UCL Université catholique de Louvain

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Design, development and testing of an atrial retractor for the minimally invasive mitral valve repair surgery

Dissertation presented by
Fanny DOLS

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Supervisors
Benoit RAUCENT, Emiliano NAVARRA

Readers
Xavier BOLLEN, Yann BARTOSIEWICZ

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Abstract

As the technologies have been improving at a drastic rate in the medical world over the past few decades, it is very important to keep doing so, so that no one will ever need to hear that their condition is inoperable. That is one of the reasons robots were introduced to surgeries. In fact, they increase the precision of the surgeon's movements, expanding the probabilities of a good outcome for some risky surgeries. Moreover, they allow to perform some surgeries in a minimally invasive way, reducing the scaring, the risk of infections and the recovery time for the patients.

One of the surgeries that is now commonly performed with a robot is the mitral valve repair surgery. The mitral valve is one of the heart valves, more specifically it is the valve separating the left atrium and the left ventricle. Even though some people with a mitral valve pathology can keep on their life without the need to operate, others are not so lucky. If the condition is serious, it can lead to heart problems, exhaustion, and sometimes to strokes.

The Da Vinci surgical system is a surgical robot that is now used all over the world. It has four robotic arms and gives the surgeon a magnified, 3D vision. One of the surgeries performed with the latter is the mitral valve repair surgery. During this surgery, one of the tools that are used is the retractor. Its role is simply to pull on the atrium walls to give a nice access to the mitral valve during the procedure.

The existing solution for the retractor is not considered optimal by several surgeons. The reason for that being it is not so easy to put in place correctly, and when it is, it does not give a proper exposure of the valve. In fact, some parts of the valve are not exposed at all.
Both flaws lead to a loss of time trying to put the retractor in place as well as risky operations because of the exposure that is not total.

The objective of this master thesis is therefore to think of a new design for this retractor. It will need to be inserted in a minimally invasive incision of maximum 15mm, and yet be deployed in the atrium to expose the 35-40mm wide valve. Moreover, it will need to be entirely made of biocompatible materials and resist the sterilization process. Eventually, it will need to work in collaboration with the other Da Vinci tools without bothering them.

As with any mechanical project, after having detailed the context and clarified the demand, the next step consists in finding alternatives. Through this process, five feasible alternatives were found. They were then compared by using comparison criteria that had been set objectively in a previous phase. Those criteria were weighted in order to emphasize the qualities that the surgeon judged more important. This comparison highlighted one alternative in particular.

The chosen alternative, which was based on the principle of swan neck lamps, was thus designed and manufactured for a first prototype. The prototype was reviewed both by engineers and surgeons in order to point out the major improvements that needed the be taken into account for the next prototype.

A second prototype was thus designed and manufactured . Once again, it was reviewed but this time it was also tested on a pig's heart. The latter has indeed an anatomy that is very similar to the human heart.
The tests, that were performed directly by the surgeon, resulted in a very positive review. The retractor performs as expected, allowing to have a very nice exposure of the valve while remaining discrete for the other tools. Moreover, it is entirely made of biocompatible materials as requested and should be sterilizable.

In addition, the solution is cheaper than the existing solution and can theoretically be used a few dozen times before needing replacement, in comparison the actual solution that needs to be replaced after 10 uses.

Once again, some minor flaws have been pointed out on the final solution and possible ways of improvements have been studied. Should a third prototype be realized, that would into account the several remarks regarding the second prototype, there is a real possibility that the resulting tool would be a reliable, effective and cheap retractor that would facilitate the task of the surgeons during the mitral valve repair surgery.

Contents

Introduction

Until only a few decades ago, having a serious heart condition unfortunately went hand in hand with a very low probability of survival. The reasons for that are plentiful.
Firstly, it took the scientific world a long time to have a profound knowledge of the heart anatomy and physiology. Once they had mastered that, the second problem encountered was that the heart function could not be stopped for more than a few seconds, making it impossible to operate on it. FIGURE 1 shows an open heart surgery using hypothermia. They lowered the body temperature by covering the patient in ice so that its organs would need less oxygen, giving them a minimum time to operate on the heart [1]. It was not until the 1950s that the first effective cardiopulmonary bypass machines were put on the market, making it one of the major breakthroughs at that time. [2]

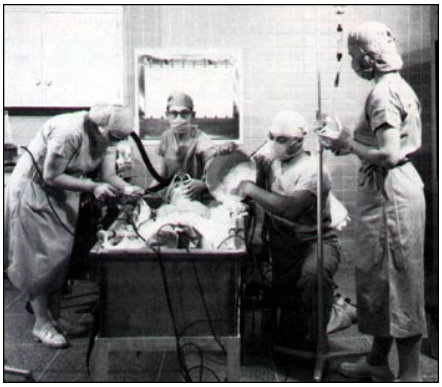


Figure 1: Open heart surgery using hypothermia

Ever since the 1950s, open heart surgeries became more and more frequent and with a constant increase in the number of successful surgeries. Two other breakthroughs can be that came after that can be pointed out: the introduction of minimally invasive procedures as well as robotic surgery. As it will be explained later in the thesis, both procedures made it possible to avoid cutting the sternum, drastically reducing the recovery time after the surgery.

The reason we are so interested in heart surgery and more specifically robotic heart surgery is because this thesis will treat about the design of a surgical tool for the mitral valve repair surgery. The mitral valve is the valve between the left atrium and the left ventricle in the heart. This surgery is done with the Da Vinci surgical system, seen in FIGURE 2, which is a surgical robot responsible of reproducing the movements of the surgeon with a precision that would not be feasible by any human in the very limited working space of the heart.

Figure 2: Da Vinci surgical system

The subject of this thesis was suggested by Dr Navarra, a cardiac surgeon at 'Cliniques Universitaires Saint Luc' in Brussels. He operates on a regular basis with the Da Vinci system on patients with a mitral valve malfunction. In this context, for the mitral valve repair surgery specifically, there is the need for a specific surgical tool, the retractor, that is responsible for pulling the atrium walls during the procedure to have a good access, both visually and robotically, to the mitral valve. Its role is crucial and the efficiency of the procedure directly relies on the retractor.
Unfortunately, the existing solution is not considered optimal by Dr Navarra as well as other surgeons. This is the reason he suggested to think of a new design for this retractor, with the main constraint that it would need to be inserted in a minimally invasive incision (max 15mm) and yet be deployed in the atrium to expose the 30-40mm wide valve.
Throughout the duration of the thesis, there has been a systematic collaboration with Dr Navarra to make sure that the understanding of the problem was correct, and in a later phase to present him the prototypes and review them with him so that he could suggest improvements.

The thesis will be divided into two main parts which are the medical context, to have a proper understanding of the problem, and then the part regarding the actual design and development of the tool.
The second part will firstly present a state of the art of the existing retractors on the market. Afterwards, a specifications analysis will be done, followed by a research for alternatives. Once an alternative is chosen, the latter will be designed and manufactured. Eventually, this will lead to a second prototype that will be tested on a pig's heart and reviewed.

Part I

Medical context

Chapter 1

The heart

Ever since the Ancient Greeks, the heart has proven to be a center of interest and curiosity for the most renown doctors. They have indeed been trying to understand fully its anatomy and physiology for millenniums.
Since this thesis is mainly about a heart surgery, it is also interesting to note that the very first successful surgery of the heart was performed by Dr. Ludwig Rehn in September 1896 [3]. However, more than half a century passed before the first successful registered open-heart surgery, performed by Dr. John Carter Callaghan in 1956. The technologies have been improving at a drastic rate ever since.

1.1 Anatomy

The first step for a better understanding of the heart is a better understanding of its anatomy, and more specifically of its location, as well as its chambers and valves.

1.1.1 Location

To understand the location of the heart, one must first understand the mediastinum, represented in FIGURE 1.1. The mediastinum is a region bounded on each side by:

- The vertebrae columanae on its posterior side
- The sternum on its anterior side
- The superior thoracic aperture, defined with the first rib, on its superior side
- The diaphragm on its inferior side
- The pleural cavities on its lateral sides

It is divided by several subdivisions: the superior mediastinum and the inferior mediastinum, itself divided into the anterior, posterior and middle mediastinum.

The heart is therefore located in the middle mediastinum which also contains the pericardial sac, the trachea and the major arteries and veins. A lateral and anterior views of the location of the heart can be seen in FIGURES 1.2 and 1.3.

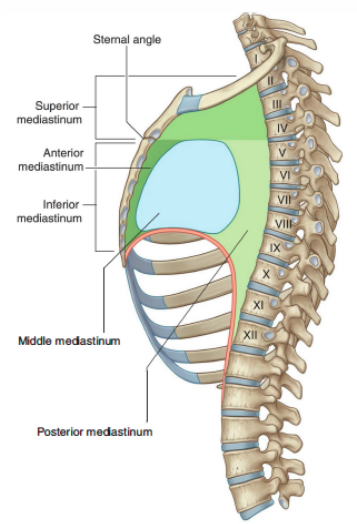


Figure 1.1: Mediastinum[4]

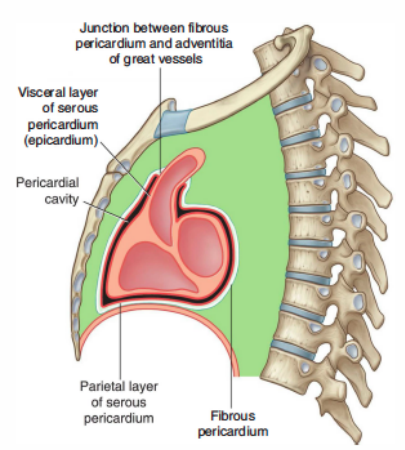


Figure 1.2: Lateral view [4]

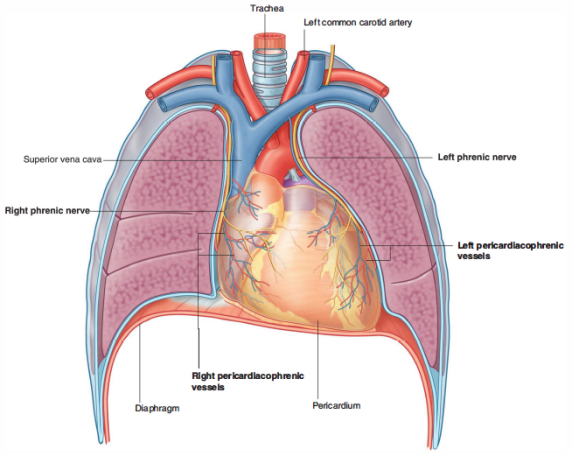


Figure 1.3: Anterior view [4]

1.1.2 Chambers

The heart can be divided into two regions, called the left and right regions. The left region contains the oxygenated blood while the right one contains the deoxygenated blood. Each side is then again divided into two chambers: the atrium and the ventricle. Therefore, there are a total of four chambers: the left and right atria and the left and right ventricles.

The anatomy of each chamber is directly linked to its function. FIGURE 1.5 is a schematic representation of the bloods cycle.

Both atria receive blood and push it into the ventricles. The right atrium receives the deoxygenated blood from the superior and inferior venae cavae and pushes it in the right ventricle. The left atrium receives the oxygenated blood from the pulmonary veins and pushes it in the left ventricle. Because they simply receive the blood and transfer it to the ventricles, the pressures are much lower than those in the ventricles and the walls are therefore thinner than those of the latter.

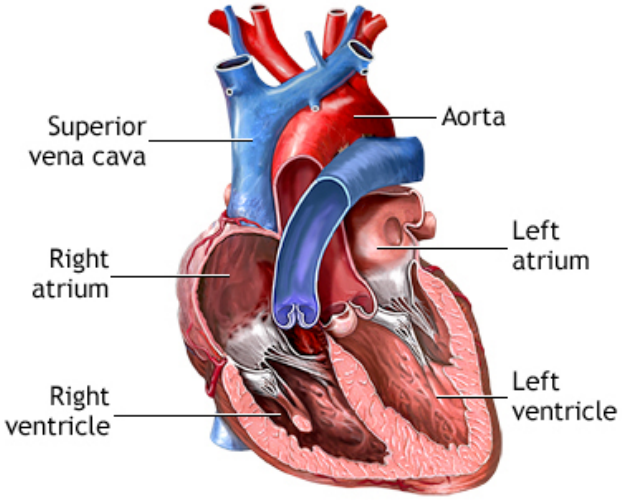


Figure 1.4: Heart chambers, anterior view [1]

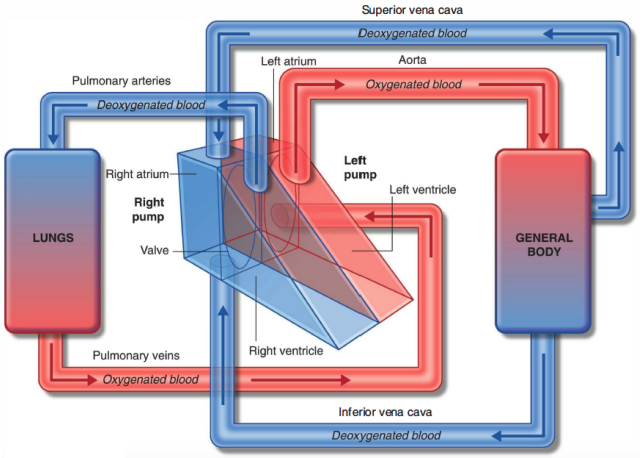


Figure 1.5: Schematic of the blood cycle in the body [4]

The ventricles receive the blood from the atria and pump it through the body. The right ventricle pumps the blood to the lungs through the pulmonary artery. The left ventricle pumps the blood to the whole body through the aorta. Because the lungs are close to the left ventricle, the force needed is less than that to pump the blood from the left ventricle to the whole body. For this reason, the walls of the right ventricle are thinner than those of the left ventricle.

1.1.3 Valves

As it can be seen in FIGURE 1.6, there are four main valves in the heart: the tricuspid valve and the pulmonary valve on the right side and the mitral valve and aortic valve on the left side.

[1] From `https://medlineplus.gov/ency/imagepages/19612.htm`

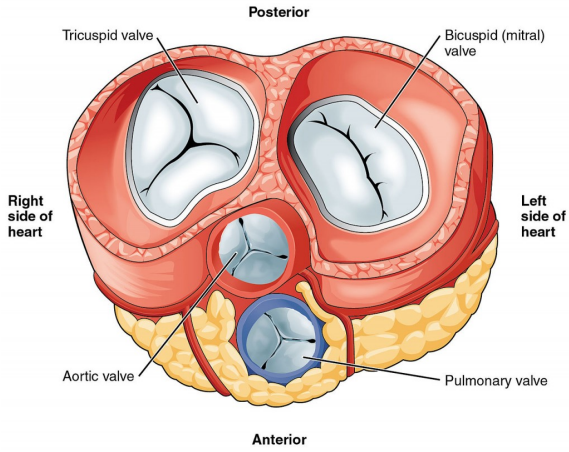


Figure 1.6: Main valves in the heart [2]

Tricuspid valve

The tricuspid valve is the valve between the left atrium and the left ventricle. It is so called because it is made of three cupsids, as can be seen again in FIGURE 1.6. A fibrous ring at the base of the valve maintains its circular shape. On FIGURE 1.7, one can notice that the three cupsids are attached in the ventricle by chordae tendineae, which are the continuation of the papillary muscles. It is the combination of these two elements that prevents the valve from reversing and falling back in the atrium after the contraction of the ventricle, which would otherwise lead to a reflux of blood in the atrium.

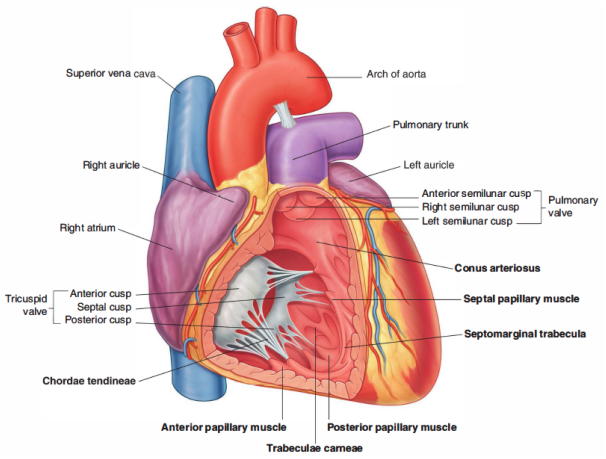


Figure 1.7: Tricuspid valve [4]

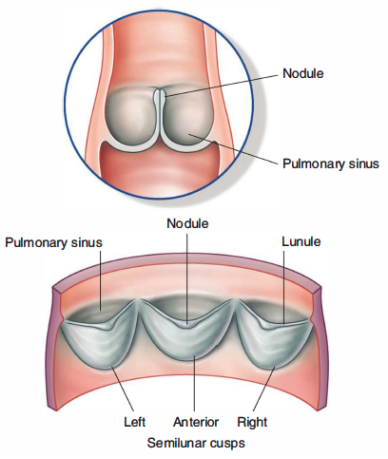


Figure 1.8: Pulmonary valve [4]

Pulmonary valve

The pulmonary valve separates the right ventricle from the pulmonary trunk. It is made of three semilunar cusps with their free edges pointing toward the pulmonary trunk. Its structure can be seen in FIGURE 1.8. After the contraction of the ventricle, the pulmonary sinus are filled with the blood falling back from the pulmonary trunk, thus maintaining the valve closed.

[2] From `http://teachmeanatomy.info/thorax/organs/heart/heart-valves/`

Mitral valve

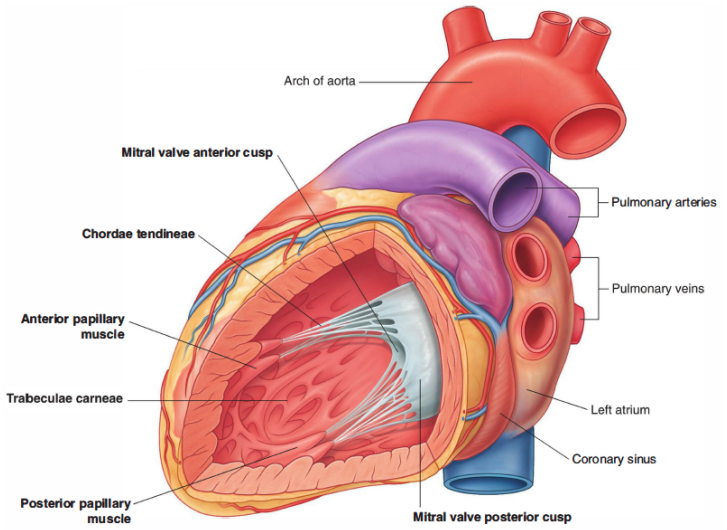


Figure 1.9: Mitral valve [4]

The mitral valve is the equivalent of the tricuspid valve but for the left heart, thus separating the left ventricle from the left atrium. Its structure is therefore very similar, with the main difference being that it is made of two cusps instead of three, as can be seen in FIGURE 1.9 where the two attachment points are quite visible. The base of these cusps is also attached to a fibrous annulus to maintain its ellipsoidal shape. The mechanism responsible for avoiding the valve from falling back into the left atrium is the same as for the tricupsid valve.

Aortic valve

The last important valve is the aortic one. It is located between the left ventricle and the aorta. Again, it is almost identical to the pulmonary valve. The only difference is the small openings in the sinus that can be seen in FIGURE 1.10, which will allow the blood to go in the coronary arteries, responsible for the irrigation of the cardiac muscle.

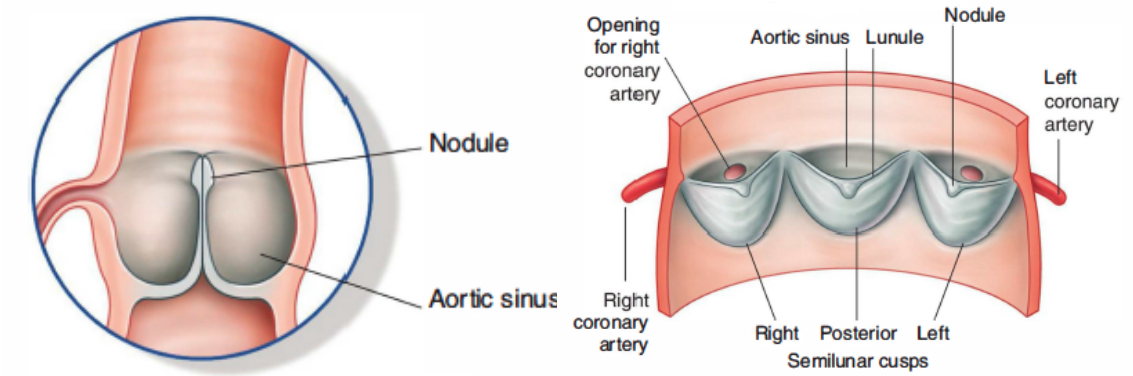


Figure 1.10: Aortic valve [4]

1.2 Physiology

Physiology refers to the branch of biology dealing with the functions and activities of living organisms and their parts, including all physical and chemical processes[3]. Indeed, it is as important as the anatomy of the heart. This will especially be of use to understand the specific function of the mitral valve.

1.2.1 Conduction system

The contraction of the heart is mainly due to three components:

- the sinus node
- the atrioventricular node (AV node)
- the His bundle

As can be seen in FIGURE 1.11, the sinus node is located in the upper right atrium, the AV node is located at the base of the right atrium and the His fiber, which is the continuation of the AV node, is located between the two ventricles, and then separates into two connections each going to their respective ventricle.

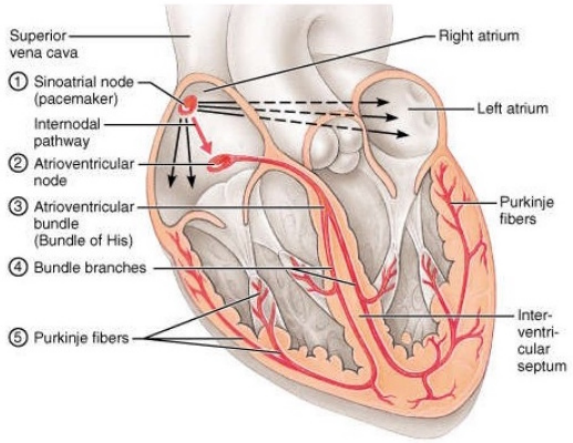


Figure 1.11: Cardiac conduction system [4]

The sinus node can be considered as the natural pacemaker of the heart. Indeed, the signal for the contraction starts there and it is therefore its frequency that sets the heart rate.
The signal spreads fast enough through the right and then left atrium so that no cardiac cells are required for both atria to contract almost simultaneously.
The propagation through both ventricles is a little bit more complicated. Indeed, the AV node constitutes the link between the atrial contraction and the ventricular contraction. It receives the signal that emanates from the sinus node. This signal then penetrates the wall between the two ventricles via the His bundle. The bundle then separates into the right branch bundle and the left branch bundle for the respective ventricles. These branches reach the Purkinje fibers, which will eventually be in contact with the myocite muscles, leading to the contraction of the ventricles. [5]

[3] `http://www.dictionary.com/browse/physiology`
[4] From `https://www.slideshare.net/Firedemon13/cardiac-conduction-system`

It is important to note that the passage of the signal through the AV node is quite slow (approximately 0.1s), allowing the contraction of the atria to end before the beginning of the ventricular contraction.

The electrocardiogram (ECG) is a graph representing the electrical activity of the heart, the horizontal axis representing the time and the vertical one the amplitude as a voltage. A normal ECG can be visualized in FIGURE 1.12. There are five noticeable curves which are usually depicted with the letters P,Q,R, S and T.
The P wave represents the atrial depolarization, the QRS complex represents the ventricular depolarization and the T wave its re-polarization. In terms of the cardiac conduction, the P wave is when the signal is at the AV node and spreads through the atrium whereas the QRS complex represents the path of the signal through the AV node, the His bundle, the branches and the Purkinje fibers.

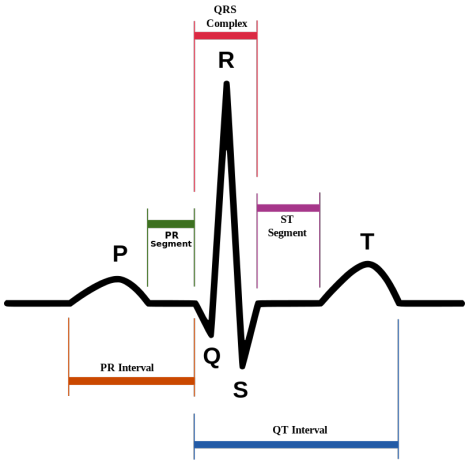


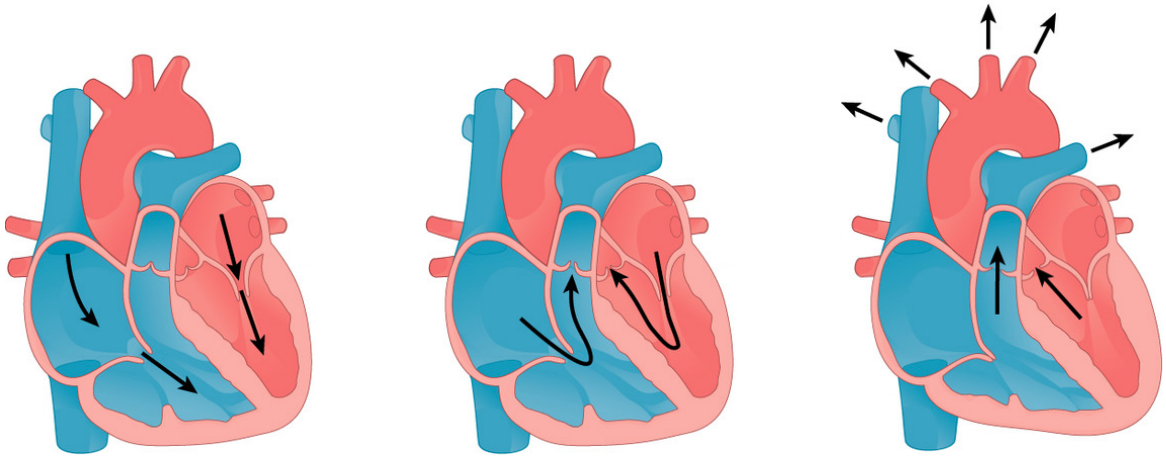
Figure 1.12: Electrocardiogram [6]

The ECG is extremely useful to get a good understanding of one's cardiac function, such as "rate and rhythm of heartbeats, the size and position of the heart chambers, the presence of any damage to the heart's muscle cells or conduction system, the effects of cardiac drugs, and the function of implanted pacemakers."[6]

1.2.2 Cardiac cycle

There are two phases in the cardiac cycle: the diastole and the systole. During the diastole phase, the heart is filled with blood whereas during the systole, the blood is pushed into the arteries.

At the beginning of the diastole, the ventricles relax and cause the closure of the aortic and pulmonary valves. At this stage, both atrioventricular (AV) valves (the mitral and tricupsid valves) are also closed. This is called the isovolumic relaxation. The AV valves then open due to the pressure gradient, allowing the blood to fill the ventricles through the atria, FIGURE 1.13a. At the end of the diastole, the atrial contraction occurs, pushing the remaining blood from the atria to the ventricles.
The systole begins with the ventricular contraction. The ventricular pressure very quickly sur-



(a) (b) (c)

Figure 1.13: Cardiac cycle[5]

passes the atrial pressure which causes the AV valves to close, FIGURE 1.13b. At this point, the pressure in the aorta still surpasses the one in the left ventricle and so the aortic valve remains closed. The same phenomena happens with the right ventricle and the pulmonary valve. Once again all the valves are closed and this is called the isovolumic ventricular contraction. As the pressure in the ventricles rises due to said contraction, it overcomes the one in the pulmonary vein and in the aorta and both the pulmonary and the aortic valves open. The blood is pushed out of the ventricles, FIGURE 1.13c. When the gradient of pressure is sufficient, both valves close again and the cycle is complete.

[5]From https://www.boundless.com/biology/textbooks/boundless-biology-textbook/the-circulatory-system-40/mammalian-heart-and-blood-vessels-226/the-cardiac-cycle-852-12097/

Chapter 2

Valve pathologies

As the goal of this thesis is to design a tool that is used for the mitral valve repair surgery, it is a good thing to understand the need to repair the valve in the first place.
The term 'valve pathologies' refers to anything that can go wrong with one of the four main valves of the heart. In this chapter, we will see the main diseases that effect the valves and how to diagnose them.

2.1 Valve disease

2.1.1 General case

There are two dominant types of valve disease which are valvular stenosis and valvular insufficiency or regurgitation.
Valvular stenosis corresponds to a narrowing of the valvular orifice, the main cause being that the leaflets are too stiff or fused.
Valvular insufficiency/regurgitation occurs when the leaflets are not able to close properly, which causes leakage of the blood while the valve should be closed.
All four valves can be affected by either of the two diseases. [7, 8]

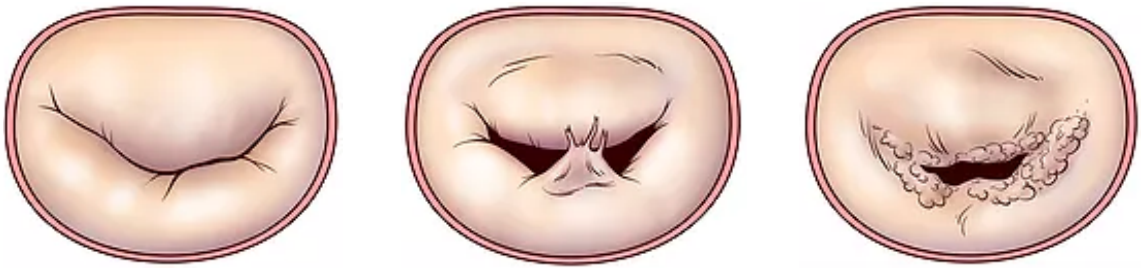
2.1.2 Mitral valve pathologies

Though every valve might have a pathology, this thesis focuses on the mitral valve which is the reason the diseases specific to the latter will be detailed. [9]

Mitral valve prolapse happens when both leaflets do not close smoothly or evenly but rather curve upward in the atrium, FIGURE 2.1b. It is most commonly due to the leaflets that are abnormally stretchy which is usually a genetic condition but it can also be a consequence of other health problems. It is the one we are most interested in as it is the disease that can be treated through surgery using the Da Vinci robot.
Mitral valve prolapse as itself is usually harmless as many people who have it, with or without symptoms, can have a perfectly normal life.
However, problems arise when there are complications. The main complication is regurgitation, when blood leaks back in the atrium during systole. This can cause blood to accumulate in the

atrium and lungs, which can lead to heart failure. It can also lead to a stroke as a clot could form and travel from the heart to the arteries or the brain. [10]

Mitral valve stenosis is the scarring resulting from rheumatic fever, which is a childhood disease, FIGURE 2.1c. It is however very uncommon as rheumatic fever itself is rare and now usually quickly treated so to avoid such complications.

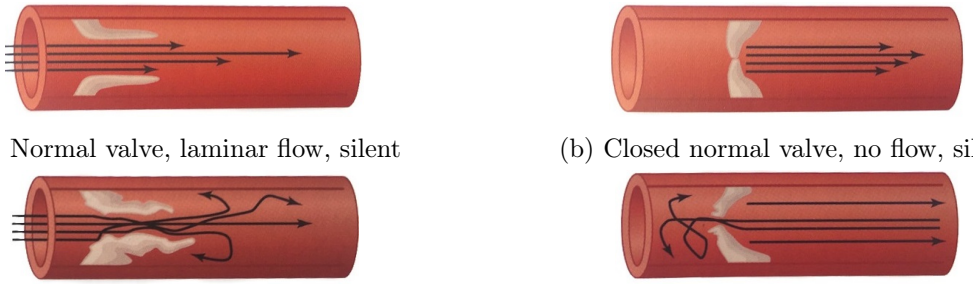


(a) Normal mitral valve (b) Mitral valve prolapse (c) Mitral stenosis

Figure 2.1: Mitral valve pathologies [1]

2.2 Diagnosis

One of the first and easiest ways to detect a valve pathology is by a physical examination, which consists in listening to the heart with a stethoscope. For a healthy heart, two sounds should be heard, due to the contraction: a low frequency sound due to the closing of the AV valves, and then a higher intensity one due to the closing of the aortic and pulmonary valves. They are simply due to the vibration of the valves when they close.
If another sound is perceivable however, this means one of the valves is defective and the sound perceived is called a *murmur*. It is due to the fact that the flow passing through the valves is no longer laminar as it should be but turbulent and therefore loud, as it is represented in FIGURE 2.2.



(a) Normal valve, laminar flow, silent (b) Closed normal valve, no flow, silent

(c) Valve stenosis, turbulent flow, murmur (d) Valve prolapse, turbulent flow, murmur

Figure 2.2: Mitral valve disease diagnosis through murmur [5]

The most common test to certify a valve pathology, besides an ECG, is an echo-cardiogram, which uses sound waves to create moving pictures of the heart. A typical echo-cardiogram can be seen in FIGURE 2.3. FIGURE 2.4 represents a Doppler ultrasound echo, which shows the

[1] From `http://www.mini-valve.com/mitral-valve`

circulation of the blood in the heart. The colors represent the speed and direction of the flow. By definition, a flow towards the transducer is represented in red while a flow away from the transducer is represented in blue [11]. An echo-cardiogram reveals numerous and interesting information such as: the size of the heart, the thickness of the ventricles, heart muscles defects, heart valve problems and blood clots. Other tests include stress testing, chest x-rays and cardiac catheterizing. In the example of a mitral valve prolapse, the blood regurgitating in the atrium during the ventricular contraction will be visible thanks to the color Doppler.[12]

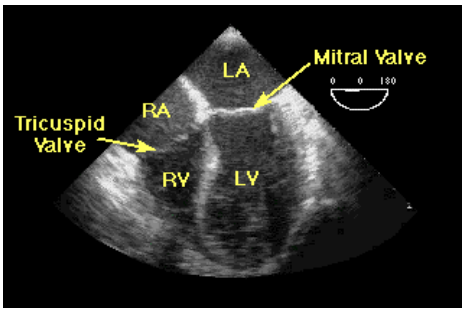


Figure 2.3: Echocardiogram

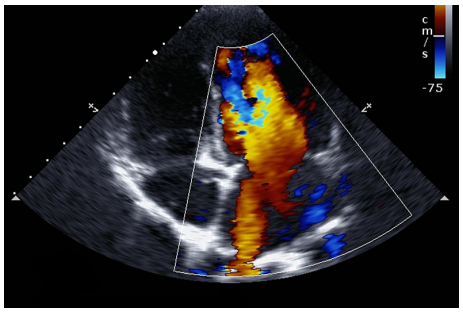


Figure 2.4: Doppler echocardiogram

Chapter 3

Mitral valve repair surgery

There are three ways to operate on a defectuous mitral valve: open-heart surgery, minimally invasive surgery and robotic surgery.
Even though mitral valve surgery is now the most performed robotic surgery, the path to get there has been rough, as cardiac surgery was the last area of surgery to be introduced to the realm of minimally invasive surgeries. This is the reason why the first minimally-invasive surgeries on the mitral valve only began in the 1990s. More specifically, the first surgery using a videoscope was performed by Dr. Carpentier in 1996. The first robotic surgery was performed two years later, again by Dr. Carpentier, with an early prototype of the Da Vinci system. It was not until 2002 that the Da Vinci was approved to be used for mitral valve repair surgeries in the USA, after several years of clinical trials. [13, 14, 15]

3.1 Open heart surgery vs. minimally invasive procedure

There are two ways to operate for a mitral valve repair, either via an open heart surgery or via a minimally invasive procedure.
The open heart surgery consists in opening the chest by making an incision of 15 to 20cm long, as can be seen on the left of FIGURE 3.1. Moreover, it is required to cut through the sternum to gain access to the heart. After the surgery, the patient will likely need to stay 4 to 8 days at the hospital and recovery should take 5 to 8 weeks. [16]

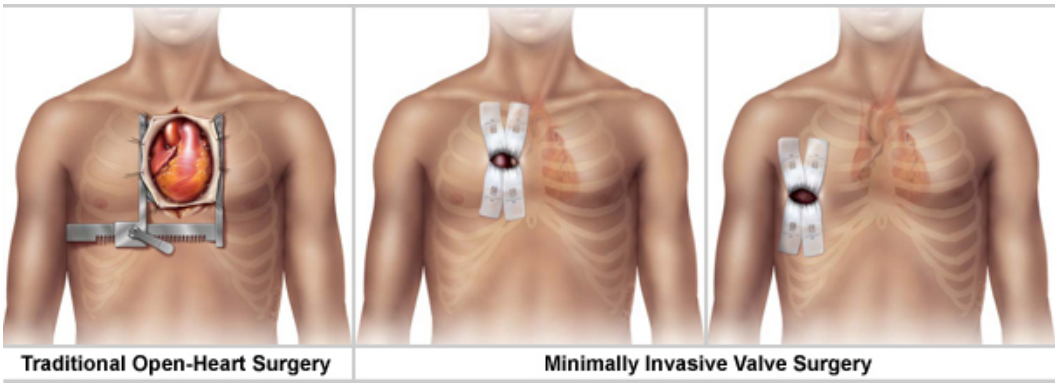


Figure 3.1: Open heart surgery vs. minimally invasive surgery [17]

For a minimally invasive surgery, the surgeon will typically make one to four small incisions (2-4cm) on the patient and a slightly bigger one for the laparoscope - "a thin tube with a tiny camera and light at the end"[18] - and the other non-robotic tools, visible on the right of FIGURE 3.1. Cutting the sternum is no longer needed in this case. The patient will need to stay 2 to 5 days at the hospital and recovery should take 2 to 4 weeks. To summarize, the advantages of a minimally invasive procedure compared to an open heart surgery are:

- Less scaring
- Less pain
- Shorter hospital stays after surgery
- Lower risks of infection and bleeding
- Shorter recovery time [19]

3.2 Da Vinci surgical system

The Da Vinci surgical system is a surgical robot that was created by the company Intuitive Surgical and put on the market in 2000. According to their website, "With the Da Vinci Surgical System, surgeons operate through just a few small incisions. The Da Vinci System features a magnified 3D high-definition vision system and tiny wristed instruments that bend and rotate far greater than the human hand. As a result, Da Vinci enables your surgeon to operate with enhanced vision, precision and control." [18]
The principle is that the surgeon performs on a console that is a few meters away from the body, as can be seen in FIGURE 3.2. He is guided by a 3D rendering, made possible by the laparoscope in the patient's body. The robot then reproduces the movements of the surgeon with a precision that would not be possible for a human. It can also bend and twist in a manner a human hand could not in a patient's body. Eventually, it cancels out the potential vibrations of the surgeon's hands, and therefore the possible errors due to said vibrations.

Figure 3.2: Da Vinci surgical system [1]

[1] From https://www.masseyattorneys.com/fda-investigation/

3.3 Surgical intervention

There are three reasons to justify the surgery:

- "Changes in your mitral valve are causing major heart symptoms, such as shortness of breath, leg swelling, or heart failure.
- Tests show that the changes in your mitral valve are beginning to harm your heart function.
- Damage to your heart valve from infection (endocardiatis)."[13]

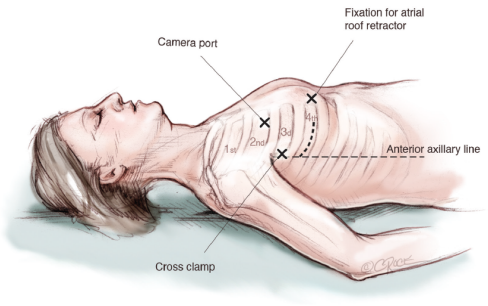


Figure 3.3: Incisions for the surgery [2]

Two surgeons are required for this surgery; one of them manipulates the Da Vinci system, while the other one stands above the patient with a nurse. The latter are responsible for all the tasks which can not be done with the Da Vinci System (making the first incisions, inserting the sewing threads, the annulus, etc.).
One of the surgeons will start by making four small incisions (1-2cm) on the right side of the patients chest for the robotic tools, and a fifth one for the endoscope, as can be seen in FIGURE 3.3. He will then proceed to the cardiopulmonary bypass. It is a system that will relay the functions of the heart and lungs to a machine so that the blood irrigation through the whole body will be maintained during the procedure. This step is crucial for the survival of the patient and allows the heart to be still while operated on. Eventually, the valve repair will consist of three main phases:

- The resection of the excessive valve leaflet, FIGURE 3.4.
- The suture of the leaflet to give back its functioning shape to the valve, FIGURE 3.5.
- The placement of an annular disk to reduce the size of the valve, FIGURE 3.6. In fact, the valve is usually extended because of the malfunction.

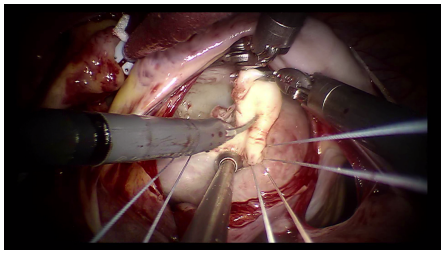


Figure 3.4: Resection of valve leaflet

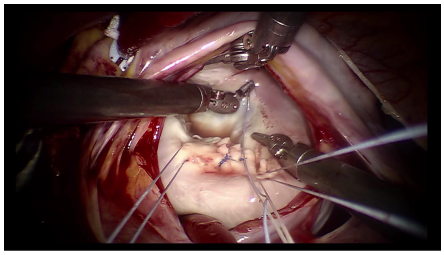


Figure 3.5: Suture of the leaflet

[2]From research gate, https://www.researchgate.net/figure/259355919_fig1_Figure-2-Chest-wall-landmarks-before-any-incisions-are-made

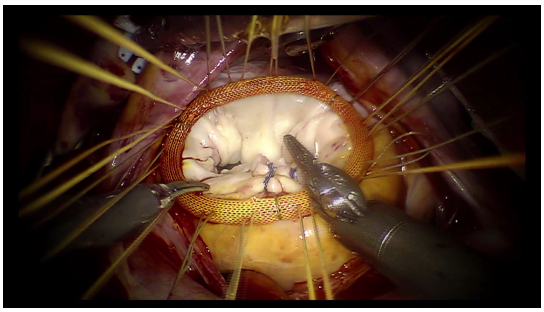


Figure 3.6: Placement of annular disk

3.4 The retractor

The role of the retractor is very simple but crucial. It is responsible for pulling on the atrium walls to make a clear access to the valve, both visually and robotically.
FIGURE 4.1 shows the retractor by itself while FIGURES 3.8 and 3.9 show the exposition of the valve before and after the retractor is deployed, the latter being the tool on the upper part of the images.

Figure 3.7: Retractor alone[3]

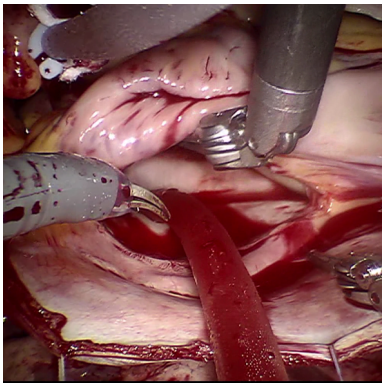


Figure 3.8: Retractor undeployed

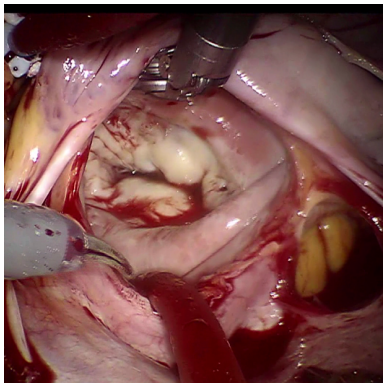


Figure 3.9: Retractor deployed

[3]From Intuitive Surgical instrument catalog, https://www.intuitivesurgical.com/images/on-site-banners/1008471rB-EU_Xi_IA_Catalog.pdf

Part II

Device design and development

Chapter 4

State of the art

As for any project in mechanical design, it is always a good thing to look at what has already been done on the subject. This research phase is done for two main reasons:

- A better understanding of the problem : the client is not happy with what is already on the market, why is that? What are the flaws of the current product and how could they be improved?
- Using the advantages of the existing solutions, if they have some, to get inspiration for the generated alternatives.

4.1 Da Vinci atrial retractor

The Da Vinci atrial retractor which was introduced in SECTION 3.4 is the retractor sold by Intuitive Surgical and comes with the Da Vinci operating system. It possesses two degrees of freedom: the translation of the two endings (green arrow on FIGURE 4.1) as well as a rotation to pull back those endings (orange rotation axis on FIGURE 4.1).
It is this retractor that is used nowadays for the robotic mitral valve repair surgery.

Figure 4.1: Da Vinci atrial retractor [20]

According to surgeons, it is not optimal. When asked about it, Dr Navarra quoted the following reasons:

- The degrees of freedom are very limited.
- It can barely be modified to fit each patient's anatomy.

– It exposes only a partial view of the valve, leaving to suggestion what lies on both sides. This is visible on FIGURES 3.4, 3.5 and 3.6.
– It is not so easy to use and the surgeon usually has to start over before he is satisfied with the resulting view. This usually leads to a loss of time, leading to a bigger amount of time on the cardiopulmonary bypass which should be avoided as much as possible.

Finally, the retractor alone costs around 1300€ and must be replaced every 10 cycles. This means that this tool alone costs 130€ per surgery. Its high cost per surgery is therefore another disadvantage that can be pointed out.

4.2 HV heart retractor

The HV heart retractor, FIGURE 4.2, is manufactured by USB-medical and was co-invented by Dr. Hugo Vanermen, cardiac surgeon at Cliniques Saint-Luc.

Figure 4.2: HV heart retractor [21]

Quoting the USB-medical advertisement, that can be found in APPENDIX A, its main advantages are the following:
– "Innovative design allows for precise positioning for optimal viewing and access of the heart. Allows the surgeon more flexibility in retractor placement, and an increased work area."
– Self-adjusting pivot blade eliminates stress on the heart by distributing pressure evenly. The specific amount of load on a given area is now greatly reduced, protecting the heart tissue from damage during retraction.
– "Hinged Blade provides even greater exposure by retracting twice as much heart tissue."
– "Blade easily adjusts through a 30°range of motion for superb positioning and results. No need to manipulate the patient."

Again according to the surgeon however, the fact that the final position needs to be fixed through small elements that need to be tightened with another tool is very constraining and not feasible using the Da Vinci operating system.

Another very similar atrial retractor is the Valve XS atrium retractor from B. Braun that can be seen in FIGURE 4.3. The main difference is that the additional part is folded but once again a second tool is required for this operation. [23]

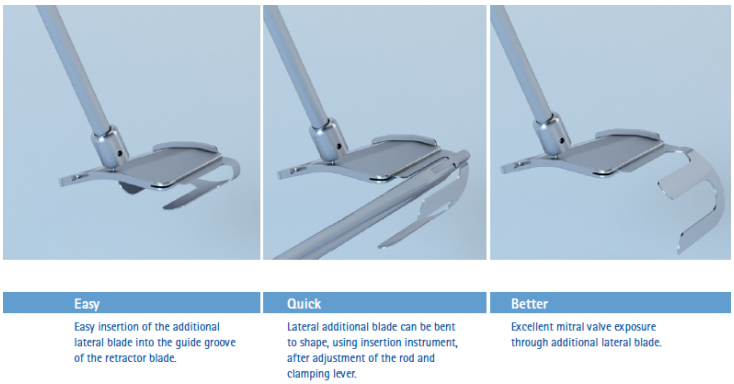


Figure 4.3: Valve XS atrium retractor, BRAUN [1]

4.3 Cosgrove valve retractor system

The Cosgrove valve retractor system in FIGURE 4.4 is one of the most commonly used retractor for the open-heart mitral valve repair and replacement surgery.

Figure 4.4: Cogrove retractor system [2]

It is manufactured by Medline and consists of a chest spreader, on which can be mounted any type of atrial retractor. One of the most frequent retractor used jointly with the Cosgrove system is the Cooley atrial retractor. It can be seen mounted on the left image of FIGURE 4.4 and alone in FIGURE 4.5. [22]

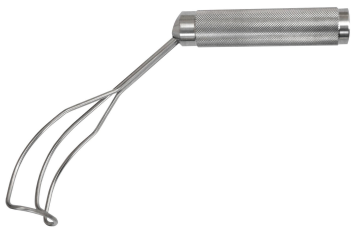


Figure 4.5: Cooley atrial retractor

Even though it is not useful for a minimally invasive surgery, this device is still interesting to study as it provides a very good exposure of the valve during the procedure.

[1] From retractor brochure, `https://www.bbraun.com/en/products/b0/valve-xs-atrium-retractor.html`
[2] Left picture from `http://www.fac.org.ar/scvc/llave/surgery/navia/naviai.htm`

Chapter 5

Functional analysis

As it was made relatively explicit by the state of the art in CHAPTER 4, the existing solutions for the atrial retractor are not optimal. They can lead to errors during the surgery and thus to an increase in the duration of the latter. It is for this reason that the surgeon requested a research in order to find an optimized design.

FIGURE 5.1 represents a typical approach for the design part in a mechanical design project. In fact, the very first step is to 'clarify and define the task'. This has already been partially done in PART I by setting the medical context as well as in CHAPTER 4 which stated the existing solutions and why the latter were not appropriate. The objective is now to clarify the problem in order to translate the request into specific and scientific terms in an organized and detailed document called the specifications.

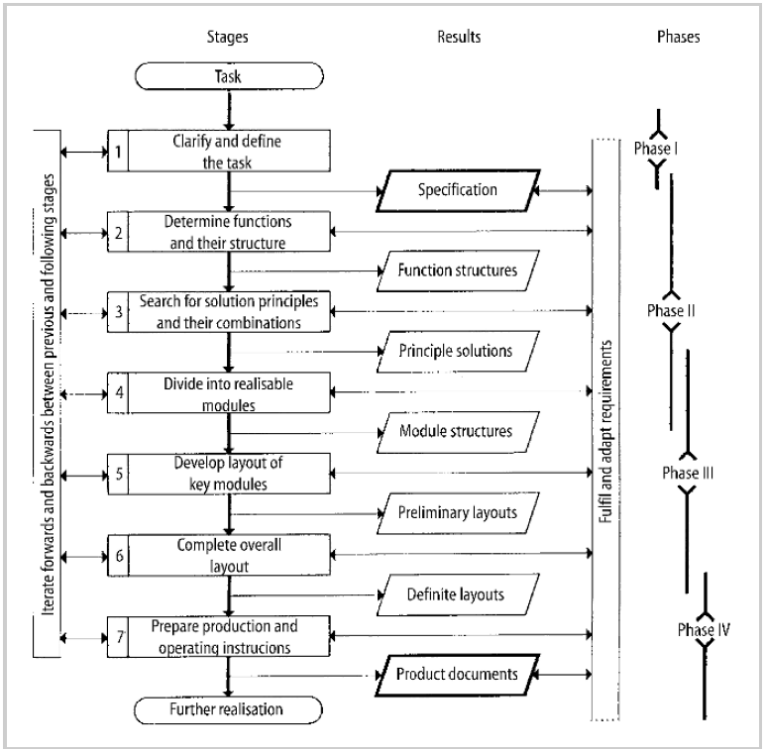


Figure 5.1: General design approach [24]

5.1 Design method

Directly following FIGURE 5.1, the design method will be the following:

- Clarify the task.
- Define the main functions through a functional analysis.
- Detail the constraints.
- Clarify the three first points in the specifications.
- Set the comparison criteria.
- Generate alternatives that correspond to the need.
- Evaluate those alternatives with the comparison criteria and choose a definite one.
- Develop the chosen alternative.
- Test the prototype. [24, 25]

5.2 Functional analysis of the need

FIGURE 5.2 represents the functional analysis as a black box type block diagram. With this diagram, two main functions are highlighted:

- F1: Expose the valve
- F2: Fix the tool

In order for the functions to be fully defined, they should come with functional requirements. For F1, the dimensions of the mitral valve need to be specified whereas for F2, the surgeon needs to fix the maximal acceptable amplitude for the relative movement of the tool.

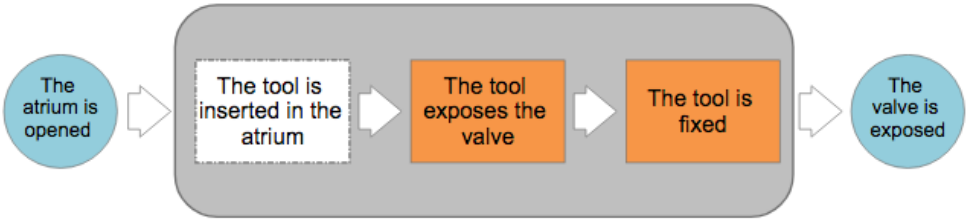


Figure 5.2: Functional block diagram

Figure 5.3: Legend functional diagram

5.3 Specifications of the need

The SPECS, FIGURE 5.4 on the following page, translate what was said in SECTION 5.2 in a detailed manner so that there is no room for random guesses.
Moreover, it includes all the constraints that need to be applied to the design.

Fanny Dols 05/11/2016 Version: 5.0	SPECS	
Context: Design of an atrial retractor to make access to the mitral valve for the minimally invasive valve repair surgery performed with the Da Vinci robot		
Date	Origin	
		Functions
5/11/16	E. Navarra	F1: Display the mitral valve to allow endoscopic, manual and robotic access
12/10/16	E. Navarra & X. Bollen	F2: Fix the tool to limit its relative movement with the patient
		Functional Requirement
12/10/16	E. Navarra & F. Dols	FR1.1: Mean dimensions of the valve (mm): • Mediolateral diameter: 38 ± 5 • Anteroposterior diameter: 38 ± 6
05/11/16	X. Bollen & F. Dols	FR 2.1: Max/min amplitude of ± 5mm
		Constraints
05/10/16	F. Dols	C1 : Ensure patient's safety
05/10/16	X. Bollen & F. Dols	C2 : Respect of the norms relative to medical devices
05/10/16	E. Navarra & F. Dols	C3: Insert the tool through a mini-invasive access
05/11/16	X. Bollen	C4: Work cojointly with the other tools
		Constraint requirement
12/10/16	F. Dols & E. Navarra	CR1.1: Do not exceed the mean normal dimensions of the left atrium (mm): 27-40x29-50
05/10	F. Dols	CR 1.2: Maximum admissible pressure on the tissues: 120mmHg, corresponding to the systolic pressure
12/10/16	E. Navarra	CR 1.3 : Should not take more than 10 seconds to remove the tool in case of emergency
05/10/16	X. Bollen	CR 2.1 : The material must be manufactured with biomaterial
05/10/16	X. Bollen	CR 2.2 : The mechanical design and production procedures must be conform to the directive MDD 93/42/EEC
05/10/16	X. Bollen	CR 2.3 : The device must be sterilisable
05/10/16	X. Bollen	CR 2.4 : The non sterilisable parts shall be isolated from the operative field with a plastic film
12/10/16	E. Navarra	CR 3.1: Maximum diameter of the cut: 15mm, maximum accepted to avoid cutting the ribs.
05/11/16	F. Dols	CR 4.1: It should maintain the working space for the Da Vinci tools (arms+endoscopic) and the other surgical tools

Figure 5.4: SPECS

5.4 Comparison criteria

Comparison criteria need to be set before starting to think about alternative solutions and in order to ensure that the final choice is made objectively. In this case, they were decided in collaboration with the surgeon so that he could decide which criteria he thought most important for the choice of the device. This importance is set by the weights, in parenthesis after the criterion. A total of seven criteria were selected.
In a later phase, the alternatives will be graded from 1 to 4. For this purpose, an indication will be given for each criterion to what scores of 1/4 and 4/4 correspond to.

Valve display (1.0) The very first objective of the tool is to display the valve as much as possible.
- 1/4 : Bad exposure.
- 4/4 : Excellent exposure.

Size intra cardiac (0.75) It should not come in the way of other tools.
- 1/4 : Bulky tool.
- 4/4 : Tool does not come in the way at all.

Patient specific (0.5) Ideally, the tool should be able to adapt itself according to the patient's heart.
- 1/4: Tool can not be adapted at all.
- 4/4: Total flexibility of the shape of the tool to adapt to the patient's anatomy.

Access size (0.5) It should occupy a minimal volume in order to make the access as small as possible.
- 1/4: The incision will need to be bigger than 15mm or one part of the tool needs to be inserted through the bigger incision
- 4/4: Tool can be inserted through an incision <5mm.

Rigidity (0.5) The tool should be as rigid as possible in order to minimize its possible relative movement.
- 1/4: Flexible tool.
- 4/4: Totally rigid tool.

Ease of use (0.25) The simpler it is for the surgeon to use, the less time he will lose fixing the tool in the correct position.
- 1/4: Will require a lot of manipulations from the surgeon to fix the tool in the desired position.
- 4/4: Will not require any manipulations from the surgeon except to insert the tool.

Speed of removal (0.25) The tool should be such that it can be removed in less than 10 seconds, as was fixed by CR 1.3 in the SPECS.
- 1/4: There is a possibility that it will take more than 1 minute to remove the tool.
- 4/4: Tool can be removed in less than 10 seconds.

Chapter 6

Alternative solutions

Once the problem is correctly defined with the SPECS, the research for alternative solutions can be done. This process led to five solutions, which will be described in this chapter.
For each alternative, a functional diagram specific to the alternative and adapted from the one in SECTION 5.2 will be presented. As a reminder, the key for those functional diagrams can be seen in FIGURE 6.1. Moreover, 'Surgeon 1' refers to the surgeon manipulating the Da Vinci console while 'Surgeon 2' refers to the surgeon above the patient.

Figure 6.1: Legend for functional diagrams

6.1 1st solution - Swan neck

The first solution is directly inspired by the principle used in 'swan neck' lamps that can be seen in FIGURE 6.2.

Figure 6.2: Swan neck lamp type [1]

The idea is thus to apply this principle in order to have two branches in the atrium. At first, they would be flexible to allow the surgeon to give it the shape he wants in order to have a good exposure of the valve. Once he is satisfied with it, he would simply have to activate a

[1] From `http://www.directindustry.fr/prod/diana-electronic-systeme-gmbh/product-41145-1292843.html`

mechanism so that the whole system is blocked. FIGURE 6.3 summarizes the succession of tasks for this alternative.

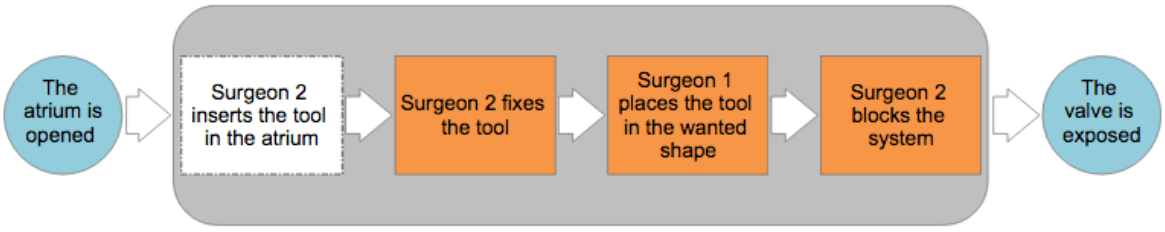


Figure 6.3: Functional diagram of the 1st solution

Hands drawings can be seen in FIGURES 6.4 and 6.5.

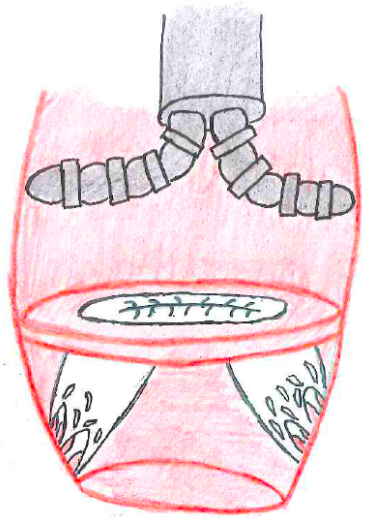


Figure 6.4: Frontal view

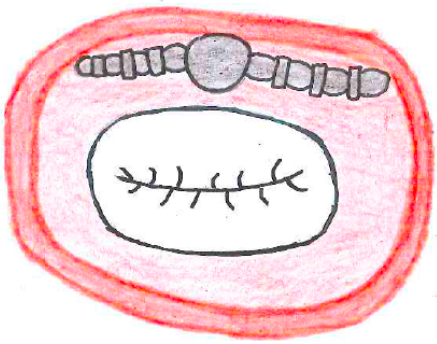


Figure 6.5: Upper view

The advantages of this solution are:

- It can take any wanted shape, thus allowing it to be easily adapted to each patient's anatomy.
- It can easily be inserted in a minimally-invasive hole.
- It is easily retracted in case of an emergency.

The main disadvantages are:

- It requires the manipulation of both surgeons to put it in place.
- It does not deploy by itself.

6.2 2nd solution - Balloon

The second solution consists in a balloon filled with water to obtain a C-like shape. When inflated, it would apply a pressure on the walls of the atrium. The succesion of tasks is detailed in the functional diagram in FIGURE 6.6 while schematic drawings can be seen in FIGURES 6.7 and 6.8.

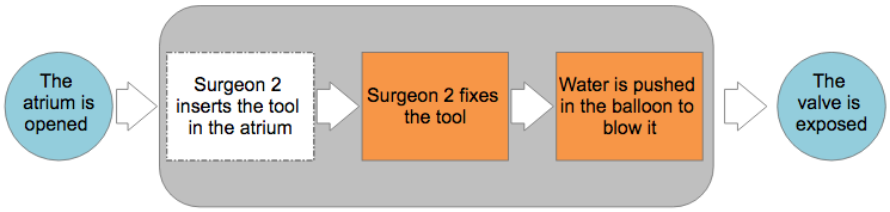


Figure 6.6: Functional diagram of the 2nd solution

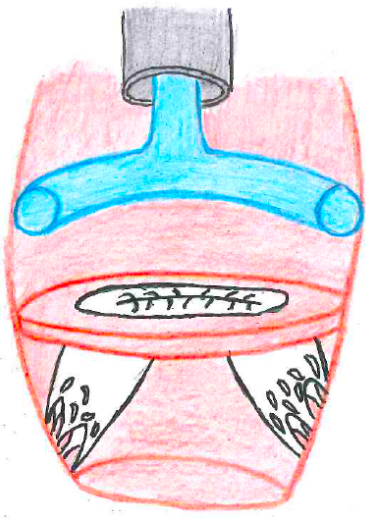


Figure 6.7: Frontal view

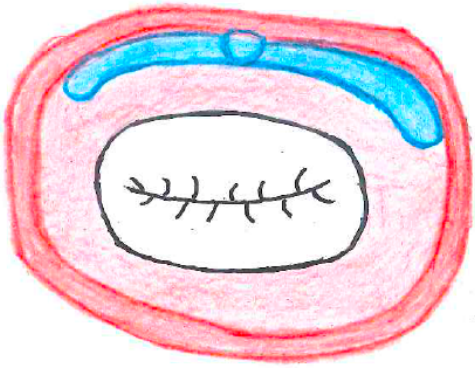


Figure 6.8: Upper view

Its main advantages are:

- The access size; when deflated, it can easily fit in a very small space
- Its ease of use, as the surgeon would only need to insert it and fill it with water after what it should take the desired shape by itself.

Its main disadvantages are:

- It can not be adapted according to the patient's heart anatomy.
- It takes a lot of space when deployed in the atrium.
- It needs to be emptied before removal, which could prove to be a crucial loss of time when confronted with an emergency.
- The membrane of the balloon needs to be very resistant to avoid being teared by the other tools.
- The feasibility of producing a balloon that could take a C-shape when filled rather than an oval shape is not ensured.

6.3 3rd solution - Sucker

The third solution consists in a system with a curved part at the end with suckers included. Ideally, the curved part would be made of two symmetrical parts in order to minimize the size of the incision needed to insert the tool. The suckers would suck the atrium walls and then pull

then backwards, as is detailed in FIGURE 6.9. Schematic drawings can be seen in FIGURES 6.10 and 6.11.

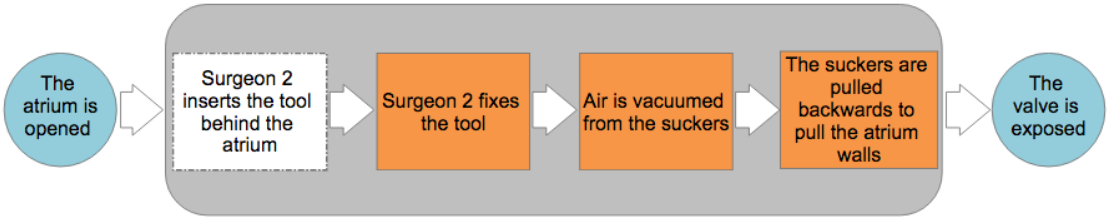


Figure 6.9: Functional diagram of the 3rd solution

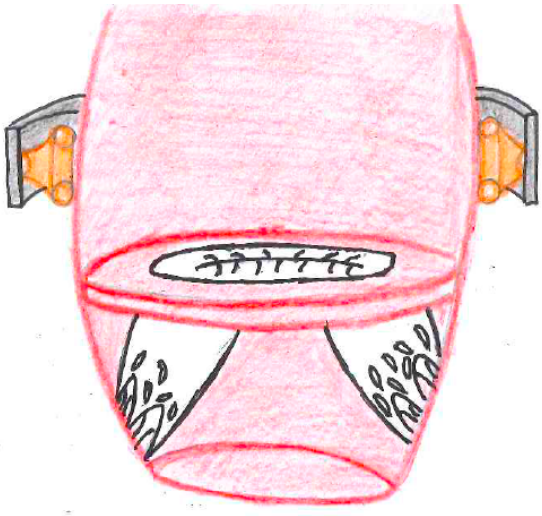


Figure 6.10: Frontal view

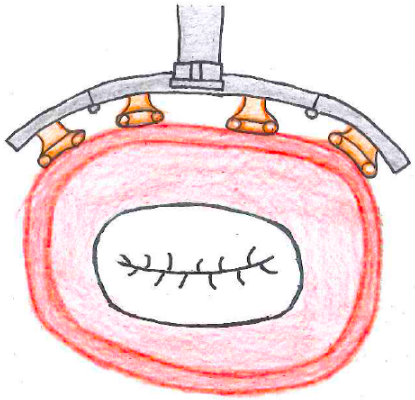


Figure 6.11: Upper view

This solution is very interesting because of its numerous advantages:

- It is easy to use.
- It gives a nice exposure of the valve.
- It does not interfere at all in the working space.
- It is very rigid, limiting the relative movements.

The main disadvantage being the insertion incision that will most probably need to be bigger than 15mm, making it mandatory for the ribs to be cut.

Unfortunately, after consulting the surgeon, he pointed out that it could not be feasible because on the side available for the retractor and behind the left atrium walls stands the right atrium. There is therefore no possible access for the tool.

Another alternative was thus introduced, still consisting of suckers, but instead of pulling from the the outside, this solution pulls the walls from the inside. Schematics drawings of the new solution can be seen in FIGURES 6.12 and 6.13.
This new solution shares most of the advantages of the first idea except for the one stating that it does not interfere with the working space.

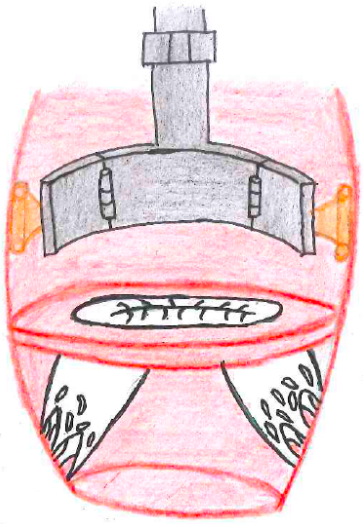


Figure 6.12: Frontal view

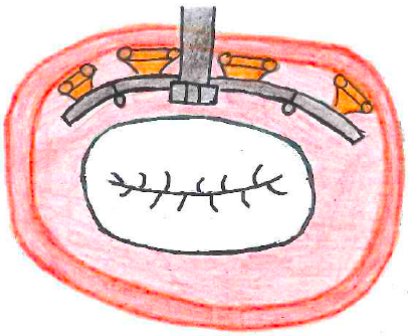


Figure 6.13: Upper view

6.4 4^{th} solution - Nitinol

The fourth solution consists in using Nitinol. Nitinol is a shape memory alloy (SMA) made of nickel and titanium.

In order to understand properly this solution, one must first understand how SMAs work. Below a certain given temperature, the alloy can take any shape wanted but when heated to said temperature, it will always take a fixed shape. This transition temperature varies between -50°and 166°depending on the alloy.
The differentiation of those two phases can be explained by the crystal theory. For the case of the Nitinol, it has two phases while solid: martensite and austenite. Under the transition temperature, it is in the martensite phase. In this phase, it is superelastic, thus allowing for multiple shapes. Above said temperature however, it is in the austenite phase, which corresponds to a cubic crystal structure, and it will therefore always take the 'parent shape'. The transformation between both phases is reversible as well as instantaneous. A summary of these transformation in relation with the heating/cooling process can be seen in FIGURE 6.14. The 'parent shape' is set by heating the alloy in the given shape at 500°C. [26]

Two of the most popular nitinol applications in the field of medicine nowadays are the dental braces and the vascular stents.
For the case of the braces, the wire linking all the braces between the teeth is made of nitinol. In fact, the temperature in the mouth is sufficient to trigger the austenite phase of the nitinol, which will thus want to get back to its curved shape. This bending will slowly force the teeth to change their curvature. FIGURE 6.15 represents the nitinol wire sold by 3M for dental use.
For the vascular stent, using nitinol allows the surgeon to bend it so that it enters in the vessels easily. However, when put in place in the body, the high body temperature will make it take its healing shape and will maintain it as long as the body temperature is sufficient.

[2]By Mmm-jun - Own work, CC BY-SA 3.0, https://commons.wikimedia.org/w/index.php?curid=23125637

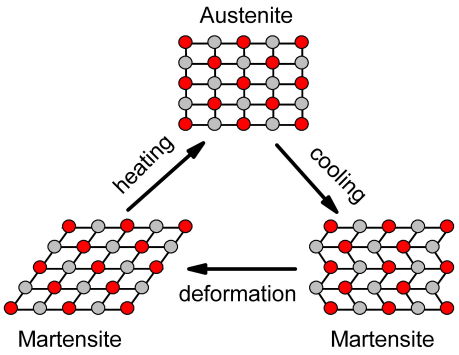


Figure 6.14: 2D view of nitinol's crystalline structure during cooling/heating cycle [2]

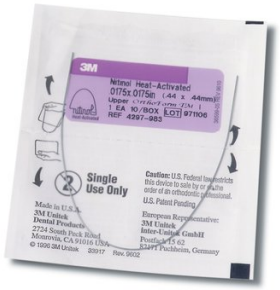


Figure 6.15: Nitinol archway from 3M©

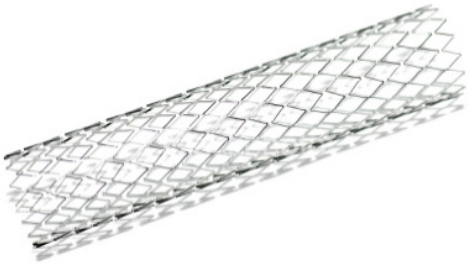


Figure 6.16: Vascular nitinol stent

Eventually, this leads to the description of the solution. In our case, nitinol would be very useful as it would bend easily to enter the small insertion hole. However, when in the atrium, it would deploy and bend as wanted due to the higher temperature in the heart than in the open space. When deploying, it would pull on the atrium walls. Its use is summarized in the functional diagram in FIGURE 6.17. Since a small wire might not be the most efficient, the solution would consists of two nitinol wires, joined together by a bio-compatible membrane. The schematic drawings of this solution can be seen in FIGURES 6.18 and 6.19.

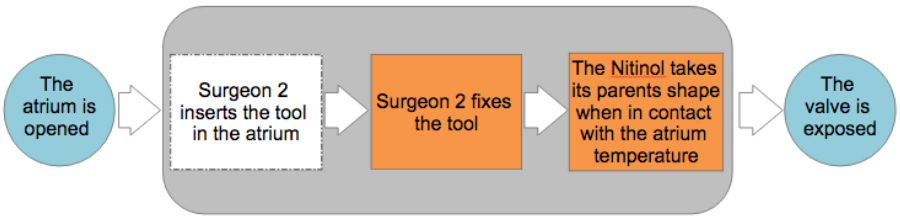


Figure 6.17: Functional diagram of the 4^{th} solution

The advantages of this solution are:

- It is easy to use. The surgeon does not have to do anything except to bend it before inserting it after what it sets itself automatically in place.
- It can easily be adapted for each patient heart's anatomy by cutting the wire to the correct length.
- Its intra-cardiac size. Theoretically, it should not take a lot of space in the atrium.

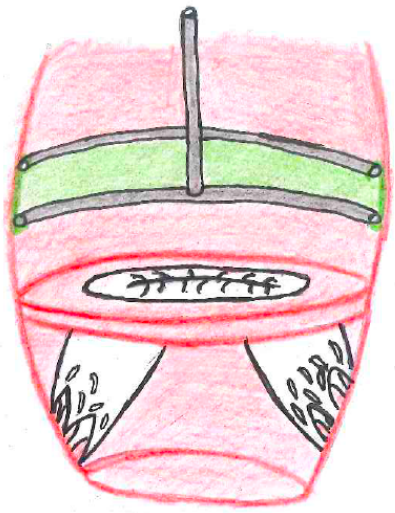


Figure 6.18: Frontal view

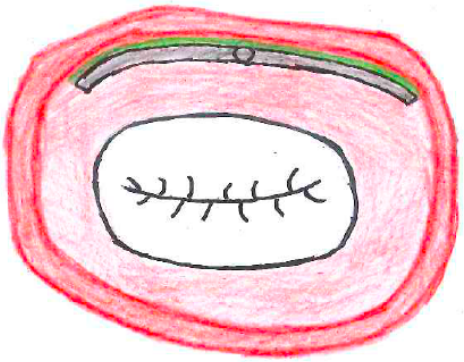


Figure 6.19: Upper view

Its main disadvantages are:

- If the heating process to get the parent shape is not done properly, the desired shape is not acquired, thus resulting in important consequences on the suregery.
- The tool can only be used for surgeries where the temperature inside the body is close to 30-35°. For some surgeries however, the body needs to be cooled down. In this case, the parent shape would not activate once in the heart.
- In order to remove the tool, it should be cooled down to be able to bend it.

6.5 5th solution - Magnet

The fifth solution consists in the use of a magnet and a piece of steel. The idea is to insert the magnet behind the atrium wall and then insert a curved metal piece in the bigger hole. The steel part would be attracted by the magnet and thus pull on the walls in order to reach the magnet. Schematic drawings can be seen in FIGURES 6.21 and 6.22.
Though here the idea still is to come behind the atrium just like the 3rd alternative, the problem of being blocked by the right atrium can be avoided since the magnet can be inserted anywhere and does not have to be exactly at the center of the curved piece.

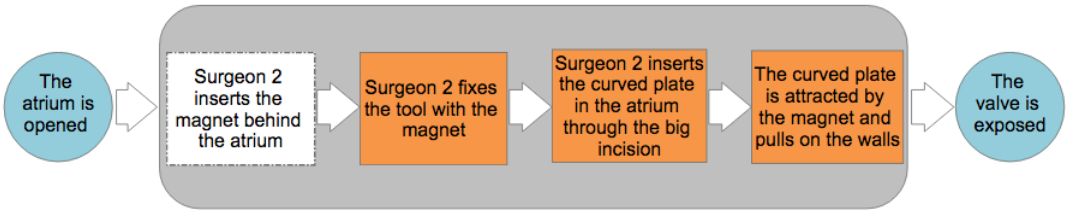


Figure 6.20: Functional diagram of the 5th solution

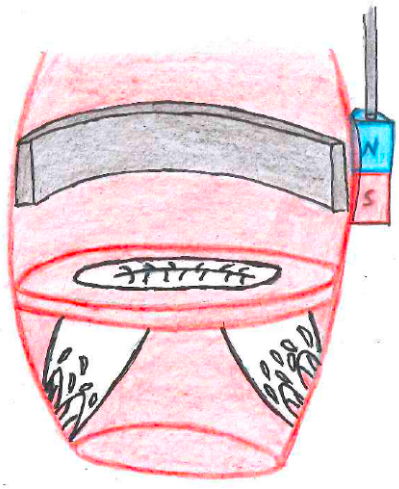


Figure 6.21: Frontal view

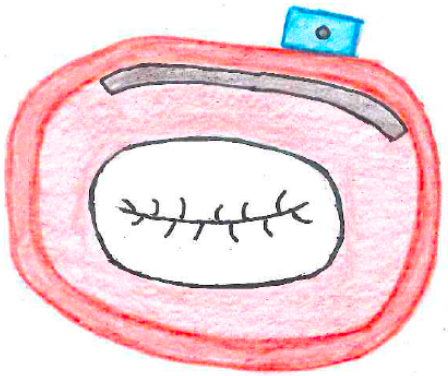


Figure 6.22: Upper view

The main advantages of this solution are:

- The valve display.
- Its rigidity. Indeed, the relative movements should be very limited with this solution.
- Its intra-cardiac size.

The main disadvantages are:

- The need to insert the curved piece through the big hole, which makes it harder to remove quickly in case of emergency and also highly affects the access size.
- It can not be modified to fit each patient's anatomy.
- The magnet might interfere with the Magnetic Resonance Imaging equipment. In addition, it is un-usable in the case of a patient with a pacemaker.
- The attraction between the magnet and the curved piece will not be smooth. The sudden extreme pressure felt by the atrium walls might damage them. Moreover, this pressure could lead to the walls not being vascularized during the procedure.

6.6 Evaluation of the alternatives

Now that all the alternatives have been defined, they can be evaluated with the comparison criteria defined in SECTION 5.4 and according to the advantages and disadvantages that were pointed out for each alternative. As it was explained in SECTION 5.4, the grades range from 1 to 4.

In addition to the weighted total, the standard deviation is also calculated. In mathematical terms, it is calculated as such:

$$\sigma = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \mu)^2}$$

Basically, standard deviation will quantify how much each term differs from the mean value. This means that a low standard deviation will correspond to an alternative with similar grades for each criterion. An alternative with a high total and a low SD means that overall, all the

grades are good. In comparison, an alternative with a high total but a high standard deviation means that some criterion will get very good grades while others will get very bad ones. To summarize, one should always look for the alternative which has the highest score *as well as* the lowest standard deviation.

	Swan neck	Balloon	Sucker	Nitinol	Magnet
Valve display (1.0)	3	2	4	3	4
Size intra-cardiac (0.75)	3	2	3	4	3
Patient specific (0.5)	4	1	1	3	1
Access size (0.5)	3	4	2	4	1
Rigidity (0.5)	4	3	4	2	4
Ease of use (0.25)	2	4	3	4	2
Speed of removal (0.25)	4	2	3	2	2
Weighted total /15	**12.25**	**9**	**11.25**	**12**	**10.25**
Standard deviation	0.76	1.13	1.07	0.90	1.28

Table 6.1: Table of comparison of the alternatives

6.7 Conclusion

The design process led to five alternative solutions, judged feasible by the surgeon. Eventually, after comparing those five alternatives, two stood out which were the 'swan neck' solution as well as the one using the Nitinol.
In agreement with the surgeon, it was decided to develop first the swan neck solution, for it was the one which had both the best weighted total as well as standard deviation. Potentially, the Nitinol solution could be developed afterwards or be combined to the swan neck solution.

Chapter 7

Pilot prototype

Now that an alternative has been selected in the previous chapter, it needs to be designed and developed to go from an idea to a finished, manufactured product.
One of the main challenges in this process is to make sure that the selected materials are biocompatible and ideally sterilisable.

7.1 Design

The first step of the development phase consisted in designing the different parts to produce their blueprints as well as choosing a material.

7.1.1 Rigid parts

The principle of the 'swan neck' like device is essentially based on a measurement device that uses the very same principle. FIGURE 7.1 shows one of those devices from Misumi© which is used to place a measurement device very precisely on the surface of the measured part.

Figure 7.1: Magnet base measurement tool from Misumi [1]

It consists of multiple identical parts that are pressed against each other thanks to a flexible cable. The tool is deployed in three phases:

– Before placing it on the wanted spot, tighten every piece together by screwing the last piece while the length of the cable is fixed on both ends. This way, each part will be pushed

[1] Picture from `http://fr.misumi-ec.com/vona2/detail/223000650503/?`

harder onto the next one. This will render the arm much less flexible but still enough so that it can be shaped to be positioned on the exact wanted location.
- Shape the arm so that it touches the surface that is supposed to be measured.
- Rotate the screw at the base to fix it temporarily. This will pull the cable downwards by a few millimeters, which will be sufficient to block it. When this phase is done, the tool should be completely rigid.

For the retractor, it was decided to use the same basic principle. However, several modifications make it differ widely:
- The obvious modification is the size. Where the measurement tool is about 20cm long, the part of the retractor inside the atrium should be around 15mm long.
- The retractor will be split into two identical arms in the atrium so that is covers the largest range possible while still being centered for an easier manipulation. This means there will also be the need for two separate cables.
- The first tightening will not be done at the end of the arm but rather at the beginning, outside the patient's body.
- The parts being tightened together will have a smaller relative height so that more can fit on each arm, allowing for a greater flexibility.

With all these modifications in mind, the device development may start.

Node pieces FIGURES 7.2 and 7.3 represent the visualization of one node piece. In order to block the cable at the end, the last part is slightly different, with a reduced diameter for the cable hole. This can be seen in FIGURES 7.4 and 7.5.

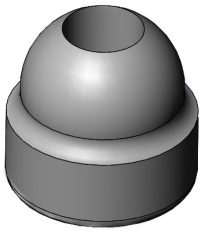


Figure 7.2: Isometric of one node piece

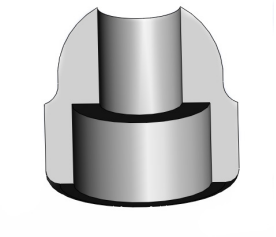


Figure 7.3: Cross-section view of one node piece

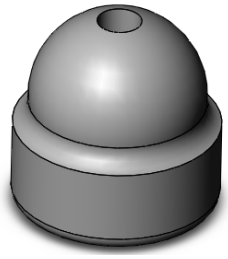


Figure 7.4: Isometric view of last node piece

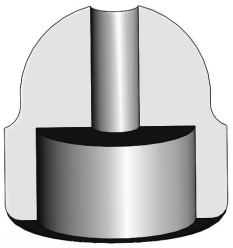


Figure 7.5: Cross-section view of last node piece

FIGURE 7.6 shows an assembly of several node pieces. As it can be observed, each piece can rotate on the curved part of another.

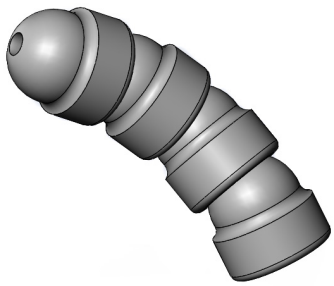


Figure 7.6: Assembly

Split node The split node is the one at the base of the two arms. It will also be the one located at the entrance of the atrium. In order to minimize the diameter of the tube in which the split node will be inserted, the holes for the passing of the cable are slanted. This will also reduce the wear of the cable as it will less likely encounter sharp edges at this location.

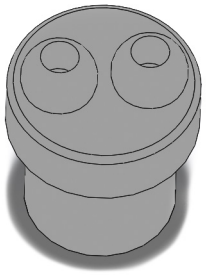


Figure 7.7: Isometric view of the split node

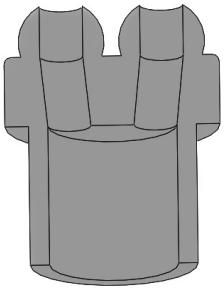


Figure 7.8: Cross-section view of the split node

Tightening and blocking system The two pieces responsible for the tightening and blocking system can be seen in FIGURES 7.11 through 7.10. The assembly for the tightening system will be explained in SECTION 7.1.2, when the cable is described.

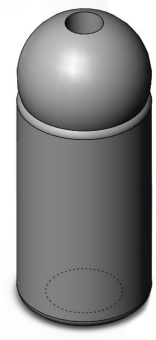


Figure 7.9: Screw 2

Figure 7.10: Screw 2

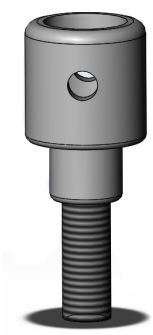


Figure 7.11: Screw 1

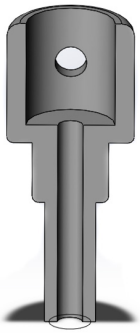


Figure 7.12: Screw 1

Assembly of the system Eventually, FIGURES 7.13 and 7.14 illustrate the whole system assembled, respectively when undeployed and deployed. Everything that is above the tube will be outside of the patient's body, available for the surgeons to manipulate. The tube itself will be between the incision and the atrium in the patient's body while the remaining parts will be the system inside the atrium acting as the retractor.

Figure 7.13: Undeployed system

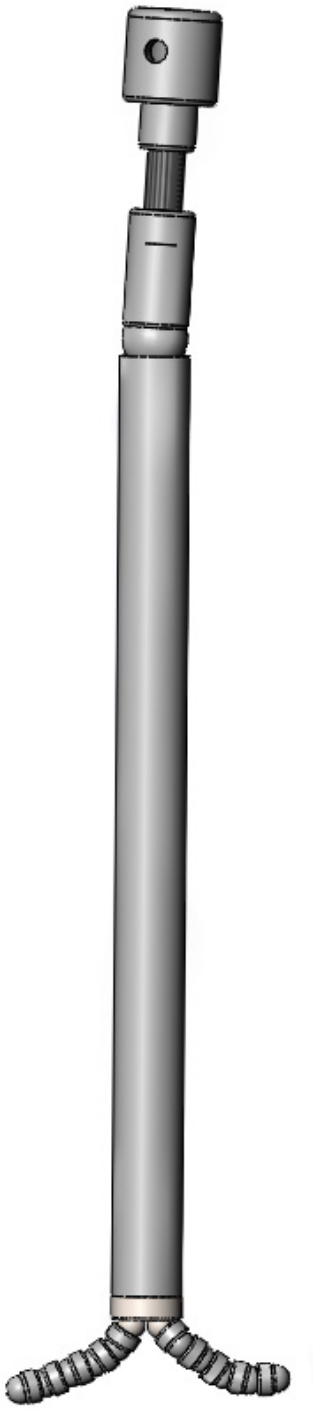


Figure 7.14: Deployed system

7.1.2 Cable

The cable represents the other main component besides the rigid parts. Until the selection of the cable, the tightening and blocking system can not be designed.
The multiple constraints for the choice of the cable are the following:

- It has to be in stainless steel, for reasons that will be explained in a later section.
- The diameter needs to be the smallest possible to minimize the size of the node pieces.
- It needs to have two endings with a bigger diameter than the cable in order for the cable to be blocked on both ends. One ending can already be assembled to the cable . However, the other one has to be assembled afterwards, when the cable is inserted through all the parts. Ideally, those endings should be small compared to the parts.

The last constraint proved to be the hardest to comply. Nevertheless, two manufacturers were found.
The firs manufacturer, Carl Stahl Technocables, offers stainless steel cables with a diameter of 0.5mm and rounded endings with a diameter of 1.5mm for the ball, as can be seen in FIGURE 7.15. [27]
This solution would have been exactly what was needed. However, it proved to be impossible for two reasons:

- The endings are mounted with a press. The second ending can therefore not be clamped by hand after having assembled the system.
- Carl Stahl only sells big quantities and do not wish to make an exception.

The second manufacturer which is thus chosen is Fips Accastillage. They offer stainless steel cables with a minimum diameter of 1mm and endings also in stainless steel such that can be seen in FIGURE 7.16. [28]

Figure 7.15: Cable assembly from Carl Stahl

Figure 7.16: Cable assembly from Fips Accastillage

The main advantage is that the second ending can be added by hand. However, the tool to clamp the stainless steel endings being very costly, it will first be tested with aluminum endings as the clamping tool for this material is much cheaper. The disadvantage however compared to the ones from Carl Stahl is that the endings have a length of approximately 6mm. A summary of the properties of the cable can be seen in TABLE 7.1

Diameter	1mm
Length	1m
Material	AISI 316
Breaking load	57.51 Kg
Mounting	7x7

Table 7.1: Properties of the cable

Once the cable choice was done, the final assembly could be done, including the tightening system and the blocking system, as can be seen in FIGURE 7.17.

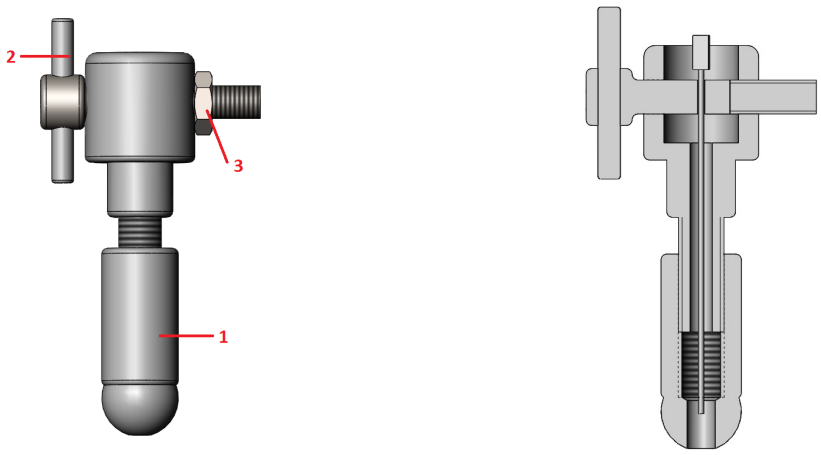


Figure 7.17: Assembly of the tightening system

The tightening and blocking system works as follow:

- Tightening: Screw part 1 towards the heart until the cable is rigid enough to give the tool the wanted shape.
- Blocking: Once the defined shape for the tool is set, screw part 2 and right after part 3 (the bolt) to avoid un-tightening.

7.2 Development

Now that all the parts have been designed, they can be manufactured. The first step consists in printing a prototype in plastics by additive manufacturing, as it is an extremely fast and cheap process which will give a good idea of the actual feasibility of the system. A reminder on the theory of additive manufacturing can be found in APPENDIX B.
Afterwards, the real manufacturing process can start, firstly by choosing the material and then by choosing the manufacturing process.

7.2.1 Feasibility check prototype

As was mentioned just above, a very first prototype is printed in plastics with the printer already available at UCL. The objective is to check the feasibility of the system. The prototype can be seen in FIGURE 7.18. The cables are not used with the plastic prototype in order to keep them for the rigid prototype. Instead, sewing thread is used.

FIGURES 7.19, 7.20 and 7.21 represent the flexibility of the tool regarding the shapes it can take when the thread is tightened.
These pictures show that the system is feasible. It acts exactly as wanted when tightened.

Figure 7.18: 1st prototype in plastics

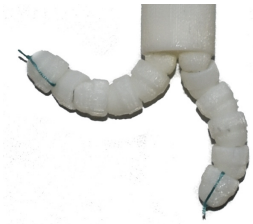


Figure 7.19

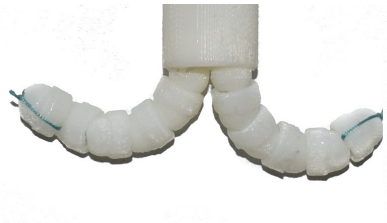


Figure 7.20

Figure 7.21

7.2.2 Choice of material

In order to make the rigid prototype, the first step is to decide in which material said prototype will be manufactured. One of the constraints of the SPECS is that the tool needs to be biocompatible. A biocompatible material is "a substance that does not threaten, impede, or adversely affect living tissue"[2]. The main types of biocompatible materials are:

- *Metals*: stainless steel, cobalt alloys, titanium alloys
- *Ceramics*: aluminum oxide, zirconia, calcium phosphates
- *Polymers*: silicones, poly (ethylene), poly(vinyl chloride), polyurethanes, polylactides
- *Natural polymers*: collagen, gelatin, elastin, silk, polysaccharide [29]

It is important to notice that FR 2.1 in the SPECS regarding the maximum amplitude of the relative movements implies that the materials should be rigid. Indeed, for the chosen alternative, there is no reason one of the parts should be flexible, except for the cable.
The choice of materials will therefore be focused mainly on the metallic family. Cobalt alloys are rejected as few manufacturers work with these kind of materials, leaving the choice between titanium or stainless steel. [30, 31]

Stainless steel is a steel alloy which contains a minimum of 10.5% of chromium, to make the steel corrosion resistant. It has been used in medical application since the 1900s for this specific property, as it is the steel that is the most corrosion resistant when in contact with biological fluid.
Other elements can be added to give it particular properties. For example, carbon and nickel will help stabilize the austenite to stainless steel.
Type 316L is commonly used for medical applications. It contains 17% to 19% of chromium and 14% of nickel. [32]

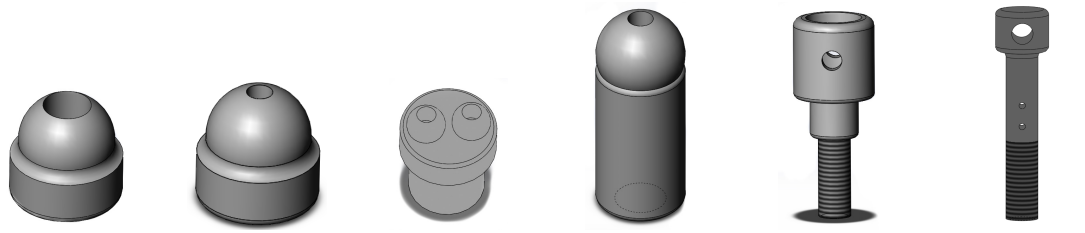
[2] `http://medical-dictionary.thefreedictionary.com/biocompatible+material`

Titanium alloy as the name suggests, contains titanium and other elements. As opposed to stainless steel, it became popular in medical applications much later, around the 1960s. The reason for this popularity being it is as strong as stainless steel, while being twice lighter. However, it is easily contaminated if exposed to hydrogen, nitrogen and oxygen, which can influence the corrosion process in this metal and may compromise its use in certain medical procedures. Moreover, it is much more expensive than stainless steel. [31]

Final choice of material Because of the two main disadvantages of Titanium that were listed above, the choice of the material for the device will focus on **stainless steels** primarily.

7.2.3 Manufacturing process

For low quantities metallic parts, two manufacturing processes need truly be considered: additive manufacturing and machining.
A summary of all the parts that need to be manufactured is represented in FIGURE 7.22.



(a) Part 1 (b) Part 2 (c) Part 3 (d) Part 4 (e) Part 5 (f) Part 6

Figure 7.22: Parts to be manufactured

Figure 7.23: Part 6

For each part, the choice of the manufacturing process will be made by comparing machining and additive manufacturing regarding the cost and the waiting time. The result is detailed in TABLE 7.2.

Part	Manufacturing process
1	Additive manufacturing
2	Additive manufacturing
3	Additive manufacturing
4	Machining
5	Machining
6	Order from stock (Misumi)

Table 7.2: Manufacturing process used for each part

The machined parts were done so directly at the UCL while the parts that were made through additive manufacturing were to be ordered at Materialise in Leuven. Eventually, the tube was ordered already manufactured to Misumi.

7.3 1st prototype

After having received all the parts, the first prototype could be assembled and reviewed.

7.3.1 Assembly

The views of the first assembled stainless steel prototype can be seen in FIGURES 7.24 through 7.27.

Figure 7.24: Retractor at rest, undeployed

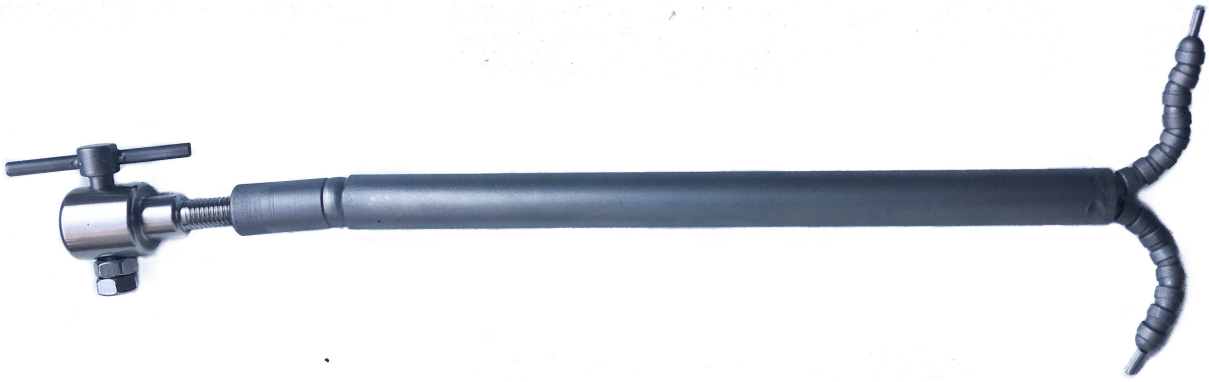
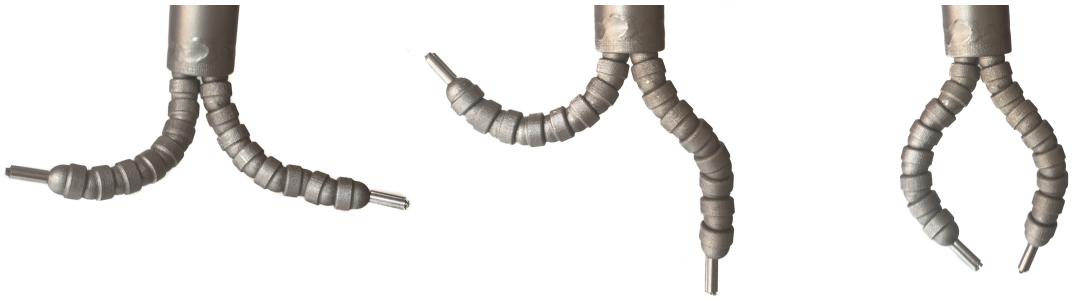


Figure 7.25: Retractor tightened, deployed



(a) (b) (c)

Figure 7.26: Possible shapes the retractor can take and maintaint

Figure 7.27: Upper view of the tightening system

As a reminder, initially, the cables were supposed to have the endings clamped once everything was assembled. However, said endings were quite big and bulky, which could have caused problems afterwards to activate the blocking system. Instead, the cables were glued in the small holes with a super glue, as can be seen in FIGURE 7.27.

7.3.2 Engineering review

For the general case, the first prototype is very promising. It serves its purpose which is to take *almost* any desired shape. Moreover, once blocked, the system is quite rigid and should normally stay put when applied against the atrium walls.

The most important remark concerns the cable; the latter has a maximal angle of curvature that was not considered. The 'left branch' of FIGURE 7.26b represents the highest the cable can go before being pulled back for curvature degrees superior than the one on the picture.

The second remark being that a joint could be added in order to add a degree of freedom to allow a rotation backwards to pull back the walls, should the system not be rigid enough to do so. This rotation would be the same as the one which already exists on the current retractor, which can be seen with the orange axis in FIGURE 4.1 in SECTION 4.1.

7.3.3 Surgeon review

After presenting the prototype to the surgeon, Dr Navarra, he suggested to make a loop of nodes instead of two branches.

7.3.4 Conclusion

To conclude this section, the 1st prototype is already promising and performing as expected. However, a new prototype will be built, with the following modifications:

- Try to find a more flexible cable that would have a lower maximal curvature limit.
- Think of a system to be able to apply a rotation backwards as an additional force to pull the atrium walls.
- Replace the two branches of the retractor by a loop.

The new prototype with those modifications will be the topic of the following section.

Chapter 8

2nd prototype

Now that the first prototype has been manufactured and reviewed, a new one can be thought, taking into account the several remarks of SECTIONS 7.3.2 and 7.3.3.

8.1 Design

8.1.1 Cable wire

As was explained, the main challenge for the new prototype is to find a more flexible cable that would allow for a greater curvature angle and therefore more freedom in the possible shapes of the retractor.
After some research, two new alternatives have been found:

- Extra flexible cable from Fips Accastillage[1]. The minimum diameter is 1.5mm and the mounting is a 7x19 mounting type. The other properties are the same as in TABLE 7.1.
- Loss prevention wire from Misumi[2] with a diameter of 1mm and a loop as blocking ending.

Unfortunately, none of the manufacturers specify the maximum curvature angle.

After having received both wires and compared them with the one from the first prototype by bending them by hand, it was concluded that the extra flexible cable from Fips was worse whereas the one from Misumi was more or less equivalent. Therefore, no solution has been found to this day for a highly flexible wire in stainless steel.

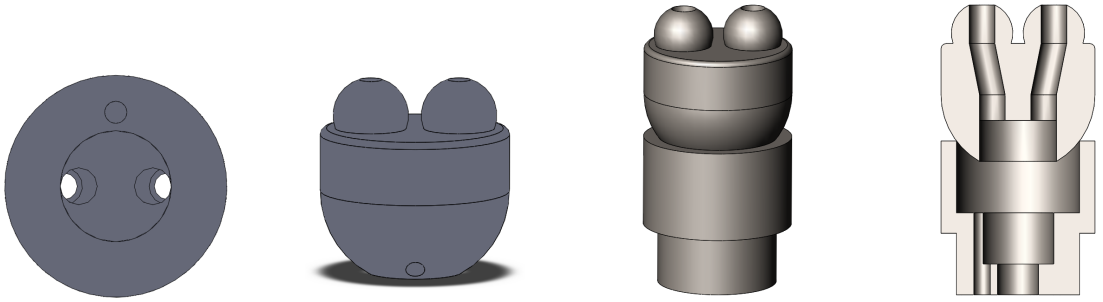
8.1.2 Rigid parts

As a reminder, the two improvements on the rigid parts are the following: introduce a new degree of freedom for a rotation allowing to pull the atrium walls backwards and make a loop instead of two branches for the part inside the atrium.

The system for the new degree of freedom can be seen in FIGURE 8.1. The idea is that the split node of the first prototype is now replaced by two separate parts, with part 1 that can be seen in FIGURES 8.1a and 8.1b. The latter now has a third hole in which a third cable wire will be welded. The cable will then follow the same path as the two others. Since the base of this

[1] https://www.accastillage-fips.fr/cable-extra-souple/53-cable-extra-souple-7x19-inox-316.html
[2] http://www.misumi-europe.com/en/catalog/vona2/detail/110300261830/?

wire is decentered, when pulling on it, it will rotate part 1 as wanted. Eventually, a spring is placed between the two parts so that when there is no pressure on the cable, the two parts stay aligned.



(a) Bottom view part 1 (b) Frontal view art 1 (c) Frontal view assembly (d) Cross section view assembly

Figure 8.1: Bifurcation assembly

Since now there is a third cable which needs to be tightened independently of the two others, the tightening system also needs to be readjusted. The latter can be seen in FIGURE 8.2. The general idea is still the same except that this time there are two screws, one for the two cables of the loop and the other for the cable of the rotating system.

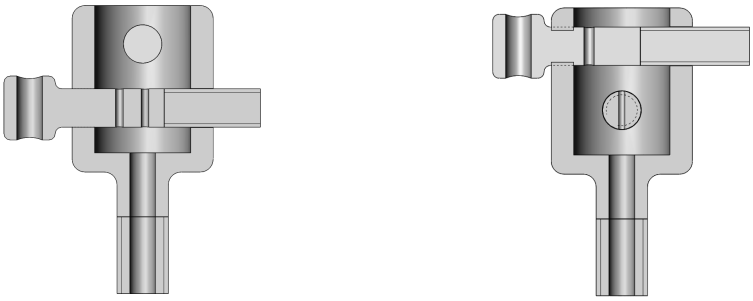


Figure 8.2: Tightening system for 2nd prototype

Eventually, the last modification consists in replacing the two branches by a loop, as can be seen in FIGURE 8.3. A joining piece is simply added. The two cables are thus be replaced by a sole one which starts and ends in each hole of the tightening system. Two holes are therefore still required in the small screws of the tightening system, as was mentioned above.

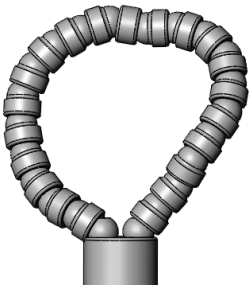


Figure 8.3: Loop at the end of the retractor

8.2 Development

Once again, every part is sent to additive manufacturing except for the big hollow part of the tightening system which is machined and the tube which is ordered to Misumi. The resulting assembled system can be seen in FIGURE 8.4.

(a) Retractor at rest (b) Retractor tightened

Figure 8.4

The solution imagined for the rotation backwards is not effective as it only allows for a very small rotation when pulling on the cable. However, it might not be critical as the results are even better than expected. The retractor can easily take an oval shape that should surround the valve and stay fixed in that position.

(a) (b) (c) (d)

Figure 8.5: Various shapes the retractor can take and maintain

FIGURE 8.5 shows how much the retractor can be adapted to any patient. Indeed, 8.5b could be used for a patient with a smaller atrium and smaller valve - a child for example. The excess length could simply be shaped to stay out of the atrium in order to only have the shape needed inside.

These results seem very promising. However, the device will need to be tested in real conditions to have the confirmation it is well suited for its specific application.

8.3 Fixation system

As is mentioned in the SPECS, SECTION 5.3, the main function is for the retractor to expose the valve. However, F2 specifies that the other important function is to *fix the tool to limit its relative movement with the patient* . Indeed, for the retractor to be fully effective, one should avoid as much as possible any movement of the latter once it is fixed in the wanted position.

For this purpose, the BookWalter system from Symmetry Surgical will be used. Indeed, they have a big panel of tools specified in fixing tools and retractors during a surgery. [33]
The fixation system will thus be made of three parts which are:

- A universal table post, FIGURE **??** that is fixed on the surgical table, as can be seen in FIGURE 8.6.
- A post coupling, to be able to fix other parts on the table post.
- A horizontal flex bar, with 360°rotation. The retractor will be fixed at the end of said bar. The 360°rotation will allow to place it correctly before fixing it.

The assembly of those three parts results in a flexible and reliable fixation system which can be seen in FIGURE 8.7.
Unfortunately, the cost of this system is significant. For this reason, it will not be tested on the retractor as it is still at the stage of a prototype. This solution for the fixation system will thus stay purely theoretical.

Figure 8.6: Fixation of table post

Figure 8.7: Assembled fixation system

8.4 Cost estimation

In the context of a mechanical design project, it is always a good thing to have a cost estimation. If the system is doing marvels but is totally unaffordable for the given purpose, it will not be of much use. Moreover, for the particular case of the retractor, it will allow for a comparison with the one that is used actually, with its cost being one of the disadvantages.

The second prototype developed in this chapter was the last one that was manufactured and tested as part of this master thesis. For this reason, it will be the latter that will be examined thoroughly for a cost estimation with the exception of the split node. The latter will be evaluated as the one of the first prototype, before the modification that was ineffective and will not be reproduced.

The prices of the 3D printed parts, the tube and the cables correspond to the actual price of the order while the parts that were manufactured were estimated by looking at the duration of the task and the quantity of material. Eventually, for the assemblies, the duration as well as the hourly rate for each task are considered.

The fixation system was not considered for the estimation as it is considered an external cost, just like the price of the Da Vinci System (2.5M€) was not considered in the price of the Da Vinci retractor.

To conclude this cost estimation, the retractor is around 40% cheaper than the one that is provided with the Da Vinci. More importantly, and even though tests will need to be done to certify that, the tool should be usable for much longer than 10 cycles. This means that the price of the tool per surgery will be drastically reduced compared to the 130€ per use for the Da Vinci retractor. In fact, if for example it is decided that the retractor can be used 20 times before replacing it, the cost per surgery would be 37.5€, which is almost a quarter the price of the Da Vinci retractor.

[2] All the FIGURE of the parts come from [33]

Process/Parts		Cost (€)
Retractor	Nodes	330
	Split node	53
	Tube	10
	Tightening piece	80
	Blocking system	100
	Cables	35
Assembly	Cable mounting (assembly and clamping)	40
	Weldings	100
TOTAL		**748**

Table 8.1: Cost estimation of the whole system

8.5 Failure and risk analysis

Normally, a 'failure modes and effects analysis' should be done which studies the potential failure of specific parts and the consequences. However, in this case, the main component that is most likely to know a failure is the cable wire. The other failure modes are for the most part caused by the assembly rather than by a specific part. For this reason, the analysis will be slightly modified and ressemble more like a risk analysis.

table 8.2 summarizes the risk analysis. Five possible failures will be detailed, with their cause, their consequence(s), their severity and the requirements to avoid it as much as possible. The scale for the severity is such: [34, 25]

- I: No relevant effect on reliability or safety
- II: Very minor, no damage, no injuries, only results in a maintenance action
- III: Minor, low damage, light injuries
- IV: Critical (causes a loss of primary function)
- V: Catastrophic (product becomes inoperative; the failure may result in complete unsafe operation and possible multiple deaths)

The risk n°3 is sadly directly inspired from a true story. Indeed in 2016 Olympus Corp., a Japanese manufacturer, had to recall a specific product from the market. The latter was a medical scope which had some locations that had not been affected by the sterilization. A specific bacteria was trapped and therefore not killed, leading to the deaths of several people. [35]

N°	What? Risk?	Cause / Failure mode	Effects / Consequences	Severity	Requirements
1	Loose part.	Cable wire breaks	Parts can lodge themselves somewhere in the heart or elsewhere and block canals/valves/etc.	V	Have a fatigue test on the mechanism to check the fatigue resistance of the cable wire. Fix a number of uses after which the cable should be replaced.
2	Damage on the atrium walls or other healthy tissues	Sharp edges, parts that can pinch some tissue when the system is tightened	Can cause sever complications during the surgery, lead to infections and to permanent damage or malfunction	IV	Make sure that there are no sharp edges (fillet every edge). If need be, re-make the fillets every x uses. Surround the loop with a flexible sheath.
3	Sterilization not 100% efficient	Some locations not reachable by the sterilization system	If a bacteria 'hides' in a place that can not be reached by the sterilization process, it could lead to an infection and potential disastrous consequences such as the death of the patient.	V	Make sure that the system can be completely loosened so that all the parts are correctly separated and the sterilization process can affect everything
4	System suddenly loosens	Cable breaks, small tightening screw breaks	It will lead to the sudden absence of exposure of the valve, which will most likely disrupt the surgeon. Moreover, could hit or disrupt other tools and make them achieve unwanted movements that could prove to be dangerous.	IV	Same as N°1
5	Welding breaks or is damaged by sterilization process	The welding was not done properly	Same effects as bad sterilization. Moreover, the detached part could pinch some healthy tissues or lead to loose parts, in which case the consequences have already been explained.	V	Laser welding specific to medical device or replace the weldings by another system

Table 8.2: Risk analysis

Chapter 9

Testing

Now that the prototype has been analyzed and reviewed theoretically, it is interesting to see it being used for its specific application.

9.1 Tests

As a first step, the retractor will be tested on a pig's heart, as there are many more available than human hearts for scientific experiments. In fact, the human heart and the pig heart have a lot of similarities regarding both the anatomy and the physiology. [36] Currently, doctors are already using tissue from pigs' hearts for human heart valves replacement, and researches have been going on for a few years now regarding pig hearts xenotransplatations, to overcome the lack of heart transplant donors. [37, 38]

Dr. Navarra therefore tested the retractor. He decided to shape it in an oval bent style, as can be seen in FIGURE 9.1. On each picture, the mitral valve is the part of the cavity that is in darker red.

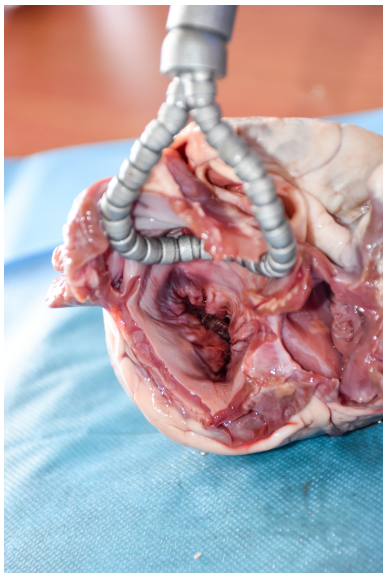
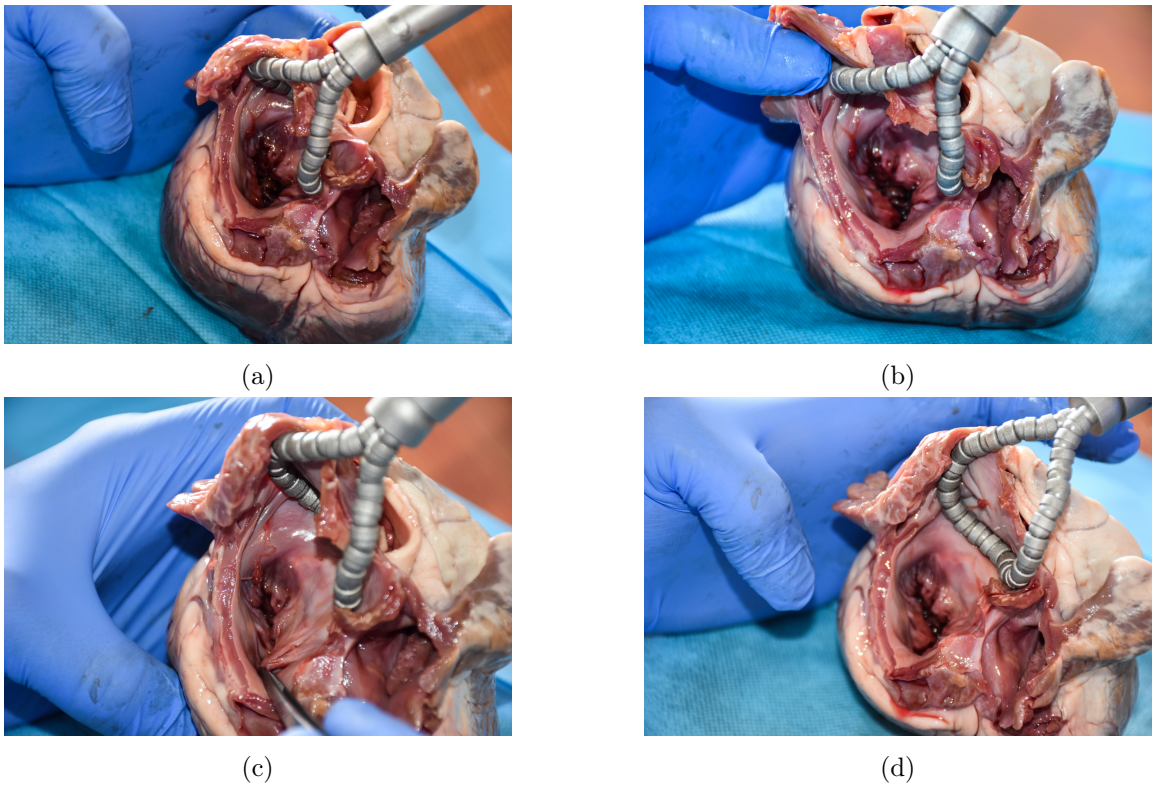


Figure 9.1: Test of retractor, shape given

FIGURE 9.2 shows several pictures taken during the tests on the pig's heart. In each picture, the mitral valve is clearly visible, and the surgeon has a total liberty to choose exactly which view he desires by adapting the tool.



(a) (b)

(c) (d)

Figure 9.2: Retractor in use

9.2 Review

9.2.1 Tests review

By obversation, one can see that the objectives of the retractor are met. It allows for a very nice exposure of the valve and stays in the given shape even when it is pulling the atrium walls. The tool can easily be shaped by hand when it is tightened so there should be no problems for the robotic arms of the Da Vinci to shape it in the atrium.
Moreover, the fact that the cable has a maximum curvature angle did not prove to be a constraint compared to what was thought before. The shape the surgeon wanted to give it did not need a bigger allowable curvature angle than the one in place.

From the surgeon point of view, Dr. Navarra was very satisfied by the results. He would however suggest the loop to be bigger for two reasons: the human mitral valve is on average a little bigger than the one on the pictures, and in addition, it would allow him to bend the retractor to make it wider and expose even better the valve.
Regarding an eventual sheat surrounding the nodes as is suggested in the risk analysis to cope with risk n°2, he thought this would not be needed as the damage on the walls would be minor. However, he did suggest to make the assembly of the nodes smoother.

9.2.2 Meeting of the SPECS

As a reminder, the SPECS can be found on page 29. This section intends to check if the protoype meets every function and constraint that was specified in the SPECS:

- *F1: Display the mitral valve to allow endoscopic, manual and robotic access*: Yes, as can be seen in FIGURE 9.2.
- *F2: Fix the tool to limit its relative movement with the patient*: Theoritically yes, as was detailed in SECTION 8.7.
- *C1: Ensure patient's safety* Shall the remarks of the 'risk analysis' be taken into account, yes.
- *C2: Respect of the norms relative to medical devices*: The tool is indeed entirely made in biocompatible materials and is sterilisable, provided the weldings are specific medical weldings.
- *C3: Insert the tool through a mini-invasive access*: The maximum diameter of the part of the tool that will be in the body is 15mm so this constraint is also satisfied.
- *C4: Work co-jointly with other tools*: Theoritically this constraint should be satisfied. However, the retractor will need to be tested in true conditions with the Da Vinci robot to certify that.

To conclude, a lot of additional tests would need to be done to certify that all the functions and constraints are satisfied with 100% certainty. However, in theory, they are all met.

9.3 Improvements

Now that the prototype has been analyzed thoroughly both before and after the tests, the different remarks can be taken into account should a third prototype be made. The obvious improvements that would need to be done will be explained in this section.

Loop Make the latter bigger, as was suggested by Dr Navarra, by making the cable longer and adding nodes. This would allow to make it wide enough in order to cover 180°of the valve.

Split node This piece would need to be re-designed for two main reasons. The first one would be to find another solution for its fixation on the tube, such as screwing it instead of welding it. Avoiding the precision laser welding would reduce the risks, as was explained in the risk analysis, as well as reduce the price of the tool by reducing the assembly costs.
The second modification would be to rethink the whole in order to minimize the diameter of the tool. This would indeed certify that it can pass between the ribs as well as reduce the cut that needs to be done on the patient.

Blocking system The blocking system with the shaft and the bolt is not very effective and quite complex to manipulate. Moreover, the fact of turning the cable on the shaft increases the wear of the cable and therefore decreases its longevity. Ideally, the new system would be simpler, faster, and without imposing angles on the cable.

Tightening system The small problem with the tightening system is that when the tension in the cable is high, the rounded surface does not always slip smoothly on the tube but rather tends to rotate the whole system, meaning it also rotates the cables. Again, this could speed up the wear process as well as disrupt the whole system. For this reason, roller bearings between the tube and the tightening part could be considered to avoid this problem.

Conclusion

The initial objective of this master thesis was to design, develop and test an atrial retractor for the minimally invasive mitral valve repair surgery, the latter being performed with the Da Vinci surgical system.

The subject was contextualized in the first part. The first chapter consisted in describing briefly the heart by explaining its anatomy and physiology. The second chapter focused on the valve pathologies, and more specifically on mitral valve pathologies. Eventually, the last chapter of the first part detailed the surgery and the role of the retractor.

The second part treated about the actual design and development of the tool. The first step, as in any mechanical design project, consisted in establishing a state of the art. The latter detailed all the existing solutions that were found in the literature.

The fifth chapter briefly detailed the functional analysis. The different phases of the chosen design procedure were explained, after what the specification of the need was investigated, leading to the specifications document. Finally, objective comparison criteria were defined.

The sixth chapter presented the five alternative solutions that were developed. For each of them, a functional diagram as well as schematic drawings were realized. Moreover, the advantages and disadvantages of each alternative were detailed. The chapter concluded in an evaluation of all the solutions and a final choice for the solution that was to be developed.

Chapters 7 and 8 focused on the first and second prototypes respectively. In both chapters, each prototype was described thoroughly regarding the design process, the manufacturing, the finished prototype, and its reviews. The end of chapter 7 consisted in describing the improvements that would be made to the second prototype. Moreover, chapter 8 also contained a cost estimation and a risk analysis for the second prototype.

Eventually, the last chapter detailed the tests that were realized on a pig's heart and their results. It also incorporated a section that checked if the retractor met all the requirements of the specifications. The last section presented the improvements that would need to be done if a fourth prototype was to be manufactured.

As it was detailed in SECTION 9.2.2, the second prototype meets all the functions, requirements and constraints that were specified in the specifications. The tool exposes the valve very nicely, at least on the pig's heart. Moreover, it is entirely made of biocompatible materials and

can supposedly withstand the sterilization process without being damaged.
In addition, the risk analysis in SECTION 8.2 enabled to point out the major flaws of the system and the parts that should be modified of improved in order to certify the safety of the patient during the surgery.
The tool is easy to use for the surgeon, and only requires a few steps to be deployed in the heart. Once it *is* in the atrium, there is no reason the surgeon should have to move it again before the end of the surgery.
Eventually, one of its biggest advantages is the total flexibility of the tool regarding the shapes it can take, meaning it can easily be adapted to any type of anatomy for any patient. The example that it performed correctly on a pig's heart whose anatomy slightly differs from the human's is a good proof of that.

Now what are the prospects for this retractor tool? If a third protoype was to be made, taking into account the several remarks of the risk analysis as well as the suggested improvements of SECTION 9.3, there is a real possibility that it would prove to be much better than the existing solution and that it could truly make a change in the mitral valve repair surgery.
However, even if it was decided to continue this project in order to get to the point where the tool would be tested in clinical trials, the path to get there would be long and rough. The first step would be to iterate the solution until a solution that looks theoretically flawless is found. Once this is done, the prototype would need to be examined thoroughly to make sure it meets all the requirements for medical devices. This would include, among many other tests, testing the device multiple times on corpses and in true conditions, thus with the Da Vinci Surgical system. This process would most certainly again lead to new iterations of the solution. Eventually, the tool could be tested and hopefully approved in clinical trials.

Even though this retractor has been designed for the minimally invasive robotic surgery, as Dr Navarra pointed out, there is no apparent reason that the tool could not be also used for open heart surgeries or minimally invasive surgeries without the robot.

On a more personal note, I have truly enjoyed every step of the way of this master thesis. It has been an incredible experience which has taught me much more than what I would have imagined. I am thrilled that what started as a vague concept on paper became an actual manufactured and functioning tool. Should this project be continued, however long the process might be, I would truly consider this as a great achievement.

List of Figures

List of Tables

Appendices

Appendix A

HV retractor

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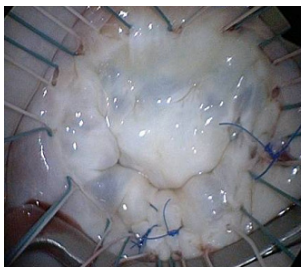
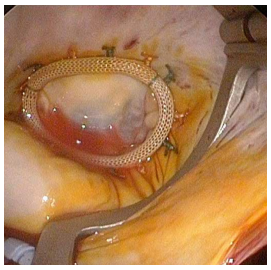

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Appendix B

Additive manufacturing

B.1 Technology

The non-technical term form additive manufacturing is '3D printing'. The two most well known technologies of additive manufacturing are *Fused deposition modeling* for 3D printing in plastic and *Laser sintering* which melt powder with a laser. Despite popular belief though, there are many more additive manufacturing technologies such as stereolithography, lost wax printing and casting, ColorJet printing, etc.
The principle however is the same for all the technologies and is represented in FIGURE B.1: from a CAD drawing, a software separates the 3D model into numerous very thin slices which will then be sent as a job to the printer.

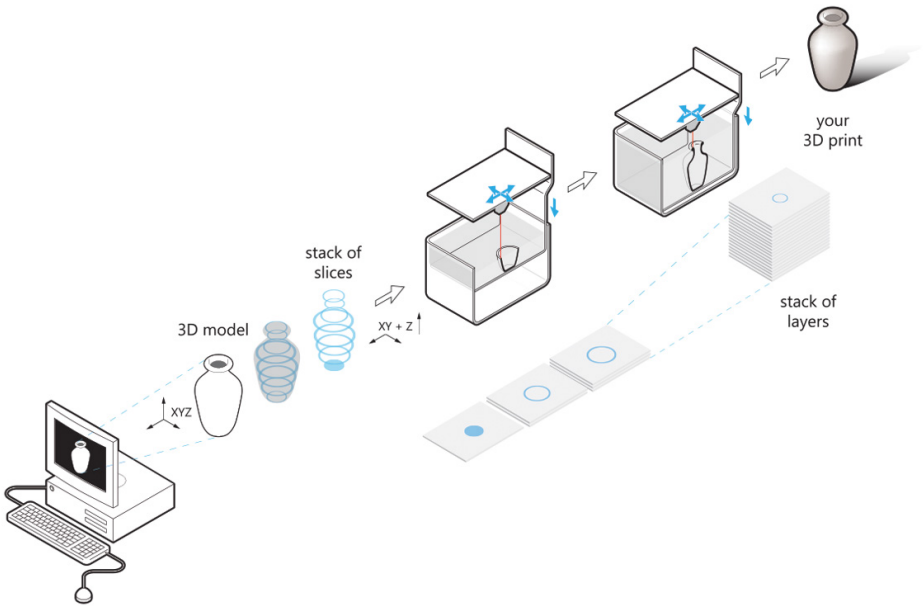

Figure B.1: Basic principle of additive manufacturing

For the designed retractor, both 'Fused deposition modeling' and 'Laser sintering' will be used, which is a reason those will be briefly explained.

B.1.1 Fused deposition

With fused deposition, a plastic wire is heated above its melting temperature. The liquefied filament is guided to form the first slice on the plate. All the other slices are then stacked up to form the 3D model. A vizualisation of the process can be seen in FIGURE B.2.
Fused deposition is used to print in plastic materials. Support structures might be necessary and will be made in a different material so that they can be broken off or dissolved once the process is complete.

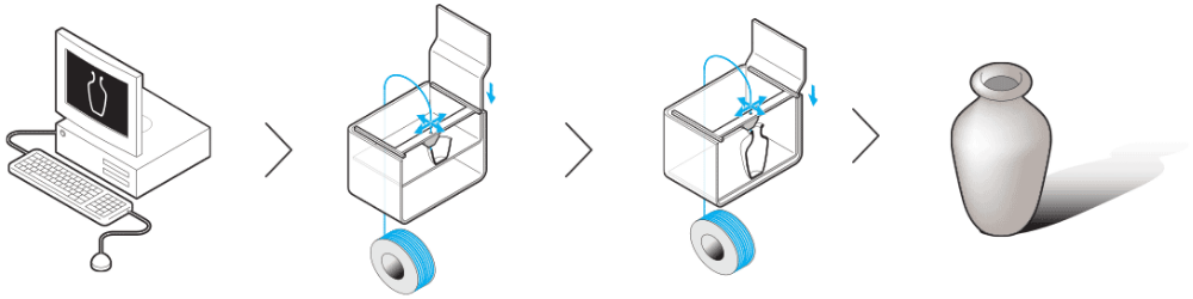

Figure B.2: Fused deposition additive manufacturing

B.1.2 Laser sintering

Laser sintering it typically used to print metallics parts. The principle is that the material comes in powder. A laser beam will then be responsible for heating the powder the desired location is that the temperature is just above the melting temperature of the powder. It will thus melt and then solidify. When one slice is done, a new layer of powder will be added so that the following slice can be executed.
The powder bath is maintained at a temperature just below the melting temperature to reduce the energy that the beam needs to produce.
The advantage in this case is that the powder will support the following slices and normally, no support structure will be needed. At the end, there will be a block of powder containing the solid model. [39]

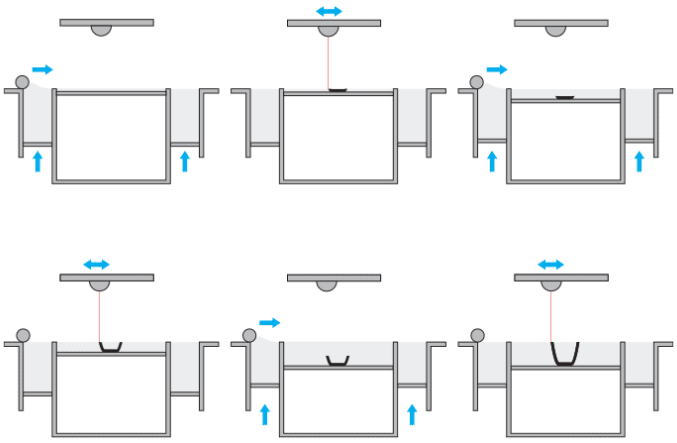

Figure B.3: Laser sintering

B.1.3 Advantages

The advantages of additive manufacturing numerous, the most interesting among those are:

- Complex parts do not cause any issue and sometimes are even faster to make than a simple cube as less material is required.
- Drastic reduction in the need for assembled parts.
- Where only a few experts can machine some elaborate mechanical parts with accuracy, anyone can design a part for 3D-printing.
- The process is a lot faster. Engineers can design, print and analyze some parts in one day where it would require weeks of waiting for the part by other means of manufacturing.
- The waste is highly reduced.
- The weight of the part is reduced as only the elements that are needed are printed.

The price can also be seen as an advantage, as will be developed later. However, this should be taken with a grain of salt in the sense that if one does not possess the printer, it can prove to be very costly, especially for laser sintering printers. [40]

B.1.4 Companies

If a prototype needed to be printed in plastics - fused deposition printer - it would be done directly at the UCL where a printer is already available.
In the case it is decided that a part would be printed in stainless steel, there needed to find a company that does that. The obvious choice was *Materialise*, a renowned company specialized in additive manufacturing and based in Leuven, Belgium. They offer additive manufacturing in more than a dozen different material types, including high-detail stainless steel.

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Rue Archimède, 1 bte L6.11.01, 1348 Louvain-la-Neuve **www.uclouvain.be/epl**