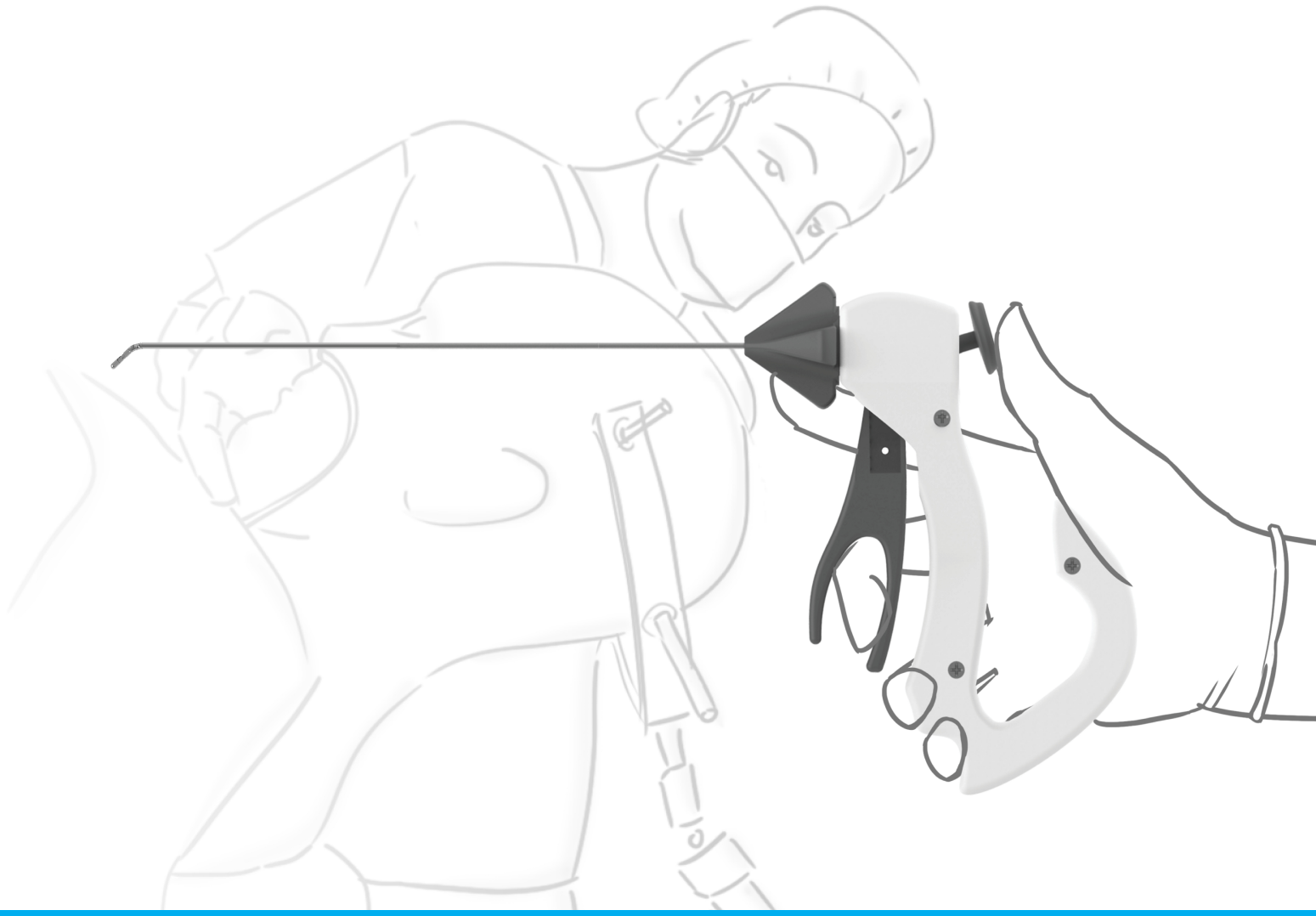

Steerable neuroendoscopic biopsy forceps

expanding the reach

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TU Delft

Steerable Neuroendoscopic Biopsy Forceps

expanding the reach

by

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Preface

This article presents the instrument that I have developed for the obtaining of my individual double degree in Integrated Product Design and Biomedical Engineering.

During this project I went through the full product design engineering cycle of performing several levels of research, ideating, prototyping, and evaluating, in order to prepare a set of recommendations for further developement of the next full prototype. To go from theory to a fully functional prototype that could be tested with the end-user was a rewarding experience, making me so enthusiastic for the future.

The project at DEAM has been such an ambiguous experience, where on the one hand I have gained a lot of confidence working in a professional environment, where I have had a taste of what it is like to work for a company, instead of for the university or an external client. However, I cannot ignore the fact that on the other hand, the whole project was tainted by the Covid-19 pandemic, and almost all of my work on it was done from my bedroom. This knocked down some of the aforementioned confidence. Nevertheless, I am proud of what I have accomplished and I hope one day parts of my design will make it to the OR, where it will improve patients' lives, patients that before could not be helped.

I want to thank all the members of my supervisory board; Jenny Dankelman, Helen Yuan, Johan Molenbroek and Wimold Peters. As a steady whole, completing each other's expertise, and individually. Jenny for the guidance on what is important to become a biomedical engineer, but also for helping me not to worry too much and to see the important things. Helen for always being there to answer my questions on literature as well as the practical matters. I want to thank Johan for being the peaceful and knowledgeable supervisor he is, never short of a relevant anecdote or applicable scientific source. I want to thank Wimold for taking me so seriously, for making me feel relevant in the world of medical device design and for offering me so much professional knowledge.

A special thanks goes out to prof. dr. Eelco Hoving, who was my connection to the clinical world. For patiently enlightening me on the practices of neurosurgery and being so clear in what he as a user needs from a surgical instrument. Although not officially part of my supervisory board, Jules Scheltes, has given me the answers to my questions concerning the mechanism design, and helped me make decisions when I was doubtful.

All other colleagues at DEAM I want to thank for being super involved and always prepared to help.

People close to me have helped me get through the process of graduating from my masters, for which I cannot thank them enough. Mom, dad, Roza, Veerle, Jeanine, Tiara, Xiao, Ilja and everyone else, thanks for being there.

M. M. Weber
Delft, October 2020

Abstract

Objective: To develop a steerable neuroendoscopic instrument (SNI) based on user requirements found by several means of user research, and to evaluate this instrument on usability and safety. Only 5% of the potential intraventricular neuroendoscopy (INE) cases are currently treated with endoscopy. For the other 95%, an endoscopic approach is impossible, due to the risk of damaging the surrounding tissue by movement of the endoscopic system, needed to reach the affected areas inside the ventricles. A hand-held SNI is theorised to overcome these problems. **Methods:** A human-centered design (HCD) approach was taken to come to engineering solutions. Expert interviews, surveys and secondary research were performed to acquire the design input. Intermediary prototypes were developed and tested. For the final experiment, 10 participants, of which one neurosurgeon, performed a task in a box trainer. The endoscope was equipped with markers, used to evaluate the movement of the endoscope during the test by means of video analysis, comparing a rigid instrument and the new prototype in a two-tailed paired T-test. Usability was measured through a questionnaire. The spans between digit 1-2, 2-5 and 1-5 of the dominant hand of the participants was measured. **Results:** A biopsy forceps with a shaft length of 290mm, with a laser-cut articulating portion of 14mm and maximum bending of 40° was developed. Handle dimensions were based on a grip between the distal phalanges and the thenar area of the palm of 10th percentile hand measurements to enforce a stable grip. Significantly less non-angular movement than in the old instrument ($p=0.009$) was observed. Angular movement reduction was significant in one direction ($p=0.032$) but not in both ($p=0.063$). The handle prototype is slightly too large. The forces on the controls were comfortable. No relationship was detected between the finger span measurements and the usability score per participant. **Conclusion:** The prototype consists of a handle design based on human factor guidelines and multiple user evaluations, and an articulate tip based on DEAM's technology, now with dimensions optimised for INE biopsy and ETV. Safety is improved by significantly limiting movement in the system during use.

Abbreviations

Endoscopic third ventriculotomy - ETV, Foramen of Monro - FoM, Intraventricular neuroendoscopy - INE, steerable neuroendoscopic instrument - SNI, Human Centered Design - HCD, User requirement - UR, Product specification - PS

Introduction

In 2019, over 11 million neurosurgical procedures were performed, of which less than 1% were endoscopic procedures, so <110 thousand [7, 9]. That is 5% of the *potential* endoscopy cases.

Neuroendoscopic procedures are infrequent because the surgical equipment is not optimised [9, 13, 23]. Literature confirms that there is a need for innovation in the neuroendoscopic equipment of today in order to help a greater number of patients [23].

Intraventricular neuroendoscopy (INE) is a relatively new way to perform brain surgery, endoscopes for neurosurgical application only became fully developed around the 1980's [17, 25]. The benefits of the endoscopic approach over other techniques are the ability to reach places deep inside the brain (where there is not enough light for microsurgery), through narrow surgical corridors and ensuring minimal damage [3].
Addtionally, IVE shortens the recovery time and hospital stay for the patients [14]. Roughly all indications for IVE are cerebrospinal fluid pathway (CSF) obstruction, caused by cysts, tumors stenosis or congenital defects [3, 24].

Some areas in the ventricles are too difficult to reach with a rigid instrument without damaging the healthy brain tissue by excessive movement of the endoscopic system. Cinalli et al. state that the main limitation of the endoscopic technique is the restricted angle of introduction of the instrument, which is coaxial with the endoscopic system. In some cases, multiple burr holes have to be placed to be able to reach the multiple target areas inside the ventricles [4]. Solving these problems could potentially increase the current 110 thousand worldwide neuroendoscopic cases to over 2 million cases, making sure many more patients can benefit from the advantages of the endoscopic approach.

This article presents the design and evaluation of a steerable neuroendocopic instrument (SNI). The goal of the design is to limit the amount of movement of the neuroendoscopic system needed to reach the targeted areas inside the ventricle (specifically during ETV/biopsy combinations), by introducing flexibility at the distal end of the instrument. This would make the procedure safer and arguably more widely applicable.

The secondary goal is to design an instrument that is in line with human factors- and ergonomics standards. As part of the study, thorough user research is used to find the user requirements (URs) to the new design, by identifying the technical, ergonomic and other occupational challenges neurosurgeons have to deal with. The engineering challenge is to translate the user requirements to quantifiable product specifications (PSs) and finally to evaluate the design on these URs and PSs.

The design of such an instrument was commissioned by prof. dr. E. Hoving, together with steerable surgical device company DEAM.

1 Methods

1.1 Overall Approach

The overall design method in this study was human-centered design (HCD), as defined by the ISO 9241-210 standard: an approach to design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors and ergonomics and usability knowledge and techniques [15]. This approach yields "a number of benefits, including improved productivity, enhanced user well-being, avoidance of stress, increased accessibility and reduced risk of harm". The first step to HCD is to research the needs of the intended user, both to find requirements to the performance of the articulate tip and to the ergonomics of the handle. Prototypes in several media (digital, paper, clay & 3D prints) were created, first of the shaft and later of the handle. Every prototype was created in order to test a specific aspect of the concept. Feedback on prototypes was thoroughly analysed and integrated in the next prototype. E.g. feedback on the dimensions of current non-articulating neuroendoscopic instruments was acquired, yielding there are no ergonomics problems and related RSI-like complaints in the users. Finally, a fully functional prototype was created, by combining the knowledge gained from user research with engineering decisions and evaluated.

Figure 14 gives an overview of the process specific to this study.

1.2 Finding the User Requirements

Roughly four studies were executed to find the user requirements to the handle and articulate tip; 1) the main interview with assignor and KOL prof. dr. Hoving, 2) a survey spread among multiple senior neurosurgeons who perform or have performed neuroendoscopy on a regular basis, 3) a follow-up survey with three of the previous survey's respondents and 4) the use of digital models to find the effects of the design variables. The interview was a was hypothesis-based, guided interview, using PowerPoint slides with sensitising quotes, questions and images. It was hypothesised that the SNI would be most beneficial in a scenario where

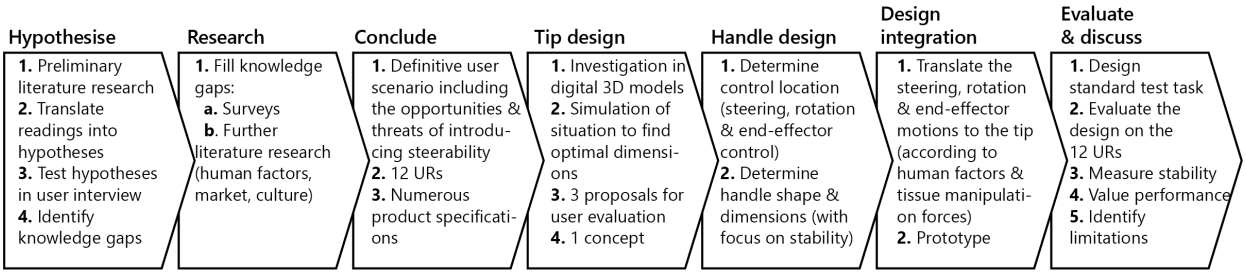

Figure 1: Overview of product design engineering process

the instrument is used to perform a procedure in the third ventricle, where the main challenge is to reach the third ventricle floor without damaging surrounding tissue, since the endoscopic system is used freehand and thus difficult to stabilise. The struggles with current instruments, and the opportunities and threats of introducing steerability were identified.

Following this exploratory interview, a survey was conducted. It was piloted with dr. Hoving. Eight respondents were identified through three channels; the Máxima Centre, ResearchGate and correspondence with Kyle Eastwood, the author of the only other study on the development of an articulating neuroendoscopic instrument [11]. All eight respondents were senior neurosurgeons, performing or having performed multiple endoscopic procedures a year. The survey consisted of 17 questions, in the categories “background information”, “technical” and “ergonomics”. Only the latter two are presented in this work. Some were open questions, in which case the answers were matched to appropriate categories afterwards. In some cases it was possible give multiple answers.

A second survey was performed to follow up on some of the findings from the first, with three of the previous participants, all neurosurgeons at the Máxima Centre. This survey consisted of a presentation of the results from the previous survey, to give the respondents the opportunity to re-evaluate the results. All questions were open and the respondents were invited to respond with in-depth information. Illustrations were used to communicate the technical aspects.

To define requirements concerning the effect of the length of the articulate tip on the reach inside the third ventricle and ultimately find the optimal dimensions, analytical calculations were performed in Matlab (see Appendix 3). The model was a simplified 2D representation of the articulating shaft, using nested loops where the insertion angle of the endoscope (B_0=15, -10° and +40°), the length of the articulate tip, the maximum bending angle (40, 50 or 80°) and the tumor location along the x-axis (-10 to +35mm) could be varied (see Figure 13) [8, 12].

The user requirements can be translated into necessary characteristics of the product. That means that one user requirement can result in multiple such characteristics. These characteristics, or product specifications, all correspond to an acceptance criterion and rationale as to why the product specification is important.

1.3 Evaluation methods

Intermediary prototype evaluations

Each prototype generation was tested with the expert user prof. dr. Hoving. The first generation of handle prototypes, developed to find the user preference in terms of handle shape and control location on that handle, was evaluated just by feeling and discussing freely. Five prototypes were developed, executed in clay.

The next five handle prototypes were developed based on the principle of enforcing a stable grip, as well as to evaluate the joystick’s appropriate dimensions, its socket’s appropriate shape and to find the user’s preference in trigger shape and location. These handle prototypes were 3D printed after 3D scanned foam models. This generation was tested in a test set-up consisting of a dummy head with a brain model and an endoscope (see Figure 2). A questionnaire was used to evaluate comfort (6 questions) and stability (5 questions) of the handle. Open and multiple choice questions were used and every all 5 concepts were evaluated by the expert user.

Final prototype experiment

To test the final prototype, a comparative test was designed where both the *stability of the instrument and reach of the tip*, as well as the *usability* (intuitiveness, physical ergonomics, overall comfort, performance in the context) were tested. Ten participants (1 expert and 9 other) carried out a standardised task with both the new prototype and the current rigid instrument. For this experiment, an especially designed box trainer was used,

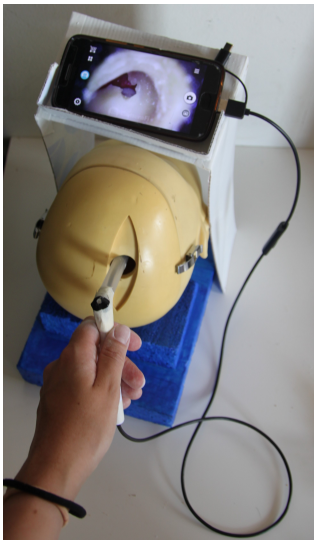

Figure 2: Test set-up for 2nd generation handle evaluation

resembling the third ventricle. The task emulates the procedure the instrument was designed for: ETV/biopsy combination. ETV is performed at the anterior floor of the third ventricle (A in Figure 4 and 5) and the biopsy is usually carried out in the posterior section of the cavity (B in Figure 4and 5). Therefore, the box has touch points in those locations. The coloured yarn at the floor represents point A and the vertical yarn represents point B. The insertion angle in the box trainer resembles the insertion angle of the trocar during a neuroendoscopic procedure (see Figure 3).

The box trainer represents the worst-case scenario in terms of stability since there is no material surrounding the shaft of the instrument providing stability like a tissue-resembling phantom would [6, 22]. This box trainer was placed in the LaproTrainer of DEAM, where the trocar plate represents the skull of the patient (see Figure 3). The box trainer is transparent so the researcher can observe.

The hands of the participants in this test were measured over three active finger spreads; spans between digit 1-2, 2-5 and 1-5. This information was used to test whether there was any relationship between the hand size and the rating of the design.

The participants are asked to perform a visual inspection of the prototype first and to rate the first five statements of the questionnaire. The statements all address the user requirements found during the user research. In some cases, multiple statements were offered per requirement. All statements are phrased positively, i.e. "the instrument feels trustworthy during use." and can be rated on a 5-point Likert scale (so 1 meaning worst and 5 meaning best rating).

Then, the hands-on task in the box trainer is performed by the participant, first with the rigid and than with the new instrument. The box trainer was always situated on a table, at around 85cm measured from the floor. After the task, the last 16 statements of the questionnaire are rated by participant. The full list of statements can be found in Appendix 4.

Seven extra statements, meant only for the neurosurgeon were included at the end of the questionnaire. These addressed rather specific aspects of the instrument, i.e. "the tip has appropriate rigidity at neutral angle". The

Figure 3: Still from the user test showing the markers (red dots on the white endoscope)

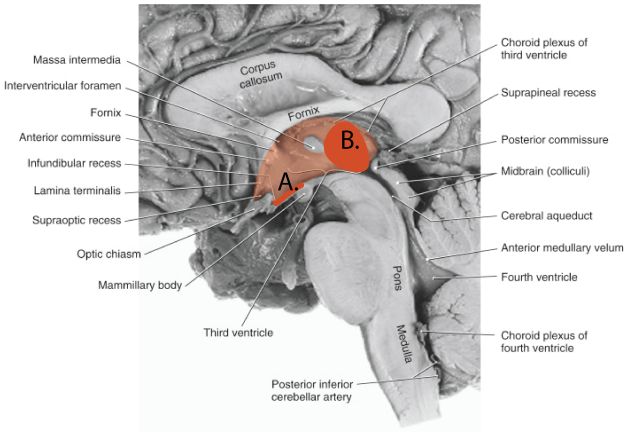

Figure 4: True anatomy of the ventricles, with the third ventricle highlighted in transparent orange and a typical tumor location highlighted in opaque orange

participants were filmed en profil. The shaft of the trocar was marked with 2 markers, which were positioned at 35mm apart from each other. Another marker on the box trainer represented the origin of the coordinate system used for the 2D video analysis. For the full set-up, see Figure 3. The footage was analysed with the software "Tracker", so the locations of the markers could be identified over time [5]. A template is created by snipping one of the frames in the footage, to only contain one of

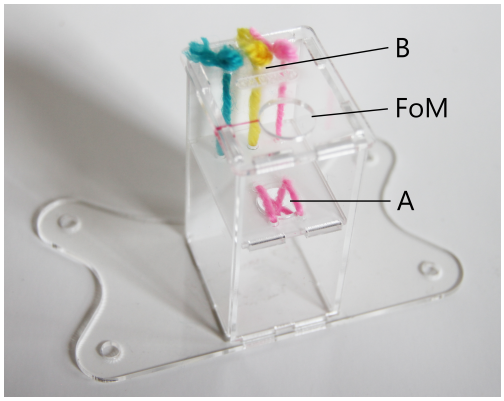

Figure 5: Laser cut box trainer designed for the final experiment, with the same touch points as in figure 4

the markers on the trocar. Every test requires a new template, to correct for light conditions. The types of movement in Figure 6 were identified from the output data of Tracker. In movement 1&3, the angle of the endoscope stays the same, whereas in movement 1, the endoscope tilts. Excel was used to process the data from the software. To identify movement type 1 and 3 (together), the path length of the frame was counted if the angle stayed the same (<1 degree variation). To identify movement type 2, the path length was counted if the angle changed (>1 degree variation). A two-tailed paired T-test was used to evaluate possible significant change in movement in the endoscopic system with the introduction of steerability.

H_0: The effect of a steerable instrument instead of a rigid instrument on movement in the system equals zero.

H_1: The effect of a steerable instrument instead of a rigid instrument on movement in the system does not equal zero.

The means per frame per participant for each type of movement while using the Minop dummy and the new prototype were compared. Since there was no time limit to the task, it was not possible to use total path lengths.

2 Results

2.1 User research outcomes

This section presents the relevant user research outcomes and the corresponding user requirements.

Interview and surveys

During the interview, prof dr. Hoving states that the ventricles of patients suitable for endoscopy are almost always enlarged. This gives extra space to work in, also in very young children. He also mentions that the Minop system is quite robust and hefty, making it impossible to use in small size ventricles nonetheless. The instrument has to stick out of the trocar by 3-5 mm to be in view of the endoscope. Usually, it has to stick out by 20-30 mm to be in focus. Prof dr. Hoving also stated that the third ventricle is the most challenging but rewarding area to operate on endoscopically and that the FoM (mean dimensions 7.3x7.4mm) often is the limiting factor when it comes to being able to doing minor adjustments of the position of the endoscopic system [8]. He advises to not redesign the dimensions of currently used end-effectors. It is indeed difficult to keep the endoscopic system completely still throughout the procedure, even though every movement causes damage.

In the survey, all respondents agree that there is a need for innovation in neuroendoscopic instruments, as they encounter problems with reach, unpredictable behaviour, crudeness, bad ergonomics and a limited range of instruments. They all express an interest in using steerable instruments. To benefit from steerability, the respondents expect a 40-90° articulation, in all planes, with the tip being around 3mm long, preferably with scissors, bipolar coagulation, biopsy forceps, normal forceps or suction. The majority states that they prefer a multi-planar distal bending section, rather than having to rotate the full shaft to reach multiple directions. None state to have to deal with CANS or RSI related complaints. For the full results, see Appendix 1.

The follow-up survey yielded that the absence of CANS and RSI might be due to the short operating times in neuroendoscopic procedures. The respondents do agree improvements can be made in the design of the controls of the handle. The weight of the endoscope is the most limiting factor to a comfortable, ergonomic posture for the surgeon. Fixation of the endoscopic system is possible, but undesirable as it limits the freedom of the surgeon.

The most significant problem is being limited to having to work in-line with the trocar. Sometimes two trajectories are needed to perform one procedure. The respondents agree that adding steerability will introduce unavoidable extra length of the shaft exiting the trocar. The respondents estimate that most end-effectors have a length of 4-10mm. The respondents estimate an added 5mm due to the flexible section, so including the

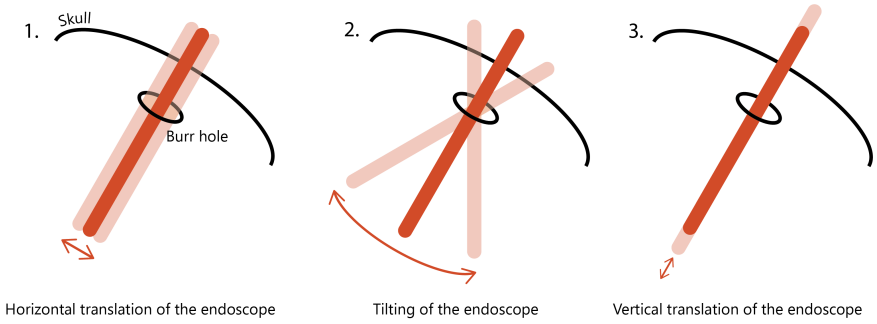

Figure 6: Types of undesirable movement

end-effector, that is a total of 12-15mm. The shorter the total length, the better, as not all ventricles are large enough to accommodate for the 15mm tip. The smaller the bending radius is, the better, as it would prevent the tip from swaying into tissue. The current end-effectors work fine and do not need any improvements.

Design requirements

From the user research, it could be derived that the core requirement is to be able to reach the floor and the posterior section of the third ventricle, without introducing more movement in the non-articulate portion of the shaft of the instrument. Figure 6 illustrates the three types of movements that should be prevented in order to minimise damage to the brain tissue and thus optimise the benefit of using a steerable instrument. Type 3 is only undesirable when happening during the procedure, not while placing and removing the endoscopic system. The rest of the requirements are presented in Table 1. The full document of the user requirements derived from the surveys and interview is included in Appendix 2.

2.2 Design of the instrument

This section presents how the requirements were met by designing the end-effector, the distal bending section of the shaft (articulate tip) and the proximal bending (the handle with joystick).

End-effector design

The end-effector was adapted from a preexisting DEAM prototype. This prototype does not use the rod system that most end-effectors on this scale use, but rather a sliding adaptor with a slot pin [16]. The slots are angled, so when the core tube is pushed by opening the trigger, the end-effector will also open. This mechanism is shorter than the rod mechanism and when opened, the parts extending from the shaft are smaller. The prototype was optimised for ETV/biopsy by redesigning the grasper jaws to biopsy cups with a sharp edge. This design is visible in Figure 7.

Distal bending section

Multiple options for the articulate shaft were considered; a simple hinge, a compliant structure or concentric tubes. Since the respondents of the survey clearly stated they expect multi-planar, reliable and smooth steering, it was decided to opt for the preexisting laser-cut tube mechanism by DEAM. This existing design was not optimised for the application of SNI. The preexisting prototype had a flexible section of around 9mm and an end-effector of 7mm in length. Considering the average height of a hydrocephalic third ventricle (see S3.1, Table 1), there is no room left to move around, so the design had to be downsized. The tip reach simulation in Matlab yielded that with a rigid tip, 22% of all tumors can be reached, where a flexible tip of 16mm can reach 58% at the desired maximum bending angle of 40° and a tip of 13mm can reach 56%.

The final design proposal for the shaft with articulate tip is a shaft with a total length of 290mm, equal to that of the current instruments. The maximum bending angle is 40°. With the selected mechanism, that means 5 laser-cut elements are needed to achieve that angle. Together with the biopsy forceps, the laser-cut articulating portion is 14mm in length. A section view of this concept is presented in Figure 7. This figure shows how the needed functionalities (rotation, steering and controlling of the end-effector) are achieved. A general formula for the shortening of the steering cables to achieve the desired maximum steering angle was created:

$$d = ((\sqrt{(360/\theta * C_1}/\pi) - a)^2 * \pi)/(360/\theta) - C_1 \quad (1)$$

C_1 being the outer bending radius, a being the inner diameter of the shaft and the steering angle being ϑ.

Nr.	User Requirement	Specification (if applicable)	Rationale/source
1.	Minimal movement of complete system during free hand use	NA	**R1** Any movement in the system transfers to the surrounding tissue and an be damaging [13]
2.	The new design can be used in commonly used trocars/endoscopes	**S2.1** The shaft is around 290mm long	**R2.1** Length of Minop & GAAB neuroendoscopic instruments [1, 19]
		S2.2 The diameter of the shaft <2mm	**R2.2** Diameter of Minop & GAAB neuroendoscopic trocar workchannels [1, 19]
3.	The new design is optimised for a combined procedure of ETV and biopsy	**S3.1** The total length of the articulating section plus the end-effector <16mm	**R3.1** 16mm is the height of a hydrocephalic 3rd ventricle on average [8]
		S3.2 Maximum required steering angle = 40°	**R3.2** Estimation by survey respondents
		S3.3 The end-effector and tip can exert at least 0.5N on the tissue	**R3.3** Maximum measured force on tissue during INE [11]
4.	The new design be used in most regular hand sizes, without introducing strain in the fingers	**S4.1** The trigger should have a length of 5 - 8.9 cm	**R4.1** Length and location should permit at least two fingers to actuate the trigger with the distal phalanges [28]
		S4.1 The handle facilitates finger spreads <76mm	**R4.2** Comfortable index finger spread [27]
		S4.3 It should be possible to lock the joystick in the desired angle	**R4.3** To position the joystick and the trigger at the same time is not desirable
		S4.4 The joystick should facilitate thumb breadths of 20 - 26mm	**R4.4** 20mm is p5 and 26 is p95 facilitating most thumb breadths [18]
		S4.5 The joystick should facilitate a travel of over 6mm	**R4.5** Minimal detectable deviation [2, 20, 21]
5	The handle is optimised for the (OR) context	**S5.1**The shaft/handle angle should be around 120°	**R5.1** Similar to the Minop instruments [1]
		S5.2 The handle does not have sharp edges or flush buttons	**R5.2** To not cut or catch the user's gloves [28]
6	The end-effector can be actively closed AND opened	NA	**R6** To be able to stretch fenestrations [13]
7	The new design feels trustworthy	NA	**R7** Neurosurgery is a traditional field of surgery

Table 1: Design requirements

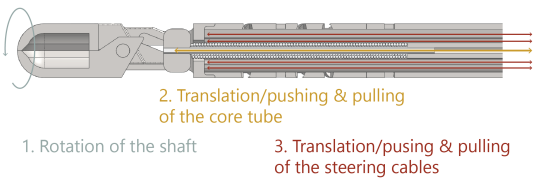

Figure 7: Section view of the tip and how the functions are controlled

This formula, with the desired 40° and the distance a = 0.53mm, a stroke of 1.9mm is needed (red arrows in Figure 7). The maximum stroke is reinforced to prevent unintended big steering movements. The next section will explain how this stroke of 1.9mm is translated to a joystick movement comfortable for the user. 8.

Figure 8: Prototypes 2.1 and 2.2

Handle design

The most important result from the first concept generation was that having to use the thumb to control the joystick renders it useless to stabilise the handle, so stability has to be achieved otherwise. The general result is that the stability of concept 2.1 and the more comfortable trigger of concept 2.2 will have to be combined into a handle that is light weight and accommodates for most hand sizes, which are the concepts presented in Figure The dimensions were satisfactory but needed minor changes regarding the rotation knob and the shape of the joystick. The full results from the questionnaire can be found in Appendix 5.

Final handle shape & ergonomics
A photo of the final prototype is shown in Figure 9, next to a rendered image including the measurements and finger spans. The joystick locks into position by means of a spring pushing the joystick's silicone outer layer into the housing, so the thumb can be used to stabilise the handle once the tip is at the desired angle. The handle is shaped like a hook, creating only crucial contact surfaces and giving the thumb multiple places to rest. The joystick is designed in such a way that the rotation of the shaft does not transfer tot the joystick. 20° of joystick tilt equals the maximum 40° of steering and the deviation is around 7mm, which is more than the mean minimum detectable deviation (see Table 1). The movement is magnified 2 times, making it direct and intuitive. The joystick is shaped like a cup; pressure can be exerted on the middle dome or on the inside edge, or even on the outside edge, which has a small ridge for grip. The dome in the middle of the cup has a diameter of 10mm and the cup has a diameter of 24mm.

The core tube actuating the end-effector requires a translation of 1.6mm to open and close the forceps and an extra millimeter to be able to apply force. The ratio of trigger input to movement at the tip is around 7, where it is around 8 in the Minop handle. At the maximum comfortable input forces, the forces on the tissue are around 8-9N when steering or grabbing tissue dependent on the angle of the tip, so more than enough force can be exerted.

All parts of the prototype are shown in the exploded view in Appendix 6. Figure 10 shows the mechanism in the handle in detail. For intuitive control, the following mechanism was designed: Since the core tube actuating the end-effector is surrounded by the steering cables, and all aforementioned parts rotate with the shaft, the steering cables are spread and guided over the white part, the 'slider beam'. They move through the 'gutters', so they run smoothly and do not buckle. Now the core tube is accessible to the part that moves over the x-axis (movement 2), the 'slider'. The slider rotates together with the shaft to prevent the steering cables from twisting up. The trigger moves the slider back and forth. The circular recess in the trigger part allows for readjustment of the core tube tension. It is still possible to steer out of view in a 0° endoscope, which has a vield of view of 30° in all directions. Only when the tip is sticking out more than 25mm, it will always stay in view. This angle is around 26° at 25mm. However, when sticking out too far, the tip will be out of focus.

Due to problems at the manufacturing facility, the designed biopsy forceps could not be delivered in time. A grasper instead of biopsy forceps were installed.

3 Experiment results

3.1 Usability

Eight out ten participants did not immediately hold the handle correctly so the grip pattern had to be explained. The shape of the handle enforces one type of grip, whereas the old instrument leaves room for movement. Six participants state that the handle is slightly too large to comfortably place the little finger in the designated spot, but it is possible. The curved shape is functional to lock the thumb in position for extra stability. Participants state the handle looks robust and trustworthy. The steerability is perfect, the control force and displacement at the joystick are appropriate and smooth, the angle at the tip is good. Deviation of the tip to the left is easier than to the right. Sometimes, the grip has to be adjusted, especially when steering bit by bit instead of immediately setting the tip to the appropriate angle. Five participants state it is exciting to use the prototype and want to keep going after they have fulfilled the task. Two participants used both hands at some point, to re-position the handle. Four participants used the hook as if the handle were a pair of scissors.

Dr. Hoving states that the insertion of the instrument in the trocar is extremely smooth (5/5). The tip at zero degrees has a good stiffness (4/5) and also at maximum bend (4/5). The grabbing force is also evaluated as good (4/5). The trigger's position is evaluated with a very poor 1/5. However, the tip's visibility is good (4/5).

The rest of the statement ratings are summarised in Figure 11, where the means were calculated from the ratings, sorted by the user requirement they represent. All statements were rated neutrally or positively on average. The lowest

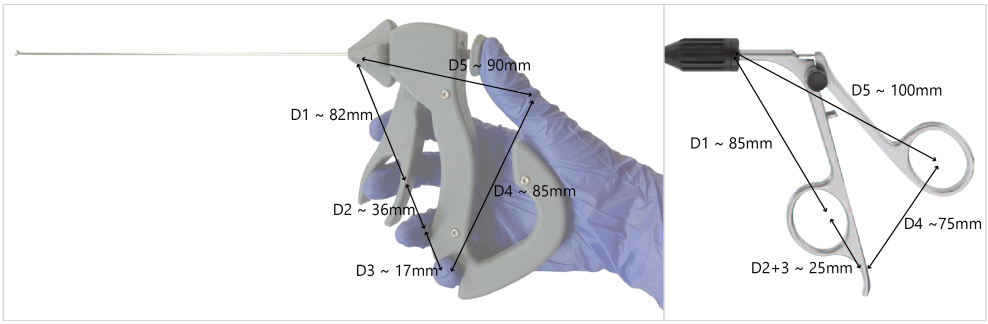

Figure 9: A photograph of the final prototype with measurements, compared to the old instrument

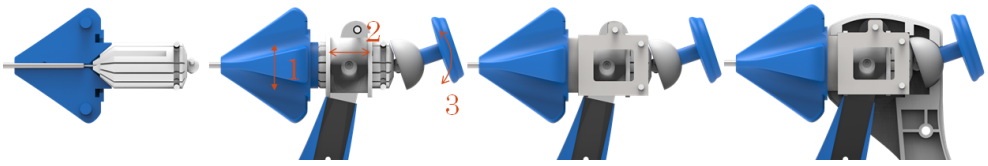

Figure 10: Proximal mechanism assembly. 1) indicates how to rotate the shaft, 2) indicates the motion to open the end-effector and 3) indicates the steering motion, the numbers correspond to the functions at the distal mechanism in Figure 7

(3/5) was on the statement “it is comfortable to hold an control the handle”. The highest rating (4.5/5) was on the statement “The forces required to operate the trigger are comfortable”. Table 2 shows the hand measurements per participant and their mean rating of the handle. No significant relationship between the mean ratings and the hand measurements could be detected.

Span 1 (2-5)	Span 2 (1-5)	Span 3 (1-2)	Mean rating
140	200	160	4.7
145	230	200	4.5
140	210	140	4.1
115	175	140	4.1
125	185	155	4
145	160	140	3.6
140	180	160	3.6
140	190	170	3.5
170	200	175	3.3
160	220	200	3.1

Table 2: Table showing hand measurements in mm together with mean rating of usability on 5-point Likert scale

3.2 Stability measurements

The means of the three categories of movement were calculated per frame for each participant. The mean non-angular movement (type 1 and 3 in

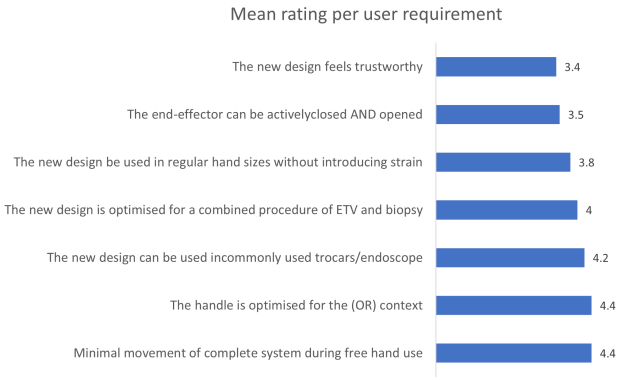

Figure 11: Mean calculated from all statements addressing the 7 specific user requirements introduced in Table 1, sorted from low to high

Figure 6) was 0.07mm (σ^2=0.0004) for the rigid instrument and 0.04mm (σ^2=0.0002) for the newly developed prototype. The mean angular movement (type 2 in Figure 6) was 0.12mm (σ^2=0.0028) for the rigid instrument and 0.18mm (σ^2=0.0072) for the newly developed prototype. In both cases, there is more movement while using the rigid instrument. The results are visualised in Figure 12. There is much more angular movement than non-angular movement in the endoscope when using either the Minop or the new prototype. There is much more variation in the angular movement. The T-test showed significantly less non-angular movement in the newly developed prototype than in

the old instrument (p=0.009). The angular movement reduction was only significant in one direction (p=0.032) but not in both (p=0.063).

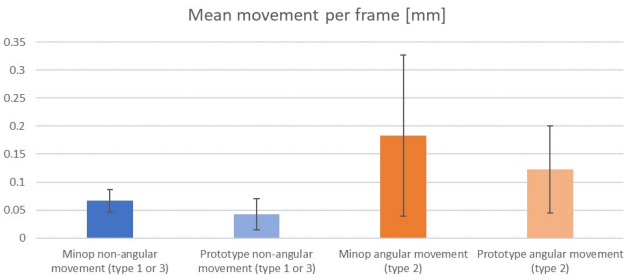

Figure 12: Graph showing the mean movement with standard deviation for both instruments and both types of movement

Discussion

In this paper, the development and evaluation of a hand-held steerable instrument for neuroendoscopy was presented. Through multi-level user research, the requirements to the design were determined. Applying DEAM's steerable cable wreath technology to the 1.8mm shaft enables the user to articulate the distal 14mm of the tip to a maximum of 40° in all directions. The steerability was evaluated by the intended user and deemed adequate. Other aspects of the performance of the tip were not evaluated, as the steering mechanism is a validated mechanism that was already applied in products that are currently on the market.

The most important finding was the significant reduction of needed movement to carry out the task in the box trainer.

The user research was performed on three levels; the interview being the most qualitative and the first survey the most quantitative. Adequate user input was found and the more superficial input with was verified with the more in-depth. More data about the exact equipment the surgeons have experience with or their hand size would have been useful to draw specific conclusions about their (bad) experience with current instruments.

Because of the installed graspers instead of the intended biopsy forceps, the tip does not perform as intended. Since the participants were still able to move the trigger during the task, it is assumed that the absence of the proper end-effector did not affect the movement data observed.

The handle design was based on human factors standards and locks the full hand into position to enforce a stable grip [18, 28]. The handle and needed input forces were evaluated as adequate but leaving too little freedom in the hand.

In sizing the final design, the focus was on theoretical requirements; the length of the trigger, the maximum comfortable reach of the fingers (as presented in Table 1. Preferably, the handle would be executed in several shapes and ratios in a future prototype, to evaluate the effect of the total size but also the several distances between the controls.

The observed asymmetry in the tip could be due to misalignment during the gluing of the steering cables, or to the fact that the shape of the handle makes it more difficult to steer to the right than to the left. This was not tested, but could be evaluated by finding more test participants both left- and right handed and test if they experience opposite asymmetry while operating the joystick.

The test set-up was always situated at the same height as there was no access to an adjustable table. The participants had widely varying heights. This might have had an effect on the comfort of the posture the participants had, being reflected in the results. The perfect table height is 0.7 - 0.8 of the elbow height, meaning the table height would have to be altered in a perfect experiment [26].

The hand measurements that were used during the interpretation of the results were measured without special equipment. How to spread the hand, although thoroughly explained, might be interpreted differently by every participant. These measurements might thus not be completely reliable. An alternative would be 3D scanning of the hand, to have a more objective insight in the size of the participants' hands.

Since the software that was used is a third party software, it is unknown how large the error is it introduces. In future research, software should be developed specifically to analyse the types of moment of the endoscope. In a perfect scenario, the tracking would be done in 3D, in order to also evaluate the movement in the frontal plane; the movement in this plane could be totally different from that in the analysed plane.

As mentioned, there is only one other publication known specifically presenting the design of a steerable neuroendoscopic instrument [11]. The development of this instrument focused mostly on the articulating tip and its performance. As a result, an extremely well evaluated and optimised compliant tip was developed. This tip can only bend in one plane, whereas the prototype presented in this report can bend in 12 planes, partially eliminating the need for rotation of the shaft and thus requiring less input of the user and decreasing movement in the system. The first author of the study was contacted. He stated that not much development went into the handle design; it was

designed to be functional (although some iterations were made), whereas the prototype presented in this report used the theory of handle design combined with input from prototype evaluations to design the shape of the handle as it is [10].

All specifications in Table 1 were met.

Conclusion

A steerable neuroendoscopic forceps for intraventricular use was developed. The final prototype was fully functional. A box trainer with standard task was developed to do the final evaluation on usability and stability during use, where 10 participants evaluated the handle. The stability analysis was done through video analysis.

A significant decrease of movement in the sagittal plane compared to the old instrument was observed during use. This proves that the use of a steerable device is much safer when trying to reach the posterior section and the floor of the third ventricle in terms of unintended manipulation of the surrounding tissue. Additionally, the results of the user evaluation were promising, as especially the user requirements concerning the performance were easily met according to the questionnaire outcomes. The handle needs another thorough design iteration concerning the degrees of freedom of the hand.

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1 Survey results

	N (%)
Would you say there is a need for innovation in neuroendoscopic instruments?	
Yes	8 (100%)
Would you be willing to adopt steerable instruments for neuroendoscopy?	
Yes	7 (87.5%)
NA	1 (12.5%)
Could you describe problems with current neuroendoscopic systems you encounter during surgery?	
Lack of flexibility	3 (37.5%)
Limited reach	2 (25%)
Heavy/large instruments	2 (25%)
Limited options in instruments	2 (25%)
Difficult hemostasis	2 (25%)
Would you say there is a ”typical neurosurgeon”? Or a noticeable generational difference between younger and older neurosurgeons?	
Yes	1 (12.5%)
No	2 (25%)
Shift towards extreme specialisation	4 (50%)
Shift towards use of technology (AI, robotics)	1 (12.5%)
Would say most intraventricular neuroendoscopy is mostly used in patients with hydrocephaly?	
Yes or almost always	5 (62.5%)
Not necessarily	4 (50%)
What amount of articulation (in degrees, measured from the shaft) would you say is necessary to reap the benefits of a steerable instrument?	
<90°	4 (50%)
<45°	4 (50%)
Is it preferable for the articulating shaft to always return to neutral position?	
No	1 (12.5%)
NA	7 (87.5%)
How many bending planes would you prefer?	
One	2 (25%)
Multiplanar	6 (75%)
Elaboration	
Safer, less manipulations needed	3 (37.5%)
Simply more freedom	2 (25%)
NA	2 (25%)
Taking into account the dimensions of the ventricles, how long do you reckon the articulating portion of the shaft should be?	
2-3mm	3 (37.5%)
3-4mm	3 (37.5%)
4-5mm	1 (12.5%)
As long as it is visible	1 (12.5%)
How many mm on average does the instrument stick out of the trocar during a regular procedure?	
4-5mm	2 (25%)
>5mm	4 (50%)
Unknown	1 (12.5%)
Varying lengths	2 (25%)
Do you think visualisation of- and interaction with a steerable instrument would be a challenge using 2D endoscopy?	
Yes, but can be learned	2 (25%)
Maybe	3 (37.5%)
No	2 (25%)
Unknown	1 (12.5%)
What type of end-effector would you want to apply steerability to?	
Scissors	4 (50%)
Graspers	6 (75%)
Biopsy forceps	3 (37.5%)
Bipolar coagulation	3 (37.5)
Suction	2 (25%)
NA	2 (25%)
Could you describe the problems you encounter with current instrument handles?	

No	1 (12.5%)
Abrupt/not smooth interactions	3 (37.5%)
Uncomfortable wrist & hand movements	2 (25%)
Unable to work like desired	1 (12.5%)
Do you think it would be egonomically preferable to transition to robot surgery for intraventricular procedures?	
Yes	1 (12.5%)
No	1 (12.5%)
No, robot surgery is still too crude	4 (50%)
No, maybe as assisting device	1 (12.5%)
Maybe	1 (12.5%)
Is there a need for innovation in the type of endoscopes? If yes, which?	
Variable angle/view endoscopes	1 (12.5%)
Variable angle/view endoscopes with ahead mounted display	1 (12.5%)
3D endoscopes	1 (12.5%)
3D endoscopes with a head mounted display	4 (50%)
Flexible external fixation of the scope	1 (12.5%)
Do you suffer from RSI-like problems or pain? If yes, could you elaborate?	
No	8 (100%)

2 User requirements & product specifications

User Requirements & Product Specifications

Project	**NeuroFlex**
Document ID	**DE_411_ProductSpecifications_To_REV01**
Version	**To_REV01**

1 Scope

This document describes the Product Specifications for the design of the NeuroFlex. Input is received from the user requirements, essential requirements, and the risk management.

The Product Specifications, describe the functional and material specification of the instrument, the specifications regarding labeling, instructions for use, user training, packaging, and the production.

	Name	Date	Signature
Author	**Maaike Weber**	**01-10-2020**	
Reviewer			

Table of content

2 Functional Specifications

UR#	User Requirement	Wish/must	Rationale & origin of UR	PS#	Functional specifications	Acceptance criteria & Rationale for functional specification
1	Minimal movement of complete system during use of NeuroFlex when the rest of the endoscopic system is used free hand.	Must	Every displacement of the system crushes the brain and may lead to irreversible damage <Ref 1,12>	1.1	Device weight	A: Lower or equal to current instruments, the weight stays below 56g R: Light instruments allow for smooth interaction and low fatigue. Current instruments do not give any problems in terms of weight.
				1.2	Insertion friction	A: User (dr Hoving) agrees that during use, friction is acceptable R: High friction in the trocar forces the surgeon to use a lot of force on the system, which can cause loads applied on the brain tissue. Dr. Hoving is representative for all users.
				1.3	Force on bending control to bend the instrument	A: Control forces are lower or equal to comfortable stabilizing forces in other hand R: Some forces will have to be applied during use, so the other hand holding the trocar should be able to counteract these
				1.4	Grip	A: Dr. Hoving agrees the instrument is comfortable to hold while operating under several angles. R: Steerability will broaden the range of possible approaches, dr. Hoving is representative of all users.
2	NeuroFlex can be used in commonly used trocars/endoscopes (minop, zero degree, 30 degree,…)	Must	Possible to use with the Minop system, which is currently used at the Máxima Center. The instrument is usable with a 0 or 30 degree endoscope, as well as with a 3D endoscope. <Ref 1,2,13>	2.1	Device Diameter	A: the instrument should have a diameter of < 3mm R: To be able to be compatible with the Minop and GAAB systems. In that case, two of these instruments could even be used next to each other in the oval channel of the Minop <Ref 4, 5>.
				2.2	Shaft length	A: 290mm R: Existing instruments have the same length. These instruments are used in the same system where the new design will be used <Ref 4>.
				2.3	Default end-effector state	A: Closed R: That way, the trocar or end-effector cannot be damaged when being pulled back in open state. Lower risk of losing biopsy samples. In case of sharp end-effectors: less risk of damaging tissue
3	The instrument is optimised for a combined procedure of ETV and biopsy	Must	This is the most challenging as the anterior and posterior section of the ventricle have to be reached, while also a very common one <Ref 1,13>	3.1	Tip length	A: end-effector+bending section ≤16mm R: Depth of hydrocephalic 3rd ventricle, so max length of the section exiting the trocar. Total physical design space is width range 9.5-27.5 (mean 14.5), height 10.9-26.3mm (mean 16) <Ref 24>

UR#	User Requirement	Wish/must	Rationale & origin of UR	PS#	Functional specifications	Acceptance criteria & Rationale for functional specification
				3.2	Max bending angle	A: 40° R: This is sufficient to reach most tumors and was noted as desirable in survey <Ref 10>
				3.3	End effector type	A: Biopsy forceps R: Only type of instrument needed to perform the procedure
				3.4	Deviation from straight position	A: Deviation of the tip of the device with respect to axis of handle ≤ 2 mm when in straight position. Deviation measured at hinge of end-effector parts. R: 2 mm displacement is maximum allowable inaccuracy as it equals the diameter of the shaft.
				3.5	Durability – bending actions	A: (in case of single use) >5 times bending R: Cappabianca et al. advice at least three biopsy specimens. It should also be possible to grab a loose piece of other tissue or stretch the ventriculostomy by opening the end effector <Ref 7,9>
				3.6	Contact with Blood	A: Device complies to Functional Specification after contact with blood for > 120 minutes. R: 120 minutes is the time a surgeon takes for a complex procedure (tumor resection), <Ref 3>.
				3.7	Bending direction	A: The tip bends in all directions (360) R: Having such freedom makes it easier to orient an move, without having to rotate the shaft.
				3.8	Grasping force applied by the jaw parts on the tissue	A: Equal to the force applicable with the Minop forceps R: Current forceps are satisfactory
				3.9	Opening width end effector	A: 4-6mm R: Stoma size <Ref 6>
				3.10	Opening/closing robustness	A: (in case of single use) ≥5 times opening & closing R: Cappabianca et al. advice at least three biopsy specimens. It should also be possible to grab a loose piece of other tissue or stretch the ventriculostomy by opening the end effector <Ref 7,9>
				3.11	In plane bending rigidity zero-degree angle	A: User (dr Hoving) agrees that during use, the in plane bending rigidity at zero-angle is acceptable. R: dr Hoving is representative for all users.
				3.12	In plane bending rigidity steered at angle	A: User (dr Hoving) agrees that during use, the in plane bending rigidity at angle is acceptable. R: dr Hoving is representative for all users.
				3.13	Perpendicular plane bending rigidity at angle	A: User (dr Hoving) agrees that during use, the perpendicular plane bending rigidity at angle is acceptable. R: dr Hoving is representative for all users.

UR#	User Requirement	Wish/must	Rationale & origin of UR	PS#	Functional specifications	Acceptance criteria & Rationale for functional specification
				3.14	End-effector grasping force	A: Equal to force needed to perform biopsy with existing instruments R: This is not a critical specification, as brain tissue is very soft and easy to slice. Current instruments are sufficient.
				3.15	Insertion angle appropriateness	A: Dr. Hoving agrees the steerable shaft accounts for an insertion angle of B_0=15°, measured from the FoM, between the instrument and the y-axis -10° and +40° R: Standard placement, assuming a 2cm variation in burr hole placement
				3.16	FoM size	A: Dr. Hoving agrees that steerability accounts for the varying size of the entry way (FoM). R: FoM diameter range 1.9-21.9 x 1.6-28.5 (mean 7.3x7.4) <Ref 24>
				3.17	Tumor location	A: Dr. Hoving agrees that a tumor that is located min. -10mm max. 35mm in ventricle reachable. R: The tumor can be located anywhere in the depth of the 3rd ventricle, which is around 35mm deep <Ref 24>
				3.18	Shape of the cups	A: Hollow cups, sharp edges, no teeth R: They should be as similar to the Minop biopsy end-effector as possible.
4	Can be used in most regular hand sizes	Must	Large and small hand will use the device	4.1	Hand size (length)	A: All controls for the functionalities are reachable by a hand with a length of 6,2 inch and of 8,1 inch. R: It is assumed that if ultimate hand sizes (5th percentile female to 95th percentile male <Ref 8> p. 34,35) reach all controls, in between sizes reach controls as well.
				4.2	Trigger Length	A: At least 5 cm long but not exceeding 8.9 cm in length <Ref 15> R: The trigger length should be sufficient to permit at least two fingers to actuate the trigger
				4.3	Trigger location & finger allocation	A: The trigger should be located so that the distal phalange for is used precision work <Ref 15> R: movements inside the brain are critical and precise
5	Device can be used right and left handed	Must	Current instruments used both in left and right hand regardless	5	Symmetry	A: Symmetric design of the handle. R: If devices is symmetric, left and right hand use is equal.
6	Feedback about the state of the tip is provided	Wish	Especially in 2D, it is difficult to see the angle at which the tip is bent or whether the end-effector is open or closed <Ref 1, 11>	6.1	Joystick position feedback	A: Dr. Hoving agrees the joystick's deviation from the neutral position adequately shows the position of the tip in respect to the shaft. R: dr Hoving is representative for all users.
7	One hand can operate the instrument and do bending, opening the grasper, rotating and	Must	Situations can occur where all these actions are needed at the same time (steering to tumor, taking biopsy, rotating at angle to	7.1	Built-in friction	A: friction in the joystick is just enough to keep the tip at an angle without perpendicular force on the tip

UR#	User Requirement	Wish/must	Rationale & origin of UR	PS#	Functional specifications	Acceptance criteria & Rationale for functional specification
	perform axial movement at the same time.		twist the tissue lose). It is uncomfortable to keep the thumb in a fixed position and possible difficult, depending on the precision. User research <Ref 1,11,13>			R: The tip should stay at an angle in free space (the ventricle) but it is safer for the tip to not be too stiff and eventually return to neutral state when forcefully hitting tissue
				7.2	Reach envelope thumb	A: Facilitating maximum Operational (comfortable random movement): 67.3 + 16.1 mm abduction/adduction 73.1 + 18.0 mm flexion/extension R: Comfortable movement for the thumb using a joystick <Ref 20>
8	Acceptable strain and stress on all fingers during use of the controls, The handling of the instrument is smoother and needs less force than current instruments	Must	In view of ergonomic guideline IEC 62366 & <Ref 11>	8.1	Joystick/thumb force	A: <2.4N R: The forces measured in these studies were measured while doing normal, comfortable grasping tasks, meaning the force is measure normal to the surface of the sensor <Ref 19>
				8.2	Trigger/middle & ring finger force	A: The force required to actuate a single finger trigger should not exceed 5 N R: Force should be sustained comfortably, without trembling or uncontrolled movement of the fingers on the lever <Ref 19>
				8.3	Reach envelope index finger	A: Spread <76mm R: 76mm passive spread is 10th percentile maximum active (produced by human) spread between index finger and other fingers <Ref 23>
				8.4	Reach envelope middle finger & ring	A: Spread <60mm R: 60mm passive spread is 10th percentile maximum active (produced by human) spread between middle & ring fingers <Ref 23>
				8.5	Reach envelope little finger & ring finger	A: Spread <78mm R: 78mm passive spread is 10th percentile maximum active (produced by human) spread between middle & ring fingers <Ref 23>
				8.6	End effector opening force	A: Smaller than closing force R: It should be equally easy to open/close, to not have to adapt for every motion. Additionally, opening the hand is a less forceful motion than closing it <Ref 22>
				8.7	Grip on handle at bending angle	A: User (dr Hoving) agrees that during use, the grip on handle at bending, force at angle is acceptable. R: dr Hoving is representative for all users.
				8.8	Smooth steering - general	A: In a test dr. Hoving agree that during use, smoothness of steering is good enough up to the maximum bending angle. R: dr Hoving is representative for all users

UR#	User Requirement	Wish/must	Rationale & origin of UR	PS#	Functional specifications	Acceptance criteria & Rationale for functional specification
				8.9	Rotation force at maximum angle	A: Torque required by ring finger to rotate the shaft at maximum bend ≤0.6 Nm <Ref 15> R: Comfortable according to medical device design handbook.
9	Possible to align jaw properly to tumor	Must	The ventricles are small, there is no room for mistakes and the forceps have to be in de perfect position to perform a biopsy User Feedback <Ref 1>	9.1	Degrees of rotation	Equal degrees of rotation as in currently available devices.
				9.2	Rotation control size	A: The control surface of a rotary control should provide adequate purchase for manipulation, extending a minimum of 0.3 cm beyond the handle housing. R: The fluted parts of the control need to be flush with the handle, while the projections extend away from the handle sufficiently for the user to be able to manipulate the control <Ref 15>
10	The instrument feels trustworthy.	Wish	When using plastic, there is a risk of the instrument seeming less trustworthy than when using SS. User Feedback <Ref 1>	10.1	Materials	A: User (dr Hoving) agrees that during use, the materials feel trustworthy and sturdy R: dr Hoving is representative for all users.
				10.2	Single use	A: Single use R: It's easier to ensure sterility, cleanliness and trustworthiness. There is no proof reusable instruments are more sustainable.
				10.3	Shaft stiffness - axial	A: Shaft has same axial stiffness as existing neuroendoscopic instruments. 2.17*10^9 N/m R: There are no problems with the stiffness of current designs.
				10.4	Shaft stiffness - bending	A: Shaft has same bending stiffness as existing neuroendoscopic instruments. 2.51*10^6 N/m R: There are no problems with the stiffness of current designs.
				10.5	Handle width	A: >10mm R: Identified as proper requirement by Van Veelen et al <Ref 21>.
				10.6	Handle Robustness	A: Device should be able to withstand a force 20.6 N. R: Average male gripping force when comfortably holding larger object with one hand, assuming users handle an expensive medical device carefully, average should be sufficient. <Ref 19>
				10.7	Familiarity	A: Dr. Hoving agrees that there is enough resemblance with the current instruments R: During the interviews, dr. Hoving was very clear that the Minop handle is very good and intuitive, qualities that are important to transfer to the new design. Additionally, the developments towards the use of HMDs <Ref 1>

UR#	User Requirement	Wish/must	Rationale & origin of UR	PS#	Functional specifications	Acceptance criteria & Rationale for functional specification
11	The end-effector can be actively closed AND opened, to be able to stretch fenestrations.	Must	User feedback; the opening motion has to be controlled for stretching fenestrations in tissue <Ref 14>	11.1	Trigger shape	A: The end-effector trigger can be actively opened and closed in opposite manners. R: Opening of fenestrations is just as important and precise as taking biopsies.
				11.2	Travel distance	A: The trigger's travel distance should be 0.6 to 1.8 cm R: This is a comfortable and easily detectable distance <Ref 15>
12	Device can be easily operated in the context	Must	The OR is a very specific challenging environment, as the user is wearing gloves etc.	12.1	Trigger position when pressed	A: When fully pressed, the trigger should not be flush with the handle nor protrude more than 0.6 cm R: If the trigger is flush, then gloves could be pinched. <Ref 15>
				12.2	Sharp edges	A: No sharp edges R: Risk of cutting glove of surgeon
				12.3	Appropriate contrast	A: The instrument is easily visible when used due to good contrast with the surrounding tissue by dr. Hoving R: dr Hoving is representative for all users.
				12.4	Shaft-handle angle	A: Around 120° (like Minop) R: Current instrument angle is satisfactory

3 Change Log

Revision	Changes	Author	Date

4 References

#	Reference
<Ref 1>	E. W. Hoving. Personal communication. 20-03-20
<Ref 2>	Observation from videos and pictures by me, 3 videos from yt, 1 set of photographs from Prof. Dr. Hoving. 2020
<Ref 3>	I.A.M.J. Broeders, *Handboek endoscopische chirurgie*. Houten, 2009
<Ref 4>	Aesculap Inc. *Product catalogue 2015*. Retrieved from: https://www.aesculapusa.com/assets/base/doc/DOC465REV_J_Laparoscopic_Catalog.pdf , visited 20170310. (DEAM Knowledge database filename: AesculapUSA_Laparoscopic_Catalog.pdf)

#	Reference
<Ref 5>	Medtronic, Covidien SILS Articulating Hand Instruments product brochure. Retrieved from: http://www.medtronic.com/content/dam/covidien/library/us/en/product/hand-instruments-and-ligation/sils-articulating-hand-instruments-brochure.pdf, visited 20170310. (DEAM Knowledge database filename: Covidien-sils-articulating-hand-instruments-brochure.pdf)
<Ref 6>	Microline ReNew Reposable laparoscopic instruments brochure 2015. Retrieved from: http://www.microlinesurgical.com/products, visited 20170313 (DEAM Knowledge database filename: Microline-brochure-renew-2015.pdf)
<Ref 7>	Genicon product catalog 2017. Retrieved from: http://geniconendo.com/products/full-catalog/ , visited 20170314 (DEAM Knowledge database filename: Genicon-Product-Catalog-2017.pdf
<Ref 8>	NASA Standards, Man-System Integration Standards (NASA-STD-3000) Revision B, July 1995 (https://msis.jsc.nasa.gov/sections/section03.htm) (DEAM Knowledge database filename: NASA STD 3000 Man Systems Integration Standards.pdf)
<Ref 9>	Medtronic, Sonicision™ System product manual. Retrieved from: http://www.medtronic.com/content/dam/covidien/library/us/en/product/ultrasonic-dissection/sonicision-system-product-manual.pdf, visited 20170310. (DEAM Knowledge database filename: sonicision-system-product-manual.pdf)
<Ref 10>	User survey with 8 senior neurorurgeons. 2020.
<Ref 11>	Questionnaire performed in March 2020 by me, 8 respondents
<Ref 12>	E-mail discussion with Kyle Eastwood February 2020
<Ref 13>	Literature study (article) by me
<Ref 14>	Concept direction evaluation E. W. Hoving
<Ref 15>	Weinger, Matthew B. et al. “Handbook of human factors in medical device design”. CRC Press Taylor & Francis Group. 2010
<Ref 16>	Sjoersma, Wouter, “Surgeons at work” Dissertation 1998
<Ref 17>	DINED, Dutch adults 2004 dined2004. https://dined.io.tudelft.nl/en/database/tool
<Ref 18>	https://www.researchgate.net/publication/268254341_Force_measurement_of_hand_and_fingers
<Ref 19>	Pylatiuk, C; Kargov, A; Schulz, S; Döderlein, L, 2006, Distribution of grip force in three different functional prehension patterns, Journal of Medical Engineering & Technology, 176-182
<Ref 20>	Tang, Jie; Zhang, Xudong; Li, Zong-Ming, 2008, Operational and maximal workspace of the thumb, Ergonomics

#	Reference
<Ref 21>	M.A. van Veelen, J.J. Jakimowicz & G. Kazemier (2009), Improved physical ergonomics of laparoscopic surgery, 161-166, https://doi.org/10.1080/13645700410033193
<Ref 22>	Park, J., & Xu, D. (2017). Multi-Finger Interaction and Synergies in Finger Flexion and Extension Force Production. Frontiers in Human Neuroscience, 11. doi:10.3389/fnhum.2017.00318
<Ref 23>	CH. WAGNER (1988) The pianist's hand: anthropometry and biomechanics, Ergonomics, 31:1, 97-131, DOI: 10.1080/00140138808966651
<Ref 24>	F. Duffner, H. Schiffbauer, D. Glemser, M. Skalej, and D. Freudenstein. Anatomy of the cerebral ventricular system for endoscopic neurosurgery: a magnetic resonance study. Acta Neurochirurgica, 145(5):359{368, jun 2003.

3 MatLab tip simulation

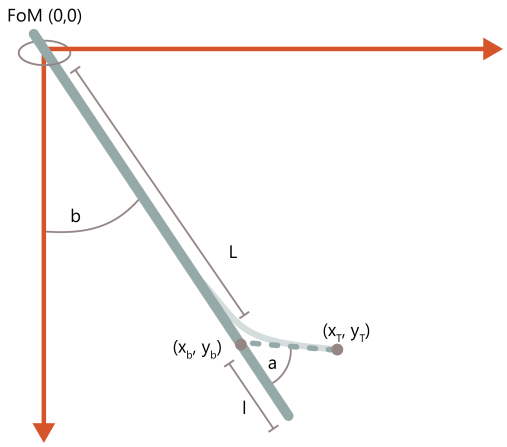
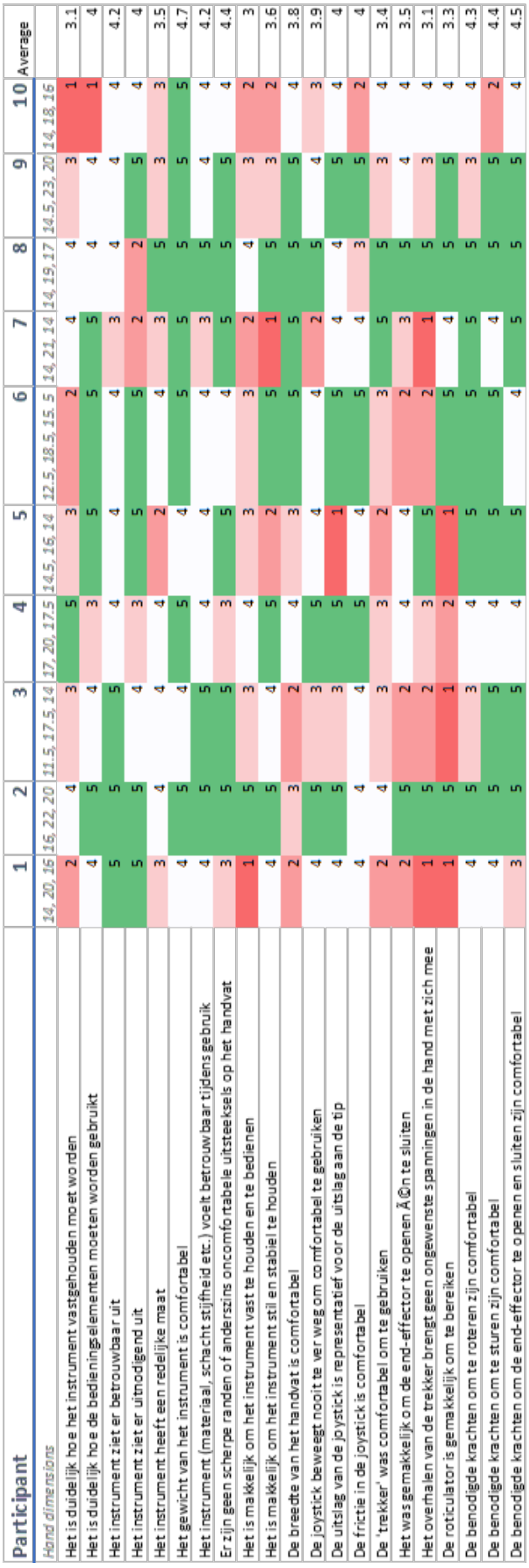


Figure 13: 2D model used for Matlab simulation

```
\clear;
L=3;
lvalues=[];
lvalues2=[];
lmin = 9999999;
lmax = 0;
lsom = 0 ;
l=0; %sw
counter=0;
unreachable = 0;
unreachabletrue = 0;
reachablel = [];
reachabletrue = [];
ltip = 7.3;
ltruevalues = [];

for a = -80:10:80
    rowvalues=[];
    for b = 1:1:40 %sw
       rowvalues= [rowvalues,a];%rowvalues= [rowvalues,a,b]; %s
       for xt = -10:1:30
            xb=L*sind(b);
            l=-xb+xt/(sind(b+a));

            lhalf = l - ltip;
            th = 0.5*(180-a);
            phi = 90 - th;
            ltrue = 2*((pi*(lhalf/tand(phi))*phi)/180)+L+ltip;
            ltruevalues = [ltruevalues, ltrue'];

            yb=-L*cosd(b);
            yt=yb-l*cosd(b+a);

            if (abs(l) ≠ Inf) && ¬isnan(l) %sw l kon ook nog -Inf en NaN zijn
                %l ≠ Inf
                l = abs(l);
                if l < lmin
                    lmin = l;
                end
                if l > lmax
                    lmax = l;
                end
                if l + L ≥ 16 %|| l<7
                    unreachable = unreachable + 1;
                else
```

```
                    reachablel = [reachablel, l'];
                end

                if ltrue ≥ 10
                    unreachabletrue = unreachabletrue + 1;
                else
                    reachabletrue = [reachabletrue, ltrue'];
                end


                counter=counter+1;
                lsom=lsom+l;
                %totall = L + l ;


               % if totall < 13
                  rowvalues = [rowvalues, l'];
                  lvalues2 = [lvalues2, l'];
                        % end

            else
                % igv niet gedefinieerd (NaN) of oneindig (+ of - Inf)
                % vullen met -1
                  rowvalues = [rowvalues, -1];
                  lvalues2 = [lvalues2, -1];

            end %l ≠ inf

        end %for xt END OF CORRECT CODE


        lvalues=[lvalues;rowvalues];

        %lbendvalues= [lbendvalues;rowvalues];
        rowvalues=[];

    end % for b
end % for a


lmaxreachable = max(reachablel);
lmean = lsom/counter ;
lmeanreachable = mean(reachablel);
reachable = counter - unreachable;
reachabletruel = counter - unreachabletrue;
perc=(reachable/length(lvalues2))*100;
perctrue=(reachabletruel/length(lvalues2))*100;
phi = 40;
l = 6.6;
lhalf = l/2;
d = 2;
r2=(lhalf/tand(phi))-0.5*d;
▵lmax = l-2*((2*r2*phi)/180) = 4;
```

4 List of statements and ratings



Participant	1	2	3	4	5	6	7	8	9	10	Average
Hand dimensions	*14, 20, 16*	*16, 22, 20*	*11.5, 17.5, 14*	*17, 20, 17.5*	*14.5, 16, 14*	*12.5, 18.5, 15.5*	*14, 21, 14*	*14, 19, 17*	*14.5, 23, 20*	*14, 18, 16*	
Het is duidelijk hoe het instrument vastgehouden moet worden	2	4	3	5	3	2	4	4	3	1	3.1
Het is duidelijk hoe de bedieningselementen moeten worden gebruikt	4	5	4	3	5	5	5	4	4	1	4
Het instrument ziet er betrouwbaar uit	5	5	5	4	4	4	3	4	4	4	4.2
Het instrument ziet er uitnodigend uit	5	5	4	3	5	5	2	2	5	4	4
Het instrument heeft een redelijke maat	3	4	4	4	2	4	3	5	3	3	3.5
Het gewicht van het instrument is comfortabel	4	5	4	5	4	5	5	5	5	5	4.7
Het instrument (materiaal, schacht stijfheid etc.) voelt betrouwbaar tijdens gebruik	4	5	5	4	4	4	3	5	4	4	4.2
Er zijn geen scherpe randen of anderszins oncomfortabele uitsteeksels op het handvat	3	5	5	3	5	4	5	5	5	4	4.4
Het is makkelijk om het instrument vast te houden en te bedienen	1	5	3	4	3	3	2	4	3	2	3
Het is makkelijk om het instrument stil en stabiel te houden	4	5	4	5	2	5	1	5	3	2	3.6
De breedte van het handvat is comfortabel	2	3	2	4	3	5	5	5	5	4	3.8
De joystick beweegt nooit te ver weg om comfortabel te gebruiken	4	5	3	5	4	4	2	5	4	3	3.9
De uitslag van de joystick is representatief voor de uitslag aan de tip	4	5	3	5	1	5	4	4	5	4	4
De frictie in de joystick is comfortabel	4	4	4	5	4	5	4	3	5	2	4
De 'trekker' was comfortabel om te gebruiken	2	4	3	3	2	3	5	5	3	4	3.4
Het was gemakkelijk om de end-effector te openen Ã© te sluiten	2	5	2	4	4	2	3	5	4	4	3.5
Het overhalen van de trekker brengt geen ongewenste spanningen in de hand met zich mee	1	5	2	3	5	2	1	5	3	4	3.1
De roticulator is gemakkelijk om te bereiken	1	5	1	2	1	5	4	5	5	4	3.3
De benodigde krachten om te roteren zijn comfortabel	4	5	3	4	5	5	5	5	3	4	4.3
De benodigde krachten om te sturen zijn comfortabel	4	5	5	4	5	5	4	5	5	2	4.4
De benodigde krachten om de end-effector te openen en sluiten zijn comfortabel	3	5	5	4	5	4	5	5	5	4	4.5

Figure 14: Full list of statements and results per participant

5 Results User Evaluation 2

Question	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Hoe comfortabel is de pols positie?	5/5	4/5	3/5	4/5	4/5
Hoe comfortabel zijn de vingers gepositioneerd?	4/5	2/5	2/5	4/5	4/5
Hoe comfortabel is de positie van de arm (elleboog flexie, elevatie vanaf schouder)	5/5	3/5	3/5	4/5	4/5
Is het openen van de “trekker” net zo comfortabel als het sluiten?	2/5	1/5	1/5	2/5	4/5
Hoe beïnvloedt het ontwerp uw totale houding?	Positief	Negatief, anders dan de Minop	Negatief	Negatief	Positief
Is de joystick comfortabel? Waarom?	Glue resistence is comfortable and creates stability; creates staged use of functions	Not usable in combination with hand position	Unnatural position of hand	Acceptable	Ja
Is het concept bruikbaar met één hand?	4/5	1/5	1/5	2/5	4/5
Was de locatie van de rotatieknop goed bereikbaar?	3/5	2/5	2/5	1/5	4/5
Is het gebruik van het concept op deze wijze (freehand) mogelijk, of heeft u fixatie nodig?	Concept is freehand te gebruiken	Not fitting natural finger movements	Too difficult	Too demanding functions for finger 4 and 3	Concept is gebruiken
Was het gebruik van de “trekker” te combineren met het sturen, of is een lock system nodig?	Combineren was moeilijk	Combineren was te moeilijk	Combineren was te moeilijk	Combineren was te moeilijk	Combineren
Hoeveel beweging voelde u in het gehele instrument tijdens gebruik? Waar kwam dat door?	Natural pose of hand; little complicated extension use.	Not stable	Unnatural	Stable position but function combination not feasible	Stable

Wat is uw favoriete concept?	Concept 1
Welke vorm van de ”trekker” heeft uw voorkeur?	Die van concept 5
Welke joystick heeft uw voorkeur?	Die van concept 1

6 Bill of materials

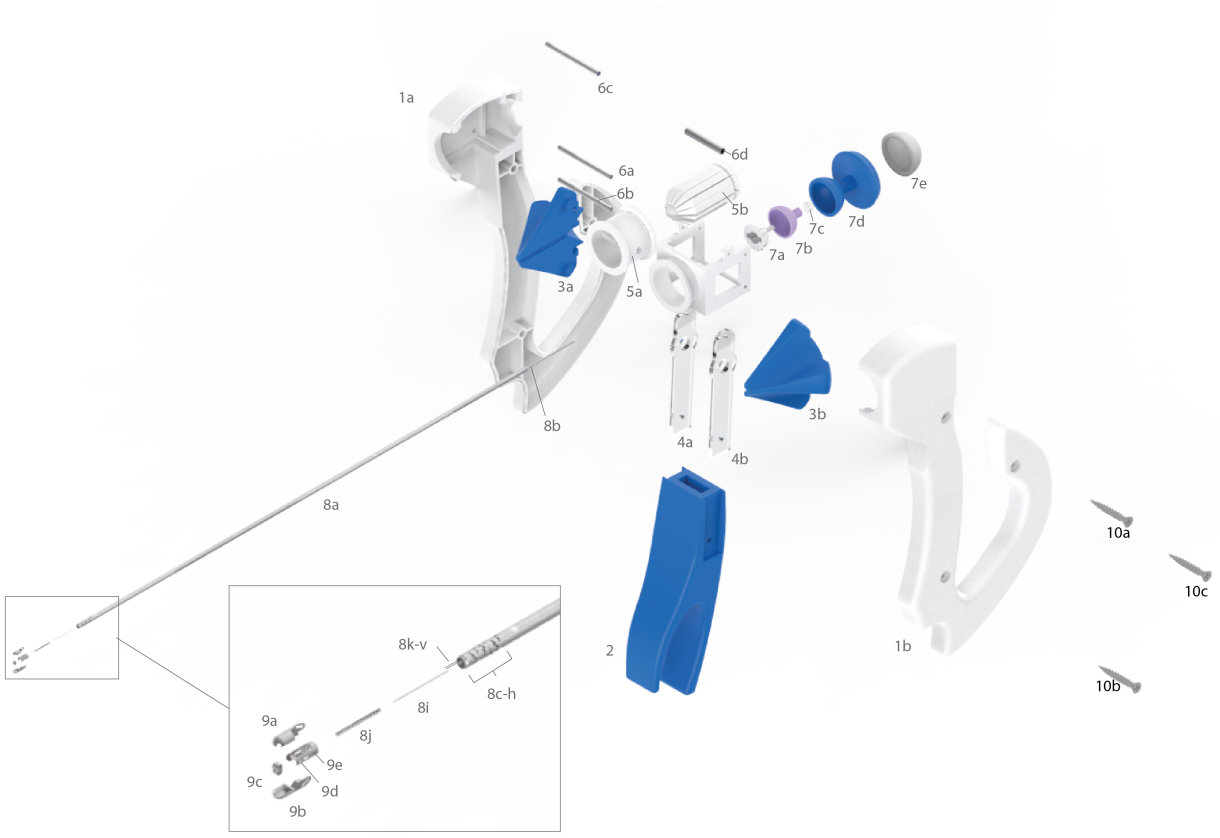


Figure 15: Exploded view with numbered parts

#	(sub assembly) name	letter	Part name	Prototype material	Weight [g]	Product material
1	Body	a	BodyShellR	Formlabs resin	23.7	PC
		b	BodyShellL	Formlabs resin	23.7	PC
2	Trigger			Formlabs resin	20.1	
3	Roticulator	a	RoticulatorR	Formlabs resin	6.8	
		b	RoticulatorL		6.9	
4	Levers	a	LeverR	PMMA	1.24	Integrated with trigger
		b	LeverL		1.24	
5	Sliding mechanism	a	Slider	Formlabs resin	2.1	PC
			SliderBeam	Formlabs resin	5.2	PC
5	Positioning pins	a	Pin1	Stainless steel	0.1	AISI 304
		b	Pin2		0.1	AISI 304
		c	Pin3		0.1	AISI 304
		d	Spacer		0.1	PC
6	Joystick	a	SteeringSphere	Formlabs resin	0.3	PC
		b	CableGuide	Formlabs resin	0.3	Transparent PC
		c	ThumbSpring	Spring steel	0.5	PC
		d	Joystick	Formlabs resin	2.6	PC
		e	Overmold	Sillicone rubber	0.6	Sillicone rubber
7	Shaft	a	OuterTube	AISI 304	2.1	AISI 304
		b	CoreTube	AISI 304	0.4	AISI 304
		c-h	LasercutContours	AISI 304	5x0.01	AISI 304
		i	CoreCable	AISI 304	0.5	AISI 304
		j	CoreSpring	Spring steel	0.9	Spring steel
		k-v	SteeringCables	AISI 304	12x.1	AISI 304
8	Tip	a	JawR		0.03	AISI 316L - 1.4432 (X2CrNiMo17-12-3)
		b	JawL		0.03	AISI 316L - 1.4432 (X2CrNiMo17-12-3)
		c	TipAdaptor	Stainless Steel ?	0.01	AISI 316L - 1.4432 (X2CrNiMo17-12-3)
		d	TipAxel		0	AISI 316L - 1.4432 (X2CrNiMo17-12-3)
		e	ShaftTipInterface		0.02	AISI 316L - 1.4432 (X2CrNiMo17-12-3)
9	Screws	a	Screw1		?	? ?
		b	Screw2	Stock part		
		c	Screw3			
				total weight	93.6	