AUTO-SUTURING DEVICE

INDUSTRIAL DESIGN PROJECT III
MDP-475

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Approval

Industrial Design Project III

Auto-Suturing Design

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External Examiner:

Internal Examiner: 27-APR-2017

Project Guide:

Chairperson:

Declaration

I declare that this written submission represents my own ideas and where other's ideas or words have been used, I have adequately cited and referenced the original sources. I also declare that I have adhered to all the principles of academic honesty and integrity and have not misrepresented or fabricated or falsified any ideas/source/fact in my submission. I understand any violation of the above will be the cause for a disciplinary action by the institute and can also issue penal action from the sources which has been thus not been properly cited or from whom proper permission has not been taken where required.

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Acknowledgement

I take this opportunity to thank the entire Industrial Design department for the success of the project.

I express my gratitude to my guide- Prof V. P. Bapat for his consistent support and faith in the project and on me. The learnings from the project has been immense. I am thankful to all the Product Design Professors and Studio Assistants for helping me in the various phase of designing.

I am grateful to Dr. Hemant Bhansali, Dr. Rupesh Ghyar & Dr. Trimbak Kawdikar from BETiC Lab, IIT Bombay and my fellow designers for contributing their valuable insights to this project.

Design Brief

To design a suturing device as a part of first aid tool kit which will be easy to carry and be usable by paramedics in emergency scenarios.

Objective

This project aims to design and developed a device which will aid in suturing of a wound using various sizes of standard needles. The device will be easy to use/operate, proper ergonomics and visual clarity while operating and simplified mechanism over the existing one.

Abstract

In medical area, suturing is the joining of tissues with needle and “thread,” so that the tissues bind together and heal. The “thread” is actually specialised suture material.

Dr Hemant Bhansali (Laparoscopic Surgeon from Nanavati Hospital, Mumbai) and Dr Rupesh Ghyar (Chief Scientist BETiC, OrthoCAD Lab, IIT Bombay) have already developed & patented an Auto-suturing device. During this project the problems related to functionality and usability were resolved.

A simpler suturing device was developed, which can be used by surgeons as well as even paramedics with reduced cognitive load resulting into ideal suturing.

The final output of the project is in the form of a full-scale model and the working has been shown in the SolidWorks software with rendered animation.

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01
Research

Introduction to Suturing

The primary goal of suturing is to approximate (bring together the wound margins) and to eliminate dead space between wound walls and edges so that underlying tissues are held together. Healing can only occur properly if the two severed areas of tissue meet properly and remain intact.

If dead space is not properly eliminated blood may pool in the wound leading to hematoma and consequently wound strength will be compromised, and thus the risk of infection will be increased. The secondary goal of suturing is minimizing scar tissue formation. Both proper healing and minimal scarring are achieved by accomplishing two main objectives.

The second objective is to achieve the best wound edge approximation. This is the process of ensuring that edges are brought together as evenly as possible during suturing. Eliminating dead space and achieving wound edge eversion and approximation are key elements for the proper healing and minimal scarring of a sutured wound.

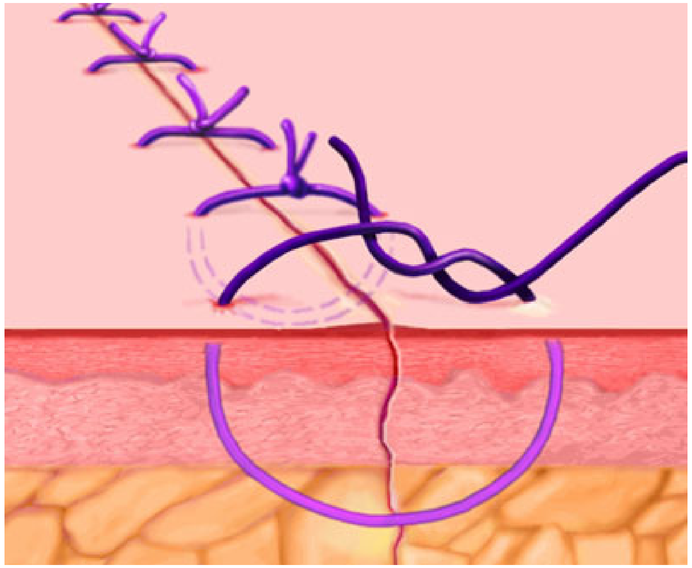


Figure 1.1 : Simple Suture
Reference: http://sutures.in/blog/what-are-continuous-sutures-and-itstypes/

The suture needles, materials, and techniques selected are at the discretion of the surgeon or medical professional assessing the wound since various types of techniques can produce different end results. The medical professional will select the appropriate needle, suture material, and suture technique depending on whether or not they want to achieve deep tissue dead space closure, lesser or greater wound tensile strength, less scarring, ease of application or care, etc.

Keep in mind that new non-suturing closure methods are being developed that may be used as alternatives to suturing closure methods.

Non-suturing methods are in some situations better options than traditional suturing methods. New methods include absorbable staples, sterile strips, and topical adhesives which can be used in combination with applied suture techniques or alone. Again, the type of suture technique or method must be determined by the treating physician or medical professional with the goal of achieving optimal wound healing and minimal scarring.

Although the use of 'Steri-Strips' and 'suturing glue' is tempting it can only be used in very superficial wounds, otherwise one gets a void below the surface with associated problems like wound inversion, hematoma formation, wound infection, and wound dehiscence. It is tempting to use these shortcuts in the paediatric trauma patient, especially if under pressure while wanting to help a child in the emergency room. If in doubt rather suture properly under aesthetic and get a pleasing result.

Choosing the correct suturing Technique:

The main driver of choice of technique in suturing is the operator's/ surgeon's personal choice in a specific situation. He/she may gravitate to a specific technique, or combination of techniques, based on his/her knowledge of suturing techniques, suturing proficiency, availability of specific suturing materials like suturing thread and needles, and experience gathered over the years as well as what works best in his/her hands.

No specific technique fulfil the exact requirements of a specific would closure.

Refer figure 1.2.

Suture Materials

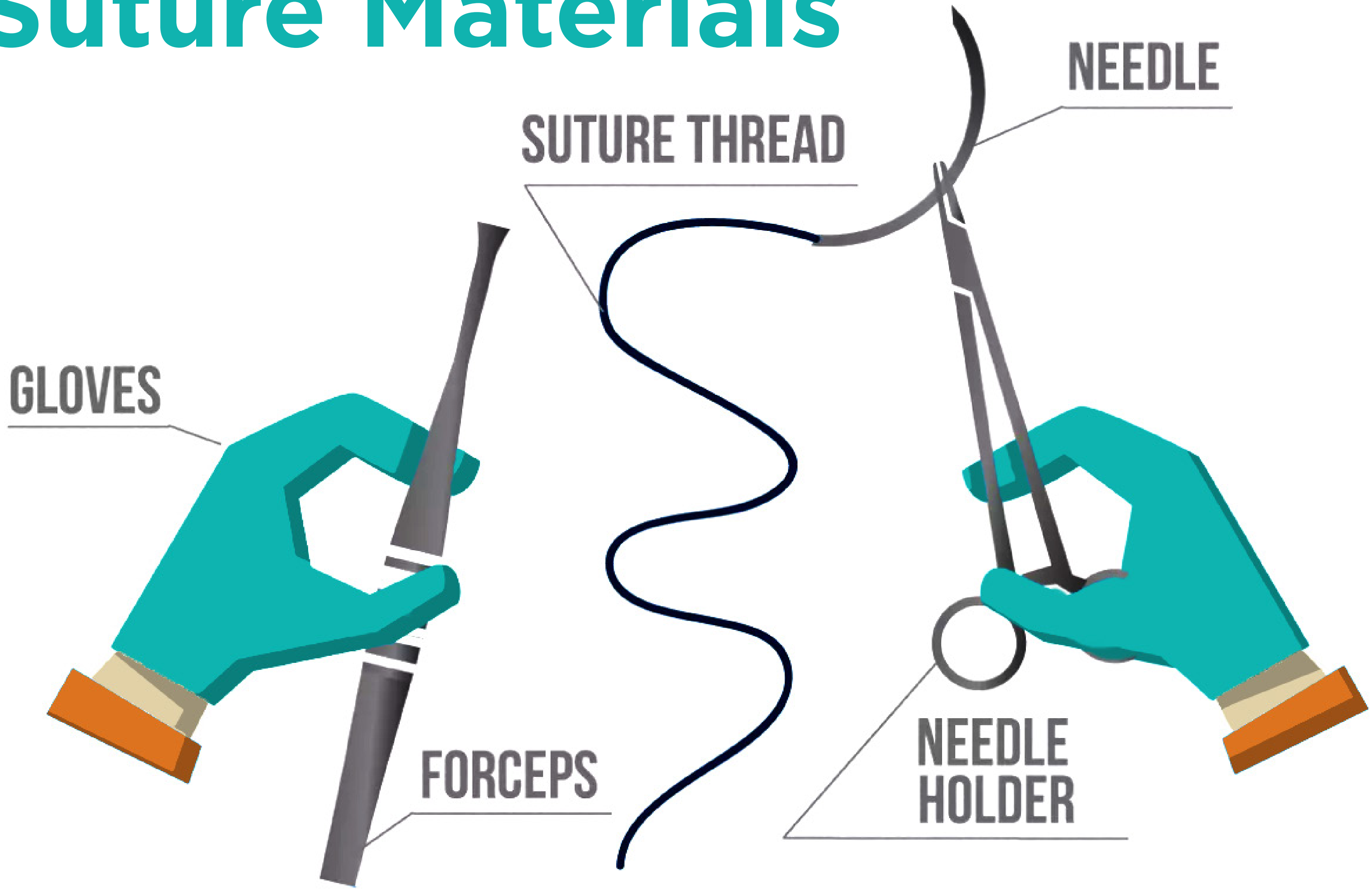


Figure 1.2 : General Suturing Materials
Reference: https://www.theapprenticedoctor.com/complete-guide-to-mastering-suturing-techniques/#tab-2

Needles

Eyed or reusable needles are needles with holes called eyes which are supplied separate from their suture thread. The suture must be threaded on site, as is done when sewing at home. The advantage of this is that any thread and needle combination is possible to suit the job at hand. Swaged, or atraumatic, needles with sutures comprise a pre-packed eyeless needle attached to a specific length of suture thread. The suture manufacturer swages the suture thread to the eyeless atraumatic needle at the factory. The chief advantage of this is that the doctor or the nurse does not have to spend time threading the suture on the needle, which may be difficult for very fine needles and sutures. Also, the suture end of a swaged needle is narrower than the needle body, eliminating drag from the thread attachment site. In eyed needles, the thread protrudes from the needle body on both sides, and at best causes drag. When passing through friable tissues, the eye needle and suture combination may thus traumatise tissues more than a swaged needle, hence the designation of the latter as "atraumatic".

There are several shapes of surgical needles. Refer figures 1.3, 1.4, 1.5.
These include:

- Straight
- 1/4 circle
- 3/8 circle
- 1/2 circle. Subtypes of this needle shape include, from larger to smaller size, CT, CT-1, CT-2 and CT-3.
- 5/8 circle
- Compound curve
- Half curved (also known as ski)
- Half curved at both ends of a straight segment (also known as canoe)

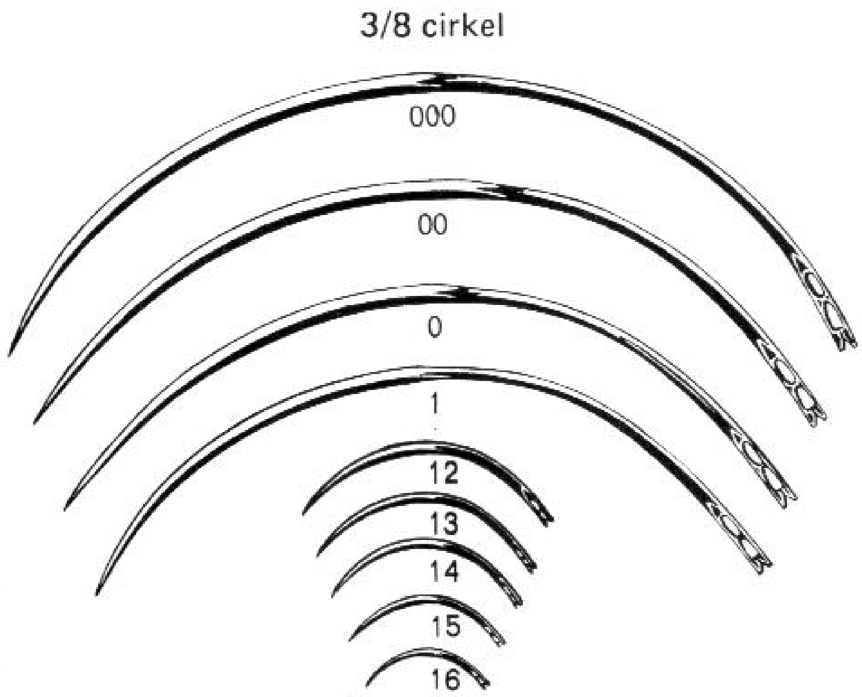


Figure 1.3 : Eyed surgical needles which form 3/8th of a circle, in different sizes
Reference: https://www.wikiwand.com/en/Surgical_suture

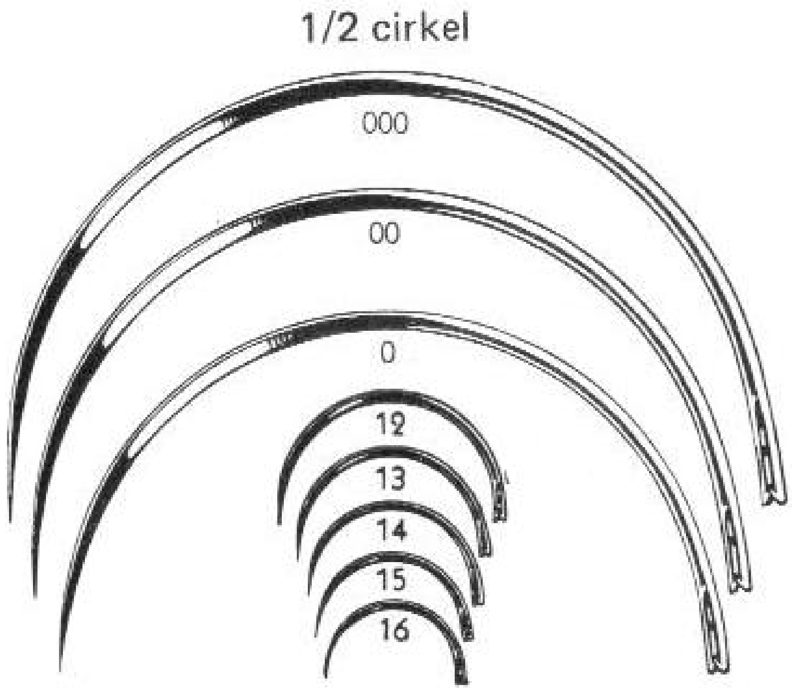


Figure 1.4 : Eyed surgical needles which are semicircular, in different sizes
Reference: https://www.wikiwand.com/en/Surgical_suture

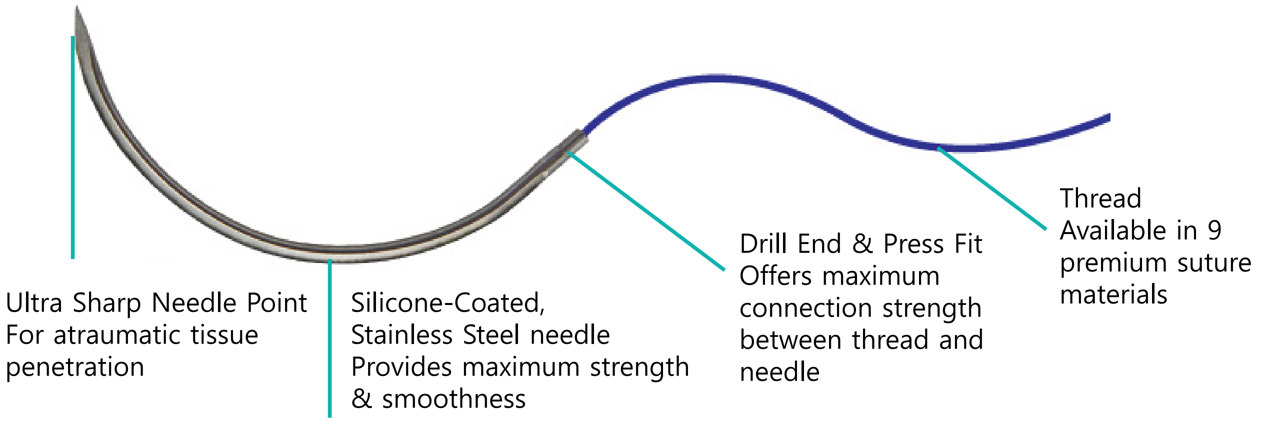


Figure 1.5 : Swaged needle
Reference: http://www.ad-surgical.com/medical_unify-sutures/

Thread

Materials

Suture thread is made from numerous materials. The original sutures were made from biological materials, such as catgut suture and silk. Most modern sutures are synthetic, including the absorbables polyglycolic acid, polylactic acid, Monocryl and polydioxanone as well as the non-absorbables nylon, polyester, PVDF and polypropylene. The FDA first approved triclosan-coated sutures in 2002; they have been shown to reduce the chances of wound infection. Sutures come in very specific sizes and may be either absorbable (naturally biodegradable in the body) or non-absorbable. Sutures must be strong enough to hold tissue securely but flexible enough to be knotted. They must be hypoallergenic and avoid the "wick effect" that would allow fluids and thus infection to penetrate the body along the suture tract.

Absorbability

All sutures are classified as either absorbables or non-absorbables depending on whether the body will naturally degrade and absorb the suture material over time. Absorbable suture materials include the original catgut as well as the newer synthetics polyglycolic acid, polylactic acid, polydioxanone, and caprolactone. Absorbable (or resolvable) medical devices such as sutures are made of polymers. The polymer materials are based on one or more of five cyclic monomers: glycolide, l-lactide, p-dioxanone, trimethylene carbonate and ε-caprolactone.

They are broken down by various processes including hydrolysis (polyglycolic acid) and proteolytic enzymatic degradation. Depending on the material, the process can be from ten days to eight weeks. They are used in patients who cannot return for suture removal, or in internal body tissues.

In both cases, they will hold the body tissues together long enough to allow healing, but will disintegrate so that they do not leave foreign material or require further procedures. Initially, there is a foreign body reaction to the material, which is transient. After complete resorption only connective tissue will remain. Occasionally, absorbable sutures can cause inflammation and be rejected by the body rather than absorbed. Non-absorbable sutures are made of special silk or the synthetics polypropylene, polyester or nylon. Stainless steel wires are commonly used in orthopedic surgery and for sternal closure in cardiac surgery. These may or may not have coatings to enhance their performance characteristics. Non-absorbable sutures are used either on skin wound closure, where the sutures can be removed after a few weeks, or in stressful internal environments where absorbable sutures will not suffice.

Sizes

Suture sizes are defined by the United States Pharmacopeia (U.S.P.). Sutures were originally manufactured ranging in size from #1 to #6, with #1 being the smallest. The manufacturing techniques, derived at the beginning from the production of musical strings, did not allow thinner diameters. As the procedures improved, #0 was added to the suture diameters, and later, thinner and thinner threads were manufactured, which were identified as #00 (#2-0 or #2/0) to #000000 (#6-0 or #6/0).

Modern sutures range from #5 (heavy braided suture for orthopaedics) to #11-0 (fine monofilament suture for ophthalmics). Atraumatic needles are manufactured in all shapes for most sizes. The actual diameter of thread for a given U.S.P. size differs depending on the suture material class.

USP designation	Collagen dia. (mm)	Synthetic absorbable dia. (mm)	Synthetic absorbable dia. (mm)	American wire gauge
11-0			0.01	
10-0	0.02	0.02	0.02	
9-0	0.03	0.03	0.03	
8-0	0.05	0.04	0.04	
7-0	0.07	0.05	0.05	
6-0	0.1	0.07	0.07	38–40
5-0	0.15	0.1	0.1	35–38
4-0	0.2	0.15	0.15	32–34
3-0	0.3	0.2	0.2	29–32
2-0	0.35	0.3	0.3	28
0	0.4	0.35	0.35	26–27
1	0.5	0.4	0.4	25–26
2	0.6	0.5	0.5	23–24
3	0.7	0.6	0.6	22
4	0.8	0.6	0.6	21–22
5		0.7	0.7	20–21
6				19–20
7				18

https://www.wikiwand.com/en/Surgical_suture

Suturing Techniques

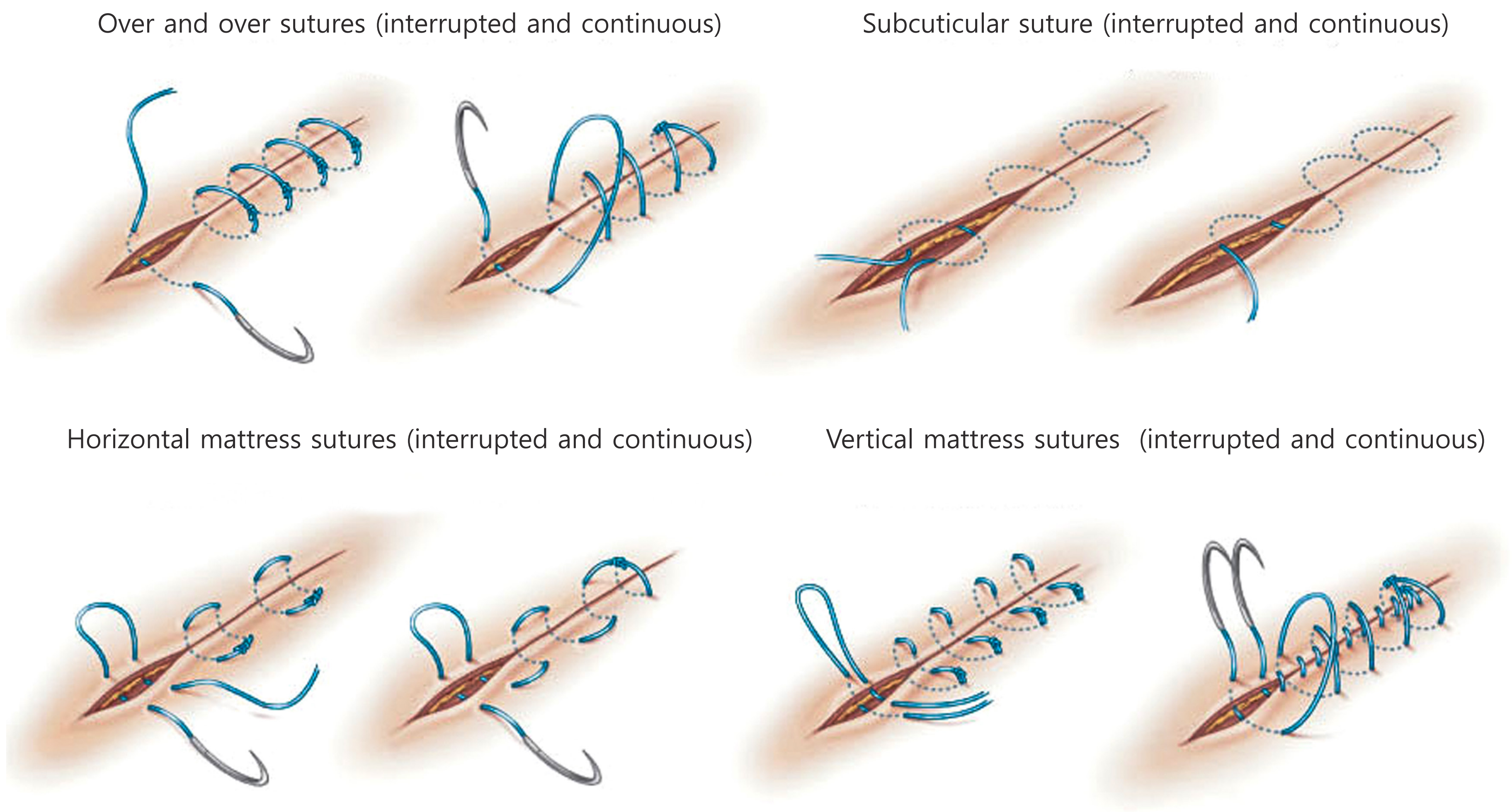


Figure 1.6 : Suturing Techniques, Image Source: Pinterest

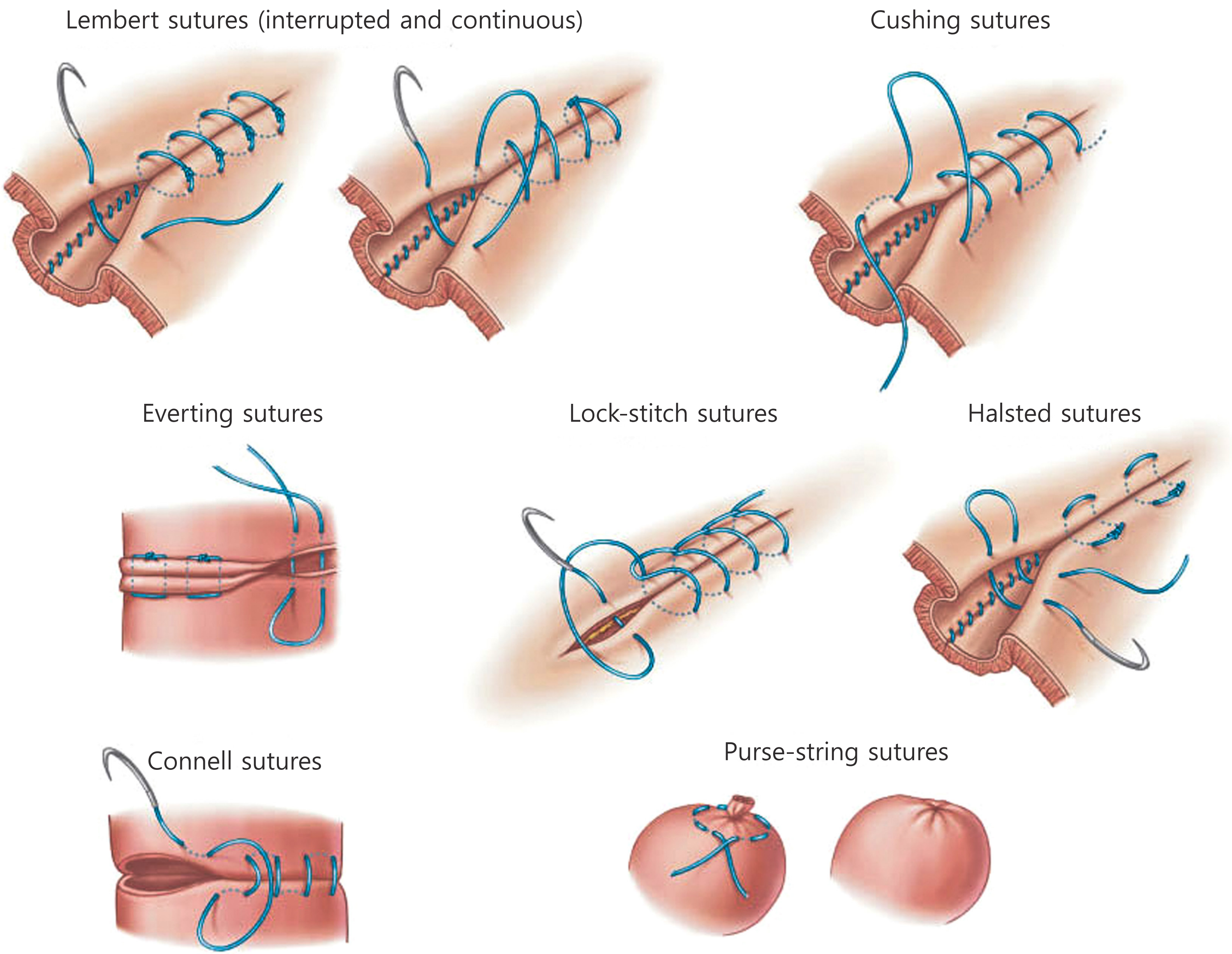


Figure 1.7 : Suturing Techniques Image Source: Pinterest

Other Suturing Techniques

Ligature Sutures

This technique is used to suture tubular structures such as blood vessels in order to stop bleeding or re-establish blood flow.

Horizontal Continuous Mattress Sutures

Certain anatomical areas for instance the retroauricular skin, are prone to wound inversion, and this is an indication for placing horizontal continuous mattress sutures.

Horizontal Half Buried Mattress or 3-Corner Sutures

The horizontal half buried mattress, or 3-corner suture, is used to close flapped or V-shaped wound edges. This technique is also used to better approximate edges of skin that of varying texture or thickness. Also, tissue ischemia is reduced by using the 3-corner suture.

Relaxation Sutures

This suture technique is used to when a wound is expected to create excessive tension. A relaxation suture allows for loosening if necessary in order to relieve such tension.

Quilting Sutures

This technique is effective at reducing the formation of seroma (swelling or lump in the underlying tissue due to serum accumulation in a localized area). A flap of skin is sutured using multiple stitches to the underlying tendinous expansion sheet (aponeurosis) that normally connects muscle tissue with its movable parts.

Retention Sutures

This technique is used to provide strong reinforcement of deep muscle and fasciae in the wall of the abdomen. Retention sutures lessen tension on the primary suture so that wound disruption is limited. The downside is that retention sutures often cause pain and severe discomfort to patients. According to one study, up to 50 percent of patients which received retention sutures required premature removal due to complaints of pain.

Frost Sutures

This suturing technique is used during surgeries of the eyelid. Frost sutures prevent the eyelid (mainly the lower eyelid) from turning outward, known as ectropion.

Double-arm Sutures or Cobbler's Sutures

This technique is preferred by some eye surgeons that desire to vertically or horizontally resect the rectus muscles. The double-arm suture is achieved by using a suture containing a needle at each end.

Issues with Ideal Suturing

S Seki (1987) of Okayama University of Japan described the precise and correct method of suturing in open surgery. He experimented extensively for understanding accuracy in open surgery suturing in restricted places. His investigations showed that refinement of surgeons' technique of operation is always ignored. He suggested that improvement of open surgery suturing technique is achievable by avoiding 4 restrictive issues. The first issue is associated with configuration of needle. Understanding the usable part of a ½ or 3/8th circle needle is very much essential. For a 3/8th circle needle, the span of needle is about 135^0. Therfore unless suture completes this span, it can not be called a good stitch. For ½ `circle needle, the suture needs to complete a span of 140^0.

The second issue deals with distance between exit or entry point of needle and span of a stitch. Ideal suturing was defined as advancing a needle along its curvature (needle circle) to minimize tissue trauma, while placing the suture with its intended span and tissue bite in the expected place. The points between entry and exit of needle are always determined by the size of the needle and the type of the tissue to be sutured.

The third issue he discusses how the needle should be held in the jaws of Needle Holder. The final issue he talks about is the movement of hand and hence needles though the tissue in either Roll-Pitch-Roll wrist configuration, or the Roll-Pitch-Yaw wrist configuration when the approach angle to the suturing surface is shallow.

Non-suturing methods

Surgical Staples

Stapling is much faster than suturing by hand, and also more accurate and consistent. Staples are primarily used in bowel and lung surgery, because staple lines are more consistent and therefore less likely to leak blood, air or bowel contents. Still, several randomized controlled trials have shown no significant difference in bowel leakage after anastomoses performed either manually with suture by experienced surgeons, or after mechanical anastomoses with staples. In skin closure, dermal adhesives (skin glues) are also an increasingly common alternative.

There is a significantly higher risk of developing a wound infection when the wound is closed with staples rather than sutures. This risk is specifically greater in patients who undergo hip surgery.

Adhesive Glue

Tissue glue is indicated for low tension wounds, or occasionally higher tension wounds that have been properly undermined and layered. Its advantages include speed of application for the clinician, painless application for the patient, and decreased tissue inflammatory response compared with sutures. Also, there is typically no need for a follow up visit unless complications with the wound occur. Skin glue can be used for children and adults.

Skin glue is usually used for simple cuts or wounds that:

- are small or minor
- are up to 5cm long
- have straight edges, which can be pulled together

Sterile Strips

Butterfly closures are adhesive bandage strips which can be used to close small wounds. They are applied across the laceration in a manner which pulls the skin on either side of the wound together. Butterfly closures may be used instead of sutures (stitches) in some injuries, because they lessen scarring and are easier to care for.

Figure 1.8 : Absorbable Staples
Reference: http://www.insorb.com/clinical/virtual_paper.html

Figure 1.9 : Dermabond Topical Skin adhesive
Reference: http://www.straconmed-supply.com/dermabond-pro-pen-box-6.html

Figure 1.10 : 3M Nexcare™ Steri-Strips
Reference: http://www.conrad.ch/ce/de/product/779121/3M-Nex-care-Steri-Strips-Wundverschlussstreif-en-YP202700008

Existing Devices & Patents

Covidien's V-Loc(TM) knotless suturing device

Covidien introduced the SILS™ Stitch Articulating Suturing instrument and is claimed to be most advanced endoscopic automated suturing device. Along with the automated functions of the current Endo Stitch™ instrument, it can rotate 360 deg. However, the biggest disadvantage being the use of T shaped specialised needle which are very thick and can damage the delicate tissue.

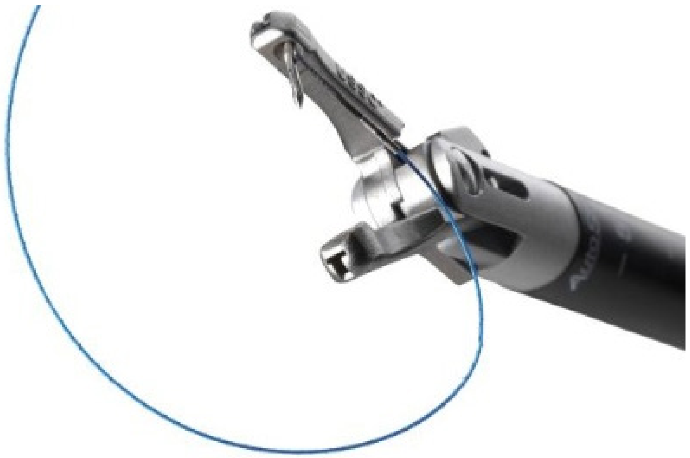


Figure 1.11 : Covidien's V-Loc(TM) knotless suturing device
Reference: https://goo.gl/bkf55X

SuturTek Endo 360

Covidien introduced the SILS™ Stitch Articulating Suturing instrument and is claimed to be most advanced endoscopic automated suturing device. Along with the automated functions of the current Endo Stitch™ instrument, it can rotate 360 deg. However, the biggest disadvantage being the use of T shaped specialised needle which are very thick and can damage the delicate tissue.

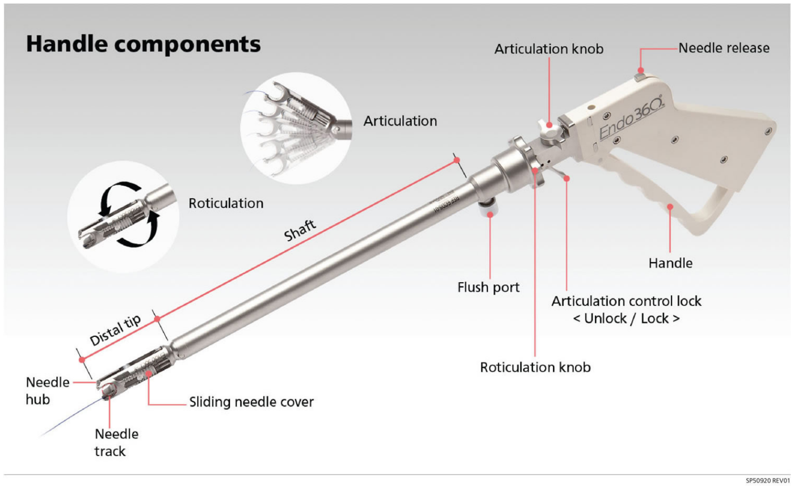


Figure 1.12 : SuturTek Endo 360
Reference: http://endoevolution.com/endo360/technology/

Patent : US 7048748 B1 By Uestuener Emin Tuncay

The product is used for suturing and tying interrupted knots but cannot be used for continuous suturing.

Patent : US4373530 by Lisa Ann Kilejian

The author describes a surgical stitching instrument of forceps-like construction having a pair of arms pivotally interconnected for movement about an axis and respectively terminating in a suture holder which has a needle receiving slot and notches on opposite sides of the slot adapted to receive a suture disposed across the slot .However, the suturing is Not as described by S Saki to be perfect.

Patent : US 4841888 A by Timothy N. Mills, Christopher P. Swain

It describs a sewing machine for forming stitches in a substrate, for example, in forming stitches in tissue during surgery, comprises a needle for passing thread into the substrate from one side thereof at a first location and for withdrawing the thread from the substrate at a second location spaced from the first location. The needle is removably operable solely from the said one side of the substrate. However, the machine like cloth sewing machine uses a thick special and fixed needle.

Current Device

This device is designed and developed by Dr. Hemant Bhansali and Dr. Rupesh Ghyar from BETiC OrthoCAD lab.

Figure 1.14 : Current Auto-Suturing Device

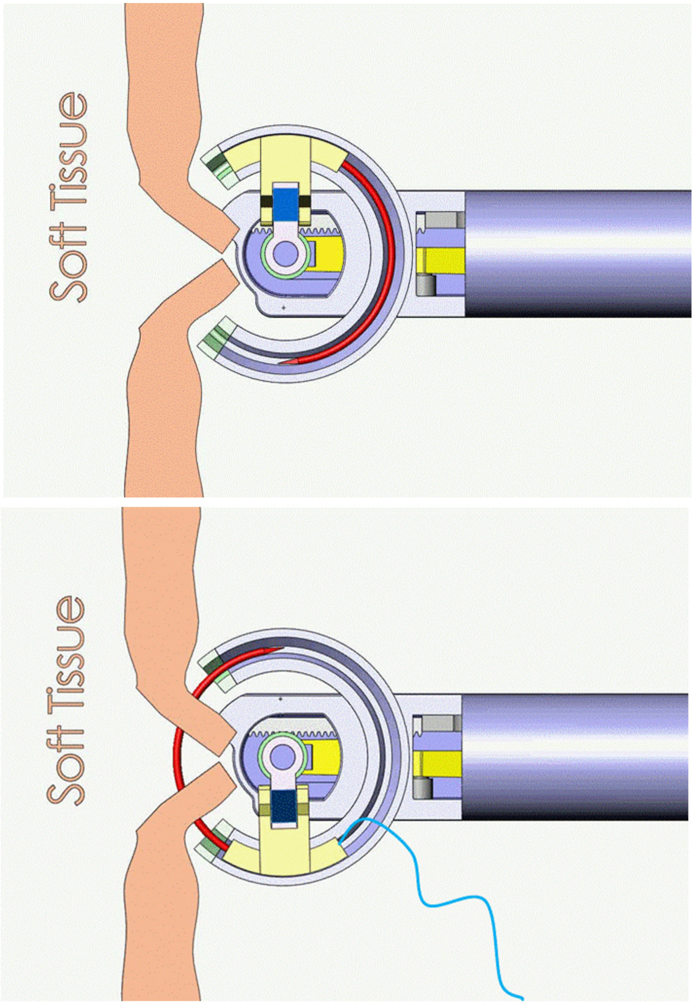


Figure 1.14 : Auto-Suturing Concept

Advantage

- Advantages
- Can be used on open injury
- Easy to operate
- Fast operation
- Saves time for suturing

Scope

- Whole new design approach if it has to work into emergency scenarios
- Usability and ergonomics
- Simplified mechanism
- Hold and move needle efficiently
- Thread positioning as it should not gets stuck in device itself
- Should keep control of needle all the time.
- Assembly-disassembly of needle can be simplify
- Consideration for knotting
- Material consideration
- Overall packaging of product

Nepal Earthquake

April 2015

Figure 1.15 : Nepal Earthquake,
Image Source http://www.belfasttelegraph.co.uk/news/world-news/nepal-earthquake-rescue-efforts-intensified-as-death-toll-crosses-2000-mark-31172101.html

After the research, I started with generating usage scenarios for the device developed by BETiC Lab so that ideas and concepts can be generated keeping these scenarios in mind and also the scenarios help make decision easier and faster. Few of them are listed below.

Scenario 1

Nepal Earthquake

The April 2015 Nepal earthquake (also known as the Gorkha earthquake) killed nearly 9,000 people and injured nearly 22,000.

Government and private hospitals were overwhelmed by the rush of patients, and running out of emergency supplies and space to store corpses.

Paramedics were dealing mostly with fractures, cuts, head injuries and internal and external bleeding.
- Dr Sanjeev Tiwari at Tribhuban University Teaching Hospital.

In this senario many lives could have been saved if the paramedics were equipped with a simple suturing device.

Each year more than half a million people bleed to death following traffic accidents, combat wounds, and other severe trauma.

Military Operations

Figure 1.16 : Military Operations, Image Source Google

Scenario 2

Military Operations

A new study finds that nearly a quarter of the 4,596 combat deaths in Iraq and Afghanistan between 2001 and 2011 were "potentially survivable," meaning that under ideal conditions — and with the right equipment or latest medical techniques — the troops may have had a fighting chance.

The study showed that uncontrolled blood loss was the leading cause of death in 90 percent of the potentially survivable battlefield cases and in 80 percent of those who died in a military treatment facility.

In this scenario many lives could have been saved if the paramedics were equipped with a simple suturing device which would be quick and easy to use. Traditional Suturing techniques are slow and requires skilled person to operate. An auto suturing device can be a appropriate option in such situations.

02
Study

Video Study at Nanavati Hospital

To study suturing operation I went to Nanavati hospital. There I closely observed the clinical environment in operation theatre, how surgeons, doctors performs the suturing operation on different kind of wounds and also documented it with videography.
Dr. Bhansali taught the technicalities to follows while suturing as well as gave me a demo of how ideal suturing should be performed.
A Slow motion analysis is being carried out from the video shooting done while suturing operations.


Figure 2.1 : Dr. Bhansali and team performing a laparoscopic operation at Nanavati Hospital

Suturing small laceration

1) Surgeon holding the needle in right hand using needle holder.

2) Holding the cut skin with the help of forcep in left hand

3) Pulling the skin little bit to get a good view of needle bite

4) Entering needle in the tissue by following the curvature of needle.

5) Exiting needler from tissue

6) Pulling the thread out from the tissue.

7) Tying the Knot using forcep

8) Cutting the thread using scissor

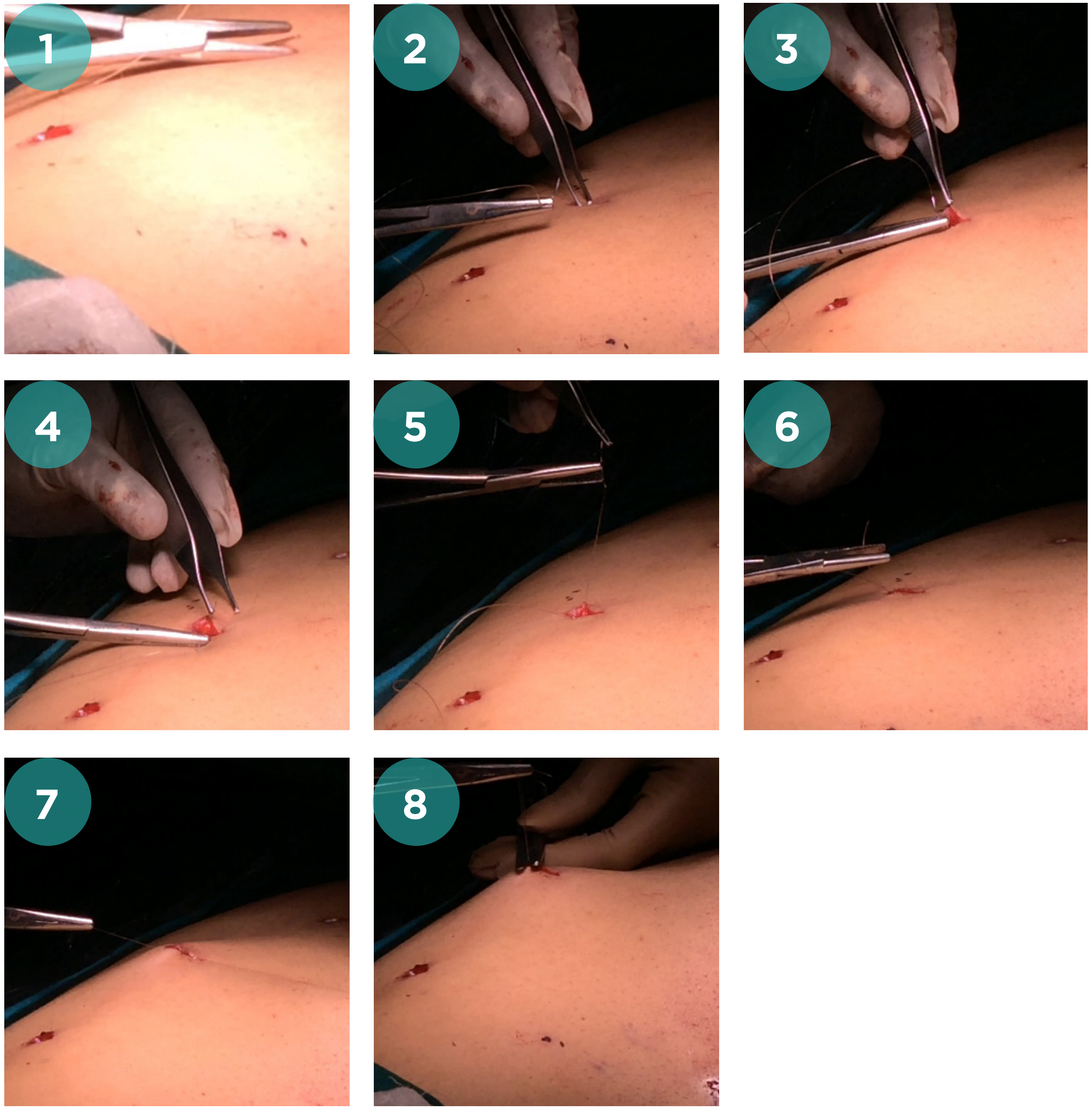


Figure 2.2 : Suturing small laceration

Suturing big wound

1) Surgeon holding the needle in right hand using needle holder.

2) Pressing the skin are to take bite

3) Entering needle in the tissue by following the curvature of needle.

4) Exiting needler from tissue

6) Pulling the thread out from the tissue.

7) Clipping forcep to the thread for later use

8) Cutting the thread using scissor at the end of operation

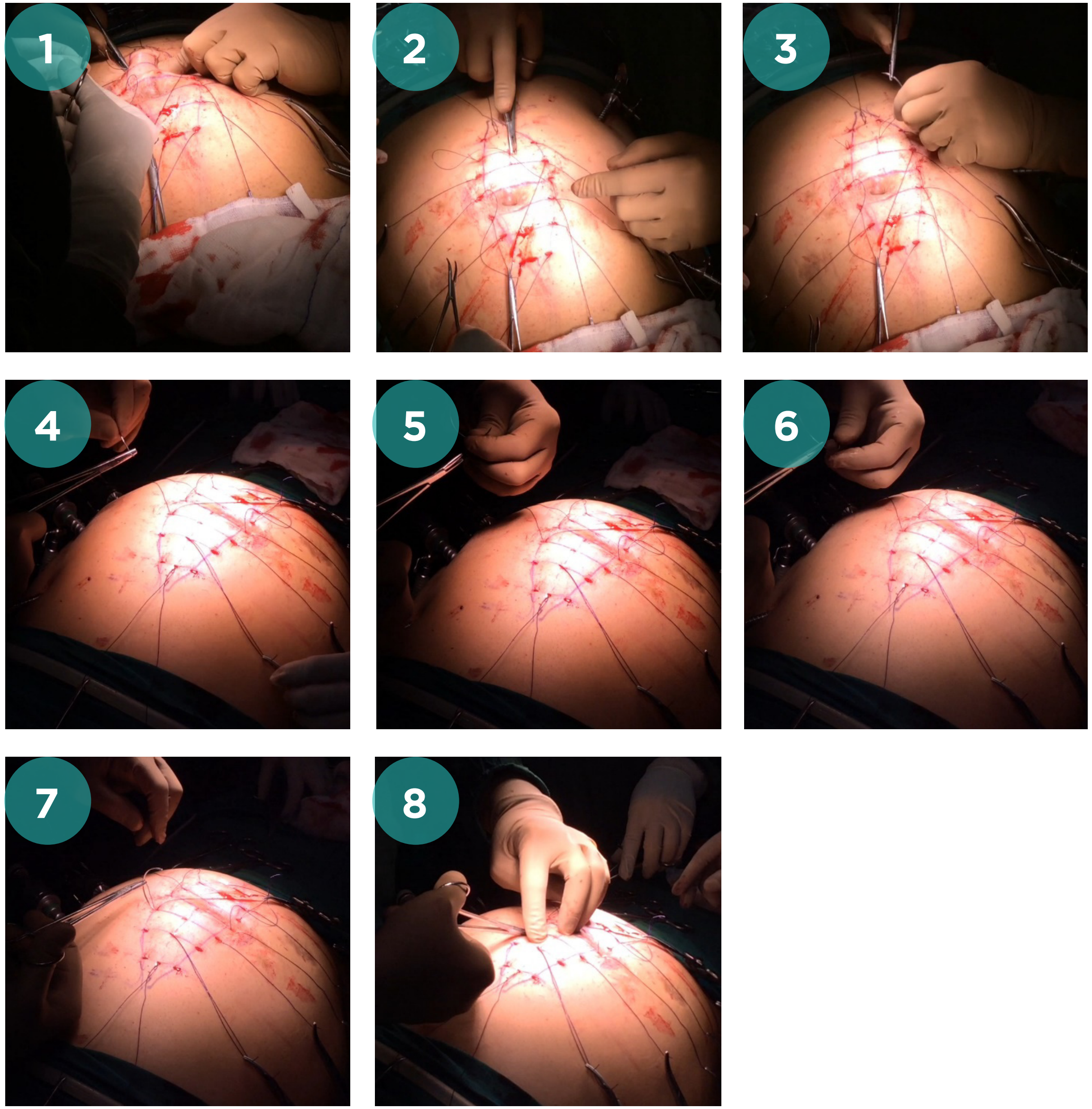
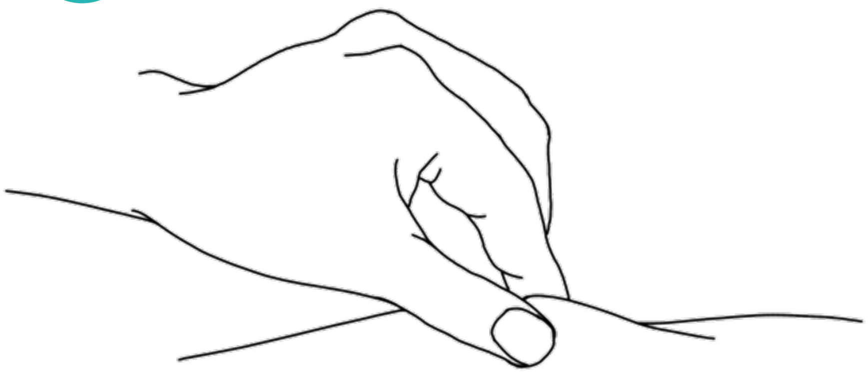


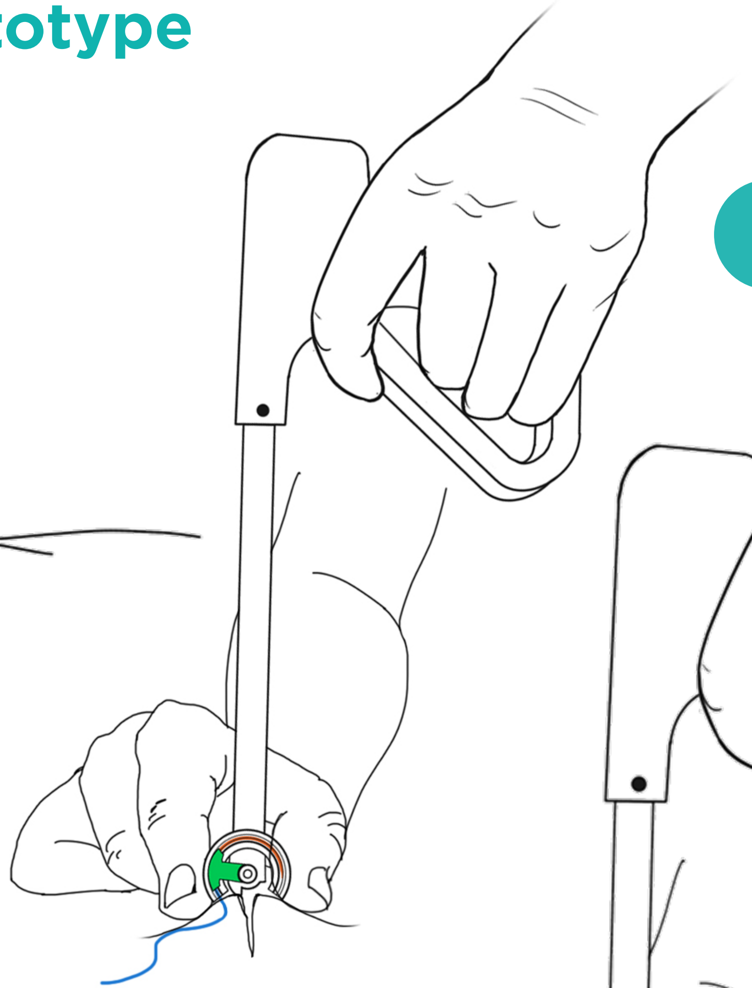
Figure 2.3 : Suturing big wound

Micro Activity Analysis

using existing prototype

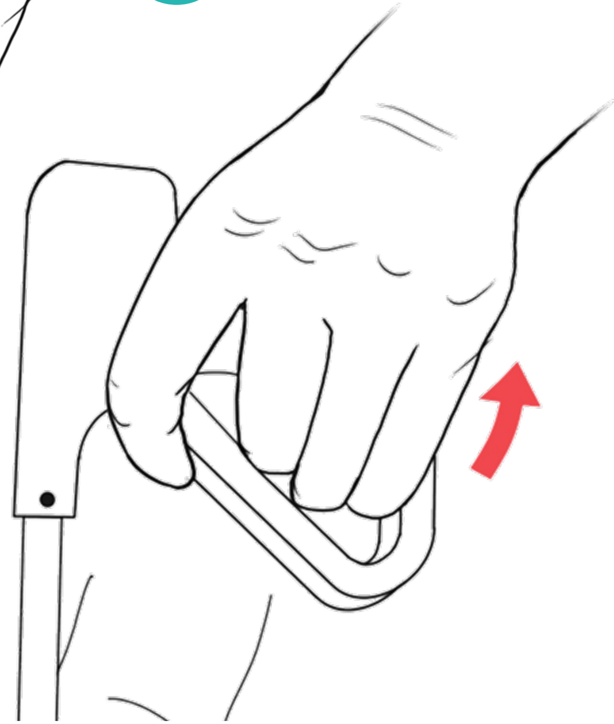
1 Pinching skin





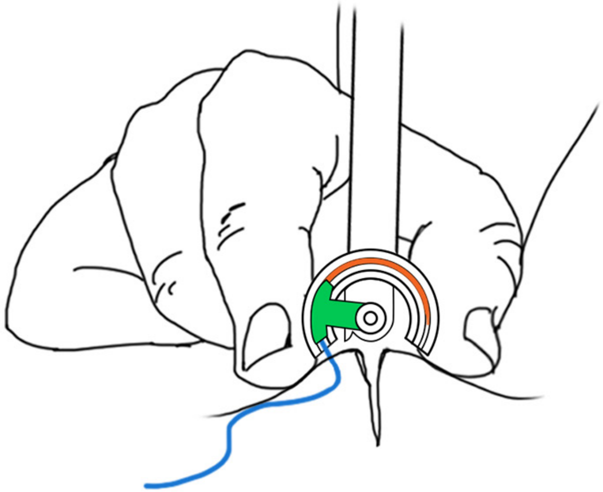
2 Placing over wound

3 Pull the lever



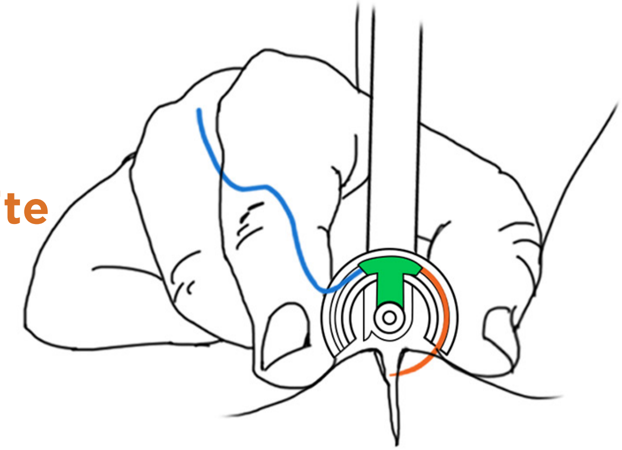
4

Grabbing needle



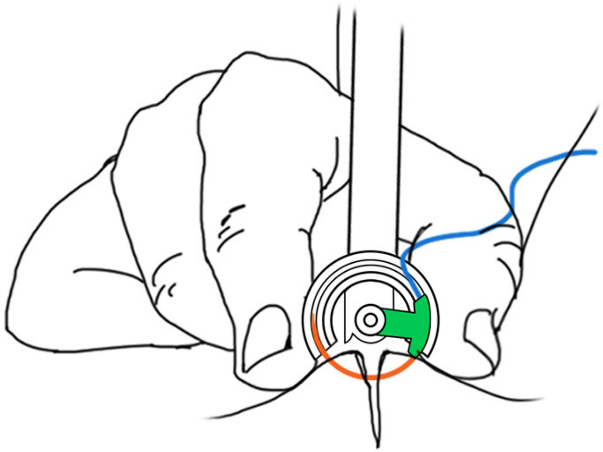
5

Taking bite



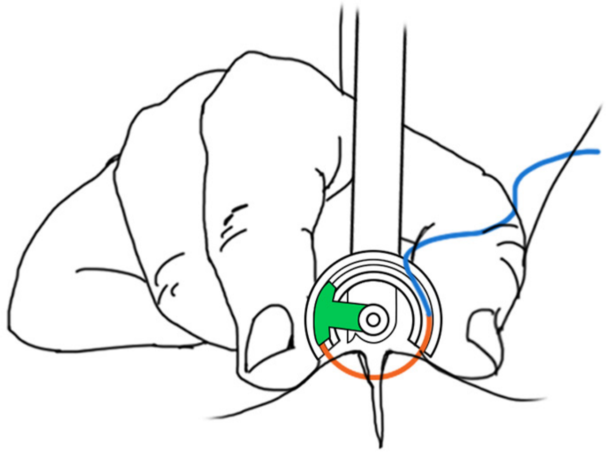
6

Exiting the tissue

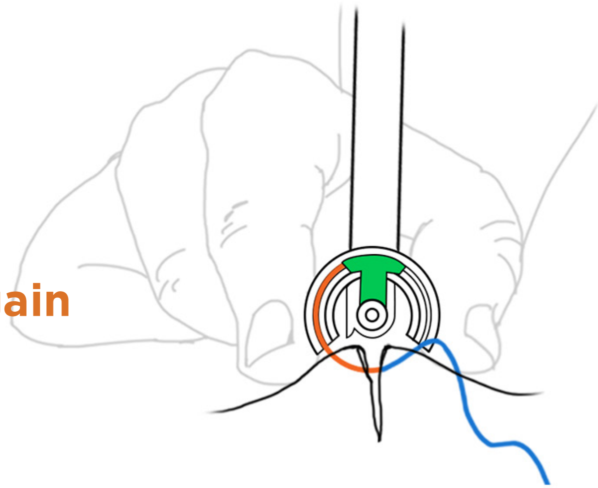


7

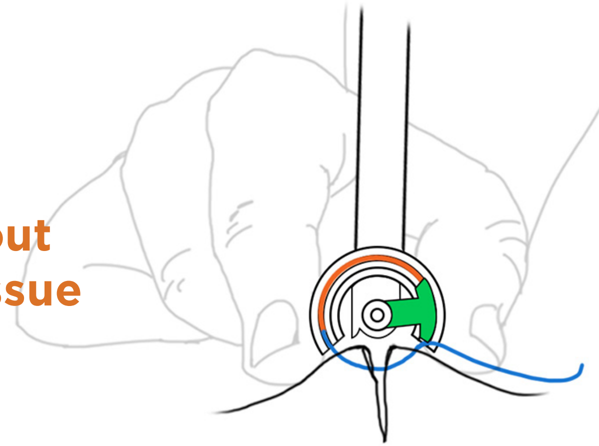
Grabber retracts



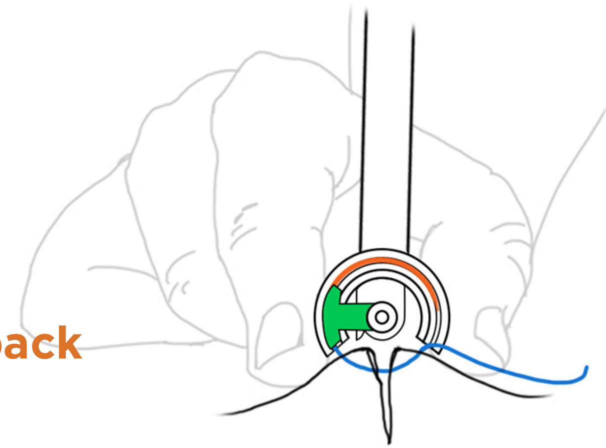
8
Graber rotates again



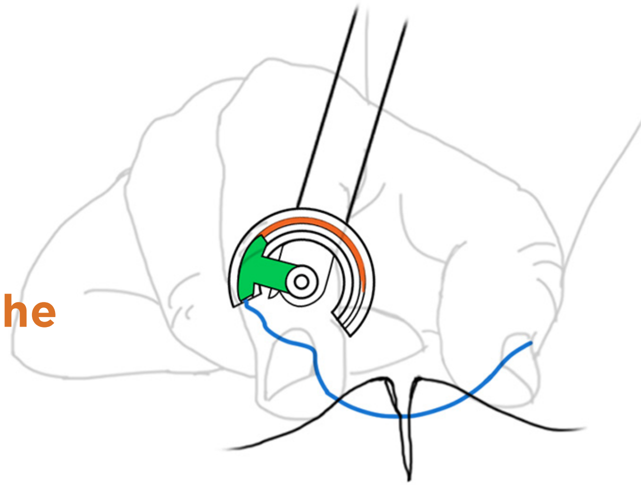
9
Needle out of the tissue



10
Grabber retracts back

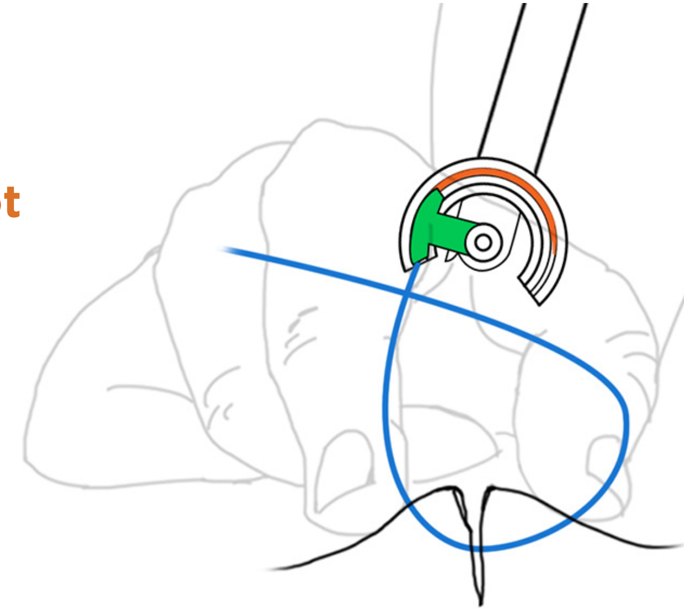


11
Pulling the thread



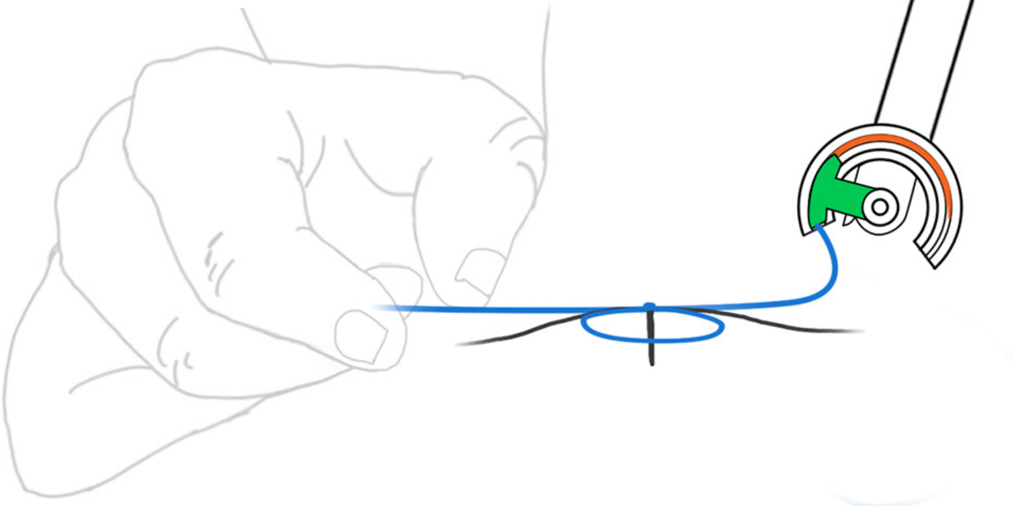
12

Tying knot



13

Pulling thread to complete knot



Understanding Users

To understand the problems of users while performing suturing operation, I met with few doctors included from beginner to the expert in suturing. I interviewed as well as learnt from them about the ways of suturing, problems occurs while performing certain actions and other aspect of wound healing. I proposed the idea of automatic suturing to them and got many different views on the same. Following are few of the insights from them:

Dr. Hemant Bhansali:
Suturing is very common task that a surgeon or doctors has to perform while operation. Most of the doctors don't know the ideal way of suturing from holding the needle, taking bite, moving the needle in accurate curved path to knotting the thread. There is a certain amount of cognitive load on surgeon while performing the task which affects how good the suturing has been done.
If the device can perform the operation in a ideal way eliminating manual errors and cognitive load, then it will become easy for surgeons, doctors, paramedics or even combat solders to perform suturing. This will also decrease the time taken of suturing considerably.

Dr. Trimbak Kawdikar:
The device should be easy to operate eliminating number of buttons. Also while using it user should get maximum stability of hands which will depend upon the ergonomics of the device. With the current device one has to lift his arm and position the device over the wound without touching in. This overhand of arm results into fatigue which has to be avoided.

Dr. Vivek Salvi:
(After seeing the current version of Auto-suturing device developed by BETiC Lab) This device can be used on superficial wounds, mostly head injury, laceration or surgical incision.

Dr. Piyush Singh:
The depth of bite taken by needle has to taken into consideration while performing the suturing with the device.

Insight from IIT Hospital:
Paramedics usually don't perform suturing. For them if required, the device has to be easy to use and very intuitive and hassle free.

Characteristics of Final Product

- The product must full fill the design requirements, It should make the process of suturing very easy.
- The time required from suturing operation should be less.
- It should use the standard swaged needle. Any changes in the needle design should be avoided.
- Product design should be adaptable for semicircular and 3/8th of a circle needle sizes varying from dia 28 to 38mm
- The mechanism should ease the knotting of the thread.
- Multiple types of suturing techniques should be able to perform with it
- Easy to used by paramedics, surgeons or doctors.
- Easy to manufacture and assemble.
- Less exposed moving parts.
- Easy to sterilised.
- It has to be economical
- Product should be fitted properly into medical environment.

03
The Brief

Design Brief

To design a suturing device as a part of first aid tool kit which will be easy to carry and be usable by paramedics in emergency scenarios.

User Profile

Based on the research and the insights I got from the user study, I pin down to the user and product profile based on which the design brief was framed.

Use Environment:
Clinical environments or non-clinical environments, moving vehicles, on battle fields by paramedics.

Primary Users:
Paramedics, surgeons, doctors, physicians, nurses, nurse practitioners, physical and occupational therapists

Secondary Users
Device user populations also include the professionals who install and set up the devices and those who clean, maintain, repair, or reprocess them.

04

Concepts

Brainstorming

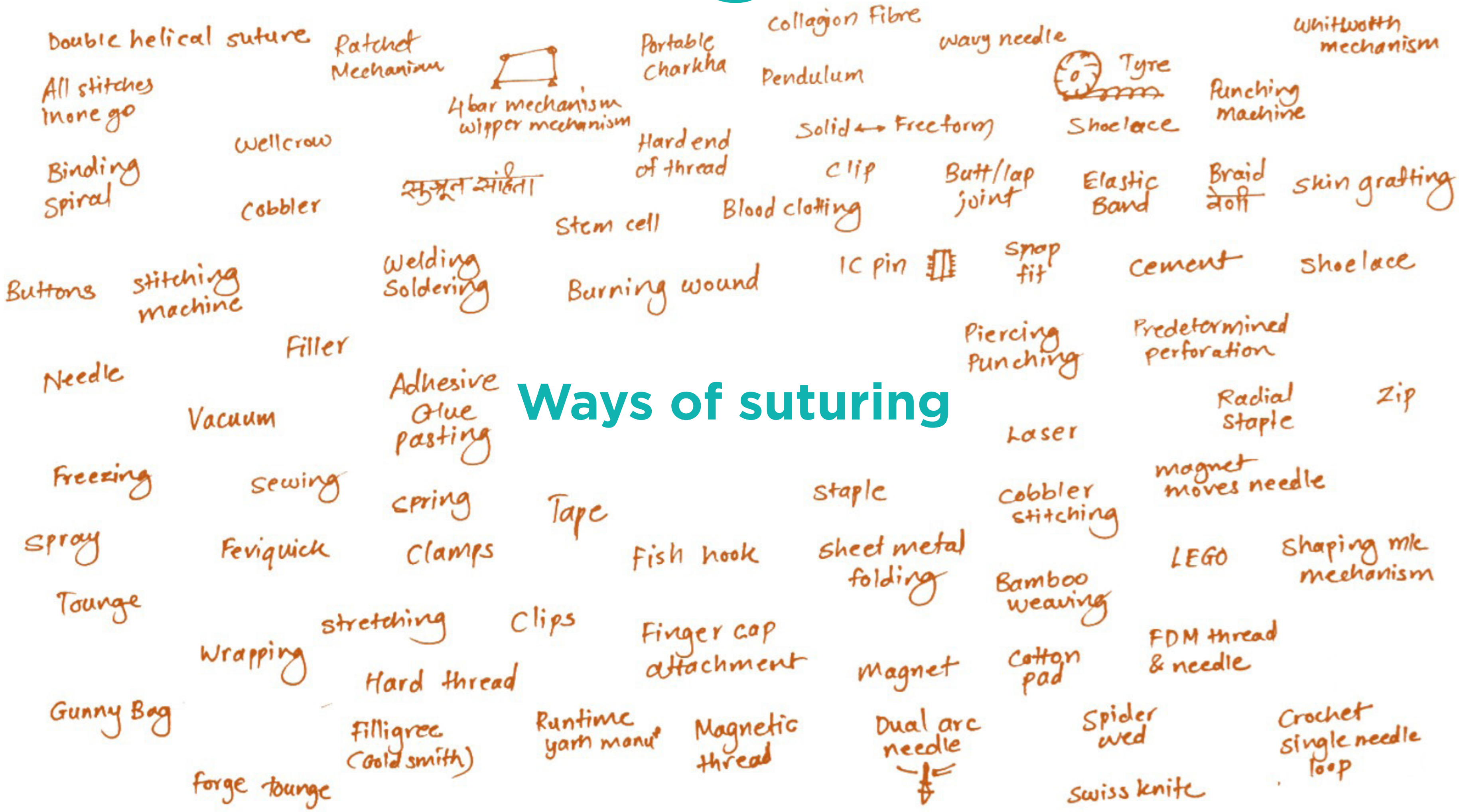


Figure 4.1 : Brainstorming 1

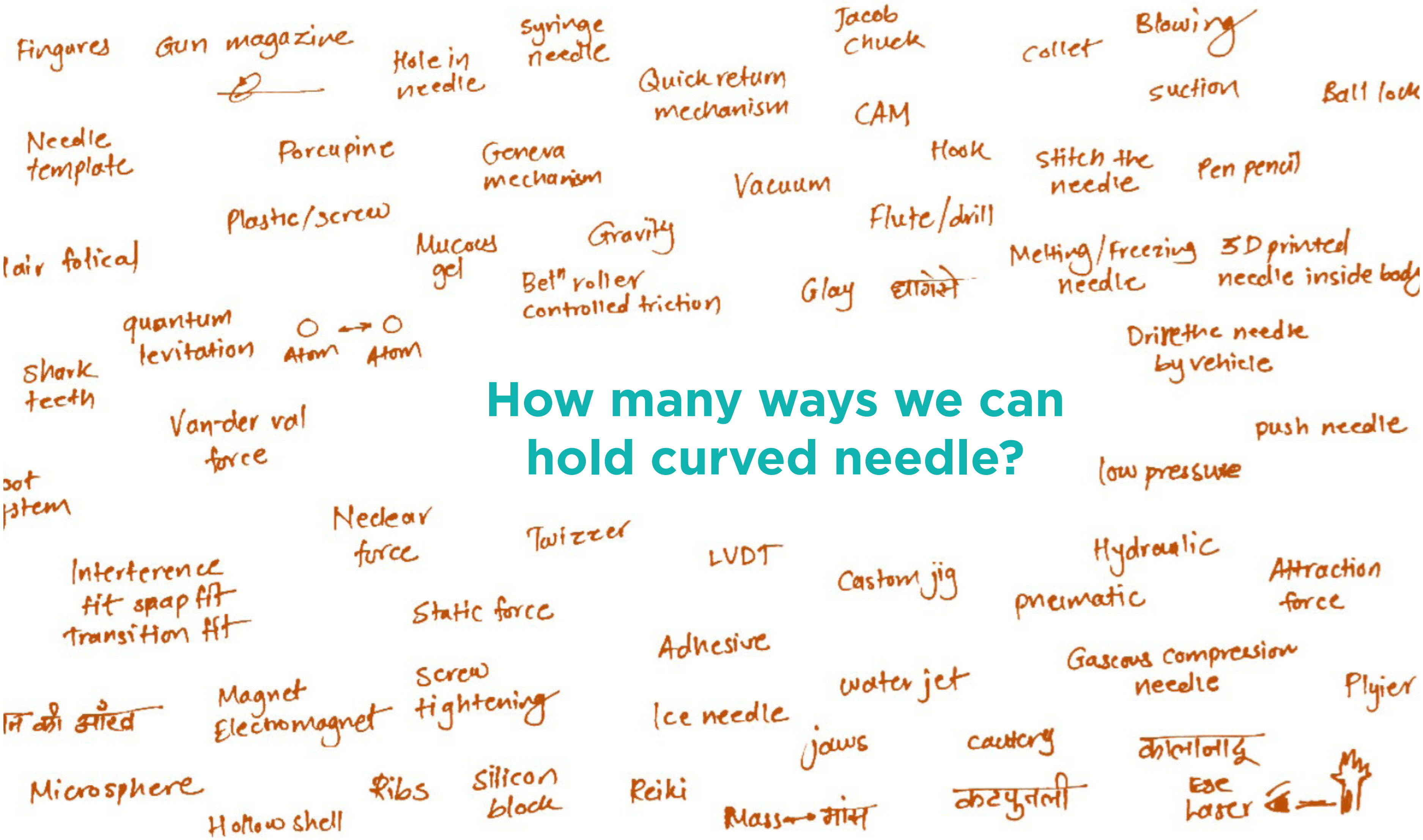
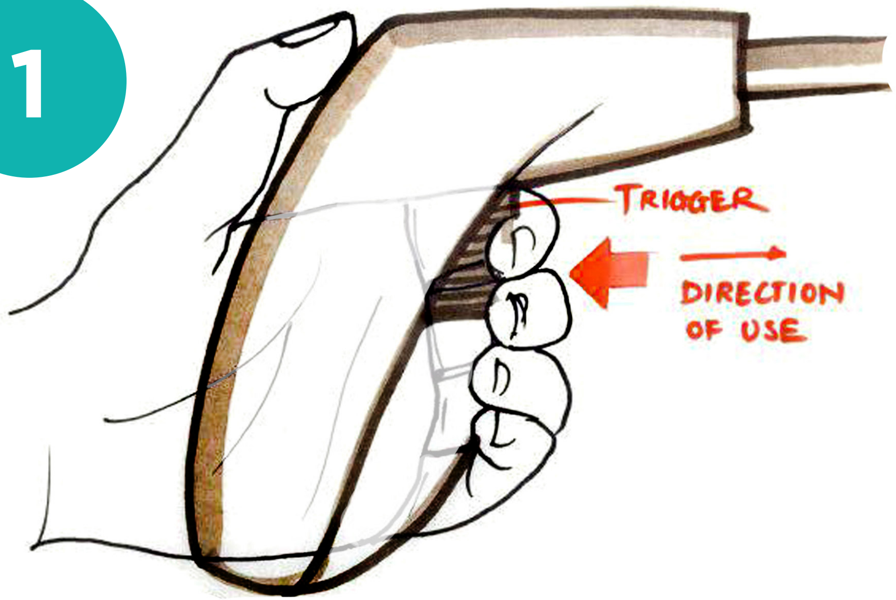


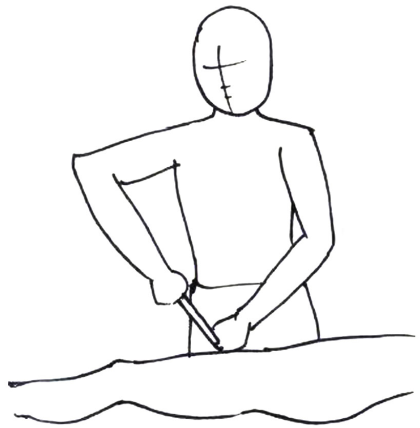
Figure 4.2 : Brainstorming 2

Initial Ideations

1



GUN-TRIGGER



2

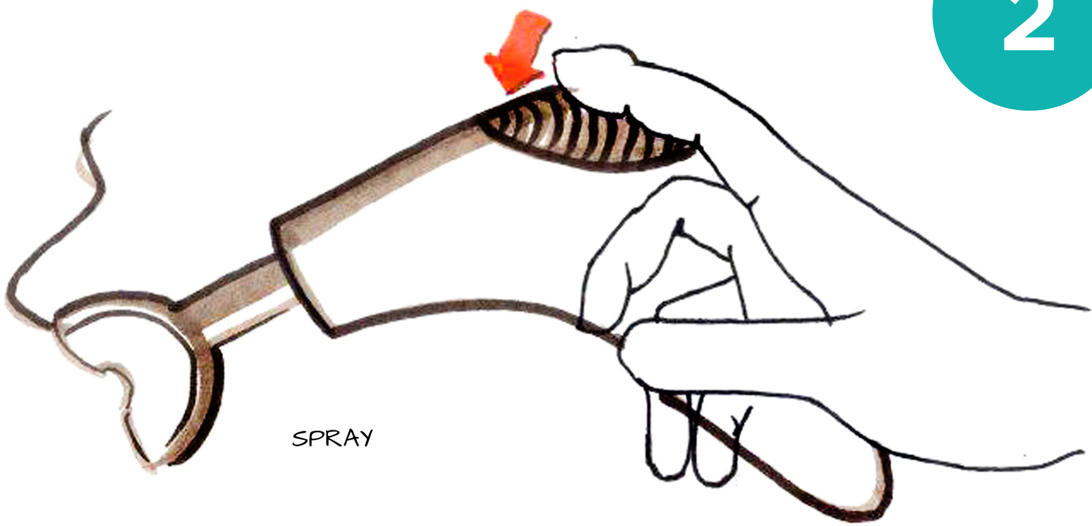
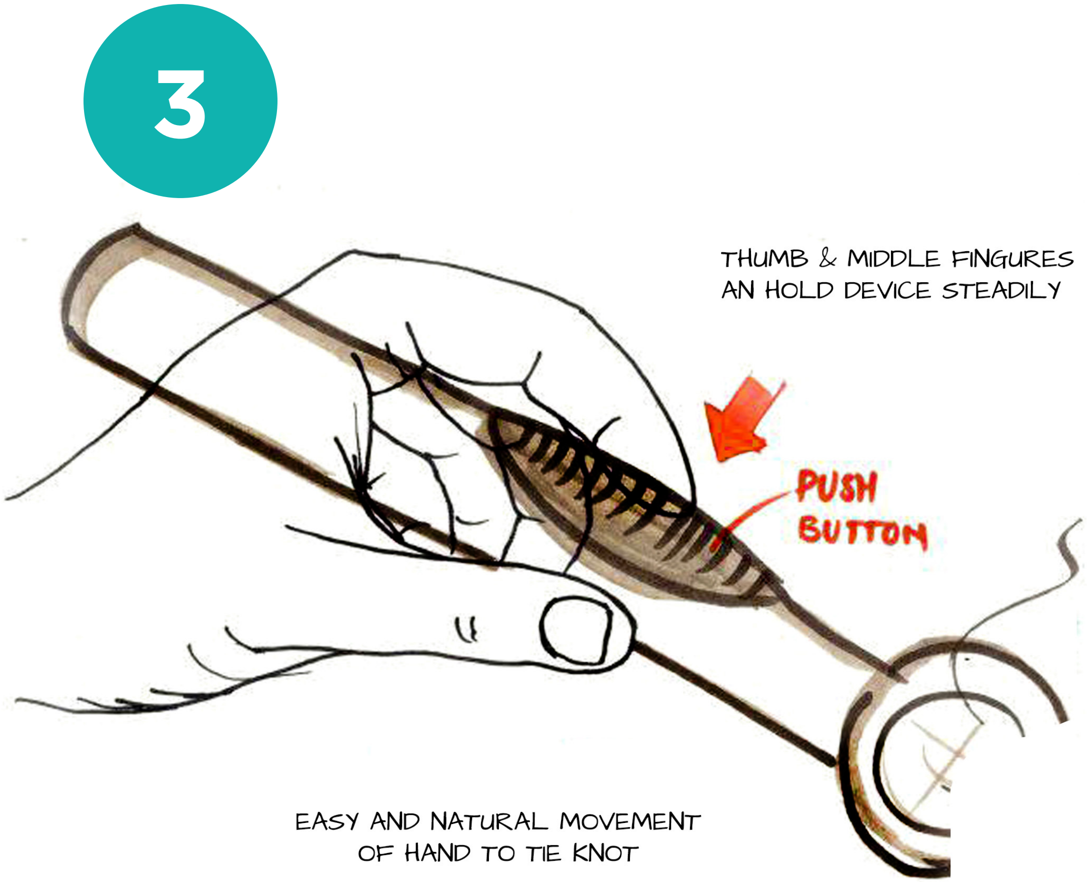
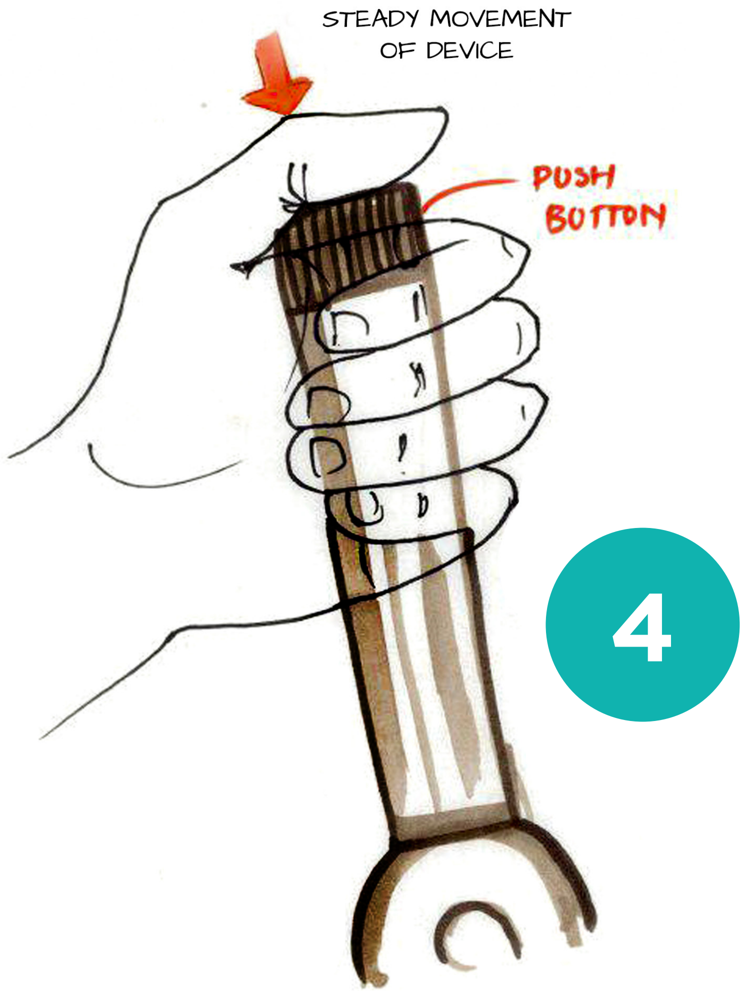


Figure 4.3 : Initial Ideation Sketches

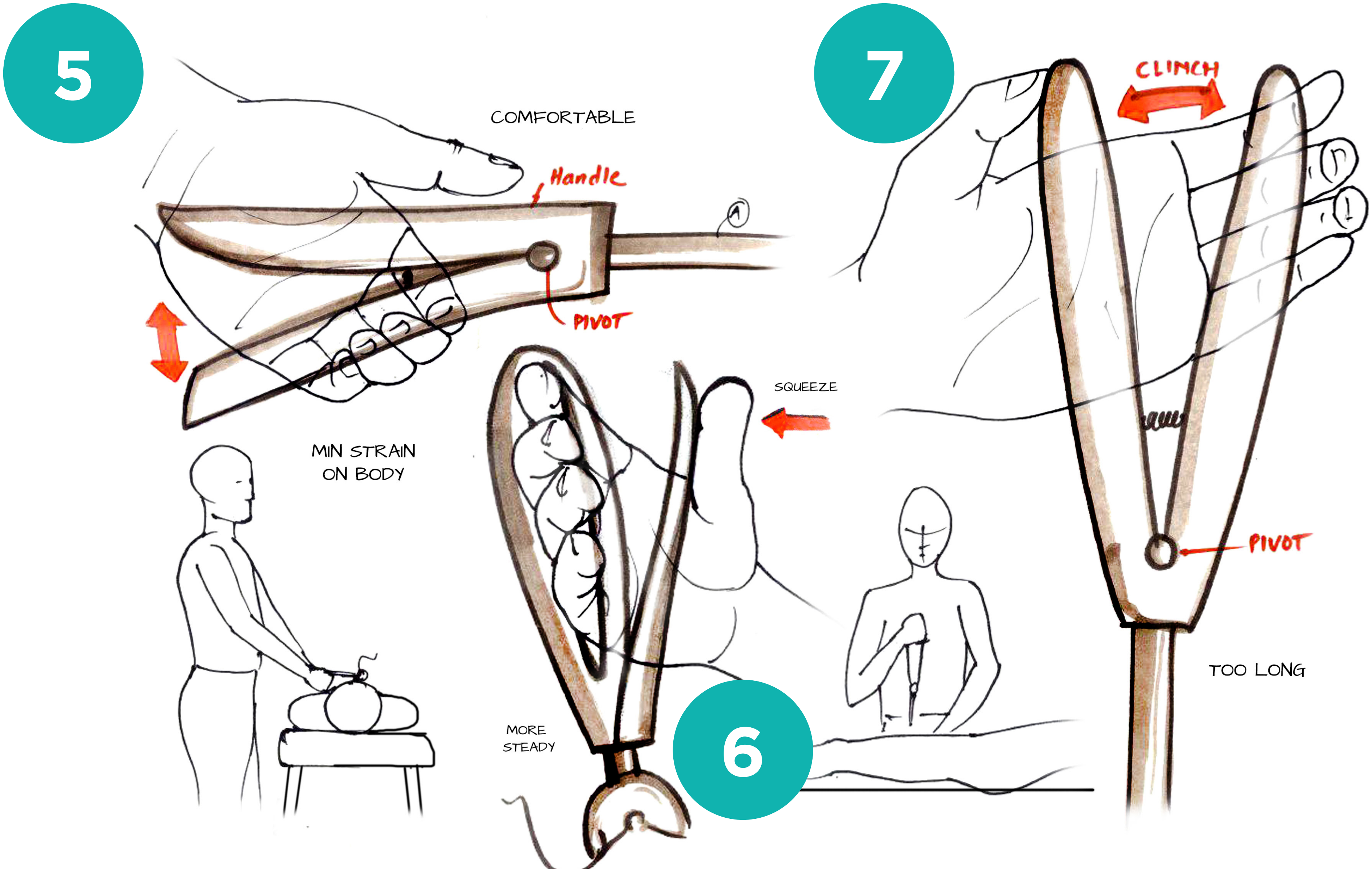
Ideation 1 and 2 propose a gun kind of concepts where the shape is angled in the middle. This allows user to grab one side and perform the operations with fingers.





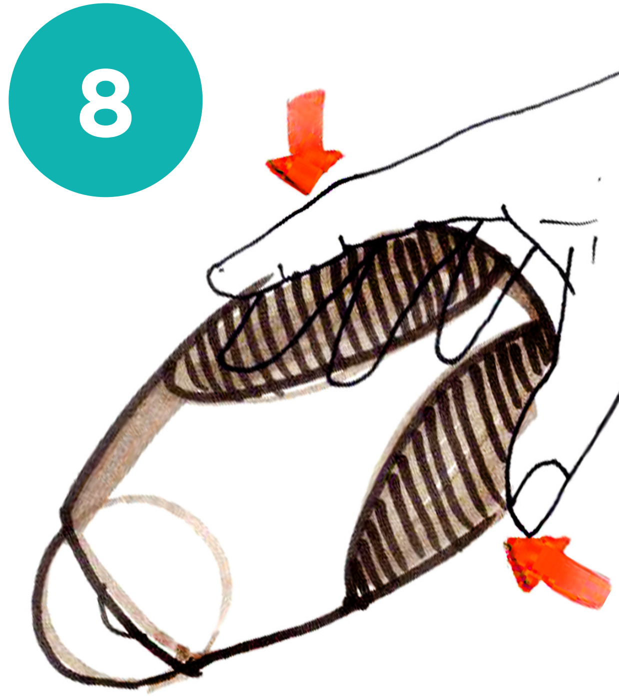
Ideation 3 and 4 proposes a pencil way of holding the device. This will give a natural way of using device with high precision. Option 3 will give natural inclined angle to the device which can be use to suture in zig-zag manner. Option 4 might loose the precision while pressing the button and will have to firmly grip the device to stay in position on top of the wound.

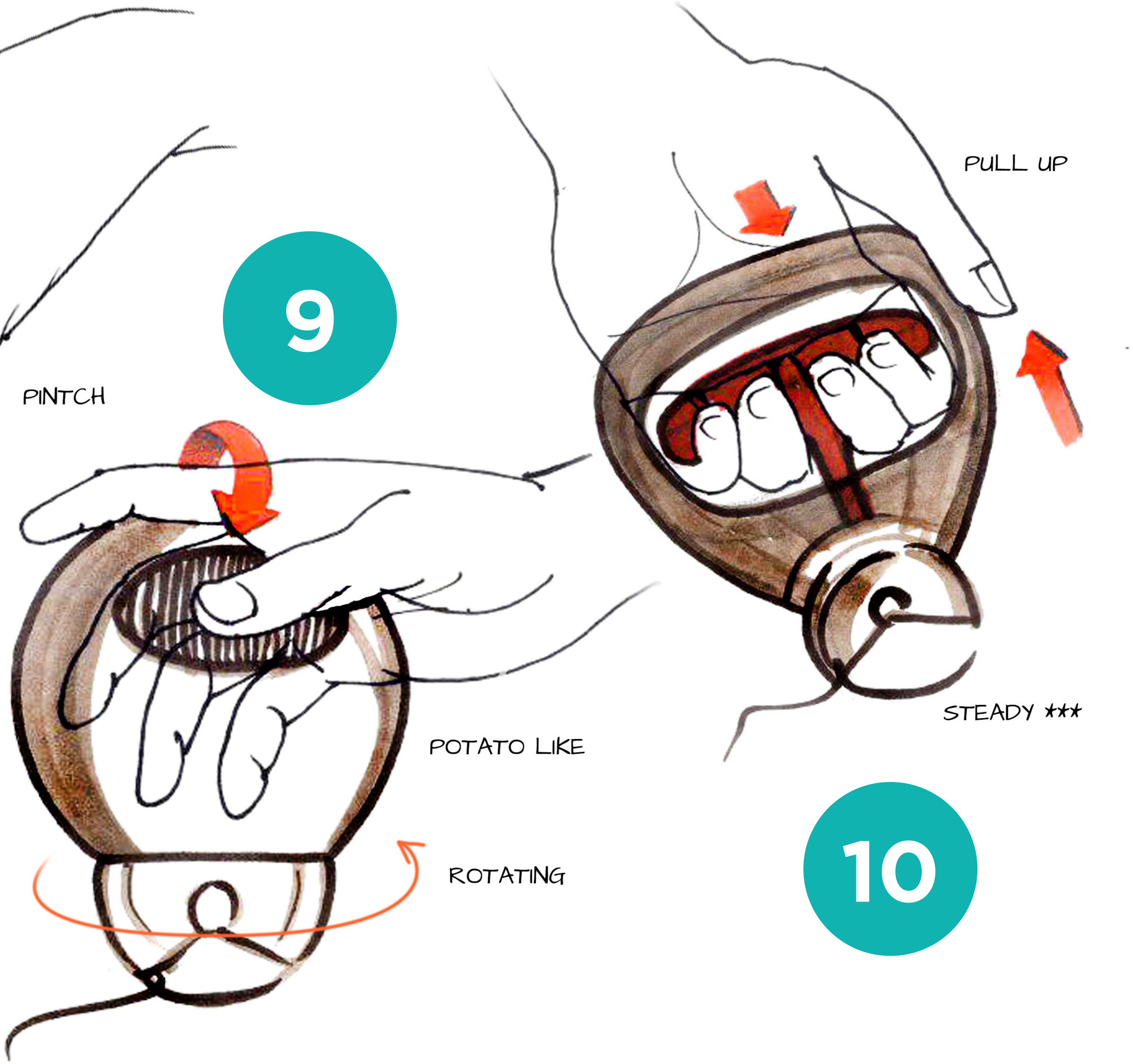
Figure 4.4 : Initial Ideation Sketches



Ideation 5, 6 and 7 proposes a scissor way of holding the device. The device can be used as same as one uses the scissor. This is less precise but can generate more force if required. Also user's arm won't be in suspended position from the body.

Figure 4.5 : Initial Ideation Sketches





Ideation 8, 9 and 10 proposes squeezing action to perform suturing. The device form factor has to be small to get good precision with this kind of action. From the point of view of being steady option 9 is the most preferable then 8 and 10 consecutively.

Figure 4.6 : Initial Ideation Sketches

Feedback on Initial Ideation

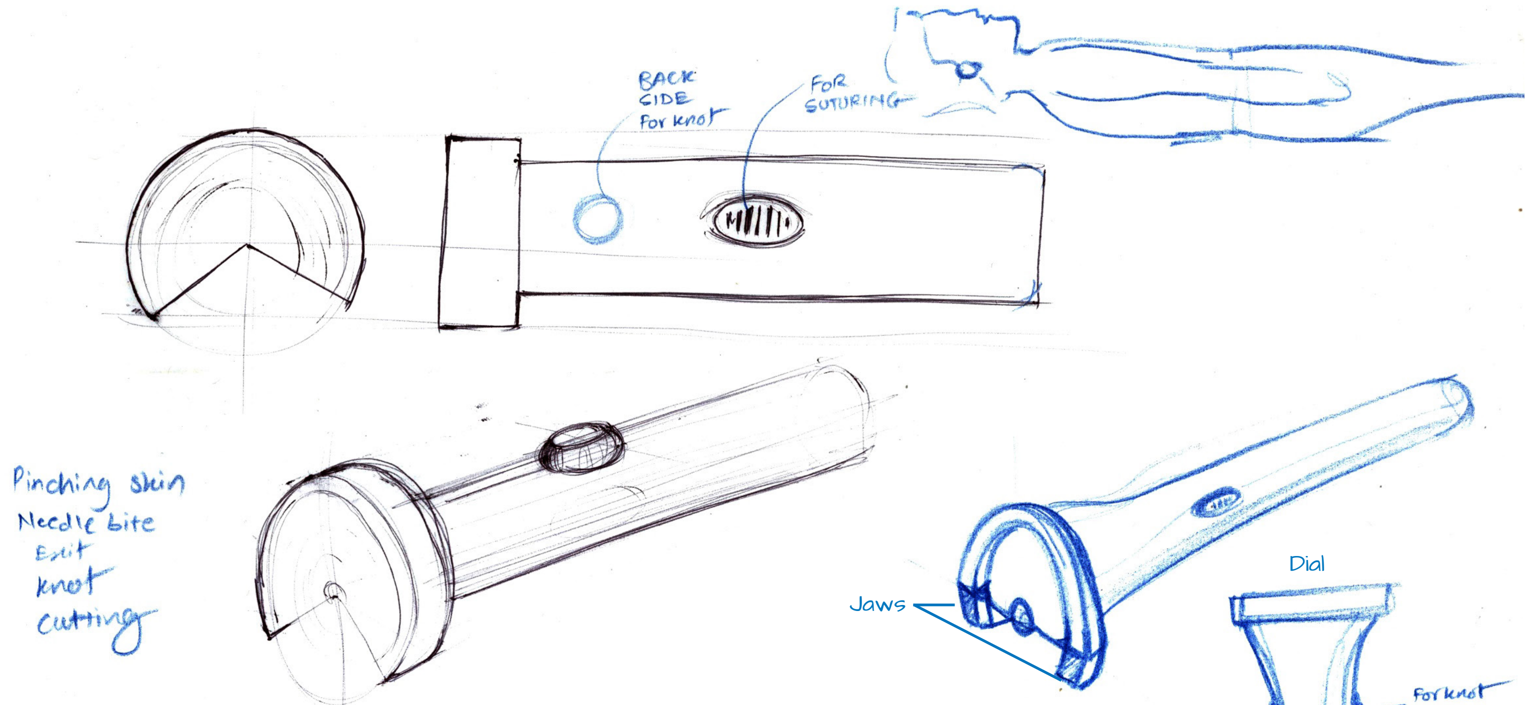
All the initial ideation concepts were showed to doctors to get there general feedback on the idea of auto-suturing device, Many questions were asked to doctors like how a device can be imagined, what can be the form, it's usability in the clinical conditions, etc. The doctors gave reviews on the sketches on the scale of 1 to 5 where 1 is for not an ideal suturing device form to 5 is for most ideal suturing device form.

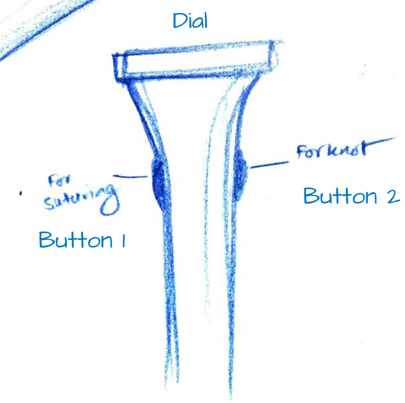
Concept No.	Review	Ratings
1	Induce stresses in the wrist, shoulder, Suspended hand position	****
2	Steady position, Can be motorised	****
3	Nice idea as a pen	****
4	Not good	**
5	Highly appropriate. No stresses on hand. Visibility of wound is more.	******

Concept No.	Review	Ratings
6	Not good	*
7	More steady	*****
8	Easy to control, precise movement.	***
9	Good	***
10	Too much stress, complicated	*

Concepts on Interaction and Usability

1

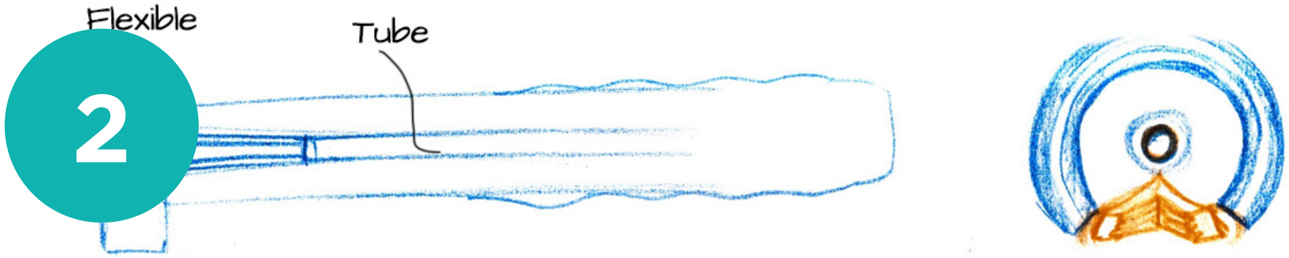




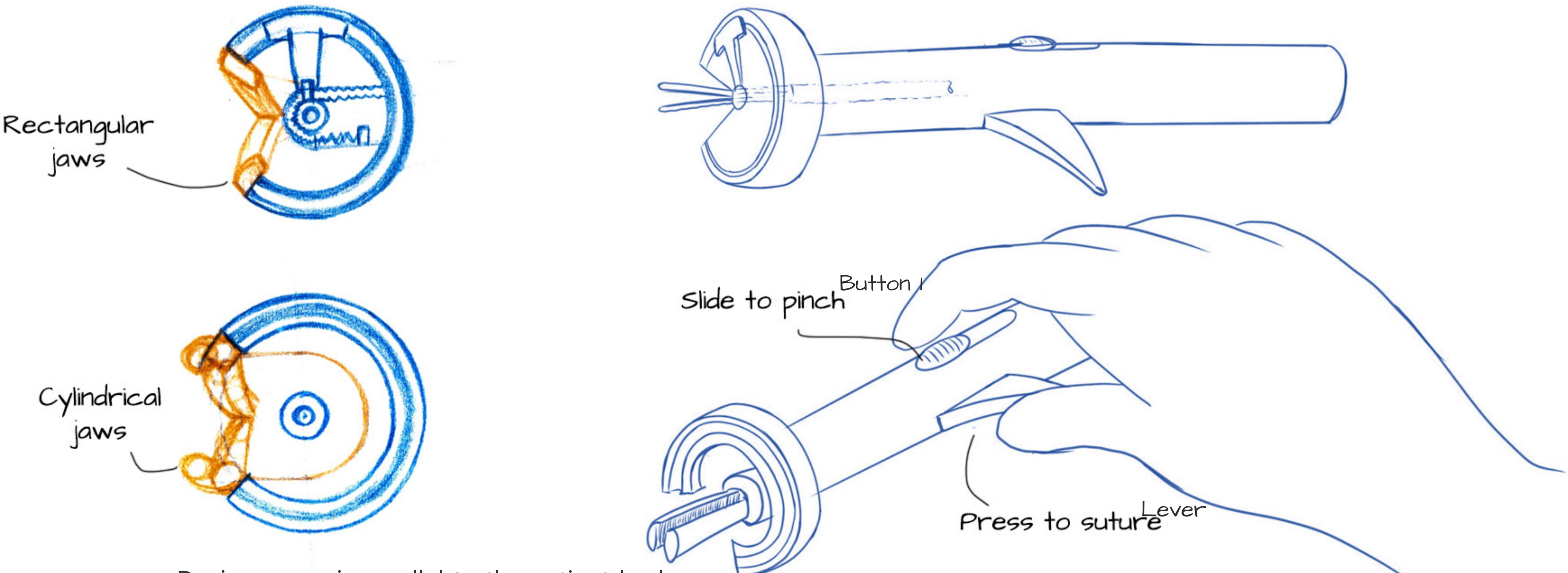
Working: As soon as user press the button 1, first the jaws will pinch the skin and then suturing action will takes place by the mechanism at the dial part of the device. Pressing button 2 will put a knot automatically to the thread.

Features: Device usage is parallel to the patient body
Press button for suturing purpose
Automatic knotting button

Figure 4.7 : Concepts 1 on Interaction and Usability



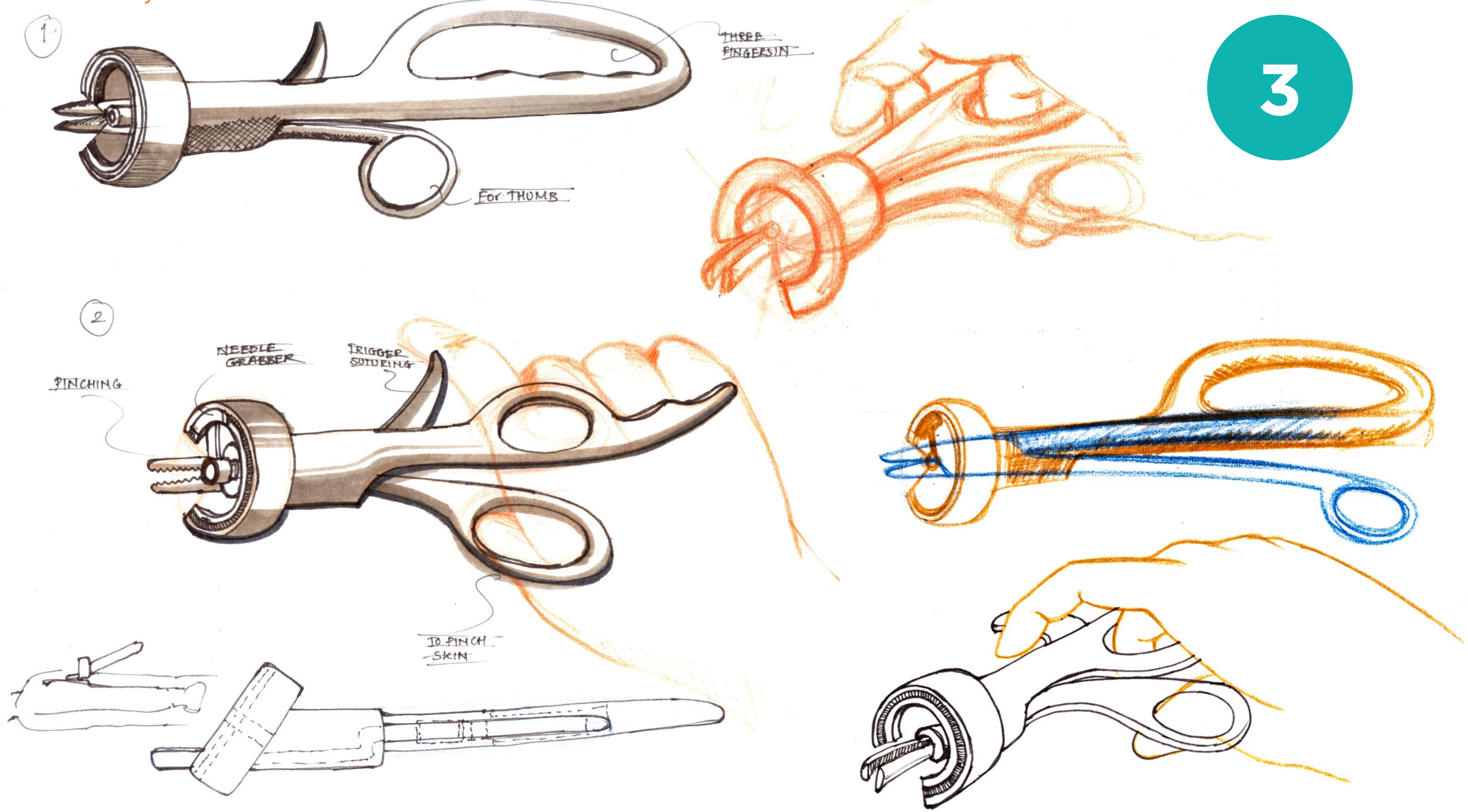
Working: As soon as user slides button 1, first the jaws will pinch the skin and then suturing action will takes place by pulling the lever.



Device usage is parallel to the patient body
Pinching skin is done by attached forcep by sliding of a button
Lever to carry out suturing operation.

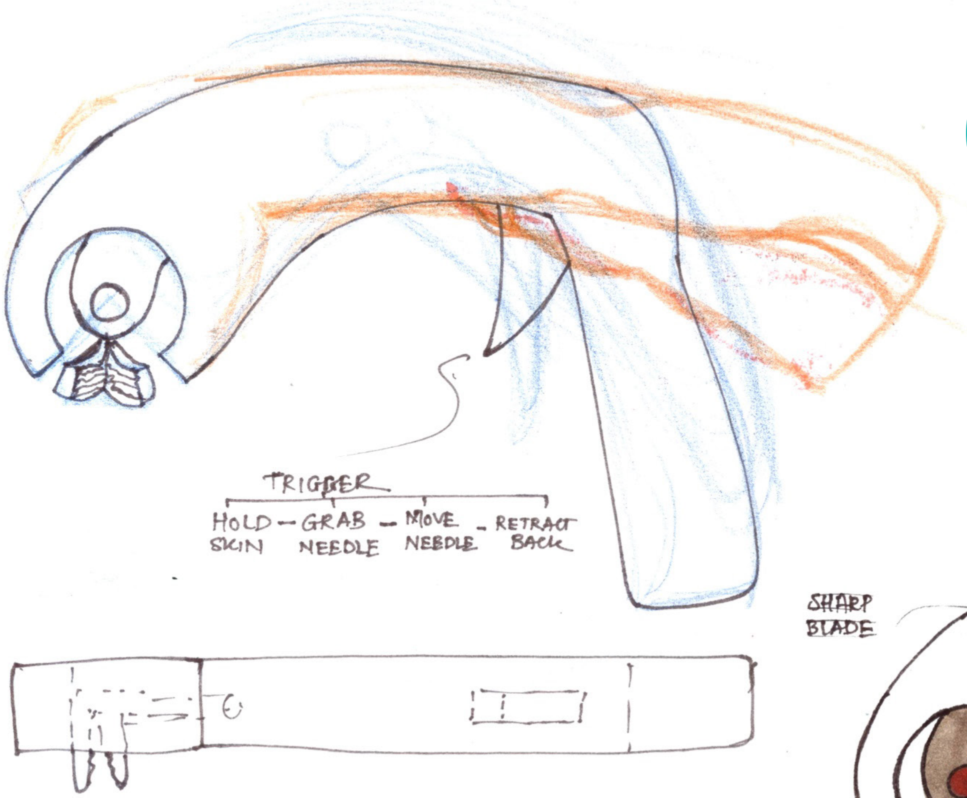
Figure 4.8 : Concepts 2 on Interaction and Usability

Figure 4.9 : Concepts 3 on Interaction and Usability



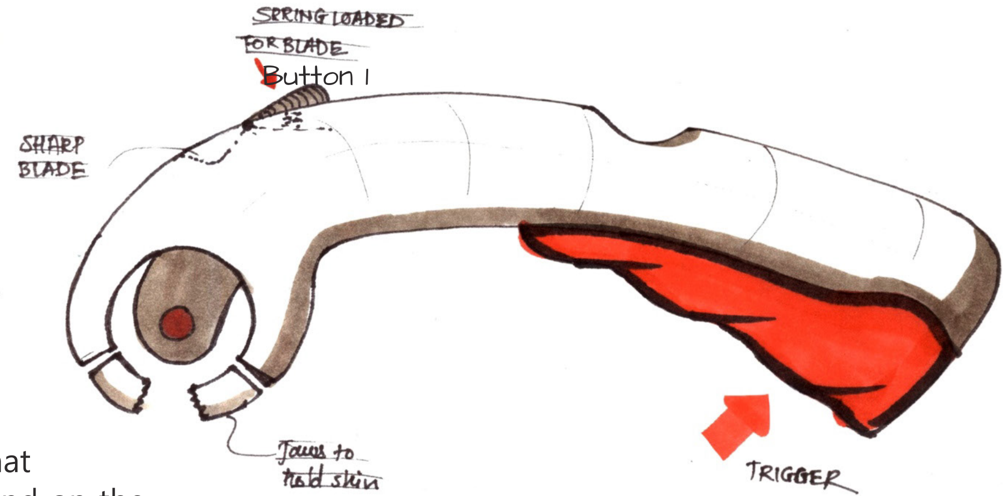
Working: User will use a scissor part for pinching of the skin and then suturing action will takes place by pulling the trigger/lever.

Features: Device usage is parallel to the patient body but front part which holds needle is tilted so that operators hand wont touch the body.
Pinching skin is done by attached scissor mechanism
Lever to carry out suturing operation.



4

Working: As soon as user pulls the trigger first the jaws will pinch the skin and then suturing action will takes place by the mechanism at the dial part of the device. By pressing button 1 a sharp cutter will come out to cut the thread.



Features:

- Device usage is perpendicular to the patient body so that operators hand won't touch the body or any other wound on the body.
- Pinching skin is done by lever itself.
- Lever to carries out first pinching operation subsequently suturing.
- Sharp cutting edge is provide to cut the thread

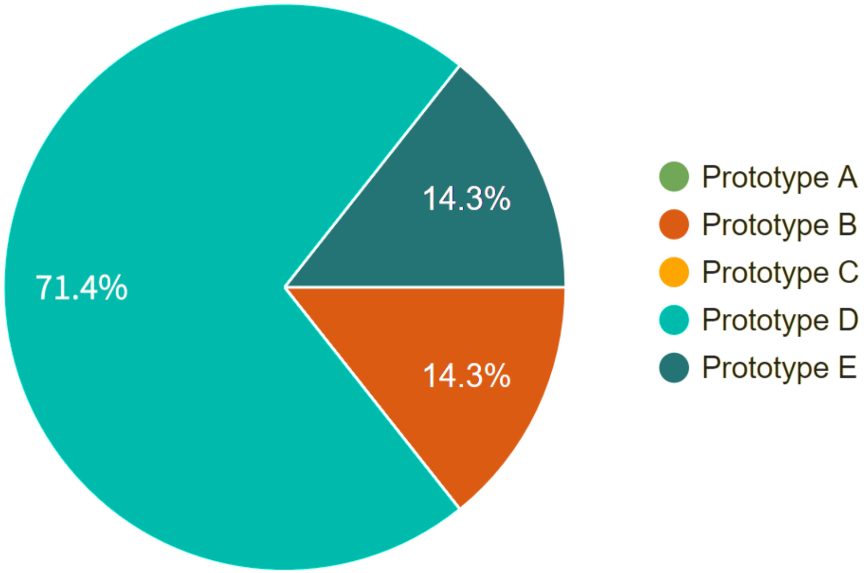
Figure 4.10 : Concepts 4 on Interaction and Usability

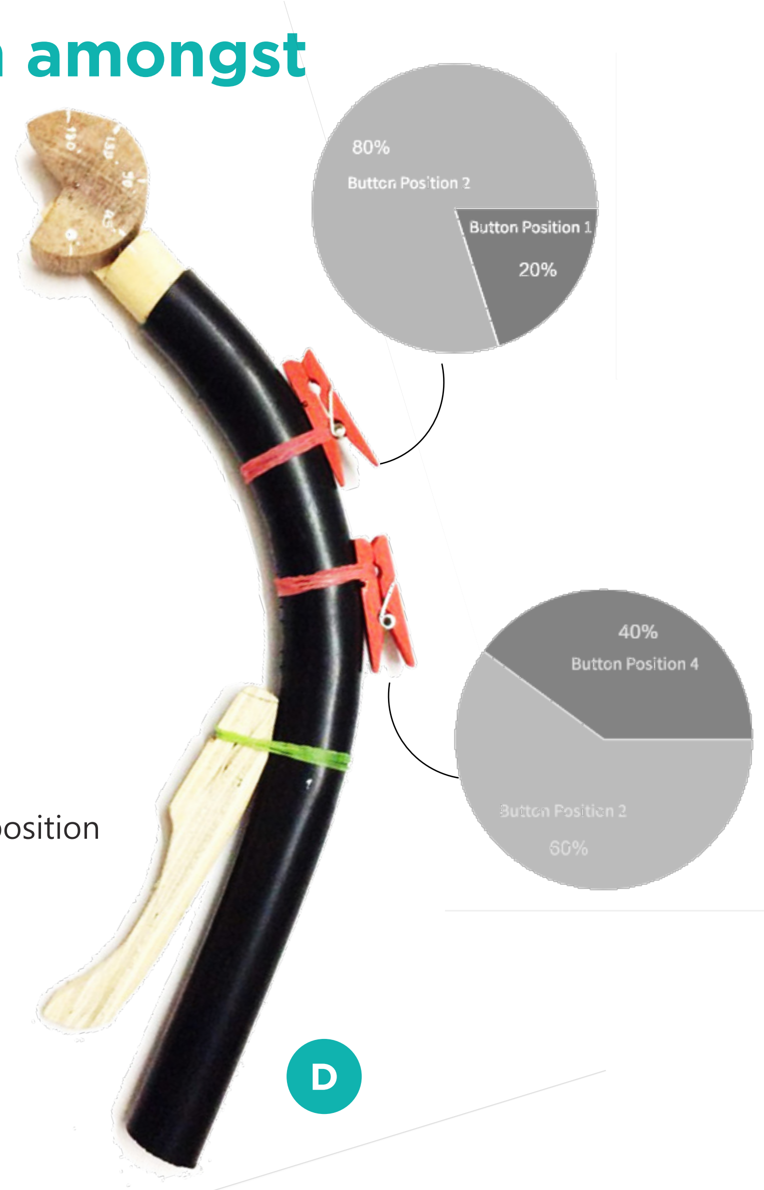
Usability Testing

Simple models are made to test the usability and interaction of the device while performing the suturing operation. Wooden clips are used to mimic the buttons and lever of the device and they were marked at position on handle. Total of 10 participants including 4 doctors, 1 medical student and 5 fellow designers were asked to imagine a situation where they have to perform suturing operation on different types of cuts/lacerations on a patient. Then they had to evaluate models on the basis of : (1) Visibility for suturing task, (2) Ergonomics, (3) Comfort button/lever positions.
This interviews gave lot of insights about best possible interaction and use cases of the device while performing the suturing.

Figure 4.11 : Models for usability testing

Result : Which is the best option amongst A, B, C, D and E ?



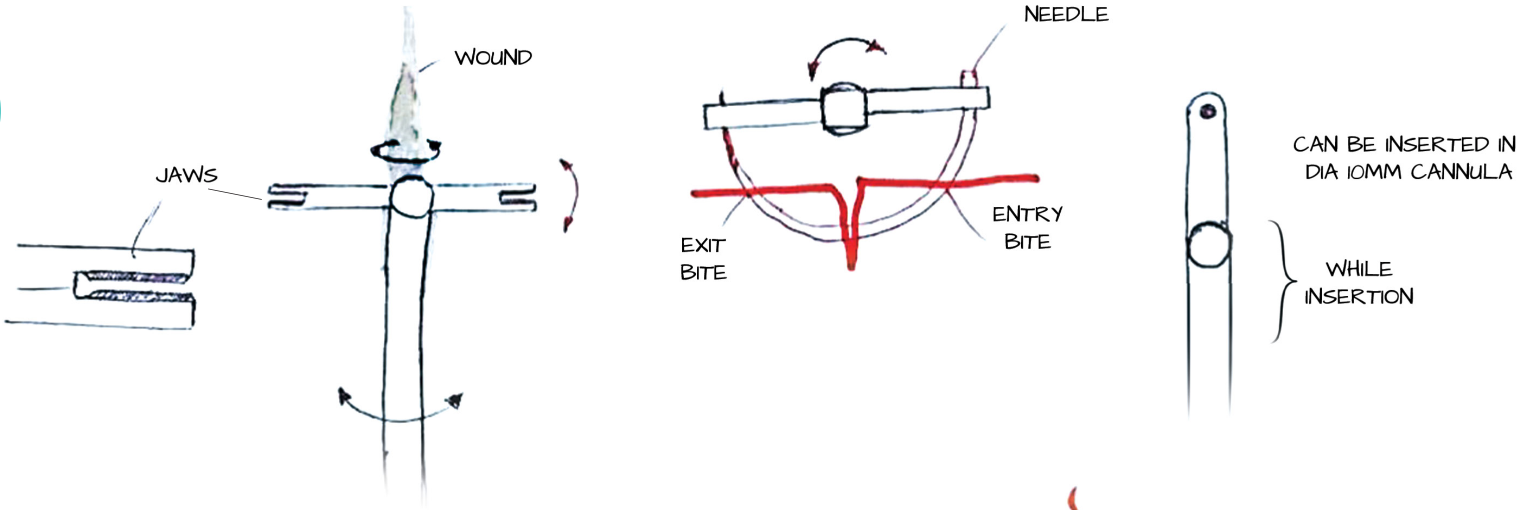


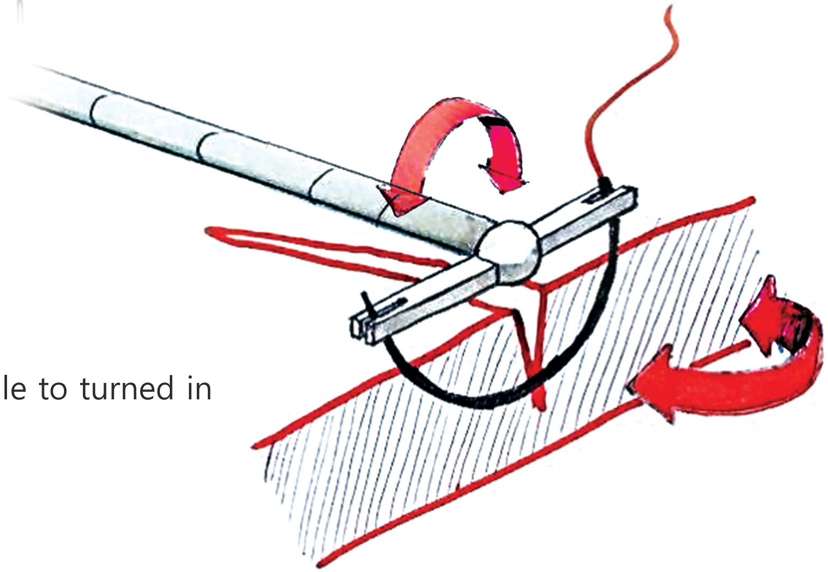
Option D was the most preferable one while operating. Its features are as following:

- Usage of device is perpendicular to the body.
- Curved shape follows natural grip
- Rotatable dial (unit when needle rotates) is preferable at angle from 0 to 90 deg.
- Button position 2 & Lever position 4 is most comfortable.
- Less overhang of hand
- More precision

Concepts on mechanism

1



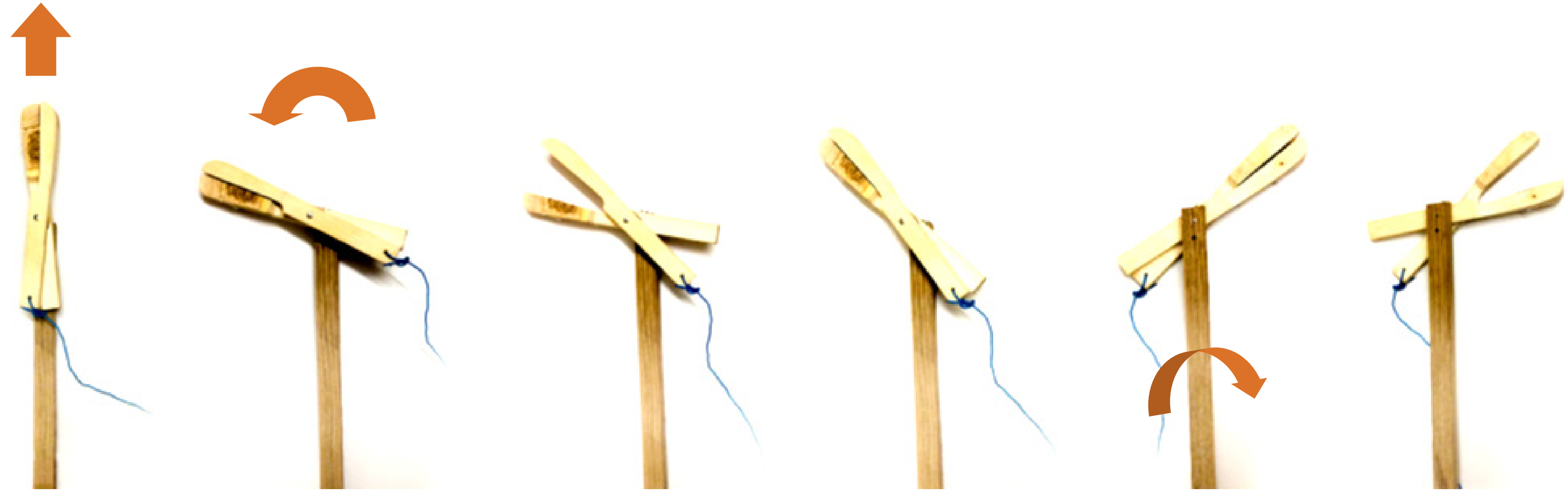


- This simple design only helps in needle to turned in a curved path by rotating its handle.
- Can go through Dia 10 mm cannula.

Figure 4.12 : Concept 1 on mechanism

2

This is a simple mechanism which help user to grab the needle and rotate it in a preferred curved path while suturing on tissues. This is concept is made taking into considerations that it can be used on superficial wounds as well as in laparoscopic surgeries. The below figure 4.13 show the step by step way of working of device.



Insert   Rotate Jaws   Open jaws   Grab needle   Rotate handle   Open jaws

Figure 4.13 : Concept 2 on mechanism

Pros:

- This device will only help needle to turned in a curved path by rotating its handle.
- Can go through Dia 10 mm cannula.
- Simple mechanism
- Easy operation (Just grabbing of needle and then rotate the handle)

Cons:

- Only serves half purpose where operator still has to manage grabbing of needle each time.
- Time for suturing is hardly minimised.
- Cognitive load on user for suturing tactics remains the same.

3

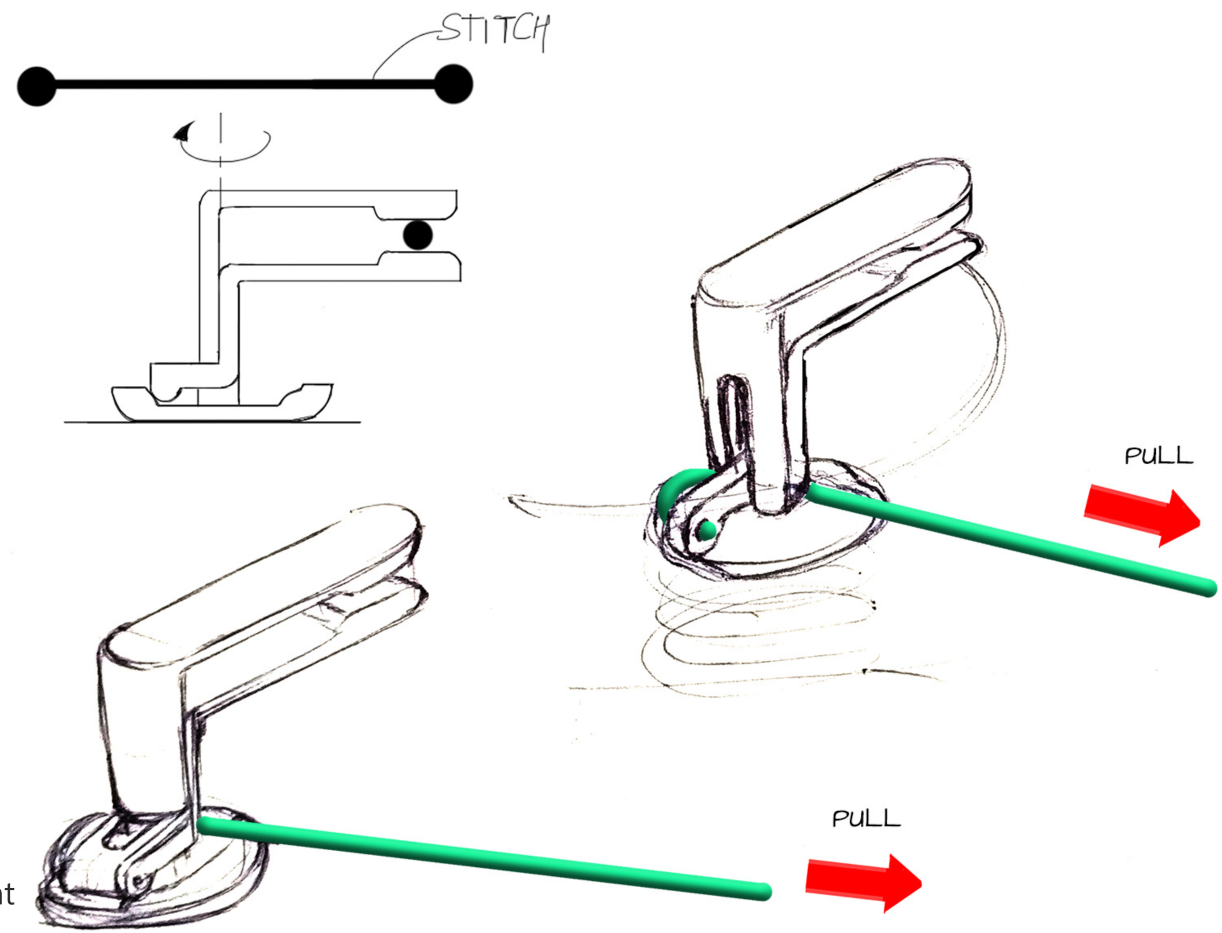
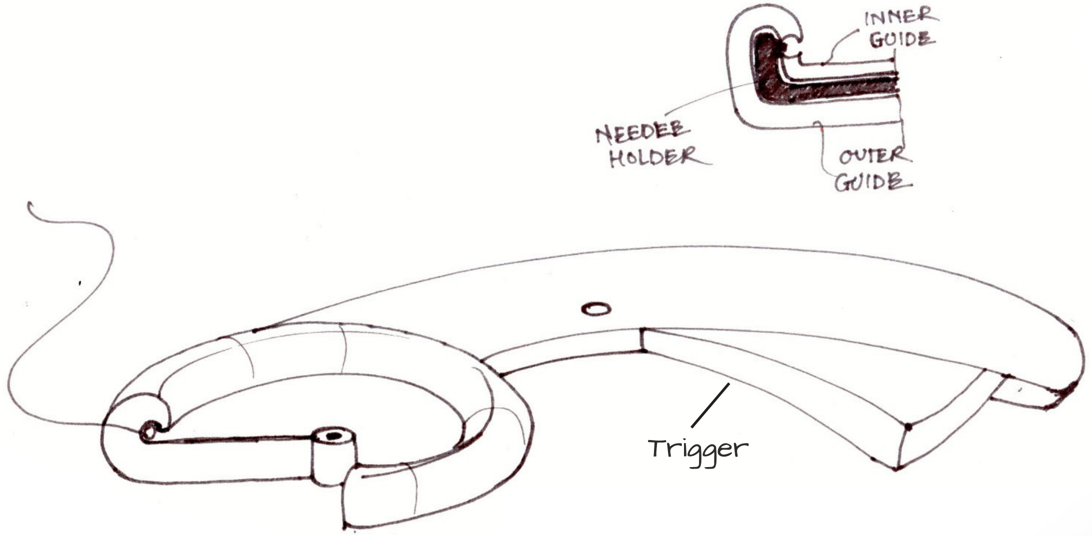
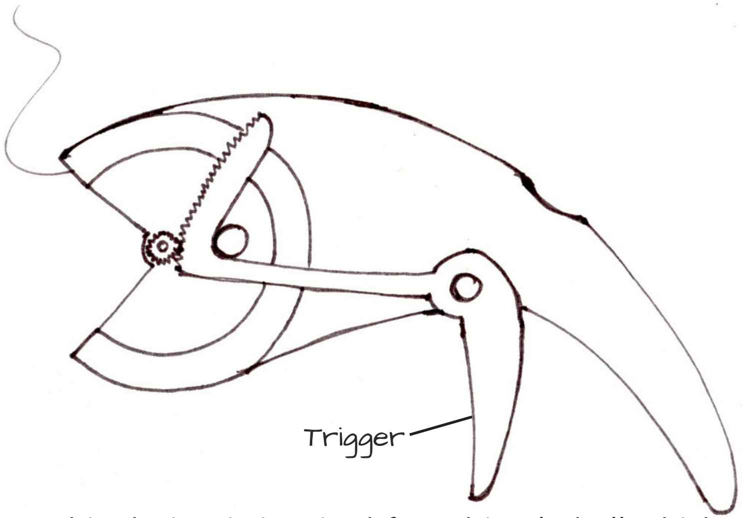


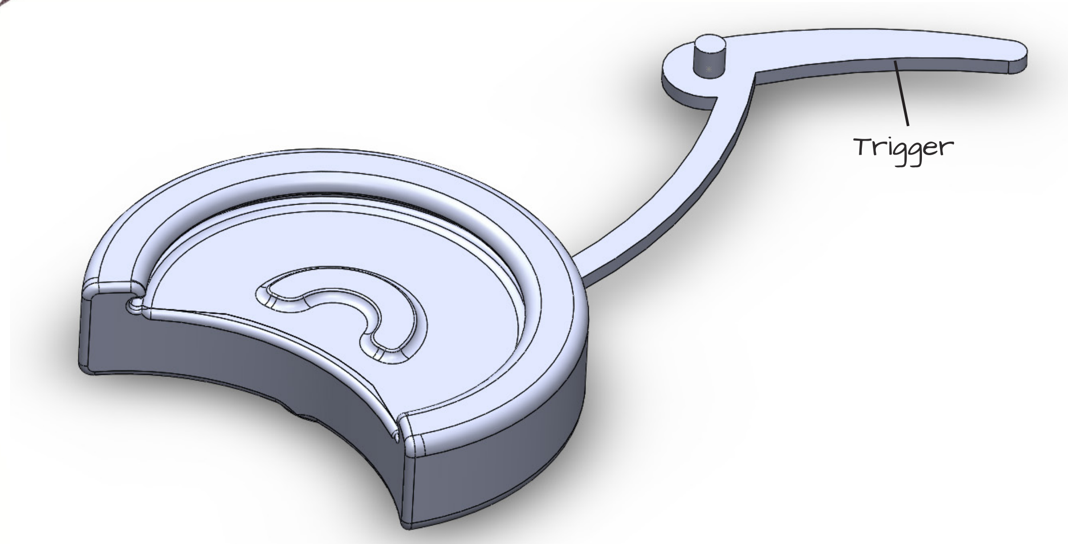
Figure 4.14 : Concept 3 on mechanism

- This is an improvement over the rack & pinion used in the current prototype developed by BETiC lab where instead of rigid rack flexible wire is used.
- Flexible rack can also be used instead of wire to rotate the needle grabber.

4

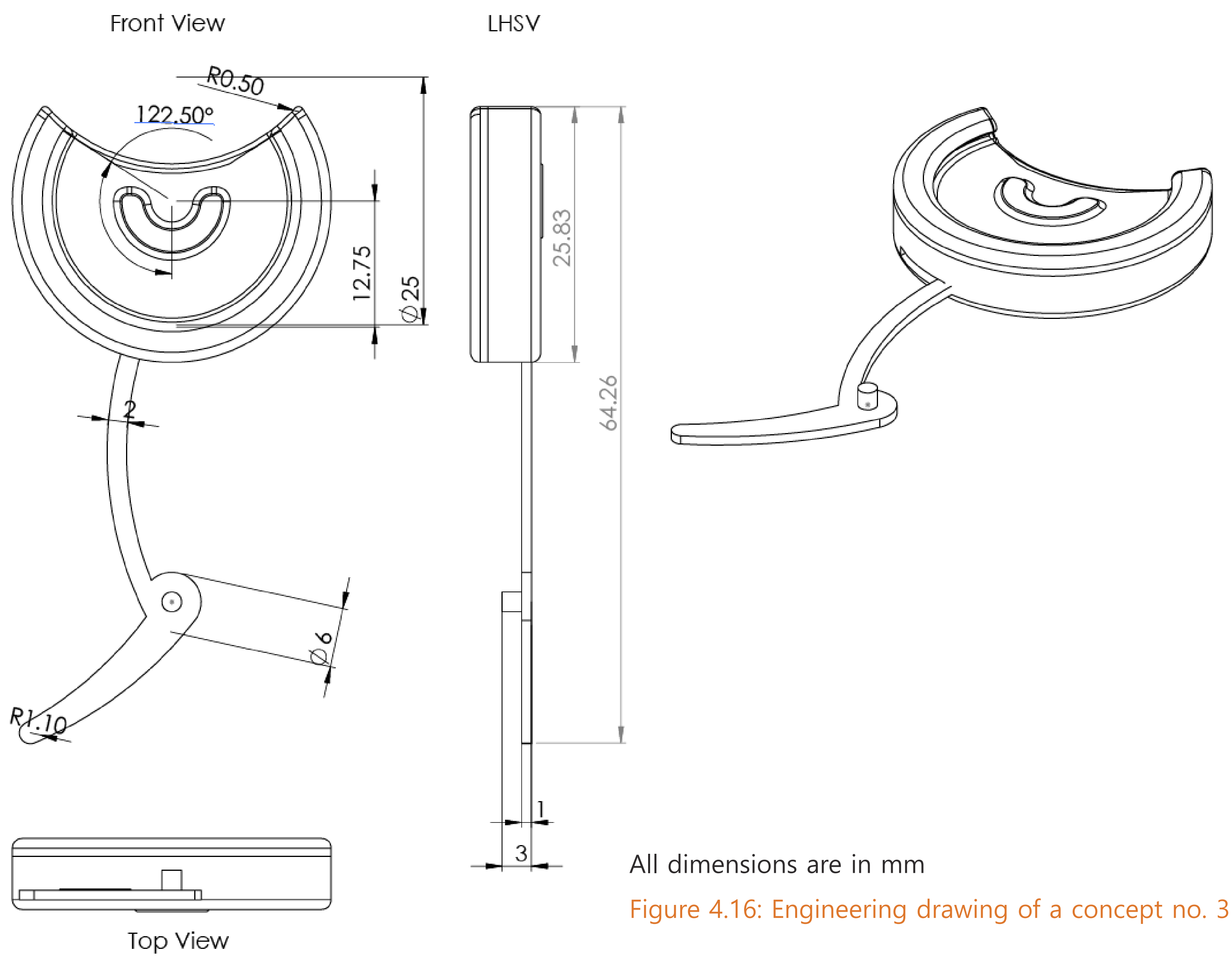






- This design is inspired from bicycle bell which replaces the rack & pinion mechanism to simpler spur gears
- Less friction between needle and guiding jaws.
- Hidden mechanism
- Grabber mechanism is simplified.

Figure 4.15 : Concept 4 on mechanism



All dimensions are in mm

Figure 4.16: Engineering drawing of a concept no. 3

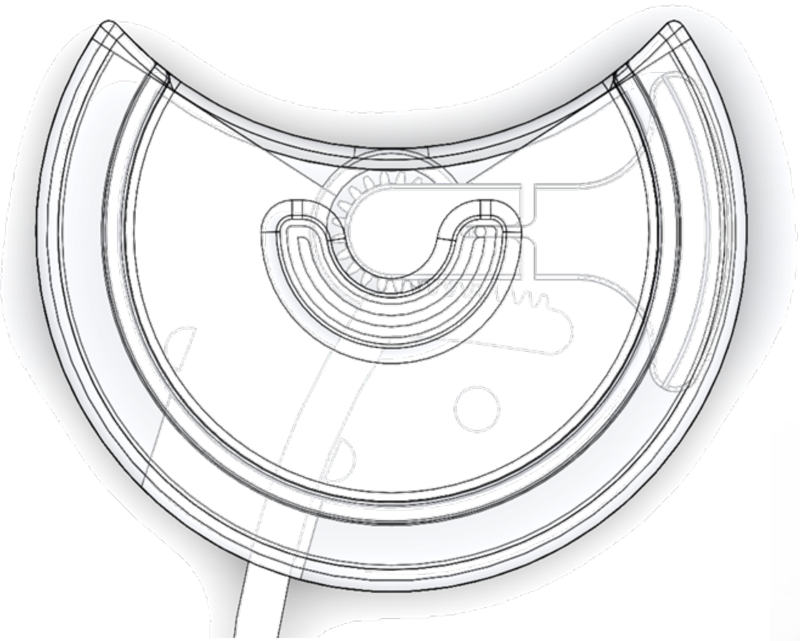


Figure 4.17 : Close View of dial mechanism of concept no.3

Figure 4.18 : Exploded View of mechanism of concept no.3

Evaluation of concepts on mechanism

To evaluate the concept the pros and cons of each and every idea wear compared to eachother.

Concept 1 and 2 requires lot of interactions to do by the users, where it has to hold the needle properly in jaws and then rotate. It doesn’t serve the purpose of eliminating the cognitive load from the user while performing the suturing operation.

Concept 3 retains the same mechanism as per the existing device, only introduce on flexible rack improves the device form factor as rack won’t come out when lever it pulled unlike the existing device. But it also doesn’t improvise the mechanism much further. Other movable parts are remains open which should be avoided.

Out of the 4 concepts on mechanism concept 4 was chosen to developed further because of the introduction of bell mechanism which looks more promising than the rack and pinion. Due to bell mechanism the lever or trigger side of the device gets simplifies. Also it uses less number of parts than the existing one as the as compared to other concepts. Concept 4 hides most of the moving parts making it safe to operate in clinical conditions. The idea of integrated forceps to grab the skin is eliminated as it would hinder in knotting operation also complicates the mechanism.

Directions

Three directions were taken into consideration while deciding material and manufacturing process for the product. Those directions are as follows:

1 One time use device

Whole device combining needle holder and handle will come up as one unit and can be use for one time only. Device can be moulded out of suitable plastic material which will be cheap and sustainable. Different devices can be made as per the different needle sizes.

2 Device can be reuse after sterilisation

Whole device combining needle holder and handle will come up as one unit and can be made of steel which can be reuse after sterilisation. Different devices can be made as per the different needle sizes.

3 One/same handle part and removable needle holder mechanism

Device can be made modular. Needle holder part which aid in suturing can be made separately with polypropylene. It's sizes will vary as per the size of the needle. On the other hand universal handle can be onto which needle holder part can be snap fit.

Concepts on Handle Design

Image Board

System Razor by KAI CORPORATION
http://www.g-mark.org/award/describe/36095?locale=en

Bottle Humidifier by Cloud and Co
http://www.fromupnorth.com/productindustrial-design-inspiration-908/

Hand Tool - Ice Cream Scoop
by Scott Shumaker
http://www.coroflot.com/scottberkley/Hand-Tool-Ice-Cream-Scoop

Dyson Air Multiplier by Sir James Dyson
http://www.dyson.com/air-treatment/cooling-fans.aspx

Wilkhahn Graph conference chair by jehs + laub
http://www.indesignlive.sg/articles/JehsLaub-for-Wilkhahn

Taking image-board as an inspiration, concepts shapes were generated considering hand posture, finger placement and the interactions with device. All the different form sketches are as follows.

Figure 4.19.1 : Inspired by swan

Figure 4.19.2 : Inspired by Hummingbird

3

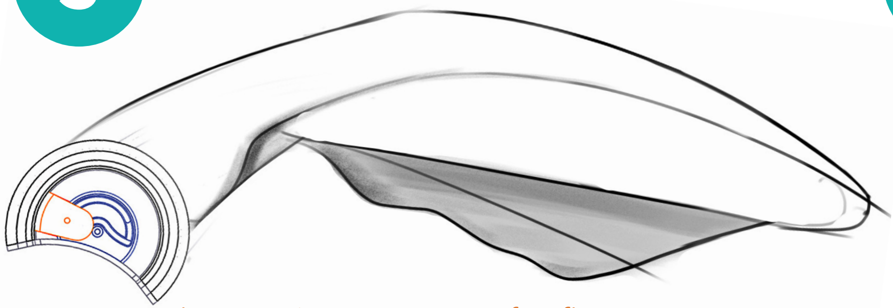


Figure 4.19.3 : Grooves for figures

6

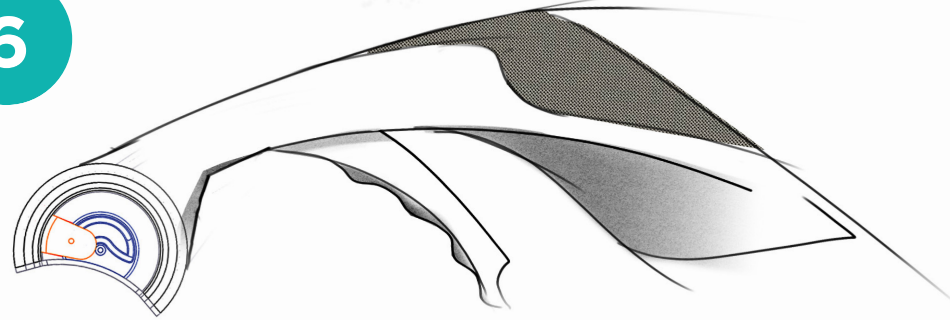


Figure 4.19.3 : Gun Handle

4

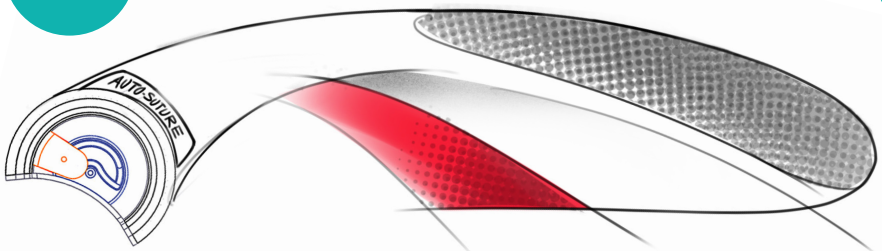


Figure 4.19.4 : Sporty Look

7

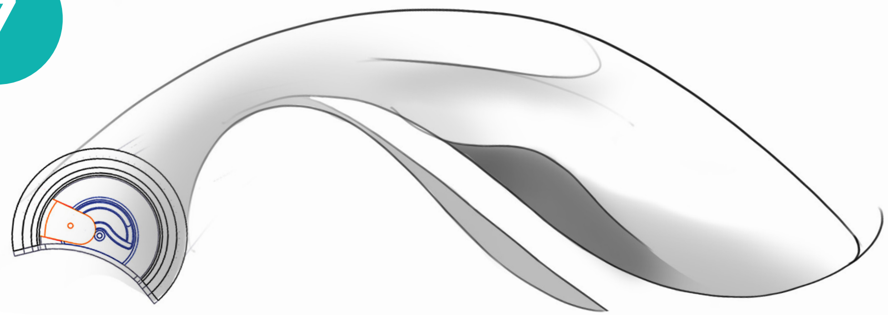
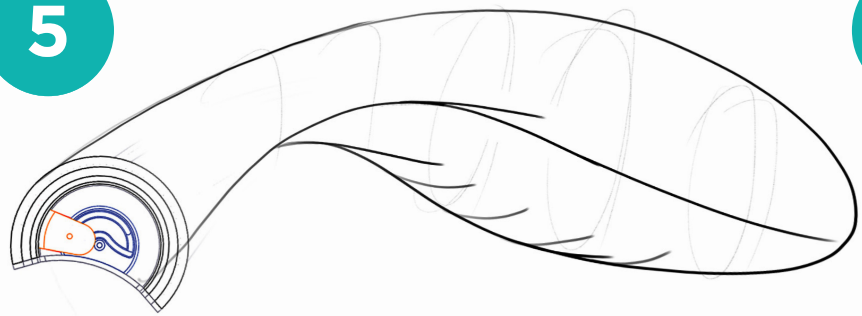


Figure 4.19.7 : Curvy

5



8

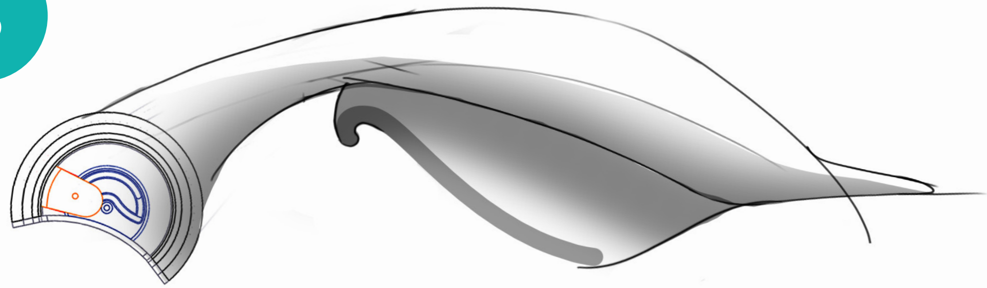


Figure 4.19.5 : Rugby Ball

Figure 4.19.5 : Question mark shape for trigger

3 tharmacol model were made to test the overall form factor and dimensions as well as to check the usability. These tharmacol model was given to number of peoples to take there reviews. Model no 1 was chosen as a final form as most of the people find it simple and better than other models.

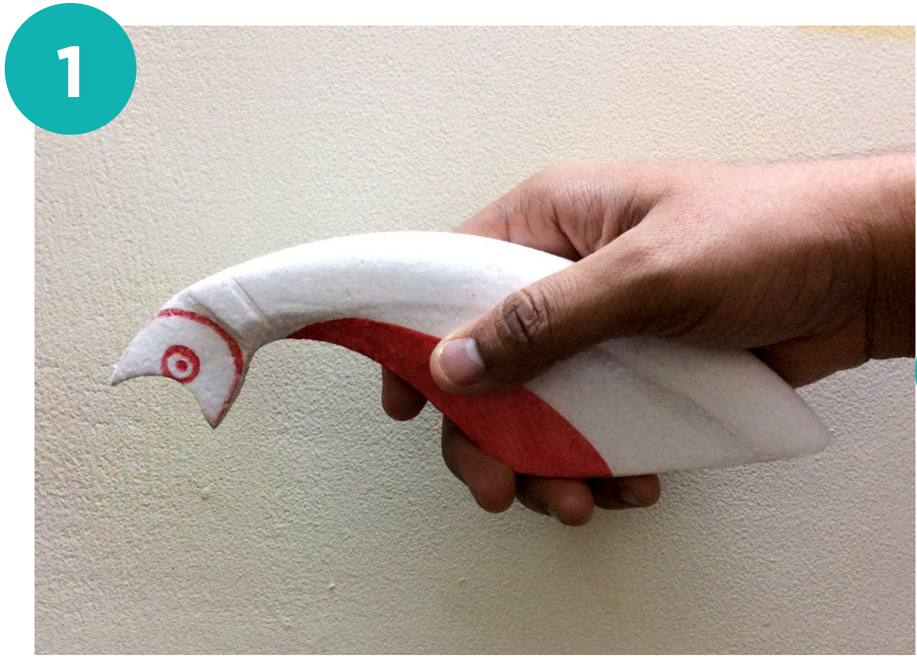


Figure 4.20 : Handle Forms

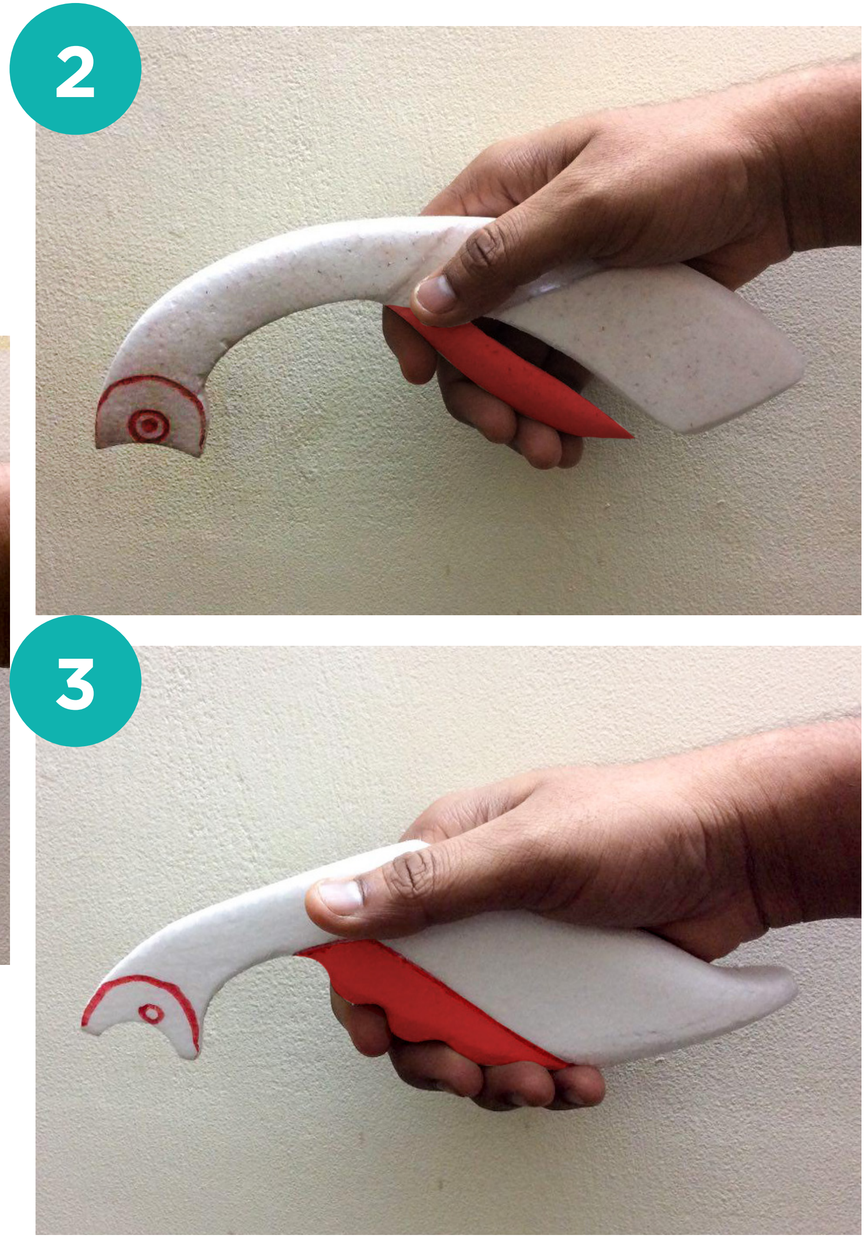


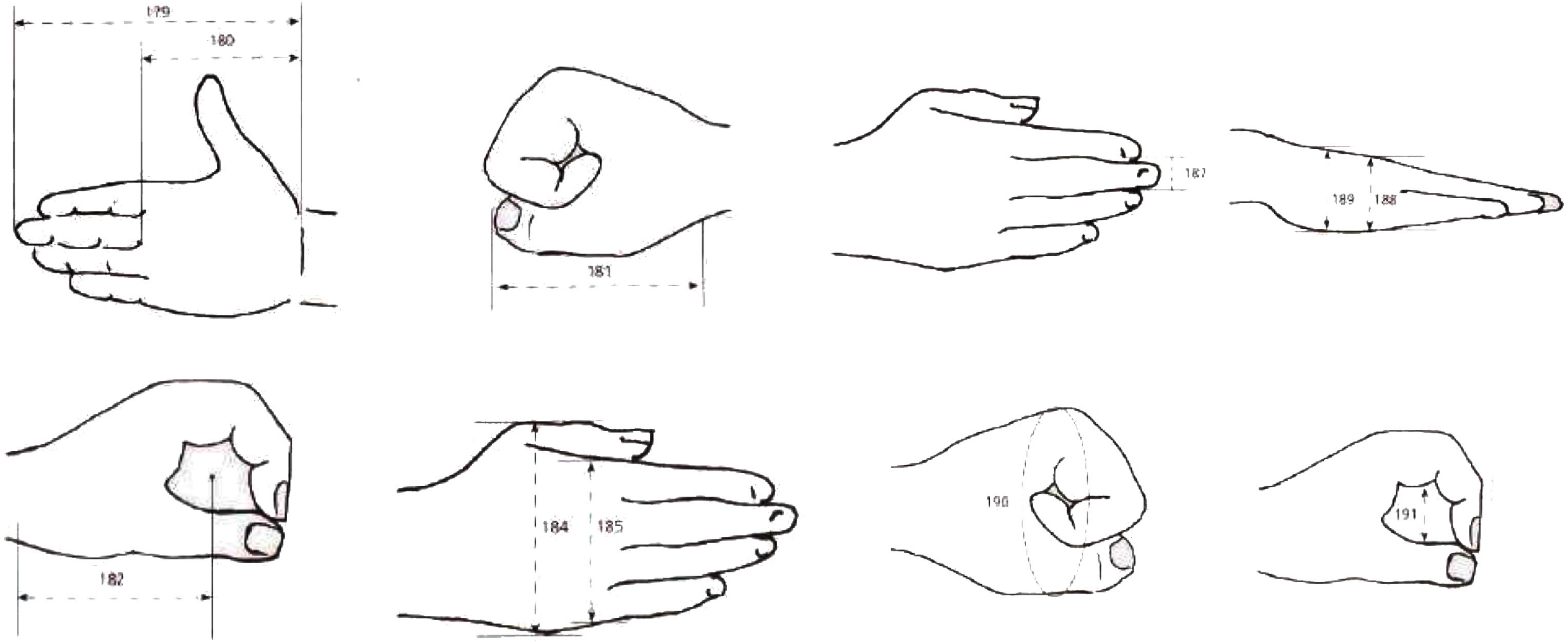
Figure 4.21 : Handle Forms

Ergonomic Study

Anthropometric Data

The tharmacol model was cross-checked with the anthropometric data from the book named 'Indian Anthropometric Dimensions' by Debkumar Chakrabarti.

The required adjustments were done in the final model. Analysing Test models also helped refining the final model.



179 Hand Length
180 Palm Length
181 Fist Length

182 Hand Grip Length
184 Hand breadth, with thumb
185 Hand breadth, without thumb

187 Finger-tip breadth
188 Hand depth at metacarpal
189 Hand depth at thumb base

190 Fist circumference
191 Grip inside diameter, Max

Figure 4.22 : Anthropometric Data

Medical Devices Handle Study

AbsorbaTack™ (ABSTACK30X) Fixation Device

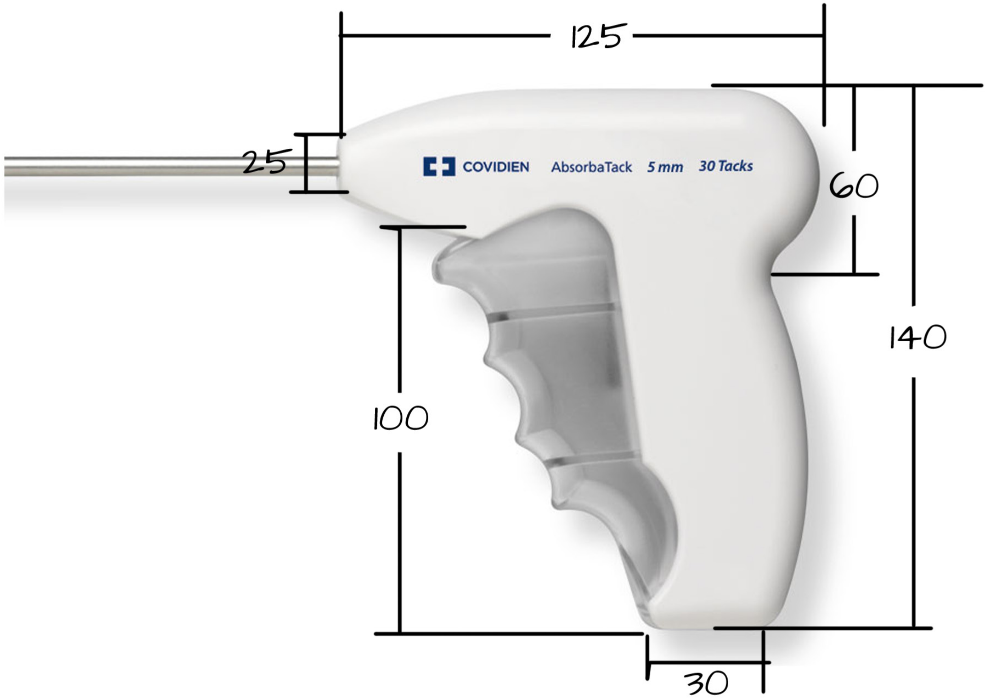


Figure 4.23 : AbsorbaTack™ (ABSTACK30X) Fixation Device

Figure 4.24

Figure 4.25

- Ergonomic pistol-grip handle. Ratcheted mechanism provides tactile feedback during firing.
- Point and shoot device

P.S..: All dimensions are in mm

Cambridge Endo Laparoscopic Needle Driver

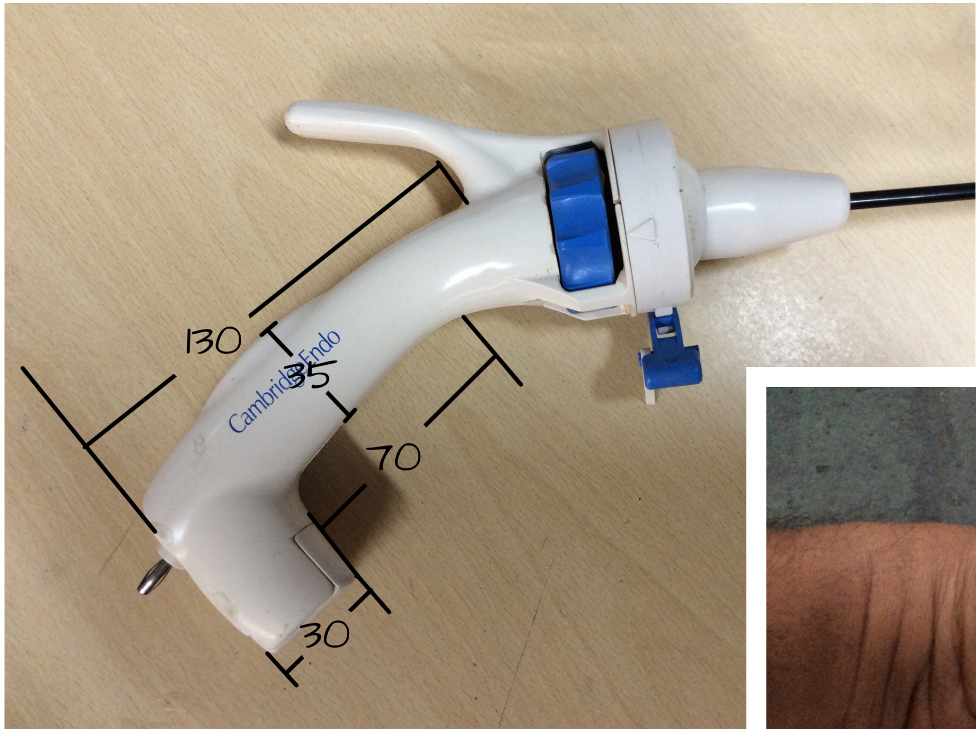


Figure 4.26 : Cambridge Endo Laparoscopic Needle Driver

- Circular handle for natural grip.
- Palm rest at the bottom
- Stopper for thenar space which the area between thumb and index finger.

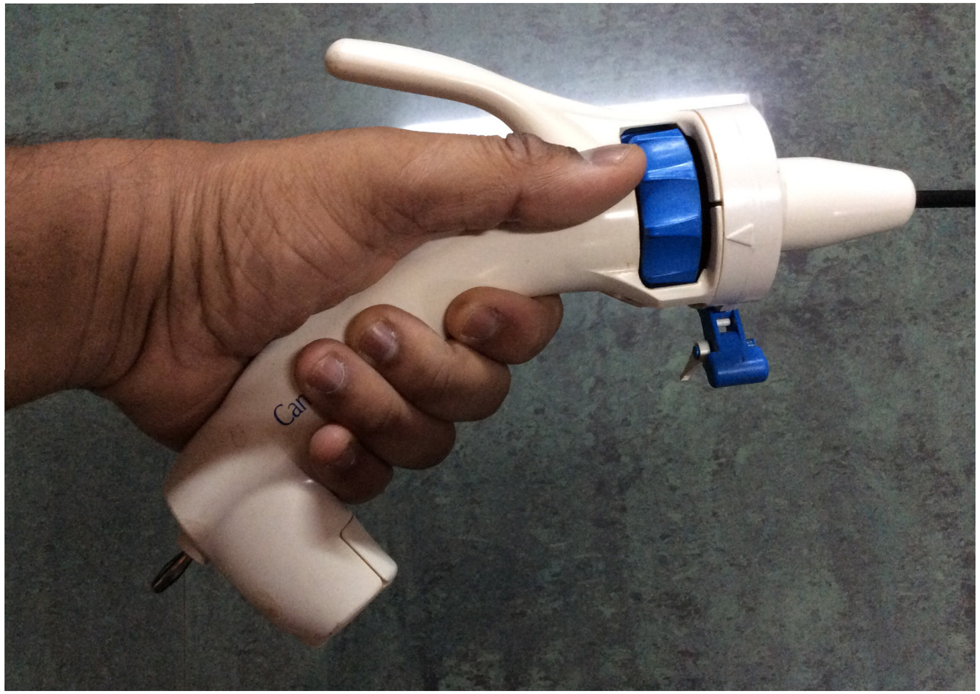


Figure 4.27

P.S.: All dimensions are in mm

HARMONIC ACE®+7

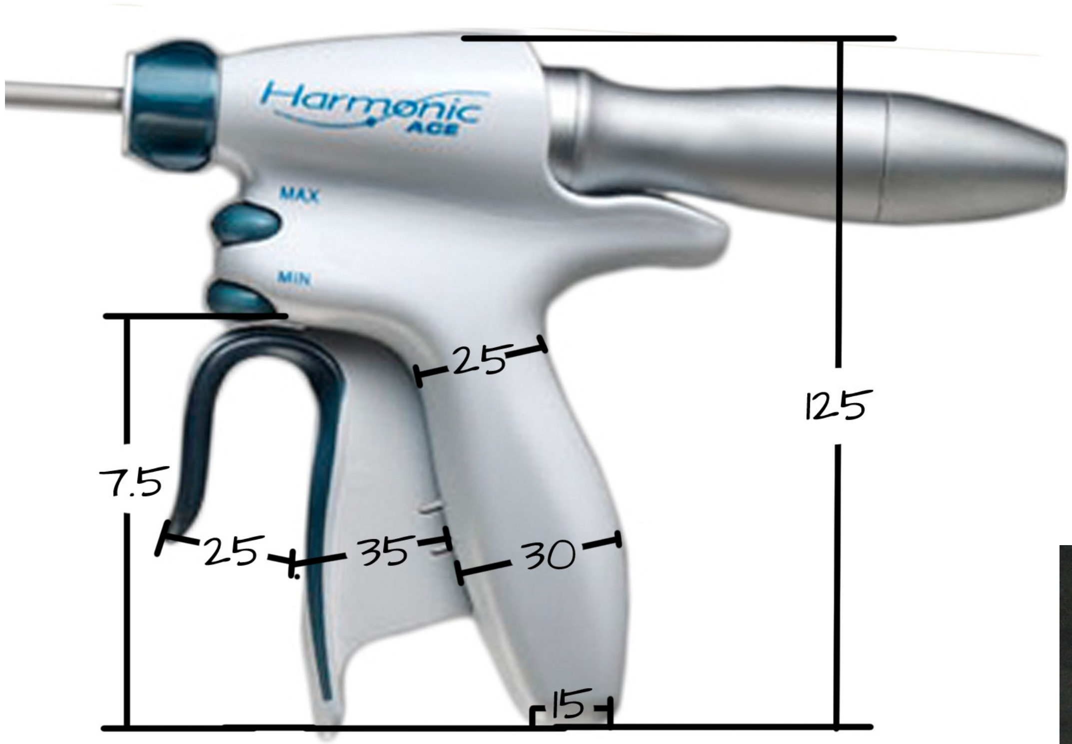


Figure 4.28 : HARMONIC ACE®+7

- Follows the shape of hand, palm.
- Device gets stuck on index finger making it more stable and avoids accidental toppling.
- Proper thumb and index figure resting grooves.

Figure 4.29

Figure 4.30

P.S..: All dimensions are in mm

Figure 4.31
Olympus -THUNDERBEAT Open Extended Jaw
https://www.olympus-europa.com/medical/en/medical_systems/products_services/product_details/product_details_100800.jsp

Figure 4.32
HARMONIC ACE®+7
http://www.ethicon.com/healthcare-professionals/products/advanced-energy/harmonic/harmonic-ace-plus-seven

Figure 4.33
THUNDERBEAT
http://medical.olympusamerica.com/products/thunderbeat

Figure 4.34
Coviden - Sonicision™ Cordless Ultrasonic Dissection Device
http://www.medtronic.com/covidien/products/ultrasonic-dissection/sonicision-13-cm

Figure 4.35
Olympus - PK TECHNOLOGY
http://medical.olympusamerica.com/products/eu-financials

Figure 4.36
Ultraformer Skin Tightening
http://www.asiapacific-beauty.com/english/products_detail.asp?fid=100&list=Equipment&fbody=body_0&ffunc=func_0

Test Models

The next step was to create representative solutions out of the concepts previously thought. The concepts were turned into 3D models in Solidworks Software. Then simulated mechanism as per the required motion.

To check the actual working of the mechanism models were 3D printed on Stratasys 3D printer with Nylon and ABS material.

Model 1

Working Principle:
This is a 3D model made for dia 28 size semicircular needle. The needle is driven by the graber. Graber slides in the guides which is spring loaded. The movement of graber to hold the needle and leave it at specific moment is controlled by the pin which slides inside the cavity in the lower guide (Ref. Fig. 4.38). As user pushes the trigger, the spur gear rotates with the guide for graber attached to it. Graber pushes the needle from outer surface and rotates 180 deg. and needles slides with it and takes the bite in the tissue. Graber release the needle retracts back to the original position. Whole assembly is hidden below the upper guide and only needle rotation can be seen from outside.

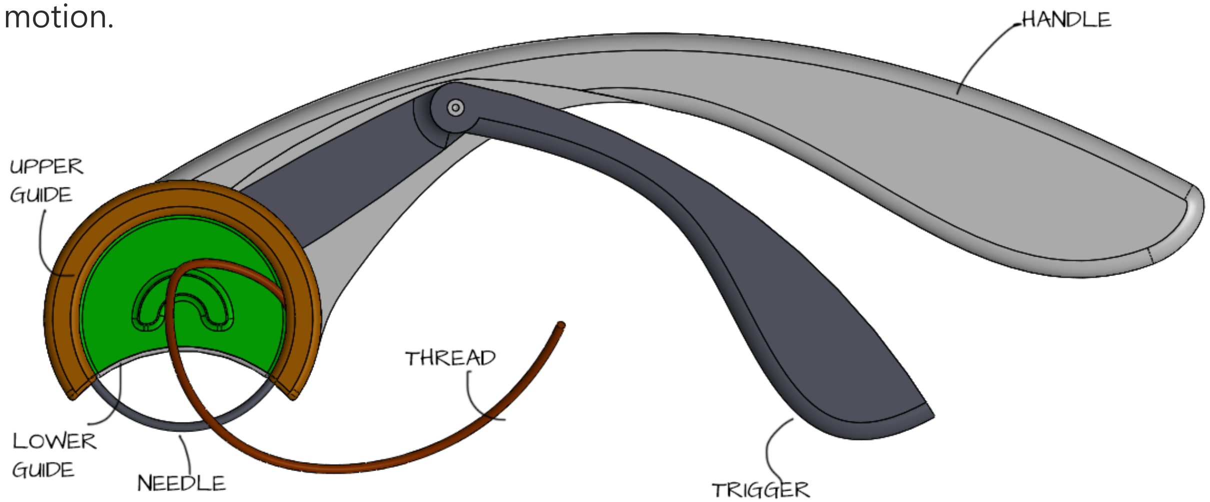


Figure 4.37

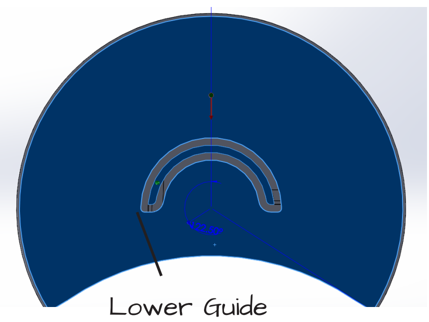


Figure 4.38

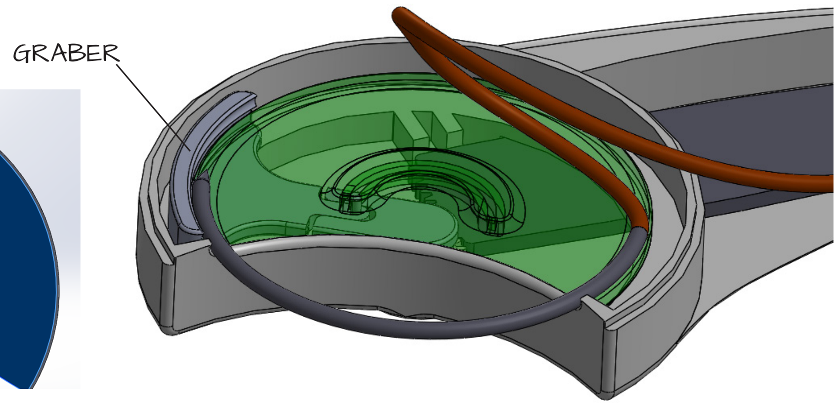


Figure 4.39

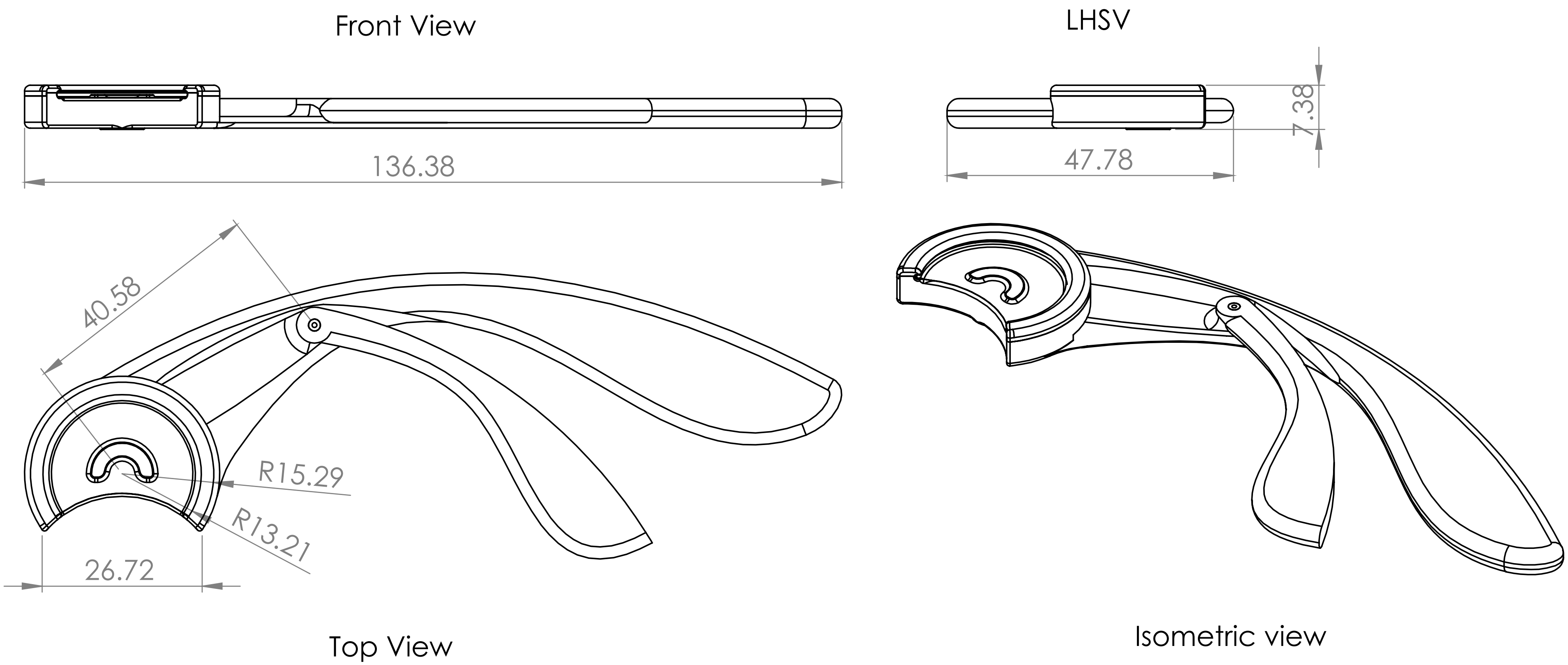


Figure 4.40 : Engineering Drawing of model 1

Materials :
Medical grade white ABS for prototyping
Medical Grade Polypropylene (PP) for Final Design

Overall Size: 136.38 x 47.78 x 7.38

Processes : Injection Moulding, Ultrasonic Welding

Cost: Approx. Rs.50-100/- per piece.

DO NOT SCALE DRAWING	REVISION V3
All dimensions are in mm	
TITLE: Auto-Suturing Device Model 1	
DWG NO. V3_Assem1	A4
SCALE:1:1	SHEET 1 OF 1

Exploded View of Model 1

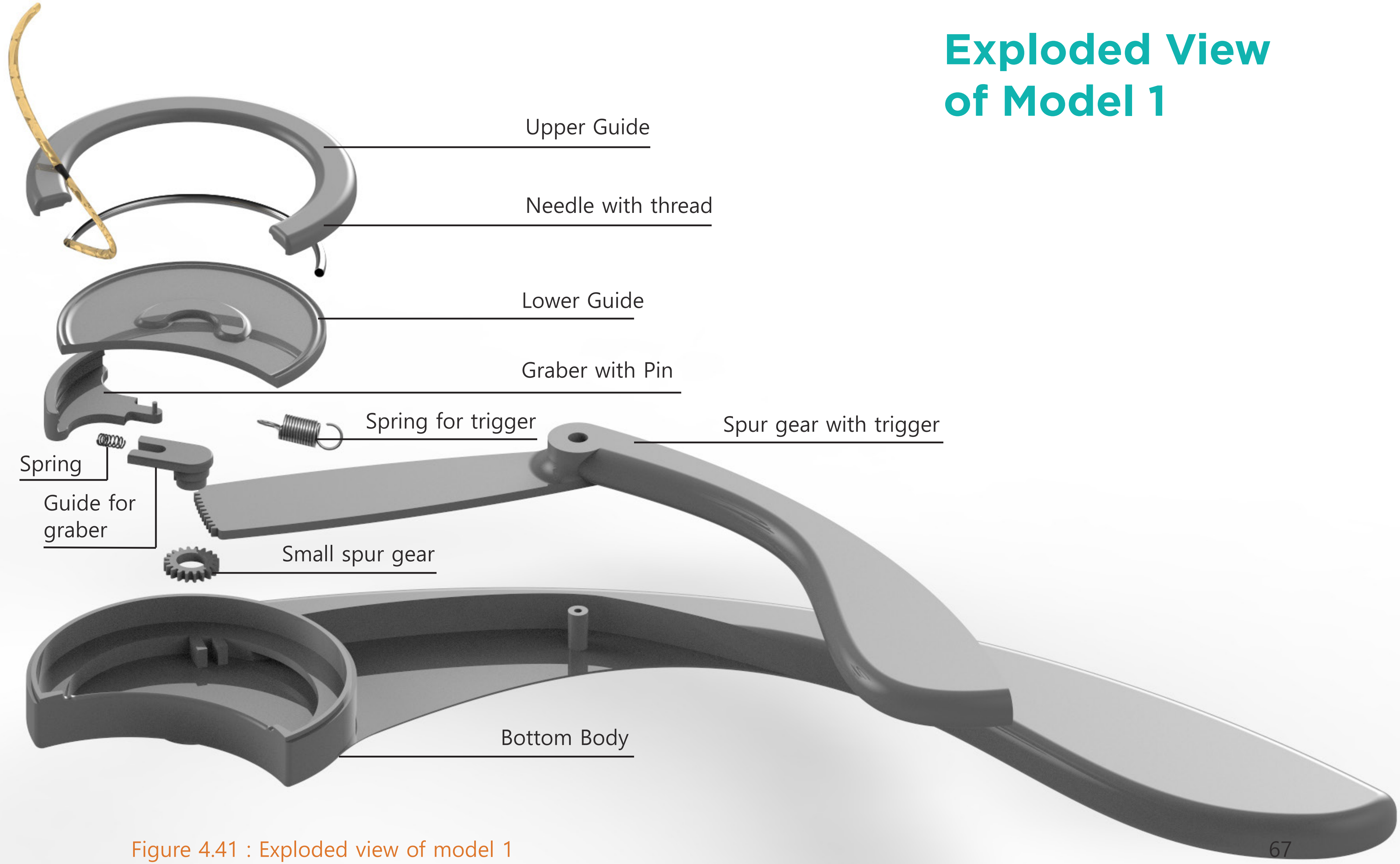


Figure 4.41 : Exploded view of model 1

3D Print of Model 1

The model was 3D printed twice the size of the original one as the available 3D printer couldn't give much finer parts. After analysing the 3D print of model 1, it realises that grabbing the needle from one side won't be efficient and might result into slippage of needle. To avoid the slippage needle has to be hold from both the sides like pinching it. Then only it will be able to slide without slipping. Also the minimum thickness of the part was taken as 1 mm, which turned out to be quite weak with the 3D print (It also depended on the fineness of the 3D print). To avoid that next model 2 designed with increase in the thickness by 0.5mm.

Figure 4.42 : 2:1 size 3D Print of Model 1

Model 2

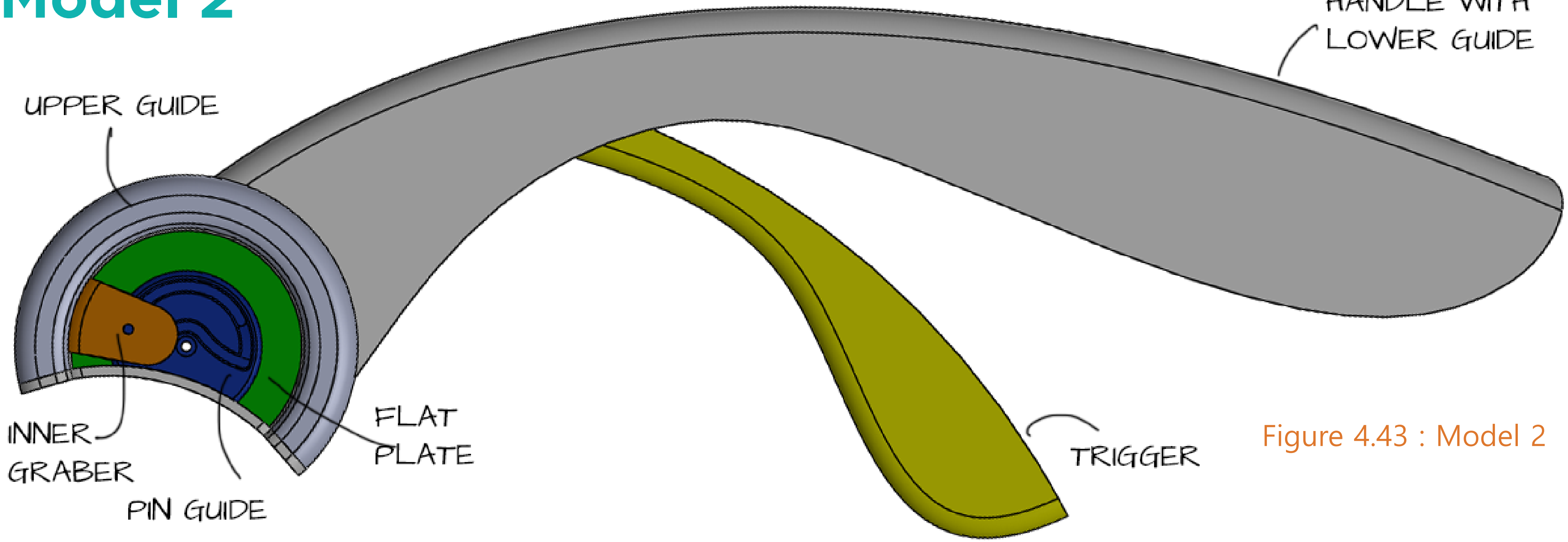


Figure 4.43 : Model 2

Working Principle:
This is a 3D model made for dia 28 size semicircular needle. The needle is driven by the inner & outer graber. Both the graber rotates as the user triggers along with the spur gear. Inner graber slides as well inside the cavity in Pin Guide part. (Ref. Fig. 4.44). Both the graber hold the needle from two sides and rotates. This insures no slippage of the needle. Upper guide and Flat Plate hides most of the parts of the assembly except the inner graber. This mechanism is most efficient than the model 1 mechanism.
Further 3D printed the model 2 to check the working of it.

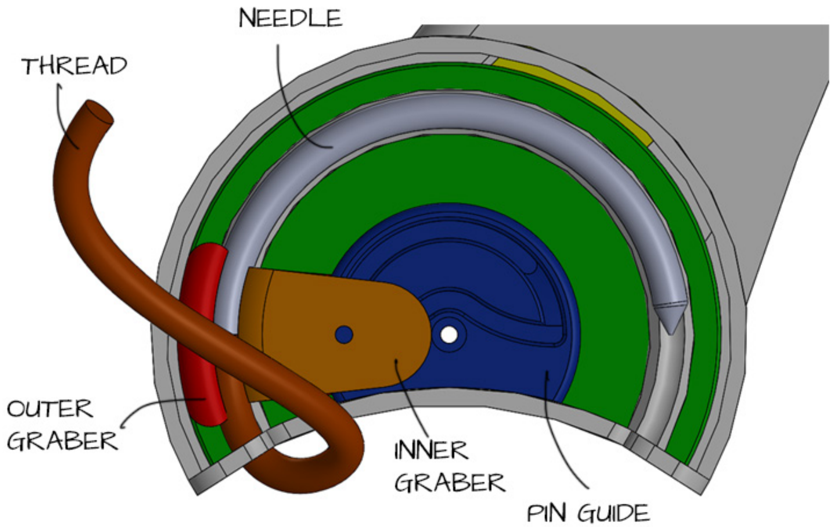


Figure 4.44

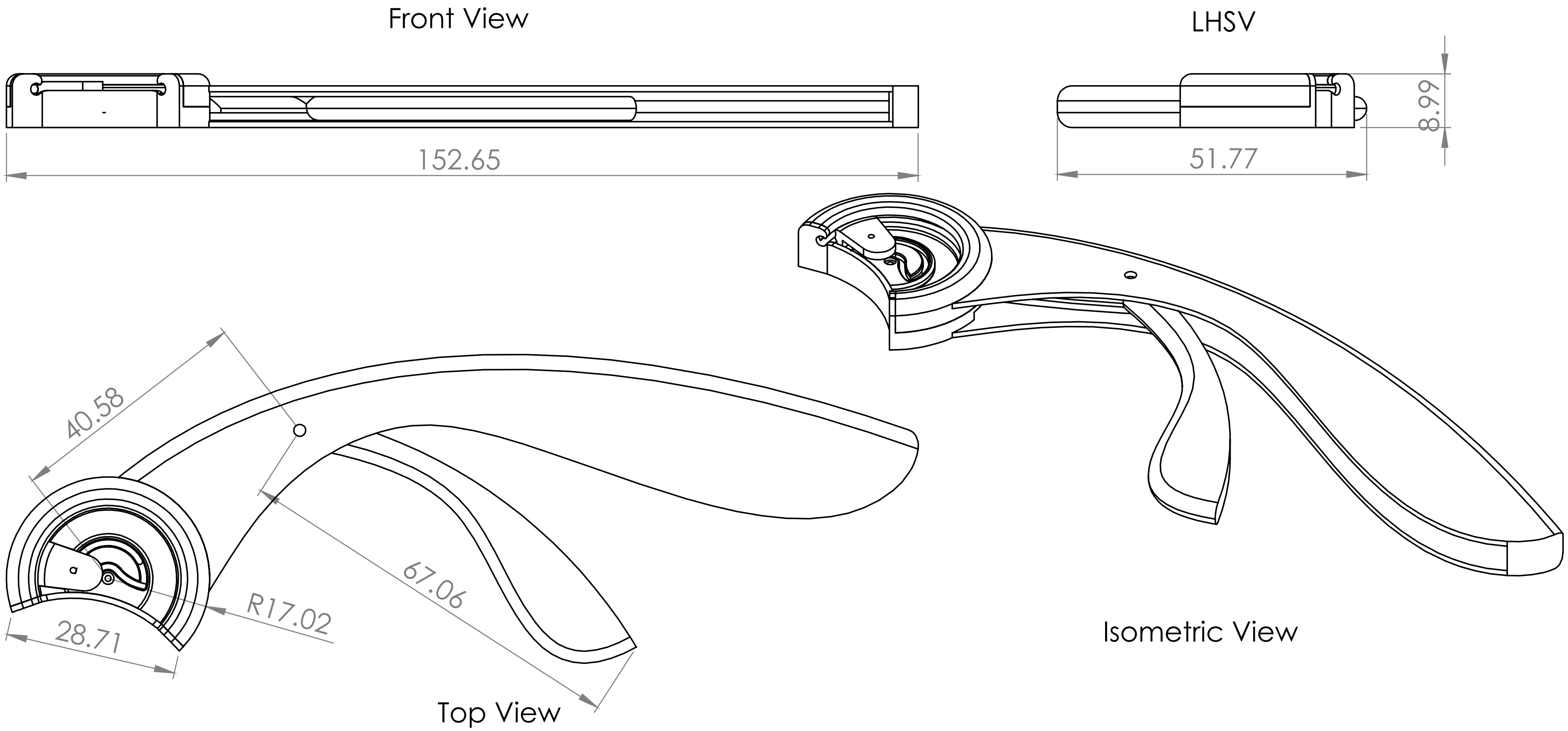


Figure 4.45 : Engineering Drawing of Model 2

Materials :
Medical grade white ABS for prototyping
Medical Grade Polypropylene (PP) for Final Design

Overall Size: 150.65 x 51.77 x 8.99

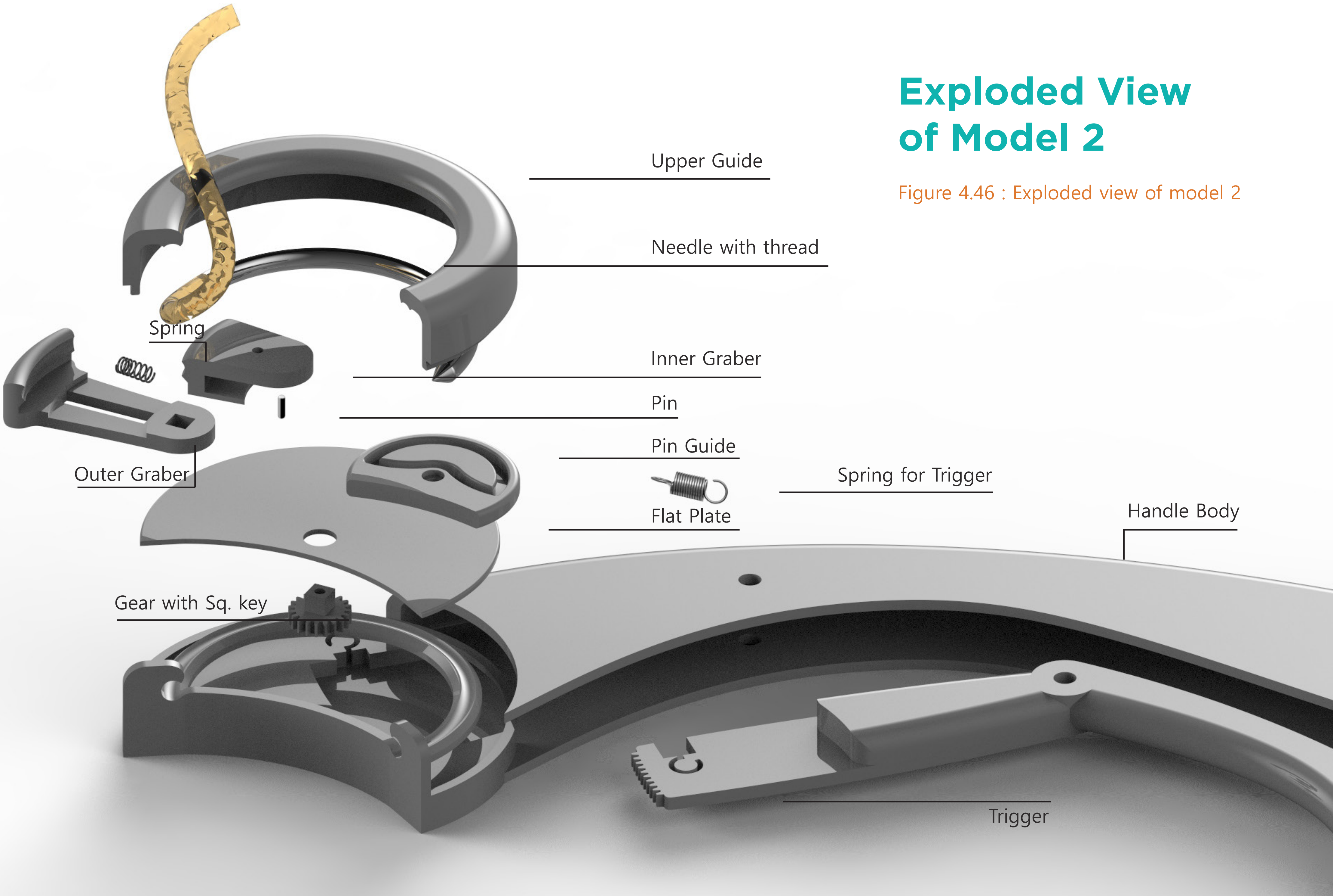
Processes : Injection Moulding, Ultrasonic Welding

Cost: Approx. Rs.50-100/- per piece.

DO NOT SCALE DRAWING	REVISION V5
ALL DIMENSIONS ARE IN MM	
TITLE: Auto-Suturing Device Model 2	
DWG NO. V5_Assem1	A4
SCALE:1:1	SHEET 1 OF 1

Exploded View of Model 2

Figure 4.46 : Exploded view of model 2



3D Print of Model 2

The model was 3D printed twice the size of the original one as the available 3D printer couldn't give much finer parts. After analysing the 3D print of model 2, it realises that it can grab and efficiently rotate the needle in a circular path. But the size of a handle is very small and it needs to follow the natural curves of the hands. Also the assembly can be simplified and it can be think of from the material point of view, that is the polypropylene parts can be flexible enough to perform the function a spring. Thus the sprigs can be avoided. Device shapes visually feels odds, so a better form language has to follow. From the learning of the two 3D printed models the final model is refined.

Figure 4.47 : 2:1 size 3D Print of Model 2

05
Final Design

Final Design

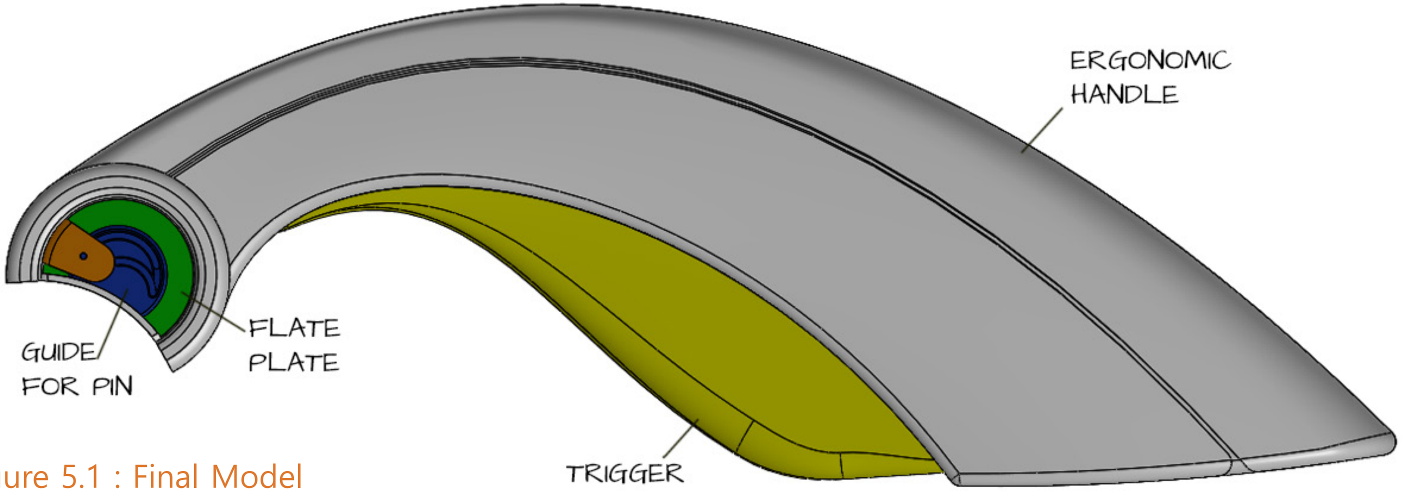


Figure 5.1 : Final Model

Working Principle is same as the model 2 except few changes. The parts has been reduced and integrated with eachother like the inner graber in inbuilt with spring by taking advantage of elastic property of Polypropylene. Spur gear is incorporated in the outer graber. Handle is following natural curve of hand. Assembly has been improvise. Such improvements making manufacturing of parts easy as well as reduces the overall costs.

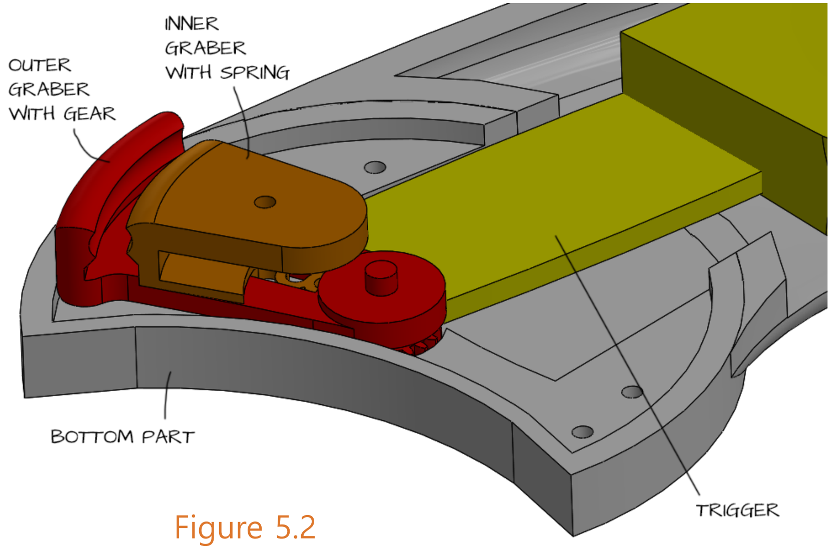


Figure 5.2

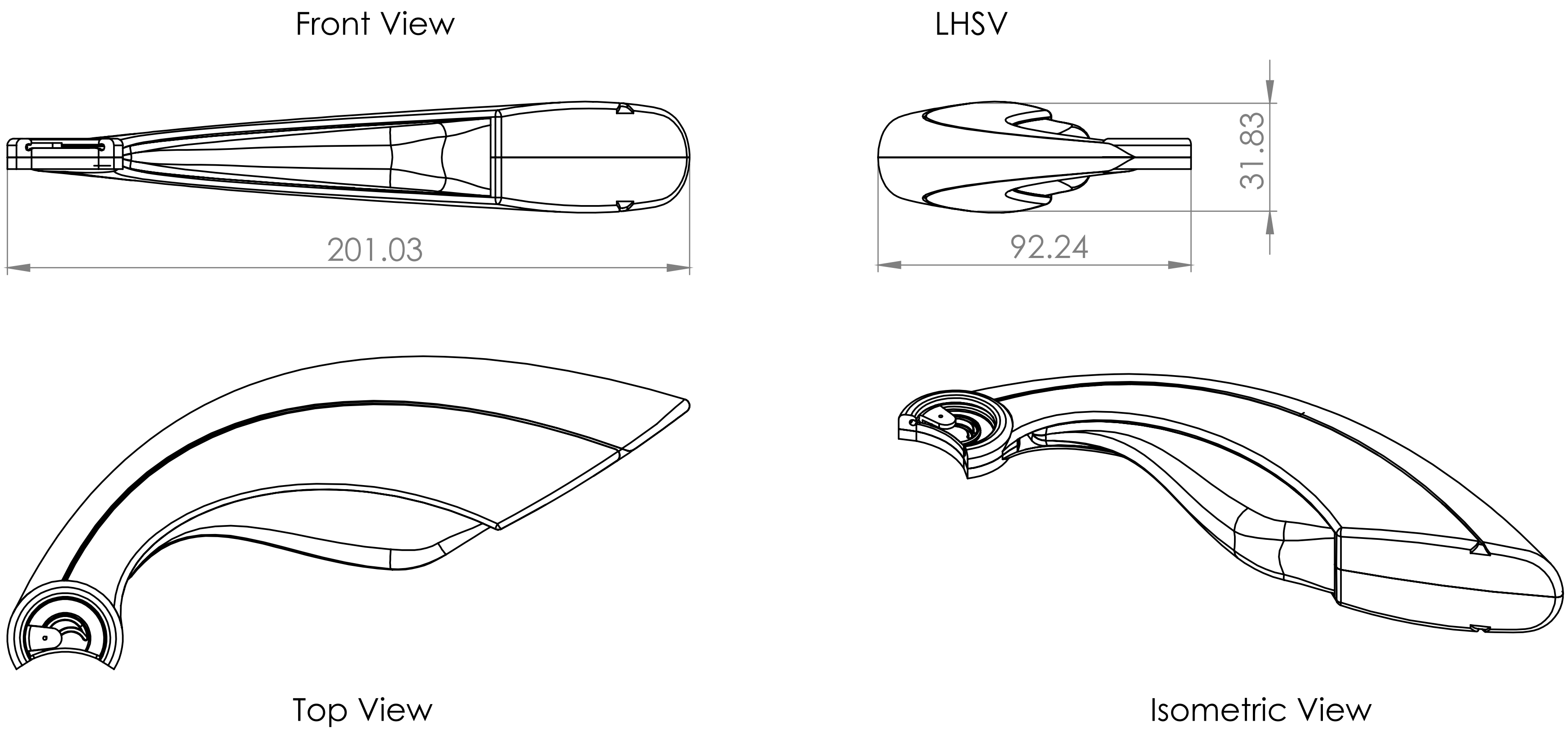


Figure 5.3 : Engineering Drawing of Final Design

Materials :
Medical grade white ABS for prototyping
Medical Grade Polypropylene (PP) for Final Design

Overall Size: 201.03 x 92.24 x 31.83

Processes : Injection Moulding, Ultrasonic Welding

Cost: Approx. Rs.50-100/- per piece.

DO NOT SCALE DRAWING	REVISION V6
ALL DIMENSIONS ARE IN MM	
TITLE: Auto-Suturing Device - Final Design	
DWG NO. V6_Assem1	A4
SCALE:1:2	SHEET 1 OF 1

Exploded View of Final Design

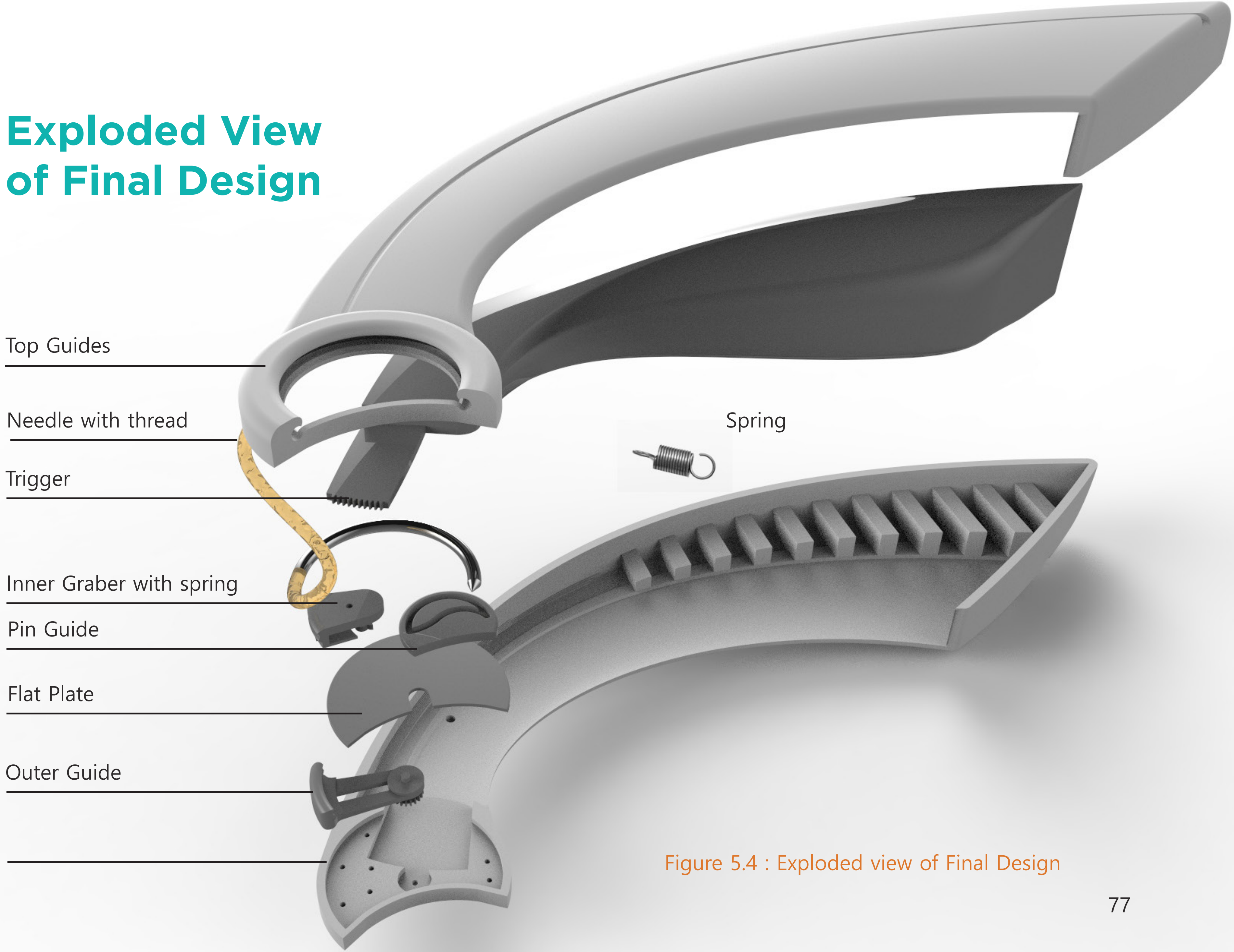
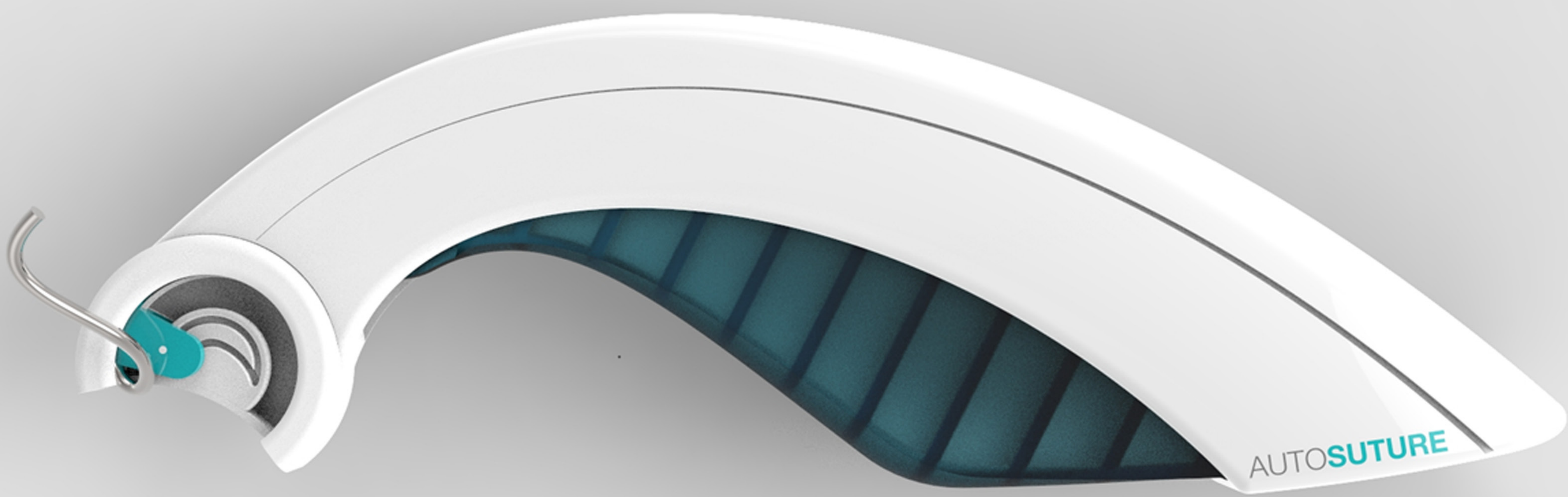


Figure 5.4 : Exploded view of Final Design

Final Render



Prototype and Packaging

Value Proposition

- This device uses the standard needle which are available in the market without tempering it. The biggest selling point.
- The device hold the needle efficiently and rotates in a circular path insures minimal injury for tissue.
- Paramedics, surgeons, doctors, physicians, nurses, nurse practitioners, physical and occupational therapists can use the device without much of practice. It take away the cognitive load from the user to perform ideal suturing.
- The manufacturing cost of the device can be approximately Rs.50 to Rs.100 makes it most economic option than other costly suturing device.
- Ergonomic handle follows the natural curvature of hand and helps hold the device firmly and steadily.
- Less number of parts compared to the existing device developed by BETiC lab. Most of the moving parts are hidden which makes it safer to use in clinical Environment.
- The device doesn't compromise on performing different types of suturing techniques. It allows many types of sutures and knots.

User’s Feedback

The device has a lot of potential in the market and it will really help us to suture properly and quickly.

- Major Kamraj, National Security Guard

If it worked then such device can be used for trauma patients specifically those with head injuries to stop blood loss on the spot.

- Dr. Vivek Salvi, Sion Hospital

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