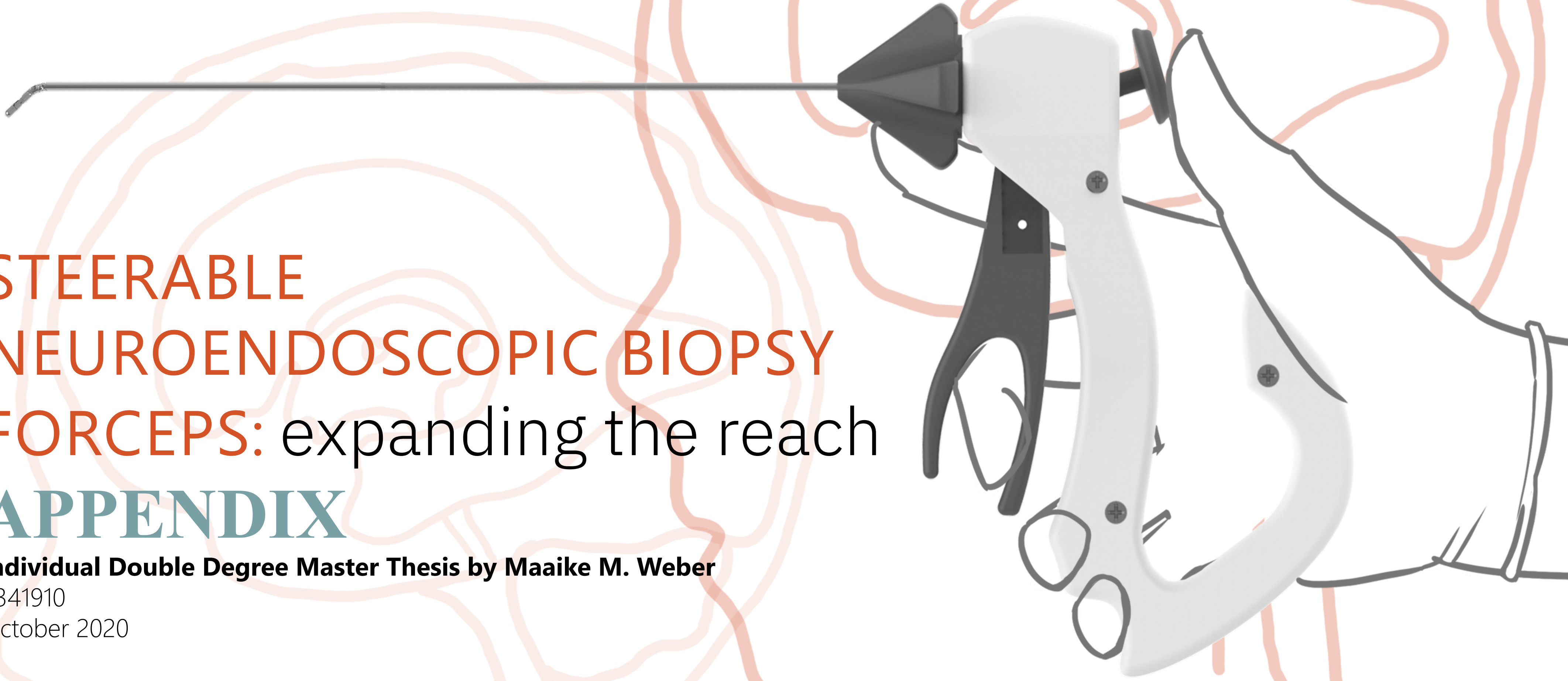


STEERABLE NEUROENDOSCOPIC BIOPSY FORCEPS: expanding the reach

APPENDIX

Individual Double Degree Master Thesis by Maaike M. Weber
4341910

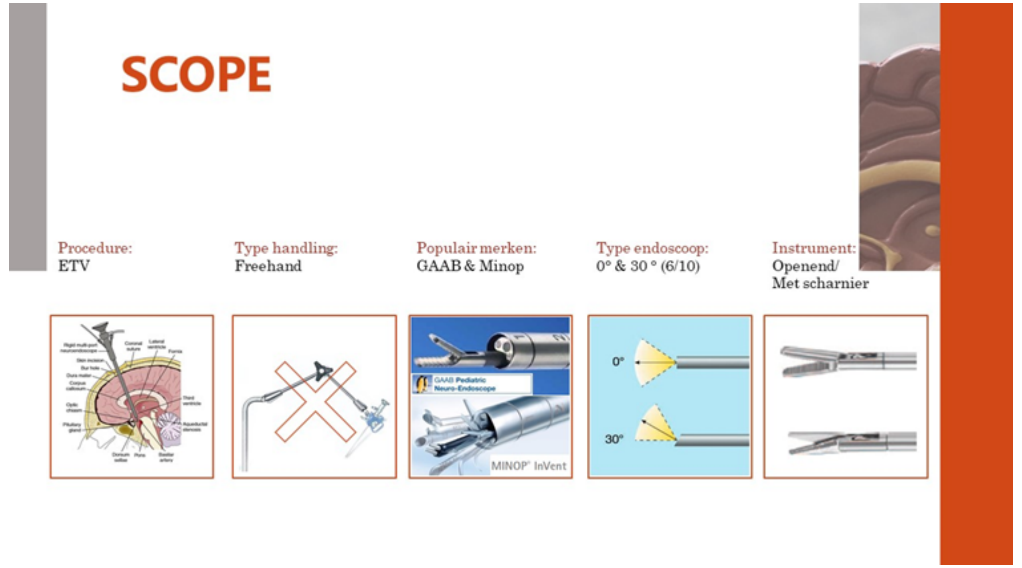
October 2020

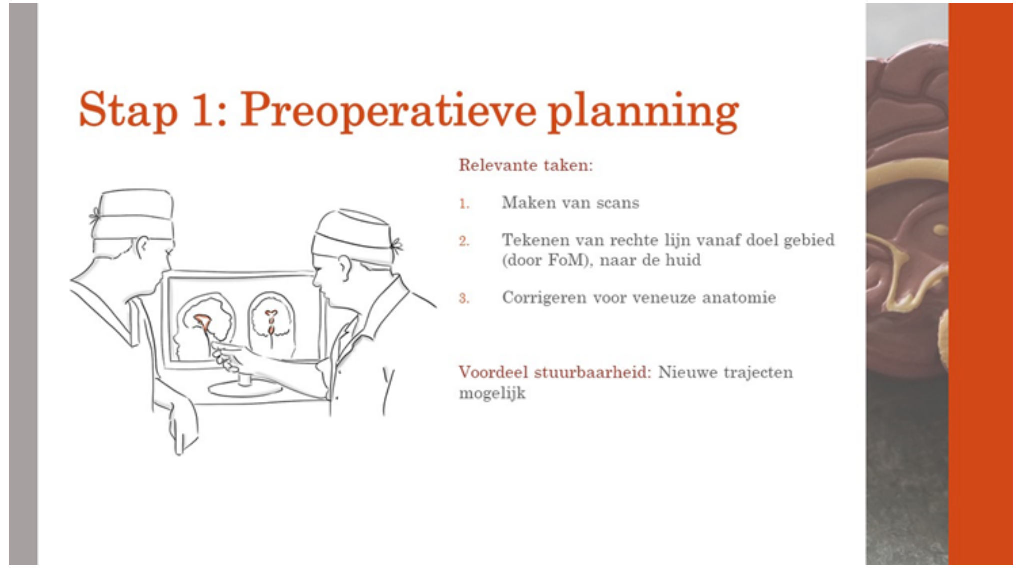
Appendix

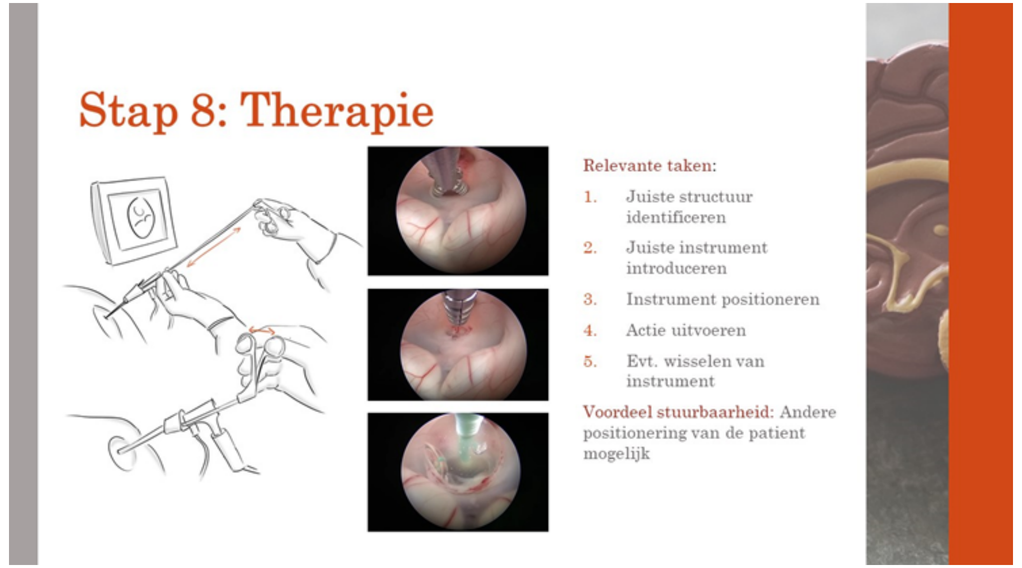
PART 1: Analysis
PART 2: Synthesis
PART 3: Evaluation
A: Lit. study
B: BME thesis article

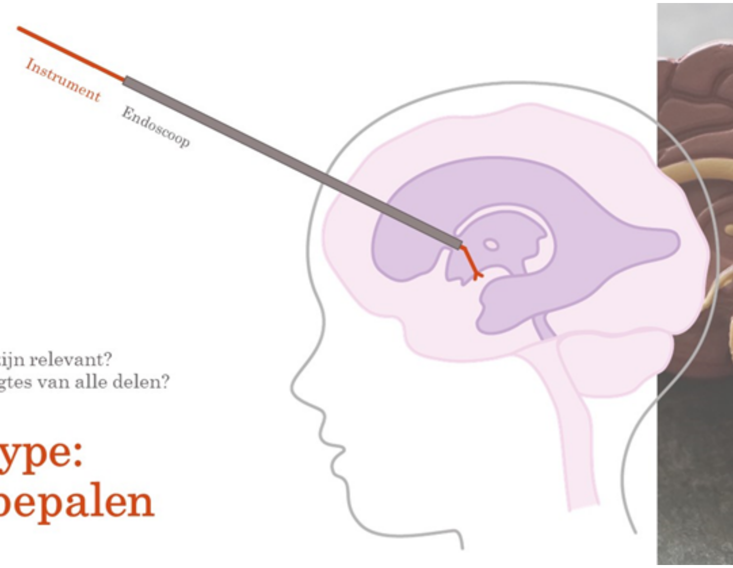
PART 1: Analysis

Appendix 1.1: Interview slides



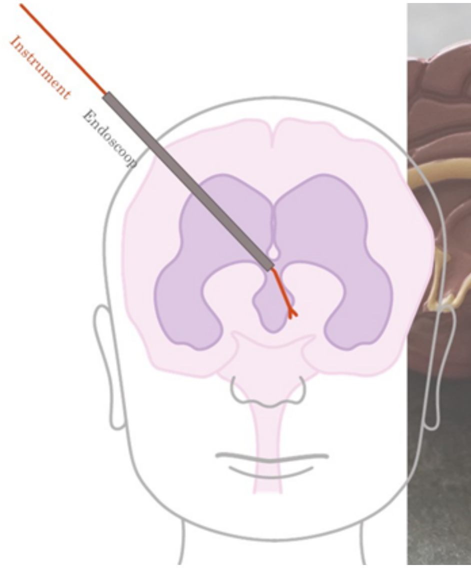






Welke hoeken zijn relevant?
Wat zijn de lengtes van alle delen?

Prototype: Hoek bepalen



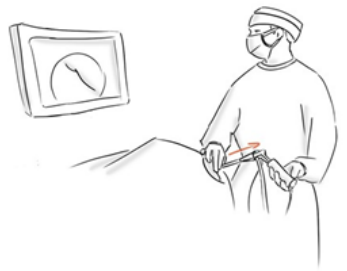
Welke hoeken zijn relevant?
Wat zijn de lengtes van alle delen?

Prototype: Hoek bepalen

Andere vragen

- Waarbinnen moeten de dimensies van de verpakking blijven (ook mbt kasten waar het in moet liggen)?
- 3D print hoofden -> welke leeftijd?
- Verspreiden van vragenlijst
- Single-use, reusable of iets er tussenin?
- Kunt u iets zeggen over het gewicht van huidige instrumenten in grammen?
  - Bent u tevreden hierover?

Stap 9: Terugtrekken van het systeem



Relevante taken:

1. Laatste check
2. Systeem in z'n geheel terugtrekken
3. Onderweg controleren op bloedingen

Voordeel stuurbaarheid: ?

Vragen:

1. Hoeveel tijd is er nu voorbij sinds het inbrengen van de trocar?
2. Is er op dit moment ergens fysiek ongemak dat is veroorzaakt door het vasthouden van de instrumenten?

Stap 10: Dichten van het gat

Relevante taken:

1. Laatste controle op bloeding
2. Dicht maken van boor gat
3. Hechten

Voordeel stuurbaarheid: Minder ingangen nodig

Vragen:

1. Komt het vaak voor dat er twee ingangen moeten worden gebruikt voor het uitvoeren van een gecombineerde ETV/biopsie?
2. Zou zo'n gecombineerde ingreep het meeste halen uit de stuurbaarheid van het instrument?
3. Is er een wezenlijk verschil in hersteltijd en cosmese als het aantal ingangen kan worden gereduceerd?

Appendix 1.2: User survey

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

Appendix 1.3: User survey

Originele vraag 1: Hoeveel millimeter steekt het instrument uit de trocar tijdens gebruik?

Antwoorden:

- 16.7%: onbekend
- 16.7%: Afhankelijk van de lens (geschat op 4-5mm)
- 33.3%: 4-5mm
- 33.3%: meer dan 5mm

Nieuwe vragen:

1.1 Komt de aangegeven lengte in uw antwoord overeen met de lengte aangegeven in de afbeelding hieronder (Figuur 1)? Indien onjuist, hoe zou u deze lengte nu schatten?

Figuur 1: Illustratie uitstekend instrument

1.2 Zijn de afmetingen van de bekjes van de huidige instrumenten (van scharen/biopsietangetjes/paktangetjes) naar behoeven? Of moet die ook worden herontworpen?

Antwoordveld, typ hier uw antwoord

1.3 Als dat zou is, wat zouden uw wensen zijn voor verbeterde bekjes?

Antwoordveld, typ hier uw antwoord

Originele vraag 2: Hoe lang denkt u dat het articulerende deel van de schacht moet zijn?

Antwoorden:

- 16.7%: 3-4mm
- 16.7%: de tip moet altijd zichtbaar zijn met de camera
- 16.7%: 4-5mm
- 50%: 2-3mm

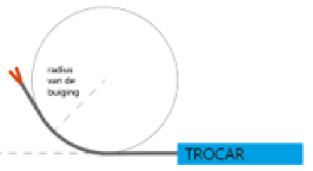
Nieuwe vragen:

2.1 Eigenlijk is de vraag hier; waar moet het 'scharnier' zitten, vanaf het uiterste einde van het instrument. Zie Figuur 2 hieronder. Hoe zou u de lengte inschatten die u daar nodig heeft?

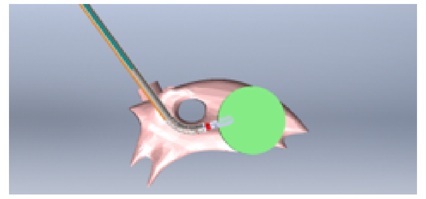
Figuur 2: Illustratie scharnierend instrument

Antwoordveld, typ hier uw antwoord

2.2 In de werkelijkheid zal het instrument niet knikken op één punt, zoals in Figuur 2 hierboven, maar buigen, zoals Figuren 3&4 hieronder. Denkt u dat dit invloed heeft op uw antwoord bij de vorige vraag?



Figuur 3: Buigradius illustratie



Figuur 4: Digitaal model van stuurbaar instrument. Tumor in groen.

Antwoordveld, typ hier uw antwoord

Originele vraag 3: Bent u voorstander van innovatie m.b.t. het type endoscoop? Zo ja, welke?

Antwoorden:

- 50%: 3D endoscopie i.c.m. een head mounted display (HMD)
- 16.7%: Variable kijk hoek i.c.m. een HMD
- 16.7%: 3D endoscopie
- 16.7%: Goede externe fixatie

Nieuwe vragen:

3.1 Kunt u uw keuze hier toelichten (vooral wat de beoogde impact is op de bruikbaarheid van de **huidige** instrumenten)?
Antwoordveld, typ hier uw antwoord

3.2 Denkt u dat een variabele kijkhoek of 3D endoscopie een vereiste is bij het gebruiken van een stuurbaar instrument? Waarom wel/niet?
Antwoordveld, typ hier uw antwoord

Originele vraag 4: Heeft u last van RSI/CANS? Zo ja, waar heeft u precies last van?

Antwoord:

100%: nee/onbekend

Nieuwe vragen:

4.1 *Repetitive strain injury/complaints of the arm, neck and shoulder*, zijn veelvoorkomende klachten bij chirurgen die minimaal invasieve ingrepen uitvoeren. De neuroendoscopische ingrepen duren echter vaak en stuk minder lang dan laparoscopische ingrepen. Is dat de verklaring voor uw afwezigheid van klachten?
Antwoordveld, typ hier uw antwoord

4.2 Als u toch een fysieke klacht heeft, wordt die veroorzaakt door het instrumentarium? Denk bijvoorbeeld aan het gewicht, of de hoek waarin het instrument staat (Figuur 5).

Figuur 5: Voorbeeld van een mogelijk problematische variabele

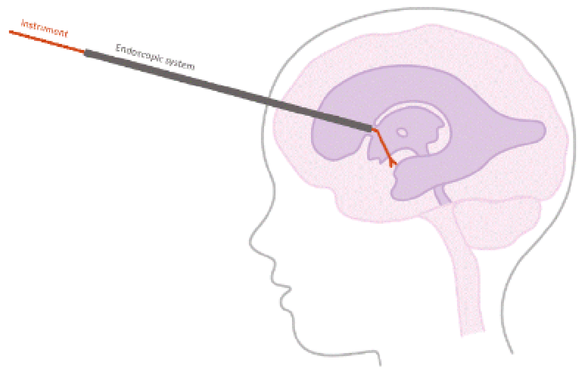
Antwoordveld, typ hier uw antwoord

Appendix 1.4: UR/PS

See external PDF "URPS"

Appendix 1.5: Questions hospital purchaser

Voor mijn afstudeeropdracht ben ik nu bezig met het ontwerpen van een stuurbaar instrument voor neuroendoscopie (denk stuurbaar biopsie tangetje).



Ik heb contact gehad met meerdere neurochirurgen voor het inwinnen van informatie over gebruikerseisen. Ik ben echter ook benieuwd naar waar ik vanuit de markt en de belangen van een ziekenhuis als organisatie/bedrijf rekening moet mee moet houden in het ontwerp. Ik hoop daarom dat u de tijd kunt vinden om een aantal vragen te beantwoorden.
Dit zijn de concrete vragen die ik daarover heb:

1. Hoe vaak komt het voor dat u compleet nieuwe/innovatieve chirurgische instrumenten, van een voor u onbekend merk etcetera, aanschaft voor het ziekenhuis?

2. Wat zijn de beslissende factoren die bij deze keuze een rol spelen? Is dat bijvoorbeeld de prijs, de aangetoonde verminderde operatie duur, esthetiek, trainingsduur, of misschien de verbeterde ergonomische handgreep?

3. Is ergonomie en het verbeteren daarvan überhaupt een groot onderwerp binnen het ziekenhuis en specifiek bij de inkoop?

4. Probeert u zelf de instrumenten ook uit voordat u ze aanschaft, of is dat op basis van specificaties op papier? Zo ja, waar let u dan op?
Of krijgt u nieuwe instrumenten aangeraden door de artsen die ze ergens anders hebben uitgeprobeerd?

5. Informeert u ook bij bijvoorbeeld chirurgisch assistenten? Wat zijn hun eisen aan een chirurgisch instrument?

5. Zijn er ook eigenschappen van de ziekenhuis faciliteiten die bepalend zijn voor de keus? Bijvoorbeeld 'dit instrument past niet in de voorraadkast, dus die kopen we niet'?

6. Zou u een wilde gok kunnen doen naar wat het Erasmus MC een redelijke prijs vindt voor een stuurbaar instrument voor neuroendoscopie. (sorry als dit een ongepaste vraag is)?

7. Is er momenteel vanuit het ziekenhuis een voorkeur voor herbruikbare of wegwerp instrumenten? Of is dit compleet afhankelijk van de prijs van het product en de toepassing?

8. Hoe lang ligt een chirurgisch wegwerp instrument typisch op de plank voordat het wordt gebruikt? Is er veel voorraad of wordt er juist op incidentie van een specifieke ingreep ingekocht?

9. Hoeveel neuroendoscopische sets zijn er aanwezig in het Erasmus MC? Van welk merk zijn die? Weet u hoe vaak die worden gebruikt?

Appendix 1.6: Cultural study

Cultural exploration

Intro

In an effort to investigate the cultural background and behaviours surrounding neurosurgeons and neurosurgery more generally, this chapter aims to answer questions about the historical background, the representation of the neurosurgeon in current media, in the west compared to eastern hemisphere etc.

Method

To achieve a somewhat complete image of the cultural background of neurosurgery, a historical overview was made, after which some specific topics from this overview were selected and elaborated on.

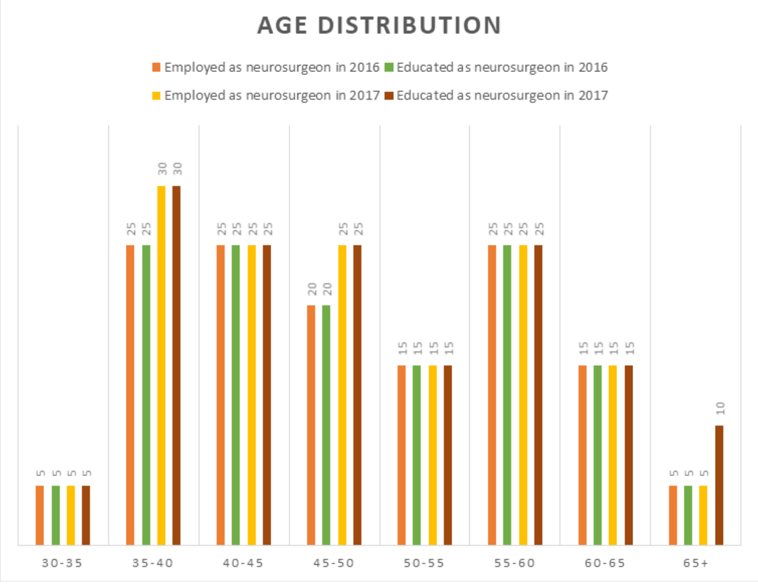
Results

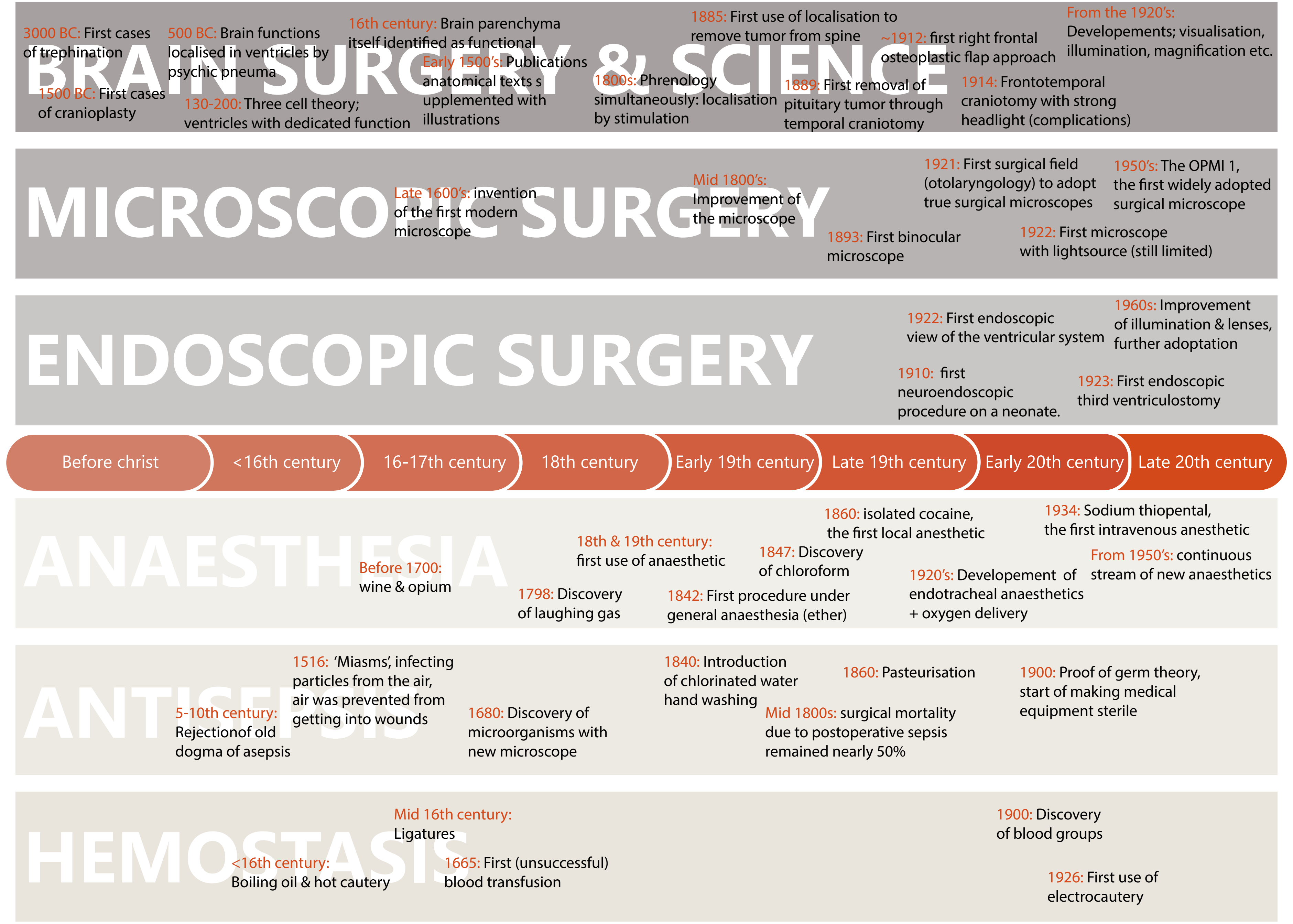
History

The history of (neuro)surgery is summarised in the figure on the next page, organised in the categories brain surgery/science, microneurosurgery, neuroendoscopic surgery, anaesthesia, antisepsis, hemostasis.
It is visible that there have been an increasing amount of developments in all areas, but especially in the areas of microscopic and endoscopic surgery. Most of the events listed in the figure are initiated by one person. They're all men, there was no mention of women in the historical reviews that were analysed.
These men are all described as courageous individuals who all swam upstream, in an attempt to improve lives of their patients. We all thank the current solutions to their hard-headedness, but the way it all is described seems somewhat lop-sided. In the end, these people were also just experimenting, in times there was no informed consent in place. In times where surgery was a way to entertain the public.
However, they were pioneers, regardless of the sacrifices. We can't ask them about their intentions, but we should assume they were good, as they had no way to predict the outcomes of their efforts. The Hippocratic school was the first to document their findings concerning severity of brain injury and which surgical approach was appropriate (460–c.370 B.C.) [84] [85]. The renaissance caused dramatic improvement, where authors like Vesalius and da Carpi published anatomical texts with illustrations. From then on, publications on anatomy and specifically brain injury kept developing. [85] [86]
It is impossible to sketch the picture of the typical brain surgeon without taking into account the history of neurosurgery. This history was presented in the timeline. The following quote summarises it very nicely:
"First and second generation neurosurgeons, without subspecialization or robust imaging/diagnostic technology, were by necessity self-taught innovators who developed many techniques that continue to be utilized today. These advances from individual brilliant minds were enhanced by collaboration with other local surgeons and specialists." [87]

(In)equality

In the database of CBS, the age and gender distribution in neurosurgeons was investigated. In 2017, 120 men were employed as a neurosurgeon, as opposed to 20 women [88]. 25 women were educated as neurosurgeon, 5 more than in 2016. However, the majority was below 40 at that time, which predicts a trend that in the new generations, the gender distribution will become more equal.



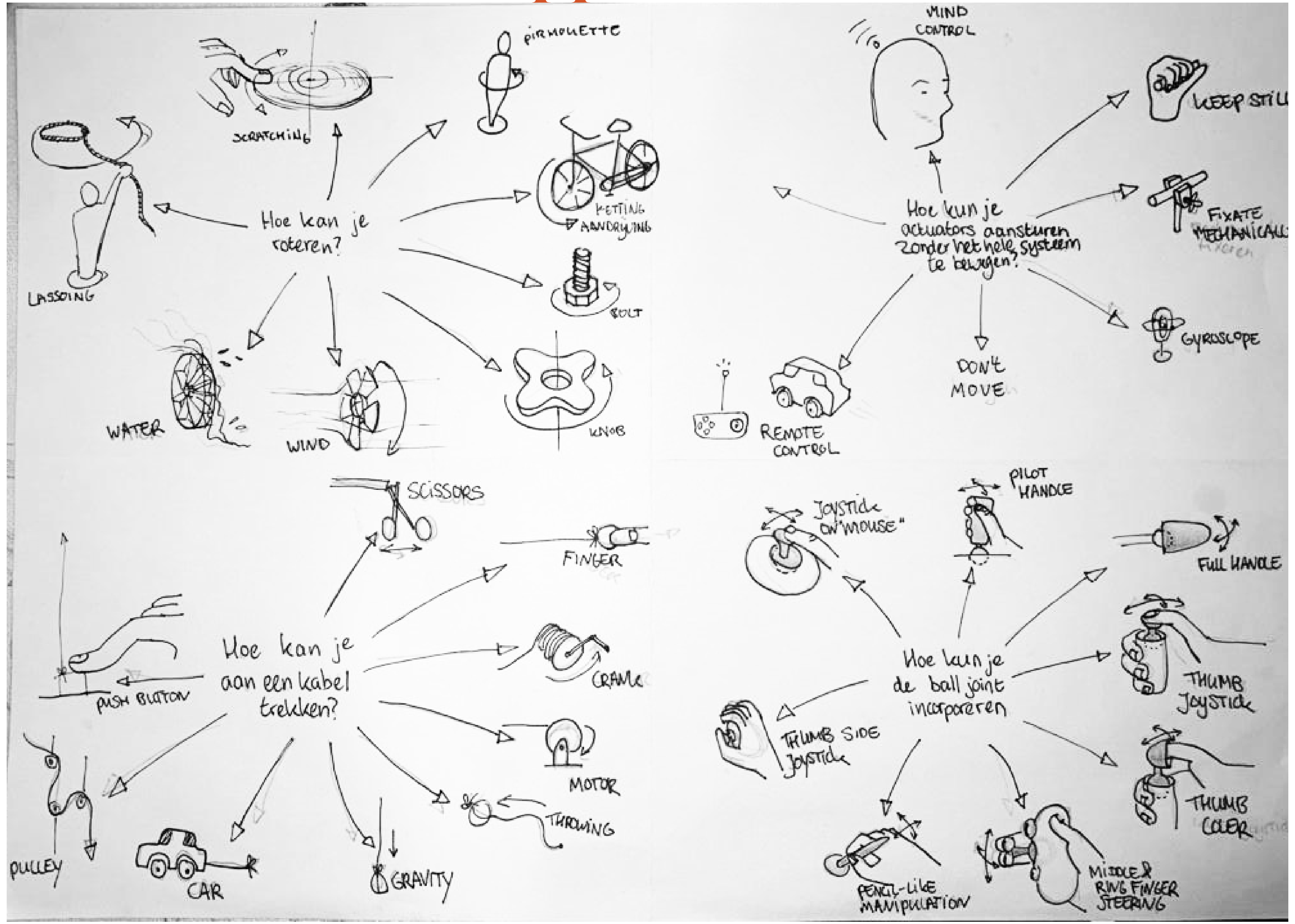


PART 2: Synthesis

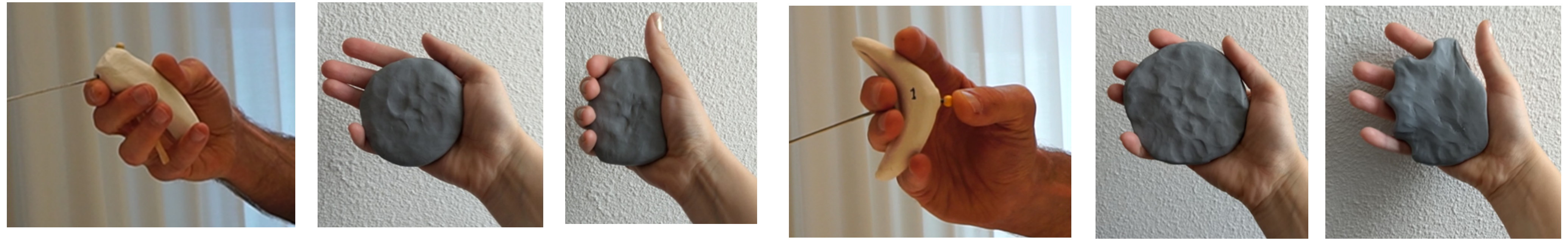
Appendix 2.1: MatLab Simulation tip variables

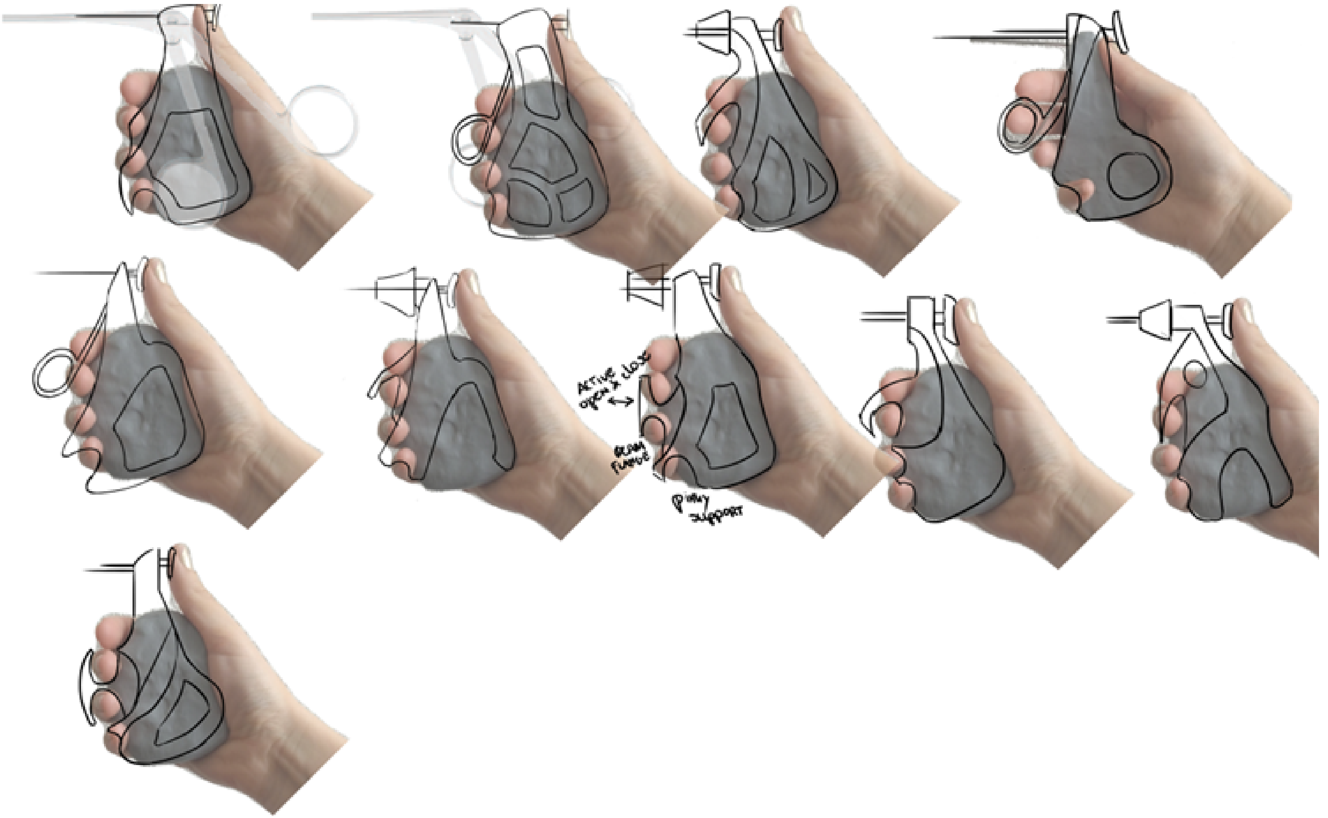
```
clear;
L=3;
lvalues=[];
lvalues2=[];
lmin = 9999999;
lmax = 0;
lsom = 0 ;
l=0; %sw
counter=0;
unreachable = 0;
unreachabletrue = 0;
reachablel = [];
reachabletrue = [];
ltip = 7.3;
ltruevalues = [];

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

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

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

            if (abs(l) ~= Inf) && ~isnan(l) %sw l kon ook nog
-Inf en NaN zijn
                %l ~= Inf
                l = abs(l);
                if l < lmin
                    lmin = l;
                end
                if l > lmax
                    lmax = l;
                end
                if l + L >= 16 %|| l<7
                    unreachable = unreachable + 1;
                else
                    reachablel = [reachablel, l'];
                end

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


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


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

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

            end %l ~= inf

        end %for xt END OF CORRECT CODE


        lvalues=[lvalues;rowvalues];

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

    end % for b
end % for a


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

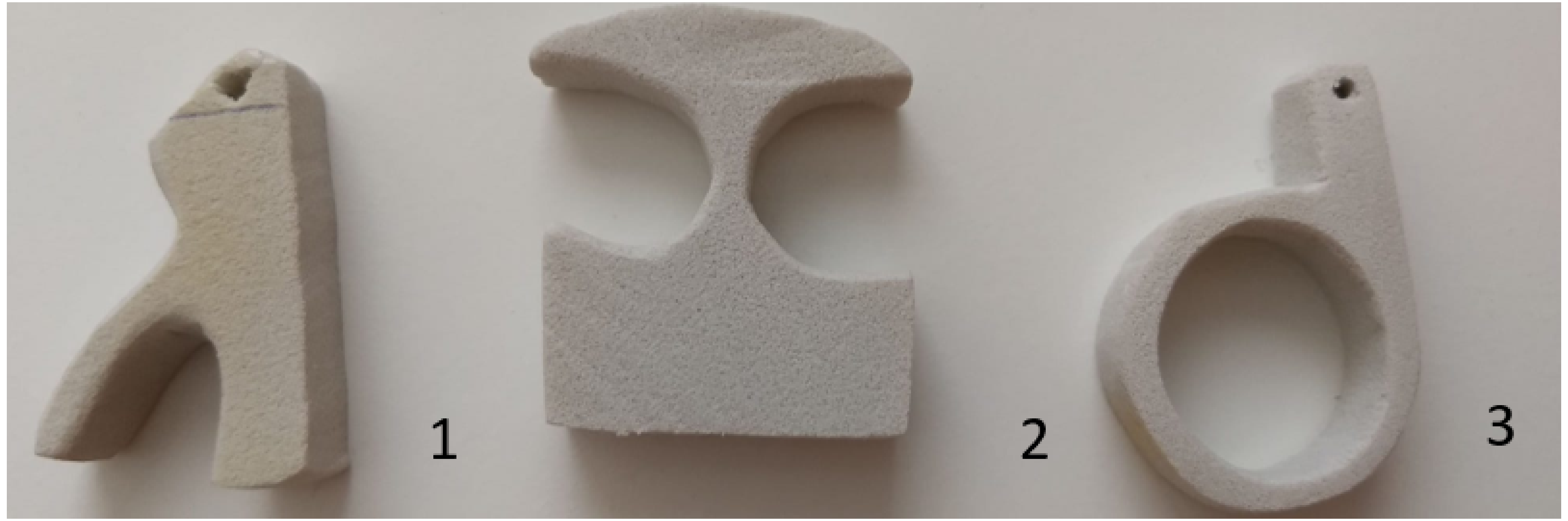

Appendix 2.2: Handle ideation



Appendix 2.3: Second generation ideation







These three triggers or levers were designed. They all have specific characteristics, which are listed below. These triggers can all be placed inside the first foam model that was developed.

Lever 1:

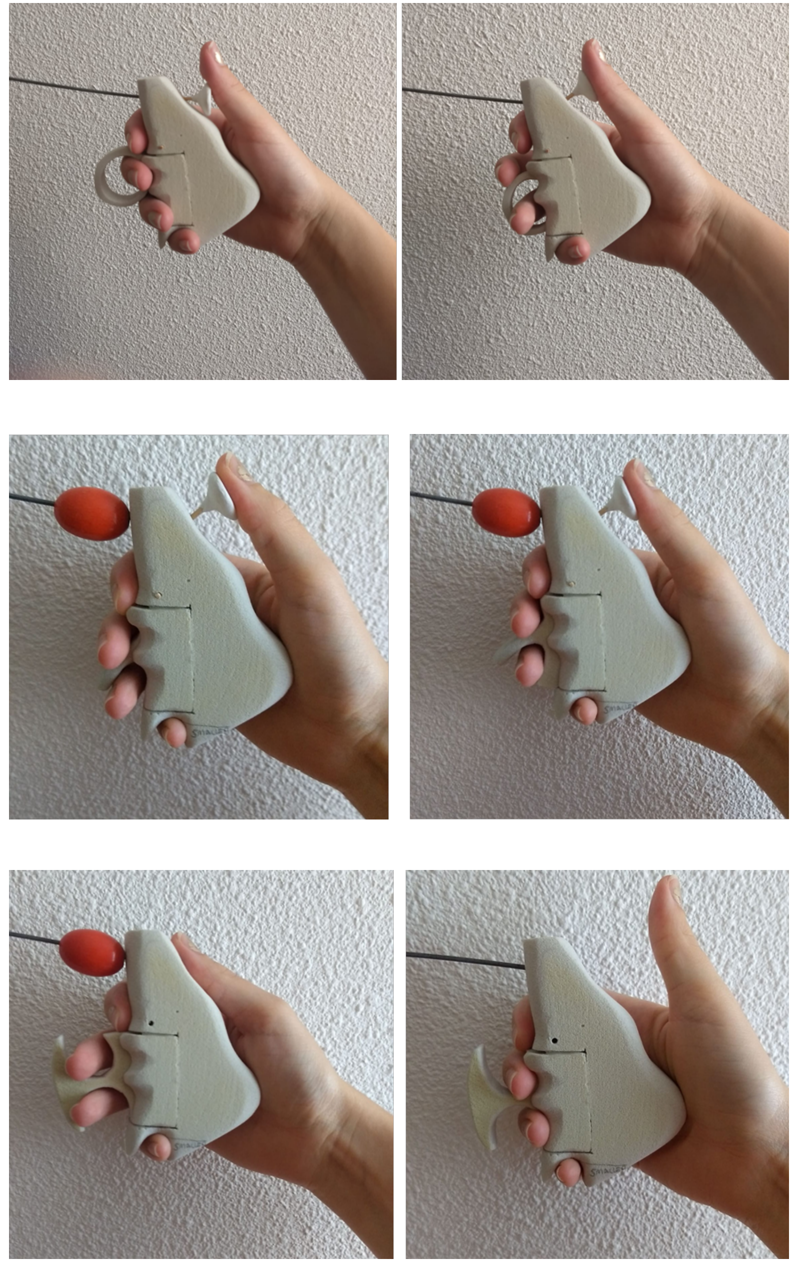
- Only one finger needed, other fingers for stabilising
- No ring, meaning easy removal of the finger
- Second finger can however help with closing
- More fingers will fit, especially when designed with an increasing width over the length

Lever 2:

- 2 fingers can be used to open/close
- Facilitates pinching between two fingers
- Can also be made to tilt (instead of slide)

Lever 3:

- Classic scissor ring
- Both fingers could be used?
- Not-used finger should not be squashed

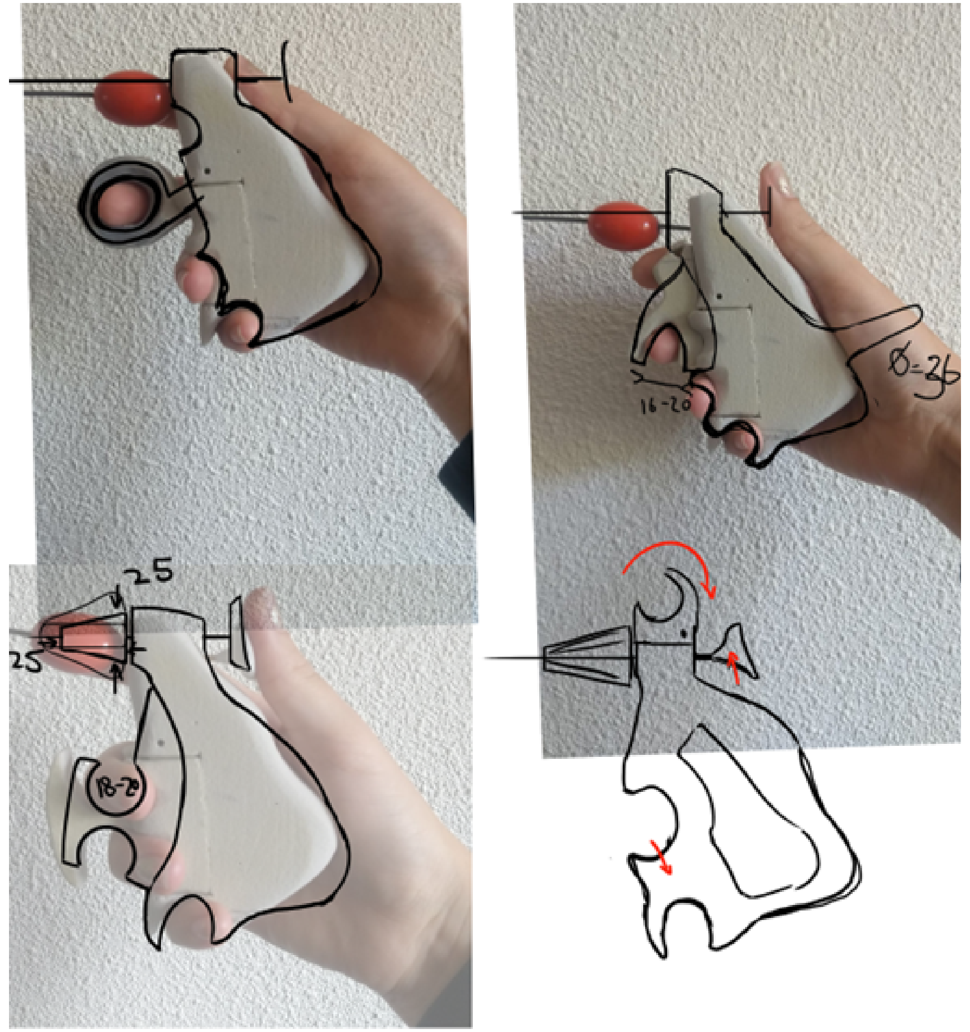


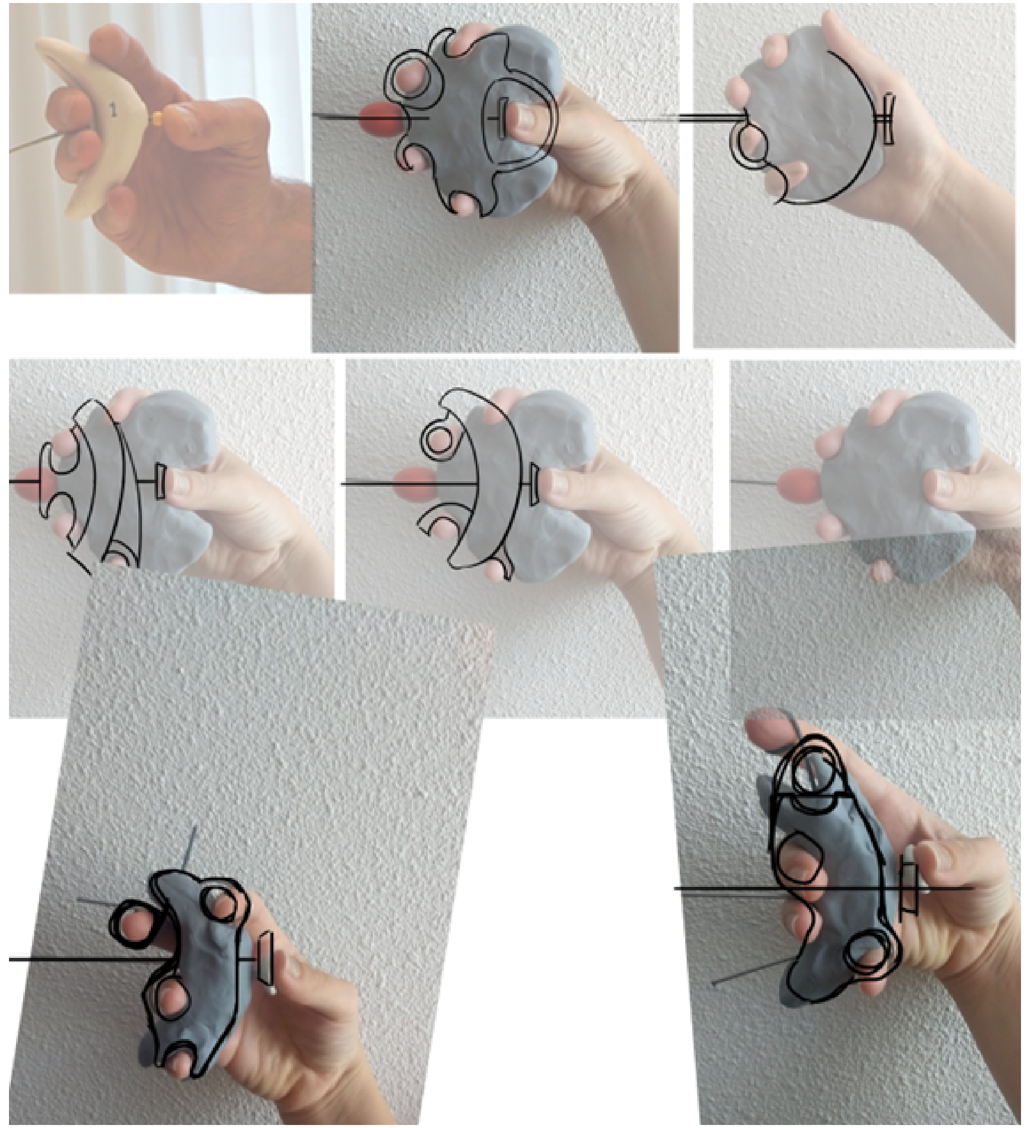
General notes
- Handle is too short
- Handle bottom is too angled
- 'butt' of the handle is too pointy
- Could be thinner
- No place to put the index finger
- If the joystick would be in-line with the shaft, it does not line up with the thumb comfortably.
    - o The pad will probably be angled.
    - o The joystick could be placed a little higher

Trigger 1
- Unclear where the index finger should rest
- Middle finger is most suitable for the end-effector
- Ring finger is a bit in the way
- Ring is too 'thick'
- Ring is too big
- Lever could be a bit longer (ring should be further away)

Trigger 2
- Very simple and comfortable
- Wrong finger though, easier to do with middle finger so bottom two fingers can be used for stability
- Important to determine perfect hinge location

Trigger 3
- 'rings' are way too large
- The middle part is nice for stability
- It not as easy to pull it out straight, it should be hinged





Appendix 2.4: 2nd generation prototypes


3D print Concept 1


3D print Concept 2


3D print Concept 3


3D print Concept 4


3D print Concept 5

Appendix 2.5: Test protocol 2nd generation

Introductory text
Vandaag zal de tweede handvat evaluatie plaatsvinden. De schacht is nog niet functioneel en de volledige ervaring zal dus nog niet realistisch zijn. Ik heb echter een taak bedacht met het oefenhoofd, met een endoscoop, om een zo realistisch mogelijk gebruik van het handvat te simuleren. Het doel van de test is het evalueren van de handvat concepten op het gebied van de eerder geidentificeerde gebruikers Eisen, zoals comfort, gebruik met één hand en stabiliteit. In grote lijnen zijn dat de volgende stappen.
Ik wil vragen om toestemming om alles te filmen en u ook vragen om hardop te denken.

Stappen onderzoeker
1. M: position head
2. M: Connect endoscope
3. Fasten screen at correct height
4. Prepair next concept
5. Check camera

Stappen gebruiker (voor elk concept)
1. Breng de endoscoop in
2. Breng het instrument in
3. Identificeer “tumor”
4. Manipuleer de “tumor” voor ~10 sec, doe hierbij alsof de knoppen functioneel zijn. Probeer vooral de knoppen tegelijk de gebruiken
5. Evaluatie vragen beantwoorden over specifieke concept, graag uw antwoorden toelichten

Questionnaire questions
- Hoe is het algehele comfort op een schaal van 1-5 (1-heel slecht comfort, 5-heel goed comfort)?
- Hoe is het comfort van de pols?
- Hoe is het comfort van de vinger posities?
- Hoe is het comfort van de arm houding?
- Hoe beinvloedt het ontwerp de totale houding?
- Is het concept goed te gebruiken met één hand?
- Hoeveel beweging voelde u in het gehele instrument tijdens gebruik? Waar kwam dat door?
- Was de “pad” van de joystick comfortabel? Waarom?
- Was het gebruik van de rotatieknop comfortable met betrekking tot de locatie van de knop
- Was het gebruik van de “trekker” comfortabel tegelijk met het sturen, of is een lock system nodig
- Is het gebruik van het concept op deze wijze (freehand) mogelijk, of heeft u fixatie nodig?
- Is het openen van de “trekker” net zo comfortable als het sluiten?

Eind evaluatie

- Welk concept heft uw voorkeur?
- Welke trekker heft uw voorkeur?
- Welke joystick “pad” heeft uw voorkeur? (plaatjes)
- Welke joystick “kom” heft uw voorkeur?

Andere vragen
- Met welke lichtsterkte opereert u en heeft u ooit problemen met zichtbaarheid door gebrek aan contrast

Appendix 2.6: Results 2nd generation evaluation

Concept 1
Observations
Pros:
1. Stable
2. Simple
3. Two fingers to always stabilise
Cons:
1. The index finger resting spot is less pro-nounced than intended

Thinking aloud
Pros:
1. Comfortable, also during use of controls
2. Best trigger shape: accommodates for most finger sizes, opening movement is counteracted by two fingers (instead of one, like in concept 1)
3. Critical movements comes from index finger and thumb
Cons:
1. The ring is unnecessary and makes the size of the user’s hand more critical
2. The rotation knob is not wide enough

Concept 2
Observations
Pros:
1. None, the whole plan of stable bottom and functional top did not work in dr. Hoving’s opinion
Cons:
1. Less intuitive

Thinking aloud
Pros:
1. Finger slots are nice
Cons:
1. Not making use of most stable fingers
2. Little too much spread in the hand

Concept 3
Observations
Pros:
1. Possibility to clamp between the fingers
2. Natural hand position
3. Not clear at first how to open and close the end-effector
Cons:
1. The pinky is the only finger counter acting the opening motion of the ring- and middle finger, while it is not strong and difficult to control independently from the ring finger.

Thinking aloud
Pros:
1. Extremely stable, as every finger has its own slot.
2. Good size and volume
3. Simple
5. Simulated “lag” in the joystick is good, as it also contributes to stability (no unwanted movements)
6. Physiological hand position, no tension
7. If needed, the handle allows for counter pressure if it was needed to press the joystick
Cons:
1. The fitting is very critical with the T-shaped handle.
2. In this design, the rotation knob is not wide enough
3. The rotation knob is almost too far away
5. Can’t rotate and “cut” at the same time, as the index finger is needed for stability

Concept 4
Observations
Pros:
1. Stable
2. Neutral wrist
Cons:
1. Unintuitive finger placement
2. Struggle to remove fingers

Thinking aloud
Pros:
1. Comfortable when static
Cons:
1. Difficult to rotate the shaft due to size/width of the rotation knob as well as the type of motion
2. Based on the assumption that rotation is not needed very often
3. Weird shape

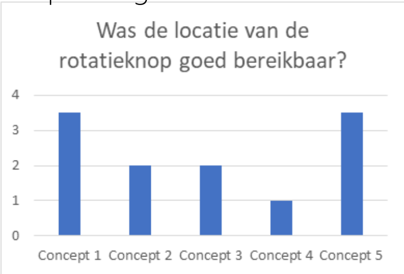
Concept 5
Observations
Pros:
1. Stable
Cons:
1. Using the trigger can cause some move-ment in the whole device

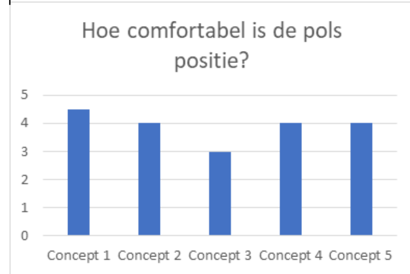
Thinking aloud
Pros:
1. Comfortable
Cons:
1. Operating the rotation knob is quite difficult

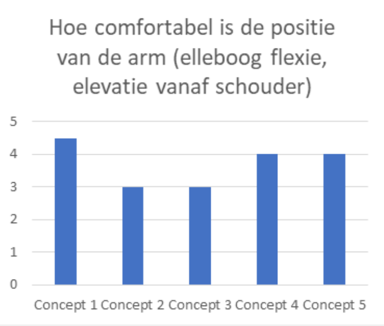
Question	Summary of results
Hoe beïnvloedt het ontwerp uw totale houding?	1: Positive 2: Negative, too different from the Minop 3: Negative 4: Negative 5: Positive to really positive
Is de joystick comfortabel? Waarom?	1: The glue resistance is comfortable and creates stability; creates staged use of functions (a ‘lag’), enough freedom, maybe the shape can be optimised 2: Not usable in combination with hand position 3: Unnatural position of hand 4: Acceptable 5: Yes
Is het gebruik van het concept op deze wijze (freehand) mogelijk, of heeft u fixatie nodig?	1: Yes 2: Controls don’t fit natural finger movements 3: Too difficult 4: Too demanding functions for finger 4 and 3 5: Yes
Was het gebruik van de “trekker” te combineren met het sturen, of is een lock system nodig?	1: Combining the use of all controls was hard but possible, some lock is needed 2-4: Combining was impossible 5: Combining was possible, a lock mechanism however is needed
Hoeveel beweging voelde u in het gehele instrument tijdens gebruik? Waar kwam dat door?	1: Natural pose of hand; little complicated extension use, pleasurable low weight 2: Not stable 3: Unnatural 4: The position is stable when not using the controls 5: The device is stable due to low weight

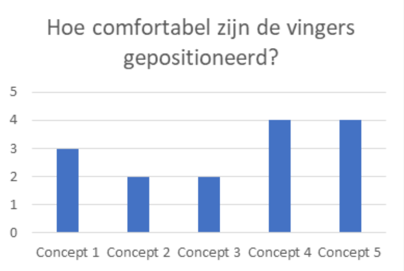
Participant	Wat is uw favoriete concept?	Welke vorm van de "trekker" heeft uw voorkeur?	Welke joystick heeft uw voorkeur?
Participant 1	Concept 1	Die van concept 5	Die van concept 1
Participant 2	Concept 5	Die van concept 5	Die van concept 5

Participant	Wat is uw favoriete concept?	Welke vorm van de "trekker" heeft uw voorkeur?	Welke joystick heeft uw voorkeur?
Participant 1	Concept 1	Die van concept 5	Die van concept 1
Participant 2	Concept 5	Die van concept 5	Die van concept 5

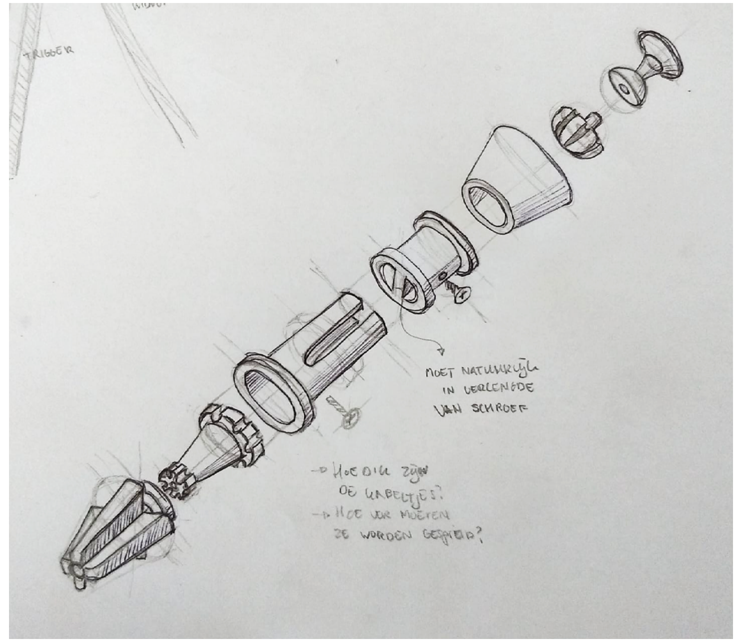


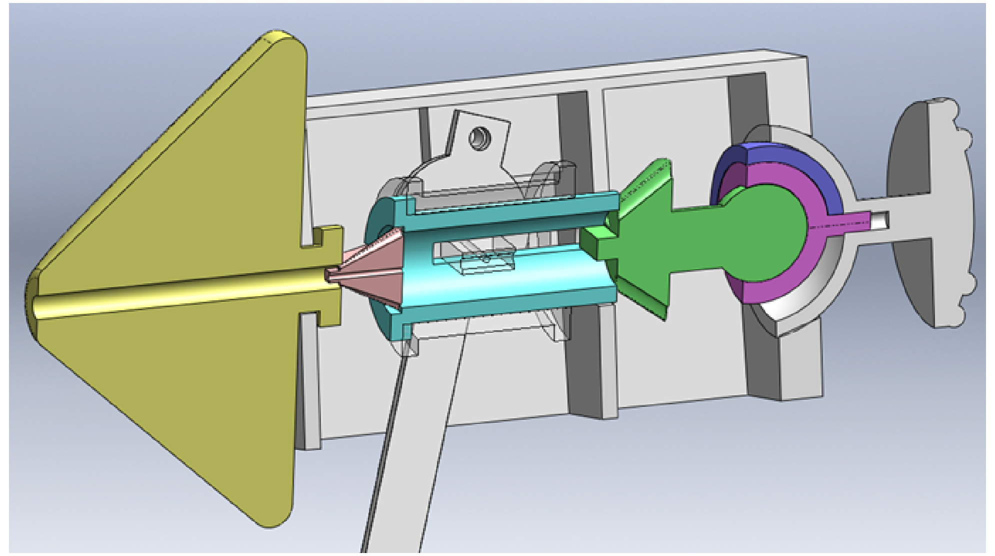


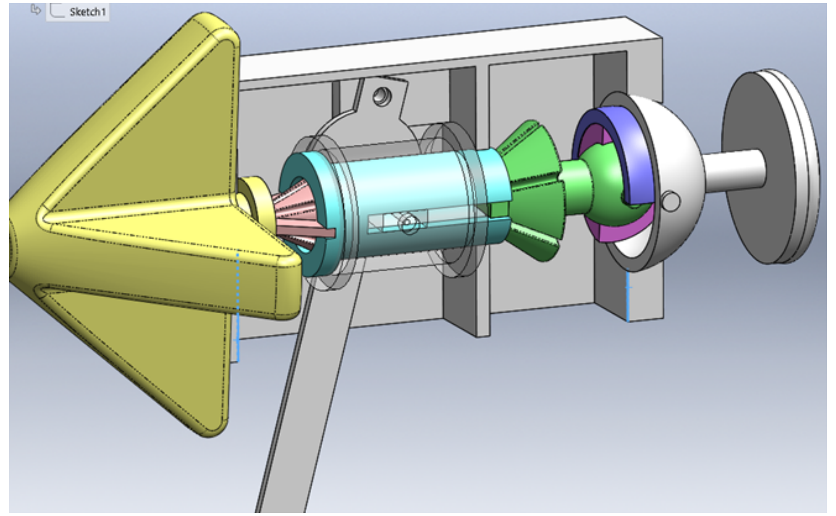


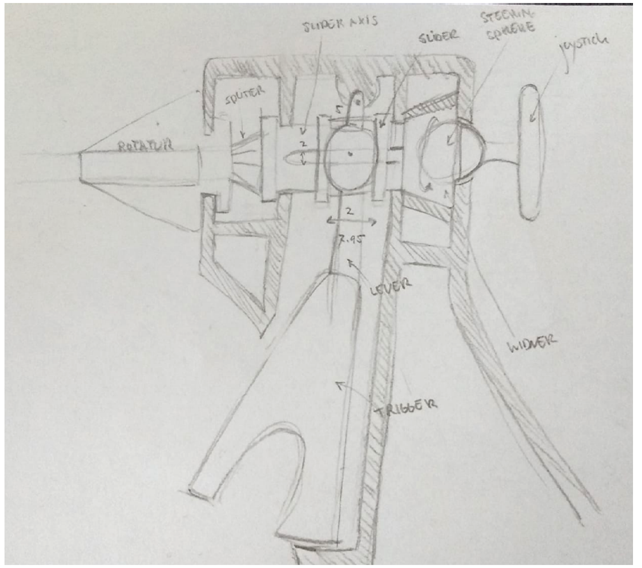


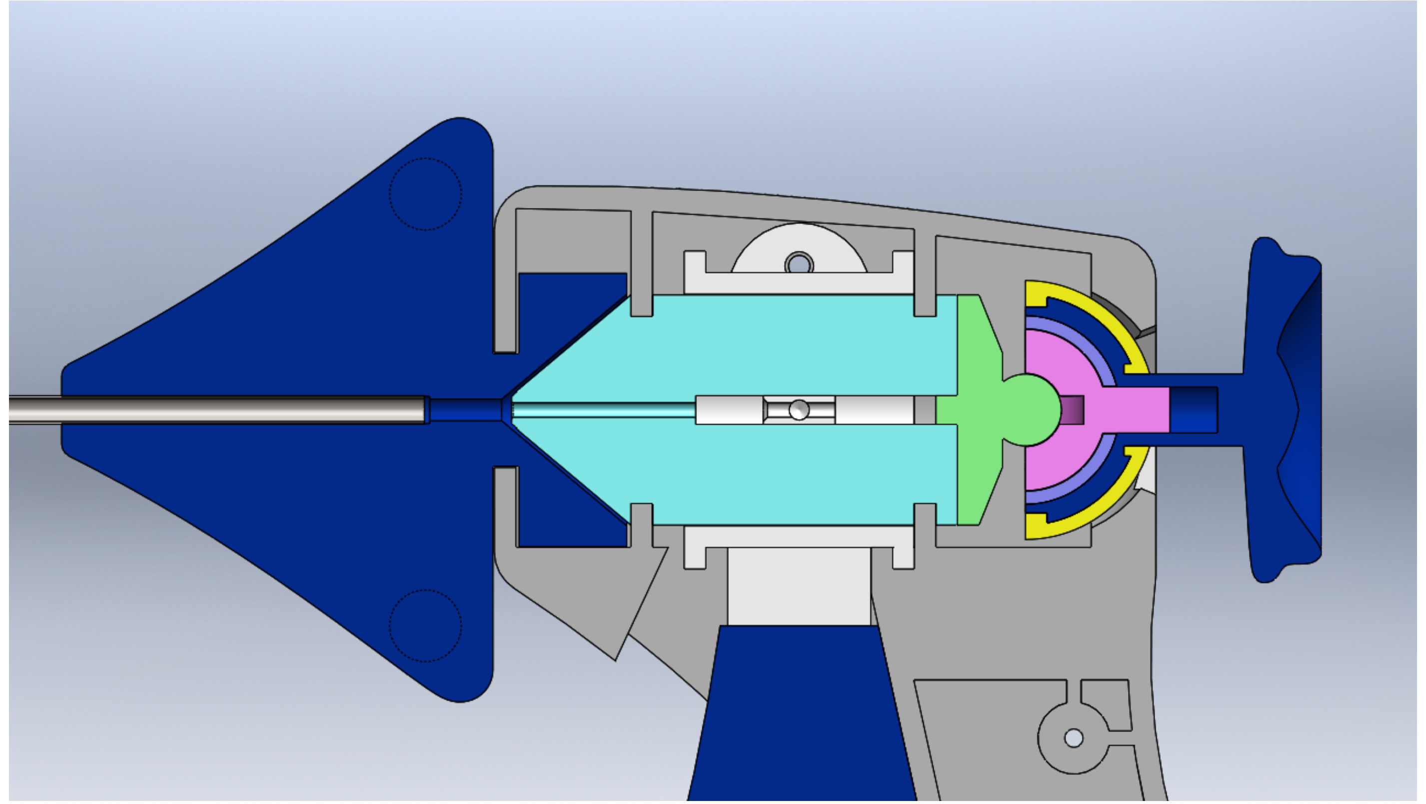
Appendix 2.7: Iterations of the mechanism

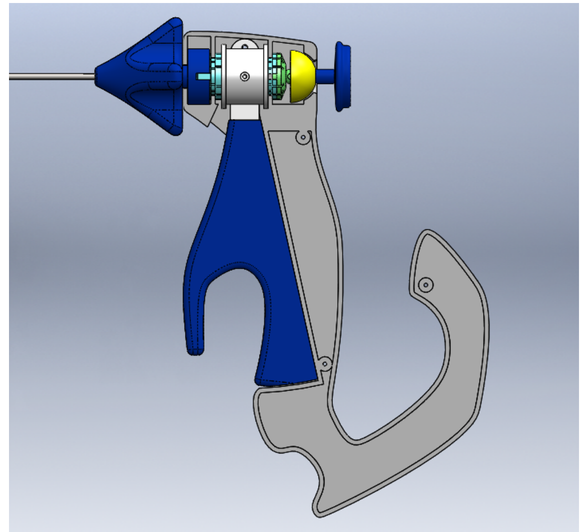


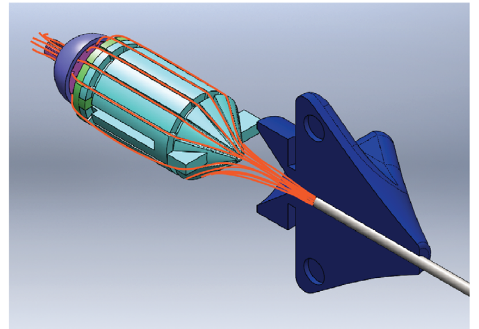




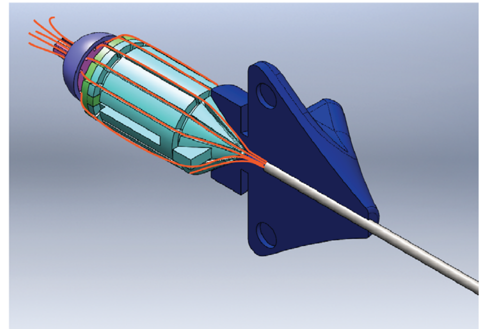




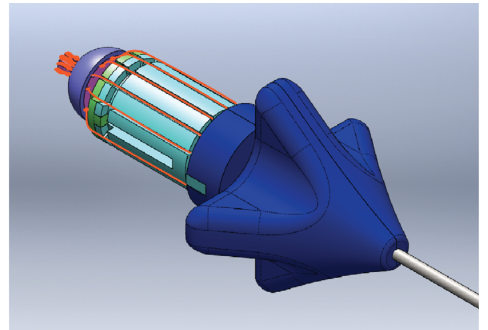




The origin of the steering cables (position in tip) can be identified after which the cables can be placed in their designated slits. If the cables would be twisted during this step, the steering mechanism will not work.

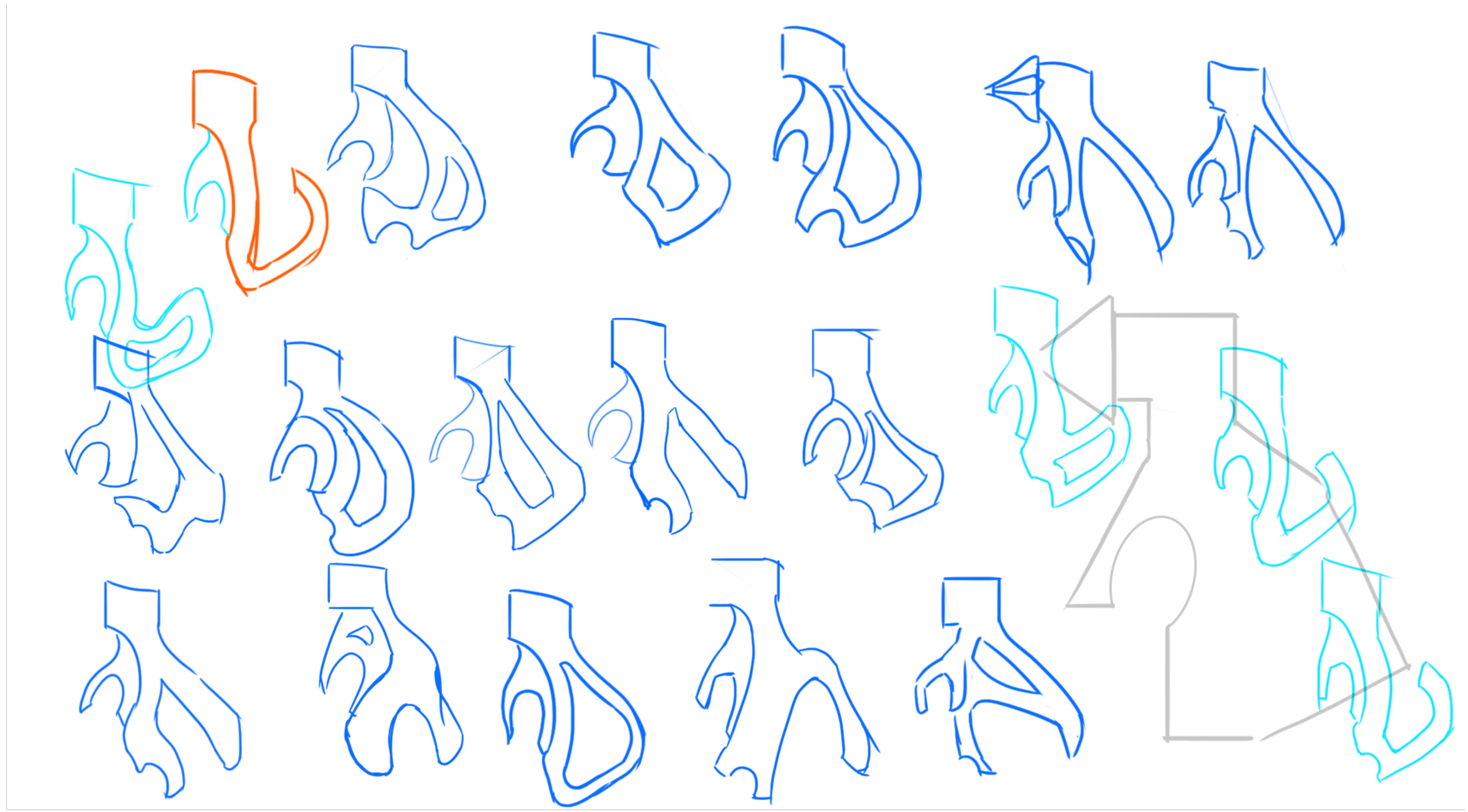


Now, the cables can be tightened to the right length and the roticulator can be moved towards the sliderbeam.



While keeping the hinge sphere and the cable guide perfectly centered, the cables can be glued to these parts. Then, the other half of the articulator can be assembled so that all cables stay in place.

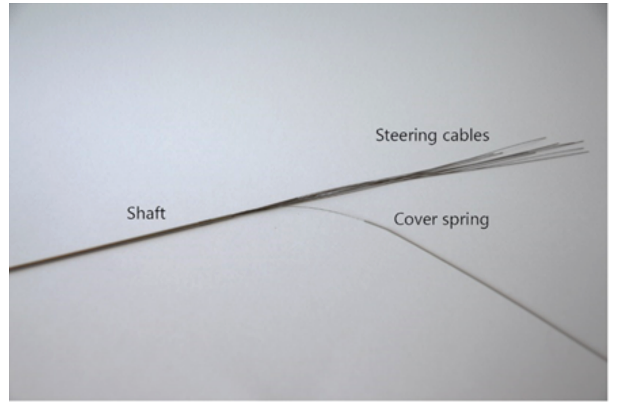
Appendix 2.8: Final prototype sketches



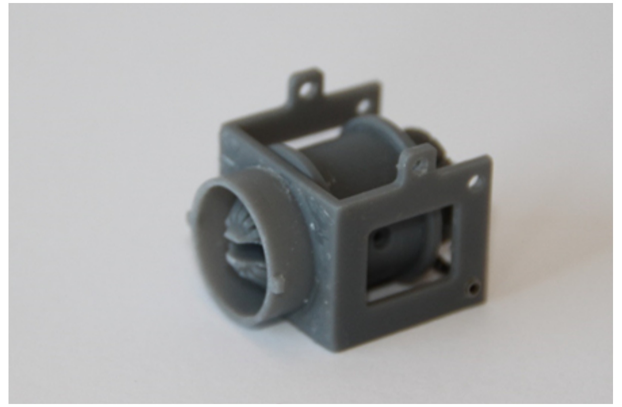
Appendix 2.9: Assembly protocol

1. The tip comes assembled, with core cable welded to shaft tip interface
2. Thread core cable through .5mm spring
3. Thread core cable through tube
4. Secure with epoxy
5. Insert lower slider beam pin in frame

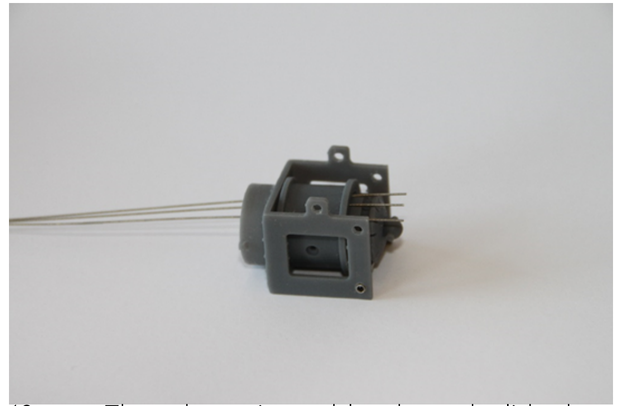
6. Install slider on sliderbeam: plastic greasing can be used to let this bearing run moore smoothly, although it is probably better to apply after installing the cables and springs.



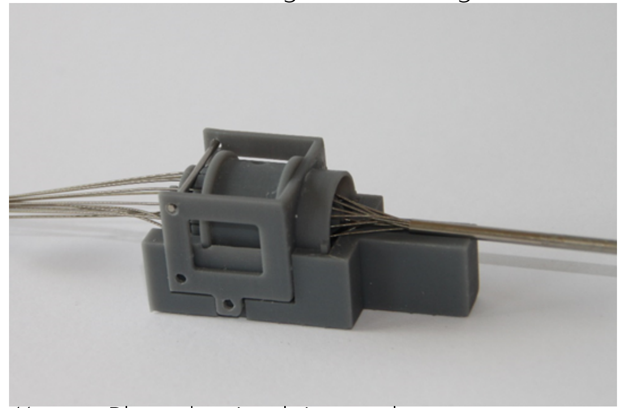
7. Thread steering cables through .5mm springs, this can be done under the microscope for easier insertion.



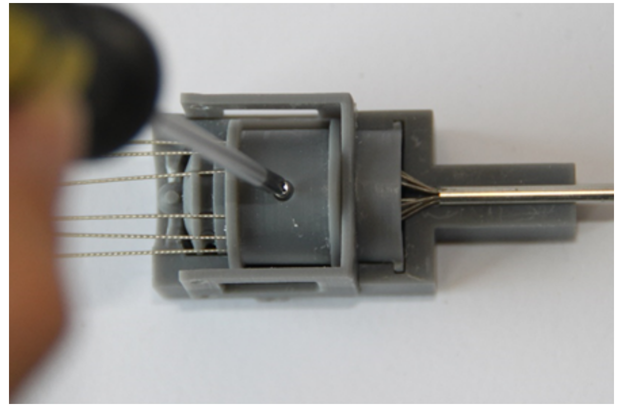
8. Place slider beam plus slider in frame, this is only possible when the slider is completely slid back towards the hinge sphere
9. Thread core tube through hole in slider



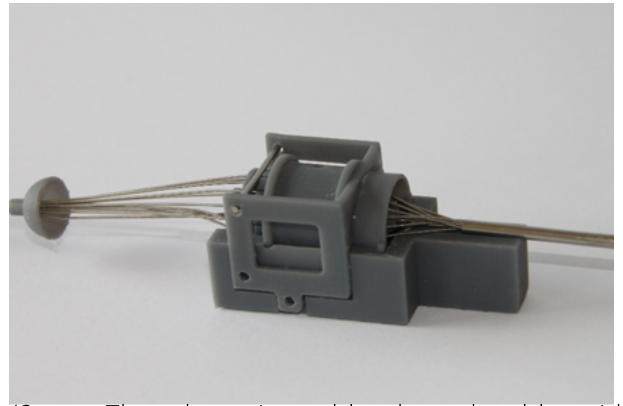
10. Thread steering cables through slider beam



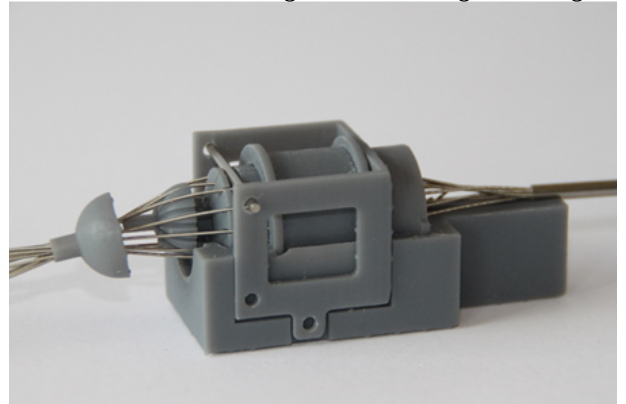
11. Place that in gluing tool



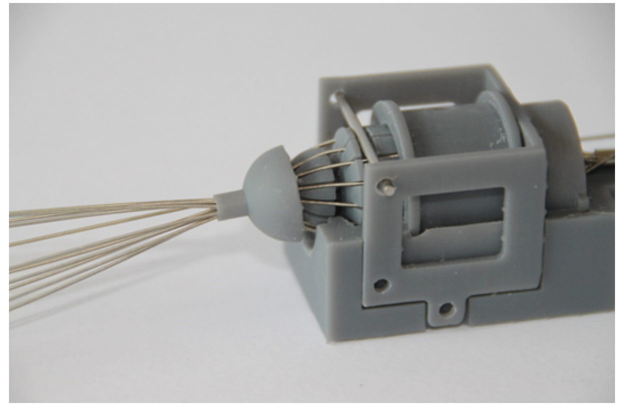
12. Screw core tube secured



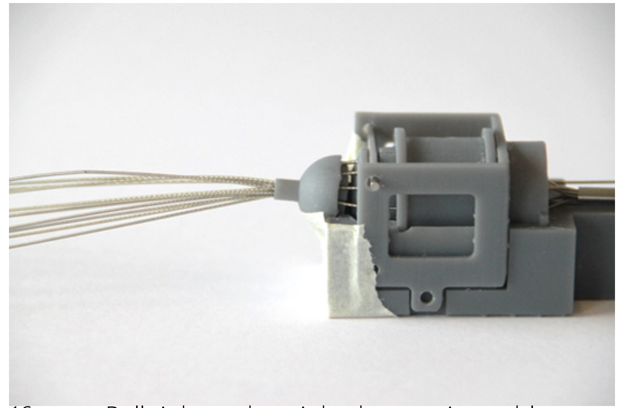
13. Thread steering cables through cable guide



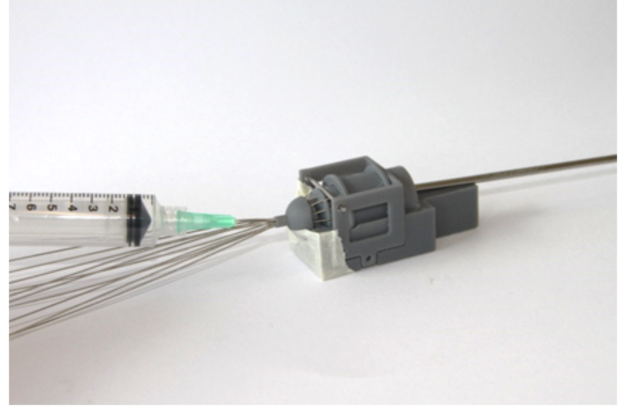
14. Place steering sphere between cables



15. Arrange steering cables in designated gutters

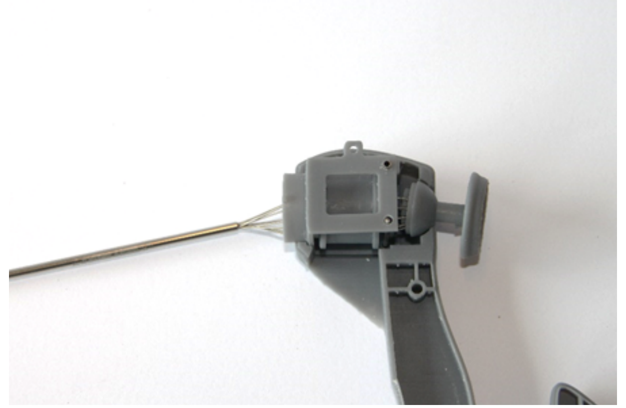


16. Pull tight and straight the steering cables

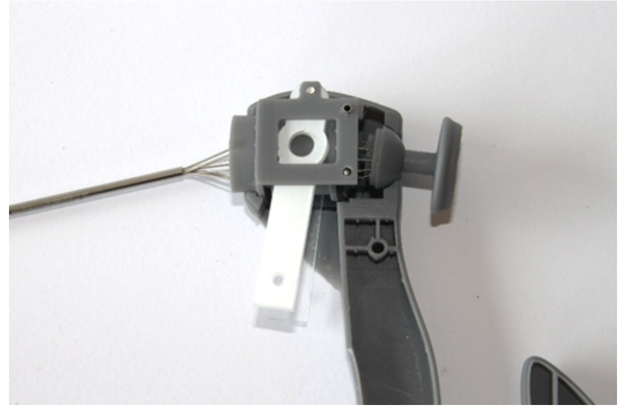


17. Place that in gluing tool
18. Remove glueing tool
19. Insert other pin
20. Insert lever pin

21. Assemble the joystick by inserting the spring



22. Place joystick on cable guide and place whole in handle



23. Insert levers

24. Apply glue

25. Place first half of the roticulator and apply glue

26. Place other half of the roticulator and apply more glue through the glue hole

27. Place other shell half and screw

Appendix 2.10: Bill of materials

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

PART 3: Evaluation

Appendix 3.1: Injection Molding results

Joystick

Quantity: 12,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (mm): 20.00 x 12.00 x 12.00
Weight (g): 2.10
Tolerance (mm): Moderate precision (<= 0.25)
Surface roughness (Î¼m): Normal polish (Ra <= 0.4)

Process parameters

1. Injection Molding
Material
Defect rate (%): 5.00
Material price ($/kg): 2.84
Part weight (g): 2.10
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00
Production
Machine clamp force (kN): 151
Hourly rate ($/hr): 25.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 75
Post-processing time (hrs.): 0.00
Production markup (%): 10.00
Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost summary

1. Injection Molding	$10,627 ($0.886 per part)
Material cost	$453 ($0.038 per part)
Production cost	$4,600 ($0.383 per part)
Tooling cost	$5,574 ($0.465 per part)
Total cost	$10,627 ($0.886 per part)

Shell parts

Quantity: 12,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (mm): 150.00 x 20.00 x 90.00
Weight (g): 47.25
Tolerance (mm): Moderate precision (<= 0.25)
Surface roughness (Î¼m): Normal polish (Ra <= 0.4)

Process parameters

1. Injection Molding
Material
Defect rate (%): 5.00
Material price ($/kg): 4.41
Part weight (g): 47.25
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00
Production
Machine clamp force (kN): 712
Hourly rate ($/hr): 30.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 268
Post-processing time (hrs.): 0.00
Production markup (%): 10.00
Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost summary

1. Injection Molding	$25,871 ($2.156 per part)
Material cost	$3,516 ($0.293 per part)
Production cost	$1,741 ($0.145 per part)
Tooling cost	$20,614 ($1.718 per part)
Total cost	$25,871 ($2.156 per part)

Slider Beam

Quantity: 12,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (mm): 33.00 x 16.00 x 27.00
Weight (g): 5.29
Tolerance (mm): Moderate precision (<= 0.25)
Surface roughness (Î¼m): Normal polish (Ra <= 0.4)

Process parameters

1. Injection Molding
Material
Defect rate (%): 5.00
Material price ($/kg): 4.41
Part weight (g): 5.29
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00
Production
Machine clamp force (kN): 267
Hourly rate ($/hr): 25.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 63
Post-processing time (hrs.): 0.00
Production markup (%): 10.00
Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost summary

1. Injection Molding	$15,300 ($1.275 per part)
Material cost	$2,341 ($0.195 per part)
Production cost	$5,445 ($0.454 per part)
Tooling cost	$7,514 ($0.626 per part)
Total cost	$15,300 ($1.275 per part)

Roticulator

Quantity: 12,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (mm): 34.00 x 15.00 x 35.00
Weight (g): 5.29
Tolerance (mm): Moderate precision (<= 0.25)
Surface roughness (Î¼m): Normal polish (Ra <= 0.4)

Process parameters

1. Injection Molding
Material
Defect rate (%): 5.00
Material price ($/kg): 4.41
Part weight (g): 5.29
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00
Production
Machine clamp force (kN): 267
Hourly rate ($/hr): 25.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 77
Post-processing time (hrs.): 0.00
Production markup (%): 10.00
Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost summary

1. Injection Molding	$13,236 ($1.103 per part)
Material cost	$1,738 ($0.145 per part)
Production cost	$4,493 ($0.374 per part)
Tooling cost	$7,005 ($0.584 per part)
Total cost	$13,236 ($1.103 per part)

Trigger

Quantity: 12,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (mm): 90.00 x 16.00 x 24.00
Weight (g): 18.02
Tolerance (mm): Moderate precision (<= 0.25)
Surface roughness (Î¼m): Normal polish (Ra <= 0.4)

Process parameters

1. Injection Molding
Material
Defect rate (%): 5.00
Material price ($/kg): 4.41
Part weight (g): 18.02
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00
Production
Machine clamp force (kN): 267
Hourly rate ($/hr): 25.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 77
Post-processing time (hrs.): 0.00
Production markup (%): 10.00
Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost summary

1. Injection Molding	$15,342 ($1.278 per part)
Material cost	$2,625 ($0.219 per part)
Production cost	$4,493 ($0.374 per part)
Tooling cost	$8,224 ($0.685 per part)
Total cost	$15,342 ($1.278 per part)

Steering sphere/cableguide

Quantity: 12,000
Material: Polycarbonate, Molded
Envelope X-Y-Z (mm): 11.00 x 11.00 x 10.00
Weight (g): 0.33
Tolerance (mm): Moderate precision (<= 0.25)
Surface roughness (Î¼m): Normal polish (Ra <= 0.4)

Process parameters

1. Injection Molding
Material
Defect rate (%): 5.00
Material price ($/kg): 4.41
Part weight (g): 0.33
Regrind ratio (%): 0.00
Additives ratio (%): 0
Material markup (%): 25.00
Production
Machine clamp force (kN): 151
Hourly rate ($/hr): 25.00
Machine setup time (hrs): 8.00
Machine uptime (%): 95.00
Production rate (parts/hr): 224
Post-processing time (hrs.): 0.00
Production markup (%): 10.00
Tooling
Number of cavities: 1
SPI mold class: Class 104
Mold-making rate ($/hr): 65.00

Cost summary

1. Injection Molding	$6,871 ($0.573 per part)
Material cost	$182 ($0.015 per part)
Production cost	$1,693 ($0.141 per part)
Tooling cost	$4,996 ($0.416 per part)
Total cost	$6,871 ($0.573 per part)

Appendix 3.2: Full results usability test

Participant	1	2	3	4	5	6	7	8	9	10	Average
Hand dimensions	*14, 20, 16*	*16, 22, 20*	*11.5, 17.5, 14*	*17, 20, 17.5*	*14.5, 16, 14*	*12.5, 18.5, 15. 5*	*14, 21, 14*	*14, 19, 17*	*14.5, 23, 20*	*14, 18, 16*	
Het is duidelijk hoe het instrument vastgehouden moet worden	2	4	3	5	3	2	4	4	3	1	3.1
Het is duidelijk hoe de bedieningselementen moeten worden gebruikt	4	5	4	3	5	5	5	4	4	1	4
Het instrument ziet er betrouwbaar uit	5	5	5	4	4	4	3	4	4	4	4.2
Het instrument ziet er uitnodigend uit	5	5	4	3	5	5	2	2	5	4	4
Het instrument heeft een redelijke maat	3	4	4	4	2	4	3	5	3	3	3.5
Het gewicht van het instrument is comfortabel	4	5	4	5	4	5	5	5	5	5	4.7
Het instrument (materiaal, schacht stijfheid etc.) voelt betrouwbaar tijdens gebruik	4	5	5	4	4	4	3	5	4	4	4.2
Er zijn geen scherpe randen of anderszins oncomfortabele uitsteeksels op het handvat	3	5	5	3	5	4	5	5	5	4	4.4
Het is makkelijk om het instrument vast te houden en te bedienen	1	5	3	4	3	3	2	4	3	2	3
Het is makkelijk om het instrument stil en stabiel te houden	4	5	4	5	2	5	1	5	3	2	3.6
De breedte van het handvat is comfortabel	2	3	2	4	3	5	5	5	5	4	3.8
De joystick beweegt nooit te ver weg om comfortabel te gebruiken	4	5	3	5	4	4	2	5	4	3	3.9
De uitslag van de joystick is representatief voor de uitslag aan de tip	4	5	3	5	1	5	4	4	5	4	4
De frictie in de joystick is comfortabel	4	4	4	5	4	5	4	3	5	2	4
De 'trekker' was comfortabel om te gebruiken	2	4	3	3	2	3	5	5	3	4	3.4
Het was gemakkelijk om de end-effector te openen Ã©n te sluiten	2	5	2	4	4	2	3	5	4	4	3.5
Het overhalen van de trekker brengt geen ongewenste spanningen in de hand met zich mee	1	5	2	3	5	2	1	5	3	4	3.1
De roticulator is gemakkelijk om te bereiken	1	5	1	2	1	5	4	5	5	4	3.3
De benodigde krachten om te roteren zijn comfortabel	4	5	3	4	5	5	5	5	3	4	4.3
De benodigde krachten om te sturen zijn comfortabel	4	5	5	4	5	5	4	5	5	2	4.4
De benodigde krachten om de end-effector te openen en sluiten zijn comfortabel	3	5	5	4	5	4	5	5	5	4	4.5

Participant 1
- Roticulator is too far away
- Handle too long
- Intuitive controls

Participant 2
- Not a lot of thinking aloud, thought it was fun to use
- Handle was appropriate size
- Handles the device smoothly and seemingly skillfully

Participant 3
- Wants to use the hook to put the thumb through it (like dr. Hoving)
- Uses a second hand to stabilise
- Weird that the steering is mirrored (with the joystick)

Participant 4
- Very nice movement, more movement in the tip than expected
- No clue how to hold it
- Uses the hook to clamp the thumb for extra stability
- Fun to use

Participant 5
- Difficult to see on the footage, but held the handle horizontally
- States that using the minop dummy, squeezing the handle comes from two directions, making it harder to prevent movement, especially angular movement. In the new design, the whole handle can be kept still with the hand, while only subtly moving the trigger with one or two fingers.

Participant 6
- The width and not the length is problematic; all controls have nice dimensions and work smoothly, it is just difficult to reach over the distance between the pad of the thumb and the tip of the middle finger, to open the end-effector
- States the use is very clear
- Squeezes little finger between trigger and handle
- From observation, hand size seems perfect
- Fun to use

Participant 7
- States that opening the trigger/end-effector is more difficult than closing
- From observation, hand size seems perfect
- Moves in and out of the trocar a lot
- Angles wrist in a weird way, not clear whether that is because of the handle or the maybe the table height.

Participant 8
- Tries all the buttons in a lot of ways
- Uses the hook to clamp the thumb for extra stability
- States it is much easier and more precise than the Minop dummy
- Uses a second hand to stabilise
- Fun to use

Participant 9
- Holds the handle very high up, to use the middle of the thumb instead of the pad/tip to operate the joystick.
- Wants to wrap whole hand around the handle instead of use the wide bottom part with a spread grip.
- Very scared to damage the prototype so very careful

Participant 10
- Only left handed participant!
- Uses the hook to clamp the thumb for extra stability
- Fun to use
- Has to get used to mirrored movement
- Uses two fingers over the trigger and the ring finger inside the trigger

Appendix 3.3: Full results stability test

	Variabele 1: New instrument movement 2	*Variabele 1: Minop movement 2*
Gemiddelde	0.123213337	0.182753191
Variantie	0.002815472	0.007244425
Waarnemingen	11	11
Gepaarde variatie	0.005029948	
Schatting van verschil tussen gemiddelden	0	
Vrijheidsgraden	20	
T- statistische gegevens	-1.968826057	
P(T<=t) eenzijdig	0.031493701	
Kritiek gebied van T-toets: eenzijdig	1.724718243	
P(T<=t) tweezijdig	0.062987401	
Kritiek gebied van T-toets: tweezijdig	2.085963447	

	Minop movement type 1 and 3	*New instrument movement type 1 and 3*
Gemiddelde	0.06636	0.042684
Variantie	0.000434	0.000223
Waarnemingen	10	10
Gepaarde variatie	0.000329	
Schatting van verschil tussen gemiddelden	0	
Vrijheidsgraden	18	
T- statistische gegevens	2.920148	
P(T<=t) eenzijdig	0.004569	
Kritiek gebied van T-toets: eenzijdig	1.734064	
P(T<=t) tweezijdig	0.009139	
Kritiek gebied van T-toets: tweezijdig	2.100922	

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B: BME Thesis article

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