# DESIGN OF A SURGEON FRIENDLY LAPAROSCOPIC DEVICE FOR ELECTROSURGERY PROCEDURES

**PRODUCT DESIGN PROJECT III**

**MDP-446**

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**2016**

# Design of a surgeon friendly laparoscopic device for electrosurgery procedures

Design project III | Report | IDP 604

Pai Sanket Satish | 146130001 | IDC, IITB
Guide: Prof. V. Bapat | Co Guide: Prof. B. Ravi

# Avowal

I declare that this written document represents my ideas in my own words and where others' ideas or words have been included, I have adequately cited and referenced the original sources. I also declare that I have adhered to all principles of academic honesty and integrity and have not misrepresented or fabricated or falsified any data, facts or sources in my submission. I understand that any violation of the above will be cause for disciplinary action by the Institute and can also evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been taken when needed.

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# Approval sheet

The project titled '**Design of a surgeon friendly laparoscopic device for electrosurgery procedure**' by Pai Sanket Satish, is approved for partial fulfilment of the requirement for the degree of 'Master of Design' in Industrial Design.

Guide

Co- Guide (for Prof. B. RAVI)

Chairperson

Internal Examiner

External Examiner

Date 18 . 5 . 16

# Acknowledgements

I would like to thank Prof. V. Bapat for his guidance and support throughout the duration of the project.

I want to thank Shreelekha and Pooja as well for helping me with this project whenever I got stuck.

I would also like to thank Kanika, Sitara, Boski, Patric, Sridhar and Nikhil for being there for me throughout the duration of this project.

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I would also like to thank the staff at IDC for their immense support and help.

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# Abstract

A laparoscopic surgery is a minimally invasive surgery where the surgeon creates small incisions on patients body in order to insert instruments and a light with camera to perform surgical procedures. Even though this surgery results in quicker recovery time and lesser pain for the patients, it is highly demanding for the surgeons.

Since the operations last for hours, there is a need to design and develop devices which minimize the surgeons discomfort while enhancing the usability. This project is an attempt to design such a device for the procedure of cutting and coagulating tissues during laparoscopic surgery.

The project is focused  on generation of a user centric ergonomic design of electrosurgical device while also trying to solve existing issues of visibility, fatigue and hygiene in the operating theatre during laparoscopic surgery.

After constant trials and multiple mock up prototypes, the device is designed to gently grip the hand and uses flexible linkages to provide comfort of use, ease of assembly and maintenance.

# Content

# Introduction

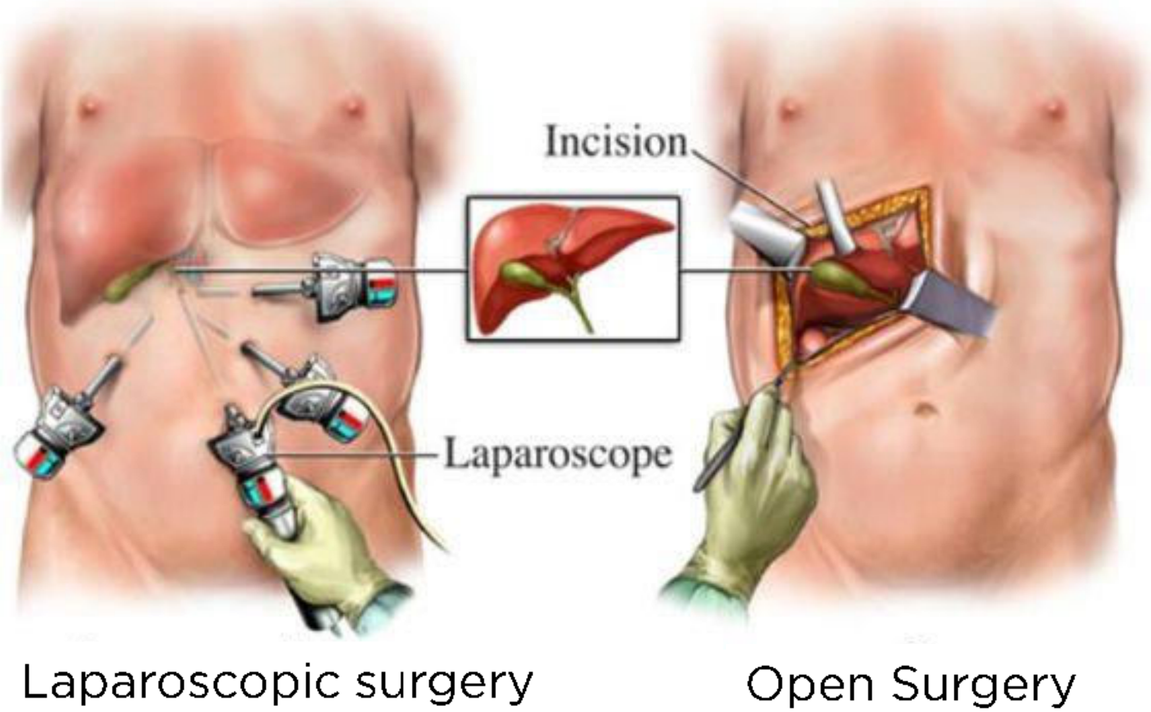



Image source: https://in.pinterest.com/pin/358951032773233798/ (as seen on 10.03.16)

Top
fig 1: difference between laparoscopic and open surgery

In medical practice, a procedure consisting of physical intervention on tissues and muscles to treat or investigate a pathological condition is termed as surgery.

Surgical procedures are usually categorised on the basis of degree of invasiveness, procedure, instruments involved and urgency. On the basis of degree of invasiveness, surgery can be categorised into open type surgery (incision of more than 20 cm and laparoscopic surgery (also known as minimally invasive/keyhole surgery)

The shift towards laparoscopy has occurred as incisions serve minimal therapeutic purpose in surgery. Also the incisions are also the usual suspects for infections which can occur post surgery..

In laparoscopic surgery, small incisions (5 to 15 mm) are made on the body through which instruments are passed along with a light source and a camera to perform the required procedures. Since this surgery is minimally invasive it offers advantages of lesser pain and quick recover time to the patient.

Since laparoscopic surgery usually lasts for hours, the surgeons performing the operations undergo a lot of mental and physical stress. Hence there is a need to relook at the entire system to identify existing pain points in order to minimise a surgeon's discomfort while performing this surgery.

Laparoscopic surgery can be further divided into robotic laparoscopic surgery (tools are attached to a remotely controlled robotic arm), and non robotic surgery (hand guided devices). For the current project, we will be focussing on electrosurgery procedure during non-robotic surgery

The use of heat in surgery is known as cautery. For the scope of this project we fill be focussing more on electrocautery and electrosurgery.

Electrocautery is the process of destroying tissues by a object which is heated using electricity. Electrosurgery on the other hand refers to the use of alternating current passing through the patient to cut and coagulate the tissues.

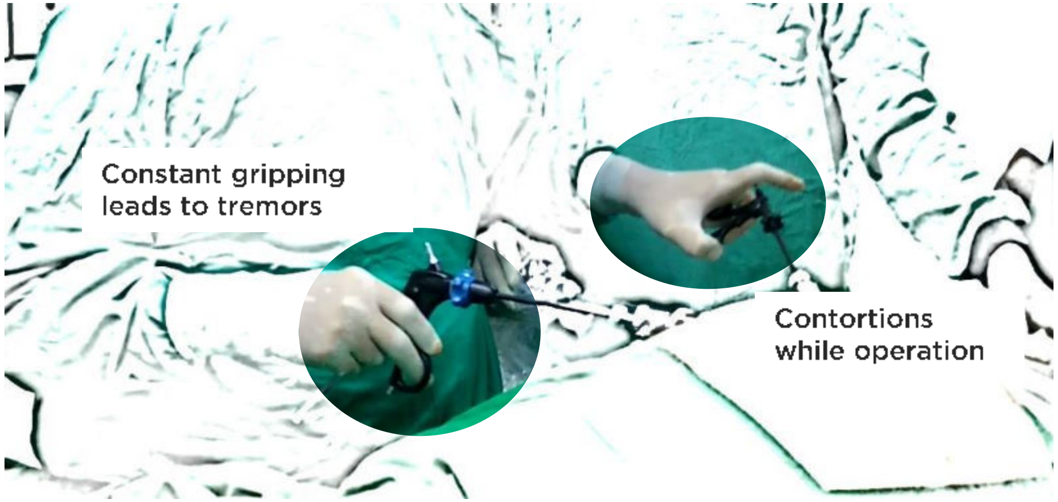
Currently there are a lot of instruments which are already available for the above mentioned procedures. However the innovation in laparoscopic devices (in terms of mechanisms used and the form) are more or less linear.

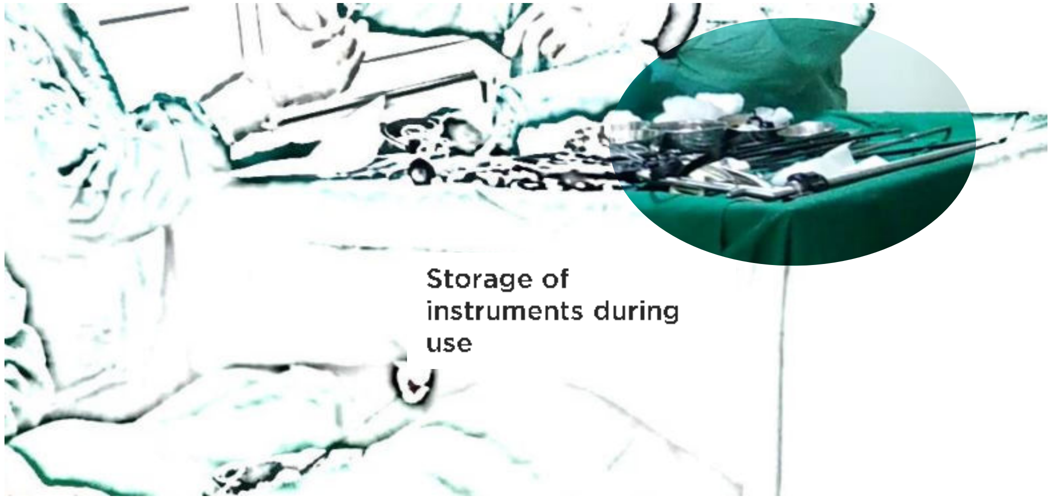
In IIT Bombay, Industrial Design Centre (IDC) in collaboration with Biomedical Engg. and Technology (Incubation) Centre (BET-iC), has managed to provide an innovative direction for development of ergonomic laparoscopic devices.

This project is an attempt to take that research forward and to generate detailed designs in order to create an ergonomic device for the specific procedure of cautery. Hence along with the said device we have also tried to look at the entire laparoscopic procedure and the modules used in it.

It also aims at looking at the entire system in general and trying to redesign the laparoscopic device in order to reduce the physical and mental demands that are placed on the surgeon

# Primary study



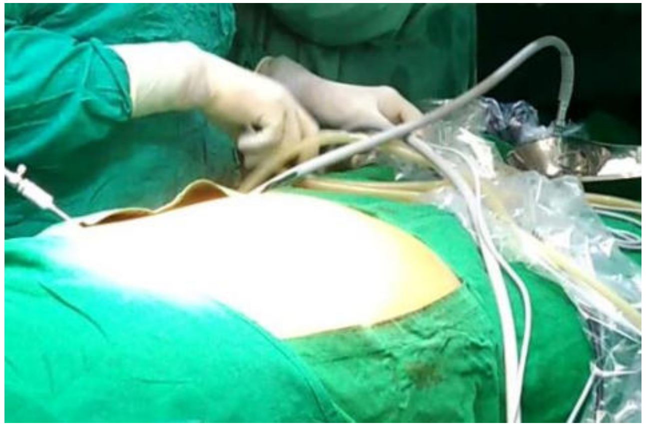

Top
fig 2: issues observed while observing the surgery

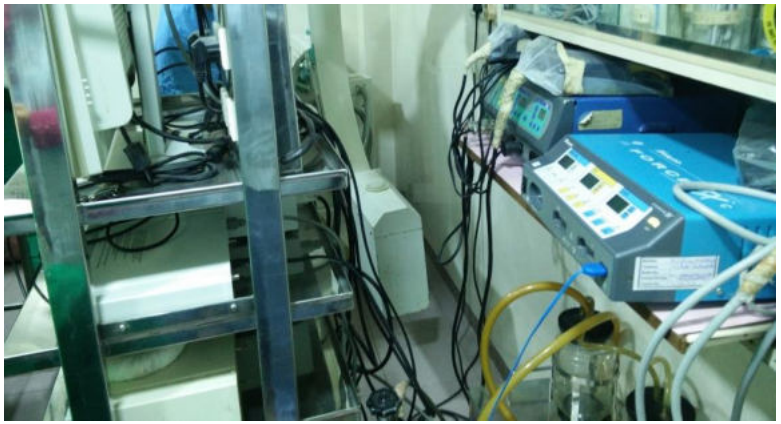
Since this design research is being done in collaboration with BET-iC, We got the opportunity to observe an operation performed by Dr. Hemant Bhansali using laparoscopic devices.

Dr. Bhansali is one of the leading laparoscopic surgeon of this country. He was also a co-guide for the previous laparoscopic device project, hence his observations and feedback was very informed and pertinent.

The overview of a laparoscopic procedure described by Dr. Bhansali is as follows.

- Small incisions are made at the certain distance from the area of operation
- Cannula (a sharp metal rod) and trocars (metal tubes) are inserted to create tunnels through which instruments can be inserted (fig 3).
- Insufflation (using liquid/gas for blowing up of abdominal wall to create space) was performed using $CO_2$ gas.
- A laparoscope (device with light & camera) was inserted into one of the trocars (fig 4).





Top left
fig 3: Cannula and Trocar

Top middle
fig 4: Inserting the Laparoscope

Top right
fig 5: Connecting cable to perform electrosurgery

Bottom. left
fig 6: Cable routing issues

Bottom right
fig 7: ESU and the trolley for the screen

- The camera is then held by he surgeons assistant
- The surgeon then inserts other laparoscopic instruments in the other trocars to perform the surgery while looking at the monitor containing visual feed from the inserted camera..

The major issues identified were as follows,

- Surgeon gets tremors in the hand due to continuously operating the tools.
- The height of the operating table is difficult to adjust during surgery.
- The device is not very manoeuvrable as the surgeon has to really contort his body to get to a specific area in the patient's body.
- The trolley for the display and instrumentation takes a lot of space and obstruct movement around the patient (fig 5).
- The ESU has a fixed position in the OT which leads to cable routing issues
- Currently there is no feedback for depth of penetration while performing electrosurgery.
- The instruments have a tendency to touch surfaces on which they are placed creating hygiene issues.
- The cables touch the patients due to routing issues which can cause infections as cables cannot be sterilised (fig 6).
- A lot of cables also create a lot of tripping hazard and electric losses.
- A communication gap was also observed between the doctor and the nurses/assistants.
- The insulation on the device wears off quickly which can lead to possibility of electric current passing through unwanted areas in the patients body.

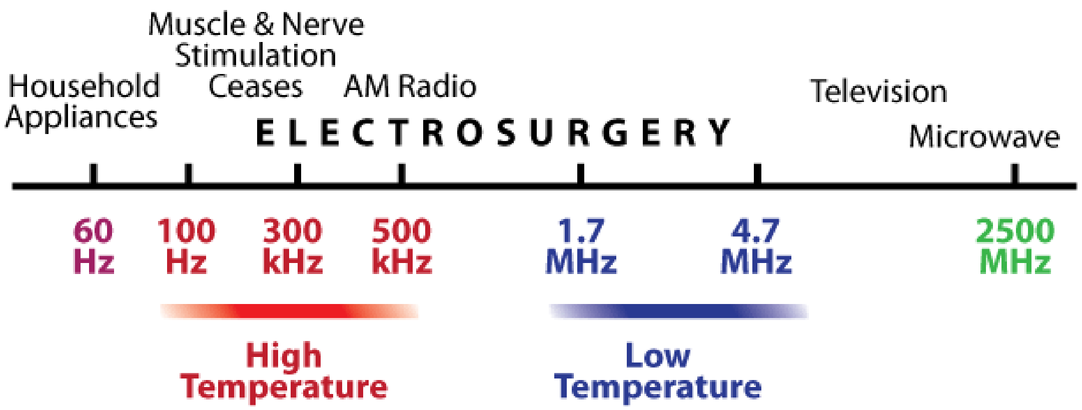



Image source: http://www.xodusmedical.com/Modules/Product (as seen on 10.03.16)

Top
fig 8: frequency band in which electrosurgery is practiced

**Principles of electrosurgery**

Electrosurgery is cutting and coagulating of tissues using alternating current passing through the patients body.

This alternating current generates heat at 500KHz to 2MHz which is used to destroy tissue in the required area.

Following changes happen in the tissue as the temperature is increased.

| Temp | Visual change | Biological change |
|---|---|---|
| 37-45°C | No effect | warming |
| 45-60°C | No/ delayed | Enzyme denature |
| 60-70°C | Blanching | coagulation |
| 70-90°C | white | Proteins denature |
| 90-100°C | Puckering | drying |
| 100°C | Smoke plum | vaporization |

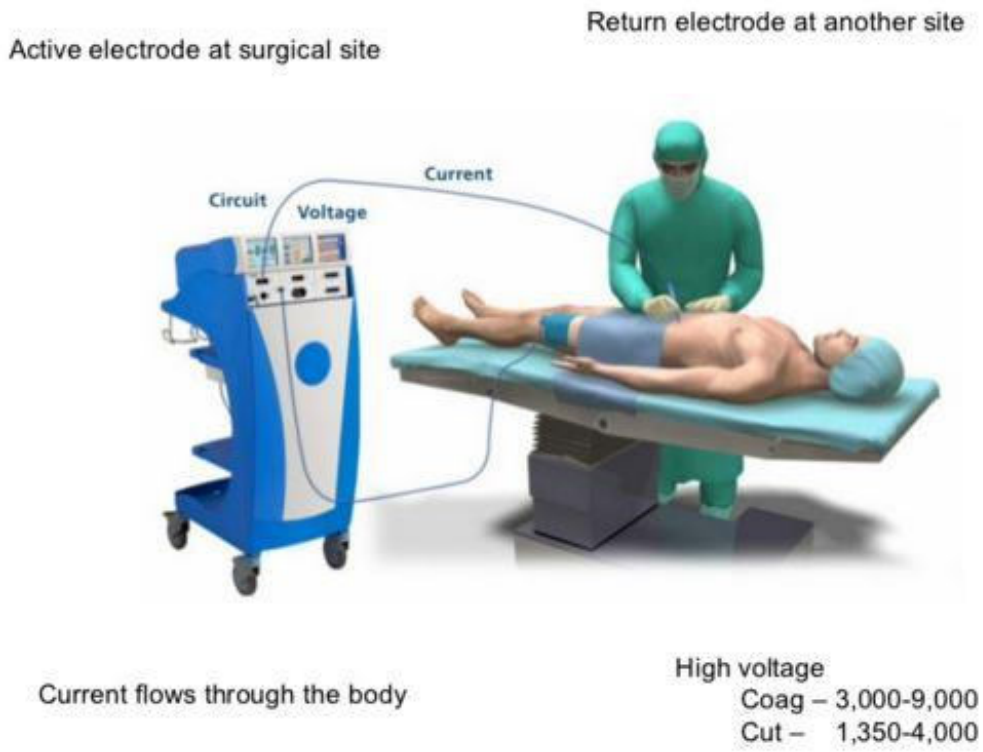



Image source: http://www.slideshare.net/AnthonyDeSalvoMD (as seen on 10.03.16)

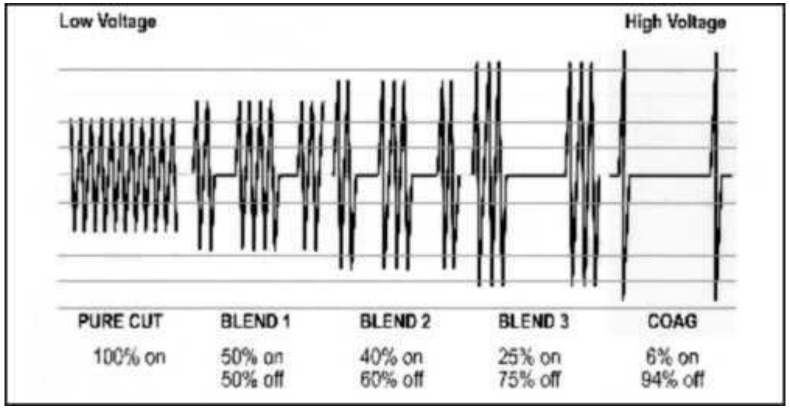



Image source: http://healthierworldamerica.com/
(as seen on 10.03.16)

Top left
fig 9: Monopolar cautery

Top right
fig 10: Waveforms for various monopolar cautery modes

## Types of Electrosurgery

Electrosurgery is usually classified into two types, monopolar and bipolar cautery based on the electrodes used.

### Monopolar cautery

In monopolar cautery, the current passes from the electrode to the tissue and then through the patient to an electrode pad.to complete the circuit.. (fig 9)

Depending on the operation the monopolar cautery consists of two major modes based on the waveforms

- Continuous or non modulated waveform of the 'Cut' mode (low voltage and higher amperage of current).

- Dampened or modulated waveform of 'Coag' mode (high voltage and lower amperage of current).

Monopolar cautery also offers 3 surgical effects

- Cutting
- Dessication
- Fulguration

### Cutting

Offers precise tissue effect at the cost of slightly ineffective haemostasis (.e.g. stopping of blood flow) . It produces a cut effect when the electrode floats above the tissue in stead of touching it.
Voltage: 1200-3500V
Frequency: 400KHz
Rated load: 300 Ohms
Power: 200-300 Watts

### Dessication

It is a more controlled dehydration process which occurs only when electrode touches the tissue
Voltage: 3500V
Frequency: 250KHz repeat at 40KHz
Rated load: 500 Ohms
Power: 120 Watts

### Fulguration

A more rapid process where electrical sparks are produced to destroy tissue. This can be achieved by placing the active electrode above target tissue to heat the air between them.
Voltage: 7000V
Frequency: 400KHz repeat at 50KHz
Rated load: 500 Ohms
Power: 120 Watts

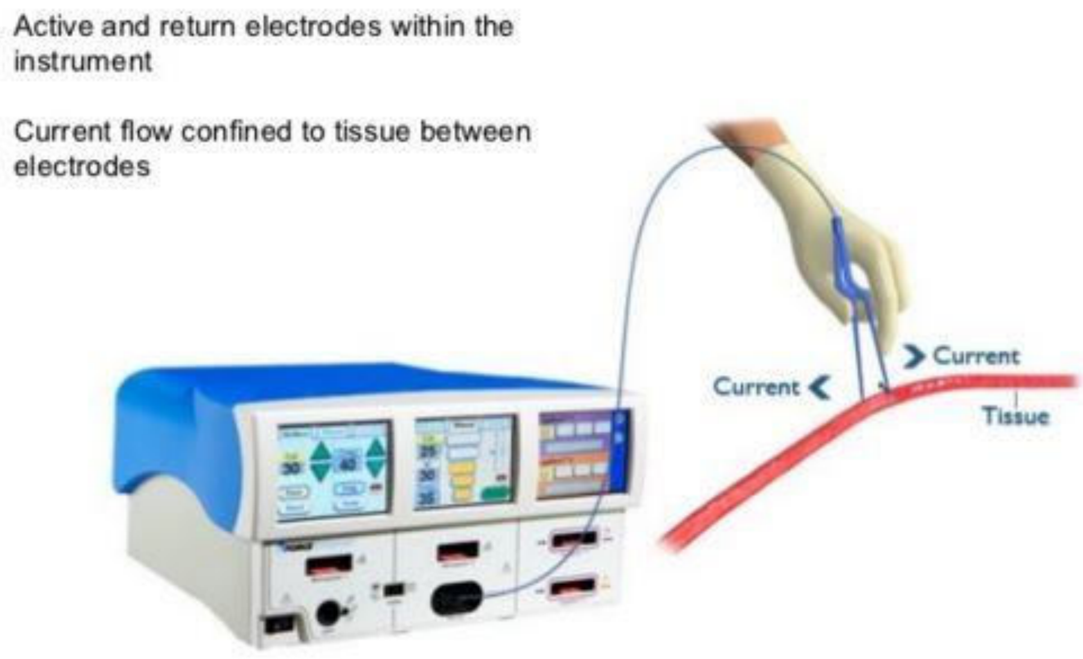



Image source: http://www.slideshare.net/AnthonyDeSalvoMD/electrosurgery-saftey
(as seen on 10.03.16)

Top left
fig 11: Bipolar cautery

## Bipolar cautery

In bipolar cautery, two jaws act as active electrodes and the current only passes through the tissue held between them. (fig 11)

Bipolar cautery uses lower voltages but has a very limited ability to cut and coagulate large areas.

Since the current only passes through the tissue held in the jaws., it provides better control and prevents additional damage to surrounding area.

This procedure offers lowers risks of unwanted electrical exposure leading to thermal injury to the patients .

Bipolar desiccation parameters
Voltage (precise): 300V
Voltage (standard): 400V
Voltage (macro bipolar): 700V
Frequency: 500KHz
Rated load: 100 Ohms
Power: 70 Watts

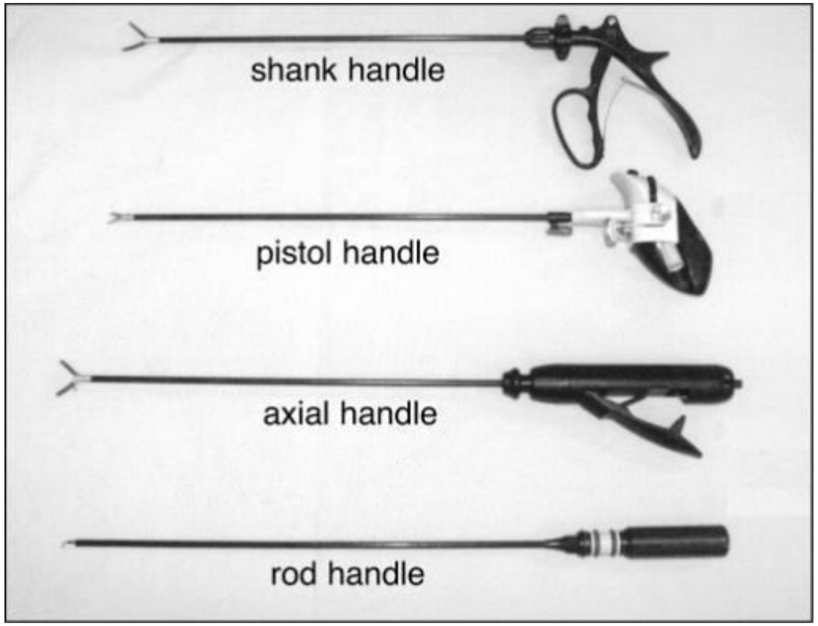



Image source: https://openi.nlm.nih.gov (as seen on 10.03.16)

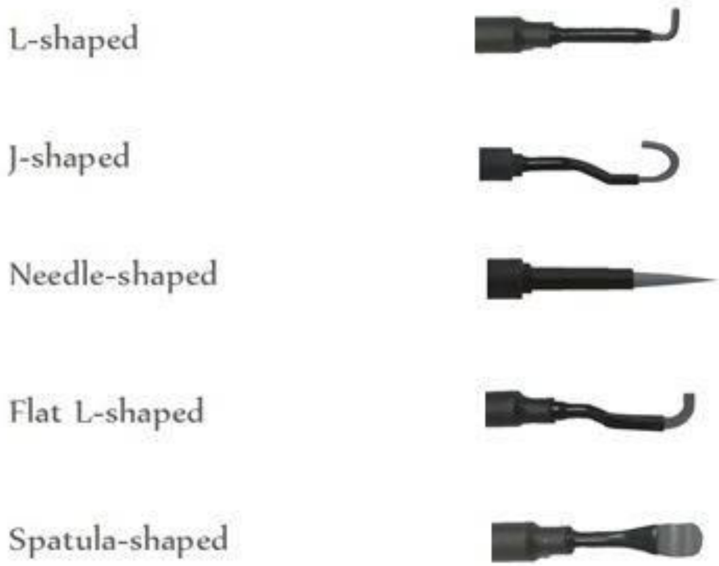



Image source: http://www.shinmed.com/ (as seen on 10.03.16)


Image source: http://www.laparoscopy.am/ (as seen on 10.03.16)

Top left
fig 12: Types of shank handles

Top right
fig 13: tips for various monopolar cautery modes

Bottom
fig 14: tips for various bipolar operations


Top
fig 15: The new product handle
(currently proposed by IDC & BET-iC)

### Types of Electrosurgery instruments

Laparoscopic instruments are usually designed to enter 5 mm to 10 mm trocar and their length varies from 18 mm to 45 mm

The shank handles can be broadly classified into four types (fig 12).

- Shank handle
- Pistol Handle
- Axial handle
- Rod handle

Out of these, the pistol handle is considered the most easy to use at the moment. However, the shank handle is the most commonly used handle at the moment.

Last year IDC in collaboration with BETiC, designed an ergonomic handle for laparoscopic devices in general.

The major difference between this new handle and the above mentioned once is: 'instead of the surgeon gripping the tool, the tool grips the surgeons hand.'

This ensures that the surgeon can rest his fingers during surgery along with experiencing better manoeuvrability

Image source: http://www.medtronic.com/
(as seen on 10.03.16)


Image source: http://www.ethicon.com/
(as seen on 10.03.16)

Image source: http://www.caiman-aesculap.com/
(as seen on 10.03.16)

Image source: http://www.wemed1.com/
(as seen on 10.03.16)


Image source: http://www.ethicon.com/
(as seen on 10.03.16)

Top left
fig 16: Ligasure

Top Middle
fig 17: Enseal

Top right
fig 18: Caiman

Bottom left
fig 19: Gyrus

Bottom Right
fig 20: Harmonic scalpel

## Existing solutions

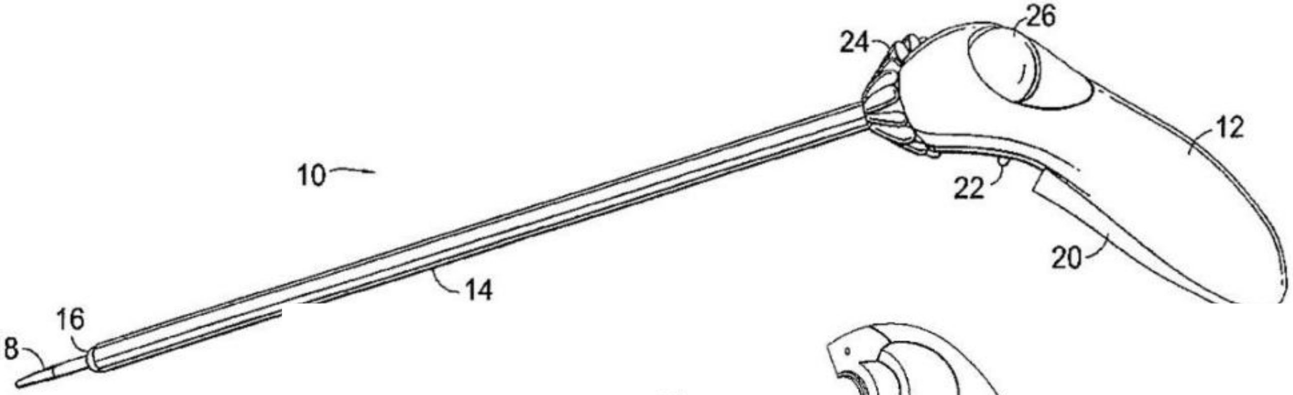
Ligasure (fig 16)
It is a bipolar device which exerts pressure on the tissue while delivering low voltage, high current. It also measures tissue impedance to change the current and voltage setting using a computer algorithm. It is available in 5-10 mm sizes

Enseal (fig 17)
This system employs a temperature sensitive matrix within the jaws to control the energy at tissue-electrode interface. Vessels of 1-7mm dia. can be sealed effectively with this instrument

Caiman (fig 18)
Caiman is similar to Ligasure but provides less thermal spread and saves time as a large jaw is used. It uses PWM (Pulse waveform modulation) instead of traditionally used impedance  to modulate current and voltage. The tip of the device also claims better articulation compared to similar devices in the market.

The Gyrus (fig 19)
This bipolar device delivers low voltage, high current by employing plasma kinetic technology. During coag. phase this device delivers rapid pulses to allow cooling in order to contain unwanted thermal spread. This device manages to hold on to the tissue without slipping during desiccation. It is available in sizes of 5-10 mm

Harmonic Scalpel (fig 20)
This device is a high frequency ultrasonic transducer. The blade of the device vibrates at 55,000 Hz. It relies mainly on mechanical energy instead of electrical to seal tissue.. Though it works like the Gyrus, it allows greater control and lesser operating temp. (50-100°C) while compared to other devices (120-400 °C). The variability can be further adjusted by the surgeon providing grater flexibility for achieving various tissue effects. The active blade is also used for cutting.



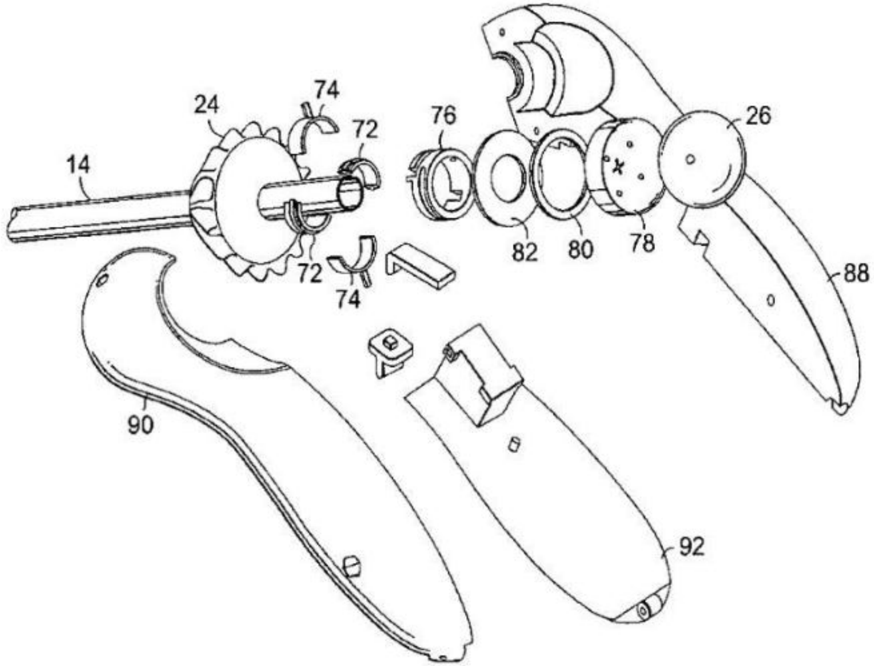




Image source: http://www.google.com/patents/US8585734(as seen on 10.03.16)

**Top**
fig 21: Device proposed in patent US 8585734 B2

**Bottom**
fig 22: Exploded view

| Sr No. | Patent No. | Name | Source |
|---|---|---|---|
| 1 | US8012166 B2 | Laparoscopic instrument tip and method of specimen collection | https://www.google.com/patents/US8012166 |
| 2 | US 8585734 B2 | Ergonomic handle and articulating laparoscopic tool | http://www.google.com/patents/US8585734 |
| 3 | US 6152923 A | Multi-contact forceps and method of sealing, coagulating, cauterizing and/or cutting vessels and tissue | https://www.google.com/patents/US6152923 |
| 4 | US 6041679 A | Endoscopic end effectors constructed from a combination of conductive and non-conductive materials and useful for selective endoscopic cautery | https://www.google.co.in/patents/US6041679 |
| 5 | EP 0577423 A2 | Endoscopic instrument system | http://www.google.com/patents/EP0577423A2?cl=en |

**Patent study**

A basic study of patents was done to understand the work done as well as on-going research in the field of laparoscopic electrosurgery devices.

Various patents were checked but not much work has been done on design of ergonomic and easy to use handle for electrosurgery devices.

The table on the left shows the patents that were studied.

Only one patent (US 8585734 B2) had data regarding ergonomic handle design. This device uses a sphere located in handle to control the motion of the tip. The handle itself is similar to pistol grip.

**'To design a surgeon friendly laparoscopic device for electrosurgery procedures'**

**Primary Need**

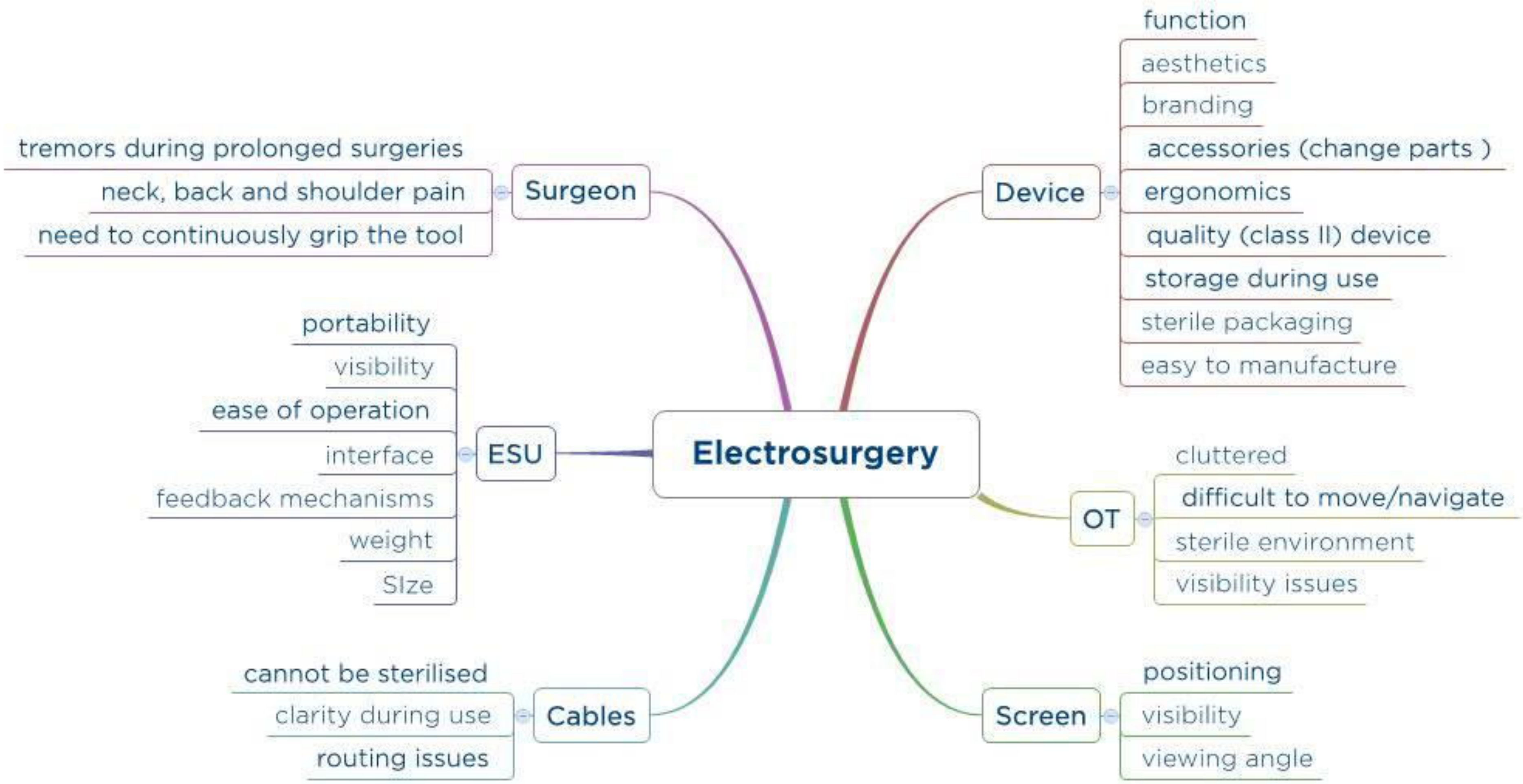
- The device should be ergonomic, manoeuvrable and easy to use.
- As it is a class II device, it should be able to withstand autoclave temperatures.
- Provision for surgeon to rest his arms and fingers during the operation should be provided.
- The device when stored during operation should not allow the tip to touch any surface

**Secondary Need**

- Cable management and routing issues to be resolved
- The height and position of the screen to be adjustable
- ESU unit should be portable and as compact as possible

**Detailed Brief**

- User related issues
    - Difficult to use
    - Surgeon cannot rest his arms
    - Difficult to manoeuvre
- Servicing issues
    - Device should be capable of withstanding class II device sterilisation
- Manufacturing issues
    - Medical grade material with high heat resistance to be used
    - The material should be easy to clean and light
- Operating condition
    - To be used in sterile conditions after sterilization
    - The surgeon will hold a device in each hand while operating
    - Other devices should be placed properly on tray near the surgeon within easy reach of at least the assistant




Top
fig 23: Mind map for electrosurgery. This was used to derive some features

# Ideation phase 1

Initially after the primary and secondary studies, a mind map was created to understand all aspects of the topic and three project approaches were proposed (fig 23).

Approach # 1 (fig 24,25)

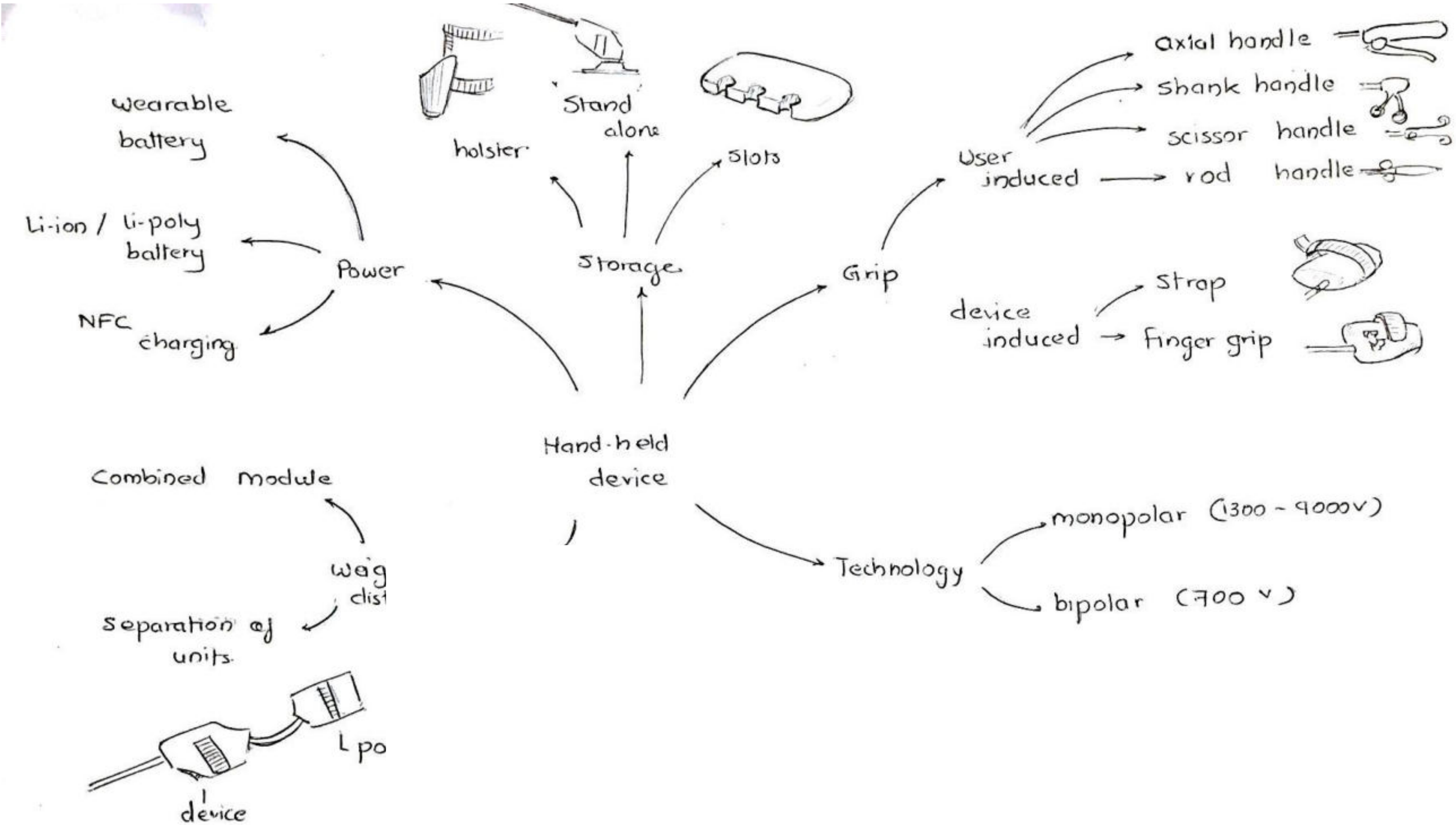
- A handheld pocket cautery device without wires
- Need to check feasibility as device is class II
- Eliminates cable issues

Approach # 2 (fig 26)

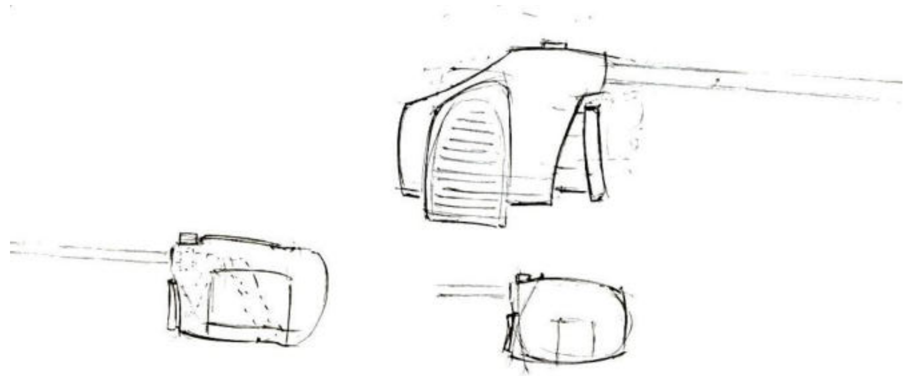
- Wearable ESU with slots for storing the laparoscopic devices
- Cable routing issue and device storage issue to be eliminated

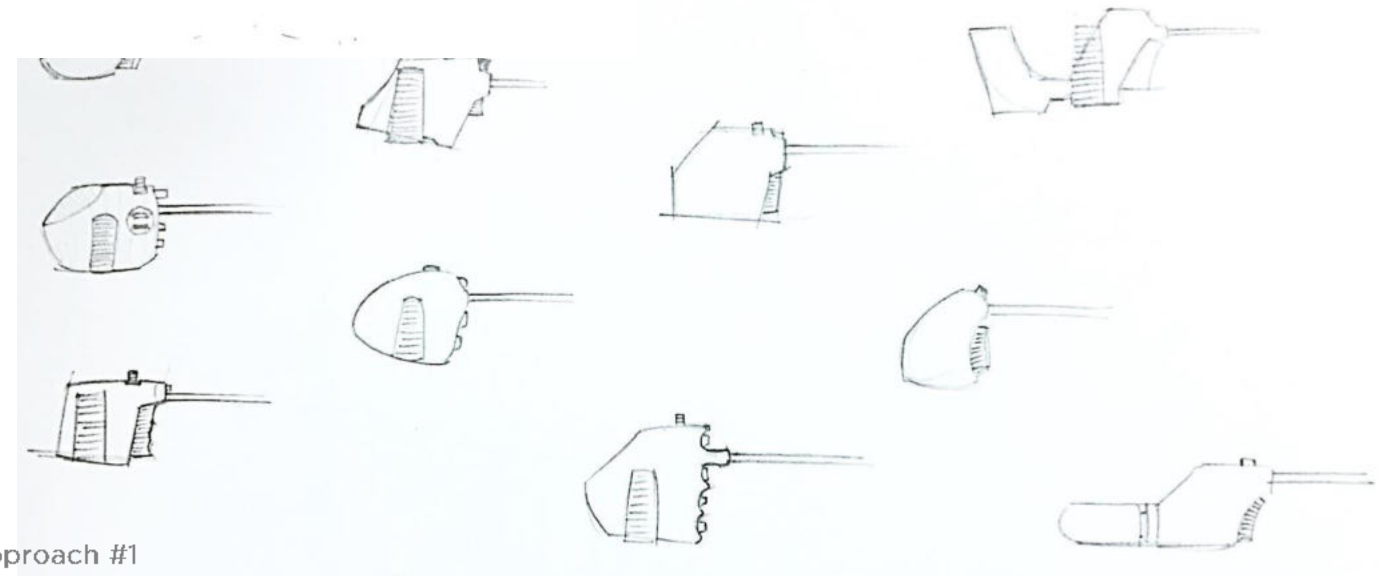
Approach # 3

- A portable trolley around the patient
- Trolley with overhead boom for cable management
- Device storage provision to be designed on the trolley

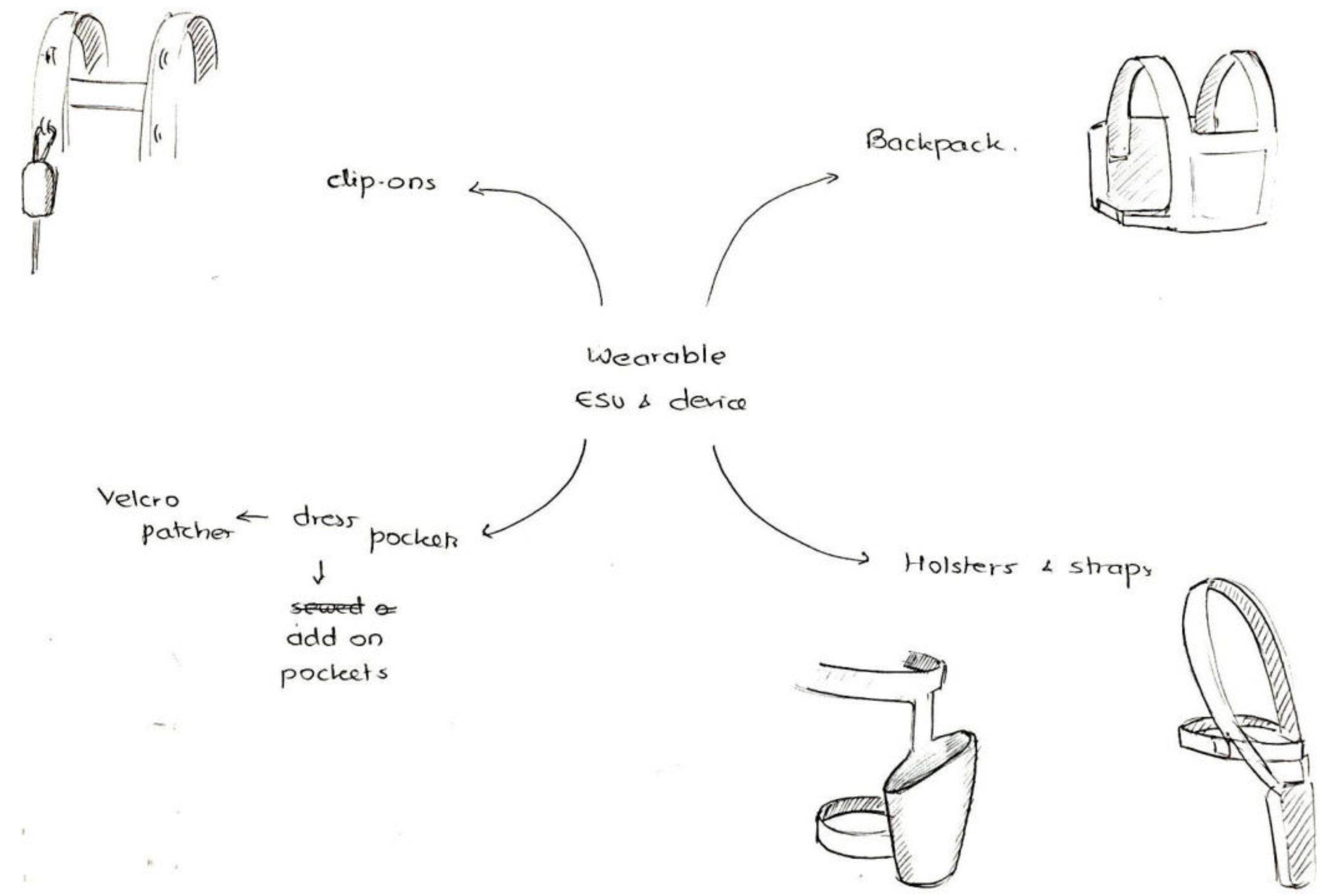



Top
fig 24: ideation for approach #1





Top
fig 25: initial sketches for approach #1




Top
fig 26: ideation for approach #2

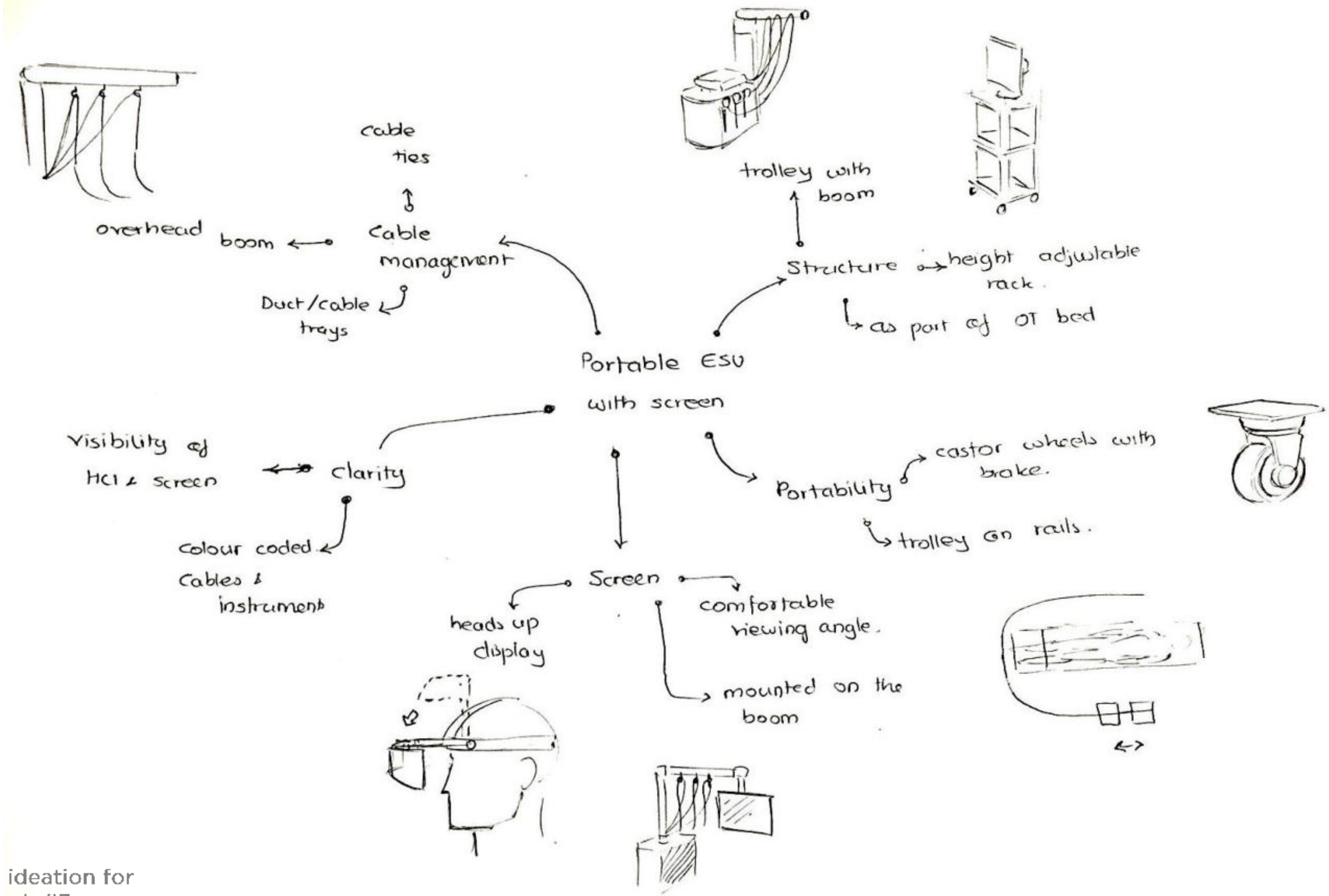



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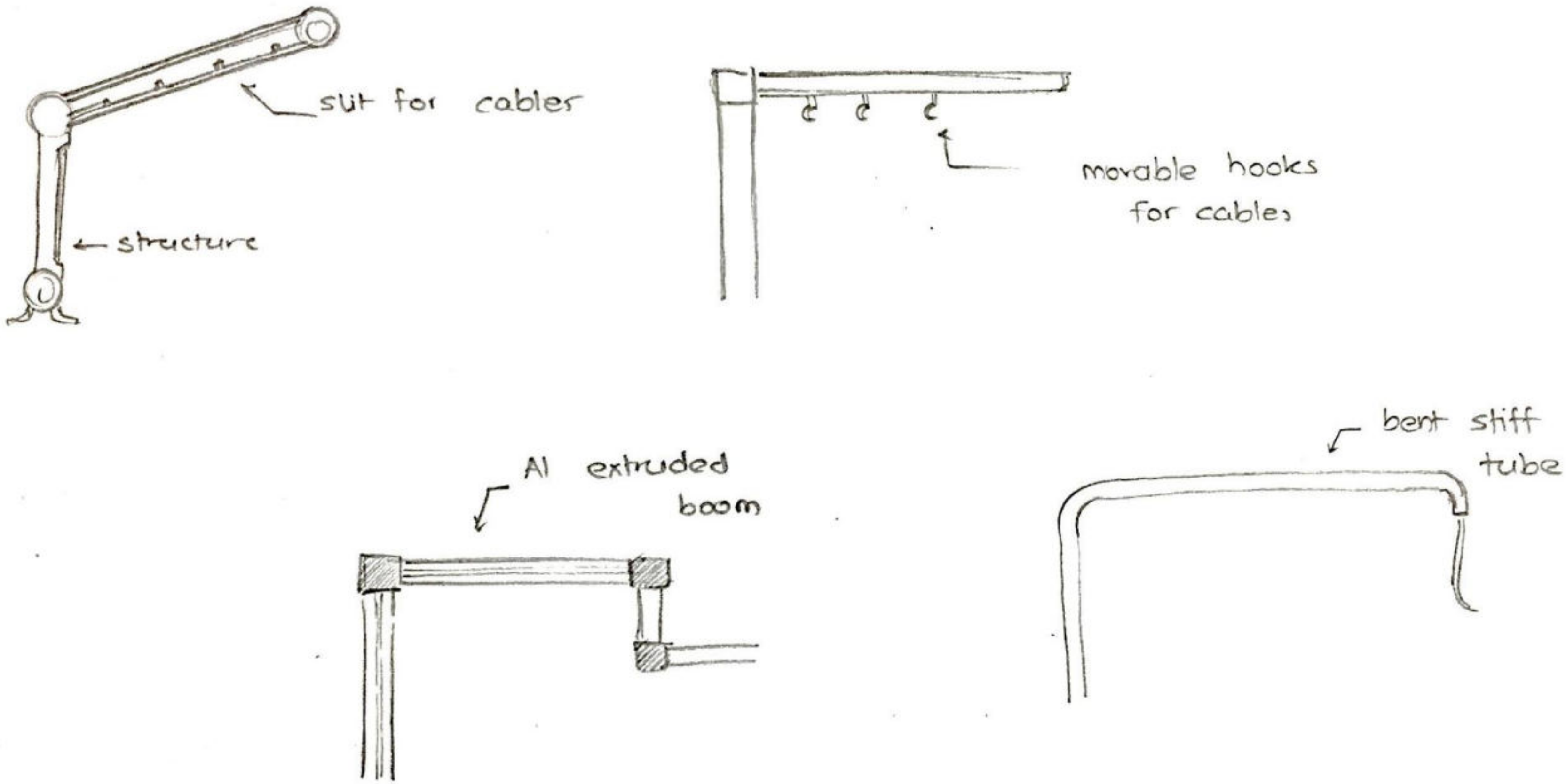
fig 27: ideation for approach #3




Top
fig 28: initial sketches for approach #2
Detailing out various ways of cable management by using a boom

# Ideation phase 2

After initial ideation, we decided to concentrate on primary objective of creating  a more usable and ergonomic device (fig 25).

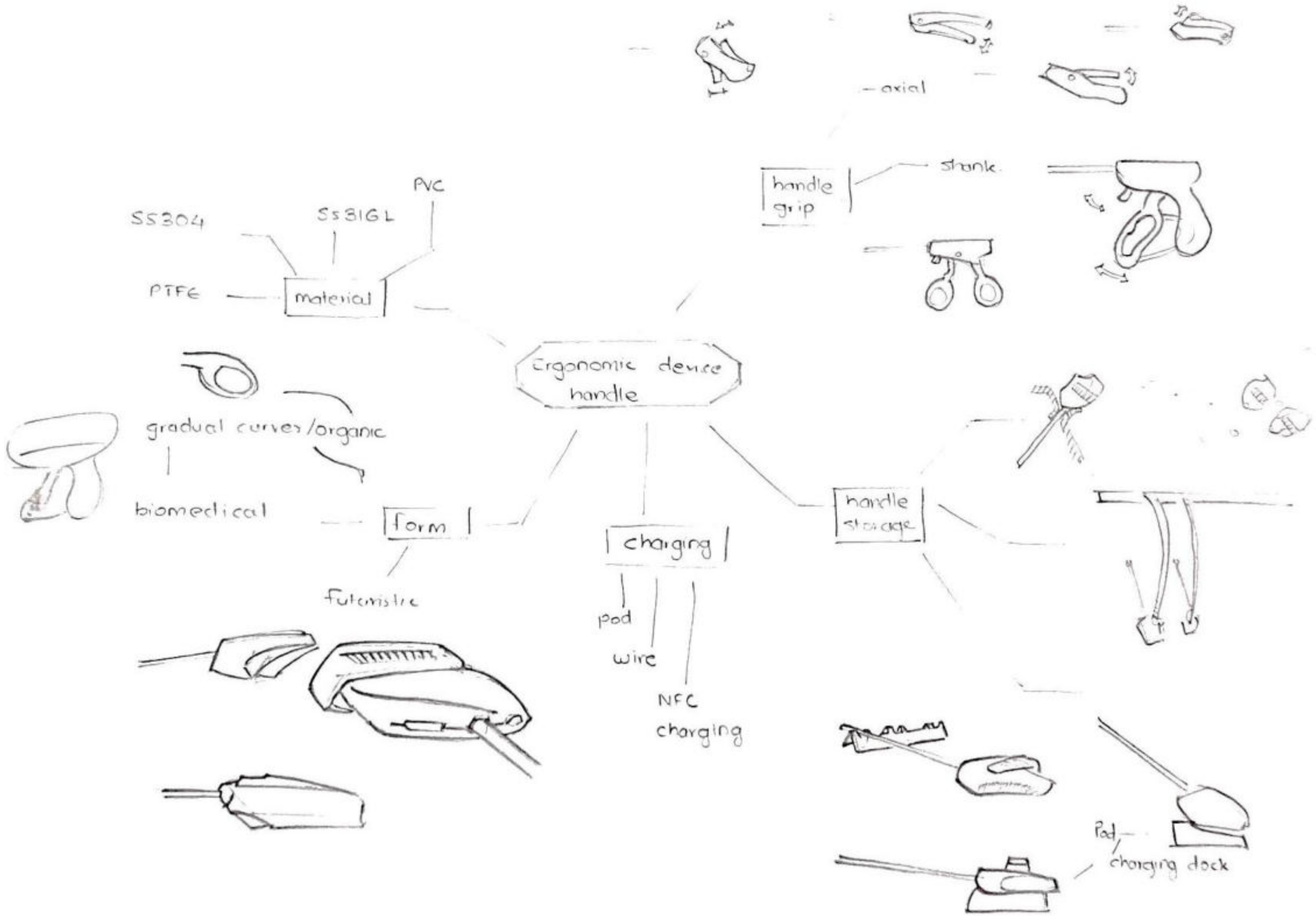
After understanding the hand movements required for the device to work, quick ideas were generated by shifting the pivot point (fig 27-28)

Some quick ideas were also generated on how the device would be placed so that the surgeon has easy access. The tip isolation was also thought of during this phase (fig 29-32)

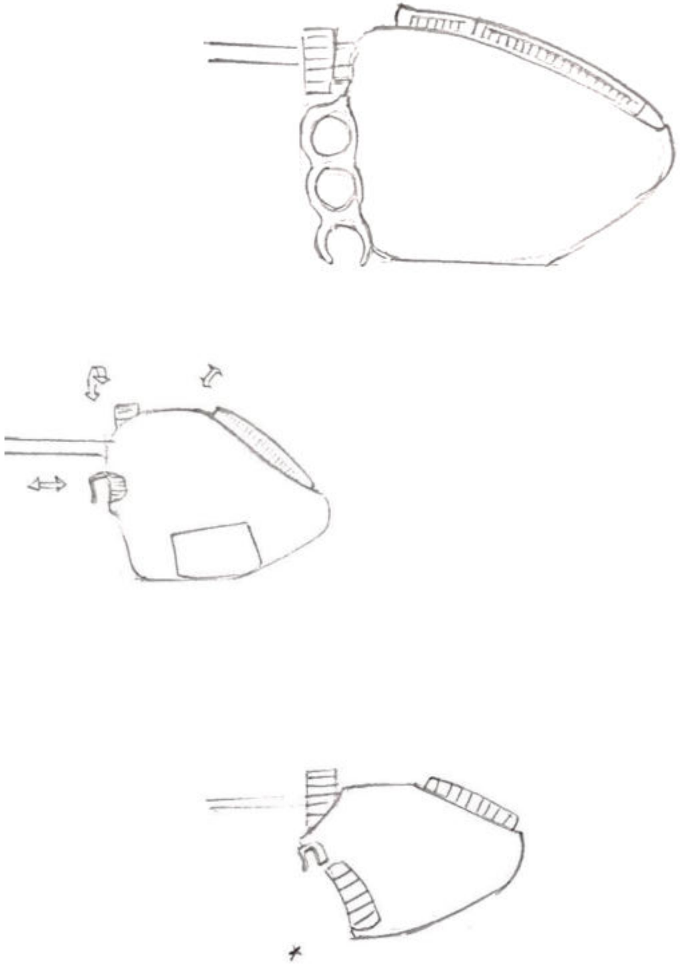
For the next phase 3 directions were chosen based on ideations done by varying location of pivot.

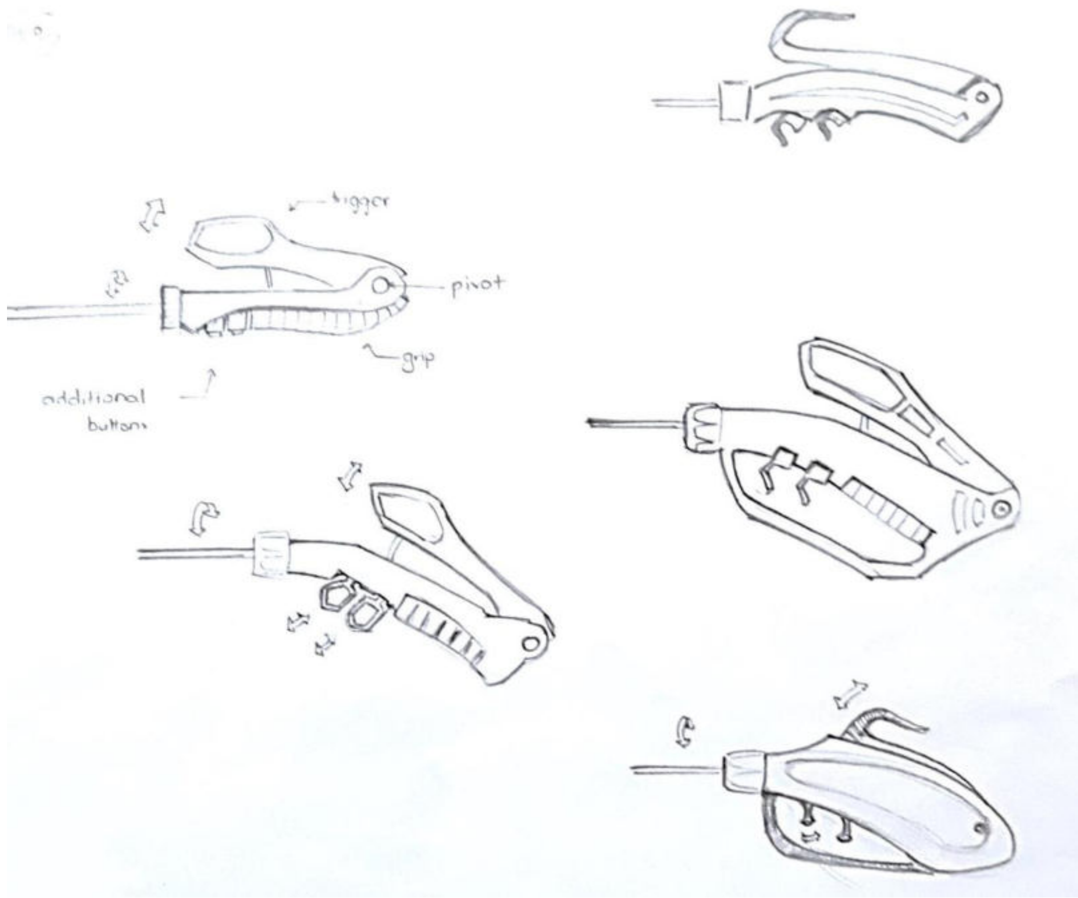
A couple of varying hand dimensions were plotted to understand the areas where the dimensional change my affect the most. Also the range of motion and bend lines were also generated.

Using this data, three concepts were created and the 1:1 mock ups were prepared for initial testing.



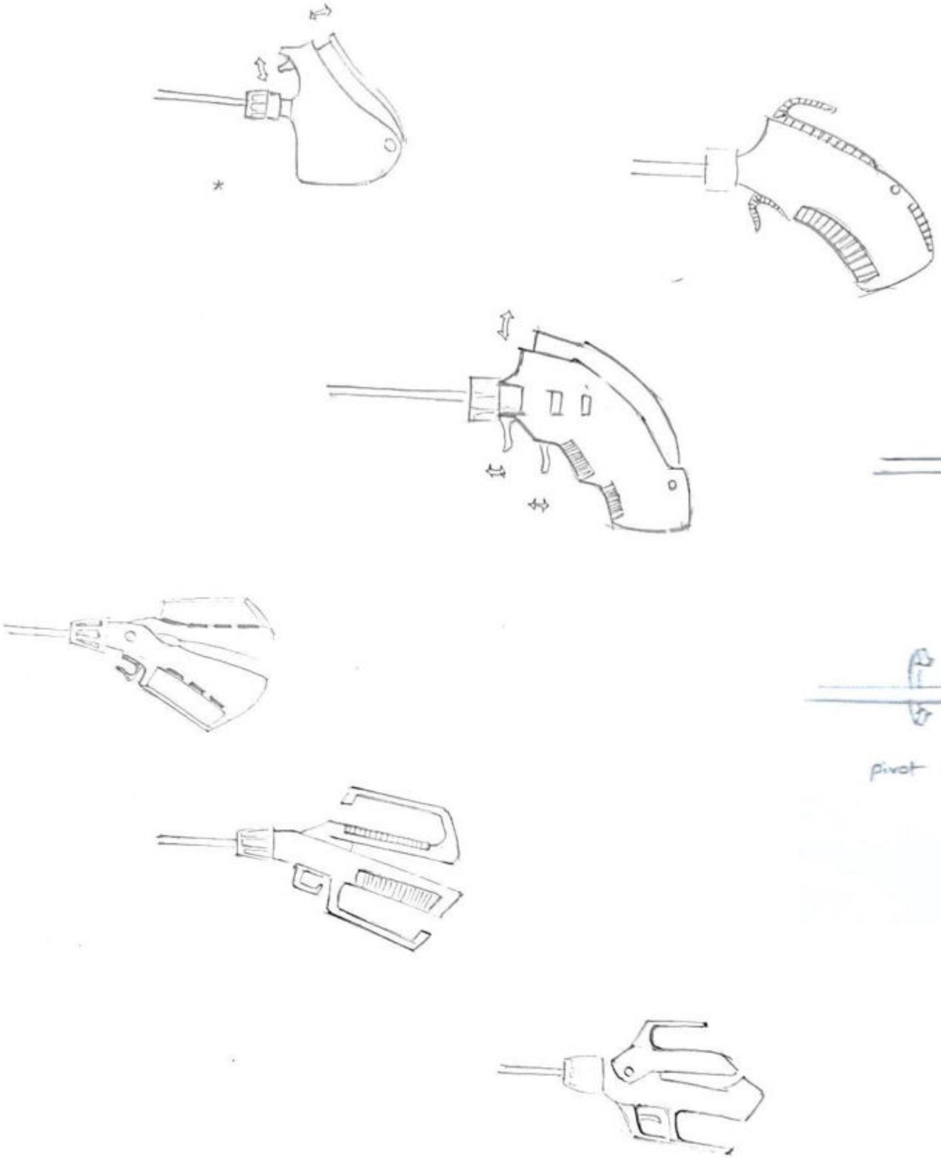

Top
fig 29: ideation for device handle, for various aspects of an ergonomic device

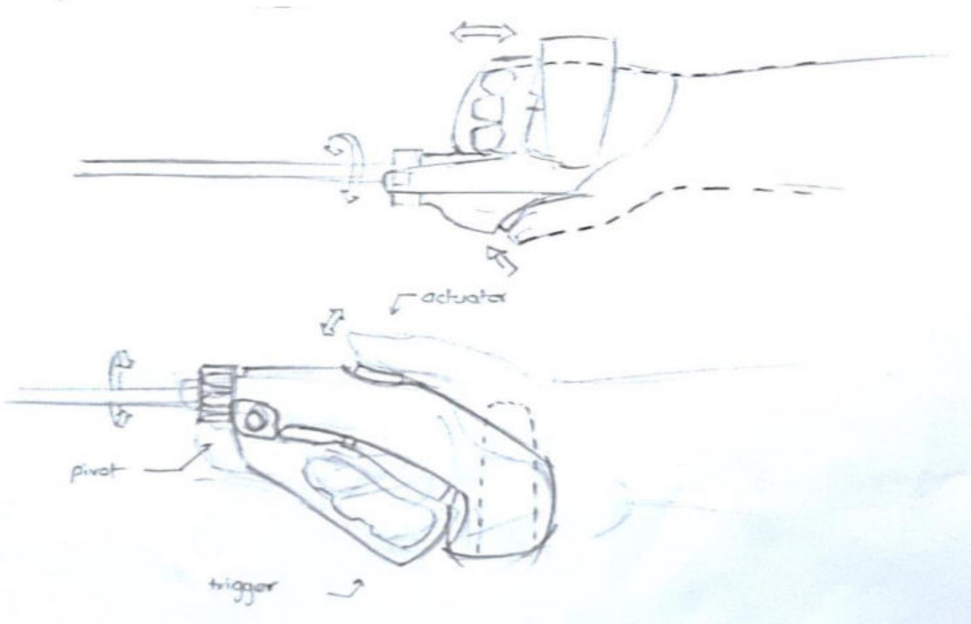





Top

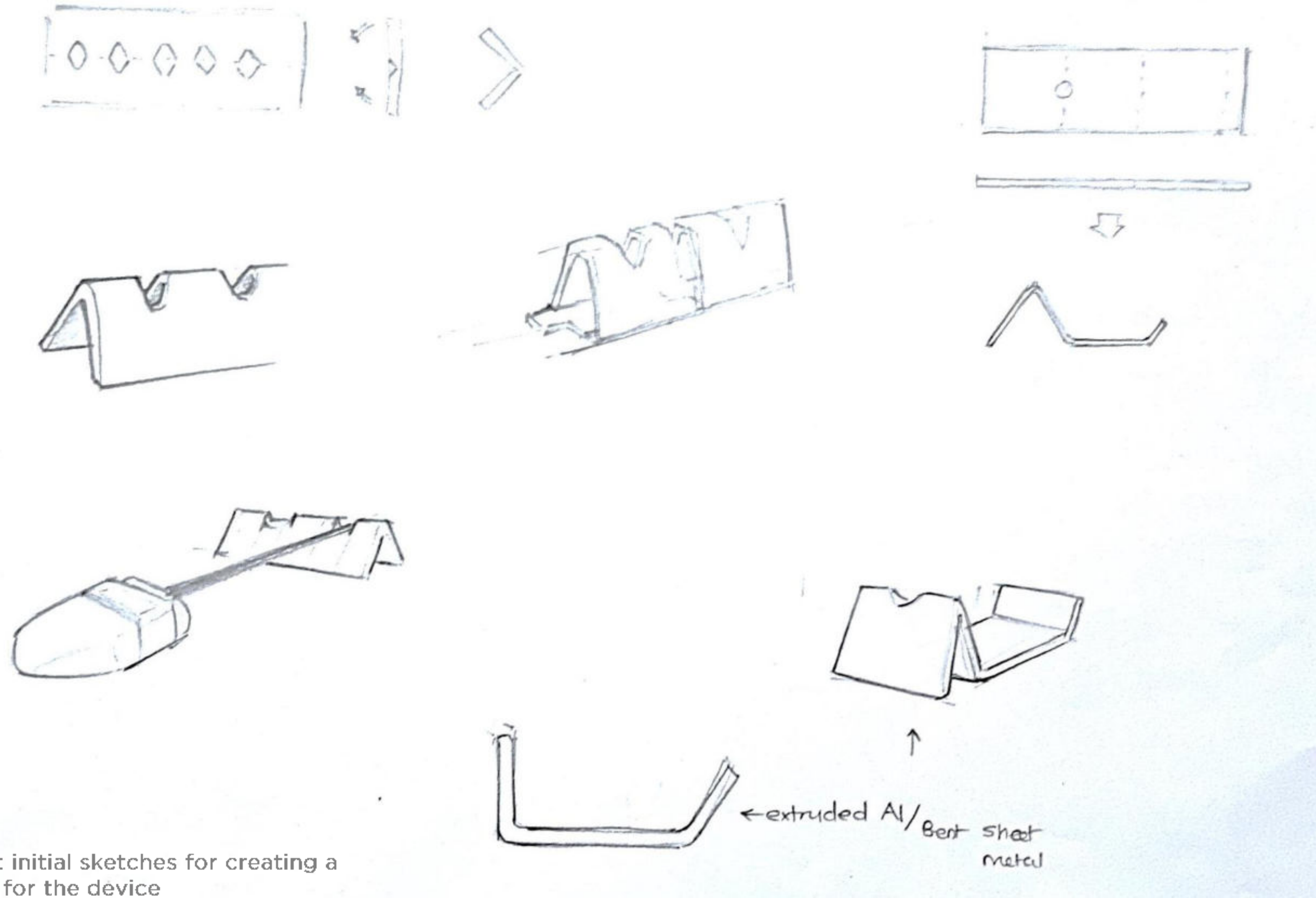
fig 30: initial sketches with palm trigger and variation of pivot point inspired by a stapler



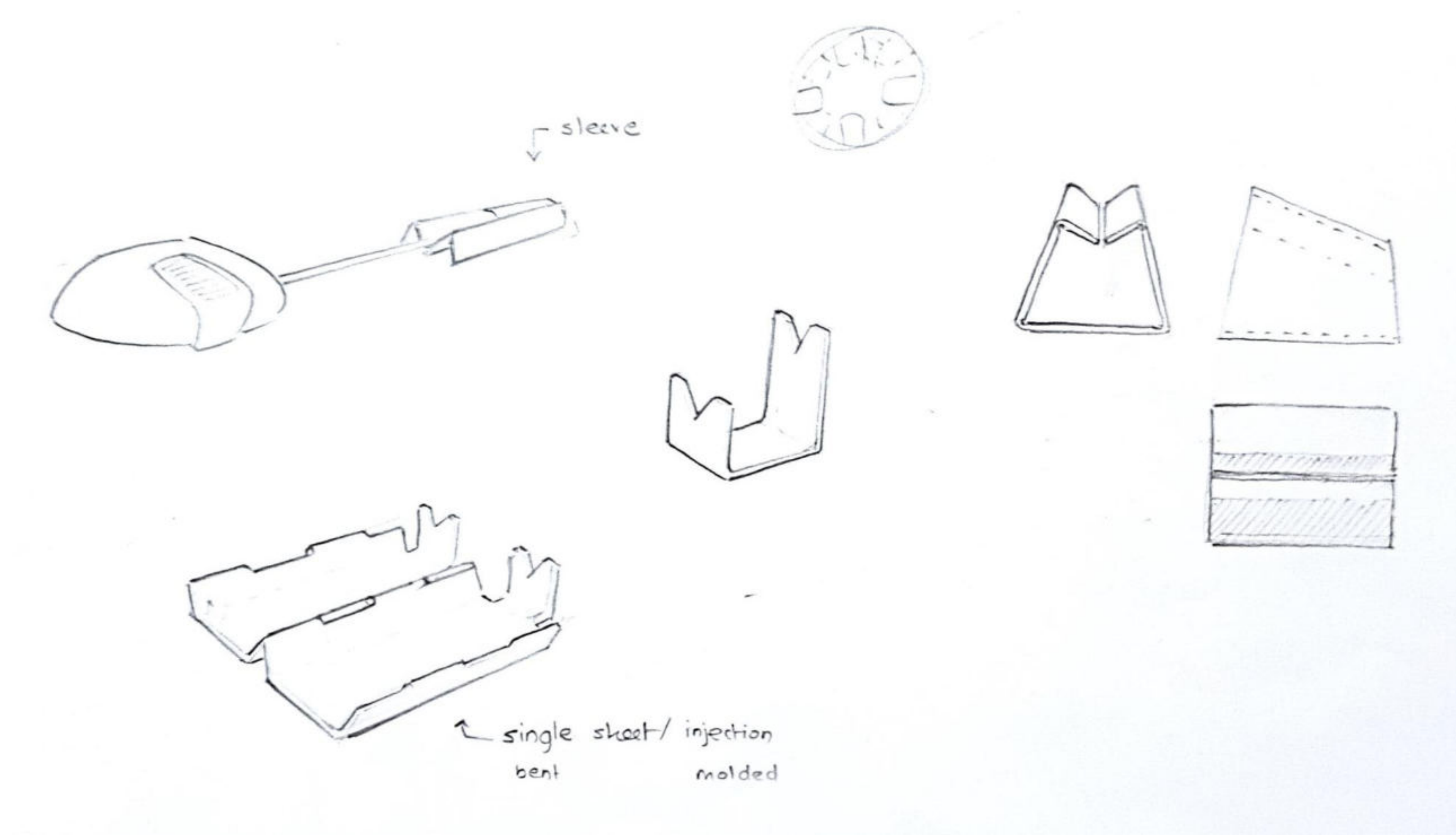




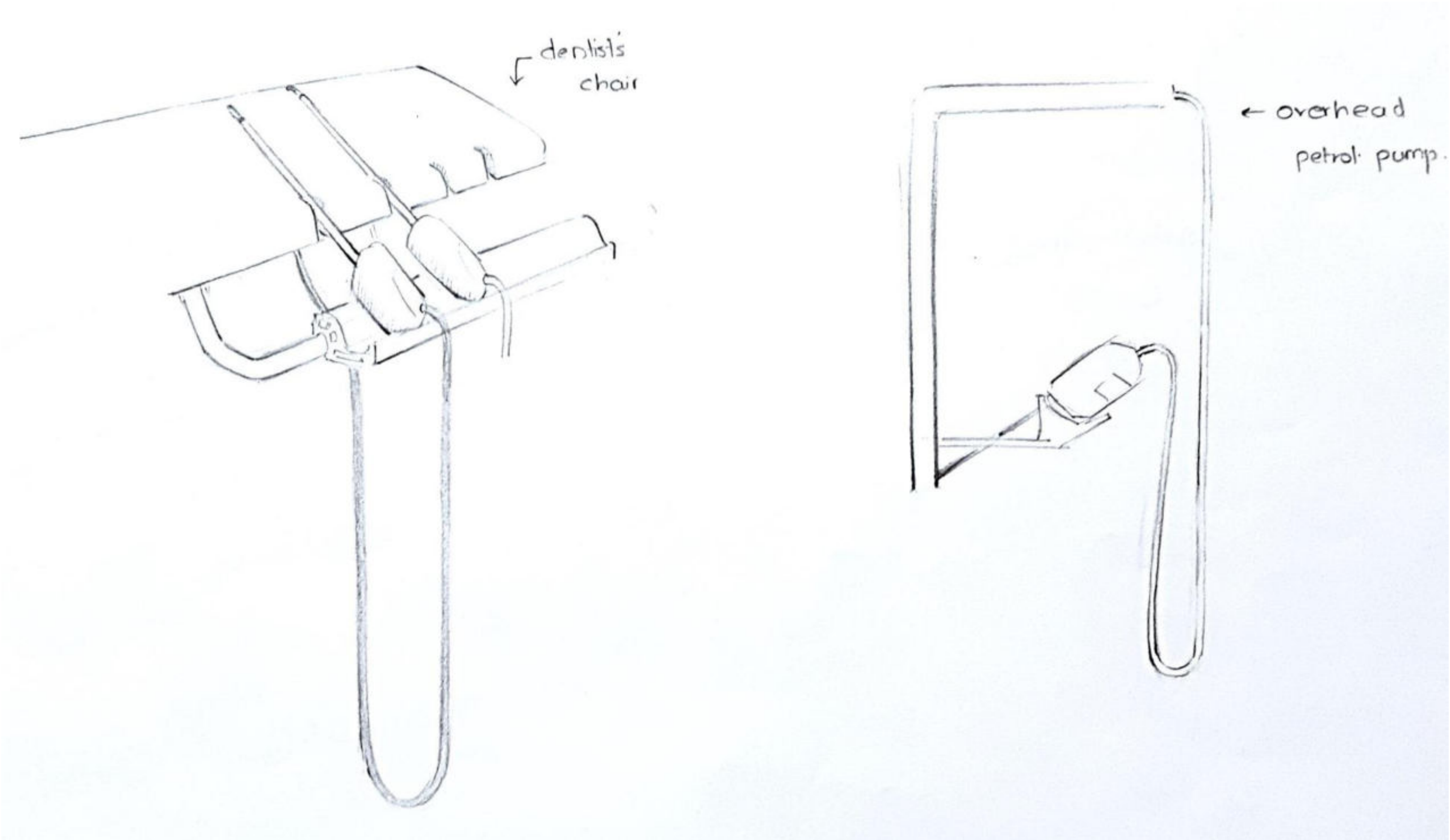
Top
fig 31: initial sketches, detailing various variations based on change in pivot point



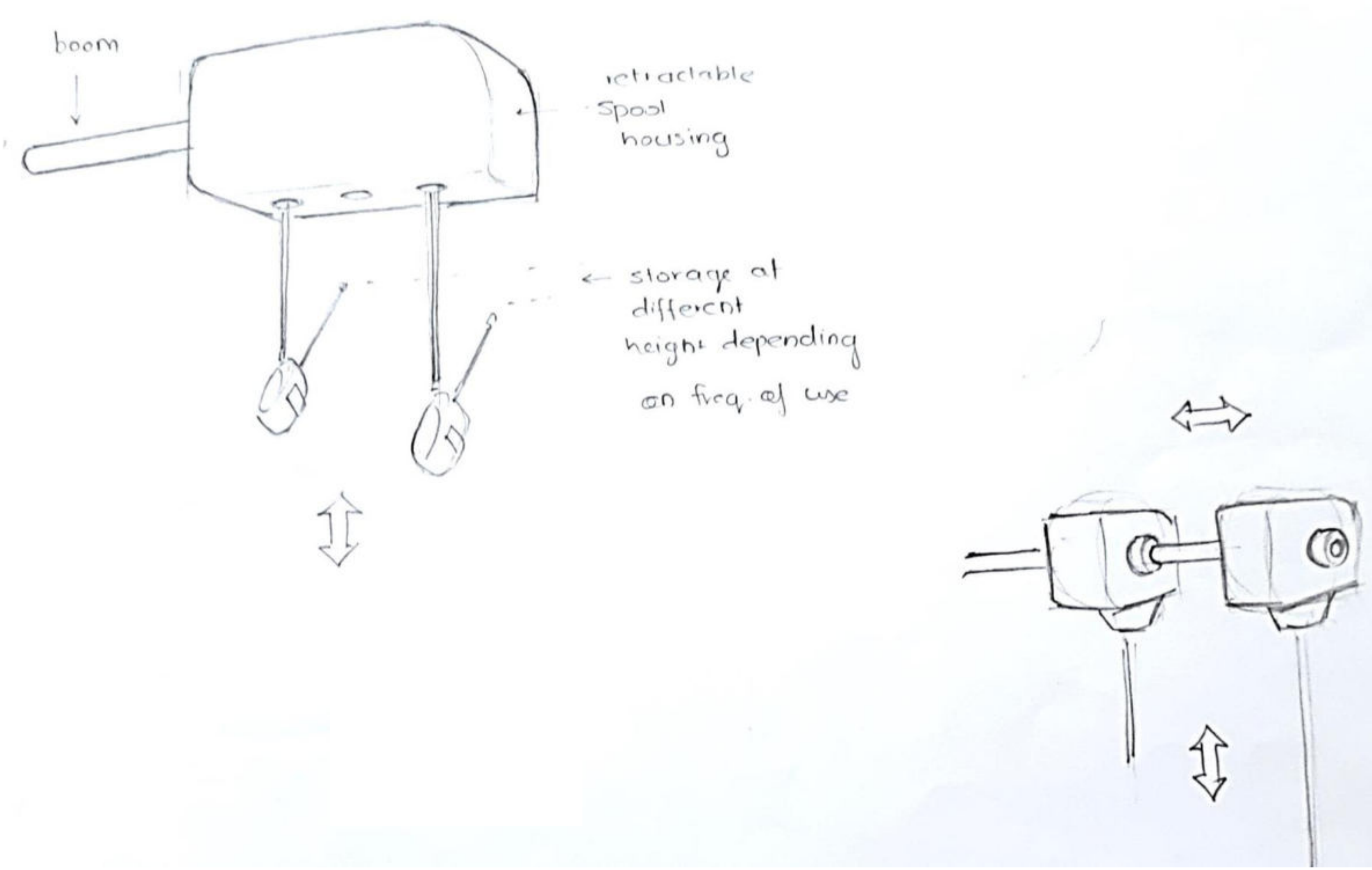

Top
fig 32: initial sketches for creating a stand for the device



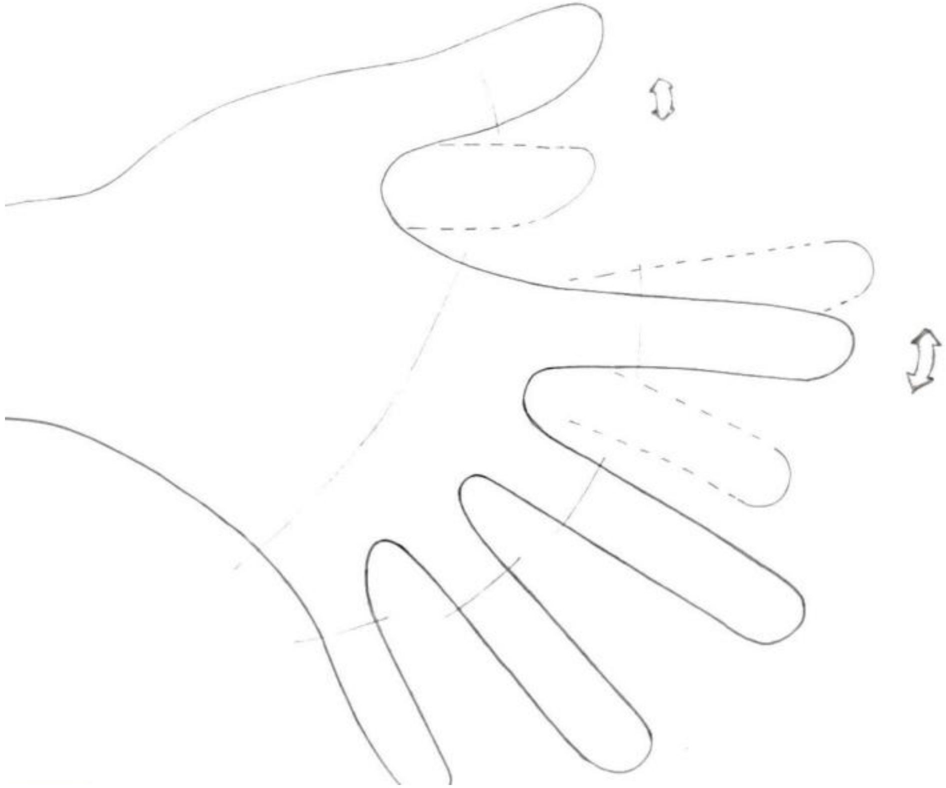

Top
fig 33: some more ideas for the stand




Top
fig 34: inspired from the dentists chair and petrol pumps

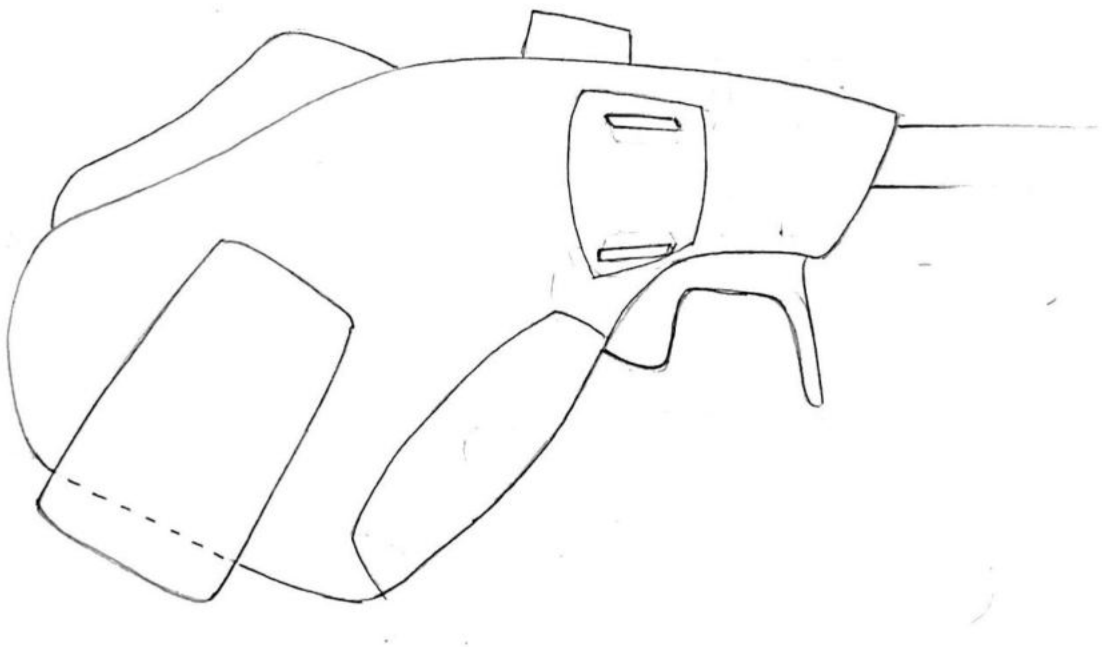



Top
fig 35: some attempts to use a retractable spool sytem



Top
fig 36: plotting hand dimensions and motions

# Concept 1

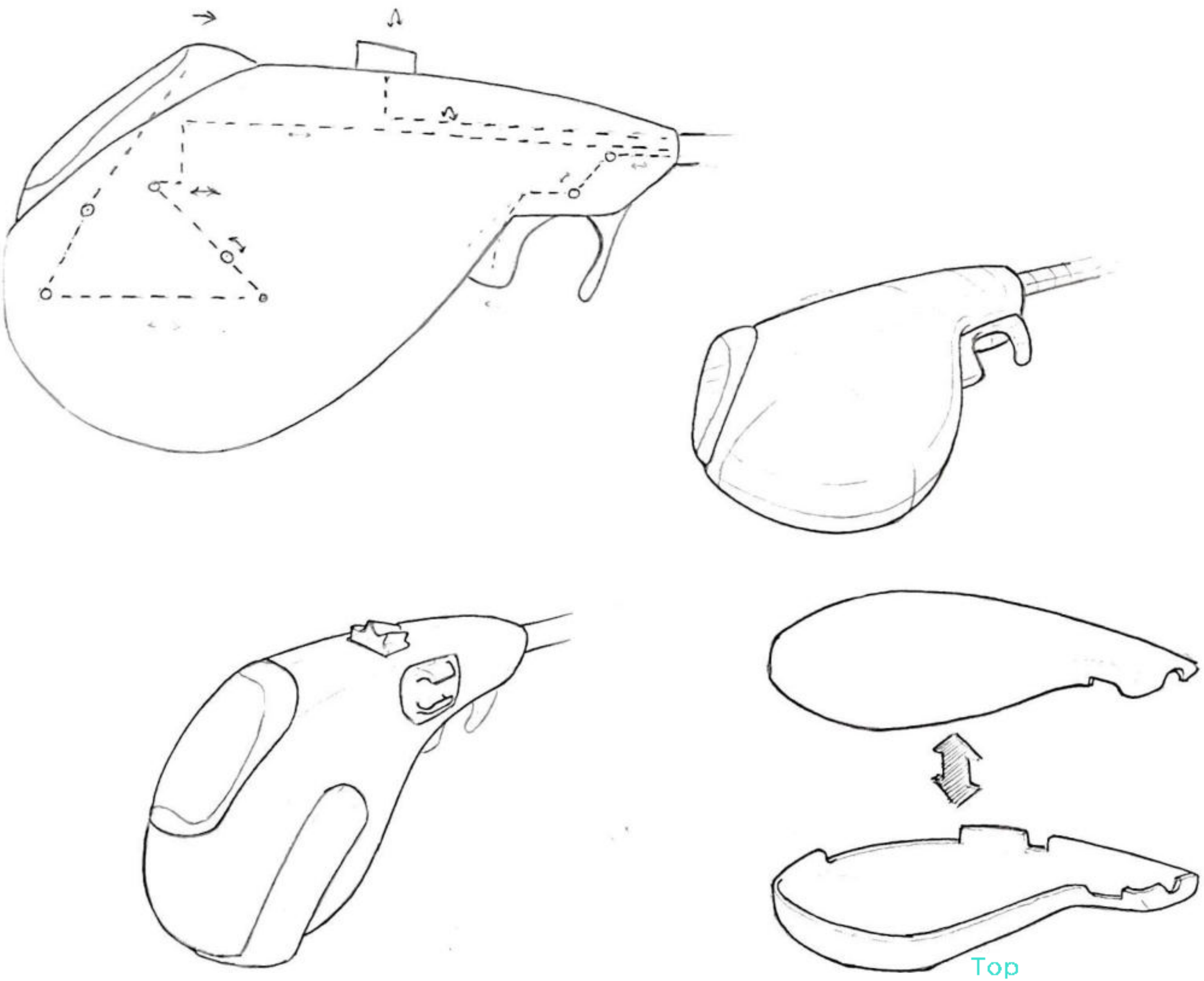


Top
fig 37: concept 1

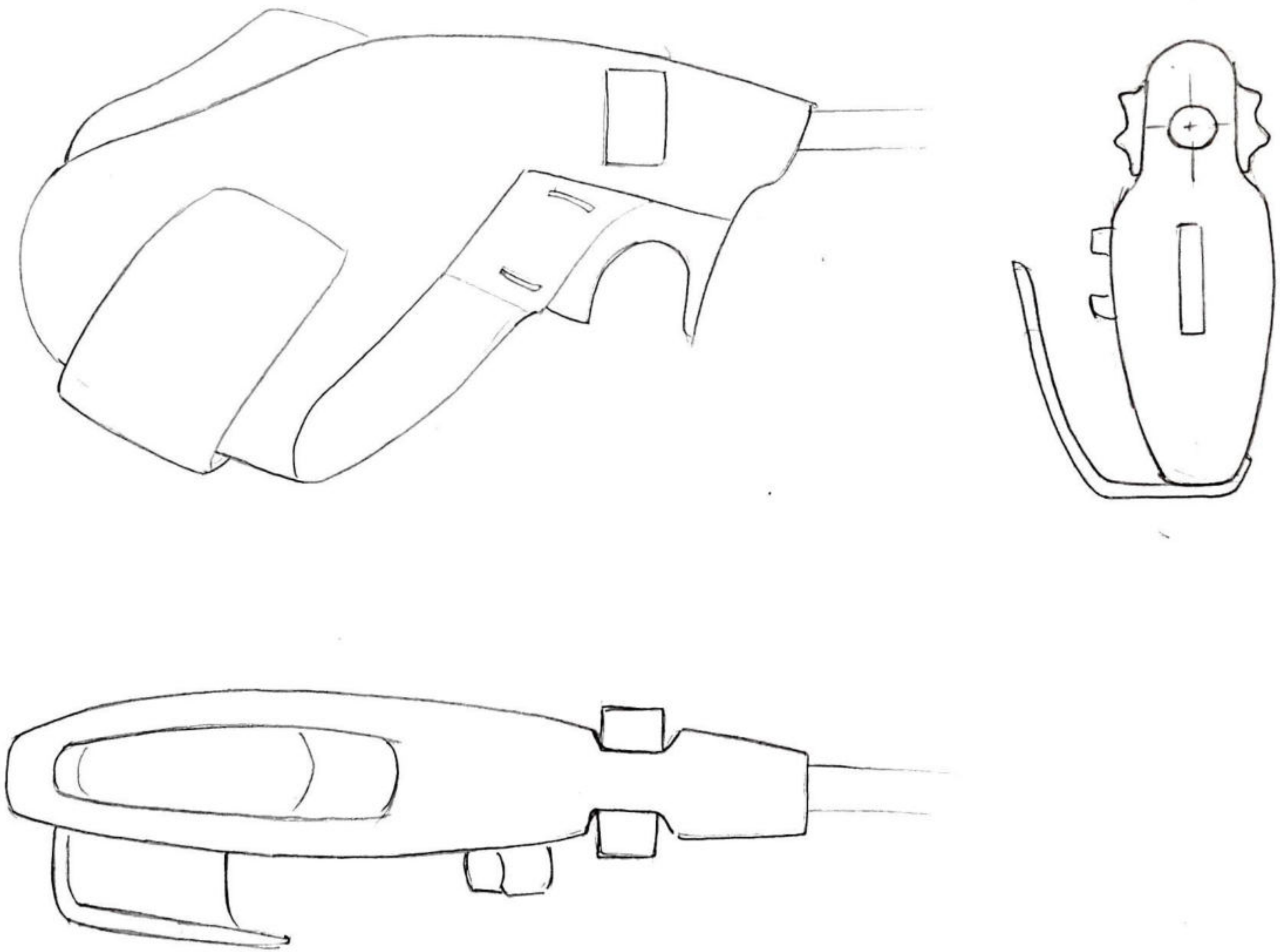
In concept 1, the thumb would rotate the knob, the index and middle fingers would operate the trigger for jaw opening, and the palm would be used to press the trigger for cutting.

When this model was tested with multiple people of varying hand sizes, the feed back was positive from people with smaller hands.

However a lot of them expressed the difficulty that a palm trigger would present.

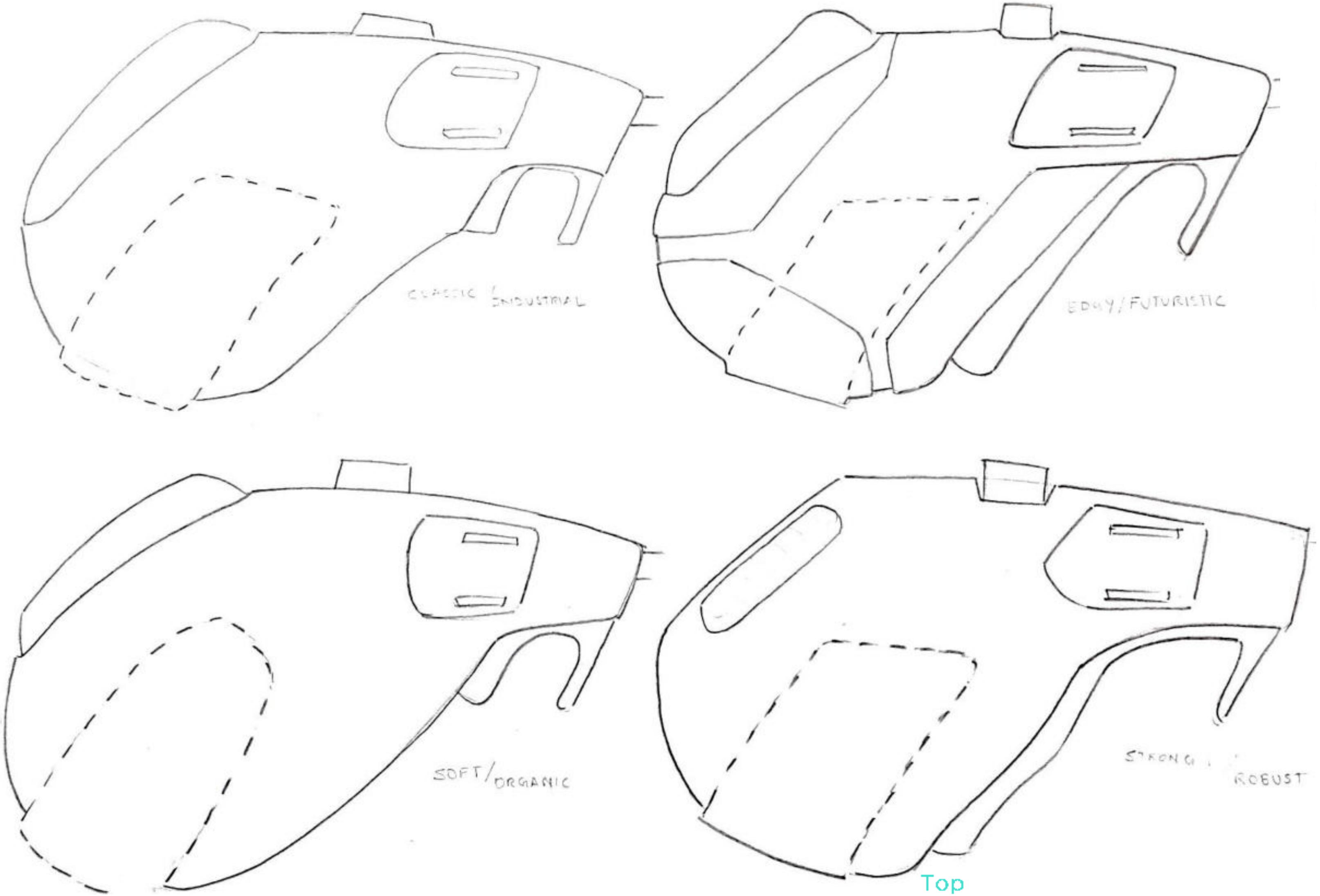


Top
fig 38: sketches explaining direction of forces on mechanism as well as parting line for outer cover



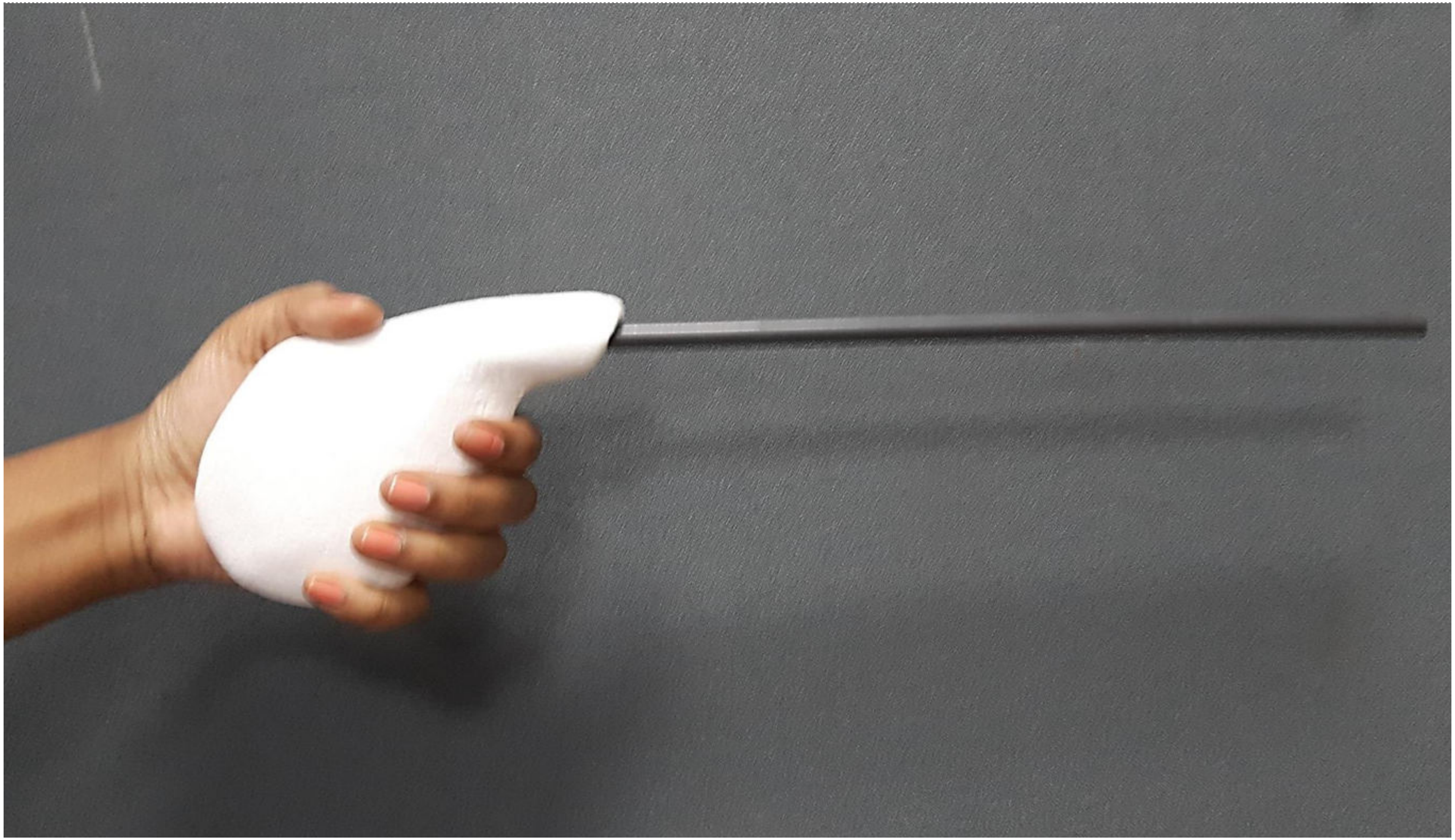
Top

fig 39: orthographic drawing




Top
fig 40: possible form variations for concept 1 based on various expressions

Top
fig 41: 1:1 mock up



Top
fig 42: user testing revealed that even though the form fits hand effectively, using palm trigger could be difficult

# Concept 2

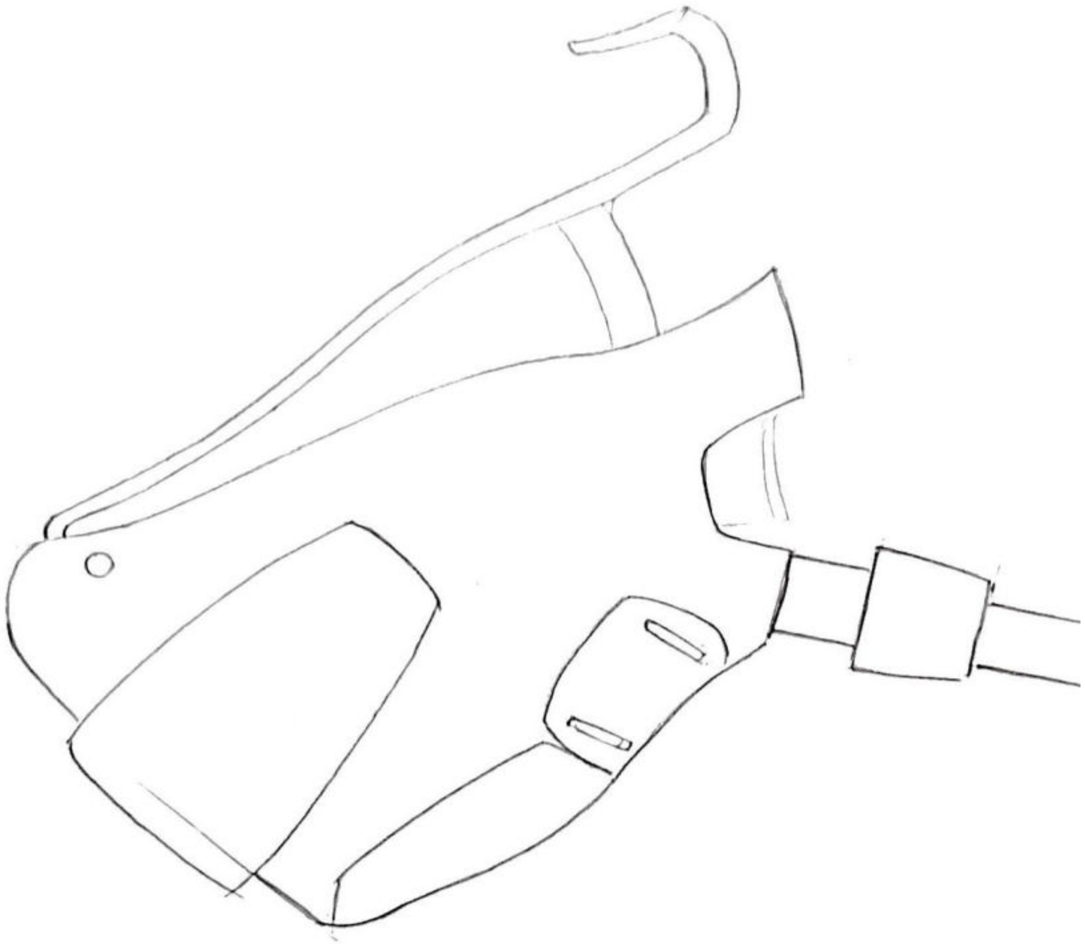
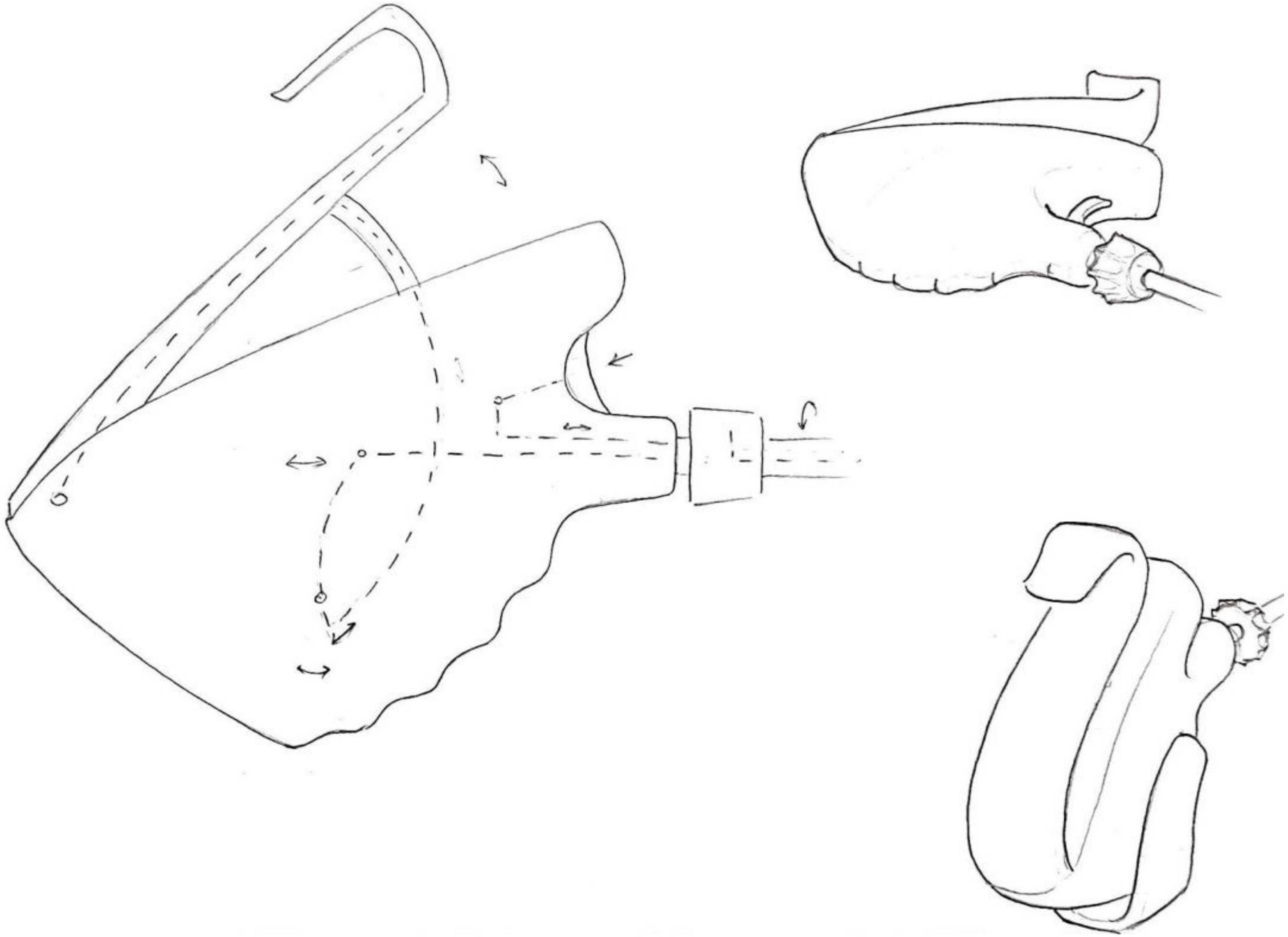



fig 43: concept 2

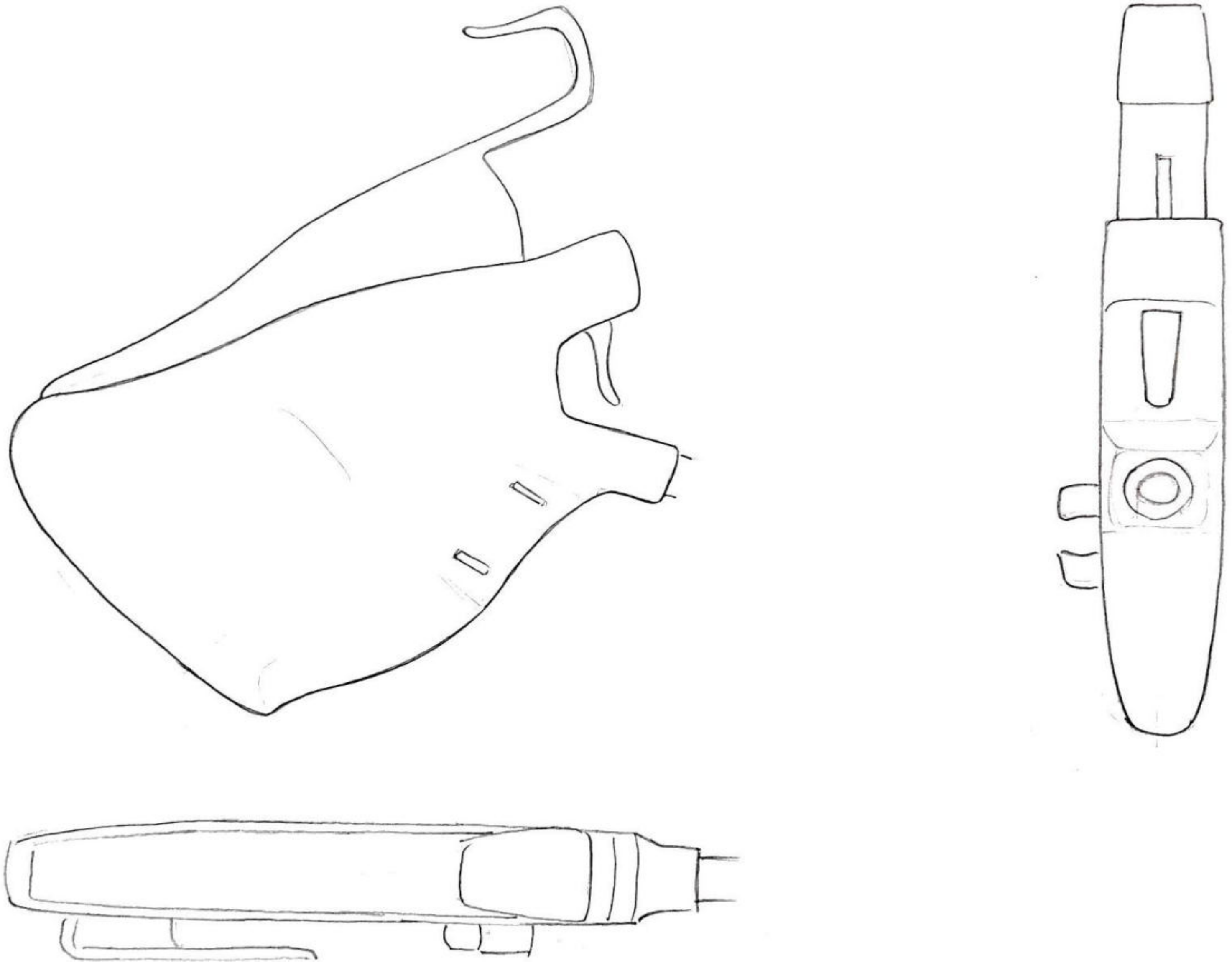
In concept 2, we wanted the device to feel more like an extension of the hand.

In this concept , the shaft extends between the grip of index and middle finger. The index finger rotates the knob, while extension of thumb, opens and closes the jaws. The cutting trigger is operated by the index finger.

Most people of varying hand sizes gave positive reviews about this grip.

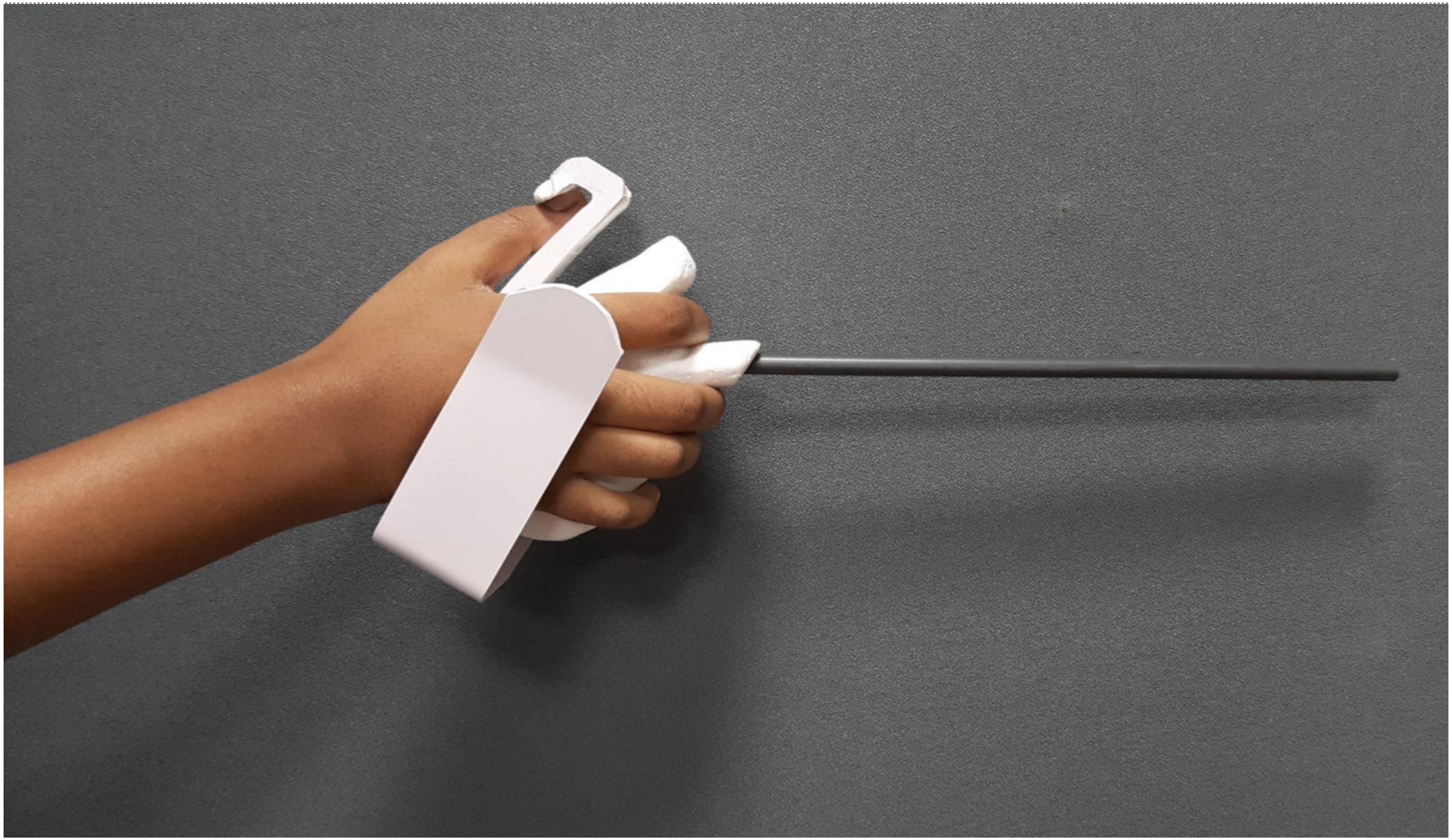


Top
fig 44: sketches highlighting the form and the direction on forces of a probable mechanism



Top
fig 45:
orthographic
drawing

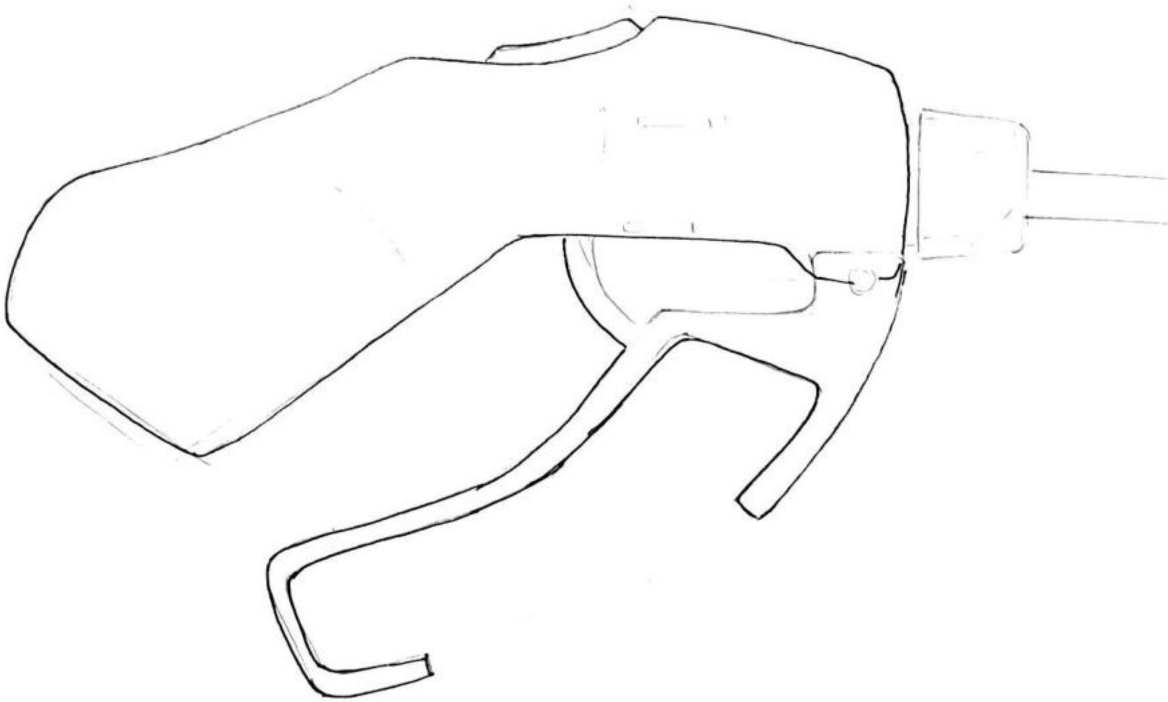
Top
fig 46: mock up



Top
fig 47: the tests showed that the devise fits various hand sizes easily, also the thumb trigger was appreciated

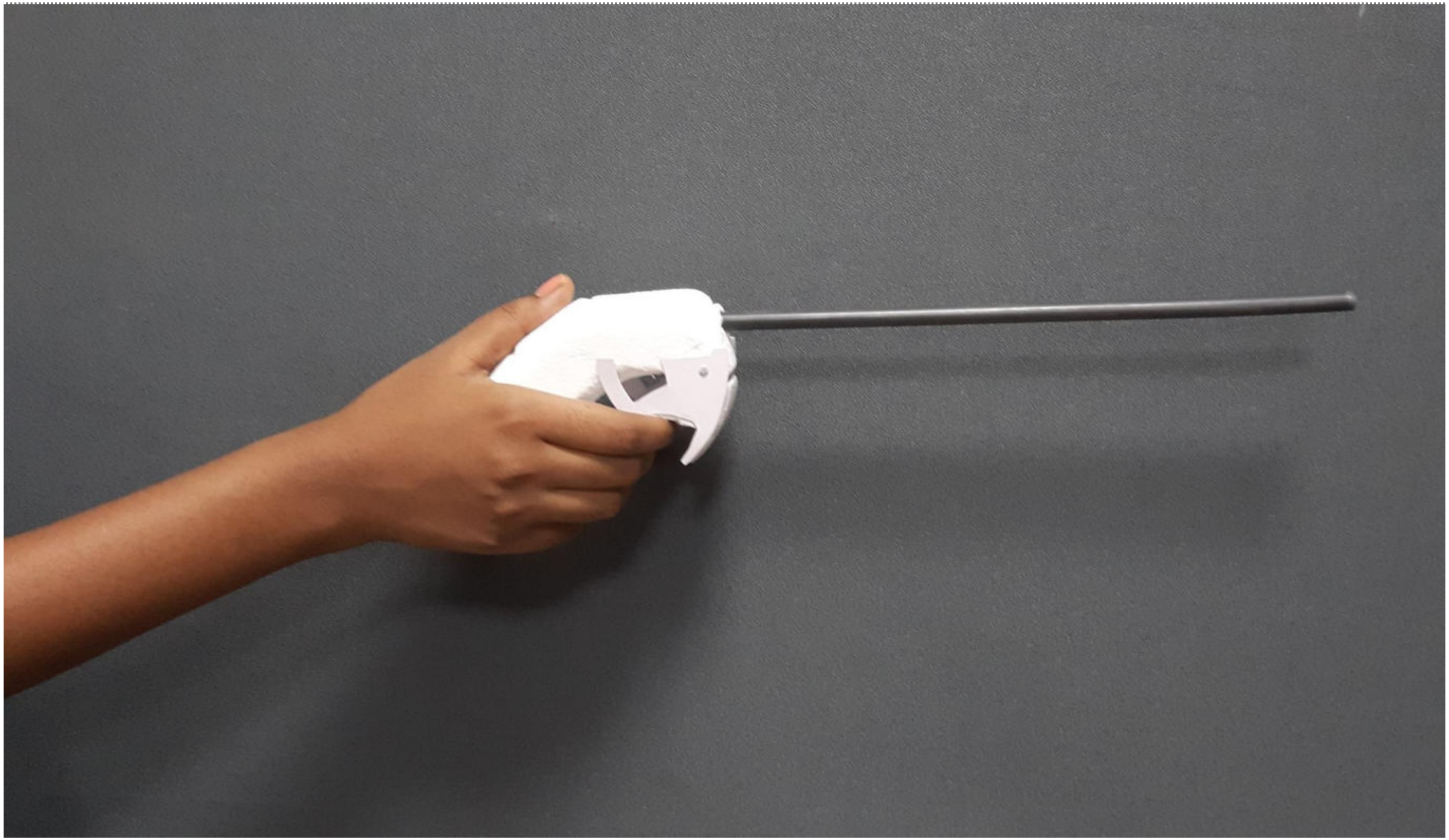
# Concept 3

Concept 3 is a slight variation on existing pistol grip. Only the location of cutting trigger is changed so that it can be pressed using the thumb.



Top
fig 48: concept 3

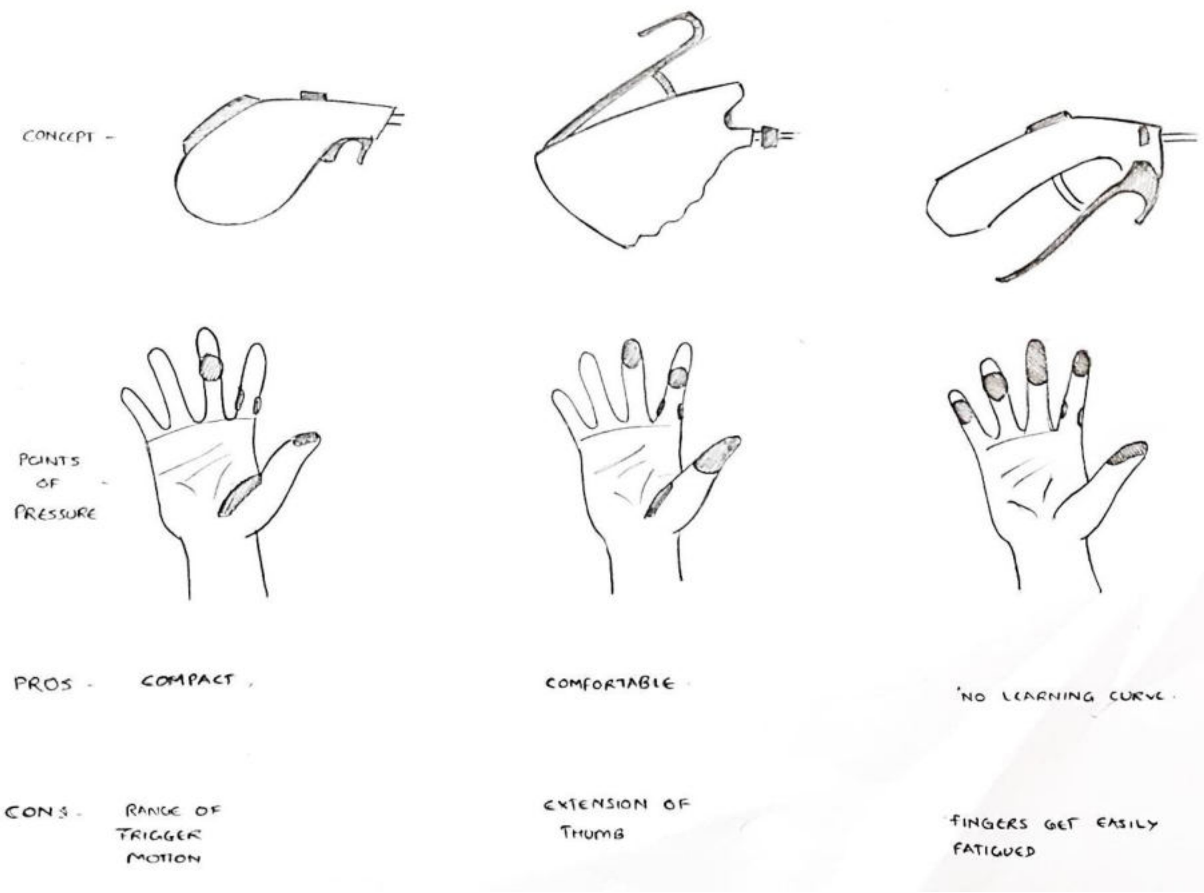
Top
fig 49: 1:1 mock up



Top
fig 50: Using 2 or 3 fingers for jaw opening would be difficult for smaller hands

Top
fig 51: mock ups

# Evaluation



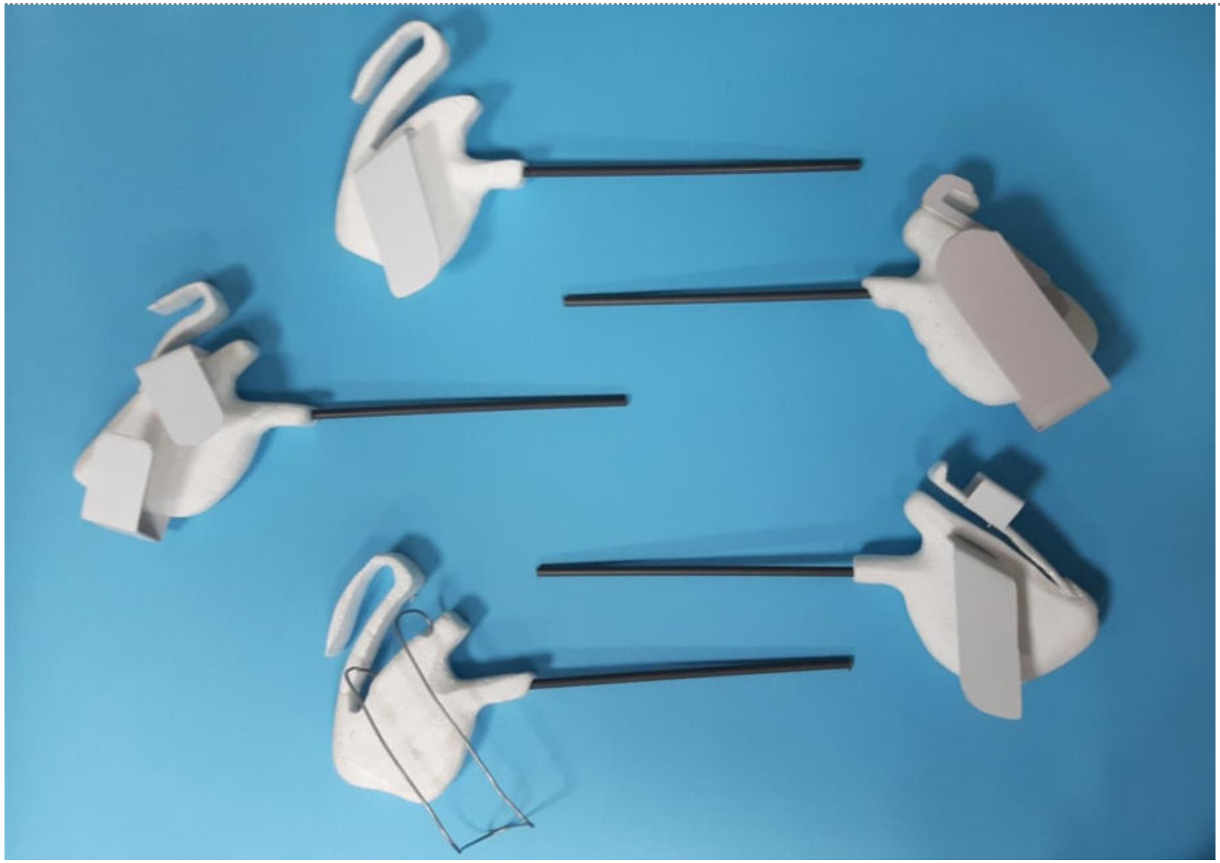

To evaluate the concepts, following criteria were considered:

- points of pressure on the hand
- restriction to intended motion
- axial movement
- gripping comfort

Based on the results of the evacuation and feedback, concept 2 was chosen for further development

Top
fig 52: concept evaluation

# Ideation phase 3



After finalizing concept 3, the next phase was to create and test retainer for the device.

The criteria was as following:

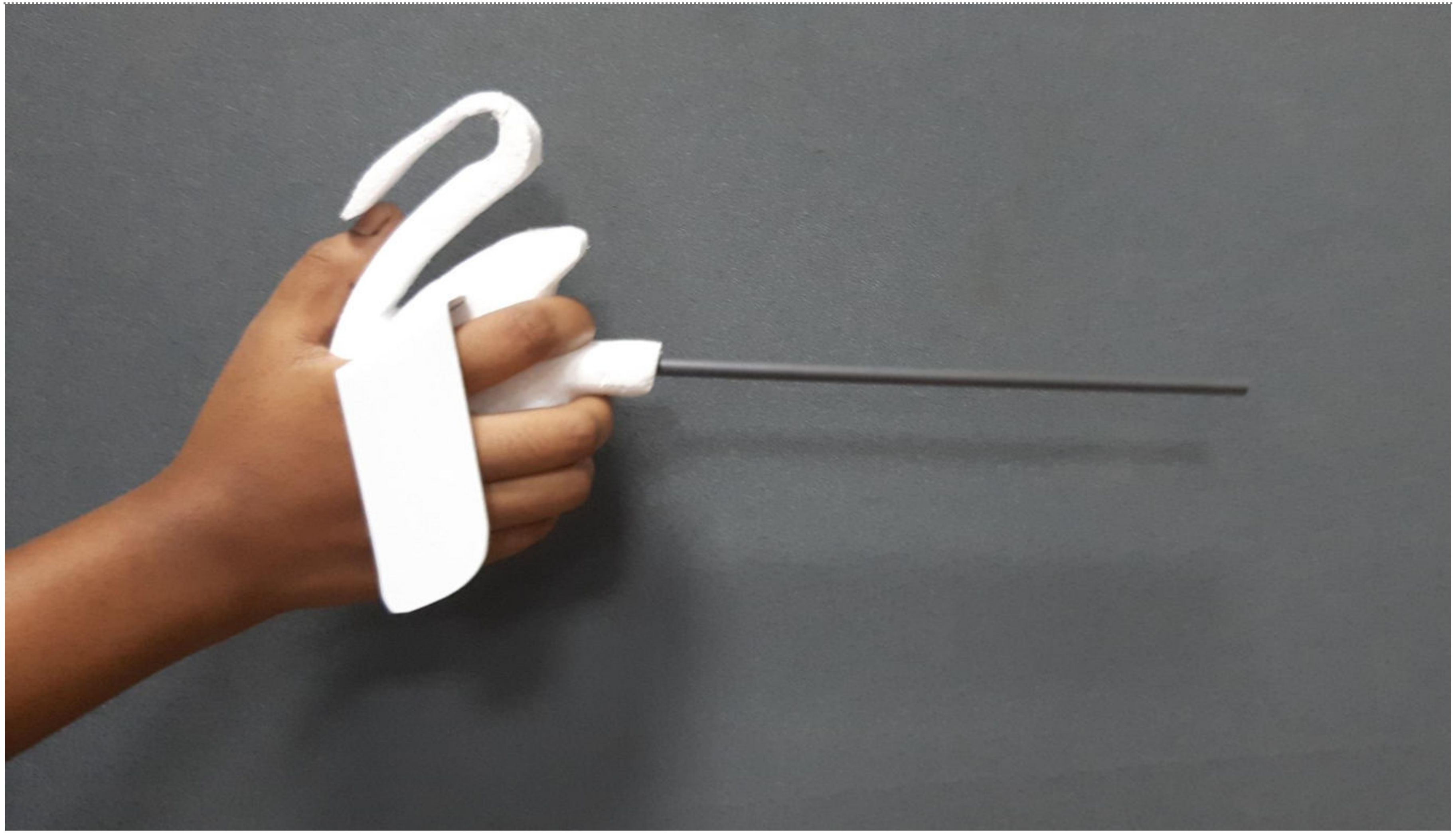
- the retaining detail should ensure that the device grips the hand
- provision of relaxing the hand without removing the device

Various types of retainers were made and tested (fig 49-54)

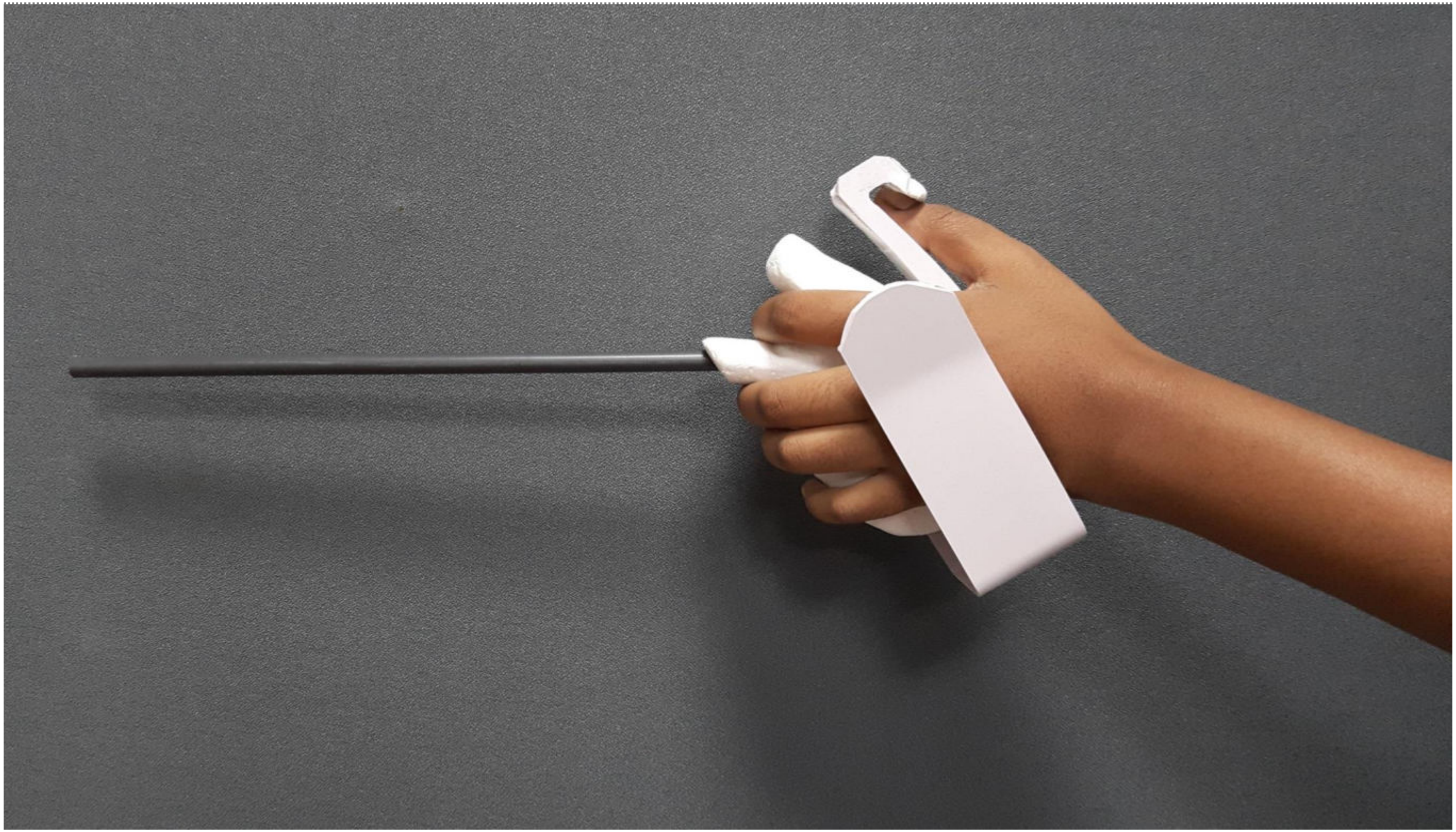
However, it was discovered that it would be difficult to create a retainer that would grip as well as feel comfortable to hands of all sizes.

Hence it was decided to use soft single finger retainers for the thumb as well as one to two more fingers.

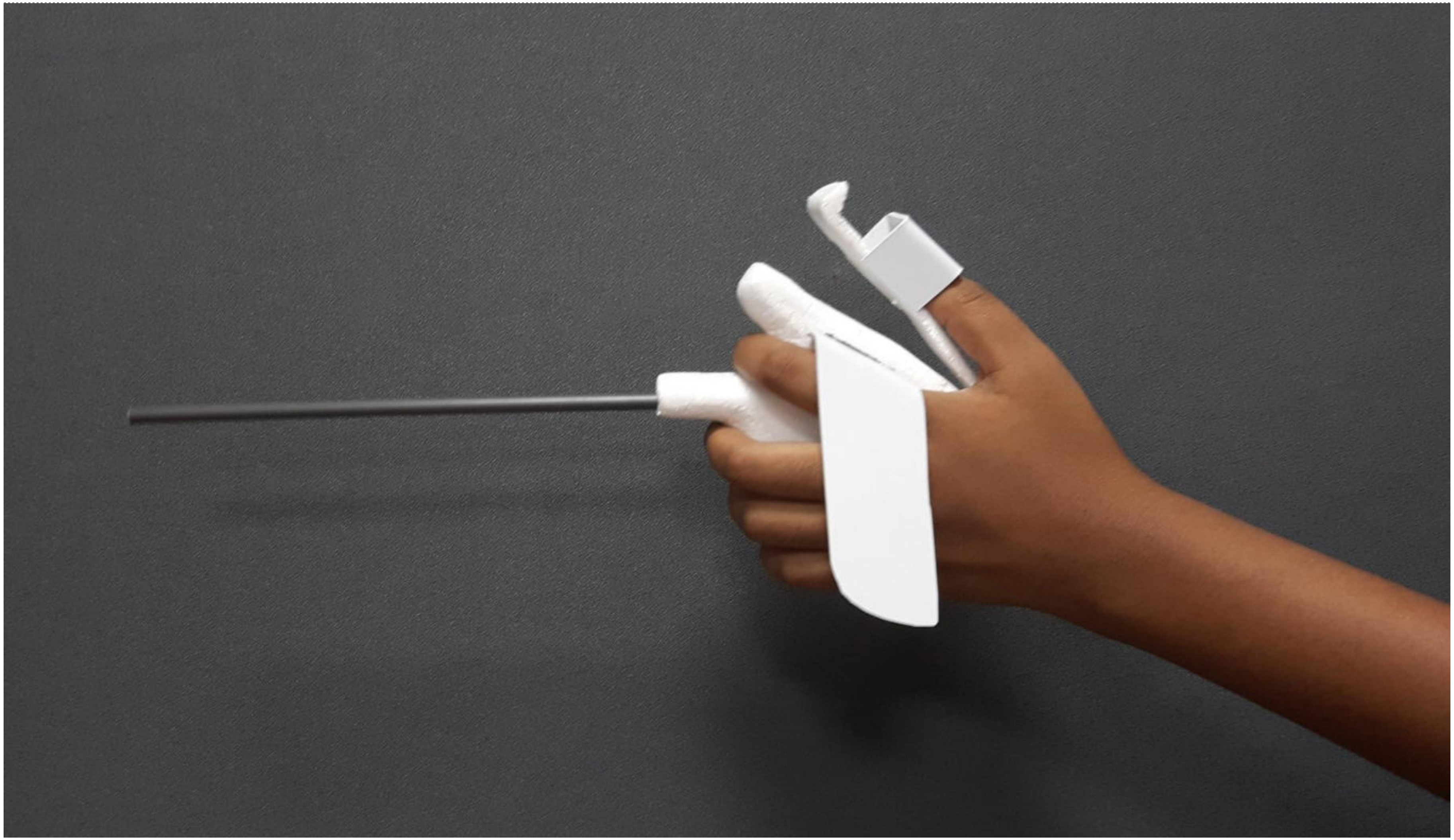
Top
fig 53: mock ups for testing retainers



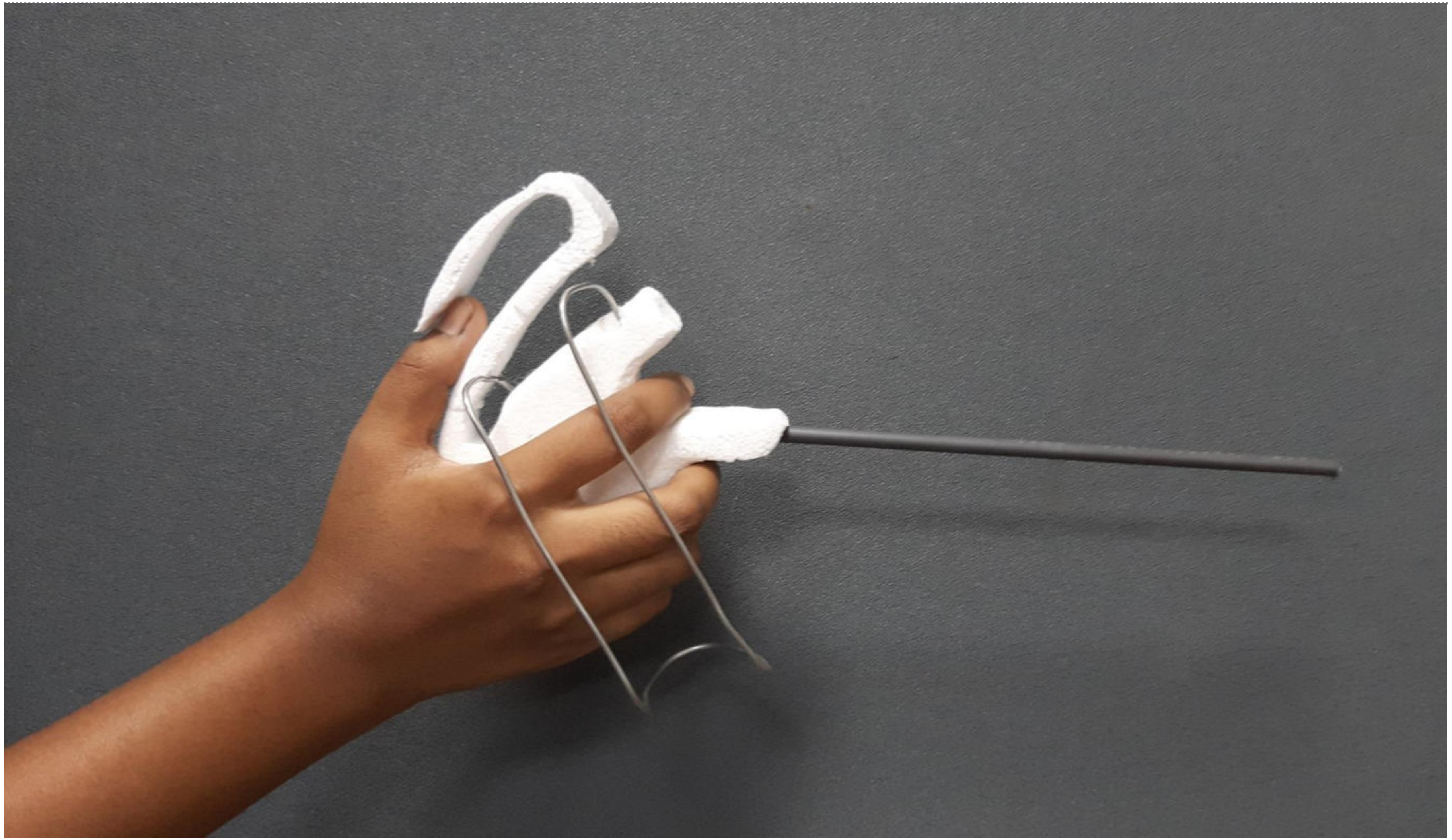
Top
fig 54: The retainer is placed over the hand to allow the device to rest on the hand



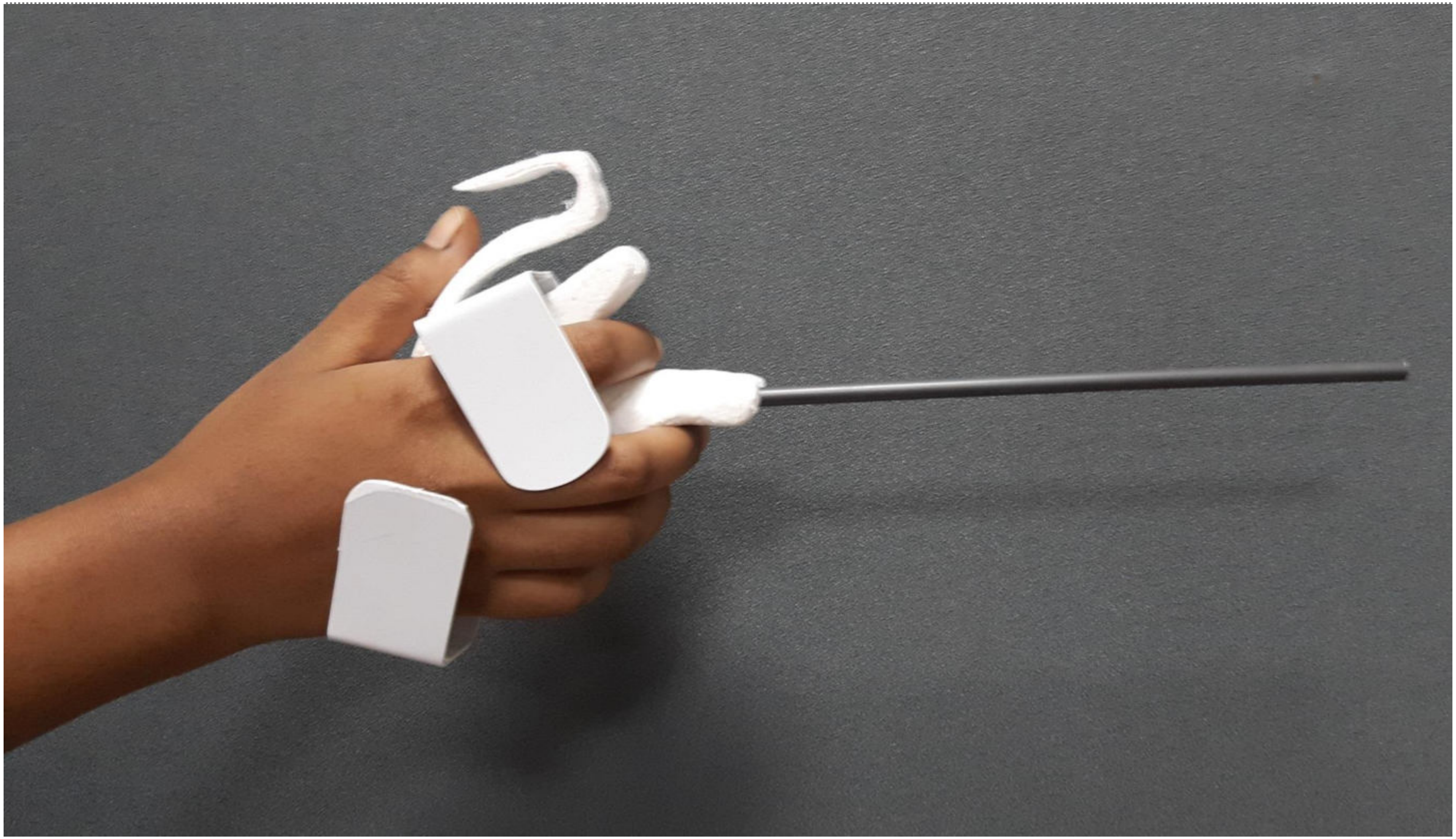
Top left
fig 55: The retainer design is a variation of fig 54, however it would be difficult to adopt it for varying hand sizes



Top
fig 56: Similar to fig 54, but the trigger uses a band for the thumb to allow easier bidirectional movement



Top left
fig 57: This was an effort to minimise the visual weight of the retainer and to use it as a stand



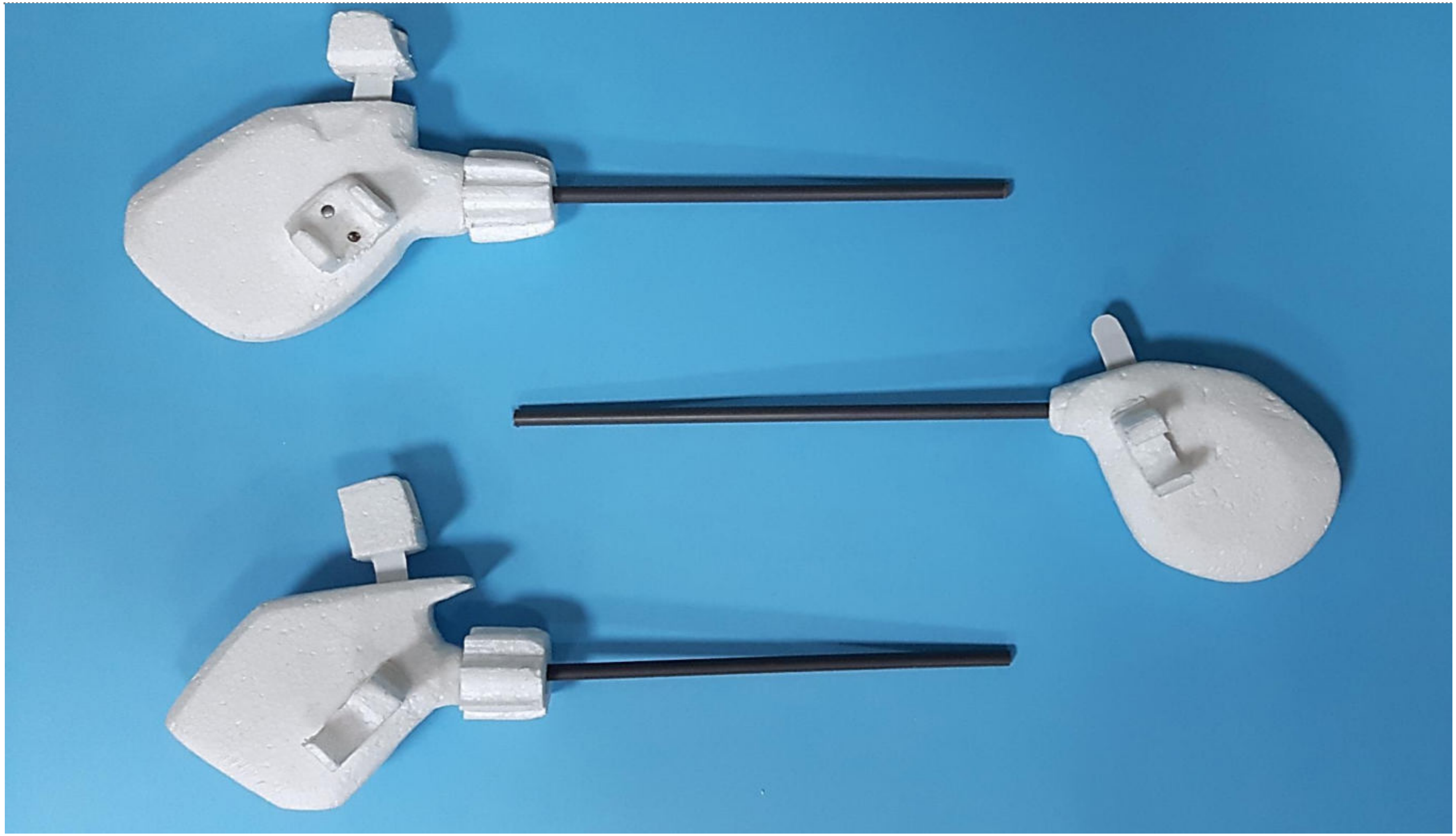
Top
fig 58: This design was the preferred one during tests as it gripped the hand in multiple planes

# Ideation phase 4

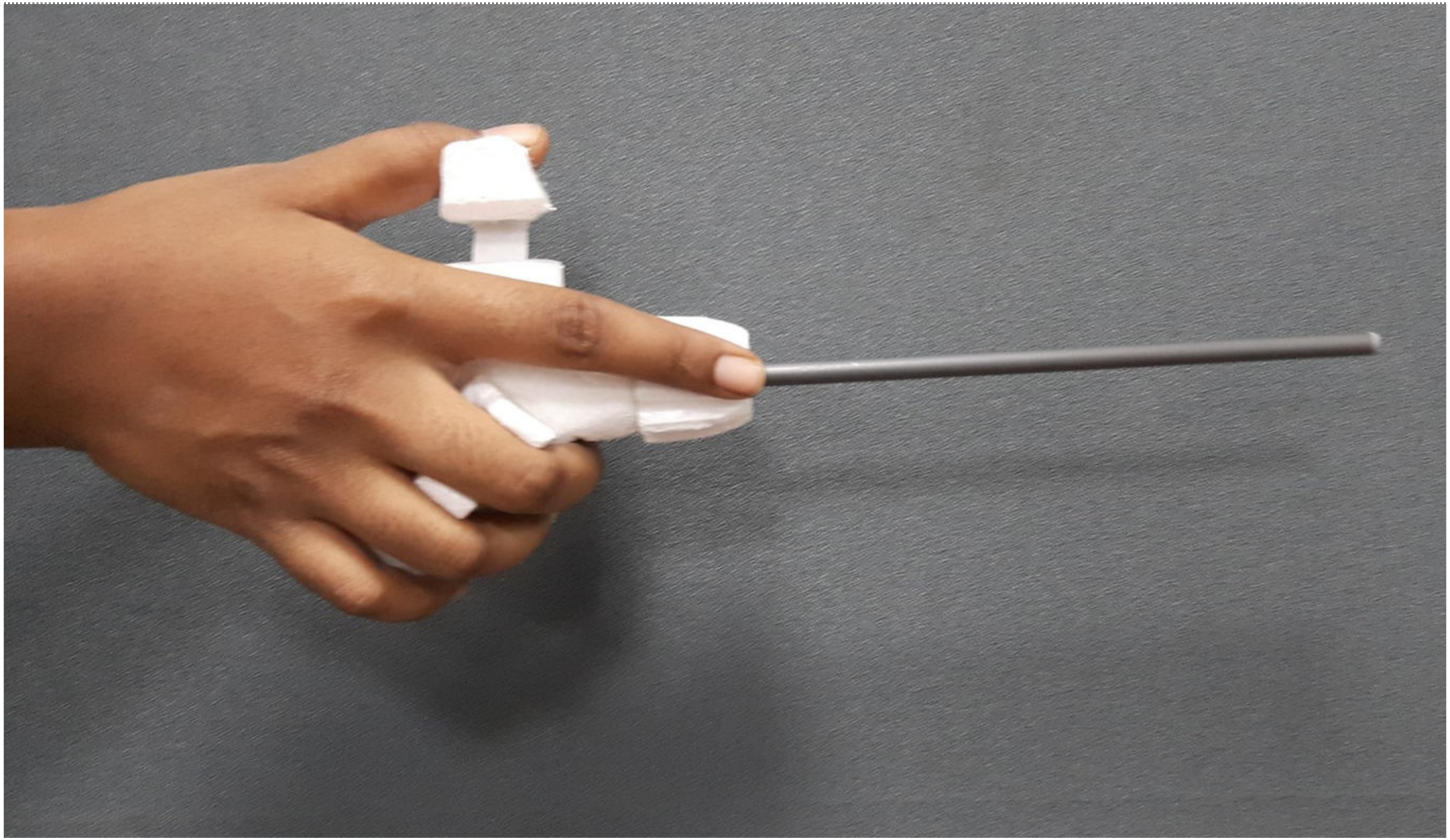
The concept  2 form was too organic, hence it was decided to geometricize the form for ease of manufacture and also to simplify the visual form.

Also these forms were the shown to doctors at Indian Medical Device Expo, (IMD-EXPO) 2016 held at College of Engineering, Pune (CoEP).

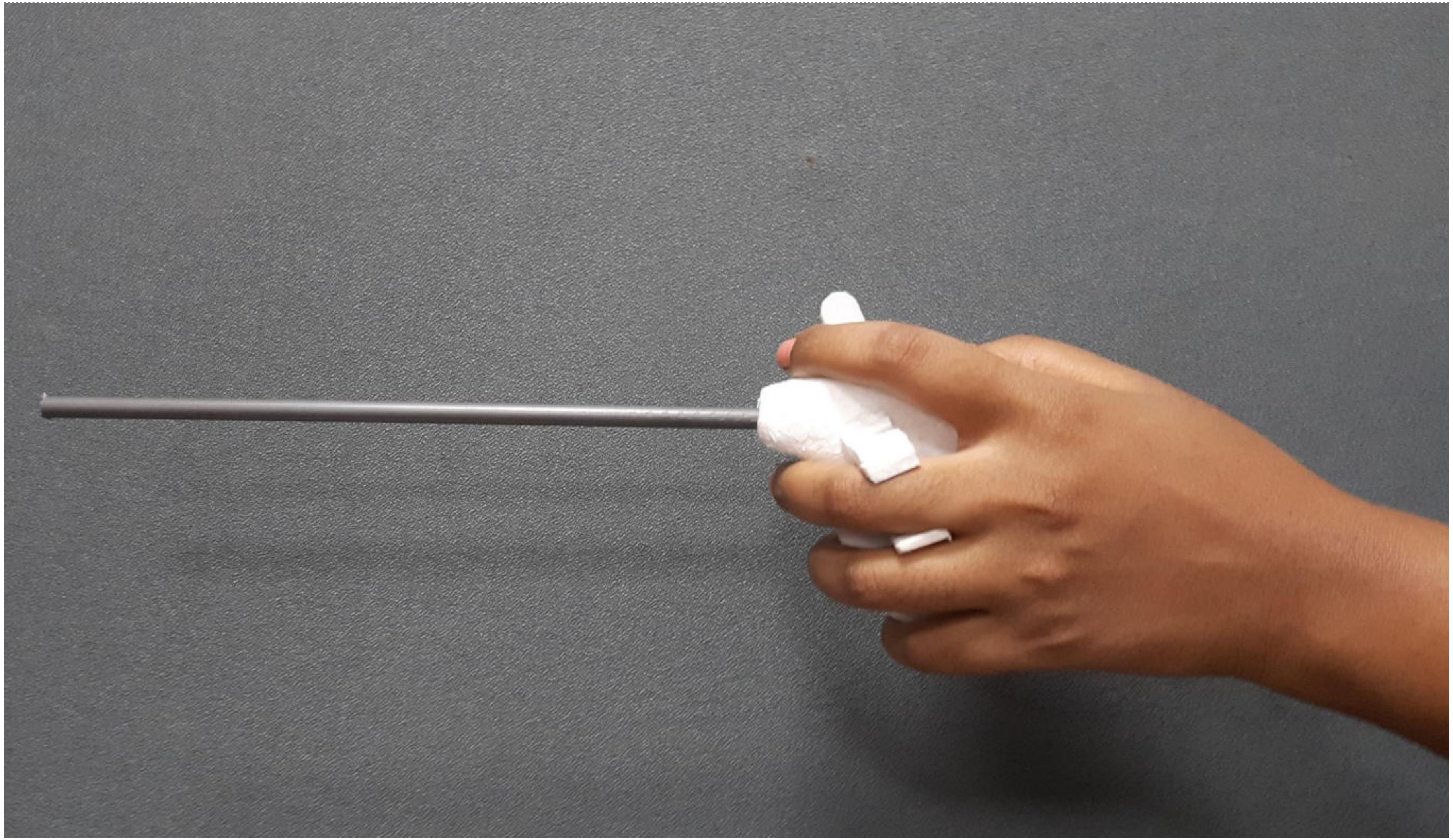
Based on their feedback it was then decided to add flexibility to the thumb operated trigger to provide a more natural motion of thumb.



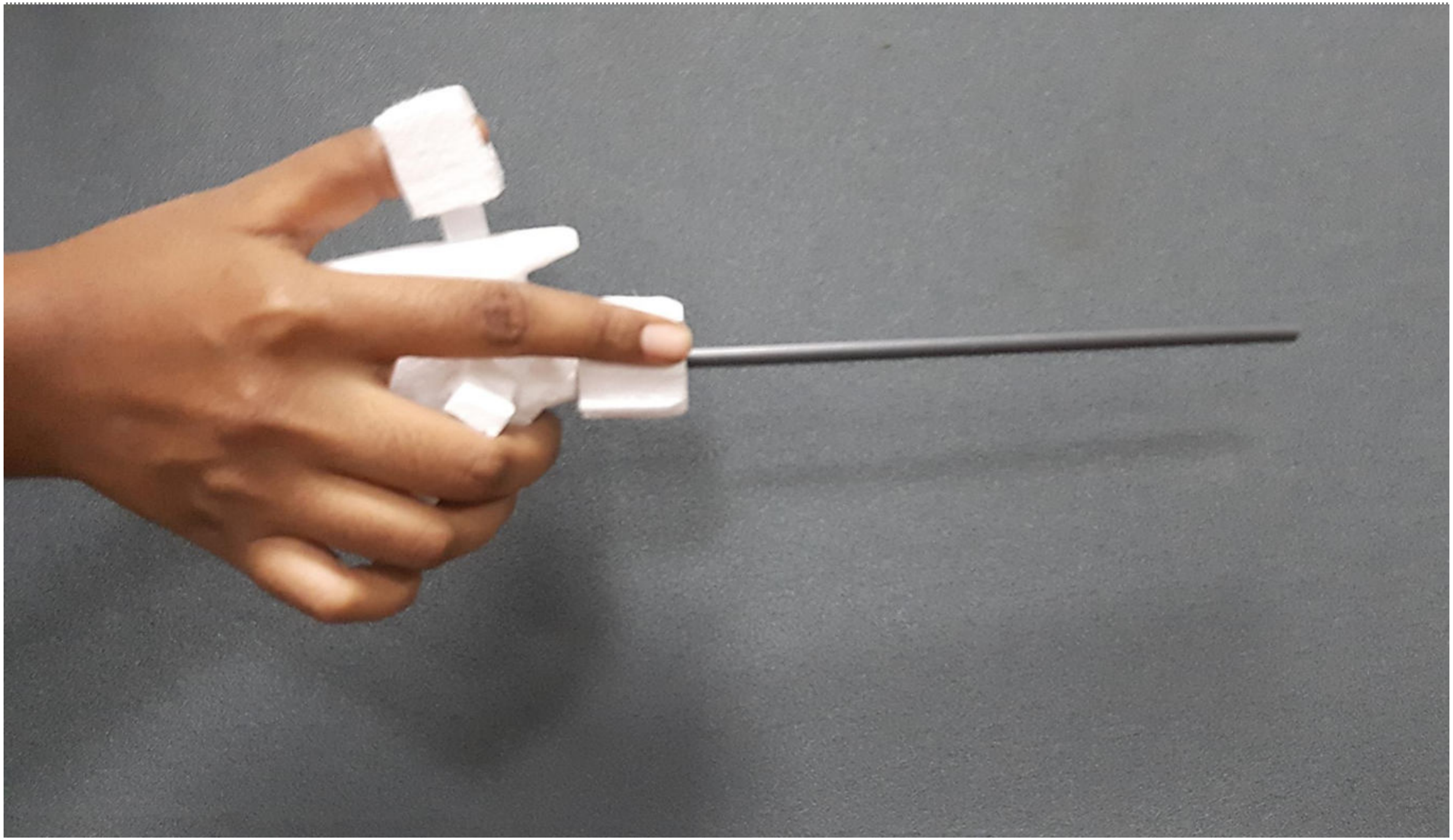
Top
fig 59: Geometricizing the forms and the use of finger retainers



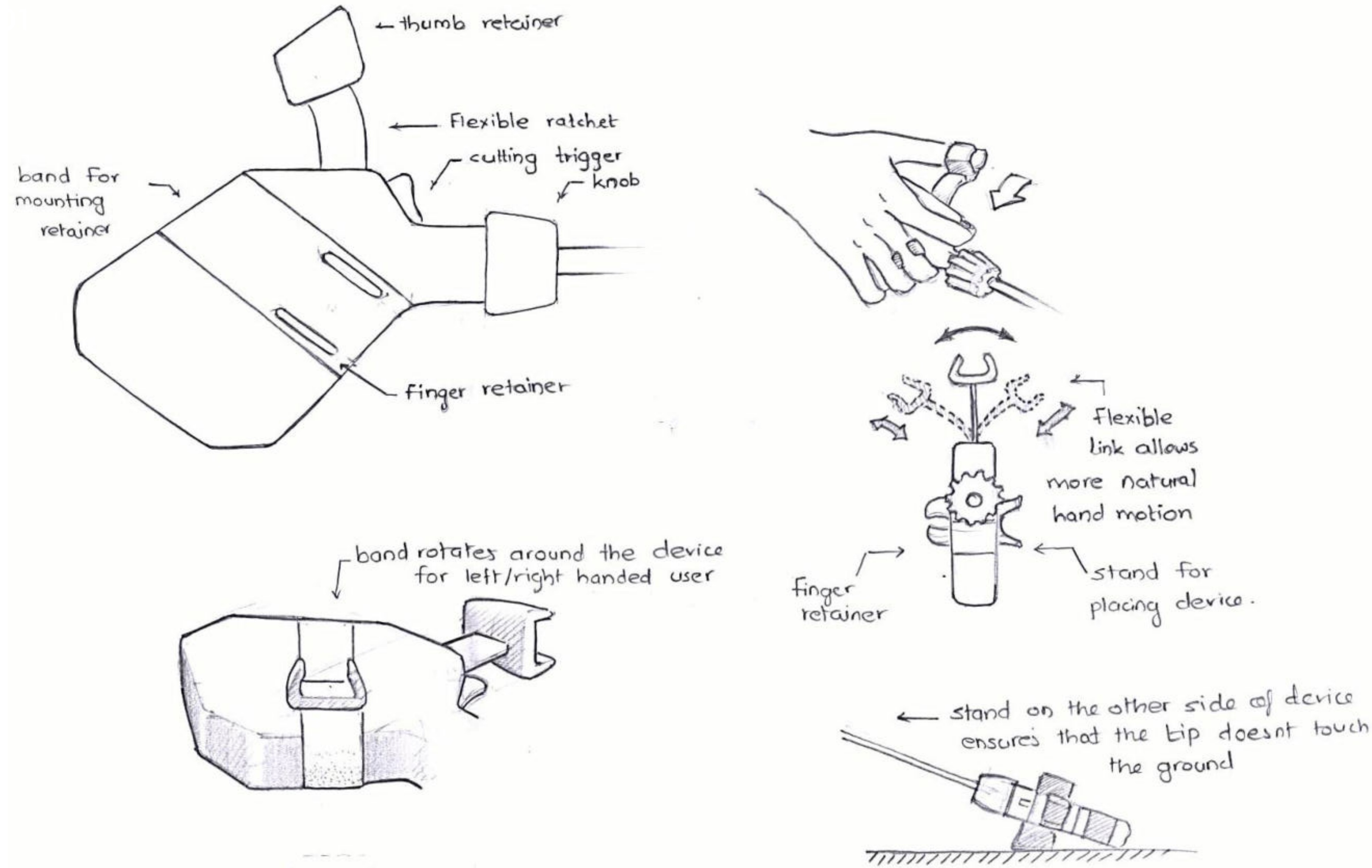
Top left
fig 60: The finger retainers work better than the previous designs allowing more flexibility



Top
fig 61: The new designs also have a more compact and uncluttered form

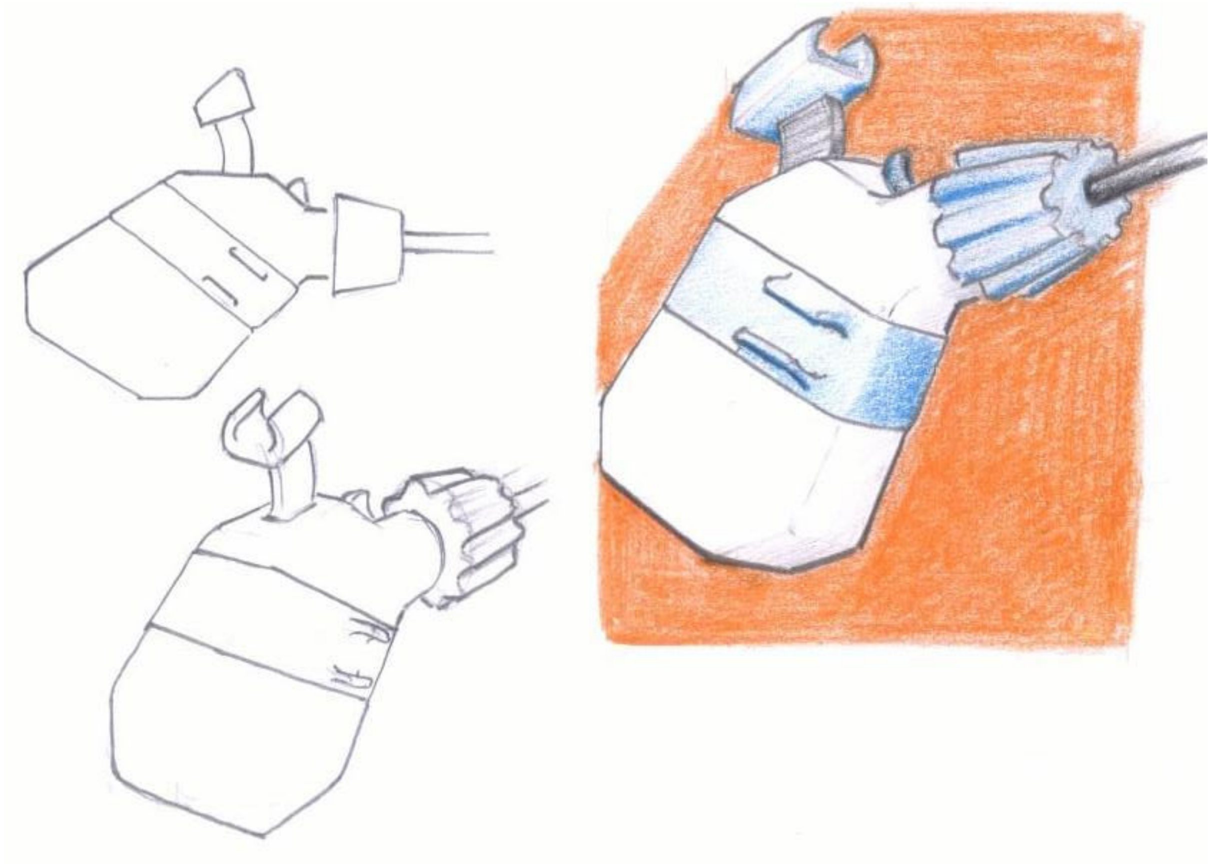


Top left
fig 62: The thumb retainer also feels more comfortable, however the thumb extension should be more natural




Top
fig 63: Final concept direction

# Ideation phase 5



The next step was to refine the form and the overall concept.

We decided to incorporate the following features in the final concept.

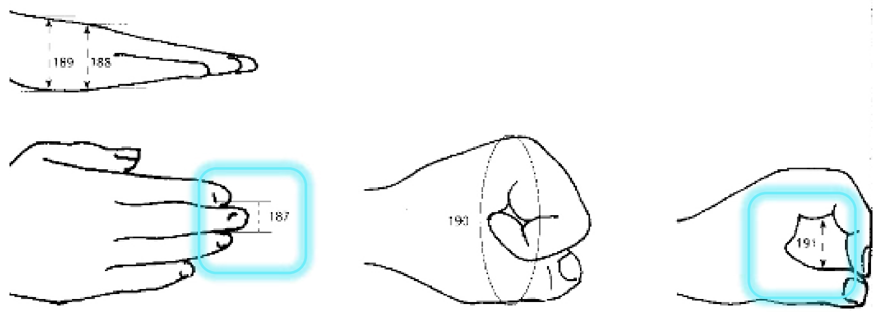
- The finger retainers provide grip while allowing the surgeon to relax the fingers without leaving the tool
- The flexible thumb ling replaces the large finger motions with natural thumb motion for jaw opening/closing
- The device allows axial hand movements without the need of additional body contortions.

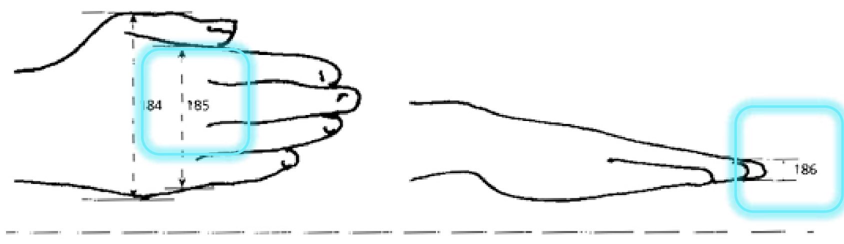
Then a mood board was created for keywords , futuristic, clean, soft and clinical.

On the basis of the mood board and final concept direction, various alternatives were created and refined for the final form.

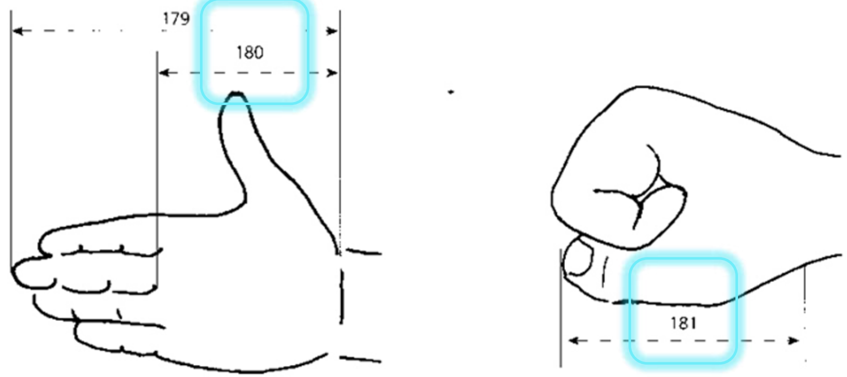
Top
fig 63: Final concept direction

Top
fig 64: Image board (clean, futuristic, light, soft)



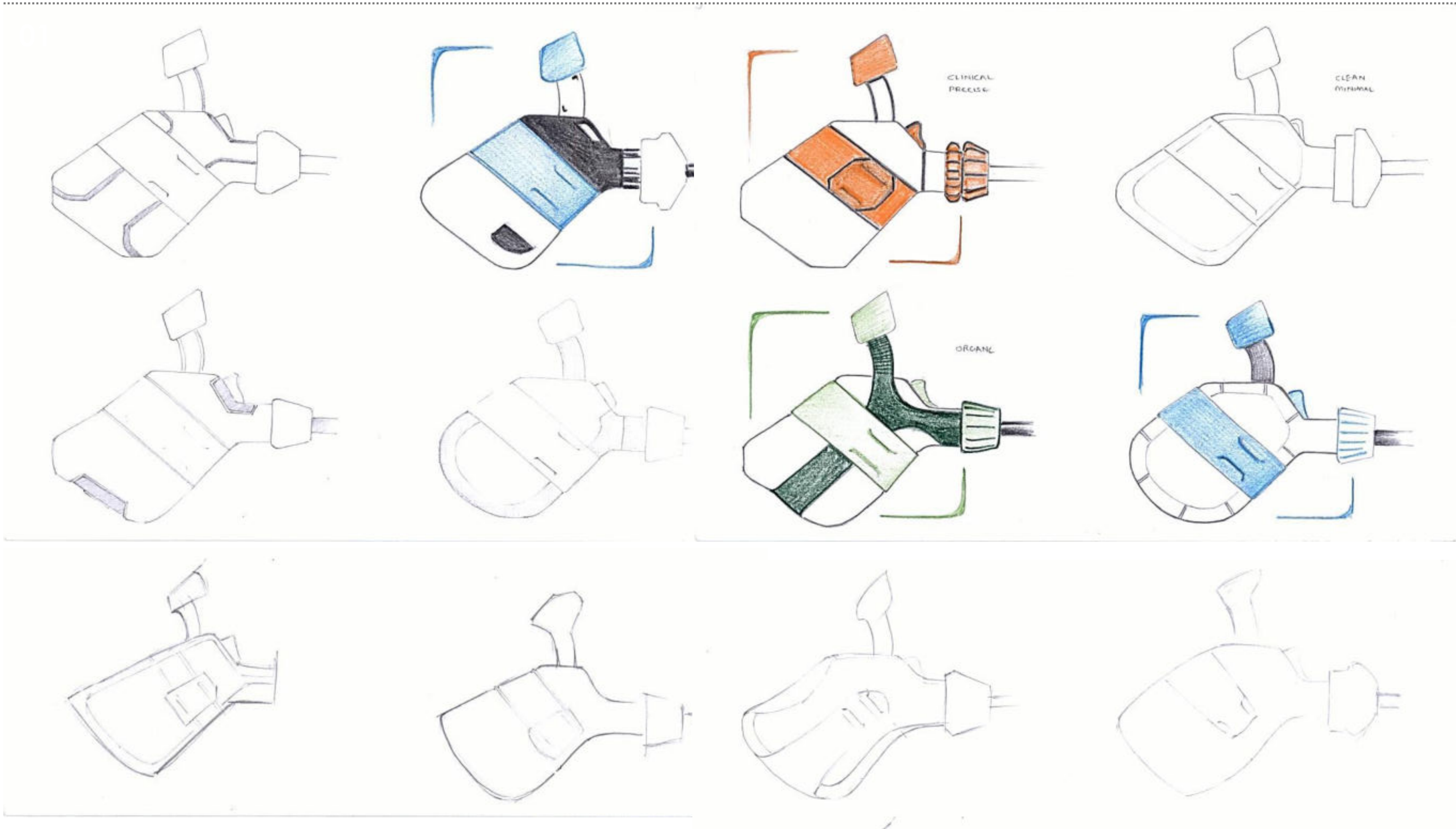

| R.No. | Parameters | | Min | Percentiles 5th | 25th | 50th | 75th | 95th | Max | Mean | ±SD | Ratio |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 187 | **Finger-tip breadth** | Male | 13 | 13 | 14 | 15 | 16 | 17 | 20 | 16 | 1 | 0.01 |
| | | Female | 10 | 11 | 12 | 12 | 13 | 15 | 16 | 13 | 1 | 0.01 |
| | | Combined | 10 | 12 | 13 | 14 | 15 | 17 | 20 | 15 | 2 | 0.01 |
| 191 | **Grip inside diameter, maximum** | Male | 39 | 42 | 46 | 49 | 51 | 56 | 60 | 50 | 4 | 0.03 |
| | | Female | 39 | 40 | 47 | 46 | 49 | 52 | 57 | 47 | 5 | 0.03 |
| | | Combined | 39 | 41 | 46 | 49 | 51 | 56 | 60 | 49 | 4 | 0.03 |
| 185 | **Hand breadth without thumb at metacarpal** | Male | 60 | 72 | 77 | 81 | 85 | 90 | 100 | 82 | 6 | 0.05 |
| | | Female | 60 | 66 | 69 | 71 | 75 | 79 | 92 | 73 | 5 | 0.05 |
| | | Combined | 60 | 68 | 74 | 79 | 84 | 90 | 100 | 80 | 7 | 0.05 |
| 186 | **Finger-tip depth** | Male | 10 | 11 | 12 | 13 | 14 | 15 | 18 | 14 | 1 | 0.01 |
| | | Female | 8 | 8 | 9 | 10 | 11 | 13 | 15 | 11 | 1 | 0.01 |
| | | Combined | 8 | 10 | 12 | 13 | 14 | 15 | 18 | 14 | 2 | 0.01 |
| 180 | **Palm length** | Male | 86 | 92 | 99 | 103 | 107 | 114 | 176 | 104 | 8 | 0.06 |
| | | Female | 84 | 86 | 91 | 94 | 97 | 103 | 113 | 95 | 5 | 0.06 |
| | | Combined | 84 | 89 | 96 | 101 | 106 | 114 | 176 | 103 | 8 | 0.06 |
| 181 | **Fist length** | Male | 73 | 85 | 93 | 99 | 105 | 115 | 127 | 101 | 9 | 0.06 |
| | | Female | 52 | 61 | 87 | 93 | 101 | 106 | 117 | 92 | 13 | 0.06 |
| | | Combined | 52 | 81 | 92 | 98 | 104 | 115 | 127 | 99 | 11 | 0.06 |



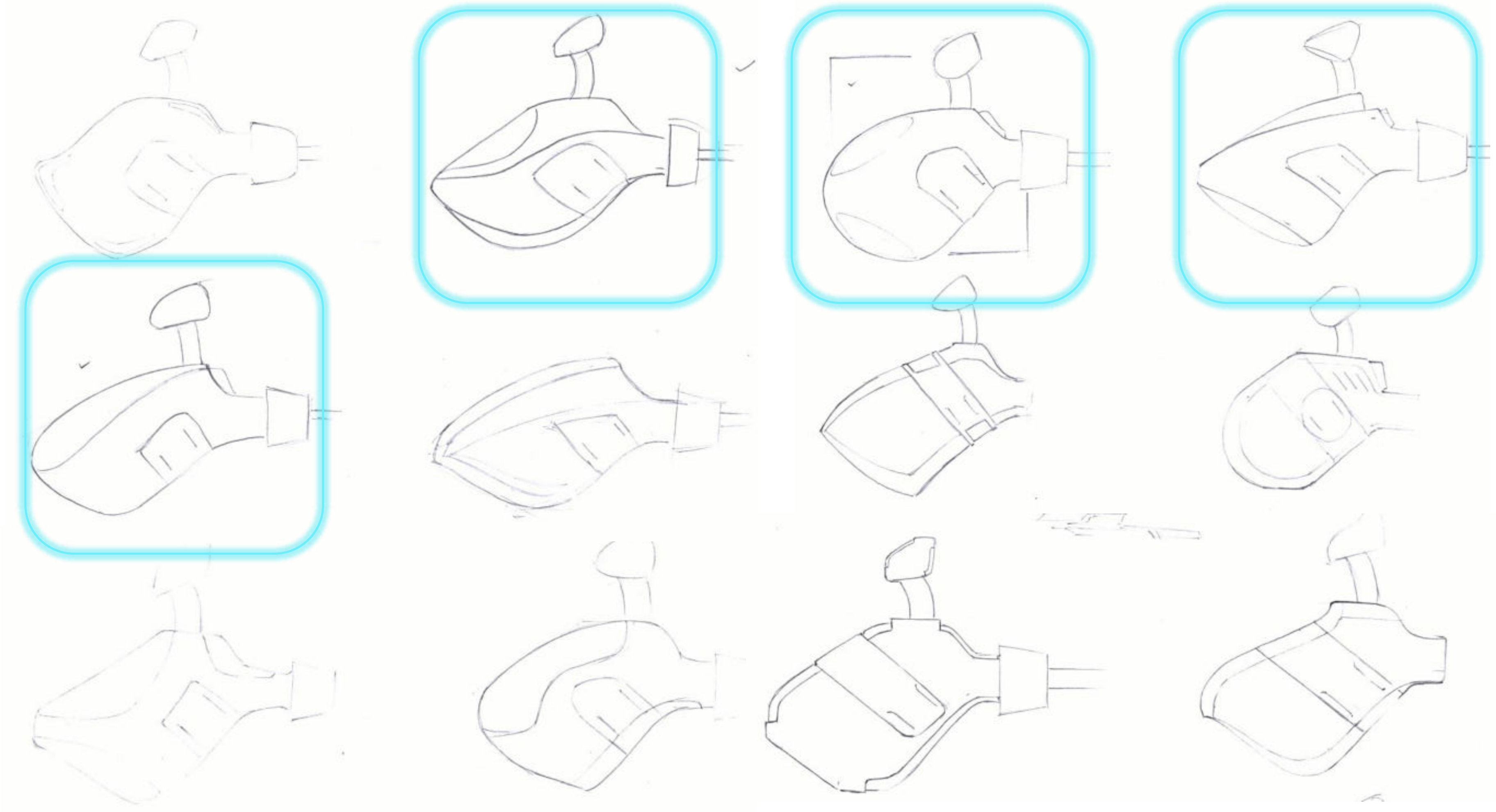

| | | |
|---|---|---|
| 180 | **Palm length** | Distance from the base of the palm to the base of the middle finger (at the palmar surface). |
| 181 | **Fist length** | Length of the hand grip in the same line of the long axis of the hand from the base of the palm to the tip of the fist, wherever found. |
| 185 | **Hand breadth, without thumb, at metacarpal** | Maximum breadth across the palm at the distal ends of the metacarpal bones (where the fingers join the palm) of the index and the little finger. |
| 186 | **Finger-tip depth** | Maximum distance between the dorsal and the palmar surfaces of the tip of the middle finger. |
| 187 | **Finger-tip breadth** | Maximum distance across the lateral surfaces of the tip of the middle finger. |
| 191 | **Grip inside diameter, maximum** | Maximum inside grip diameter, measured by sliding the hand down a graduated cone until the tips of the thumb and the middle finger remain touched to each other. |

Image source: http://iitg.vlab.co.in/?sub=72&brch=171 (as seen on 14.04.16)

Top left
fig 65: Anthropometric data was referred to generate device dimensions. The above image highlights the dimensions which will be considered during detailed design

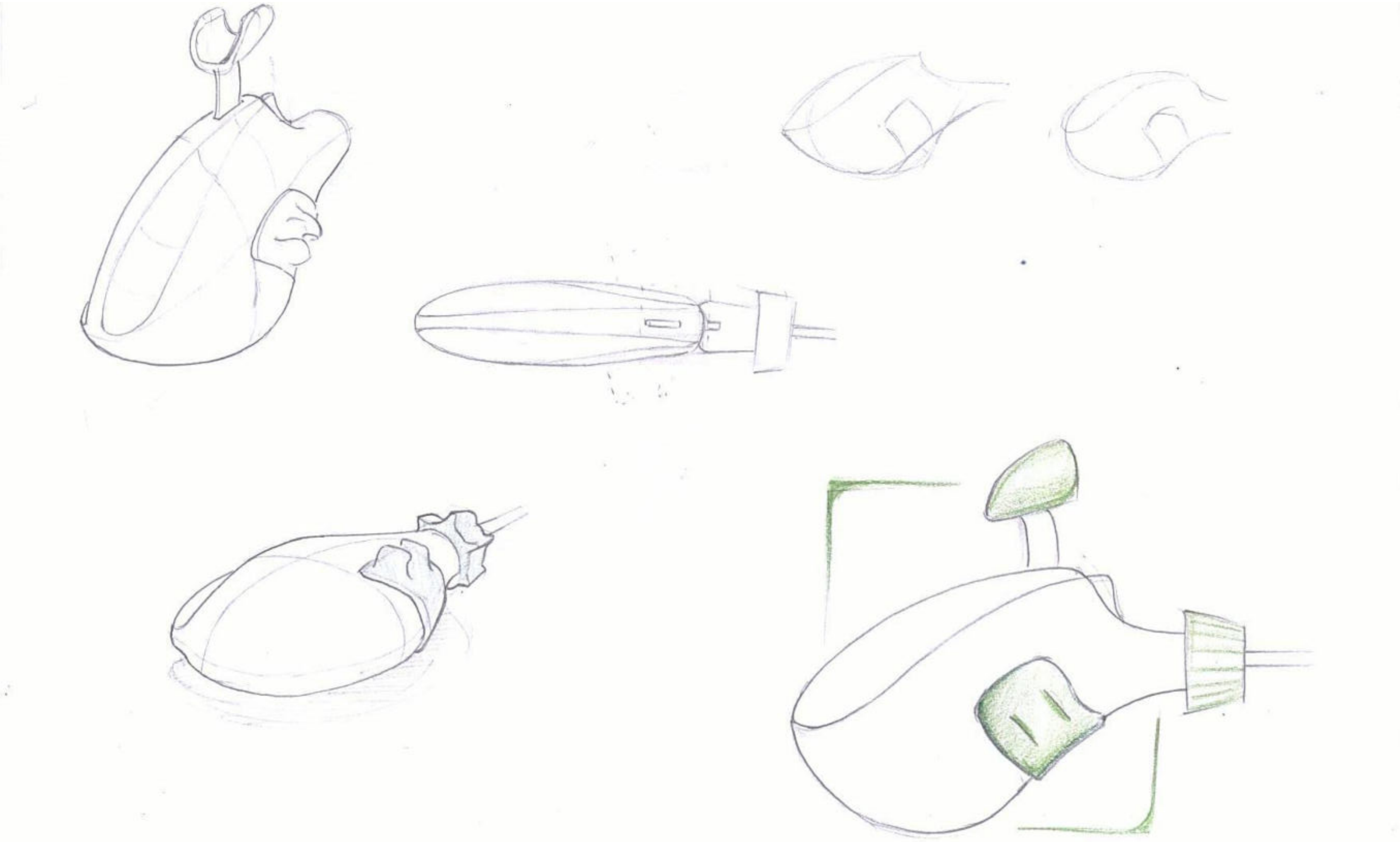



Top
fig 66: Form exploration stage 1. Since most of the forms were similar, exploration continued.

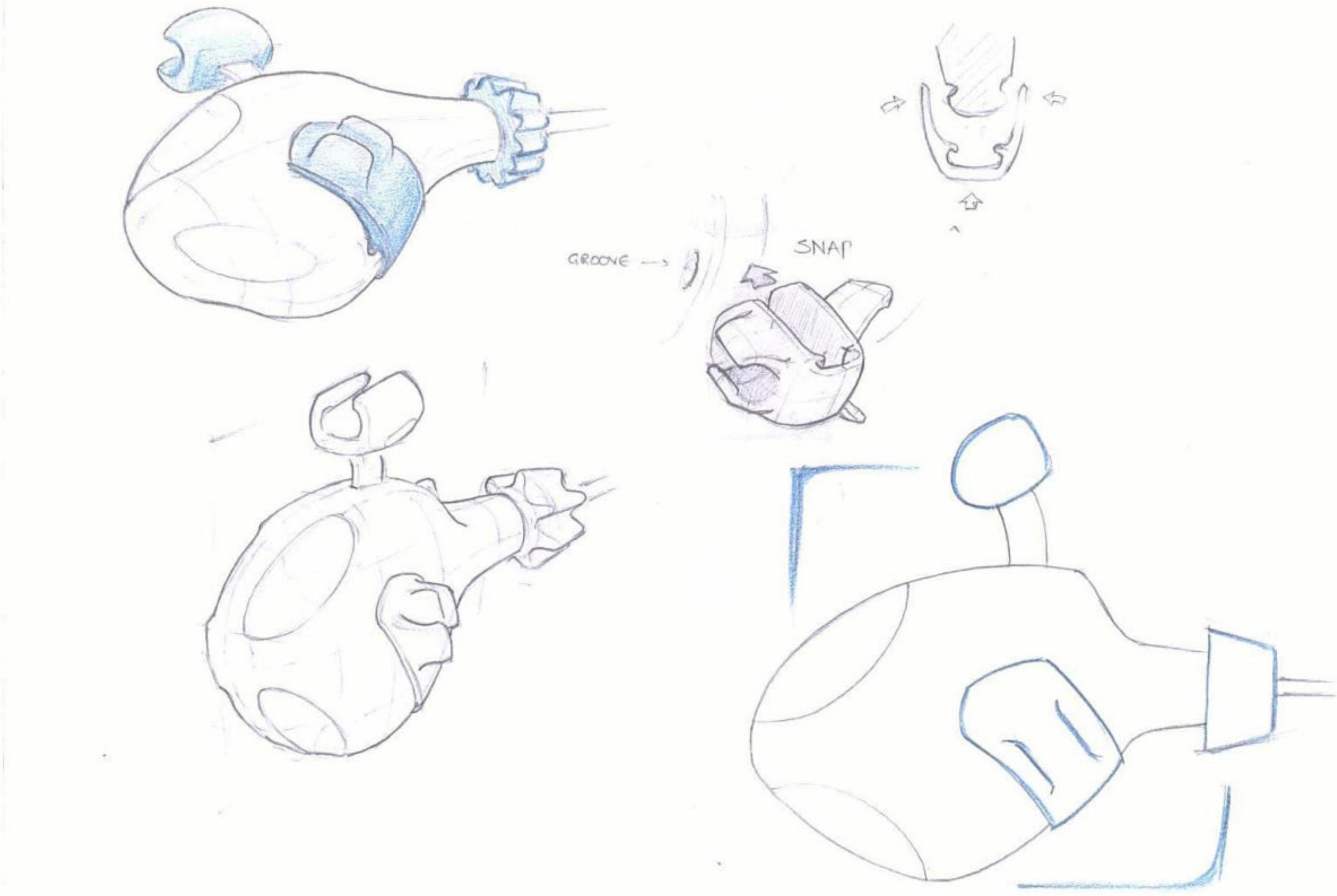


Top left

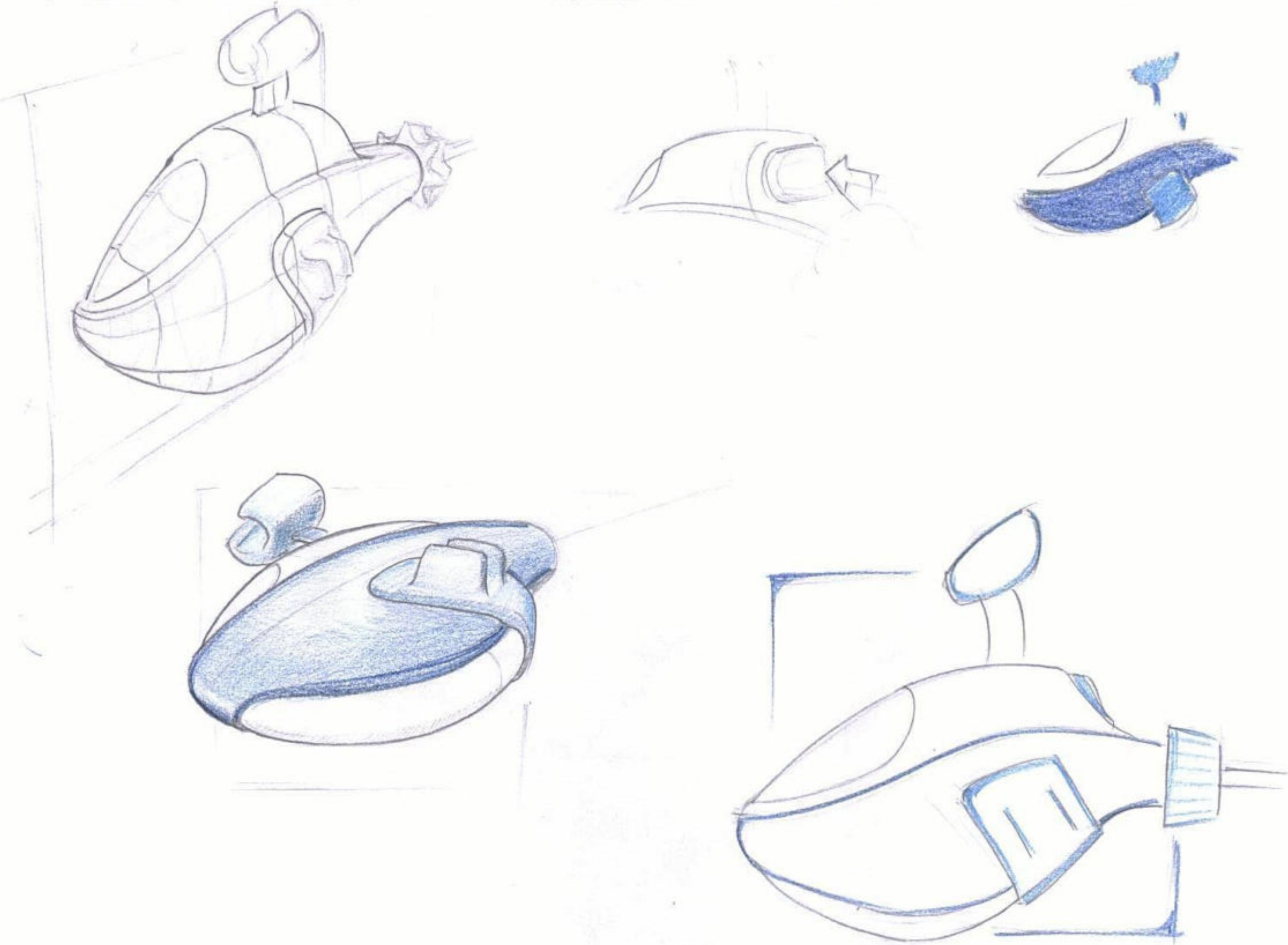
fig 67: The highlighted sketches are the final four forms selected for further detailing.



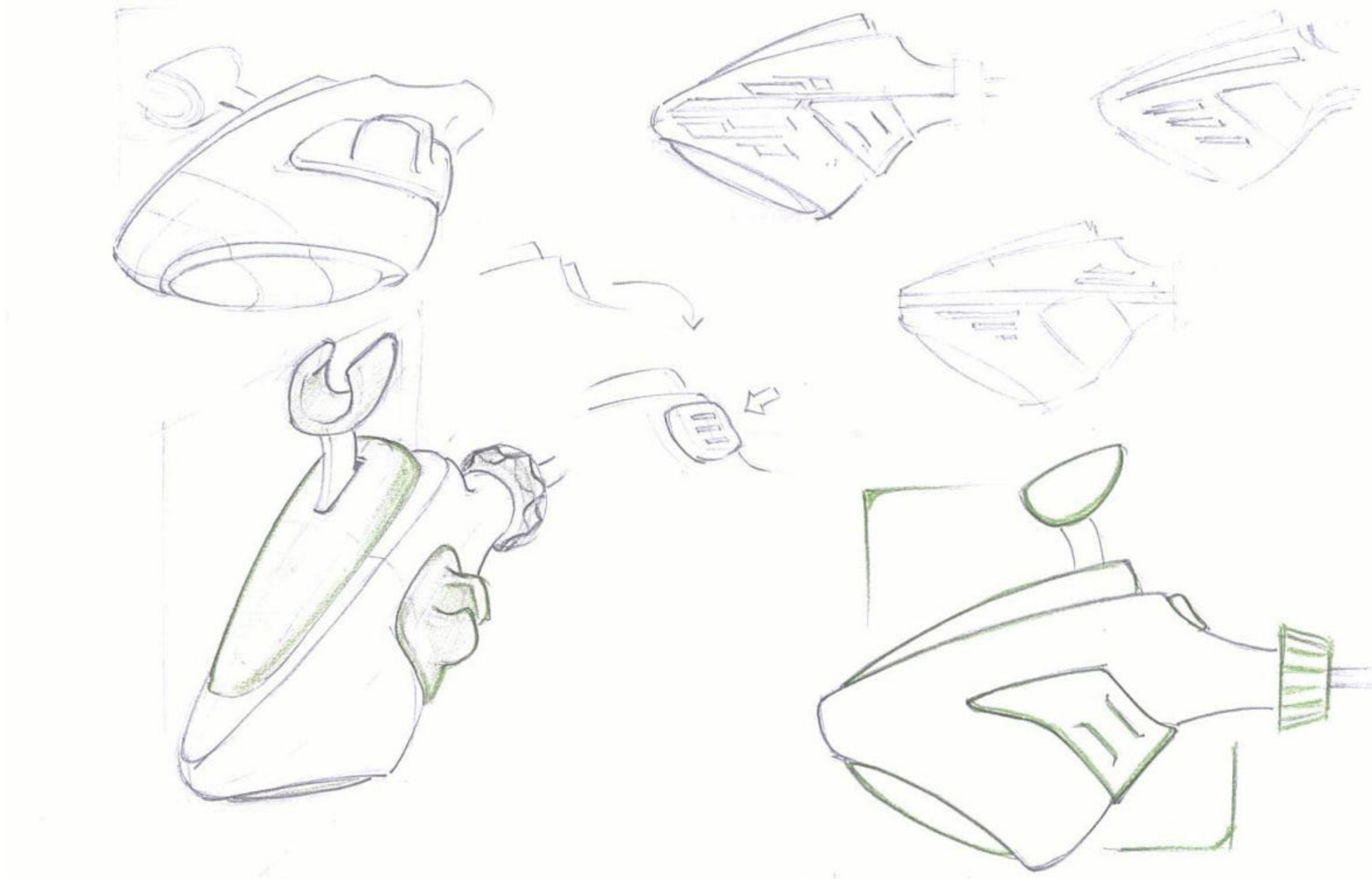
Top
fig 68: detailed sketches of selected forms




Top left
fig 69: we finally decided to use a snap on detail to fix index finger retainer on the device. The detailed was designed so that just turning it would change the device from right handed to left handed .

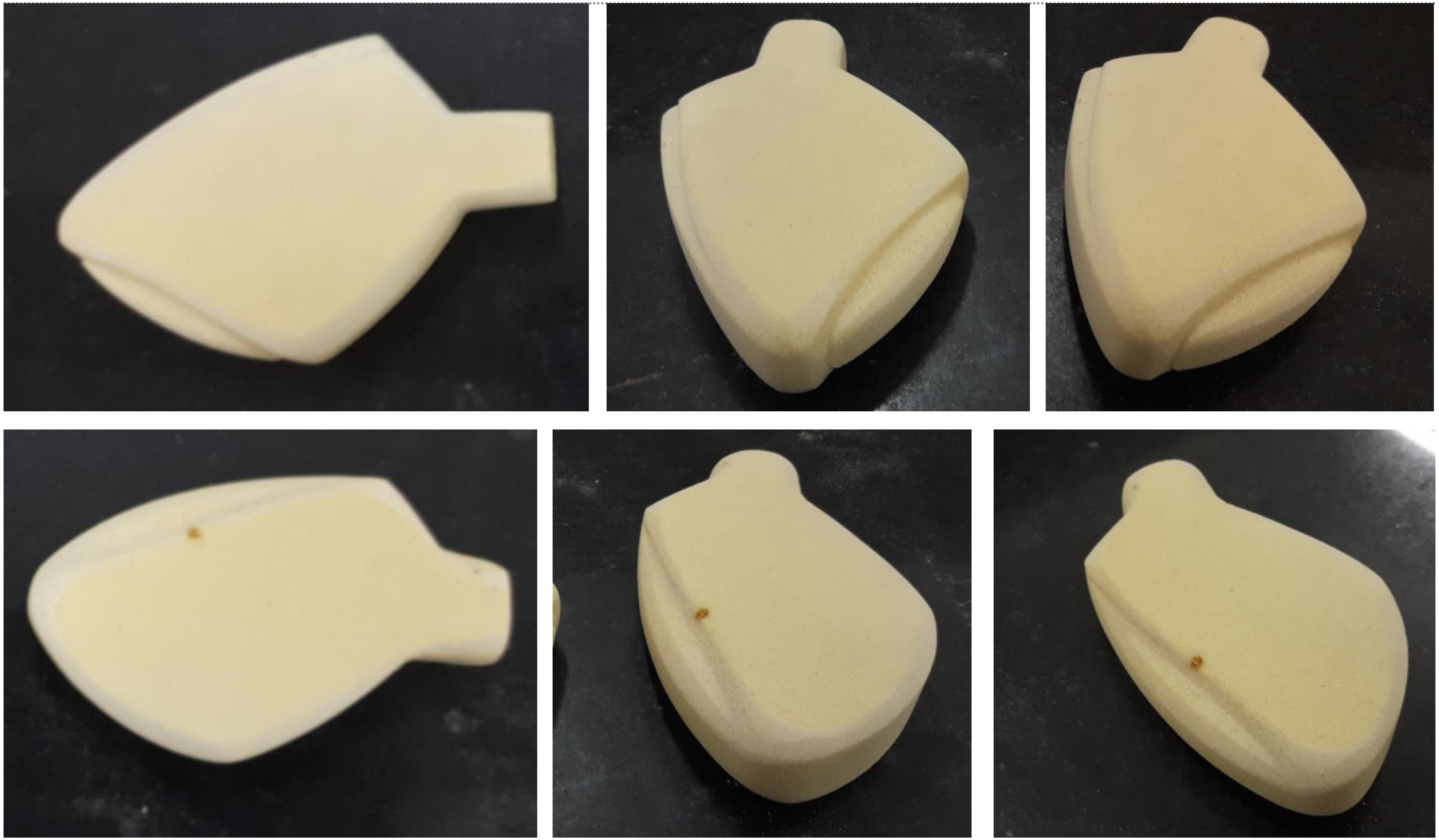


Top
fig 70: Detailed sketches of selected forms. This form was selected for quick mock up stage

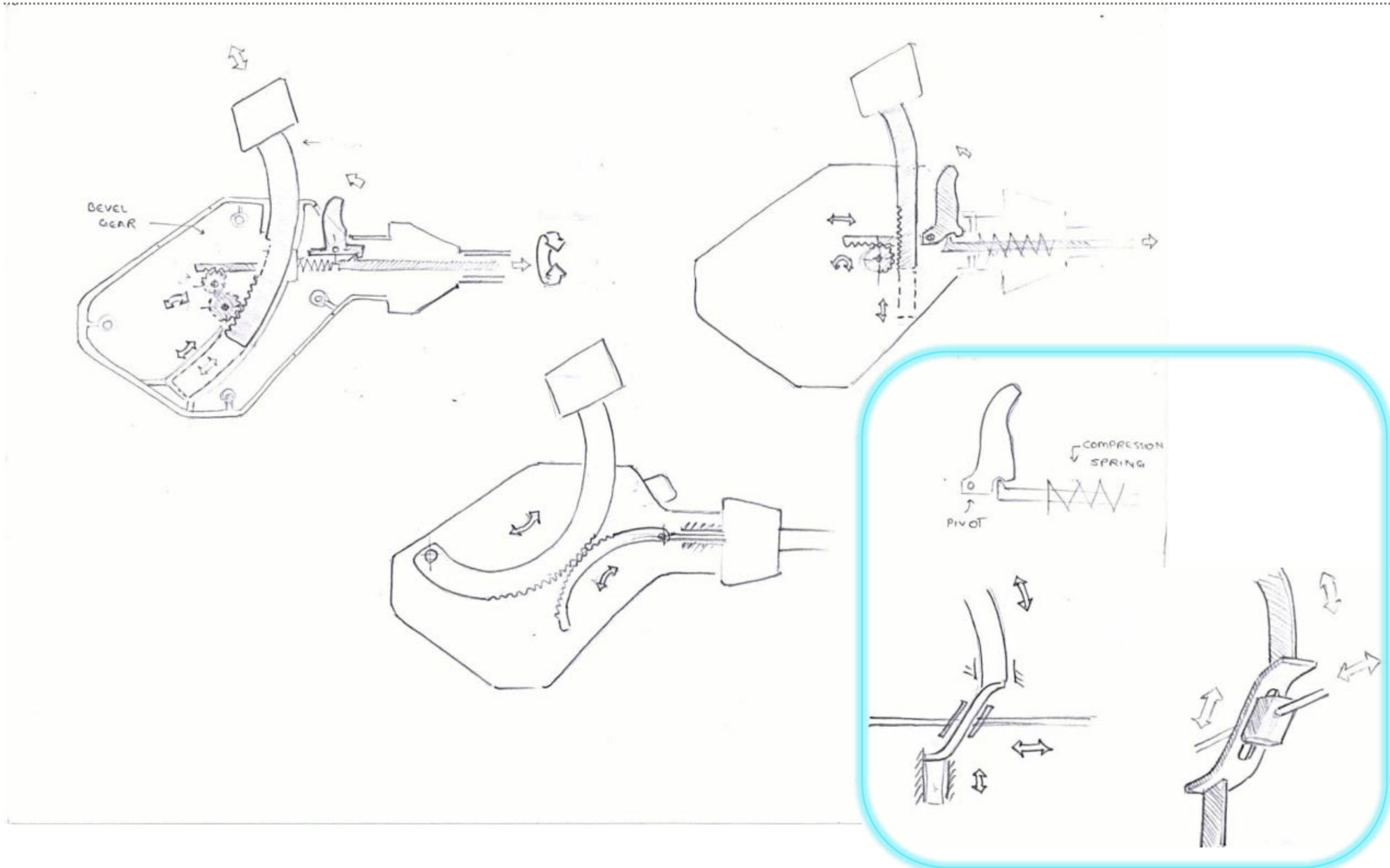


Top left

fig 71: Detailed sketches of selected forms. This form was selected for quick mock up stage



Top
fig 72: The quick mock ups of the forms selected. The form on the top side of the page was finalised.

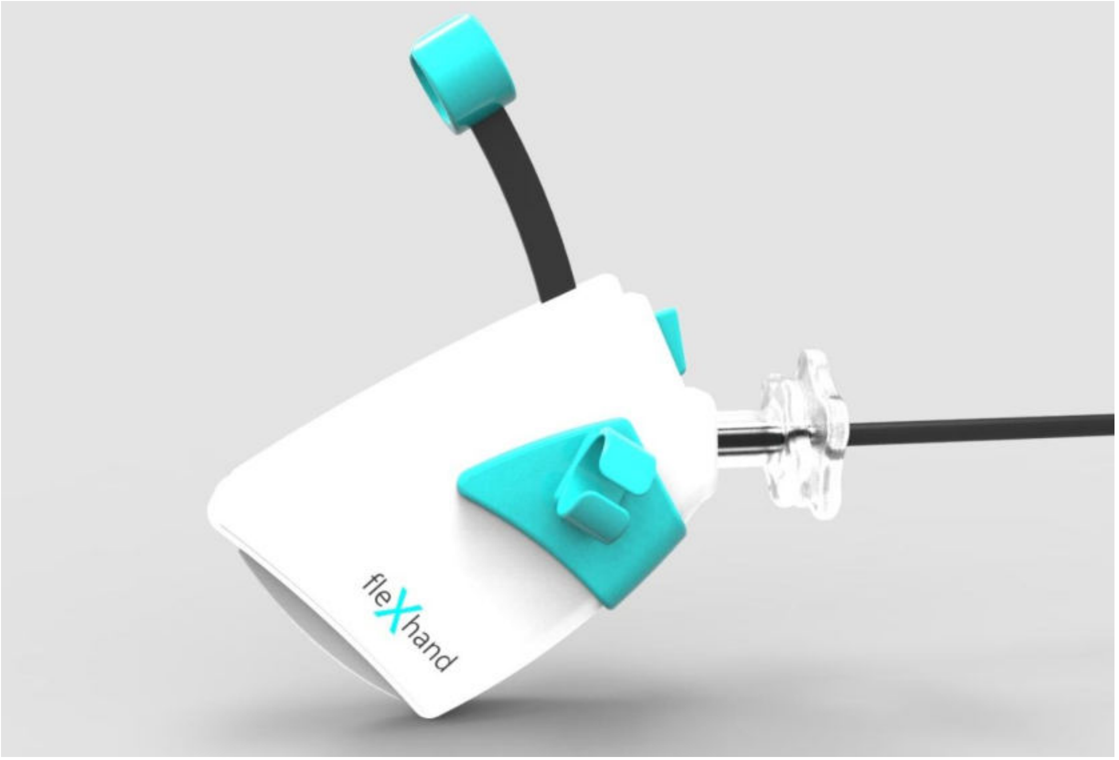



Top left

fig 73: Ideation for the mechanism to be used for jaw opening and closing, as well as trigger for jaw cutting. The highlighted mechanism was selected because of the minimal parts and ease of assembly as well as maintenance

Top
fig 74: The product name and logo were explored and finalised

# Final concept

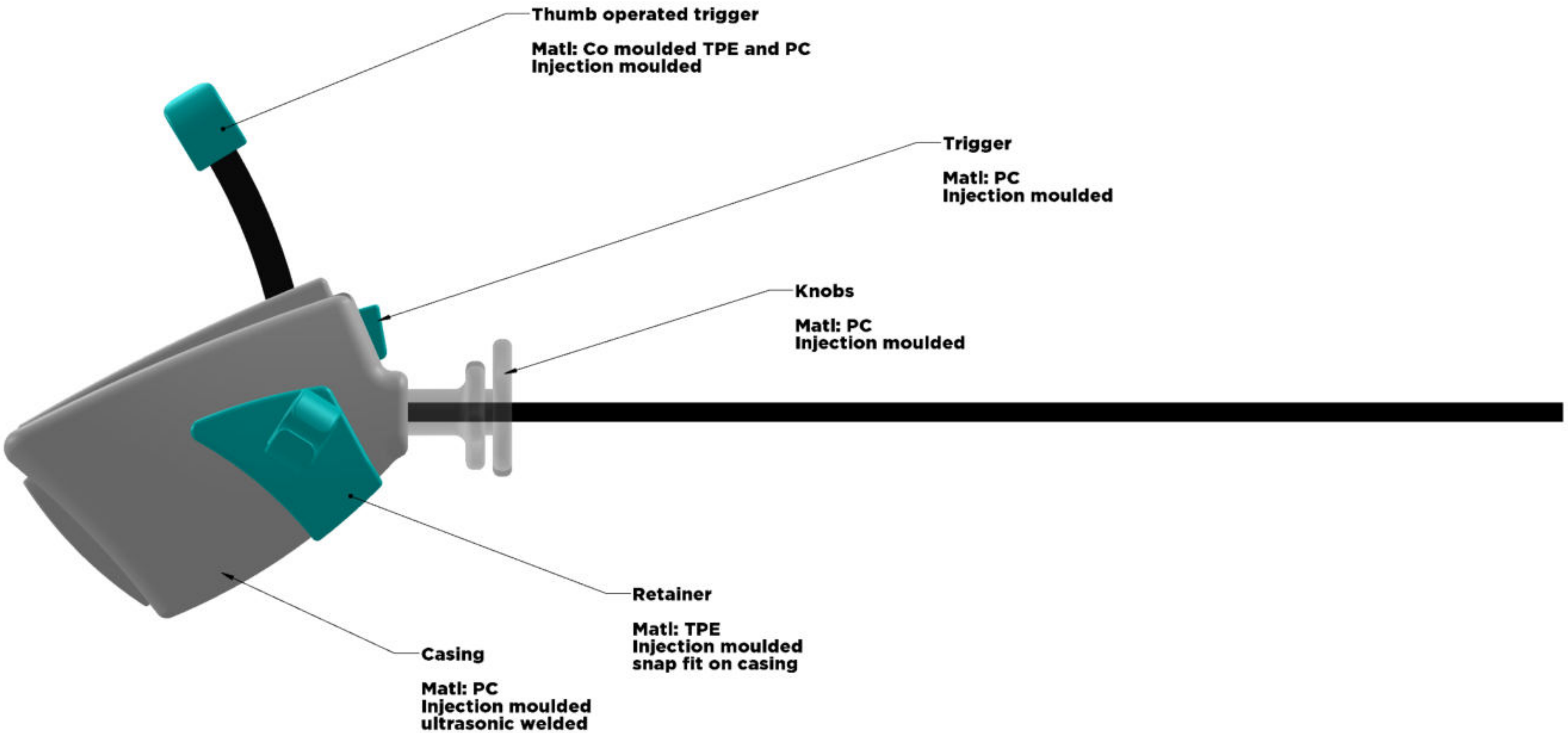



Top

fig 76: Final concept

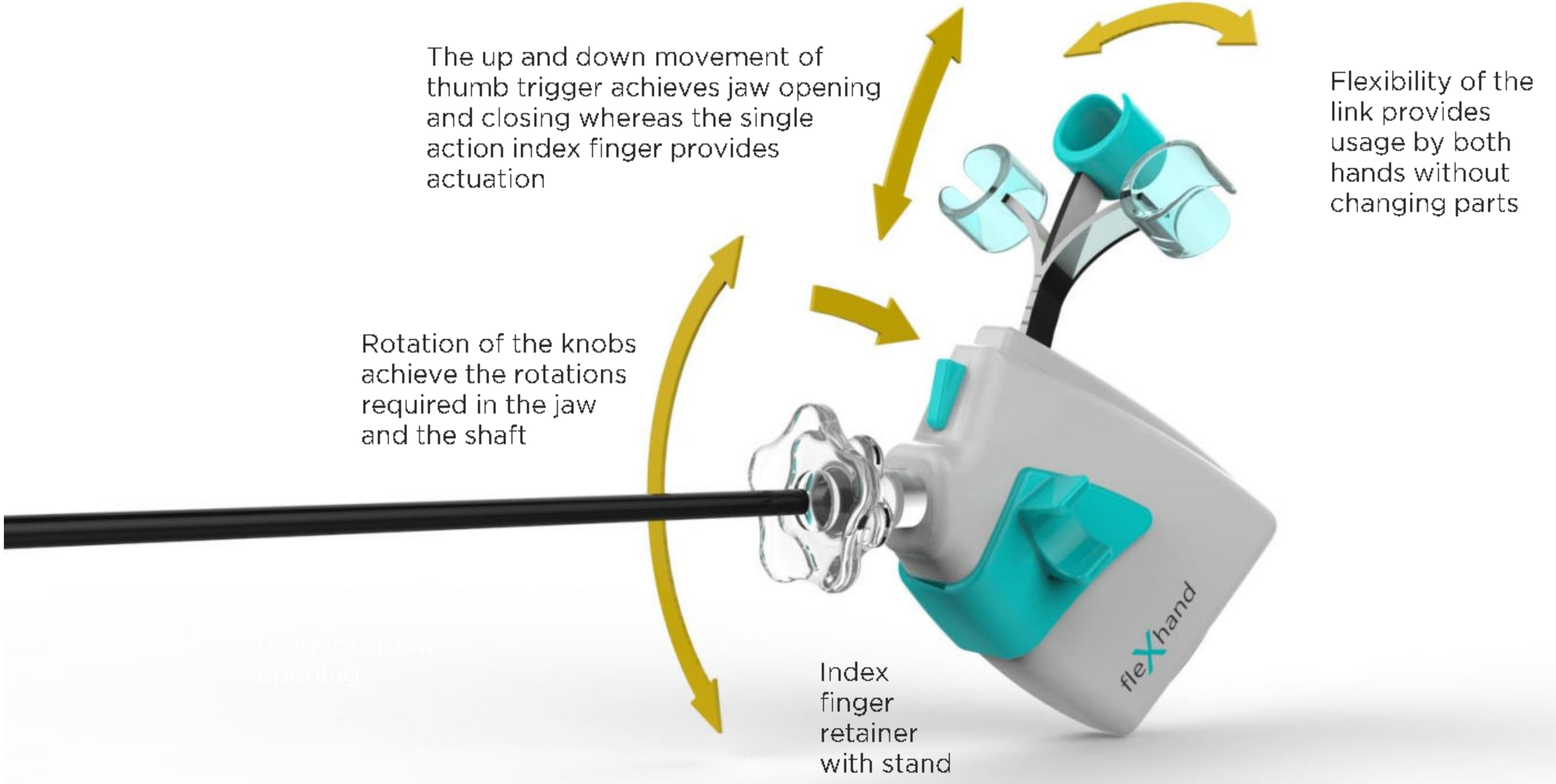
The final concept consists of following Salient features:

- Flexible thumb trigger, provides more instinctive hand movement for jaw opening and closing. The flexibility allows the trigger to be operated by both sides.
- The thumb and index finger retainer ensures that the device grips the users hand allowing the surgeon to relax his/her fingers while working and maintaining hold over the device
- The index finger retainer contains a stand which ensures that the tip does not touch anything when the device is kept on the surgical tray
- The mechanism is simplified to linkages from gear and rack mechanisms to ensure reduction of weight and ease of assembly and maintenance.



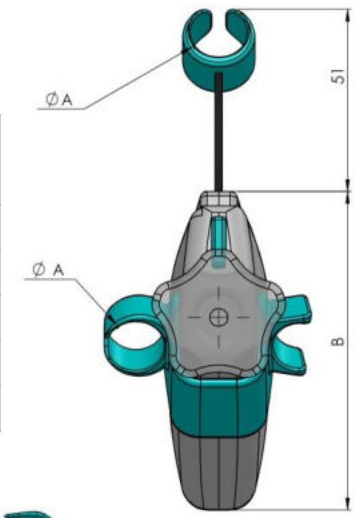

Top

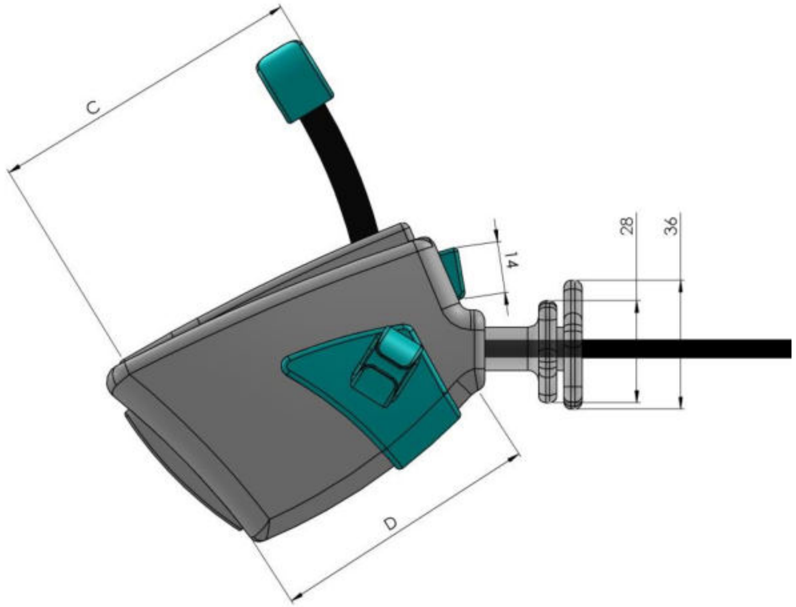
fig 77: parts with material details

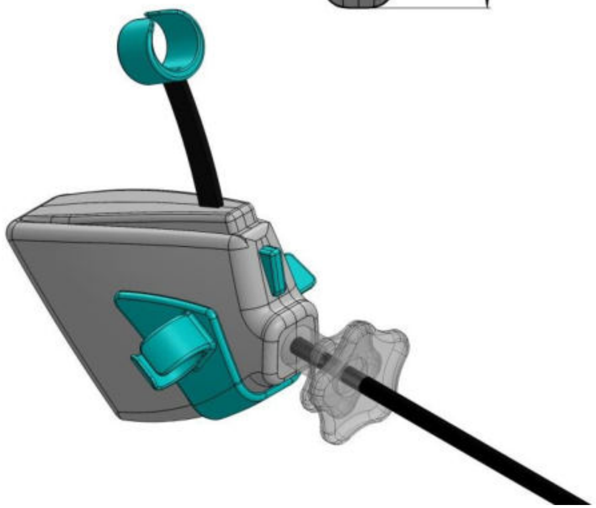


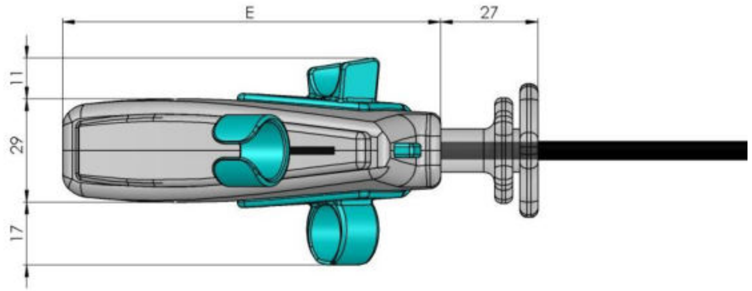

Top
fig 78: Final concept features with range of motion

| Dim. (percentile) | Small (15th) | Medium (50th) | Large (85th) |
|---|---|---|---|
| A | 12.5 | 14 | 16 |
| B | 71 | 79 | 87 |
| C | 86 | 98 | 110 |
| D | 71 | 79 | 87 |
| E | 89 | 97 | 105 |






Top
fig 79: The dimensions of the device with a table showing three sizes of device.

The outer body of the device will be made out of injection moulded HDPE, whereas the thumb and index finger retainers will be made using silicone.

The wire from ECU will be connected to the underside of the device. This ensures that the wires don't obstruct the surgeon while operation .

The stand  makes the device sit at an angle, ensuring that the tip of the device doesn't get contaminated by unnecessary contact with the tray.

The device will be sterilised using EtO (Ethylene Oxide) gas instead of autoclave to ensure minimum thermal deterioration of the materials used. The materials were selected on the basis of their chemical resistance to EtO as well as their usage in the biomedical device industry.

Top
fig 80: Final concept prototype

# Future scope

The next step of the project will be to produce working prototypes and testing them extensively. The validation for design in terms of the fatigue caused over long duration of usage.

The next phase of project should also focus on design for manufacture and working out a packaging solution for this product.

Once the handle is validated, a range of laparoscopic products can then be produced for different kinds of procedure.

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