‘Improving the fixation of an epicardial lead with a left ventricle pacemaker lead placement device for video assisted thoracic surgery’

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UNIVERSITEIT TWENTE.

‘Improving the fixation of an epicardial lead with a left ventricle pacemaker lead placement device for video assisted thoracic surgery’

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FOREWORD

For my Bachelor assignment I was looking for a company where I would work in a team. I like working with other people and team projects often require managing, which I am very interested in. Besides that, I was also looking for an engineering assignment rather than a design assignment. In Demcon I found the company which could provide me this assignment. As a modern company which is thriving and keeps on growing, Demcon provided me with an amazing environment to perform my assignment. Therefore I want to thank the people who made this possible for me. First of all I want to thank my supervisor at Demcon, Marleen Ruijter, who guided me through the process and made me feel at home at Demcon. Secondly I would like to thank my supervisor at the University of Twente, Edsko Hekman, for checking what I was doing every once in a while. Next I would also like to thank my examiner Eric Lutters, for taking the time to read my thesis and to grade my presentation. I would also like to thank my colleagues, Hernes Jacobs and Anne de Jager, for the little brainstorms we often had and their ideas on how to turn the result of this assignment into a success. Finally it would also like to thank Benno Lansdorp and Frank Bakker for the conversations we had and giving me insights in the fields of project management and business development.

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SAMENVATTING

Demcon ontwikkeld een tool die gebruikt gaat worden om via video assisted thoracic surgery (VATS) een pacemaker lead aan de buitenkant van het hart te schroeven. De huidige tool die voor VATS gebruikt word is hier niet voor ontwikkeld en heeft veel punten die verbeterd kunnen worden. In samenwerking met twee thoraxchirurgen van het UMCG wordt er daarom een nieuwe tool ontwikkeld. Deze ontwikkeling heeft al geleid tot een proof of principle (POP). Uit het testen van deze POP kwamen een aantal verbeterpunten naar voren. De gene waar deze opdracht zich op focust is het daadwerkelijk fixeren van de lead. Dit wordt momenteel nog met de hand gedaan terwijl de chirurg op die manier weinig controle heeft over de lead en de arts moet gokken hoeveel rotaties de lead in het hart is geschroefd. Het doel van deze opdracht is om met een oplossing te komen, waarmee de TEDD de lead gecontroleerd in het hart schroeft, zonder dat daar expertise en gevoel van de arts bij komt kijken. De oplossing die daarvoor is bedacht is dat de lead dicht bij de helix wordt vastgegrepen met een op basis van vorm berustend mechanisme wat zich in de delivery tube van de TEDD bevindt. Het enige wat de arts nog hoeft te doen is aan een knop te draaien totdat deze niet meer verder gedraaid kan worden. In de tussentijd heeft de TEDD de lead in het hart geschroefd en op het juiste moment los gelaten. Van dit ontwerp is een POP gemaakt waarbij de werking van het mechanisme is getest. Het testen van de POP leverde veelbelovende resultaten op en heeft laten zien dat er een mechanisme ontwikkeld is waarmee door een rechte buis een lead gecontroleerd in het hart geschroefd kan worden. Verdere ontwikkeling van Demcon is nodig om het ook toepasbaar te maken op een flexibele buis en om de diameter te verkleinen.

ABSTRACT

Demcon is developing a tool which will be used to place a lead on the outside of the heart. This tool will be used in the video assisted thoracic surgery (VATS) procedure. The current tool used in this procedure isn't developed for VATS and has a lot of things that could be improved about it. Therefore a tool is deve-loped especially for VATS in collaboration with two thoracic surgeons of the UMCG (Academic Medical Centre Groningen). This development has led to a proof of principle (POP). From testing this POP some points that need improvement surfaced. The one that's the subject of this assignment is the actual fixation of the lead. This is currently done by hand, while the surgeon has little to no control and feeling on the lead. The surgeon has to guess how often he rotated the helix into the heart. The goal of this assignment is therefore to come with a solution with which the TEDD will screw the lead into the heart with more control, and without the expertise and experience of the surgeon playing a role. The solution was found in a mechanism which works based on its shape. This mechanism is located in the tip of the TEDD. The only thing that the surgeon has to do is turn a knob forward until he cannot turn it any further. In the meantime the TEDD has screwed the lead into the heart and released it at the correct moment. This design has been realized into a POP and its functioning is tested. The testing provided promising results and showed that a mechanism is developed which is able to fixate a lead in a straight tube onto the heart with more control than the current situation. Demcon now needs to further develop the design so it still functions when it is put inside a flexible tube.

CHAPTER I: INTRODUCTION

One possible cause of heart failure is cardiac dyssynchrony. In that case the left- and right side of the heart are not in sync. In order to resynchronize the contractions of the heart's ventricles, a cardiac resynchronization device is placed. This device uses lead in both the ventricles to stimulate both ventricles at the same time again. The normal procedure to place these lead is trans-venous (through the veins). However, this does not always succeed, especially with the left ventricle. The alternative options to fixate the lead on the heart in that case are open chest surgery or mini-thoracotomy, which are very invasive for the patient. But besides open chest surgery and mini-thoracotomy a relatively new method can be used for placing epicardial leads. This is video assisted thoracic surgery (VATS). With three small incisions, a camera and tools are inserted in the patient's body. This procedure is much less invasive for the patient. For the surgeon however, there are no tools available that have been especially designed for VATS. The tool that is currently used for this procedure is designed for open chest surgery or mini-thoracotomy. However, the surgeons are currently using this tool to fixate an epicardial lead on a beating heart. The surgeons also indicated that a lot can be improved about this tool. Demcon is therefore developing a tool especially for VATS in cooperation with two thoracic surgeons from the Universitair Medisch Centrum Groningen (UMCG). This documents describes the process of how one specific functionality of this tool is improved. The goal of this assignment is to improve the fixation of the lead. This has to be done more controlled and should depend less on the expertise of the surgeon. This document is structured as follows:

Chapter II: Background information about the heart and an analysis of the procedure.
Chapter III: Shows the workflows of the FasTac tool and the Proof Of Principles (POPs), and compares them with each other
Chapter IV: Gives an idea of the context of the TEDD
Chapter V: Gives a description of the assignment and the demarcation.
Chapter VI: Describes which experiments have been performed in order to gain more knowledge about the fixation of the lead.
Chapter VII: Describes the partial solutions that were combined to create the concept.
Chapter VIII: Describes the concept
Chapter IX: Describes the final design.
Chapter X: Describes the POP which is used to test the design.
Chapter XI: Describes the testing of this POP and discusses the results
Chapter XII: States a conclusion and recommendations are given.
Chapter XIII: Contains the references used in this document.

Appendix A: Contains an abbreviations list.
Appendix B: Contains a list with the explanation of medical terms.
Appendix C: Contains the action plan and planning that was setup for this assignment.
Appendix D: Contains a visualization of the workflow of the FasTac tool.
Appendix E: Contains a visualization of the workflow of the first POP.
Appendix F: Contains a visualization of the workflow of the second POP.
Appendix G: Contains a visualization of the workflow of the second POP when used intercostal.
Appendix H: Contains a calculation of the stresses on the click fingers.

CHAPTER II: BACKGROUND INFORMATION

Feeling dizzy, nauseous and having the tendency to faint, may indicate a heart problem. There are many types of heart problems, all with different treatments. One of those treatments is a pacemaker. A peacemaker is an electronic device which is placed inside your body, near your shoulder, and is connected to your heart via electrodes. Those electrodes, called leads, transfer the pulses that the pacemaker generates to you heart (Symptomen: Harstichting, sd). To understand how this process works, it is necessary to understand how the heart works and what it's anatomy looks like

The heart

The heart consists out of two sides: the left and the right side of the heart. When looking at a picture of the heart, the left side of the heart is on the right side. This is due to the fact that a picture of the heart is looked at like someone is looking at a photograph. On a photograph the left part of someone's body is on the right side of the picture. The main function of the heart is to pump blood trough the blood vessels. This process starts in the right side of the heart. Oxygen-depleted blood enters the right heart. Both sides of the heart are divided into two chambers. The small, upper one, where the blood enters the heart, is called the atrium. Via the atrium the blood flows to the lower and bigger chamber, called the ventricle, where it is being pumped out of the heart. This right side then pumps it to the lungs via which the oxygen-rich blood enters the left atrium. From the left atrium the blood flows to the left ventricle (LV), which then has to pump it through your entire body, from the tip of your toes all the way to the top of your head. The left side has a much bigger muscular wall than the right side. Especially the LV, since it has to pump blood through the entire body. (Kenny, 2008)

Pacemakers

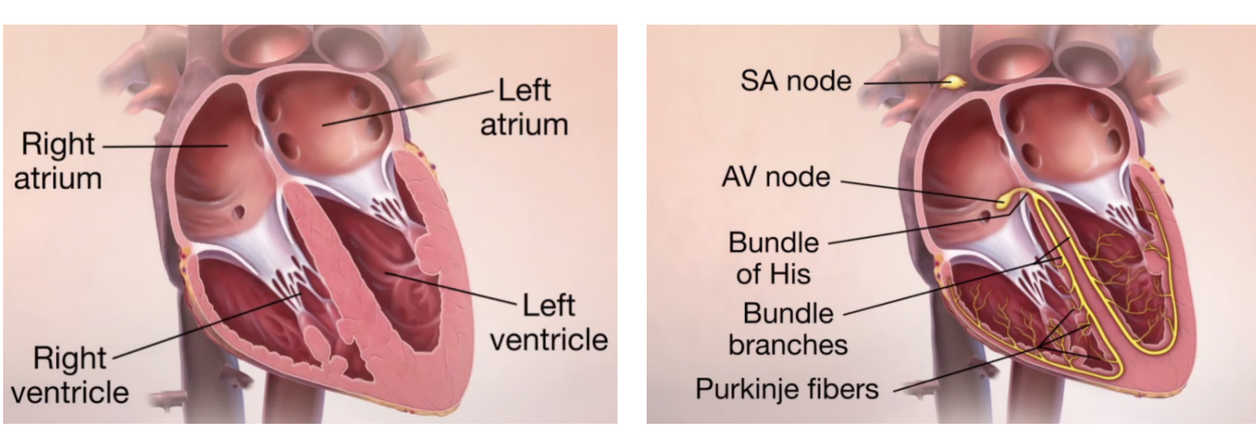
If one of the atria or ventricles is not pumping as it should, the blood flow and the heart rate are affected. A pacemaker is used to solve this malfunctioning of the heart. There are different kinds of pacemakers. Some pacemakers stimulate the atria and others the ventricles. Which pacemaker is implanted depends on the kind of heart problem you have. In general there are four types of pacemakers.

AAI Pacing (Atrium paced, Atrium sensed, Inhibited by sensed atrial event)

This pacemaker is pacing the atrium. The pacemaker detects if the atrium beats like it should. When the atrium doesn't beat like it should, the pacemaker sends an electric pulse through the lead to the atrium, which will make it contract. The lead is placed on the spot of the Sinus node. Therefore the signal travels freely and down the correct channels into the ventricle, causing a natural heartbeat. This pacemaker is especially used for patients which suffer from Sinus Node Disease, causing the normal signal regularity and rate to be affected.

VVI Pacing (Ventricle paced, Ventricle sensed, Inhibited by sensed ventricular event)

When VVI pacing, the pacemaker focuses on the ventricle. It monitors if the ventricle beats like it should, and just as with AAI pacing it sends a pulse through the lead if it doesn't. A reason why the ventricle is not



Figures 1&2: Anatomy and physiology of the heart *(Medmovie)*

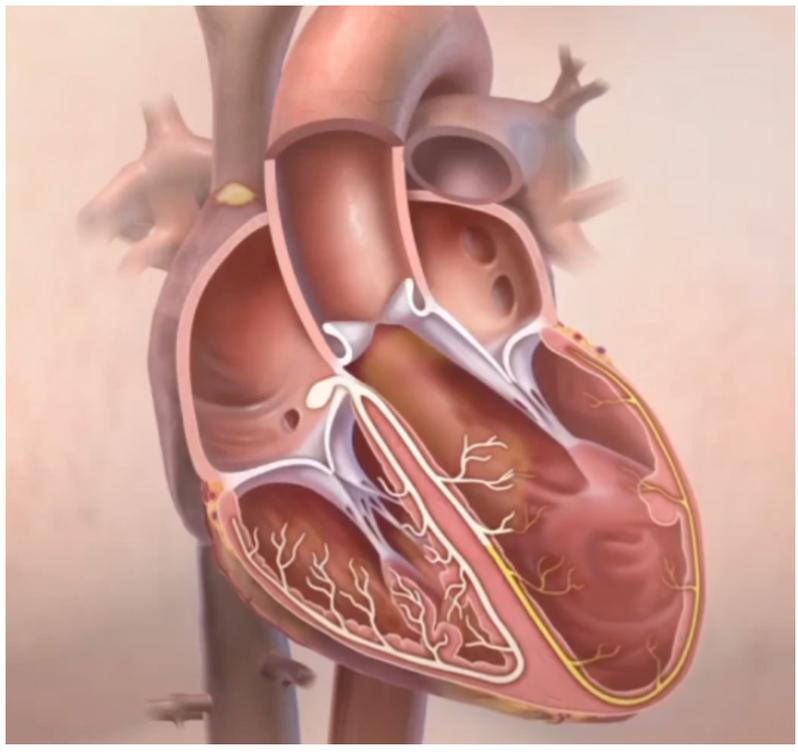
beating like it should, can be an unstructured beating in the atrium. Due to many small electrical pulses in the atrium, the signals in the atrium are going crazy. As indicated in AAI pacing, the signal in the atrium causes the ventricle to beat. But since the signals in the atrium are small and going crazy, not enough signals reach the ventricle. VVI pacing solves this problem. It is also possible that VVI pacing is used when the atria beat as they should. The cause in that case can be that the electrical signals in the ventricle itself are going crazy. When there are many little signals in the ventricle it won't contract enough to pump blood to the brains and the rest of body, causing fainting and possible death if the patient is not reanimated.

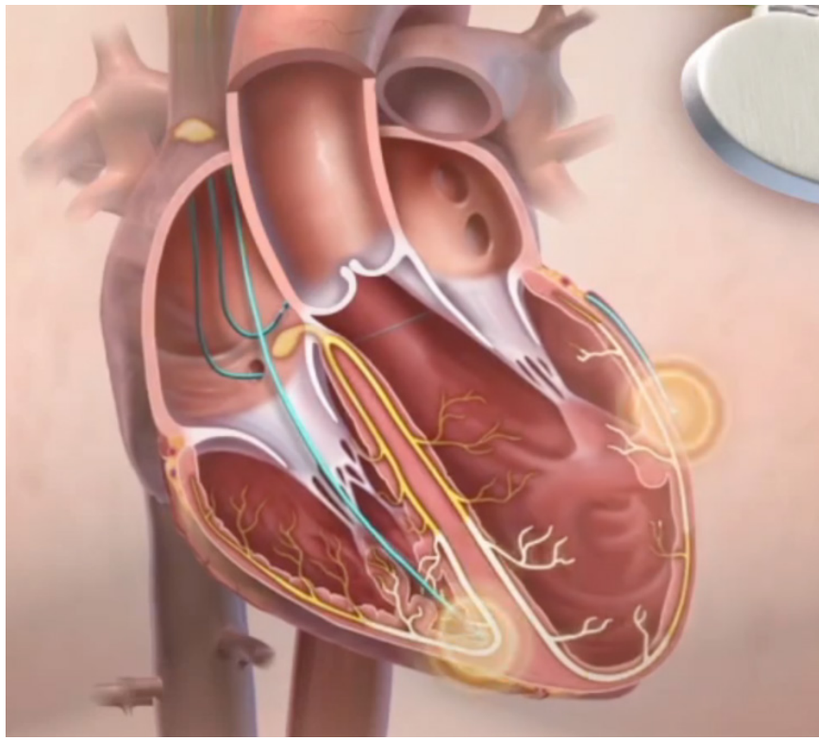
DDD Pacing (Dual-chamber paced, Dual-chamber sensed, triggered and inhibited by ventricular and atrial events (Dual))

When DDD pacing, the atrium and the ventricle are both being paced, because sometimes the atrium doesn't beat and sometimes the ventricle doesn't. This pacemaker is used for people with Heart Blocks. The signal is then getting blocked in between the atrium and the ventricle, which is called a septum. The pacemaker can sense a physiological heart rate in the top of the heart and can make sure that the bottom of the heart beats accordingly.

CRT Pacing (Cardiac Resynchronization Therapy Pacing)

The methods described above only took one side of the heart into account. But it is possible that the left and right part of your heart are out of sync. This can occur when the left bundle branch is blocked. This is called a left bundle branch block (LBBB). LBBB delays the signal and therefore causes the LV to contract later compared to the RV. CRT pacing focuses on resynchronizing the left and right side of the heart. In order to solve this, a third lead is placed on the left ventricle (LV). It is critical that this lead is placed on the exact spot where contraction of the heart is the delayed the most. (Buck, Maass, Nieuwland, & al, 2008). The pacemaker then senses that a signal is given in the right atrium and the heart starts to contract. The pacemaker then sends a signal to the LV causing it to contract and by doing so the signal in the LV is given at the same time as on the right side of the heart and therefore the heart is running in sync again, increasing the blood flow and correcting the heart rate.

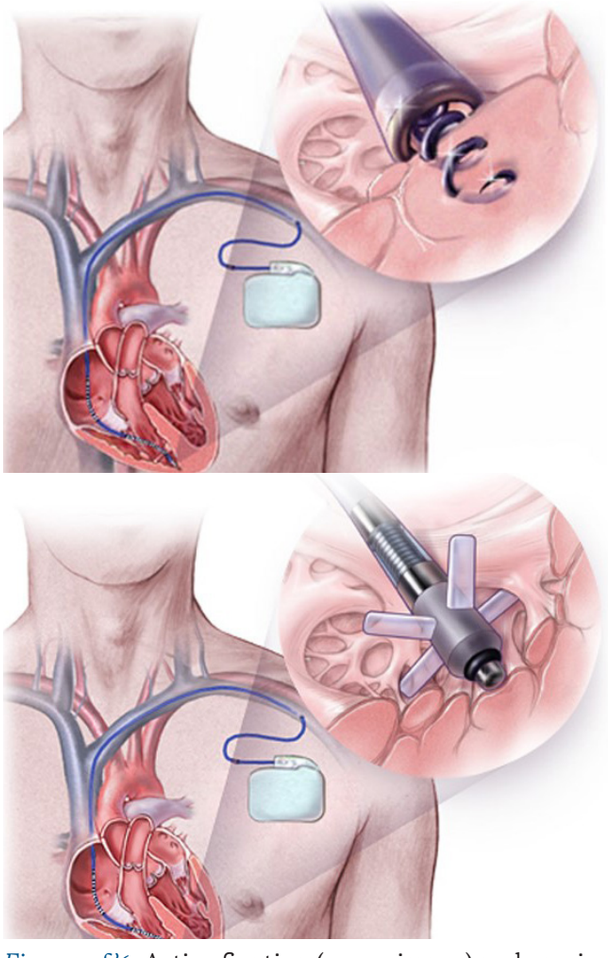




Figures 3&4: Bundle block without (upper image) and with CRT pacemaker (lower image)*(Medmovie)*

The leads

Just like pacemakers, several different pacemaker leads exist. The leads are divided into two major categories: passive- and active-fixation leads. Active leads are hooked or screwed into the heart tissue, whereas passive-fixation leads are poked into the heart tissue. There is also a big difference between epicardial leads and endocardial lead. Epicardial leads are attached to the outside of the heart, whereas endocardial lead are placed on the inside of the heart. Besides that there's also the difference between unipolar and bipolar lead. Unipolar leads have only one pole at the end of the lead and use the pacemaker's metal as the other end. For this reason unipolar leads are more likely



Figures 5&6: Active fixation (upper image) and passive fixation (lower image) *(Medmovie)*

to pick up stray electrical signals and can stimulate other chest muscles. Bipolar leads have both poles at the end of the lead. Therefore they are bigger than unipolar leads but their electrical circuit is shorter. (Medtronic Pacemaker Leads , 2016)

Placing the leads for CRT pacing

The leads have to be placed onto the heart in order to make the pacemaker work. The preferred way to do this is via the veins. A cardiologist uses a catheter to enter the bloodstream and to position the lead. He enters the coronary sinus (CS), the collection of veins that run across the heart itself and which collects the blood from the myocardium. He then screws the lead on the correct place in the heart and retracts the catheter. The positive thing about this method is that it's minimally invasive. The cardiologist just makes a small incision to enter the bloodstream and no big cuts are made in the patient's body. However, the major downside of this method is that it often doesn't succeed. Since the cardiologist is limited to the vascular system, the ideal spot to place the lead can often not be reached. Other causes are lead dislocation, stimulation of the phrenic nerve (which causes a continual hiccup), or lacking of a suitable side-branch to place the electrode. It turns out to be technically not feasible in approximately 10% of the patients (Gras, Bocker, Lunati, & al, 2007) and the nonresponse rate is suggested to be between 20% and 30% (Ypenburg, et al., 2008). However, CRT pacing is one of the cornerstones of the treatment of heart failure in patients with an intraventricular conduction delay and has received a class I indication (conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective) in recent guidelines.

Therefore alternative methods have been developed and if transvenous placement turns out to be not feasible, another method is used. The most frequently used alternative is surgery. The lead is placed on the outside of the heart (epicardial). In the early days this used to be done by open chest surgery. An increasingly popular method is minithoracotomy. Minithoracotomy uses a much smaller opening to perform the surgery compared to the open chest procedure. When open chest surgery or minithoracotomy is performed, the doctor has a good visual on the heart. He can also choose the perfect location to place the lead and is not limited to the CS anymore. However, open chest surgery and minithoracotomy are very drastic for the patient and the recovery takes a long time. Another epicardial solution, which is rather new, is video assisted thoracoscopic surgery (VATS) (Ernest & Lau, 2009). VATS is a minimal invasive surgery and it uses three small openings in between the ribs (intercostal) of the patient. In these openings a trocar is inserted. A trocar forms the working channel into the chest (thorax). It forms an easy and stable entry for the camera and the pliers which the doctor will use to cut the lining of the heart (pericardium) and place the lead onto the heart. VATS has the same advantages as open chest surgery but since it is minimal invasive the patient is able to recover much better from the procedure. Several studies have shown that placement of an epicardial lead on the left ventricle through

VATS is safe and effective (Rajwinder, Jutley, & David, 2008) (Fernández, García-Bengochea, & Ledo, 2004) and some authors even consider the implantation of the LV pacing lead by VATS as a primary option in CRT (Navia, Atik, & Grimm, 2005)

VATS Procedure

Before the surgery starts, images of the heart are being made (figure 7). With a technique called speckle tracking, active and passive motion can be distinguished and the site of latest contraction can be determined (Voskoboinik, McGavigan, & Mariani, 2016) (Figure 7). Once the optimal location is found, the patients is anesthetized and covered up and the lung is ventilated with a double lumen tube. During the first stage of the surgery the patient is positioned on his right side (right lateral decubitus). The patient is then prepped and draped and the surgeon marks the end of the shoulder blade (scapula) and the seventh or eighth intercostal space (Figure 8). An incision is made for trocar insertion and CO¬2 insufflation. A camera is inserted through the trocar and when the lung is collapsed, two ports for instruments are created (Figure 9). The pericardium is grasped and incised with scissors, posterior (behind) to the phrenic nerve, gaining access to the posterolateral wall (situated on the side and towards posterior aspect) and anterolateral (situated in front and to one side) wall of the left ventricle (Figure 10). The heart is then inspected and a vital part of heart muscle (myocardium) is identified. The screw-in lead is attached to the posterolateral or anterolateral aspect of the left ventricle free wall (Figure 11). When the lead is positioned, pacing threshold and impedance are assessed (Figure 12). When inadequate the lead is repositioned until the adequate values are acquired. The entire lead is brought into the pleural space (the membrane enveloping the lungs and lining the walls of the thoracic cavity) (Figure 13). The lung is then ventilated and the lead is trapped between the lung and the thoracic wall near the second intercostal space. The trocars are removed and incisions closed. During the second stage of the surgery the patient is positioned supine (on his back) and prepped and draped. The incision over the pacemaker pocket is opened and the device is removed. The posterior wall of the pocket is incised followed by blunt dissection (separating tissues along natural lines of cleavage without cutting) to the thoracic wall. The pleural space is entered through the second or third intercostal space and creates a tunnel between the pleural space and the pacemaker pocket. The LV lead is located and pulled through the incision and connected to the pacemaker (Figure 14). The tunnel and the posterior wall of the pocket are then closed, just like the pacemaker pocket. (Schouwenburg, Klinkenberg, Maass, & Mariani, 2014)

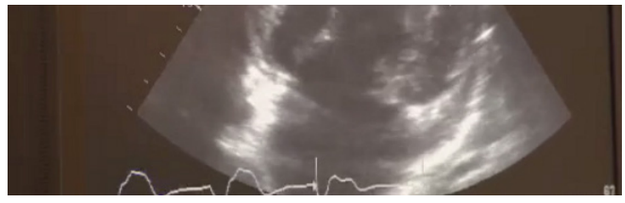


Figure 7: Speckle tracking

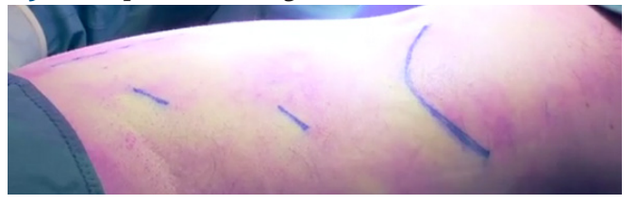


Figure 8: Drawing the incisions

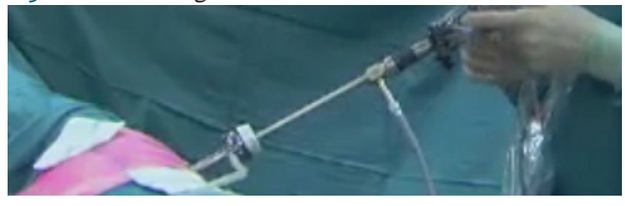


Figure 9: Putting in the throcar

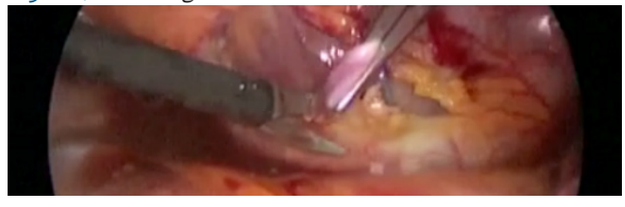


Figure 10: Cutting the pericardium

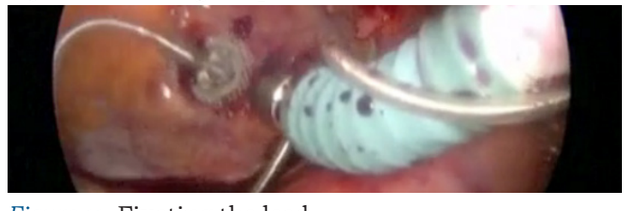


Figure 11: Fixating the lead

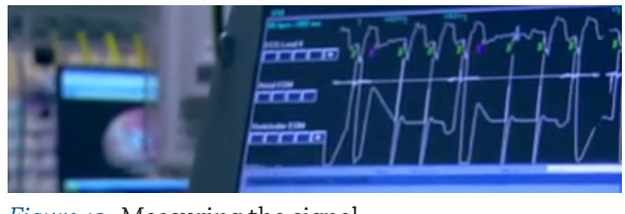


Figure 12: Measuring the signal

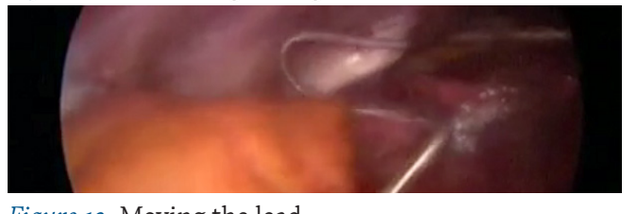


Figure 13: Moving the lead

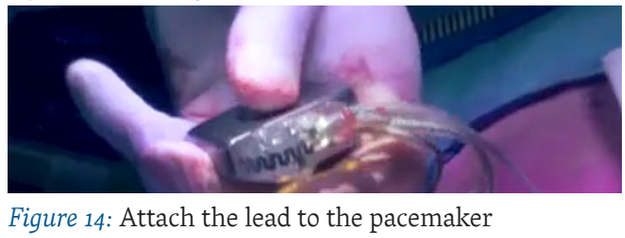


Figure 14: Attach the lead to the pacemaker

Current tool

As mention before, the VATS technology is relatively new and starting to gain popularity. Therefore, tools that are used to place the lead on the LV during VATS are not designed for this procedure. Those have been designed for open chest surgery or minithoracotomy, where the surgeon has much more space and freedom of movement compared to VATS. The tools currently used are the Greatbatch Medical FasTac Flex Epicardial Lead Implant Tool and the FasTac Lead Introducer. The surgeons at the UMCG use the FasTac Flex Epicardial Lead Implant Tool because it gives more freedom than the FasTac lead Introducer. The tip of the FasTac Flex Epicardial Lead Implant Tool can be rotated and articulated. The lead that gets clamped at the tip is the Greatbatch Medical MyoPore. The screw of this lead is perpendicular to the lead itself, as displayed in figure 15. The tip of the lead is clamped into the tip of the FasTac Flex Epicardial Lead Implant Tool. One of the trocars is removed and the FasTac Flex Epicardial Lead Implant Tool is inserted into the body of the patient. The nozzle of the implant tool is put in the desired position and the lead is screwed into the beating heart. The lead is released and the implant tool is removed from the patient's body. Drawback of using the FasTac Flex Epicardial Lead Implant Tool is that the tool is not able to temporarily fixate on the heart. Therefore it is difficult for the surgeon to place the lead on the correct spot on the heart since the heart is beating. The tool is also not able to measure if the lead is placed on the correct spot. The screwing in of the lead is also causing some problems, because the
lead whirls around the device since the lead is positioned on the outside. The tool has grooves on the shaft to click the lead in, in order to overcome this problem. However, these grooves can't be used during VATS because the surgeon cannot remove the lead from the grooves since the surgeon can't reach them. In appendix D the workflow of this tool is visualized. In appendix D the workflow of the FasTac tool is visualized.

In short, the point of the FasTac that needs improvement are:

- It is difficult to screw in the lead in the right spot since it is not possible to temporarily fixate on the heart.
- It is not able to measure if the device is positioned on the optimal spot before screwing in the lead.
- The lead winds up around the shaft of the delivery device.
- The delivery device does not fit though a trocar.

Figure 15: FasTac Flex Epicardial Lead Implant Tool *(Greatbatch Medical)*

CHAPTER III: WORKFLOWS OF DIFFERENT POPs

In this chapter, the workflows of the different POP's will examined. Demcon already has two POPs. The first one is based on a specially developed hook electrode which is shot into the heart. The second POP uses a screw in lead, but is designed for using only one trocar. So not only the lead will go through the TEDD, but also the camera and the tools to cut the pericardium. This tool can however also been used for the approach with three trocars in which only the lead travels through the TEDD. All these POPs have in common that they are able to temporarily fixate on the heart, fit through the trocar, and the lead does not wind up since it is inside the delivery device. Still, their workflows differ a lot. POP2 does even have two workflows. The workflows are described below and are summarized

First Proof of Principle (POP1)

The first POP was created in collaboration with the UMCG. It was designed for the intercostal approach and used to deliver just the lead, and is put in one of the in total three trocars during VATS. Besides the fact that it fits through the trocar it is also able to temporarily fixate on the heart in order to deliver the lead more easier on the right spot. It works different and uses a different lead compared to the FasTac Flex Epicardial Lead Implant Tool. The POP1 uses a specially developed hook electrode which is shot into the heart, where the FasTac uses a screw electrode which is screwed into the heart. When the pericardium is cut open, the hook lead is frontloaded into the POP. The POP is then inserted into the trocar. The safety cap is removed and the bigger pipe is pulled back, exposing the vacuum pad. The nozzle is them moved and turned in the desired position and the vacuum is turned on. The vacuum pad is sucked onto the heart, fixating the POP to the heart. Measurement is performed to check if the optimal spot is obtained. This POP does not have this functionality, but the future TEDD will. If the POP is positioned on the optimal location, the safety pawl is pushed back and the trigger is pulled. The hook electrode is shot into the heart and the POP is removed from the trocar, leaving the electrode behind.
The hook electrode used in this procedure was, just as the delivery device, a POP. It was developed to overcome the problems with the screwing of the lead. Instead of a rotation a translation was made (trigger being pulled) and instead of three movements (three rotations) it took only one to place the lead. Tests had been performed to see which design of the hook electrode worked the best. The hooks worked and the electrode was properly attached to the heart during lab tests. During the cadaver test however, the hooks didn't work properly and did not puncture the heart as expected. Demcon also decided to not design the lead themselves but focus on the placement device instead. In appendix E, the workflow on POP1 is visualized

In short the POP1's unique features are that:

- It uses a hook electrode which is shot into the heart .
- It uses vacuum to temporarily fixate on the heart.
- It fits through a trocar
- It is used intercostal and therefore three openings are made for the procedure.

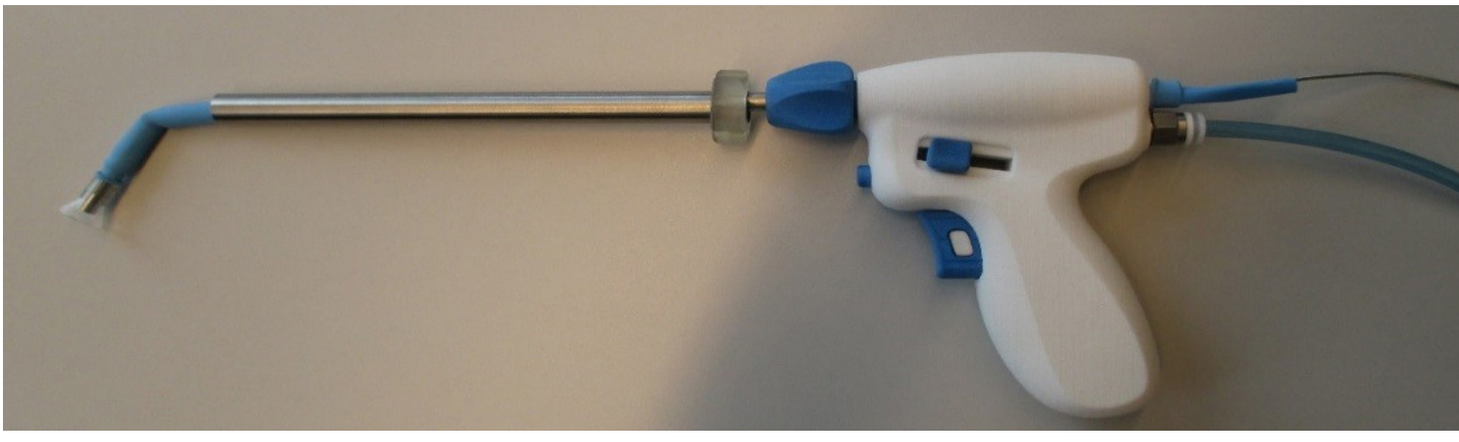


Figure 16: First POP

The second POP (POP2)

The second POP differs a lot from the first POP. It does not only look different, but is has also other functionalities. That is logical since it is developed for a different approach. The second POP is developed for the subxiphoid approach (via incision underneath the breastbone) of the heart, where the first POP was developed for the intercostal (between the ribs) approach. This means that only one trocar is used to insert instruments into the thoracic cavity. This is a major difference with POP2. The camera and the tools to open the pericardium therefore also need to go through the device, instead of just the lead. These tools are also changed a lot during the surgery with one tool going out of the POP2 and another one in. An incision is made just underneath the breastbone, creating space for the trocar. The POP is insert into the trocar and via the tool a scope is insert into the body to navigate to the heart. When near the heart, the vacuum pad is extended and the vacuum activated. The scope is retracted and a tool to cut the pericardium is inserted into the POP. An opening in the pericardium is made and the opening tool is retracted. The scope is inserted into the POP again and the vacuum is stopped. The vacuum pad is folded in and retracted and the opening is entered with the trocar. CO_2 is blown in to create space and the POP is inserted again. The target area is approached and the vacuum pad expanded and positioned. Then the vacuum is turned on and the POP is temporarily fixated to the heart. Measurements indicate whether the optimal spot is reached. The current POP does not have this functionality, but the future TEDD will. If the optimal spot is reached the scope is removed and the catheter with lead is inserted. The lead is screwed into the heart and it is measured whether it is working. The catheter is removed, the vacuum is stopped and the POP is retracted from the trocar. The lead which is used for this procedure is the Medtronic Select Secure 3830, a bipolar lead with straight tip parallel to the lead which is screwed into the heart. Demcon made a visualization of the workflow which is displayed in appendix F.

In short the POP2's unique features are that:

- It uses a screw in lead which is not clamped by the delivery device.
- It uses vacuum to temporarily fixate on the heart.
- It fits through a trocar
- It is used subxiphoid, are therefore only one opening is made for the procedure.

Alternative approach using POP2

The second POP was built for subxiphoid approach of the heart. In consultation with the surgeons at the UMCG, it turned out that the intercostal approach is preferred. The second POP was developed for the subxiphoid approach and therefore only one opening is made. The POP2 therefore has to be able to guide not only the lead to the heart but also the camera and a cutting tool. This tools however can off course also be used for the intercostal route where three incisions are made. It will then only be used to deliver the lead and not to guide the camera and/or cutting device. With an intercostal approach the POP2 will be inserted after the pericardium is cut open. The following part of the procedure is described below.

A catheter is prepared and the lead is inserted in the catheter, outside the body. When in the right spot, the lead is secured airtight in the catheter. This catheter is inserted in the Total Epicardial Device Delivery (TEDD). The TEDD is then inserted into the trocar and roughly positioned on the right spot. The tip of the TEDD is articulated in the desired angle. The vacuum pad is positioned on the heart and the vacuum is turned on. The TEDD is temporarily fixated on the heart and measurements are performed to check if it is positioned on the spot of the most delayed contraction. If not, the vacuum is removed and the TEDD is fixated on another part of the heart.

Figure 17: Second POP

Once the optimal spot has been found, the lead can be screwed in. The air lock of the catheter which was introduced into the TEDD in the beginning is loosened and the lead is being turned, causing the helix on the end of the lead to screw into the heart. The signal is tested and the TEDD removed. A slitter (little knife) is used to cut the lead loose from the catheter since the lead's connector will not fit through. The TEDD is removed from the trocar. The workflow of the POP2 when used intercostal is visualized in appendix G.

In short, the unique features of the intercostal approach with the POP2 are that:

- It uses a screw in lead which is not clamped in the delivery device.
- It uses vacuum to temporarily fixate on the heart.
- It fits through a trocar
- It is used intercostal and therefore three openings are made for the procedure.

Overview of the workflows

	Current intercostal procedure with FasTac	New intercostal procedure with POP1	New subxiphoid procedure with POP2	New intercostal Procedure with POP2
Delivery device	FasTac	POP1	POP2	POP2
Lead	MyoPore	Hook electrode	Medtronic SelectSecure 3830	Medtronic SelectSecure 3830
Fixation of the lead	Screw in lead pinched in the delivery device and fixated by the turning of a knob on the device.	Shoots in a specially developed hook electrode by pulling a trigger.	Screw in lead, screwed in by hand. The lead is inserted in the TEDD with a catheter and is screwed in by hand, outside of the body.	Screw in lead, screwed in by hand. The lead is inserted in the TEDD with a catheter and is screwed in by hand, outside of the body.
Advantages	Great control and transfer of rotation on the lead.	Fixate the lead with one press on a button. Is able to temporarily fixate on the heart and is able to measure if the location is optimal. Fits through trocar	Is able to temporarily fixate on the heart. Procedure can be performed by cardiologists instead of thoracic surgeons. Only one entry necessary. Fits through 12mm trocar. Future functionality is to be able to measure if the location is optimal.	Is able to temporarily fixate on the heart. Fits through 12mm trocar. Future functionality is to be able to measure if the location is optimal.
Disadvantages	Cannot temporarily fixate on the heart. Cannot measure if the optimal location is reached. Does not fit through a trocar. Lead winds up around the device when screwing in the lead and is therefore hard to retrieve.	Brand new lead needs to be developed.	Difficult to screw the lead into the heart since there is not much control on the lead. Impossible to operate with just two hands.	Difficult to screw the lead into the heart since there is not much control on the lead. Impossible to operate with just two hands.

Table 1: Overview of workflows

Chapter IV: Context

This assignment is commissioned by Demcon. Within Demcon, this assignment is part of a larger project, called the SNN TEDD. The abbreviation TEDD has been mentioned before and stands for Total Epicardial Device Delivery. SNN is the abbreviation for Samenwerkingsverband Noord-Nederland (The Northern Netherlands Provinces Alliance). SNN is a subsidy project, which means that the TEDD project is not a commercially project for a customer. Therefore there is much more freedom within the research. Customers often have predefined goals and requirements which have to be met. In a subsidy project the researchers define these requirements and determine what the main goal of the research is and how this will be implemented. The incentive in subsidy projects differs from commercial projects since the subsidy project has as main objective to gain knowledge where as a commercially project has as main goal to deliver something to the customer which he needs. In customer projects all the intellectual property created by the engineers will be owned by the customer. In subsidy projects the intellectual property will be owned by Demcon itself, or shared with the project partners, like in this project the UMCG. The results of subsidy project therefore can also be used to create turnover when the result of the research is taken into production or sold to a third party. The final TEDD can be sold and Demcon and its partners can decide how they are going to do that. Sure, Demcon focuses on research and the engineering, but for this tool they've aquired a patent and now it is possible to sell the production rights to a third party and claim a share of the profit made by the production partner. However, making money is not the main incentive. The main incentive is to gain knowledge and to gain a name and prominence in the medical sector for this instance.

Prices

It is also important to know that the TEDD will be a disposable and not a tool that will be re-used. This is important since it changes the future production numbers massively. This is part of the business model of many manufacturers since they generate more turnover this way. The FasTac, which is currently used in the UMCG, is also a disposable and costs €713,90 tax included. The epicardial leads used for CRT pacing cost between €500,- and €600,- and a CRT pacemaker costs €3200,-.

Number of CRT placements

In 2011 140 per million people received a CRT device. Expected is that this number will climb to 400 on annual base in the next years (Brignole, et al., 2013). In approximately 10% of these CRT placements the transvenous procedure fails (Cazeau, Alonso, Jauvert, Lazarus, & Ritter, 2003) (Bristow, et al., 2004) (Abraham, et al., 2002). This gives between 14 to 40 CRT devices per million people that need alternative placement.
The western population (defined as Europa, USA and Japan) have a population of 900 million. 511 million Europeans plus 325 million Americans and 127 million Japanese. The 14 to 400 per million of those 900 million are the market population.
The TEDD will be marketed in the western world (defined as Europe, USA and Japan). Since the patent is acquired, DEMCON will be the only provider of this technique to the distributor. Medtronic has a market share of 50% for cardiac rhythm products and will therefore be a great partner. If a company as Medtronic is chosen as partner this can lead to a market pentration of 35% to 40%.

The minimum expected market potential (based on 2011) is therefore 14 * 900 * 0.35 = 4410 (Number of epicardial procedures per million people x population in the marketing area x market pentration).
The maximum expected market potential (based on 2011) is 40 * 900 * 0,35 = 14400 (Number of epicardial procedures per million people x population in the marketing area x market pentration).
Thus the potential market for the TEDD, based on the failed CRT's will be between 4410 and 14400 on annual base.

There are reasons to believe that this procedure will be the first choice to place epicardial leads, since this procedure seems to be very easy to perform and offers a great chance of success. This means that even more CRT's will be placed using VATS and the TEDD. This can increase the numbers even more, but it is really hard to estimate these numbers since the numbers could even double or perhaps even triple. However, these estimations give a sense of the magnitude of the production numbers.

Patents

A patent investigation was performed during the development of the first POP. It showed that there are several instruments which are developed for epicardial lead placement. One of the patents that was found was the patent of the FasTac tool. The research showed that there were devices which enabled the surgeon to measure if the optimal location was reached, to temporarily fixate on the heart, or like the FasTac: place a lead on the heart. However, there was no device that was able to do all those three things. Demcon claimed the patent for this device and has also acquired it.

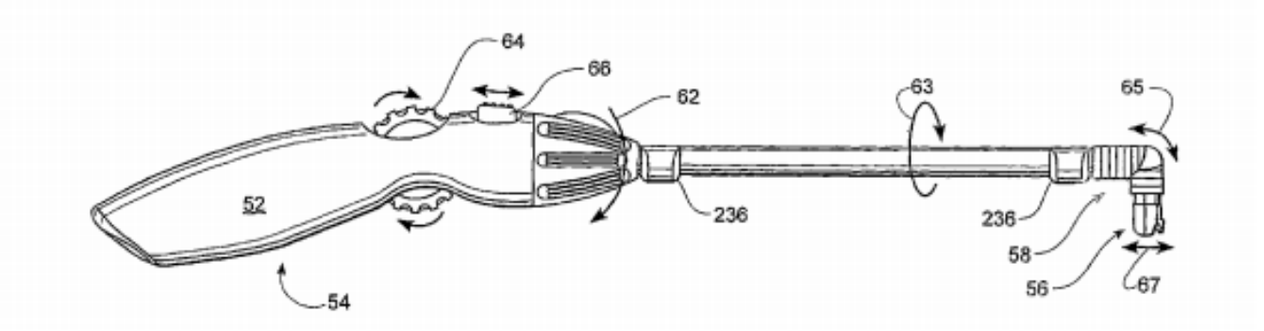


Figure 18: Image of the FasTac tool patent *(Espacenet)*

CHAPTER V: ASSIGNMENT

In the Universitair Medisch Centrum Groningen (UMCG) video-assisted placement of epicardial leads is performed. The surgeons at the UMCG are pioneers in this approach. It is a relative new method to place epicardial pacemakerleads. The tools they use are designed for open chest or minithoracotomy. As stated in the previous chapter, this tool has four major points of improvement. It is unable to temporarily fixate to the heart, it is unable to measure if it is on the optimal spot before the lead is screwed in, the lead winds up around the shaft of the delivery device and the tool does not fit through a trocar. It was also mentioned how POP1 and POP2 improved these shortcomings. However, the POPs also have points that need to be improved in order to make it a better delivery device. This assignment focuses on one of these points: screwing the lead into the heart. The POP1 used a hook electrode, which, after some discussion was decides will no longer be used. With the POP2 the lead is screwed in by hand. The lead is inserted into the TEDD with a catheter and screwed in the heart by hand. This is very difficult. The surgeon cannot apply much vertical force on the lead and the lead winds itself up in the catheter. The surgeon does not know how many times the lead is rotated near the helix, has little control on the lead and it is difficult to feel if the lead is fixated enough. The assignment described in this document tries to tackle that problem. As principle the POP2 is used with the intercostal approach. This since it was chosen to continue with a screw in lead and the preferred approach from the surgeons of the UMCG was the intercostal approach.

With this principle two problems occur when the lead has to be screwed into the heart:

- It is difficult to operate the POP2 with two hands: the total system becomes too big to hold and is also very wobbly and therefore it is unable to operate with two hands.

- It's difficult to screw in the lead. Since the point where the surgeon turns on the lead is a long way removed from the point where the tip of the lead has to screw into the heart, he is not able to push the screw against the heart which is necessary to drive the screw in the heart. The lead is also winding itself up instead of screwing into the heart.

The renewed POP should solve these problems. It should increase the usability and functionality of the TEDD a lot. The most important things the new POP has to do are:

- Make the use of a catheter in order to place the lead unnecessary. The purpose of the catheter should be integrated in the TEDD.

- The TEDD has to be operated with two hands. One hand to hold the TEDD and another one to control it.

- The driving in of the helix should be easier. It has to be easier to apply a vertical force on the lead and to screw the lead into the heart. The surgeon should therefore have more control on the lead.

Approach.

The workflow of the different POPs and the current method have already been defined. It has become clear that the catheter is used because the POP2 is developed for the subxiphoid approach and that it is not user friendly. It has also become clear that it is not easy to fixate the lead in the current situation since the lead is not rigid enough and the surgeon is not able to apply a vertical force to the heart. In the next phase the requirements will be defined in order to state what the result of the assignment should be able to. Then some experiments have to be performed in order to gain knowledge about what is important when the surgeon needs to screw the helix into the heart. This will lead to a couple assumptions which also has to be tested and will result in several partial solutions. The partial solutions have to be combined into one concept. Thereafter this concept will be altered and modified and have to be realized in order to test its performance. After the tests have been performed a conclusion can be drawn and recommendations can be given .

Demarcation

This assignment focuses on the part of the procedure that starts from the moment that the pericardium is opened and the TEDD is unboxed, until the moment where the TEDD is removed from the patient's body. This assignment will not focus on the opening of the pericardium or the methods to measure if the optimal spot is reached. This assignment uses the Medtronic

Select Secure 3830 lead as model for the lead and uses the mechanics of the previous POPs to maintain the remaining functions (temporarily fixating and articulating). The controls and functionality will determine mostly what the TEDD is going to look like. The changes in the exterior design will all be functional. The form follows function principle will be used. The esthetic and ergonomic part of the exterior design is not part of this assignment. This assignment only focuses on the part where the lead is inserted into the TEDD and how it is screwed into the heart.

CHAPTER VI: REQUIREMENTS

The goal of this assignment is to optimize the introduction and placement of an epicardial lead. Since this product is still in the POP phase, clinical requirements will not be addressed in this assignment. This assignment is about the mechanism which is used to insert the lead into the TEDD, screw the lead into the heart and remove the TEDD from the patient's body. During this assignment attention has been paid on how the lead is inserted into the TEDD and how the TEDD is prepared for use by the surgeon or his assistant. The TEDD will be used as a disposable, this is a part of the business model of many medical devices. This assignment is only a small part of the complete product. The result of this assignment will be a part of the future TEDD. Since some other aspects of the TEDD are not yet in the next phase, some requirements will not be met with the POP. For example: It is a future goal of the TEDD to fit through an 8mm trocar. The result of this assignment has to achieve that requirement, but the POP will not. This since the vacuum cap from the old POP will be used, since the temporary fixation method is out of scope for this assignment, and this vacuum cap does not fit through an 8mm trocar. However, the part of the POP that is the subject of this assignment does have to fit through 8mm, since that is a requirement for the future TEDD. The requirements are therefore especially for the part of the POP that is in scope of this assignment. So the requirement will not be rejected when the POP won't fit through the 8mm trocar, as long as the part of the POP that is in scope of this project does fit through the 8mm trocar. Comments are added to clarify these thing for every requirement.

The requirements are divided into three categories.

- Technical requirements: These are the requirements which create the technical boundaries for the device.
- Operator requirements: These requirements describe the requirements for the use of the product.
- Patient requirements: These requirements describe the requirements for the patient on whom the TEDD will be used.

In the requirements tables abbreviations will be used. Their meaning is stated below:

Prio= Priority. Every requirement is important but they are prioritized in order to deliver the greatest and most immediate business benefits early. The prioritizing is done by giving them a number:

3= Very important. This are the most important requirements which the TEDD needs to meet in order to be considered a success.

2= Describes a requirement which is still important but can satisfied in other ways is necessary

1= Describes a requirement which is desirable but not necessary.

FG= Describes a requirement which does not play a role at this moment, but is important in the future and therefore should be kept in mind

VM= Verification method. The verification method describes how a requirement will be verified.

A= Analysing. Verification of requirement by analysis.

D= Demonstration. Verification of requirement by Demonstration

T= Testing. Verification of requirement by testing

Number	Technical requirement assignment spcecific	Prio	VM	Comments
TE001	The TEDD should maintain its current functions when used intercostal.	3	D	The improvement in placing the lead should not be at expense of the existing functionalities of the POP2.
TE002	The TEDD has to fit through an 8mm trocar.	3	D	The future TEDD has to fit through an 8mm trocar. The POP of this assignment will not fit through 8mm since the old fixation method will be used and the vacuum cap doesn't fit through an 8 mm trocar.
TE003	When the lead is placed, the TEDD has to be removed without the use of external devices.	2	D	No other equipment, like slithers for example, should be needed.
TE004	The TEDD has to be sterilizable.	FG	D	The POP doesn't have clinical requirements. The final TEDD does, it has to be sterilizable.
TE005	The TEDD will be used as a disposable	3	A	Therefore it does not have to be resterilizable
TE006	The POP will only focus on the fixation mechanism and the temporarily fixation on the heart.	3	A	Bending of the tip and measuring if the optimal location is reached is out of scope. The vacuum is taken in account since it was relatively easy to add to the POP.
TE007	The TEDD will be rotated around the shaft by rotating the entire handheld.	1	D	It's not required to rotate the shaft separately from the handheld as in POP1
TE008	The TEDD will use the intercostal approach	3	D	Therefore it is possible for the lead to be front loaded, since the lead is the only thing that will be inside the TEDD.

Table 2: Technical Requirements

Number	Operater Requirements	Prio	VM	Comments
OP001	The TEDD should enable the surgeon to press the screw against the heart.	3	T	This will ease the driving of the screw into the heart.
OP002	The TEDD should enable the surgeon to have more control and mastery of the lead when screwing it in the heart.	3	T	In the current situation the motion performed on the lead does not get transferred properly.
OP003	The TEDD should be able to be operated with two hands.	3	T	
OP004	TEDD should make it easier for the surgeon to place the lead in comparison with the current POPs and the FasTac tool.	3	T	The handlings to screw the lead in should be simplified. Not excellent surgeons should also be able to successfully screw the lead in.

Table 3: Operator requirements

Number	Patient Requirements	Prio	VM	Comments
PA001	The chance of a successful surgery should not decrease.	3	T	
PA002	The chance of a successful surgery should increase.	2	T	The TEDD has added functionalities compared to the POPs and the FasTec which should decrease the number of incorrectly placed leads.
PA003	The TEDD should not increase the chance on complications for the patient.	3	T	Hematomas as result of temporarily fixation on the heart are not seen as complications
PA004	The TEDD should decrease the change of complications for the patient.	2	T	Since the TEDD is able to measure the location before the lead is screwed in, the change of myocardial trauma is decreased since the lead can be screwed directly on the right location.

*Table 4:*Patients requirements

CHAPTER VII: EXPERIMENTS

In order to create a better understanding of how the lead behaves under different circumstances and which factors play an important role when the lead is screwed in, several experiments have been performed. In this chapter, these experiments are described. It is describes what the reasons were to do these experiments, what the results were and what could be concluded from the results.

Experiment 1: Impact of the dimensions of the delivery tube

The first question that raised was what the impact of the diameter and length of the delivery tube was through which the lead is guided to the heart. When it was attempted to place the lead on a chicken breast, it felt like the diameter and length of this delivery tube played a vital role in the control the surgeon had on the lead. Based on the feeling of this experience the assumption was made that the lead winds up in the delivery tube of the TEDD and therefore the control on the lead is lost. A simple experiment was performed in which the diameter and length of the delivery tube was varied.

Goal

The goal of this experiment is to check whether the diameter of length of the delivery tube have an impact on the control on the lead and the transmission of the number of rotations of the lead to the helix.

Method

To check what the impact of the diameter and length of the delivery tube is, different configurations were made which were used to screw a lead into a pig heart. One had a longer length, and one a larger diameter. There was also a configuration made with and without the attachment which is used on the current catheter, since the inner diameter of this piece differs from the inner diameter of the rest of the delivery tube. This resulted in a total of four configurations. Each configuration was tested five times. Each time, the lead was turned three times at the most remote end of the delivery tube and it was checked how many times the helix was screwed into the chicken breast. The tube with an inner diameter of 3mm is the tube of the catheter used in the second POP and which is used for trans-venous lead placement. The results can be found in the table below.

Configurations

#1	Length: 125mm	Diameter: 3mm	Attachment: No
#2	Length: 250mm	Diameter: 3mm	Attachment: No
#3	Length: 125mm	Diameter: 6mm	Attachment: No
#4	Length: 125mm	Diameter: 3mm	Attachment: Yes

Configuration	n	Rotations of lead	Rotations of helix in the heart
#1	1	3	2,5
	2	3	2,5
	3	3	2,5
	4	3	2
	5	3	2,5
#2	1	3	2,5
	2	3	2,5
	3	3	2
	4	3	2,5
	5	3	2,5

Configuration	n	Rotations of lead	Rotations of helix in the heart
#3	1	3	1,5
	2	3	1,75
	3	3	1,5
	4	3	2
	5	3	1,5
#4	1	3	2
	2	3	1
	3	3	1,25
	4	3	1,5
	5	3	1,25

Table 5: Results of experiment 1

Interpretation of the results
From these results a couple of things become clear. First it all, configuration 1 and configuration 2 show us that the length of the delivery tube is irrelevant compared to the width for the amount of rotations of the helix. Comparing configuration 1 and configuration 3 shows us that the width however is relevant since the results from configuration 3 are worse than from configuration 1. Comparing configuration 1 and configuration 4 shows us that the attachment also has an impact. The results of configuration 4 are surprising: They are the worst, even though configuration 4 is almost the same as configuration 1 (which had the best results). The attachment seems to have a huge impact.

Conclusion
The conclusion from this experiment is that the diameter of the delivery tube has a larger impact on the winding up of the lead than the length, even if only a small part of the delivery tube has a larger diameter (like the attachment).

Further experiments
None of the configurations managed to screw the helix of the lead in as many times as it was turned. This raised the assumption that the lead has to be grabbed near the helix in order to screw it in as many times as it is turned. Another experiment was set up to check this.

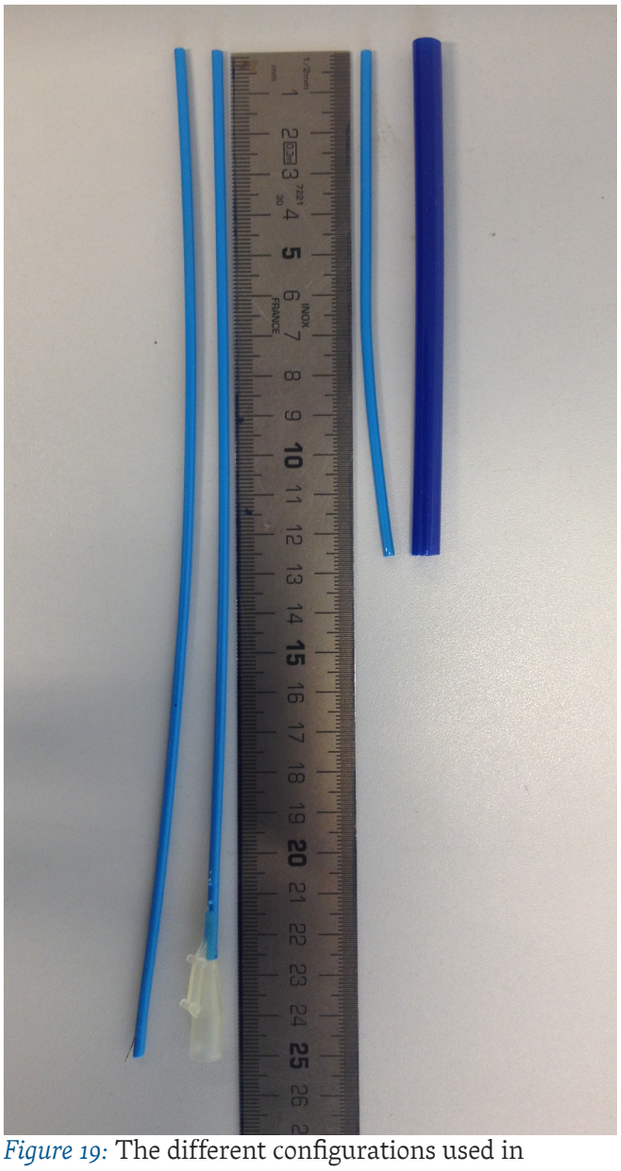


Figure 19: The different configurations used in experiment 1

Experiment 2.1: Robustness of turning at the tip

As a result of experiment 1, an experiment was performed to check if the helix would screw three times into the heart if the lead was turned three times near the helix. This idea raised when the lead was turned at a distance. It was felt that the lead was winding up itself, and that that was the reason why the surgeon has little control on the lead. The assumption rose that this could be overcome by grabbing the lead near the helix.

Goal

The goal of this experiment is to check whether the lead will screw three times into the heart if the lead is grabbed near the helix and then turned three times.

Method

The experiment was performed on a pig's heart. The lead was grabbed near the helix and turned three times. This was checked by a mark on the lead. When the lead was turned three times it was checked how many times the helix went into the heart. The lead was screwed into different parts of the heart. In the myocardium, in area's with more fat and near veins. Special attention was paid to the anterolateral and posterolateral wall. This is the site where epicardial leads are placed most frequently. Once the lead was turned ten consecutive times into the heart, there was moved on to next location.

Results

On all the locations the lead turned three times into the heart when it was turned near the helix. The only area's that were difficult where the area's extremely close to veins. The success of screwing the lead in also depended from the amount of vertical force. The lead needed to be pushed against the heart with a certain force in order to directly screw into it instead of scratching its surface.

Interpretation of the results

The results show that the assumption was right. The lead will screw in three times when it is grabbed near the helix and is then turned three times. That the lead struggled to go in three times near the veins is not strange and secondly no problem. It is not strange since a vein is small tube and when you want to screw something in that small tube it will get stuck. That makes is harder for the helix to screw further in the heart. Besides that it is not a problem since the lead will not be placed near veins.

Conclusion

The lead will be screwed three times into the heart when is grabbed and turned three times near the helix.

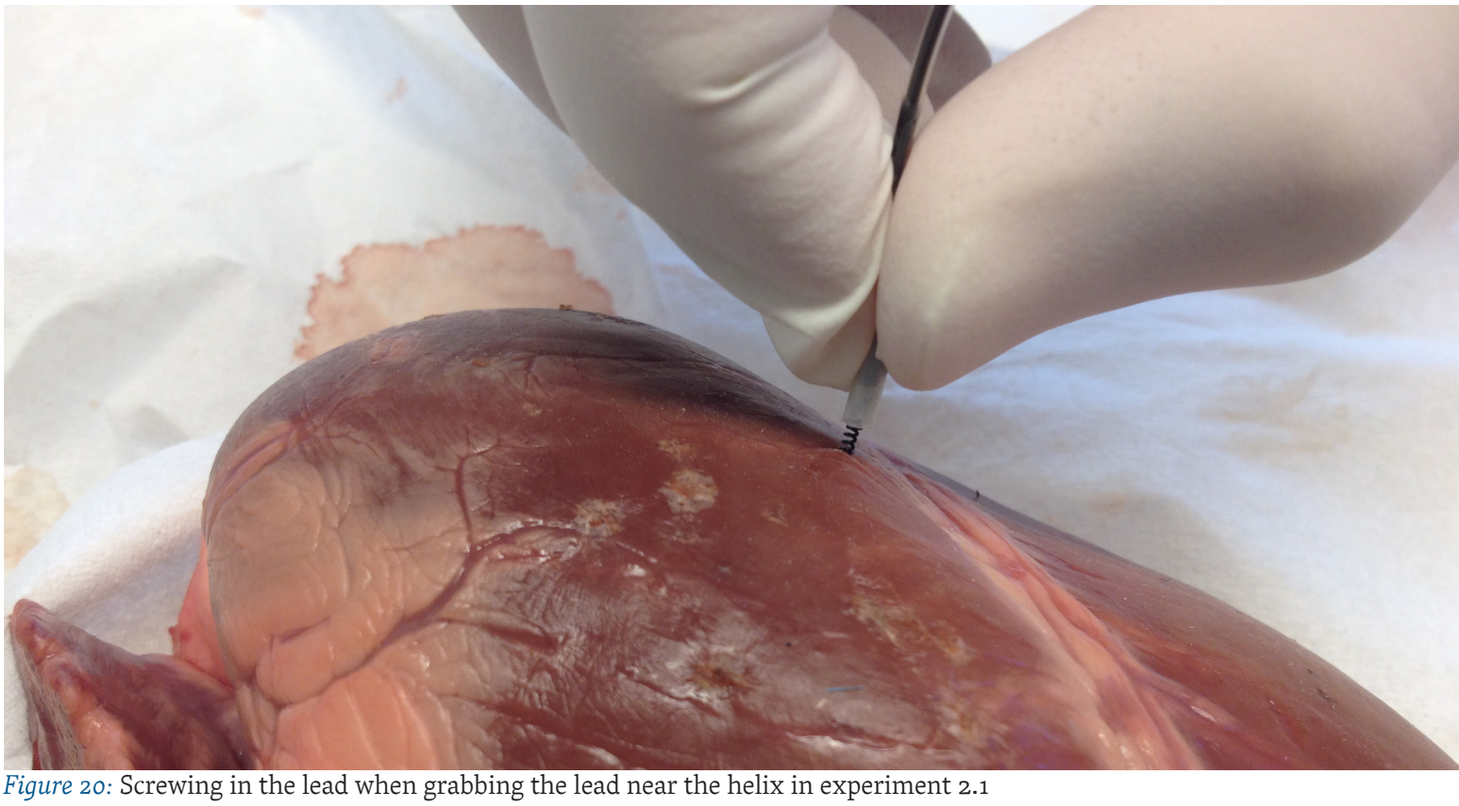


Figure 20: Screwing in the lead when grabbing the lead near the helix in experiment 2.1

Experiment 2.2: What indicates that the lead is fixated properly?

In order to make an automatic fixation mechanism it was important to know what indicates that the lead was screwed in enough. Because if this is known, that has to be the point where the mechanism has to stop screwing the lead further into the heart. During a brainstorm the idea rose that the torque that is needed to screw the lead in changes when it is screwed in far enough.

Goal

The goal of experiment was to check if it seemed as if a certain momentum was reached when the lead was screwed in enough. If the momentum differed to much there would not have been done a complicated experiment to find out how high this momentum is. Besides that it was also a goal to check for other identifiers that the lead is fully fixated.

Method

It was felt if a certain torque was reached when the lead was screwed in properly. Besides that there was felt for other identifiers. The results of this experiment are feelings and not numbers.

Results

The torque needed to screw in the lead changed a lot on different spots on the heart. Therefore it became unclear what indicated that the lead was fully fixated. At least it was for certain that it was not the momentum that was required to screw in the lead.

Conclusion

The amount of torque that is needed to screw in the lead is not an indicator that the lead is fully fixated.

Experiment 3: Needed vertical force

To measure the needed amount of vertical force on the lead that was sensed in experiment 2.1, a setup was designed in which this force could be measured.

Goal

The goal of this experiment is to find out how much vertical force is needed to let the helix immediately screw into the heart instead of scratching the surface first.

Method

A setup was build where weights could be attached to the lead. The lead was positioned above the pig's heart and rested on its surface. The lead was held in vertical position by a tube which was clamped in a stand. A flexible sleeve was put on the lead and a tie wrap was put on this sleeve to hold the weights. Nuts were placed around to lead and stacked upon the tie wrap to increase the vertical force on the tip. The lead was then turned without applying vertical force and it was monitored how well the tip of the screw gripped into the myocardium.

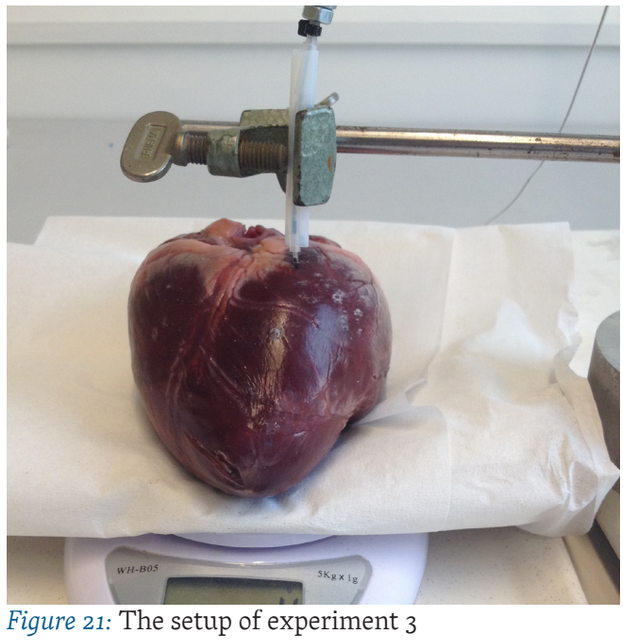


Figure 21: The setup of experiment 3

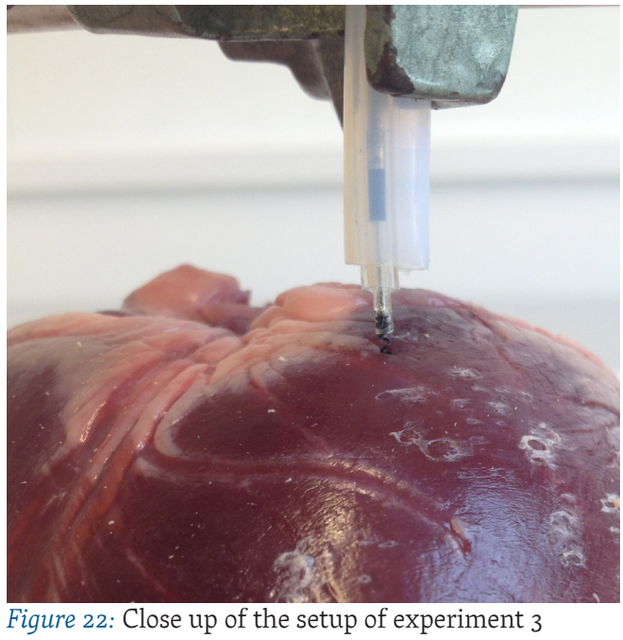


Figure 22: Close up of the setup of experiment 3

Results

With the first four nuts placed (three times an M5 nut and one M6) nothing happened and the screw did not grip the myocardium. After the fifth nut (another M6) was added, it started to sometimes grab the myocardium and screwed itself in. However, this did not happen on all the locations on the heart. The lead started to screw itself in consistently and really easy after 16.2 grams (three times M5, three times M6 and one time M8) where stacked on the lead. This result was measured several times by removing nuts and

adding them back on, with the same result.

Interpretation of the results
The minimal needed weight to let the lead directly screw into the heart in this experiment was approximately 16 grams, this equals a vertical force of slightly less than 16 Newton. However, it should be kept in mind that this test is very pragmatic in order to gain quick results. The leads that were used during the test had been used before and therefore the tip of the helix was not as sharp as the tip of a new lead. It was also not excluded that the operator of the experiment did apply vertical force on the lead when rotating it. This experiment is therefore rather used to picture its magnitude than to give a really accurate number. But, when using a brand new lead, this number should be sufficient, since a new lead screws in easier compared to an used one.

Conclusion
The minimal required weight on the lead to let the lead screw in the heart immediately is approximately 16 grams, which equals to a force of just under 0.16 Newton.

Experiment 4: Verification of correct fixation of the lead

It was unclear what the quantifications were for a good lead fixation. The lead's manual stated the following: 'Gently pull back on the lead and check for resistance to verify fixation. A properly fixated helix will remain in position.' This can be interpreted as if it doesn't matter whether the helix is screwed in one of five turns. Since this is an important thing to know for the automation of fixating the helix, Medtronic (the lead provider) was contacted. Therefore experiment 4 is not really an experiment, but since it provided valuable information is treated as if it is one. Their answer was that the number of required rotations of the helix depends very much on the position of the lead on the heart, the condition of the tissue and the kind of tissue. This is good news, because it means the delivery device does not have to be super accurate in delivering the helix in the heart with a specific amount of rotations. It doesn't matter if the lead is screwed in a rotation more or less regarding the fact that it should be fixated properly.

Conclusion
There is not a particular number of rotations that the helix needs to be in the heart. Since the helix has five rotations there is some slack. Therefore we do not have to know exactly where the heart will be on one millimeter accurate.

CHAPTER VIII:
THE PARTIAL SOLUTIONS

In this chapter the concept will be discussed. There is made one concept, which is then engineered into the next version and into the final design. The design choices will be elaborated and the versions will be evaluated.

One concept

But first of all clarification is needed why there is only one concept. The reason for that is that the difficulty of the TEDD lies in the integrations of all its functionalities. That is also what makes it unique, that it has all the functionalities in the little space that is available. It was not difficult to find partial solutions for the different functionalities, but what was difficult was combining them into one device which has all the needed functionalities. That is also the reason why the choice is made to create one concept and to improve this concept, instead of creating multiple concepts and choice one of those as final design, since there was only one configuration in which all the solutions for the different functionalities could work together.

To create a concept, the TEDD is divided into functionalities. For these functionalities, several solutions have been made and collected in an morphological scheme (figure x).

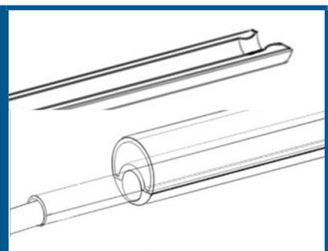
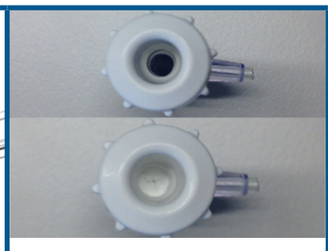
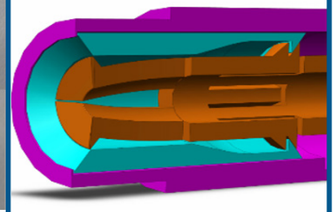
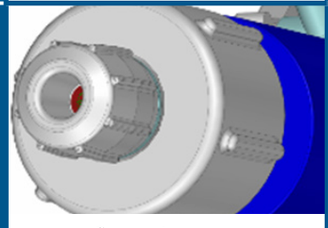
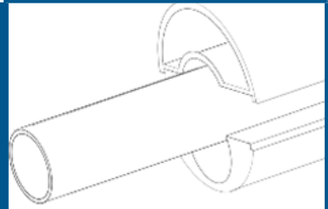
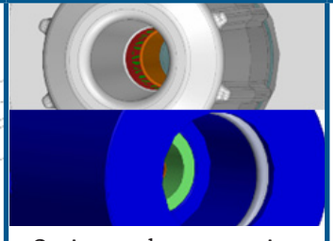
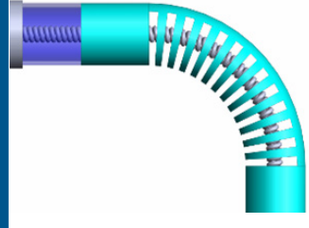
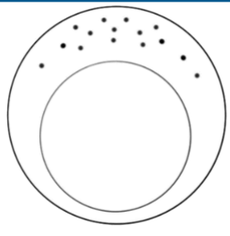
Variable diameter	 Partible sleeve	 squeezable ring	 Clicking fingers
Automatic fixation	 Screwing cap	 Storing torque	
Vacuum	 Seperate vacuum tunnel	 O-ring and squeeze ring	
Bending part	 Part with incisions	 Locally reinforced	

Table 6: Morfological scheme

Partial solutions

The difficult part of improving the fixation of the lead is the integration with the rest of the TEDD. The TEDD has several functionalities which all have to be maintained and need to fit through an 8mm trocar. The functionalities and the choices made for each function are elaborated in this part.

Variable diameter in the tip and grabbing near the helix

The diameter in the tip has to be variable in order to grab the lead near the helix and still enable the connector to fit through. Several ideas where conceived. The first was a partible sleeve in which the lead was clicked. This way the lead was grabbed near the helix with friction, and released when the surgeon separated the two halves. When the sleeve was separated, it can be removed and the connector will fit through. The problem was that it was unable to retract the delivery device when the helix was screwed into the heart. Since there is no space to separate the halves and since the helix will pull the heart when the sleeve is pulled back because it is still clicked in the sleeve. Another idea was based on the same principle as the catheter uses: a rubber ring that is squeezed between two parts and therefore reduces its diameter. This seemed quite difficult, since a quite strong force is needed that would have to be transferred through a piece that is able to bend. Besides that it would be unable to suck vacuum, since the vacuum pad is air tight isolated from the pump by this rubber ring. The last concept was that of click fingers. Based on their shape and material properties, these fingers are folded in when they are retracted underneath the middle ring (blue) and grab the lead. When the lead is turned from behind, it will automatically release the lead after 4 windings, since the blue part will be stopped by the outer tube, and the click fingers will turn underneath it. The last part is the major reason why this concepts is chosen. With the other concepts the surgeon still has to guess if the lead is in far enough and has to decide when he releases the lead. In the click fingers concepts, he does not have to worry about this since the lead will be released automatically on the right moment.

Vacuum

The POP2 had several vacuum valves. This was in order to maintain the vacuum, even when the devices it guided to the heart where retracted from the TEDD and others where inserted. Since the new POP will only carry the lead this can be simplified. It has to be possible to insert the lead in the TEDD without the help of the catheter, which is required in the current situation. One solution divided the TEDD into two tubes: one for the vacuum and one for the lead. The tube for the lead could then be separated and the lead could easily be delivered. However, in that case the problem emerges which is described above: the lead could not be retracted without pulling the heart. It also would become impossible to bend the tip of the TEDD. Another option was to just remove all the heavy valves and just use the vacuum valve that is already used on the back of POP2: the same as the catheter uses. It is used in combination with an O ring since the valve is placed in a part which will rotate inside the main body.

Automatically fixate the lead to the heart

Since the lead has to be rotated and translated, the concept that directly came to mind was that of a screwing cap. If the lead is grabbed near the helix with a part that is connected to this screwing cap, the helix would be rotated and moved forward with the thread of the screwing cap. Therefore it can be controlled how the helix is screwed into the heart. This solution is position guided and uses position to assure the lead screwing into the heart instead of a force guided solution as suggested in experiment 3. Another method which could be used is the one which was discovered by accident: torque. In one of the experiments it became clear that the lead could be wound up, and that it would fixate itself when it is released. In order to do so it has to be pushed to the heart and grabbed near the helix. This principle however seemed much more complicated compared to the screwing cap. It was also more uncertain whether it would work compared to the screwing cap. Therefore the screwing cap has been chosen as propulsion of the lead. The technique of winding the lead and then releasing it could be kept in mind, since it was a wish from the surgeons that the lead could be fixated with one push on a button.

Bending of the tip

There are several ways to make sure that the tip of the TEDD is able to bend. Both previous POPs use a plastic part with incisions in it in order to allow it to

bend in one direction. The first one was made by just making incisions in one side of a plastic tube, and used a spring in order to bend it back in its original position. The second POP used a specially designed part which was 3D-printed. Besides the fact that it could bend in one direction it also functioned as a spring a little. However these parts where not that strong and therefore broke off and needed an additional spring to bend them back in position. A more reliable but more difficult to realize bending part would be a part with more material and reinforcement in one side of the tube, causing it to bend in the other direction when the tip is pulled backwards. This method is also used in the catheter. However, this cannot be tested in small amounts, since there has to be made a special mold. Another potentially interesting option is a company which claims to be able to laser cut the shapes used for the bending part of POP2 in memory metals. This would make the bending part more reliable and rigid.

Combining the partial solutions

From all the different functionalities the solution with the most potential and that would be best able to integrate in the tool were picked. For some it was needed to alter them a little, in order to make it work. For example the concept with the fingers. In the first ideas, the blue ring was not there. It was just the outer ring which had the shape of the middle ring included (The blue part was integrated in the pink part). However, that way it would have been impossible to turn the orange part in it, since it is being squeezed by the same part as in which it has to rotate. To overcome that, the blue ring was added, the blue part. The blue part squeezed the fingers together and was able to turn inside the pink part. Also an O ring had to be added to the knob at the back which had the function of the screwing cap. This in order to conceive the vacuum within the TEDD. The only functionality which is not fully defined is the bending part. There are several options with some uncertainty around it. The bending part similar to that of the catheter looks like it could work, but cannot be tested since it is very expansive to produce that type of tubes for such a small number of examples. The solution with memory metals is also very uncertain, since the first meeting with the company that claims to be able to make this part has yet to take place. Therefore the bending part is not exactly defined, but several possibilities are known which just have to be examined more closely. The timespan of this assignment is too short to do so. Therefore the bending part is treated as a black box and is not more specified than the possible solutions. However it is analyzed what the effects of bending could be on the mechanism in the tip. This is done in the chapter of the final design.

CHAPTER IX:
THE CONCEPT

The first concept is the result of combining several partial solutions. Its mechanism is based on two principles. The first major principle is that the lead is grabbed near the helix, inside the delivery tube. Since the TEDD has to fit through an 8mm trocar and the connector has a diameter of 4mm, there is little space left for a grabbing mechanism. The solution was found in a mechanism that works based on the shape and properties of the materials of the different parts. One part has 4 fingers at the end closest to the heart (orange). These fingers fit inside the delivery tube but they do not fit inside the part (light blue) between them and the delivery tube. So once the lead is inserted into the TEDD, that middle part is pulled over the fingers. The shape of the fingers and the shape of the middle part (relatively orange and blue) cause the fingers of the orange part to bend and they are squeezed together, reducing the inner diameter of the orange part from 4mm to 1.3mm and trapping and grabbing the lead in-between them. This is where the other mechanism becomes important. A major knob at the back of the TEDD. Once the lead is secured, this knob has to be turned until it can't turn any further. The knob is connected to the main body with a thread, causing the orange part to move forward when the knob is turned. Since the orange part turns and moves forward, the helix is screwed into the heart. After a couple of winds the blue parts hits the pink part, and since the orange part fits through the pink part, the fingers of the blue part will snap over the grooves in the orange part when the turning of the knob is continued. This causes the fingers on the orange part to move outward again and they release the lead. The inner diameter is enlarged to 4mm again so the connector will fit through. The solution to fixate the lead is therefore position guided instead of force guided,

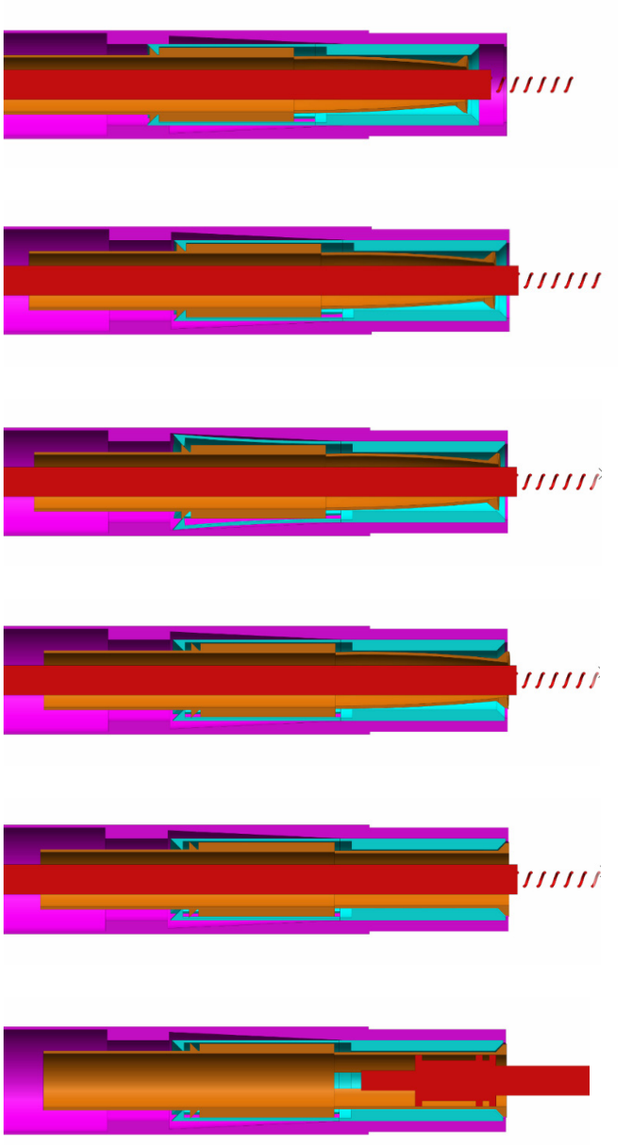


Figure 23,24,25,26,27 & 28: Vizualisation of the concept

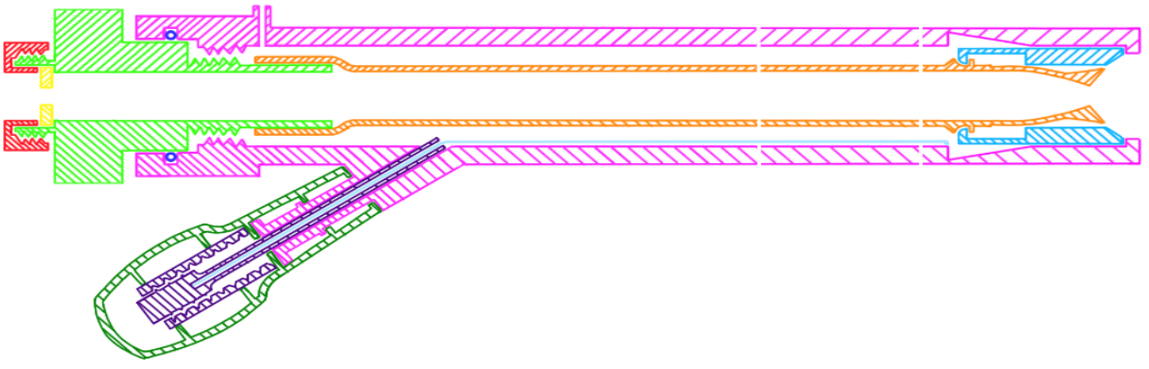


Figure 29: Drawed section view of the concept

as suggested in experiment 3. Since the lead is also moving forward, it is already forced into the heart, it doesn't need an additional force to do so. With this concept the surgeon just has to turn the knob until he cannot turn it any further. He then simply removes the TEDD from the trocar and pulls the lead through. The vacuum is still obtained thanks to an O-ring in-between the knob and the body, and an outtake where the suction device is placed. The bending of the TEDD can be achieved by choosing the right material for the orange part at the location where it has to bend. In an ideal situation the orange part can be made from one piece. In that case there are no connections which can break or cause trouble. However, research has to be done to check if this is possible since the front part needs to be sturdy and grab the lead, while the part behind it has to bend. This can me more difficult than expected. The bending part has to be torsionally stiff but still be able to bend. The tube of the catheter which is currently used has those properties, and a similar tube could perhaps be used for this part. It then even might be possible to make the orange part out of one piece since the material of the catheter tube seems suited to be used for shaping the clicking fingers.
The most important part of this concept is that the success of fixating the lead becomes less dependent from the skill of the surgeon. It is easier to fixate the lead and it gives the surgeon more assurance that the lead is fixated enough. The only thing that the surgeon has to do is turn the knob until he cannot turn it any further. It takes away the feeling on the lead for the surgeon, but it gives him more certainty that the lead is fully screwed in, and therefore the surgeon doesn't need to have a feeling of the lead anymore. It takes away the uncertainty of turning on the lead and not exactly knowing how many times the lead turns at the helix.

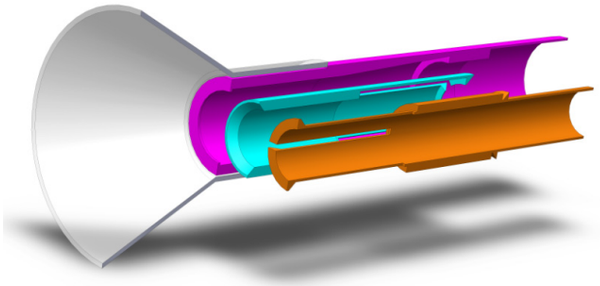


Figure 30: Render of the nozzle of the concept

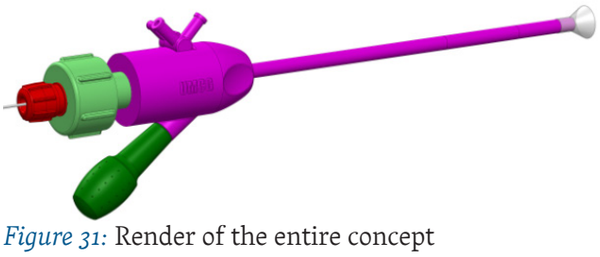


Figure 31: Render of the entire concept

Second version of the concept

The second version of the concept is an improved version of the previous concept. In the previous concept the blue part had also click fingers, this made it possible to let the orange part slide underneath it and release the lead but also made sure that the orange part would not slip underneath it by accident. However, this takes extra space, since the fingers of the blue part bend upwards. It also requires a shape from the tip section of the pink part that is difficult to realize. Therefore the design of the nozzle has changed and the blue part became a cylinder. The fingers of the blue part are added to the orange part and therefore there is just one part with bending elements. This also saves space, since less space is required for parts that needs to bend. And since the tools had to fit through an 8mm trocar, every millimeter of extra space is important. This concept was then further engineered, giving the fingers a more optimal shape by reducing material on the ends of them (causing them to bend more evenly) and by rounding some edged reducing the tension on them.

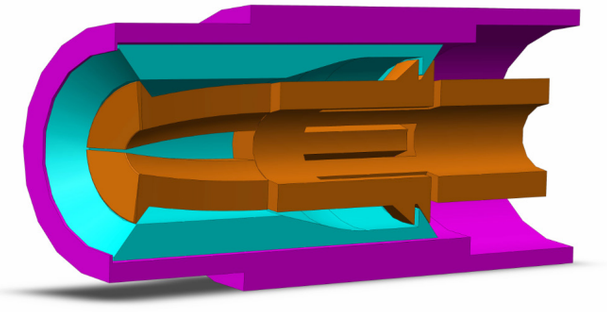


Figure 32: Render of the new nozzle of the concept

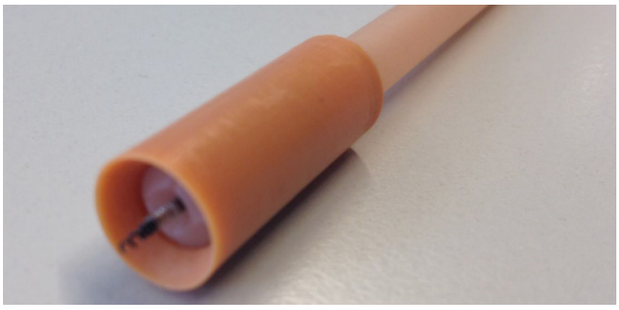
Calculating the force on the click fingers

Before the POP of the grabbing mechanism was 3D printed it was uncertain whether it would work. Perhaps it wouldn't work or the fingers even might break off. In order to make the chance of success as high as possible and to have an idea whether it might possibly work, an estimation is made of the stresses in the click fingers. With a calculation it became clear that the stresses were in an acceptable range and had a high potential to not break off. The calculation can be found in appendix H.

Testing the grabbing concept before making the final design

Since the parts in the nozzle are very tiny and there are a lot of uncertainties, it has been decided to first build a separate POP of the nozzle before building the entire POP. This way some modifications could

be added, increasing the change of a working POP. The parts were rapid prototyped and 3D printed. Four different configurations were made. One variable was the diameter of the nozzle and the other the angle of the fingers. The diameter was varied between 8mm and 12mm and the angels where 30° and 45°. The final product has to fit through a 8mm trocar, but since the parts were 3D printed, they are not as rigid as when they would be produced for mass production. Therefore they were also printed with a diameter of 12mm in order to increase the change of a working POP. When the parts arrived they were assembled and tested. First of all if they could hold a lead and release it on the right time. When they proved to be able to do so, they were tested on a pig's heart, where they showed their potential.



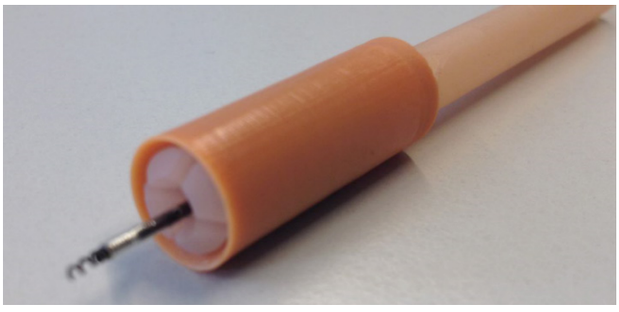


Figure 33, 34 & 35: Photo's of the POP of the nozzle

The final design

In the final design all the functionalities are integrated and attention has been paid to the actions the surgeon has to undertake in order to use the TEDD after unboxing. One important change was made. An extra slope was added on the click fingers that hold the cylinder in place, as depicted in figure . This was done to improve the preparation procedure of the TEDD. In the concept the cylinder could only release the lead once, and could not be placed back in position since the shape of the click fingers prevent it from doing so. By adding the extra slope, the surgeon can grab the lead by turning the knob back since the cylinder can slip over the inner click fingers from behind. The surgeon then has to just screw the knob back 8 turns and then screw the knob back until it cannot screw anymore. This is more user friendly then when the surgeon has to slip on the cylinder from the front by hand. The rapid POP from the nozzle also showed that it was easy to overshoot the second click fingers so the shape of their grooves has been optimized. In an ideal situation the lead can be stored under tension. Then the surgeon only has to unbox the lead and start turning the big knob until he cannot turn it any further. However is too easy to that say that the final TEDD will work like that since its likely to have impact on the lead if it is lying pre-stressed for so long. Perhaps it could cause the lead to fail or stick to the delivery device.

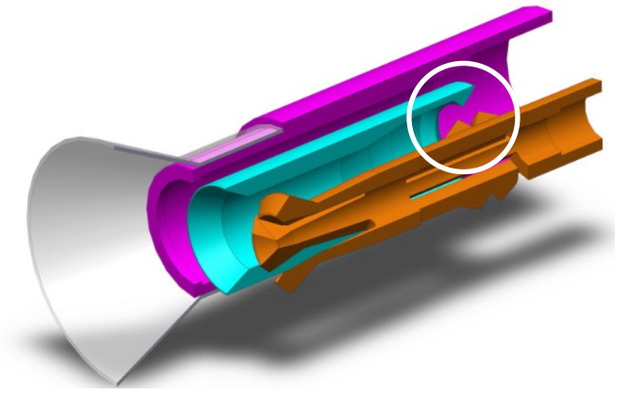


Figure 36: The renewed nozzle, with extra slope

This TEDD is much easier to operate since the most difficult part, screwing in the lead, has been automated. The surgeon does not have to guess if the lead is fixated enough anymore and requires much less training in order to develop the super refined feeling that is needed in order to sense whether the lead is being fixated. The only thing the surgeon needs to do is turn the knob on the back and he will fixate the lead as well as releasing it. This concept is easy to integrate in the current procedure. The TEDD will become important after the point in the procedure

where the pericardium is opened. At that moment the TEDD will be unboxed. The TEDD is lying in the box with the lead already inside the delivery tube. The lead is already positioned in the optimal position and roughly hold in place by the vacuum valve on the back of the TEDD. The fingers are extended and the lead is not grabbed near the helix. The assistant unboxes the TEDD and hands it over to the surgeon. The surgeon winds the main knob on the back 8 times counterclockwise, and by doing so grabs the lead. The TEDD is then inserted through the trocar. The suction cup is placed on the heart and the vacuum is activated. The location is measured and it is checked whether the optimal location is reached. If so, it is time to screw in the lead. The surgeon turns the main knob as many times as possible, screwing in the lead, and releasing it after 4 winds. The signal is checked, the vacuum removed and the TEDD retrieved from the body.

Future improvements on the final design

The final design will fit through an 8 mm trocar if some adjustment are made. The second row of click fingers needs to be bigger. The outer rings clicks over it to easy. This is since the parts are printed. The hook on the outer ring is modelled very tiny, since the printer is having impurities with concern to the size. That can be expanded, just like the hooks on the clink fingers themselves. In addition to that it is suggested to realize the parts from a more sturdy material. Now they are printed from a rather soft plastic. But aside from the fact that the outer ring doesn't click that good on the inner ring it functions good. The test performed on the pig's heart were, also for the 8mm configuration, surprisingly positive.

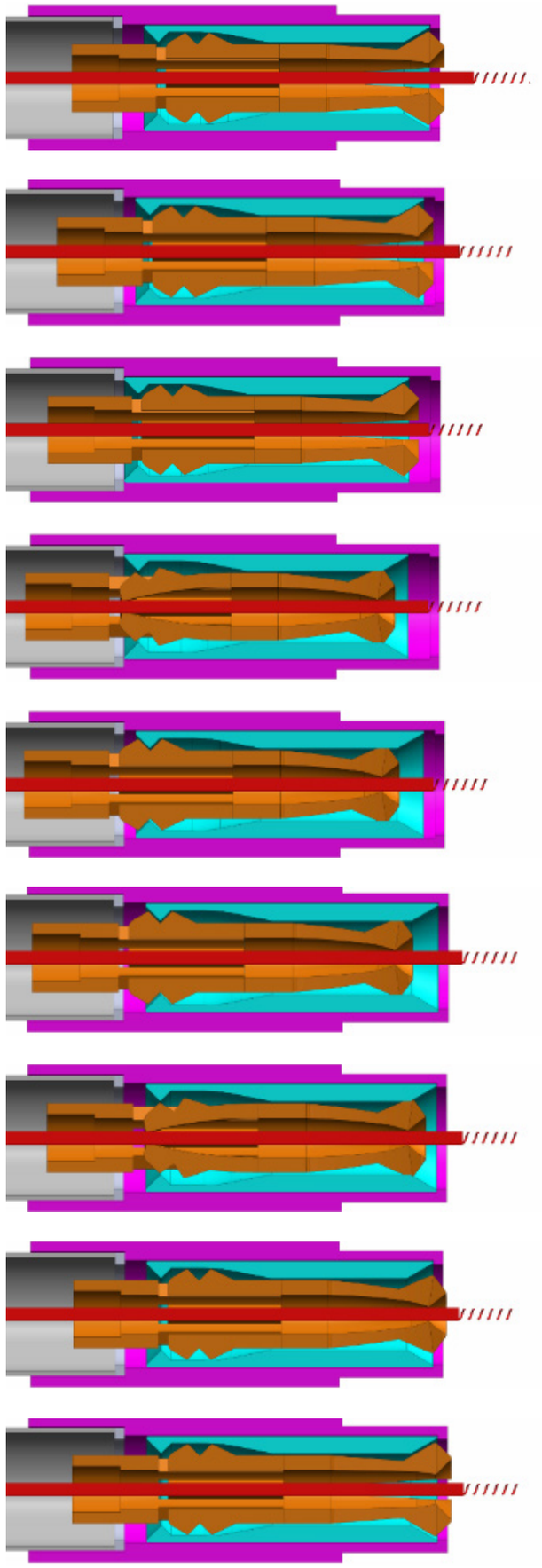


Figure 37: Grabbing and releasing the lead

CHAPTER X:
THE POP MODEL

Due to the time limit choices had to be made with relation to functionalities. Which functionalities will the POP have and which not. The main focus of this research is improving the fixation of the lead. Therefore the new mechanism to grab the lead and screw the lead into the heart is integrated in the POP. The vacuum did not require a huge effort to integrate into the POP and is therefore also integrated. A cavity for an O ring is created in the POP and an intake for the suction machine in inserted. For the POP it was also decided to create the parts with thread on them separately from the 3D printed parts (yellow and blue). Printing thread is possible, but it won't be working as smooth as if it was made with a lathe. Therefore two parts were created which were inserted into the printed parts. The pitch of the thread is 0.7mm per revolution. This number is chosen since that is the average pitch of the lead. The lead was checked under a microscope where it is easier to see the five windings. The last functionality: being able to bend the tip of the TEDD, is not integrated into the POP. This may seem as one of the easiest functions to integrate but that's not true. In order to bend the delivery device a lot of extra connections had to be made and more attention would be required to make the POP air tight for the vacuum. Therefore it is chosen to not integrate the bending functionality in the POP. Nevertheless it should be taken into account that bending of the tip may have consequences for the functioning of the nozzle mechanism. Therefore an analysis is made.

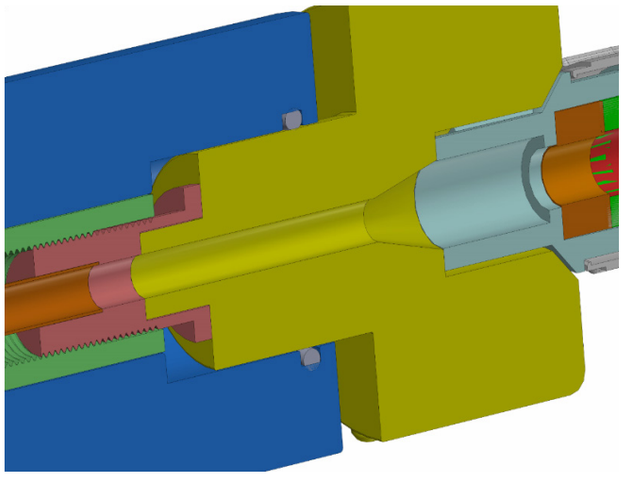


Figure 38: The knob and the parts with thread

Figure 39: Image of lead under the microscope

Consequences from the bending part

Since the bending part is not included in the POP model, it will not be tested what the effect of bending in the tip is on the effectiveness of the grabbing mechanism. In order to say something about the effect from bending the tip an analysis has been made.

What happens when the tip is bend and the knob is turned, is that the inner tube is forced forward. The inner tube goes straight until it meets the outer tube and then is forced around the corner, and directly going back to the center, since it meets the grabbing mechanism there. Since this causes the orange tube

Figure 40: Render of the entire POP model

to deviate from the optimal location, which is in the center and where its length in the bending part does not change, the location of the grabbing mechanism in the tip changes. In order to know how fatal this is, it has to be known how large the difference is between this position and the optimal position. Since the bending angle of the TEDD is 90°, the length of the ideal position is the circumference of a quarter circle and is calculated by $L = 1/2 * r * \pi$. The bending radius of the TEDD is set on 20mm in the example. In the previous POP this was 15mm so it should provide a save outcome. 20mm seems small, but the bending is done when the TEDD is inside the patient's body and therefore space is limited. The length of the optimal position is $L = 1/2 * 20 * \pi = 31.42$mm. 20mm needs to be added to this for the straight ends, so the total length of the optimal position is 51.42mm. The length of the orange bending tube in the situation displayed in figure X is 53.15mm. That is a difference of 1.73mm, which is equal to just less than 2,5 rotations in the tip. This means that when the tip is bend, the orange part of the grabbing mechanism is pulled back 1.73mm. This means that there has to be 1.73mm left behind the blue ring, once it is snapped on the orange part. There is some space left, since once the orange hook had passed underneath it, it wants to slide in the groove of the orange part, sliding forward a little. However, this gap is not 1.73mm but approximately 0.9mm, leaving a little 0.8mm, which the orange part is pulled back underneath the bleu ring, causing it to snap loose. This could be fixed when the surgeon turns the lead forward 1,5 rotations before its bends the tip. He then creates more space between the blue part and its offset, which is necessary when the orange part is pulled back thanks to the increased length in the bending part. Another solution is to guide the orange part in the red part. By adding a couple of ribs inside the red bending part, the orange part will follow the optimal position more closely, and therefore will be pulled back less than 0.9 mm when the tip is bend. In that case the surgeon does not have to rotate the orange part forward.

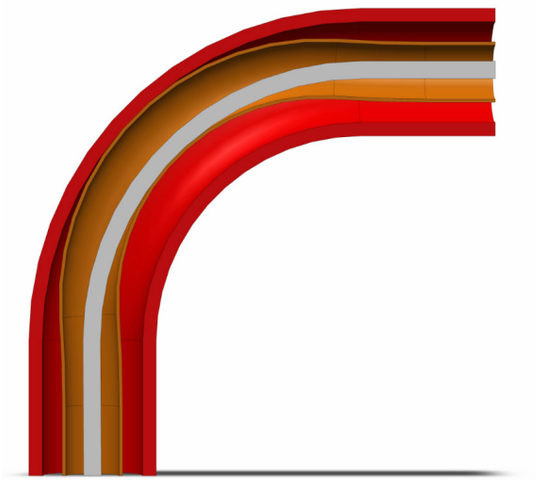


Figure 41: Bending part in suboptimal position

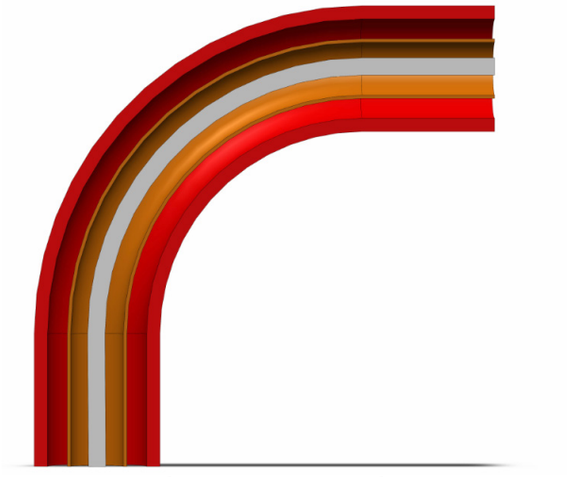


Figure 42: Bending part in optimal position

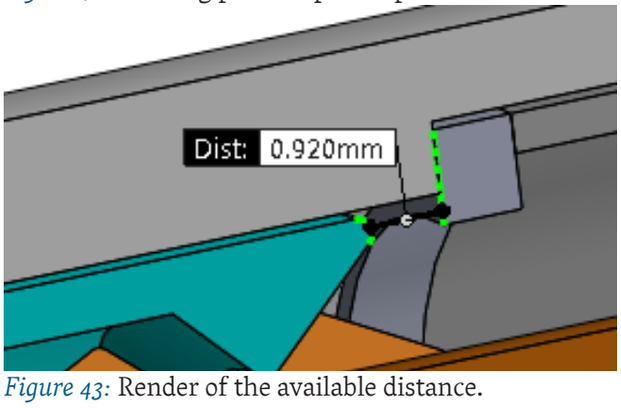


Figure 43: Render of the available distance.

POP assembly and testing

The POP consist of a couple of parts that are 3D printed, parts that are fabricated on a lathe and parts that are bought. They are assembled by hand and painted in order to give them a nice finish and make the look like a real instrument. The POP will be tested on a pig's heart. During this experiment the vacuum will be activated and it will be tested how well the mechanism works. The POP will not be inserted through a trocar. This since it will not fit through. The front exterior tube of the nozzle is 3D printed, and is given extra thickness in order to make it sturdy enough. The inner diameter has the correct size to fit through a trocar, so it is just a matter of choosing a different fabrication technique since it was easier to fabricate. The testing of the POP will be used to check whether the requirements are met. Some requirements had to be verified by experiments. When the POP will be used to fixate leads on the pig's heart, attention will be paid to the following requirements:

- TE 003: When the lead is placed, the TEDD has to be removed without the use of external devices.

- OP001: The TEDD should enable the surgeon to press the screw against the heart

- OP002: TEDD should enable the surgeon to have more control and mastery of the lead when screwing it in the heart

- OP003: The TEDD should be able to be operated with two hands

- OP004: TEDD should make it easier for the surgeon to place the lead in comparison with the current POP

Besides the points listed above, it will be also checked how many times the lead is screwed into the heart and checked if this is constant.

CHAPTER XI: TESTING OF THE POP

Goal

The goals of this test is to verify the functioning of the designed mechanism. First of all it is checked if it works properly and if it is possible to fixate the lead with the POP. Besides its overall functioning, the results and experiences of the testing are compared with the requirements. It is checked whether the mechanism met the requirements and where it doesn't it is checked why.

Method

The POP was tested by using it to fixate a lead on a pig's heart. It was attempted to fixate the lead with the mechanism and it was then checked if the lead was fully screwed into the heart. If the lead was not fully screwed in, it was measured how many times it was screwed in. During the different trials, the location on the heart on which the lead was fixated was varied. The result was noted for ten consecutive times. During the test the vacuum pomp was attached and it was checked if the POP was still able to fixate temporarily to the heart.

Results

Trial number	Rotation in the heart
1	Fully screwed in
2	Fully screwed in
3	Fully screwed in
4	Fully screwed in
5	Fully screwed in
6	Fully screwed in
7	2
8	Fully screwed in
9	Fully screwed in
10	Fully screwed in

Table 7: Results of the testing of the POP

It was possible to suck the POP to the heart with the vacuum. However, the suction power was a lot less compared to the POP 2. During the fixation of the lead it was sensed that the feeling of what happens with the lead is gone. As operator you don't have any idea what is happing with the lead and how many rotations it has made. It was also measured what happened when the lead was grabbed even closer to the helix and further away from the helix. What happened when de lead was grabbed even closer to the helix is that the helix does hit the heart to late, and therefore does not screw into the heart. When the lead is grabbed further away from the helix, the helix is still properly screwed in, unless the lead is grabbed so far from the helix that when the knob is turned back, the helix still sticks out of the opening of the POP and therefore will fold itself up in the vacuum pad when pressed to the heart. It therefore is unable to screw into the heart. One thing that did not function properly was that the lead got stuck in-between two fingers when the knob is screwed back. The lead is therefore not centered anymore.

Interpretation of the results

The results show very clearly that it mechanism works very good. In almost all the trials, the lead was fully screwed in. Trial number 7 is the only exception and still there, the lead is screwed in far enough. The expected reason why the lead in trial 7 did only screw in two times, is that the tissue of the heart on the location of trial 7 was in a very bad condition. The pig's heart that has been used during this test has been defrosted and frozen again multiple times. The tissue on the location of trial 7 was therefore very dry, causing the lead to get stuck in the membrane that's around the heart, instead of piercing it.

As mentioned, the feeling of what happens with the lead is gone. However, in the previous POPs that was also the case. There you felt that something was happening with the lead, but the operator also didn't know what happened with the lead near the heart.

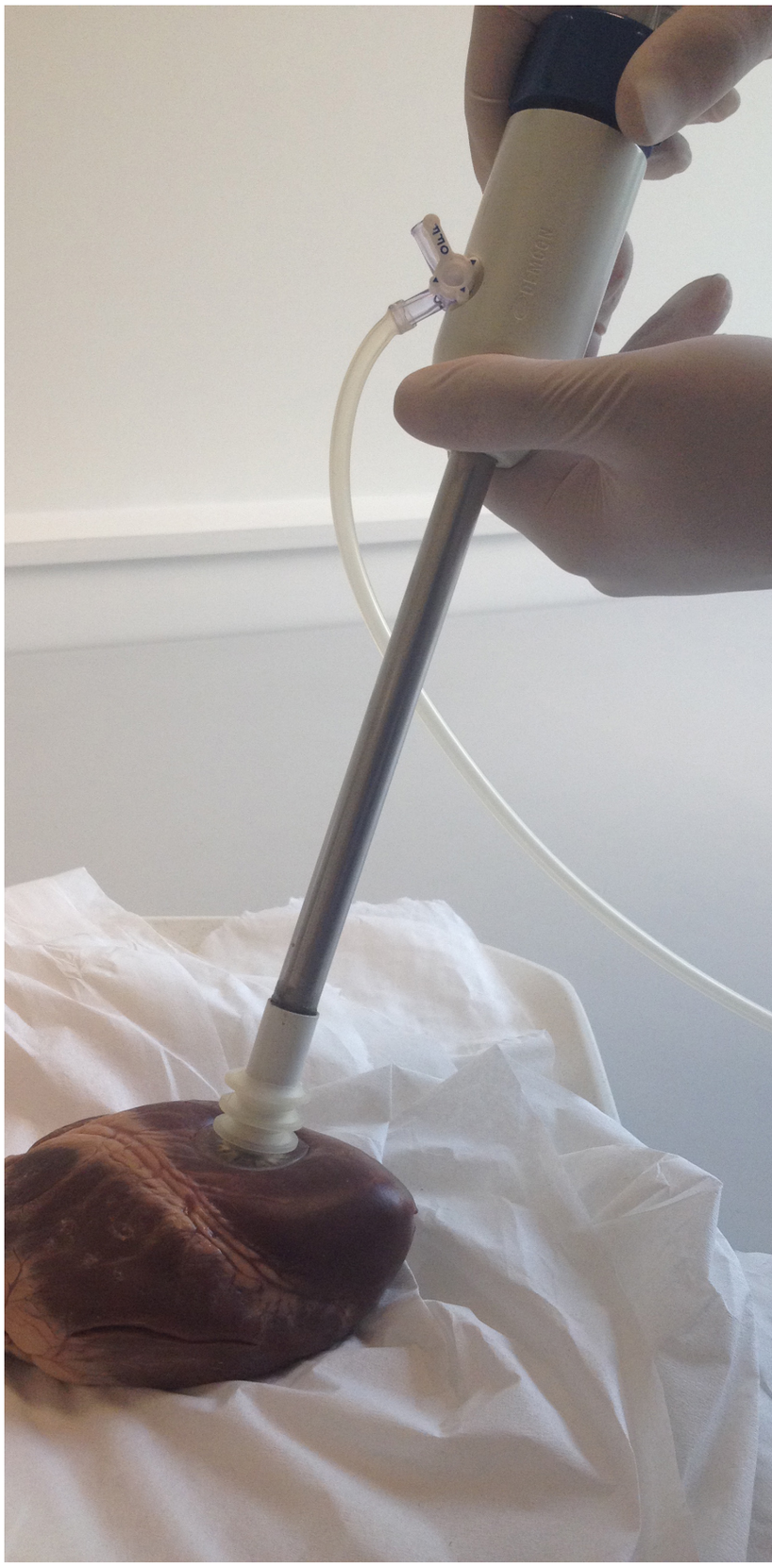
The variation in the position of where the lead is grabbed, showed that the position of the lead in the TEDD does not come super accurate. The position of the lead proved to be accurate enough when it is held in place by the rear vacuum valve. The lead was successfully screwed in the heart, even when this positioning was altered.

One point that needs to be improved is the fact that the lead gets stuck when grabbing it. The openings between the fingers are larger than the lead and therefore the lead gets stuck in-between them when it is grabbed. This has to be solved.

Another point that could be improved is the fact that the grabbing of the lead takes much rotations of the main knob. This knob has to be rotated 8 times in order to grab the lead. However, this knob is turned by hand, and when someone turns something with his hand, his hand rotates this object slightly more than half a rotation instead a full rotation since it is anatomically very hard to rotate your hand 360°. Therefore it takes about 15 rotation by hand to grab the lead.

Verification of the requirements
Some requirements of the POP are verified by experiments as stated in the chapter requirements. This experiment is conducted to verify these requirements. The result of this can be read in the next chapter, verification of requirements.

Conclusion
The conclusion of this experiment is that the designed mechanism works as expected. It is able to fully fixate the lead on a more automated way. The lead is grabbed, rotated and released as expected and proved to almost always fully fixate the helix. Further focus is needed on the clicking fingers. With the POP the lead is often snapped between two, instead of snapped in the middle of the four and therefore does not work.



CHAPTER XII: VERIFICATION OF REQUIREMENTS

Not all requirements are verified by tests. Table 7 shows all the requirements and shows whether they are met or not. An explanation is given on how a requirement is met or why it is not met.

Number	Requirement	VM	ST	Rationale
TE001	The TEDD should maintain its current functions when used intercostal.	D	✗	The bending part has not been taken in account in this assignment. Therefore the POP is also not able to bend. An analysis has been made to check the effect of the bending part, and it seems to be possible to integrate the solution with the bending part, but further research needs to be conducted in order to check this.
TE002	The TEDD has to fit through an 8mm trocar.	D	✗	This requirement is not met. Little attention was paid in the POP to the 8mm requirement. This since priority was given to check the principle of the grabbing mechanism. In the final design, the mechanism fits through an 8mm trocar. A few changes need to be made to the inner clicker part, since the grooves on its second row of clicking fingers are too small. But if that is done, the TEDD will fit through an 8mm trocar. But, in the current state, it won't.
TE003	When the lead is placed, the TEDD has to be removed without the use of the external devices.	D	✓	The testing of the POP showed that the TEDD is the only device required for the surgery with respect to the lead. The catheter and the slitter are not needed anymore to fixate the lead and to retrieve the TEDD from the patient's body
TE004	The TEDD has to be sterilizable.	D	✗	As mentioned in the demarcation, there is no attention paid to this. It is a future goal that the TEDD needs to be sterilizable.
TE005	The TEDD will be used as a disposable.	D	✓	It is designed to be a disposable. No analysis have been made on the potential costs of the TEDD and therefore it is uncertain if the TEDD will be able to be sold for the price of a disposable.
TE006	The POP will only focus on the fixation mechanism and the temporarily fixation on the heart.	A	✓	The POP that was used to test the designed mechanism did not include a bending part and a sensing part.
TE007	The TEDD will be rotated around the shaft by rotating the entire handheld.	D	✓	In the final design it is not possible to rotate the shaft separately from the rest of the device
TE008	The TEDD will use the intercostal approach.	D	✓	The TEDD is designed for the intercostal approach. The lead is the only thing that fits through the delivery tube, and it will not be used to guide a camera and or cutting tools to the heart.

Number	Requirement	VM	ST	Rationale
OP001	TEDD should enable the surgeon to press the screw against the heart	T	✓	The test showed that the lead is pressed to the heart because it is propelled with the thread in the knob. Therefore it is forced forward, pressing against the heart and piercing it easily.
OP002	TEDD should enable the surgeon to have more control and mastery of the lead when screwing it in the heart	T	✓	The test with the POP showed that this requirements is met. Since the lead is fixated into the heart by rotating the knob instead of the lead itself, there is not much feeling of what is happening with the lead. However, it does gives the surgeon more control. The rotations he makes with the knob are also made near the heart. The surgeon can therefore better control the lead and has more certainty that the lead is fixated into the heart.
OP003	The TEDD should be able to be operated with two hands.	T	✓	The test showed that the TEDD is easy to operate with two hands. One hand is used to hold the TEDD and the other to rotate the knob, activate the vacuum and release the lead from the rear vacuum valve.
OP004	The TEDD should make it easier for the surgeon to place the lead in comparison with the current POPs and the FasTac tool.	T	✓	It has become much easier to fixate the lead. With the previous POP it was hard to screw the helix into the myocardium. With the new POP it is very easy and as the results show, the lead was fully fixated almost any time. The lead is not only fixated more easily, but also better. Compared to the POP2, the lead is screwed in further into the myocardium and goes easier into the heart
PA001	The change of a successful surgery should not decrease.	T	N. A.	It is not possible to test this requirement in this phase. This will become clear from clinical studies.
PA002	The change of a successful surgery should increase	T	N. A.	It is not possible to test this requirement in this phase. This will become clear from clinical studies.
PA003	The TEDD should not increase the chance on complications for the patient.	T	N. A.	It is not possible to test this requirement in this phase. This will become clear from clinical studies.
PA004	The TEDD should decrease the chance on complications for the patient	T	N. A.	It is not possible to test this requirement in this phase. This will become clear from clinical studies.

Table 8: Requirement verification table

CHAPTER XIII: CONCLUSION AND RECOMMENDATIONS

The conclusion of this assignment is that a mechanism has been designed which makes it easier for the operator to fixate an epicardial lead to the heart. The test showed that this mechanism works and that it screws in the helix completely. The TEDD is easier to operate compared to the POP2 and can be operated by one person better than the POP2. It also pushes the screw to the heart and automates when how many times the lead is rotated into the heart and when the lead is released from the device. Beside the TEDD, no other devices, like a cathether and slitter, are necessary with respect to the lead. It makes it therefore easier for the surgeon to fixate the lead on the heart and increases the change for a successful surgery and decreases the chance on complications.

However, some things need more attention. First of all does de grabbing of the lead need attention. The lead does now get stuck between two fingers and does not get grabbed as intended. A possible solution is to let the TEDD be packaged when it is already winded back 5 rotations. The diameter is already decreased a little after 5 rotation, but the lead is not clamped. This solutions also causes that surgeon does not have to rotate the knob that much anymore. There are just 3 rotations of the knob necessary instead of 8.

The bending part is another part which requires further research. The bending part has not been taken into account in the POP since this would increase the complexity of the POP too much for the time available. In this assignment an analysis was made of the effect of the bending part on the location of the lead and the increase o reduction in the number of winds. From this analysis it seemed as if it the mechanism would still work when the delivery tube was bended 90 degrees. There are several possible solution, known within Demcon, and mentioned in the chapter concept, partial solutions, which could be used for the bending part

The temporarily fixating with the vacuum also requires further research. It has to be checked if the suction is still enough to fixate on a beating heart, this since the test of the POP was perfomed on a pig's heart that did not beat anymore.

The last thing that needs attention is the diameter of the POP. Since the parts of the grabbing mechanism were 3D printed it was chosen to give the POP a diameter of 12mm. That was since the 12mm version looked way more sturdy than the 8mm version. The 8mm version did also work, but needed some changes. The grooves on the second row of click fingers were also too little to hold the outer click ring on its place. The grooves on these finger can be increased. Also it had a very thin wall and it looked as if it would break very quick. However, at the end of this assignment, a meeting with the surgeons of the UMCG was held. There the requirements of the future product were discussed again and the surgeons said that the aim was to let the TEDD fit through a 10mm trocar. This gives the TEDD a 25% larger radius and therefore the inner clicker can be made thicker, and the grooves in it deeper. It can also be checked what happens when the second row of click fingers are removed. This would decrease the complexity of the part. This since during the test of the POP, it seemed as if the second click fingers didn't do much. It felt as if the outer clicker stayed on its position relative to the inner clickers since the friction between the inner clicker and the outer clicker ring was larger than the friction between the outer clicker ring and the front exterior tube. This also causes the grabbing mechanism to be shorter, which is important since there is not much space inside a patient's body near its heart during VATS.

Concluding, a mechanism has been developed which has proven to be able to deliver an epicardial lead through a straight tube more controlled. The next thing for Demcon is to integrate the bending part and to reduce the diameter to fit through a 8mm trocar.

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