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Design of Catheters for Navigation and Positioning in the Cardiovascular system

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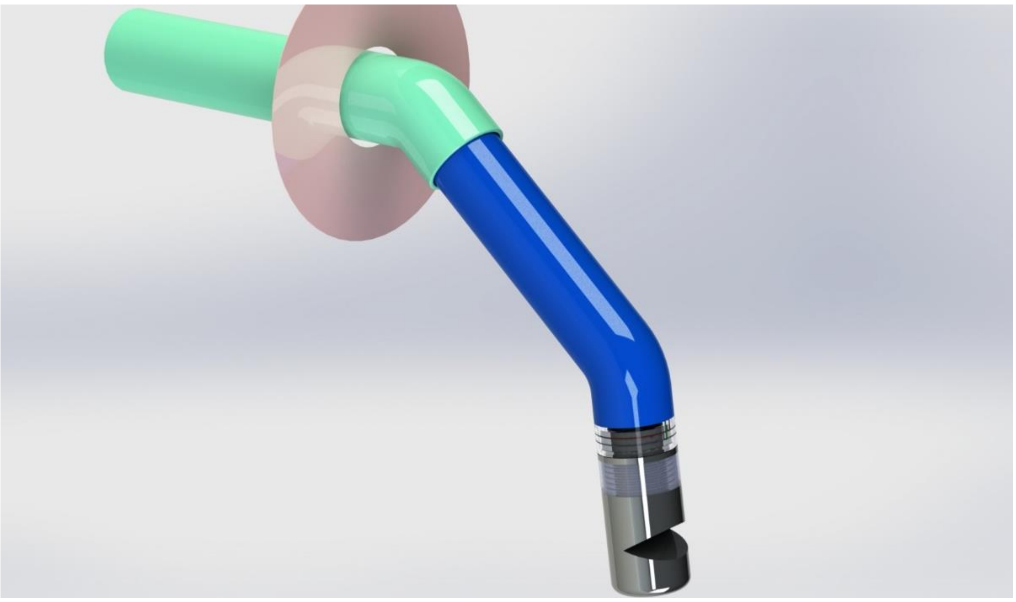

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PREFACE

This Master thesis has been conducted as a cooperation between Norwegian University of Life Sciences (NMBU), dept. of Mathematical Science and Technology, and Oslo University Hospital, The Intervention Centre. The purpose of the collaboration has been to develop a proof of concept for the procedure described, so that The Intervention Centre can further develop the required parts.

Although catheters-based surgery is a field far from what we are used to work with, this master thesis has indisputably been extremely interesting and exciting to work on. It has opened up for a more widely mindset and it has forced us to think along new lines. It has been especially stimulating to see that conventional mechanical principles can be implemented into medical technology.

We would like to thank everyone who has contributed to this project. Dr. Nils Bjugstad and Dr. Jan Kåre Bøe at NMBU for providing us with guidelines and supervision throughout the project and to Carlos Salam Bringas for helping us with 3D design drawings. We would also like to sincerely thank the staff at the Intervention Centre for assisting us throughout the development process and for enabling us to observe live interventions in person. A special thanks goes to Dr. Jacob Bergsland and Dr. Ole Jacob Elle for their enthusiasm, knowledge and guidance throughout the entire project, and for their belief in our ideas and solutions.

Ås, May 15th 2015

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ABSTRACT

Minimally invasive procedure is a term for catheter-based surgical procedures where surgical instruments are introduced through a minimal size incision in the skin, to reach internal organs. The surgical instruments are placed at the distal end of the catheter, the catheter tip, and a handle located on the outside of the patient controls the catheter. Limited steerability of the catheter can lead to complications and make it challenging to reach the required positions.

The main objective for this master thesis has been to identify and examine the possibilities for a precise positioning of catheters in the cardiovascular system, where the distal end of the catheter can be placed in a exact position. Furthermore, the aim was to develop proposals for a proof of concept where the treatment device can be positioned as exactly as possible by available imaging methods, where they are compatible to each other. The maneuvering area was limited to the left ventricle, where the catheter should be able to perform mitral valve repair. Ideally, it should be able to reach all points on the inside of the heart. With these properties, the can be adopted to other procedures, such as ablation.

Level of experience with cardiologists who perform the minimally invasive procedures plays an extremely important role in catheter-based surgery. As a metaphor, one can say that it is physically possible to walk on a line over Niagara Falls without a safety net, there exist people who master such a challenge. However, is it safe to recommend this to everyone? The same can be said for catheter-based mitral valve interventions. These are extremely demanding applications, where it is required extensive experience to perform procedures with low risks. The challenge mainly lies in the design of the steering mechanism for the catheter, where a more accurate steerability would make cardiologists with less experience adopt significantly faster to the procedure.

The master thesis can be divided into two parts; one research and one concept development part. In the research phase, the current methods for catheter steerability were investigated and an external test was performed to identify the needs for an improved steerability. The development phase has been conducted using Osborne's method, where the catheter was split into the required features and considered individually. Pugh’s method was conducted to evaluate and rate the various ideas, and the concepts were further shaped and tested by 3D drawings in SolidWorks.

The project is the first phase of a concept development project for designing a catheter with improved steerability. Therefore, a final selection of materials or metric measurements is not completed. The aim of the development work has been to move the steering mechanism from the catheter handle to the distal end of the catheter. It was assessed that this relocation could lead to a more precise positioning because of the

reduction of drag forces along the catheter path from the handle and to the distal end. Production methods are partially studied and described, but a complete explanation has not been made.

The final result of the project is an S-shaped movement in multiple planes, where the guiding catheter conducts the first bend using conventional techniques. The steerable catheter makes the second bend by pushing and pulling two wires individually or simultaneously, forcing the catheter to deflect. This will also make it possible to achieve omnidirectional deflection. Local rotation in the distal end of the catheter is made possible by a rotation mechanism, a reel, which controls the rotation with two strands that are being pulled. The reel makes it possible to obtain precise rotations at the distal end independently from the rest of the catheter. In addition, a coil made of a shape memory alloy provides the catheter tip with an elongating movement, where the coil elongates when voltage is applied. A docking station is connected to the coil spring, where the operation device is attached. The total system provides the catheter with the possibility to make an S-shaped movement through all three planes.

SAMMENDRAG

Minimal invasive prosedyrer er en betegnelse på kateter-baserte, kirurgiske inngrep hvor operasjonsinstrumenter sendes gjennom et minimalt stort snitt i huden, for å nå indre organer. De kirurgiske instrumentene er plassert i den distale enden av kateteret, katetertuppen, og kateteret styres fra et håndtak på utsiden av pasienten for å nå de ønskede og nødvendige posisjonene for å kunne utføre operasjonen. Begrenset styrbarheten hos kateteret kan imidlertid føre til komplikasjoner og gjøre det utfordrende å nå de nødvendige posisjonene.

Hovedmålet for denne masteroppgaven har vært å identifisere og undersøke mulighetene for en nøyaktig posisjonering av katetere i det kardiovaskulære systemet, hvor den distale enden av kateteret kan plasseres i en eksakt posisjon. Videre er formålet å utvikle forslag til et konsept hvor behandlingenheten kan plasseres så nøyaktig som mulig ved hjelp av tilgjengelige avbildningsmetoder, hvor de er kompatible med hverandre. Manøvreringsområdet har vært begrenset til den venstre ventrikkel, hvor kateteret skulle være i stand til å utføre mitralklaffreparasjon. Ideelt sett bør det være i stand til å nå alle punkter på innsiden av hjertet for å kunne brukes i andre prosedyrer, som for eksempel ablasjon.

Grad av erfaring hos kardiologene som utfører de minimal invasive inngrepene spiller en ekstremt stor rolle i kateter-basert kirurgi. Som en metafor kan man si at det er mulig å gå på line over Niagara falls uten sikkerhetsnett. Det eksisterer mennesker som behersker en slik utfordring, men er det å anbefale for alle? Noe av det samme kan sies om kateter-basert mitralklaffreparasjon. Dette er ekstremt krevende operasjoner, hvor det forutsettes lang erfaring for å kunne utføre inngrepene med lav risiko. Mye av utfordringen ved designet av styrbare kateteret ligger dermed i å gjøre styrbarheten lettere for kardiologer som ikke nødvendigvis har lang erfaring.

Masteroppgaven kan deles inn i to deler; en forsknings- og en konseptutvikling del. I forskningsfasen, ble de nåværende metodene for kateterets styrbarheten undersøkt og en ekstern undersøkelse ble utført for å identifisere behovet for en forbedret styrbarhet. Utviklingsarbeidet har forgått ved bruk av Osbornes metode, hvor kateteret ble splittet ned i nødvendige funksjoner og sett på individuelt. Pughs metode er brukt for å vurdere de ulike idéene, og videre ble konseptene formet og testet ved 3D-tegning i SolidWorks.

Selve prosjektet har omhandlet første fase av et rent konseptutviklingsprosjekt. Det er derfor ikke foretatt endelige valg av materialer eller metriske mål. Målet for utviklingsarbeidet har vært å flytte selve styringsmekanismen fra håndtaket av kateteret til den distale enden av kateteret. Det ble vurdert at dette kunne medføre en mer presis posisjonering fordi det fjerner de motvirkende kreftene langs katetrets bane fra håndtaket og frem til bevegelsen i den distale enden. Produksjonsmetoder er delvis studert og beskrevet, men en fullstendig redegjørelse er ikke blitt foretatt.

Det endelige resultatet av prosjektet gir kateteret muligheten til å oppnå en S-formet bevegelse, hvor guiding-kateteret gjennomfører den første defleksjonen ved hjelp av konvensjonelle prosedyrer. Den andre defleksjonen utføres av det styrbare kateter, hvor to wire som blir trukket i vekselvis eller samtidig, tvinger kateteret til å deflektere og gjør det mulig å oppnå omnidireksjonal defleksjon. Lokal rotasjon i den distale enden av kateteret er mulig ved hjelp av en rotasjonsmekanisme, formet som en snelle, som styrer rotasjonen ved hjelp av to tråder som blir trukket i vekselvis. Denne lokale rotasjon gjør det dermed mulig for kateteret å rotere operasjonsinstrumentet som er forankret på katetertuppen uten å påvirke den proksimale delen. I tillegg er en springfjær av «shape-memory» materiale festet på kateterspissen, hvor fjæren forlenges når strøm tilføres. Det totale konseptet, som utgjør resultatet av denne masteroppgaver, gir kateteret mulighet til å utføre en S-formet bevegelse i tre plan.

LIST OF ABBREVIATIONS

Table 1: List of abbreviations.

CPB	Cardiopulmonary Bypass
CDS	Clip Delivery System
DOF	Degrees of Freedom
GA	General Anesthesia
FEP	Fluorinated Ethylene Propylene
IPD	Integrated Product Development
MR	Mitral Regurgitation
MIS	Minimally Invasive Surgery
SUD	Single Use Devices
TAVI	Trans Aortic Valve Implementation
PEEK	Polyether Ether Ketone
PEI	Polyetherimide

TABLE OF CONTENTS

Page no.:

1 INTRODUCTION

This first chapter is an introduction to the field of cardiovascular surgery, which mean operations on the heart and great vessels. The introduction includes the procedure of traditionally open-heart surgery versus minimally invasive procedures in the heart, as well as a presentation of the heart anatomy.

1.1 Background

The background for this master thesis is a surgical intervention that is for repair of mitral valve disorder in the heart. The procedure is conducted by a long, thin catheter, which is introduced into the femoral artery in the groin, and follows the blood vessels into the heart. From a handle near the patient's groin, the cardiologist can operate the distal end of the catheter using a device connected to the distal end of the catheter.

The procedure is conducted on patients diagnosed with mitral regurgitation (MR), a disorder in the heart where the mitral valve does not close properly [1]. This causes blood to flow backwards to the upper heart chamber and the amount of blood provided to the rest of the body is decreased. The disorder this causes is preferably repaired via open-heart surgery. The interventional procedure is, however, chosen for patients who are considered either high-risk or too sick for open-heart surgery, and therefore they will not withstand the strain.

Figure 1 shows the transfemoral catheter intervention, where the catheter is inserted into an incision in the leg through the femoral artery and follows the blood vessels until the catheter enters the heart.

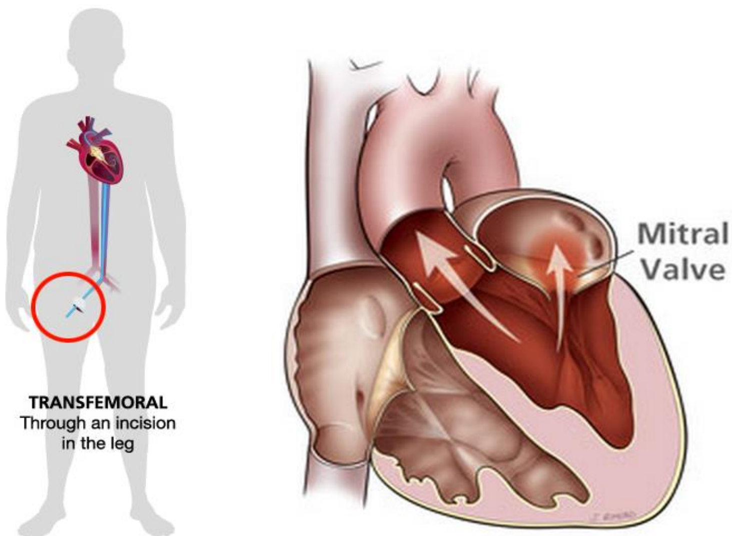

Figure 1: a) Transfemoral catheter intervention [52], b) In mitral regurgitation, mitral valve leaflets do not meet, allowing back flow of blood into the left atrium [1].

1.2 Anatomy of the Cardiovascular System

The Cardiovascular system contains the heart and the circulatory system. This includes arteries, veins and capillaries that transport blood throughout the body. The heart consists of four chambers, two atriums and two ventricles, where the blood flows into the atriums, through the ventricles and out of the arteries. The heart is positioned in the middle of the chest with apex, the inferior tip of the heart, pointing towards the left side. This causes the heart mass to be 2/3 on the left side of the body. [2].

At resting heart rate, the heart muscle normally contracts 60 to 80 times a minutes to supply oxygen and nutrients to the tissues. The blood circulates in two pathways: the pulmonary circulation (through the lungs) and the systemic circulation (throughout the body). In the pulmonary circulation, deoxygenated blood flows out of the Pulmonary artery to the lungs and returns oxygenated through the Pulmonary veins. In the systemic circulation oxygenated blood flows via the left ventricle and through Aorta before it enters the arteries and capillaries. Deoxygenated blood returns from the body via the veins to the Superior and the Inferior vena cava [3]. *Figure 2* shows directions of the blood flow in and out of the heart, where the blue color is deoxygenated blood and red is oxygenated blood.

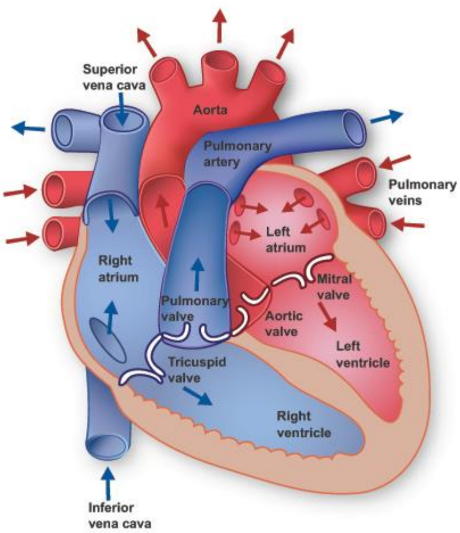

Figure 2: Illustration of the heart anatomy with directions of the blood flow [34].

1.3 Traditionally Cardiac Surgery

Conventional cardiac surgery generally entails exposure of the heart and great vessels through a median sternotomy, a surgical procedure in which a vertical inline incision is made along the sternum (breastbone), see the illustration below [4]. This is traditionally done as an open-heart procedure where the chest is cut open to perform surgery on the internal structure of the heart. Once the heart is exposed, the patient is connected to a heart-lung bypass machine, a cardiopulmonary bypass (CPB). This machine leads the blood past the heart and enables surgeons to operate on the heart under a bloodless and motionless condition. While the heart is stopped, the CPB replaces the heart's pumping function and provides the rest of the body with oxygenated blood.

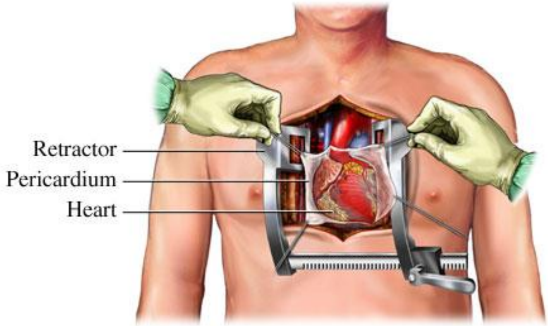

Figure 3: Illustration of the open-heart procedure where a vertical incision is made along the sternum (breastbone) [46].

There is a various number of risks associated with traditionally open-heart surgery. Infection, stroke and in worst-cases death, are some of the outcomes of a cut open chest. The patients in need of heart procedures are often old and weak, and the surgery can therefore represent a major trauma for their body and health. [5]

The open-heart surgery requires general anesthesia (GA), a medical procedure where the patient is rendered unconscious. Not all patients can handle the strain that GA implies, and this requires for alternative methods. Some of the procedures are therefore done minimally invasive, as described in the next chapter.

1.4 Minimally Invasive Cardiac Surgery

Minimally invasive cardiac surgery enables surgeons to perform heart operations through substantially smaller incisions and can also circumvent the need for CPB [4]. The procedure can be conducted when the patient is set under conscious sedation, a combination of medicines that helps the patient to relax and to block pain. The catheter, a long, thin tube, is passed through one of the incisions, and with help from different imaging technologies the surgeons can get a view of the surgical area. The purpose of this method is to reduce the postoperative recovery period and pain, and to provide a better cosmetically result. According to Balaguer et al. minimally invasive approaches have revolutionized the cardiac surgery among every other surgical subspecialty. Today, many of the most technically challenging open procedures can be performed minimally invasively and provide superior results [4].

Cardiac surgery procedures have traditionally been considered to possess a significant complexity and invasiveness, and they were therefore the last of the surgical specialties to embrace the principles of minimal invasiveness. Today, a number of cardiac procedures are being performed minimally invasive. [6]

The catheter

The catheter is a hollow, thin tube that can be inserted into the body cavities. The catheter can thereby allow surgical instruments to access the body, or they can be used to transport fluids in and out of the body. The process of inserting a catheter into the body is called catheterization.

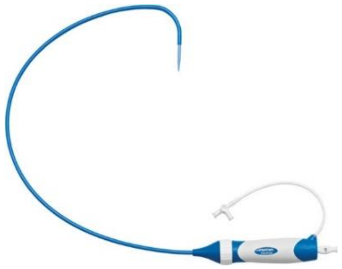

Figure 4: The picture shows a steerable catheter, where the handle in the proximal end of the catheter controls the movements of the distal end.

Catheters can be made of a range of different polymers, including silicon, rubber, latex or thermoplastic elastomers. Silicon is a common choice because it is biocompatible and does not react to the body fluids or other medical fluids which it might come in contact with. The catheter tip needs to be made of a soft material to avoid conflicting harm or injury inside the blood vessels. In medicine, the diameter of the catheter is measured by using a Catheter Scale, called French. 1 French equals 1/3 of a millimeter. Adult diagnostic catheters have a common size between 5 and 7 mm, which corresponds to 15-21 Fr.

The Procedure

In the minimally invasive procedures considered in this report, the catheter is being introduces through the femoral artery in the groin, a procedure called transfemoral intervention. The catheter is then manually pushed upwards through the blood vessels before it enters the heart, see the figure below. When the distal end of the catheter has entered the required location within the heart, the surgeon can transport operation devices through the hollow catheter. The surgery is then being conducted by steering the device(s) from an outer handle at the proximal end of the catheter.

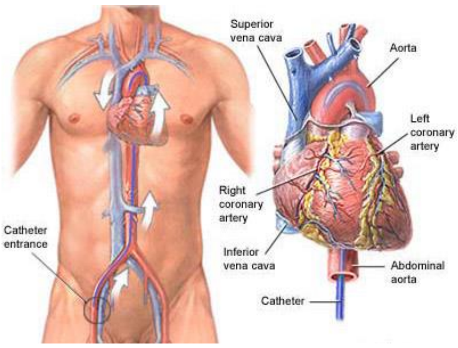

Figure 5: The catheter enters through the femoral artery in the groin and follows the blood vessels to the heart. [7]

The figure above illustrates how the catheter is inserted into the blood vessels through the femoral artery, guided through blood vessels in the cardiovascular system and into the heart through aorta. However, for mitral repair procedures, the catheter reaches the heart through inferior vena cava and penetrates the atrieseptum, the wall between left and right atrium, before it enters the left atrium.

The figures below illustrate how the guide catheter is inserted through inferior vena cava and penetrating atrieseptum. The steerable catheter is inserted through the guide catheter into left atrium and is positioned to grip the mitral valve.

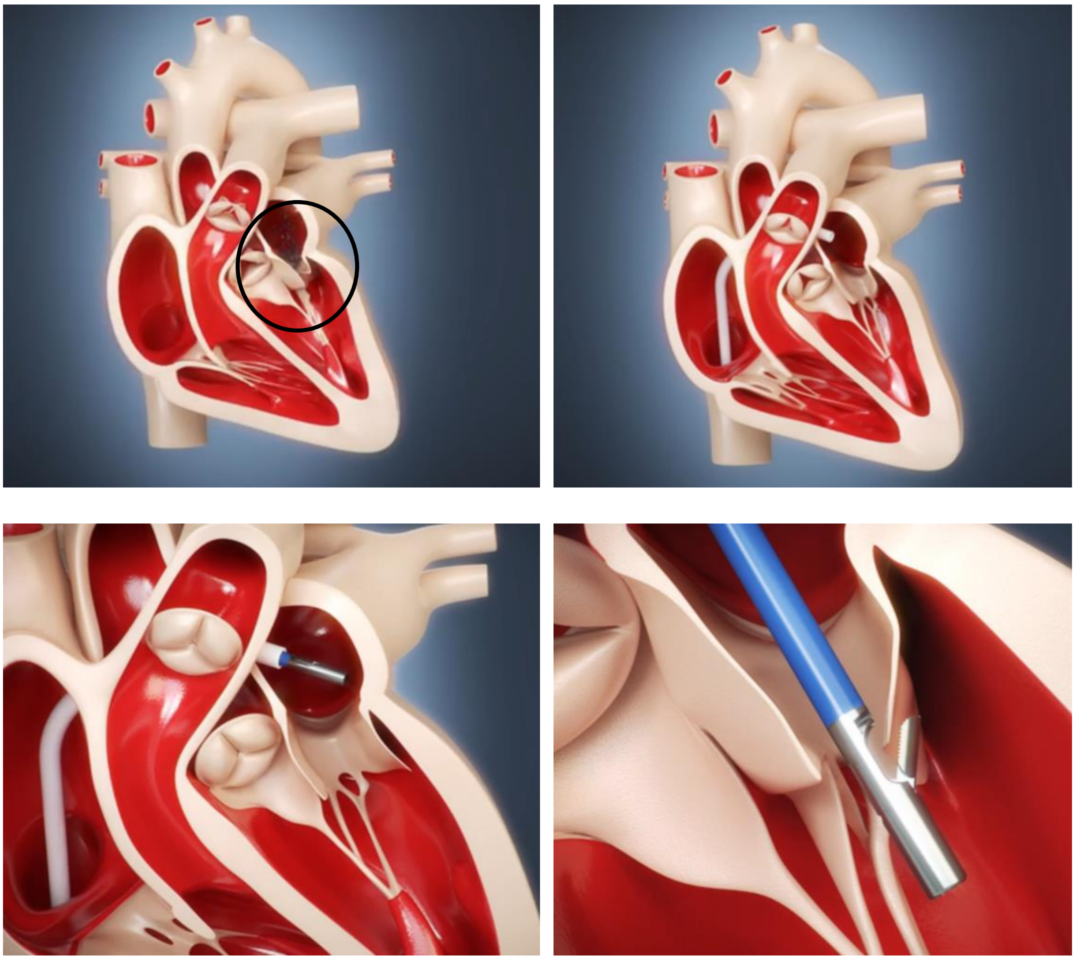

Figure 6: The figure shows a) a heart with a defect mitral valve, b) a guide catheter is placed with standard techniques, c) the steerable catheter is introduces through the guide catheter and into the left atrium, d) the steerable catheter is position to grip one of the leaflets on the mitral valve [51].

1.5 Current methods for navigation of catheters

This chapter describes different methods for how catheters are currently being maneuvered inside of the body during minimally invasive surgery. Today, there exist a wide range of different ways for navigating snake-shaped devices and the development in this area is continuously increasing. However, the following chapter will only involve some of the methods that are currently being used in minimally invasive heart surgery.

Principles of movement in the distal end of the catheter

Three basic movements are currently used to maneuver the distal end of the catheter; the deflection, rotation and elongation. These are essential when considering the steerability of the distal end of the catheter. These principles are referred to as conventional steerability in this thesis.

1. **Deflection of the catheter**

The principle refers to a bending movement of the distal end of the catheter, independent from the rest of the catheter.

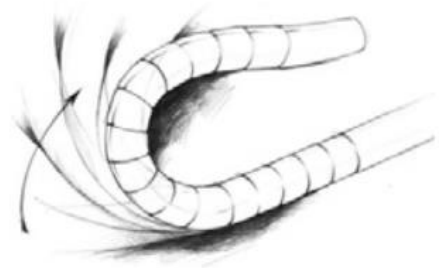

Figure 7: Deflection of the distal end. [8].

2. **Rotation of the catheter**

The principle refers to the ability to turn the distal end of the catheter with a like-for-like movement from the proximal section of the catheter.

Figure 8: Rotation of the distal end [8].

3. **Elongation of the catheter**

The principle refers to the ability to move the distal end of the catheter in longitudinal direction. This is done by a like-for-like longitudinal movement between the proximal end and the distal of the catheter.

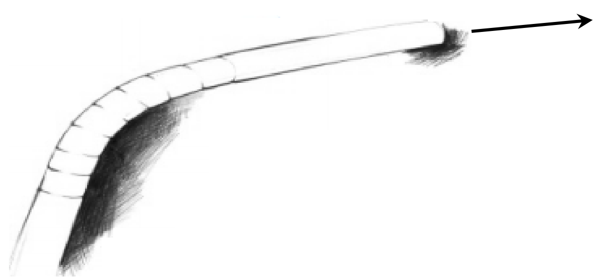

Figure 9: Elongation of the distal end [8].

1.5.1 Pulley Catheters – Maneuvering with strands and pulleys

Strands combined with pulleys is the most common principle behind a deflectable catheter, hereafter referred to as *pulley catheters*. Strands are anchored near the distal end of the catheter, through lumens (longitudinal hollowed paths) in the catheter wall. By pulling a strand, the catheter tip deflects as a result of the shortened strand. This enables the catheter to deflect in a number of different directions depending on the number of strands in the catheter.

The handle at the proximal end of the pulley catheter comes in several different versions. Some handles are operated with a rotational device, where the surgeon twists the handle and the torque is then translated into a pull force and transported to the pulleys at the catheter tip. Other versions use a knob, which are shoved back or forth and respectively deflect or straighten the catheter tip, see figure 3 for an illustration of the knob.

Figure 10: a) Deflection using a knob [57] b) Deflection using a rotational device [58]

The catheter handle can either be connected to a docking station or being replaced with a robotic arm. The purpose in both cases is to increase the accuracy of steering and stability, either by changing the exchange ratio for manually steering, or by connecting it to a computer system. A computer system can perform very accurate motions by being remotely controlled and protect personnel from radiation.

Figure 11: a) Magellan robotic system by Hansen [9], b) the surgeon remotely controls the catheter [10].

Products using Pulley Catheters

MitraClip and BioCardia are two examples of pulley catheters. An introduction to the two of them is given below. Both equipment are used for percutaneous mitral valve repair for patients suffering from the symptoms of mitral regurgitation.

1.5.1.1 MitraClip

The MitraClip device repairs mitral regurgitation, by opposing the posterior and the anterior leaflets using one or more clip. The percutaneous mitral repair system is based on a technique where a clip, rather than a suture is used to repair the mitral leaflets [11]. This prevents the reverse blood flow up in the left heart chamber, which is caused by the mitral valve disorder, and reduces the level of mitral regurgitation [14].

The MitraClip system consists of a steerable guide catheter and a clip delivery system (CDS). The figure below shows the detachable clip at the distal end and the delivery system and steering device at the proximal end of the MitraClip system. The clip is a mechanical device with two arms that can open and close, with a span of approximately 2 cm, by control mechanisms on the CDS.

Figure 12: a) The Mitraclip system with steerable guide catheter and the CDS [13] b) the detachable clip [14].

The guide catheter is introduces over a guide wire. The tip of the guide catheter is delivered to the left atrium using a transseptal approach over a guide wire and a tapered dilator. The MitraClip repair procedure consists of four main steps. Step (1) transseptal puncture and steerable guide catheter insertion; this is where the dilator on the tip of the catheter is used to gradually advance the guide into the left atrium, through the atrieseptum that separates left and right atrium. In the left atrium, the dilator and the guide wire is removed leaving the guide catheter, which can provide the operation tools. Step (2) steering and positioning of the guide catheter and CDS; the guide catheter has entered the left atrium and a steering knob at the proximal end allows for flexion and movement of the distal tip. The steerable catheter with the MitraClip system is introduces through the guide catheter. Step (3) leaflet grasping, leaflet insertion assessment, and clip closure; the clip is precisely positioned and the clip arms are opened for final position. Step (4) MitraClip deployment and system removal.

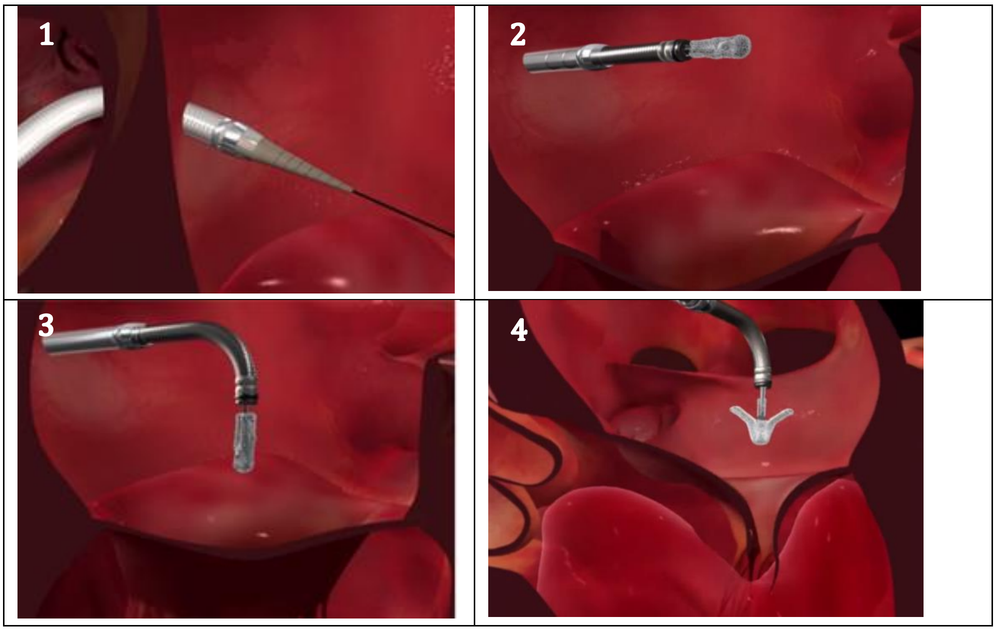

Figure 13: The MitraClip procedure: (1) A guide catheter is inserted into the left atrium through septum, (2) the steerable catheter in introduced through the guide catheter, (3) positioning and steering of the steerable catheter, (4) the clip is precisely positioned and the clip arms are opened for final position [15].

1.5.1.2 BioCardia Morph Catheter

The Morph Universal Guide Catheter manufactured by BioCardia is a set of steerable and deflectable catheters. The catheter can deflect and provide customized curvature while maintaining its precise inner diameter. The entire catheter is rotated by a like-for-like movement of from the handle.

The catheters are used for percutaneous interventional procedures, where the distal end is controlled from a handle at the proximal end. The catheters have a thin wall structure with a braided shaft of Nitinol for torque response, [41].

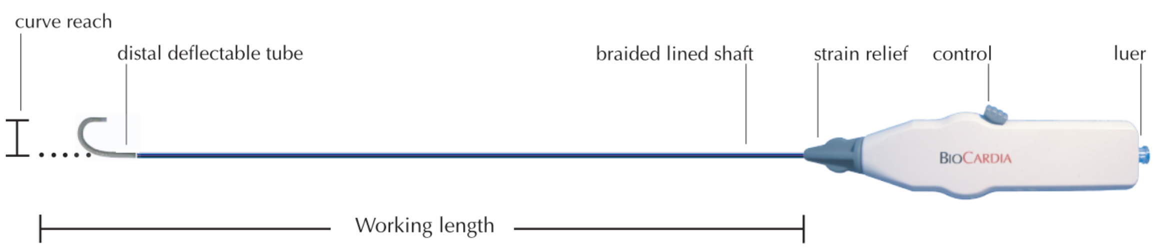

Figure 14: BioCardia's Universal Deflectable Guiding Catheter [41].

1.5.2 Remote Magnetic Navigation of the catheter

Remote Magnetic Navigation in interventional cardiology is a method where a magnetic field is utilized to control the catheter. Magnets are placed ouside the patient's body in the operating theater, and by changing the magnet field, the distal end of the catheter is pulled in various directions. This causes the catheter to bend and move into desired positions. The surgeon is located in a room next to the operating theatre to avoid radiation and can control the system with a joystick.

The figure below shows how the magnets are placed on each side of the patient's bed and can be moved by the heavy machinery that supports them.

Figure 15: The Niobe® ES magnetic navigation system with two permanent adjustable magnets mounted on mechanical frames situated at either side of the fluoroscopy able [42].

The Stereotaxis Niobe® ES magnetic navigation system

A remote magnetic navigation system is the Stereotaxix Niobe® ES. Two permanent magnets mounted on two pivoting arms located on either side of the surgical bed, navigate the catheter. This is achieved by moving the magnets relative to each other, and therefore cause change in the magnetic field. This change moves the permanent magnet mounted on the distal tip of the catheter. The inside of left atrium is being mapped my measuring the impedance at several point on the heart wall with the catheter tip. The locations of these points are reported back to a computer, which builds a 3D-model of the chamber based on the coordinates relative to each other. A physician sits in the room next to the operating room, using only a joystick to operate the system[43].

Below is a list of pros and cons for the Stereotaxis magnetic navigation system.

- **Pros**
  - Very flexible catheter, which avoids puncturing of the heart and can make any turns.
  - The rigid part is small.
  - Physician avoid radiation because they can sit in another room.
  - Less radiation exposure for the patient.

- **Cons**
  - Complex system, which makes it expensive.
  - Cardiology labs must be totally renovated to shield the rest of the facility from the strong magnetic field that guides the robot.

- **General challenges linked to Magnetic Navigation**
  - Difficult to achieve the S-shape combined with a telescope function to reach every corner in left ventricle.
  - Difficult to isolate which part of a telescopic catheter tip that should be moved.
  - Difficult to deflect in xy-plane and then further into the xz-plane, see the figure below.

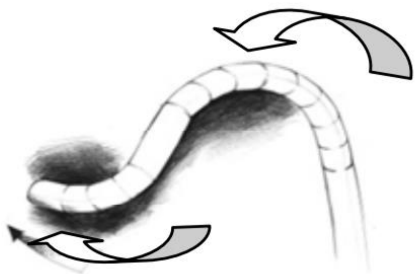

Figure 16: Deflection in xy-plane and thereafter in z-plane [8].

1.6 Challenges linked to current methods for navigation

The challenges considered in this chapter are linked to the technology used in the pulley catheters; BioCardia and MitraClip.

- **Flexibility – deflecting an already deflected catheter**

The current methods when using BioCardia and MitraClip allow limited flexibility when the catheter tip is already deflected. The device on the catheter tip should preferable have the possibility to be positioned perpendicular on the treatment area in any position inside of the heart. This is however challenging when the catheter tip is already deflected because this will involve an S-shaped deformation of the catheter.

The two figures below illustrates these challenges.

- *Figure 16a)* illustrates how a deflected catheter is not able to reach the dark area in the figure. This demands an S-shaped deformation of the catheter. Neither will it be possible to touch the red line that is positioned perpendicular to the catheter position.

- *Figure 16b)* shows how the catheter meets challenges when it is maneuvered down to the left ventricle because this demands movement in the longitudinal direction. The catheter used in MitraClip operations, solves this issue by using a telescope effect after the catheter has been deflected. However, the upper wall of left ventricle will not be reachable because an S-shape deformation of the catheter is not possible. Movement in the Z-plane is also challenging in this state.

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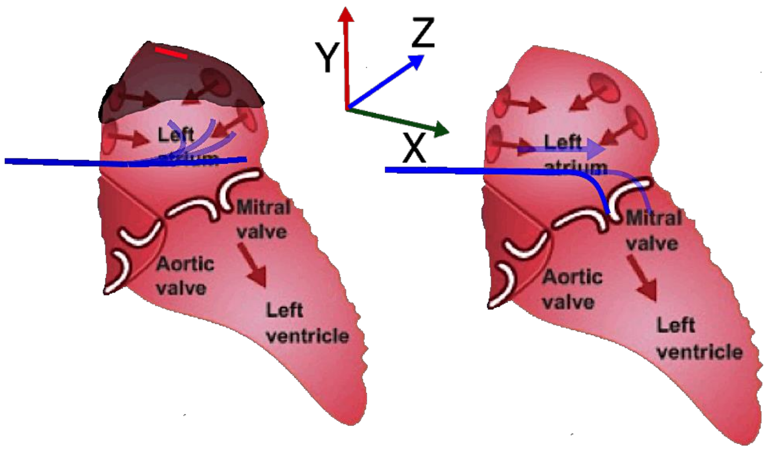


Figure 17: a) Deflecting the catheter in the left atrium, b) longitudinal movement of a deflected catheter.

- **Accuracy – challenging to reach precise positions**

Due to the length and turns, which the catheter has to pass in endovascular surgery, drag forces occur on the catheter as well as the strands inside the pulley catheters. These drag forces decreases the positioning accuracy on the distal end of the catheter, both in longitudinal direction as well as deflection and rotation.

1.7 Imaging Technology

In minimally invasive surgery, it is crucial to know the exact locations of the surgical tools and important anatomical structures at all-time[16]. The surgeon is therefore dependent on the use of imaging technology to conduct the surgery, which gives a visualization of the catheter and device inside of the patient body. Complex cardiovascular procedures require precise, powerful imaging systems. Ultrasound and fluoroscopy are currently the most frequently used imaging techniques in minimally invasive surgery, in addition to X-ray computed tomography that is used pre-operative to map the patient's body[17].

Below follows a short introduction to each of them.

- **Ultrasound Imaging**

Ultrasound imaging provides pictures from inside of the body using sound waves. This involves the use of a small transducer, or a probe, and ultrasound gel placed directly on the skin. High-frequently sound waves are transmitted from the probe through the gel and into the body. The transducer collects the sound waves that bounce back and a computer uses those sounds to create an image [18].

- **Fluoroscopy**

Fluoroscopy shows a continuous X-ray image on a monitor, like an X-ray movie, and obtains real-time moving images of the interior of an object. An X-ray beam that is passed through the body carries out the process. The image is transmitted to a monitor so the movement of a body part can be seen in detail [19].

- **X-ray Computed Tomography (CT)**

Prior to the minimally invasive procedure, the patient needs to have performed a physical examination. This includes a CT scan, where series of X-ray pictures are being combined to create cross-sectional images of bones and soft tissues inside of the body. Since access to the heart through the femoral artery is preferable, the diameter of this artery needs to be measure in advance of the endovascular procedure. This is being measured with help from CT scan of the body. The minimum required size of the femoral artery is 7 mm in order to be able to perform transfemoral interventions [20].

Figure 18: The ultrasound image shows a leaking mitral valve before surgery [35].

1.8 Hypothesis

The hypothesis for this master thesis is that the catheter for use in minimally invasive procedures can be maneuvered easier and more precise by improving the steering mechanisms for the catheter.

1.9 Key Issues

The key issues for the conventional catheters are listed below. These issues form the backdrop for the project objective and the project plan, which are described in the next chapter.

- For conventional catheters, it is not possible to rotate the distal end of the catheter independently from the rest of the catheter. This leads to inaccurate rotations of the surgical device.

- Drag forces occur along the catheter's path from the handle to the distal end of the catheter. This leads to inaccurate deflection of the distal end of the catheter, and limit the steerability.

- When a deflection is made on the distal end of the catheter, it is not possible to move the distal end in longitudinal direction without moving the entire catheter. This limit the operation tool to reach desired positions.

1.10 Quality Assurance

The development of the device(s) in this project report has been reviewed and commented regularly, by surgeons and cardiologists at The Intervention Centre, Oslo University Hospital, and has been subjected to modifications and further development accordingly.

2 PROJECT PLAN

The Project plan includes the main objective and the secondary objectives for the project, as well as the activity plan and the list of milestones. The constraints for the project are listed in the end of this chapter.

2.1 Project Objective

The following objectives are defined for this master thesis.

The main objective is to identify and examine the possibilities for a precise positioning of catheters in the cardiovascular system, where the distal end of the catheter can be placed in a exact position. Furthermore, the aim is to develop proposals for a proof of concept where the treatment device can be positioned as exactly as possible by available imaging methods, where they are compatible to each other. The development process will be reported, including the results, and the concept-generating phase will be described in detail.

Secondary Objectives

The following objectives are listed to fulfill the main objectives for the project.

1. Hold a project kick-off meeting with all the involving parties in the project.
2. Define the project specifications.
3. Identify the existing methods for navigation and positioning of catheters in the cardiovascular system and their technical challenges.
4. Develop the functional analysis.
5. Brainstorm and identify possible solutions.
6. Conduct the concept screening.
7. Test parts of the concept alternatives.
8. Develop and roll out the external test.
9. Choose the final solution/concept.
10. Visualize the concept in CAD drawings.
11. Complete the report and hand in.
12. Conduct a presentation of the chosen concept with materials and methods.

2.2 Project Schedule

The following time and work schedule is developed to assist the project progression to be easier to follow. The work schedule defines the amount of time spent on each activity with help from a Gantt-diagram. The milestones are highlighted in red with a linked text for each milestone in the table below.

Table 2: Schedule for project activities.

Activity / Duration (no. of weeks)		Week																	
		2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Project kick-off	2	1																	
Define tasks and project description	1		2																
Information gathering	4					3													
Functional analysis	1						4												
Brainstorming	6											5							
Concept screening	5														6				
Tested parts of the concept																8			
Report writing	15																		12
Technical drawing	8																10		
External testing	2													7	9				
3D Printing	2																		
Presentation	2																		11

Milestones

The milestones, marked with red in the project plan table, are described in the below table.

Table 3: List of Milestones.

Number	Milestone	Deadline
1	Held the project kick-off meeting	9. January 2015
2	Project specifications are defined	19. January 2015
3	Finalized the research period and written a draft for the review part in the report	13. February 2015
4	Developed the functional analysis	16. February 2015
5	Finalized the brainstorming process	20. March 2015
6	Fulfilled the concept screening	10. April 2015
7	Fulfilled an external test	27. March 2015
8	Tested parts of the concept	10. April 2015
9	Chosen the final concept	24. April 2015
10	Finalized the CAD drawings	1. May 2015
11	Finalized the project report and handed in	14. May 2015
12	Finalized the master presentation	22. May 2015

2.3 Project Limitations

Due to time restrictions, the following limitations are set for the project. These are the aspects that will not be considered or conducted throughout the project phase.

- There will only be developed a concept for the solution. This means that the product not will be completely developed when the project is finalized.
- The area for the surgery where the concept will function is restricted to be surgeries within the left atrium and the left ventricle.
- It will be lumen from the proximal end to the distal end of the catheter, which can carry the contrast fluid and the wire to the operation device that is placed in the distal end. This narrow the inner space of the diameter and the inner part of the catheter can never be fully blocked.
- The outer diameter of the steerable catheter must not exceed 8 mm (24 F).
- The maximum length of a rigid part of the catheter at the distal end can not be more than 25 mm, in order to enable the catheter to make desired bends.
- The steerability of the distal end of the catheter should be compatible with an operation device docked on the distal end. This need to be taken into consideration when developing the catheter.
- Costs evaluations will not be considered in this project.
- Precise measurement will not be specified.
- The concept will not be practically tested.

3 TERMINOLOGY

This chapter is an overview of terminology used in this master thesis, including definitions, symbols and other terminology that is essential to the thesis.

3.1 Definitions

Table 4: List of definitions.

Definition	Explanation
Abdominal	The body structure between chest and pelvis.
Ablation	Catheter ablation is a minimally invasive medical procedure used to treat arrhythmias (irregular heart rhythms). A specialized cardiologist called an electrophysiologist performs the ablation.
Angiography	Radiography of blood or lymph vessels.
Apex	The inferior tip of the heart.
Atrial fibrillation	An abnormal heart rhythm characterized by rapid and irregular beating.
Atrioventricular	Between the atrium and ventricle.
Biocompatibility	How biomaterials interact with the human body and eventually how those interactions determine the clinical success of a medical device.
Cardiovascular system	System that permits blood to circulate inside of the body.
Cardiac arrhythmia	A group of conditions in which the heart beat in irregular, too fast or too slow.
Endovascular surgery	Method that is being conducted to reach organs through blood vessels.
Incision	Surgical cut made in skin or flesh to reach inner structure of the body.
Laparoscopy	A minimally invasive surgery that uses a thin, lighted tube put through an incision in the belly to look at inner structure of the body.
Median sternotomy	Type of surgical procedure in which a vertical inline incision is made along the sternum.
Omnidirectional deflection	A deflection in every direction.
Pathogenic	Cause diseases.
Pelvis	The large bony frame near the base of the spine.
Pericardium	A double-walled sac containing the heart and the roots of the great vessels.
Percutaneous	In surgery, percutaneous refers to any medical procedure where access to inner organs or other tissue is done via needle-puncture of the skin, rather than by using an "open" approach where inner organs or tissue are exposed (typically with the use of a scalpel).
Pulley catheter	Catheter type that uses strands and pulleys to deflect the distal end.

Table 4 continues.

Definition	Explanation
Retractor	Surgical device used to actively separate the edges of a surgical incision or to hold back underlying organs.
Septum	Tissue wall that divides a cavity or structure of the body.
Sternum	The breastbone, a long flat bony plate shaped like a capital "T" located anteriorly to the heart in the center of the thorax.
Thorax	The chest, the area between the belly and the neck.
Tomography	A technique for displaying a representation of a cross section through a human body.
Transapical	Through the apex of the heart.
Transfemoral	Through the femoral vein or artery.
Treatment device	The device, which is in contact with the actual treatment area (e.g. electrode on the ablation catheter or a grip device for mitral valve repair)

3.2 Symbols

The following table list the symbols used in this master thesis.

Table 5: Table of symbols.

Symbol	Definition	Unit
m	Module	mm
Z	Number of teeth	-
h	Height of teeth	mm
D	Diameter	mm (Fr)
C	Centre distance	mm
u	Gear ratio	-

Fr. French Catheter Scale – scale used to measure the external diameter of a catheter.

$$1\ French\ = \frac{1}{3} * mm\ ,1\ mm\ = 3 * French$$

3.3 Formulas and Equations

Calculation of Epicyclical Spur Gears Systems [22]

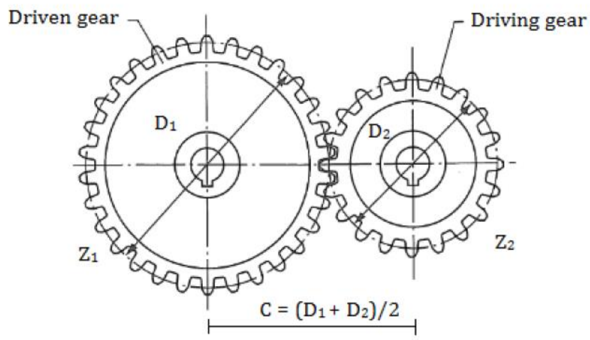


Figure 19: The epicyclical gears system [47].

Table 6: Spur Gears Formulas.

Symbol	Formula	Explanation	Definition
m		Module	The ratio between the centre distance and the avarage number of teeth.
Z_n		No. of teeth	The number of teeth on the gear n.
h	$h = 2{,}25 * m$	Height of teeth	The height from the root diameter to the outside diameter.
D	$D = m * Z$	Pitch diameter	The diameter of the pitch circle.
D_R	$D_R = m* (Z + 2)$	Root diameter	The minor diameter of the gear.
D_O	$D_O = m * (Z + 2{,}5)$	Outside diameter	The major diameter of the gear.
C	$C = (d_1+d_2)/2 = m*(Z_1 + Z_2)/2$	Centre distance	The distance between the center of the two shafts
u	$u = Z_2/Z_1$	Gear Ratio	The ratio between the teeth on both gears.

Number of teeth

Good meshing conditions limit the choice of the number of teeth of each gear in a gear system, see the table below.

Table 7: Number of teeth.

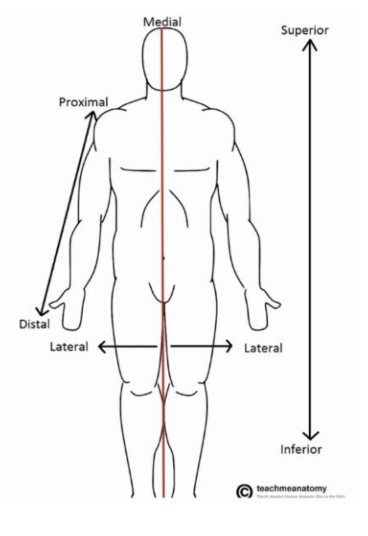
	Number of teeth				
Z_1	13	14	15	16	17
Z_2	13 to 16	13 to 26	13 to 45	14 to 101	14 to ∞

3.4 Other terminology

Terms of location

The table below describes the term of location used in medical terminology.

Table 8: Anatomic terms of location[45].

<table>
<tr><th colspan="2">Anatomic terms of location</th></tr>
<tr><td>Superior – Upper
Inferior – Lower
Proximal – Inner
Distal – Outer
Posterior – Rear
Anterior – Frontal
Lateral – Side</td><td>
</td></tr>
</table>

Pressure inside of the heart

Blood pressure is a measurement of the forces on the walls in the arteries as the heart pumps blood throughout the body. There are two stages of interest when measuring the blood pressure; this is the systolic and the diastolic pressure.

- ***Systolic pressure*** is the maximum arterial pressure during the left ventricle contraction. The time at which ventricular contraction occurs is called systole.
- ***Diastolic pressure*** is the minimal arterial pressure between the heartbeats. This is when the heart muscle relaxes, before it refills with blood and dilates (expands).

From mmHg to MPa: 1 mmHg = 133,3 MPa

Table 9: Blood pressure categories for systolic and diastolic blood pressure [50].

Blood Pressure Category	Systolic [mmHg]	Diastolic [mmHg]
Low	less than **90**	less than **60**
Normal	less than **120**	less than **80**
Prehypertension	**120 – 139**	**80 – 89**
High (Hypertension) Stage 1	**140 – 159**	**90 – 99**
High Blood Pressure (Hypertension) Stage 2	**160** or higher	**100** or higher

4 METHODOLOGY

The methodology used in this master thesis is based on the dynamic problem-solution interaction that demand use of creative techniques. The tools used to manage these interactions are mainly brainstorming, with Osborne's method, and concept screening with help from Pugh's method. Also the SCAMPER technique was an essential part of the creative phase. In this chapter follows a review of the methodology used in the master process.

4.1 Integrated Product Development

Integrated product development (IPD) is a product development method that is being used to provide more efficient product development processes. Compared to traditionally product development models IPD operates more widely and includes a broader platform of disciplines. In addition to this interdisciplinary approach, the main purpose with use of IPD is to follow a certain pattern and do the development tasks in the correct order. This ensures that no actions are missed out.

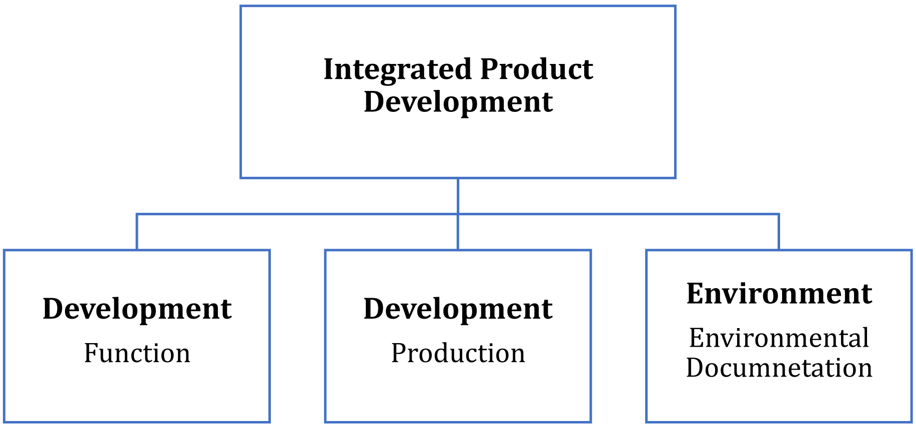


Figure 20: A schematic overview of IPD.

4.2 Functional Analysis

Listing all the required functions for the concept and dividing them into smaller parts conduct the functional analysis. This is a tool that is being used to provide an overview over all required components for the concept and simplifies the concept development phase.

The primary function(s) are first being listed and then being split into the required secondary functions, which are demanded to implement the primary function. The secondary functions are decomposed to sub-functions and the components that are required to carry out the sub-functions are listed in the column to the right in the analysis.

4.3 Osborne's scamper-technique

Alex Faickney Osborne developed the idea behind «brainstorming» and popularized this expression which means, "using the brain to storm an creative idea". Brainstorming is the creative technique where you solve a problem by spontaneously and uncritically listing all potential solutions to the problem. This method claims that two principles contribute "idea efficacy". The first is to avoid any form of criticism and negative feedback in the creative process. This absence of criticism is crucial for the method to provide creativity. The aim is to reach for quantity instead of quality.

The SCAMPER technique is linked to Osborne's brainstorming theory. This method uses a set of direct questions that encourage the group or individual to think about how to improve existing ideas by asking a number of questions. The questions are related to each of the factors in the SCAMPER technique. SCAMPER is a mnemonic that stands for the seven verbs that is shown in the figure below. The figure shows how the technique represents a loop where the idea is reversed a number of times until the optimal version of the solution is obtained.

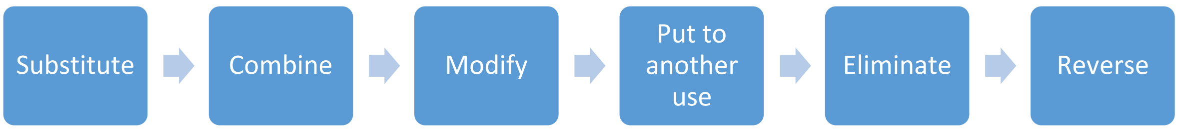


Figure 21: The steps in the SCAMPER method.

The method is conducted by asking a number of questions that is linked to each of the seven factors illustrated in figure 21. After the brainstorming process, the different ideas should be taken into consideration and it should be provided as many questions and answers as possible. Examples of these questions are given in the table below. The aim is to generate a wide range of ideas and evaluate them afterwards with help from the questions.

Table 10: A description of SCAMPER [23].

Letter	Meaning	Description
S	Substitute	Can parts be substituted to improve the existing product?
C	Combine	Can the product or parts of it be combined with other?
A	Adapt	Can parts from another product be adapted?
M	Modify	Can parts be modified to improve the product?
P	Put to another use	Can the product be used in another setting?
E	Eliminate	Can the product be improved by eliminating parts?
R	Reverse	Can parts or segments be reversed/ switch place/do the opposite/reorganize parts to improve?

4.4 Pugh's Method

Pugh's method, after Stuart Pugh, is a tool to help choose the best out of a variety of different solutions linked to a certain problem. The method is conducted by having a list of alternative solutions and a set of criteria that the solutions will be evaluated based on. This generates a scoring matrix, also known as the Pugh matrix, that conducts a method for concept selection. The criteria will then be given a weighted score, which implies the importance of the criteria for the given problem.

The aim is to develop a decision-matrix, which compares alternative concepts in an effective way. By scoring concepts relative to each other, they can be evaluated and the optimal concept can be chosen. The Pugh matrix applied in this project uses the following seven step scoring system for evaluating the alternative concepts.

Table 11: The scoring system for Pugh`s matrix.

Scoring	Description
6	Meets criterion extremely good
5	Meets criterion very good
4	Meets criterion good
3	Meets criterion as well as datum
2	Meets criterion not as well as datum
1	Meets criterion worse than datum

4.5 Software

All 3D models and animation are made in Solid Works version 2014/2015, assisted by CATIA Composer for illustration photos. The step-by-step book Creating Animations, is used for animation guidelines [40].

4.6 References

The Vancouver referencing system is used in this master thesis. The references are referred to in square brackets in the text and listed in chapter *16. References.*

4.7 Product Development Process

Figure 22 illustrates the estimated flow in the project development process, from defining the project objective to presentation of the results.

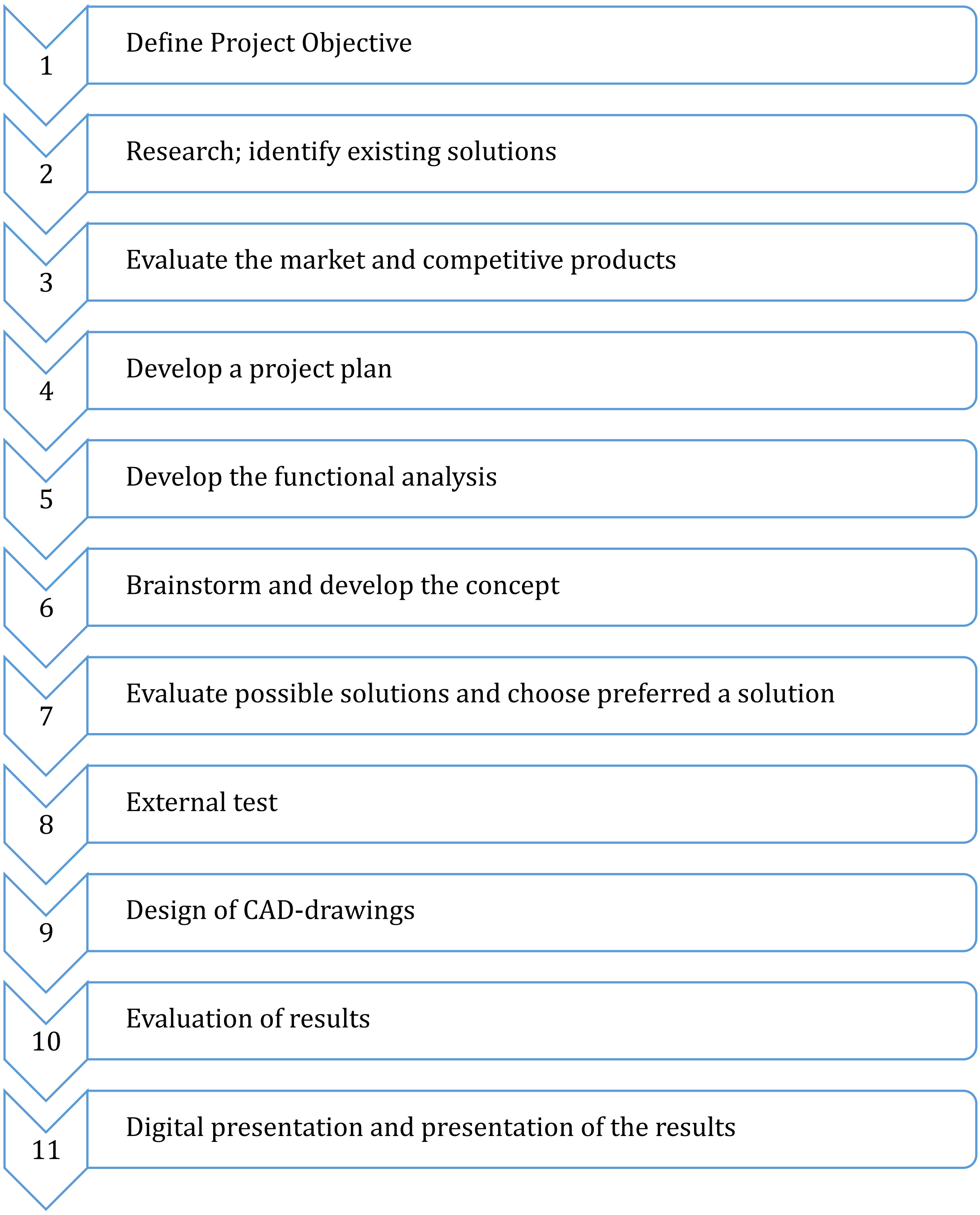


Figure 22: The product development process in chronologically order.

5 PRODUCT SPECIFICATIONS

The product specifications include metric specifications and functional requirements in terms of size, space, mobility, safety aspects and property evaluations. In addition, a review of marked potential and technical bottlenecks are conducted.

5.1 Product requirements

Size

The steerable catheter follows the guiding catheter into the left heart chamber. The inner diameter of the guiding catheter is 8 mm (24 French) and this provides the catheter with an absolute maximum diameter of 8 mm, see the figure below.

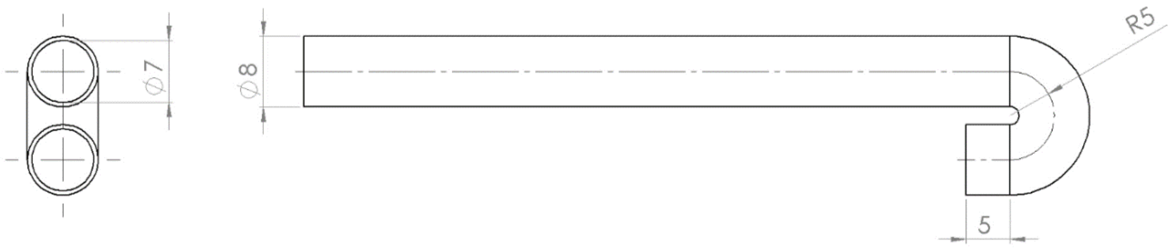


Figure 23: Sketch of the catheter with metrical specifications, all values in mm.

The length of the catheter, distal to the ben, should be as small as possible in order not to demand too much space. This value is set to 5 mm but could be changed if required.
The defection radius should be as small as possible so that required space to obtain a bend is kept to its minimal. The minimum radius is set to 5 mm.

Rigid part

Since the steerable catheter passes through the guiding catheter in bends, there is a limit for how long part of the catheter that can be rigid. This is because a long rigid part of the catheter not will be possible to pass through a bend while it will not be flexible enough. The limit for this rigid length in the catheter is set to maximum 25 mm.

Kink resistible surface

The catheter needs to have a peripheral structure, which makes the tube kink resistible. This is of absolute importance for the catheter, since a kink along the catheter path would potentially result in critical scenarios for the inner structure of the catheter. The strands and wires operating the catheter are entirely dependent on having a free path from the proximal to the distal end of the catheter. To obtain this kink resistible surface, the catheter wall is supported by a coil shaped spring or a grid structure. In addition, the shape of the cross-section profile prevents the catheters surface from collapsing.

Lumens

The catheter needs to contain hollow paths along its longitudinal direction in order to enable transport of fluids and operation tools to the treatment area. These hollow paths are called lumens. The catheter consist of either one or more lumens, referred to as a single-lumen or a multi-lumen catheter respectively. For steerable catheters that are used in mitral valve repair, the minimum number of lumens is two. One for the contrast dye and one for a guide wire or a wire to steer the operation device.

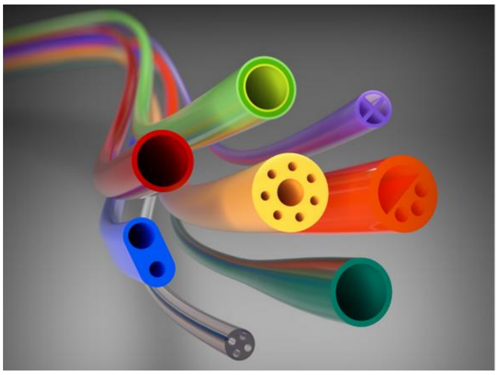


Figure 24: Illustration of the lumens inside of the catheter [24].

Mobility

The required movements of the catheter is isolated to the steerability after entering the left atrium. The figure below illustrates the catheter's path from the inferior vena cava, into the right atrium, through atrieseptum and into the left atrium. These movements are conducted by the guide catheter, and the steerable catheter is introduces through this guide catheter. However, when the steerable catheter is inserted through the guide-catheter, it needs to be able to navigate to any desired position inside of the left heart chamber, see figure 25.

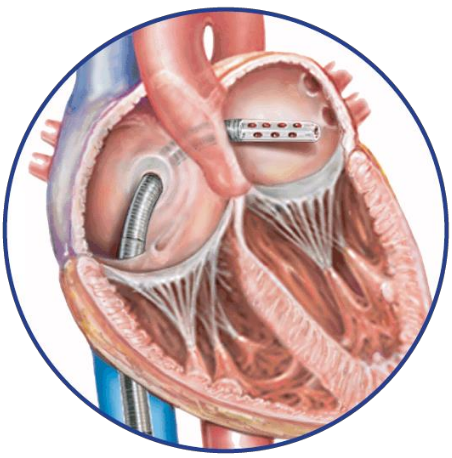


Figure 25: The path for the catheter from inferior vena cava through atrieseptum and into the left heart chamber [21].

Space

Both the available volume and the mobility need to be evaluated when considering the metric specifications for the catheter. Since the heart anatomy varies greatly among patient, there is no standard size of the heart.

The company 3B Scientifics is a manufacturer of didactic material for scientific, medical and patient education. Their 7 parts heart model is being used as the basis for the size of the left ventricle, (the measures are from the 1:1 heart model) [56].

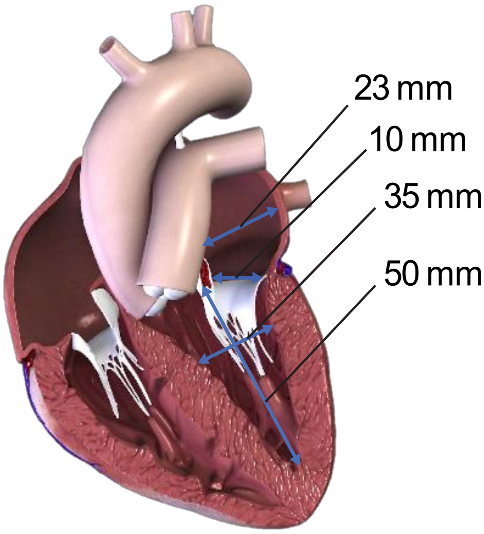


Figure 26: Heart figure that shows the metric size of the left ventricle.

Safety aspects

- **Precision**

Catheter-based interventions entails some risks. Bleeding, infection and pain may occur along the catheter's path or at the target area. This can cause substantial damage. Therefore, precision is critically important.

- **Electricity**

There must be ensured that no voltage is leaked out of the catheter. The amount of electricity needs to be considered to avoid cardiac arrhythmia.

- **Shape**

The catheter needs to avoid having sharp edges and uneven surfaces on the outer catheter wall in order to prevent damage of the tissue.

Required Degrees of Freedom (DOF)

The requirements for the catheter will be to reach all points inside of the left heart chamber. Making this achievable, deflection, rotation and elongation of the catheter will be necessary.

The figure below shows the required degrees of freedom for the catheter, which implies the number of independent parameters that define the configuration for the catheter and determine the state of the physical system.

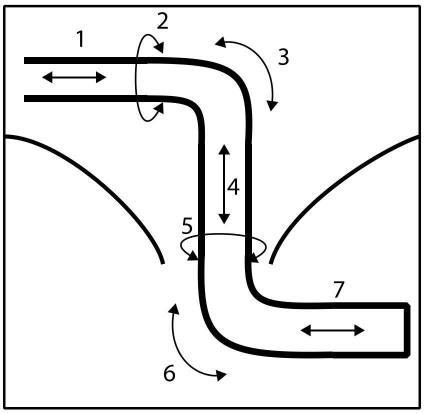


Figure 27: Degrees of Freedom for the catheter, marked with numbers. The splines on the left and right side in the figure illustrates the mitral valve leaflets.

As shown in figure 27, the catheter requires seven degrees of freedom. Each of these are described in the table below.

Table 12: Degrees of Freedom with descriptions.

DOF number	Description
1	The catheter is inserted through septum and needs to be able to move in the longitudinal direction.
2	If the catheter cannot deflect omnidirectional, the catheter needs to be able to rotate to adjust the deflection.
3	A deflection is required to be able to change direction of the catheter.
4	To be able to reach the base of the ventricle, the catheter must move downwards in longitudinal direction.
5	Rotation is needed after the elongation in order to adjust the next deflection.
6	A deflection is needed to make an S-shape and to reach all points on the ventricle wall.
7	A longitudinal movement in the tip of the catheter is preferably to reach the desired point on the ventricle wall.

These listed degrees of freedom will be considered in the concept development process.

5.2 Property evaluation

Listing all relevant properties and rating them makes an evaluation of key product features for the steerable catheter. Ten features are chosen and given a weighted score based on their importance concerning the catheter. The rating is conducted by using a score from 1 to 6, where 6 is considered an extremely important property for the catheter and 1 is considered an irrelevant property.

Table 13: Product property evaluation.

Property	Description	Score	Explanation
Steerability	The ability to maneuver the catheter.	6	The main objective of the project is to develop an improved steerability for the catheter; therefore, this has the highest possible priority.
Accuracy	The degree of precision in which the catheter may be positioned.	6	The aim is to obtain a great accuracy in order to be able to place the catheter as precise as possible.
Visual design	The products appearance.	2	The visual design and esthetic are not of any importance, and has therefore a low priority.
Retail Price	The price per unit.	2	Medical equipment is expensive. The price will therefore not play a significant role in the concept development.
Safety	How safe the catheter is in terms of risks of damage inside the body.	6	Safety is extremely important when the catheter is being placed inside a human body.
Cleaning	How easy the device is to keep clean.	1	The catheter will be a single-use-device device and it will not be necessary to clean it for re-use.
Size	The diameter of the catheter.	5	The diameter needs to fit in to the guide catheter, and cannot exceed 8 mm (24 F).

Table 13 continues.

Property	Description	Score	Explanation
Weight	The weight of the catheter.	4	The weight must be considered because it needs to be strong enough to withstand the blood flow in the veins.
Operating costs	Costs when using the device.	1	The cost applied will not play a significant role for the catheter.
Start costs	Single start-up cost required.	3	The start-up cost can vary greatly depending on the chosen method for the catheter.
User friendliness	How easy the catheter is to use. Amount of experience that is required to use it.	4	The optimal solution would be to have a method for maneuvering the catheter that any qualified cardiologist or surgeon could use. To make it easy to use will therefore be a high priority.
Ergonomic adaption	If the catheter is adapted to fit inside the human body.	6	This is absolutely necessary and of the highest priority.
Flexibility	Capable of deflect easily without breaking.	6	Both the catheter tip and the catheter need to be absolutely kink resistible and easy to deflect.

Focus on maneuverability, safety and ergonomics

To summarize the property evaluation in the table above, it will be reasonable to state that the properties of highest importance are maneuverability and safety. The ability to maneuver the catheter is the main purpose of the catheter, and this has therefore been given the highest priority. It is inevitable that this factor will be the most important one in order to provide the catheter with the preferred function. However, this property includes a wide range of other functions, which will be displayed in the next chapter in the functional analysis. Since the catheter will be used within a patient during surgery, the requirement for safety is at its maximum level and inevitably an extremely important criterion.

5.3 Market needs and product potential

According to a study made by BCC research, the global market for minimally invasive surgery devices and equipment was about $14.5 billion in 2013. This market reached about $15.4 billion in 2014 and is expected to reach $21.5 billion in 2019, registering a compound annual growth rate (CAGR) of 6.8% for the period 2014-2019 [25].

It comes from the study that a growing number of surgical procedures are carried out using minimally invasive techniques. This has created a multibillion-dollar market for specialized devices and instruments used for these procedures. The market includes monitors and imaging equipment, electrosurgical devices, handheld instruments, auxiliary devices, and accessories.

The patient, the hospitals and the government should all have a great interest in expanding the marked for minimally invasive devices. The procedure is performed without making a major incision, resulting in fewer traumas for the patient and yielding significant cost savings. The shorter hospitalization times for the patient and reduces therapy requirements, results in a better life quality for the patients and would help them to sooner be able to get back to work or to a normal life. To get patient faster back to their work implies great socio-economic consequences for the society. This should be a reason why the government would have great incentives to support research and development revolving the field of minimally invasive surgical devices. Other benefits are less pain, less need for postsurgical pain medication and less likelihood of complications related to the incision.

Efficient minimally invasive procedure is therefore necessary in the years to come, as the demand will be increasing. Since the average life expectancy is increasing and people have a bigger need for repairing defects within the heart, the demand for a more secure, faster and cheaper devices are inevitable. As per today, around 95 % percent of the total cost for the minimally invasive procedures are linked to the devices and the instruments. With an increasing market and demand for these procedures, development of the devices in order to make them more efficient and easier to use will need to be put on the agenda.

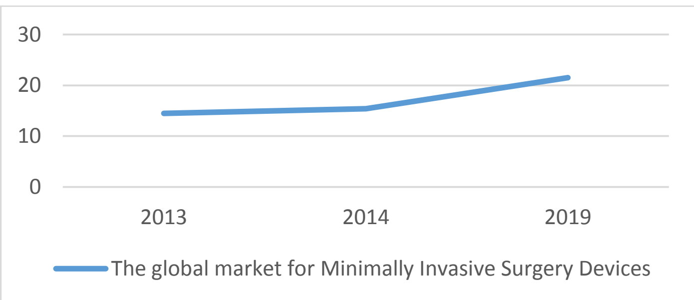


Figure 28: The figure shows the increasing global market for minimally invasive surgery devices, the numbers on the vertical axis is in million dollars.

5.4 Technological bottlenecks

Below is a list of the bottlenecks and issues that are linked to the product.

Size

- The diameter of the catheter cannot exceed 8 mm (24 Fr). This can be a challenge considering inter alia micro motors or telescopic catheters that require a certain amount of space.

Usability

- The catheters and devices have restricted use by surgeons and cardiologist. However, it will be preferable to develop a product that does not require a great amount of experience to use it. The eager is to develop a catheter with an easier steering system than the existing ones.

External steering

- Since the catheter tip is places inside the left heart chamber when the precise positioning is demanded, this requires an external steerable system. This constitutes therefore the most challenging bottleneck for the product.

Imaging technology

- The catheter needs to be made of a material that is compatible with the currently used imaging technology in minimally invasive surgery.

Heart Anatomy

- The organic formed heart implies a challenge for the navigation within it. Patients have individual differences in the heart anatomy and this needs to be taken into consideration.

Blood Flow

- The blood stream that flows in the heart when the operation is taking place involves a challenge for the surgeon trying to reach different positions inside of the heart. The mitral valve will open and close continuously and therefore it is challenging to grip the valve.

A beating heart

- The heart muscle will constantly contract and expand, as the heart is not connected to a heart-lung machine under minimally invasive procedures. This constant movement of the heart implies difficulties when operating inside of it.

6 EXTERNAL TEST

An external test is conducted to identify the required features for a steerable catheter. This chapter includes the objectives and the review of the test, including interpretation of results.

6.1 Objectives of the test

The purpose of the external test was to identify what type of challenges that is the most common to experience when carrying out interventions with use of steerable catheters.

The objective of the external test was to identify the following:

- How much experience is needed to manage the steerable catheters that are currently being used.
- What are the challenges linked to today's steerable catheters.
- What features are the most critical for the steerability of the distal end of the catheter.
- Which additional features would have made maneuvering of the catheter easier and more precise.

6.2 Selection of Population

Cardiologists who hold experience within the fields of cardiovascular surgery are chosen as the test population for this external test. They are chosen because they are the actual users of the steerable catheters and they can therefore explain and classify the challenges or possible improvements for the steerability.

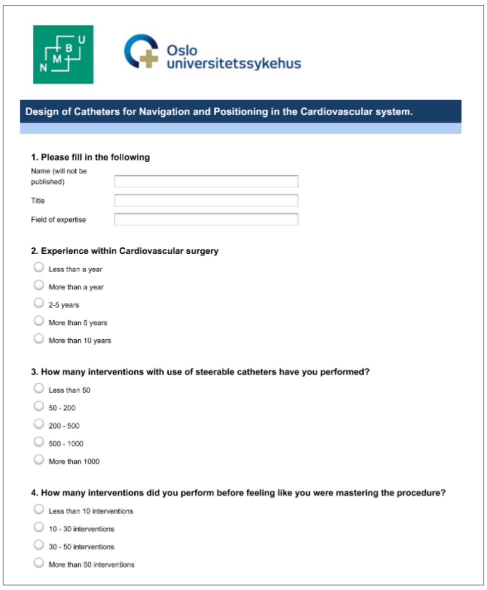
The cardiologists contributing to this external test are working at Oslo University Hospital and Haukeland University Hospital.

6.3 Content and type of Questionnaire

The questionnaire, which can be found in Appendix A, was build up with a contact information field as an introduction, classifying the name, title and field of expertise with the questioned.

In the following, questions identifying the years of experience were listed, how many interventions they have made and how many they made before they felt as if they were mastering the procedure.

In the following, six statements were made to have the test persons to tick off from strongly disagree to strongly agree.


Oslo universitetssykehus

Design of Catheters for Navigation and Positioning in the Cardiovascular system.

1. Please fill in the following

Name (will not be published)

Title

Field of expertise

2. Experience within Cardiovascular surgery

- Less than a year
- More than a year
- 2-5 years
- More than 5 years
- More than 10 years

3. How many interventions with use of steerable catheters have you performed?

- Less than 50
- 50 - 200
- 200 - 500
- 500 - 1000
- More than 1000

4. How many interventions did you perform before feeling like you were mastering the procedure?

- Less than 10 interventions
- 10 - 30 interventions
- 30 - 50 interventions
- More than 50 interventions

Figure 29: The external test.

6.4 Interpretation of results

The most relevant results from the external analysis will be listed and considered in this chapter. A short review of the most essential questions is given, along with related interpretations. All of the results from the test are collected and presented in Appendix B.

The respondents

There were six respondents to the external analysis, all of them cardiologists, with the following experience with cardiovascular surgery: two with 2-5 years of experience, two with more than five years and two with more than ten years. Of these six respondents, two have performed less than 50 interventions, two have performed between 200 and 500, and two respondents have performed more than 1000 interventions.

To the question "How many interventions did you perform before feeling like you were mastering the procedure?", two answered 10-30 interventions, one answered 30-50 interventions and three answered more than 100. This is an essential question to the master thesis, because the degree of experience plays a significant role when considering the catheter's steerability. It was registered that there was a correlation where respondents with less experience answered that they needed less interventions before feeling as they were mastering the procedure. This might imply that the perception of the expression "mastering" may differ among the respondents.

Statements

Six statements were made, where the respondents were ticking off either strongly disagree, disagree, irrelevant, agree or strongly agree. The results are listed below.

- 83,3 % of the respondents agreed to that, "Limited steerability in the distal end of the catheter can lead to complications during minimal invasive procedures." 16,7 % ticked off irrelevant.
- 50 % of the respondents disagreed and 33,3 % agreed to that, "Deflection of the distal end of the catheter does not meet the need for accurate navigation within the heart." 16,7 % ticked off irrelevant.
- 60 % of the respondents disagreed and 40% agreed to that, "Rotation of the distal end of the catheter does not meet the need for accurate navigation within the heart."
- 100 % of the respondents agreed to that, "Local rotation in the distal end of the catheter would have made the procedure easier and more accurate."
- 83,3 % of the respondents disagreed and 16,7 % agreed to that "Longitudinal movement of the catheter does not meet the need for accurate navigation within the heart."
- 83,3 % of the respondents agreed to and 16,7 % strongly disagreed that, "Local elongation in the distal end of the catheter would have made the procedure easier."

The comments that were submitted to the statements can be summaries into the following: "Improved steerability will improve success rate and reduce the risk of complications because you can reach the area of interest with less force. Rotation and elongation are less important than deflection, as these movements can be achieved by rotation and forward/backward movement of the entire catheter, respectively." From the statements, interpretation can be made that a better steerability in the distal end would improve the catheter and lead to less complication. Local rotation is a desirable feature for the catheter. Local elongation in the distal end would also make the procedure easier and more accurate

Challenges associated with the steerability

The respondents listed the following challenges associated with today's steerable/deflectable catheters.

- Limited degree of accuracy. Challenging to obtain both steerability/flexibility in addition to penetrability/stiffness.
- Lack of tactical feedback and liability to produce multiple curves at the distal catheter tip.

Improvements of the features

The respondents would have changed or improve the following for rotation, deflection and elongation respectively:

a) **Rotation**: It would be preferable to have a local rotation at the catheter curvature in the distal end and avoid rotations of the entire catheter. Rotation can be difficult due to chorda (the threads) in the left ventricle, which can block the movements. Should be possible to measure the degree of rotation to make it more accurate.
b) **Deflection**: It should be possible to measure the degree of deflection to make it more accurate. It would be preferable to enable deflection in more than one plane, and to increase the radius of the curvature.
c) **Elongation:** It should possible be measure the degree of elongation to make it more accurate. Local elongation of the tip beyond the curvature would improve the reachability.

Rating of the features

From the rating of the features, 100% of the respondents rated deflection as the number one feature for the catheter. Rotation and elongation came on a shares 2nd and 3rd rating. The background for this rating, is because elongation and rotation always can be conducted by manually pushing and rotation the handle at the proximal end. Deflection is therefore a crucial feature for the steerable catheter, to be able to reach desired positions.

6.5 Recommendations

The output from the external test needs to be taken into consideration in the concept development, when considering and evaluating the features for the catheter. Recommendations from the external test are listed below:

- Local rotation of the curvature in the distal end would make the catheter-based procedure easier and more accurate.
- Local elongation of the tip beyond the curvature is preferable, because this would improve the reachability.
- Deflection is the most crucial feature for the catheter.
- The movement considering rotation, deflection and elongation, should be able to be measured to enable a more accurate movement. This could also make the system memorize certain positions and make it possible to re-enter them.
- The ideal catheter would give feedback on tissue contact and characteristics, it should be easy handled and soft to follow cardiac tissue motion and movement. It should be possible to obtain multiple curves, and adjustable curvature.

7 ANALYSING THE CATHETER FUNCTIONS AND STRUCTURE

7.1 Functional Analysis

To identify the required components for the catheter, a functional analysis has been developed, see the figure below. An explanation to the figure is given on the next page.

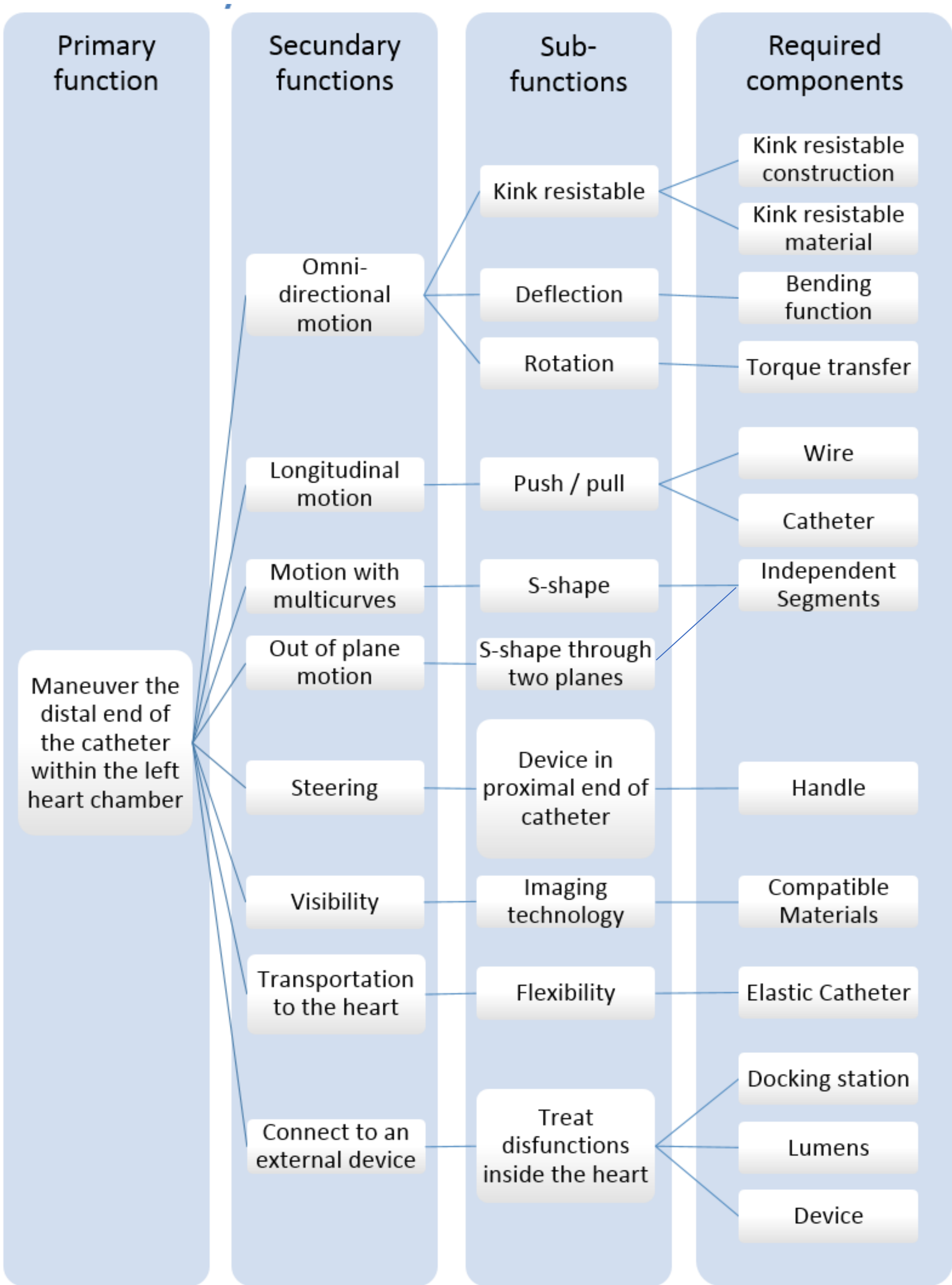


Figure 30: The functional analysis with primary, secondary and sub-functions.

Explanation of the functional analysis

The three first vertical lines of boxes in the functional analysis displays the primary, secondary and a sub-functions for the catheter's ability to steer the distal end. The required sub-function are spited down to a list of components that is required to build up the main function for the catheter. This column of required components becomes the background for the development phase, where the most relevant components will be investigated.

Interpretation of the functional analysis

The functional analysis illustrates that the maneuvering of the distal end of the catheter is the main function for the catheter's ability to steer the distal end. To maneuver the catheter there is listed a number of required secondary functions in the second column. The most relevant secondary function for this project is assumed to be the *Omnidirectional motion* and the *Longitudinal motion*. Deflection, rotation and elongation are therefore included in the concept development phase. In the development phase, these three functions are considered isolated and ideas for each of them are being brainstormed to collect as many alternatives for solutions as possible.

This functional analysis figure gives an impression of the initial brainstorming, which led to the alternatives displayed in the next chapter. The primary function was divided into smaller segments and made the use of Osbourne's method easier to conduct. The figure below illustrates the three main features for the catheter, which is being considered in chapter 8.

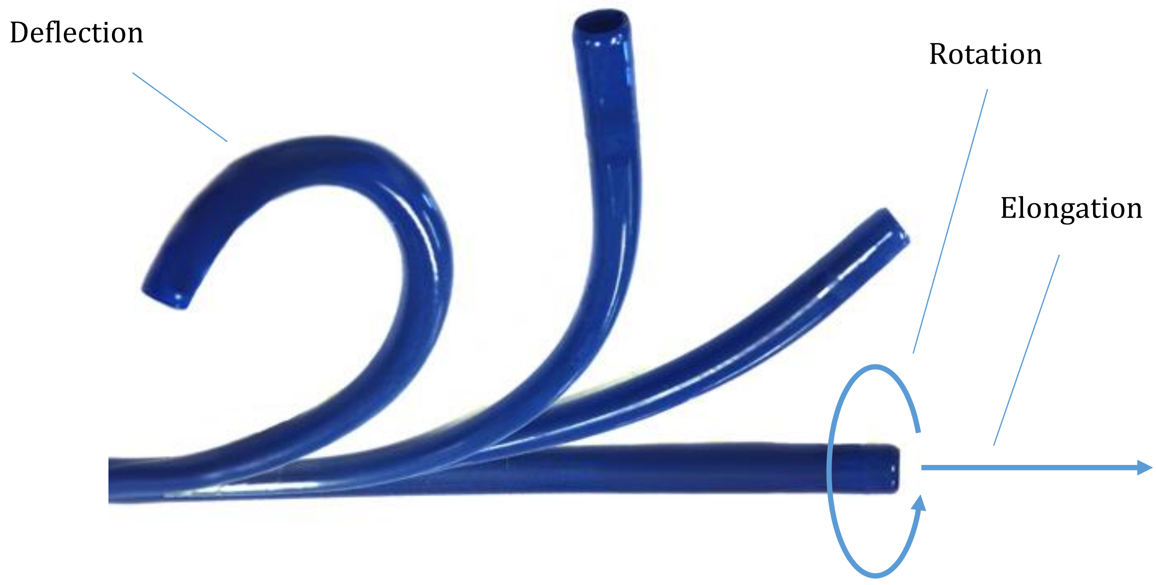


Figure 31: Illustration of deflection, rotation and elongation [39].

7.2 Catheter Structure

The catheter is build up as a multi-layer tube consisting of different materials to obtain the preferred properties. The following is a short review of the catheter's inner structure.

Braided/coiled inner diameter

To make the catheter kink-resistible, the inner catheter wall is build up with a coiled structure. The structure consist of braided wires made of 304 stainless steel of variable tempers or Nitinol. The wires can be either flat or round, see the figure below where the catheter has a flat-braided inner wire structure.

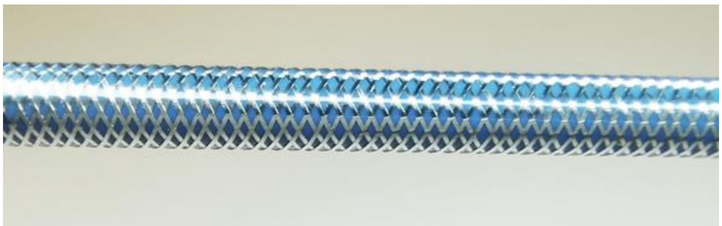


Figure 32: A catheter with a flat-braided catheter structure to make it kink-resistible [39].

The braided wall can be adopted by varying the pitch coils and varying the pick count braids. The design can then be changed along the catheter shaft, integrating multiple transition zones to achieve different stiffness characteristics [8]. A less stiff part of the catheter would bend easier, and in this way the catheter can be manipulated to bend on certain, preferred areas along its path.

Tubing design for Catheters

Surgical procedures become less and less invasive, and the medical devices need to be increasingly smaller. Creating miniaturized components for medical devices can be challenging, as micro-parts and micro-tubing cannot be produced using standard extrusion machines. Instead, this calls for micro-extrusion technology [26]. Micro-extrusion is a mainstay of medical device manufacturing which enables the extrusion of tubes with outer diameters down to the size of 150 μm [27]. A micro-extrusion system consists of the extruder, the die head, the sizing unit, the puller and the control unit. To meet the increasingly demand by medical device companies for thinner walls and tighter tolerances on tubing, in-line ultrasonic wall measurement gauges are essential for quality control. This provides a perfect melt, free of contaminants, gels and bubbles [26].

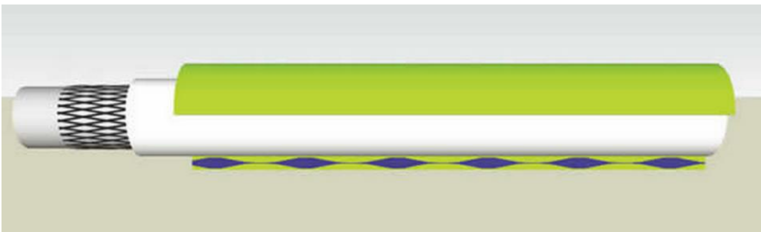


Figure 33: Illustration of the catheter, displaying the inner layers that it consists of [27].

7.3 Material Science

Material Science plays a significant role in medical technology. The last decades this field has undergone distinctive changes; from the use of inert structural materials to materials built for a specific function. Focus on material properties in technology research and development processes is necessary to optimize the material's capabilities.

Materials in Catheters

Selecting the raw material is the first step in manufacturing any micro-component. Micro-tubes can be made from polyurethane, nylons and high-temperature thermoplastics such as PEEK, PEI and FEP. Polyamides are preferred material because of their strength, and medical device manufacturers are also requesting more PEEK because of its ability to withstand heat [26].

Smart Materials

A material type that has this ability to adapt to the environment in which they are operating is classified as smart or intelligent materials. Smart materials have the intrinsic and extrinsic capabilities to respond to stimuli and environmental changes and to activate their functions according to these changes [28]. They are grouped into the following categories:

- ***Piezoelectric material***; convert electrical energy into mechanical strains. The piezoelectric material undergoes mechanical changes when electrical polarization is induced in the ceramic crystal, or vice versa. These materials is characterized by having complicated crystal structures with a low degree of symmetry, [29].

  The figure below shows how a wind power generator, which is build up by piezoelectric material, turns the flexing of an omnidirectional shaft directly into electricity. The piezoelectric structures (toroids) compress and stretch when the tube is flexed in any direction, converting any motion directly into electricity [38].

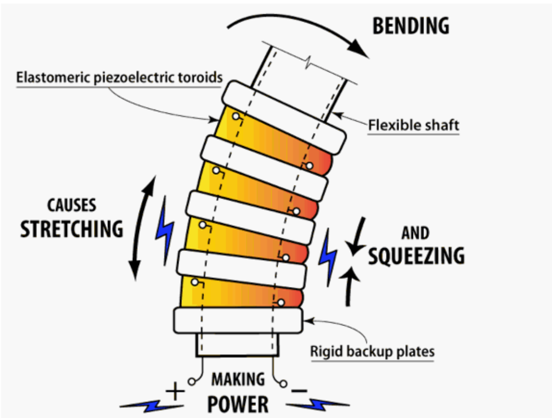


Figure 34: A solid-state wind power generator turns the flexing of an omnidirectional shaft directly into electricity, using piezoelectric material [38].

- ***Electrostrictive material***; convert electrical energy to mechanical change in the same way as piezoelectric. However, electrostrictive materials will always produce displacements in the same direction because the mechanical change is proportional to the square of the electric field.

- ***Optical fibers*** are flexible, transparent fibers that are used in fiber-optic communication, because it permits transmission over longer distances. The optical fiber is made of extremely high-purity silica, which must be free from contaminants [32].

- ***Shape Memory Alloys*** undergo phase transformations when they are placed under a certain temperature. This effect results from a reversible crystalline phase change known as martensitic transformation. When the alloy then is heated to its pre-memorized temperature, the material will attempt to recover to its austenitic original shape [30].
    - **Nitinol**, is a shape memory alloy that is frequently being used in medical equipment. Nitinol (NiTi) is a nickel-titanium alloy that distinguishes from other materials by its shape memory and super elastic characteristics [31]. Inserting Nitinol stents (small metal mesh tubes) in the arteries to treat narrow and weak arteries illustrates how the smart material properties of Nitinol are used to make the catheter insertion possible. The following list describes this procedure.
        1. In the start position, the stent is expanded and in its original shape (austenitic shape).
        2. The stent is cooled down and mechanically crushed into a smaller diameter (in its martensitic shape).
        3. The cold stent is inserted into a delivery system sheath (a catheter). When the catheter in inserted into the patient's body, the stent gets heated up, but is constrained and keeps its martensitic shape.
        4. During the delivery of the stent, the sheath is removed and the stent self-expands to the austenitic shape, with help from a balloon catheter.

The figure below shows a self-expanding Nitinol stent system, which ensures accurate and controlled deployment at the target site.

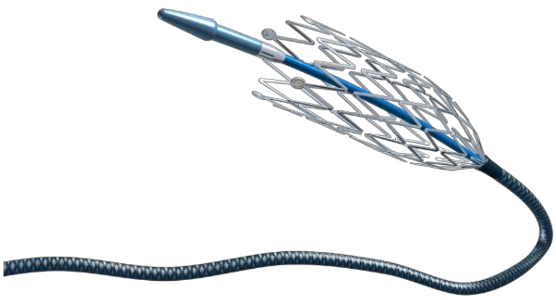


Figure 35: Self-Expanding Nitinol Stent System [36].

7.4 Soft robotics

Flexible, steerable catheters can be considered as a soft robot. Soft robots will consist of a flexible body that possess an ability to deform their shape as dictated by various environments [44]. The soft robotics is an emerging field that introduces a number of new challenges for the roboticists. One of the most challenging sides of soft robots is the soft actuator, since most conventional actuators consist of rigid component. Soft actuator, however, has the ability to deform along with the surrounding structure, which is necessary for the catheter.

One of these soft actuators is Nitinol, since its unique martensitic transformation makes it inherent flexible. The Nitinol crystal lattice transforms from the martensitic state to the austenite state and produces up to 4% length change as it is heated through the transition temperature range [44]. In order to create larger stroke lengths out of a small lattice structure alteration, Nitinol can be restructured into coil springs.

Figure 36: Illustration of a soft robot [54].

7.5 Shape Alternatives

The evaluation of different form- and esthetic alternatives falls in under the design phase of the development process. In this phase both the esthetically and the ergonomically requirements need to be taken into consideration.

The size plays a significant role in the shape evaluation for the catheter. The cardiovascular anatomy sets the limitations for the catheter shape and size, because the catheter tube needs to fit within the blood vessels and the heart chamber.

The three primary shapes are square, circle and triangle, which can be seen from the figure below. When it comes to design, it is being distinguished between organic and inorganic shapes. The organic shapes are associated with natural forms and emulates living thing, while inorganic shapes makes use of non-living things [33].

Organic design often has soft transitions and more details, as per inorganic design there is sharp edges, minimalism and simple structure.

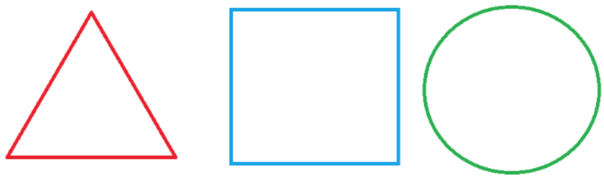


Figure 37: Illustration photo of the three primary shapes; triangle, square and circle.

For the catheter, it is necessary to choose an organic shape that can be moved within a patient's body. Soft edged and transitions is strictly required to prevent the catheter from inflicting injuries along its path inside of the patient. A flexible cylindrical catheter with a soft tip that would not cause any harm in conflict with the blood vessel walls is inevitable to maneuver the catheter.

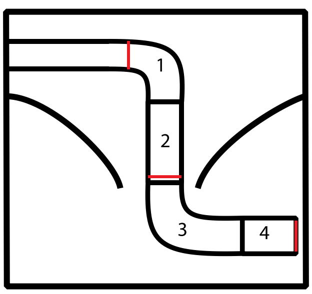
The outer shell of the catheter need to have a smooth surface roughness to avoid collection of blood and tissues along the catheter wall.

7.6 Main Concept

In this sub-chapter, the functional analysis is simplified and developed into a main concept for the catheter. This concept imply the catheter´s desirable functions. Below is a schematic illustration of these functions and a description of how they will interact to maneuver the steerable catheter.

The main concept is described first and then three sub concepts. In the figures below are the left heart chamber simplified and shown as a rectangle. This rectangle is divided into two chambers by the mitral valve, the upper and the lower chamber.

The main goal for the catheter is to be able to reach the rectangle wall anywhere on its inner surface. To obtain this goal, the catheter should be able to form an S-shape. Additionally, it should be able to rotate the distal end, and elongate segment 2 and 4 (see figure 17). The main concept can be divided into the following four operations;



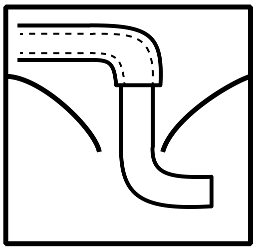
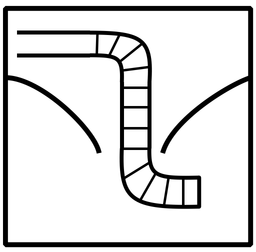
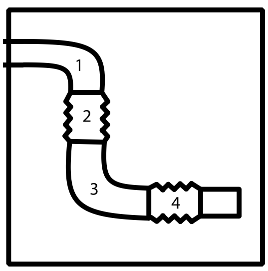
1. Bend
2. Elongate
3. Bend
4. Elongate

Figure 38: Illustration of the main concept, where the red line display the rotational areas.

The red line shows where the catheter should be able to rotate. Ideally, this should be a local rotation, meaning that only the part distal to the red lines is affected by the rotation. This gives the possibility to navigate in all three planes, additionally to rotation about all three axes. A docking station attaches the surgical device to the distal end of the whole catheter system, and it is therefore preferable to obtain local rotation in this area.

The number on the figure describes the different steps in the navigation of the catheter. These numbers are referred to in the table below, where three sub-concepts are listed to show how the main concept can be obtained.

Table 14: Description of the three alternative sub-concepts.

Illustration	Description
	**Catheter-in-catheter** **1.** The tip of the first catheter is deflected to reach the desired position. **2-3.** A second, inner catheter is introduced through the main lumen of the first catheter. Elongation (step 2) is obtained by pushing the inner catheter. When desired position is reached, the distal end of the inner catheter can be deflected. **4.** Another catheter is introduced to obtain the last elongation. Alternatively, a wire attached to the device can be used for elongation in the last step.
	**Follow the head technology** **1-4.** A single catheter is divided into several segments. When the distal segment of the catheter has reach desired position for a bend, the segment deflects. The catheter is then pushed in longitudinal direction. When segment nr 2 reaches the coordinates where segment 1 is deflected, it deflects exactly the same way as the first. This principle goes on until the last segment. When the head segment does a new direction change, the following segments copy that direction change at the exact same coordinates.
	**Deflection – telescope – deflection – telescope** This is a single catheter with the ability to deflect and telescope twice along its path to create an S-shape. **1.** The proximal deflection area of the catheter is deflected at first. **2.** A telescopic function elongates segment 2 **3.** The distal deflection area (segment 3) deflects. **4.** A telescopic function elongates segment 4.

These three sub-concept sets the basis for the brainstorming process in chapter 8.

8 CONCEPT DEVELOPMENT PROCESS

This chapter shows the brainstorming phase of the project. From the functional analysis, the maneuverability for the catheter was divided into three parts; deflection, elongation and rotation. These features are individually being considered and ideas for each of them are listed in the below tables. In addition, solutions for the operative force are considered in the first sub-chapter.

8.1 Alternatives for operative force

To develop a more precise maneuvering, it is necessary to consider the entire catheter's steerable mechanism. This mechanism is therefore divided into two parts: *the operative force* that provides the required force to operate the catheter and *the steering mechanism*, which operates at the target area to conduct the maneuvering. In the conventional catheters that used in today's minimally invasive procedures, the source is always located on the outside of the patient's body (at the proximal end of the catheter).

As described in chapter 1.3, the distance between the source and operational force implies several complications for the steering mechanism. Drag forces along the catheter path occur due to this distance and result in imprecise movements of the catheter tip. In addition, the drag forces makes it difficult to reach the desired target area where the operation shall take place.

To avoid these drag forces, one solution is to relocate the operational force closer to the distal end of the catheter. The operative force will then be located inside if the catheter, as the figure below illustrates. A decreased distance between the operative force and the steering mechanism opens up for a significant more precise catheter maneuverability. However, the diameter size on the catheter is a restriction that makes the relocation of the operative force challenging.

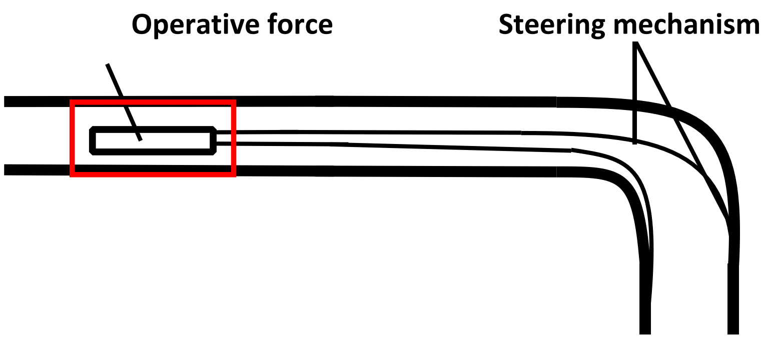


Figure 39: The source and the operative force in deflection.

The below list of alternatives for the operative force presents how the device that applies the forces can be designed to fit inside of the catheter at the distal end.

Table 15: Alternatives for the effecting force.

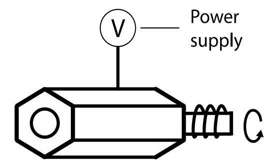
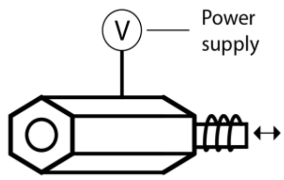
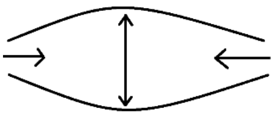
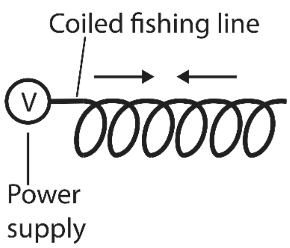
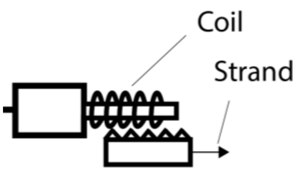
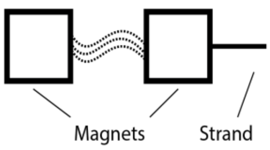
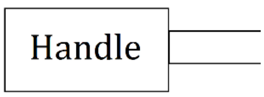
Illustration	Description	Pros	Cons
A - Rotating piezo motor 	A motor of piezo electrical material starts moving when voltage is supplied. This causes the threaded rod inside of the motor to rotate [55].	• Creates accurate steering from the proximal end of the catheter, without drag forces.	• Might not be strong enough to move the catheter.
B - Linear piezo motor 	A motor of piezo electric material starts moving when voltage is supplied. The motor starts to wiggle and causes a threaded rod to linearly move back and forth [55].	• Requires small space • Can be placed near to the impact • Extremely accurate	• The electric power might be too high •Temperature might be too high
C- Balloon as an artificial muscle 	A balloon is covered with a special woven mesh, which can only expand sideways, not in longitudinal direction. Since the volume of the balloon is prevented from expand in the longitudinal elongation, it has to compensate by moving the increasing volume sideways. Expansion of the balloon will therefor shortening of the whole system in longitudinal direction, appendix C.	• No use of hard materials. • Might provide great forces.	• Might take up too much space in a catheter. • Inaccurate.
D - Coiled fishing line 	A fish line loaded with weight is twirled until it coils. When heated, either by electricity or a heat source, the space between each coil decreases. This results in a contraction and the fishing line applies a force to the wire/strand it is connected to. When cooled again, the contraction releases, see appendix C.	• A simple mechanism • Takes up a small area • Strong compared to its size • A cheap solution	• Might require too much electric power, which can disturb the heart function. • Might operate in too high temperature

Table 16 continues.

Illustration	Description	Pros	Cons
E- Electric rotational motor 	An electric rotating motor with a threaded shaft. This shaft rests on/ is connected to a block, which have triangular slots across the longitudinal direction. This design makes the block move back and forth.	• Can obtain an accurate motion depending on the thread pitch. • Mechanical and precise transmission.	• Electric rotational motors require a certain amount of space.
F - Magnets 	Electro active magnets moves back and forth by changing their magnetic strength. The movement this causes pulls in a strand that is attached to one of the magnets.	• Potentially space saving • Can be placed near the impact. • Tension free when introduced.	• Difficult to get accurate enough. • Can be disrupted by other magnetic devices in the operating theatre.
G - Manual power transmission/ Handle 	Conventional catheters are being maneuvered by the surgeon manually rotating the handle at the proximal end of the catheter, outside of the patient.	• Like-for-like movements. • Conventional method.	• Inaccurate movements. • Drag forces occur.

The pros and cons for the alternatives listed in the table above will be taken into consideration and evaluated in the concept screening in the next chapter.

8.2 Feature Options for the steering mechanism

The three movements for the catheter is elongation (movement in the longitudinal direction), deflection (to bend the catheter tip) and rotation of the catheter tip. Alternative solutions for each of them are listed and given a short evaluation in this chapter.

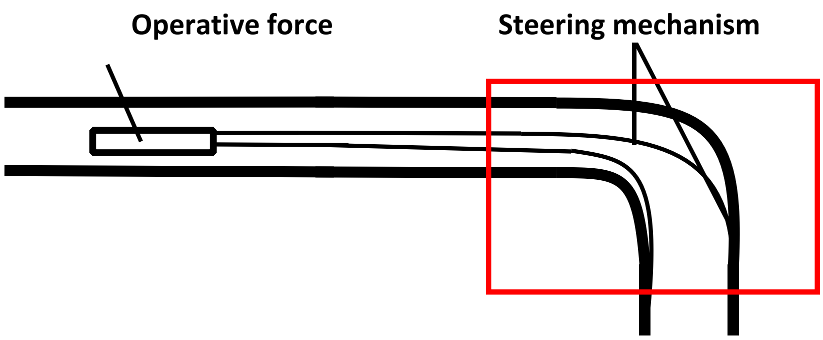


Figure 40: Alternatives for the steering mechanism (deflection, elongation, rotation) is listed in this chapter.

8.2.1 Deflection alternatives

As describes earlier in this chapter, the aim has been to relocate the operative force closer to the distal end of the catheter. By doing this, it will open up for a wide range of new alternatives for how to deflect the distal end of the catheter. This chapter is a result of the brainstorming that has been conducted looking at the deflecting movement of the catheter isolated.

In the table below, are the different alternatives for how to conduct a deflection. An evaluation of each of them is given the two columns to the right in the table.

Table 16: Deflection alternatives.

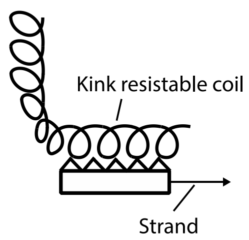
Illustration	Description	Pros	Cons
A - Rotational coil spring 	Twisting the coil at the proximal end will make the block with slots move back and forth, depending of which way the spring is turned.	• Can relocate the pulling and pushing force closer to the proximal end.	• If the coil passes several turns in alternating planes, concerning the tension on drag forces against the catheter wall, twisting it will be difficult and inaccurate.

Table 17 continues.

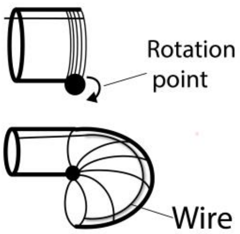
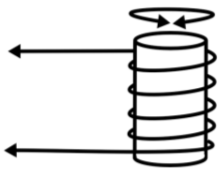
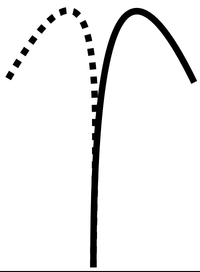
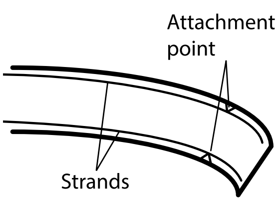
Illustration	Description	Pros	Cons
B - Flexible ventilation hose 	A coil-formed wire is covered with a flexible material. A wire is attached along the upper section of the wall and anchored at the tip of the tube to move the tunnel. The two ends of the tube are connected at the lower end. When the wire is pushed, the tube will form a 180-degree turn, without collapsing.	• Potentially need less longitudinal space when deflecting. • Can make tight turns • Flexible construction	• Material between the coil folds when pulled together and steels space from the inner diameter of the catheter. • Rigid devices with a length longer than the diameter of the catheter will be difficult to transport through the deflected turn.
C - Rotation rod 	Two strands are coiled around each end of a rod. The rod will rotate in two direction, depending on which stand that is pulled. Combined with other ideas this principle can help changing direction of something, see appendix C.	• Only requires pull motion. • Can be controlled from a distance.	• Could be difficult to place in a tube shape without stealing too much of the inner diameter.
D - Pre-tensioned hose 	The catheter is pre-stressed to a deflected position. By pulling a strand attached to the catheter tip, the catheter will deflect in the opposite way of the pre stressed way.	• Only need one strand or wire for full deflection in each plane.	• Requires relatively high force to deflect it from tension state to the opposite side.
E - Conventional pulleys 	Strands attached to the catheter tip and carried in lumens from there until the source. By pulling the strands, the catheter tip will deflect in different planes.	• Mechanical • Concept proved • A cheap solution	• If it follows several turns in a long path, drag forces will affect it.

Table 17 continues.

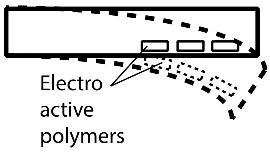
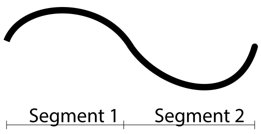
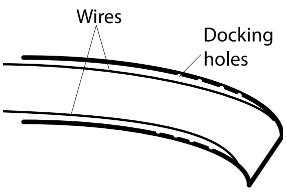
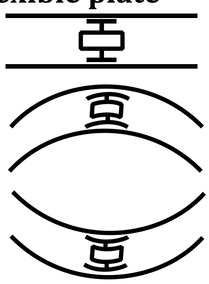
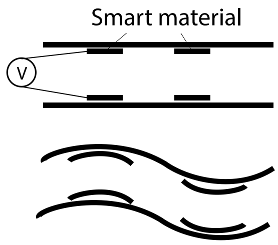
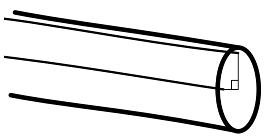
Illustration	Description	Pros	Cons
F - Electro active polymers 	Plates of electro active polymers are connected to electric power. Electricity makes the plates deflect in different degrees.	• Relatively small. • Can be integrated in the catheter wall. • No wires or cables, besides electrical cables, are necessary.	• Temperature and voltage could be too high (has to be investigated) • Challenging to freeze the polymers in a temporary state.
G - Multiple memory shape 	A wire with different alloys in different segments. Each alloy has its own activation temperature. This way, the wire will gradually deflect.	• Can be deflected gradually.	• Can be difficult to get accurate enough.
H - Multi-attachable wire 	A wire can be attached to different "docking holes" along the longitudinal direction inside of the catheter wall. In these holes, the wire can be fastened, and by pulling/pushing the wire, it will get the catheter to bend in different directions. Then, by unlocking the wires from the attached tracks, the wire can be moved to another docking position along the catheter wall and attached there, to make a new deflection.	• The attach point for the wires can be changed, and this gives the opportunity to deflect the catheter at several places without the need for more strands. • This use of wires to deflect the catheter is a conventional and approved method.	• When one deflection is carried out, it will be necessary to change the coordinates of the bended part if the catheter needs to reach further in the longitudinal direction.
I - Pistons with flexible plate 	Two pistons with a flexible plate at its distal ends. When the upper piston is moves upwards, the lower piston is retracted.	• Can make an S-shaped movement.	• Might not work. Needs to be tested.

Table 17 continues.

Illustration	Description	Pros	Cons
J – Shape memory alloys 	Plates of smart material (ex. Nitinol) are integrated in the wall of the hose. The amount and direction of deflection can be controlled by electric power. When the smart material is deflected, the hose will adapt this shape.	• Few parts • No drag force because of turns. • Ability to make an s-shape • Can be remotely steerable.	• The smart material is probably not strong enough to deflect the hose and resist external forces.
K - Perpendicular wires 	Two wires are placed 90 degrees relative to each other, seen from a cross-sectional view of the catheter profile. The wires can both be pushed and pulled. Combination of different push/pull states gives deflection opportunities in all three dimensions.	• Requires few parts, only two wires. • 1:1 motion transmission (makes the steering natural)	• 1:1 motion transmission (makes it inaccurate) • Tension and drag forces along the catheter.

The pros and cons for the alternatives listed in the table above will be taken into consideration and evaluated in the concept screening in the next chapter.

8.2.2 Elongation alternatives

Considering the elongating movement of the catheter, the purpose is to investigate how the catheter can be extended from a certain point along the catheter path. The reason why this movement is necessary is due to the fact that a bend on the catheter will cause the whole bended part of the catheter to move in the previous longitudinal direction, instead of the required extension of the catheter tip, see the illustration below. Movement 1 shows the actual movement when the catheter is being pushed as the arrow is implicating. Movement 2 shows the desirable longitudinal movement of the catheter.

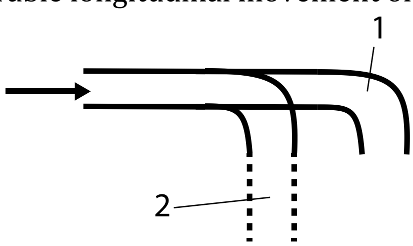


Figure 41: Movement of a catheter when it is pushed in longitudinal direction, 1 shows actual movement and 2 shows the desired movement.

In the table below, are the different alternatives for how to conduct a longitudinal movement for a catheter. An evaluation of each of them is given to the right in the table.

Table 17: Elongation alternatives.

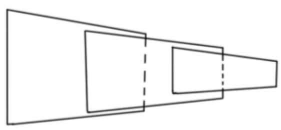
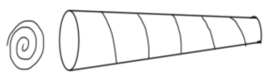
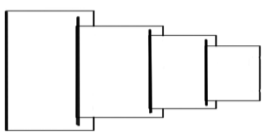
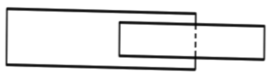
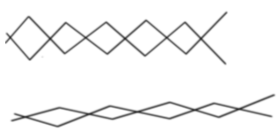
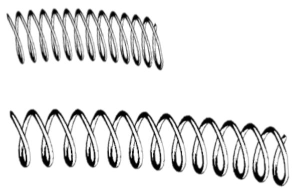
Illustration	Description	Pros	Cons
A – Telescope 	A traditionally telescope with conical cylinders placed in layers under each other, makes the elongating motion by pulling the inner cylinder. The rest of the layers follow the inner cylinder because the cylinders are formed to be conical.	• Simple method. • Creates a tight catheter wall when it is extended.	• Cannot be locked halfway. • Unstable when not completely extended. • Difficult to contract.
B – Telescope spira 	Paper rolled together to form a spiral. Pulling the inner end of the paper, while slightly rotate it, will elongate the spiral.	• Simple concept. • Relatively strong.	• Both longitudinal and rotational motion is required.
C - Hydraulic Piston 	Traditional hydraulic piston concept. Chambers are filled with liquid and the pistons are pushed upwards, one by one.	• Strong • Only one axis motion is required. • Liquid is easy to transport through turns along a path.	• Many parts. • Inaccurate. • Require double motion technology
D - Pipe in pipe 	Pipe in pipe concept. The main pipe is "elongated" by pushing another pipe out of it.	• Simple • Flexible	• Inaccurate from long distance.
E – Smart mesh 	Compressing it sideway elongates the mesh construction. Smart material like nitinol operated with electric power can be used for this.	• Can potentially be accurate if operated with electric power.	• Can be difficult to stop it in the desired position. • Might not be strong enough keep it stable.

Table 18 continues.

Illustration	Description	Pros	Cons
F – Coil spring 	Can be elongated by pulling it or release the tension of a compressed coil. This motion can be operated with electric power if a smart material makes the coil.	• No drag force if operated with electric power.	• Can deform sideways. • A certain tension is required to avoid collapsing.

The pros and cons for the alternatives listed in the table above will be taken into consideration and evaluated in the concept screening in the next chapter.

8.2.3 Rotational alternatives

Considering the rotation of a catheter tip, the issue is to manage to rotate the tip from a distance without rotating the entire catheter. When rotating the catheter manually from the proximal end, drag forces along the catheter path leads to an imprecise rotation at the catheter tip. Issues to consider in this case include the space restriction in the catheter, how to locate the rotational force in the tip of the catheter etc.

In the table below, are the different alternatives for how to implement the rotation of the catheter tip. An evaluation of each of them is given to the right in the table.

Table 18: Rotating alternatives.

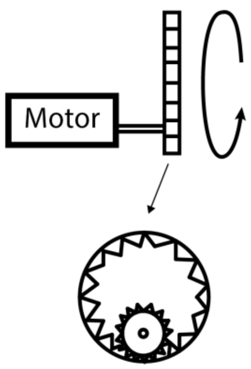
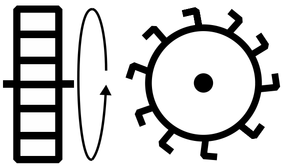
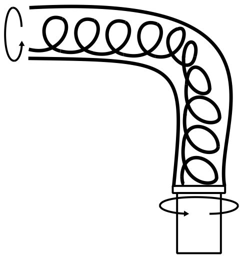
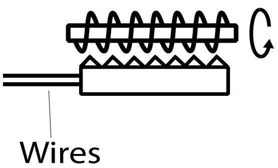
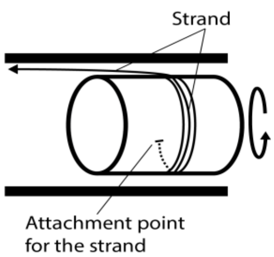
Illustration	Description	Pros	Cons
A – Gears 	A motor is connected to a gear with inside teeth, which is connected to a segment of the catheter. This provides a local rotation.	• Accurate • The rotating force is applied near to the impact, which reduce drag forces.	• Rotating motors might require too much space.

Table 19 continues.

Illustration	Description	Pros	Cons
B – Water wheel 	Pouring water on a wheel with blades or buckets outside will cause it to rotate.	• No drag forces along the catheter's path.	•Inaccurate
C – Coil spring 	A coiled spring in a tube. Rotation in proximal end of the coil results in a rotation at the distal end, maintaining the center of the coil and the center of rotation as the same point, even if the tube deflects at several places.	• Simple principle • Can rotate when deflected, without loosing its coordinates.	• If the load is too heavy, the coil will build up torsional stress, and start bending.
D – Wire and coil 	A wire is connected to a block with extruded triangular tracks, transverse to the longitudinal direction. The tracks are connect to a threaded rod, which starts to rotate when the block is moved back and forth. The rod is connected to the catheter via gears, and catheter rotates.	• The force can be generated close to the impact.	• Might demand a high force to
E – Strand in a track 	A strand is placed in a track around a rotational part of the catheter. This strand is then locked in a position on the catheter, so it will rotate as the strand is pulled in one direction.	• Transform longitudinal motion into rotation • Can rotate the catheter tip from the proximal end.	• Need to have an independent part of the catheter to make it rotate separately.

The pros and cons for the alternatives listed in the table above will be taken into consideration and evaluated in the concept screening in the next chapter.

9 CONCEPT SCREENING

The alternatives listed in the previous chapter is evaluated and rated in a concept-screening phase, which is described in this chapter. The chapter includes the development of the decision-matrix, the entire screening and the preferred alternatives that comes out as the result of the screening.

9.1 Development of the decision-matrix

Pugh's method is used to screen the concepts and make an evaluation based on a weighted score for each concept alternative. The method is putting the options up against each other and comparing them using a standard benchmark. A number of benchmarks or criteria are thereby chosen in advance of the screening phase, and the options are given a score for each of the benchmarks.

The concept screening process contains the following steps:

1. Prepare the selection matrix (choose criteria and weight them)
2. Give the concepts a score for each criteria
3. Calculate a weighted score sum for each concept
4. Select the concepts with the best scores
5. Evaluate the results of the screening

Point scale

The concepts are given points from 1 to 6, where 6 is given when the feature meets the criteria extremely good and 1 is given when the feature meets the criteria worse than datum. The features get one score for each selection criteria and from there it will be calculated a weighted score sum, depending on how the criteria are valued for the respective feature.

Criteria

The alternatives will be evaluated based on the following four criteria: complexity, accuracy, flexibility and compatibility. A description of them and how they are evaluated is given below.

- **Complexity – weighted 10 %**

  How complex the structure of the respective alternative is. This is a composed criterion, including the number of parts the solution contains, how the structure is build up, etc. Since the complexity is considered a negative property, a system with low complexity gives a high score and opposite.

- **Flexibility – weighted 40 %**

How flexible the catheter is regarding movements in three dimensions, including the possibility to obtain an S-shaped movement. The proportion of the left heart chamber that can be reached by the catheter tip.

- **Accuracy – weighted 30%**

How accurate the catheter can be maneuvered with use of the respective alternative. How close can the catheter tip be placed to the target area.

- **Compatibility - weighted 20%**

This evaluates how compatible the alternatives are across all of the categories; deflection, rotation and elongation. An alternative that is easy to combine with alternatives from another category is given a high score because this provides the solution with a positive feature.

The criteria will however have a specific meaning for the each of the categories, and a description of each screening process is given in the next chapter.

9.2 Screening of possible solutions

In this chapter follows a detailed screening for each of the feature alternatives; operative forces, deflection, elongation and rotation.

9.2.1 Screening of operative forces

A description of how the four criteria are being evaluated considered the alternatives for the operative force is given below.

- **Complexity – weighted 10 %**

The number of parts that the system consist of makes it more complex, or if the system requires voltage to function.

- **Flexibility – weighted 40 %**

How flexible the operative device is due to the types of movement it can provide.

- **Accuracy – weighted 30 %**

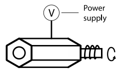
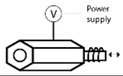
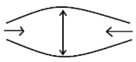
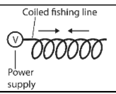
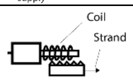
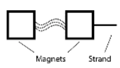
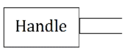
How precise movements or forces that can be provided by the operative force.

- **Compatibility – weighted 20 %**

How easily it is can be connected to the steering mechanisms to provide the power transmission.

The table on the next page shows the result from the screening, which is the average scores from our individual screening.

Table 19: Screening of operative forces.

Screening of operative forces										
		Complexity		**Flexibility**		**Accuracy**		**Compatibility**		**Weighted SUM**
	Weighting	10 %		40 %		30 %		20 %		
	Sketch	S	WS	S	WS	S	WS	S	WS	
A		5	0,5	5	2	5,5	1,65	4	0,8	4,95
B		4	0,4	5	2	6	1,8	4,5	0,9	5,1
C		3,5	0,3	3,5	1,6	2,5	1,05	3,5	0,6	3,55
D		3	0,3	4	1,6	3	0,9	4	0,8	3,6
E		3	0,3	4	1,6	5	1,5	4,5	0,9	4,3
F		3	0,3	4	1,6	3	0,9	3	0,6	3,4
G		5	0,5	4	1,6	4	1,2	4	0,8	4,1

*S = score and WS = weighted score

It comes from the screening of the alternatives for the operating force that the solution with linear and rotational piezo motor, are the two best solutions. They will be considered in the next chapter, to see if they can be adopted to the concept.

9.2.2 Screening of deflection alternatives

A description of how the four criteria are being considered with regards to the deflection alternatives is given below.

- **Complexity – weighted 10 %**

How complex the system to deflect the catheter is. The number of parts that the system consists of makes it more complex, or if the system requires voltage to function.

- **Flexibility – weighted 40 %**

How flexible the catheter is with regards to movement in more than one plane, S-shaped movement etc. How bendable the catheter is using the respective system.

- **Accuracy – weighted 30 %**

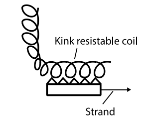
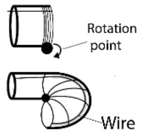
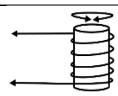
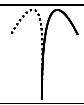
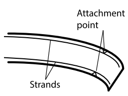
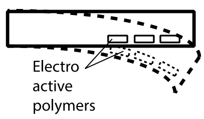
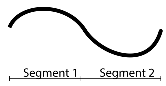
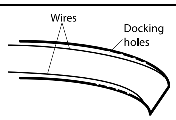
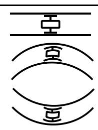
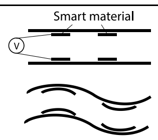
How precise the catheter tip can be deflected.

- **Compatibility – weighted 20 %**

How easily it can be combined with the alternatives from rotation and elongation categories.

The table below shows the result from the screening, which is the average scores from our individual screening.

Table 20: Screening of deflection alternatives.

Deflection screening										
		Complexity		**Flexibility**		**Accuracy**		**Compatibility**		**Weighted SUM**
	Weighting	10 %		40 %		30 %		20 %		
	Sketch	S	WS	S	WS	S	WS	S	WS	
A		4,0	0,4	4,0	1,6	3,5	1,1	3,5	0,7	3,5
B		4,0	0,4	4,0	1,6	3,5	1,1	4,5	0,9	3,5
C		4,5	0,5	3,5	1,4	4,0	1,2	4,5	0,9	3,5
D		5,0	0,5	3,5	1,4	3,5	1,1	4,0	0,8	3,4
E		5,0	0,5	4,0	1,6	3,5	1,1	4,5	0,9	3,6
F		3,5	0,4	5,5	2,2	5,0	1,5	4,0	0,8	4,6
G		2,0	0,2	4,5	1,8	4,0	1,2	4,0	0,8	3,7
H		4,5	0,5	4,5	1,8	4,5	1,4	4,0	0,8	4,0
I		3,0	0,3	3,5	1,4	3,0	0,9	2,5	0,5	3,0
J		4,0	0,4	4,5	1,8	4,0	1,2	4,5	0,9	3,9
K		6,0	0,6	5,0	2,0	5,0	1,5	5,0	1,0	4,6

*S = score and WS = weighted score

It comes from the screening of the deflection alternatives that the solution with electro active polymers and the solution with perpendicular wires attached to a ring, are the two best solutions. They will be considered in the next chapter, to see if they can be adopted to the concept.

9.2.3 Screening of rotation alternatives

A description of how the four criteria are being considered with regards to the rotation alternatives is given below.

- **Complexity – weighted 30 %**

How complex the system to rotate the catheter is. The number of parts the system consist of makes it more complex, or if the system requires voltage to function.

- **Flexibility – weighted 40 %**

How flexible the catheter is, regarding movement in more than one plane, S-shaped movement etc. How bendable the catheter is, using the respective system.

- **Accuracy – weighted 30 %**

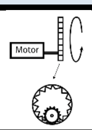
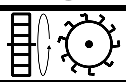
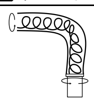
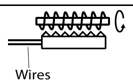
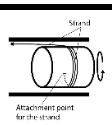
How precise the distal end of the catheter can rotate.

- **Compatibility**

How easily the rotation alternative is combined with the alternatives from deflection and elongation categories.

The table below shows the result from the screening, which is the average scores from our individual screening.

Table 21: Screening of rotation alternatives.

Rotation screening											
		Complexity		**Flexibility**		**Accuracy**		**Compatibility**		**Weighted SUM**
	Weighting	10 %		40 %		30 %		20 %		
	Sketch	S	WS	S	WS	S	WS	S	WS	
A		4,0	0,4	5,5	2,2	5,0	1,5	3,0	0,6	4,7
B		3,5	0,4	3,0	1,2	1,5	0,5	1,5	0,3	2,3
C		5,0	0,5	5,0	2,0	4,0	1,2	4,5	0,9	4,6
D		3,5	0,4	4,0	1,6	4,5	1,4	4,0	0,8	4,1
E		4,5	0,5	5,5	2,2	5,0	1,5	4,5	0,9	5,1

*S = score and WS = weighted score

It comes from the screening of the rotational alternatives that the solution with gears that are connected to a rotational motor and the solution with strands that make an inner catheter rotate are the two best solutions. They will be considered in the next chapter, to see if they can be adopted to the concept.

9.2.4 Screening of elongation alternatives

A description of how the four criteria are being considered with regards to the rotation alternatives is given below.

- **Complexity – weighted**

How complex the elongation system is. The number of parts included in the system.

- **Accuracy – weighted**

How accurate the catheter can be elongated.

- **Flexibility – weighted**

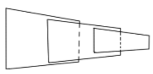
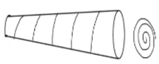
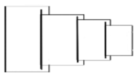
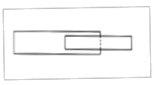
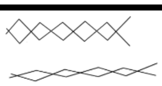
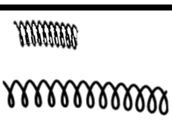
How flexible the elongation function is, regarding how long it can be elongated compare to how much space it demands when longitudinal folded or retracted.

- **Compatibility – weighted**

How easily it is combined with the alternatives from deflection and rotation categories.

The table below shows the result from the screening, which is the average scores from our individual screening.

Table 22: Screening of elongation alternatives.

Elongate screening										
		Complexity		**Flexibility**		**Accuracy**		**Compatibity**		**Weighted SUM**
	Weighting	10 %		40 %		30 %		20 %		
	Sketch	S	WS	S	WS	S	WS	S	WS	
A		4,0	0,4	3,0	1,2	3,5	1,1	2,5	0,5	3,2
B		4,5	0,5	4,0	1,6	4,0	1,2	4,0	0,8	4,1
C		3,5	0,4	4,5	1,8	3,5	1,1	3,0	0,6	3,8
D		6,0	0,6	4,0	1,6	5,5	1,7	5,0	1,0	4,9
E		3,5	0,4	4,5	1,8	4,5	1,4	3,0	0,6	4,1
F		5,0	0,5	5,0	2,0	4,5	1,4	5,0	1,0	4,9

*S = score and WS = weighted score

It comes from the screening of the elongation alternatives that the solution with a catheter in a catheter and the solution a coil that can be extended and contracted, are the two best solutions. They will be considered in the next chapter, to see if they can be adopted to the concept.

9.3 Preferred Alternatives

The alternatives that obtained the highest scores under the concept-screening phase are listed in the tables below. The tables gives an explanation of why the alternatives are chosen and how they can function as a combined system with other alternatives.

For the deflection alternatives, the three alternatives with the highest score are selected and brought to the next stage in the development phase.

Table 23: Top three alternatives for the operative force.

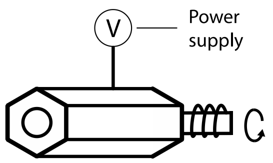
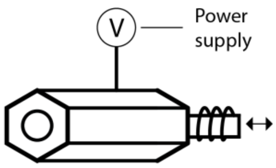
Illustration	Description
	The ***rotational piezo electric*** motor is chosen because it is a small motor that can transfer relative high power transmission for its small size. The rotation can be stopped in extremely accurate positions.
	The ***linear piezo electric motor*** is chosen because it can obtain very high degree of accuracy and take up a relatively small amount of space. A strand or wire is attached to the rod of the motor, so that the strand can be pulled.

Table 24: Two system alternatives for deflection are selected.

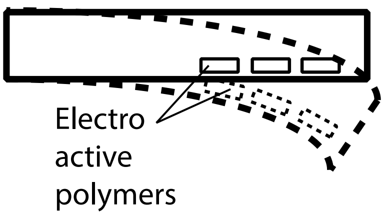
Illustration	Description
	The ***perpendicular wires*** is chosen because it is a simple and an effective method for deflecting a tube. The two wires are pushed and pulled to maneuver the bend of the catheter. It requires a minimum number of wires to be able to deflect the catheter tip in three planes.
	***Electro active polymers*** places along the inside of the catheter would give it an automatically steering and make it easier to control the movement. The polymers are supplied with voltage and bended a certain number of degrees depending on how much voltage that is supplied.

Table 25: Two system alternatives for rotation are selected.

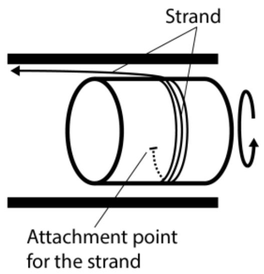
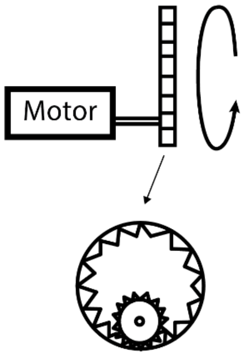
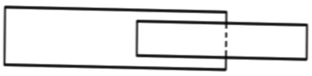
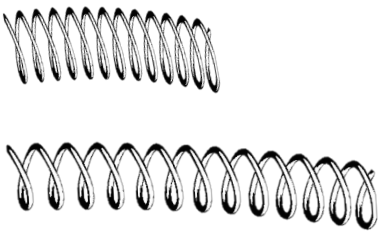
Illustration	Description
	The solution with ***two strands in a track*** has the advantage of obtaining a great accuracy. Due to a certain drag displacement in the strand, the inner tube will rotate the corresponding displacement. This requires however an independent inner tube in the catheter, so that it can rotate independently from the catheter.
	The solution with ***gears***, is chosen because it can implement an extremely accurate rotation of the catheter tip if it is compatible with a motor of the required small size. It can implement local rotation at the distal end by connecting the independent distal end to the outer gear, which will make the catheter to rotate.

Table 26: Two system alternatives for elongation are selected.

Illustration	Description
	***Catheter in a catheter*** is a simple and easy-to-use principle that can obtain a displacement in the longitudinal direction. It can be combined with different sources or it can have a manually steering from the proximal end of the catheter. The inner catheter can have outer threads, so that it can be more accurate. Additionally, the threads will make it possible to "freeze" the catheter in any longitudinal position.
	A ***coil spring*** comes with several advantages. It can be compressed into a short longitudinal length, and likewise, elongated to long longitudinal length. This space saving function is beneficial in the given circumstances inside of the heart. A coil spring made of smart material can change shape in this manner, by adding voltage to cause temperature changes. Coated with a flexible material, this can be a part of the steerable catheter.

10 CONCRETIZATION OF SOLUTIONS

This chapter reflects how the concept development took place after the concept screening was conducted and finalized. This phase involves testing and evaluation of various solutions through 3D drawings in SolidWorks, as well as discussion of possible combination of solutions.

10.1 First concept

The selected solutions based on the screening, assembled to form the desired concept for controllability of the catheter. This concept entails that the catheter can deflect in one direction, and that the entire curvature can rotate by means of a rotary mechanism. This allows the catheter to achieve omnidirectional rotation.

The concept is selected because the catheter thus only needs one wire to deflect. A spring made of a shape memory alloy, such as Nitinol, is located at the distal end between the rotational coil spring and the surgical instrument. This provide elongated movement of the surgical device.

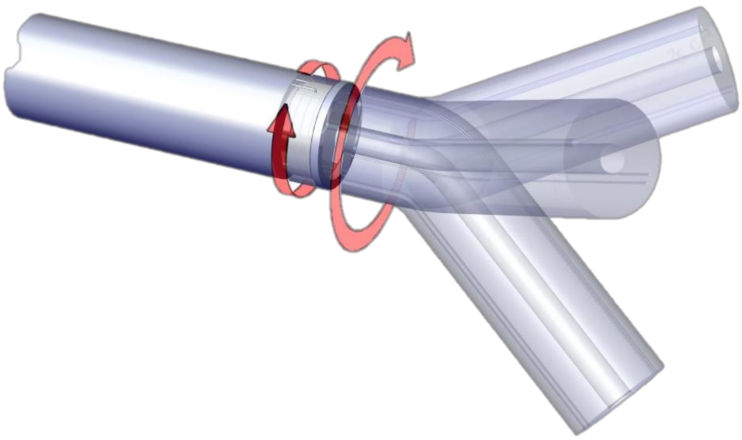


Figure 42: The figure illustrates the first concept where the deflection on the distal end can be rotated to reach all the desired positions with the tip of the catheter.

In the following, a more detailed description of all of the components that constitute the concept is given.

The components are:

1. Wire that provides deflection
2. Rotation device:
    a. Rotation with gears
    b. Rotation with strands
3. Elongating coil spring

1. Wire that provides deflection

A ring is attached to the distal end of the catheter and the wire is connected to this ring. The constructed mate constrains movement in the longitudinal direction. As a result, pushing or pulling the wire forces the catheter to deflect. The catheter wall has a built-in coil spring, which determines where the deflection will occur. By having larger and smaller distances between the springs, the catheter create respectively sharper and gentler deflections, see figure below.

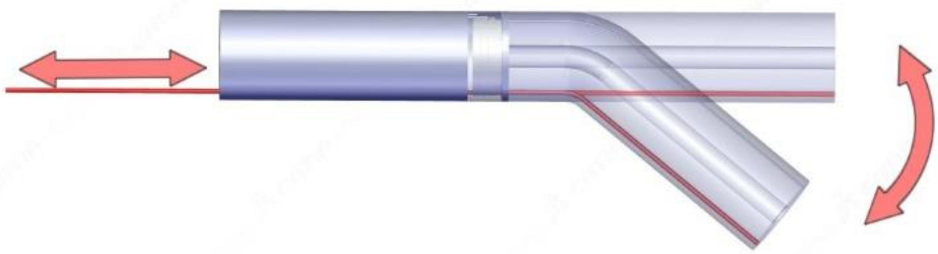


Figure 43: The wire (marked as a red line) controls the deflection. When its pushed to the right in the figure the catheter deflect, and it goes back to its original form by pulling the wires to the left again.

2. The two rotation principles

Both of the rotational principles that scored the best in the concept screening are considered in this chapter. The reason is because both of them can provide precise remote rotation of an independent part of the catheter. Below is a more detailed description of the two principles for rotation.

a. Rotation with gears

A micro motor transmits torque to a driving spur gear, which in turn transfers torque to a larger spur gear positioned centered in the catheter. The entire gear system allows the catheter on both sides of the rotation mechanism to rotate independently. The gear types are spur gears or straight cut gears, which is a simple type of gear, consisting of a disk with the teeth projecting radially. The edge of each tooth is straight and aligned parallel to the axis of rotation.

The following procedure is the calculation of the gear system:

Assuming a gear system where gear 1 is a planet gear with pitch diameter D_1 and Z_1 number of teeth. Gear 2 is the smaller gear with pitch diameter D_2 and Z_2 number of teeth, which surrounds gear 1. C is the average diameter, which is the distance between the two gear shafts.

Following calculations have been conducted to decide the sizes for the gear system. Given the following formula from the Spur Gears Formula table in Abbreviations.

(1) $$C = \frac{D_1+D_2}{2} = \frac{m}{2}(Z_1 + Z_2)$$

Gear 1 is placed centered in the catheter, while four gears of gear 2 is placed around, like an epicyclical gearing system where only one of the surrounding gears are driving. The other gears are placed to stabilize the planet gear in the middle, gear 1. Since the outer diameter of the entire gear system has a limit of 7 mm, the following equation can be applied.

$$2 * \left(C + \frac{D_{O2}}{2}\right) \leq 7\,mm \rightarrow C + \frac{D_{O2}}{2} \leq 3{,}5\,mm$$

Where

$$D_{O2} = m * (Z_2 + 2)\ and\ \ C = \frac{m}{2} * (Z_1 + Z_2)$$

This gives

$$\frac{m}{2} * (Z_1 + Z_2) + \frac{m}{2} * (Z_2 + 2) \leq 3{,}5\,mm$$

$$\frac{m}{2} * (Z_1 + 2Z_2 + 2) \leq 3{,}5\,mm$$

The number of teeth are chosen from table 7 in *Terminology*, $Z_2 = 16$ and $Z_1 = 101$, which gives m equal to:

$$m = \frac{7}{101 + 34} = 0{,}05185\,mm$$

The pitch diameters can then be calculated:

$D_1 = m * Z_1 = 5{,}24\,mm$

$D_2 = m * Z_2 = 0{,}83\,mm$

The gear ratio is: $u = \frac{Z_2}{Z_1} = \frac{16}{101} = 0{,}16$

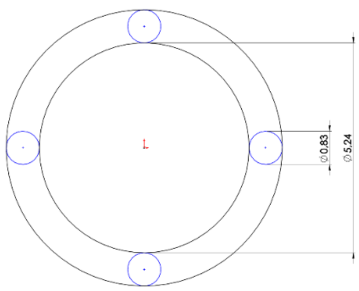


Figure 44: The sketch shows the size of the gears D_1 = 0,83 mm and D_2 = 5,24.

The rotational mechanism with gear is illustrated in the 3D drawing below, where one of the small gears has a longer shaft so it can be connected to a micro motor which transfers torque to it.

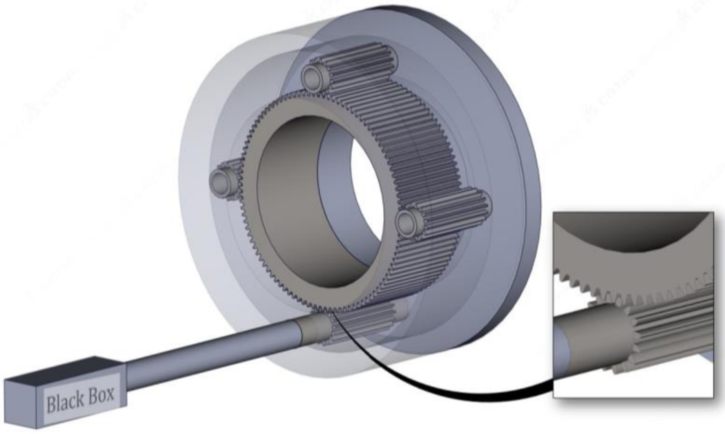


Figure 45: 3D drawing of the rotation with gears.

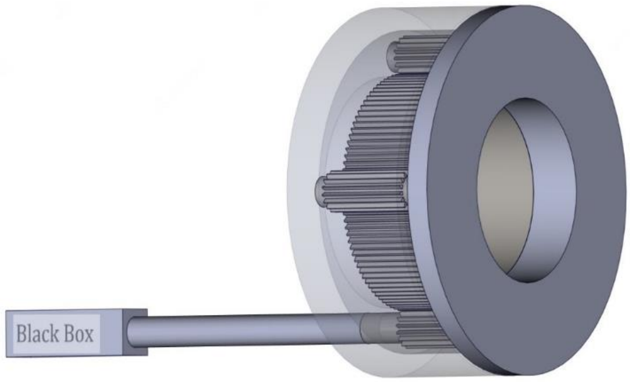


Figure 46: a) The rotation mechanism with gears.

The planet gear will have an extruded part on the distal side, which may be welded onto the distal part of the catheter. See a drawing of the planet gear, showing this feature, below.

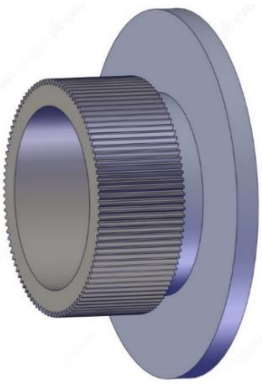


Figure 47: The planet gear with an extruded part where the distal part of the catheter can be fastened.

b. Rotation with threads

Two strands are attached to two independent tracks on a cylinder, which is protected and locked inside of a reel, as illustrated in the figure below.

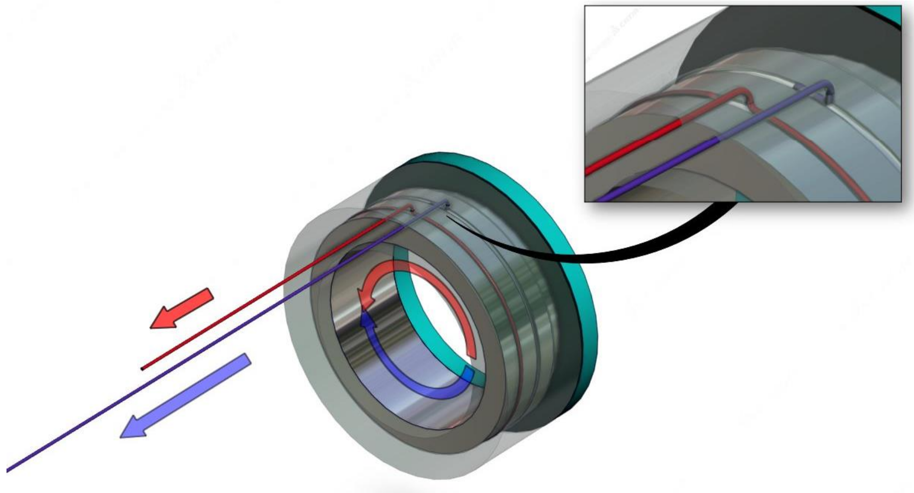


Figure 48: Rotation with strands, where the arrows show how the directions of the strands corresponds to the rotation of the reel.

The reel consist of an inner and an outer case, where two strands are attached to two holes on the inner case of the reel. This provides a rotation on the inner case when one of the strands are pulled, as shown in the figure above. The advantage of this solution is that it can both be applied using conventional techniques, where the rotation is controlled from a handle at the proximal end of the catheter, or that it can be controlled by a micro motor in the distal end.

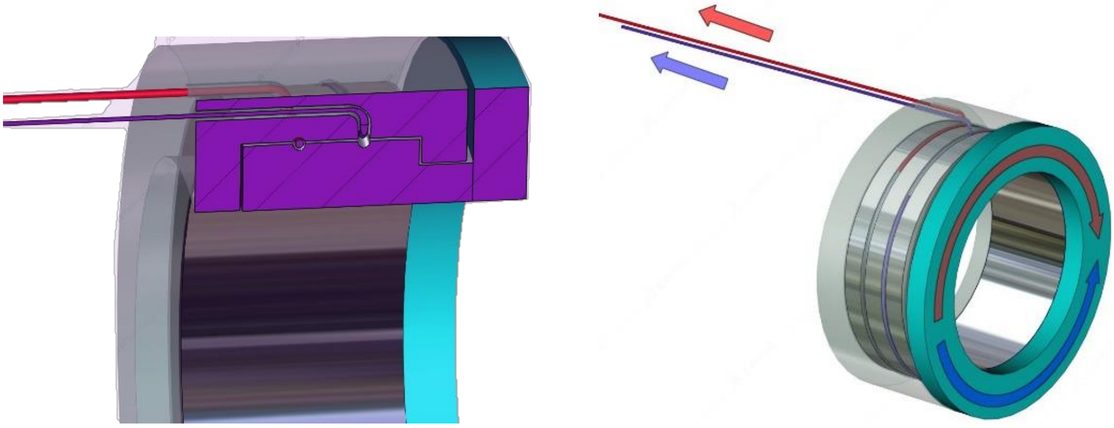


Figure 49: a) The cross-section view of the rotational reel, b) the reel with arrows that implicate the directions for the rotation when the respective strands are being pulled.

3. **Elongating coil spring made of smart material**

To get the elongating movement of the distal end of the catheter, it is attached a compressed spring between rotational device and the docking station for the surgical instrument. The coil spring is made of a shape memory alloy that makes it extract when electricity it applied to it and to contract when the electricity is removed. The material is set to be in a specific shape at its start temperature, and will change to a pre-memorized shape when it reaches a certain temperature, or when voltage is applied. In the start position, the coil spring is completely folded, so that it may be extended and obtain its pre-memorized shape when the elongation is desired.

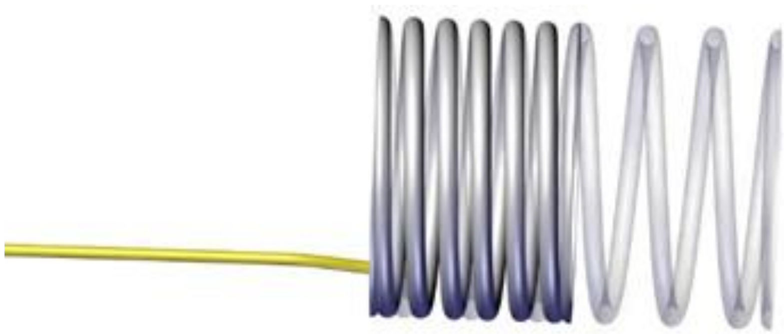


Figure 50: The coil spring in compressed and elongated condition.

Challenges linked to the concept

For the concept that has been explained above to be feasible, the actual deflection needs to occur distally relative to the rotation mechanism. If the wire should have been controlled from the proximal side of the rotation, the wire would have had to go completely in the middle of the catheter to avoid being affected by the rotation. This is not possible when lumens for contrast dye and the surgical instruments occupies the central part of the catheter.

Deflection on the distal end of the rotation mechanism is , however, possible using a micro motor to pull the wire. Assumptions is made that a micro motor with a maximum diameter of 2 mm has a strong enough engine performance to make the distal end of the catheter deflect. Power cords to the engine passed through a lumen, which is dominated by the rotation mechanism. Because there is only one wire, it will only require one motor to achieve deflection.

However, it turns out that it is desirable to achieve a deflection with a small as possible radius in order to obtain an as flexible as possible movement of the catheter. For this to be possible, it is necessary for the distal end to have as few rigid parts as possible. A micro motor positioned near the distal end provides a rigid part in the distal end, which counteracts the possibilities of achieving a small and flexible deflection.

10.2 Second concept

The first concept was revised and it was decided that the original idea with two wires that is placed perpendicular to each other, can perform the same operation as a wire and a rotation. To ensure local rotation in the distal end of the catheter, the rotation device is relocated to the distal end. Much of the reason why this concept is considered better than concept 1 is that it opens up for a much more precise rotation locally in distal end. Deflection is now controlled by two wire that is attached to a ring entirely in the distal end, and these are managed in and two micro motors which are located more proximal to avoid rigid portions at the distal end. Elongation of the distal end is the same as in the first concept, with a spring of smart material (for example Nitinol), which is controlled by means of the applied electricity.

S-Shape with help from guide catheter

The aim throughout the project has been to obtain an S-shaped movement with the catheter. This is not possible to obtain with the concept described above. It turns out, however, that if the guiding catheter is used to indicate the direction for the steerable catheter in the left atrium, an S-shape may be possible, and one should in principle be able to reach all points inside the left ventricle, see the figure below.

11 PROJECT RESULTS AND EVALUATIONS

This chapter gives a presentation of the projects results and an evaluation of possible challenges linked to the chosen concept.

11.1 Chosen concept

This is a review of the final result, including a detailed description of the chosen parts. See the figure below for an overview over all the selected parts.

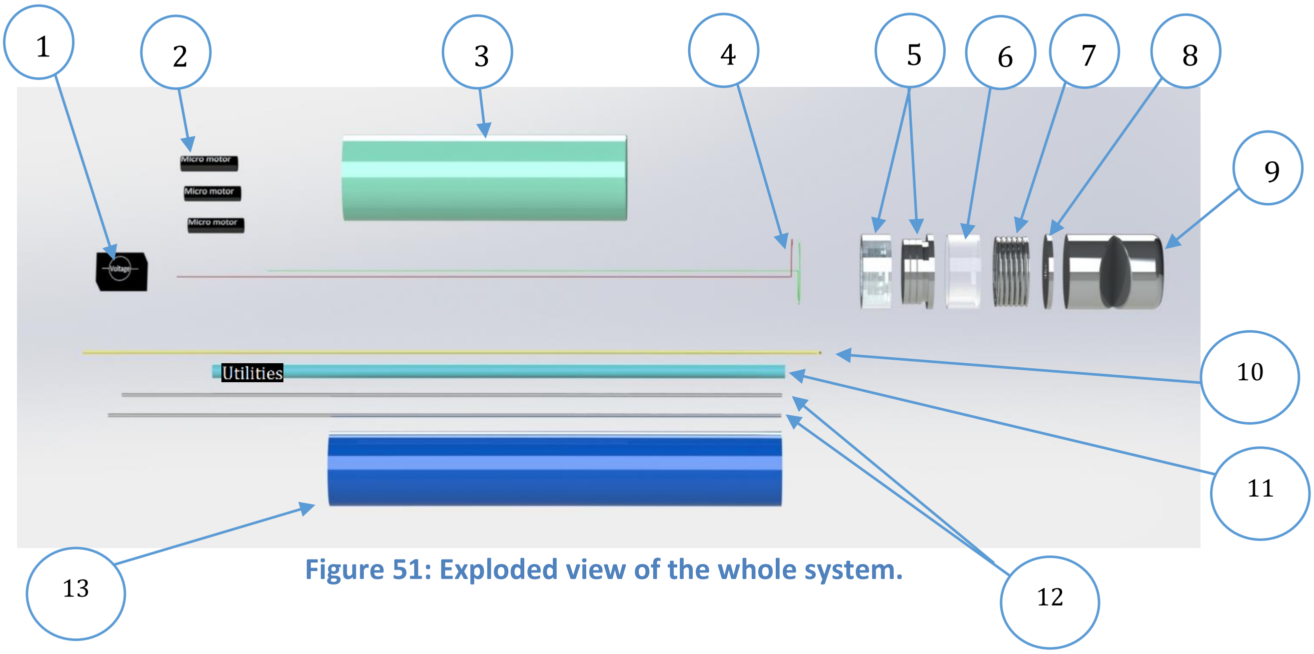


Figure 51: Exploded view of the whole system.

Table 27: Part number and part name.

Part number	Part name	Comment
1	Voltage box	Black box.
2	Micro motor	Black box.
3	Guide catheter	Developed part.
4	Strands	Developed part.
5	Inner and outer case, rotational reel	Developed part.
6	Coating, coil spring	Developed part.
7	Coil spring	Developed part.
8	Docking station	Developed part.
9	Surgical device	Black box.
10	Power cable, coil spring	Developed part.
11	Utilities (contrast dye etc.)	Black box.
12	Wires	Developed part.
13	Steerable catheter	Developed part.

All of the parts in the table above are described in the following.

Table 28: Description of the parts

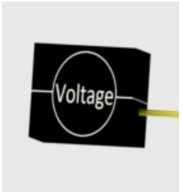
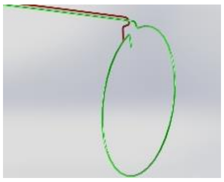
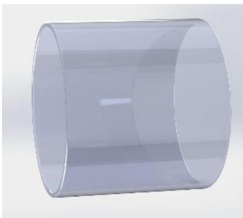
Description of parts	Drawing
1 – Voltage box One voltage box supplies the coil spring with voltage through the power supply cable (part 11). This is a black box in the concept, and is not developed.	
2 – Micro motor The three micro motors controls the movement of the wires and the strands. Further specifications must be done, therefore these parts are considered as black boxes in the concept.	
3 – Guide catheter A guide catheter is an already developed part, where the deflection is controlled by conventional techniques (strands or wires).	
4 – Strands The two strands control the rotational reel, further description will be given below.	
5 – Inner and outer case, rotational reel The rotational reel consists of an inner and outer case that are connected so they can obtain independent rotation. A further description of this concept is given below. The inner case consists of a core and an extruded lip.	
6 – Coating, coil spring To cover the coil, there is a coating of a flexible material fastened on the outer structure of the coil. The coating follows the elongation and contracts when the coil is compressed to its original shape.	

Table 29 continues.

Description of parts	Drawing
7 – Coil spring One coil spring of a shape memory alloy is connected in between the rotation reel and the docking station. The coil elongates when the power cable supplies it with voltage. The elongating mechanism is further described below.	
8 – Docking station A docking station is formed as a disc to connect the coil spring and the surgical device.	
9 – Surgical device A surgical device is supposed to reach the desired positions. This parts is considered a black box and is not developed.	
10 – Power cable A power cable supplies the coil spring with voltage.	
11 – Utilities The utilities is a collective term for contrast dye, wire for the surgical device and other parts that need to reach from the proximal to the distal end of the catheter. This is considered a black box for the concept, that need to lye centered in the catheter.	
12 – Wires Two wires control the defection. They are connected to the outer case of the rotational reel in one end, and in one micro motor each in the other end. On the outer case, they are connected perpendicular to each other, when looking at the section view of the catheter.	
13 – Steerable catheter The steerable catheter is a long, flexible tube that encloses the whole system and prevents contaminants from the body to enter the inner structure of the catheter.	

Further, the three main components of the concept, deflection, rotation and elongation, are described more detailed.

Rotation

The rotation device works in the same way as a fishing reel, where the inner case of the reel rotates independently from the shell. The rotation of the inner case is controlled by two strands, see the figure below.

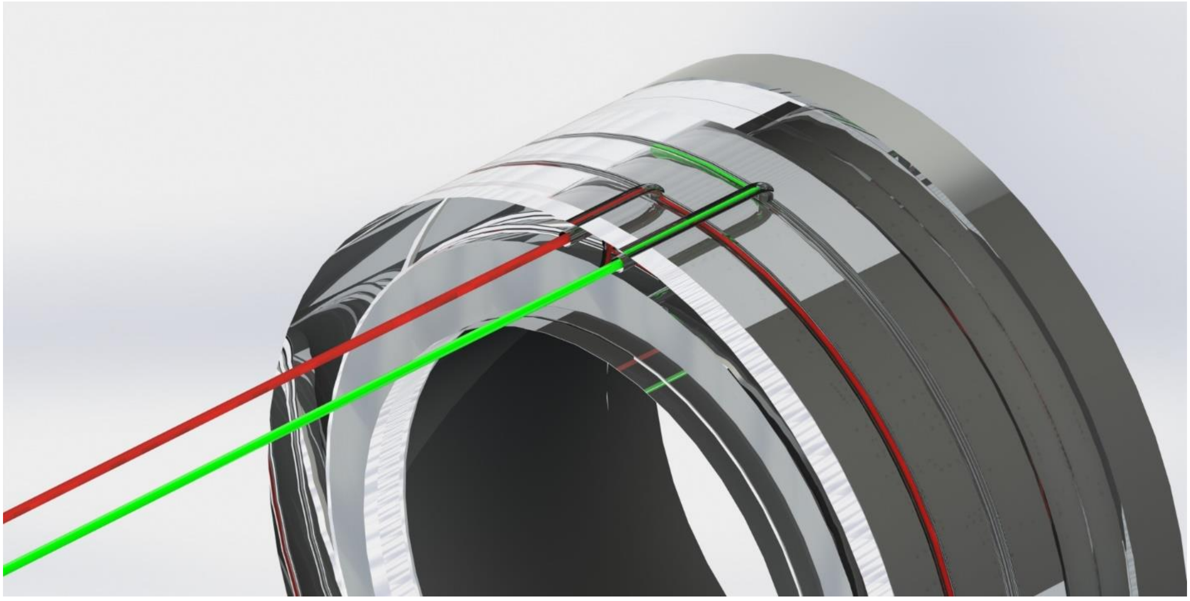


Figure 52: The rotational reel with two strands that controlls the rotation of the inner case.

The following procedure is conducted to fasten the strand to the inner case. The proximal end of the green strand is attached to a hole in the inner case, which can be seen in figure 53 a). The inner case is rotated 360 degrees to the left, to reel up the strand along the guiding track. When the green strand is reeled up, the red strand is attached and reeled up by pulling the green strand, see figure 513 b) and c).

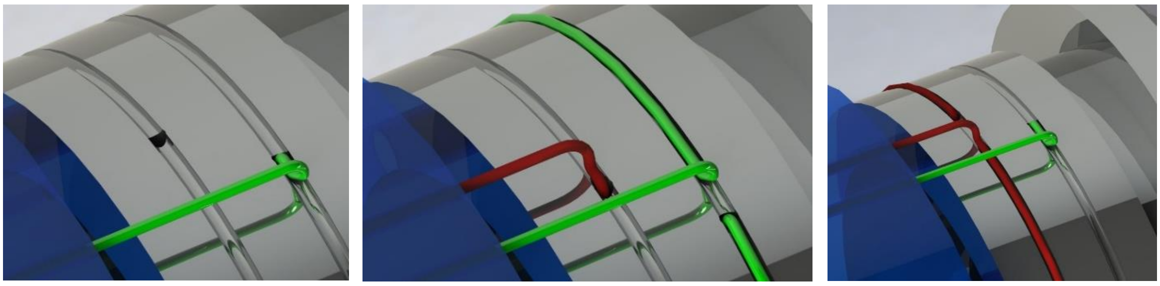


Figure 53: a) The green strand is attached to a hole in the inner case, b) the red strand is attached and ready to be reeled up, c) the red strand is reeled up on the inner case.

The strands are alternating being pulled to rotate the reel; pulling the green strand will rotate the inner case to the right. Pulling the red strand will rotate the inner case to the left. By keeping both stands tight at any time, the rotation can be locked in the desired position. Degree of rotation can be measured by sensors in the inner rotational case or by monitoring the pulled strand length by the motor. In this way, extremely accurate rotational movement can be measured.

The inner case consists of a core located on the inside of the outer case and an extruded lip on the outside, as shown in figure 54.

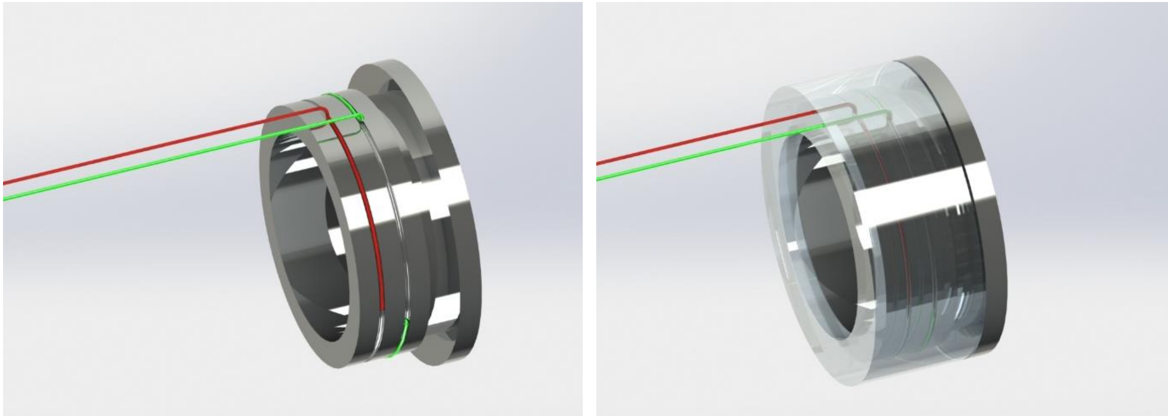


Figure 54: The rotation device a) without the outer case and b) with the outer case (made transparent to show where strands are located).

The rotation device are printed in one piece to allow the individual rotation of the inner case, without any loose parts. As shown in figure 55, a track in the shell guides the strands onto the inner case. This cause a translation from linear to rotational movement.

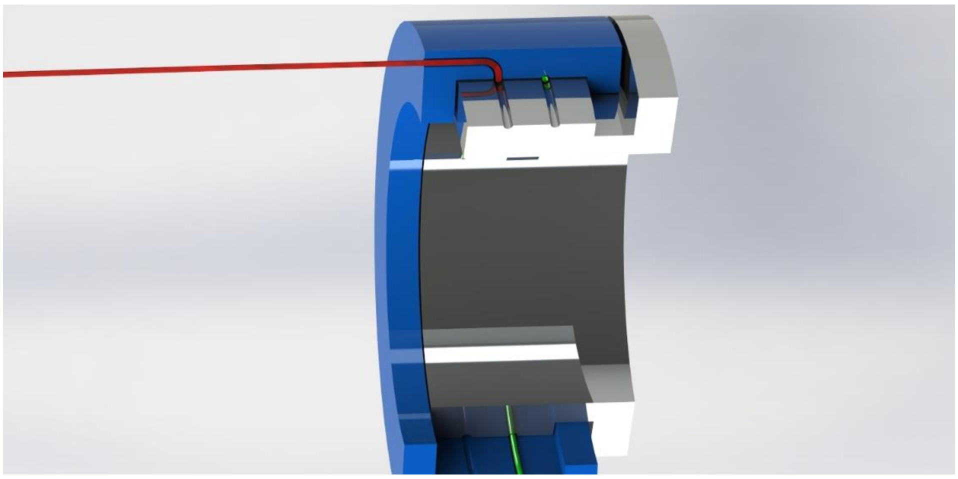


Figure 55: Cross-section view of the rotation device.

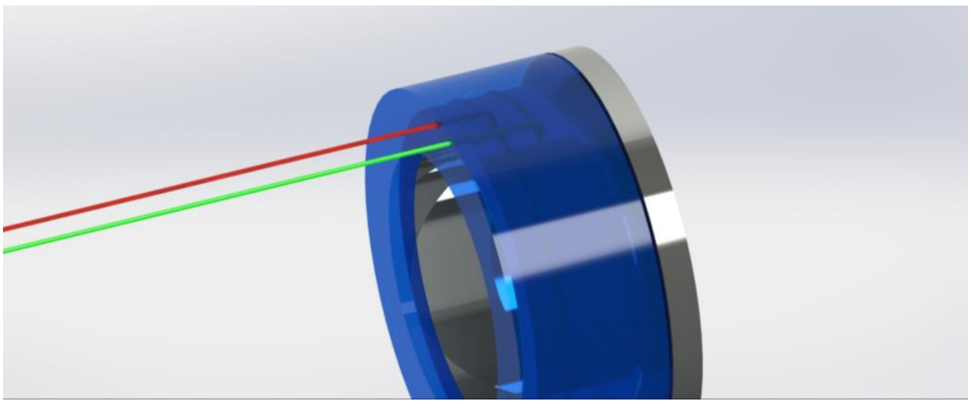


Figure 56: The rotation device with the outer and inner case and the strands.

Elongation

Longitudinal movement of the distal end is done by a coil spring of shape memory alloy that is pre-shaped to an elongated form and enter this shape when it is supplied with voltage. See the figure below.

Figure 57: a) the coil spring compressed and b) the coil spring elongated.

To cover the coil, there is a coating of a flexible material fastened on the outer structure of the coil. The coating follows the elongation and contracts when the coil is compressed to its original shape.

The surgical device on the distal end can thereby obtain a longitudinal movement and fine-tune its position. See this elongating movement of the distal end in the figures below.

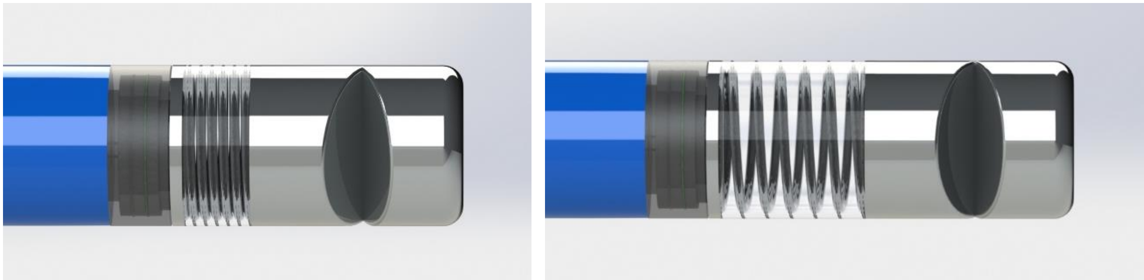


Figure 58: The elongating coil enable the surgical device to fine-tune its position.

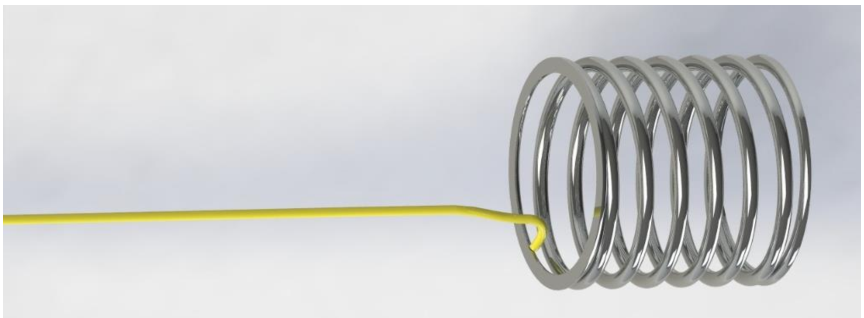


Figure 59: The coil spring with the power cable that supplies it with voltage.

Deflection

The rotation device is attached to the distal end of the catheter and the wires is connected to this device. These constructed mates constrains the movement in the longitudinal direction. As a result, pushing or pulling the wire forces the catheter to deflect.

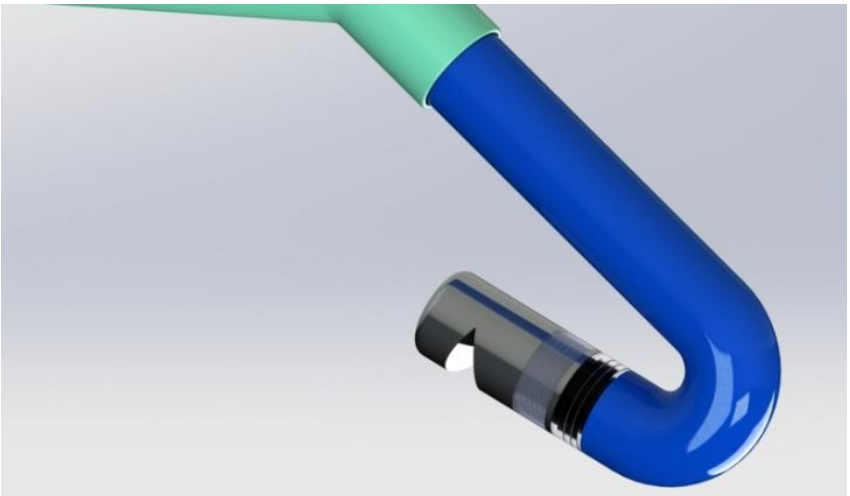


Figure 60: The catheter can bend due to two wires that are being pulled and/or pushed.

The wires are attached directly to the rotation shell. This way the rotation shell works as a deflection ring, translating the force from the wire to the entire cross section of the catheter. The aim of the deflection ring is to avoid the catheter from collapsing when its deflected. See how the wires are connected to the outer case of the rotation device in the figure below.

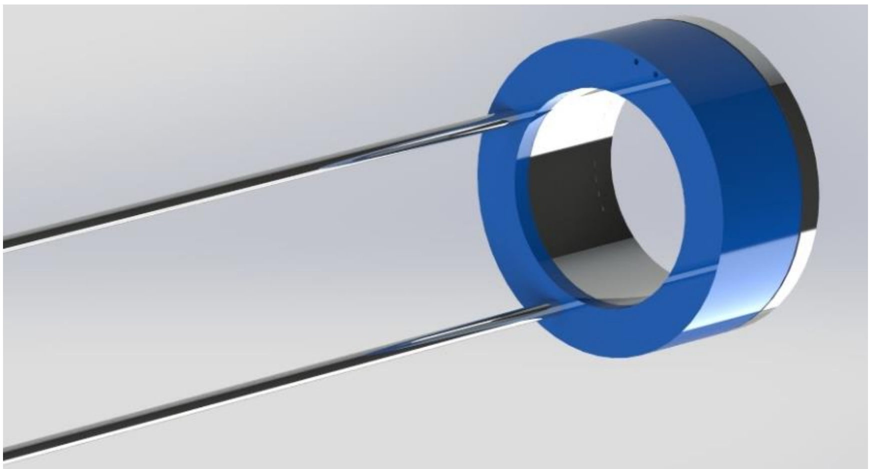


Figure 61: The wires are attached perpendicular to each other on the rotation device.

Pulling and pushing the lower wire (see figure 61) deflects the catheter up and down respectively. Pushing and pulling the second wire results in deflection to the right and left respectively. Combinations of the two wires makes deflection in any direction achievable. The two wires can support each other to secure a stable deflection, see the figures on the next page to see how deflections can be obtained.

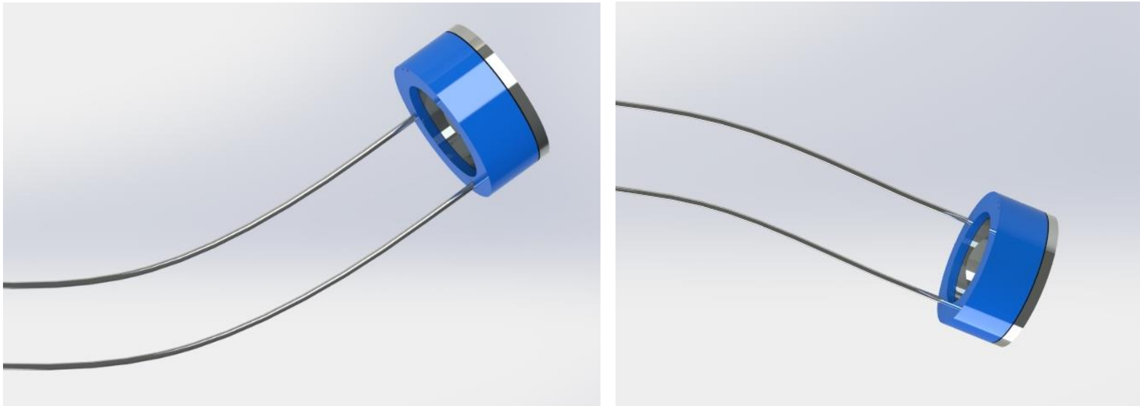


Figure 62: a) Deflection upwards and b) Deflection downwards.

Micro motors inside the catheter operates the strands and wires, where one motor for each wire and one common motor for both strands. An electric source outside the catheter (in the proximal end), supplies the spring coil with voltage, causing the spring to elongate.

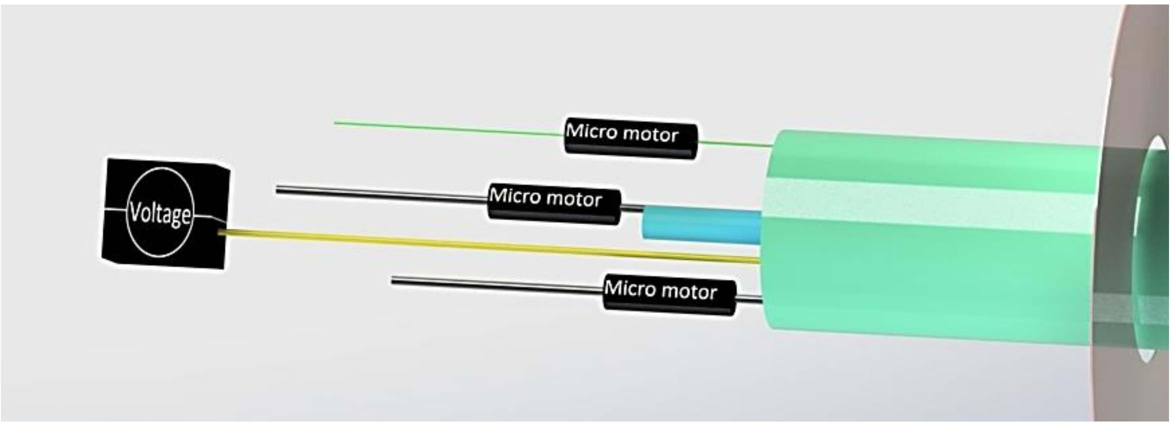


Figure 63: Micro motors are placed inside of the catheter, as the figure shows.

The motors are located inside of the steerable catheter in lumens. Micro motors and voltage supply are set as black boxes in this report, due to lack of adequately investigation. The light blue catheter in the center represents different utilities used to operate a surgical device in the distal end of the catheter. This may for instance be wires for motion translation or contrast dye. The yellow tube is power cable supplying voltage to the spring coil.

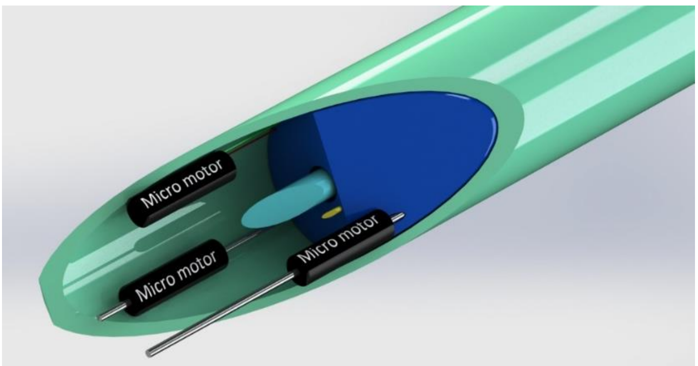


Figure 64: A cross-section view of the catheter, displaying the three micro motors.

The entire concept

The developed concept is a combination of deflection, rotation and elongating. The procedure for this movement is describes in the steps below. The aim for the surgical device is to move from septum until it reaches and are able to grip the mitral valve leaflet, see the figure below.

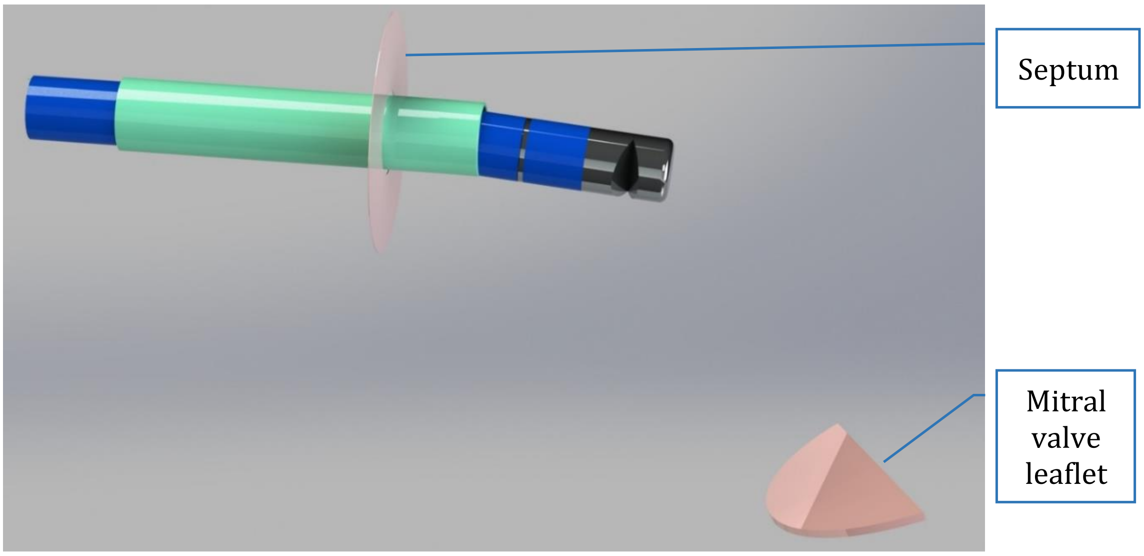


Figure 65: The desired movement of the catheter is from septum to the mitral valve.

Step 1: Insert and deflect the guide catheter

A guide catheter is introduced through the septum and the steerable catheter is introduced though the guide catheter. The distal end of the steerable catheter is introduced into the left atrium before the guide catheter deflect, to avoid conflicts in the bend. The deflection of the guide catheter is adjusted to set the course for the steerable catheter, where the deflection is controlled by conventional techniques (strands or wires).

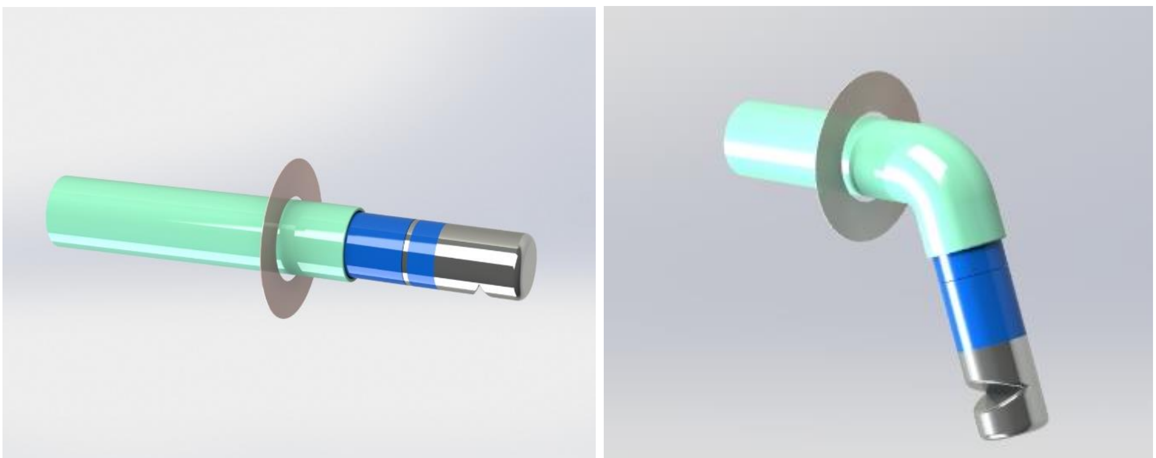


Figure 66: a) The steerable catheter is inserted through the guide catheter and b) the guide catheter deflects to set the course for the steerable catheters.

Step 2: Rotation of the guide catheter

Rotation of the guide catheter by a like-for-like movement from the handle to the distal end, sets the course for the steerable catheter. Septum is made bigger in the figures below to emphasize the two separate rooms, when the catheter deflects into a new planes.

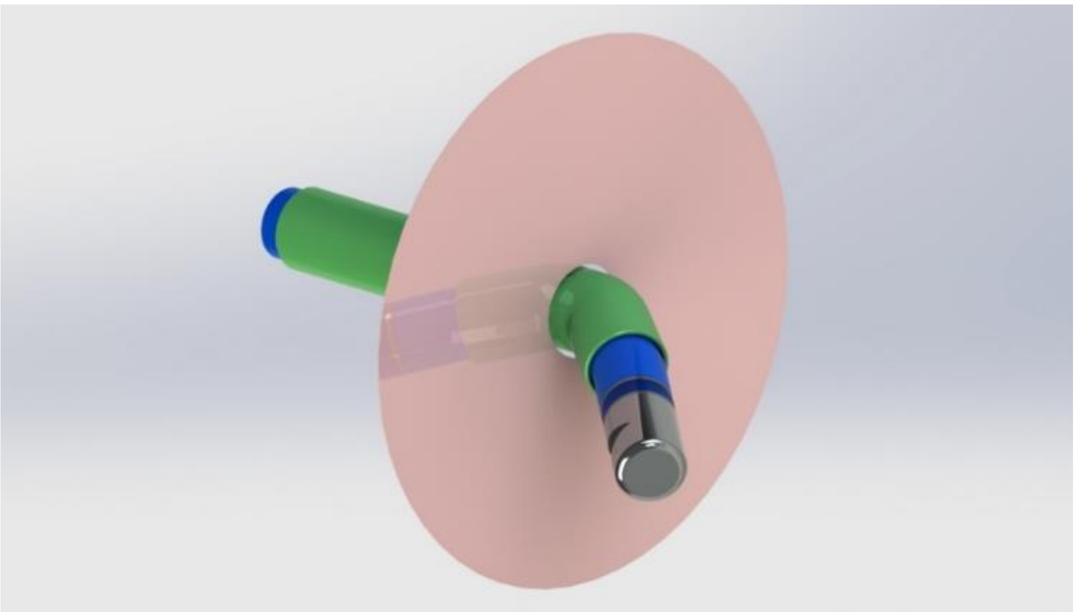


Figure 67: Rotation of the guide catheter sets the course for the steerable catheter.

Step 3: Elongation of the steerable catheter

The steerable catheter can now elongate by manually pushing it from the proximal end.

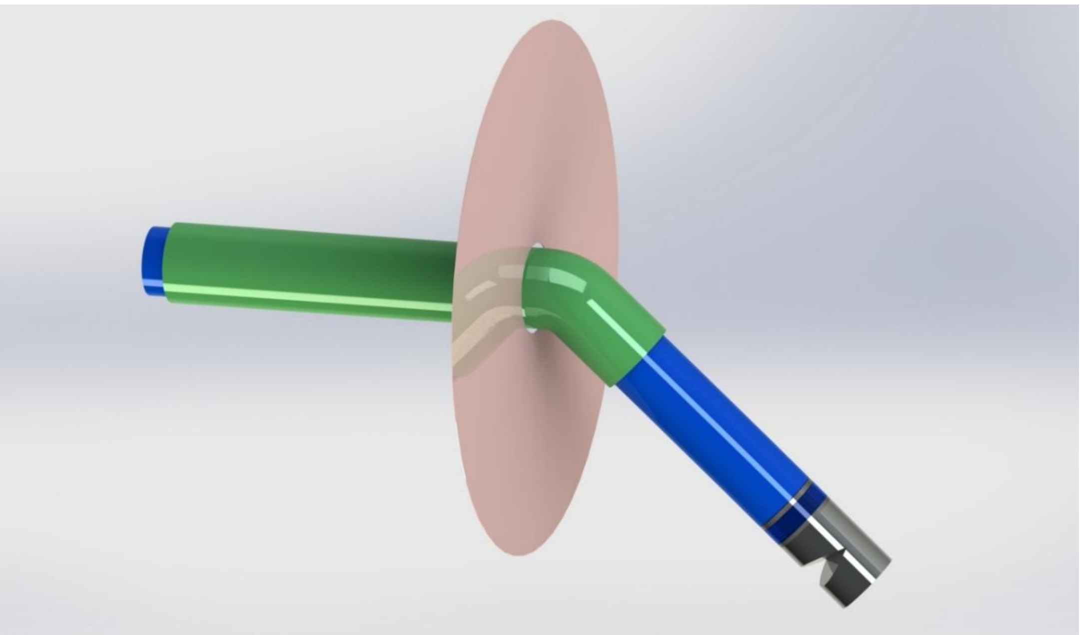


Figure 68: The steerable catheter is pushed from the proximal end to elongate.

The total procedure for when the guide catheter sets the course for the steerable catheter is explained in the step-by-step illustration below.

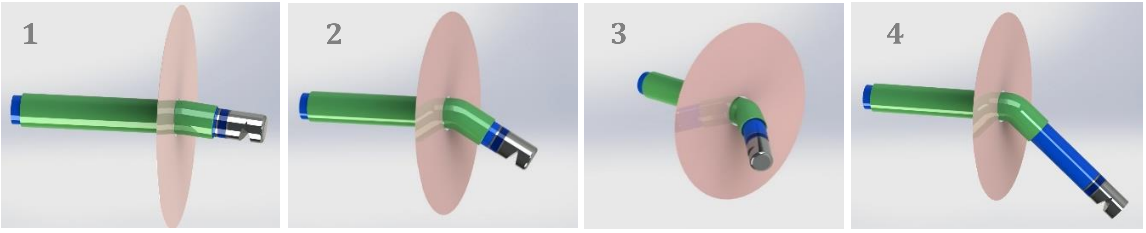


Figure 69: Step-by-step summary of the movements from when the guide catheter sets the course for the steerable catheter, and assist its movement.

Step 4: Deflection of the steerable catheter.

The distal end of the main catheter can be deflected in all three planes, due to the perpendicular wires. This enable the catheter to reach the shape as illustrated in the figure below, which is the desired shape when reaching for the mitral valve leaflet.

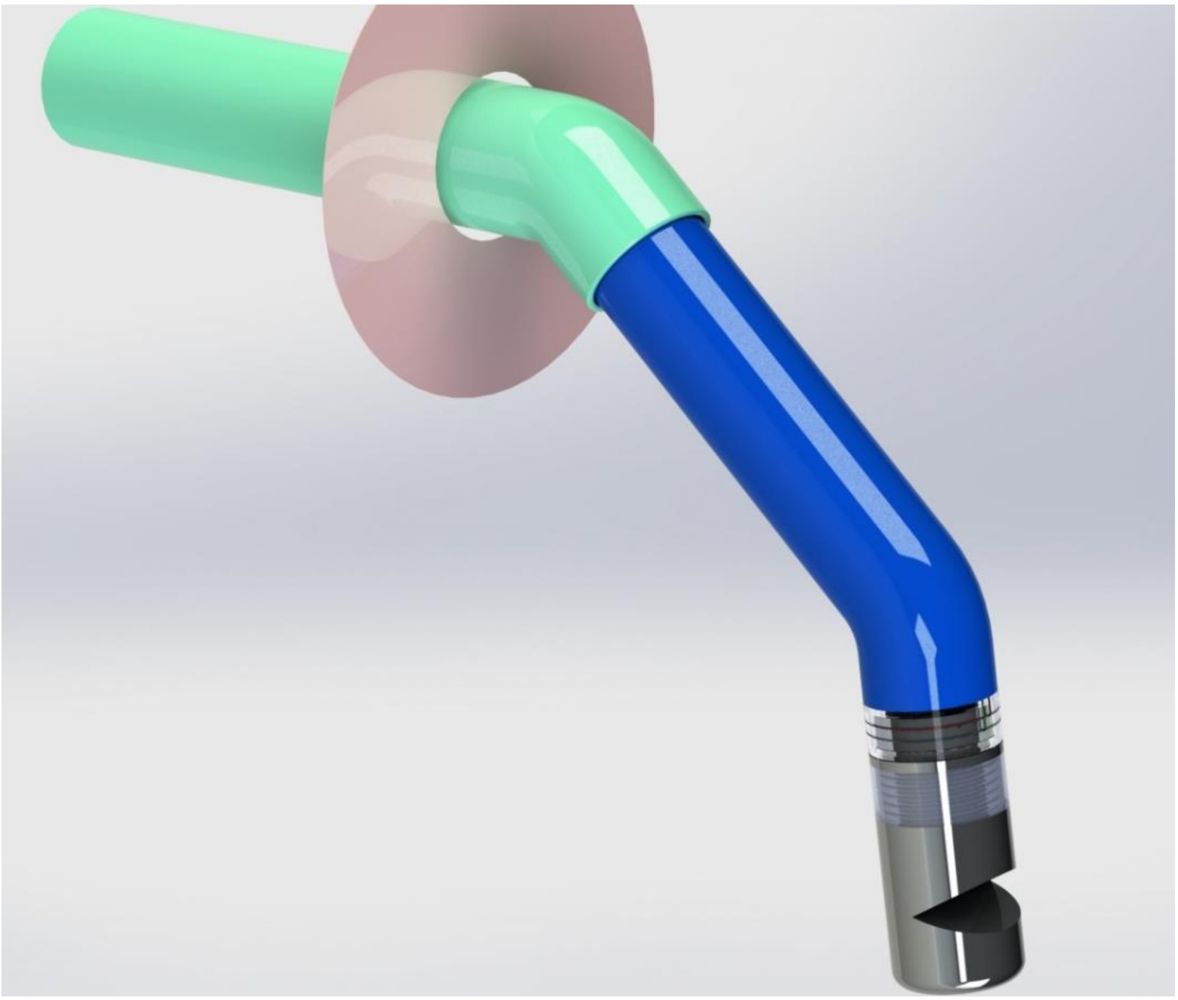


Figure 70: Deflection of the distal end due to the perpendicular wires.

Step 5: Fine-tuning

Local elongation and local rotation in the distal end of the catheter enable the surgical device to fine-tune its position. The device is then able to grip the leaflet, see the step-by-step illustrations below.

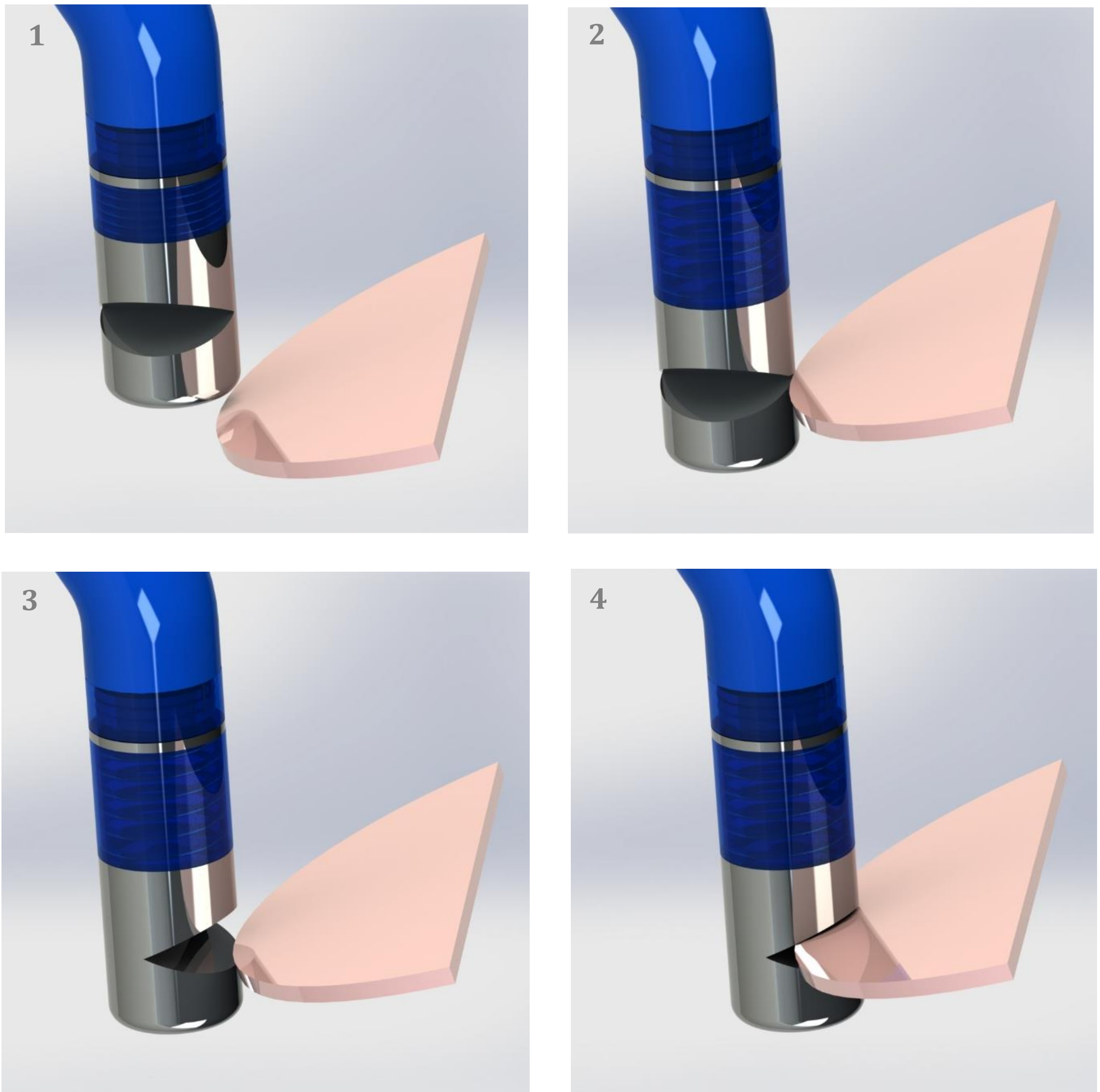


Figure 71: 1) First position, where the device does not reach the leaflet, 2) local elongating enables fine-tuning, 3) local rotation enables the device to reach the desired angle and 4) the device is able to grip the leaflet.

11.2 Evaluation of possible challenges

The following challenges are linked to the concept and need to be considered when developing the concept further.

Challenges linked to the coil spring

- When the coil spring is elongated, it might not be strong enough to hold the surgical device in position.
- The length of the elongation is not measured and the coil spring might not be able to elongate as far as the figures in this chapter implies.
- The coil spring might not be able to stop in an arbitrary position, which would be preferable.

Challenges linked to the rotation reel

- The path angle in the rotation device can possibly lead to drag forces. In worst case, the strands can get stuck in between the inner and the outer case.
- It may not obtain smooth enough rotations, without some type of bearings between the outer and inner case.
- The device must be 3D printed in order to obtain its function. The inner case needs to be integrated in the outer case to avoid loose parts.
- The gap between the inner case lip and the outer case needs to be covered in order to avoid tissues to get stuck.

Challenges linked to the deflection with wires

- It can be challenging to obtain sharp deflections.
- It an be challenging to transform the longitudinal force into a straight deflection when pushing a wire.

12 PRODUCT DESIGN

This chapter is a CAD presentation of the concept, with 3D drawings of the different parts of the concept.

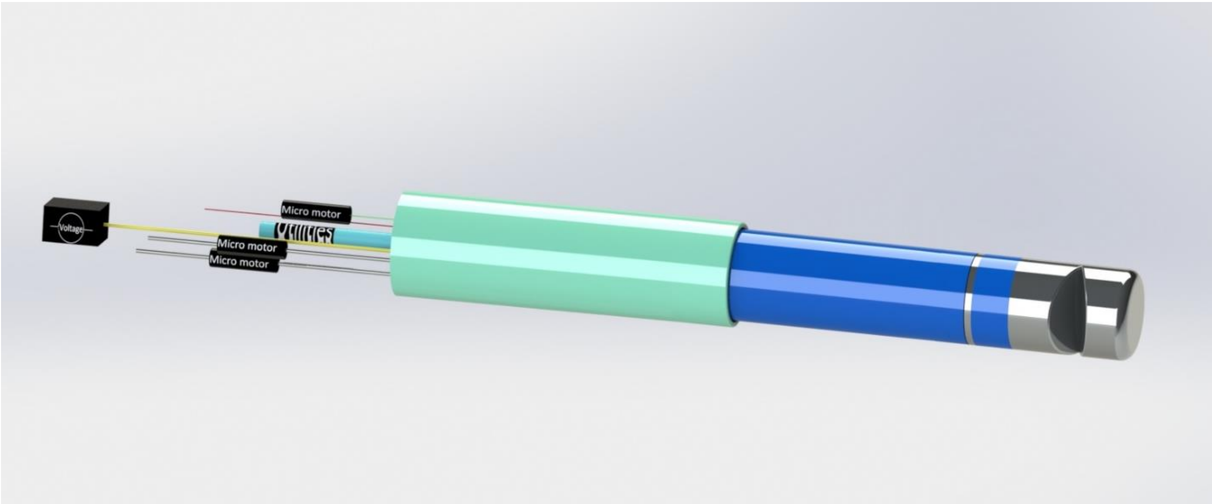


Figure 72: An overview over the entire catheter system.

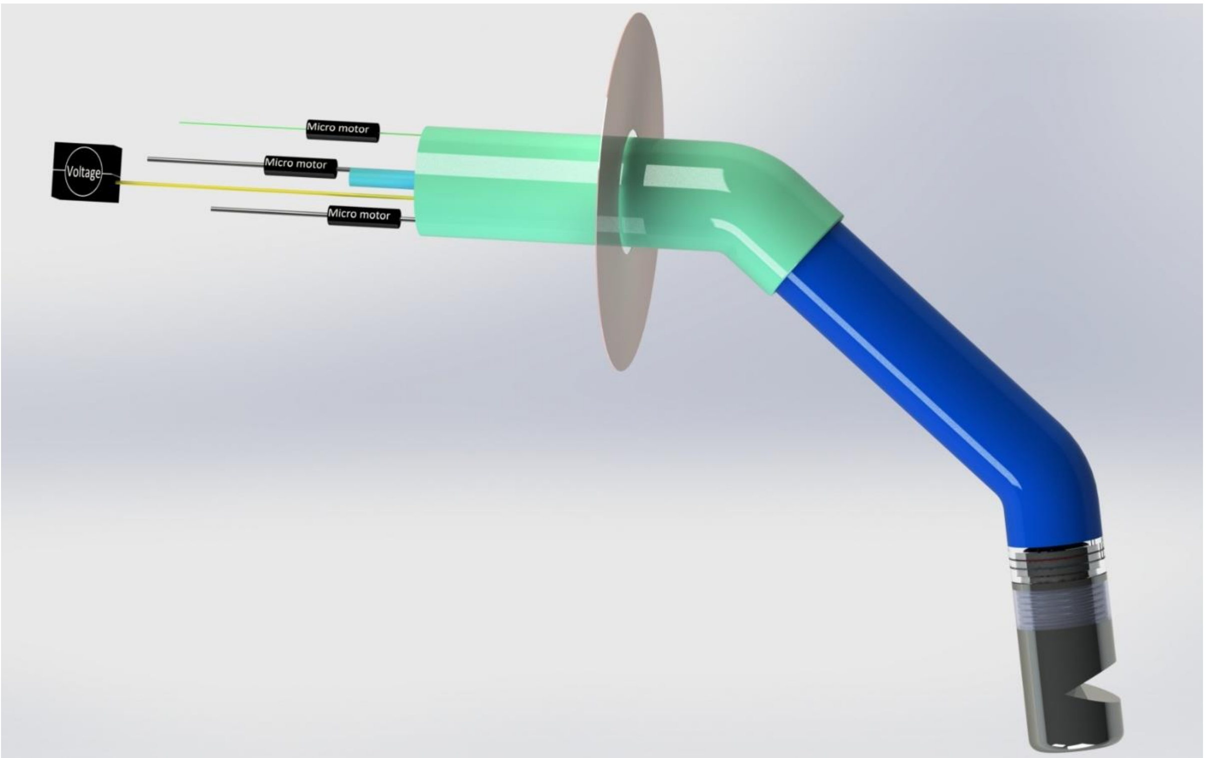


Figure 73: Overview of the complete catheter system when the guide catheter and the steerable catheter are deflected.

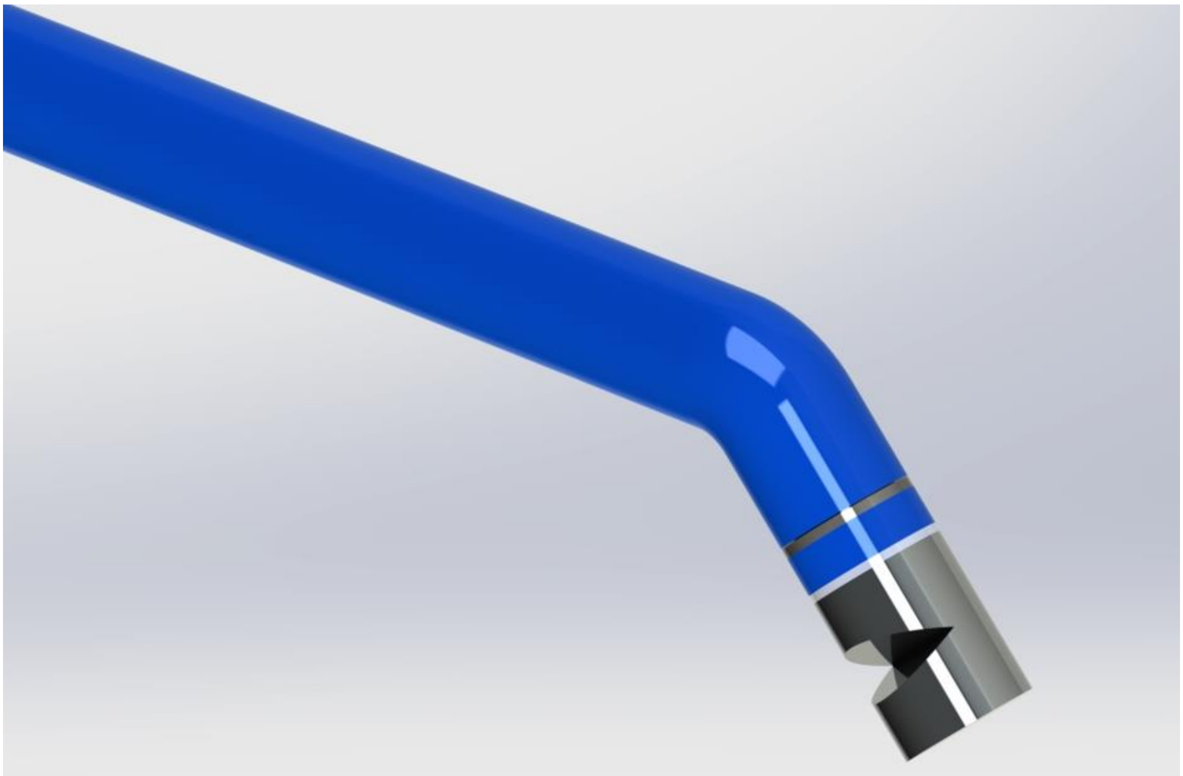


Figure 74: Deflection in the distal end of the steerable catheter.

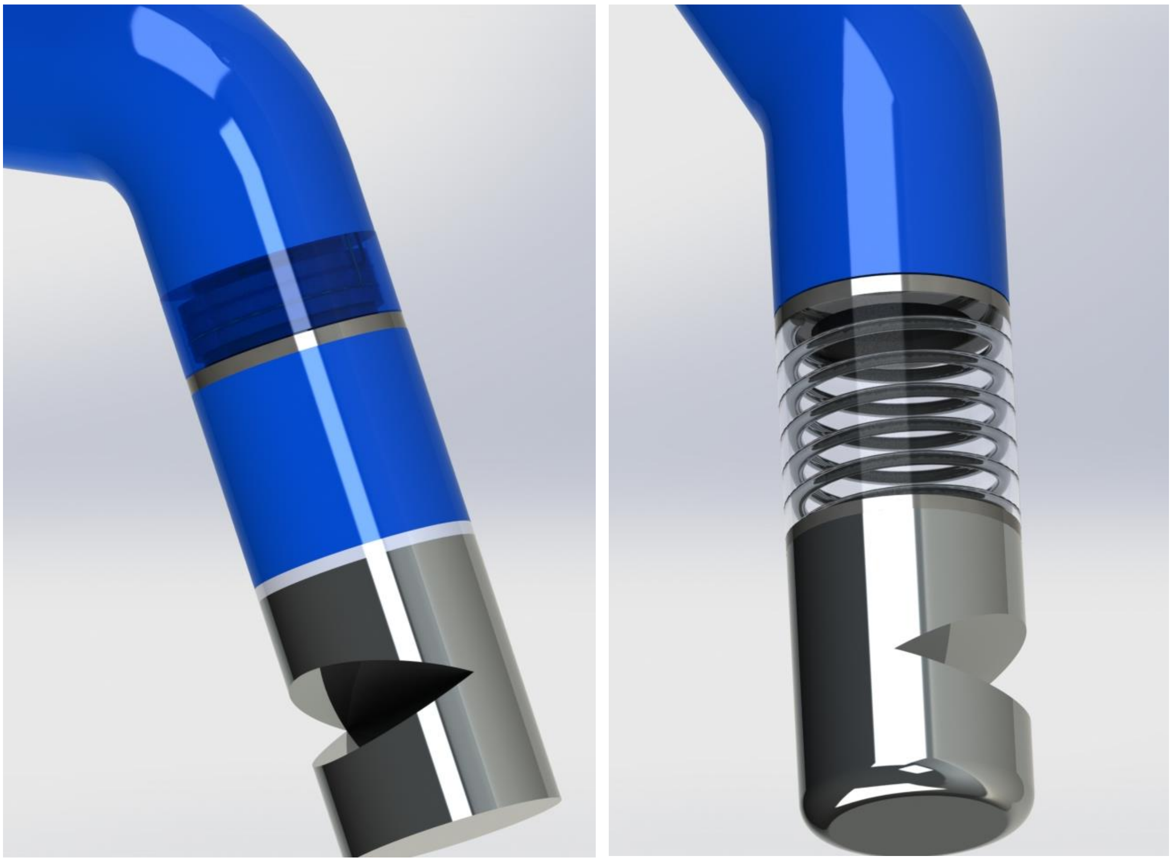


Figure 75: Detailed view of the local elongation a) with coating and b) without coating around the coil spring.

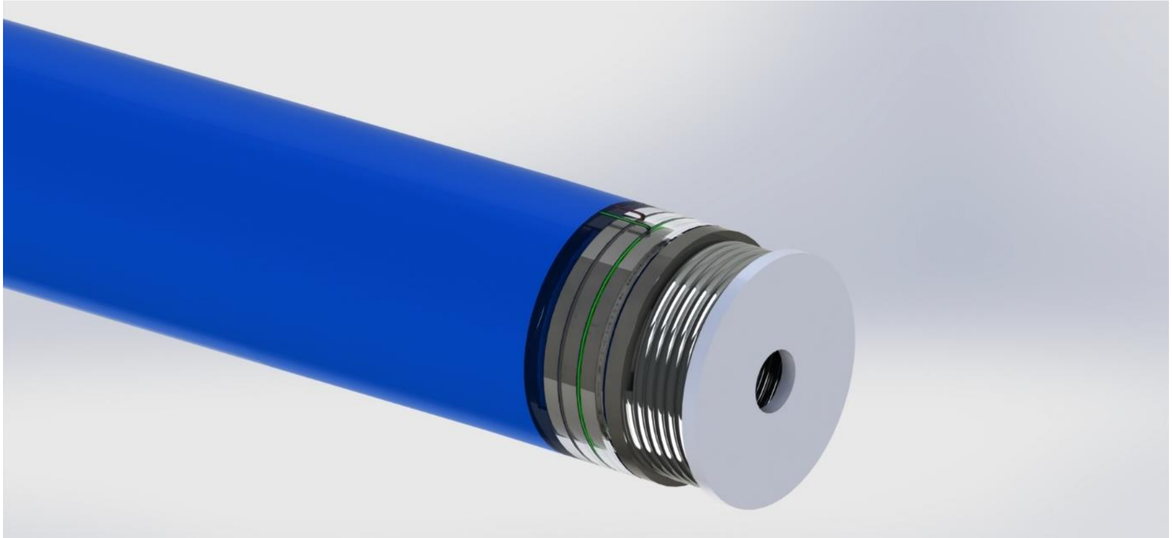


Figure 76: Detailed view of the docking station.

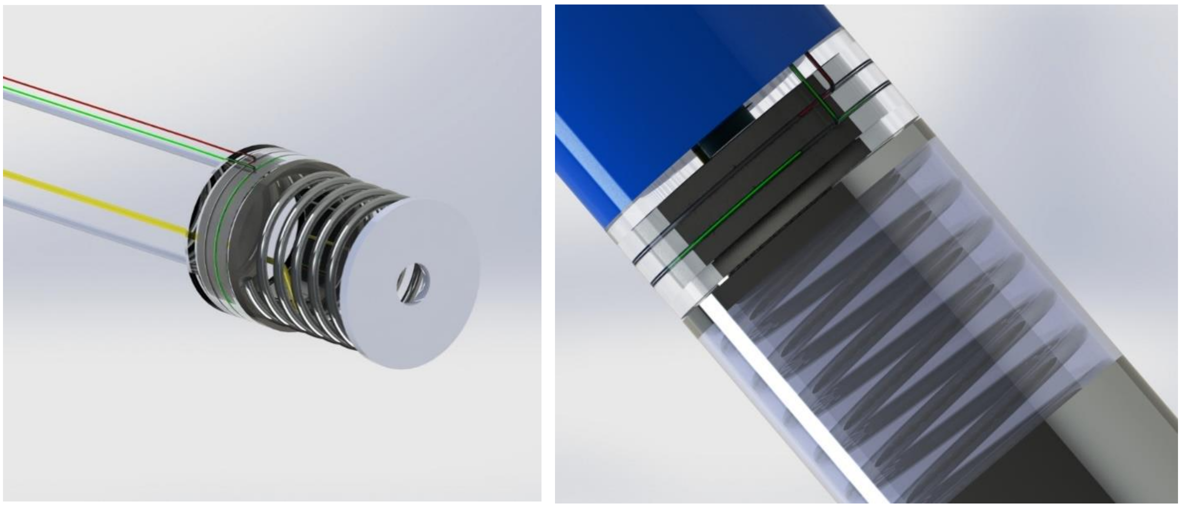


Figure 77: a) docking station and inner structure, b) elongated coil spring

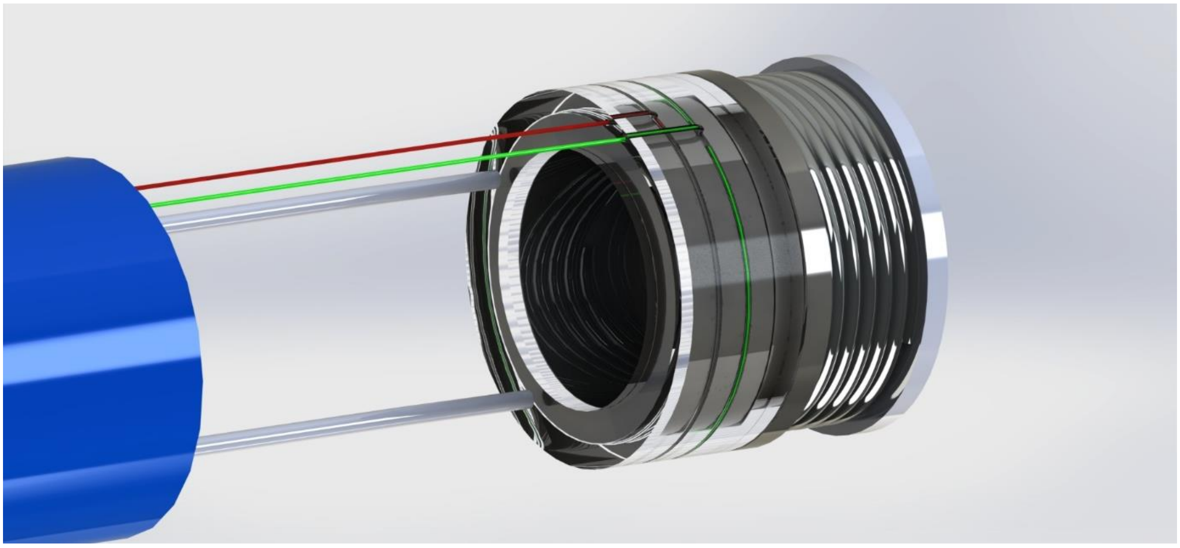


Figure 78: The wires and strands are attached to the rotation reel.

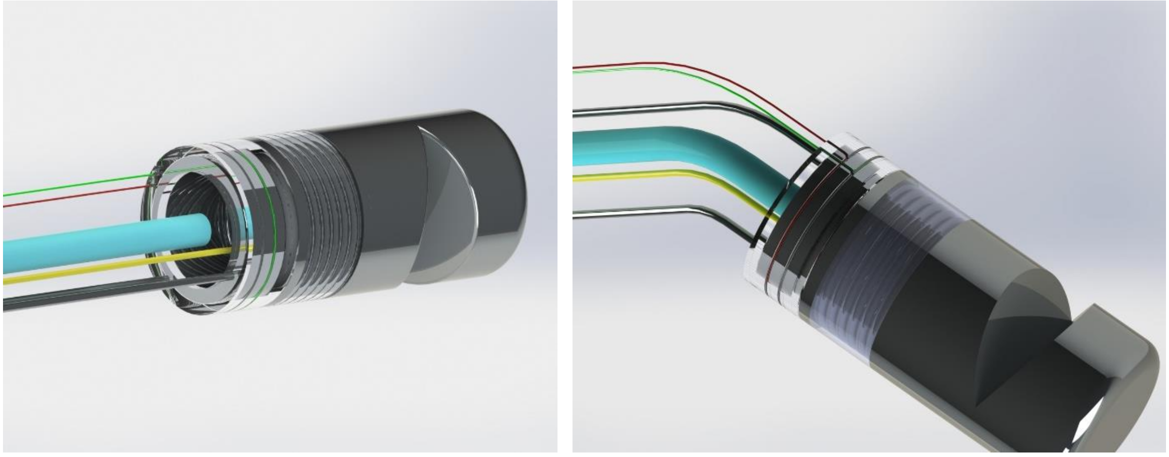


Figure 79: A stripped catheter a) in straight condition and b) deflected condition.

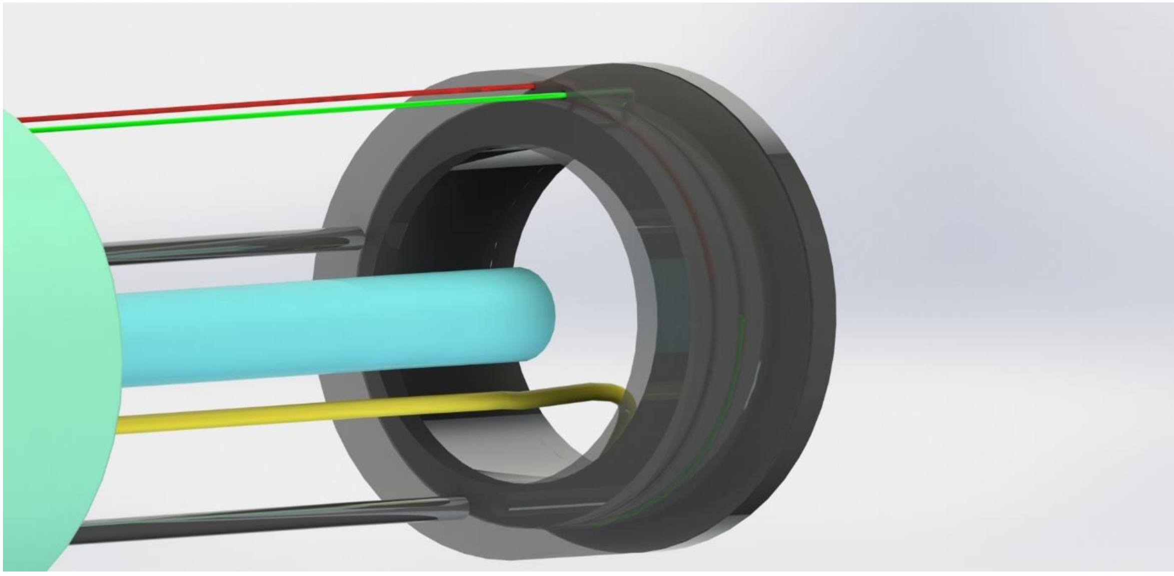


Figure 80: The inside of the catheter, with wires, strands, utilities and power cable.

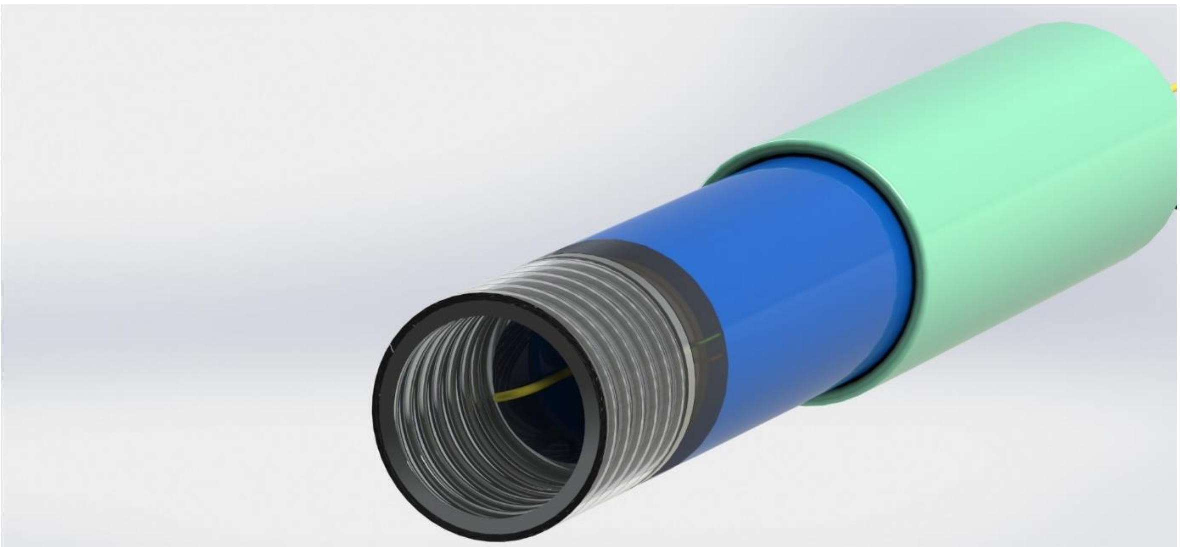


Figure 81: The yellow power cable supplies the coil spring with voltage.

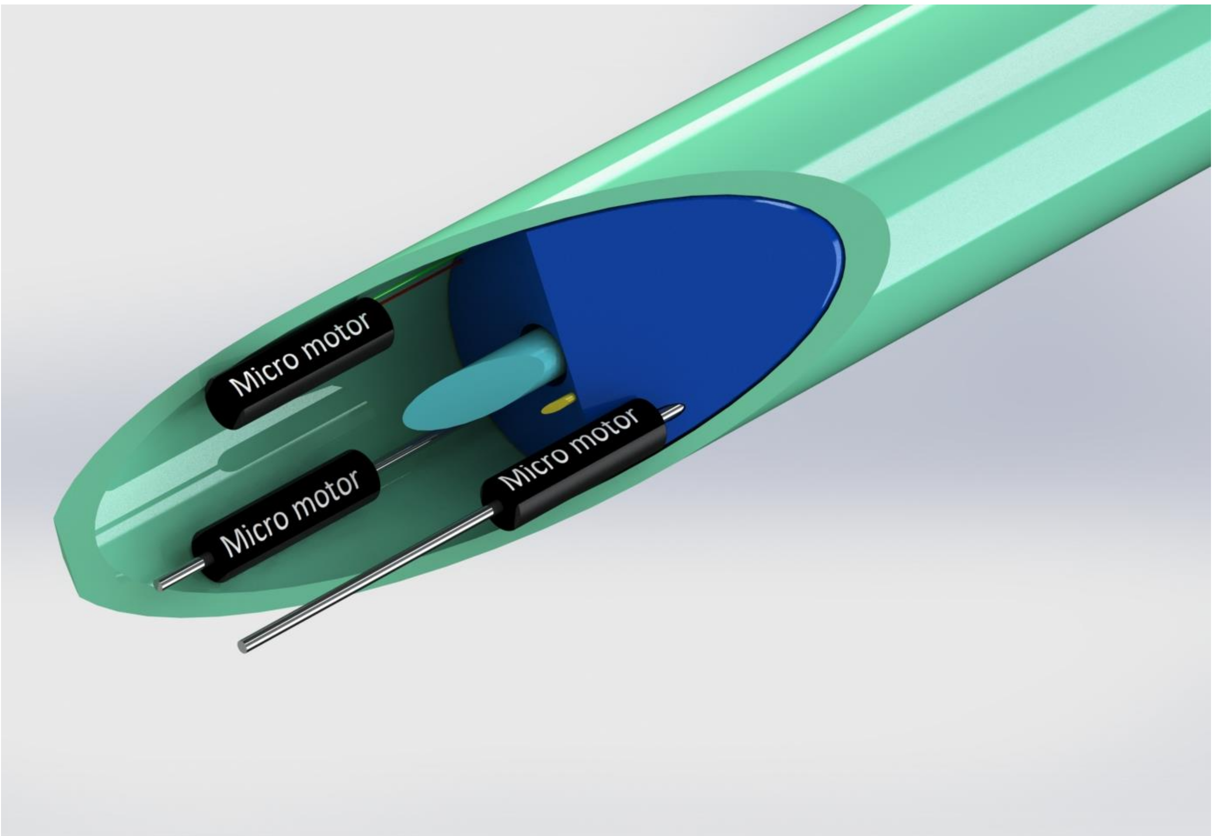


Figure 82: Cross-section view of the catheter where the micro motors are placed.

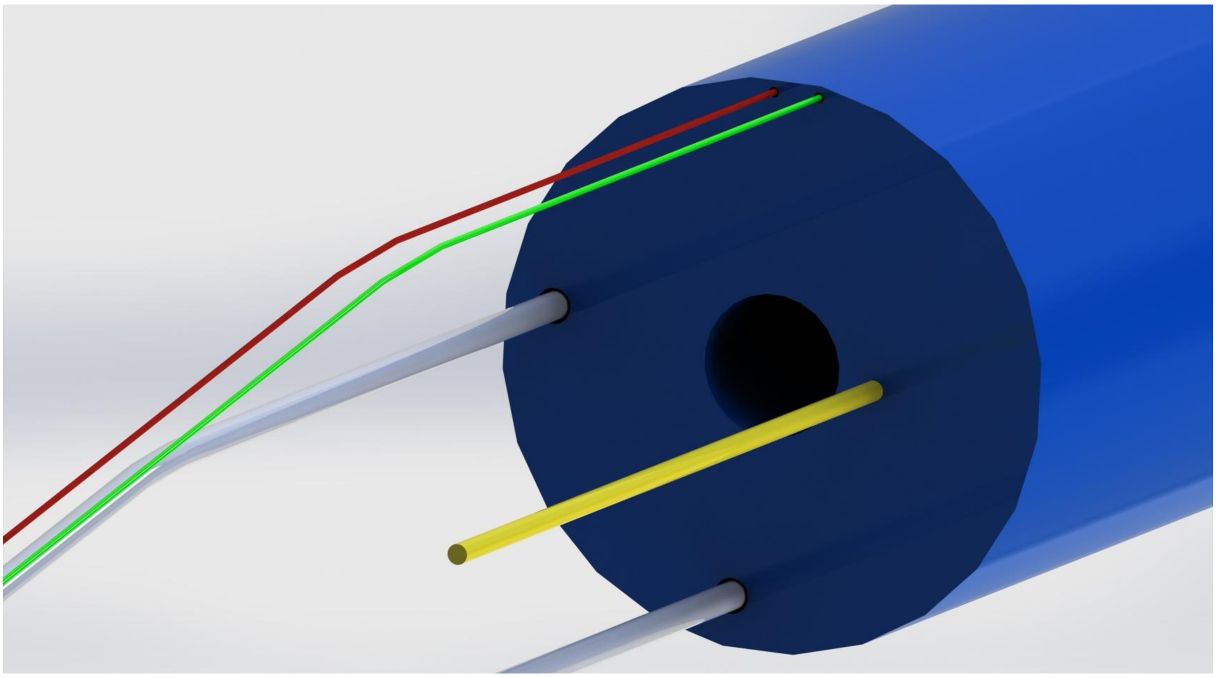


Figure 83: Cross-section view of the catheter, displaying the inner wires, strands and power cable.

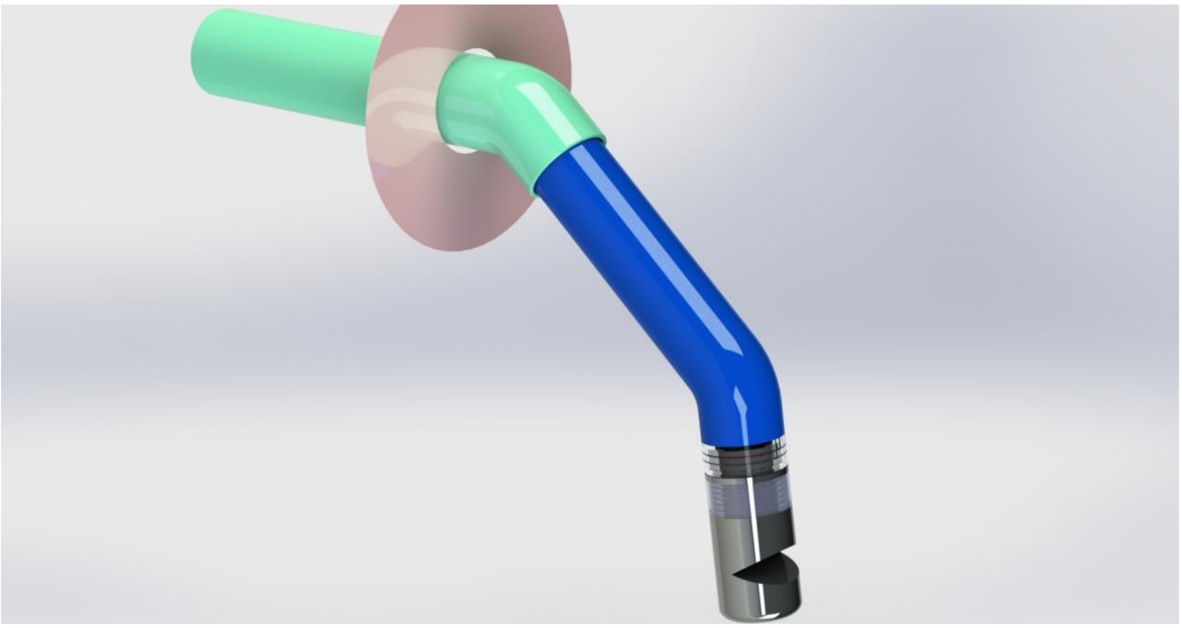


Figure 84: The complete catheter system when it is deflected.

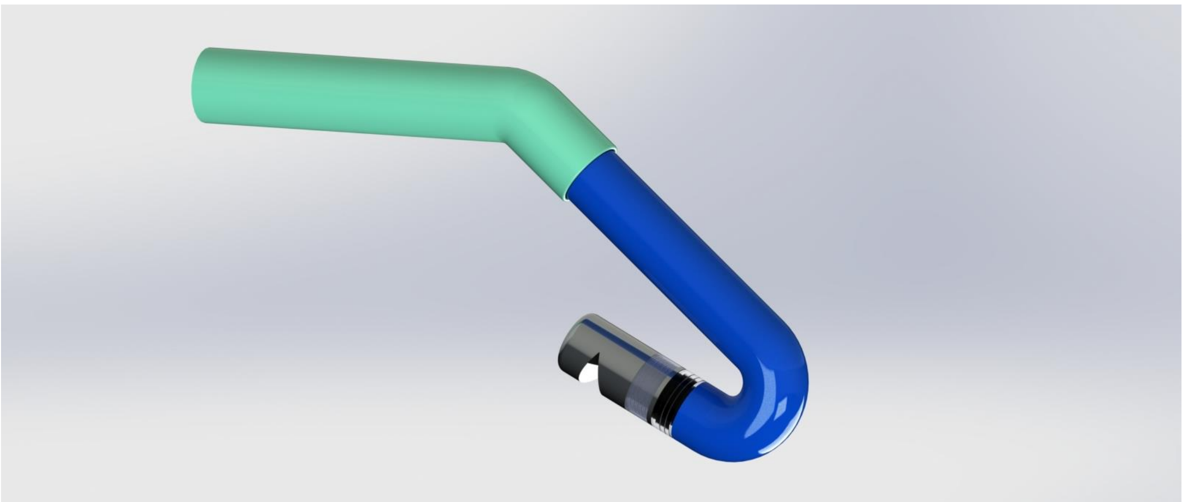


Figure 85: a) Deflection of the distal end.

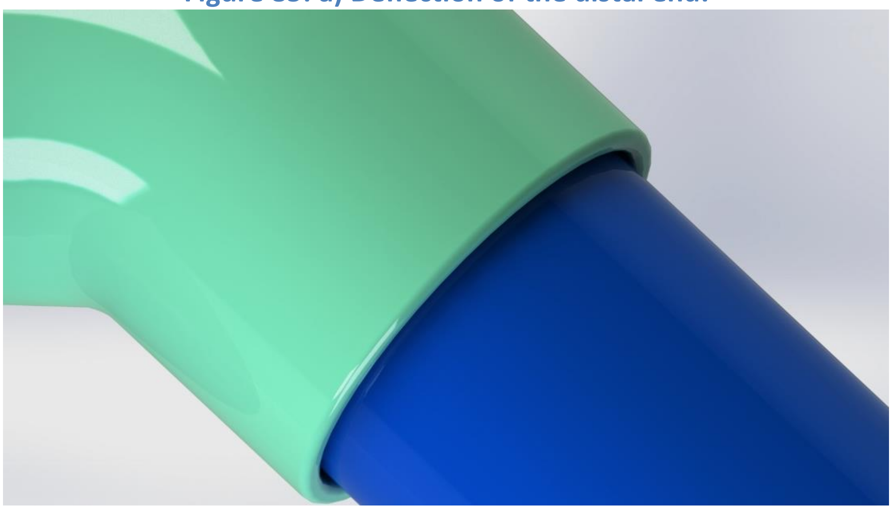


Figure 86: Detailed view of the guide catheter and the steerable catheter.

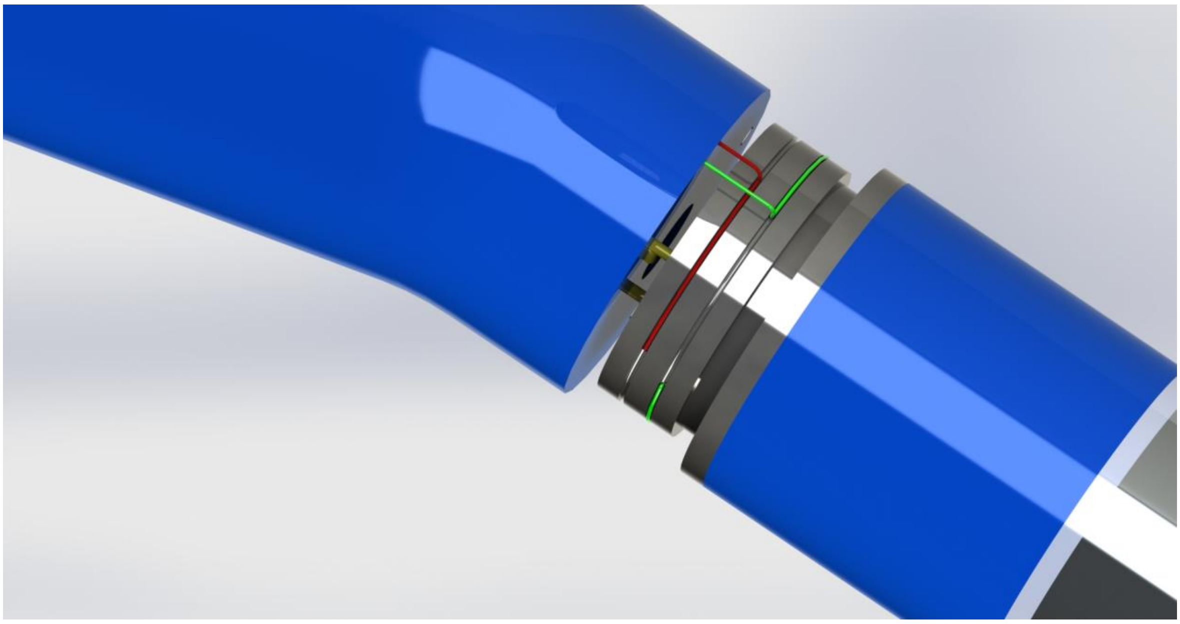
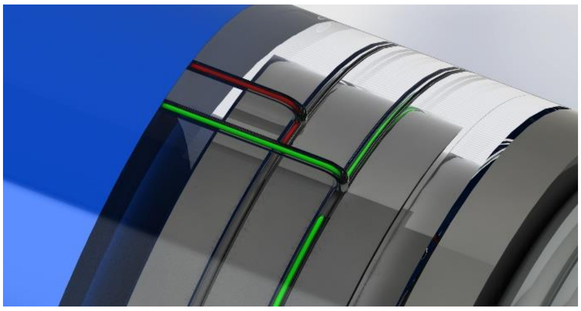


Figure 87: Detailed view of the rotation device on the catheter.



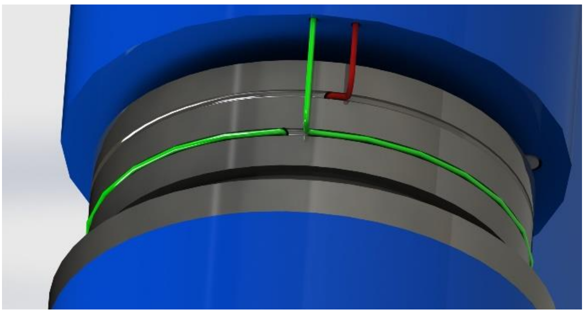
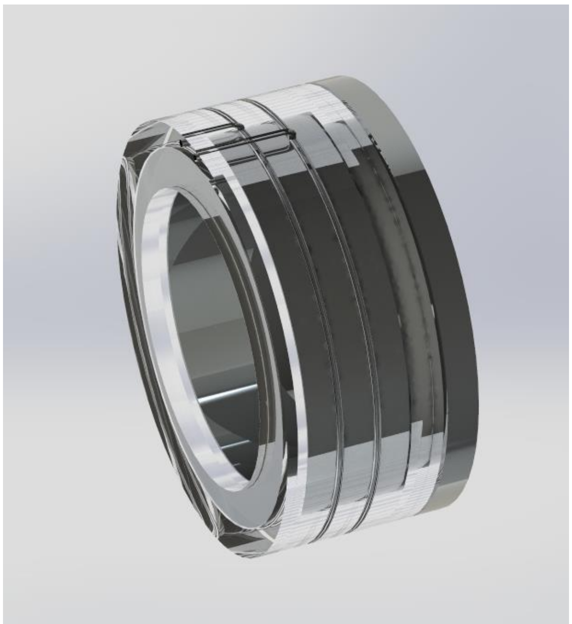


Figure 88: a) Rotation reel with strand, b) rotation reel where inner case is exposed.



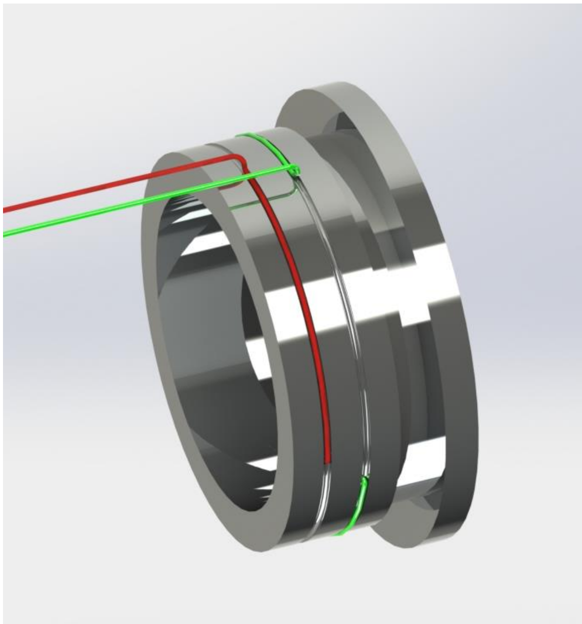


Figure 89: a) The entire rotation reel, b) the inner case of the rotation reel.

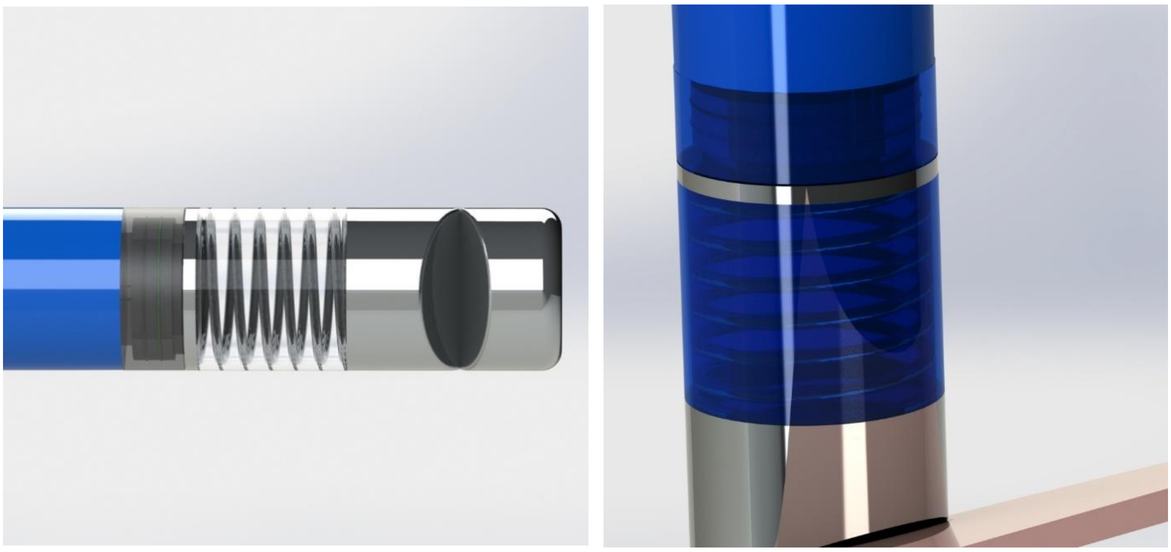


Figure 90: The elongated coil spring with transparent coating.

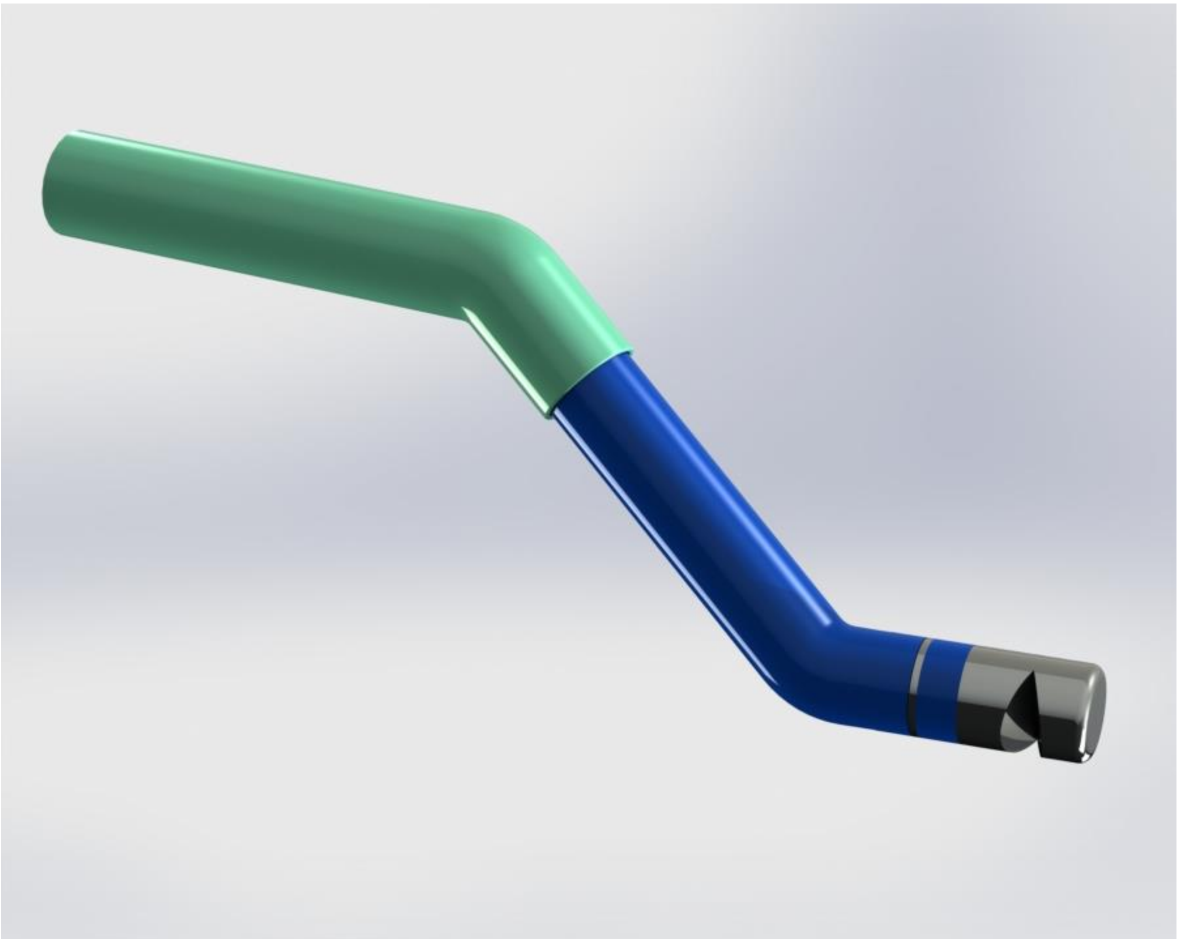


Figure 91: The concept is able to obtain an S-shape as shown in the figure.

13 MAINTENANCE AND RECYCLING

This chapter discusses the maintenance and recycling of medical equipment. First, in general and then a more specific consideration for the developed components.

13.1 Maintenance and recycling of medical equipment

Health care is a large contributor to waste production in hospitals. Medical equipment is often marked as single-use-devices (SUDs), which prevents the hospitals from reprocessing them. Reprocessing and reusing SUDs can save costs and reduce medical waste [48].

Reprocessing of medical equipment is however most common for non-invasive devices. Invasive devices for reuse need to be a closed system in order to avoid contaminants to reach and fasten inside of the catheter, and to ensure that the devices are kept sterile. Sterile catheters are SUDs, which are not approved to be washed and reused. Washing and reuse of medical catheters can potentially leave pathogenic bacteria, viruses and other microorganisms on the catheters, which infect the patient [49].

If invasive catheters, which cannot be reused, consists of one of more parts containing valuable material, the specific part(s) is collected and sent for recycling.

13.2 Maintenance and recycling for the steerable catheter

For the catheter in this report, it is only developed a concept and the maintenance for the components are not taken into consideration at this early stage. Materials have not been selected for the different components and therefore it is hard to say anything about the maintenance. However, the components are invasive devices and it is therefore reasonable to assume that reuse is unrealistic. Blood and tissues will leave microorganisms on the catheter, which can cause infections.

The parts can be recycled by sending them for re-printing after sterilization. In the re-printing procedure, metals and plastics are processed in different ways. Metals must be made into powder and plastics must be melted into blocks, which can be used in 3D printers. This reuse of the materials will have the potential to reduce costs and increase the catheter life cycle.

14 PROCESS EVALUATION AND DISCUSSION

This chapter is reviewing evaluations and discussions related to the project process.

Wide objective

The project objective was to investigate if the catheters used in trans femoral mitral valve repair can be controlled easier and more precise. This is an extremely wide objective, which has led to a number of challenges along the way. The hypothesis was deliberately designed this way to open up for creative thinking and to think in new ways. This resulted in a great amount of time spent on charting the problem with existing catheter-based methods. Initially it looked to us like catheters used today worked just fine, and it was challenging to get to the bottom of the necessary improvements for the controllability of the catheter

Challenging to identify disadvantages linked to the catheter's steerability

The medical environment is very closed, and this implied some challenges during the research phase. To collect information linked to disadvantages of a product, the information needs to be acquired through the users. At the start we met some skepticism when requesting dissatisfaction with the catheters from the cardiologists. When we questioned which functions that would improve the control of the catheter, the common reply was that there is no problems with the way they are controlled. It is, however, impossible to develop a new concept for a method, if the challenges linked to the old method is not identified.

As a result, the research phase ended up being extremely time-consuming. The task demanded a bigger picture to understand the objective. We looked at the operations online, studying cardiac anatomy, identified the existing mechanisms to steer the catheters and identified which patents that existed in this field. Continuously, through the research phase, we found new research material that was relevant for the task. Whether it was new patents, new materials or existing methods that were not fully commercialized. Often it emerged challenges that we had not thought of. It made it difficult to set a line for this research part and start the development of a concept.

Through a number of live observations at Oslo University Hospital, observing catheter-based TAVI interventions, laparoscopy and ablation interventions, we gained a lot of useful knowledge by talking to cardiologists, surgeons, nurses and radiographers. The external test became a confirmation of those answers, documenting that for example local rotation at distal end, is a significant and desired improvement of controllability.

It was desirable from our side to see whether any features or material types with special characteristics from the typical technology and mechanical engineering world, could be adopted into the brainstorming and eventually into our solution.

Concept development
It appeared in the later part of the product development phase that we had found incorrect information about how much force the chosen piezo motor could operate. This meant that we were unsure if our solution could work with this motor. The rotational solution with gears depended on a rotational micro motor and we therefore had to resume searching for the new type engines. We eventually found a new supplier, which told us that it should be possible to develop a suitable motor. Self-criticism must be taken, for not contacting the manufacturer of piezo motors earlier and get a precise answer to our request.

At the initial face, we had great faith in smart materials and electroactive polymers. The idea was to place elements with such materials in the catheter wall, and enable deflection by applying electrical voltage. However, it was difficult to determine whether this would be possible because these materials basically transforms from a state A to a state B without the ability to freeze the motion in between. A materials expert at our University, who thought that it would be difficult to stop this deflection at the desired positions, confirmed this. In retrospect, we found a scientific article from Japan that showed the use of smart materials in exactly the same way as we had intended to implement. [53] This means that this might be possible, which would be a great advantage for the steering of the catheter. This should therefore be investigated further.

The solution
This master thesis is the initial face of many years work. Develop a concept for improving the steer ability of catheters is s huge task. A schedule of 4,5 months in this context, only makes it possible to scratch the surface of this subject. We have tried to concretize the challenges linked to our solution and provided a basis for further work, as far possible. In addition, we listed concrete proposals for further development.

Our concept solutions can prove to be functional, but to verify the solution it is required practical testing and calculations. The concept needs to be tested repaired and retested, several times. The types of materials and motors needs to be revised and considered replaced. Further research of these issues could open up new solutions and perhaps make the selected ideas to be built and tested in one-to-one scale.

Some of the things that could have been done differently when working on this thesis, are listed below.

- The external test could have been preformed at an earlier stage, to document the needs for more precise steerable catheters from a cardiologists point of view.
- We should have formulated a more precise objective from the start. This would probably have led to a more efficiently process of sourcing out the specific and necessary background information.

- There could have been done some hand calculations during the research period, so that metrics could have been considered from the start. Not only in terms of movement and degrees of freedom, but also in terms of required forces.
- Several experts on material science could have been contacted to verify properties on smart materials and the possibility for use in our setting. This would have done the process of finding suitable materials more efficient.
- Ideally, the research part and the concept development, concerning the product itself, could have been two independent projects.
- The chosen concept should preferably have been tested physically in a scaled model. Due to time restrictions, this was however not conducted.

-

15 CONCLUSION AND FURTHER ASPECTS

The objective of this master thesis was to identify and examine the possibilities for a precise positioning of catheters in the cardiovascular system. Furthermore, the aim is to develop proposals for a proof of concept where the treatment device can be positioned as exactly as possible by available imaging methods, where they are compatible to each other. This objective is conducted and a concept where the catheter can obtain an S-shaped movement with local rotation and elongation in the distal end is developed.

15.1 Results and recommendations

The result is a concept where the catheter can obtain an S-shape across three planes when its supported by a guide catheter with conventional steerability. The guide catheter makes the first deflection and the steerable catheter is pushed through the guide catheter to make the longitudinal movement before it makes the second deflection. After the second deflection, a rotation device enables local rotation in the distal end where the operation device is connected. A coil spring of shape memory alloy is fine-tuning the longitudinal positioning, which can elongate independently from the rest of the catheter.

The following elements are developed and included in the result:

a) **A cylindrical reel** that can rotate its distal side 360 degrees in both directions independently of the proximal side. The reel is controlled by two strands, which alternating are being pulled to control the rotation.

b) **A coil spring of a shape memory alloy** is connected between the rotational mechanism and the operation device. The coil can elongate when supplied with voltage and fine-tune the operation device in the longitudinal direction.

c) **Two wires** are placed inside lumens along the longitudinal direction of the catheter. These lumens are located 90 degrees relative to each other, seen from a cross-section view of the catheter profile.

Materials for the developed components are not selected. As a result, considerations concerning compatibility to imaging technology are not performed. Therefore this needs to be considered in the further work.

It is recommended to use micro motors inside of the catheter to relocate the operative force, which controls the steerability, to the distal end. This will potentially make the movements more precise because it reduces the drag forces along the catheters path.

15.2 Further Work

The proposed concept developed in this project require further work and testing in order to fully investigate its functionality. The following list of activities needs to be taken into consideration in the further aspects of this project

- Calculation of required forced applied to the catheter to obtain steerability, needs to be done.
- Careful selection of materials must be done. The materials selected for the final products must be biocompatible and well suited for commercial production. In addition, some of the components need to be visible using available imaging technology.
- Investigation and selection of micro motors need to be done in order to find motors with suitable sizes and performance.
- Precise measurement must be specified in order to practically test the concept.
- The concept needs to be practically tested. After testing the individual components, the models can be revised according to the findings and the revised models can be prototyped. Producing the prototypes can be conducted through collaborations with third parties or through independent funding. In this process the selection of materials will be conducted according to industry standards.

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17 APPENDIXES

APPENDIX A – The Questionnaire from the External Test

APPENDIX B – Question Summaries from the External Test

APPENDIX C – Experiments

Design of Catheters for Navigation and Positioning in the Cardiovascular system.

1. Please fill in the following

Name (will not be published) ____________________

Title ____________________

Field of expertise ____________________

2. Experience within Cardiovascular surgery

- ○ Less than a year
- ○ More than a year
- ○ 2-5 years
- ○ More than 5 years
- ○ More than 10 years

3. How many interventions with use of steerable catheters have you performed?

- ○ Less than 50
- ○ 50 - 200
- ○ 200 - 500
- ○ 500 - 1000
- ○ More than 1000

4. How many interventions did you perform before feeling like you were mastering the procedure?

- ○ Less than 10 interventions
- ○ 10 - 30 interventions
- ○ 30 - 50 interventions
- ○ More than 50 interventions

Design of Catheters for Navigation and Positioning in the Cardiovascular system.

Rate the following statements from strongly disagree to strongly agree.

5. Limited steerability in the distal end of the catheter can lead to complications during minimal invasive procedures

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
○	○	○	○	○

6. Deflection of the distal end of the catheter does not meet the need for accurate navigation within the heart.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
○	○	○	○	○

7. Rotation of the distal end of the catheter does not meet the need for accurate navigation within the heart.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
○	○	○	○	○

8. Local rotation in the distal end of the catheter would have made the procedure easier and more accurate.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
○	○	○	○	○

9. Longitudinal movement of the catheter does not meet the need for accurate navigation within the heart.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
○	○	○	○	○

10. Local elongation in the distal end of the catheter would have made the procedure easier.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
○	○	○	○	○

Design of Catheters for Navigation and Positioning in the Cardiovascular system.

11. Any comments to the previous statements?

12. What are the challenges associated with today's steerable/deflectable catheters?

13. What would you like to have changed or improved with today's catheters, considering rotation, deflection and elongation respectively?

Rotation

Deflection

Elongation

14. What is the best/most accurate catheter you have used (name and/or manufactor)? Explain why.

15. What type of feature do you find most critical to obtain a precise positioning of the catheter tip? Arrange the listed features.

Rotation

Deflection

Elongation

16. Give a short explanation to your rating.

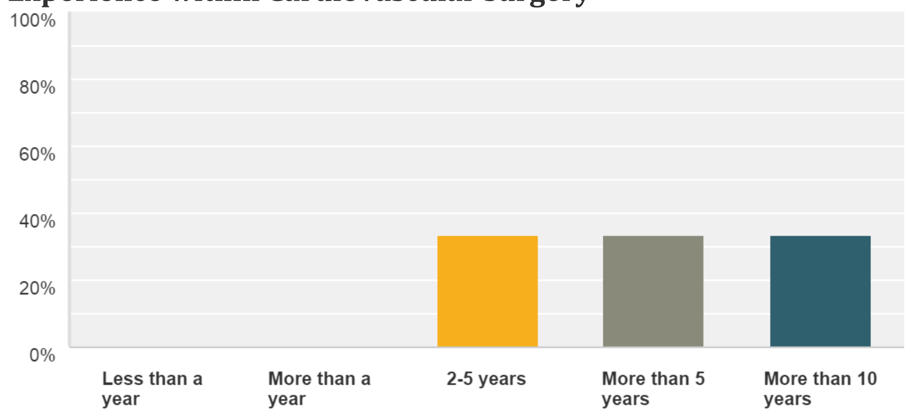
17. Describe your imaginary ideal catheter, considering the features in the distal end of the catheter.

Thank you so much for your time!

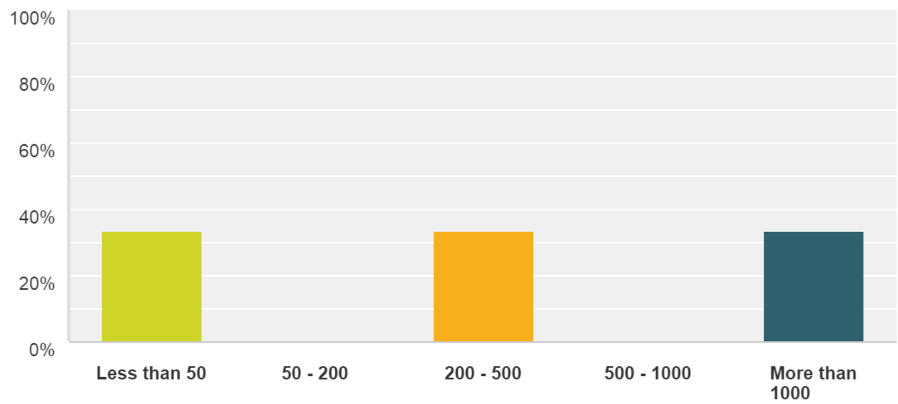
APPENDIX B Results from the External Test

This appendix contains the collected answers from the external test.

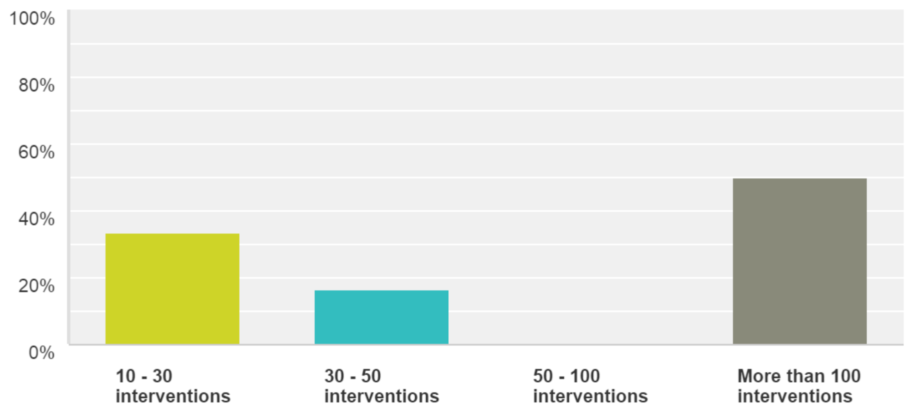
Experience within Cardiovascular surgery



How many interventions with use of steerable catheters have you performed?



How many interventions did you perform before feeling like you were mastering the procedure?



Limited steerability in the distal end of the catheter can lead to complications during minimal invasive procedures.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
0%	0%	16,7%	83,3%	0%

Deflection of the distal end of the catheter does not meet the need for accurate navigation within the heart.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
0%	50%	16,7%	33,3%	0%

Rotation of the distal end of the catheter does not meet the need for accurate navigation within the heart.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
0%	60%	0%	40%	0%

Local rotation in the distal end of the catheter would have made the procedure easier and more accurate.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
0%	0%	0%	100%	0%

Longitudinal movement of the catheter does not meet the need for accurate navigation within the heart.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
0%	83,3%	16,7%	0%	0%

Local elongation in the distal end of the catheter would have made the procedure easier.

Strongly disagree	Disagree	Irrelevant	Agree	Strongly agree
0%	0%	0%	83,3%	16,7%

The comments to the statements were the following:

"In general, improved steerability will improve success rate and reduce the risk of complications - because you can reach the area of interest with less force. Rotation and elongation are less important than deflection - as these movements can be achieved by rotation and forward/backward movement of the entire catheter, respectively."

"My experience transcather only - with Abbott Vasculars MitraClip system, and answers are related to this. (Treating more than 60 cases of mitral regurgitation) (also have experience with Medtronic's core valve system and Boston's Lotus valves for treatment of aortic stenosis - more than 150 cases)"

What are the challenges associated with today's steerable/deflectable catheters?

1. Limited degree of accuracy. "Memory" - would be good to reposition the catheter in exactly the same position as previously. This should be applied to all (rotation, deflection and elongation)
2. Challenge of steerability/flexibility vs. penetrability/stiffness.
3. Thick and rigid catheters.
4. I feel that lack of tactical feedback and liability to produce multiple curves at the distal catheter tip are some disadvantages with current technology.

What would you like to have changed or improved with today's catheters, considering rotation, deflection and elongation respectively?

- **Rotation**
  1. Accuracy and the possibility to measure degree of rotation.
  2. Difficult due to chorda in left ventricle.
  3. Rotation of the catheter curvature only (not the shaft).
- **Deflection**
  1. Accuracy and the possibility to measure degree of deflection.
  2. Deflection in more than one plane.
  3. Deflection and increase in radius of the curvature.
- **Elongation**
  1. Accuracy and the possibility to measure degree of elongation.
  2. Ability to elongate catheter in the left ventricle can limit the procedure.
  3. Elongation of the tip beyond the curvature to produce reach.

What is the best/most accurate catheter you have used (name and/or manufactor)? Explain why.

With respect to movement it is the Medtronic 8mm – However, this is not best for mapping due to the large tip. RF Contractor (Dual-Curve) Series Ablation Catheters.

What type of feature do you find most critical to obtain a precise positioning of the catheter tip? Arrange the listed features.
(The features are rates from 1-3, see the results in the table below)

	1	2	3
Rotation	**0%**	**50%**	**50%**
Deflection	**100%**	**0%**	**0%**
Elongation	**0%**	**50%**	**50%**

Give a short explanation to your rating.

1. Rotation is problematic due to chordae in left ventricle.
2. Rotation is often easiest to conduct by rotation the entire catheter, while deflection enables the possibility for movements around corners.
3. Deflection is beyond the most important feature as elongation is produced by advancing the catheter and rotation by rotating the catheter

Describe your imaginary ideal catheter, considering the features in the distal end of the catheter.

1. Thin, with dual curve and independent movement in all planes. Possibility to re-position the catheter to the exact same curves - (rotation, deflection and elongation). Bipolar with narrow spacing of the bipoles. (4 poles - with possibility to configure for several bipolar measurements).
2. Depends a lot on what the intention of the catheter is - full valve deployment or concerning repairs. It is impossible to cover this fully.
3. Relative soft and flexible in multiple planes.
4. The ideal catheter would give feedback on tissue contact and characteristics, it should be easy handled and soft to follow cardiac tissue motion/movement. Multiple curves, adjustable curvature.

APPENDIX C – EXPERIMENTS

Several experiments were conducted throughout the brainstorming phase to test different ideas. This is a review of some of the experiments that were completed.

- **FISHING LINE**

Procedure: A fishing line, approx. 40 cm long, was connected to an electric drill in one end and a weight of around 100 gram in the other end. The rotation of the weight was locked in the end were the weight was connected, and the electrical drill twined up the fishing line until it formed a coil. The coil was then warmed by a hairdryer to fasten in its shape. A coiled artificial muscle of a fishing line was then created.

Test: The coiled fishing line was tested as an artificial muscle, to see if it would contract when it was heated up. The coil was therefore connected to a weight of about 200 gram and the hairdryer was used to warm up the coil. As the Video 1 on the attached disk shows, the coil lifts the weight when it is being heated, see the picture from the experiment below.

Figure 1: a) Picture from the experiment.

Reference [55] gives a more detailed overview of the field of coiled fishing lines as synthetic muscles and is one of the pages where we got the inspiration to do the experiment.

- **BALLOON ARTIFICIAL MUSCLE**

Procedure: A balloon was put inside of a net with a mesh that only cold expand sideways and not in longitudinal direction, see the figure below. The net was bought in a grocery store, used to pack red onions.

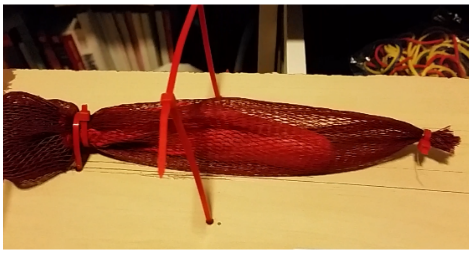


Figure 2: A balloon was put inside of a net that ensure expansion sideways and not in longitudinal direction.

The balloon was then connected to pump, which filled it with air to increase its volume. Since the volume of the balloon was prevented from expand in longitudinal direction it had to compensate by moving the increased volume sideways. The expansion of the balloon was therefore shortening the whole system in the longitudinal direction and a force was applied from the balloon-net system to the rod that was connected to it. See the whole experiment in Video 2 on the disk attached. The figures below shows a three-step movement of the system in the expanded position.

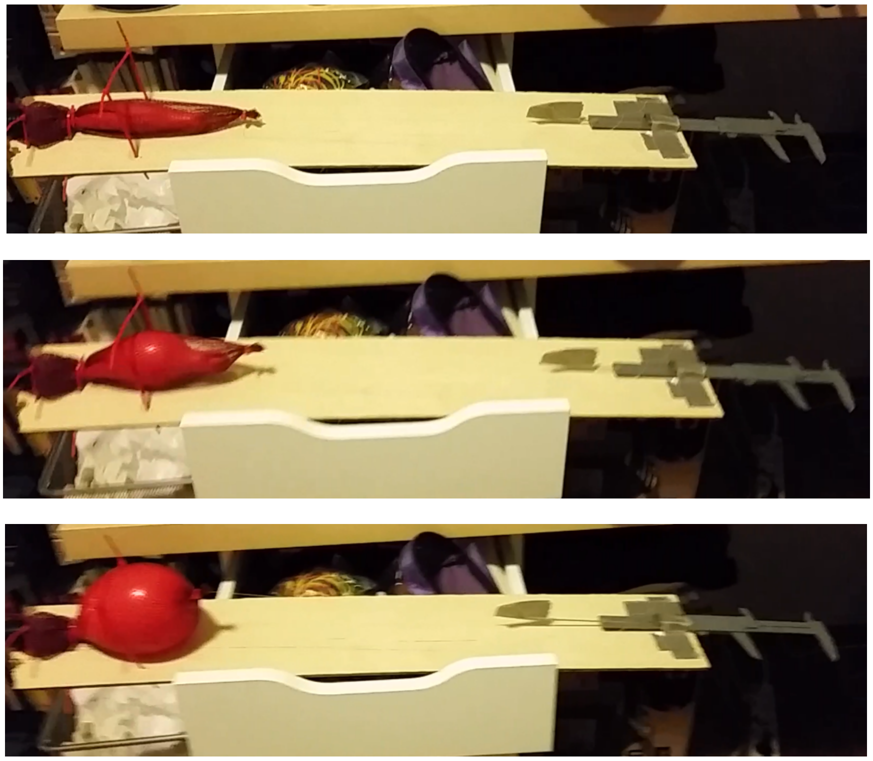


Figure 3: Three steps from when the balloon is expanding and shortened in the longitudinal direction to apply a force to the rod that its connected to. A caliper is connected to it to measure the shortened length.

- **ROTATION ROD**

Procedure: The rotation mechanism was tested to see the transmission of linear movement to rotation. See video of the experiment in Video 3 on the attached disk. The figure below shows a picture from the experiment.

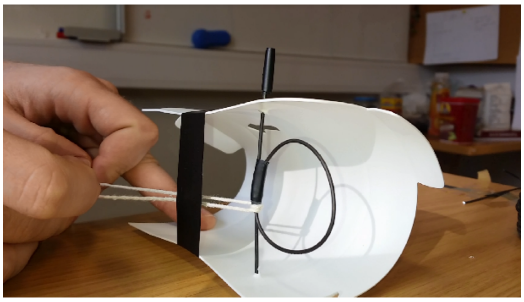


Figure 4: Picture from the experiment of the rotation rod.

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