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

Daan Hendrik Ekkelenkamp

DEMCON

UNIVERSITEIT TWENTE.

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

Author
Daan Hendrik Ekkelenkamp
S1462393
Industrieel Ontwerpen
7 juli 2016

Employer
Demcon
Institutenweg 25
7521 PH Enschede

Examination board
Dr. Ir. D. Lutters
Ir. E. E. G. Hekman
Ir. M. Ruijter

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. [classified]Van dit ontwerp is een POP gemaakt waarbij de werking is getest. Het testen van de POP leverde veelbelovende resultaten op en heeft laten zien dat [classified]. Verdere ontwikkeling van Demcon is nodig om [classified]

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 [classi-fied]This design has been realized into a POP and its functioning is tested. [classified]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 [classified] 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

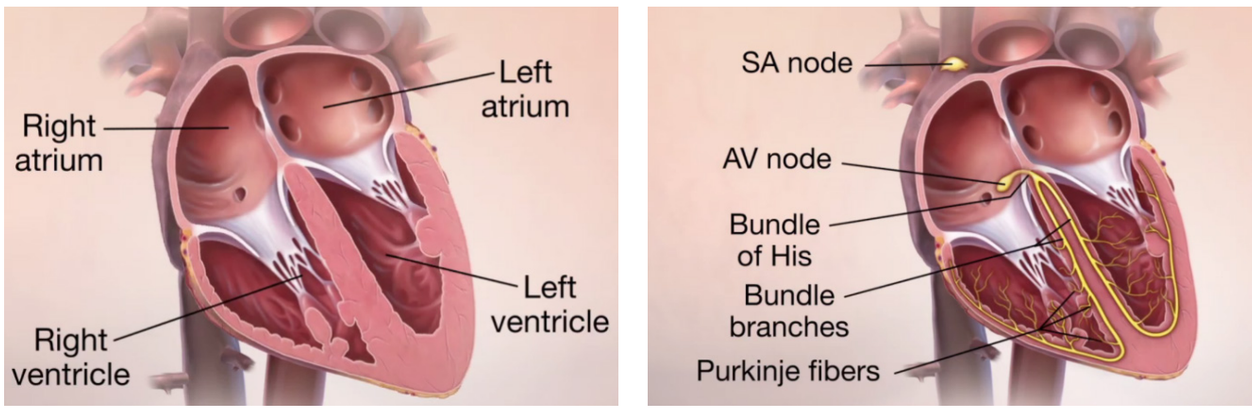
If one of the atria or ventricles is not pumping as it should, the blood flow and the heart rate are affected. A pacemaker is used to solve this malfunctioning of the heart. There are different kinds of pacemakers. Some pacemakers stimulate the atria and others the ventricles. Which pacemaker is implanted 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)*

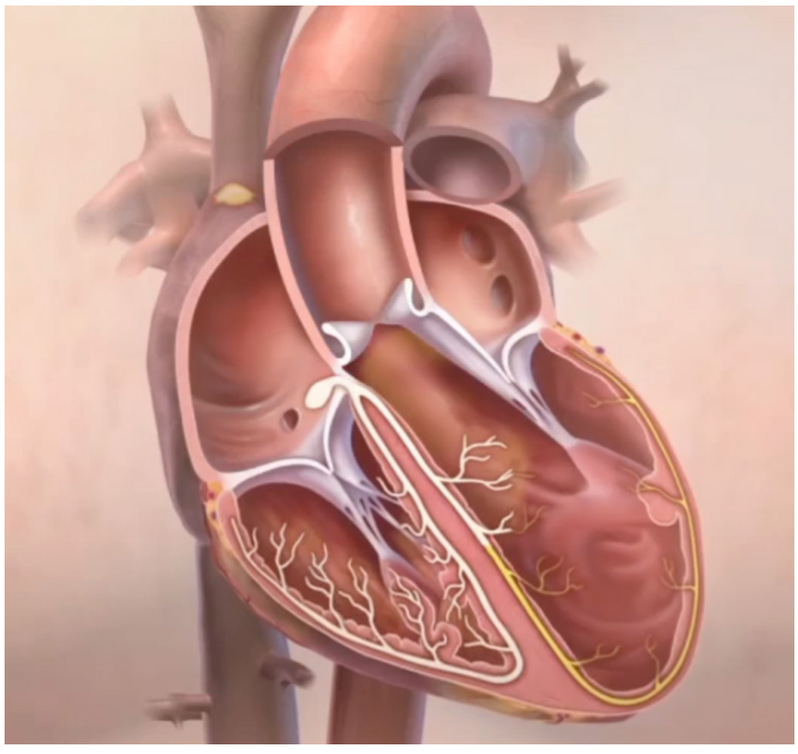
beating like it should, can be an unstructured beating in the atrium. Due to many small electrical pulses in the atrium, the signals in the atrium are going crazy. As indicated in AAI pacing, the signal in the atrium causes the ventricle to beat. But since the signals in the atrium are small and going 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.

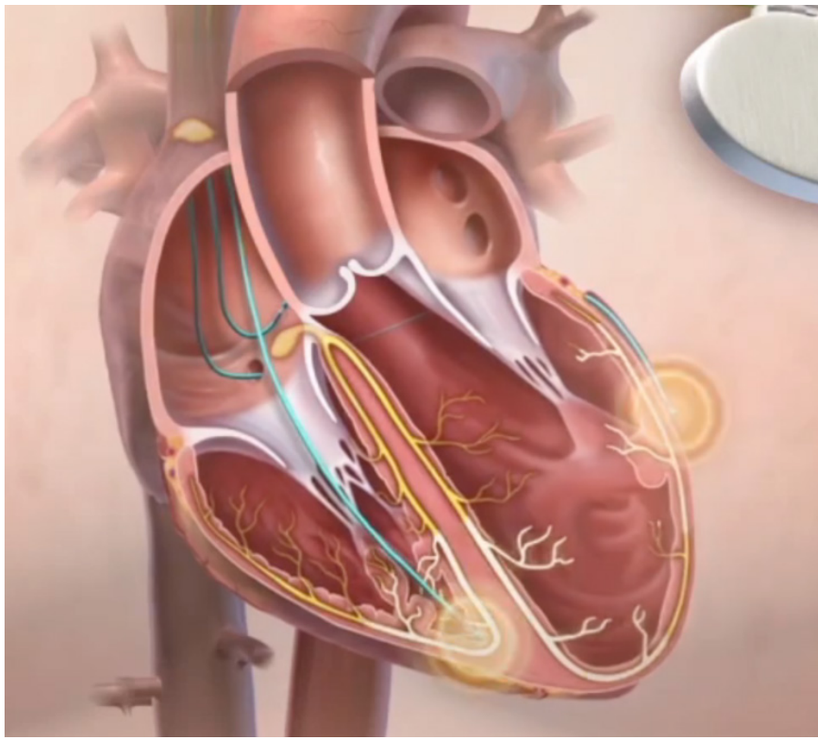
DDD Pacing (Dual-chamber paced, Dual -chamber sensed, triggered and inhibited by ventricular and atrial events (Dual))

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.

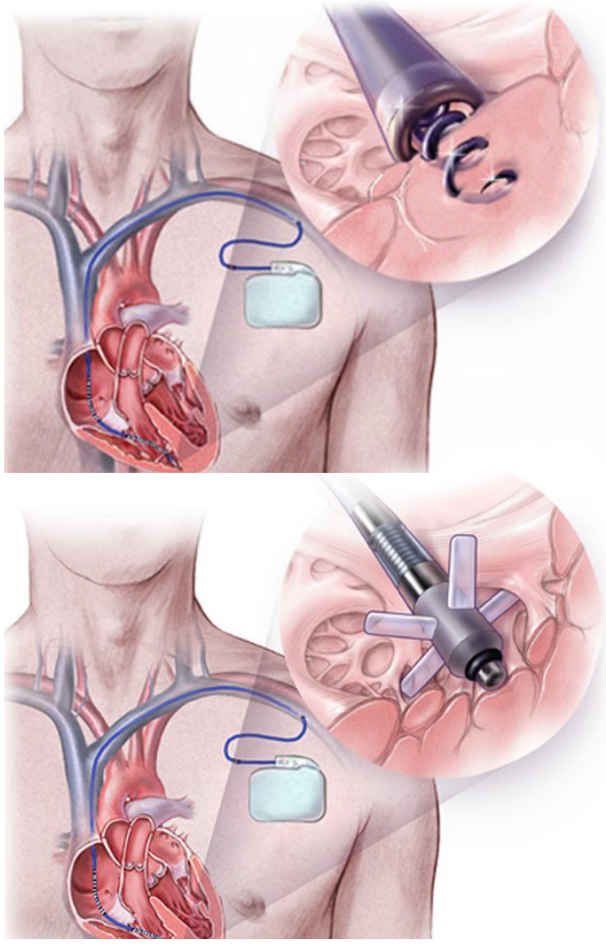




Figures 3&4: Bundle block without (upper image) and with CRT pacemaker (lower image)*(Medmovie)*

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)

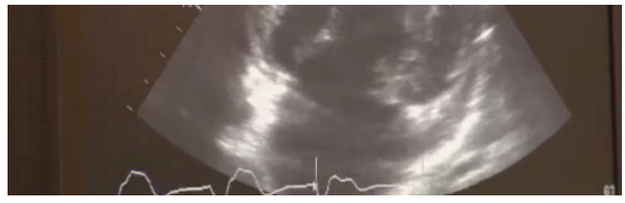


Figure 7: Speckle tracking

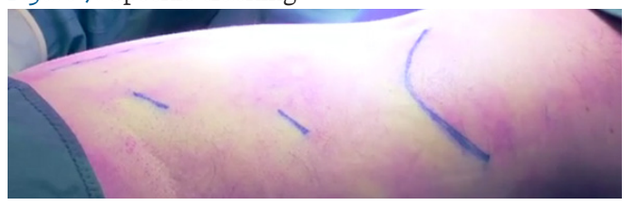


Figure 8: Drawing the incisions

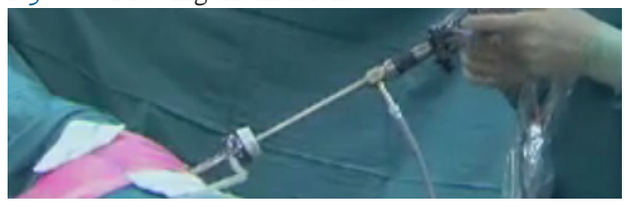


Figure 9: Putting in the throcar

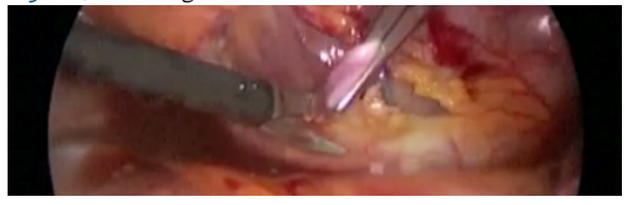


Figure 10: Cutting the pericardium

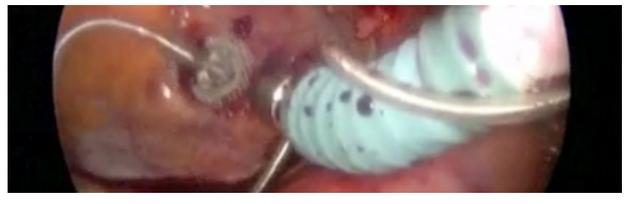


Figure 11: Fixating the lead

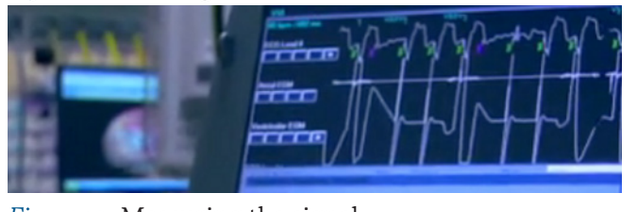


Figure 12: Measuring the signal

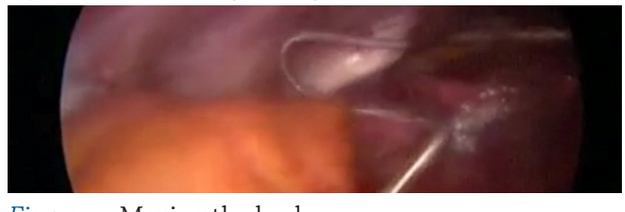


Figure 13: Moving the lead

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.

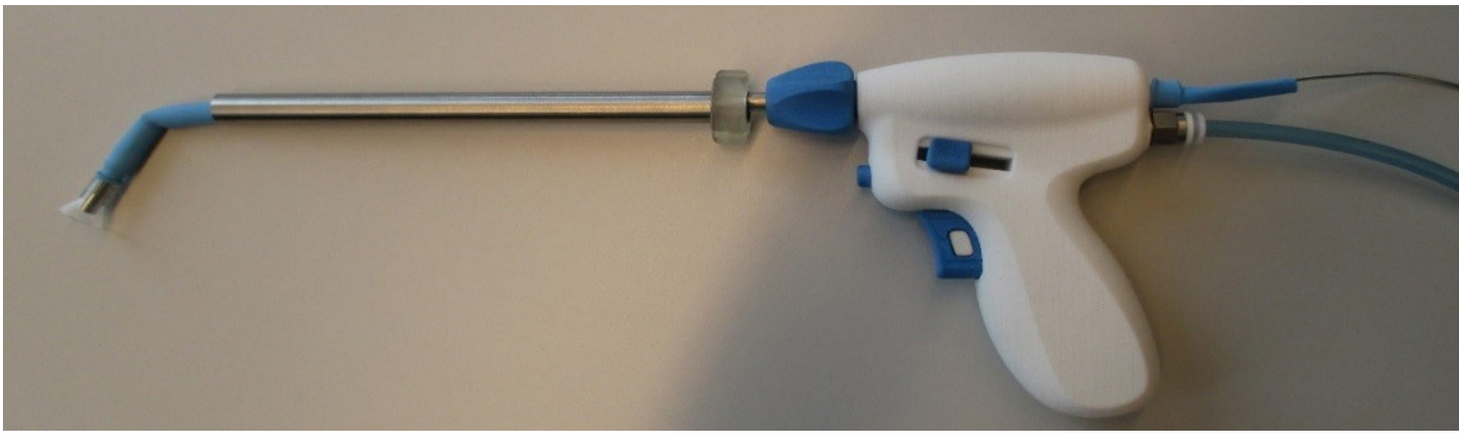


Figure 16: First POP

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

[classified]

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.

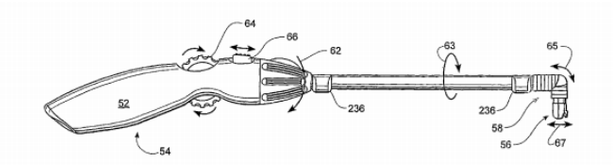


Figure 18: Image of the FasTac tool patent *(Espacenet)*

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.

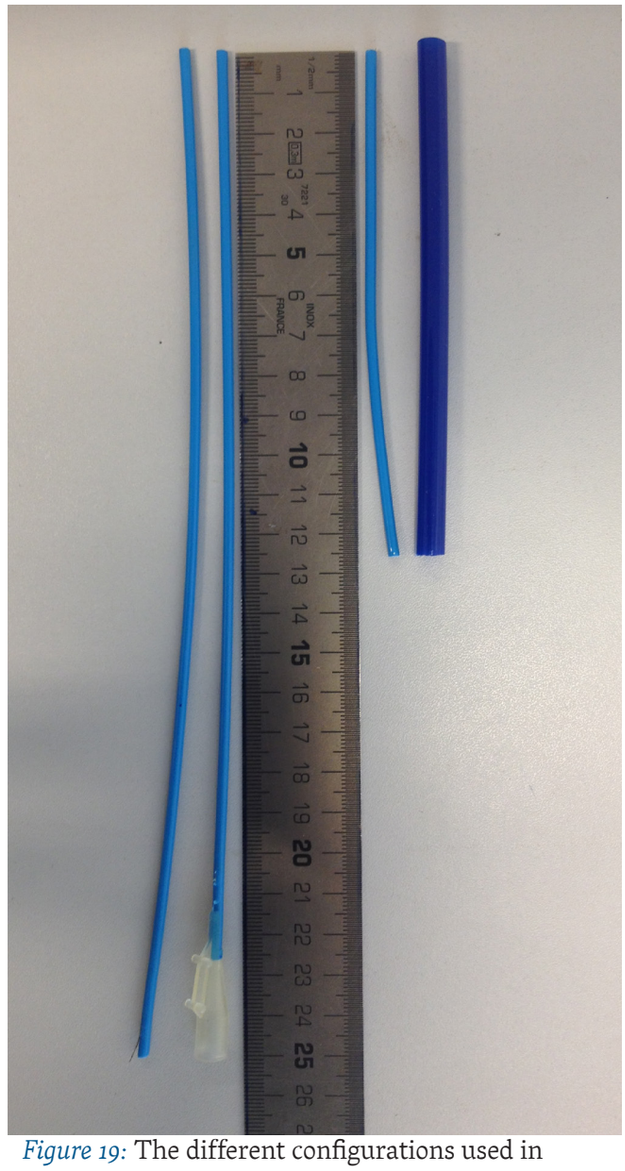


Figure 19: The different configurations used in experiment 1

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.

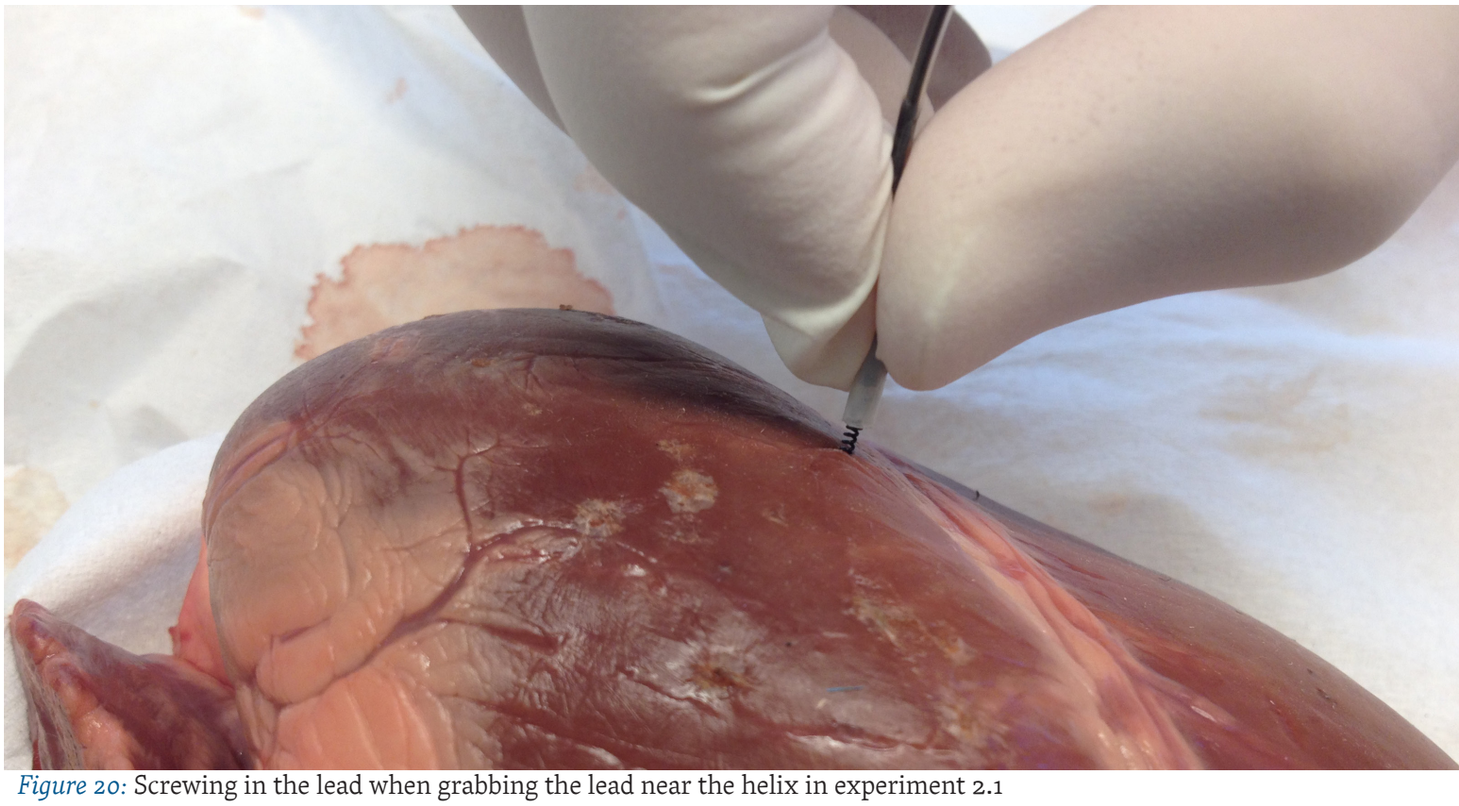


Figure 20: Screwing in the lead when grabbing the lead near the helix in experiment 2.1

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.

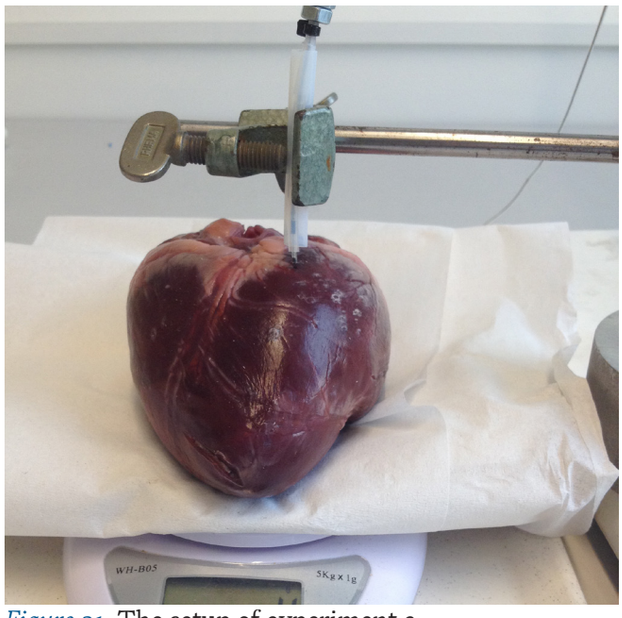


Figure 21: The setup of experiment 3

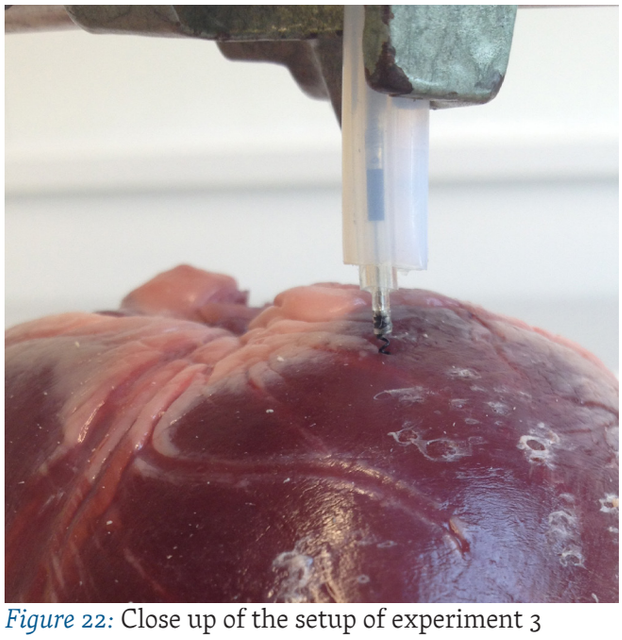


Figure 22: Close up of the setup of experiment 3

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
{classified]

Partial solutions
[classified

CHAPTER IX:
THE CONCEPT

The first concept is the result of combining several partial solutions. Its mechanism is based on two principles. [classified]

CHAPTER X:
THE POP MODEL

POP assembly and testing

[classified]

Figure 39: Image of lead under the microscope

Figure 40: Render of the entire POP model

CHAPTER XI:
TESTING OF THE POP

[Classified]

CHAPTER XII:
VERIFICATION OF REQUIREMENTS

[classified

CHAPTER XIII: CONCLUSION AND RECOMMENDATIONS

[classified]

CHAPTER IVX: REFERENCES

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