**Evaluation of Master Devices for TAVI/TAVR Teleoperated Robot**

**Abstract**

This thesis work intends to find the most suitable master device type for a TAVI/TAVR teleoperated robot, capable of controlling the 2 DOF (translation and rotation) of the different catheters and guide wires used during the intervention.

After a state-of-the-art research in catheter handling teleoperated robots, four different master devices were tested, each device controls each one of the 2 DOF independently. The first device with completely digital inputs (Keyboard type), the second device hybrid with 1 digital input (translation) and 1 analogical input (rotation) (Remote Controller type), and the remaining two devices with completely analogical inputs (Joystick type and Catheter type).

Each device was tested under three different experiments and by the appreciation of the users, the first two experiments were designed as a follow the target task assessing the precision and response of each DOF independently. The third experiment was designed as a navigation task, using both DOF, measuring the time and smoothness of the movements and path followed until reaching the goal.

The results of the experiments and the user’s poll responses indicate that the Joystick type device has a better overall performance for controlling the 2 DOF of a regular catheter used in TAVI/TAVR surgery.

**Symbols**

TAVI/TAVR – Transcatheter aortic valve implantation/replacement  
AS – Aortic Stenosis  
FDA – Food and Drug Administration  
DOF – Degrees of freedom

**Introduction**

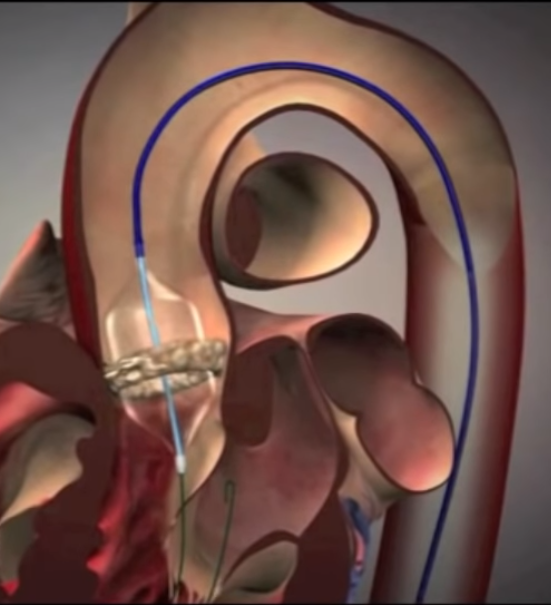
* **TAVI/TAVR**

TAVI/TAVR stands for Transcatheter Aortic Valve Implantation/Replacement (In the following only named TAVI), which is a minimal invasive surgery meant to treat AS (Aortic Stenosis), a condition caused for the calcification of the aortic valve, making it harder and thicker [4]. This condition in the valve disturbs the blood flow going into the aortic artery, making the heart work harder.

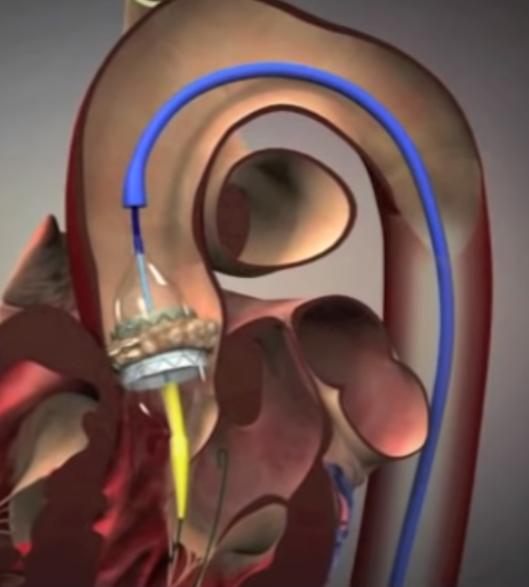
[5](watch the video for more visual understanding)

TAVI surgery is performed through an incision in the groin, where a sheath is placed in order to give access to a variety of guide wires and catheters to the aortic artery. Different guide wires and catheters are used to first gain access to the aortic arch, then go through it and finally gain access to the left heart ventricle crossing the calcified aortic valve. Each one of these steps require a combination of axial and rotation movements performed by the surgeon to avoid damages in the artery and valve.

Once access to the left ventricle of the heart is granted, a balloon-expandable mounted on a catheter is inserted and positioned in the calcified valve. When in position, the balloon is expanded in order to retract the leaflets of the diseased valve.



Last, the new aortic valve is inserted mounted on a catheter and placed over the retracted old calcified valve. After the new valve is in position and fully expanded, the leaflets start working regulating the blood flow. If the placement was successful, the catheter and guide wire are retracted and the groin incision closed.



During the whole surgery, the physicians have visual guidance help provided by fluoroscopy image (2D image), in order to track the position of the catheter and wires at any time, as well as the positioning of the balloon-expandable and the new aortic valve when being deployed.

* **Motivation**

TAVI procedure has become more popular since the FDA approved, in 2016, the procedure for intermediate risk patients that present sever AS [1], and estimates predict that numbers in North America and Europe will raise more than double (270 000 patients annually) if it is approved for low risk patients [2].

Each one of these surgeries suppose a risk not only for the patients, but for every interventionalist present in the room, given that per each intervention interventionalists are exposed to a median of 5.5 mRad produced by the fluoroscopy imaging [3], being cardiologist, the medical professionals exposed to the highest amounts of radiation [6]. Recent studies have shown that:

* + 85% of the brain tumors found in interventionalists are located on the left side of the brain, consistently with the closest side of the brain to the radiation source in the surgery room [6].
  + 50% of the interventionalists have significant posterior subcapsular lens changes, causing propensions to cataracts [7].

[13]

In order to mitigate the risks inherent to radiation exposure, a common practice is wearing a leaded suit as protective equipment. These suits have to be worn at any time while the fluoroscopy imaging system is turned on. Such suits are commonly made of lead and may weight up to 7 Kgs. This additional weight may cause orthopedic issues as proven in recent studies:

* + 60% have suffered spine issues after 21 years in practice [8].
  + 33% miss work due to orthopedic issues [9]

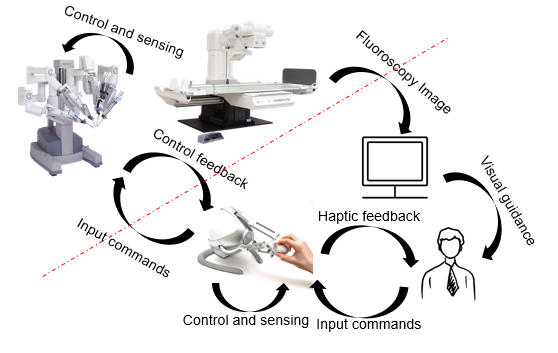
[12]

This is why we believe TAVI procedures should be performed assisted by a teleoperated robot, allowing this way to set the interventionalists away from the radiation source. Although many teleoperated robots already exist in the market for surgeries involving the use of catheters, none has been developed specifically for TAVI and its specific needs.

* **Teleoperation**

A teleoperated surgical robot allows the surgeon to be located away from the operation table, and thus, for TAVI procedure, away from the radiation source. Teleoperation has proven in similar surgeries to reduce the radiation in patients on 17% [10] and to reduce as well the exposure to the primary surgeon in 95% [11], beside the orthopedic benefits implied by not wearing the lead suits at all times during the surgery.

As depicted in figure () the working station for the surgeon can be located away from the operation table, together with the fluoroscopy imaging screen and the master device, which may be actuated for haptic feedback, giving the surgeon another dimension given that the visual cues are poorly displayed in a black and white 2D image.



* **Objective**

This thesis work intends to find the most suitable master device type for a TAVI/TAVR teleoperated robot, capable of controlling the 2 DOF (translation and rotation) of the different catheters and guide wires used during the intervention.

**State of the art**

Teleoperated robots for similar types of surgeries as TAVI have been developed. In table () is appreciated robot’s characteristics, such as the type of catheter they handle, the kind of intervention they were created for and the kind of master slave they operate with.

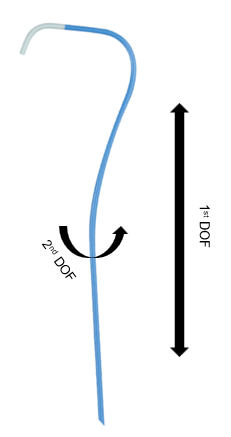
|  |  |  |  |
| --- | --- | --- | --- |
| **Company – Robot name** | **Catheter Type** | **Surgery type** | **Master device type** |
| **Catheter Robotics Inc. – The Amigo remote control system [14]** | **At least 3 DOF, steerable catheter** | **Electrophysiology (EP), and radiofrequency catheter ablation of arrhythmias** | **Remote Controller** |
| **Stereoaxis – Niobe [15]** | **At least 3 DOF, steerable catheter** | **Endocardial ablation, gastrointestinal endoscopy, and others.** | **Regular 2D or 3D mouse** |
| **Hansen Medical – Sensei X** | **At least 3 DOF, steerable catheter** | **Atrial Fibrillation (AF), and other arrhythmia procedures.** | **Combination of keyboard, and haptic device in delta robot configuration.** |
| **Auris – Monarch [16]** | **At least 3 DOF, steerable catheter** | **Bronchoscopic visualization and access to patient airways for diagnostic and therapeutic procedures.** | **Videogame console type remote controller with buttons and joysticks.** |
| **Commercial Robots – CorPath GRX [17]** | **2 DOF catheters and guide wires.** | **Percutaneous coronary intervention (PCI) and Pulmonary vein isolation (PVI)** | **Joysticks** |

Devices like Niobe and Monarch are highly costly and complex (much more than needed for a TAVI intervention, not mentioning that TAVI catheters could not be operated by Niobe magnetic fields, since they are plastic), on the other hand The Amigo system was designed to overcome these points having simpler and cheaper designs. Nevertheless, all these systems are designed to operate steerable catheters with 3 or more DOF, which make them an overkill for TAVI surgery, however, the concept behind their robotic devices could be simplified and adapted to only manage the 2 DOF necessary for TAVI.

Moreover, the CorPath GRX is the system with more similarities to what is needed for TAVI, handling 2 DOF catheters, guide wires and a stent balloon. However, TAVI surgery requires more than one catheter and guide wire to gain access to the left ventricle of the heart, as well as managing the new aortic valve deployer catheter.

**Chosen Devices and Characteristics**

Every device was chosen to control independently each one of the catheters DOF as shown in figure (). In this section the mechanics, electronics and functioning of every input device is explained. After, a comparison between all device’s characteristics, advantages and disadvantages is made.



* **Keyboard**

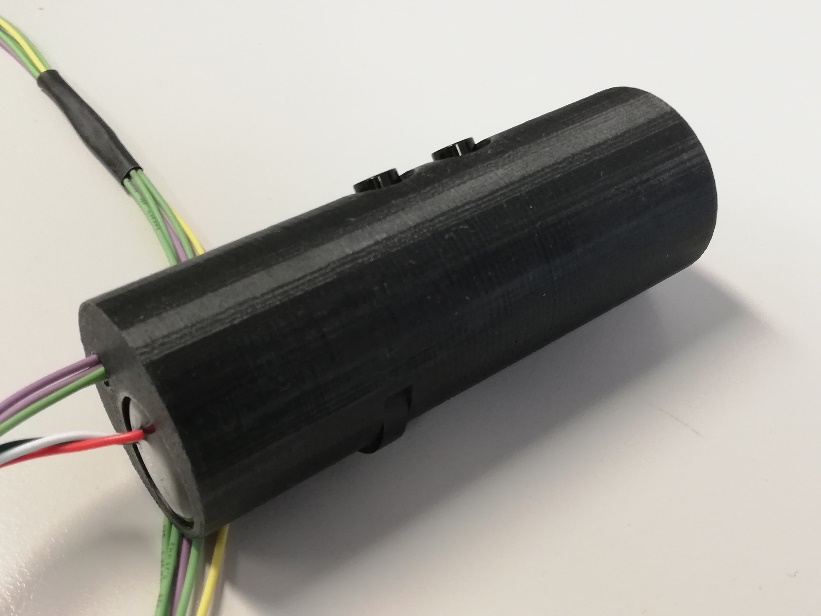
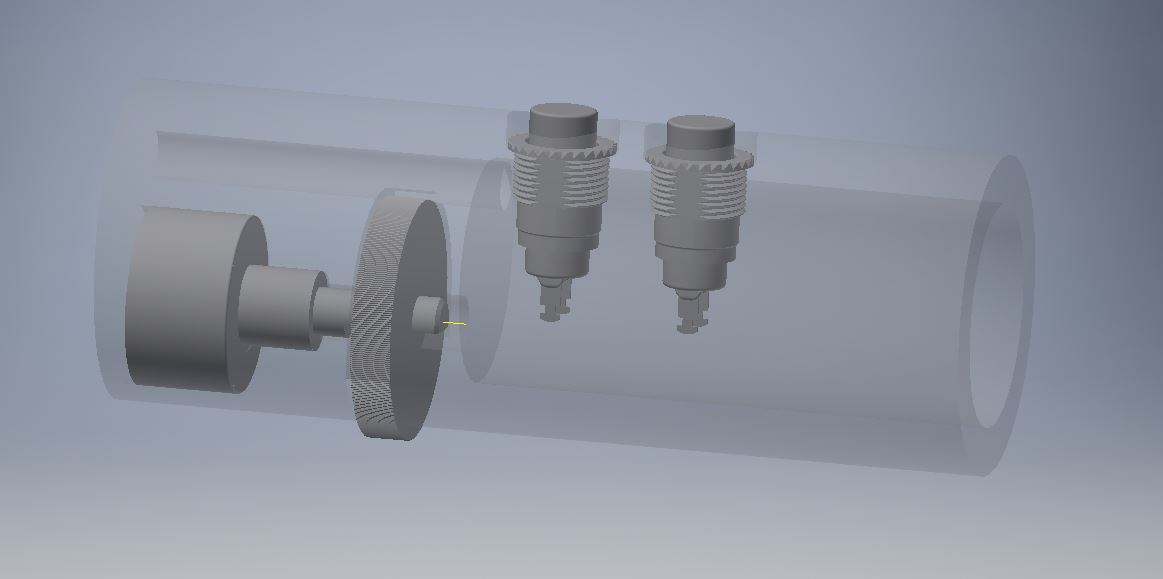
The keyboard device intends to represent any other device only controlled by on-off buttons, working in a digital configuration. For this experiment a numerical keypad was used figure ().

The control of the catheter was performed with the arrow key, being t UP and Down arrow key the control for the 1st DOF of the catheter. The 2nd DOF was controlled with the RIGHT and LEFT arrow keys.

 V7-KP1019-USB-4EB with USB connection

* **Remote**

The Remote device is a combination of on-off buttons and an analogical sensor figure (). The 1st DOF of the catheter is controlled by two push buttons in a digital configuration. The 2nd DOF is controlled by a non contacting rotatory position sensor, which gives a semi-analogical reading with a 12 BIT resolution per 360 degrees. It Is important to notice that the experiment setup as can be seen in section () uses an Arduino with a 10BIT ADC channel, which trims the initial sensor’s 12BIT resolution.

 push buttons C&K 8532T1ZBE2

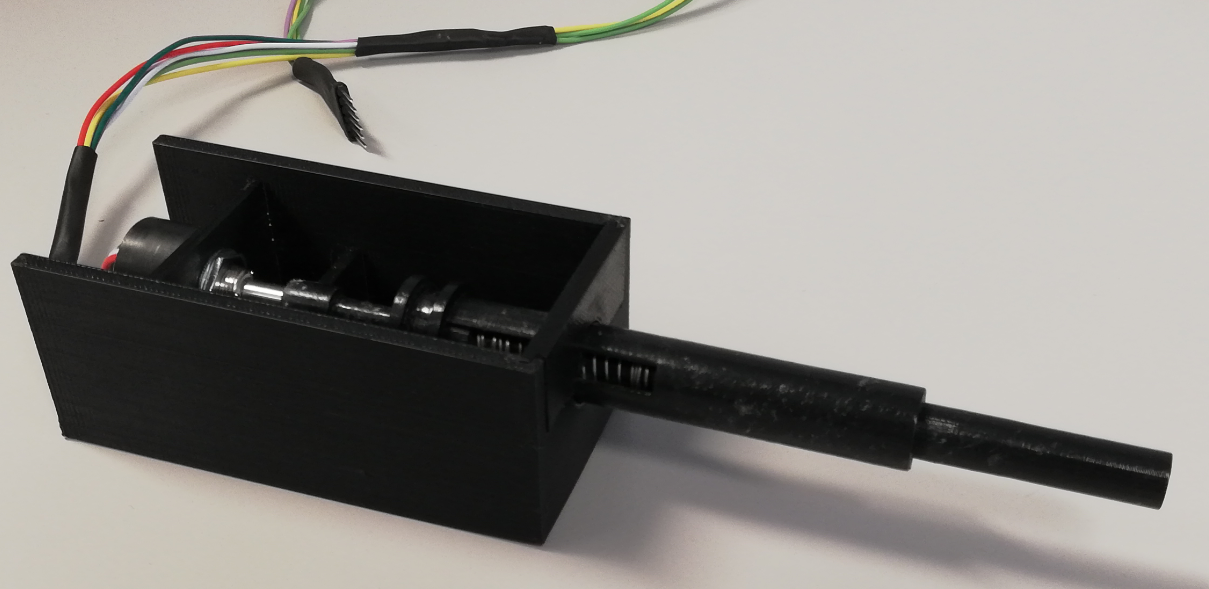
* **Joystick**

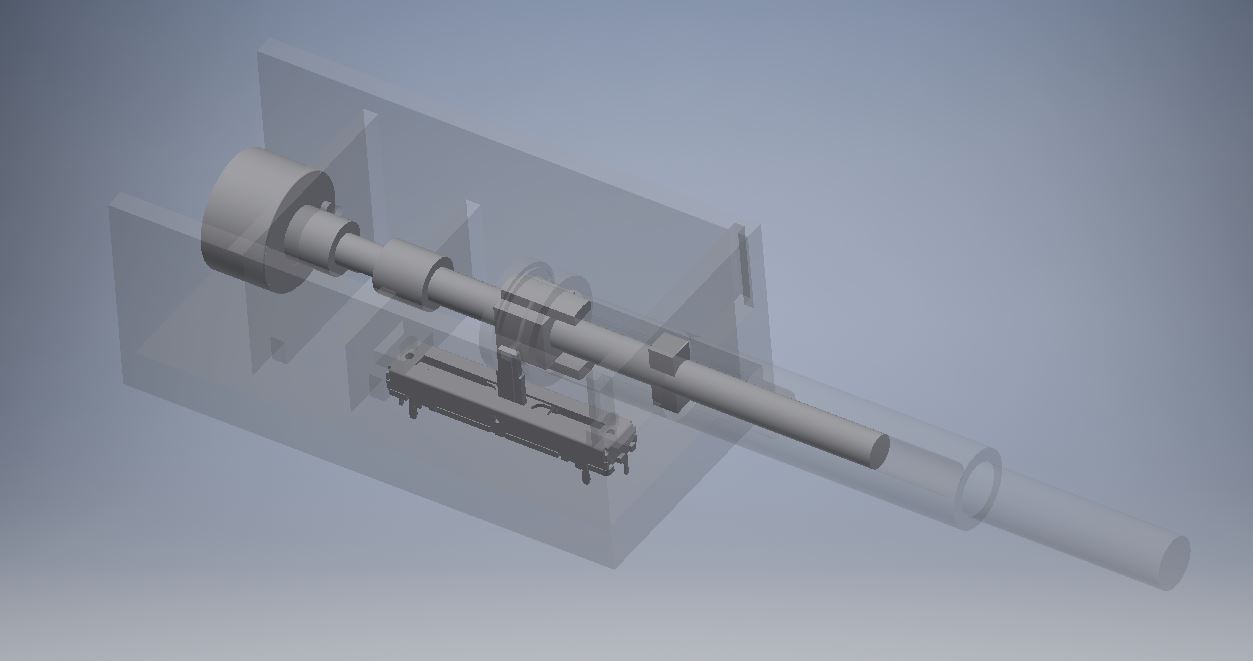
The Joystick device is implemented with fully with analogical sensors figure (). The 1st DOF of the catheter is controlled by a regular 5Kohm potentiometer, mapped on the pitch movement of the joystick. The 2nd DOF is also controlled by regular 5Kohm potentiometer mapped to the yaw movement of the joystick. The potentiometers have essentially infinite resolution, only trimmed by the Arduino’s ADC channel (See section () for experiment setup) used to read out the sensors.



* **Catheter**

The Catheter device is a combination of on-off buttons and an analogical sensor figure (). The 1st DOF of the catheter is controlled by two push buttons in a digital configuration. The 2nd DOF is controlled by a non contacting rotatory position sensor, which gives a semi-analogical reading with a 12 BIT resolution per 360 degrees. It Is important to notice that the experiment setup as can be seen in section () uses an Arduino with a 10BIT ADC channel, which trims the initial sensor’s 12BIT resolution.

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**Advantages and disadvantages**

**Experiment Environment**

**Experiment 1st DOF**

**Experiment 2nd DOF**

**Experiment Maze**

**Results and Discussion**

**Conclusions**

**Apendix**

**Bibliography**

[1] Mahmaljy H, Young M. Transcatheter Aortic Valve Replacement (TAVR/TAVI, Percutaneous Replacement) [Updated 2019 May 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK431075/>

[2] Andras P Durko, Ruben L Osnabrugge, Nicolas M Van Mieghem, Milan Milojevic, Darren Mylotte, Vuyisile T Nkomo, A Pieter Kappetein, Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections, European Heart Journal, Volume 39, Issue 28, 21 July 2018, Pages 2635–2642, <https://doi.org/10.1093/eurheartj/ehy107>

[3] Alejandro Aquino, Ali J. Khiabani, Matthew C. Henn, Alan Zajarias, Spencer J. Melby, Marc Sintek, John Lasala, Puja Kachroo, Eric Novak, Hersh S. Maniar, Radiation Exposure During Transcatheter Valve Replacement: What Cardiac Surgeons Need to Know, The Annals of Thoracic Surgery, 2019,

[4] Díez, José G. “Transcatheter aortic valve implantation (TAVI): the hype and the hope.” Texas Heart Institute journal vol. 40,3 (2013): 298-301.

[5] “Transcatheter Aortic Valve Replacement (TAVR) Program.” Maimonides Medical Center, https://www.maimonidesmed.org/heart-vascular-institute/centers/structural-heart-center/tavr.

[6] Roguin A, et al. Brain tumours among interventional cardiologists: a cause for alarm? Report of four new cases from two cities and a review of the literature. Eurointervention 2012;7:1081-1086.

[7] Vano E, et al. Radiation-associated lens opacities in catheterization personnel: results of a survey and direct assessments. Journal of Vascular Interventional Radiology 2013;2: 197-204.

[8] Dehmer G, et al. Occupational Hazards for Interventional Cardiologists, The Society for Cardiovascular Angiography and Interventions. Catheterization and Cardiovascular Interventions; 2006;68, 6, 974-976.

[9] 5. 211-407:63; 2004 Interv Cardiovasc Catheter. practice contemporary in problems health orthopedic of prevalence: cardiologists interventional of hazards Occupational. al et, J G

[10] Smilowitz N, et al. Robotic-Enhanced PCI Compared to the Traditional Manual Approach. J Invasive Cardiol, 2014;26(7):318-321.

[11] Weisz G, et al. Safety and Feasibility of Robotic Percutaneous Coronary Intervention: PRECISE Study. J American College of Cardiol, 2013, Vol 61, No. 15: 1596-1600.

[12] “Revolution Full Overlap Lumbar Vest & Skirt - 703.” Infab, <https://www.infabcorp.com/product/revolution-full-overlap-lumbar-vest-skirt-703/>.

[13] “Shimane Prefectural Central Hospital.” EIZO, <https://www.eizoglobal.com/solutions/casestudies/spch/index.html>.

[14] Zohaib A. Shaikh, Michael F. Eilenberg, Todd J. Cohen, The Amigo™ Remote Catheter System: From Concept to Bedside, The Journal of Innovations in Cardiac Rhythm Management, 2017, 2795–2802

[15] “Stereotaxis Products.” Stereotaxis, <http://www.stereotaxis.com/products/#!/niobe>.

[16] “Transforming Medical Intervention.” Auris Health, <https://www.aurishealth.com/monarch-platform>.

[17] “Corindus Vascular Robotics.” Corindus Vascular Robotics, https://www.corindus.com/.

Some feedback from my side. Please try to incorporate it into the thesis:

* Improve scaling of some graphs (so that the space is used for the bars/curves)
* Change terminology of “analog” and “digital” devices, as this is really misleading
* Very important: Please mention Andre Plass and his role as co-supervisor!!
* Provide a complete list of parameters of the four different input devices: include properties such as delay/latency, friction quality (high, low), reliability/quality of the buttons, ergonomics (how it “feels”), etc. and try to integrate such differences into the discussion/conclusion
* Say what the challenge and task of the surgeon is, express it by facts and numbers and then derive the needs for the hardware and the experiments. E.g. how is the reference trajectory oriented on the movement of the surgeon? Is there a link at all?
* Try to find more literature about similar tracking tasks, a) in surgery and b) in general haptic/drawing tasks outside surgery. Add the literature
* You showed the other devices available. But say, what the problems are, that have an effect to us (why do we develop a new device and why did you what you did with respect to the existing devices)