Master thesis

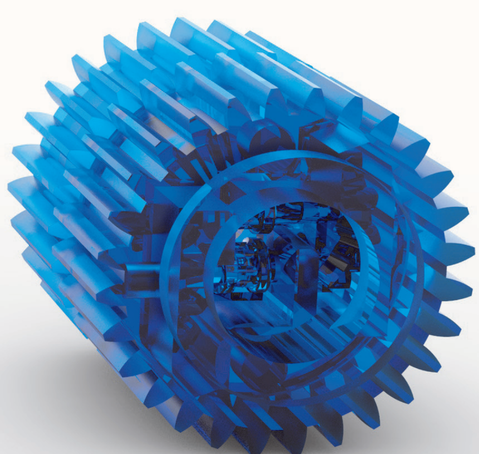
Design of a needle control device for MRI-guided intervention

Graduate student
Charlotte Kemp

Supervisory team
R.H.M. Goossens
A.L.M. Minnoye
D.G.H. Bosboom

Delft, February 2020

Delft University of Technology
Faculty Industrial Design Engineering
Master Integrated Product Design
Specialisation Medisign



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Education
Master Integrated Product Design
Medisign specialization
Faculty of Industrial Design Engineering
Delft University of Technology

Client
Radboud Universitair Medisch Centrum
Department of Radiology and Nuclear Medicine
Nijmegen

Soteria Medical BV
Arnhem

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TU Delft Soteria Medical Radboudumc

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Welcome to my master thesis, a report that is written to conclude my master study Integrated Product Design at the faculty of Industrial Design Engineering, Delft University of Technology.

Simultaneously to the beginning of my graduation, I worked on the Medisign book "Product for Healthcare" which includes all Medisign-oriented graduation projects of the past three years. It gave a great overview of possibilities and narrowed down my search for my own assignment. While compiling the Medisign book, I was most interested in chapter Clinical Technologies and I figured out I wanted to collaborate with a hospital or a company that works closely with a hospital. In July, a mutual relation (Sanne de Smet and Jacky de Rooij) put me in contact with Dennis Bosboom and so began my graduation project.

I am amazed by the amount of energy that could be put into a project when you are passionate about it. I have exactly learned what I wanted and could put my personal recommendations from previous assignments into practice. I can truly say that I have designed a product that could add value to healthcare and create an impact on the status quo. This project is everything I wished for.

Enjoy reading,

Charlotte Kemp
February 2020

Acknowledgments

Although graduation is an individual project, I could never have done it without the help and support of some people. Therefore, I want to thank them all for the help, support and energy they have invested in my project.

Richard, you are the chair of my graduation committee, but you also coached me in many other courses during my master's and bachelor studies. I always thought you give great feedback, are fast in responding and invested in the project. Thank you so much for the help and inspirational talks.

Sander, thank you for the motivation and guidance you gave me. We met every two weeks and you provided me with direct, useful feedback and tips. I always left with new insights, new ways to proceed and new energy. Thank you for being a great mentor.

Dennis, this project would never exist without you. I am the first graduate that you have ever supervised and I think for both of us that is exciting and new. But I couldn't have asked for any more support. You showed me the hospital and spin-off environment, you responded immediately to all my questions and remarks, and you were just as excited as me when we finished the CT test, maybe even more. Thank you so much for the past few months and let's see where we can take it!

Hubald, I want to thank you, not only for your tremendous contribution in creating the control unit and proof-reading my report, but also for your sharp advice and loving support.

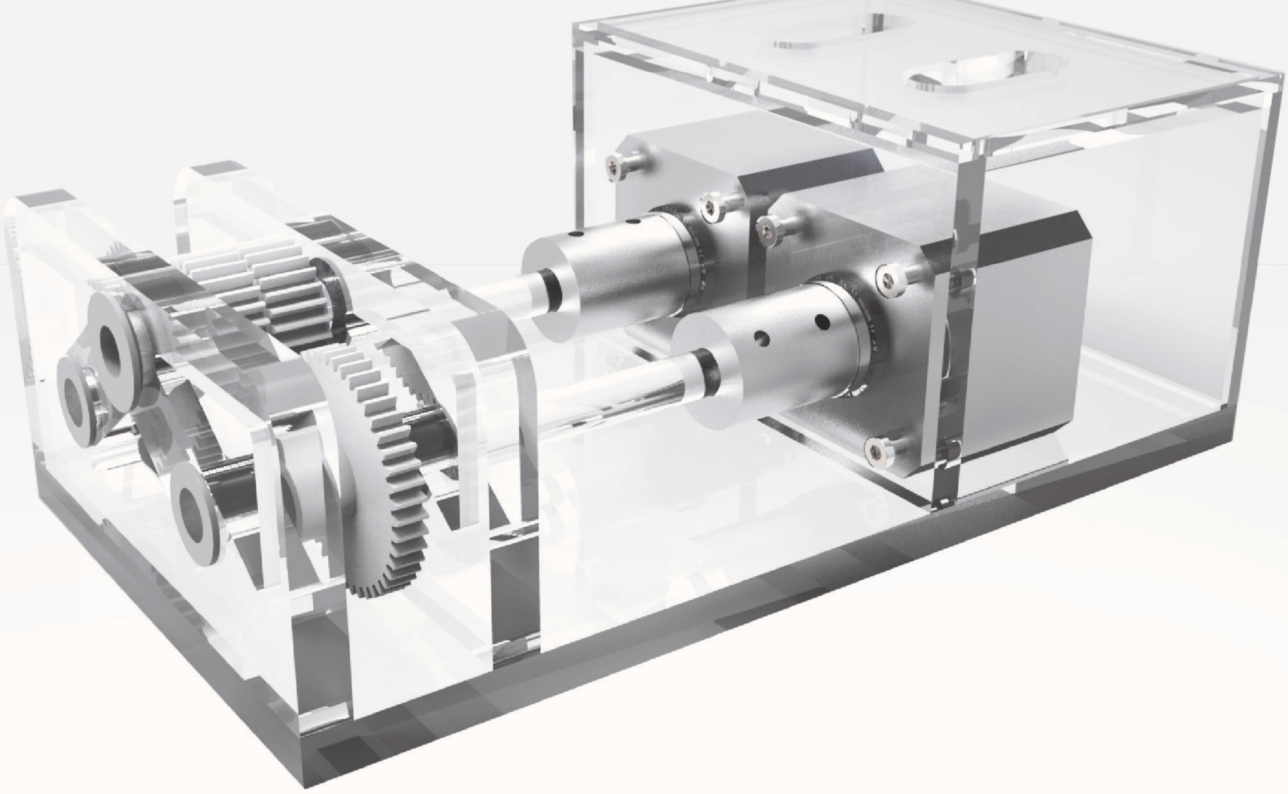
PMB and MTB3D guys, thank you so much for helping me out and giving me advice on building the prototype. Also for the urgent actions that I asked for.

Staff from the Radboudumc and Soteria Medical, I have had a great experience at the hospital and Soteria Medical. Thank you for your openness and inclusiveness. I always felt welcome. A special thanks to Gerrit Tigelaar who gave me a quick workshop on SLA printing and immediately printed my design.

Arianne, I want to thank you for our daily coffee break. We both carried out a fulltime indivudual project and you were a lot of support to me.

Hannah and Laetitia, you have advised me in my visual communication and form language analysis. Even though it was not a learning goal, I have improved a lot on my visualization skills. Thank you for the tips and insights.

Furthermore, I would like to thank my parents, friends and family who supported and coped with me during the last few months.



Needle control device

Executive summary

This report presents the design of the needle control device that could perform interventions remotely in an MRI-environment. Performing interventions in an MRI is desired since the scans provide direct feedback of the position of the needle and the targeted tissue and therefore, the physician is ensured that the targeted tissue will be treated. Another benefit of performing interventions in an MRI is that the path towards the targeted tissue is mapped out and automated, so no extra healthy internal tissue is damaged. The recovery time of the patient is faster compared to recovery time from a regular-proceeded intervention.

The needle control device consists of three parts: the driver, the motor and the control unit. During the project, a focus is set on the design of the driver, yet the motor is also in scope to create a design proposal for the total product.

The driver contains a tunnel through which a needle could be inserted. Inside the driver, a plastic gear system is established that grabs the needle and steers it forward, backward and rotates it. With these movements, a flexible pre-curved needle could be steered in any direction.

Gears

The driver consists of two main spur gears supported by two worm gears to translate the motor transmission. Inside the main gears, a smaller gear system is hidden which is activated by the rotations of the two main gears. By rotating the main gears simultaneously, a rotational movement is conducted and by rotating them separately, a lineair movement is conducted.

Validation of the driver

To validate the design of the driver, a prototype has been built. It is made from 3D-printed gears, powered by stepper motors and a control unit including a uniquely-designed PCB. The prototype and control unit are connected by 8m cables to cover the distance between the scanner and the radiation-free control room. Since the motors include metal parts and therefore cannot be used in an MRI, the tests are performed in a CT. The prototype drives the needle through a phantom while being scanned continuously. The result shows that the needle could be tracked while it is performing a mapped-out path.

Final design

Parallel to the design of the driver, a final design proposal for the needle control device is created. It is based on the interactions with the users and is therefore presented in the four main activities: assembling the device, opening the driver, fixing the driver to the patient and fastening the motor to the MRI bed. The final design proposal is based on sterility, control for the physician and intuitive use for all users.

So, two parallel processes have been executed: a proof of principle and a final design proposal. For both processes, an evaluation is made and recommendations are given. The conclusion is that a thorough exploration and elaboration of the driver have been executed and a start is made with the final design. For future steps, it is recommended to integrate both processes and work towards creating a minimum viable product.

Glossary and abbreviations

CAD
Computer-Aided Design; in this case: 3D models made in the program SolidWorks

DOF's
Degrees Of Freedom, defining the position and orientation of a body

FDM printing
Fused Deposition Modeling, a method of 3D printing that makes use of filament and heating. A known FDM printer is Ultimaker and is the main 3D printing technique in the faculty of Industrial Design Engineering

MRI
Magnetic Resonance Imaging is a medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body

MR-compatible
Able to be used in an MRI scanner

PCB
Printed Circuit Board

PCL
Programmable Logic Controller, used in the control unit of the RCM

Radboudumc
Radboud Universitair Medisch Centrum

RCM
Remote Controlled Manipulator, designed by Soteria Medical

RPM
Rotations per minute

SLA printing
Stereolithography printing, a method of 3D printing that makes use of resin and a laser

Table of contents

1 Assignment and Approach

This chapter shows the results of the preliminary phase, where the assignment is set with its corresponding boundaries. Furthermore, it covers the project partners with their roles and responsibilities and the approach to fulfill the assignment. The goal of this phase is to describe the project on a process level and provide an introduction.

1.1 Project partners

The project is carried out in collaboration with multiple stakeholders. Here they are stated with their roles and responsibilities. It describes their involvement and the background of the assignment.

Radboudumc

The Radboud universitair medisch centrum is one of the eight university medical centers in the Netherlands and is located in Nijmegen. The project is carried out at the Radiology and Nuclear Healthcare department.

Role in the project

Radboudumc facilitates a workplace at the Radiology and Nuclear Healthcare department, creates test facilities and makes experience in a hospital possible. The hospital is visited weekly. Questions about healthcare-related issues and the human body are answered here.

TU Delft

Delft University of Technology (TU Delft) is the educational institute for which this assignment is executed. To be more specific: it is executed for the master Integrated Product Design with specialization Medisign within the faculty Industrial Design Engineering.

Role in the project

The role of TU Delft within the assignment is to guide from a university perspective and decide if the outcomes are of a sufficient academic level. The supervisors are consulted every two weeks.

Soteria Medical is a spin-off company of the Radiology and Nuclear Healthcare department of the Radboudumc, Nijmegen. They have six full-time employees all over the world, but their base lays in Arnhem. Soteria's first product is a robotic device which takes prostate biopsies in an MRI-guided intervention, called the remote-controlled manipulator (RCM). The setup of the robot consists of three parts: (1) an actuator that controls the needle, (2) the motor unit and (3) a controller (PCL). It is wired with tubes of seven meters that provide hydraulic pressure. The pressure enables the motors and let the physician take prostate biopsies from a distance.

Role in the project

Soteria Medical provides knowledge and insights of their RCM to develop the next robot. They are experts in the development of medical equipment and contribute to the process by sharing their experiences.

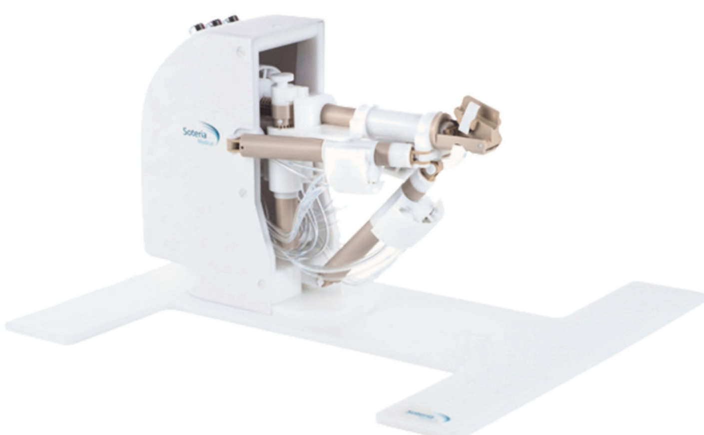


Figure 1. The RCM of Soteria Medical

1.2 Assignment

The establishment of the graduation assignment has been a process on its own. Multiple iterations are taken to develop an assignment that includes all facets of interests, but is also feasible within the given time.

The assignment builds upon the first robot of Soteria Medical. Where their first robot could only capture biopsies, Soteria Medical sees an opportunity to redesign their robot to do much more in an MRI scanner.

Currently, many new medical products/procedures include putting sensors and camera's into patients. But with an MRI, it is the other way around: the patient is put into the sensor/camera. It is a less invasive procedure while obtaining the same result.

Furthermore, accuracy is a valuable aspect in diagnosis and treatment of tissues and organs that change position and shape while in surgery. For example, it is hard to track the precise location of a tumor in the abdominal area while the patient is breathing. When the patient lays in an MRI, the physician could see clearly at all times where the precise location is. So, it would be convenient to have surgery in an MRI.

To perform interventions in an MRI, a device should exist that makes any wire/needle/catheter/tube/etc. remotely steerable since the physician needs to be positioned in the control room. Onward, all wires/needles/catheters/tubes etc. are named by the term needle.

So, the device should be remote-controlled, MR-compatible, and make a needle steerable.

The project brief could be seen in appendix I.

With these statements, the graduation assignment is set:

'Design a needle control device for MRI-guided interventions'

1.3 Project Boundaries

In addition to the assignment, boundaries need to be defined to conduct the project within the given time. This section describes these boundaries to set the scope of the project.

Scope

The main layout for the new device is already there and has similarities with the RCM: the new robot will exist out of three main parts (figure 2). The driver unit is placed in the MRI, is attached to the skin of the patient and takes care of the direction of the needle. The driver unit is connected to the hydraulic motor unit, and this motor unit is again connected to the operational machines behind the wall where the physician is directing the robot, the control unit.

The focus of this project lays on the development of the driver unit. A mechanism needs to be designed to control the needle. Next to that, the robot will be designed as a whole which includes the driver and motor unit. The control unit and connection from motor to control unit is put out of scope.

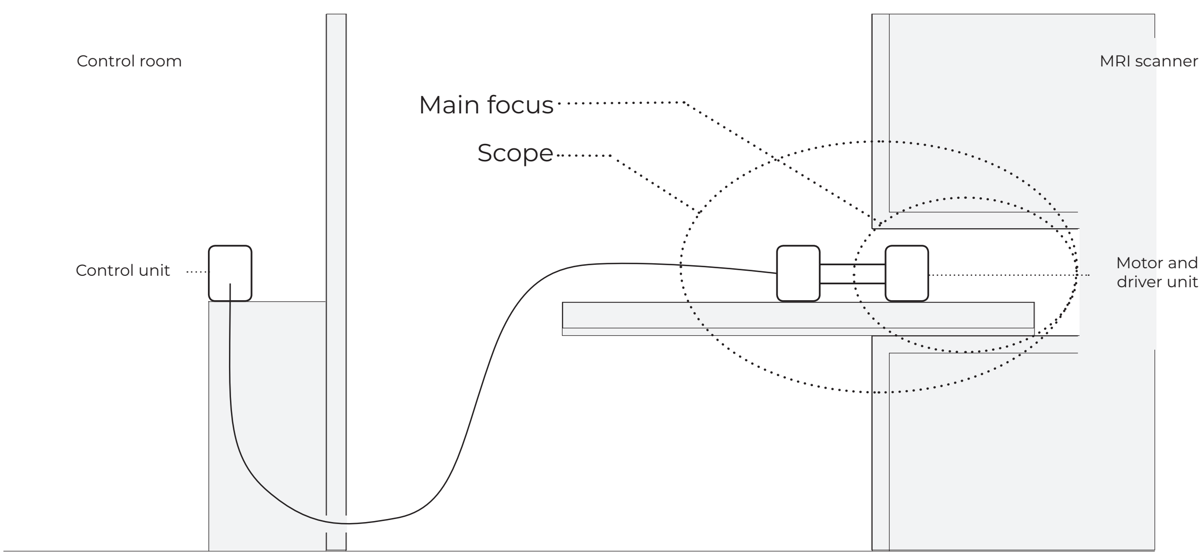


Figure 2. Visualization of project boundaries

1.4 Project approach

To get from assignment to result, an iterative process is undertaken. It is visualized in figure 3 and is based on the process of Roosenburg & Eekels (1998). This section shows a schematic overview of the different phases that the project went through.

In the preliminary phase, the assignment and approach are established. With the information and boundaries, subjects for the analysis could be explored. From many subjects, a few are chosen to investigate. This was not only desktop research, but also experimenting with gels, needles and gears from a mechanical toy kit. The desktop research consists of a case study, form study and literature research. All gathered information is summarized in conditions for the needle control device. This list of conditions is used several times in the design process to check if the ideas still comply with the initial conditions.

The list of conditions also served as a start for idea generation. Several ideation methods are used to ensure all ideas have been put on paper. The ideas are clustered and formed into design directions. With decision-making methods, a concept choice is made.

As mentioned in section “Project boundaries” the main focus is the driver unit, but also the motor unit is in scope. To test the design of the driver unit, a proof of principle is made. This prototype is not a reflection of the final design; it only shows if the mechanism is working as expected.

The final design proposal does reflect the overall design and serves as communication of the design decisions. So, after the concept is defined, the process is split up into two parallel paths that either test the functions or reflects the final design.

In both paths, multiple aspects are investigated and many iterations have taken place to come to a final functional prototype and visual representation.

Lastly, the functional prototype and final design proposal are evaluated and validated. The deliverables are a report, presentation and poster to conclude the assignment.

This process may seem chronological and linear, but a design process is far from that. It is an iterative path and for this project, the most extensive iterative behavior took place in the elaboration and embodiment phase.

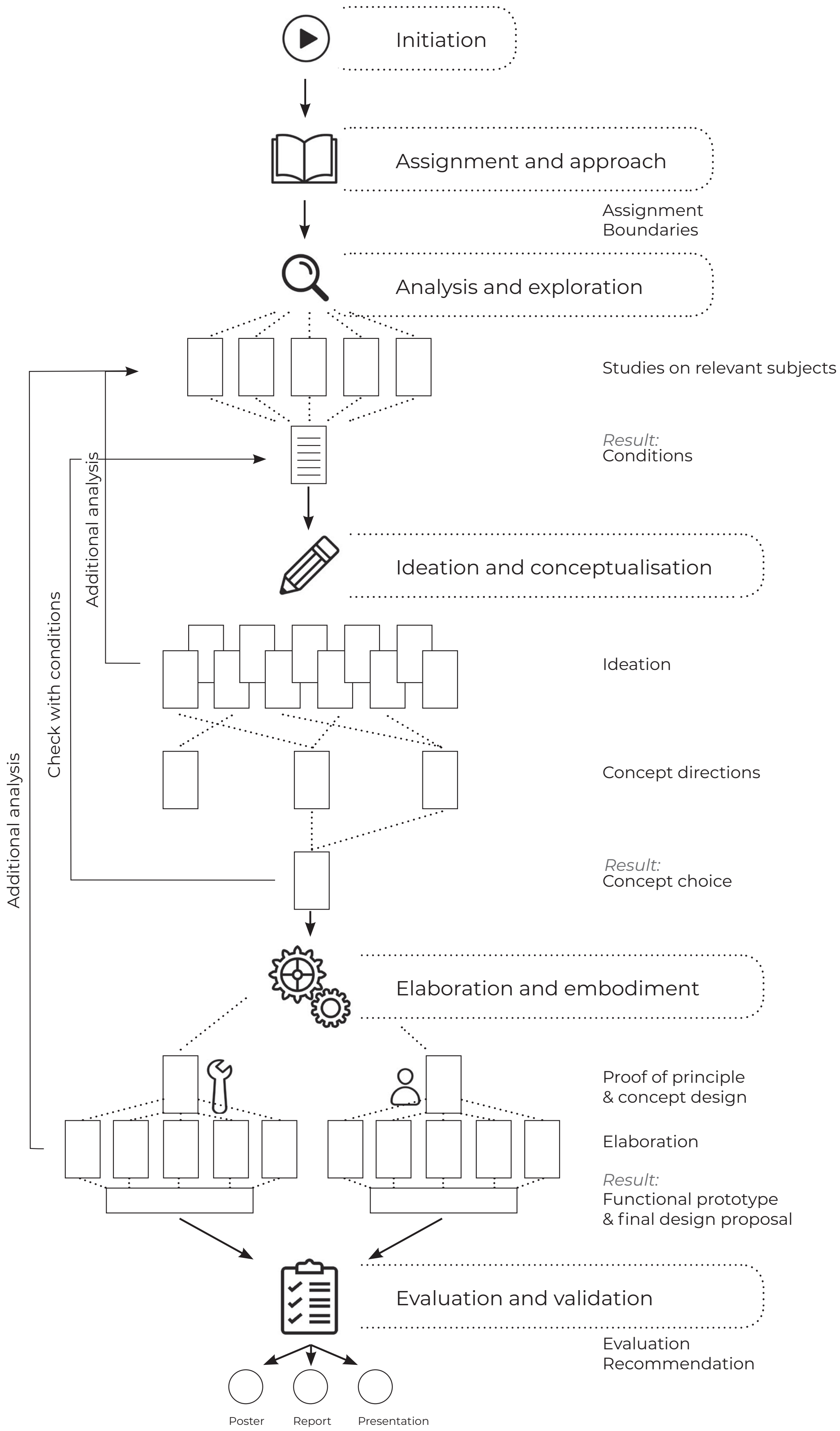
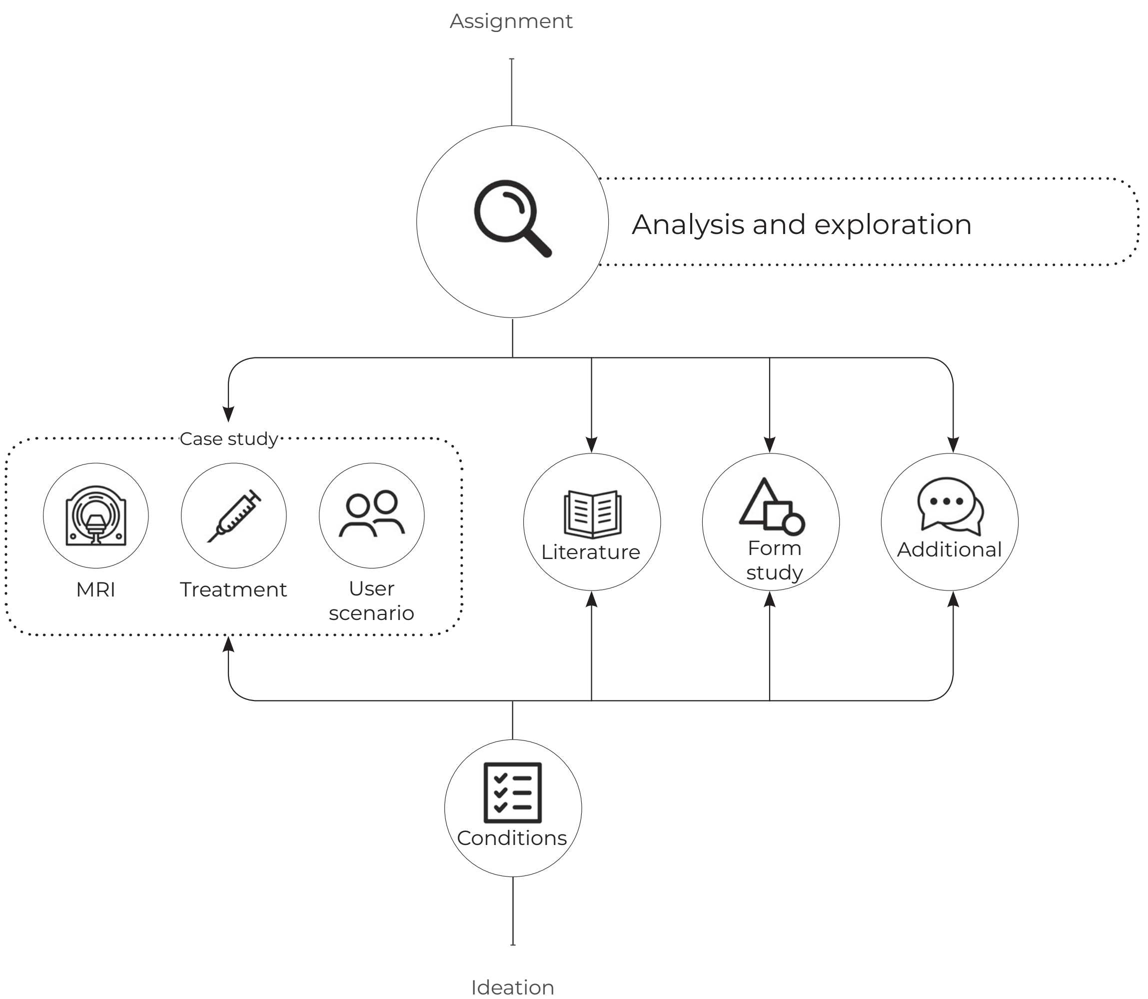


Figure 3. Project approach


Assignment
Analysis and exploration
Case study
MRI
Treatment
User scenario
Literature
Form study
Additional
Conditions
Ideation

2 Analysis and exploration

The main objective of this phase is to get a clear understanding of the context and existing research and products. This is achieved by performing analysis studies on relevant subjects. All information leads up to a list of key conditions that the product has to apply to.

2.1 Case study

The assignment states a broad user scenario, where every kind of needle could be used for all interventions in an MRI. Therefore a case study is chosen to make the design process more focussed. This section provides information in the current situation, the desired user scenario, and the market in which it would operate.

The case study that will be used for this assigment, is a man who is suffering from brain tumors. Currently the treatment is surgery where the tumors are removed from the brain. While removing the tumor, a margin is taken into account to ensure the tumor is completely resected. Hereby, healthy tissue is removed which is not preferable, especially not in the brain.

Furthermore, determining the exact location of the tumor in surgery is hard since the brain sags in a little when the skull is opened. The prepared scans are no longer accurate when the surgery has started.

Hence, the issues in the current situation are that (1) removing the tumor is not sufficiently accurate which results in removal of healthy brain tissue, and (2) the prepared scans are not reliable in surgery since the brain changes shape.

Brachytherapy

A promising procedure for treating brain cancer is brachytherapy. Today it is mainly used to treat prostate cancer, but it could be used for many other forms. Brachytherapy consists of radioactive 'seeds' (droplets) that are delivered in the tumor. In this case, the seeds are radioactive liquid. The liquid sends strong radiation, but only in a small range so it will only damage a small piece of tissue. The physician needs to make a plan where to put the seeds in the brain to erase the tumor, without damaging the surrounding brain tissue.

User scenario

On the next page, a visualization of the user scenario could be viewed. It shows the future rundown of a patient and physician, using the needle control device.

Market

The market is comparable with the market for the RCM of Soteria Medical: sell to hospitals and manufacture in low volume. Since the device needs to be MR compatible and there is no intention to use non-ferrous metal, the expenses will be relatively low. An elaborate estimation is made in chapter Elaboration and Embodiment, page 60.

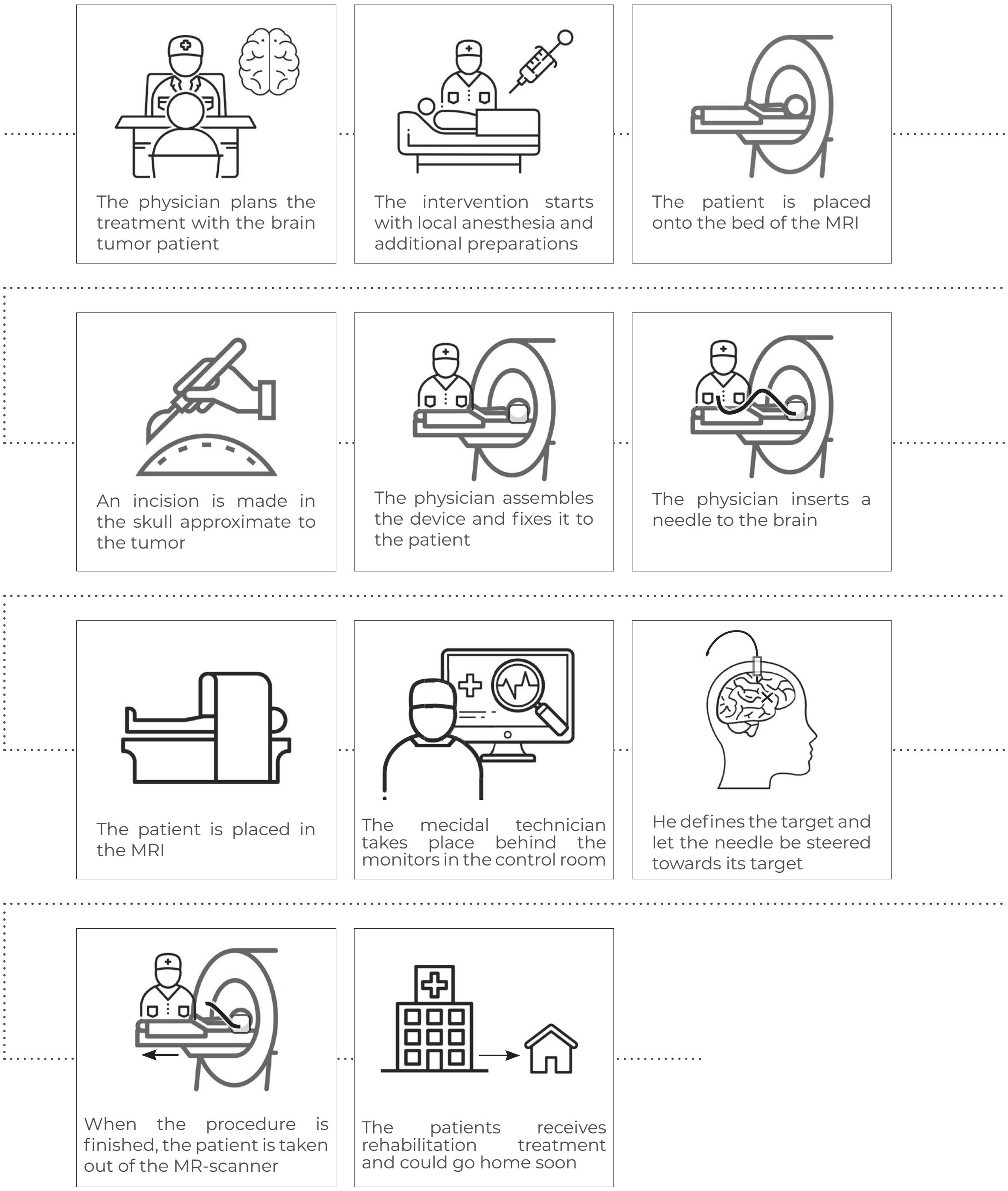


Figure 4. Scenario case study

2.2 Literature

In the academic literature, many papers have been dedicated to the design and evaluation of remote-controlled intervention machines. In this chapter, the relevant articles are highlighted and served as inspiration for further development of this master thesis.

This master thesis depends on a hypothesis, which reads: **if the needle is pre-curved, the needle could be steered by translational and rotational movement towards a target.**

When the needle is curved and experiences a forward translation, it will follow the path of least resistance and make a curve (figure 5). If the needle is rotating with a constant speed and experiences a forward translation, it will make a straight line (figure 6). So, the needle needs to experience two degrees of freedom (DOF's): one linear and one rotational translation.

In this chapter, the hypothesis is checked with literature. Certainly, many variables could influence the outcome, so in the literature is also searched for crucial variables, like shape and usage of the needle and the test setup. Therefore, this section is divided into "Needle design" and "Machine design".

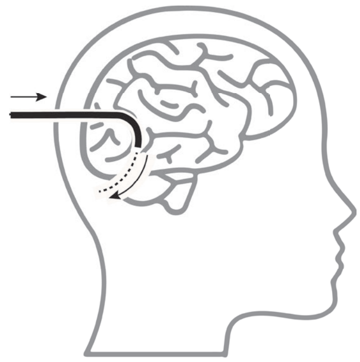


Figure 5. Linear movement

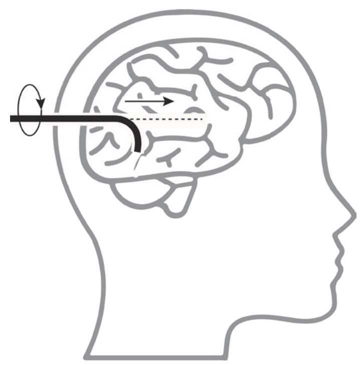


Figure 6. Rotational movement

Needle design

Many options are researched and discovered for making a needle steerable. M. Scali et al. (2018) wrote a review of needle-like instruments for steering through solid organs, whereby she distinguished mechanisms that induce deflection by a pre-defined shape and induce deflection by an actuator. Also, she distinguished mechanisms that induce deflection in several planes. Her results are summarized in figure 7. It gives an overview of the possibilities in needle steering.

According to the hypothesis, the needle used for the scenario is placed on the left side of the chart, the pre-defined deflection angle.

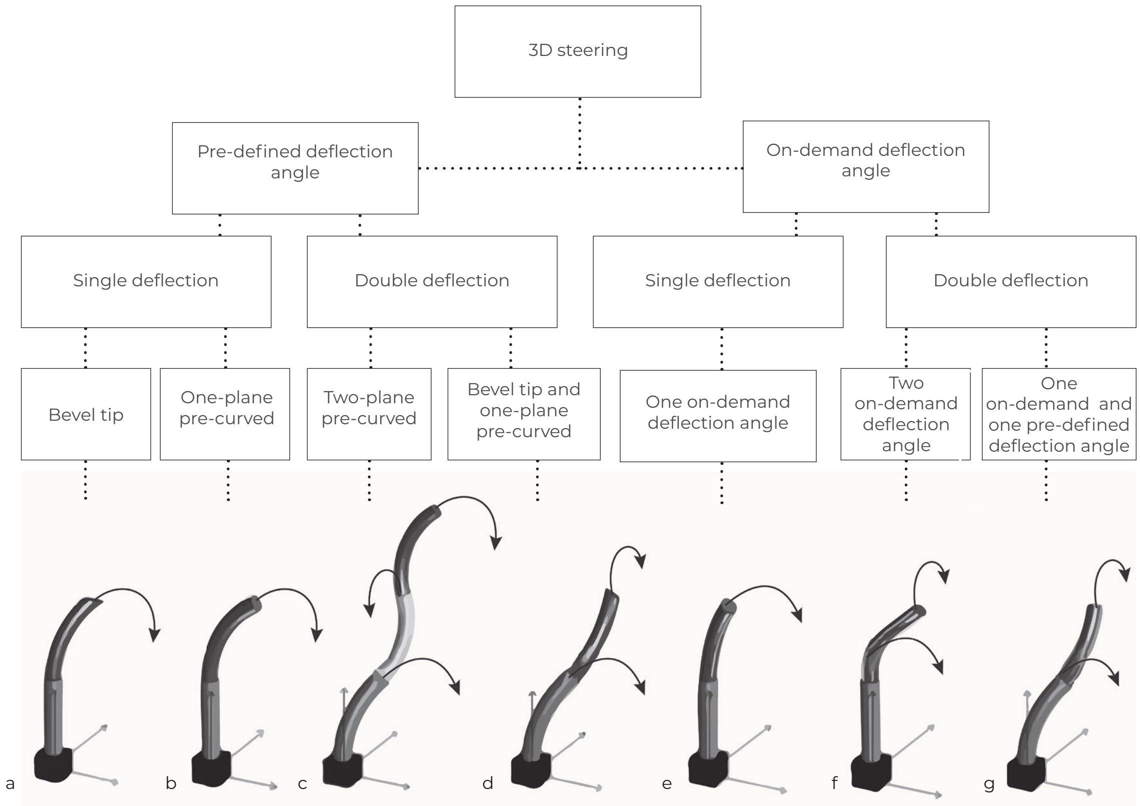


Figure 7. Review of M. Scali et all

Pre-curved needles

A pre-defined shape means that the needle is pre-curved and/or the tip of the needle is bevel-shaped. These shapes cause deflection, researched by Wedlick and Okamura (2009). Their experiments show that flexible pre-curved needles possess greater dexterity than bevel-tipped needles and achieve radii of curvature similar to fixed pre-bent needles.

Furthermore, they show that needles with large pre-curved lengths (x > 40 degrees) could not be steadily rotated within the tissue. They store torsional energy until they are eventually able to overcome the rotational resistance and snap to another angle. With pre-curved lengths smaller than 40 degrees, this behavior was not shown.
These findings suggest that no needle with large angles could be used for this project, while the large angles are desirable in small areas like the brain.

Nevertheless, some remarks can be made from this study concerning the variables: the material of the needle that Wedlick and Okamura uses is Nitinol (an alloy of titanium and nickel), which cannot be used in MRI. Furthermore, Wedlick and Okamura use translucent Plastisol rubber for the phantom. It raises the question of what is suitable for the design of the needle and the phantom.

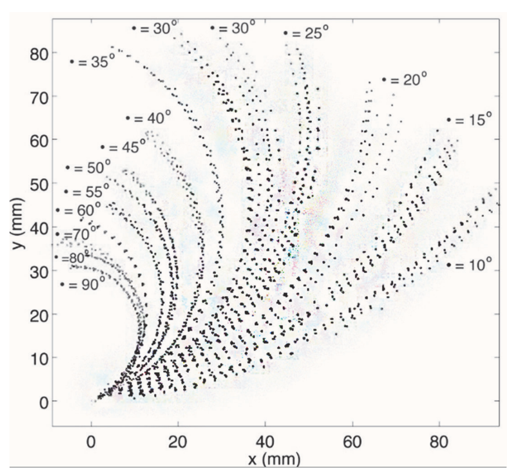


Figure 8. Positions of needle tips in the phantom. Insertion speed = 1,5 mm/s

The takeaways from this study are that...

- needle with only a bevel tip are not suitable for this case, it needs to be pre-curved like needle b, c and d in Scali's overview

- torsional energy needs to be taken into account: how stiff is the needle and how much friction does it produce by its curvature?

- the needle design and the phantom material are variables that require a more in-depth analysis

Bevel tips and actuators

Ko et all (2011) wrote a paper on a programmable bevel tip. They show in their paper what the effect is of the angle of the bevel tip on deflection. Although this gives insight into the process of deflection, it is not relevant for the design of the needle control device, since it is the driver that needs to be designed, not the needle.

The same applies to deflection by actuators. An example of this kind of needle is the design of Ayvali et all: they use shape-memory alloy wires that control the shape of the needle.

Machine design

Not only the articles are interesting for needle design, but also the test setups are valuable. In this study, the setups are extracted from their research and compared with each other. In total, nine setups are compared. They are shown in appendix II. All setups consist of a (pre-curved) needle, a control machine and a phantom.

Studies are found relevant when the setup examines the behavior of a pre-curved needle by translational and rotational movement. The number of studies that are found, indicate that it is possible to steer a pre-curved needle by translational and rotational movement. Still, it is uncertain if it suits for all needles and phantoms since every paper uses different sorts. Many studies used nitinol needles, and the phantoms differ from a block of gelatin to canine. Their main goal is to design a remote-controlled catheter system.

A common feature is found for the design of the setups: their rotational subsystem is mounted on a translational subsystem (or the other way around), which provides the insertion and rotational motion needed for steering. So the linear and rotational movement is seen as a separate entity. Hereby, the advantage is that it is relatively easy to design, adjust and repair, but on the other side it makes the system unnecessarily large and bulky. Designing a desirable and viable product out of these setups is hard, while it is often attempted.

Only the setup of Meng et all (2017) has both subsystems integrated: the bionic fingers provide the translational as the rotational movement.
There are a few takeaways from this study:

- Many others use the principle of steering a needle by translational and rotational movement, but they all use different needles, machines and phantoms

- All setups are easy to design, build and repair, but are also large and bulky

2.3 Form study

Currently, there are no other similar devices on the market next to the remote-controlled catheter systems. The innovative character of the device asks for a recognizable appearance to prevent rejecting by the medical staff.

Familiarity of design has a great influence on the acceptance of products (Mugge et all, 2017). Therefore, a form study is performed to discover repetitive features that could be used in the design of the final design proposal.

In figure 9, the RCM is shown in a schematic view to accentuate its shape. The right side shows a sleek and polished design with a large curve and prominent knobs. It reflects professionalism, trustworthiness and understandability. The left side shows robust and bulky axis which may be perceived as scary and intimidating. For the steerable needle robot, the right side will serve as an example for its shape and knob design.

Furthermore, a form analysis has been performed on comparable medical equipment. This includes similar machines from the literature, existing products used in an MRI and other medical apparatus that include similar components. Also, some examples of other industries are included. The overviews could be seen in appendix III.

The conclusion of the form analysis is that they all have geometric shapes with well-rounded edges related to the RCM. The way of integrating the geometric shapes serves as inspiration. The colors are mostly white and grey with bright colors for user clues. At last, it provides ideas for potential knobs, cables, connections between the motor and driver unit.

The conclusions of this form study are:

- familiar characteristics of medical equipment should be used in the design of the steerable needle robot to enhance the acceptance of the user
- Geometric forms with well-rounded edges should be used for the design
- To make a resemblance with the RCM, the large curve could be integrated

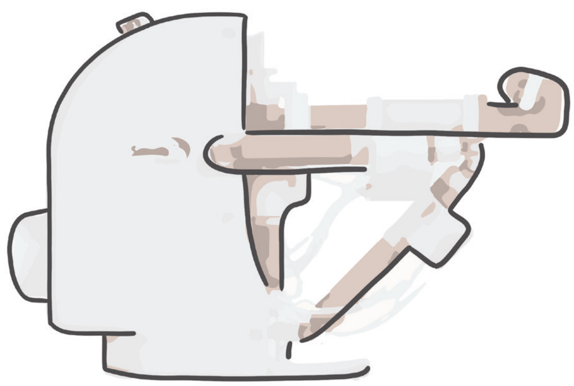


Figure 9. Schematic view of the RCM

2.4 Additional analysis

Next to the case study, literature review and form analysis, some additional analysis has been conducted. Solely, they are not noteworthy, but altogether it has led to an in-depth understanding of the topic.

The start of this assignment is marked by an informal interview with prof. dr. ir. P. Breedveld. The meeting serves as a catalysator for the literature study: what keywords to use, how to search, which fields do exist and which fields are interesting. However Breedveld is specialized in needle design rather than machine design, the outcomes help in structuring the literature review and gave a kickstart in search terms.

Furthermore, similar principles for different industries are found. The principle is not only suited for the medical environment, but it also used in mining or plumbing. A plumber needs inspection material to see where the blockage in pipes is. With an endoscope camera, he could steer the camera in through the pipes while making use of the stiffness of the flexible cable. Another example is a horizontal directional drilling machine, used for installing pipes under a river or large obstacle. The drilling machine has a chamfered side on its drill, like a bevel-tipped needle. While the pipe is rotating, it will follow a straight path, but when it is not rotating and only receives a forward movement, "it allows the head to move in its chamfer direction." (youtube video horizontal directional drilling machine, 2018)

Additionally, small experiments have been performed with gelatin models and nylon wire (1mm and 0,5mm in diameter), and small setups are made with gears from a mechanical toy kit. From the gelatin experiments, it is experienced how much friction is caused by the gelatin and how stiff and sharp the wires are. It helped in getting acquainted with the topic and see what factors are important for testing.

To sum up, the additional analysis sparks new ideas, provides direction for the topics in the analysis and serves as a catalyst for ideation.

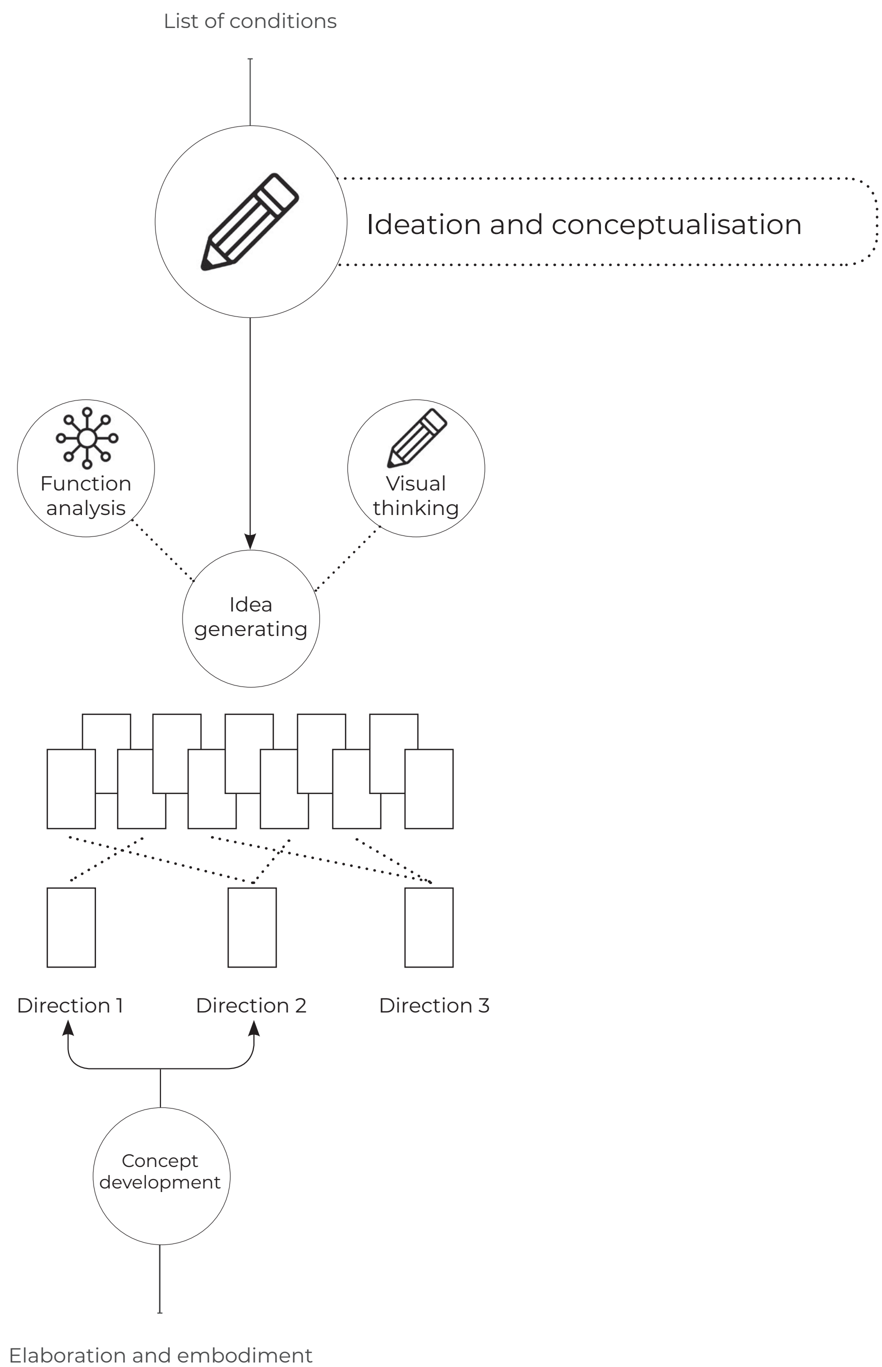
2.5 List of conditions

This section presents the list of conditions, which are extracted from the studies and concludes the analysis and exploration phase.

When the results of all analyses are accumulated, a summation of findings is found. The findings are translated to useful boundaries for designing. Not only do they define the start of ideation and are a support in chosing ideas, they also serve as a check for the final design proposal.

A complete list of conditions could be found in appendix IV. The fundamental conditions are stated here:

- A hollow, flexible, pre-curved needle should be able to be controlled be the driver, since it needs to deliver radioactive liquid
- The needle needs to receive two DOF's from the driver (one rotational and one translational movement) to be able to reach every target in the brain
- The device should be remote-controlled
- The device should be able to be placed on every spot near the patient's head
- The device should fit in an MRI
- The device should be MR-compatible, which means that non-magnetic materials should be used
- The device will be designed for a low volume
- Creating a resemblence of the needle control device and the RCM is aimed


List of conditions
Ideation and conceptualisation
Function analysis
Visual thinking
Idea generating
Direction 1
Direction 2
Direction 3
Concept development
Elaboration and embodiment

3 Ideation and conceptualization

The goal of this chapter is to show the process of finding the best solution to the assignment and the development of it. It starts with the ideation that results in many small ideas. The ideas are isolated or merged into design directions and developed into a concept.

3.1 Idea generating

The literature studies on needle and machine design have given inspiration to start ideating, but to ensure all ideas have been put on paper, different methods are used. The methods challenge to see the assignment from multiple perspectives and therefore create ideas from multiple angles.

Function analysis

The method that has created the most ideas is the function analysis. By abstracting the device of the scenario to its basic functions, an overview is created of what the device should be able to perform. It stimulates creativity and prevents from "jumping to conclusions", which is to say immediately elaborating on the first idea that comes to mind, or getting stuck in that idea (Van Boeijen et all, 2013). The use of this method was necessary since a possible solution was already carried out in some sketches of D.G.H. Bosboom. In figure 10, the function analysis of the driver unit is shown. It has served as a catalyst for new mechanism ideas for the driver unit.

Also, other methods are used like visual thinking, How-Tos and the Morphological Chart from the Delft Design Guide (Van Boeijen et all, 2013), but did not spark as many ideas as the function analysis. A representation of all ideas is seen in figure 11.

The result of the ideation phase is more than 200 generated ideas for the driver unit and the device as a whole.

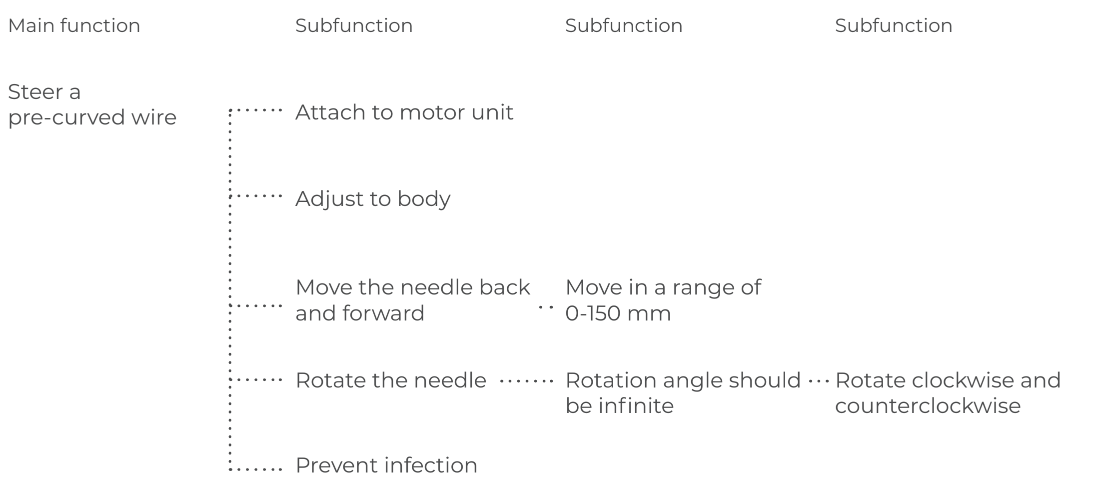


Figure 10. Function analysis

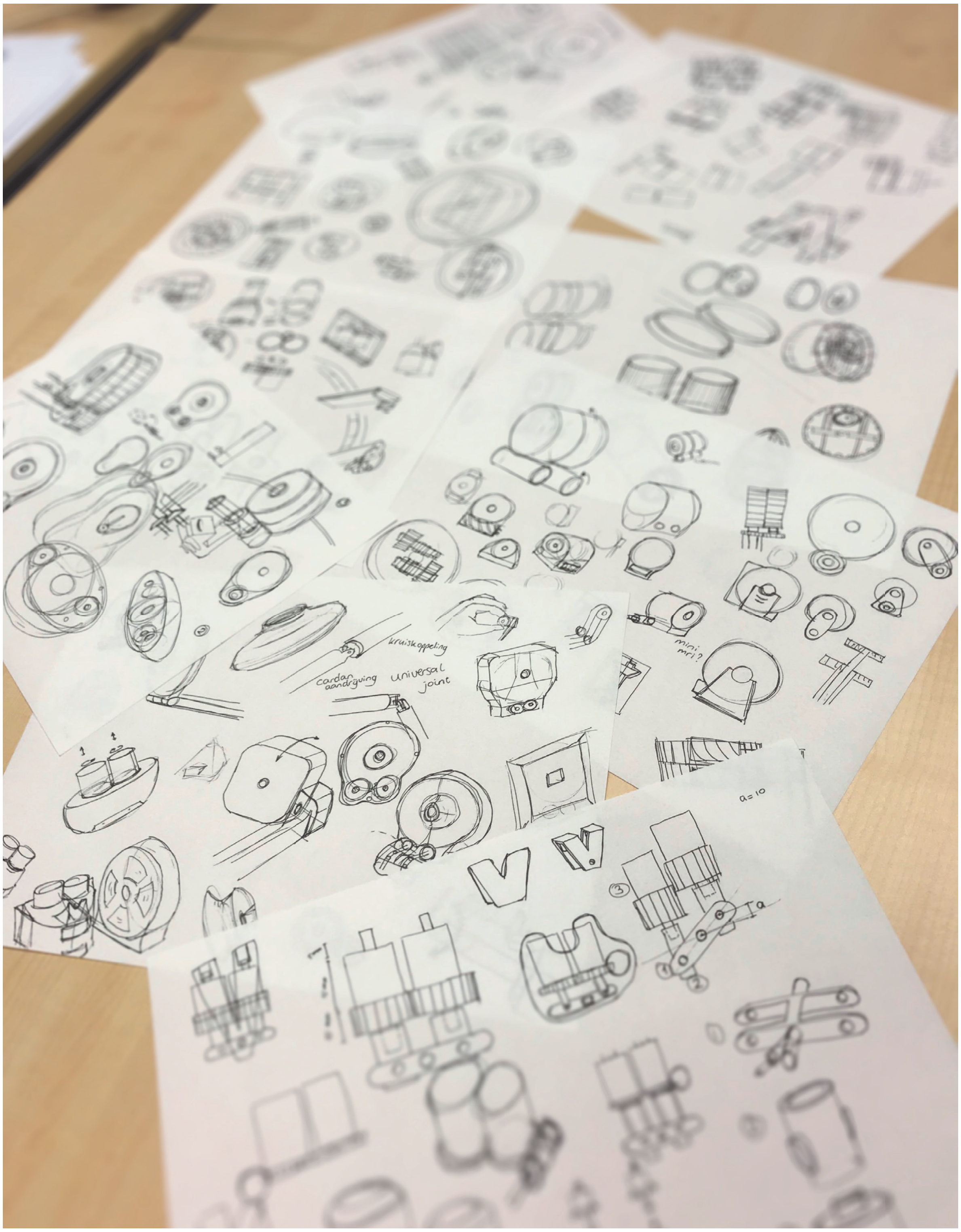


Figure 11. Representation of first ideation

3.2 Concept directions

To choose between ideas, similarities between ideas are found and could therefore be clustered. The clusters enforce ordering ideas and facilitate decision making.

The 200 ideas are divided into ideas for the driver design and ideas for the complete product. The last category of ideas is not used for the concept development, but is stored and used during the elaboration phase for the final design.

For concept development, the ideas for driver design are used. They are clustered based on the arrangement of gears and result in six clusters. They could be seen in figure 13.

Again, they can be clustered on their principle. It results in three directions for the driver (figure 12).

Direction 1 makes use of the original idea proposed by D.G.H. Bosboom. It consists of two main gears that have a set of internal gears that cause the translation. The two main gears enable the rotational movement.

Direction 2 makes use of a roll principle and is originated from Meng's bionic fingers of the literature study. In his machine designs, the principle of rolling a needle between fingers is converted to a mechanical system. The two beams move in a linear matter to roll the needle. Different from fingers, this mechanical system could also rotate around its axis. So, it creates a linear and rotational movement.

Direction 3 uses two threaded rods and has no demonstrable origin; it originated from the method 'visual thinking'. This direction makes use of the difference in speed of the two rods. When both rods rotate at a similar speed, the needle will move linearly. When there is a difference in speed of the rods, the gears rotate and create a rotational movement.

Concept direction choice

Multiple criteria have been taken into account when deciding on which concept to continue with. Those criteria are based on the kind of transmission, the fixation to the patient and corresponding sterility issues, convenience of use and level of manufacturing and costs. They are derived from the list of conditions. Decision-making methods are used like the Harris Profile and the DATUM method, but the most influential method for chosing has been experimenting. By making small models of gears, nuts and bolts, the principles are evaluated and validated .

After experimenting, it is found to eliminate direction 3 due to the complexity of the transmission.

Direction 1 and 2 have different strengths and weaknesses. Both directions could have a simple fixation to the patient, but direction 2 has a relatively complex principle and contains more parts than direction 1. On the other hand, direction 2 would be preferred by the user since the needle could be interrupted and taken out of the driver at any time during an intervention. This level of control is not possible in direction 1.

It requires another iteration of ideation to merge the benefits of both directions into the final concept.

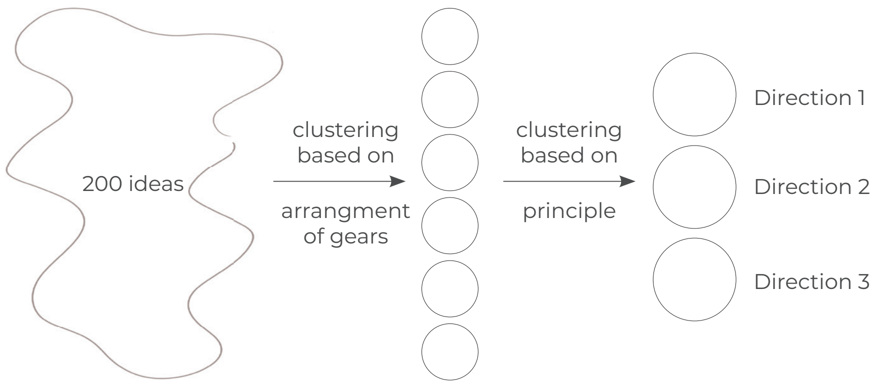


Figure 12. Process towards the three directions

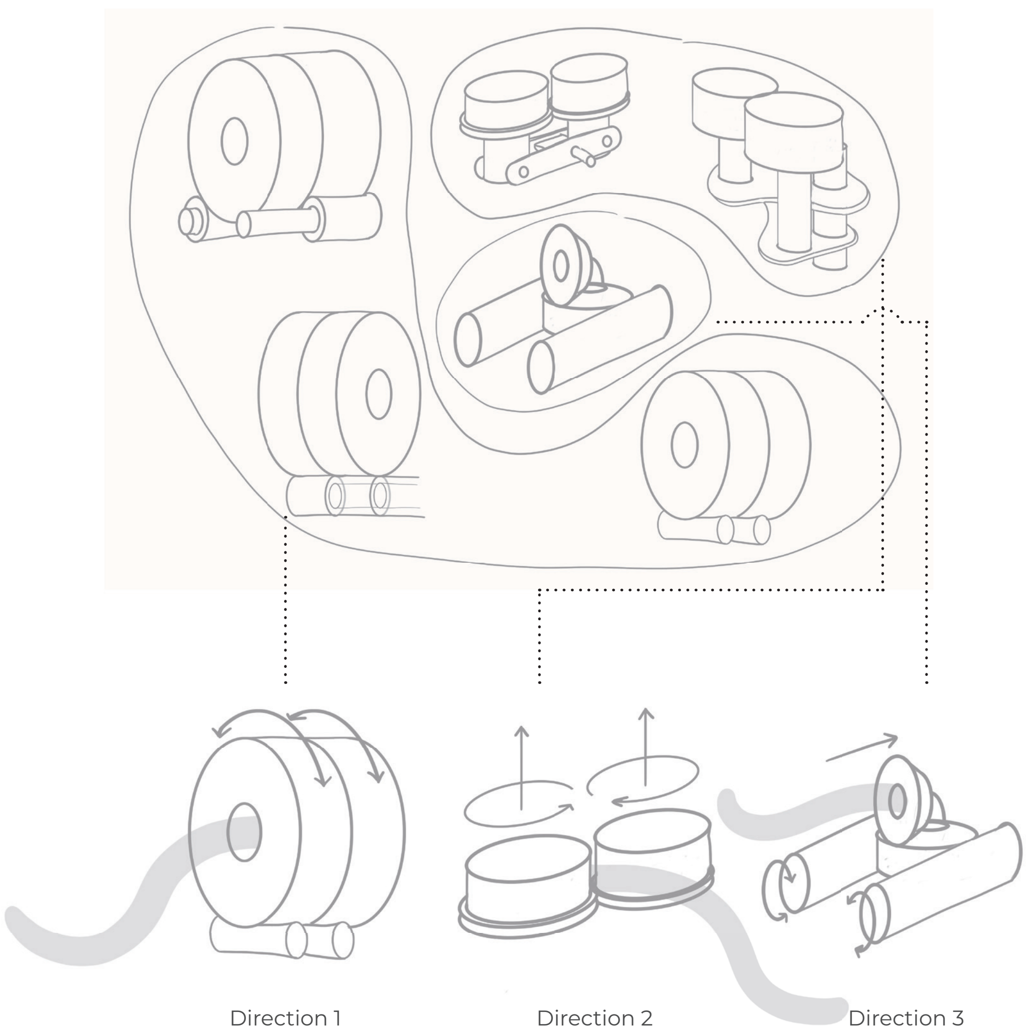


Figure 13. Process from six clusters to three directions

3.3 Concept development

The two directions are merged and developed into one concept. This section aims to show the result and check it with the project assignment.

The solution to solve the weaknesses of both directions is a driver that could be opened up. In that way, the principle of direction 1 is chosen with the extra feature for the user to take out or insert a needle at any time.

The final concept of the needle control robot consists of (1) a driver with an internal gear system and is driven by two support gears, and (2) a product design of the needle control robot that has a detachable driver and could reach every spot on the patient. The motor unit is able to 'roll back' and the arm to the driver is able to bend to follow the angle of the body.

The shape of the driver depends on the dimensions of the gears and the kind of support gears. This will be determined in the elaboration phase.

Furthermore, it is still unknown how the driver could be opened up and what restrictions are induced by this design decision.

Figure 15 shows the concept that is taken to the elaboration and embodiment phase.

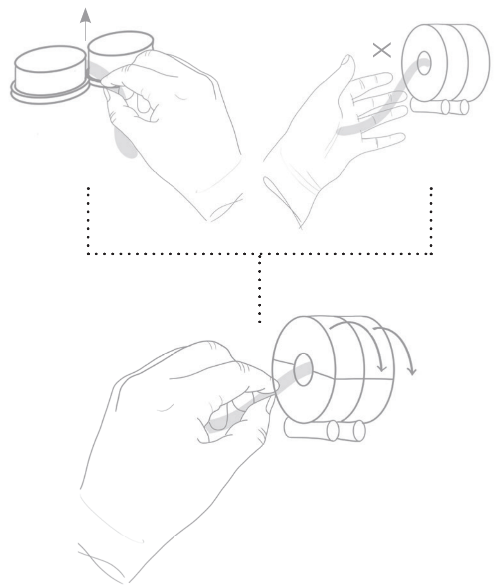
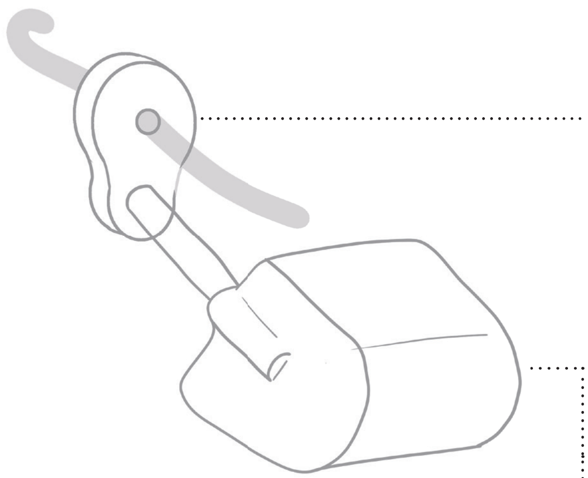


Figure 14. Solution of opening the driver



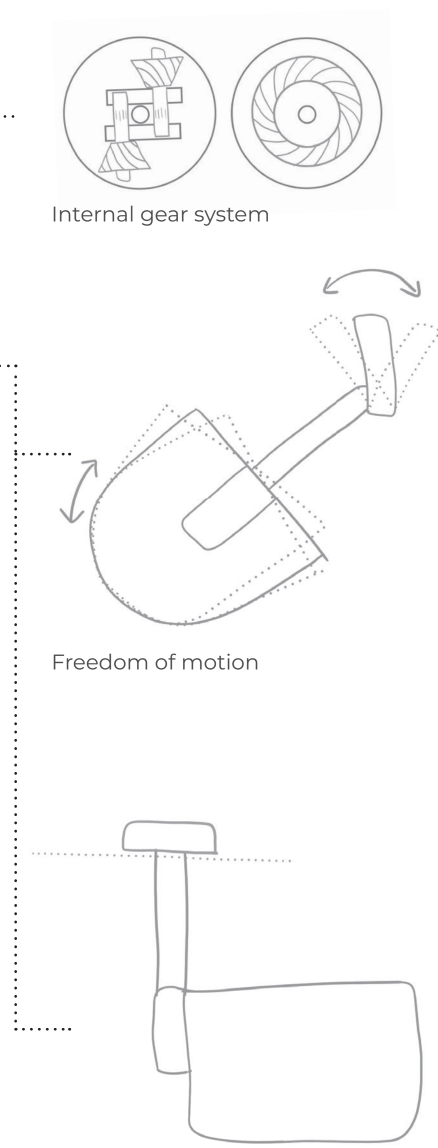
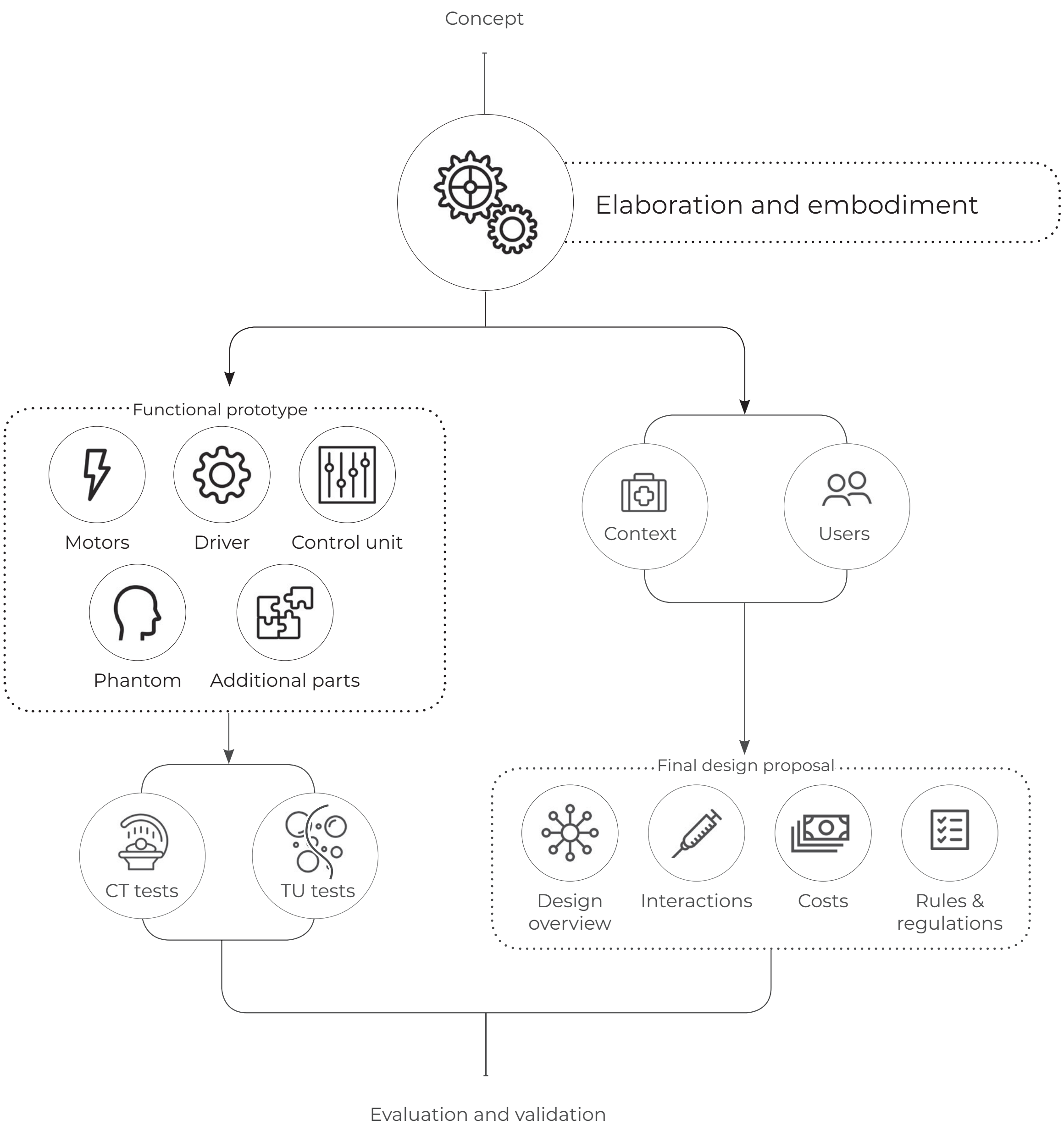


Figure 15. Concept

Complying with the conditions

When looking back on the conditions, it is seen that it satisfies most conditions. Some conditions are not covered in the concept yet, e.g. the sterility. Furthermore, the assumption is made that the motor will be small enough to fit with a patient in the MRI setting.

These notes should be taken into account when the concept is elaborated.



Concept
Elaboration and embodiment
Functional prototype
Motors
Driver
Control unit
Phantom
Additional parts
Context
Users
CT tests
TU tests
Final design proposal
Design overview
Interactions
Costs
Rules & regulations
Evaluation and validation

4 Elaboration and embodiment

The concept is developed in two parallel processes: a proof of principle and the final design proposal. The proof of principle is the embodiment of the mechanism and demonstrates the principle of the concept. The final design proposal is the elaboration of the concept. This chapter provides the results and the process towards those results.

4.1 Proof of principle

This chapter is split up by the different parts of the prototype to provide structure to the decision-making process. Per part, the iterations and decisions are shown and explained.

The proof of principle is made to test the hypothesis of a curved needle being steered towards a target. The hypothesis reads: **if the needle is pre-curved, the needle could be steered by translational and rotational movement towards a target.** In the literature chapter, the hypothesis is reviewed with the work of others and served as inspiration for new ideas. The prototype is built to show if the hypothesis also applies to the design of the driver unit.

Prototype

The prototype consists – similar to the concept – of a driver, motors and a control unit. All parts are designed and assembled in the 3D CAD program SolidWorks and from those 3D files, technical drawings and STL-files have been extracted. The prototype consists of 71 parts in total, including 34 parts designed.

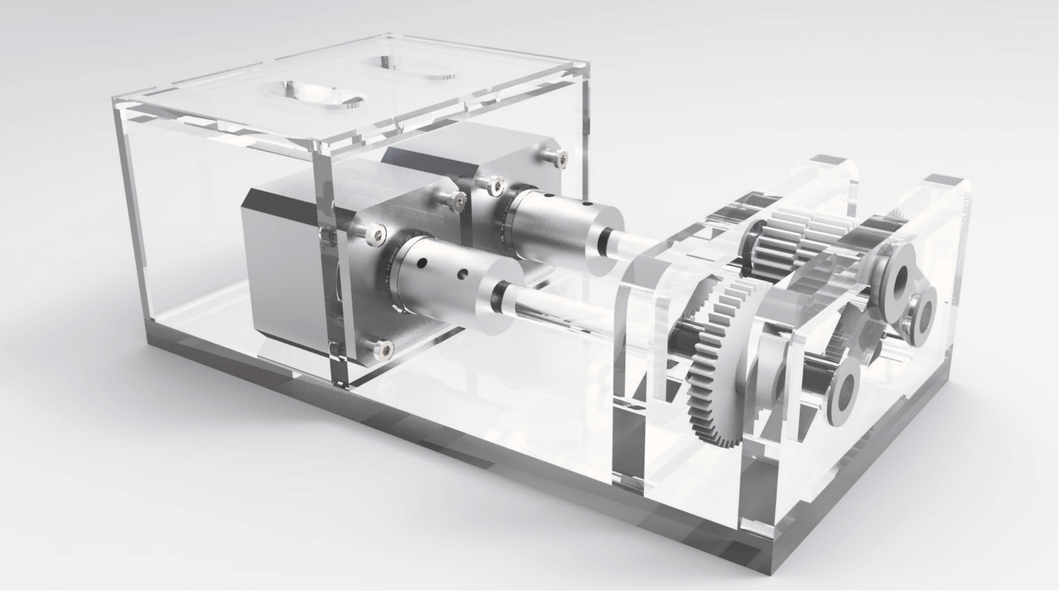


Figure 16. The motor and driver of the final prototype

Driver

The driver unit is the focus of this prototype. It is fastened in the prototype by two transparant rods and bearings, and primarily consists of main gears and their support gears. Within the main gears, a smaller system is hidden which consists of pinion gears integrated with their axes and a hold plate to keep them in place. It could be seen in figure 17 and 18.

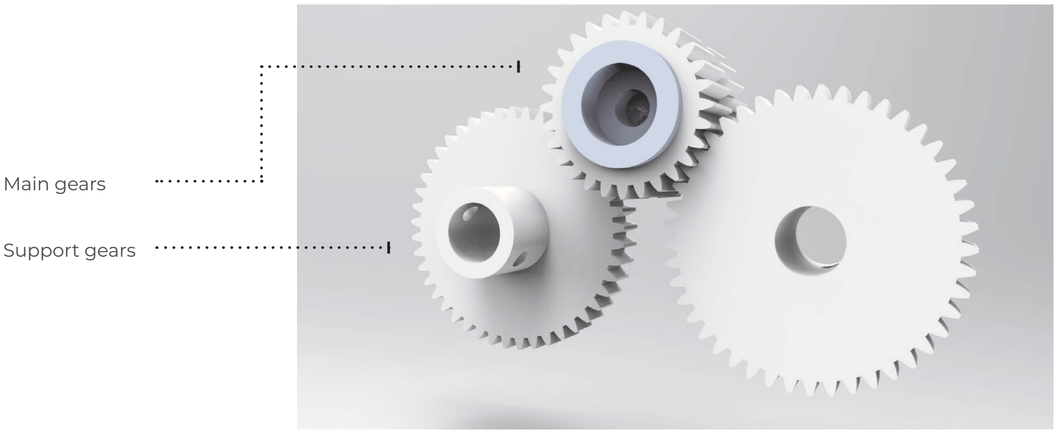


Figure 17. The driver

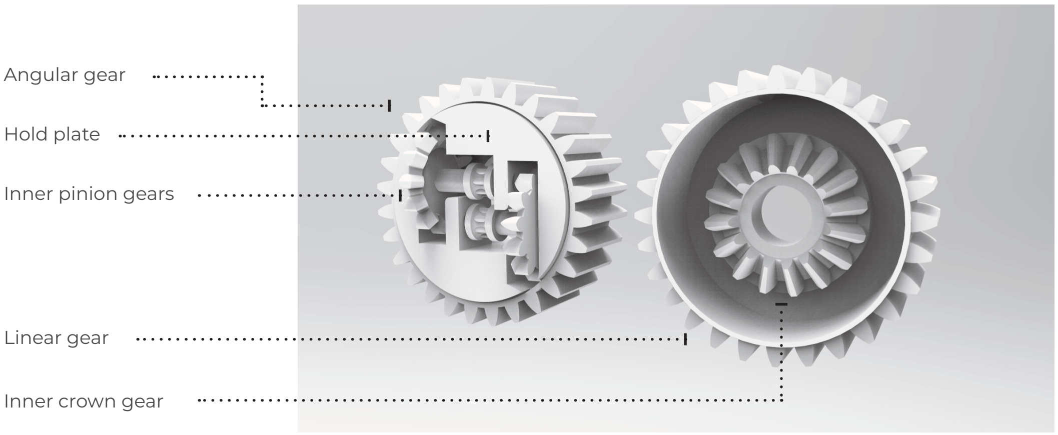


Figure 18. Opened up main gears

The transmission between the supporting gears and the main gears is relatively simple. It is a straight spur gear relation. Only the modulus of the gears matters when it comes to designing the system. The modulus is the ratio between the number of teeth and the circular pitch. In the prototype, they have a modulus of 0.8, with the supporting gears having 45 teeth and the angular/ linear gears having 28 teeth.

The inner gears, however, are much more challenging. They are based on a hypoid gear system, which means that the axes of the involving gears are not intersecting. They are only

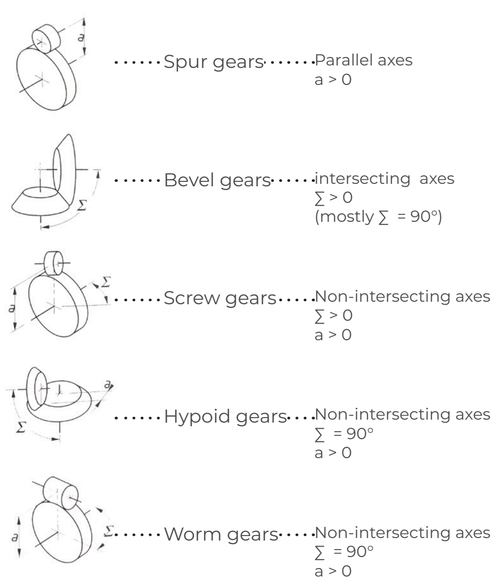


Figure 19. Different kinds of gears (Muhs et all, 2005)

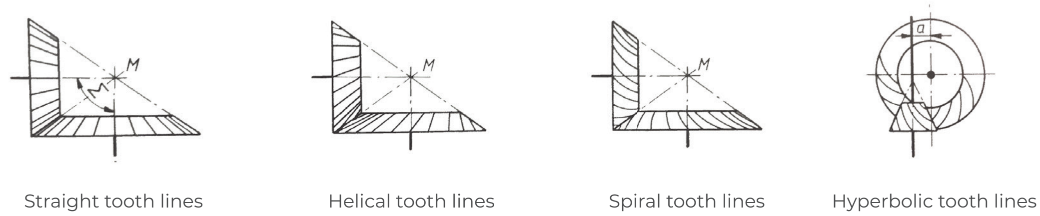


Figure 20. Hypoid gears with perpendicular axes (Muhs et all, 2005)

perpendicular to each other (see figure 19). It is a combination of a regular bevel gear and a worm gear. It consists of two small gears, called pinion gears, and one bigger gear called the crown gear. In this report, they will be referred to as pinions and crown.

The hypoid system makes the shape of the pinion teeth more complex: a hyperbolic shape is needed to obtain line contact (Muhs e.a., 2005) (figure 20). Attempts have been made to design hyperbolic teeth, but by lack of skills and time to construct this hyperbolic pinion and spiral crown, a less complex shape is chosen for prototyping. In subsection “Process” this is elaborated.

Also, the size of the driver is an issue in manufacturing. The desired diameter of the driver is +/- 20 mm, determined from the semi-flat surface of a human head. The consequence is that the gears become too small for a regular FDM 3D-printer, like an Ultimaker which has a 0,4mm nozzle. It needs to be produced by an SLA printer, which could have an accuracy of 0,01mm. The solution for this issue is that all designs are primarily printed on a 2:1 scale in an FDM printer.

Not many iterations have been conducted on the grip of the pinions on the needle, although it is a crucial part for functioning. The current grip is a cavity of 1,45mm diameter, with the needle having a diameter of 5 French (1,67mm). Furthermore, teeth are added to create grip.

Process

Four iterations in gear design are made to create a smooth-running system.

In the first iterations, no gear library is used and all parts are made manually. It has been time-consuming, but pays itself in deepening knowledge of gears and gear design. After this iteration, it is clear that the pinion and crown need hyperbolic-shaped teeth, but translating it to a CAD model is a step too far.

In the second iteration, libraries are used and a regular bevel gear is turned into a pinion (figure 21). All features are a separate part, which makes it easy to adjust and redesign, but also caused fitting issues. Again, these issues resolved in deepening knowledge about tolerances and using different production methods.

In the third iteration, a comfortable level in designing gears and using libraries is reached. The measurements of a spur gear are derived and turned into a spiral bevel pinion, which fitted on a bevel crown (figure 22). The pinion with its axis is made into one part to avoid any fitting issues. Even though this design is an improvement on the simple bevel gear from the second iteration, it does not lead to line contact between the pinion and crown. In theory, it is a better shape, but for the dimensions that these models are made in, it does not make a significant difference. So in the last iteration, a step back is made to the bevel gears (figure 23).

Still, the gears did not run smoothly. By increasing the diameter of the tunnel, a clear view is created to see the gears operating and two disturbances are found: (1) when the main gears rotate in one direction, the pinions are pressed in their place but when the main gears rotate in the other direction, the pinions are lifted and get stuck in the crown, and (2) the pinions have too much space to move in their place and could reach the top of the main gears, which results in grinding the surfaces. Both disturbances have caused the driver to lock or operate less smoothly.

Disturbance 1 is solved by adding a hold plate that keeps the gears in place. For disturbance 2, it is obvious to reduce the space of the pinions and tighten them in the housing. However, this is not desired since the pinions need to rotate without resistance. The disturbance is solved by increasing the diameter of main gears to prevent the gears from grinding.

Finally, the final design of the driver is scaled to 22mm in diameter and is printed by MTB3D on a Formlabs 3 printer (SLA). It is chosen to print in the 'tough' resin which is often used for gears. This material only comes in a blue transparent appearance (figure 24).

The result is a smooth-running system that satisfies the dimension condition of +/- 20mm.

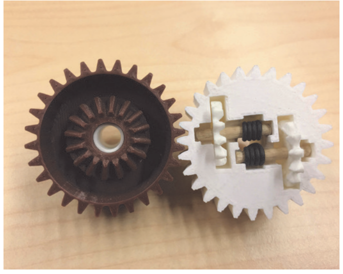


Figure 21. Model of iteration 2

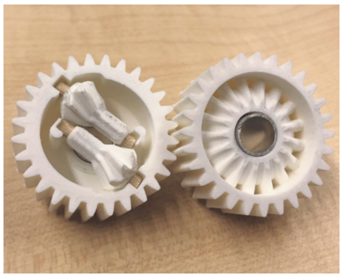


Figure 22. Model of iteration 3

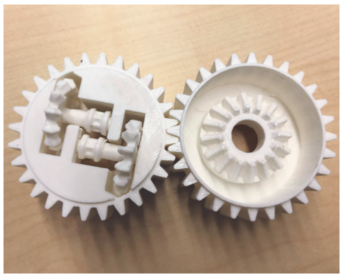


Figure 23. Model of iteration 4

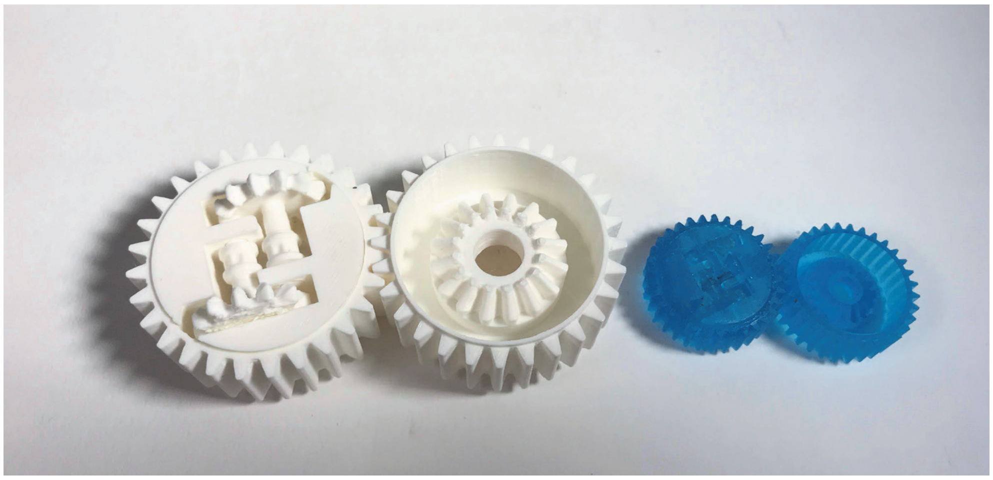


Figure 24. Model of iteration 4 after scaling

Motors

The motors used for the final design, rely on a hydraulic system. It is still a concept that is not tested yet (see appendix V), but it is based on the motor system of Soteria Medical's RCM. Since the focus is put on the driver unit, the motor unit should cause the least problems and therefore it is chosen to integrate existing motors. The consequence is that the prototype cannot be tested in the MRI since there are metal parts involved.

Still, a close resemblance to the hydraulic motors is sought when choosing the motors. To move the needle straightforward, the gears should spin continuously at a speed of max 120 RPM (2 rotations per second), according to the motor concept. A DC motor would fit this task. However, the motor should also be able to take steps, like a servomotor. However, a disadvantage of the servomotor is that they do not excel in continuous rotation, while this is highly important for needle control. A stepper motor is suitable for continuous rotation. Furthermore, stepper motors are able to make significant small and precise steps. Therefore it is chosen to continue with stepper motors.

Yet, there is a lot to choose amongst stepper motors. Normally, the 28BYJ-48 unipolar motors are chosen for prototyping. They are small, easy to use and cheap, but they also have low torque. To overcome irregularities in power transmissions, it is decided to choose a more powerful motor. This is the NEMA17, a bipolar stepper motor. The regular NEMA17 has 200 steps per rotation, but for this prototype, the most accurate version is chosen which has 400 steps per rotation. This decision is made to ensure that the steps can be made small enough.

Together with a stepper motor, a stepper driver is needed to control the motor. It is widely advised to use the Stepstick DRV8825 with the NEMA17. It is easy to use and affordable. A stepper driver enables to control the motor and to split up the steps even further, which comes in handy when making ultra-small steps. The DRV8825 makes it possible to make full steps, 1/2, 1/4, 1/8, 1/16 and even 1/32 step. This means that the motor is able to make 400*32= 12 800 steps per rotation. For the prototype, 1/8 step is small enough to control the gears within the desired range, which is minimally 0,05mm movement of the needle per step of the motor.

The motors are placed in an acrylic box and screwed to the base. The wires are extended to eight meters by soldering, to bridge the space between the scanner and the control room.

For more information on the motors and drivers, see appendix VI.

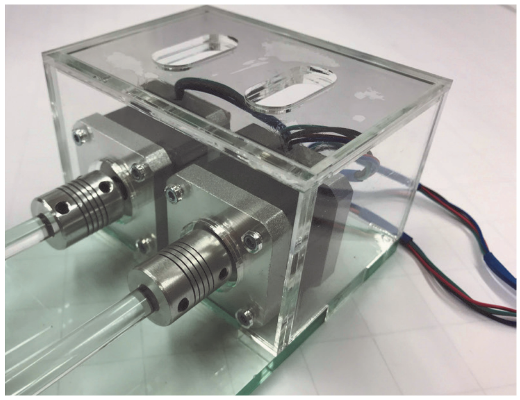


Figure 25. Motor unit

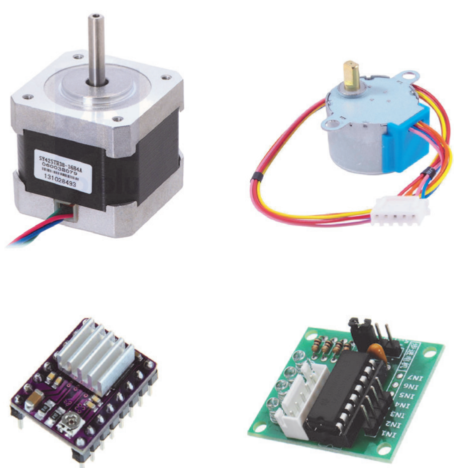


Figure 26. The motors Nema 17 and 28BYJ-48 with their stepper drivers DRV8825 and ULN2003

Control unit

The control unit makes it possible to control the gears. It consists of two knobs, one for the linear movement and one for the angular movement. Knobs could be used to rotate, but could also be used as a button. By turning and pushing the knobs, the gears are controlled. There is a manual mode, a digital mode and a driving mode. The actions of the control unit are visualized in table 1.

START			
Push	Linear knob	=	Select a mode
MANUAL MODE			
Rotate	Linear knob	=	Move motor 1 by 40 steps
Rotate	Angular knob	=	Move motor 1 and motor 2 simultaneously by 11 steps
Push	Angular knob	=	Go to driving mode, which means rotating motor 1 and 2
DRIVING MODE			
Rotate	Linear knob	=	Rotate motor 1 faster or slower than motor 2
Push	Linear or angular knob	=	Stop rotating
DIGITAL MODE			
No knobs are used. In a serial monitor, insert the path in terms of linear and angular position the needle has to follow and press enter. The motors will act according to the specified command.			

Table 1. Functions of the control unit

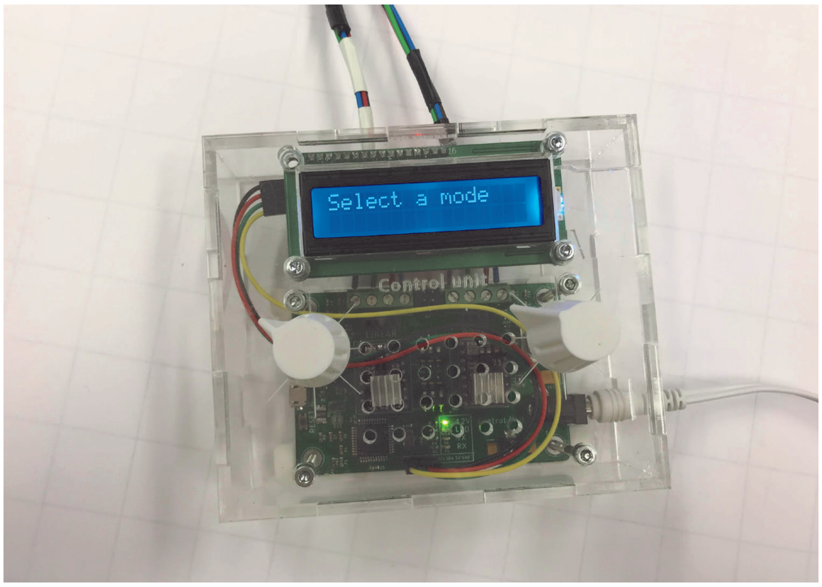


Figure 27. Control unit

The values for the number of steps and speed are derived from a ratio table including all power transmissions (appendix VII). The values are based on the user scenario and practicalities of the software. When a linear movement is desired, only the linear gear should rotate (motor 1). When the needle should rotate around its axis, the angular gear AND the linear gear should rotate simultaneously, otherwise the needle will also go forth or backwards.

One step of the linear knob is translated to 40 steps of the linear motor, which results in 0,1mm movement of the needle. This causes high accuracy and a feeling of control for the user. For the angular movement, one step of the knob is translated to 11 steps of the motors, which results in 1 degree movement.

Thus, all values in the manual mode are set for high accuracy. The values for the driving mode are also set for accuracy, but could be accumulated for bigger steps in the phantom.

The control unit runs on a uniquely designed PCB (figure 29), including a Atmel ATmega32U4, 8-bit AVR microcontroller which is known as the chip of the Arduino Leonardo. Furthermore, it contains two DRV8825's, step switches, two rotary encoders (acts like digital potmeters, a device that converts angular motion to digital output signals that also could be pushed), a connection for an LCD screen, a connection for the motors (female pin headers), a connection for the motors (screws), a power inlet 12V, a USB inlet 5V and corresponding resistors, capacitors, LEDs and built-in safety parts. The PCB is designed in the program Autodesk Eagle and made in Shenzhen, China. The parts are ordered from Farnell and personally assembled on the PCB.

Creating the control unit began with a simple setup of an arduino and potmeters. It is developed towards designing a PCB where every line of code is tested with an arduino. The overview of the taken steps are shown in Appendix VIII which also includes the code and files from Eagle.

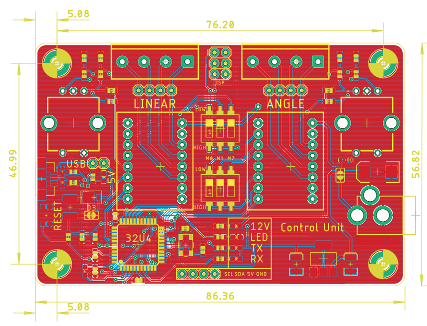


Figure 28. Dimensions of the PCB

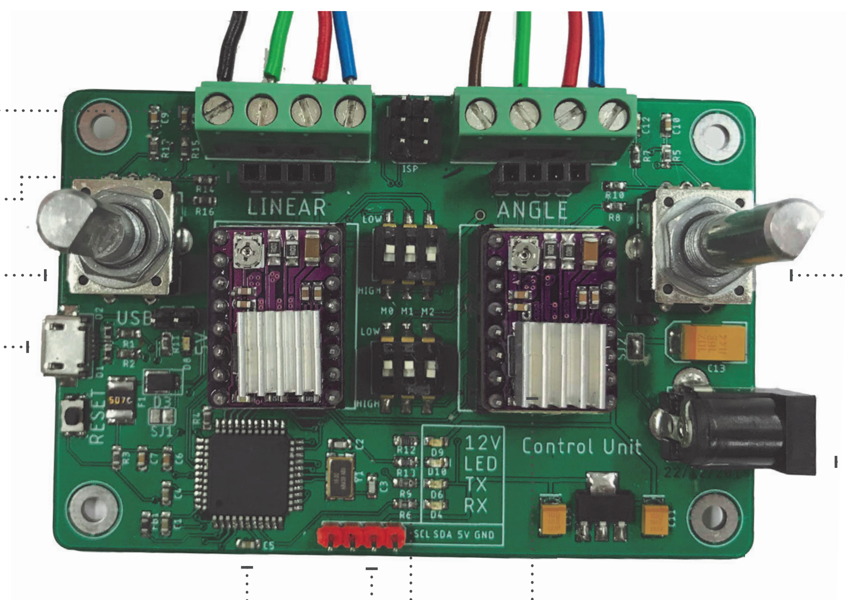


Figure 29. Final PCB with all components

Phantom

To simulate the human brain, a phantom is used which is made from candle gel (figure 30). It is comparable to ballistic gel which is used to simulate human tissue e.g. in testing protection gear. This substance must resemble human tissue closely, as the results are evaluated by the paths the needle makes in the phantom. If the phantom does not resemble human tissue well enough, the results will not lead to valid conclusions.

In many papers (Swaney et all, 2013; Scali et all, 2017; Scali et all, 2018; Burrows et all, 2017; Wedlick, Okamura, 2009; Ko et all, 2011; and probably many more) gelatin is used as a phantom for human tissue, but gelatin also causes a lot of friction for a needle since its main ingredient is water. Candle gel is more greasy and therefore resembles the human tissue better.

The visual characteristics of a candle gel phantom are similar to a gelatin phantom, but candle gel has the advantage that it does not melt at room temperature. Gelatin needs to be stored in a fridge, and within 2-3 hours it already shows signs of melting.

So, despite gelatin is widely used in most papers, candle gel is resembling human tissue better and is easier to store. Therefore, it is the best choice for this research.

Additional parts

Next to the driver, motors and control unit, the prototype consists of additional parts. The additional parts are:

- Needle
- Bearings integrated with Luer lock
- Casing of the motor/driver and control unit
- Motor coupling
- Knob design
- PCB support

The most noteworthy iterations are made for the needle and the Luer lock integration.

Two catheters that expired their sterility date have been made available for testing. They are >1 meter long, have a pre-curved tip, are hollow but still quite stiff. It is hard to squeeze and always wants to return to its initial position. To make suitable for testing, the wires are cut in lengths of 400mm.

Furthermore, a Luer lock is used in the prototype. The Luer lock is integrated with a driver bearing and serves as a connector between medical guiding tubes and the prototype. A Luer lock is a standard threaded connection that every medical attachment contains. With a Luer lock, all medical tubes, wires and needles could be fastened.

For more detail on the additional parts, see Appendix IX.

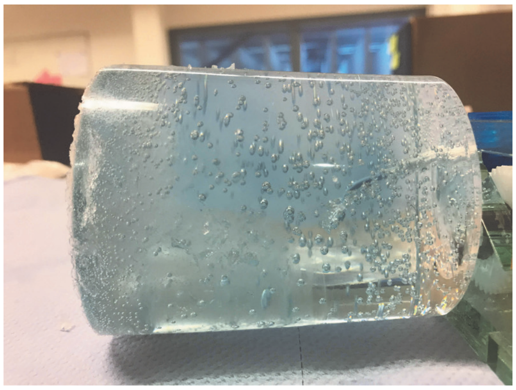


Figure 30. The phantom

Figure 31. Luer lock

The result is a finished prototype whereby the driver could be remotely controlled in a manual mode and digitally.

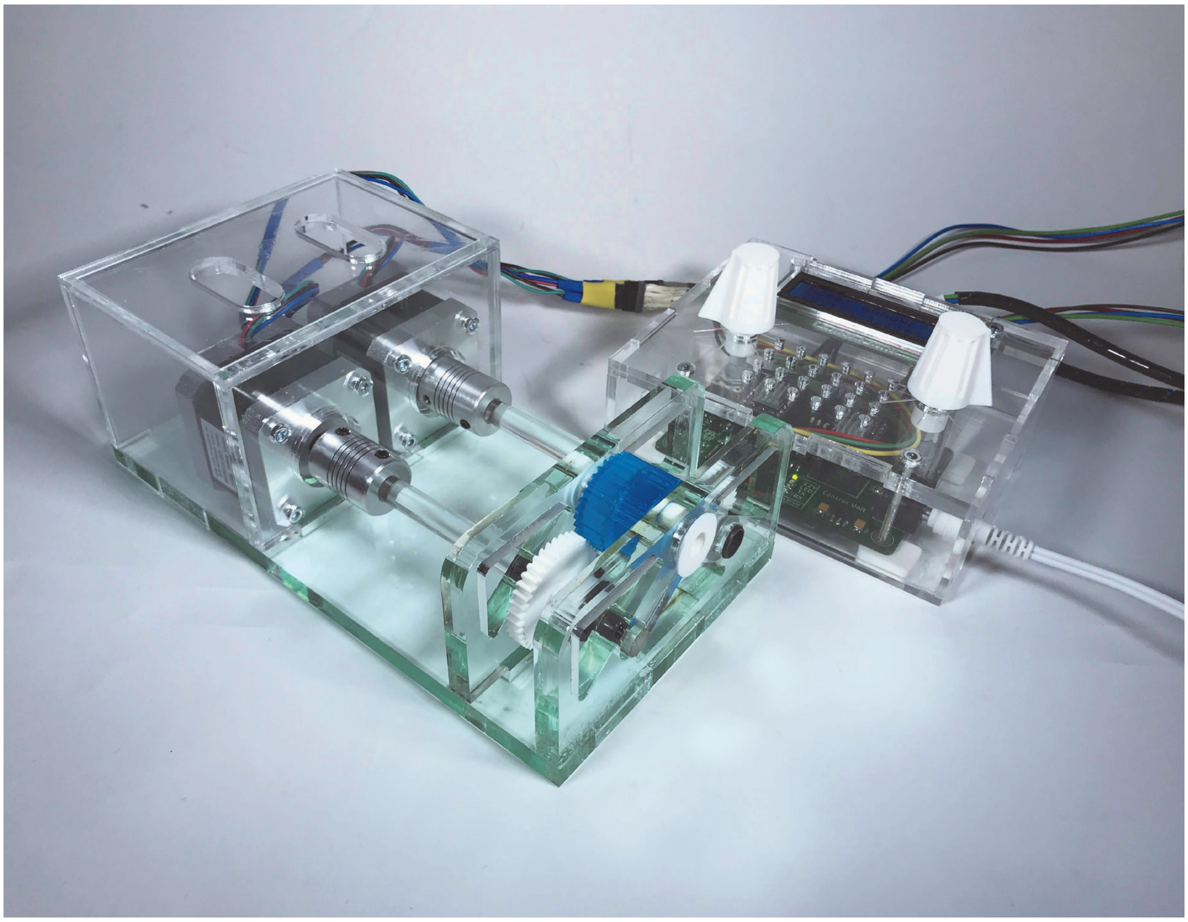


Figure 32. Final prototype

Test setup

Since metal parts are used in the prototype, the tests cannot take place in an MRI scanner. To simulate the situation in an MRI, the CT scanner is used. While MRI drives on magnetism to create images, a CT scanner uses X-ray. For the best images, the metal should not be part of the scanned area, but is able to be in the same room.

A test plan is made to conduct the research. It includes the goal of testing, the expectations, location and time, attendees, means, setup and method. The main goal of testing is to check the working principle of the gears, while being remotely controlled based on the scans. It will give insights into how well the needle could be tracked and how easy it is to control the needle on a distance.

The full test plan could be viewed in appendix X.

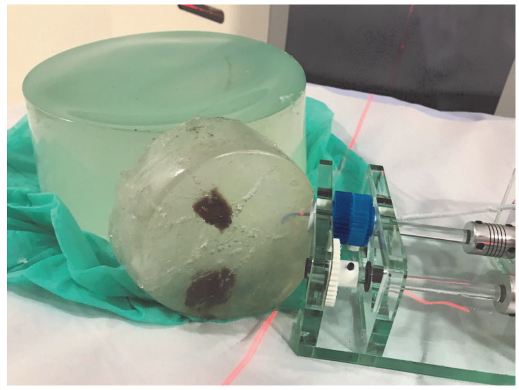


Figure 33. Finding the right plane manually

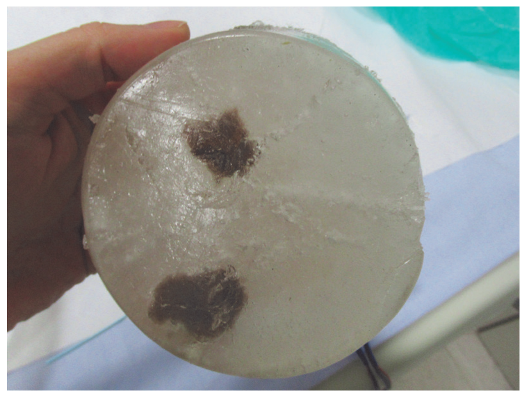


Figure 34. Phantom with traces of the needle

Test results

The result of the CT test is a continuous scan (a movie of 30 seconds) that shows the path of the needle. Unfortunately, the time frame of the continuous scan was too short for the accurate steps in linear mode and the displacement could not be tracked. But the driving mode did provide the right speed of the needle to detect motion in the scans. So the driving mode was used and that resulted in a straight path through the phantom (figure 34).

The scans show that the needle is clearly visible despite the scattering by metal parts in the scan area. However the needle is visible, it took many trials before the needle was found. The CT has fixed scan planes when a continuous scan is made, so the prototype and phantom must be moved manually to find the needle. This difficulty will not be present in MRI, since the plane is adjustable even when a continuous scan is made.

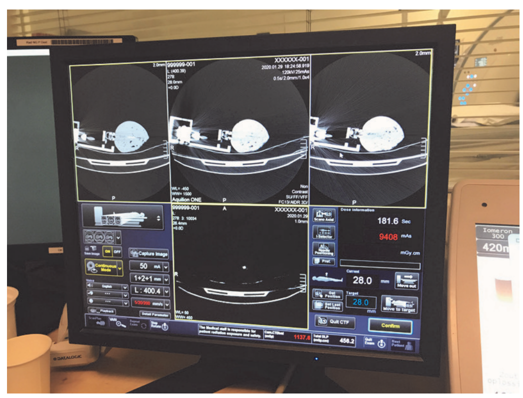


Figure 35. Scans

Furthermore, it was complicated to control the needle remotely. The lack of direct visual feedback is underestimated, but it is not inevitable. Radiologists are trained to read scans and if a scenario asks for manual input instead of the digital path, the radiologist could intervene with direct accurate steps.

So the result of the CT test is that the needle has conducted a straight path. The needle was easy to track, but hard to control by lack of direct visual feedback.

Test TU Delft

The prototype could not only make straight lines, but also a curved path. Therefore another small-scale test is executed at the TU Delft with the same setup, minus the CT scanner. The direct visual feedback made it easier to conduct this test. Also, a curved path is conducted by hand to compare the results of the prototype and eliminate the grip factor (figure 36).

The needle follows the directions of the control unit and bends as expected. A clear distinction between straight and curved paths are shown in figure 35. However, the grip is not strong enough to pursue the curved path after 50 to 60mm. The resistance of the needle in the phantom becomes too high and slips in the driver.
When the needle is controlled by hand (so without the prototype), the paths could be longer since there is no slipping. It shows the possibilities of the prototype.

Also, it is seen that the curvatures in the phantom are not identical to the curvature of the tip of the needle. This could be due to the stiffness of the needle. It indicates that this type of needle is not suitable for small curvatures.

The conclusion is that the prototype is able to steer a needle through the phantom, following a set path. Still, by hand better results are achieved. This is due to the grip that the driver has on the needle. Also, it could be possible that the needle is too stiff. In the evaluation and recommendations, the effect of the grip is elaborated. Overall, these tests could be seen as a trial for clinical studies.

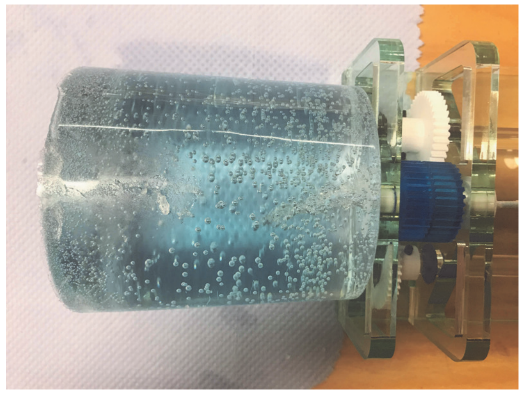


Figure 34. Top view of the driver and phantom

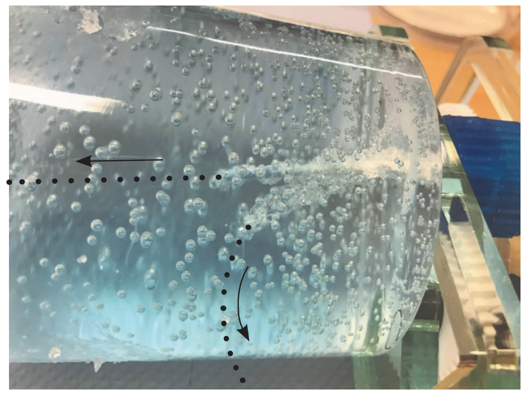


Figure 35. Straight and curved paths performed by the prototype

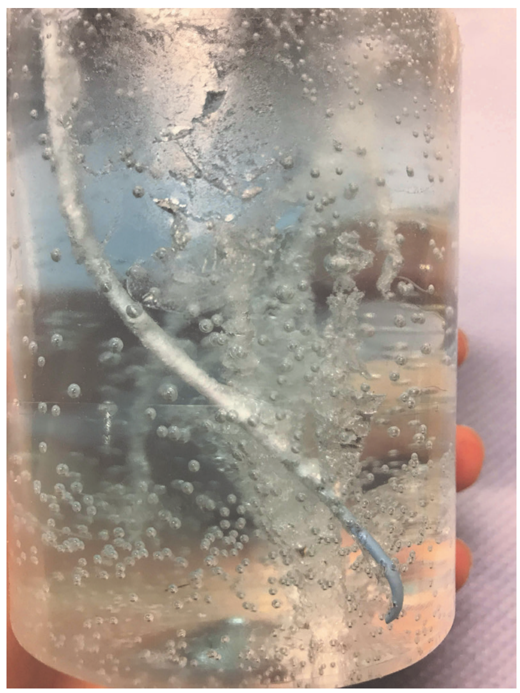
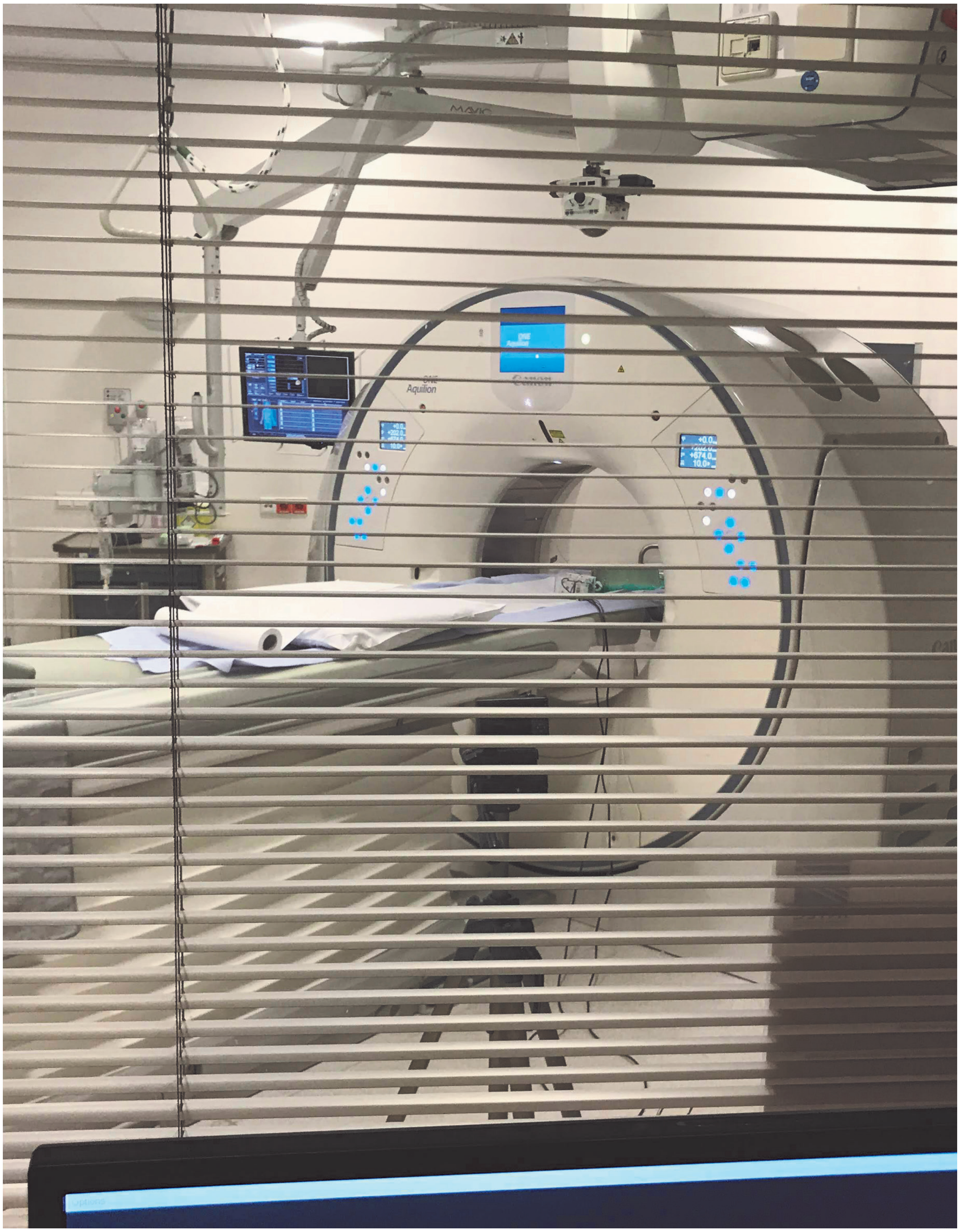


Figure 36. Paths made by hand



4.2 Final design proposal

Next to the prototype, a final design proposal is made. It contains an elaboration on the MRI-environment, the users and their interaction with the product. Furthermore, an estimation of the production and costs, and the application of rules and regulations are given. This chapter aims to communicate what the needle control device could be capable of.

Design overview

An overview of the final design proposal is presented. It includes its key features and an elaboration on the improved interventions, MRI environment, and user and interactions.

Key features

Innovative way of performing interventions

- Integration of improved imaging techniques and remote-controlled surgery
- Scan-driven execution
- Focused and aimed interventions
- Minimal internal damage
- Fast recovery

Continuous control

- Interruptions of the digital execution possible at any time
- Ability to perform the remote intervention manually
- Both remotely and non-remotely controlled actions possible

Effortless proceedings

- Effortless fixation to the MR bed
- Intuitive fastening to the patient
- Easy access to the needle
- Simple insertion and extraction of the needle

Multi-purpose

- Multiple procedures possible
- Different kinds of needles applicable

Improved interventions

The needle control device initiates an innovative way of performing interventions. Instead of taking scans and using them in surgery, the surgery takes place in the MRI. Procedures could be executed with higher accuracy than before since the distinction between tissues is visible and the expectation is that it would increase the success rate. Besides the higher accuracy, the elimination of human error could also cause an increase in success rates. When the target and the needle are identified on the scans, a path is digitally created and executed, which eliminates human error. Although the process is automated, the physician is always able to intervene.

Not only will the success rate increase, but patient satisfaction also increases since less internal damage is done. This results in shorter recovery time.

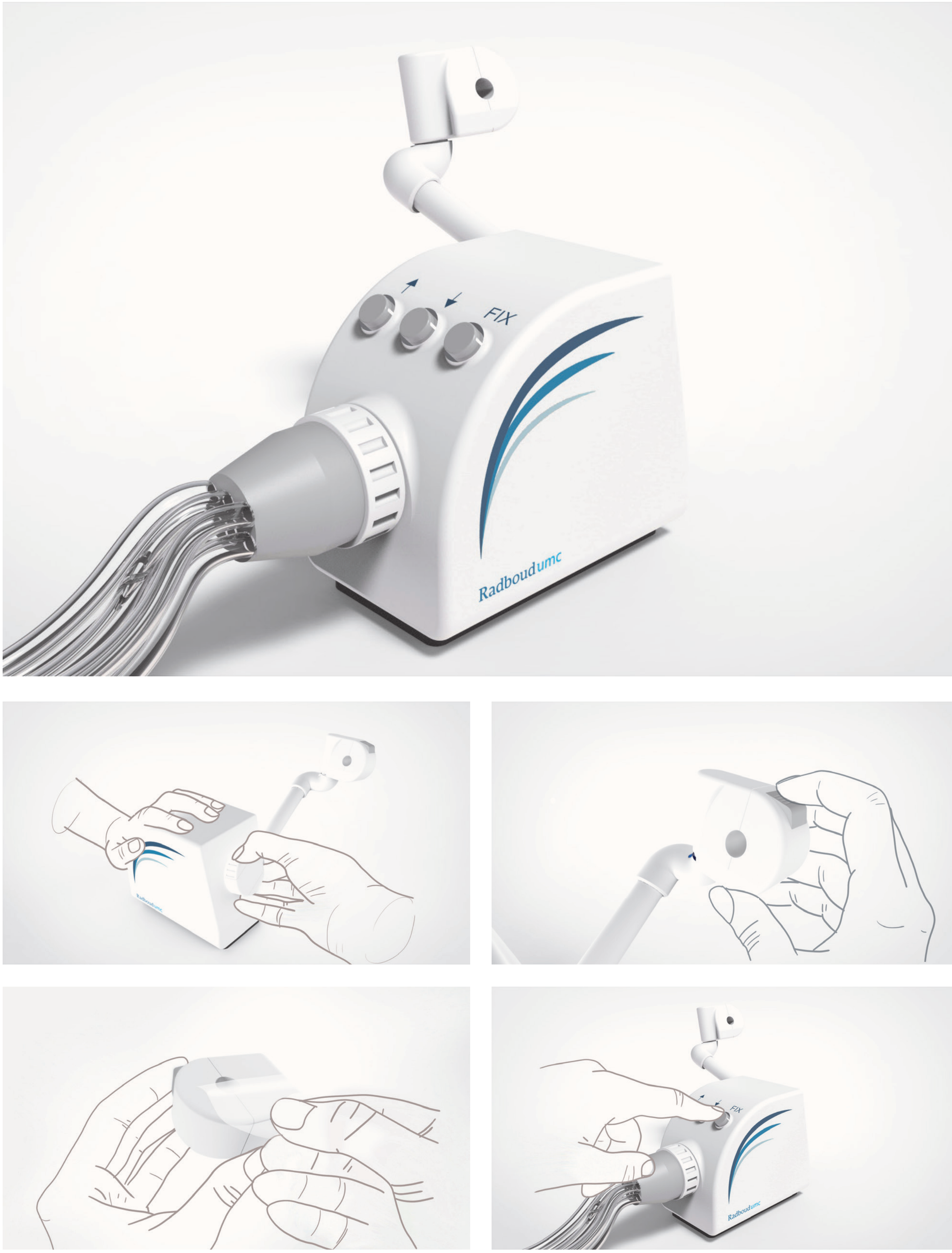


Figure 37. Final design proposal

MRI environment

The MRI environment creates dimensional and material constraints for the final design. Since the diameter of the entrance of the MRI is 700mm and the human head is 21cm (DINED, >P95, M+W), the remaining space is not big (see figure 39). Furthermore, the MRI environment does not allow ferrous metals. Nonferrous metals that do not interfere with the magnetic fields could be used in the design, but it is safer and cheaper to avoid those materials and choose for the option: plastic.

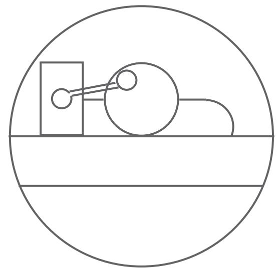


Figure 38. Space in the MRI

Together with the ideas from the ideation phase, this was the starting point for further elaboration of the concept.

The lack of space in the MRI creates a boundary and rethinking the transmissions from motor to driver is needed. This 3D problem asks for 3D solutions, so a foam models are made to create and validate ideas. Finally, the right amount of transmissions is found and a 3D-printed model is created to verify the idea. It contains of 4 DOF's. It fits the head of a patient in the MRI environment and can reach every spot. All dimensions of the model could be viewed in appendix XI.

User and interaction

There are multiple users for the needle control device. Obviously, the patient is involved since he receives the treatment of the device, but he is not a direct user. The direct users are a sterile physician and the laboratory technician (LabTech). The sterile physician assembles the devices and inserts it in the patient before he goes into the MRI. The LabTech makes the scans and determines the path that the needle should follow. He will stay in the control room and handle the device from there. More medical staff could be involved to execute supporting tasks, but have no direct role in the procedure.

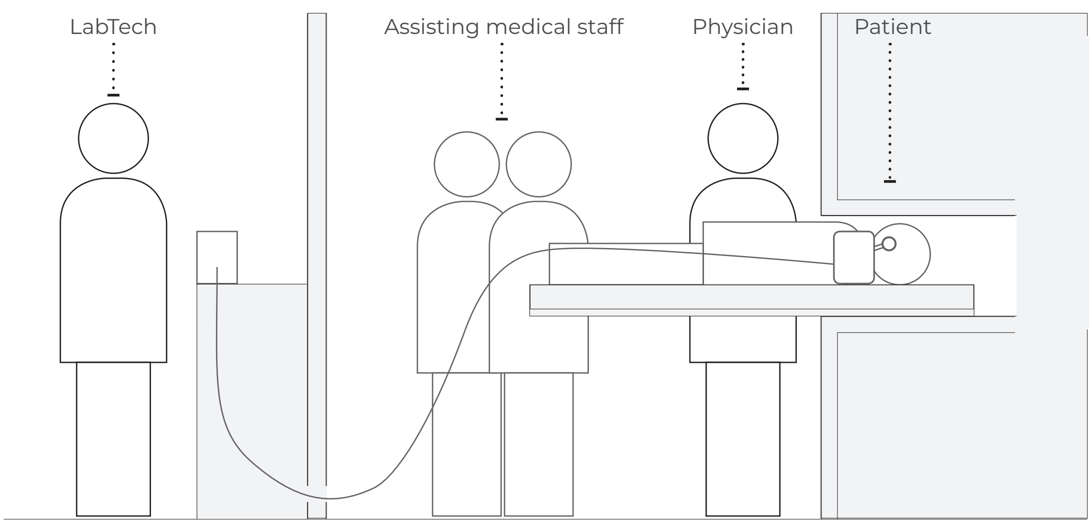


Figure 40. Users of the needle control device

The users will undertake several steps to perform an intervention with the needle control device. The interactions with the device are presented to explain all features of the needle control device.

Assembling the device

Since the device takes part in interventions, it needs to be sterile. Sterilizing the motor would be a hard task and therefore also expensive, so it is chosen to exclude the motor from the sterile area. This is done by placing a sterile barrier between the motor and the driver and covering the motor with a medical sheet, like all non-sterile devices in an operating room. A good example is the da Vinci Surgical System machine (figure 42), where all motors and arms are covered before every intervention. After the intervention, these parts do not need to be sterilized. The sterile barrier in the motor is marked by a rubber ring that keeps all dirt, fluids and human particle away.

On the other hand, the driver needs to be sterile. After an intervention, it is a hard and costly process to sterilize the driver, while the costs of the driver itself are not high. Therefore it is chosen to make the driver disposable. It is not a sustainable decision when it comes to the resources, but in this case, the extra costs for sterilizing are exceeding a sustainable decision. Furthermore, the driver unit is consists of one kind of material, so it could be researched if the driver unit is able to be recycled.

So, based on the features of the DaVinci system, the motor unit and the driver+arm are a seperate entity. Also, the driver+arm are a disposable.

Figure 41. Division between the motor unit and the driver unit

Figure 42. DaVinci Surgical System machine

Opening the driver

The driver could be opened to insert a needle. Opening the driver is not only useful for inserting the needle, but also allows the physician to interrupt at any point of the intervention and continue the procedure by hand. For other cases than brain interventions, also the initial part of an intervention could start with manual actions, subsequently followed by reaching the target by the needle control device. For example when a difficult spot in the lungs or stomach needs to be reached. The first part towards the lungs or stomach is faster and easier done by hand. The hard part of the intervention could be performed under vision of the MRI.

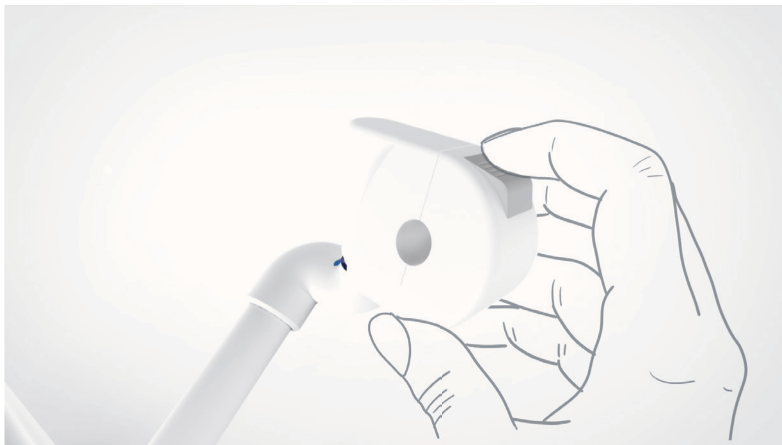


Figure 43. Opening the driver

Fixing the driver to the patient

During the tests with the functional prototype, it is experienced that the connection between the phantom and the prototype needs to be strong. Since the prototype is quite heavy and the phantom is large and has a great resistance to the table, the force was not an issue but certainly, the driver encounters a large force. For the final design, it is proposed to fix the driver to the patient with medical glue which is integrated into the driver as a sticker. The glue will counteract the resistance force on the needle in human tissue in a linear manner. It is estimated that the glue could also counteract the rotational force, but no prove or relating example is found yet. Recommendations are presented on page X.

Figure 44. Removing the sticker

Fastening the motor

To keep the driver fixed onto the patient, also its axes and motor should hardly move. The motor is fastened by drawing a vacuum. With a rubber seal on the bottom of the motor, the bottom is drawn vacuum to a plastic board and acts as a suction cup.

The use of a plastic board is originated from Soteria's RCM. They use a plastic board with a thickness of 10mm and formed into a double T shape. The board is placed underneath the legs of the patient whose weight will could the board in place. The double T shaped is used for comfort of the patella. For the needle control device, this shape is not needed since a rectangular-shaped board could be placed under the pillow of the MRI. The patient will not experience any discomfort regarding the board.

When the driver is placed onto the patient, the location of the motor will follow. By a simple push on the Fix-button, the motor will create a vacuum and is fastened to the board.

The axes from motor to driver also need to be fixed. For now, it is assumed that using friction will fasten the axes sufficiently. This principle is also used in lighting systems (consumer and medical) and screen mounting systems.

It must be said that it is an assumption that the friction is enough the encounter the force of the transmission gears. In the examples, no transmission of power needs to be conducted in the axes, so it is likely that this fixation needs to be added to the design. It will add a step of fastening the axes in the user scenario. Again, recommendations are given on page X.

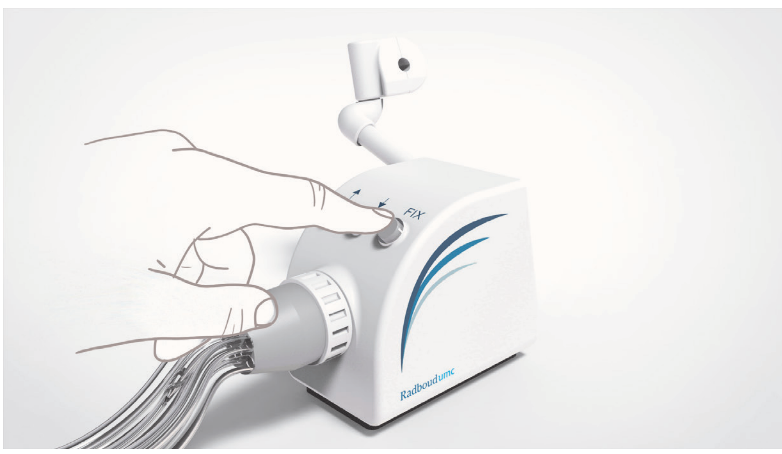


Figure 45. Fastening the motor

Figure 46. Double T shape of the RCM board and examples of lighting and screen mounting systems

Production and costs

When the needle control device is produced, the production methods do not have to be similar to the methods that are used in the prototype. However, 3D-printing could be the right choice since the production volume is low. Also, the grips could easily be adapted to a certain needle. It depends on the intervention and supplementary equipment, so the buyer could make a unique order. This flexibility in design and low volume of production make 3D-printing a great option. An additional benefit is that the start-up costs are relatively low.

Nevertheless, a substantiated decision could be made when the embodiment of the final product is made. Then, the production and costs of the motor and control unit also could be taken into account.

With the current knowledge, it is estimated that the device could be made within 3000 euros. This included the material, production and assembling costs.

Part	Costs
Driver unit	€300
Motor unit	€800
Control unit including air pressure control	€1500

Even when the costs for the software, certification and development are included, the needle control device would be sold for a relatively low price.

Rules and regulations

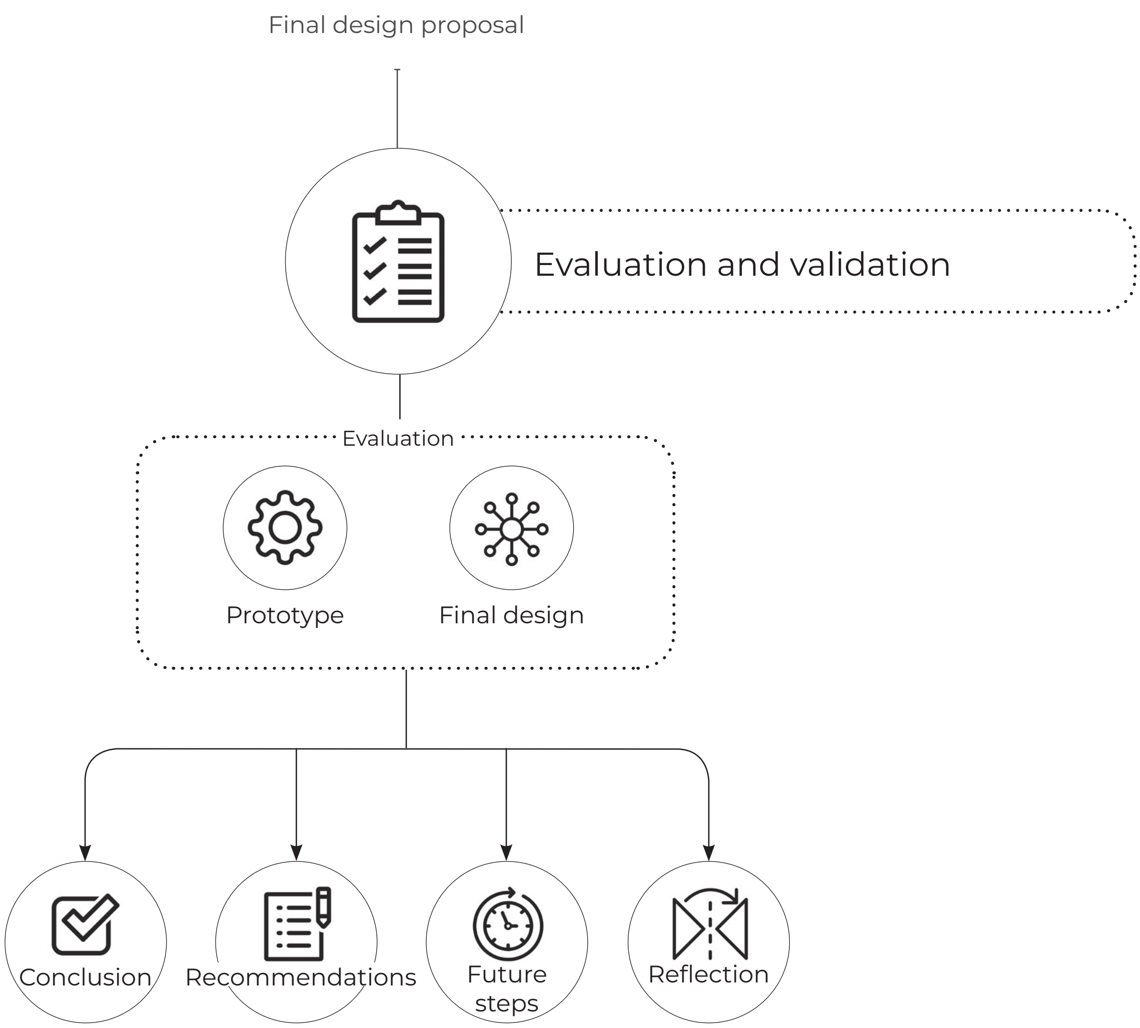
To sell the needle control device in Europe, a CE-mark is needed. A CE-mark divides its products into three classes, rising in level of risk.

The needle control device is a medical device that is activated by hydraulic pressure, intended for short time use (non-implantable) and could be in direct contact with the central nervous system. This means that it will fall in Class III according to the MD-classification flowchart and the flowchart of the NEN (NEderlandse Norm), which states:

"Surgically invasive devices intended for short-term use and are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system."

It belongs to the highest ranking in medical devices since it has the highest risks and could be life-threatening. Other examples of Class III are pacemakers and breast implants.

In appendix XII, the elaboration on rules and regulations and future steps for getting a CE-mark is stated.


Final design proposal
Evaluation and validation
Evaluation
Prototype
Final design
Conclusion
Recommendations
Future steps
Reflection

5 Evaluation and validation

An extensive evaluation of the results is presented and the validation is discussed. From the evaluation, the conclusion emerges followed by found recommendations and future steps. Furthermore, a personal evaluation is presented. This chapter intends to look back on the project and conclude if the goals, that are determined in the project brief are achieved.

5.1 Evaluation

This section provides the insights that are obtained during the tests and states which aspects could be improved. Also, an underlying pattern in iterations of the driver is found. It forms the structure for the evaluation of the driver.

One of the statements in the project brief (appendix I) is that it is expected to deliver a prototype that "works smoothly". Translated to the current knowledge, this means that the gears run without locking and skimming, have a grip on the needle and translate the motor power to control the needle. With some compromises to the original design of the prototype, this is achieved. The compromises will be discussed in the subsection Functional prototype. Furthermore, the discussion of the test is presented. The results of the tests in the CT have consequences on the final design proposal. This is discussed in subsection Final design proposal.

Functional prototype

The design of the prototype is developed in the 3D CAD program SolidWorks, whereupon the prototype is built. However the CAD model has endured several iterations, the prototype was not working initially. Many steps have been taken to go from the designed model towards a working prototype. These steps and other issues are summed here.

Driver

The different stages of iterations is shown in figure 47. It shows the flow from gear design to designing the final prototype of the driver. During this project, the most energy and time has been put in iteration 1, 2 and 3. Although main knowledge of the driver was gained during those first iterations - and so the last iterations would go faster, there was not enough time to finalize those last phases the right way. However, many ideas to conduct the last iterations have been popped up and are stated in the recommendations.

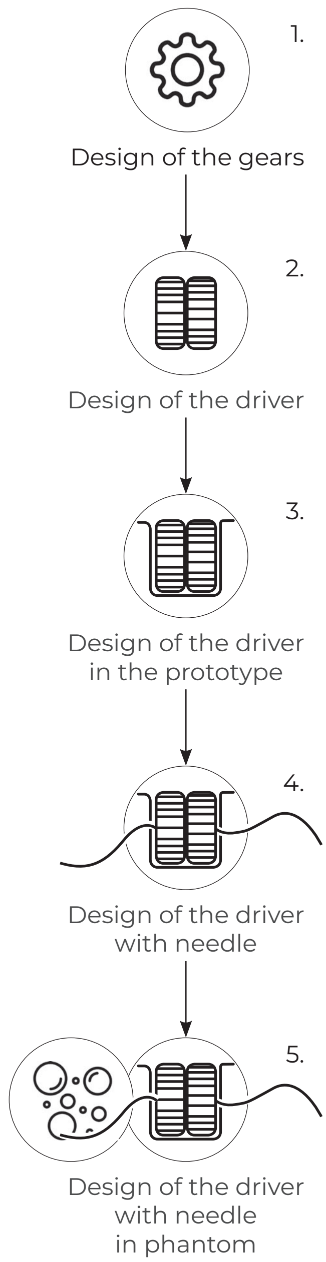


Figure 47. Five design iterations

Per iterations, an evaluation is presented.

1. Design of the gears

Bevel gears are used in the prototype instead of hyperbolic-shaped gears due to time constraints. Still, the gears are well-performing, because the offset of the inner gears is small enough to be ignored and extra lubricant is used. However, it would be better to use the hyperbolic-shaped gears in the final design of the needle control device. It will minimize the chance of locking, reduce the required power of the motor and creates less vibration and noise.

2. Design of the driver

The design of the driver consists of placement and dimensions of gears and other parts. In the first designs, it was assumed that the gears would keep each other in place by their teeth. However, this dynamic location was not suited to keep the gears in place. It provided too much freedom for skimming and locking, and therefore the inner gears need to be captured in their housing. As a result, the holding plate is added to the driver. It raises the number of parts, but is essential for the performance of the driver. The holding plate is a fast solution to an emergent problem; there was no thorough ideation conducted and potentially, a better solution could be found.

3. Design of the driver in the prototype

Until this stage, most tests have been conducted by hand to see how the gears are performing. Manually, mistakes or small hiccups could be covered easily and unconsciously. So, it was a surprise when the driver did not perform well in the prototype while it worked perfectly by hand. The source is a tolerance issue. The driver had too much freedom in the prototype to tilt, causing the driver to lock. This situation never happened by hand, since the driver parts were always kept in place. By adding tenths of millimeters, the right balance between a tight fit and enough freedom for rotation was found. It was a trial and error process, but success came fast since the right problem was identified.

4. Design of the driver with a needle

The action of inserting a needle in the driver had a great effect on the performance of the prototype. While the driver without needle was effortless to move, the driver with needle produced some friction. The inner axes were pulled apart and pushed against its housing. The extra offset also affected the operation of the gear system. Although it adds more resistance and a higher chance of locking, the motors could still handle it with their low current. The resistance is taken for granted for the prototype, but when a prototype is made with the right motors and control unit another design iteration is needed for this stage.

5. Design of the driver with a needle in a phantom

The last hurdle is the resistance of the needle in the phantom. The design iterations in this phase are focused on the grip of the inner axes on the needle. A few versions of the grips are made, but none of them resulted in more grip. In the intersection of teeth design, they all differ, but after fabrication, the difference was barely notable since the scale of the teeth is miniature.

To continue with the designed grips, alternative solutions have been tried, like lubricating the needle with soap to stimulate the passage through the phantom and modifying the driver axes with a soldering iron to create spikes for more grip. Finally, some tape made the difference: the driver got enough grip on the needle to overcome the resistance of the phantom on the needle. This could mean that the needle should have a larger diameter/the grip diameter should be smaller, or that the change in surface texture made the difference. In chapter 4.3, multiple recommendations are given to eliminate the tape.

Tests

The tests have taken place in the CT scanner instead of the MRI. The expectations were that it would be a downgrade on visibility in scans, but all other practicalities would be similar. This was however not the case. In CT, a continuous scan of 30 seconds could be made within one plane, while an MRI can film for a much longer period and in multiple planes. This would ease the finding of the needle and tracking it. During the tests, it took some trials before the needle was found.

The short period of filming in the CT also affected the path of the needle. The set values for manual motion were too accurate: the steps became too small to be visible in the 30 seconds scan, so it was chosen to only use the driving mode. In that mode, bigger steps could be made and the movement of the needle became visible. An additional benefit was the direct feedback: from the control room, there was a good sight on the needle that was sticking out of the prototype and showed if the needle was rotating or not.

Also, the right 90-degree guidewire from the initial test plan has not been included in the test setup since it would cause too much friction. Without the guidewire, the prototype needed to be turned 90 degrees and the motors came in the scan area. In the scans, it was also found that not only the motor included metal, but also the set screws in the support gears of the driver. The metal causes a lot a scatter in the scan, however the needle is still visible and trackable.

Remaining parts

Although the motor and control unit are not resembling to the final design, they are simulating the desired situation as close as possible. The stepper motors do resemble the motor concepts in torque and speed, but this could only be validated when the motor concepts are turned into actual motors. Currently, it is still a concept.

The control unit operates smoothly and effortless with the prototype. However, to control the needle control device accurately in the desired situation, more research is needed in Human Machine Interaction and user experience. For this project, the driver was the focus.

Measurable requirements for the type of needle not found during the tests or in the literature. Although there is a suspicion that the needle at the test was too stiff, no measurable requirements could be noted. This still needs to be figured out.

To conclude, a thorough exploration and elaboration of the first phases of the driver design are executed, but further elaboration on the last phases are needed to gain grip.

Final design

The final design is presented based on its interactions with the medical staff. It shows that it is designed from their point of view. However, this could also mean that certain design choices are not compatible with technical decisions. The design proposal has been a parallel process to the functional prototype, and little time has been taken to integrate the outcomes of both processes. This could result in design solutions that are not practical in realizing them. For future steps, another design iteration needs to be taken to comply the final interaction design with the functional principle.
An evaluation is conducted on the fixation, the validation and the overall design.

Fixation

It is not ensured that the device will stay still when it is operating. The motor and the driver are fixed, but transmissions arms depend on the friction of the housing. There is no guarantee that this friction is sufficient to resist the movement of the transmission axes. In the recommendations, ideas are given to solve this uncertainty.

Validation

Although it was planned to test the final design proposal with the end-user, this test is not executed. The available test time is given to the functional prototype and the driver. The validation for the design comes from the feedback of D.G.H. Bosboom. Despite his opinion is not doubted, it is colored and it would be valuable to get feedback from other intended users.

Also, user tests could confirm the dimensions of the final design and the actual use. In a schematic view, the device seems to fit in the MRI with patient, but it also depends on the handling of the medical staff. It could be possible that certain activities are more convenient when it is designed differently.

Overall design

Based on the recommendations and feedback of the users, still many aspects of the final design proposal could be changed. If the dimensions of the motor concept would be smaller, a different design could be made that fits perpendicular to the patient. The current dimensions of the motor concept do not allow the motor to be perpendicular to the patient. This also influences the number of transmissions: it may not need four rotating axes and the transmissions could be simpler.

To conclude, it could be stated that a solid start is made with the final design of the needle control device. The design is initiated from the user scenario, but still a many aspects could change when it is further elaborated.

5.2 Conclusions

The conclusion summarises the final outcomes, look back on the case study with respect to the test results and reflect on the project goals.

All in all, it can be said that a thorough exploration and elaboration of the driver have been executed and a start is made with the final design.

To excel both parts, they must be integrated whereupon a focus is needed on the embodiment of the complete product. For now, the functional prototype shows that the driver is able to execute a mapped-out path by a needle with a pre-curved tip. The final design visualizes the implementation and the intended use.

The needle control device delivers an innovative way to perform procedures with the aim to increase their success rates. It combines a relatively simple principle of mechanical parts with highly advanced imaging techniques, which can result in higher accuracy. The execution could be completely automated, but still the medical staff is in control and could interrupt at any moment. Even though it is relatively cheap, it could have a great impact on the success rate of interventions and therefore on patient satisfaction.

When looking back on the case study and the results of the test, it must be concluded that the brain tumor could not be erased by the prototype yet. The driver could steer the needle in curved, mapped-out paths, but the curves are relatively big. If the intervention has started and the tumor has a 30mm offset, it would be hard for the prototype to reach it. Nevertheless, solutions could be found to overcome this issue. Possibly, a less stiff needle could solve it.

By reflecting on the project brief, it can also be said that the goals are achieved: a device is designed that could make a needle steerable. The focus has been on prototyping and testing and also the personal learning goals are accomplished.

5.3 Recommendation

The evaluation of the prototype and the final design results in recommendations for future steps. These recommendations can be taken into account when this project proceeds.

Driver

- Replace the bevel gears by hyperbolic-shaped gears
- Perform another iteration on the hold plate
- Perform another iteration on the grip. In figure 48, some suggestions are already shown
- Perform functionality tests with multiple needles
- Perform functionality test with the intended support gears (worm gears)

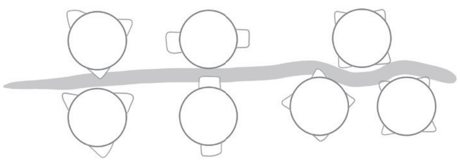


Figure 48. Suggestions for the grip

Final design

- Start with embodying the motor concepts. That will result in final dimensions for the motor unit, which has a great impact on the final design. If the length of the motor unit will be smaller than 100mm, it could be placed perpendicular to the patient and multiple power transmissions could be skipped. Then, other shapes are possible.
- Research the level of friction in the arms: is the friction sufficient to encounter the power transmissions? If not, a fastening manner should be designed.
- Research the fixation of the driver to the patient: is a sticker sufficient? Is an elastic band useful or are other fixation options needed to counteract the rotational force?
- Perform desirability tests: how is the product perceived by users? Do they want to use it?
- An extra step is needed to use the findings from the form study to the final design

Future steps

First, the complete product should be finalized. To start, the functional study and design study of this project should be integrated. This will take some more iterations for the final design. Meanwhile, the development of the motor concept could start.

The device should be made into a minimum viable product that could be presented to the market and receive its CE approval. Possibly, another case study is chosen that does not interfere with the cardiac and central nervous system to ease the certification process. This could influence the final design.

When the minimum viable product is made, the development of the needle control device will continue to include all intended functionalities and could be used in multiple kinds of interventions.

5.4 Personal evaluation

Five months ago I started with a project brief where I had to fill in my personal learning goals. These goals were mainly determined by the course Advanced Embodiment Design, where I did not learn what I hoped for. So the graduation project is my second chance. The learning goals in the project brief stated:

- Focus on prototyping and testing
- Getting acquainted with technical-medical subjects
- Get to know the hospital/company working environment

Focussing on prototyping and testing definitely worked out as I hoped for. I started testing with gelatin already in September and could not wait with creating new gears. I am also pleased with the other two learning goals. I dove into a subject that I am intrinsically motivated for and got to know the environment of the Radboudumc as well as Soteria Medical in Arnhem.

I learned a lot about gears, tolerances, materials and 3D print options, but also certain aspects on project and personal level. This point are summarized in the following lists:

Keep doing on project level:

- Prototype from the beginning. It does not only accelerate the ideation and decision-making process, but also keeps me motivated and focussed.
- Performing extra analysis and allowing yourself to reconsider or expand the analysis when needed
- Prioritize your work and keep to the schedule. My notebook is full of TODO lists and especially revised ones.

Do differently on project level:

- First, work with libraries or other things that already exist to get acquainted with the subject.
- Check regularly your plan with the ones who give feedback, even when a plan is not completely worked out yet. I did not do this and it hold me back from getting in contact with my supervisors. After the midterm, I realized that every moment of feedback is valuable and not everything needs to be worked out to present it.
- Take time to 'zoom out'. During the project, I reflected on my process every week and planned all activities for the coming week, but I found it difficult to zoom out for more than two weeks. I did not place myself in the time span of five months, because I thought that was too vague. But now I see that it could have helped me to structurize certain processes and maybe end up with a more integrated result for the final design.

Lessons learned on personal level:

- Prioritizing work and personal needs, which could mean that you have to stop what you want to do
- Being patient in prototyping. Making things take time
- Flexibility in self-made planning: I tend to get frustrated when I misjudge myself
- Delegating or skipping certain tasks: I do not have the skill for everything, and it is okay to ask someone for help

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