

Design of an Ergonomic Laparoscopic Device

Industrial Design Project 3 Report



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Avowal

I asseverate, that the present work has been produced without the help of third party and only with the denoted references All parts that have been taken from sources are indicated. This work has never been presented to an examination board.

Name:

Roll Number:

Date:

Signature:

Approval

Industrial Design Project II

“To design an ergonomic laparoscopic device for surgery” - By Baisampayan Saha

M.Des, Industrial Design Batch 2013-15, is approved as a partial fulfillment of requirement of Post Graduate degree in Industrial Design.

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Abstract

In the world of medicine and surgery, Laparoscopic Surgery has been a gift to the mankind. It has replaced open body surgeries in many cases, where recuperation and healing takes time. But as condition of patients improved dramatically, by taking less time for the patients to recover from the surgeries and return back to normal day to day activities, the condition of the doctors also changed. Due to lack of properly designed tools for laparoscopic surgeries, the doctors are now facing stressful conditions while performing surgeries. Many doctors reported about numbness in their thumb and discomfort in their upper extremities after performing a laparoscopic surgery.

An attempt is made to understand the difficulties faced by the surgeons while performing such surgeries and come up with a design of an ergonomic and comfortable instrument for laparoscopic surgery.

Introduction

During general open body surgery, an incision of at least 20cm is made in the body. Patient undergoing an open surgery takes longer time to heal and resume daily activities. Thus the idea of making smaller incisions and still be able to perform a surgery emerged and got developed into the procedure called laparoscopic surgery, which is specifically done for abdominal and pelvic regions.

Laparoscopic surgery is also called as minimally invasive surgery or band-aid surgery or key hole surgery. It is a modern surgical procedure in which small incisions are made in the body far from the actual location and tubes are inserted through the incisions for doing the surgery. This type of surgery is developed in the early 18th century and is difficult to credit one individual for the invention of this method. The first known laparoscopic surgery was done on a dog. Though framework to perform laparoscopic surgeries were there for a long time, but could be materialised only after the development of a video computer chip, that would allow to zoom and project images on a television screen. The first human laparoscopic surgery was performed by French physician Mouret [1]

Laparoscopic surgery can last for hours. This can lead to high stress induced on the surgeon and his / her assistants both physically and mentally. Many surgeons have reported to face pain in their hand and upper extremities after a long

surgery. Some has reported to even feeling of numbness in their thumb or hand after the surgeries.

There are a plethora of instruments available in the market to choose from. But most of them fail to satisfy the ergonomic criteria of a perfect instrument. There are a few which the doctors have given more preference than others in respect of the ease and comfort of use. Some of these instruments are either operated by one hand or sometimes help of another hand is required to operate some functions.

In IIT Bombay, Biomedical Engineering and Technology (Incubation) Centre (BET-iC) at Orthocad Lab has developed some novel laparoscopic instruments which incorporate the functionality of few instruments into one instrument and also developed some new improved instruments.

An attempt is made to make these devices ergonomic, so that it leads to less pain and stress when used by the doctor in a long operation procedure.

Literature Review

Primary Research

The design research is in collaboration with BETiC, IIT Bombay. Dr. Hemant Bhansali who is a reputed laparoscopic surgeon at Nanavati Hospital is deeply associated with BETiC for the development of various laparoscopic device. The project of designing ergonomic & modular handle for these instruments is also been advised by him. Various inputs regarding how a laparoscopic surgery is done as well as the difficulties faced by them while operating a patient has been jotted down to have a clear idea while designing the device.

The process of laparoscopic surgery as described by Dr. Bhansali: Small incisions are made in the body which are bit far from the

actual location of the operation. Carbon-dioxide gas is then inserted in the body to inflate it. Tubes called as trocar and sharp rods called cannula is inserted in the body through these incisions. Trocar and cannula can be seen in Fig 1. Trocars has a membrane that does not let the gas out of the body through them. Specially designed surgery tools are then put inside the body through the trocars. One of the instrument is a camera with a light source that shows the inside of the body, which helps the surgeon in operation. A video device is kept at the eye level of the doctor that shows the inside of the body of the patient. The camera is held by an assistant of the doctor and is maneuvered by the instructions of the



Fig. 1: Trocar and cannula (<http://trade.indiamart.com/details.mp?offer=4609790391> : As viewed on 15.04.2015)



Fig. 2: Laparoscopic surgery (<http://urocareforyou.com/3d-vision-laparoscopy/> : As viewed on 02.02.2015)

surgeon. The surgeon then inserts other laparoscopic instruments such as gaspers, scissors or cauterisers, etc depending upon the need of the surgery. Fig 2 shows an usual laparoscopic surgery setting.

According to Dr. Bhansali, there is a lack of haptic feedback between the instruments and what is happening inside the body of the patient, if the doctor is using a scissor and is applying force to cut a tissue, it is solely on the expertise of the surgeon to know how much force has to be applied by looking at the monitor, so that he/she does not damage tissues inside the body of the patient or cause internal bleeding.

The current instruments have a maximum of six degrees of freedom and mainly two primary functions. The monitor that is used in the surgery for viewing the internal organs of the patient should be kept at the eye level of the surgeon which can be seen in Fig 2.

The operating table should be at the height of the naval of the surgeon for easy access to tools and also it is found to be the appropriate height ergonomically.

The surgical instruments are sometimes attached with wires. When wires are attached, the surgeon has to carry the excess load of the wire along with the instruments while oper-



Fig 3: Image depicts different arm-hand gestures adopted by the surgeon during laparoscopic surgery.

ating. These sometimes induces stress in the arms of the surgeon, causing numbness and pain in the hand and the upper extremities. The wires attached to the instruments can be seen in Fig 2.

The camera that is inserted in the body of the patient is controlled by an assistant of the surgeon. The surgeon directs the assistant to move the camera by looking into the TV screen where the surgeon can look inside the patient's body. Sometimes the movement of the camera and the movement of the instrument controlled by the surgeon mismatches due to lack of coordination between the doctor and the assistant. These type of incidents sometimes causes stressful environment in the operation theatre and can also cause accidental minor internal injuries inside the patient's body.

Fig. 3 at the left side has four human figures. The first three figures are standing facing the page. If we observe the figure's hand gestures, we would observe that the hand gesture in each image is slightly different in each case. These are the gestures that a surgeon has to primarily do while performing a surgery. Observe the awkward hand positions. Since the laparoscopic instruments are not designed ergonomically and also the area to the surgery is very less, the doctor has to manage in a very tight space.

In the fourth figure, we can see the doctor is slightly bent towards the patient. With the awkward hand positions and a slight bent in the torso of the body, a long duration of surgery is bound to cause pain and numbness in the fingers and upper extremities of the body.

Secondary Research

Generic Problem: Discomfort in holding the laparoscopic instrument during surgery for a long period of time. The range of motion is also restricted during the surgery due to the typical handle design of the instrument. And finally, the handle of the instrument to be modular and compatible with a variety of other instruments required during the surgery. The laparoscopic surgical instrument can be divided into three different categories: scissors, graspers and dissectors.

In one of the surveys done, it was found that about 8% - 12% of doctors out of 149 reported to suffers from pain in the neck and upper

extremities after performing laparoscopic surgeries. Efforts required by forearm and thumb muscles are significantly greater when laparoscopic surgeries were done. Some other difficulties include two-dimensional viewing of the three-dimensional surgical field which makes it difficult for the doctor as the they have to view a screen to know exactly where the instrument inside the patients body is going. As a result surgical tasks that take seconds in open surgical procedures take minutes in laparoscopic surgeries. Thus surgeons report upper body fatigues and occasional numbness in hand [2].

Laparoscopic surgery has many benefits over open surgery, less blood loss to quick patient recovery time. But it has had an effect over the surgeons too. Many surgeons were reported to have pains in their upper extremities and neck and also sudden numbness in their hands. Surgeons see the video output of a camera which is inserted into the patient body on a TV to perform the surgery. As the three-dimensional view of the surgery is converted into a two-dimensional view and seen on a screen, there lies many ergonomic problems with the technique.

One of the main problem in laparoscopic surgeries is the manipulation problem of the instruments by the surgeons. The degrees of freedom of the manipulation of the instruments by the surgeons is very less, thus creating too much of stress on the muscles of hand and upper extremities of the surgeons.

Constantly looking up in the screen and then with limited degree of freedom conducting a surgery can be a herculean task for surgeons. Patkin [5] when reviewed the human interface problems in a laparoscopic surgery, he suggested that it is high time that the design of a laparoscopic operating environment should be approached ergonomically.

Thus, there is an opportunity in designing a laparoscopic instrument which is correct,

functional and also aesthetically pleasing as a marketable product.

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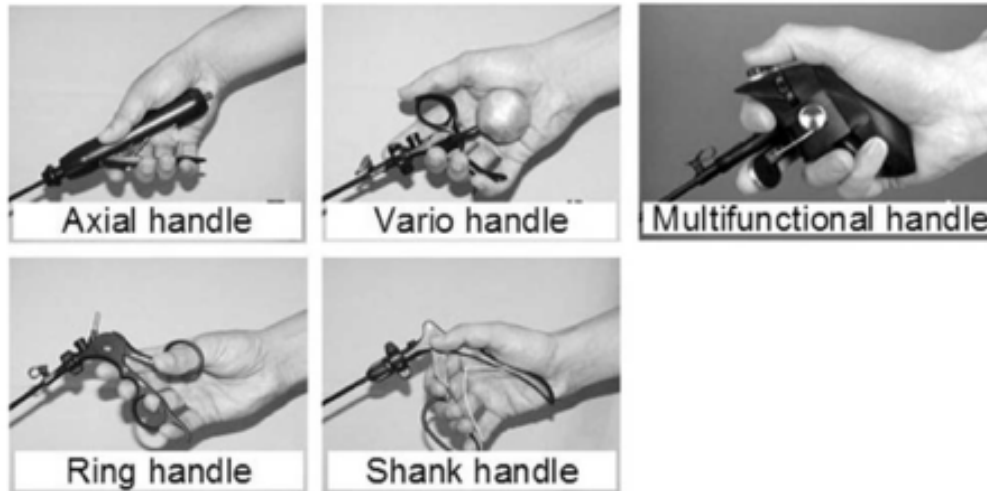


Fig 4: Different types of laparoscopic handles. [3]

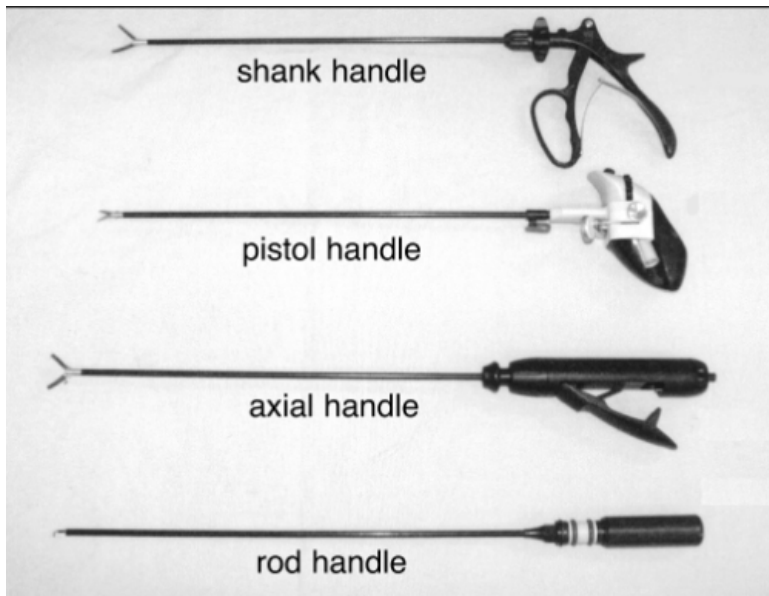


Fig 5: Different types of laparoscopic handles. (http://openi.nlm.nih.gov/detailedresult.php?img=3015407_jsls-5-1-7-g02&req=4 : As seen on 15.04.2015)

Existing Solutions:

Different types of handles are there in the market as an attachment for laparoscopic instrument. Some of the types are: [3]

- Axial type handle
- Vario type handle
- Multifunctional type handle
- Ring type handle
- Shank type handle
- Rod Type

Fig 4 and Fig 5 shows different types of laparoscopic devices described above.

The rod type device that can be seen in Fig 5 is a type of laparoscopic instrument which when held in the hand, remains straight with the hand axis. One does not have to bend the wrist to hold this device.

The axial type of device which can be seen in both Fig 4 and Fig 5 is a modification of the rod type handle. It has a lever that is actuated with the 4 fingers except the thumb, which holds the rod structure of the device.

The pistol type or the multi-functional type devices are supposed to be one of the best ergonomic devices that are there in the market. The body of the device which is held by the palm is like the gripping part of camera body. The buttons are placed on the body to manipulate the different functions of the instrument. But still, since it has different buttons and while actuating the buttons, the user could not see them, it creates a bit of confusion during surgery.

The Vario type of instrument that is seen in Fig 4 is another type of ergonomic instrument. The device has a ball that fits inside the palm cavity. The buttons and lever are kept at the front of the device, which are then actuated by different fingers as per the need of the surgeon. But this device also has some limitations. Since it is a ball that fits into the hand, sometimes it does not fit properly. As only a small portion of the surface area of the device touches the palm, it gets painful during long surgery hours.

The ring type or the scissor type device is the most common and cheap laparoscopic device that is there in the market and can be seen in Fig 4. The handles of the device are like the scissors and hence the name ring type or scissor type. One of the major drawback of this device is that it stresses out the digital nerves flowing in the fingers that are inserted into the

ring for actuating the device, thus causing fatigue and numbness in the hand very easily. This type of device is considered the worst when ergonomics is considered.

Preliminary Work: A new type of laparoscopic instrument has been developed by BETiC. The handle part has to be designed so that the same handle can be used in a variety of other surgical instruments.

Market Potential: Global laparoscopic device market will be worth US \$8.5 billion by 2018 with 7.5 million surgeries performed worldwide [4].

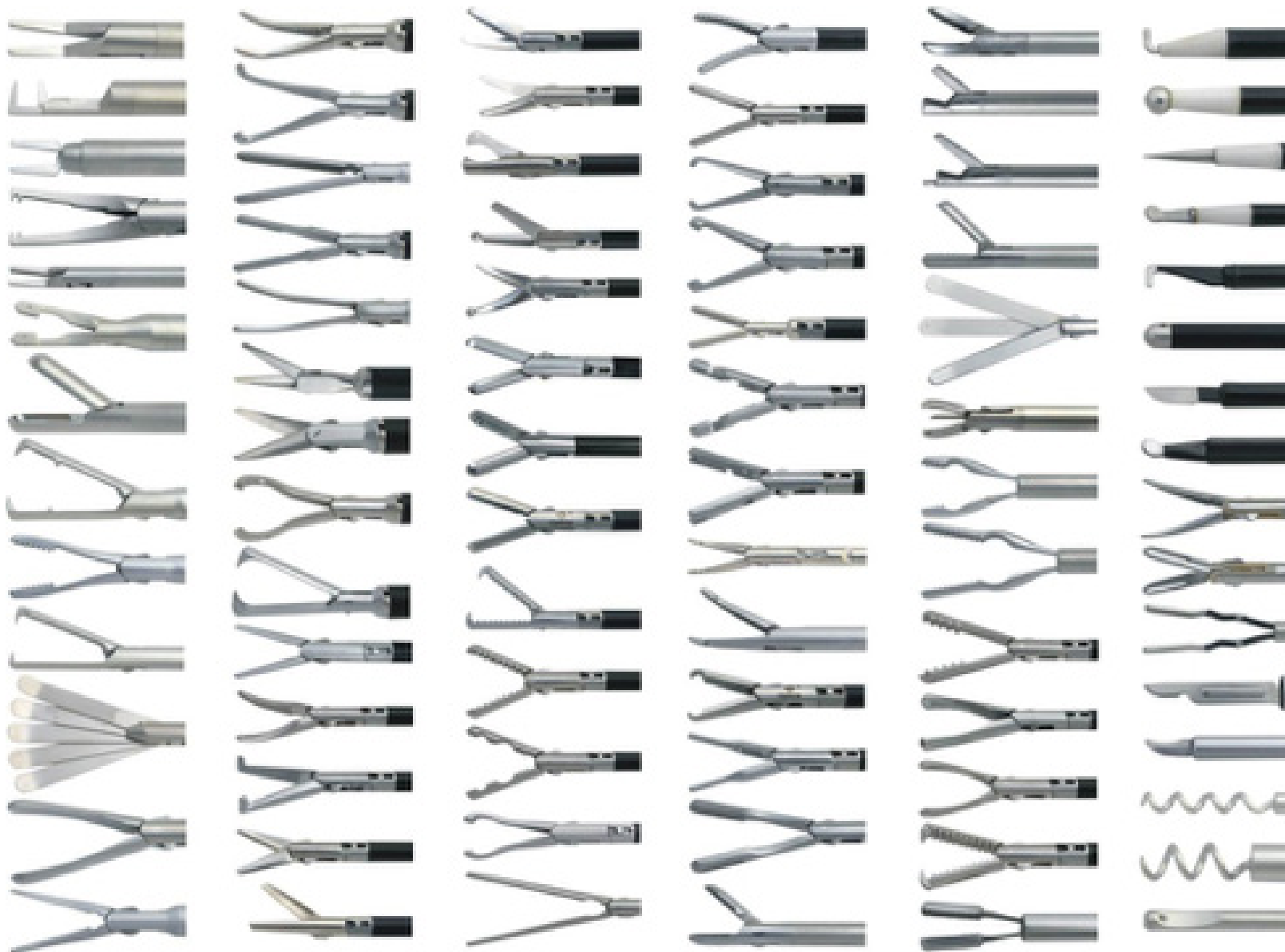


Fig. 6: Different types of instruments in laparoscopy.

<http://www.intechopen.com/source/html/18349/media/image2.jpg> : As viewed on 21.01.2015

Different types of laparoscopic instruments heads are shown in Fig. 6. Each type of head has a function of its own. Few general functions are grasping a tissue, cutting a tissue, suturing a tissue or cauterizing it.

Some of the primary movements of a laparoscopic instrument head can be seen in Fig 7.

The shaft of the instrument has a head attached to it that has various functions. The head can have jaws in order to grasp or cut tissues or can have a pointed tip for cauterising tissues. Some of the general movement of a laparoscopic head are given below:

i. Opening of the jaws or the grasper or the front part.

ii. Rotation of the grasper:

- rotation on a fixed axis
- rotation of the grasper using a ball and socket joint

iii. Upward and downward movement of the grasper.

iv. Movement of needles inside the laparoscopic instrument if any.

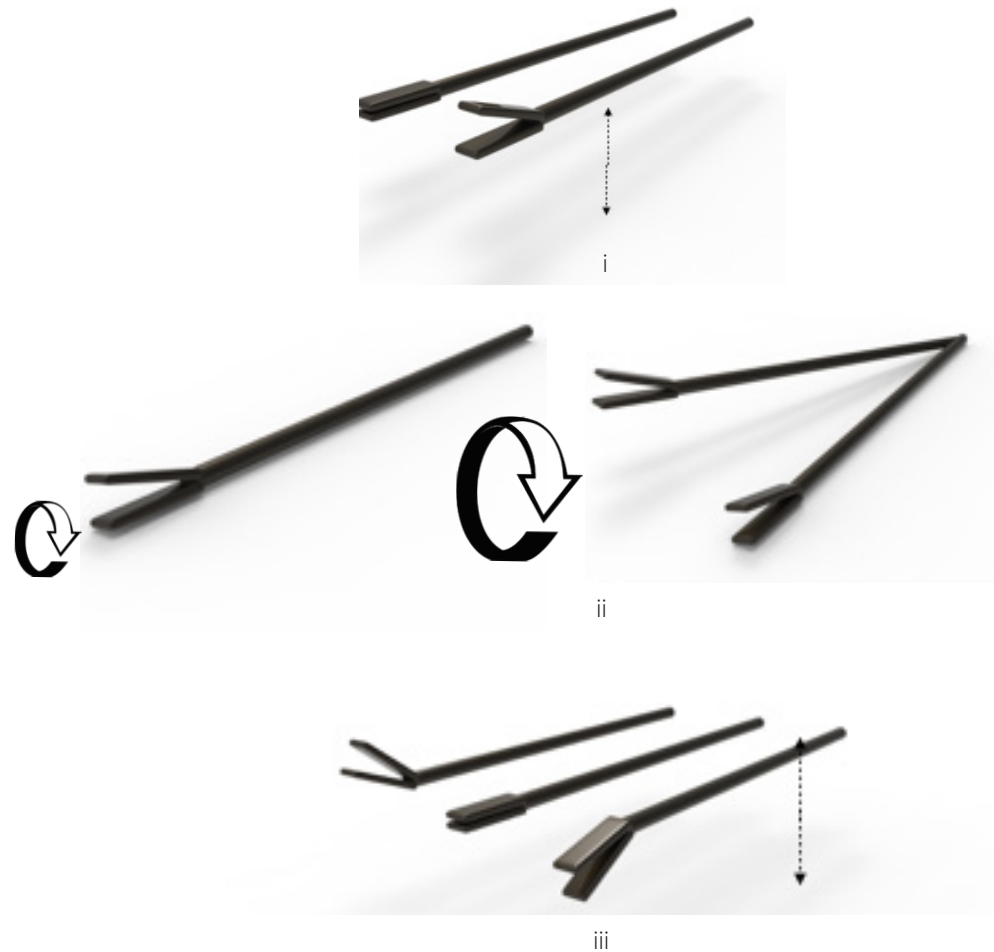


Fig. 7: Movements of laparoscopic instrument head

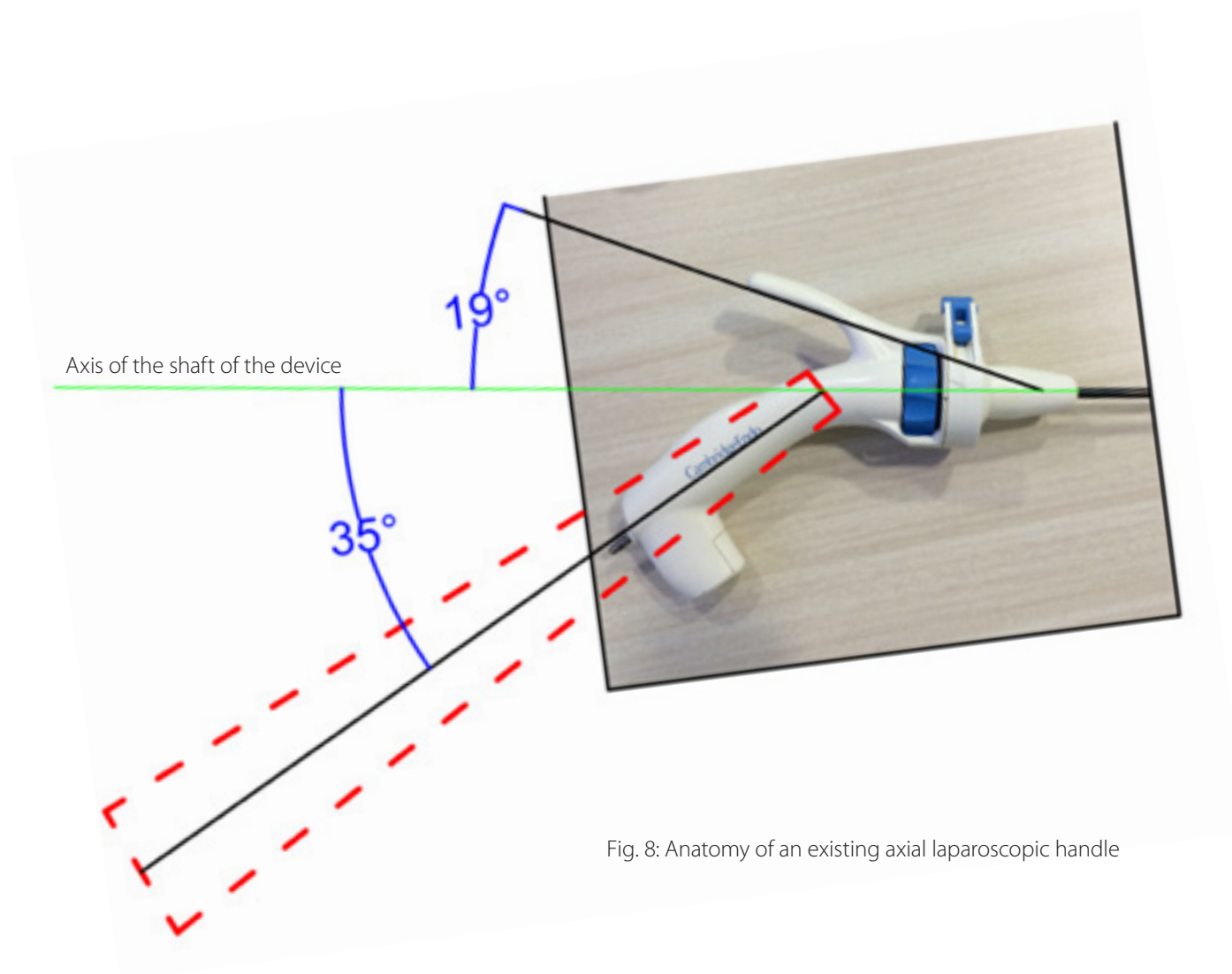


Fig. 8: Anatomy of an existing axial laparoscopic handle

Ergonomic Principles

Principles for designing multi-functional hand controls: [6]

1. The Operator should not have to observe the controls to operate it.
2. The hand should remain in contact with the primary controls through out critical operations of the system.
3. Auxillary controls should be able to be activated without loss of physical contact with the primary controls

Principles of hand tools and device design: [6]

1. Maintain a straight wrist. Bent handles ($19^{\circ} \pm 5^{\circ}$) for all tools. Ulnar deviation was found to be 2.6 times greater when the straight handle hammer was used. Fig 8 shows the different angles in an existing axial laparoscopic handle.
2. Avoid tissue compression stress.
3. Avoid repetitive finger action.

So, from the above ergonomic study, we come to the conclusion that for a better product, the above ergonomic consideration must be there.

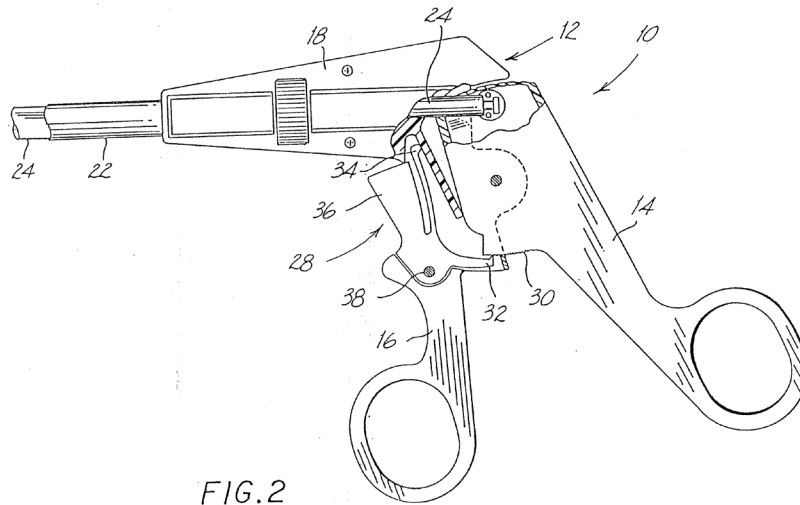


FIG. 2

Fig. 9: Handle design by David T. Green, Ernest Aranyi, Ian J. Tovey

<http://www.google.com/patents/EP0584723B1?cl=en>
As seen on 15.01.2015

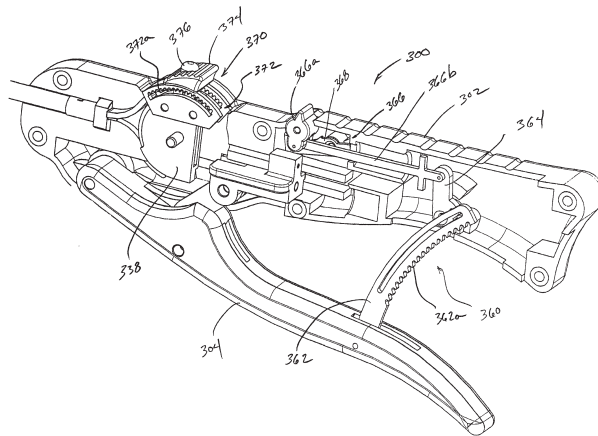


Fig. 10: Handle design by Eric J. Taylor, Peter Hathaway, Kevin Sniffin

<http://www.google.co.in/patents/US8795325>
As seen on 15.01.2015

Relevant Patents

It is therefore necessary, to look into the market or do a patent search, wheather such kind of products are already available or not.

Fig 9 shows the drawing of a laparoscopic handle that was patented by David T. Green, Ernest Aranyl, Ian J. Tovey. Various patents were filed for this design, mainly for the improvement in the jaw mechanism and the mechanism inside the body of the handle.

Fig 10. shows a handle design by Eric J. Taylor, Peter Hathaway, Kevin Sniffin. This is patent for an axial type handle. Various patents were filed for this device design. From locking mechanism to the shape of the device has been filed as a patent.

In the facing page, we can see various patents that are relevant to the design of a laparoscopic device. I referred to these patents so as to find out if any work has been done to make the device more ergonomically viable, but could not find a patent that talks about design of a laparoscopic device that is comfortable in the hands of a surgeon.

No.	Patent No.	Name	Source
1	EP 0584723 B1	Handle for endoscopic surgical instruments and jaw structure	http://www.google.com/patents/EP0584723B1?cl=en
2	US 5476479 A	Handle for endoscopic surgical instruments and jaw	www.google.co.in/patents/US5476479
3	US 8795325 B2	Handle assembly for articulated endoscopic	www.google.co.in/patents/US8795325
4	CA 2075333 C	Handle for endoscopic surgical instruments and jaw	www.google.co.in/patents/
5	EP 0543107 B1	Endoscopic surgical instruments and jaw structure	www.google.co.in/patents/EP0543107B1?cl=en
6	US 20120109186 A1	Articulating laparoscopic surgical instruments	www.google.co.in/patents/
7	US 5483952 A	Handle for surgical instruments	www.google.co.in/patents/US5483952
8	US 1470914 A	Universal handle for surgical instruments	www.google.co.in/patents/US1470914

9	US 5830231 A	Handle and actuating mechanism for surgical	www.google.co.in/patents/US5830231
10	US 5472439 A	Endoscopic surgical instrument with rotatable inner	www.google.co.in/patents/US5472439
11	US 5350391 A	Laparoscopic instruments	www.google.co.in/patents/US5350391
12	US 2790437 A	Surgical instrument	www.google.co.in/patents/US2790437
13	US 5368605 A	Laparoscopic surgical instrument	www.google.co.in/patents/US5368605
14	US 8551077 B2	Handle for a surgical instrument and surgical	www.google.co.in/patents/US8551077
15	US 8080004 B2	Laparoscopic surgical instrument	www.google.co.in/patents/
16	US 8696649 B2	Laparoscopic surgical instrument having rotatable handles with a coupler feature	www.google.co.in/patents/US8696649
17	EP 2677947 A1	Ergonomic and versatile handles for tools including surgical instruments	www.google.co.in/patents/EP2677947A1?cl=en
18	US 5366476 A	Handle for laparoscopic instrument	www.google.co.in/patents/US5366476
19	US 20140025047 A1	Surgical instruments with improved dexterity for use in minimally invasive surgical procedures	www.google.co.in/patents/US20140025047
20	US D343453 S	Handle for laparoscopic surgical instrument	www.google.co.in/patents/
21	US 8585734 B2	Ergonomic handle and articulating laparoscopic tool	www.google.co.in/patents/US8585734
22	US 20140051936 A1	Ergonomic and Versatile Handles for Tools Including Surgical Instruments	www.google.co.in/patents/US20140051936
23	US 5860995 A	Laparoscopic endoscopic surgical instrument	www.google.co.in/patents/US5860995
24	EP 2471473 A1	Apparatus for laparoscopic surgery	www.google.co.in/patents/EP2471473A1?cl=en
25	US 5782749 A	Laparoscopic surgical instrument with adjustable grip	www.google.co.in/patents/US5782749

Feasibility Assessment

Preliminary Work

The physician involved is Dr. Hemant Bhansali (MS;FCPS;FICS;FACG(US); PhD (Lap.Surgery), who is a leading laparoscopic surgeon in the country. He has been awarded a Ph. D in Laparoscopic Surgery in the Faculty of Medicine by Maharashtra University of Health Sciences (MUHS) which is a FIRST in India. Currently, he is the Programme Director for Laparoscopic Surgery at Maharashtra University of Health Science, Nashik. He is also affiliated as a laparoscopic surgeon with various hospitals (at Mumbai) like: Nanavati, Kohinoor, BSES, Karuna. He is also a Sr. Faculty at Ethicon Institute of Surgical Education at Ethicon, Johnson and Johnson.

Innovation Potential

There is certainly a need to innovate an ergonomic laparoscopic instrument. The device needs to be designed to follow the principles of ergonomics so that fatigue and stress caused to the surgeons during surgeries gets reduced. The handle should be designed in such a way that it is modular and can be attached with a variety of other surgical instruments.

The human & machine interface of the laparoscopic surgery instrument can also be taken up as a design challenge.

Design Brief

Statement

"To design an ergonomic laparoscopic device for surgery".

Objectives and Scope

- Study the existing designs in detail
- Identify the functional requirements
- Develop innovative concepts towards the solution
- Fabricate prototype for physician feedback on surgical and functional suitability
- Optimise the design based on the feedback

Primary Need

For any given laparoscopic surgery, surgery needs about 10-15 basic sets of laparoscopic devices which are autoclaved and kept ready for surgery.

Different functions should be indicated by suitable color coding.

Device should be so designed to make a very natural extension of a surgeon's hand, allowing to do little stretching of fingers without keeping the device down during long surgery hours.

Secondary Need

Design should be of global standard to make it competitive and not to present a typical "jugad" image of Indian Products.

Ideations

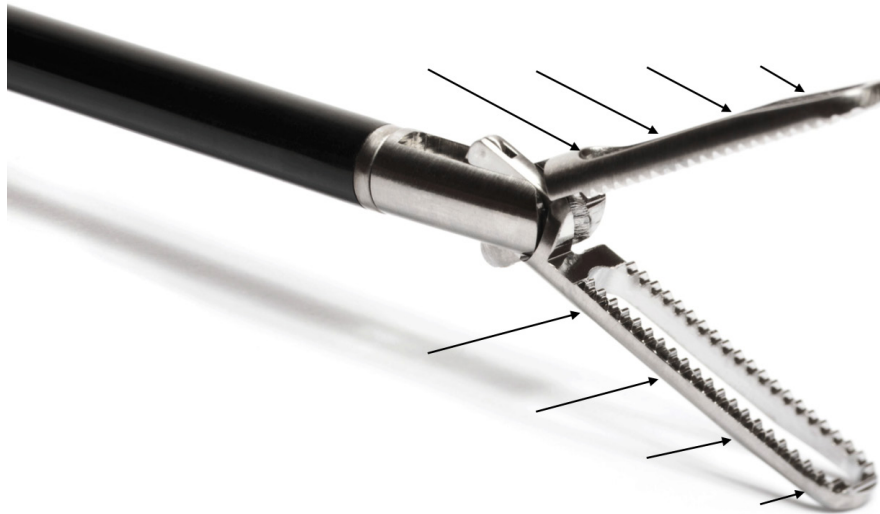


Fig. 11: Force distribution in a grasper.

Referring to the ergonomic principles of designing hand tools from [6] and from Fig 8, we see that the most ergonomic laparoscopic tool referred by Dr. Bhansali was also violating the ergonomic principles. So a thought was given for a solution which was a paradigm shift in the way we generally laparoscopic devices are perceived. Why not make it a movable and adjustable console from which the operation can be done? It should not be complex as already available automated laparoscopic devices such as da vinci surgery module.

The first point for ideation was taken as the basic grasping mechanism itself. Dr. Bhansali during the interview told that, the force exerted by a grasper is not equally transmitted to a tissue. The tip of the grasper exerts less force than the end of it. Fig 11 shows exactly the same thing. Some ideation were done which explored different mechanism for the grasper that would exert force equally.

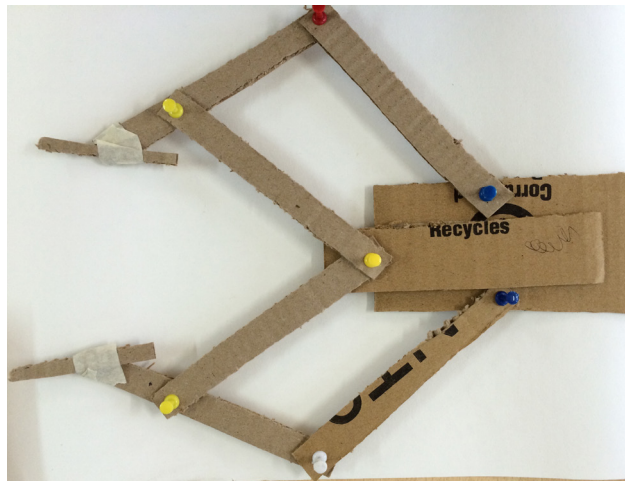
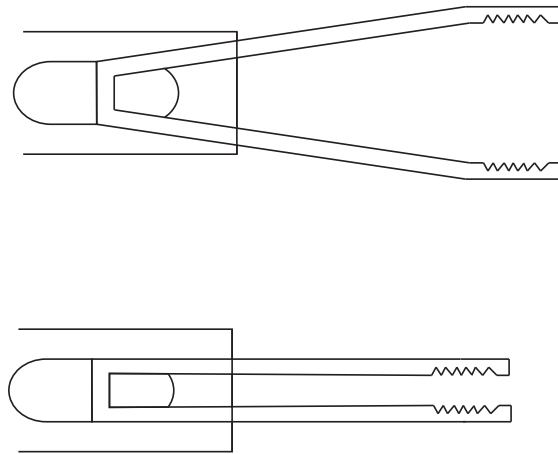


Fig. 12.1 & Fig12.2 : Different grasping mechanisms

Fig. 12.1 and Fig 12.2 Shows exploration of mechanisms for grasper. Fig 8.1 shows a mechanism where a tong type of a grasper head is used. The tong can be made of spring steel. The normal state of the tong is in a V shape. But when the tong is forced to come inside a tube, it closes its jaws. Since the jaws move parallel to each other, the force exerted would be uniformly distributed.

In Fig. 12.2, exploration with four bar mechanism are done. Various configurations are tried to check which allows parallel movement of the jaws for equal distribution of force. All the configurations were tried on paper mock-ups to better understand the complexity of the structure. And finally the configuration shown in the Fig 8.2 was giving almost parallel movement of the grasper jaw.

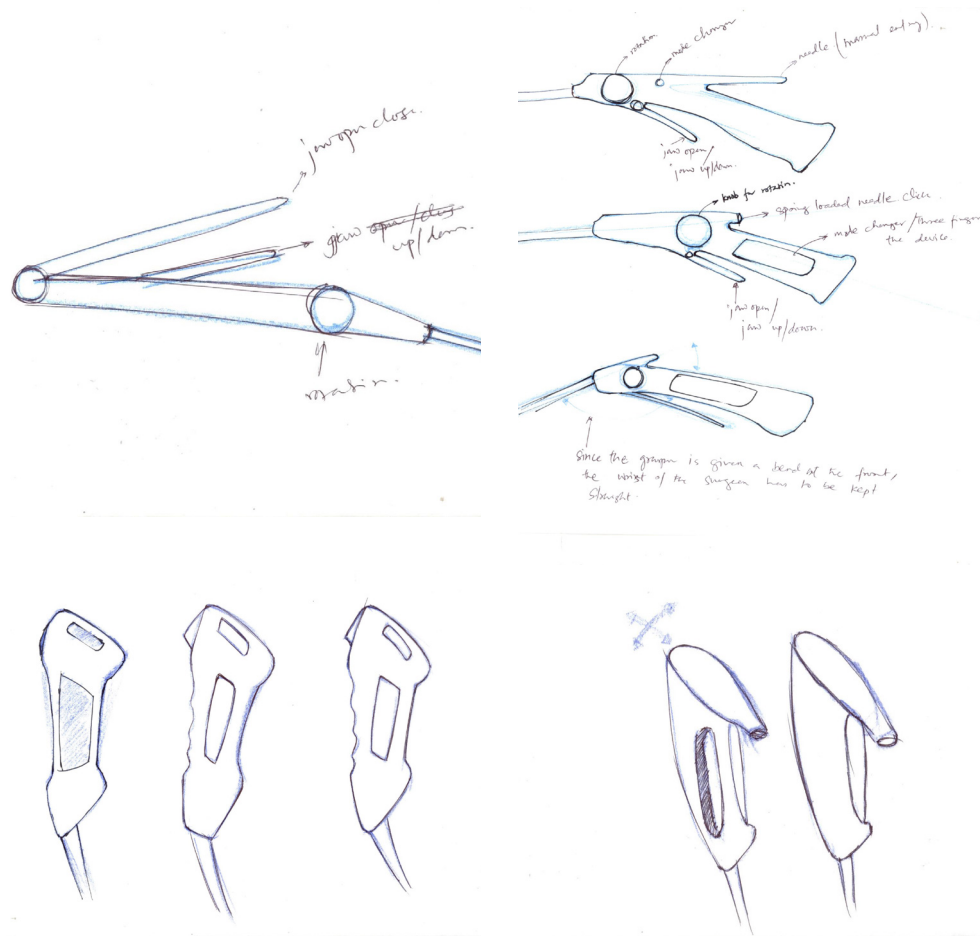


Fig. 13: Different variations of handle design

Mapping Fingers

The ergonomic principles of hand tool design says that there should not be repetitive finger action and repetitive tissue compression stress has to be eliminated. To better understand these principles, some mock up of handles were made, so that we can have a feel of the handle and how it would feel in the hand. Before starting the handles, some basic ideation were done, so as to know what shape of handle has to be made.

Fig. 13 Shows different ideations for handle design. Top two are derived taking analogy from staplers and the bottom two are derived taking analogy of joy-stick and an existing axial type laparoscopic device.



After the ideation were done on paper, mock-ups of them were made and slight variations of them were done depending upon the feel when hold in the hand. Fig 14 shows 2 mock ups. The top two mock-up was based on an existing axial laparoscopic device. A separate cylindrical piece was added to it at the side. This cylindrical piece was given as a rotating knob. The green marks shows positions of buttons on the handle.

The bottom two pictures shows two sides of the same mock-up. Analogy from joystick is taken and made into this mock-up. Green color are marked in places where fingers can go easily while holding the mock-up in hand.

Fig. 14 : Different mock-ups of handle design

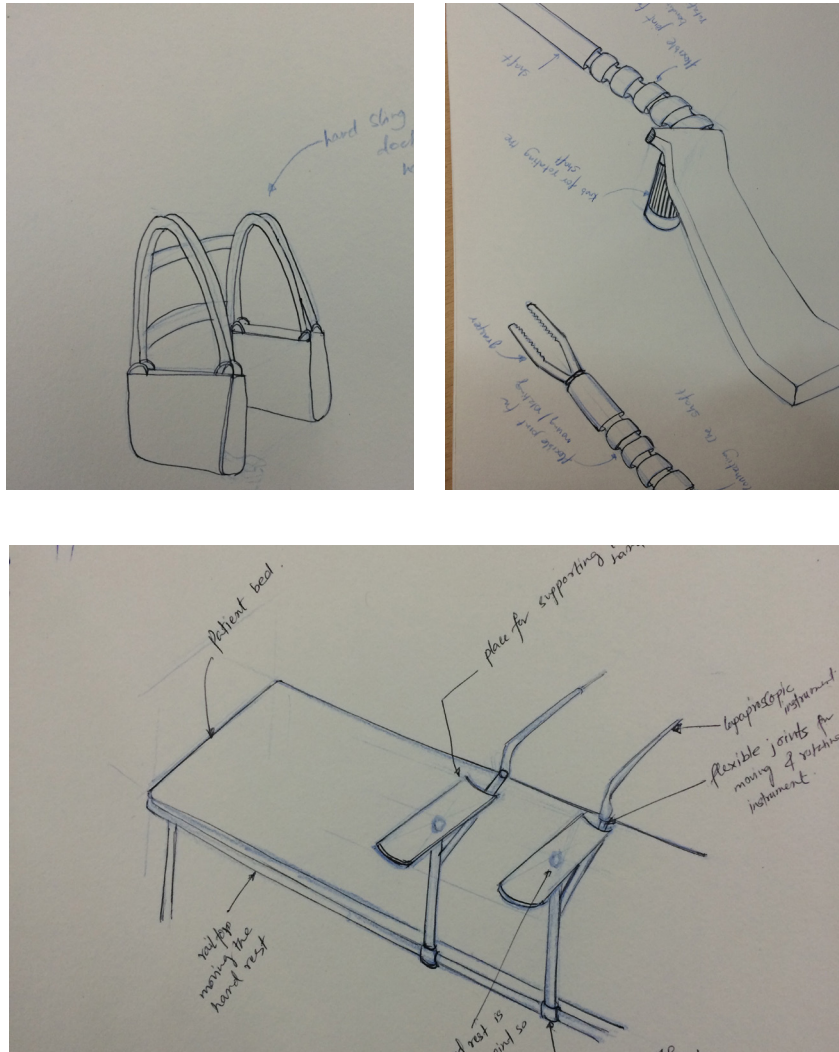
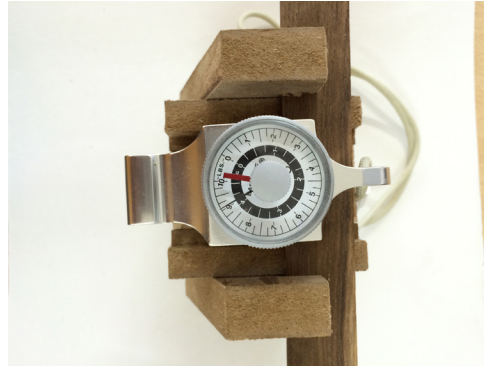


Fig 15 shows another set of ideations. These ideations are mainly done to keeping in mind that the resultant outcome would be a console based device for the laparoscopic surgery. The first image in Fig 15 is a sling that would be worn by the surgeon so that it would support the surgeon's hand against the shoulders, reducing some stress on the hand while doing surgery. The next image at the top right hand side shows a flexible shaft in the laparoscopic device for easy maneuverability. The image at the bottom is an ideation where the laparoscopic device is fixed to the operation theatre bed and can be moved by sliding on the rails on which it is fixed. There are two arm supports which allows the surgeon to keep his / her hands and perform the operation without actually being carrying the weight of the laparoscopic device all the time during the operation.

Fig. 15.1, 15.2 & 15.3 : Another set of ideation for the device



Ergonomics Study

A jig was made so that maximum force generated by each finger that would be mapped on to the device for some function can be calculated. As per theory, the resistance generated by each button or knob or dial has to be less than 30% of the maximum force generated by a finger. A pinch gauge is used to measure the force.

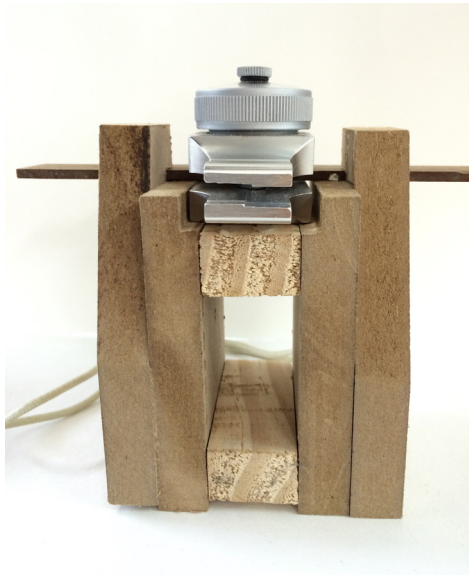


Fig. 16 shows the pinch gauge attached with the jig. A set of people has to be tested before coming to a conclusion about how much resistance has to be kept for each button when the laparoscopic console would be assembled.

Fig. 16 : Jig for measuring

2nd Phase of Ideation

Till now, the ideations that were done were based on the feed back provided by BETiC team and Dr. Bhansali on the problems faced in laparoscopic operations and videos seen from various websites about how the laparoscopic operations were done. Till this phase, the idea was to mechanise the instruments used in the surgery and make it a console controlled or operated device.

But the whole thought process changed when Dr. Bhansali allowed us to see a live laparoscopic surgery. So, we visited 2 different hospitals to see and observe how the surgeon and the assistants move around during the surgery and also around the surgery table. When the

insights gained from the surgery were compared with the ideations that had been done so far, we understood that all the ideations that we have done till now won't work in the current Indian scenario. The intermediate stage between manual and totally robotic surgery with Da Vinci robot was too much ambitious and hence it was decided to develop a manual device with better comfort.

We understood, we have to keep the laparoscopic instruments hand held only but the design has to be changed in such a way that it is ergonomic and does not stress out the hand and the upper body of the surgeon during the operation.

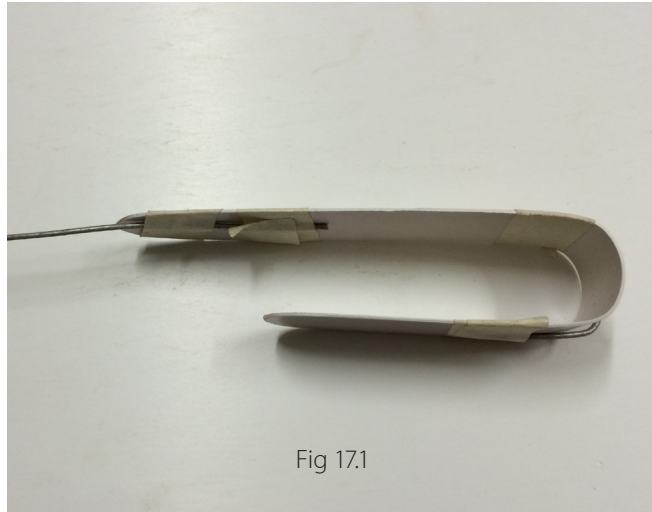


Fig 17.1

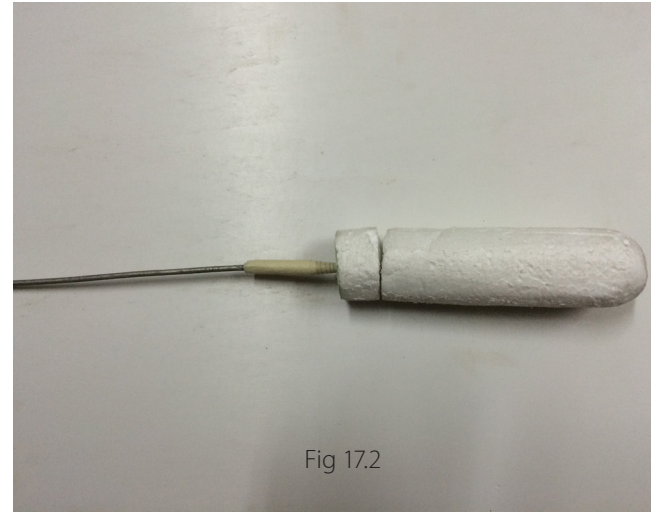


Fig 17.2

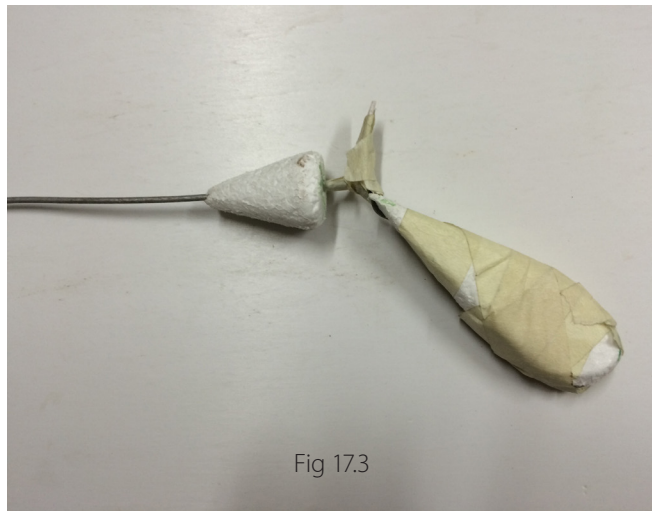


Fig 17.3

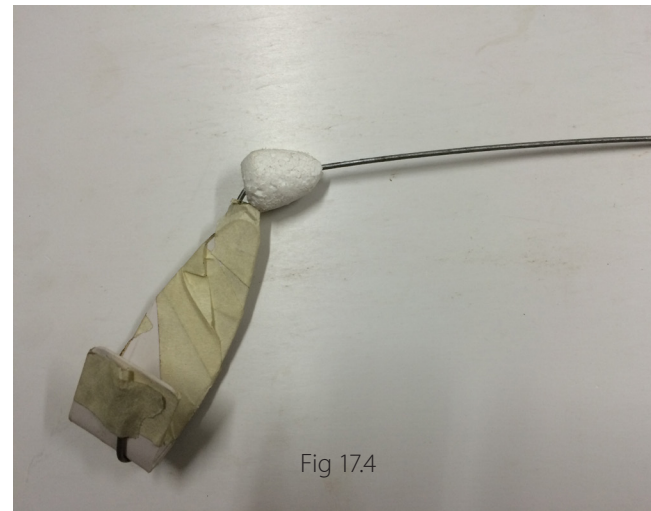


Fig 17.4

Fig. 17.1, 17.2, 17.3, 17.4 : Ideations of different types of handles

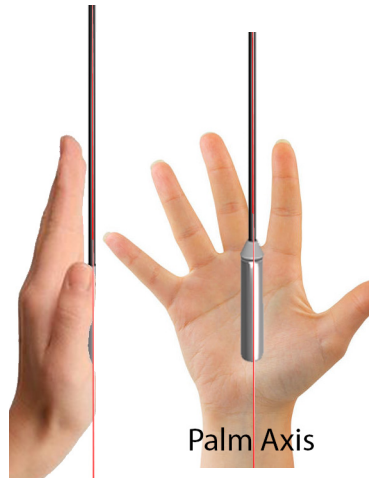


Fig. 18.1: A red line showing the centre axis of the hand and the instrument when put together

As seen on 12.04.15 : https://www.healthtap.com/user_questions/594441, <https://gracemagazine.wordpress.com/2009/06/25/portion-control/>

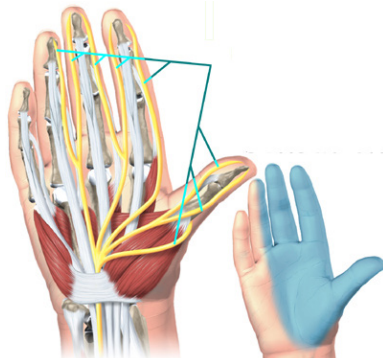


Fig. 18.2: Digital nerves in yellow

As seen on 12.04.15 : <http://nerve-paintoday.blogspot.in/2011/02/proper-palmar-digital-nerve-pain.html>

After observing two surgeries, we decided that we would concentrate on the handle part of the laparoscopic device. Though there are various problems in the current laparoscopic surgery system, we felt that one of the most important thing was the design of the handle of the instrument, poor quality of material use, poor machining and details like lock on gripper. Since most of the surgeons reported to have pain in the palm and the upper extremities while performing long duration surgeries, and also the digital nerves (Fig 18.2) in their fingers get stressed out and they start feeling pain, we decided to work on the shape and ergonomics of the handle. The mechanism of the device is also considered in the design process.

Based on the observation, a new set of ideas were done and some quick and dirty mock-ups were made so as to get a feel of how the handle would fit in the hand. Parts for rotation which are usually there in the actual instruments are also put in the mock-ups to see how the fingers would be used to operate the rotation knobs. Fig 17.1, 17.2, 17.3, 17.4 shows some mock-ups of handles.

The main consideration that was kept while designing the handles was that the axis of the hand and the axis of palm and the axis of the instrument should remain in one line while the surgeon holds the instrument, which is

shown in the Fig 18.1. This arrangement would allow less bending and rotation of the palm during surgery thus reducing stress induced on the muscles in the palm resulting in less pain. Fig 17.1 shows a type of handle which is held straight in the palm, with the thumb supporting the lower part of the instrument and also pressing it for controlling the instrument. Fig 17.2 is held in the palm in the same manner but has a rotation knob at the front which is operated by the index finger. Fig 17.3 is like a pistol grip handle. The shaft of the instrument and the handle has been given a certain angle due to which when the surgeon holds the instrument, the axis of the shaft and the palm get in line with each other. The handle in Fig 17.4 is almost the same but has a separate grip coming out from the side of the handle to hold the palm, so that when the surgeons hand gets fatigued due to stress, the surgeon does not have to put down the instrument, the instrument will cling on to the palm, thus allowing the surgeon to stretch out the fingers for sometime before resuming the surgery again. Fig 17.3 and Fig 17.4 both has a rotating knob at the front of the handle to rotate the shaft of the instrument with the index finger.

After showing the mock-ups to peers and friends and having them hold the mock-ups and telling which ones are comfortable, Fig 17.2 and Fig 17.4 came out to be the best ones

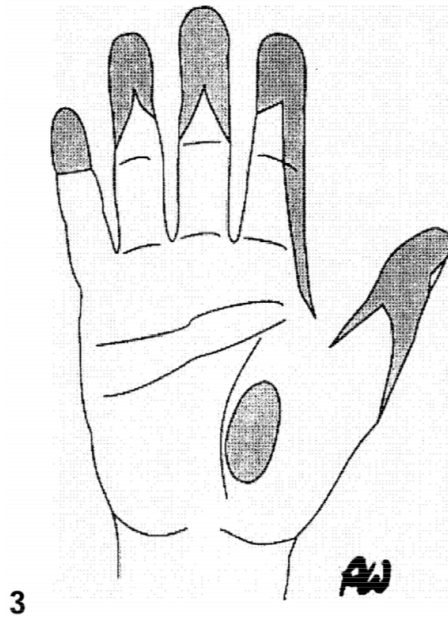


Fig 19: Functional zones in a palm required to manipulate a laparoscopic device

Instruments for minimally invasive surgery, U. Matern, P.Waller, 1998



Fig 20: A vegetable peeler

As seen on 12.04.15 : <http://nikas-culinaria.com/2006/07/23/amazing-gadget-chefn-vegetable-peeler/>

and Fig 17.4 was a bit more liked by the people due to the side palm support.

When the mock-ups were compared with the existing instruments, the mock-ups were better fit in the hand as digital nerves running in our fingers are not getting stressed out now.

But the designs of the mock-ups were not full filling all functional requirements of the desired instrument. Mapping all the fingers on those designs were a little bit difficult. So we thought of changing the design that would incorporate the functions of fingers easily.

As the mock-up in Fig 17.2 was more appropriate ergonomically and Fig 17.4 was more comfortable as it was supporting the device on the side of the palm, a marriage of both the designs were thought to be a viable solution for the new design. In the mean time, a research paper was found which showed the functional zones in a person's palm that would be required to manipulate a laparoscopic instrument. The mechanoreceptors of the tactile sense are mainly situated at the fingertip of index and middle finger, which is then followed by the thumb. The area just underneath the last joint in the thumb also acts as the area which helps in grasping.[8] Fig 19 shows the various functional zones of the palm required for manipulating a laparoscopic device.

As parallel product studies were also going on side by side, we came across a very interesting product, a vegetable peeler. Fig 20 shows the vegetable peeler. It sits on the palm and has a finger support for better action and grip. This feature of finger grip, functional zones of the hand and ideations in Fig 17.2 and 17.4 were taken and their best features were merged to form a new concept of laparoscopic device which is totally new from the present ones.

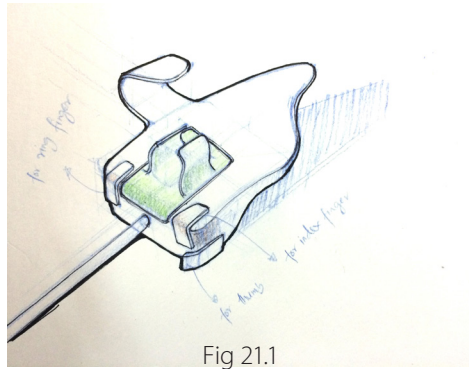


Fig 21.1

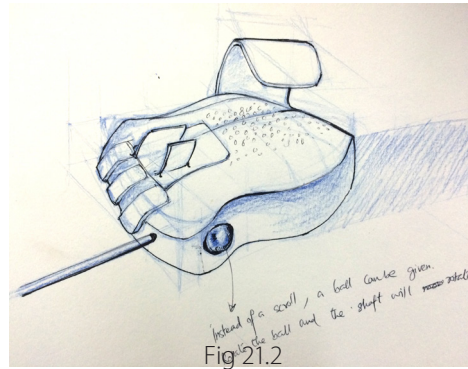


Fig 21.2

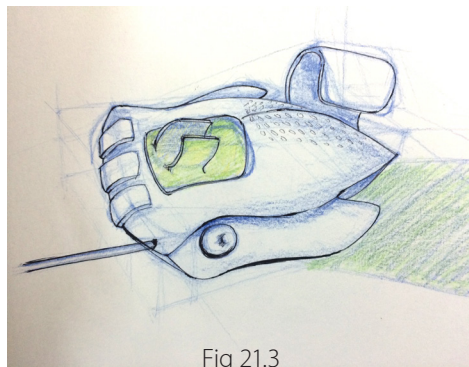


Fig 21.3

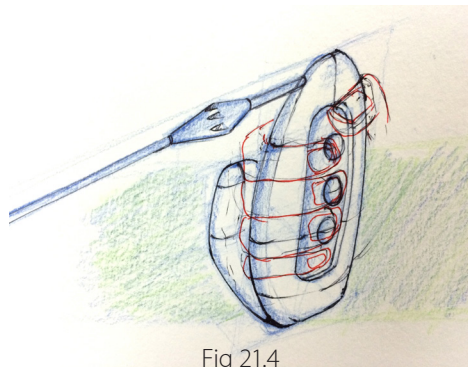


Fig 21.4

Fig. 21 : Ideations of different types of handles

With a clear direction of what changes and modification that has to be done in the current stage of ideation, started to sketch out the form factor of the handle. The Fig 21 shows four different variations of the handle design that has a finger grip, a palm grip and that utilises the palm surface for maximum effectiveness for manipulating different functions of the laparoscopic device.

Fig 21.1 has a side extruded part for support of muscles below thumb, Fig 21.2 and Fig 21.3 are similar ideas with slight difference of wings given at Fig 21.3 for better palm support. The idea in Fig 21.4 is different from other ideas. It has buttons at one side and one side has a palm support. It does not have a finger support as others. When hold it would appear as if someone is holding a tapered cylindrical handle. The position of the hand can be seen in Fig 21.4, where the hand is drawn in red ink.

Quick and dirty mock-ups of different these ideations are made so as to understand the ergonomics of the handles when hold in hand. PU foam and styrene are used to make these quick mock-ups. A average hand size was taken to fabricate the mock-ups. On the basis of feedbacks of Dr. Bhansali, at a later stage the mock-ups would be built using proper anthropometric if he feels the designs are promising.



Fig 22.1 : First iteration of new handle design



Fig 22.2 : Second iteration of new handle design

Fig 22.1 was the first iteration of the rough mock-up of the design that was made by combining all the desired features from the other concepts. It had a finger support for better grip. To reduce strain on the palm, a side support for the device to the palm was also provided. The second iteration of the device is shown in Fig 22.2. The only difference in both the design is that the position of shaft has been changed to a side next to the index finger of the hand. Functions of the new design are as follows:

1. A rotation knob is also provided for rotating the shaft around its axis.
2. Three other buttons are provided for manipulating the shaft of the device. The index finger would manipulate the primary action of the device.
3. The next most important thing is done by the middle finger and the thumb is used to rotate the shaft.
4. The button for ring finger is not mapped and could be assigned any function depending upon the necessity. One of the function can be controlling the cautery.
5. There is a future scope of properly mapping the functions of middle and ring finger buttons

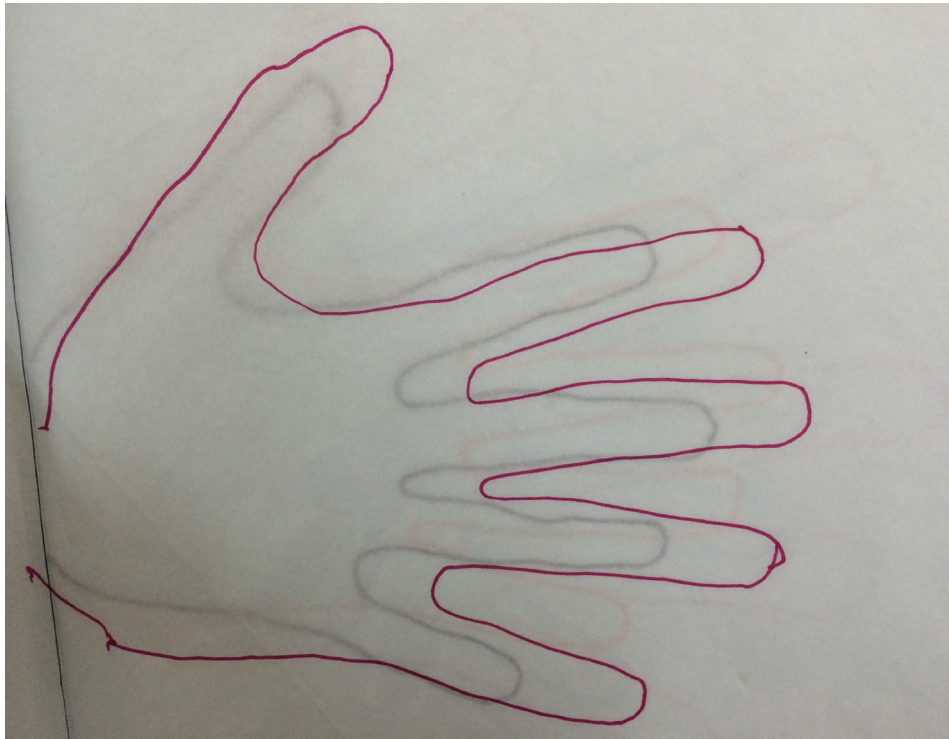


Fig 23: Comparison of different palm sizes

Anthropometric study

After taking feedbacks from a select group of people about the device, it was time that a device with proper dimension to be made. For this, a small study was conducted on to what size would be proper so that atleast person's ranging from 5th percentile to 50th percentile can use the device.

The palm size of different persons were traced on tracing paper. The palm size ranged from 5th to 95th percentile. Each tracing sheet were taken and put on top of another so that the underlying sheet can be seen. This allowed us to compare the hand sizes and decide what can be the possible device dimension. Fig 23 shows a stack of tracing paper used for comparison.

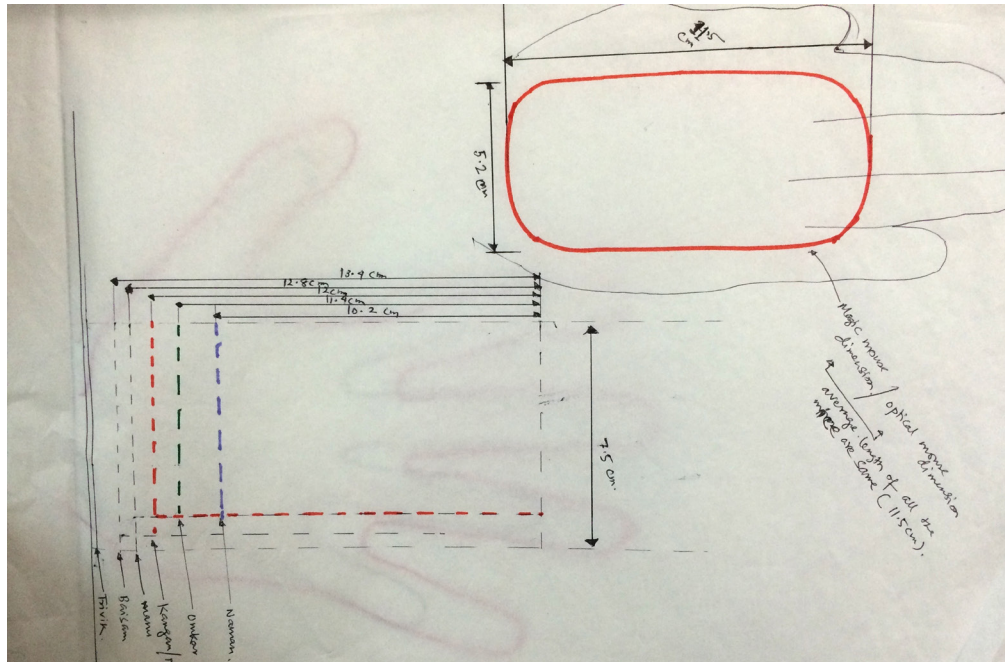


Fig 24: Comparison of different palm sizes

Fig 24 shows several tracing papers with outlines of different palm sizes were stacked on top of each other. The effective area of the palm which one uses for holding something is then made by using a rectangle. The width of the rectangle matches with the palms meta-carpal size.

It was getting difficult to decide upon the dimension of the device. So a parallel hand held product was taken and its dimension compared. We found out that a computer mouse has a general length of 11.5 cm, which fits in most of the human palm. For the width of the device, the 5th percentile metacarpal size of a palm was taken, which is 68mm. So, the first mock-up size was decided for 5th percentile palm size. Various hand sizes can be found in the table below in the left hand size. [8]

Hand Dimensions (mm).

Parameters	5th	50th	95th
1 Hand length	158	179	197
2 Palm length	89	102	114
3 Hand Breadth at Metacarpal III	68	80	90
4 Radio Ulnar breadth	49	55	60

Table: Ergonomic Dimensions of an adult hand [8]

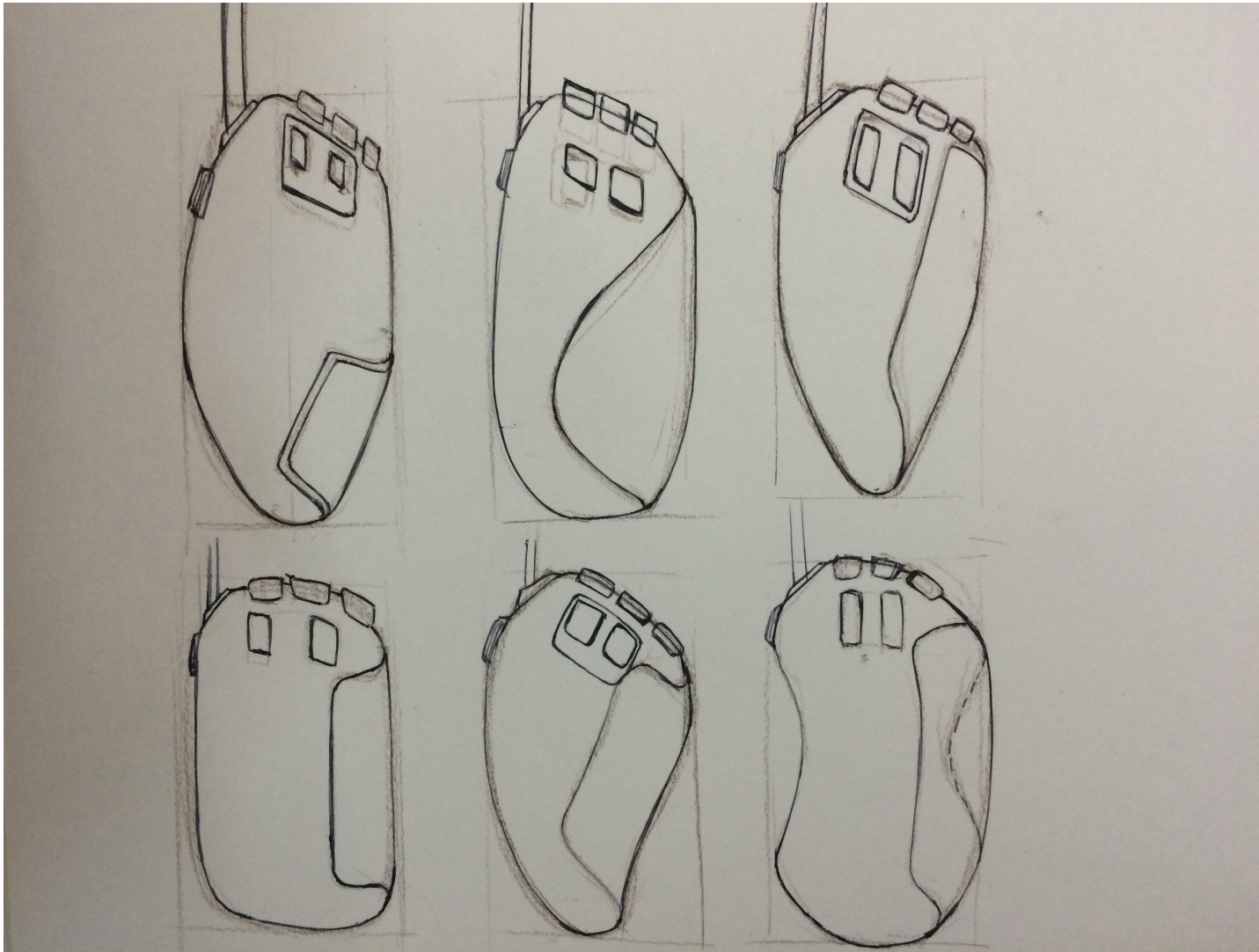


Fig 25: Ideations on the form factor of the device

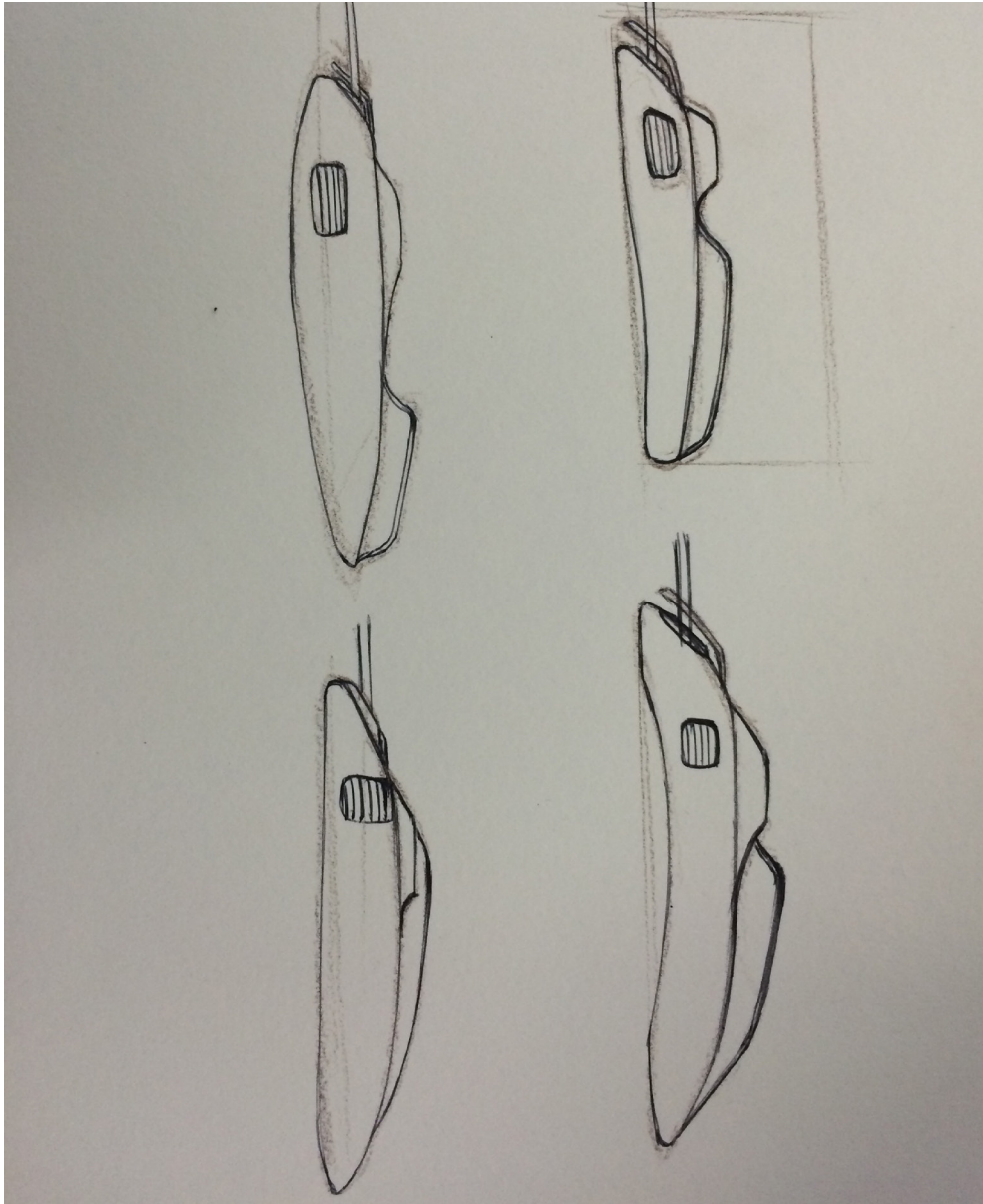


Fig 26: Ideations on the form factor of the device

Forms Exploration

The dimensions of the device are fixed. The first version of the mock-up was done based on some early ideations which were based on the contours of the palm. So a form exploration exercise was done to come up with interesting form keeping the base form same as the first mock-up. Fig 25 and Fig 26 shows different form explorations of the concept.

The form exploration mainly concentrated on the oval shape of the device. It played with various forms factor. The form factor was made as an abstraction of the palm. So that when it is put on, it becomes a part of the palm itself and does not look like a foreign thing fixed on the hand. The finger support position and also the variation in form of the palm support was done.

Then, the side profile of the device was done in various forms that can be seen in Fig 26.

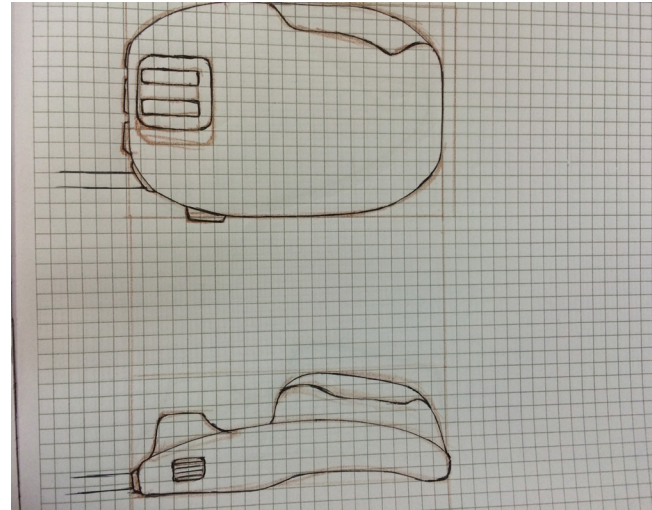
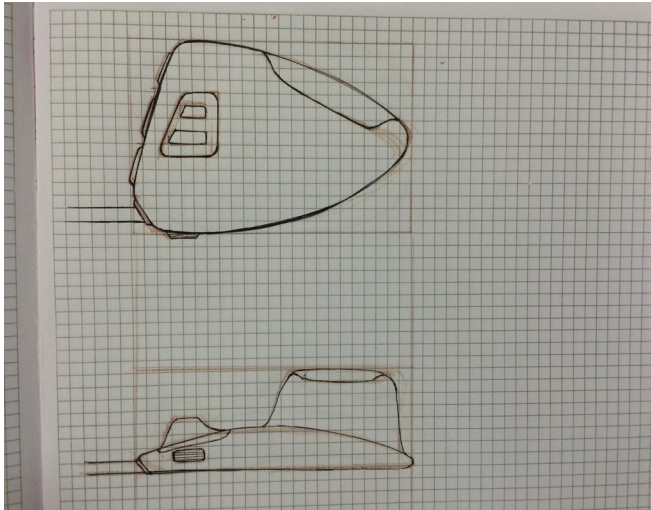
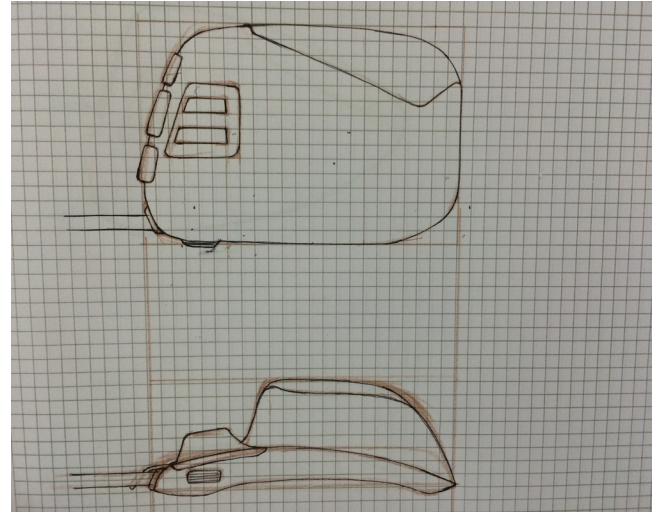
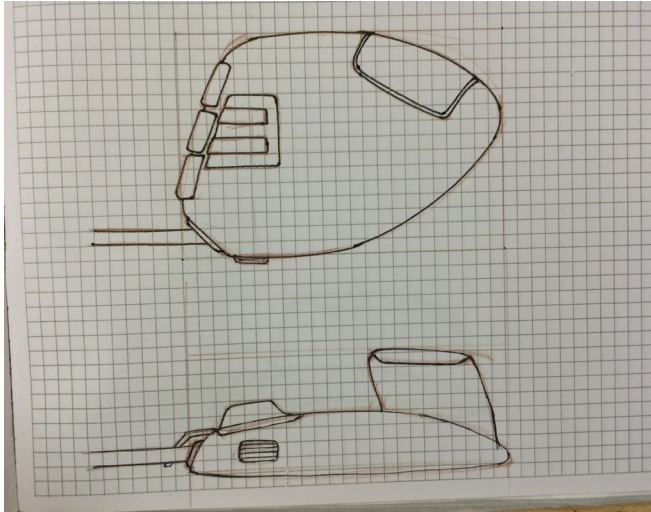


Fig. 27: 1:1 sketches of ideations on grid paper

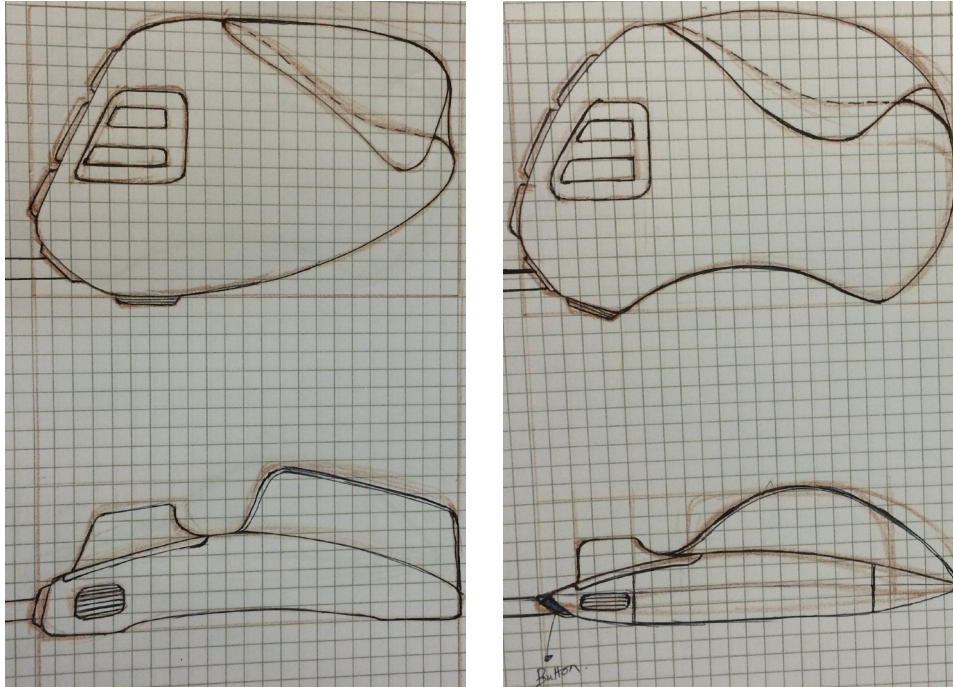


Fig. 28: 1:1 sketches of ideations on grid paper

After a general form exploration of the concept, a 1:1 scale sketches were done on grid papers so that one can understand different proportions of the elements in the form factor. This helped us to understand what should be the size of different components of the design. Fig 27 and Fig 28 shows the 1:1 scale sketches of the form exploration.

The ideations that can be seen in Fig 25 and Fig 26 are put on grid paper and minor tweaks were done here and there to come up with a form which is aesthetically looking good.



Fig. 29: 1:1 scale mock-up for 5th percentile palm

Fig 29 shows a 1:1 scale mock-up for 5th percentile palm size. It has 3 buttons for manipulating all the functions the device. The first button is for the index finger which would do most of the primary functions of the device, that is from grasping or holding of tissue to cutting and cauterising tissues. The next 2 buttons are for moving the front head up and down for hard to reach areas during operation. The left hand side has a knob which is for rotating the shaft of the device, which also has the grasper connected at the head.

There is a finger support given for the middle finger and a side support for the palm. One has to slide the palm into the device. The finger support would hold the middle finger in place for a proper grip and the side support would hold the hand fixed with the device body for a good grip. This two support will also not let the device fall away from the surgeon's hand.

Thus allowing the surgeon to stretch out the fingers during long operation hours and when the doctor will feel numbness in the hand.

The shape of the device is chosen in such a way that it fits the contours of the palm easily. This device is made for right handed person as majority of the person in world are right handed and only about 7% of the population are left handed. The black dots on the mock-up was for 3D scanning of the model.

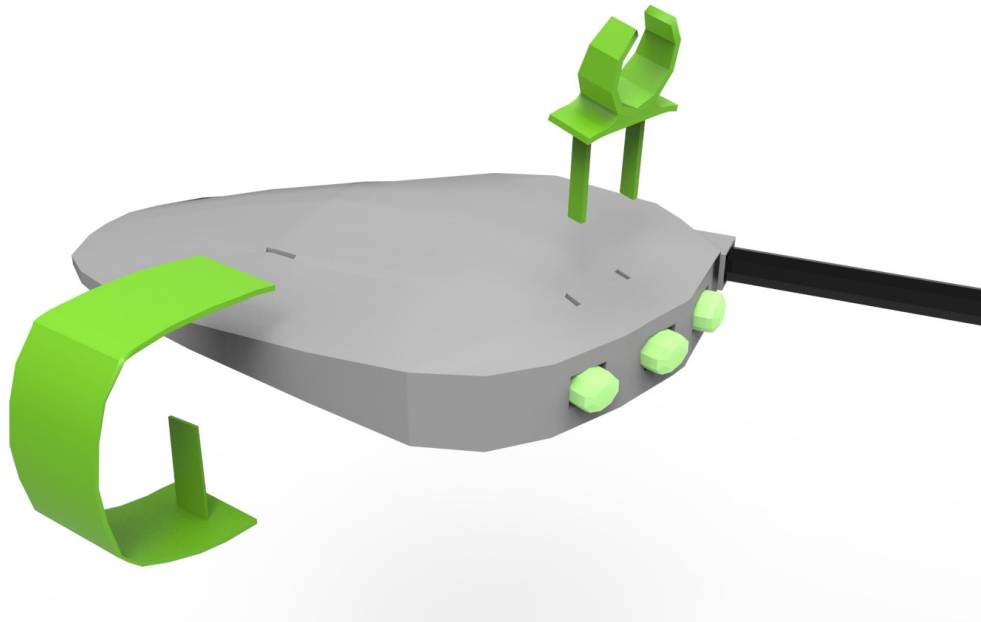


Fig. 30: Modified grip design

In Fig 29 we have seen a right hand laparoscopic device. Right now most of the laparoscopic devices are designed for right handed people only. Though population of left handed people are very less. We wanted to modify our design so that the device can be configured as right handed or left handed after its purchase by the user itself.

Fig 30 shows a modified design of the earlier concept shown in Fig 29. The design is made symmetrical on both sides of the horizontal plane of the device shown in Fig 30. The finger grip and the palm grip has been given dowel pin like supports at the bottom which would be inserted into the shell of the device so as to fix the grips. So, if a surgeon is left handed then the surgeon has to fix the grips accordingly. This simple modification in the design led it to be an ambidextrous design.

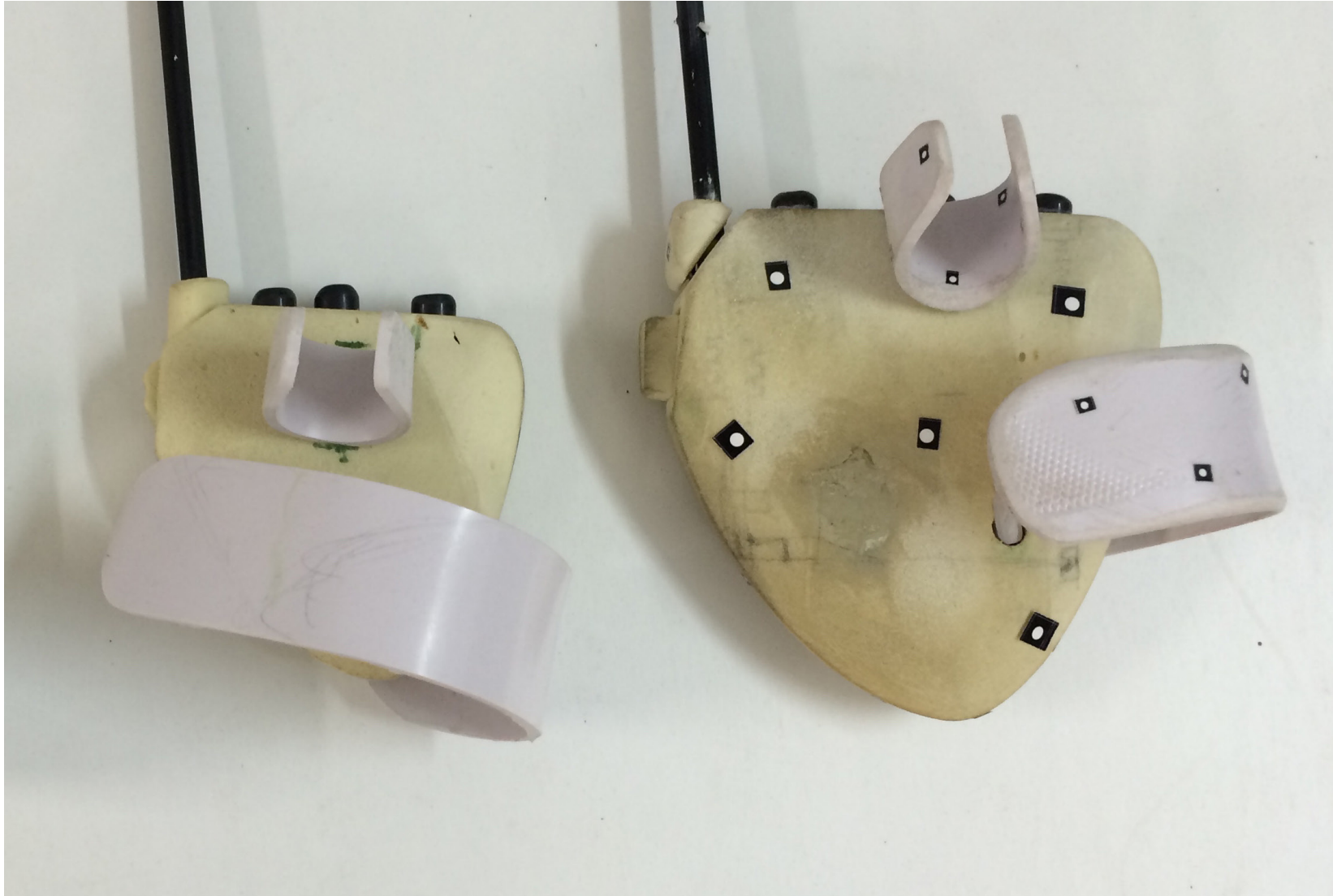


Fig. 31: Modified device design for 50th and 95th percentile palm size

With the modified device design where the finger and the palm grips are modular. So, if the person is left-handed or right handed, the person would fix the finger and the palm grip on accordingly. Thus, getting saved from manufacturing two separate devices one for right hand and one for left hand.

Two new mock-ups of the devices were made. One for the 95th percentile palm size and another for the 50th percentile palm size. The width of the device for 95th percentile was taken as 90mm and for the 50th percentile it was taken as 80mm. Fig 31 shows the two new mock-up models of different sizes. The first one from left is the 50th percentile size and the second one is the 95th percentile size.

The premise of making two new mock-ups of different dimensions was that the earlier mock-up of 5th percentile was not fitting properly in the hand of the 50th percentile palm size and for 95th percentile, it was getting very small. So, we have the option of either going for separate devices from 5th to 95th percentile in three categories as 5th percentile size device, 50th percentile size device and 95th percentile size device.

Both the devices were shown to a select group of people to wear it on their palm and give feedback. Most of them felt the 50th percentile

device is good in respect to the size but a little smaller would have been perfect.

The small white dots on black paper that can be seen in the photo in Fig 31, are markers for 3D scanning the mock-ups



Fig 32: Feedback session with Dr. Bhansali. (From left, clockwise: Prof. V. Bapat, Baisam, Dr. Bhansali, Prof. G. G. Ray, Prof. B. Ravi)

Feedback from Dr. Bhansali

Dr. Bhansali was thrilled and happy with the new design as it addressed the ergonomic requirement of a device which would lead to less stress during long operation hours to the surgeons. Though there are few devices that are more ergonomical than the current low cost laparoscopic devices, this new design will be more comfortable than anyother device.

Few suggestions that he gave were to shift the position of the shaft in-between the index finger and the middle finger for better precision and manoeuvrability of the device. The buttons should be color coded. The primary function of the device can be grasping and can also be dissecting, depending upon the function, the buttons are to be given different color so as to avoid confusion during surgery.

The functions of the device are to be mechanised and not automated as the control of the device during the surgery should be in the hands of the surgeon. The feedback session can be seen in Fig 32.

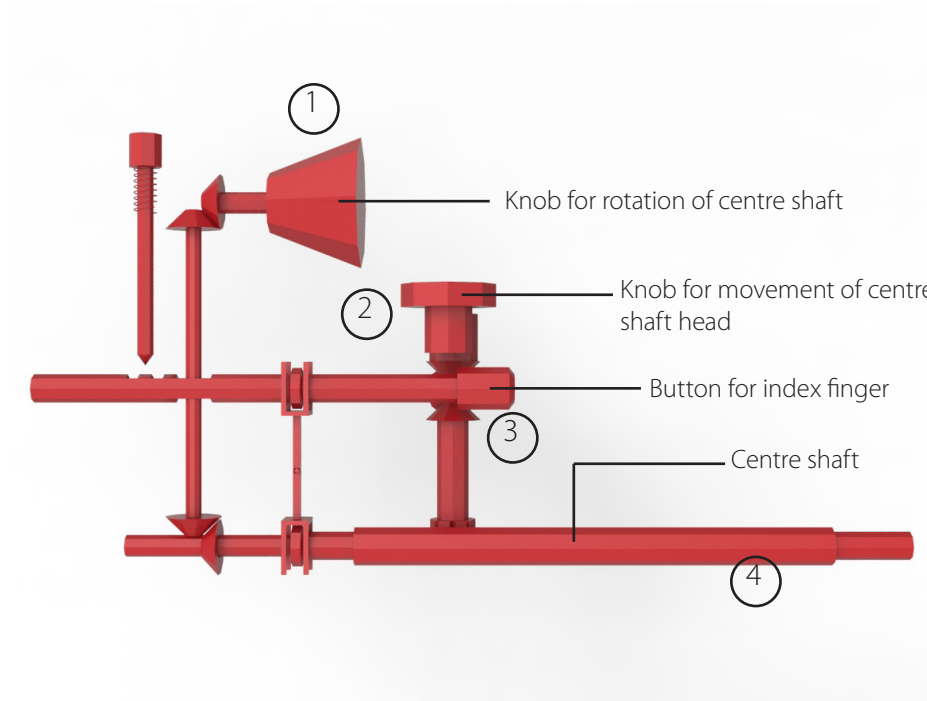


Fig 33: One of the earlier version of the mechanism

The Mechanism

After the feedback session with Dr. Bhansali, it was decided that the shaft of the device would be shifted from the side of the device to in-between the index finger and the middle finger. This changed a lot of things. The mechanism that we had thought of earlier would no longer work now as the shaft got offset to almost in the middle of the device.

Fig. 33 shows one of the earlier mechanism that we had developed after the feedback session with Dr. Bhansali.

1. The knob shown in (1) is the knob for rotating the centre shaft shown in (4)
2. The knob shown in (2) is the knob for moving the head, that is fixed in the centre

shaft up and down. The mechanism here is a auto locking mechanism, i.e, if the user wont rotate the knob, the head will also not move up and down, even if forces are applied on it.

3. The button shown in (3) is the button that would do all the primary actions of the device, i.e, grasping, dissecting, etc.

In the mechanism shown in Fig 33, the volume taken up by the mechanism was getting too high, therefore increasing the width of the device which was not at all acceptable. Moreover, we were having problem withlocking mechanisms inside the device, due to space constraints. Therefore, it was decided that a new mechanism would be formulated that would reduce the size of the device and also would be easy to assemble in one plane. In the mechanism shown in Fig 33, the whole parts were divided into 2 planes, which was increasing the volume as well as the complexity of giving support to the mechanism.

The mechanism shown in Fig 34 is the new mechanism that has been modified to tackle all the problems that we had faced earlier. All the parts in the mechanism has been put in one plane, which reduce the internal volume of the mechanism and thus the device width got restricted to a size of 35mm.

The operation of the new mechanism is almost same as the mechanism shown in Flg 33, with some minor modifications.

1. The knob shown in (1) is the knob for rotating the centre shaft shown in (4). The knob is changed to cylindrical shape so that it can fit into the new mechanism properly and reduce the width of the device which was planned earlier.

2. The knob shown in (2) is the knob for moving the head, that is fixed in the centre shaft up and down. The mechanism here is a auto locking mechanism, i.e, if the user wont rotate the knob, the head will also not move up and down, even if forces are applied on it. This mechanism is a modification of the earlier one. Here we have given worm and worm gear for auto locking. The gears are linked with a linkage mechanism for better control.

3. The button shown in (3) is the button that would do all the primary actions of the device, i.e, grasping, dissecting, etc.

Fig 35 shows the dimensional details of the parts and the casing and also the internal arrangement of the mechanism with the casing.

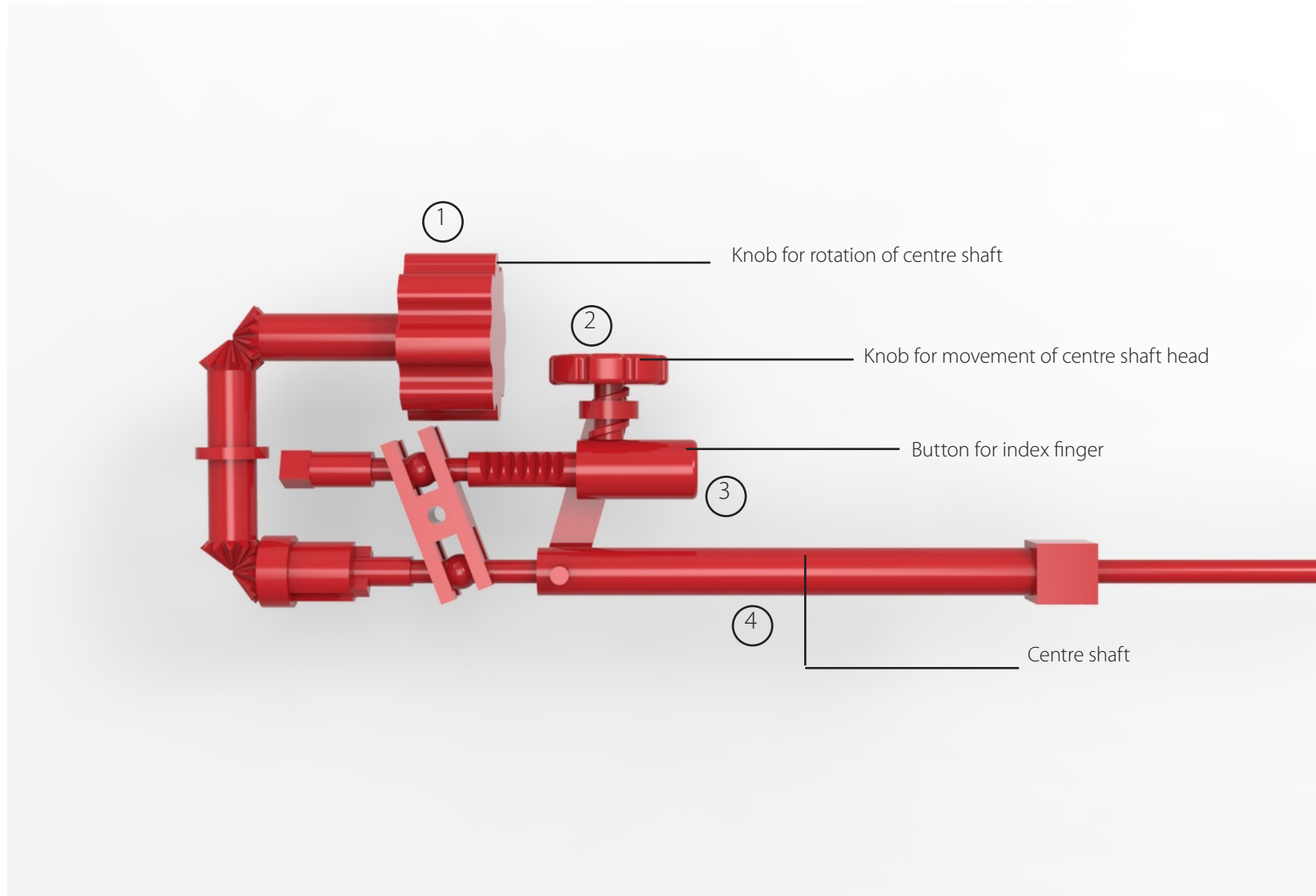


Fig 34: Modified mechanism

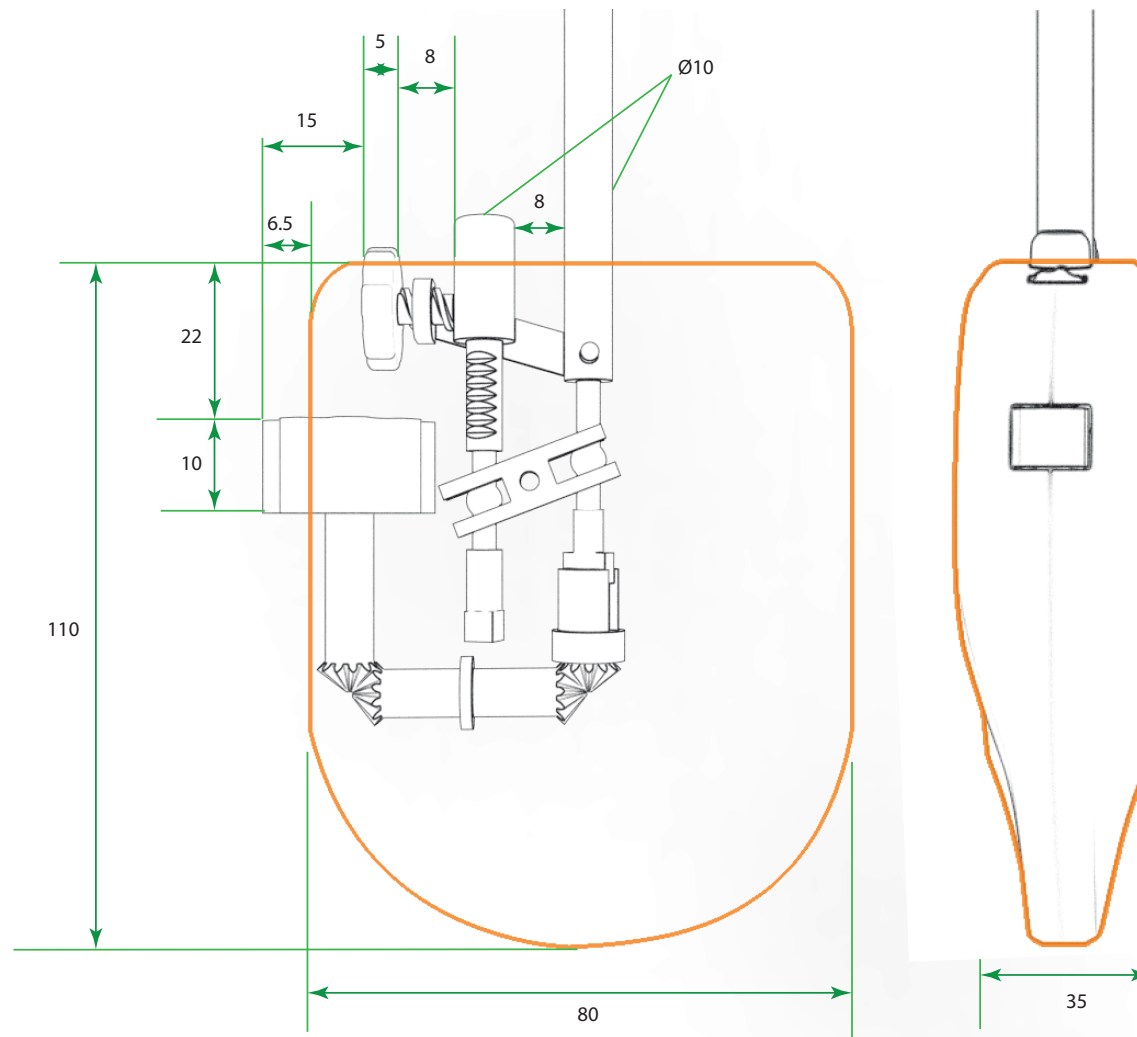


Fig 35: Dimensions of the mechanism with the casing on top of it shown in orange color

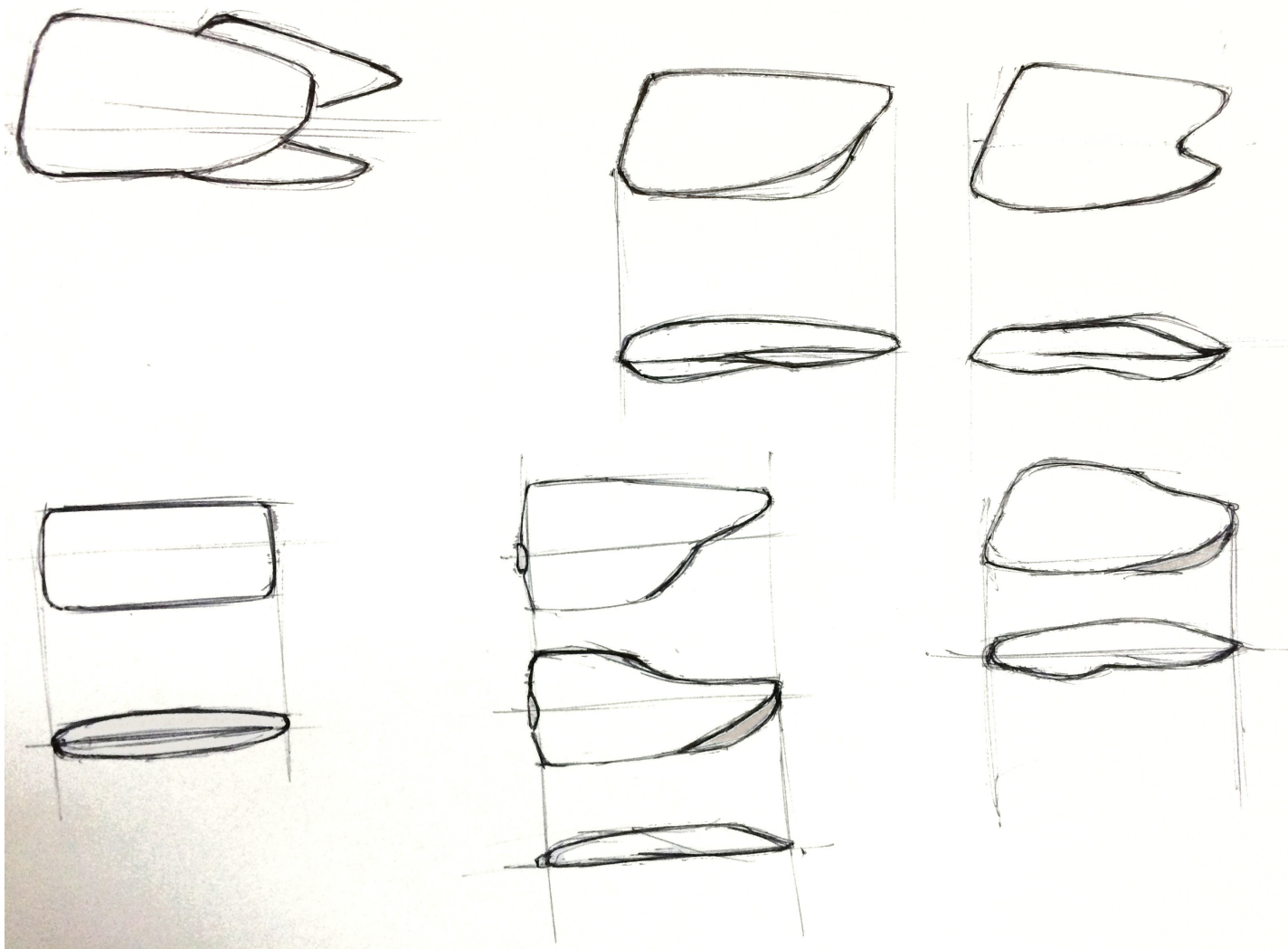


Fig 36: Forms exploration for the final model



Fig. 37.1



Fig. 37.2



Fig. 37.3

Fig. 37: Mock-ups for final form exploration

Forms Exploration

After feedback session with Dr. Bhansali, it was clear that we have to change the mechanism that we had earlier planned for the device. To accommodate the new mechanism, that can be seen in Fig 34, 35, we had to tweak the form factor of the device a little bit. Keeping the earlier design as the base design, we started form exploration of the device again as seen in Fig 36 and Fig 37. Ideations were again based on the previous derived form. The main idea was to improve upon the aesthetics of the form and also make it more functional and tuned with the new mechanism dimensions.

The ideation was divided into two types, form factor with a smooth form that can sit comfort-

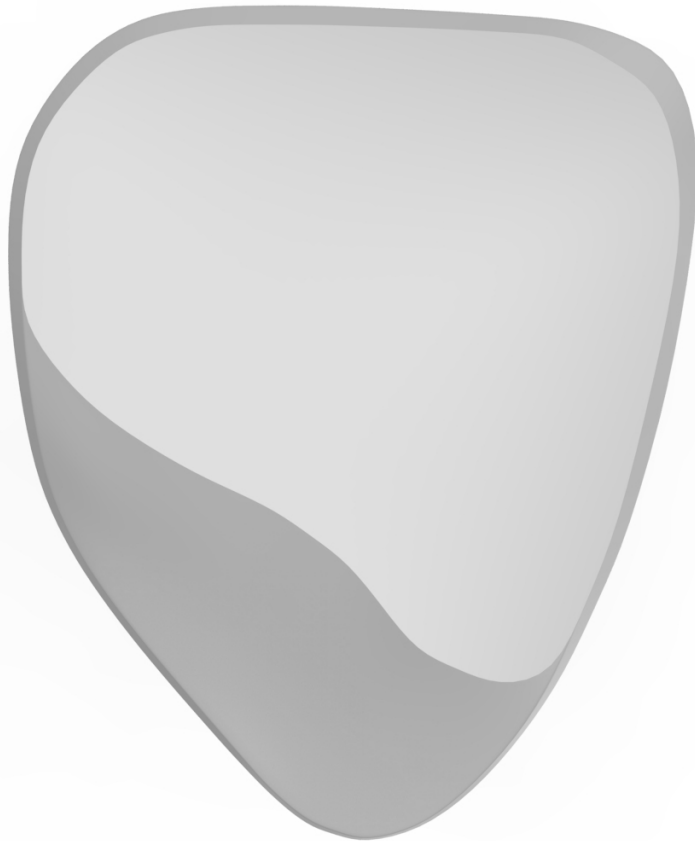


Fig. 38: Top view of final form

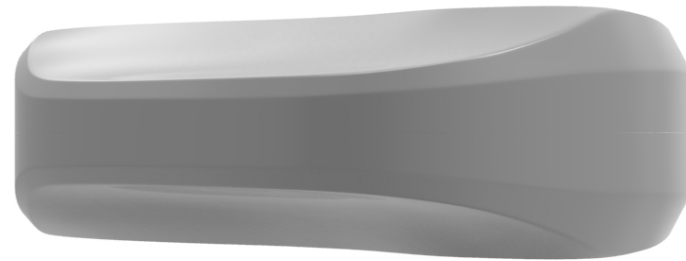


Fig. 39: Back view of final form

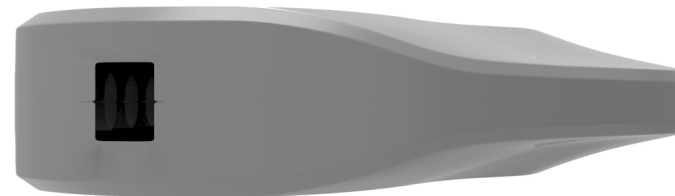


Fig. 40: Side view of final form

ably inside the palm, that mimics the smooth form of the hand, shown in Fig 37.1. The other type was a form factor that is little bit boxy in form and has sharp lines and chamfers that depicts the precisionness of the device, which can be seen in Fig 37.2, 37.3. The chamfers are given in such a way that the sharp lines do not hurt the hand when held in the palm for a longer period.

Out of Fig 37.2 and Fig 37.3, Fig 37.2 was selected as the final form as this design was going well with the internal dimension of the mechanism. The form factor of Fig 37.2 was tweaked a bit and was taken as the final design of the handle for the device.

The tweaked design can be seen in Fig 38. The form is an abstraction of the form of a palm. A slope is given on the form. The slope runs along a curvature. This curvature defines the form similar to that of a palm. The slope is not only for aesthetic treatment of the boxy form but it is also functional. If we see the form in Fig 39, 40, we can see the slope is not a straight plane. It has a slight curvature. This slope supports the muscle just below the thumb and at the end of the palm.

In Fig 39, we can see on the right hand side, the chamfer width gradually increases. This was done to break the monotony of the chamfer running throughout the form and also make

it smoother to hold in hand. By making the chamfer width more, it sits inside the palm easily.

The form is divided into two parts and an imaginary plane can be visualised at the middle, then the form is identical and is a mirror image of each other from the mid plane, thus making it easier for both left and right handed person to use the device.

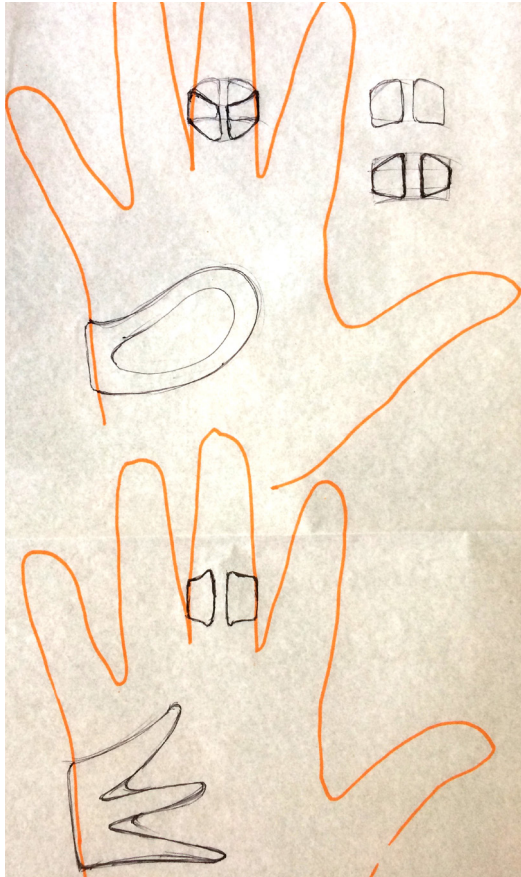


Fig. 41.1

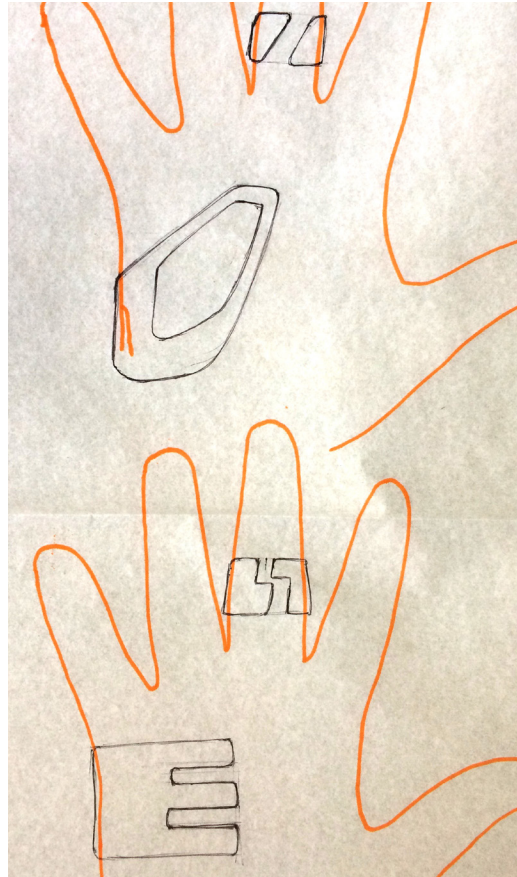


Fig. 41.2

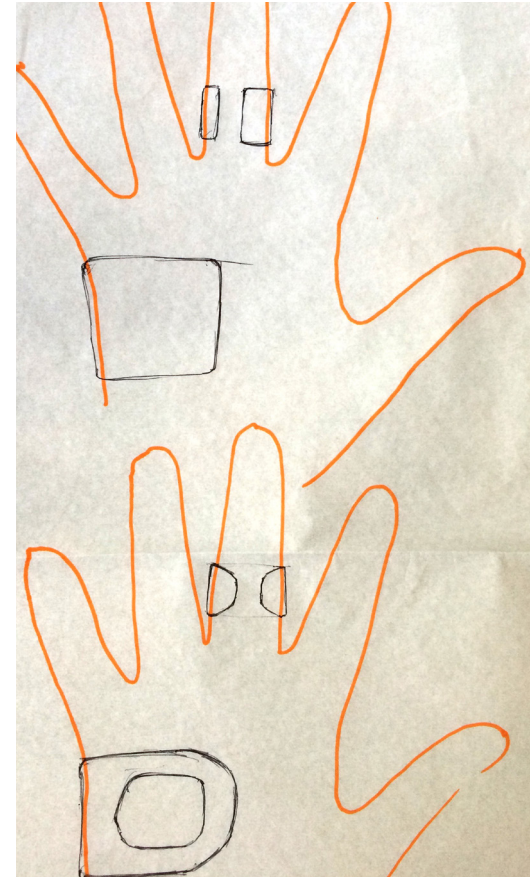


Fig. 41.3

Fig. 41 Form exploration for the finger and palm grip

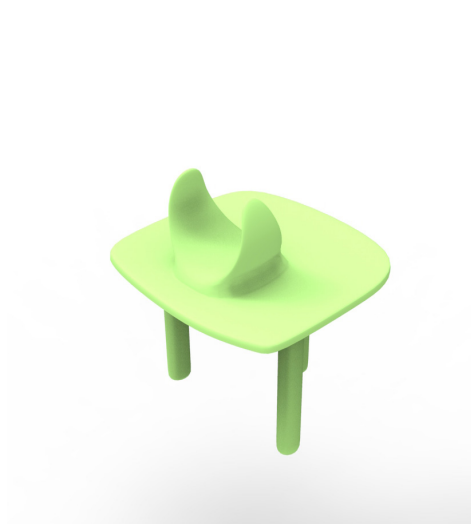


Fig. 42.1

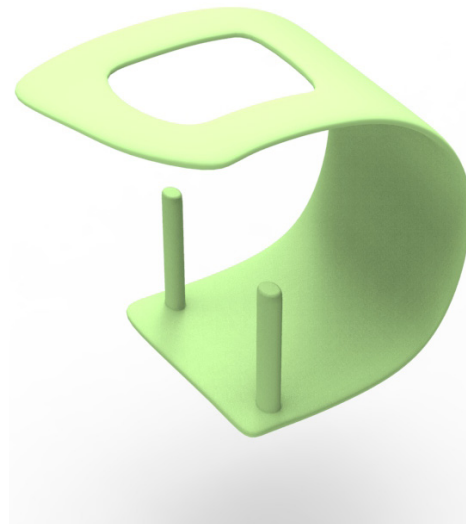


Fig. 42.2

Fig 42 : Finger and palm support

After the form exploration of the shell of the device, form exploration of the finger support and palm support were done. Exploration were inspired from the shape of a fork to the legs to frogs for creating innovative gripping support for the palm. At the end the bottom idea at Fig 41.3 were taken, as that form was fitting the form of the device well. This form was taken also keeping in consideration for the branding of the product. The hole at the palm support was also helped in gripping the palm properly without giving too much of stress on the palm muscles and nerves.

Fig 42 shows the design of the finger and the palm support. Fig 42.1 is the finger support and Fig 42.2 is the palm support.

I took up inspiration from wearables and jewellery form with an intension of making a fashion statement in the form of the grip and palm support.

Mood Board for Color

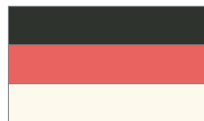
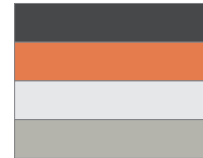
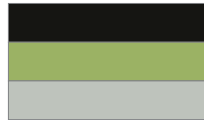


Fig. 43.1 Mood board for color palette

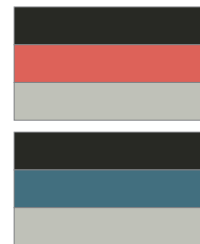
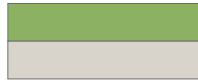
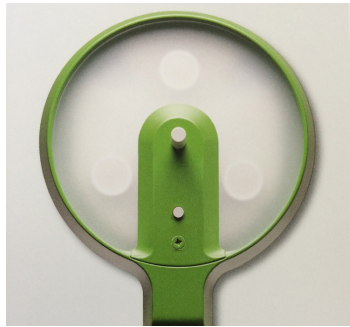


Fig. 43.2 Mood board for collar palate



Fig. 43.3 Mood board for collar palate

Color plays a very important role in the aesthetics of a product. So in order to come up with a color combination, a mood board was created. The mood boards can be seen in the Fig 43.1, 43.2, 43.3. This mood board was created using products that won RED DOT award in 2014. It was found that lime green, red, blue, black are very commonly used.

Since the device in question is a medical product, the combination of white and green were taken as the main color. The body is kept white as it is a neutral color and also it denotes purity which goes hand in hand with the nature of the environment in which the device would be used. The green color goes well with white and pops out a breeze of freshness when looked together. The finger grip and the palm grip are given the lime green color.

The shaft of the device is given black color. Both the knobs were also given black color as the functions generated by them are to control the shaft. The index finger button is the most important button and does the most important and primary action of the device. It is given blue in color. The middle finger button and the ring finger button are not assigned any function as of now in the mechanism. As more functions are needed by the surgeon, it can be mapped to the button. As of now, the middle finger button is given a red color, taking in hypothesis that the button would be used to

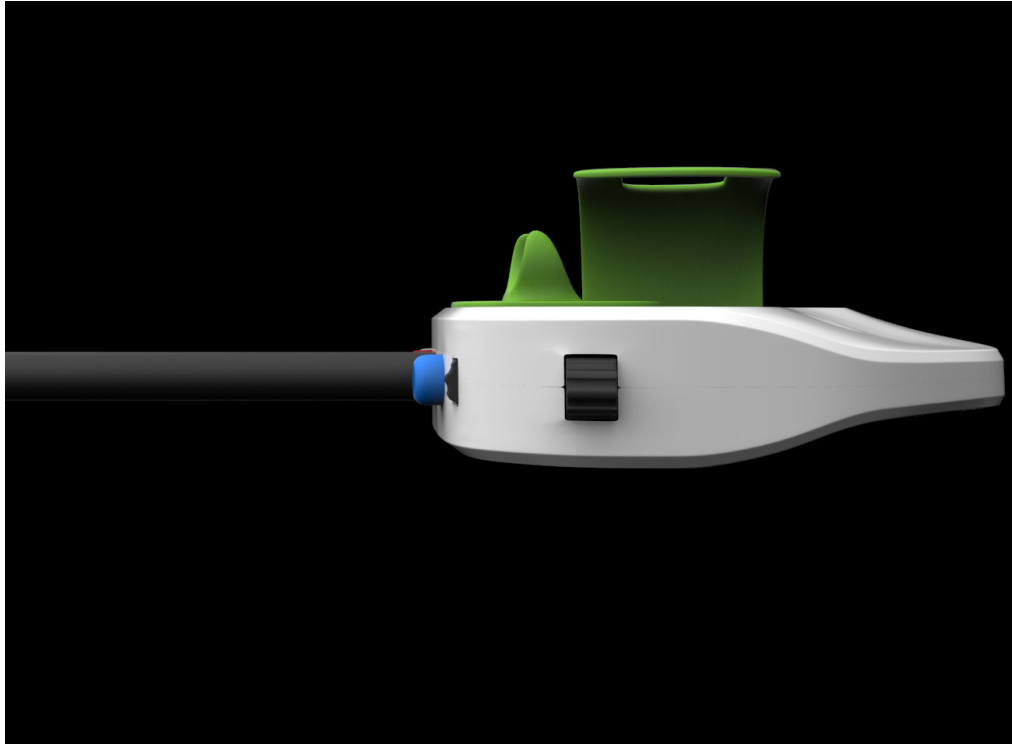


Fig 44: Final color combination of the device

control the cautery which is now peddle actuated by the leg. The ring finger button is given a light grey color as it has not been mapped to any function. Fig 44, 45 shows the final color combination of the device.

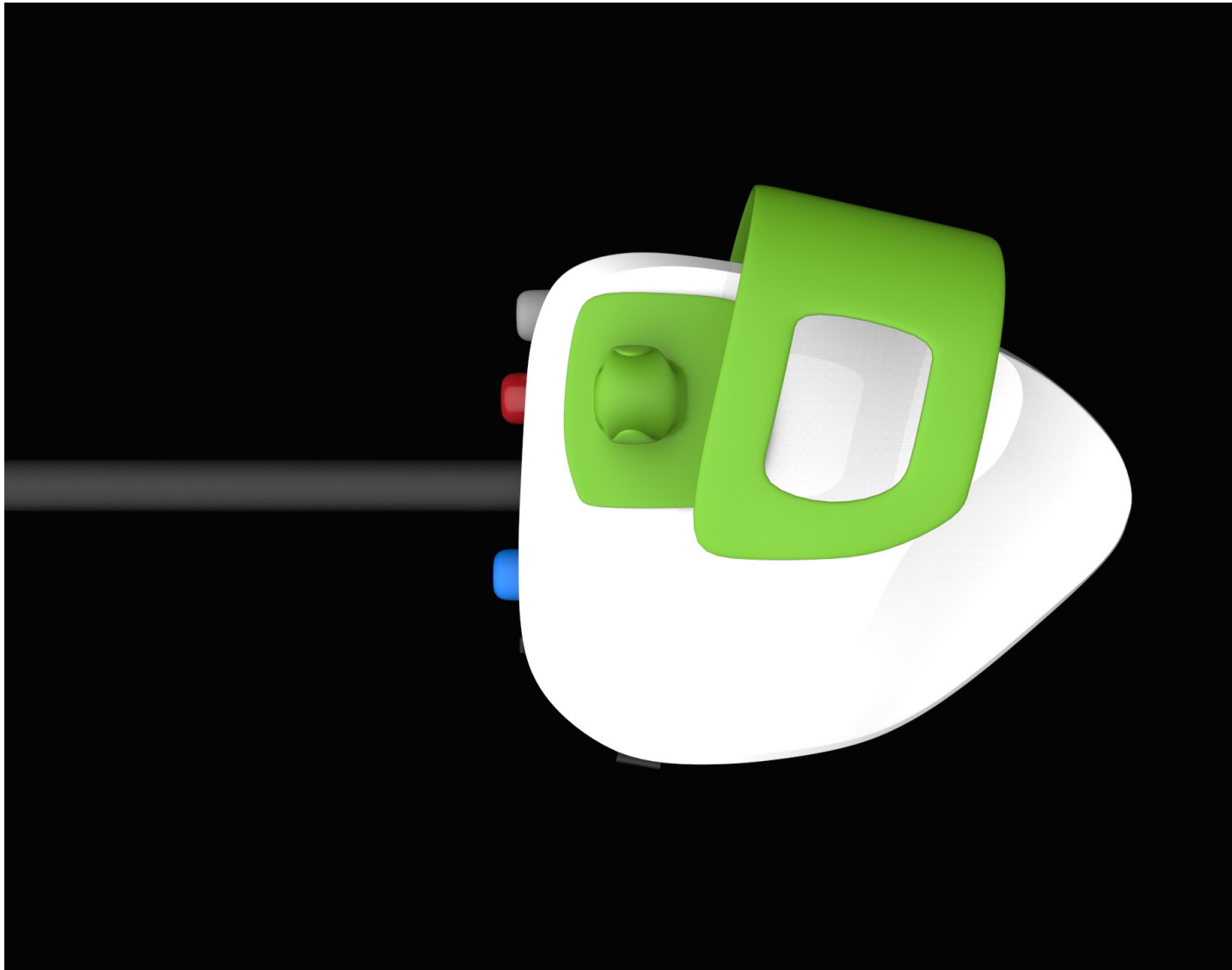


Fig 45: Final color combination of the device

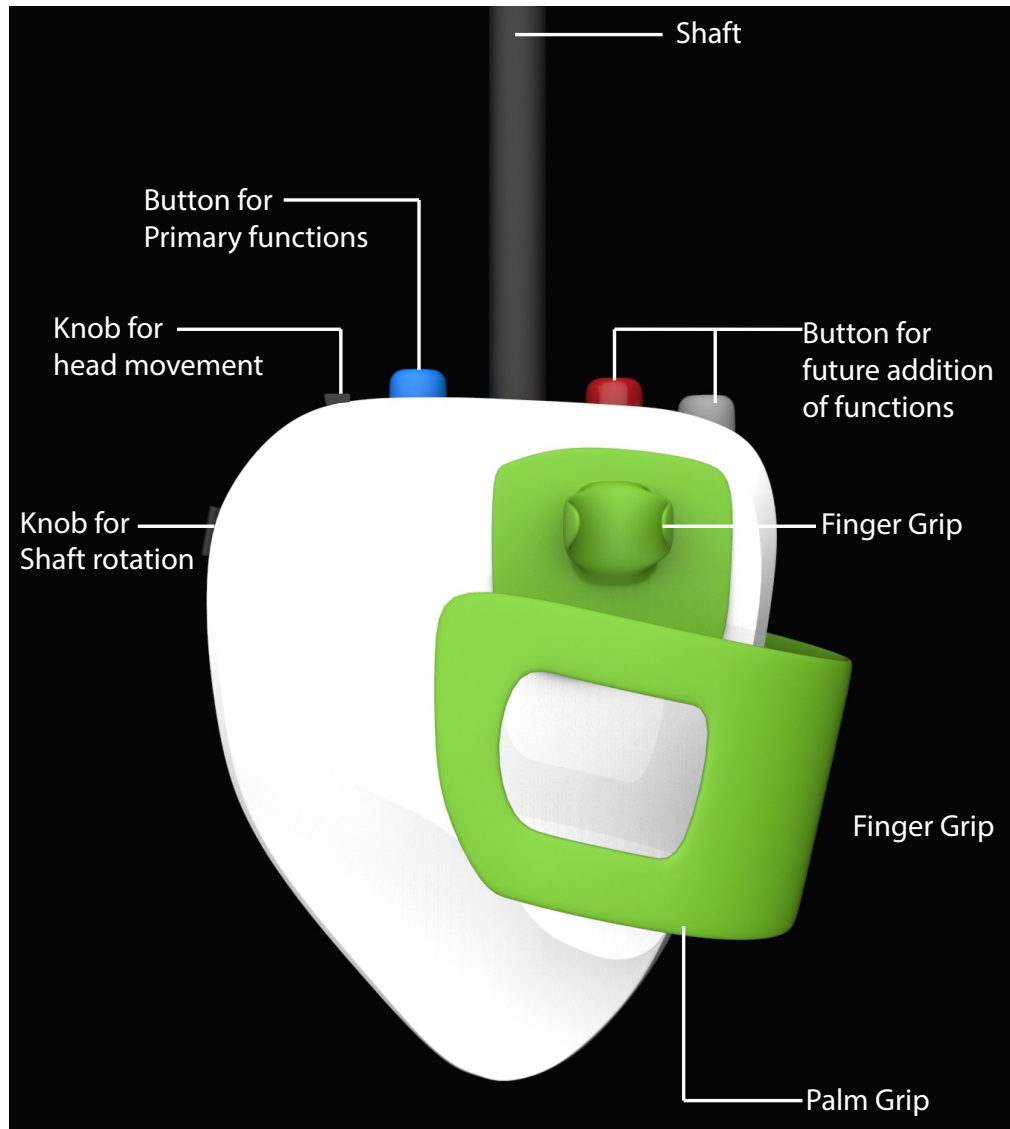


Fig 46 : Final mock-up with functions defined

Provision for future addition

If we look at Fig 46, all the functions in the device have already been defined. But if we look at the two buttons (red and grey) at the top, it has been mentioned that those two buttons are for future addition of functions.

Right now, the cautery system is pedal based and is pushed by the leg, the red button can be used as to substitute that into finger operated. The cautery can even become wireless by including batteries inside the device. Thus making it more comfortable to use.

The grey button can be used for very specialised functions like locking the camera onto a specific organ. So irrespective of the movement of the assistant, the camera would move accordingly and doctor would get a steady image of the inside of the patient body.

Material and Hygiene

Since the device would be used for laparoscopic operations, hygiene of the device is one of the paramount factor. To maintain the hygiene standards, the material has to be carefully selected so that it can be autoclaved (sterilization process) and also the material has to be biocompatible.

For this medical grade Nylon 12 is chosen as the material for the device, which has a melting point of 178° - 180° C .Thus it can withstand the steam temperature of the autoclaving device of about 121° C . The parts for mechanism can also be manufactured with nylon 12 but can also be made with medical grade stainless steel 304L and 316L.

The material for finger grip and palm grip is selected as TPE (Thermoplastic Elastomer) which is an alloy of plastic and rubber. It exhibits both the properties of rubber and plastic, so it would be an excellent material for grips. The melting temperature of TPE is over 200° C, so it would sustain the autoclaving temperature also.

Costing

Detail costing of this device can not be done at this stage as various components for inside mechanism are getting evolved.

The total volume of material used in manufacturing the top and bottom shell along with the internal parts for mechanism is 84.96126 cubic cm. The parts are made of nylon 12 which has a density of 1.02 g /cubic cm [9]. Thus the total weight of the assembly comes out to be 88.66 grams.

The cost of 1000g of nylon 12 is Rs. 350 and the cost of 1000g of medical grade nylon 12 is Rs. 450. Thus the cost of 88.66 g of nylon 12 is roughly Rs. 50

Since we have not explored the cost for manufacturing the device, we are yet to know the exact cost of the device. But since, it is a new product, and moulds and dies would be made for it, that would be a costly affair.

Also there would be set-up cost of the machineries and also other prototyping and testing cost.

Though it is going to be mass manufactured one, its not a typical consumer product of a larger volume like 5,00,000 - 10,00,000 per year.

Thus taking in consideration all these points, we can have a rough estimate of 5 times the cost of the material used in manufacturing the device. So an estimated cost of the pastic part comes out to be around $5 \times \text{Rs. } 50 = \text{Rs. } 250$

So, the cost of metal parts can be accounted as roughly Rs. 500 (micro-machined high precision parts).

So the cost will come to be around Rs. 1000 and roughly the sale price can be around roughly Rs. 3000 to Rs. 4000.

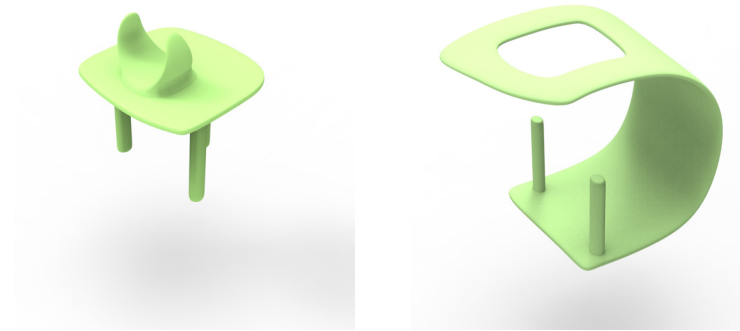


Fig 47.1 Finger support and Palm Support

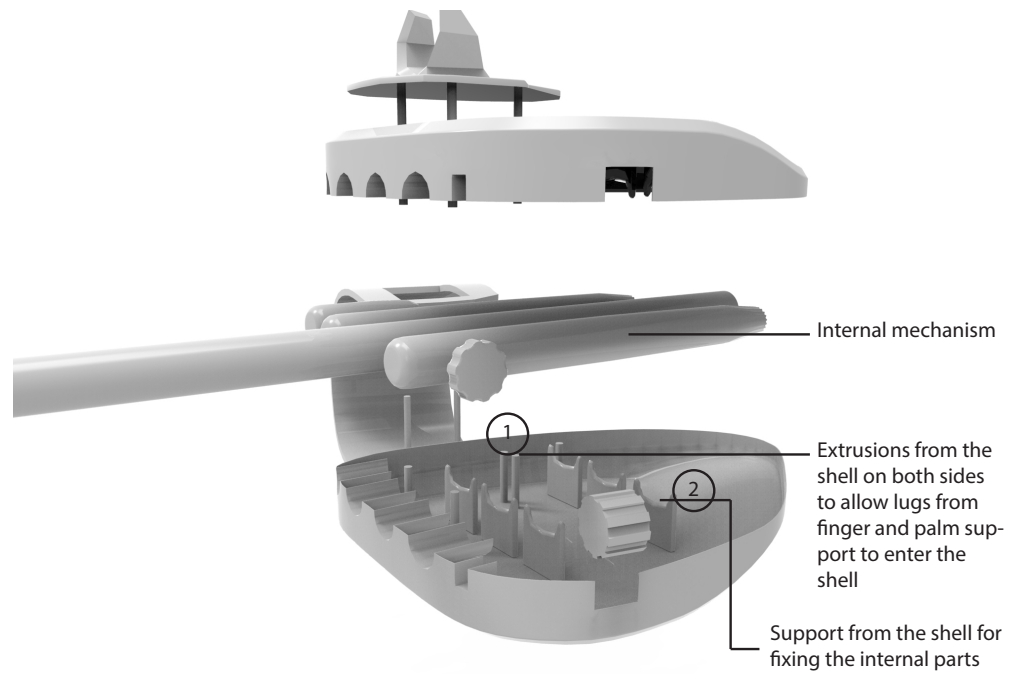


Fig 47.2 Internal Structure of the shell

Details : Manufacturing

In Flg 47.1 we can see the finger support and palm support have thin rod like extrusions coming out of them. These are for fixing the supports on to the shell.

In Fig 47.2 we can see the internal structure of the shell.

1. In ① we can see, rod like structures coming out of the shell. These structures have through holes and are there in both upper and lower shell. They accommodate the supports of the finger and palm support.

2. In ② we see supports with semi-circular cuts coming out of the shell. They are there in both the upper and lower shell. When both the shells are closed together they form a circular hole. On top of this semi-circular cut sits the internal parts. They are hold in place by the upper and lower supports that are coming down from the shell.

The upper and lower part of the shell are moulded parts. They are joined together by ultra-sonic welding. They can also be joined together by snap-ons on both side of the shell.



Fig 48 : Branding on the palm grip

Branding

① Xhand

Since, it is a very specialised product and stands out among the category of similar products, branding becomes a very important factor for its success in the market.

② **X**hand

The shape of the device was like a small stone, that perfectly in the grasp of the palm, so the name of "PEBBLE" was thought off. Then we thought, "PEBBLE" was a very common name and was shared by name products in the market already. The name has to be unique. The product is used for surgery and is used for hold in the hand. Unlike other, it fits perfectly in the palm and when hold in hand, it seems it

③ **Xhand**

④ **Xhand**

Fig 49 : Branding

has become a part of the arm itself or we can say it has become an extension of the arm or

hand in which the device is hold. Thus came the name, "Xhand", extension of hand.

Xhand was tried out in several fonts. Fig 49 shows 4 different variations of the name Xhand in different fonts. The 4th one shown in Fig 49 was taken as the final one. The word hand was written in bold in font "Alfa Slab one", which was giving importance to the word hand. The letter X which represents extension has been given a thin font of "Myriad Pro light" and has been modified to stand out and create a balance between the two parts "X" and "hand". The branding has been put on the palm grip top as it was the best position to view the name of the device, which can be seen in Fig 48.



Fig. 50.1



Fig. 50.2



Fig. 50.3

Fig. 50 : Comparison of devices



Fig. 51 : Types of grips when various devices are held in hand

Comparision of existing devices with new concept

For comparing the device, we have taken both the new device that has been conceptualised and also the devices that are there in the market. In one hand, we have worn an existing device and in another a 1:1 scale mock device, which can be seen in Fig 50. In right hand, the new device has been worn and in the left hand the existing device.

In Fig 50.1, 50.2 and 50.3 we can see, while the new device has been hold in hand, there has been very less bending of the wrist, whereas in the left hand, the wrist has been particularly bent to a certain extent. Due to which the median nerve gets stressed out and hand and palm starts to pain. Thus, the new device would be less painfull in long hour surgeries.

In Fig 50, we can see that the finger grips are also different. It can be clearly seen in Fig 51. In Fig 51, the 1st two devices from the left, then fingers have to be inserted into a sort of a ring to operate the device, thus stressing out the digital nerves (refer Fig 18.2, page 33) and causing numbness and pain during long surgery hours. In the 3rd picture of Fig 51, we can see, the fingers are not inserted into any rings and thus saved from damaging the digital nerves in the fingers.

Thus we can conclude, the new concept is ergonomically superior than the existing devices in the market. Various images of the 1:1 scale mock-up of the device can seen in the next few pages from Fig 52 to Fig 55.



Fig. 52 : Finger grip and Palm grip with the logo



Fig. 53 : The device with the finger grip and the palm grip



Fig. 54 : The device



Fig. 55 : The device

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