Cardiobot - A Robotic System for TAVI Intervention Haptic Feedback Device

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Abstract

The Transcatheter Aortic Valve Implantation (TAVI) is a standard surgical intervention to replace the aortic valve. Fluoroscopy is used to give the surgeon a visual feedback of the guidewire position. The continuous radiation during the intervention leads to higher cancer risk for the surgeons, since the procedure is done several times a week.
To reduce the radiation on the surgeon, a telerobotic system with the aim to separate the place of the actual insertion and the control of that motion is proposed. Therefore an input device with haptic feedback is needed.
This thesis shows the derivation of first requirements and concepts for such a device. 8 prototypes were build and tested with Dr. med André Plass and Dr. med Maurizio Taramasso from Universitätsspital Zürich. Based on their input, requirements and concepts for a stationary and a mobile handheld device are derived.
As a result of the evaluation a mobile handheld device is proposed in this thesis, that can control the inserting motion of the guidewire or a catheter either over "position to position" or "position to velocity".
In the future the first concepts can be fully developed. For evaluating the feasibility, a functioning prototype should be build and tested.

Acknowledgements

I would like to thank my thesis supervisor Prof. Dr. Robert Riener, the head of the Sensory Motor Systems Lab at ETH Zurich, and Dr. med. André Plass of Universitätsspital Zürich. Their support in the process of writing this thesis was exceptional.
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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 System Lab. This thesis would not be possible without their help.
In the end, I would also like to thank my colleague Luca Stendardo for his helpful comments on this thesis and for his support during the semester.

Contents

Abbreviations

BMI Body Mass Index

DOF Degrees of Freedom

ETH Eidgenössisch Technische Hochschule

FFB Force Feedback

PARTNER Placement of Aortic Transcatheter

PCI Percutaneous Coronary Interventions

STS Society of Thoracic Surgeons

TAVI Transcatheter Aortic Valve Implantation

1. Introduction

About 2 % of people over 65 years are affected by aortic stenosis (Czarny and Resar, 2014). The narrowing and calcification of the aortic valve leads to mechanical obstruction for the blood, pumped out of the main chamber (Fortis Escorts Hospital Delhi). Replacing the old valve is done with Transcatheter Aortic Valve Replacement. If a minimal invasive technique is necessary due to the medical conditions of the patient, Transcatheter Aortic Valve Implementation is used.

During the intervention the surgeons rely on haptic feedback of the guidewire and visual feedback from a fluroscopy image. The latter exposes the physicians to radiation which leads to a higher cancer risk.

Therefore, a telerobotic system is needed to control the procedure from a safe distance. A potential input device should have a haptic feedback and has to fulfill several requirements regarding ergonomy, sensors, safety, input and feedback.

First, a general overview of the TAVI is given. The idea of a telerobotic system is introduced in chapter 2. In chapter 3, existing devices for telecontrol the motion of a guidewire and/or catheter are described. Further, general requirements are defined with the help of an experiment. With the aim to develop a device, best suited for the physicians, 8 prototypes were build and tested with two physicians from Universitätsspital Zürich .

Finally, in chapter 4 concepts with specific requirements are derived and discussed. The conclusion of the thesis is written in chapter 5.

2. Theory

2.1. The Procedure

2.1.1. Transcatheter Aortic Valve Implantation (TAVI)

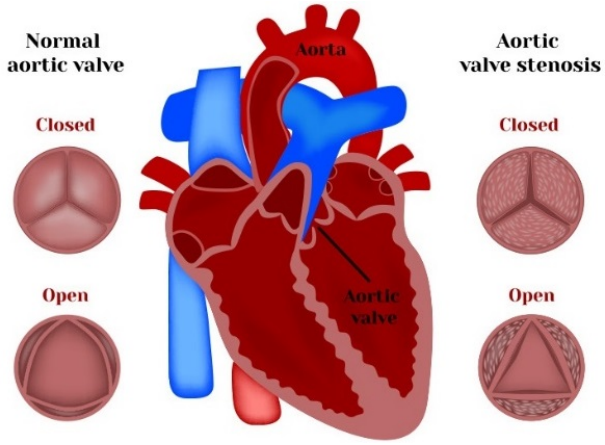


Figure 2.1.: Scheme of the difference between a normal aortic valve, depicted on the left, and aortic valve stenosis on the right. Both are shown in the closed as well as the open state. Source: Fortis Escorts Hospital Delhi

Aortic valve stenosis is one of the most common heart valve diseases. It is caused by inflammation or calcification of the valve.
Replacing the aortic valve can be done through a traditional surgical intervention. If the patient's medical conditions do not allow a traditional surgery, minimal invasive techniques such as the transfemoral TAVI or the transapical TAVI procedure are used.
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 an advanced age.
In the following, only the transfemoral approach will be described in detail, because this project is strictly related to this procedure.

2.1.2. Transfemoral TAVI

The intervention is started by inserting a sheath in the inguinal area to gain access to the femoral artery. Afterwards a guidewire is inserted through the sheath into the femoral artery 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, 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.

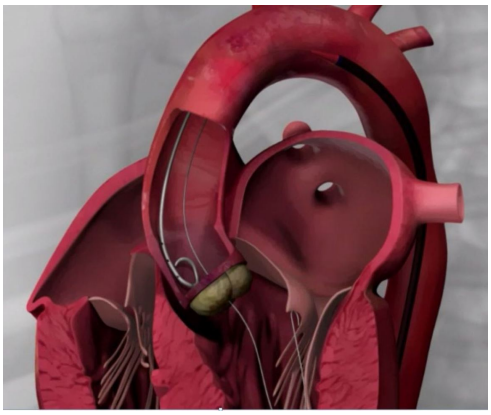
A catheter is then pushed over the guidewire into the patient's body and brought in position of the old, calcified valve (Figure 2.2b). The catheter can be equipped with a balloon to push the old valve apart and to create space for the insertion of the new valve. Alternatively, the catheter can be equipped 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 fully deploys 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.

2.1.3. Safety of the TAVI Procedure

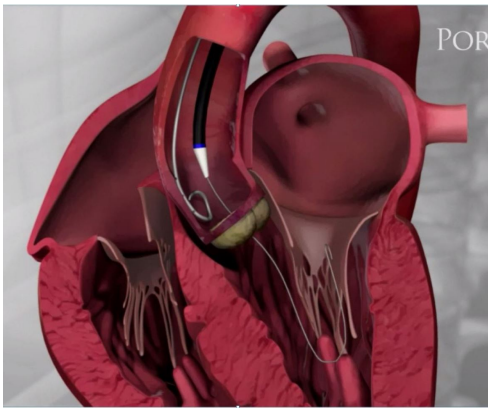
The transvenous insertion of a pulmonary valve prosthesis was described for the first time by Bonhoeffer et al. (2000). They assumed, that a similar technology might also be used to replace other cardiac valves.
Two years later Cribier et al. (2002) performed the first percutaneous replacement of the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

Two studies called PARTNER trials (Placement of AoRtic TraNscathetER Valves) were conducted to provide a comparison between the TAVI procedure and the traditional surgical method. PARTNER 1 trial had been carried out over a period of one year and later PARTNER 2 over two years.

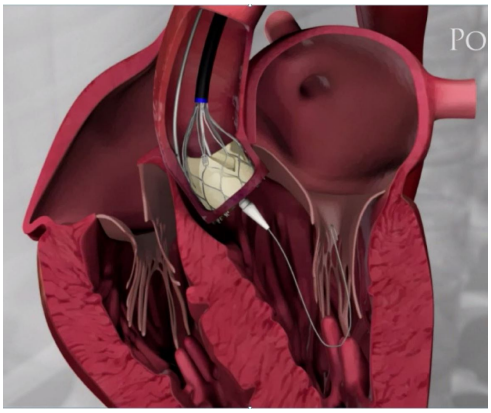
The results of PARTNER 1 trial were highly promising: After 30 days the mortality rate of the transcatheter group was 3.4 % and 6.5 % in the surgical group. After one year the mortality rate was 24.2 % for TAVI and 26.2 % for the traditional surgery. Further, PARTNER 1 revealed concerning signals about possible vascular and technical complications. Small imperfections in positioning of the valve prosthesis caused a change in haemodynamics of the blood vessel. This increases 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



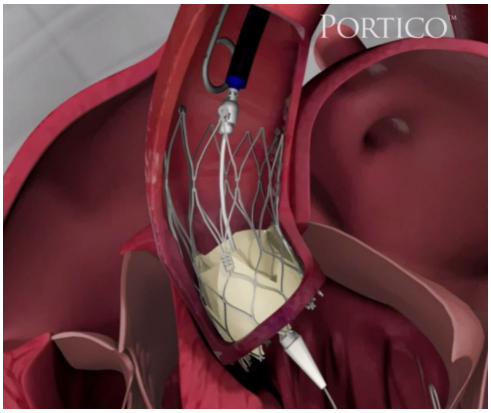
(a) Inserting guidewire through the aortic valve.



(b) Insertion of a catheter with artificial valve over the guidewire.



(c) Opening of stent and placing of the valve.



(d) Fully deploying of the valve and withdrawing of the catheter.

Figure 2.2.: Overview of main steps of the TAVI procedure.
Source: Maisano and Nietlispach

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 (Schaff, 2011).
The results of PARTNER 2 trial have been published a year ago. 2032 patients had been examined and for the first time the trial included also patients with an intermediate surgical risk and a STS-Score (Society of Thoracic Surgeons) of 4 % to 8 % (Eggebrecht, 2016). The STS-Score is calculated "to decide whether a patient should undergo a surgical or transcatheter aortic valve replacement." (Jancin, 2014)

The new data of PARTNER 2 show that TAVI has become a relatively safe intervention, with complications in only three cases of 994 (0.3 %). After two years mortality rate 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. However it is important to remember that TAVI requires continuous X-Ray fluoroscopy. This results in radiation exposure of patients 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 aortic valve prosthesis are steps with high radiation exposure.

Daneault et al. (2012) examined the radiation exposure during TAVI and compared 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 BMI (Body Mass Index) 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 comparison the average annual human exposure to ionizing radiation is 2.4 mSv (UNSCEAR, 2010, p.338).
In conclusion, one can see that the average radiation exposure of TAVI is similar to PCI. However 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 compared to the one of the surgeons 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

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 of radiation exposure of the medical staff.
One possible solution to this 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 guidewire, catheter or pigtail are referred as guidewire for simplicity, if not written explicitly.

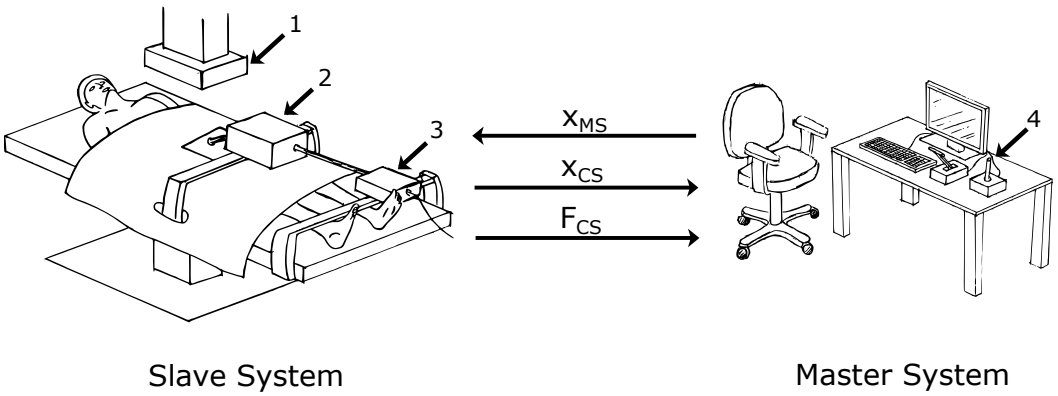


Figure 2.3.: Overview of our idea and the according transferred data. The Slave System consists of the drive mechanism for the guidewire (2) and a secondary unit (3) for locking the guidewire in a certain position. The Master System includes different input devices to control the motion of the Slave 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.

The system in the operation room, shown in Figure 2.3, is composed of a catheter propelling device called main unit (2), which is placed on the patient. It can be mounted directly on the operating table or on a support arm that can be installed in proximity of the table. The catheter propelling device can be coupled with a secondary unit (3), 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 catheter is pushed inside the patient's body through an insertion cannula into the femoral artery and into the aorta. A fluoroscopy device (1) 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 as well as the patient's vital signs. 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.

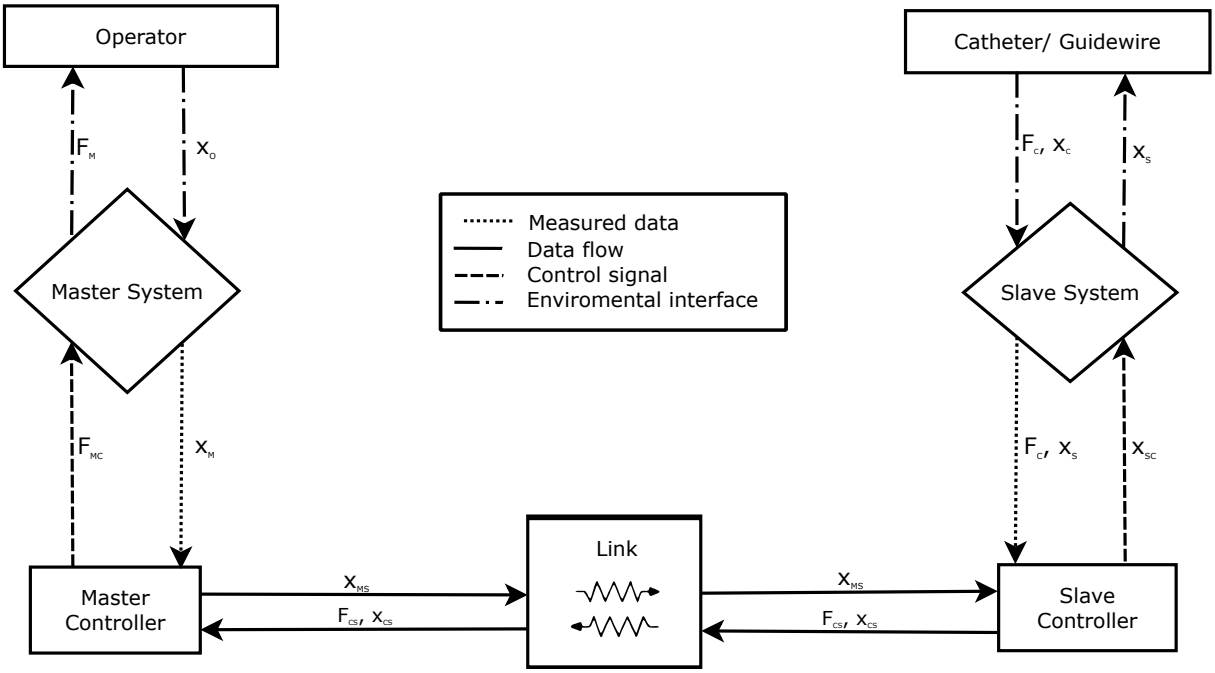


Figure 2.4.: Flowchart showing the interaction between the Slave and Master System. The Master System contains the input device with all its actuators and sensors, whereas the Slave System includes the drive mechanism with all its actuators and sensors.

A scheme of the promised teleoperated robot is depicted in Figure 2.4. It consists of a human operator, a master system with force feedback for input, a slave system which guides the catheter and two controllers.

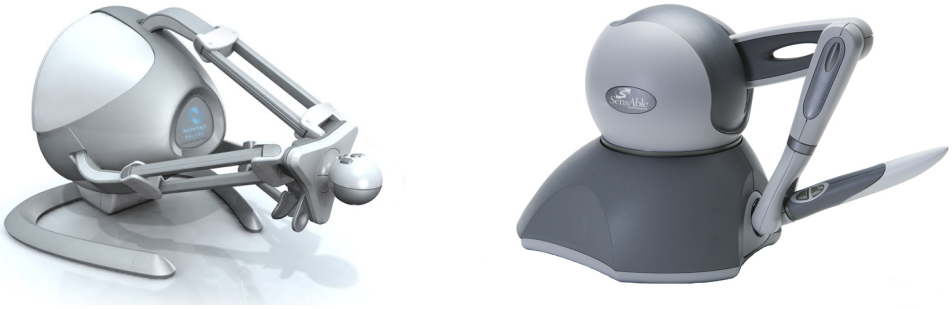
The surgeon controls the position x_M of a master system with his motion x_O. The measured motion x_M is transferred to a master controller which sends the data x_{MS} over a linkage to the slave controller. It translates the input data x_{MS} into a control signal x_{SC} that governs the motion of the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

3. Methodology and Experiments

3.1. State of the Art

There are different approaches in designing force feedback devices for telecontrol. In the following there is given a small overview of currently used mechanisms to control the motion of a catheter and guidewire.

3.1.1. Force Feedback Manipulator



(a) Novint Falcon
Source: Delft Haptics Lab (2014a)

(b) Phantom Omni
Source: Delft Haptics Lab (2014b)

Figure 3.1.: Commercially available Haptic Feedback Manipulators

These Systems have three DOF (Degrees of Freedom). With the help of additional handles, they are able to have passive six DOF. However force feedback can just be given actively in three DOF.
The position and orientation of the manipulator is measured. Electrodynamic actuators, levers and cables are used to generate a force feedback (Kern et al., 2009, p.34). Commercially available systems are for example the above depicted Novint Falcon and Phantom Omni (Figure 3.1).
Guo et al. found in their experiment that the Phantom Omni had a problem with "vibration of the hand, causing the displacement of the Phantom Omni device not steady"(Guo et al., 2017, p.925). Furthermore, motor problems lead to an error of about 0.06 N between the real and the purposed force. They conclude, the summed up error could be about 10% Guo et al. (2017). Furthermore "they do not allow the natural steering–torquing action" (Govindarajan Srimathveeravalli et al., 2010, p.166).
A more advanced system is the omega.7 haptic device by Force Dimension. It has active three DOF of force feedback, active three DOF of torque feedback and active grasping. It allows a maximum rotation of 240° (Force Dimension).

3.1.2. Manipulator Guided

The Corindus Inc. patented a system (Figure 3.2) that is manipulator guided. In addition the department of Professor Shuxiang Guo at Kagawa University (Guolab) invented a system that uses a similar system.

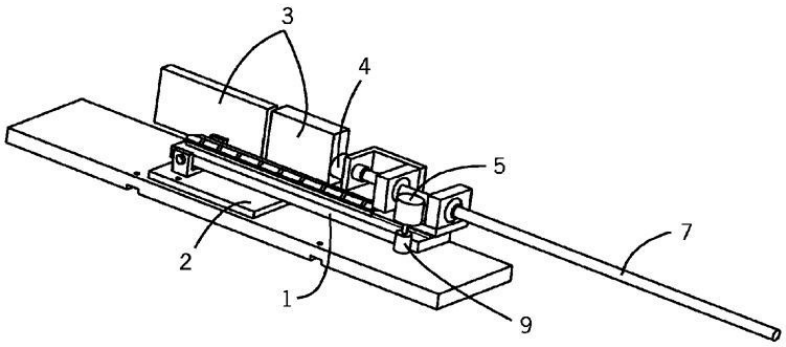


Figure 3.2.: Haptic device depicted in the Corindus patent. A manipulator is mounted on a sled for controlling the axial motion of a guidewire. Turning the handle rotates the guidewire. Source: Beyar et al. (2012)

A manipulator (7) is mounted on a slide (1), which allows the axial motion whereas the manipulator itself allows a rotational motion. Sensors (4, 5) are measuring the motion. The system of Corindus Inc. has an build in safety feature. For using the handle it has to be lifted up. If the slide (1) touches the base (2) an electric circuit is closed and the slave system will stop instantly Beyar et al. (2012).

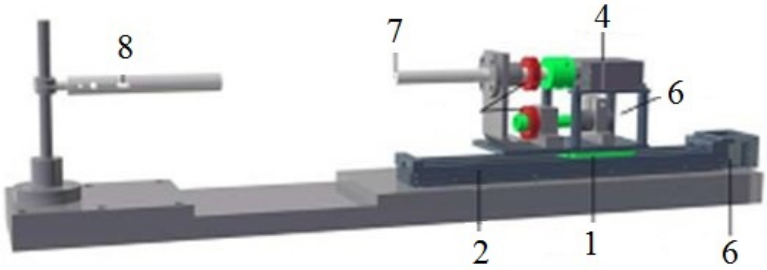


Figure 3.3.: Haptic device invented at Guolab. It consists of a manipulator mounted on a sled, allowing axial control of the guidewire. In addition it can be turned to rotate the wire. Source: Guo et al. (2012)

The system invented by the Guolab of Professor Shuxiang Guo (Figure 3.3) has no safety feature, but has force feedback by using motors (6) to create a torque feedback as well as an axial feedback Guo et al. (2012).

Problems resulting in this construction are that it is necessary to reset the handle after the maximum axial movement allowed by the slide is reached.

3.1.3. Joystick

Figure 3.4.: Control unit of the Corindus Corpath System. For controlling the motion the catheter joysticks are used.
Source: Corindus Inc.

The commercially available System of Corindus Inc. uses joysticks to control the motion of the catheter (Figure 3.4). The advantage is the unlimited length of a stroke. Feedback is not implemented.

3.1.4. Catheter Guided

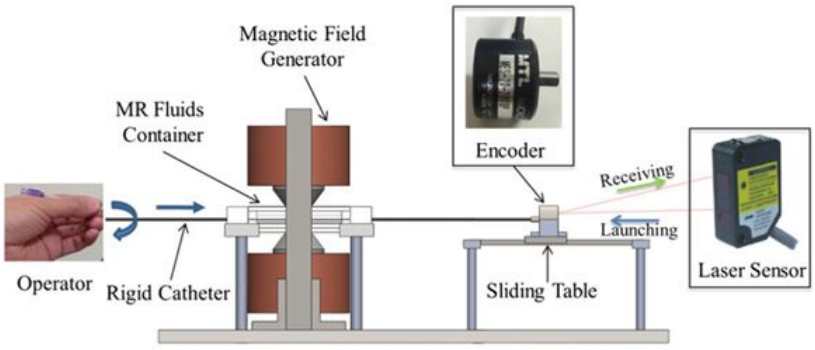
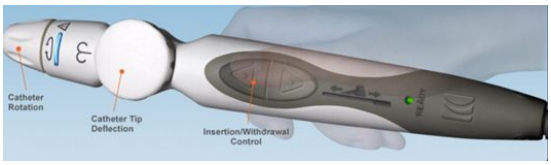


Figure 3.5.: Haptic device using magnet-rheological fluid. The applied magnetic field changes the viscosity of the fluid which leads to an increased resistance on the catheter in axial direction.
Source: Song et al. (2017a, p.2)

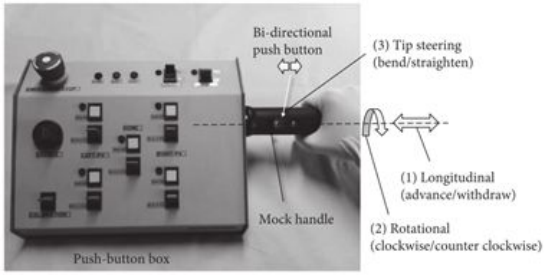
The haptic device uses a rigid catheter as a manipulator (see Figure 3.5). It allows two DOF. One end is mounted on a slide and the other end is controlled by the operator.

The catheter is guided through a sealed tube with magnet-rheological (MR) fluid. With two electromagnets a magnetic field is created which leads to a change in viscosity of the fluid. The change is sensed as a resistance in the axial motion. A torque feedback is not implemented (Song et al., 2017a). The feedrate is either measured with an optical sensor (Song et al., 2017b) or a radial encoder on which the rigid catheter is clamped on. For distance measurement a laser sensor is used Song et al. (2017a).

3.1.5. Catheter Handle Like



(a) Input device used in the Amigo System. The remote controller allows the control of the catheters tip deflection and motion in axial and rotational direction.
Source: Catheter Precision



(b) Input device used in CathROB. The Handle mounted on the push-button box allows a longitudinal motion to advance or withdraw the catheter and rotation for clockwise or counter clockwise motion of the catheter. Additionally a push button to control the tip steering is implemented.
Source: Cercenelli et al. (2017)

Figure 3.6.: Catheter Handle like input devices

As a variation the Amigo Remote Controller from Catheter Precision Inc. (Figure 3.6a) is a system that adopts the normal shape and function of a catheter handle Shaikh et al. (2017). It consists of elements to control the rotational motion, to deflect the catheter tip and for insertion/withdrawal. Furthermore, an infrared beam that has to be interrupted by the hand of the operator to start the device, works as a security mechanism Khan et al. (2013).

In addition, CathROB, which is under development at University of Bologna, Italy, uses a remote controller (Figure 3.6b), inspired by a catheter handle. It has the ability to control the axial motion over pushing/pulling of the handle, which is itself anchored to a setup box. Turning the handle rotates the catheter. In addition, there are two buttons for catheter tip deflection (Cercenelli et al., 2017).

Both systems have in common that their main goal is to adopt the haptic feeling of a normal catheter handle.

Summing up, different types of input devices to control a guidewire or a catheter are on the market. Most of them designed to work with a specific slave system which are not suited for the TAVI (Stendardo, 2017). The high complexity of using magnet-rheological fluid (chapter 3.1.4) as well as the large space occupying manipulator guided systems are not applicable to use in our system. The force feedback manipulators (chapter 3.1.1) have more DOF as needed which adds unnecessary complexity to the system. In addition their limited rotation does not allow a natural twisting motion, which is necessary for advancing the guidewire. Using a joystick (chapter 3.1.3) seems practicable. In chapter 3.3 some of the ideas here presented are used to derive first mockups and evaluated with two surgeons.

3.2. Experiment: Feedrates

For defining some first requirements for implementation, the inserting velocity of a guidewire during the TAVI procedure had to be determined . According to Dr. med André Plass there are four different feedrates necessary for a telerobotic system for the TAVI. In the following they are named as "slow", "medium", "fast" and "emergency".

The experiment was conducted with the help of Dr. med André Plass and Dr. med Maurizio Taramasso from Universitätsspital Zürich.

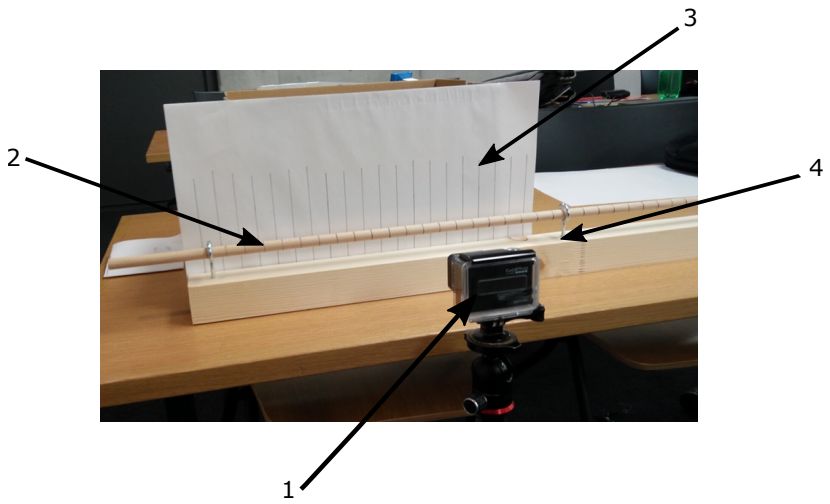


Figure 3.7.: Experimental setup to determine the feedrates.

It consisted of a guiding system (4), a stick (2) and a white background screen (3) with marks every 2 cm (see Figure 3.7). Both physicians were asked to move the stick according to their perception of the different velocities. The movement of the stick was filmed with a GoPro 3+ (1) with a resolution of 848x480 pixel and 240 fps.

To determine the feedrates the number of frames for the stick to pass a distance of 2 cm were counted. The resulting speed was calculated with the following formula:

$$\text{Speed} = \frac{0.02\ m \cdot 240\ \text{fps}}{\text{Number of Frames}} \tag{3.1}$$

This experiment led to the following results:

Feedrate	Velocity [m/s]	Range [m/s]
slow	0.15	0.25
medium	0.35	0.56
fast	0.8	0.52
emergency	1.6	0.64

Figure 3.8.: Resulting feedrates of the conducted experiments

The experiment was executed for every feedrate nine times. The value for "slow" is the slowest velocity, which was measured. The values of "medium" and "fast" are the average velocities of all measurements for the according velocity (see Table A.1).

For the case "emergency" it was decided to take 1.6 m/s, which is the highest calculable value. Due to limitations of the number of frames, three of nine attempts for "emergency" could not be evaluated. Since the velocity was faster 1.6 m/s the number of frames for a stick movement of 2 cm could not been counted precisely.

Due to the fact that the whole measurement is based on their perception and general limitation of the experimental setup, the measurements for "medium", "fast" and "emergency" have a wide range of about 0.5 m/s to over 0.64 m/s. "Slow" could be defined more precise with a range of 0.25 m/s.

3.3. Experiment: Mockups

For further information about what type of input device would be preferred by the physicians, 8 mockups were build. They were tested by the two surgeons Dr. med André Plass and Dr. med Maurizio Taramasso, both experienced with the TAVI procedure.

3.3.1. Mockup 1

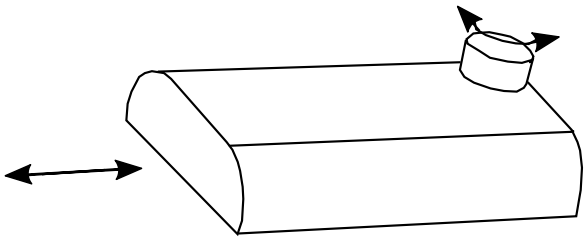


Figure 3.9.: Mockup 1, consisting a block mounted on a slide and a turnable knob. Moving the block in the axial direction controls the axial motion of the catheter. Turning the knob controls the rotation of the guidewire.

The first mockup (Figure 3.9) consists of a sliding block (pull and push) and on top a knob for rotational motion. According to the surgeons, this system brings the danger of sliding back- and forwards. This unintentional fast movement can lead to an unsteady inserting motion.

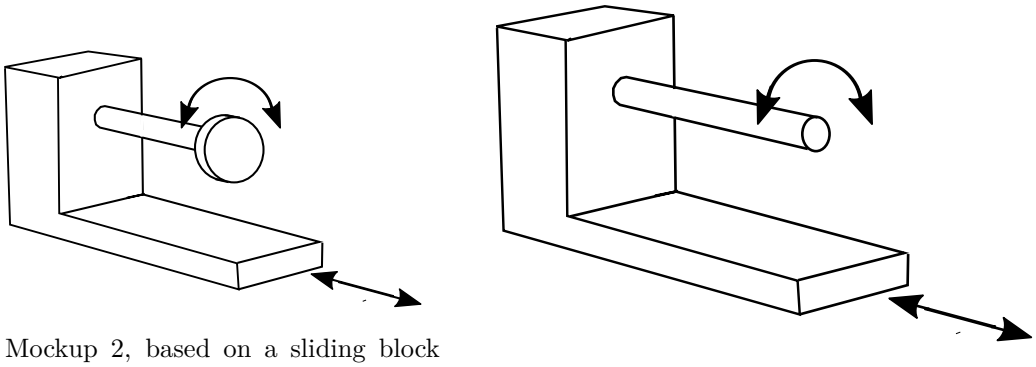
Furthermore, the knob should be installed perpendicular to the base. An advantage is the simple construction of the mockup.

3.3.2. Mockup 2 and 3

Both mockups are based on a manipulator guided device. It consists of a base on a sliding mechanism which allows an axial motion. On the base there is attached a rotatable handle. It consists in mockup 2 (Figure 3.10a) of a disk mounted in front of the manipulator and in mockup 3 (Figure 3.10b) of a manipulator. Both are turnable to receive the rotational input.

Implementing a torque sensor does not require any complicated mechanisms since it can be placed direct between the manipulator and the slide.

The physicians added that both systems would be practicable. The wheel on mockup 2 would not be really necessary since a rotating manipulator would be enough.



(a) Mockup 2, based on a sliding block with turnable disc mounted in front of a stick. With axial motion of the block, advance and withdrawal of the guidewire is controlled, whereas turning the disc rotates the wire.

(b) Mockup 3, consisting of a sliding block with a turnable manipulator. Moving the block in axial direction controls the axial motion of the wire. Turning the manipulator rotates the guidewire.

Figure 3.10.: Mockup 2 and 3

3.3.3. Mockup 4

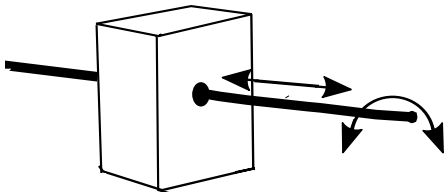


Figure 3.11.: Mockup 4, representing an input device using magnet-rheological fluid to achieve a haptic feedback in axial direction. As a manipulator a normal catheter can be used. The system allows rotational as well as axial control input.

The fourth mockup (Figure 3.11) should represent the catheter guided system invented at Guolab, Kagawa University (see chapter 3.1.4). Lacking the magnet-rheological fluid it was more an abstract mockup to ask their opinion on this solution. Both weighted the complexity using magnet-rheological fluid higher than to have an actual normal feeling of inserting a catheter. According to them exact mirroring of the actual insertion is not necessary.

3.3.4. Mockup 5

In contrary to the previous mockups, this system is used with two hands (Figure 3.12). One hand controls a turnable disc for rotational input and the other hand controls a lever. It is inspired by the thrust levers used in airplanes.

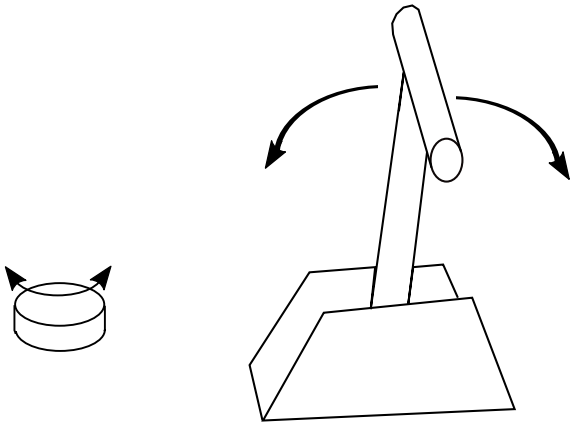


Figure 3.12.: Mockup 5, showing the rotary disc to control the rotation of the guidewire on the left and on the right the lever for axial control of the wire.

The overall system is simple. There is just one DOF per input device. Disadvantages were seen by the surgeons in the two hands control. It uses more space and is not preferred by them. In addition the wheel to control the catheter motion should be mounted perpendicular to the ground.

3.3.5. Mockup 6

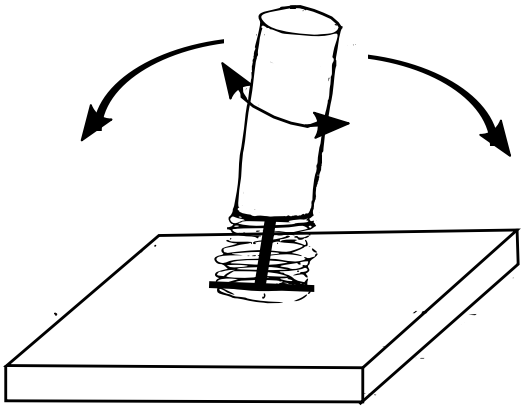


Figure 3.13.: Mockup 6, showing a joystick with 2 DOF. It allows a forwards and backwards motion as well as turning of the handle.

The sixth mockup (Figure 3.13) should simulate a joystick with two DOF. A forward and backward motion of the joystick is used for pulling and pushing of the catheter whereas a turning of the handle controls the rotation of the catheter. Both surgeons preferred this system and added that a panic button for fast removal of the catheter and 3 stages of feedrate are needed.

3.3.6. Mockup 7

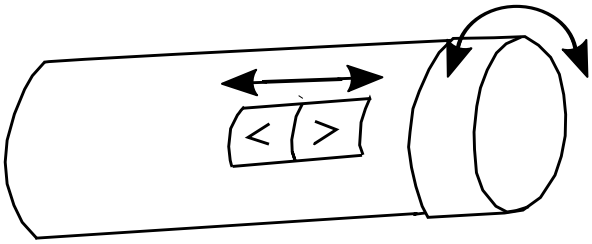


Figure 3.14.: Mockup 7, depicting a mobile remote controller. The motion of a guidewire can be controlled with the rotation of the wheel in front and two buttons for the axial motion.

The seventh mockup (Figure 3.14) adopts some of the design elements of the Amigo Remote Controller. It is designed as a handheld only device with a turnable part in front for controlling the rotation and two buttons for pushing and pulling of the catheter.

Both surgeons mentioned that it would be easier to replace the button with a thumb wheel like used in modern computer mouses. Moreover a sliding mechanism for the different feedrates would be appreciated.

3.3.7. Mockup 8

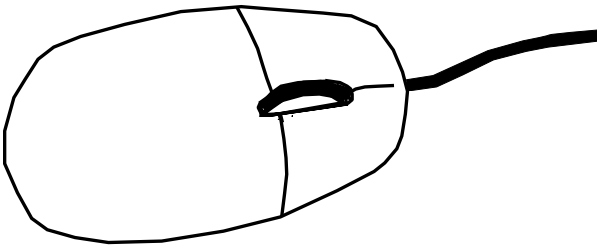


Figure 3.15.: Mockup 8 is a computer mouse. The scroll wheel is used to control the axial motion and the buttons to rotate the guidewire.

The last mockup is a normal computer mouse (Figure 3.15). The turning wheel would be used to control pushing as well as pulling the guidewire, whereas the buttons control the rotating motion of the guidewire. The system itself is well known and most of the people are familiar with it. According to the physicians, the using of buttons to control the rotational motion of the catheter is too abstract and not intuitive.

Summing up the evaluation of the testing, two possible implementations of an input device are preferred by the surgeons. Firstly a stationary device similar to a thrust lever used in airplanes with the variation of implementing the rotational control into the handle (see chapter 3.3.4). Secondly a mobile remote controller with rotation wheel in front (see chapter 3.3.6).

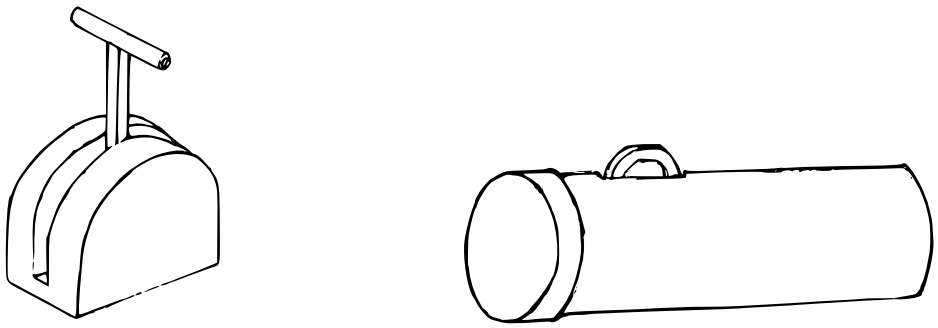
Additionally, it was made clear that for rotational control a wheel should be placed perpendicular to the ground adapting the natural motion of controlling the guidewire. Furthermore the level of abstraction is limited. On one hand the actual inserting motion has not to be mirrored by the system but on the other hand buttons to control the rotation are too abstract. A manipulator mounted on a slide is also not preferred due to its danger of leading to an unsteady motion.

4. Requirements and Concepts

In this chapter requirements and some first concepts based on the experiments and their evaluation are derived. The requirements are divided into six subchapters that contain some general guidelines followed by concepts with more specific requirements for a stationary as well as for a mobile handheld device.

4.1. General

The proposed input device should have two DOF to control one axial and one rotational movement of the guidewire. Since it should not get in direct contact with the patient, the system does not have to be sterilisable.



(a) Concept 1 consists of a lever with a handle. The lever can be moved upwards and downwards to control the insertion or withdrawal of a guidewire. To control the rotation of the wire the handle can be turned.

(b) Concept 2, depicting a mobile remote controller. The turnable disc in front controls the rotation of the guidewire whereas with the thumbwheel the wire is advanced or withdrawn. The thumbwheel can also be replaced with a slider.

Figure 4.1.: General proportions of the two concepts

The overall form of concept 1 adapts a thrust lever used in aircrafts (Figure 4.1a). It allows rotational control of the catheter with turning the handle and axial control with moving the lever. It is designed as a stationary device.

The second concept implements a turning wheel in the front for rotation control of the guidewire and for axial control a second scroll wheel or slider. Figure 4.1b shows the possible use of a thumb wheel for axial control.

4.2. Ergonomy

"Virtually every health care worker is at risk for injury or discomfort when using medical hand tools", which can also have a bad impact on the patient (Weinger, 2010, p.646). Therefore ergonomy plays an important role in designing a haptic feedback device, since a surgeon should be able to use it on a daily basis.

4.2.1. Concept 1

The part which gets in direct contact with the surgeon is the handle. There are different forms of handles. Often knobs or T- shaped handles are used. A well-known application of a T-shaped handle is for example the thrust lever in airplanes.
In this case, the knob is not preferred because it is more difficult to control especially in a low position (± 70° to 90°). Therefore, a T- shaped handle will be proposed . Furthermore the length of the handle should be at least 12.5 cm (Weinger, 2010, p.675).

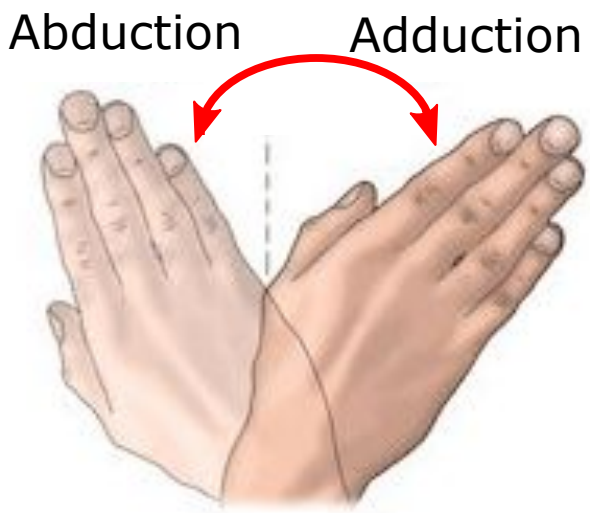


Figure 4.2.: Scheme showing the hand movement for abduction and adduction.
Source: Chick (2015)

According to Weinger (2010, p.112) the 95 % mobility of wrist movements are for adduction 30° (male), 36.5° (female) and for abduction 40° (male), 37° (female). Chengalur et al. (2004, p.59) states for adduction 30° and for abduction 20°. But there is no further information either on sex or the percentile of humans.

So for an ergonomic use the comfortable motion of the wrist is limited to about 70° (maximal adduction to maximal abduction). As a result there cannot be made a continuous full rotation. Therefore a system is proposed that rotates the catheter in a continuous rotation if the handle is deflected in abduction or adduction until the handle is back in the 0° position. The more it is deflected, the faster the catheter rotates until the maximum velocity is reached.

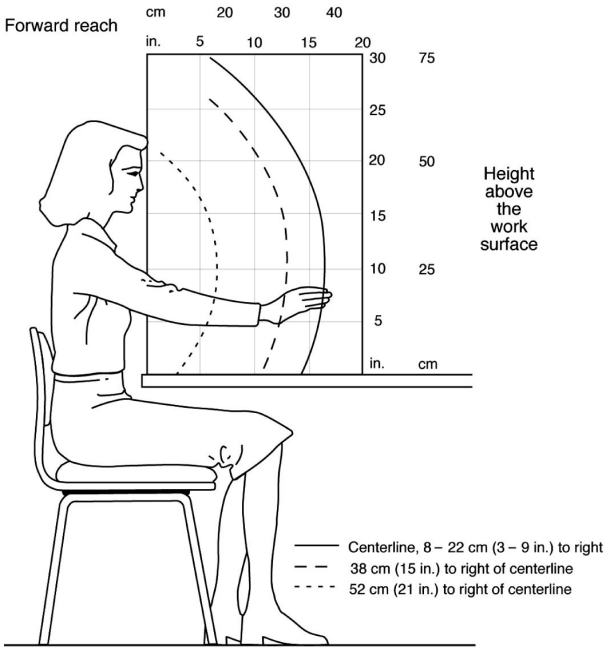


Figure 4.3.: Forward reach capability for a 5th- percentile female's right hand. The three curves indicate, that the reach capability is depending on the height of the hands above the work surface as well as by the distance of the arm to the the centerline.
Source: Chengalur et al. (2004, p.196)

Additionally there is also a limitation in the range of forward reach capability of a human operator (Weinger, 2010, p.114) as it can be seen in Figure 4.3. Therefore the device should not exceed the depicted forward range with the handle in the lowest position of about 38 cm in a height of 6 cm. This leads to a limitation of the lever length.

4.2.2. Concept 2

According to Weinger (2010, p.675) a handheld device should have a diameter between 2.5 cm and 4 cm. All edges should be rounded with an radius of 0.8 mm (Fraser, 1980, p.47). The overall shape should adapt to the natural shape of the hand to prevent any slipping and excessive force on different sides of the palm.

The device itself should consist of non-porous materials so the retention of biological products is prevented. In addition a high friction coefficient to prevent slipping, a neutral handle temperature and non-conductivity are required for the material. Since it is designed as a portable

handheld device a maximum tool weight of 1.8 kg should not be exceeded (Weinger, 2010, p.678-679).

4.3. Input

There are two different approaches to control the axial movement of a telerobotic system.
First our position input x_M of the master system can be directly translated to a desired position x_S of the guidewire. So a discrete change in angle or change in axial position translates in a specific range of distance by which the catheter is moved in axial direction by the slave system. This is called "position to position".

Alternatively our position input x_M can be related to a velocity $\dot{x}_S$ of the guidewire, which is known as "position to velocity" (see Figure 2.4).
There was suggested to have the four feedrates slow, medium, fast and emergency. As shown in chapter 3.2, slow corresponds to a velocity of 0.15 m/s, medium to 0.35 m/s, fast to 0.8 m/s and emergency to 1.6 m/s.

4.3.1. Concept 1

Position to Position

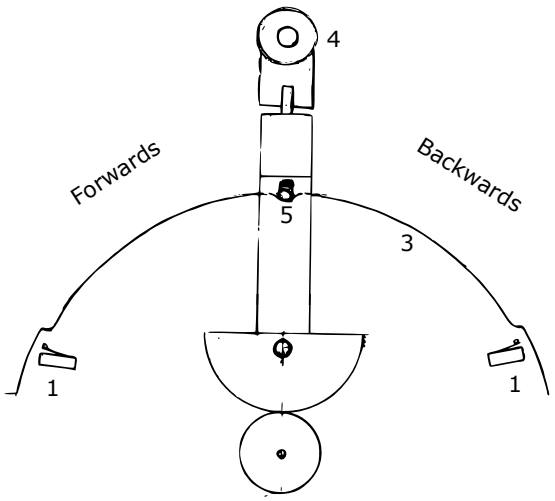


Figure 4.4.: Guiding system for "position to position". It allows a lever motion of 180°.

The lever allows a possible motion of 180°. Figure 4.4 shows the lever in the neutral position of 0°. A forward as well as the backward motion of the guidewire corresponds to an angle range of 90°. The change of angle corresponds linearly to a change in axial position of the guidewire.

This motion could be implemented with a small pin (5) that is connected to the lever and slides on a guide. The maximum axial inserting distance is limited with this device. An entire insertion of the guidewire needs several strokes. Microswitches (1) are mounted at both endpositions to give an impulse to the slave system to lock the guidewire after one stroke.
In the case a resistance is sensed, the operator wants to switch in backwards mode. For the case that the endstop has not been reached, a small button implemented in the handle (4) locks the guidewire. If it is locked the lever can be pulled back in the neutral position without having an effect on the guidewire motion.

Position to Velocity

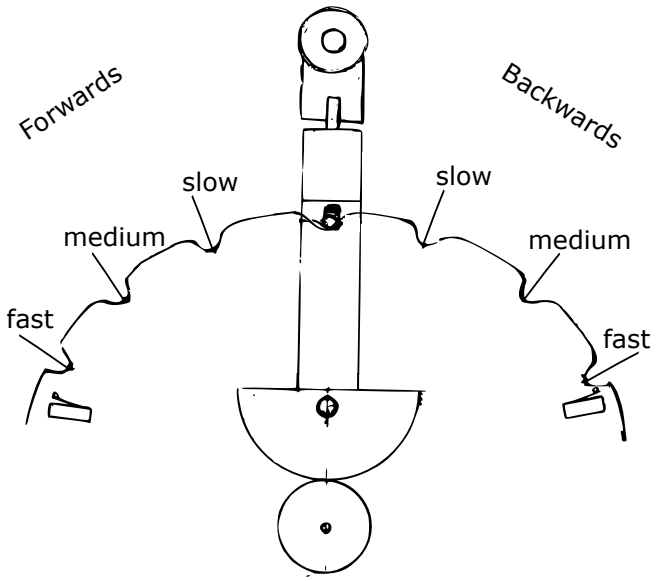


Figure 4.5.: Guiding system for "position to velocity". The guiding has predefined hollow parts for the pin to slide in.

The guide used to allow different velocities has predefined lower areas for the pin as shown in Figure 4.5. For switching between feedrates a resistance has to be actively overcome .

4.3.2. Concept 2

Position to Position

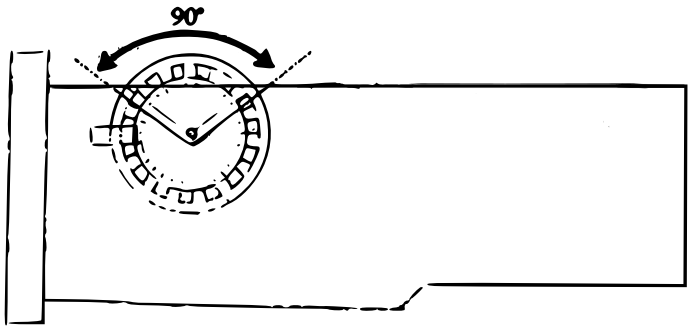


Figure 4.6.: Implementation of a thumbwheel to control the axial input. For better control the part accessible for the thumb should be 90°.

As a result of the mockup evaluation the implementation of a thumbwheel is proposed. The wheel should be comfortable for different thumb sizes and the part open, which is in contact with the thumb, should be 90°. The resistance for turning the wheel should be below 5.6 N (Weinger, 2010, p.265).

Position to Velocity

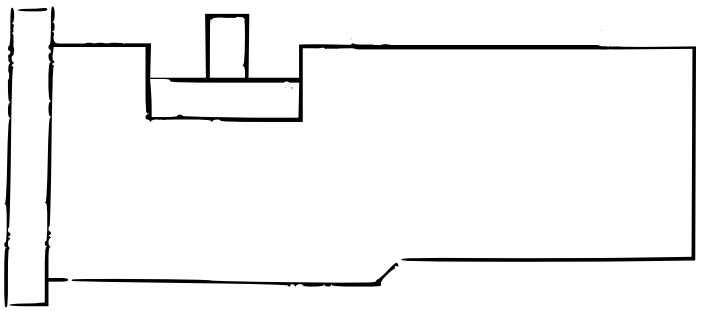


Figure 4.7.: Implementation of a linear transducer to control the axial input.

In this concept, the scroll wheel is replaced with a small sliding mechanism.
The different feedrate stages can be accessed by defined areas of the transducer. Weinger (2010, p.272) recommends a slider force of 3.1 N to "accommodate impaired users and protect against overshoot." Additionally a slider to switch between forwards and backwards motion has to be implemented on the side.

4.4. Feedback

Performing the TAVI, the physicians rely on visual feedback and the sensed resistance on the catheter. Since the latter is not present in a telecontrolled system, it has to be replaced with haptic feedback.

According to Siciliano and Khatib (2016, p.1070) the main "requirements for actuators and mechanical transmission in impedance-type haptic devices are: low inertia, low friction, low torque ripple, back-driveability, and low backlash."

4.4.1. Concept 1

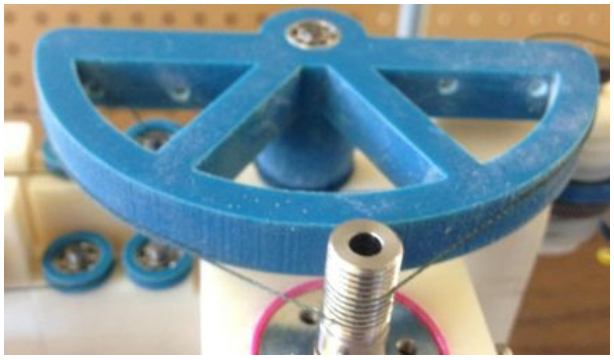


Figure 4.8.: Possible implementation of cable-capstan transmission to give haptic feedback. The cable is wrapped several times around a pulley mounted on a DC motor. The ends of the cable are locked on a second blue drum.
Source: Zhao (2015, p.62)

To give a haptic feedback a cable capstan transmission could be used (see Figure 4.8). It consists of a pulley mounted on a DC motor around which a smooth cable is wrapped. The requirements for "no-slip [and] high friction contact between the cable and the pulleys is maintained through several wraps of the cable" (Siciliano and Khatib, 2016, p.1070). Depending on the torque supplied by the motor, this mechanism leads to application of a force against the motion of the user.

Position to Position

It is crucial that the lever cannot be moved further in the direction of increasing resistance, when the maximum allowable resistance is reached. This constraint could be implemented with a virtual wall.

Position to Velocity

Since the lever is hold in a defined position with a pin according to the desired feedrate, the feedback force has to overcome the additional force pushing the pin out of its hollow. The haptic feedback consists of a force pushing the lever back in the neutral position.

4.4.2. Concept 2

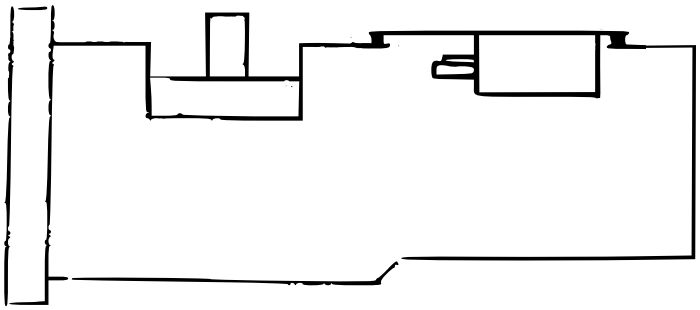


Figure 4.9.: Possible implementation of a vibrational element to give haptic feedback. The above depicted idea can also be used replacing the slider with the thumbwheel for "position to position".

In contrary to concept 1 a cable-capstan transmission cannot be implemented for a slider. Therefore a vibrating plate located under the area of the palm for haptic feedback will be proposed. The advantage of using just a small plate for vibration is that tactile stimulation is just located on the palm. There is no disturbance in the fingers and therefore no loss of control over the input mechanism of the master system. These leads to the additional requirement of damping the whole case against the vibrating part so that the sensors and the input mechanism are not disturbed.
Kern et al. (2009, p.57) recommends for the vibration element a frequency in the range of 200 Hz to 300 Hz and an amplitude of 0.1 μm to 0.2 μm. The vibrational element can also be used if the slider is replaced with a thumbwheel for "position to position" control.

4.5. Sensor

In our system different sensors regarding measuring the inputs of the operator have to be implemented. One is needed for measuring the input for the rotational and one for the axial control. Both sensors should have a small latency. Bedikian (2013) suggests for motion control a threshold of about 30 ms, which seems also applicable for the sensors used in the proposed haptic feedback controller.

4.5.1. Concept 1

Due to the limitation of the maximum wrist movement (maximum abduction to maximum adduction) the sensor should allow the sensor for concept 1 at least a rotation of about 70° (see chapter 4.2.1). Furthermore a sensor for measuring the deflection of the lever is required. A range between 0 and 180° should be suitable for it.

For giving feedback over the cable-capstan transmission the position of the DC motor shaft needs also to be measured. Therefore the DC motor has to have a build in encoder.

4.5.2. Concept 2

In contrary to concept 1, here the sensor for the rotation wheel in front as well as for the thumb wheel in the case "position to position" should allow multiple rotations. Moreover, according to Dr. med André Plass, the rotation wheel should allow a rotation of at least 200° at once and a speed of 360 °/s.

The slider suggested for the case "position to velocity" could be implemented using a linear potentiometer. It should be capable of distinguishing at least 3 different stages, which correspond to the feedrates "slow", "medium" and "fast" determined in chapter 3.2.

4.6. Safety

Since the slave system of a telerobotic system for TAVI is in direct contact with the patient, safety plays an important role in the design.

The development of a haptic input device has to take into account two different security mechanisms.
Firstly a mechanism to prevent an unintentional motion of the whole system and secondly an emergency button. Pushing the button leads to a fast removal of the guidewire.

Additionally there has to be a switch to lock the catheter in a certain position.

4.6.1. Concept 1

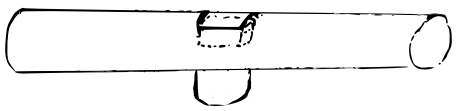


Figure 4.10.: Implementation of a possible security mechanism in the handle. The sensor should detect when the operator touches the handle.

To ensure that the system only starts if it is under control of an operator a sensor can be implemented in the handle, which detects when the hand of the operator touches it (see Figure 4.10).

The emergency button can be installed on the side of the lower casing. It has to be accessible for left handed as well as for right handed people. This could be achieved with implementing on both sides a button.

4.6.2. Concept 2

Like for concept 1 a sensor to detect the hand of the physician is necessary and could be implemented in the in the back of the device (Figure 4.11).

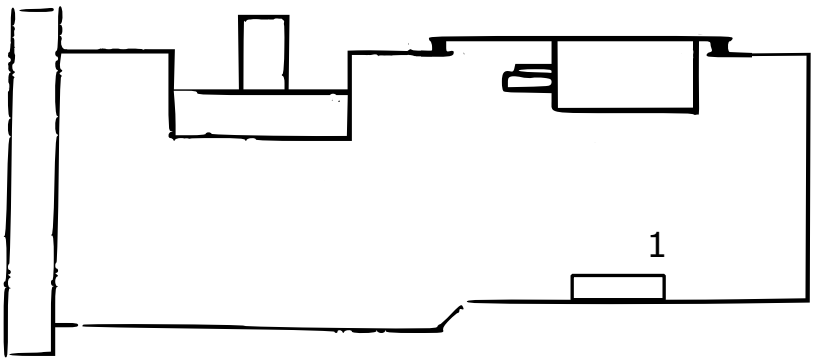


Figure 4.11.: Security mechanism using a sensor (1) to detect when the device is hold by the physician. In addition to the above depicted case of "position to velocity" it can also be implemented for "position to position" by replacing the slider with a thumbwheel.

Additionally, as mentioned above, an emergency button is required. A state change push-button like used in most emergency stops could be used for this task. It could be integrated in the rotational wheel at the front of the device, like depicted in Figure 4.12. To prevent unintentional pushing, it could be secured by a cap which can be folded upwards to reach the button.

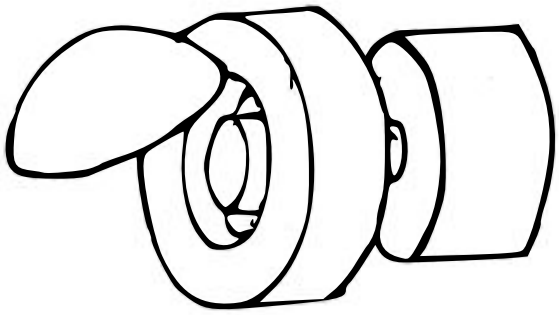


Figure 4.12.: Implementation of an emergency button into the front of the rotational wheel. A cape is added to protect the state change button against unintentional pushing.

4.7. Signal Transmission

Two different transmission paths have to be taken into account.

First, the transmission of the visual information of the X-Ray unit to the display and secondly the transmission of information between the master and the slave system.
Since the time delay between acquiring the fluoroscopy image and displaying it has not been solved, this thesis concentrates on the requirements of transmission between the slave and master system (Song et al., 2017b, p.404). According to Kern et al., the measured information of a telemanipulation system can be transmitted with a bandwidth of 1 kHz to 10 kHz, while movements of the user can be attained with a bandwidth of 5 Hz to 15 Hz. The tremble of the operator hand leads to high frequency signals, which are filtered out by using the lower bandwidth.

Furthermore this leads to the requirement of a unidirectional data rate of 240 kbit/s (8 bit) or 480 kbit/s (16 bit) for 1 kHz until 2.4 Mbit/s (8 bit) or 4.8 Mbit/s (16 bit) for 3 DOF (Kern et al., 2009, p.390ff).

4.8. Requirements for Wireless Device

Since the concept 2 is meant to be mobile, it is suggested to use a wireless transmission for data exchange between the master and slave system.
According to Liu et al. (2012), there are used mainly IEEE 802.11, GPRS/GSM and Bluetooth for wireless transmission. However the bandwidth of Bluetooth (max. 1 Mbit/s) and GPRS/GSM is limited. Therefore, they are not suitable for controlling systems and real-time monitoring. Additionally, for GPRS/GSM transmission fees have to be paid.

On the other hand Wireless LAN (IEEE 802.11) has a sufficient bandwidth and fast data channel (Liu et al., 2012). Therefore, a possible data transmission for such a telerobotic system could be based on Wireless LAN.

4.9. Discussion

Based on experiments with two surgeons familiar with the TAVI procedure two concepts for a possible haptic feedback device are derived.

In contrast to the commercially available force feedback manipulators, the concepts are simpler since they have exactly the number of DOF needed. In addition, to use one of the commercial devices it would be necessary to develop a manipulator suited for the TAVI intervention. As shown in chapter 3.1, other existing input devices are not suitable for our system. This is due to their limitation to a specific slave system, to its occupied space or unnecessary complexity. The experiments have shown that mobility is a preferred property, which cannot be guaranteed to this extent by existing force feedback manipulators, catheter guided and manipulator guided systems. Therefore to develop a new haptic feedback device customized to the TAVI and based on simple mechanism is reasonable.

A stationary device like shown in the first concept has the advantage that it could be used sitting at a desk and data transmission could be done over a cable. The tradeoff is the lack of mobility and an unnatural twisting motion. Another disadvantage could be the implementation of the two input mechanisms: The force feedback for the case "position to velocity" could be challenging due to the fact that, additional to the feedback force, there has to be a force overcome to push the pin out of the hollow part of the guide. An additional vibrational element in the handle could be used to give feedback in this case. However it would add unwanted complexity to the system.
Using the proposed guidings, the maximum inserting distance for on stroke is limited. Therefore the implementation of microswitches has to be taken into account. If one stroke is made, the lever touches the microswitch and the guidewire is locked in the actual position until the handle is back in the neutral position 0°. Afterwards a second stroke can be made.
If not an entire stroke could be made, a button has to be implemented in the handle to lock the guidewire.

Concept 2 has the advantage of being a mobile handheld device. Its rotational control mechanism is preferred by the surgeons. The mobility leads to additional requirements regarding guaranteeing a stable, fast and sufficient bandwidth of data connection to the slave system. Exchange of data could be done over cable or a Wireless LAN. For the latter it has to be taken into account, that power supply with batteries, a base station for charging as well as for transmitting the input signals is needed. However these requirements can be solved relaying on existing technologies and used systems.

Using just the thumb wheel for a whole insertion of the guidewire could lead to fatigue of the operator's thumb. Additionally "position to velocity" is lacking a direct control for a precise motion of the guidewire. The physician can only control four stages of velocity and starting or stopping of the motion. To solve these disadvantages and to allow a faster procedure, implementing a combination of "position to position" and "position to velocity" is recommended.

The operator could decide, if he wants to insert the guidewire with constant defined feedrate or to insert it controlled by his own precise motion. Since the pass until the aortic arch is more or less straight, the operator could use a defined velocity. To pass the aortic arch and the aortic valve the physician might switch to the "position to position" mode.

The combination can be implemented in concept 1 with using the guiding for "position to velocity" (see Figure 4.4). To switch into "position to position" the small pin has to be locked in an upper position above the guide, so the lever is free to move 180°.

In concept 2 have to be included both input systems shown in chapter 4.3.2. Mounting both 90° apart seems practicable. Since the proposed device has a round shape it should be simple to switch between both by turning the device 90° of its main axis.

Both concepts seem to be applicable. Concept 2 has the advantage of greater mobility and the possibility of a continuous inserting motion. Weighting both a higher than having a stationary device with actual force feedback it is reasonable to recommend a haptic feedback device based on concept 2.

Further development should concentrate on designing an actual prototype and evaluating the feasibility, especially the combination of the two control approaches. Additionally the feedrate values should be verified in an animal experiment with a functioning prototype.

5. Conclusions

TAVI is a standardized intervention. For visual feedback of the guidewire position fluoroscopy is used. The repeated exposure to radiation leads to a higher cancer risk for the surgeons. To decrease the radiation a telerobotic system is proposed. It separates the place of the guidewire insertion exposed to radiation and the control of it in a safe distance.
For controlling a haptic feedback device is needed. The haptic feedback should replace the lost feedback of the sensed resistance inserting the guidewire with the fingers.

Different master systems to control the motion of a guidewire are available on the market. Mostly connected to a specific slave system. The existing force feedback manipulators are stationary and do not allow the steering as well as twisting motion wished by the physicians for the TAVI.

Two experiments were conducted. One to determine the velocities of four feedrate stages and one to get to know what type of input device is preferred by the physicians. The first experiments showed that the feedrate slow corresponds to a velocity of 0.15 m/s, medium to 0.35 m/s, fast to 0.8 m/s and emergency to 1.6 m/s.

The evaluation of the second experiment with the two surgeons Dr. med André Plass and Dr. med Maurizio Taramasso from Universitätsspital Zürich led to two devices. First, a stationary device adopting the design of a thrust lever used in airplanes (concept 1) and second, a portable remote controller (concept 2).

Based on their input, requirements and first concepts for the two devices are derived.
The simple mechanism with two DOF and feedback just in one direction of concept 1 has more advantage than a commercial feedback manipulator like Novint Falcon. The advantages of concept 2 in comparison to available force feedback manipulators are the greater mobility and the control mechanism for catheter rotation, based on the preferred input approach of two surgeons.

The discussion showed, that a combination of the two control approaches "position to position" and "position to velocity" is recommended. Possible implementations for both are shown and discussed.

To sum up, the proposed systems have the advantage of being simple and customized for the TAVI procedure. Weighting the mobility and the preferred mechanism for controlling the rotation of the guidewire higher than having actual force feedback and being stationary, a haptic input device based on concept 2 is recommended.
It is a mobile remote controller with haptic feedback implemented with a vibrational element. With its thumbwheel and the slider to control the axial motion as well as the rotation wheel in front for controlling the twisting motion of the guidewire it allows a continuous insertion of the guidewire.

A. Appendix

A.1. Declaration of Originality

ETH

Eidgenössische Technische Hochschule Zürich
Swiss Federal Institute of Technology Zurich

Declaration of originality

The signed declaration of originality is a component of every semester paper, Bachelor's thesis, Master's thesis and any other degree paper undertaken during the course of studies, including the respective electronic versions.

Lecturers may also require a declaration of originality for other written papers compiled for their courses.

I hereby confirm that I am the sole author of the written work here enclosed and that I have compiled it in my own words. Parts excepted are corrections of form and content by the supervisor.

Title of work (in block letters):

Cardiobot - a robotic system for TAVI interventions:
Haptic feedback device

Authored by (in block letters):

For papers written by groups the names of all authors are required.

Name(s):	**First name(s):**
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Zürich, 28.12.2017	Linard Furck

For papers written by groups the names of all authors are required. Their signatures collectively guarantee the entire content of the written paper.

A.2. Experimental Data

Attempt	Phys.	$\frac{frames}{0.02\,\mathrm{cm}}$ 1	2	3	Speed $[\frac{m}{s}]$ 1	2	3	Average Speed $[\frac{m}{s}]$
Slow	AP	31	25	28	0.15483871	0.192	0.171428571	0.17275576
	AP	12	15	17	0.4	0.32	0.282353	0.334118
	MT	24	30	25	0.2	0.16	0.192	0.184
Medium	AP	13	20	14	0.369230769	0.24	0.342857143	0.317362637
	AP	8	8	6	0.6	0.6	0.8	0.666667
	MT	12	14	14	0.4	0.342857	0.342857	0.361905
Fast	AP	6	7	7	0.8	0.685714286	0.685714286	0.723809524
	AP	4	5	6	0.8	0.96	0.8	0.986667
	MT	6	5	6	0.8	0.96	0.8	0.853333
Emergency	AP	5	3	3	0.96	1.6	1.6	1.386666667
	AP	3	3	4	1.6	1.6	1.2	1.466667
	MT	<3	<3	<3	>1.6	>1.6	>1.6	>1.6

Table A.1.: Experimental measurements of Feedrates. Nine measurements were made for every feedrate. Six of them were conducted by Dr. med André Plass (AP) and 3 by Dr. med Maurizio Taramasso (TM)

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