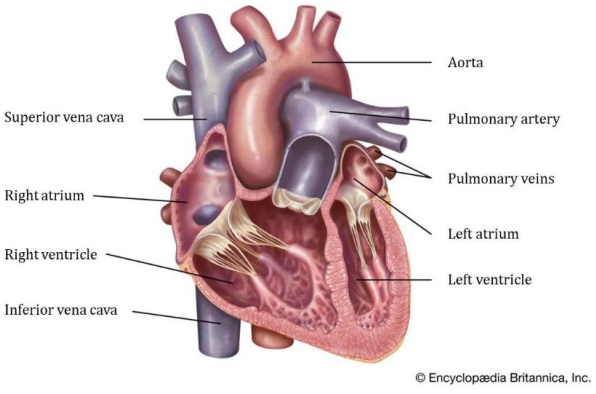

Figure 2-1: Overview of heart chambers and great vessels, taken from [9].

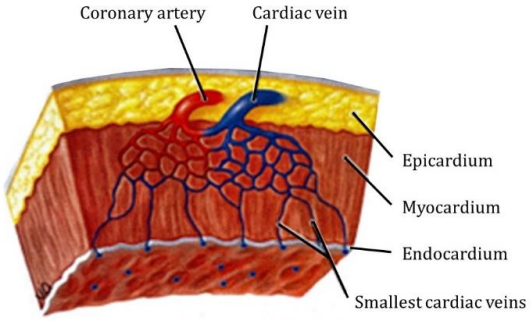

Figure 2-2: Layers of the heart wall, taken and adapted from [7].

The heart is made of three layers (Figure 2-2). The outer layer is the epicardium, consisting of fatty tissue, nerves and blood vessels which provide oxygen to the heart. Next, the myocardium layer, the thickest layer of the heart wall, consists of thick cardiac muscle aligned in a specific way to act as the pumping mechanism of the heart. Finally, the endocardium which lines the inner membrane and valves of the heart [7].

2.2 Pumping System

The heart acts as a self-adjusting suction and pressure pump of blood. The contraction of the muscular heart wall and the heart valves control the pumping of the blood. From the body through the vena cava, the right atrium receives the oxygen-depleted blood. It is then pumped to the right ventricle from where it is ejected to the lungs through the pulmonary trunk to receive oxygen from the lungs. The oxygen-rich blood travels through the pulmonary veins to the left atrium, from where it will be pumped into the left ventricle. Contraction of the left ventricle pumps the oxygen-rich blood through the aorta for distribution to the body [7, 8].

The pumping of blood by contracting and relaxing the heart muscle is called the cardiac cycle. During the cardiac cycle, there are two phases called the diastole and the systole. During the diastole the chamber relaxes and elongates, allowing them to fill with blood [7, 8]. During systole, the chambers shorten and contract, pumping the blood out of the chambers. Both the atria and ventricles have a diastole and a systole. However, they alternate, when the atria are in the diastolic phase the ventricles are in the systolic phase and the other way around.

2.3 Coronary System

The coronary system of the heart consists of a network of vessels going across the surface of the heart, supplying the myocardium with oxygenated blood. The coronary system has two main coronary arteries with their origin at the beginning of the aorta, which branches out as the Right Coronary Artery (RCA) and the Left Coronary Artery (LCA). Both of these again branch out into two essential coronary arteries. The branches of the RCA are the Right Marginal Artery (RMA) and the Posterior Interventricular Artery (PIA). The LCA branches into the Left Anterior Descending artery (LAD) and the Left Circumflex artery (LCx). From these six mentioned coronary arteries there are many more branches that in total form the coronary system. However, these six are the most important ones [7]. An overview can be seen in Figure 2-3.

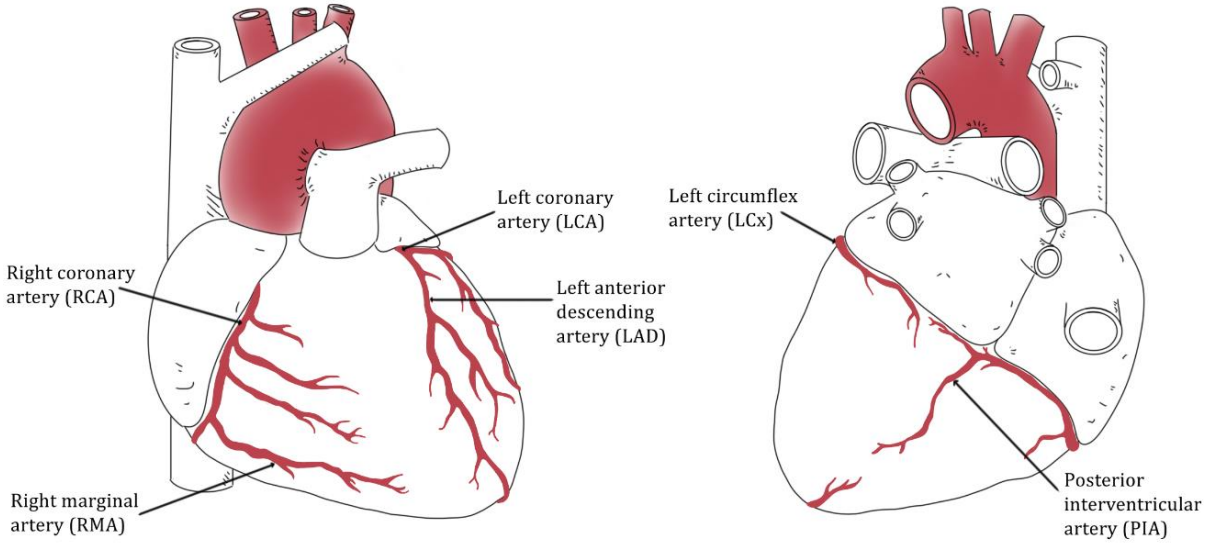

Figure 2-3: Six most important coronary arteries. Illustrated with inspiration from [10].

2.4 Hemodynamics

Hemodynamics relates to the principles of blood flow and how this blood flow behaves through the heart and circulatory system, providing insight into the relation between the heart's pumping function and the circulation of blood flow throughout the body. The basic terms that are correlated to hemodynamics are volume, flow, pressure, resistance, and velocity [11]. These basic terms can be found in several important parameters to describe hemodynamics or the hemodynamic state. An important parameter is cardiac output, which is dependent on stroke volume and heart rate.

Heart Rate (HR): Number of times the heart beats per minute.

Stroke Volume (SV): The amount of blood that is ejected from either ventricle during one heartbeat.

Cardiac Output (CO): The amount of blood flow delivered by the heart per minute. CO is the product of heart rate and stroke volume, $CO = SV * HR$ [12].

Another important parameter to describe hemodynamics is arterial Blood Pressure (BP). Blood pressure is measured in millimetres of mercury (mmHg) and is taken from two different pressure measurements. These are the systolic pressure, the maximum pressure at the moment of the heartbeat, and the diastolic pressure, the minimum pressure during the rest period of the heartbeat. BP is written as the systolic pressure over the diastolic pressure e.g. $90/60$ mmHg [13]. Mean Arterial Pressure (MAP) is the parameter that is used to provide information on the hemodynamic state. MAP can be estimated in two ways. For the body to perfuse its vital organs, a MAP of a minimum of 60 mmHg is required. When the MAP is below 60 mmHg, known as hypotension, blood cannot reach all tissue. When a MAP of below 60 mmHg occurs during a prolonged time it can cause severe damage to the organs [14].

Mean Arterial Pressure (MAP): The average arterial pressure during one cardiac cycle, calculated using the Diastolic Pressure (DP) and the Systolic Pressure (SP), $MAP = \frac{2(DP)+SP}{3}$ [14].

Mean Arterial Pressure (MAP): The product of cardiac output and total peripheral vascular resistance (TPR). $MAP = CO * TPR$ [15]

Total Peripheral vascular Resistance (TPR): The amount of force required to create and maintain blood flow throughout the circulatory system.

During OPCAB surgery, the hemodynamic status of the patient is constantly monitored. This is done using an arterial line, typically inserted into an easily accessible artery such as the radial or femoral artery. This setup provides continuous information on the patient's blood pressure and MAP of the patient throughout the surgery and during manipulation of the heart. During OPCAB surgery the heart is manipulated to provide access to all anastomosis sites. These manipulations include vertical and horizontal tilting of the heart, grabbing the heart, and placing the stabilizer to keep the heart in the correct place. These manipulations can cause the supply vessels to be compressed limiting the blood flow into the atria. The manipulations can also influence the filling of the ventricles. This can be caused by compression on the ventricles limiting their ability to expand, and it can also be caused by the lifting of the ventricles causing them to be pointed upwards too much, creating a mechanical compression of the vena cava and pulmonary veins.

The effects of heart manipulation all cause limitations of the blood flow of the heart and affect the cardiac output due to the Frank-Starling law. This states that the more the myocardial fibres are stretched by filling the chambers with blood, the more energy is stored in the fibres, causing a higher force of contraction of the ventricles creating the stroke volume [16]. When the inflow of blood into the heart is limited, the stretching of the fibres becomes less, reducing the contraction force and resulting in a lower cardiac output. A solution to increase the cardiac output is to put the patient in a Trendelenburg position, tilting the table to where the patient's legs are put above their heart, creating a 20° incline. Improving the blood flow to the heart and brain of the patient. Increasing the MAP through an increased venous return and filling of the atria subsequently leads to a larger cardiac output.

2.5 Coronary Artery Disease

Coronary Artery Disease (CAD) is a condition where the blood flow in the coronary arteries is reduced, resulting in a limited supply of oxygen and nutrients running through the coronary arteries and to the heart muscles. This causes degradation and ischemia of the heart muscle, which can lead to a myocardial infarction better known as a heart attack. The reduced blood flow is a result of the narrowing and occlusion of the coronary arteries, which is caused by the progressive formation of fatty plaque onto the inner layer of the coronary arteries. The term used to describe this phenomenon is atherosclerosis [7]. The formed plaque in the vessels can burst open, possibly causing the formation of a blood clot, nearly obstructing the entire vessel. When the occlusion has totally obstructed the coronary artery, there is a high probability that parts of the heart muscle start dying when no immediate interventions are taken [17]. Worldwide, CAD is the number one cause of death, responsible for 9.44 million deaths (16%) in 2021 [1, 2].

The three most common sites of coronary artery occlusion in order of occurrence are the LAD, the RCA, and the LCx, accounting for at least 85% of all occlusions [7]. Figure 2-4 visualizes the 6 most common places where the occlusions happen. Leaving the occlusion untreated can cause unpleasant and severe complications, from chest pains to heart failure [18].

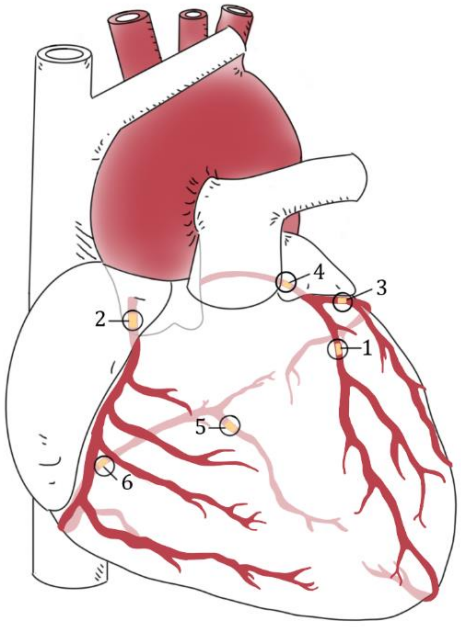

Figure 2-4: Most common coronary occlusion sights. Illustrated with inspiration from [7].

2.5.1 Treatments of CAD

The course of treatment is dependent on the severity of the CAD of the patient. The three most used treatments for CAD are conservative treatment, Percutaneous Coronary Intervention (PCI), and Coronary Artery Bypass Graft surgery (CABG). When conservative treatment and PCI do not apply to the patient, CABG is the surgical intervention that will be performed. CABG is one of the most commonly performed cardiac surgeries [19].

During CABG, a detour of the occluded coronary artery is created. A harvested segment of a vein or artery, e.g. the left internal thoracic artery of the patient, or a combination of both are used as grafts. The graft acts as a newly added blood supply and is connected distal of the occlusion. It restores the oxygenation of the heart muscle by bypassing the obstruction [7, 19]. During the procedure, a CardioPulmonary Bypass (CPB) can take over the functions of the heart and lungs. When the CPB is used during the procedure it is known as an ON-pump Coronary Artery Bypass Graft (ONCABG) which is the dominant procedure performed globally. Another way to perform this procedure is without a CPB. Here, the heart continues to beat and the blood flow through the coronary arteries remains normal. This is known as the Off-Pump Coronary Artery Bypass graft (OPCABG) procedure.

2.5.2 OPCAB Surgery

The steps of OPCAB surgery are illustrated by de Vries [3] and updated and adapted by Buitenhuis [5], see Figure 2-5. In total, the surgery, including pre-op and finishing takes around five hours. The OPCAB procedure itself typically takes two to four hours, depending on the number of bypasses and any complications that may arise during surgery. The graft material that is utilized is most often the Left Internal Mammary Artery (LIMA) in combination with a radial artery (harvested from the arm) or saphenous vein (harvested from the leg).

During the preoperative phase, the operating room is prepared, the patient is anaesthetised, and the skin is sterilized. Once the patient is under anaesthesia, a full median sternotomy is performed by making an incision over the sternum. The skin is separated from the sternum and bleeding points are cauterized. During cauterisation, a heated instrument burns the blood vessels to reduce bleeding. Subsequently, the sternum is divided by a reciprocal saw and the mammary spreader is placed in this opening. The sternum is expanded using the spreader, creating a clear view of the pericardium. The LIMA is isolated, while simultaneously the other graft material is harvested.

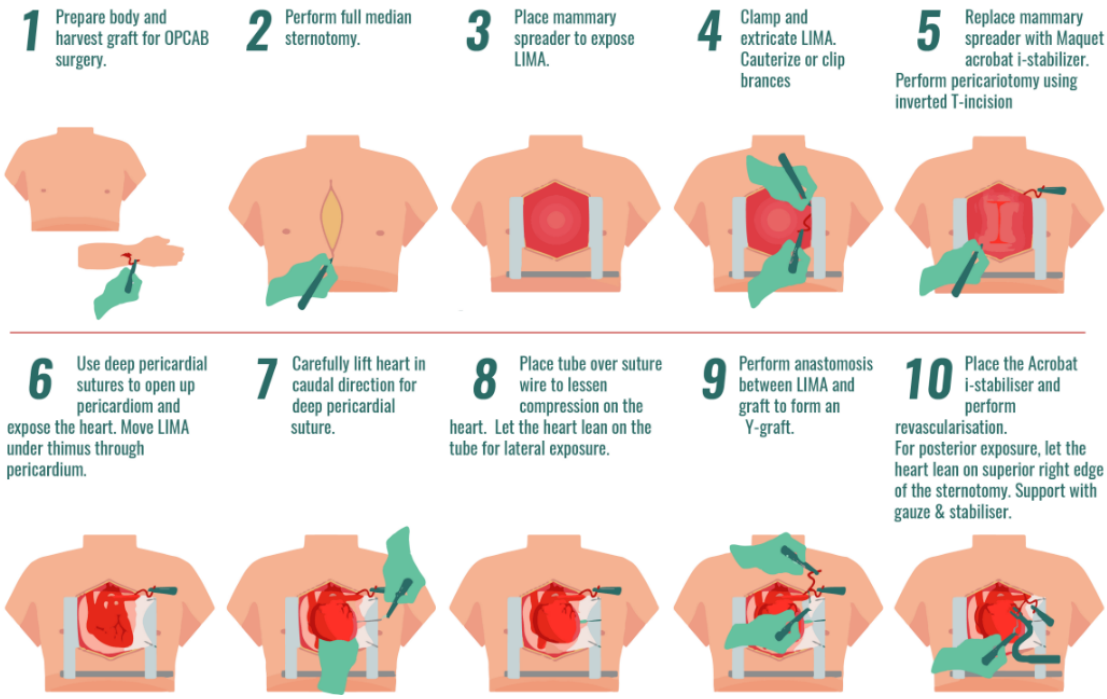

Figure 2-5: The 10 steps of the OPCAB procedure using the Left Internal Mammary Artery (LIMA) and ulnar artery to form a Y-graft and perform the bypass, updated and adapted by Buitenhuis from de Vries [5].

Preparation of the grafted material consists of cauterizing and/or clipping the harvested vessels. The spreader on the sternum is replaced with the Acrobat I-stabilizer. After which a T-incision is performed on the pericardium, exposing the anterior wall of the heart. With the opened pericardium, the LIMA is moved through the pericardium.

The steps to expose the targeted area vary depending on the location of the bypass. For placing a graft onto the LAD, which is located on the anterior side of the heart, no manipulation of the heart is required. However, to gain access to the lateral part of the heart, manipulation of the heart is required. This can be done by slightly elevating the apex of the heart and putting gauze underneath it. When more exposure of the lateral side is needed, a suture is placed in the pericardium, known as a pericardial stitch. During a pericardial stitch, the surgeon holds the heart and elevates it slightly. A suture is placed at the bottom of the pericardium and covered by a soft rubber tube to protect the heart. This suture goes along the heart and is attached to the retractor. The pericardial stitch is a way to stabilize the heart while providing a way to gain exposure to the heart by putting different levels of tension on the suture. Gaining access to the posterior wall of the heart requires a different method of heart manipulation. In this approach, the apex is elevated towards the head of the patient. Subsequently, the heart is oriented upwards and positioned to rest on the top right corner of the pericardium. The heart is fixated in this position with the stabilizer.

Throughout each method of heart exposure, continuous monitoring of the patient's hemodynamic status is essential. Once the parameters are stable, the stabilizer is fixated onto the targeted area of the anastomosis. The stabilizer uses eight small vacuum suction cups to fixated itself onto the heart and diminishes the local movement. After securing the stabilizer and ensuring sufficient cardiac function, the anastomosis between the graft material and the targeted vessel is performed. Following, a quality check to detect any leakages, ensure proper flow, and pulsatility index is conducted. Upon confirmation of successful revascularization, the CABG procedure is concluded.

2.5.3 OPCAB vs ONCAB

It has been reported that the use of CPB during CABG may lead to adverse effects on the patient [20]. Hence, there has been increasing interest in performing CABG without a CPB, known as the aforementioned OPCAB procedure. OPCAB was promoted, due to its potential to avoid the adverse effects associated with ONCAB surgery. Unfortunately, debate persists regarding whether OPCAB or ONCAB surgery is better [20-22]. The literature describes the advantages of both OPCAB and ONCAB procedures. Table 2-1 presents an overview of the identified advantages found in the literature. The advantages of OPCAB surgery must be considered with the understanding that the results reflect the procedure being performed by an experienced surgeon, as specifically highlighted in the research of Naito et al. [23]

Table 2-1: Advantages of OPCAB and ONCAB.

Advantages OPCAB surgery	Ref	Advantages ONCAB surgery	Ref
Decreased morbidity and mortality rates.	[23-25]	Better revascularization [1]	[24, 25]
Reduction in the occurrence of post-surgical cerebral micro-emboli.	[24]	No risk of having to switch to on-pump surgery.	[24]
A better solution for high-risk and older patients.	[22, 24, 25]	More surgeons are familiar with the procedure.	[25]
Shorter length of hospital stay.	[21, 23]	A better option for emergency situations.	[24]
Reduced coagulopathy.	[21]		
Fewer transfusions needed.	[21]		
Less myocardial injury and ischemic injury.	[21, 26]		
Reduction in early post-operative strokes.	[27, 28]		

[1] This has however been debunked by Raja et al.[20] and Puskas et al. [21]

Reported outcomes indicate that OPCAB and ONCAB are almost comparable in renal failure [29] and comparable in delayed strokes [28]. Furthermore, Forouzannia et al. [30] concluded that OPCAB and ONCAB showed equivalent results across several additional factors. Gaudino et al. performed an extensive review comparing ONCAB and OPCAB and again concluded that the benefits of OPCAB remain debated [22]. During OPCAB surgery there is an increased difficulty to perform an anastomosis on the posterior side of the heart. The location of the anastomosis is of importance in the higher occurrence of incomplete revascularization [20]. Moreover, the complexity of accessing the anastomosis site may influence the necessity to switch to on-pump surgery. This switch may be caused by the need to manipulate the heart for optimal exposure, which can potentially lead to an unstable hemodynamic status. When the unstable condition of the patient does not improve, interventions, including switching to on-pump, are taken to stabilize the patient. Surgeons with low or moderate experience in OPCAB surgery are more likely to switch to on-pump [31]. Incomplete revascularization and conversion to on-pump both increase the risk of the surgery.

2.6 Conclusion Background

The risk of the patients during surgery could be reduced by providing a simulator to practise the anastomosis on the posterior wall of the heart, as well as practising heart manipulations with hemodynamical feedback. According to Bougioukakis et al. [32], surgeons can achieve comparable results between OPCAB and ONCAB after performing 80 OPCAB surgeries. However, superior post-operative results were only observed after 290 OPCAB surgeries. Facilitating access to a simulator creates a controlled environment for practising the OPCAB procedure. This is essential to surgeons given that the benefits of OPCAB surgery are dependent on the surgeon's expertise.

3 Problem Analysis

This chapter provides a problem analysis of the OPCAB simulator, starting with a recapitulation of the stakeholder analysis of Moejes [6] which provides background information on the desired characteristics of an OPCAB simulator according to cardiothoracic surgeons. The goal of that analysis was to gain insight into the difficulties of the OPCAB procedure as well as expert opinion from the cardiothoracic surgeons on what features they find important in an OPCAB simulator.

From the results of Moejes [6] it became clear that the two main challenges of OPCAB surgery were 1) manipulation of the heart while keeping the hemodynamic status stable and 2) performing anastomosis on complicated small space regions. The result also provided insight into what was important according to the interviewees to implement in a simulator. The top two answers on desired features were 1) having a beating heart, and 2) hemodynamic functions [6], See Figure 3-1.

Desired characteristics	Percentage of interviewees with that answer
A beating heart	64%
Hemodynamic status	64%
Realistic simulator	36%
Comparable positioning of the heart to reality	36%
Usage of scenarios	36%
Fluid in the coronaries	36%
Shunt usage	27%
Possibility to perform anastomoses	27 %
Different sizes coronaries	27%
Remaining answers	54%

Figure 3-1: Results of the desired OPCAB simulator characteristics, taken from Moejes [6].

This demonstrates that just having a hemodynamic function as a feature is not sufficient, the hemodynamic functions need to respond to the actions of the user.

User needs check

Over time, (See the work of De Vries 2018 [3] and Buitenhuis 2022 [5]) some functions of the OPCAB simulator have stopped being developed, were removed or have even been lost. At the start of the work described in this thesis, a user needs check of the existing simulator prototype was conducted. The objective was to determine an up-to-date status of the prototype, starring from the established user needs list by Moejes [6] and De Jong [4].

The results of the user needs check can be found in Table 3-1. This table shows that only 25% of the user needs have ben correctly implemented in the latest prototype, supporting that improvements on the OPCAB simulator are needed. Of the twelve user needs listed in the table, the first two user needs are related to the manipulation of the heart and a feedback system (a complete list of user needs can be found in Appendix A: User Needs Analysis). Neither of the first two user needs, in Table 16A-1, UN01 'Enables realistic manipulation', and UN02 'Contains a feedback system on heart manipulation' has been implemented in the simulator prototype, since the work of the previous students was focussed on the development of the beating heart.

Table 3-1: Results requirements check of the previous prototype.

Requirement	Percentage
It is currently correctly implemented in the simulator.	25%
It is implemented in the simulator but should be improved.	33%
It was at some point implemented in the simulator, but it has since been lost.	17%
It is not implemented in the current simulator.	25%

The stakeholder analysis by Moejes [6] showed that heart manipulation and hemodynamic feedback were most important. However, the user needs check showed that these characteristics have not yet been implemented in the OPCAB simulator. This observation provides substantiation for the formulation of the main design goal of the thesis.

4 Fidelity Analysis Current OPCAB Simulators

Chapter 1 highlighted the need for further development of the OPCAB developed by the University of Twente. It is essential to verify whether other researchers and companies have already addressed this need. Therefore, an analysis of the current advancements in OPCAB simulators was performed to see whether the need for further development and improvements of the OPCAB simulator is substantiated.

This analysis is performed to determine the fidelity levels of the current OPCAB simulators. Fidelity in simulation refers to the level of realism that is replicated by a model [33]. This analysis answers the sub-research question: *What are the current advancements in OPCAB simulators, and how can implementing a fidelity classification aid in the understanding of developing an OPCAB simulator prototype?* This analysis examines the components of OPCAB simulators, among other aspects. This evaluation of the fidelity analysis can provide information on what elements (e.g. hemodynamic feedback) are missing to help establish the design goal of the thesis.

4.1 Introduction to Fidelity Analysis

Simulators create the opportunity for surgeons to practice surgical procedures in a safe environment. Development of an OPCAB simulator has not been restricted to the University of Twente other developments and commercially available OPCAB simulators have been mentioned in literature over the past decades. To gain insight into what is lacking in the current simulators, a fidelity analysis comparing the current simulators has been performed. The steps of this analysis are provided in this chapter. The result of the analysis is an overview of all OPCAB simulators currently mentioned in the literature. This overview also provides a classification of the fidelity level of the simulators. Fidelity is the level of realism that is replicated in a simulation. Further explanation on fidelity will be provided in Section 4.3. The fidelity analysis is based on a paper by Duinmeijer et al. [34], where an objective method to classify ECMO (Extracorporeal Membrane Oxygenation) simulators as low-, mid- or high-fidelity level simulators was created. An adapted version of this method was used for the classification of OPCAB simulators.

4.2 Desk Study

De Jong [4] and Moejes [6] have previously worked on the development of earlier versions of the OPCAB simulator described in this thesis. During their research, state-of-the-art research on existing beating heart simulators was performed. The overview of Moejes specifies criteria for simulators that were designed for OPCAB. Her list of OPCAB simulators that fulfil these criteria and were in existence in 2020 was used as a starting point. In addition, a literature review was performed to see if there were new OPCAB simulators that were developed in the last 4 years. For the literature, the in- and exclusion criteria of the literature on OPCAB simulators were as follows:

- Research material is derived from Scopus;
- Research material is taken from its original source;
- The literature contains information on OPCAB simulation models;
- The literature has not been retracted;
- The language of the literature material should be English;
- Simulators should have a physical aspect to them;
- Search string used: TITLE-ABS-KEY ((OPCAB AND (simulat* OR device OR training AND model)) OR (Off AND pump AND CABG AND (simulat* OR device OR training AND model)) OR (off AND pump AND beating AND heart AND (simulat* OR device OR training AND model))) AND PUBYEAR > 2018 AND PUBYEAR < 2025

The scoping review resulted in 20 results of which 4 were relevant. One of the relevant literature papers was an article published in 2022 by Whittaker et al. [35] on recommendations for simulators in cardiac surgical training. In this paper, an overview of OPCAB simulators described in the current literature was provided. A similar article was published in 2021 by EL-Andari et al. [36] on how simulators played a role in revascularization techniques. OPCAB simulators are listed in this review, one of which is a training model published in 2016. Neither the state-of-the-art of De Jong and Moejes [4, 6] nor the review paper of Whittaker [35] mentions this OPCAB training model. The OPCAB simulators from the paper of Whittaker et al. [35], the paper of El-Andari [36], and the research from De Jong and Moejes [4, 6] resulted in a total of 11 OPCAB simulators. Of which 8 OPCAB simulators from De Jong and Moejes, 2 OPCAB simulators from the review paper of Whittaker et al., and 1 simulator from the review paper of El-Andari. The 2 OPCAB simulator prototypes developed by the University of Twente were added to the list of OPCAB simulators, as it is useful to determine their fidelity classification alongside the other OPCAB simulators. In total, this created a list of 13 simulators, of which are 3 currently commercially available, 2 that are no longer available, 6 described in the literature, and 2 prototypes developed by the University of Twente.

4.3 Fidelity Classification

To determine the fidelity classification of the OPCAB simulators a similar method of Duinmeijer et al. [34] was used. Duinmeijer et al. [34] use existing definitions of different types of fidelity to determine the overall fidelity level of ECMO (Extracorporeal Membrane Oxygenation) simulators. The different fidelity definitions created three sub-categories on which the simulators were reviewed to determine the overall fidelity. These sub-categories were: definition-based fidelity, component fidelity, and customization fidelity. The definitions of these sub-categories were derived from the Healthcare Simulator Dictionary [37] and are being explained in further detail in the next section. To review the OPCAB simulators three levels of fidelity were established low-, mid-, and high-fidelity. The overall fidelity was the result of the median of the definition-based, component, and customization fidelity. For each simulator, it was also specified whether the materials of the simulator used porcine (P), synthetic (S) or human cadaver (H) materials or a combination of these materials. One of the simulators used live miniature pigs and is specified as live porcine (LP).

4.3.1 Definition-based Fidelity

According to the Healthcare Simulation Dictionary, Definition-Based Fidelity (DBF) is to what extent a simulation can replicate the real-life version it recreates [37]. To further explain DBF, it can be divided into 4 different categories:

1. Conceptual fidelity, which determines whether the simulator is based on computational (C) or physical components (P);
2. Functional fidelity, where the level of response of the simulator related to the action of the participant is determined;
3. Physical fidelity, which is related to the level of realism of the simulated actions. Taking the look, sound, and feel of the simulator into consideration;
4. Psychological fidelity, which again is related to the level of realism of the simulated actions. However, this definition is focused on perceived realism and at what level the simulated actions evoke psychological factors such as emotions and beliefs;

Using these categories to determine the DBF level of the simulators provides a guideline on how to assess the information that was available on the OPCAB simulators. The functional, physical, and psychological fidelity level could be determined as low, mid, or high, which resulted in a minus (-) for low, a plus-minus (+/-) for mid, and a plus (+) for high-rated simulators. The calculated median of these results determined the DBF classification. However, the level of functional, physical, and psychological fidelity can only be an educated guess because these definitions are based on perceptions and are therefore subjective.

4.3.2 Component Fidelity

Component fidelity uses the main components specific to OPCAB surgery as a basis to determine the level of fidelity. The main OPCAB components were based on knowledge gathered during this thesis and on discussions and feedback by Frank Halfwerk and Jutta Arens. This resulted in a total of 24 components. The components are divided into 4 categories: anatomical components, operational components, scenario components, and environment components. The full list of components can be found in the component fidelity result tables in Appendix B. The 24 components were used as a guideline to determine the level of component fidelity. Low-fidelity was assigned to the OPCAB simulators that had ≤ 8 of the components, mid-fidelity was assigned to the OPCAB simulators that had between 9 and 16 components, and high-fidelity was assigned to the OPCAB simulators that had ≥ 17 components. The available information on the simulators was used to determine the number of components for each OPCAB simulator.

4.3.3 Customization Fidelity

Customization fidelity is used to determine the level of customization to change the parameters of the OPCAB simulator to provide the ability to simulate different patients and scenarios. Six parameters were determined to change the simulated OPCAB patient and/or scenario. These parameters are taken and adapted from the research of Duinmeijer et al. [34]. The resulting parameters are sex, age, size, disease/anatomy, BMI, and skin colour. Low-fidelity was assigned to the OPCAB simulators that had 1 of the parameters, mid-fidelity when the number of parameters was between 2 and 4, and high-fidelity when it had 5 or 6 parameters. Again the available information of the simulators was used to determine the number of parameters for each OPCAB simulator.

4.3.4 Overall Fidelity

For the overall fidelity, the median of the definition, component, and customization fidelity was calculated. Based on this outcome a final overall low-, mid-, or high-fidelity level was allocated to every individual OPCAB simulator. Based on the outcomes of the three fidelity categories, the simulators are ranked from low to high fidelity.

To provide visual aid of what a low-, mid-, or high-fidelity OPCAB simulator can look like Figure 4-1 shows three OPCAB simulators with a low, mid-, and high overall fidelity level. A graphical overview of all 13 simulators can be found in Appendix B: Fidelity Analysis.

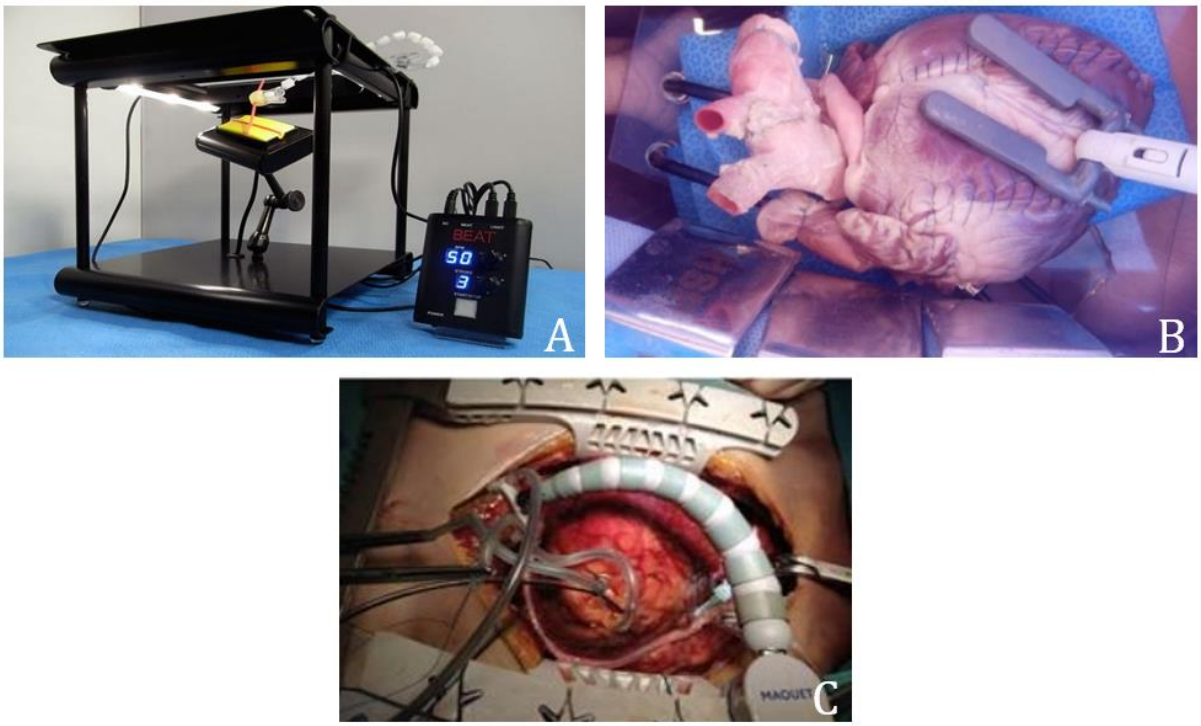

Figure 4-1: Overview of OPCAB simulators with different fidelity levels. (A) Low-fidelity OPCAB simulator developed by BEAT by EBM [38]; (B) Mid-fidelity level OPCAB simulator developed by Maluf et al. [39]; (C) High-fidelity OPCAB simulator developed by Bouma et al. [40].

4.4 Results Fidelity Analysis

4.4.1 Definition-based Fidelity

The result of the classification of the definition-based fidelity of OPCAB simulators is visualized in Table 4-1: Definition-based fidelity. Reviewing this result showed that 11 (85%) OPCAB simulators consisted of a combination of computational and physical parts and 2 (15%) OPCAB simulators only had a physical part. The results of the fidelity level of the OPCAB simulated showed that 3 (23%) simulators were low-fidelity, 7 (54%) simulators were mid-fidelity, and 3 (23%) had a high-fidelity level. From the high-fidelity level simulators, two use a porcine heart for the simulator and the other uses a human cadaver as a base for the simulator. This shows that there are currently no high-definition-based fidelity OPCAB simulators made from synthetic material.

Table 4-1: Definition-based fidelity of OPCAB simulators.

	Source	Device	Material	Conceptual fidelity	Functional fidelity	Physical fidelity	Psychological fidelity	Definition-based fidelity
A	EBM (2024) [38]	BEAT	S	C+P	-	-	-	Low
	The Chamberlain Group (2024) [41]	High-fidelity CT surgical trainer	S	C+P	-/+	+	-/+	Mid
	KindHeart (2024) [42, 43]	Cardiac surgery simulator	P	C+P	+	-/+	+	High
B	Izzat (1998) [44]		S+P	C+P	-	-	-	Low
	Reuthebuch (2002) [45]	Zurich heart-trainer	S	C+P	-/+	+	-/+	Mid
C	Donias (2003) [46]		P	P	-	-/+	-	Low
	Maluf (2015) [39]		S+P	C+P	-/+	-/+	-/+	Mid
	Wu (2021) [47]		S+P+H	C+P	-/+	-/+	-/+	Mid
	Liu (2016) [48]		LP	P	-/+	-/+	+	Mid
	Ribeiro (2017) [49]		S+P	C+P	-/+	+	+	High
	Bouma (2015) [40]		H	C+P	+	+	+	High
D	University of Twente (2020)[4, 6]	De Jong & Moejes	S	C+P	-/+	-/+	-/+	Mid
	University of Twente (2022)[5]	Buitenhuis	S	C+P	-/+	-	-/+	Mid

A = Commercially available, B = No longer available, C = Described in literature, D = University of Twente; S = Synthetic, P = Porcine, H = Human cadavers, LP = Living porcine; C = Computational, P = Physical; - = Low, -/+ = Mid, + = High.

4.4.2 Component Fidelity

The result of the four determined categories related to the component fidelity as well as the overall classification of the component fidelity can be found in Table 4-2. The tables of the Anatomical Components (AC), Operational Components (OC), Scenario Components (SC), and Environment Components (EC) can be found in B: Fidelity Analysis. Reviewing OPCAB simulators based on their components resulted in 3 (23%) low-fidelity, 8 (62%) mid-fidelity, and 2 (15%) high-fidelity simulators. Of the 2 OPCAB simulators that had high-level fidelity, one was based on a human cadaver, and the other one was a training method on live miniature pigs. All 13 (100%) of the OPCAB simulators had a beating function, 11 of the OPCAB simulators (85%) were shaped like a heart, and 7 (54%) showed a visual representation of a patient. 9 (69%) of the OPCAB simulators had hemodynamic functions (9 could change the heartbeat, and 3 could replicate arrhythmias). However, only one (8%) of the OPCAB simulators provided hemodynamical feedback, which was the simulator based on live animals. This demonstrates that none of the fabricated OPCAB simulators had hemodynamical feedback as a function. When taking an overall look at the materials used for each simulator, 5 (38%) are made from synthetic material; 2 (15%) are made from porcine material; 1 (8%) uses live miniature pigs; 3 (23%) are made from a combination of synthetic and porcine materials; 1 (8%) simulator uses a combination of synthetic, porcine, and human materials; and 1 (8%) uses human cadavers.

Table 4-2: Component fidelity of OPCAB simulators.

	Source	Device	Material	AC (11)	OC (6)	SC (4)	EC (3)	Total (24)	Component fidelity
A	EBM (2024) [38]	BEAT	S	2	1	1	0	4	Low
	The Chamberlain Group (2024) [41]	High-Fidelity CT Surgical Trainer	S	8	4	2	1	15	Mid
	KindHeart (2024) [42, 43]	Cardiac surgery simulator	P	8	3	1	1	13	Mid
B	Izzat (1998) [44]		S+P	2	1	2	0	5	Low
	Reuthebuch (2002) [45]	Zurich heart-trainer	S	7	3	3	2	15	Mid
C	Wu (2021) [47]		S+P+H	7	2	0	1	10	Mid
	Donias (2003) [46]		P	8	2	1	1	12	Mid
	Ribeiro (2017) [49]		S+P	9	4	1	1	15	Mid
	Maluf (2015) [39]		S+P	8	3	0	3	14	Mid
	Bouma (2015) [40]		H	11	5	2	2	20	High
	Liu (2016) [48]		LP	9	2	3	3	17	High
D	University of Twente (2020)[4, 6]	Buitenhuis	S	5	1	0	2	8	Low
	University of Twente (2020)[4, 6]	De Jong & Moejes	S	8	3	0	2	13	Mid

A = Commercially available, B = No longer available, C = Described in literature, D = University of Twente; S = Synthetic, P = Porcine, H = Human cadavers, LP = Living porcine; AC = Anatomical Component, OC = Operational component, SC = Scenario component, EC= Environment component.

4.4.3 Customization Fidelity

The classification of the customization fidelity level of the OPCAB simulators is depicted in Table 4-3. Overall the OPCAB simulators scored lowest on this fidelity type. There were 11 (85%) OPCAB simulators that resulted in a low-fidelity level, only 1 (8%) of the OPCAB simulators had a mid-fidelity level, and one (8%) of the OPCAB simulators had a high-level rating. The simulator that had a high customization fidelity level, is the simulator based on human cadavers, the customization is not something that can be changed but is depended on the cadavers that were available for the study. Less than half of the OPCAB simulators (30%) were able to adjust for a different disease and/or anatomy parameter for the simulated heart. One (8%) of the OPCAB simulators could adjust for different ages. Even though 7 (54%) of the simulators could have a different sex, this is only because porcine hearts were used for these simulators, and the porcine hearts used could be of a different sex. Therefore, only the anatomy of the heart differs in sex, the other aspects are the same.

It can be argued that, although different cadavers or porcine hearts may have various features, making them customizable according to this view on reviewing customization fidelity. However, the customization features depend on the available materials, as their properties cannot be altered. When changing the definition of customization to features that can be altered, no (0%) simulator can change the sex, age, or skin colour. Resulting in 1 (8%) OPCAB simulator with a mid-fidelity level and 10 (92%) with a low-fidelity classification for customization. In Table 4-3, the results where customization cannot be altered are displayed in blue.

Table 4-3: Customization fidelity of OPCAB simulators.

	Source	Device	Material	Sex	Age	Size	Disease/ anatomy	BMI	Skin colour	Total (6)	Customization fidelity
A	EBM (2024) [38]	BEAT	S	No	No	No	No	No	No	0	Low
	KindHeart (2024) [42, 43]	Cardiac surgery simulator	P	Yes	No	No	No	No	No	1 (0)	Low
	The Chamberlain Group (2024) [41]	High-Fidelity CT Surgical Trainer	S	No	No	Yes	Yes	Yes	No	3	Mid
B	Izzat (1998) [44]		S+P	No	No	No	Yes	No	No	1	Low
	Reuthebuch (2002) [45]	Zurich heart-trainer	S	No	No	No	Yes	No	No	1	Low
C	Donias (2003) [46]		P	Yes	No	No	No	No	No	1 (0)	Low
	Ribeiro (2017) [49]		S+P	Yes	No	No	No	No	No	1 (0)	Low
	Maluf (2015) [39]		S+P	Yes	No	No	No	No	No	1 (0)	Low
	Wu (2021) [47]		S+P+H	Yes	No	No	No	No	No	1 (0)	Low
	Liu (2016) [48]		S+P	Yes	No	No	No	No	No	1 (0)	Low
	Bouma (2015) [40]		H	Yes	Yes	Yes	Yes	Yes	Yes	6 (0)	High (Low)
D	University of Twente (2020)[4, 6]	De Jong & Moejes	S	No	No	No	No	No	No	0	Low
	University of Twente (2022)[5]	Buitenhuis	S	No	No	No	No	No	No	0	Low

A = Commercially available, B = No longer available, C = Described in literature, D = University of Twente; S = Synthetic, P = Porcine, H = Human cadavers, LP = Living porcine; Blue results are the features that can be argued whether they are customizable.

4.4.4 Overall Fidelity

To summarize the results of the different fidelity categories mentioned above, the median for each OPCAB simulator was calculated. The simulators are ranked from low to high fidelity. The ranking is determined based on the outcomes of the three fidelity categories. Due to some simulators achieving identical distributions of low, mid, and high results, there are a total of six distinct overall ranks. Table 4-4 shows the results of the overall fidelity. The desk study resulted in a total of 13 OPCAB simulators, which in the end resulted in 4 (30%) low-fidelity, 8 (62%) mid-fidelity, and only 1 (8%) high-fidelity OPCAB simulator.

In total, the three different fidelity categories showed only 4 (30%) OPCAB simulators with at least one high-level fidelity rating, 3 (23%) for definition-based fidelity, 2 (15%) for component fidelity, and 1 (8%) for customization fidelity. 3 (23%) of the high-level ratings belonged to the same simulator, which is the simulator mentioned in the paper of Bouma et al.[12]. Which is the simulator that is based on a human cadaver. The other 3 (23%) high-level ratings were allocated to the Cardiac surgery simulator [6], the simulator mentioned in the paper of Ribeiro et al. [14] and the live miniature pig simulator mentioned in the paper Liu et al. [49]. These three simulators are based on the use of a porcine heart or live miniature pig. These results show that there are no synthetically based OPCAB simulators that have an overall or specific high-level fidelity rating.

Table 4-4: Overall Fidelity of OPCAB simulators.

	Source	Device	Material	Definition-based fidelity	Component fidelity	Customization fidelity	Overall fidelity
	EBM (2024) [38]	BEAT	S	Low	Low	Low	**Low**
6	Izzat (1998) [44]		S+P	Low	Low	Low	**Low**
	Donias (2003) [46]		P	Low	Mid	Low	**Low**
5	University of Twente (2022) [5]	Buitenhuis	S	Mid	Low	Low	**Low**
	Reuthebuch (2002) [45]	Zurich heart-trainer	S	Mid	Mid	Low	**Mid**
	University of Twente (2020) [4, 6]	De Jong & Moejes	S	Mid	Mid	Low	**Mid**
	Wu (2021) [47]		S+P+H	Mid	Mid	Low	**Mid**
4	Maluf (2015) [39]		S+P	Mid	Mid	Low	**Mid**
3	The Chamberlain Group (2024) [41]	High-Fidelity CT Surgical Trainer	S	Mid	Mid	Mid	**Mid**
	KindHeart (2024) [42, 43]	Cardiac surgery simulator	P	High	Mid	Low	**Mid**
	Ribeiro (2017) [49]		S+P	High	Mid	Low	**Mid**
2	Liu (2016) [48]		LP	Mid	High	Low	**Mid**
1	Bouma (2015) [40]		H	High	High	High (Low)	**High (High)**

1-6 is the rank of the OPCAB simulator 1 is the highest 6 is the lowest; S = Synthetic, P = Porcine, H = Human cadavers, LP = Living porcine; Blue result is the simulator that can be argued whether it is customizable.

4.5 Discussion Fidelity Analysis

The purpose of the analysis was to create an objective classification overview of the fidelity level of current OPCAB simulators. In the end, a structured overview of the overall fidelity classification of the OPCAB simulators was created, where the categories definition, component, and customization fidelity were taken into account. This new classification method of reviewing OPCAB simulators indicates that there currently is only one high-level fidelity OPCAB simulator which uses human cadavers as its main material, showing that there are no synthetic-based OPCAB simulators with a high-fidelity rating.

Even when the argued customization, as discussed in Section 4.3.3, of the OPCAB simulator from Bouma et al. [40] is categorized as low-fidelity, the overall fidelity classification remains a high-fidelity simulator. This is because the result is based on the median for classification, which remains unchanged.

Something to note that is interesting is that one of the simulator's names is the High-Fidelity CT Surgical Trainer. Yet from this classification method the overall fidelity resulted in a mid-fidelity OPCAB simulator.

4.5.1 Limitations

Even though a thorough desk study has been performed, the list of OPCAB simulators could be incomplete. For example, only English-written literature was included in the search, giving the possibility that an OPCAB simulator could have been missed due to the language of the paper. In addition, only Scopus was used as a literature database during the desk study.

When evaluating the OPCAB simulators on the different categories, components and customization, it is only taken into account when the simulator has that element. However, having a certain element does not guarantee that it has a similar quality. The components added to a simulator can vary in quality level. In addition to the method of classifying simulators on their fidelity level, it should be recommended to take into account the level of quality of the parts of the simulator. The final list of OPCAB simulators was established in January 2024 and is only accurate until that moment. The list of simulators can be revised when new OPCAB simulators are developed.

4.6 Conclusion Fidelity Analysis

With the results from the fidelity classification, it became clear that there currently are no synthetic-based OPCAB simulators with a high-fidelity rating. Besides, there is no simulator that does not use live animals, which has a type of hemodynamical feedback. Understanding the limitations of the current advancements provides opportunities to identify what has not yet been developed and substantiate further research and progress in those areas. Answering the research question *What are the current advancements in OPCAB simulators, and how can implementing a fidelity classification aid in the understanding of developing an OPCAB simulator prototype?*

5 Design Assignment

In this chapter, the results of the previous analyses are summarized to create a problem definition. With the problem definition, a design goal is formulated. Providing information on the project's aim, identifying the specific areas where the OPCAB simulator should be improved and further developed during the work described in this thesis.

5.1 Problem Definition

From the literature related to ONCAB versus OPCAB (see Section 2.5.3), it became clear that OPCAB surgery would only become beneficial when performed by experienced surgeons. To become experienced in the OPCAB procedure, surgeons should have performed the steps of OPCAB surgery multiple times. Having a simulator to train the steps of OPCAB surgery provides the surgeons with the opportunity to learn the basic skills of OPCAB surgery in a safe environment before continuing their training on patients. When the simulator has a higher level of fidelity the experience and learning environment created become more realistic, making the change from simulation to real life less apparent.

From the stakeholder analysis, it became apparent that having a beating heart and hemodynamical functions were the two most desired characteristics for an OPCAB simulator. A user need check was performed on the current prototype. This showed that currently no hemodynamic functions are implemented and the beating heart could use improvements.

A fidelity analysis was performed on the current OPCAB simulators and developments to provide information on the current advancements in OPCAB simulators. Creating a fidelity classification overview of all OPCAB simulators. During the analysis, a list of components needed in an OPCAB simulator was established, including hemodynamic feedback. Of the 11 OPCAB simulators, only one simulator based on live miniature pigs had a hemodynamic feedback component. The only simulator that had a high-fidelity classification used human cadavers. This shows there is a gap in the current developments of high-fidelity OPCAB simulators that have a hemodynamic feedback system implemented.

5.2 Design Goal

With the necessity for an OPCAB simulator that has hemodynamic functions, coupled with the gap in the current OPCAB simulators that offer these capabilities, the objective for further development became evident and substantiated. Thus the goal of this thesis can be stated as:

Developing a prototype OPCAB simulator that functions as a proof of concept, featuring a life-like beating heart and an integrated hemodynamic feedback mechanism.

To create a better-guided development towards the design goal, research questions have been defined. For the background and substantiation research of the design goal, a research question was formulated:

- *What are the current advancements in OPCAB simulators, and how can implementing a fidelity classification aid in the understanding of developing an OPCAB simulator prototype?*

This question has previously been answered during the fidelity analysis of current OPCAB simulators in the previous chapter (Section 4.6). At the end of the development steps of the OPCAB simulator prototype, the hemodynamic function of the final design will be tested and evaluated, answering two more research questions:

- *Does the hemodynamic feedback system of the OPCAB simulator prototype accurately detect and show incorrect manipulation of the heart?*
- *How does the fidelity level classification of the new OPCAB simulator prototype compare to the previous prototype?*

5.2.1 Boundaries

Some boundaries have been set to prevent the thesis from being never-ending, as numerous additions could be implemented and improved to the OPCAB simulator.

- The movement mechanism of Buitenhuis [5] (Figure 5-1) will be set as the starting point of the beating heart. Improvement in the beating heart design will be based on the current movement mechanism.
- Blood-filled coronary arteries and an anastomosis check will not be implemented in the prototype, even though it is an important function of the OPCAB simulator it has no influence on the hemodynamic function. During the design, it will be taken into account that this eventually needs to be implemented in the final simulator. The hemodynamical feedback system will only be a proof of concept, iteration to improve the design can be made during future work on the simulator after it has been proven that the basic function works.
- Only one heart will be made, using the dimensions of an adult male heart. The addition of different-sized hearts can be implemented in the future when the only step left is to add more customization to the simulator.

Figure 5-1: Movement mechanism of Buitenhuis [5].

6 Requirements

In this chapter, a function analysis is presented, which is based on the analyses of the previous chapters. From these functions, a program of requirements for the OPCAB simulator was established.

6.1 Function Analysis

With the results of the stakeholder analysis and the user needs established by Moejes [6] and De Jong [4, 6], coupled with the fidelity analysis, a clear understanding of the necessary functions of the OPCAB simulator emerges. A function analysis was set up to create an overview of these essential functions which can be seen in Figure 6-1. The function analysis will help gain insight into parts that need to be developed and implemented into the OPCAB simulator. Even though this thesis only focuses on specific parts of the OPCAB simulator, it is useful to have a total function analysis as a reference for future work.

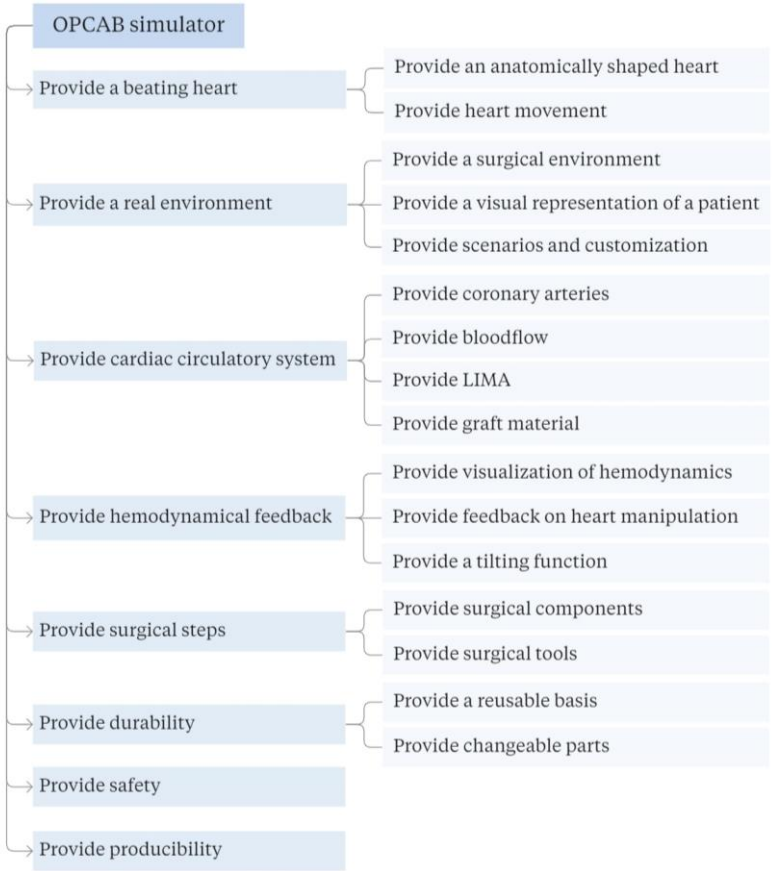

Figure 6-1: Function analysis of the OPCAB simulator.

6.2 Program of Requirements

A program of requirements is necessary to make an OPCAB simulator that fulfils the functions established in the function analysis. The function analysis was split into 11 functional component categories for the program of requirements. For each category requirements were set up and design specifications related to that requirement were added.

The four previous students who worked on this project all set up their own requirements and product specifications [3-6]. To ensure the continuity of their work, their determined requirements and specifications were reviewed. Relevant requirements were selected and/or modified to be added to the new program of requirements. When a requirement was taken from one of the previous students, their thesis is referenced in the requirement.

The most noticeable adaptation compared to the previous sets of requirements is in the movement of the heart. In the requirements lists set by De Jong [4] and adopted by Buitenhuis [5] a requirement was set on the lengthening and widening of the heart. In the beginning of the work described in this thesis, the same requirement on lengthening and widening of the heart was used, However, during the later stages of this thesis, it was discovered that this requirement had incorrect values. The mistake originated from a misinterpretation by the first researchers of the literature that was used to substantiate this requirement. The values for widening and lengthening (in the paper titled, radial and longitudinal strain [50]) were overestimated because they were related to the strain and deformation of the heart wall during the systole phase of the heart [51], rather than the widening during the diastolic phase, as it was initially interpreted. In order to correct this mistake, a new paper by Carlsson et al. [52] was found, containing information on the total volume change and longitudinal lengthening of the heart. After the discovery of the mistake, the results of that paper – with much smaller values – were used to substantiate new requirements on the movement of the heart. More detailed information about the results of that paper can be found in Appendix C: Requirements.

Using the surgical components, anatomical components and customization components established during the fidelity analysis, additional requirements were identified and added to the program of requirements.

Table 6-1 shows the requirements categories of the heart, movement, and hemodynamics of the OPCAB simulator, as they are most relevant to the design goal of this thesis. The total program of requirements with all 11 categories can be found in Appendix C: Requirements. In the requirements a fluid-powered system is mentioned, more detailed information on this part is given in Section 8.1.

Table 6-1: Requirements on the heart, movement, and hemodynamics of the OPCAB simulator.

02	**Heart**					
	Requirement		Specification	Value	Unit	Ref.
02-01	The heart model should have human-like dimensions	02-01.01	Total heart length	80-140	mm	[5]
		02-01.02	Total heart width diameter	85-150	mm	[53]
		02-01.03	Total heart depth diameter	60	mm	[5]
02-02	The heart should have an anatomically correct look	02-02.01	The heart model has simulated atria and ventricles	True	N.A.	
		02-02.02	The heart model contains the pericardial part of the vena cava, aorta, pulmonary vein, and pulmonary artery	True	N.A.	
05	**Movement**					
	Requirement		Specification	Value	Unit	Ref.
05-01	The simulator should have a life-like beating heart	05-01.01	Heart rate of beating heart	50-100	BPM	
		05-01.02	Total heart volume change	8.2 ± 0.8	%	[54]
		05-01.03	Heart model longitudinal lengthening	0,9 ± 0,5	%	[54]
		05-01.04	Maximum heart transverse area increase	17,8	%	[54]
		05-01.05	Heart model clockwise twisting atria	7 ± 3	°	[5]
		05-01.06	Heart model counter-clockwise twisting ventricles	12 ± 6	°	[5]
		05-01.07	Correct phasing and combination of cardiac movements	True	N.A.	[4]
05-02	The beating heart should be fluid-powered	05-02.01	Simulator has a fluid-pumping system	True	N.A.	
		05-02.02	Base fluid reservoir	> 8 of total fluid in heart	%	[54]
		05-02.03	Apex fluid reservoir	> 8 of total fluid in heart	%	[54]
06	**Hemodynamics**					
	Requirement		Specification	Value	Unit	Ref.
06-01	The simulator should show simulated hemodynamics	06-01.01	Display heart rate	True	N.A.	
		06-01.02	Display blood pressure	True	N.A.	
06-02	The simulator should measure simulated hemodynamics	06-02.01	Measure simulated blood pressure	True	N.A.	
06-03	The simulator should give feedback on the manipulation of the heart	06-03.01	Show change in hemodynamics if flow into atria is compromised	True	N.A.	
		06-03.02	Show the change in hemodynamics if flow into ventricles is compromised	True	N.A.	
		06-03.03	Show change in hemodynamics if the heart is compressed	True	N.A.	
06-04	The simulator should be able to tilt	06-04.01	Simulator can be put in Trendelenburg's position	True	N.A.	

02, 05, and 06 are the numbers related to the total 11 categories.

7 Material Analysis Simulated Heart

This chapter presents a material analysis that was performed to determine the most suitable material to use during the further development of the simulated heart of the OPCAB surgery.

7.1 Current Prototype Material Shortcomings

The movement mechanism of the heart designed by Buitenhuis [5] (Figure 7-1) is made of 3D printed Thermoplastic PolyUrethane (TPU). Unfortunately, the current movement mechanism has some shortcomings in its design. A shortcoming of the movement mechanism is that it suffers from air leakage. A quick fix to this flaw in the design of K. Buitenhuis was to insert a balloon in the apex of the design. Unfortunately, this solution did not result in stopping all of the air leakage as the balloon was only inserted in the apex of the movement mechanism and not in the base. This still allowed air leakage in the base of the balloon and therefore limits the functions of the movement mechanism.

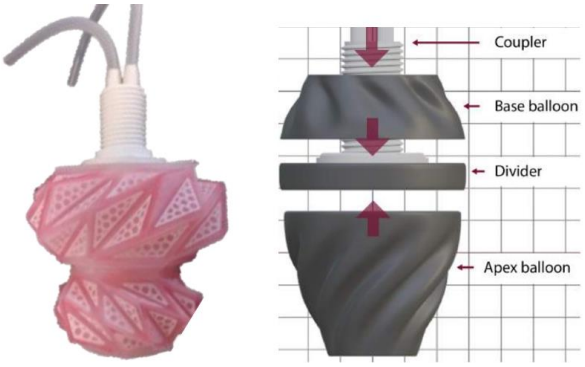

Figure 7-1: Origami balloon (left). Movement mechanism (right).

During the design of the movement mechanism of Buitenhuis, it was chosen to make the final design out of TPU [5]. Some information was lacking on the reason to use this material, as well as on testing of alternative flexible materials. The thesis did mention that using 3D printed TPU required fewer production steps to create the mechanism compared to De Jong's previous origami balloon design (Figure 7-1) [4]. During the design of the origami balloon, De Jong tested different materials for her design. This resulted in the selected material being silicone with added reinforcements as it was discovered that solely silicone was not strong enough and in need of extra support.

The origami balloon design consists of sharp corners, triangles, and diamond shapes. At the same time, the design of Buitenhuis resembles something like a sculpted cone shape with rounded corners along the curves. Questioning whether the material analysis of De Jong can be used in de design of Buitenhuis. In addition tot this, one of the materials tested by De Jong was TPU. The result was that TPU did not work for her design, even having a comment which said that creating an airtight model made from TPU is inconvenient [4]. Nevertheless, the material Buitenhuis chose for his design is TPU.

Another shortcoming of TPU is that, despite being a flexible material, Buitenhuis's movement mechanism still felt quite stiff and did not resemble the realistic feel of a heart.

A material analysis was undertaken to establish whether changing the material could remediate these shortcomings. Material properties and production methods, along with practical fabrication information on materials, were collected to identify the most suitable material for the development of the OPCAB simulator's heart.

7.2 Material Properties and Production Methods

To better understand the material properties of the different materials relevant material property terms are shortly explained in Appendix D: Material Analysis.

7.2.1 Material properties

The material of the movement mechanism of Buitenhuis [5] was TPU, which has a shore hardness of 95A. This shows that it is a flexible material, however on the shore A scale it is quite a stiff material. C. Park and J. Kim [55] performed a study on reproducing the physical properties of a pig's heart, to get a better understanding of what to replicate when developing a 3d printed heart model. They determined that a porcine heart has a shore hardness of ≈15A. With this as a reference for shore hardness to try to replicate in the movement mechanisms, 5 materials ranging from 25A to 95A that were available at the University of Twente were used for the material analysis. An overview of the mechanical properties of these five materials can be found in Table 7-1.

Table 7-1: Material properties of the potential materials. Data is gathered from their technical data sheets.

Material	**Porcine**	**Silicone**		**Resin**		**TPU**
	[55]	RT 625[57]	HT 33 [58]	Elastic resin [59]	Flexible resin [60]	[56]
Ultimate tensile strength (MPa)	N.A.	6,5	4,7	3,23	3,7	39
Elongation at break (%)	N.A.	600	430	160	120	580
Shore hardness	15A	25A	33A	50A	80A	95A

The research of C. Park and J. Kim [55] only involved the shore hardness the other properties were not mentioned in the study.

Of the available materials, both silicones had a similar elongation at break, but none of the materials had a similar ultimate tensile strength when compared to TPU. The potential materials were not compared to the ultimate tensile strength and elongation at break of a porcine heart. The simulated heart aims to be reusable and, therefore, it is not required to possess similar properties to a real heart in these aspects. Shore hardness influences the tactile properties of the material and is, therefore, considered during material comparison.

7.2.2 Production methods

The production methods related to the materials that will be tested are Liquid casting of silicone, 3D FDM (Fused Deposition Modelling) printing, and 3D SLA (Stereolithography) printing. In the thesis of van Lochem [61], similar research on these production methods was presented. Information from her comparison was used to explain and compare the production methods related to the available materials. A short description and the pros and cons of the production methods is provided in Table 7-2. The three production methods all have advantages and disadvantages, and all have a risk for imperfections that can lead to the design not being air or fluid-tight.

Table 7-2: Overview of production methods adapted from [61].

Liquid casting of silicone	3D FDM Printer w/ Ultimaker	3D SLA printing w/ Formlabs
Creating a mould for the silicone to go in. The silicone is prepared, mixed, and poured into the mould. And as a last step, the silicone is vulcanized.	FDM stands for fused deposition modelling, an additive manufacturing technique using thermoplastic filament. This material is extruded through a heated nozzle onto a heated plate. Creating shapes layer-by-layer.	SLA stands for stereolithography, an additive manufacturing technique using liquid resin as a material. Layer-by-layer resin is added and cured by UV lighting, creating complex shapes.
Pro's	**Pro's**	**Pro's**
Water and airtight	Fast production	Can create a high level of detail
Easily reproducible	Compatible with printing TPU	Fluid and airtight
Con's	**Con's**	**Con's**
Creating the mould can become complex	No fluid and air tightness	The material never stops curing
Optimization of the design requires a new mould design	No high level of detail	Should be available at the UT. However, both the printers at the UT are malfunctioning
Air bubbles can be formed during filling, creating a risk of imperfections	No guarantee that the print has no imperfections	No guarantee that the print has no imperfections

7.3 Material Prototype Fabrication

The physical comparison of the materials provides more information whether the fabrication of the parts matches the theoretical information. To perform the material analysis on a more realistic heart size, it was decided to enlarge the design for each prototype by a factor of 1,5. To reduce the fabrication time of the new material prototypes, only the bottom part (apex) of the movement mechanism was created, and the dividers were made from TPU for most material prototypes. All material prototypes are displayed in Figure 7-2. Overview tables with information gathered during the fabrication process of the prototypes can be found in Appendix D: Material Analysis.

Figure 7-2: Prototypes of the different materials.

During the process of fabricating the material prototypes, it became clear that printing flexible resin was more challenging than anticipated. Multiple attempts were required to successfully print the design. The flexible resin designs were also found to be fragile and tore easily.

The five material prototypes were tested to see whether they were watertight. As a precaution for the TPU, as it was known to not be fluid-tight, a rubber coating was applied to the inside of the prototype. During the evaluation, the prototypes were filled with water and pressurized by adding more water through a syringe to simulate the intended inflation and twisting motions. The TPU and elastic resin prototypes exhibited leaking when pressurized, while the other three materials showed no indications of leaking.

7.3.1 Comparing Silicones

During the fabrication of the different materials, it became evident that TPU and the printed resins showed certain disadvantages. Consequently, it was decided that silicone would be the preferred material for the remained of the work. From the initial testing and fabrication of the silicone prototypes, no clear preference for one of the two silicones could be identified. The silicones showed minor differences in material properties, but more pronounced differences in curing time and cost. RT 625 has a higher price and a longer curing time, both around four times the values of HT 33. However, the shore hardness of RT 625 is closer to the shore hardness of the heart muscle. To facilitate a selection or preference between the silicones, a comparison test was conducted to determine whether the minor differences in material properties displayed differences in the prototypes. Details of the comparison test and results can be found in Appendix D: Material Analysis.

During the comparison test, both silicone models were once more filled with water and subjected to pressure. While the models were pressurized, the widening and lengthening of the model were measured. The resulting median of the widening and lengthening of the model of both materials appeared similar, as evidenced in Table 7-3.

Table 7-3: Median with standard deviation of widening and lengthening of both silicone materials.

	RT 625	**HT 33**
Widening (%)	11.49 ± 0.59	10.42 ± 0.282
Lengthening (%)	2.7 ± 0.34	2.4 ± 0.48

A Mann-Whitney U test was conducted to assess whether the results of the two data sets indicated statistical differences. The Mann-Whitney U test was deemed suitable as the data displayed a non-normal distribution. The result of the test revealed no significant difference between the two data sets.

The silicone prototypes of the simulated heart were compared with volume changes observed in the human heart. The research of Carlsson et al. [52] investigated the total volume change of the heart and was used as the reference. Their results were used to calculate the maximum area decrease of a transverse slice of the heart. Data from the statistical test were collected to calculate the area decrease of both materials. A comparative overview of these results is presented in Table 7-4, showing that both materials are comparable. However, the values slightly exceed the values observed in the real heart.

Table 7-4: Overview results of silicone comparison test and real heart.

	RT 625	**HT 33**	**Heart**
Maximum area decrease of a transverse slice of the heart (%)	18,09	19.71	15.2

The values of RT 625 and HT33 are the calculated mean of the area using data from the comparison test. The value of the heart is the mean measured by Carlsson et al. [52].

7.4 Conclusion Material Analysis

The material analysis showed that silicone would be the preferred material for the development of the simulated heart. Given that the two silicones produced statistically similar outcomes and closely mirrored the performance of the actual heart, the decision was based on additional factors, including curing time and material availability. This resulted in the decision that HT 33 silicone was selected as the optimal material for further development of the simulated heart.

8 Design Phase

This chapter will describe the conceptual design phase of the OPCAB simulator, where in the end a final concept will be chosen to further develop. Before the iteration process starts, context and substantiation of the change from a pneumatic to a fluid system are introduced. The ideation is divided into three areas: the simulated heart, the actuation system, and the hemodynamic systems. Elements from these different ideation groups are combined, generating two concepts. The chapter concludes with a decision on which concept will be further developed into a prototype.

8.1 Change in Power System

In the requirements of the OPCAB simulator provided in Section 6.2, requirement 05.02 states that "The beating heart should be fluid powered". In the concluding chapter of Buitenhuis [5], it was recommended to upgrade the pneumatic system, as the current system was already facing challenges in generating sufficient power to create the desired characteristics of the beating heart. Rather than connecting the system to a more powerful compressor, an alternative power system could be considered. The system should take the design goal of developing a life-like beating heart with an integrated hemodynamic feedback mechanism into account. Since hemodynamics is linked to the power and blood flow of the cardiac system, a fluid-powered system would be a logical choice. Comparable systems are found in a mock circulatory loop system, which is used to test artificial heart devices [62].

Table 8-1 compares the different aspects of a pneumatic and fluid system applicable to designing an OPCAB simulator. Overall, the fluid system has more advantages in recreating hemodynamics power, and weight. Based on this comparison and discussions with Edsko Hekman it was decided to convert the power system of the OPCAB simulator from a pneumatic to a fluid-powered system. This decision was made while keeping in mind that having a fluid-powered system is most in line with recreating the real-life situation, aiding to the improvement of the fidelity of the OPCAB simulator.

Table 8-1: Comparing a pneumatic or a fluid system to different aspects.

	Pneumatic system	**Fluid system**
Flow	Air is compressible, so it only needs to be pumped in.	Water is non-compressible, so it needs to be pumped in and out.
Power	The system needs power to fill the whole heart fully with air for each heartbeat.	The system needs only a small amount of power to fill the change in size per heartbeat.
Weight	The weight of the heart is light and not similar to the real-life situation.	The weight of the heart matches a real-life situation.
Hemodynamics	Adding hemodynamics is more complicated.	Recreating hemodynamics is easier as it is similar to the real situation.
Leakage	Leakage of air has few consequences.	Leakage of water can cause problems.

8.2 Ideation

It was decided to modify the conical shape of the previous prototype from a circular to an oval shape. An oval-shaped heart better reflects the anatomically correct shape. In addition, measurements of the length, width, and depth were conducted on a pig's heart, providing a width-to-depth ratio of 1:0,85. The selection for the material was changed from TPU to silicone as explained in Chapter 1. This material and the oval shape have been taken into consideration during the design phases of the OPCAB simulator.

8.2.1 Simulated Heart Ideation

Switching the power system from air to fluid required a redesign of the flow system of the heart. When using air, only pumping into the atria (base) and ventricles (apex) is required. In the case of fluid, also consideration must be given to how the fluid will exit the system. Five ideas on fluid flow system designs are shown in Figure 8-1. In Appendix E: Design Phase a detailed version with extra information on needed parts and brief explanations of the fluid flows through the heart designs is provided.

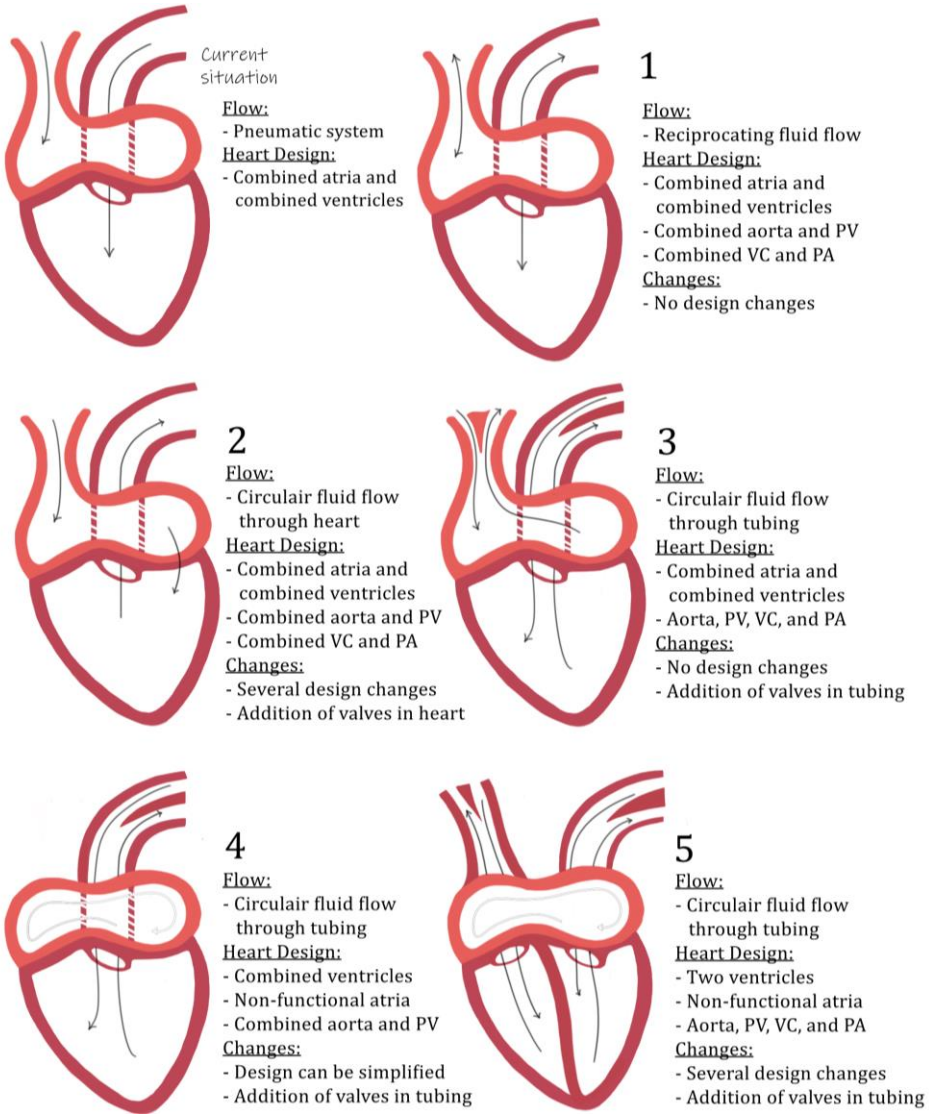

Figure 8-1: Ideation on flow system designs with five alternative ways for fluid flow, compared to the pneumatic design of Buitenhuis [5] (current situation). → Arrows represent the fluid flow. PV = Pulmonary vein, VC= Vena cava, and PA: Pulmonary artery.

Flow system 2 requires the addition of valves into the heart, while the flow system 3, 4, and 5 require only valves in the tubing. Sketches of mechanical valves can be found in Appendix E: Design Phase.

To create an efficient and smooth fluid flow system, larger inlets and tubing are important, reducing the power needed to move the fluid as the flow resistance is lower in a larger opening. The tubing of the current pneumatic system has an inner diameter of 3 mm. A wider diameter has as a consequence that the inlet and coupling system design needs a new iteration, providing the opportunity to combine the inlet system with the addition of the supply vessels of the heart. This change will be further explained in Section 8.3.

8.2.2 Actuation System Ideation

In addition to the ideation of how fluids behave within the heart, it is important to also consider mechanisms by which the fluid is pushed throughout the system (from now on that system will be referred to as the actuation system). Different techniques can be considered as the actuators of the fluid system. Pre-concepts using a rotational, linear and roller pump were created, these are presented in Figure 8-2. The three pre-concepts use an actuator to generate the fluid flow from one or two fluid reservoirs to the simulated heart.

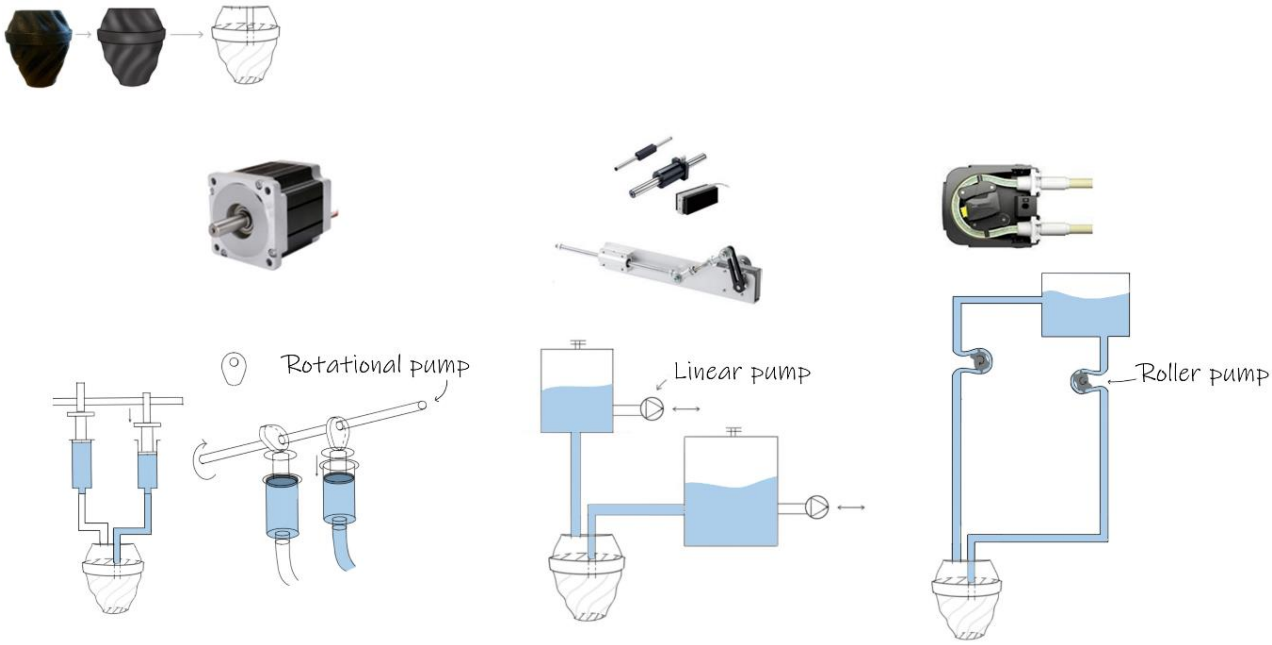

Figure 8-2: Three pre-concept sketches for an actuation system and a sketch for a fluid reservoir.

8.2.3 Hemodynamic System Ideation

Previous students have started the process of implementing a hemodynamic feedback system into the OPCAB simulator. De Vries [3] suggested the addition of an Inertial Measurement Unit (IMU) to the tip of the heart, Popnikolova et al. [63] started the addition of implementing an air pressure sensor in the atria, however, no prototype of this has been tested. An IMU is a small chip which can measure the orientation of the object it is attached to (Figure 8-3 left). When it is attached to the heart it can provide information on the motion the heart makes during the simulated surgery. In the tests performed by de Vries, it was discovered that the beating of the simulated heart caused

a rather large error margin in the data [3]. Several improvements in code were essential to make the IMU work properly.

Moreover, the IMU solely offers data on the heart's orientation and movement. The output of the IMU has to be translated into what outputs are correct and incorrect movements. Knowing the incorrect movements is the complicated part of heart manipulation during OPCAB surgery. Understanding which heart manipulations cause problems in hemodynamics is precisely the purpose of the simulator, forming a cyclical process.

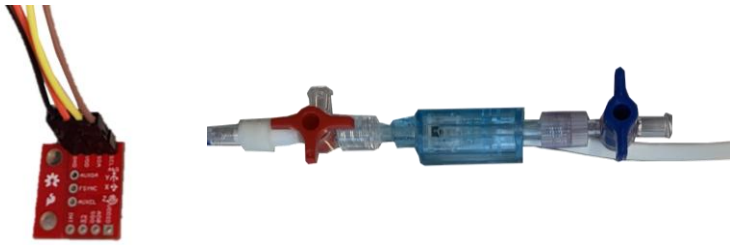

Figure 8-3: IMU (left) [3] and blood pressure transducer (right).

The solution for hemodynamic feedback proposed by Popnikolova et al. [63] is implementing air pressure sensors. With the decision to change the system from pneumatic to fluid, the use of air pressure sensors becomes obsolete. A fluid pressure sensor could be a solution to observe hemodynamic feedback. During OPCAB surgery maintaining stable blood pressure is critical to the hemodynamic state of the patient. To achieve a high-fidelity simulator it is vital to closely replicate this. During surgery, intra-arterial blood pressure transducers (Figure 8-3 right) are used to monitor the patient's blood pressure. During each cardiac contraction, pressure is generated and detected by this transducer, which converts the data from the detected pressure into an electrical signal. Subsequently, this signal is transmitted to a monitor, providing information per heartbeat [64]. The pressure transducer is based on fluid pressure detection which could be implemented in the fluid flow system of the OPCAB simulator.

For the design in this work, it was decided to implement a blood pressure transducer, as it is closest to the real-life situation. The principle has been proven and the sensor is mass-produced and can instantly be connected to medical tubing.

8.3 Concepts

With the ideation of the fluid flow of the heart and the actuation system, two more detailed concepts were developed, both concept sketches are depicted in Figure 8-4. Flow systems 1 and 4 were preferred for implementation into a concept. The other flow systems either required twice the number of components or complex design changes to become functional. The first concept A, combines flow system 1 with a linear pumping system, creating a reciprocating flow. Flow system 1 is closest to the current design, consequently minimizing the required adaptations. Two pressure transducers are connected to the system, providing information on the flow in the combined atria and combined ventricles.

The second concept B, is a combination of an adapted version of flow system 4 and a roller pump forming a circular flow. Flow system 4 is a simplified version of the current system, as it combines all four chambers of the heart into a single movement, thereby eliminating the 2 different diastolic and systolic phases of the atria and ventricles. While developing this design is simple, it deviates from the complex movements of the real-life heart. One pressure transducer is connected to the system, only providing information on either the in or outflow of the heart.

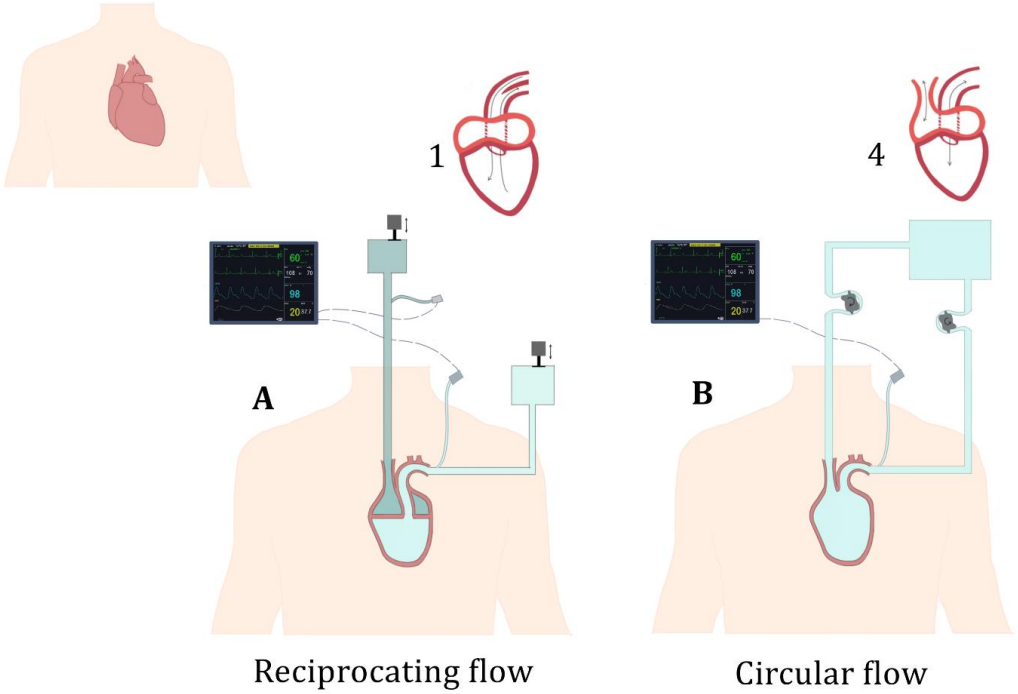

Figure 8-4: Designed concept sketches. A) Reciprocating flow design using two linear motors and two pressure transducers, based on flow system 1. B) Circular flow design using two roller pumps and one pressure transducer, based on flow system 4.

The addition of the supply vessels of the heart and the changing of the inlet design of the heart were briefly mentioned during the ideation of the fluid flow system. Adding supply vessels to the heart helps implement an important part of the hemodynamic feedback during heart manipulation. Section 2.4 mentions that compression of the supply vessels limits the blood supply to the atria, lowering the blood pressure of the patient as a result. When functional supply vessels are added to the simulator, it provides the opportunity to practice heart manipulations and receive feedback on whether the supply vessels are compressed during the manipulation.

In the current prototype, the supply vessels are not included and only a non-functional aorta is implemented to hide the inlet system on top of the centre of the atria. The idea is to simulate the vena cava and pulmonary vein, as they are the supply vessels of the atria and are more flexible and compressible than the aorta and pulmonary artery. Sketches on how the simulated vena cava and pulmonary vein fit within the heart, while also being connected to the combined atria can be seen in Figure 8-5 and Appendix E: Design Phase.

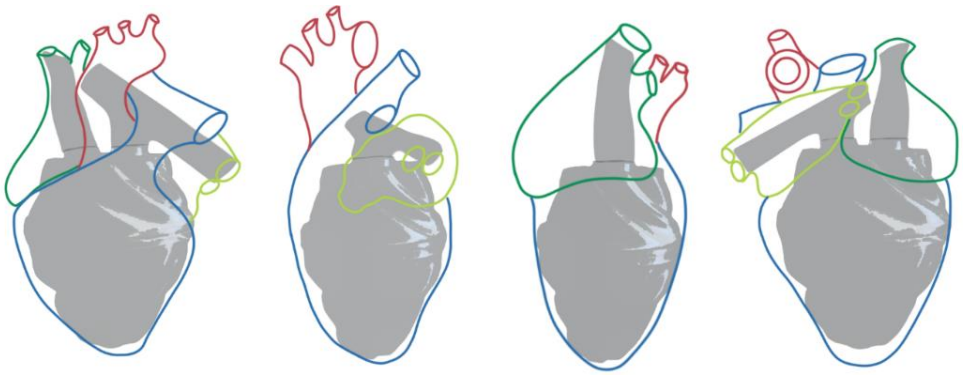

Figure 8-5: Schematic overview of placement of the simulated heart with vena cava and pulmonary vein inside an anatomical heart. **Red**: Aorta, **Blue**: Pulmonary artery and combined ventricles, **Green**: Vena cava and right atrium, **Lime**: Pulmonary veins and left atrium.

8.4 Conclusion Design

Creating a functional beating heart with hemodynamic feedback with a simpler design is preferable, as it simplifies the production and development process. It was decided that Concept A, with the addition of the pulmonary vein and vena cava, would be the best starting point for developing a prototype. Concept A provides the option to simulate more functions of the heart and can provide hemodynamic feedback on the atria and ventricles. Concept B has a simpler design, however, it deviates from the complex movements of the real-life heart. Also, in Concept B, the hemodynamic feedback system can provide less information. Concept B was considered as a fall-back option.

9 Final Prototype Design

This chapter introduces the final design of the OPCAB simulator and the development of a prototype.

9.1 Final Design

The final design builds on the concept plan introduced in the previous chapter. It is an iteration of concept A (Figure 8-4) and consists of the developed simulated heart, the actuation system, and the hemodynamic feedback system. Along with this are, the torso model with a pericardial sack and LIMA, and the surgical equipment, including the retractor and stabilizer. In total, this creates the total OPCAB simulator design.

9.1.1 The Simulated Heart

The simulated heart consists of a functional heart design and a visual heart sleeve. The functional heart is placed into the sleeve. All parts of the simulated heart are visible in

Figure 9-1.

Functional heart

The functional heart is an adapted version of the twisted conical shape of the heart that was developed by Buitenhuis [5]. Modifications to this design were made to create a more anatomically correct shape. This was done by enlarging the design and making a more oval shape in the transverse plane. The atria are connected to a simulated silicone vena cava, and the ventricles are connected to a simulated silicone pulmonary vein. The diameter and wall thickness of the vena cava and the pulmonary vein are close to real-life measurements. However, the shape has been simplified as only the functional parts of the supply veins needed to be recreated. For the connection between the pulmonary vein and ventricle, the connection needs to go through the atria. A ½ inch coupler is used to enable this connection. All parts of the functional part of the heart are joined using silicone glue to establish a fluid-tight bond.

Visual sleeve

The visual sleeve consists of a realistic heart sleeve, an aorta, and a pulmonary artery. Attached to the sleeve are small latex tubes that simulate the coronary arteries. The same latex tubing is provided as the graft material. The idea is that the coronary arteries can be taken from the heart sleeve after an anastomosis is performed and will be replaced by new ones. After removing the anastomosed arteries, fluid can be put into the latex tubes to verify and check whether the anastomosis has been performed correctly.

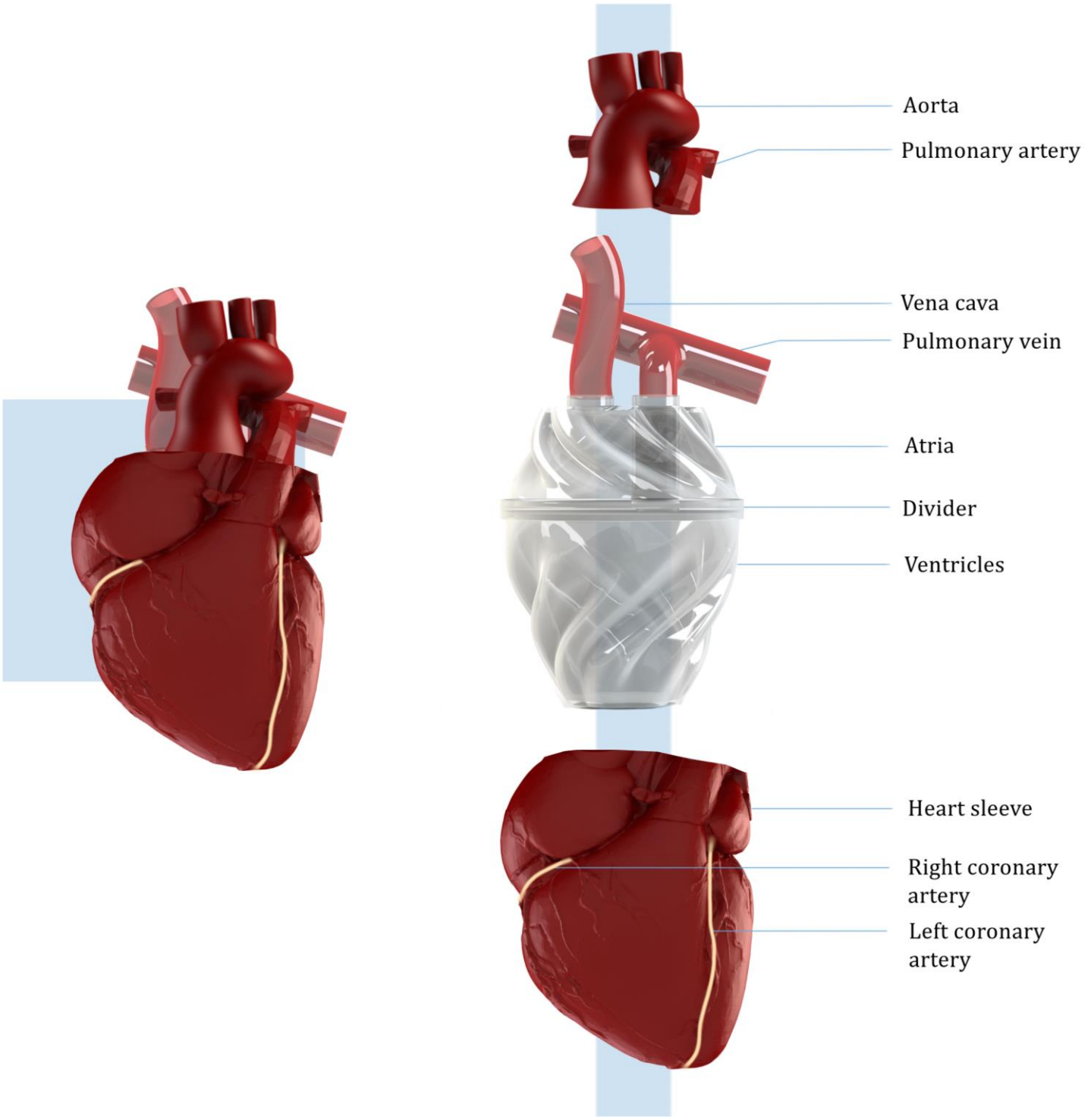

Figure 9-1: Final design of the simulated heart. The functional heart includes a vena cava, pulmonary vein, atria, divider, and ventricles. The visual heart sleeve includes an aorta, pulmonary artery, heart sleeve and coronary arteries.

9.1.2 The Actuation and Hemodynamic System

The actuation system is responsible for the fluid transport within the simulated heart. It utilizes a rotational motor movement that is translated to generate a linear movement. This linear movement is then translated to push and pull the fluids in the atria and ventricles, creating a reciprocating fluid flow. Although the same actuator is used for both the atria and the ventricles, the fluids are separated from each other. Two syringes are aligned in such a way that when one syringe is pushed in, the other is pulled out. This arrangement results in a flow mechanism where the atria are filled and the ventricles are emptied simultaneously.

The system uses ½ inch tubing to connect to the simulated heart. Connectors with luer locks are placed between the tubing segments. The luer lock connectors are used as a filling system and to attach the two blood pressure transducers (See Appendix G: Final Prototype Design).

The two blood pressure transducers provide the information for the hemodynamic feedback system through the monitor of the heart-lung machine located in the Blood Lab of the University of Twente. The monitor will display the registered pressures during the simulated surgery. Incorrect heart manipulation will result in a pressure increase, indicating and displaying the improper movements by the user. Figure 9-2 provides a schematic overview of how the actuation system, the heart, and the hemodynamic sensors are linked to each other.

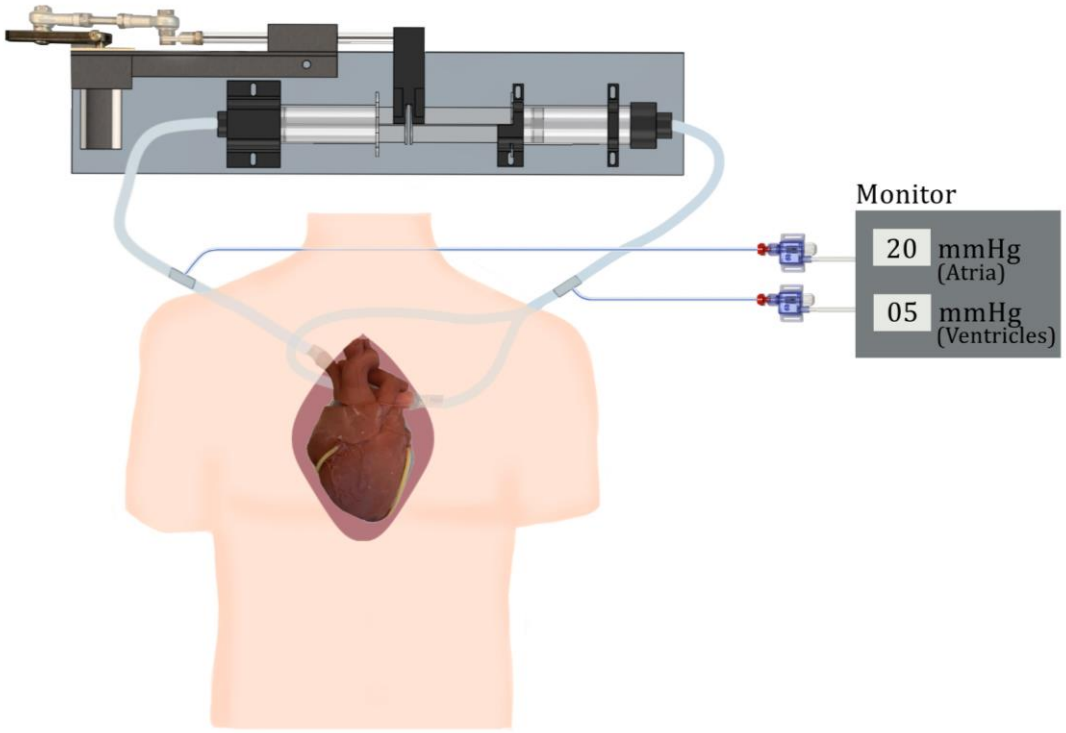

Figure 9-2: Schematic overview of how the actuation system and hemodynamic feedback system are connected to the heart of the OPCAB simulator. The pressure transducers are connected to the monitor and display the simulated blood pressure of the atria and ventricles.

9.2 Prototype Development

A prototype is developed based on the conceptual design described in Section 9.1. The prototype development is split up into two components: the simulated heart and the actuation system. Figure 9-3 displays simplified drawings of the two separate systems. The fabrication of the prototypes is briefly described and visualized below. Since the hemodynamic sensors are ready-made parts, no prototype of this is required. However, incorporating these sensors must be considered during the development of the heart and actuation system.

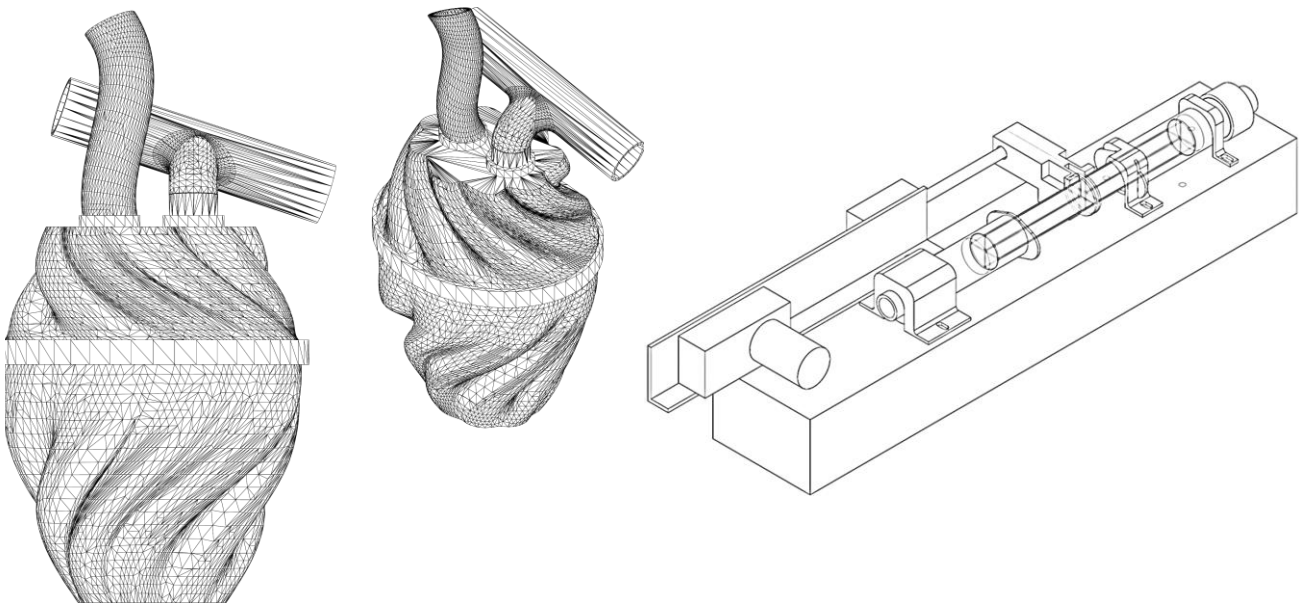

Figure 9-3: Left) Mesh of the functional heart prototype. Right) Schematic drawing of the actuation system.

9.2.1 Simulated Heart Prototype Development

The heart of the OPCAB simulator will be made of HT 33 silicone as substantiated in Section 7.3.1. An overview of the parts of the simulated heart is depicted in Figure 9-4. The overview distinguishes between the functional part of the simulated heart, which will be connected to the actuation system, and the visual parts, which are necessary for realism and performing the anastomosis. The heart sleeve design was based on an online available STL file of a heart scan [65] of a heart, which was then converted into a 3d model of a mould using Blender. The simulated coronary arteries are latex tubes with a 4 mm outer diameter with a 1 mm wall thickness.

The silicone parts of the heart are created using moulds. The heart design incorporates a total of eight silicone parts, creating the need for eight moulds. A description of how the moulds were designed can be found in Appendix G: Final Prototype Design. An overview of all designed moulds can be seen in Figure 9-5. All moulds except those for the aorta and pulmonary artery were redesigned in the framework of this thesis.

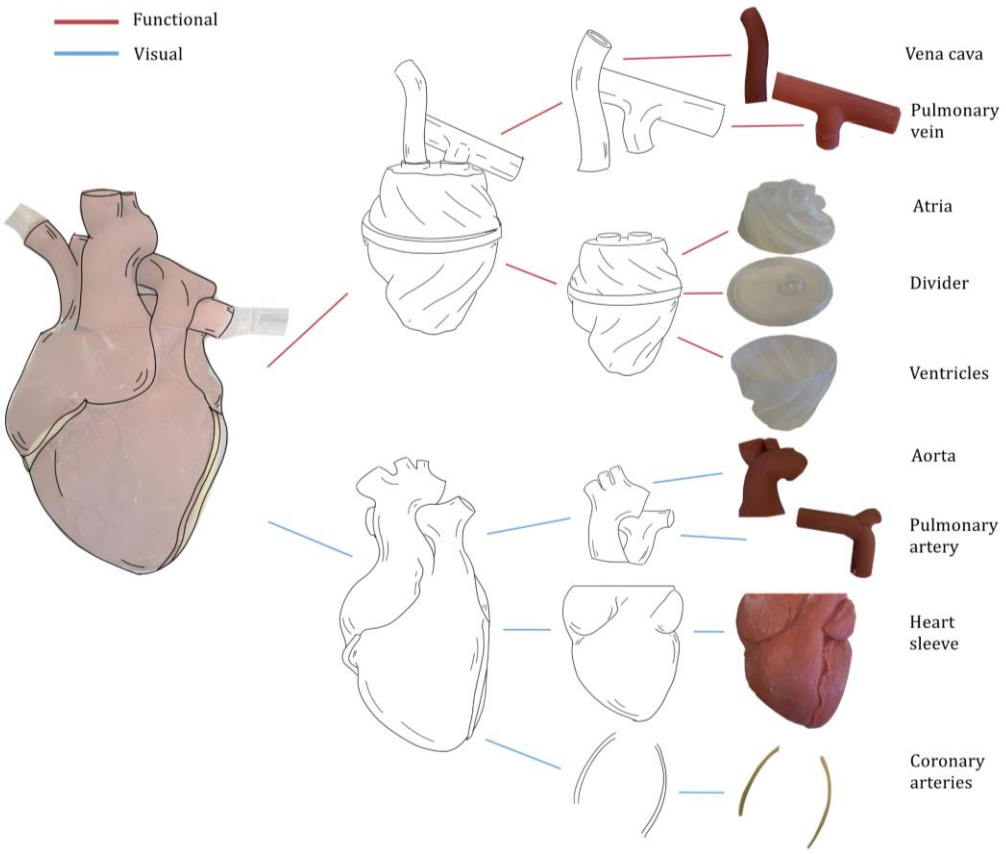

Figure 9-4: Overview of the prototype parts of the simulated heart. Split into the **functional** and **visual** parts of the heart design. First showing a sketch of the part and follows with the fabricated prototype part.

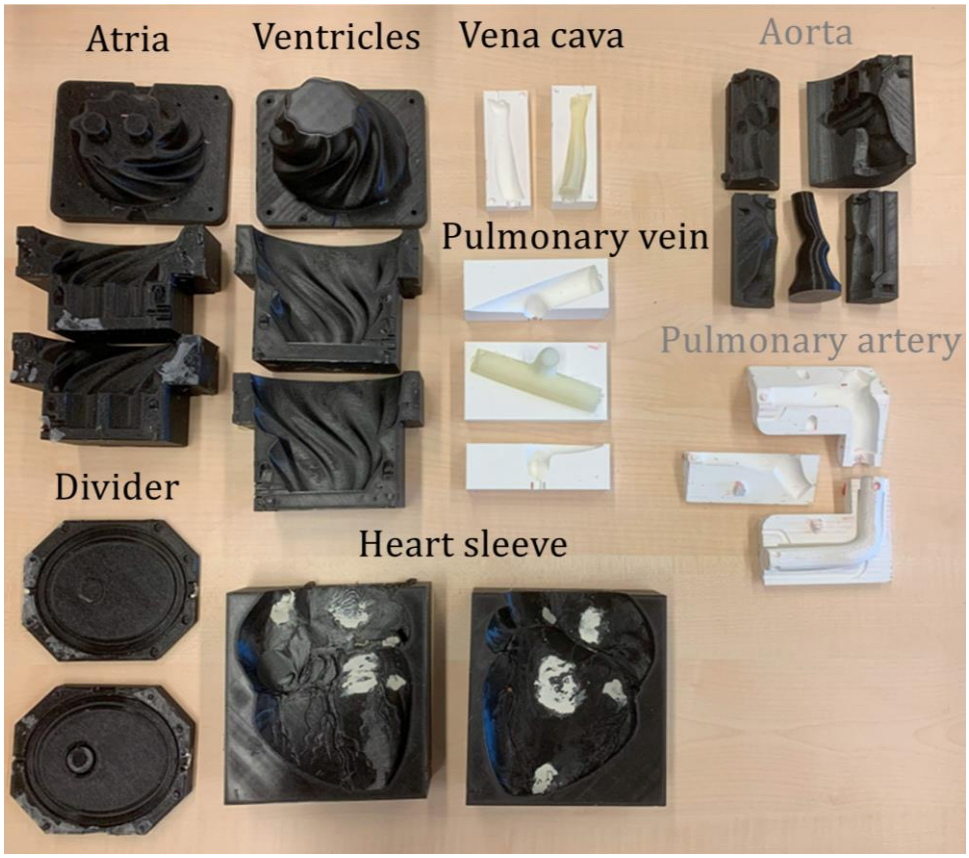

Figure 9-5: 3D printed moulds of the simulated heart parts. **Black:** new mould designs, **Grey:** moulds adapted and taken from De Jong [4].

9.2.2 Actuation System Prototype Development

For the actuation system of the OPCAB simulator, it was decided to develop a prototype that uses a reciprocating flow system and linear motors. Initially, the concept required two linear motors, one to fill the atria and another to fill the ventricles. However, to simplify the synchronisation of the motors that is necessary to create a correct heartbeat beat it was opted to use one motor for the prototype. The single motor was used to simultaneously pump fluid from the atria and fill the ventricles with fluid, and the other way around.

The new, simplified design was assessed to establish whether the concept of a reciprocating flow mechanism using a rotational motor with a crank mechanism can be used as a basis design to achieve the desired functionality and requirements of implementing a hemodynamic feedback system to the OPCAB simulator.

The actuation system consists of two syringes to move the fluid, driven by one rotary motor and a slider-crank mechanism (Figure 9-6 shows the rotary motor with a slider-crank mechanism). Modifications have been made to these syringes to create a larger opening, enabling connection to ½ inch tubing. Connection components have been designed and 3d printed to connect the following:

- Slider-crank mechanism to syringe plungers;
- Syringes to tubing;
- Syringe to a plexiglass box;

Figure 9-6: Slider-crank mechanism driven by a rotary actuator DC24V 120 RPM (Rotations Per Minute).

A plexiglass box to mount all parts on was constructed using laser-cut parts and assembled using acetone as an adhesive. Most of the connection parts are designed to be secured using nuts and bolts as couplers. However, the syringe-to-tubing connector uses silicone glue as an adhesive to ensure a fluid-tight seal. Figure 9-7 illustrates the configuration of the 3d printed parts, the slider-crank mechanism, syringes, and plexiglass box.

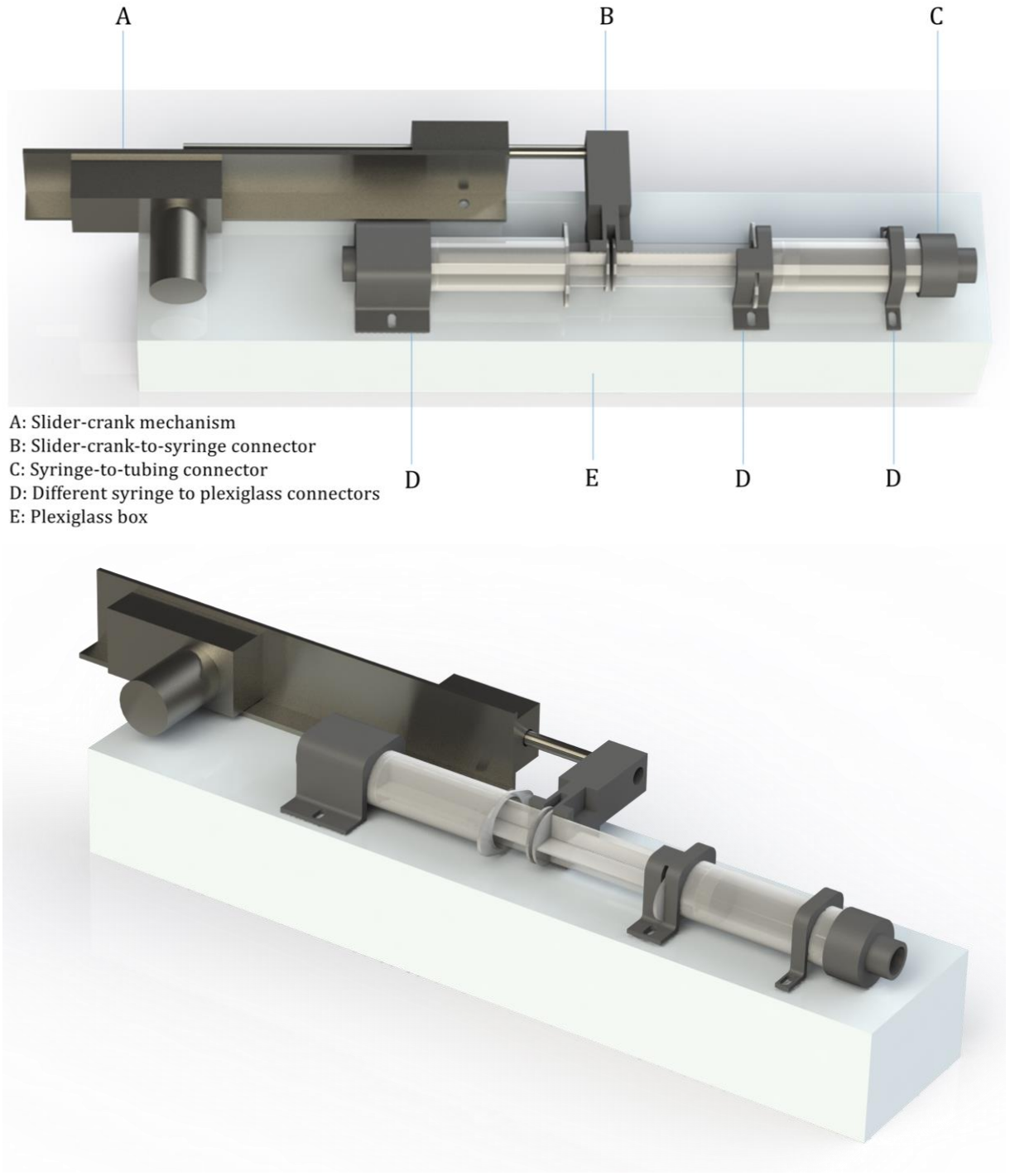

Figure 9-7: 3D render model of the actuation system. B, C, and D are the 3D-printed connection parts.

9.2.3 Final Prototype Design

Figure 9-8 shows the prototype of De Jong next to the simulated heart prototype developed during the work of this thesis. The most noticable design change is in the simulated heart.

Figure 9-9 illustrates the developed prototype of the OPCAB simulator, which consists of the simulated heart within the torso model, along with the medical equipment (retractor and stabilizer) and actuation system. Additional images can be found in Appendix G: Final Prototype Design

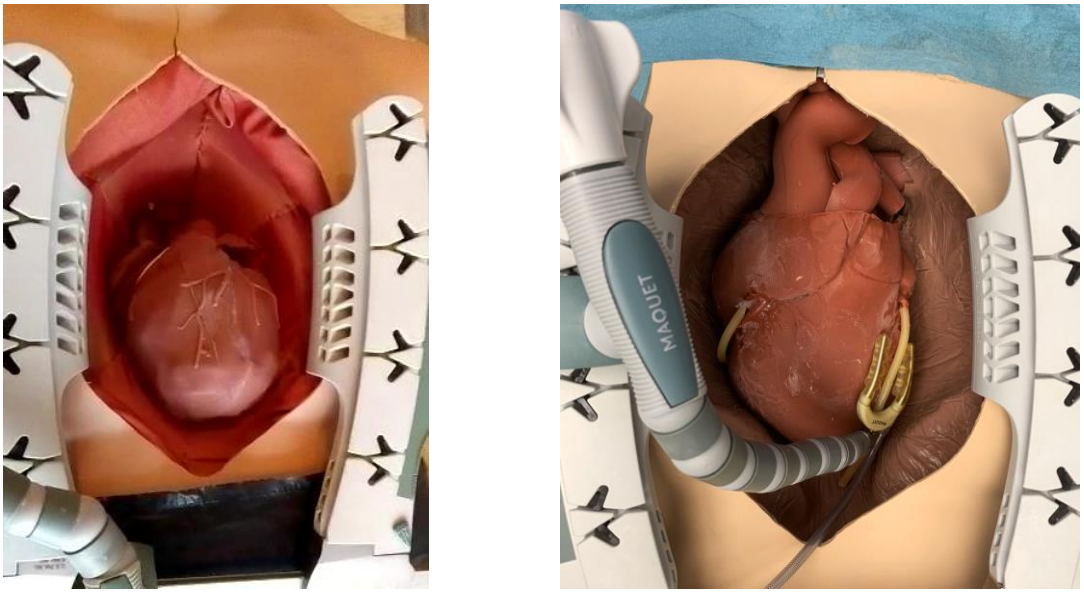

Figure 9-8: Left) Final prototype design of the simulated heart of De Jong [4]; Right) Final prototype design of the simulated heart developed by the author of this thesis.

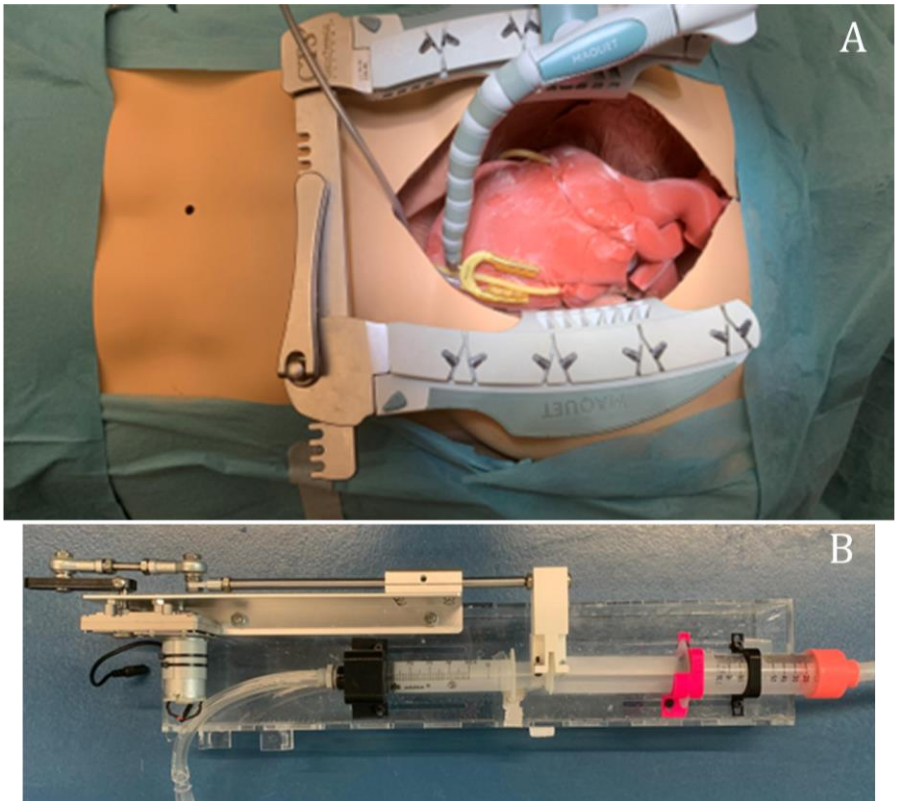

Figure 9-9: Images of the final prototype design A) OPCAB simulator B) Actuation system.

10 Prototype Design Evaluation

In this chapter, the prototype design will be tested and evaluated on several aspects to verify whether the final prototype design of the OPCAB simulator meets the design goal: **Developing a prototype OPCAB simulator that functions as a proof of concept, featuring a life-like beating heart and an integrated hemodynamic feedback mechanism**.

10.1 Simulated Heart Evaluation Tests

Requirements related to creating the movement of a realistic life-like beating heart were provided in Section 6.2. The final prototype design of the simulated heart underwent verification tests related to the angle of twist and volume change of the heart.

10.1.1 Angle of twist

Purpose:

The angle of twist is determined in order to evaluate whether the ventricles have the required counter-clockwise twist and the atria the clockwise twisting.

Methods:

The location of the bottom of the ventricles and the top of the atria, with and without the heart sleeve were recorded. Video images, capturing the heart at its largest and smallest points, were taken and overlayed. A visible separation line from the moulding of the silicone was still present. This line was used as a guide for measuring the twist.

From this, the angles of (counter) clockwise twist between the largest and smallest points were calculated, using the program ImageJ. This was calculated for the ventricles without sleeve, the ventricles with sleeve, and the atria without sleeve. Because there was no system to secure the sleeve on top of the atria, it was not possible to take measurements for the atria with the sleeve were taken, nor accurate measurements of the angle of twist from the atria with the sleeve.

The results of the twist of the ventricles and atria without the heart sleeve will be compared to the requirements.

Results:

Figure 10-1 shows an example of how the overlayed images were used to calculate the angle of twist. The results of the measurements of the angle of twist validation test and the required angle of twists are listed in Table 10-1. The complete set of results from ImageJ can be found in Appendix G: Final Prototype Design.

Table 10-1: Measured and required angle of twist for the ventricles and atria.

	Measured twist (°)	Required twist (°)
Ventricles	15,02	12 ± 6
Ventricles with heart sleeve	4,91	12 ± 6
Atria	7,60	7 ± 3
Atria with heart sleeve	N.A.	7 ± 3

Discussion:

The measured twist of the ventricles is 15 degrees, which achieves the required counter-clockwise twist of 6- 18 degrees when it is applied to the simulated heart without sleeve. However, the results show that the twist of the ventricles with the heart sleeve was only one-third of the level of twist of the ventricles without the heart sleeve, albeit not far from the minimum required. This result could be expected, as the designed sleeve was intended solely as a visual enhancement for the simulator. It is expected that after adjustments or additions to ensure the sleeve twists smoothly with the ventricles, the required twist can be achieved. Furthermore, the addition of the sleeve increases the wall thickness, thereby requiring more power to achieve the necessary movement of the heart.

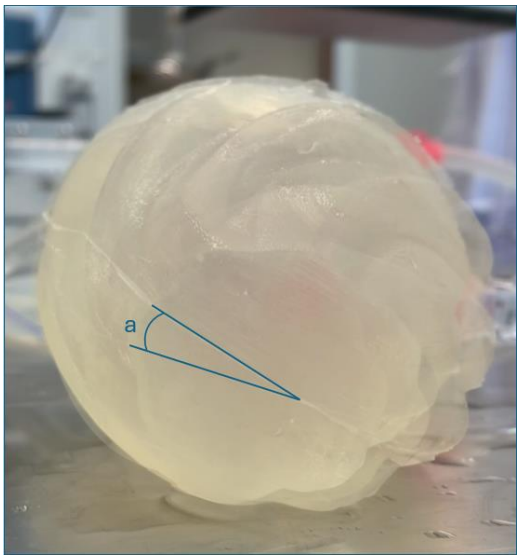

Figure 10-1: Image of how the angle (a) of twist of the ventricles was measured.

The angle of twist of the atria was measured to be 7,6 degrees, which falls within the requirement set of a counterclockwise twist between 4 and 10 degrees. The measurement of the atria with the heart sleeve was not performed, but if the same reduction caused by the sleeve is applied to the atria twist, the result would be 2,5 degrees, which is just below the requirement.

10.1.2 Heart volume change

Purpose:

The design specification for total heart volume change requires a percentage between 8.2% ± 0.8%. Since the simulated heart is powered by a fluid system, this volume change should be achieved by having a specified amount of fluid moved in and out to generate the movement of the heart. Unfortunately, the volume change cannot be directly translated to a volume of fluid. Since the system uses silicone tubes, volume changes can be absorbed there. Additionally, volume change is lost due to the silicone divider in the heart. When fluid is pushed into the atria or ventricles the wall divider moves with it, reducing the visible volume change in the atria and ventricles. Thus, to achieve an 8% total volume change of the heart, considerably more than 8% should be added to the system.

Besides the correction for volume changes, to simulate a correct heart movement, also the location of the volume change is of importance in replicating a life-like beating heart.

Methods:

Videos of the side and front view were recorded, and overlays of these images were created to compare the size differences between the heart in its normal (empty) state and its filled state (See Figure 10-2).

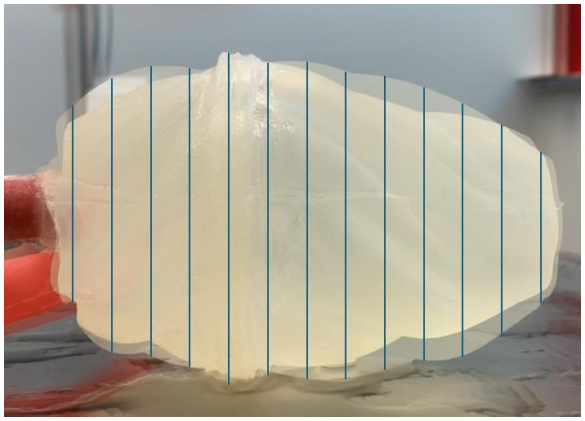

Figure 10-2: Overlay side view of the volume change in the simulated heart with the 13 measuring slices.

Similar to the method performed by Carlsson et al. [52] in their study on total heart volume variations, the heart was divided into 13 evenly spaced measuring slices. These measuring points provided data on the diameter changes in the depth and width of the heart. Using the diameter measurements, the total area of the filled and empty heart was calculated.

This data was used to determine the volume change of the slices of the simulated heart. A graph (Figure 10-3, left) was plotted to visually represent these measurements.

To establish whether the volume changes were located at the correct location, the percental volume change per slice was plotted. This was done for our prototype, while the real heart data from Carlsson et al. [52] were used. This approach, by using a similar method, allows for a direct comparison. (Information about Carlsson et al.'s graphs can be found in Appendix C: Requirements).

Results:

For the newly developed prototype, a resulting graph of the volume differences between the filled and empty heart per slice is shown in Figure 10-3 (left). The plot of the change in volume can be found in Figure 10-3 (right). Detailed data, e.g. images of the overlays can be found in Appendix G: Final Prototype Design.

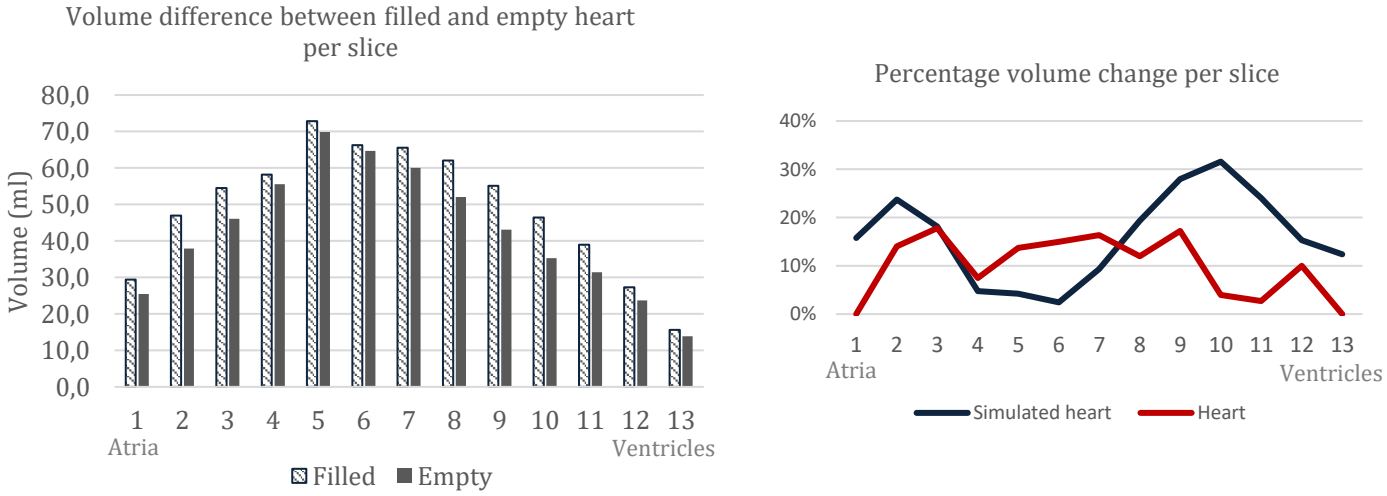

Figure 10-3: Left) Graph of volume changes per slice of the simulated heart. Right) Percentage of volume change per slice; **blue** line is this study, **red** line from [52].

Discussion:

Carlsson et al. [52] state that the largest volume change was found at the largest plane, where the atria and ventricles meet. The heart's percental volume change per slice is the red line of Figure 10-3 (right) gathered from the data of Carlsson et al. [52].

In the results of the volume change per slice of the simulated heart, it can be seen that the largest volume change in the simulated heart (this study) is not at the largest point of the heart. This becomes more visible in the blue line of Figure 10-3 (right), which depicts the percental change per slice.

The largest plane of the simulated heart is the location of the divider, which is the most rigid part of the heart. So it is logical that the maximum change is not found here.

In some places, the percentage of volume change exceeds the volume change percentage of the real heart. With the addition of the sleeve, this too high volume change will likely be reduced. The heart sleeve that was used does not fit tightly, creating air gaps between the simulated heart and the visual heart sleeve. The use of an improved sleeve is expected to reduce the total volume change of the heart.

10.2 Hemodynamic Feedback Fechanism

Purpose:

A test to evaluate whether the hemodynamic feedback mechanism functions properly was performed. The specific aim of this test was to investigate whether the hemodynamic feedback system shows pressure changes during incorrect manipulations of the simulated heart.

Methods:

During initial testing, it was observed that the designed pulmonary vein was too flexible due to a thin wall thickness that was created to replicate the real-life vein thickness. This thinner wall thickness created instability in the pulmonary vein as it was the most flexible part of the simulator. When the actuation system was connected and began pumping fluids, the pulmonary vein deformed excessively, leading to self-vacuuming and compromising the system’s functionality. To mitigate this issue, an adaptation was implemented to strengthen the wall by increasing the wall thickness of the pulmonary vein, thereby enhancing its structural rigidity and preventing the occurrence of self-vacuuming.

A fluid-filled actuation system was connected to the pressure transducers via a luer lock system. The output of the transducers was displayed on the monitor of the heart-lung machine. Pictures of the transducer output on the monitor can be seen in Figure 10-4.

A baseline measurement to establish the range of pressures during no manipulation was executed. To test whether the hemodynamic feedback system showed pressure changes during incorrect manipulations, the heart prototype was manipulated in ways known to have a negative effect on blood pressure during a real-life OPCAB surgery. Seven manipulations included six compression locations and lifting of the apex of the heart upward. Figure 10-5 provides details on the compression locations.

The seven manipulations were repeated six times and it was observed whether the compression or lifting showed a noticeable change in pressure.

Figure 10-4: Screen capture of the hemodynamic feedback evaluation test. Left: OPCAB simulator. Right: monitor with output of the pressure transducers, atria output (19) and ventricle output (-1) in mmHg.

Results:

Baseline measurement: range between 15 and 30 mmHg for the atria and for the -13 and 35 mmHg ventricles. A summary of the results per manipulation can be seen in Table 10-2. Appendix H: Prototype Design Evaluation has a link to the recording result of the test.

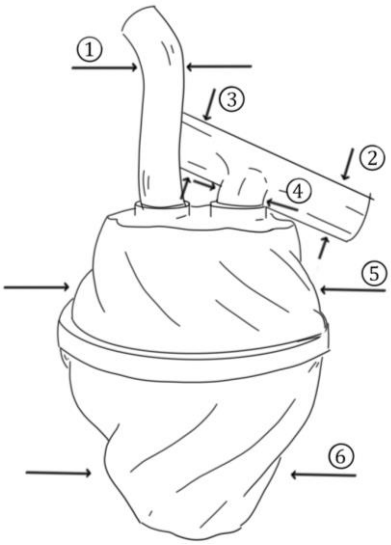

Figure 10-5: Overview of compression locations during hemodynamic feedback evaluation.

Table 10-2: Results of the hemodynamic feedback evaluation.

	Manipulation	Result	Pressure difference result
1	Compressing the vena cava	6/6	✓
2	Compressing the left branch of the pulmonary vein	0/6	×
3	Compressing the right branch of the pulmonary vein	0 /6	×
4	Compressing the pulmonary vein	6/6	✓
5	Compressing the atria	6/6	✓
6	Compressing the ventricles	6/6	✓
7	Lifting the apex of the heart upwards	6/6	✓

-/6: amount of measured results ✓: Positive pressure difference result, ×: Negative pressure difference result.

Discussion:

Overall the hemodynamic feedback system shows whether an incorrect manipulation of the simulated heart was performed. Compression specific to the left or right branch of the pulmonary vein did not result in a noticeable pressure difference. The other manipulations did show a noticeable change in pressure during the manipulation. For lifting of the apex the changes were small . Although this pressure is different from what is expected in real-life surgery, the primary objective was to determine whether any observable pressure difference would occur.

10.3 Requirements Evaluation

The design specifications of the prototype of the final design were compared to the list of requirements established in Section 6.2. The results are based on the functional heart without the sleeve. The relevant categories include the heart, the movement, and the hemodynamics. Table 10-3 presents the design specifications, the results, and whether or not the specification was achieved. Discussion on the requirements evaluation is presented in Section 11.1.1

Table 10-3: Design specification results on the heart, movement, and hemodynamics of the OPCAB simulator.

Heart					
	Specification	Value	Unit	Result	Achieved
02-01.01	Total heart length	80-140	mm	118 mm	✓
02-01.02	Total heart width diameter	85-150	mm	102 mm	✓
02-01.03	Total heart depth diameter	60	mm	86 mm	×
02-02.01	The heart model has simulated atria and ventricles	True	N.A.	True	✓
02-02.02	The heart model contains the pericardial part of the vena cava, aorta, pulmonary vein, and pulmonary artery	True	N.A.	True	✓
Movement					
	Specification	Value	Unit	Result	Achieved
05-01.01	Heart rate of beating heart	50-100	BPM	40-60	✓
05-01.02	Total heart volume change	8.2 ± 0.8	%	17.36 %	×
05-01.03	Heart model longitudinal shortening	0,9 ± 0,5	%	2.37%	×
05-01.04	Maximum heart transverse area increase	17,8	%	31.6 %	×
05-01.05	Heart model clockwise twisting atria	7 ± 3	°	7.60 °	✓
05-01.06	Heart model counter-clockwise twisting ventricles	12 ± 6	°	15,02 °	✓
05-01.07	Correct phasing and combination of cardiac movements	True	N.A.	False	×
05-02.01	Simulator has a fluid-pumping system	True	N.A.	True	✓
05-02.02	Atria fluid reservoir	> 8% of 125 ml	%	50 ml	✓
05-02.03	Ventricles fluid reservoir	> 8% of 250 ml	%	100 ml	✓
Hemodynamics					
	Specification	Value	Unit		
06-01.01	Display heart rate	True	N.A.	False	×
06-01.02	Display blood pressure	True	N.A.	True	✓
06-02.01	Measure simulated blood pressure	True	N.A.	True	✓
06-03.01	Show change in hemodynamics if flow into atria is compromised	True	N.A.	True	✓
06-03.02	Show the change in hemodynamics if flow into ventricles is compromised	True	N.A.	True	✓
06-03.03	Show change in hemodynamics if the heart is compressed	True	N.A.	True	✓
06-04.01	Simulator can be put in Trendelenburg's position	True	N.A.	True	✓

✓: Requirement is achieved, ×: Requirement is not achieved

10.4 Fidelity Level Evaluation

The initial overall fidelity classification (Section 4.3) of the prototypes developed by De Jong and Moejes was mid-fidelity and ranked 4, while the subsequent prototype by Buitenhuis fell into a low-fidelity classification and ranked 5. A fidelity level evaluation and comparison were conducted to assess whether the new prototype of the final design has shown an improvement in fidelity classification and ranking.

The results of the overall fidelity classification and ranking are presented in Table 10-4, including the results of the newly developed prototype into the total overall fidelity classification and ranking. Table 10-5 provides further details on the specific categories that determine the overall fidelity.

The overall fidelity of the new prototype is a mid-level which is comparable to the previous prototype of De Jong and Moejes, but an improvement compared to Buitenhuis. The new prototype ranked second in the total list of OPCAB simulators.

When looking at the specific categories, it is revealed that the new prototype achieved a high level of component fidelity, indicating improvements in this specific area. The new prototype incorporates twice the number of components compared to the previous design developed by Buitenhuis. Definition-based and customisation fidelity scored the same as the previous prototypes. This is to be expected, as the scope of the thesis was not on improving these categories.

Table 10-4: Overall fidelity classification and ranking including the new OPCAB simulator prototype.

	Source	Material	Definition-based fidelity	Component fidelity	Customization fidelity	Overall fidelity
	EBM (2024) [38]	S	Low	Low	Low	**Low**
6	Izzat (1998) [44]	S+P	Low	Low	Low	**Low**
	Donias (2003) [46]	P	Low	Mid	Low	**Low**
5	Buitenhuis (2022) [5]	S	Mid	Low	Low	**Low**
	Reuthebuch (2002) [45]	S	Mid	Mid	Low	**Mid**
	De Jong & Moejes (2020) [4, 6]	S	Mid	Mid	Low	**Mid**
	Wu (2021) [47]	S+P+H	Mid	Mid	Low	**Mid**
4	Maluf (2015) [39]	S+P	Mid	Mid	Low	**Mid**
3	The Chamberlain Group (2024) [41]	S	Mid	Mid	Mid	**Mid**
	Pels (2024)	S	Mid	High	Low	**Mid**
	KindHeart (2024) [42, 43]	P	High	Mid	Low	**Mid**
	Ribeiro (2017) [49]	S+P	High	Mid	Low	**Mid**
2	Liu (2016) [48]	LP	Mid	High	Low	**Mid**
1	Bouma (2015) [40]	H	High	High	High (Low)	**High (High)**

1-6 is the rank of the OPCAB simulator 1 is highest; S = Synthetic, P = Porcine, H = Human cadavers, LP = Living porcine. Blue text results are from the simulator that is argued to be customizable.
Marked in blue is the simulator developed by the author of this thesis.

Table 10-5: Specification of the definition-based, component, and customisation fidelity of the previous prototype and current prototype. Specifics on component fidelity can be found in Appendix H: Prototype Design Evaluation.

Device	Conceptual fidelity	Functional fidelity	Physical fidelity	Psychological fidelity	Definition-based fidelity
De Jong & Moejes [4, 6]	C+P	-/+	-/+	-/+	Mid
Buitenhuis [5]	C+P	-/+	-	-/+	Mid
Pels	C+P	-/+	-/+	-/+	Mid

Device	AC (11)	OC (6)	SC (4)	EC (3)	Total (24)	Component fidelity
De Jong & Moejes [4, 6]	8	3	0	2	13	Mid
Buitenhuis [5]	5	1	0	2	8	Low
Pels	9	4	2	2	17	High

Device	Sex	Age	Size	Disease/ Anatomy	BMI	Skin colour	Total (6)	Customisation fidelity
De Jong & Moejes [4, 6]	No	No	No	Yes	No	No	1	Low
Buitenhuis [5]	No	No	No	No	No	No	0	Low
Pels	No	No	No	No	No	No	0	Low

C: Computational, P: Physical; -: Low, -/+: Mid, +: High; AC: Anatomical components, OC: operational components, SC: scenario components, EC: environmental components.

11 Discussion & Conclusion

This chapter contains the discussion, consisting of an evaluation of the requirements and points out some limitations of the project, recommendations for future work, and a conclusion.

11.1 Discussion

This section discusses the design evaluation of the new OPCAB simulator prototype, specifically evaluating how well the prototype met requirements for the heart, movement, and hemodynamics. The numbers and results have been summarized in these three categories in Table 10-3 in Chapter 10.3. Due to the scope of the project, the evaluation was limited to these three relevant categories, rather than the eleven categories outlined in the total program of requirements found in Appendix C: Requirements.

An important limitation that arose during the project is discussed in this section.

11.1.1 Requirements Evaluation Discussion

In the heart category of Table 10-3, all requirements were not met, except for requirement 02.01.03, relating to the total heart depth diameter. The final prototype of the work described in this thesis exceeded this requirement by 2,5 cm. This overshot requirement is the result of the incorporation of new reference measurements for the heart's length and width, resulting in an increase in the overall heart size. However, no new references for the depth were found. To maintain the correct proportions of the heart, it was decided to enlarge the heart's depth accordingly, resulting in a measurement that failed to meet the set (obsolete) requirement.

In the movement category of Table 10-3, six of the ten requirements were met. Three requirements related to the volume change of the heart were not achieved and exceeded the requirement. As mentioned in Section 10.3, those requirements were assessed with the heart without the sleeve, which affected the result to exceed the requirement. The sleeve was designed primarily for visual aid and has not yet been optimized to seamlessly incorporate the movement mechanism of the heart's functional components. To avoid negatively impacting the measurements, the requirements evaluation was conducted without the sleeve. Without using the sleeve, exceeding the volume change requirements does not necessarily indicate a flaw in the design. If the heart, will be combined with an improved sleeve, and the motions would still be excessive, the volume change can easily be adjusted by reducing the amount of fluid pumped in and out of the heart. In that way, it will become possible to comply with the requirements that are now not met.

The other requirement in the movement category that has not been fulfilled in the final prototype design is 05-01.07. This requirement states that the heart should include correct phasing and cardiac movements. The simulated heart does show correct cardiac movements by moving and

twisting the heart similarly to a real heart. However, the phasing is only slightly incorrect. In a real heartbeat, a small pause occurs between the atrial and ventricular contraction. The final design does not include this small pause. The reciprocating flow of the atria and ventricles are aligned with each other and powered by the same motor. The addition of a pause phase can easily be implemented when the actuator system of the heart consists of two motors.

In the category Hemodynamics of Table 10-3 all requirements were met except one: 06-01.01, “Display heart rate. The heart rate of the actuation system of the OPCAB simulator is in the final design regulated by the RPM of the linear actuation system. The full monitoring system still needs to be developed.

11.1.2 Limitations

At the beginning of the thesis, a boundary was set to use the design of Buitenhuis [5] as a starting point for the design. It was assumed that since designs with established requirements, as evaluated by Buitenhuis [5] and De Jong [4], were deemed correct, they could once again be implemented during this project. Buitenhuis [5] evaluated his new movement mechanism using these requirements. Therefore, the shape and functioning of this mechanism were reused as the starting point of this project. However, later in the project, it was discovered that the reference used as substantiation for the requirements on the enlargement of the heart during a heartbeat were the measurements of a different parameter of the heart and did not relate to the volume change of the heart. A new reference paper was found, resulting in new information on how the heart volume changes during a heartbeat. New requirements were established and the evaluation of the design was done using these new parameters. However, the discovery of the incorrect requirements occurred after the development of the heart design had already been completed. Due to time constraints, it was not possible to make full adjustments to better align the design with the newfound information and requirements.

The requirement tests on the angle of twist, heart volume change and hemodynamic feedback were conducted and interpreted on the functional heart without the visual heart sleeve. The tests were conducted without the heart sleeve, as it was solely designed sleeve as a visual enhancement for the simulator and would negatively skew the performance of the functional heart. Not including the sleeve presents a limitation in the evaluation of the complete OPCAB simulator.

11.2 Recommendations

Several recommendations have emerged from this project and may provide a guide for future developments and improvements of the OPCAB simulator.

During the project when the chosen concept was adapted to make a prototype, the design was simplified to first create a proof of concept using only one motor before incorporating a second motor and better-designed fluid reservoirs. The use of a second motor will likely improve the design because, when two motors are implemented, the movements of the atria and ventricles are no longer dependent on each other. In the current design, the same force is used to pull fluid from the atria and simultaneously fill the ventricles, doubling the force needed by the actuator system. With the adaptation of a two-motor system, the linear actuators would only need to either push or pull the fluids, thereby creating increased force and the capability to simulate a higher heart rate and arrhythmias. Additionally, as previously noted, this adaptation could contribute to

improving the phasing of the heartbeat, enabling the small pause that should be introduced so that it can fulfil requirement 05-01.07 (See 11.1.1) Regarding the linear actuator, further research should be performed to determine the most suitable type of motor for this design. Currently, rotational movement is translated into linear movement, however, implementing a motor that directly creates linear movement could improve the system. Additionally, consideration could be given to implementing a roller pump, as described in the concept phase, which is adapted to generate a reciprocal flow.

In the final prototype, the filling of the system with fluids was challenging. Some ideation should be done on how to effectively fill the system with fluids where no air pockets remain in the heart. Currently, there are luer-lock connections that function as valves to fill the system with water and remove the air bubbles. However, filling the heart while it is located inside the torso proved difficult to eliminate all air bubbles. Having the heart inside the torso is an important factor for the simulator, therefore, this issue should be addressed in future work.

In the hemodynamic feedback system, the output of the transducers is different than from the real-life situation. This is not something negative, as the simulator is designed to indicate a wrong manipulation, and not to indicate a real-life blood pressure. However, in a future version of the prototype, a system should be added that reads the pressure transducers' output and translates them into realistic blood pressure values which would be displayed on a monitor. An added sound indication could also provide feedback when the blood pressure is out of the normal range for a longer period.

A recommendation that follows from the limitation mentioned above (Section 11.1.2), is on adapting the shape of the functional part of the heart. The shape of the functional heart has the divider as the largest point of the heart, but due to the divider, the volume change at that point is very limited compared to the rest of the heart, which is contradictory to the research of Carlsson et al. [52] on the volume change of a real heart. Additionally, the design of the heart sleeve has a more anatomically correct shape and does not nicely fit around the functional part of the heart. This leads to gaps and limits the twist and movement of the simulated heart. Improvements in the shape of the functional part of the heart and placement of the divider should be implemented in the redesign in future work. Likewise, improvements on the heart sleeve itself are required. With the shapes of the heart sleeve and functional heart being different, the movements are not effectively translated. Both the heart and sleeve should be taken into account when redesigning the shape. Furthermore, the current sleeve design does not include a connection part to keep the sleeve in the correct place. Within the design of the connection part of the sleeve to the heart, a way to correctly attach the heart to the pericardial sack could be implemented.

At the current point of development of the OPCAB simulator, knowing that there are improvements to be made, feedback of surgeons could be asked to confirm whether they agree with the intended improvements and additions. Conducting a pilot surgery test on the simulator at this stage is premature given the current developmental state of the simulator. Only after addressing and implementing recommended improvements, a pilot test with surgeons should be performed.

The result of the fidelity level check of the evaluation of the final design showed that the overall fidelity classification of the newly developed OPCAB simulator is mid-level fidelity. This is the same as the design of De Jong and Moejes but is an improvement compared to Buitenhuis. Moreover, the rank of the new OPCAB simulator design achieved a rank of 2 out of 6, an improvement over the design of De Jong and Moejes, which ranked 4 out of 6. In the overall fidelity analysis, only

the simulator of Bouma et al. [40] with a 1 out of 6 rank. Which is a simulator that utilizes human cadavers and has an estimated cost of 3765 euros per day [40].

Given that the design goal of the project is focused on improving the beating heart and incorporating a hemodynamical feedback mechanism, it is logical that the improvement was most substantial in component fidelity and less in customization and definition fidelity. Resulting in the overall classification of a mid-fidelity classification, even though the ranking improved. A third of the fidelity level classification is focused on the customization of an OPCAB simulator. Adding customization to the simulator is something that should be focused on later in the development process after the current components of the simulator have proven to work and are approved by the surgeons. Nevertheless, it is an important function of the simulator to be implemented and should be taken into consideration during the next iterations of the design.

Future work on an addition to the fidelity analysis of OPCAB simulators is adding an analytic hierarchy process on all parts that determine the fidelity level of the OPCAB simulator. This will provide the next developer with knowledge on identifying the most important parts of the OPCAB simulator according to a focus group of potential users. The results of this method can assist in creating a structured plan identifying which components need priority to implement next.

11.3 Conclusion

This thesis describes the development of an improved OPCAB simulator. The OPCAB simulator was created by developing an improved silicone beating heart design which is powered by a fluid flow system, where hemodynamic feedback is included through implementing medically used pressure transducers. Thus, the design goal of this thesis has been achieved, which was to develop a prototype OPCAB simulator that functions as a proof of concept, featuring a life-like beating heart and an integrated hemodynamic feedback mechanism.

The fidelity analysis of the current OPCAB simulators indicated that no OPCAB simulators currently include a hemodynamic feedback system without the use of live animals, making the development of the design cutting edge. However, it is important to acknowledge that further iterations of the design are necessary. The focus of future work should be on optimizing the actuation system of the beating heart and improving the shape and connection of the functional heart in combination with the heart sleeve. When an improved design has been approved by pilot tests with cardiothoracic surgeons, research in implementing customization features is recommended.

As an overall conclusion, this thesis resulted in a final proof of concept design of a beating heart OPCAB simulator with an implemented hemodynamic feedback system. This overall contributes to advancing the field of medical simulator training, which is crucial given the constant need for well-trained surgeons to help those in need.

12 Terms and Abbreviations

12.1 List of Terms

Term	Literature definition
Anastomosis	"To connect two organs or body spaces by surgery" [66]
Apex	"The pointed end of an organ" [66]
Atherosclerosis	"A form of arteriosclerosis (= hardening of the arteries) that is caused by a fatty substance building up inside the arteries" [66]
Cardiac cycle	"The complete sequence of events in the heart from the beginning of one beat to the beginning of the following beat" [67]
Cauterisation	"The action of burning body tissue using heat or a chemical, to stop an injury from bleeding or getting infected, or to remove harmful cells" [66]
Cerebral mirco-emboli	Cerebral: "Relating to the brain or the cerebrum" Embolus: "Something, such as a blood clot or an air bubble, that blocks a blood vessel and stops the flow of blood" [66]
Coagulopathy	"Coagulopathy is defined as a condition in which the blood's ability to clot is impaired" [68]
Coronary arteries	"Either of two arteries that arise one from the left and one from the right side of the aorta immediately above the semilunar valves and supply the tissues of the heart itself" [67]
Diastole	"The period of time when the heart is filling with blood after contraction" [66]
Fidelity	"The degree to which the simulation replicates the real event and/or workplace; this includes physical , physiological, and environmental elements" [37]
(Frank-)Starlings law	"A statement in physiology: a muscle that is stretched within normal limits at the time of stimulation contracts more strongly than one that is completely relaxed" [67]
Hemodynamics	"A branch of physiology that deals with the circulation of the blood" [67]
Ischemia	"A medical problem in which there is not enough blood flowing to a part of the body, usually because the arteries have become too narrow. It can lead to very serious health conditions" [66]
Morbidity	"The morbidity of a disease is how many people have it in a particular population" [66]
Mortality	"The number of deaths within a particular society and within a particular period of time" [66]
Myocardium	"The muscle that forms the walls of the heart" [66]
Pericardium	"The double layer of tissue that surrounds the heart" [66]
Revascularization	"A way of improving the blood supply to part of the body either in a medical operation or as a natural process" [66]
Systole	"the part of a heart's action where it pushes blood out" [66]
Trendelenburg position	"A position of the body for medical examination or operation in which the patient is placed head down on a table inclined at about 45 degrees from the floor with the knees uppermost and the legs hanging over the end of the table" [67]

12.2 List of Abbreviations

BP	Blood Pressure
CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CO	Cardiac Output
CPB	CardioPulmonary Bypass
DBF	Definition-Based Fidelity
DP	Diastolic Pressure
ECMO	ExtraCorporeal Membrane Oxygenation
EOST	Engineering Organ Support Technologies
FDM	Fused Deposition Modelling
HR	Heart Rate
IMU	Inertial Measurement Unit
LAD	Left Anterior Descending artery
LCA	Left Coronary Artery
LCx	Left Circumflex artery
LIMA	Left Internal Mammary Artery
MAP	Mean Arterial Pressure
mmHg	Millimetres of mercury
MST	Medisch Spectrum Twente
ONCAB	ON-pump Coronary Artery Bypass
OPCAB	Off-Pump Coronary Artery Bypass
PIA	Posterior Interventricular Artery
PCI	Percutaneous Coronary Intervention
RCA	Right Coronary Artery
RIMA	Right Internal Mammary Artery
RMA	Right Marginal Artery
RPM	Rotations Per Minute
SLA	Stereolithography
SP	Systolic Pressure
SV	Stroke Volume
TPR	Total Peripheral vascular Resistance
TPU	Thermoplastic PolyUrethane

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15 References

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16 APPENDIX

During the writing of this thesis ChatGPT was used to provide inspiration and improve the formulation of the sentences written by the author. This was done to enhance the overall quality of writing. After the tool was used, the author analysed, reviewed, and edited the responses to meet the thesis quality standard. Full responsibility for the content of the work is taken by the author.

16.1 A: User Needs Analysis

Table 16A-1 User needs analysis results.

	User needs	State
UN01	Enables realistic manipulation	
UN02	Contains a feedback system on heart manipulation	
UN03	Has an anatomically correct look	
UN04	Beats realistically	
UN05	Has a realistic heart rate	
UN06	Contains a heart with realistic, different-sized coronary arteries	
UN07	Enables realistic positioning within the thorax	
UN08	Has a realistic amount of workspace around it in the pericardium	
UN09	Enables the assessment of anastomosis quality	
UN10	Enables assessment of completeness of patency by containing fluid in coronaries	
UN11	Is compatible with the surgical tools for OPCAB	
UN12	Allows for use with a complete team	

It is currently implemented in the simulator
It is implemented in the simulator but should be improved
It was at some point implemented in the simulator, but it has since been lost
It is not implemented in the current simulator

16.2 B: Fidelity Analysis

16.2.1 Graphical overview simulators

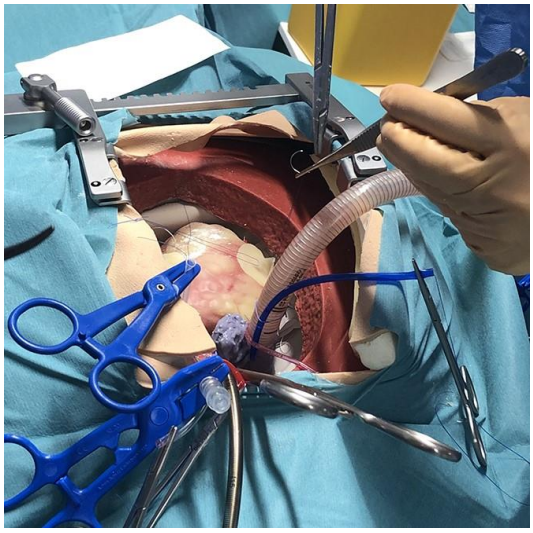


Figure 16B-1: The Chamberlain Group, High-fidelity CT surgical simulator [41] is a mid-fidelity OPCAB simulator, which uses pneumatic air to simulate the beating heart. Consisting of a thorax with an embedded pericardium and a heart with coronary arteries.

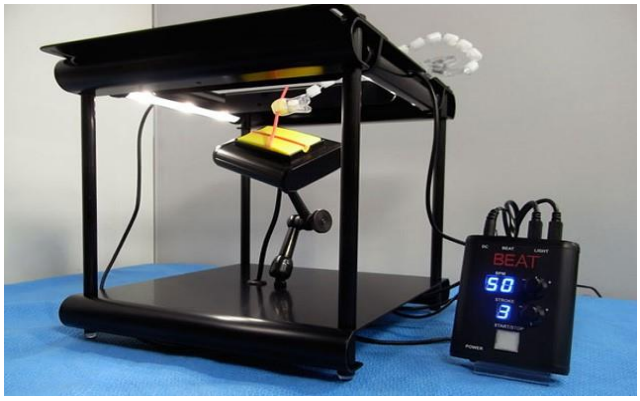


Figure 16B-2: EBM, Beat [38] is a low-fidelity OPCAB simulator which consists of a beating platform with a vessel attached to it to practise anastomosis.

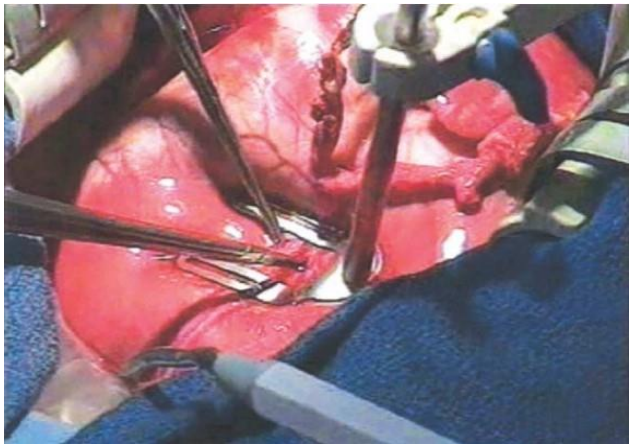


Figure 16B-3: Kindheart, Cardiac surgery simulator [42, 43] is a mid-fidelity OPCAB simulator that uses a porcine heart that is connected to a pneumatic pump.

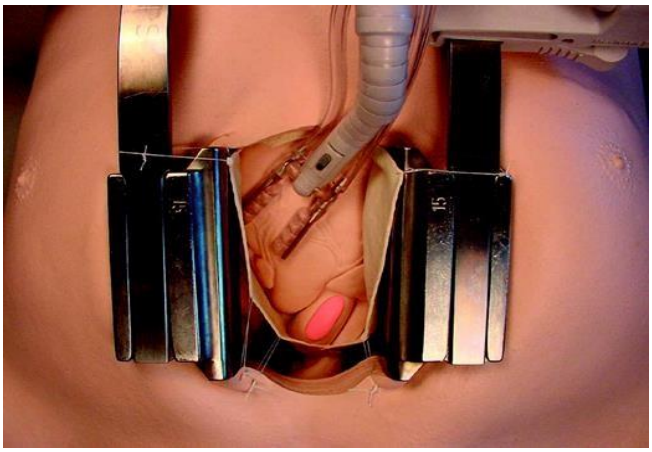


Figure 16B-4: Reuthebuch, Zurich heart-trainer [45] is a mid-fidelity OPCAB simulator consisting of a torso, inflatable lungs, a pericardium, and a heart containing coronary arteries. All are made using synthetic materials.

Figure 16B-5: Izzat [44] is a low-fidelity OPCAB simulator consisting of a platform with a motor underneath it to mimic the beating of the heart. Placed on top of that is a porcine artery to mimic the coronary artery.

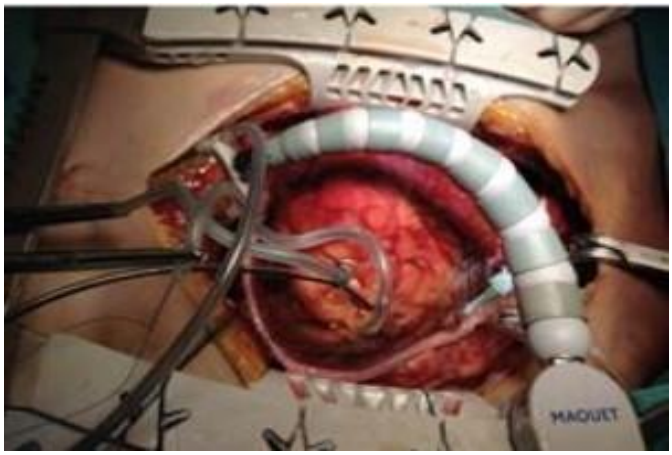


Figure 16B-6: The simulator described in the research of Bouma et al. [40] is a high-fidelity OPCAB training model using embalmed human cadavers. Then an intra-aortic balloon pump was placed in the left ventricle and filled with saline to mimic the beating of the heart at the desired frequency. The grafting material was harvested from the same human cadaver.

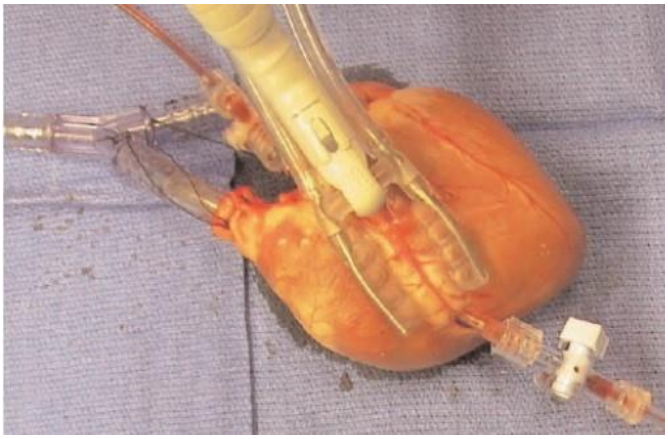


Figure 16B-7: The OPCAB simulator described in the research of Donias et al. [46] is a low-fidelity beating heart model. Using a porcine heart which is connected to a pump to create the beating function. The left descending coronary artery is connected with tubes to a saline bath with an aquarium pump to create a blood flow.

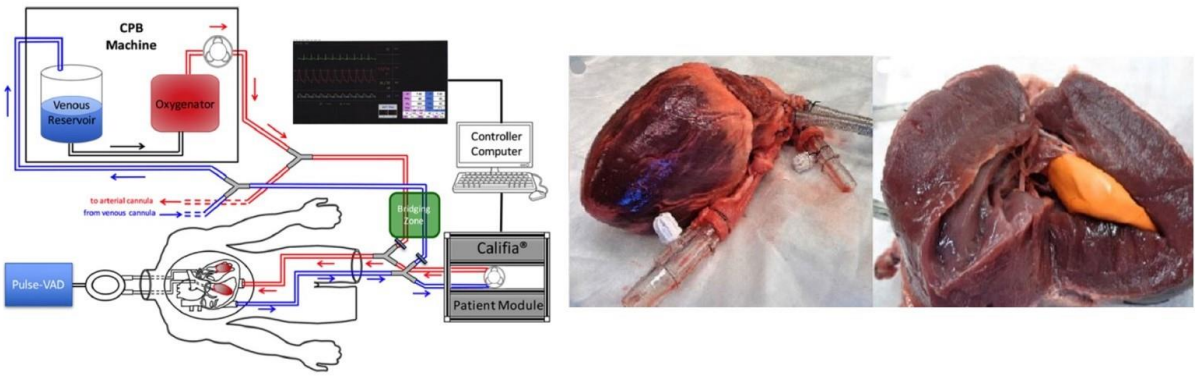


Figure 16B-8: The cardiac surgery simulator described in the research of Ribeiro et al. [49] is a mid-fidelity OPCAB simulator incorporating three parts, a porcine heart, a ventricular assist device, and the Califia cardiopulmonary bypass simulator.

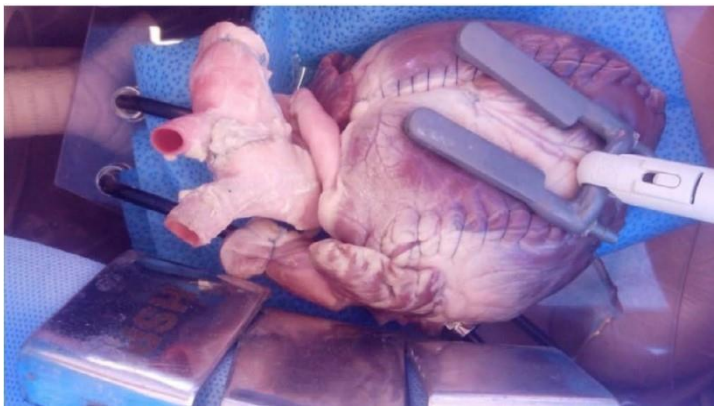


Figure 16B-9: The training model described in the research of Maluf et al. [39] is a mid-level fidelity OPCAB simulator. Where an intra-aortic balloon pump is inserted inside the left ventricle of a porcine heart creating a rhythmic movement of the atria ventricles and great vessels, the graft materials are silicone tubes.

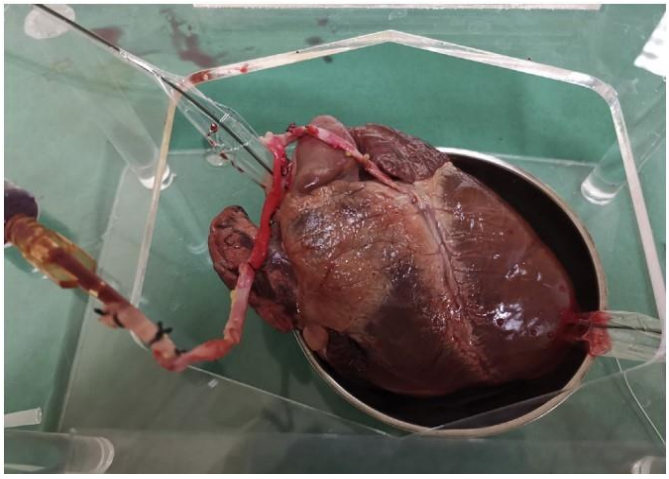


Figure 16B-10: The beating heart simulator described in the research of Wu et al. [47] is a mid-level fidelity OPCAB simulator using a combination of synthetic materials, a porcine heart and human graft material. An intra-aortic balloon pump in the left ventricle was used by filling the balloon with helium, to mimic the beating of the heart.

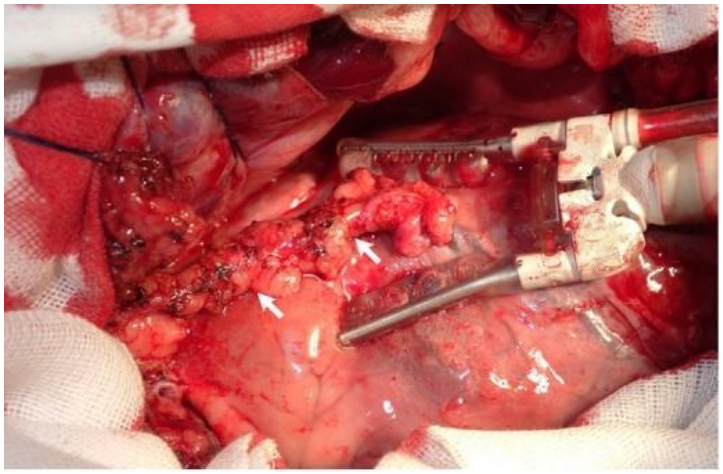


Figure 16B-11: The OPCAB training model described in the research of Liu et al. [48] is a mid-level fidelity simulator based on using live animals. The animals used were miniature pigs which were put under general anaesthesia, intubated and mechanically ventilated during the procedures. After the training, the animals were euthanized. The graft material used is porcine carotid arteries.

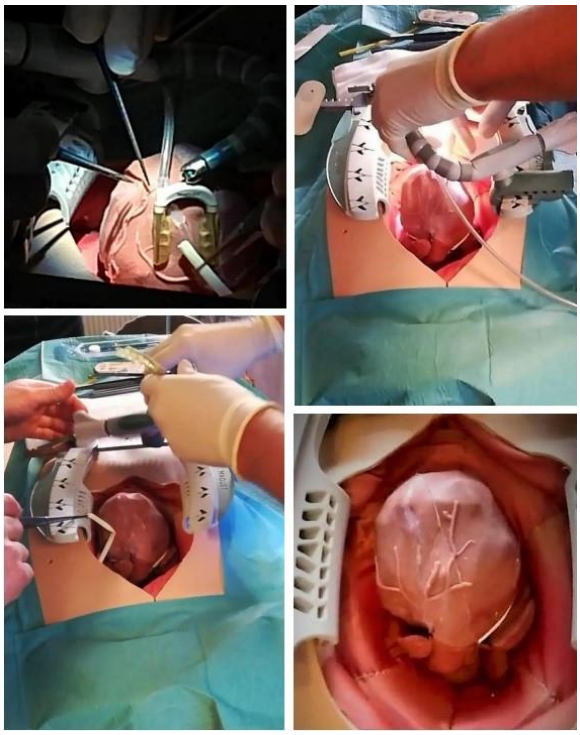


Figure 16B-12: University of Twente, De Jong & Moejes [4-6]. This is a mid-fidelity OPCAB simulator consisting of a pneumatically powered silicone origami-shaped heart located in a torso.

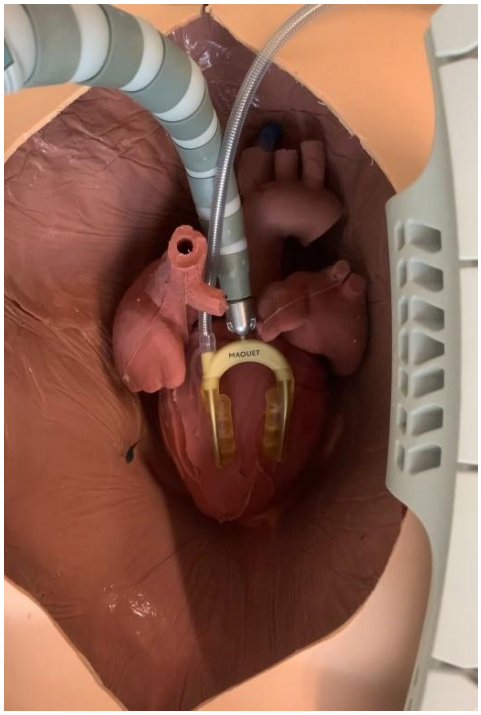


Figure 16B-13: University of Twente, Buitenhuis [18]. This is a low-fidelity OPCAB simulator which is an adaptation of the simulator developed by De Jong and Moejes.

16.2.2 Component fidelity tables

Table 16B-1: Anatomical components.

Device	Heart shaped	Beating	Twist motion	Pericardium	Coronary arteries	Blood flow coronary arteries	Aorta	Superior vena cava	Valves	LIMA/ RIMA	Visual representation of patient
The Chamberlain Group	1	1	0	1	1	0	1	1	0	1	1
EBM	0	1	0	0	1	0	0	0	0	0	0
KindHeart	1	1	1	0	1	1	1	1	1	0	0
Reuthebuch	1	1	0	1	1	0	1	1	0	0	1
Izzat	0	1	0	0	1	0	0	0	0	0	0
Bouma	1	1	1	1	1	1	1	1	1	1	1
Donias	1	1	1	0	1	1	1	1	1	0	0
Ribeiro	1	1	1	1	1	0	1	1	1	0	1
Maluf	1	1	1	0	1	0	1	1	1	0	1
Wu	1	1	1	0	1	0	1	1	1	0	0
Liu	1	1	1	1	1	1	1	1	1	0	0
De Jong & Moejes	1	1	1	1	1	1	1	0	0	0	1
Buitenhuis	1	1	1	1	0	0	0	0	0	0	1

Table A16B-2: Operational components.

Device	Pericardial stitch	Anterior/ lateral anastomosis possible	Posterior anastomosis possible	Check on quality of anastomosis	Loosen in situ LIMA/ RIMA	Conversion to on pump
The Chamberlain group	1	1	1	0	0	1
EBM	0	1	0	0	0	0
KindHeart	0	1	1	0	0	1
Reuthebuch	1	1	1	0	0	0
Izzat	0	1	0	0	0	0
Bouma	1	1	1	1	1	0
Donias	0	1	0	1	0	0
Ribeiro	1	1	1	0	0	1
Maluf	0	1	1	1	0	0
Wu	0	1	0	1	0	0
Liu	0	1	0	1	0	0
De Jong & Moejes	1	1	1	0	0	0
Buitenhuis	1	0	0	0	0	0

Table A16B-3: Scenario and environment components.

Source	Heartbeat can change	Hemodynamic feedback	Arrythmia's	Different graft materials	Surgical environment	Stabilizer	Monitor
The Chamberlain group	1	0	0	1	1	0	0
EBM	1	0	0	0	0	0	0
KindHeart	1	0	0	0	1	0	0
Reuthebuch	1	0	1	1	1	1	0
Izzat	1	0	1	0	0	0	0
Bouma	1	0	0	1	1	1	0
Donias	1	0	0	0	0	1	0
Ribeiro	1	0	0	0	0	0	1
Maluf	0	0	0	0	1	1	1
Wu	0	0	0	0	1	0	0
Liu	1	1	1	0	1	1	1
De Jong & Moejes	0	0	0	0	1	1	0
Buitenhuis	0	0	0	0	1	1	0

16.3 C: Requirements

16.3.1 Total Volume Change Heart

In the paper of Carlsson et al. [52] on total heart volume variations, the total volume change during a cardiac cycle is calculated. The relevant results of the research are displayed in this Appendix. In Figure 16C-1 the results of the volumetric change per heart layer are displayed, additionally, some calculated percentages for specific layers are added in the figure.

- Total volume change of the heart = 8,2 ± 1.2 % (minimum 5%, maximum 11%);
- Longitudinal lengthening = 0,9 ± 0,5 % (minimum -2%, maximum 3%);
- Largest volume change is in the region of the atrioventricular plane movement;

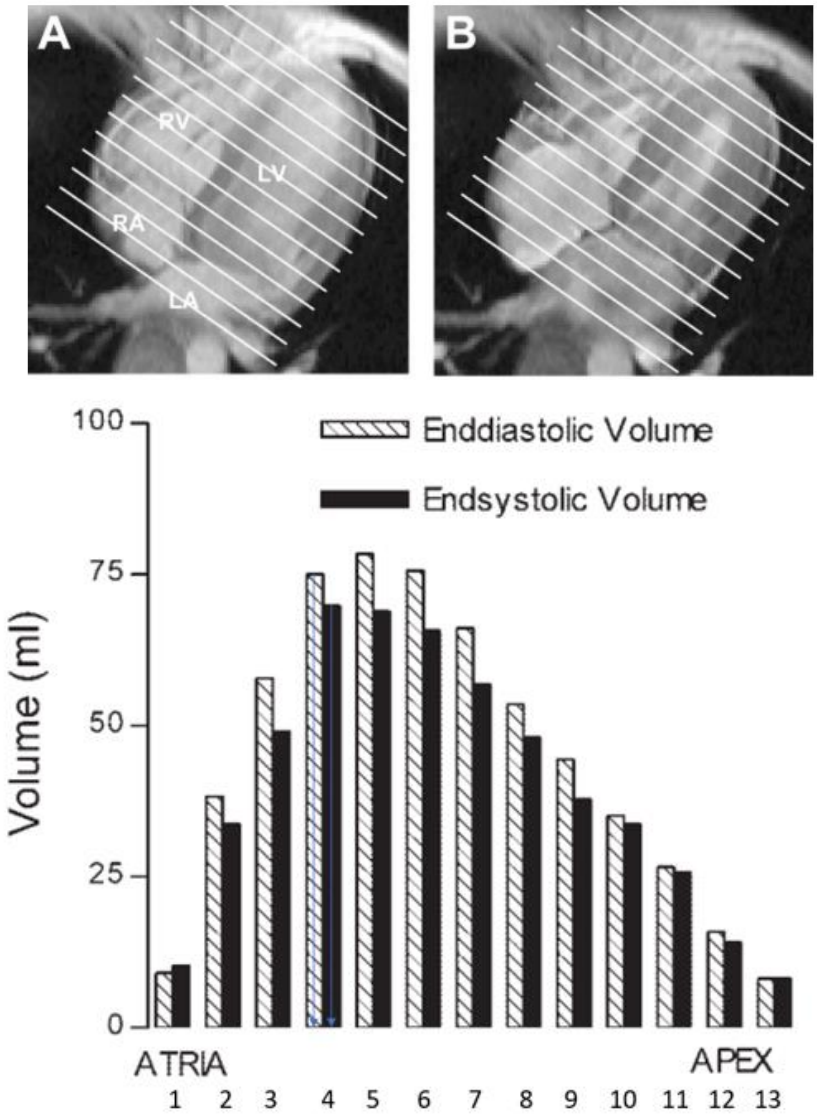


Figure: 16C-1: Results of volumetric change in total heart volume.

16.3.2 Program of Requirements

A total program of requirements has been established (Table 16C-1). The structure of how the requirements were set up has changed. Separating the requirements based on the different functionalities and adding which design specifications relate to that requirement. Previous requirements have been adapted and new requirements have been added. Using the function analysis created 11 functional components categories of the OPCAB simulator.

Table 16C-1: Full program of requirements.

01	**Simulator**					
	Requirement		Design Specification	Value	Unit	Ref.
01-01	The total simulator should be easy to lift	01-01.01	Total system weight	<15	kg	[4]
01-02	The total simulator should fit through a door	01-02.01	Total system width	<630	mm	[4]
01-03	The total simulator should fit on a desk	01-03.01	Total system length	<1200	mm	[4]
01-04	The simulator should be easy to set up and close	01-04.01	Set up time	≤10	min	[4]
		01-04.02	Close up time	≤10	min	[4]
02	**Heart**					
	Requirement		Specification	Value	Unit	Ref.
02-01	The heart model should have human-like dimensions	02-01.01	Total heart length	80-140	mm	[5]
		02-01.02	Total heart width diameter	85-150	mm	[53]
		02-01.03	Total heart depth diameter	60	mm	[5]
02-02	The heart should have an anatomically correct look	02-02.01	The heart model has simulated atria and ventricles	True	N.A.	
		02-02.02	The heart model contains the pericardial part of the vena cava, aorta, pulmonary vein, and pulmonary artery	True	N.A.	
03	**Visual representation**					
	Requirement		Specification	Value	Unit	Ref.
03-01	The simulator should have a torso with human-like dimensions	03-01.01	Torso length	449 ± 116	mm	[4]
		03-01.02	Torso width	301 ± 33	mm	[4]
		03-01.3	Torso chest circumference	1011 ± 16	mm	[4]
03-02	The simulator should have a realistic workspace	03-02.01	The torso has a sternotomy opening	True	N.A.	[4]
		03-02.02	Length sternotomy opening	180	mm	[3]
		03-02.03	Width sternotomy opening	100	mm	[6]
03-03	The simulator should have a realistic size pericardium	03-03.01	Pericardium length	180	mm	[3]
		03-03.02	Pericardium width	100	mm	[3]
		03-03.03	Pericardium depth	160	mm	[3]
03-04	The pericardium should have human-like properties	03-04.01	Pericardium material has elastic membrane properties	True	N.A.	[3]
		03-04.02	Pericardium is firmly connected inside the torso	True	N.A.	[3]

04	Cardiac circulatory system					
	Requirement		Specification	Value	Unit	Ref.
04-01	The simulator should have coronary arteries	04-01.01	The heart model at least has the two primary coronary arteries	True	N.A.	
		04-01.02	The coronary arteries should relatively be in the correct place on the heart wall	True	N.A.	
04-02	The coronary arteries with human-like properties	04-02.01	Lumen radius coronary artery	2-3	mm	[4]
		04-02.02	Wall-thickness coronary artery	1	mm	[4]
		04-02.03	Material coronary arteries should have vessel-like properties	True	N.A.	[3]
		04-02.04	Coronary arteries move with the heart wall	True	N.A.	[6]
		04-02.05	There should be a blockage in the coronary arteries	True	N.A.	[4]
04-03	The coronary arteries should have a simulated blood flow	04-03.01	The coronary arteries have a leak-free fluid transport	True	N.A.	[6]
		04-03.02	The liquid of the fluid transport system simulates blood	True	N.A.	[3]
		04-03.03	The fluid transported is pumped through	True	N.A.	[3]
		04-03.04	The fluid system has a reservoir to contain the blood	1000	ml	[3]
		04-03.05	The fluid system has a refillable reservoir	True	N.A.	[3]
04-04	The simulator should have a human-like LIMA	04-04.01	The LIMA is fixated on the superior left side of the pericardium	True	N.A.	[3]
		04-04.02	LIMA is a tube with an opening on the bottom	True	N.A.	
		04-04.03	LIMA diameter	19-26	mm	[69]
		04-04.04	LIMA wall-thickness	180-430	µm	[69]
04-05	Human-like graft material should be provided	04-05.01	Graft material with a diameter of radial artery	188-280	mm	[70]
		04-05.02	Graft material with a wall-thickness of radial artery	248-316	µm	[54]
		04-05.03	Graft material with a diameter of saphenous vein	310-850	mm	[69]
		04-05.04	Graft material with wall-thickness of saphenous vein	180-650	µm	[69]
		04-05.05	Graft material is a tube with open ends	True	N.A.	[3]

05	**Movement**					
	Requirement		Specification	Value	Unit	Ref.
05-01	The simulator should have a life-like beating heart	05-01.01	Heart rate of beating heart	50-100	BPM	
		05-01.02	Total heart volume change	8.2 ± 0.8	%	[54]
		05-01.03	Heart model longitudinal lengthening	0,9 ± 0,5	%	[54]
		05-01.04	Maximum heart transverse area increase	17,8	%	[54]
		05-01.05	Heart model clockwise twisting atria	7 ± 3	°	[5]
		05-01.06	Heart model counter-clockwise twisting ventricles	12 ± 6	°	[5]
		05-01.07	Correct phasing and combination of cardiac movements	True	N.A.	[4]
05-02	The beating heart should be fluid-powered	05-02.01	Simulator has a fluid-pumping system	True	N.A.	
		05-02.02	Base fluid reservoir	> 8 of total fluid in heart	%	[54]
		05-02.03	Apex fluid reservoir	> 8 of total fluid in heart	%	[54]
06	**Hemodynamics**					
	Requirement		Specification	Value	Unit	Ref.
06-01	The simulator should show simulated hemodynamics	06-01.01	Display heart rate	True	N.A.	
		06-01.02	Display blood pressure	True	N.A.	
06-02	The simulator should measure simulated hemodynamics	06-02.01	Measure simulated blood pressure	True	N.A.	
06-03	The simulator should give feedback on the manipulation of the heart	06-03.01	Show the change in hemodynamics if flow into atria is compromised	True	N.A.	
		06-03.02	Show the change in hemodynamics if flow into ventricles is compromised	True	N.A.	
		06-03.03	Show change in hemodynamics if the heart is compressed	True	N.A.	
06-04	The simulator should be able to tilt	06-04.01	Simulator can be put in Trendelenburg's position	True	N.A.	

07	**Surgical steps**					
	Requirement		Specification	Value	Unit	Ref.
07-01	The simulator should provide the surgical steps needed for OPCAB	07-01.01	Possibility to perform pericardial stitch	True	N.A.	[6]
		07-01.02	Possibility to perform anterior anastomosis	True	N.A.	[5]
		07-01.03	Possibility to perform lateral anastomosis	True	N.A.	[5]
		07-01.04	Possibility to perform posterior anastomosis	True	N.A.	[5]
		07-01.05	Provide feedback on the anastomosis quality	True	N.A.	[6]
		07-01.06	Possibility to loosen in sito the LIMA/ RIMA	True	N.A.	
		07-01.07	Possibility to do a conversion to on-pump surgery	True	N.A.	
07-02	The simulator should provide the necessary surgical tools	07-02.01	Simulator has an Acrobat-I retractor	True	N.A.	[6]
		07-02.02	Simulator has a stabilizer compatible with the Acrobat-I retractor	True	N.A.	[3]
		07-02.03	Monitor with necessary information	True	N.A.	[6]

08	**Durability**					
	Requirement		Specification	Value	Unit	Ref.
08-01	The simulator should have a changeable outer layer	08-01.01	Lifespan of at least 1 surgery cycle	>2	h	[3]
		08-01.02	Simulator has replaceable coronary arteries	True	N.A.	[3]
		08-01.03	Simulator has a replaceable LIMA	True	N.A.	
		08-01.04	Simulator has a replaceable pericardium for pericardial stitch	True	N.A.	
08-02	The simulator consists of a reusable basis	08-02.01	Lifespan of the reusable basis for multiple surgery cycles (100*2 hours)	200	h	[3]

09	Scenarios and Customization					
	Requirement		Specification	Value	Unit	Ref.
09-01	Simulator can simulate different scenarios	09-01.01	Changeable heartbeat	True	N.A.	[3]
		09-01.02	Possibility to simulate arrhythmias	True	N.A.	[6]
09-02	Simulator provides customizable parts	09-02.01	Different-sized coronary arteries	True	N.A.	[6]
		09-02.02	Different-sized graft material	True	N.A.	[6]
		09-02.03	Different sized hearts	True	N.A.	
		09-02.04	Customizable pericardium	True	N.A.	[6]
		09-02.05	Customizable sex of the simulator	True	N.A.	
		09-02.06	Customizable skin colour	True	N.A.	

10	Safety					
	Requirement		Specification	Value	Unit	Ref.
10-01	The simulator should be safe to use	10-01.01	Closing down at any point in the procedure	True	N.A.	[4]
		10-01.02	No exposed electrical components	True	N.A.	[3]
		10-01.04	Use of certified tubing	True	N.A.	[5]
10-02	The simulator should be waterproof	10-02.01	Comply with waterproof code	IPX3	N.A.	[5]

11	Production					
	Requirement		Specification	Value	Unit	Ref.
11-01	Should be easy to produce	11-01.1	Production steps per mechanism	<15	N.A.	[5]
11-02	Should be designed for small batch size	11-02.1	Use production techniques relevant to small batch size	True	N.A.	[5]
		11-02.2	Costs at badge size of 35	12.500	€	[4]
11-03	System should be compatible	11-03.1	All mechanisms and parts should be compatible with each other	True	N.A.	[6]

16.4 D: Material Analysis

16.4.1 Material Property Terms

Ultimate tensile strength: This is the maximum stress a material can withstand while being stretched before breakage.

Elongation at break: The percentage of a material that is stretched/deformed before it breaks. The percentage is based on the original dimensions. This material property gives insight into the ductility and toughness of the material.

Shore hardness: This is a property that is connected to the flexibility and hardness of a material. The shore hardness of a material is determined by the resistance to indentation. Shore hardness is a useful measurement for flexible materials. There are three levels of scales ranging from 0 to 100, 0 being the softest and 100 the hardest (see Figure 16D-1). The three scales are there to provide more specifics on the different categories of material [71].

- Shore 00: includes highly flexible products e.g. gels and foams;
- Shore A: includes a range of highly flexible materials up to semi-rigid materials e.g. rubbers and plastics;
- Shore D: includes materials from semi-rigid up to hard again including plastics and rubbers;

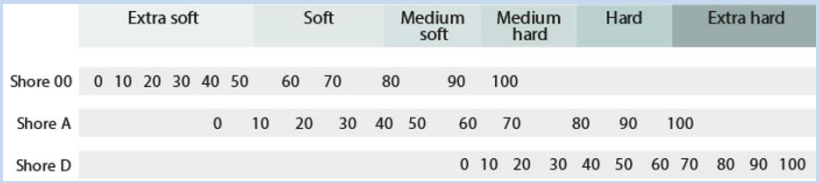


Figure 16D-1: Shore hardness scale.

16.4.2 Material Prototype Information

Table 16D-1:TPU.

Production steps	This prototype was 3D printed with the Ultimaker 3 using TPU 95A as material. The printer settings were reused from the prototype of Kilian Buitenhuis
Aftercare	- Removal of imperfections of the print (sanding/cutting) - After printing the inside of the material was coated with a waterproof roof sealing paste, as an attempt to make the material airtight. As it was already known that the material had leakages
Attempts	1 for a correct print with a wall thickness of 0.8 mm
Time	Lid: 3 h 30 m; Bottom: 3 h
Weight	
Price	Ultimaker TPU 95A €72 per 750 gram
Initial observations	N/A

Table 16D-2: Flexible resin.

Production steps	This prototype was 3D printed with the Formlabs 3L using flexible resin 80A, it is printed at the DesignLab of the University of Twente. Because of this, finding the correct setting for the machine is done by someone else. Visible holes and tears were patched, as it was not possible to create a new prototype.
Aftercare	- Post curing of 10 min is recommended - Support structure has the be removed
Attempts	1st print: Too thin of a wall thickness leading to inconsistencies in the print, causing holes and tearing to appear. Making the lid from flexible resin showed some deformation in the design. 2nd print: With a wall thickness of 2 mm, was unfortunately never made, due to a malfunction of the printer in the design lab. Causing them to stop printing flexible resin.
Time	Bottom: 13 h 25 m
Weight	40 gram
Price	Formlabs Flexible 80A Resin $199 per 1 litre
Initial observations	- During transport, the top part of the prototype was damaged - Material takes some time to bounce back to its original position

Table 16D-3: Elastic resin.

Production steps	This prototype was 3D printed with the Formlabs 3L using elastic resin 50A, it is printed at the DesignLab of the University of Twente. Because of this, finding the correct setting for the machine is done by someone else
Aftercare	- Post curing of 10 min is recommended - Support structure has the be removed
Attempts	2 For the first print incorrect settings were used. The wall thickness of the parts has been made 2mm as a precaution, learned from the attempts of the other resin
Time	Bottom: 12 h
Weight	84 gram
Price	Formlabs elastic 50A Resin $199 per 1 litre
Initial observations	- During the making in the DesignLab something heavy was put on top of the top part. Therefore, it unfortunately tore one of the parts.

Table 16D-4: HT33 Silicone.

Production steps	For this prototype, a 3-part mould was designed in Solidworks and printed with an Ultimaker using PLA as the material. For the silicone 9/10th of the base and 1/10th part catalyst had to be weighted out. Green dye was added to make a distinction between the 2 silicone parts made. The base, catalyst, and dye were combined and vacuum-mixed to prevent air bubbles in the silicone. The mould is prepped with a little bit of the mixed silicone to make it sealed shut. The prepping is done by creating a thin layer of silicone to the bottom parts of the mould and putting it in the oven at around 40 °C to cure. The rest of the prepared silicone is kept in the freezer for the time the mould is prepped, this is done to delay the curing process of the silicone. After around 25 minutes the mould is prepped, and the silicone can be poured in. Put in the inner/top part of the mould and make sure the mould is filled. After which the silicone will cure.
Aftercare	- Taking the prototype out of the mould - Removal of the sealing material
Attempts	1
Time	Mould: 17 h; Curing: 3 h
Weight	88 gram
Price	Zhermack €42.75 per kg
Initial observations	- As a precaution for failure of the prototype a wall thickness of 4 mm was created - The mould design should be improved as the inner part kept being pushed up and had to be cable-tied in place. As a result, the prototype does not have an even thickness throughout.

Table 16D-5: RT 625.

Production steps	For this prototype, the same 3-part mould of the other silicone part was reused. For the silicone 1/2 of the base and 1/2 part catalyst had to be weighted out. The base, catalyst, and dye were combined and vacuum-mixed to prevent air bubbles in the silicone. The mould is prepped with a little bit of the mixed silicone to make it sealed shut. The prepping is done by creating a thin layer of silicone to the bottom parts of the mould and putting it in the oven at around 40 °C to cure. The rest of the prepared silicone is kept in the freezer for the time the mould is prepped, this is done to delay the curing process of the silicone. After around 25 minutes the mould is prepped, and the silicone can be poured in. Put in the inner/top part of the mould and make sure the mould is filled. After which the silicone will cure.
Aftercare	- Taking the prototype out of the mould - Removal of the sealing material
Attempts	1
Time	Mould: 17 h; Curing: 12 h
Weight	84 gram
Price	Wacker €190 per kg
Initial observations	- As a precaution for failure of the prototype a wall thickness of 4 mm was created - The mould design should be improved as the inner part kept being pushed up and had to be cable-tied in place. As a result, the prototype does not have an even thickness throughout.

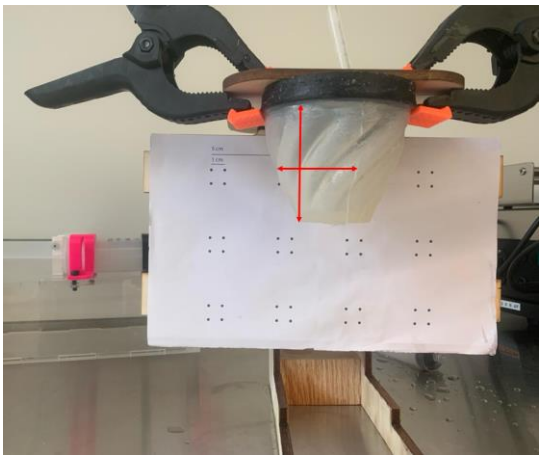
16.4.3 Silicone Comparison Test

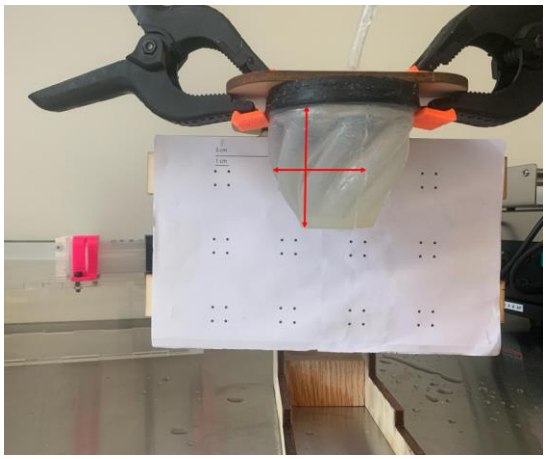
The silicone prototypes were attached to a standard to take photos of the model after which they were analysed by measuring the diameter widening and longitudinal lengthening. The setup of the standard and prototype can be seen in Figure 16C-2.

Figure 16C-2: Set-up of silicone comparison test.

The prototypes were filled with water and connected to a syringe with 40 ml of water. An initial measurement used as a reference point was taken at this point. After this 40 ml was inserted into the prototype a picture was taken to capture the maximum inflation of the prototype, this was repeated 10 times. Using these pictures the width and length of the prototypes were measured, and when compared to the reference point a percentage difference in lengthening and widening was calculated for both materials. The resulting tables can be found below. An example of how the width and length of the prototype were measured can be seen in Figure 16C-3.

Figure 16C-2: Example of a lengthening and widening comparison measurement.





From the data in the result tables, no clear conclusion could be stated. Therefore a small statistical analysis was performed. Providing information on the mean of the results. Still, it is difficult to say whether one material performs differently. To see whether the results are significantly different a Mann-Whitney U test was performed. This test can be done because the data set shows a non-normal distribution is seen in the histograms that are plotted in SPSS.

It should be noted that to be able to distinguish between the two silicones, colouring was added to the RT625 material. This could have influenced the outcomes of the tests. However, it was decided to assume this did not influence the results as no information on how this reacts with the silicone is known.

Result tables of HT33 silicone

Table 16D-6: Results diameter widening HT 33.

	Picture measurement	**Cm**	**Difference %**
0 without water	3,4	6,07	
0 with water	3,51	6,27	
1	3,72	6,64	8,75
2	3,79	6,77	10,67
3	3,95	7,05	15,04
4	3,88	6,93	13,13
5	3,82	6,82	11,49
6	3,82	6,82	11,49
7	3,79	6,77	10,67
8	3,84	6,86	12,04
9	3,86	6,89	12,58

Table 16D-7: Results of longitudinal lengthening HT 33.

	Picture measurement	**Cm**	**Difference %**
0 without water	4,96	8,41	
0 with water	4,96	8,41	
1	5,05	8,56	1,81
2	5,08	8,61	2,42
3	5,13	8,69	3,43
4	5,08	8,61	2,42
5	5,08	8,61	2,42
6	5,08	8,61	2,42
7	5,05	8,56	1,81
8	5,09	8,63	2,62
9	5,09	8,63	2,62

Result tables of RT 625

Table 16D-8: Results diameter widening RT 625.

	Picture measurement	Cm	Difference %
0 without water	2,88	5,14	
0 with water	2,9	5,18	
1	3,2	5,71	11,11
2	3,16	5,64	9,72
3	3,19	5,70	10,76
4	3,15	5,63	9,38
5	3,21	5,73	11,46
6	3,22	5,75	11,81
7	3,16	5,64	9,72
8	3,18	5,68	10,42
9	3,17	5,66	10,07

Table 16D-9: Results of longitudinal lengthening RT 625.

	Picture measurement	Cm	Difference %
0 without water	4,63	8,27	
0 with water	4,63	8,27	
1	4,73	8,45	2,16
2	4,76	8,50	2,81
3	4,76	8,50	2,81
4	4,76	8,50	2,81
5	4,75	8,48	2,59
6	4,77	8,52	3,02
7	4,78	8,54	3,24
8	4,75	8,48	2,59
9	4,75	8,48	2,59
10	4,73	8,45	2,16

Statistics comparison test

```
EXAMINE VARIABLES=Percentage Percentage2 BY Type
  /PLOT BOXPLOT HISTOGRAM NPPLOT
  /COMPARE GROUPS
  /PERCENTILES(25,50,75) HAVERAGE
  /STATISTICS DESCRIPTIVES
  /CINTERVAL 95
  /MISSING PAIRWISE
  /NOTOTAL.

NPAR TESTS
  /M-W= Percentage Percentage2 BY Type(0 1)
  /STATISTICS=DESCRIPTIVES QUARTILES
  /MISSING ANALYSIS
  /METHOD=EXACT TIMER(5).
```

Figure 16D-2: Screenshot syntax SPSS.

Table 16D-10: Results of the SPSS comparison test.

	Type		Statistic	Std. Error
Percentage widening	HT 33	Mean	11,761	0,589
		Median	11,488	
		Std. Deviation	1,767	
		Skewness	0,250	0,717
		Kurtosis	1,053	1,400
	RT 625	Mean	10,494	0,282
		Median	10,417	
		Std. Deviation	0,847	
		Skewness	0,269	0,717
		Kurtosis	-1,294	1,400
Percentage lengthening	HT 33	Mean	2,441	0,159
		Median	2,419	
		Std. Deviation	0,477	
		Skewness	0,703	0,717
		Kurtosis	1,895	1,400
	RT 625	Mean	2,678	0,108
		Median	2,700	
		Std. Deviation	0,341	
		Skewness	-0,195	0,687
		Kurtosis	-0,144	1,334

Table 16D-11: Results from the Mann Whitney U test.

	Percentage widening	Percentage lengthening
Mann-Whitney U	28,00	19,00
Asymp. Sig. (2-tailed)	0,057	0,161

16.5 E: Design Phase

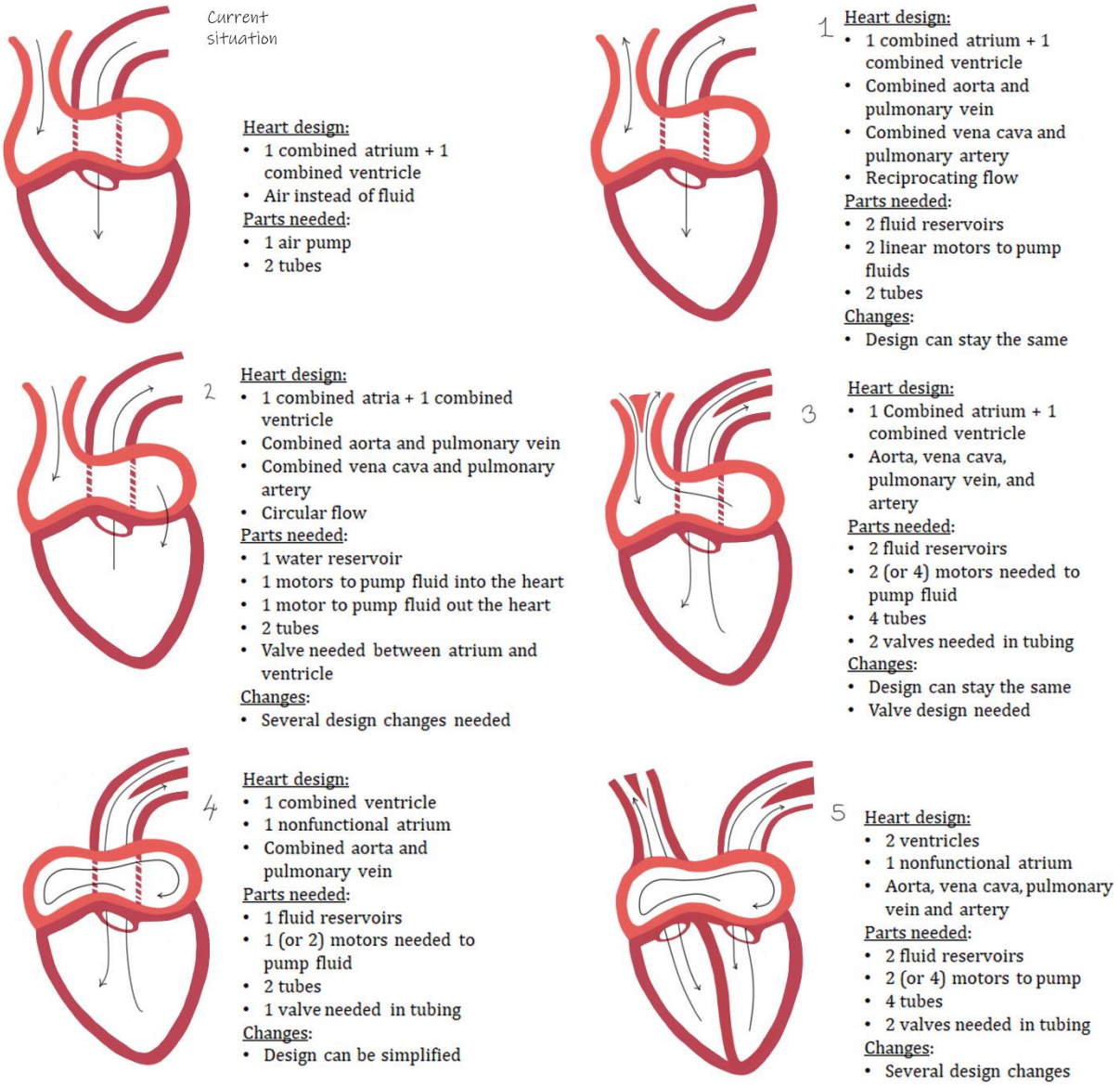


Figure 16E-1: Flow system ideation with information on heart design, parts needed to build this type of flow system, and changes compared to the previous design.

1. The fluid flows and reciprocates through the same two tubes connected to the combined atria and combined ventricles;
2. The fluid flows in a circular circuit from the combined atria to the combined ventricles and then exits the heart.;
3. The fluid flows into the combined atria and combined ventricles through two tubes and out through two other tubes;
4. The fluid flows in and out of the combined ventricles through two tubes, while the combined atria are filled with fluid but do not experience flow;
5. The fluid enters and exits two separate ventricles via a total of four tubes, while the combined atria are filled with fluid but do not experience flow;

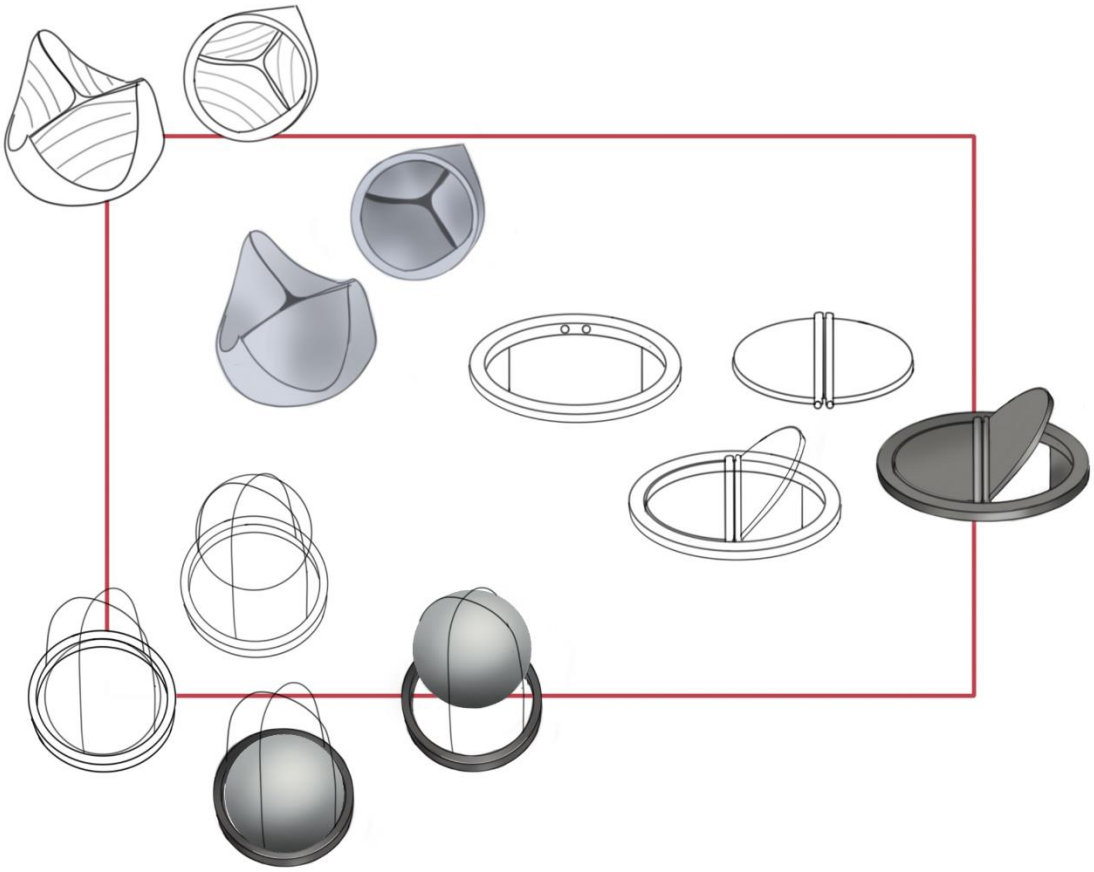


Figure 16E-2: Mechanical valves ideation.

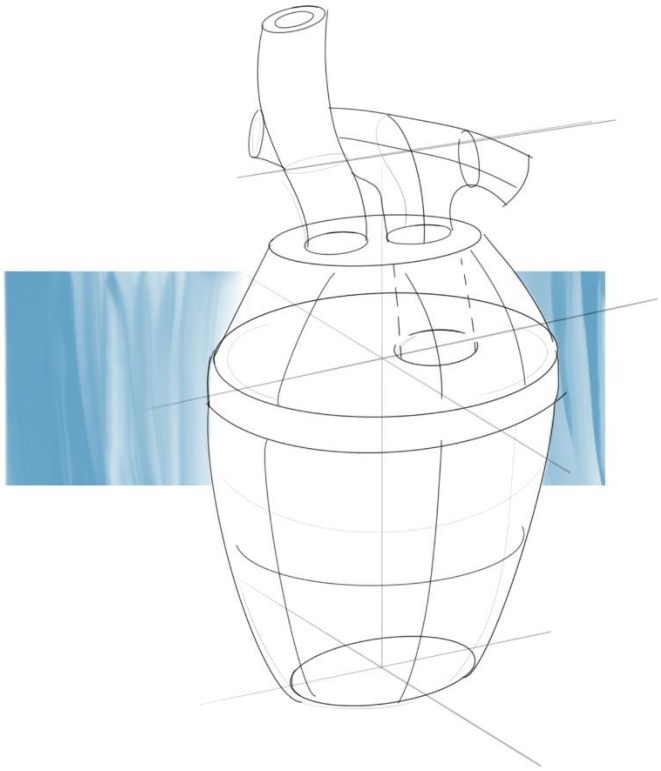


Figure 16E-3: Sketch of addition of pulmonary vein and vena cava.

16.6 G: Final Prototype Design

16.6.1 Actuation and Hemodynamic System

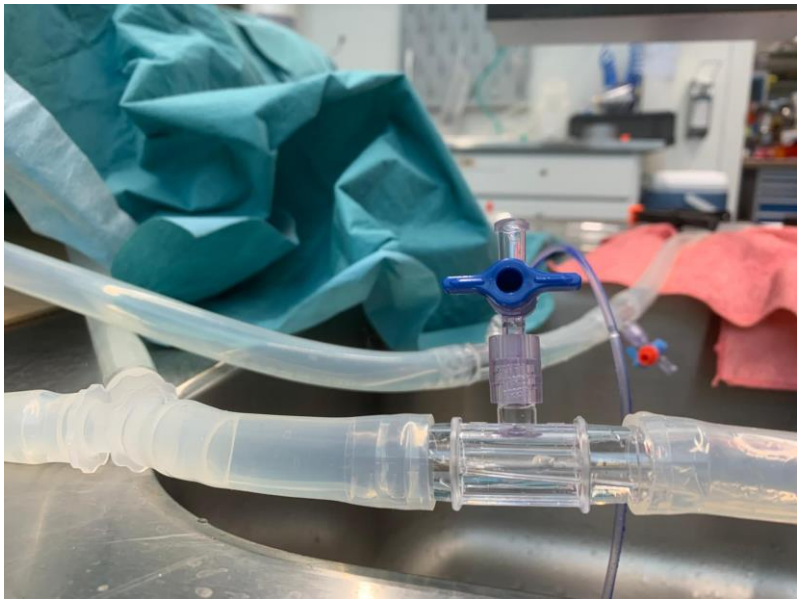


Figure 16G-1: Image of luer lock system with valve to fill the system with fluids.

16.6.2 Prototype

Mould Fabrication explanation

The moulds (excluding the sleeve) are designed using SolidWorks. First, the required part of the heart was modelled, after which a negative of the part was created. This negative part was divided into two or more parts to ensure the part could be easily removed from the mould. In and outflow paths were incorporated in the mould design to create a flow path for the silicone, similar to an injection mould design. A connection part was added to the bottom of the mould that fits a syringe filled with silicone, and small air holes were added to the top to allow air to escape when the mould filled. These small holes also indicated when the mould was completely filled with silicone, as the material would start to emerge from them. Once all the mould parts were designed, they were converted to an STL file for 3D printing. The moulds were printed with PLA using an Ultimaker printer in the Rapid Prototype Lab at the University of Twente. To create the hollow vena cava and pulmonary vein, a dissolvable inner part was required in the mould. The inner parts of the mould for the pulmonary vein and vena cava were made from PVA, a plastic that is soluble in warm water

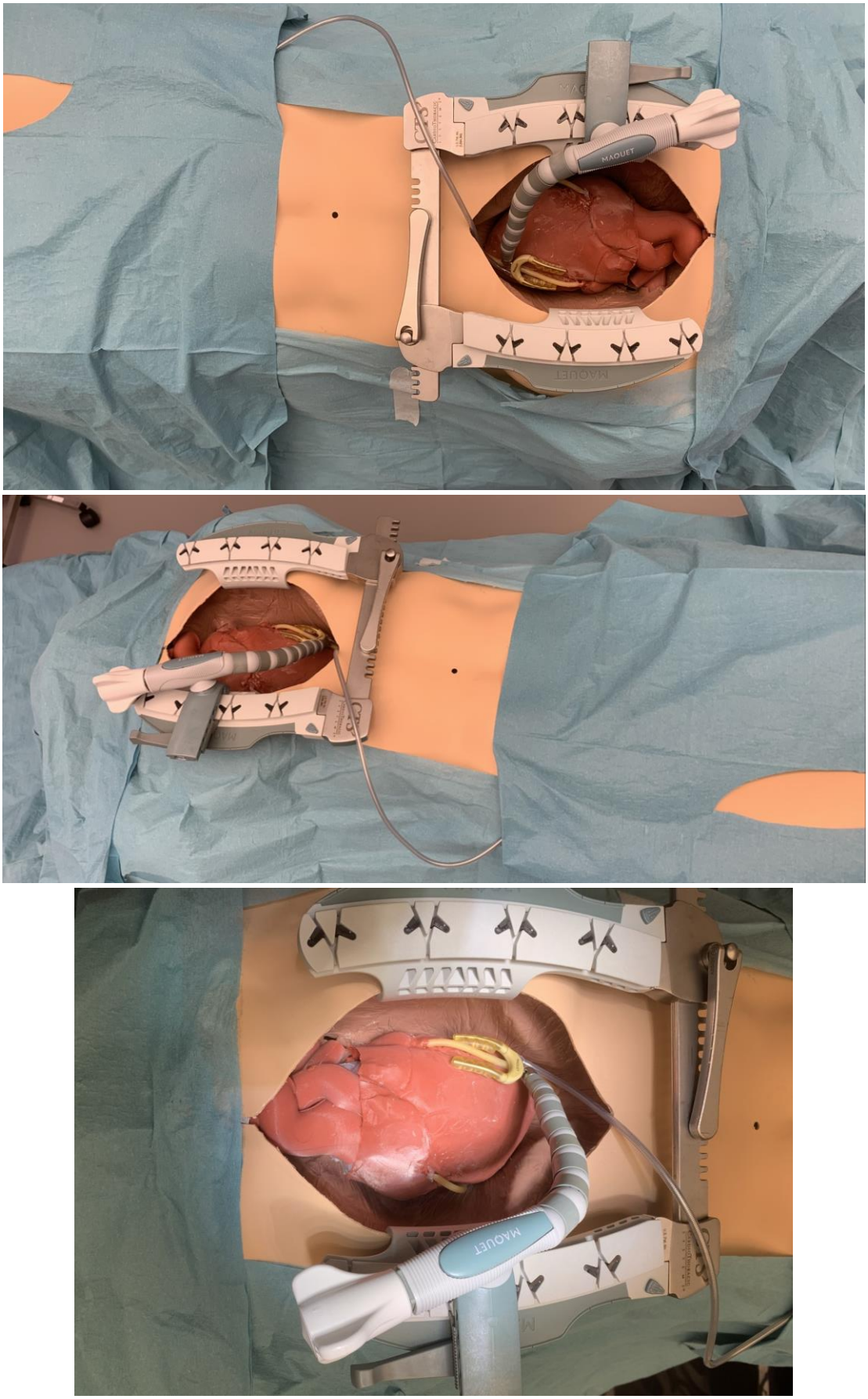
16.6.2.1 Prototype Parts

Prototype parts OPCAB simulator.zip

Prototype parts OPCAB simulator

16.6.3 Final Prototype Design

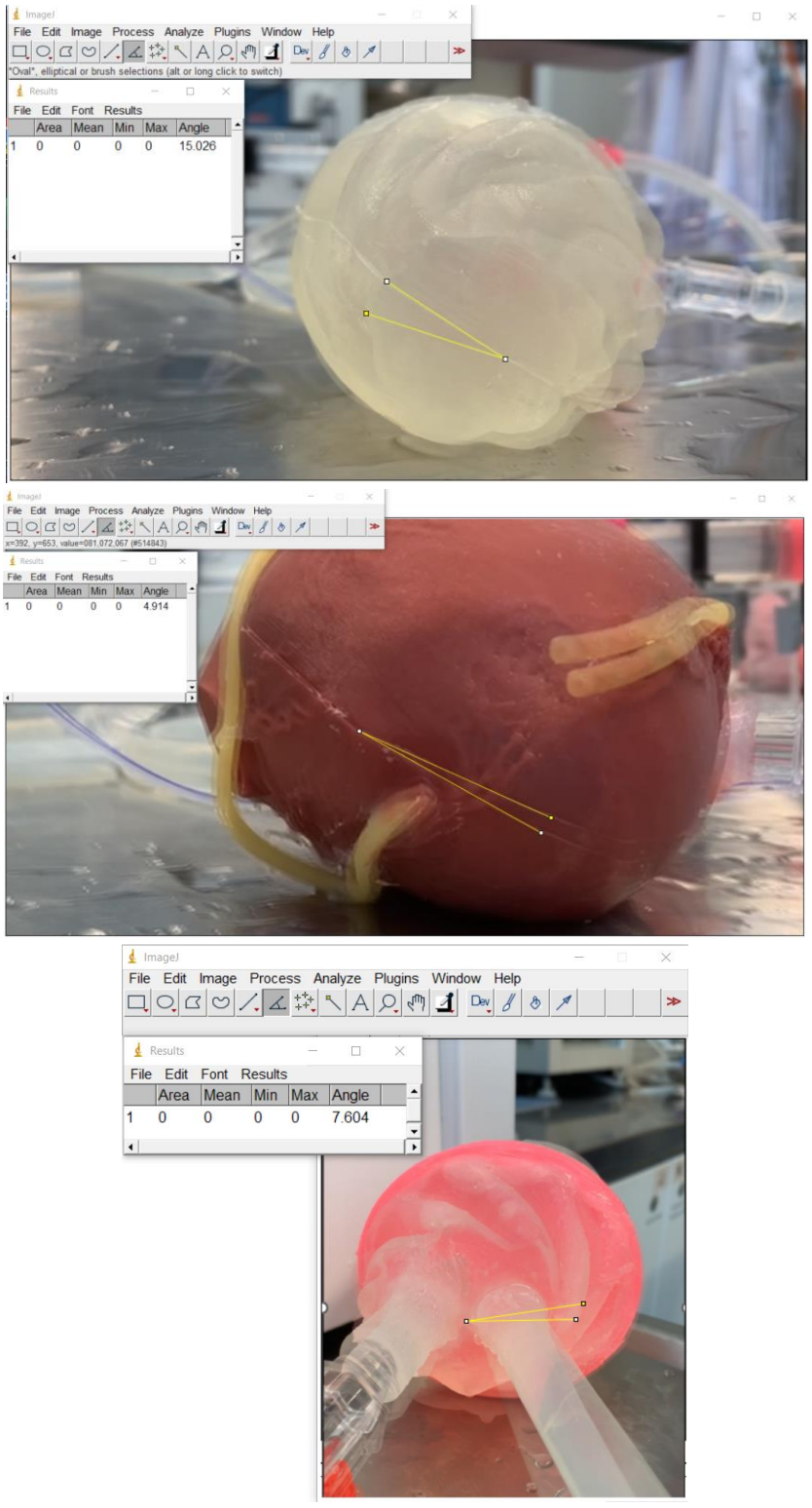
Figure 16G-2: Additional images of the OPCAB simulator.



16.7 H: Prototype Design Evaluation

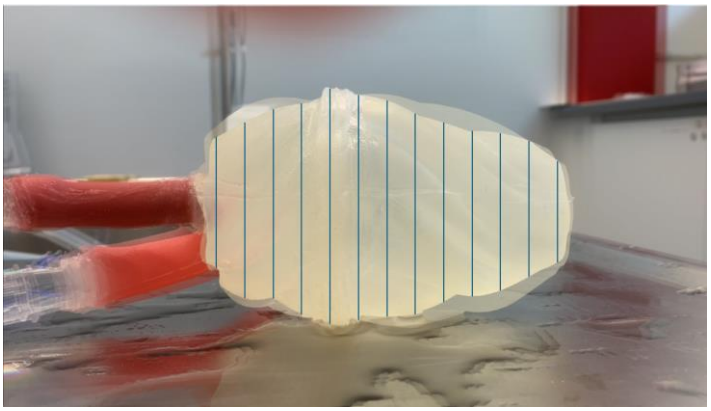
16.7.1 Evaluation Twist

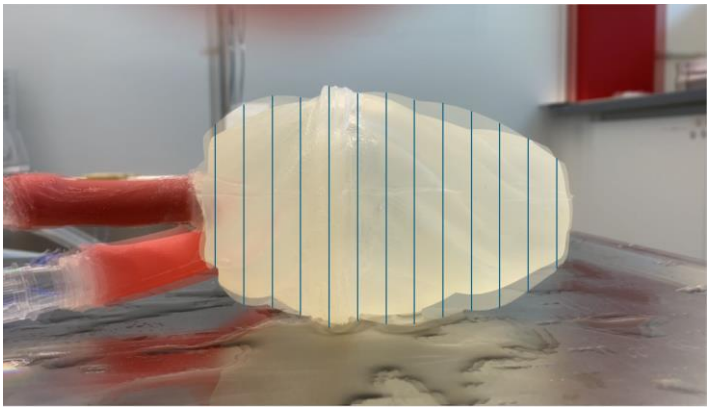
Figure 16H-1: Images of angle of twist measurements using ImageJ.



16.7.2 Evaluation Volume change

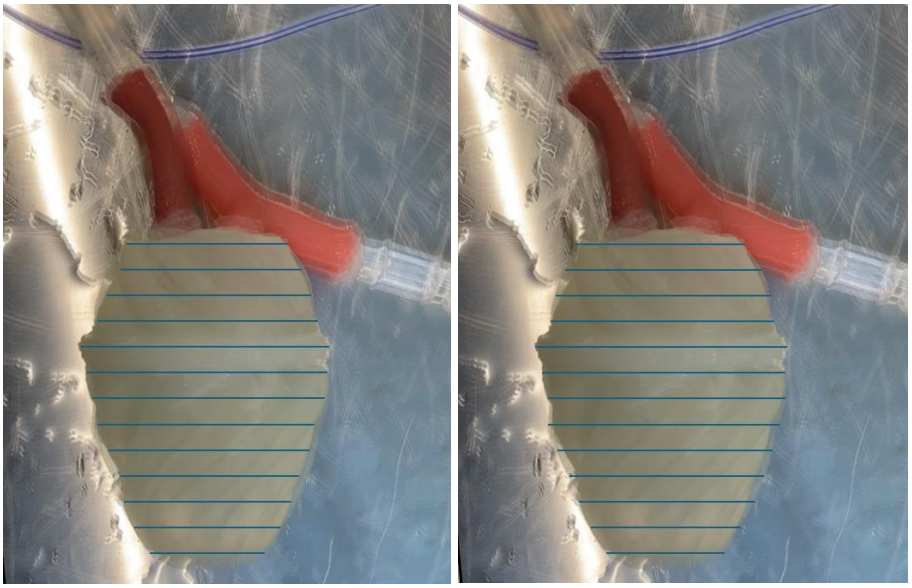
Figure 16H-2: Side view images and table of volume slice measurements.





	Empty	Filled
1	4,86	5,33
2	6,50	7,39
3	6,99	7,84
4	7,81	8,06
5	8,70	8,95
6	8,31	8,43
7	8,00	8,55
8	7,43	8,29
9	6,64	7,93
10	6,12	7,38
11	5,82	6,83
12	5,02	5,64
13	3,75	4,09

Figure 16H-3: Front view images and table of volume slice measurements.



	Empty	Filled
1	6,66	7,04
2	7,44	8,09
3	8,40	8,85
4	9,06	9,20
5	10,24	10,38
6	9,91	10,01
7	9,56	9,78
8	8,91	9,54
9	8,26	8,85
10	7,34	8,01
11	6,88	7,26
12	6,01	6,18
13	4,73	4,88

16.7.3 Hemodynamical Feedback Evaluation

Hemodynamic feedback test results.mp4

16.7.4 Fidelity Evaluation Final Design

Full tables of Component fidelity

Table 16H-1: Anatomical components.

Device	Heart shaped	Beating	Twist motion	Pericar-dium	Coronary arteries	Blood flow coronary arteries
De Jong & Moejes	1	1	1	1	1	1
Buitenhuis	1	1	1	1	0	0
Pels	1	1	1	1	1	0
	Aorta	**Superior vena cava**	**Valves**	**LIMA/ RIMA**	**Visual repre-sentation of patient**	
De Jong & Moejes	1	0	0	0	1	
Buitenhuis	0	0	0	0	1	
Pels	1	1	0	1	1	

Table A16H-2: Operational components.

Device	Pericar-dial stitch	Anterior/ lateral anastomo-sis possible	Posterior anastomosis possible	Check on quality of anastomosis	Loosen in situ LIMA/ RIMA	Conver-sion to on pump
De Jong & Moejes	1	1	1	0	0	0
Buitenhuis	1	0	0	0	0	0
Pels	1	1	1	1	0	0

Table A16H-3: Scenario and environment components.

Device	Heart-beat can change	Hemody-namic feedback	Arrythmia's	Different graft ma-terials	Surgical environ-ment	Stabilizer	Monitor
De Jong & Moejes	0	0	0	0	1	1	0
Buitenhuis	0	0	0	0	1	1	0
Pels	1	1	0	0	1	1	0