Design of an ergonomic handle to operate a novel biopsy needle for ductoscopy

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***Abstract*— Most breast lesions, both benign and malignant, originate in the epithelium of the lactiferous ducts and the mammary glands. Ductoscopy is a minimally invasive procedure that enables visualization of the ductal epithelium using a micro-endoscope. Sakes et al. have developed a novel biopsy needle which is capable of high precision resection of high-density breast tumor tissue out of the ductal walls. In this study a handle to operate this biopsy needle is developed. The designed handle integrates all components needed to perform a biopsy; a micro-endoscope, the irrigation fluid and the biopsy needle. The handle is operable with one hand and comprises an actuation mechanism that enables rotation and translation of the needle through one single button. The exterior design of the handle has been designed to optimize comfort during operation and maximize precision of the procedure.**

I. INTRODUCTION

Breast cancer is the most diagnosed cancer in women, with 25.4% of new diagnosed cases in 2018 [1]. Most breast lesions, both benign and malignant, originate in the epithelium of the lactiferous ducts and the Terminal Duct Lobular Unit (TDLU, i.e. the mammary glands). Current techniques of diagnosis such as palpation, breast ultrasound and mammography are inconclusive; lesions can usually only be found when the breast mass is about ⌀5-10mm when using mammography, or a minimum of ⌀10mm when using palpation. By the time the mass is of this size it has been growing for at least 8 years [2], [3]. A minimally invasive technique called mammary ductoscopy or ductoscopy can detect these lesions in an early stage, as small as ⌀0.1mm [3] [1], after which action can be taken immediately.

A. Background ductoscopy

Ductoscopy is an alternative method for visualizing intra-ductal breast lesions. Figure 1 gives an overview of a ductoscope currently used in hospitals and its main components. It consists of a ⌀1.15mm cannula in which a ⌀0.85mm micro-endoscope, irrigation fluid and other tools can be inserted. This results in a cannula with (a maximum of) three separate internal channels. The cannula is attached to a handle by a Luer lock (Figure 1, part 12).

When performing this minimal invasive technique, the cannula is inserted into the nipple. To ensure the comfort of the patient, the nipple area is given a local anesthetic. After the insertion of the cannula, the lactiferous ducts are dilated using a saline solution. The micro-endoscope provides high quality images directly to a screen (10.000px). A physician can directly visualize the lactiferous ducts and potential lesions. Due to the magnification of the micro-endoscopic footage, smaller lesions (⌀0.1mm) can be found compared to the lesions found by conventional breast cancer diagnosing methods (mammography; a sensitivity of 74% for breast lesions smaller than 10mm with a single head camera system and increased to 90% for dual-head systems [6]).

Current devices used to obtain histological specimens during a ductoscopy include cytological brushes, biopsy baskets and forceps (see Appendix I). Cytological brushes are devices with radially oriented bristles, similar to those of a pipe cleaner. The bristles are extended and withdrawn multiple times from the area of interest to obtain useful cells from the lesion. Biopsy forceps have hollow forcipes to resect and enclose the tissue. Biopsy baskets are flexible metallic coils which are expanded in or distal to the lesion to retract sample tissue [7]. These techniques are often used in combination with ductal lavage cytology, which consists of injecting saline into the lactiferous ducts and consequently retrieving this using suction to obtain epithelium cells. Using this technique cells can be retrieved from the narrowest ducts which cannot be reached by a ductoscope, however the quality of the retrieved cells is usually not sufficient for histological examination.

B. Problem

Although the different ductoscopy techniques have increased the possibility of obtaining useful tissue out of the

[1]In The Netherlands ductoscopy is currently only performed on patients with Pathological Nipple Discharge (PND). This being mainly unilateral, nonphysiologic nipple discharge from a single duct unit. Of women with PND, 5-15% are diagnosed with breast cancer or ductal carcinoma in situ (DCIS) [4], [5]

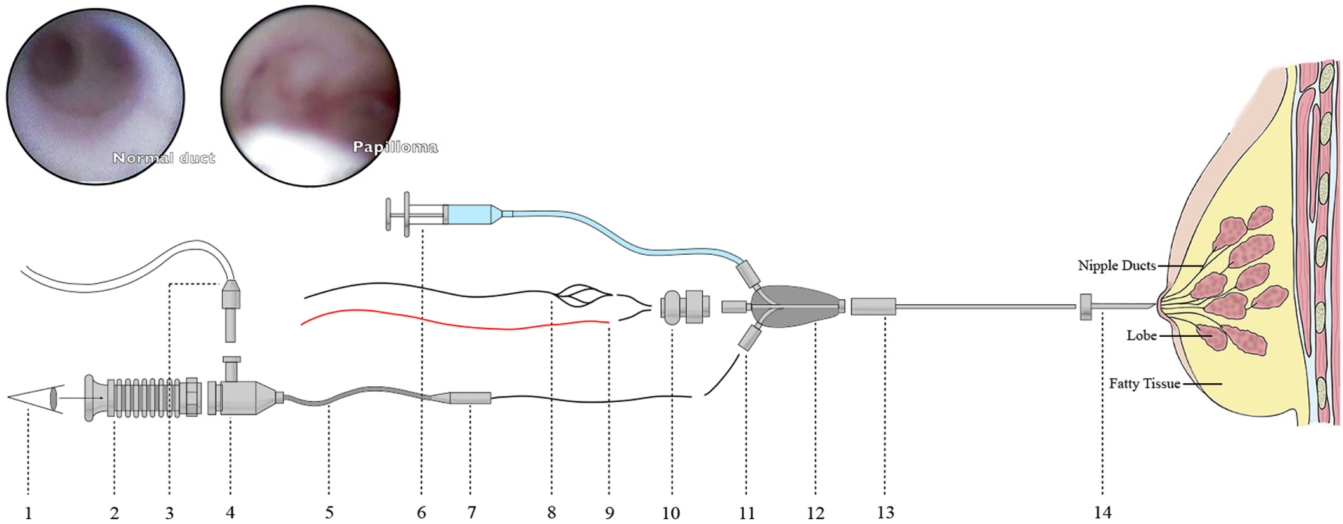


Fig. 1: Overview of a ductoscope. The ductoscope contains a cannula (⌀1.15 1.4 mm; stainless steel or polyshaft tube (13)) connected to a hub/handle (12) to insert the micro-endoscope (7 inserted in 11), irrigation fluid (6), and other tools (such as a biopsy basket (8) and laser wire (9) via a connector (10)). During the first step of the procedure the physician enlarges the lactiferous ducts using the lumen expander (14), followed by the insertion of the cannula (13) containing the micro-endoscope. To obtain the images, the micro-endoscope is coupled to an auto fluorescence endoscopic imaging system (3, 4, 5, and 7) via a custom-made eyepiece (2). When the lactiferous ducts is entered a salt solution (6) is used to enlarge the lactiferous ducts diameter. During the procedure the physician can view the lactiferous ducts on a LCD monitor (1). After the entire breast is examined the instrument is extracted, finishing the procedure. Retrieved from Sakes et al. (2018)

ductal walls for examination, current instruments are not yet capable of high-precision resection of high-density breast tumor tissue [8]. In addition, all instruments are limited by the minimal diameter of the devices. It is not (yet) possible to reach the narrowest branches of the lactiferous ducts and the TDLU.

C. Proposed solution

Sakes et al. (2018) have developed a novel biopsy needle which is capable of high-precision resection of high-density breast tumor tissue out of the ductal walls. This biopsy needle is similar to the biopsy needle depicted in Figure 1 but differs regarding the design of the cannula. Figure 2 shows a cross-section of the cannula with concentric tubes and 4 main elements. A mobile ⌀1.1mm outer tube/cannula wall made of nitinol (1), surrounding an ⌀0.9mm immobile inner tube made out of stainless steel, which together form the biopsy needle. The ⌀0.45mm micro-endoscope (4) is surrounded by irrigation fluid (3). This cannula is connected to the handle by a Luer lock. For this needle a handle is to be developed that allows proper use of the needle, integrates the different elements of the ductoscope and is easy to use.

D. Objective

The goal of this research is to design an ergonomic one-handed operable handle, which accommodates precise translation and rotation of the biopsy needle developed by Sakes et al. (2018) shown in Figure 2.

E. Structure of this report

Section II and III list the design process of the handlepiece and of the actuation mechanism respectively. Subsequently, IV will first elaborate on the combination of the inner and the outer design, after which a final choice is made on which the design will be fine tuned and tested. Section V discusses further improvements on the final handle prototype and section VI gives a conclusion.

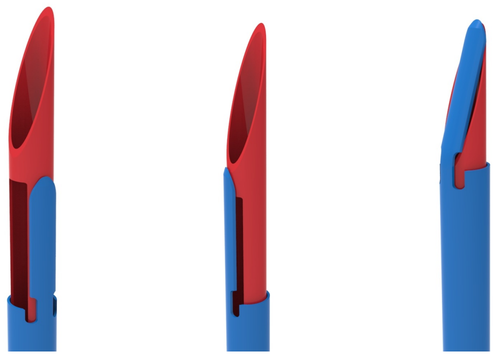


Fig. 2: The novel biopsy needle developed by Sakes et al. (2018). A ⌀1.1mm mobile outer tube/cannula made of nitinol (blue), surrounding an ⌀0.9mm immobile inner tube (red) which is cut off at an angle. Together they form the biopsy needle. The irrigation fluid and the endoscope are run through the inner tube. The outer tube can translate and rotate along the inner tube and enclose a piece of tissue in the void of the inner needle.

II. Design process: Handlepiece design

The design process is divided into two sections; the design of the handlepiece and the design of the actuation mechanism. In this section the process of designing the handlepiece is described. First an ergonomic study is performed to determine the requirements, then the methodology is explained and subsequently the conceptual designs are presented.

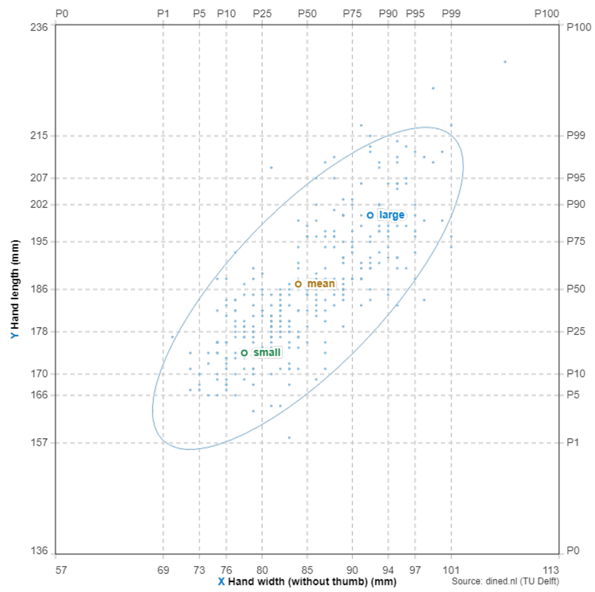


Fig. 3: Measurements of hand widths (without thumb) vs. hand lengths of Dutch male and female adults between 20 and 60 years. Retrieved from DINED [9].

A. Requirements

To determine the ergonomic requirements of the handlepiece design, an ergonomic study has been performed. This study examines the measurements of the average (Dutch) human hand. In examining measurements of the human hand, data from DINED, an anthropometric database from TU Delft, has been used [9]. The chosen population consists of Dutch male and female adults between 20 and 60 years. The three chosen relevant measurements were the *hand width* (across palm without thumb), *hand length* (measured from the lower end of the palm to the tip of the middle finger) and the *grip circumference*. The last measurement is only available for Dutch adults between 20 and 30 years. Figure 3 shows that the mean of the hand width and the hand length is 85mm and 187mm respectively, with a standard deviation of 7mm and 13mm respectively. According to this data, hand sizes have been categorized into small, normal and large subgroups, which are used in the survey, section II-C. Evaluation of the grip circumference data indicates that mean grip circumference is 129mm, with a standard deviation of 13mm. From Figure 3 it can be observed that plotting hand length against hand width gives an elliptical shape, which indicates for some correlation between these two measurements. This information provides an indication of dimension boundaries of the handle. Furthermore, the center of gravity of the instrument should be as close to the virtual center point as possible; this helps to diminish a pendulum effect. Also, regarding a high precision and control procedure, it is conventional to use a trilateral grip, as well as adding textured control surfaces to reduce slippage and optimize control [10].

Following the ergonomic study and additional medical requirements, the subsequent list of requirements for the design of the handlepiece has been set up:

- A handle that caters small, normal and large hands (based on average Dutch hand sizes)
- A grip circumference of 129mm $\pm$ 13mm
- Easy, intuitive design
- Lightweight; no more than 0.3kg.
- At least two input channels
- One output channel
- Easy (dis)assembling
- Sterilization with alcohol and hot water (90°C)
- Operable with one hand, either left or right
- Textured control surfaces are desired
- A trilateral grip is preferred
- The center of gravity should be as close to the virtual center point as possible

B. Handlepiece categorization

To make a complete overview of the different handle models suitable for the design, the ACCREx method will be used [11]. Medical instruments are commonly based on the same geometrical shapes. The used shapes are categorized as follows; pen-shape, nunchuck-shape (based on the Wii nunchuck (*Nintendo, Tokyo, Japan*), a type of controller for a game console), pistol-shape and syringe-shape [7]. Almost all medical handle shapes can be subdivided into those four categories. These shapes mostly differ in the way they are held, which can either be a finger or a palm grip, and the minimal amount of fingers needed to hold the handle in position. The shapes were plotted against each other in Appendix II-A, Figure 13, to examine all possible shape combinations based on the four ”main” shapes. This resulted into ten different handle designs. These combinations were then compared to another set of variables; the grip (finger- or palm-grip) and amount of fingers with which the handle can be operated, which can be seen in Appendix II-B, Figure II-B. From these categorizations four different handle types (1a. pen-shape, 2b. nunchuck, 4b. hybrid and 4d. pistol) were chosen to be examined in more detail in section II-C.

C. Conceptual design

To come up with the best concepts a survey amongst the four chosen handle types was performed, which will be explained in this section. Consequently, the two best scoring handlepieces in the survey are worked out in more detail.

1) The survey: According to the categorization made in section II-B four simple clay models were made of which three can be seen as simplified representations of a pen, a nunchuck and a pistol. The fourth handle is a hybrid handle, which can be seen as a combination between a syringe and a nunchuck shape. The choice was made not to make a model of the syringe due to the fact that it would be fairly similar to the pen shape and that another palm-grip is preferred due to stability (see Appendix II-B, Figure 14). The models are shown in Figure 4.

Fig. 4: Clay models of the handle prototypes. From left to right: pistol, pen, nunchuck and hybrid.

(a) Nunchuck

(b) Hybrid

Fig. 5: a) The nunchuck handle in use. The thumb is placed on top and the index finger on the left/right-hand side. The middle finger may also be used in the final design. b) The hybrid handle in use. The thumb is positioned on top and the index finger is placed on the front top plane. The middle finger may also be used in the final design.

To determine the optimal shape of the handle, a survey (Dossier V) was performed amongst 20 various participants. These participants differ in age, sex, hand dimension, profession and left- or right-handedness. The four different clay models were tested (first individually, later in comparison to each other) and rated on the basis of *comfort*, *stability* and *precision*. Participants ranked the handles from favourite (1 point) to least favourite (4 points) in every category. Subsequently all points were added up; the lowest amount of points indicated the best outcome. Furthermore, the participants could indicate which digits they would prefer to use to actuate a movement followed by the preferred action of this digit (pushing, shoving and/or scrolling). Following the results from the survey, the two best rated handles are chosen to be optimized.

The results of the survey are shown in Table I. The results show a clear preference towards one handle over the other three; the nunchuck. Overall it received the best rating across the three categories (comfort, stability and precision). The hybrid handle scored second-best overall. Therefore, these two designs will be developed further.

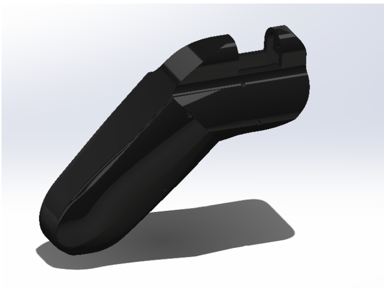
Amongst men the nunchuck received the best rating across all three categories, whereas women varied in preference. Left- and right-handed people scored similar and participants with a medical background showed the same preference as the average preference altogether. No significant preference differences were found based on hand sizes. Results of the performed t-tests to compare means of same variable between groups are found in Appendix III. Except for the difference between left and right-handed people for stability of the pen-shape handle no statistically significant mean differences were found for all other comparisons made. Based on these outcomes the nunchuck and the hybrid handle were chosen as the two handles to optimize. For these two handles the preferred digits for actuating any button are examined. Figure 5 shows the possible digit positions to actuate any button on these handles. According to the survey results, participants using the nunchuck, preferably use their index finger and thumb, but would also use their middle finger for actuation. The index finger could be used to push and the thumb could be used to either push, shove or scroll. When using the hybrid handle the thumb and index finger are, again, favorite. The thumb could push or shove, whereas the index finger preferably only pushes. Extensive survey results can be found in Dossier III.

2) The nunchuck handle: The clay nunchuck was taken as a starting point for the detailed design of the nunchuck handle in SolidWorks 2018 (*Dassault Systmes SolidWorks Corporation, Waltham, USA*). The Wii nunchuck, an ergonomic laparoscopic handle design [12], [13], and the results of the ergonomic study were the basis for the dimensions of the nunchuck-shaped handle. From the articles of Gonzlez et al. and van Veelen et al. it became clear that an angle of 45° between the needle and the handle was preferred in a laparoscopic device. Since for a laparoscopy precise handling and insertion of a needle through a small opening is also needed, it can be used as a guideline for a ductoscopy handle design. With these matters considered, a first concept version of the handle was designed and 3D-printed. This design was evaluated for its comfort and usability, which implies looking at the position of the buttons; whether they are reachable and with which digits, whether there are uncomfortable sharp corners or any pressure points etc. Several iterations occurred, implying adjusting the SolidWorks model based on the feedback, 3D printing it and assessing again, until the desired shape was reached. A total of three iterations were done to optimize

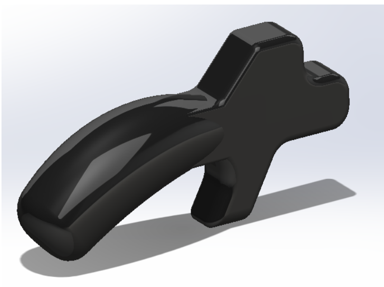
TABLE I: Survey results

Category	Design	Total points	Male	Female	Left-handed	Right-handed	Medical background	Non-medical	Small hands	Medium hands	Large hands
Comfort	Gun	45	23	22	12	33	10	35	14	31	8
	Pen	69	33	36	14	55	14	55	25	38	11
	Nunchuck	30	14	16	6	24	6	24	12	17	3
	Hybrid	53	30	23	8	45	10	43	16	34	8
Stability	Gun	53	23	30	14	39	12	41	20	27	12
	Pen	64	32	32	9	55	13	51	24	42	6
	Nunchuck	39	19	20	9	30	7	32	14	22	6
	Hybrid	44	26	18	8	36	8	36	12	29	6
Precision	Gun	65	30	35	15	50	12	53	24	37	10
	Pen	43	26	17	5	38	9	34	11	29	8
	Nunchuck	43	20	23	9	34	10	33	17	23	7
	Hybrid	49	24	25	11	38	9	40	18	31	5
Average	Gun	54.33	25.33	29.00	13.67	40.67	11.33	43.00	19.33	31.67	10.00
	Pen	58.67	30.33	28.33	9.33	49.33	12.00	46.67	20.00	36.33	8.33
	Nunchuck	37.33	17.67	19.67	8.00	29.33	7.67	29.67	14.33	20.67	5.33
	Hybrid	48.66	26.67	22.00	9.00	39.67	9.00	39.67	15.33	31.33	6.33

Notes Table I: Most important survey results categorized in comfort, stability and precision. Total number of participants is 20; 10 males and 10 females; 4 left-handed and 16 right-handed; 4 participants with a medical background and 16 with a non-medical background; 7 small hand-sized, 10 medium hand-sized and 3 large hand-sized participants. The participants rated the handles from highest (1 point) to lowest (4 points) in every category. The best-scoring handle within each category is thus the one with the lowest amount of points, and is highlighted green.



(a) Nunchuck



(b) Hybrid

Fig. 6: Final concept SolidWorks models of a) the nunchuck and b) the hybrid handle

the design, which are explained more elaborate in Dossier I-A.1. Eventually a final concept was developed, which can be seen in Figure 6.

3) The hybrid handle: The first design of the handle was based on a M5 Microdebrider (*Medtronic, Dublin, Ireland*), a state of the art device used for rhinoplasty surgery [10]. With this device in mind the clay model was developed and optimized for comfort and usability. This was also the basis for the first design made in SolidWorks. Just as the design of the nunchuck, this model was 3D-printed and evaluated. After this evaluation two more iterations were done to come up with the perfect design. The main changes made were the elongation and enlargement of the back shaft, adding bigger fillets to make the edges more comfortable and bending the back shaft 45° to follow the shape of your hand better. The front part was initially reduced in size but when assembling both the inner mechanism and the hybrid design it became clear that more space was needed. After 3 iterations the final concept was printed which can be seen in Figure 6.

III. Design process: actuation mechanism

In this section the process of designing the actuation mechanism is described. First the requirements of the actuation mechanism are listed, then the methodology is explained and subsequently the first conceptual designs are presented.

A. Requirements

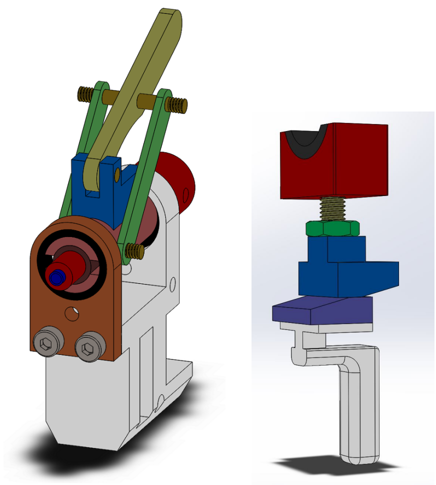
To ensure that the actuation mechanism enhances the capability and functionality of the novel biopsy needle designed by Sakes et al. (2018), the internal mechanism should meet the following requirements:

- 2mm forward and backwards translation of the biopsy needle
- 90° clockwise and counter clockwise rotation of the biopsy needle
- Possibility to “lock” the entire mechanism when no displacement of the needle is desired
- Precise handling by the user, a margin of $\pm$ 0.5° rotation and $\pm$ 0.05mm translation is allowed
- Keeping the actuation mechanism clean and thus free from sterilization is desired

B. Actuation mechanism categorization

To explore all available options for an internal working mechanism that meets the requirements, following the AC-CREx methodology, a distinction has been made between translation and rotation movement. These categories were subdivided in types of actuation; mechanical, electrical, pneumatic or hydraulic, and in direct or indirect drive. For these categories different mechanisms were found based on the type of transfer medium (gears, bars, belts and shapes). Appendix II-C, Figure 15 gives an overview of all possible translation and rotation mechanisms found. Electric, pneumatic and hydraulic categories have not been further elaborated on since this type of actuators are deemed too complex for the size and purpose of the to be designed device. Furthermore, extra rules and requirements are set for medical devices which do not work solely mechanical, thus the choice was made to only explore mechanical mechanisms.

All rotation and translation mechanisms have been evaluated against a set of criteria which include: precision of handling; complexity; continuous movement; easy (dis)assembling; weight; scalability and intuitive use, and given points accordingly. The schematic overview in Appendix II-D, Table II and Table III gives an overview of the final points obtained for each working principle. The best scoring mechanisms were selected to be combined. From these combinations two prototypes follow; a *bar linkage-slider translation combined with a direct rotation* and a *rack and pinion translation with a bevel gear rotation*. These concepts are further elaborated on in section III-C.



(a) (b)

Fig. 7: a) Bar linkage-slider with direct rotation. Pressing or rotating yellow rod actuates the red tube which is connected to the outer needle. b) Retention-mechanism located behind the bar linkage-slider (not shown in (a)). By pulling the white handle pressure exerted by the red block on the actuation mechanism (red part in Figure a) is increased, inhibiting movement of the needle.

C. Conceptual design

In this section the two prototypes for the actuation mechanism, following from the categorization and evaluation in section III-B, are explained.

1) Bar linkage-slider with direct rotation : In essence this mechanism is a different version of the Scott Russell Linkage [14] and is shown in Figure 7. It consists of a (yellow) lever used to actuate the needle, two (green) connection rods that couples the motion of the lever to a pink and red tube. The outer tube (pink) can only rotate and contains a slot to enforce horizontal motion of the rods. The inner tube (red) is connected to the outer cannula of the needle (see Figure 2) with a set screw and thus both can rotate and translate. The inner tube of the needle will run through the inner tube of the mechanism (red).

A retention-mechanism ensures the needle remains in position, this is shown in Figure 7b. By pulling the handle (white), two inclined planes (blue, purple) slide over each other increasing the pressure of the screw (green, yellow) against the block (red) and thus increasing the pressure on the needle, inhibiting movement.

2) Rack and pinion translation with bevel gear rotation: This mechanism is shown in Figure 8. The translation of the needle is controlled by turning the green wheel on top of the design. This wheel drives a rack and pinion system, of which the rack is connected to the needle. To ensure a high resolution translation, a gearbox with ratio 8,68:1 is added to the system. For the required translation of 2mm, the green wheel would have to rotate 1.842π radians.

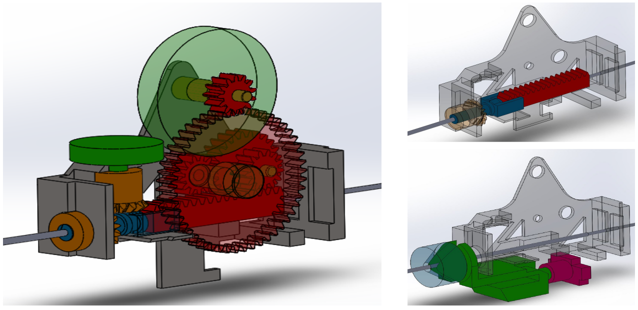
To achieve rotation of the needle two bevel gears (orange) are used. In this design a ratio of 1:1 is used, but this could be altered to 2:1 or 3:1. This initial choice was made with the procedure in mind. If the tip of the needle reaches the final position the outer tube will have to rotate a total of 0.5π radials. For this application the resolution of movement is less important since the goal is to rotate over the full distance and this can easily be accomplished by a trained physician in the current design.

The needle is connected to the rack via a connection-bar (blue, Figure 8a). This part is needed since the needle both rotates and translates, whereas the rack may only translate. The outer part of the needle is connected to the lighter blue part with a small setscrew, and the inner part of the needle passes through the rack. The lighter blue part can rotate but not translate with respect to the darker blue part, allowing the needle to rotate without rotating the rack.

To ensure the needle remains in position a retention-mechanism has been incorporated, shown in Figure 8b. This mechanism consists of a, not shown, spring that applies constant pressure to the green button in a way that the tip of button, consisting of two halves of a cone, are pressed into a mirrored shaped mould (transparent blue, Figure 8b). As the needle passes through the cone the two halve parts exert pressure onto the needle, keeping it from moving. When pressing the green button, i.e. moving it backwards, pressure is released from the needle allowing it to move.

IV. Complete handle design

In this section two complete handle design are introduced. After evaluation by physicians one design is chosen. Integration of the endoscope and the irrigation channel are explained, as well as the material selection. Eventually the final design and its evaluation will be introduced.



(a) (b)

Fig. 8: a) Rack and pinion translation and bevel gear rotation. Rotating the upper green wheel drives a rack and pinion. The rack is connected to the outer needle. Rotation of the needle is achieved via a set of orange bevel gears. b) Top: *Connection mechanism*; connects the rack to the needle, separating translation from rotation movement. Bottom: *Retention mechanism*; a spring exerts pressure on the green button, pressing into two half cones onto the into the blue mold, inhibiting the needle to move.

A. Combined interior and exterior design

Integrating the two chosen interior and exterior designs have led to two complete prototypes; a nunchuck handle with a bar linkage-slider translation and direct rotation mechanism and a hybrid handle with a rack and pinion translation and bevel gear rotation mechanism as shown in Figure 5a and b respectively. Further on these will be referred to as "nunchuck" and "hybrid".

B. Evaluation at the hospital

To determine whether the two conceptual handle designs meet the expectations of the end-user, the handles were tested amongst two physicians at Universitair Medisch Centrum Utrecht (UMCU), Dr. A.J. Witkamp (surgeon-oncologist, UMCU) and Dr. M. Filipe (PhD at the department of Surgical Oncology, UMCU). It was made clear to them that both actuation mechanisms could be placed in either handle design. After careful consideration and in collaboration with the physicians the choice was made to further refine the nunchuck handle in combination with the bar linkage-slider mechanism. Below the remarks of the physicians regarding the two conceptual designs are stated. These remarks were incorporated into the final design of the handle prototype.

- Shape-wise the nunchuck is preferred over the hybrid due to the fact that it is an easy, intuitive design and an underhand pen-grip is possible. The ability to switch between a palm-grip and a pen-grip provides more stability and precision.
- To make an underhand pen-grip possible the head of the nunchuck handle should become thinner.
- Overall the nunchuck handle should be made a bit thinner, which makes it better to handle.
- Relocate the position of the input channels from the bottom of the handle closer to the needle because of the limited length of the endoscopes used.
- If possible, rubber grip-pads should be added.
- The bar linkage mechanism is preferred to the rack and pinion mechanism due to the fact that this mechanism can be operated with only one finger. Furthermore it is intuitive in use.
- To maximize the usability of the retention-mechanism an off/on-switch is preferred instead of a button which is continuously pressed.

C. Integration micro-endoscope and irrigation

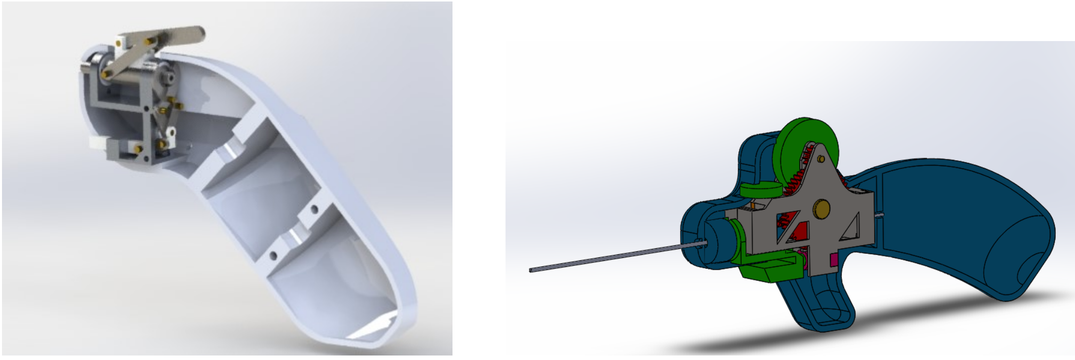
To achieve integration of the micro-endoscope and irrigation channel two input channels have been designed. An overview is given in Figure 10. The micro-endoscope (which is connected to an optic shifter) and the irrigation channel are connected to a combiner, which combines two input channels into one output channel. The combiner resembles the device currently used when performing a ductoscopy (also shown in use in Figure 1. The combiner is coupled with a Luer lock to a coupling tube, inclined at 45° with a radius of curvature of 5mm. The coupling tube slides over the inner needle, guiding the micro-endoscope and irrigation fluid through the inner needle.

To maximize user comfort the endoscope and irrigation channels have been integrated inside the handle. This way all cables exit at the back of the handle. The handle is designed to be printed in two mirrored pieces, for easy (dis)assembly. This way, to attach the irrigation fluid channel and optic shifter, the handle is opened and the channels are connected using two Luer locks. By sliding the two pieces over each other the handle is form-closed in the *width-direction* of the handle. Using a bolt and a nut the handle is force-closed in the *length-direction*. Appendix V outlines the sterilization protocol for the handle after usage. By using a disposable cannula around the needle the handle and mechanism do not come in contact with the "contaminated" needle and thus sterilization after each procedure is not necessary. However sterilization of all the parts is possible

D. Material selection

For the final design to function properly the material selection is very important. To have a good "feeling of what the needle is doing, a low friction is needed in the inner mechanism. This is achieved by using plain bearings both between the inner and outer tube and between the outer tube and the housing (see Figure 7a, orange part). The use of bearings for the other connection points is not possible due to the spare available space. Therefore, all shafts are made of brass and all rods and tubes are made of stainless steel. This combination is made because of the relatively low coefficient of friction between brass and stainless steel (0.4 [15]) and the good corrosive resisting properties of these materials[16].

For the handle the types of materials are limited because the material must be compatible with additive manufacturing. A satisfactory material is polycarbonate. Because of it is high glass transition temperature it will not deform easily when cleaned with hot water and, if needed, it can be sterilized with alcohol. Furthermore, the material has a relatively low density making it complying with the weight requirement of the handle [17].



(a) (b)

Fig. 9: a) Nunchuck handle with bar linkage-slider translation and direct rotation; b) Hybrid handle with rack and pinion translation and bevel gear rotation

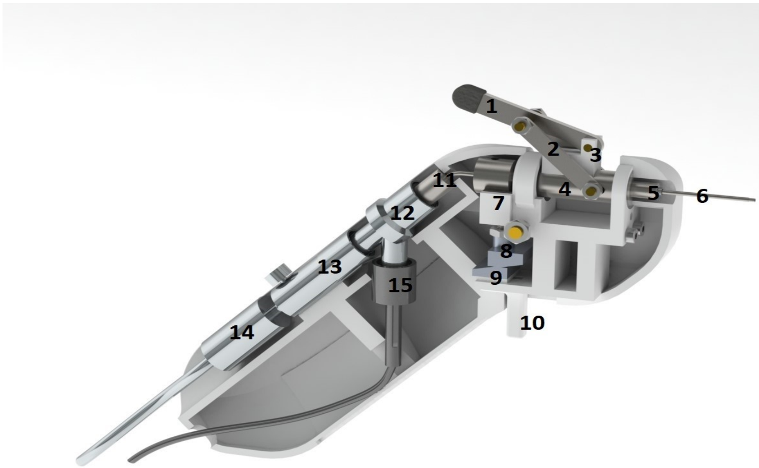


Fig. 10: Final design of the handle. It consists of a lever (1), used to actuate the needle, a connection rod (2), that couples the rotation of (1) to a horizontal motion. A pivot (3), which enables rotation of (1), an outer tube (4), which can only rotate and contains a slot to enforce horizontal motion of (6). An inner tube (5), which is connected to the outer needle with a set screw and can rotate and translate. A needle (6). A brake pad (7), which is pressed against (5) to lock the system. A height adjustable inclined plane (8), the distance between this part and (7) can be increased or decreased with a nut to increase or decrease the amount of friction applied by (7). An inclined plane (9), in combination with (8) decreases and changes the direction of the actuation force to release or press the brake pad against (5). A switch (10), if moved forward reliefs pressure applied by (7) on (5), which enables the system to be used. If then moved backwards causes (7) to be pressed against (5) and thus locking the mechanism. Coupling (11), connects the inner needle with (14) and (15). A combiner (12), combines the inputs of (14) and (15) in to one output. It is connected to (11) by a Luer lock. An optic shifter (13), which enables length adjustment and connection point of (14). It is attached to (14) with a set screw and connected to (12) by a Luer lock. Optics (14), enables visualization of the lactiferous ducts and an irrigation channel (15), used to flush and expand the lactiferous ducts, are connected to (12) by a Luer lock.

E. Final design

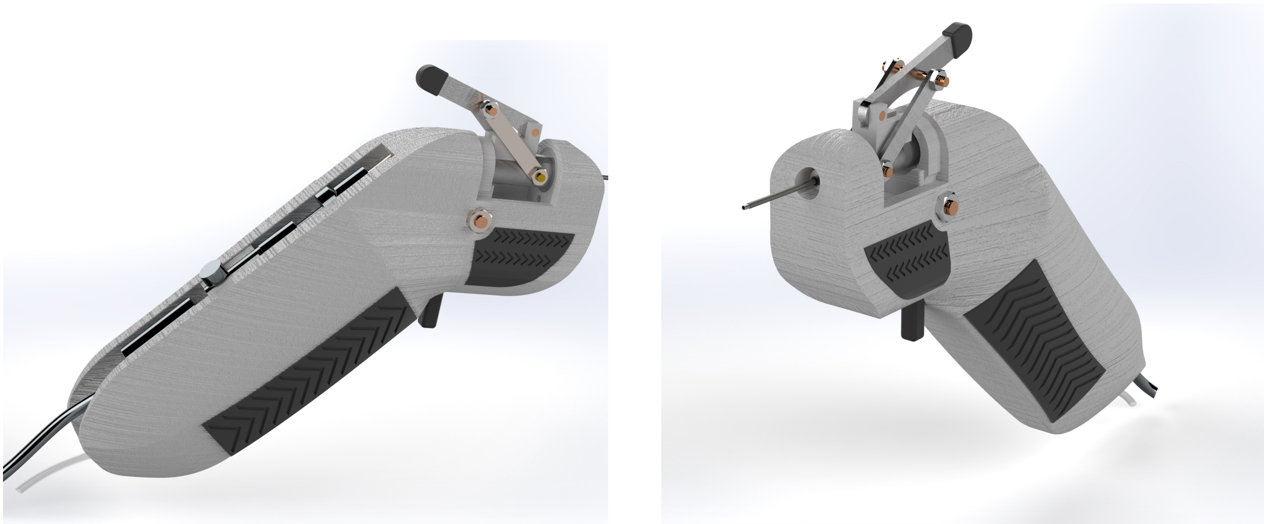
The final design comprises the nunchuck handle with the bar-linkage slider actuation mechanism. The handle design was overall preferred by the participants in the survey and the physicians in the hospital. The bar-linkage actuation mechanism was preferred over the rack and pinion mechanism because of the integration of rotation and translation actuation in one button. Based on the recommendations of the physician, the design of the handle was altered to incorporate a pen-like grip, which increases precision during the insertion of the needle into the nipple. After insertion the grip can be changed to the standard grip in which the buttons can be operated. Rubber grip pads have been placed alongside the handle for a better handling and comfort.

The final design of the handle for the biopsy needle developed by Sakes et al. (2018) is shown in Figure 11. The positioning of the inner mechanism can be seen in Figure 10.

F. Evaluation of the final design

In order to evaluate whether the final prototype meets the predetermined design requirements different tests have been performed. The findings are discussed below.

1) Rotation and translation: The actuation mechanism is able to perform a 2mm translation and 90° rotation of the biopsy needle. The required precision was 90±0.5° and 2±0.05mm. This precision could not be tested using the current prototype, however it is highly expected that the design meets this precision when professionally manufactured.



(a) Side view (b) Frontal view

Fig. 11: Final design based on the recommendations of the physicians; integrating the input channels, including a pen-grip and rubber-pads for stability and comfort.

2) The retention-mechanism: Based on an estimated clamping force of 15N, the force needed to unlock the mechanism is 6N, whereas the needed force to lock the mechanism is 8.9N. Since more force can be applied by flexing compared to extending the finger, the locking is done by flexion of the index finger. Buckling and yielding of the material is not expected to be a problem since the critical load of the thread is several orders of magnitude higher compared to the expected load. Stress on the material also remains far below the yield strength of the stainless steel thread. No reliable estimate could be obtained of the deformation of the rubber pad under the estimated forces. A complete overview of the calculations can be found in Appendix IV-B.

3) Weight: The final prototype has been 3D printed in R5 reaching a total weight of 50g. The actuation mechanism has a total weight of 20g. Including the needle, the two input channels to integrate the micro-endoscope and irrigation fluid with the handle and all necessary connection parts the total handle weight will not surpass the requirement of a maximum of 0.3kg.

V. Discussion

A. Summary of main findings

The final design comprises the nunchuck handle with a bar-linkage slider actuation-mechanism. The complete handle integrates two input channels for the micro-endoscope and the irrigation fluid with one output channel for the biopsy needle. The actuation mechanism achieves the desired rotation and translation of the biopsy needle and can be locked via a designed retention-mechanism. The actuation mechanism can be kept free from sterilization after each procedure by using a disposable tube around the needle. The handle is operable with one hand, using the index finger to (un)lock the needle and the thumb to actuate the needle. A palm- and pen-grip have been integrated in the design. This has been done to achieve the desired precision during insertion of the needle in the nipple (using the pen-grip) and accurate resection of the tissue with the needle (using the palm-grip). The handle is lightweight; the total weight, including input and output channels, does not surpass 0.3kg. The materials chosen for the design are polycarbonate for the handlepiece (as this material is easy to sterilize), brass for the axes and stainless steel for the rods and tubes of the actuation mechanism (mainly to achieve low friction in the mechanism). The handle design has been finished using a textured, rubber surface to increase stability and comfort for the user.

B. Limitations of this study

The survey has been conducted amongst twenty participants, which is a relatively small group. Most of them did not have a medical background. For a better evaluation of the handlepiece design a larger group of medical orientated participants is desired. Furthermore, only two (male) physicians have evaluated the handle design. To achieve a broader support of the chosen design it should be tested amongst a larger group of physicians with different hand sizes, preferably including women. At the moment the procedure is only performed in the Netherlands at the UMCU, therefore this is something that can be done when the procedure has expanded across more academic and general hospitals.

Another limitation of this study is the manufacturing of the actuation mechanism. Since the scale of the components of the mechanism is very minute it was hard to manufacture these with the desired precision using the available equipment. The final design of the complete handle should be manufactured using professional equipment.

C. Recommendations for future research

The handle has not yet been used in practice. For future research a clinical trial to test the functionality of the complete handle should be performed (implying integration of the input channels, the actuation mechanism and the needle). Preferably this should be performed amongst a larger group of physicians to test for widespread support of the chosen design. It should also be tested whether the handle caters all users of the target group or whether it is preferred to make the handle adjustable over a certain range.

The final design integrates the input channels within the handle, implying that after every procedure the handle should be opened to sterilize the used needle, set a clean needle in place and couple the input channels. Practicality should be tested.

As further down-scaling of the biopsy needle could be desired it might be possible that the handle should be adjusted too. This is something to take into account in future research.

VI. Conclusion

In this study a handle to operate the novel biopsy needle developed by Sakes et al. 2018 has been designed. This devise has been developed to explore the mammary ducts and simultaneously do a biopsy to study the tissue ex-vivo. The design of the handlepiece is based on the Nintendo Wii Nunchuck, a laparoscopic handle design and the results of a small conducted ergonomic study. The actuation mechanism is a bar linkage-slider system, based on the Scott Russel linkage with the addition of rotating the needle directly by rotating the lever. Additionally, a retention-mechanism has been integrated. The handle has been optimized by 3D-printing the design, evaluating, redesigning and subsequently iterating over again.

The final design of the handle is shown in Figure 11. The positioning of the inner mechanism can be seen in Figure 10.

Acknowledgements

We would like to thank Dr. Ir. Aimée Sakes for guiding us through the process of designing the handle and providing us with helpful insights along the way, as well as Dr. A.J. Witkamp and Dr. M. Filipe for providing us with feedback on the designed prototypes and the necessary medical information. Also we would like to thank D. Jager and R. van Starkenburg for providing insight into the general manufacturing process and for manufacturing the final handle prototype.

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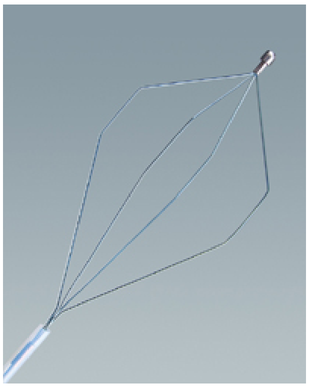
APPENDIX I
CURRENT DEVICES USED IN DUCTOSCOPY

(a) Cytology brush [18]



(b) Biopsy basket [19]

(c) Biopsy forcipes [20]

Fig. 12: Current devices used in ductoscopy

APPENDIX II
ACCREx CATEGORIZATIONS

A. *Handlepiece design: shape categorization*

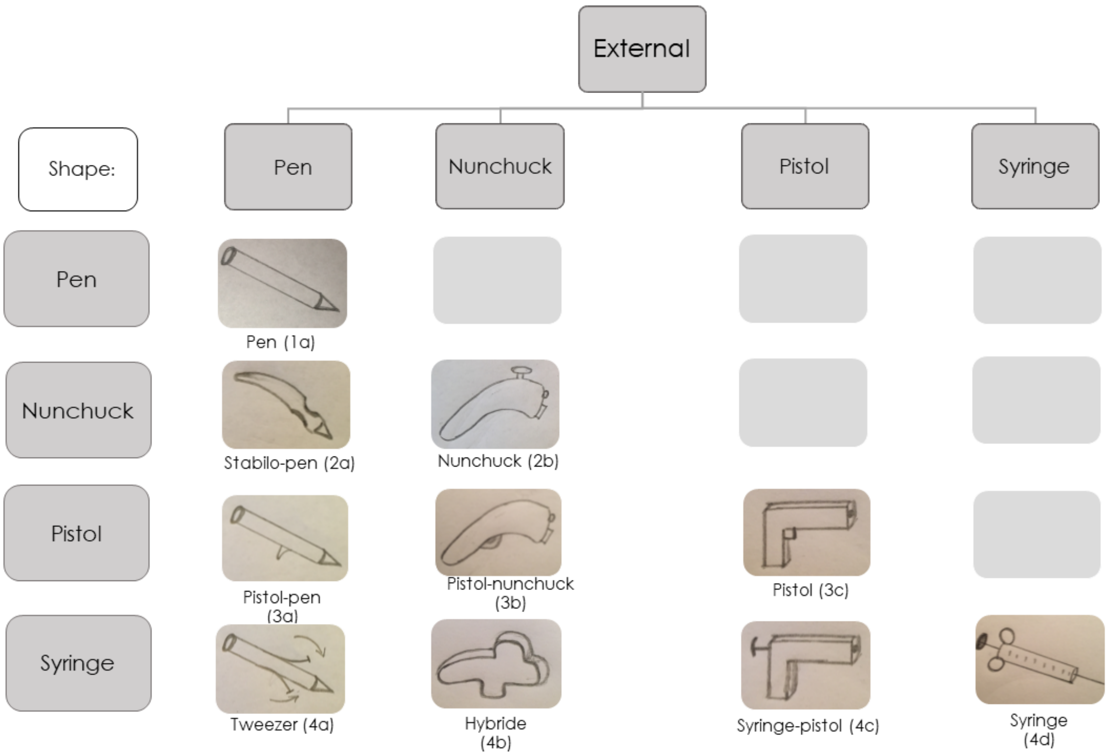


Fig. 13: Handlepiece design: overview possible shapes following from combining the four basic forms; pen, nunchuck, pistol and syringe shape.

B. Handlepiece design: grip categorization

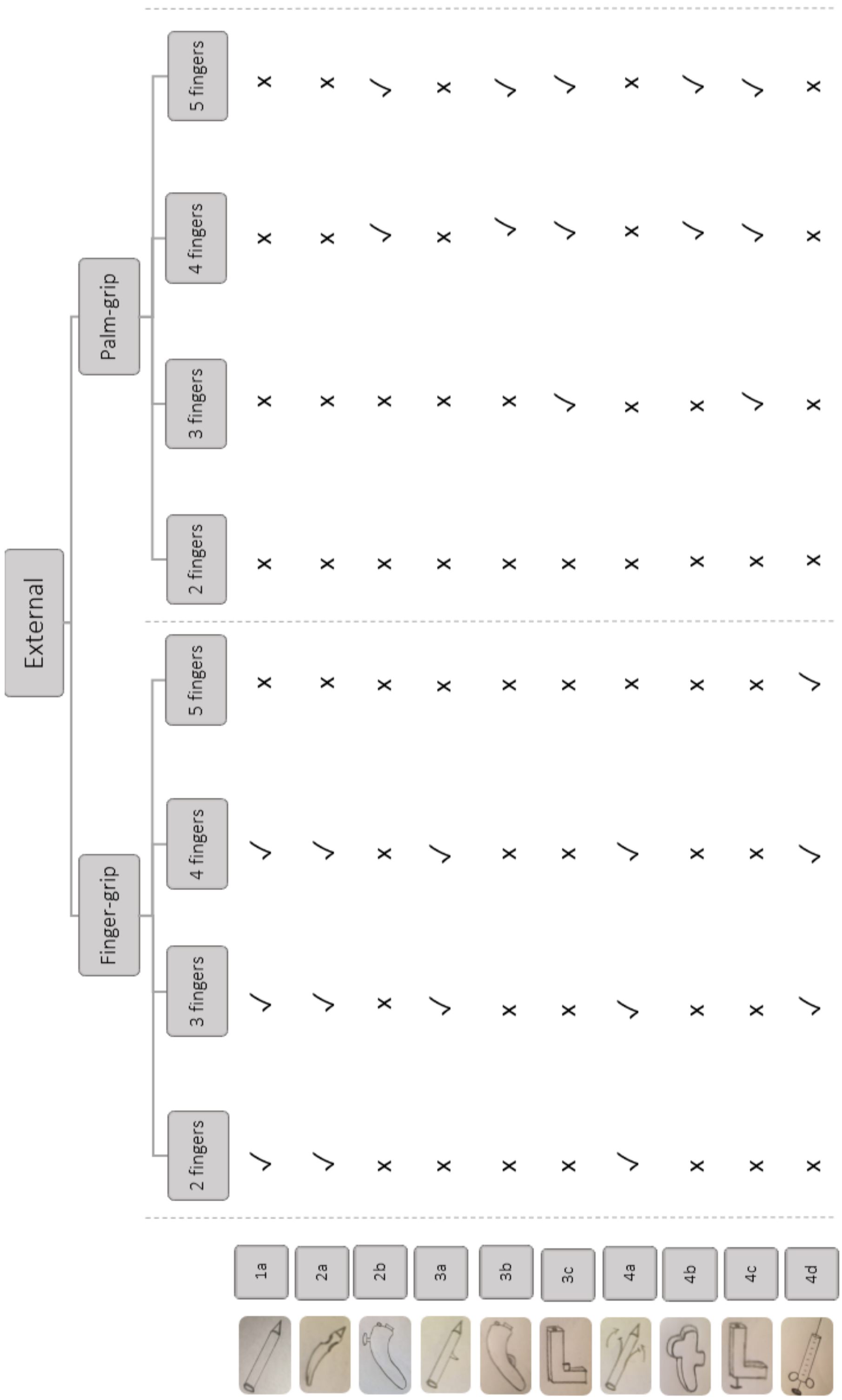


Fig. 14: Handlepiece design: grip-categorization of all possible shapes following from Figure 13. A check mark indicates the indicated handlepiece can be held with either a finger grip or a palm grip and with the indicated number of fingers.

C. Inner working mechanism: ACCREx categorization

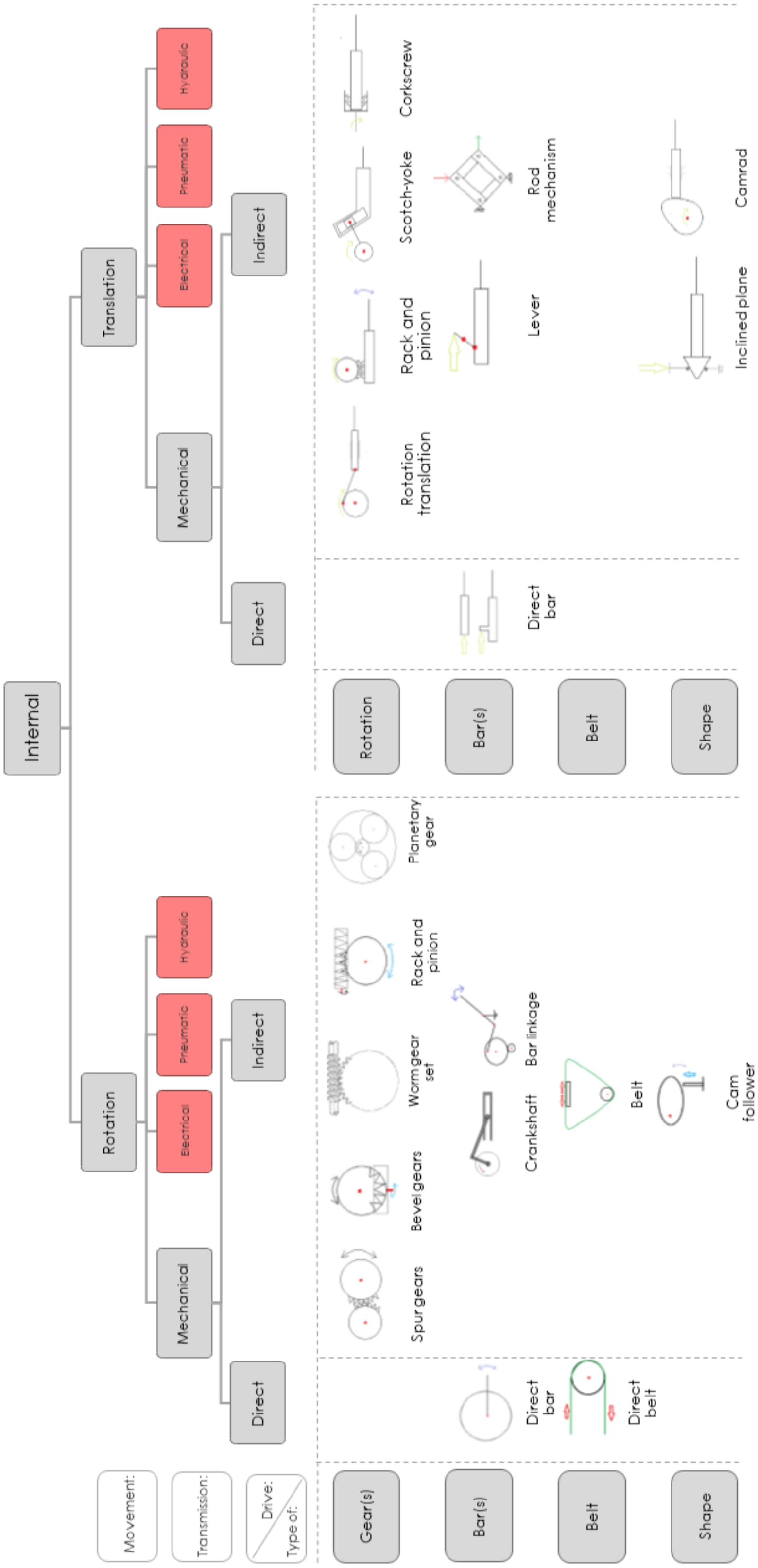


Fig. 15: Inner working mechanism categorization according to 1) type of movement; 2)type of transmission; 3)direct of indirect drive; and 4) type of actuator (gear, bar, belt or shape).

D. Inner working mechanism: morphological overview rotation and translation mechanisms

TABLE II: Overview score different rotation mechanisms

Criteria and mechanisms	CW/CCW rotation	Precision	Continous move-ment	Easy (dis)-assembling	Simplicity	Weight	Scalability	Intuitive use	**Total score**
Direct bar	1	5	1	5	5	5	1	5	**28**
Direct belt	1	2	1	4	4	4	1	5	**22**
Bar linkeage	1	3	1	3	3	4	3	4	**22**
Spur gears	1	4	0	4	4	3	3	4	**23**
Crankshaft	1	4	1	3	4	3	3	4	**23**
Belt	1	2	1	4	4	3	2	4	**21**
Worm gear set	1	4	0	3	4	2	2	4	**20**
Rack and pinion	1	4	0	3	4	2	3	4	**21**
Cam-follower	1	2	0	4	4	4	2	2	**19**
Planetary gear	1	4	0	1	2	2	1	4	**15**
Bevel gears	1	4	0	4	4	4	3	4	**24**

Notes table II: Each rotation mechanism identified in Figure 15 is evaluated against a set of criteria which include: clockwise/counterclockwise rotation (0=no, 1=yes); precision of handling (1=imprecise, 5=precise); continuous movement (0=no, 1=yes); easy (dis)assembling (1=difficult, 2=easy); simplicity (1=complex, 5=simple); weight (1=heavy, 5=light); scalability (1=difficult to scale, 5=easy to scale) and intuitive use (1=not intuitive, 5=intuitive), and given points accordingly. Two best-scoring mechanisms are highlighted green.

TABLE III: Overview score different translation mechanisms

Criteria and mechanisms	Back-and forward	Precision	Continuous move-ment	Easy (dis)-assembling	Simplicity	Weight	Scalability	Intuitive use	**Total score**
Direct bar	1	1	1	4	4	5	1	5	**22**
Lever	1	1	1	4	4	4	3	4	**22**
Inclined plane	1	3	1	3	3	4	2	5	**22**
Rot-translation	1	4	1	4	4	4	3	3	**24**
Rack and pinion	1	4	0	4	4	4	3	5	**25**
Corkscrew	1	4	1	3	3	3	3	3	**21**
Camrad	1	3	0	4	4	3	2	2	**19**
Scotch-yoke	1	4	1	3	2	3	4	3	**21**
Rod mechanism	1	4	1	3	4	4	2	4	**23**

Notes table III: Each translation mechanism identified in Figure 15 is evaluated against a set of criteria which include: back-and forward translation (0=no, 1=yes); precision of handling (1=imprecise, 5=precise); continuous movement (0=no, 1=yes); easy (dis)assembling (1=difficult, 2=easy); simplicity (1=complex, 5=simple); weight (1=heavy, 5=light); scalability (1=difficult to scale, 5=easy to scale) and intuitive use (1=not intuitive, 5=intuitive), and given points accordingly.Two best-scoring mechanisms are highlighted green.

Appendix III
Results t-tests survey

TABLE IV: t-test results for mean comparisons for the different handle types between groups of variables *Comfort*, *Stability* and *Precision*

Variable - handle shape	**Gender**		**Background**		**Left-right handed**	
	diff.	t-test	diff.	t-test	diff.	t-test
Comfort						
Pistol	0.1000	(0.23)	-0.313	(-0.57)	0.938	(1.84)
Pen	-0.300	(-0.88)	-0.0625	(-0.14)	0.0625	(0.14)
Nunchuck	-0.200	(-0.73)	0	(0.00)	0	(0.00)
Hybrid	0.700	(1.41)	0.188	(0.29)	-0.813	(-1.30)
N	20		20		20	
Stability						
Pistol	-0.700	(-1.30)	-0.438	(-0.63)	1.063	(1.61)
Pen	0	(0.00)	-0.0625	(-0.11)	-1.188*	(-2.53)
Nunchuck	-0.100	(-0.32)	0.250	(0.64)	0.375	(0.98)
Hybrid	0.800	(1.55)	0.250	(0.37)	-0.250	(-0.37)
N	20		20		20	
Precision						
Pistol	-0.500	(-1.17)	0.313	(0.57)	0.625	(1.17)
Pen	0.900	(1.66)	-0.125	(-0.17)	-1.125	(-1.66)
Nunchuck	-0.300	(-0.82)	-0.438	(-0.96)	0.125	(0.27)
Hybrid	-0.100	(-0.20)	0.250	(0.40)	0.375	(0.60)
N	20		20		20	

t statistics in parentheses; * $p<0.05$. ** $p<0.01$, *** $p<0.001$

Notes table IV: The t-test compares the means between the two groups, the null hypothesis being that the difference between the means is zero. The t-statistic is the ratio of the mean of the difference to the standard error of the difference.

```
%STATA code for performing different t-tests
clear
cd "\\campus.eur.nl\users\Students\354798sv\Desktop\TU DELFT"
use "survey_results.dta"

%perform some t-tests: by gender
estpost ttest comfortabel_pist comfortabel_pen comfortabel_n comfortabel_h, by(geslacht)
esttab using testgender.csv, replace  t wide mtitle("diff." )

estpost ttest stabiel_pist stabiel_pen stabiel_n stabiel_h , by(geslacht)
esttab using testgender.csv, append wide mtitle("diff." )

estpost ttest nauwkeurig_pist nauwkeurig_pen nauwkeurig_n nauwkeurig_h , by(geslacht)
esttab using testgender.csv, append wide mtitle("diff." )

%perform some t-tests: by medicalnomedical

estpost ttest comfortabel_pist comfortabel_pen comfortabel_n comfortabel_h, by(medicalnomedical)
esttab using testmed.csv, replace wide mtitle("diff." )

estpost ttest stabiel_pist stabiel_pen stabiel_n stabiel_h , by(medicalnomedical)
esttab using testmed.csv, append wide mtitle("diff." )

estpost ttest nauwkeurig_pist nauwkeurig_pen nauwkeurig_n nauwkeurig_h , by(medicalnomedical)
esttab using testmed.csv, append wide mtitle("diff." )

%perform some t-tests: by rechtslinkshandig

estpost ttest comfortabel_pist comfortabel_pen comfortabel_n comfortabel_h, by(rechtslinkshandig)
esttab using testhand.csv, replace wide mtitle("diff." )

estpost ttest stabiel_pist stabiel_pen stabiel_n stabiel_h , by(rechtslinkshandig)
esttab using testhand.csv, append wide mtitle("diff." )

estpost ttest nauwkeurig_pist nauwkeurig_pen nauwkeurig_n nauwkeurig_h , by(rechtslinkshandig)
esttab using testhand.csv, append wide mtitle("diff." )
```

APPENDIX IV
CALCULATIONS

A. *Retention mechanism*

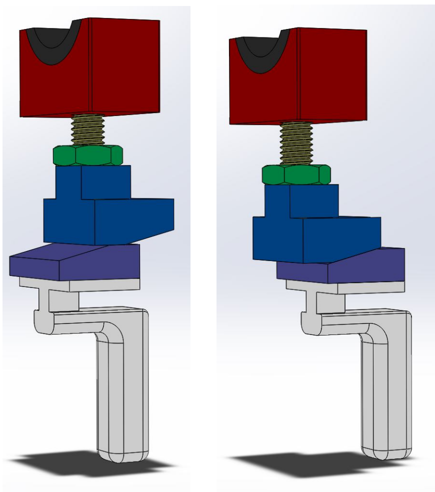
1) Calculations needed to lock and unlock the mechanism: In the retention-mechanism, used in the final design of the nunchuck handle (also shown in Figure 7), a thread is loaded under tension. To make sure that this thread will not buckle or deform plastic, calculations were made. These can be found in the script below mad with Matlab 2018b (Mathworks, Natick, USA). In order to perform the calculations the following assumptions have been made:

- The internal friction in the needle was approximately 4N [3]. To make sure that the friction applied by the brake pads is considerably higher than the friction in the mechanism and needle, a factor of 4.5 is chosen as a reasonable factor, giving a friction of 18N. Taking into account a dynamic dry friction coefficient for steel on rubber of 1.2 [15] gives a clamping force of 15N.
- The dynamic dry friction coefficient of steel on steel is 0.4. [15]

The calculations showed the following:

- To unlock the mechanism the applied force has to overcome the friction between the two inclined planes in the retention mechanism. In the locked position the inclined planes are horizontally aligned (Figure 16a). The needed force to unlock the mechanism is 6N
- In the unlocked position the inclined planes form an angle of inclination of approx. 14 degrees (Figure 16b). The needed force to lock the mechanism is 8.9N
- The critical load is several orders of magnitude higher than the expected load on the thread
- The stresses in the material remain also far bellow the yield strength of the stainless steel thread
- So both buckling and yielding of the thread will not be a problem for the expected load of 15N

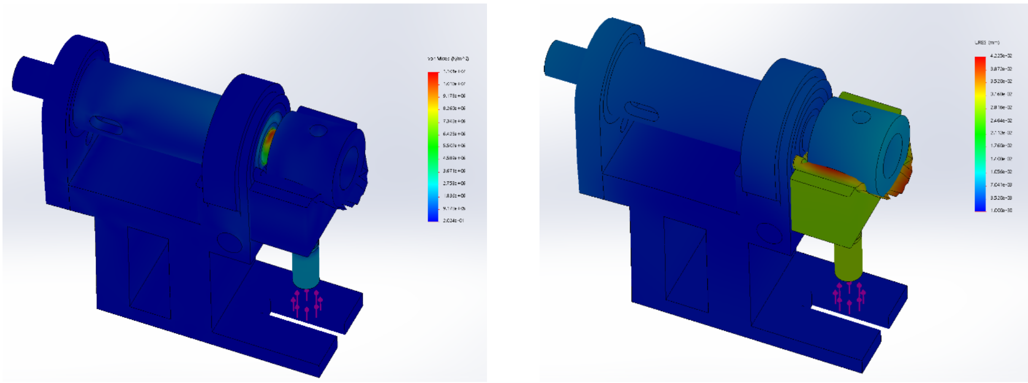
Since you can exert more force by flexing your finger compared to extending, the locking is done by flexion and unlocking by extension of the index finger. Furthermore the locking mechanism is adjustable with a screw allowing for larger or smaller clamping forces.



(a) (b)

Fig. 16: a) Locking mechanism in locked position, inclined planes are horizontally aligned. b) Locking mechanism in unlocked position, inclined planes have slid down over each other

2) SolidWorks simulation for plastic and elastic deformation of the material: The contact force needed to lock the mechanism must not deform the mechanism in a way that it causes parts to yield. To make sure this does not happen in the current design with the applied forces, a simulation has been performed in SolidWorks. The results can be seen in Figure 17. The simulation shows that the highest stresses occur in on of the strongest parts or the mechanism, namely the stainless steel inner tube. These stress remain far below the yield strength. Figure 17b shows that the frame and the inner and outer tube nearly do not deform which is needed for accurate movement of the needle. As expected the rubber friction pad deforms quit a lot, however the deformations in Figure 17 are not on scale.



(a) (b)

Fig. 17: SolidWorks simulation. a) Von Mises stress in the actuation mechanism due to a contact force of 15N in the locking mechanism. b) Displacements in the actuation mechanism due to a contact force of 15N in the locking mechanism. Shown deformations are not on scale.

3) Deformation of the rubber pad: To determine the initial position of the rubber pad, the deformation of the rubber pad has been calculated. For this calculation the Hertzian contact mechanics do not apply, because of the conforming surfaces and the large strains[21]. To make a reasonable estimation in the performed calculations, the following assumptions have been made:

- The contact force is evenly distributed over the projected surface
- Elastic behaviour can be assumed

The needed deformation was determined in four ways:

- Using the projected surface of the rubber pad, the stored elastic energy in the rubber can be approximated. This energy must be equal to the work applied to compress the rubber. From this the displacement can be calculated. This was approximately 0.11mm
- Using the projected surface of the rubber pad and calculate the strain. With the strain, the change in thickness of the rubber pad can be calculated. This was approximately 0.21mm
- Using a static linear SolidWorks simulation gives a displacement of 0.063mm
- Using a non linear SolidWorks simulation gives a displacement of 0.033mm

As can be clearly seen that these calculations are not very reliable, because of the nonlinear behaviour of rubber and the large deformations. So to make sure that enough contact pressure is applied the amount of displacement can be changed by turning a nut of the retention mechanism.

```
%Calculations on the yield strength and critical buckling load
clear all, close all, clc

As=5.03*10^-6;              %effective cross section of bolt [m]
d=2*sqrt(As/pi);
L=5*10^-3;                  %Length of unsupported bolt [m]
K=0.5;                      %effective length factor for two fixed ends
E=210*10^9;                 %Young's modules for steel [MPa]
I=pi/64*d^4;                %Moment of inertia [m^4]
Pcr= pi^2*E*I/(K*L)^2       %critical load

F=15;                       %compressive force applied to bold [N]
sigma=F/As                  %Compressive stress in blod [Pa]

%Calculations on the force needed to lock and unlock the mechanism
clear all, close all, clc

mu=0.4;                          %coefficient of friction between the two inclined planes
alpha=atand(1.5/6);              %angle of the two inclined planes [deg]
Fd=15;                           %contact force needed to create sufficient friction to lock the mechanism [N]

Fu=mu*Fd                         %Force needed to unlock the mechanism [N]
Fl=(sind(alpha)+mu*cosd(alpha))/(cosd(alpha)+mu*sind(alpha))*Fd %Force needed to lock the mechanism [N]
```

B. *Friction in the actuation mechanism*

The amount of friction in the actuation mechanism is very small. Initially the idea was to measure the friction force using a tension gauge (NL = unster), however total friction in the mechanism was too small to be measured with the available tension gauge. At some angle of inclination the mechanism overcomes the friction force keeping it from displacement and the lever drops due to the gravity force. This is shown in Figure 18. The moment exerted at this point gives an indication of the *maximum* amount of friction in the mechanism. The following information is relevant for the performed calculation:

- α = 40°; maximum angle of inclination of the actuation mechanism w.r.t. the horizontal plane (X) before yellow lever overcomes the friction force in the mechanism
- β = 22.9°; angle of the yellow lever with respect to the $x - axis$ in the initial position
- ϕ = 46.1°; angle of the connection rod with respect to the $x - axis$ in the initial position
- The connection point of the green rod to the yellow lever is the point of gravity of the active part of the actuation mechanism, comprising of the lever, one connection axis connecting the rods to the lever and 6 nuts
- Total weight of this part is 4.19g

```
clear all, close all, clc

beta=0.4;                          %angle between the lever and direction of the horizontal movement
alfa=40/180*pi;                    %angle at which the gravity is in equilibrium with the friction
pfi=asin(15/22*sin(beta)+10/22);   %angle between the connection rod and the direction of the horizontal
    movement
mu=0.4                             %coefficient of friction between brass and steel
R=0.001;                           %radius of axis
Fn0=0.04;                          %initialassumption of force excerted by the connection rod to the
    lever
Fn=0;                              %initiation value
Fz=4.2*10^-3*9.81;                 %force of gravity excerterd by the lever
for i=1:200                        %iteration to determine the force excerted by the lever
    Fn=Fn0;
    Fax=Fn*cos(pfi-beta)-Fz*cos(0.5*pi-(alfa+beta));     %horizontal force on pivot point
    Fay=Fz*sin(0.5*pi-(alfa+beta))-Fn*sin(pfi-beta);     %vertical force on pivot point
    Fn0=(Fz*sin(0.5*pi-(alfa+beta))*0.015-mu*R*sqrt(Fax^2+Fay^2))/(sin(pfi-beta)*0.015);
end
Fw=cos(pfi)*Fn                     %horizontal friction
Fwp=mu*sqrt(Fax^2+Fay^2)           %friction in pivot point
Fwt=Fw+Fwp                         %total friction
```

From this calculation follows that the friction is in the order of tens of mN

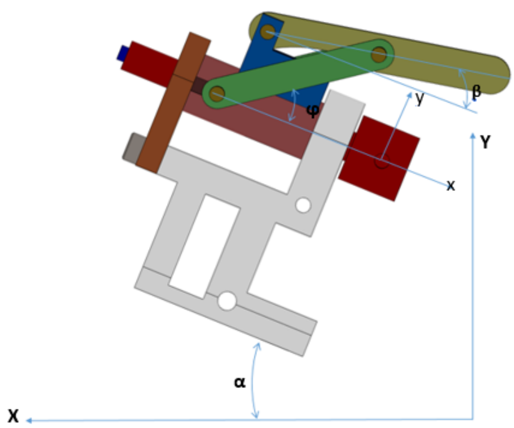


Fig. 18: Schematic representation of the maximum angle (α) of the actuation mechanism w.r.t. the horizontal plane (X) for the yellow lever to overcome the friction force in the mechanism.

APPENDIX V
STERILIZATION PROTOCOL

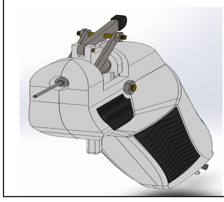
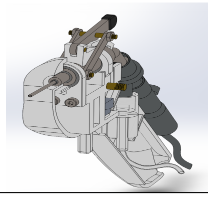
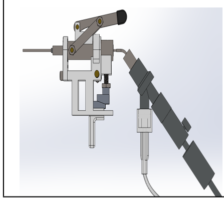
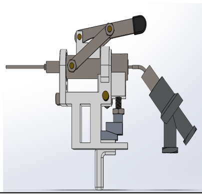
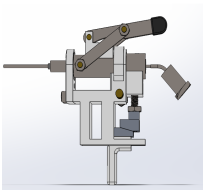
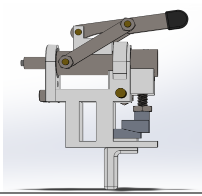
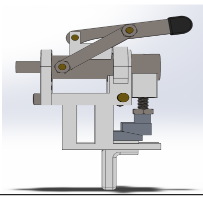
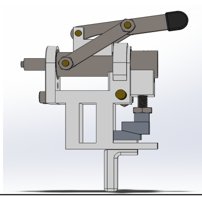
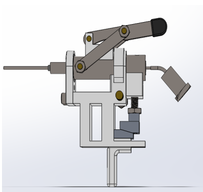
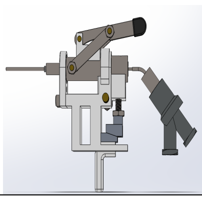
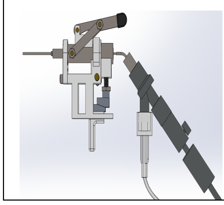
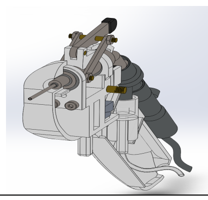
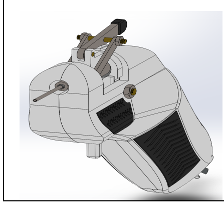
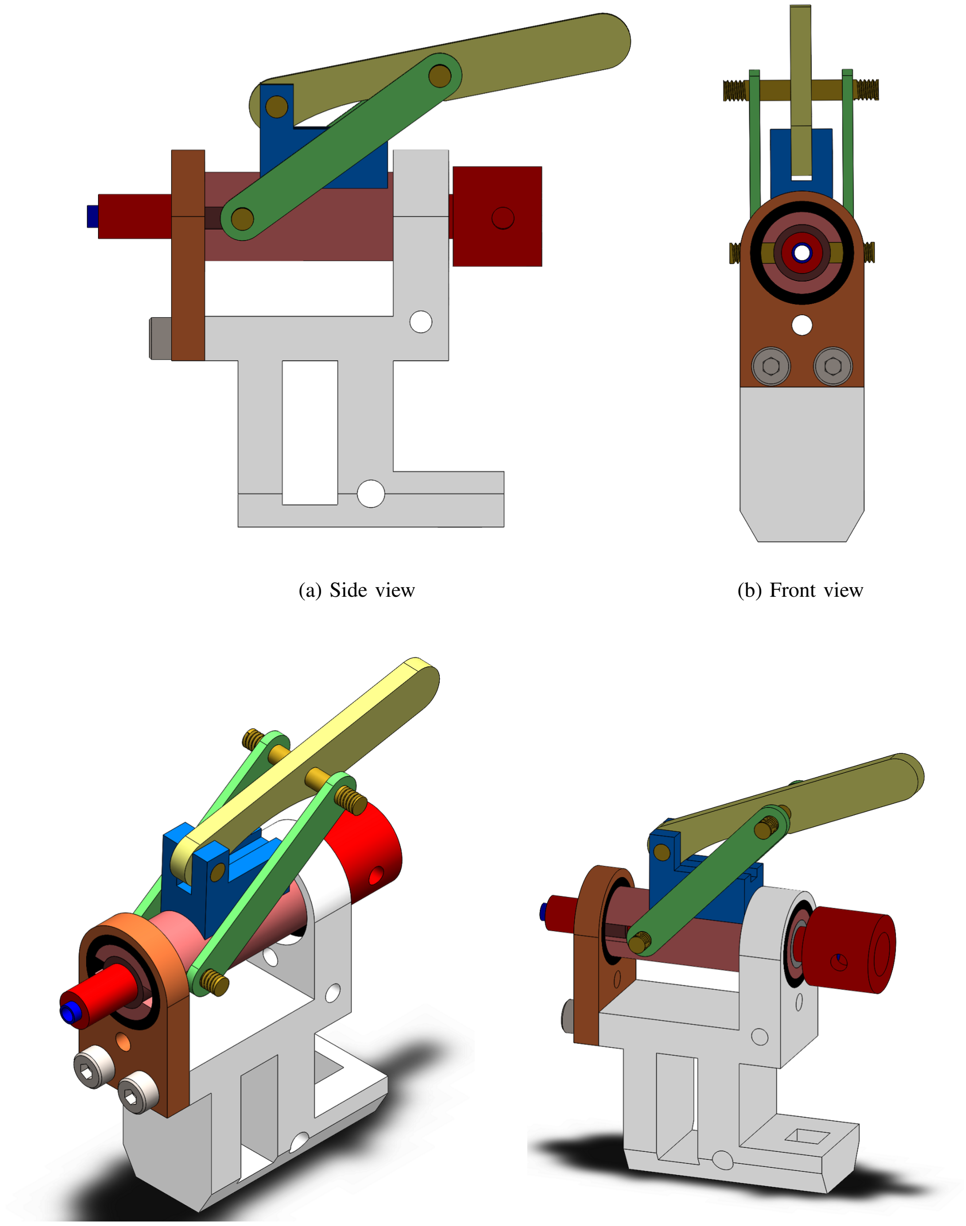
	**Step 1:** After the device has been used, remove the bolt holding the handle together. Then the two halves of the handle can be separated.		**Step 2:** Remove the mechanism from the handle
	**Step 3:** Uncouple the irrigation channel and the endoscope.		**Step 4:** Uncouple the coupling between the irrigation channel, endoscope and the needle.
	**Step 5:** Loosen the set screw which holds the outer needle in place. Remove the entire needle in one go.		**Step 6:** Remove the disposable cannula from the actuation mechanism. Since the mechanism and handle did not come in contact with these patient the do not have to be further sterilized
	**Step 7:** Sterilization of the couplings, needle and endoscope		**Step 8:** Insert a new disposable cannula in the actuation mechanism
	**Step 9:** Insert needle in the cannula. Tighten the set screw to lock the outer needle in place		**Step 10:** Attach the coupling between the irrigation channel, endoscope and the needle
	**Step 11:** Attach the irrigation channel and endoscope		**Step 12:** Place the mechanism in one halve of the handle. Guide the wires through the channels in the handle out of the handle.
	**Step 13:** Put the two halves of the handle back together and tighten the bolt holding the handle in place		

TABLE V: Step-by-step sterilization protocol

Appendix VI
Section views actuation mechanisms

A. Bar linkage-slider with direct rotation



(a) Side view

(b) Front view

(c) Front perspective

(d) Rear perspective

Fig. 19: Bar linkage-slider with direct rotation mechanism view from different angles

B. Rack and pinion translation with bevel gear rotation

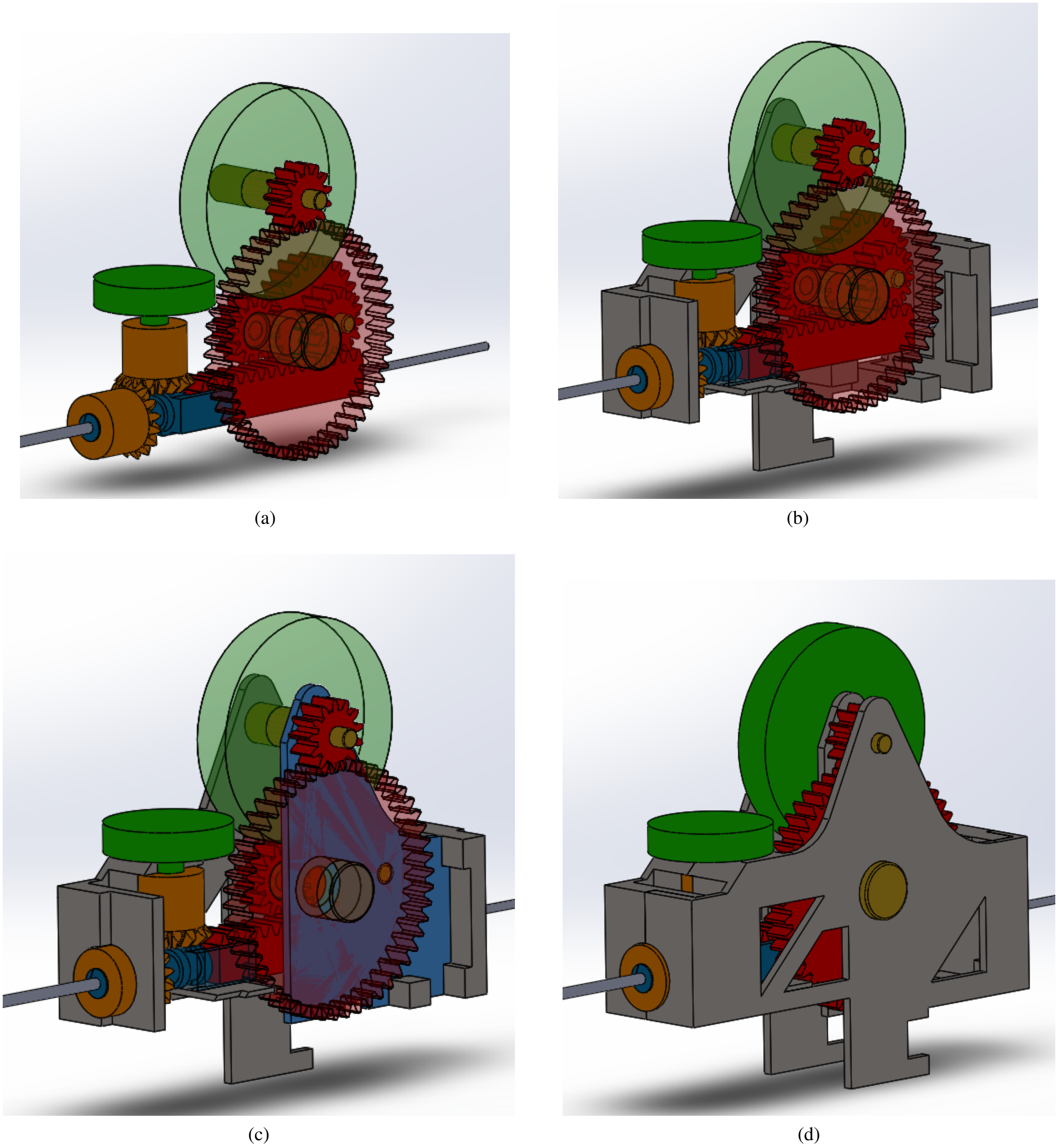


Fig. 20: Rack and pinion translation with bevel gear rotation mechanism, different views

Dossier

I. Concept development: handlepiece

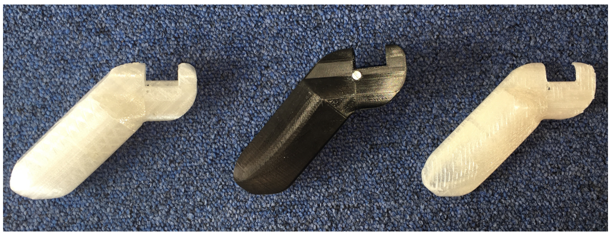
A. Handlepiece

To optimize the handlepiece iterations were performed. Below the iterations process of the handlepieces are described.

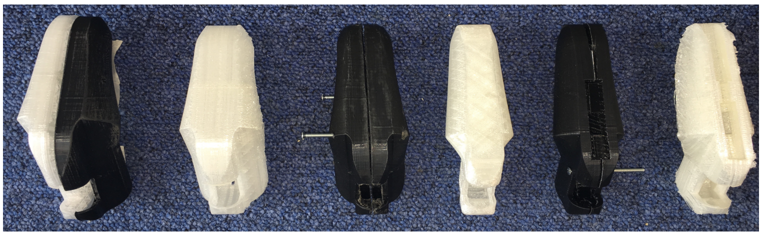
1) Nunchuck development: The first version of the handle was too long, too thick and contained sharp corners, which did not make it very comfortable to hold. These things were adjusted in the second version. The second version was a lot more comfortable to hold, but was still a bit too large. So, the third version again was made a bit thinner. This version was shown to dr. A.J. Witkamp and dr. M. Filipe. They expressed that it placed comfortably in the hand, but preferred a smaller size. Furthermore, they wanted the ability the hold the handle as a pen for easy manipulation of the needle during insertion. However, for this the front part was too big for easy handling. For the forth version these remarks were considered, leading to a smaller handle which can also be held in a pen grip. The front part for the pen grip had a V-shape, but this was not very comfortable. Therefore, for the fifth version the V-shape was flipped, making the handle in the pen grip better to hold. To make the handle easier to assemble and disassemble some elevated edges were added to the different halves of the handle such that they would lock into each other and could be held in place by one screw instead of three. To make all parts (the endoscope, irrigation channel, etc.) fit in the handle properly, an cut out was made at the top of the handle, but this did not affect the ergonomics of the handle.

The first version of the handle focused only on the exterior design of the handle; the interior design was not considered. For the second iteration the interior was already partly designed to accommodate the mechanism but, as it was printed as one part, the mechanism could not be placed inside. This was done because during this phase of the design the exterior was deemed more important. For the third version, the interior design was further improved to better accommodate the mechanism, and the button for the retention-mechanism was moved from the front to the bottom of the handle. For the forth version the interior did not change. For the fifth version, the retention-mechanism was changed, so to make room for this mechanism some changes had to be made to the interior. Furthermore, room was made to house the endoscope and irrigation channel. However, this was not enough so for the sixth version this was further increased.

(a) Side view of Nunchuck iterations 1-3 (from left to right)



(b) Side view Nunchuck iterations 4-6 (from left to right)



(c) Top view Nunchuck iterations 1-6 (from left to right)

Fig. 21: Nunchuck iterations

2) Hybrid development: During evaluation of the first version of the hybrid design, it was clear that it was not long enough and the back part was too flat, so it did not fit comfortably in the hand. Also the top and front were to small to fit the actuation mechanism. To account for this the top was put more backwards and the front was made wider and higher. Together with elongation and enlargement of the back, the second iteration was designed and printed. This version was again evaluated and some points of improvement were found. The bottom part was too far to the back, this made it difficult to hold it using the ring finger and little finger. Also because the front is now bigger, the edges were to sharp. The radius of fillets had to increase to overcome this. After implementing these changes the third design was printed. This was the design we showed to dr. A.J. Witkamp and dr. M. Filipe at the UMCU. They generally liked the handling and comfort of the handlepiece, but they preferred the possibility of a pen-grip from the nunchuck over the hybrid design. After this meeting it was decided to not further develop the hybrid handlepiece, but to focus on developing the nunchuck design alone.

Fig. 22: Side view Hybrid iterations 1-3 (from left to right)

II. Concept development: actuation mechanism

This section gives an overview of the concept development process of the three most promising actuation mechanisms. In terms of the locking mechanism only one good option was available: using friction. The use of friction could be incorporated in the design in many ways.

A. Concept phase 1

1) Concept 1: Crankshaft mechanism: One of the concepts for an actuation mechanism was a crankshaft mechanism for the translation and a worm wheel combined with a planetary gear set for the rotation. To determine the dimensions of the crankshaft mechanism a MATLAB script was made. A crankshaft mechanism shows nonlinear behaviour but on a certain interval this can be accurately approximated by a linear function. This showed however that the angle of rotation needed to give a 2 mm translation was rather small in the order of 20 degrees. Because accurate positioning is necessary a transmission is needed to increase the angle of rotation. This is done by using two gears of 12 and 45 teeth, resulting in an increase of the angle of rotation by a factor of 3.75. An even larger gear ratio would increase the accuracy of the positioning however the needed gearbox would become too big for the give space. Furthermore, it is not very comfortable if you have to spin a wheel multiple times for the resulting translation.

Using a planetary gear set however, would make the rotation mechanism unnecessary complex. Initially the decision for the combination of a worm wheel with a planetary gear was made on the fact that a worm wheel has a large gear ratio, resulting that you have to turn the wheel multiple times to rotate the needle over 90 degrees. The advantage of such worm wheel is that it is not back driveable, making an extra locking mechanism unnecessary. So to decrease the negative effects of a worm wheel a transmission is needed. Because you need a large transmission ratio a planetary gear is a good option. Unfortunately the use of such planetary gear would make the system too large for the desired application as two of these transmissions are needed for the right transmission ratio. Therefore this idea for a rotation mechanism was abandoned and instead two bevel gears were used for the rotation. Of this concept a prototype was made shown in Figure 23. This prototype was scaled by a factor two for easy construction and testing. This prototype showed that the mechanism would become too big for the handle due to the large gears needed and long crankshaft. Furthermore, the prototype showed that an extra linear guide was needed to stabilize the mechanism, making the entire system more complex. Because of the eventual complexity and poor scalability this concept was not further used, however the idea of a crankshaft mechanism for translation of the needle has been used in further development of this concept.

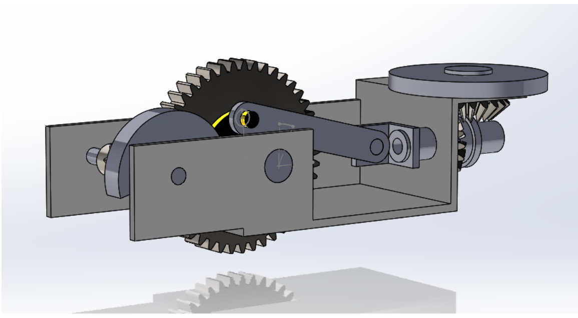


Fig. 23: Crankshaft mechanism

2) Concept 2: Rack and pinion with bevel gear rotation: This concept follows from combining the rack and pinion mechanism for translation with the bevel gear rotation. Figure 24 presents an first SolidWorks model of this mechanism. The translation of the needle is controlled by turning the green wheel on top of the design. This wheel drives a rack and pinion system, of which the rack is connected to the needle. However, to ensure a high resolution of translation, a gearbox with ratio 8,68:1 is added to the system. For the required translation of 2 mm, the green wheel would have to rotate 1.842 radians. The gearbox ratio was initially chosen to be 8:1, however this proved difficult with the commonly available gears and was therefore altered. For the rotational mechanisms two bevel gears are being used. In the initial design a ratio of 1:1 is used, but this could be altered to for example 2:1 or 3:1. This initial choice was made with the procedure in mind. If the tip of the needle reaches the final position the outer tube will have to rotate a total of 0.5 radians. For this application the resolution of movement is less important since the goal is to rotate over the full distance and this can easily be accomplished by a trained physician in the current design. Finally there is the retention-mechanism. It was designed in such a matter that movement is inhibited, unless a button is pressed. The mechanisms works by pushing, with a spring, two halves of a cone into a similarly shaped mould. As the needle passes through the cone the two halve parts exert pressure onto the needle, keeping it from moving. When pressing the green button, i.e. moving it backwards, pressure is released from the needle allowing it to move.

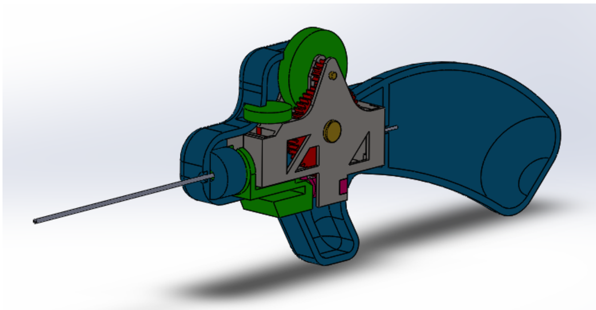


Fig. 24: Rack and pinion mechanism

3) Concept 3: Corkscrew mechanism: The corkscrew mechanism is based on the working principle of a corkscrew. Figure 25 presents a first SolidWorks model of this mechanism. Translation of the needle is achieved by turning a wheel at the end of the design. As with a corkscrew, the outer part is held stationary by the user, while the inner parts translate. Due to the nature of this system, the inner axis also rotates when it is translating. This connection has to be uncoupled by some sort of joint, i.e. a ball-socket joint. Finally, the rotation of the needle has to be accommodated, this is however not shown in the design. The proposed solution was to directly connect the, only translating, inner axis to a wheel. This wheel would not be fixed to the axis, but would be connected by means of a key way. This allows the rotational control over the axis, while still letting it translate freely. By increasing the diameter of the wheel, a higher resolution for the movement can be achieved.

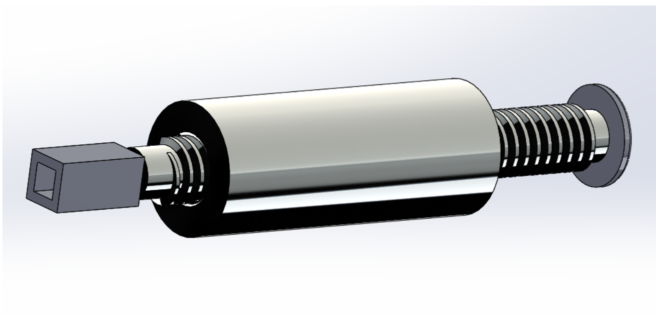


Fig. 25: Corkscrew mechanism

B. Concept phase 2

After the three different concepts developed in Phase 1 II-A the Corckscrew mechanism was dropped and the other two actuation mechanisms have been further developed for each handlepiece prototype.

1) Concept 1: Bar linkage-slider mechanism: The idea of a crankshaft mechanism for translation of the biopsy needle has led to the concept of the “Bar linkage-slider mechanism”. The concept of the crankshaft mechanism needed very large gears to achieve the large gear ratio needed in this concept. Therefore, based on the idea of a crankshaft mechanism a linkage mechanism has been developed which would be more compact and therefore more suitable for the application. There are many kinds of linkage mechanisms. As the system must be very compact, as few as possible linkages should be used for translation. Furthermore, as few linkages are favourable to minimize friction in the design, since in every moving connection point there will be frictional losses. With this in mind two concepts were made and evaluated using MATLAB.

- Three rod mechanism. In which two of the rods are guided along a linear path
- Two rod mechanism. An adaptation of the Scott Russel Linkage [3] and the crankshaft mechanism

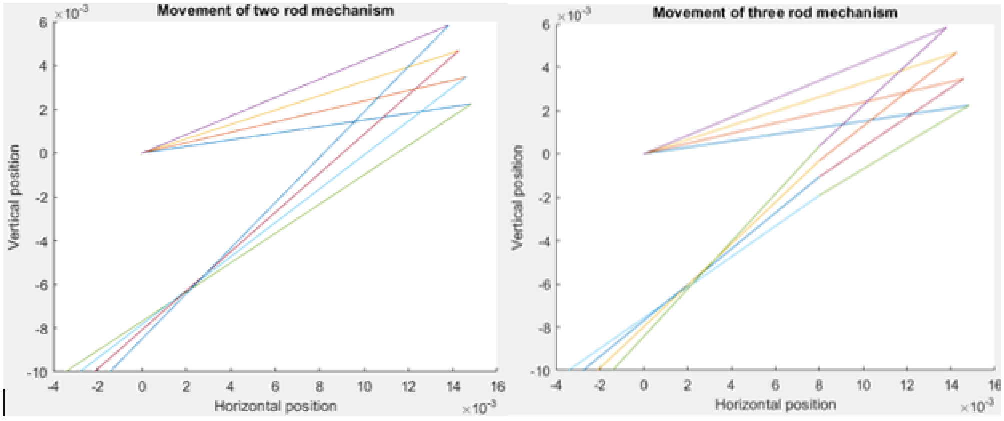


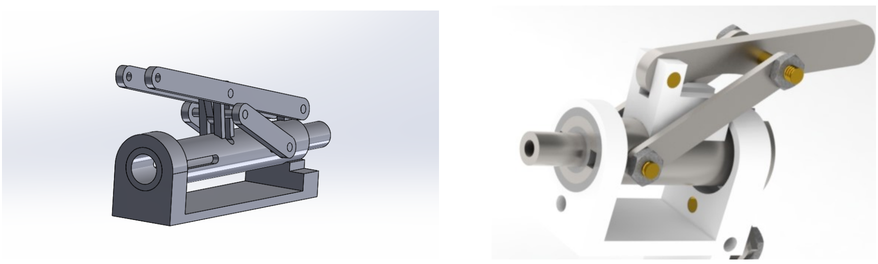
Fig. 26: MATLAB simulation of movement of a two-rod mechanism (left) and three-rod mechanism (right)

Both mechanisms showed a nonlinear relation between the angle of rotation of the driving rod and the horizontal translation of the inner tube. So a combination for the different rod lengths had to be found where the mechanism showed a nearly linear relation. For the three-rod mechanism two of the rods were almost in one line in the movement interval and thus could be approximated by a two rod mechanism, this can be clearly seen in Figure 26.

For the finale design a two rod mechanism was used for the translation motion, a first SolidWorks model of this concept is shown in Figure 27b. For comparison in Figure 27a a model of the three-rod mechanism can be seen.

To accomplish the translation with a good accuracy the driving rod should have a length of 15 mm and the rod between the lever (driving rod) and the inner tube a length of 22 mm. Furthermore the vertical offset between the inner tube and the pivot point of the driving rod is 10 mm. This offset is needed to make the system more compact, because otherwise everything had to be placed into one line. The translation of 2 mm by an error of 0.1% is achieved by rotating the lever (driving rod) over an angle of 0.25 radians.

For rotation a very simple mechanism was chosen; a direct drive. This implies that the outer tube is directly rotated by the actuating lever. This allows for both rotational and translation movement to be incorporated into one switch.



(a) (b)

Fig. 27: a) Three rod mechanism. b) Two rod mechanism

2) Concept 2: Rack and pinion mechanism: The design of the rack and pinion mechanism did not differ much from the first concept. The translation of the needle is controlled by turning a wheel on top of the design. This wheel drives a rack and pinion system, of which the rack is connected to the needle. To ensure a high resolution of translation, a gearbox with ratio 8,68:1 is added to the system. For the required translation of 2 mm, the actuation wheel would have to rotate 1.842π radians.

For the rotational mechanisms two bevel gears are used. In the initial design a ratio of 1:1 is used, but this could be altered to for example 2:1 or 3:1. This initial choice was made with the procedure in mind. If the tip of the needle reaches the final position the outer tube will have to rotate a total of π radians. For this application the resolution of movement is less important since the goal is to rotate over the full distance and this can easily be accomplished by a trained physician in the current design.

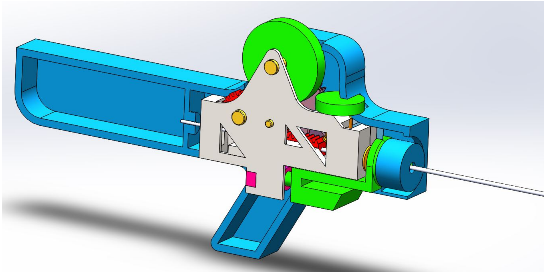


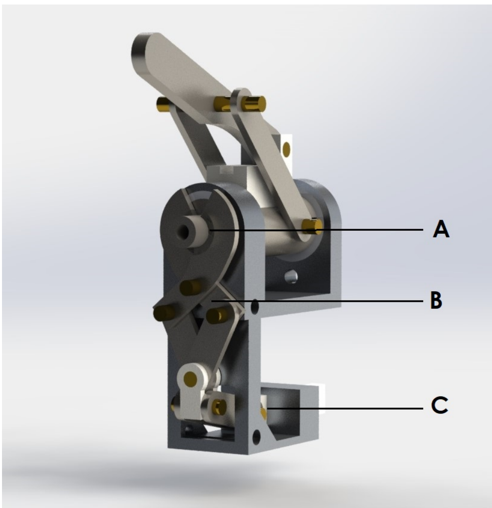
Fig. 28: SolidWorks model of the “Rack and pinion translation with bevel gear rotation mechanism” integrated into the “hybrid” handle

C. Retention mechanism

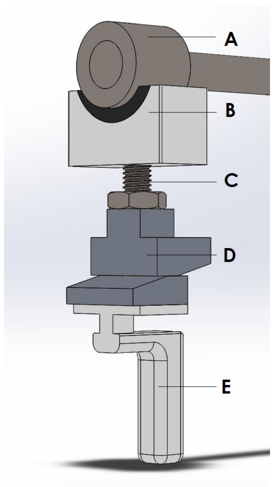
To prevent unwanted movement of the needle a retention mechanism has been developed for each actuation mechanism. Below the iteration process of this design process will be described.

1) Bar linkage-slider development: Retention-mechanism 1: The first concept of the retention-mechanism consists of a gripper which clamps the rotation and translation mechanism preventing undesired movement. To release the gripper a button must be pushed which causes through a bar mechanism the scissors of the gripper to open and thus enables further manipulation of the mechanism. Unfortunately, when this was incorporated into a prototype it did not work satisfactory. The force needed to release the gripper was too high to be easily used and the clamping force was to low to disable the needle from movement. So, the design of the clamping mechanism needed to be altered.

2) Bar linkage-slider development: Retention-mechanism 2: For the new design of the clamping mechanism a rubber pad is being pressed against the inner tube from underneath. This is done with the help of two inclined planes. One of the planes is attached to a button which can be moved horizontally. The other plane is connected with a screw to the rubber pad. This screw can be used to increase or decrease the clamping force. When at rest the two inclined planes are in contact with each other on a horizontal surface, in this case the clamping force is the highest. When the button is pushed forward the two inclined planes will slide down over each other and thus lowering the clamping force. The force needed to move the button is only determined by the friction between the two planes. To lock the mechanism again the button must be pulled back. The force needed to move the button is determined by the friction between the two planes and the effect of the inclined planes. The effect of the inclined planes is that the force needed to press the button is lower than the applied clamping force. So, the highest force needed is when the mechanism is being locked. You can exert the largest force in flexion of the index finger so that is why the locking is done by pulling the button back and unlocking the mechanism by pushing the button forward by extending the index finger. The amount of force needed can be found in Appendix IV-B.



(a)



(b)

Fig. 29: a) First concept retention mechanism for bar linkage-slider actuation mechanism. By pressing button (C), pressure exerted by two grippers (B) onto the actuation mechanism. The material (A) between the two grippers and the actuation mechanism is rubber. b) Final version retention mechanism. By pulling the handle (E), pressure exerted by block (B) on the needle (A) is increased, inhibiting movement of the needle.

3) Rack and pinion: Retention mechanism: The retention-mechanism ensures that the needle cannot move when this is undesired. Most of the time during the procedure the needle has to be hold stationary and thus being inhibited to move, even when the physician accidentally touches either of the control wheels. To accomplish this a mechanism is placed which always inhibits movement, unless the green button on the underside of the design is pressed. The mechanisms works by pushing two halves of a cone into a similarly shaped mould. Since there is a needle going through the two halves of the cone, the cone will not properly fit into the mould and will therefore apply a pressure onto the needle, keeping it from moving. The two halves of the cone are pushed into the mould by a spring, placed exactly behind the button. By varying the material of the halves, the spring constant or the initial length of the spring, the force on the needle can be adjusted, keeping it from moving around.

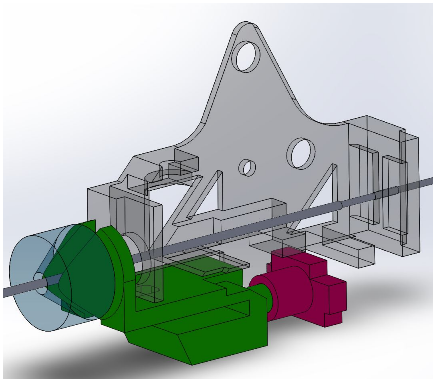


Fig. 30

III. SURVEY EXTENSIVE RESULTS

TABLE VI: Results of the compared rating of the handles per category. Per categorization a rating from 1-4 is given to compare comfort, stabilty and precision amongst the four handles, with 4 being the worst and 1 being the best. Therefore the handle with the lowest total score will be marked as the best handle.

Participant number	Nr 1	Nr 2	Nr 3	Nr 4	Nr 5	Nr 6	Nr 7	Nr 8	Nr 9	Nr 10	
Age	22	18	24	27	18	18	17	26	24	24	
Gender	Male	Male	Male	Female	Female	Female	Female	Male	Female	Female	
Degree	Bachelor	VWO	Bachelor	Master	VMBO	-	-	Bachelor	VWO	Master	
Profession/study	MSc Chemical Eng	Medicine	Civil Eng.	Teacher	HAVO	HAVO	-	Sustainable energy	Mechanical Eng.	Medicine	
Right/left-handed	Right	Right	Right	Right	Right	Left	Right	Right	Links	Links	
Hand size	Medium	Large	Medium	Small	Small	Medium	Small	Medium	Small	Medium	
Comfort - gun	2	2	3	1	1	2	1	2	4	3	
Comfort - pen	4	3	4	4	3	3	4	3	3	4	
Comfort - nunchuck	1	1	1	2	2	1	2	1	2	2	
Comfort - hybrid	3	4	2	3	1	4	3	4	1	1	
Stability - gun	2	4	2	2	4	3	1	2	4	3	
Stability - pen	4	2	4	4	3	1	4	3	3	4	
Stability - nunchuck	3	1	1	3	2	2	2	1	2	2	
Stability - hybrid	1	3	3	1	1	4	3	4	1	1	
Precision - gun	4	2	3	4	4	3	2	1	4	4	
Precision - pen	3	4	4	1	3	2	1	3	1	1	
Precision - nunchuck	1	3	1	3	2	1	3	2	3	3	
Precision - hybrid	2	1	2	2	1	4	4	4	2	2	

Participant number	Nr 11	Nr 12	Nr 13	Nr 14	Nr 15	Nr 16	Nr 17	Nr 18	Nr 19	Nr 20	TOTAL
Age	18	56	31	59	26	21	24	20	22	21	
Gender	Female	Female	Male	Male	Female	Male	Male	Male	Female	Male	
Degree	HBO	Master	Master	Master	Master	VWO	Bachelor	VWO	Bachelor	HAVO	
Profession/study	Nurse	Procesmanager	Teacher	-	Mechanical Eng.	Mechanical Eng.	Architecture	Mechanical Eng.	Biomedical Eng.	Business Economics	
Right/left-handed	Right	Right	Left	Right	Right	Right	Right	Right	Right	Right	
Hand size	Small	Small	Large	Medium	Large	Medium	Medium	Medium	Small	Medium	
Comfort - gun	3	2	3	1	3	4	2	3	2	1	45
Comfort - pen	4	4	4	4	4	1	3	4	3	3	69
Comfort - nunchuck	2	1	1	3	1	2	1	1	1	2	30
Comfort - hybrid	1	3	2	2	2	3	4	2	4	4	53
Stability - gun	4	4	4	1	4	3	1	3	1	1	53
Stability - pen	3	3	1	4	3	4	3	4	4	3	64
Stability - nunchuck	2	1	3	3	2	2	2	1	2	2	39
Stability - hybrid	1	2	2	2	1	1	4	2	3	4	44
Precision - gun	4	4	4	2	4	4	3	3	2	4	65
Precision - pen	1	1	1	4	3	1	1	4	3	1	43
Precision - nunchuck	3	2	2	3	2	3	2	1	1	2	43
Precision - hybrid	2	3	3	1	1	2	4	2	4	3	49

TABLE VII: The gun handle - Results of the available fingers, their placement and the actuation action. Hand comfort can be ranked from 1 (highly unpleasant) to 5 (highly pleasant). Free fingers indicates which fingers are free to possibly actuate buttons, 1 meaning they are free and 0 meaning they are not. Preferred fingers indicates which which fingers are preferred by the participant to use to actuate possible buttons (either free fingers or not), 1 meaning a preference and 0 meaning no preference. Actuation is indicated per plane. T (thumb), I(index finger), M (middle finger), R (ring finger) and L (little finger) are pared with possible actions: 1 (push), 2 (shove) and 3 (rotate). When no number is added all three actions are deemed possible.

Participant number	**Nr 1**	**Nr 2**	**Nr 3**	**Nr 4**	**Nr 5**	**Nr 6**	**Nr 7**	**Nr 8**	**Nr 9**	**Nr 10**	**Nr 11**	**Nr 12**	**Nr 13**	**Nr 14**	**Nr 15**	**Nr 16**	**Nr 17**	**Nr 18**	**Nr 19**	**Nr 20**
Hand comfort	5	3	4	4	3	4	5	4	2	3	3	2	4	4	4	4	4	5	4	3
Free fingers:																				
Thumb	1	1	1	0	0	0	1	1	1	0	1	1	1	1	1	1	0	1	1	0
Index finger	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Middle finger	1	1	1	0	1	0	0	0	1	1	1	1	1	1	1	1	1	0	0	0
Ring finger	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	0
Preferred fingers																				
Thumb	0	0	1	0	0	0	0	1	1	0	0	1	0	1	1	1	0	1	1	0
Index finger	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
Middle finger	1	0	1	0	1	0	0	0	0	1	1	0	1	1	0	0	0	0	0	0
Ring finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Actuation																				
Left plane	T2	M1	T	-	-	I1	T1	T	I2+3, T	I	-	T3,	M1	I3	T1+2	T1+3	T	T3	T1	-
Right plane	-	-	I, M	I1+2	-	T1	-	I	-	-	I2+3	-	-	-	I1+2	I2	I	I2+3	I2	-
Top plane	-	T1	-	-	-	I1	-	T	T	-	-	I2	-	-	T1	T2+3	T	-	-	T3
Bottom plane	M1	I1	-	-	M1	-	I1	-	M1	M1	M1	M1	I1	M1	I1, M1	M2	-	-	-	I1

TABLE VIII: The gun handle - Results of the available fingers, their placement and the actuation action. Hand comfort can be ranked from 1 (highly unpleasant) to 5 (highly pleasant). Free fingers indicates which fingers are free to possibly actuate buttons, 1 meaning they are free and 0 meaning they are not. Preferred fingers indicates which which fingers are preferred by the participant to use to actuate possible buttons (either free fingers or not), 1 meaning a preference and 0 meaning no preference. Actuation is indicated per plane. T (thumb), I(index finger), M (middle finger), R (ring finger) and L (little finger) are pared with possible actions: 1 (push), 2 (shove) and 3 (rotate). When no number is added all three actions are deemed possible.

Participant number	**Nr 1**	**Nr 2**	**Nr 3**	**Nr 4**	**Nr 5**	**Nr 6**	**Nr 7**	**Nr 8**	**Nr 9**	**Nr 10**	**Nr 11**	**Nr 12**	**Nr 13**	**Nr 14**	**Nr 15**	**Nr 16**	**Nr 17**	**Nr 18**	**Nr 19**	**Nr 20**
Hand comfort	5	3	4	4	3	4	5	4	2	3	3	2	4	4	4	4	4	5	4	3
Free fingers:																				
Thumb	1	1	1	0	0	0	1	1	1	0	1	1	1	1	1	1	0	1	1	0
Index finger	0	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Middle finger	1	1	1	0	1	0	0	0	1	1	1	1	1	1	1	1	1	0	0	0
Ring finger	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	0
Preferred fingers																				
Thumb	0	0	1	0	0	0	0	1	1	0	0	1	0	1	1	1	0	1	1	0
Index finger	1	1	1	1	0	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
Middle finger	1	0	1	0	1	0	0	0	0	1	1	0	1	1	0	0	0	0	0	0
Ring finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Actuation																				
Left plane	T2	M1	T	-	-	I1	T1	T	I2+3, T	I	-	T3,	M1	I3	T1+2	T1+3	T	T3	T1	-
Right plane	-	-	I, M	I1+2	-	T1	-	I	-	-	I2+3	-	-	-	I1+2	I2	I	I2+3	I2	-
Top plane	-	T1	-	-	-	I1	-	T	T	-	-	I2	-	-	T1	T2+3	T	-	-	T3
Bottom plane	M1	I1	-	-	M1	-	I1	-	M1	M1	M1	M1	I1	M1	I1, M1	M2	-	-	-	I1

TABLE IX: The pen handle - Results of the available fingers, their placement and the actuation action. Hand comfort can be ranked from 1 (highly unpleasant) to 5 (highly pleasant). Free fingers indicates which fingers are free to possibly actuate buttons, 1 meaning they are free and 0 meaning they are not. Preferred fingers indicates which which fingers are preferred by the participant to use to actuate possible buttons (either free fingers or not), 1 meaning a preference and 0 meaning no preference. Actuation is indicated per plane. T (thumb), I(index finger), M (middle finger), R (ring finger) and L (little finger) are pared with possible actions: 1 (push), 2 (shove) and 3 (rotate). When no number is added all three actions are deemed possible.

Participant number	**Nr 1**	**Nr 2**	**Nr 3**	**Nr 4**	**Nr 5**	**Nr 6**	**Nr 7**	**Nr 8**	**Nr 9**	**Nr 10**	**Nr 11**	**Nr 12**	**Nr 13**	**Nr 14**	**Nr 15**	**Nr 16**	**Nr 17**	**Nr 18**	**Nr 19**	**Nr 20**
Hand comfort	2	3	3	5	4	4	3	2	4	2	3	5	2	1	2	5	3	3	2	2
Free fingers:																				
Thumb	1	0	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	0
Index finger	0	1	1	1	1	1	0	1	1	1	1	1	1	0	1	0	1	1	1	0
Middle finger	1	0	0	0	1	0	0	0	0	0	0	0	0	1	1	1	0	0	0	1
Ring finger	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
Preferred fingers																				
Thumb	0	0	0	0	0	0	1	1	1	0	1	1	0	1	1	0	0	1	1	1
Index finger	0	1	0	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1
Middle finger	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Ring finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Actuation																				
Left plane	T2	-	-	-	T1	I1	T1, I1	T1	T1	T1	-	T1	-	-	T1	-	I	T1	T1	R1
Right plane	M2+3	I1+2	-	-	I1	T1	-	-	M1	I1	-	-	-	-	I1	I	-	-	I1	L3
Top plane	-	-	-	I1	-	-	-	-	-	-	I1	I2+3	D1+3, I1+3	-	-	-	-	I3	-	-
Bottom plane	-	-	-	-	-	-	-	-	-	-	T1	-	-	-	-	-	-	-	-	-

TABLE X: The nunchuck handle - Results of the available fingers, their placement and the actuation action. Hand comfort can be ranked from 1 (highly unpleasant) to 5 (highly pleasant). Free fingers indicates which fingers are free to possibly actuate buttons, 1 meaning they are free and 0 meaning they are not. Preferred fingers indicates which which fingers are preferred by the participant to use to actuate possible buttons (either free fingers or not), 1 meaning a preference and 0 meaning no preference. Actuation is indicated per plane. T (thumb), I(index finger), M (middle finger), R (ring finger) and L (little finger) are pared with possible actions: 1 (push), 2 (shove) and 3 (rotate). When no number is added all three actions are deemed possible.

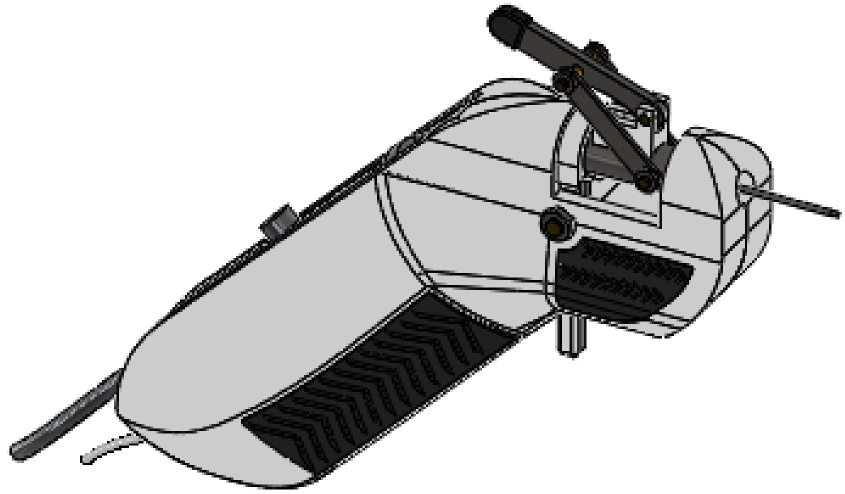
Participant number	**Nr 1**	**Nr 2**	**Nr 3**	**Nr 4**	**Nr 5**	**Nr 6**	**Nr 7**	**Nr 8**	**Nr 9**	**Nr 10**	**Nr 11**	**Nr 12**	**Nr 13**	**Nr 14**	**Nr 15**	**Nr 16**	**Nr 17**	**Nr 18**	**Nr 19**	**Nr 20**
Hand comfort	5	4	5	4	4	4	4	5	4	4	4	5	5	2	5	5	5	4	4	4
Free fingers:																				
Thumb	1	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	1	1	0
Index finger	1	1	1	0	1	0	0	1	1	1	1	1	1	0	1	1	1	1	1	0
Middle finger	1	1	0	0	1	0	0	0	0	1	1	1	1	1	1	1	1	0	1	0
Ring finger	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1
Little finger	0	1	0	0	0	0	1	0	0	0	0	1	0	0	0	0	1	0	1	1
Preferred fingers																				
Thumb	0	1	1	1	1	1	0	1	1	0	0	1	0	1	1	1	1	1	1	0
Index finger	1	1	1	0	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	0
Middle finger	0	0	0	0	0	0	0	1	0	1	1	0	1	1	0	0	0	0	0	1
Ring finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Actuation																				
Left plane	T2	L1, R1	-	T1	T	-	-	-	-	I2+3, M2+3	-	T	-	I3	-	-	-	-	T2	M1
Right plane	I1+2	I1+2	I	-	-	-	-	L1+2, M1+2	-	-	-	M2	-	-	I1+2	-	I	I2+3	I2	L3
Top plane	-	T	T	T2	-	T1	-	T3	T	T	-	I1+2	-	-	T	T2	T	T	I1	-
Bottom plane	M2+3	-	-	-	-	-	I1	-	I	-	I, M	L1	I2+3, M2+3	M3	-	I1	-	-	-	-

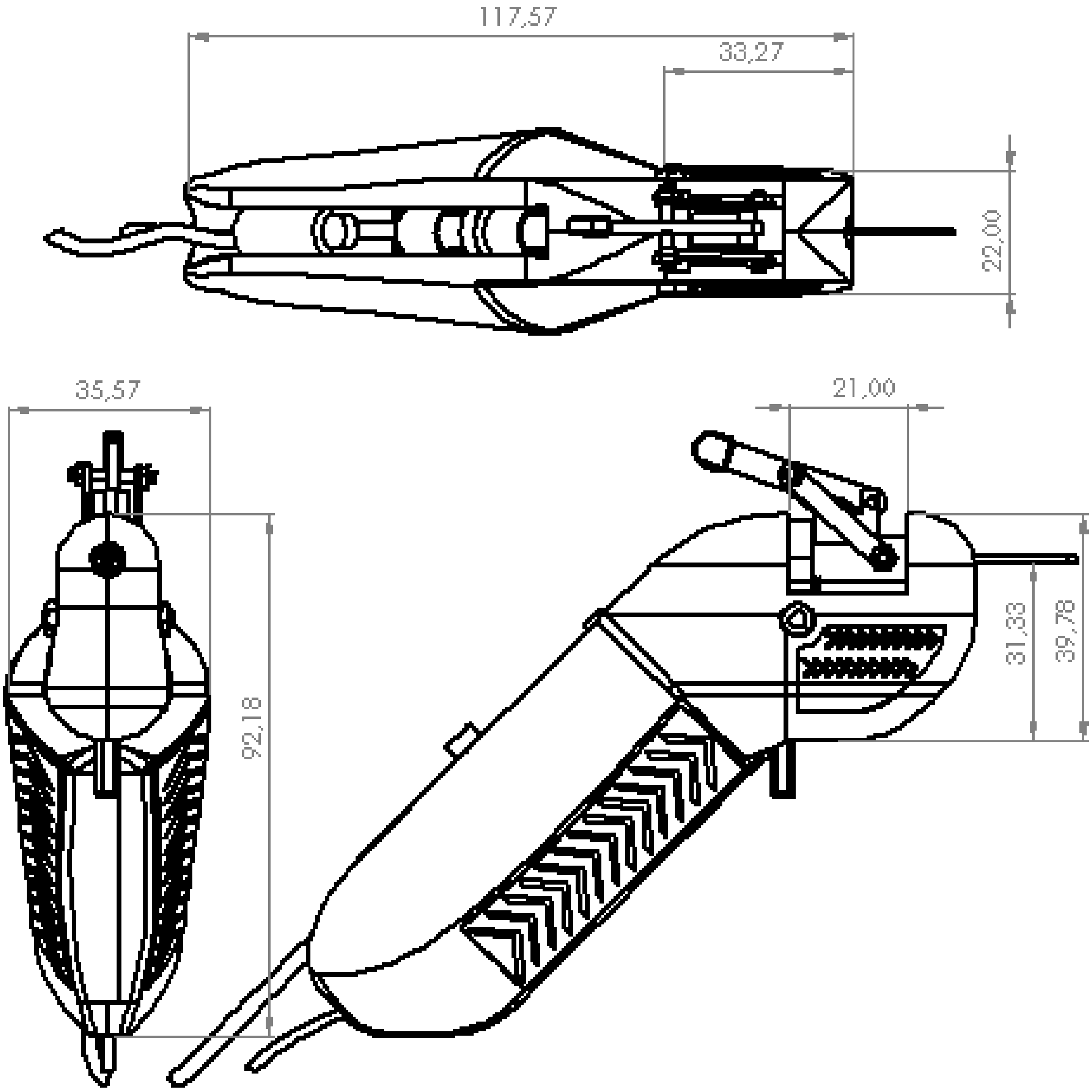
TABLE XI: The hybrid handle - Results of the available fingers, their placement and the actuation action. Hand comfort can be ranked from 1 (highly unpleasant) to 5 (highly pleasant). Free fingers indicates which fingers are free to possibly actuate buttons, 1 meaning they are free and 0 meaning they are not. Preferred fingers indicates which which fingers are preferred by the participant to use to actuate possible buttons (either free fingers or not), 1 meaning a preference and 0 meaning no preference. Actuation is indicated per plane. T (thumb), I(index finger), M (middle finger), R (ring finger) and L (little finger) are pared with possible actions: 1 (push), 2 (shove) and 3 (rotate). When no number is added all three actions are deemed possible.

Participant number	**Nr 1**	**Nr 2**	**Nr 3**	**Nr 4**	**Nr 5**	**Nr 6**	**Nr 7**	**Nr 8**	**Nr 9**	**Nr 10**	**Nr 11**	**Nr 12**	**Nr 13**	**Nr 14**	**Nr 15**	**Nr 16**	**Nr 17**	**Nr 18**	**Nr 19**	**Nr 20**
Hand comfort	4	2	4	2	4	3	4	2	4	5	4	2	4	3	4	5	3	5	2	2
Free fingers:																				
Thumb	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	0
Index finger	1	1	0	1	1	0	0	1	1	1	1	1	1	0	1	1	1	1	0	0
Middle finger	0	0	0	0	1	0	1	0	1	0	1	1	1	1	1	1	1	0	0	0
Ring finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1
Preferred fingers																				
Thumb	0	1	1	0	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	0
Index finger	1	1	1	1	0	0	1	1	1	1	1	0	1	0	1	1	1	1	1	1
Middle finger	0	0	1	0	0	0	0	0	1	0	0	1	1	1	0	0	0	0	0	1
Ring finger	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Little finger	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Actuation																				
Left plane	T2+3	-	-	T1+3	T	I1	-	T	-	-	-	T	-	-	T1+2	-	T	-	-	R1
Right plane	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	I1	-	L3
Top plane	I1	I1, T	T	I1	-	T1	T1	I	T, I1	T1, I	T1, I1	I2	I1+3	T1	I1+3, T	I1, T2+3	I	T1+3	T2	-
Bottom plane	-	-	-	-	-	-	I1	-	M1	-	M3	M1	M1	M3	-	M1	-	-	-	-

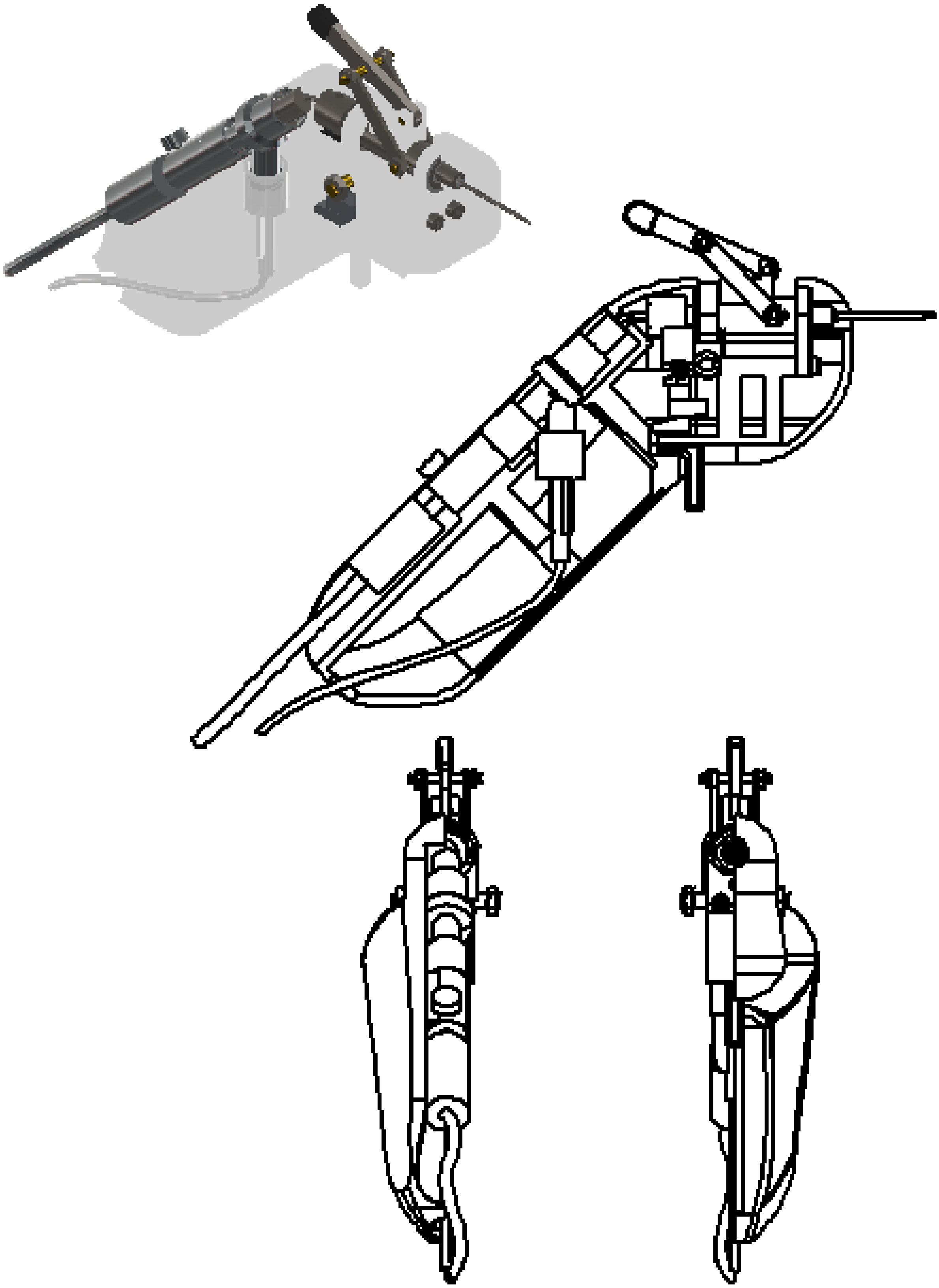
IV. Technical drawings final design

A. Drawings of exterior part of the handle

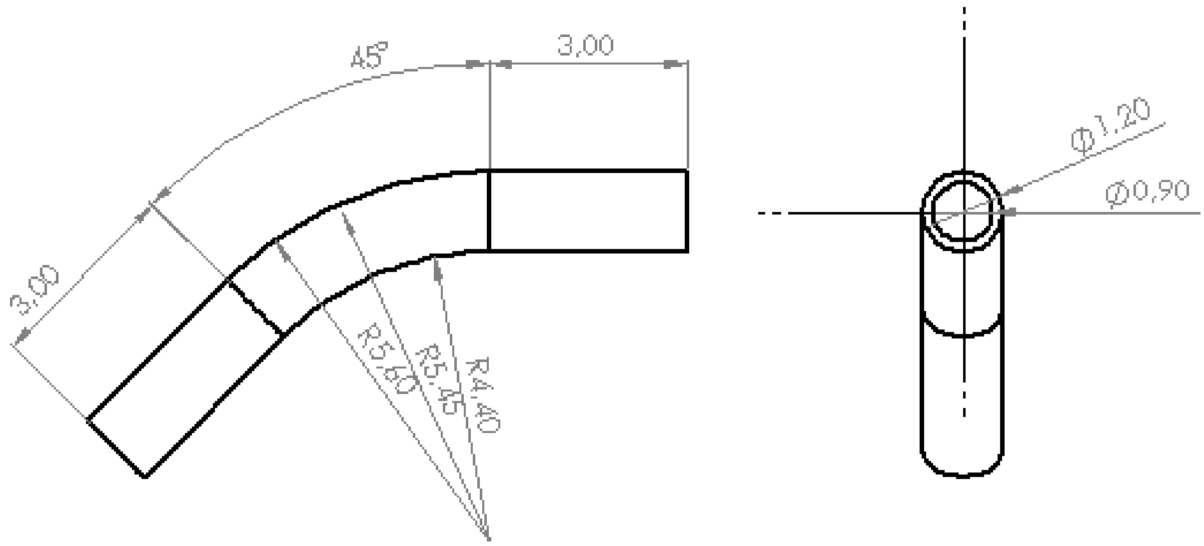




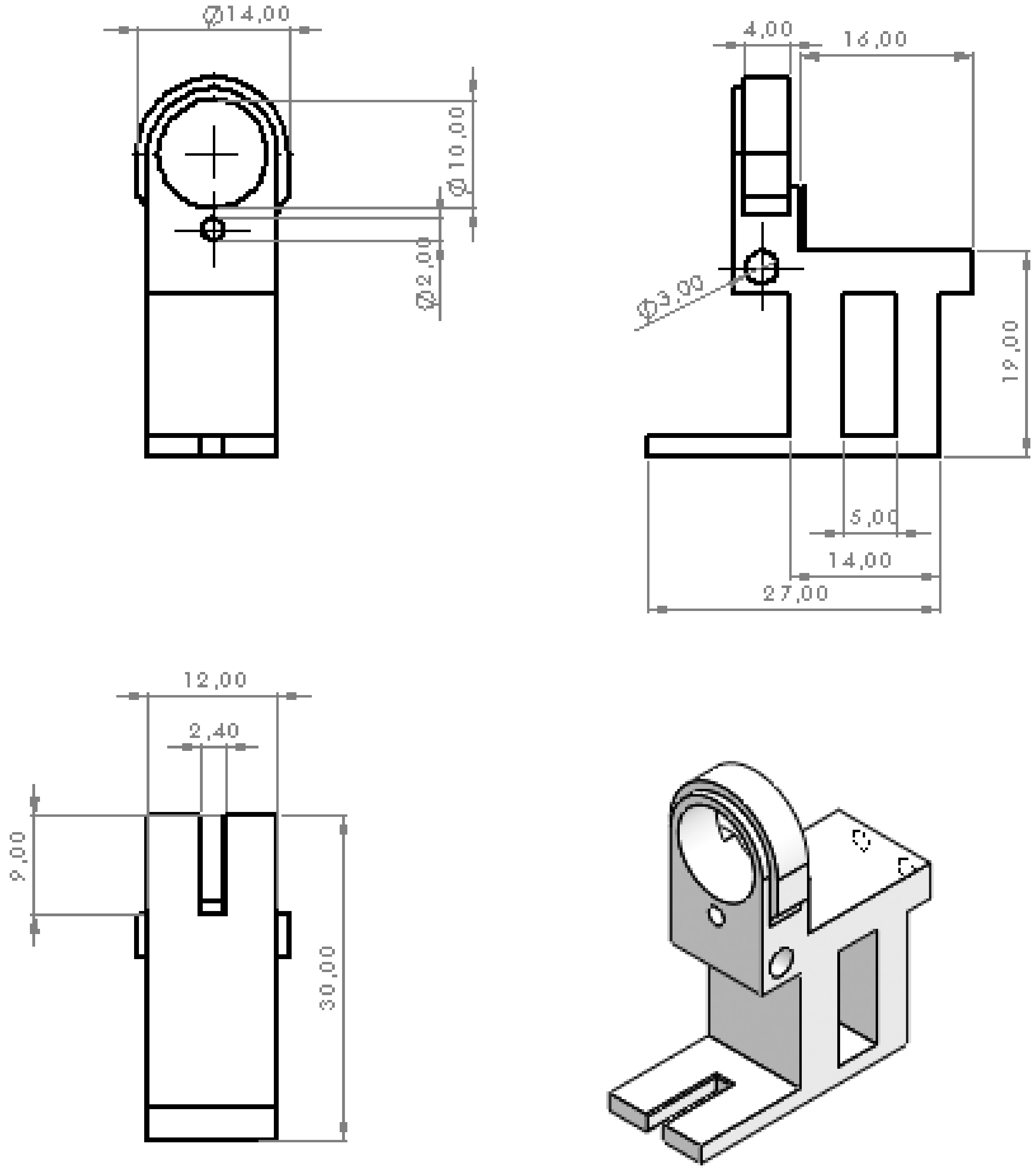
B. Drawings of interior part of the handle



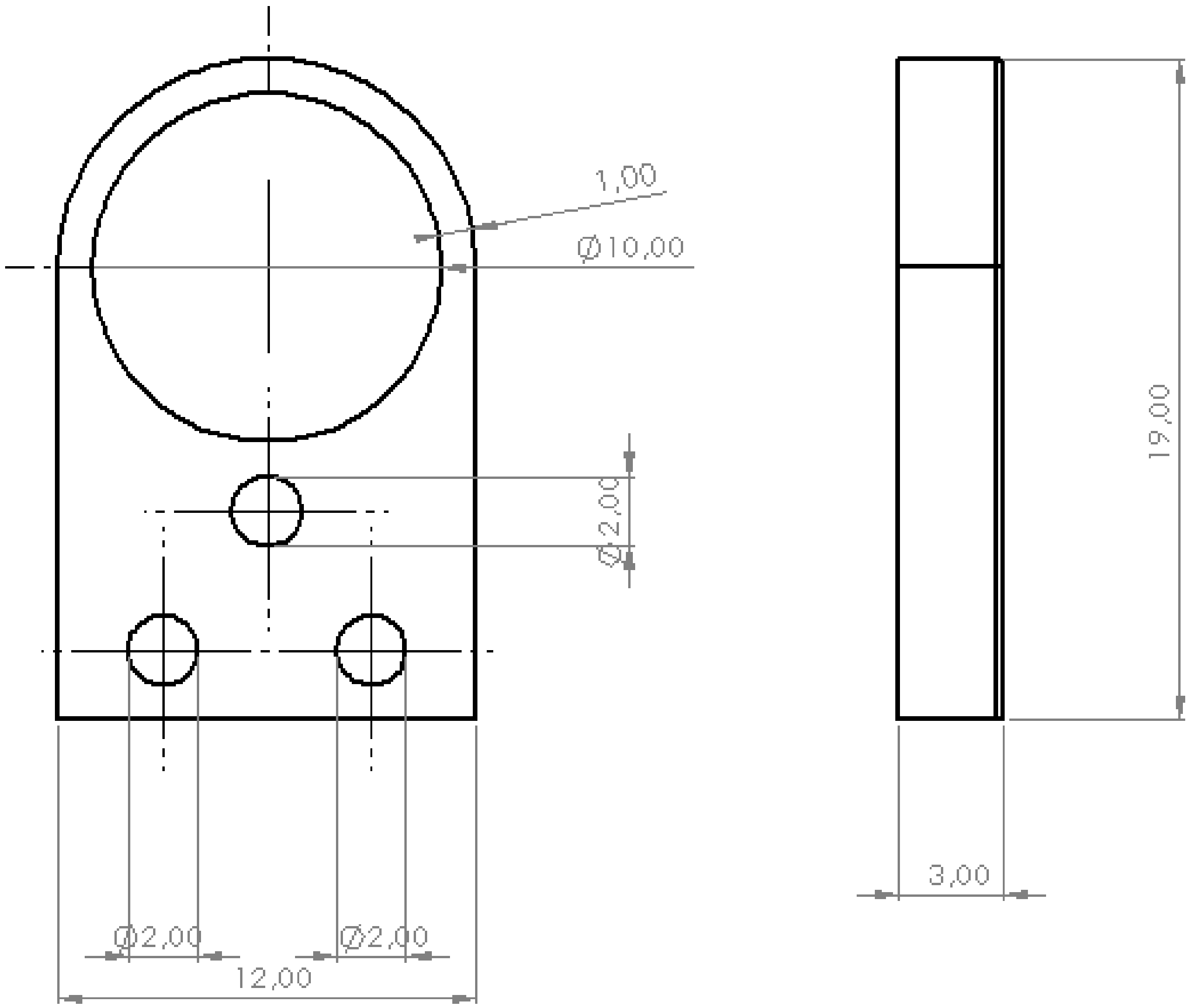
C. Drawings of connection tube



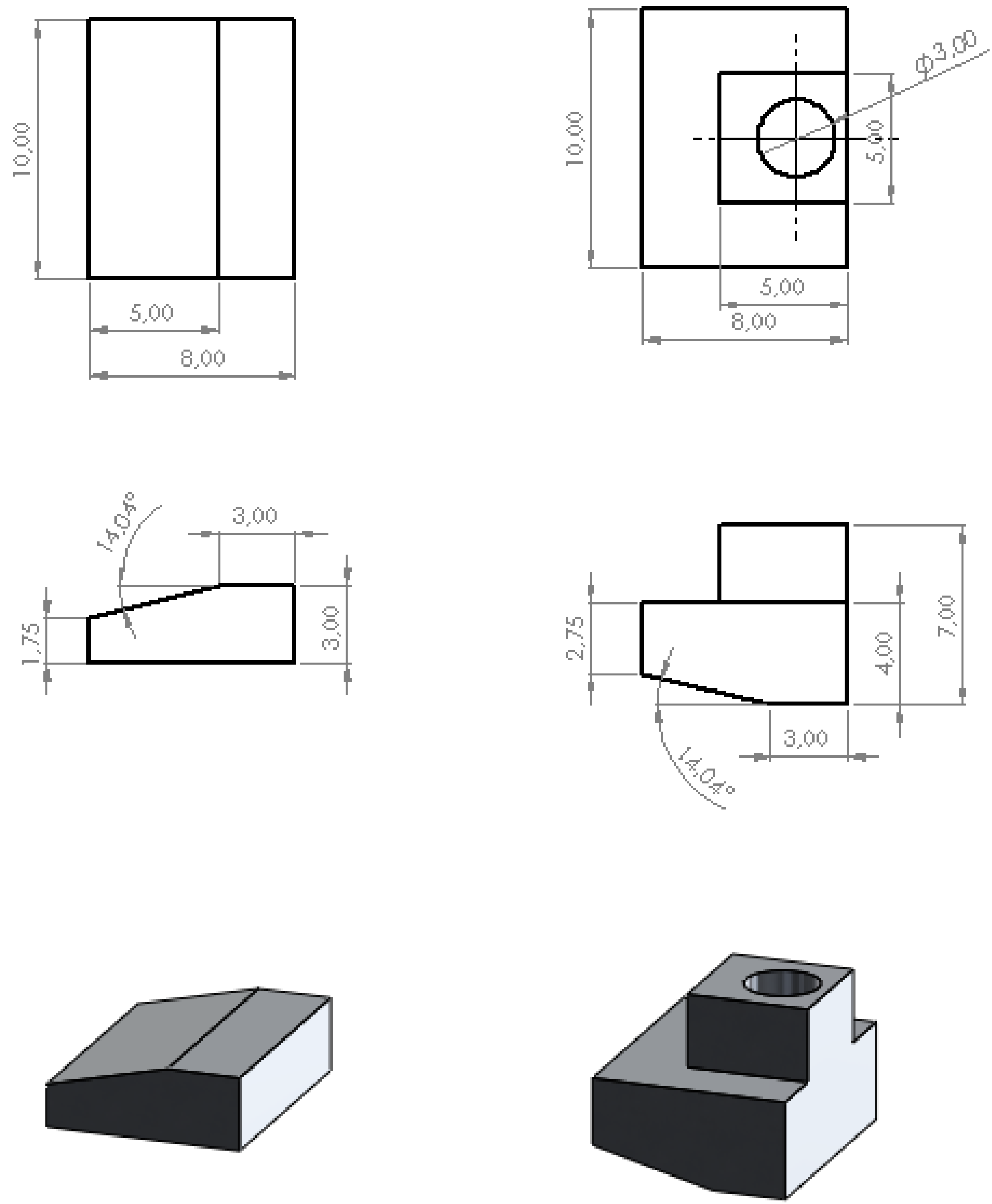
D. Drawings of large frame



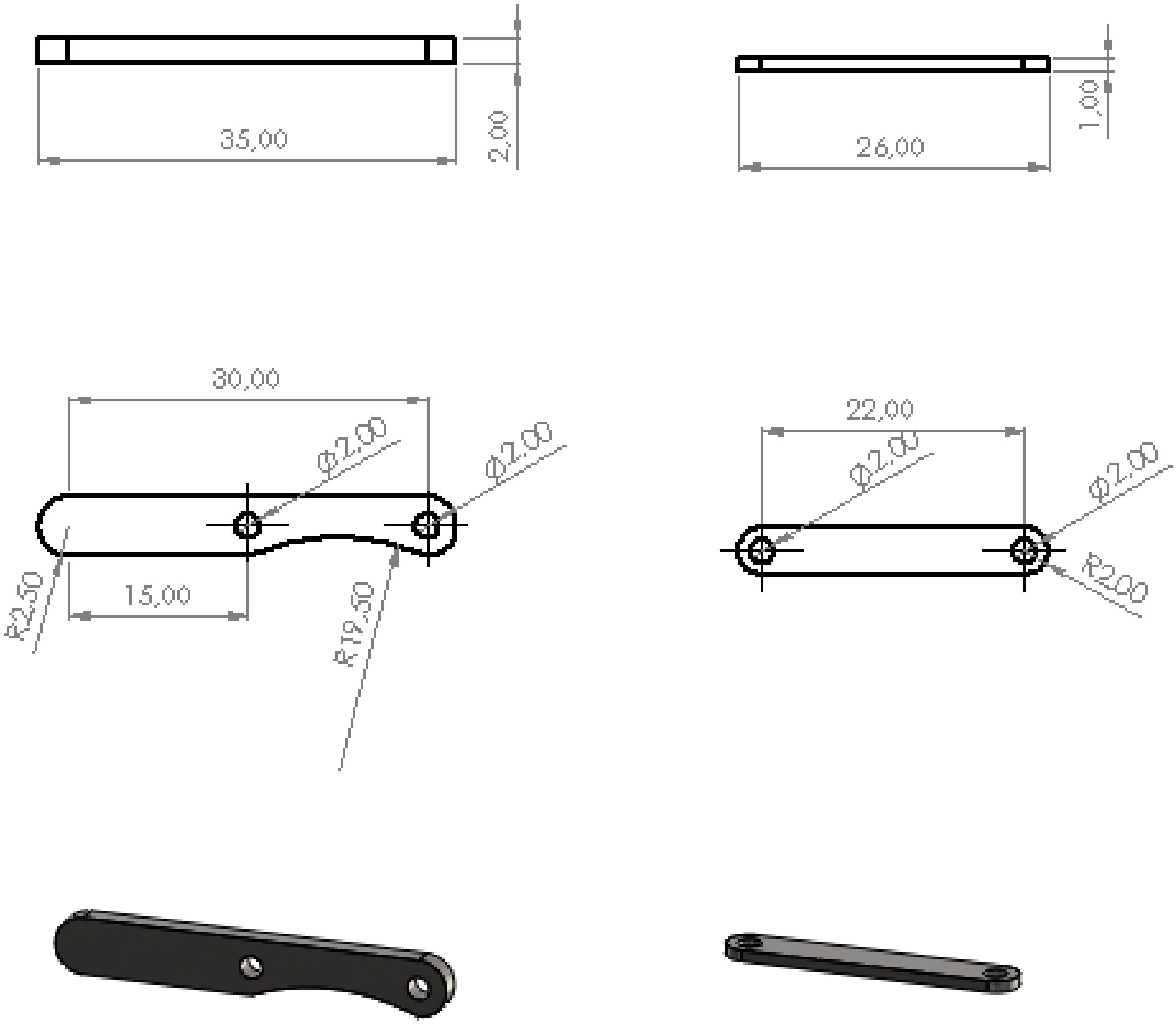
E. Drawings of smart frame



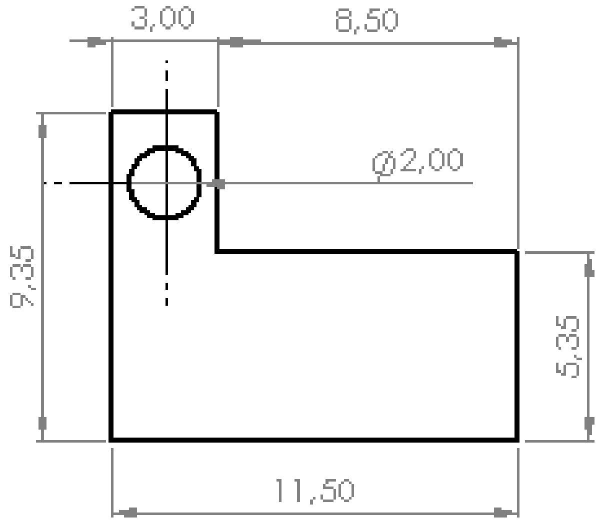
F. Drawings of adjustable inclined plane

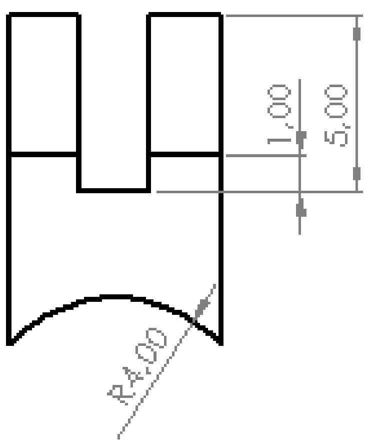


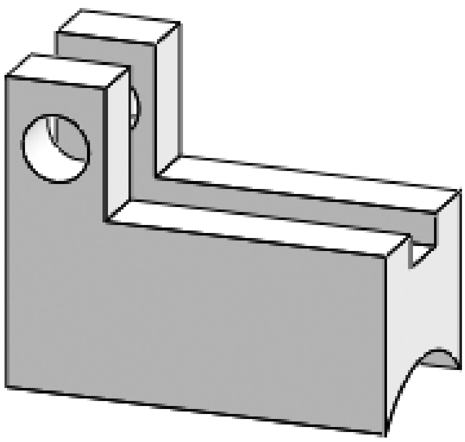
G. Drawings of lever



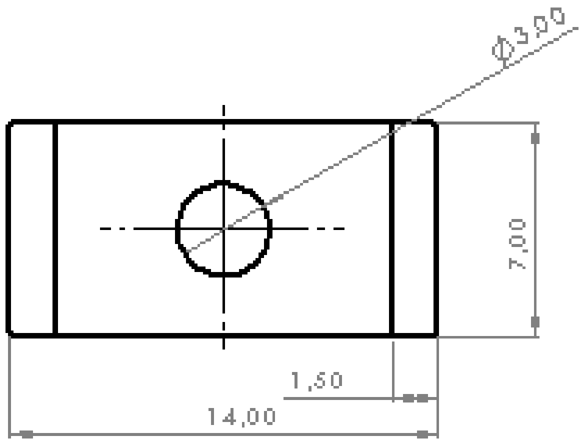
H. Drawings of pivot point

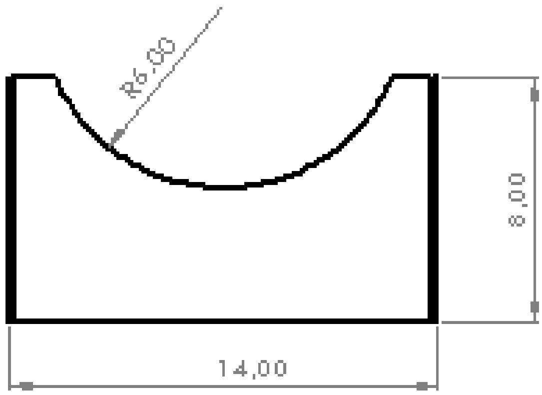


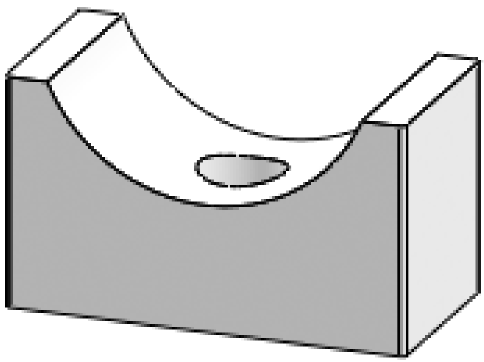




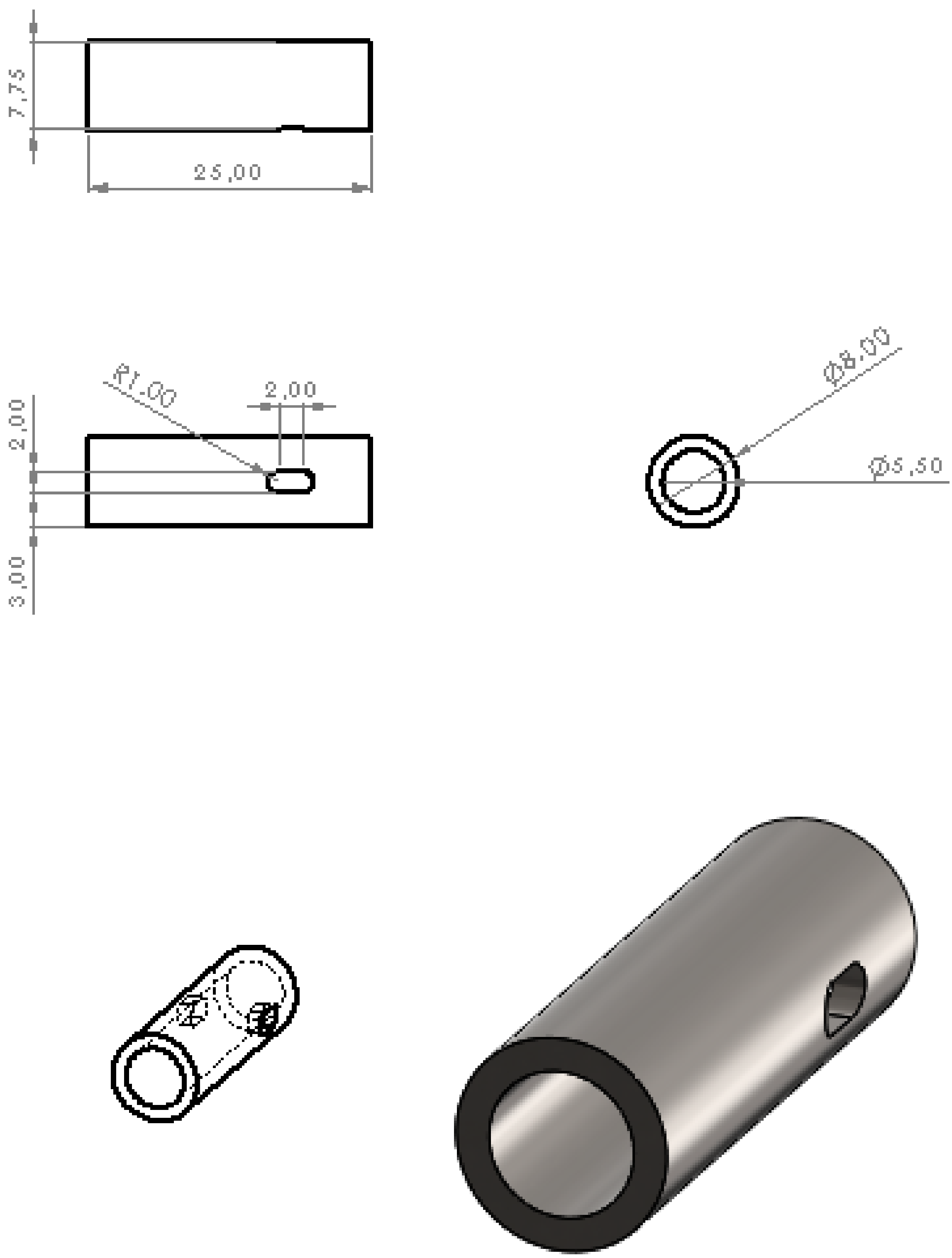
I. Drawings of brake block



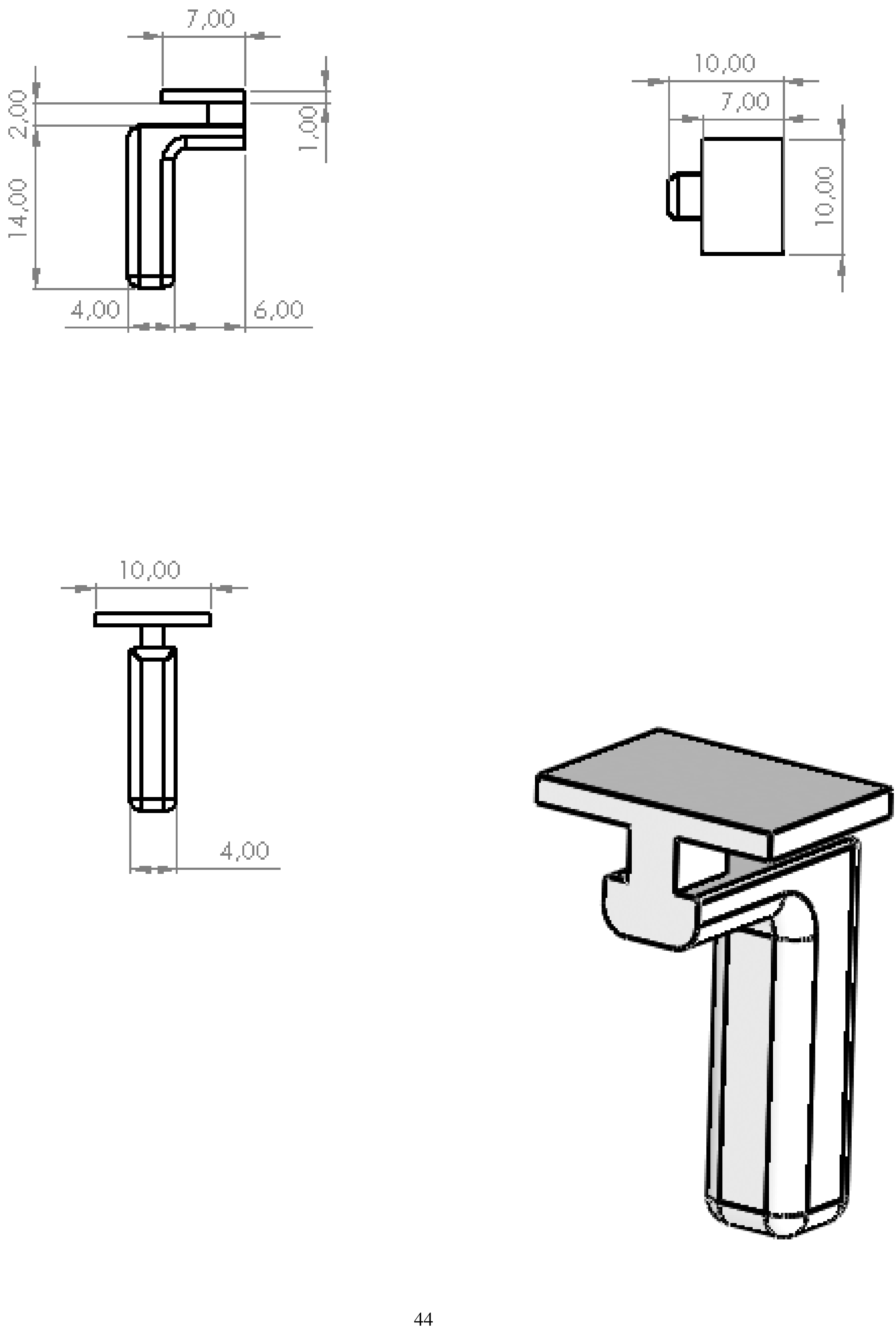




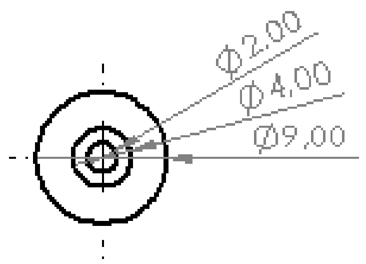
J. Drawings of outer tube

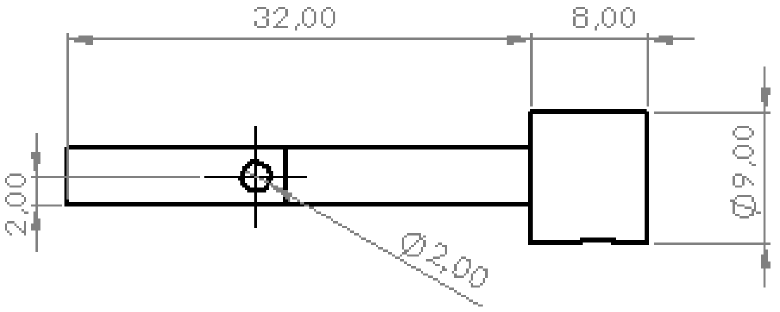


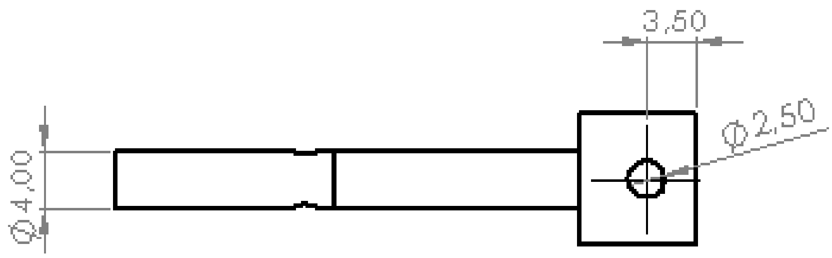
K. Drawings of locking mechanism button

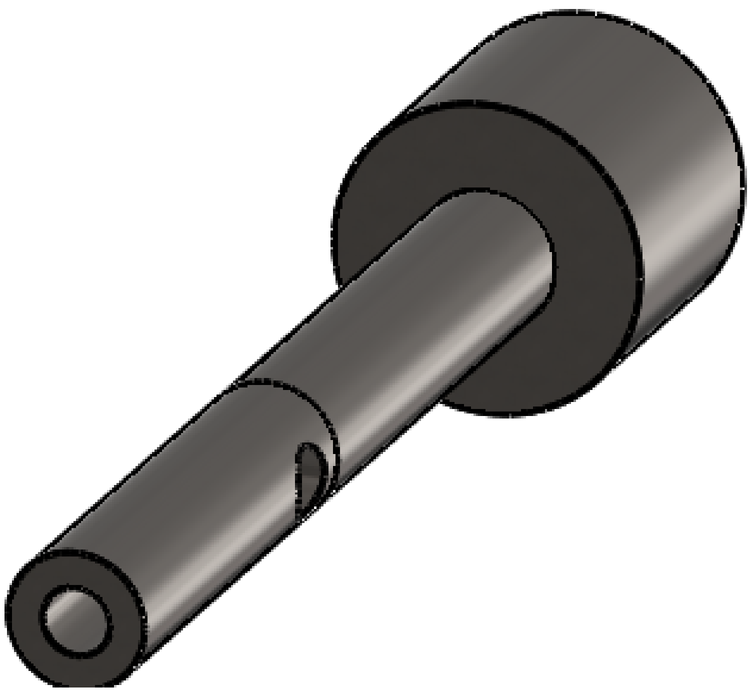


L. Drawings of inner tube









Survey handvat voor ductoscopie

Wat is je leeftijd?

____

Wat is je geslacht?

☐ Man ☐ Vrouw ☐ Dat vertel ik liever niet

Wat is je hoogst behaalde diploma?

____

Wat is je beroep? Als je nog studeert, wat studeer je?

____

Ben je rechts- of linkshandig?

☐ Rechtshandig ☐ Linkshandig

Wat zijn de afmetingen van je hand?

☐ Groot ☐ Middel ☐ Klein

Algemene info procedure

De verschillende handvatten die je zo meteen gaat testen zijn mogelijke prototypes voor een kijkoperatie in een (vrouwelijke) borst. Tijdens deze operatie wordt een licht flexibele naald via de tepelingang ingebracht waarmee vervolgens de melkkanalen onderzocht kunnen worden. De arts heeft één hand vrij waarmee het apparaat bediend kan worden en gebruikt de andere vrije hand om de borst naar behoeve te vervormen om de naald in de melkkanalen te kunnen sturen. Met het handvat moet een roterende en een translerende beweging van de naald kunnen worden bewerkstelligd. Deze bewegingen moeten met de vingers die het handvat omklemmen worden aangestuurd.

Handvat 1: Pistool

1. Neem het handvat in je hand. Hoe ligt het in de hand?

☐ Zeer prettig ☐ Enigszins prettig ☐ Neutraal ☐ Enigszins onprettig ☐ Zeer onprettig

2. Welke vinger(s) zijn vrij om te gebruiken om iets in beweging te zetten?

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

3. Welke vinger(s) zou je (het liefst) willen gebruiken? (deze kunnen eventueel niet vrij zijn op dit moment)

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

4. Geef op onderstaande afdeeldingen de volgende dingen aan:
    a. Op welke plekken je graag knoppen zou willen hebben, geef deze aan met een kruisje
    b. Met welke vinger je deze knop zou bedienen (Schrijf op D voor duim, W voor wijsvinger, M voor middelvinger, R voor ringvinger en P voor pink)
    c. Hoe je deze knoppen zou willen bedienen; 1 voor duwen, 2 voor schuiven, 3 voor roteren

Linker aanzicht

Boven aanzicht

Rechter aanzicht

Handvat 2: Pen

1. Neem het handvat in je hand. Hoe ligt het in de hand?

☐ Zeer prettig ☐ Enigszins prettig ☐ Neutraal ☐ Enigszins onprettig ☐ Zeer onprettig

2. Welke vinger(s) zijn <u>vrij</u> om te gebruiken om iets in beweging te zetten?

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

3. Welke vinger(s) zou je (het liefst) <u>willen</u> gebruiken? (deze kunnen eventueel niet vrij zijn op dit moment)

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

4. Geef op onderstaande afbeeldingen de volgende dingen aan:
    a. Op welke plekken je graag knoppen zou willen hebben, geef deze aan met een kruisje
    b. Met welke vinger je deze knop zou bedienen (Schrijf op D voor duim, W voor wijsvinger, M voor middelvinger, R voor ringvinger en P voor pink)
    c. Hoe je deze knoppen zou willen bedienen; 1 voor duwen, 2 voor schuiven, 3 voor roteren

Linker aanzicht


Boven aanzicht

Rechter aanzicht

Handvat 3: Nunchuck

1. Neem het handvat in je hand. Hoe ligt het in de hand?

☐ Zeer prettig ☐ Enigszins prettig ☐ Neutraal ☐ Enigszins onprettig ☐ Zeer onprettig

2. Welke vinger(s) zijn vrij om te gebruiken om iets in beweging te zetten?

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

3. Welke vinger(s) zou je (het liefst) willen gebruiken? (deze kunnen eventueel niet vrij zijn op dit moment)

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

4. Geef op onderstaande afdeeldingen de volgende dingen aan:
   a. Op welke plekken je graag knoppen zou willen hebben, geef deze aan met een kruisje
   b. Met welke vinger je deze knop zou bedienen (Schrijf op D voor duim, W voor wijsvinger, M voor middelvinger, R voor ringvinger en P voor pink)
   c. Hoe je deze knoppen zou willen bedienen; 1 voor duwen, 2 voor schuiven, 3 voor roteren

Linker aanzicht Boven aanzicht Rechter aanzicht

Handvat 4: Hybride

1. Neem het handvat in je hand. Hoe ligt het in de hand?

☐ Zeer prettig ☐ Enigszins prettig ☐ Neutraal ☐ Enigszins onprettig ☐ Zeer onprettig

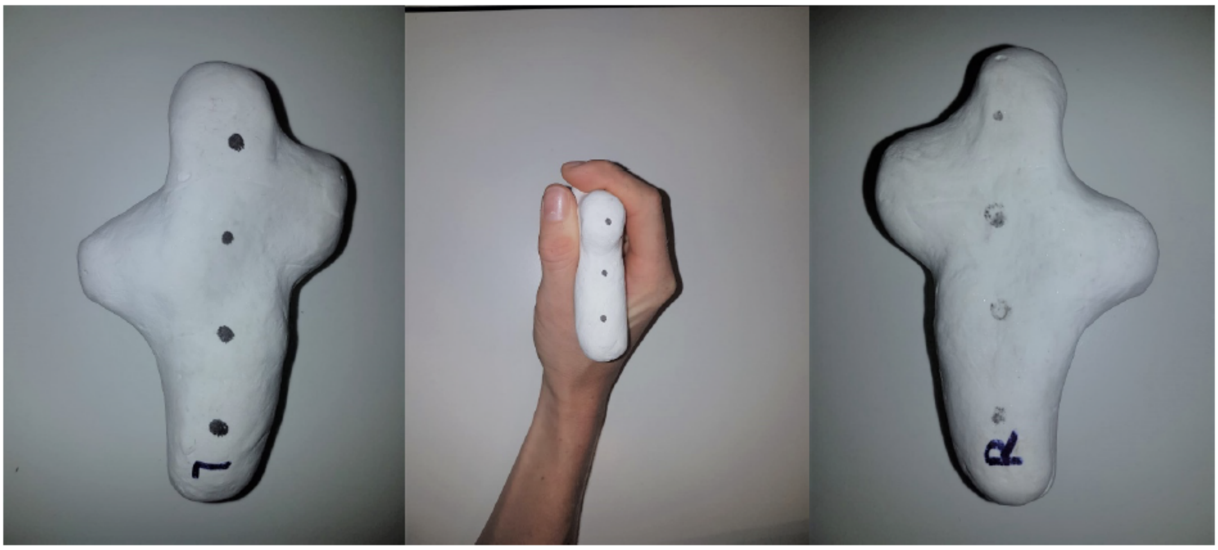
2. Welke vinger(s) zijn <u>vrij</u> om te gebruiken om iets in beweging te zetten?

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

3. Welke vinger(s) zou je (het liefst) <u>willen</u> gebruiken? (deze kunnen eventueel niet vrij zijn op dit moment)

☐ Duim ☐ Wijsvinger ☐ Middelvinger ☐ Ringvinger ☐ Pink

4. Geef op onderstaande afbeeldingen de volgende dingen aan:
    a. Op welke plekken je graag knoppen zou willen hebben, geef deze aan met een kruisje
    b. Met welke vinger je deze knop zou bedienen (Schrijf op D voor duim, W voor wijsvinger, M voor middelvinger, R voor ringvinger en P voor pink)
    c. Hoe je deze knoppen zou willen bedienen; 1 voor duwen, 2 voor schuiven, 3 voor roteren



Linker aanzicht Boven aanzicht Rechter aanzicht

Nu gaan we de vier handvatten vergelijken:

Met het oog op de medische procedure die ermee uitgevoerd moet worden, rangschik de vier verschillende handvatten van meest (1) naar minst (4) comfortabel om vast te houden

☐ Pistool ☐ Pen ☐ Nunchuck ☐ Hybride

Met het oog op de medische procedure die ermee uitgevoerd moet worden, rangschik de vier verschillende handvatten van meest (1) naar minst (4) stabiel om vast te houden

☐ Pistool ☐ Pen ☐ Nunchuck ☐ Hybride

Met het oog op de medische procedure die ermee uitgevoerd moet worden, rangschik de vier verschillende handvatten van meest (1) naar minst (4) nauwkeurig in gebruik

☐ Pistool ☐ Pen ☐ Nunchuck ☐ Hybride

Dankjewel voor je medewerking!