# CardioBot – A Robotic System for TAVI Intervention
# Robotic Catheter System

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## Abstract

The Transcatheter Aortic Valve Implantation (TAVI) is a standard surgical intervention to replace the aortic valve. For this intervention, fluoroscopy is used to provide real-time imaging to give the surgeon a visual feedback of the guidewire and catheter position. Specialised surgeons perform this type of intervention several times a week, which exposes them to high doses of radiation and high cancer risk.

A first concept for a telerobotic system for TAVI intervention is derived to decrease radiation exposure of the surgeons.

After introducing the subject, an overview of the state of the art is given. To define the requirements for the telerobotic system, different experiments are performed with the help of Dr. med André Plass and Dr. med Maurizio Taramasso. Based on their input, the general requirements for the slave system in the operating room are defined.

The system should be able to control the axial and rotational movement of a guidewire or catheter while being inserted into the artery of the patient. Building on that, first elementary concepts, based on translation and rotation of a guidewire or catheter, are developed. The first concept for the propelling unit is based entirely on friction wheels, the second concept only partially and the third concept uses a completely different approach based on a belt system.

In the future the first prototypes based on the presented concepts can be build and tested.

## Acknowledgements

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I would also like to thank Dr. med. Maurizio Taramasso for supporting us during the experiments and providing us with valuable additional information.

Special thanks to the Universitätsspital Zürich, which allowed us to visit the operation room and gain a deeper insight into the TAVI intervention.

I also express my gratitude to Michael Herold-Nadig and the whole Sensory Motor Systems Lab. This thesis would not be possible without their help.

In the end, I would also like to thank my colleague Linard Furck for his helpful comments on this thesis and for his support during the semester.

# Contents

# 1 Introduction

The Transcatheter Aortic Valve Implantation (TAVI) is performed using constant X-Ray fluoroscopy for visual feedback. This exposes the surgeons to a significant dose of radiation during the whole intervention which leads to a higher cancer risk for them. To avoid this, the idea is to develop a telerobotic system, that can be controlled from a safe distance.

A robotic system for the TAVI procedure produces many benefits and increases safety for the patient, as well for the operator. Radiation exposure is minimized and movements are executed more efficiently. The goal is to develop a robotic system that can be installed easily and quickly.

This thesis will be focused on the slave system that operates on the patient in the operating room. My colleague Linard Furck's thesis will be focused on the haptic feedback system to safely control the system from a distance.

# 2 Theory

## 2.1 The Procedure

### 2.1.1 Transcatheter Aortic Valve Implantation (TAVI)

The aortic valve stenosis is one of the most common heart valve diseases today and it is caused by inflammation or calcification of the valve. Replacing the aortic valve can be done through a traditional surgical intervention or, if the patient's medical conditions do not allow a traditional surgery, through minimal invasive techniques such as the transfemoral TAVI (Transcatheter Aortic Valve Implantation) or the transapical TAVI procedure. The major advantage of these procedures is that the activity of the heart does not have to be suspended, in order to replace the valve. This is useful in cases where the patient has already cardiovascular diseases or has an advanced age. In the following, only the transfemoral approach will be described in detail, because our project is strictly related this procedure.

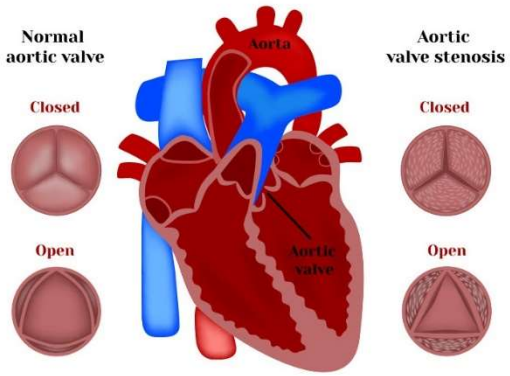



**Figure 2.1:** Aortic Valve Stenosis
Source: Fortisescorts.in

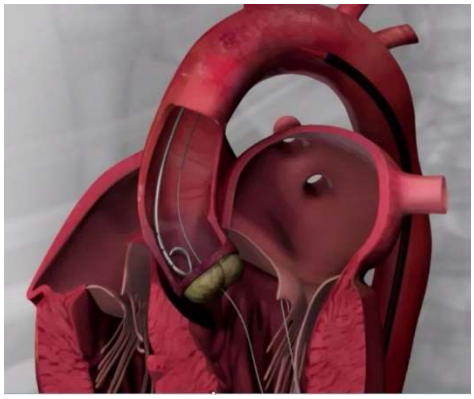
### 2.1.2 Transfemoral TAVI

The intervention is started by inserting a sheath in the inguinal area to gain access to the femoral artery. A guidewire is then inserted through the sheath into the femoral artery. The guidewire is later used to facilitate the insertion of the catheter, which contains a stent with the aortic valve prosthesis. The physician pushes the guidewire upwards to the aortic arch and then through the calcified aortic valve and into the left ventricle (Figure 2.2a). At the same time, a tiny tube called "pigtail" is also inserted through the inguinal access. The tip of this tube has the shape of a pigtail and it is used to locate the aortic valve as well as to inject contrast medium. This is used to check for leakage during and after the insertion of the new valve.

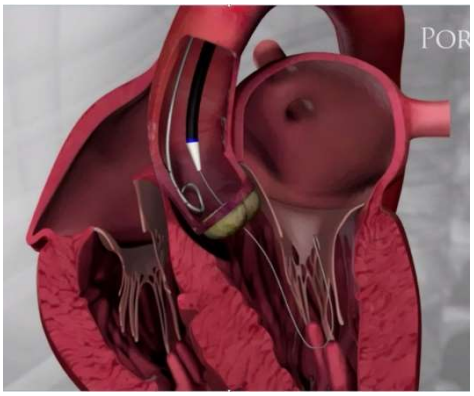
A catheter is then pushed over the guidewire, introduced into the patient's body and brought in position of the old, calcified valve (Figure 2.2b). The catheter can be equipped with a balloon to push the old valve apart and to create space for the insertion of the new valve. Alternatively, the catheter can be equipped directly with a stent that contains the new valve. In this case the stent develops enough radial force to push the old valve apart and to adhere directly on the vessel walls of the aorta (Figure 2.2c). During the inflation of the balloon and/or placement of the stent with the new valve, fast ventricular pacing is used. This is important in order to minimize heart flow rate and heart movement and to allow a precise placement of the aortic valve prosthesis.

The new valve prosthesis is not deployed all at once, but partially. This is necessary to verify, with the aid of the contrast medium, that it is placed correctly and that there is no leakage. If needed, the valve can be resheathed and repositioned until the surgeon is satisfied with the position. Finally, the physician deploys fully the valve (Figure 2.2d).

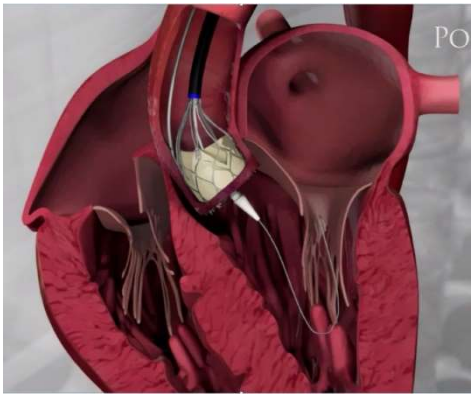
A light cardiac insufficiency may be present even after total deployment of the new valve, but it should disappear within three days after the intervention. Finally, the system is completely withdrawn from the patient and the TAVI intervention is completed.



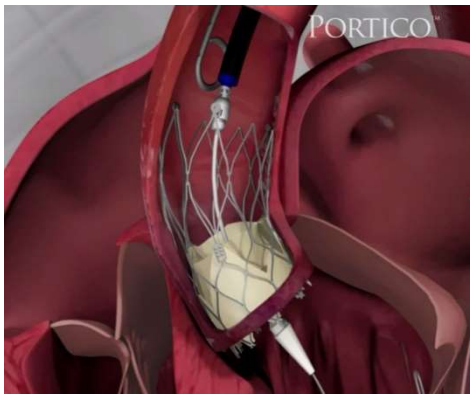
**a)** Inserting guidewire through valve



**b)** Inserting catheter with artificial valve



**c)** Opening of catheter and placing the valve




**d)** Correct placing of valve and withdrawing of the catheter

**Figure 2.2:** Overview of the TAVI procedure
Source: Maisano and Nietlispach

### 2.1.3 Safety of the TAVI Procedure

According to Hartzell Schaff (2011) the transvenous insertion of a pulmonary valve prosthesis was described for the first time in 2000 by Bonhoeffer et al. They assumed, that a similar technology might also be used to replace other cardiac valves. Two years later Cribier et al. (2002) performed the first percutaneous replacement of the aortic valve. From that point on the technology evolved rapidly and two relatively mature technologies, SAPIEN Transcatheter Heart Valve (Edwards Lifesciences) and CoreValve Revalving System (Medtronic), are used on a regular basis today.

The so called PARTNER trials (Placement of Aortic Transcatheter Valves) provide a comparison between the TAVI procedure and the traditional surgical method. PARTNER 1 trial has been carried out over a period of one year and later PARTNER 2 over two years. The results of PARTNER 1 trial (Hartzell, 2011) are very promising: After 30 days the mortality rate of the transcatheter group was 3.4% and 6.5% in the surgical group. After one year the mortality rate was 24.2% for TAVI and 26.2% for the traditional surgery. Further, PARTNER 1 revealed concerning signals about possible vascular and technical complications. Small imperfections in positioning of the valve prosthesis caused a change in haemodynamics of the blood vessel and this increased the risk of an embolic stroke. The TAVI procedure showed a risk of embolic stroke of 5.5% after 30 days and 8.3% after a year. The traditional surgical method in comparison showed values of 2.4% and 4.3% respectively. Today, these technical imperfections have largely been overcome by increased operator experience and technical improvement of the implantable device (Hartzell, 2011). The results of PARTNER 2 trial have been published a year ago (Eggebrecht, 2016). 2032 patients have been examined and for the first time the trial included also patients with an intermediate surgical risk and an STS-Score of 4-8% (Society of Thoracic Surgeons). The STS-Score is calculated "to decide whether a patient should undergo a surgical or transcatheter aortic valve replacement." (Jancin, 2014).

The new data form PARTNER 2 show that TAVI has become a relatively safe intervention, with complications in only three cases out of 994 (0.3%). After two years rate of mortality or severe embolic stroke was 18.5% for TAVI and 21% for traditional surgery. Patients who received a transfemoral TAVI showed an even lower mortality or severe embolic stroke rate of 16.3%. The haemodynamic properties have also been better after TAVI intervention than after traditional surgery. Over a period of two years the transvalvular gradient was lower and the valve opening significantly bigger. (Eggebrecht, 2016)

In conclusion TAVI seems to be an advanced intervention which brings a lot of benefits to the patient, but it is important to remember that TAVI requires continuous X-Ray fluoroscopy. This results in radiation exposure of patient and surgeons and therefore, an examination of the radiation doses is necessary. The insertion of the guidewire through the aorta and through the calcified aortic valve, the dilation of the old valve with a balloon as well as the insertion of the stent with the aortic valve prosthesis are steps with high radiation exposure. Daneault et al. (2012) examined the radiation exposure during TAVI and compares it to other PCI's (percutaneous coronary interventions). The following results are presented in the paper:

1. Radiation exposure during TAVI is comparable to other percutaneous coronary procedures.
2. The transapical TAVI approach shows lower dose of radiation in comparison to the transfemoral TAVI approach.
3. A higher body weight and a higher Body Mass Index (BMI) were associated with greater amounts of radiation.

Due to the access and closure of the femoral artery, extra fluoroscopic time is needed in the transfemoral approach compared to the surgical access of the ventricle apex in the transapical approach. It is also important to consider that in case of complications during the transfemoral TAVI, it is often necessary to use extra fluoroscopy time, whereas this is often not the case in the transapical approach. Here, management of complications often requires urgent surgical treatment that does not involve fluoroscopic imaging. High body weight and BMI value are also associated with higher radiation because larger

patients require more energy to generate sufficient imaging. This does not change the duration of the intervention though.

An estimator called “effective dose” (E) is used to compare the exposure to radiation of different procedures. It is calculated using to the actual physical dose delivered and weighting factors that consider the radiosensitivity of each organ as well as the age of the patient. The paper states that for transfemoral TAVI E is equal to 42 mSv, for transapical TAVI E = 16 mSv and for other PCI E = 29 mSv. In conclusion one can see that the average radiation exposure of TAVI is similar to PCI, but it is important to consider that normally TAVI patients have a higher age than PCI patients. Radiogenic cancers do not appear until a period of years or decades. So, the risk of cancer for the patient due to radiation during TAVI is considerably low.

Knowing that cancer risk due to radiation should not play a major role for the patient, it is important to find new strategies to decrease radiation exposure for all surgeons involved in the procedure.

## 2.2 The Idea

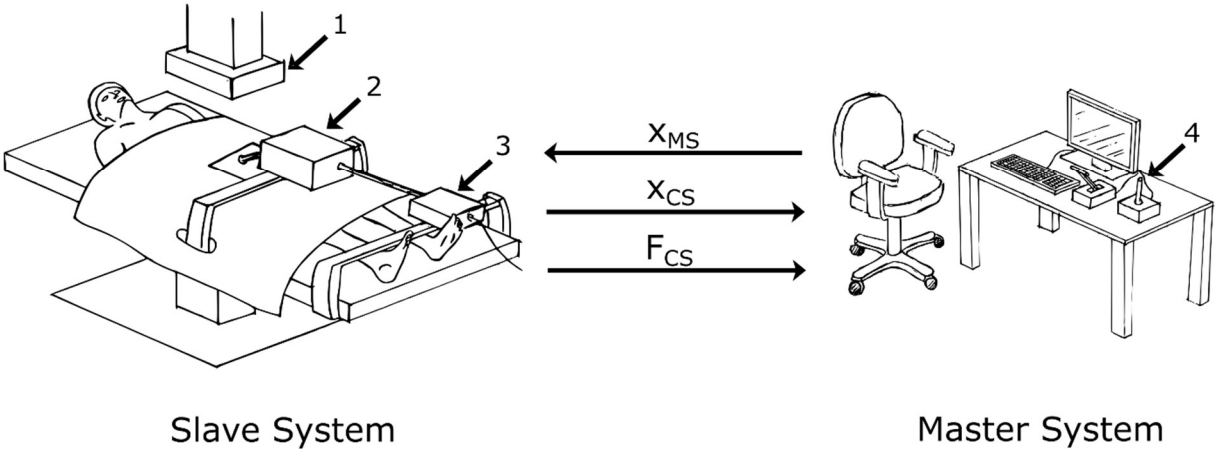



**Figure 2.3:** Overview of our idea and the according transferred data. The Slave System consists of the drive mechanism for the guidewire (2) and a secondary unit (3) for locking the guidewire in a certain position. The Master System includes different input devices to control the motion of the Slave System. Between the two systems information about the position of the Master System $x_{MS}$, the position of the guidewire $x_{CS}$ and the Force on the guidewire $F_{CS}$ are exchanged.

Inserting a guidewire as well as the catheter and performing the whole TAVI procedure requires a real-time image showing the continued progress of the guidewire or catheter through the patient’s body. This is generally achieved with X-Ray fluoroscopy, which generates a high level of X-Ray radiation and exposes the medical personnel to significant danger. It is therefore very important to reduce the risk that comes from radiation exposure of the medical staff. One possible solution to that problem is to perform the TAVI procedure, or parts of it, from a safe distance with the help of a remote controlled robotic system.

From this point on, if not written explicitly, guidewire, catheter or pigtail are referred as guidewire for simplicity.

The system in the operation room is composed of a guidewire propelling device called main unit (2) and a secondary unit (3). Both are placed on the patient. The system can be mounted directly on the operating table or on a support arm that can be installed in proximity of the table. The main unit is coupled with the secondary unit, which may be used to lock the guidewire in the desired position and to correct the

position of the wire while operating on the catheter. This allows to simultaneously manipulate catheter and guidewire.

The guidewire is pushed inside the patient's body through an insertion cannula into the femoral artery and into the Aorta. A fluoroscopy (1) device provides real-time images showing the position of the guidewire.

A control console outside the operation room (or at a safe distance) is used to control the robotic system. It is composed of user input devices (4) and one or more monitors, which can be used to display fluoroscopy images and other relevant information received from the sensors of the system. The patient's vital signs can also be displayed on the monitors. Three different input devices are depicted in the image: a more classical device, such as a keyboard, a joystick and a device that works similar to an airplane's thruster. A possible input device can be designed in a way that mimics the actual catheter and gives the operator a more natural feeling. Alternatively, a completely abstract approach can be used to control the catheter, as long as it is easy to use. Different input devices can be combined in order to separate different functions on multiple devices.

### 2.2.1 Flowchart

The promised teleoperated robot consists of a human operator, a master system with force feedback for input, a slave system which guides the catheter and two controllers.

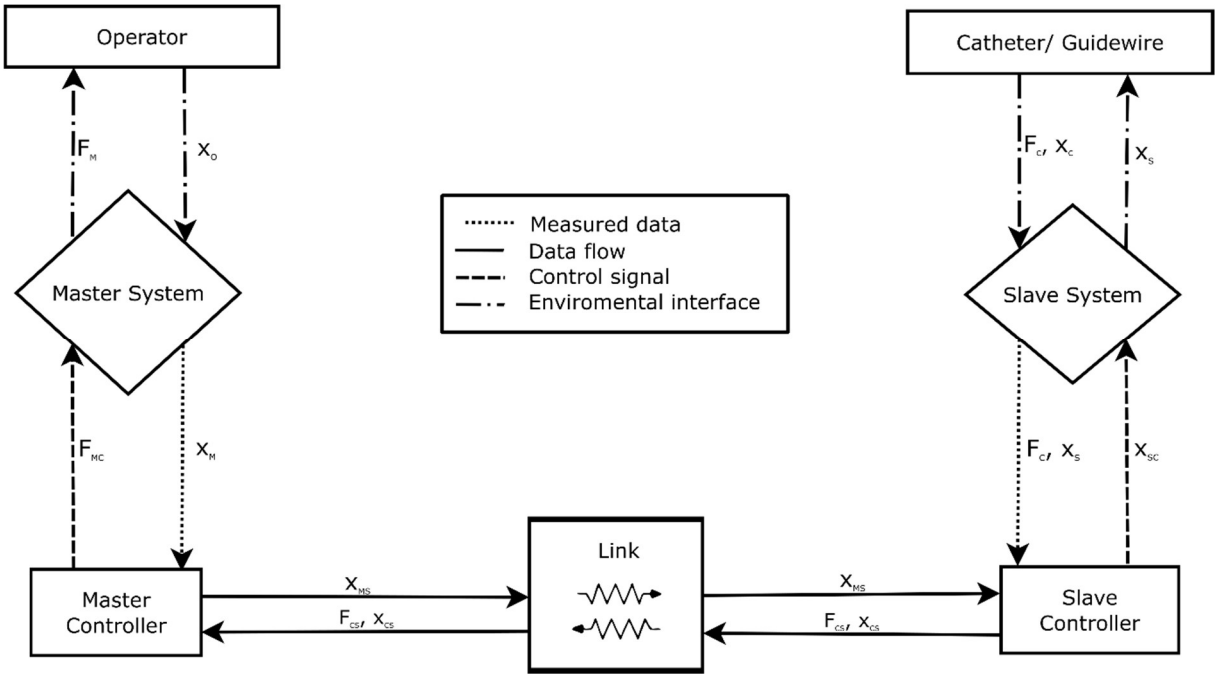



**Figure 2.4:** Flowchart showing the interaction between the Slave and Master System. The Master System contains the input device with all its actuators and sensors, whereas the Slave System includes the drive mechanism with all its actuators and sensors.

The surgeon controls the position $\mathbf{x_M}$ of a master system with his motion $\mathbf{x_O}$. The measured motion $\mathbf{x_M}$ is transferred to a master controller which sends the data $\mathbf{x_{MS}}$ over a linkage to the slave controller. It translates the input data $\mathbf{x_{MS}}$ into a control signal $\mathbf{x_{SC}}$ that governs the motion of the slave system with position control. This leads to a movement of the catheter $\mathbf{x_S}$. The position of the catheter $\mathbf{x_C}$ as well as the force on the catheter $\mathbf{F_C}$ is measured and transferred back to the slave controller. Afterwards they are translated into the signals $\mathbf{F_{CS}}$ and $\mathbf{x_{CS}}$ which are send back to the master controller. It uses force control by giving the master system the signal $\mathbf{F_{MC}}$ which is translated to an according force $\mathbf{F_M}$ on the operator.

# 3 Methodology and Experiments

In this chapter, an analysis of existing devices and their working principle is given. In total, seven systems will be presented and the most important features for our project will be summarised. After that, the experiments that were performed are presented and based on that, the requirements for the slave system are derived.

## 3.1 Targets

### 3.1.1 Main Targets of the Overall Project

First of all, the long-term targets of this project are to analyse the TAVI intervention and to examine which steps are feasible with a robotic system. After that, the goal is to develop a prototype which is entirely controlled through a human operator from a safe distance. In the next stage of this project, the idea is to transmit data from CT measurements and planning of the intervention to the robotic system, in order to create a partially or fully autonomous system. Automation is possible, because TAVI is a highly standardized procedure.

### 3.1.2 Targets of this Bachelor Thesis

For this bachelor thesis the targets were first to look for existing systems that can control or manipulate a catheter or guidewire and list the advantages and disadvantages of every system for our purpose. After that, we have defined the requirements to the system and collected the necessary data through experiments. With this knowledge, first elementary concepts were developed that are based only on translating and rotating a guidewire.

## 3.2 State of the Art

Our project aims to develop a robotic system which supports the surgeon during the TAVI procedure and helps to decrease radiation exposure of the medical staff. However, the idea of using a robotic system during catheter interventions is not new and there have been several attempts to develop such systems. At the moment there are various market-ready systems, which allow to steer and manipulate a guidewire or catheter from a safe distance from the radiating source. The following systems have not been designed for TAVI and there are also no other systems today that work for the TAVI intervention, but their functioning principle might be interesting for our purpose. Five market-ready systems will be presented:

- Corindus System
- Hansen Medical Robotic Systems
- Niobe System
- Amigo Catheter System
- CathROB (still in development)

Additionally, a helpful research prototype has been developed for endovascular interventions:

- System for Endovascular Teleoperated Access (SETA)

Another interesting solution comes from the field of simulation training:

- Flexible Endoscope Training

In the following, a short description of the systems is given and the advantages and disadvantages of their working principle for the TAVI intervention are mentioned.

### 3.2.1 Corindus System (Corindus Vascular Robotics, MA, USA)

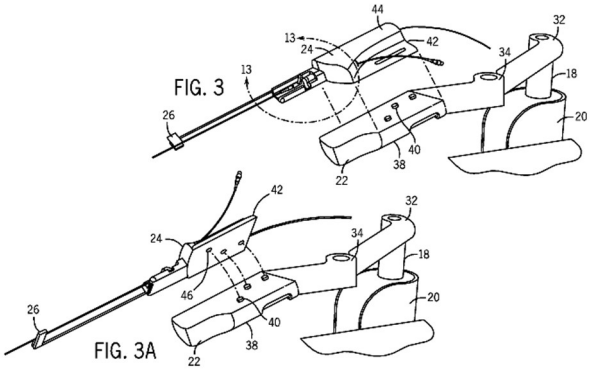



**Figure 3.1:** Complete Corindus System

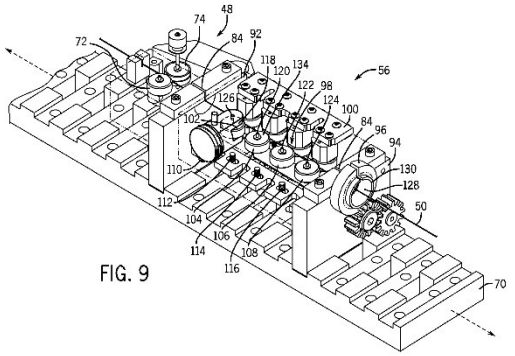



**Figure 3.2:** Axial and rotational drive mechanism

The Corindus robotic catheter system was developed to perform percutaneous coronary interventions (PCI). These procedures are used to treat patients with diseased and often obstructed heart arteries. This intervention is performed by introducing a guidewire through the femoral artery, the same way it is done during the TAVI intervention. The system is composed of a cassette, including an axial and a rotational drive mechanism, and a moveable arm, which functions as a base for the removable cassette. The cassette includes a first axial drive mechanism for the guidewire which moves the wire along its longitudinal axis and a second axial drive mechanism for the working catheter. The cassette includes also a rotational drive mechanism to rotate the guidewire. There is no rotational mechanism for the working catheter, it is only pushed forward. (Wenderow et al., 2013, p. 29)

Taking a closer look on the axial and rotational drive for the guidewire (Fig. 3.2) we can see that the system is based on a friction wheel mechanism. The axial drive mechanism is composed of a first (72) and second wheel (74) working togheter to drive the wire in axial direction. The force between the two rollers can be adjusted with a spring mechanism. (Wenderow et al., 2013, p. 32)

The rotational drive mechanism is composed of four pairs of wheels (102, 104, 106, 108) which move towards one another and apply sufficient pressure to rotate the guidewire along its longitudinal axis, while still permitting the guidewire to move in axial direction. The rotation of the guidewire results from the torque exerted on the housing which contains the four pairs of rotational wheels and from the frictional force between guidewire and wheels. For easy insertion and removal of the guidewire, it is also possible to move the wheels of axial and rotational drive apart. (Wenderow et al., 2013, p. 33)

#### Advantages and Disadvantages

If we would use this working principle for the TAVI intervention, the advantages of the system would be a relatively simple mechanics, as the movement is completely based on wheels. This design has two degrees of freedom, which are sufficient for the TAVI intervention. Additionally, the cassette can be detached at any time, which is always useful during interventions. The disadvantages are that the cassette can only be used once, probably for sterility reasons and a system based on wheels might possibly cause high point load on the catheter that contains the valve prosthesis.

### 3.2.2 Hansen Medical Robotic Systems

**Figure 3.3:** The Magellan System
Source: Hansen Medical

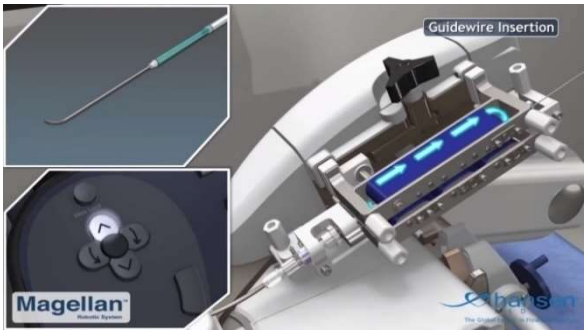



**Figure 3.4:** Guidewire translation
Source: Youtube

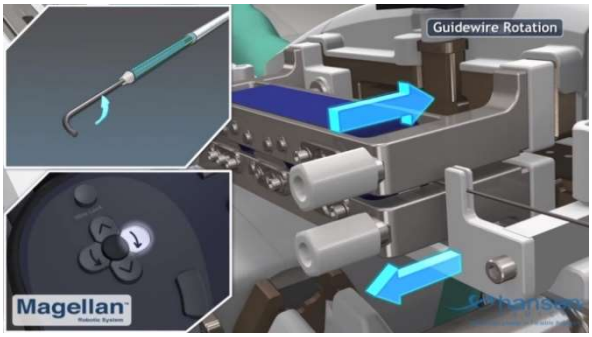



**Figure 3.5:** Guidewire rotation
Source: Youtube

The Magellan System by Hansen Medical (from www.hansenmedical.com) is a robotic device that assists the surgeon in navigating peripheral blood vessels and can be used for a variety of endovascular procedures. The system works with specific, steerable sheaths which allow a precise steering of guidewires and catheters remotely controlled from a separate workstation. For example, for cardiac ablation procedures a standard electrophysiology catheter is introduced in a steerable sheath and then inserted into the patient's blood vessel. This means that this system uses standard equipment, but it is always controlled with an outer sheath which implies a higher invasiveness compared to the manual intervention. The motor unit is based on a belt drive system. It uses two belts, one on the upper and one on the lower side, and it creates a motion with two degrees of freedom. It allows the tool to advance axially and to rotate about its own axis. Advancement is achieved by letting both belts run in forward direction and rotation is created by a shearing motion of the two belts.

#### Advantages and Disadvantages

As stated before, the system uses standard guidewires and catheters, but they are introduced in sheaths and this increases the invasiveness of the intervention. On the other hand, this creates a high catheter stability which can be very helpful for the surgeons. The way the motor unit was designed decreases significantly the pressure on the catheter and it decouples advancement from rotation of the tool. This means that it is possible to rotate the guidewire without having to advance at the same time. With such a belt drive system it is not possible to continuously rotate the working tool, but rotation up to a few complete revolutions should be possible.

### 3.2.3 Niobe System (Stereotaxis Inc., MO, USA)

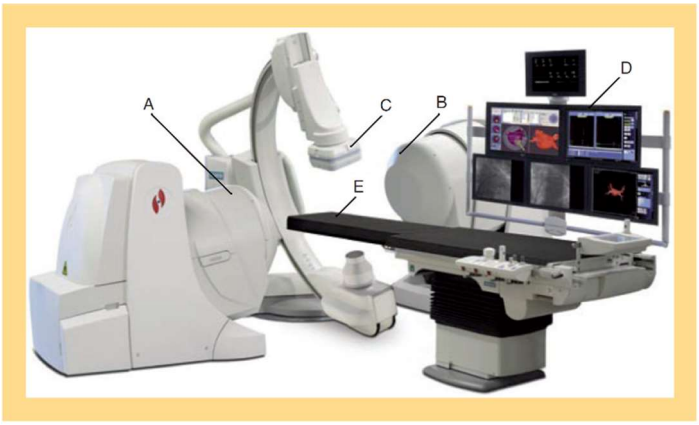



**Figure 1. Robotic magnetic navigation system (Niobe®, Stereotaxis, Inc., USA).** It consists of **(A,B)** two permanent magnets, **(C)** a fluoroscopic scanner, **(D)** visualization displays and **(E)** a patient's table.
Adapted from [101].

**Figure 3.6:** Niobe System
Source: Carpi et al.

The Niobe System is the leading technology to control medical tools in the human body from outside with a magnetic field. No other technology has comparable capabilities and is being used in clinical practice. (Carpi et al., 2009)

The system is based on two permanent magnets placed on both sides of the patient, who is lying on the operating table. The fluoroscopy device is placed above the patient and provides the surgeon with the needed real-time images to identify the position and orientation of the tool being maneuvered inside the body. The permanent magnets can be rotated inside their housings which themselves can be tilted. In this way it is possible to create a uniform magnetic field inside the patient's body. The field can be rotated and oriented as desired within a defined body portion. Special catheters with tiny permanent magnets in the tip and in distal portions are introduced in the patient's body and their orientation can be controlled from outside through the rotation of the magnetic field. (Carpi et al., 2009, p. 2,6)

Niobe is used to perform a cardiac ablation procedure. This procedure is used to scar small areas in the heart through electrical pulses that may cause heart rhythm problems.

#### Advantages and Disadvantages

Although this system allows to control very precisely the movements of the catheter with the magnetic field inside the body and it is also less invasive than other systems, there are no parts or working principles that can be adopted for a TAVI robotic system. Using magnetic steering for our system would mean that it would also be necessary to develop special TAVI equipment for the system. Developing a system that uses standard equipment is a fundamental requirement of this project, as it is stated in chapter 3.4.

### 3.2.4 Amigo Catheter System (Catheter Precision Inc., NJ, USA)


**Figure 3.7:** The Amigo Catheter System
Source: Shaikh, Eilenberg, Cohen

The Amigo Catheter System was designed for cardiac ablation procedures. In contrast to the Hansen Medical Magellan System and the Niobe System, it uses the internal steering mechanism of standard electrophysiology catheters. This means that this system was designed for catheters that have three degrees of freedom (translation, rotation and tip deflection).

The Amigo System is mounted directly on the operating table over the patient. It is based on a rail system for longitudinal movement and an electric actuator which allows rotation of the catheter. The Amigo System is able to control all three degrees of freedom of the catheters, which means that it can also control the tip (deflecting or straightening).

Another important aspect of Amigo is its manual override function, which allows to quickly remove the catheter from the system for manual operation, and then re-attach it to the system without compromising catheter sterility or positioning. (Shaikh, Eilenberg, Cohen, 2017, p. 2)

#### Advantages and Disadvantages

As stated above, the Amigo System has a very simple design, intuitive controls and it can be mounted directly on the operating table. It is a cheap solution without any automatization or sensors and it uses the internal steering mechanism of the EP-catheter. A helpful feature of this system is its manual override function. Amigo seems to be safe and effective, but it is not very compact (size: 101 × 137 × 112 cm) and quite heavy (weight: 32 kg). (Cercenelli et al., 2017, p. 2)

The most useful feature of this system for our purpose is probably the way it is mounted on the operating table, using a bridge-like structure, without the need of an external table or base.

### 3.2.5 CathROB (University of Bologna)

Many Systems available today for remote catheter manipulation typically require special catheters or equipment, are excessively large or time-consuming to set up. The goal of CathROB was to develop a system that is light, fast to install and that could assist the surgeon in crucial phases of the intervention. (Cercenelli et al., 2017, p. 1)

CathROB was designed for cardiac ablation procedures and it works with electrophysiology catheters. It is equipped with a force sensor, an intuitive user interface and functions for automatic catheter navigation and repositioning. The system is considered safe, since it uses conventional EP-catheters inserted through conventional introducer sheaths. Therefore, the system does not change the normal catheter forces on the heart and the normal bending and buckling properties of the catheter. (Cercenelli et al., 2017, p. 3)

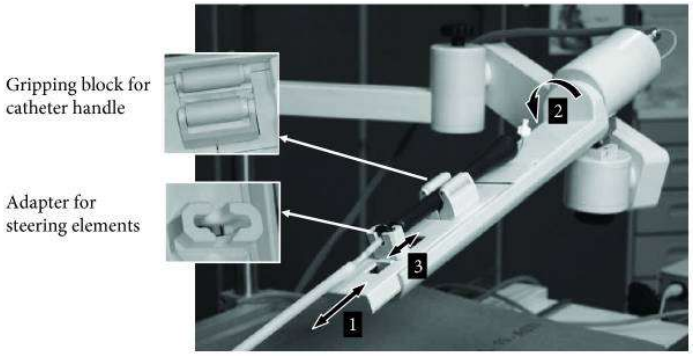



**Figure 3.8:** CathROB disposes of three degrees of freedom and is composed of three main units: 1) Advance and withdraw, 2) Rotation, 3) Steering of the catheter tip
Source: Cercenelli, Bortolani, Marcelli

The motion unit has a minimum size of 53 x 8 x 11 cm and a maximum size of 73 x 8 x 11 cm. The paper of Cercenelli et al. (2017) does not state clearly how far the catheter can be advanced, but my assumption is that it is only possible to advance the catheter of 20 cm. This means that the system is only designed for "on-site" operations and it is not possible to perform the entire intervention with this system. The fact that it is possible to remove the catheter anytime and to take manual control of the catheter, supports my assumption. CathROB disposes of a telescopic sheath that helps to stabilise the connection between the catheter handle and the introducer sheath giving access to the blood vessel. Additionally, the telescopic sheath helps to reduce the friction between the catheter and the introducer sheath. It is important to say that no part of the entire system enters the patient's body. One big advantage of CathROB is that it can be used with different kinds of standard EP-catheters. The steering adapter (point 3 on the image) can be exchanged and thus be adapted to different catheters. (Cercenelli et al., 2017, p. 4)

#### Advantages and Disadvantages

CathROB is extremely compact and very fast to install and set up. As stated before, it uses standard EP-catheters and the internal steering mechanism to keep the costs low, but at the same time it is also equipped with electronic assistance devices such as a force sensor and navigation functions. The control unit has very intuitive controls and the catheter can be detached very rapidly from the system to manually control the operations. The only apparent disadvantage seems to be the limited forward motion of only 20 cm.

### 3.2.6 System for Endovascular Telerobotic Access (SETA)

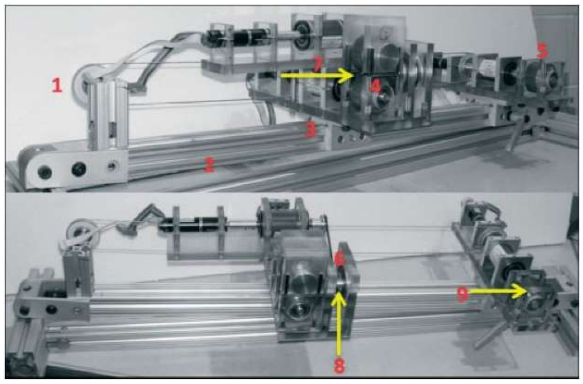



**Figure 3.9:** SETA patient side slave mechanism. 1, Pulley for travelling cart 2: Mounting arm 3: Travelling cart 4: Linear drive for guidewire 5: Linear drive for catheter 6: Steering stage for catheter 7: Entry point for guidewire, 8: Steering point for catheter and 9: Exit point of catheter into body
Source: Srimathveeravalli

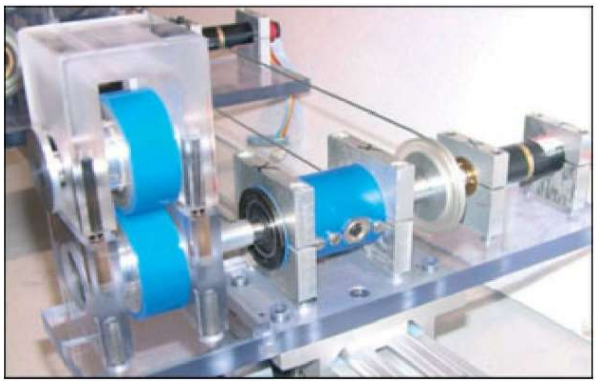


**Figure 3.10:** Operating principle (left) and construction of the insertion – withdrawal linear actuator (right)
Source: Srimathveeravalli

The group of Govindarajan Srimathveeravalli et al. (2010) investigated design specifications for safe motion and force limits for endovascular surgery. Based on this experience they constructed a teleoperated, haptically enabled system called System for Endovascular Telerobotic Access (SETA).

SETA's working principle is based on two translational stages and one steering stage, allowing simultaneous manipulation of catheters and guidewires. The linear actuators are constructed with friction wheels. The steering mechanism is designed with a special gripper-and-pulley system, which behaves like an axial bearing that transmits power radially while allowing axial slip. SETA features three points of manipulation (near the cannula, at the catheter hub and at the distal end of the guidewire), which are similar to the points used by the surgeon during a manual intervention. (Srimathveeravalli et al., 2010)

The study conducted by Srimathveeravalli et al. to identify the basic forces in endovascular interventions is also of particular interest for our project. Thanks to SETA, the group was able to detect the normal slip error with friction wheels. It was found that the mean slip error was lower than 0,4 mm for 100 mm length of insertion. More information about this study is presented in chapter 3.3.

#### Advantages and Disadvantages

The system is designed relatively simple. It carries out all movement with rotational electric motors and pulleys and it is able to self-adjust to different diameters. However, the system was not designed specifically for TAVI and the fact that there is a separation of guidewire and catheter drive might not be ideal for our purposes. This separation is simply not necessary for TAVI, because guidewire and catheter are introduced successively and not at the same time. Finally, this system is only a research prototype that has only been tested in vitro and not in vivo.

### 3.2.7 Flexible Endoscope Training

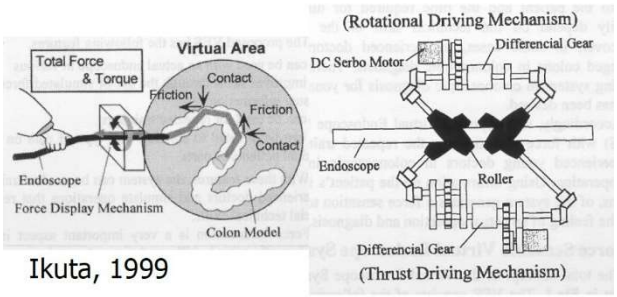



**Figure 3.11:** Version 1, Ikuta 1999

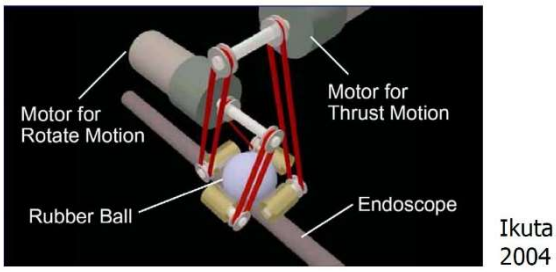



**Figure 3.12:** Version 2, Ikuta 2004

The last solution comes from the field of simulation training. It is a flexible endoscope training device which comes in two versions. The first one (Ikuta, 1999) is based on two pairs of rollers, two on the top of the endoscope and two on the bottom. The rollers are placed at a 45 degree angle to the endoscope and they can be controlled individually in order to create either a forward thrust motion or a rotational motion. The second version (Ikuta, 2004) includes a rubber ball that is placed on top of the endoscope and driven with two motors, one for thrust motion and one for rotational motion. With this setup it is possible to create a forward motion and at the same time a rotational motion of the endoscope.

#### Advantages and Disadvantages

The big advantage of this system is that it is extremely compact. In fact, it creates advancing and rotation of the endoscope with the same components. Additionally, no movement of the housing or other external elements is involved. The negative aspect of such a system is that it is not easy to implement and it may be difficult to create a reliable movement with tools that have a smaller diameter than endoscopes, such as catheters or guidewires.

### 3.2.8 Adoptable Solutions

| | Motion Elements | Force/ Loading | Installation | Control Unit |
|---|---|---|---|---|
| **Corindus System** | Movement based on wheels | Point load, possible high pressure | — | — |
| **Hansen Medical** | Motion based on belt system | No point load, low pressure | — | — |
| **Niobe System** | — | — | — | — |
| **Amigo** | — | — | Mounted on operating table | Intuitive control interface |
| **CathROB** | Detachable any time | — | — | Save different position, navigation |
| **SETA** | Self adjusting, Gripper | — | — | — |
| **Flexible Endoscope Training** | Comb. of movement, stationary housing | — | — | — |

**Figure 3.13:** Solutions that can be adopted

Based on the analysis conducted until this point, it is possible to sum up the solutions of the state of the art that can be adopted for our robotic system. Figure 3.13 shows a table with the properties of every system that might be important for our system. In chapter 4, different concept ideas will be presented. Their functioning principle is based on the properties highlighted in yellow in this table.

This section concludes the analysis of the TAVI procedure, the problematics of it and the analysis of the state of the art for catheter or guidewire manipulating systems. Even if none of the systems currently available could be used for the TAVI intervention, their functioning principles are very useful for our purpose. In the following sections and chapters, requirements and first concepts are derived for a robotic system for the TAVI intervention.

## 3.3 Experiments

In the following sections, the requirements for the TAVI robotic system are derived. It was necessary to conduct experiments in order to gain more information about the feeding velocities of the guidewire and about the maximum axial resistance force during the insertion of the guidewire.

### 3.3.1 Additional Information on Surgeon Motion Data

The group of Srimathveeravalli et al. (2010, p. 3, 4) has conducted a study to gain more knowledge about the typical motion patterns of surgeons during endovascular interventions. The study was conducted on female rabbits and even if the results might not be exactly the same as during an intervention on a human patient, the values that were collected can be seen as a good starting point. The measurements were done by collecting the hand motion data of the interventionalist.

The results of this study showed that the interventionalist moved the tool with a maximum velocity of 500 mm/s, a maximum axial force of 4,5 N, a maximum torque of 8 Nm and a pinch force of 0,75 N.

### 3.3.2 Conduction of Experiment

For our project, we have conducted experiments to determine the axial resistance force at which the surgeons would stop feeding the guidewire into the femoral artery of the patient. Additionally, we wanted also to determine the maximum feeding velocity of guidewire. For this thesis, the value of the maximum resistance force is of bigger importance and, therefore, only the experiment related to that value will be presented. The experiments related to the feeding velocities are presented in the thesis of my colleague Linard Furck.

**Figure 3.14:** Execution of the experiment

**Figure 3.15:** Experiment setup

The experiment was made with the help of Dr. med André Plass and Dr. med Maurizio Taramasso. They were asked to push a handle with the same force they would exert on a guidewire according to their feeling. The handle was connected to a Kistler Low Force Sensor (+/- 50 N) that was able to record the maximum force exerted by the surgeons. During the experiment they were asked to simulate first a low resistance situation. After that, they were asked to push the handle with the biggest force they would exert on the guidewire in a higher resistance situation.

The experiment was performed once with Dr. André Plass only and then a second time with Dr. Plass and Dr. Taramasso. The mean values of all measurements are listed below.

| **Plass** | | Attempt 1 | Attempt 2 |
|---|---|---|---|
| Normal | Mean [N] | 3,64 | 2,74 |
| High-Resistance | Mean [N] | **6,38** | **5,02** |
| | Minimum [N] | 5,72 | 4,13 |
| | Range [N] | 1,98 | 1,84 |
| | | | |
| | | | |
| **Taramasso** | | Attempt 1 | |
| Normal | Mean [N] | 1,97 | |
| High-Resistance | Mean [N] | **5,66** | |
| | Minimum [N] | 5,15 | |
| | Range [N] | 1,16 | |

**Figure 3.16:** Summary of all Measurements

The value of 5,69 N was the average of all high-resistance values at which the surgeons stopped pushing and 4,13 N was the lowest value at which one of the two surgeons stopped. These values will be important for the requirements of our system. It is interesting to notice that our values are not far away from the value of 4,5 N of Srimathveeravalli et al. (2010, p. 3,4). The range of values that were measured was quite high (up to almost 2 N). This is probably because of the fact that the surgeons were not holding an actual catheter and because the experiment was based on their perception. The table with the complete measurements can be found in the appendix of this thesis.

## 3.4 Requirements for the Slave System

### 3.4.1 Indications on Sterility

Sterility is a major concern for a robotic system that is in the operating room during an intervention. The system must have certain mechanical properties, but at the same time be resistant to heat, moisture and solvents used during sterilization.

Hospitals use two different sterilization procedures: moist heat and dry heat sterilization. Moist heat sterilization takes place between 121 – 134 °C with a vapor pressure of 3 bar, while dry heat sterilization occurs at 180 °C.

There are three types of plastics that are particularly indicated for a robotic system: PPSU (Polyphenylsulfone), PEEK (Polyether ether ketone) and PEKK (Polyether ketone ketone). According to Polytron Kunststofftechnik (2011), they have good mechanical properties and are also indicated for repeated sterilisation. There are also different metallic materials that can be used to build surgical instruments (ÖGSV Fachkundelehrgang II, 2008), for example stainless hardened chrome steel, unalloyed lacquered sheet steel or anodized aluminium. Most of the commercially available motors and servos cannot be inlaid in detergent for sterilization, because this would damage the bearing and lubrication. Recently, Maxon Motors Inc. have developed the first sterilisable motor system (ECX series) that can withstand up to 2000 sterilization cycles. (from www.maxonmotor.ch)

### 3.4.2 Installation

The parts that get in contact with the guidewire as well as the parts that are placed in proximity of the access to the patient's arteries have to be sterilised. Motors or servos that cannot be sterilised should be covered.

The system should not be too big or too heavy, easy to position and quick to build up. A system that can be mounted directly on the operating table would be a preferred option. A system that allows to detach the guidewire at any time without compromising the positioning or sterility would be of great advantage.

### 3.4.3 Geometry

With this system, we want to use standard guidewires and standard catheters, so standard equipment has to be compatible. The wires and catheters used during the TAVI intervention have a diameter range that goes from 0,90 mm to 10 mm.

### 3.4.4 Movement

The system should allow a movement of two degrees of freedom: advancing and twisting of guidewire. It must be possible to lock the guidewire in a certain position. Additionally, it should be possible to slightly move the guidewire forwards and backwards, even during operations with the catheter. This is necessary to perform position corrections of the guidewire, while the catheter with the valve prosthesis is introduced into the patient's vessel.

### 3.4.5 Linear Movement

The system should have a stroke length of about 2 meters and reach a maximum velocity of 1,6 m/s. This value comes from the experiments on the feeding velocity of the guidewire. For this point it is important to point out that the priority is on safety for the patient. This means that it is important to make sure that the feedback system is fast enough to react to possible resistance encountered by the guidewire during the intervention. Otherwise, the maximum velocity has to be reduced. The system should also have three velocity steps (slow, medium, fast) and an emergency pullback mode.

### 3.4.6 Rotation

It should be possible to rotate at least about 200° at once. An optional requirement is that guidewire can be rotated continuously. A rotational precision of at least 90° is required and a value of 360°/s can be taken as a target value for rotational speed. These values are based on the experience of the surgeons involved.

### 3.4.7 Sensors

Our system should be equipped with a force sensor and a position sensor. The force sensor is needed first of all to provide force feedback to the surgeon and as a safety mechanism for the patient.

During our experiments we have found the resistance values at which the system has to give a warning to the surgeon and interrupt the transmission for safety reasons. These values are 4,00 N for the warning and 5,50 N for the interruption of the transmission. The warning is given at the lowest resistance force at which the surgeons stopped pushing the handle during our experiments. Interruption of transmission takes place at the mean value of all stop-resistance forces of our experiments. Once the system stops the transmission, the surgeon still has to have the possibility to override the limitation, if he decides that it is safe to proceed with the intervention.

The position sensor has to have an accuracy of 5mm. This value is also based on the experience of the surgeons involved.

# 4 Concepts and Discussion

In the following, first concept ideas for the propelling unit (main unit) and for the secondary unit are derived. After giving an overview about the working principle, the main advantages and disadvantages of the different concepts are discussed.

## 4.1 Main Unit – First Concept

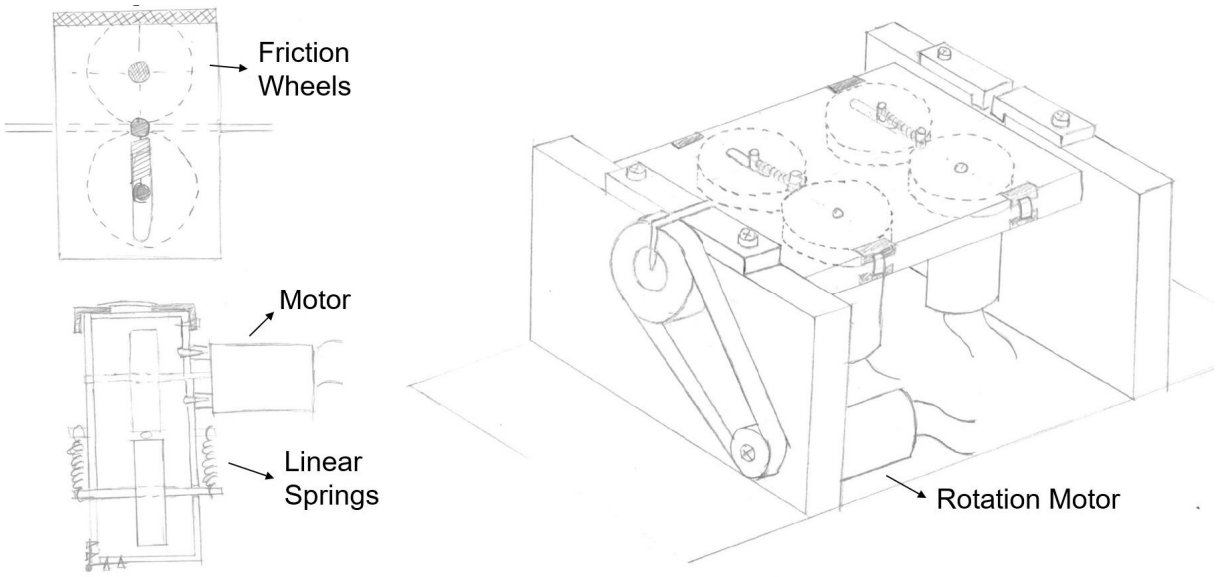



**Figure 4.1:** Drawings of the first concept

The first concept of the main unit uses friction wheels for propelling interventional tools. Drive is given to the upper wheel (left image), while the lower wheel creates a self-adjusting mechanism and moves along the axis perpendicular to the axial direction of the guidewire. In this way it is possible to use different catheters or guidewires with different diameters without any external adjustments. Linear springs are used to make sure that there is always enough gripping force on the tools. The wheels are placed inside a custom made housing and the motors are mounted directly to this housing.

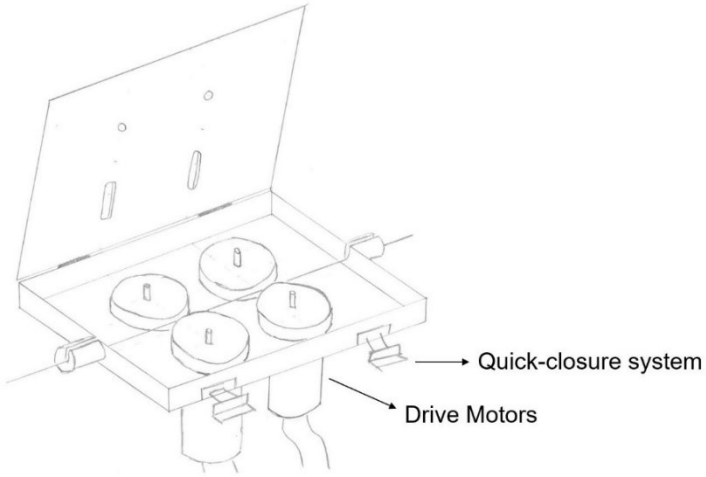



**Figure 4.2:** Drawing of the Housing with Motors

The whole system is then placed on two support structures, which allows the housing to rotate. This is achieved with a separate motor that exerts a rotational torque on the housing.

Advancement of the guidewire is achieved with the friction wheels, while rotation is achieved through rotation of the whole housing between the support structures. The housing disposes of a quick-closure system and, after removing the springs, it can be opened to allow easy removal and insertion of a guidewire. If necessary, replacement of the friction wheels is also possible.

## 4.2 Main Unit – Second concept

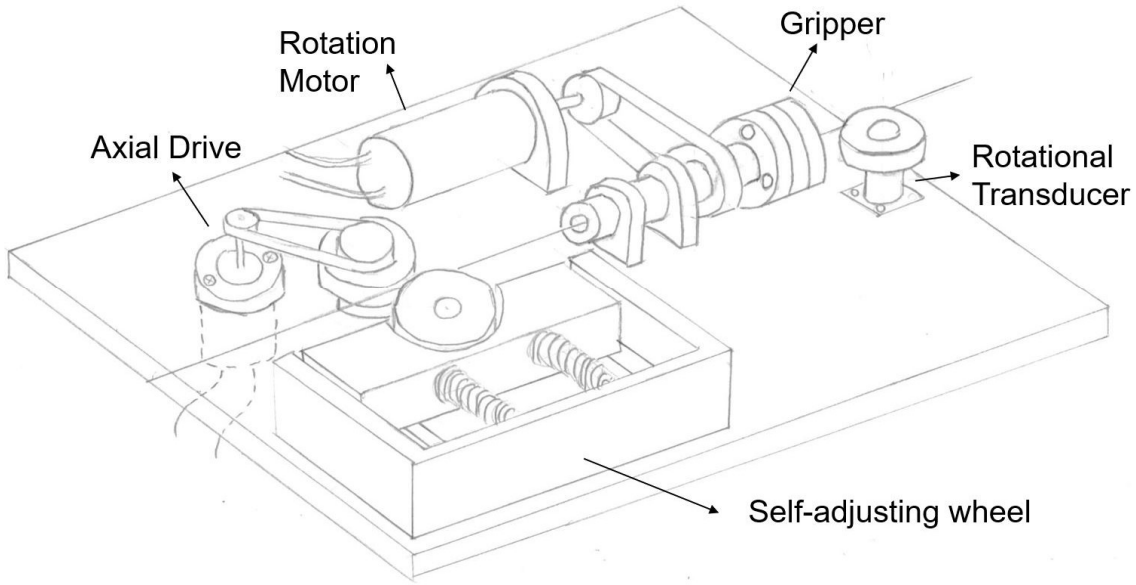



**Figure 4.3:** Drawing of the second concept

The second concept for the main unit uses also friction wheels for the axial drive, but rotation of the guidewire is achieved with a device called “gripper”. The axial drive is composed of a rotational electric motor, which gives drive to one wheel, and of a second, self-adjusting wheel that acts as an idler. Springs in the self-adjusting mechanism make sure that the wheels of the axial drive are always pushed onto the interventional tools with the right force. The gripper is driven by an additional rotational electric motor and this concept disposes also of a rotational transducer that measures the advancement of the guidewire. In this way it is possible to measure the advancement of the interventional device in a second position. This creates an additional safety mechanism that allows to detect slip between the friction wheels of the axial drive and the guidewire. The other concepts could also be equipped with such a rotational transducer to detect eventual slip.

### 4.2.1 Gripper

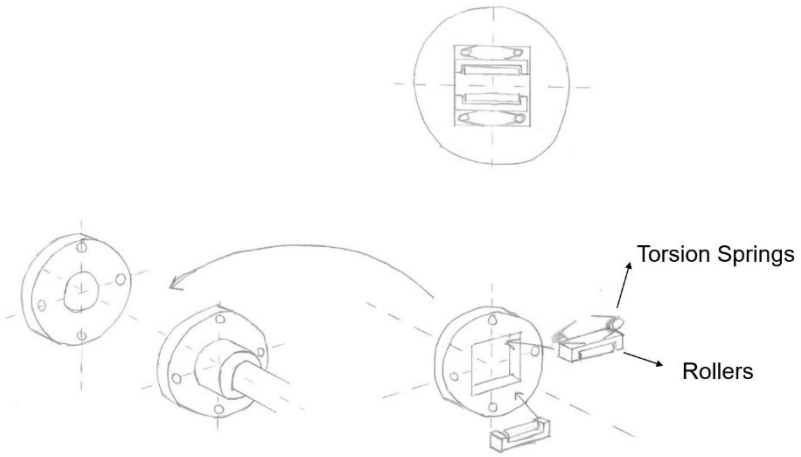



**Figure 4.4:** The Gripper Device

Rotation of the guidewire is achieved with a device called “gripper”. It is composed of three disks mounted together and the guidewire passes through the centre of those disks. The central disk disposes of two rollers and two pairs of torsion springs. The torsion springs push the rollers on the guidewire that passes between them. If now the whole gripper device is rotated, friction force between rollers and guidewire creates torque and in this way the guidewire can be rotated. While this rotation takes place, the device still allows axial slip, so this means that with this device it is possible to decouple rotation from advancement of the guidewire.

## 4.3 Main Unit – Third Concept

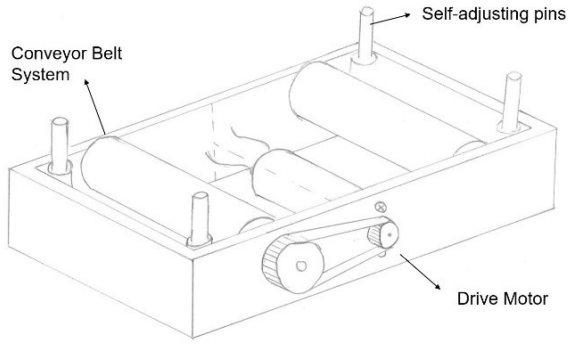



**Figure 4.5:** Lower housing containing a drive motor and the lower conveyor belt system

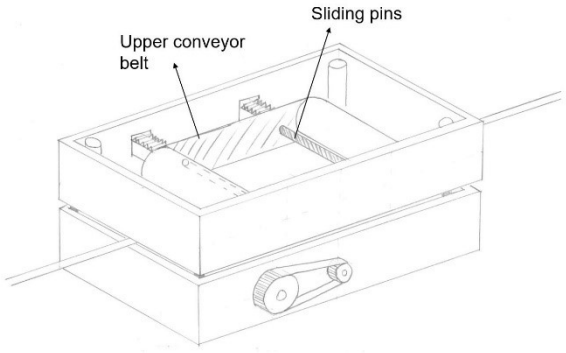



**Figure 4.6:** Complete system, composed by lower and upper housing

The third concept is based on a conveyor belt system and it is composed of a lower and an upper housing, each of them containing one belt. The guidewire passes between the two housings and it is driven by the conveyor belt system.

The lower unit (left image) disposes of a drive motor, that powers the rollers of the lower belt system. In the drawings there is no belt on the rollers to give a better overview of the system and to clarify better the way this concept works. The upper housing is put on four self-adjusting pins, which connect the two units and create a self-adjusting mechanism to changing diameters of the guidewire.

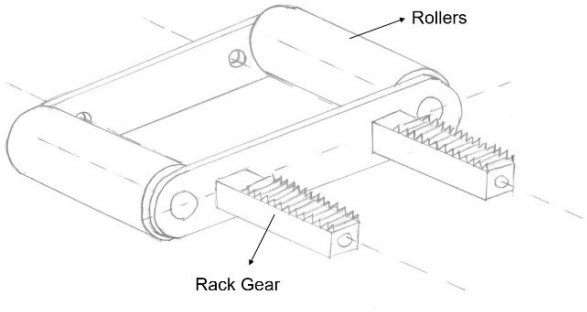



**Figure 4.7:** Upper conveyor belt

The upper conveyor belt is designed in a way that it can slide sideways on two sliding pins and create a rotating motion of the guidewire. The sliding pins are attached to the upper housing and go through the holes of the upper conveyor belt. This sideway motion is created with two motors that will be mounted on the upper housing and that drive directly the rack gear on the upper belt. These two motors are not depicted in the drawings for reasons of clarity, but they can be mounted on the inside or on the outside of the upper housing, depending on the solution that is chosen after further evaluation.

In the end, this concept creates a motion of the guidewire with two degrees of freedom: translation with the drive motor in the lower housing and rotation with two additional motors on the upper housing.

## 4.4 Secondary Unit

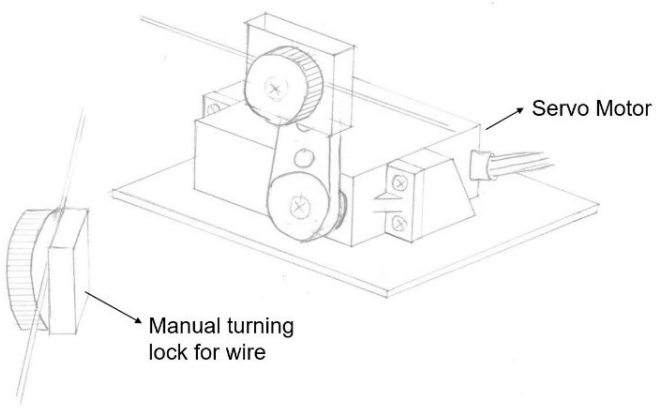



**Figure 4.8:** Secondary Unit to hold guidewire in position and under tension

The concepts presented until this point are all for the main unit and contain the whole drive mechanism for the guidewire. However, the slave system is also composed of a secondary unit, placed behind the main unit. It is used to hold the guidewire in position and under tension, as well as to correct the position of the wire while operating on the catheter with the main unit. In this way it is possible to control the guidewire and the catheter at the same time.

This secondary unit can be implemented with a servo motor, that disposes of a manual turning lock for the guidewire. Servo motors with metal gearing are characterised by high setting precision as well as high setting force and could be a good choice for this type of task.

The guidewire gets in contact only with the manual turning lock, so theoretically it is sufficient to sterilise or replace that part after every intervention.

## 4.5 Discussion

Based on the collected data and on the requirements, four concept ideas were derived, three for the main unit and one for the secondary unit.

In theory, the first concept allows a continuous rotation of the guidewire, but because of the wires and power supply of the motors that are mounted on the housing, rotation is only possible to a certain extent. Nevertheless, the minimum rotation of 200° should be achievable with this system. The housing with the friction wheels can be opened at any time, but in order to remove the catheter from the system, the housing has to be in horizontal position. In this way, the openings of the support structures are in line with the opening on the housing itself. This means that the surgeon cannot take out the guidewire at any time, but he has to first rotate it into the right position to remove it. The parts that get in contact with the guidewire and that have to be sterilisable are the friction wheels and the housing that contains them. This means that after every intervention the housing has to be removed from the system and sterilized, while the friction wheels could simply be replaced.

For the rotation of the guidewire, the second concept disposes of a device (gripper) that allows to decouple the rotational movement from the advancement of the guidewire. The axial drive however, does not rotate and this means that the spring force of the drive mechanism has to be set in a way to allow rotation of the guidewire about its axis. In the case that it is not possible to implement this in a reliable way, an active detachment of the axial drive from the guidewire is necessary to allow rotation. This would mean that the surgeon could only chose between performing a rotation or a translation of the guidewire, but not performing both at the same time. Another important aspect of this system is that, due to the way the gripper device was designed, it is not possible to completely remove the guidewire from the system at any time during the intervention. The parts that get in contact with the guidewire are the gripper device and the friction wheels of the axial drive. For sterilization, the friction wheels could be replaced after the intervention and the gripper could be constructed with sterilisable materials and then simply disassembled.

For the third concept, it is important to make sure that there is always the right gripping force on the tools. The curb weight of the upper housing might be sufficient to create the necessary pressure on the tools, or alternatively, linear springs have to be included into the self-adjusting mechanism. The only parts that get in contact with the interventional tools are the two belts and those could be simply replaced or sterilized after the intervention, depending on the type of material used.

Comparing the three concepts for the main unit, it is important to notice that for the first and third concept, the guidewire can be accessed relatively easy. This is not the case for the second concept, because of the way the gripper device is build. Another aspect to point out is that the first and the third concept allow to perfectly decouple rotation from advancement of the guidewire. For the second concept, this becomes a lot more difficult to implement.

The concept that can be sterilised best is probably the third one. The guidewire gets in contact only with the two belts of the system, which could be simply replaced after every intervention.

Based on these considerations, the most practical concepts are the first and the third one. My suggestion is to further evaluate the feasibility of those two concepts and then choose the one that is going to be built and tested.

The secondary unit was designed in a way that includes a manual turning lock. It is also possible to create a device that disposes of a controllable, automatic lock for the guidewire. Here, further evaluation is necessary to find out which type of locking mechanism is preferred for the TAVI intervention.

# 5 Conclusions

The goal of this bachelor thesis was to derive the requirements and first elementary concepts for a robotic system that will be able to perform the TAVI intervention in the future. At this point of the project we have only focused on the movement of the guidewire or of the catheter and not on the deployment of the valve itself. The concepts are also based only on translation and rotation of the guidewire or catheter.

For the slave system it was possible to derive three different concepts for the propelling unit and one concept for the guidewire locking unit. This thesis also tries to propose concepts that are based on three different functioning principles, so that our successors will have a variety of options to choose from. The first concept for the propelling unit is based entirely on friction wheels, the second concept only partially and the third concept uses a completely different approach based on a belt system. For the continuation of this project it is important to focus on one concept idea and to further develop it as well as to build a first prototype.

To determine the right requirements for the system, it was necessary to perform different experiments. We have got good results in the right order of magnitude, but the range of values measured was quite high. For further development, these experiments could be repeated in a more controlled way and with more specialized equipment.

This thesis gives a fundamental guiding for a further development of a telerobotic system that assists the surgeons during the TAVI procedure.

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# List of Figures

## Appendix

Complete measurements of the experiment, all values in Newton:

| Plass | Attempt 1 | Attempt 2 | | Taramasso | Attempt 1 |
|---|---|---|---|---|---|
| Normal | 2,7 | 3,32 | | Normal | 1,54 |
| | 6 | 1,81 | | | 1,49 |
| | 3,75 | 2,7 | | | 2,18 |
| | 3,93 | 2,64 | | | 2,19 |
| | 3,23 | 2,88 | | | 2,33 |
| Mean: | 3,64 | 2,74 | | Mean: | 1,97 |
| | | | | | |
| Resistance | 5,72 | 5,97 | | Resistance | 5,15 |
| | 5,16 | 5,97 | | | 5,52 |
| | 7,7 | 4,1 | | | 7,67 |
| | 8,49 | 4,97 | | | 6,31 |
| | 5,72 | 4,13 | | | 3,37 |
| Mean: | 6,38 | 5,02 | | Mean: | 5,66 |

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